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# QIAsymphony® RGGQ MDx (US) User Manual (Volumes 1 and 2)

US version



QIAGEN GmbH  
QIAGEN Strasse 1  
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GERMANY



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This document contains the following:

QIASymphony RGQ MDx (US) User Manual (Volume 1)

QIASymphony SP/AS Instruments and QIASymphony Management Console (QMC)

For use with software version 5.0

US version

QIASymphony RGQ MDx (US) User Manual (Volume 2)

Part I: Rotor-Gene® Q MDx User Manual (US)

Part II: Rotor-Gene AssayManager® IVD (US) Core Application User Manual

Part III: Rotor-Gene Q MDx Installation Guide (US)

For use with Rotor-Gene Q software version 2.3.4 or higher and Rotor-Gene AssayManager version 1.0.x (where  $x \geq 5$ )

US version



# QIASymphony RGQ MDx (US) User Manual (Volume 1)

## Volume 1 of 2

QIASymphony SP/AS Instruments and  
QIASymphony Management Console  
(QMC)

For use with software version 5.0

US version



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# 1 Safety Information

This user manual (volume 1) contains information about warnings and cautions that must be followed by the user to ensure safe operation of the QIASymphony® SP/AS instruments and to maintain the instruments in a safe condition.

Possible hazards that could harm the user or result in damage to the instrument are clearly stated at the appropriate places throughout this user manual (volume 1).

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

The following safety conventions are used throughout this user manual (volume 1).

**WARNING** The term WARNING is used to inform you about situations that could result in **personal injury** to you or other persons.



Details about these circumstances are given in a box like this one.

**CAUTION** The term CAUTION is used to inform you about situations that could result in **damage to the instruments** or other equipment.



Details about these circumstances are given in a box like this one.

**Note:** The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

## 1.1 Proper use

**WARNING/  
CAUTION**



### **Risk of personal injury and material damage**

Improper use of the QIASymphony SP/AS may cause personal injuries or damage to the instruments.

The QIASymphony SP/AS must only be operated by qualified personnel who have been appropriately trained.

Servicing of the QIASymphony SP/AS must only be performed by QIAGEN Field Service Specialists.



**CAUTION****Damage to the instrument**

Avoid spilling water or chemicals onto the QIASymphony SP/AS. Instrument damage caused by water or chemical spillage will void your warranty.

**Note:** Do not place items on top of the QIASymphony SP/AS hoods.

**CAUTION****Damage to the instrument**

Do not lean on the touchscreen when it is folded down.

**Note:** In case of emergency, switch off the QIASymphony SP/AS instruments and unplug the power cord from the power outlet.

Note: Perform the maintenance as described in Section 15. QIAGEN charges for repairs that are required due to incorrect maintenance.

## 1.2 Electrical safety

**Note:** If operation of the instruments is interrupted in any way (e.g., due to interruption of the power supply or a mechanical error), first switch off the QIASymphony SP/AS instruments, then disconnect the electrical cord from the power supply and contact QIAGEN Technical Services.

**WARNING****Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous. Intentional interruption is prohibited.

**Lethal voltages inside the instrument**

When the instrument is connected to line power, terminals may be live. Opening covers or removing parts is likely to expose live parts.

When working with the QIASymphony SP/AS instruments:

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Do not adjust or replace internal parts of the instruments.
- Do not operate the instruments with any covers or parts removed.
- If liquid has spilled inside the instruments, switch off the instruments, disconnect them from the power outlet, and contact QIAGEN Technical Services.
- The instrument shall be installed in a way that the power cord is accessible.

If the QIASymphony SP/AS becomes electrically unsafe, prevent other personnel from operating them, and contact QIAGEN Technical Services.

The instruments may be electrically unsafe when:

- The QIASymphony SP/AS or the line power cord appears to be damaged.
- The QIASymphony SP/AS has been stored under unfavorable conditions for a prolonged period.
- The QIASymphony SP/AS has been subjected to severe transport stresses.
- Liquids have come into direct contact with electrical components of the QIASymphony SP/AS.
- The power cord has been exchanged with a non-official power cord.

## 1.3 Environment

### 1.3.1 Operating conditions

#### **WARNING**



#### **Explosive atmosphere**

The QIASymphony SP/AS is not designed for use in an explosive atmosphere.

#### **WARNING**



#### **Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 5 cm (1.97 in.) at the rear of the QIASymphony SP/AS.

Slits and openings that ensure the ventilation of the QIASymphony SP/AS must not be covered.

## 1.4 Biological safety

Note: Specimens and reagents containing materials from humans should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as *Biosafety in Microbiological and Biomedical Laboratories*, HHS ([www.cdc.gov/biosafety.htm](http://www.cdc.gov/biosafety.htm)).

### WARNING



#### Sample containing infectious agents

Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations. Always wear safety glasses, gloves, and a lab coat.

The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or OSHA,\* ACGIH† or COSHH‡ documents. Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

Note: Samples may contain infectious agents. You should be aware of the health hazard presented by such agents and should use, store and dispose of such samples in accordance with the required safety regulations.

\* OSHA: Occupational Safety and Health Administration (United States of America).

† ACGIH: American Conference of Government Industrial Hygienists (United States of America).

‡ COSHH: Control of Substances Hazardous to Health (United Kingdom).

## 1.5 Chemical safety

### WARNING



#### Hazardous chemicals

Some chemicals used with the QIAsymphony SP/AS instruments may be hazardous or may become hazardous after completion of the protocol run. Always wear safety glasses, gloves, and a lab coat. The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Safety Data Sheets (SDSs) or OSHA,\* ACGIH<sup>†</sup> or COSHH<sup>‡</sup> documents.

Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

### Toxic fumes

Note: If you work with volatile solvents, toxic substances, etc., you must provide an efficient laboratory ventilation system to remove vapors that may be produced.

### WARNING



#### Toxic fumes

Do not use bleach to clean or disinfect QIAsymphony SP/AS instruments. Bleach in contact with salts from the buffers can produce toxic fumes.

### WARNING



#### Toxic fumes

Do not use bleach to disinfect used labware. Bleach in contact with salts from the buffers can produce toxic fumes.

## 1.6 Mechanical hazards

The hoods of the QIAsymphony SP/AS instruments must remain closed during operation. Only open the hoods when instructed to do so by the software.

**WARNING****Moving parts**

To avoid contact with moving parts during operation of QIAsymphony SP/AS instruments, the instruments must be operated with the hoods closed. If the hood sensors are not functioning correctly, contact QIAGEN Technical Services.

**WARNING****Strong magnetic field**

Do not place QIAsymphony SP/AS instruments near magnetic storage systems (e.g., computer discs).

Do not use metal tools when handling the magnetic rods.

Do not allow the magnetic rods to come into contact with other magnets.

**WARNING****Damage to the instrument(s)**

Make sure to install the magnetic-head guards before operating the QIAsymphony SP.

## 1.7 Heat hazard

The QIAsymphony SP supports a lysis station that can be heated, if required by the protocol. In addition, both the QIAsymphony SP and the QIAsymphony AS support a UV lamp.

**WARNING****Hot surface**

The lysis station and the UV lamps can reach temperatures of up to 90°C (194°F). Avoid touching them during operation.

## 1.8 Maintenance safety

**WARNING/  
CAUTION****Risk of personal injury and material damage**

Only perform maintenance as described in this user manual (volume 1).

Note: Perform the maintenance as described in Section 15. QIAGEN charges for repairs that are required due to incorrect maintenance.

**WARNING/  
CAUTION**



**Risk of personal injury and material damage**

Improper use of QIAsymphony SP/AS instruments may cause personal injuries or damage to the instruments.

QIAsymphony SP/AS instruments must only be operated by qualified personnel who have been appropriately trained.

Servicing of QIAsymphony SP/AS instruments must only be performed by QIAGEN Field Service Specialists.

**CAUTION**



**Risk of fire**

When cleaning QIAsymphony SP/AS instruments with alcohol-based disinfectant, leave the instrument hoods open to allow flammable vapors to disperse.

Only clean QIAsymphony SP/AS instruments with alcohol-based disinfectant when worktable components have cooled down.

**CAUTION**



**Damage to the instrument(s)**

Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean QIAsymphony SP/AS instruments.

**CAUTION**



**Damage to the instrument(s)**

Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the QIAsymphony SP/AS instruments. Spray bottles should be used only to clean items that have been removed from the worktables.

**CAUTION**



**Damage to the instrument hood(s) or side panels**

Never clean the instrument hood(s) or side panels with alcohol or alcohol-based solutions. Alcohol will damage the hood and the side panels. To clean the hood(s) and side panels, use distilled water. .

**CAUTION****Damage to the instrument(s)**

After wiping the drawers, the perforated metal plate and lysis station with paper towels, make sure that no bits of paper towel remain. Pieces of paper towel remaining on the worktable could lead to a worktable collision.

**WARNING/  
CAUTION****Risk of electric shock**

Do not open any panels on the QIAsymphony SP/AS instruments. Only perform maintenance as described in this user manual (volume 1).

**CAUTION****Damage to the instrument(s)**

Make sure to install the tip guards correctly before operating QIAsymphony SP/AS instruments.

**CAUTION****Damage to the instrument**

Make sure to install the magnetic-head guards before operating the QIAsymphony SP.

## 1.9 Waste disposal

Used consumables, such as sample tubes, sample prep cartridges, 8-Rod Covers, disposable filter-tips, reagent tubes, and elution racks, may contain hazardous chemicals or infectious agents from the purification or assay setup process. Such wastes must be collected and disposed of properly according to local safety regulations.









**WARNING****Hazardous chemicals and infectious agents**

The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.






For disposal of waste electrical and electronic equipment (WEEE), see Appendix A, page 423.

## 1.10 Symbols for the QIAasympphony SP/AS instruments

The following symbols appear on the QIAasympphony instruments and in this user manual (volume 1). The heat hazard symbol appears on the QIAasympphony SP but not on the QIAasympphony AS.

Symbol	Location	Description
	Lysis station	Heat hazard — the temperature of the lysis station can reach up to 90°C (194°F)
	QIAasympphony SP – near the tip rack slots/tip disposal bag QIAasympphony AS – on the worktable, near the magnetic lock of the hood	Biohazard — the tip rack slots, waste, and the worktable may be contaminated with biohazardous material and must be handled with gloves
	Robotic arm	Avoid looking directly into UV light. Do not expose your skin to UV light
	Robotic arm	Moving parts – make sure to keep the hood and drawers closed during operation
	Next to the type plate on the back of the instrument	Laser radiation – do not stare into beam
	Type plate on the back of the instrument	CE mark for Europe
	Type plate on the back of the instrument	FCC mark of the United States Federal Communications Commission
	Type plate on the back of the instrument	RCM mark for Australia



Symbol	Location	Description
	Type plate on the back of the instrument	RoHS mark for China (the restriction of the use of certain hazardous substances in electrical and electronic equipment)
 	Type plate on the back of the instrument	WEEE mark for Europe
	Type plate on the back of the instrument	Legal manufacturer
	On the worktable	Consult instructions for use
<b>Rn</b>	User manual cover	R is the revision of the user manual; n is the revision number

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## 2 Introduction

Thank you for choosing the QIAasymphony RGQ MDx (US) instruments. We are confident they will become an integral part of your laboratory.

The *QIAasymphony RGQ MDx (US) User Manual* consists of two volumes.

- *QIAasymphony RGQ MDx (US) User Manual Volume 1* provides information for operating the QIAasymphony SP and AS instruments, and supplies details about the functions and features of the QIAasymphony Management Console (QMC).
- *QIAasymphony RGQ MDx (US) User Manual Volume 2* provides information for operating the Rotor-Gene Q MDx and Rotor-Gene AssayManager software.

Before using the instruments, it is essential to read this user manual (volumes 1 and 2) carefully. The instructions and safety information in the user manual (volumes 1 and 2) must be followed to ensure safe operation of the instruments and to maintain the instruments in a safe condition.

**Note:** Images of instrument screens and files used throughout this user manual (volumes 1 and 2) are examples and may differ from the actual screen or file you are using. Throughout this user manual, a note is added to indicate situations that are not intended for use with FDA approved or cleared nucleic acid tests.

### 2.1 General information

#### 2.1.1 Technical assistance

At QIAGEN, we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding QIAasymphony SP/AS instruments or QIAGEN® products in general, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

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For technical assistance and more information, please contact QIAGEN Technical Services (see the back cover or visit [www.qiagen.com](http://www.qiagen.com)).

### 2.1.2 Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual (volume 1). Please contact QIAGEN Technical Services.

## 2.2 Intended use

The QIAAsymphony RGQ MDx system is intended for in vitro diagnostic (IVD) use in performing FDA cleared or approved nucleic acid testing in clinical laboratories. It comprises the QIAAsymphony SP, QIAAsymphony AS, and Rotor-Gene Q MDx instruments. The QIAAsymphony SP is an automated system for performing sample preparation for nucleic acid testing. The QIAAsymphony AS is an automated system for performing assay setups for nucleic acid testing. The Rotor-Gene Q MDx is a real-time nucleic acid amplification and detection system which measures nucleic acid signals from amplified DNA using fluorescent detection.

## 2.3 Requirements for QIAAsymphony SP/AS users

The following table covers the general level of competence and training necessary for transportation, installation, use, maintenance and servicing of QIAAsymphony SP/AS instruments.

<b>Task</b>	<b>Personnel</b>	<b>Training and experience</b>
Delivery	No special requirements	No special requirements
Installation	QIAGEN Field Service Specialists only	Appropriately trained and experienced personnel familiar with use of computers and automation in general
Routine use (running protocols)	Laboratory technicians or equivalent	Professional users, such as technicians and physicians, trained in molecular biology techniques
Routine maintenance	Laboratory technicians or equivalent	Professional users, such as technicians and physicians, trained in molecular biology techniques
Servicing and annual maintenance	QIAGEN Field Service Specialists only	Regularly trained, certified and authorized by QIAGEN

### 2.3.1 Training for QIAsymphony SP/AS users

Customers are trained by a QIAGEN representative upon installation of the QIAsymphony SP/AS instrument(s). The training takes 1–3 days, depending on the subject and the knowledge level of the customer.

Basic training covers general operation of the system, user management, configuration, QIAsymphony Management Console (QMC) software, regular maintenance, and basic troubleshooting. Application-specific topics will be addressed in an advanced training.

QIAGEN can also provide retraining, for example, after software updates, or for new laboratory personnel. Please contact QIAGEN Technical Services to get more information about retraining.

## 2.4 QIAsymphony Cabinet SP/AS

The QIAsymphony Cabinet SP/AS is an optional accessory for QIAsymphony SP/AS instruments. QIAsymphony Cabinets are specially designed for positioning the QIAsymphony SP/AS instruments in your laboratory. For more information, visit [www.qiagen.com/qiasymphonyrgqmdxusivd](http://www.qiagen.com/qiasymphonyrgqmdxusivd) or contact QIAGEN Technical Services.

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## 2.5 Glossary

For a glossary of terms used in this user manual (volume 1), refer to Section 18.

## 2.6 QIASymphony SP/AS accessories

For information about QIASymphony SP/AS accessories, refer to Appendix B.

## 3 Startup Procedure

The unpacking and installation of QIASymphony SP/AS instruments is carried out by a certified QIAGEN Field Service Specialist. A member of your group who is familiar with laboratory and computer equipment should be present during the installation.

See "Packing List QIASymphony SP" and "Packing List QIASymphony AS" for a full list of components that are supplied with each instrument.

### 3.1 Site requirements

The QIASymphony SP/AS must be located out of direct sunlight, away from heat sources and away from sources of vibration and electrical interference. The site of installation should be free of excessive drafts, excessive moisture, excessive dust, and not subject to large temperature fluctuations.

**Note:** If you need to move your QIASymphony SP/AS instruments, contact QIAGEN Technical Services.

#### **WARNING**



#### **Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 5 cm (1.97 in.) at the sides and rear of the QIASymphony SP/AS instruments.

Slits and openings that ensure the ventilation of QIASymphony SP/AS instruments must not be covered.

#### 3.1.1 Workbench

We recommend positioning QIASymphony SP/AS instruments on the QIASymphony Cabinet SP/AS. The QIASymphony Cabinet SP/AS is not included in the equipment supplied.

If you position the QIASymphony SP/AS instruments on an alternative workbench, it must be very stable and rated for approximately 400 kg (880 lb.). The minimum surface area of the tabletop should be the size of the complete QIASymphony SP/AS [width: 185 cm (72.8 in.), depth: 73 cm (28.7 in.)]. Do not use workbenches with rollers or wheels. We recommend a stable wooden or metal construction with a rigid tabletop and supports.

It is important that the workbench is dry, clean and vibration-proof, and that the tabletop does not bend.

**Note:** It is extremely important that QIASymphony SP/AS instruments are placed on a stable surface.

See Section 16 for the weight and dimensions of QIASymphony SP/AS instruments.

For further information about required specifications of the workbench, contact QIAGEN Technical Services.

## 3.2 General features

### 3.2.1 Hood(s)

The instrument hood(s) protects users from the moving robotic arm and from potentially infectious material on the worktable. The hood(s) can be manually opened to gain access to the worktable (e.g., for cleaning). During operation of the QIASymphony SP/AS, the hood(s) must remain closed and should only be opened when instructed to do so by the software.

The hood(s) is locked:

- During sample preparation on the QIASymphony SP
- During an assay run on the QIASymphony AS

If force is used to open the hoods during a run, the run will be paused.

**Note:** Pausing a run will result in all samples being flagged as “unclear”. For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all “unclear” samples.

**Note:** If the hoods are opened during a run, the instruments will not immediately stop. The instruments will stop when processing of the current protocol step is finished. In some cases, this may take some time.

---

### 3.2.2 Touchscreen

The QIAAsymphony SP/AS is controlled using a swivel-mounted touchscreen. The touchscreen allows the user to, for example, select and run protocols, and upload/download files (e.g., Assay Control Sets) from/to a USB stick.

### 3.2.3 USB ports

The USB ports at the front-left and front-right of the QIAAsymphony SP allow connections of the QIAAsymphony SP/AS to a USB stick and a handheld bar code scanner (supplied with the QIAAsymphony SP). New protocols, Assay Control Sets, new labware files (e.g., files enabling new types of tubes to be used with the QIAAsymphony SP), and work lists can be uploaded to the QIAAsymphony SP via the USB port. Data files, such as system log files, report files, loading information files and rack files can also be transferred via the USB port from the QIAAsymphony SP to the USB stick.

**Note:** Do not remove the USB stick while downloading or uploading files.

### 3.2.4 Network interface

The network interface allows connections of the QIAAsymphony SP/AS instruments to a network via a CAT5 Ethernet network cable.

### 3.2.5 Status LEDs

Light-emitting diodes (LEDs) at the front of QIAAsymphony SP/AS instruments are illuminated when sample preparation or assay setup is in progress. The status LEDs flash when a batch/run is finished or if an error occurs. Touching the screen turns off the flashing.



### 3.2.6 Switching on the QIAasymphony SP/AS

#### Getting started



#### Preparing the QIAasymphony SP/AS before startup

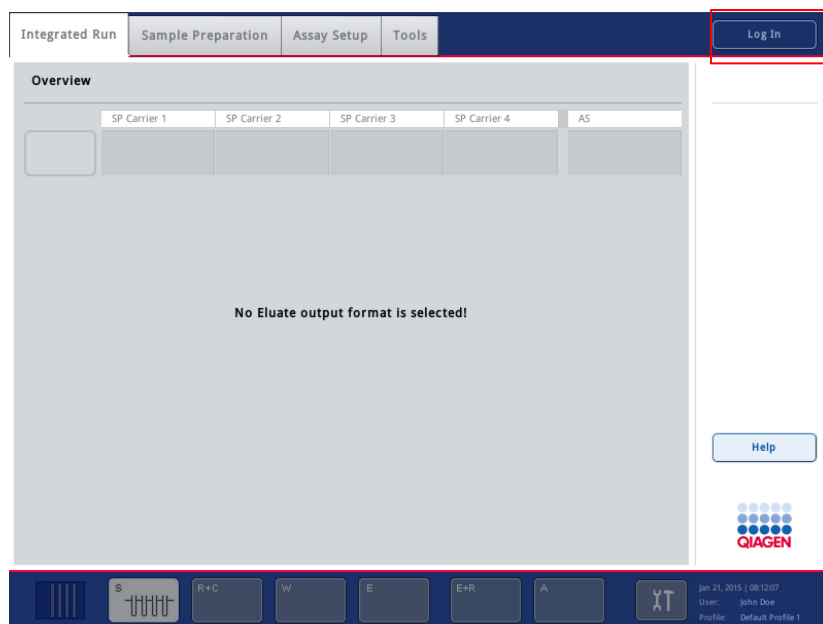
**Note:** An empty unit box must be placed into slot 4 (see Section 9.1.5) of the “Reagents and Consumables” drawer because during initialization, the handler goes down into the unit box in position 4. If the unit box is not empty, the handler will crash.

Make sure that the liquid waste bottle, tip disposal bags, and waste containers are empty.

Make sure that all drawers and both hoods are closed.

**Note:** If the hood(s) is opened during instrument startup, the system test will fail.

After successful startup, QIAsymphony SP/AS instruments are ready for use. The **Integrated Run** screen will be displayed.



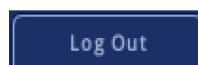
**Note:** Before using the QIAsymphony SP/AS, the user must log in by pressing the Log In button. For information about user accounts, see Section 4.4.

### 3.2.7 Logging out

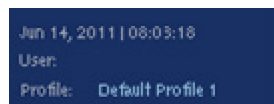
After pressing the **Run** button, you have the option to log out. The run will continue.

#### Active logout

To log out, press the **Log Out** button at the top of the **Sample Preparation** or **Assay Setup** screen.



If you are logged out, the status bar only displays the date and time.



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### Automatic logout

After a defined period of user inactivity, the user currently logged in is automatically logged out. The default setting for this period of user inactivity is 15 minutes. Ask the "Supervisor" to adjust the time period to suit your needs or to switch it off, if required.

### 3.2.8 Switching off the QIASymphony SP/AS

To switch off the QIASymphony SP/AS instruments, press the power switch at the front of the QIASymphony SP in the lower left corner. We recommend switching off the instruments after use.

The power switch is also the emergency stop of the QIASymphony SP/AS instruments. In case of emergency, switch the instruments off using the power switch.

**Note:** Do not switch off the instruments during sample preparation or assay setup unless you need to stop the instruments due to an emergency. You will not be able to resume the protocol or assay run and the samples cannot be processed further by the QIASymphony SP/AS.

**Note:** The QIASymphony SP/AS instruments will lose all inventory information when the instruments are switched off.

**Note:** After the QIASymphony SP/AS instruments are switched off, the power switch flashes a few times. When the power switch stops flashing, it is safe to switch the QIASymphony SP/AS instruments on again.

## 4 User Settings

### 4.1 Configuration

The user with the "Supervisor" user ID can change a range of configuration settings using the **Configuration** menu.

To configure a parameter, proceed as follows:

1. Log in with the "Supervisor" account details.
2. Press the **Tools** tab.
3. Press the **Configuration** button.
4. The **Configuration** menu appears.
5. Select the relevant tab and depending on which parameter will be modified (i.e., date and time, default tube types, system settings, or process parameters), proceed as outlined in the following sections.

#### Tabs in the Configuration menu

<b>Time/Language</b>	Enables the user to configure the date and the time.
<b>Adapters AS</b>	Enables the user to configure the adapters and holders for the QIAsymphony AS.
<b>Tubes</b>	Enables the user to configure the default tube type for different tube inserts for the QIAsymphony SP.
<b>System 1</b>	Enables the user to configure system settings.
<b>System 2</b>	Enables the user to configure system settings.
<b>Process Profiles</b>	Only the "Supervisor" can change configuration settings.
<b>Maintenance</b>	Enables the user to configure maintenance settings.
<b>General Process</b>	Enables the user to configure individual process parameters that affect operation of both the QIAsymphony SP and the QIAsymphony AS.
<b>Process SP 1</b>	Enables the user to configure individual process parameters that affect operation of the QIAsymphony SP.

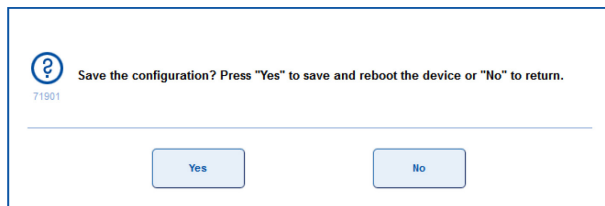
<b>Process SP 2</b>	Enables the user to configure individual process parameters that affect operation of the QIASymphony SP.
<b>Process SP 3</b>	Enables the user to configure individual process parameters that affect operation of the QIASymphony SP.
<b>Process AS</b>	Enables the user to configure individual process parameters that affect operation of the QIASymphony AS.

**Important:** FDA cleared or approved nucleic acid tests require **Default Profile 1** configuration settings and changes to the configuration settings for General Process, Process SP 1, Process SP 2, Process SP 3, and Process AS are not permitted.

## Command bar

<b>Tools</b>	Press the <b>Tools</b> button to access the <b>Tools</b> menu.
<b>Cancel</b>	Press to close the <b>Configuration</b> menu without saving changes.
<b>Save</b>	Press to save changes made to parameters in the individual tabs. If only the settings for the default tubes were changed, there is no need to restart the QIASymphony SP/AS instruments.
<b>Save + Reboot</b>	Press to save changes made to parameters in the individual tabs, and to restart the QIASymphony SP/AS instruments. The button is only active if the changes require a reboot of the instruments.

Upon pressing a button, a warning message appears. Press **Yes** to continue.



A second message then appears to inform you that the change is not part of a software configuration. See Section 4.3.1 for details about software configuration profiles.

## 4.2 Configuring the QIAAsymphony SP/AS instruments

### 4.2.1 Date and time

The current date and time is displayed in the status bar and also appears in run documentation such as the result file.

To configure the date and time, proceed as follows:

1. Select the **Time/Language** tab in the **Configuration** screen.

The screenshot shows the 'Tools | Configuration' window with the 'Time / Language' tab selected. The interface includes a top navigation bar with tabs: 'Time / Language', 'Tubes', 'System 1', 'System 2', 'Maintenance', 'Process Profiles', 'General Process', and 'Pro'. Below the tabs, the 'Time' section has input fields for hours (23), minutes (44), and seconds (03), along with an 'Undo' button. The 'Date' section has input fields for month (10), day (01), and year (2017). The 'TimeZone' section has a dropdown menu showing 'Europe/Zurich'. The 'Language' section has a dropdown menu showing 'English'. On the right side, there are buttons for 'Tools', 'Cancel', 'Save', and 'Help'. The bottom status bar displays the date and time 'Jan 21, 2015 | 08:12:07', the user 'Supervisor', and the profile 'Default Profile 1'. The QIAGEN logo is also visible in the bottom right corner.

#### Time/Language tab.

2. Change the time and date settings by pressing the corresponding text fields.
3. The **Keyboard** screen will appear where values need to be entered.
4. If necessary, select a city in the **Available time zones** list.
5. Press the **Save + Reboot** button to save the changes.

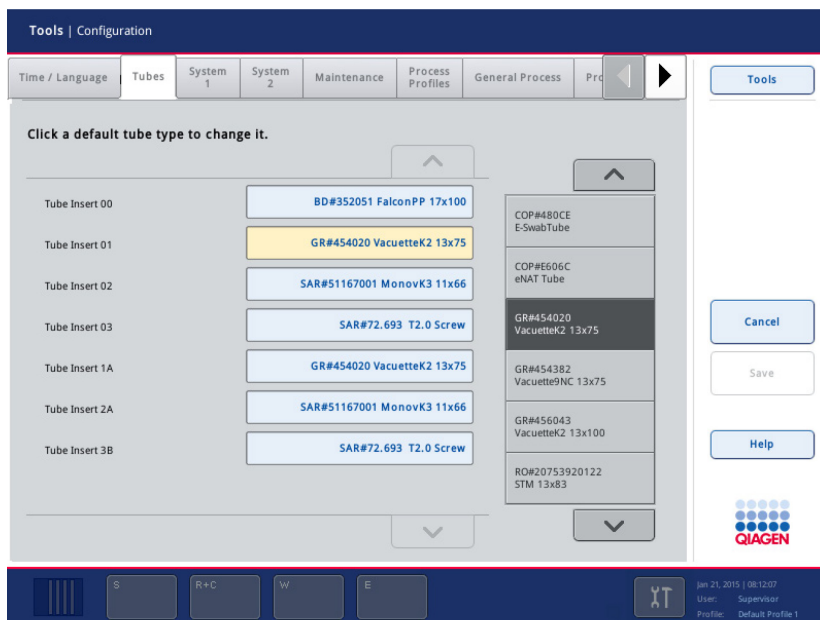
The QIAAsymphony instrument(s) will restart.

## 4.2.2 Default tube types

The default tube type for different tube inserts can be configured for the QIAAsymphony SP.

To set the default tube types, proceed as follows:

1. Select the **Tubes** tab.



### Tubes tab.

2. Change the default tube type for the different tube inserts by pressing the corresponding text fields.
3. Select the tube type from the list on the right.
4. If necessary, repeat steps 2–3 for the other tube inserts.
5. Press **Save** to save the changes.

**Note:** Changing the default tube type for the different tube inserts affects the default tube type for internal control (IC) tubes. A limited number of tube types can be used with internal controls (see the Instructions for Use (Handbook) of the corresponding assays for details). In some cases, the supervisor may wish to change the default tube type to a tube type that cannot be used with the IC. The user must then manually override the default IC tube type during the **Define IC's** dialog by selecting the **IC Tubes** button.

### 4.2.3 Adapters and holders (QIAsymphony AS)

For QIAsymphony AS, available adapters and the available quantities must be configured. The software requires this information to determine which reagent holders are needed and how many sample and assay adapters can be used for a defined run.

Note: At installation, the QIAGEN Field Service engineer will set up the numbers of available adapters.

**Note:** If a new adapter or an additional adapter is received, ensure that this adapter is configured in the software. If it is not configured, it will not be recognized by the software.

To configure available adapter(s) and holder(s), proceed as follows:

1. Select the **Adapters AS** tab. A list of adapters and holders is displayed.

Tools | Configuration

Time / Language | Adapters AS | Tubes | System 1 | System 2 | Maintenance | Process Profiles | General

Enter the number of adapters for AS

96-Well Round Bottom QS	3
CamusGeneDisc adapter	3
Elution Microtube Rack QS	3
LC Capillaries 32 QS	3
Micro Tube Screw Cap QS	3
PCR Plate 96 QS	3
RG Strip Tubes 72 QS	3
Reagent Holder 1 QS	3

Cancel

Save

Help

QIAGEN

Jan 21, 2015 | 08:12:07  
User: Supervisor  
Profile: Default Profile 1

#### Adapters AS tab.

2. Enter the available number of adapters and holders. To do this, press on the associated field for a particular adapter or holder.



The **Adapter Count Configuration** screen will appear.

Adapter Count Configuration

Please enter number of adapters.

20

7 8 9 ← DEL

4 5 6

- 1 2 3 1 2 3

E 0 . # +=

A B C

Clear

Cancel

OK

QIAGEN

Jan 21, 2015 | 08:12:07

User: Developer

Profile: Default Profile 1

3. Enter the correct number using the keyboard.
4. Press **OK** to continue.
5. Repeat steps 2–5 for all adapters and holders.
6. Press **Save**.

#### 4.2.4 System settings

The “Supervisor” can configure system settings in the **System 1** and **System 2** tabs.

To change any of the settings, proceed as follows:

1. Select the System 1 or System 2 tab.
2. Press on a field to modify it, or press Yes or No.
3. When all required changes have been made, press **Save + Reboot**. The QIASymphony instrument(s) will restart.

Tools | Configuration

Time / Language Adapters AS Tubes System 1 System 2 Maintenance Process Profiles Genera

Tools

Number of days for which a password is valid (0 = password does not expire): 60

Number of minutes after which system logs out automatically (0 = Auto Logoff deactivated): 15

Enable strong password policy? No Yes

Number of allowed login attempts 0

Cancel

Save

Help

QIAGEN

Jan 21, 2015 | 08:12:07  
User: Supervisor  
Profile: Default Profile 1

**System 1 tab.**

## Dialog panel

### Password Expiry Period (0 = password does not expire)

Specifies the number of days for which the password is valid. If "0" is entered, the password will not expire.

### Auto Logoff Period in minutes (0 = Auto Logoff deactivated)

Indicates the number of minutes of inactivity until the user is logged off automatically. If "0" is entered, automatic log off is deactivated and the user will not be logged out automatically.

### Enable strong password policy?

Defines whether the standard password policy is used or if a stronger password policy is used.

If **No** is selected, the standard password policy is used.

If Yes is selected, the restrictive password policy is set.

A password for the restrictive password policy must fulfill the following requirements:

- Comprise at least 8 characters
- Be different from the user name
- Differ from the last 10 recent user passwords
- Contain at least 2 upper case, 2 lower case, 2 numeric and 2 special characters

### Number of allowed login attempts

Defines how many login attempts are allowed before a user is deactivated.

Note: Only the "Supervisor" can reactivate a deactivated user.

If "0" is entered, restriction on the number of allowed login attempts is deactivated.

The screenshot displays the 'Tools | Configuration' window for the QIAAsymphony RGQ MDx (US) system. The 'System 2' tab is active, showing configuration options for the second system. The options include:

- Enable DHCP? (No/Yes buttons)
- IP address: (127 . 0 . 0 . 1)
- Netmask: (255 . 255 . 255 . 0)
- Gateway IP address: (Empty fields)
- DNS servers: (Empty field)
- Domain search suffix: (Empty field)
- Is Assay Setup installed? (No/Yes buttons)

On the right side, there are buttons for 'Tools', 'Cancel', 'Save', and 'Help'. The bottom status bar shows the user is 'Supervisor' and the profile is 'Default Profile 1'.

### System 2 tab.

## Dialog panel

<b>Enable DHCP?</b>	<p>Defines whether the dynamic host control protocol (DHCP) is enabled.</p> <p>Set to <b>Yes</b> if you are using a dynamic IP address. In this case, the system retrieves an IP address during start up and transmits the host name to the local name server. The IP address value is ignored.</p> <p>Set to <b>No</b> if you are using a static IP configuration. In this case, enter the IP address in the following IP address field.</p> <p>Check with your local network administrator that the DHCP server is running in the local area network.</p>
<b>IP address</b>	<p>If you are not using the DHCP, enter the static IP network address provided by your IT department.</p> <p>It is important to ensure that any IP address is coordinated with the local network administrator. It can cause network failures if an IP address is duplicated.</p>
<b>Netmask</b>	<p>Enter the netmask IP settings provided by your IT department. If the DHCP is not used, the IP-Netmask defines the size of the subnet where the system is located.</p>
<b>Gateway IP address</b>	<p>Enter the IP address of the network node provided by your IT department. This is usually a router or a bridge that connects the local network to another network.</p>
<b>DNS servers</b>	<p>Enter the list of name servers provided by your IT department. Multiple servers can be entered, separated by spaces.</p>
<b>Domain search suffix</b>	<p>The primary search domain is usually the same as the domain name of the system. There may be additional search domains; these can be separated with commas or spaces.</p> <p>This option has to be set together with the local network administrator.</p>
<b>Is Assay Setup installed?</b>	<p>Select <b>Yes</b> – IVD applications require that the QIASymphony SP is connected to a QIASymphony AS.</p>

## 4.3 Process settings

The "Supervisor" can modify the software configuration of the QIAAsymphony SP/AS instruments in the **Process Profiles** tabs of the **Configuration** menu. A range of configuration parameters can be adjusted, and these changes can be saved in configuration profiles so that it is possible to switch between different configurations.

### 4.3.1 Changing the software configuration

Process configuration settings are saved in a single file called a process configuration file.

**Note:** **Default Profile 1** is the software configuration that is automatically preselected.

**Note:** IVD applications require the use of **Default Profile 1**.

Profile description: **Default Profile 1**

#### General Process

Number of days for which a work list is valid?	1
Validate eluate racks with bar coded tubes?	No
Use magnetic head sensors (sample prep cartridges)?	No
Use magnetic head sensors (8-rod covers)?	No
Can process when Mandatory maintenance task is due?	No
Enable use of expired reagents?	No
Allow information for single samples in work list to be overwritten?	Yes
Frequency of temperature recording?	300

#### Process SP 1

Enable use of sample racks without bar codes?	Yes
Enable use of sample tubes without bar codes?	Yes
Automatically assign a randomly-generate ID to samples which are not read or without bar codes?	No
Enable use of duplicate bar codes in a run?	No
Enable leading and/or trailing whitespaces in sample IDs?	No

Allow assignment of randomly-generated IDs to elution racks?	No
Confirm bar code of elution rack before removing?	No
On which elution slots should adapter bar codes be scanned?	1

#### Process SP 2

Enable use of reagent cartridges with different lot numbers in the same SP batch?	No
Check combination of protocol and recommended labware during run definition?	Yes

#### Process SP 3

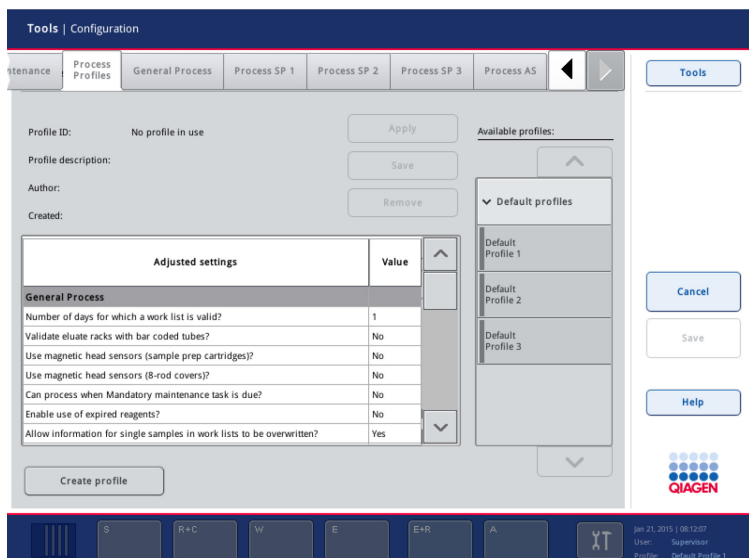
Number of seconds enabled for user intervention before batch suspension?	0
Enable operator to change default tube types?	Yes
Write start batch confirmation files?	No
Allow processing of samples without a work list entry?	Yes
Allow combination of multiple work lists for one batch?	Yes
Allow partial use of work lists?	Yes
Warn, if sample sequence differs from work list entry sequence?	No
Check sample tube type required by work list?	No
Check elution rack ID required by work list?	No

#### Process AS

Force eluate rack ID confirmation for loading?	No
Time frame for acceptable delay of downstream processing (minutes)?	30
Require kit bar code scan for AS reagents?	Yes

### Selecting a process profile

1. Select the **Process Profiles** tab.



**Process Profiles** tab.

2. Select **Default Profile 1** in the **Available profiles:** list on the right.  
Profiles are listed under the categories **Default profiles** and **Custom profiles**. If there are no custom profiles available, this category will not be available.
3. Press **Apply**.
4. Press **Save + Reboot**.

## 4.4 User accounts

The QIAAsymphony SP/AS recognizes 2 different user roles:

### Supervisor

The "Supervisor" role enables preparation and running of batches and assay runs. The "Supervisor" can configure the users, default tube types for the QIAAsymphony SP, and adapters/holders for the QIAAsymphony AS. The "Supervisor" can also configure the system and define custom configuration profiles. In addition, the "Supervisor" can:

- Transfer input and output files, process files, and most instrument setup files from QIAAsymphony SP/AS instruments to the USB stick.
- Transfer rack files, work list files, process files, and most instrument setup files from the USB stick to the QIAAsymphony SP/AS instruments.
- Manage the user account for other users; they can also adjust the configuration settings.

- Synchronize rack files, work list files, process files, and most instrument setup files between the QIAasympphony SP/AS instruments and the USB stick.

## Operator

The “Operator” role enables preparation and running of batches and assay runs. In addition, the “Operator” can:

- Transfer input and output files from QIAasympphony SP/AS instruments to a USB stick.
- Transfer rack files and work lists from a USB stick to the QIAasympphony SP/AS instruments.

Before operating the QIAasympphony SP/AS, the user accounts must be defined (see Sections 5.11.3 and 5.11.4).

If no user is logged in, all drawers are locked.

### 4.4.1 Create new users

The “Supervisor” must use the following default password the first time they log in: **ive2ad**.

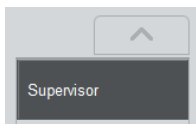
To create new users or to reset user passwords, follow the steps below.

1. Log in as “Supervisor”.



The **Please select user** screen will open.

2. Select the **Supervisor** button.



The **Please enter password** screen will open.

3. Enter the password in the blue field and confirm with **OK**.

**Note:** If you are logging in as “Supervisor” for the first time, you must change the default supervisor password. To do this, follow the instructions in the touchscreen.

The **Sample Preparation** screen will be displayed again.

The “Supervisor” user ID is now visible in the status bar on the lower right.



Jun 14, 2011 | 08:03:18  
User: Supervisor  
Profile: Default Profile 1

4. Press the **Tools** tab.



The **Tools** menu will be displayed.

5. Press the **User Management** button.



The **User Management/Please select user** screen appears.

6. Press the **Add User** button.



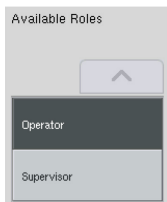
The **Create User** screen appears.

7. Enter new user settings in the blue fields and confirm with **Next**.



The **Assign Roles** screen appears.

8. Select the role of the user account to be created.



The selected role will be highlighted inverse.

9. Press the arrow button to assign the selected role to the newly created user account.



The new user will be added to **User Roles**.

10. Press **Finish**.



The login information of the newly created user account will be saved.

#### 4.4.2 Activate/inactivate user accounts

User accounts cannot be deleted. The user with the "Supervisor" user ID must deactivate the user account so that it is no longer displayed in the **Activated Users** list.

To inactivate/activate a user account, follow the steps below.

1. Log in as "Supervisor". See steps 1–3 of Section 4.4.1 for more information.



2. Press the **Tools** tab.



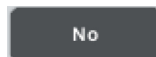
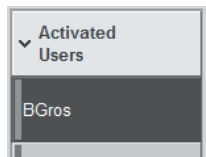
The **Tools** menu will be displayed.

3. Press the **User Management** button.



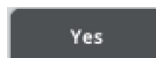
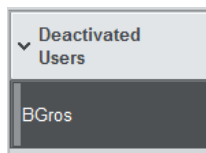
The **User Management/Please select user** ("Supervisor" login) screen appears.

4. Deactivation: Select the user name from the list in the **Activated Users** package and press the **No** button.



The selected user will be removed from the list and transferred to the **Deactivated Users** list.

5. Activation: Select the user name from the list in the **Deactivated Users** package and press the **Yes** button.



The selected user will be removed from the list and transferred to the **Activated Users** list.

6. Press **Save** to confirm the changes.



#### 4.4.3 System request for password change

You may be prompted by the instrument software to enter a new password. This may happen the first time you log in, after the "Supervisor" resets your password, if your password has expired, or if the "Supervisor" switches from the standard password policy to a stronger (restrictive) password policy (see section 4.2.4).

Note: When only one "Supervisor" is currently enabled, and he/she exceeds the maximum number of attempts for a password authentication from the QMC, the account is disabled for 30 seconds. When the 30 second block has expired, the last enabled "Supervisor" can try again to enter a password.

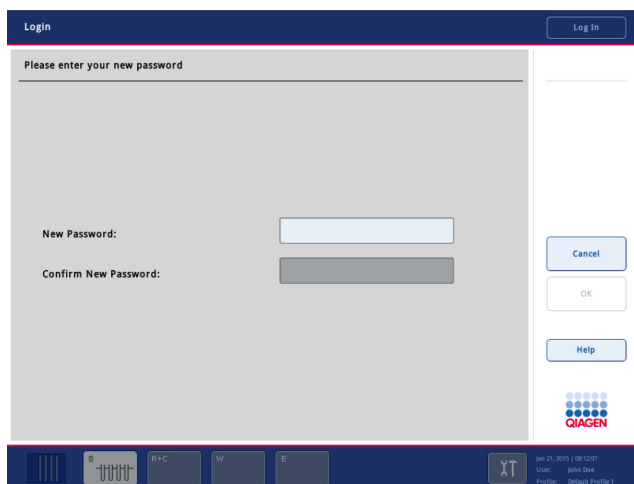
**Note:** Passwords expire after 60 days by default.

This setting can be changed by the "Supervisor" in the **Configuration** menu in the **System 1** tab. It is also possible to deactivate the password expiration setting.

If a password has expired, you will be prompted to enter a new password after logging in.

To change your password, follow the steps below.

1. Press **New Password**.



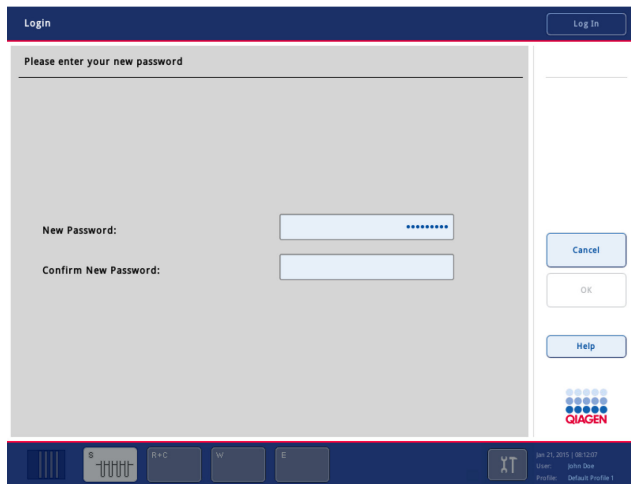
The screenshot shows a login window with a dark blue header bar containing the word "Login" and a "Log In" button. Below the header, a grey panel displays the text "Please enter your new password". Inside this panel, there are two input fields: "New Password:" and "Confirm New Password:". To the right of the input fields are three buttons: "Cancel", "OK", and "Help". At the bottom of the window, there is a status bar with various icons and text, including the QIAGEN logo.

2. Press in the New Password field. The **Keyboard** screen appears.

**Note:** The password must be a minimum of 8 characters. It should not be same as the login name and it must differ from the previous 10 passwords. If the strong password policy is enabled, the password must be a minimum of 8 characters — 2 upper case, 2 lower case, 2 numeric and 2 special characters. It should not be same as the login name and it must differ from the previous 10 passwords.

3. Enter a new password and press **OK**.

The **Login/Please enter your new password** screen appears again.



4. Press in the **Confirm New Password** field.

The **Keyboard** screen appears again. Enter the new password again to confirm it.

5. Press **OK**.



The **Login/Please enter your new password** screen will appear again.

#### 4.4.4 User request for password change

It is also possible to change your password independently of the password expiration.

1. Press the **Login** button and select your user name from the list.



The **Keyboard** screen appears.

2. Enter your password and confirm with **OK**.



The **Sample Preparation** screen appears.

- Press the **Tools** tab and select the **User Management** button.



The **User Management/Your user data** screen appears.

- Press the **Change PWD** button.



The **User Management/Please enter your new password** screen appears.

A screenshot of the "User Management" screen. The title bar is dark blue with "User Management" in white. Below the title bar, the main area is light gray. On the left, there are three labels: "Old Password:", "New Password:", and "Confirm New Password:". To the right of each label is a text input field. The "Old Password" field is highlighted. On the right side of the screen, there is a vertical toolbar with buttons: "Tools", "Cancel", "Ok", and "Help". At the bottom of the screen, there is a dark blue status bar with a "QIAGEN" logo and some text.

- Press the **Old Password** text field.
- Enter the old password in the **Keyboard** screen and press **OK**.



The **User Management/Please enter your new password** screen appears again.

7. Press the **New Password** text field.

Note: The password must be a minimum of 8 characters. It should not be same as the login name and it must differ from the previous 10 passwords. If the strong password policy is enabled, the password must be a minimum of 8 characters – 2 upper case, 2 lower case, 2 numeric and 2 special characters. It should not be same as the login name and it must differ from the previous 10 passwords.

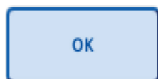
8. Enter a new password in the **Keyboard** screen and press **OK**.

The **User Management/Please enter your new password** screen appears again.

9. Press the **Confirm New Password** text field.

The **Keyboard** screen appears.

10. Confirm the new password and press **OK**.



The new password is now active.

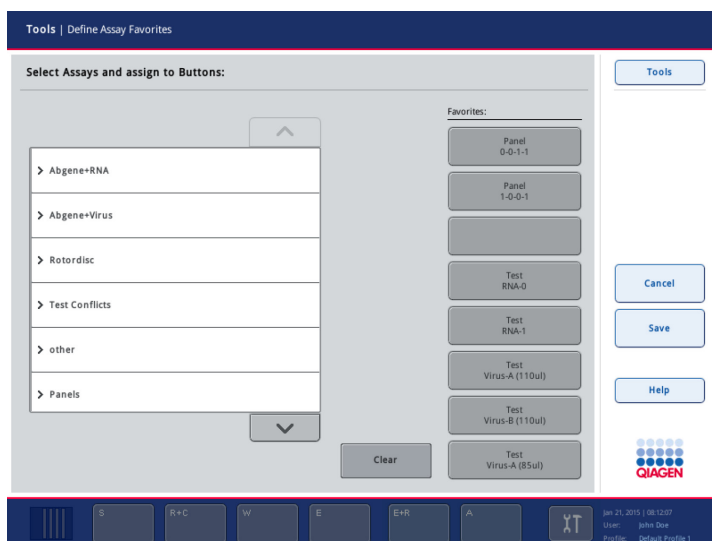
## 4.5 Assay favorites

In the integrated mode, personalized assay favorites can be defined for quicker assignment within the setup screen for **Integrated Operation**.

1. Press the **Tools** tab and select **Assay Favorites**.



The **Define Assay Favorites** screen appears as shown below.



The dialog contains a list showing the available assays for **Integrated Setup** and the set of favorite buttons identical to the ones in the **Integrated Setup** screen. The buttons are labeled with the defined favorite assays, if already assigned, otherwise the label is empty.

2. Select the assay to assign as a favorite.
3. Assign the selected assay to a selected blank **Favorites** button.



The assay will be displayed on the assigned favorite button.

4. Press **Save**.



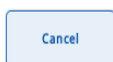
Changes are saved in the user data, enabling user-specific configuration of the **Favorites** buttons.

5. To remove assays as favorites, select the button and then press **Clear**.



The selected assay will be removed from the **Assay Favorites**.

6. If **Cancel** is pressed, a message appears warning that all changes will be lost.





## 5 Sample Preparation User Interface

The QIASymphony Operating Software is developed exclusively for use with the QIASymphony SP/AS instruments.

The software has the following menus that are required for operation of the QIASymphony SP/AS:

- **Tools** screen for accessing these menus:
    - **Maintenance SP**
    - **Service SP**
    - **Maintenance AS**
    - **Service AS**
    - **File Transfer**
    - **Rack Browser**
    - **Labware Browser**
    - **Instrument Report**
    - **User Management**
    - **Configuration**
    - **Assay Favorites**
  - **Sample Preparation** menu to control the individual drawers and for logging in to the instrument.
  - **Maintenance SP** menu within the **Tools** menu for performing routine maintenance procedures (see Section 15) and to operate individual modules of the QIASymphony SP.
  - **Service SP** menu within the **Tools** menu for performing service protocols, to initialize the instrument, and to transfer files (e.g., result files, log files, Assay Control Set files, or labware files) from the USB stick to the QIASymphony SP/AS instruments (see Section 7.3).
  - **Maintenance AS** menu for performing routine maintenance procedures. See Section 15 for more details about maintenance procedures.
  - **Service AS** menu for performing service protocols and initializing the instrument.
- Note:** The **Maintenance AS**, **Service AS** and **Assay Favorites** menus are also accessible from the **Tools** screen. These menus are only required for operating the QIASymphony AS. For more information about these menus, see Sections 4.5, 6.4, and 6.5.
- **File Transfer** menu within the **Tools** menu for downloading and uploading files to/from the USB to the QIASymphony SP/AS instruments.

- **Rack Browser** menu within the **Tools** menu for viewing rack files saved on the QIAAsymphony SP/AS instruments.
- **Labware Browser** menu within the **Tools** menu for viewing additional information about labware.
- **Instrument Report** menu within the **Tools** menu for creating reports that help QIAGEN Technical Services with troubleshooting.
- **User Management** menu within the **Tools** menu for managing users and passwords.
- **Configuration** menu within the **Tools** menu for setting configuration parameters.
- **Assay Favorites** menu within the **Tools** menu for defining commonly used assay workflows.

A protocol is a set of instructions that allows the QIAAsymphony SP to perform an application. The Instructions for Use (Handbook) for the assay you are using will tell you which protocol you should use.

An Assay Control Set is the combination of a protocol plus additional parameters, such as internal control. For example, if an internal control is used, the Assay Control Set defines the protocol, the internal control, and optional identification of the internal control through bar code reading.

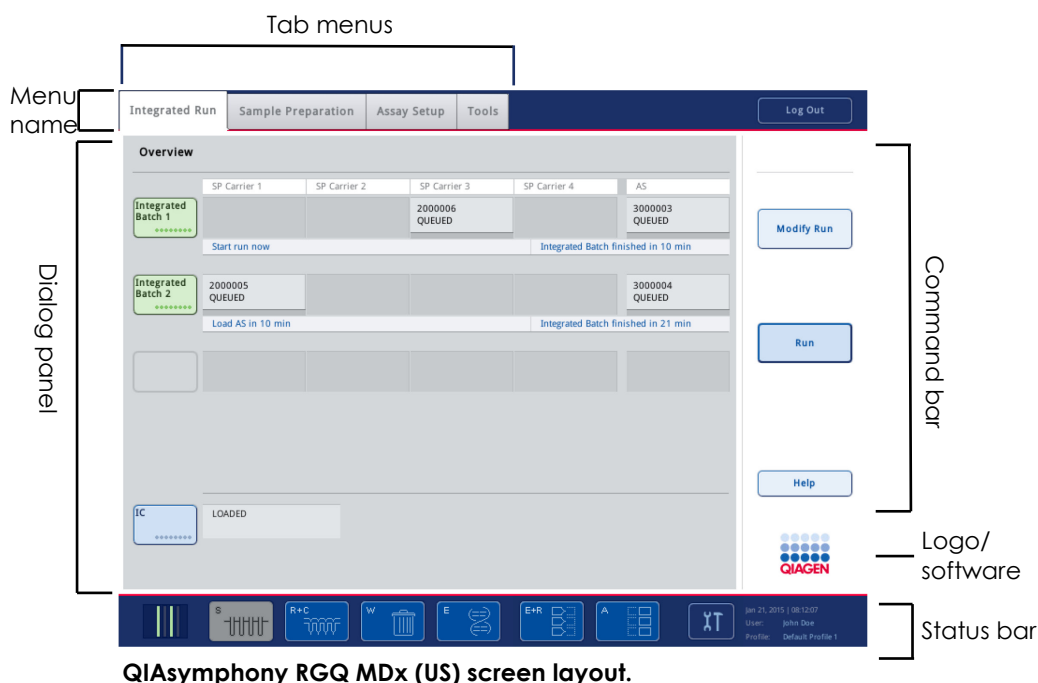
## 5.1 Starting the QIAAsymphony software

If the QIAAsymphony SP is switched off, switch the instrument on by pressing the power switch at the front-left of the QIAAsymphony SP. The QIAAsymphony SP performs initialization tests and the startup screen will be displayed.

Once initialization is complete, the sample preparation menu is displayed and the user can log in.

## 5.2 Software features common to all screens

The software uses a number of features common to all screens to provide information about actions performed and instrument status.



### 5.2.1 General screen elements

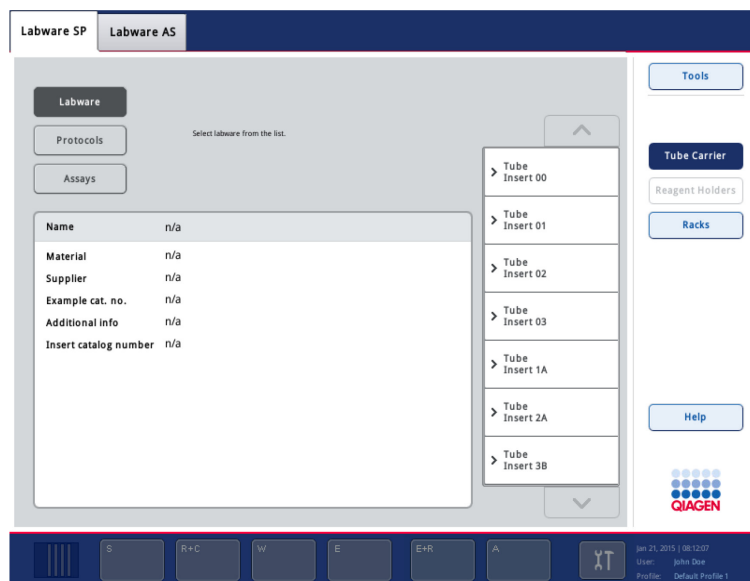
Each software screen contains the same general elements.

**Menu name** Shows the menu that is active. With some menus, more than one tab is available. For example, the **Labware Browser** menu contains two tabs:

- **Labware SP** tab
- **Labware AS** tab

**Dialog panel** The dialog panel is the part of the screen in which information is displayed. Some dialog panels may also contain buttons and text fields. For more information, refer to the description of the corresponding screen.

Command bar	The command bar contains buttons that enable the user to select information, proceed through a workflow, cancel a workflow, call up the software help texts or access other menus and screens. For more information, refer to the description of the corresponding screen.
Status bar	The status bar provides information about the different drawers of the QIASymphony SP/AS instruments and information about date and time and the user who is currently logged in.
QIAGEN logo	Displays the software version.



**Labware SP tab of the Labware Browser menu.**

### 5.2.2 Tab menus

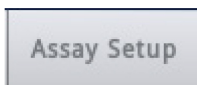


The **Integrated Run** tab is used to:

- Define integrated runs
- View information about the status of defined integrated runs (i.e., progress, batch status, estimated time remaining, and the next user interaction required for each integrated batch)



The **Sample Preparation** tab is used for viewing details of the loaded samples on QIASymphony SP.



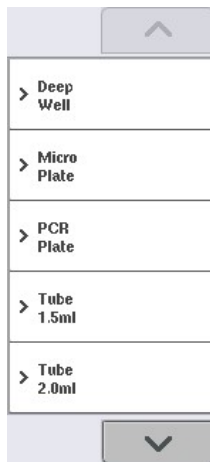
The **Assay Setup** tab is used to view information about the QIAsymphony AS and remove completed assays.



The **Tools** tab provides access to several menus required for operation of QIAsymphony SP/AS instruments.

### 5.2.3 Up and down arrows

Some dialog panels contain lists with parameters that can be selected by the user.



**Example of a list in the QIAsymphony software.**

To move up through the list, press the up arrow. To move down through the list, press the down arrow.

In some lists, an item can be directly selected whereas in other lists a category must first be selected followed by the item. An item or category is selected by pressing it.

### 5.2.4 Messages

During operation of the QIAsymphony SP/AS instruments, messages may appear that provide the user with general information, inform the user that operator input is required, or provide information about warnings and errors. Each type of message contains a symbol for easy identification by the user.



This symbol is displayed if the message contains information about an error.



This symbol is displayed in warning messages.



This symbol is displayed if input by the user is required.



This symbol is displayed if the message provides the user with information.

### 5.3 Status bar

The status bar allows the user to view information about the status of each of the QIAsymphony SP drawers and the QIAsymphony AS drawers.



#### 5.3.1 Batch status icon

The way the batch status icon is displayed varies according to the loading state of the tube carrier on the QIAsymphony SP.



**Batch status icon.** The batch status icon provides the user with information about each sample batch.

The color of each tube carrier denotes the status of the associated batch (see “Colors of drawer buttons”, Section 5.3.1 for more information).



**The status of batch 4 is “QUEUED”.**

### 5.3.2 Drawer buttons

There is a button for each of the QIAAsymphony SP drawers in the status bar. If a drawer button is pressed or if the drawer is opened, the corresponding software screen described below appears.

**Note:** For the QIAAsymphony RGQ MDx (US), there is a button for each of the QIAAsymphony AS drawers next to the QIAAsymphony SP drawer buttons in the status bar. See Section 6.1.2 for more details.



Press the **S** button to open the **Sample Preparation/Define Sample Rack Type** screen.

If the **S** button is flashing, press the button so that the warning or error message can be displayed.



Press the **R+C** button to open the **Consumables/8-Rod Covers/Tubes/Filter-Tips/Reagent Cartridges** screen.



Press the **W** button to open the **Waste** screen.



Press the **E** button to open the **Elution Slot/Configure Racks** screen.

#### S button

The button for the "Sample" drawer is active if the **Batch Overview** or **Sample View** screen of the **Sample Preparation** menu is displayed.

#### R+C button

The button for the "Reagents and Consumables" drawer is active if the **Consumables/8-Rod Covers/Tubes/Filter-Tips/Reagent Cartridges** screen is displayed. This screen appears when the **R+C** button is pressed.

If insufficient consumables and reagents are loaded for the queued batches, the **R+C** button becomes yellow and flashes. After opening the **Consumables/8-Rod Covers/Tubes/Filter-Tips/Reagent Cartridges** screen the **R+C** button becomes gray again.

## W button

The button for the “Waste” drawer is active when the **Waste** screen is displayed. This screen appears after the **W** button has been pressed.

If there is insufficient space in the “Waste” drawer for used 8 Rod Covers or sample prep cartridges, the **W** button becomes yellow and flashes. After opening the **Waste** screen, the button becomes gray again.

## E button

The button for the “Eluate” drawer is active if either the **Sample Preparation/Elution Slot/Configure Racks** or the **Sample Preparation/Elution Slot** screen is displayed. One of these screens appears when the **E** button is pressed or if the “Eluate” drawer is opened.

**Note:** The **E** button becomes green and the arrow symbols flash if an elution rack is ready to be removed from the “Eluate” drawer.

## Colors of drawer buttons

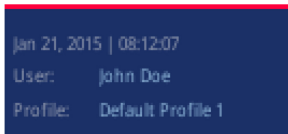
The color of each button changes to show the current status of the drawer.

Gray	This shows that the drawer is active.
Yellow and flashing	<p>If an error occurs, the drawer button turns yellow and flashes to alert the user.</p> <p>If the run is stopped either by the user or due to an error, the <b>S</b> button becomes yellow and flashes. If the button is then pressed, the corresponding error message is displayed. The user must then press the <b>OK</b> button to continue. The <b>S</b> button becomes gray again.</p>
Blue	If one of the drawer buttons is active, the buttons for the other drawers are displayed in blue.
Anthracite	If the “Eluate” drawer or <b>Sample Preparation/Input Rack</b> screen is open, the buttons for the other drawers become anthracite.
Green with flashing arrows	This applies only to the <b>E</b> button for the “Eluate” drawer. The <b>E</b> button becomes green and the arrow symbols flash if an elution rack is ready to be removed from the “Eluate” drawer.



### 5.3.3 Date and time

Date and time are displayed at the bottom right of the status bar.



### 5.3.4 User logged in

The name of the user currently logged in is displayed below the date and time.

## 5.4 Command bar

The command bar is at the right of each screen. The buttons that appear in the command bar vary according to the screen displayed.

### 5.4.1 General buttons

When you press the buttons, the following actions will be initiated:



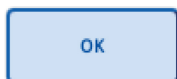
Closes the screen without saving the changes.



Opens the next screen in the workflow.



Opens the previous screen.



Saves the changes and closes the current screen.



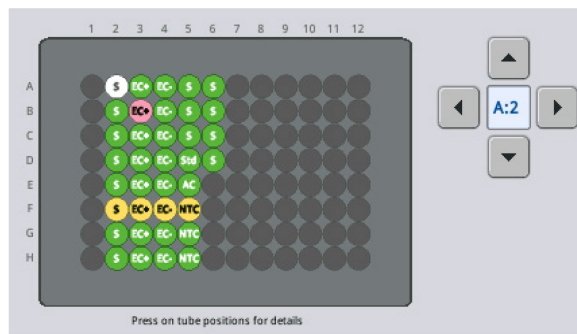
Provides information to help the user complete the current screen.



Displays the software version.

## 5.5 Schematic plates

Schematic plate diagrams are used in some screens to display racks and their contents. Press on a position to show its details, or select a position using the arrow buttons.



**Example schematic plate.**

Blue



Position is assigned to a batch.

Light green



Position is assigned to a batch that is currently being processed.

Dark green



Position has been processed.

Hatched



Position is blocked or reserved and cannot be used.

Yellow



Sample has the status "unclear".

Red



Sample has the status "invalid".

Gray



Position is empty.

White



Position is currently selected.



Moves selection one position to the right.



Moves selection one position to the left.



Moves selection one position up.



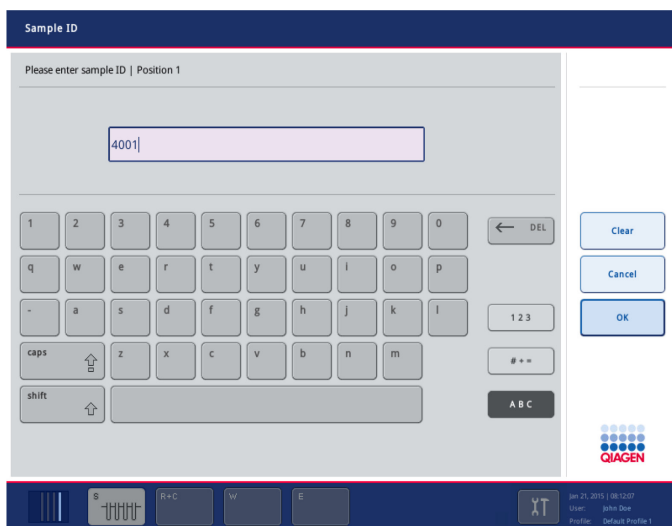
Moves selection one position down.

## 5.6 Screens (all menus)

### 5.6.1 **Keyboard** screen

A virtual keyboard is displayed in the **Keyboard** screen, enabling, for example, sample IDs, elution rack IDs and elution slot IDs to be scanned with a handheld scanner or to be manually entered.

If a software screen contains a text field that is colored light pink, press the text field and the **Keyboard** screen appears automatically.



**Keyboard screen.**

## Buttons in the command bar

In addition to general buttons (see Section 5.4.1), the **Keyboard** screen displays the following button.



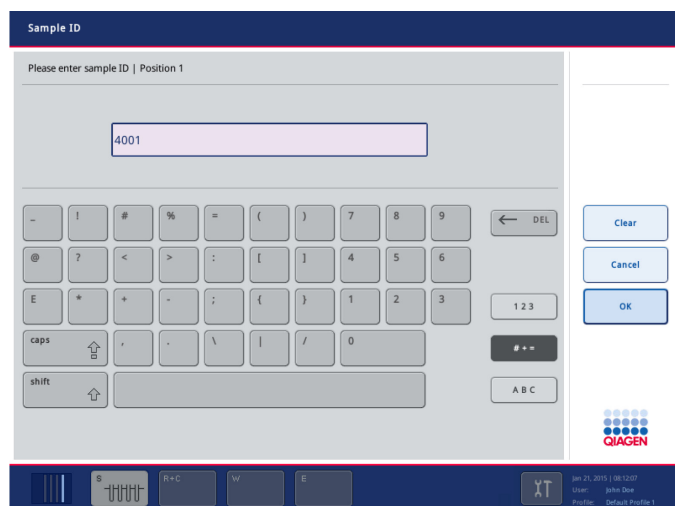
Removes text from the text field.

## Text field

The text field displays scanned or manually entered text and numbers.

## Virtual keyboard

The virtual keyboard is based on a standard “QWERTY” keyboard. The default view of the virtual keyboard is the “ABC” view, with letters and numbers displayed. To enter symbols, press the **Symbols** button.



### 5.6.2 Consumables/Cartridges/Filter-Tips screen

This screen consists of 2 dialog panels – the **Consumables** dialog panel and the **Sample Calculation** dialog panel. It provides information about 8-Rod Covers, sample prep cartridges, reagent cartridges, filter-tips, and an additional buffer bottle (not required for all protocols; see the Instructions for Use (Handbook) for the assay you are using for more information).

This screen enables the bar code of the buffer bottle to be scanned or entered. If consumables or reagents are missing, information will be provided in this screen.

Note: Press the Tip Information button for a recommendation on tip loading.

Consumables | Cartridges / Filter-Tips

Cartridges	Reserved	Available	Missing
8-Rod covers	2	12	0
Sample prep cartridges	12	84	0

Tip Information

Tips	Reserved	Available	Missing
Tips 1500 µl	72	320	0
Tips 200 µl	16	192	0

Reagents	Reserved	Available	Missing
Accessory-Trough-12			
ETOH	0	124595	0
Accessory-Trough-5			
ETOH	0	124595	0
BufferBottle-1			
Buffer	0	unknown	0
Reagentbox-1			
Q5L2	8000	40614	0
Q5B1	20800	72603	0
Q5W1	24000	81582	0
Q5W5	24000	81582	0
Q5W2	48000	86582	0

Buffer bottle bar code

Sample Calc.

Consumables

Bottle ID

OK

Help

Jan 21, 2015 | 08:12:07  
User: John Doe  
Profile: Default Profile 1

Consumables/Cartridges/Filter-Tips screen (Consumables dialog panel).

Consumables | Cartridges / Filter-Tips

Cartridges	Estimated Samples
8-Rod covers	64
Sample prep cartridges	72

Tips	Estimated Samples
Tips 1500 µl	88
Tips 200 µl	157

Reagents	Estimated Samples
Accessory-Trough-12(ETOH)	200
Accessory-Trough-5(ETOH)	200
BufferBottle-1(Q5X1)	200
Reagentbox-1	37
Reagentbox-2	0

The sample calculator dialog shows the possible processable number of sample, with the current loaded consumables.  
The limiting consumable is highlighted.  
Extra tips for e.g. the IC-Check or cist detection are not included in the calculation of the reserved consumables.

Selected Application/ACS  
Virus 1000

Applications/ACS:  
Virus  
Virus 1000  
Virus 1000 IntCtrl2

Sample Calc.

Consumables

Bottle ID

OK

Help

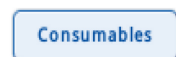
Jan 21, 2015 | 08:12:07  
User: John Doe  
Profile: Default Profile 1

Consumables/Cartridges/Filter-Tips screen (Sample Calculation dialog panel).

## Command bar



Opens the **Sample Calculation** dialog panel.



Opens the **Consumables** dialog panel.



Displays the **Keyboard** screen. If the application requires an additional bottle of buffer, the bar code can be entered either manually or using a handheld bar code scanner. The bar code enables the QIAAsymphony SP to identify which buffer has been loaded.

## Dialog panel

### Consumables panel

The **Consumables** dialog panel displays information in tabular format about reagents and consumables that are reserved, available, or missing. If an additional buffer bottle is required for the protocol, the bar code is displayed in this dialog panel.

### Sample Calculation panel

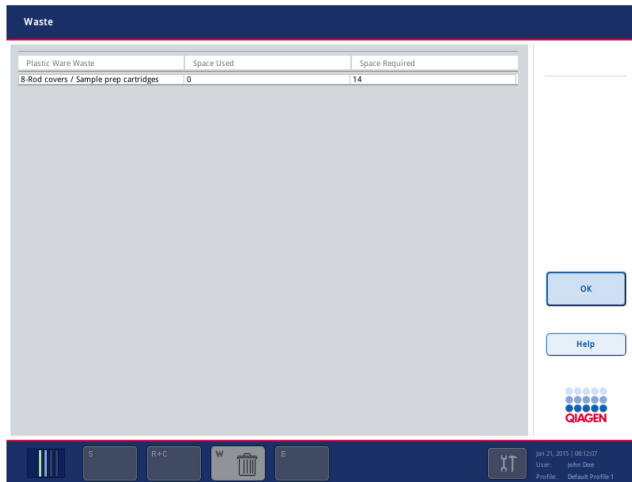
The **Sample Calculation** dialog panel displays information about the remaining number of samples that can be processed with the reagents and consumables that are currently loaded on the worktable. Any reagents and consumables that are reserved by scheduled batches are not included in the calculations. Limiting resources are shown in red. Numbers relate to the particular Assay Control Set that is selected in **the Applications/ACS** list.

**Note:** Since the default elution volume is used for calculations, the actual number of additional samples that can be processed may differ slightly.

The calculation is updated if an application/ACS is selected or changed or after finishing a new inventory scan.

### 5.6.3 Waste screen

This screen displays information about used consumables and liquid waste.



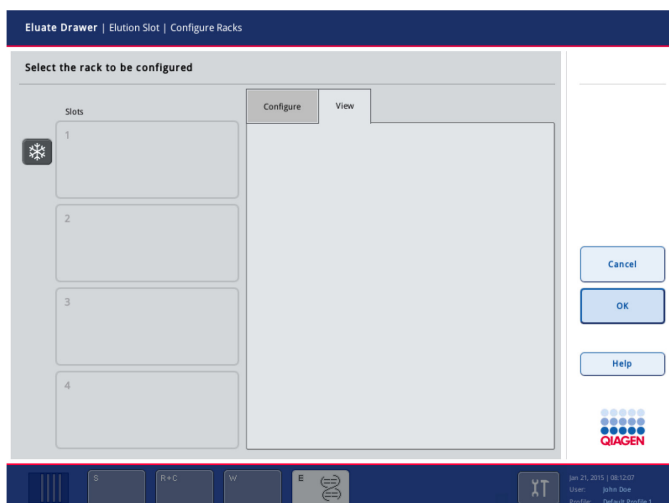
**Waste screen.**

### Dialog panel

The dialog panel displays information in tabular format about used consumables.

### 5.6.4 Eluate Drawer/Elution Slot/Configure Racks screen

This screen is displayed when the **E** button is pressed.

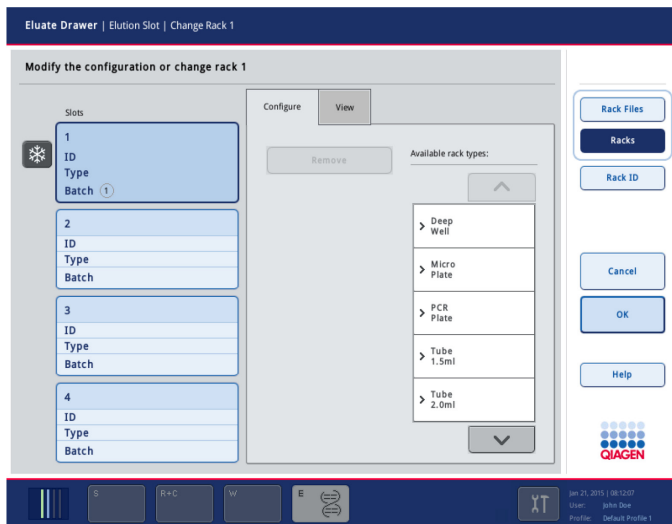


**Eluate Drawer/Elution Slot/Configure Racks screen.**

**Note:** To be able to assign or remove elution racks, the "Eluate" drawer must be open.

### 5.6.5 Eluate Drawer/Elution Slot/Change Rack X screen

This screen is displayed when the **E** button is pressed and a slot is selected.



**Note:** To be able to assign or remove elution racks, the “Eluate” drawer must be open.

## 5.7 Tools tab

The **Tools** tab provides access to several menus, required for operation of the QIAsymphony SP/AS instruments.

**Note:** The **Tools** tab cannot be accessed from every screen, for instance it cannot be accessed during run definition.

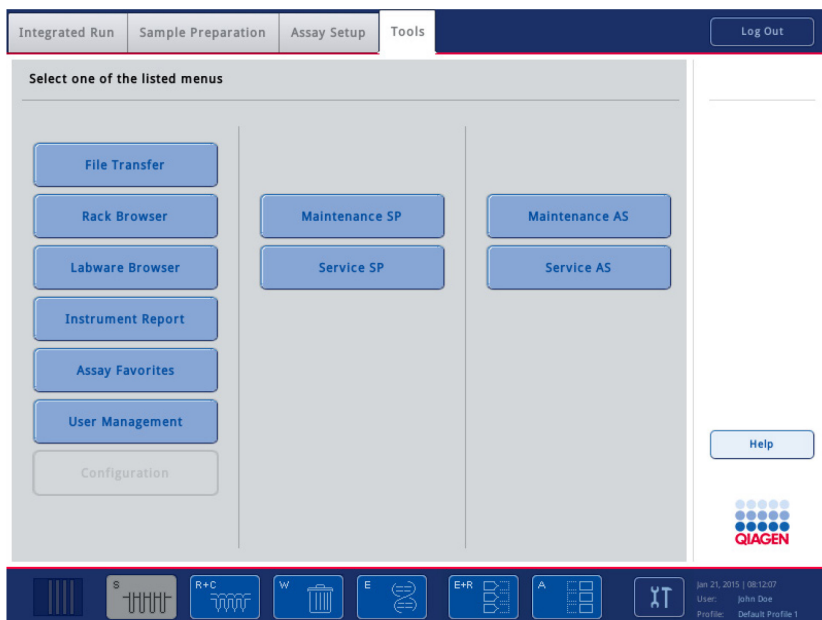
Access rights to the menus are dependent on the role assigned to the user. A “Supervisor” can access all of the menus, and an “Operator” can access all of the menus except the **Configuration** menu.

After initialization, the **Sample Preparation** menu is displayed.

To access any of the other **Tools** menus:

1. Press the **Tools** tab.
2. Select the menu to be accessed by pressing the appropriate button in the **Tools** screen.





Tools screen ("Operator" logged in).

The "Operator" can access the following menus:

- **Maintenance SP**
- **Service SP**
- **User Management**
- **File Transfer**
- **Instrument Report**
- **Rack Browser**
- **Labware Browser**

The "Supervisor" can access the following menus:

- **Maintenance SP**
- **Service SP**
- **Configuration**
- **User Management**
- **File Transfer**
- **Instrument Report**
- **Rack Browser**
- **Labware Browser**

## Dialog panel

The dialog panel contains buttons that enable access to other menus. If the user does not have access rights, if a batch is running, or if an unfinished workflow is opened, some buttons may be disabled.

**Note:** For detailed information about the menus that are required for operation of the QIASymphony SP (Maintenance SP and Service SP), refer to Sections 5.10 and 5.12.

A blue rectangular button with rounded corners and a thin border, containing the text "File Transfer" in a small, dark blue font.


Opens the **File Transfer** menu.

For detailed information, see Section 5.13.

A blue rectangular button with rounded corners and a thin border, containing the text "Rack Browser" in a small, dark blue font.

Opens the **Rack Browser** menu.

For detailed information, see Sections 5.15 and 6.7.

A blue rectangular button with rounded corners and a thin border, containing the text "Labware Browser" in a small, dark blue font.

Opens the **Labware Browser** menu.

For detailed information, see Sections 5.16 and 6.6.

A blue rectangular button with rounded corners and a thin border, containing the text "Instrument Report" in a small, dark blue font.

Opens the **Instrument Report** menu.

For detailed information about how to create an instrument report file, see Section 5.14.

A blue rectangular button with rounded corners and a thin border, containing the text "Assay Favorites" in a small, dark blue font.

Opens the **Assay Favorites** menu.

For detailed information about how to configure "Favorite" assays for an integrated run, see Section 4.5.

A blue rectangular button with rounded corners and a thin border, containing the text "User Management" in a small, dark blue font.

Opens the **User Management** menu.

This button has different functionality depending on whether a "Supervisor" or an "Operator" is logged in.

For detailed information about managing users, see Section 4.

Configuration

Opens the **Configuration** menu.

This button is only active if the “Supervisor” is logged in.

After configuration, the QIAsymphony SP/AS instruments may need to be restarted. Therefore, this button is only active if there is no output on the QIAsymphony SP or on the QIAsymphony AS.

For detailed information about how to configure the QIAsymphony SP/AS instruments, see Section 4.

Maintenance SP

Opens the **Maintenance SP** menu.

For detailed information, see Section 5.10.

Service SP

Opens the **Service SP** menu.

For detailed information, see Section 5.12.

Maintenance AS

Switches to the assay setup user interface and displays the **Maintenance AS** menu for the QIAsymphony AS.

For detailed information, see Section 6.4

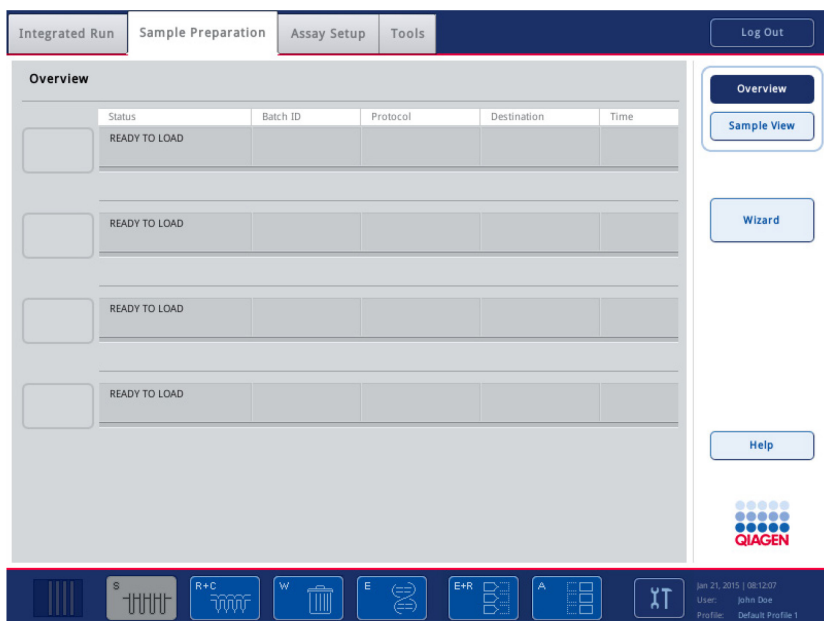
Service AS

Switches to the assay setup user interface and opens the **Service AS** menu.

For detailed information, see Section 6.5.

## 5.8 Sample Preparation menu

The **Sample Preparation** menu is used to view information about the QIASymphony SP and the progress and state of sample preparation.



**Sample Preparation menu (Sample Preparation tab).**

### Sample Preparation

To select the Sample Preparation tab, press the appropriate name.

### Sample View

To select the **Sample View** screen, press the **Sample View** button in the command bar.

### Log In/Log Out

The **Log In** button is displayed at the top right of every screen. The **Log In/Log Out** button enables the user to log in with a different user ID.

The user can log in with either the "Supervisor" or the "Operator" user ID.

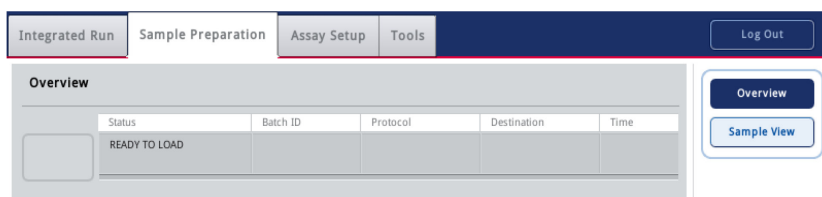
The user with the “Supervisor” user ID can:

- Upload Assay Control Sets, protocols, process configuration profiles, cartridge information, duration files, rack files, work lists, scripts and labware files from the USB stick to the QIASymphony SP.
- Download result files, log files, instrument reports, duration files, rack files, work lists, Assay Control Sets, protocols, cartridge information, users, scripts and labware files from the QIASymphony to a USB stick.
- Synchronize files on the QIASymphony SP with files saved on a USB stick (e.g., for deletion of files on the QIASymphony SP) and vice versa.
- Configure date, time, and the default tube types.
- Manage users and passwords

The user with the “Operator” user ID can:

- Define and run batches
- Download result files and log files
- Clear result files
- Change their own password

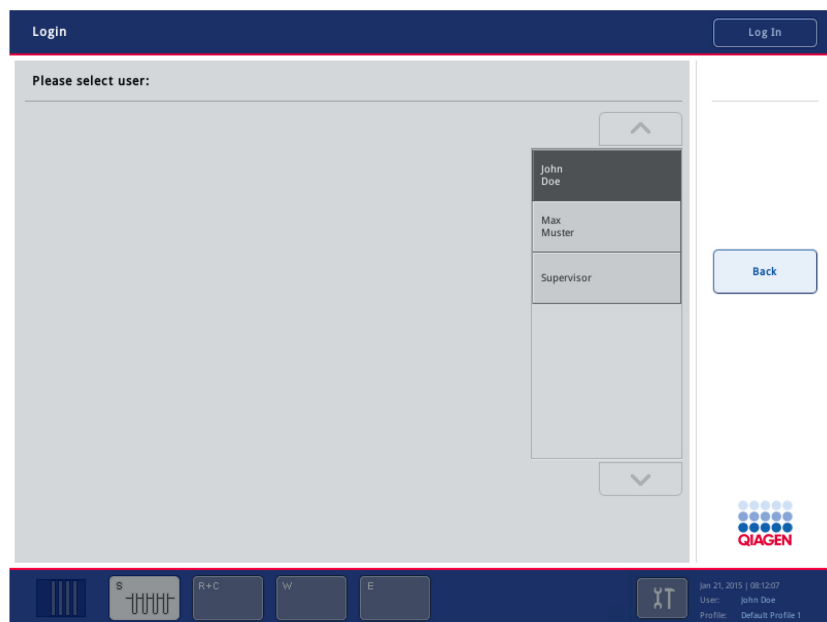
**Note:** Users with the “Operator” user ID can also download log files, result files, confirmation files, instrument reports, rack files and work lists. They are also able to upload rack files and work lists.



If the **Log Out** button is pressed, the user currently logged in is logged out.

### 5.8.1 Login screen

The **Login** screen displays the list of users with active user accounts.



**Login screen.**

#### Dialog panel

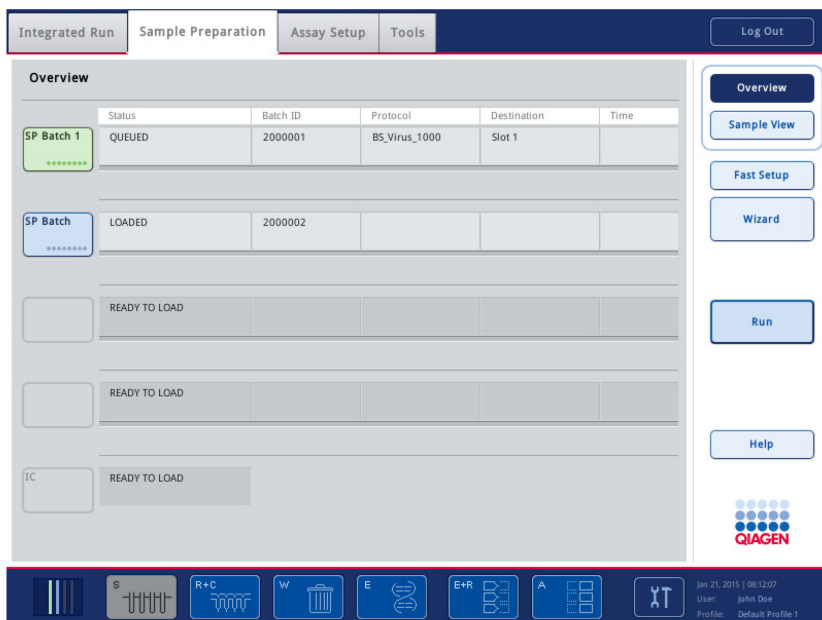
##### Users list

To log in to the QIAsymphony SP, select the corresponding login name from the **Users** list. The **Keyboard** screen then appears, which enables the user to enter their password. Press **OK** to complete the log in.

After successful login, the **Sample Preparation/Overview** screen is displayed. Depending on your assigned role ("Supervisor" or "Operator"), you have different access rights.

### 5.8.2 Sample Preparation tab — Sample Preparation/Overview screen

The **Sample Preparation** tab shows the status of all sample batches. It also enables the user to assign internal controls to positions in the fifth tube carrier (position A). For samples loaded in tubes, the position of the **Batch** button corresponds to the loaded sample slot. For example, if a tube carrier is loaded into "Slot 2", the second **Batch** button becomes light blue.

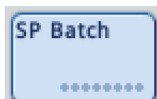


## Sample Preparation tab.

### Sample batch status

The status of each sample batch is denoted by the color of the relevant **Batch** button.

Blue



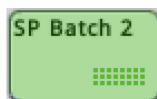
The sample batch is loaded. The position of the **Batch** button corresponds to the slot number that the tube carrier was loaded into.

Light green



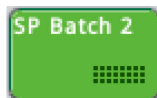
The batch is loaded and queued. Assay Control Set and elution slot have been assigned.

Green



The samples in the batch are being processed.

Dark green



The samples in the batch have been processed and purified nucleic acids eluted. If further batches are to be eluted into separate elution racks, this elution rack can be unloaded.

Orange



All batches currently being processed are paused. The batches can be either continued or stopped.

Red

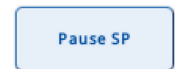


The batch has been stopped by either the user or due to an error. If processing was stopped due to an error, the **S** button, which corresponds to the "Sample" drawer, becomes yellow (see Section 5.3.1).

### Command bar



The button is active if at least one batch has been queued. Press **Run** to start batch validation. If the defined batch is successfully validated, the run will start. If there is a problem with the defined batch during validation, a warning will appear with more information.



If a run is in progress, the **Pause SP** button is visible. The **Pause SP** button should only be pressed in an emergency. After pressing **Pause SP**, the QIASymphony SP completes the current command being processed, pauses the protocol, and changes the sample state to "unclear". If the protocol has been paused either by the user or due to an error, a **Stop SP** and **Continue SP** button appears (see Section 17).

**Note:** The drawers of the QIASymphony SP will be unlocked and the samples of the processed batch will be flagged as "unclear".



The **Stop SP** button appears if the current run is paused. Press **Stop SP** to stop all currently running batches. Batches that have been queued but have not yet been processed remain queued.

**Note:** Refer to Appendix E for information about worktable cleanup.



The **Continue SP** button appears if the current run is paused. Press the **Continue SP** button to continue the run.

**Note:** A run should only be paused in an emergency.



## Dialog panel

**SP Batch** The status of each batch is shown. Depending on the batch status, pressing the **SP Batch** button may result in an action being performed.

**SP Batch X**

**New ...**

- **READY TO LOAD** — the **SP Batch** button is inactive in this state.
- **LOADED** — if the **SP Batch** button is pressed, the batch definition workflow starts.
- **STOPPED/COMPLETED** — if the **SP Batch** button is pressed, the batch will be removed and new samples can be loaded. Pressing the **SP Batch** button has the same effect as removing the tube carrier for that slot.
- **PAUSED** — the **SP Batch** button is inactive in this state.

**Note:** The "X" represents the batch number as a substitute for the Batch ID. See Section 5.8.3 for more details.

**IC**

The **IC** button is for the internal control and is only active if internal controls are loaded in a tube carrier. Depending on the status of the internal control, pressing the **IC** button may result in an action being performed.

- **READY TO LOAD** — the **IC** button is inactive in this state.
- **LOADED** — if the **IC** button is pressed, the **Sample Preparation/Internal Controls** screen is displayed. This screen enables the user to view the loaded internal controls. If tubes are not bar code labeled or if an error occurred during bar code reading, this can be resolved in this screen.  
  
If batches are being processed and additional internal controls need to be loaded, press this button to unlock the **IC** carrier slot so that the tube carrier can be removed.
- **ON HOLD** — a carrier with internal controls is not currently inserted, but it was previously inserted and then removed. The QIAAsymphony SP retains the information about the previously loaded internal controls if the **Sample Preparation/Internal Controls** screen is open.

## Table

<b>Status</b>	<p>The batch status is displayed.</p> <p><b>READY TO LOAD</b> — samples can be loaded.</p> <p><b>LOADED</b> — samples are loaded and can be defined for processing.</p> <p><b>QUEUED</b> — samples are loaded and the batch is defined. The batch is queued for processing.</p> <p><b>RUNNING</b> — the batch is running. Loaded samples in the batch are being processed.</p> <p><b>COMPLETED</b> — all samples in the batch have been processed. If the elution rack will not be used for collection of eluates in further batches, the elution rack can be removed from the “Eluate” drawer and the result file can be downloaded.</p> <p><b>PAUSED</b> — processing of the batch has been paused. The samples of the processed batch will be flagged as “unclear”.</p> <p><b>STOPPED</b> — the batch has been stopped either by the user or due to an error. The samples are lost and cannot be manually processed.</p>
<b>Batch ID</b>	The assigned batch ID is shown here.
<b>Protocol</b>	If a batch is queued, the name of the protocol to be run is displayed.
<b>Destination</b>	The corresponding elution slot is displayed. For batch processing, it is necessary to assign an elution rack to the selected elution slot in the “Eluate” drawer.
<b>Time</b>	The actual elapsed time is displayed.

## Progress bar

The progress bar displays information about the protocol being run. Each protocol is made up of steps such as lyse, bind, wash and elute. The progress bar displays information about the actual step of the protocol being performed and also the total progress in percent for the whole protocol. Additionally, the progress bar displays the remaining run time in real-time.

processing Lyse: 12%	Remaining: 00:01h Endtime: 13:47
----------------------	----------------------------------

**Note:** Run time estimation is based on stored run times of previous, valid runs with identical settings.

### 5.8.3 Sample Preparation tab — Sample Preparation/Sample View screen

Information is displayed about samples that will be processed, are currently being processed or have been processed.

**Note:** A warning symbol appears in the **Sample View** screen if at least one sample is flagged as “invalid”.

Bl	Src	Pos	Labware	Sample ID	Assay Control Set	Status	Dest	Pos
1	1	1	BD#352051 FalconPP 17x100	1001	Virus 1000	invalid	1	(1..16)
1	1	2	BD#352051 FalconPP 17x100	1002	Virus 1000	valid	1	(1..16)
1	1	3	BD#352051 FalconPP 17x100	1003	Virus 1000	valid	1	(1..16)
1	1	4	BD#352051 FalconPP 17x100	1004	Virus 1000	valid	1	(1..16)
1	1	5	BD#352051 FalconPP 17x100	1005	Virus 1000	valid	1	(1..16)
1	1	6	BD#352051 FalconPP 17x100	1006	Virus 1000	valid	1	(1..16)
1	1	7	BD#352051 FalconPP 17x100	1007	Virus 1000	valid	1	(1..16)
1	1	8	BD#352051 FalconPP 17x100	1008	Virus 1000	valid	1	(1..16)
1	1	9	BD#352051 FalconPP 17x100	1009	Virus 1000	valid	1	(1..16)
1	1	10	BD#352051 FalconPP 17x100	1010	Virus 1000	valid	1	(1..16)
1	1	11	BD#352051 FalconPP 17x100	1011	Virus 1000	valid	1	(1..16)
1	1	12	BD#352051 FalconPP 17x100	1012	Virus 1000	valid	1	(1..16)
1	1	13	BD#352051 FalconPP 17x100	1013	Virus 1000	valid	1	(1..16)

**Sample View screen.**

#### Command bar

The command bar is as described in Section 5.8.2, page 80.

#### Dialog panel

Information about the samples is provided in tabular format. When the elution rack is removed, all information about the samples is automatically removed from the table. If eluates from samples processed in earlier runs have not been removed from the “Eluate” drawer, information about these samples remains in the table.

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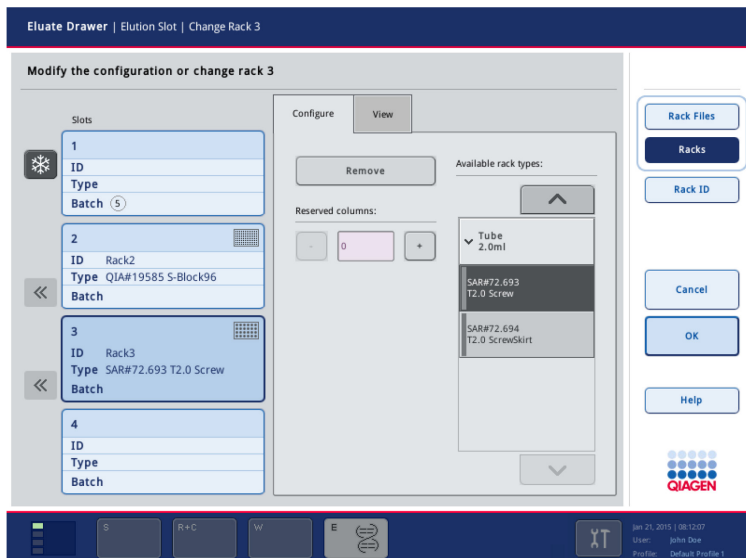
## Table

<b>Bt.</b>	<p>Number of the batch. Batches are numbered consecutively in the order in which they have been defined, starting with Batch 1. The batch numbering is therefore independent of the corresponding sample slots.</p> <p>Batch numbering starts again at 1 if all batches and eluates are removed from the QIA Symphony SP, or after Batch 99. In the latter case, a batch number will not be reused if the elution plate of the batch has not yet been removed.</p>
<b>Src.</b>	The sample slot number.
<b>Pos.</b>	The position in the tube carrier or the sample rack is displayed.
<b>Labware</b>	The labware used is shown.
<b>Sample ID</b>	ID (bar code, virtual bar code, or Position_BatchID) is shown.
<b>Assay Control Set</b>	The name of the assigned Assay Control Set is displayed.
<b>Vol. In</b>	The input volume, which is defined in the protocol, is displayed.
<b>Vol. Out</b>	The elution volume is displayed.
<b>Status</b>	<p>The sample state is displayed. There are 3 possible sample states: "valid", "unclear", and "invalid".</p> <p>The state of individual samples is also shown by the text color in the table.</p> <ul style="list-style-type: none"><li>● Light green — "valid"</li><li>● Light pink — "unclear"</li><li>● Pink — "invalid"</li></ul>
<b>Dest.</b>	The elution slot that is used by the batch.
<b>Pos.</b>	The elution section of the corresponding elution slot is displayed.
<b>Protocol</b>	The protocol that is used by the batch is displayed.

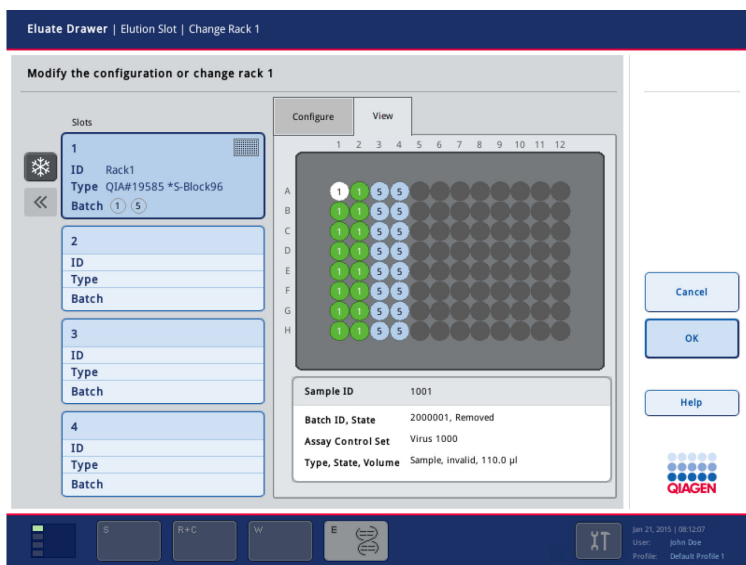
#### 5.8.4 Eluate Drawer/Elution Slot screen

If the “Eluate” drawer is opened, the **Eluate Drawer/Elution Slot** screen appears. If the “Eluate” drawer is empty and an elution rack has not yet been assigned, the information fields and the tabs are empty.

Close the “Eluate” drawer to proceed to the **Eluate Drawer/Elution Slot/Configure Rack X** (where X = 1 to 4) screen.



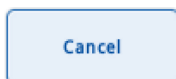
**Eluate Drawer/Elution Slot screen (Configure tab).**



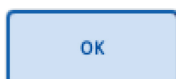
## Eluate Drawer/Elution Slot screen (View tab).

**Note:** Images of instrument screens and files used throughout this user manual (volumes 1 and 2) are examples and may differ from the actual screen or file you are using.

### Command bar



If the "Eluate" drawer is open, a message appears that tells the user to close the "Eluate" drawer. If the **Cancel** button is pressed after the "Eluate" drawer has been closed, the screen closes without saving the changes. An inventory scan of the "Eluate" drawer is performed to check the inventory of the "Eluate" drawer against the slot/rack assignment made in the **Sample Preparation/Elution Slot** screen.







If the "Eluate" drawer is open, a message appears that tells the user to close the drawer. If the **OK** button is pressed after the drawer has been closed, the changes are saved and the screen is closed. An inventory scan of the "Eluate" drawer is performed to check the inventory of the "Eluate" drawer against the slot/rack assignment made in the **Sample Preparation/Elution Slot** screen.

### Dialog panel

#### Elution slot button 1

Select to enter the **Sample Preparation/Elution Slot/Add Elution Rack** screen or **Sample Preparation Elution Slot/ Remove Elution Rack** screen. The elution slot can be selected by either pressing the corresponding button or by scanning the corresponding bar code label on the elution slot in the "Eluate" drawer.

The following symbols can be displayed:

-  — Only coolable slot with EMT allowed.
-  — Cooling of elution slot suppressed.
-  — Elution rack can be removed.
-  — "Padlock" symbol, the elution rack is in use and cannot be removed.

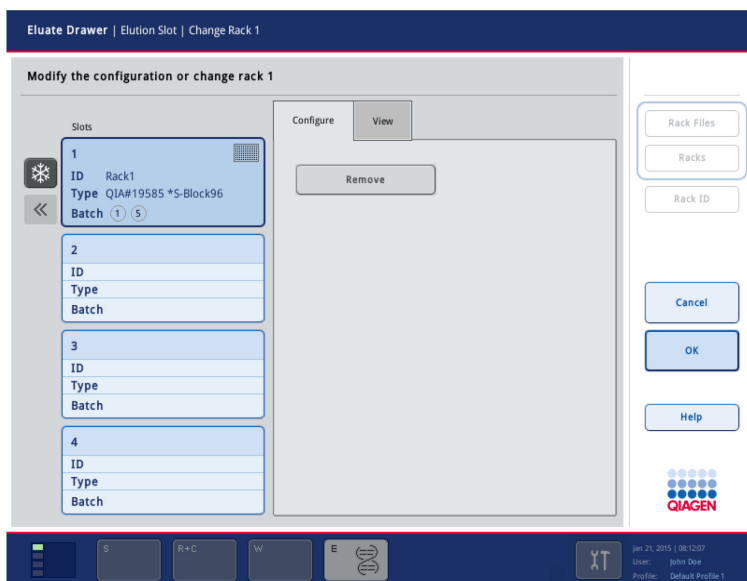


Press to switch cooling on “Elution slot 1” on or off. If the selected protocol requires elution rack cooling, do not switch cooling off.

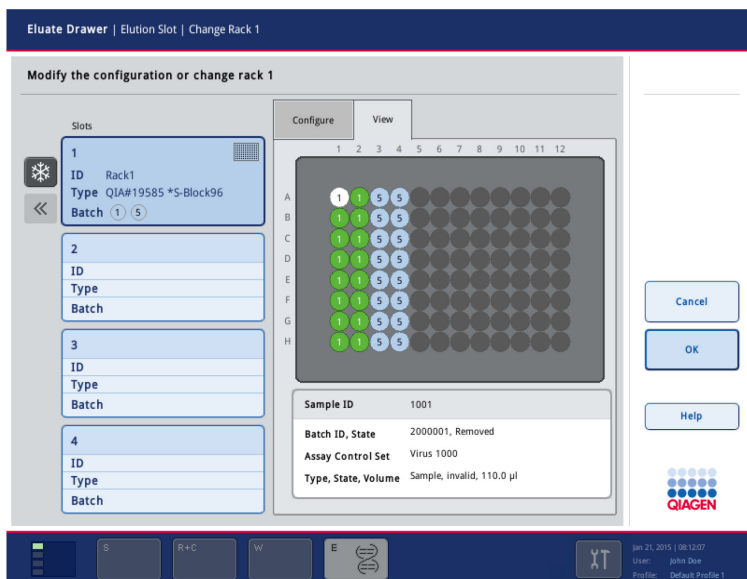
### 5.8.5 Eluate Drawer/Elution Slot/Change Rack X screen

If an elution slot is selected when the “Eluate” drawer is open, the **Eluate Drawer/Elution Slot/Change Rack X** screen is shown.

Close the “Eluate” drawer to show the **Eluate Drawer/Elution Slot/Configure Rack X** screen.



**Eluate Drawer/Elution Slot/Change Rack X screen (Configure tab).**



Eluate Drawer/Elution Slot/Change Rack X screen (View tab).

## Command bar

**Rack Files**

Displays the **Available rack files** list in the **Configure** tab. This button is visible only if the **Configure** tab is selected.

**Racks**

Displays the **Available rack types** list in the **Configure** tab. This button is visible only if the **Configure** tab is selected.

**Rack ID**

Press to open the **Keyboard** screen. This enables the user to enter an elution rack ID. The ID will be displayed in the elution slot button.

**Note:** Instead of manually entering the ID, the handheld bar code scanner should be used to scan the ID.

**Note:** If a rack file is found for the entered ID, it is assigned automatically.

**Cancel**

A message appears telling the user to close the "Eluate" drawer.

**OK**

A message appears telling the user to close the "Eluate" drawer.







**Note:** If an elution rack was already assigned to the selected slot when the **Eluate Drawer/Elution Slot** screens were entered, the **Rack Files**, **Racks**, and **Rack ID** buttons are inactive. If you want to place a different rack on the slot, remove the currently defined rack first by pressing the **Remove** button in the **Configure** tab.

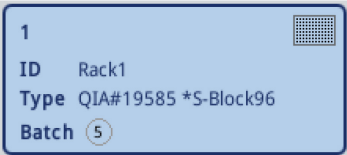
**Dialog panel**

**Elution slot button 1** Press to select the corresponding slot. The elution slot can be selected by either pressing the corresponding button or by scanning the corresponding bar code label on the elution slot in the “Eluate” drawer.

The following symbols can be displayed:

-  — Only coolable slot with EMT allowed.
-  — Cooling of elution slot suppressed.
-  — Elution rack can be removed.
-  — “Padlock” symbol, the elution rack is in use and cannot be removed.

If the elution slot is to be used for a batch that has already been defined, additional information is displayed.



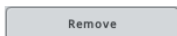
For batches that have already been defined, the batch number is also displayed.

The background color of the batch number indicates whether the batch is queued (blue), running (light green), or finished (green). Blocked batches are hatched.



Press the button to change whether cooling of the elution rack placed on “Elution slot 1” is suppressed. If the selected protocol requires elution rack cooling, cooling must not be suppressed.

## Configure tab



This button is active if the << symbol is displayed for the selected slot. Press to remove the rack from the selected slot. Depending on the software configuration of your QIAsymphony SP, you may have to enter the ID of the elution rack to be removed. In this case, the **Keyboard** screen appears. Enter the ID of the elution rack either manually using the keyboard or using the handheld bar code scanner.

### Reserved columns field

This option is available if a rack type has been defined for the selected slot, the rack on the selected slot is empty and no batch defined for this elution slot is running. Columns on the left side of the rack can be marked as reserved for other purposes and will remain untouched by the batch processing. Use the + and – buttons to adjust the number of reserved columns.

## Available rack files list

If **Rack Files** is selected, the list of all rack files that can be assigned to the elution slots is displayed. To assign a rack file, proceed as follows:

1. Select the slot by pressing the appropriate slot button.
2. If **Racks** is selected, press **Rack Files**.
3. Select the rack file by pressing the item in the list. Use the up and down arrows to scroll through the list.

## Available rack types list

The list displays all available elution rack categories with rack types that are allowed for the selected elution slot. To select the rack type that will be placed onto the selected slot, proceed as follows:

1. Select the slot by pressing the appropriate slot button.
2. If **Rack Files** is selected, press **Racks**.
3. Select the EMTR elution rack category by pressing the item in the list. Use the up and down arrows to scroll through the list.

**Note:** Only the EMTR is allowed for QIAsymphony RGQ MDx (US) workflows.

4. A list of rack types in the selected category that can be assigned to the selected elution slot is displayed.

5. Select type of rack by pressing the item in the list. Use the up and down arrows to scroll through the list.

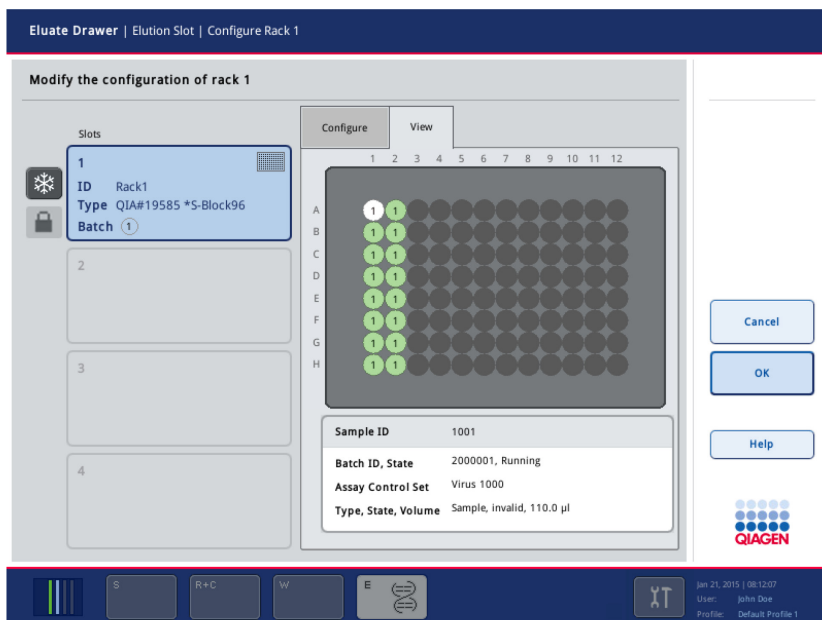
#### 5.8.6 Eluate Drawer/Elution Slot/Configure Rack X screen

If an elution slot is selected when the "Eluate" drawer is closed, the **Eluate Drawer/Elution Slot/Configure Rack X** screen is shown.

Open the "Eluate" drawer to enter the **Eluate Drawer/ Elution Slot/Change Rack X** screen.

The screenshot shows the "Eluate Drawer | Elution Slot | Configure Rack 1" screen. The main area is titled "Modify the configuration of rack 1". On the left, under "Slots", there are four slot configurations. Slot 1 is selected and shows "ID Rack1", "Type QIA#19585 \*S-Block96", and "Batch 1". Slots 2, 3, and 4 are empty. On the right, the "Configure" tab is active. It features a "Remove" button, a "Reserved columns" section with a minus button, a text box containing "0", and a plus button. Below this is a list of "Available rack types": NU#260252 \*DeepWell96 RB, QIA#19585 \*S-Block96 (highlighted), QIA#19588 \*EMTR, RE#STBR96-300 \*TubeRack300, and TS#3711 \*1.4ml 2DStorageT. On the far right, there are buttons for "Rack Files", "Racks", "Rack ID", "Cancel", "OK", and "Help". The bottom status bar shows icons for "S", "R+C", "W", and "E", along with a date/time display (Jan 21, 2015 | 08:12:07) and a profile name (Default Profile 1).

**Eluate Drawer/Elution Slot/Configure Rack X screen (Configure tab).**



**Eluate Drawer/Elution Slot/Configure Rack X screen (View tab).**

#### Command bar



Closes the screen without saving the changes. An inventory scan of the “Eluate” drawer is performed to check the inventory of the “Eluate” drawer against the slot/rack assignment mode before the **Eluate Drawer/Elution Slot** screens were entered.



Saves the changes and closes the screen. An inventory scan of the “Eluate” drawer is performed to check the inventory of the “Eluate” drawer against the slot/rack assignment made in the **Eluate Drawer/Elution Slot/Change Rack X** screen.

#### Dialog panel

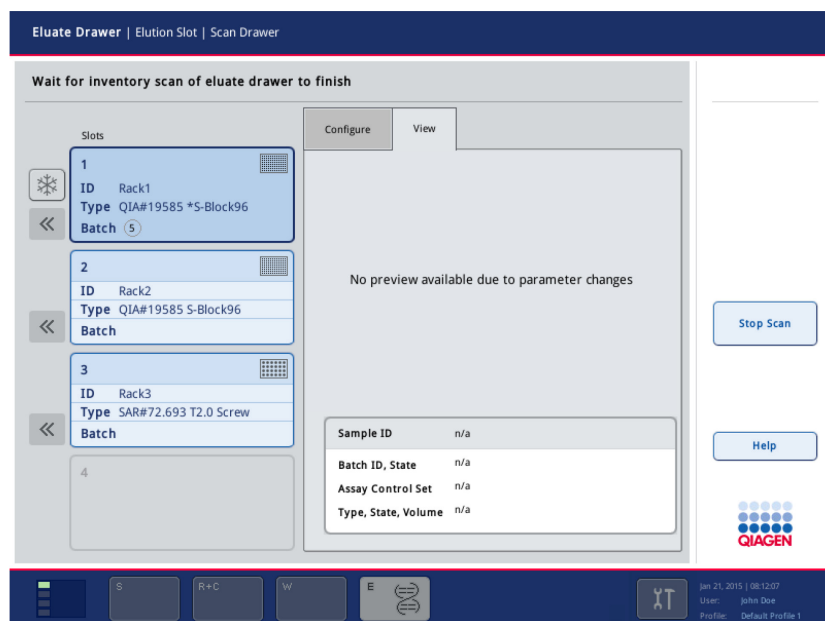
The dialog panel is the same as for the **Eluate Drawer/Elution Slot/Change Rack X** screen (Section 5.8.5) if the “Eluate” drawer has been opened since entering the **Eluate Drawer/Elution Slot** screens.

If the “Eluate Drawer” has not been opened since entering the **Eluate Drawer/Elution Slot** screens, there are the following exceptions:

- The **Remove** button, the **Available rack types** list and the **Available rack files** list in the **Configure** tab are not available.
- The buttons that correspond to an elution slot without an assigned rack are disabled.

### 5.8.7 Eluate Drawer/Elution Slot/Scan Drawer screen

This screen is shown when a scan of the “Eluate” drawer is in progress.

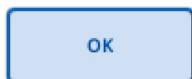


Eluate Drawer/Elution Slot/Scan Drawer screen.

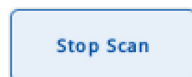
#### Command bar



This button is not active on this screen.



This button is not active on this screen.



Stops the inventory scan of the “Eluate” drawer that is in progress, and then opens the previous screen.

## Dialog panel

The dialog panel is the same as for the **Eluate Drawer/Elution Slot/Configure Rack X** screen (Section 5.8.6).

## 5.9 Configuration menu

The **Configuration** menu enables the "Supervisor" to edit a range of configuration parameters. For more details, see Section 4.

## 5.10 Maintenance SP menu

The **Maintenance SP** menu enables components of the instrument to be used without running a protocol. Tools for performing routine maintenance procedures or for cleanup of the worktable are also available. See Section 15 for more details about maintenance procedures.

**Important:** Before using the **Cleanup** tool, refer to Section 15 of this manual. Only use these tools as indicated and according to the given instructions.

### 5.10.1 Maintenance SP screen



**Maintenance SP screen.**

## Dialog panel

For more information about the **Maintenance SP** menu, refer to Section 15.

### 5.11 User Management menu

The **User Management** menu enables the “Supervisor” to create new users, to reset passwords, to change user roles and to activate/inactivate user accounts. This menu enables the “Operator” to change their password independently from the password expiration setting.

#### 5.11.1 User Management/Please select user screen

The **User Management** screen enables the user to perform actions regarding user management. The exact screen that is displayed depends on the rights of the user logged in (“Supervisor” or “Operator”) the screen appears with differences.

User Management/Please select user screen for the “Supervisor”.

## Command bar



Press to change your own password.



This option is only available to the "Supervisor". Press to create a new user account.



This option is only available to the "Supervisor". Press to change the role of an existing user.



Press to save the changes. This button is active if the changes have not been saved and inactive if no changes have been made.

### Dialog panel

<b>Login name</b>	Displays the login name of the user. This cannot be changed.
<b>First name</b>	Active if a user account is selected in the list. Press to change the first name.
<b>Last name</b>	Active if a user account is selected in the list. Press to change the last name.
<b>New Password</b>	Active if a user account is selected in the list. Press to enter a new password.
<b>Confirm new Password</b>	Active if a user account is selected in the list. Press to confirm the previously entered new password.
<b>User activated</b>	<p>Active if a user is selected who is not logged in.</p> <p><b>Yes</b> — user account is activated and is displayed in the login name list and can be selected for user log in.</p> <p><b>No</b> — user account is inactivated and is not displayed in the login name list. Users with inactivated user accounts cannot log in to the QIASymphony SP.</p>

### Users list

The **Users** list contains all known users. Users with activated user accounts are listed in the package **Activated Users**. Users with inactivated user accounts are listed in the package



**Deactivated Users.** By default, the **Activated Users** package is selected. Press the corresponding item in the list to select the user account to be modified.

### 5.11.2 User Management/Please enter your new password screen

This screen allows the user to change an existing password. It appears if a user has pressed the **Change PWD** button in the **User Management/Please select user** or **User Management/Your user data** screen.

The screenshot shows the 'User Management' screen with the 'Please enter your new password' dialog. The dialog contains three input fields for 'Old Password', 'New Password', and 'Confirm New Password'. To the right of the input fields are buttons for 'Tools', 'Cancel', 'Ok', and 'Help'. The QIAGEN logo is located at the bottom right of the dialog. The bottom of the screen shows a navigation bar with icons for 'S', 'R+C', 'W', and 'E', and a status bar displaying the date 'Jan 21, 2015', time '08:12:07', and user profile 'John Doe, Default Profile 1'.

User Management/Please enter your new password screen.

#### Dialog panel

- |                             |   |
|-----------------------------|---|
| <b>Old Password</b>         | Press to access the <b>Keyboard</b> screen to enter the old password.                 |
| <b>New Password</b>         | Press to access the <b>Keyboard</b> screen to enter the new password.                 |
| <b>Confirm New Password</b> | Press to access the <b>Keyboard</b> screen to reenter the new password to confirm it. |

### 5.11.3 Create User screen

This screen enables a new user account to be added. The screen appears if the "Supervisor" presses the **Add User** button in the **User Management/Please select user** screen.

**Create User**

Please enter data for new user

**Login:** Max Muster

First name (optional): Max

Last name (optional): Muster

**Initial Password:** ●●●●●●

**Confirm initial Password:** ●●●●●●

Bold fields are required.

Cancel

Next

Help

QIAGEN

S R+C W E Jun 14, 2011 08:03:18 User: John Doe Profile: Default Profile 1

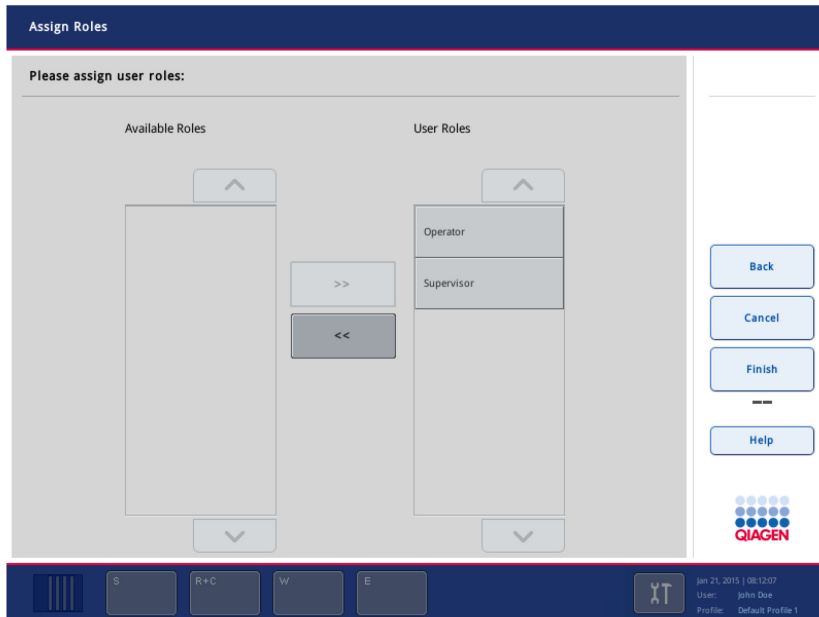
Create User screen.

#### Dialog panel

<b>Login</b>	Press to access the <b>Keyboard</b> screen to enter the user login name.
<b>First name (optional)</b>	Press to access the <b>Keyboard</b> screen to enter a first name. This is optional.
<b>Last name (optional)</b>	Press to access the <b>Keyboard</b> screen to enter a last name. This is optional.
<b>Initial Password</b>	Press to access the <b>Keyboard</b> screen so that an initial password for the user can be entered.
<b>Confirm initial Password</b>	Press to access the <b>Keyboard</b> screen to reenter the initial password to confirm it.

#### 5.11.4 Assign Roles screen

This screen allows the assignment of a certain role/certain roles to a specific user. The screen appears if the "Supervisor" has pressed the **Change Role** button in the **User Management/Please select user** screen.



**Assign Roles screen.**

##### Dialog panel

**User Roles** list     This list displays the assigned role(s) of the selected user.


**Available Roles** list     This list displays the available user roles.

##### User roles


There are 2 types of user role:

- Supervisor — can manage users, transfer/synchronize files, configure the QIAasymphony SP/AS instruments and operate the QIAasymphony SP/AS instruments. For more information refer to Section 4.4.
- Operator — can operate the QIAasymphony SP/AS instruments. For more information refer to Section 4.4.

To assign a role to the selected/new user, follow the instructions below.

1. Select the role to be assigned from the **Available Roles** list.
2. Press the  button.
3. The selected role is assigned to the user and appears in the **User Roles** list.

You can also remove an assigned role from the user.

1. Select the role to be removed in the **User Roles** list.
2. Press the  button.
3. The role is removed from the user and appears in the **Available Roles** list again.

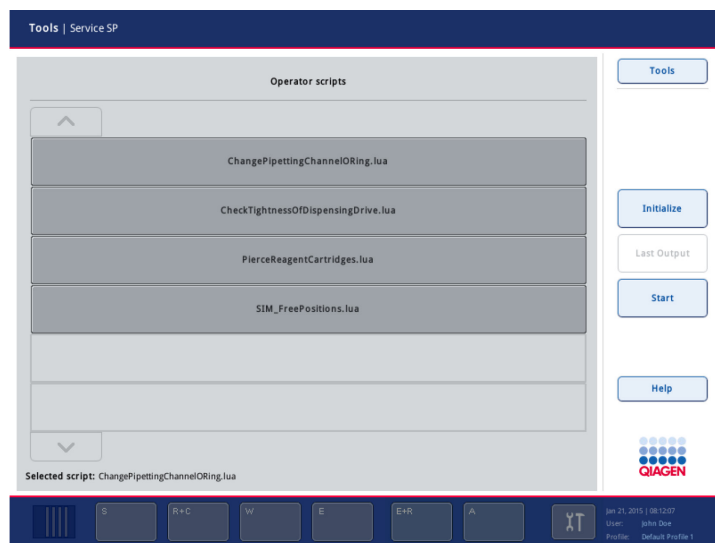
**Note:** If a user has only one assigned role and this should be changed, first assign the new role and then remove the old one. This is because a user must always have at least one assigned role.

## 5.12 Service SP menu

The **Service SP** menu enables the user to run operator service scripts or initialize the QIAsymphony SP instrument.

### 5.12.1 Script Execution tab

The **Script Execution** tab enables the user to run **Operator scripts**, which are service protocols. The available scripts are displayed in the **Operator scripts** list. Use the up and down arrows to scroll through the list. Select the script to be run by pressing the appropriate button.



## Script Execution tab.

### Command bar

Initialize

Allows the user to initialize the QIASymphony SP. When the button is pressed, a message appears that asks the user to select whether all devices except for the sample input module should be initialized. Press **Yes** to initialize the QIASymphony SP; press **No** to cancel the initialization.

During initialization, the magnetic head, lysis station and robotic arm move to their home positions. Sample prep cartridges that were being processed will be transferred to unit boxes in the "Waste" drawer and filter-tips discarded.

**Note:** If the QIASymphony SP hood is closed, the initialization is carried out automatically when the instrument is switched on.

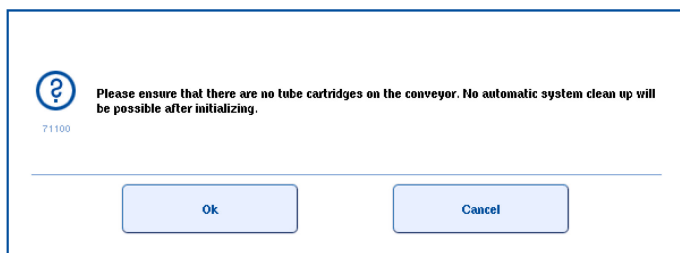
**Note:** If also using the QIASymphony AS, both hoods must be closed for initialization to take place when the instruments are switched on. If one or both of the hoods are open, an error message will appear.

Last Output

This button is enabled after an operator service script has been performed. When pressed, it opens the script output.

Start

Starts the selected operator service script. While the selected script is being performed, an output message appears that provides information about the script being performed and the results (see "Output dialog panel", on next page).



A message appears when the **Initialize** button is pressed

---

## Dialog panel

<b>Operator</b>	Scripts available to the current operator are displayed and can be
<b>scripts list</b>	selected by pressing the appropriate button.
<b>Selected script</b>	The selected script is displayed here.

## Operator scripts

The following scripts are available.

<b>SIM_FreePositions.lua</b>	Initializes the sample input module.
<b>PierceReagentCartridge.lua</b>	Enables piercing of the reagent cartridge.
<b>ChangePipettingChannel ORing.lua</b>	Enables the tip-adapter O-ring to be replaced. See Section 15 for more information.
<b>CheckTightnessOfDispensingDrive.lua</b>	Enables the tip-adapter pump to be tested for wear and tear.

## Output dialog panel

The **Output** dialog panel displays the output of the selected operator service script.

## Command bar

A rectangular button with rounded corners, a blue border, and the word "Initialize" in blue text.

Allows the user to initialize the QIASymphony SP. When the button is pressed, a message appears that asks the user to select whether all devices except for the sample input module should be initialized. Press **Yes** to initialize the QIASymphony SP; press **No** to cancel the initialization.

During initialization, the magnetic head, lysis station and robotic arm move to their home positions. Sample prep cartridges that were being processed will be transferred to unit boxes in the "Waste" drawer and filter-tips discarded.

**Note:** If the QIASymphony SP hood is closed, the initialization is carried out automatically when the instrument is switched on.

**Note:** If also using the QIASymphony AS, both hoods must be closed for initialization to take place when the instruments are switched on. If one or both of the hoods are open, an error message will appear.

A rectangular button with rounded corners, a blue border, and the word "Clear" in blue text.

Clears the content of the **Output** dialog panel.

A rectangular button with rounded corners, a blue border, and the word "Back" in blue text.

Displays the **Operator Script** dialog panel.

## Dialog panel

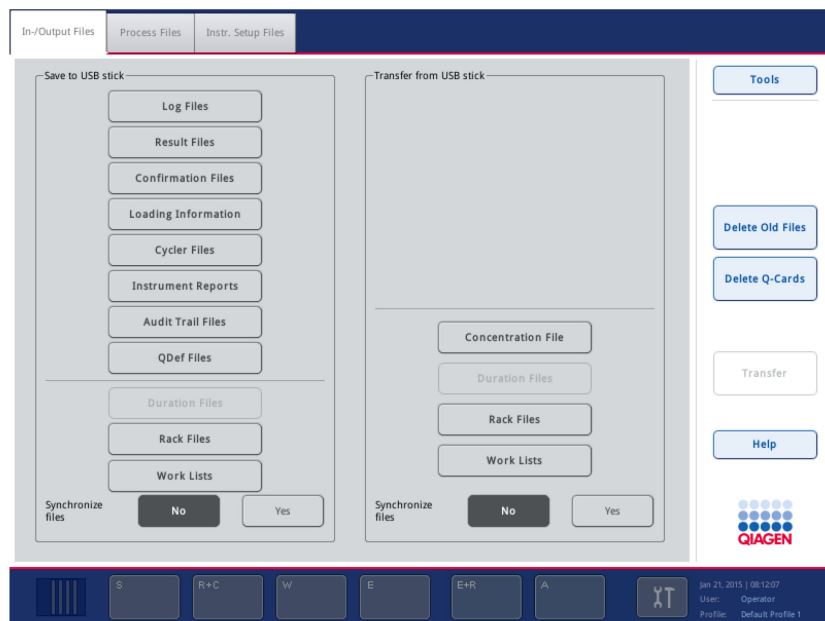
If the **Clear** button has not been pressed, the output of the selected service script is shown here.

### 5.13 File Transfer menu

The **File Transfer** menu enables the user to download files from the QIASymphony SP to the USB stick, and allows the user to upload files to the QIASymphony SP from the USB stick. The buttons that can be selected depend on the role of the user. Some buttons are only visible if the QIASymphony AS is installed. For more detailed information about handling files, see Section 7.

### 5.13.1 In-/Output Files tab

The **In-/Output Files** tab enables the user to download output files to the USB stick, to upload input files from the USB stick to the QIAAsymphony SP, or to synchronize in-/output files on the QIAAsymphony SP with files on a USB stick and vice versa.



**In-/Output Files tab.**

#### Command bar



Press to delete input and output files (except log files), older than a defined number of days. The default is 10 days.



Press to transfer selected file types to the QIAAsymphony SP or to a USB stick, depending on which panel (**Save to USB stick** or **Transfer from USB stick**) was selected.



Press to go back to the tools overview.



## Dialog panel

### Save to USB stick panel

Press the corresponding button(s) to download files of the selected type(s) to an inserted USB stick (see Section 7).

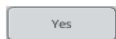
Log Files	Press to download system log file(s).
Result Files	Press to download result file(s).
Confirmation Files	Press to download start batch confirmation files.  <b>Note:</b> Start batch confirmation files are not relevant for FDA cleared or approved nucleic acid tests.
Loading Information	Press to download loading information file(s). Only visible, if the QIAsymphony AS is installed.
Cycler Files	Press to download cycler files.
Instrument Reports	Press to download instrument report file(s).
Duration Files	Press to download instrument duration file(s).
Rack Files	Press to download rack file(s).
Work Lists	Press to download work list(s).
Audit Trail Files	Press to download audit trail file(s).
Yes	Press <b>Yes</b> if selected files should be synchronized when <b>Transfer</b> is pressed.
No	Press <b>No</b> if selected files should not be synchronized when <b>Transfer</b> is pressed.

## Dialog panel

### Transfer from USB stick

Press the corresponding button(s) to upload files of the selected type(s) from the USB stick to the instrument (see Section 7 for more information).

Concentration File	Press to upload the concentration file.
Rack Files	Press to upload the rack file(s).
Work Lists	Press to upload work list(s).
Duration Files	Press to upload duration file(s).



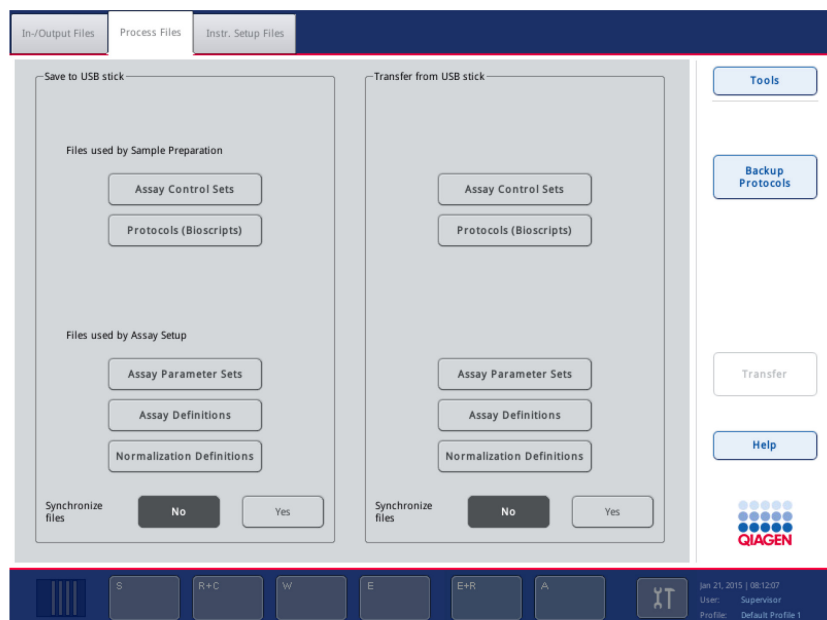
Press **Yes** if selected files should be synchronized when **Transfer** is pressed.



Press **No** if selected files should not be synchronized when **Transfer** is pressed.

### 5.13.2 Process Files tab

The **Process Files** tab enables the user to download process files to the USB stick, to upload process files from the USB stick to the QIAasympphony SP, or to synchronize process files on the QIAasympphony SP with files on the USB stick and vice versa.



**Process Files tab (QIAasympphony SP/AS instruments).**

#### Command bar



Press to transfer selected file types to the QIAasympphony SP or to a USB stick, depending on which panel (**Save to USB stick** or **Transfer from USB stick**) was selected.

## Dialog panel

### Save to USB stick panel (Supervisor only)

Press the corresponding button(s) to download files of the selected type(s) to an inserted USB stick (see Section 7 for more information).

Assay Control Sets	Press to download Assay Control Set file(s).
Protocols (Bioscripts)	Press to download protocol file(s).
Assay Parameter Sets	Press to download Assay Parameter Set file(s). Only visible, if the QIAsymphony AS is installed.
Assay Definitions	Press to download Assay Definition file(s). Only visible, if the QIAsymphony AS is installed.

**Synchronize files** Press **Yes** if the selected files should be synchronized when **Transfer** is pressed (see Section 7.4 for more information about synchronization of files).

Press **No** if selected files should not be synchronized.

### Transfer from USB stick panel (Supervisor only)

Press the corresponding button(s) to upload files of the selected type(s) from the USB stick to the QIAsymphony SP/AS. See Section 7 for more information.

Assay Control Sets	Press to upload Assay Control Set file(s).
Protocols (Bioscripts)	Press to upload new protocol file(s).
Assay Parameter Sets	Press to upload Assay Parameter Set file(s). Only visible, if the QIAsymphony AS is installed.
Assay Definitions	Press to upload Assay Definition file(s). Only visible, if the QIAsymphony AS is installed.

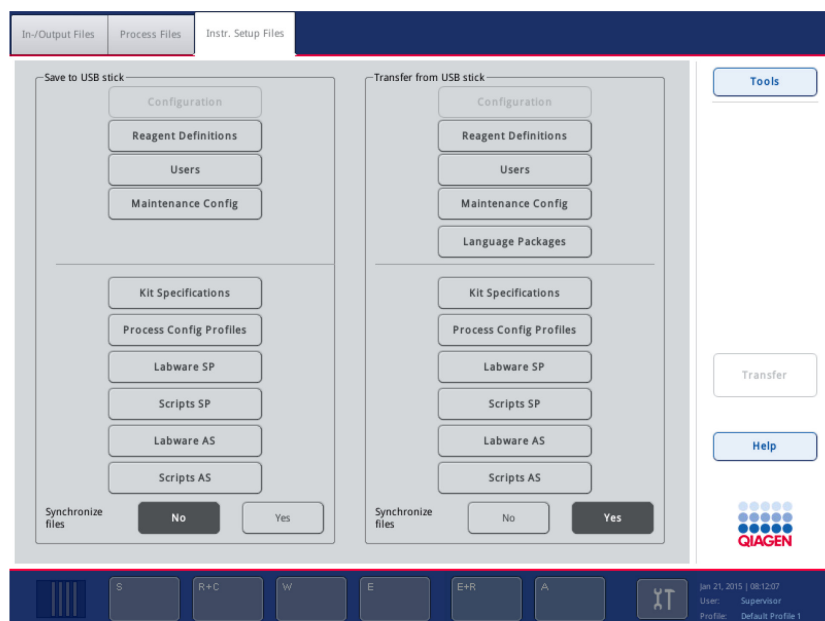
**Synchronize files** Press **Yes** if the selected files should be synchronized when **Transfer** is pressed (see Section 7.4 for more information about synchronization of files).

Press **No** if selected files should not be synchronized.

**Backup Protocols** Press Backup Protocols to download all protocol files from QIAsymphony SP/AS to the USB stick.

### 5.13.3 Instr. Setup Files tab

The **Instr. Setup Files** tab enables the user to download instrument setup files to the USB stick, to upload instrument setup files from the USB stick to the QIAasymphony SP, or to synchronize instrument setup files on the QIAasymphony SP with files on the USB stick and vice versa.



**Instr. Setup Files tab (QIAasymphony SP/AS instruments).**

#### Command bar



Press to transfer selected file types to the QIAasymphony SP/AS or to the USB stick, depending on which panel (**Save to USB stick** or **Transfer from USB stick**) was selected.

#### Dialog panel

##### **Save to USB stick panel** (Supervisor only)

Press the corresponding button(s) to download files of the selected type(s) to an inserted USB stick (see Section 7 for more information).



Press to download custom process configuration profiles.



Press to download information about the reagent definition.

Users	Press to save information about all created users to an USB stick. To restore the data on the QIAsymphony SP, contact your QIAGEN Field Service Specialist.
Maintenance Config	Press to download maintenance configuration.
Labware SP	Press to download the QIAsymphony SP labware file(s).
Scripts SP	Press to download operator service scripts for the QIAsymphony SP.
Labware AS	Press to download the QIAsymphony AS labware file(s).
Scripts AS	Press to download operator service scripts for the QIAsymphony AS.

**Synchronize files** Press **Yes** if the selected files should be synchronized when **Transfer** is pressed (see Section 7.4 for more information about synchronization of files).  
Press **No** if selected files should not be synchronized.

#### ***Transfer from USB stick panel (Supervisor only)***

Press the corresponding button(s) to upload files of the selected type(s) to an inserted USB stick (see Section 7 for more information).

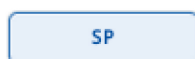
Process Config Profiles	Press to upload custom process configuration profiles.
Reagent Definitions	Press to upload new reagent cartridge information.
Users	Press to restore user information.
Maintenance Config	Press to upload maintenance configuration.
Labware SP	Press to upload new QIAsymphony SP labware packages.
Scripts SP	Press to upload operator service scripts for the QIAsymphony SP.
Labware AS	Press to upload QIAsymphony AS labware packages.
Scripts AS	Press to upload operator service scripts for the QIAsymphony AS.

**Synchronize files** Press **Yes** if the selected files should be synchronized when **Transfer** is pressed (see Section 7.4 for more information about synchronization of files).  
Press **No** if selected files should not be synchronized.

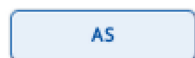
## 5.14 Instrument Report menu

The **Instrument Report** menu displays information to help QIAGEN Technical Services with troubleshooting. The displayed information updates every time the **Instrument Report** menu is selected.

### Command bar



Displays information about the QIAsymphony SP.



Displays information about the QIAsymphony AS.

### 5.14.1 Overview tab

This tab displays information about the QIAsymphony SP (e.g., serial number, software version, free disk space and memory), contact information for QIAGEN Technical Services and the option to create an instrument report file.

The screenshot shows the "Tools | Instrument Report" window. The "Overview" tab is selected, displaying information for "QIAsymphony SP and AS". The information includes: Serial number: 0000sim ; 0000sim, Software version: 5.0.3 (development), Free memory: 2176.6 MB ; 2176.4 MB, and Free disk space: 0.0 MB. Below this is "Contact information for Technical Service" with contact details for QIAGEN Technical Service. At the bottom, there is a section "Create instrument report files" with a text input for "Number of days" (set to 1) and two buttons: "Create" and "Create + Save To USB". On the right side of the window, there are buttons for "Tools", "SP", "AS", and "Help". The QIAGEN logo is also visible. The bottom status bar shows the date "Jan 21, 2015 | 08:12:07", the user "John Doe", and the profile "Default Profile 1".

Instrument Report menu (Overview tab).

## Dialog panel

**Number of days** Specifies the number of days for which an instrument report file will be created.



Creates an instrument report file.



Creates an instrument report file and saves it to the USB stick.

### 5.14.2 Configuration tab

This tab displays all configuration settings in alphabetical order, including default tube types and the process configuration profile that is currently selected.

**Note:** This tab also displays the number of available adapters.

The screenshot shows the "Tools | Instrument Report" window. The "Configuration" tab is selected, displaying a table of settings. The table has two columns: "Setting" and "Value". The settings are listed in alphabetical order. To the right of the table are buttons for "Tools", "SP", "AS", and "Help". At the bottom of the window is a status bar with a QIAAGEN logo, a date/time stamp, and user information.

Setting	Value
Activate inventory scan?	Yes
Active process configuration profile	None
Allow assignment of randomly-generated IDs to elution racks?	No
Allow combination of multiple work lists for one batch?	Yes
Allow information for single samples in work lists to be overwritten?	Yes
Allow partial use of work lists?	Yes
Allow processing of samples without a work list entry?	Yes
Allow unloading of elution racks with unprocessed batches during a run?	Yes
Assay Setup Installed	Yes
Auto Logoff Period in minutes (0 = Auto Logoff deactivated)	15
Automatically assign a randomly-generated ID to samples with bar code reading errors?	No
Automatically assign rack type using bar code?	User
Can process when Mandatory maintenance task is due?	false
Check combination of protocol and recommended labware during run definition?	Yes
Check elution rack ID required by work list?	No
Check sample tube type required by work list?	No
Confirm bar code of elution rack before removing?	No

**Configuration tab.**

### 5.14.3 Errors tab

This screen displays the 100 most recent error messages from the system error log file. Messages are listed in chronological order. Use the arrows to scroll through the messages.

The screenshot displays the 'Errors' tab in the QIAGEN QIAlytics software. The interface includes a top navigation bar with 'Tools | Instrument Report'. Below this is a tabbed interface with 'Overview', 'Configuration', 'Errors' (selected), 'Protocols', 'Inventory', 'Labware', 'Hardware', and 'Counters'. The 'Errors' tab shows a list of 100 most recent error messages in chronological order. The messages are displayed in a scrollable area. On the right side, there are buttons for 'Tools', 'SP', and 'AS'. Below these is a 'Help' button. At the bottom, there is a status bar with a date and time 'Jan 21, 2015 | 08:12:07', a user name 'John Doe', and a profile name 'Default Profile 1'. The QIAGEN logo is visible in the bottom right corner.

Tools | Instrument Report

Overview Configuration **Errors** Protocols Inventory Labware Hardware Counters

Tools

SP

AS

Help

QIAGEN

Jan 21, 2015 | 08:12:07  
User: John Doe  
Profile: Default Profile 1

### Errors tab.



#### 5.14.4 Protocols tab

This tab displays information about the protocols and samples that were processed in the latest runs. The file type table shows the source and version number of each protocol and Assay Control Set used in previous batches. Each row in the table corresponds to one file.

ID	File type	Name	Version	Authentic
2000001	Protocol	BS_13-015_AC_TransferEluate_C_		QIAGEN file
2000001	Assay control set	13-015_AC_TransferEluate_C_96	3	Custom file
2000002	Protocol	BS_Virus_1000	1.00	QIAGEN file
2000002	Assay control set	Virus 1000	3	Custom file

ID	Samples	Start time
2000001	24	2017-01-10 23:56:05
2000002	4	

#### Protocols tab.

#### File type table

The file type table shows the source and version number of each protocol and Assay Control Set used in previous batches. Each row in the table corresponds to one file.

<b>ID</b>	The ID of the batch in which the file was used.
<b>File type</b>	The file type (e.g., Protocol, Assay Control Set).
<b>Name</b>	The file name.
<b>Version</b>	The version number of the file.
<b>Authentic</b>	"QIAGEN file" indicates that the file was provided by QIAGEN. "Custom file" indicates that the file was provide by or modified by the user.

Batch table

This table shows the number of samples processed by each batch, and the date and time when the batch was started. Each row in the table corresponds to one batch.

- Name

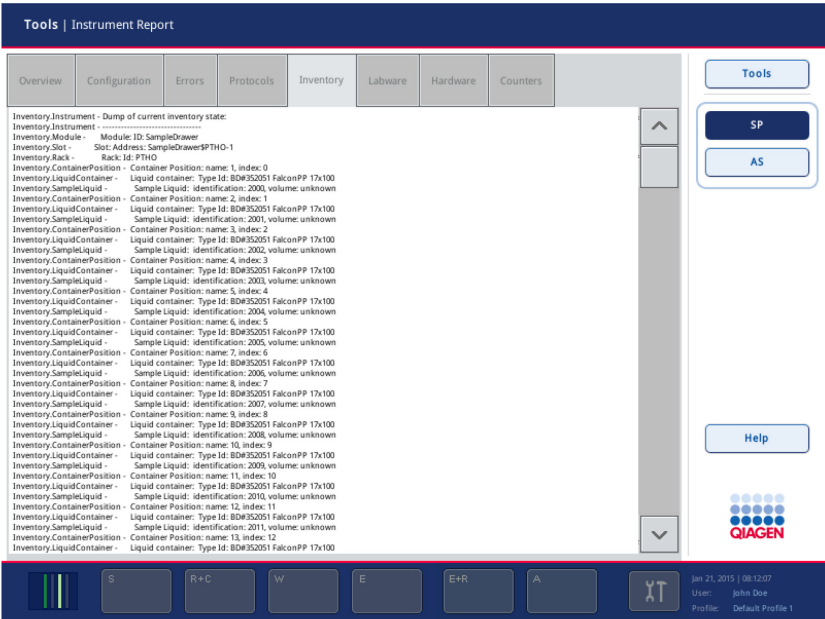
The file name.
- Version

The version number of the file.
- Authentic

“QIAGEN file” indicates that the file was provided by QIAGEN.  
“Custom file” indicates that the file was provided by or modified by the user.

5.14.5 Inventory tab

This screen displays the result of the latest inventory scan (i.e., it shows what items are loaded on the worktable).



Inventory tab.

5.14.6 Labware tab

This screen shows the version numbers of all the Labware files that are installed on the QIAsymphony SP.

Tools | Instrument Report

OverviewConfigurationErrorsProtocolsInventoryLabwareHardwareCounters


Labware	Version
00	119
01	115
02	116
03	110
1A	111
2A	111
3B	109
AB#0600 *PCR96	113
AB#0700 *PCR96 LowPro	111
AB#0765 *0.8ml StoragePlate	102
AB#0765 0.8ml StoragePlate	100
AB#0800 *PCR96 SkirtLowPro	110
AB#0800 PCR96 SkirtLowPro	104
AB#0932 2.2mlSPMarkII	102
AB#AB-1185 *2.0ml2DPlate	102
AB#AB-1185 2.0ml2DPlate	103
ABT#4J7130 DeepWell96 RB	100
AlcoTroughRack	106


Tools

SP

AS

Help



S


R+C

W

E

E+R

A



Jan 21, 2015 | 08:12:07  
User: John Doe  
Profile: Default Profile 1

Labware tab.

5.14.7 **Hardware** tab

This screen displays information relating to the instrument hardware.

Tools | Instrument Report

OverviewConfigurationErrorsProtocolsInventoryLabwareHardwareCounters

Hardware module	Present	Initialized
1-wire	present	n/a
Can Nodes	present	n/a
Date	present	n/a
Eluate	present	initialized
Extractor	n/a	initialized
I2c	present	n/a
Lysis	n/a	initialized
PiercingDevice	n/a	initialized

Hardware module	Firmware version
Eluate	2.15 (Build 0056) 2010-02-09 TX SIM
Extractor	0.0.0
Lysis	0.0.0
PiercingDevice	2007-10-29sim
PipettingCh1	3.2E (Build 0230) 2016-11-23 PX SIM
PipettingCh2	3.2E (Build 0230) 2016-11-23 PX SIM
PipettingCh3	3.2E (Build 0230) 2016-11-23 PX SIM
PipettingCh4	3.2E (Build 0230) 2016-11-23 PX SIM

Tools

SPAS

Help

S

R+C

W

E

E+R

A

Jan 21, 2015 | 08:12:07  
User: John Doe  
Profile: Default Profile 1

**Hardware tab.**

**Hardware check and initialization table**

<b>Hardware module</b>	Indicates a hardware module.
<b>Present</b>	Indicates whether a particular hardware module is present. For hardware modules that cannot be checked “n/a” is shown. “Present” indicates that the hardware module is present. “Failed” indicates that the check failed. In this case, more detailed information about the error is displayed.
<b>Initialized</b>	“initialized” indicates that the hardware module has been initialized. “uninitialized” indicates that the hardware module could not be initialized. “n/a” indicates that it is not possible to initialize this hardware module.

**Firmware version table**

This table shows the firmware version for all hardware modules that use separate firmware.

### 5.14.8 Counters tab

The **Counters** screen shows the values of all hardware counters. This screen also allows the “Supervisor” to reset the hardware counters for the O-rings.

**Note:** The hardware counters for O-rings are also automatically replaced by the O-ring replacement maintenance script.

To manually reset the hardware counters for the O-ring of a specific pipetting channel, press **Reset counter group....** Select the appropriate pipetting channel and press **OK**.

The screenshot shows the 'Tools | Instrument Report' window with the 'Counters' tab selected. The main area displays a table of hardware counters with columns for Name, Module, Group, Value, and Unit. A 'Reset counter group...' button is located at the bottom left of the table. On the right side, there are buttons for 'Tools', 'SP', 'AS', and 'Help'. The bottom status bar shows the date 'Jan 21, 2015 | 08:12:07', the user 'John Doe', and the profile 'Default Profile 1'.

Name	Module	Group	Value	Unit
SP System ON time	System	SP System	0	hours
SP Started runs	System	SP Runs	1	cycles
SP Completed runs	System	SP Runs	1	cycles
SP Processed samples	System	SP Runs	24	cycles
SP Fan 1 ON time	System	SP Fan1	0	hours
SP Fan 2 ON time	System	SP Fan2	0	hours
SP Hoodlock ON time	System	SP Hoodlock	0	hours
SP Hoodlock switch cycles	System	SP Hoodlock	0	cycles
SP UV ON time	UV	SP UV	0	hours
SP UV switch cycles	UV	SP UV	0	cycles
SP Sample Input Carrier locking cycles	Sample Input	SP Sample Input	2	cycles
SP Sample Input Barcode Camera read cycles	Sample Input	SP Sample Input	2	cycles
SP Reagentdrawer locking ON	Drawer	SP Reagent Drawer Lock	0	hours
SP Reagentdrawer switch cycles	Drawer	SP Reagent Drawer Lock	0	cycles
SP Wastedrawer ON time	Drawer	SP Waste Drawer Lock	0	hours
CP Masterdeck ON time	Deck	CP Master Deck Lock	0	hours

**Counters tab.**

#### Dialog panel



Enables the user to reset the hardware counters for the O-ring of a specific pipetting channel. Select the appropriate pipetting channel and then press **OK**.







## 5.15 Rack Browser menu

This menu allows the user to view rack files that are currently saved on the QIAsymphony SP. The contents of the rack file are displayed graphically on a schematic of a plate. Additional rack information (i.e., rack ID, rack type, modification date) and position information is also shown. It is possible to filter for rack files used within a certain time frame (e.g., today, this week, last week). It is also possible to search for racks with a particular rack ID.

For the QIAsymphony RGQ MDx (US) system there are 2 tabs – **Assay Racks** and **Eluate Racks**. For information on the **Assay Racks** tab, see Section 6.7.

**Note:** This menu cannot be used to modify rack files.

### Command bar

	Displays the <b>Tools</b> menu.
	Displays the rack files that were modified today.
	Displays the rack files that have been modified since 00:00 of Monday of the current week, including the rack files that were modified today. This option is preselected by default.
	Displays the rack files that were modified between 00:00 of Monday last week and 00:00 of Monday of the current week.
	Displays the rack files that were modified before 00:00 of Monday last week.
	Enables users to manually enter and then search for IDs using the <b>Keyboard</b> screen.

### 5.15.1 Eluate Racks tab

This tab displays information about which racks can be used as elution racks (i.e., output racks). There are 2 additional tabs within this tab — the **Rack Details** and **Sample Details** tabs.

Sample Racks Eluate Racks Assay Racks Normalization Racks

1 2 3 4 5 6 7 8 9 10 11 12

A B C D E F G H

Press on tube positions for details

Rack Details Sample Details

Rack ID 1234-1

Rack type QIA#19585 \*S-Block96

Last modified 2009-03-17T07:49:44

Positions with liquid 32

Samples 11

Std/Cont/EC 1/2/16

Select rack file

1234-4

1234-3

1234-2

1234-1

1013740123456789000002

1013740123456789000001

Tools

Today

This week

Last week

Other

Find ID

Help

QIAGEN

Jan 21, 2015 | 08:12:07

User: John Doe

Profile: Default Profile 1

### Rack Details tab.

Sample Racks Eluate Racks Assay Racks Normalization Racks

1 2 3 4 5 6 7 8 9 10 11 12

A B C D E F G H

Press on tube positions for details

Rack Details Sample Details

Sample ID Smpl-A2

Sample type Sample

Sample state valid

Volume 100.0 µl

Internal Control n/a

Concentration n/a

Edited by user false

Select rack file

1234-4

1234-3

1234-2

1234-1

1013740123456789000002

1013740123456789000001

Tools

Today

This week

Last week

Other

Find ID

Help

QIAGEN

Jan 21, 2015 | 08:12:07

User: John Doe

Profile: Default Profile 1

### Sample Details tab.

Schematic plate The selected rack is displayed as a schematic diagram. Positions in the rack are color coded. Select a position by pressing on it, or by using the arrow buttons, to display information about that position.

For more information about schematic diagrams of plates, see Section 5.5.

**Rack Details** tab Displays details about the selected rack (e.g., rack ID, rack type, date last modified).

**Sample details** tab Displays details about the sample that is currently selected in the rack. Details include sample ID, sample type, sample state and volume.

**Select rack** file list Lists rack IDs, in descending order by last modification date. Only rack IDs that fit to the current time filter (i.e., today, this week, last week, other) are displayed. When a rack ID from this list is selected, details about this rack are displayed in the corresponding tabs.

## 5.16 Labware Browser menu

The **Labware SP** tab of the **Labware Browser** menu enables the user to view information about labware that can be used with the QIASymphony SP.

**Note:** Refer to the Instructions for Use (Handbook) for the assay you are using for information on application-specific labware.

**Note:** For more information about the **Labware AS** tab, see Section 6.6.1.

Select **Tube Carrier** to view information about sample tubes that can be used with the tube carrier, or select **Racks** to view information about which sample and elution racks can be used.



### 5.16.1 Tube Carrier screen

This screen displays information about which tubes can be used with the tube carrier, and with which protocols. For information about labware, press **Labware**. For information about protocols, press **Protocols**.

#### Command bar



Displays the **Tools** menu.



Opens the **Tube Carrier** screen. This screen displays information about which sample tubes can be used with the tube carrier. This button is not available in the Protocols or Assays dialog panels.



Opens the **Racks** screen. This screen provides information about which sample and elution racks can be used. This button is not available in the Protocols or Assays dialog panels.



Opens the Reagent Holders screen. This screen provides information about which reagent holders are available.



Opens the Sample Tubes dialog panel and provides information about which sample tubes can be used. This button is not available in the Labware dialog panel.



Opens the IC Tubes dialog panel and provides information about which IC tubes can be used. This button is not available in the Labware dialog panel.

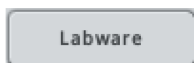


Opens the Input Racks dialog panel and provides information about which sample racks can be used. This button is not available in the Labware dialog panel.



Opens the **Output Racks** dialog panel and provides information about which elution racks can be used. This button is not available in the Labware dialog panel.

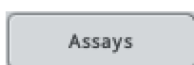
## Dialog panel



Opens the **Labware** dialog panel. See below for more information.



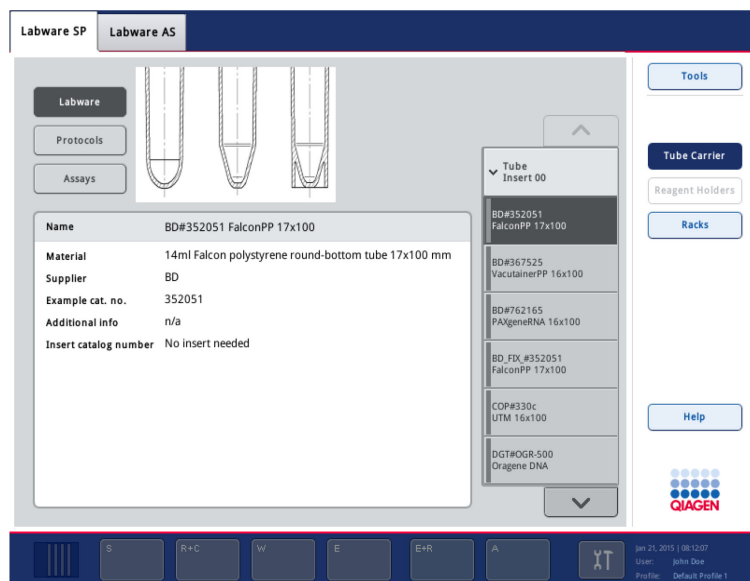
Opens the **Protocols** dialog panel. See below for more information.



Opens the Assays dialog panel. See below for more information.

## Labware dialog panel

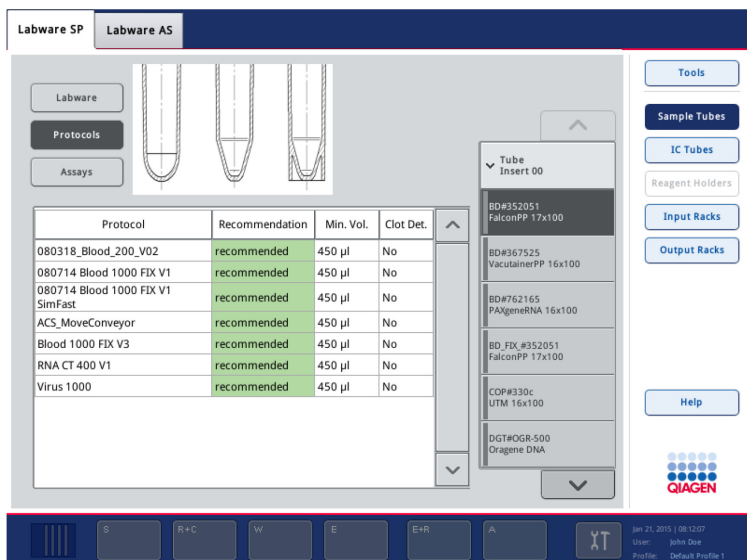
This dialog panel is displayed when **Labware** is selected in the dialog panel. Available sample tubes are listed on the right. Information about the selected item of labware, including an image, is displayed.



Tube Carrier screen (Labware dialog panel).

## Protocols dialog panel

This dialog panel is displayed when **Protocols** is selected. The protocols that can be run with the selected item of labware are shown in a table.



Tube Carrier screen (Protocols dialog panel).

**Protocol** The name of the protocol.

**Recommendation** Indicates whether the selected item of labware is recommended for use with a particular protocol.

**Note:** Labware recommendations for a specific assay may be more restrictive. Refer to the Instructions for Use (Handbook) for the assay you are using.

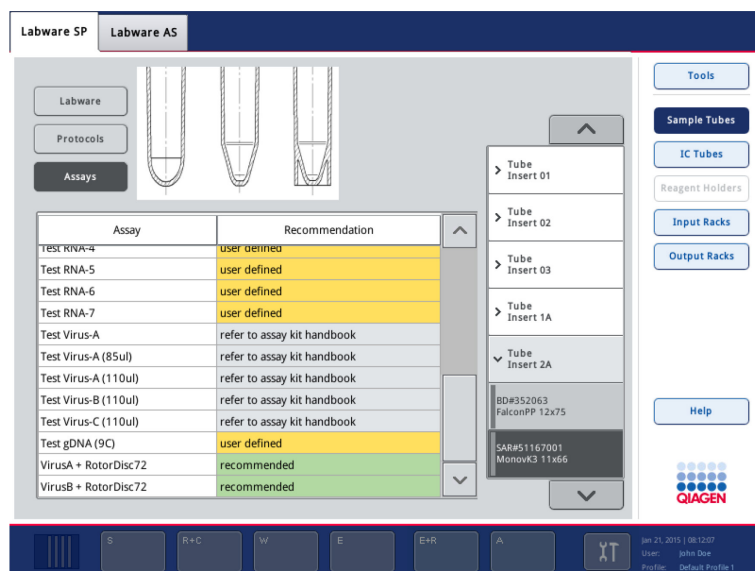
- Green indicates that the labware is recommended for use with the protocol.
- Red indicates that the labware is not recommended for use with the protocol.
- Yellow indicates that it is the responsibility of the user to validate system performance using these tube formats for any procedures used in their laboratory and that these tubes are not covered by the QIAGEN performance evaluation study.

**Min. Vol.** Indicates the minimum sample volume that can be used with this item of labware.

**Clot Det.** Indicates whether clot detection can be used with this item of labware. "Yes" indicates that clot detection can be used and "No" indicates that clot detection cannot be used.

## Assays dialog panel

This dialog panel is displayed when **Assays** is selected. The assays that can be run with the selected item of labware are shown in a table.



Sample Tubes screen (Assays dialog panel).

### Assay

The name of the assay.

### Recommendation

Indicates whether the selected item of labware is recommended for use with a particular assay.

**Note:** Labware recommendations for a specific assay may be more restrictive. Refer to the Instructions for Use (Handbook) for the assay you are using.

- Green indicates that the labware is recommended for use with the protocol.
- Red indicates that the labware is not recommended for use with the protocol.
- Yellow indicates that it is the user's responsibility to validate system performance using these tube formats for any procedures used in their laboratory.
- Gray indicates that the user must refer to the assay kit handbook to get information about the labware recommendation.

### 5.16.2 Racks screen

This screen displays information about selected sample racks. Sample racks are selected from the list on the right.

#### Command bar



Displays the **Tools** menu.



Opens the **Tube Carrier** screen. This screen displays information about which sample tubes can be used with the tube carrier. This button is not available in the Protocols or Assays dialog panels.



Opens the **Reagent Holders** screen. This screen displays information about which tube types can be used with the reagent holders.



Opens the **Racks** screen. This screen provides information about which sample and elution racks can be used. This button is not available in the Protocols or Assays dialog panels.



Opens the Sample Tubes dialog panel and provides information about which sample tubes can be used. This button is not available in the Labware dialog panel.



Opens the IC Tubes dialog panel and provides information about which IC tubes can be used. This button is not available in the Labware dialog panel.



Opens the Input Racks dialog panel and provides information about which sample racks can be used. This button is not available in the Labware dialog panel.



Opens the **Output Racks** dialog panel and provides information about which elution racks can be used. This button is not available in the **Labware** dialog panel.

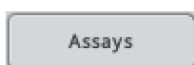
## Dialog panel



Opens the **Labware** dialog panel. See the following section for more information.



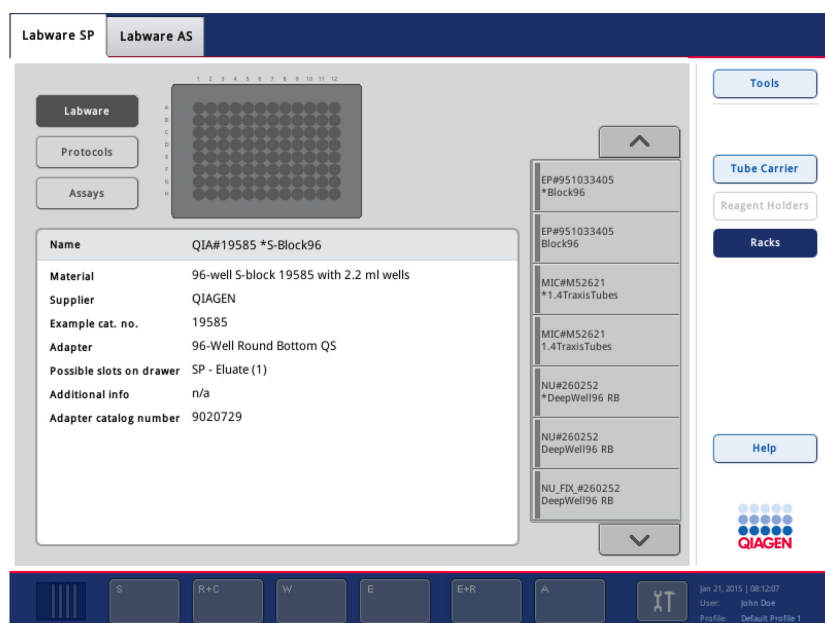
Opens the **Protocols** dialog panel. See the following section for more information.



Opens the Assays dialog panel. See the section below for more information.

## Labware dialog panel

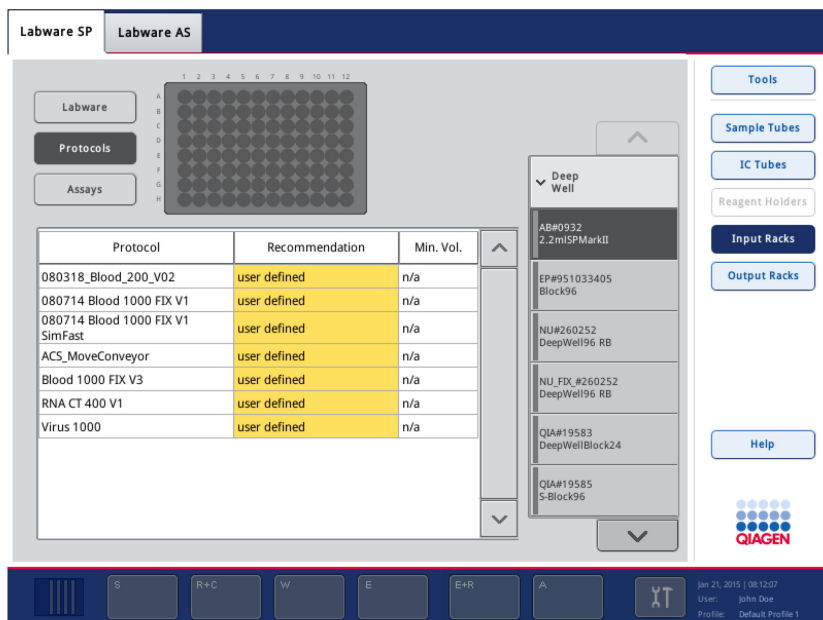
This dialog panel is displayed when **Labware** is selected in the command bar. Available sample racks are listed on the right. Information about the selected item of labware, including an image, is displayed.



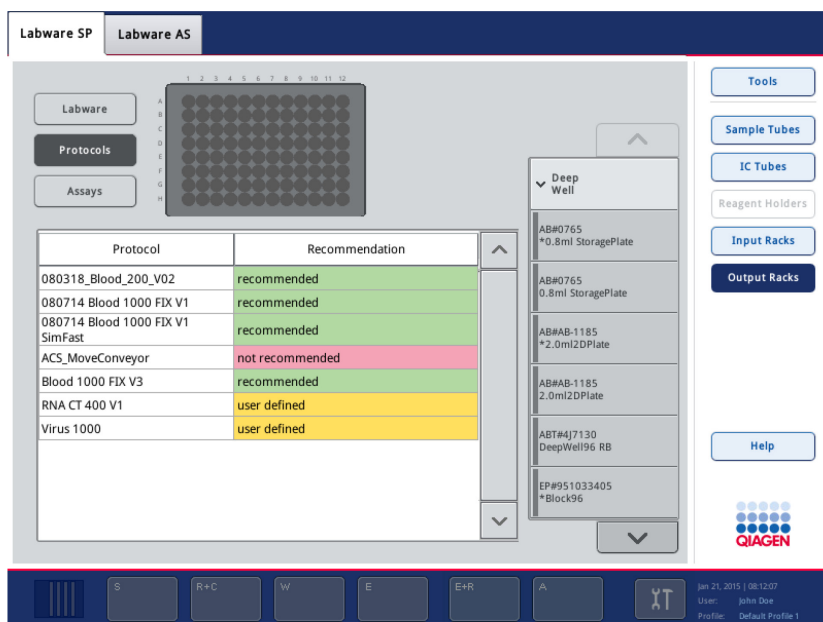
Racks screen (Labware dialog panel).

## Protocols dialog panel

This dialog panel is displayed when **Protocols** is selected. The protocols that can be run with the selected item of labware are shown in a table. Select **Input Racks** to view information about selected sample racks, or select **Output Racks** to view information about selected elution racks.



Racks screen (Input Racks dialog panel).



Racks screen (Output Racks dialog panel).

- Protocol

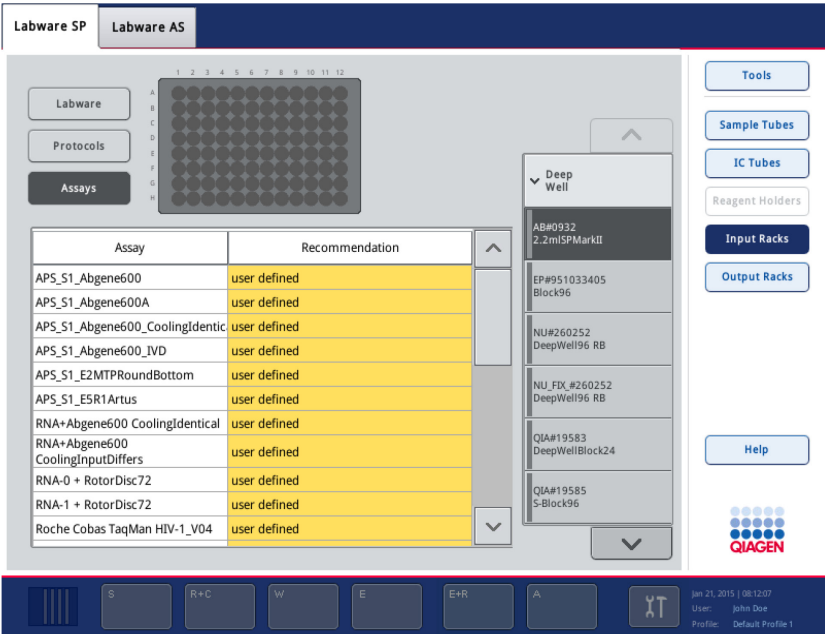
The name of the protocol.
- Recommendation

Indicates whether the selected item of labware is recommended for use with a particular protocol.

  - Green indicates that the labware is recommended for use with the protocol.
  - Red indicates that the labware is not recommended for use with the protocol.
  - Yellow indicates that it is the user's responsibility to validate system performance using these tube formats for any procedures used in their laboratory.

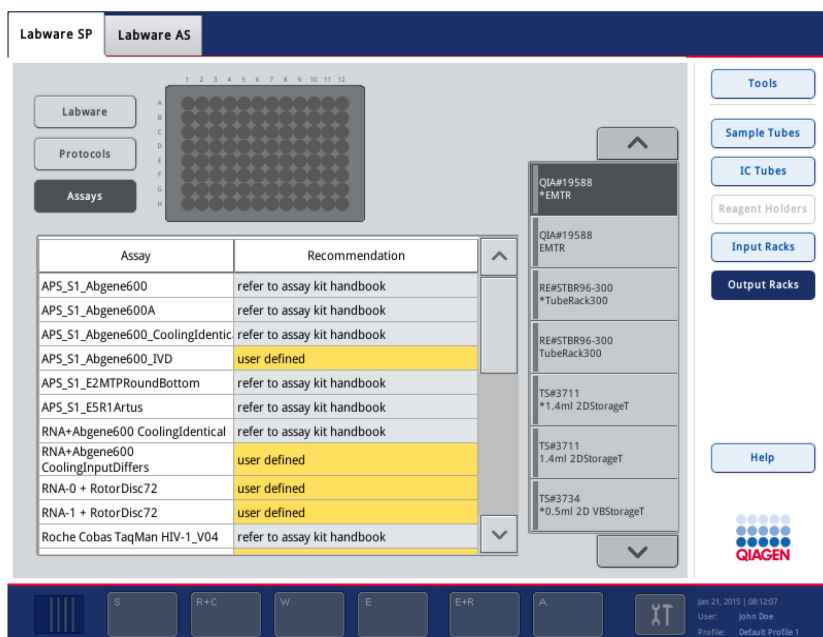
Assays dialog panel

This dialog panel is displayed when Assays is selected. The assays that can be run with the selected item of labware are shown in a table. Select Input Racks to view information about selected sample racks, or select Output Racks to view information about selected elution racks.



Assays screen (Input Racks dialog panel).





Assay screen (Output Racks dialog panel).

### Assay

The name of the assay.

### Recommendation

Indicates whether the selected item of labware is recommended for use with a particular assay.

- Green indicates that the labware is recommended for use with the protocol.
- Red indicates that the labware is not recommended for use with the protocol.
- Yellow indicates that it is the user's responsibility to validate system performance using these tube formats for any procedures used in their laboratory.
- Gray indicates that the user must refer to the assay kit handbook to get information about the labware recommendation.

## 6 Assay Setup User Interface

The **Labware AS** tab of the **Labware Browser** enables users to view detailed labware information for the QIAsymphony AS.

**Note:** Refer to the Instructions for Use (Handbook) for the assay you are using for information on application-specific labware.

An Assay Definition is a set of instructions that allows the QIAsymphony AS to perform an assay run.

An Assay Parameter Set is the combination of an Assay Definition plus additional parameters, such as replicate count and number of assay standards.

### 6.1 Software features

See Sections 5.2 to 5.4 for detailed information about "Software features that are common to all software screens", the "Status bar", and the "Command bar". In addition, read the following sections for features that are specific to the assay setup user interface.

#### 6.1.1 Status bar

The status bar allows the user to view information about the status of each of the QIAsymphony SP drawers and the QIAsymphony AS drawers.



**Status bar.**

**Note:** See Section 5.3 to see what the status bar looks like in the sample preparation user interface.

## Batch status icon

The way the batch status icon is displayed varies according to the loading state of the tube carrier on the QIAAsymphony SP.



**Batch status icon.** The batch status icon provides the user with information about each sample batch.

The color of each tube carrier denotes the status of the associated batch (see Section 5.3.1 for more information).



**The status of batch 4 is QUEUED.**

## 6.1.2 Drawer buttons

In the status bar of the assay setup user interface there is a button for each of the QIAAsymphony AS drawers adjacent to the QIAAsymphony SP drawer buttons.

**Note:** See Section 5.3.1 for more details for each of the QIAAsymphony SP drawers in the status bar.



When an assay run has been defined, press the **E+R** button to open the **Loading Information** screen. This button flashes yellow if there are insufficient adapters or rack positions available for the defined runs. In this situation, if you press on the button, a message appears informing the user why it is not possible to start the run.



When an assay run has finished, this button flashes green. In this situation, if you press on the button, a message appears informing the user that the run has been completed. Press **OK** to confirm the message.

If there are insufficient assay racks available for the selected assays, this button flashes yellow. In this situation, if you press on the button, a message appears informing the user why it is not possible to start the run.

### 6.1.3 Help button



Press for information about the current screen and how to proceed. For more information about this function, see "Troubleshooting" (Section 14).

## 6.2 Integrated Run tab

The **Integrated Run** tab is used to:

- Define integrated runs
- View information about the status of defined integrated runs (i.e., progress, batch status, estimated time remaining, and the next user interaction required for each integrated batch).

	SP Carrier 1	SP Carrier 2	SP Carrier 3	SP Carrier 4	AS
Integrated Batch 1			2000006		3000003
			QUEUED		QUEUED
	Start run now		Integrated Batch finished in 10 min		
Integrated Batch 2	2000005				3000004
	QUEUED				QUEUED
	Load AS in 10 min		Integrated Batch finished in 21 min		

**Integrated Run tab.**

Each row represents one integrated batch with its related SP and AS batches. Columns **SP Carrier 1–4** indicate where in the “Sample” drawer an SP batch was loaded, and AS batches are shown in the column **AS**. The **Integrated Run** screen shows the status of each SP and AS batch within an integrated run.

	SP Carrier 1	SP Carrier 2	SP Carrier 3	SP Carrier 4	AS
Integrated Batch 1 *****			2000006 QUEUED		3000004 QUEUED
Start run now			Integrated Run finished in 10 min		

**Integrated batch row.**

**Integrated batch status**

The status of an integrated run is indicated by the color of the **Batch** button.

Light green



An integrated run is loaded and queued. Press to remove the integrated run, or press **Run** to start the integrated run.

Medium green



An integrated run is currently being processed.

Orange



An integrated run has been paused. The run can be continued or canceled. See Section 13.3.6 for more details.

**Note:** Pausing a run will result in all samples being flagged as “unclear”. For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all “unclear” samples.

Red



An integrated run has been canceled by the user or terminated due to an error.

Green



An integrated run has been processed and the assays can be removed from the “Assays” drawer. After pressing to remove the assay run, remove the assays. For more information, see Section 13. Cooling will be switched off automatically.

Yellow



The integrated run has an AS batch and can be replanned.

#### Command bar



The **Run** button is enabled if an integrated run has been queued. Press **Run** to start the run.



If an assay run is in progress, the **Pause AS** button is available. The **Pause AS** button should only be pressed in an emergency. After pressing **Pause AS**, the QIAsymphony AS completes the current command and then pauses the assay run. Samples will always be flagged as "unclear" if the run has been paused.

If the assay run has been paused by the user or due to an error, the **Stop AS** and **Continue AS** buttons appear (see Section 13.3.6).

**Note:** Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.

**Note:** The QIAsymphony AS drawers will be unlocked.



If a run is in progress, the **Pause SP** button is visible. The **Pause SP** button should only be pressed in an emergency. After pressing **Pause SP**, the QIAsymphony SP completes the current command being processed and then pauses the protocol. Samples will always be flagged as "unclear" if the run has been paused.

If the protocol has been paused either by the user or due to an error, the **Stop SP** and **Continue SP** buttons appear (see Section 13.3.6).

**Note:** Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.

**Note:** The drawers of the QIAsymphony SP will be unlocked.

**Stop AS**

The **Stop AS** button appears if the current assay run is paused. Press **Stop AS** to cancel the assay run that is currently being processed.

**Note:** Samples will be flagged as "invalid" and further processing of samples is not possible.

**Note:** For information about removing assays if an assay run has been canceled, see Section 13.

**Stop SP**

The **Stop SP** button appears if the current run is paused. Press **Stop SP** to stop all currently running batches. Batches that have been queued but have not yet been processed remain queued.

**Note:** Refer to Appendix E for information about worktable cleanup.

**Continue AS**

The **Continue AS** button appears if the current assay run is paused. Press **Continue AS** to continue the assay run. Samples will always be flagged as "unclear" if the run was paused.

**Note:** An assay run should only be paused in an emergency.

**Continue SP**

The **Continue SP** button appears if the current run is paused. Press the **Continue SP** button to continue the run. Samples will always be flagged as "unclear" if the run was paused.

**Note:** A run should only be paused in an emergency.

**Refresh AS**

The **Refresh AS** button appears if an SP batch was removed from an integrated run. The AS batch may become switched to "REFRESHABLE" (this means that some eluates were removed from AS batch as a result of the remove action). The batch can continue to run, leaving the removed positions empty. Samples are marked as "Removed" on the screen and in the result file.

Alternatively, the user can press **Refresh AS**. In this case, the AS batch is replanned without the removed eluates. The system generates new loading instructions (since fewer reagents are needed for fewer eluates). The old loading instructions remain, but must not be used.

A rectangular button with a light blue background and a thin blue border. The text "Remove Run" is centered in a dark blue, sans-serif font.

The **Remove Run** button appears after stopping a QIAAsymphony AS or QIAAsymphony SP run (see Section 13.3.6). The system asks the user if he wants to keep batches. If **Refresh AS** is currently available, a second message box asks if the user wants to refresh now.

A rectangular button with a light blue background and a thin blue border. The text "Define ICs" is centered in a dark blue, sans-serif font.

The **Define ICs** button is for the internal control and is only active if internal controls are loaded in a tube carrier. Depending on the status of the internal control, pressing the **Define ICs** button may result in an action being performed.

- **READY TO LOAD** — the **Define ICs** button is inactive in this state.
- **LOADED** — if the **Define ICs** button is pressed, the **Sample Preparation/Internal Controls** screen is displayed. This screen enables the user to view the loaded internal controls. If tubes are not bar code labeled or if an error occurred during bar code reading, this can be resolved in this screen.

If batches are being processed and additional internal controls need to be loaded, press this button to unlock the IC carrier slot so that the tube carrier can be removed.

- **ON HOLD** — a carrier with internal controls is currently not inserted, but it was previously inserted and then removed. The QIAAsymphony SP retains the information about the previously loaded internal controls if the **Sample Preparation/Internal Controls** screen is open.



## Dialog panel

### Buttons

Integrated Batch X	<p>The status of each integrated batch is shown. Depending on the batch status, pressing the <b>Batch</b> button may result in an action being performed.</p> <ul style="list-style-type: none"><li>● <b>READY TO LOAD</b> — the <b>Batch</b> button is inactive in this state.</li><li>● <b>LOADED</b> — the <b>Batch</b> button is inactive in this state.</li><li>● <b>STOPPED/COMPLETED</b> — if the <b>Batch</b> button is pressed, the integrated batch will be removed. This includes all SP and AS batches from the integrated batch.</li></ul>
--------------------	---

Note: The "X" represents the batch number as a substitute for the Batch ID.

### Table view

<b>SP Carrier 1–4</b> and <b>AS</b>	<p>The assigned batch ID is shown here.</p> <p>Current batch progress is displayed.</p>
<b>SP Carrier 1–4</b> <b>C</b>	<p>The batch status is displayed.</p> <p><b>QUEUED</b> — samples are loaded and the batch is defined. The batch is queued for processing.</p> <p><b>RUNNING</b> — the batch is running. Loaded samples in the batch are being processed.</p> <p><b>COMPLETED</b> — all samples in the batch have been processed. If the elution rack will not be used for collection of eluates in further batches, the elution rack can be removed from the "Eluate" drawer and the result file can be downloaded.</p> <p><b>PAUSED</b> — processing of the batch has been paused. Samples will always be flagged as "unclear" if the run was paused.</p> <p><b>Note:</b> Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.</p> <p><b>STOPPED</b> — the batch has been stopped either by the user or due to an error. The samples are lost and cannot be manually processed.</p>

## AS

The assay run status is displayed.

**QUEUED** — the assay run is queued for processing.

**RUNNING** — the assay run is in progress. Loaded samples are being processed.

**COMPLETED** — all samples in the assay run have been processed.

**PAUSED** — the assay run has been paused. Samples will always be flagged as “unclear” if the run has been paused.

**Note:** Pausing a run will result in all samples being flagged as “unclear”. For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all “unclear” samples.

**STOPPED** — the assay run has been stopped by the user or due to an error. The samples are lost and cannot be manually processed.

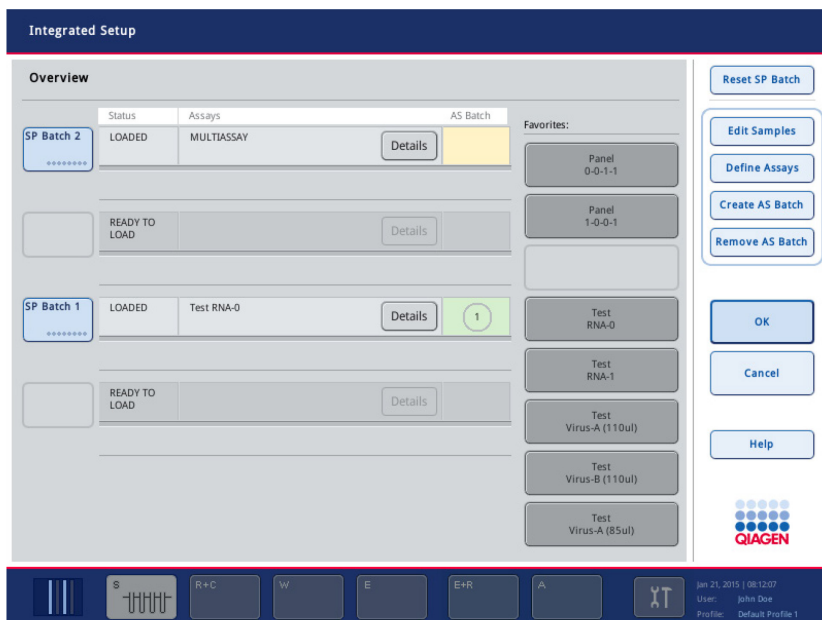
### Status bar

The status bar displays information about the next required user interaction and the estimated duration of integrated batch execution.



### 6.2.1 Integrated Setup screen

The **Integrated Setup** screen shows the QIASymphony SP batches and their related QIASymphony AS batches, if any. The user can assign or unassign one or more assays to/from all sample positions.



Integrated Setup screen.

## Command bar

### Reset SP Batch

Removes all assigned assays from the selected SP batch (i.e., all actions performed in the screen **Define Assays** are undone).

This action can only be performed while the SP batch is in the "LOADED" state.

### Edit Samples

The **Edit Samples** button opens the **Integrated Setup/Batch X/Define Samples** screen (see Section 6.2.2 about using the tube carrier).

### Define Assays

The **Define Assays** button opens the **Assay Assignment** screen (see Section 6.2.3 about using the tube carrier).

### Create AS Batch

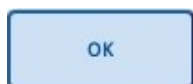
The **Create AS Batch** button assigns a new AS batch to (a) previously selected SP batch(es).

### Remove AS Batch

The **Remove AS Batch** button removes an assigned AS batch from its related SP batch(es).

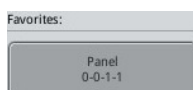


Closes the screen without saving the changes and cancels the assay definition process.

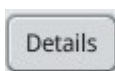


Press to save changes and proceed to the **Integrated Setup** screen.

### Dialog panel



Buttons in the **Favorites** list enable the user to assign "Favorite" assays to (a) previously selected SP batch(es) (see "Favorite assays", page 271).



Opens a message box that provides detailed information about the assigned assays and the integrated batch with its AS and SP batches. In addition, it shows the required assay positions and assay racks on the QIASymphony AS.

#### Blue



The sample batch is loaded. For samples in tubes, the position of the **Batch** button corresponds to the slot number that the tube carrier was loaded into.

#### Light green



The batch is loaded and queued. Assay Control Set and elution slot have been assigned.

#### Green



The samples in the batch are being processed.

#### Dark green



The samples in the batch have been processed and purified nucleic acids eluted. If further batches are to be eluted into separate elution racks, this elution rack can be unloaded.

Orange



All batches currently being processed are paused. The batches can be either continued or stopped.

Yellow



The batch has errors regarding sample/ internal control tubes or sample IDs.

### 6.2.2 Integrated Setup/Batch X/Define Samples screen (tube carrier)

The **Define Samples** screen is displayed when selecting **Edit Samples** in **Integrated View**. This screen displays information about all 24 positions of the tube carrier.

It enables the user to edit sample tube information and also to manually correct any bar code reading errors.

Positions where errors are detected (e.g., unknown bar codes or duplicate bar codes) become yellow. The information on the next page refers to samples loaded in the tube carrier.

Integrated Setup | Batch 1 | Define Samples

Sample Tube Selection

01 - 08	09 - 16	17 - 24
1 1001 BD#35205... P 17x100	9 1009 BD#35205... P 17x100	17 1017 BD#35205... P 17x100
2 1002 BD#35205... P 17x100	10 1010 BD#35205... P 17x100	18 1018 BD#35205... P 17x100
3 1003 BD#35205... P 17x100	11 1011 BD#35205... P 17x100	19 1019 BD#35205... P 17x100
4 1004 BD#35205... P 17x100	12 1012 BD#35205... P 17x100	20 1020 BD#35205... P 17x100
5 1005 BD#35205... P 17x100	13 1013 BD#35205... P 17x100	21 1021 BD#35205... P 17x100
6 1006 BD#35205... P 17x100	14 1014 BD#35205... P 17x100	22 1022 BD#35205... P 17x100
7 1007 BD#35205... P 17x100	15 1015 BD#35205... P 17x100	23 1023 BD#35205... P 17x100
8 1008 BD#35205... P 17x100	16 1016 BD#35205... P 17x100	24 1024 BD#35205... P 17x100

Inserts/Sample tubes:

- > Tube Insert 00
- > Tube Insert 01
- > Tube Insert 02
- > Tube Insert 03
- > Tube Insert 1A
- > Tube Insert 2A

Buttons: Select All, Clear, ID/Type, Tubes, Cancel, Ok, Help

QIAGEN

Jan 21, 2015 | 08:12:07  
User: John Doe  
Profile: Default Profile 1

Integrated Setup/Batch X/Define Samples screen (Sample Tubes mode).



**Integrated Setup /Batch X/Define Samples screen (ID/Type mode).**

### Command bar (Sample Tubes mode)



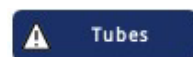
Enables the user to select all samples.



Allows the user to edit sample IDs and sample types. If sample tube types can be selected, the button is active. When the button is pressed, the dialog switches to "ID/Type" mode, which is described below.

**Edit Sample ID** screen appears.

The button is inactive if the software configuration of your QIAAsymphony SP does not allow sample IDs to be edited.



Enables the user to change the tube type. The button is inactive if sample tubes cannot be edited by pressing the sample position buttons in the dialog panel.

The button is active, if the sample ID can be edited when the sample position button is pressed.

**Note:** Before a tube type can be assigned or a sample ID edited, the user must first select the position in which the information should be edited.

## Command bar (ID/Type mode)



Enables the user to select all samples.



Select to view and edit sample IDs and sample types.

When pressed, the dialog switches to "ID/Type" mode.

**Note:** Before a tube type or ID can be assigned, the user must select the position in which the information should be edited. It is possible to select more than one position to assign multiple tube types at the same time.

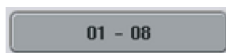


Select to view and change the tube type.

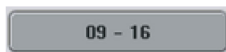
When pressed, the dialog switches to "Sample Tubes" mode.

**Note:** Before a tube type can be assigned, the user must first select the position in which the information should be edited. It is possible to select more than one position to assign multiple tube types at the same time.

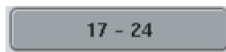
## Dialog panel



Press to select/deselect sample positions 1–8.



Press to select/deselect sample positions 9–16.

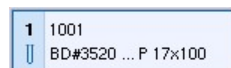


Press to select/deselect sample positions 17–24.

Individual sample buttons (1–24)

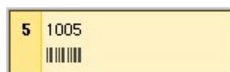
### "Sample tubes" mode

Each sample button displays information about the sample ID (bar code or virtual bar code) and the detected/assigned tube type.



Individual positions can be selected by pressing the appropriate sample button. If the **Sample ID** button is then pressed, the **Keyboard** screen appears. This enables the user to enter a sample ID.

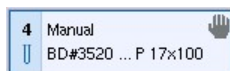
**Note:** The button becomes yellow if a bar code reading error or a duplicate bar code is detected.



The bar code symbol in the example above shows that the insert bar code was not read. If the bar code appears in the sample ID position, this signifies that the tube bar code was not read.

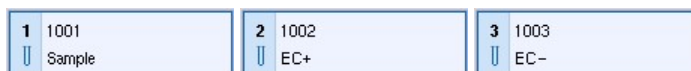
If the QIAasympphony SP/AS instrument detects duplicate bar codes the positions with the same bar codes are colored yellow. A bar code symbol, which denotes a reading error, is not displayed.

If sample information was entered manually, a hand symbol is displayed at the top right of the sample position button.



### “ID/Type” mode

Each sample button displays information about the sample ID (bar code) and the detected/assigned sample type.



### **Inserts/Sample tubes list**

If the dialog panel is in “Sample Tubes” mode, a list of inserts and sample tubes is displayed. The inserts are listed first and after an insert has been selected, the user can select a tube type from the list. To change the insert or tube type, follow the steps below.

1. Select the position(s) to be corrected.
4. Press the appropriate tube insert item in the list.

The list shows all available sample tube types that can be used with the selected insert.

5. Assign a tube type by selecting it from the list.

**Note:** If the “ID/Type” mode is active, the **Inserts/Sample tubes** list is not displayed.

**Note:** Refer to the Instructions for Use (Handbook) for the assay you are using for information on downloading labware.



### Dialog panel (ID and sample type editing)

If the dialog panel is in "ID/Type" mode, buttons for editing ID and sample type are displayed.



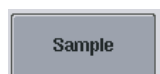
Allows the user to edit sample IDs. When the button is pressed, the **Edit Sample ID** screen appears.

The button is inactive if the software configuration of your QIAsymphony SP/AS instrument does not allow sample IDs to be edited.

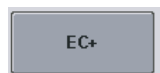


Allows the user to generate and overwrite a sample IDs.

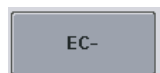
The button is inactive if the software configuration of your QIAsymphony SP/AS instrument does not allow sample IDs to be edited.



When pressed, the sample type of the selected samples is set to "Sample".



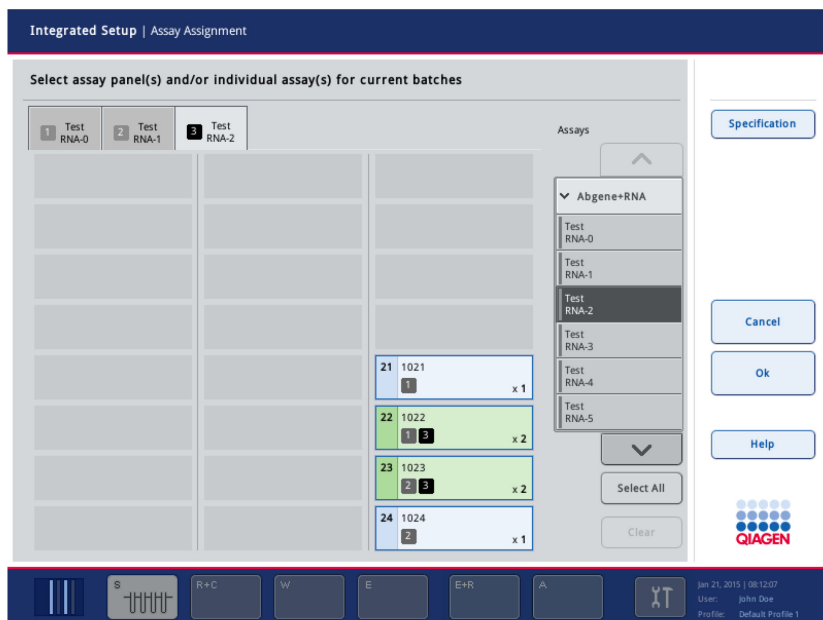
When pressed, the sample type of the selected samples is set to "EC+" (positive external control).



When the button is pressed, the sample type of the selected samples is set to "EC-" (negative external control).

### 6.2.3 Assay Assignment screen

After selecting **SP batch** in the **Integrated Setup** view, press **Define Assays**. The **Assay Assignment** screen shows the positions of defined samples and selected assays are shown in tabs. The user can assign or unassign one or more assays to/from the sample positions.



**Assay Assignment screen.**

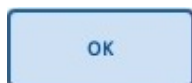
#### Command bar



Opens the **Assay Specifications** screen (see Section 6.2.4).

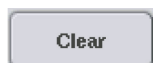


Closes the screen without saving the changes and cancels the assay definition process.



Saves changes and opens the **Integrated Setup** screen. The button is active if no conflicts are present.

#### Dialog panel



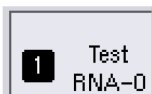
Deletes the assigned Assay Parameter Set(s) from selected sample position(s).



Enables the user to select all positions that are defined on the rack. Only available when no position on the rack is selected.



Otherwise, the **Deselect All** button is enabled. The **Deselect All** button enables the user to deselect all selected positions.



Shows the assigned assays on sample positions. Each number on a sample position represents an assay on its assay tab. For example, the sample position has assignments for assay “Test RNA-0” and two other assays.

#### Assays list

Available assays and panels are displayed in a list. To select an assay or panel, select the entry from the list.

#### Tab view

The tab view shows all assigned assays. Each assay tab has at least one assigned sample.

### 6.2.4 Assay Specifications screen

After pressing **Specification** in the **Assay Assignment** screen, the **Assay Specifications** screen shows the specifications for each selected assay.

**Assay Specifications screen.**

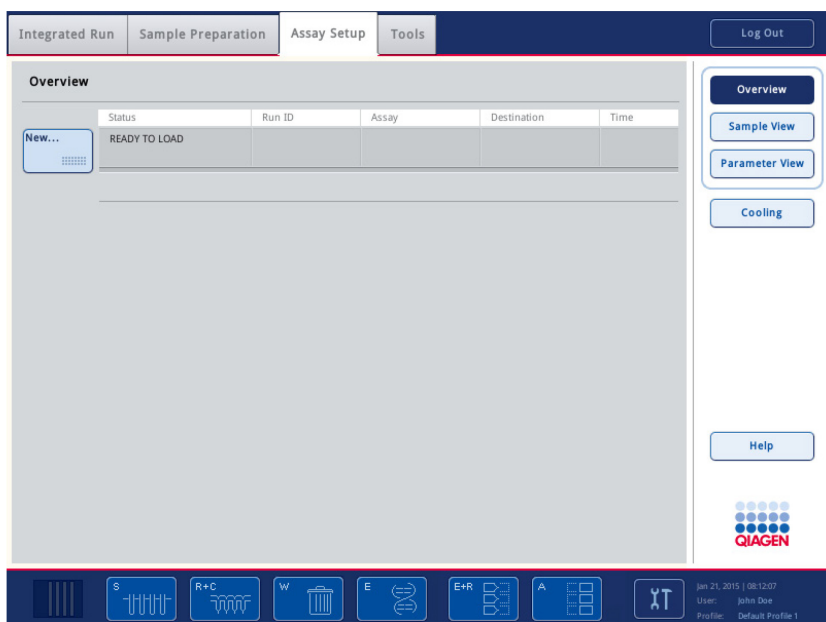
### 6.2.5 Sample Preparation/Internal Controls screen

For more information about this screen, see Section 9.4.1.

## 6.3 Assay Setup tab

In this screen, the user can:

- View information about the QIAasymphony AS, including the progress and status of assay setup
- Remove completed assays



### 6.3.1 Assay Setup tab — Assay Setup/Overview screen

The **Overview** screen indicates the status of AS batches within integrated runs. It also enables the user to remove assays.

If an assay run is queued or in progress, the temperatures of the cooling positions can be seen in real time.

## Overview screen.

### Assay run status

The status of the assay run is indicated by the color of the **Batch** button.

Blue



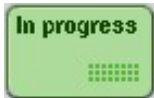
No assay run is currently defined. Define a new assay using the **Integrated Run** tab.

Light green



An assay run is loaded and queued. Press to remove the current AS batch of an integrated run.

Medium green



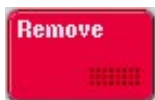
Samples in the assay run are currently being processed.

Orange



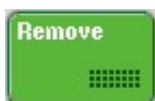
The assay run currently being processed has been paused. The run can be continued or canceled. See Section 13.3.6 for more details.

Red



The assay run has been canceled by the user or terminated due to an error. If processing was stopped due to an error, the **E+R** button, which corresponds to the "Eluates and Reagents" drawer, becomes yellow.

Green



An assay run has been processed and the assays can be removed from the "Assays" drawer. After removing the assays, press to remove the assay run. Cooling will be switched off automatically.

#### Command bar



The **Temperature Status** screen appears after pressing the **Cooling** button in the AS **Overview** screen (see Section 6.3.5).



This button is enabled when either the **Sample View** or **Parameter View** is open. Press this button to open the assay setup **Overview** screen.



Opens the **Sample View** screen. This screen displays information in a tabular format about samples that will be processed, are currently being processed, or that have been processed.



Opens the **Parameter View** screen. This screen displays information in a tabular format about Assay Parameter Sets and specifications for samples that will be processed, are currently being processed, or that have been processed.



Opens the **Temperature Status** screen. This screen enables the temperatures of the cooling slots to be checked.



The **Run** button is enabled if an assay run has been queued. Press **Run** to start batch validation. If the defined assay run is successfully validated, the assay run will start. If there is a problem with the defined assay run during validation, a warning will appear with more information.

A light blue rectangular button with rounded corners and a thin blue border. The text "Pause AS" is centered in a bold, dark blue font.

#### Pause AS

If an assay run is in progress, the **Pause AS** button is available. The **Pause** button should only be pressed in an emergency. After pressing **Pause**, the QIAAsymphony AS completes the current command and then pauses the assay run. Samples will always be flagged "unclear" if the run has been paused.

If the assay run has been paused by the user or due to an error, the **Stop** and **Continue** buttons appear (Section 13.3.6).

Note: Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.

**Note:** The QIAAsymphony AS drawers will be unlocked.

A light blue rectangular button with rounded corners and a thin blue border. The text "Stop AS" is centered in a bold, dark blue font.

#### Stop AS

The **Stop AS** button appears if the current assay run is paused. Press **Stop** to cancel the assay run that is currently being processed.

**Note:** For information about removing assays if an assay run has been canceled, see Section 13.

A light blue rectangular button with rounded corners and a thin blue border. The text "Continue AS" is centered in a bold, dark blue font.

#### Continue AS

The **Continue AS** button appears if the current run is paused. Press **Continue** to continue the run. Samples will always be flagged as "unclear" if the instrument was paused and then continued.

**Note:** An assay run should only be paused in an emergency.

## Dialog panel

### Buttons

- Batch** button      The assay run status is displayed. Depending on the assay run status, pressing the **Batch** button may result in an action being performed.
- **READY TO LOAD** — press the **Batch** button **New ...** to start the assay definition process.
  - **QUEUED** — press the **Batch** button **Remove** to remove the assay run and stop cooling.
  - **STOPPED/COMPLETED** — press the **Batch** button **Remove** to remove the assay run and stop cooling.
  - **PAUSED** — the **Batch** button is inactive in this state.
  - **Note:** Pausing a run will result in all samples being flagged as “unclear”. For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all “unclear” samples.

### Table view

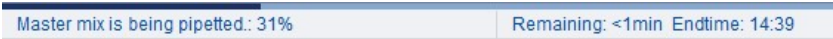
- Status**      The assay run status is displayed.
- **READY TO LOAD** — a new assay run can be defined.
  - **QUEUED** — samples have been loaded and the assay run is defined. The assay run is queued for processing.
  - **RUNNING** — the assay run is in progress. Loaded samples are being processed.
  - **COMPLETED** — all samples in the assay run have been processed.
  - **PAUSED** — the assay run has been paused. Samples will always be flagged as “unclear” if the instrument is paused.
- Note:** Pausing a run will result in all samples being flagged as “unclear”. For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all “unclear” samples.
- **STOPPED** — the assay run has been stopped by the user or due to an error. Processing of the samples cannot be restarted and cannot be manually processed.



<b>Run ID</b>	The Run ID, which is assigned by the QIAAsymphony SP/AS instruments, is displayed here.
<b>Assay</b>	If an assay run is queued, the name of the Assay Parameter Set is displayed, if only a single Assay Parameter Set has been assigned.
<b>Destination</b>	The “Assay” slot in which the assay will be set up is displayed.
<b>Time</b>	The actual elapsed time is displayed.

Progress bar

The progress bar displays information about the protocol that is currently being run. The step of the protocol that is currently being performed and the progress as a percentage of the whole protocol is displayed. Additionally, the progress bar displays the estimated duration of batch execution.



**Note:** Run time estimation is based on stored run times of previous, valid runs with identical settings.

Dialog panel (cooling display)

The cooling display becomes visible on the assay setup **Overview** screen if an assay run is queued or in progress. Temperature information for all used cooling positions for the current batch is displayed.

Eluate + Reagents	Current Temperature	Target Temperature
Slot 1	--	--
Slot 2	5.0°C	6.0°C
Slot 3	4.6°C	6.0°C
Assays	Current Temperature	Target Temperature
Slot 4	--	--
Slot 5	5.0°C	6.0°C
Slot 6	6.1°C	6.0°C

A green background indicates that the current temperature is within the defined range and a yellow background indicates that the temperature is currently outside the defined target range.

### 6.3.2 Assay Setup/Sample View screen

The **Sample View** screen displays information about samples that will be processed, are currently being processed, or that have been processed.

**Note:** A warning symbol appears in the **Sample View** screen if one or more samples are flagged as “invalid”.

The screenshot displays the 'Sample View' screen. At the top, there is a navigation bar with tabs: 'Integrated Run', 'Sample Preparation', 'Assay Setup', and 'Tools'. A 'Log Out' button is located on the right. Below the navigation bar is a table with the following columns: 'Src.', 'Pos.', 'Sample ID', 'Assay', 'Vol. In', 'Vol. Out', 'Status', 'Dest.', and 'Pos.'. The table contains 17 rows of sample data. To the right of the table is a sidebar with buttons: 'Overview', 'Sample View' (highlighted), 'Parameter View', 'Cooling', 'Run', and 'Help'. At the bottom of the screen is a command bar with various icons and a status area showing the date 'Jan 21, 2015', time '08:12:07', user 'John Doe', and profile 'Default Profile 1'.

Src.	Pos.	Sample ID	Assay	Vol. In	Vol. Out	Status	Dest.	Pos.
2	A:1	Sample 1	PCR_1_RG	110.0	20.0	unprocessed	2	1
2	B:1	Sample 2	PCR_1_RG	110.0	20.0	unprocessed	2	2
2	C:1	Sample 3	PCR_1_RG	110.0	20.0	unprocessed	2	3
2	D:1	Sample 4	PCR_1_RG	110.0	20.0	unprocessed	2	4
2	E:1	Sample 5	PCR_1_RG	110.0	20.0	unprocessed	2	5
2	F:1	Sample 6	PCR_1_RG	110.0	20.0	unprocessed	2	6
2	G:1	Sample 7	PCR_1_RG	110.0	20.0	unprocessed	2	7
2	H:1	Sample 8	PCR_1_RG	110.0	20.0	unprocessed	2	8
2	A:2	Sample 9	PCR_1_RG	110.0	20.0	unprocessed	2	9
2	B:2	Sample 10	PCR_1_RG	110.0	20.0	unprocessed	2	10
2	C:2	Sample 11	PCR_1_RG	110.0	20.0	unprocessed	2	11
2	D:2	Sample 12	PCR_1_RG	110.0	20.0	unprocessed	2	12
2	E:2	Sample 13	PCR_1_RG	110.0	20.0	unprocessed	2	13
2	F:2	Sample 14	PCR_1_RG	110.0	20.0	unprocessed	2	14
2	G:2	Sample 15	PCR_1_RG	110.0	20.0	unprocessed	2	15
2	H:2	Sample 16	PCR_1_RG	110.0	20.0	unprocessed	2	16
2	A:3	Sample 17	PCR_1_RG	110.0	20.0	unprocessed	2	17

**Sample View screen.**

#### Command bar



For descriptions of the buttons in the command bar, see the “Command bar” section of the **Overview** tab (Section 6.3.1).

#### Dialog panel

Information about the samples is provided in a table. When an assay run is removed, all information about the samples is automatically removed from the table.

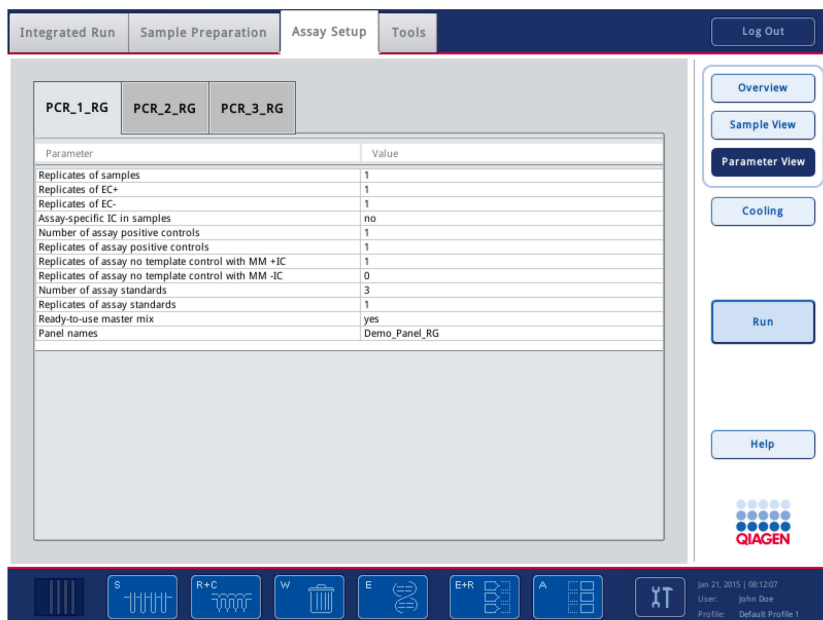
#### Table view

- Src.** The slot position of the sample rack is displayed.
- Pos.** The position in the sample rack is displayed.
- Sample ID** ID (bar code, virtual bar code, or automatic ID assigned by the instrument) is shown.

<b>Assay</b>	<p>The name of the assigned Assay Parameter Set is displayed.</p> <p>If the Assay Parameter Set was assigned by the work list, the symbol  is displayed. If the sample is not linked to the Assay Parameter Set in the work list, but is linked to a different Assay Parameter Set, the symbol  is displayed.</p>
<b>Vol. In</b>	The input volume is displayed.
<b>Vol. Out</b>	Template volume for assay point is displayed.
<b>Status</b>	<p>The sample state is displayed. There are 6 possible sample states: "unprocessed", "in process", "valid", "unclear", "invalid", and "removed" (see "Sample status", Section 7.7 for more information).</p> <p>The state of individual samples is also shown by the color in the table.</p> <ul style="list-style-type: none"> <li>● Light green — "valid"</li> <li>● Light pink — "unclear"</li> <li>● Pink — "invalid"</li> <li>● White — "unprocessed"</li> <li>● White — "in progress"</li> </ul>
<b>Dest.</b>	The slot of the assay rack is displayed.
<b>Pos.</b>	The position in the assay rack is displayed.
<b>Assay Definition</b>	The assay definition used for the run.

### 6.3.3 Assay Setup/Parameter View screen

The **Parameter View** screen displays information about Assay Parameter Sets and specifications for samples that will be processed, are currently being processed, or that have been processed.



**Parameter View screen.**

## Command bar

For descriptions of the buttons in the command bar, see the “Command bar” section of the **Overview** tab (Section 6.3.1)

## Dialog panel

Information about the assay parameters is provided in tabular format for each Assay Parameter Set. The parameters show the default values (i.e., the values that will be used for the run).

### Assay parameters

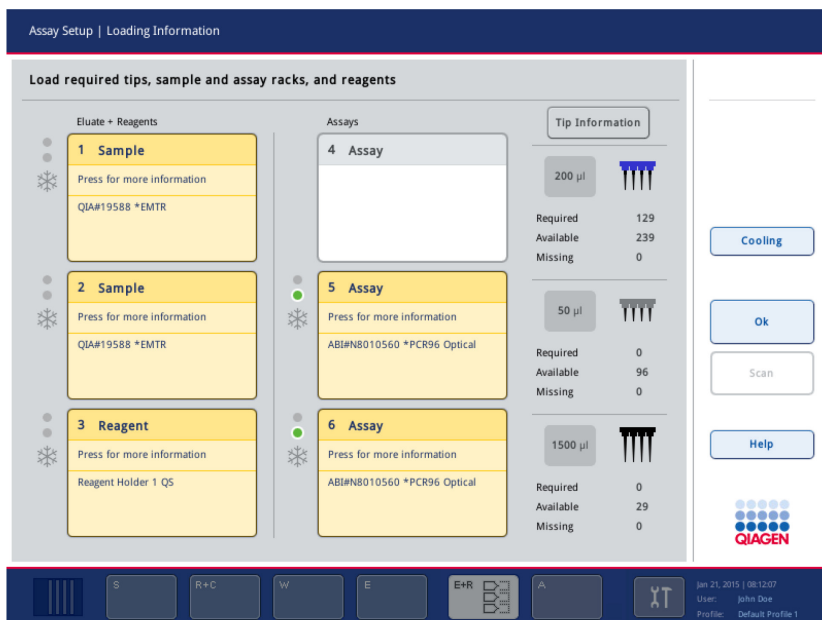
Replicates, Samples	Number of replicates for a sample.
Replicates, EC+	Number of replicates for a positive extraction control.
Replicates, EC-	Number of replicates for a negative extraction control.

Assay-specific IC in samples	"Yes", if IC is included in samples, or "No" if IC for samples should be added to the master mix.
Replicates, assay positive controls	Number of replicates for an assay positive control.
Number of assay positive controls	Number of assay positive controls.
Replicates, assay no template control with MM+IC	Number of replicates for the no template control with MM+IC.
Replicates, assay no template control with MM-IC	Number of replicates for the assay no template control with MMC-IC.
Number of assay standards	Number of assay standards.
Ready-to-use master mix	"No" means the QIAsymphony AS prepares the master mix.
Panel name	Name of the panel.

#### 6.3.4 **Loading Information** screen

To open the **Loading Information** screen, press the **E+R** or **A** button.

The **Loading Information** screen shows the worktable and its positions. Slots that must be loaded with racks are highlighted yellow. The user can press a slot to view detailed loading information for that slot and to load it. In addition, the required, available, and missing number of tips is displayed.



### Loading Information screen.

**Note:** Images of instrument screens and files used throughout this user manual (volumes 1 and 2) are examples and may differ from the actual screen or file you are using.

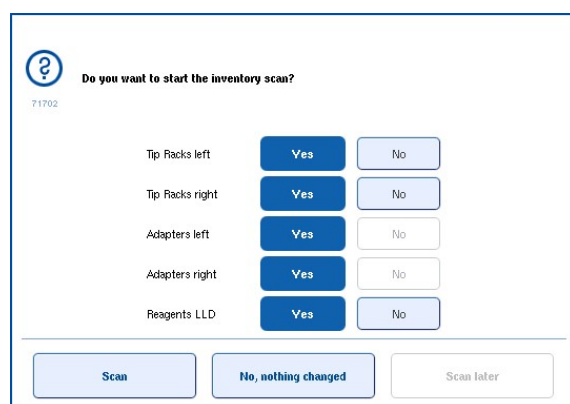
Note: Press Tip Information to get recommended tip loading information.

### Command bar



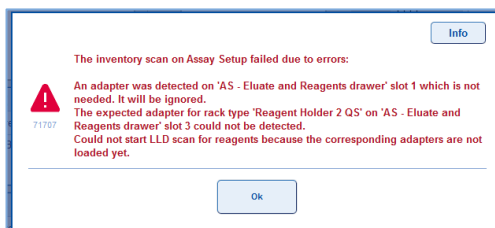
Enables the user to perform an inventory scan.

When pressed, the following message appears.



To scan the loaded consumables, select the components and then press **Scan**.

If the system detects loaded/removed racks differing from information given by the user, an error message appears.



In this case, press **OK** to return to the **Loading Information** screen. Make the required modifications, and then perform the inventory scan again.

**Note:** Additional validations are performed when the run is started. A successful validation after loading does not mean that the run can be successfully started.



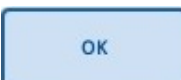
This button appears when an inventory scan is in progress. Press to cancel the current inventory scan. A message will appear. Press **OK** to return to the **Loading Information** screen.



Enables the user to go to the **Temperature Status** screen.



Closes the screen without saving the changes and cancels the loading process.



Closes the screen.

### Dialog panel

**Sample slot** Press on a **Sample** slot to view detailed loading information for that slot.

**Reagent slot** Press on a **Reagent** slot to view detailed loading information for that slot.

**Assay slot** Press on an **Assay** slot to view detailed loading information for that slot.

### Sample or Assay slot

The **Plate View** and **List View** provide detailed loading information for the selected sample or assay rack.

For an integrated run, slot 2 is shown with “Adapter available” information “yes (currently on the QIAsymphony SP)”. This means that the rack is loaded on the QIAsymphony SP and will be moved automatically to the QIAsymphony AS when it is needed for pipetting eluates. Therefore, it is not possible to load another rack on the slot; a rack is loaded, but it is not visible to the user on the QIAsymphony AS.

Assay Setup | Loading Information

Load sample rack into the correct adapter on slot 1

1 2 3 4 5 6 7 8 9 10 11 12

A

B

C

D

E

F

G

H

1 2 3 4 5 6 7 8 9 10 11 12

A

B

C

D

E

F

G

H

Press on tube positions for details

Rack

Sample

Rack ID

S1\_3000017\_0000sim

Rack type

QIA#19588 \*EMTR

Adapter type

Elution Microtube Rack QS

Adapter available

no

Labware category

Deep Well

Plate View

List View

Cancel

Load

Help

QIAGEN

S

R+C

W

E

E+R

A

jan 21, 2015 | 08:12:07

User: John Doe

Profile: Default Profile 1

Plate View screen — example slot 1.

Assay Setup | Loading Information

Load assay rack into the correct adapter on slot 5

Pos.	ID	Type	State	Volume Out	Assay
A:1	A1_S2_3000018	S	unprocessed	25.0 µl	PCR_7_96well
B:1	B1_S2_3000018	S	unprocessed	25.0 µl	PCR_7_96well
C:1	C1_S2_3000018	S	unprocessed	25.0 µl	PCR_7_96well
D:1	D1_S2_3000018	S	unprocessed	25.0 µl	PCR_7_96well
E:1	E1_S2_3000018	S	unprocessed	25.0 µl	PCR_7_96well
F:1	F1_S2_3000018	S	unprocessed	25.0 µl	PCR_7_96well
G:1	G1_S2_3000018	S	unprocessed	25.0 µl	PCR_7_96well
H:1	H1_S2_3000018	S	unprocessed	25.0 µl	PCR_7_96well
A:2	A2_S2_3000018	EC+	unprocessed	25.0 µl	PCR_7_96well
B:2	B2_S2_3000018	EC+	unprocessed	25.0 µl	PCR_7_96well
C:2	C2_S2_3000018	EC+	unprocessed	25.0 µl	PCR_7_96well
D:2	D2_S2_3000018	EC+	unprocessed	25.0 µl	PCR_7_96well
E:2	E2_S2_3000018	EC+	unprocessed	25.0 µl	PCR_7_96well
F:2	F2_S2_3000018	EC+	unprocessed	25.0 µl	PCR_7_96well
G:2	G2_S2_3000018	EC+	unprocessed	25.0 µl	PCR_7_96well
H:2	H2_S2_3000018	EC+	unprocessed	25.0 µl	PCR_7_96well
A:3	A3_S2_3000018	EC-	unprocessed	25.0 µl	PCR_7_96well
B:3	B3_S2_3000018	EC-	unprocessed	25.0 µl	PCR_7_96well

Plate View

List View

Rack ID

Automatic ID

Cancel

Load

Help

QIAGEN

S

R+C

W

E

E+R

A

jan 21, 2015 | 08:12:07

User: John Doe

Profile: Default Profile 1

List View screen — example slot 5.

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## Command bar

Plate View

Opens the **Plate View** screen. This screen provides detailed loading information about the selected **Sample** or **Assay** slot.

List View

Opens the **List View** screen. This screen provides detailed loading information about the selected **Sample** or **Assay** slot in a tabular format (i.e., position, sample ID, sample type, sample status, sample volume, and the assays that will be processed with the sample).

Rack ID

Press to scan or manually enter a rack ID (only for assay racks).

Automatic ID

Press to generate a rack ID (only for assay racks).

Cancel

Closes the screen without saving the changes.

Load

Press when loading the rack.

If the **Assay Setup/Manual Input** screen appears, scan the bar code with the bar code scanner, or enter the rack ID manually and press **OK** (this step may be skipped depending on configuration settings). See Appendix C for a list of compatible bar code types. The **Assay Setup/Loading information** screen reappears.

The system will check during the inventory scan whether the rack was loaded correctly.

Remove

Press when unloading the rack.

If the **Assay Setup/Manual Input** screen appears, scan the bar code with the bar code scanner, or enter the rack ID manually and press **OK** (this step may be skipped depending on configuration settings). The **Assay Setup/Loading information** screen reappears.

The system will check during the inventory scan whether the rack was unloaded correctly.

Reagent slot

The **Plate View** and **List View** provide detailed loading information for the selected **Reagent slot**.

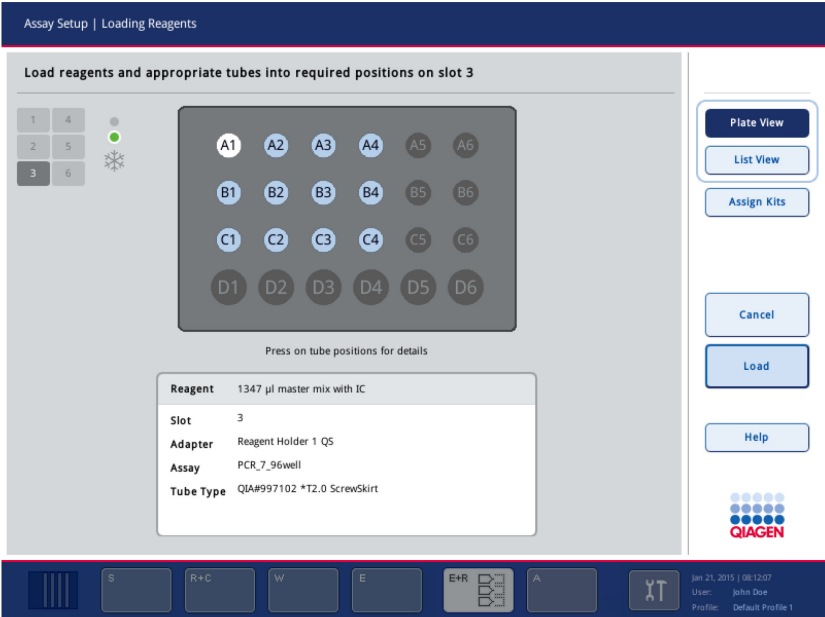
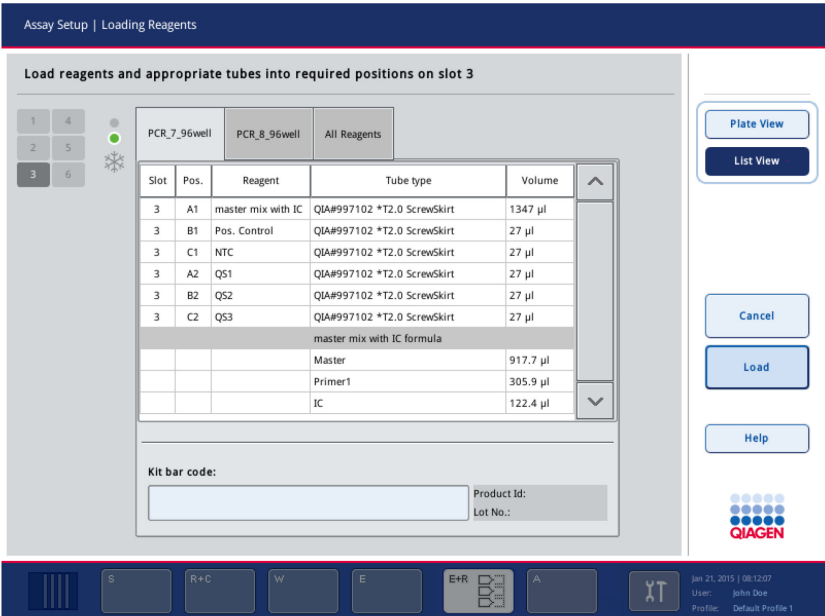


Plate View screen — example slot 3.



List View screen — example slot 3.

## Command bar

Plate View

Opens the **Plate View** screen. This screen provides detailed loading information about the selected **Reagent** slot. See "Schematic plates", Section 5.5 for detailed information about schematic plates.

List View

Opens the **List View** screen. This screen provides detailed loading information about the selected **Reagent** slot in a tabular format (i.e., slot number, reagent position, reagent, tube type, reagent volume).

When more than one assay is configured, each assay is displayed in a separate tab.

Cancel

Closes the screen without saving the changes.

Load

Press when loading the reagent rack. The system will check during the inventory scan whether the rack was loaded correctly.

Remove

Press when unloading the reagent rack. The system will check during the inventory scan whether the rack was unloaded correctly.

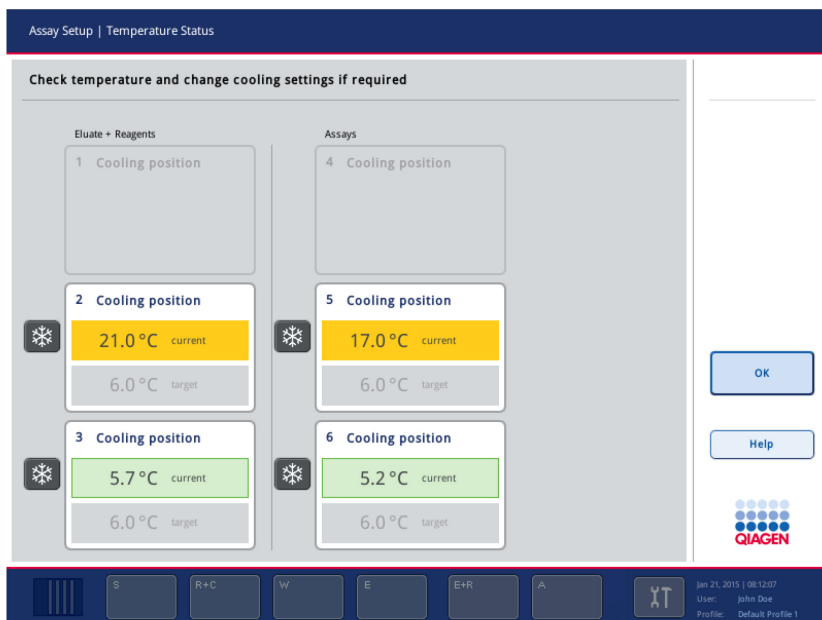
Assign Kits

Enables the user to enter a kit bar code. Press on the field. You can enter a bar code in the screen that appears.

### 6.3.5 Temperature Status screen

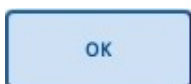
To open the **Temperature Status** screen, press **Cooling** in the **Loading Information** screen or the assay setup **Overview** screen.

The **Temperature Status** screen shows the worktable and its cooling positions. For each cooling position used during the run the current and the target temperature is shown.



Temperature Status screen.

#### Command bar



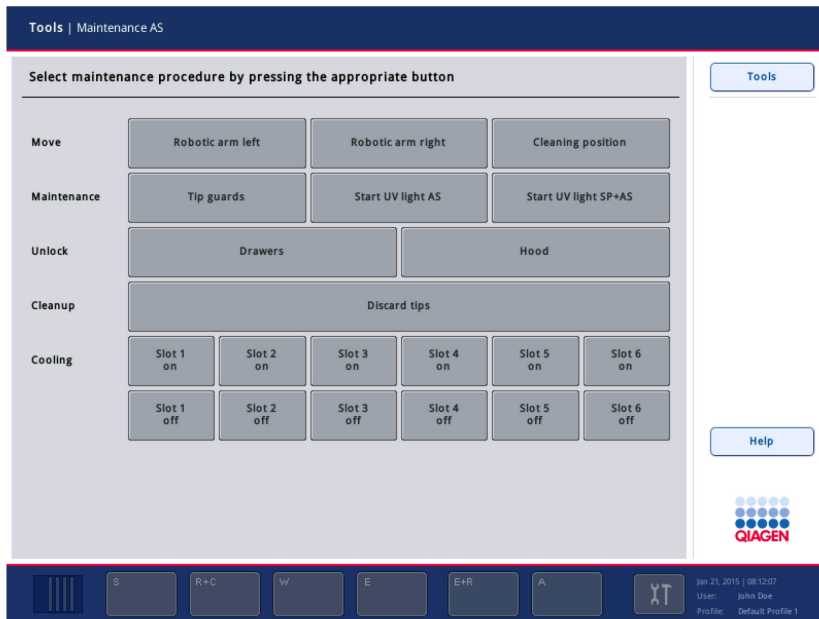
Press **OK** to save changes and return to the **Loading Information** screen or the assay setup **Overview** screen.

## 6.4 Maintenance AS menu

The **Maintenance AS** menu enables operation of parts of the QIA Symphony AS, without performing an assay run. Tools for performing routine maintenance procedures and for worktable cleanup are also available.

**Note:** Detailed information about maintenance procedures and the **Cleanup** tools, see Section 15.

### 6.4.1 Maintenance AS screen



Maintenance AS screen.

#### Dialog panel

##### Move Arm

**Robotic arm left** Moves the robotic arm to the left.

**Robotic arm right** Moves the robotic arm to the right.

**Cleaning position** Moves the robotic arm to the middle and front.

##### Maintenance

**Tip guards** Moves the robotic arm to the middle and front.

**Start UV light AS** Opens the **Input/UV cleanup** screen for QIAsymphony AS. Enter the duration (minutes) of the UV decontamination, and then press **OK**. For more information, see Section 15.

**Start UV light SP+AS** Opens the Input/UV cleanup screen for QIAsymphony SP+AS. Enter the duration (minutes) of the UV decontamination, and then press **OK**. For more information, see Section 15.

## Unlock

### Drawers

Unlocks all instrument drawers. If a malfunction results in the drawers remaining locked, this script allows the user to manually unlock the drawers.

If the drawers remain locked after performing the script, switch off the instrument. If the problem persists, contact QIAGEN Technical Services.

### Hood

Unlocks the hood of the QIAAsymphony AS. If an error results in the hood remaining locked, this script enables the user to manually unlock it.

If the hood remains locked after performing the script, switch off the instrument. If the problem persists, contact QIAGEN Technical Services.

## Cleanup

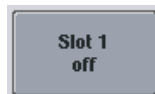
### Discard tips

Discard tips from the tip adapters.

## Cooling



Turns on the cooling on slot 1 to 4°C.



Turns off the cooling on slot 1.

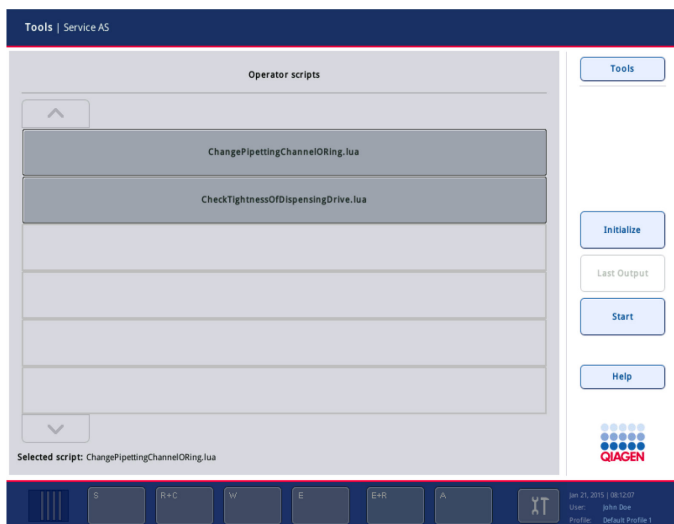
**Note:** There are corresponding buttons for slots 2–6.

## 6.5 Service AS menu

### 6.5.1 Script Execution tab

The **Script Execution** tab of the **Service AS** menu enables the user to run "Operator scripts", which are service protocols. The available scripts are displayed in the **Operator scripts** list. Use the up and down arrows to scroll through the list. Select the script to be run by pressing the appropriate script.

**Note:** The selected script is indicated at the bottom left of the screen.



### Script Execution tab of the Service AS menu.

#### Command bar

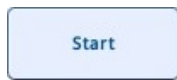


Allows the user to initialize the QIAsymphony AS. When the button is pressed, a message appears that asks the user whether to initialize the instrument. Press **Yes** to initialize the QIAsymphony AS; press No to cancel the initialization.

**Note:** If the QIAsymphony SP/AS hoods are closed, the initialization is carried out automatically when the instruments are started. If one or both of the hoods are open, the initialization cannot be completed. An error message will appear. If both hoods are open, the instruments will not initialize during startup.



The output dialog panel is displayed, which enables review of the output information of the last script performed.



Starts the selected operator service script. While the selected script is being performed, an output message appears that provides information about the script being performed and the results.

#### Dialog panel

##### Operator scripts list

Scripts available to the current operator are displayed and can be selected by pressing the appropriate button.

##### Selected script

The selected script is displayed here.

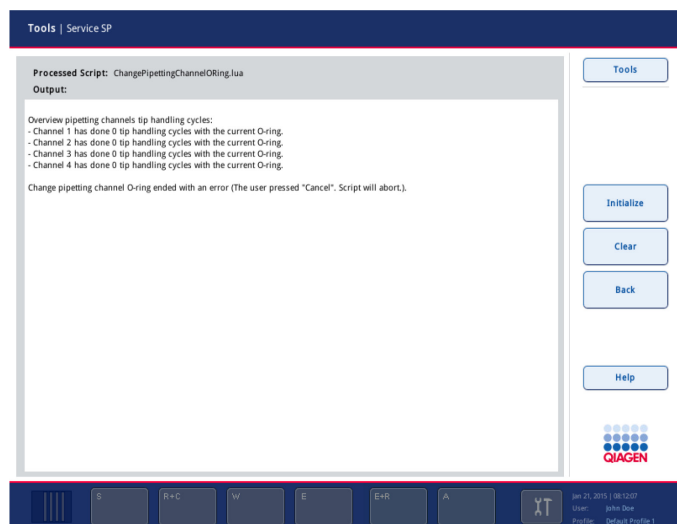
## Operator scripts

The following script is applicable.

**ChangePipettingChannel** Enables the tip-adaptor O-ring to be replaced. See  
**ORing.lua** Section 15 for more information.

## Output dialog panel

The **Output** dialog panel displays the output of the selected operator service script.



## Output dialog panel.

### Command bar

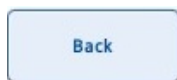


Allows the user to initialize the QIAAsymphony AS. When the button is pressed, a message appears that asks the user whether to initialize the instrument. Press Yes to initialize the QIAAsymphony AS; press No to cancel the initialization.

Note: If the QIAAsymphony SP/AS hoods are closed, the initialization is carried out automatically when the instruments are started. If one or both of the hoods are open, the initialization cannot be completed. An error message will appear. If both hoods are open, the instruments will not initialize during startup.



Clears the content of the **Output** dialog panel.



Displays the **Operator Script** dialog panel.



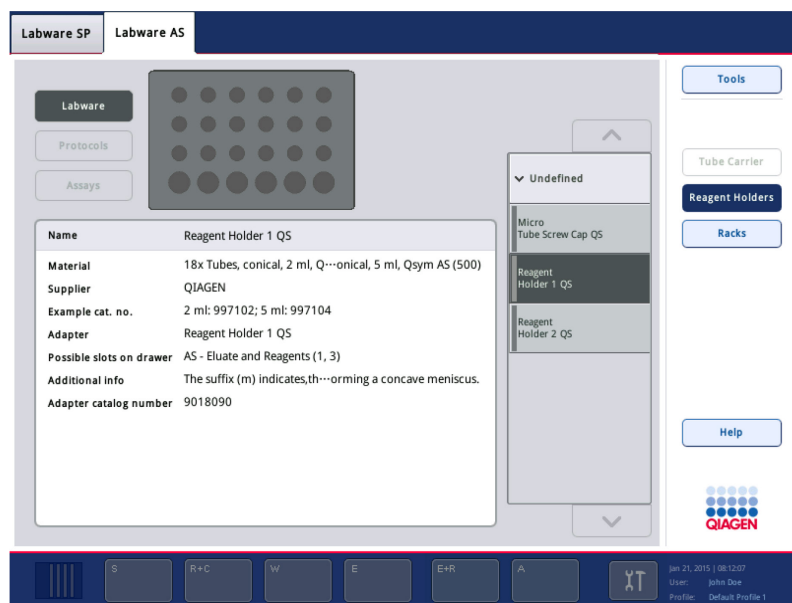
## Dialog panel

If the **Clear** button has not been pressed, the output of the selected service script is shown here.

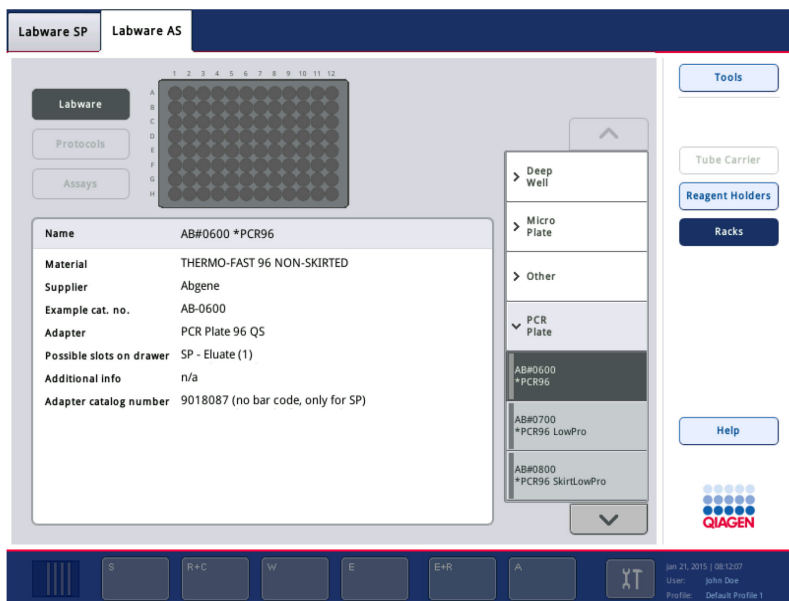
## 6.6 Labware Browser menu

The **Labware AS** tab of the **Labware Browser** menu enables the user to view information about labware that can be used with the QIAsymphony AS.

### 6.6.1 Labware AS tab



**Reagent Holders view.**

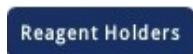


**Racks view.**

## Command bar



This button is not active in the **Labware AS** tab. It is only active in the **Labware SP** tab.



Opens the **Reagent Holders** view in which information about reagent holders is displayed.



Opens the **Racks** view in which information about racks is displayed.

## Dialog panel

**Labware** button This button has no function in the **Labware AS** tab.

**Protocols** button This button is inactive in the **Labware AS** tab.

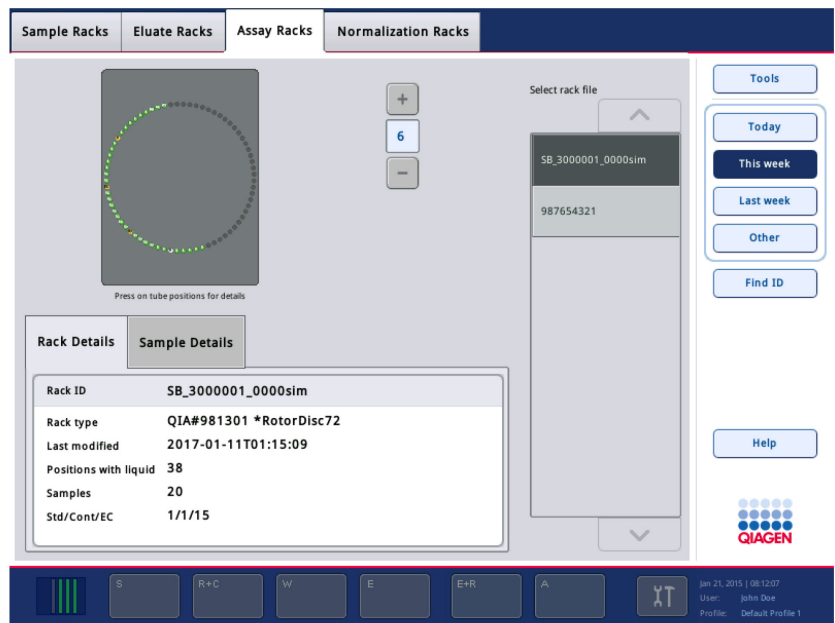
**Labware list** Enables the user to select an item of labware. Labware is grouped into categories (e.g., Deep Well, Micro Plate). Use the arrows to scroll through the list of labware. Detailed information about the selected item of labware (e.g., supplier, example cat. no.) and an image is then displayed in the dialog panel.

## 6.7 Rack Browser menu

This menu allows the user to view rack files that are currently saved on the QIAsymphony RGQ MDx (US). There are 2 tabs — **Assay Racks** and **Eluate Racks**. For more information about the **Rack Browser** menu and for information about the **Eluate Racks** tab, see Section 5.15.

### 6.7.1 Assay Racks tab

This tab displays information about which racks can be used as assay racks.



**Assay Racks tab.**

## Command bar



Displays the rack files that were modified today.



Displays the rack files that have been modified since 00:00 of Monday of the current week, including the rack files that were modified today. This option is preselected by default.



Displays the rack files that were modified between 00:00 of Monday last week and 00:00 of Monday of the current week.



Displays the rack files that were modified before 00:00 of Monday last week.



Enables the user to manually enter and then search for IDs using the **Keyboard** screen.

## Dialog panel

Schematic plate

The selected rack is displayed as a schematic diagram. Positions in the rack are color coded. Select a position by pressing on it, or by using the arrow buttons, to display information about that position.

For more information about schematic diagrams of plates, see Section 5.5.

**Rack Details** tab

Displays details about the selected rack (e.g., rack ID, rack type, date last modified).

**Sample Details**  
tab

Displays details about the sample that is currently selected in the rack. Details include sample ID, sample type, sample state, and volume.

**Select rack file**  
list

Lists rack IDs, in descending order by last modification date. Only rack IDs that fit to the current time filter (i.e., today, this week, last week, other) are displayed. When a rack ID from this list is selected, details about this rack are displayed in the corresponding tabs.

---

## 7 Handling Files

The QIAsymphony SP/AS instruments recognize 2 different types of user — “Operator” and “Supervisor”.

**Note:** The QIAsymphony SP/AS instruments are provided with one user account with “Supervisor” rights. The “Supervisor” has to create user accounts for users with the “Operator” role.

Each role confers different access rights and allows the user to perform different types of action.

### “Operator”

The “Operator” enables transfer of the following file types from the QIAsymphony SP/AS instruments to the USB stick:

- Log files
- Result file SP
- Result file AS
- Confirmation files
- Loading information
- Instrument Reports
- Audit Trail files
- Rack files
- Work lists

The “Operator” enables transfer of the following file types from the USB stick to the QIAsymphony SP/AS instruments:

- Rack files
- Work lists

In addition, the “Operator” enables synchronization of the following file types between the QIAsymphony SP/AS instruments and the USB stick:

- Rack files
- Work lists

---

## **“Supervisor”**

The “Supervisor” enables transfer of the following file types from the QIAsymphony SP/AS instruments to the USB stick:

- Log files
- Result files
- Confirmation files
- Loading information
- Instrument Reports
- Audit Trail files
- Duration files
- Rack files
- Work lists
- Assay Control Sets
- Protocols (Bioscripts)
- Assay Parameter Sets
- Assay definitions
- Process configuration profiles
- Reagent definitions
- User information
- Maintenance Config.
- Labware SP
- Service scripts SP
- Labware AS
- Service scripts AS

The “Supervisor” enables transfer of the following file types from the USB stick to the QIAsymphony SP/AS instruments:

- Duration files
- Rack files
- Work lists
- Assay Control Sets
- Protocols (Bioscripts)
- Assay Parameter Sets

- Assay definitions
- Process configuration profiles
- Reagent definitions
- Labware SP
- Service scripts SP
- Labware AS
- Service scripts AS

In addition, the "Supervisor" enables synchronization of the following file types between the QIAsymphony SP/AS and the USB stick:

- Rack files
- Work lists
- Assay Control Sets
- Protocols
- Assay Parameter Sets
- Assay definitions
- Process configuration profiles
- Labware SP
- Labware AS

The "Supervisor" can also back up the file that contains information about all user accounts created.

Files can be handled directly using a USB stick (as described in this section) or, alternatively, using the **File Transfer** tool in the QIAsymphony Management Console. Result files, work list files, loading information files, and log files can also be handled using the **Automatic File Transfer** tool.

For more information about both tools refer to Section 22 and Section 25. If the **Automatic File Transfer** tool is used, the user with the "Supervisor" user ID must assign a password to the **File Transfer** user. See Section 25 for details about how to do this.

**Note:** For successful file transfer, the protocol, Assay Control Set, and assay definition must be transferred before the Assay Parameter Set. For an integrated run, a protocol, Assay Control Set, assay definition, and Assay Parameter Set must be transferred.

## 7.1 Summary QIAsymphony SP/AS files

This table provides a summary of QIAsymphony SP/AS files, listed in alphabetical order.

File type	Description	Source
Assay Control Set (ACS)	The combination of a protocol for the QIAsymphony SP, plus additional parameters defined (e.g., internal control).	Provided by QIAGEN.
Assay Definition (AD)	A set of instructions for the QIAsymphony AS that enables the instrument to perform an assay setup.	Provided by QIAGEN.
Assay Parameter Set (APS)	The combination of an Assay Definition with additional parameters defined (e.g., number of replicates and assay standards).	Provided by QIAGEN.
Audit Trail	Tracks all user input for QIAsymphony SP/AS configuration and run setup.	Automatically created in *.xml and *.html format.
Configuration profile	Defines the configuration settings (process and system) for the QIAsymphony SP and AS instruments.	Default profile 1 is supplied by QIAGEN.
Duration file	Provides information on duration of script execution.	Created by the system when executing scripts. Can also be moved from one instrument to another.
Labware AS	Provides information about consumables for use with the QIAsymphony AS.	Provided by QIAGEN.
Labware SP	Provides information about consumables for use with the QIAsymphony SP.	Provided by QIAGEN.
Loading information	Data file that contains detailed information about which reagents, sample rack(s), assay rack(s), and disposable filter-tips are required for setup of the QIAsymphony AS worktable.	Generated by the QIAsymphony AS, after pressing <b>Queue</b> in the assay definition process.
Log files	Data file(s) that contain general information about the QIAsymphony SP/AS instruments, user interactions, and details about the protocol being run.	Generated by the QIAsymphony SP/AS.

Table continued on next page



Table continued from previous page

<b>Task</b>	<b>Personnel</b>	<b>Training and experience</b>
Maintenance Config.	Defines the required and optional configuration settings for maintenance of the QIAsymphony SP and AS instruments.	Default Maintenance Config provided by QIAGEN. Certain adaptations by customer possible.
Process configuration profile	Contains all configured process parameters.	Default process profiles are provided by QIAGEN.
Protocol	A set of instructions for the QIAsymphony SP that allows the instrument to perform automated purification procedure.	Provided by QIAGEN.
Rack file	Contains information about sample racks or assay racks (i.e., rack type, rack ID, sample volumes, and sample IDs).	Can be automatically generated by the QIAsymphony SP/AS instruments, or can be created and modified manually.
Reagent definition	The cartridge information/reagent definition files provide information that is required for recognizing the different reagent cartridges.	Provided by QIAGEN.
Result files	Data file that is generated for each protocol or assay run that is performed on the QIAsymphony SP/AS instruments.	The final result file is generated by the QIAsymphony SP/AS instruments when the protocol has finished, or when the assay run is finished and the assays have been removed.
Scripts AS	A set of instructions for maintenance procedures on the QIAsymphony AS.	Provided by QIAGEN.
Scripts SP	A set of instructions for maintenance procedure(s) on the QIAsymphony SP.	Provided by QIAGEN.
Users	Contains information about the users that have been configured and the corresponding access rights.	Updated by the QIAsymphony SP/AS instruments whenever the user configuration is updated.
Work list	Provides information that assigns specific samples to Assay Control Sets or Assay Parameter Sets.	Can be generated by a LIMS, or can be manually generated.

## 7.2 Using a USB stick with the QIAsymphony SP/AS instruments

The QIAsymphony SP/AS instruments have 2 USB ports enabling connection of USB devices. The USB ports are at the front of the QIAsymphony SP in the lower left and lower right corners.

A USB stick is supplied with the QIAsymphony SP. Only use the provided USB stick for transfer of files between the instruments and a PC.

**Note:** Do not plug any devices in to USB ports other than the USB stick and handheld scanner supplied with the QIAsymphony SP.

### Plugging in the USB stick

Plug the USB stick into one of the USB ports at the front of the QIAsymphony SP.

The QIAsymphony SP will automatically recognize the USB stick.



### Removing the USB stick

The USB stick can be removed by simply unplugging it from the USB port.

**Note:** Do not remove a USB stick when it is in use (e.g., during file transfer). If the USB stick is removed while in use, loss of data may occur. Please note that data transfer may take some time.

---

## 7.3 Data transfer via the USB stick

### 7.3.1 Setting up the USB stick

**Note:** If you are using the QIAsymphony Management Console to synchronize your data, the file/folder structure of the USB stick is set up automatically.

Set up the following file/folder structure on the USB stick:

<b>/data/AssayControlSets/</b>	Directory for Assay Control Sets
<b>/data/AssayDefinitions/</b>	Directory for Assay Definitions
<b>/data/AssayParameterSets/</b>	Directory for Assay Parameter Sets
<b>/data/BioScripts/</b>	Directory for protocols
<b>/data/ConcentrationData</b>	Directory for concentration data files

**Note:** This folder (**ConcentrationData**) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.

<b>/data/Config/Profiles</b>	Directory for process profiles
<b>/data/Duration</b>	Directory for duration files
<b>/data/Labware/AS</b>	Directory for QIAsymphony AS labware files
<b>/data/Labware/SP</b>	Directory for QIAsymphony SP labware files
<b>/data/config/Maintenance</b>	Directory for QIAsymphony Maintenance config files
<b>/data/translation</b>	Directory for QIAsymphony language packs

**Note:** This folder (**translation**) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.

<b>/data/KitSpecifications</b>	Directory for QIAAsymphony AS kit specifications
<b>Note:</b> This folder ( <b>KitSpecifications</b> ) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.	
<b>/data/QDefFiles</b>	Directory for QIAAsymphony SP QDef files
<b>Note:</b> This folder ( <b>QDefFiles</b> ) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.	
<b>/data/RackFiles/</b>	Directory for rack files
<b>/data/ReagentDefinitions</b>	Directory for reagent cartridge information
<b>/data/ServiceScripts/AS/operator</b>	Directory for QIAAsymphony AS operator service scripts
<b>/data/ServiceScripts/SP/operator</b>	Directory for QIAAsymphony SP operator service scripts
<b>/data/ServiceScripts/AS/maintenance</b>	Directory for QIAAsymphony AS maintenance scripts
<b>/data/ServiceScripts/SP/maintenance</b>	Directory for QIAAsymphony SP maintenance scripts
<b>/data/Users/</b>	Directory for user data
<b>/data/Worklists/</b>	Directory for work lists
<b>/log/</b>	Directory for log files
<b>/log/AuditTrail</b>	Directory for log files
<b>/log/CyclerExport</b>	Directory for cycler files
<b>Note:</b> This folder ( <b>CyclerExport</b> ) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.	
<b>/log/InstrumentReports/</b>	Directory for instrument report files

<b>/log/LoadingInformation/</b>	Directory for loading information files
<b>/log/Results/AS/</b>	Directory for QIAsymphony AS result files
<b>/log/Results/SP</b>	Directory for QIAsymphony SP result files
<b>/log/StartBatchConfirmation/SP</b>	Directory for confirmation files

**Note:** This folder (**StartBatchConfirmation/SP**) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.

Data can be transferred from the USB stick to the QIAsymphony SP/AS instruments (uploaded) and also from the QIAsymphony SP/AS instruments to the USB stick (downloaded).

### 7.3.2 Transferring files from the QIAsymphony SP/AS to the USB stick

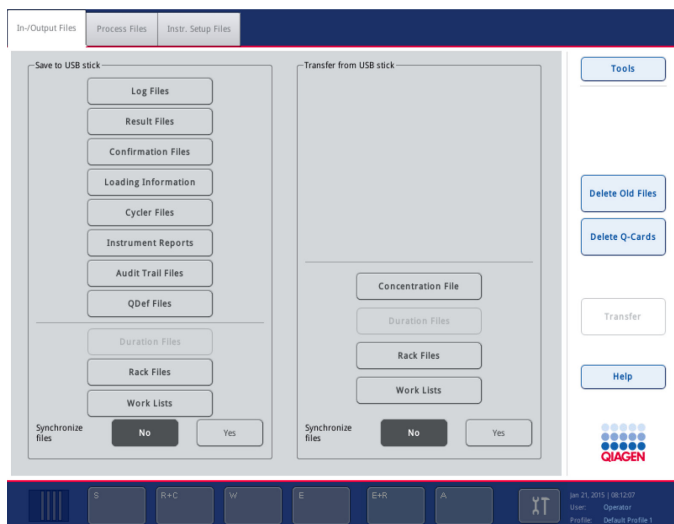
**Note:** File transfer of both QIAsymphony SP and QIAsymphony AS files is performed using the **File Transfer** menu. For a summary of file types, see Section 7.1.

To store the data generated by the QIAsymphony SP/AS instruments, you can transfer files to the USB stick or via the QIAsymphony Management Console.

If you are using the QIAsymphony Management Console, refer to Sections 19 to 31 for more details.

To transfer files from the QIAsymphony SP/AS instruments to the USB stick, follow the steps below.

1. Log in to the QIAsymphony SP/AS instruments. See page 175 for a summary of which file types the "Supervisor" and "Operator" roles have access to transfer.
2. Insert the USB stick into one of the USB ports at the front of the QIAsymphony SP.
3. Press **File Transfer** in the **Tools** screen. The **In-/Output Files** tab of the **File Transfer** menu opens.



**In-/Output Files tab of the File Transfer menu.**

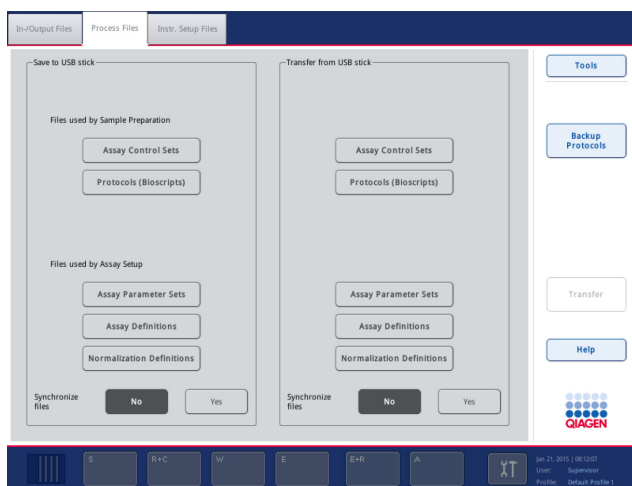
4. Select one of the file transfer tabs (**In-/Output Files**, **Process Files**, **Instr. Setup Files**).  
The following files can be transferred to the USB stick from the different tabs.

Tab	Files that can be transferred to the USB stick
<b>In-/Output Files</b>	Log files Result files Confirmation files Loading information files Instrument Reports Audit Trail files Duration Files Rack files Work lists
<b>Process Files</b>	Assay Control Sets Protocols Assay Parameter Sets Assay Definitions
<b>Instr. Setup Files</b>	Configuration (there may be some entries that are not visible to all users) Process configuration profiles Reagent definitions

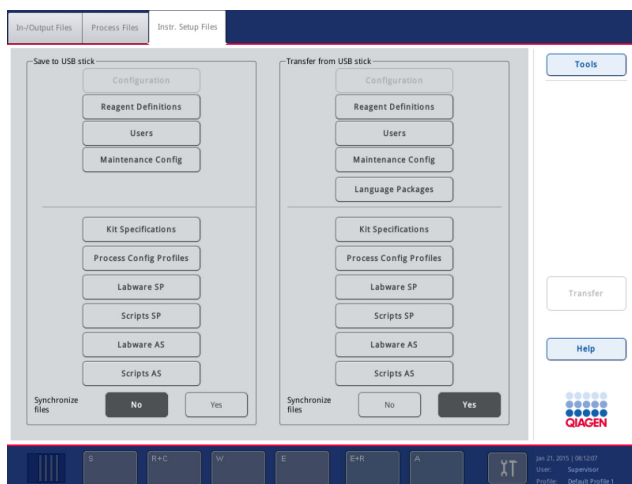
## Tab

## Files that can be transferred to the USB stick

Users files  
Maintenance Config.  
Labware SP and AS files  
Service scripts SP  
Service scripts AS



### Process Files tab.



### Instr. Setup Files tab.

5. Select the file type(s) to be downloaded to the USB stick by pressing the appropriate button in the **Save to USB stick** panel.

**Note:** To save time, select more than one file type.

6. Press the **Transfer** button in the command bar of the screen to transfer the selected files to the USB stick.
7. A message appears informing you that the files will be transferred from the QIAsymphony SP/AS instruments to the USB stick. Press **Yes** to confirm that the files should be transferred.
8. During data transfer, an information message will be displayed.
9. After successful data transfer, a message will appear confirming data transfer.
10. Remove the USB stick.

**Note:** Do not remove the USB stick during data transfer otherwise loss of data may occur.

### 7.3.3 Transferring files from the USB stick to the QIAsymphony SP/AS

**Note:** File transfer of both QIAsymphony SP and QIAsymphony AS files is performed using the **File Transfer** menu. For a summary of file types, see Section 7.1.

You can transfer files from the QIAsymphony Management Console to the QIAsymphony SP/AS instruments. Alternatively, if you are not connected to the network, you can transfer files using the USB stick.

Transfer files from the USB stick to the QIAsymphony SP/AS instruments as follows:

1. Copy the files to be uploaded to the corresponding directory on the USB stick. See Section 7.3.1 for the folder structure on the USB stick.
2. Log in to the QIAsymphony SP/AS instruments. See Section 7 for a summary of which file types the "Supervisor" and "Operator" user IDs have access to transfer.
3. Insert the USB stick into one of the USB ports at the front of the QIAsymphony SP.
4. Press **File Transfer** in the **Tools** screen to enter the **In-/Output Files** tab.
5. Select one of the file transfer tabs (**In-/Output Files**, **Process Files**, **Instr. Setup Files**). The following files can be transferred from the USB stick from the different tabs.

Tab	Files that can be transferred from the USB stick
<b>In-/Output Files</b>	Duration Files Rack files Work lists
<b>Process Files</b>	Assay Control Sets Protocols

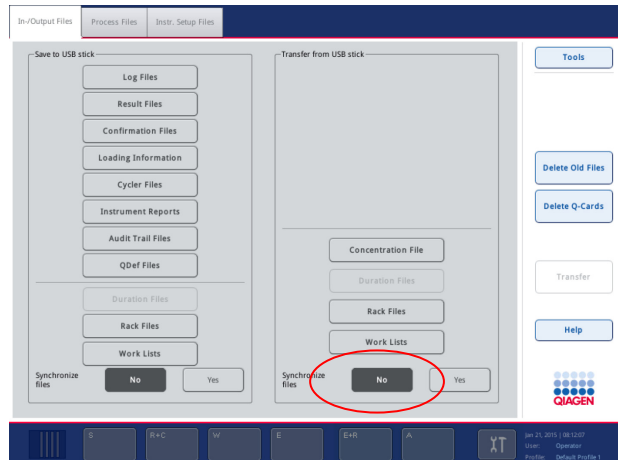


Tab	Files that can be transferred from the USB stick
	Assay Parameter Sets
	Assay Definitions
<b>Instr. Setup Files</b>	Configuration (there may be some entries that are not visible to all users)
	Process configuration profiles
	Maintenance Config.
	Reagent Definitions
	Labware SP
	Scripts SP
	Labware AS
	Scripts AS

- Select the file type(s) to be uploaded to the QIAasymphony SP/AS instruments by pressing the appropriate button(s) in the **Transfer from USB stick** panel.

**Note:** You can select more than one file type at once.

**Important:** Make sure that **Synchronize files** is set to **No**.



- When the first file type has been selected, the **Transfer** button becomes active. Press the **Transfer** button to transfer all selected file types from the USB stick to the QIAasymphony SP/AS instruments.
- A message appears informing you that the files will be transferred from the USB stick to the QIAasymphony SP/AS instruments. Press **Yes** to confirm that the files should be transferred.
- During data transfer, an information message will be displayed.
- After successful data transfer, a message will appear confirming the data transfer.

11. Remove the USB stick.

**Note:** Do not remove the USB stick during data transfer otherwise loss of data may occur.

## 7.4 Synchronization of files

Files stored on the QIAsymphony SP/AS instruments can be synchronized with files on the USB stick.

- If the file already exists on the QIAsymphony SP/AS it will be overwritten.
- Files that exist on the QIAsymphony SP/AS instruments but do not exist on the USB stick are deleted from the QIAsymphony SP/AS instruments.
- After synchronization the content of files of the same type that are stored on the QIAsymphony SP/AS instruments and the USB stick are identical.

Users with "Supervisor" and "Operator" access rights are allowed to synchronize different file types, as outlined in the table below.

"Operator"

The "Operator" enables synchronization of the following file types between the QIAsymphony SP/AS instruments and the USB stick:

- Rack files
- Work lists

"Supervisor"

The "Supervisor" enables synchronization of the following file types between the QIAsymphony SP/AS instruments and the USB stick:

- Rack files
- Work lists
- Assay Control Sets
- Protocols
- Assay Parameter Sets
- Assay Definitions
- Process configuration profiles
- Labware SP
- Labware AS

- Instrument Report files

#### 7.4.1 Synchronizing files on QIAsymphony SP/AS with files on the USB stick

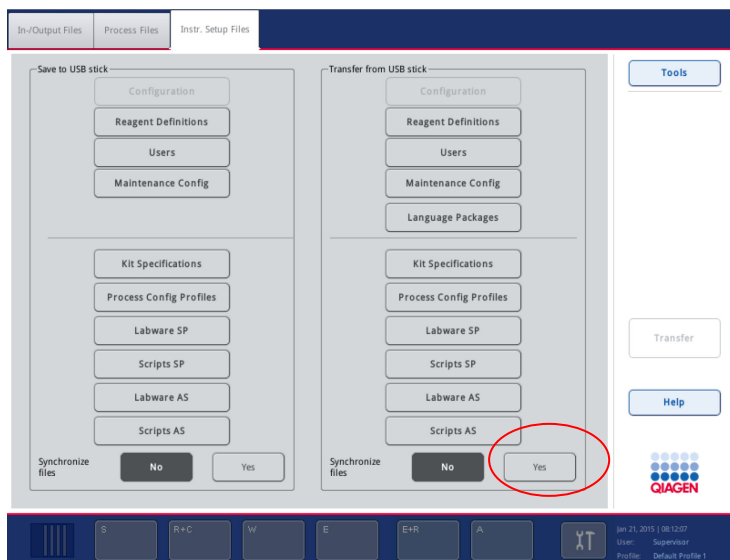
Files on the QIAsymphony SP/AS instruments can be synchronized with files on the USB stick.

To synchronize files on the QIAsymphony SP/AS instruments with files on the USB stick follow the steps below:

1. Log in to the QIAsymphony SP/AS instruments.
2. Prepare the USB stick with the files for synchronization. Store the files you want to upload to the QIAsymphony SP/AS instruments in their corresponding folders on the USB stick (e.g., a newly defined rack file in the folder **/data/Worklists/**).
3. Insert the USB stick into one of the USB ports at the front of the QIAsymphony SP.
4. Press **File Transfer** in the **Tools** screen to enter the **In-/Output Files** menu.
5. Select one of the file transfer tabs (**In-/Output Files**, **Process Files**, **Instr. Setup Files**). For example, to synchronize work lists, select the **In-/Output Files** tab.
6. Select the file type(s) on the QIAsymphony SP/AS instruments that should be synchronized with the files on the USB stick by pressing the appropriate button(s) in the **Transfer from USB stick** panel.

**Note:** You can select more than one file type at the same time. The number of file types that can be selected by the user is limited by the user role.

7. Set **Synchronize files** to **Yes** by pressing the **Yes** button.



8. Press the **Transfer** button in the command bar of the screen to synchronize the selected files type(s).
9. A message appears informing you that the files will be synchronized. Check that the information is correct. To continue with the synchronization, press **Yes**.
10. After successful synchronization, a message will appear confirming synchronization. Press **OK** to continue.
11. Remove the USB stick.  
**Note:** Do not remove the USB stick during data transfer otherwise loss of data may occur.
12. Log out of the QIAsymphony SP/AS instruments (for more information, see Section 3.2.7).

#### 7.4.2 Synchronizing files on the USB stick with files on QIAsymphony SP/AS

Files on the USB stick can be synchronized with files on the QIAsymphony SP/AS.

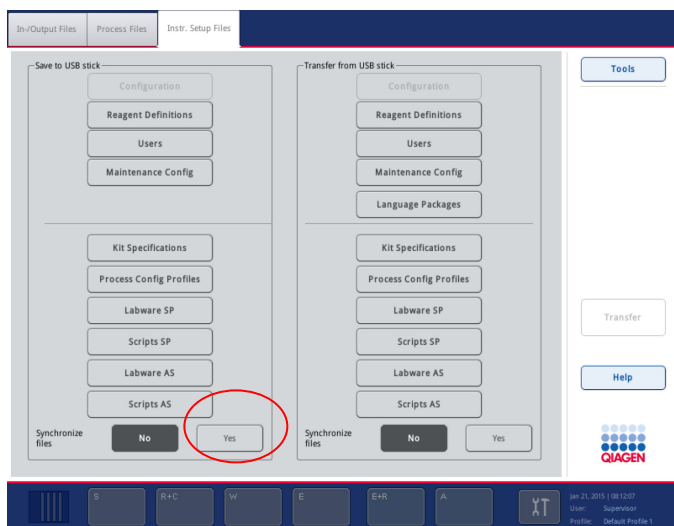
This means that files stored on the QIAsymphony SP/AS are transferred to the USB stick. If the file already exists on the USB stick it will be overwritten by the file from the QIAsymphony SP/AS instruments. Files that exist on the USB stick but do not exist on the QIAsymphony SP/AS instruments are deleted from the USB stick.

To synchronize files on a USB stick with files on the QIAAsymphony SP/AS follow the steps below.

1. Log in to the instrument with the "Supervisor" user ID.
2. Prepare the USB stick for synchronization. Insert the USB stick into one of the USB ports at the front of the QIAAsymphony SP.
3. Press **File Transfer** in the **Tools** screen to enter the **In-/Output Files** tab menu.
4. Select one of the file transfer tabs (**In-Output Files**, **Process Files**, **Instr. Setup Files**).
5. Select the file type(s) that should be synchronized by pressing the appropriate button(s) in the **Save to USB stick** panel.

**Note:** You can select more than one file type at once.

6. Set **Synchronize files** to **Yes** by pressing the **Yes** button.



7. Press the **Transfer** button in the command bar of the screen to synchronize the selected files.
8. A message appears informing you that the files will be synchronized. Check that the information is correct. To continue with the synchronization, press **Yes**.
9. After successful synchronization, a message will appear confirming synchronization.
10. Remove the USB stick.

**Note:** Do not remove the USB stick during data transfer otherwise loss of data may occur.

11. Log out of the QIAAsymphony SP/AS instruments (for more information, see Section 3.2.7).

## 7.5 Deleting files

Different tools can be used to delete files from the QIAasymphony SP/AS instruments. We recommend using the **File Transfer** tool of the QIAasymphony Management Console.

If the QIAasymphony SP/AS is not connected to the network, there is a method for deleting all input and output files, except log files (Section 7.5.1), and a method for deleting all other files (Section 7.5.2).

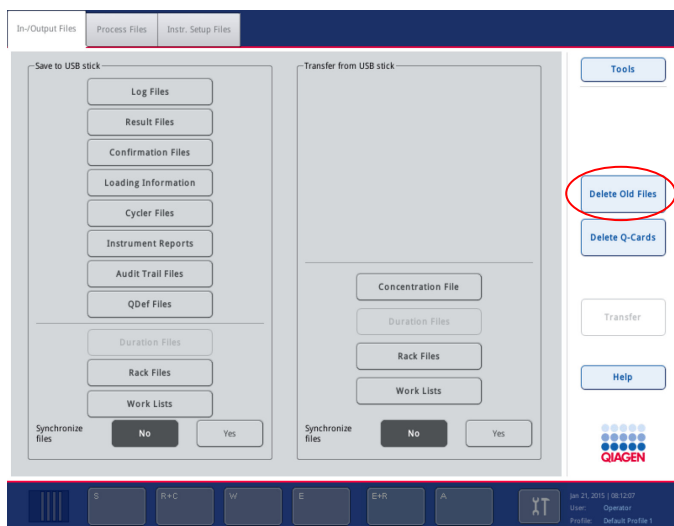
### 7.5.1 Deleting input and output files from the QIAasymphony SP/AS

The user will be notified when the QIAasymphony SP/AS instruments are short of storage space for output files (i.e., result, rack, work list, instrument report and loading information).

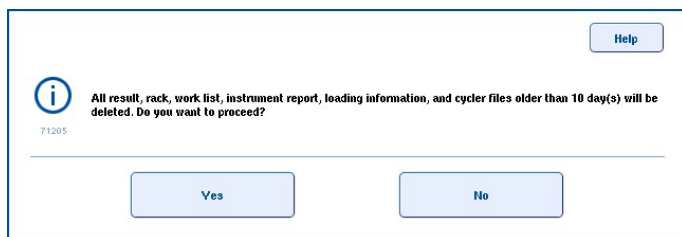
All input and output files, except log files, can be deleted from the QIAasymphony SP/AS instruments using the touchscreen. Follow the steps below to delete files older than 10 days. This time period is the default setting and can be adjusted upon request by QIAGEN Field Service Specialists.

To delete these files, follow the steps below.

1. Press **File Transfer** in the **Tools** screen.
2. Select the **In-/Output Files** tab.



3. Press **Delete Old Files** in the command bar of the screen. The following message appears.



4. Press **Yes** to delete the old files.

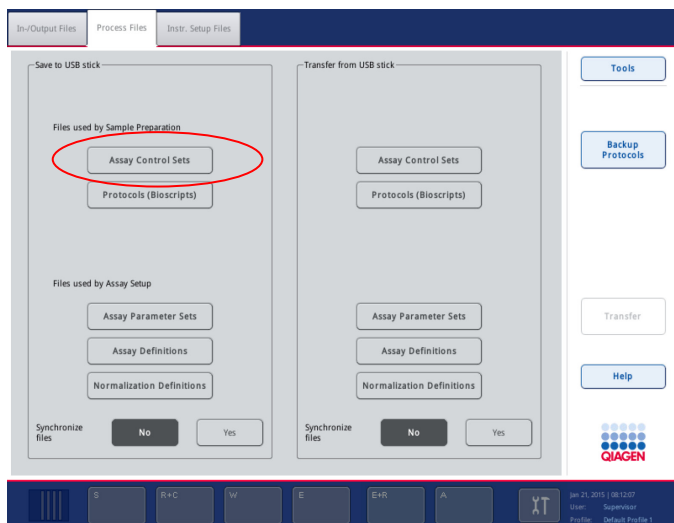
After the files have been successfully deleted, a message will appear confirming the deletion. Press **OK** to confirm the message.

### 7.5.2 Deleting other files

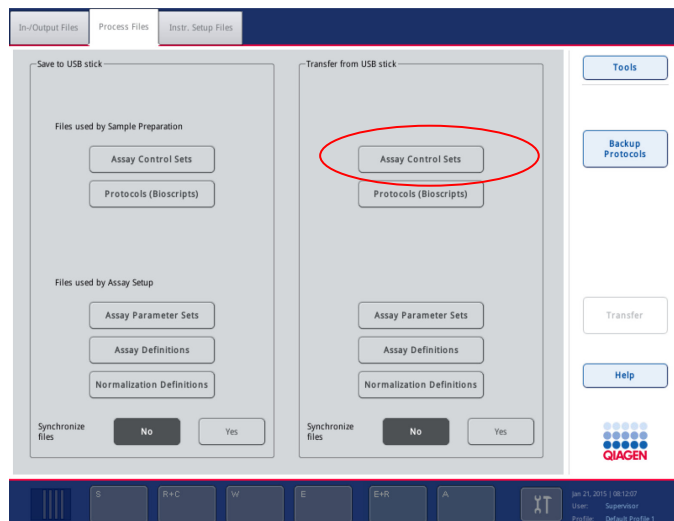
If your QIAasymphony SP/AS is not connected to the network, use the synchronize function if you need to delete file types other than input and output files from the QIAasymphony SP/AS. With the synchronize function you can delete the file types in the table in Section 7.4.

The following example guides you through the steps required to delete some of the Assay Control Sets from the QIAasymphony SP/AS.

1. Delete all Assay Control Sets saved on the USB stick in **data/AssayControlSets**.
2. Log in to the instruments with the "Supervisor" user ID.
3. Insert the USB stick into one of the USB ports at the front of the QIAasymphony SP.
4. Press **File Transfer** in the **Tools** screen.
5. Select the **Process Files** tab.



6. Select Assay Control Sets by pressing the **Assay Control Sets** button in the **Save to USB stick** panel.
- Important:** Make sure that **Synchronize files** is set to **No**.
7. Press the **Transfer** button in the command bar on the right side of the screen.
8. A message appears informing you how many files will be transferred from the QIAAsymphony SP/AS instruments to the USB stick. To continue with file transfer, press **Yes**.
9. After successful data transfer, a message will appear confirming data transfer.
10. Remove the USB stick.
11. Connect the USB stick to a PC.
12. Delete the Assay Control Sets that should be removed from the QIAAsymphony SP/AS instruments. Access the files on the USB stick using Windows® Explorer or the QIAAsymphony Management Console.
13. Insert the USB stick into one of the USB ports at the front of the QIAAsymphony SP again.
14. Press **File Transfer** in the **Tools** screen.
15. Select the **Process Files** tab.



16. Select Assay Control Sets as the file type by pressing the **Assay Control Sets** button in the **Transfer from USB stick** panel.
17. Set **Synchronize files** to **Yes** by pressing the **Yes** button.
18. Press the **Transfer** button in the command bar on the right side of the screen.
19. A message appears informing you how many files will be deleted from the QIAAsymphony SP/AS instruments. To continue, press **Yes**.



20. After the files have been successfully deleted, a message will appear.
21. Remove the USB stick.
22. Log out of the QIAsymphony SP/AS instruments (for more information, see Section 3.2.7).

## 7.6 QIAsymphony SP result file

Result files are generated for each elution rack. When the elution rack is removed from the "Eluate" drawer, the corresponding result file is generated and can be downloaded from the QIAsymphony SP/AS instruments.

The file name is created automatically with the following nomenclature:

YYYYMMDDHHMMSS\_ElutionRackID.HTM

YYYYMMDDHHMMSS\_ElutionRackID.XML

When downloading the result files, the \*.htm and \*.xml files are available as zipped (\*.zip) files on the USB stick.

When using the **File Transfer** tool, these files will be automatically unzipped.

### Result file content

#### General information

Elution rack ID	ID of the elution rack used.
Elution rack type	Type of the elution rack used.
Elution slot number	Number of the elution slot used.
Overall status check	"Passed" if all samples have been processed correctly. "Unclear", if at least one sample is unclear, but there are no invalid samples. "Failed" if samples have not been processed correctly.
File	Name of the *.xml result file.
Start time	The time at which processing of the first batch started.
End time	The time at which processing of the last batch finished.

Eluate removed	Time at which the elution rack was removed.
QIASymphony SP serial number	Serial number of the QIASymphony SP on which the run was executed.
Software Version	Current software version.
Process Configuration Profile	The process configuration profile that was used when the batch was processed. See Section 4.3 for details about process configuration profiles.

#### *Reagent rack information*

Reagent Rack Number	Number of the reagent rack used (i.e., 1, 2, or 3).
Reagent Rack Slot	Number of the reagent rack slot used.
	<b>Note:</b> In case that the buffer bottle is exchanged, the number is incremented. This means, in this case the number does not identify the slot.
Homogeneity check	"Passed" if the lot numbers/IDs of the reagent rack and enzyme rack are matching. "Failed" if they do not match.
Reagent Rack Description	Description of the reagent rack used.
Reagent Cartridge Lot Number	Lot number of the reagent cartridge used.
Enzyme Rack Lot Number	Lot number of the enzyme rack used.
Expiration Date	Expiration date of the reagent rack.

#### *Reagent information*

Position	The index of the reagent (i.e., 1, 2, or 3).
Buffer	Name of the buffer.
Lot Number	Lot number of the reagent.
Quantity	Volume of reagent used.
Expiration Date	Expiration date of the reagent.
Expired	"Yes" if the reagent has expired. "No" if the reagent has not expired.

The reagent information is listed for each reagent that is listed in the inventory before the start of the batch.

#### *Batch information*

Batch ID	Batch ID generated by the QIAAsymphony SP.
Assay Control Set	Name of the Assay Control Set.
Protocol name	Name of the protocol used.
User	Name of user who queued the batch.
Batch queuing time	Date and time at which the batch was queued by the user.
Start Time	Date and time at which the batch was started by the user.
End Time	Date and time at which processing of the batch finished.
Sample Rack Slot	The sample rack slot used. Number 1–4 for the tube carrier.
Carrier type	Type of carrier (i.e., "Tube" if a tube carrier was used).
Sample Rack ID	ID of the sample rack.

#### *Internal control information*

IC	Name of the internal control.
Bar code	Bar code of the internal control.
Assay Control Set	Name of the Assay Control Set.
Tube position (labware)	Position of the internal control (IC) tube in the IC carrier, and the tube type.
Position/Level detection	Internal control position and aspiration mode for liquid-level detection: "C"=capacitive, "P"=pressure, "N"=none.
Time	Creation time.
Message ID	ID of the message.

Message	Message text.
Command	Defines the protocol command affected by the message.

The internal control information is listed for each internal control that is used during processing.

#### *Assay control set information*

In addition, information for each Assay Control Set that was used for processing is listed.

Batch ID	ID of the batch that uses the ACS.
Assay Control Set	Name of the ACS; each ACS is mentioned only once per batch.
ACS authentic	Specifies if the assay control set is a genuine QIAGEN-ACS: <ul style="list-style-type: none"> <li>• "QIAGEN file" if it is a genuine ACS</li> <li>• "Custom file" otherwise</li> </ul>
IC	Name of the IC that was used by the ACS.
Bar code	ID of the IC (bar code from IC tube).

The following user actions are listed in the messages table:

- manual changes to sample bar codes
- pause
- continue
- stop

#### *"Sample" table information*

Sample ID	ID of the sample.
Labware	Input labware type. The carrier type is "Tube". In case of tube carriers, the labware of the tubes is shown.
Input position	Name of the input position.
Type	Indicates the sample type, i.e., sample or extraction control.

Liquid-level detection	Aspiration mode for liquid-level detection: "C"= capacitive, "P"= pressure, "N"= none.
Output position	Name of the output position.
Assay Control Set	Name of the Assay Control Set.
Reagent rack (beads + reagents)	Number of the reagent rack for beads and reagents.
Regent rack (enzymes)	Number of the reagent rack for enzymes.
IC tube position/Liquid-level detection	Internal control position and aspiration mode for liquid-level detection: <ul style="list-style-type: none"> <li>● "C"= capacitive</li> <li>● "P"= pressure</li> <li>● "N"= none</li> </ul>
Eluate volume	Indicates the elution volume. Depending on the protocol, this field may or may not appear. If the elution volume is in bold font, the elution volume was defined by the user.
Minimal eluate volume	Indicates the minimum elution volume in the elution rack at the time of transfer. Depending on the protocol, this field may not be shown. If this field is in bold font, the elution volume was defined by the user.
Initial elution volume	The initial volume of buffer. This field is displayed depending on the protocol.
Validity of result	"valid", "unclear", "invalid". If sample is "unclear" or "invalid", error codes are listed.

The sample information is listed for each sample that is processed.

*"Work list" table information (optional)*

Work list	Lists name of used work list.
-----------	-------------------------------

## Abbreviations

S	Sample
EC+	Positive extraction control
EC-	Negative extraction control
C	Capacitive
P	Pressure
N	None

## Temperature information

Batch	Batch ID.
Lysis temperature	Status information of the lysis temperature: "OK" or "not OK".
Cooling position temperature	Status information of the cooling position temperature: "OK", "not OK", "disabled" or "not required".

The temperature information is listed for each batch that is processed.

## Deletion of result files

The user will be notified when the QIAAsymphony SP is short of storage space for result files. The user can then choose to delete files older than 10 days from the instruments. For more information, see Section 7.5.1.

The validity of result files can be checked using a **Checksum Validator** tool. This tool is part of the QIAAsymphony Management Console. For detailed information, see Section 23.

## Sample status

Samples are classified in one of three ways.

- "valid" — the sample was processed correctly.

**Note:** Pipetting performance is not monitored.

- "unclear" — if the run was paused, the samples will be generally classified as "unclear". Furthermore, unclear classification is possible in some cases where insufficient sample volume is available or the cooling temperature is out of range.

**Note:** Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.

- "invalid" — a serious error occurred during sample processing (e.g., the run may have stopped and could not be continued).

If a sample is classified as "invalid", it will not be processed further. The sample will be removed from the sample prep cartridge and transferred to the liquid waste container.

**Note:** If the elution rack has not been removed from the "Eluate" drawer, sample classifications can be viewed in the **Sample View** screen of the **Sample Preparation** menu. After the elution rack has been removed, sample classifications are documented in the result file.

## 7.7 QIASymphony AS result file

A result file is generated for each assay run. It contains all information about the defined assay run and its parameters. For further details about the content of a result file, see the tables below.

A preliminary version of the result file is generated during the assay run. When the run is removed from the "Assays" drawer (see Section 13.3.4 for details about how to do this), the final version of the result file is created. The result file can then be downloaded from the QIASymphony SP/AS instruments.

The filename is generated automatically with the following nomenclature:

ResultFile\_YYYYMMDD\_HHMMSS\_RunID.HTM

ResultFile\_YYYYMMDD\_HHMMSS\_RunID.XML

When downloading the result files, the \*.htm files are available as zipped (\*.zip) files on the USB stick. When using the **File Transfer** tool, these files can be transferred individually and will be automatically unzipped.

Preliminary files are available as \*.htm files. The file name contains the suffix \_preliminary.

**Note:** A single result file is generated for each assay setup run for AS batches in integrated mode. Therefore, each result file can contain information about up to 2 sample racks and more than one Assay Parameter Set.

**Note:** When performing an integrated run, one result file is generated for each AS batch. The "Sample rack ID" in the QIASymphony AS result file is identical to the "Elution rack ID" in the corresponding QIASymphony SP result file and in its file name. The run time and

date in the AS result file and in the SP result file should be the same. If samples are classified as "invalid" or "unclear" in the QIAAsymphony AS result file, the corresponding QIAAsymphony SP result file will provide more information about the validity of the result.

**Note:** Preliminary result files contain the comment "This is a preliminary result file. It will be overwritten with the final result file, when the last output plate is removed. Please note that final status information may deviate from preliminary status. For final sample assessment please use final result file". The comment is highlighted in yellow. Preliminary result files are for information and troubleshooting only and cannot be transferred to Rotor-Gene AssayManager.

## Result file content

### General information

User	Name of user who defined the run.
Role	Role of the user who assigned the run (i.e., "Operator" or "Supervisor").
Run ID	Run ID generated by the QIAAsymphony AS.
Overall status check	General information about the run status. If "Passed" is displayed, the run (including SP run for Integrated run) was successful. "Unclear" is displayed if at least one sample is unclear, but there are no invalid samples. "Failed" is displayed if errors occurred during the run. See Section 14 for more details about errors.
Start time (yyyy-mm-dd hh:mm:ss)	Time at which the AS run was started.
End time (yyyy-mm-dd hh:mm:ss)	Time at which the AS run (for Integrated run) ended. This is defined as the time at which the last sample was transferred to the assay rack.
Duration (hh:mm:ss)	Duration of the AS run (for Integrated run).
QIAAsymphony AS SN	Serial number of the QIAAsymphony AS.
Software Version	Current software version.
Process Configuration Profile	Configuration profile that was used when defining the run.



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Loading file	File name of the *.xml loading information file.
Result file	File name of the *.xml result file.

### *Reagent information*

#### Kit bar codes

Assay	Name of the selected Assay Parameter Set.
Bar code	Kit bar code for the used assay. QIAGEN bar code must be entered, providing information about lot number and expiration date.
Product No.	The product number of the QIAGEN kit is displayed.
Lot. No.	Lot number of the used kit.
Expiration date	Expiration date of the used kit (mm/dd/yyyy).
Status	"OK" indicates that the kit had not passed the expiry date.
Accepted	"n/a" indicates that expired kits were not used.

### *Assay information*

#### Sample rack information

Sample rack ID	ID of the sample rack used.
Slot	Position of the sample rack in the "Eluate and Reagents" drawer. This can be slot 1 or 2.  <b>Note:</b> In an Integrated run, this can only be slot 2.
Rack type	Name of the selected rack type.
Adapter type	Name of the required adapter for the selected rack type. For a list of applicable adapters please see the Instructions for Use (Handbook) for the assay you are using.

Rack file status	Name of the rack file and the status of the system-generated rack file for the sample rack is displayed here. "Signature valid" indicates that the rack file was created by the QIAAsymphony SP/AS instruments, "Signature invalid" indicates that the rack file was manually modified, or "Signature unsigned" indicates that the rack file was not created by the QIAAsymphony SP/AS instruments, or that the signature was removed. If not used a rack file: "created".
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#### Assay rack information

Assay rack ID	ID of the assay rack used.
Slot	Position of the assay rack in the "Assays" drawer. This can be slot 4, 5, or 6.
Rack type	Name of the selected rack type.
Adapter type	Name of the required adapter for the selected rack type. For a list of applicable adapters please see the Instructions for Use (Handbook) for the assay you are using.

#### Detailed information for Assay Rack X on Slot Y

Dest. Pos.	Destination position of a specific template.
Sample ID	ID of the sample.
Type	<p>Defines the type of sample. For further details, see "List of abbreviations" in this section.</p> <p>If the type was changed automatically (e.g., for 2-step PCR), also indicates the original sample type.</p>
IC SP	Name of the internal control (IC) that was used during sample preparation on the QIAAsymphony SP. This is based on information defined in the rack file, for further details see Section 7.11.

Source slot	Source slot of specific template (i.e., slot 1, 2, or 3).
Source pos.	Source position of a specific template.
Assay	Name of the selected Assay Parameter Set (APS) for a specific template.
Work list	Index of the work list used. If a work list was not used, "n/a" is displayed in this field. A table below this one assigns an index to each used work list.
MM transfer	Shows whether the master mix (MM) was transferred to a specific position. "Done" indicates that the master mix transfer was successful. "-" indicates that a problem occurred during master mix transfer.
Template transfer	Shows whether the template was transferred to a specific position. "Done" indicates that template transfer was successful. "-" indicates that a problem occurred during template transfer.
Validity AS result	Shows the validity of an assay run for each assay position (i.e., "valid", "unclear", or "invalid"). See "Sample status", page 209 for more information.  "Removed" if assay point was removed without replanning the batch (only possible in integrated run).

#### Abbreviations

AC	Assay control
EC+	Positive extraction control
EC-	Negative extraction control
IC	Internal control
n/a	Not applicable
NTC	No template control
NTC+IC	No template control containing master mix with internal control

NTC-IC	No template control containing master mix without internal control
S	Sample
Std	Assay standard

#### *Slot temperature profiles*

Slot temperature profiles are listed only, if a temperature violation was detected.

Time	Time at which the temperature was documented.
Slot x	Temperature of the specific slot. X defines the slot number.

#### *Time span information*

Time span information is listed for the different steps of assay setup for each assay that is set up during a run.

Start	Start time of the step in the assay run.
End	End time of the step in the assay run.
Duration (hh:mm:ss)	Time taken for a particular step within the assay run.
Max. allowed duration (hh:mm:ss)	Maximum duration of an assay run. This is defined in the assay definition. If "n/a" is displayed this indicates that there is no maximum duration defined in the assay definition.
Creation of master mix	Time taken from the transfer of the first reagent to the transfer of the last reagent.
Reagents on instrument slot X	Time taken from pressing of <b>Load</b> button until transfer of last reagent to master mix.
Run	Total duration of the assay setup run.
Sample loaded	Time taken from pressing of <b>Load</b> button until transfer of first sample.

**Note:** In case of integrated run, this time span is not shown, since the rack is loaded automatically by the transfer module.

Transfer of master mix	Time from the transfer of the master mix to the first assay position to the last assay position.
Transfer of samples	Time from the transfer of the first sample to the transfer of the last sample.
Waiting time until unloading, rack X	Measured from the last transfer to assay rack X to the removal of the run.

#### *Assay parameter information*

The "Assay parameters" section provides information about the following assay parameters:

APS format version	Version of the *.xml structure of an Assay Parameter Set.
APS version	Assay Parameter Set version.
Last change	Date that the Assay Parameter Set was last modified (yyyy/mm/dd).
Author	Name or role of the user that created the Assay Parameter Set.
APS authentic	"Custom file" indicates that the Assay Parameter Set was modified by a user and is not intended for use with FDA cleared/approved nucleic acid tests. "QIAGEN file" indicates that this is an original file from QIAGEN and has not been modified by a user.
Number of samples, excluding controls	Number of samples, not including assay controls.
Assay definition	Name of the Assay Definition.
AD version	Version of the Assay Definition.
AD authentic	"Custom file" indicates that the Assay Definition was modified by a user. "QIAGEN file" indicates that this is an original file from QIAGEN and has not been modified by a user.
Cycler group	Name of the cycler group to which the assay definition refers.

Template volume (μl)	Template volume used for each assay position.
Master mix volume (μl)	Volume of master mix used for each assay position.
Pattern based positioning	<p>"Yes" is only shown if Assay Parameter Set defines a user-defined output pattern.</p> <p><b>Note:</b> Not relevant for FDA cleared or approved nucleic acid tests.</p>
Assay parameters	
Replicates, samples	Number of sample replicates.
Replicates, EC+	Number of positive extraction control replicates.
Replicates, EC–	Number of negative extraction control replicates.
Assay-specific IC in samples	Indicates whether an assay specific internal control is present in samples. "Yes" indicates that there is an assay specific internal control in samples. "No" indicates that there is no assay specific internal control in samples.
Number, assay positive controls	Number of assay positive controls.
Replicates, assay positive controls	Number of replicates of assay positive controls.
Replicates, assay no template controls (with MM+IC)	Number of replicates of no template controls with master mix and internal control.
Replicates, assay no template controls (with MM–IC)	Number of replicates of no template controls with master mix and without internal control.
Number, assay standard	Number of assay standards.
Replicates, assay standard	Number of replicates of assay standards.
Ready-to-use master mix	"No" indicates that a ready-to-use master mix was not used.

#### *Detailed run information*

This section lists any errors that may have occurred during the assay run. See "Instrument Troubleshooting", Section 14, for more details about errors.

### Sample status

Samples that are processed on the QIASymphony AS are classified as "valid", "unclear", or "invalid", and are color coded according to their state in the QIASymphony AS result file.

"valid" (green)      The sample was processed correctly.



[2]: S

"unclear" (yellow)      If the run was paused, the samples will be generally classified as "unclear". Furthermore, unclear classification is possible in some cases where insufficient sample volume is available or the cooling temperature is out of range.



unclear, 31115

"invalid" (red)      A serious error occurred during sample processing (e.g., the run stopped and could not be continued). An "invalid" sample cannot be processed by the QIASymphony AS and cannot be assigned to an Assay Parameter Set.



[3]: S

"Removed"      If SP batch was removed from integrated run, related assay points are marked as removed.

**Note:** If the assay rack has not been removed from the "Assays" drawer, sample states can be viewed in the **Sample View** screen of the **Assay Setup** menu. After the assay rack has been removed, sample states are documented in the result file.

## 7.8 Loading information file

After queuing a run in the "integrated setup" screen the loading information file will be created and can be printed. The loading information file contains detailed information about required reagents, sample rack(s), assay rack(s), and disposable filter-tips for setting up an assay run on the QIASymphony AS.

The filename is generated automatically with the following nomenclature:

LoadingInformation\_YYYYMMDD\_HHMMSS\_Run ID.htm

LoadingInformation\_YYYYMMDD\_HHMMSS\_Run ID.xml

When downloading a loading information file, the \*.htm and \*.xml file are available as zipped (\*.zip) files on the USB stick. When using the **File Transfer** tool, these files will be automatically unzipped.

### **Content of loading information file**

#### *General information*

User	Name of user who defined the run.
Role	Role of the user who assigned the run (i.e., "Operator" or "Supervisor").
Date (yyyy mm-dd)	Date of run.
Run ID	Run ID generated by the QIAsymphony AS.
QIAsymphony AS SN	Serial number of the QIAsymphony AS.
Loading file	File name of the *.xml loading information file.

#### *Reagent information*

Adapter	Name of the required reagent adapter. For a list of applicable adapters please see the Instructions for Use (Handbook) for the assay you are using.
Slot	Position of the reagent adapter on the "Eluate and Reagents" drawer. This could be slot 1 or slot 3.
Assay	Name of the Assay Parameter Set.
Assay definition	Name of the Assay Definition.
Reagent	Reagent names as defined in the Assay Definition.
Conc.	Concentration of specific reagents such as assay standards.
Volume (µl), required	Volume of reagent(s) that must be available on the worktable before starting an assay run.
Tube type	Required consumables for holding reagent(s) on the worktable.



Pos.	Position of reagent tube(s) on the reagent adapter.
<i>Sample rack information</i>	
Sample rack ID	ID of the sample rack used.
Slot	Position of the sample rack in the "Eluate and Reagents" drawer. This will be slot 1.
Rack type	Name of the selected rack type.
Category	Name of the category to which the rack type belongs.
Adapter type	Name of the required adapter for the selected rack type. For a list of applicable adapters please see the Instructions for Use (Handbook) for the assay you are using.
Rack file status	If no rack file was used, the field contains the value "created". When a rack file was used, the field displays the rack file name and the status of the input rack file's signature ("signed" or "manually created or imported"). Additionally, if the user has manually changed the volume of a rack file position and the state is not "signed", the status text is enhanced with the string "modified by user on the touchscreen".
<i>Assay rack information</i>	
Assay rack ID	ID of the assay rack used.
Slot	Position of the assay rack in the "Assays" drawer. This can be slot 4, 5, or 6.
Rack type	Name of the selected rack type.
Adapter type	Name of the required adapter for the selected rack type. For a list of applicable adapters please see the Instructions for Use (Handbook) for the assay you are using.
Plasticware	Number of strip tubes that must be loaded into

the defined positions.

*Tip information*

Tip type	Tip types used for the run. These can be 50, 200, and/or 1500 µl.
Required tips	Number of tips of a specific type that are required for a run.

*Notes*

This section lists things that must be done or checked before starting a run.

- Empty tip waste
- Provide tip disposal bag (waste bag)
- Install tip chute

*QIASymphony AS instrument layout*



**Important:** For FDA cleared or approved nucleic acid tests, use tip rack positions 1, 2, 3, 7, 8, and 9 in the QIASymphony AS drawers.

## Deletion of loading information files

The user will be notified when the QIASymphony SP/AS instruments are short of storage space for loading information files. For more information about deleting files, see Section 7.5.

## 7.9 Audit trail files

QIASymphony SP/AS creates an audit trail file where all relevant events and user actions are permanently stored. A unique audit trail file is created for each day. The audit trail file stores all events that create, modify or delete electronic records.

In detail, the following events are stored:

- User login (successful/unsuccessful) and logout
- Every user action that creates, modifies, and deletes data, user data, system configuration, reports, archives and result files
- Upload/download of files (e.g., Assay Definitions, Assay Parameter Sets, labware files, etc.) to QIASymphony
- Execution of maintenance scripts
- Acknowledgement of tasks in the maintenance scheduler
- Start and end of runs

Audit trail files are automatically generated and saved on QIASymphony SP/AS instruments in \*.xml format in the folder directory /log/AuditTrail.

## Naming convention

File names are created automatically with the following nomenclature:

AuditTrail\_Instrumentname\_YYYYMMDD\_HHMMSS.html

AuditTrail\_Instrumentname\_YYYYMMDD\_HHMMSS.xml

When downloading audit trail files, the \*.html and \*.xml files are available as zipped (\*.zip) files on the USB stick. When using the File Transfer tool, these files will be automatically unzipped.

## Content of audit trail file

Timestamp	Date and time of event in format yyyy-MM-dd hh:mm:ss.
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Action	Description of the relevant event.
UserID	Name of the user during the event.
Device type	QIAsymphony SP or QIAsymphony AS.

Event name	Category of the event (e.g., login event, QMC file transfer event, etc.).
------------	---

To ensure the integrity/validity of audit trail files, these files are signed automatically with a digital signature. The validity of audit trail file signatures can be checked using the Checksum Validator tool, which is part of the QIAAsymphony Management Console (QMC). For detailed information, see Section 23 and the *QIAAsymphony Management Console User Manual*.

### Instrument Report

Audit trail files are part of the instrument report. When the user generates an instrument report for support purposes, the audit trail files are included in the report.

### Deleting audit trail files

A user with the “Supervisor” role can delete audit trail files from the device using the QMC File Transfer tool (see Section 22).

## 7.10 Work list files

Work list files are designed to reduce manual editing during run definition. They enable automatic assignment of samples to Assay Parameter Sets. Work list files can be generated by a Laboratory Information Management System (LIMS) or manually by the user. The “Work list tool” is available for download from [www.qiagen.com/qsrqmdxusivd](http://www.qiagen.com/qsrqmdxusivd). The versions supported by Microsoft® Windows® and Office are listed on this web site. This Microsoft Excel® tool enables work lists to be created quickly and easily. Work lists can be saved in \*.xml format, which is compatible with the QIAAsymphony SP/AS instruments.

If a sample ID matches a sample ID that is defined in a work list file, the assigned Assay Parameter Set will be preselected in the software. If a sample ID is associated with more than one work list, and these work list files are associated with incompatible Assay Parameter Sets, the user will need to resolve this on the touchscreen.

Work list files must be created as tab delimited text files (\*.txt or \*.csv) in a text editor (e.g., Notepad or Microsoft Excel), or using the **Work list tool** for Microsoft Excel that is available for download from the **Resources** tab at [www.qiagen.com/qsrqmdxusivd](http://www.qiagen.com/qsrqmdxusivd).

Before the work lists can be transferred to the QIAsymphony SP/AS instruments they must be converted to \*.xml format (see “CSV Conversion Tool”, Section 24, for details about how to do this).

Work lists that are in \*.xml format can be transferred to the QIAsymphony SP/AS instruments using a USB stick or the **File Transfer** tool and **Auto Transfer** tool of the QIAsymphony Management Console (see Section 22 and Section 25 for more details). Work list files are saved as \*.xml files on the QIAsymphony SP/AS instruments in the directory **/data/Worklists**.

**Note:** Using Default Profile 1, work list files expire after 1 day. Expired work lists cannot be used and will be automatically deleted by the system.

### Work list configuration parameters

A number of work list parameters determine how the QIAsymphony SP/AS instruments handle work lists. These parameters are displayed in the **General Process** and **Process SP 3** tabs of the **Configuration** menu.

Work list parameters in the **General Process** tab:

- Number of days for which a work list is valid?
- Allow information for single samples in work lists to be overwritten?

Work list parameters in the Process SP 3 tab:

- Allow processing of samples without a work list entry?
- Allow combination of multiple work lists for one batch?
- Allow partial use of work lists?
- Warn, if sample sequence differs from work list entry sequence?
- Check sample tube type required by work list?
- Check elution rack ID required by work list?

### Creating work list files

We recommend creating work list files using the **Work list tool** that is available for download from the **Resources** tab at [www.qiagen.com/qsrqgmdxusivd](http://www.qiagen.com/qsrqgmdxusivd). This tool enables users to quickly and easily create work list files that can be saved in \*.csv or \*.xml format.

Work list files can also be created in text editors (e.g., Notepad or Microsoft Excel). A tab delimited text file, created in a text editor, must have the layout in the following table to

enable it to be converted into \*.xml format. Each row in the table represents one line in the text file. In addition, see the examples (page 218) for the layout of a work list file created in Notepad, and the layout of a work list file created in Microsoft Excel.

The tab delimited text file must have the same field delimiter that is configured in the **CSV Conversion** tool of the QIASymphony Management Console. The recommended delimiter is ";". This delimiter is also the default delimiter in Microsoft Excel.

**Note:** Text is case sensitive. Blank lines will be ignored by the conversion. Blanks within a line should only be used if they belong to a name or attribute.

Row 1 —FileType;Worklist;1	Specifies the file type. This is required for the <b>CSV Conversion</b> tool.
Row 2 — Table;Worklist	Specifies the next table. This is required for the <b>CSV Conversion</b> tool.
Row 3 —SampleID;AssayControlSetName; AssayParameterSetName;RequiredSPSample TubeType;RequiredSPElutionRackID	<p>Specifies the table headers.</p> <p>Defines what information must be entered into which column.</p> <p><b>Note:</b> The column "RequiredSPSample TubeType" is not applicable.</p> <p><b>Note:</b> The column "RequiredSPElutionRackID" is not applicable.</p>
Row 4 — Sample IDs and the associated Assay Control Sets and Assay Parameter Sets are listed.	Specifies which Assay Control Set (may remain empty for integrated run) and Assay Parameter Sets should be used to process a sample. Each row defines one sample.

**Note:** For consumables and rack types, the names defined in the software must be used. Please refer to the assay Instructions for Use (Handbook) for a list of applicable consumables and rack type names.

Work list file created with Notepad

```
File Edit Format View Help
FileType;worklist;1

Table;worklist;
SampleID;AssayControlSetName;AssayParameterSetName
1;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
2;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
3;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
4;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
5;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
6;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
7;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
8;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
9;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
10;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
EC+ 1;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
EC- 1;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
11;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
12;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
13;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
14;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
15;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
16;Cellfree200_V3 default IC;OneStep_RT-PCR 96 (45+5) V1
1;;Quantifast Probe RT-PCR 96 (15+10) V1
2;;Quantifast Probe RT-PCR 96 (15+10) V1
3;;Quantifast Probe RT-PCR 96 (15+10) V1
4;;Quantifast Probe RT-PCR 96 (15+10) V1
```

Work list file created with Microsoft Excel

	A	B	C	
1	FileType	Worklist		1
2				
3				
4				
5				
6	Table	Worklist		
7	SampleID	AssayControlSetName	AssayParameterSetName	
8	1	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
9	2	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
10	3	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
11	4	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
12	5	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
13	6	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
14	7	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
15	8	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
16	9	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
17	10	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
18	EC+ 1	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
19	EC- 1	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
20	11	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
21	12	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
22	13	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
23	14	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
24	15	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
25	16	Cellfree200_V3 default IC	OneStep_RT-PCR 96 (45+5) V1	
26	1		Quantifast Probe RT-PCR 96 (15+10) V1	
27	2		Quantifast Probe RT-PCR 96 (15+10) V1	

**Note:** Be sure to include the specifier "1", highlighted in the red circle. The **CSV Conversion** tool requires this numeric specifier for recognition of the work list file.

**Note:** For integrated runs the "AssayControlSetName" column can remain empty.



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## 7.11 Rack file

Rack files contain information about elution racks or assay racks (i.e., rack type, rack ID, sample ID, sample type, sample volumes, assay volumes). Rack files can be generated automatically by the QIAAsymphony SP/AS instruments (e.g., for elution racks processed on the QIAAsymphony SP). The unique rack ID of a sample or assay rack enables the QIAAsymphony SP/AS instruments to identify the corresponding rack file. When the rack ID is entered, the QIAAsymphony SP/AS instruments scan the rack file directory and select the correct rack file. Only one rack file can be assigned to each slot per assay run.

Existing rack files are updated during an assay run. For example, if the original sample volume was 200 µl and 50 µl was used during an assay run, the rack file is updated and will inform the user that only 150 µl sample volume remains.

Rack files that are in \*.xml format can be transferred to the QIAAsymphony SP/AS instruments using a USB stick or the **File Transfer** tool of the QIAAsymphony Management Console (see Section 22).

**Note:** Rack files can be used several times. They have no expiry date.

**Note:** Rack files can be downloaded from the QIAAsymphony SP/AS as \*.xml files and can be converted into \*.csv format using the **CSV Conversion** tool of the QIAAsymphony Management Console (see Section 24).

**Note:** Rack files are not deleted automatically, except for those which do not contain any rack position information. For information about how to delete rack files see Section 7.5.

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## 7.12 Instrument report file

Instrument report files are password-protected \*.zip files that are only intended for QIAGEN Technical Services, to help with troubleshooting.

You may be requested by QIAGEN Technical Services to create an instrument report file in the **Instrument Report** menu. In this case, refer to Section 14.3.2 in "Troubleshooting" for more details. For more details about information that can be found in the **Instrument Report** menu, see Section 5.14.

## 7.13 Log files

The log files are data files that contain general information about the QIAsymphony SP/AS, user interactions, and details about the protocol being run.

The log files are written in plain text documents and can be displayed using a text editor (e.g., Notepad).

To download a log file to the USB stick, see page 183. Log files can also be downloaded using the QIAsymphony Management Console. See Section 22 and Section 30 for more information.

Log files contain information that may be required for Troubleshooting and for QIAGEN Technical Services.

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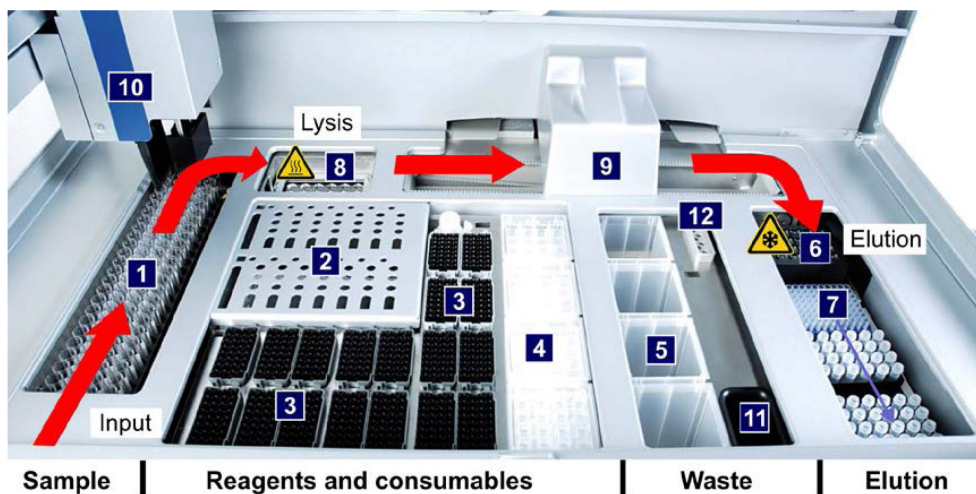
## 8 QIAAsymphony SP Features

The section describes how to operate the QIAAsymphony SP instrument, including how to load and unload the worktable.

The QIAAsymphony SP performs fully automated purification of nucleic acids using magnetic-particle technology. Samples can be processed in batches of up to 24 samples. The instrument controls integrated components including a lysis station, 4-channel pipetting system, robotic gripper, and an array of magnetic rods that are protected by rod covers. These rods can pick up or release magnetic particles in the wells of a sample prep cartridge, depending on whether the magnetic rods are inserted in the rod covers or not.

The QIAAsymphony SP is preinstalled with various protocols and corresponding Assay Control Sets for purification of RNA, genomic DNA, and viral and bacterial nucleic acids. For more information refer to the Instructions for Use (Handbook) for the assay you are using.

The user loads reagents (in prefilled, sealed reagent cartridges) and consumables into the appropriate drawer, loads the samples, and selects an (integrated) protocol using the touchscreen. The user then starts the (integrated) protocol, which refers to a protocol containing all necessary commands for sample lysis and purification. A fully automated inventory scan (either after closing the individual drawers or before the run starts) helps to ensure that the QIAAsymphony SP is correctly set up for the protocol.



- |   |                           |    |                        |
|---|---------------------------|----|------------------------|
| 1 | Sample input              | 7  | "Elution slots 2-4"    |
| 2 | Reagent cartridges        | 8  | Lysis station (heated) |
| 3 | Filter-tips               | 9  | Magnetic head          |
| 4 | Consumables               | 10 | Robotic arm            |
| 5 | Waste compartment         | 11 | Tip waste chute        |
| 6 | "Elution slot 1" (cooled) | 12 | Tip park station       |

**Note:** Elution slots 2-4 are not intended for use with FDA cleared or approved nucleic acid tests.

### 8.1.1 Basic principle

Sample preparation using the QIASymphony SP usually consists of 4 main steps: lyse, bind, wash, and elute.

- Samples are lysed in the lysis station, which can be heated, if required by the protocol.
- Nucleic acids bind to the surface of the magnetic particles and are washed to remove contaminants.
- Purified nucleic acid is eluted.

The QIAAsymphony SP processes a sample containing magnetic particles as follows:

- A magnetic rod protected by a rod cover enters a well containing the sample and attracts the magnetic particles.
- Sample prep cartridges are positioned below the magnetic rod with its cover.
- The QIAAsymphony SP uses a magnetic head containing an array of 24 magnetic rods, and can therefore process 24 samples simultaneously. Steps 1 and 2 are repeated several times during sample processing.

## 8.2 Instrument features

### 8.2.1 Magnetic head

The magnetic head is comprised of an array of 24 magnetic rods for processing magnetic particles, a conveyor, and magnetic-head guards.



**Magnetic head of the QIAAsymphony SP.**

The magnetic head comprises a rod-cover drive for mixing samples and a magnetic-rod drive for separation and resuspension of magnetic particles.

The conveyor moves the sample prep cartridges from the start position to the processing position and, finally, to the output position.

The magnetic-head guards move underneath the magnetic head and help to prevent contamination of the worktable or samples by any liquid that may drip from the rod covers.

**Important:** To prevent liquid from entering the QIAasympphony SP, only operate the instrument with the magnetic-head guard installed.

### 8.2.2 Lysis station

The lysis station, a heated orbital shaker, enables automated lysis of up to 24 samples in 1 batch. After sample lysis, the lysis station moves upward so that samples can be transferred for further processing.



**Lysis station.**

### 8.2.3 Robotic arm

The robotic arm provides accurate and precise positioning of the robotic gripper and pipettor head. The robotic arm also includes an optical sensor, a 2D bar code camera, and a UV lamp.

#### **Robotic gripper**

The robotic gripper transfers consumables (8-Rod Covers and sample prep cartridges) to the required position on the worktable during sample preparation.

### **Pipettor head**

The pipettor head is mounted on the robotic arm and moves in the X, Y, and Z directions in order to reach different locations on the worktable.

The pipettor head contains 4 pipetting channels with high-precision syringe pumps that are connected to tip adapters. The tip adapters can be attached to disposable filter-tips. The syringe pumps can operate simultaneously to allow aspiration and dispensing of small volumes of liquid via the attached disposable filter-tips.

Each pipetting channel can perform two types of liquid-level detection: capacitive-based liquid-level detection (cLLD) and pressure-based liquid-level detection (pLLD). To detect the liquid level, changes in capacitance or pressure between the disposable filter-tip and the liquid are measured (application-dependent and liquid-dependent).

### **Tip guards**

Each pipettor head is equipped with 4 tip guards. During a run, the tip guards are positioned below the disposable tips to catch any drops of liquid that may fall. This helps to minimize the risk of cross-contamination.



**Tip guards help to prevent cross-contamination.**

### **Optical sensor**

During an inventory scan, the optical sensor checks that the consumables are correctly loaded in the drawers and that there are sufficient consumables loaded for the run.

### **UV lamp**

A UV lamp is mounted on the robotic arm and is used to decontaminate the worktable of the respective instrument.

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See Section 15.7 for information about operating the UV lamp.

## 8.3 Bar code reader

### 8.3.1 Sample input bar code reader

The QIAsymphony SP has an integrated bar code reader that can read bar codes on tube carriers and sample tubes. A default tube type must be defined for each type of insert used. The tube type is automatically assigned when the insert bar code is read.

Primary tubes can be labeled with bar codes. Refer to the Instructions for Use (Handbook) for the assay you are using for allowed tube formats.

The integrated bar code reader of the "Sample" drawer scans:

- The position bar codes of the tube carriers.
- The bar code labels on sample tubes.

Each slot in a tube carrier has a bar code at the back of the slot. If the position is empty, the bar code at the back of the slot can be read by the bar code reader. This enables the QIAsymphony SP to detect which positions in the tube carrier contain a tube and which are empty.

If you are using sample tubes that are not labeled with bar codes, tubes containing small volumes of liquid or clear liquids may not be detected. In this case, use a blank bar code label to enable detection of the sample tube.

The scanned sample ID lists can be manually corrected and assigned into batches based on existing sample information or following user input. For more information, refer to Section 13.3.1.

Four tube carriers are available for use with sample tubes, positive full process controls, and negative full process controls. A fifth tube carrier accommodates tubes containing internal controls that will be added to the samples during the process.

### 8.3.2 Reagents and consumables 2D bar code reader

As part of the inventory scan of the "Reagents and Consumables" drawer, the 2D bar code camera on the QIAsymphony SP identifies the different reagents in the reagent



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cartridge and also checks that the correct reagent cartridge has been loaded. The 2D bar code reader is attached to the robotic arm.

### 8.3.3 Bar code types

The handheld scanner and the **Sample Input** bar code reader can read bar codes of the following types:

- Code 39
- Code 128 and subtypes
- Codabar

**Important:** Do not use the bar code Interleaved 2 of 5. This bar code type has a high information density and no checksum. It can therefore generate errors.

To ensure error-free bar code reading, slide tube carriers into the "Sample" drawer so that loading takes 3 seconds or longer (0.2 meters/second).

For information about attaching 1D bar code labels to tubes, refer to Appendix C.

### 8.3.4 Handheld scanner

The handheld scanner may be connected via USB connection to one of the USB ports of the QIAsymphony SP/AS instruments.

When using the QIAsymphony Cabinet SP/AS (see Appendix F), the handheld scanner is delivered with a magnetic holder. The magnetic holder can only be fixed to the metallic parts of the cabinet.



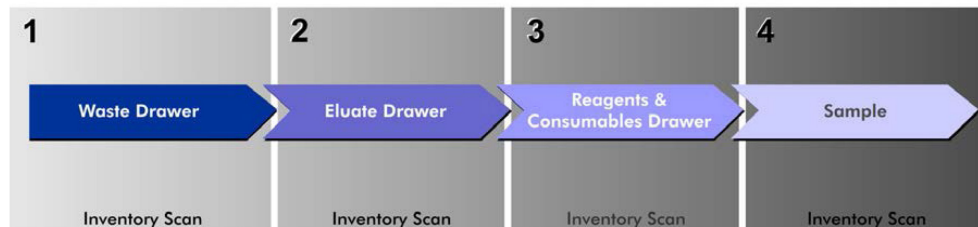
**Handheld scanner.**

**Note:** To enable easy use of the bar code scanner, we recommend positioning the magnetic holder on the middle metallic panel.

**Note:** For safe operation, hang the handheld scanner in its holder after use.

## 9 Loading QIASymphony SP Drawers

This section describes how to load and unload the worktable and how to perform inventory scans to operate the QIASymphony SP instrument.



**Workflow of loading QIASymphony drawers.**

**We recommend loading the drawers in the order:**

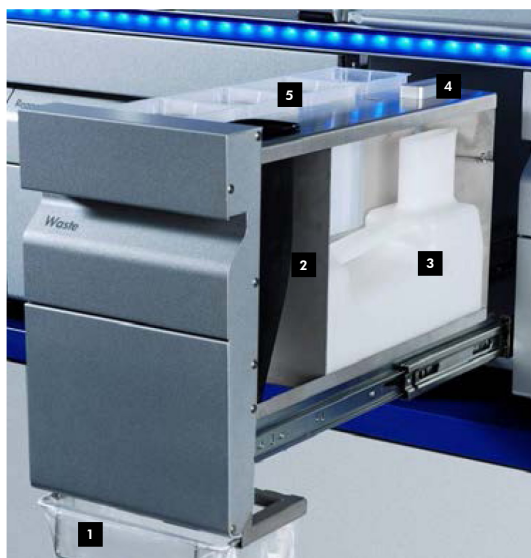
1. **“Waste” drawer**
2. **“Eluate” drawer**
3. **“Reagents and Consumables” drawer**
4. **“Sample” drawer**

### 9.1 Loading the “Waste” drawer

Used 8-Rod Covers and sample prep cartridges are discarded by the robotic gripper into the “Waste” drawer and are collected in 4 unit boxes in the drawer.

A container in the “Waste” drawer collects liquid waste from the sample preparation procedure.

Used disposable filter-tips are discarded into a tip disposal bag or waste bin. A tip park station in the waste drawer allows used tips to be temporarily stored on the worktable for reuse in a later protocol step.



- |                          |                    |
|--------------------------|--------------------|
| 1 Tip disposal bag       | 4 Tip park station |
| 2 Tip chute              | 5 Empty unit boxes |
| 3 Liquid waste container |                    |

We recommend loading items into the “Waste” drawer in the following order:

1. Insert empty liquid waste container (be sure to remove lid before placing into the drawer).
2. Insert tip chute.
3. Insert tip park station.
4. Insert empty unit boxes (make sure there is an empty unit box in slot 4).
5. Install empty tip disposal bag.

#### 9.1.1 Tip park station

The tip park station is on top of the liquid waste container. It channels liquid waste from the filter tips into the liquid waste container and also enables temporary storage of filter-tips that will be reused in a subsequent protocol step.

To load the tip park station into the “Waste” drawer, follow the steps below.

1. Open the “Waste” drawer.
2. Ensure that the tip park station is properly inserted; otherwise an error may occur during the inventory scan.

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The tip park station will be automatically detected during the inventory scan.

### 9.1.2 Liquid waste container

The liquid waste container is used to collect all liquid waste generated during sample preparation.

To load the liquid waste container into the “Waste” drawer, follow the steps below.

1. Open the drawer.
2. Place the liquid waste container at the rear right.
3. Gently press the container downwards to put it properly in place.

**Note:** Make sure to remove the lid from the liquid waste container before you load the container into the drawer.

**Note:** Make sure to empty the liquid waste container at the end of each run.

**Important:** Be careful when handling the liquid waste container. It may contain infectious material.

**Note:** The “Waste” drawer can only be closed when the liquid waste container is in place.

Note: Do not autoclave the liquid waste container.

### 9.1.3 Tip chute

The tip chute enables collection of used disposable filter-tips from the pipetting system. Used tips are collected in a tip disposal bag or, when using the QIA Symphony Cabinet SP/AS, a waste bin.

**Note:** Make sure that the tip chute is placed into the “Waste” drawer. Install a tip disposal bag or position the waste bin before running a sample batch.

**Note:** If using the QIA Symphony SP instrument with the QIA Symphony Cabinet SP, refer to Appendix F for information about setup of the tip chutes.

The tip chute will be detected during the inventory scan.

#### 9.1.4 Tip waste collection

##### Tip disposal bag

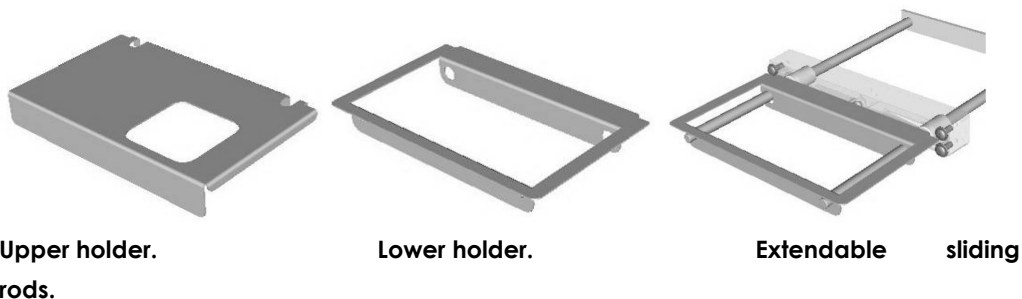
When using the QIAsymphony SP instrument without the QIAsymphony Cabinet SP, the tip disposal bag must be mounted below the “Waste” drawer.

##### Mounting the tip disposal bag

**Note:** The following procedure for mounting the tip disposal bag is not used with the QIAsymphony Cabinet SP/AS.

To mount the tip disposal bag proceed as follows:

Each tip disposal unit consists of an upper and lower holder that grip the tip disposal bag, and 2 extendable sliding rods that hold the complete assembly.



To install a tip disposal bag, proceed as follows:

1. Pull out the holder and sliding rods.
2. Grip the upper part of the holder and pull it toward you.
3. Lift the upper part of the holder and pull it backwards until the cutouts are resting on the rods.
4. Attach the tip disposal bag to the lower part of the holder.
5. Attach the upper part of the holder to the lower part, and slide in the rods by pushing them toward the instrument.

**Note:** The tip disposal bag is not checked during the inventory scan. Ensure that a tip disposal bag is installed before starting a batch.

**Note:** If the tip disposal bag is not properly installed, a tip jam may occur. Ensure that the tip disposal bag is correctly installed and is not crinkled.

To remove a tip disposal bag, proceed as follows:

1. Pull out the holder and sliding rods. Grip the upper part of the holder and pull it toward you.
2. Lift the upper part of the holder and push it backwards until the cutouts are resting on the rods.
3. Remove the disposal bag from the lower part of the holder.
4. Attach the upper part of the holder to the lower part, and slide in the rods by pushing them toward the instrument.

Discard the waste according to your local safety regulations.

If using the QIAAsymphony SP in combination with the QIAAsymphony Cabinet SP, refer to Appendix F for information about tip disposal.

Note: The instrument does not check for the presence of a tip disposal bag. If a QIAAsymphony Cabinet SP is not used and a tip disposal bag is not installed, tips will not be collected and will fall to the surface below the instrument.

## **Waste bin**

When using the QIAAsymphony Cabinet SP, tips are disposed directly into the waste bin, located below the waste chute exit.

### **9.1.5 Unit boxes**

Used sample prep cartridges and 8-Rod Covers are collected in unit boxes. There are 4 slots for unit boxes in the “Waste” drawer and, for increased ease of use and process safety, unit boxes can only be loaded in the correct orientation.

Depending on the purification procedure being run and the number of samples, the space needed for used consumables in the “Waste” drawer will vary.

To load the “Waste” drawer with unit boxes, follow the steps below.

1. Remove the lid from the unit box.
2. If the unit box contains a spacer, make sure to remove this.
3. Place the unit box into one of the unit box slots.



#### **Unit box slots.**

**Note:** The spacer at the bottom of an empty 8-Rod Cover unit box must be removed before the unit box is placed into the "Waste" drawer, otherwise an error may occur during the inventory scan.

**Important:** An empty unit box must be placed into slot 4. During initialization the handler goes down into the unit box in position 4. If the unit box is not empty, the handler will crash.

**Note:** Do not empty partially filled unit boxes. Partially filled unit boxes will be detected during the inventory scan and can be used until they are full.

**Note:** Do not throw away the lids of open unit boxes. They can be used to cover unit boxes after a run.

#### 9.1.6 Closing the "Waste" drawer

After preparing the "Waste" drawer, the drawer must be closed to initiate the inventory scan.

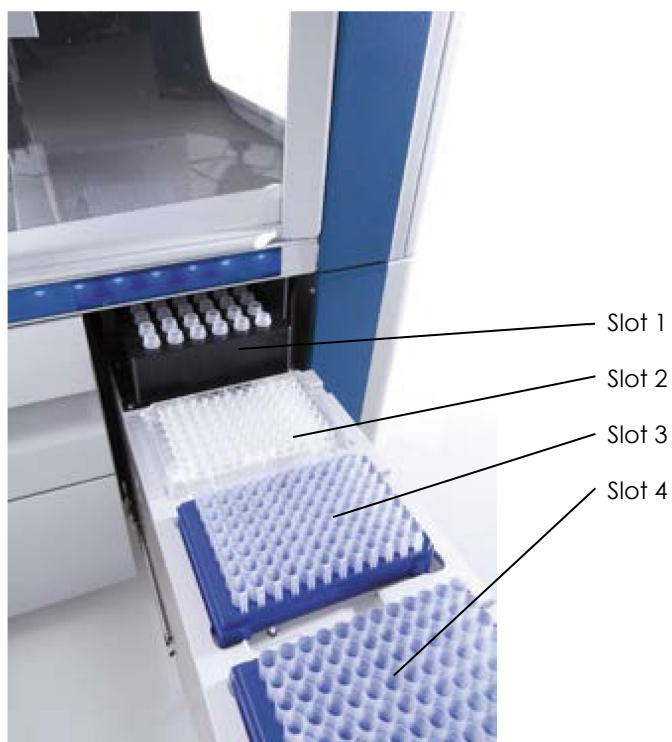


## 9.2 Loading the “Eluate” drawer

### 9.2.1 Features of the “Eluate” drawer

Purified nucleic acids are transferred to the “Eluate” drawer. The “Eluate” drawer contains 4 slots that can be used for elution into plates or tubes.

**Note:** “Elution slots 2–4” are not for use with FDA cleared or approved nucleic acid tests.



**The “Eluate” drawer.**

Slot	Description
1	“Elution slot 1” enables eluate cooling and requires use of a specially designed cooling adapter for the Elution Microtubes CL (cat. no. 19588).  Cooling parameters are defined in the protocol.
2,3	“Elution slot 2” and “Elution slot 3” will not be used in integrated runs.
4	Elution slot 4” will not be used in integrated runs.

## Adapters

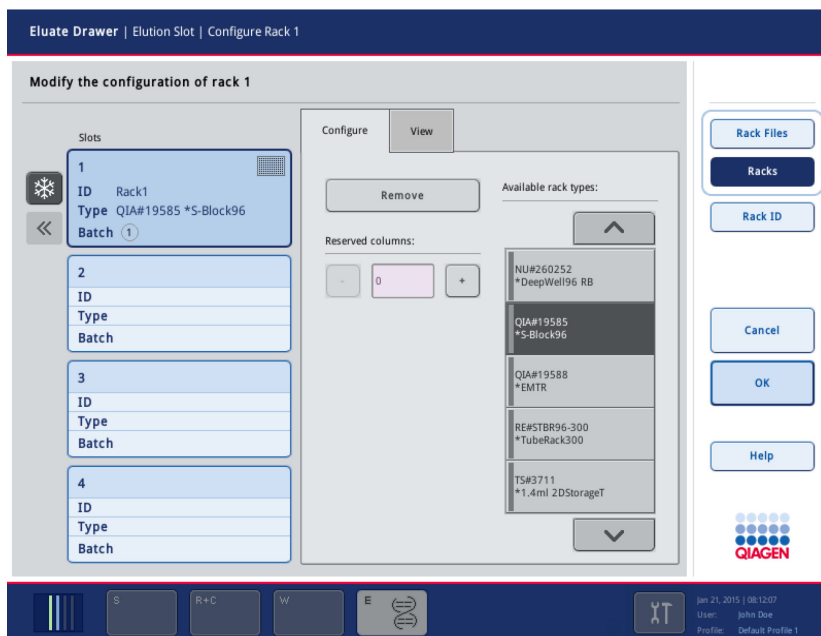
Only the Elution Microtubes CL (cat. no. 19588) in the respective cooling adapter, Elution Microtube Rack QS (Cooling Adapter, EMT, v2, Qsym, cat. no. 9020730), in combination with the QIAAsymphony SP/AS Transfer Frame can be used.

**Note:** A handheld scanner is used to identify bar codes on elution racks and elution slots in the “Eluate” drawer.

### 9.2.2 Loading procedure

To load the “Eluate” drawer, follow the steps below.

1. Prepare the elution rack, cooling adapter, and transfer frame.
2. Open the “Eluate” drawer to display the **Elution Slot/Configure Racks** screen.
3. Press the slot **1** button in the touchscreen of the elution slot.
4. Scan the bar code using the handheld scanner.
5. The entered elution rack ID is displayed in the screen.



6. Place the elution rack with well A1 in the upper left corner into the respective cooling adapter. Place the assembly, together with the transfer frame, onto elution slot 1. Make sure that the rack is positioned correctly into the respective cooling adapter.

**Important:** If using Elution Microtubes CL racks, remove the bottom by gently

twisting the rack until the bottom separates before loading into the respective cooling adapter.

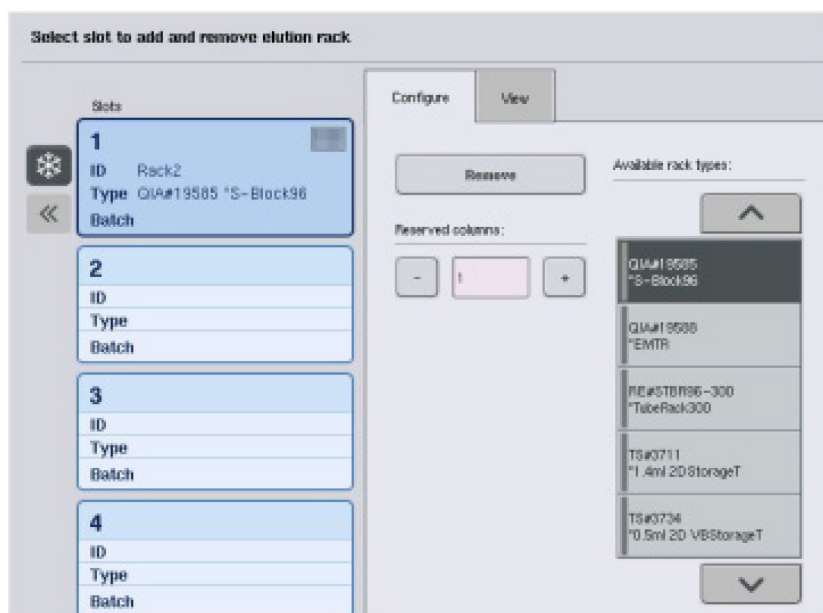
7. To set up an integrated run, make sure to use slot 1. Place the elution rack into the appropriate cooling adapter.

**Note:** Elution rack cooling cannot be turned off because it will result in “unclear” flagging of samples.

**Note:** For FDA cleared or approved nucleic acid tests, Rotor Gene AssayManager will invalidate all “unclear” samples.

**Note:** The QIAAsymphony SP provides automated assignment of elution racks. If you are using an Elution Microtube Rack (EMTR), scan the bar code of the rack and the elution rack type will be automatically selected by the QIAAsymphony SP.

**Note:** Columns cannot be reserved because integrated runs do not support this feature.



Close the “Eluate” drawer and press **OK**. The QIAAsymphony SP performs an inventory scan of the “Eluate” drawer.

**Note:** It is not possible to proceed to the next screen until the inventory scan is complete.

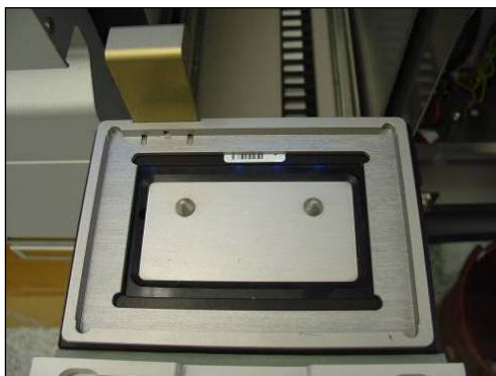
### 9.2.3 Transfer module

Within the integrated mode, elution racks will be automatically transferred from the QIASymphony SP via the transfer module to slot 2 of the “Eluate and Reagents” drawer of the QIASymphony AS instrument.

The transfer frame consists of a base frame and a handle. For automatic transfer of an elution rack to the QIASymphony AS via the transfer module, ensure that the transfer frame is installed before placing the relevant adapter onto slot 1 of the “Eluate” drawer

To install the transfer frame, follow the steps below.

1. Place the transfer frame onto slot 1, so that the 4 pins under the base frame fit into the screw holes of slot 1. The handle should face toward the back-left corner of slot 1.



**Transfer frame placed onto slot 1 of the “Eluate” drawer.**

2. Place the appropriate adapter and elution rack on top of the transfer frame.



**Adapter placed onto the transfer frame on slot 1 of the “Eluate” drawer.**

The “Eluate” drawer is locked during the integrated run (from selecting **Define run** until **Remove integrated run**) and during the inventory scan of the “Eluate” drawer.

If no integrated run is booked in the system and no inventory scan occurs, the “Eluate” drawer can be opened or closed.

#### 9.2.4 Unloading the “Eluate” drawer

Elution racks must be manually unloaded from the “Eluate” drawer.

In integrated run mode, an elution rack on “Elution slot 1” will be automatically transferred from the QIAsymphony SP to the AS module to start the reaction setup. Afterwards, the elution rack will be automatically transferred back to the QIAsymphony SP “Eluate” drawer.

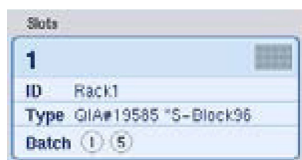
When an elution rack is removed, the rack file for the elution rack is finalized and the result file for the elution rack is generated. The rack file and result file can be downloaded using the QIAsymphony Management Console or via file transfer from the QIAsymphony SP to the USB stick.

For a detailed description of how to manually remove elution racks, see the following sections.

##### Manually removing an elution rack

**Note:** Make sure that the completed integrated run is removed from the system otherwise the “Eluate” drawer is still locked.

1. Open the “Eluate” drawer.  
The **Eluate Drawer/Elution Slot** screen appears.
3. Select elution slot 1.



The **Eluate Drawer/Elution Slot/Change Rack X** screen appears.

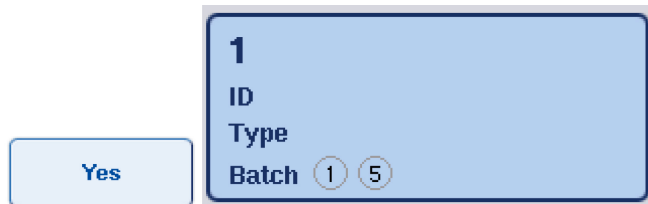
4. Press the **Remove** button in the **Configure** tab to remove the elution rack from the inventory.

A message asking whether you want to remove the elution rack from the selected slot appears.



5. Press **Yes** to continue.

The **Eluate Drawer/Elution Slot/Change Rack X** screen is displayed. The rack on the selected slot is removed.



6. Remove the elution rack, with the cooling adapter and the transfer frame, from the elution slot.
7. After unloading the elution rack, cooling adapter, and transfer frame, close the "Eluate" drawer.

The **Eluate Drawer/Elution Slot/Configure Rack X** screen appears.

8. Press the **OK** button.



The QIAsymphony SP performs an inventory scan of the "Eluate" drawer. Afterwards the **Sample Preparation/Overview** screen is displayed.

**Note:** As soon as the **OK** button or **Yes** button is pressed, the cooling in "Elution slot 1" will be turned off.

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## 9.3 Loading the “Reagents and Consumables” drawer

The “Reagents and Consumables” drawer accommodates all consumables and reagents required for the protocol run.

Before starting a protocol run, the drawer must be loaded with the appropriate reagents in prefilled, sealed reagent cartridges, sample prep cartridges, 8-Rod Covers, and disposable filter-tips. In some cases, a buffer bottle may be required.

Depending on the kit being used, different types or amounts of consumables may be required. For more information, refer to the Instructions for Use (Handbook) for the assay you are using.

### 9.3.1 Loading consumables

#### **Unit boxes**

Consumables required for sample preparation are placed onto the QIASymphony SP worktable in unit boxes. Unit boxes are provided with a lid. There are 4 slots for unit boxes.

To load unit boxes, follow the steps below.

1. Remove the lid from the unit box and keep for later use. Lids can be used to reclose partially used unit boxes.
2. Place unit boxes containing either unused 8-Rod Covers or sample prep cartridges into the “Reagents and Consumables” drawer.

Unit boxes are designed so that they fit into the instrument drawer only in the correct orientation.



### Consumables used in sample preparation on the QIAAsymphony SP.

Each unit box slot in the “Reagents and Consumables” drawer can be used either for a unit box filled with sample prep cartridges or a unit box filled with 8-Rod Covers. Partially used unit boxes can be loaded into the drawer since the number of sample prep cartridges or 8-Rod Covers they contain will be detected during the inventory scan.

Typically, more sample prep cartridges will be required than 8-Rod Covers and this needs to be taken into account when loading the QIAAsymphony SP with unit boxes.

**Note:** Do not refill partially used unit boxes. The number of sample prep cartridges or 8-Rod Covers is detected during the inventory scan.

Important: Make sure that there is at least one empty unit box in slot 4 (slot closest to you).

**Note:** Do not throw empty unit boxes away. Empty unit boxes can be used in the “Waste” drawer for collection of used sample prep cartridges and 8-Rod Covers during the purification procedure.

**Note:** Before loading unit boxes onto the system, ensure that sample prep cartridges and 8-Rod Covers have not become stuck within the unit boxes.

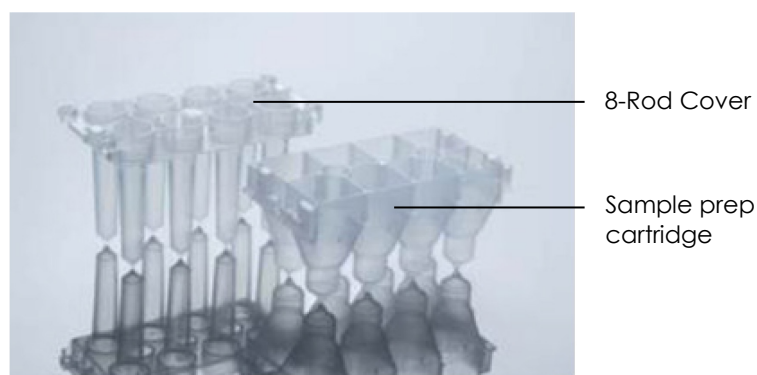
### 8-Rod Covers

An 8-Rod Cover is an array of 8 rod covers that cover the magnetic rods of the magnetic head.

- Each unit box can hold a maximum of twelve 8-Rod Covers.



- There is a spacer between the bottom of the unit box and the last 8-Rod Cover.
- A specific pattern on the top and bottom edge of an 8 Rod Cover enables automatic detection by the QIAAsymphony SP during the inventory scan.
- The number of 8-Rod Covers in a unit box is also detected during the inventory scan.



**8-Rod Covers and sample prep cartridge.**

### **Sample prep cartridges**

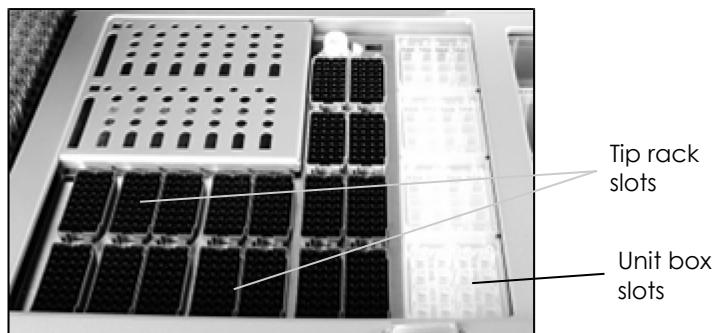
Sample prep cartridges are the vessels used by the QIAAsymphony SP during purification of nucleic acids. Each well of a sample prep cartridge can hold up to 3 ml of liquid.

Sample prep cartridges are provided in sealed unit boxes. Each unit box can hold a maximum of 28 cartridges. A specific pattern on the top and bottom edge of a sample prep cartridge enables automatic detection by the QIAAsymphony SP during the inventory scan. The number of sample prep cartridges in a unit box is also detected during the inventory scan. The robotic handling system can pick up a maximum of 3 sample prep cartridges simultaneously.

### **Tip racks**

- The QIAAsymphony SP uses 1500 µl filter-tips and 200 µl filter-tips.
- Filter-tips are provided in sealed blister packs, with 32 filter-tips in one tip rack.
- For ease of use, racks containing 1500 µl filter-tips are black and racks containing 200 µl filter-tips are blue.
- Each type of tip rack has a different pattern on the upper and lower side. This enables detection of the type of filter-tip during the inventory scan.
- There are 18 tip rack slots.
- Tip racks can be placed in any of the slots since rack position, tip type, and number of tips are detected during the inventory scan.

- The number of tips required per sample varies depending on the protocol being run.



#### Tip racks.

To load the QIAasympphony SP with tip racks, follow the steps below.

1. Hold the tip rack between 2 fingers by the recessed grips.
2. Gently squeeze the tip rack together and place it into a tip rack slot.

**Note:** To ensure detection of the tip racks during the inventory scan, make sure that the tip racks are properly seated in the tip rack slot and that none of the protrusions on the tip racks are broken.

**Note:** Each tip type contains a filter to help prevent cross-contamination.

Recommendation: Load more than the required number of filter-tips of each size so that sufficient filter-tips are available for automated error handling.

In addition, we recommend to load tips preferably in rear tip rack slots. For more information about tip loading, press the Tip Information button (see page 70, page 159, and page 283).

**Note:** Do not refill partially used tip racks. A mixture of various tip sizes in one rack will result in an error during the run. The number of filter-tips will be detected during the inventory scan.

### 9.3.2 Reagent cartridges

The required reagent cartridges are determined by the assay being run and the integrated run parameters. For more information refer to the Instructions for Use (Handbook) for the assay you are using.

- Reagents required for the purification procedure are provided in prefilled, sealed reagent cartridges.

- Up to 2 reagent cartridges can be loaded into the “Reagents and Consumables” drawer.
- For ease of use, reagent cartridges fit only in the correct orientation. The user first vortexes the magnetic-particle trough and then removes the seal from the magnetic-particle trough. Remove the lids from the tubes and place into the appropriate slot to prevent mix up. When the piercing lid has been properly installed before loading, the reagent cartridge is then automatically opened by the QIAAsymphony SP, which eliminates manual handling and pouring of reagents.
- Each individual reagent in the reagent cartridge is labeled with a 2D bar code, enabling tracking of reagents through the entire purification procedure.
- Before the run starts, the system checks whether the reagent volumes are sufficient for the chosen protocol.



- |                            |                |
|----------------------------|----------------|
| 1 Reagent cartridge holder | 4 Enzyme rack  |
| 2 Magnetic-particle holder | 5 Piercing lid |
| 3 Reagent troughs          |                |

The reagent cartridge contains sufficient reagents for up to 192 samples, depending on the QIAAsymphony DSP Kit being used. Refer to the Instructions for Use (Handbook) for the assay you are using for more information. Troughs of partially used reagent cartridges should be sealed immediately after use with Reuse Seal Strips (provided in the QIAAsymphony DSP Kit).

---

**Note:** Do not refill partially used reagent cartridges or exchange the reagent cartridge of a running batch as this may lead to performance and pipetting errors.

**Important:** The length of time that the reagent cartridge is open must be kept as short as possible. Refer to the Instructions for Use (Handbook) for the assay you are using for more information.

Note: Before loading, the reagent cartridge and the magnetic particle trough must be vortexed. Refer to the Instructions for Use (Handbook) for the assay you are using for more information.

Note: Before loading the reagent cartridge, the tubes within the enzyme rack must be uncapped. The caps can be placed underneath the enzyme rack on the reagent cartridge holder.

Important: The piercing lid has sharp edges and can damage your gloves.

All reagent troughs and enzyme racks are labeled at the side with the name of the buffer contained in the trough. A unique 2D bar code on top of each trough enables the QIASymphony SP to detect the reagent cartridge and the contents of each trough.

The composition of the reagent cartridge is kit-specific. Do not mix troughs from different kits and/or kits with different lot numbers.

Visually check all reagent troughs for precipitates. If precipitates are present, refer to the Instructions for Use (Handbook) for the assay you are using for more information.

**Note:** Make sure that reagents and enzymes are at room temperature (15–25°C) before placing into the “Reagents and Consumables” drawer.

**Note:** Do not autoclave a prefilled reagent cartridge. Do not change the order of the troughs within the reagent cartridge.

**Note:** Avoid shaking the reagent cartridge since this may cause buffers to foam, resulting in liquid-level detection errors.

**Note:** Open and close the reagents and consumables drawer gently to avoid spilling reagents.

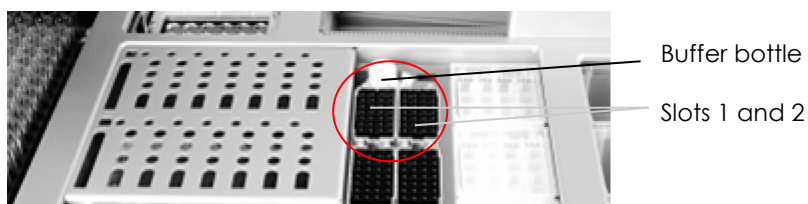
Note: Do not refill partially used reagent cartridges or exchange the reagent cartridge of a running batch as this may lead to performance and pipetting errors.

### 9.3.3 Buffer bottle

Depending on the kit being used, an additional bottle of buffer may be provided. The bottle is prefilled with up to 60 ml of reagent.

To load the QIAasympphony SP with the buffer bottle, follow the steps below.

1. Remove the screw-cap from the buffer bottle.
2. Press **Bottle ID** in the **Load Reagents** screen.
3. Scan the buffer code by using the handheld bar code scanner. Alternatively, type in the bar code using the **Keyboard** screen.
4. Place the bottle into the slot behind the rear end of the tip rack slots 1 and 2.



**Buffer bottle slot.**

The buffer bottle and volume of buffer will be automatically detected during the inventory scan.

**Note:** Open and close the reagents and consumables drawer gently to avoid spilling reagents.

### 9.3.4 Unloading reagents and consumables

#### **Reagent cartridges**

To remove a reagent cartridge from the "Reagents and Consumables" drawer, follow the steps below.

1. Open the drawer.
2. Pull the reagent cartridge to the left and slide it out of the slot.

To avoid evaporation of reagents, we strongly recommend resealing the troughs of the reagent cartridge immediately after use. Reseal the troughs using Reuse Seal Strips provided in QIAasympphony DSP Kits. Replace screw-caps on the tubes in the enzyme rack.

For storage, remove the reagent cartridge and enzyme rack from the reagent cartridge holder and store according to the Instructions for Use (Handbook) for the assay you are using. The reagent cartridge holder can then be used in combination with other kits.

If the reagent cartridge is empty, remove it from the reagent cartridge holder and discard it according to your local safety regulations.

### **Tip racks**

Tip racks can be left in the "Reagents and Consumables" drawer. Tip racks only need to be removed in the following situations:

- The tip racks are empty.
- Maintenance will be performed (e.g., decontamination using the UV lamp).
- The instrument will not be used for a long period of time.

To remove a tip rack from the QIA Symphony SP, follow the steps below.

1. Hold the tip rack between two fingers by the recessed grips.
2. Gently squeeze the tip rack together.
3. Remove the tip rack.
4. If you need to remove the tip racks prior to performing maintenance procedures, the tip racks can be replaced after maintenance has been performed.

### **Unit boxes (8-Rod Covers and sample prep cartridges)**

Unit boxes can be left in the "Reagents and Consumables" drawer. Unit boxes only need to be removed in the following situations:

- The unit box is empty.
- Maintenance will be performed (e.g., decontamination using the UV lamp).

To remove a unit box from the "Reagents and Consumables" drawer, follow the steps below.

1. Open the "Reagents and Consumables" drawer.
2. Grasp the unit box by its upper edge.
3. Pull it out of the drawer.
4. Replace the lids of partially used or unused unit boxes.
5. Empty unit boxes must be saved for collection of used sample prep cartridges and 8-Rod Covers in the "Waste" drawer.

**Important:** Sample prep cartridges in the unit boxes can contain residual liquid from the extraction run. Seal unit boxes with lids before disposal to avoid spillage of residual liquid.

## 9.4 Loading the “Sample” drawer

Samples can be loaded into the “Sample” drawer in either primary or secondary tubes. For more information about compatible tubes, refer to the Instructions for Use (Handbook) for the assay you are using.

Use of tube carriers enables samples to be loaded in a variety of formats. A tube carrier for up to 24 primary tubes or tubes containing internal controls with diameters of 8–16 mm can be used with the QIAAsymphony SP.

### 9.4.1 Loading tube carriers

#### **Loading samples using a tube carrier**

##### *Preparing sample tubes for the tube carrier*

The QIAAsymphony SP tube carrier can accommodate up to 24 sample tubes of the following outer diameter:

- 14–16 mm (no insert required)
- 13 mm (tube insert 1a; cat. no. 9242058)
- 11 mm (tube insert 2a; cat. no. 9242057)
- Sarstedt® tube 2 ml (insert 3b; cat. no. 9242083)
- Insert snap cap tube (insert 5a; cat. no. 9244701)

For more information, refer to the Instructions for Use (Handbook) for the assay you are using.



**Example of insert for tube carrier.**

**Note:** Place the tubes into the tube carrier in a way that all bar codes are oriented to the left so that they can be read by the bar code reader.

The instrument detects tube size by reading the bar code on the insert or on the tube carrier. If a tube is used that is not the default tube type for a certain insert, the user must specify the tube type when defining the sample batch. Default tubes can also be configured.

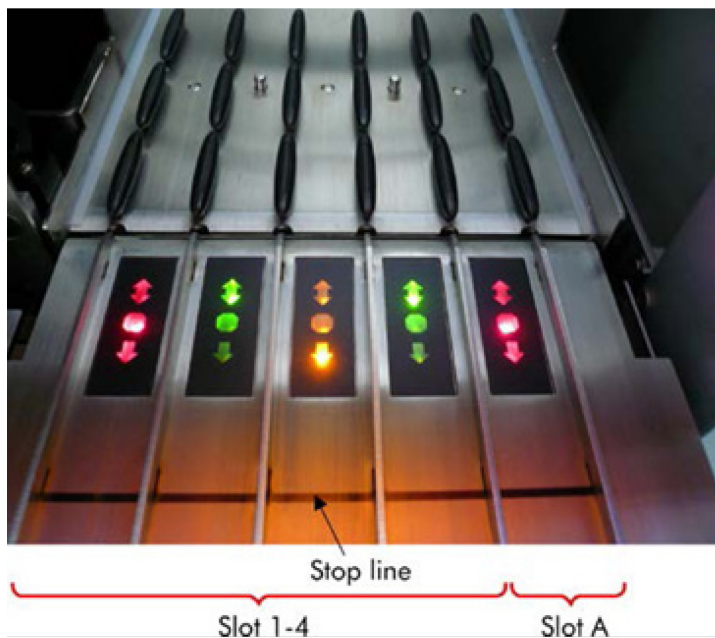
### Inserting samples using a tube carrier

1. Open the "Sample" drawer by pulling the door toward you.

Five slots are available. The first 4 slots can accommodate tube carriers containing sample tubes, positive full process controls, and negative full process controls. The fifth slot "A" accommodates a tube carrier containing internal controls.

The status of each slot is shown by LEDs located behind the stop line. The LEDs may be illuminated in green, orange, or red.

- Green — slot is free and ready for loading
- Orange — tube carrier is loaded
- Red — slot is currently locked



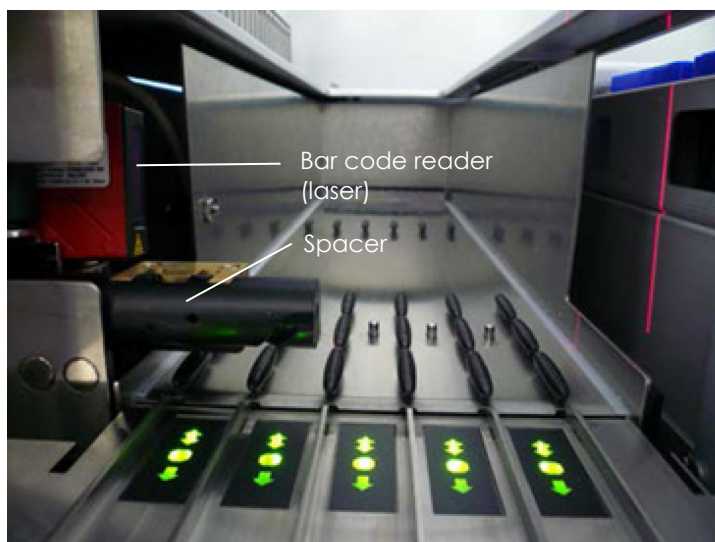
**Slot status.**

2. Gently slide the tube carrier into the appropriate slot. Insert up to the stop line, and wait until the bar code reader has moved forward.





**Sliding a tube carrier into the appropriate slot.**



**Location of bar code reader and spacer.**

3. As soon as the bar code reader is in position, the slot unlocks and the green LED starts to flash. Slide the carrier into the slot until it locks.
4. The bar code reader reads bar codes on the carrier, inserts, and corresponding sample tubes (if bar coded). Upon successful loading, the LED changes from green to orange.
5. The bar code reader returns to the home position.
6. To add more sample tubes in different slots, follow procedure as described in this section. Otherwise close the "Sample" drawer.

**Note:** Be sure to support the tube carrier with your second hand during the loading process. Otherwise, there is a risk of handle breakage.

**Note:** Make sure to slide the carrier smoothly into the slot otherwise an error may occur.

**Note:** Only a tube carrier containing internal control can be loaded into "Slot A". Tube carriers containing samples must be loaded into "Slot 1", "Slot 2", "Slot 3", or "Slot 4".

**Note:** If you need to load two tubes with the same bar code/ID in the same tube carrier, do not place them side by side. Otherwise an error will occur.

**Note:** If you are using sample tubes that are not labeled with bar codes and that are in different inserts, either use one insert type per tube carrier or leave at least one position empty between different types of insert.

**Note:** If you are using sample tubes that are not labeled with bar codes and the QIAAsymphony SP has a configuration other than configuration 3, tubes containing smaller volumes of liquid or clear liquids may not be detected. In this case, use a blank bar code label to enable detection of the sample tube.

**Note:** To ensure correct liquid level detection, push the tubes down to the bottom of the tube carrier or insert, if inserts are used.

### Continuous loading

It is also possible to load and queue additional samples when a run is already in progress. In this mode, you can only assign Assay Parameter Sets that are compatible with the currently loaded reagent cartridge(s).

Continuous loading on the QIAAsymphony SP is possible for up to 96 samples in any number of batches (up to 12), provided that the consumables drawer is fully loaded before commencing the first batch.

After loading the samples, the system allows the user to correct bar code reading errors, change labware, and assign Assay Parameter Sets.

Before starting a run with continuous loading, ensure that:

- Additional reagents that are required (e.g., ethanol, buffer in 60 ml buffer bottle) are loaded.
- Enough tips, reagents, waste space and consumables are loaded for all runs including subsequent runs loaded via continuous loading.

### Unloading a tube carrier

If the tube carrier slot is not locked (LED is not illuminated red), the tube carrier can simply be removed from the slot. The tube carrier can be removed as soon as the samples have been transferred.

Depending on the batch status, different actions can be carried out after removing the tube carrier.

### Loading internal controls

The internal control to be used is defined in the corresponding Assay Control Set. Assigning an Assay Control Set to a sample not only specifies which protocol should be used but also which internal control should be added to the sample.

**Note:** Internal controls must be loaded via a tube carrier in sample "Slot A".

**Note:** Do not load internal controls into "Slots 1–4".

Eight different internal controls can be used per batch of 24 samples and up to 24 different internal controls can be used for one run. Tubes containing internal control must be placed into the appropriate insert for the tube type before loading into the tube carrier.

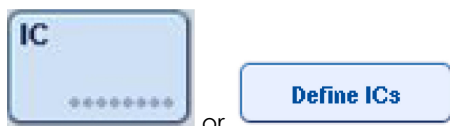
Loading of the required internal controls for ordered batch(es) is validated before run start.

If the tubes containing internal control are bar code labeled and identification of the tubes is defined in an Assay Control Set, the QIA Symphony SP automatically detects which internal control is located in each position.

If the tubes are not bar code labeled, information about the internal control must be entered manually.

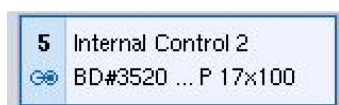
After insertion of the tube carrier into "Slot A", follow the steps below to enter information about the internal control.

1. Press the **IC** (in **Sample Preparation** screen) or **Define ICs** (in **Integrated Run** screen) button to check or modify the internal controls.



The **Internal Controls** screen appears.

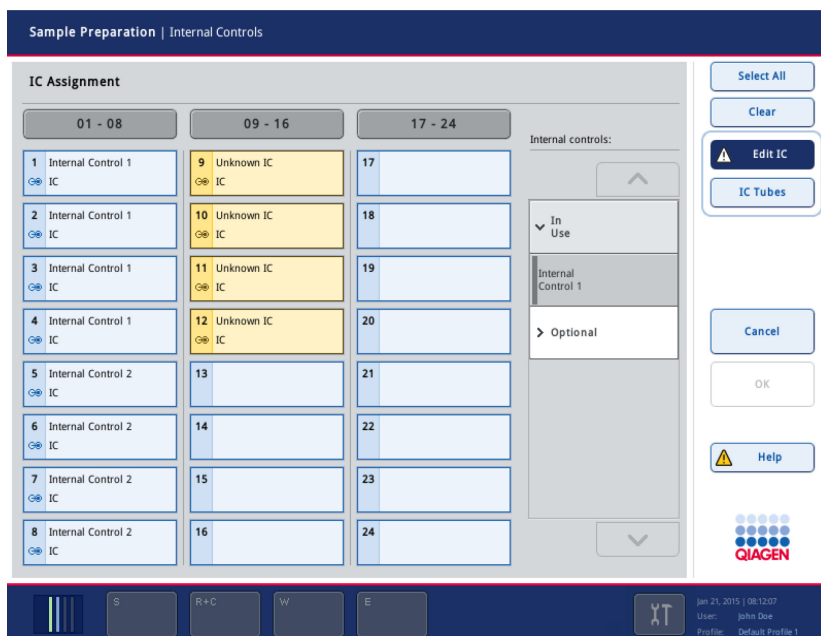
2. Select the position that needs an internal control to be manually assigned by pressing the button.



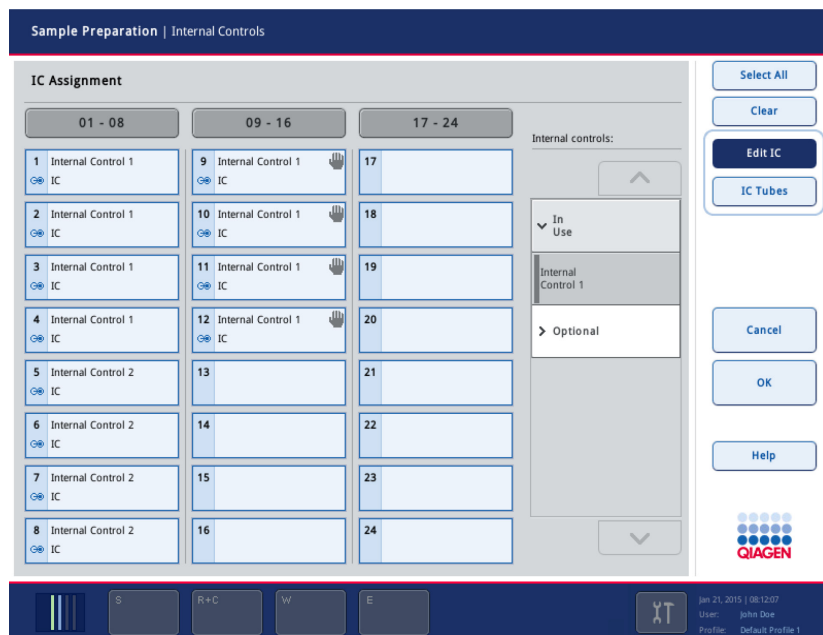
3. Select the internal control in the **Internal controls:** list.



4. Press **OK** to assign internal controls to the selected positions.



5. Press **OK** to confirm the overall assignments of internal control.



Internal controls are ordered into groups:

Group	Description
Required	Batch(es) is queued. The QIA Symphony SP knows which internal controls are required to run the queued batches. The required internal controls are not detected automatically and have to be assigned to the detected positions.
In use	The QIA Symphony SP either has automatically detected an internal control or it was manually assigned to a particular position in the fifth tube carrier. These internal controls are listed under the category "In use".

**Important:** If the internal control was labeled with a bar code but the bar code was not correctly read, the associated position button becomes yellow. To continue, the internal control has to be manually assigned using the internal controls displayed in the **Internal controls:** list. If the internal control was not labeled with a bar code but the QIA Symphony SP detected that a tube was present, **Unknown IC** is displayed in the corresponding position. The internal control has to be manually assigned using the internal controls displayed in the **Internal controls** list.

**Note:** Although you can leave this screen without manually assigning the positions labeled **Unknown IC**, be sure to assign all required internal controls before starting a run; otherwise the run cannot be started.

### Unloading internal controls

Internal controls in a tube carrier can be removed from the QIAAsymphony SP when the carrier slot is unlocked.

- If batches are running and you need to load additional internal controls, unlock the carrier "Slot A" by pressing the **IC** button in the Sample Preparation screen:



or **Define ICs** button in the **Integrated Run** screen:



- If the QIAAsymphony SP does not need to access the tube carrier in "Slot A", the internal controls can be unloaded.
- Remove the carrier with internal controls from "Slot A" by gently sliding it out of the "Sample" drawer.

### Loading internal controls during a run

After unloading the tube carrier containing the internal control, the tube carrier containing a new internal control has to be inserted again. Define internal control(s) as previously described.

## 9.5 Performing inventory scans (SP)

An inventory scan of each drawer of the QIAAsymphony SP must be performed before a sample preparation protocol can be run. The QIAAsymphony SP uses a laser to check the type and number of consumables, and the type and location of adapters loaded in each drawer. A bar code detection system recognizes and scans 1D or 2D bar codes (e.g., on the reagent cartridge). The laser and bar code camera are integrated in the robotic arm. This ensures that positions over the whole worktable can be scanned. The inventory scan is drawer-specific. This means that only the drawer that has been opened will be scanned for changes.

### 9.5.1 Inventory scan of the “Reagents and Consumables” drawer

The inventory scan of the “Reagents and Consumables” drawer is divided into 2 main parts, each with several subparts.

#### **Laser scan — reagent cartridge**

Reagent cartridge slots are scanned. The instrument will check first for sealed troughs in the respective reagent cartridge.

**Note:** If you forget to place the lid onto the reagent cartridge, the samples in the batch may be lost. However, the presence of the piercing lid is detected during the inventory scan, which means that the error will be detected before the run has started.

**Important:** Ensure that all 2D bar codes are accessible by the sensor.

2D bar codes on reagent troughs, the magnetic-particle trough, and the enzyme rack are checked. In addition, the piercing status of the reagent cartridge is checked.



#### **2D bar codes.**

- If the reagent cartridge is sealed and not pierced, the liquid level of all reagents in the reagent cartridge is set to the original value. An additional liquid-level check will not be performed.
- Both reagent cartridge slots are scanned.

**Note:** Do not mix enzyme racks, buffer, or magnetic-particle troughs from different reagent cartridges or kits with different lot numbers.

**Note:** Ensure that the buffer troughs fit correctly within the reagent cartridge otherwise liquid-level detection errors may occur.

**Note:** Avoid shaking the reagent cartridge since this may cause buffers to foam, resulting in liquid-level detection errors.

**Note:** Do not refill partially used reagent cartridges or exchange the reagent cartridge of a running batch as this may lead to performance or pipetting errors.

#### **Laser scan — tip rack slots**

- All 18 tip rack slots are scanned to determine the type of tip rack loaded.
- All tip rack slots in which a tip rack was detected are scanned to determine the number of tips. If a tip is detected in the first and last position of the tip rack, the tip rack will be categorized as full. If the first or last tip is missing, a full scan will be performed to determine the number of tips in the tip rack.

#### **Laser scan — unit boxes**

- The unit box slots are scanned to detect the presence of unit boxes in the 4 slots.
- Afterwards, the type (8-Rod Cover or sample prep cartridge) and number of consumables are determined.

#### **Liquid-level scan of detected reagents**

This scan is only performed if the liquid level is not known (e.g., for a partially used reagent cartridge).

- Liquid-level scan of detected reagents.
- Liquid-level check of the buffer bottle (if detected).

**Note:** The inventory scan will only enable detection of the liquid level of open and recognized vessels.

**Note:** These checks use 1500 µl and 200 µl filter-tips. If insufficient tips are available or if one of the tip types is missing, the inventory scan will be canceled and queued sample batches cannot be started.

#### **Partial inventory scan**

If you need to repeat an inventory scan for the "Reagents and Consumables" drawer (e.g., if a change has been made on the worktable), you can perform a partial inventory scan.



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Do you want to start the inventory scan on "Reagents and Consumables drawer"?

Tip Racks	<input type="button" value="Yes"/>	<input type="button" value="No"/>
Unit Boxes	<input type="button" value="Yes"/>	<input type="button" value="No"/>
Reagents	<input type="button" value="Yes"/>	<input type="button" value="No"/>
Buffer Bottle (optional)	<input type="button" value="Yes"/>	<input type="button" value="No"/>
Accessory Trough (optional)	<input type="button" value="Yes"/>	<input type="button" value="No"/>

### 9.5.2 Inventory scan of the "Waste" drawer

The inventory scan of the "Waste" drawer consists of a laser scan. It does not perform 2D bar code scans, liquid-level detection, or checks of the liquid waste container. It is therefore important that the user checks the liquid waste container and empties it before starting a batch.

#### Laser scan

- The tip park station slot is scanned. This checks that the tip park station is mounted.
- The tip chute slot is scanned. This checks that the tip chute is installed.
- The unit box slots are scanned. First, each of the 4-unit box slots is scanned to detect whether a unit box is in the slot. Afterwards, the content of each box is determined (e.g., amount and type of consumables in each box).

### 9.5.3 Inventory scan of the "Eluate" drawer

The QIAsymphony SP checks the elution slots to make sure that selected elution slots contain an elution rack with the respective cooling adapter and transfer frame.

If the QIAsymphony SP detects a discrepancy between the expected and actual elution rack loaded in the "Eluate" drawer, a message appears in the touchscreen prompting the user to correct the problem. Open the "Eluate" drawer and place the elution rack onto the correct position or edit the slot/rack assignment in the touchscreen.

---

A message appears in the following situations:

- The detected bar code and the adapter bar code specified in the labware file are different.
- A bar code is detected but the selected labware file does not specify an adapter bar code.
- No bar code is detected, but the selected labware file specifies an adapter bar code that is required.

**Note:** The QIAAsymphony SP only detects whether an elution slot is occupied by an elution rack or adapter and is not able to identify the elution rack type on the respective elution slot.

In addition, without the transfer frame, no integrated runs can be ordered.

## 10. QIAasympphony SP Run Definitions

This section describes how to set up and configure a sample preparation run.

### 10.1 Configuring a sample type

**Note:** By default, the sample type is "Sample".

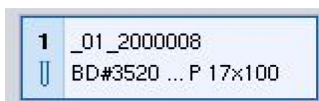
To change a sample to a positive extraction control (EC+) or negative extraction control (EC-), follow the steps below to ensure correct processing on the QIAasympphony AS.

**Note:** For analysis, the full process controls have to be loaded and selected as either EC+ or EC- in the same pattern expected by Rotor-Gene AssayManager. Otherwise, Rotor-Gene AssayManager will deny analysis of the complete integrated run.

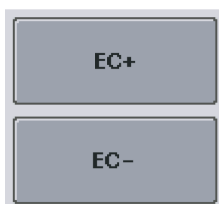
1. Press **ID/Type** in the **Sample Preparation/Batch/Define Sample** screen.



2. Select the samples for which the sample type shall be changed by pressing the corresponding buttons.



3. Press **EC+** or **EC-** to change the sample type from "Sample" to positive extraction control (EC+) or negative extraction control (EC-).



**Note:** Sample types are saved in the rack file for the corresponding elution rack. It is not possible to change the sample types later.

## 11. QIAasympphony AS Features

The QIAasympphony AS performs fully automated assay setup using a 4-channel pipetting system, and interfaces directly with the QIAasympphony SP, enabling automation of sample to assay setup. During assay setup, the touchscreen displays the assay setup user interface, providing information about assay runs, including their progress.

QIAasympphony AS protocols are called Assay Definitions. Assay Parameter Sets define the parameters for a protocol. These files, including other QIAasympphony AS files (e.g., result files), can be transferred to/from QIAasympphony SP/AS instruments via the USB ports on the QIAasympphony SP.

When an assay run has been defined, the software automatically calculates the worktable requirements for a defined run (e.g., number and type of filter-tips, volume of reagent). An automated inventory scan (performed when the drawers are closed or before an assay run starts) ensures that each drawer is correctly set up for the defined assay run.

Refer to the instructions for the transfer module in Section 9.2.3.

### 11.1 QIAasympphony AS principle

An assay setup run using the QIAasympphony AS consists of 3 main steps — master mix preparation, master mix distribution, and transfer of templates (e.g., samples, assay controls, and assay standards).

1. Master mix is prepared with the required reagents. The volume of each master mix component depends on the number of reactions to be set up. After preparation, a mixing step is performed to ensure that the master mix is homogeneous.
2. Master mix is distributed to the appropriate tube positions in the “Assays” drawer.
3. Assay controls, assay standards, and samples are transferred to the appropriate tube positions in the “Assays” drawer.

## 11.2 Instrument features



- |                                       |                                |
|---------------------------------------|--------------------------------|
| 1 Input adapters (transfer positions) | 5 Tip waste                    |
| 2 Input adapters                      | 6 "Eluate and Reagents" drawer |
| 3 PCR output adapters                 | 7 "Assays" drawer              |
| 4 Disposable tips                     | 8 Robotic arm                  |

### 11.2.1 QIAAsymphony AS hood

During an assay run, the QIAAsymphony AS hood is locked. If force is used to open the hood during an assay run, the run will be paused.

**Note:** Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.

---

**Important:** If the QIAAsymphony AS hood is opened, the instrument will not immediately stop. The instrument will stop when processing of the current protocol step is finished. In some cases, this may take some time.

### 11.2.2 QIAAsymphony status LEDs

LEDs at the front of the QIAAsymphony AS are illuminated when an assay run is in progress. The status LEDs flash when an assay run is finished or if an error occurs. Touching the screen turns off the flashing.

### 11.2.3 Robotic arm

This feature is the same as for the QIAAsymphony SP, except it does not support a robotic gripper. As part of the inventory scan on the "Eluate and Reagents" and "Assays" drawers, the 2D bar code camera on the robotic arm identifies occupied/empty slots and the corresponding adapter types.

## 12. QIAsymphony AS Drawers

### 12.1 “Eluate and Reagents” drawer

Purified nucleic acids are transferred to the “Eluate and Reagents” drawer from the “Eluate” drawer of the QIAsymphony SP by automatic transfer (via the transfer module). The “Eluate and Reagents” drawer has 3 positions — slots 1, 2, and 3 — that have options for cooling and can accommodate plates and tubes in special adapters. Slot 2 is used to accommodate sample racks, and slots 1 and 3 can be used to accommodate reagent racks. In addition, there are 6 positions that can be used to accommodate disposable filter-tips in tip racks.

**Important:** For FDA cleared or approved nucleic acid tests, use tip rack positions 1, 2, 3, 7, 8, and 9 in the QIAsymphony AS drawers (see figure, page 212).

An adapter is available for the following consumable:

- Elution Microtubes CL, cat. no. 19588

Reagent holders are available for holding reagents in 2 ml tubes and 5 ml tubes:

- Reagent holder 1 (18 x 2 ml tubes, 6 x 5 ml tubes)
- Reagent holder 2 (18 x 2 ml tubes, 2 x 5 ml tubes)
- Micro Tube Screw Cap QS (24 x 2 ml tubes)

#### 12.1.1 Filter-tips

The QIAsymphony AS uses the same disposable filter-tips as the QIAsymphony SP. In addition to 200 µl and 1500 µl filter-tips, the QIAsymphony AS also uses 50 µl filter-tips. Tip racks containing 50 µl filter-tips are gray.

**Note:** Only use filter-tips designed for use with QIAsymphony SP/AS instruments.

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## 12.2 “Assays” drawer

Assays are set up in tubes in the “Assays” drawer. The “Assays” drawer has 3 positions — slots 4, 5, and 6 — that can be cooled and used to accommodate assay racks in special adapters. It also has 6 positions that can be used to accommodate disposable filter-tips in tip racks (see Section 12.1 for more information about disposable filter-tips).

**Important:** For FDA cleared or approved nucleic acid tests, use tip rack positions 1, 2, 3, 7, 8, and 9 in the QIASymphony AS drawers (see figure, page 212).

An adapter is available for the following consumable:

- Rotor-Gene Strip Tubes

For more information about the types of tubes that can be used in the “Assays” drawer and the corresponding names used in the software, refer to the Instructions for Use (Handbook) for the assay you are using.

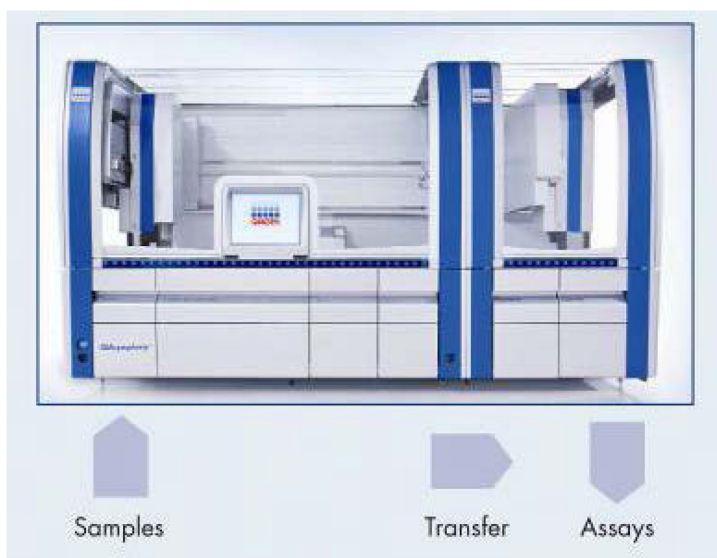
**Important:** Do not mix reagents from different lots, because such mixing cannot be tracked by QIASymphony SP/AS.



## 13. QIAsymphony AS Basic Functions

### 13.1 Integrated operation

An integrated run consists of a sample preparation run on the QIAsymphony SP and then an assay setup run on the QIAsymphony AS. Eluates are automatically transferred from the QIAsymphony SP to the QIAsymphony AS via the transfer module without user interaction. An integrated run is defined in the software for the complete sample to assay setup workflow before starting the run.



**Integrated operation.**

### 13.2 Preparing a run

Before defining a run, available adapter(s) and holder(s) must be configured in the software. If work list(s) and rack file(s) will be used in the run, these files must be transferred to QIAsymphony SP/AS instruments.

For detailed information about transferring process files, work lists, rack files, and concentrations data files, see Section 7.

## 13.3 Loading an integrated run

Follow the steps below after switching on the instrument and logging in as a user.

1. Load all items of the QIAAsymphony SP/AS removed previously by maintenance, if not already done (e.g., tip chutes, drop catcher, magnetic-head guards, tip disposal bags, empty waste bottle and tip park station).
2. Close the QIAAsymphony SP/AS hoods.
3. Switch to the **Integrated Run** user interface.
4. Load the QIAAsymphony SP "Waste" drawer.
5. Load the "Eluate" drawer with the correct rack inside the corresponding cooling adapter, together with the transfer frame on "Elution slot 1". Assign the eluate rack to "Elution slot 1" on the touchscreen and start the scan.
6. Load the "Reagent and Consumables" drawer for sample preparation according to the Instructions for Use (Handbook) for the assay you are using.

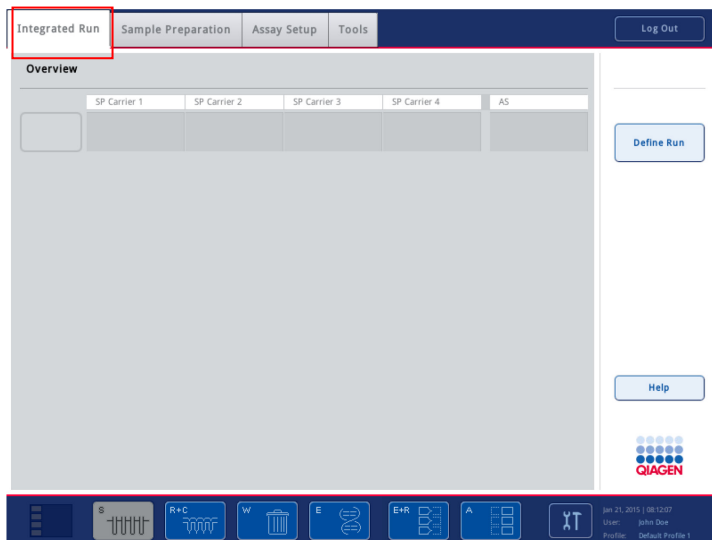
### 13.3.1 Defining an integrated run

When defining an integrated run, screens guiding you through the steps appear on the touchscreen.

It is only possible to define an integrated run if an eluate rack and a transfer frame have been loaded on "Elution slot 1" of the QIAAsymphony SP. To save time, the system checks for the transfer frame during the rack carrier inventory scan.

Select the **Integrated Run** tab in the overview screen, and then press **Define Run**.

The **Integrated Setup** screen appears.



If an error message appears, see Section 14 for information about solving the problem.

The **Integrated Setup** screen provides an overview of the defined batches and/or allows batches to be defined.

To define a batch, follow the steps below.

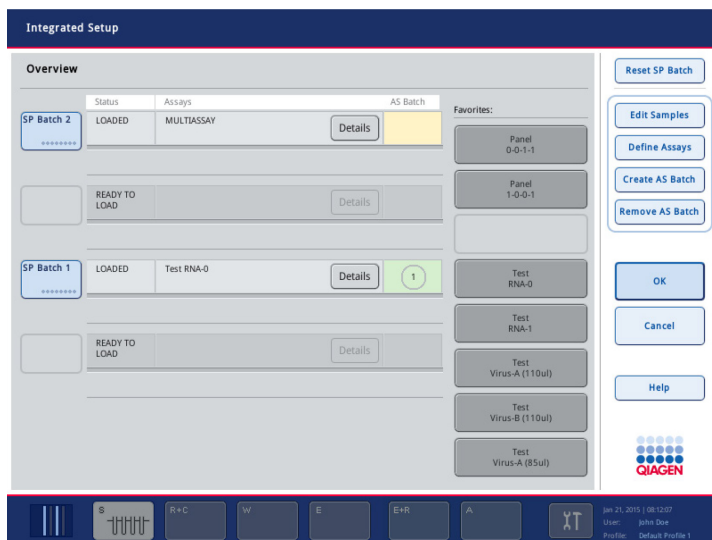
1. Select the batch button.
2. Edit samples.

This includes resolving errors in the sample IDs of the sample tubes and changing ID/Type from "Sample" to "EC+/EC-" for required controls in the tube carrier.

For correct definition and positioning, refer to the Instructions for Use (Handbook) for the assay you are using.

3. Assign an assay to all samples of a batch or define individual assays for a batch.

4. Create or remove AS batches from their related SP batch.



An integrated run consists of one or more integrated batches. An integrated batch is a combination of one or more SP batches and one AS batch. Hence, the eluates of several SP batches can be processed in one AS batch.

To define an integrated batch, follow the steps below:

1. Load a tube carrier. The loaded batch is displayed on the touchscreen.
2. Assign assays to sample positions.
3. Create an AS batch for the related SP batch(es).

Create AS Batch

4. Queue the integrated run.

OK

### Assigning assays to sample positions

Assays can be assigned to samples using:

- **Favorite** assays
- The **Assay Assignment** screen (manual assignment)
- Work lists

## Favorite assays

First, you need to set up a list of **Favorite** assays and then follow the steps below (see Section 4.5).

1. Select the desired SP batch(es).
2. Select the desired **Favorite** assay.

## Assigning assays using the Assay Assignment screen

1. Select the SP batch.

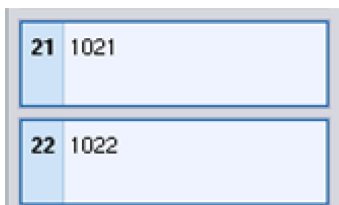


2. Press **Define Assays** in the **Integrated Setup** screen.
3. The **Assay Assignment** screen appears. Here, assays can be assigned to specific sample positions.



4. Select the sample positions to which the assay should be assigned.

These will be shown in light blue before selection and darker blue after selection.



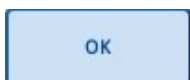
5. Alternatively, select all the samples by pressing **Select All**.



6. Select the desired assay from the "Assays" list.

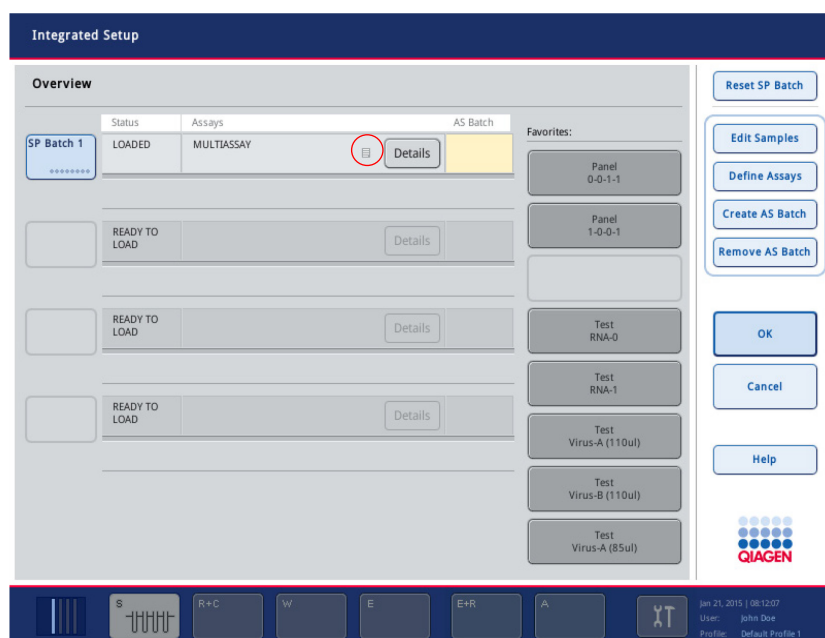
The selected assays will be assigned to the selected positions. A number will appear in the bottom right corner of the assigned sample positions. This number indicates the number of assays that have been assigned to a particular sample.

7. Press **OK**. The **OK** button becomes inactive when at least one conflict exists.



## Assigning assays using work lists

If a work list(s) is used, assays are automatically assigned to samples via their written bar code(s), as defined in the work list(s). Those batches that have assays assigned to them by work lists are marked with a work list symbol in the **Assays** column (circled in the image below). Depending on the configuration, the assignments can be edited in the **Assay Assignment** screen by pressing the **Define Assays** button.



**Note:** Based on configurations settings, a warning might appear if the sequence recognized in the sample carrier is not the same as the sequence of samples in the work list.

**Note:** If the work list has been assigned, the Assay Control Set is automatically assigned to samples for which the sample ID matches a defined sample ID in the work list. Depending on the configuration setting, it might not be possible to change this automatic assignment.

## Creating AS batches

An AS batch can be created either from a single SP batch or from more than one SP batch.

To create an AS batch, follow the steps below.

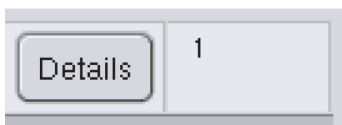
1. In the integrated setup **Overview** screen, press one or more SP batches to select them.
2. When selected, the batch button(s) will change to gray.



3. Press the **Create AS Batch** button.

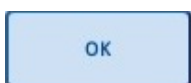


An AS batch will be created for the selected SP batches. A number will appear in the **AS Batch** column. This number indicates which AS batch a particular SP batch is linked to.



4. Press **OK**.

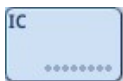
The created integrated batches are queued. Afterwards the **Main Screen** appears.



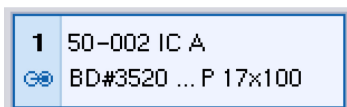
**Note:** To unlink an AS batch from an SP batch, press the SP batch(es) to select them, and then press **Remove AS Batch**.

## Defining internal controls

1. First load the internal controls into "Slot A" of the "Sample" drawer.
2. Press **IC** in the **Integrated Run** tab. The **Sample Preparation/Internal Controls** screen appears.



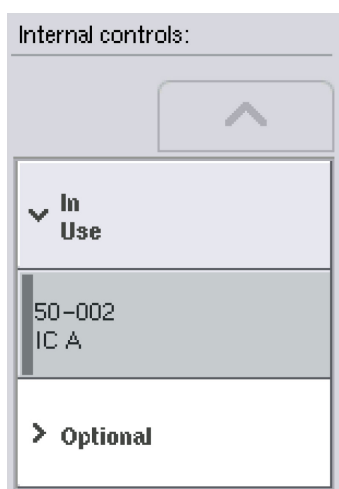
3. Press the loaded internal control(s) to select them.



4. If the tube type differs from the default, press the **IC Tubes** button, and select a tube type.



5. Select an internal control from the **Internal controls** list. The selected internal control will be assigned to the selected loaded internal control(s).



6. Press **OK**.



The selected internal controls will be assigned to the selected internal control tubes.  
The **Main Overview** screen appears again.

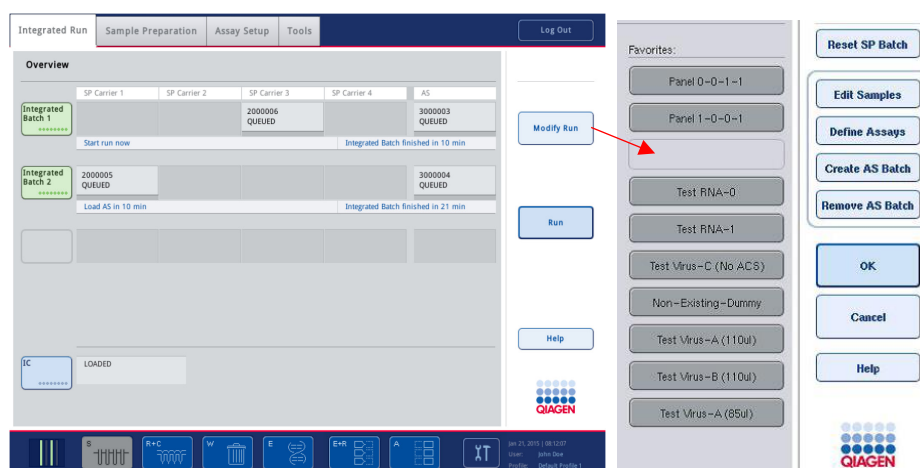


## Starting an integrated run

1. Load the QIAAsymphony SP worktable (see Section 9).
2. Start the integrated run by pressing **Run**.
3. While the integrated run is being processed, load the QIAAsymphony AS worktable.

## Modifying an integrated run

If an integrated run has already been defined, the **Integrated Run** screen displays the status of all defined integrated batches and the relationship between SP and AS batches.



1. Press **Modify Run**. The **Integrated Setup** screen appears and displays an overview of the defined batches.



Use the **Remove AS Batch** button to remove an AS batch from the integrated run of the related SP batch (the SP batch will remain unchanged).

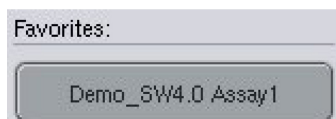
This button is unavailable if the AS batch has been started.



3. The **Edit Samples** button allows bar code reading errors for sample tubes to be resolved. In addition, sample IDs, sample types, and sample labware can be modified.



4. Assign the assay to all samples of a batch via the favorite buttons.



Alternatively, if assay **Favorites** are not used, define assays for a batch.



5. Use the **Create AS Batch** button to assign an AS batch to one or more SP batches.



**Note:** After creation of the AS batch it is important to check in the **Assay Setup/Loading Information** screen to confirm if the loaded full process controls will be dispensed to the correct position on the assay rack. To do this, press the **Sample** button and check the individual positions for correct **Type** (EC+ or EC-).

**Important:** It is possible to change the order in which batches of an integrated run are processed by manually unloading, reloading and redefining an integrated batch.

**Important:** Be aware that if you use the functions **Modify Run** and **Create AS Batch** after an integrated run has been queued, the order in which SP and AS batches are processed by the system may be different to the order in which batches would be processed if AS batches were created before queuing the integrated run.

For more detailed information, refer to Appendix D.

**Note:** At least one assay has to be assigned to samples of the QIAasymphony SP batch.

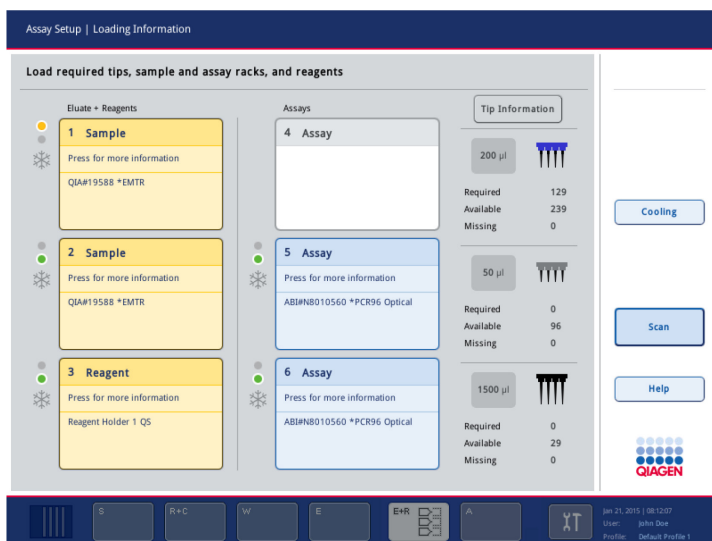
**Note:** This action can also be performed for completed QIAasymphony SP batches, allowing automated assay setup of samples for which purification has already been completed.

### 13.3.2 Loading an integrated run

First, load the QIAasymphony SP. Then load the QIAasymphony AS. (Optional: Load the QIAasymphony AS when the QIAasymphony SP is running).

This section outlines how to load samples, reagents and consumables onto the QIAasymphony AS.

In addition, the **Loading Information** screen provides an overview of which labware, consumables and adapters are required for a run. The number and type of filter-tips that are required is displayed. Press a particular slot for more detailed information.

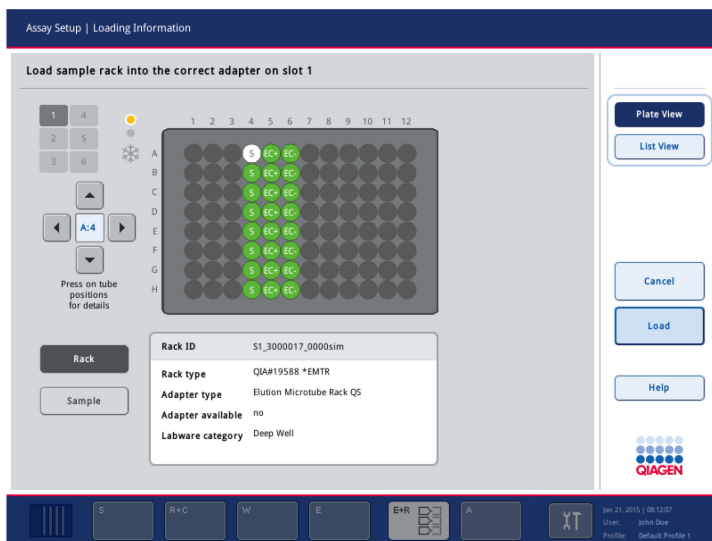


## Viewing sample racks

### Sample slots

Press a sample slot for detailed loading information. A schematic diagram of the sample rack appears. Press an individual position to view information about a particular sample. You can also use the arrows to select a position. When **Sample** is pressed, the sample ID, sample type, status, and sample volume are displayed, as well as the assay to which this sample has been assigned.

To view information about all of the samples in the sample rack in tabular format, press **List View**.

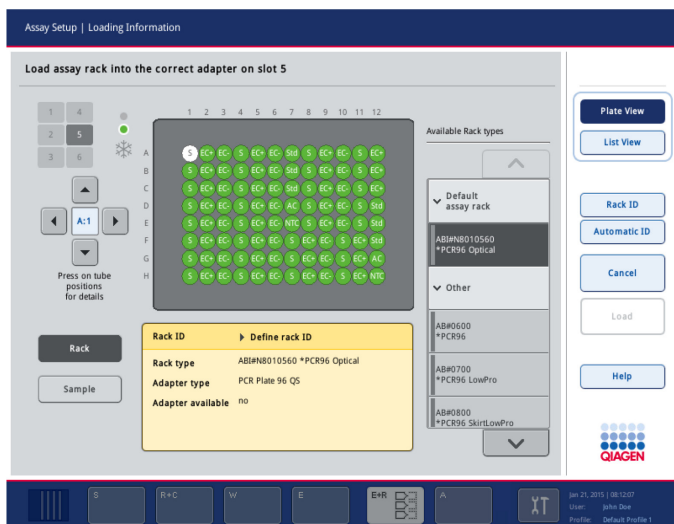


**Note:** The sample rack is transferred from the QIAAsymphony SP to the QIAAsymphony AS. Therefore, the sample rack does not need to be loaded onto the QIAAsymphony AS for an integrated run.

## Loading assay rack(s)

### “Assay” slots

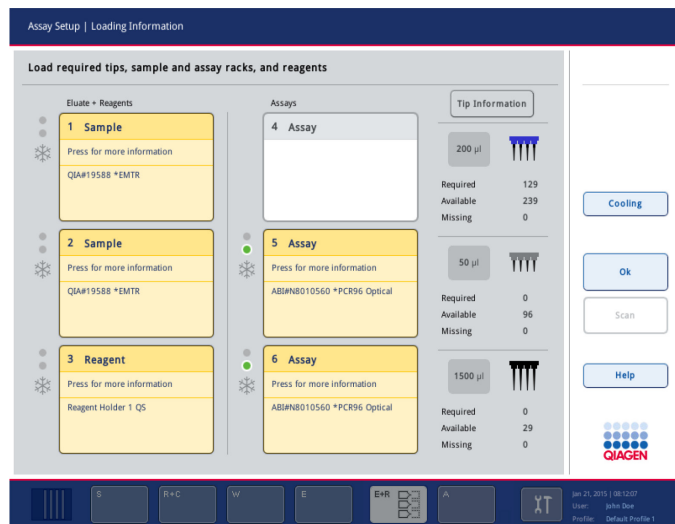
Press an assay slot for detailed loading information. A schematic diagram of the assay rack appears. Press an individual position to view information about the sample at that position. You can also use the arrows to select a position. When **Sample** is pressed, the sample ID, sample type, status, and volume are displayed, as well as the assay to which this sample has been assigned.



To view information about all of the positions in the assay rack in tabular format, press **List View**.

### Assay racks

The required number of assay rack(s) is calculated by the software. The maximum number of assay racks is 3.

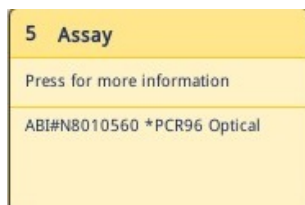


**Loading information screen with assay racks assigned to slot 5 and 6.**

“Assay” slots are assigned automatically by the software, the assignment cannot be changed by the user. The assignment depends on the processing workflow. Slot 5 is processed first, then slot 6, and then finally slot 4.

### Assigning assay racks

1. Open the “Assays” drawer. Temporary cooling for the defined slots is started.
2. In the “Assay Setup/Loading information” screen, press the first “Assay” slot to be loaded (highlighted yellow). Detailed loading, information for the slot is shown.



3. Assign rack ID.



A rectangular button with rounded corners, light blue background, and a thin blue border. The text "Automatic ID" is centered in a blue, sans-serif font.

4. Place the cooling adapter with empty strip tubes (without caps) on the correct "Assay" slot.

Ensure that the appropriate adapter is used with each assay rack.

5. Press **Load**. The **Assay Setup/Loading information** screen appears again. The loaded slot is now blue.

A rectangular button with rounded corners, light blue background, and a thin blue border. The text "Load" is centered in a blue, sans-serif font.

6. If more assay racks have to be loaded, repeat steps 2–5 for the second assay slot.
7. Leave the "Assays" drawer open to enable loading of disposable filter-tips.

**Note:** The required amount of strip tube segments (each consisting of four strip tubes) and corresponding positions will be displayed. Ensure that the correct positions are used. The positions will not be checked during the inventory scan.

### Assigning assay rack ID(s)

The assigned assay rack ID will be used to create a rack file. The name of the rack file is "RackFile\_rack ID".

**Note:** Be aware that some symbols may not be used in the rack file name and some symbols will be converted.

To assign rack IDs, follow the steps below.

1. Press **Rack ID**.

A rectangular button with rounded corners, light blue background, and a thin blue border. The text "Rack ID" is centered in a blue, sans-serif font.

The **Manual Input** screen appears.

Manually enter an assay rack ID. Alternatively, use the bar code scanner to enter a rack ID.

The entered assay rack ID will appear in the corresponding "Assay" slot and the slot will now appear blue.

2. Press the Automatic ID button. The software will automatically assign an ID with the format "SlotNr\_RunID\_Suffix" (e.g., S5\_1000017\_0000).

A rectangular button with rounded corners, light blue background, and a thin blue border. The text "Automatic ID" is centered in a blue, sans-serif font.

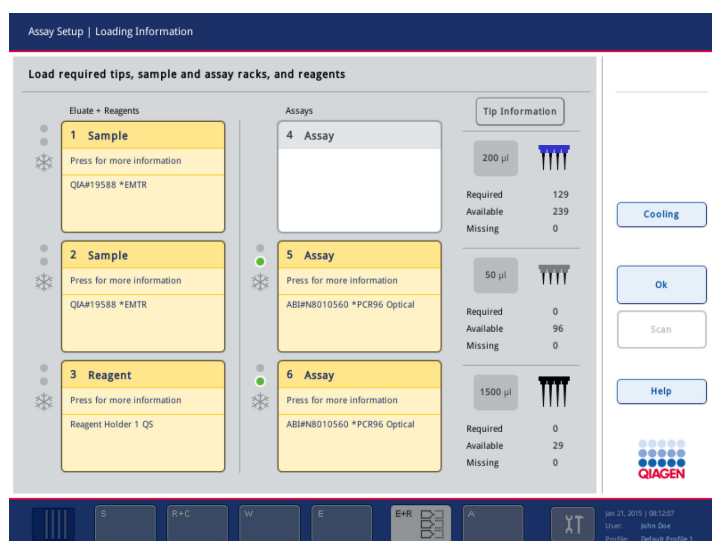
A rack ID is automatically assigned to the selected "Assay" slot(s) and the slot(s) will now appear blue.

### Loading reagent slots

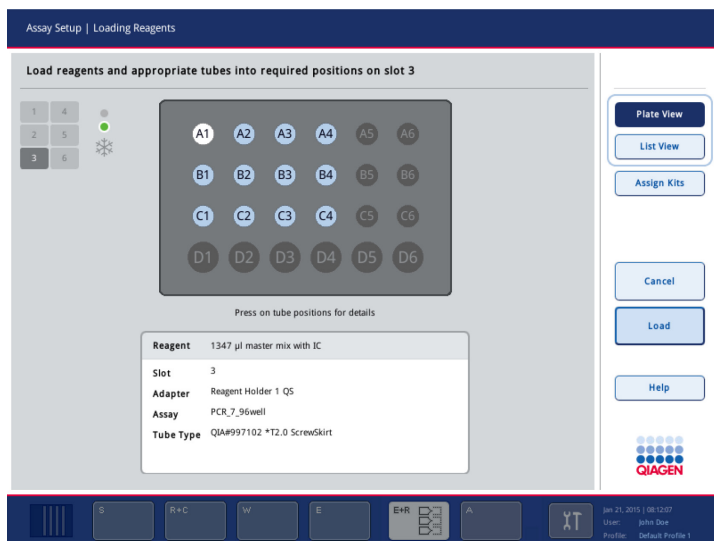
**Note:** Ensure that the correct labware is used. Use of labware that is different from that defined in the **Loading Information** screen may result in an error during preparation or transfer of the master mix. This could result in damage to the QIAasympy AS.

To load a reagent adapter with reagents, follow the steps below.

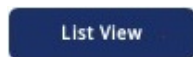
1. Open the “Eluate and Reagents” drawer.
2. In the **Assay Setup/Loading information** screen, press the “Reagent” slot (shown in yellow). The detailed loading information for the slot is shown.



3. Place the appropriate precooled reagent adapter onto the defined "Reagent" slot.
4. Press the "Reagent" slot(s) to view detailed information about the required reagents, tubes, and corresponding volumes. The **Loading Reagents** screen appears. A schematic of the reagent adapter that will be used is displayed on the screen.



5. Press an individual position to view loading information for that particular position. The position will change from blue to white and detailed information about the reagent, tube type, and volume for that position on the adapter will be displayed in the table.
6. To view loading information about all reagents for a particular assay, press **List view**.



7. Load the required reagents and empty tubes in the defined positions.
8. Press **Load**.



The **Assay Setup/Loading information** screen appears again. The loaded slot is now shown in blue.

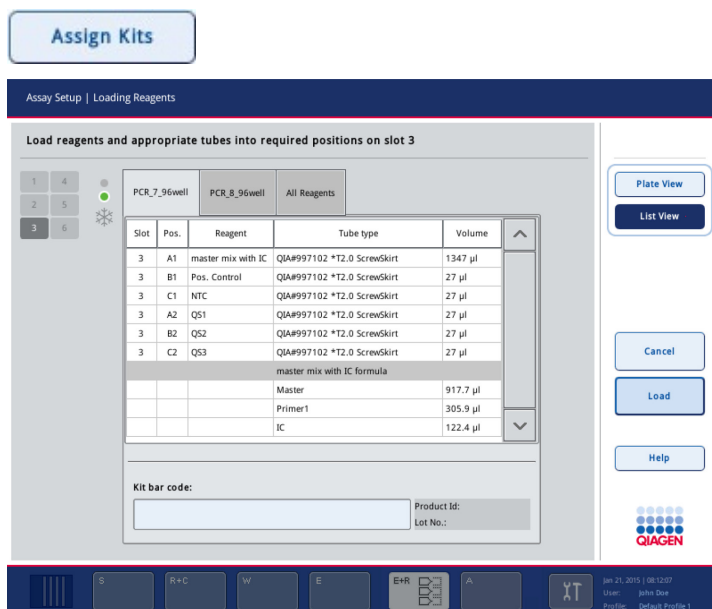
9. If a second reagent rack has to be loaded, repeat steps 1–10 for the second “Reagent” slot.
10. Leave the “Eluate and Reagents” drawer open to enable loading of disposable filter tips.

#### Entering reagent kit bar codes

The Assign Kits button includes an exclamation mark when the kit bar code is not assigned. To enter a reagent kit bar code for each assay, follow the steps below.

1. Switch to **List View**, or press the **Assign Kits** button.





2. Press the **Kit bar code** field.
3. Manually enter the bar code, or enter a bar code using the bar code scanner.
4. Press **OK** to return to the **Loading Reagents** screen. If the bar code scanner was used, the **Loading Reagents** screen will automatically reappear.
5. The software validates the kit bar code of known format and checks the lot number and expiration date.

**Note:** Entered kit bar codes, including additional information (i.e., expiration date, product number and lot number), are tracked in the result file.

Note: For QIAGEN kits, do not mix kits with different lot numbers in one run.

### Loading disposable filter-tips

Up to 6 tip racks can be placed in the "Eluate and Reagents" drawer and the "Assays" drawer (i.e., a total of 12 tip racks). Tip rack position, tip type and number of tips are detected during the inventory scan. The number of tips required varies depending on the assay(s) being run.

Three different types of disposable filter-tips can be used on the QIA Symphony AS — 50 µl, 200 µl and 1500 µl. Tip information is displayed on the right side of the **Loading Information** screen. For each tip type, the number of required, available, and missing tips is listed.

We recommend that you load more tips than the actual number of required tips calculated by the software. Filter-tip consumption can be affected by some processes

on the QIAAsymphony AS (e.g., liquid-level detection). In addition, we recommend to load tips preferably in rear tip rack slots. For more information about tip loading press the Tip Information button.

**Important:** For FDA cleared or approved nucleic acid tests, use tip rack positions 1, 2, 3, 7, 8 and 9 in the QIAAsymphony AS drawers (see figure, page 212).

Tip Information	
200 µl	
Required	0
Available	122
Missing	0
50 µl	
Required	0
Available	96
Missing	0
1500 µl	
Required	0
Available	29
Missing	0

**Note:** The number of individual tips is displayed, and not the number of tip racks (one tip rack contains 32 tips).

**Note:** The number of available tips is calculated by the software based on the previous run and inventory scan. If the number of available tips does not correspond with the number of required tips, a message will appear during the inventory scan.

To load a disposable filter-tip rack, follow the steps below.

1. If not already open, open the “Eluate and Reagents” and/or the “Assays” drawer.
2. Hold the tip rack with 2 fingers, using the grips.
3. Gently squeeze the tip rack and place it into a tip rack slot.

**Note:** Ensure that the tip racks are properly seated in the tip rack slot and the plastic protrusions are not damaged so that the tip racks will be identified during the inventory scan.

**Important:** For FDA cleared or approved nucleic acid tests, use tip rack positions 1, 2, 3, 7, 8, and 9 in the QIAAsymphony AS drawers (see figure, page 212).

### 13.3.3 Checking cooling temperatures (optional)

Cooling temperatures are shown in an overview screen.

Press the **Cooling** button in the **Loading Information** screen. The **Temperature Status** screen appears.

The QIASymphony AS automatically starts cooling after the adapters have been loaded virtually on the touchscreen. The current temperature of the cooling positions is updated in real time. If the current temperature is outside the target temperature, the slot will appear yellow. If the current temperature is within the target temperature the slot will appear green.

The target temperature is defined in the assay definition and cannot be changed using the touchscreen.

The cooling settings for "Sample", "Reagents" and "Assay" slots can be switched on, if the rack is not yet loaded (precooling).

**Note:** The temperature of the cooling positions throughout an assay run is documented in the result file.

To switch cooling on, follow the steps below.

1. Press the snowflake button to the left of the cooling position to be switched on.

Cooling for that position will be switched on, and the slot will appear black.



2. To switch cooling off again, press the snowflake button to the left of the cooling position to be switched off.

The snowflake button will appear gray.

**Note:** If a rack is loaded, cooling cannot be switched off.

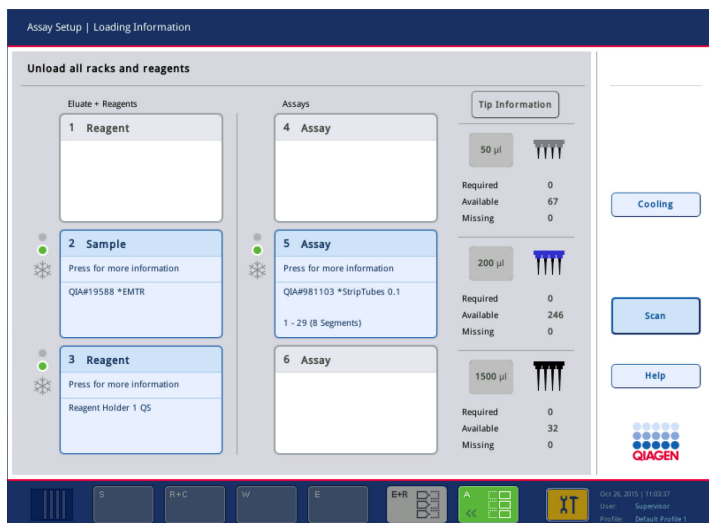
### 13.3.4 Removing assays after an AS run

When an assay run is completed or canceled, the assays must be removed from the "Assays" drawer. The assays will not be automatically removed from the QIAAsymphony AS.

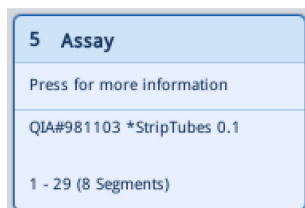
If the status of a run is shown as "Queued", "Stopped", or "Completed", the assay rack(s) and adapter(s) can be removed.

1. Open the "Assays" drawer.

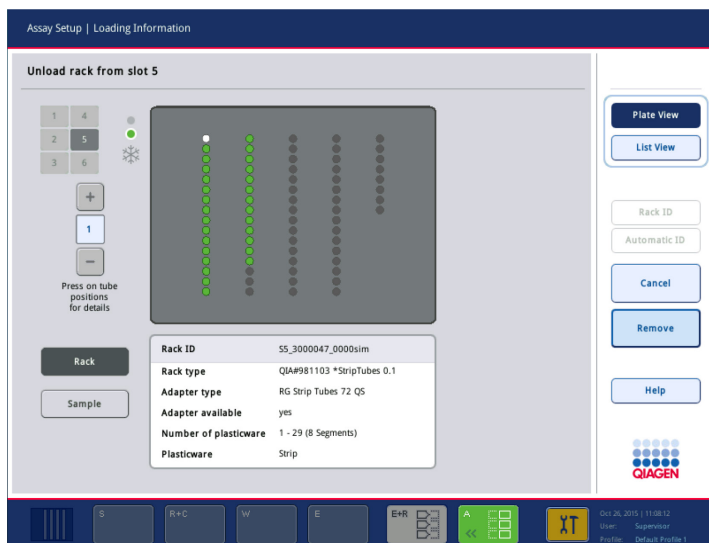
The **Assay Setup/Loading Information** screen appears.



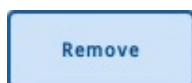
2. Press the first assay rack to be removed.



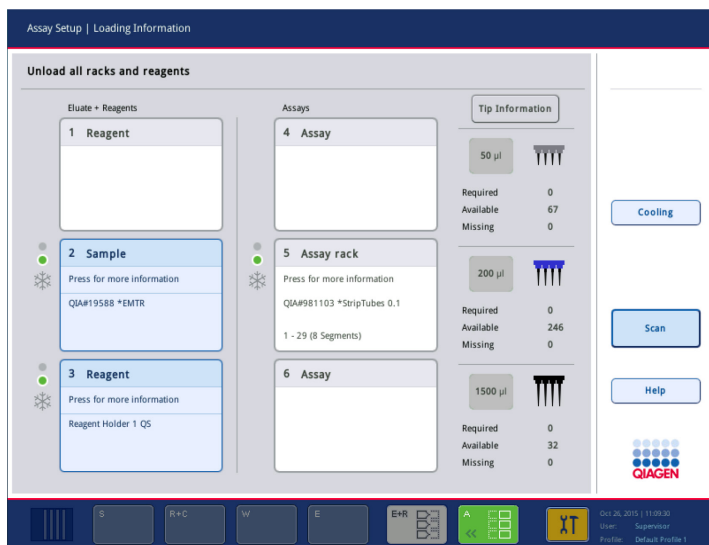
The detailed screen for the slot appears.



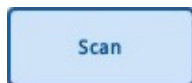
- Press **Remove** and unload the rack.



The **Assay Setup/Loading Information** screen appears again. The "Assay" slot now appears white and slot cooling is turned off.



- Close the "Assays" drawer. Press **Scan**. A dialog box appears.



Do you want to start the inventory scan?

71702

Tip Racks left	<b>Yes</b>	No
Tip Racks right	<b>Yes</b>	No
Adapters left	<b>Yes</b>	No
Adapters right	<b>Yes</b>	No
Reagents LLD	<b>Yes</b>	No

**Scan** **Cancel**

5. Select **Yes** for **Adapters right** only.
6. Press **Scan**.

### Unloading the worktable

After the inventory scan is performed, the **Assay Setup/Loading Information** screen appears again.

Proceed as follows:

1. Open the "Eluate and Reagents" and "Assays" drawers. The Loading Information screen appears.
2. Press a sample rack to be removed.

**2 Sample**

Press for more information

SAR#72.694 \*T2.0 ScrewSkirt

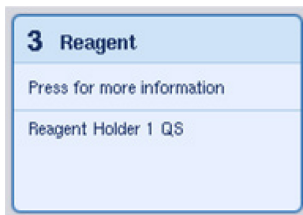
The detailed screen for that slot appears.

3. Unload the selected sample rack from the drawer and then press Remove in the touchscreen.

**Remove**

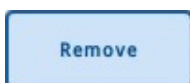
If there is a second sample rack, repeat this process for the other rack.

- Press a reagent rack to be removed.



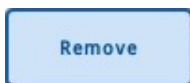
The detailed screen for that slot appears.

- Unload the reagent rack from the drawer and then press Remove in the touchscreen.



If there is a second reagent rack, repeat this process for the other rack.

- Remove empty tip racks.



- Empty the tip disposal bag.
- Close the drawers and press Scan to perform an inventory scan.



When the inventory scan is complete, the Assay Setup/Overview screen appears.

Status	Run ID	Assay	Destination	Time
COMPLETED	3000082	Demo_SV40_Training Independent	Slot 5	00:00:13h

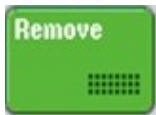
  

Elate + Reagents	Current Temperature	Target Temperature
Slot 1	--	--
Slot 2	4.6°C	4.0°C
Slot 3	4.6°C	4.0°C

Assays	Current Temperature	Target Temperature
Slot 4	--	--
Slot 5	4.6°C	4.0°C
Slot 6	--	--

9. Press Remove in the Assay Setup/Overview screen



If more QIAAsymphony AS runs are to be performed, proceed with loading the next QIAAsymphony AS run.

**Note:** The loading instructions for the next QIAAsymphony AS run are already displayed. It is possible but not necessary to proceed with loading the next batch now.

**Note:** In integrated mode, the sample rack staying in the QIAAsymphony SP cannot be removed in this step.

### 13.3.5 Procedure after run completion

After the inventory scan is performed and the **Assay Setup/Loading Information** screen appears again, follow the steps below.

**Note:** The integrated run must be removed on the touchscreen otherwise the “Eluate” drawer is not accessible.



#### QIASymphony AS

1. Remove the elution rack, including adapter, from the "Eluate" drawer.
2. Remove the reagent tubes including adapter(s).
3. Replace the tip disposal bag after each run.

#### QIASymphony SP

1. Remove consumables, reagent cartridges and buffer bottle.  
**Note:** Be sure to seal reagent cartridges with Reuse Seal Strips. Store partially used reagent cartridges according to the Instruction for Use (Handbook) of the assay you are using.
2. Empty the liquid waste container.
3. Unload the unit boxes from the "Waste" drawer.
4. Unload elution rack.

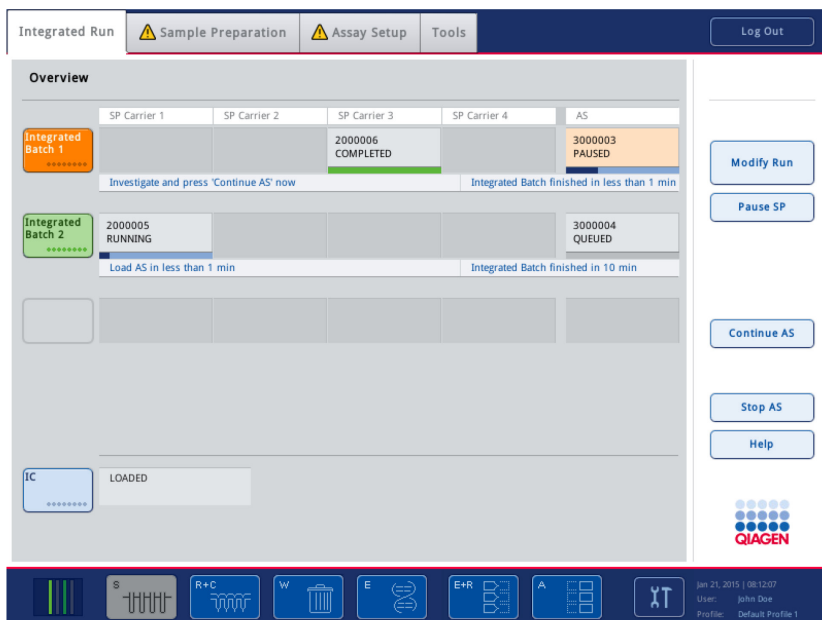
### 13.3.6 Pausing, resuming, and stopping an integrated run

#### Pausing a QIASymphony SP or a QIASymphony AS run

A run on the QIASymphony SP or the QIASymphony AS can be paused by pressing the **Pause SP** or **Pause AS** button in the **Integrated Run** screen. If a QIASymphony SP or a QIASymphony AS run is paused, the pipetting step is completed before the run pauses.

The screen below is displayed when the **Pause SP** or **Pause AS** button is pressed.

**Note:** Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.



If the run is paused, two options are available: the run can be resumed or stopped.

**Note:** Pausing a run interrupts the sample preparation or assay setup procedure and may affect the performance.

**Note:** Only pause a run in an emergency.

**Note:** Processed samples will be flagged as “unclear” as soon as the QIAAsymphony SP or QIAAsymphony AS is paused and the run is resumed.

**Note:** Pausing a run will result in all samples being flagged as “unclear”. For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all “unclear” samples.

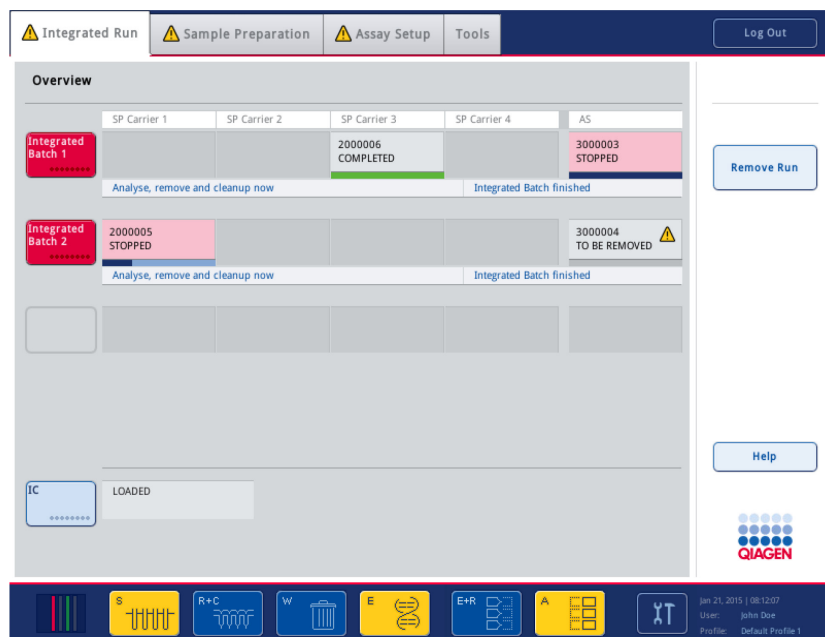
### Resuming a run

To resume a run, press the **Continue SP** or **Continue AS** button. Processed samples will be flagged as “unclear” as soon as the QIAAsymphony SP/AS is paused and continued.

**Note:** Pausing a run will result in all samples being flagged as “unclear”. For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all “unclear” samples.

## Stopping a run

If a QIAasymphony SP or QIAasymphony AS run is paused, press the **Stop SP** or **Stop AS** button to stop the integrated run. On pressing **Stop SP**, all batches currently being processed will be stopped, although AS batches previously started will be completed. On pressing **Stop AS**, all SP batches currently being processed will be completed.



If the run is stopped, all processed samples are flagged with "invalid". It is not possible to process these samples further.

After stopping a QIAasymphony SP or a QIAasymphony AS run or if the run stops due to an error, the buttons of the affected drawers flash. Press the flashing button(s) to display the warning or error messages.

## 13.4 Performing inventory scans (AS)

An inventory scan of each drawer of the QIAsymphony AS must be performed before an assay run can be started. This is performed in the same way as for the QIAsymphony SP drawers.

### 13.4.1 Inventory scan of “Eluate and Reagents” drawer

The inventory scan of the “Eluate and Reagents” drawer consists of the following steps in the following order:

1. Bar codes of slots 1–3 or bar codes of adapters on slots 1–3 are scanned.

**Note:** For a particular slot, either the bar code of the slot is scanned or, if an adapter is present on the slot, the bar code of the adapter is scanned.

- Bar codes of slots 1–3 are scanned to determine whether the slots are empty or occupied.
- Bar codes of adapters on slots 1–3 are scanned to determine whether a particular adapter type is present on a particular slot.
- If the expected and current status of the slots/adapters do not match, a message will appear to prompt the user to correct the problem.

**Note:** The QIAsymphony AS is not able to identify the type of consumables on the adapter. It is therefore important that the correct plates/tubes are loaded on the adapters, as defined in the software.

2. Tip rack slots are scanned.

- The disposable filter-tips are scanned to ensure that the correct tip type has been loaded and that there are sufficient filter-tips available for the defined assay run.
- If a tip is detected in the first and last position of the tip rack, the tip rack will be categorized as full. If the first or last tip is missing, a full scan will be performed to determine the number of tips in the tip rack.
- If there are not enough filter-tips of the correct type available, a message will appear on the touchscreen prompting the user to load more tips.

## Partial inventory scan

If you need to repeat an inventory scan for the “Eluate and Reagents” drawer (e.g., if a change has been made on the worktable), you can perform a partial inventory scan. You can choose to scan the following worktable items separately:

- Tip Racks left
- Tip Racks right
- Adapters left
- Adapters right
- Reagents LLD

71702

Do you want to start the inventory scan?

Tip Racks left	<input type="button" value="Yes"/>	<input type="button" value="No"/>
Tip Racks right	<input type="button" value="Yes"/>	<input type="button" value="No"/>
Adapters left	<input type="button" value="Yes"/>	<input type="button" value="No"/>
Adapters right	<input type="button" value="Yes"/>	<input type="button" value="No"/>
Reagents LLD	<input type="button" value="Yes"/>	<input type="button" value="No"/>

### 13.4.2 Inventory scan of the “Assays” drawer

The inventory scan of the “Assays” drawer is performed on slots 4–6 as for slots 1–3 of the “Eluate and Reagents” drawer.

If an inventory scan of the “Assays” drawer needs to be repeated, it is also possible to perform a partial inventory scan where tip racks and adapters can be scanned separately.

After the inventory scan has been performed, the inventory of the QIA Symphony SP/AS instruments is updated. The system switches off temporary cooling for the slots and switches on cooling for loaded slots.

**Note:** The inventory scan must be performed before a run can be started.

For information about the inventory scan, see Section 9.5.

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### 13.4.3 Transfer to a PCR cycler

After assay setup, assays are removed from the QIAasymphony AS and are manually transferred to the Rotor-Gene Q MDx for detection. Result files can be exported from QIAasymphony SP/AS instruments to the Rotor-Gene Q MDx.

## 14 Instrument Troubleshooting

### 14.1 Error messages and warnings

If a problem occurs during operation of the QIAasympphony SP and/or AS, an error message or warning will appear on the touchscreen. More information about the different symbols that may occur in error messages is provided below.

#### 14.1.1 Messages

During operation of the QIAasympphony SP/AS instruments, messages may appear that provide the user with general information, inform the user that operator input is required, or provide information about warnings and errors. Each type of message contains a symbol for easy identification by the user.



This symbol is displayed if the message contains information about an error.



This symbol is displayed in warning messages.



This symbol is displayed if input by the user is required.



This symbol is displayed if the message provides the user with information.

If the error has an error code it is displayed on the left side of the message, below the error symbol (see below). The error message is displayed in the middle of the dialog box.



### 14.1.2 Errors indicated in the status bar

In some cases, errors are indicated by the drawer buttons flashing yellow in the status bar. Press the flashing button to view the error message and follow instructions.



### 14.1.3 Errors indicated in the tab headers

The different tab headers support an error indicator within the tab. Thus, in some cases, errors are indicated by a warning sign icon next to the tab header name.

### 14.1.4 Errors indicated in the command bar

In case of an error, a warning sign icon will be displayed within the menu button affected, next to the name.

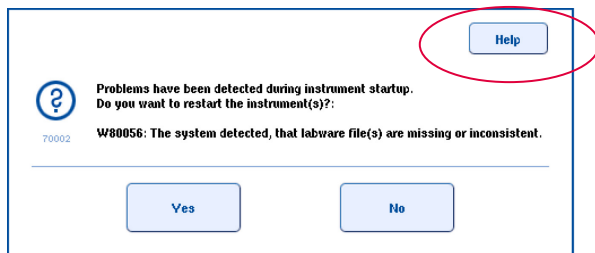
Switch to the affected tab, or press the command bar button concerned, for an overview of the error situation within the dialog.

### 14.1.5 Messages with **Help** button

If a message appears with a **Help** button, the user has access to instructions about how to solve the problem.

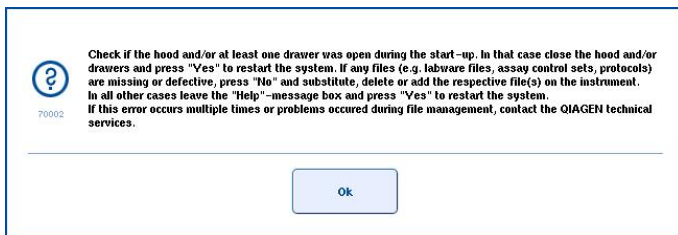
Proceed as follows:

1. Press the **Help** button. A new message will appear.



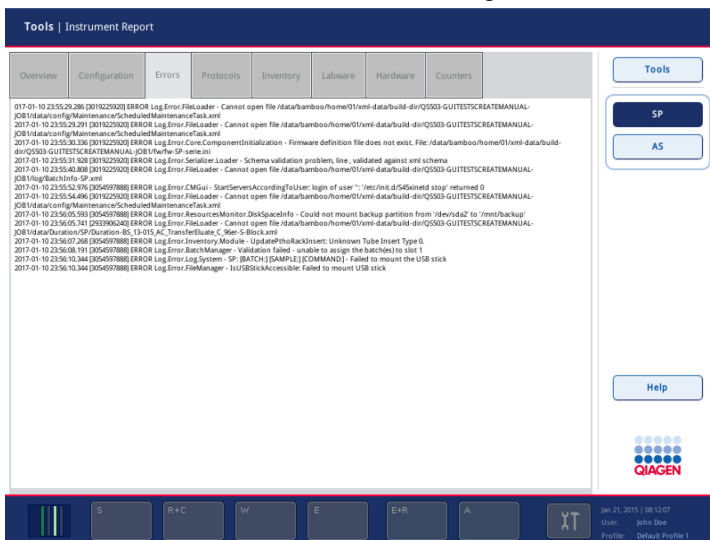
2. Carefully read the instructions and then press **OK**.





3. Close the message and follow the instructions.

**Note:** To read the message again, select **Instrument Report** in the Tools screen. Then select the **Errors** tab. Recent error messages will be listed there.



#### 14.1.6 Messages without **Help** button

If a message appears that does not have a **Help** button, perform one of the following:

- Confirm the message and then follow the instructions that were outlined in the message.
- If the message has an error code, follow the instructions listed in Section 14.4, Section 14.5, Section 14.6 and Section 14.7.

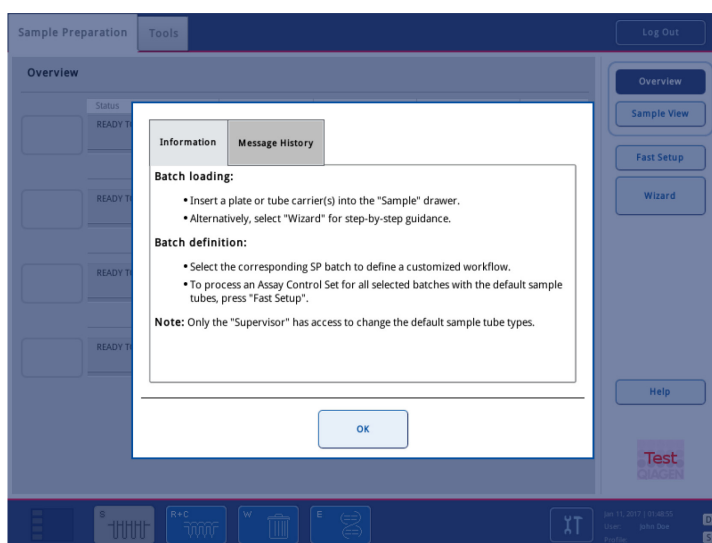
**Note:** If a message appears that has an error code that is not listed, contact QIAGEN Technical Services.

- If the message does not have an error code, refer to Section 14.4 for context-specific errors and associated instructions.
- Call QIAGEN Technical Services if recommended or required.

## 14.2 Software help boxes

In order to assist and guide the user, the QIAasymphony SP/AS provides a software help for all screens.

To access the software help texts, press the **Help** button in the command bar, which appears in all screens. Pressing this **Help** button will open a dialog in front of the actual screen. The displayed text within the help message gives advice on how to handle the current screen. To return to the original screen, press **OK** inside the help dialog.



**Help dialog.**

### 14.2.1 Structure of software help boxes

A help box consists of a maximum of 5 different tabs (in the following sequence): **Errors**, **Information**, **Instruction**, **Check List**, and **Message History**.

#### **Errors**

Displays additional information on dialog content that is marked as erroneous. The tab filters the information for selected positions, if they exist.

#### **Information**

Displays notes about the screen's behavior and/or information about the screen's view. The help text describes options for the user in context.

<b>Instruction</b>	Shows a detailed description of the steps the user will need to execute.
<b>Check List</b>	Includes a selection of different topics the user may check for the actual context. The particular checks described within the checklist do not need to be rigorously executed.
<b>Message History</b>	All last messages can be viewed again by selecting the respective message.

**Note:** A software help dialog may consist of fewer than the 5 types of text.

## 14.3 Contacting QIAGEN Technical Services

If an error persists and you need to contact QIAGEN Technical Services, make a record of the incident and create an instrument report file.

### 14.3.1 Make a record of the incident

1. Note down all steps that were performed before and after the error occurred.
2. Document any messages that appeared on the touchscreen.

**Note:** It is important that you can tell us the error code and the associated text. This information will help the QIAGEN Field Service Specialist and Technical Services to resolve the error.

**Note:** In some cases the software does not list the error message on the touchscreen. The error is documented in the system log file either for the QIAsymphony AS or QIAsymphony SP.

**Note:** It is possible to view the last message in the Help dialog, Message History.

3. Note the date and time at which the error occurred.
4. Provide a detailed description of the incident. For example, provide a photograph of the worktable and record the following information:
  - Where on the QIAsymphony SP/AS instruments did the error occur?
  - In which step of the protocol did the error occur?
  - What was observed (e.g., has something broken, are tips or sample prep cartridges in unusual places on the worktable?) and what was expected?
  - Was there any unexpected noise?

5. In addition, if relevant, provide the following information.

- If tips were lost during pipetting, provide the lot number and tip type.
- Were tip racks manually refilled?
- Which reagent adapter, including manufacturer and ordering number, was used?
- Which sample and eluate racks, including manufacturer and ordering number, were used?
- Which assay rack, including manufacturer and ordering number, was used?

### 14.3.2 Creating an instrument report file

If you are requested by QIAGEN Technical Services to create an instrument report file, proceed as follows:

1. Log in to the instrument(s).
2. Select **Instrument Report** in the **Tools** menu. The **Overview** tab of the **Instrument Report** menu appears and instrument data will be retrieved.

Tools | Instrument Report

Overview Configuration Errors Protocols Inventory Labware Hardware Counters

**QIASymphony SP and AS**

Serial number: 0000sim ; 0000sim      Software version: 5.0.3 (development)  
Free memory: 2176.6 MB ; 2176.4 MB      Free disk space: 0.0 MB

**Contact information for Technical Service**

If you need technical assistance, contact QIAGEN Technical Service. Local contact information for your time zone (Europe/Zurich) is Techservice-eu@qiagen.com. For telephone support contact your local Technical Service hotline.

**Create instrument report files**

To create an instrument report file to send to QIAGEN Technical Service that includes data from the past X days, enter the number X below, and press "Create". To save the resulting instrument report file directly to the USB stick, insert the USB stick and press "Create + Save To USB" instead of "Create".

Number of days:            

Jan 21, 2015 08:10:07  
User: John Doe  
Profile: Default Profile 1

3. To create an instrument report for the QIASymphony SP, select **SP**. To create an instrument report for the QIASymphony AS, select **AS**.
4. Enter the number of days for which you want the instrument report file to cover.
5. Press **Create**, or to save the file directly to the USB stick, insert the USB stick and then press **Create + Save to USB**.

To download all instrument report files to the USB stick, see Section 7.3.2. Instrument report files can also be downloaded using the QIASymphony Management Console (see Section 22).

**Note:** If an instrument incident (i.e., problem, crash, etc.) occurs, generate an instrument report file and ensure that all files and information are available for QIAGEN Technical Services.

## 14.4 General errors that do not have error codes

Error	Comments and suggestions
The startup screen does not appear and the status LEDs are not illuminated.	Contact QIAGEN Technical Services.
Error occurs during an assay run.	An assay run was in progress on the QIAsymphony AS and an error occurred. The QIAsymphony SP/AS instruments must be switched off. Upon restarting the instruments, it is not possible to continue with the assay run or a protocol that was in progress at the same time on the QIAsymphony SP.
Error occurs during a protocol.	If a protocol was in progress on the QIAsymphony SP and an error occurs, the QIAsymphony SP/AS instrument must be switched off. Upon restarting the instruments, it is not possible to continue with the protocol or an assay run that was in progress on the QIAsymphony AS.

### 14.4.1 File handling errors

Error	Comments and suggestions
USB stick or other USB device was not recognized.	Only use the USB stick provided with the QIAsymphony SP. Try connecting the USB stick to the other USB port. Restart the QIAsymphony SP/AS instruments.  <b>Note:</b> For file transfer, use the QIAsymphony Management Console.
Signature invalid/Invalid checksum.	During file transfer via a USB stick, the new files are loaded again. If a file (e.g. Assay Control Set, Assay Parameter Set) is unsigned, an error message will be displayed ("signature

Error	Comments and suggestions
	invalid" or "invalid checksum"). However, the name of the invalid file is not given. The newly transferred file could be invalid, but this is not necessarily the case. Check the validity in the QIASymphony Management Console. Delete any unsigned files. Do not delete other file types.

#### 14.4.2 File errors

##### General file errors

Error	Comments and suggestions
File not transferred.	Check that the file is in the correct folder on the USB stick.
Invalid checksum.	Ensure that the file was created by QIAGEN, the QIASymphony SP/AS instruments, or using the QIASymphony Management Console.

##### Rack file errors

Error	Comments and suggestions
Rack file could not be loaded.	<p>Ensure that the rack file has been uploaded to the QIASymphony SP/AS instruments.</p> <p>Check the parameter <b>Ready for AS</b>. This parameter should be set to <b>Yes</b>.</p> <p>If it is not set to <b>Yes</b>, the rack file must be modified. To do this, convert the *.xml file to *.csv format using the <b>CSV Conversion</b> tool of the QIASymphony Management Console. Then, correct the parameter using Microsoft Excel or Notepad. See Section 7.10 for more information.</p>

Error	Comments and suggestions
Rack file contains wrong labware.	<p>Ensure that the racks/tubes and adapters that are written in the rack file are compatible with the QIAAsymphony SP/AS instruments. For a full list of compatible racks and adapters, refer to the Instructions for Use (Handbook) for the assay you are using.</p> <p>Ensure that the names of the racks and adapters are correctly spelled and that there are no incorrect blanks at the beginning or the end of the names.</p>
Sample positions are incorrect.	<p>For a user-generated rack file convert the *.xml file back to *.csv format using the <b>CSV Conversion</b> tool of the QIAAsymphony Management Console. Correct the positions of the samples using Microsoft Excel or Notepad.</p> <p>Ensure that the correct rack file is selected.</p>
Rack file could not be found.	<p>Ensure that the correct rack file has been transferred to the QIAAsymphony SP/AS instruments.</p> <p>Ensure that the correct rack file has been transferred to the QIAAsymphony SP/AS instruments before starting assay definition.</p> <p>The rack file must be in a format that can be recognized by the QIAAsymphony SP/AS instruments (i.e., *.xml). Ensure that the rack file has been converted from *.csv format to *.xml format using the <b>CSV Conversion</b> tool of the QIAAsymphony Management Console.</p>
Content of system generated file is wrong.	<p>Check whether actualization is correct.</p> <p>Ensure that no errors occur during the process.</p>

## Work list errors

Error	Comments and suggestions
Work list could not be found.	<p>Ensure that the correct work list has been transferred to the QIAsymphony SP/AS instruments before starting assay definition.</p> <p>Ensure that the work list has not expired and has been converted to *.xml format using the <b>CSV Conversion</b> tool of the QIAsymphony Management Console.</p>
Assay list does not display expected Assay Parameter Set.	<p>Ensure that the work list has not expired. Ensure that the Assay Parameter Set(s) and Assay Definition files that are defined in the work list have been transferred to the QIAsymphony SP/AS instruments before starting assay definition.</p> <p>Ensure that the name and unique ID of the Assay Parameter Set that is defined in the work list is identical to the name and unique ID that is defined in the Assay Parameter Set.</p>

## Labware errors

Error	Comments and suggestions
The QIAsymphony AS labware is not available in the <b>Assay Setup   Sample Rack(s)</b> and <b>Assay Setup   Assay Rack(s)</b> screen.	<p>Ensure that the labware file has been transferred to the <b>Labware AS</b> folder.</p> <p>Ensure that the labware file was saved in the correct folder on the USB stick (<b>data/Labware/AS/</b>).</p> <p>Ensure that the labware file has been transferred to the QIAsymphony SP/AS instruments before starting assay definition.</p>



## Cycler file errors

Error	Comments and suggestions
Cycler file is not created or is not correct for the cycler.	<p>The QIA Symphony SP/AS instruments automatically create a cycler file when an assay run is finished. The format of the cycler file depends on the assay rack type.</p> <p>Ensure that the correct cycler file format for the assay rack(s) is defined in the Assay Parameter Set. If necessary, modify the cycler file format in the Assay Parameter Set using the Process Definition editor tool of the QIA Symphony Management Console.</p> <p>If the required assay rack format for a particular cycler file format is not available to be selected in the QIA Symphony Management Console, ensure that the available assay racks are updated in the QIA Symphony Management Console. See the <i>QIA Symphony Management Console User Manual</i> for more details about how to do this.</p>

## Result file AS errors

Error	Comments and suggestions
The final result file is not created./Only a preliminary result file is visible.	<p>The QIA Symphony SP/AS instruments create a preliminary result file when an assay run is started. The final result file is created when <b>Remove</b> is pressed at the end of an assay run.</p> <p>If using automatic transfer, check in the related folder to see if the correct printer is listed.</p> <p>Ensure that you are looking in the correct folder for the QIA Symphony SP result files or the QIA Symphony AS result files. The correct folder is log/Results/SP or log/Results/AS.</p>

Error	Comments and suggestions
Sample status.	<p>If errors/problems occur during an assay run, sample status can be affected.</p> <p>If samples were successfully processed, the sample status is "valid". If the batch was paused, the samples will be "unclear" and if, for example, cooling problems occur during a run, the sample status may be "unclear". If problems occur during master mix or sample transfer, the sample status is "invalid".</p> <p><b>Note:</b> Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.</p> <p>If, in the integrated run, a QIA Symphony SP rack file is used on the QIA Symphony AS, the sample status will only be changed if errors/problems occur during the assay run. If sample status is changed, the reason for this change will be recorded in the QIA Symphony AS result file. The message, the message ID, and the sample status is listed in the "Detailed Run Information" section of the QIA Symphony AS result file.</p>

#### Loading information file errors

Error	Comments and suggestions
The loading information file is not created or printed.	<p>A loading information file should be generated after pressing <b>Queue</b>.</p> <p>Ensure that you are looking for the loading information file in the correct folder. The correct folder is <b>\log\LoadingInformation</b>.</p> <p>If using the automatic file transfer tool of the QIA Symphony Management Console, check in the related configuration to see if the correct printer is listed.</p>

## Log file errors

Error	Comments and suggestions
General transfer problems.	Ensure that the QIASymphony SP/AS instruments are connected to the network when using the QIASymphony Management Console for file transfer.  Ensure that the USB stick is correctly plugged in.

### 14.4.3 Tip waste errors

Error	Comments and suggestions
Tips are stacking in the tip chute.	Ensure that the tip disposal bag is empty and that it is not jammed between the drawer and the workbench.
Tips are spilled in the lab.	Ensure that the tip disposal bag is correctly attached to the waste bag holder.

### 14.4.4 **Configuration** menu errors

Error	Comments and suggestions
The adapter for AS is not displayed in the configuration dialog.	Ensure that you have transferred the adapter file(s) to the <b>Labware AS</b> folder.

#### 14.4.5 Inventory scan errors

Error	Comments and suggestions
Run cannot be started because an inventory scan has to be performed.	<p>Before the user can start a run, an inventory scan of each drawer except the "Sample" drawer must be performed.</p> <p>Open and close the drawers to start the inventory scan.</p> <p>If an inventory scan has already been performed, do not open the hood before starting the run. If the hood was opened after performing an inventory scan the scan has to be carried out again.</p>
Inventory scan does not start.	<p>Ensure that the hood and all drawers are properly closed.</p>
The inventory scan of the drawers detects an adapter on "slot X" although no adapter has been placed there/Adapter bar code not readable.	<p>Ensure that the bar codes on the drawer are clean and can be easily read.</p> <p>Do not expose the QIAsymphony SP/AS instruments to direct sunlight (see Section 4.2).</p> <p>If there is an unneeded adapter on the elution slot, be sure to remove it.</p>
Consumables are not recognized correctly by inventory scan.	<p>Check that consumables (unit boxes, buffer bottle, tip racks, Accessory Trough, tip chute, etc.) are placed correctly on the corresponding drawer.</p> <p>Check that lids of unit boxes and buffer bottle have been removed.</p> <p>Only place Accessory Troughs into tip rack slots 5 and 12 (SP).</p> <p>Open and close the drawer and start the inventory scan again.</p> <p>Ensure that the tip chute is correctly installed on the QIAsymphony (SP and AS).</p> <p>Note: It is recommend to load only full tip racks.</p>

Error	Comments and suggestions
	Note: Do not refill partially used unit boxes.
Volume check of buffer bottle failed.	Make sure that the bottle contains sufficient volume of buffer.
Volume check of the Accessory Trough failed.	<p>Make sure that the Accessory Trough contains sufficient volume of ethanol. For more information, refer to the handbook of the QIAAsymphony Kit you are using.</p> <p>Perform another inventory scan of the "Reagents and Consumables" drawer.</p>
Reagent cartridge was not opened automatically by the system.	<p>Make sure that a piercing lid was attached to the reagent cartridge.</p> <p>Note: If the inventory scan detects an unopened reagent cartridge, the reagent cartridge will be opened automatically before the first use in a protocol.</p>
One or more buffers were not recognized.	Make sure that the Reuse Seal Strips have been removed from the troughs of the reagent cartridge.
The elution drawer was opened while an inventory scan was running and the Elution Rack screen cannot be exited.	The scan of the "Elution" drawer is queued and will be performed as soon as the current inventory scan has finished.
After starting and closing the "Eluate Drawer" dialog without changes, the inventory scan of the "Eluate" drawer starts.	This is the correct behavior if you open and close the hood and press No, nothing changed on the displayed message box. After this, a full scan will be performed on leaving the "Eluate Drawer" dialog without changes.

Error	Comments and suggestions
The bar code of an elution or assay rack cannot be read using the handheld bar code scanner.	<p>Make sure that the handheld bar code scanner is correctly connected to the QIAsymphony SP/AS instruments. Try to read other bar codes with the scanner. Ensure that all bar codes can be easily read.</p> <p>Check that the bar code format can be read by the handheld bar code scanner. See Appendix A for a list of compatible bar code types.</p> <p>Define the elution slot/elution rack using the touchscreen.</p>
Sample bar codes are not read properly/not detected.	<p>Only use compatible bar codes. Refer to Appendix A for detailed information about compatible bar codes.</p> <p>Be sure that bar codes can be easily read and are oriented to the left.</p>
Tube/plate carrier was not recognized during loading.	<p>Be sure to position the bar code at an appropriate height in the rack. Make sure that the bar code fits into the cut-out of the tube carrier and position the bar code at the height of the plate carrier's bar codes.</p> <p>If you are using duplicate sample bar codes do not place them next to each other in the sample carrier. In this case, place different sample bar codes between the identical ones.</p> <p>Remove the carrier and insert again more slowly.</p> <p>Remember to pause at the stop line.</p>

## 14.5 QIAsymphony SP errors that do not have error codes

### 14.5.1 "Eluate" drawer

Error	Comments and suggestions
Filter-tips are bent or deformed after eluate transfer.	Be sure to define the correct type of eluate rack on the corresponding elution slot. Make sure that the elution rack is correctly positioned on the elution slot. Only use elution racks that are compatible with the specified adapter.

Error	Comments and suggestions
Tips/channels are incorrectly positioned on the elution slot during the elution step.	Make sure to place the elution rack onto the elution slot in the correct orientation. Be sure to insert and to define the same sample tube. Only use compatible sample tubes/ racks. For more information about tubes and racks, refer to the Instructions for use (Handbook) for the assay you are using.
The "Eluate" drawer cannot be opened.	<p>The "Eluate" drawer is locked during the entire integrated run.</p> <p>If the "Eluate" drawer cannot be opened after removing the integrated run, open the <b>Maintenance</b> menu and press the <b>Drawers</b> button under <b>Unlock</b>.</p>
It is not possible to define an elution rack.	Open the "Elution" drawer and leave the drawer open while defining an elution rack.
Eluates are not in the corresponding elution rack as described in the result file.	Be sure to set up the elution rack with well A1 at the upper left corner.
After closing the "Eluate" drawer, the information about the elution rack entered by the user was not stored by the system and an error message is displayed after performing the inventory scan.	After you have entered information about the elution rack, press the <b>Add</b> button before you close the drawer so that the changes to the information are saved.

### 14.5.2 "Sample" drawer

Error	Comments and suggestions
Sample carrier locks do not release and/or bar code reader does not move forward.	Make sure that the LEDs in the "Sample" drawer are illuminated green. Be sure to insert all tube carriers with the bar codes oriented to the left. Move the carrier up to the stop line and wait. Make sure that all bar codes can be read. If this does not resolve the problem, restart the QIASymphony SP/AS instruments.

### 14.5.3 "Waste" drawer

Error	Comments and suggestions
Liquid in the "Waste" drawer.	Check that the lid of the liquid waste container has been removed. Make sure to insert the liquid waste container in the correct orientation. If the liquid waste container overflowed, contact QIAGEN Technical Services to ensure that the liquid did not cause malfunctions.
"Waste" drawer cannot be opened.	The "Waste" drawer is locked during a run and during the inventory scan. If the drawer cannot be opened after the protocol has finished, open the <b>Maintenance SP</b> menu and select <b>Drawers</b> under <b>Unlock</b> .
"Waste" drawer cannot be closed.	Make sure to place the liquid waste container in the "Waste" drawer at the right-hand side of the drawer. Remove the lid of the liquid waste container before you place it in the "Waste" drawer.



#### 14.5.4 "Reagent and Consumables" drawer

Error	Comments and suggestions
The "Reagents and Consumables" drawer cannot be opened.	<p>The "Reagents and Consumables" drawer is locked during a run and during the inventory scan.</p> <p>If the drawer still cannot be opened after the protocol has finished, open the Maintenance SP menu and select <b>Drawers</b> under <b>Unlock</b>.</p> <p>Be sure that both piercing devices/reagent cartridges have been moved to the lower position. If not, open the <b>Maintenance SP</b> menu and select <b>Piercing Device 1/2 down</b> under <b>Move</b>.</p> <p><b>Note:</b> Do not use force to open the drawer.</p>

#### 14.5.5 Errors that may occur when starting a batch/run

Error	Comments and suggestions
Run button is inactive.	Make sure that the tube carrier has been loaded and that the batch status is <b>QUEUED</b> .
One or more batches cannot be queued.	<p>The system detected 2 or more samples with the same sample ID. Make sure the sample ID is unique.</p> <p>Sample ID could not be read during loading of the tube carrier. Remove the tube carrier and reload it more slowly. Make sure that all bar codes are oriented to the left and are readable.</p>

Error	Comments and suggestions
Wrong sample IDs are shown in sample view.	<p>If two or more tube carriers are inserted:</p> <ul style="list-style-type: none"> <li>● Remove all carriers.</li> <li>● Insert a carrier and wait until the bar code camera has returned to its home position and the corresponding batch has changed state.</li> <li>● Insert remaining carriers in the same way.</li> <li>● Before inserting a new carrier, wait until the corresponding batch has changed state.</li> </ul>

#### 14.5.6 Protocol errors

Error	Comments and suggestions
Assay Parameter Set is not displayed.	Make sure that the Assay Parameter Set, Assay Control Set, Assay Definition, and Bioscript were transferred to the QIAAsymphony SP.

#### 14.5.7 Errors that may occur while operating the QIAAsymphony SP

Error	Comments and suggestions
One or more channels had a Z-drive movement error.	<p>Be sure to insert and to define the same tube. Only use compatible tubes. For more information, refer to the Instructions for Use (Handbook) for the assay you are using.</p> <p>Make sure that the tubes are properly inserted in the tube carrier/adaptor. Use an appropriately sized tube or rack for the volume.</p> <p>If filter-tips are still attached to the tip adapters, open the <b>Maintenance SP</b> menu and select <b>Cleanup</b> under <b>Cleanup</b>. Select the <b>Crash occurred</b> branch of the cleanup procedure.</p> <p><b>Important:</b> After successful cleanup, it is necessary to empty all slot positions in the "Sample" and "Eluate" drawers and restart the machine. New runs can then be started.</p>

Error	Comments and suggestions
Sample is not detected by the system and is flagged as "invalid".	Make sure the samples do not contain foam. Be sure to use at least the minimum volume of sample required for the protocol. For more information, refer to the Instructions for Use (Handbook) for the assay you are using.
Nothing happens when the <b>Cleanup</b> button in the <b>Maintenance SP</b> menu is pressed.	Check that the hood and all drawers are closed.
Lysis timer exceeded the time limit.	<p>The lysis time of the sample batch was exceeded. Do not pause the run during the lysis step.</p> <p><b>Note:</b> If another inventory scan of the "Eluate" drawer is performed after the run has started, this may result in the samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.</p>

#### 14.5.8 Protocol run interruption

Error	Comments and suggestions
System paused due to too few consumables in the "Reagents and Consumables" drawer.	<p>Open the "Reagents and Consumables" drawer and add missing items. Close the drawer and perform an inventory scan.</p> <p><b>Note:</b> Samples will be flagged as "unclear". For FDA cleared and approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.</p> <p><b>Note:</b> If one or more tip adapters cannot pick up filter-tips, contact QIAGEN Technical Services.</p>
Inventory scan of the "Eluate" drawer	Each time the "Eluate" drawer is opened and closed an inventory scan must be performed. During the scan the batch/run is paused, which leads to samples being

Error	Comments and suggestions
starts even though a batch is running.	<p>flagged as "unclear". The batch continues when the inventory scan has finished. After a successful scan of the "Eluate" drawer, the user must press Close to continue.</p> <p>Note: All drawers except the "Eluate" drawer are unlocked during an inventory scan of the "Eluate" drawer.</p>
The protocol was interrupted or stopped by the system due an error.	<p>The worktable must be cleaned up. Open the <b>Maintenance SP</b> menu and select Cleanup under <b>Cleanup</b>. Select the <b>Crash occurred</b> branch of the cleanup procedure (see Appendix E).</p> <p><b>Important:</b> After successful cleanup it is necessary to empty all slot positions in the "Sample" and "Eluate" drawer and restart the machine. New runs can then be started.</p>
The system stopped because an 8-Rod Cover or sample prep cartridge could not be released from the robotic gripper.	<p>Switch off the QIASymphony SP/AS instruments and try to remove the 8-Rod Cover or sample prep cartridge from the QIASymphony SP manually. If it cannot be removed manually, contact QIAGEN Technical Services.</p> <p>Note: Do not initialize the QIASymphony SP/AS instruments.</p>

## 14.6 QIASymphony AS errors that do not have error codes

### 14.6.1 Assay definition errors

Error	Comments and suggestions
Wrong rack file content.	<p>Ensure that the content of the selected rack file is correct.</p> <p>If the content is not correct, it can be modified using the touchscreen or the QIASymphony Management Console.</p>
Wrong rack type.	<p>If possible, return to the Sample Rack(s) screen and change the rack type. If this is not possible, press Cancel and restart the assay definition process.</p>

Error	Comments and suggestions
	If you are using a rack file, ensure that the correct rack file is selected.
Wrong volume information for the eluate rack.	<p>If the actual sample volume available is greater than the volume that was defined in the Sample Rack Layout screen, overflow may occur during aspiration.</p> <p>If the actual sample volume available is lower than the volume that was defined in the Sample Rack Layout screen, signals may be missing.</p>
Sample cannot be assigned to an APS.	<p>Samples with the status "invalid" cannot be processed on the QIAAsymphony AS and therefore cannot be selected during assay definition.</p> <p>Ensure that the sample you want to select is not "invalid".</p>
Assay list does not display expected Assay Parameter Set.	<p>Ensure that the required Assay Parameter Set(s) and Assay Definition files have been transferred to the QIAAsymphony SP/AS instruments before starting assay definition.</p> <p>Check all categories in the Available assays list for the expected Assay Parameter Sets.</p> <p>Check whether the expected Assay Parameter Set was configured for usage in Independent or Integrated mode.</p> <p>In Assay Setup/Assay Selection screen, if using a work list, switch between the Assay list and the Work list mode and check all categories in the Available assays list for the expected Assay Parameter Sets.</p> <p>Note: This only applies in Independent mode.</p>

#### 14.6.2 Errors occurring during an assay run

##### Problems with labware or with liquid spills

Error	Comments and suggestions
Liquids in adapter.	Ensure that all consumables are placed in the correct positions on the worktable. The inventory scan does not

Error	Comments and suggestions
	check whether the correct tubes/plates are placed in the corresponding adapters.
Condensation on the worktable.	Depending on the environment in the laboratory, it is possible that condensation forms on the worktable. Wipe away condensation according to the daily maintenance procedures (see Section 15.5).
Filter-tips are bent or deformed after liquid transfer.	Ensure that the correct rack type is defined on the correct slot.  Ensure that the rack is correctly positioned on the adapter.  Only use rack types that are compatible with the defined adapter.

#### Assay run interruption

Error	Comments and suggestions
The protocol was interrupted or stopped by the system due to an error.	Remove consumables from the worktable.  Any stop, pause, or interruption of a protocol will lead to samples being flagged as "unclear" or "invalid".  <b>Note:</b> Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.
Not enough liquid found.	Ensure that the correct volume is provided and that the plates/tubes and adapters as defined in the assay definition are provided.  Ensure that there are no air bubbles on the surface of the liquid.  Add more liquid.

### 14.6.3 Data analysis errors

Error	Comments and suggestions
Missing sample signal.	<p>Possible evaporation: If eluates/assays are left to stand on the QIAsymphony SP/AS instruments for a long time after a run is complete, evaporation will occur. Ensure that eluate racks and assay racks are removed immediately when a run is completed.</p> <p>Check if the eluate volume as defined in the rack file or on the touchscreen is higher than the actual eluate volume. The QIAsymphony SP/AS instruments may not be able to transfer the correct sample volumes. This may result in reduced performance.</p> <p>Fluctuations in eluate volumes: It is recommended to check the assay rack visually for differences in sample volumes. Large differences in volume indicate that the actual eluate volume differs from the expected volume and that insufficient eluate was transferred to the assay rack. If problems persist, reduce the eluate volume.</p> <p>Ensure the correct adapters and consumables, as defined for the current run, are loaded on to the worktable. Use of different consumables may result in damage to the QIAsymphony SP/AS instruments and may cause pipetting problems.</p> <p>Ensure that the assay rack and the elution rack are set up in the correct orientation, with well A1 in the upper left corner. If two elution racks are in use, ensure that the elution racks on slot 1 and slot 2 are correctly placed.</p> <p>Ensure that the correct sample tubes are loaded, as defined in the run. Only use sample tubes/racks that are compatible with the QIAsymphony SP/AS instruments. For a full list of compatible sample tubes/racks, visit <a href="http://www.qiagen.com/goto/QIAsymphony">www.qiagen.com/goto/QIAsymphony</a>.</p>

## 14.7 Integrated run errors

### 14.7.1 “Eluate” drawer

Error	Comments and suggestions
The “Eluate” drawer cannot be opened.	<p>The “Eluate” drawer is locked as soon as <b>Define Run</b> button in the <b>Integrated Run/Overview</b> is selected (see Section 13.3.1).</p> <p>It is only possible to open the “Eluate” drawer if no integrated batch is loaded or queued in the <b>Integrated Run/Overview</b> screen. To open the “Eluate” drawer, remove <b>Integrated Batch(es)</b> in the <b>Integrated Run/Overview</b> (see Section 13.3.4).</p>

### 14.7.2 Removal of an integrated run

Error	Comments and suggestions
Integrated batch cannot be removed in the <b>Integrated Run Overview</b> .	<p>To remove an Integrated run which cannot be removed in the <b>Integrated run/Overview</b>, the Assay Setup has to be manually booked out from the system (e.g., if sample preparation has finished and the AS batch cannot be started due to a previously stopped AS batch).</p> <p>To manually book out the AS batch from the integrated run, remove the AS batch by selecting the <b>Assay Setup</b> tab and press <b>Remove</b> in the Overview screen (see Section 13.3.4). After removing the AS batch, return to the <b>Integrated Run/Overview</b> and remove the Integrated run by pressing the <b>Integrated Batch X</b> button (see Section 13.3.4).</p>



### 14.7.3 Maintenance, service, and configuration

Error	Comments and suggestions
Maintenance is not accessible.	Remove loaded Integrated batches to access the <b>Maintenance</b> menu.
Service is not accessible.	Remove loaded Integrated batches to access the service menu.
Configuration is not accessible.	Remove eluate plate and scan the empty eluate drawer.

## 15 Maintenance

The table below describes the personnel required to carry out the maintenance to ensure optimal performance of your QIAAsymphony SP/AS instruments.

Type of task	Frequency	Personnel
Regular maintenance	At the end of each run	Laboratory technicians or equivalent
Daily maintenance	At the end of each day, after the regular maintenance	Laboratory technicians or equivalent
Weekly maintenance	Once per week, after the regular and daily maintenance	Laboratory technicians or equivalent
Annual maintenance and servicing	Once per year	QIAGEN Field Service Specialists only

**Note:** The safety information must be read thoroughly and understood before starting maintenance and servicing work.

### 15.1 Maintenance scheduler

The maintenance scheduler assists the user with managing all maintenance tasks. It reminds the user of tasks that are due, provides an overview of the maintenance schedule and keeps a record of the maintenance data.

Maintenance tasks can be divided into two categories:

- Regular maintenance
- Time-based maintenance

Regular maintenance procedures are event-driven tasks that must be performed after the respective event has finished. (e.g., regular maintenance SP and/or AS, regular maintenance integrated run).

Time-based maintenance procedures are time-dependent tasks that have a fixed time schedule (e.g., daily, weekly, and monthly QIAAsymphony SP/AS tasks, as well as annual maintenance). Annual maintenance can only be confirmed by QIAGEN Technical Services. All maintenance tasks from QIAGEN are classified as mandatory.

Note: It is not possible to postpone or modify a mandatory maintenance task. When a mandatory task is due, the task must be performed. Depending on the Application Process files, it is either possible to use the QIAAsymphony without flagging, with flagging, or the QIAAsymphony denies to start a run.

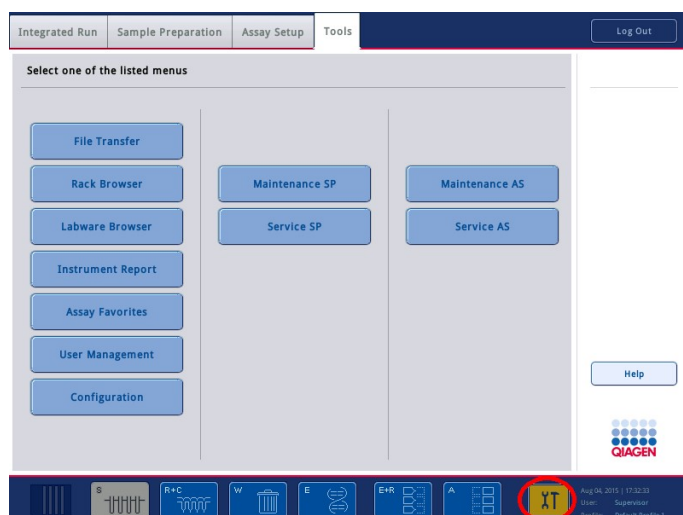
The maintenance scheduler is accessed using the Tools icon in the status bar (see image below). The Tools icon color indicates the status:



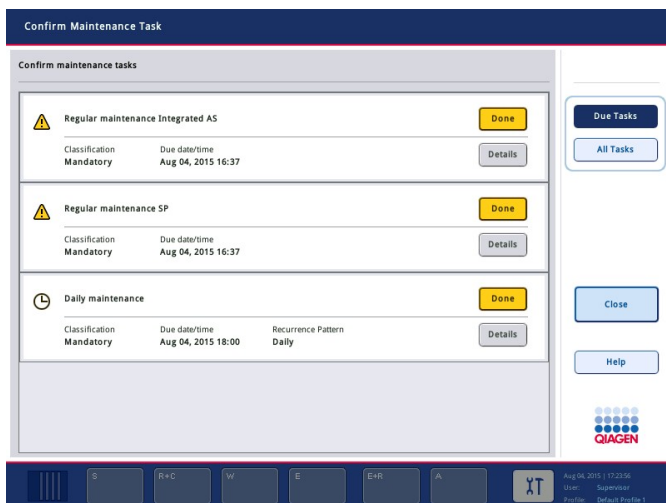
Blue: No pending maintenance tasks are due.



Yellow: One or more maintenance tasks are due.



All maintenance tasks are listed in the Confirm Maintenance Task screen with their title, classification, due date/time and their recurrence pattern. Scheduled maintenance must be confirmed upon task completion by pressing the Done button.



A confirmation can be canceled by pressing the Undo button. The Details button opens a message box listing all maintenance steps belonging to a maintenance task. The maintenance tasks are ordered with event-driven tasks listed first at the top, followed by date-driven tasks that are sorted according to their due date.

#### 15.1.1 Confirming a maintenance task

To confirm a maintenance task:

1. Press the yellow flashing Tools icon in the status bar.
2. After performing the respective maintenance, press Done. The selected task is confirmed, the background color changes to gray, the icon changes to an OK symbol and the confirmation date is displayed.

If the task is time-based, the next due date is scheduled.

Note: If you unintentionally confirm a maintenance task, press Undo to revert the task state to unconfirmed.

#### Displaying detailed steps for a maintenance task

To display all the required steps for a specific maintenance task, press the Tools icon and then press Details for a specific task. A message box is shown with a description of all necessary maintenance steps.

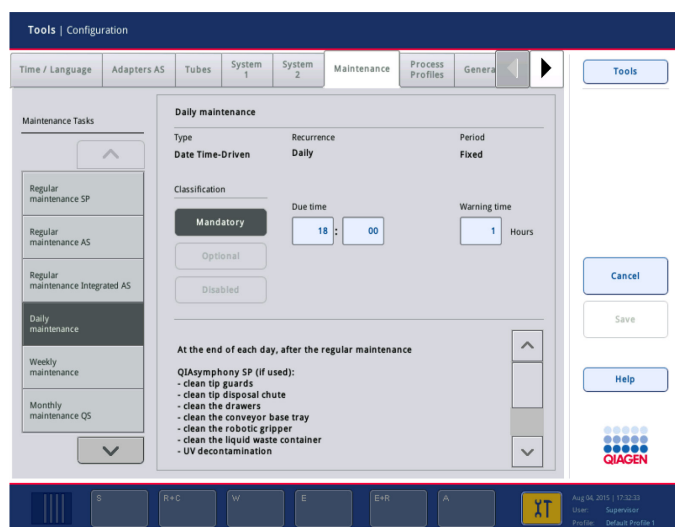
#### 15.1.2 Postponing a maintenance task

Time-based maintenance tasks can be postponed once if (for example) you are working on a time-consuming batch and cannot start the maintenance immediately. For a postponed task, the due time is set to 23:59 of the current day. The user must confirm the

task the next day but cannot postpone the task a second time. To postpone a task, press Postpone.

### 15.1.3 Configuring the maintenance settings

The supervisor can configure the maintenance settings in the Tools/Configuration menu. Only the due time and warning time can be modified.



Different maintenance tasks can be selected in the Maintenance Tasks list:

- For Daily maintenance, it is possible to select the Due time and Warning time.
- For Weekly maintenance, in addition to the Due time and Warning time, the weekday when the maintenance should occur can be selected.
- For Monthly maintenance, the Due time, Warning time and Day of month can be selected.
- The Annual maintenance and servicing can only be initially set after the software update performed by the "Supervisor". The Due time, Warning time and Day, Month and Year of the last Annual service visit must be set. All following Annual maintenance and servicing tasks can only be confirmed by QIAGEN Technical Services.

## 15.2 Cleaning

**Note:** If liquid is spilt on the QIAsymphony SP/AS worktables, wipe it away as soon as the run has finished in accordance with the required safety regulations. Do not allow the liquid to dry.

**Note:** If solvents or saline, acidic, or alkaline solutions are spilt on QIASymphony SP/AS instruments, wipe them away immediately.

## Cleaning agents

Use the following disinfectants for cleaning:

### *Disinfectants*

- DECON-QUAT® 100 (Veltex Associates, Inc.; [www.sterile.com](http://www.sterile.com)) — quaternary ammonium salt based disinfectant concentrate. Contains 5% alkyl dimethylbenzylammonium chloride and 5% alkyl dimethylethylbenzylammonium chloride). For submerging worktable items.
- 0.1 M NaOH
- Ethanol (80%)
- Chlorine bleaching agent (1%)

### *Removal of RNase contamination*

- 5 PRIME RNaseKiller (5 PRIME, cat. no 2500080) — for cleaning surfaces and submerging worktable items
- 0.1 M NaOH — as an alternative to 5 PRIME RNaseKiller for cleaning surfaces and submerging worktable items

### *Removal of nucleic acid contamination (DNA and RNA)*

- DNA-ExitusPlus™ IF (AppliChem, cat. no. A7089; indicator-free variant of DNA-ExitusPlus) — for cleaning surfaces and submerging worktable items
- DNAZap™ Solutions (Life Technologies, cat. no. AM9890M)

**Note:** If you want to use disinfectants different from those recommended, ensure that their compositions are similar to those described.

Note: If solvents or saline, acidic or alkaline solutions are spilled on QIASymphony SP/AS instruments, wipe them away immediately.

**Note:** Do not use alcohol or alcohol-based disinfectants to clean the QIASymphony SP/AS hoods or side panels.

Note: Contact the instrument supplier if there are questions regarding the use of cleaning agents.

**Note:** Exposure of the QIASymphony SP/AS hoods and side panels to alcohol or alcohol-based disinfectants will cause surface cracking. Clean the QIASymphony SP/AS hoods and side panels with distilled water or DECON-QUAT 100 only.

**CAUTION****Damage to the instrument(s)**

After wiping the drawers and lysis station with paper towels, make sure that no bits of paper towel remain. Pieces of paper towel remaining on the worktable could lead to a worktable collision.

### 15.3 Servicing

Contact your QIAGEN Field Service representative or your local distributor for more information about flexible Service Support Agreements from QIAGEN.

**Note:** Disconnect the line power cord from the power outlet before servicing.

### 15.4 Regular maintenance

Regular maintenance is required after each run on the QIASymphony SP/AS. A separate maintenance routine should be performed for the QIASymphony SP and QIASymphony AS.

**Note:** Before running a service protocol from the **Maintenance SP** or **Maintenance AS** menu, ensure that the QIASymphony SP/AS hoods are closed.

#### 15.4.1 Regular disposal of tips

- To avoid contamination, the tip disposal bag must be emptied before starting the next run.
- Residual liquid from the tip disposal chute may drip.
- Pay attention to the safety information.
- When using the QIASymphony Cabinet SP/AS, the waste bin should be emptied to avoid contamination inside the cabinet.
- Check the waste bin regularly.
- Residual liquid from the tip disposal chute may drip inside the cabinet.

For detailed QIASymphony Cabinet SP/AS information, refer to Appendix F.

The underlined words are the keywords the user sees on the touchscreen within the maintenance scheduler (see “Displaying detailed steps for a maintenance task,” page 326).

1. Remove eluates: Remove eluates from the "Eluate" drawer.
2. Download the result file(s) (optional): As an optional step, download the result file(s) and ensure that the files have been backed up.
3. Remove used sample tubes/plates: Remove used sample tubes/plates from the "Sample" drawer and discard according to your local safety regulations.
4. Remove reagent cartridges: Remove reagent cartridges from the "Reagents and Consumables" drawer.  
  
Seal partially used reagent cartridges and store according to the instructions in the handbook of the QIAAsymphony kit you are using. Discard used reagent cartridges according to your local safety and environmental regulations.
5. Replace the tip disposal bag: Replace the tip disposal bag before starting the next run.
6. Discard unit boxes: Close unit boxes filled with waste plasticware and discard according to your local safety regulations.
7. Check the magnetic-head guards: Check the magnetic-head guards and clean if required.
8. UV decontamination (optional): Perform UV decontamination of the worktable (optional).

**Note:** When using the QIAAsymphony Cabinet SP/AS, the waste bin should be emptied to avoid contamination inside the cabinet.

For detailed information, refer to Appendix F.

If required, clean the magnetic-head guards before starting the next protocol run. Proceed as follows:

1. Open the Maintenance SP menu and run the service protocol Magnetic head guards. Gently raise the catches to release the magnetic-head guards.
2. Wipe the magnetic-head guards with ethanol-based disinfectant and incubate as appropriate.
3. Wipe with a lint-free cloth moistened with water and wipe dry with paper towels. Replace the magnetic-head guards.
4. Open the Maintenance SP menu and run the service protocol Open magnetic head guards.



**WARNING****Damage to the instrument(s)**

Make sure to install the magnetic-head guards before operating the QIASymphony SP.

#### 15.4.2 Regular maintenance (AS) (integrated and independent)

The underlined words are the keywords the user sees on the touchscreen within the maintenance scheduler (see “Displaying detailed steps for a maintenance task,” page 326).

1. Remove assay run: Remove the assay run by pressing the Remove button.
2. Remove assays: Remove assays from the “Assays” drawer.  
If desired, transfer assays directly to the PCR cycler.
3. Download the result file(s) (optional): Download the result file and, if available, the cycler file. Ensure that these files have been backed up.
4. Remove used sample tubes/plates: Remove used sample tubes/plates from the “Eluate and Reagents” drawer. Either store safely or discard according to your local safety regulations.
5. Remove reagent tubes and bottles: Remove reagent tubes and bottles from the “Eluate and Reagents” drawer. Discard according to your local safety regulations.
6. Discard empty tip racks.
7. Replace the tip disposal bag: Replace the tip disposal bag before starting the next assay run.
8. UV decontamination (optional): Perform UV decontamination of the worktable.

**Note:** Do not refill used tip racks.

**Note:** When using the QIASymphony Cabinet AS, check if the tip disposal bag is full. The waste bin should be emptied to avoid contamination inside the cabinet.

For detailed information, refer to Appendix F.

### 15.5 Daily maintenance (SP/AS)

After performing the last run of the day, perform the regular maintenance procedure and, in addition, the daily maintenance procedure.

**Note:** Before running a service protocol from the **Maintenance** menu, ensure that the QIASymphony SP/AS hoods are closed.

**Note:** Pay attention to the safety information.

The underlined words are the keywords the user sees on the touchscreen within the maintenance scheduler (see “Displaying detailed steps for a maintenance task,” page 326).

### 15.5.1 Pipetting system tip guards (SP/AS)

#### Clean pipetting system tip guards

1. Open the **Tools** screen and press **Maintenance SP** or **Maintenance AS**.
2. Move the robotic arm to the cleaning position by pressing **Tip guards**.
3. Remove all 4 tip guards by pushing each tip guard upward until it clicks out of place and can be removed.
4. Soak in a glyoxal and quaternary ammonium salt based disinfectant (e.g., Gigasept Instru AF) for at least 15 minutes.
5. Rinse with water and wipe dry with paper towels.

#### **CAUTION**



#### **Damage to the instrument(s)**

Make sure to install the tip guards correctly before operating QIASymphony SP/AS instruments.

### 15.5.2 Tip disposal chute

If using the QIASymphony Cabinet SP/AS, refer to Appendix F).

#### **QIASymphony SP**

#### Clean tip disposal chute

1. Remove the tip disposal chute from the “Waste” drawer.
2. Soak in a glyoxal and quaternary ammonium salt based disinfectant for at least 15 minutes.
3. Rinse with water and wipe dry with paper towels.

## QIAsymphony AS

### Clean tip disposal chute

1. Open the **Tools** screen and press **Maintenance AS**.
2. Press **Robotic arm left** to move the robotic arm to the left.
3. Open the QIAsymphony AS hood.
4. Remove the tip disposal chute from the worktable.
5. Soak in a glyoxal and quaternary ammonium salt based disinfectant for at least 15 minutes.
6. Rinse with water and wipe dry with paper towels.

**Note:** Residual liquid from the tip disposal chute may drip.

### 15.5.3 Drawers and lysis station (SP)

#### Clean drawer and lysis station

1. Remove all removable objects (tube carriers, adapters, inserts, liquid waste station/tip park station, tip disposal chute, liquid waste bottle, waste bag holder, reagent box holder) from the drawers.
2. Wipe the drawers, the removed objects, and the lysis station with ethanol-based disinfectant and incubate as appropriate. Then wipe with a cloth moistened with water and dry with paper towels. Return the objects to the drawers.
3. Clean top plate of the piercing device.
4. **Optional:** Clean the removed objects by soaking them in a glyoxal and quaternary ammonium salt-based disinfectant according to the manufacturer's instructions. After incubation according to manufacturer's instructions, rinse the removed objects thoroughly with water.

**Note:** There are spikes below the piercing device in the "Reagents and Consumables" drawer that ensure that the reagent cartridge is correctly positioned. Take care when cleaning the "Reagents and Consumables" drawer.

**Note:** Do not autoclave the waste bottle.

#### 15.5.4 Drawers (AS)

##### Clean the drawers

1. Remove all removable objects (tubes/plates, adapters) from the drawers.
2. Wipe the drawers and the removed adapters with quaternary ammonium salt based disinfectant and incubate as appropriate. Then wipe with a cloth moistened with water and dry with paper towels. Return the objects to the drawers.
3. **Optional:** Clean the removed adapters by soaking them in a glyoxal and quaternary ammonium salt based disinfectant according to the manufacturer's instructions. After incubation according to manufacturer's instructions, rinse the removed objects thoroughly with water.
4. We recommend storing the adapters at 4°C, so that they will be precooled and ready for use in the next assay run.

#### 15.5.5 Conveyor base tray (SP) — optional

##### Clean the conveyor base tray (optional)

1. Carefully remove the conveyor base tray from below the magnetic head.
2. Soak in a glyoxal and quaternary ammonium salt based disinfectant for at least 15 minutes.
3. Rinse with water and wipe dry with paper towels.

**Note:** The tray can also be autoclaved at 121°C for 20 minutes.

#### 15.5.6 Robotic gripper (SP)

##### Clean the robotic gripper

1. Wipe the robotic gripper with a lint-free cloth moistened with ethanol-based disinfectant. Incubate as appropriate.
2. Wipe with a lint-free cloth moistened with water and dry with paper towels.

**Note:** Only wipe the weight. Do not wipe the rods, otherwise the ball mechanism may become jammed.

### 15.5.7 Liquid waste container (SP)

#### Clean the liquid waste container

1. Remove the liquid waste container from the "Waste" drawer.
2. Empty the liquid waste container. Dispose of the liquid waste according to your local safety regulations.
3. Clean the liquid waste container with a glyoxal and quaternary ammonium salt based disinfectant according to the manufacturer's instructions.
4. Rinse the liquid waste container with deionized water.
5. Replace the liquid waste container in the "Waste" drawer.

## 15.6 Weekly maintenance (SP/AS)

The underlined words are the keywords the user sees on the touchscreen within the maintenance scheduler (see "Displaying detailed steps for a maintenance task," page 326).

### 15.6.1 File management

#### Download files (SP/AS)

1. Download the result file(s) (for QIA Symphony SP and QIA Symphony AS) and loading information files (QIA Symphony AS only) as described in Section 7.3 and ensure that the files are backed up.
2. Delete result files older than 10 days (default setting) as described in Section 7.5.

### 15.6.2 Touchscreen

#### Clean the touchscreen

Wipe the touchscreen with ethanol-based disinfectant. Then wipe with a cloth moistened with water and dry with paper towels.

### 15.6.3 QIA Symphony SP/AS hoods

#### Clean the hoods

To clean the hoods of QIA Symphony SP/AS instruments, wipe the surface with a soft lint-free cloth moistened with deionized water, or use wipes soaked with DECON-QUAT 100. Then wipe dry with a dry soft lint-free cloth or paper towel.

**Note:** Do not use ethanol-based disinfectant; use distilled water or DECON-QUAT 100 only.

#### 15.6.4 Tube carriers (SP)

##### Clean the tube carriers and inserts

1. Remove tube carriers and inserts and soak them in disinfectant. Incubate for at least 15 minutes, then rinse with water and dry with paper towels.
2. Check the condition of the bar code labels and ensure that they are not scratched.

#### 15.6.5 Optical sensor (SP)

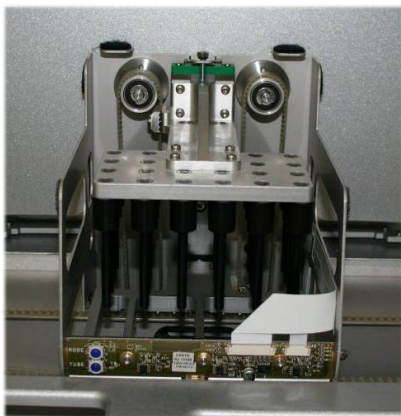
##### Clean the optical sensor

Wipe the window of the optical sensor with a lint-free cloth. Moisten the cloth with 70% ethanol if required.

#### 15.6.6 Magnetic head (SP)

##### Clean the magnetic head

1. Remove the cover from the magnetic head.
2. Move the magnetic head up and carefully push the rod cover holder down.



3. Wipe the exterior of the magnetic head with a lint-free cloth moistened with ethanol-based disinfectant, and incubate as appropriate.
4. Wipe with a lint-free cloth moistened with water and dry with paper towels.

---

**Note:** Insert the cloth from the sides of the magnetic head in order not to damage the cable and electronic board at the front.

#### 15.6.7 Liquid waste container (SP)

##### Clean the liquid waste container

1. Remove the liquid waste container from the "Waste" drawer.
2. Empty the liquid waste container. Dispose of the liquid waste according to your local safety regulations.
3. Disinfect the liquid waste container using ethanol-based disinfectant.
4. Replace the liquid waste container in the "Waste" drawer.

#### 15.6.8 Adapters (AS)

##### Clean adapters

1. Remove the adapters from the "Eluate", "Eluate and Reagents", and "Assays" drawers and soak them in disinfectant. Incubate for at least 15 minutes.
2. Rinse with water and dry with paper towels.
3. Check the condition of the bar code labels and ensure that they are not scratched.

### 15.7 UV decontamination of the worktable

The underlined words are the keywords the user sees on the touchscreen within the maintenance scheduler (see "Displaying detailed steps for a maintenance task," page 326).

##### UV decontamination

UV decontamination should be performed daily. It helps to reduce possible pathogen contamination of the QIASymphony SP/AS worktables. The efficiency of inactivation has to be determined for each specific organism and depends, for example, on layer thickness and sample type. QIAGEN cannot guarantee complete eradication of specific pathogens.

UV decontamination of the QIASymphony SP and AS can be started either sequentially or in parallel.

**Important:** Before starting the UV irradiation procedure, ensure that all samples, eluates, reagents, consumables and assays have been removed from the worktable. Close all drawers and the hoods. Once the UV irradiation procedure has been started, it will continue for the defined period of time, or until interrupted by the user.

We recommend using the following formula to calculate the duration of decontamination in minutes:

$$\text{Dose (mW x s/cm}^2\text{)} \times 10.44 = \text{Duration (seconds)}$$

1. Remove all removable objects (tubes/plates, adapters, consumables, tip disposal chute) except for the liquid waste bottle from the drawers.
2. Enter the **Maintenance** screen, and press **Maintenance SP** or **Maintenance AS**.



The **Maintenance AS** button is only available if you are using QIASymphony SP/AS instruments.

3. Press the Start UV light AS button, or the Start UV light SP button, or the Start UV light SP+AS button.



The **Input/UV cleanup/Duration** screen will open.

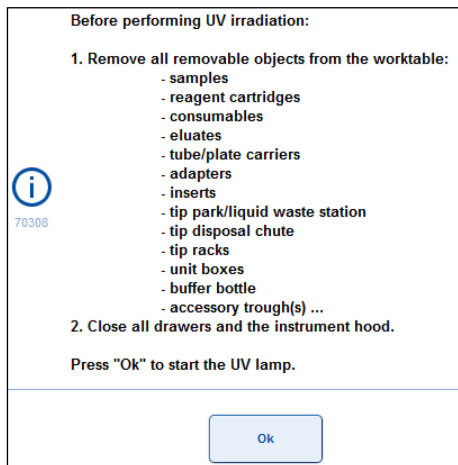
4. Enter the duration of the decontamination in minutes.

The UV irradiation time is pathogen-dependent and should be determined by the user. Use the formula above to calculate the irradiation time and then enter the time into the input box. The default setting is 15 minutes.



A message appears asking you to check whether all plasticware and consumables have been removed from the worktable.





5. Confirm that all removable objects have been removed from the worktable by pressing **OK**.

The UV irradiation procedure starts and the robotic arm moves over the worktable surface for the set irradiation duration.

**Note:** To stop the UV irradiation procedure before the defined period of time has elapsed, press **Cancel**. The procedure will stop as soon as the robotic arm completes the current movement.



## 15.8 Monthly maintenance (SP/AS)

The underlined words are the keywords the user sees on the touchscreen within the maintenance scheduler (see "Displaying detailed steps for a maintenance task," page 326).

### Change tip adapter O-ring

This section describes how to replace the tip-adapter O-ring. The tip-adapter O-ring must be changed monthly for both the QIAsymphony SP and QIAsymphony AS.

We recommend replacing the O-rings every month using the "O-Ring Change Tool Set" (cat. no. 9019164).

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Before removing the old O-ring, the new O-ring must be prepared. These steps should be performed for both the QIAsymphony SP and the QIAsymphony AS instruments.

For instructions, refer to the quick guide that is equipped with the "O-Ring Change Tool Set". If there is no "O-Ring Change Tool Set" available, contact QIAGEN Technical Services.

## 16 Technical Data SP/AS

QIAGEN reserves the right to change specifications at any time.

### 16.1 Environmental conditions

#### Operating conditions

Power consumption QIAsymphony SP and QIAsymphony AS	100–240 V AC, 50/60 Hz, 1400 VA  Mains supply voltage fluctuations are not to exceed 10% of nominal supply voltages. The inlet is on the QIAsymphony SP; in combined operation, the maximum power consumption is 1400 VA (SP: 800 VA; AS: 600 VA).
Overvoltage category	II
Air temperature	18–26°C (64.4–78.8°F)
Relative humidity	20–75% (noncondensing)  Maximum 75% relative humidity
Altitude	Up to 2000 m (6500 ft.)
Place of operation	For indoor use only
Pollution level	2
Environmental class	3K2 (IEC 60721-3-3)  3M2 (IEC 60721-3-3)

#### Transportation conditions

Air temperature	25°C to 70°C (–13°F to 158°F) in manufacturer's package
Relative humidity	Maximum of 75% (noncondensing)
Environmental class	2K2 (IEC 60721-3-2)  2M2 (IEC 60721-3-2)

### Storage conditions

Air temperature	5°C to 40°C (41°F to 104°F) in manufacturer's package
Relative humidity	Maximum of 85% (noncondensing)
Environmental class	1K2 (IEC 60721-3-1) 1M2 (IEC 60721-3-1)

## 16.2 Mechanical data and hardware features

### QIAsymphony SP

Dimensions	Width: 128 cm (50.4 in.) Height: 103 cm (40.6 in.) Depth: 73 cm (28.7 in.)
Weight	175 kg (385.8 lb.)

### QIAsymphony AS

Dimensions	Width: 59 cm (23.2 in.) Height: 103 cm (40.6 in.) Depth: 73 cm (28.7 in.)
Weight	90 kg (198 lb.)

### QIAsymphony SP and AS (integrated operation)

Dimensions	Width: 185 cm (72.8 in.) Height: 103 cm (40.6 in.) Depth: 73 cm (28.7 in.)
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Weight	265 kg (584 lb.)
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**Note:** Weight does not include packaging of the QIAsymphony Cabinet SP/AS.






## 17 User Interface Addendum









This section provides an overview of the QIAsymphony SP/AS user interface. The names of tabs, tools, and buttons are displayed in alphabetical order. The availability of the software options is denoted using the following abbreviations:







- IR = Integrated run (QIAsymphony SP/AS) application
- TIs = Tools options for QIAsymphony SP/AS







In addition, the name of each menu option is provided together with a description of the option. Several workflows may use the option, and workflow-specific descriptions are included.

For detailed information about the user interface refer to Sections 5 and 6.

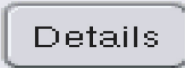






Button	Availability	Menu option and description
	TIs	<b>User Management/User Overview</b> Enables creation of a new user account.
	IR	<b>Assay Assignment</b> Shows all selected Assay Parameter Sets in the tab view.
	TIs	<b>File transfer/Process Files</b> Enables download/upload of Assay Control Set file(s).
	TIs	<b>File transfer/Process Files</b> Enables download/upload of Assay Definition file(s).
	TIs	<b>Tools</b> Opens the <b>Assay Favorites</b> menu. Allows definition of assay favorites.








Button	Availability	Menu option and description
	IR	<p><b>Tls File transfer/Process Files</b></p> <p>Enables download/upload of Assay Parameter Set file(s).</p>
	IR	<p><b>Sample Rack(s)/Loading Information</b></p> <p>Enables generation of a rack ID (only for assay racks).</p>
	IR	<p><b>Integrated Setup/Sample Preparation</b></p> <p>Opens the previous screen.</p>
		<p><b>Tls File transfer/Process Files</b></p> <p>Press to transfer all protocols, assay control sets and, if QIASymphony AS is installed, additional assay definitions and assay parameter sets from QIASymphony SP to USB stick.</p>
	IR	<p><b>Consumables/Cartridges/Filter-Tips</b></p> <p>Displays the <b>Keyboard</b> screen to enter or scan the bottle ID.</p>
	IR	<p><b>Tls Miscellaneous</b></p> <p>Cancels a completed workflow without saving the changes.</p>
		<p><b>Tls Files transfer/Instr. Setup Files</b></p> <p>Enables upload/download of new reagent cartridge information.</p>
		<p><b>Tls User Management/User Overview</b></p> <p>Enables you to change your password.</p>





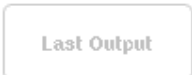


Button	Availability	Menu option and description
	Tls	<b>User Management/User Overview</b>  Enables the role of an existing user to be changed. This option is only available to the "Supervisor".
	IR	<b>Integrated Setup/Define Sample/Sample ID</b>  Removes text from the text field. Enables the user to clear positions and remove sample ID and sample type.
	IR	<b>Integrated Setup</b>  Deletes the assigned Assay Parameter Set(s) from selected sample position(s).
	IR	<b>Consumables</b>  Switches back from the <b>Sample Calculation</b> to the <b>Consumables</b> view.
	Tls	<b>Tools</b>  Displays the <b>Configuration</b> menu. Only available for the "Supervisor".
	Tls	<b>Transfer files/In-/Output Files</b>  Enables download of start batch confirmation files.  <b>Note:</b> Not relevant for FDA cleared or approved nucleic acid tests.






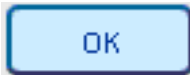
Button	Availability	Menu option and description
 	IR	<p><b>Sample Preparation/Command bar/Assay Setup</b></p> <p>Continues the run on the paused subsystem. The <b>Continue SP</b> or <b>Continue AS</b> button appears if the current run is paused on the respective subsystem. After pausing, the samples of the processed batch will be flagged as “unclear”.</p> <p><b>Note:</b> A run should only be paused in case of an emergency.</p> <p><b>Note:</b> Pausing a run will result in all samples being flagged as “unclear”. For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all “unclear” samples.</p>
	Tls	<p><b>Instrument Report</b></p> <p>Creates an instrument report file.</p>
	IR	<p><b>Integrated Run</b></p> <p>Enables definition of an internal control. This button is active only when internal controls are loaded in a tube carrier.</p>
	IR	<p><b>Integrated Setup</b></p> <p>Opens the <b>Assay Assignment</b> screen.</p>
	Tls	<p><b>File transfer/In-/Output Files</b></p> <p>Deletes input and output files (except log files) that are older than a defined number of days. The default is 10 days and can be adjusted upon request by QIAGEN Field Service Specialists.</p>









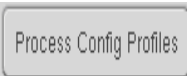


Button	Availability	Menu option and description
	IR	<b>Integrated Setup</b> Opens a message box that provides detailed information about the assigned assays and the integrated batch.
	IR	<b>Integrated Setup</b> Enables the user to deselect all selected positions.
	IR	<b>Integrated Setup</b> Opens the Sample Preparation/ Batch X/Define Samples screen.
	IR	<b>Define Samples/Sample Rack Layout</b> Sets the sample type of the selected samples to <b>EC+</b> (positive external control).
	IR	<b>Define Samples/Sample Rack Layout</b> Sets the sample type of the selected samples to <b>EC-</b> (negative external control).
	Tls	<b>Sample Preparation/Tools</b> Opens the <b>File transfer</b> menu, enabling transfer of selected file types to the QIAsymphony SP/AS or to the USB stick.
	Tls	<b>Rack browser/Sample Racks</b> <b>Rack browser/Eluate Racks</b> <b>Rack browser/Assay Racks</b> Enables the user to manually enter and then search for IDs using the <b>Keyboard</b> screen.




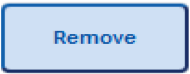

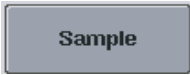
Button	Availability	Menu option and description	
	IR	<b>Sample Preparation/Integrated Setup</b> Allows the user to assign a virtual ID to selected samples without bar codes. The virtual ID is displayed as: “_PositionNumber on Tube Carrier_Unique Batch ID”.	
	IR	Tls	<b>Miscellaneous</b> Provides information to help the user complete the current screen.
		Tls	<b>Instrument Report</b> Displays the <b>Instrument Report</b> menu.
	IR	<b>Integrated Setup</b> Allows the user to edit sample IDs and sample types.	
	IR	<b>Integrated run</b> Displays the <b>Inserts/Tube types</b> list. This enables the user to assign the correct tube type to the position.	
		Tls	<b>Service SP/Service AS</b> Allows the user to initialize the QIAsymphony instrument. After pressing the button, press <b>Yes</b> to initialize or <b>No</b> to cancel.
		Tls	<b>Labware browser/Labware SP</b> Opens the <b>Input Racks</b> dialog panel and provides information about which sample racks can be used.








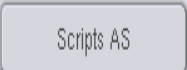
Button	Availability	Menu option and description
	Tls	<b>Labware browser/Labware AS</b> <b>Labware browser/Labware SP</b> Opens the <b>Labware</b> dialog panel.
	Tls	<b>File transfer/Instr. Setup Files</b> Enables download/upload of QIAsymphony AS labware file(s).
	Tls	<b>Tools</b> Opens the <b>Labware Browser</b> menu.
	Tls	<b>Instr. Setup Files</b> Enables download/upload of the QIAsymphony SP labware file(s).
	Tls	<b>Service SP/Service AS</b> Opens script output. This button is enabled after an operator service script has been performed.
	Tls	<b>Rack browser/Sample Racks</b> <b>Rack browser/Eluate racks</b> <b>Rack browser/Assay Rack</b> Displays the rack files that were modified between 00:00 of Monday last week and 00:00 of Monday of the current week.
	IR	<b>Loading Information</b> Enables a reagent rack to be loaded. Press when loading the reagent rack. The system will check during the inventory scan whether reagent, sample, and assay racks were loaded correctly.

Button	Availability	Menu option and description
	Tls	<b>File Transfer/In-/Output Files</b> Enables download of loading information file(s). Only visible when the QIASymphony AS is installed.
	Tls	<b>File Transfer/In-/Output Files</b> Enables download of system log file(s).
	Tls	<b>Tools</b> Switches to the assay setup user interface and displays the <b>Maintenance AS</b> menu for the QIASymphony AS.
	Tls	<b>Tools</b> Displays the <b>Maintenance SP</b> menu.
	Tls	<b>File Transfer</b> Ensures that selected files should not be synchronized when <b>Transfer</b> is pressed.
	IR	<b>Assay Setup</b> Saves changes and returns to the recent screen.
	IR	<b>Assay Setup/Eluate Drawer</b> Closes the screen.
	IR	<b>Eluate Drawer</b> Performs an inventory scan of the "Eluate" drawer to check the inventory of the "Eluate" drawer against the slot/rack assignment made in the <b>Eluate Drawer/Elution Slot/Change Rack X</b> screen.









Button	Availability	Menu option and description
	IR	<b>Sample Racks/Eluate Racks/Assay Racks</b> Displays the rack files that were modified before 00:00 of Monday last week.
	Tls	<b>Labware browser/Labware SP</b> Opens the <b>Output Racks</b> dialog panel and provides information about which elution racks can be used.
	IR	<b>Sample Preparation/Assay Setup</b> Opens the assay setup <b>Overview</b> screen. This button is enabled when either the <b>Sample View</b> or <b>Parameter View</b> is open.
	IR	<b>Sample Preparation</b> Pauses the QIASymphony SP. The <b>Pause</b> button should only be pressed in an emergency. After pressing <b>Pause</b> , the QIASymphony SP completes the current command being processed, pauses the protocol, and changes the sample state to "unclear". If the protocol has been paused either by the user or due to an error, the <b>Stop</b> and <b>Continue SP</b> buttons appear.  <b>Note:</b> Pausing a run will result in all samples being flagged as "unclear". For FDA cleared or approved nucleic acid tests, Rotor-Gene AssayManager will invalidate all "unclear" samples.







Button	Availability	Menu option and description
	IR	<b>Sample Preparation</b>  Pauses the QIASymphony AS. The <b>Pause</b> button should only be pressed in an emergency. After pressing <b>Pause</b> , the QIASymphony AS completes the current command being processed, pauses the protocol, and changes the sample state to "unclear". If the protocol has been paused either by the user or due to an error, the <b>Stop</b> and <b>Continue AS</b> buttons appear.
	IR	<b>Assay Setup</b>  Opens the <b>Parameter View</b> screen. This screen displays information in a tabular format about Assay Parameter Sets and specifications for samples that will be processed, that are currently being processed, or that have been processed.
		TIs <b>File Transfer/Instr. Setup Files</b>  Enables download of custom process configuration profiles.
		TIs <b>File transfer/Process Files</b>  Enables download/upload of protocol file(s).
	IR	TIs <b>Miscellaneous</b>  Displays the available sample rack types in the control panel.

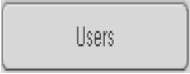



Button	Availability	Menu option and description
		<p>Tls    <b>Miscellaneous</b></p> <p>Displays the <b>Rack Browser</b> menu for viewing rack files saved on the QIAsymphony SP/AS instrument.</p>
	IR	<p><b>Assay Setup/Sample Preparation</b></p> <p>Displays the available rack files in the control panel.</p>
		<p>Tls    <b>File Transfer/In-/Output Files</b></p> <p>Enables upload/download of the rack file(s).</p>
	IR	<p><b>Eluate Drawer</b></p> <p>Enables a rack ID to be scanned or manually entered.</p>
	IR	<p><b>Loading Information/Loading Reagents</b></p> <p>Enables a reagent rack to be removed. Press when unloading the reagent rack. The system will check during the inventory scan whether the rack was unloaded correctly.</p>
		<p>Tls    <b>Labware browser/Labware AS</b></p> <p>Opens the <b>Reagent Holders</b> view in which information about reagent holders is displayed.</p>
	IR	<p><b>Sample Rack Layout</b></p> <p>Sets the sample type of the selected samples to <b>Sample</b>.</p>

Button	Availability	Menu option and description
	IR	<b>Consumables</b> <b>Cartridges</b> Opens the <b>Sample Calculation</b> dialog panel.
	IR	<b>Integrated Setup/Define Samples</b> Allows the user to edit the IDs of the selected position(s) on the rack grid. When the button is pressed, the <b>Manual Input</b> screen appears.
	IR	<b>Eluate Drawer/Integrated Setup</b> Displays the <b>Keyboard</b> screen, enabling the user to manually enter sample IDs.
	IR	<b>Integrated Setup/Sample Preparation</b> Enables the user to change the tube type.
	IR	<b>Overview</b> Opens the <b>Sample View</b> screen. This screen displays information in a tabular format.
	Tls	<b>User Management/User Overview</b> Saves changes.
	IR	<b>Assay Setup</b> Enables the user to enter a kit bar code. Press the field. You can enter a bar code in the screen that appears.
	Tls	<b>File Transfer/Instr. Setup Files</b> Enables upload/download of operator service scripts for the QIAsymphony AS.



Button	Availability	Menu option and description
		<p>Tls <b>File Transfer/Instr. Setup Files</b></p> <p>Enables upload/download of operator service scripts for the QIAsymphony SP.</p>
	IR	<p><b>Integrated Setup</b></p> <p>Enables the user to select all samples.</p>
		<p>Tls <b>Tools</b></p> <p>Opens the <b>Service AS</b> menu under which special service functions (e.g., for maintenance or instrument re-initialization) can be initiated.</p>
		<p>Tls <b>Tools/Sample Preparation</b></p> <p>Opens the <b>Service SP</b> menu under which special service functions (e.g., for maintenance or instrument re-initialization) can be initiated.</p>
	IR	<p><b>Assay Assignment</b></p> <p>Opens the <b>Assay Specifications</b> screen.</p>
		<p>Tls <b>Tools</b></p> <p>Starts the selected operator service script.</p>
	IR	<p>Command bar</p> <p>Stops the AS run. The <b>Stop</b> button appears if the current assay run is paused.</p>
	IR	<p><b>Command bar</b></p> <p>Stops the SP run. The <b>Stop SP</b> button appears if the current run is paused.</p>

Button	Availability	Menu option and description
	IR	<b>R&amp;C Drawer</b> <b>W Drawer</b> <b>E Drawer</b> <b>E&amp;R Drawer</b> <b>A Drawer</b> <p>Stops the inventory scan of the “Eluate” drawer that is in progress, and then opens the previous screen.</p>
	Tls	<b>Rack browser/Sample Racks</b> <b>Rack browser/Eluate Racks</b> <b>Rack browser/Assay Rack</b> <p>Displays the rack files that have been modified since 00:00 of Monday of the current week, including the rack files that were modified today. This option is preselected by default.</p>
	Tls	<b>Rack browser/Sample Racks</b> <b>Rack browser/Eluate Racks</b> <b>Rack browser/Assay Rack</b> <p>Displays the rack files that were modified today.</p>
	Tls	<b>Maintenance SP</b> <p>Opens/returns to the <b>Tools</b> menu.</p>
	IR	<b>File transfer/Instr. Setup Files</b> <b>File transfer/Process Files</b> <b>File transfer/In-/Output Files</b> <p>Enables transfer of selected file types to the QIAsymphony SP/AS or to the USB stick.</p>
	IR	<b>Labware SP</b> <p>Opens the <b>Tube Carrier</b> screen.</p>

Button	Availability	Menu option and description
	Tls	<b>Instr. Setup Files</b> Saves information about all created users to a USB stick. Press to download the Assay Control Set file(s).
	Tls	<b>Tools</b> Opens the <b>User Management</b> menu for managing users and passwords.
	Tls	<b>File Transfer/In-/Output Files</b> Enables upload of work list(s).
	Tls	<b>File Transfer/In-/Output Files</b> Enables selected files to be synchronized when <b>Transfer</b> is pressed.

## 18 Glossary

Term	Description
AC	Abbreviation for assay control.
AD	Abbreviation for Assay Definition.
Adapter	Metal block that can hold consumables (e.g., microplate) on the worktable. For a list of available adapters, refer to the Instructions for Use (Handbook) for the assay you are using.
APS	Abbreviation for Assay Parameter Set.
"Eluate and Reagents" drawer	QIAsymphony AS drawer into which sample racks, filter-tips, and reagents are placed.
"Assays" drawer	QIAsymphony AS drawer into which assay racks are placed and in which assays are set up.
Assay Control Set	The combination of a protocol plus additional parameters, such as internal control.
Assay definition	A set of instructions for the QIAsymphony AS that allows the instrument to perform an assay run.
Assay Parameter Set	The combination of an Assay Definition with additional parameters defined, such as replicate count and number of assay standards. In Integrated run mode, it is also connected to the ACS.
Assay rack	Name of the output formats of the QIAsymphony AS.
Assay rack ID	Identification number that is associated with an assay rack. This can be manually or automatically entered.
Assay specific IC	An internal control (IC) used during sample preparation that is specific for a particular assay. If this assay is selected on the

Term	Description
	QIASymphony AS, the master mix for those samples does not need an internal control.
Bar code camera (2D)	A device on the QIASymphony SP that reads bar codes on consumables.
Bar code scanner	A handheld device that enables scanning of bar codes and conversion of them into data that is transmitted to the QIASymphony SP/AS.
Buffer bottle	An additional bottle of buffer that is placed into the "Reagents and Consumables" drawer, if required by the protocol.
Conveyor	A component of the QIASymphony SP that moves sample prep cartridges below the magnetic head during sample preparation.
Cycler file	A data file that is generated by the QIASymphony that can be transferred to certain cyclers (i.e., Rotor-Gene Q). The cycler file contains information about sample ID, sample position, and concentration and unit of assay standards.  <b>Note:</b> Not relevant for FDA cleared or approved nucleic acid tests.
EC–	Abbreviation for negative extraction control.
EC+	Abbreviation for positive extraction control.
Eluate	Purified nucleic acids.
"Eluate" drawer	Drawer into which purified nucleic acids are eluted.
Elution rack	Name of the output format of the QIASymphony SP. An elution rack can be used as the input format for the QIASymphony AS.
Error code	A number that is associated with a specific error that occurred on the QIASymphony SP/AS instruments.

<b>Term</b>	<b>Description</b>
Filter-tip	A consumable that is picked up by a tip adapter during operation of the QIAAsymphony SP/AS instruments. Liquid is aspirated into and dispensed from a filter-tip.
Hood	The QIAAsymphony SP/AS hoods protect users from the moving robotic arms and from potentially infectious material on the worktable.
IC	Abbreviation for internal control.
Integrated run	An integrated run consists of a sample preparation run on the QIAAsymphony SP and then an assay setup run on the QIAAsymphony AS. Eluates are automatically transferred from the QIAAsymphony SP to the QIAAsymphony AS via the transfer module. An integrated run is defined in the software for the complete workflow before starting the run.
Internal control	QIAGEN assay kits contain a second heterologous amplification system which is detected as an internal control (IC) in a second fluorescence channel. The IC allows the user both to control the nucleic acid isolation procedure and to check for possible PCR inhibition.
Inventory scan	An inventory scan is performed to check that drawers are correctly loaded and that the QIAAsymphony SP/AS instruments have all required reagents and consumables for a protocol.
Labware	A piece of labware is a plastic/consumable item (e.g., PCR plate, microplate, reagent tubes, filter-tips) that samples, reagents, assays are put into and that can be used on the QIAAsymphony SP/AS instruments.
Loading information file	A data file generated by the QIAAsymphony AS that contains detailed information about required reagents, sample rack(s), assay rack(s), and disposable filter-tips.

<b>Term</b>	<b>Description</b>
Lysis station	A component of the QIASymphony SP that accommodates sample prep cartridges and enables automated lysis of up to 24 samples in one batch.
Log file	Data file(s) generated by the QIASymphony SP/AS instruments that contains general information about the instruments, user interactions, and details about the protocol being run.
Magnetic head (MH)	An array of 24 magnetic rods for processing magnetic particles.
Magnetic-head guards	The magnetic-head guards move below the magnetic head during sample preparation and catch any drops that may fall from the 8-Rod Covers.
MM	Abbreviation for master mix.
MM+IC	Abbreviation for master mix with internal control.
MM-IC	Abbreviation for master mix without internal control.
n/a	Not applicable
Network interface	The network interface allows connection of the QIASymphony SP/AS instruments to a network via an ethernet cable.
NTC	Abbreviation for no template control.
NTC-IC	Abbreviation for no template control with master mix, without internal control.
NTC+IC	Abbreviation for no template control with master mix and with internal control.
Optical sensor	A component of the QIASymphony SP and AS that checks that consumables are correctly loaded in the "Reagents and Consumables", "Eluate and Reagents", and "Assays" drawer during an inventory scan.

<b>Term</b>	<b>Description</b>
Panel	A group of Assay Parameter Sets.
Piercing device	A device integrated in the "Reagents and Consumables" drawer that enables reagent cartridges to be automatically opened by the QIASymphony SP.
Piercing lid	A lid that is placed on top of the reagent cartridge that enables the reagent cartridge to be automatically opened by the QIASymphony SP.
Pipettor head	A component of the QIASymphony SP/AS instruments that aspirates and dispenses liquid. Each pipettor head contains 4 syringe pumps, each of which is connected to a tip adapter.
Power switch	A button located at the front left of the QIASymphony SP in the bottom-left corner. It allows the user to switch the QIASymphony SP/AS instruments on and off.
Protocol	A set of instructions for the QIASymphony SP that allows the instrument to perform an automated purification procedure.
QIASymphony Cabinet SP/AS	Cupboard that is specially designed to position the QIASymphony SP/AS instruments.
QIASymphony Management Console	Software that is provided with the QIASymphony instrument(s) that enables users to manage files, create Assay Control Sets and/or Assay Parameter Sets, convert .csv formatted rack files or work list files into .xml files, and to check that result files have not been modified.
Rack file	File that contains information about sample racks or assay racks (i.e., rack type, rack ID, sample volumes, assay rack volumes). Rack files can be generated manually or automatically.
Rack type	Type of rack that will be used on the worktable.



Term	Description
Reagent cartridge	An item of labware that contains a magnetic-particle trough, reagent troughs, and enzyme rack. A reagent cartridge is prefilled with reagents.
Reagent holder	An adapter that holds reagent tubes on the QIASymphony AS. There are 2 available reagent holders (Reagent Holder 1 and Reagent Holder 2) that support different tube types at the same time.
"Reagents and Consumables" drawer	Drawer that accommodates consumables and reagents required for the protocol run.
Result file SP	A data file that is generated by the QIASymphony SP for each elution rack. The file contains general information, batch-related information, and information about the reagent cartridge.
Result file AS	A data file that is generated by the QIASymphony AS for each assay run/AS batch in integrated mode. It contains all information about the defined assay run and its parameters.
Robotic gripper	A component of the QIASymphony SP robotic arm that transfers consumables (sample prep cartridges and 8-Rod Covers) to the required position on the worktable during sample preparation.
8-Rod Cover	An array of 8 rod covers that cover the magnetic rods of the magnetic head.
Run status	Indicates the status of a batch or assay run. This could be <b>READY TO LOAD, QUEUED, RUNNING, COMPLETED</b> or <b>STOPPED</b> . For more details, see Section 6.
"Sample" drawer	Drawer that accommodates samples in primary or secondary tubes or multi-well sample racks.

<b>Term</b>	<b>Description</b>
Sample prep cartridge	A vessel with 8 wells that is used by the QIAsymphony SP for purification of nucleic acids.
Sample rack	A rack for holding samples.
Sample rack ID	Identification number/code that is assigned to a sample rack. This can be automatically or manually assigned.
Sample tube	A tube for holding a sample containing nucleic acids to be purified.
Sample status	Indicates the status of a sample. This could be "valid", "unclear", or "invalid".
Slot	A worktable position on the QIAsymphony SP and AS.
Status LEDs	Blue illuminated status bar, located at the front of the QIAsymphony SP and AS. When the instrument(s) are switched on, the status bar is illuminated.
Target temperature	The temperature which cooling positions will be cooled to, as defined in the Assay Definition.
Tip adapter	Each pipetting channel is equipped with a tip adapter which picks up the disposable tips from the tip rack.
Tip chute	Passage through which used tips are disposed of from the QIAsymphony SP/AS worktables. Each instrument has a separate tip chute.
Tip disposal bag	Used tips are stored in a tip disposal bag. They are ejected from the QIAsymphony SP or AS worktable through a tip chute and into a tip disposal bag.
Tip guard	The tip guard is positioned below the disposable tip to avoid aerosol contamination.
Tip rack slots	Positions on the QIAsymphony SP and AS worktable that accommodate tip racks containing filter-tips.

<b>Term</b>	<b>Description</b>
Touchscreen	The user interface that allows the user to operate the QIASymphony SP and AS.
Transfer module	Located under the separation window between the QIASymphony SP and AS, the transfer module enables automatic transfer of eluate racks from the QIASymphony SP to the QIASymphony AS.
Tube carrier	A carrier that can accommodate up to 24 tubes.
Unit box	A plastic box with a lid that contains either sample prep cartridges or 8-Rod Covers.
UV lamp	A light source of ultraviolet light for worktable decontamination.
Validation	The QIASymphony Operating Software checks if the file(s) that are transferred to the QIASymphony SP/AS instruments meet certain criteria. For instance the software verifies whether all files have a specific *.xml structure.
"Waste" drawer	Drawer in which used consumables and liquid waste from the sample preparation procedure is collected.
Worktable	The surface of the QIASymphony SP or QIASymphony AS where sample preparation or assay setup takes place.
Work list	File that enables automatic assignment of samples to Assay Control Sets and Assay Parameter Sets. Work list files can be generated by a LIMS or manually by the user.

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## 19 Introduction to QlAsymphony Management Console (QMC)

### 19.1 About this section

Sections 19–31 describe the features of the QMC software and associated tools, and enable the user to manage files, convert the format of rack files or work list files, and check that files have not been modified.

Information about the QMC is provided in the following sections:

1. Introduction to QlAsymphony Management Console
2. QlAsymphony Management Console
3. Features of the QlAsymphony Management Console
4. **File Transfer** Tool
5. **Checksum Validator** Tool
6. **CSV Conversion** Tool
7. **Auto Transfer** Tool
8. **IC Calculator** Tool
9. Getting Started
10. Configuration
11. Logging in and Connecting
12. Managing Files
13. QMC Troubleshooting

## 20 QIAsymphony Management Console

The QMC allows users to manage application process files by manual download and upload (File Transfer), and provides set up of automatic file transfer of the result files (Automatic File Transfer). Additional tools for converting work lists (CSV Conversion) or calculating the required IC (IC Calculator) are available to support the user.

### 20.1 Available tools

The QMC includes the following tools:

- **File Transfer** tool
- **Checksum Validator** tool
- **CSV Conversion** tool
- **Automatic File Transfer** tool
- **IC Calculator** tool

For more information about the tools, see Section 21.2 and Sections 22 to 26.

### 20.2 Controlling the mouse

The following terms for controlling the mouse are used in this user manual.

Term	Action
Click	Click with the left mouse button.
Right-click	Click with the right mouse button.
Double-click	Double click on the left mouse button.
Highlight	Place the pointer over an item and click the left mouse button. The item becomes highlighted.
Select <b>XXX/xxx</b>	In the toolbar, select the <b>xxx</b> submenu from the <b>XXX</b> menu.

## 20.3 Installing the QIAsymphony Management Console

**Note:** Failure to follow these instructions may lead to unsuccessful installation of the QMC.

### 20.3.1 Minimum PC requirements

The table below lists the minimum PC requirements for the QIAsymphony Management Console.

**Note:** PC must be supplied by the user.

PC feature	Requirements
Supported operating systems	Microsoft Windows 7 and 10
Disk space	50 MB of available hard drive space
Memory	512 MB of RAM
USB port	Available USB port for Mass Storage Devices
Network	Available TCP/IP network (necessary for remote access)
Monitor/color settings	1024 x 768 screen resolution with 256 colors
CD-ROM drive	CD-ROM drive (for software installation only)

**Note:** If a firewall is installed on the PC, it may prevent files from being transferred.

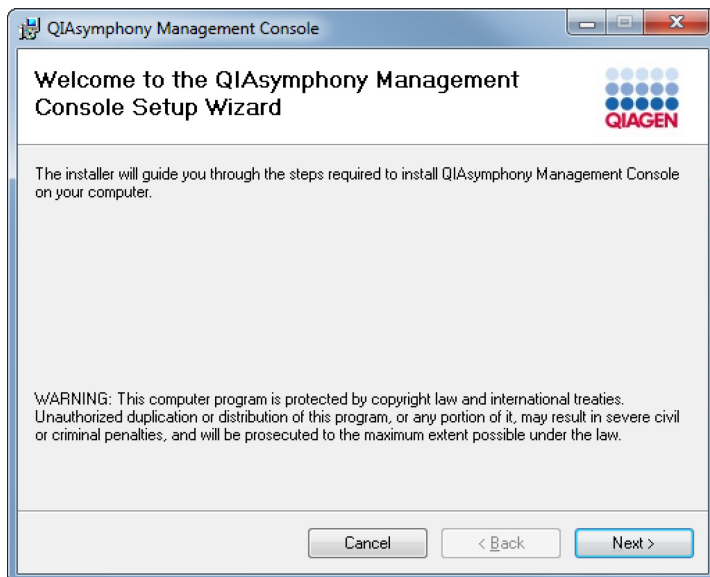
**Note:** A PDF reader is required for use with the **IC Calculator** tool.

### 20.3.2 Installation

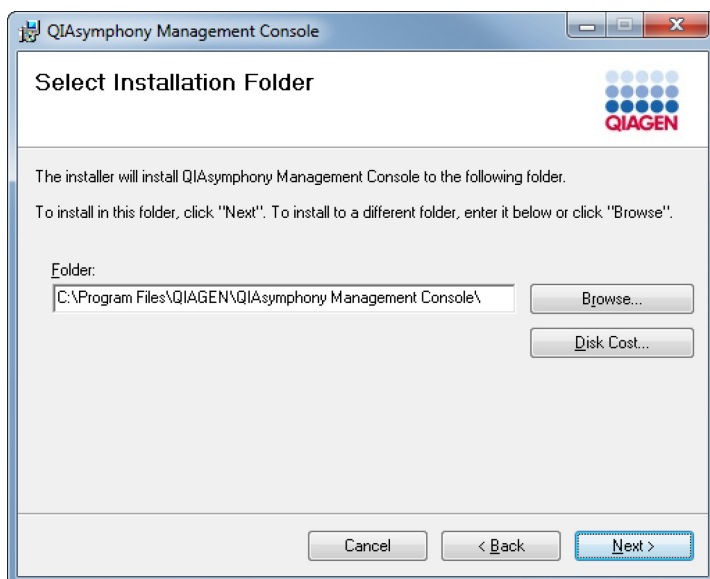
Begin installation of the QMC as follows.

1. Check that the minimum PC requirements (see Section 20.3.1, above) are met.
2. If an older version of the QMC software is installed on the PC, first remove the old version before proceeding with the installation. For more information, see Section 20.4.
3. Insert the QMC installation CD into the CD-ROM drive of the PC.
4. To launch the installation, right-click **Start** and select **Explore**. Browse to the CD-ROM drive and the QMC installation files.

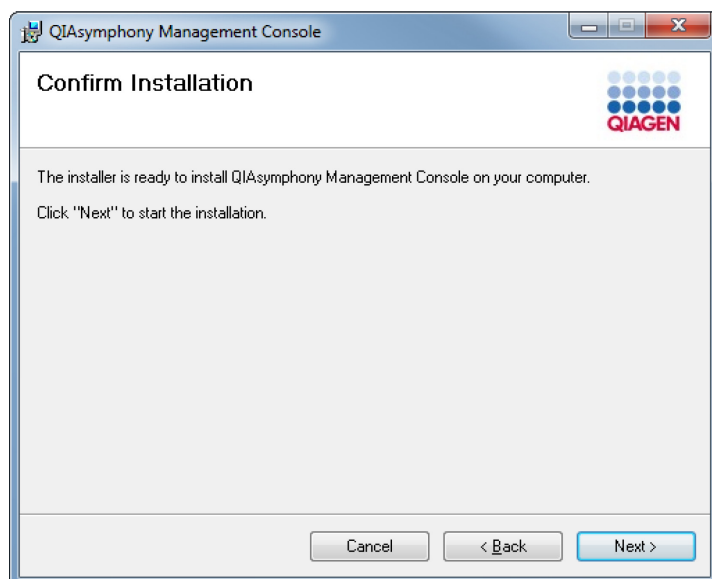
5. Double-click the **Setup.exe** file. The QMC Setup Wizard is launched. The wizard installs the necessary components to the PC.



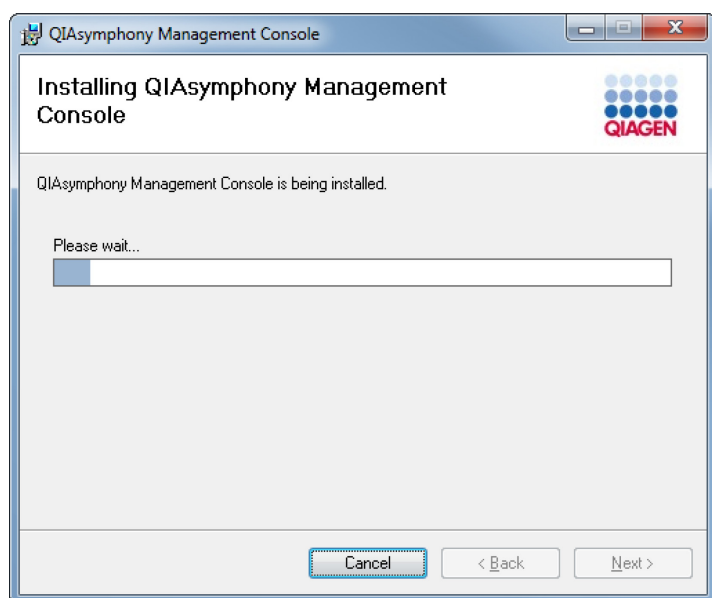
6. Click **Next** to continue.
7. Select the installation folder for the QMC by following the instructions in the dialog box. Click **Next** to continue.



8. Click **Next** to continue.

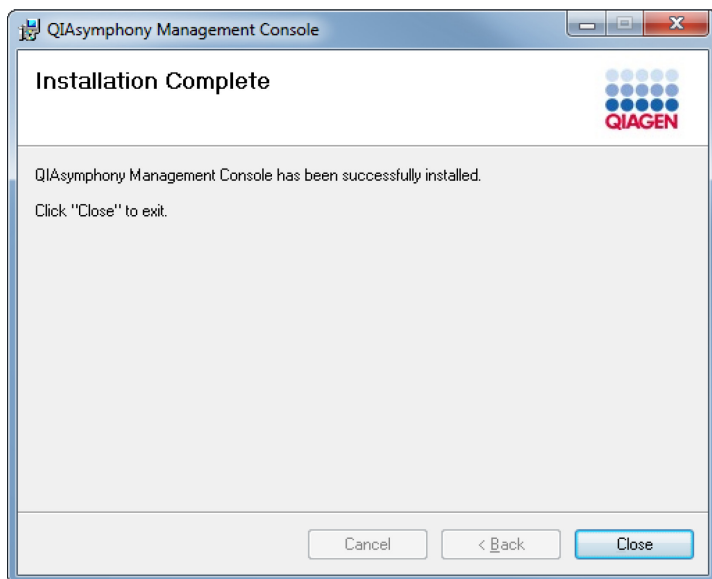


9. A dialog box opens that shows the progress of the installation procedure.





10. When the installation has finished, click **Close** to exit the installation wizard.



## 20.4 Uninstalling the QIASymphony Management Console software

**Note:** Before installing a new version of the QMC software, save all result and log files in a different folder, and then delete all remaining files and folders from the old software version. A new file/folder structure will need to be created when the new version of the software has been installed.

Uninstall the QMC software before installing a newer version as follows:

1. Click **Start**.
2. Select **Control Panel**.
3. Select **Add or Remove Programs**.
4. Select the **QIASymphony Management Console** from the list and click **Uninstall**.

After the management console has been successfully uninstalled, a newer version can be installed.

**Note:** All local data will remain on the PC.

## 20.5 Launching the QIAsymphony Management Console

Launch the QMC as follows:

1. Click **Start** and select **All Programs/QIAGEN/QIAsymphony Management Console** from the **Start** menu.

The QMC is launched and the **File Transfer** tool is displayed.

2. If you are launching the QMC for the first time, a dialog box will be displayed that asks you whether the same directories that are on the remote site (QIAsymphony or USB stick) should be created. If you click **Yes**, the subdirectories are created in the default main (root) directory (**C:/Program files/QIAGEN/ QIAsymphony Management Console**).

If you click **No**, the data directories will not be created in the default root directory. The dialog box will also be displayed if QIAsymphony has other subdirectories in addition to those found in the default main (root) directory. Click **Yes** to update the data structure.

If an older version of the QMC was installed and has been uninstalled by following the steps in Section 20.4, the defined root directory for the **File Transfer** tool will be kept. If the dialog box described above is displayed, click **Yes** to update the subdirectories so that they have the same structure as those on the QIAsymphony SP/AS.

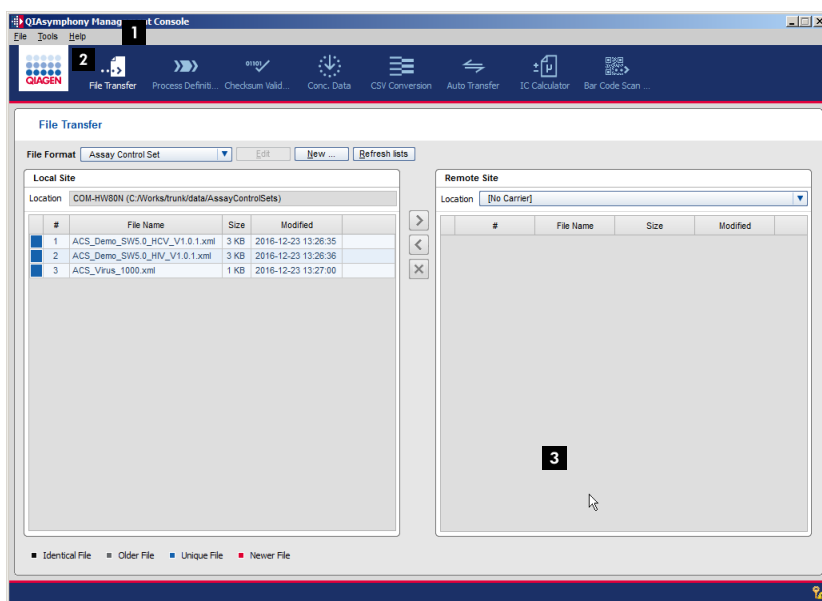
3. When the QMC is launched for the first time, you may need to configure the general options and the options for the **File Transfer**, **Checksum Validator**, **CSV Conversion**, and **Auto Transfer** tools (for detailed information, see Section 28).
4. To manage files on the QIAsymphony SP/AS, log in to the QIAsymphony (for detailed information, see Section 29).

**Note:** The QMC does not show up properly when Windows runs with a zoom factor (for example, 125%). On the PC, go to the Windows Control Panel, select Display and set the zoom factor to 100%. When the PC has a high resolution display connected, it might additionally be required to reduce the screen resolution in the control panel; otherwise the QMC screens might be so small that the text cannot be read.

## 21 Features of the QIASymphony Management Console

The main screen of the QMC automatically appears when the QMC is launched. Each screen of the QMC provides:

- A menu bar for selecting various options
- A tools list enabling selection of tools (see Section 20.1)
- An information bar
- An information panel (except in the main screen)



- 1 Menu bar                      3 Information bar
- 2 Tool bar

**QIASymphony Management Console main screen.**

### 21.1 Menu bar

The menu bar contains the **File**, **Tools**, and **Help** menus.

The submenus of these drop-down menus are black when enabled and gray when disabled.

### 21.1.1 File menu

**Login** The **Single Sign On – Login** dialog box appears (see Section 29.1). This enables the user to connect to the QIASymphony via a network.

**Note:** It is not possible to connect to the QIASymphony if the instrument is switched off.

**Note:** The QIASymphony Management Console and the QIASymphony must have the same software version (i.e., software version 4.0).

**Logout** This enables the current user to log out and disconnect from the QIASymphony.

**Exit** Closes the QMC.

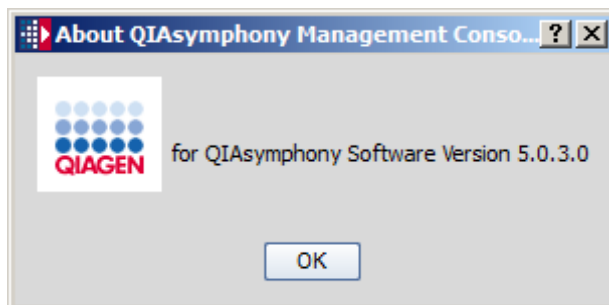
### 21.1.2 Tools menu

**Options** The **Options** dialog box appears (see Section 28.1).

List of available tools Opens the selected tool

### 21.1.3 Help menu

**About** The **About QIASymphony Management Console** dialog box appears and displays information about the management console, including the version number.



---

## 21.2 Tool list

All available tools are displayed in this list. Currently, the following tools are available:

- **File Transfer** tool
- **Checksum Validator** tool
- **CSV Conversion** tool
- **Auto Transfer** tool
- **IC Calculator** tool.

Individual tools are described in the following sections.

### 21.2.1 **File Transfer** tool

The **File Transfer** tool enables file exchange between the QIAsymphony and a predefined local path on an external PC or network, using either a connection or using a USB stick (see Section 30).

### 21.2.2 **Checksum Validator** tool

The **Checksum Validator** tool enables validation of Result Files as well as all protected files on the QIAsymphony (see Section 30.5).

### 21.2.3 **CSV Conversion** tool

The **CSV Conversion** tool enables the format conversion of files in \*.csv and \*.xml format (see Section 30.6).

### 21.2.4 **Auto Transfer** tool

The **Auto Transfer** tool enables automatic transfer of result, log, and loading information files from the QIAsymphony to a predefined directory as well as automatic transfer of work lists from the local PC or network to the QIAsymphony (see Section 30.4.2). Newly transferred result files and loading information files can also be printed automatically (see Section 30.4).

### 21.2.5 **IC Calculator** tool

The **IC Calculator** tool assists for calculating the volumes of individual components of the internal control (IC) mix for the QIAsymphony SP (see Section 26).

## 21.3 Information bar

The information bar is located at the bottom of the screen and when a user is logged in it displays information about the name of the current user, date and time of login, and the QIAsymphony host name. In addition, a symbol is displayed enabling the operator to easily see whether a user is currently logged in.



**Login** Date and time of login is displayed.

**Account** The name of the user currently logged in is displayed.

**Host** The QIAsymphony host name that has been selected for remote access is displayed. By default, the host name is **qsspxxxx**, where **xxxx** is the serial number of the QIAsymphony SP.



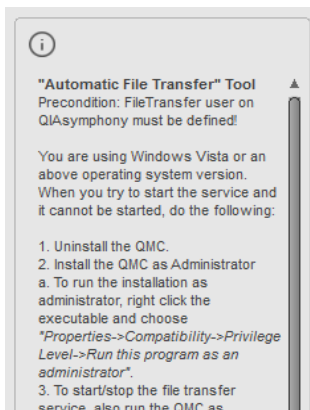
Symbol denotes that a user is currently logged in.



Symbol denotes that no user is currently logged in.

### 21.3.1 Information panel

The information panel is located on the right side of the screen. This panel provides helpful information about the current screen. Use the up and down arrows to scroll through the text.



**Example information panel.**

## 22 File Transfer Tool

Files can be uploaded, downloaded, or deleted using the **File Transfer** tool. Files can be managed via connection to the QIAsymphony or using a USB stick (see Section 7).

The **File Transfer** tool enables the following:

- Exchange of files between the QIAsymphony and a predefined local path on an external PC or network.
- Deletion of files on the predefined local path or network, QIAsymphony, or USB stick.
- Transfer of files from a predefined local path or network to a USB stick.
- Transfer of files from a USB stick to the predefined local path or network.

When using a QIAsymphony connection, the role of the user that established the connection affects the types of files that can be managed, as described in the following table.

Operator	<p>The “Operator” enables transfer of the following file types from the QIAsymphony to the QMC.</p> <ul style="list-style-type: none"><li>● Audit Trail</li><li>● Instrument Report</li><li>● Log files</li><li>● Rack files</li><li>● Result files</li><li>● Work lists</li><li>● Instrument report file</li><li>● Loading information</li><li>● Start Batch Confirmations</li></ul> <p>The “Operator” enables transfer of the following file types from the QMC to the QIAsymphony.</p> <ul style="list-style-type: none"><li>● Rack files</li><li>● Work list</li></ul>
Supervisor	<p>The “Supervisor” enables transfer of the following file types from the QIAsymphony to the QMC.</p> <ul style="list-style-type: none"><li>● Audit Trail</li></ul>

- 
- Instrument report files
  - Duration file
  - Labware
  - Log files
  - Rack files
  - Result files
  - Service script maintenance
  - Service scripts operator
  - Work list
  - Process configuration profile
  - User management
  - Maintenance configuration files
  - Assay Control Set
  - Protocol
  - Reagent definition
  - Assay definition
  - Assay Parameter Set
  - Loading information

The “Supervisor” enables transfer of the following file types from the QMC to the QIAsymphony.

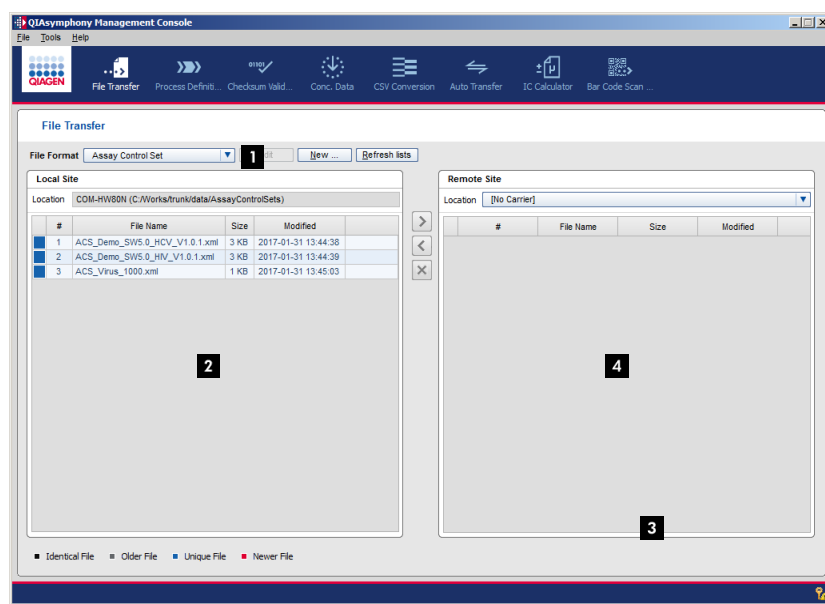
- Labware
- Process configuration profile
- Rack files
- Service script maintenance
- Service script operator
- Work list files
- User management file
- Assay Control Set
- Protocol
- Assay definition
- Assay Parameter Set
- Reagent definition



## File Transfer tool

The **File Transfer** tool displays several features including:

- A **File Format** drop-down menu that enables the type of file to be selected.
- **Edit** and **New** buttons that are enabled when **Assay Control Set** or **Assay Parameter Set** is selected as file type, and the user is logged in as "Supervisor".
- A **Remote Site** selection box that enables selection of the remote site (USB stick or connected QIAsymphony).
- A list of files stored on the predefined local path or network (for more information, see page 401), displayed according to selected file type.
- A list of files stored on the remote site, if available, displayed according to selected file type.



- 1 **File Format** drop-down menu    3 **Remote Site** selection box  
2 **Local Site** file list    4 **Remote Site** file list

### 22.1 File Format drop-down menu

Available file types are displayed in the **File Format** selection box. The items displayed in the list vary depending on whether a user is logged in and the user role.

File types in the following table are displayed in the **File Format** selection box.

User	Selectable file types	Action
No user logged in	Assay Control Set	Files saved on the predefined local path on the PC or network are listed in the local path file list.
	Assay definitions	
	Assay Parameter Set	Files can be deleted from the local path.
	Audit Trail	
	Configuration	Files can be transferred from the local path (root directory) to the USB stick or from the USB stick to the local path.
	Data recording file SP	
	Data recording file AS	Files on the USB stick can be deleted.
	Duration file SP	
	Duration file AS	
	Instrument report files	
	Labware AS	
	Labware SP	
	Loading information	
	Log files	
	Maintenance configuration	
	Process configuration profile	
	Protocol	
	Protocol, unfinished	
	Rack files	
	Reagent definitions	
	Result files AS	
	Result files SP	
	Service script developer AS	
	Service script developer SP	
	Service script maintenance AS	
	Service script maintenance SP	
	Service script operator AS	
	Service script operator SP	
	Service script service AS	
	Service script service SP	
	User management	
	Work List	
	Work Table	

User	Selectable file types	Action
"Operator"	Audit Trail Instrument report files Loading information Log files Rack files Result files AS Result files SP Work list	<p>Files saved on the predefined local path on the PC or network are listed in the local path file list.</p> <p>Files can be deleted from the local path.</p> <p>Files can be transferred to the USB stick or from the USB stick to the local path.</p> <p>Files on the USB stick can be deleted.</p> <p>All listed file types can be downloaded from the QIAsymphony to the local path.</p> <p>Work list and rack files can be uploaded from the local path to the QIAsymphony.</p> <p>All listed file types, except log files can be deleted from the QIAsymphony.</p>

User	Selectable file types	Action
"Supervisor"	Assay Control Set	Files saved on the predefined local path on the PC or network are listed in the local path file list.
	Assay definitions	
	Assay Parameter Set	
	Audit Trail	Files can be deleted from the local path.
	Duration file SP	Files can be transferred to the USB stick or from the USB stick to the local path.
	Duration file AS	
	Instrument report file	Files on the USB stick can be deleted.
	Labware AS	
	Labware SP	Work lists, rack files, Assay Control Sets, protocols, Assay Parameter Sets, assay definitions, labware files, service scripts, process configuration profiles, and information about reagent cartridges can be transferred to the QIAsymphony.
	Loading information	
	Log files	
	Maintenance Config	
	Process configuration profile	
	Protocol	
	Rack files	
	Reagent definitions	
	Result files AS	
	Result files SP	
	Service script maintenance SP	
	Service script maintenance AS	
	Service script operator SP	
	Service script operator AS	
	User management	
	Work list	

**Important:** When transferring a new labware package using the QMC, ensure that the set of files that is in the installation package is completely transferred to the QIAsymphony. In addition, ensure that any files that are not included in the package (marked blue on the **Remote Site** in the **File Transfer**) are removed from the QIAsymphony.

### 22.1.1 Buttons next to **File Format** selection box

<b>Edit</b>	This button is enabled if <b>Assay Control Set</b> or <b>Assay Parameter Set</b> is selected as file type and one Assay Control Set or Assay Parameter Set is highlighted.
<b>New</b>	This button is enabled if <b>Assay Control Set</b> or <b>Assay Parameter Set</b> is selected as file type.
<b>Refresh lists</b>	Click to update the Local Site and <b>Remote Site</b> file list.

## 22.2 **Remote Site** selection box

Remote sites are listed in the **Remote Site** selection box. Use this list to select the remote site (QIAsymphony or USB stick) you want to work with. The QMC can either be connected to the QIAsymphony or to a USB stick. Alternatively, the QMC can be used offline.

- To connect to the QIAsymphony, you must first log in.
- To connect to a USB stick, user login is not required.

## 22.3 **Local Site** and **Remote Site** file lists

Available files on the local path and remote site are displayed in the **Local Site** file list and **Remote Site** file list, respectively. Files are displayed according to the selected file type.

The local path is configured in the **Options** dialog box of the **Tools** menu (see Section 28.1).




### 22.3.1 Displayed file information

Additional information about the listed files is shown in the following table.

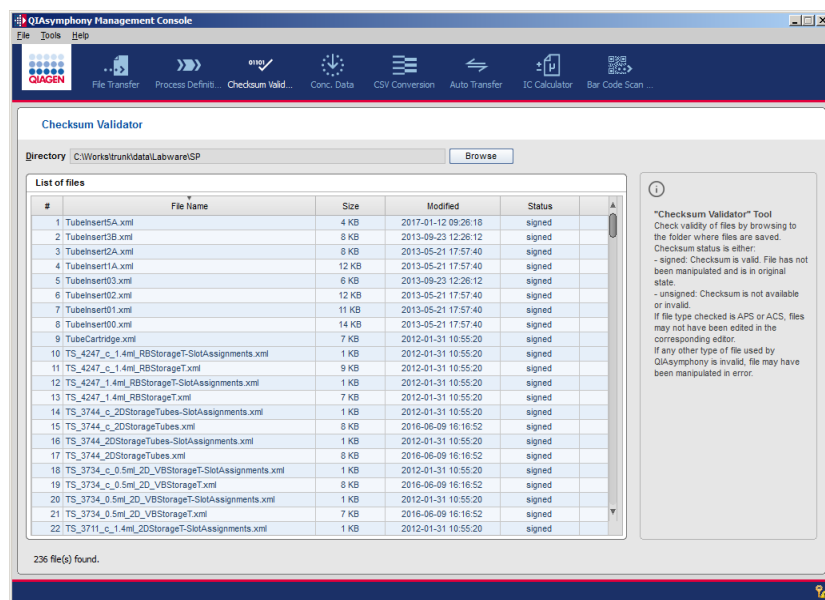
Use of colors	<div><div>■ Identical File</div><div>■ Older File</div><div>■ Unique File</div><div>■ Newer File</div></div> <ul style="list-style-type: none"><li>● <b>Identical File</b> — the file is identical on the remote and local site</li><li>● <b>Older File</b> — the file is older than the other file and exists on both the remote and local site</li><li>● <b>Unique File</b> — the file exists on either the remote site or the local site, but not on both</li><li>● <b>Newer File</b> — the file is newer than the other file and exists on both the remote and local site</li></ul>
# (number)	The number of the file.
File Name	The full file name is displayed.
Size	The size of the file is displayed.
Created	The date and time of file creation are optionally displayed. This information is configured in the <b>Options</b> dialog box of the <b>Tools</b> menu (see Section 28.1).
Modified	The date and the time at which the file was last modified are optionally displayed. This information is configured in the <b>Options</b> dialog box of the <b>Tools</b> menu (see Section 28.1).
Read	The date and the time at which the file was last accessed are optionally displayed. This information is configured in the <b>Options</b> dialog box of the <b>Tools</b> menu (see Section 28.1).
Status	Indicates the checksum status: <ul style="list-style-type: none"><li>● <b>Signed</b> — checksum is valid and the file has not been modified.</li><li>● <b>Unsigned</b> — checksum is invalid indicating that the file was modified without using a suitable editor or the checksum is not available.</li></ul>

---

### 22.3.2 Actions

- Double-click the highlighted file to open the appropriate editor and display the contents of the file.
- Right-click the highlighted file to open the context menu.
- Click  to copy a file from the remote site to the local path.
- Click  to copy a file from the local path to the remote site.
- Click  to delete files on either the local path or remote site, if permitted.

## 23 Checksum Validator Tool



### The Checksum Validator tool.

The **Checksum Validator** tool provides the following for selecting a file.

- Browse** Button for opening the **Browse Directory** dialog box, which enables the folder in which the files are located to be selected.
- Directory** Field that displays the selected directory.
- x file(s) found** Indicates the total number of files listed in the main panel.

The results of the checksum validation for the selected file are displayed in the main panel. The local path is configured in the **Options** dialog box of the **Tools** menu (see Section 28.1).

- #** The number of the file.
- File Name** The full file name is displayed.
- Size** The size of the file is displayed.
- Created** The date and time of file creation are optionally displayed. This information is configured in the **Options** dialog box of the **Tools** menu (see Section 28.1).

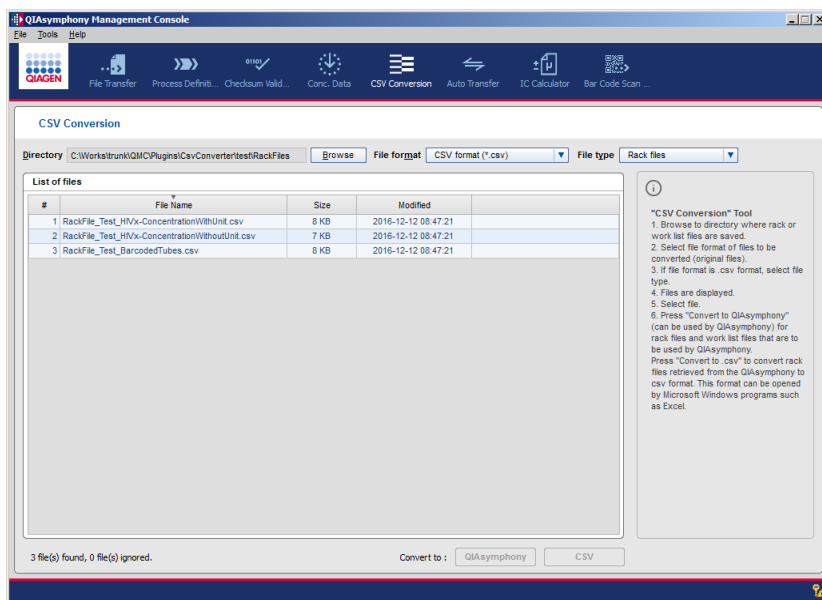


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<b>Modified</b>	The date and the time at which the file was last modified are optionally displayed. This information is configured in the <b>Options</b> dialog box of the <b>Tools</b> menu (see Section 28.1).
<b>Read</b>	The date and the time at which the file was last accessed are optionally displayed. This information is configured in the <b>Options</b> dialog box of the <b>Tools</b> menu (see Section 28.1).
<b>Status</b>	Indicates the checksum status: <ul style="list-style-type: none"><li>● <b>Signed</b> — checksum is valid and the file has not been modified.</li><li>● <b>Unsigned</b> — checksum is invalid indicating that the file was modified without using a suitable editor or checksum is not available.</li></ul>

## 24 CSV Conversion Tool

The **CSV Conversion** tool enables the format conversion of \*.csv and \*.xml files.



CSV Conversion screen.

- x file(s) found, x file(s) ignored** Indicates the number of files that were found to correspond to the search criteria, and the number of files that did not correspond to the search criteria. The "found" files are listed in the main panel.
- Directory** The selected directory is listed.
- Browse** Opens the **Browse Directory** dialog box, enabling the user to search for the folder in which the files are located.
- File format selection box** The available file formats are listed. Options for \*.csv files (e.g., file extension and file delimiter) can be defined in the **Options** dialog box of the **Tools** menu (see Section 28.1).
- File type** Available file types are listed. It is possible to convert rack files to both \*.csv and \*.xml format and work list files from \*.csv to \*.xml format.
- #** The number of the file.
- File Name** The full file name is displayed.

---

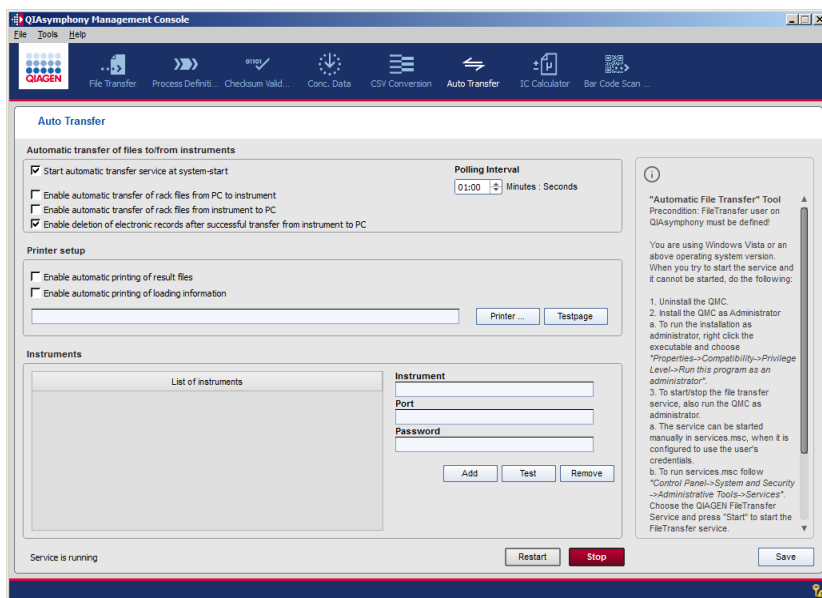
<b>Size</b>	The file size is displayed.
<b>Created</b>	The date and time of the file creation are displayed. This optional display is configured in the <b>Options</b> dialog box of the <b>Tools</b> menu (see Section 28.1).
<b>Modified</b>	The date and time of the last modification of the file are displayed. This optional display is configured in the <b>Options</b> dialog box of the <b>Tools</b> menu (see Section 28.1).
<b>Read</b>	The date and time the file was last accessed are displayed. This optional display is configured in the <b>Options</b> dialog box of the <b>Tools</b> menu (see Section 28.1).
<b>Status</b>	The file status is displayed. The status of the file is always "unknown".
<b>Convert to: QlAsymphony</b>	Allows you to convert selected files in *.csv format to *.xml format.
<b>Convert to: CSV</b>	Allows you to convert the selected files in *.xml format to *.csv format.

## 25 Auto Transfer Tool

The **Auto Transfer** tool enables the configuration of automatic transfer of result and log files from the QIAAsymphony to a predefined directory. Result and loading information files are transferred to the predefined directory. Result and loading information files are deleted after successful transfer. Log files are transferred to the predefined directory and remain on the QIAAsymphony. In addition, the tool enables newly transferred result and loading information files to be automatically printed.

**Note:** Do not use the **Desktop** or any of the subdirectories in **My Documents** as the predefined directory. The **Auto Transfer** tool does not have read or write permission for these directories.

**Note:** To use a network directory, follow the procedure in Section 28.6.1. In the default configuration, the **Auto Transfer** tool does not have read or write permission for these directories.



<b>Start automatic transfer service at system start</b>	<p>Check this box to enable the automatic startup of the <b>AutoFileTransfer</b> on starting Windows. By default, this parameter should be enabled.</p> <p>Administrator rights are required for Windows to start or stop this service.</p>
<b>Polling interval</b>	<p>Enter a time for the polling interval. This setting determines how often the QIAsymphony Management Console checks for availability of new files.</p>
<b>Enable automatic transfer of rack files from PC to instrument</b>	<p>Check this box to enable automatic transfer of rack files from PC to instrument.</p>
<b>Enable automatic transfer of rack files from instrument to PC</b>	<p>Check this box to enable automatic transfer of rack files from instrument to PC.</p>
<b>Enable deletion of electronic records after successful transfer from instrument to PC</b>	<p>When selected, the following electronic record file types on QIAsymphony will be deleted after successful transfer:</p> <ul style="list-style-type: none"> <li>● Worklists</li> <li>● StartBatchConfirmation (SP and AS)</li> <li>● Result files (SP and AS)</li> <li>● LoadingInformation</li> <li>● AuditTrail</li> </ul>
<b>Enable automatic printing of result files</b>	<p>Check this box to enable result files to be automatically printed.</p>
<b>Orientation</b>	<p>Select whether to print result files in landscape or portrait.</p>
<b>Enable automatic printing of loading information</b>	<p>Check this box to enable loading information files to be automatically printed.</p>
<b>Orientation</b>	<p>Select whether to print loading information files in landscape or portrait.</p>
<b>Printer</b>	<p>Click this button to display the <b>Print</b> screen, which contains the list of available printers, and select a printer.</p>

<b>Text field</b>	The selected printer is displayed.
<b>Test page</b>	Click to print a test page on the selected printer.
<b>Instrument</b>	Enter the hostname of the QIAsymphony SP, from which files should be automatically transferred.
<b>Port</b>	Enter the port of the connected QIAsymphony (port 80).
<b>Password</b>	<p>Allows a password to be entered for the <b>FileTransfer</b> user. In order to manage the <b>FileTransfer</b> user and thus to configure its password:</p> <ul style="list-style-type: none"> <li>● Log in to the QIAsymphony SP/AS as a user with the role "Supervisor".</li> <li>● Go to <b>Tools</b> and select <b>User Management</b>.</li> <li>● Select the user <b>FileTransfer</b> in the <b>Activated Users</b> selection and provide a password for it.</li> </ul> <p>Refer to "User Accounts", Section 4.4, for detailed information about how to manage the user accounts and how to configure the password.</p> <p>This password does not expire but can be changed if required. The password can only be set by a user with the "Supervisor" user role.</p>
<b>List of instruments</b>	Displays all configured instruments.
<b>Add</b>	Adds the automatic file transfer configuration to the instrument displayed in the <b>Instruments</b> dialog field.
<b>Test</b>	Tests the connection to the configured instrument.
<b>Remove</b>	Removes the selected instrument configuration from the list.
<b>Text label</b>	Indicates whether the <b>QIAGEN File Transfer</b> service is currently running.
<b>Restart</b>	Restarts the <b>QIAGEN File Transfer</b> service (button enabled when service is running).

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<b>Start</b>	Starts the <b>QIAGEN File Transfer</b> service (button enabled when service is not running).
<b>Stop</b>	Stops the <b>QIAGEN File Transfer</b> service (button enabled when service is running).
<b>Save</b>	Saves configuration changes.

**Note:** After changing the root directory for the **Auto Transfer** tool, the **QIAGEN File Transfer** service must be stopped and restarted (see Section 30.4.3).

**Note:** The User Account Control (UAC) from Windows prevents use of the **Start/Stop** and **Restart** buttons. In this case, deactivate the UAC (contact Microsoft for more details about how to do this). If it is not possible to deactivate the UAC, or if you choose not to deactivate the UAC, you can start/restart the **QIAGEN File Transfer** Service from within the Windows service configuration. To do this, the QIAGEN File Transfer Service must be configured with actual user credentials, see Section 28.6.1.

## 26 IC Calculator Tool

The QIAasympphony Internal Control Calculator enables calculation of the volume of reagent required to prepare the internal control-carrier RNA mixture (IC-carrier RNA mixture) in specific tubes.

**Note:** If no internal control is used, a carrier RNA-buffer AVE mixture must be used (see “Calculating reagent volumes”, Section 26.2).

The screenshot shows the QIAasympphony Management Console with the IC Calculator tool active. The interface is divided into several sections:

- Input:** Includes dropdowns for ACS (Demo\_SWS\_0\_HV V1.0.1) and Labware (SAB72.693 T2.0 Screw), a text field for Number of samples (20), and a dropdown for Elution volume (90). Below this is the Internal control mode section with radio buttons for Internal Control/Elate (selected) and Internal Control/Sample. A Calculate button is present.
- Calculation data:** A section with a numbered list item 1, showing Initial elution volume (102 µl), Volume internal control per sample (20.4 µl), and Carrier RNA per sample (5 µl).
- Result:** Contains a Pipetting scheme table and a Remark section.
- Pipetting scheme table:**

Internal control(µl)	Carrier RNA(µl)	Buffer(µl)	Total volume(µl)
554.9	136.0	669.1	1360.0
- Remark:** Composition of IC mix in single tube
- Number of tubes:** 1 for IC-Mixture
- Instructions:** A numbered list (1-6) on the right side of the window provides step-by-step guidance for using the tool.
- Buttons:** A Print button is located at the bottom right of the main window.

### 26.1 Before using the IC Calculator tool

The following steps must be performed to enable the functionality of the **IC Calculator** editor tool.

1. Define the root directory (main directory) in the **File Transfer** tab of the **Options** dialog (page 399).
2. Transfer Protocols and existing Assay Control Sets from the QIAasympphony to the corresponding subdirectories of the root directory (page 400).



## 26.2 Calculating reagent volumes

To calculate the required reagent volumes, proceed as follows:

1. Select the Assay Control Set that you want to use for processing the samples.
2. Enter the number of samples to be processed.
3. Select the labware to be used for internal control (IC).
4. Select whether you would like to specify the internal control volume per eluate or the internal control volume per sample.
5. If you chose to specify the internal control volume per eluate, select the elution volume, otherwise skip this step.

When selecting the elution volume, ensure that the same volume is selected when defining samples on QIAasymphony SP.

Enter the required amount of internal control (IC) per sample/eluate that is needed for the downstream process. If IC is not required, enter **0**.

**Note:** Carrier RNA will automatically be added, if it is necessary for the respective protocol.

7. Press the **Calculate** button.
8. (Optional) Print the result of the calculation using the **Print** button to create a pdf that summarizes the calculation data.
9. Prepare the IC-mixture as shown in the result. If multiple IC tubes are required, be sure to first prepare the mixture in one large tube and then dispense that mixture to the individual tubes. This ensures that the ratio of reagents is the same in every IC tube.

## 26.3 Structure of dialog box

### 26.3.1 Input panel

<b>ACS</b>	Assay Control Set to be used for processing the samples.
<b>Number of samples</b>	Number of samples to be processed with the IC-mixture.
<b>Labware</b>	Labware to be used for internal control (IC).
<b>Elution Volume</b>	Elution volume to be produced by the QIAasymphony SP. Only selectable if <b>Internal Control/Eluate</b> is selected.

<b>Internal Control/Eluate</b>	The amount of internal control per eluate required for the downstream process.
<b>Internal Control/Sample</b>	The amount of internal control per eluate required for the downstream process.
<b>Volume internal control per sample</b>	The amount of internal control to be added to each sample by the QIASymphony SP. Cannot be modified and is shown for information purposes.
<b>Carrier RNA per sample</b>	The amount of carrier RNA that will be added to each sample by the QIASymphony SP. Cannot be modified and is shown for information purposes.

### 26.3.2 **Result** panel

<b>Pipetting scheme</b>	Defines the amount of reagents that have to be pipetted for preparation of the IC-mixture.
<b>Remark</b>	Shows additional advice for preparation of IC-mixture.
<b>Total dispense volume per single tube</b>	Also shows the amount of IC-mixture that is to be dispensed into each individual IC tube.
<b>Number of tubes</b>	Defines the number of IC tubes that have to be loaded on the IC carrier.

## 27 Getting Started

To get the most out of the QMC and the tools included, we recommend that users follow the workflow described below.

**Note:** When a new version of the QMC is installed, the options settings from the previous version are kept. New tools must be configured separately.

1. Create a directory on your local PC or on the network (if several users need to work with the same data) that will be used as the main (root) directory for the **File Transfer** and **Process Definition** editor tools. We recommend naming the directory according to the host name of your QIAsymphony (default is **qsspxxxx**; where **xxxx** is the serial number of the QIAsymphony SP) to enable you to easily identify the data stored in this directory.

2. **Optional:** To use the **Auto Transfer** tool and print function, create a directory on your local PC or on the network (if several users need to work with the same data) in which the downloaded files (e.g., result files and log files) for individual instruments will be saved.

**Note:** Do not select the **Desktop** or any of the subdirectories listed in **My Documents** as the predefined directory. The **Auto Transfer** tool does not have read or write permission for these directories.

Note: If you want to use a network directory as the root directory for the **Auto Transfer** tool, see the notes in Section 28.6.1.

3. Configure options for the QMC and tools. For more information, see Section 28.

**Note:** When specifying the root directory for the **File Transfer** and **Auto Transfer** tools, browse to the directory created in step 1.

4. After configuring the options, a dialog box opens that asks whether the same directories as those on the QIAsymphony should be created in the root directory. Click **Yes** to create the same data structure in the root directory.

If the data structure is already available, the dialog box is not displayed.

5. If you want to transfer result, loading information, or log files automatically from the QIAsymphony SP/AS, open the **Auto Transfer** tool and enter the required information.

**Note:** If the PC is shut down, the automatic file transfer service is also shut down. The **File Transfer** service starts again automatically the next time the PC is switched on.

- 
6. Transfer protocols, Assay Control Sets, assay definition files, Assay Parameter Sets, and labware files from the QIASymphony to the corresponding subdirectories in the defined root directory.

The **File Transfer** tool can be used for the transfer when the PC is connected to the QIASymphony. Alternatively, a USB stick can be used if the QIASymphony is not connected.

**Note:** If the files are provided on a USB stick, use the "File Transfer" tool to transfer the data to the root directory. For more information, see Section 30.2.

7. Close the QMC and launch it again. The QMC is now ready for use.

## 28 Configuration

The appearance of the QMC and the way that information is displayed can be configured to suit user needs. Various settings for the QMC and associated tools can be configured in the **Options** dialog box of the **Tools** menu.

### 28.1 Options dialog box

To change QMC settings, complete the following steps.

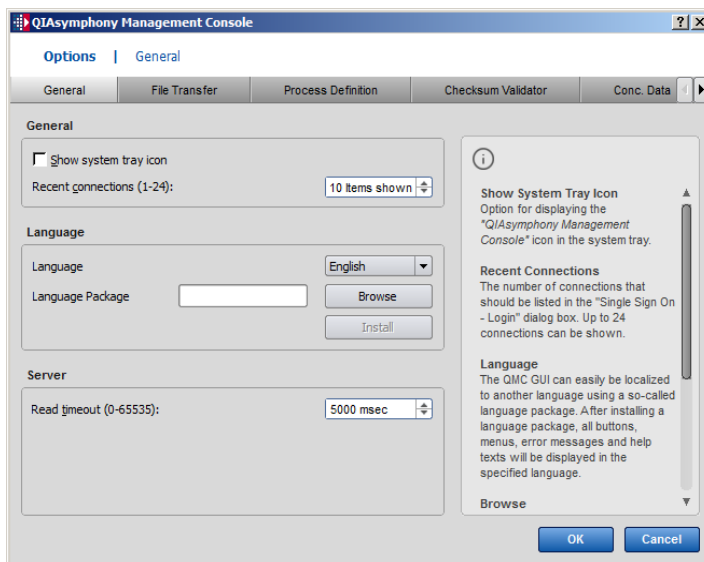
1. Select **Tools/Options**. The **Options** dialog box is displayed.
2. Select the tab of the tool to be configured. The corresponding parameters appear.
3. Change the settings according to your needs.
4. Click **OK**.

The following buttons are available in the **Options** dialog box.

- OK** Closes the dialog box and saves the changes.
- Cancel** Closes the dialog box without saving the changes.

The Options dialog box provides a **General** tab, as well as a tab for each of the available tools (except the **IC Calculator**). The tabs are described in detail below.

### 28.2 General tab



### 28.2.1 General panel

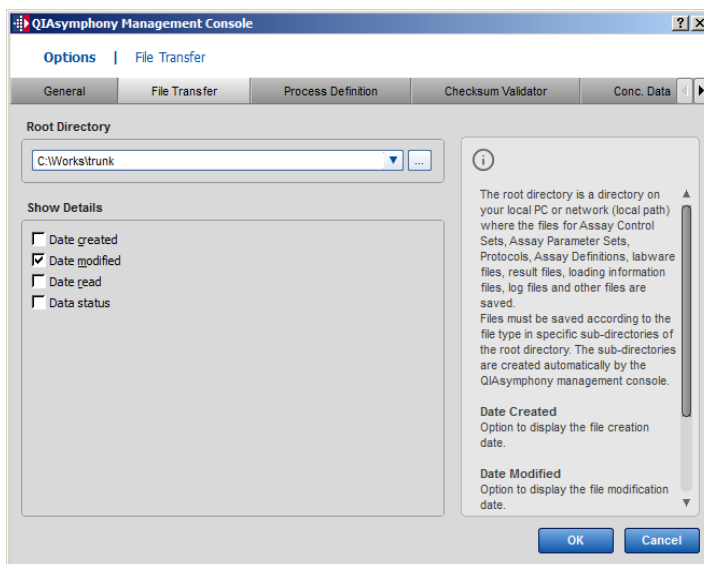
<b>Show System Tray Icon</b>	Checkbox for displaying the QIAsymphony Management Console icon in the system tray.
<b>Recent connections</b>	The number of connections that should be listed in the <b>Single Sign On – Login</b> dialog box. Up to 24 connections can be shown.

### 28.2.2 Server panel

<b>Read timeout</b>	The number of milliseconds before a timeout occurs due to an unfinished remote read operation.
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## 28.3 File Transfer tab

### 28.3.1 Root Directory panel



Enables the user to browse for a root directory.

The root directory is a directory on your local PC or network (local path) where the files for Assay Control Sets, Assay Parameter Sets, protocols, assay definitions, labware files, result files, loading information files, log files, and other files are saved. Files must be saved

according to the file type in specific subdirectories of the root directory (see table on the next page). The subdirectories are created automatically by the QMC.

**Note:** If the maximum amount of files is exceeded in one of the subfolders, the performance of the QMC may be affected. Therefore, it is recommended to move the files (e.g., log files) to a backup folder if many files have been accumulated.

The **Root Directory** panel has the following features:

- A selection box that enables selection of previously used directories for the local path. The selected directory is displayed.
- A browse button that enables the user to search for the root directory (local path).

File folders in the following table are found in the root directory for the **File Transfer** tool.

Directory	File type
root\data\AssayControlSets	Assay Control Set
root\data\AssayDefinitions	Assay definitions
root\data\AssayParameterSets	Assay Parameter Sets
root\data\AssayParameterSetReports	Assay Parameter Set reports
root\data\BioScripts	Protocol
root\data\ConcentrationData	Concentration files
<b>Note:</b> This folder (ConcentrationData) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.	
root\data\config\Maintenance	Process configuration maintenance
root\data\config\Profiles	Process configuration profiles
root\data\Duration\AS	Duration files AS
root\data\Duration\SP	Duration files SP
root\data\ICCalculatorReports	IC calculator reports
root\data\Labware\AS	Labware AS
root\data\Labware\SP	Labware SP
root\data\RackFiles	Rack files
root\data\ReagentDefinitions	Reagent definitions
root\data\ServiceScripts\AS\Developer	Service scripts developer AS

Table continued on next page





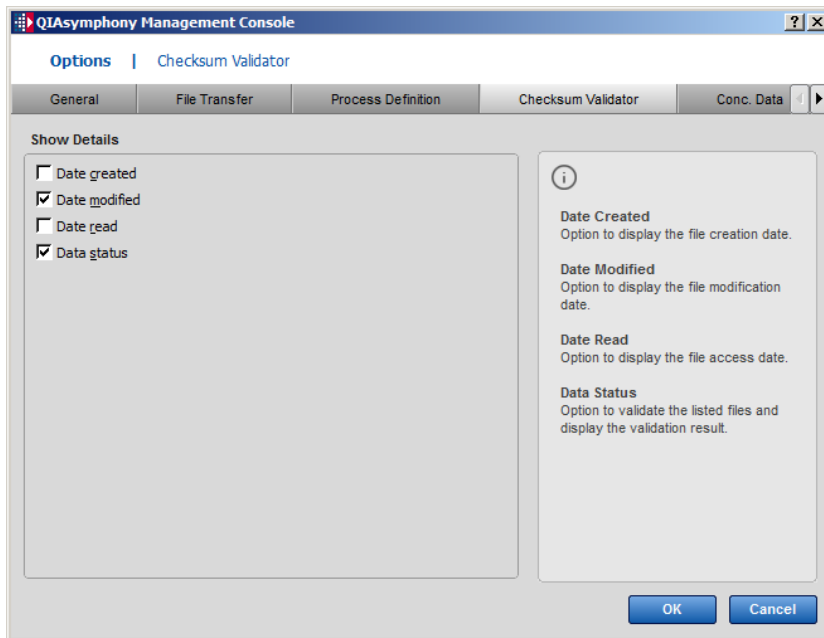
Table continued from previous page

Directory	File type
root\data\ServiceScripts\AS\Maintenance	Service scripts maintenance AS
root\data\ServiceScripts\AS\Operator	Service scripts operator AS
root\data\ServiceScripts\AS\Service	Service scripts service AS
root\data\ServiceScripts\SP\Developer	Service scripts developer SP
root\data\ServiceScripts\SP\Maintenance	Service scripts maintenance SP
root\data\ServiceScripts\SP\Operator	Service scripts operator SP
root\data\ServiceScripts\SP\Service	Service scripts service SP
root\data\Users	User management
root\data\Worklists	Work list files
root\log	Log files
root\log\AuditTrail	Audit Trail files
root\log\CyclerExport	Cycler Files
<b>Note:</b> This folder (CyclerExport) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.	
root\log\InstrumentReports	Instrument report files
root\log>LoadingInformation	Loading information files
root\log\Results\AS	Result files AS
root\log\Results\SP	Result files SP
root\log\StartBatchConfirmation	Start batch confirmation files
<b>Note:</b> This folder (StartBatchConfirmation) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.	

### 28.3.2 Show Details panel

- Date created** Option to display the file creation date.
- Date modified** Option to display the file modification date.
- Date read** Option to display the file access date.
- Data status** Option to validate the listed files and display the validation result.

## 28.4 Checksum Validator tab

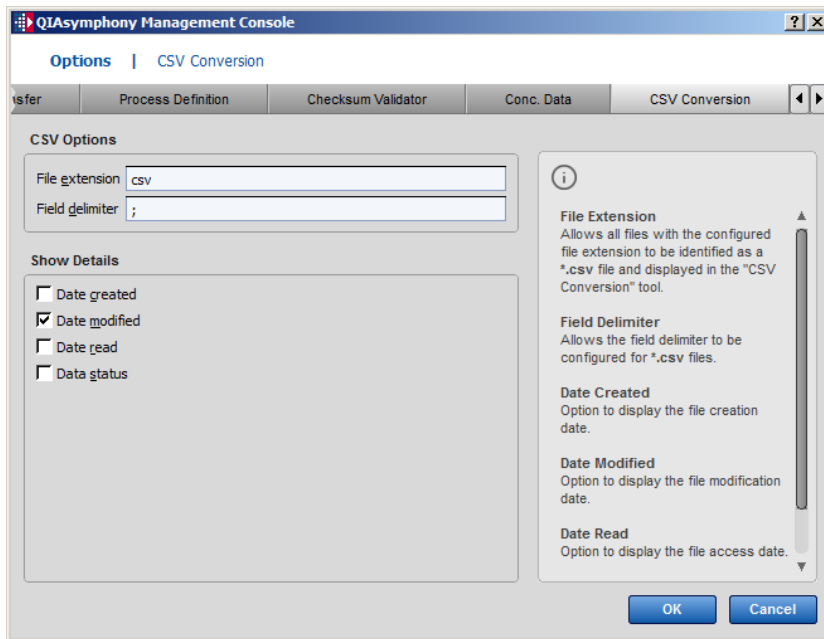


### 28.4.1 Show Details panel

- |                      |  |
|----------------------|--|
| <b>Date created</b>  | Option to display the file creation date.                              |
| <b>Date modified</b> | Option to display the file modification date.                          |
| <b>Date read</b>     | Option to display the file access date.                                |
| <b>Data status</b>   | Option to validate the listed files and display the validation result. |

## 28.5 CSV Conversion tab

### 28.5.1 CSV Options panel



**File extension** Allows all files with the configured file extension to be identified as a \*.csv file and displayed in the **CSV Conversion** tool.

**Field delimiter** Allows the field delimiter to be configured for \*.csv files.

### 28.5.2 Show Details panel

**Date created** Option to display the file creation date.

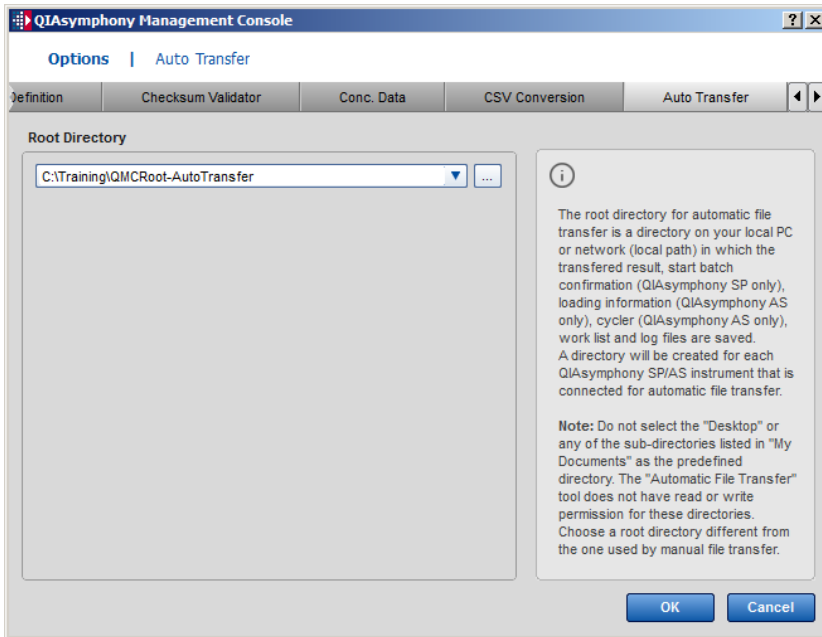
**Date modified** Option to display the file modification date.

**Date read** Option to display the file access date.

**Data status** Option to validate the listed files and display the validation result.

## 28.6 Auto Transfer tab

### 28.6.1 Root Directory panel



Enables the user to browse for a root directory.

The root directory for automatic file transfer is a directory on your local PC or network (local path) in which the transferred files are saved. A directory will be created for each QIASymphony instrument that is connected for automatic file transfer.

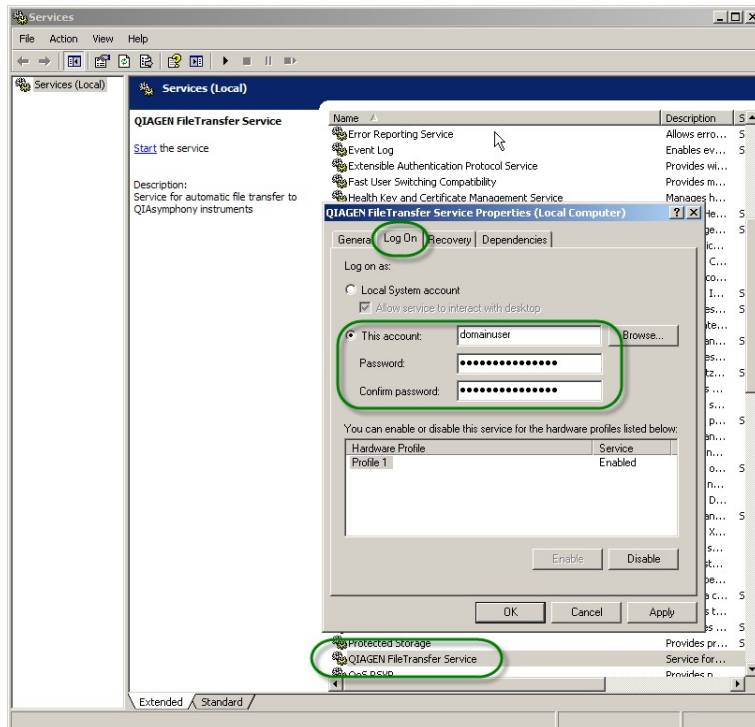
**Note:** Do not select the **Desktop** or any of the subdirectories listed in **My Documents** as the predefined directory. The **Auto Transfer** tool does not have read or write permission for these directories.

**Note:** Depending on your local IT setup, it may be necessary to proceed as follows if you want to save transferred files to a network directory.

1. The domain administrator should:
  - Establish an account for a domain user (you may need to contact your local IT administrator).
  - Configure the remote file system to be fully accessible via the domain user.

2. Configure the service to run as the domain user:

- Open the Windows service configuration in **Settings/Control Panel/Administrative Tools/Services**.
- Locate the **QIAGEN File Transfer** service and open its properties.
- Enter the user and password of the domain account in the **Log On** tab.



3. Enter the path to the network directory in the form

\\<server>\<shared\_folder>\<subpath> as root directory in the **Auto transfer** tab of the QMC options dialog.

**Note:** The shared file system cannot be accessed via the "letter" of a mapped drive (e.g., Z:\), and therefore use the full name of the drive, to be specified in the form \\<server>\<shared\_folder>\<subpath>, either manually or by selecting it from the network environment.

Directory	Content
<root directory>\instruments\<instrument id> \import\Results\AS	Result files downloaded from the QIAAsymphony AS that have not yet been printed
<root directory>\instruments\<instrument id> \import\Results\SP	Result files downloaded from the QIAAsymphony SP that have not yet been printed
<root directory>\instruments\<instrument id> \import>LoadingInformation	Loading information files downloaded from the QIAAsymphony AS that have not yet been printed
<root directory>\instruments\<instrument id> \import\Results\AS\printed	Result files downloaded from the QIAAsymphony AS that have been successfully printed
<root directory>\instruments\<instrument id> \import\Results\SP\printed	Result files downloaded from the QIAAsymphony SP that have been successfully printed
<root directory>\instruments\<instrument id> \import>LoadingInformation\printed	Loading information files downloaded from the QIAAsymphony AS that have been successfully printed
<root directory>\instruments\<instrument id> \import\Logfiles	Log files
<root directory>\instruments\<instrument id> \import\CyclerExport	Cycler files, exported from the QIAAsymphony AS <b>Note:</b> Not applicable for Rotor-Gene AssayManager
<root directory>\instruments\<instrument id> \import\StartBatchConfirmation\SP	Start batch confirmation files downloaded from the QIAAsymphony SP
<b>Note:</b> This folder (StartBatchConfirmation\SP) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.	
<root directory>\instruments\<instrument id> \import\StartBatchConfirmation\AS	Start batch confirmation files downloaded from the QIAAsymphony AS
<b>Note:</b> This folder (StartBatchConfirmation\AS) is required for instrument function but it is not used with FDA cleared or approved nucleic acid tests.	
<root directory>\instruments\<instrument id> \export\Worklists	Work lists
<root directory>\instruments\<instrument id> \failed	Files for which upload failed
<root directory>\instruments\<instrument id> \sent	Files for which upload succeeded

## 29 Logging In and Connecting

To enable remote access to the QIAsymphony, you must log in to the QMC and connect with the QIAsymphony via the network. The QIAsymphony can be connected via the local network or can be connected directly to a stand-alone PC, which is not connected to the local network.

To connect to the QIAsymphony using a stand-alone PC, a crossover network cable is required. In addition, the QIAsymphony configuration must be modified. This can be done by QIAGEN Field Service or by a user with supervisor rights (the support of a local IT administrator may be required). For more information, see “System settings”, Section 4.2.4. The network properties of the local PC should be set to:

- Internet protocol — Enter a specific IP address
- Net mask — 255.255.255.0

**Note:** You can only connect to the QIAsymphony when it is switched on.

To log in, complete the following steps.

1. Switch on the QIAsymphony and launch the QMC.  
For more information, see Section 20.5.
2. Select **File/Login**.  
The **Single Sign On – Login** dialog box appears.
3. Enter the host name and the port (**port 80**) for the QIAsymphony or, alternatively, select one of the recent connections listed in the dialog box.
4. Enter your user name and password.  
**Note:** When the QMC is connected to the QIAsymphony, the user names and passwords that are valid on the QIAsymphony can also be used to log into the QMC.
5. Click **OK**.

## 29.1 Single Sign On – Login dialog box

The **Single Sign On – Login** dialog box enables the user to gain access to all tools by logging in just once.

**Note:** For more details about automatic transfer of files, see Section 30.4).



The Single Sign On – Login dialog box.

### 29.1.1 Recent Connections panel

**Connection** Previous connections are displayed. The maximum number of connections displayed is configured in the **Options/General** dialog box of the **Tools** menu (see Section 28.1).

### 29.1.2 Server panel

**Host** Enter the host name or the IP address of the QIAsymphony to which you want to connect.

**Port** Enter the number of the connection port (**port 80**).



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### 29.1.3 Login panel

<b>User ID</b>	Enter your user name. The same user ID that is valid on the QIAsymphony is also valid for the QMC.
<b>Password</b>	Enter your password. The same password that is valid on the QIAsymphony is also valid for the QMC.

### 29.1.4 Buttons

<b>OK</b>	Closes the dialog box and saves the changes.
<b>Cancel</b>	Closes the dialog box without saving the changes.

## 30 Managing Files


### 30.1 Using the **File Transfer** tool via a connection

The **File Transfer** tool allows files to be transferred between the QIAsymphony and the local path on the PC or network using a connection.

#### 30.1.1 Downloading files from the QIAsymphony

Files can be downloaded from the QIAsymphony to the local path on the PC or network using the **File Transfer** tool.

To download files, complete the following steps.


1. Log in to the QMC and connect to the QIAsymphony using your user account (see Section 29).
2. Select the remote site of the QIAsymphony where the files to download are located.
3. Select the type of file to download. All available files of the selected type are listed.
4. Highlight the file(s) to copy to the local path or network, and click . The file that is copied appears in the local path file list.

**Note:** Result Files and Loading Information Files are stored in zip format on the QIAsymphony. When using the **Auto Transfer** or **File Transfer** tool, they are automatically saved as \*.htm and \*.xml files in the appropriate folders.

#### 30.1.2 Uploading files to the QIAsymphony

Files can be uploaded to the QIAsymphony from the local path on the PC or network using the **File Transfer** tool.

To upload files, complete the following steps.

1. Log in to the QMC and connect to the QIAsymphony using your user account (see Section 29).
2. Select the remote site of the QIAsymphony where the files will be uploaded.
3. Select the type of file to be uploaded. All available files of the selected type are listed.
4. Highlight the file(s) to be copied to the QIAsymphony, and click . The file that is copied appears in the remote site file list.

---


## 30.2 Transferring files using a USB stick

The **File Transfer** tool allows files to be transferred between the local path on the PC or network and a USB stick.

As soon as a USB stick that does not have a data directory is connected to the PC, a message will appear asking whether the same data structure as in the root directory should be created on the USB stick. Click **Yes** to automatically create the data directory with subdirectories on the USB stick.

### 30.2.1 Uploading files to a USB stick


Files can be transferred from the local path on the PC or network to a USB stick using the **File Transfer** tool.

1. Insert the USB stick into the USB port of the PC.
2. Optional: If a message appears asking whether the data directory should be created, click **Yes**.
3. Select the path of the USB stick in the remote site list.
4. Select the type of file to be uploaded. All available files of the selected type are listed.
5. Highlight the file(s) to be copied to the USB stick in the local path file list, and click . The file is copied to the USB stick and appears in the remote site list.

### 30.2.2 Downloading files from a USB stick

Files can be downloaded from a USB stick to the local path on the PC or network using the **File Transfer** tool.


**Note:** Make sure that the defined data directory and subdirectories have been created on the USB stick (see Section 28.3).

1. Insert the USB stick into the USB port of the PC.
2. Select the path of the USB stick as remote site.
3. Select the type of file to download. All available files of the selected type are listed.
4. Highlight the file(s) to be copied from the USB stick in the remote site file list, and click . The file is copied to the local path and appears in the local path file list.

### 30.3 Deleting files using the **File Transfer** tool

Files can be deleted from a USB stick, the local path or network, or the QIAsymphony using the **File Transfer** tool.

**Note:** To avoid loss of data, take care when handling files on the QIAsymphony.

1. Log in to the QMC and connect to the QIAsymphony using your user account (see Section 29).
2. Select the type of file to be deleted. All available files of the selected type are listed.
3. Highlight the file(s) to be deleted either on the local path or network or the remote site, and click .

A message is displayed to confirm the deletion. After confirmation, the file is deleted from the selected site and no longer appears in the file list.

### 30.4 Automatic printing and file transfer using the **Auto Transfer** tool

#### 30.4.1 Automatic printing of result and loading information files

The **Auto Transfer** tool can be configured to automatically print result and loading information files as soon as they become available. To use this tool, the QIAsymphony must be connected to a network and switched on.

1. Log in to the QMC and connect to the QIAsymphony using your user account. For more information, see Section 29.
2. Launch the **Auto Transfer** configuration tool by selecting the corresponding icon in the tools list.
3. Check **Enable automatic printing of result files**.
4. Optional: Select whether to print result files in landscape or portrait format.
5. Check **Enable automatic printing of loading information**.
6. Optional: Select whether to print loading information files in landscape or portrait.
7. Browse to select the printer on which the files should be printed.
8. Optional: Print a test page.

9. Configure the settings for the instrument from which the files should be automatically transferred. Enter the host name, port, and the corresponding password for the "FileTransfer" user.

The password must be configured on the QIAsymphony (see section "Password" in Section 25).

Refer to "User Accounts", Section 4.4, for detailed information about how to manage the user accounts and how to configure the password.

10. Click **Add**.
11. Optional: Test the connection to the QIAsymphony by clicking **Test**.

**Note:** If the PC is shut down, the automatic file transfer service is also shut down. The **File Transfer** service starts again automatically the next time the computer is turned on.

#### 30.4.2 Automatic transfer of files

The **Auto Transfer** tool can be configured to transfer rack, result, loading information, and log files automatically to a predefined directory. The zipped files are automatically extracted. In addition, available work lists can be uploaded to the QIAsymphony automatically.

1. Log in to the QMC and connect to the QIAsymphony using your user account (see Section 29).
2. Launch the **Auto Transfer** tool by selecting the corresponding icon in the tools list.
3. Configure the parameters for the instrument from which the files should be automatically transferred. Enter the host name, port, and the corresponding password for the "FileTransfer" user.
4. Click **Add**.
5. Optional: Test the connection to the QIAsymphony by clicking **Test**.

**Note:** If the PC is shut down, the automatic file transfer service is also shut down. The **File Transfer** service starts again automatically the next time the computer is turned on.

**Note:** If a work list with the same name already exists, it will be overwritten by the automatic file transfer.

**Note:** It is not possible to delete a work list from the instrument via automatic file transfer. To disable/delete a work list, overwrite the work list by a work list without sample information.

---

### 30.4.3 Restarting the **QIAGEN File Transfer** service

After changing the root directory for the **Auto Transfer** tool the user must restart the **QIAGEN File Transfer** service.

To restart the **QIAGEN File Transfer** service:

1. Open the **Auto Transfer** tool.
2. Press **Restart**.

To stop the **QIAGEN File Transfer** service:

1. Open the **Auto Transfer** tool.
2. Press **Stop**.

**Note:** Shutting down the QMC does not stop the **Auto Transfer** tool. To stop the **Auto Transfer** tool you must either shut down the PC or stop the tool directly in the QMC.

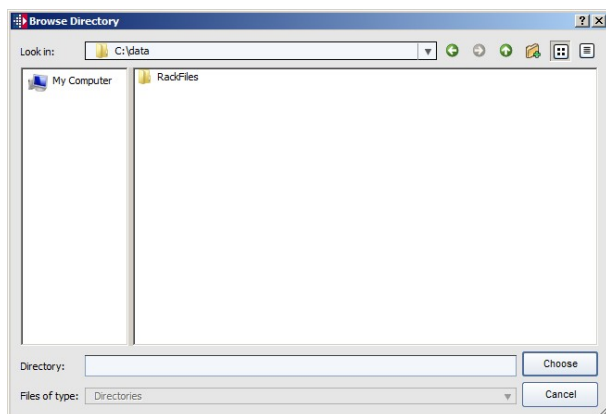
## 30.5 Checksum validation using the **Checksum Validator** tool

The validity of files is displayed directly in the file list in the **Status** column, when specified in the **File Transfer** tool (see Section 28). Files not located in **root/data/** can be validated using the **Checksum Validator** tool.

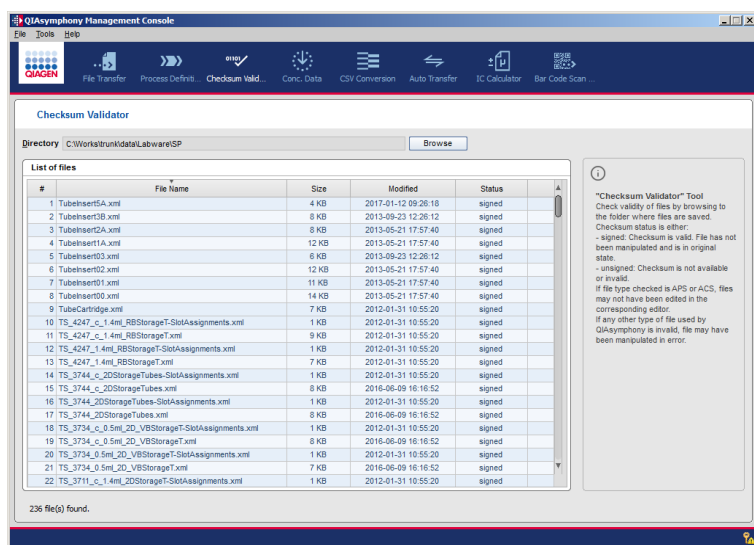
To validate the checksum of a file using the **Checksum Validator** tool, complete the following steps.

1. Select the **Checksum Validator** tool from the tool list.
2. Click **Browse** to search for the directory that contains the files to be checked (e.g., result files).

The **Browse Directory** dialog box appears.



3. Select the folder and click **Choose**. All files with checksum are validated. The result is displayed in the list. The column **Status** contains the result of the validation ("signed" or "unsigned").



## 30.6 Converting the file format using the **CSV Conversion** tool

The **CSV Conversion** tool is used to convert the format of files in \*.csv and \*.xml format.

The **CSV Conversion** tool enables:

- Conversion of rack files in \*.csv format to \*.xml format
- Conversion of rack files in \*.xml format to \*.csv format
- Conversion of work list files in \*.csv format to \*.xml format

---

**Note:** Before starting file conversion, ensure that the file extension and file delimiter is correct. To check this, go to **Tools/Options**, and then select **CSV Conversion**.

### 30.6.1 Converting a file from \*.csv to \*.xml format

To convert a \*.csv file to an \*.xml file that is in a format recognized by QIAAsymphony, complete the following steps.

1. Select the directory where the file to be converted is located. Click **Browse** to search. The **Browse Directory** appears. Select a folder and then click **Choose**. We recommend saving the file in the appropriate directory in the root (local path) directory (e.g., rack files should be saved in **root\data\RackFiles** and work lists in **root\data\Worklists**).
2. Select **CSV format** as **File Format**.
3. Choose the file type to be converted from the **File type** list.
4. Select the file to be converted.
5. Press **Convert to QIAAsymphony**. The converted file is saved in the directory selected in step 1.

**Note:** The converted file (rack file, work list file) can be used by the QIAAsymphony.

### 30.6.2 Converting a rack file from \*.xml to \*.csv format

**Note:** It is only possible to convert rack files from \*.xml format to \*.csv format.

1. Select the directory where the file to be converted is located. Click **Browse** to search. The **Browse Directory** appears. Select a folder and then click **Choose**. We recommend saving the file in the appropriate directory in the root (local path) directory (e.g., rack files should be saved in **root\data\RackFiles**).
2. Select **QIAAsymphony format** as **File Format**.
3. Select the file to be converted.
4. Press **Convert to CSV**. The converted file is saved in the directory selected in step 1.



## 30.7 Process files

Process files are used by the QIAAsymphony SP/AS to process the workflow from sample preparation through assay setup. The files in the following table are required:

### QIAAsymphony SP/AS process files

Name of process file	Folder where process file is stored	Function of process file
Protocol	root\data\BioScripts	Describes the sample preparation workflow. In addition, pipetting information is defined.
Assay Control Set (ACS)	root\data\AssayControlSets	Defines combinations of Protocols with internal controls and elution volume. Every sample being processed must be assigned an Assay Control Set.
Assay definition	root\data\AssayDefinitions	Describes the pipetting parameters for the assay and defines default assay parameters.
Assay Parameter Set (APS)	root\data\AssayParameterSets	Defines which assay is processed together with the assay parameters (e.g., number of replicates).

## 31 QMC Troubleshooting

### Comments and suggestions

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#### Connection errors

- |  |  |
|--|--|
| a) Invalid user name or password       | Check whether the user name is correct. Make sure to enter the correct password.   |
| b) Invalid session ID                  | If you restarted the QIAsymphony, be sure to reconnect to the instrument via the QIAsymphony Management Console.   |
| c) Connection could not be established | <p>Check the connection between the PC and the QIAsymphony. Make sure that the QIAsymphony is switched on.</p> <p>If a firewall is installed, make sure that it does not prevent connection to the QIAsymphony.</p> <p>Certain Antivirus Software has functionality to monitor and filter communication on port 80 (HTTP). This may lead to communication problems between the QMC and the instrument.</p> <p>Possible solutions:</p> <ul style="list-style-type: none"><li>● Change the communications port on the instrument from port 80 to another port. This should be performed by a service technician.</li><li>● Disable the HTTP port filtering function in the Antivirus Software.</li></ul> |

#### File errors

- |                          |  |
|--------------------------|--|
| a) Type version mismatch | Software version of the QMC is not compatible with the application software version. |
| b) Unable to remove file | The file to be removed may be in use. Make sure that the file is not in use.         |
| c) Unable to open file   | The file to be opened may be in use. Make sure that the file is not in use.          |

### Comments and suggestions

- |   |   |
|---|---|
| d) No files visible on the local folder | Check the correct root directory under <b>Tools/Options/File Transfer</b> to refer to the root folder with the local files. |
|---|---|

### QIAGEN File Transfer Service errors

- |   |  |
|---|--|
| a) No printer selected  | To print a test page, make sure to select a printer. If printing is successful, <b>Test page sent to printer</b> will be displayed.  |
| b) Failed to send test page to printer  | The test page was not printed on the selected printer. Check that the printer is correctly connected.  |
| c) Cannot add instrument. Please fill out the instrument field                                    | The user pressed the <b>Add</b> button but did not enter the host name of the instrument into the <b>Instrument</b> field. Make sure to add the host name.                       |
| d) Invalid port number. Please enter a numeric port number between 1 and 65535 (inclusive)        | The user pressed the <b>Add</b> button and entered an incorrect port number. Enter a port number between 1 and 65535 (inclusive) or leave the <b>Port</b> field empty.           |
| e) Test connection. No instruments to be checked  | The user pressed the <b>Test</b> button but did not select the instrument to be tested. To test the connection, make sure to select an instrument.                               |
| f) Saving failed. Could not save configuration to file. See the log file for detailed information | The user pressed <b>Save</b> but the file was not successfully saved. See the log file for the reasons for the failure ( <b>root\log\Plugin FileTransferConfiguration.log</b> ). |
| g) Error when reading from  | File transfer was unsuccessful. The <b>QIAGEN File Transfer</b> service will wait for one minute and will then try to read the   |

### Comments and suggestions

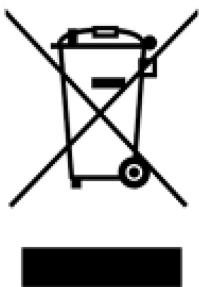
file. File transfer is not processed	configuration file again as long as no action is performed. If the problem persists, contact QIAGEN Technical Services.
h) Directory X referenced in file Y does not exist. File transfer is not processed	File transfer was unsuccessful. After the interval specified in the configuration file, the <b>QIAGEN File Transfer</b> service tries to reload the configuration file and to validate it. Check whether the directory was deleted.
i) Connection to instrument X failed	Connection to the selected instrument was unsuccessful. The PC will try to connect to the instrument again based on the time set in the <b>Polling Interval</b> field.
j) File X was not received by Y. Transfer of file X to Y failed	Data transfer from the QIAsymphony to the PC or from the PC to the instruments was unsuccessful. Transfer the file manually.
k) File X could not be deleted on Y	The file was successfully transferred from the QIAsymphony to the PC or the PC to the instrument but could not be deleted from the instruments. Delete the file manually.
l) File X was received from Y but unzipping on PC failed	The file was successfully transferred to the PC but could not be unzipped. Unzip the file manually.

## Appendix A

### Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users in the European Union.

The European Directive 2002/96/EC on WEEE requires proper disposal of electrical and electronic equipment when it reaches its end of life. The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local legislation. The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.



QIAGEN accepts its responsibility in accordance with the specific WEEE recycling requirements and, where a replacement product is being supplied by QIAGEN, provides free recycling of its WEEE-marked electronic equipment in Europe. If a replacement product is not being purchased from QIAGEN, recycling can be provided upon request at additional cost. To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

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## FCC declaration

The "United States Federal Communications Commission" (USFCC) (in 47 CFR 15. 105) declared that the users of this product must be informed of the following facts and circumstances.

"This device complies with part 15 of the FCC:

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation."

"This Class A digital apparatus complies with Canadian ICES-0003."

The following statement applies to the products covered in this user manual (volume 1), unless otherwise specified herein. The statement for other products will appear in the accompanying documentation.

**Note:** This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

QIAGEN GmbH Germany is not responsible for any radio television interference caused by unauthorized modifications of this equipment or the substitution or attachment of connection cables and equipment other than those specified by QIAGEN GmbH, Germany. The correction of interference caused by such unauthorized modification, substitution, or attachment will be the responsibility of the user.

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## Liability clause

QIAGEN shall be released from all obligations under its warranty in the event repairs or modifications are made by persons other than its own personnel, except in cases where the Company has given its written consent to perform such repairs or modifications.

All materials replaced under this warranty will be warranted only for the duration of the original warranty period, and in no case beyond the original expiration date of original warranty unless authorized in writing by an officer of the Company. Read-out devices, interfacing devices, and associated software will be warranted only for the period offered by the original manufacturer of these products. Representations and warranties made by any person, including representatives of QIAGEN, which are inconsistent or in conflict with the conditions in this warranty shall not be binding upon the Company unless produced in writing and approved by an officer of QIAGEN.

## Appendix B

### QIASymphony SP/AS accessories

Product	Contents	Cat. no.
Sample Prep Cartridges, 8-well (336)	8-well sample prep cartridges for use with the QIASymphony SP	997002
8-Rod Covers (144)	8-Rod Covers for use with the QIASymphony SP	997004
Filter-Tips, 200 µl (1024)	Sterile, Disposable Filter-Tips, racked; (8 x 128)	990332
Filter-Tips, 1500 µl (1024)	Sterile, Disposable Filter-Tips, racked; (8 x 128)	997024
Tip Disposal Bags (15)	For use with the QIASymphony SP/AS instruments	9013395
Reagent Cartridge Holder (2)	For use with the QIASymphony SP	997008
Tube Insert, 13 mm, sample carrier, Qsym (24)	Primary tube adapter (13 mm, with tube insert 01) for use with the QIASymphony SP tube carrier	9242058
Tube Insert 02, 11 mm, Revision, sample carrier, Qsym (24)	Primary tube adapter (11 mm, with tube insert 02) for use with the QIASymphony tube carrier	9242057
Insert, 2.0 ml v2, samplecarr. (24), Qsym	Secondary tube adapter (for 2 ml screw-cap tubes, tube insert 3B) for use with the QIASymphony tube carrier	9242083
Cooling Adapter, 2ml, v2, Qsym	Cooling adapter for 2 ml screw-cap tubes; for use with the QIASymphony SP/AS instruments	9020674
Cooling Adapter, EMT, v2, Qsym	Cooling adapter for EMT racks; for use with the QIASymphony SP/AS instruments	9020730
Starter pack, QIASymphony AS	Pack includes consumables required for operating the QIASymphony AS	997199
Tubes, conical, 5 ml, Qsym AS (500)	Conical tubes (5 ml) for holding reagent	997104
Filter-Tips, 50 µl, Qsym AS (1024)	Sterile, Disposable Filter-Tips, racked; (8 x 128)	997120
Tubes, conical, 2 ml, Qsym AS (500)	Conical tubes (2 ml) for holding reagent	997102



Product	Contents	Cat. no.
Cooling Adapter, RG Strip Tubes 72, Qsym	Adapter for holding 18 strips of 4 tubes; for use with the QIASymphony AS only	9018092
Cooling Adapter, Reagent Holder 1, Qsym	Adapter for holding 18 x 2 ml conical tubes, and 6 x 5 ml conical tubes; for use with the QIASymphony AS only	9018090
Cooling Adapter, Reagent Holder 2, Qsym	Adapter for holding 18 x 2 ml conical tubes, 2 x 5 ml conical tubes, and 2 x reagent bottles, 30 ml; for use with the QIASymphony AS only	9018089

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# Appendix C

## Bar code labels

### Specifications of 1D bar codes

Width	Bar code line width of 0.128–0.305 mm.
Print quality	Bar codes with a line width of 0.128 mm must be printed in high resolution.
Position	When using primary tubes, bar codes should be positioned 1 cm from the bottom of the tube. The bar code reader has a reading area of 8 cm. Bar codes should be attached to Sarstedt tubes so that the tube bar code is no higher than the insert bar code.

## Appendix D

### Processing order of an integrated run

If the functions **Modify Run** and **Create AS Batch** are used after an integrated run has been queued, the order in which SP and AS batches are processed by the system may be different from the order in which batches would be processed if AS batches were created before queuing the integrated run.

**Note:** After creation of the AS batch it is important to check in the **Assay Setup/Loading Information** screen to confirm if the loaded full process controls will be dispensed to the correct position on the assay rack. To do this, press the **Sample** button and check the individual positions for correct **Type** (EC+ or EC-).

The following 2 examples show how the order in which batches are processed can differ.

#### Example 1 — AS batches created before queuing integrated run

Two integrated batches are defined before the integrated run is queued:

- Integrated batch 1: SP batch 1 and SP batch 3 are used to create AS batch 1.
- Integrated batch 2: SP batch 2 and SP batch 4 are used to create AS batch 2.

The order in which the SP and AS batches will be processed is as follows:

	SP batch 1	SP batch 2	SP batch 4	SP batch 4	AS batch 1	AS batch 2
Integrated batch 1	1	–	2	–	3	–
Integrated batch 2	–	4	–	5	–	6

SP batches for integrated batch 1 will be processed first, followed by the AS batch for this integrated batch.

Then, SP batches for integrated batch 2 will be processed, followed by the AS batch for this integrated batch.

### Example 2 — AS batches created after queuing integrated run

Two integrated batches are defined after the integrated run is queued:

- Integrated batch 1: SP batch 1 and SP batch 3 are used to create AS batch 1.
- Integrated batch 2: SP batch 2 and SP batch 4 are used to create AS batch 2.

The order in which the SP and AS batches will be processed is as follows:

	SP batch 1	SP batch 2	SP batch 4	SP batch 4	AS batch 1	AS batch 2
Integrated batch 1	1	–	3	–	4	–
Integrated batch 2	–	2	–	5	–	6

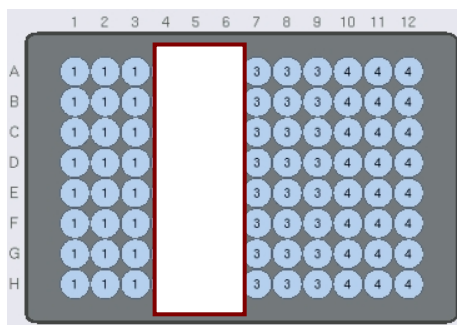
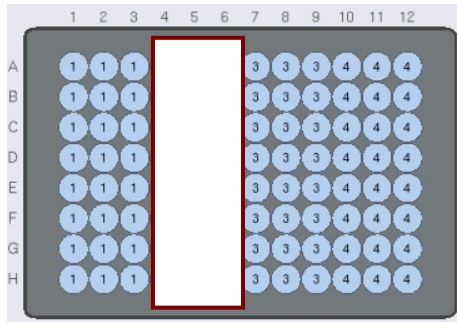
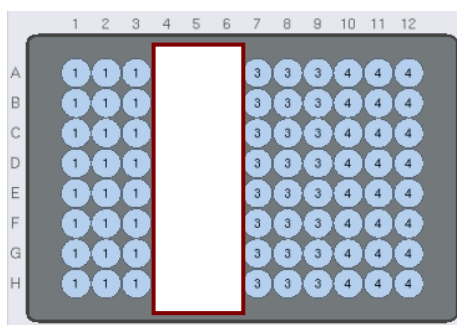
In this case, SP batches 1, 2, and 3 will be processed sequentially. When SP batch 1 and SP batch 3 have been processed, AS batch 1 will be processed. Then SP batch 4 will be processed, and finally AS batch 2 will be processed.

**Note:** If this processing order is not desirable for your integrated run (i.e., you do not want to delay processing of AS batches), we recommend that you manually unload samples from the “Sample” drawer before starting the integrated run, reload the samples, and then redefine the batches for your integrated run, taking care to create AS batches before queuing the run.

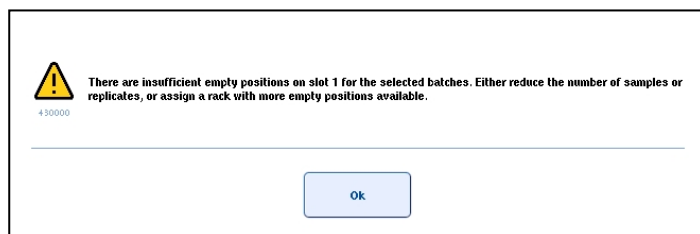
## Manually changing the processing order

After queuing an integrated run, it is possible to manually change the order in which SP batches are processed.

If a tube carrier is unloaded, empty positions on the eluate rack are created. Then, if the tube carrier is reloaded, these free positions are replaced with the new samples and now have a different processing position. In the example shown below, the batch in columns 4–6 had processing order 2, but after reloading, the batch now has processing order 5.



Be aware that, if the original SP batch only covered 2 columns and not 3 columns (e.g., if the original SP batch contained 9 samples), the maximum number of samples that can be reloaded equals the number of positions in the 2 free columns (i.e., 16). If an attempt is made to reload more than 16 samples, the following error message will appear:



**Note:** In this case, to reload 17–24 samples, it is recommended to manually unload all tube carriers from the “Sample” drawer, then reload all samples, and redefine the integrated run.

# Appendix E

## Cleanup

We recommend only performing cleanup if the QIAAsymphony SP/AS instruments were not switched off after an error occurred, and if no changes were made to the consumables loaded on the worktable.

**Note:** Rodslots are the black magnetic rods of the magnetic head (MH).

**Important:** Do not manually remove any consumables from the worktable unless instructed to do so. Ensure that safety instructions are followed. Dispose of liquid waste and used consumables according to your local safety regulations.

### WARNING

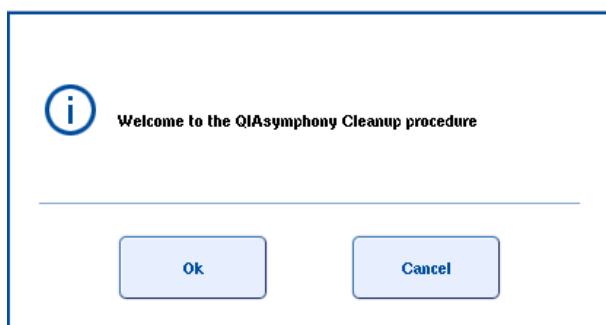


### Hazardous chemicals and infectious agents

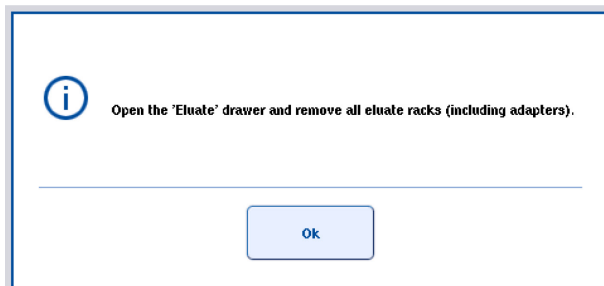
The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

To perform cleanup, proceed as follows:

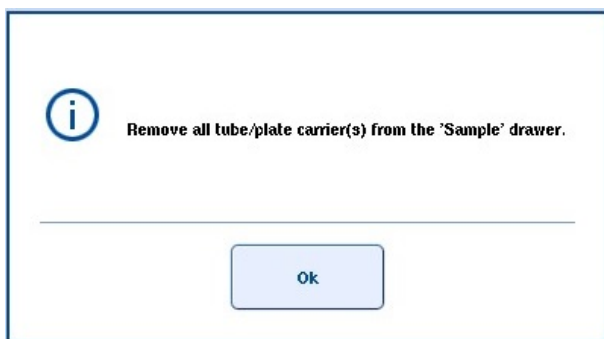
1. Press **Cleanup** in the **Maintenance SP** screen.
2. The following **Welcome** message is displayed.



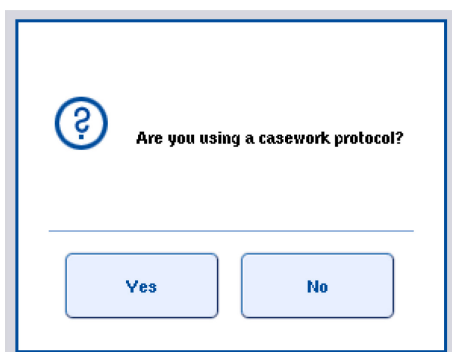
3. Press OK to continue. The following message appears.



4. Remove all elution racks from the "Eluate" drawer
5. Press **OK** to continue. The following screen appears.

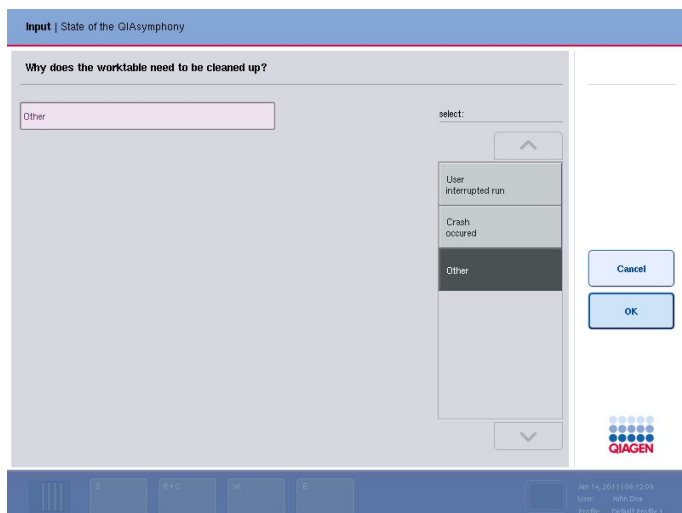


6. Remove all sample carriers.
7. Press **OK** to continue. The following message appears.



8. Press **No**. The following screen appears.





9. Select the appropriate branch of the cleanup (**User interrupted run**, **Crash occurred**, or **Other**). See table for more information. Press **OK** to continue.

**Note:** If the QIASymphony SP/AS was restarted, the **Other** branch is automatically selected. Proceed to step 10.

<b>User interrupted run</b>	Select if the user paused and stopped the run and no error occurred. No manual intervention is required.  <b>Important:</b> Cannot be used if an inventory scan was performed after the batch was canceled/stopped, or if the QIASymphony SP/AS instruments were restarted by the user. In these cases, use the <b>Other</b> branch of the automatic cleanup instead.
<b>Crash occurred</b>	Select if an error occurred. Cleanup is semi-automatic, some manual intervention is required.
<b>Other</b>	Select in all other cases not outlined by the <b>User interrupted run</b> and <b>Crash occurred</b> . Cleanup is semi-automatic, some manual intervention is required.

10. Follow the instructions on the screens. They will guide the user step-by-step through the cleanup protocol.

**Note:** By following the instructions on the screen, all used consumables will be removed from the magnetic head and worktable, and all liquids in sample prep cartridges will be discarded.

After cleanup, empty all slot positions (i.e., in the "Sample" and "Eluate" drawer).

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# Appendix F

## QlAsymphony Cabinet SP/AS Information

### **About this section**

Appendix F in Sections 1–7 describes the features of the QlAsymphony Cabinet SP/AS.

Information about the QlAsymphony Cabinet SP/AS is provided in the following sections:

1. Introduction
2. Safety Information
3. General Description
4. Installation Procedures
5. Maintenance and Cleaning Procedures
6. Technical Data for QlAsymphony Cabinet SP/AS
7. Warranty

# 1 Introduction

Thank you for choosing the QIASymphony Cabinet SP/AS. We are confident it will become an integral part of your laboratory.

## 1.1 Intended use of the QIASymphony Cabinet SP/AS

The QIASymphony Cabinet SP/AS is an optional accessory for the QIASymphony SP/AS. The QIASymphony Cabinet SP/AS is specially designed for positioning the QIASymphony SP/AS in your laboratory.

## 1.2 Abbreviations

Abbreviations used throughout this user guide are listed in the following table.

Abbreviation	Product name
Cabinet SP/AS	QIASymphony Cabinet SP/AS
Cabinet SP	QIASymphony Cabinet SP
Cabinet AS	QIASymphony Cabinet AS

# 2 Safety Information

Before using the Cabinet SP/AS it is essential that you read this user guide carefully and pay particular attention to the safety information. The instructions and safety information in the user guide must be followed to ensure safe use of the Cabinet SP/AS and to maintain the Cabinet SP/AS in a safe condition.

## 2.1 Proper use

### WARNING



#### **Risk of personal injury and material damage**

To avoid personal injury and material damage, do not attempt to move the Cabinet SP/AS by yourself. If you need to change the location of your Cabinet SP/AS and QIAAsymphony SP/AS, contact QIAGEN Technical Services.

### WARNING



#### **Risk of personal injury and material damage**

Never relocate the Cabinet SP/AS with the QIAAsymphony SP/AS instrument(s) installed on top! Any relocation must be performed or supervised by authorized QIAGEN Field Services.

### CAUTION



#### **Damage to the Cabinet SP/AS**

Only trained and certified QIAGEN personnel are authorized to unpack and install the Cabinet SP/AS.

### WARNING



#### **Risk of personal injury**

Always use the magnetic holder to store the handheld bar code scanner when not in use.

Never put down the handheld bar code scanner on top of the QIAAsymphony SP/AS instrument.

## 2.2 Biological safety

### WARNING



#### **Infectious agents**

The Cabinet SP/AS or the laboratory environment may be contaminated with infectious agents.

If applicable, wear safety glasses, gloves, and a lab coat.

The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe.

**CAUTION****Consumables compartment**

The consumables compartment of the Cabinet SP/AS may only be used to store plasticware and kits. It may not be used to store biological material.

## 2.3 Maintenance safety

**WARNING****Hazardous chemicals and infectious agents**

Always wear personal protective equipment (PPE) in the lab.

Basic equipment includes:

- Nitrile chemical-resistant gloves (2 pairs of gloves are recommended)
- Lab coat
- Safety glasses (shatterproof)

**CAUTION****Spilling of liquid**

If water or chemicals have been spilled on the Cabinet SP/AS, it must be cleaned as described in the Maintenance section.





## 2.4 Waste disposal

Used tips may contain hazardous chemicals or infectious agents from the purification and/or assay setup process. Such wastes must be collected and disposed of properly according to local safety regulations.

**WARNING****Hazardous chemicals and infectious agents**

The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

## 2.5 Symbols on the Cabinet SP/AS

Symbol	Location	Description
	Type plate, waste compartment, and waste bins	Biohazard symbol
	Type plate on the back of the Cabinet(s)	Warning symbol
	Type plate on the back of the Cabinet(s)	Consult instructions for use
	Type plate on the back of the Cabinet(s)	Legal manufacturer

## 3 General Description

The Cabinet SP/AS is comprised of the Cabinet SP and the Cabinet AS.

Benefits of the Cabinet SP/AS include:

- Supports and correctly positions the QIAasympathy SP/AS instrument(s)
- Directly interfaces with each instrument, so that QIAasympathy SP and AS instruments can be operated as an integrated system
- Storage of consumables inside the Cabinet SP
- No mounting of external waste bag(s) is needed

### 3.1 Features of the Cabinet SP/AS



- |                        |                            |
|------------------------|----------------------------|
| 1 Consumables cupboard | 5 Magnetic holder          |
| 2 Waste compartment SP | 6 Magnetic skirting boards |
| 3 Waste compartment AS | 7 Tip chute SP             |
| 4 Metal cover          | 8 Tip chute AS             |

#### 3.1.1 Consumables cupboard

The Cabinet SP contains a consumables cupboard. There is an adjustable shelf inside the consumables cupboard. This space is intended for storage of consumables.

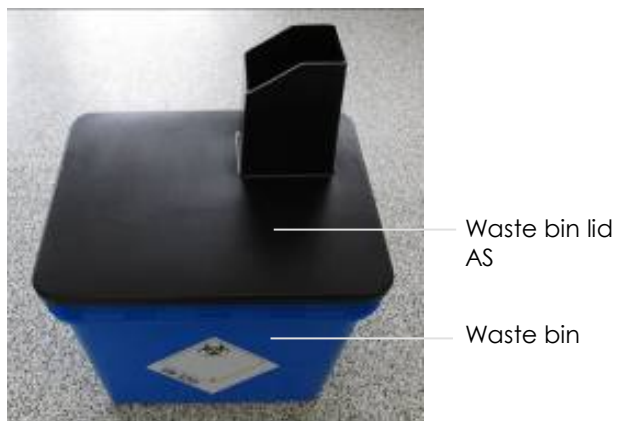
### 3.1.2 Waste compartments

The Cabinet SP and Cabinet AS each contain waste compartments. In the waste compartments, a waste bin is connected to each tip disposal chute to collect tips that are ejected from the QIAsymphony SP/AS, avoiding any contamination of the waste compartment.

### 3.1.3 Waste bin

The Cabinet SP/AS will be delivered with two waste bins, including two different black waste bin lids.

**Note:** The waste bin lids have filler necks specific for the Cabinet SP and Cabinet AS waste compartments — for details see “Installation Procedures”, page 446.



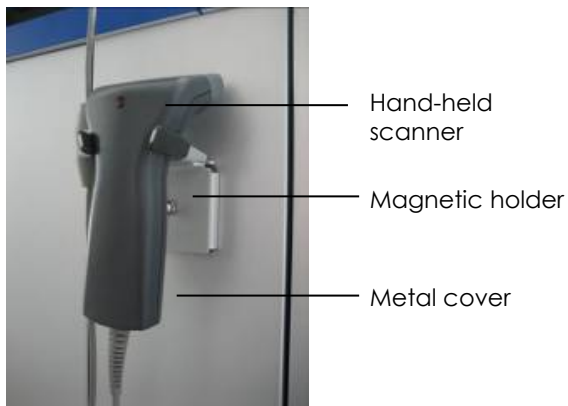
### 3.1.4 Metal cover

The Cabinet SP/AS supports 3 metal covers to attach the magnetic holder.

### 3.1.5 Magnetic holder

The magnetic holder (supplied with the Cabinet SP), which positions the handheld bar code scanner, can be magnetically attached to the metal cover.





### 3.1.6 Magnetic skirting boards

The magnetic skirting boards around the bottom edge of the Cabinet SP/AS can be removed for cleaning purposes. See "Maintenance and Cleaning Procedures", page 452, for more details.

### 3.1.7 Magnetic positioning aids

Positioning aids can be used to enable correct positioning of the waste bins. The Cabinet SP comes with 3 positioning aids, whereas the Cabinet AS has 4.



**Magnetic positioning aids.**

3

### 3.1.8 Tip chutes

On the upper interior surface of each waste compartment, there is a tip disposal channel.

- The end of the inserted tip chute SP is positioned so that it slightly contacts the drop catcher when the "Waste" drawer is closed.
- The end of the inserted tip chute AS extends through the Cabinet AS disposal channel.



**Tip chute SP and tip chute AS.**

Specialized waste chutes are required for the Cabinet SP/AS.



**Waste chute SP and waste chute AS.**

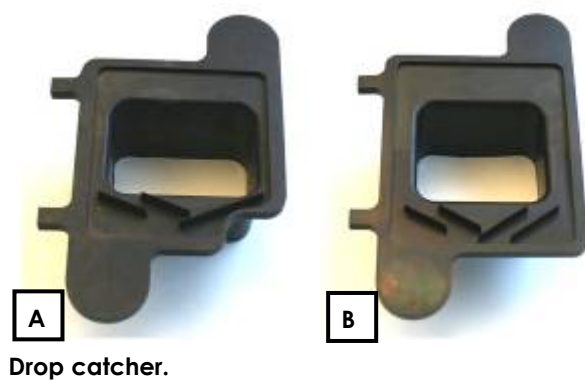
**Note:** For details on inserting the tip and waste chutes, see “Maintenance and Cleaning Procedures”, page 452.

### 3.1.9 Drop catcher (QIAsymphony SP only)

The drop catcher is positioned beneath the closed "Waste" drawer of the QIAsymphony SP.

It has 2 primary functions:

- Keeps the tip and waste chutes in close proximity to each other.
- Prevents droplets from contaminating the waste compartment of the Cabinet SP.





## 4.3 Delivery and installation

### CAUTION



#### **Damage to the Cabinet SP/AS**

Only trained and certified QIAGEN personnel are authorized to unpack and install the Cabinet SP/AS.

The Cabinet SP is supplied with:

- Magnetic holder for the handheld bar code scanner
- Positioning aids (x3)
- Tip chute SP
- Waste chute SP
- Drop catcher
- Waste bin
- Waste bin lid SP

The Cabinet AS is supplied with:

- Positioning aids (4)
- Tip chute AS
- Waste chute AS
- Waste bin
- Waste bin lid AS

### WARNING



#### **Risk of personal injury and material damage**

To avoid personal injury and material damage, do not attempt to move the Cabinet SP/AS by yourself. If you need to change the location of your Cabinet SP/AS and QIAsymphony SP/AS, contact QIAGEN Technical Services.

## 4.4 Adjusting the shelf

The shelf is adjustable as follows:

- The shelf rests on a set of notches
- There are 5 sets of notches at different heights in the consumables cupboard (indicated by arrows in the figure below)
- To adjust the level of the shelf lift the shelf upwards
- Reposition the shelf on a different set of notches
- Make sure the shelf rests horizontally on a set of notches



## 4.5 Magnetic holder for the handheld scanner

- Position the magnetic holder on one of the metal covers, next to one of the USB ports of the QIAsymphony SP.
- When the bar code scanner is not in use, always place it into the holder.
- The magnetic holder can be moved as desired.

**Note:** To enable easy use of the bar code scanner, we recommend positioning the magnetic holder on the middle metal cover, near the USB port.



**WARNING**



**Risk of personal injury**

Always use the magnetic holder to store the handheld bar code scanner when not in use.

Never put down the handheld bar code scanner on top of the QIAsymphony SP/AS instrument.

#### 4.6 Preparing the waste bin(s)

When using the Cabinet SP/AS for the first time, you must prepare the waste bin for correct disposal of used tips.

1. Insert a plastic bag into the waste bin (recommended).
2. Select the corresponding waste bin lid (see figures, below) and close the waste bin.



**Waste bin lid SP and waste bin lid AS.**



3. Open the waste compartment door.
4. Insert the magnetic positioning aids.



**Magnetic positioning aids.**



**Waste compartment Cabinet SP.**



5. Place the waste bin with the lid (SP or AS) directly underneath the corresponding waste chute, so that the tips fall directly through the chute into the waste bin.



**Waste bin SP and waste bin AS.**

6. Reposition the magnetic aids around the base of the waste bin to hold the waste bin in a safe position.

**Note:** After each run, check if the waste bin is full. Dispose of used filter tips and prepare the waste bin(s) as previously described.



**Waste bin correctly inserted.**

**WARNING**



**Hazardous chemicals and infectious agents**

The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

## 5 Maintenance and Cleaning Procedures

**Important:** If liquid is spilt on the QIASymphony Cabinet SP/AS, wipe it away immediately in accordance with the required safety regulations. Do not allow the liquid to dry.

**Note:** The following maintenance information for the Cabinet SP/AS does not include any information concerning the cleaning procedures of the QIASymphony SP/AS instruments. Information for cleaning the QIASymphony SP/AS is given in Section 15.

### WARNING



#### Hazardous chemicals and infectious agents

Always wear personal protective equipment (PPE) in the lab.

Basic equipment includes:

- Nitrile chemical-resistant gloves (2 pairs of gloves are recommended)
- Lab coat
- Safety glasses (shatterproof)

### 5.1 Cleaning agents

**Note:** Different disinfectants from those recommended may be used. Ensure that their compositions are similar to those described below.

We recommend DECON-QUAT 100, a quaternary ammonium salt-based disinfectant concentrate, for submerging tip and waste chutes (contains 5% alkyldimethylbenzylammonium chloride and 5% alkyldimethylethylbenzylammonium chloride).

### 5.2 Daily cleaning procedures

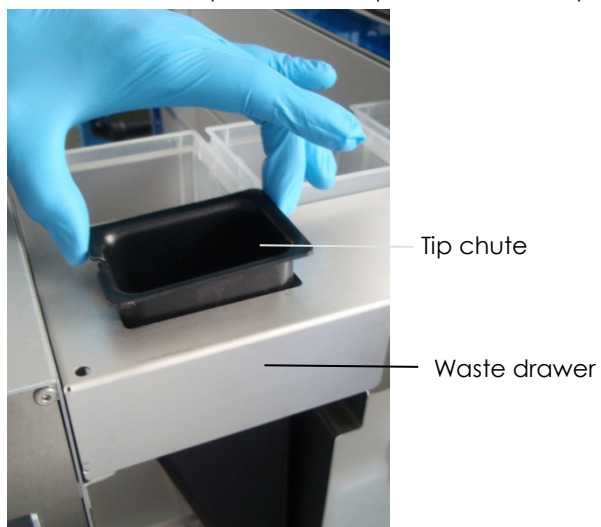
After completing the last protocol of the day on the QIASymphony SP/AS, perform the following cleaning procedures in addition to the daily cleaning procedures described in Section 15.

#### 5.2.1 Cabinet SP: Removing the tip and waste chutes, and drop catcher

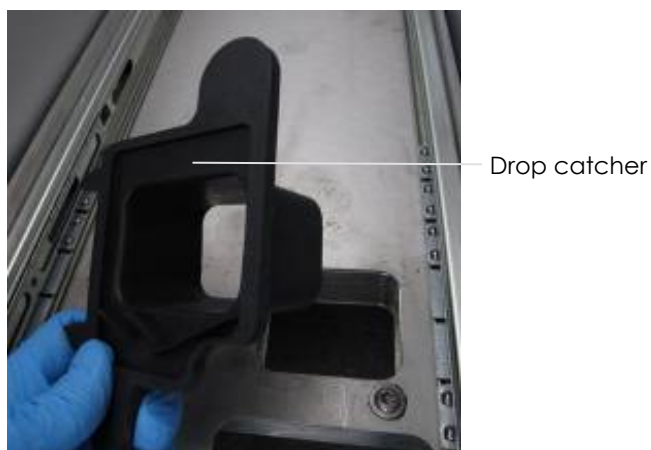
1. Open the QIASymphony SP hood.
2. Open the "Waste" drawer.

3. Remove the tip chute SP from the "Waste" drawer as shown in the next figure.

**Note:** Residual liquid from the tip chutes and drop catcher may drip.

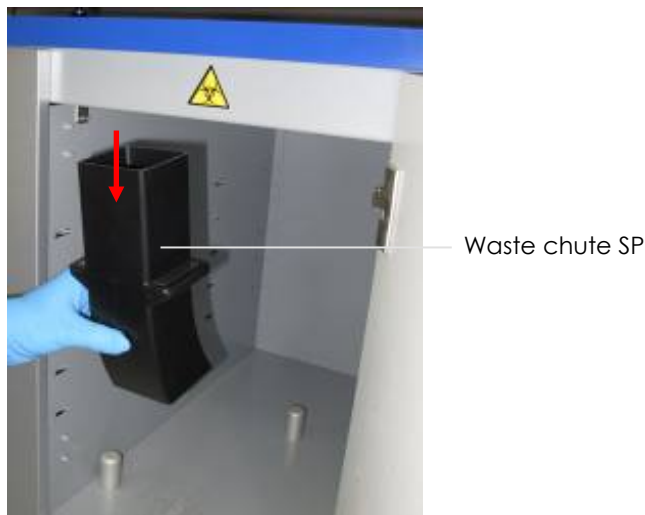


4. Remove the drop catcher as shown in the next figure.



5. Close the QIA Symphony SP "Waste" drawer.
6. Open the Cabinet SP waste compartment.
7. Remove the waste bin.

8. Remove the waste chute SP by pulling it down.



#### 5.2.2 Cabinet SP: Cleaning procedure

1. Soak the tip chute SP, waste chute SP, and the drop catcher in a glyoxal and quaternary ammonium-salt-based disinfectant for at least 15 minutes.
2. Rinse both chutes and the drop catcher in water and wipe dry with paper towels.
3. Wipe clean the tip disposal channel of the Cabinet SP with an ethanol-based disinfectant.
4. When the "Waste" drawer is opened, the tip chute SP may drip onto the surface of the QIAAsymphony SP and/or Cabinet SP. If necessary, wipe the surface of the contaminated areas with an ethanol-based disinfectant. Then, wipe with a cloth moistened with water and dry with paper towels.

### 5.2.3 Cabinet AS: Removing the tip and waste chutes

1. Open the QIAsymphony AS hood.
2. Remove the tip chute AS as shown in the next figure.

**Note:** Residual liquid from the tip chute AS may drip.



3. Open the Cabinet AS waste compartment.
4. Remove the waste bin.
5. Remove the waste chute AS by pulling it down.



#### 5.2.4 Cabinet AS: Cleaning procedure

1. Soak both tip chutes in a glyoxal and quaternary ammonium-salt-based disinfectant for at least 15 minutes.
2. Rinse both chutes in water and wipe dry with paper towels.
3. Wipe clean the tip disposal channel of the Cabinet AS with an ethanol-based disinfectant.
4. If necessary, wipe the surface of the Cabinet AS with an ethanol-based disinfectant. Then wipe with a cloth moistened with water and dry with paper towels.

### 5.3 Weekly cleaning procedures

Wipe the exposed surfaces of the Cabinet SP/AS with ethanol-based disinfectant once a week.

#### 5.3.1 Cleaning the waste bin lid(s)

1. Open the corresponding Cabinet (SP or AS) waste compartment.
2. Remove the waste bin.
3. Remove the waste bin lid.
4. Soak the lid in a glyoxal and quaternary ammonium-salt-based disinfectant for at least 15 minutes.
5. Rinse the lid in water and wipe dry with paper towels.
6. Replace the lid on the waste bin.
7. Reinsert the waste bin directly underneath the appropriate waste chute.

### 5.4 Insertion of clean parts: Cabinet SP

Prepare the Cabinet SP and QIASymphony SP "Waste" drawer in the following order:

- Step 1: Insert the waste chute SP
- Step 2: Insert the drop catcher
- Step 3: Insert the tip chute SP

#### 5.4.1 Inserting the waste chute SP

1. Open the Cabinet SP waste compartment.



**Waste chute SP.**

2. Ensure that the waste chute SP is used.  
**Note:** The waste chute SP is longer than the waste chute AS.
3. Hold the waste chute SP so that it curves towards the back and is directly underneath the tip disposal channel opening.
4. Push the waste chute SP softly upwards, into the slot of the drop catcher.



5. The waste chute SP is held in position by magnets.



6. Place the waste bin with lid directly underneath the waste chute



7. Close the Cabinet SP waste compartment.



#### 5.4.2 Inserting the drop catcher

1. Open the QIAAsymphony SP hood.
2. Open the QIAAsymphony SP "Waste" drawer.
3. Insert the drop catcher as shown in the figures below.
4. Ensure that the drop catcher is properly inserted.



#### 5.4.3 Inserting the tip chute SP

1. Insert tip chute SP. Ensure that the notch faces forward, toward the front of the "Waste" drawer (see figure, below).



2. Close the "Waste" drawer.
3. Close the QIAAsymphony SP hood.

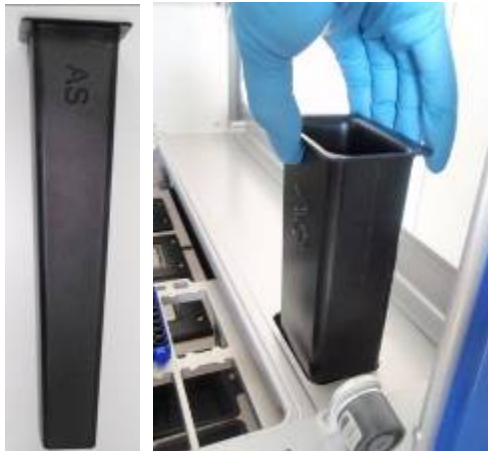
## 5.5 Insertion of clean parts: Cabinet AS

Prepare the Cabinet AS and QIA Symphony AS in the following order:

- Step 1: Insert the tip chute AS
- Step 2: Insert the waste chute AS

### 5.5.1 Inserting the tip chute AS

1. Open the QIA Symphony AS hood.
2. Insert the tip chute AS (see figure, below).



3. Close the QIA Symphony AS hood.

### 5.5.2 Inserting the waste chute AS

1. Open the Cabinet AS waste compartment.
2. Ensure that the waste chute AS is used.

**Note:** The waste chute AS is shorter than the waste chute SP.

3. Hold the waste chute AS so that it curves towards the back and is directly underneath the tip disposal channel opening.



4. Push the waste chute AS softly upwards. The waste chute AS is held in position by magnets.
5. Place the waste bin with lid directly underneath the waste chute.



6. Close the Cabinet AS waste compartment.

## 6 Technical Data for QIAsymphony Cabinet SP/AS

### Transportation conditions QIAsymphony Cabinet SP/AS

Air temperature	–25°C to 70°C (–13°F to 158°F) in manufacturer's package
Relative humidity	Maximum of 75% (noncondensing)
Environmental class	2K2 (IEC 60721-3-2) 2M2 (IEC 60721-3-2)

### Storage conditions QIAsymphony Cabinet SP/AS

Air temperature	–5°C to 40°C (41°F to 104°F) in manufacturer's package
Relative humidity	Maximum of 85% (noncondensing)
Environmental class	1K2 (IEC 60721-3-1) 1M2 (IEC 60721-3-1)

## 7 Warranty

The QIAsymphony Cabinet SP/AS is supplied with a 1-year warranty.

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# QIAsymphony® RGQ MDx (US) User Manual (Volume 2)

## Volume 2 of 2

Part I: Rotor-Gene® Q MDx User Manual (US)

Part II: Rotor-Gene AssayManager® IVD (US)  
Core Application User Manual

Part III: Rotor-Gene Q MDx Installation Guide  
(US)

For use with Rotor-Gene Q Software version 2.3.4 or higher  
and Rotor-Gene AssayManager version 1.0.x (x ≥ 5)

US version



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1115335



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# QIASymphony RGQ MDx (US) User Manual

## Volume 2, Part I

Rotor-Gene Q MDx User Manual (US)

# 1 Safety Information

Before using the Rotor-Gene Q MDx instrument, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

The following types of safety information appear throughout this manual.

**WARNING** The term WARNING is used to inform you about situations that could result in **personal injury** to you or other persons.



Details about these circumstances are given in a box like this one.

**CAUTION** The term CAUTION is used to inform you about situations that could result in **damage to the instrument** or other equipment.



Details about these circumstances are given in a box like this one.

The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

## 1.1 Proper use

**WARNING** **Risk of personal injury and material damage**



Improper use of the Rotor-Gene Q MDx may cause personal injuries or damage to the instrument.

The Rotor-Gene Q MDx must only be operated by qualified personnel who have been appropriately trained.

Servicing of the Rotor-Gene Q MDx must only be performed by QIAGEN Field Service Specialists.

Perform the maintenance as described in Section 9. QIAGEN charges for repairs that are required due to incorrect maintenance.

**WARNING****Risk of personal injury and material damage**

Rotor-Gene Q MDx is a heavy instrument. To avoid personal injury or damage to the instrument, take care when lifting.

**WARNING****Risk of personal injury and material damage**

Do not attempt to move the Rotor-Gene Q MDx during operation.

**CAUTION****Damage to the instrument**

Avoid spilling water or chemicals onto the Rotor-Gene Q MDx. Damage caused by water or chemical spillage will void your warranty.

**Note:** In case of emergency, switch off the Rotor-Gene Q MDx at the power switch at the back of the instrument and unplug the power cord from the power outlet.

**WARNING****Risk of personal injury and material damage**

Do not try to open the lid during an experiment, or while the Rotor-Gene Q MDx is spinning. Otherwise, if you overcome the lid lock and reach inside, you risk contact with parts that are hot, electrically live, or moving at high speed, and you may injure yourself and damage the instrument.

**WARNING****Risk of personal injury and material damage**

If you need to stop an experiment quickly, turn off the power to the instrument, then open the lid. Let the chamber cool before reaching inside. Otherwise you risk injury by touching parts that are hot.

**WARNING****Risk of personal injury and material damage**

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

**WARNING****Risk of personal injury and material damage**

Loose paper underneath the Rotor-Gene Q MDx interferes with instrument cooling. It is recommended that the area beneath the instrument is kept free of clutter.

**CAUTION****Damage to the instrument**

Always use a locking ring on the rotor. This stops caps from coming off tubes during an experiment. If caps come off during an experiment, they may damage the chamber.

**CAUTION****Damage to the instrument**

Visually inspect and make sure the rotor is not damaged or deformed before each run.

If you touch the Rotor-Gene Q MDx during an experiment, while you are charged with static electricity, in severe cases the Rotor-Gene Q MDx may reset. However, the software will restart the Rotor-Gene Q MDx and continue the experiment.

## 1.2 Electrical safety

Disconnect the line power cord from the power outlet before servicing.

**WARNING****Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous. Intentional interruption is prohibited.

**Lethal voltages inside the instrument**

When the instrument is connected to line power, terminals may be live, and opening covers or removing parts is likely to expose live parts.

To ensure satisfactory and safe operation of the Rotor-Gene Q MDx, follow the advice below:

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Do not adjust or replace internal parts of the instrument.
- Do not operate the instrument with any covers or parts removed.
- If liquid has spilled inside the instrument, switch off the instrument, disconnect it from the power outlet, and contact QIAGEN Technical Services.

If the instrument becomes electrically unsafe, prevent other personnel from operating it, and contact QIAGEN Technical Services; the instrument may be electrically unsafe when:

- It or the line power cord appears to be damaged.
- It has been stored under unfavorable conditions for a prolonged period.
- It has been subjected to severe transport stresses.

**WARNING**



**Electrical hazard**

The instrument has an electrical compliance label which indicates the voltage and frequency of the power supply as well as fuse ratings. The equipment should only be operated under these conditions.

## 1.3 Environment

### Operating conditions

**WARNING**



**Explosive atmosphere**

The Rotor-Gene Q MDx is not designed for use in an explosive atmosphere.

**CAUTION**



**Damage to the instrument**

Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.

The Rotor-Gene Q MDx must be located out of direct sunlight.

## 1.4 Biological safety

Specimens and reagents containing materials from biological sources should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, HHS ([www.cdc.gov/od/ohs/biosfty/biosfty.htm](http://www.cdc.gov/od/ohs/biosfty/biosfty.htm)).

### Samples

Samples may contain infectious agents. You should be aware of the health hazard presented by such agents and should use, store, and dispose of such samples according to the required safety regulations.

#### WARNING



#### Samples containing infectious agents

Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations. Always wear safety glasses, gloves, and a lab coat.

The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or OSHA,\* ACGIH,<sup>†</sup> or COSHH<sup>‡</sup> documents. Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

\* OSHA: Occupational Safety and Health Administration (United States of America).

<sup>†</sup> ACGIH: American Conference of Government Industrial Hygienists (United States of America).

<sup>‡</sup> COSHH: Control of Substances Hazardous to Health (United Kingdom).

## 1.5 Chemicals

### **WARNING**



#### **Hazardous chemicals**

Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run.

Always wear safety glasses, gloves, and a lab coat.

The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Safety Data Sheets (SDSs) or OSHA\*, ACGIH†, or COSHH‡ documents.

Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

### **Toxic fumes**

If working with volatile solvents or toxic substances, you must provide an efficient laboratory ventilation system to remove vapors that may be produced.

## 1.6 Waste disposal

Used consumables and plasticware may contain hazardous chemicals or infectious agents. Such wastes must be collected and disposed of properly according to local safety regulations.

## 1.7 Mechanical hazards

The lid of the Rotor-Gene Q MDx must remain closed during operation of the instrument.

### **WARNING**



#### **Moving parts**

To avoid contact with moving parts during operation of the Rotor-Gene Q MDx, the instrument must be operated with the lid closed.

### **WARNING**



#### **Risk of personal injury and material damage**

Open and close the lid of the Rotor-Gene Q MDx carefully to avoid trapping fingers or clothing.

**CAUTION****Damage to the instrument**

Make sure that the rotor and locking ring are installed correctly. If the rotor or locking ring show signs of mechanical damage or corrosion, do not use the Rotor-Gene Q MDx; contact QIAGEN Technical Services.

**CAUTION****Damage to the instrument**

The Rotor-Gene Q MDx must not be used if the lid is broken or if the lid lock is damaged.

Make sure that the rotor and locking ring are installed correctly. Only use rotors, locking rings, and consumables designed for use with the Rotor-Gene Q MDx. Damage caused by use of other consumables will void your warranty.

**CAUTION****Damage to the instrument**

When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can block. Allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on.

**WARNING****Moving parts**

In case of breakdown caused by power failure, remove the power cord and wait 10 minutes before attempting to manually open the lid.

**WARNING****Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 10 cm (3.94 in.) at the sides and rear of the Rotor-Gene Q MDx. Slits and openings that ensure the ventilation of the Rotor-Gene Q MDx must not be covered.



## 1.8 Heat hazard

### **WARNING**



#### **Hot surface**

The Rotor-Gene Q MDx chamber can reach temperatures above 120°C (248°F). Avoid touching it when it is hot.

### **WARNING**



#### **Hot surface**

When pausing a run, the Rotor-Gene Q MDx will not be cooled completely to room temperature. Exercise caution before handling the rotor or any tubes in the instrument.

## 1.9 Maintenance

Perform the maintenance as described in Section 9. QIAGEN charges for repairs that are required due to incorrect maintenance.

### **WARNING/ CAUTION**



#### **Risk of personal injury and material damage**

Only perform maintenance that is specifically described in the user manual.

### **WARNING**



#### **Risk of fire**

When cleaning the Rotor-Gene Q MDx with alcohol-based disinfectant, leave the Rotor-Gene-Q MDx lid open to allow flammable vapors to disperse.

Only clean the Rotor-Gene Q MDx when the chamber components have cooled down.

### **WARNING/ CAUTION**



#### **Risk of electric shock**



Do not disassemble the Rotor-Gene Q MDx instrument.

**CAUTION****Damage to the instrument housing**

Never clean the instrument housing with alcohol or alcohol-based solutions. Alcohol will damage the housing. To clean the housing, use distilled water only.

## 1.10 Symbols on the Rotor-Gene Q MDx

Symbol	Location	Description
	Near the sample chamber, visible when lid is open	Heat hazard — the temperature of the chamber can reach temperatures above 120°C (248°F)
	Back of the instrument	Consult instructions for use
	Type plate on the back of the instrument	CE mark for European conformity
	Type plate on the back of the instrument	In vitro diagnostic medical device
	Type plate on the back of the instrument	CSA listing mark for Canada and the USA
	Type plate on the back of the instrument	Legal Manufacturer
	Type plate on the back of the instrument	Waste Electrical and Electronic Equipment (WEEE)
	Type plate on the back of the instrument	FCC mark of the United States Federal Communications Commission

Symbol	Location	Description
	Type plate on the back of the instrument	RCM mark for Australia
	Type plate on the back of the instrument	RoHS mark for China (the restriction of the use of certain hazardous substances in electrical and electronic equipment)

---

## 2 Introduction

Thank you for choosing the Rotor-Gene Q MDx. We are confident it will become an integral part of your laboratory.

Before using the Rotor-Gene Q MDx, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

### 2.1 About this user manual

This user manual provides information about the Rotor-Gene Q MDx in the following sections:

1. Safety Information
2. Introduction
3. General Description
4. Installation Procedures
5. Operating Procedures — Hardware
6. Operating Procedures — Rotor-Gene Q Software
7. Operating Procedures — Rotor-Gene AssayManager Software
8. Access Protection
9. Maintenance Procedures
10. Optical Temperature Verification
11. Troubleshooting
12. Glossary

The appendices contain the following:

- Technical data
- FCC Declaration and information on disposal
- Rotor-Gene Q MDx instrument and accessories
- Liability clause

---

## 2.2 General Information

### 2.2.1 Technical assistance

At QIAGEN we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the Rotor-Gene Q MDx or QIAGEN products in general, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance and more information, call one of the QIAGEN Technical Services Departments or local distributors (see back cover).

For up-to-date information about the Rotor-Gene Q MDx, visit  
**<http://www.qiagen.com/products/rotor-geneqmdx.aspx>**.

### 2.2.2 Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time.

In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

## 2.3 Intended use of the Rotor-Gene Q MDx

The Rotor-Gene Q MDx instrument is designed to perform real-time thermal cycling, detection, and/or quantification using PCR in clinical applications.

The Rotor-Gene Q MDx is intended to be used only in combination with QIAGEN kits indicated for use with Rotor-Gene Q instruments for applications described in the respective QIAGEN kit handbooks.

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If the Rotor-Gene Q MDx instrument is used with other than QIAGEN Kits, it is the user's responsibility to validate the performance of such product combination for any particular application.

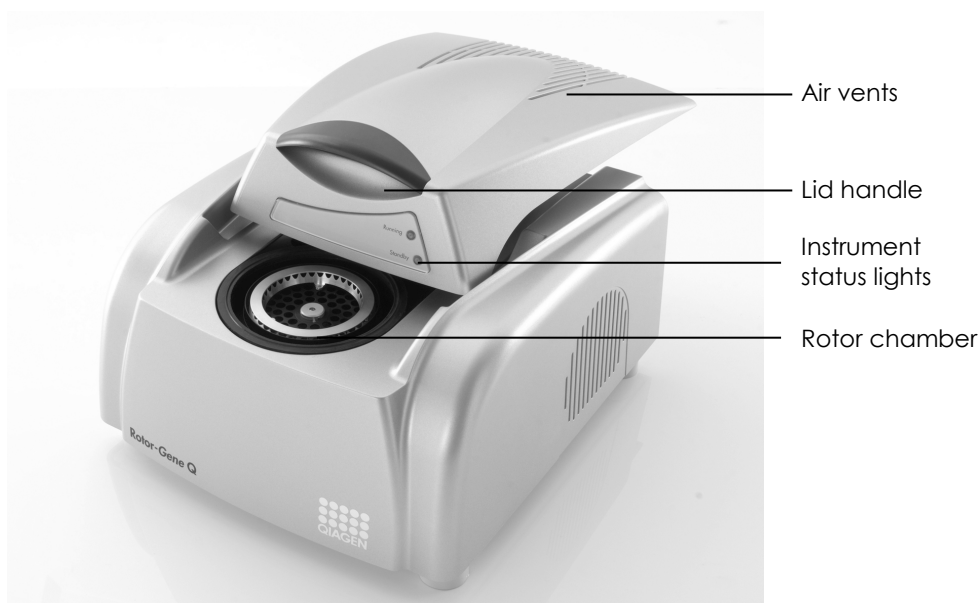
The Rotor-Gene Q MDx instrument is intended for in vitro diagnostic use.

The Rotor-Gene Q MDx instrument is intended for use by professional users, such as technicians and physicians trained in molecular biological techniques and the operation of the Rotor-Gene Q MDx instrument.

## 3 General Description

The Rotor-Gene Q MDx is an instrument that enables real-time PCR. It is highly suited for in vitro diagnostic applications.

The powerful and user-friendly Rotor-Gene Q software provides simplicity for beginners as well as an open experimental platform for advanced users.



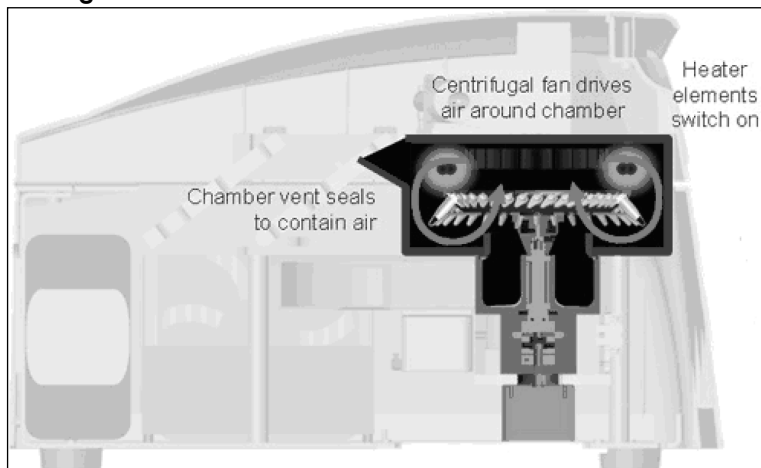
### 3.1 Thermal performance

The Rotor-Gene Q MDx uses a sophisticated heating and cooling design to achieve optimal reaction conditions. The unique rotary format ensures optimal thermal and optical uniformity between samples which is critical for precise and reliable analysis.

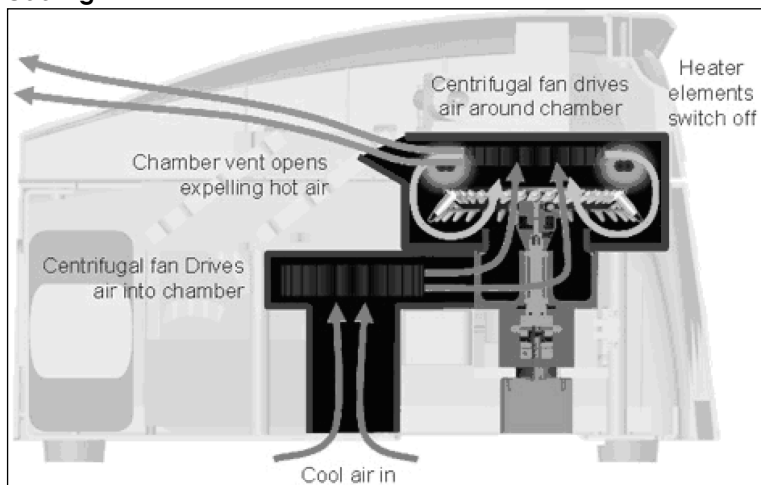
Samples spin continually at 400 rpm during a run. Centrifugation prevents condensation and removes air bubbles, but does not pellet DNA. In addition, samples do not need to be spun down prior to a run.

Samples are heated and cooled in a low-mass-air oven. Heating is achieved by a nickel-chrome element in the lid. The chamber is cooled by venting the air out through the top of the chamber while ambient air is blown up through the base.

## Heating



## Cooling



**Illustration of the heating and cooling system.**

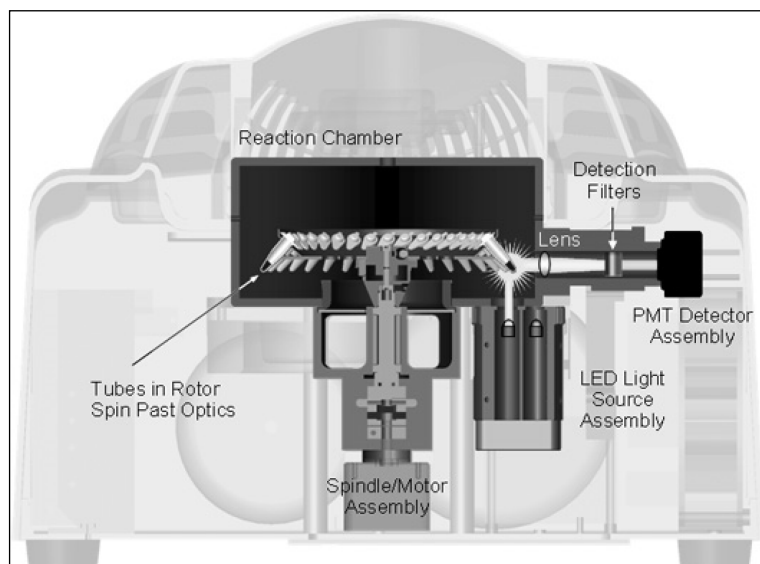
## 3.2 Optical system

With a choice of up to 6 excitation sources\* and 6 detection filters\* combined with a short, fixed optical path, the Rotor-Gene Q MDx can be used for multiplex reactions, ensuring minimum fluorescence variability between samples and eliminating the need for calibration or compensation.

\* Red and HRM Channels are not intended for use with FDA cleared or approved nucleic acid tests.



Samples are excited from the bottom of the chamber by a light-emitting diode. Energy is transmitted through the thin walls at the base of the tube. Emitted fluorescence passes through emission filters on the side of the chamber and is then collected by a photomultiplier. The fixed optical path ensures consistent excitation for every sample, which means that there is no need to use a passive internal reference dye such as ROX™.



**Illustration of the optical system.**

## 4 Installation Procedures

### 4.1 Site requirements

The Rotor-Gene Q MDx instrument must be located out of direct sunlight, away from heat sources, and away from sources of vibration and electrical interference. Refer to Appendix A for the operating conditions (temperature and humidity). The installation site should be free of excessive drafts, excessive moisture, excessive dust, and not subject to large or frequent temperature fluctuations as may be present, for example, in the air flow of an air conditioning unit.

Refer to Appendix A for the weight and dimensions of the Rotor-Gene Q MDx instrument. Ensure that the workbench is dry, clean, vibration proof, and has additional space for accessories. For further information about required specifications of the workbench, contact QIAGEN Technical Services.

**Note:** It is extremely important that the Rotor-Gene Q MDx instrument is placed on a stable surface that is level and vibration-free. For guidance, refer to the operating conditions in Appendix A.

The Rotor-Gene Q MDx instrument must be placed within approximately 1.5 m (59 in.) of a properly grounded (earthed) AC power outlet.

#### **WARNING**



#### **Explosive atmosphere**

The Rotor-Gene Q MDx instrument is not designed for use in an explosive atmosphere.

#### **WARNING**



#### **Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 10 cm (3.94 in.) at the sides and rear of the Rotor-Gene Q MDx.

Slits and openings that ensure the ventilation of the Rotor-Gene Q MDx must not be covered.

---

## 4.2 AC power connection

### Power requirements

The Rotor-Gene Q MDx operates at:

- 100–240 V AC at 50–60Hz, 520 VA (peak)

Make sure that the voltage rating of the Rotor-Gene Q MDx is compatible with the AC voltage available at the installation site. Mains supply voltage fluctuations are not to exceed 10% of nominal supply voltages.

### Grounding requirements

To protect operating personnel, QIAGEN recommends that the Rotor-Gene Q MDx be correctly grounded (earthed). The instrument is equipped with a 3-conductor AC power cord that, when connected to an appropriate AC power outlet, grounds (earths) the instrument. To preserve this protection feature, do not operate the instrument from an AC power outlet that has no ground (earth) connection.

### Installation of AC power cord

Connect one end of the 3-conductor AC power cord to the socket located at the rear of the Rotor-Gene Q MDx instrument. Connect the other end to the AC power outlet.

## 4.3 PC requirements

The laptop computer, supplied with the Rotor-Gene Q MDx, fulfills the requirements of the Rotor-Gene Q software and Rotor-Gene AssayManager software. Minimum laptop computer requirements for the Rotor-Gene Q software are detailed in the following table.

### PC system requirements

Description	Minimum requirement
Operating system	Microsoft Windows 10 Professional Edition 64-bit Microsoft® Windows 7 Professional edition (32- and 64-bit)* (Service Pack 1)
Processor†	Intel® Core™ 2 Duo 1.66 GHz or better
Main memory†	Minimum 1 GB RAM
Hard disk space†	Minimum 10 GB HDD
Graphics	Adapter and screen with at least 1200 x 800 pixels
Ports	USB port or RS-232 serial port
DVD-ROM drive	1
Pointing device	Touchpad or mouse or equivalent is required
Bluetooth®	Must be switched off
Power options	Never turn off hard disks, hibernate, or go to standby

\* Microsoft Windows 10 or Windows 7 Professional edition is required to run the Rotor-Gene Q software with security features (see Page 587). Security features are not available if the Home edition of Windows 10 or Windows 7 is used.

† When using Rotor-Gene AssayManager version 1.0

## 4.4 Configuration for Windows security

The laptop computers that are provided by QIAGEN for use with your Rotor-Gene Q MDx instrument have Microsoft Windows 10 or 7 pre-installed and are configured with a standard (non-administrative) Windows user account and with an administrator account. In routine usage of the system, the standard account is to be used as both Rotor-Gene Q software and Rotor-Gene AssayManager version 1.0 are designed to run without administrator rights. The administrator account shall only be used to install the Rotor-Gene Q or the Rotor-Gene AssayManager version 1.0 software and a virus scanner (please see page 511 for details of anti-virus software). Use of the administrator account is indicated by a red desktop background. Please make sure, that you always log-in as standard-user for routine use.

---

The default password of the administrator account is as follows: "Q1a#g3n!A6". Please change the administrator password after first login. Please make sure that the password is secure and does not get lost. There is no password for the standard operator account.

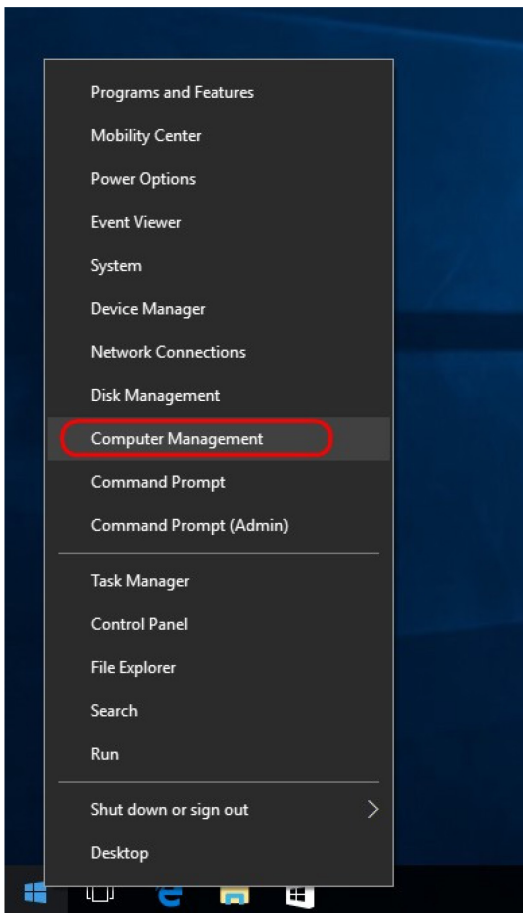
If your configuration is different and no non-administrative account is contained, system administrators should setup an additional standard Windows user account to prevent accidental access to critical system areas, such as "Program Files", "Windows" directory (e.g. access to installation or uninstallation functionality, including applications, operating system components, date/time settings, Windows updates, firewall, user rights & roles, anti-virus activation), or performance relevant settings like power saving.

To create a user account in Windows, please follow the steps outlined in the following section of this handbook.

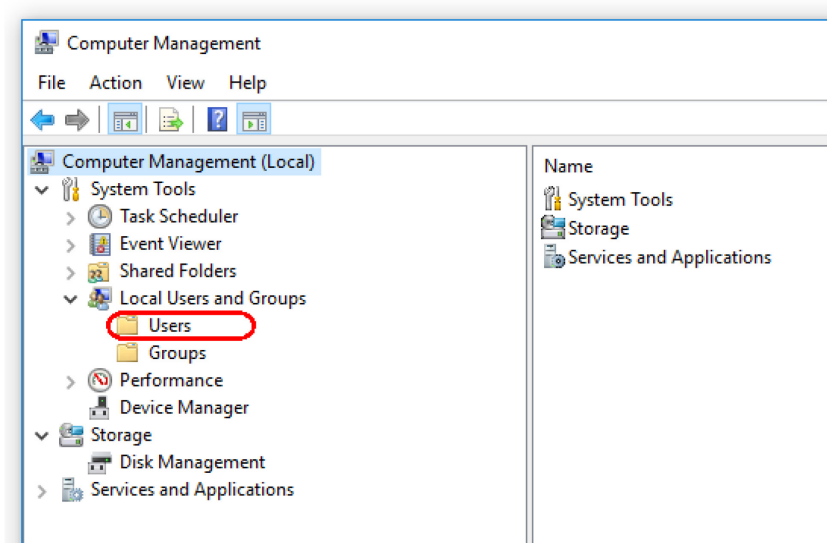
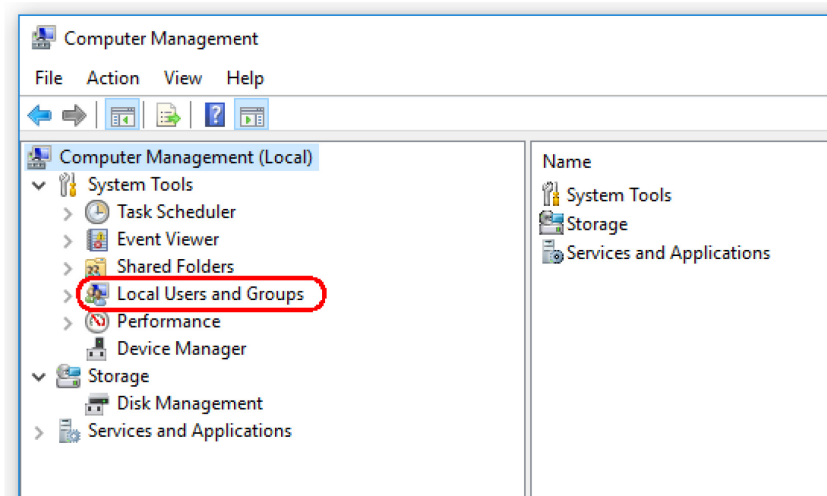
#### 4.4.1 Windows 10 security

To create a standard user account in Windows 10, please follow these steps:

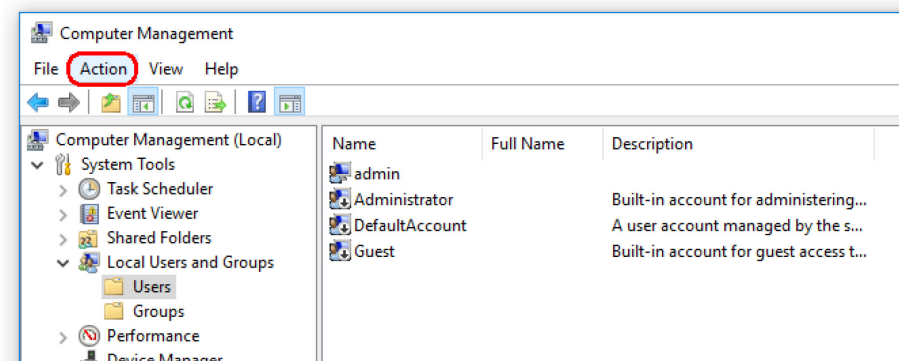
- 1 Right-click on the Windows icon in the lower-left corner of the screen. Select **“Computer Management”**.



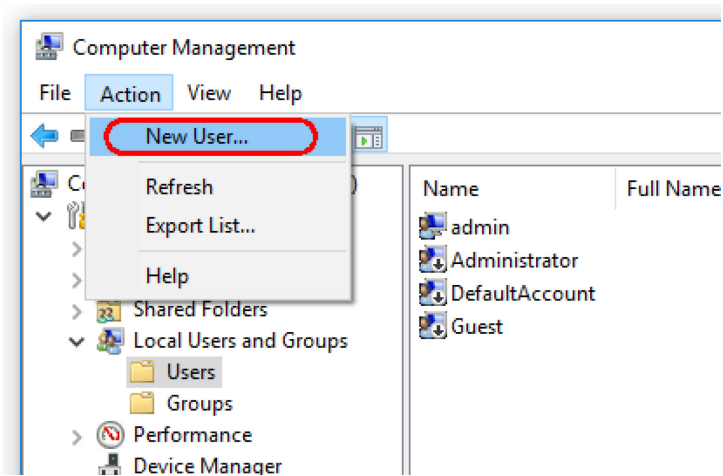
- 2 Expand **“Local Users”** and **“Groups”**.



- 3 Select **"Users"**. With Users highlighted, click **"Action"**.



4 Select **"New User..."**





New User

User name: Operator

Full name:

Description:

Password: .....

Confirm password: .....

☒ User must change password at next logon

☐ User cannot change password

☐ Password never expires

☐ Account is disabled

Help Create Close

- 5 Enter the user name "**Operator**" and set a password that is compliant with your security rules.
- 6 Uncheck "**User must change password at next logon**" to allow more options.

The screenshot shows a 'New User' dialog box with the following fields and options:

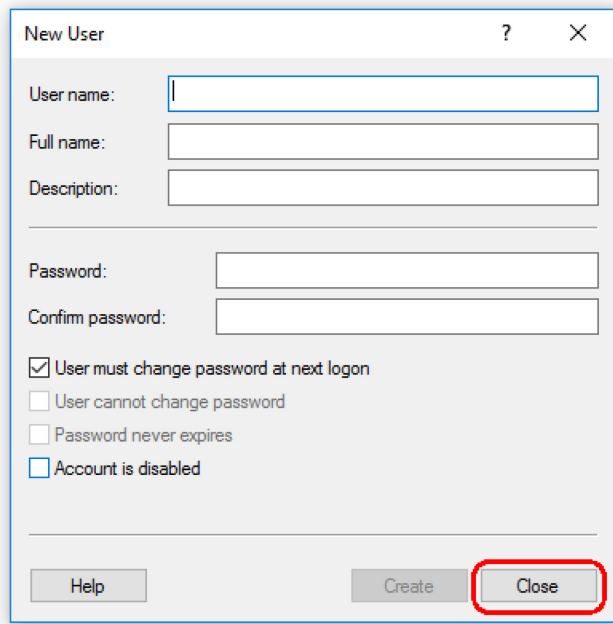
- User name: Operator
- Full name: (empty)
- Description: (empty)
- Password: (masked with dots)
- Confirm password: (masked with dots)
- ☐ User must change password at next logon
- ☐ User cannot change password
- ☐ Password never expires
- ☐ Account is disabled

Buttons at the bottom: Help, Create, Close. The 'Create' button is highlighted with a blue border. A red rectangle highlights the password fields and the four checkbox options.

7 Click **Create** to finish.

This screenshot is identical to the one above, showing the 'New User' dialog box with the same fields and options. In this view, the red rectangle highlights the 'Create' button at the bottom of the dialog.

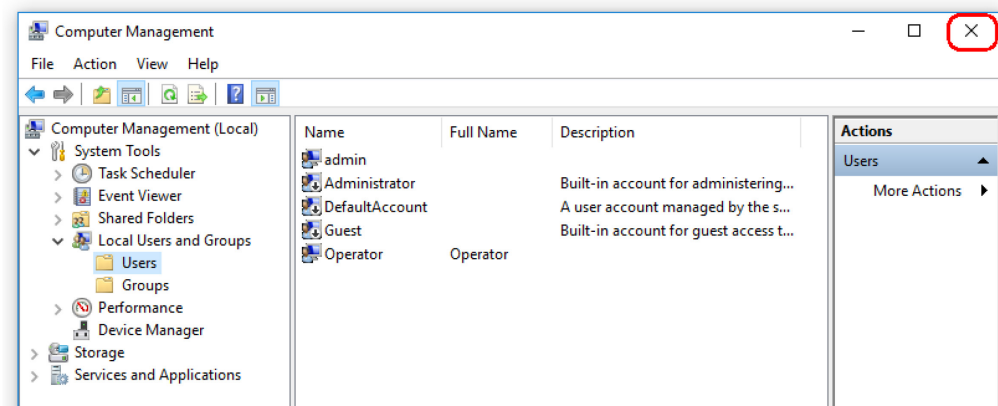
- 8 Add another user or click **"Close"**. All existing local users are shown in the Users list.



The "New User" dialog box is shown with the following fields and options:

- User name: [text box]
- Full name: [text box]
- Description: [text box]
- Password: [text box]
- Confirm password: [text box]
- ☒ User must change password at next logon
- ☐ User cannot change password
- ☐ Password never expires
- ☐ Account is disabled

Buttons at the bottom: Help, Create, and Close (highlighted with a red circle).

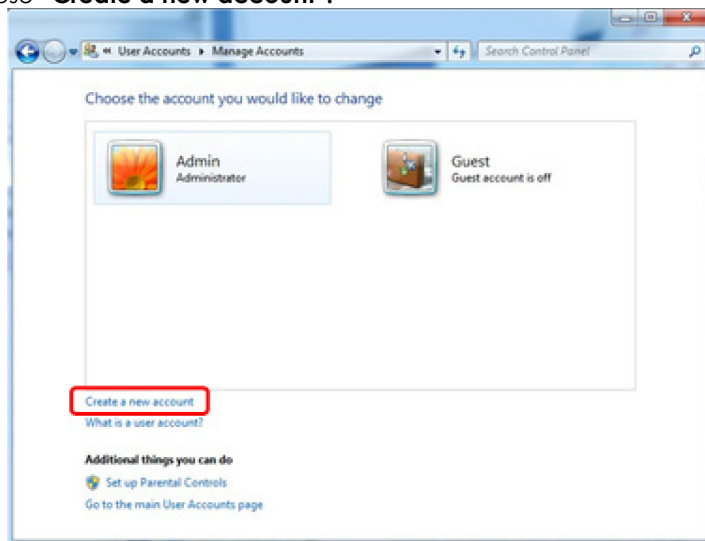


9. Close **"Computer Management"**.

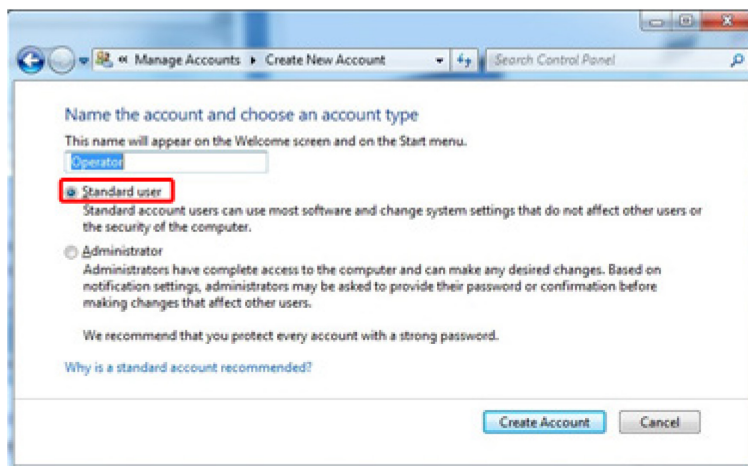
**Note:** Change the password of the currently logged-in user by pressing the key combination CTRL + ALT + DELETE and selecting **"Change a password"** from the available options.

#### 4.4.2 Windows 7 security

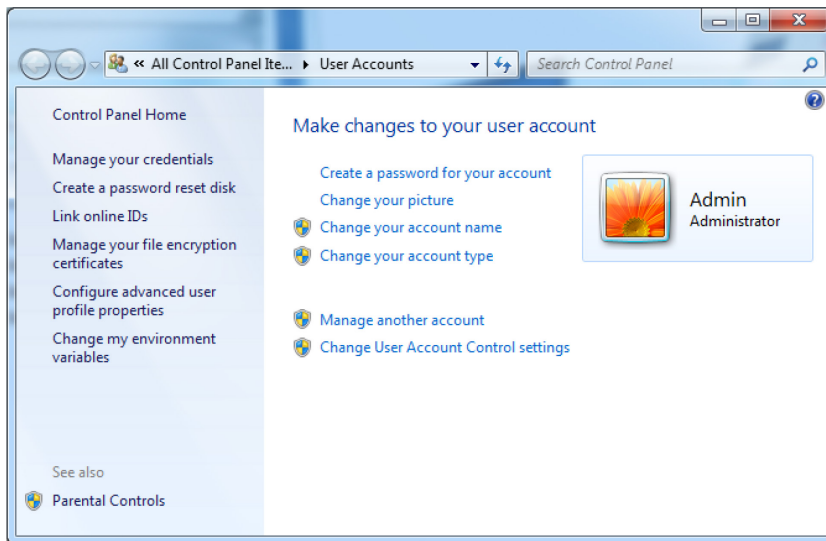
1. Open the Windows control panel via the “**Start**” menu and select the “**User Accounts**”/“**Manage Accounts**”.
2. Chose “**Create a new account**”.



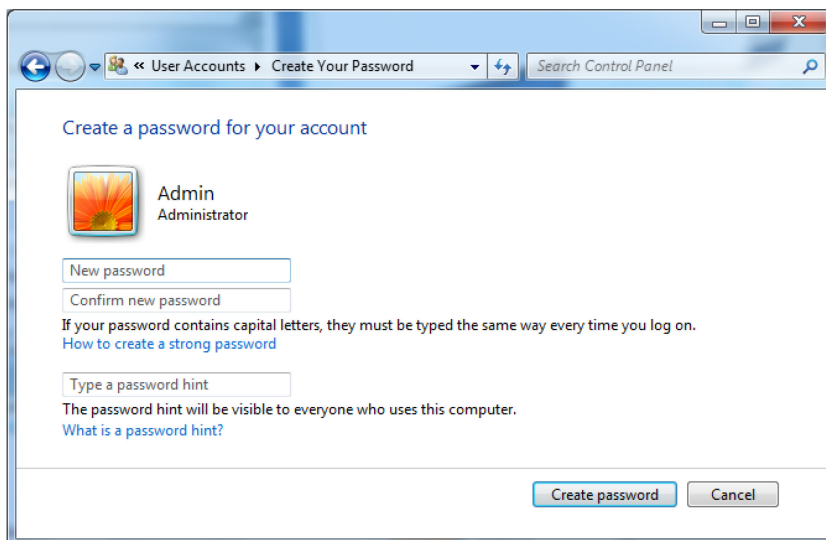
3. Name the account and select “**Standard User**” as the account type.



4. Click “**Create Account**”.
5. Go back to User Accounts and create a password for the Administrator account.



6. Enter the password and select **"Create a password for your account"**.



**Note:** This password will be needed for installing future updates of Rotor-Gene AssayManager v1.0, or for backup and restore purposes. Please make sure that the password is secure and does not get lost.

## 4.5 Unpacking the Rotor-Gene Q MDx

The Rotor-Gene Q MDx is delivered with all the necessary components for setting up and running the instrument. The box also contains a list of all the components provided.

**Note:** Check this list for completeness to ensure that all the components are present.

**Note:** Check the instrument and delivered accessories for transport damage before installation.

The accessories box sits on top of the foam packing. The accessories box contains:

- *Rotor-Gene Q MDx Installation Guide (US)*
- CD (Rotor-Gene Q software)
- CD (*Rotor-Gene Q MDx User Manual (US)*)
- CD (*Rotor-Gene Q User Manual*)
- Loading Block 96 x 0.2 ml Tubes\*
  - \* Not intended for use with FDA cleared or approved nucleic acid tests
- Loading Block 72 x 0.1 ml Tubes
- Rotor Holder (dismantled for safe transport)
- 36-Well Rotor (this rotor is red in color)\*
  - \* Not intended for use with FDA cleared or approved nucleic acid tests
- 36-Well Rotor Locking Ring\*
  - \* Not intended for use with FDA cleared or approved nucleic acid tests

The following items are packed on each side of the foam packing:

- USB and RS-232 serial cable
- International power cable set
- PCR Tubes, 0.2 ml (1000)\*
  - \* Not intended for use with FDA cleared or approved nucleic acid tests
- Strip Tubes and Caps, 0.1 ml (1000)

Once all these components have been removed from the box, remove the foam packing on top of the Rotor-Gene Q MDx. Carefully remove the Rotor-Gene Q MDx from the box and unwrap the plastic cover. Open the lid by sliding it towards the back to access the reaction chamber.

The following items are already installed inside the Rotor-Gene Q MDx:

- A 72-Well Rotor (this rotor is blue in color)
- A 72-Well Rotor Locking Ring

A laptop computer is included with your Rotor-Gene Q MDx instrument.

Rotor-Gene AssayManager software is supplied on a separate installation DVD.

Once you have unpacked the Rotor-Gene Q MDx, proceed with installation as described below.

## 4.6 Accessories

Accessories can be ordered separately for use with the Rotor-Gene Q MDx. For more details, see Appendix B in Part I of Volume 2.

## 4.7 Hardware installation

Once the Rotor-Gene Q MDx has been unpacked, proceed with installation as described below.

### CAUTION

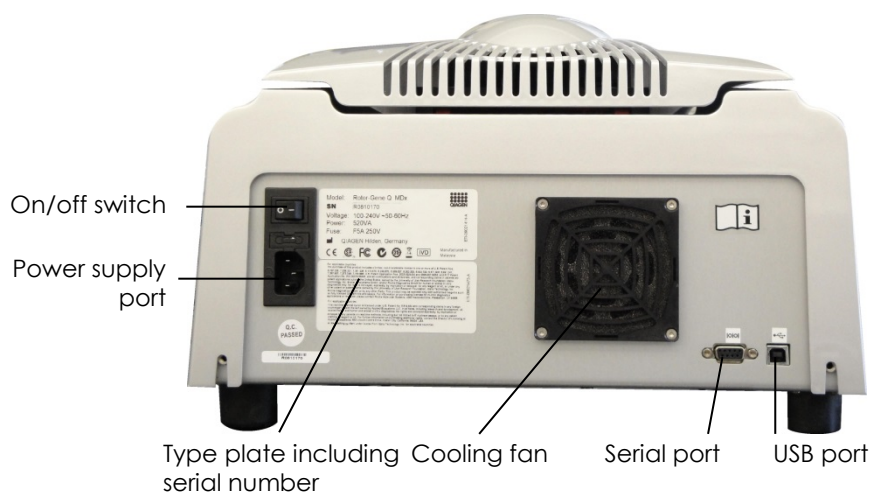


#### Damage to the instrument

When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can block. Allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on.

1. Place the Rotor-Gene Q MDx on a level and vibration-free surface.
2. Ensure that there is sufficient space behind the instrument for the lid to open fully.
3. Ensure that the power switch at the back of the instrument can be reached easily.
4. Do not obstruct the back of the instrument. Ensure that the power cord can be easily detached if required, to disconnect power to the instrument.
5. The Rotor-Gene Q software should be installed before the laptop computer is connected to the Rotor-Gene Q MDx. Please refer to Section 4.8 below or the *Rotor-Gene Q MDx Installation Guide (US)* in Part III of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual* on how to install the Rotor-Gene Q software.

6. Connect the supplied USB cable or RS-232 serial cable to a USB or communications port on the back of the computer.
7. Connect the USB or RS-232 serial cable to the back of the Rotor-Gene Q MDx.
8. Connect the Rotor-Gene Q MDx to the power supply by connecting one end of the AC power cord to the socket located at the rear of the Rotor-Gene Q MDx and the other end to the AC power outlet.



**Note:** Connect the Rotor-Gene Q MDx to the computer with the USB or serial cables delivered with the instrument. Do not use other cables.

## 4.8 Rotor-Gene Q software installation

**Note:** Rotor-Gene Q software and Rotor-Gene AssayManager are softwares for routine testing in combination with Rotor-Gene Q MDx instruments. The two (2) softwares are used independently of each other but reside on the same computer. Refer to the specific assay Instructions for Use (Handbook) to determine the appropriate software to be used.

1. To install the Rotor-Gene Q software, insert the CD (Rotor-Gene Q software) delivered with the instrument into the CD/DVD drive of the computer.
2. Select **Install Operating Software** in the window that appears.

**Note:** Please refer to the *Rotor-Gene Q MDx Installation Guide (US)*, in Part III of Volume 2 of the *QIAsymphony RGQ MDx (US) User Manual*, for easy installation and for guidance through the next steps of software installation.



## Rotor-Gene Q — Pure Detection

■ Install Operating Software

■ Exit

Sample & Assay Technologies

3. Once the Rotor-Gene Q software has been installed a desktop icon will be created automatically.
4. Switch on the Rotor-Gene Q MDx by moving the toggle switch, located at the back on the right-hand side, to the "I" position. A blue "Standby" light on the front of the Rotor-Gene Q MDx indicates that the instrument is ready for use.

**Note:** When starting connected to a computer for the first time, the Rotor-Gene Q MDx will be recognized by the operating system and a number of messages will appear. Please refer to the *Rotor-Gene Q MDx Installation Guide (US)*, in Part III of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*, for guidance.



5. Double-click the **Rotor-Gene Q Series Software** desktop icon on your computer screen to initiate the Rotor-Gene Q software.



6. A **Welcome** window appears the first time the Rotor-Gene Q software is started, but does not appear for subsequent Rotor-Gene Q software upgrades.

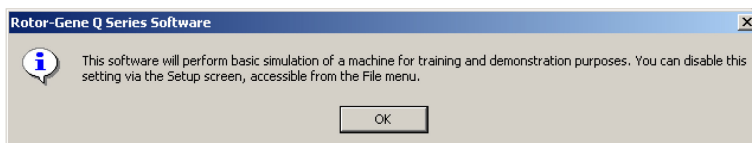


- Machine Serial Number:** Type in the serial number (7 numeric digits), which can be found on the type plate on the back of the Rotor-Gene Q MDx.
- Port:** Choose either USB or serial cable. Select the appropriate communications port or click the **Auto-Detect** button.
- Auto-Detect:** When using this option, the corresponding USB or serial port will be detected automatically and displayed in the **Port** drop-down list.

**Run in Virtual Mode (For Demonstration):** Checking this box allows installation of the Rotor-Gene Q software on a computer that is not connected to a Rotor-Gene Q MDx. The Rotor-Gene Q software is fully functional and can simulate runs.

**Note:** If this box is checked and a Rotor-Gene Q MDx is connected to the computer, the following message appears before the run starts: **You are about to run in Virtual mode.** To perform a real run, the setup must be changed in the **Setup** window (see Section 6.3.1).

**Begin:** When all the information has been entered, click **Begin**. Wait until initialization is finished, which may take a few seconds. If virtual mode was chosen the following message appears:

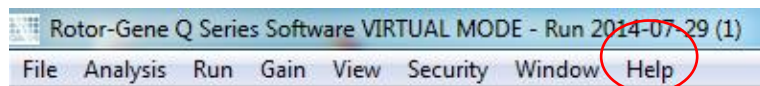


If the **Run in Virtual Mode** box is unchecked, the software initializes and opens automatically.

**Exit Program:** Clicking on this button exits the program.

## 4.9 Rotor-Gene Q software version

To find the Rotor-Gene Q software version number, click on the **Help** button in the menu bar, then select **About This Software....**



The **About This Software...** window displays general information about Rotor-Gene Q software, including the version of the Rotor-Gene Q software and the serial number and model of the instrument.



Rotor-Gene Q software may be freely copied for use within an organization that owns a Rotor-Gene Q MDx. Rotor-Gene Q software may not be copied and distributed to others outside the organization.

#### 4.10 Rotor-Gene Q assay package installation

Assay packages contain the required files to run and analyze individual types of assays. A separate software installation is required for each assay package. The installation copies the required files to the system and creates one or more shortcuts on the desktop. The installation and use of each specific assay package is described in detail in the corresponding Instructions for Use (Handbook).

#### 4.11 Additional software on connected computers

Rotor-Gene Q software manages time-critical processes during the PCR run and the data acquisition process. For this reason, it is important to ensure that no other processes use significant system resources and thus slow down the Rotor-Gene Q software. It is particularly important to pay attention to the points listed below.

System administrators are advised to consider any impact that a modification to the system may have on the resources before implementing it.

#### 4.11.1 Virus scanners

QIAGEN is aware of the threat that computer viruses cause to any computer that exchanges data with other computers. Rotor-Gene Q software is expected to be primarily installed in environments where local policies are in place to minimize this threat. However, QIAGEN recommends the use of a virus scanner in any case. The selection and installation of an appropriate virus scanning tool is in the customer's responsibility. However, QIAGEN has validated the Rotor-Gene Q software with the QIAGEN laptop in combination with the following two virus scanners to show compatibility:

- Symantec Endpoint Protection V12.1.6
- Microsoft Security Essentials V4.10.209 \*

Please refer to the product page on QIAGEN.com for the latest versions of anti-virus software that have been validated in combination with Rotor-Gene Q software and Rotor-Gene AssayManager v1.0.

If a virus scanner is selected, make sure that it can be configured in a way that the database folder path can be excluded from the scan. Otherwise, there is the risk of database connection errors. Since the Rotor-Gene AssayManager v1.0 creates new database archives dynamically, it is required to exclude the folder path to the files and not single files. We do not recommend the use of virus scanners where only single files can be excluded, e.g. McAfee Antivirus Plus V16.0.5. If the computer is used in an environment without network access, please also make sure that the virus scanner supports offline updates.

To get consistent results after installation of a virus scanner, a system administrator should ensure the following:

- As explained above, the database folder path of the Rotor-Gene AssayManager 1.0 needs to be excluded from file scans, which depending on the MS SQL server version that initially created the database, is as follows: C:\Program Files\Microsoft SQL Server\MSSQL10\_50.RGAMINSTANCE\MSSQL\DATA or C:\Program Files\Microsoft SQL Server\MSSQL12.RGAMINSTANCE\MSSQL\DATA

\* **Note:** After installation of "**Microsoft Security Essentials**", you shall check that Windows updates are deactivated since the installation might activate this setting (please read chapter "**Operating system updates**").

- Updates to the virus database are not performed when the Rotor-Gene AssayManager v1.0 is in use
- Please make sure that full or partial scans of the hard drive are disabled during real-time PCR data acquisition. Otherwise there is a risk of adverse impact on the performance of the instrument.

Please read the manual of your selected virus scanner for configuration details.

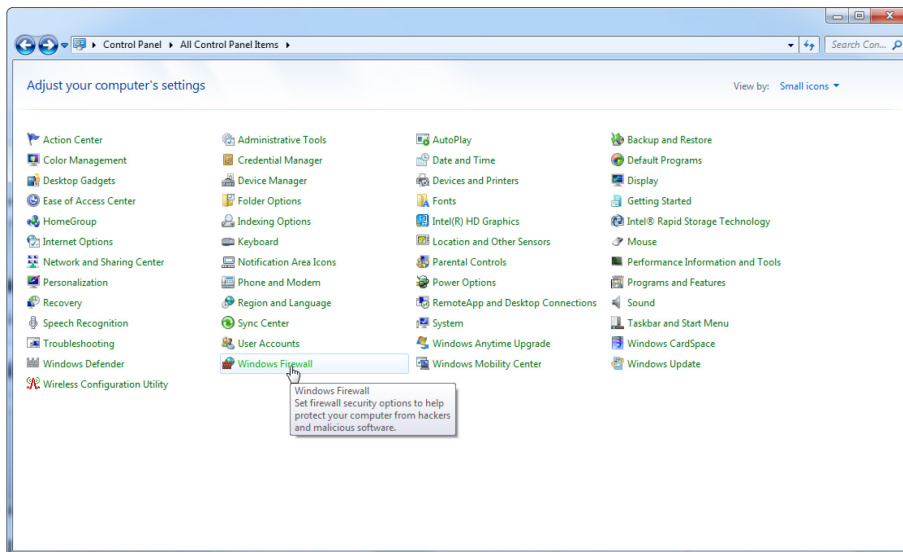
#### 4.11.2 Firewall and network

Rotor-Gene Q software and Rotor-Gene AssayManager v1.0 can run either on computers without network access, or can run in a network environment, if a remote database server is used. For networked operation, the firewall on the laptop computer provided by QIAGEN is configured in a way that inbound traffic is blocked for all ports, except those ones required to establish a network connection.

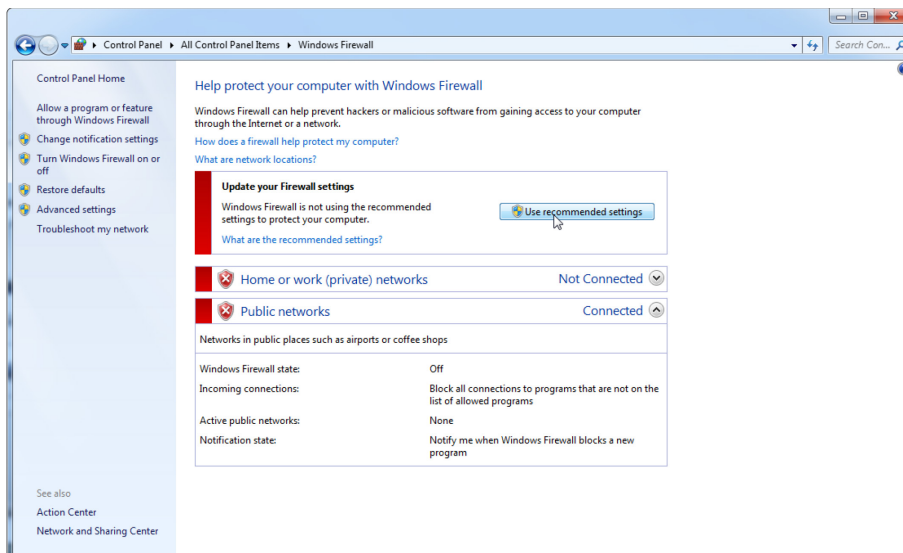
Please note that blocking incoming connections does not affect responses to requests triggered by the user such as updating anti-virus definition files, or connecting the Rotor-Gene AssayManager v1.0 to the centralized database server. Outgoing connections are allowed as this may be required for retrieving updates or when the Rotor-Gene AssayManager v1.0 is configured to work with a centralized database server.

If your configuration is different, QIAGEN recommends you configure the firewall in the same way as described above. To this end, a system administrator has to login and has to perform the following steps:

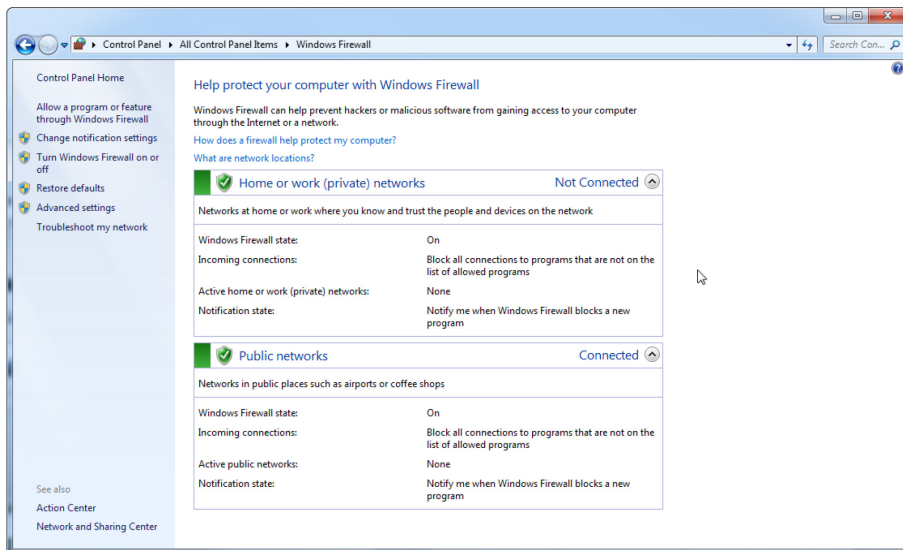
- 1 Open the “**Control Panel**” and select “**Windows Firewall**”.



2. Select **"Use recommended settings"**.



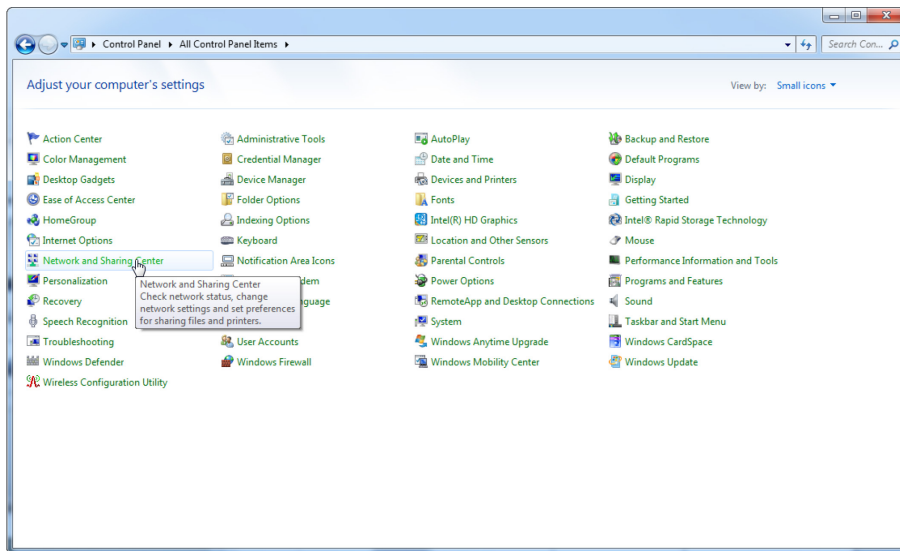
3. Check that the following settings are active:



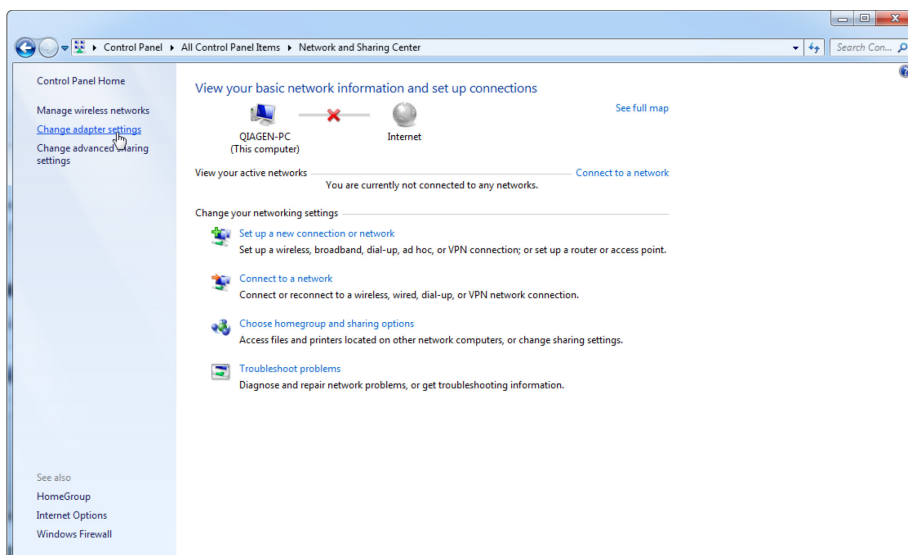


For security and reliability reasons cable-based network access instead of Wi-Fi shall be used. The laptop computers that are provided by QIAGEN have a disabled Wi-Fi adapter. If your configuration is different, a system administrator must disable the Wi-Fi adapter manually and this can be performed by following the steps below:

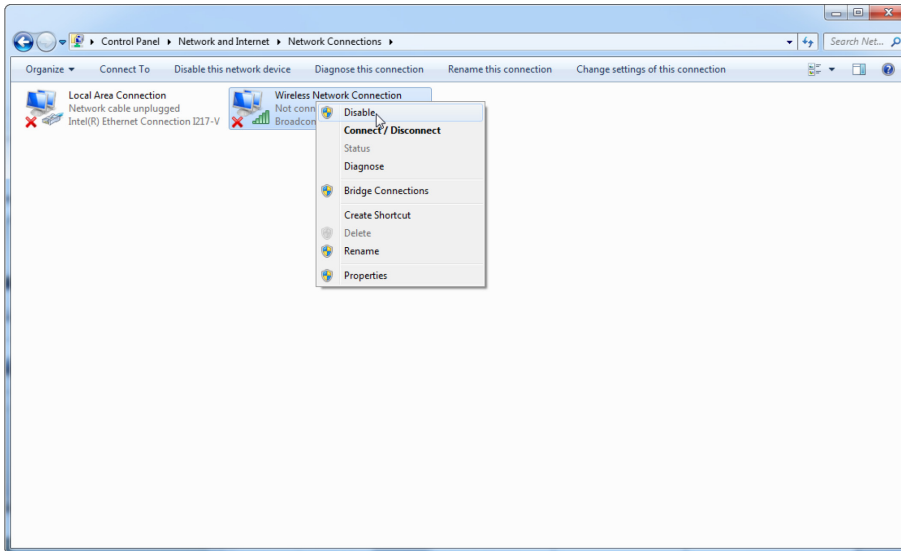
- 1 Open the **"Control Panel"** and select **"Network and Sharing Center"** (on Windows 10, just search for **"Control Panel"** to open it).



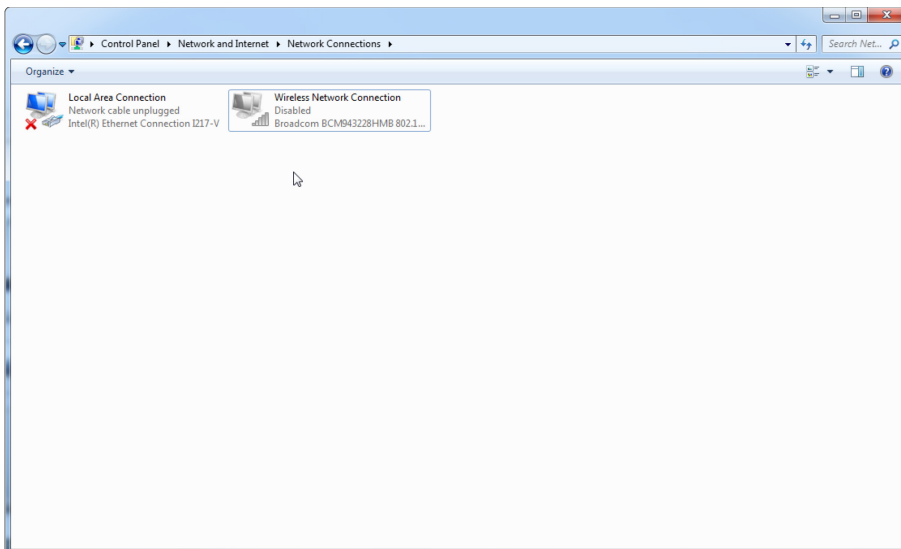
- 2 Select **"Change adapter settings"**.



- 3 Hover over "**Wireless Network Connection**", press the right mouse button, and select "**Disable**" from the context menu.



- 4 Check that the "**Wireless Network Connection**" is disabled.



### 4.11.3 System tools

Many system tools may use significant system resources even without any user interaction. Typical examples of such tools are:

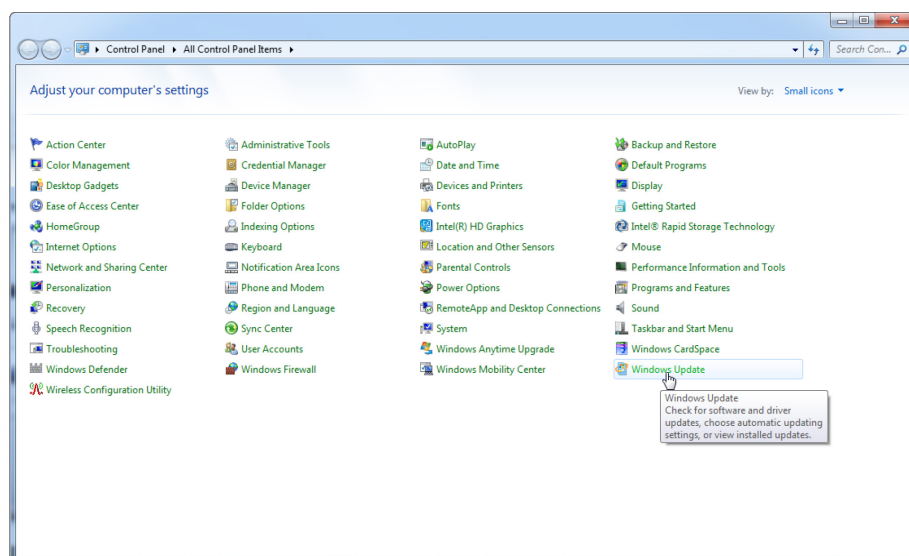
- File indexing, which is performed as a background task by many contemporary office applications
- Disk defragmentation, which often also employs a background task
- Any software that checks for updates on the internet
- Remote monitoring and management tools

**Note:** Due to the dynamic nature of information technology products and systems, this list may be incomplete. Tools may be released that are not known at the time of writing. It is important that system administrators take care that such tools are not active on the Rotor-Gene Q MDx during a PCR run.

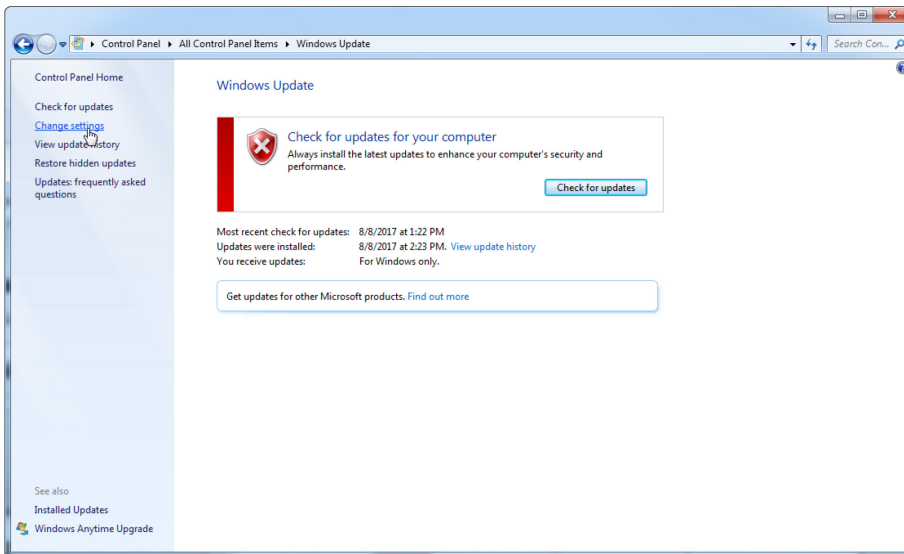
### 4.11.4 Operating system updates

The laptop computers provided by QIAGEN is configured in a way that automatic updates of the operating system are disabled. If your configuration is different, a system administrator must disable any automatic update process of the operating system which can be done by the following steps:

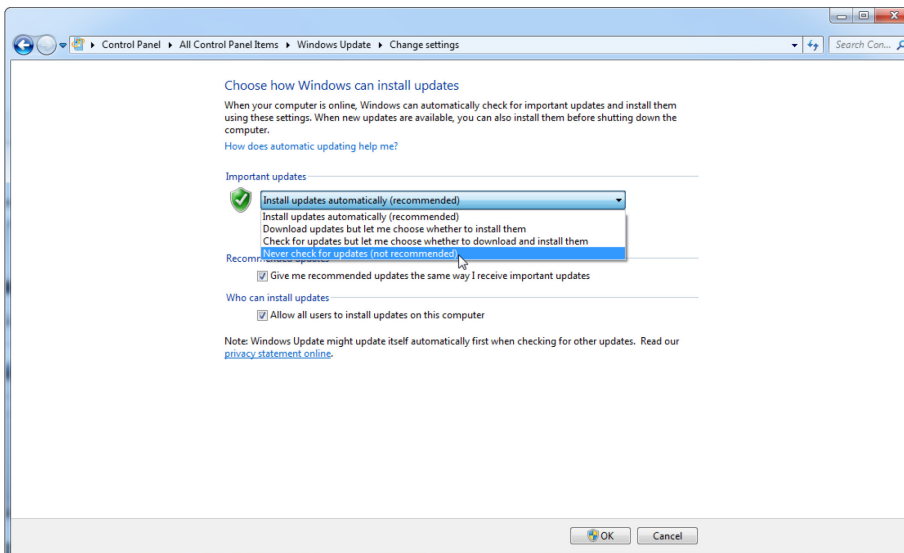
- 1 Open the “**Control Panel**” and select “**Windows Update**”.



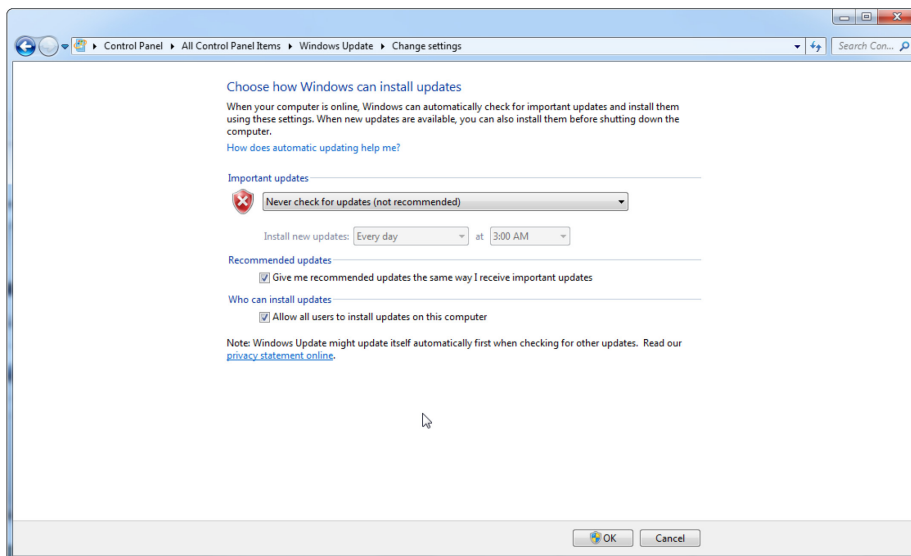
2 Select **"Change settings"**.



3 Select **"Never check for updates"**.



4 Check that option “**Never check for updates**” is active.



In case updates are required due to uncovered security vulnerabilities, QIAGEN provides mechanisms to install a defined set of validated Windows security patches either online, or as offline package, prepared on a separate computer with internet connection.

Please visit the product page on QIAGEN.com for more information.

## 4.12 Updating software

Software updates are available from the QIAGEN website at **[www.qiagen.com/products/rotor-geneqmdx.aspx](http://www.qiagen.com/products/rotor-geneqmdx.aspx)**. Software updates can also be accessed also from the “**Help**” menu in the software. To download the software, it is necessary to register online.

## 4.13 Installing Rotor-Gene AssayManager Version 1.0

See the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual* for information about installing Rotor-Gene AssayManager version 1.0.x (x ≥ 5).

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## 4.14 Updating Rotor-Gene Q software

Software updates for Rotor-Gene Q software are available from the QIAGEN website at <http://www.qiagen.com/products/rotor-geneqmdx.aspx>. Software updates can also be accessed also from the "**Help**" menu in the software. To download the software, it is necessary to register online.

## 5 Operating Procedures — Hardware

This section describes operation of the Rotor-Gene Q MDx.

### 5.1 72-Well Rotor

The 72-Well Rotor is blue in color. The 72-Well Rotor and 72-Well Rotor Locking Ring are used with Strip Tubes and Caps, 0.1 ml, which can be used for volumes as low as 20 µl. The caps provide a safe and reliable seal.



#### Rotor specifications

Rotor type	Well capacity	Sample no.	Tube type	Recommended reaction volume
72-Well Rotor	100 µl	72	Strip Tubes and Caps, 0.1 ml	20–50 µl

#### CAUTION



#### Damage to the instrument

Visually inspect and make sure the rotor is not damaged or deformed before each run.

## 5.2 Manual reaction setup

**IMPORTANT:** Adequate controls should be used in each run to ensure reliable results.

**Note:** Refer to the specific assay Instructions for Use (Handbook) to determine the appropriate reaction setup to be used.

Reactions can be prepared using the Loading Block 72 x 0.1 ml Tubes (for Strip Tubes and Caps, 0.1 ml set up with a single-channel pipet), or the Loading Block 72 x 0.1 ml Multi-channel (for Strip Tubes and Caps, 0.1 ml set up with a multichannel pipet). Blocks are made of aluminum and can be precooled.

The Loading Block 72 x 0.1 ml Tubes (pictured) holds 18 Strip Tubes (4 x 0.1 ml) as well as up to eight 0.5 ml tubes, and up to sixteen 0.2 ml tubes. The procedure below describes the reaction setup for the 72-Well Rotor.

1. Place the Strip Tubes into the Loading Block and aliquot the reaction components.

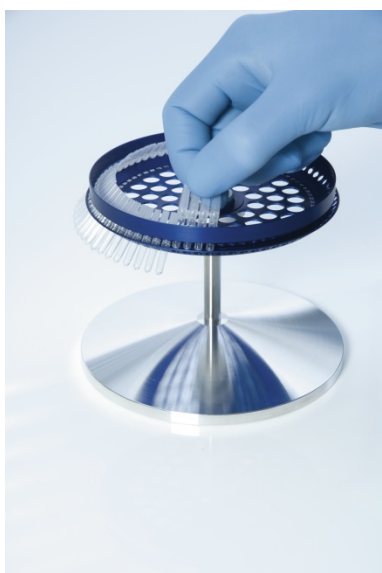




2. Place the Caps securely on the Strip Tubes and visually inspect to confirm a tight seal.



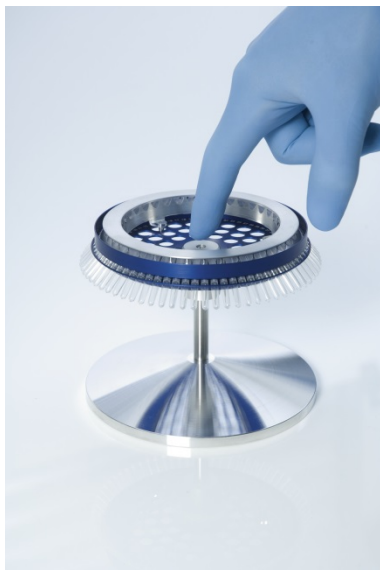
3. Insert the Strip Tubes into the 72-Well Rotor, ensuring that each tube sits correctly in place in the correct orientation. Samples will not be optimally aligned over the detection system if not placed correctly in the rotor. This could result in a reduction in acquired fluorescence signal and detection sensitivity. A Rotor Holder that enables easy tube loading is provided with the instrument.



**IMPORTANT:** To achieve maximum temperature uniformity, each position in the rotor must contain a tube. Filling all positions in the rotor ensures even airflow to every tube. Keep a set of empty capped tubes available that can be used to fill any unused positions.

4. Insert the 72-Well Rotor Locking Ring onto the 72-Well Rotor by pushing the 3 locating pins through the outer holes of the rotor.

The Locking Ring ensures that caps remain on tubes during a run.



5. Insert the assembly into the Rotor-Gene Q MDx chamber by clicking into place using the locating pin on the rotor hub. To remove, simply push down on the rotor hub to release and pull out.



6. Close the lid and select the icon on the computer desktop for the desired assay.

---

## 5.3 Automated reaction setup

See Volume 1 of the *QIASymphony RGQ MDx (US) User Manual* and the specific assay Instructions for Use (Handbook) for instructions to use the QIASymphony AS for automated reaction setup.

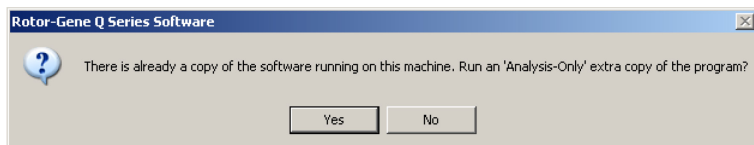
## 6 Operating Procedures — Rotor-Gene Q Software

**Note:** This chapter describes the Rotor-Gene Q software. For Rotor-Gene AssayManager software, see the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

### 6.1 Set up and perform run

A new run is started by double clicking on the template icon that is located on the desktop. More than one template icon may be available on the desktop, depending on the number of assay packages installed and the number of templates each assay package supports. Make sure that you select the right one according to the descriptions in the respective Instructions for Use (Handbook) for the assay you are using.

Ensure that no other instance of the software is running. If you get the following message box, press **No**, close all other instances, and try again.



The software starts up and presents the assay specific user interface. The procedure for entering sample data and performing the run is assay dependent. Please refer to the Instructions for Use (Handbook) for the assay you are using for further information on the workflow.

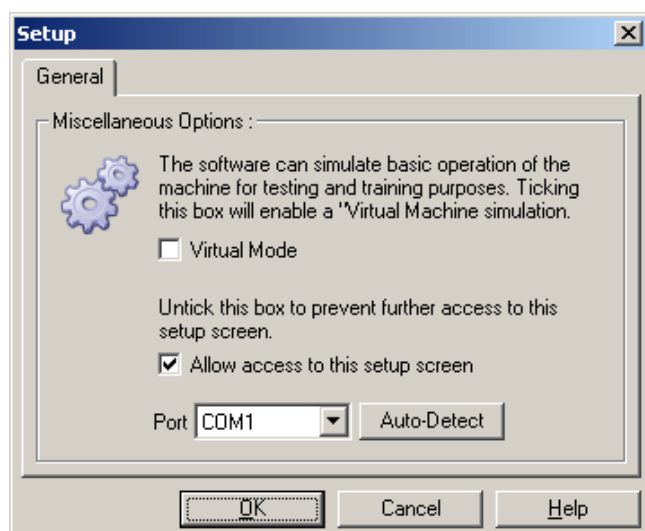
### 6.2 Analysis

The analysis is started automatically after the run is completed. As the analysis is assay dependent, please refer to the Instructions for Use (Handbook) for the assay you are using for more information on results and report files.

## 6.3 File menu

### 6.3.1 Setup

The initial setup of the Rotor-Gene Q MDx should be completed during installation. However, this option allows a change to the Rotor-Gene Q MDx connection setup, if this should be required after the initial installation.



**Virtual Mode:** Select this option if the software will be used without a connected Rotor-Gene Q MDx. The software retains all functions. This mode is useful for demonstration purposes, data analysis, and setting up templates.

**Allow access to this setup screen:** If this option is not checked during setup, this window can no longer be accessed. This security measure prevents users from altering the settings. To reestablish access, contact your distributor.

**Port:** Select the correct communication port to enable communications between the computer and the Rotor-Gene Q MDx.

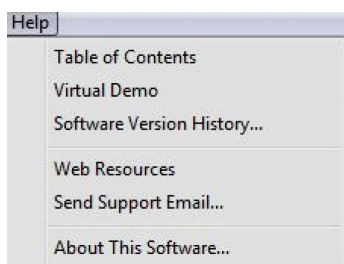
**Auto-Detect** If you are unsure which port to select, click **Auto-Detect** to search for all available ports.

## 6.4 Windows menu

This menu enables the windows to be tiled vertically or horizontally, or arranged in a cascade. Further options are accessible by clicking the arrow on the right of the **Arrange** button.

## 6.5 Help function

When using the **Help** button or **Help** menu the following pull-down menu will open:



**Table of Contents:** This accesses the **Help** function.

**Virtual Demo:** This links to a QIAGEN webpage with an interactive demonstration of the software.

**Software Version History...:** This provides a brief overview of new features added since the previously installed software release.

**Web Resources:** This opens a new browser window with a QIAGEN webpage that contains valuable latest information on Rotor-Gene Q MDx instruments and corresponding reagents.

**About This Software...:** This provides information about the connected machine, the serial number of the Rotor-Gene Q MDx, and the software version.

### 6.5.1 Send Support Email

The **Send Support Email...** option in the **Help** menu allows you to send a support email to QIAGEN including all relevant information from a run. The **Save As** option will save all the


information to a file that you can copy onto a disk or across a network if you do not have access to email on the computer running the Rotor-Gene Q MDx.

When you use the support email function on the laptop computer provided with the Rotor-Gene Q MDx (country dependent) for the first time, you will have to configure your email settings.

**Note:** You can make the entries of the IT manager of your company.

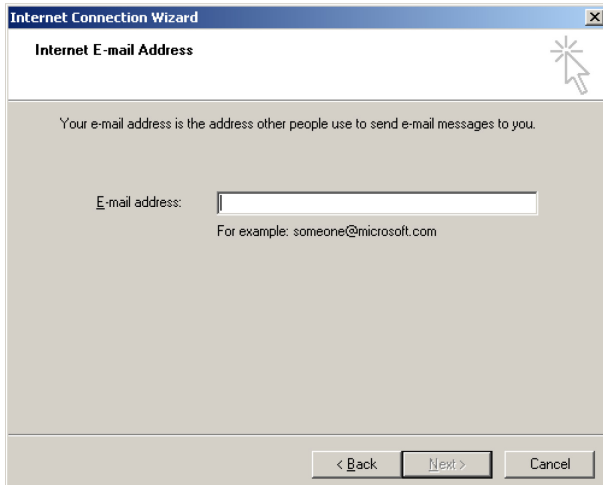
### Configure the email settings

1. Click the option **Send Support Email....** The following window will open.



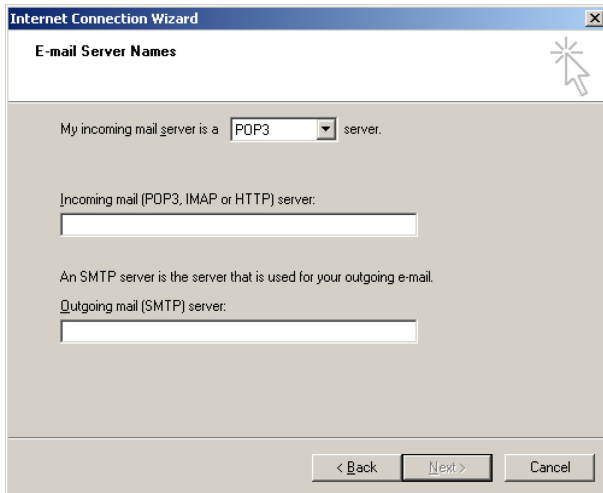
The screenshot shows a window titled "Internet Connection Wizard" with a close button in the top right corner. The window has a header bar with the title. Below the header, the title "Your Name" is displayed. A mouse cursor is pointing at a question mark icon in the top right corner of the main content area. The main content area contains the text: "When you send e-mail, your name will appear in the From field of the outgoing message. Type your name as you would like it to appear." Below this text is a label "Display name:" followed by a text input field. Below the input field is the text "For example: John Smith". At the bottom of the window are three buttons: "< Back", "Next >", and "Cancel".

2. Type in your name and click **Next**. The **Internet Email Address** window will open.



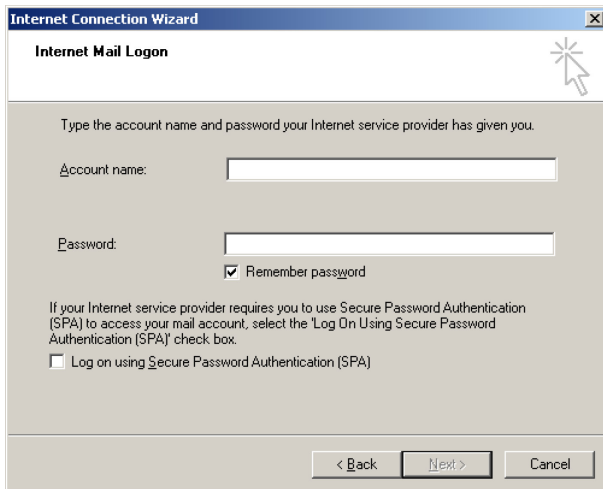
The screenshot shows a window titled "Internet Connection Wizard" with a close button in the top right corner. The window has a header bar with the title. Below the header, the title "Internet E-mail Address" is displayed. A mouse cursor is pointing at a question mark icon in the top right corner of the main content area. The main content area contains the text: "Your e-mail address is the address other people use to send e-mail messages to you." Below this text is a label "E-mail address:" followed by a text input field. Below the input field is the text "For example: someone@microsoft.com". At the bottom of the window are three buttons: "< Back", "Next >", and "Cancel".

3. Type in your email address and press **Next**. The **Email Server Names** window will open.



The screenshot shows the 'Internet Connection Wizard' window with the title 'E-mail Server Names'. It contains a dropdown menu for 'My incoming mail server is a' set to 'POP3'. Below this are two text input fields: 'Incoming mail (POP3, IMAP or HTTP) server:' and 'Outgoing mail (SMTP) server:'. At the bottom are three buttons: '< Back', 'Next >', and 'Cancel'.

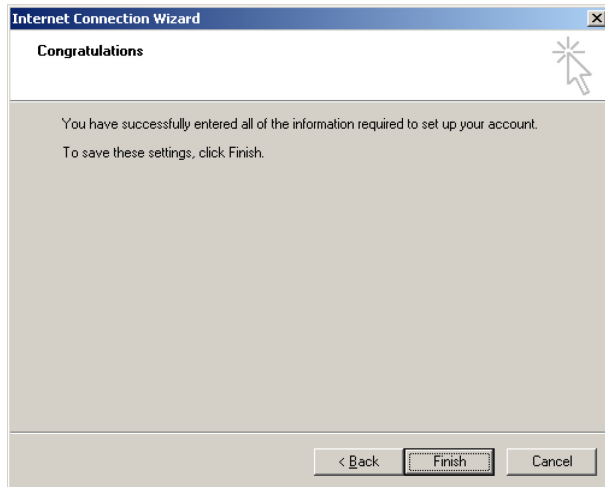
4. Select the type of mail server for incoming mails and specify the server names for incoming and outgoing emails. Then press **Next**. The window **Internet Mail Login** will open.



The screenshot shows the 'Internet Connection Wizard' window with the title 'Internet Mail Login'. It contains a text input field for 'Account name:' and another for 'Password:'. Below the password field is a checked checkbox labeled 'Remember password'. Further down is a checkbox labeled 'Log on using Secure Password Authentication (SPA)' which is currently unchecked. At the bottom are three buttons: '< Back', 'Next >', and 'Cancel'.

5. Enter your email account name and password and select, if your server uses secure password authentication. Then click **Next**. The **Congratulations** window will open.

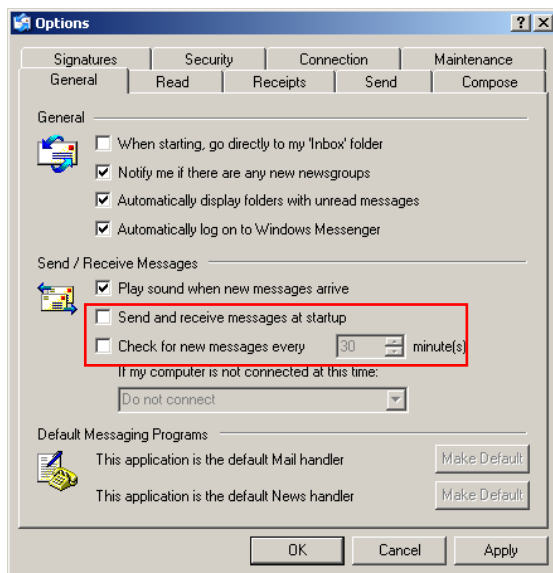




6. Confirm with **Finish** to complete the email account setup.

### Setting up in Outlook

1. Open **Outlook Express** from the **Start** menu (**Start, All programs, Outlook Express**).
2. Select **Tools** and then **Options**. The window below appears.



**Important:** To avoid any retrieval of emails during PCR runs, disable the default entries in the **Send/Receive Messages** screen.

3. Disable **Send and receive messages at startup**.
4. Disable **Check for new messages every 30 minutes**.
5. Confirm changes with **OK**.

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## 7 Operating Procedures — Rotor-Gene AssayManager Software

For Rotor-Gene AssayManager software, see the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

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## 8 Access Protection

**Note:** This chapter describes access protection for Rotor-Gene Q software. For Rotor-Gene AssayManager software, see the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

Rotor-Gene Q software includes features that enable it to operate securely. When it is correctly configured, the software can ensure that:

- Access to the Rotor-Gene Q MDx or the analysis software is restricted to user groups
- Modifications to run files are logged
- Unauthorized modifications are detected (signatures)
- Templates used to perform runs are logged
- Sample names are protected

### Integration with Windows security

To provide a strong level of accountability, Rotor-Gene Q software does not manage security internally. Accounts, groups, and passwords are all managed using the Windows built-in security model (Windows security). Integration allows the same password that provides access to network files and programs to control Rotor-Gene Q software access, leading to less administration. In larger organizations, for example, network administrators can easily remove access to ex-users due to the centralized security model.

For this reason, setting up the Rotor-Gene Q software securely primarily involves configuration of the Windows security roles according to best practices.

### Prerequisites

To use security, you must be running Windows 10 Professional edition or Windows 7 Professional edition. The security features cannot be used with Windows 10 or Windows 7 Home editions, as the Home editions do not have the fine-grained access model used by the software. The software must be installed with the **Force authentication through Windows domain** option.

**Note:** The Windows Security menu will not appear if you are logged into a Linux Samba domain. You must have either a local logon or a Windows server to use the security features.

For configuration of Windows security, see Section 4.4 Configuration for Windows security on page 494

## 8.1 User accounts

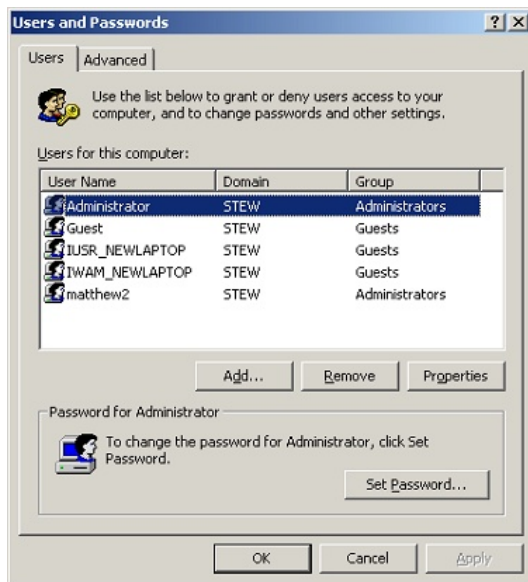
This section describes how to set up the system to run Rotor-Gene Q software securely.

To use the security features, the software must be installed with the **“Force authentication through Windows domain”** option. This queries the Windows domain for your access level and credentials and is essential for providing the accountability and security features.

### 8.1.1 Creating a new user account

Create user accounts for each user of the Rotor-Gene Q software. For each user, repeat the steps below until all accounts have been created.

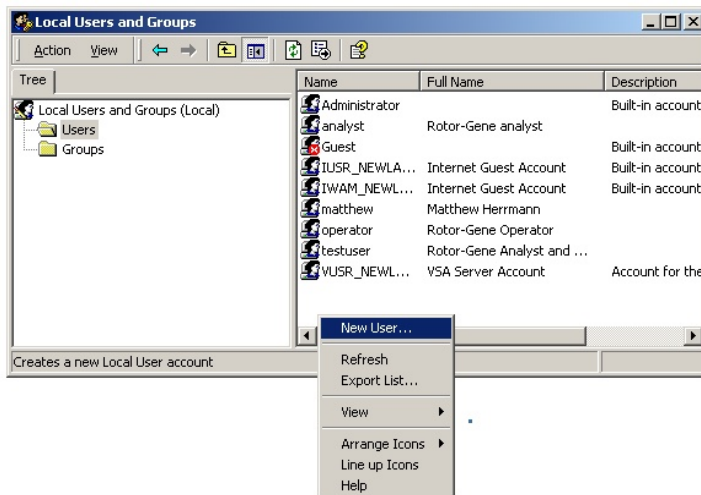
1. To create a new user, select **“Start/Settings/Control Panel”**.
2. Double-click on **“Users and Passwords”**.



3. Click the **“Advanced”** tab, then click the **“Advanced”** button.



4. In the window that appears, select the “**Users**” folder. Right-click on the right-hand window and select “**New User**”.



5. Enter a username and password. By default, the user will be created with normal access privileges. This means they can run software but not install new programs or change system settings.

**New User**

User name: newuser

Full name: New User

Description:

Password: xxxxx

Confirm password: xxxxx

☒ User must change password at next logon

☐ User cannot change password

☐ Password never expires

☐ Account is disabled

Create Close

6. Click **“Create”**. You can now log on as this user.

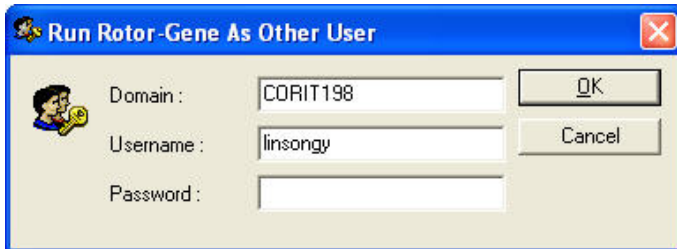
### 8.1.2 Assigning roles to each user

You should now assign roles to each user. Access is divided into the following options:

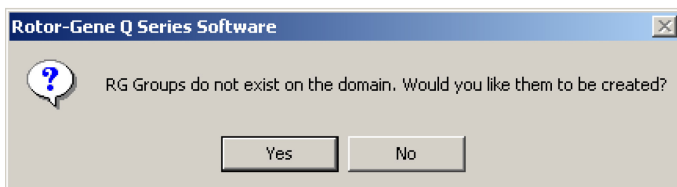
- Rotor-Gene Q Operator — can perform runs but cannot generate reports or perform analysis
- Rotor-Gene Q Analyst — can analyze run data and generate reports but cannot perform new runs
- Rotor-Gene Q Operator and Analyst — has the capabilities of both roles
- Administrator — can unlock sample names and perform all operations of Analysts and Operators
- None — access to the software is denied

### To assign roles:

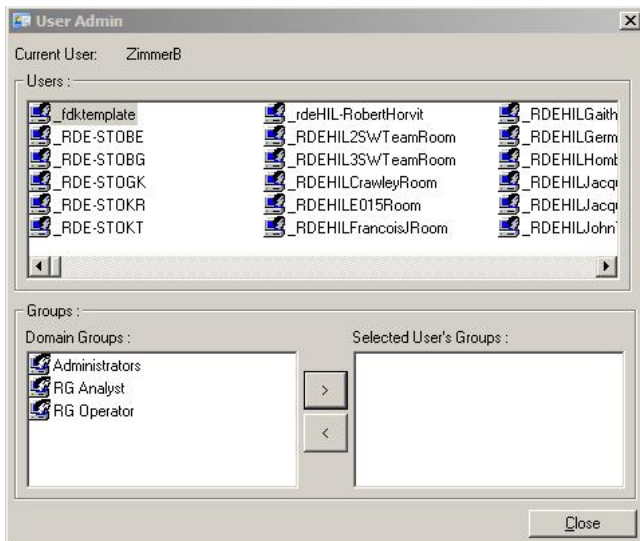
1. Log in to Windows as an administrator or use the “**Rotor-Gene Q Software Login**” icon to open the software and log in.



2. After the software is open, click on the “**Security**” menu. The first time the “**Security**” menu is accessed, Rotor-Gene Q software configures a number of system groups that will control access to the software.

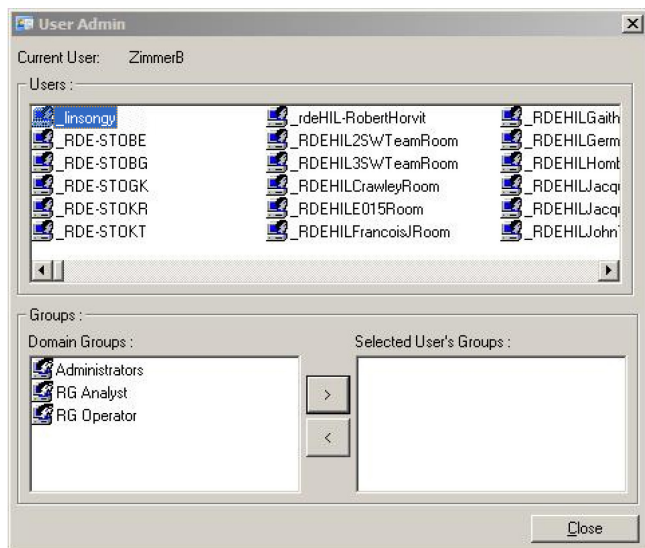


3. Click “**Yes**”. The “**User Admin**” window appears. In the top panel, all the users of the computer are displayed. Some accounts are used by the system so they may be unfamiliar. The bottom pane shows the groups assigned to the user.

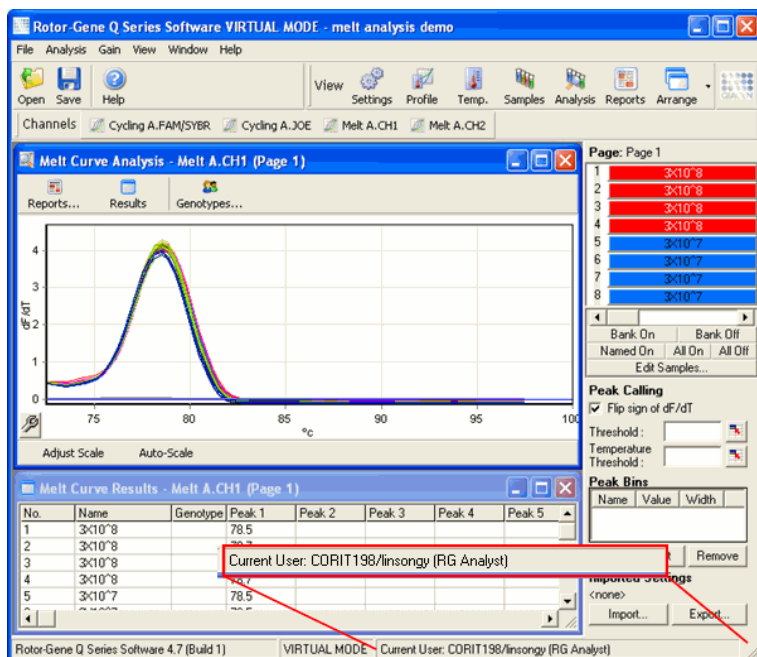


4. To assign a group to a user, select the user's name from the list. The bottom panel will update. If the user has no groups, they cannot launch the software. In the example below, we assign the user “linsongy” to the **RG Analyst** group by selecting

the group on the left-hand side, then clicking the ">" button. Groups can be removed by selecting them, then clicking the "<" button.



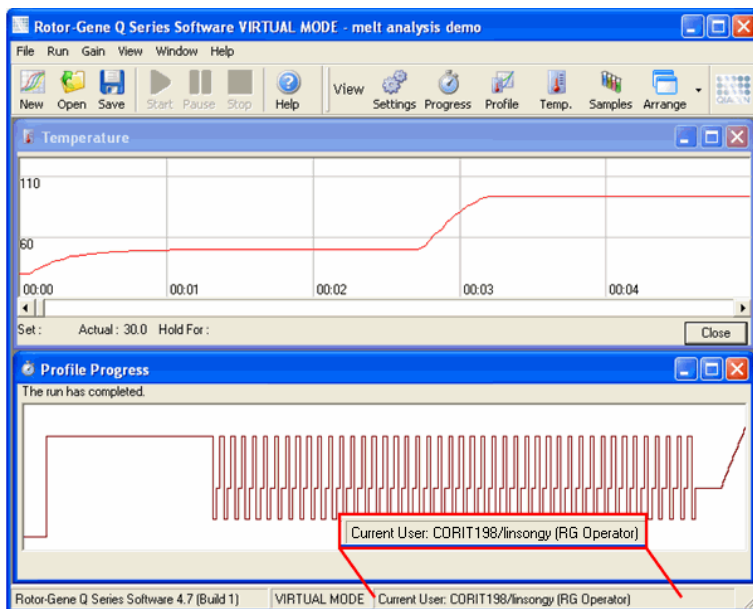
- Now log in as this user. As an **RG Analyst**, the **"Run"** menu and **"Profile"** button are unavailable. However, existing files can be opened and analyzed, as shown in the screenshot below. The status bar indicates that the user "linsongy" is an **RG Analyst**.



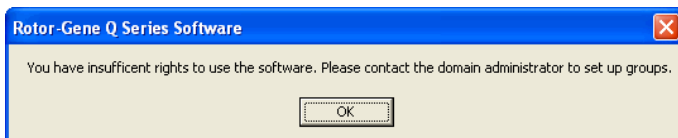
- By logging in as an administrator again, **"RG Operator"** rights can be assigned to "linsongy" and the software can be launched again. This time, the **"Analysis"** menu and **"Reports"** button are missing, and the **"Run"** menu is enabled.



7. The status bar indicates that the user "linsongy" belongs to the "RG Operator" group.



8. If you log in as administrator and remove all groups from the user "linsongy", the following message will appear when "linsongy" opens the software.



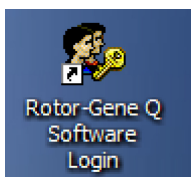
### 8.1.3 Running multiple users on the same computer

To use the Rotor-Gene Q software with multiple users, all users need to have access rights to the Rotor-Gene Q software. The current user first has to log out of Windows. A different user can then log into Windows with their own account and access the Rotor-Gene Q software.

Should it be unfeasible for each user to log out of Windows repeatedly, a "lab user" Windows account can be created by the IT department. The "lab user" will be logged into Windows all the time and each Rotor-Gene Q user can log into the Rotor-Gene Q software with their own credentials. However, the "lab user" Windows account should have no access rights to the Rotor-Gene Q software so no one can accidentally log into the Rotor-Gene Q software with the "lab user" Windows account

### To set up multiple users:

1. Using the “**Rotor-Gene Q Software Login**” icon, users can open their user account in the Rotor-Gene Q software.



2. Enter the username and password in the box that appears.



3. The domain is either the computer you are logging into or the name of your local network. Consult your network administrator if unsure which domain to enter in this field.

**Note:** After logging in, all of the user files will be available for that user. Each user can save files in their own area. This ensures a high level of security.

**Note:** Each user should log out after their run has completed to prevent other users from performing a run in their name.

## 8.2 Configuration for Windows 7 security

This section describes how to set up the system to run Rotor-Gene Q software securely.

To use the security features, the software must be installed with the **Force authentication through Windows domain** option. This queries the Windows domain for your access level and credentials and is essential for providing the accountability and security features.

## 9 Maintenance Procedures

Maintaining the working performance of the Rotor-Gene Q MDx is easy. Optical performance is maintained by ensuring that the lenses, located at both the emission and detection source, are clean. This is achieved by gently wiping a cotton tip applicator, moistened with ethanol or isopropanol,\* over the lenses.

**Note:** Clean the lenses at least once a month, depending on usage. Wipe the rotor chamber at the same time.

Keep the work bench area clean and free from dust and sheets of paper. The air inlet of the Rotor-Gene Q MDx is at the bottom and loose material such as paper or dust may compromise performance.



To avoid dust build up, keep the lid of the Rotor-Gene Q MDx closed when the instrument is not in use.

If the rotor chamber becomes contaminated, it can be cleaned by wiping the surfaces with a lint-free cloth dampened (but not dripping) with a 0.1% (v/v) bleach solution.\* Wipe the chamber with a lint-free cloth dampened with PCR-grade water to remove traces of bleach.

\* When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, consult the appropriate Safety Data Sheets (SDSs), available from the product supplier.

## 10 Optical Temperature Verification

Optical Temperature Verification (OTV) is a method that verifies the in-tube temperature in a Rotor-Gene Q MDx. While it is not required for the Rotor-Gene Q MDx, calibration of in-tube temperature can be a laboratory requirement. The OTV method provides a means for users to comply with this requirement, including if there are site specific calibration intervals. OTV is performed using a Rotor-Disc® OTV Kit (see Appendix B).

A short introduction to the OTV principle is given here. Performance of the OTV procedure is explained in the Rotor-Gene Q software. For a more detailed description of the OTV procedure, including a troubleshooting guide, please refer to the *Rotor-Disc OTV Handbook*.

**Note:** Rotor-Gene AssayManager software is not used for the OTV procedure.

### 10.1 OTV principle

OTV uses the optical properties of 3 thermochromatic liquid crystals (TLC)\* as absolute temperature references. When heated, TLCs change from opaque to transparent at very precise temperatures (50°C, 75 °C, and 90 °C). TLCs do not themselves fluoresce. Therefore, it is necessary to cover the excitation source with a fluorescent insert so that the TLC transition points can be detected by the Rotor-Gene Q MDx optical system. TLCs that are below their transition temperature are opaque and reflect light. Some of the reflected light scatters towards the detector, increasing fluorescence. When the in-tube temperature reaches the TLC transition point, the TLC becomes transparent, and light passes through the sample rather than being reflected toward the detector, resulting in a decrease in fluorescence. The change in fluorescence is used to determine the precise transition temperature of each TLC. The transition temperature is compared with the temperature reported by the factory calibration file for the OTV Rotor-Disc to verify whether the Rotor-Gene Q MDx is within temperature specification.

\* When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, consult the appropriate Safety Data Sheets (SDSs), available from the product supplier.

## 10.2 Rotor-Disc OTV Kit components

The following components are required to run an OTV:

- A Rotor-Disc OTV Kit, which includes:
  - Sealed Rotor-Disc 72 OTV Rotor (contains TLCs)
  - Fluorescent scatter plate insert (this insert is white for the Rotor-Gene Q MDx instruments)
  - A CD that contains the following files: OTV file with serial number (\*.otv); OTV test template file (\*.ret); OTV handbook (\*.pdf); Certificate of Conformity (\*.pdf); OTV Reference run (\*.rex)
  - Product Sheet
- Rotor-Disc 72 Rotor
- Rotor-Disc 72 Locking Ring

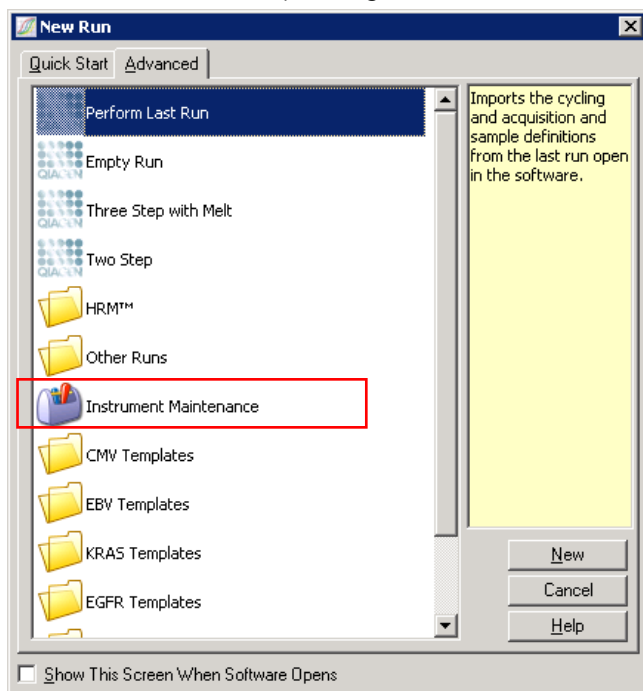
## 10.3 Running an OTV

1. Place the fluorescent insert over the emission lens in the bottom of the Rotor-Gene Q MDx chamber.
2. Place the OTV Rotor-Disc into a Rotor-Disc 72 Rotor. Secure using a Rotor-Disc 72 Locking Ring. Place the assembly into the Rotor-Gene Q MDx and click into place. Close the Rotor-Gene Q MDx lid.

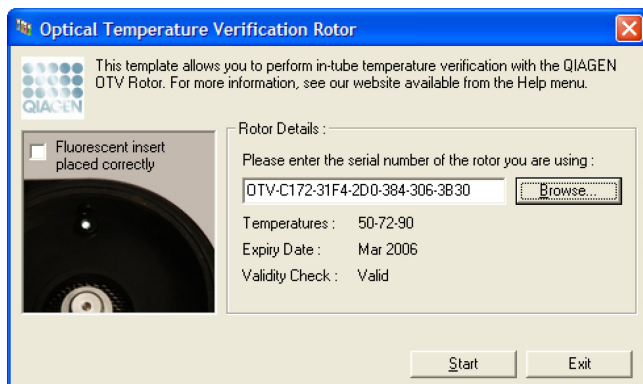


3. Access the Advanced wizard in Rotor-Gene Q software by selecting the **Advanced** tab in the **New Run** window. In the Advanced wizard, click on **Instrument Maintenance** and then **OTV**.

**Note:** Rotor-Gene AssayManager software is not used for running an OTV.

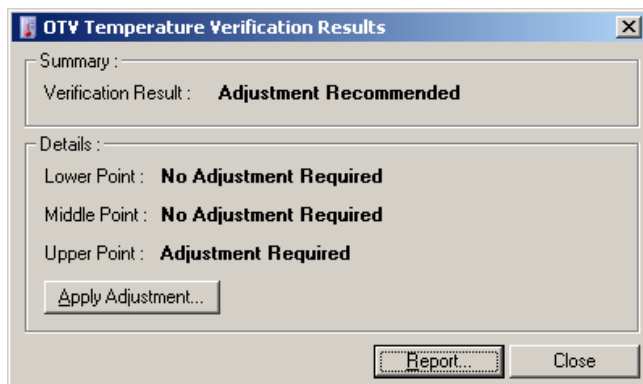


4. The wizard prompts for the OTV serial number. This number can be read from the label on the OTV Rotor-Disc or can be imported from the CD by clicking on **Browse** and choosing the .otv file provided on the CD. Once the number is entered, click **Start**.



5. The Rotor-Gene Q software then prompts for a filename for the run. Then the run begins.

6. The run performs a series of melts that determine the thermal characteristics of the Rotor-Gene Q MDx.



7. When the run is finished, the Rotor-Gene Q software indicates whether the Rotor-Gene Q MDx is within specification.
8. If adjustment is required, the user must click **Apply Adjustment**. This prompts the user to perform a verification run. After the verification run is complete, no adjustment should be required. If further adjustment is required, contact your distributor or QIAGEN Technical Service.
9. When the Rotor-Gene Q MDx is within specification, a report of the run can be reviewed and printed.

# 11 Troubleshooting

## 11.1 Log Archives

The Rotor-Gene Q software keeps an unmodified record of each run, along with diagnostic information, in its **Log Archive** repository. By using the **Help, Send Support Email** option, you can send an e-mail along with all the necessary diagnostic information to QIAGEN Technical Service (see Section 6.5.1).

To save disk space, only Log Archives of the 60 most recent runs are stored. Older run **Log Archives** will be overwritten as new run log archives are created.

## 11.2 General instrument errors

**Note:** This section provides information about general instruments errors when using Rotor-Gene Q software. When using Rotor-Gene AssayManager, see also the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

Error message	Comments and suggestions
Can't open the serial port<COMPORT>	<p>This error occurs on Rotor-Gene Q software startup if the software cannot communicate with the instrument via the configured COM port. This is commonly caused by faulty cables, loose cables, faulty serial ports, faulty USB ports, a USB driver problem, or a USB-to-serial converter driver problem.</p> <p>Reconnect or replace the cable. Reinstall the appropriate drivers. Start the Rotor-Gene Q software in <b>Virtual Mode</b> and select <b>Setup/Auto-Detect</b> button from the <b>File</b> menu to reset the configured COM port.</p>
Chamber Lid Open Could not continue run; the chamber lid was opened	<p>This error occurs when the Rotor-Gene Q software has detected the lid is open in the middle of a run.</p>



Error message	Comments and suggestions
during a run. Please reset the machine, and restart the software.	Reset the machine and restart the Rotor-Gene Q software.
Chamber Lid Open The instrument chamber lid is open. Please close the lid and then click Continue.	<p>This error occurs when the user tries to start a run while the instrument lid is open.</p> <p>Close the lid of the instrument chamber and then click <b>Continue</b>.</p>
Communication Corrupted	<p>This error occurs when the data received from the instrument does not conform to the expected pattern.</p> <p>Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument.</p> <p>Please contact your distributor or QIAGEN Technical Service.</p>
Communication Out Sequence Instrument has received data from the machine that is out of sequence.	<p>This error occurs when the data received from the instrument are not in the correct order.</p> <p>Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument.</p> <p>Please contact your distributor or QIAGEN Technical Service.</p>
Communication Protocol Error A communication protocol error occurred with this run.	<p>This error occurs when the communication protocol configured in the firmware is not the same as the expected protocol.</p> <p>Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the communication protocol or the instrument.</p>

Error message	Comments and suggestions
Detector motor jam, stopped machine	<p>This error can occur when the Rotor-Gene Q MDx is started immediately after delivery in cold climates.</p> <p>In this case, allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on.</p> <p>If the error persists, please contact your distributor or QIAGEN Technical Service.</p>
<p>Fatal Hardware Malfunction</p> <p>The instrument detected that there was a fatal hardware malfunction. Do not attempt to re-use the machine until the machine has been serviced by your distributor.</p>	<p>This error occurs when the Rotor-Gene Q software has detected a fatal hardware malfunction and has activated a safe-protection procedure to turn off the machine.</p> <p>Turn off the instrument immediately and contact your distributor or QIAGEN Technical Service.</p>
<p>Machine Error</p> <p>This run was stopped as machine errors occurred that could not be recovered from. Please contact your distributor if this occurs again, attaching a support archive file.</p>	<p>This error occurs when the Rotor-Gene Q software has detected errors on the machine that could not be recovered from. The software has stopped the run.</p> <p>Try another run. If the problem persists, contact your distributor or QIAGEN Technical Service and attach a support archive file.</p>

Error message	Comments and suggestions
Machine Unplugged  The instrument is not responding and failed with the message <ERROR MESSAGE>. This is an unrecoverable failure, please reset the instrument and restart the software.	<p>This error occurs if the instrument does not communicate with the Rotor-Gene Q software after a defined timeout interval. It is often caused by an instrument fault or by excessive activity from the PC, which causes a packet to be lost.</p> <p>Common Rotor-Gene Q software-related causes include processor-intensive tasks, such as antivirus resident protection or antivirus scheduled scans, wireless cards, or infrared cards.</p> <p>Disable or uninstall the relevant processor-intensive software/task.</p> <p>Reset the instrument and restart the Rotor-Gene Q software.</p> <p>Please contact your distributor or QIAGEN Technical Service if the problem persists.</p>
Machine Unplugged  The instrument is not connected to your computer on <PORT NAME>. Reconnect the serial cable to the back of the computer and then click <b>Continue</b> .	<p>This error occurs when the serial or USB communication to the instrument is lost.</p> <p>Reconnect the serial or USB cable to the back of the computer and then click the <b>Continue</b> button.</p>
Object variable or with block variable not set	<p>This error occurs on Rotor-Gene Q software startup if the default experiment template file has become corrupt. This may happen if the Rotor-Gene Q software/computer is shut down without exiting correctly, for example, during a power outage.</p> <p>Delete the file <b>C:\Program Files\Rotor-Gene Q Software\Templates\normal.ret</b> and then restart the software.</p>

Error message	Comments and suggestions
<p>Rotor Speed Failure</p> <p>Time out while setting the rotor speed.</p>	<p>This error occurs when the Rotor-Gene Q software has attempted to set the rotor speed and failed to set the target speed within a time-out period.</p> <p>Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument.</p> <p>Please contact your distributor or QIAGEN Technical Service.</p>
<p>Serial Port In Use</p> <p>The serial port is currently being used by another application. Close any applications such as communications or synchronization software and then retry.</p>	<p>This error occurs when the Rotor-Gene Q software tries to connect to the machine on the configured COM port when the port is being used by another software.</p> <p>Close any applications such as communications or synchronization software and then retry.</p>
<p>Shutdown timeout</p> <p>The instrument has exceeded the expected time to shutdown. Please reset the machine, and reset the software.</p>	<p>This error occurs when the Rotor-Gene Q software has issued shutdown command to shut down the instrument and the machine keeps sending data back after an expected grace period of time.</p> <p>Reset the machine and restart the Rotor-Gene Q software.</p>
<p>Temperature Protection Activated</p> <p>The instrument detected that the chamber temperature increased above a safe level. It has therefore entered a self-protection mode. Please</p>	<p>This error occurs when the Rotor-Gene Q software has detected the chamber temperature has increased to above a safe level and hence activated a safe-protection procedure.</p> <p>Turn off the instrument immediately and contact your distributor or QIAGEN Technical Service.</p>

Error message	Comments and suggestions
turn off the instrument and contact your distributor if the problem persists.	
Thermistor Is Open  The instrument detected that the thermistor is open, and so to prevent damage to the machine, it has been turned off. Please contact your distributor if this occurs again.	This error occurs when the Rotor-Gene Q software has detected that the thermistor is open and therefore cannot read the temperature; the software has then activated a safe-protection procedure to turn off the machine.  Turn off the instrument immediately and contact your distributor or QIAGEN Technical Service.
Unrecoverable errors occurred  This run was stopped as machine errors occurred that could not be recovered from. Please contact your distributor if this occurs again, attaching a support archive file.	This error occurs in the middle of the run after the Rotor-Gene Q software has made all possible attempts to recover and failed.  Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument.  Please contact your distributor or QIAGEN Technical Service.

### 11.3 Rotor-Gene AssayManager troubleshooting

For Rotor-Gene AssayManager software, see the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

## 12 Glossary

Term	Description
Acquisition	Acquisition is the collection of fluorescent data. Each acquisition (set of fluorescent data) from a channel is displayed in the software as unanalyzed data in a "Raw channel" window. This data can be analyzed using the options in the "Analysis" menu.
Channel	A channel consists of a light emitting diode (LED) with an excitation filter paired with an emission filter. The LED and excitation filter excite samples at a given wavelength. Fluorescence emitted by samples is passed through the emission filter, before being detected by a photomultiplier.
Gain	The Rotor-Gene Q MDx uses a photomultiplier to collect fluorescence photons and convert them to electronic signals. The gain is a setting that determines the sensitivity of the photomultiplier. If the gain is set too high, the signal is oversaturated. If the gain is set too low, it is not possible to differentiate signal from background noise.
Gain Optimisation	Gain Optimisation is a process that dynamically adjusts the gain setting, allowing an appropriate setting to be selected which results in optimal signal detection.
Loading Block	Loading Blocks are aluminum blocks available in different formats which are used to hold tubes during reaction setup.
Locking Ring	Locking Rings are metal rings that fit onto the rotor to prevent tubes and caps from coming loose during operation of the Rotor-Gene Q MDx. Loose caps and tubes could cause damage to the instrument.
Rotor	The metal rotor holds tubes in the Rotor-Gene Q MDx. It enables samples to spin in the instrument chamber and ensures that samples are correctly aligned with the optical system. The rotor is secured with a Locking Ring.

# Appendix A

## Technical data

QIAGEN reserves the right to change specifications at any time.

### Operating conditions

Power	100–240 V AC, 50–60Hz, 520 VA (peak) Power consumption < 60 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages.
Fuse	F5A 250 V fuse
Heat dissipation/ thermal load	Average: 0.183 kW (632 BTU/hour) Peak: 0.458 kW (1578 BTU/hour)
Overvoltage category	II
Air temperature	18 to 30°C (64 to 86°F)
Relative humidity	10–75% (noncondensing)
Altitude	Up to 2000 m (6500 ft.)
Place of operation	For indoor use only
Pollution level	2
Environmental class	3K2 (IEC 60721-3-3) 3M2 (IEC 60721-3-3)

### Transportation conditions

Air temperature	–25°C to 60°C (–13°F to 140°F) in manufacturer's package
Relative humidity	Max. 75% (noncondensing)
Environmental class	2K2 (IEC 60721-3-2)

### Storage conditions

Air temperature	15°C to 30°C (59°F to 86°F) in manufacturer's package
Relative humidity	Max. 75% (noncondensing)
Environmental class	1K2 (IEC 60721-3-1)

### Mechanical data and hardware features

Dimensions	Width: 370 mm (14.6 in.) Height: 286 mm (11.3 in.) Depth (without cables): 420 mm (16.5 in.) Depth (door open): 538 mm (21.2 in.)
Weight	12.5 kg (27.6 lb.) standard configuration
Capacity	Up to 72 samples per run using a 72-Well Rotor
Software	Rotor-Gene Q software, version 2.3.4 or higher, supplied on the installation CD provided, and Rotor-Gene AssayManager version 1.0.x (where x ≥ 5), supplied on the installation DVD provided

### Thermal specifications

Temperature range	35°C to 99°C (95°F to 210.2°F)
Temperature accuracy	±0.5°C
Temperature resolution	±0.02°C (smallest programmable increment)
Temperature uniformity	±0.02°C (standard deviation)



**Optical specifications**

Excitation sources	High energy light-emitting diodes
Detector	Photomultiplier
Acquisition time	4 seconds

---

## FCC Declaration

The "United States Federal Communications Commission" (USFCC) (in 47 CRF 15. 105) declared that the users of this product must be informed of the following facts and circumstances.

"This device complies with part 15 of the FCC:

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation."

"This Class B digital apparatus complies with Canadian ICES-0003."

The following statement applies to the products covered in this manual, unless otherwise specified herein. The statement for other products will appear in the accompanying documentation.

**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and meets all requirements of the Canadian

Interference-Causing Equipment Standard ICES-003 for digital apparatus. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that the interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

Consult the dealer or an experienced radio/T.V. technician for help.

---

QIAGEN GmbH Germany is not responsible for any radio television interference caused by unauthorized modifications of this equipment or the substitution or attachment of connection cables and equipment other than those specified by QIAGEN GmbH, Germany. The correction of interference caused by such unauthorized modification, substitution or attachment will be the responsibility of the user.

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## Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

In the European Union, the European Directive 2002/96/EC on WEEE requires proper disposal of electrical and electronic equipment when it reaches its end of life.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.



Recycling can be provided by QIAGEN upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements, and where a replacement product is being supplied by QIAGEN, free recycling of its WEEE-marked electronic equipment is provided.

To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

## Appendix B

### Rotor-Gene Q MDx instrument and accessories

Product	Contents	Cat. no.
Rotor-Gene Q MDx (US) Platform	Real-time PCR cycler with 6 channels*, laptop computer, software, accessories, 1-year warranty on parts and labor  * Red and HRM Channels are not intended for use with FDA cleared or approved nucleic acid tests.	9002035
<b>Accessories</b>		
Strip Tubes and Caps, 0.1 ml (250)	250 strips of 4 tubes and caps for 1000 reactions	981103
Strip Tubes and Caps, 0.1 ml (2500)	10 x 250 strips of 4 tubes and caps for 10,000 reactions	981106
72-Well Rotor	For holding Strip Tubes and Caps, 0.1 ml; requires Locking Ring 72-Well Rotor	9018903
Locking Ring 72-Well Rotor	For locking Strip Tubes and Caps, 0.1 ml, in the 72-Well Rotor	9018904
Loading Block 72 x 0.1 ml Tubes	Aluminum block for manual reaction setup with a single-channel pipet in 72 x 0.1 ml tubes	9018901
Rotor-Disc OTV Kit	Kit for optical temperature verification of Rotor-Gene systems, includes a Rotor-Disc preloaded with thermochromatic liquid crystals, fluorescent inserts, CD with calibration files; requires Rotor-Disc 72 Rotor and Locking Ring or Rotor-Disc 72 Starter Kit	981400
Rotor Holder	Metal free-standing holder for assembling tubes and Rotor-Discs into rotors	9018908

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at [www.qiagen.com](http://www.qiagen.com) or can be requested from QIAGEN Technical Services or your local distributor.

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## Appendix C

### Liability clause

QIAGEN shall be released from all obligations under its warranty in the event repairs or modifications are made by persons other than its own personnel, except in cases where the Company has given its written consent to perform such repairs or modifications.

All materials replaced under this warranty will be warranted only for the duration of the original warranty period, and in no case beyond the original expiration date of original warranty unless authorized in writing by an officer of the Company. Read-out devices, interfacing devices and associated software will be warranted only for the period offered by the original manufacturer of these products. Representations and warranties made by any person, including representatives of QIAGEN, which are inconsistent or in conflict with the conditions in this warranty shall not be binding upon the Company unless produced in writing and approved by an officer of QIAGEN.

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# QIAasymphony RGQ MDx (US) User Manual

## Volume 2, Part II

Rotor-Gene AssayManager IVD (US) Core Application User Manual

# 1 Safety Information

The user-friendly Rotor-Gene AssayManager® has been specifically developed for use with up to 4 different Rotor-Gene® Q MDx instruments. Before using Rotor-Gene AssayManager, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the cycler and to maintain the instrument in a safe condition.

The Rotor-Gene AssayManager user manual does not provide detailed information about the Rotor-Gene Q MDx instrument hardware and maintenance but provides a summary below. The Rotor-Gene AssayManager manual only describes the functionality of the Rotor-Gene AssayManager software version 1.0.x (x ≥ 5) in combination with Rotor-Gene Q MDx instruments.

## Safety information for the Rotor-Gene Q MDx cycler

The following types of safety information appear throughout the Rotor-Gene Q MDx cycler manual.

**WARNING** The term WARNING is used to inform you about situations that could result in **personal injury** to you or other persons.



Details about these circumstances are given in a box like this one.

**CAUTION** The term CAUTION is used to inform you about situations that could result in **damage to the instruments** or other equipment.



Details about these circumstances are given in a box like this one.

The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

## Proper use

### **WARNING/ CAUTION**



#### **Risk of personal injury and material damage**

Improper use of the Rotor-Gene Q MDx may cause personal injuries or damage to the instrument.

The Rotor-Gene Q MDx must only be operated by qualified personnel who have been appropriately trained.

Servicing of the Rotor-Gene Q MDx must only be performed by QIAGEN Field Service Specialists.

QIAGEN charges for repairs that are required due to incorrect maintenance.

### **WARNING/ CAUTION**



#### **Risk of personal injury and material damage**

Rotor-Gene Q MDx is a heavy instrument. To avoid personal injury or damage to the instrument, take care when lifting.

### **WARNING/ CAUTION**



#### **Risk of personal injury and material damage**

Do not attempt to move the Rotor-Gene Q MDx during operation.

### **CAUTION**



#### **Damage to the instrument**

Avoid spilling water or chemicals onto the Rotor-Gene Q MDx. Damage caused by water or chemical spillage will void your warranty.

**Note:** In case of emergency, switch off the Rotor-Gene Q MDx at the power switch at the back of the instrument and unplug the power cord from the power outlet.

**WARNING/  
CAUTION**



**Risk of personal injury and material damage**

Do not try to open the lid during an experiment, or while the Rotor-Gene Q MDx is spinning. Otherwise, if you overcome the lid lock and reach inside, you risk contact with parts that are hot, electrically live, or moving at high speed, and you may injure yourself and damage the instrument.

**WARNING/  
CAUTION**



**Risk of personal injury and material damage**

If you need to stop an experiment quickly, turn off the power to the instrument, then open the lid. Let the chamber cool before reaching inside. Otherwise you risk injury by touching parts that are hot.

**WARNING/  
CAUTION**



**Risk of personal injury and material damage**

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

**WARNING/  
CAUTION**



**Risk of personal injury and material damage**

Loose paper underneath the Rotor-Gene Q MDx interferes with instrument cooling. It is recommended that the area beneath the instrument is kept free of clutter.

**CAUTION**



**Damage to the instrument**

Always use a locking ring on the rotor. This stops caps from coming off tubes during an experiment. If caps come off during an experiment, they may damage the chamber.

If you touch the Rotor-Gene Q MDx during an experiment, while you are charged with static electricity, in severe cases the Rotor-Gene Q MDx may reset.

## Electrical safety

Disconnect the line power cord from the power outlet before servicing.

### **WARNING**



#### **Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instruments or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

#### **Lethal voltages inside the instruments**

When the instruments are connected to line power, terminals may be live. Opening covers or removing parts is likely to expose live parts.

To ensure satisfactory and safe operation of the Rotor-Gene Q MDx, follow the advice below:

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Do not adjust or replace internal parts of the instrument.
- Do not operate the instrument with any covers or parts removed.
- If liquid has spilled inside the instrument, switch off the instrument, disconnect it from the power outlet, and contact QIAGEN Technical Services.

If the instrument becomes electrically unsafe, prevent other personnel from operating it, and contact QIAGEN Technical Services; the instrument may be electrically unsafe when:

- It or the line power cord appears to be damaged.
- It has been stored under unfavorable conditions for a prolonged period.
- It has been subjected to severe transport stresses.

### **WARNING**



#### **Electrical hazard**

The instrument has an electrical compliance label which indicates the voltage and frequency of the power supply as well as fuse ratings. The equipment should only be operated under these conditions.

## Environment

### Operating conditions

#### **WARNING**



#### **Explosive atmosphere**

The Rotor-Gene Q MDx is not designed for use in an explosive atmosphere.

#### **WARNING**



#### **Risk of explosion**

The Rotor-Gene Q MDx is intended for use with reagents and substances supplied with QIAGEN kits. Use of other reagents and substances may lead to fire or explosion.

#### **CAUTION**



#### **Damage to the instrument**

Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.

The Rotor-Gene Q MDx must be located out of direct sunlight.

## Biological safety

Specimens and reagents containing materials from biological sources should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, HHS ([www.cdc.gov/od/ohs/biosfty/biosfty.htm](http://www.cdc.gov/od/ohs/biosfty/biosfty.htm)).

### Samples

Samples may contain infectious agents. You should be aware of the health hazard presented by such agents and should use, store, and dispose of such samples according to the required safety regulations.

**WARNING****Samples containing infectious agents**

Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations. Always wear safety glasses, gloves, and a lab coat.

The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or OSHA,\* ACGIH,<sup>†</sup> or COSHH<sup>‡</sup> documents. Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

**Chemicals****WARNING****Hazardous chemicals**

Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run.

Always wear safety glasses, gloves, and a lab coat.

The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Safety Data Sheets (SDSs) or OSHA§, ACGIH<sup>\*\*</sup>, or COSHH<sup>††</sup> documents.

Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

**WARNING****Risk of fire**

When cleaning the Rotor-Gene Q MDx with alcohol-based disinfectant, leave the Rotor-Gene Q MDx door open to allow flammable vapors to disperse.

Only clean the Rotor-Gene Q MDx when worktable components have cooled down.

\* OSHA: Occupational Safety and Health Administration (United States of America).

<sup>†</sup> ACGIH: American Conference of Government Industrial Hygienists (United States of America).

<sup>‡</sup> COSHH: Control of Substances Hazardous to Health (United Kingdom).

§ OSHA: Occupational Safety and Health Administration (United States of America).

<sup>\*\*</sup> ACGIH: American Conference of Government Industrial Hygienists (United States of America).

<sup>††</sup> COSHH: Control of Substances Hazardous to Health (United Kingdom).



## Toxic fumes

If working with volatile solvents or toxic substances, you must provide an efficient laboratory ventilation system to remove vapors that may be produced.

## Waste disposal

Used consumables and plasticware may contain hazardous chemicals or infectious agents. Such wastes must be collected and disposed of properly according to local safety regulations.

For disposal of waste electrical and electronic equipment (WEEE), see page 827.

## Mechanical hazards

The lid of the Rotor-Gene Q MDx must remain closed during operation of the instrument.

### WARNING



#### Moving parts

To avoid contact with moving parts during operation of the Rotor-Gene Q MDx, the instrument must be operated with the lid closed.

### WARNING



#### Risk of personal injury and material damage

Open and close the lid of the Rotor-Gene Q MDx carefully to avoid trapping fingers or clothing.

### CAUTION



#### Damage to the instrument

Make sure that the rotor and locking ring are installed correctly. If the rotor or locking ring show signs of mechanical damage or corrosion, do not use the Rotor-Gene Q MDx; contact QIAGEN Technical Services.

### CAUTION



#### Damage to the instrument

The Rotor-Gene Q MDx must not be used if the lid is broken or if the lid lock is damaged.

Make sure that the rotor and locking ring are installed correctly. Only use rotors, locking rings, and consumables designed for use with the Rotor-Gene Q MDx. Damage caused by use of other consumables will void your warranty.

**CAUTION****Damage to the instrument**

When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can block. Allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on.

**WARNING****Moving parts**

In case of breakdown caused by power failure, remove the power cord and wait 10 minutes before attempting to manually open the lid.

**WARNING****Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 10 cm (3.94 in.) at the sides and rear of the Rotor-Gene Q MDx.

Slits and openings that ensure the ventilation of the Rotor-Gene Q MDx must not be covered.

Heat hazard

**WARNING****Hot surface**

The Rotor-Gene Q MDx chamber can reach temperatures above 120°C (248°F). Avoid touching it when it is hot.

**WARNING****Hot surface**

When a run is paused, the Rotor-Gene Q MDx will not be cooled completely to room temperature. Exercise caution before handling the rotor or any tubes in the instrument.

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## 2 Introduction

Thank you for choosing Rotor-Gene AssayManager version 1.0. We are confident it will become an integral part of your laboratory.

Rotor-Gene AssayManager is software for routine testing in combination with Rotor-Gene Q MDx instruments. Rotor-Gene AssayManager is able to read in sample information, set up experiments, control up to 4 different Rotor-Gene Q MDx cyclers, acquire data from these instruments, automatically analyze results, and create reports.

Rotor-Gene AssayManager consists of different components working together. The core application is complemented by different plug-ins that contain assay type specific analysis and visualization of the results. The core application is mandatory for working with Rotor-Gene AssayManager. Optionally additional plug-ins can be installed. At least one plug-in must be installed. Not all plug-ins are available in all countries. Refer to **[www.qiagen.com/Products/Rotor-GeneAssayManager.aspx](http://www.qiagen.com/Products/Rotor-GeneAssayManager.aspx)** to discover our continuously expanding range of plug-ins.

### 2.1 About this user manual

This user manual provides information about Rotor-Gene AssayManager in the following sections:

1. Safety Information
2. Introduction
3. General Description of Rotor-Gene AssayManager
4. Getting Started
5. Basic Concepts and General Software Usage
6. Using Rotor-Gene AssayManager
7. Maintenance
8. Troubleshooting
9. Abbreviations
10. Glossary

The appendices contain the following:

- Abbreviations and File Endings
- Liability Clause

- License Terms

**Note:** The screenshots show examples of how to use the Rotor-Gene AssayManager software. Some of the names used in this manual are only examples and may look different in the lab of the end user. This particularly applies to the use of cycler names.

**Note:** In this manual, the cycler names "Cycler 1", "Cycler 2", "Cycler 3", and "Cycler 4" are used. Further information about how to configure cycles can be found under in Section "Managing cyclers" and Section "**Cycler Management** tab".

## 2.2 General information

### Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time.

In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

### Version management

This document provides information about Rotor-Gene AssayManager version 1.0.x (x ≥ 5).

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## 3 General Description of Rotor-Gene AssayManager

### Product configuration

Rotor-Gene AssayManager is a software for routine testing in combination with the Rotor-Gene Q MDx real-time PCR instruments.

The software consists of a core application, modular plug-ins, and assay profiles. While the core application contains the main functionalities (e.g., cyclers control, configurations), it can be extended with multiple plug-ins containing specific functionalities. For each specific diagnostic application, a specific assay profile is required, which contains assay specific information (e.g., parameter values). The specific combination of core application, plug-in, and assay profile determines a specific routine testing application. (See Section 5.7 "Plug-in concept" for more information.)

Rotor-Gene AssayManager allows control and operation of the Rotor-Gene Q MDx instrument and contains algorithms for analysis of data generated with the Rotor-Gene Q MDx. Rotor-Gene AssayManager supports the user in importing sample specific information and in performing all aspects of the experiment result analysis procedure. The result analysis is started and processed fully automatically after finishing an experiment, and appropriate result reports can be generated.

Rotor-Gene AssayManager does not replace the standard Rotor-Gene Q software with its full breadth of functionalities. Rather it allows running and analyzing PCR tests in a highly controlled environment making use of assay profiles dedicated to specific PCR assays, as well as automated result reporting, thus giving maximum process safety and reliability.

### Product functions

Rotor-Gene AssayManager includes these 3 main functionalities:

#### 1) **Cycler control**

Rotor-Gene AssayManager controls the Rotor-Gene Q MDx cycler, i.e., the software will provide all functions to set up, start, and run real-time PCR experiments on up to 4 Rotor-Gene Q MDx cyclers in parallel. Rotor-Gene AssayManager can also be used for

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experiment result release and reporting only. In this case the software can be installed on a computer not necessarily connected to a Rotor-Gene Q MDx cycler.

## **2) Data analysis**

Rotor-Gene AssayManager analyzes the real-time PCR raw data according to well defined assay specific rules and generates result reports comprising information on the validity or invalidity of the assay and individual samples.

## **3) Data management**

Rotor-Gene AssayManager imports sample-specific information from QIAasymphony® or via a LIMS. Data from the PCR experiment are then used for analysis. After analysis the system is able to export data.

### **Modes of operation**

Rotor-Gene AssayManager offers the Closed Mode of operation for IVD applications.

### **Closed Mode**

The Closed Mode is used for assays that have been created and validated by QIAGEN. These assays can only be modified by QIAGEN.

In Closed Mode, assays are run and analyzed without the permission to modify the corresponding assay profiles.

The analysis in Closed Mode includes core analysis, assay and sample analysis, and, depending on plug-in, also a fully automatic data scan (AUDAS).

To run and analyze an assay in Closed Mode a corresponding closed mode plug-in is required.

## Requirements for Rotor-Gene AssayManager software users

The following table covers the general level of competence and training necessary for delivery, installation, routine use, maintenance, and servicing of the Rotor-Gene AssayManager software.

<b>Task</b>	<b>Personnel</b>	<b>Training and experience</b>
Delivery	No special requirements	No special requirements
Installation	Laboratory technicians or equivalent, IT personnel	Basic IT knowledge of installing software
Routine use	Laboratory technicians or equivalent	Professional users such as technicians and physicians, trained in molecular biology techniques and the functionalities of the Rotor-Gene Q MDx
Maintenance	Laboratory technicians or equivalent, IT personnel	Professional users such as technicians and physicians, trained in molecular biology techniques and the functionalities of the Rotor-Gene Q MDx
Service	QIAGEN Field Service Specialists only	Regularly trained, certified, and authorized by QIAGEN

## Training for Rotor-Gene AssayManager software users

To use the Rotor-Gene AssayManager software no special training is required. The user has to read the accompanying documentation before using the Rotor-Gene AssayManager software.

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## 4 Getting Started

This section of the user manual describes the system requirements for Rotor-Gene AssayManager version 1.0.x ( $x \geq 5$ ) and how to install and configure Rotor-Gene AssayManager before the software can be used.

**Note:** Checksum confirmation is required to secure software integrity after web download was successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of any downloaded file is started. For detailed information on confirmation of software integrity during download and file transfer, please check the "QIAGEN software integrity verification process" description document, which is provided on the QIAGEN webpage.

### 4.1 Installing Rotor-Gene AssayManager

Rotor-Gene AssayManager version 1.0.x ( $x \geq 5$ ) and the UDT basic plug-in are available on DVDs. The software cannot be downloaded from the internet. The DVD provides installation, update, and uninstall process for Rotor-Gene AssayManager, the Rotor-Gene AssayManager database, and the Rotor-Gene AssayManager plug-ins.

For a diagnostic application, an assay specific assay profile is required. See "Importing/exporting an assay profile", page 758, for details. (Plug-ins and assay profiles are delivered with different data carriers).

Rotor-Gene AssayManager v1.0 uses a database (Microsoft® SQL Server® Express) to store all data. The database can be installed locally or on a remote system. For maintaining the database, download the RGAM Database Backup Tool software on the QIAGEN webpage. For detailed information about backup and restore instructions, refer to the "Maintenance" section in the Rotor-Gene AssayManager Core Application User Manual.

**Note:** Most screenshots in this document were created using Windows 7. If there is no difference between Windows 7 and Windows 10, no additional screenshots were created for Windows 10. Only if the behavior is different between both operating system versions, a separate description was added.



**Note:** Plug-ins cannot be uninstalled. In case you want to uninstall a plug-in, the core application must be uninstalled together with the plug-in. See “Uninstalling Rotor-Gene AssayManager”, page 598, for details.

**Note:** It is not possible to install Rotor-Gene AssayManager v1.0 on a computer or an existing database server, that already has Rotor-Gene AssayManager v2.1 installed. Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. In addition, Rotor-Gene AssayManager v2.1 does not replace Rotor-Gene AssayManager v1.0.

**Note:** Plug-ins for Rotor-Gene AssayManager v1.0 are not compatible with Rotor-Gene AssayManager v2.1.

Rotor-Gene AssayManager can be installed with 3 different configurations:

Task	Description
Install on stand-alone computer*	<ul style="list-style-type: none"><li>• A user with local system administration privileges installs the database (Microsoft® SQL Server Express) including initial data, the Rotor-Gene AssayManager core application, and at least one Rotor-Gene AssayManager plug-in on a computer.</li><li>• The user is completely guided by the installation wizard and will be prompted for input, if necessary.</li></ul>

Task	Description
Create new central database and install Rotor-Gene AssayManager on additional computers*	<ul style="list-style-type: none"> <li>• A user with all required database administration privileges installs only the database (Microsoft SQL Server Express) including initial data on a server.</li> <li>• The server is connected via local area network to the computers of the application users.</li> <li>• Rotor-Gene AssayManager core application and at least one Rotor-Gene AssayManager plug-in are installed on one or multiple computers by a user with local administration privileges. During installation, the user is prompted for connection to the database, which has to be provided by the database administrator.</li> </ul>

Task	Description
Use existing database server and install Rotor-Gene AssayManager on one or multiple computers*	<ul style="list-style-type: none"> <li>• A user with all required database administration privileges uses the installation wizard to install only a new database instance including initial data on an existing database server.</li> <li>• The database administrator is responsible to check whether the database server fulfills the Rotor-Gene AssayManager requirements. He is also responsible to perform all database administration tasks necessary to back up the system before installation. Furthermore, the database administrator must guarantee the functionality of the system after the successful installation or a failed installation.</li> <li>• Rotor-Gene AssayManager core application and at least one Rotor-Gene AssayManager plug-in are installed on one or multiple computers by a user with local administration privileges. During installation, the user is prompted for connection to the database, which has to be provided by the database administrator.</li> </ul>

\* The term "computer" is used to describe a notebook or a PC, and not a server.

#### 4.1.1 Requirements

A computer with the required specifications for operating the Rotor-Gene Q MDx instrument and Rotor- Gene AssayManager v1.0 is supplied as part of the Rotor-Gene Q MDx instrument which is referred to as "QIAGEN laptop" in the following text. In general, the following minimum requirements must be fulfilled to run Rotor-Gene AssayManager v1.0.

## PC system requirements

Description	Minimum requirement
Display	1024 x 768 pixel resolution or higher
Supported operating systems	Windows 10 with version 1709 or newer Windows 7 Professional edition (64- or 32-bit) Service Pack 1
Disk space	250 GB
Processor	Intel® Core™ i3-380M Processor or higher
Memory	4 GB RAM recommended
USB interface	2 USB 2.0 ports. If necessary, USB Hub can be ordered through QIAGEN Contact <a href="http://www.qiagen.com">www.qiagen.com</a> for details
DVD-ROM drive	1
Pointing device	Touchpad or mouse or equivalent is required
Service packs required	Microsoft Windows XP Professional: Service Pack 3
Bluetooth®	Must be switched off
PDF viewer or similar	Already installed
Power options	Never turn off hard disks, hibernate, or go to standby

**Note:** Any outstanding Windows update needs to be applied before installing Rotor-Gene AssayManager v1.0. Otherwise the installation procedure might fail.

**Note:** The installation of Rotor-Gene AssayManager v1.0 can only be performed with administrator privileges.

**Note:** A stable power connection is required. Unstable power connections can cause loss of data.

**Note:** Do not directly connect any network device, such as a computer or QIASymphony SP/AS, to the computer hosting the Rotor-Gene AssayManager v1.0 via an ethernet crossover cable or using Auto-MDIX. Do not apply any changes to network-related elements of the computer or any other operation system-related actions while the Rotor-Gene AssayManager v1.0 is started. This may result in data loss or indefinable behavior.

### 4.1.2 Internationalization

The standard language on a notebook delivered by QIAGEN is set to English (American). The language of the software itself is English. Rotor-Gene AssayManager uses the

computer language settings to display dates and decimal separators in the corresponding format. To change the language settings of the computer, select **Control Panel** from the Windows start menu and select **Local language settings**.

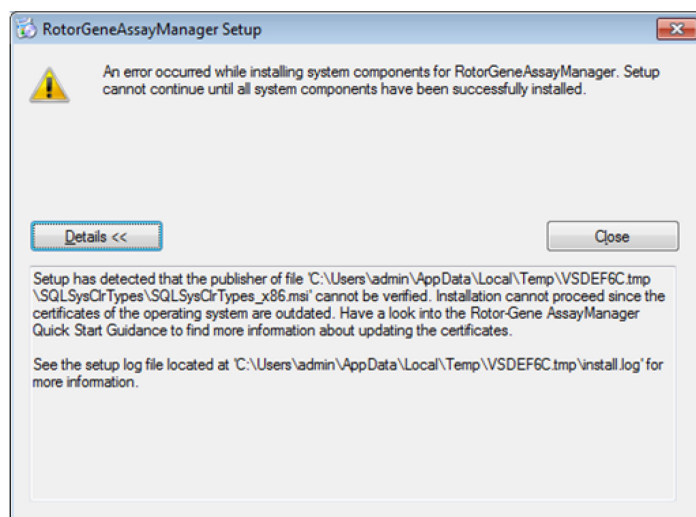
## 4.2 Installing core application and plug-ins

### 4.2.1 Outdated certificates on Windows 7

All installation packages, contained in the Rotor-Gene AssayManager v1.0 installer are signed with validated certificates, trusted by Microsoft. This validity is checked by the operating system for every new program which shall be installed on the system. To be able to verify the validity of installer packages, the operating system maintains a list of trusted root certification authorities which is updated automatically by the so-called "automatic root update mechanism" introduced by Microsoft during the lifetime of Windows 7.

If your operating system or the list of trusted root certification authorities is in an outdated state, Microsoft cannot verify the validity of the prerequisite packages, installed by the Rotor-Gene AssayManager v1.0 installer. This will result in the following error message during installation:

"Setup has detected that the publisher of file '...' cannot be verified. Installation cannot proceed since the certificates of the operating system are outdated." (see screenshot below – note: the error message is only shown if you click on "Details <<" button).



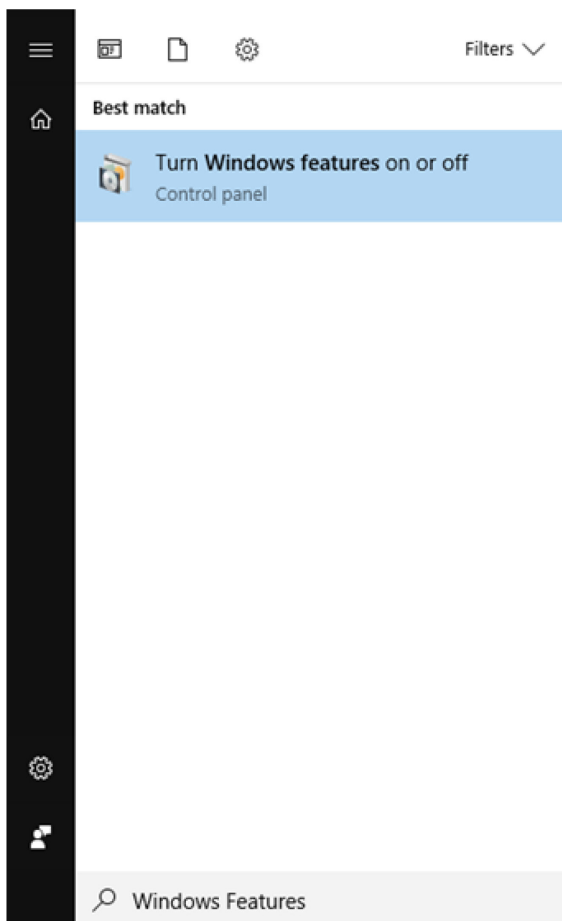
Visit the QIAGEN website for updates and instructions to solve this problem.

## 4.2.2 Installation Prerequisites on Windows 10

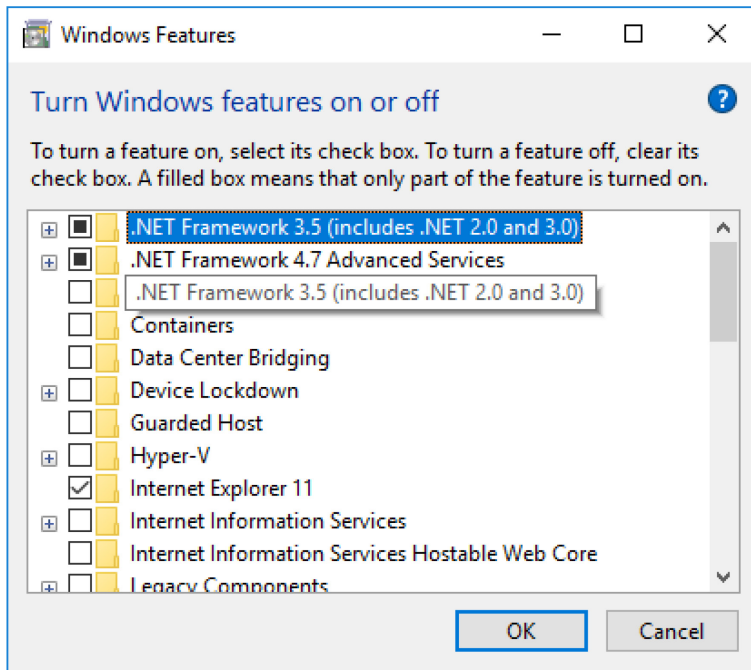
The Microsoft SQL Server installed together with Rotor-Gene AssayManager v1.0 needs a pre-installed Microsoft .NET Framework in version 3.5. If you use a laptop, distributed by QIAGEN, this installation is already done. If your configuration is different, you may have to install the .NET Framework 3.5 manually on Windows 10 operating systems. There are two options to do so:

### 4.2.2.1 Installation with the feature manager (active internet connection required)

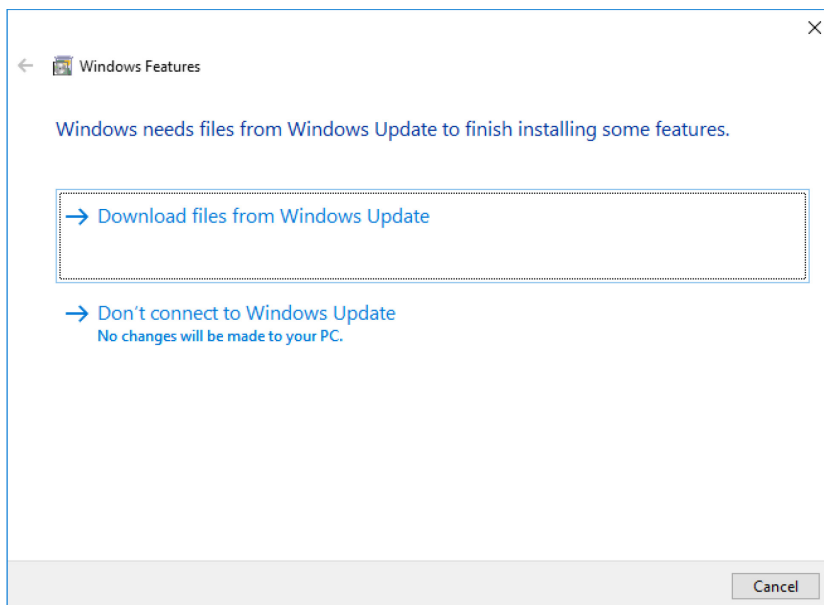
1. Click on "Start" and type "Windows Features".
2. Click on "Turn Windows features on or off".



3. Select the .NET Framework 3.5 (includes .NET 2.0 and 3.0) check box and click on OK.



4. On the next screen select "Download files from Windows Update". Please note: You must be connected to the internet.



5. If you see the message "Windows completed the requested change", the installation process is completed successfully. You can continue installing Rotor-Gene AssayManager v1.0.

#### 4.2.2.2 Installing the core application v1.0

For computer system requirements, refer to "Requirements", page 581.

**Note:** Rotor-Gene AssayManager v1.0 uses several software packages provided by third parties. If not already installed on the system, these software packages are automatically installed at the beginning of the Rotor-Gene AssayManager software v1.0 setup. Depending on the installed software packages, a reboot of the system may be required before proceeding with the setup.

**Note:** The system must be virus and spyware free to install the Rotor-Gene AssayManager v1.0 software.

Rotor-Gene AssayManager requires an MS SQL Server 2014 Express instance with mixed mode authentication and TCP/IP network protocol activated for installation. The installation process depends on whether MS SQL Server 2014 Express already is installed or should be installed on the local system or whether Rotor-Gene AssayManager shall be installed with a remote connection to an existing SQL Server on an external system:

- If MS SQL Server 2014 Express is already installed on the local system or a remote connection to an existing SQL server or an external system, the installation of MS SQL Server 2014 Express is skipped and the installation continues with the installation of Rotor-Gene AssayManager application.
- If MS SQL Server 2014 Express was not installed previously, the first step in the installation process is the installation of MS SQL Server Express 2014 and then the Rotor- Gene AssayManager application is installed.

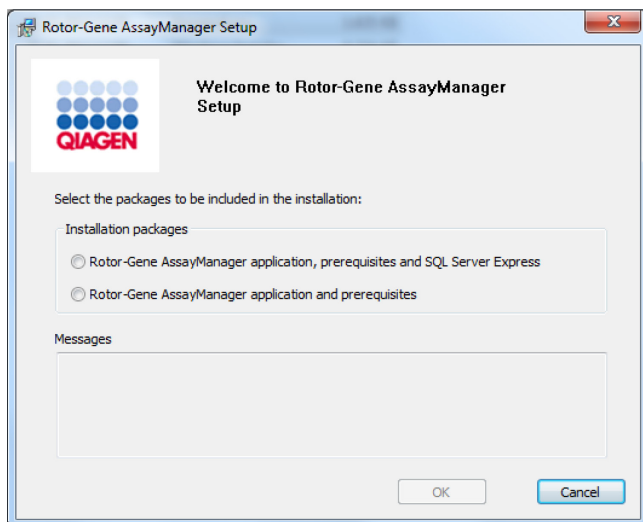
**Note:** During installation process, click **Back** to go a step back in the installation process. Click **Cancel** to stop and end the installation process.

#### Installing the Rotor-Gene AssayManager version 1.0.x (x ≥ 5)

1. Place the DVD in the computer's DVD drive.

The setup wizard automatically opens the **Rotor-Gene AssayManager Setup** window.





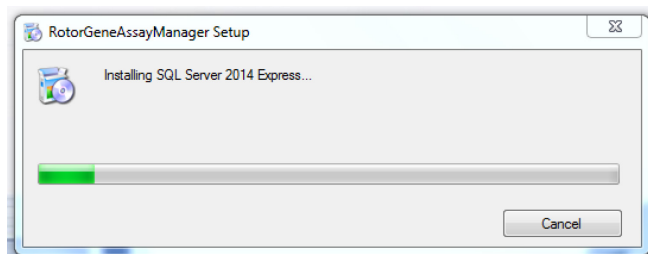
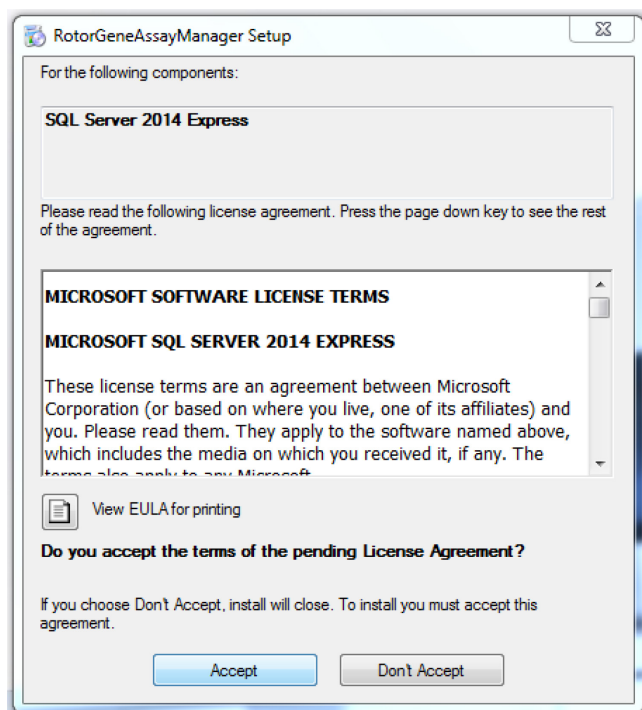
**Note:** If the setup wizard does not start automatically, double-click **My Computer** and select the DVD drive. Double-click **setup.exe** to start Rotor-Gene AssayManager v1.0 installation.

2. The further installation process depends on whether SQL Server 2014 instance with mixed mode authentication and TCP/IP network protocol is activated for installation.
  - If the installation wizard could not detect an SQL Server installed on your system and you want to install the SQL Server locally on your system, select **Rotor-Gene AssayManager application, prerequisites, and SQL Server Express** and proceed with step 4.
  - If the installation wizard detects an existing SQL Server on your system, a corresponding message will be shown in the messages box below. The upper option **Rotor-Gene AssayManager application, prerequisites, and SQL Server Express** is disabled.
  - If you want to install Rotor-Gene AssayManager v1.0 with a remote connection to an existing SQL Server on an external system, select the option **Rotor-Gene AssayManager application and prerequisites**.

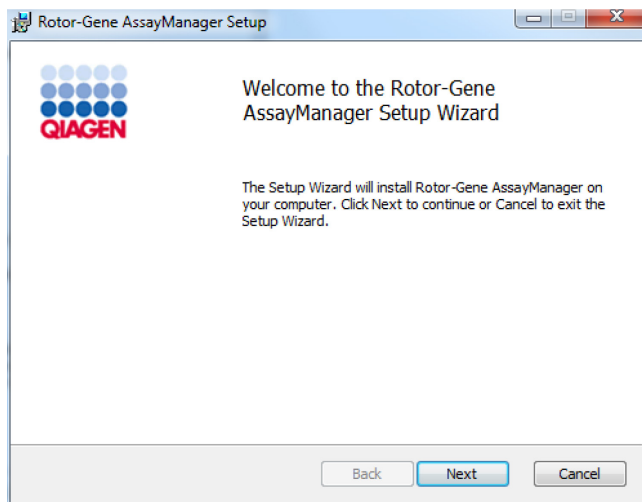
**Note:** A stable network connection is required for use of an existing SQL Server on an external system. Unstable network connections can cause database connection loss, and loss of data.

3. Click **OK** to proceed.
4. If applicable, the SQL Server will be installed. Click **Accept** to start the installation of MS SQL Server 2014 Express.

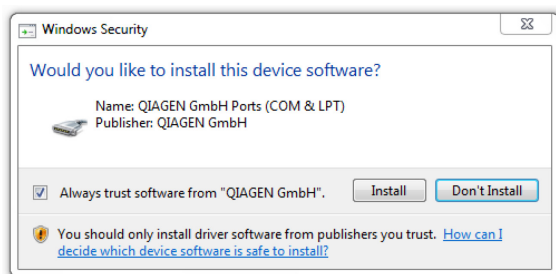
The installation progress window is displayed:



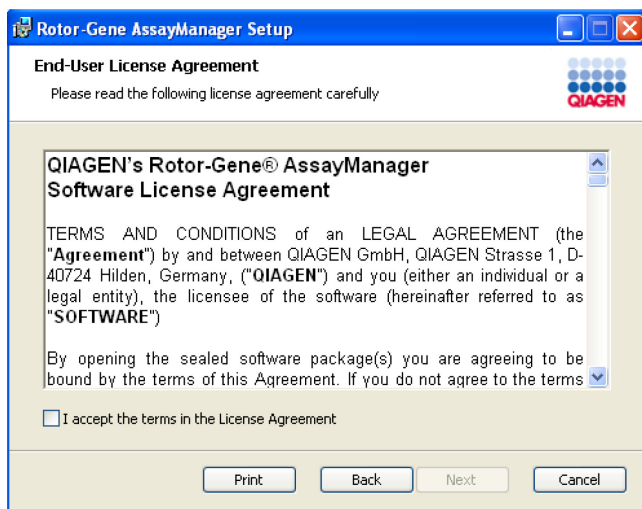
5. The **Rotor-Gene AssayManager Welcome** screen will automatically be opened.



6. Click **Next** to start the installation procedure.
7. The following Windows security message may appear during the installation process. Click **Install this driver software anyway**.

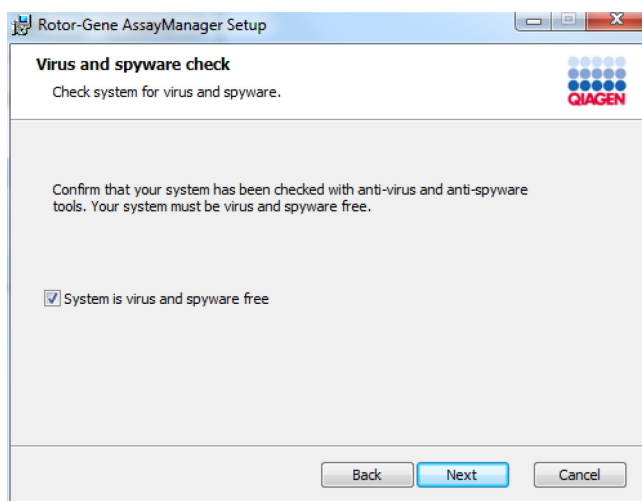


8. Depending on the software packages already installed on the system, different license agreements for the required software packages will be displayed.



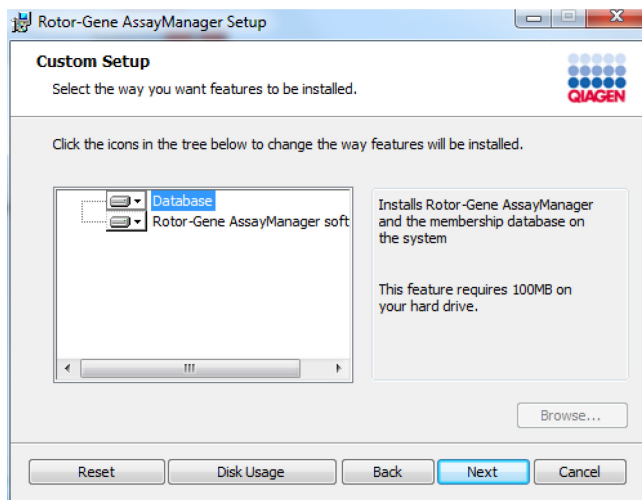
Read the license agreements and accept by checking **I accept the terms in the License Agreement** and click **Next**.

9. The **Virus and spyware check** window is opened:

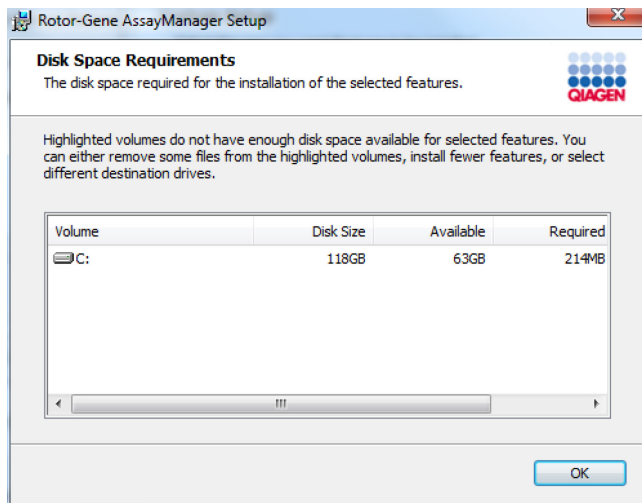


Confirm that the system is virus free by activating the **System is virus and spyware free** option and click **Next**.

10. The **Custom Setup** screen is displayed.



11. Click **Disc Usage** to get an overview of the available and required disc space.



Click **OK** to close the window.

12. Select the features to be installed.

- Features **Database** and **Rotor-Gene AssayManager software** both selected:

For a stand-alone desktop scenario with application and database on one computer, both features must stay selected.

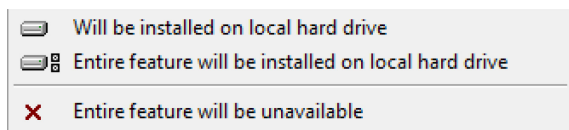
- Feature **Rotor-Gene AssayManager software** only selected:

For the installation of the application accessing a central database server, the **Database** feature must be deselected and the **Rotor-Gene Assay Manager software** feature must stay selected.

- Feature **Database** only selected:

For installation of a central database server only, the **Rotor-Gene Assay Manager software** feature must be deselected and the feature **Database** must stay selected.

**Note:** For selection or deselection of features use the drop-down menu.



The first 2 options displayed here are identical. Select the corresponding feature. The third option deselects the corresponding feature.

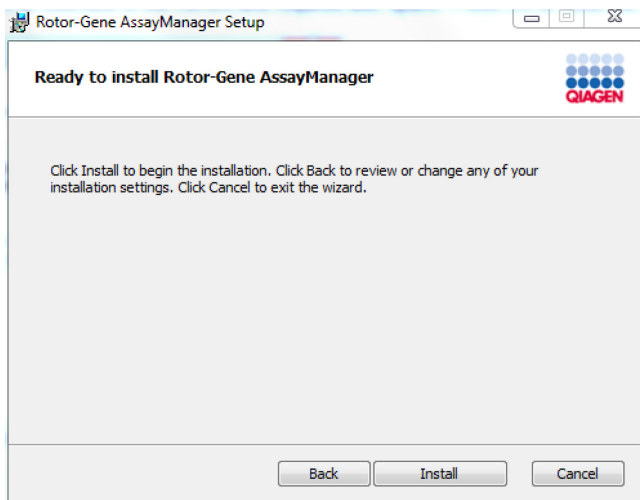
13. Click **Next** to proceed with the installation of the selected features.
14. Optional: This step is necessary only if no SQL Server "RGAMINSTANCE" was detected or if the **Database** feature has been deselected in step 12. Otherwise, this screen will be skipped.

Fill in the required parameters.

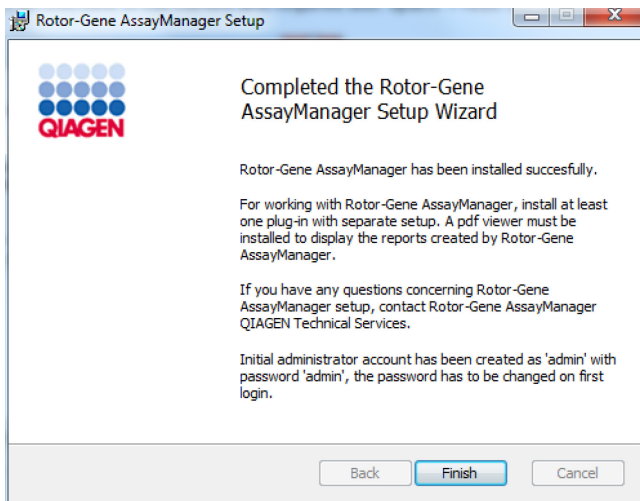
To check the database connection, click **Check database connection**. If you encounter problems during the connection process to the database server, contact your local system administrator.

15. To proceed with the installation, click **Next**.

16. Click **Install** to start the installation.



17. After the installation is completed click **Finish** to close the window.



18. After the installation, Rotor-Gene AssayManager can be started either from the Windows start menu under **QIAGEN/Rotor-Gene AssayManager** or using the desktop icon



**Note:** Future Rotor-Gene AssayManager updates will be provided on the QIAGEN webpage and/or distributed by QIAGEN on CD/DVD to the customer.

#### 4.2.2.3 Installing plug-ins

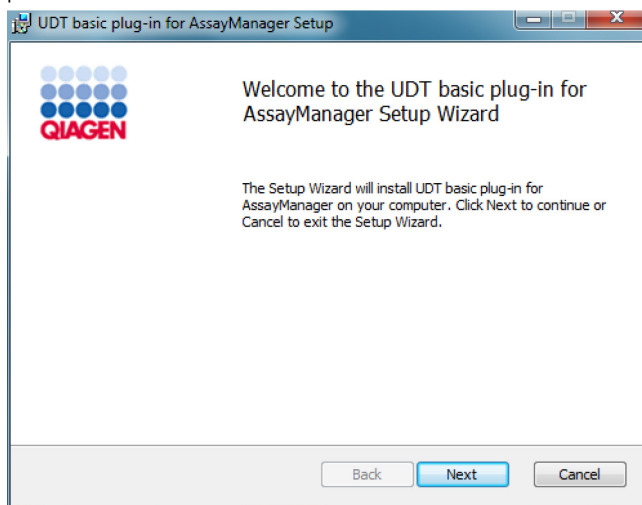
For the use of Rotor-Gene AssayManager at least one plug-in must be installed.

**Note:** Plug-ins for Rotor-Gene AssayManager v2.1 are not compatible with Rotor-Gene AssayManager v1.0.

**Note:** The installation of the UDT basic plug-in is taken as an example for the installation of any plug-in.

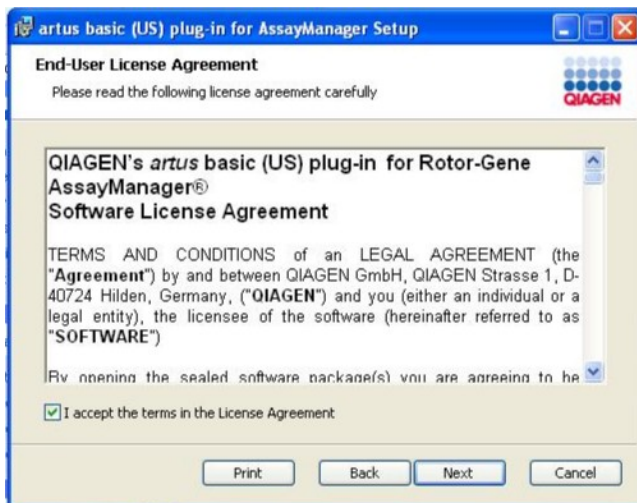
##### Installing a Rotor-Gene AssayManager plug-in

1. Place the DVD in the computer's DVD drive.
2. Double-click **My Computer** and select the DVD drive. Double-click **UDTBasic.Installation.msi** to start the UDT basic plug-in setup wizard. Click **Next** to proceed.

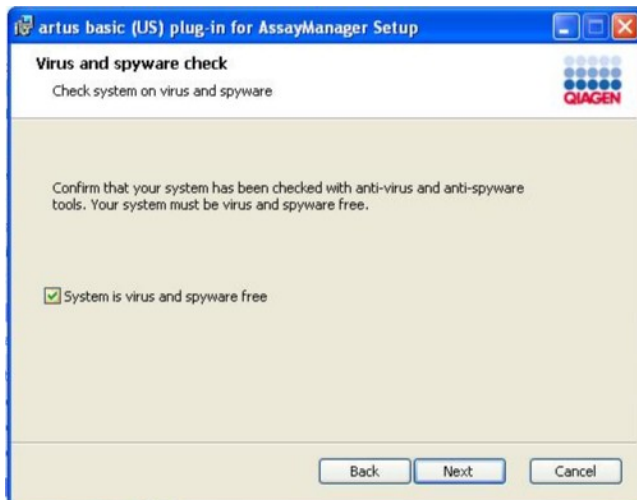


3. Read and accept the license agreement by clicking the checkbox and click **Next**.

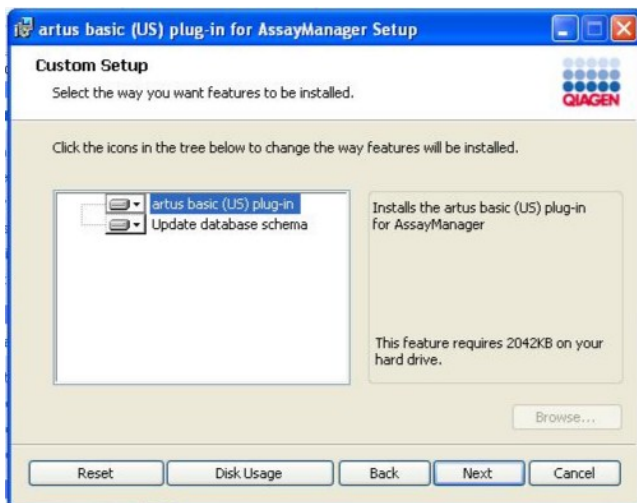




3. Confirm that your system is virus and spyware free by checking the corresponding check box and click **Next**.



4. Select the features to be installed.



- Features **UDT basic plug-in** and **Update database schema** selected:

For a stand-alone desktop scenario with application and database on one computer, both features must stay selected.

- Feature **UDT basic plug-in** selected:

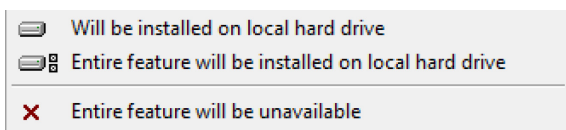
This feature updates the Rotor-Gene AssayManager v1.0 core application with the UDT basic plug-in. It is needed always if the Rotor-Gene AssayManager v1.0 and its database are installed on one system. The feature can be deselected only if a database server without the Rotor-Gene AssayManager v1.0 application is to be updated.

- Feature **Update database schema** selected:

After the Rotor-Gene AssayManager v1.0 installation, the database schema contains unspecified Rotor-Gene AssayManager v1.0 tables only. This feature adds the UDT-specific tables.

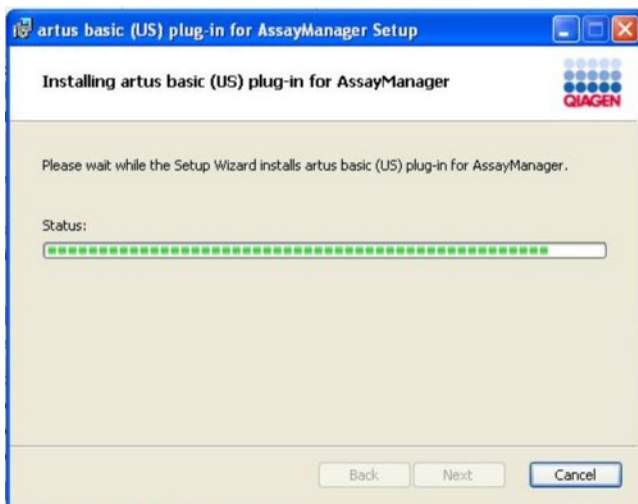
This feature is needed if the Rotor-Gene AssayManager v1.0 and its database are installed on one system. The feature can be deselected only if the database is installed on a separate server and was updated by a prior UDT basic plug-in installation.

**Note:** For selection or deselection of features use the drop-down menu.



The first 2 options displayed here are identical. Select the corresponding feature. The third option deselects the corresponding feature.

5. Click **Disc Usage** to get an overview of the available and required disc space. Click **OK** to close the window. Click **Next** to proceed with the installation of the selected features.
6. Click **Install** to start the installation of the plug-in.



7. Wait until the installation process has finished.



8. After the installation is completed click **Finish** to close the window.
9. After next restart of Rotor-Gene AssayManager v1.0 the installed plug-in is available.

### **Related topics**

"Installing the core application", page 586

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#### 4.2.2.4 Additional software on connected computers

Rotor-Gene AssayManager v1.0 software manages time-critical processes during the PCR run and the data acquisition process. For this reason, it is important to ensure that no other processes use significant system resources and thus slow down the Rotor-Gene AssayManager v1.0 software. It is particularly important to pay attention to the points listed below.

System administrators are advised to consider any impact that a modification to the system may have on the resources before implementing it.

#### 4.2.2.5 Configuration for Windows security

See Section 4.4 Configuration for Windows security on page 494.

#### 4.2.2.6 Virus scanners

See Section 4.11.1 Virus scanners on page 511.

#### 4.2.2.7 Firewall and Networks

See Section 4.11.2 Firewall and networks on page 512.

#### 4.2.2.8 Operating System Updates

See Section 4.11.4 Operating system updates on page 517.

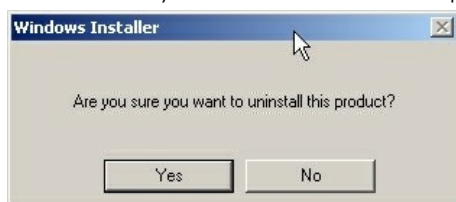
### 4.3 Uninstalling Rotor-Gene AssayManager

**Note:** The uninstall process of the Rotor-Gene AssayManager software will remove the core application as well as all installed plug-ins. It is not possible to uninstall only a plug-in, as this will create inconsistencies in the database and ceases further access to corresponding datasets.

## Uninstalling Rotor-Gene AssayManager and all installed plug-ins from your computer

**Note:** If you want to uninstall Rotor-Gene AssayManager, close the application first. Otherwise, Rotor-Gene AssayManager might not be uninstalled completely.

1. Select **QIAGEN/Rotor-Gene AssayManager/Uninstall Rotor-Gene AssayManager** from the Windows **Start** Menu.
2. Confirm that you want to uninstall the product by clicking **Yes**.



3. The Windows installer program starts to uninstall the entire Rotor-Gene AssayManager.

## 4.2 First login

After successful installation of Rotor-Gene AssayManager, the system administrator needs to log in for a first configuration of the software.

1. Enter user ID "admin" and password "admin".
2. Select the **Closed Mode** and confirm with **OK**.
3. Change the default password to a new, secure password.
4. The **Settings** tab in the **Configuration** environment will be opened.

**Note:** All users without the "Administrator" role can ask the administrator to reset the password. However, if the administrator forgets the administrator password, they must contact QIAGEN Technical Services to reset the password, which requires an on-site visit by a QIAGEN service engineer.

**Note:** It is strongly recommended to create at least one additional user account, without an "Administrator" role, at first login. If a single user of Rotor-Gene AssayManager aggregates different user roles including the "Administrator" role, there is a high risk that the access to the software will be completely blocked if this user forgets the password!

**Note:** The administrator after installation does not have the access rights for the **Setup environment**. This environment can be accessed for users with the role "Operator".

### Related topics

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"Section 6.1.1 Logging in and logging out", page 725

"Section 5.1.2 User management", page 603, and "**Setup** environment", page 604, and "**Configuration** environment", page 606, both in this section.

### 4.3 First configuration

Before Rotor-Gene AssayManager can be used, the creation of user profiles and the registration of one or several Rotor-Gene Q MDx cyclers in the **Configuration** environment are essential. For details about these tasks refer to:

"Section 6.2.3 Managing cyclers", page 763

"Section 6.2.4 Managing users", page 768

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## 5 Basic Concepts and General Software Usage

In the following chapter the concepts and the general software usage of Rotor-Gene AssayManager are described.

### 5.1 Concepts

Rotor-Gene AssayManager uses multiple concepts to facilitate tasks and processes. The following topics describe these concepts in detail:

- Modes
- User management
- Session management
- Rotor-Gene AssayManager and other QIAGEN products
- Clarification of terms experiment and assay

#### 5.1.1 Modes

Rotor-Gene AssayManager can be operated in 2 separate modes of operation with separate individual characteristics:

- Closed Mode
- User Defined Test Mode (UDT Mode)

**Note:** The UDT Mode is not intended for use with FDA cleared or approved nucleic acid tests.

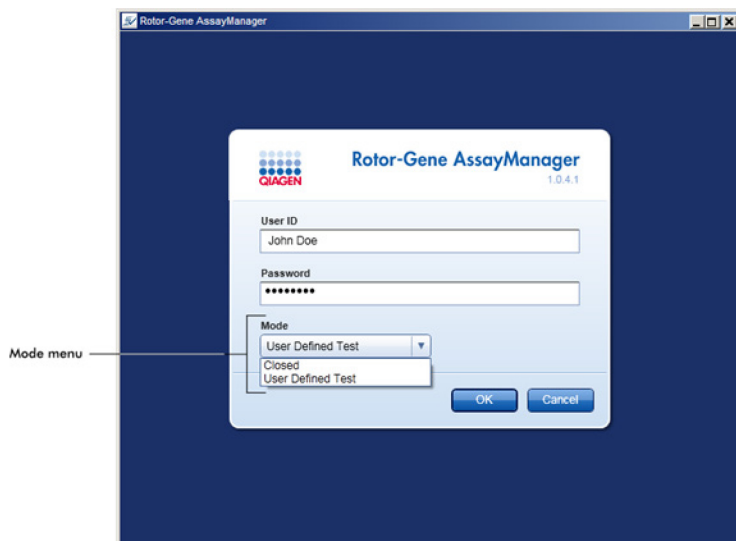
#### **Closed Mode**

The Closed Mode is used for assays that have been created and validated by QIAGEN. These assays can only be modified by QIAGEN. In Closed Mode, assays are run and analyzed without the permission to modify the corresponding assay profiles.

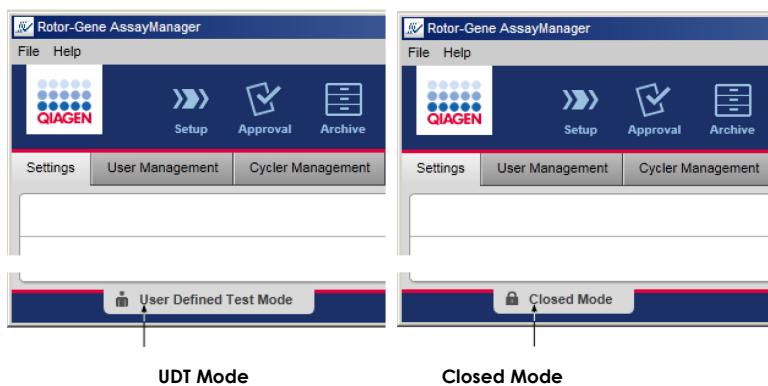
The analysis in Closed Mode includes core analysis, assay and sample analysis, and depending on plug-in, also a fully automatic data scan (AUDAS).

To run and analyze an assay in Closed Mode a corresponding closed mode plug-in is required.

The mode is selected from the Rotor-Gene AssayManager login screen. The login screen contains 2 fields to enter the user ID and the password, as well as an additional drop down menu to select the mode of operation.



After the user has logged in, the selected mode is displayed in the status bar:





### 5.1.2 User management

User interactions with the system must be assignable to an individual person. Therefore, each user must log in before the Rotor-Gene AssayManager software can be used. After finishing work the user should log out or lock the application.

A role must be assigned to every user. It is also possible to assign multiple roles to a single user. The following properties are stored in the database for a user:

- First name
- Last name
- User ID
- Password
- Role(s)

#### **Related tasks**

"Creating a user profile", page 768

"Changing user profile settings", page 770

- Changing name/last name
- Changing password
- Changing role

"Activating/deactivating a user profile", page 772

"Setting password policies and auto-lock timer", page 773

#### **User roles**

Different Rotor-Gene AssayManager functions can only be accessed by users with certain roles. All available user roles and their permissions are listed in the following table:

Role	Description
Administrator	The administrator has only permissions to: <ul style="list-style-type: none"><li>• configure the system</li><li>• manage users</li><li>• create and edit report profiles</li><li>• manage archives</li></ul>

Role	Description
Assay Developer	<p>The assay developer has all necessary permissions to create an assay profile in UDT Mode.</p> <p><b>Note:</b> The assay developer has no permissions to create or modify assay profiles for FDA cleared or approved nucleic acid tests in Closed Mode.</p>
Operator	<p>The operator has all permissions necessary to:</p> <ol style="list-style-type: none"> <li>6. create a work list</li> </ol> <ul style="list-style-type: none"> <li>• apply the work list</li> <li>• view the analysis results</li> </ul> <p>The operator cannot release assay results.</p>
Approver	The approver is the only user with permissions to release assay results.
Super User	The super user has all available permissions of all available rules as a convenient way to grant all permissions to one user.

The following actions can be performed by every role:

- Logging in and logging out (page 725)
- Locking and unlocking (page 729)
- Changing user profile settings (page 770)

The following tables give an overview about permissions of the different user roles in the different environments.

#### Setup environment

Task	Description	Admin*	Op*	Ap*	SU*
Access <b>Setup</b> environment	User can enter the <b>Setup</b> environment	–	+	–	+
Apply runs	User can apply runs in the <b>Setup</b> environment	–	+	–	+

\* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

### Approval environment

Task	Description	Admin*	Op*	Ap*	SU*
Access <b>Approval</b> environment	User can enter the <b>Approval</b> environment	+	+	+	+
Release test results	User can release test results in the <b>Approval</b> environment	-	-	+	+
Create support package	User can create support packages in the <b>Approval</b> environment	+	+	+	+

\* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

### Archive environment

Task	Description	Admin*	Op*	Ap*	SU*
Access <b>Archive</b> environment	User can enter the <b>Archive</b> environment	+	+	+	+
Create support package	User can create support packages in the <b>Approval</b> environment	+	+	+	+

\* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

### Service environment

Task	Description	Admin*	Op*	Ap*	SU*
Access <b>Service</b> environment	User can enter the <b>Service</b> environment	+	-	+	+
View audit trail	User can access the audit trail in the <b>Service</b> environment	+	-	+	+

\* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

## Cycler environment

Task	Description	Admin*	Op*	Ap*	SU*
Access <b>Cycler</b> environment	User can enter the <b>Cycler</b> environment	+	+	-	+
Release cyclers	User can add a comment, release a cycler, stop a process, and close pop-ups in the <b>Cycler</b> environment	-	+	-	+

\* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

## Configuration environment

Task	Description	Admin*	Op*	Ap*	SU*
Access <b>Configuration</b> environment	User can enter the <b>Config.</b> environment	+	-	-	+
Configure system settings	User can configure all settings in the <b>Configuration</b> environment	+	-	-	+
Manage cyclers	User can access the <b>Cycler Management</b> tab in the <b>Configuration</b> environment	+	-	-	+
Manage users	User can access the <b>User Management</b> tab in the <b>Configuration</b> environment	+	-	-	+
Manage assay profiles	User can access the <b>Assay Profiles</b> tab in the <b>Config.</b> environment	+	-	-	+
Manage report profiles	User can access the <b>Report Profiles</b> tab in the <b>Config.</b> environment	+	-	-	+

\* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

## Password policy

Unless otherwise defined the password must be between 8 and 40 characters long. An administrator can also define, in the settings of the **Configuration** environment, if using CLIA complaint password rules is mandatory. According to CLIA, a password has to contain at least:

- 8 characters
- 2 upper case characters
- 2 lower case characters
- 2 numeric characters
- 2 special characters

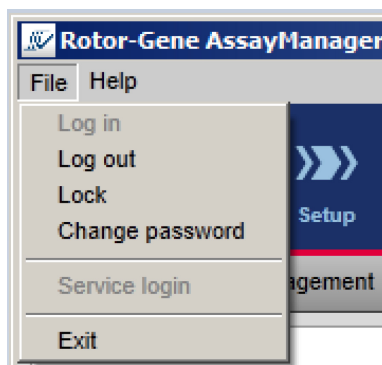
An administrator can also define the password renewal interval. A user must renew his password after the renewal interval has passed. Note that the last 10 passwords cannot be reused.

## Related topics

"Setting password policies and auto-lock timer", page 773

### 5.1.3 Session management

To start working with Rotor-Gene AssayManager, a user has to start a new session by logging in. Logging in is possible from the login screen either after the application was started or after a previous session was finished.



**Log out from main menu**

Logging out is possible using the command from the main menu or the logout button in the status bar.



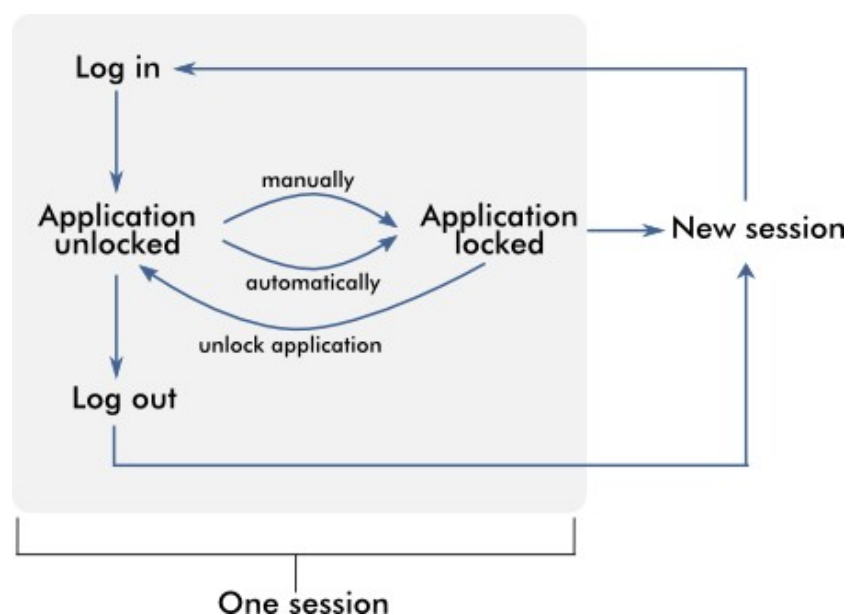
## Log out from status bar

To prevent misuse, a user can lock the application. Rotor-Gene AssayManager also has an auto-lock timer that locks the application automatically after a predefined time without user interaction (an administrator can customize the auto-lock feature (see "Setting up the auto-lock timer", page 773). If locked, the user can either continue working by unlocking the application or alternatively another user can start a new session.

The automatic locking feature does not interrupt or impact the operation of the cyclers. Started runs are not interrupted or impacted if:

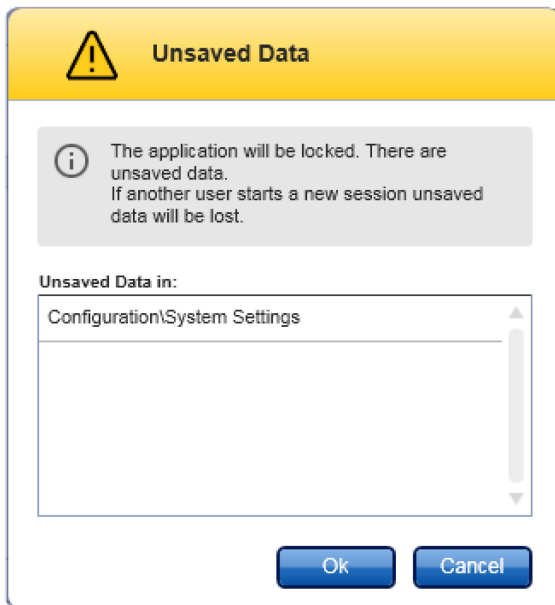
- a user logs out
- another user starts a new session
- or the application is locked (automatically or manually)

The following graphic illustrates the session, locking concepts, and their interdependencies:

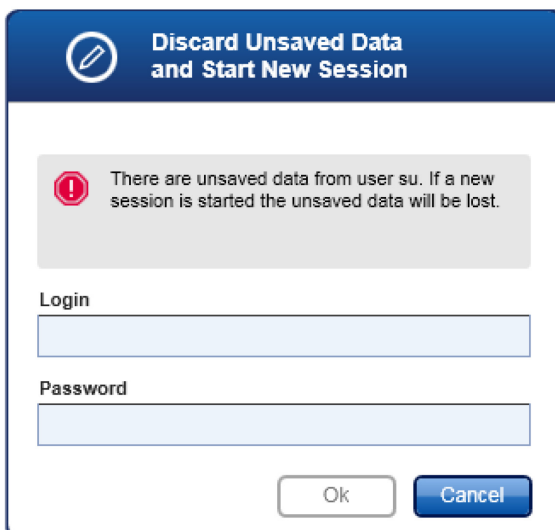


### Behavior if unsaved data exist

If a user locks the application and unsaved data exist, a dialog is opened containing a list of all environments with unsaved data:



If another user wants to start a new session, a dialog is shown containing a warning that unsaved data from the previous user exist, and the unsaved data are lost if the new session is started.



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#### 5.1.4 Rotor-Gene AssayManager version 1.0 and other QIAGEN products

Rotor-Gene AssayManager has different interfaces and data exchange features with other QIAGEN products and external Laboratory Information Management Systems (LIMS).

With Rotor-Gene AssayManager, up to 4 different Rotor-Gene Q MDx instruments can be controlled simultaneously. Each connected cycler can send raw acquisition data back to Rotor-Gene AssayManager.

**Note:** The Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. In addition, Rotor-Gene AssayManager v2.1 does not replace the Rotor-Gene AssayManager v1.0.

**Note:** Rotor-Gene AssayManager and Rotor-Gene Q software may be installed on the same computer in parallel. But only one of the programs can have an active connection to a Rotor-Gene Q MDx at a particular time.

##### Scenario 1

In case the Rotor-Gene Q software is started prior to Rotor-Gene AssayManager and connected to a cycler first, Rotor-Gene AssayManager is not able to set up a connection to the cycler. Shut down the Rotor-Gene Q software. Restart Rotor-Gene AssayManager to control the cycler with Rotor-Gene AssayManager.

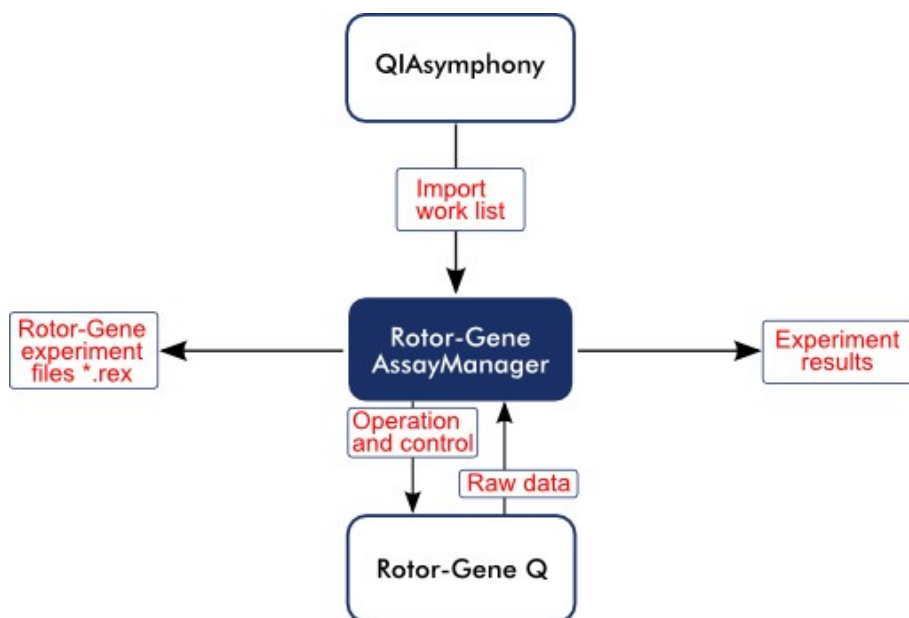
##### Scenario 2

In case Rotor-Gene AssayManager is started prior to the Rotor-Gene Q software and connected to a cycler first, the Rotor-Gene Q software is not able to set up a connection to the cycler. Shut down Rotor-Gene AssayManager. Restart the Rotor-Gene Q software to control the cycler with the Rotor-Gene Q software.

Result files from the QIAAsymphony AS can be used to generate work lists in Rotor-Gene AssayManager. All relevant sample and assay related information are automatically set, and manual input during work list setup is minimized.



The following graphic illustrates the possible interactions between Rotor-Gene AssayManager and the other systems.



#### Related topics

"Importing a work list", page 733

Exporting a \*.rex file ("Show Assays screen", page 680)

"Setting up a run", page 732

#### 5.1.5 Experiment vs. assay

**Note:** For FDA cleared or approved nucleic acid tests, an "experiment" contains 1 "assay".

## 5.2 General software usage

The following section describes the general software usage concept of Rotor-Gene AssayManager.

### 5.2.1 Use of color

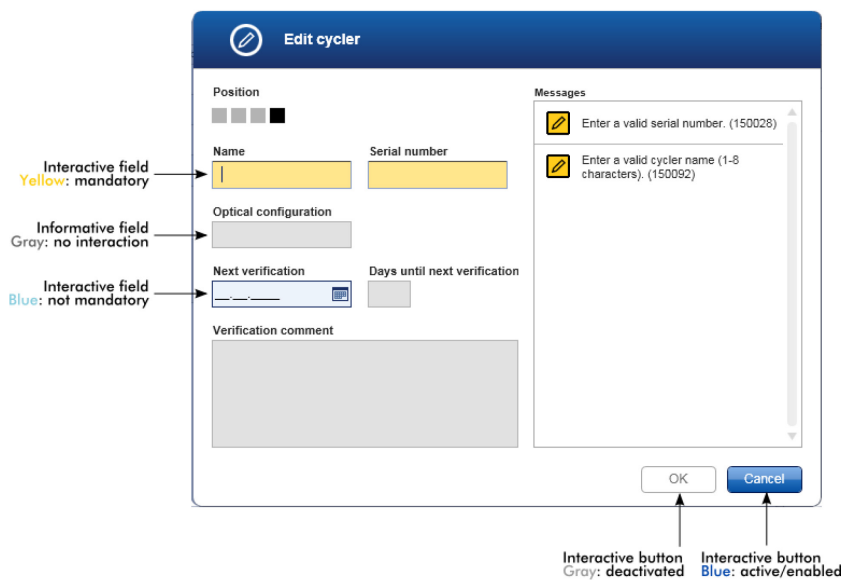
For an optimal user interaction Rotor-Gene AssayManager has a specific color concept for presenting information.

The following table provides an overview about the different colors used in the software and their dedicated meanings.

Color	Description
Light blue	The field is interactive and clickable
Dark blue	The field is selected or focused
Gray	The field is read-only and can neither be selected nor activated
Yellow	The field requires input

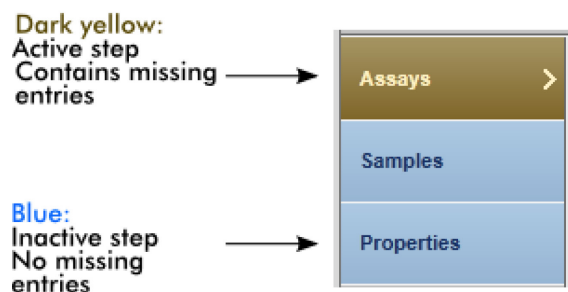
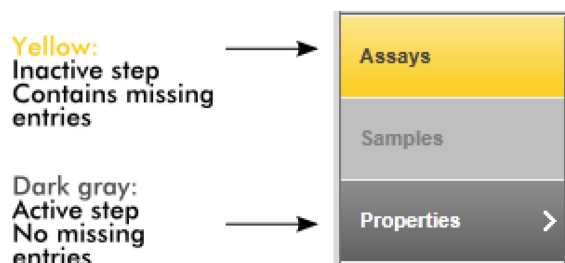
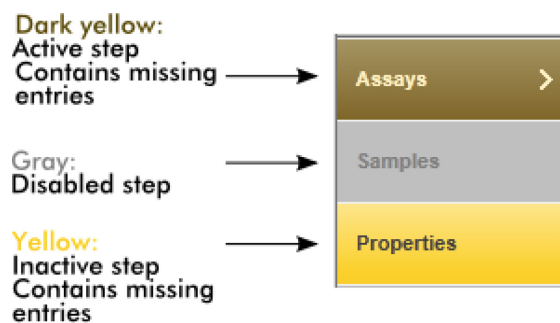
#### Example 1

The following dialog example gives an explanation of the color concept.







## Example 2

When creating a new work list in the **Setup** environment, there are 3 step buttons (**Assays**, **Samples**, and **Properties**) for the different steps to complete. The coloring concept of the step buttons is shown in the following graphic.



## 5.2.2 Displaying errors and warnings

Errors and warnings are essential information for the user. These messages point to a problem or an erroneous situation. Rotor-Gene AssayManager differentiates between 4 different problem levels.

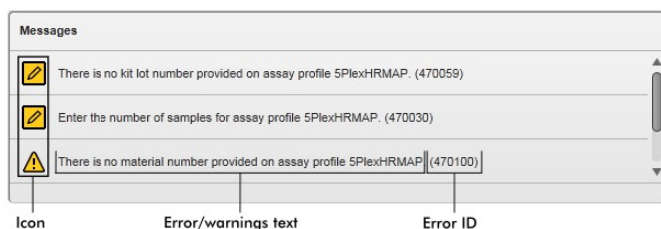
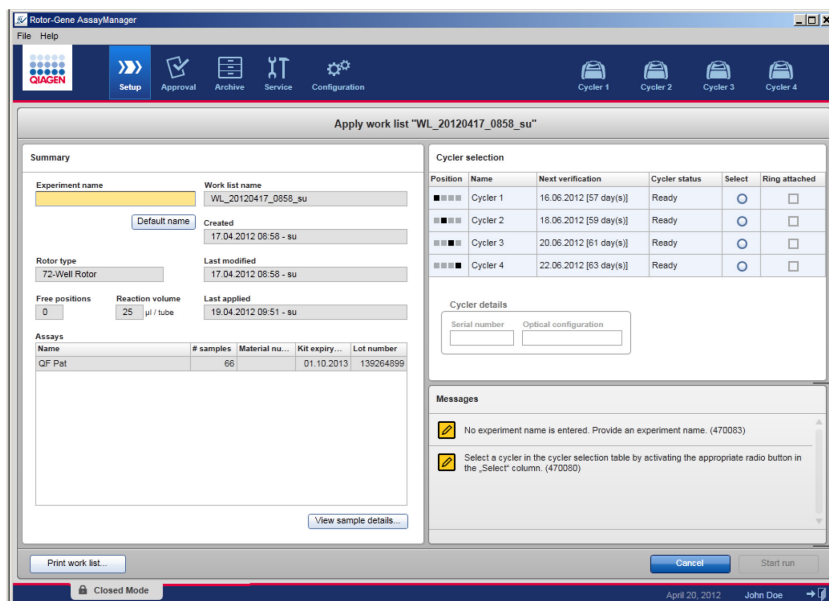
Priority	Name	Icon	Description of functionality	Action required by user
1	System error		A combination of not acceptable incidents	User interaction required
2	Validation error		An error that occurs due to a missing or invalid user input	User interaction required
3	Warning		Situation could be optimized by further input	User interaction possible, but not mandatory
4	Information		A message containing additional information about the current situation	User interaction not possible

All existing errors and warnings are displayed with the corresponding icon either in a separate messages area or as a pop-up window. If applicable, the messages area lists all currently existing errors and warnings sorted with descending priority.

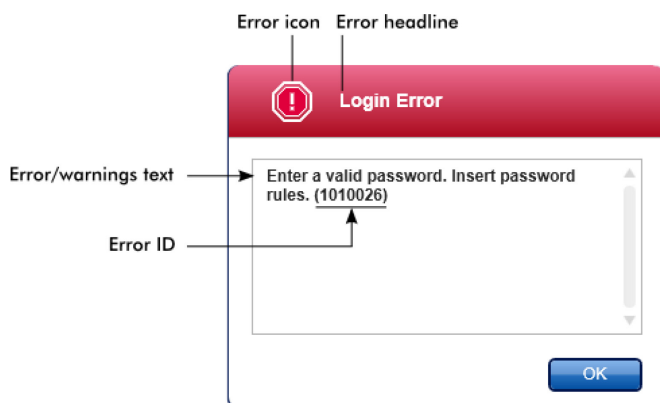
### Messages area

The following screenshot shows possible errors and warnings during work list creation in the **Setup** environment. The messages are displayed with the corresponding icon, the error text, and the error ID in brackets.

**Note:** The screenshots are shown as examples and may appear differently.



### Detailed view of the Messages area



### Error messages pop-up window

**Note:** Each error ID is unique. In case QIAGEN Technical Services needs to be contacted for troubleshooting, have the error ID ready.

### 5.2.3 Entering data

#### Shortcuts

The following hot keys are available in Rotor-Gene AssayManager:

- Copy and paste operations (**CTRL+C** and **CTRL+V**)
- Navigation (tab key, cursor keys)

While entering data, the following keyboard shortcuts can be used:

- **F2** to start editing
- **Escape** to cancel the input
- **Return** to commit an input

#### Identifying interactive fields

All interactive elements where a user can enter data are marked with a black triangle symbol (▲) in their upper right corner.

The following example is taken from the work list creation step in the **Setup** environment:

Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan
QuantiFast Pathogen...	QF Pat	2.0.0	6					

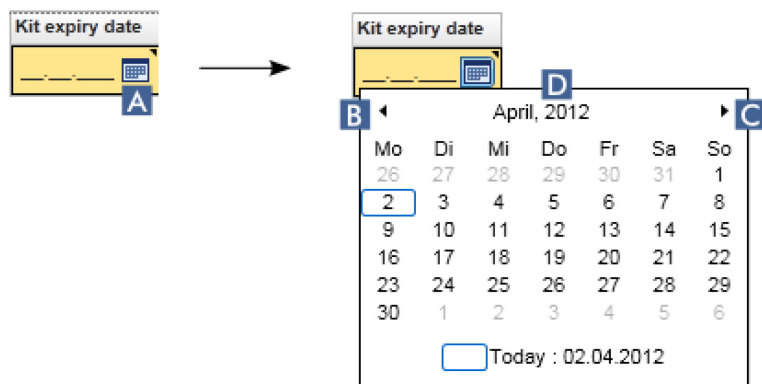
Interactive fields:  
Yellow = mandatory field  
Blue = not mandatory

Assay position

#### Date picker: Entering date in date fields

Dates can either be entered manually into date fields using the keyboard or using an interactive date picker in form of a pop-up calendar. A calendar icon () is positioned at the right of every date field.

Clicking the calendar icon (A) opens the pop-up calendar.



Change to the previous/next month by clicking the arrow icons (B) and (C). Hovering over the year label (D) displays additional control arrows, which are used to quickly jump to the next (up arrow) respectively previous year (down arrow).



### Entering a date using the date picker

Click the calendar icon  (A) next to the date field.

The calendar pop-up is shown.


Continue using the following scheme:

To	Do this
Change the year	<p>Hover the mouse over the year (D). Date is displayed in blue. Additional control arrows are shown.</p> <p>Click the "up" arrow to change to the next year. Click the "down" arrow to change to the previous year.</p>
Change the month/day	<p>Click the left arrow (B) to change to the previous month. Click the right arrow (C) to change to the next month. Click the date of the desired day.</p>

The date picker disappears and the date field is populated with the selected date.

## 5.2.4 Working with tables

### Sorting tables

Some tables in Rotor-Gene AssayManager give the possibility to sort the contained data by column. Sortable tables can be recognized by the **Sort** indicator icon () in one of the column headers. The data in the table are sorted according to this column. Two different icons exist to visualize an ascending or descending sorting order.



Ascending sorting      The table is sorted by the selected column in ascending order.




Descending sorting      The table is sorted by the selected column in descending order.

To toggle the sorting order from ascending to descending or vice versa, click the column header with the **Sort** indicator icon. To sort the data in the table according to another column, click the column header of the respective column.

In the example below, the **Assay selection** table is sorted by the **Experiment** column in ascending order.

**Sort indicator icon**



Assay selection			
<input type="checkbox"/>	Experiment	Assay	# samples
▶ <input type="checkbox"/>	QF Pat_20120417_0949	QuantiFast Pathogen PCR...	66
▶ <input type="checkbox"/>	QF Pat_20120417_0959	QuantiFast Pathogen PCR...	66
▶ <input type="checkbox"/>	QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66

### Selecting cells

A certain cell area can be selected by clicking in the first cell, holding down the left mouse button, and dragging to the last cell of the area. Selected cells are highlighted in dark blue color. To make multiple selections of non-adjacent cells, hold down the **CTRL** key and click the cells to select.



## Copying data from a table


Copying data from a table is possible by first selecting the cells to be copied and then using **CTRL+C**. The contents of the selected cells are copied to the clipboard. The copied cells can easily be pasted to another area within Rotor-Gene AssayManager or to another software for further processing using **CTRL+V**.

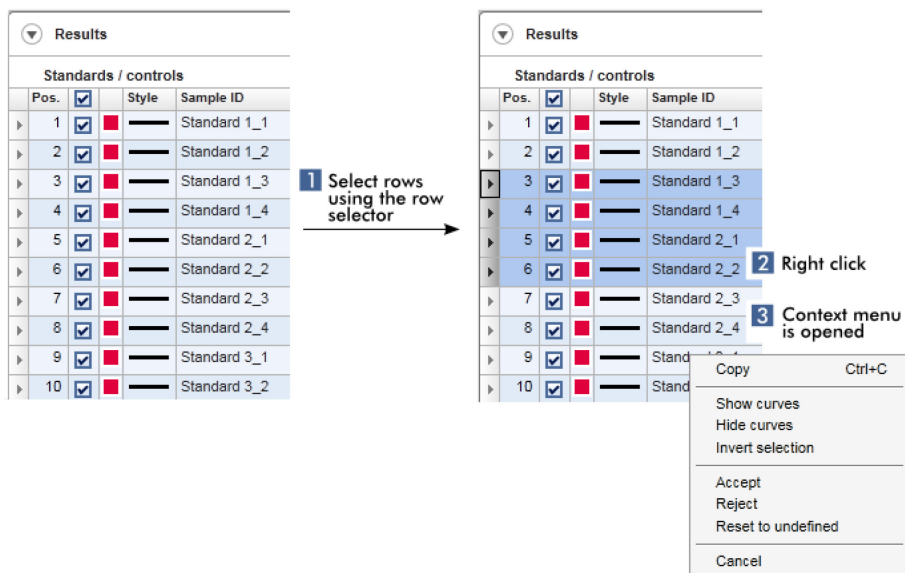
Assay selection			
	Experiment	Assay	# samples
▶	QF Pat_20120417_0949	QuantiFast Pathogen PCR...	66
▶	SYBR_20120417_0953	Rotor-Gene SYBR Green...	48
▶	QF Pat_20120417_0959	QuantiFast Pathogen PCR...	66
▶	SYBR_20120417_1007	Rotor-Gene SYBR Green...	48
▶	QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66

1. Select cells to be copied  
2. CTRL-C to copy the content  
3. Paste in spreadsheet application

	SYBR_20120417_0953	Rotor-Gene SYBR Green PCR Demo Kit	
	QF Pat_20120417_0959	QuantiFast Pathogen PCR +IC	
	SYBR_20120417_1007	Rotor-Gene SYBR Green PCR Demo Kit	
	QF Pat_20120417_1009	QuantiFast Pathogen PCR +IC	

## Context menu

Tables have context menus with varying commands. The context menu in Rotor-Gene AssayManager is opened with a right-click on selected cells. In tables with a row selector there is an additional context menu when first selecting rows by clicking the row selector  of the row and then clicking the right mouse button.



### 5.2.5 Working with graphs

Rotor-Gene AssayManager provides graph functions, such as zooming, panning, and selecting samples to easily examine a graph in detail. The following topics describe how to use these functionalities.

Tasks covered in this section related to working with graphs:

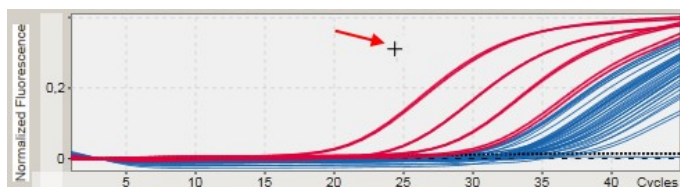
- Zooming in
- Zooming out
- Panning
- Selecting/deselecting samples
- Sample information in graphs

## Zooming in a graph

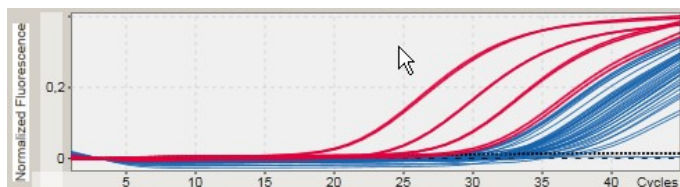
For zooming in a graph in Rotor-Gene AssayManager, an individual zoom area can be selected as in the following example of an amplification plot from the **Approval** environment.

### Zooming in a graph

1. Move the cursor over the graph's area. The cursor changes to cross hairs.

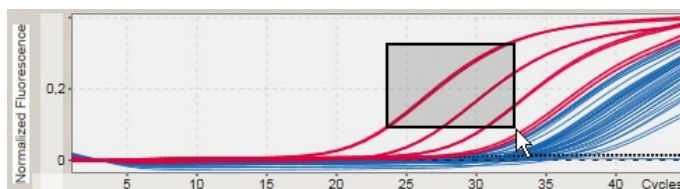


- 2 (a) Click and hold down the left mouse button. The mouse icon changes from cross hairs to the cursor icon.

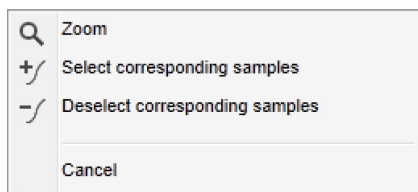


- (b) Drag the cursor until the end of the area to zoom in.

A dark gray rectangle visualizes the selected area, as long as the left mouse button is held down.



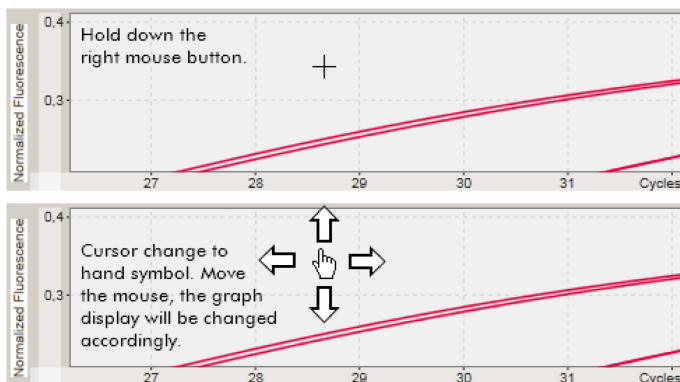
- (c) Release the left mouse button. The following menu pops up:



- 3 Left-click **Zoom**. The graph will be zoomed to the selected area.
- 4 To scroll in the zoomed graph in vertical or horizontal direction just click right in the graph area, hold down the right mouse button, and move the mouse.

### Example

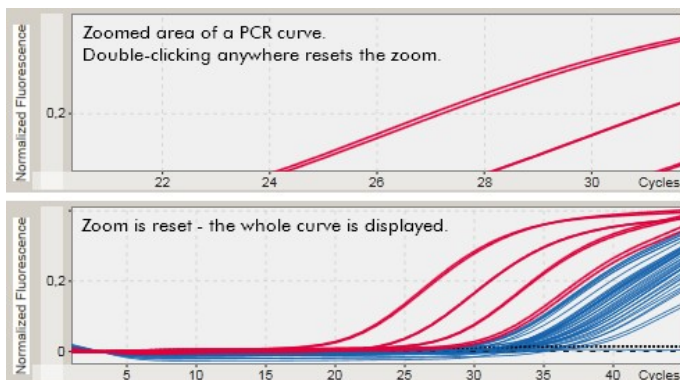
Holding down the right mouse button and moving the mouse will change the graph's display accordingly



### Zooming out a graph

#### Zooming out a graph

Double-click anywhere in a graph area to reset the zoom function to default-scale and see the whole graph.



### Selecting/deselecting samples

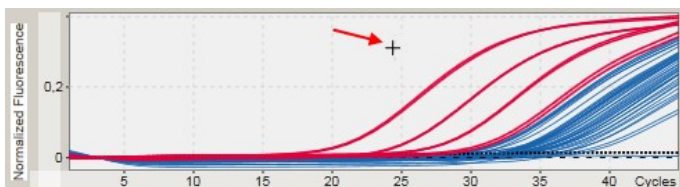
Rotor-Gene AssayManager provides two methods to select or deselect samples in an amplification plot:

- Using a graph
- Using check boxes

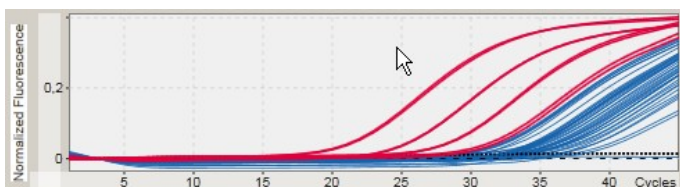
### Selecting/deselecting samples using a graph

1. Move the cursor over the graph area.

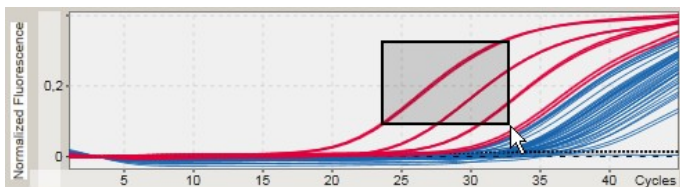
The mouse cursor icon changes to cross hairs.



2. (a) Click and hold down the left mouse button. The mouse icon changes from cross hairs to the cursor icon.





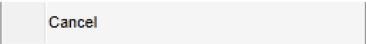
2. (b) Drag the cursor until the end of the area to zoom in. A dark gray rectangle visualizes the selected area, as long as the left mouse button is held down.



2. (c) Release the left mouse button. The following menu pops up:

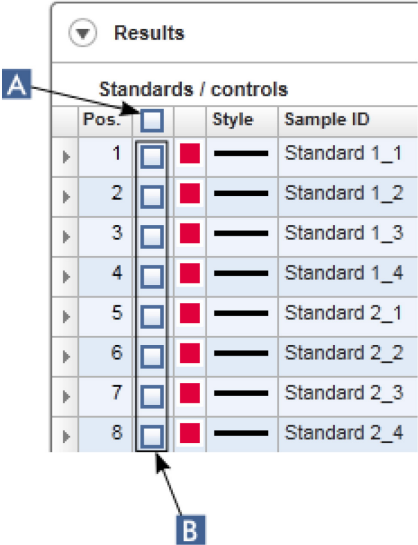


3. Left-click at the desired option.

To	Click
Select all samples within the selected area	 Select corresponding samples
Deselect all samples within the selected area	 Deselect corresponding samples
Cancel the process	

*Select/deselect samples using check boxes*

Samples are selected or deselected by activating or deactivating the corresponding check boxes in the results table.



To	Do
Select all samples in the table	Activate the check box in the column header (A)
Select a specific sample in the table	Activate the check box in the corresponding sample row (B)
Deselect all samples in the table	Deactivate the check box in the column header (A)

To	Do
Deselect a specific sample in the table	Deactivate the check box in the corresponding sample row (B)

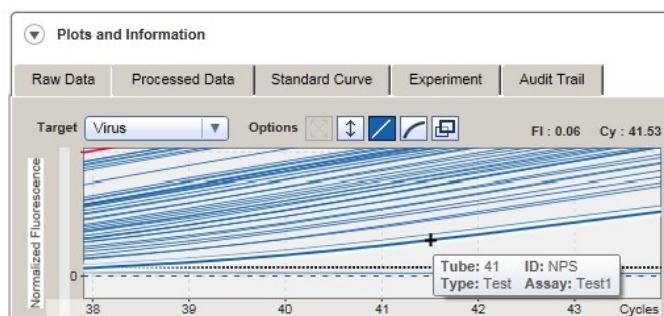
**Note:** The check box icon in the column header changes depending on the number of selected samples.

- ☐ No sample is selected
- ☒ One or more samples are selected
- ☒ All samples are selected

### Sample information in graphs

To get sample information corresponding to a specific curve, hover the mouse over the curve. The curve will be highlighted, and a tooltip containing the following information will be displayed:

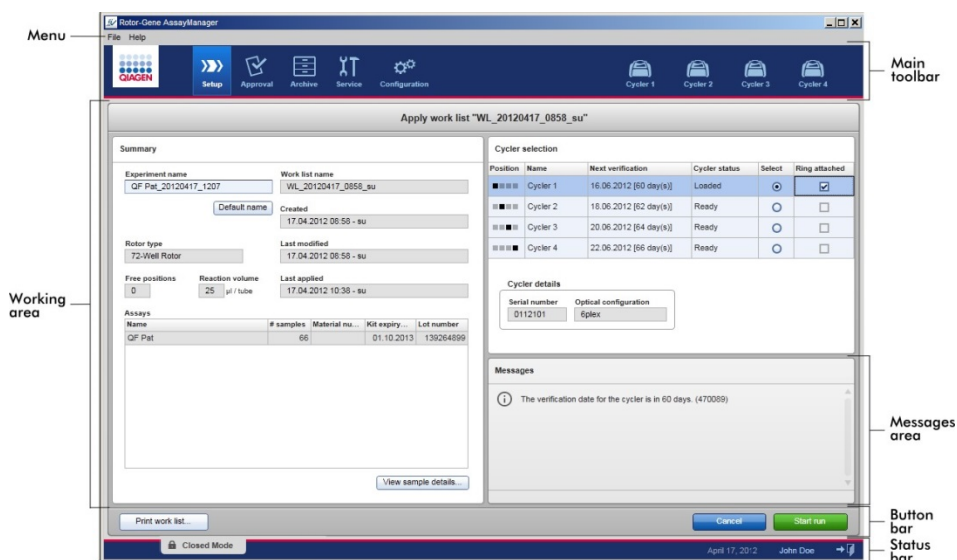
- Tube number
- ID
- Assay type
- Assay short name



## 5.3 Rotor-Gene AssayManager workspace

Rotor-Gene AssayManager is divided into different environments. These environments can be accessed by using the dedicated icons in the main toolbar. The following environments are available:

- **Setup** environment
- **Approval** environment
- **Archive** environment
- **Service** environment
- **Configuration** environment
- **Cycler** environment



The workspace of an environment consists of an environment-specific working area and of the following general elements:

- Menu
- Main toolbar
- Working area
- **Messages** area
- Button bar
- Status bar



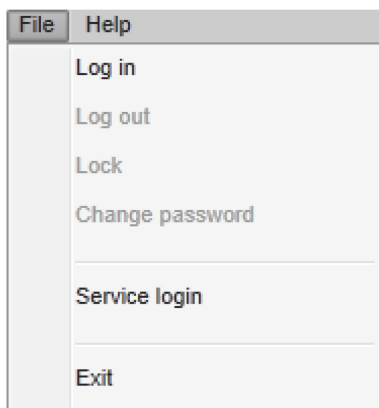
## 5.4 General elements

The following general user interface elements are described in this section:

- Menu
- Main toolbar
- **Messages** area
- Button bar
- Status bar

### 5.4.1 Menu

#### File menu

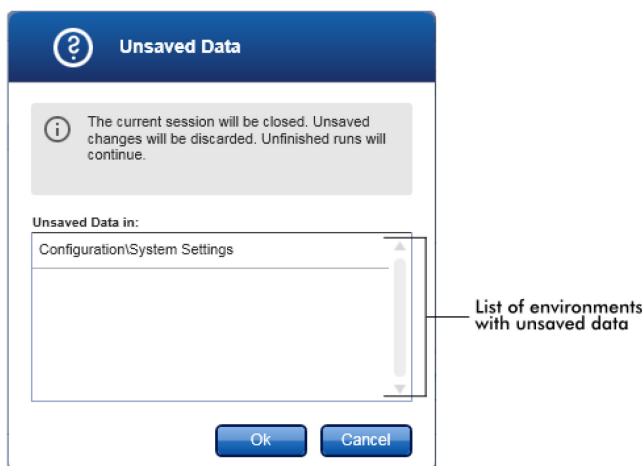


#### *Log in*

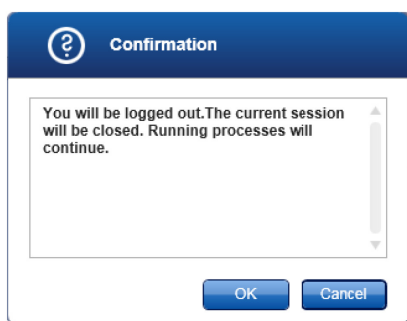
Select **Log in** to log in to Rotor-Gene AssayManager. This option is grayed out if a user is already logged in.

#### *Log out*

This enables the current user to log out. If there are unsaved data, the following warning is shown with a list of environments where unsaved data exist.



If there are no unsaved data, the following dialog is shown:



### Lock

This locks the current session. To unlock, the logged in user has to enter the password.

### Change password

This opens a dialog to change the password. The old password has to be entered, followed by the new password and a confirmation of the new password.

### Service login

This option is for login of a QIAGEN Field Service Engineer. This field is grayed out if a user is already logged in.

### Exit

Selecting **Exit** closes Rotor-Gene AssayManager. If there are unsaved data, a warning will appear.

## Help menu

The **About Rotor-Gene AssayManager** dialog box appears and displays information about the Rotor-Gene AssayManager and the loaded plug-ins including the version numbers.

### 5.4.2 Main toolbar

The main toolbar contains two areas:

- Environment icons
- Cyclor icons



#### Environment icons

The environment icons are used to change to the corresponding environment. The currently active environment is highlighted.

Rotor-Gene AssayManager has different environments.

- **Setup** environment (page 632)
- **Approval** environment (page 657)
- **Archive** environment (page 678)
- **Service** environment (page 682)
- **Configuration** environment (page 687)

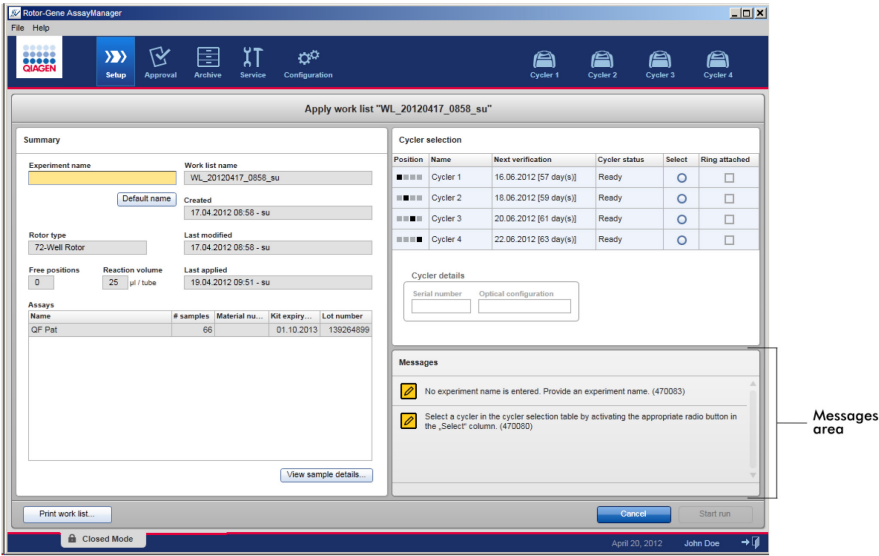
#### Cyclor icons

The cyclor icons visualize the up to 4 registered cyclers managed by Rotor-Gene AssayManager. Clicking a cyclor icon changes the screen to the corresponding cyclor screen. For details, see "**Cyclor** environment", page 646.

### 5.4.3 Messages area

Depending on the selected environment and the corresponding dialog within the environment, there is a **Messages** area containing all warnings, errors, and information related to the current operation.

Example: **Messages** area in the **Setup** environment



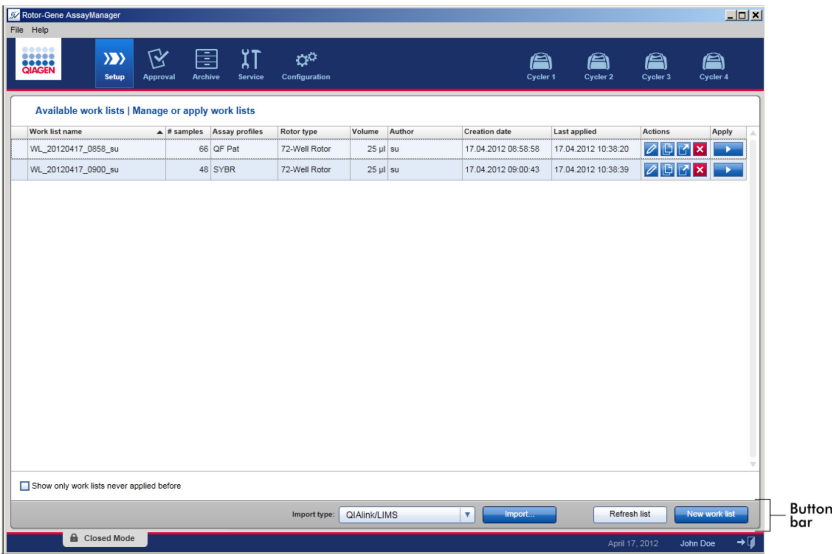
## Related topics

“Use of color”, page 612

“Displaying errors and warnings”, page 614

### 5.4.4 Button bar

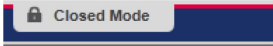
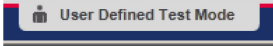
The button bar is placed at the bottom of the screen. It contains buttons specific for the selected environment.



5.4.5 Status bar

The status bar is always visible and gives an overview about the session status.



Status bar element	Explanation
Mode indicator	<p>Indicates the current user mode, i.e., Closed Mode or User Defined Test Mode (UDT Mode)</p> <p>If the user is logged in in Closed Mode, the label <b>Closed Mode</b> and the corresponding icon is shown.</p>  <p>If the user is logged in in User Defined Test Mode, the label <b>User Defined Test Mode</b> and the corresponding icon is shown.</p>  <p><b>Note:</b> The User Defined Test Mode is not intended for use with FDA cleared or approved nucleic acid tests.</p>
Date	<p>Shows the current date.</p>
User name	<p>Shows first and last name of the user currently logged in.</p>
Log out button	<p>Logs out the current user. If there are unsaved data, a warning will appear.</p>

Related topics

"Modes", page 601



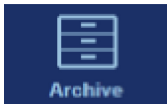


"Logging in and logging out", page 725

## 5.5 Environments

Rotor-Gene AssayManager contains different environments.

An overview of access rights for different user roles can be found in "User roles", page 603.

You can switch to another environment by clicking the appropriate button. The icon of the currently active environment is highlighted with white font and a blue gradient background color.

Environment	Description
	Used for creation, management and application of work lists.
	Used to search for unreleased assays and for the release of dedicated runs. Experiment reports are created on release of run.
	Used to search for fully released experiments and to generate experiment reports using predefined report profiles.
	Used to adjust the settings of Rotor-Gene AssayManager.
	Used to stop or finish a run and to release a cycler after a run is finished.

### 5.5.1 Setup environment

The **Setup** environment is one of the core parts of the Rotor-Gene AssayManager application. It automatically appears after a user with the assigned role of an Operator successfully logs in to Rotor-Gene AssayManager. The **Setup** environment consists of 3 different screens where tasks can be assigned.

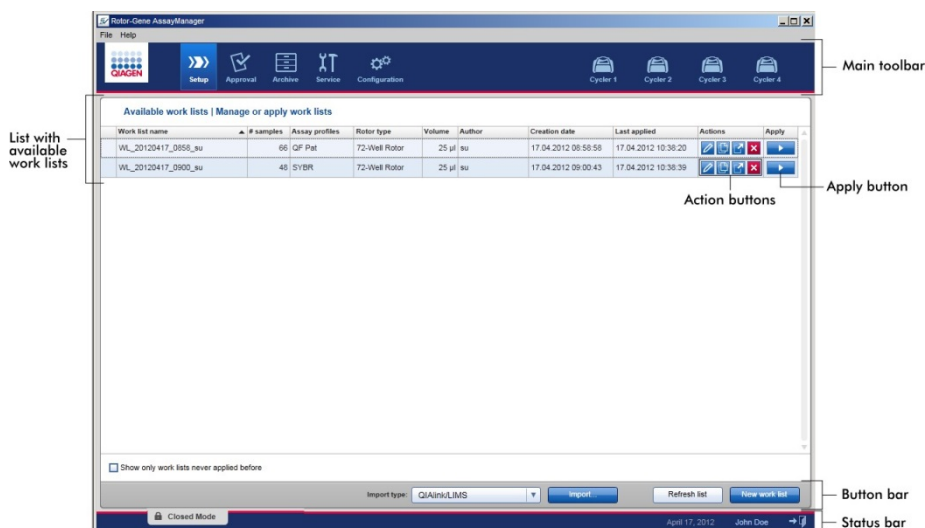
Screen	Assigned tasks
<b>Available work lists</b>	<ul style="list-style-type: none"> <li>• Creating a new work list*</li> <li>• Importing a work list</li> <li>• Editing a work list*</li> <li>• Duplicating a work list*</li> <li>• Exporting a work list</li> <li>• Deleting a work list</li> <li>• Applying a work list</li> </ul>
<b>Create new work list</b>	Create a new work list: <ul style="list-style-type: none"> <li>• <b>Assays</b> step</li> <li>• <b>Samples</b> step</li> <li>• <b>Properties</b> step</li> </ul>
<b>Apply work list</b>	Set up run and apply a work list

**\*Note:** The tasks “creating a new work list”, “editing a work list”, and “duplicating a work list” are not intended for use with FDA cleared or approved nucleic acid tests.

## Available Work Lists View

The **Available work lists** view contains two areas:

- A table with available work lists (stored in the internal database)
- The button bar at the bottom of the screen






### The **Available work lists** table

The **Available work lists** table displays the following information for all currently available work lists:

- Status icon
- Work list name
- Number of samples
- Assay profiles
- Rotor type
- Reaction volume
- Author
- Creation date
- Last applied

The data in the table is sortable. By clicking at the column header, the table's data is sorted in ascending order. By clicking at the column header again, the table's data is sorting in descending order.

A status icon is displayed in the very left column of a work list in case of existing warnings or errors. Possible icons are:

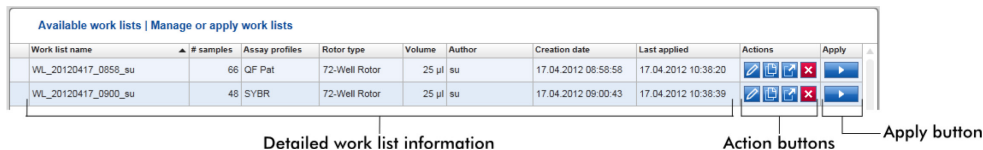
Icon	Description
	Deactivated assay profile or expired kit
	Message: "This work list contains invalid samples" A work list contains invalid samples.
	The work list is currently locked.

**Note:** Moving the mouse over the icon reveals a tooltip with detailed information about the problem.

Available work lists   Manage or apply work lists							
Work list name	# samples	Assay profiles	Rotor type	Volume	Author	Creation date	Last applied
 WL_20120417_0858_su	66	QF Pat	72-Well Rotor	25 µl	su	17.04.2012 08:58:58	17.04.2012 08:58:58
This work list contains the deactivated assay profile QuantiFast Pathogen PCR +IC version 2.0.0. Activate the assay profile and update the work list.							







In the very right columns of a work list, the **Action** buttons and the **Apply** button can be found.




Work list name	# samples	Assay profiles	Rotor type	Volume	Author	Creation date	Last applied	Actions	Apply
WL_20120417_0858_su	66	QF Pat	72-Well Rotor	25 µl	su	17.04.2012 08:58:58	17.04.2012 10:38:20	[Edit] [Duplicate] [Export] [Remove]	[Apply]
WL_20120417_0900_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	17.04.2012 10:38:39	[Edit] [Duplicate] [Export] [Remove]	[Apply]

Detailed work list information      Action buttons      Apply button


### Action buttons

Icon	Label/title	Description
	<b>Edit work list</b>	<p>Editing a work list means modifying its parameters in the <b>Edit work list</b> view. The parameters of the work list can be modified using the <b>Edit work list</b> view.</p> <p><b>Note:</b> Work lists imported from QIA symmetry or LIMS to the software cannot be edited.</p> <p>See "Creating/editing a work list", page 732.</p>
	<b>Duplicate work list</b>	<p>Creates a copy of the selected work list. A copy of the selected work list is created. This copy can subsequently be edited in the <b>Edit work list</b> view.</p> <p><b>Note:</b> This icon is disabled for work lists imported from QIA symmetry or LIMS.</p> <p>See "Creating/editing a work list", page 732.</p>
	<b>Export work list</b>	<p>Exports the work list as *.iwl file. The intended use of this function is to exchange work lists between different Rotor-Gene AssayManager installations using the import/export function.</p>
	<b>Remove work list</b>	<p>Removes the work list from the system. A warning must be confirmed before the work list is deleted.</p>

### Apply button


Icon	Label/title	Description
	<b>Apply work list</b>	<p>The work list is applied (i.e., the run is performed) and further details have to be entered in the <b>Run work list</b> view.</p> <p><b>Note:</b> This button is enabled if the work list is not locked.</p> <p>See "Apply work list view", page 639.</p>

### Check box

Icon	Description
	<p><i>If not activated.</i></p> <p>Displays all work lists, regardless if they already have been applied or not edited.</p> <p><i>If activated</i></p> <p>Displays only work list that have not been applied yet.</p>

**Note:** The **Available work lists** table might become very long and confusing. This table might contain a number of work lists that you do not need anymore.

Remove the work lists you do not need anymore at regular periods:

1. Click the **Remove work list** button (.
2. Confirm the warning **Work List Removal** by clicking **OK**. The deleted work list disappears from the **Available work lists** table.
3. Repeat these steps for any other work list you want to remove.

## The button bar

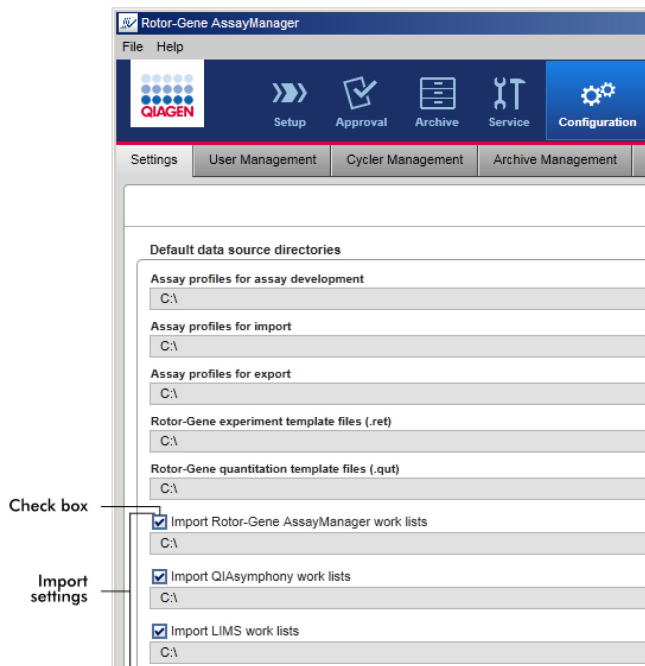
The button bar is arranged at the bottom of the screen:



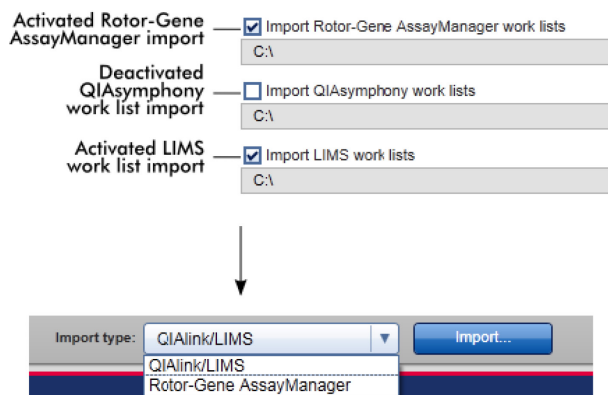
Label/title	Description
<b>Import type</b>	<p>Drop-down menu to select the import source file type for the import work list command. Rotor-Gene AssayManager can import work lists from QIAlink®/LIMS, QIAsymphony, and other Rotor-Gene AssayManager installations.</p> <p>Possible values:</p> <ul style="list-style-type: none"><li>QIAlink/LIMS</li><li>QIAsymphony</li><li>Rotor-Gene AssayManager</li></ul> <p>The entries in this menu depend on the import settings in the <b>Configuration</b> environment.</p>
<b>Import</b>	<p>Import a work list from a file. A file selection dialog is opened where the work list to be imported can be selected. The source type is determined by the item selected in the drop-down menu <b>Import type</b>.</p>
<b>New work list</b>	<p>Create a new work list. This button links to the <b>Create new work list</b> screen.</p> <p><b>Note:</b> Creating a new work list is not intended to be used with FDA cleared or approved nucleic acid tests.</p>

### Import source file

The group box **Default data source directories** in the **Settings** tab of the **Configuration** environment defines whether the import of external work lists (from Rotor-Gene AssayManager, QIAAsymphony, or a LIMS) is possible and determines the source directory.



A check box in front of the 3 import settings determines if the corresponding import setting is activated or not. If the check box is activated, the import of this specific work list is enabled. The **Import type** drop-down menu in the **Setup** environment is populated with this import option.



---

The **Import QIASymphony work lists** option is deactivated in the example above. The QIASymphony import option is removed from the **Import type** menu.

#### **Tasks related to the Available work lists view**

"Creating/editing a work list", page 732

"Exporting a work list", page 736

"Importing a work list", page 733

"Starting a run", page 738

#### **Apply work list view**

Selecting the **Apply** button either in the **Available work lists** view or in the **Create New/Edit work list** view links to the **Apply work list** view.

In the **Apply work list** view the following tasks can be accomplished to start a run:

- Define an experiment name
- View sample details
- Print a work list
- Select a cyclor
- Confirm that the locking ring has been attached to the rotor
- Start the run

Furthermore, detailed information about the work list and the cyclor are displayed.

## Work list information

- Work list name
- Creation date
- Last modification date
- Last application date
- Rotor type
- Number of free positions
- Reaction volume
- Assays used in the work list
  - Assay name
  - Number of samples
  - Material number
  - Kit expiry date
  - Lot number

## Cycler information

- Position
- Name
- Next verification date
- Cycler status
- Serial number
- Optical configuration

The screenshot shows the 'Apply work list' dialog box in the Rotor-Gene Assay Manager software. The dialog is titled 'Apply work list "WL\_20120417\_0858-su"'. It is divided into four main sections:

- Summary:** Contains fields for Experiment name (WL\_20120417\_0858-su), Work list name (Default name), Created (17.04.2012 08:58 - su), Rotor type (72-Well Rotor), Last modified (17.04.2012 08:58 - su), Free positions (0), Reaction volume (25 µl / tube), Last applied (17.04.2012 10:38 - su), and Assays (QF Pat, 66, 01.10.2013, 139264899).
- Cycler selection:** Contains a table with columns: Position, Name, Next verification, Cycler status, Select, and Ring attached. The table lists four cyclers: Cyclor 1, Cyclor 2, Cyclor 3, and Cyclor 4.
- Cycler details:** Contains fields for Serial number and Optical configuration.
- Messages:** Contains a list of messages, including 'No experiment name is entered. Provide an experiment name. (470053)' and 'Select a cycler in the cycler selection table by activating the appropriate radio button in the "Select" column. (470050)'.

The bottom of the dialog has a Button bar with buttons for Print work list, Cancel, and Start run.

## Summary area

The **Summary** area is intended to enter a mandatory experiment name. The **Summary** area also provides detailed information about the work list and its incorporated assay(s). Sample details can be displayed in a secondary table.

**Summary**

Experiment name  Work list name

Created

Rotor type  Last modified

Free positions  Reaction volume  µl / tube Last applied

**Assays**

Name	# samples	Material nu...	Kit expiry...	Lot number
QF Pat	66		01.10.2013	139264899

Label/title	Description
<b>A</b>	
<b>Experiment name</b>	<p>Input box to enter a mandatory experiment name. The experiment name must fulfill two requirements:</p> <ul style="list-style-type: none"> <li>• The experiment name must not exceed 80 characters</li> <li>• The experiment name must be unique</li> </ul>
<b>B</b>	
<b>Default name</b> button	<p>A default name is entered automatically in the experiment name input box using the name pattern defined in the <b>Configuration</b> environment.</p> <p>Further information can be found in "<b>Configuration</b> environment/<b>Settings</b> tab", page 689.</p>
<b>C</b>	
Data field	<p>Shows the following data:</p> <ul style="list-style-type: none"> <li>• <b>Free positions</b> <ul style="list-style-type: none"> <li>• Number of free positions</li> </ul> </li> <li>• <b>Reaction volume</b> <ul style="list-style-type: none"> <li>• Reaction volume</li> </ul> </li> </ul>

D

Data field                      Shows the following data:

- **Work list name**
  - **Created**
  - **Last modified**
  - **Last applied**
- Work list name
  - Creation date
  - Last modification date
  - Last application date

E

**Assays** table                      Table with a list of all assays incorporated in the work list.  
For every assay the following data is shown:

- Assay name
- Number of samples
- Material number
- Kit expiry date
- Lot number

F

**View sample details**              Overview of the samples in the work list in the form of a  
table. The table can be printed by clicking **Print work list**  
(G, see table below).

Work list "artus CMV RG PCR CE" | Samples

Pos	Style	ID	Type	Targets	Assay	Status	Comment
1		Quantification Standard 1	QS	CMV Test Target,...	CMV		sample comment 1
2		Quantification Standard 2	QS	CMV Test Target,...	CMV		sample comment 2
3		Quantification Standard 3	QS	CMV Test Target,...	CMV		sample comment 3
4		Quantification Standard 4	QS	CMV Test Target,...	CMV		sample comment 4
5		Negative Control	NTC	CMV Test Target,...	CMV		sample comment 5
6		Sample ID 1	Test	CMV Test Target,...	CMV		sample comment 6
7		Sample ID 2	Test	CMV Test Target,...	CMV		sample comment 7
8		Sample ID 3	Test	CMV Test Target,...	CMV		sample comment 8
9		Sample ID 4	Test	CMV Test Target,...	CMV		sample comment 9
10		Sample ID 5	Test	CMV Test Target,...	CMV		sample comment 10
11		Sample ID 6	Test	CMV Test Target,...	CMV		sample comment 11
12		Sample ID 7	Test	CMV Test Target,...	CMV		sample comment 12
13		Sample ID 8	Test	CMV Test Target,...	CMV		sample comment 13
14		Sample ID 9	Test	CMV Test Target,...	CMV		sample comment 14
15		Sample ID 10	Test	CMV Test Target,...	CMV		sample comment 15
16		Sample ID 11	Test	CMV Test Target,...	CMV		sample comment 16
17		Sample ID 12	Test	CMV Test Target,...	CMV		sample comment 17
18		Sample ID 13	Test	CMV Test Target,...	CMV		sample comment 18

Caption

☒ valid

☐ ? unclear

☐ ! invalid

G

Print Work list ...

Close



## Cycler selection area

The **Cycler selection** area mainly consists of the **Cycler selection** table, which lists all available and usable cyclers with the following data:

- Position of cycler
- Name of cycler
- Next temperature verification date (residual days in brackets)

**Note:** Temperature verification is optional. If no date for temperature verification is defined, this field will be empty.

### Status of cycler

The **Cycler details** table below displays the **Serial number** and the **Optical configuration** of the selected cycler.

The screenshot shows a web interface for cycler selection. It features a table titled 'Cycler selection' with 6 columns: Position, Name, Next verification, Cycler status, Select, and Ring attached. There are 4 rows of data, each representing a cycler. Below the table is a 'Cycler details' section with two input fields: 'Serial number' and 'Optical configuration'.

Position	Name	Next verification	Cycler status	Select	Ring attached
■ ■ ■ ■	Cycler 1	16.06.2012 [60 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 2	18.06.2012 [62 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 3	20.06.2012 [64 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 4	22.06.2012 [66 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>

Cycler details

Serial number:

Optical configuration:

The **Cycler selection** table has 4 rows, representing the maximum of 4 cyclers that can be operated by Rotor-Gene AssayManager. If fewer than 4 cyclers are configured, residual table rows will be disabled.

All compatible cyclers with the status **Ready** can be selected for the work list to be applied using the **Select** radio button. After successful cycler selection, the dedicated **Ring attached** check box will become active. Confirm that the locking ring is attached to the rotor by activating the **Ring attached** check box to start the cycler.

**Note:** A successful cycler selection requires at least that the optical configuration of a cycler matches the configuration defined by the assay profiles referenced in the work list.

Cycler selection					
Position	Name	Next verification	Cycler status	Select	Ring attached
■ ■ ■ ■	Cycler 1	16.06.2012 [60 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 2	18.06.2012 [62 day(s)]	Ready	<input checked="" type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 3	20.06.2012 [64 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 4	22.06.2012 [66 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>

Status of "Start run" button changes  
when "Ring attached" option is activated



Cycler selection					
Position	Name	Next verification	Cycler status	Select	Ring attached
■ ■ ■ ■	Cycler 1	16.06.2012 [60 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 2	18.06.2012 [62 day(s)]	Loaded	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>
■ ■ ■ ■	Cycler 3	20.06.2012 [64 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 4	22.06.2012 [66 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>

### Button bar

The button bar contains 3 interactive buttons.

Label/title	Description
<b>Print work list</b>	<p>Generation of a work list report in *.pdf format with the following structure:</p> <p><b>Work list name</b></p> <p><b>Creation date and time, user name</b></p> <p><b>Rotor information</b></p> <ul style="list-style-type: none"> <li>● Rotor type</li> <li>● Volume</li> </ul> <p><b>Assays</b></p> <ul style="list-style-type: none"> <li>● Assay profile name</li> <li>● Version</li> <li>● Kit information</li> <li>● Material number</li> <li>● Expiry date</li> <li>● Lot number</li> <li>● Sample details</li> </ul> <p><b>Sample details</b></p> <ul style="list-style-type: none"> <li>● Position</li> <li>● Sample ID</li> <li>● Target(s)</li> <li>● Type</li> <li>● Assay</li> <li>● Comment</li> </ul> <p><b>Note:</b> The work list can also be printed by clicking the <b>View sample details...</b> button.</p>
<b>Cancel</b>	<ul style="list-style-type: none"> <li>● The application process is canceled.</li> <li>● The <b>Apply work list</b> screen is closed.</li> <li>● The <b>Available work lists</b> screen is shown.</li> </ul>

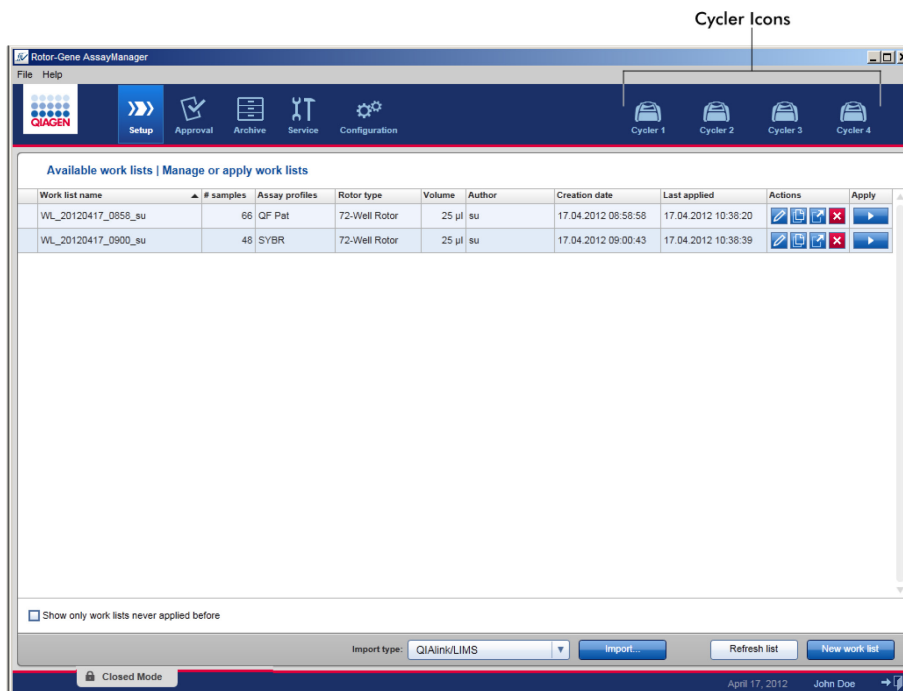
Label/title	Description
<b>Start run</b>	<p>After the start of the cycling process, the cyclers screen of the selected cycler is displayed.</p> <p><b>Note:</b> The <b>Start run</b> button is disabled by default. This button is activated if the user has selected a cycler in the <b>Cycler selection</b> table and has confirmed that the locking ring has been attached.</p> <p>When the user clicks the <b>Start run</b> button, the following actions are performed:</p> <ul style="list-style-type: none"> <li>• The experiment is saved in the database.</li> <li>• The run is started.</li> <li>• Rotor-Gene AssayManager switches to the <b>Cycler</b> environment of the selected cycler.</li> </ul>

#### Create new/edit work list view

**Note:** Creating a new work list and editing a work list is not intended for use with FDA cleared or approved nucleic acid tests.

#### 5.5.2 **Cycler** environment



The **Cycler** environment is used for the cyclers and gives an overview about all Rotor-Gene Q MDx instruments accessible by Rotor-Gene AssayManager. Up to 4 different Rotor-Gene Q MDx cyclers can be registered and subsequently controlled by Rotor-Gene AssayManager in parallel. The different cyclers are represented by individual **Cycler** icons, which are always displayed at the very top right of the Rotor-Gene AssayManager screen.





The content of the **Cycler** environment depends on whether a cycler is currently idle, in operation, or whether a run has been stopped but not yet released. The visual appearance of the cycler icon indicates the current state of the cycler.

### Cycler icon





The **Cycler** icon changes its appearance depending on the progress and the result of the run.

Environment	Description
	Cycler idle
	Cycler working (The progress indicator visualizes the run progress.)

**Progress Indicator**

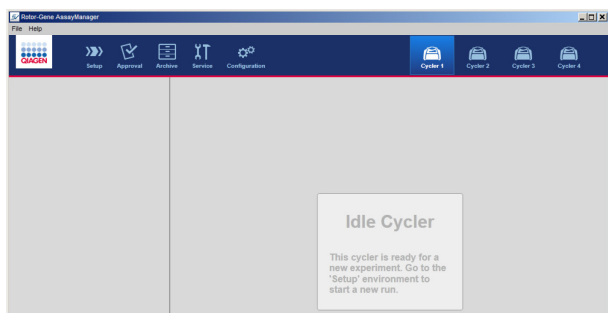
Environment	Description
	Run finished successfully
	Run stopped (either by clicking <b>Stop Process</b> or an error occurred)

Further cycler icons are listed below.

Environment	Description
	Cycler offline
	Cycler activated
	Invalid verification
	Run stopped and cycler offline

## Idle Cyclor screen

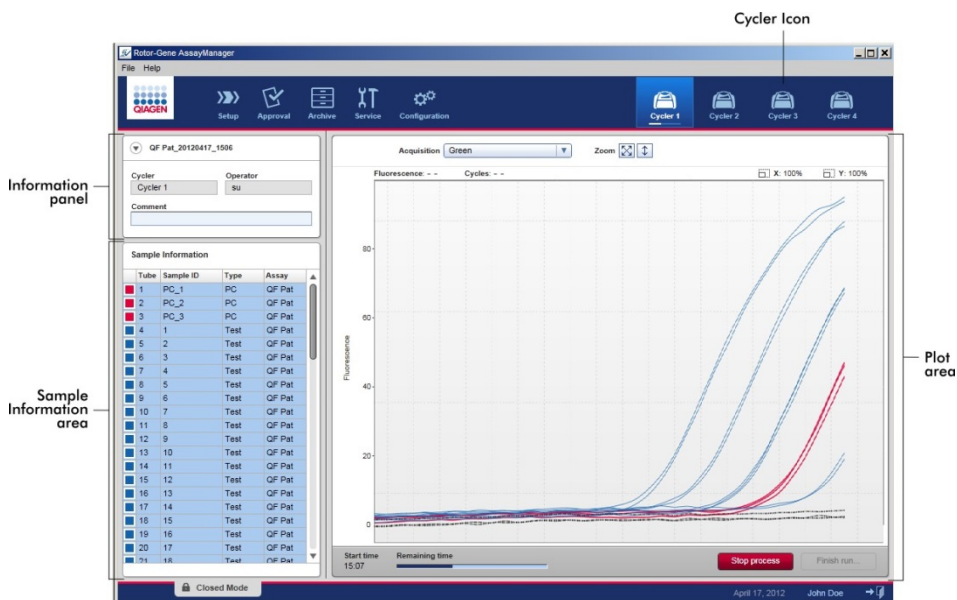
In case a cyclor is idle, clicking the corresponding icon displays the following screen:



To start a run on an idle cyclor, apply an existing work list from the **Available Work Lists** table.

## Active Cyclor screen

If a cyclor is active, a run has been finished or stopped manually and has not yet been released, a plug-in specific screen will be displayed.



The amplification of the samples is displayed in real time in the plot area. After the run process has finished, the run is released and the sample results can be approved.

It is possible to stop the process before it is finished. If the **Stop process** button is clicked during the run, a confirmation dialog with the message **The run will be stopped** appears. Click **OK**. The run is stopped as soon as the device has finished a profile step. This can

take up to 60 seconds. The experiment is stored on the database with the result status **Run stopped**. Afterwards, the **Finish run** button is enabled and the **Stop process** button is disabled.

The cyclers screen consists of 4 areas:

- Information panel
- **Sample information** area
- Plot area
- **Cycler** icon

Information panel

Label	Explanation
"Collapse" icon	The collapse icon is used to collapse the information panel to a single row to gain screen space to enlarge the <b>Sample information</b> area. If the area is collapsed, only the experiment name is shown.
Experiment name	Experiment name as defined during work list setup.
A	Name of the cycler
B	Comment field, maximum 256 characters are allowed
C	Operator name

**Sample information area**

The **Sample information** area lists all samples of the run in a table with the following columns:

- Line color (derived from the work list)










- Sample position on rotor
- Sample ID
- Sample type:
  - **Test** Test sample
  - **NTC** No template control
  - **PC** Positive control
  - **EC+** Positive extraction control
  - **EC-** Negative extraction control
  - **QS** Quantitation standard
- Assay short name

Sample Information				
	Tube	Sample ID	Type	Assay
Non-Test samples	1	PC_1	PC	QF Pat
	2	PC_2	PC	QF Pat
	3	PC_3	PC	QF Pat
Test samples	4	1	Test	QF Pat
	5	2	Test	QF Pat
	6	3	Test	QF Pat
	7	4	Test	QF Pat
	8	5	Test	QF Pat
	9	6	Test	QF Pat
	10	7	Test	QF Pat
	11	8	Test	QF Pat
	12	9	Test	QF Pat
	13	10	Test	QF Pat
	14	11	Test	QF Pat
	15	12	Test	QF Pat
	16	13	Test	QF Pat
	17	14	Test	QF Pat
	18	15	Test	QF Pat
	19	16	Test	QF Pat
	20	17	Test	QF Pat
	21	18	Test	QF Pat








The number of rows is equal to the number of wells on the rotor. If the number of samples used is less than the number of wells on the rotor, the sample type **Empty** is assigned to unused rotor positions.

### Behavior of the Sample information area

The acquisition plots for specific samples can be hidden or shown in the plot area. Click in the row of the designated sample. By default, all samples used are shown and hence highlighted in a dark blue color. Rows of disabled samples (i.e., hidden acquisition plot) are colored in brighter blue.

Sample Information				
	Tube	Sample ID	Type	Assay
	1	PC_1	PC	QF Pat
	2	PC_2	PC	QF Pat
	3	PC_3	PC	QF Pat
	4	1	Test	QF Pat
	5	2	Test	QF Pat
	6	3	Test	QF Pat
	7	4	Test	QF Pat

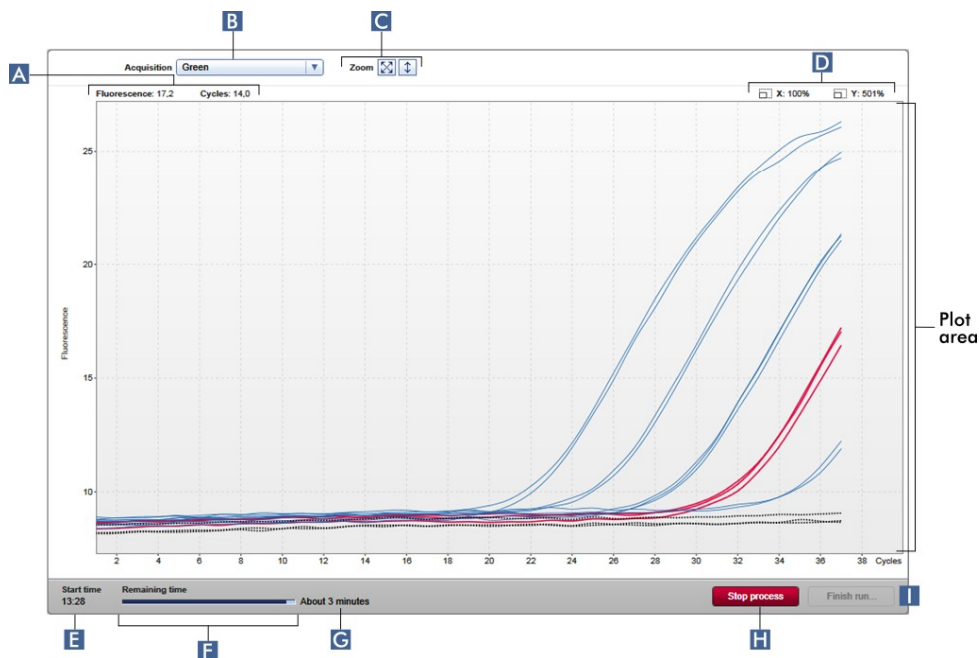
Acquisition plots are enabled by default for all samples. The row is colored in dark blue.


Sample Information				
	Tube	Sample ID	Type	Assay
	1	PC_1	PC	QF Pat
	2	PC_2	PC	QF Pat
	3	PC_3	PC	QF Pat
	4	1	Test	QF Pat
	5	2	Test	QF Pat
	6	3	Test	QF Pat
	7	4	Test	QF Pat


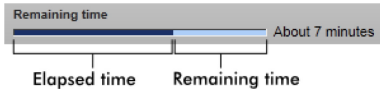
In the example above, the amplification curves of tubes 2, 3, and 5 have been disabled. These rows are colored in brighter blue.

### Plot area

The plot area displays the amplification curves for a selected acquisition of the different samples recorded by the Rotor-Gene Q MDx in real time.



Label	Explanation
<b>A</b>	
Coordinates	Shows the coordinates of the current mouse position. If the mouse cursor is within the plot area, the mouse cursor changes to cross hairs (+). The current coordinates are displayed in this field.  The coordinates are shown as <b>Fluorescence</b> and <b>Cycles</b> values.
<b>B</b>	
Target selection menu	Selects the acquisition target used for the plots.
<b>C</b>	
Graph options	Displays options to modify the scaling of the plot.   The plot is scaled to 100%. The whole plot is displayed fitted in the graph area. The scale is reset to display from 0 to 100 fluorescence units. The x-axis is set to a maximum value

Label	Explanation
	equal to the number of cycles in the run profile, and the y-axis is set to 100.
	The auto scale button fits the scale to the maximum and minimum readings in the data. The y-axis range is restricted to the lowest and highest measured fluorescence value. The x-axis is set to a maximum value equal to the number of cycles in the run profile.
<b>D</b>	
Zoom factors	Displays zoom factors separately for the x-axis and the y-axis.
<b>E</b>	
<b>Start time</b>	Displays the start time of the run.
<b>F</b>	
Progress indicator bar	<p>Displays the progress of the experiment. The indicator bar visualizes the acquisition progress: the dark blue colored part of the bar visualizes the elapsed time; the brighter blue colored part, the remaining time of the experiment.</p>  <p>The text over the progress indicator changes depending on the current status of the run:</p> <ul style="list-style-type: none"> <li>• <b>Remaining time:</b> Ongoing experiment</li> <li>• <b>Analyzing:</b> Experiment was finished, analysis has started</li> <li>• <b>Ready:</b> Experiment analysis finished</li> </ul>
<b>G</b>	
Remaining time estimation	Displays the estimated remaining time.
<b>H</b>	
<b>Stop process</b>	Stops the run.

Label	Explanation
	<p>After clicking the <b>Stop process</b> button, a warning dialog must be confirmed to stop the run. The run will be stopped as soon as the device has finished a profile step. This can take up to 60 seconds.</p> <p>The status <b>Run stopped</b> is assigned to the experiment in the internal database.</p>
I	
<b>Finish run</b>	Finish the run.

### Finishing a run

After clicking **Finish run** the following dialog is opened:

The behavior of this dialog depends on the **Finish run** setting defined in the **Configuration** environment. The administrator can set the option that a run has to be released before it can be approved. If this option is activated, the administrator can further define that the release must be signed:

#### Finish run

- ☐ Run has to be released before starting approval
- ☒ Release of run has to be signed

If this setting is deactivated, the run can be approved in the "Approval" environment without releasing the run.

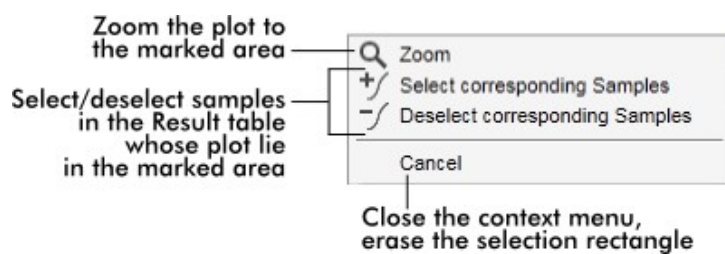
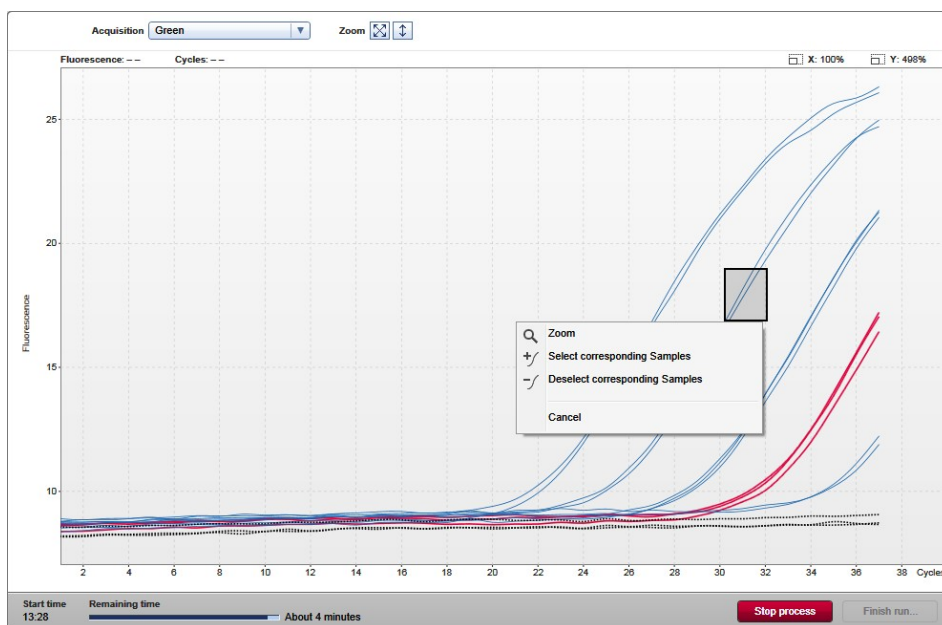
For further information, see "**Configuration** environment", page 687.

### Behavior of the plot area


The plot area has interactive functionalities:

#### Context menu

An area of the amplification plot can be selected. Click and hold the left mouse button and drag the mouse pointer. A context menu appears with the options to zoom, select, or deselect corresponding samples.



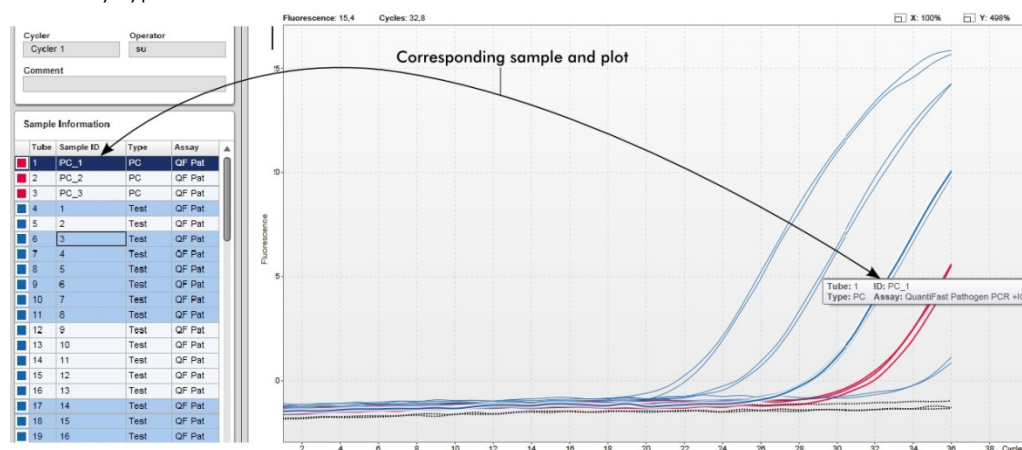
## Zoom

Clicking **Zoom** in the context menu zooms the amplification plot to the selected area. By right-clicking and holding down the mouse button, the cursor changes to a hand symbol () . The amplification plot area can be scrolled in all directions by moving the mouse. Double-click anywhere in the amplification plot area to reset the zoom to 100%.

## Identification of amplification curves

Hovering the mouse over an individual amplification curve highlights the curve in the amplification plot and displays a tooltip with the following data:

- Tube number
- Sample type
- Sample ID
- Assay type



The corresponding sample in the **Sample information** table is highlighted in darker blue to visualize its position in the table.

## Tasks related to the Cycler view

"Managing cyclers", page 763"

"Finishing and releasing a run", page 742"

## 5.5.3 Approval environment

The **Approval** environment is used to search for unreleased assays and to release the assay. The **Approval** environment mainly consists of two different screens:

- **Filter** screen: Used for filtering and selecting specific assays for the release process

- **Approval** screen: Used for checking the assay result and releasing the assay

**Note:** All functions of the **Approval** environment can be used by users with the user role “Approver”. A user with the user role “Operator” can also access this environment, but without rights to approve or release data.

Assays intended to be approved can be filtered by defining search criteria. After applying the filter options, the corresponding assays are displayed in the table next to the filter options section. To start the release process, the assays to be released are selected by checking the corresponding check box and clicking **Start approval**.

## Filter screen

The **Filter** screen is intended to

- Filter for not yet released assays
- Select assays to start the approval process

It consists of two parts:

- **Filter options** area at the left-hand side of the screen
- **Assay selection** area at the right-hand side of the screen

The screenshot displays the Rotor-Gene AssayManager software interface. The top menu bar includes 'File' and 'Help'. Below the menu is a toolbar with icons for 'Setup', 'Approval' (highlighted), 'Archive', 'Service', 'Configuration', and four 'Cycler' buttons (Cycler 1 to Cycler 4). The main window is divided into two primary sections: 'Filter options' on the left and 'Assay selection' on the right.

**Filter options area:** This section contains fields for 'Start date' (18.03.2012) and 'End date' (18.04.2012). Below these are checkboxes for 'Use advanced filter options' and 'Filter assays'. Under 'Filter assays', there are checkboxes for 'erlus CMV RG PCR CE', 'erlus CMV RG PCR CE (short)', 'erlus HI Virus-1 RG RT-PCR CE', and 'erlus HI Virus-1 RG RT-PCR...'. There are also radio buttons for 'Assay status' (Successful, Failed, Both) and 'Release status' (Unreleased, Partially, Both). Further down, there are input fields for 'Filter experiment name', 'Filter contained sample IDs', 'Filter operator', and 'Filter cycler serial number'. At the bottom of this section are 'Reset filter' and 'Apply filter' buttons.

**Assay selection area:** This section contains a table with the following columns: Experiment, Assay, # samples, Operator, Run date, and Status. The table lists various assays, including 'QuantFast Pathogen PCR...' and 'Rotor-Gene SYBR Green...'. At the bottom right of this section is a 'Start approval' button.

At the bottom of the window, there is a status bar showing 'Closed Mode', the date 'April 18, 2012', and the user 'John Doe'.



Initially, the **Assay selection** area is empty. Specific criteria in the filter options have to be defined and applied to search for specific assays. All assays matching these criteria will be listed in the **Assay selection** area.

Using the check boxes, the user selects one or multiple assays to be approved. By clicking the **Start approval** button the **Approval** screen appears.

### Filter options area

The screenshot shows a 'Filter options' dialog box. On the left, two labels with leader lines point to specific parts of the dialog: 'Date filter options' points to the date selection fields, and 'Advanced filter options' points to the 'Use advanced filter options' checkbox and the subsequent filter criteria section. The dialog itself has a title bar 'Filter options'. Inside, there are two date pickers for 'Start date' (18.03.2012) and 'End date' (18.04.2012). Below these is a checkbox labeled 'Use advanced filter options' which is checked. A letter 'A' is placed next to this checkbox. Below the checkbox is a section for 'Filter assays' with a list of assay names and checkboxes. Below that are two columns of radio buttons for 'Assay status' (Successful, Failed, Both) and 'Release status' (Unreleased, Partially, Both). Below these are four more filter criteria, each with a checkbox and a text input field: 'Filter experiment name', 'Filter contained sample IDs', 'Filter operator', and 'Filter cyclor serial number'. At the bottom of the dialog are two buttons: 'Reset filter' and 'Apply filter'. A letter 'B' is placed below the 'Reset filter' button, and a letter 'C' is placed below the 'Apply filter' button.

### Use advanced filter options

By default, the filter options are set to search for assays of the last month. All other filter options are disabled. To enable the advanced filter options, the check box **Use advanced filter options** (A) must be checked.

**Note:** Filtering for text is not case sensitive. For example, if "sample01" is entered in the **Filter contained sample IDs** box, samples with IDs "Sample01" and "SAMPLE01" are also considered as matching samples.

**Reset filter** button

The **Reset filter** button (B) resets all filter options to the default values.

**Apply filter** button

The **Apply filter** button (C) starts the filter process.

All experiments matching the filter criteria will be listed in the **Assay selection** area.

*Date filter options*

Enter a start date and an end date in the corresponding fields to filter for assays with a run start date in the defined date interval.

Dates can either be manually entered or using the date picker.

There are restrictions:

- Wildcard characters are not allowed
- Dates must be entered completely

**Use advanced filter options** check box

Click in the check box next to **Use advanced filter options** (A) to activate the advanced filter options.

Filter criterion	Explanation
<b>Filter assays</b>	<p>To filter for specific assays, activate the <b>Filter assays</b> check box. All assays are displayed in a list. A check box in front of every assay row allows selection of individual assays.</p> <p>Multiple assay selections are possible to search simultaneously for different assays.</p>
<b>Assay status</b>	<p>Filter for the assay status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none"><li>● Successful</li></ul>

Filter criterion	Explanation
	<ul style="list-style-type: none"> <li>● Failed</li> <li>● Both</li> </ul>
<b>Release status</b>	<p>Filter for the release status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none"> <li>● Unreleased</li> <li>● Partially</li> <li>● Both</li> </ul> <p><b>Note:</b> The release status <b>Partially released</b> is not applicable for FDA cleared or approved nucleic acid tests.</p>
<b>Filter experiment name</b>	Filter for the experiment name by activating the check box and entering an experiment name.
<b>Filter contained sample IDs</b>	<p>Filter for specific sample IDs by activating the check box and entering one or multiple sample IDs.</p> <p>Multiple sample IDs have to be entered in individual rows without any separators.</p>
<b>Filter operator</b>	Filter for a specific operator by activating the check box and selecting an operator from the list.
<b>Filter cyclor serial number</b>	Filter for a cyclor serial number by activating the check box and entering a cyclor serial number (only digits).

### Assay selection area

The **Assay selection** area consists of a table containing experiments. These experiments meet the search criteria defined in the **Filter options** area.

A


Experiment	Assay	# samples	Operator	Run date	Status
<input type="checkbox"/> QF Pat_20120417_0949	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 09:49:42	
<input type="checkbox"/> QF Pat_20120417_0959	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 09:59:57	
<input type="checkbox"/> QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:09:08	
<input type="checkbox"/> QF Pat_20120417_1022	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:22:48	

B

Start approval

## Row selector

The row selector  is a tool select and deselect assays in the assay selection table.

Single assays are selected by activating the check box  of the corresponding experiment. Use multiple check boxes to select multiple assays.

Clicking the row selector highlights the current row in dark blue. The row selector icon changes:

 Deactivated row selector

 Activated row selector

To highlight adjacent rows, click the first element's row selector, hold down the left mouse button, and move the cursor to the last element to be highlighted. All rows in between are highlighted. Use the **Control** key to make multiple selections of non-adjacent rows.

## Context menu

The context menu of the row selector is used to select or deselect the highlighted assay.

Select


Deselect

Invert selection




Cancel

Label/title	Description
<b>Select</b>	Activates the check box for all highlighted assays.
<b>Deselect</b>	Deactivates the check box for all highlighted assays.
<b>Invert selection</b>	Inverts the status of the check box for all highlighted assays, i.e., selected assays are unselected and vice versa.
<b>Cancel</b>	Closes the context menu.

#### Assay selector check box

The assay selector check box  is used to select the assays to be approved. To select all assays for the approval process, activate the check box in the column header (A).

The column select icon changes according to the number of selected assays:

-  No assay selected
-  One or more assay(s) selected, but not all
-  All assays selected

#### **Experiment** column

The **Experiment** column has the name defined before starting the run.

#### Assay validity

This column shows the validity status of an assay.

This field is empty if the assay is valid.

If an assay is invalid, this is indicated by a warning  icon

The reason for an invalid status is indicated in a tooltip.

Label/title	Description
<b>Run failed</b>	A problem with the cyclor or the cyclor connection.
<b>Run stopped</b>	A run was stopped manually.

Label/title	Description
<b>Assay invalid</b>	Invalid external controls can lead to an invalid assay. For details refer to the detailed analysis.
<b>Analysis failed</b>	Various reasons. Contact QIAGEN Technical Services.

### Assay

The **Assay** column has the full name of the assay(s) used for this experiment.

### # samples

This column contains the number of samples.

### Operator

This is the operator's name.


### Run date

This is the run date of the experiment.

### Status column

This column indicates the release status of the experiment.

If this field is empty, no samples from this assay have been released yet.

If not all samples have been released, this assay has the status **Partially released**. This is indicated by the  icon.

If an assay is locked, the column shows a lock  icon.

### Start approval button

Click the **Start approval** button to start the approval process of the selected assays. This button is enabled if at least one assay is selected.

By clicking this button, the **Approval** screen is displayed. All selected assays get the status **Locked**.

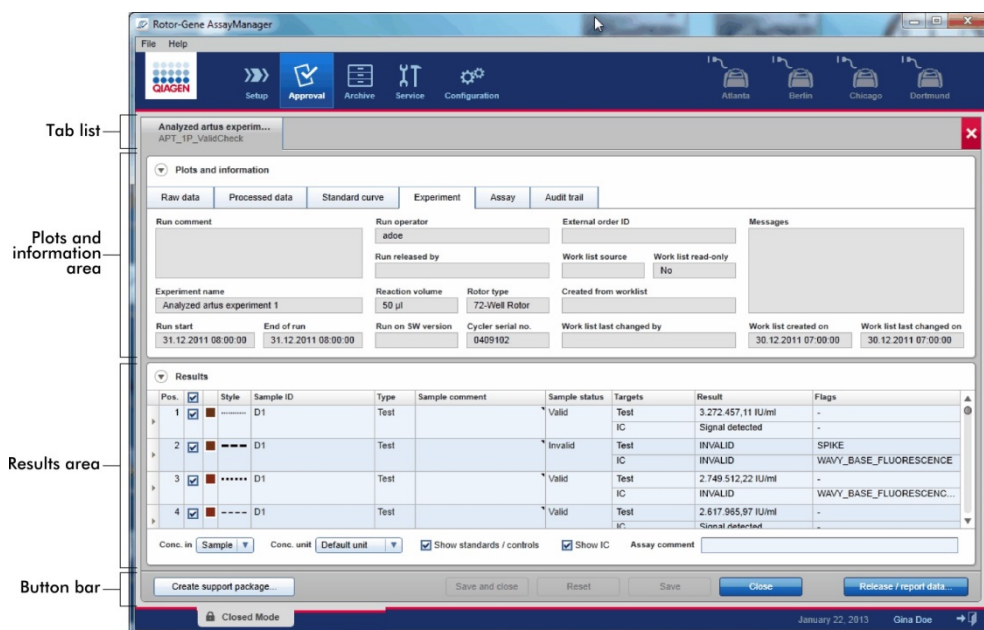
## Approval screen

**Note:** The approval appearance of the approval screen may be different depending on the plug-in of the assay used. For details regarding different approval procedures, refer to the corresponding Rotor-Gene AssayManager plug-in user manuals.

The **Approval** screen is used to:

- Check the result of an assay
- Release an experiment and create a report
- Create a support package to facilitate support in case of problems


The results of the samples of the previously selected assay can be reviewed and have to be finally released. A released assay will no longer be available in the **Approval** environment. This assay will be moved to the **Archive** environment (see "Archive environment", page 678).



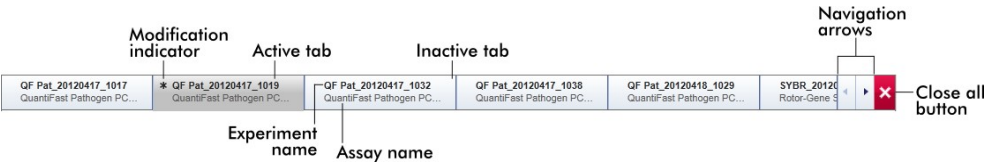
The **Approval** screen consists of the following 4 areas:

Area	Functionality/tasks
Tab list	<p>All assays selected in the previous step are displayed in the tab list. This allows the user to work on multiple assays simultaneously.</p> <p>In case the screen space is insufficient to fit all assays, navigation arrows are added to the tab list</p>
<b>Plots and information area</b>	<p>This area contains various data about an experiment.</p> <p>This area is subdivided in up to 6 separate tabs (depending on the selected assay and the currently used plug-in).</p>
<b>Results area</b>	<p>This area contains details about the samples.</p>
Button bar	<p>This area contains buttons to save, close, reset, and finally release the selected sample results of the assay.</p>

**Tab list**

All assays chosen for approval in the previous **Assay selection** step are listed in the tab list. Every selected assay is displayed as a tab with the experiment name and the assay name in the tab header. The currently active tab is highlighted gray. The inactive tab(s) are light blue. If an experiment contains unsaved modifications, this will be indicated by a  symbol beside the experiment name.

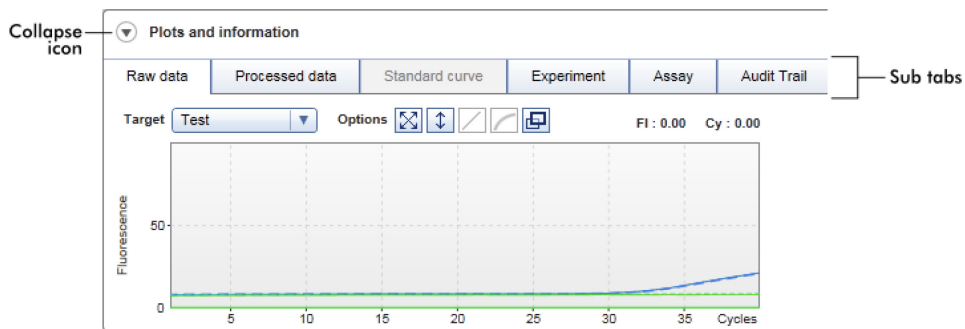
A tab is closed by clicking the **Close** button in the button bar. The red close button at the very right of the tab list is used to close all tabs. In case the screen size is not sufficient to display all assay tabs, a left and right arrow symbol is displayed to navigate between the tabs.



**Plots and information area**

The **Plots and information area** is subdivided into sub tabs:





### **Raw data**

### **Processed data**

### **Standard curve**

These tabs are graphic focused.

They show amplification plots of raw and processed data as well as the standard curve, respectively (depending on the selected assay and the currently used plug-in).

### **Experiment**

### **Assay**

These tabs are data focused.

They show detailed data about the experiment and the assay.

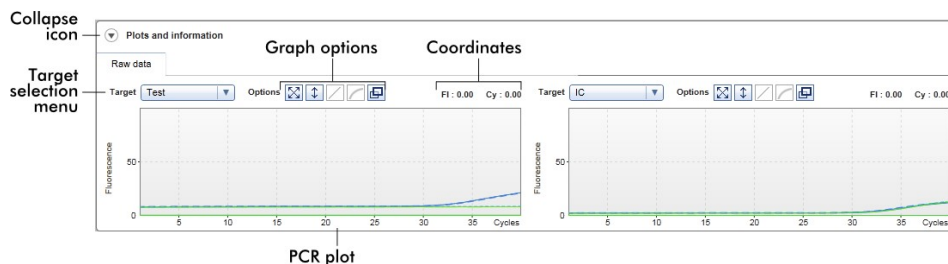
### **Audit Trail**







This tab shows all actions that are recorded on the audit trail.

**Note:** The collapse icon (▼) is used to collapse the **Plots and information** or the **Results** area to gain screen space for the other area. If an area is collapsed to a single row, the icon changes to ► for expanding the area back to the default size.

### **Raw data sub tab**

The **Raw data** sub tab displays a plot of the fluorescence measured during the assay run. The line styles and colors used in the plots are defined during the creation of the corresponding assay profile. The availability of raw data depends on the currently used plug-in.



Icon	Label/title	Description
	"Collapse" icon	Collapses the <b>Plots and information</b> or the <b>Results</b> area to gain screen space for the other area.
	<b>Target</b> selection menu	Selects the target source used for the corresponding plot.
	Graph option	This button resets the scale of the y-axis (visualization of the fluorescence) from 0 to 100 fluorescence units. The x-axis is set to a maximum value equal to the number of cycles in the run profile.
	Graph option	The auto-scale button attempts to fit the scale of the y-axis to the maximum and minimum readings in the data. The x-axis is set to a maximum value equal to the number of cycles in the run profile.
	Graph option	Disabled in <b>Raw data</b> sub tab.
	Graph option	Disabled in <b>Raw data</b> sub tab.
	Graph option	Clicking the <b>Full screen</b> button enlarges the amplification plot to maximum size. Clicking it again will scale down the amplification plot back to normal size.
	Coordinates	Shows the coordinates of the mouse pointer (cross hairs) in the amplification plot area in the amplification plot. First, the fluorescence value

Icon	Label/title	Description
		<p>on the y-axis is displayed, followed by the cycle value on the x-axis.</p> <div style="text-align: center;"> <div>Fl : 28.80    Cy : 5.36</div> <div>Fluorescence    Cycle</div> <div>value            value</div> </div> <p>Coordinates are displayed only if the cursor is over the amplification plot. Otherwise the coordinate values are set to 0.</p>

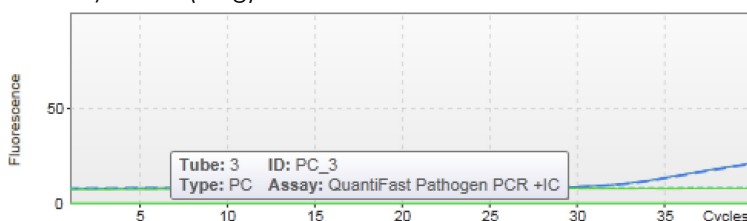
### Behavior of the plot area

When the mouse is hovered over the amplification plot, the cursor changes to cross hairs (⊕).

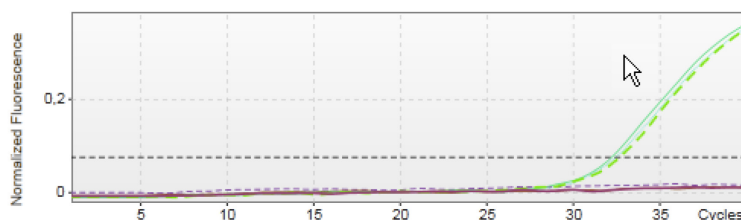
The current position of the mouse cursor over the amplification plot is displayed in real time in the coordinates field.

Hovering with the mouse over the amplification curve of a specific sample opens a tooltip displaying the following information:

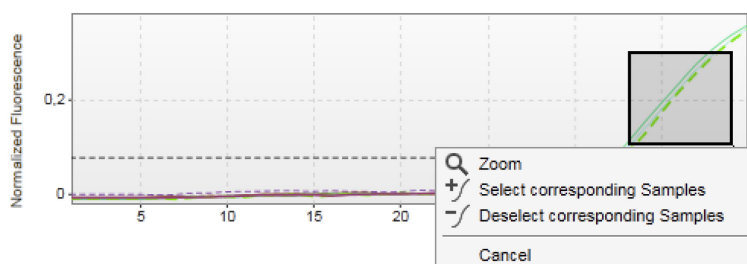
- Tube number
- Sample ID
- Sample type
- Assay name (long)



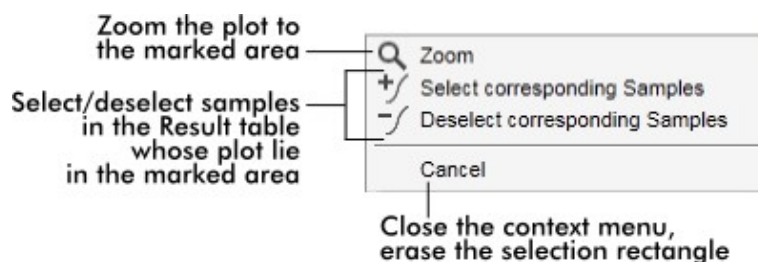
An area of the amplification plot can be selected by clicking and holding the left mouse button and dragging the mouse pointer. A context menu with several options appears.



Hold down the left mouse button and drag the mouse to the end point.



Functions of the context menu



**Note:** Navigation in a zoomed amplification plot




By right-clicking and holding down the mouse button the cursor changes to a hand symbol (🖱️). The plot area can be scrolled in all directions by moving the mouse. Double-click anywhere in the amplification plot area to reset the zoom to 100%.

### **Processed data** sub tab

The availability of processed data depends on the currently used plug-in. The **Processed data** sub tab has the same elements and the same behavior as the **Raw data** sub tab with only a few differences:

- The raw fluorescence data are normalized using the internal algorithm of Rotor-Gene AssayManager according to the settings of the corresponding assay profile.
- The graph options are partially different.

The following table describes only the differences to the **Raw data** sub tab.

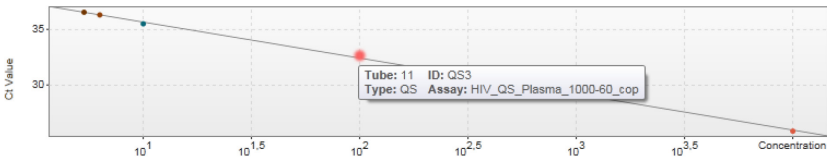
Icon	Label/title	Description
	Graph option	Disabled in <b>Processed data</b> sub tab.
	Graph option	By clicking the <b>Linear scale</b> button, the amplification plot is displayed using a linear scale. If this option is selected, the <b>Linear scale</b> button is highlighted in dark blue color.
	Graph option	By clicking the <b>Logarithmic scale</b> button, the amplification plot is displayed using a logarithmic scale. If this option is selected, the <b>Logarithmic scale</b> button is highlighted in dark blue.

**Standard curve** sub tab

The **Standard curve** sub tab displays the standard curve as a result of plotting the C<sub>T</sub> values of the quantitation standards on the y-axis against their concentration on the x-axis.

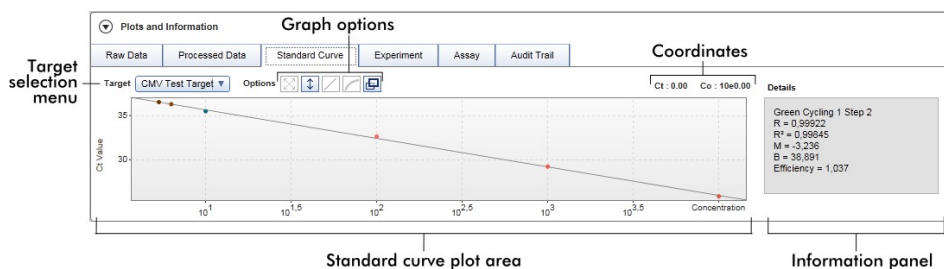
For easy identification, the color of the data points corresponds with the style for the individual samples selected in the assay profile. Additionally, hovering with the mouse over the data point of a specific sample opens a tooltip displaying the following information:

- Tube number
- Sample ID
- Sample type
- Assay name (long)



**Note:** The standard curve is only available for quantitative assays and certain plug-ins.

The **Plots and information** area consists of a standard curve plot area where the curve is displayed, and an information panel with statistical information about the curve.



### Standard curve plot area

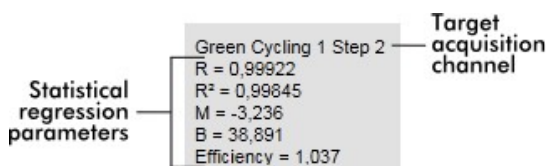
The layout is similar to the **Raw data** and **Processed data** sub tabs:

- A drop-down menu to select the target
- Graph option buttons to manage the plot
- A coordinates field

The coordinates field displays C<sub>T</sub> and concentration values of the current cursor position in the plot.

### Information panel

The information panel provides information about the acquisition channel and statistical parameters describing the parameter values of the regression analysis:



The statistical regression parameters are described in the following table.

Parameter	Explanation
R	Root extracted from R <sup>2</sup>
R <sup>2</sup>	The correlation coefficient R <sup>2</sup> is a statistical parameter to measure the fit of the data points to the regressed line. In general, the standard curve should have an R <sup>2</sup> value = 0.990. However, the individual limit for this value can be set during assay profile creation.

Parameter	Explanation
M	Slope of curve.
B	Curve offset.
Efficiency	Describes the amplification efficiency in a PCR.

### Experiment sub tab

The **Experiment** sub tab provides detailed information about the experiment.

Plots and information

Raw data
Processed data
Standard curve
**Experiment**
Assay
Audit Trail

Run comment

Run operator  
su

External order ID

Messages

Run released by

Work list source  
QIAAsymphony

Work list read-only  
Yes

Experiment name  
QF Pat\_20120417\_0949

Reaction volume  
25

Rotor type  
72-Well Rotor

Created from worklist  
WL\_20120417\_0856\_su

Run start  
17.04.2012 09:49:42

End of run  
17.04.2012 09:52:17

Run on SW version  
0.8.6.2

Cycler Serial No.  
0112101

Work list last changed by  
su

Work list created on  
17.04.2012 08:58:58

Work list last changed on  
17.04.2012 08:58:58

### Assay sub tab

The **Assay** sub tab provides detailed information about the selected assay.

Plots and information

Raw data
Processed data
Standard curve
Experiment
**Assay**
Audit Trail

Assay profile name  
Quantifast Pathogen PCR +IC

# standards and controls  
6

Material number

Short name  
QF Pat

# test samples  
66

Kit expiry date  
01.10.2013

Version  
2.0.0

Reserved rotor positions  
72

Kit lot number  
138264899

### Audit trail sub tab

The **Audit trail** sub tab contains detailed information about any substantial events of the experiment in adjacent order.

An example is shown.

Plots and information				
Raw data	Processed data	Standard curve	Experiment	Audit Trail
Date and time	User ID	Message ID	Message	Signed
11.05.2012 09:31:22	su	540015	Approval: Experiment-634716579113812101 assay Quantifast Pathogen PCR +IC sample PC_1 in tube position 1 state set from Undefined to Accepted.	
11.05.2012 09:31:22	su	540015	Approval: Experiment-634716579113812101 assay Quantifast Pathogen PCR +IC sample PC_2 in tube position 2 state set from Undefined to Accepted.	

### Results table

All samples and external controls are listed in separate rows of the results table. If a sample has multiple targets, the row is further split and the results of every individual target are displayed.

**Note:** The appearance of the results table may be different depending on the plug-in currently used. For details, refer to the corresponding Rotor-Gene AssayManager plug-in user manual.

Results table

Results table options


Pos.	<input checked="" type="checkbox"/>	Style	Sample ID	Type	Sample comment	Sample status	Targets	Result	Flags
1	<input checked="" type="checkbox"/>	-----	D1	Test		Valid	Test	3.027 268.90 IU/ml	-
2	<input checked="" type="checkbox"/>	-----	D1	Test		Invalid	IC	Signal detected	-
3	<input checked="" type="checkbox"/>	-----	D1	Test		Invalid	Test	INVALID	UPSTREAM_SPIKE_OTHER_T...
4	<input checked="" type="checkbox"/>	-----	D1	Test		Invalid	IC	INVALID	UPSTREAM_WAVV_BASE_FL...
5	<input checked="" type="checkbox"/>	-----	D1	Test		Invalid	Test	INVALID	UPSTREAM_OTHER_TARGET...
6	<input checked="" type="checkbox"/>	-----	D1	Test		Invalid	IC	INVALID	UPSTREAM_WAVV_BASE_FL...
7	<input checked="" type="checkbox"/>	-----	D1	Test		Valid	Test	2.429 148.62 IU/ml	-
8	<input checked="" type="checkbox"/>	-----	D1	Test		Invalid	IC	Signal detected	-

Cons. in:  Cons. unit:  ☒ Show IC ☐ Set assay to be valid Assay comment:

The **Results** table contains the following columns.

#### Row selector

The row selector  enables the user to select and deselect samples in the results table.

Selecting single samples is simply done by activating the check box  of the corresponding sample. Use the row selector to select multiple samples.

Clicking the row selector highlights the current row and the row selector icon changes. The highlighted row will be colored in dark blue.



Deactivated row selector



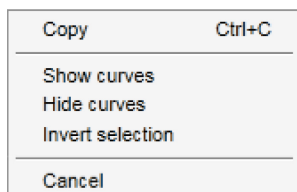
Activated row selector

To highlight adjacent rows, click the first element's row selector, hold down the left mouse button, and move the cursor to the last element to be highlighted. All rows in between are highlighted. Use the **Control** key to make multiple selections of non-adjacent rows.

#### Context menu

The context menu of the row selector is used to select or deselect the highlighted assay.





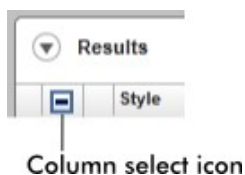
Label/title	Description
<b>Copy</b>	Copies the content of the selected rows to the clipboard (the individual cells are separated by tab characters, the row start is characterized with a carriage return).
<b>Show curves</b>	Shows the curves of the selected samples in the amplification plot.
<b>Hide curves</b>	Hides the curves of the selected samples in the amplification plot.
<b>Invert selection</b>	Inverts the row selection.
<b>Cancel</b>	Closes the context menu.

#### Graph selector check box

The graph selector check box ☐ is used to show or hide the amplification curve of the selected sample.

- ☐ Hide the amplification curve of the sample.
- ☒ Show the amplification curve of the sample.

The column select icon changes according to the number of selected samples.



- ☐ No sample selected
- ☒ One or more sample(s) selected, but not all



All samples selected

Click the column select icon to easily select or deselect all samples.

#### *Line color and line style*

These columns are used to display the line color and style of the PCR amplification curve used for the sample.

#### *Sample ID*

This column displays the sample ID of the sample (as defined during work list setup).

#### *Sample comment*

A comment can be entered for every sample. A maximum of 256 characters is allowed. Comments already entered during work list setup are shown.

#### *Sample status*

This is the status of the sample after analysis. Possible values are:

- Valid
- Invalid

#### *Targets*

The targets column displays all targets related to the sample. The sample row is split, and every target is displayed in a separate row.

#### *Result*

This column contains the Rotor-Gene AssayManager target evaluation result. Possible results are:

- Concentration value including a concentration unit
- Signal detected
- No signal
- Invalid

#### *Flags*

Flags are exceptions identified by Rotor-Gene AssayManager analysis. Possible flags are listed in the corresponding Rotor-Gene AssayManager plug-in user manual.

## Results table options

**Note:** The **Results** table options differ from plug-in to plug in. Refer to the relevant plug-in manual for details.


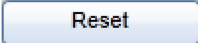



Conc. in  Conc. unit  ☒ Show standards / controls ☒ Show IC Assay comment

Results table options are described in the following table.

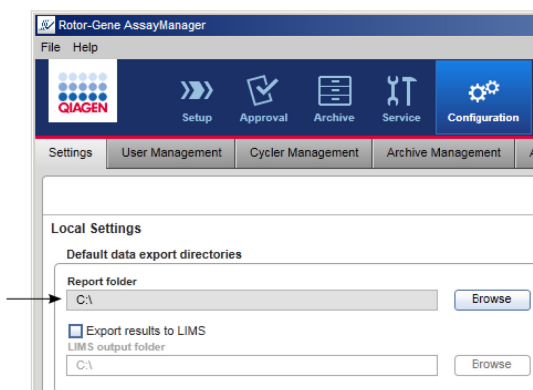
Option	Explanation
Conc. in <input type="button" value="Sample"/>	Depending on the selection in this drop-down list, the detected concentration will automatically be calculated for the eluate or the original sample material (before sample preparation). This function is only available for quantitative assays with a conversion factor defined in the assay profile.
Conc. unit <input type="button" value="Default Unit"/>	If several concentration units are defined in the assay profile, this menu is populated with the default concentration unit and alternative concentration units. The desired concentration unit can be selected from this drop-down list.
<input checked="" type="checkbox"/> Show standards / controls	Show/hide the display of standards/controls in the <b>Results</b> table.
<input checked="" type="checkbox"/> Show IC	By default, this check box is activated if an assay contains a target of type IC. Deactivate the check box to hide the IC specific results (target name, C <sub>T</sub> value, result, and result flag) from the <b>Results</b> table.
Assay comment <input type="text"/>	Text field to enter a comment about the assay.  Comment must not exceed 256 characters. After the first sample has been released, the comment cannot be changed.

## Button bar

**Note:** The available functions in the button bar differ from plug-in to plug-in. Refer to the relevant plug-in manual for details.

Title/label	Explanation
	Saves all changes and closes the current assay.
	Discards all unsaved changes.  <b>Note:</b> Visualization options, such as <b>Show IC</b> , check boxes of samples, etc., are not changed.
	Saves all changes; remains in this dialog.
	Closes the selected experiment. If there are unsaved changes, a warning will be displayed.
	Opens a dialog to release test results and create a report. The status of the assay is set to "Fully released".

A \*.pdf report file is saved in the folder defined in the **Configuration** environment, under **Settings/Local Settings/Folders for exporting/Report** folder.



#### 5.5.4 **Archive** environment

The **Archive** environment is used to search for released assays and to generate experiment reports.

**Note:** Filtering in the **Archive** environment is limited to the currently active archives. Inactivated archives are not included in the filtering. Different archives can be activated or deactivated using the **Archive Management** tab in the **Configuration** environment.

The **Archive** and the **Approval** environments have very similar layouts.

**Note:** After finishing, the status of an assay can be one of the following:

- Unreleased: assay has not been released yet
- Fully released: assay has been released

Unreleased experiments can be accessed in the **Approval** environment.

Fully released experiments can be accessed in the **Archive** environment.

The main tasks (searching and reporting data) are carried out in two different screens:

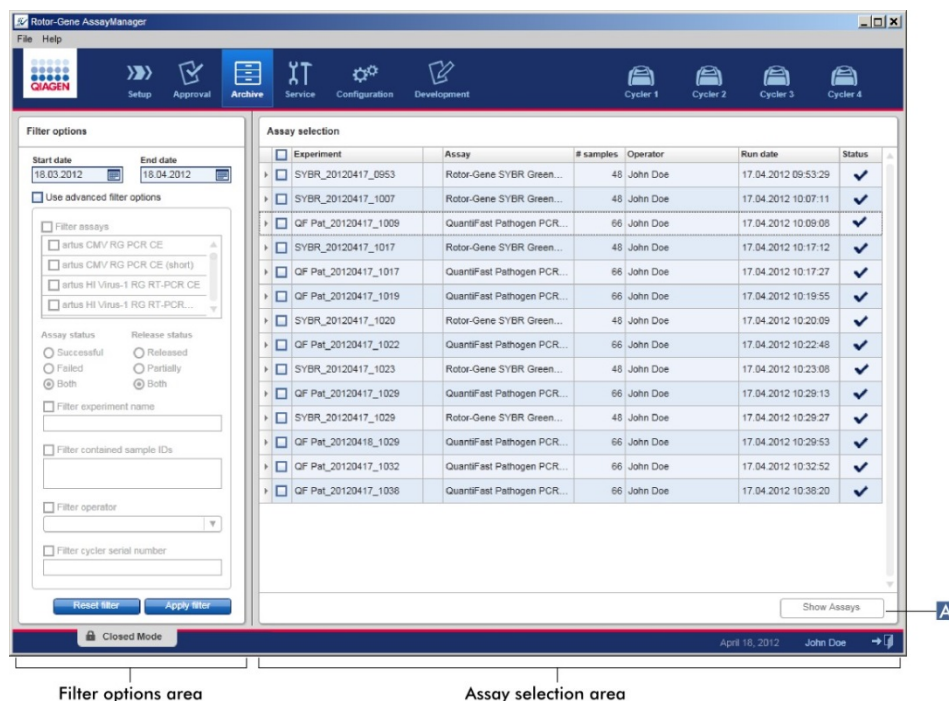
- Filter options and assay selection screen
- Showing assays screen

## Filter Screen

The **Filter** screen is used to search for and select partially or fully released experiments. The layout and behavior is identical to the **Filter** screen of the **Approval** environment. The only differences are:

Only experiments with status "Fully Released" are shown

The **Show assays** button (A) is shown instead of the **Start approval** button



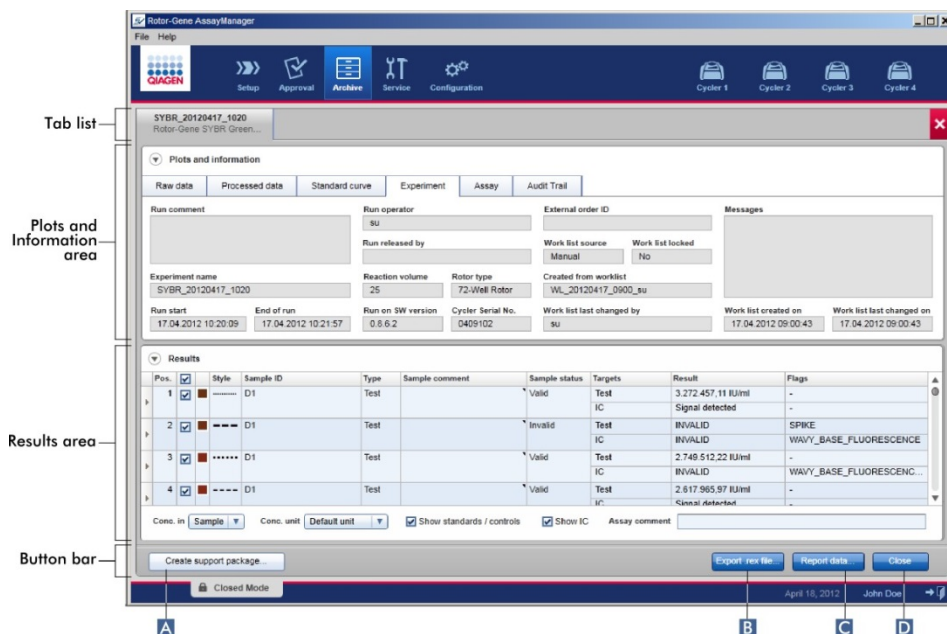
For details about the functionality of the **Filter** screen, see “**Approval environment**”, page 657.

## Show Assays screen

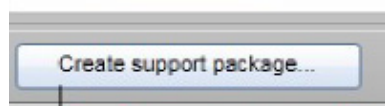
The **Show Assays** screen of the **Archive** environment is used for the following tasks:

- Check experiment data of fully released experiments
- Create a support package to facilitate support in case of problems
- Print reports as \*.pdf file

The layout of this screen is very similar to the Approval screen in the **Approval** environment. Some functions are disabled here, for example the approval buttons in the results table as well as the assay comment field. Released assays cannot be modified.



### Button bar functions

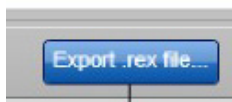


Rotor-Gene AssayManager has a built-in support function. In case problems with a specific experiment occur, a support package can be generated. This file can be sent via email to QIAGEN Technical Services.

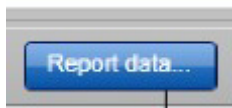
The name of the generated support package has the format: **<Experiment name>\_<Assay name>\_<Timestamp>.zip**

Click **Create support package** (A), to generate the support package. A save file dialog is opened to select the target directory for the support package.

The default directory for saving the support package file is set in the **Configuration** environment under the **Settings** tab in the support packages option.



The **Export .rex file** button (B) exports raw data of all assays from an experiment to a \*.rex file. This button is only enabled if all assays of the experiment are completely released.



The **Report data** button (C) creates a report of the experiment as a \*.pdf file.



The **Close** button (D) closes the **Show Assays** screen and returns to the **Filter** screen of the **Archive** environment.

---

### 5.5.5 **Service** environment

The **Service** environment contains the **Audit Trail** tab.

#### **Audit Trail tab**

The audit trail is a record of all user actions. All actions are traced in the audit trail and can be filtered and printed out. The Rotor-Gene AssayManager audit trail is designed to support compliance with FDA CFR Title 21, Part 11 Electronic Records, Electronic Signatures.

All activities of a user are logged in an audit trail categorized in 8 different contexts:

- Installation
- User
- Session
- Profile
- Settings
- Cyclor
- Work list
- Experiment

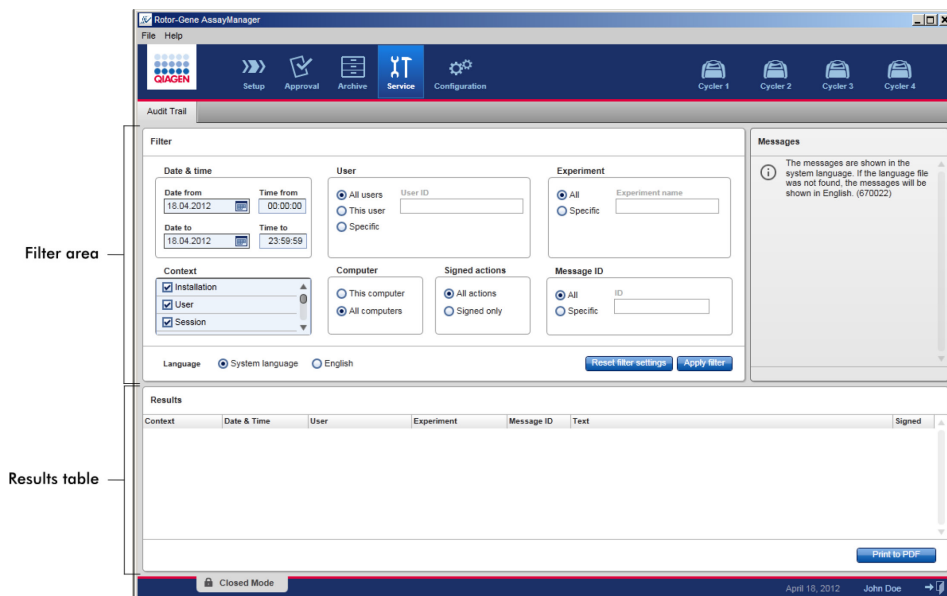
The content of the audit trail can be accessed using the **Service** environment. Here, various filter criteria can be selected and applied. The **Audit Trail** tab contains 2 areas:

- **Filter** area
- **Results** table

There is a **Print to PDF** button

The user defines filter criteria in the **Filter** area and applies the filter. All entries in the audit trail matching the filter criteria will be listed in the **Results** table.





The content of the matching entries in the **Results** table are not editable; the table cannot be sorted. It is possible to select a row and copy the content to the clipboard using the **CTRL+ C** shortcut.

A \*.pdf report file of the matching entries can be generated by clicking the **Print to PDF** button.

## Filter area

The features of the **Filter** area are described in the following table.

Filter	Explanation
<b>A</b>	
<b>Date &amp; time</b>	Enter a date in the <b>Date from</b> and <b>Date to</b> fields either manually or using the date picker. Enter a time in the <b>Time from</b> and <b>Time to</b> fields.
<b>B</b>	
<b>User</b>	
<b>All users</b>	Activate to filter for all users.
<b>This user</b>	Activate to filter for the current user.
<b>Specific</b>	Activate and enter a user ID in the <b>User ID</b> field.
<b>C</b>	
<b>Experiment</b>	
<b>All</b>	Activate to filter for all experiments.
<b>Specific</b>	Activate and enter a name in the <b>Experiment name</b> field.
<b>D</b>	
<b>Context</b>	<p>Select a context to filter for from the <b>Context</b> menu by activating the corresponding check box. Multiple selections are possible. By default all check boxes are activated.</p> <div> <input checked="" type="checkbox"/> Installation         <input checked="" type="checkbox"/> User         <input checked="" type="checkbox"/> Session         <input checked="" type="checkbox"/> Profile         <input checked="" type="checkbox"/> Settings         <input checked="" type="checkbox"/> Cyclor         <input checked="" type="checkbox"/> Worklist         <input checked="" type="checkbox"/> Experiment       </div>

Filter	Explanation
<b>E</b>	
<b>Computer</b>	If Rotor-Gene AssayManager is installed in a network on multiple computers, this setting allows filtering for a specific computer name. In a single computer installation environment, this setting is less useful.
<b>This computer</b>	Activate to filter for the computer in use.
<b>All computers</b>	Activate to filter for all computers.
<b>F</b>	
<b>Signed actions</b>	The administrator can define in the <b>Settings</b> tab of the <b>Configuration</b> environment that the release of a run and the release of test results have to be signed (see Signing release of a run option, page 693, and Signing release of test results option, page 696). This filter option is used to filter for signed actions only.
<b>All actions</b>	Activate to filter for all actions.
<b>Signed only</b>	Activate to filter for signed actions only.
<b>G</b>	
<b>Message ID</b>	
<b>All</b>	Activate to filter for all messages.
<b>Specific</b>	Activate to filter for specific message(s) and enter a message ID in the <b>Message ID</b> field.
<b>H</b>	
<b>Language</b>	Select a language.
<b>I</b>	
<b>Reset filter settings</b>	Reset the <b>Filter</b> settings to the default values (see below).

Filter	Explanation
<b>J</b>	
<b>Apply filter</b>	Apply the selected filter criteria. All entries in the audit trail matching the filter criteria are listed in the results table.

The default values and selections for the **Filter** area are as follows:

Filter	Default setting
<b>Date from</b>	Current date
<b>Date to</b>	Current date
<b>Time from</b>	00:00:00
<b>Time to</b>	23:59:59
<b>User</b>	<b>All users</b> activated
<b>Computer</b>	<b>All computers</b> activated
<b>Signed actions</b>	<b>All actions</b> activated
<b>Message ID</b>	<b>All</b> activated
<b>Experiment</b>	<b>All</b> activated
<b>Context</b>	All check boxes are selected

## Results table

The **Results** table lists all entries in the audit trail matching the filter criteria.

Results						
Context	Date & Time	User	Experiment	Message ID	Text	Signed
Session	18.04.2012 08:00:02	John Doe (su)		1030012	su logged in successfully in User Defined Test mode.	
Experiment	18.04.2012 09:11:31	John Doe (su)	QF Pat_20120417_...	540015	Approval: Experiment QF Pat_20120417_1019 assay QuantiFast Pathogen PCR +IC sample 1 in tube position 4 state set from Undefined to Accepted.	
Experiment	18.04.2012 09:11:31	John Doe (su)	QF Pat_20120417_...	540015	Approval: Experiment QF Pat_20120417_1019 assay QuantiFast Pathogen PCR +IC sample 10 in tube position 13 state set from Undefined to Accepted.	
Experiment	18.04.2012 09:11:31	John Doe (su)	QF Pat_20120417_...	540015	Approval: Experiment QF Pat_20120417_1019 assay QuantiFast Pathogen PCR +IC sample 11 in tube position 14 state set from Undefined to Accepted.	
Experiment	18.04.2012 09:11:31	John Doe (su)	QF Pat_20120417_...	540015	Approval: Experiment QF Pat_20120417_1019 assay QuantiFast Pathogen PCR +IC sample 12 in tube position 15 state set from Undefined to Accepted.	

The contents of the matching entries in the **Results** table are not editable, and the table cannot be sorted. It is possible to select a row and copy the content to the clipboard using **CTRL + C**.

Columns of the **Results** table are described in the following table.

Column	Description
<b>Context</b>	Context of the entry  Possible values are: <ul style="list-style-type: none"> <li>● Installation</li> <li>● User</li> <li>● Session</li> <li>● Profile</li> <li>● Settings</li> <li>● Cyclor</li> <li>● Work list</li> <li>● Experiment</li> </ul>
<b>Date &amp; Time</b>	Date and time
<b>User</b>	Name of the user logged in the audit trail
<b>Experiment</b>	Name of the experiment logged in the audit trail
<b>Message ID</b>	ID of the message
<b>Text</b>	Text of the audit trail message
<b>Signed</b>	Indication if the audit trail entry is signed or not

**Print to PDF** button



Print the audit trail messages to a \*.pdf file.

#### Tasks related to the Service environment

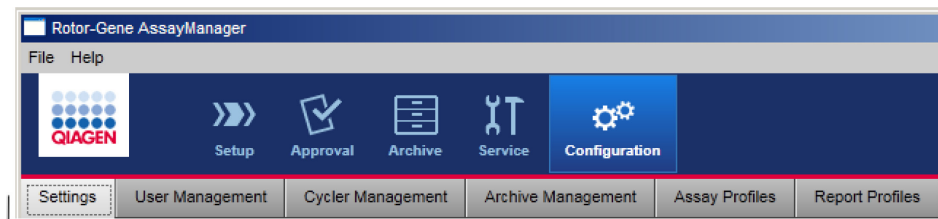
"Working with audit trails", page 756

#### 5.5.6 Configuration environment

The settings of Rotor-Gene AssayManager can be adjusted in the "Configuration" environment. Furthermore, different users, cyclers, archives, assay profiles, and report profiles can be managed.

**Note:** Only users with the role “Administrator” can access this environment.

The Configuration environment is organized in 6 different tabs.



Configuration environment is organized in six tabs

The following table shows the tabs and their assigned roles.

Tab	Assigned tasks
<b>Settings</b>	<ul style="list-style-type: none"><li>● Define global settings</li><li>● Define local settings</li></ul>
<b>User Management</b>	<ul style="list-style-type: none"><li>● Add user</li><li>● Edit user data</li><li>● Modify user roles</li><li>● Change password</li><li>● Activate/deactivate user</li></ul>
<b>Cycler Management</b>	<ul style="list-style-type: none"><li>● Set up new cyclers</li><li>● Remove cyclers</li><li>● Enter next verification date</li></ul>
<b>Archive Management</b>	Activate/deactivate archives
<b>Assay Profiles</b>	<ul style="list-style-type: none"><li>● Activate/deactivate assay profiles</li><li>● Import assay profiles</li></ul>
<b>Report Profiles</b>	<b>Note:</b> FDA cleared or approved nucleic acid tests provide a fixed content and layout for the report. Report profiles are not applicable.

#### Tasks related to the Configuration environment

“Administrative tasks”, page 757

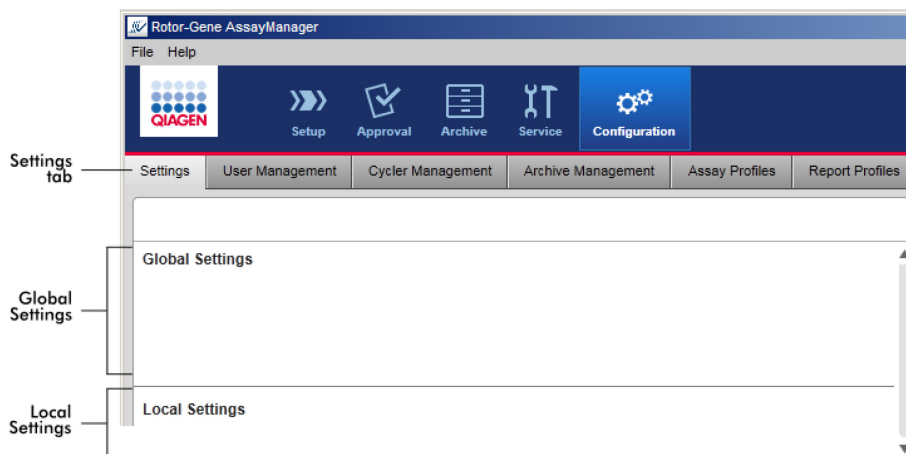
## Settings tab

The **Settings** tab is divided in two areas:

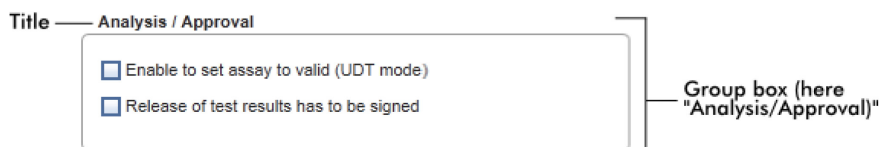
- **Global Settings**
- **Local Settings**

**Global Settings** are stored in the database. They are "global" for all clients connected to the database.

**Local Settings** are only applied to the currently used computer.



**Note:** Thematically associated settings are bundled in group boxes. Every group box has a title.



## Global Settings area

Miscellaneous settings are defined in the global settings. These are bundled in 7 group boxes.

**Global Settings**

**Experiment A**

☐ Use work list name

☒ Select pattern

Format of generated experiment names

AS1\_AS2\_AS3\_20110513\_0430

User-definable section

☒ Assay profile short names

☒ Date

☒ Time

☐ Operator

**Work list D**

Format of generated work list names

WL\_20110513\_0430\_Operator

User-definable section

WL

☒ Date

☒ Time

☒ Operator

☐ Enable processing of unclear samples

☒ Enable checksum for LIMS import

Closed mode

☐ Material number required

☐ Valid expiry date required

☐ Lot number required

UDT mode

☐ Material number required

☐ Valid expiry date required

☐ Lot number required

**Finish run B**

☐ Run has to be released before starting approval

☐ Release of run has to be signed

**Analysis / Approval E**

☐ Enable to set assay to valid (UDT mode)

☐ Release of test results has to be signed

**Reporting C**

Page header image

No Image Configured

Report concluding image

No Image Configured

**Cycler verification management F**

☐ Disable unverified cyclers

**User management G**

Password renewal interval

30 days

☒ Use CLIA compliant password rules

Auto-lock timer

30 minutes

The group boxes are:

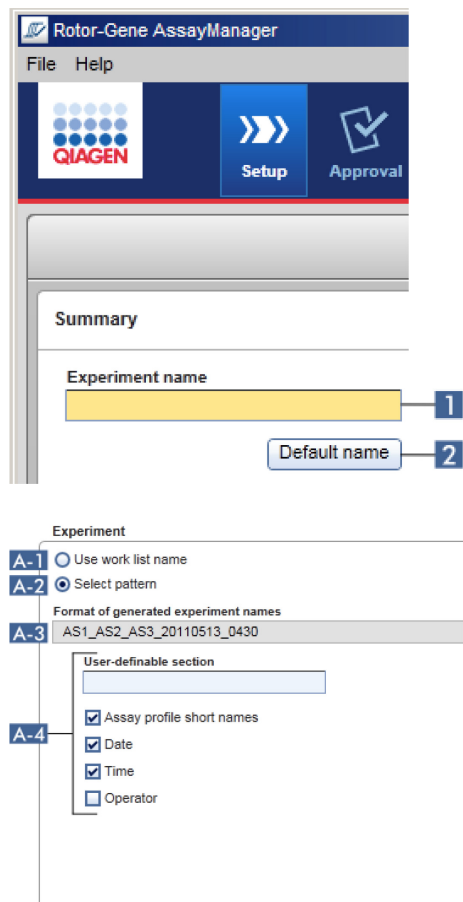
- **Experiment (A)**
- **Finish run (B)**
- **Reporting (C)**
- **Work list (D)**
- **Analysis/Approval (E)**
- **Cycler verification management (F)**
- **User management (G)**

#### Group box **Experiment**

The settings in the **Experiment** group box define the default naming scheme for experiments. To apply a work list, an experiment name must be entered. The user can either enter an arbitrary name in the **Experiment name** field (1), or let Rotor-Gene



AssayManager automatically generate a default name by clicking **Default name** (2). This default name can be configured in the **Experiment** group box.



Activate **Use work list name** (A-1) to use the same name as given to the work list that is applied.

Activate **Select pattern** (A-2) to define a specific naming scheme.

The **Format of generated experiment names** field (A-3) displays the current work list name definition.

The **Format of generated experiment names** field is empty if the **Use work list name** button is selected.

☒ Use work list name  
☐ Select pattern

Format of generated experiment names

User definable string

If the **Select pattern** button is selected, the resulting experiment name is shown in this field.

☐ Use work list name  
☒ Select pattern

Format of generated experiment names

QIAGEN\_20120217\_0836

The scheme for the default name (A-4) consists of 5 options:

- **User-definable section**
- **Assay profile short names**
- **Date**
- **Time**
- **Operator**

Activating the check box in front of the last 4 options includes these in the experiment name. The options are separated by a “\_” (underscore) character in the experiment name. A user definable section with a maximum of 15 characters is entered directly in the corresponding field. The order of the individual information cannot be changed. If a user definable section is entered, the resulting experiment name will always start with this section.

Rotor-Gene AssayManager is delivered with the following default settings:

Format of generated experiment names

Exp\_AS1\_AS2\_AS3\_20120327\_1359

User-definable section

Exp

☒ Assay profile short names  
☒ Date  
☒ Time  
☐ Operator

The text in the field **Format of generated experiment names**, here **Exp\_AS1\_AS2\_AS3\_20120327\_1359**, results from:

- Exp: the input in the **User definable section**
- AS1\_AS2\_AS3: the **Assay profile short names**
- 20120327: the current date
- 1359: the current time

#### Group box **Finish run**

The user can set this option for finishing a run:

- If a user must release a run before the approval can be started
- If a user must sign the run release by entering the password

**Finish run**

**B-1** ☐ Run has to be released before starting approval

**B-2** ☐ Release of run has to be signed

If the check box Run has to be released before starting approval (B-1) is activated the user must click **Release** (or **Release and go to approval**) after a run has finished to transfer the experiment to the **Approval** environment.

As long as an experiment is not released this way, it will not be listed in the **Approval** environment and cannot be approved.

**Finish run**

Position: ☐ ☐ ☐ ☐ Name:  Run status:

Experiment name:

Errors during run:

Comment:

Password:

User must release experiment

The check box **Release of run has to be signed** (B-2) is available only if the check box **Run has to be released before starting approval** (B-1) was activated before.

If the **Release of run has to be signed** option is activated, the **Release** and **Release and go to approval** buttons are disabled after the run has finished.

The user must sign the release by entering his password in the **Password** field. If the correct password is entered, then the **Release** and **Release and go to approval** buttons are enabled. The user can then release the experiment to the **Approval** environment.

### Group box **Reporting**

The **Reporting** group box is used to customize the layout of reports using images. This is not supported for FDA cleared or approved nucleic acid tests.

### Group box **Work list**

The **Work list** group box bundles various options concerning work lists, e.g., the naming scheme for default names, requirements for material numbers, etc.

The field **Format of generated work list names** (D-1) displays the current default work list name definition, as it results from the selected options with the **User definable section** (D-2).

The entry and selections in D-2 define the default name for manually created work lists.

**Note:** Manually creating a work list is not intended for use with FDA cleared or approved nucleic acid tests

**Note:** The **Enable processing of unclear samples** check box function (D-3) is not applicable for FDA cleared or approved nucleic acid tests.

Regardless of the selection in D-3 here, unclear samples will be handled as “invalid” samples by the plug-in and no usable results are assigned by Rotor-Gene AssayManager after the run is finished. Affected samples will get an “INVALID” flag as result.

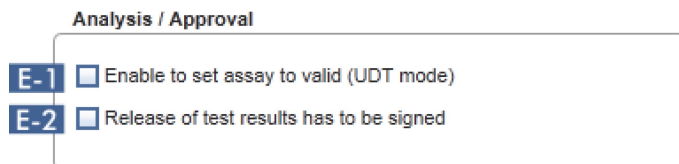
If the **Enable checksum for LIMS import** check box (D-4) is activated, the checksum algorithm is applied for work list import from a LIMS. If not activated, Rotor-Gene AssayManager does not verify the checksum of a work list to be imported from a LIMS.

If the check boxes (D-5 and D-6) in front of the options material number, kit expiry date, and the lot number in the work list group box are activated, the associated entries in the imported work lists are mandatory during work list setup. If the check boxes are not activated, the associated entries are optional.

These options can be set independently for work list setup in Closed Mode (options in D-5) and UDT Mode (options in D 6).

#### Group box **Analysis/approval**

These settings influence the **Approval** environment.



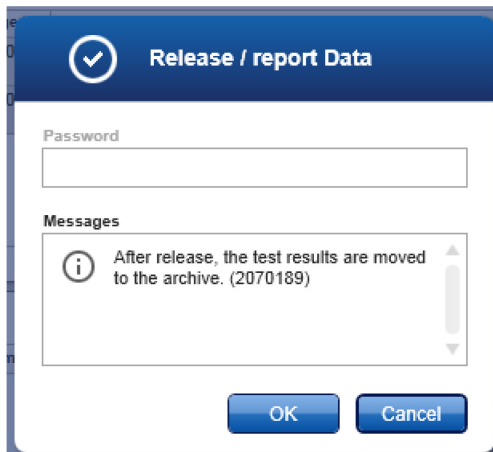
The screenshot shows a group box titled "Analysis / Approval". Inside the box, there are two settings, each with a label on the left and a checkbox on the right:

- E-1** ☐ Enable to set assay to valid (UDT mode)
- E-2** ☐ Release of test results has to be signed

The option of the check box **Enable to set assay to valid (UDT mode)** (E-1) is only available in the UDT mode and not intended for use with FDA cleared or approved nucleic acid tests.

If the check box **Release of test results has to be signed** (E 2) is activated, the release of test results in the **Approval** environment has to be signed with the approver's password.

The following examples illustrate this behavior by comparing the deactivated/activated **Release of test results has to be signed** (E 2) check box and the resulting dialog in the release step of the Approval environment.



The screenshot shows a dialog box titled "Release / report Data" with a checkmark icon in the top left corner. The dialog contains a "Password" field, a "Messages" section with an information icon and text, and "OK" and "Cancel" buttons at the bottom.

Release / report Data

Password

Messages

After release, the test results are moved to the archive. (2070189)

OK Cancel

User releases test samples simply by clicking **OK**.



The dialog box has a blue header with a checkmark icon and the text "Release / report Data". Below the header is a "Password" field with a yellow background. Underneath is a "Messages" section containing two items: a yellow pencil icon with the text "Enter your password to sign your approval electronically. (2070193)" and an information icon with the text "After release, the test results are moved to the archive. (2070189)". At the bottom are "OK" and "Cancel" buttons.

The approver's password must be entered before test samples are released.

The **OK** button is disabled by default and is activated once the correct password is entered.

#### Group box **Cycler verification management**

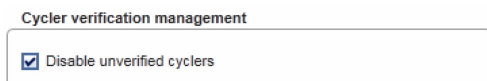


The group box is titled "Cycler verification management". It contains a label "F-1" and a checkbox labeled "Disable unverified cyclers", which is currently unchecked.

Rotor-Gene AssayManager continuously checks the status of connected cyclers concerning verification.

The option **Disable unverified cyclers** check box (F-1) determines if cyclers with a verification status past due are automatically disabled or not.

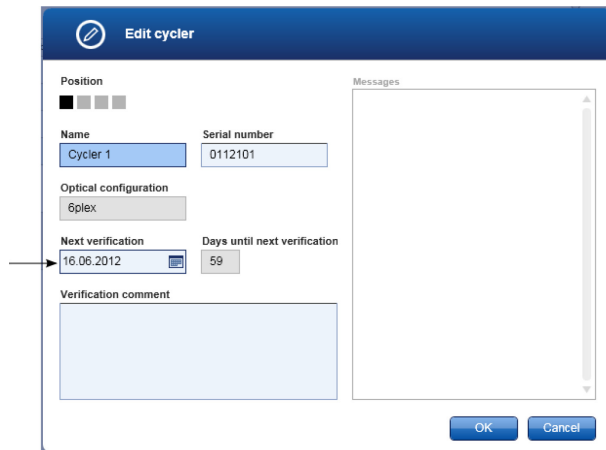
#### Check box **Disable unverified cyclers** activated



The group box is titled "Cycler verification management". It contains a checkbox labeled "Disable unverified cyclers", which is now checked.

If the verification of a cycler is already expired, the cycler's status is set to **Needs verification**. This cycler is no longer available for experiments.

To enable a cyclor again, a temperature verification needs to be performed. An administrator needs to enter a valid, future **Next verification date** in the **Edit cyclor** dialog (see arrow).



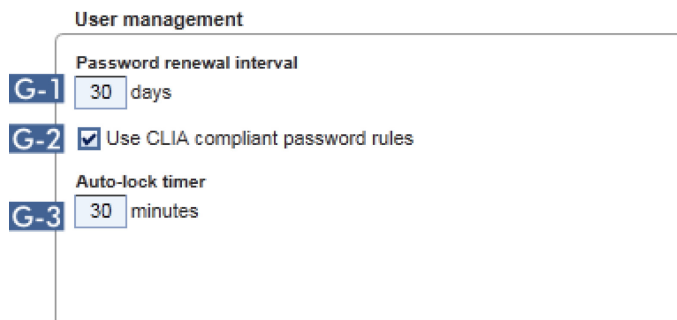
Check box **Disable unverified cyclors** deactivated



If the check box is deactivated, cyclors can be used for experiments even if the verification is already expired.

### Group box **User management**

The settings in this group box influence the password renewal interval, password rules, and the auto-lock timer.





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The **Password renewal interval** setting (G-1) defines the time interval for a renewal of user passwords. The value must be in the range of 0–999 days.

**Note:** If the value is set to 0, the password never expires.

If the **Use CLIA compliant password rules** checkbox (G-2) is activated, users must use CLIA compliant passwords. This means a password has to contain at least 2 upper case characters, 2 lower case characters, 2 numerical characters, and 2 special characters.

If the **Use CLIA compliant password rules** checkbox is deactivated, a password must have at least 8 and no more than 40 characters.

The **Auto-lock timer** setting (G-3) controls the auto-lock function. If there is no user interaction, the application will be locked automatically after the time defined in this field. The value must be in the range of 0–60 minutes.

**Note:** If the value is set to 0, the auto-lock is deactivated and the application will never be locked automatically.

#### *Local settings*

The user defines export directories and source directories for the local installation. These defined settings are applicable only to the local computer. The user can define a specific directory by clicking **Browse** and selecting the specific export/source directory.

**Local Settings**

**Default data export directories**

**A** Report folder  
C:\ Browse

☐ Export results to LIMS

**B** LIMS output folder  
C:\ Browse

**Default data source directories**

**C** Assay profiles for assay development  
C\ Browse

**D** Assay profiles for import  
C\ Browse

Assay profiles for export  
C\ Browse

**E** Rotor-Gene experiment template files (.ret)  
C\ Browse

**F** Rotor-Gene quantitation template files (.qut)  
C\ Browse

☒ Import Rotor-Gene AssayManager work lists  
**G** C\ Browse

☐ Import QIAsymphony work lists  
**H** C\ Browse

☒ Import LIMS work lists  
**I** C\ Browse

**J** Exported experiments  
C\ Browse

**K** Report profiles  
C\ Browse

**L** Support packages  
C\ Browse

**M** Rotor-Gene experiments (.rex) for assay profile testing  
C\ Browse

**Export directories**

**Source directories**

### Report folder (A)

Target directory where reports generated in the **Approval** or **Archive** environment are saved.

### LIMS output folder (B)

Target directory where export data for a LIMS are saved. Initially, this option is disabled. To enable this option, the associated check box **Export results to LIMS** must be activated.

☐ **Export results to LIMS**

If this check box is activated, results released in the **Approval** environment are exported in a LIMS compatible file to the specified directory. The target LIMS system must be configured in a way that it searches for new files in the same directory as specified here.

### Assay profiles for assay development (C)

Source directory for assay profiles for development in UDT Mode.

**Note:** This is not relevant for closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

### Assay profiles for import (D)

Source directory for assay profiles to be imported into the Rotor-Gene AssayManager database via the **Assay Profiles** tab in the **Configuration** environment.

### Rotor-Gene experiment template files (.ret) (E)

Source directory for Rotor-Gene experiment template files (\*.ret) used in the "Development" environment of the UDT Mode.

**Note:** This is not relevant for closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

### Rotor-Gene quantitation template files (.qut) (F)

Source directory for Rotor-Gene quantitation template files (\*.qut) used in the **Development** environment of the UDT Mode.

**Note:** This is not relevant for closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

### Import Rotor-Gene AssayManager work lists (G)

☒ Import Rotor-Gene AssayManager work lists

### Import QIA symmetry work lists (H)

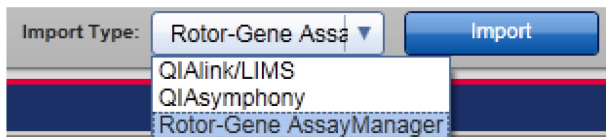
☒ Import QIA symmetry work lists

### Import LIMS work lists (I)

☒ Import LIMS work lists

Rotor-Gene AssayManager can import work lists from other Rotor-Gene AssayManager installations, QIA symmetry, and LIMS. The user can select which of these 3 import options shall be available by activating the check boxes G, H, and I.

The import type menu in the **Setup** environment will be populated with the selected import options accordingly.



### Exported experiments (J)

Destination for \*.rex files exported from the **Archive** environment.

### Report profiles (K)

Directory for importing and exporting report profiles.

**Note:** This is not relevant for closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

### Support packages (L)

Destination for support packages created from the **Approval** or **Archive** environment.

### Rotor-Gene experiments (.rex) for assay profile testing (M)

Source directory for Rotor-Gene experiments (\*.rex files) to be tested in the **Development** environment of the UDT Mode.

**Note:** This is not relevant for closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

### Tasks related to the Settings environment

"Managing cyclers", page 763

"Creating/editing a work list", page 732

"Finishing and releasing a run", page 742

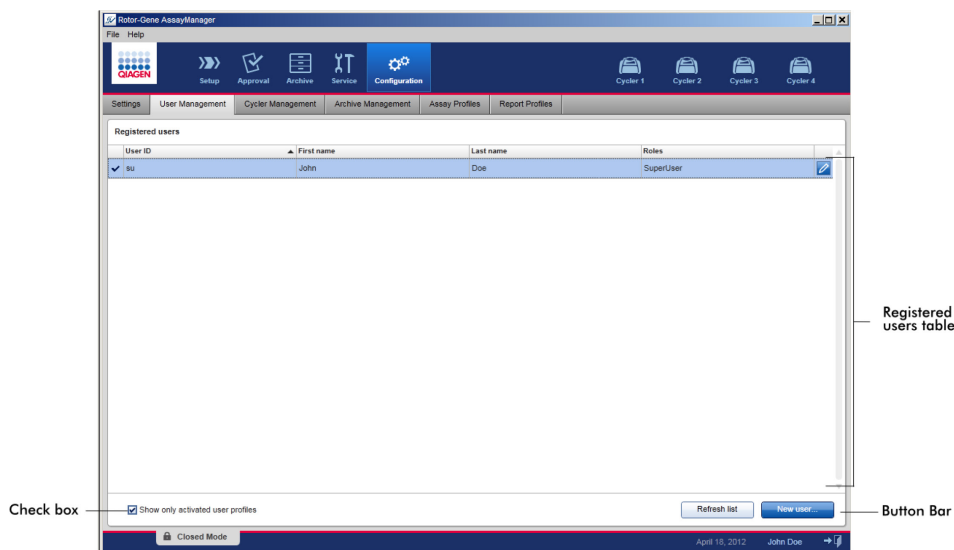
"Managing users", page 768

### User Management tab

The **User Management** tab provides an overview of all configured user profiles and the possibility to manage these user profiles. For details about users and their roles refer to "Concepts/User management", page 603.

The **User Management** tab consists of 2 parts:

- **Registered users** table
- Button bar

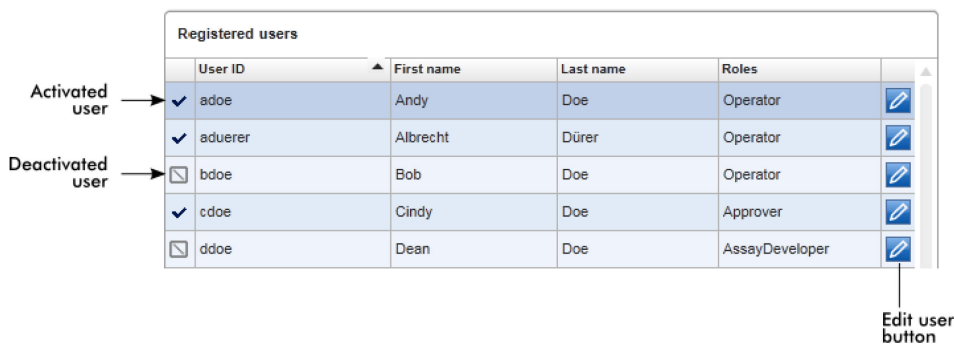





### **Registered users** table

The **Registered users** table lists all user profiles already configured in Rotor-Gene AssayManager. A user profile can be activated or deactivated.

To display a deactivated user profile in the table, the **Show only activated user profiles** check box must be deactivated.

The activation status of a user profile is displayed in the first column of the table.



Column	Explanation
User status	<p>Status of the user profile.</p> <p>A user profile can be deactivated or activated. The activation status is displayed by the icon in the first column of the table.</p> <p> User is activated</p> <p> User is deactivated</p> <p><b>Note:</b> Deactivated user profiles will only be shown in the table if the <b>Show only activated user profiles</b> checkbox is deactivated. If the checkbox is activated, only profiles of activated users will be shown.</p>
User ID	Shows the user ID.
First name	Shows the user's first name.
Last name	Shows the user's last name.
Roles	<p>Shows the user's roles. In case multiple roles are assigned to a user, all roles are listed sequentially and separated by comma.</p> <p><i>Example</i></p> <div> <div> <div>User with single role</div> <div>Administrator</div> </div> <div> <div>Approver, AssayDeveloper, Operator</div> <div>AssayDeveloper, Operator</div> <div>Operator</div> <div>User with single role</div> </div> <div>Users with multiple roles</div> </div>
Edit user button 	<p>The <b>Edit user</b> button opens the <b>Edit User</b> dialog where properties and settings can be modified for a user.</p>

The screenshot shows the 'Edit User' dialog box. It has a blue header with a pencil icon and the text 'Edit User'. The form contains several fields and controls, each labeled with a letter in a blue box:

- A** points to the 'First name' text field containing 'John'.
- B** points to the 'Last name' text field containing 'Doe'.
- C** points to the 'User ID' text field containing 'SU'.
- D** points to the 'Password' and 'Confirm password' text fields, both containing masked characters (dots).
- E** points to the 'Activate user' checkbox, which is checked.
- F** points to the 'Messages' text area.
- G** points to the 'Roles' list box, which contains a scrollable list of roles: Administrator, Approver, AssayDeveloper, Operator, and SuperUser (which is checked).
- H** points to the 'OK' button.
- I** points to the 'Cancel' button.

#### First name (A)

There is a maximum of 50 characters in this field.

#### Last name (B)

There is a maximum of 50 characters in this field.

#### User ID (C)

ID must be unique and may not exceed a maximum of 40 characters. User IDs containing the words QIAGEN, Service, and User in combination are not allowed.

#### Password fields (D)

These fields are used to set a new password for the user.

The password must be in the range of 8–40 characters. If CLIA complaint password rules are activated in the **Settings** tab, the password has to contain at least 2 upper case characters, 2 lower case characters, 2 numerical characters, and 2 special characters.

The password must be re-entered exactly in the **Confirm password** field.

#### Activate user check box (E)

Click this check box to activate or deactivate a user.

#### Messages (F)

Messages, warnings, and errors are displayed.

## **Roles (G)**

The check boxes are used to assign roles to a user profile. Activate the selection in front of a role to assign this role to the current user profile. It is possible to assign multiple roles to a user profile. For details, see "User roles", page 603.

## **OK button (H)**

Click to confirm the current settings, close the dialog, and go back to the **User Management** tab.

## **Cancel button (I)**

Click to cancel the current settings, close the dialog, and go back to the **User Management** tab.

## **User Management** button bar



These buttons are always enabled.

Click **Refresh list** to update the **Registered users** table by retrieving the list of users from the internal database.

Click the **New user** button to create a new user profile.



The following **Add user** dialog is opened:

The screenshot shows the 'Add user' dialog box. It features a blue header bar with a pencil icon and the title 'Add user'. The main area contains several input fields: 'First name', 'Last name', 'User ID', 'Password', and 'Confirm password'. The 'First name', 'Last name', 'User ID', and 'Password' fields are highlighted in yellow. To the right of these fields is a 'Roles' section with a list of roles: Administrator, Approver, AssayDeveloper, Operator, and SuperUser, each with an unchecked checkbox. Below the roles is a 'Messages' section with two error messages: 'Enter a valid first name (1-50 characters). (150040)' and 'Enter a valid last name (1-50 characters). (150041)'. At the bottom right are 'OK' and 'Cancel' buttons. The 'OK' button is disabled.

Characteristics upon opening the dialog are:

- All fields are empty
- The following mandatory fields are colored in yellow:
  - **First name**
  - **Last name**
  - **User ID**
  - **Password**
- **Activate user** check box is activated
- No role is selected
- **OK** button is deactivated

All elements in the **Add user** dialog are equal to those in the **Edit user** dialog described above.

Click **OK** to confirm all entries and go back to the **User Management** tab.

If the **Activate user** check box is checked, the new user profile is added to the **Registered users** table and is selected.

If the **Activate user** check box is unchecked, the new user profile is added to the internal database but not shown in the **Registered users** table.

## Tasks related to the User Management tab

"Creating a user profile", page 768

"Changing user profile settings", page 770

"Activating/deactivating a user profile", page 772

## Cycler Management tab

The **Cycler Management** tab gives an overview of the configured cyclers, their properties, and their current status.

The **Cycler Management** tab mainly consists of two parts:

- **Registered Cyclers** table with two buttons for every cycler
  - **Edit cycler** button
  - **Delete cycler** button
- **Verification comment for selected cycler** area

Registered cyclers table

Verification comment area

Edit cycler button

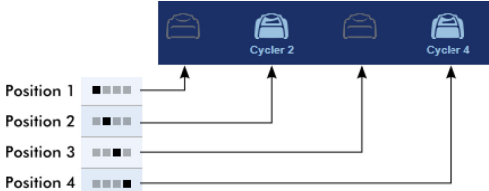
Delete cycler button

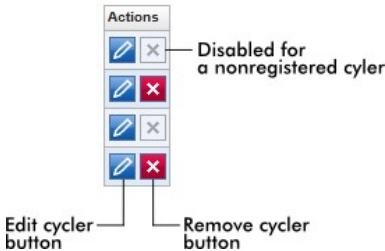
Position	Name	Serial number	Optical configuration	Next verification	Cycler status	Actions
■ ■ ■ ■	Cycler 1	0112101	6plex	16.06.2012 [59 day(s)]	Ready	[Edit] [Delete]
■ ■ ■ ■	Cycler 2	0409102	5plex	18.06.2012 [61 day(s)]	Ready	[Edit] [Delete]
■ ■ ■ ■	Cycler 3	1209103	5plex HRM	20.06.2012 [63 day(s)]	Ready	[Edit] [Delete]
■ ■ ■ ■	Cycler 4	1109104	5plex HRM	22.06.2012 [65 day(s)]	Ready	[Edit] [Delete]

## Registered Cyclers table

The **Registered Cyclers** table consists of 4 rows. Every row represents one of the up to 4 configurable cyclers. If no cyclers are configured yet, all columns except the position column are empty. The following graphic shows an example configuration with cyclers registered in positions 2 and 4. Positions 1 and 3 do not contain any data.

Registered cyclers						
Position	Name	Serial number	Optical configuration	Next verification	Cycler status	Actions
■ ■ ■ ■	---	---	---	---	---	[Edit] [Delete]
■ ■ ■ ■	Cycler 2	0409102	5plex	18.06.2012 [61 day(s)]	Ready	[Edit] [Delete]
■ ■ ■ ■	---	---	---	---	---	[Edit] [Delete]
■ ■ ■ ■	Cycler 4	1109104	5plex HRM	22.06.2012 [65 day(s)]	Ready	[Edit] [Delete]

Column	Explanation
Position	<p>A graphic represents the configurable cyclers. The current cycler position is indicated by a black square.</p>  <p>In this example, the first and third cycler positions are not registered. Their icons are inactive.</p>
Name	<p>Name of the registered cycler.</p> <p>This column:</p> <ul style="list-style-type: none"> <li>● Must not be empty</li> <li>● Name must have 1–8 characters</li> <li>● Name must be unique</li> </ul>
Serial number	<p>Serial number of the registered cycler. This column:</p> <ul style="list-style-type: none"> <li>● Must not be empty</li> <li>● Number must be unique</li> <li>● Number must match a connected cycler</li> </ul> <p>After the serial number of a connected cycler is entered, its optical configuration is automatically checked by Rotor-Gene AssayManager and displayed in the "Optical configuration" box. This box remains empty if no cycler with the entered serial number is connected.</p>
Optical configuration	Optical configuration of a registered cycler.
Next verification	<p>Next temperature verification date and remaining days until that date.</p> <p>This field can be empty. If it is set to empty, the <b>Verification comment</b> text box is disabled and its content is cleared.</p>

Column	Explanation
	<p>If the date is expired, the <b>Verification comment</b> text box is disabled.</p> <p>If a date is set, the date must be in the future.</p>
<b>Cycler status</b>	<p>Shows the current status of a registered cycler. Possible values are:</p> <ul style="list-style-type: none"> <li>● <b>Offline</b>: cycler is not connected or connected but not switched on</li> <li>● <b>Ready</b>: cycler is ready</li> <li>● <b>Needs verification</b>: verification has expired</li> <li>● <b>Loaded</b>: cycler is loaded and ready to be run</li> <li>● <b>Running</b>: cycler is currently running</li> <li>● <b>Run stopped</b>: user has stopped a run while the cycler was running</li> <li>● <b>Run complete</b>: run has finished successfully</li> <li>● <b>Run failed</b>: error occurred during the run</li> <li>● <b>Run stopped, cycler disconnected</b>: cycler was disconnected when it had the status <b>Run stopped</b></li> <li>● <b>Run complete, cycler disconnected</b>: cycler was disconnected when it had the status <b>Run complete</b></li> <li>● <b>Run failed, cycler disconnected</b>: cycler was disconnected during a run or when it had the status <b>Run failed</b></li> </ul>
<b>Actions</b>	<p>The actions column contains buttons for:</p> <ul style="list-style-type: none"> <li>● Editing the cycler's properties</li> <li>● Removing a cycler</li> </ul> 

### **Remove cycler button**

If the **Remove cyclier** button is clicked, the following dialog will be displayed and has to be confirmed with **OK** to remove a cyclier.

A dialog box with a blue header bar containing a question mark icon and the text "This cyclier will be deleted." Below the header, there are three fields: "Position" with four small squares (the third is black), "Name" with the text "Cyclier 3", and "Serial number" with the text "1209103". At the bottom right, there are two buttons: "OK" and "Cancel".

### **Edit cyclier** button

If the **Edit cyclier** button is clicked, the **Edit cyclier** dialog will be displayed.

An "Edit cyclier" dialog box with a blue header bar containing a pencil icon and the text "Edit cyclier". The dialog is divided into several sections. On the left, there are four lettered labels: A, B, D, and E. On the right, there is a lettered label F. At the bottom left, there is a lettered label G. The fields are: "Position" (A) with four squares (the third is black); "Name" (B) with the text "Cyclier 4"; "Serial number" (C) with the text "1109104"; "Optical configuration" (D) with the text "5plex HRM"; "Next verification" (E) with the date "22.06.2012"; "Days until next verification" (F) with the number "65"; and "Verification comment" (G) with the text "Traveling is murder of prejudices." At the bottom right, there are two buttons: "OK" and "Cancel".

### **Position (A)**

This graphic represents the configurable cycliers. The current cyclier position is indicated by a black square.

### **Name (B)**

The name of the cyclier in this field can be edited.

### **Serial number (C)**

The serial number of the cyclier in this field can be edited.

### **Optical configuration (D)**

The optical configuration of the cyclier cannot be edited; it is read-only.

### **Next verification (E)**

---

The next verification date can be entered manually or using the date picker.

#### **Days until next verification (F)**

This field displays the number of remaining days until the verification date. The field cannot be edited.

#### **Verification comment (G)**

This text field is used to enter an optional verification comment.

#### **Tasks relating to the Cyclers Management tab**

"Adding a cycler", page 764

"Editing cycler settings", page 766

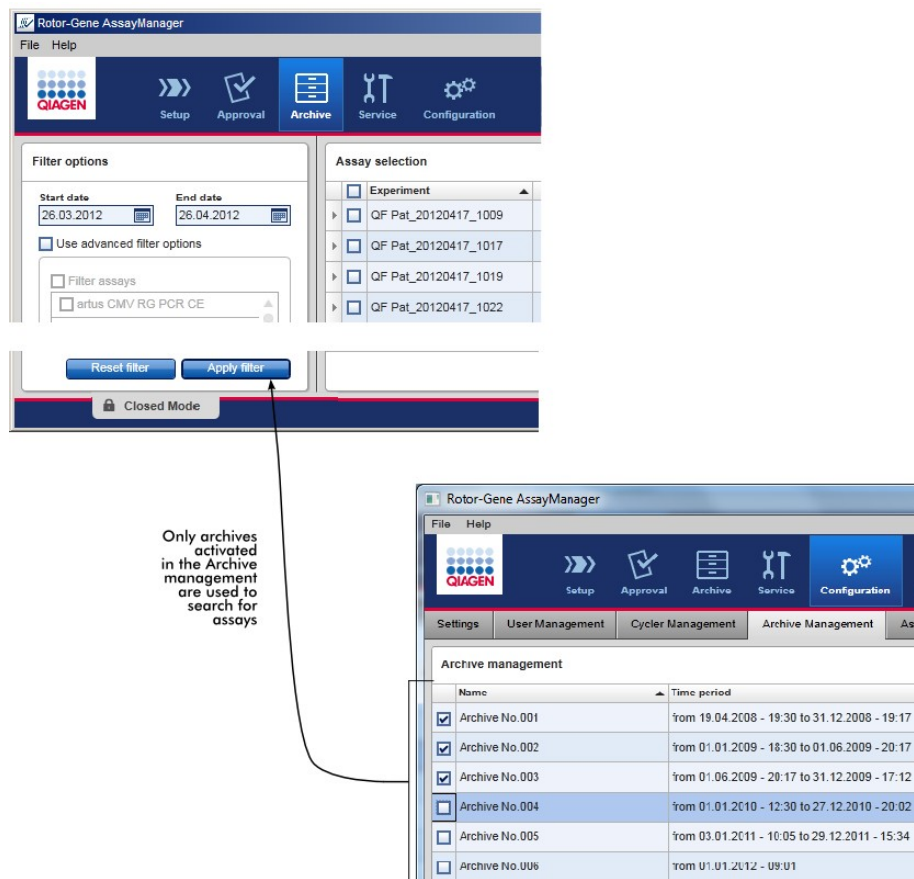
"Removing a cycler", page 767

#### **Archive Management tab**

The **Archive Management** tab is used to define which archives are browsed for experiment data during assay selection in the Archive environment.

#### *Background information*

When a run is finished, all experiment data and audit trails are stored in the main database until all sample results of the experiment are released in the **Approval** environment. After release of the sample results the experiment data are accessible via the **Archive** environment.



### Characteristics of an archive database

An archive database covers a certain time span that is defined by the date of the first and the last audit trail message stored in the database.

#### Archive Management

Name	Time period
<input checked="" type="checkbox"/> Archive No.001	from 19.04.2008 - 19:30 to 31.12.2008 - 19:17

Time period of archive

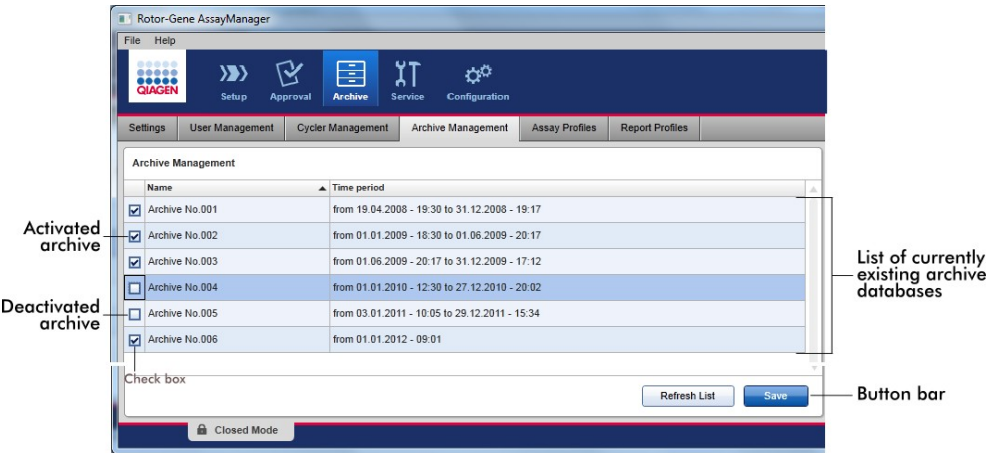
An archive database has a size of 10 GB. If a database is close to its maximum capacity, the database is marked as "closed" and a new archive database is created automatically.

All these processes concerning the creation and management of archive databases are automatically performed in the background. The main database only contains data from current, non-released, or not fully released experiments.

Tasks related to the **Archive Management** tab

The **Archive Management** tab consists of two parts:

- **Archive Management** table
- Button bar



**Archive Management** table

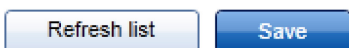
The **Archive Management** table lists all currently existing archive databases.

Column	Explanation
Check box	<p>A check box column indicates if an archive database is currently active or inactive. Only active archive databases will be browsed for experiment data searched from the <b>Archive</b> environment.</p> <p>Deactivated databases will not be included in a search. In addition, audit trail messages related to the archived experiments will not be shown in the <b>Service</b> environment if the dedicated archive database is deactivated.</p>
<input checked="" type="checkbox"/>	<p>The corresponding archive database will be browsed for experiment data when searched from the "Archive" environment.</p>
<input type="checkbox"/>	<p>The corresponding archive database will not be browsed for experiment data when searched from the <b>Archive</b> environment.</p>



Column	Explanation
	Audit trail messages related to the experiments stored in this database and other audit trail messages in the time span of the database cannot be found in the <b>Service</b> environment.
<b>Name</b>	Name of the archive database.
<b>Time period</b>	Time period covering all experiments in the archive.  Start date ("from"): Creation date of the first audit trail entry in the database.  End date ("to"): Creation date of the latest audit trail entry in the database.  The end date of the active archive is empty.

#### **Archive Management** button bar



Click **Refresh list** to discard unsaved modifications.

Click **Save** to save all modifications.

#### **Tasks related to the Archive Management tab**

"Managing archives", page 775

#### **Assay Profiles tab**

An assay profile is a protocol that defines how Rotor-Gene AssayManager processes a certain assay. Every assay profile requires a specific plug-in since it parameterizes the analysis of the corresponding assay that is performed by the plug-in.

The **Assay Profiles** tab in the **Configuration** environment is used to manage assay profiles, i.e., importing, exporting, activating, and deactivating assay profiles. Assay profiles cannot be edited in this tab.

Assay profiles can clearly be identified by their name and a version number. It is possible to have several assay profiles with the same name but different version numbers but only one can be active. All other assay profiles with this name are automatically deactivated.

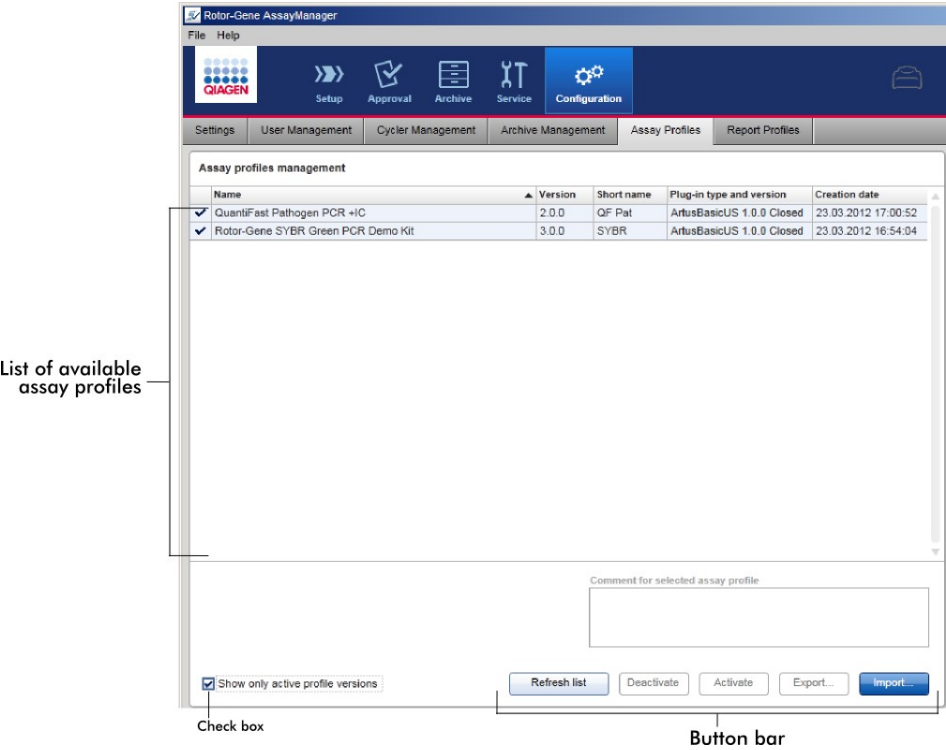
*Example*

The following screenshot shows an example where an assay profile “Rotor-Gene SYBR Green PCR Demo Kit” exists in two different versions, 3.0.0 and 5.0.0. Only one version can be active. Version 3.0.0 is deactivated (☐) , and version 5.0.0 is activated (☒).

<input type="checkbox"/>	Rotor-Gene SYBR Green PCR Demo Kit	3.0.0	SYBR
<input checked="" type="checkbox"/>	Rotor-Gene SYBR Green PCR Demo Kit	5.0.0	SYBR

The **Assay Profiles** tab consists of two parts:

- **Assay profiles management** table
- **Assay Profiles** button bar



**Assay profiles management table**

The **Assay profile management** table lists all available assay profiles, i.e., all assay profiles stored in the current Rotor-Gene AssayManager installation. Every assay profile is displayed in a separate row.

The table is sortable. Clicking the corresponding column header will sort the table according to the selected column. A cell in the header of the corresponding column indicates the sorting column (▲ for ascending order, ▼ for descending order).

Assay profiles management					
<input checked="" type="checkbox"/>	Name	Version	Short name	Plug-in type and version	Creation date
<input checked="" type="checkbox"/>	QuantiFast Pathogen PCR +IC	2.0.0	QF Pat	ArtusBasicUS 1.0.0 Closed	23.03.2012 17:00:52
<input checked="" type="checkbox"/>	Rotor-Gene SYBR Green PCR Demo Kit	3.0.0	SYBR	ArtusBasicUS 1.0.0 Closed	23.03.2012 16:54:04

**Note:** With the check box **Show only active profile versions** it can be determined if deactivated assay profiles are shown in the table or not.

☐ Show only active profile versions

If the box is activated (☒) , only activated assay profiles are shown; deactivated assay profiles are hidden.

If the box is deactivated (☐) , both activated and deactivated assay profiles are shown.

Column	Explanation
Status	Status of the assay profile. <div> <input type="checkbox"/> Deactivated assay profile  <input checked="" type="checkbox"/> Activated assay profile </div>
Name	Name of the assay profile.
Version	Version number of the assay profile.
Short name	Short name of the assay profile
Plug-in type and version	Plug-in type and version the assay profile was created with.
Creation date	Creation date of the assay profile.

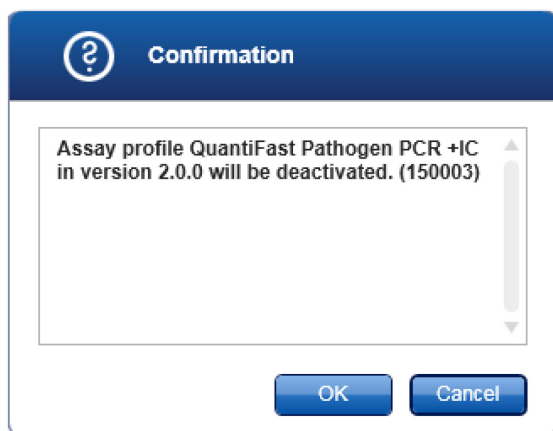
### Assay profiles button bar




Click **Refresh list** to update the list of all available assay profiles.

Click **Deactivate** to deactivate the selected assay profile.

To confirm deactivation of the selected assay profile, click **OK** in the **Confirmation** dialog.

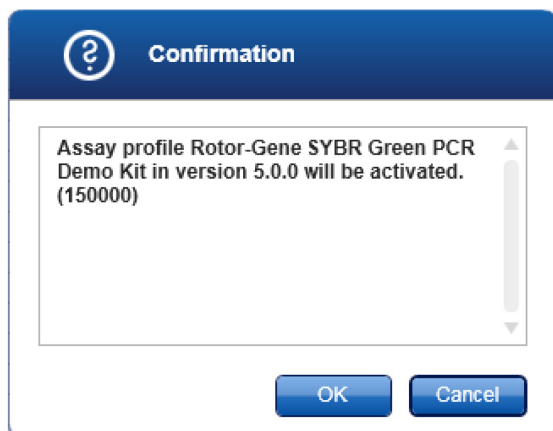


If the check box **Show only active profile versions** is deactivated, the deactivated assay profile is listed in the table with the  icon in its status column.

If the check box is activated, the deactivated assay profile is no longer listed in the table.

Click **Activate** to activate the selected assay profile.

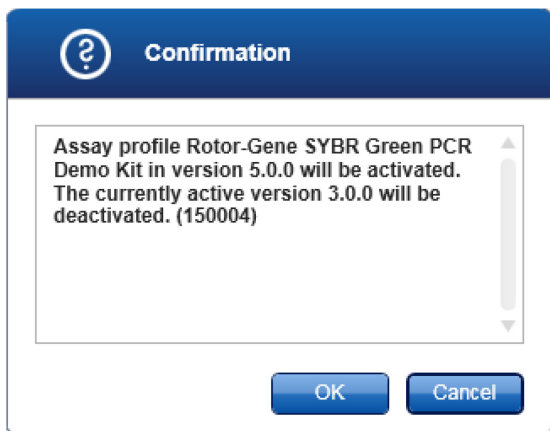
To confirm activation of the selected assay profile, click **OK** in the **Confirmation** dialog.



The icon of the assay profile changes from deactivated () to activated ().

The check box **Show only active profile versions** must be deactivated to list activated and deactivated assay profiles in parallel in the table.

If another version of the assay profile is active, the following dialog is displayed.

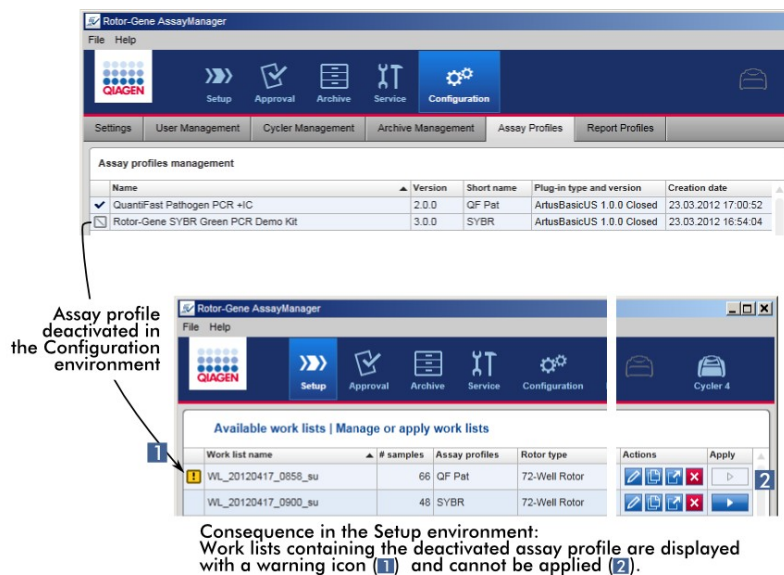


Confirm with **OK** to disable the other version.

Click **Export** in the **Assay profiles** button bar to exports an assay profile (file extension \*.iap). A dialog is opened to select the destination directory and a file name. The selected assay profile will be exported accordingly.

Click **Import** to import an assay profile. A dialog is opened to select the assay profile (file extension \*.iap). The selected assay profile will be imported to the assay profile management table.

**Note:** The relationship between deactivating assay profiles in the **Configuration** environment and work lists in the **Setup** environment is explained in the following figure.



If an assay profile is deactivated in the **Configuration** environment, work lists in the **Setup** environment containing this assay profile can no longer be applied.

### Tasks related to the Assay Profiles tab

"Activating/deactivating an assay profile", page 760

"Importing/exporting an assay profile", page 758

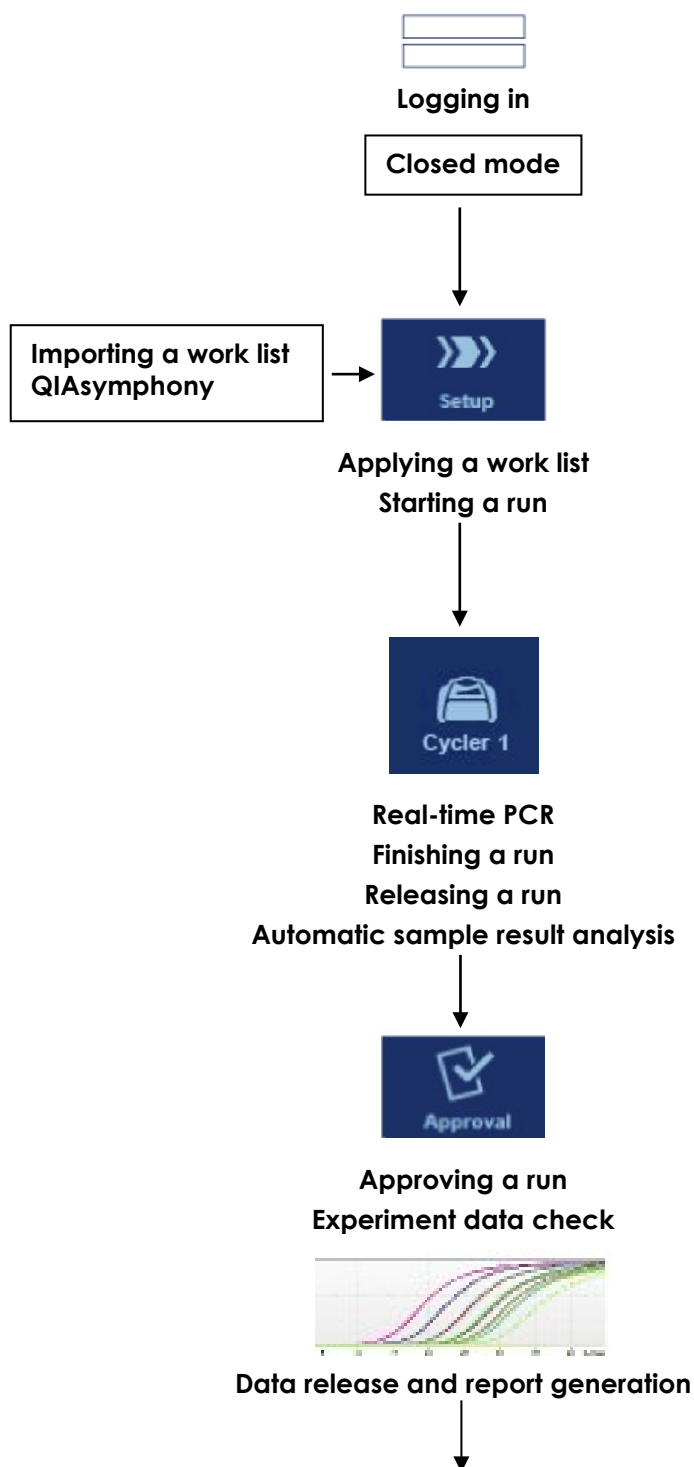
### Report Profiles

A report containing various data about an experiment can be generated by Rotor-Gene AssayManager in a \*.pdf file format.

**Note:** FDA cleared or approved nucleic acid tests come with a fixed content and layout for the report. Report profiles are not applicable.

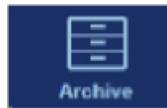
## 5.6 General workflow

The following graphic summarizes the work flow in Rotor-Gene AssayManager.



---

**After release, experiment  
data are transferred to the  
archive**



**Searching for experiments**



## 5.7 Plug-in concept

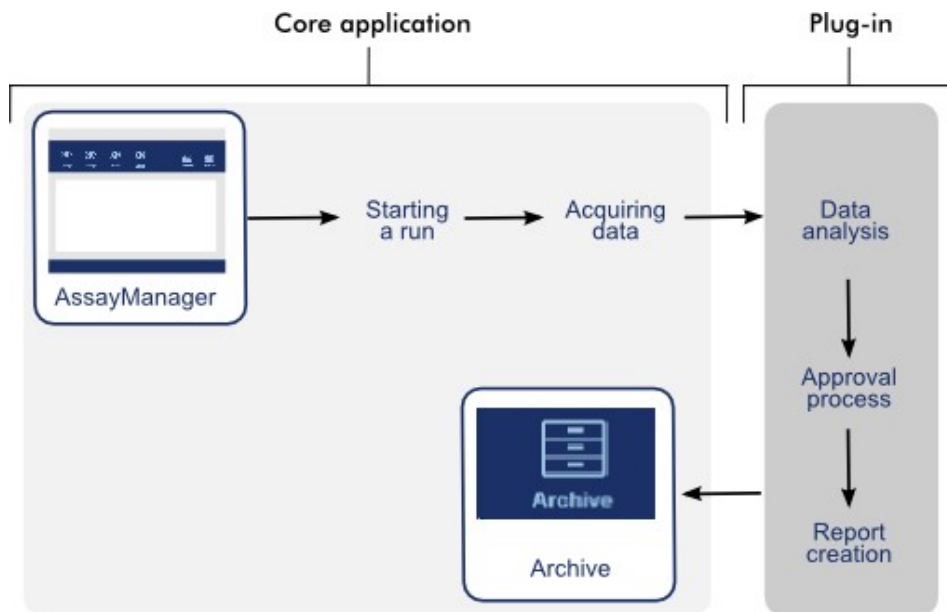
Rotor-Gene AssayManager is a versatile application. The number of assay types that can be processed can even be expanded with its plug-in architecture.

The general work flow is provided by the core application and its frame work. The work flow for specific assays — including analysis — is provided by plug-ins. An assay profile is a protocol that defines how Rotor-Gene AssayManager processes a certain assay. Every assay profile requires a specific plug-in since it parameterizes the analysis of the corresponding assay that is performed by the plug-in.

Plug-ins cover the control of the following tasks:

- Processing of acquired data
- Analysis algorithms
- Presentation of results (GUI layout of the approval work flow)
- Layout and structure of report contents
- Output to LIMS

The following graphic illustrates the plug-in concept:



## 6 Using Rotor-Gene AssayManager

The work flow in Rotor-Gene AssayManager can be divided in two sections:

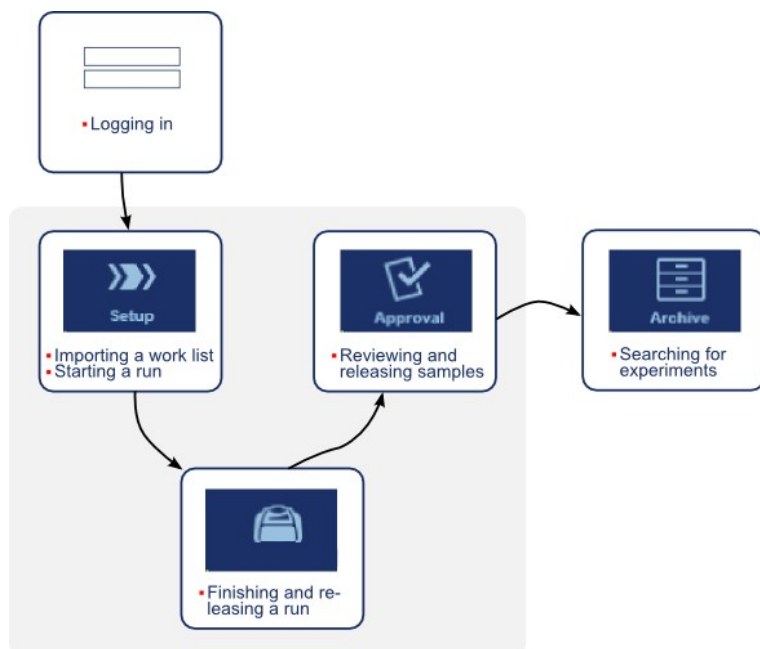
- Standard tasks: tasks that are performed on a daily basis
- Administrative tasks: tasks performed to manage and configure the work flow

### 6.1 Standard tasks

The following tasks are performed by users who are involved in the routine work of a lab, i.e., running experiments and analyzing data.

- Logging in and logging out (page 725)
- Locking and unlocking (page 729)
- Setting up a run (page 732)
- Starting a run (page 738)
- Finishing and releasing a run (page 742)
- Approving a run (page 746)
- Working with reports (page 754)
- Working with audit trails (page 756)

The following graphic gives an overview of the work flow in Rotor-Gene AssayManager:



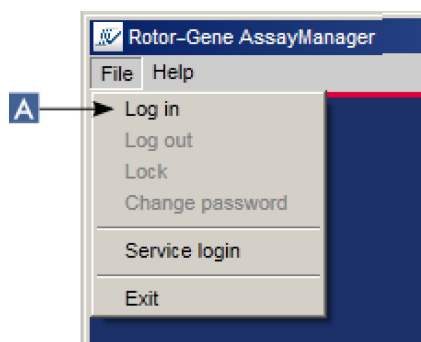
### 6.1.1 Logging in and logging out

All user interactions in Rotor-Gene AssayManager are assigned to a specific user. Therefore, every user must be authenticated using a specific user ID and password. Before leaving the computer, a user is advised to lock the application or to log out.

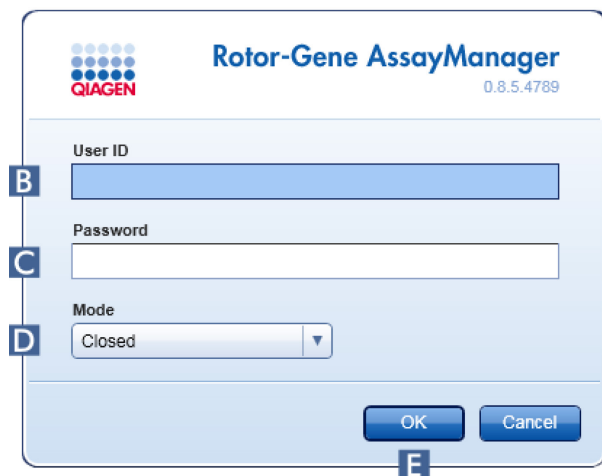
#### Logging in to Rotor-Gene AssayManager

1. Launch Rotor-Gene AssayManager.

If a user has logged out from a previously launched session, select **Log in** (A) from the main menu.



The login screen is shown.



2. Enter the user ID in **User ID** field (B).
3. Enter the password in the **Password** field (C).
4. Select **Closed** from the **Mode** drop-down menu (D).
5. Click **OK** (E).

**Note:** Closed mode plug-ins may not be available in all countries. If Closed mode plug-ins are not installed, a log-in in **Closed** mode will give you only very limited access to administrative tasks. You can neither perform experiments nor any analysis. The User Defined Test mode is not for use with FDA cleared or approved assays.

The user is logged in and forwarded to the default screen that matches their role as listed in the table below. Users with multiple roles are forwarded to the default screen of their first matching role.

For example, a user with the role Administrator is forwarded to the **Settings** tab in the **Configuration** environment. A user with roles Operator and Approver will be forwarded to the **Setup** environment.

Role	Environment	Screen/tab
Operator	<b>Setup</b>	<b>Available work list</b> screen
Approver	<b>Approval</b>	<b>Filter assays</b> screen
Assay developer (Closed Mode)	<b>Configuration</b>	<b>Report Profiles</b> tab
Administrator	<b>Configuration</b>	<b>Settings</b> tab
Super User	<b>Configuration</b>	<b>Settings</b> tab

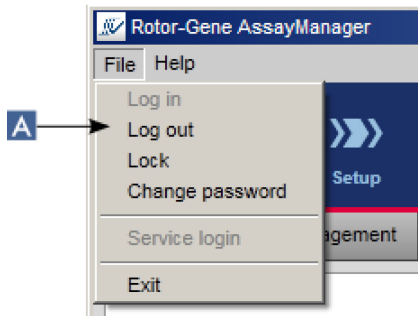
The selected mode is indicated at the bottom of the screen.



## Logging out of Rotor-Gene AssayManager

The user can choose between two alternative methods to log out. The user can either use the **Log out** command in the main menu or the log out button in the status bar.

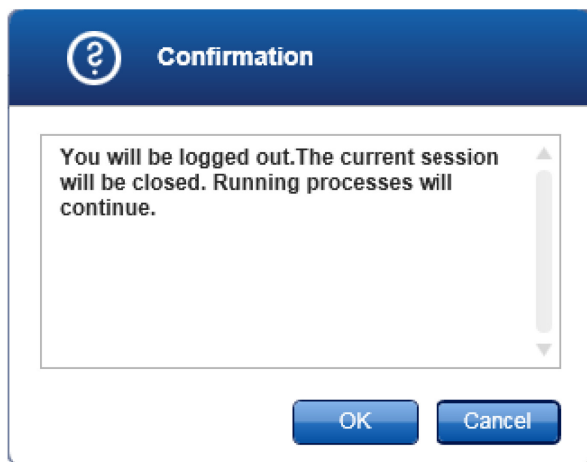
1. Click **Log out** (A) in the main menu.



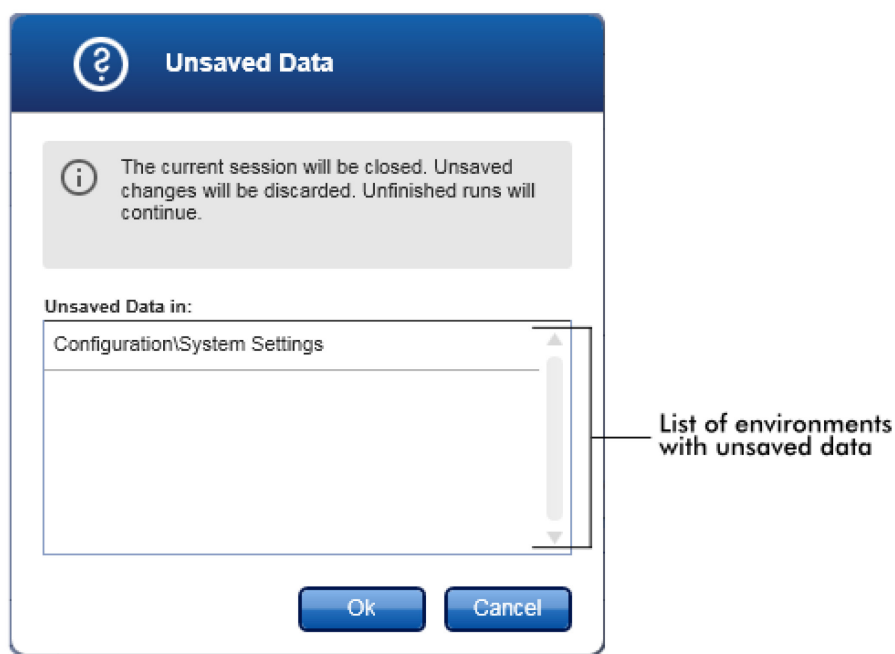
Alternatively, click log out button (B) in the status bar.



A **Confirmation** dialog is shown.



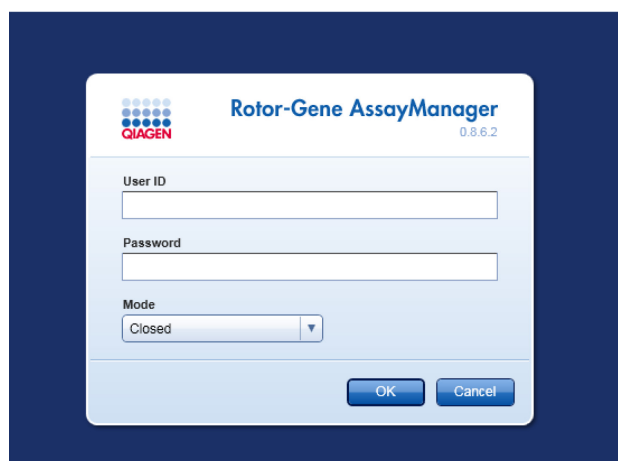
If unsaved data exist, an **Unsaved Data** dialog is shown with a list of all environments containing unsaved data.



2. Click **OK**.

Clicking **Cancel** cancels the log out and closes the dialog.

The user is logged out and the login screen is shown.



**Note:** If a user logs out, active cyclers will continue.

## Related topics

"Managing users", page 768

"Modes", page 601

"Session management", page 607

"Main toolbar", page 629

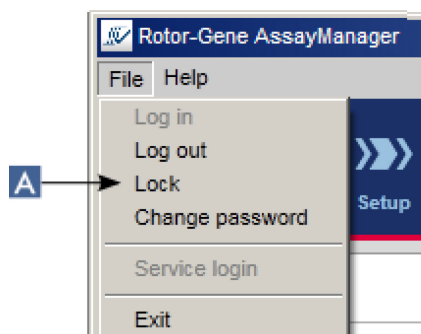
"Status bar", page 631

### 6.1.2 Locking and unlocking Rotor-Gene AssayManager

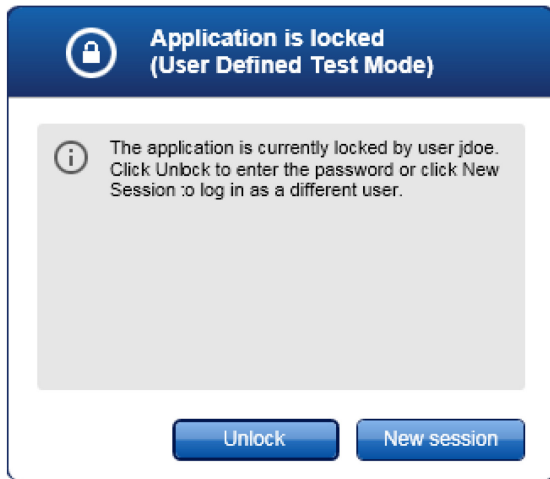
The application can be locked to restrict access. The locked application can be either unlocked by the user who has locked it, or a new session can be started.

#### *Locking Rotor-Gene AssayManager*

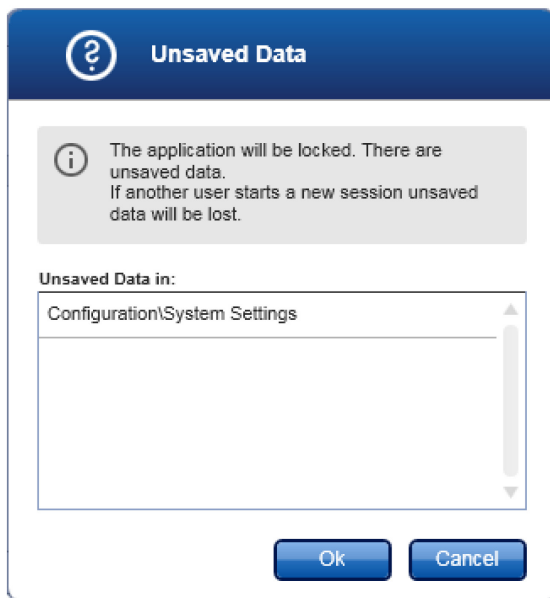
1. Click Lock (A) in the main menu.



If no unsaved data exist, the application is locked and the following dialog is displayed:



If unsaved data exist, an **Unsaved Data** dialog is shown with a list of all environments containing unsaved data.



2. Click **OK** to confirm locking the application.

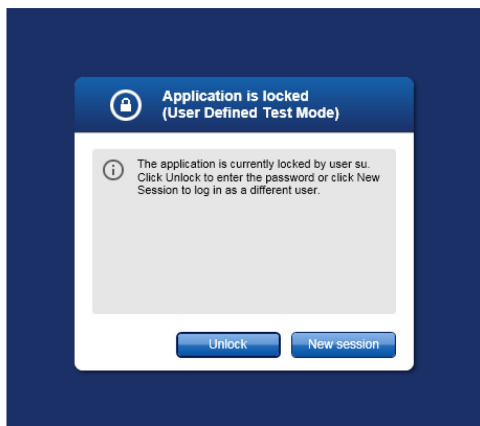
Following confirmation, the **Application is locked** dialog is shown.

Clicking **Cancel** cancels the lock and closes the dialog.



## Unlocking Rotor-Gene AssayManager

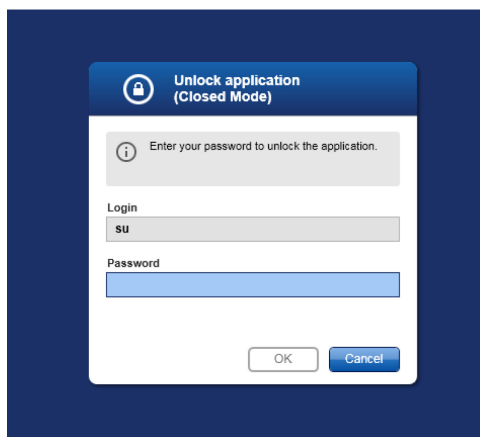
A precondition for unlocking is that the application was locked. The following screen is shown:



1. Click **Unlock**.

The **Unlock application** dialog is opened.

**Note:** The user name in the login field is set to the user who last locked the application. Only this user is allowed to unlock the application.



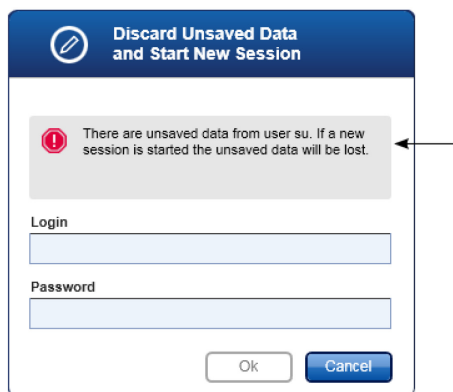
3. Enter the password in the **Password** field.
4. Click **OK**.

The application is unlocked.

It is possible to start a new session if the application is locked by another user.

Click **New session** in the **Application is locked** dialog.

The following dialog is shown if the previously logged in user did not save all data.



5. To start the new session and discard unsaved data, log in and enter a password then click **OK**.

#### Related topics

"Managing users", page 768

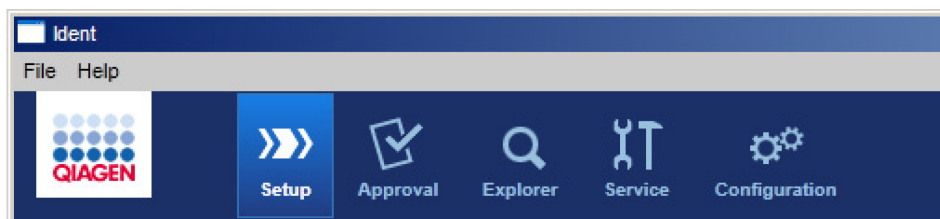
"Session management", page 607

#### 6.1.3 Setting up a run

A work list is used to define an experiment, i.e., which assays shall be applied, their order, the number of samples, etc.

Work lists contain an assay profile that is intended to run in an experiment.

All tasks related to work lists are carried out in the **Setup** environment.



**Note:** Use only assay kits with the same lot number for setting up an assay.

#### Creating/editing a work list

A work list is created in the **Setup** environment. This environment automatically appears on login for users with the role of an Operator.

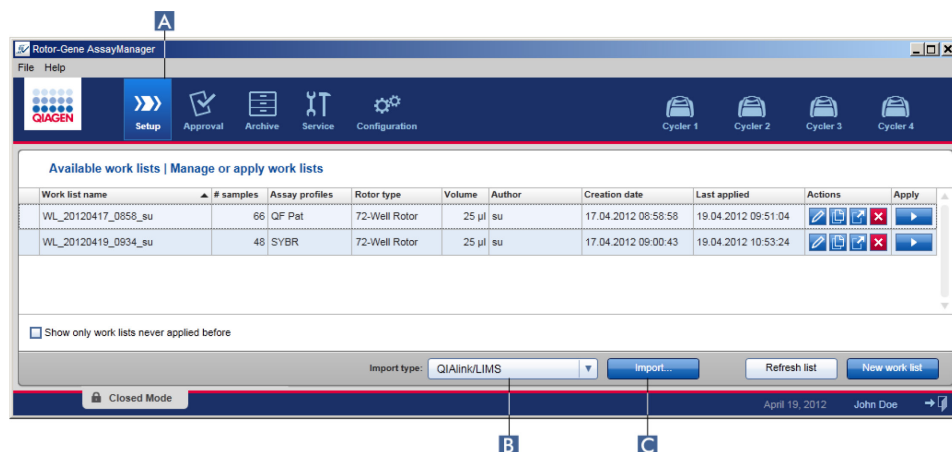
Initially, the **Available work lists** screen is shown with a list of all currently available work lists on the system.

To change to the **Create new work list** screen where the new work list is set up, click the **New work list** button at the bottom right of the screen

**Note:** Creating a new work list is not intended for use with FDA cleared or approved nucleic acid tests. For FDA cleared or approved nucleic acid tests see Importing a work list, below.

### Importing a work list

Importing a work list is a function used either to exchange work lists between different Rotor-Gene AssayManager installations or to import work lists from an upstream laboratory device (for example a LIMS or QIAasympphony).



The import command is located in the **Setup** environment (A) and consists of two elements:

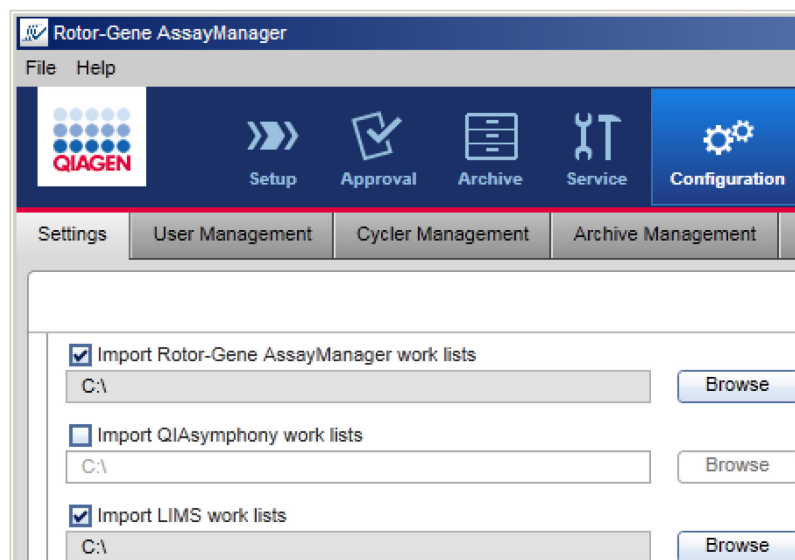
the **Import type** drop-down menu (B) to select the source of the file and the **Import** button (C).

A work list can be imported from the following sources from the **Import type** drop-down menu:

Source	File extension	Description
Rotor-Gene AssayManager	*.iwl	Export Rotor-Gene AssayManager work list
QIAsymphony	*.xml	Result file from QIAsymphony AS
QIALink/LIMS	*.iwl	Work lists from QIALink or LIMS

After a work list to be imported has been selected, Rotor-Gene AssayManager internally checks its syntax and signature. If the check is successful, the work list will be imported and added to the **Available work lists** table. Otherwise the work list will be rejected with a corresponding error message.

**Note:** The entries in the **Import type** drop-down menu depend on the settings set in the **Settings** tab of the **Configuration** environment. An Administrator can activate/deactivate each of the 3 possible import options.



1. Change to the **Setup** environment by clicking the **Setup** icon in the main toolbar.
2. Select the source for the work list to be imported from the **Import type** drop-down menu.

If the menu is disabled or necessary entries are missing, these can be customized in the **Configuration** environment in the **Settings** tab. Save any changes in the settings.

3. Click **Import**.

The **Select file** dialog opens. By default, the directory set for this import type in the **Configuration** environment is shown.

4. Change to the directory where the file to be imported is located. Select it and click **Open**.

Rotor-Gene AssayManager internally checks the signature and the syntax of the work list. Rotor-Gene AssayManager can check the validity of the product number and the expiry date of the kit used for the assay setup.

**Note:** The setting, whether a valid product number, etc., is required, is enabled in the **Settings** screen of the **Configuration** environment.

The screenshot shows a 'Work list' dialog box with the following sections:

- Format of generated work list names:** A text field containing 'WL\_20110513\_0430\_Operator'.
- User definable string:** A text field containing 'WL'.
- Checkboxes:**
  - ☒ Date
  - ☒ Time
  - ☒ Operator
  - ☐ Enable processing of unclear samples
  - ☒ Enable checksum for Import
- Closed mode:**
  - ☐ Product number required
  - ☐ Valid expiry date required
  - ☐ Lot number required
- UDT mode:**
  - ☐ Product number required
  - ☐ Valid expiry date required
  - ☐ Lot number required

Annotations on the left and right sides of the dialog box point to the 'Closed mode' and 'UDT mode' sections respectively, with labels: 'Requirements settings for work lists in Closed Mode' and 'Requirements settings for work lists in UDT Mode'.

These requirements can be set independently for the Closed Mode and the UDT Mode. If the setting is set to be "required" for one of the three options (checkbox is activated), then the imported result file from QIAsymphony AS must contain the information.

Further details can be found in the description of the **Configuration** environment under **Settings** (page 689).

5. The work list is imported and added to the list of available work lists.

**Note:** The name of a work list imported from QIAsymphony is automatically created with the following information separated by an underscore:

- "QS" as identifier for work lists imported from QIASymphony
- Batch ID of the QIASymphony AS run
- "S" + slot number of QIASymphony AS, where the assay was set up
- Rack ID of QIASymphony AS run
- Start date of QIASymphony AS run in format "YYYYMMDD"
- Start time of QIASymphony AS run in format "HHMMSS"

Where the QIASymphony AS result file contains information about several batches, this information will be separated in different work lists.

## Related topics

"Settings tab", page 689

"Rotor-Gene AssayManager version 1.0 and other QIAGEN products", page 610

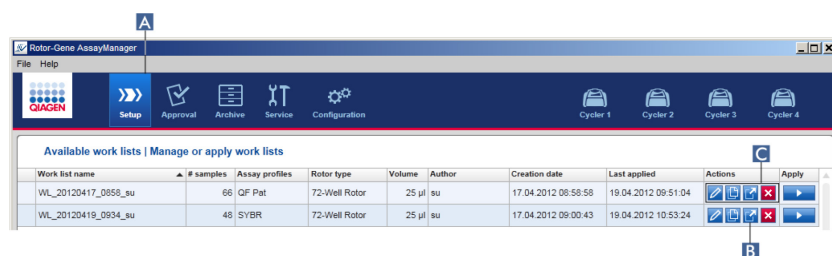
"Available Work Lists View", page 633

## Duplicating a work list

**Note:** This functionality is not available for imported work lists from QIASymphony, i.e., FDA cleared or approved nucleic acid tests.

## Exporting a work list

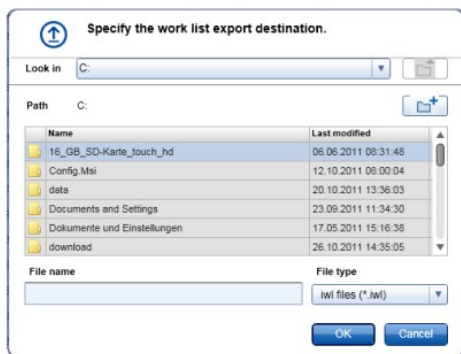
Exporting a work list is used to exchange work lists between different Rotor-Gene AssayManager installations that are using different databases.



The export functionality can be found in the **Setup** environment (A). The **Actions** bar (C) in the **Available work lists** table includes the **Export work list** button (B).

1. Change to the **Setup** environment by clicking the **Setup** icon in the main toolbar.
2. Move the mouse cursor to the **Actions** bar of the work list you want to export.
3. Click the **Export work list** button.

A dialog opens to select the target directory and the file name. The directory set in the **Configuration** environment is preselected by default.



4. Browse to the designated directory.
5. Enter a file name for the exported work list.
6. Click **OK**.

The work list will be saved under the entered file name and with the extension \*.iwl.

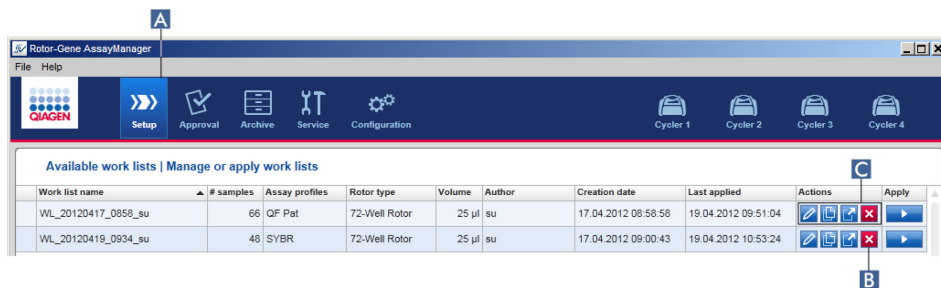
#### Related topic

“Available Work Lists View”, page 633

#### Deleting a Work List

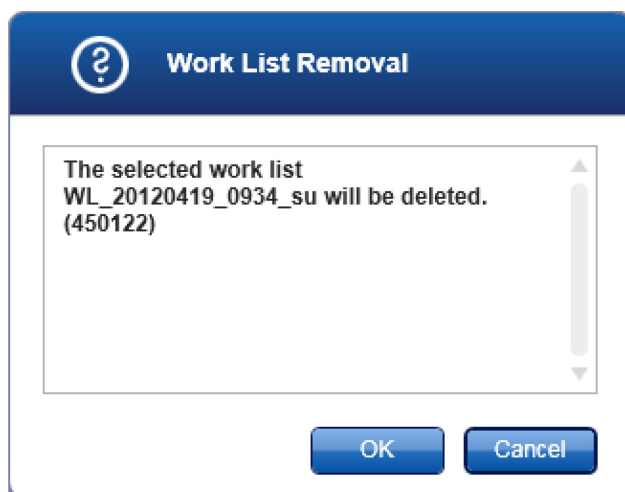
1. Change to the **Setup** environment by clicking the **Setup** icon in the main toolbar (A).

All available work lists are displayed in the table.



2. Locate the work list you want to delete, and click the corresponding **Delete work list** button (B) in the **Actions** bar (C) of the appropriate row of the table.

The **Work List Removal** confirmation dialog is shown.



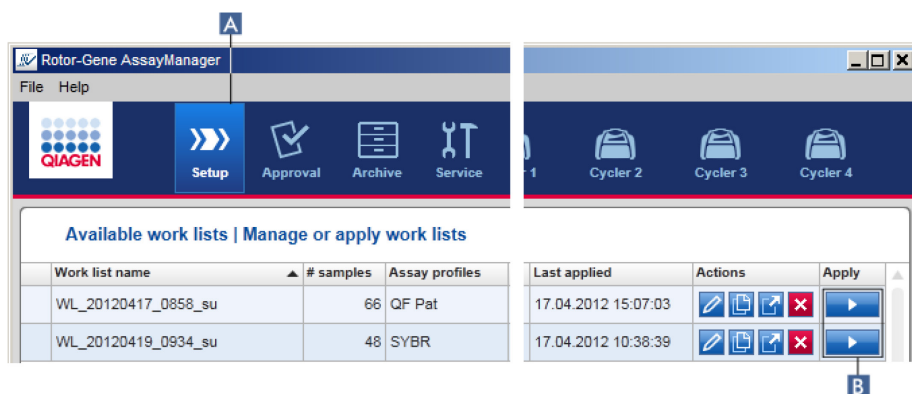
3. Click the appropriate button.

Click **OK** to delete a work list and return to the **Setup** start screen. The selected work list entry will be deleted from the database and then disappears from the work list table.

Click **Cancel** to cancel the delete process and return to the **Setup** start screen. The selected work list entry will remain as before.

#### 6.1.4 Starting a run

A run can be started from the **Available work lists** table in the **Setup** environment (A) by clicking the **Apply** button (B) in the button bar of the appropriate work list entry.



After the run is triggered, the **Apply work list** screen is opened. The user must enter an experiment name and select a cyclizer. An overview of the samples can be displayed and printed to a \*.pdf file.



**Note:** An experiment name must be entered. The length of the experiment name is limited to 80 characters. The experiment name must be unique in the database. The default name is defined under **Settings** in the **Configuration** environment. The default name for the experiment name is defined as follows:

<Assay profile short names>\_<YYYYMMDD>\_<HHMM> e.g., AS1\_AS2\_AS3\_20120327\_1359.

If the default name exceeds 80 characters, you may have to shorten the name manually to meet the requirements.

1. Change to the **Setup** environment by clicking the **Setup** icon in the main toolbar.  
The **Setup** environment is opened. All available work lists are displayed.

2. Select the work list you want to apply. Click the **Apply work list** button in the last column of the row.

The **Apply work list** screen opens. It consists of 3 areas: **Summary**, **Cycler selection**, and **Messages**.

Position	Name	Next verification	Cycler status	Select	Ring attached
■ ■ ■ ■	Cycler 1	16.06.2012 [58 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 2	18.06.2012 [60 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 3	20.06.2012 [62 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 4	22.06.2012 [64 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>

3. Enter the name of the experiment in the **Experiment name** field (C), or click **Default name** (D) to generate a name automatically.
4. Click the **Select** radio button (E) to select a cycler with the status **Ready**.
5. Activate the **Ring attached** check box (F) to confirm you have attached the locking ring.

The **Start run** button (G) is now activated.

- Click the green **Start run** button to start and apply the run.

Click **Cancel** to abandon the preparation of the run. This screen will close and the **Available work lists** screen is shown.

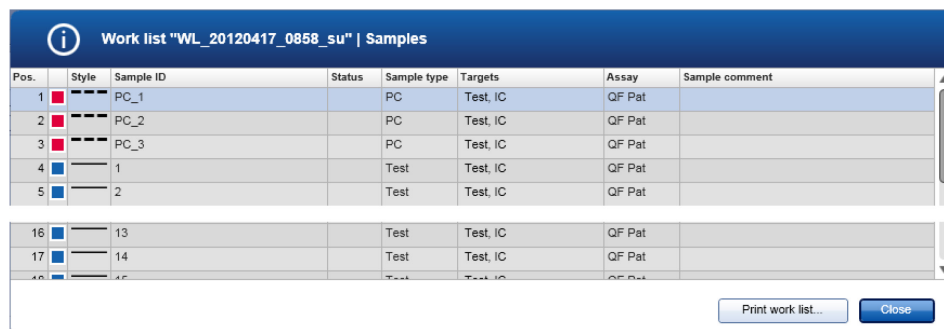
After the run is started with the **Start run** button, the following happens:

- The experiment is saved to the database.
- The run is started.
- The application switches to the cyclor environment of the cyclor selected for the run.

#### Optional Step

The user can get detailed information about the samples using the **View sample details...** (H) and **Print work list...** buttons (I).

Click **View sample details...** to open a scrollable list with detailed information about the samples:



Pos.	Style	Sample ID	Status	Sample type	Targets	Assay	Sample comment
1	■	PC_1		PC	Test, IC	QF Pat	
2	■	PC_2		PC	Test, IC	QF Pat	
3	■	PC_3		PC	Test, IC	QF Pat	
4	■	1		Test	Test, IC	QF Pat	
5	■	2		Test	Test, IC	QF Pat	

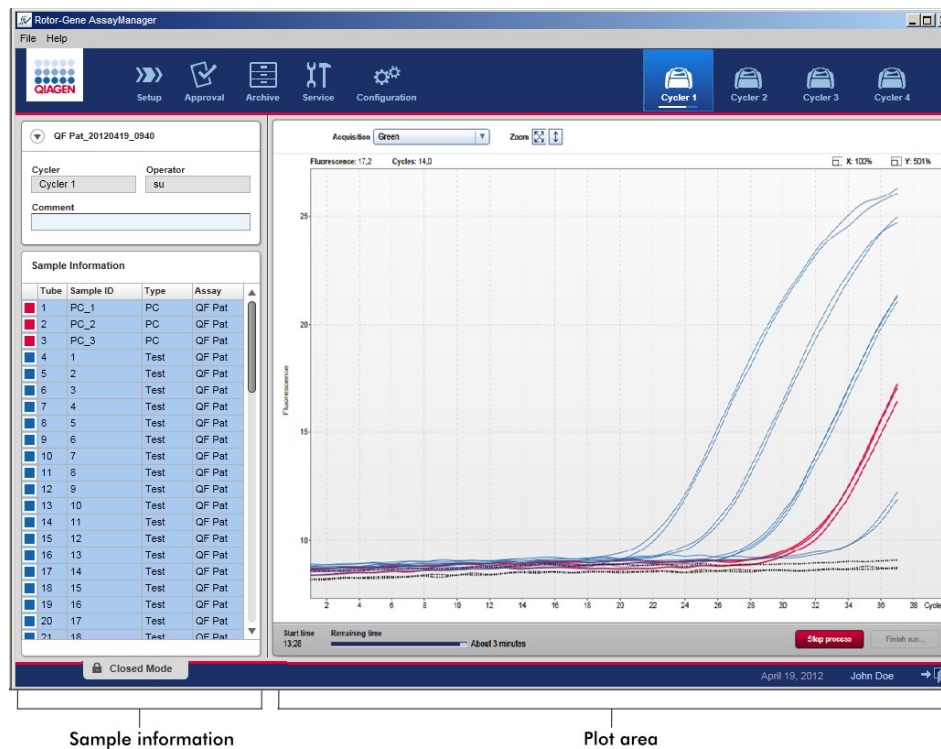
A \*.pdf file with this data can be generated either by clicking **Print work list...** from this screen or from the **Apply work list** screen.

Column	Description
Pos.	<p>Displays the position of the sample in the rotor. The position of a sample is determined by the assay profile and the order of the assay profiles in the <b>Assays</b> step (in case the work list consists of multiple assay profiles).</p> <p>The maximum position number is restricted by the selected rotor type.</p>

Column	Description
Line color	The color of a sample's amplification curve in the PCR plot is set by the assay profile.
Style	The line style of a sample's amplification curve in the PCR plot is set by the assay profile.
Sample ID	The sample ID is imported with the QIAsymphony work list.
Status	<p>Possible statuses of samples from a QIAsymphony work list are:</p> <ul style="list-style-type: none"> <li>● Valid</li> <li>● Invalid</li> <li>● Unclear</li> </ul>
Sample type	<p>The sample type is imported with the QIAsymphony work list and has to match the values given by the assay profile. Possible values are:</p> <ul style="list-style-type: none"> <li>● <b>Test:</b> Test sample</li> <li>● <b>NTC:</b> No template control</li> <li>● <b>PC:</b> Positive control</li> <li>● <b>EC+:</b> Positive extraction control</li> <li>● <b>EC-:</b> Negative extraction control</li> <li>● <b>QS:</b> Quantitation standard</li> </ul>
Targets	Acquisition target given by assay profile
Assay profile name	Short assay profile name given by assay profile. Hovering over the short assay profile name shows a tooltip with the full assay profile name.
Comment	The comment column may be empty. If a comment is filled in, it must contain no more than 256 characters.

### 6.1.5 Finishing and releasing a run

After a run is started, the environment of the selected cyclizer is displayed. This screen mainly consists of the sample information at the left and the plot area at the right.



During the run process and depending on the currently used plug-in, the amplification curves will be displayed and updated in real time. A progress indicator at the bottom left and a progress indicator placed underneath the cyclizer's icon show the run progress.

It is possible to stop the run by clicking **Stop process**.

Both sample information and plot area provide interactive functionalities to check the amplification curves of single (or multiple) samples.

**Note:** At the start of the run, all samples are selected and marked blue and all amplification curves are shown.

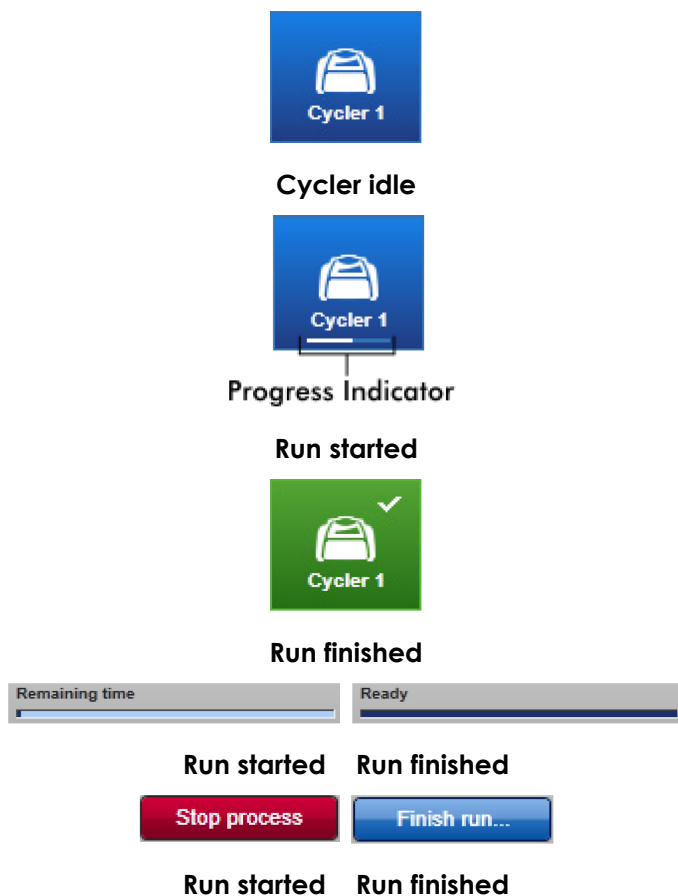
Click a single sample row in the sample information table to select/deselect a sample.

To make multiple selections, move to the first sample to be selected, hold down the left mouse button, and drag the mouse to the last sample.

The status of the first selected sample defines whether these samples are selected or deselected. If the first sample was initially selected, all samples will be deselected and vice versa.

### Finishing a run

The cyclers icon and progress indicator, **Remaining time** bar, and button labels change from the start to the end of a run. When the run has finished, the cycler icon will change.



The **Stop process** button changes its label to **Finish run**.

The Operator must click **Finish run** to finalize the run.

**Note:** If **Stop process** is clicked during the run or an error occurs, the run is stopped and the cyclor icon changes to:



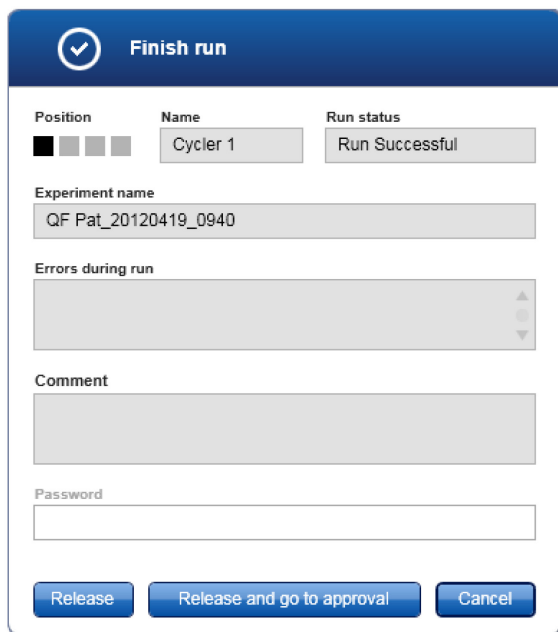
For more information, see "**Cyclor** environment", page 646.

1. Change to the corresponding **Cyclor** screen by clicking its icon in the main toolbar.

The **Cyclor** screen is displayed.

2. To finish a run, click **Finish run**.

The **Finish run** dialog is opened. It provides details about the position and the name of the cyclor, the run status, the experiment name, errors during run, and a comment. Depending on the run properties, some of the fields may be empty.

A dialog box titled "Finish run" with a blue header bar containing a checkmark icon. The dialog contains several fields: "Position" with four colored squares (black, grey, light grey, white), "Name" with a text box containing "Cyclor 1", "Run status" with a text box containing "Run Successful", "Experiment name" with a text box containing "QF Pat\_20120419\_0940", "Errors during run" with a scrollable text area, "Comment" with a large text area, and "Password" with a text box. At the bottom are three buttons: "Release", "Release and go to approval", and "Cancel".

3. Select the desired option.

Click **Release** to release the cyclor.

Click **Release and go to approval** to release the cyclor and change to the **Approval** environment.

Click **Cancel** to cancel the release process and change to the **Cyclor** view.

When the user releases the cyclor, the following processes are triggered:

- The cyclers are released and ready for a new run.
- The run is stored in the internal database with all experiment data (sample information, etc.).

### Difference if release of run has to be signed

The Administrator can determine that the release of a run must be signed. This option is set in the **General settings** tab of the **Configuration** environment.



If the option was set, the run has to be signed with a password (user profile password).

The buttons **Release** and **Release and go to approval** are disabled. These buttons are enabled only if a valid password is entered in the **Password** field of the **Finish run** dialog.

The image shows the 'Finish run' dialog box with the following fields: Position (Cycler 1), Name (Cycler 1), Run status (Run Successful), Experiment name (SYBR\_20120419\_1053), Errors during run (empty), Comment (empty), and Password (empty). The Password field is highlighted in yellow and labeled 'Password field' with an arrow. At the bottom are three buttons: Release, Release and go to approval, and Cancel.

**Note:** After a run is finished and the cycler is released, open the lid, remove the rotor, and discard the samples immediately.

---

## Related topics

"**Settings** tab, page 689

"**Cycler** environment", page 646

### 6.1.6 Approving a run

After a run has finished and the cycler has been released, the experiment will be stored in the internal database. The analysis of the acquired data is performed automatically depending on the plug-in corresponding to the assay profile and the rules and parameter values defined by the assay profile.

Rotor-Gene AssayManager provides test results that must be released by a user with the role of an approver. Depending on which Rotor-Gene AssayManager plug-in is currently in use, the individual approval process may differ.

In this section only the general functions are described. For details about the individual approval process, refer to the corresponding plug-in user manual.

## Filtering Experiments

The first step in the approval process is to filter the assay to be approved. This is done by using filter criteria in the **Approval** environment.

This environment mainly consists of two parts: a **Filter options** panel at the left and the **Assay selection** table at the right. The filter criteria are defined in the **Filter options** area. All assays matching the criteria will be listed in the **Assay selection** table at the right.

The simplest filter is the search for assays within a certain date range. Advanced filter options allow the user to define further filter criteria.

The following tables provide explanations of the filter criteria.



### Simple filter

Criterion	Comment
Date range	<p>Enter a start date and an end date in the corresponding fields to filter for assays with a run start date in the defined date interval.</p> <p>Dates can either be manually entered or entered using the date picker.</p> <p>Restrictions:</p> <ul style="list-style-type: none"><li>● Wildcard characters are not allowed</li><li>● Dates must be entered completely</li></ul>

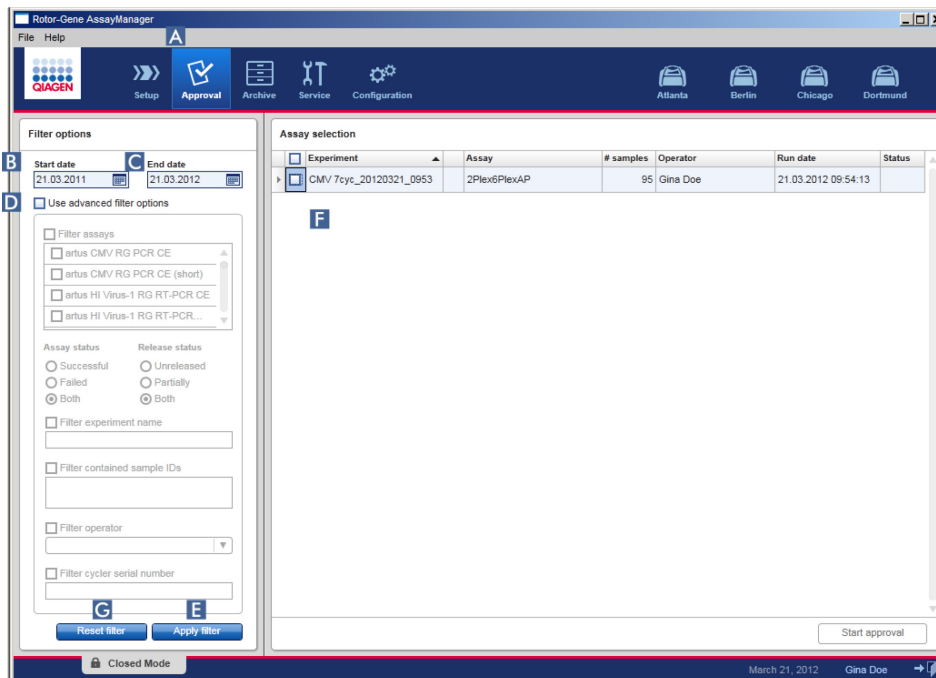
### Advanced filter options

Criteria	Comment
<b>Filter assays</b>	<p>To filter for specific assays, activate the <b>Filter assays</b> check box. All assays are displayed in a list. A check box in front of every assay row allows selection for individual assays.</p> <p>Multiple assay selections are possible to search simultaneously for different assays.</p>

<b>Assay status</b>	<p>Filter for the assay status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none"> <li>● Successful</li> <li>● Failed</li> <li>● Both</li> </ul>
<b>Release status</b>	<p>Filter for the release status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none"> <li>● Unreleased</li> <li>● Partially</li> <li>● Both</li> </ul> <p><b>Note:</b> The release status <b>Partially released</b> is not applicable for FDA cleared or approved nucleic acid tests.</p>
<b>Filter experiment name</b>	Filter for certain assays by activating the check box and entering an experiment name.
<b>Filter contained sample IDs</b>	Filter for specific sample IDs by activating the check box and entering one or multiple sample IDs. Multiple sample IDs must be entered in individual rows without any separators.
<b>Filter operator</b>	Filter for a specific operator by activating the check box and selecting an operator from the list.
<b>Filter cyclser serial number</b>	Filter for a cyclser serial number by activating the check box and entering a cyclser serial number (only digits).

### Filtering assays

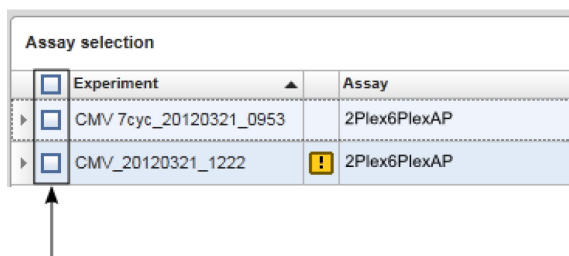
1. Change to the **Approval** environment by clicking the **Approval** icon (A) in the main toolbar.
2. In the **Filter options** section in the left panel of the screen, select the appropriate filter criteria.



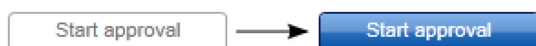
3. Enter a start and an end date in the **Start date** (B) and **End date** (C) fields either manually or using the date picker.
4. To use advanced search criteria, activate the **Use advanced filter options** check box (D).
5. Select the appropriate filter options. Multiple selections are possible.
6. Click **Apply filter** (E) to search the internal database for experiments meeting the criteria defined in the previous step.

All assays meeting the filter criteria will be listed in the **Assay selection** table (F) in the right panel of the **Approval** environment.

7. Activate the check box in front of the assay to approve. It is possible to select multiple assays.



The **Start approval** button is activated when at least one assay is selected:



8. Click **Start approval**.

**Note:** Click **Reset filter** (G) to reset the selected filter options to the default values, i.e., start date set to one month ago, end date set to today, advanced filter options deactivated.

### Approving samples

**Note:** Depending on which Rotor-Gene AssayManager plug-in is currently in use, the individual approval process may differ. For details regarding different approval procedures, refer to the corresponding Rotor-Gene AssayManager plug-in user manuals. In this manual, example screens and procedures for the UDT basic plug-in are shown.

### Reviewing Assay Data

*Reviewing data of a specific assay*

After the approval process is started, a screen is opened, split into two main areas: **Plots and information** and **Results**. If multiple assays were selected, all the selected assays will be listed in the tab list.

Depending on the assay type, experiment information can be reviewed in six different sub tabs:

- **Raw data**
- **Processed data**
- **Standard curve**
- **Experiment**
- **Assay**
- **Audit trail**

By default, the **Experiment** sub tab is opened upon starting the approval process.

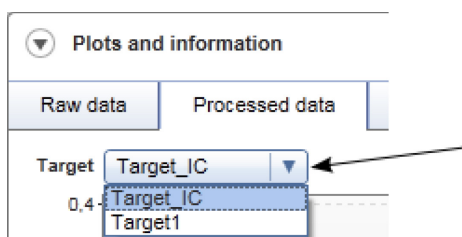
By default, all samples of an assay are selected.

1. To display only the amplification curves of specific samples, click the **Column select** icon in the header of the results table to deselect all samples.

Results

Pos.	Style	Sample ID	Type	Sample comment	Sample status	Targets	Result	Flags
1	<input checked="" type="checkbox"/>	D1	Test		Valid	Test IC	3.027.268,90 IU/ml Signal detected	-
2	<input checked="" type="checkbox"/>	D1	Test		Invalid	Test IC	INVALID INVALID	UPSTREAM, SPIKE, OTHER_T... UPSTREAM, WAVY_BASE_FL...
3	<input checked="" type="checkbox"/>	D1	Test		Invalid	Test IC	INVALID INVALID	UPSTREAM, OTHER_TARGET... UPSTREAM, WAVY_BASE_FL...
4	<input checked="" type="checkbox"/>	D1	Test		Valid	Test IC	2.429.148,62 IU/ml Signal detected	-

2. Click the **Sample selector** check box of the samples where amplification curve should be displayed.
3. Select the target from the **Target** drop-down list.



4. Review the individual amplification curves.

## Concept of buttons in artus plug-in

### Release of assay

After clicking **Start approval** in the **Assay selection** screen, the **Approval** screen will be displayed.

The amplification curves of all samples and external controls are automatically analyzed, and a specific result is determined. Tailored analysis parameters and rules are applied to the raw data of samples and external controls. This ensures the detection of any abnormal or invalid amplification curve behavior by Rotor-Gene AssayManager.

Result table options

Conc. in Sample ▼    Conc. unit Default unit ▼    ☒ Show standards / controls    ☒ Show IC    Assay comment

**A**                      **B**                      **C**                      **D**                      **E**

Option	Explanation
<b>A</b> Conc. in <span>Sample</span> ▼	Depending on the selection in this drop-down list, the detected concentration will automatically be calculated for the eluate or the original sample material (before sample preparation). This function is only available for quantitative assays with a conversion factor defined in the assay profile.
<b>B</b> Conc. unit <span>Default Unit</span> ▼	If several concentration units are defined in the assay profile, this menu is populated with the default concentration unit and alternative concentration units. The desired concentration unit can be selected from this drop-down list.
<b>C</b> <input checked="" type="checkbox"/> Show standards / controls	Show/hide the display of standards/controls in the <b>Results</b> table.
<b>D</b> <input checked="" type="checkbox"/> Show IC	By default, this check box is activated if an assay contains a target of type IC. Deactivate the check box to hide the IC specific results (target name, CT value, result, and result flag) from the <b>Results</b> table.
<b>E</b> Assay comment <input type="text"/>	Text field to enter a comment about the assay. Comment must not exceed 256 characters. After the first sample has been released, the comment cannot be changed.

## General information about releasing samples

The results of all samples determined by Rotor-Gene AssayManager are shown in the **Results** area of the **Approval** screen.

Pos.	Style	Sample ID	Type	Sample comment	Sample status	Targets	Result	Flags
1	■	D1	Test		Valid	Test IC	3.272.457,11 IU/ml Signal detected	- -
2	■	D1	Test		Invalid	Test IC	INVALID INVALID	SPIKE WAVY_BASE_FLUORESCENCE
3	■	D1	Test		Valid	Test IC	2.749.512,22 IU/ml INVALID	- WAVY_BASE_FLUORESCENC...
4	■	D1	Test		Valid	Test IC	2.617.965,97 IU/ml Signal detected	- -

The **Results** area contains the **Results** table with the detailed information about the individual samples.

- Position
- Color
- Style
- Sample ID
- Type
- Sample comment
- Sample status
- Targets
- Result
- Flags

Click the **Release/report data...** button to release the sample results and generate a report as a \*.pdf file. If a LIMS export is configured, the LIMS export file will also be generated.

**Note:** Click **Close** to close this screen and change to the **Assay selection** screen

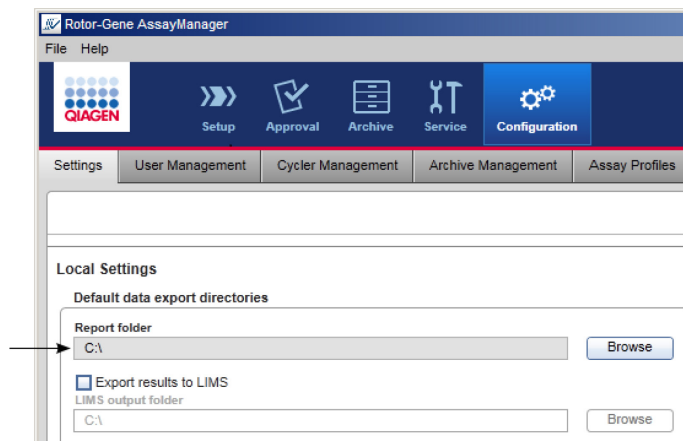
**Note:** Click **Create support package** to generate a support package from the current experiment.

### 6.1.7 Working with reports

A report can be generated either during the release of sample results in the **Approval** environment (see “Approving a run”, page 746) or from the **Archive** environment if experiments are already released.

**Note:** For FDA cleared or approved nucleic acid tests, the content and layout of the report is set by the plug-in.

**Note:** The target directory to save the generated report is defined in the **Settings** tab of the **Configuration** environment.

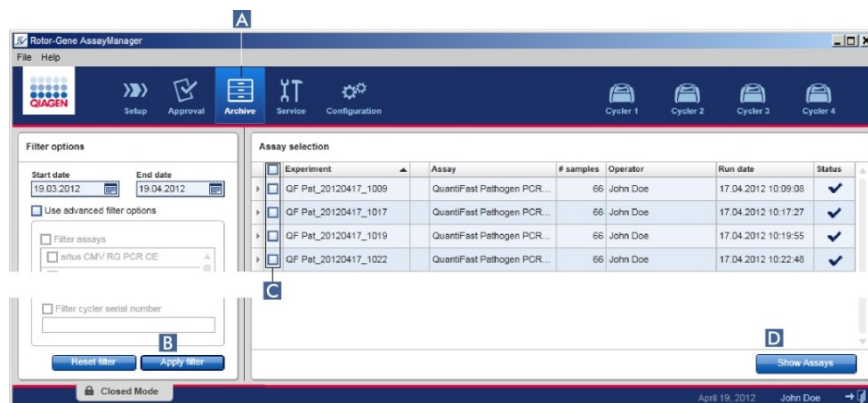




## Creating a report in the Archive environment

1. Click **Archive** (A) in the main toolbar to change to the **Archive** environment.

The **Assay selection** screen is displayed.

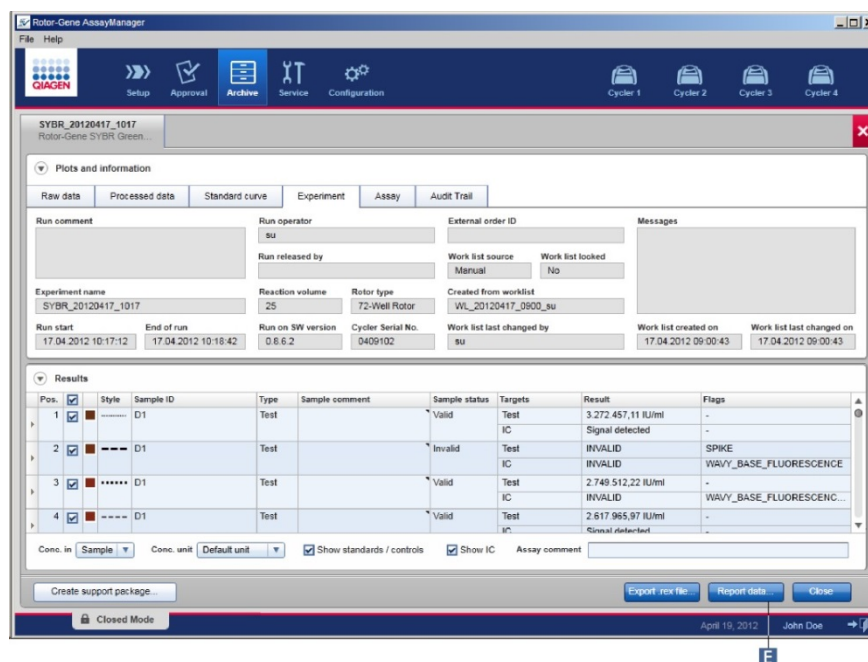


2. Select the appropriate filter options from the left panel and click **Apply filter** (B).

A list with assays matching the filter options is displayed.

3. Select one or multiple assays by activating the corresponding check boxes (C).

4. Click **Show assays** (D).



5. Click **Report data...** (E) in the button bar.

A report of the selected experiment is generated as a \*.pdf file and saved in the report folder defined in the **Configuration** environment.

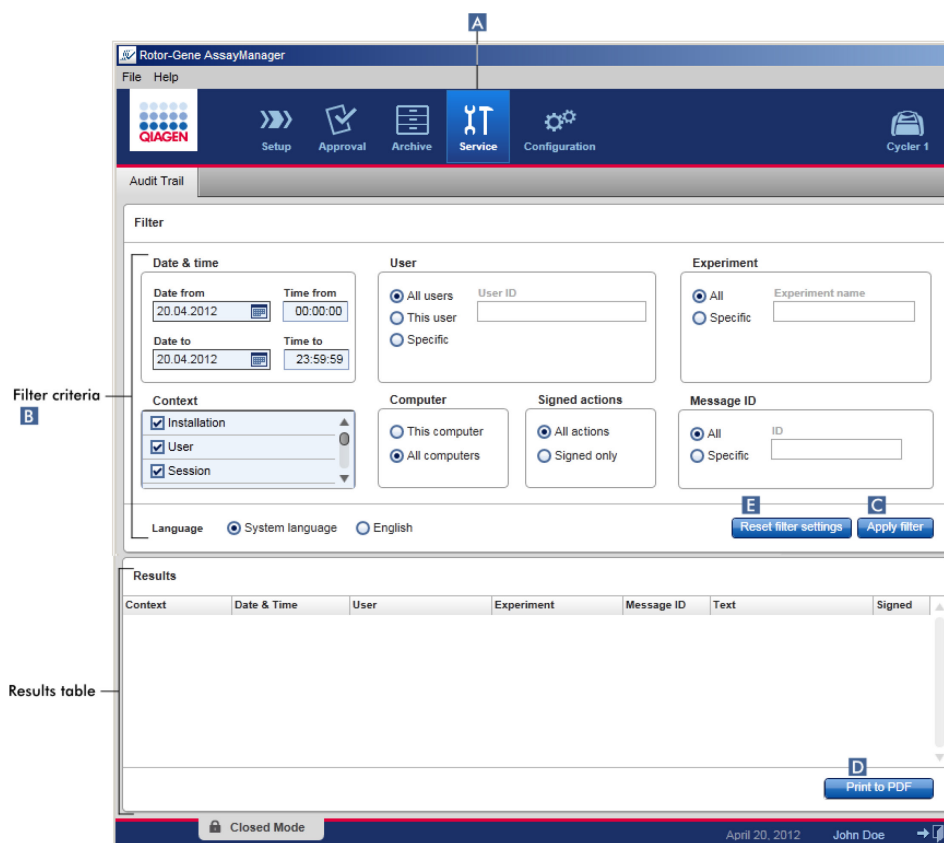
## Related topics

"**Archive** environment", page 678

"**Approval** environment", page 657

### 6.1.8 Working with audit trails

The audit trail logs all actions performed in Rotor-Gene AssayManager. In the **Service** environment, various filter criteria can be selected to filter the audit trail entries. All entries matching the filter criteria are listed in the **Results** table.



### Filtering for audit trail entries

1. Click **Service** (A) in the main toolbar.

The **Service** environment contains an **Audit Trail** tab containing:

- A **Filter** area to apply various filter criteria.
- A **Results** table where matching audit trail entries are listed.

2. Select filter criteria from the group boxes in the filter criteria area (B). Different filter criteria can be combined. The following filtering options can be used:

- **Date**
- **User**
- **Experiment**
- **Context**
- **Computer location**
- **Signed actions**
- **Message ID**

3. Click **Apply filter** (C).

All entries in the audit trail matching the filter criteria are listed in the **Results** table.

4. Click **Reset filter settings** (E) to set default filter options.

5. Click **Print to PDF** (D) to create a \*.pdf file containing the filter criteria and the dedicated audit trail entries.

This \*.pdf file has to be saved manually, if necessary.

**Note:** If the number of entries matching the filter criteria exceeds 1200 entries, an error message is shown. Adjust the filter settings.

### Related topics

"**Service** environment", page 682

## 6.2 Administrative tasks

The following administrative tasks can be performed by those users logged in as administrators.

**Warning:** Rotor-Gene AssayManager shall not be used with the admin account of Microsoft Windows operating system.

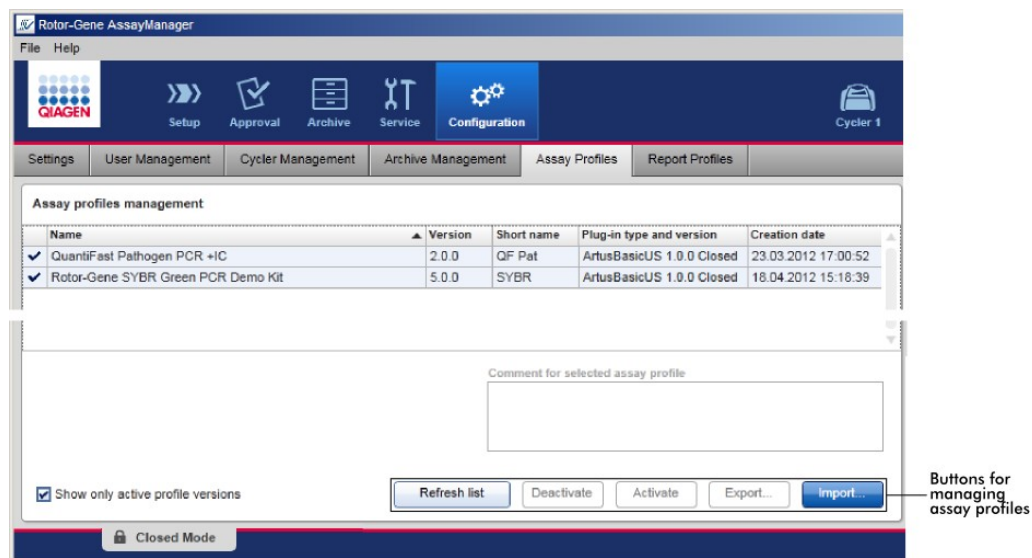
This section covers the following administrative topics:

- Managing assay profiles
- Managing report profiles
- Managing cyclers
- Managing users
- Managing archives
- Working with audit trails
- Customizing settings

### 6.2.1 Managing assay profiles

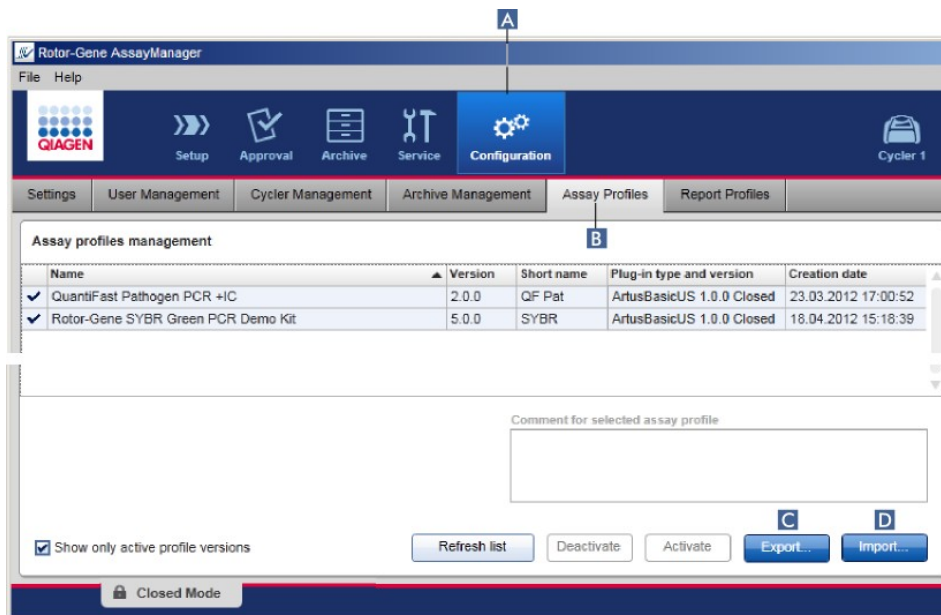
Assay profiles can be managed in the **Assay Profiles** tab of the **Configuration** environment.

All previously imported assay profiles are listed in a table. A button bar at the bottom of the screen contains all commands to manage assay profiles. Assay profiles can be activated, deactivated, imported, and exported.



#### Importing/exporting an assay profile

Rotor-Gene AssayManager provides an import/export feature for assay profiles to exchange assay profiles between different Rotor-Gene AssayManager installations. The imported assay profile is available for the creation of new work lists. This is done in the **Setup** environment. Newly developed assay profiles have to be imported before they can be used in Rotor-Gene AssayManager.



### Exporting an assay profile

The export of closed mode assay profiles (i.e. FDA cleared or approved nucleic acid tests) is not possible. The **Export** button (C) is deactivated.

### Importing an assay profile

1. Click **Configuration** (A) in the main toolbar.
2. Select the **Assay Profiles** tab (B).
3. Click **Import** (D).

The **Select file** dialog is opened.

4. Go to the directory containing the assay profile you want to import.
5. Select the assay profile, and click "Open".

The selected assay profile is loaded and added to the list of available assay profiles.

**Note:** The same version of an assay profile cannot be imported twice.

### Related topics

**Configuration** environment/**Assay Profiles** tab, page 715

"Setting up a run", page 732

"**Setup** environment", page 632

## Activating/deactivating an assay profile

Assay profiles can be activated and deactivated.

Only activated assay profiles are available for creating and applying work lists in the **Setup** environment.

Deactivated assay profiles cannot be used but can be reactivated by an administrator if required.

Existing work lists containing a deactivated assay profile can no longer be applied. This is indicated in the status column of the **Setup** environment.

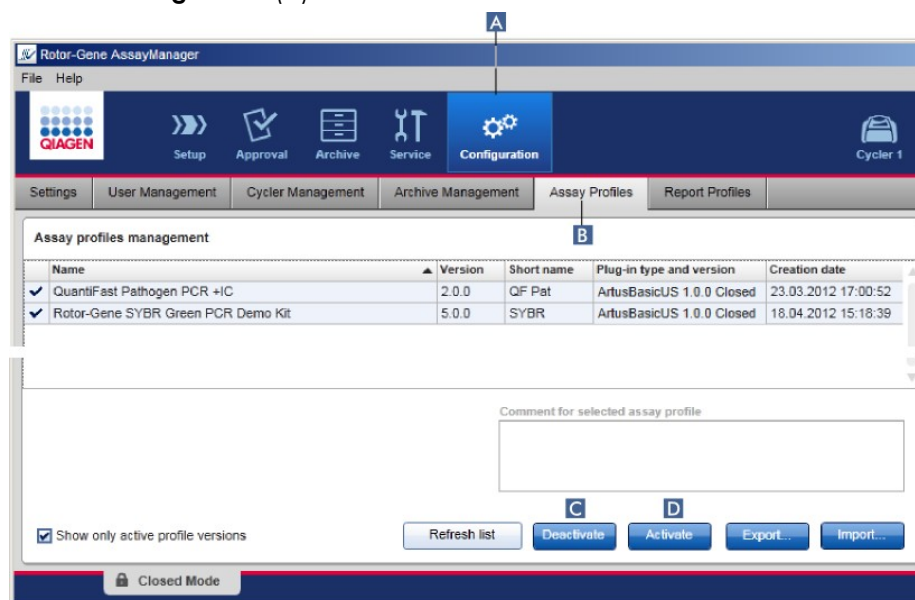
By default, the **Show only active profile versions** check box at the bottom left of the screen is activated.

To see activated and deactivated assay profiles in parallel in the list, deactivate the check box.

Activated  and deactivated  assay profiles can be differentiated by their icons.

## Deactivating an assay profile

1. Click **Configuration** (A) in the main toolbar.



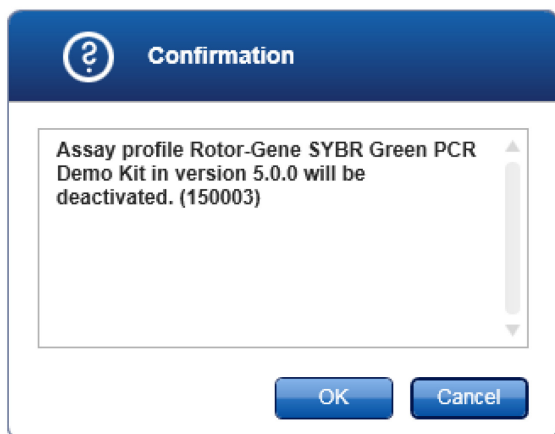
2. Select the **Assay Profiles** tab (B).

3. Select the assay profile to be deactivated by clicking in the corresponding table row.

The selected row is marked blue.

4. Click **Deactivate** (C).

The following confirmation dialog is opened:



5. Click **OK**.

The selected assay profile will be deactivated. The icon of the assay profile changes from  to  in the assay profiles table.

Assay profiles management		Assay profiles management	
Name		Name	
	QuantiFast Pathogen PCR +IC		QuantiFast Pathogen PCR +IC
	Rotor-Gene SYBR Green PCR Demo Kit		Rotor-Gene SYBR Green PCR Demo Kit

### Activating an assay profile

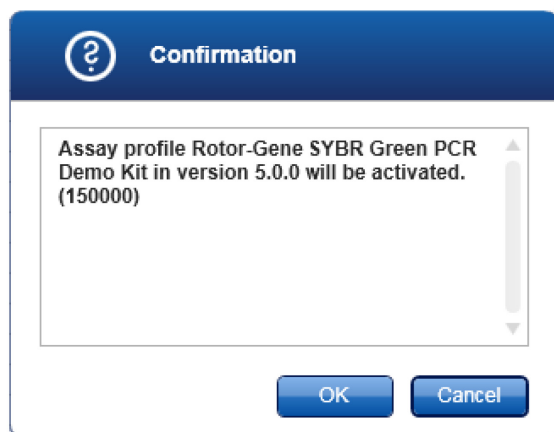
1. Click **Configuration** (A) in the main toolbar.
2. Select the **Assay Profiles** tab (B).
3. Ensure that the **Show only active profile versions** check box is deactivated.

Otherwise deactivated assay profiles are not shown and cannot be activated.



☐ Show only active profile versions

4. Select the assay profile to activate by clicking in the corresponding table row.  
The selected row is marked blue.
5. Click **Activate** (D).

The following confirmation dialog is opened:



6. Click **OK**.

The selected assay profile will be activated. The icon of activated assay profile changes from  to  in the assay profiles table.

**Note:** Only one version of an assay profile can be active. If another version of an active assay profile is activated, the previous one is automatically deactivated.

#### Related topics

**Configuration** environment/**Assay Profiles** tab, page 715

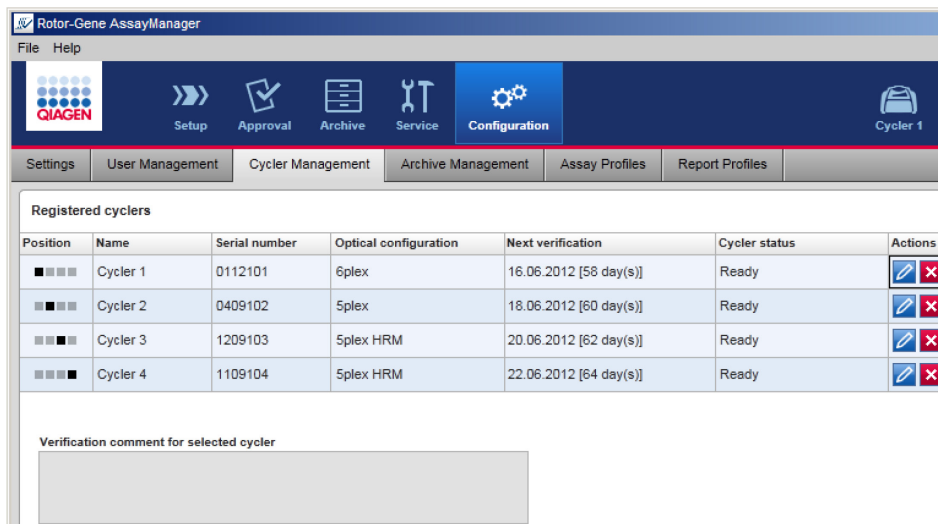
#### 6.2.2 Managing report profiles

**Note:** For FDA cleared or approved nucleic acid tests, the content and layout of the report is set by the plug-in.



### 6.2.3 Managing cyclers

Rotor-Gene AssayManager can manage and operate up to 4 different Rotor-Gene Q MDx instruments in parallel. The cyclers can be configured and managed in the **Cycler Management** tab of the **Configuration** environment.



Possible cycler states are:

Status	Description
Offline	The cycler is either connected or not connected but not turned on.
Ready	The cycler is activated and ready.
Loaded	The cycler is loaded.
Needs verification	The cycler needs to be verified.
Running	The cycler is performing a run.
Run stopped	The cycler was stopped but has not yet been released.
Run complete	The run finished successfully.
Run failed	An error occurred during the run.

Status	Description
<b>Run stopped, cyclers disconnected</b>	The cyclers have been disconnected after the run has been stopped but have not been released yet.
<b>Run complete, cyclers disconnected</b>	The cyclers were disconnected after the run had been completed.
<b>Run failed, cyclers disconnected</b>	The cyclers were disconnected after the run had failed.

### Adding a cycler

**Note:** Rotor-Gene AssayManager is only compatible with Rotor-Gene Q Series built after November 2009 having a 7-digit serial number (e.g., R1234567). Older Rotor-Gene Q/Rotor-Gene 6000 models (6-digit serial number) cannot be operated with Rotor-Gene AssayManager version 1.0.x (x ≥ 5).

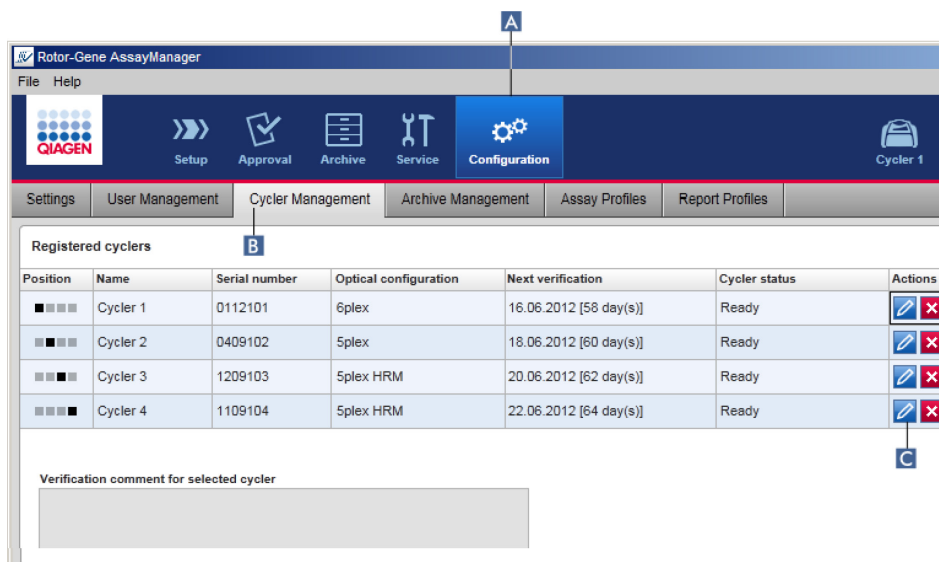
1. Connect the USB cable supplied to a USB port of the computer.
2. Connect the USB cable to the back of the Rotor-Gene Q MDx.
3. Connect the Rotor-Gene Q MDx to the power supply.  
Connect one end of the AC power cord to the socket located at the rear of the Rotor-Gene Q MDx and the other end to the AC power outlet.
4. Once the software has been installed, switch on the Rotor-Gene Q MDx by moving the switch, located at the back on the right-hand side, to the "On" position.

**Note:** Each Rotor-Gene Q MDx has to be registered by Windows before it can be used by Rotor-Gene AssayManager. The registration is performed automatically when a connected cycler is switched on.

**Note:** For details about hardware installation and the installation of the Rotor-Gene Q software, refer to Sections 3 and 4 in Part III of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

5. Open Rotor-Gene AssayManager.

**Note:** If Rotor-Gene AssayManager was previously open, switch off the Rotor-Gene Q MDx and switch it on again.



6. Click **Configuration** (A) in the main toolbar.

7. Select the **Cycler Management** tab (B).

**Note:** The cycler must be connected to the computer and switched on before it can be registered in Rotor-Gene AssayManager.

8. Click the **Edit cycler** icon (C) of an empty row.

The **Edit cycler** dialog opens.

**Edit cycler**

Position: ■ ■ ■ ■

Name:  (D)

Serial number:  (E)

Optical configuration:

Next verification:  (F)

Days until next verification:

Verification comment:

Messages:

OK Cancel

9. Enter a name with up to eight characters in the **Name** field (D).

10. Enter the serial number of the connected Rotor-Gene Q MDx in the **Serial number** field (E).

The optical configuration of the cycler will automatically be recognized by Rotor-Gene AssayManager when the name and serial number are entered.

- Optional: Enter a date when the cycler next needs verification in the **Next verification** field (F). Include a **Verification comment**.

The comment field can be used to specify what kind of verification shall be performed at the defined date.

- Click **OK** to add the Rotor-Gene Q MDx to the **Registered cyclers** table.

**Note:** If more than one cycler is registered in Rotor-Gene AssayManager, we highly recommend labeling each cycler clearly on the front instrument housing with the specific name given during registration. This simplifies identification of cyclers when loading or when several cyclers are running in parallel. It avoids the necessity to refer to the serial number on the type plate.

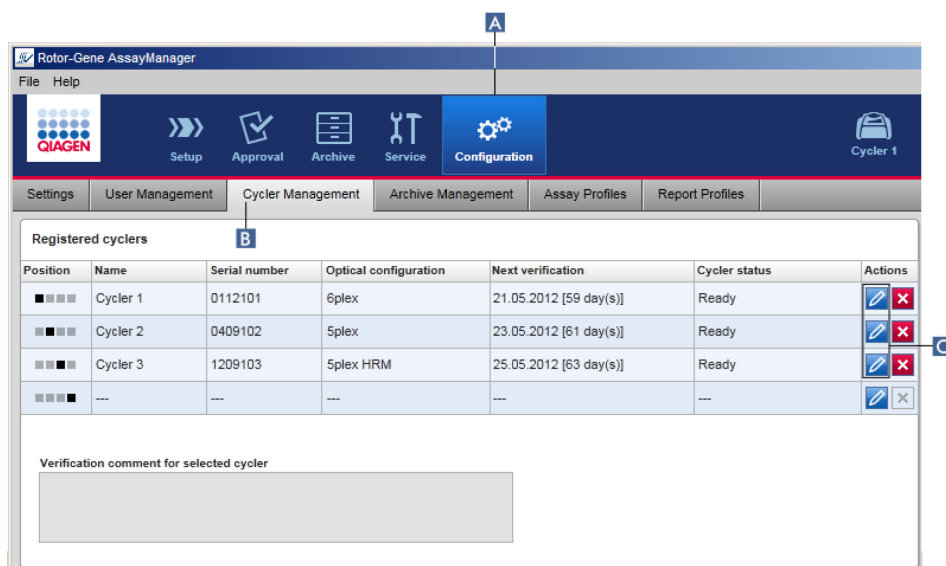
## Related topics

"Setting up a run", page 732

"Cycler environment", page 646

## Editing cycler settings

- Click **Configuration** (A) in the main toolbar.
- Select the **Cycler Management** tab (B).



- Click the **Edit cycler** icon (C) of a cycler that is already registered.

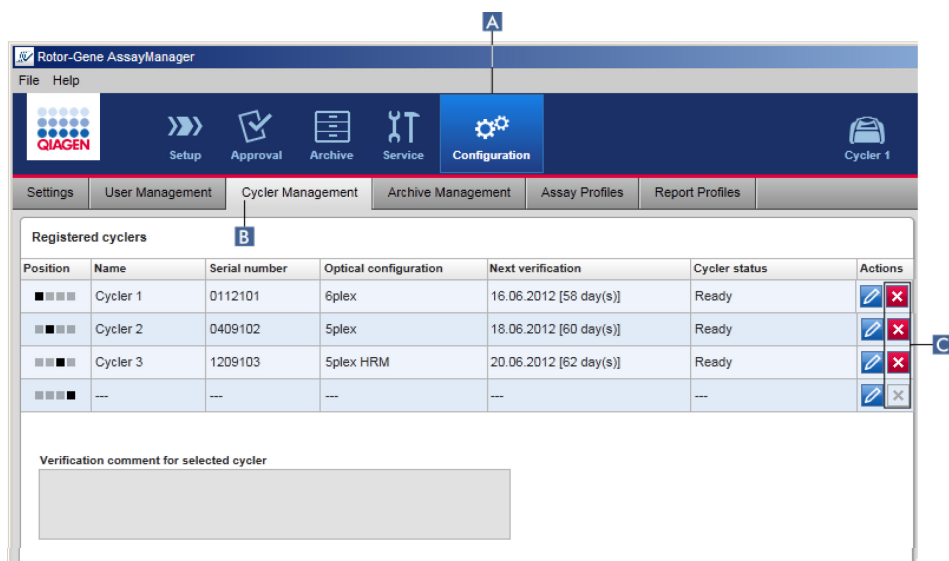
The **Edit cyclers** dialog opens.

4. Edit the cyclers name, the next verification date, and the verification comment.
5. Click **OK** to update the cyclers configuration.

## Removing a cycler

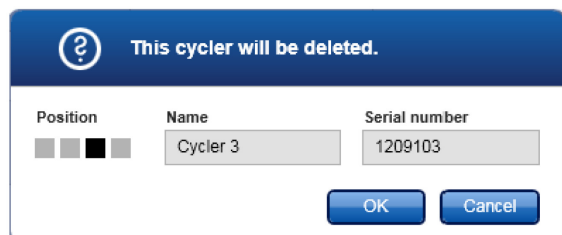
**Note:** Cyclers can only be removed if they are offline, ready, or with the status **Needs verification**.

1. Click **Configuration** (A) in the main toolbar.
2. Select the **Cycler Management** tab (B).



3. Move the mouse to the row containing the cycler to be removed from the **Registered cyclers** table.
4. Click the **Remove cycler** button (C).

The following confirmation dialog is opened.



5. Click **OK**.

The selected cycler is removed from the **Registered cyclers** table and cannot be used.

## Related topics

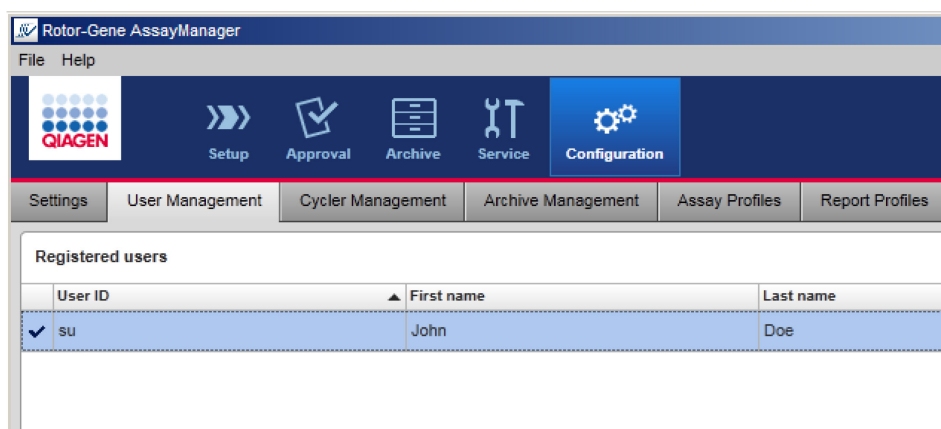
"Setting up a run", page 732

"**Cycler** environment", page 646

### 6.2.4 Managing users

A user with the assigned role "Administrator" can add new user profiles or activate, deactivate, and modify existing user profiles. User profiles cannot be deleted but only deactivated, if necessary.

Users are managed in the **User Management** tab of the **Configuration** environment.

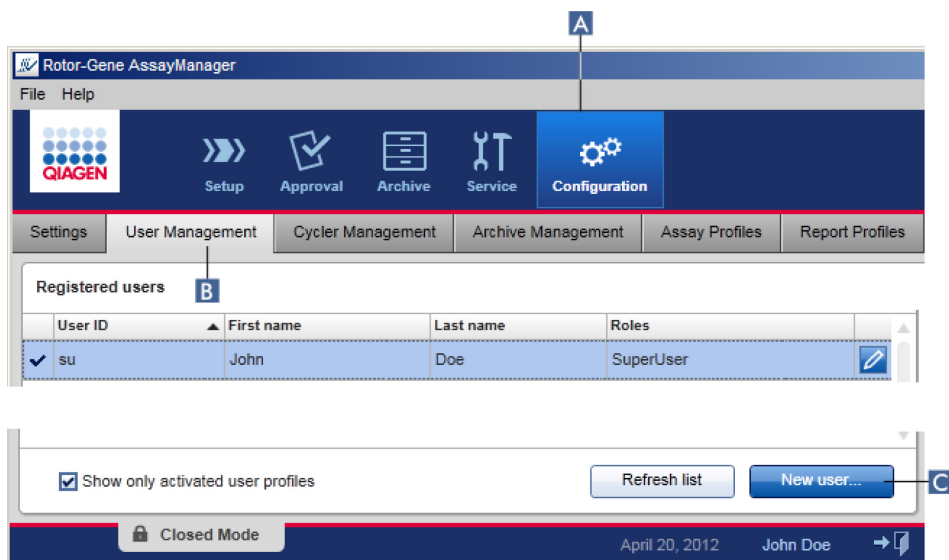


The following topics are covered in this section:

- Creating a user profile
- Changing user profile settings
- Activating/deactivating a user profile
- Setting password policies and auto-lock timer

### Creating a user profile

1. Click **Configuration** (A) in the main toolbar.
2. Select the **User Management** tab (B).



3. Click **New user...** (C).

The **Add user** dialog opens.

The 'Add user' dialog box is shown. It has the following fields and controls:

- First name** (D): Text input field.
- Last name** (E): Text input field.
- User ID** (F): Text input field.
- Password** (G): Text input field.
- Confirm password** (H): Text input field.
- Roles** (J): A list box containing: Administrator, Approver, AssayDeveloper, Operator, and SuperUser.
- Activate user** (I): A checked checkbox.
- Messages**: A list of validation errors:
  - Enter a valid first name (1-50 characters). (150040)
  - Enter a valid last name (1-50 characters). (150041)
- Buttons**: 'OK' and 'Cancel' at the bottom.

4. Enter the first name, the last name, and a user ID in the corresponding fields (D, E, and F).
5. Enter a password in the **Password** field (G).
6. Enter the password again in the **Confirm password** field (H).

**Note:** The password must be in the range of 8–40 characters. If CLIA complaint password rules are activated in the **Settings** tab of the **Configuration** environment, the password

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has to contain at least 2 upper case characters, 2 lower case characters, 2 numerical characters, and 2 special characters.

7. The **Activate user** check box (I) is activated by default. To create a deactivated user profile, deactivate this check box.
8. Activate the check boxes in the **Roles** table (J).  
These are the roles that will be assigned to the user. It is possible to assign multiple roles to a user.
9. Click **OK**.  
The new user profile is added to the **Registered users** table.

**Note:** The user must change the password at the first login.

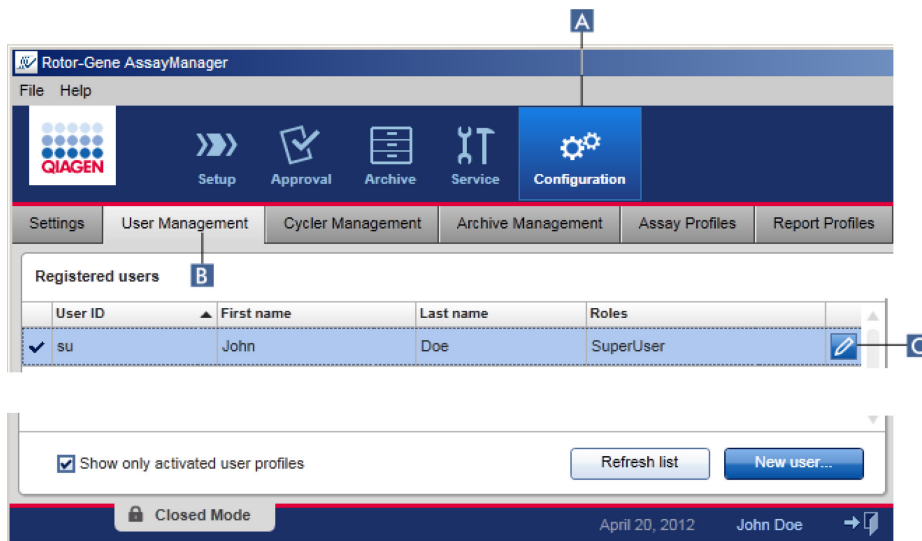
**Note:** Password rules can be set up in the **Configuration** environment in the **Settings** tab.

### Changing user profile settings

**Note:** A user ID can never be edited or removed. However, the following data can be modified:

- First name
  - Last name
  - Password
  - Roles
1. Click **Configuration** (A) in the main toolbar.
  2. Select the **User Management** tab (B).





3. Click the **Edit user** icon (C) of a user profile.

The **Edit User** dialog opens.

4. If applicable, modify the name of the user in the **First name** (D) or **Last name** (E) fields.
5. If applicable, enter a new password in the **Password** field (F).
6. Enter it again in the **Confirm password** field (G).
7. Toggle the **Activate user** check box (H) to change the activation status of the user.
8. If applicable, modify the check boxes in the **Roles** table (I). It is possible to assign multiple roles to a user.
9. Click **OK**.

The user profile will be updated according to the modifications made.

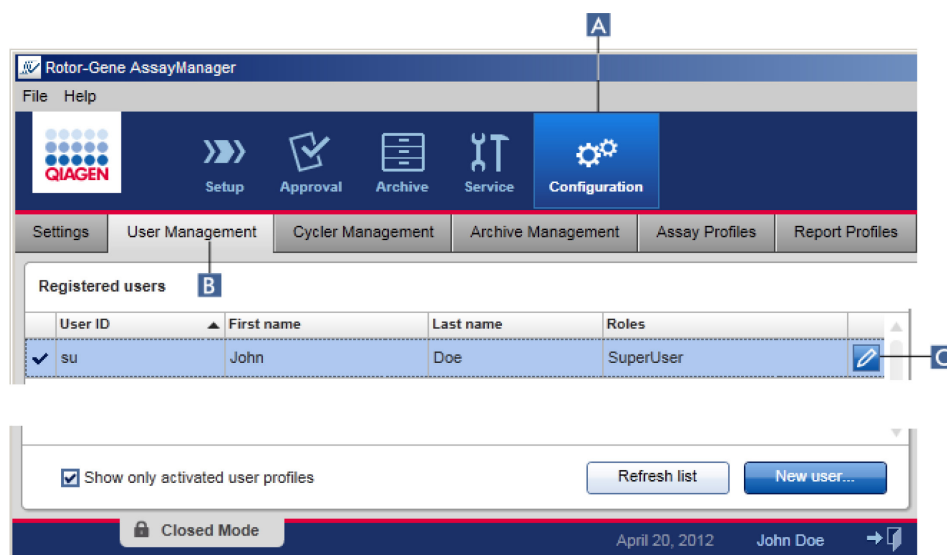
**Note:** The user must change the password at the next login.

### Activating/deactivating a user profile

A user profile can never be deleted but only deactivated. This ensures that actions in the audit trails can always be tracked back to a specific user.

**Note:** Only the status of a user who is currently not logged in can be changed.

**Note:** Deselect **Show only activated user profiles** to make deactivated user profiles visible in the **Registered users** table.





#### Deactivating a user

1. Click **Configuration** (A) in the main toolbar.
2. Select the **User Management** tab (B).
3. Click the **Edit user** icon (C) of a user profile.


The **Edit User** dialog opens.

4. Uncheck the **Activate user** check box (D) to deactivate the user profile.
5. Click **OK**.

The user profile is deactivated. Its status icon in the **Registered users** table changes from  to .

#### Activating a user

1. Click **Configuration** (A) in the main toolbar.
2. Select the **User Management** tab (B).
3. Ensure that the check box **Show only activated user profiles** is unchecked to make deactivated user profiles visible.
4. Click the **Edit user** icon (C) of a deactivated user profile.  
The **Edit User** dialog opens.
5. Activate the **Activate user** check box (D) to activate the user profile.
6. Click **OK**.

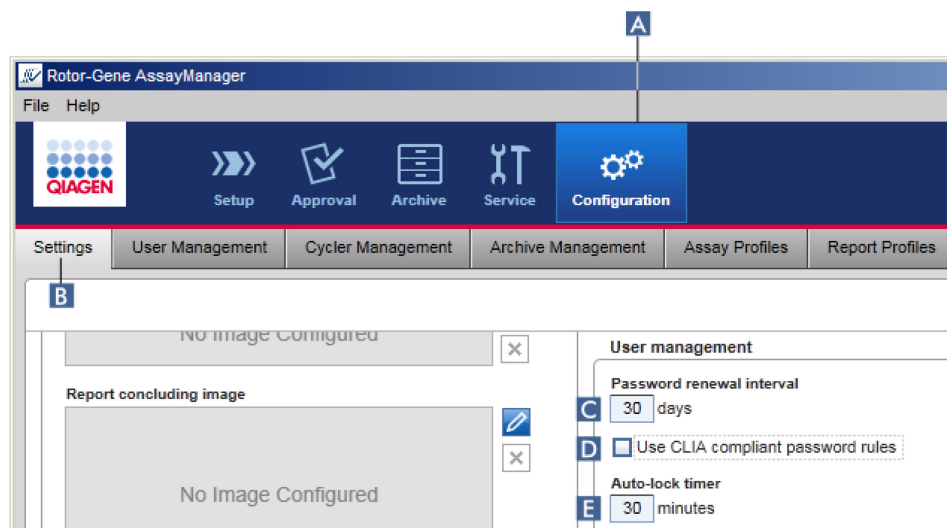
The user profile is activated. The status icon in the "Registered users" table changes from  to .

#### Setting password policies and auto-lock timer

A user with assigned role "Administrator" can set up password policies and the auto-lock timer in the **Settings** tab of the **Configuration** environment.

Passwords for user profiles have to be changed after the specified number of days. The administrator can also define that CLIA compliant password rules must be applied for password creation.

The auto-lock timer locks the application after a certain time without user interaction.



#### Setting the password renewal interval

1. Click **Configuration** (A) in the main toolbar.
2. Select the **Settings** tab (B).
3. Go to the **User management** group box.
4. Enter the number of days in the **Password renewal interval** field (C).  
After this interval the password for a user profile should expire.

**Note:** Entering a value of 0 means the password will never expire.

#### Activating CLIA compliant password rules

1. Click **Configuration** (A) in the main toolbar.
2. Select the **Settings** tab (B).
3. Go to the **User management** group box.
4. Activate the check box **Use CLIA compliant password rules** (D).  
The user is required to use CLIA compliant passwords.

Further information on password rules can be found in "Password policy", page 607.

### *Setting up the auto-lock timer*

1. Click **Configuration** (A) in the main toolbar.
2. Select the **Settings** tab (B).
3. Go to the **User management** group box.
4. Enter the number of minutes after which the application will be locked in the **Auto-lock timer** field (E).

After the specified time without user interaction, the application will be locked.

**Note:** Entering a value of 0 means the auto-lock timer is deactivated and the user is never logged out automatically.

### **Related topics**

"Managing users", page 768

"User roles", page 603

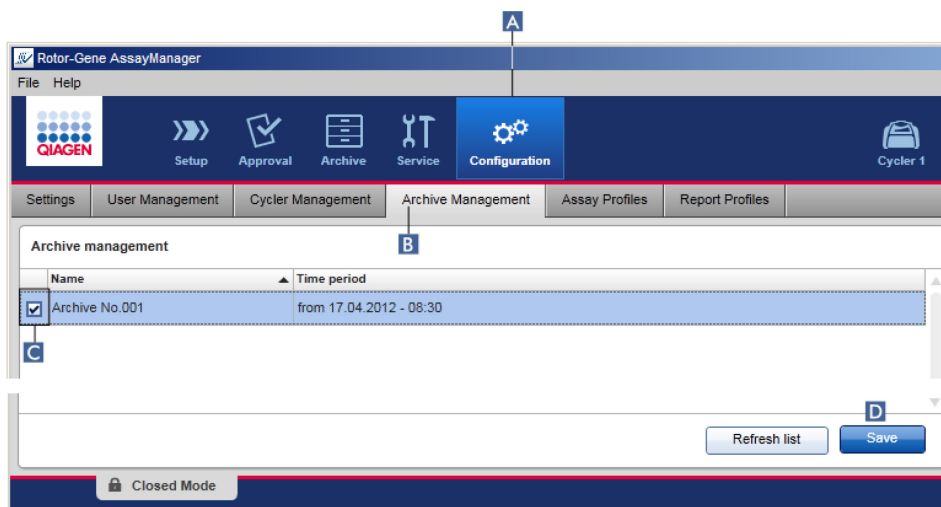
## 6.2.5 Managing archives

Rotor-Gene AssayManager creates archives to save and archive experiment data with a size of up to 10 GB each. A new archive is created automatically when the archive currently used is full.

When filtering for specific experiments in the **Archive** environment is applied, only activated archives are browsed. By default, this is the archive currently in use. If searching becomes too slow due to increasing data sizes, archives can be deactivated.

It is possible to include deactivated archives in the browsing process by reactivating them in the **Archive Management** tab of the **Configuration** environment.

**Note:** Browsing in several archives will slow down the search time of Rotor-Gene AssayManager.



### Activating or deactivating an archive

1. Click **Configuration** (A) in the main toolbar.
2. Select the **Archive Management** tab (B).

The **Archive Management** screen contains a table listing all existing archives. A check box at the beginning of every row (C) indicates if an archive is activated or deactivated.

If the check box is checked, the archive is activated.

If the check box is unchecked, the archive is inactivated.

3. Check the check box of an archive to activate it.  
Uncheck the check box of an archive to deactivate it.
4. Click **Save** (D).

### 6.2.6 Customizing settings

A user with the assigned role "Administrator" can customize the settings in the **Configuration** environment. The settings are divided into two sections, **Global settings** and **Local settings**.

**Global settings** are stored in the database and affect all clients using the database.

**Local settings** affect only a specific computer. For details, see "**Settings** tab", page 689.

## 7 Maintenance

Rotor-Gene AssayManager version 1.0x (x ≥ 5) is software and does not need to be maintained in general. However, the database requires maintenance.

### Maintaining the database

**Important:** It is important to back up the database.

- In the case of computer failure, you are able to recover your data from your last backup.
- It is not possible to back up the content of the computer's hard disc directly to get a backup of the database.

The Rotor-Gene AssayManager (RGAM) Database Backup Tool software has been specifically developed for the use with the Rotor-Gene AssayManager v1.0 software.

RGAM Database Backup Tool is software for the automatic backup creation of the Rotor-Gene AssayManager database (Microsoft SQL Server Express) using Windows Task Scheduler. The RGAM Database Backup Tool has the functionality to restore previously created backup files automatically.

For maintaining the database, download the RGAM Database Backup Tool software on the QIAGEN webpage. Refer to the RGAM Database Backup Tool User Manual for further information

### Precondition

A special software tool is needed for creating a backup of the Rotor-Gene AssayManager database.

The Microsoft SQL Server Management Studio Express (SSMSE) is a graphical management tool for SQL Server 2014 R2 Express used as database in Rotor-Gene AssayManager. See <http://www.microsoft.com> for instruction on how to download and install the SSMSE.

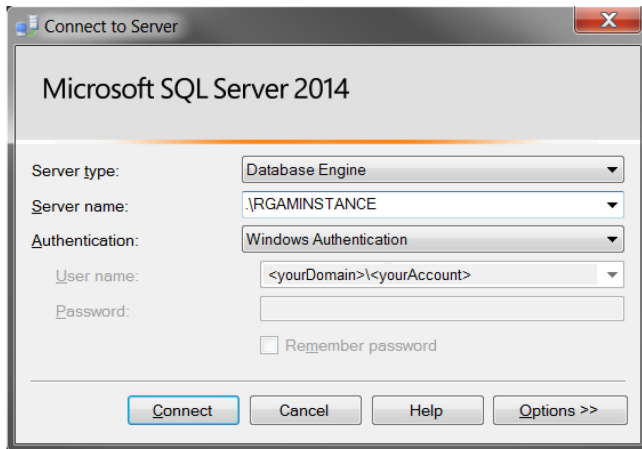
**Note:** Select for download a Microsoft SQL Server Management Studio Express version for 32-bit computer systems. These are typically denoted with "x86" in the file name.

**Note:** You must have administration privileges for installing the SSMSE.

## First start

**Note:** You must have appropriate rights for working with the SSMSE.

When starting SSMSE you must authenticate yourself. The name of the server is RGAMINSTANCE.



## Hints for backing up a database

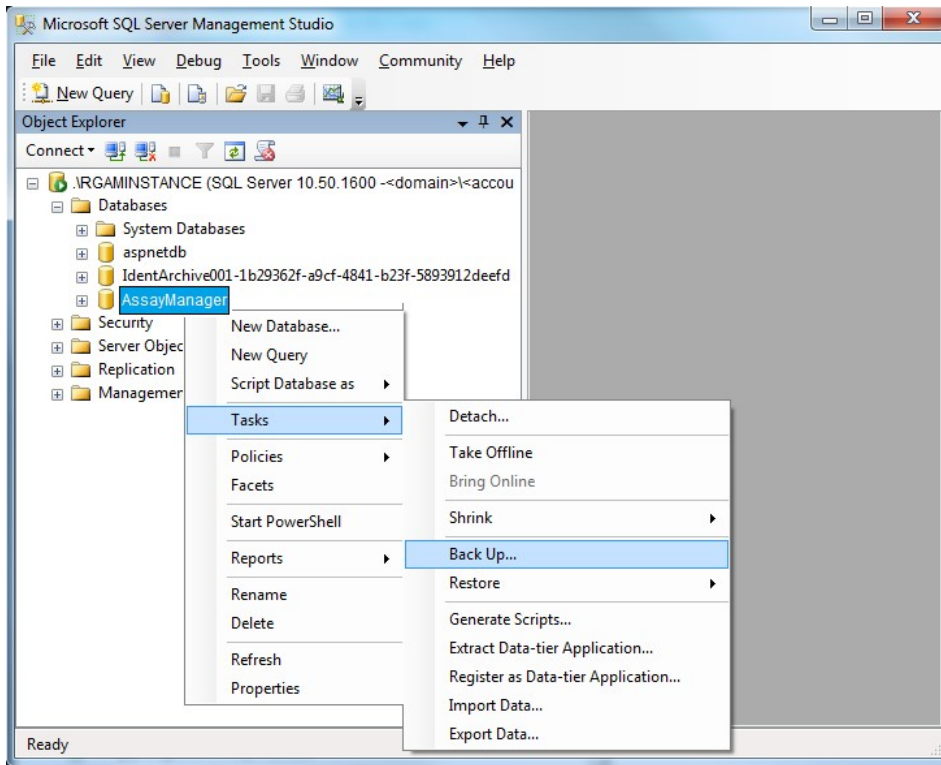
- Before backing up the database, close Rotor-Gene AssayManager.
- Make sure no runs are active.
- Make sure all changes are saved.
- Make sure all remotely connected Rotor-Gene AssayManager instances are shut down.

Back up the following databases:

- aspnetdb
- Rotor-Gene AssayManager
- All databases starting with "IdentArchive"



To access the backup option dialog, select the context menu entry for the desired database.



Further information for setting up the backup of the database according to your demands can be obtained from the Help function of the SSMSE or from <http://www.microsoft.com>.

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## 8 Troubleshooting

This section provides information about what to do if an error occurs when using Rotor-Gene AssayManager v1.0.

### Resolving error messages and warnings

Error messages and warnings are displayed when a problem occurs during the operation of Rotor-Gene AssayManager v1.0. All messages have an error ID, which is displayed at the end of the error message.

It is possible that several errors are combined in only one message. Refer to the error IDs listed in this section if an error message or warning appears.

If error messages or warnings appear that are not listed here or if the error cannot be resolved, note the error ID, the error text, and the steps leading to the error then contact QIAGEN Technical Services.

**Note:** If QIAGEN Technical Services needs to be consulted for troubleshooting of an error, note the steps leading to the error and the information from any dialog boxes that appear (or at least the error IDs). This will help the QIAGEN Technical Service Specialist to resolve the error.

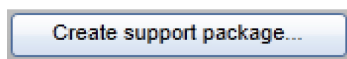
If there are problems with a specific experiment, create a support package and send it to QIAGEN Technical Services.

### Creating a support package

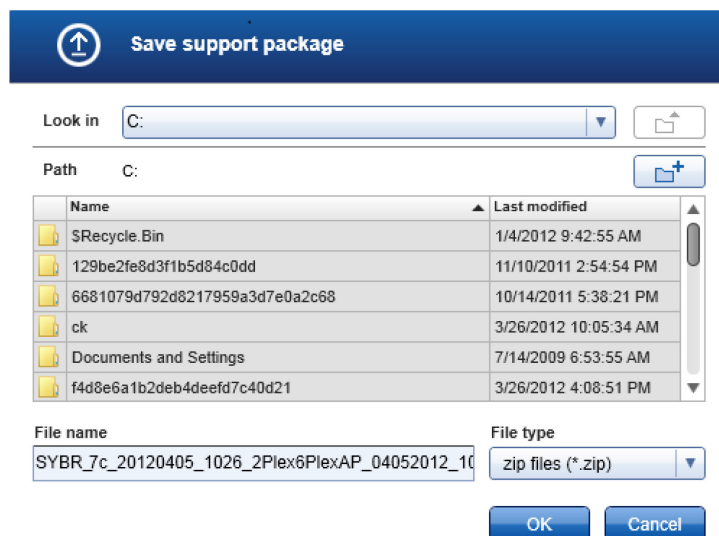
Rotor-Gene AssayManager v1.0 provides the possibility to create support packages containing all relevant information about a specific experiment.

Depending on the approval status of the erroneous experiment, go to the **Approval** environment, select the correct experiment, and start the approval process, or go to the **Archive** environment and let the assay data be displayed.

Click **Create support package...** at the bottom left of the screen to create a support package for the selected experiment.



A dialog opens for selecting a file name and the directory where the support package will be saved. The default support package file name contains the experiment name followed by the assay profile name, the current date, and time.



The support package will be saved as a single file containing all relevant information about the experiment. This file can be attached to an email and sent to QIAGEN Technical Services for troubleshooting.

**Note for laboratories using several installations of Rotor-Gene AssayManager v1.0:** A support package should always be created at the computer that was connected to the Rotor-Gene Q MDx during processing the erroneous experiment to ensure that all relevant information is included.

## 8.1 System setup

This section contains information about potential errors during system setup.

Error description	Comments and suggestions
Computer or Rotor-Gene Q MDx does not turn on	Check the power connection. The power cable might be loose or faulty. Reconnect or replace the cable.
Rotor-Gene AssayManager cannot communicate with cyclor	Check the cable connection between Rotor-Gene Q MDx and the computer. The USB cable might be loose or faulty. Reconnect or replace the cable. Only use cables and accessories supplied by QIAGEN that are dedicated for connecting the Rotor-Gene Q MDx. Switch off the Rotor-Gene Q MDx and switch it back on again. Close the Rotor-Gene Software, if applicable. Restart Rotor-Gene AssayManager.
Rotor-Gene AssayManager does not start	
(a) Rotor-Gene AssayManager is not installed	Install Rotor-Gene AssayManager
(b) Old version of Microsoft Windows	Rotor-Gene AssayManager can only be operated with Windows 10 or Windows 7 Professional edition.
(c) No plug-in installed	Rotor-Gene AssayManager consists of the core software and plug-ins with application specific components. At least one plug-in must be installed to be able to use Rotor- Gene AssayManager.
Rotor-Gene AssayManager does not work properly and freezes before the user can log in	Rotor-Gene AssayManager is only compatible with Windows 10 and Windows 7 Professional editions. Windows Vista® may cause severe problems when using Rotor-Gene AssayManager. Update to Windows 7 Professional edition or

Error description	Comments and suggestions
	install Rotor-Gene AssayManager on another computer with a compatible Windows version.

## 8.2 Operation

This section contains information about potential errors during operation of Rotor-Gene AssayManager version 1.0.x (x ≥ 5).

*Instrument-related errors not covered by an error ID*

Error description	Comments and suggestions
Weak or no fluorescence signal detected	Open the lid of the Rotor-Gene Q MDx and ensure that the lenses, located at both the emission and the detection sources, are clean. This is achieved by gently wiping a cotton tip applicator, moistened with ethanol, over the lenses. For details see the Maintenance section of the <i>Rotor-Gene Q MDx User Manual (US)</i> in Part I of Volume 2 of the <i>QIAAsymphony RGQ MDx (US) User Manual</i> .
Erroneous instrument performance	Keep the work bench area clean and free from dust and sheets of paper. The air inlet of the Rotor-Gene Q MDx is at the bottom. Loose material such as paper or dust may compromise performance.
Run cannot be started	Close the lid of the Rotor-Gene Q MDx before starting.

## Software-related errors

Error description	Comments and suggestions
Second Rotor-Gene AssayManager installation cannot access data from another installation	If several Rotor-Gene AssayManager installations are used, ensure that core software and plug-ins of all installations have exactly the same version. Software upgrades have to be applied simultaneously to all computers sharing Rotor-Gene AssayManager data.
QIASymphony AS result file cannot be imported to Rotor-Gene AssayManager	<p>Rotor-Gene AssayManager is only compatible with QIASymphony software version 4.0 or higher. Update your QIASymphony system to the latest software version.</p> <p>The QIASymphony AS result file must match an assay profile in the Rotor- Gene AssayManager database.</p>
The background in plots is printed in black	<p>Some printer drivers are configured in a way that the transparent background colors used in the Rotor-Gene Assay Manager plots are printed in black. Check the manual of your printer how to change this configuration.</p> <p>Technical background: To ensure that the displayed results of the plots are exactly the same as the printed reports, the background colors need to be transparent.</p>

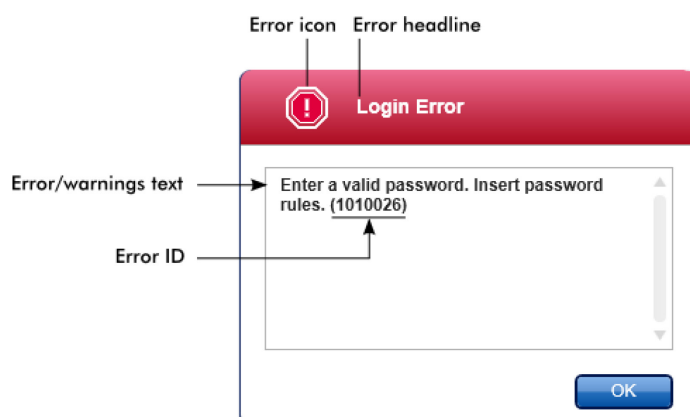
## General errors

Error description	Comments and suggestions
Incorrect rotor loading	Load tubes in the correct orientation into the rotor ensuring that each tube sits correctly in place. Samples will not optimally be aligned over the detection system if not placed correctly in the rotor. This could result in a reduction of the acquired fluorescence signal and the detection sensitivity.
Missing locking ring	Always attach the dedicated locking ring to the rotor before starting a run. The locking ring ensures that caps remain on tubes during a run and that tubes sit correctly in place.
Rotor not completely filled	To achieve maximum temperature uniformity, each position in the rotor must contain a tube. Filling all positions in the rotor ensures even airflow to every tube. Keep a set of empty capped tubes available that can be used to fill any unused positions.
The bar code of a QIAGEN kit cannot be read using the handheld bar code scanner	Make sure that the handheld bar code scanner is correctly connected to the computer and configured properly, e.g., that data will be sent after pressing <b>Enter</b> . Try to read other bar codes with the scanner. Ensure that all bar codes can be easily read.
Login error	<p>Check whether the user name is correct.</p> <p>Make sure to enter the correct password. Note that after 3 unsuccessful log-in attempts the user profile will be locked. In that case, another registered user with the role of an administrator has to reactivate the user profile.</p>

Error description	Comments and suggestions
Sample position is incorrect	When setting up an experiment be sure to place the reaction tubes in the correct positions of the rotor. During work list setup, the sample details and their respective positions can be displayed or printed using the <b>View sample details...</b> or the <b>Print work list...</b> buttons respectively. Do not invert the strip tubes during transfer from assay setup to the rotor.

### 8.3 Error messages and error codes

The source of a message is indicated in the error ID. The general structure of an error ID is shown in an example of an error dialog.



The following table lists all error messages that might occur during operation of Rotor-Gene AssayManager. If QIAGEN Technical Services needs to be contacted, provide the service specialist with the following information:

- Actions performed before the error message occurred
- Error ID

**Note:** The error ID is unique and helps QIAGEN Technical Services to clearly identify the error message.



Error ID	Error text
30007	Assign at least one role to user {0}.
30008	The following roles in the database are obsolete: {0}. Contact QIAGEN Technical Services.
30009	Could not find the following role '{0}' in the database. Contact QIAGEN Technical Services.
30011	The database connection is lost. Running experiments will continue; they will be saved automatically into the database as soon as the connection is restored. Log in again. If the problem persists, contact your system administrator.
30013	The application initialization failed because the database connection is not available. The application will exit now. Contact your local administrator.
30014	Could not log-in to the application. The database connection is lost. Contact your local administrator.
30017	Rotor-Gene AssayManager is already started on this computer.
110000	The new assay profile failed. Check the assay profile content and load again.
110005	Assay profile could not be loaded.
110006	The assay profile could not be saved. The system could not write to file system. Contact your local administrator.
110007	The required plug-in {0}, version {1}, for the selected assay profile is not available. Ask your software administrator to install the plug-in.
110008	In Closed Mode only assay profiles distributed by QIAGEN can be loaded. The selected file is not a QIAGEN original file. Switch to User Defined Test Mode to open the selected assay profile.

Error ID	Error text
110009	In User Defined Test Mode (UDT Mode), you cannot load profiles distributed by QIAGEN for Closed Mode. The file will not be loaded. Log in in Closed Mode to load this file.
110010	The signature of the file is invalid. It will not be loaded. Provide a valid signature.
110019	The selected assay profile contains an unknown rotor type. Select a different assay profile.
110036	The selected run template cannot be used with the selected plug-in "{0} {1} {2}".
110038	The run profile could not be loaded. The optical configuration does not match any of the cyclers currently available.
110039	The run profile could not be loaded.
110040	The optical configuration is unknown
110044	The run template of the current assay profile does not match the run settings of the .rex-file.
110048	One or more steps in the assay profile editor are invalid. Correct these invalid steps to start the assay profile tester.
110049	The .rex file at {0} cannot be accessed. Check if the .rex file path is correct.
110055	The color channels of the run profile of the current assay profile do not match the .rex file color channel {0}. Select another assay profile or .rex file.
110056	The samples of an assay must be arranged without gaps. At .rex file tube position {0} on page {1} a sample is positioned after a gap.
110057	Based on the assay profile, a {0} sample is expected in .rex file tube {1} but the .rex file contains a {2} sample. Adjust the assay profile or select another .rex file.

Error ID	Error text
110058	There is no plug-in available with name {0}, version {1} and application mode {2}.
110059	The signature of .rex file {0} is invalid. It cannot be loaded. Select another .rex file.
110060	The samples of an assay must be arranged without gaps. The .rex file page {0} contains empty tubes that do not reach the end of the file.
110061	Not all control samples of the current assay profile are specified in .rex file.  Adjust the assay profile or select another .rex file.
110072	A .rex file was loaded, but the analysis cannot be started. Reasons:
110073	The selected .rex file could not be loaded. Reasons:
110088	Assay profile version '{0}' does not match with the current Rotor-Gene AssayManager version.
110092	This assay profile was created with plug-in {0} version {1} and application version '{2}' and cannot be upgraded.
110093	The assay profile could not be mapped to the .rex file. Adjust the assay profile or select another .rex file.
150001	There is already a profile in the database with the same name and version. The file you selected will not be imported.
150006	File {0} does not exist.
150007	The signature of the file is invalid. The file will not be imported. Provide a valid signature.
150008	The resource has an invalid document format. Contact QIAGEN Technical Services.
150029	The file contains an incomplete or invalid assay profile. The file will not be imported.

Error ID	Error text
150030	Enter a valid assay profile path.
150032	The file cannot be read. It will not be imported.
150033	The signature of the file is invalid. The file will not be imported. Provide a valid signature.
150034	The plug-in required by the selected assay profile is not installed. Install the required plug-in and repeat the import of the assay profile.
150035	In Closed Mode, you can only import profiles distributed by QIAGEN. The file you selected will not be imported. Log in in User Defined Test Mode to import this file.
150036	In User Defined Test Mode, you cannot import profiles distributed by QIAGEN for the Closed Mode. The file you selected will not be imported. Log in in Closed Mode to import this file.
150037	Assay profile could not be loaded {0}.
150038	The selected assay profile contains an unknown rotor type. Select a different assay profile.
150043	Assay profile could not be imported.
150113	{0} could not be loaded. The file reading failed. Select a different image file.
150114	The assay profile could not be activated. It refers to assay parameter set names already present in the following active assay profile(s): {0}
150115	The assay profile could not be imported. It refers to assay parameter set name and volume pair combinations already present in the following active assay profile(s): {0}
150134	The Assay profile was created with Rotor-Gene AssayManager version {0}, which is not compatible to the currently installed version {1}.

Error ID	Error text
150138	Assay Profile export failed because: {0}
190000	The unique application ID is not stored in the registry. Contact your local administrator.
190001	Cannot read the unique application ID that is stored in the registry. Contact your local administrator.
190002	Cannot write Rotor-Gene AssayManager unique application ID to the registry. Start the application again with administration rights.
190015	File {0} does not exist.
190019	The resource has an invalid document format. Contact QIAGEN Technical Services.
190021	Rex channel reference key not found.
190023	Rex file export failed. Reason: {0}
190024	Experiment validation failed. Reason: {0}
190026	The experiment validity check failed.
190027	Failure to get acquisition channel reference.
190031	The .rex file import created an invalid experiment: {0}. Retry or select another .rex file.
190032	The .rex file specifies a rotor which is unknown to the system. Select another .rex file.
190034	Signature could not be validated.
190035	Failed reading the file.
190036	Signature could not be validated.
190037	The resource has an invalid document format. Contact QIAGEN Technical Services.

Error ID	Error text
190038	The access to the selected file or folder is denied. Select a different file or folder.
190039	Unexpected I/O error with file {0}. Contact QIAGEN Technical Services.
190040	An unsupported operation was called on the file system or memory resources. Contact QIAGEN Technical Services.
190041	The directory path to the file {0} does not exist. Select another path.
190044	The file {0} is already used.
190045	File {0} does not exist.
190046	File {0} does not exist at the path {1}.
190047	Invalid argument used.
190048	Path must not contain /.:  ?><\ and leading white spaces.
190049	The provided file path is invalid. Enter a valid path.
190050	Invalid path {0} accessed. Access a valid path.
190051	XML signature invalid.
190052	Not supported operation called on the file-system or memory resources.
190053	Path too long. : {0}
190054	The resource has an invalid document format. Contact QIAGEN Technical Services.
190055	The access to the selected file or folder is denied. Select a different file or folder.
190056	Unexpected I/O error with file {0}. Contact QIAGEN Technical Services.

Error ID	Error text
190057	An unsupported operation was called on the file system or memory resources. Contact QIAGEN Technical Services.
190061	A Rotor-Gene AssayManager work list from file {0} cannot be imported. The work list was exported with a different application mode. Make sure the application modes are the same.
190062	The Rotor-Gene AssayManager work list from file '{0}' cannot be imported. It contains assay profiles which are not available. Select another file.
190063	The Rotor-Gene AssayManager work list from file {0} cannot be imported. It contains assay profiles which are either not installed or deactivated.
190064	The Rotor-Gene AssayManager Work List from file '{0}' cannot be imported, because it contains a rotor type that is not available.
190065	The Rotor-Gene AssayManager Work List from file '{0}' cannot be imported. The following error occurred: {1}
190066	The Rotor-Gene AssayManager Work List '{0}' cannot be exported. The following error occurred: {1}
190067	The file was created using Rotor-Gene AssayManager {0}, it cannot be opened. Make sure the versions are the same.
190069	Schema validation failed: {0}
190070	Failed reading the file
190071	XML signature invalid.
190072	The resource has an invalid document format. Contact QIAGEN Technical Services.
190073	Signature could not be validated.

Error ID	Error text
190074	The optical configuration is unknown. Select a compatible run profile.
190080	This work list cannot be used in {0} mode.
190081	One of the run profiles contains a run profile entry of an unsupported type. Select another run profile.
190121	The file '{0}' does not match the QIAsymphony AS result file specification. The file cannot be imported.
190123	No active assay profile matches the APS '{0}', the QIAGEN original setting 'not required' and the volume pair '{1} µl, {2} µl' explicitly.
190124	No active assay profile matches the APS '{0}', the QIAGEN original setting 'required' and the volume pair '{1} µl, {2} µl' explicitly.
190125	The referenced assay profiles '{0}' are not compatible to each other. Reasons:
190126	The assay kit information check of APS '{0}' produced the following errors:
190127	The number of assay points is '{0}'. This number exceeds the number of tubes on the rotor of the referenced assay profiles '{1}'.
190128	The assay profile '{0}' referenced by APS '{1}' does not refer to exactly one rotor type.
190129	The assay point arrangement does not match the assay profile '{0}'. At position '{1}' the type '{2}' was expected, but the type '{3}' was found.
190131	The QIAsymphony AS result file '{0}' cannot be imported: Reason: '{1}'
190132	The created work list test samples contain replicated sample IDs, but the referenced Assay Profile '{0}' does not allow this.



Error ID	Error text
190134	The QIAAsymphony AS result file at '{0}' contains an invalid checksum. The file cannot be imported.
190135	The unknown slot name '{0}' is not supported by Rotor-Gene AssayManager.
190136	The number of assay points is '{0}'. This number is not supported.
190137	The unknown sample type '{0}' of assay point '{1}' at position '{2}' is not supported by Rotor-Gene AssayManager. Select another sample type.
190138	The unknown assay point state '{0}' of assay point '{1}' at position '{2}' is not supported by Rotor-Gene AssayManager.
190139	The output position sequence of the assay points contains gaps, positions multiple times or do not start at 1. This is not supported by Rotor-Gene AssayManager.
190140	The reaction volume of the APS '{0}' is not supported by the corresponding assay profile '{1}'.
190141	The resource has an invalid document format. Contact QIAGEN Technical Services.
190142	The LIMS file at '{0}' does not match the interface specification. The LIMS file cannot be imported.
190143	The rotor type is not available in this system.
190144	The required assay profile '{0} {1}.{2}.{3}' is not available in this system. Select another assay profile.
190145	Enter a valid lot number for assay '{0}'.
190146	The kit expiry date for assay {0} is expired or not specified. Use a non-expired kit.

Error ID	Error text
190148	The referenced assay profiles are not assay compatible. Reason: The rotor types do not match.
190149	The QIAlink/LIMS worklist at {0} contains an invalid checksum.
190150	The unknown login mode "{0}" is not supported by Rotor-Gene AssayManager.
190151	The unknown sample type "{0}" is not supported by Rotor-Gene AssayManager.
190152	The unknown upstream status "{0}" is not supported by Rotor-Gene AssayManager.
190153	The export of the QIAlink/LIMS result file failed. The samples were only saved but not released.
190154	The sample arrangement does not match the assay profile '{0}'.
190156	The assay profile {0} does not allow replicates. Remove the replicates.
190157	The file cannot be read. It will not be imported.
190158	The referenced assay profiles are not cycling compatible. Reasons:
190160	No active Assay Profile matches the APS {0}.
190161	The Rotor-Gene AssayManager work list from file {0} cannot be imported. Reason: The assay {1} contains an invalid assay kit. Select a work list with a valid assay kit.
190165	The data cannot be used.
190175	There are no test samples, positive or negative extraction controls specified, but the referenced assay profile '{0}' specifies a sample eluate volume pair.

Error ID	Error text
190176	The specified sample input volume and the eluate volume pair do not match the assay profile '{0}'. At position '{1}' the type '{2}' specifies '{3} µl, {4} µl' but '{5} µl, {6} µl' was expected.
190178	A work list with the name '{0}' already exists in the database. The file '{1}' may already have been imported. Create a work list with a unique name.
190180	The file was created using Rotor-Gene AssayManager {0}, it cannot be opened. Make sure the versions are the same.
190183	The file cannot be read. The system supports interface version {0}, but the file is designed for version {1}.
190184	The resource has an invalid document format. Contact QIAGEN Technical Services.
190187	Autogain is not defined for all channels which are used for acquisitions.
190191	The QIALink/LIMS result file does not specify identical reaction volumes.
190192	The referenced assay profiles are not assay compatible. Reason: The reaction volumes do not match.
190193	The APS '{0}' do not specify identical reaction volumes.
270000	The public token of the plug-in does not match with the public token configured in the database. Plug-in: {0}.
270001	The following plug-ins are missing in the plug-in manager: {0}. Contact your system administrator to upgrade your installation. The application will exit now.
270003	RotorGene AssayManager is needed in version {0}, you have installed version {1}. Please contact your system administrator to upgrade your installation. The application will exit now.

Error ID	Error text
270004	The following plug-in is not found on this system {0}. Please contact your system administrator to upgrade your installation. The application will exit now.
310001	Could not load the plug-in assembly.
310002	Could not find the IModule derived class to initialize the plug-in.
310003	The public token of the assembly does not match with the public token in the list.
310005	Could not find experiment {0}
310006	Plug-in not found for provided key.
310007	Assembly name information does not match with the configuration of the plug-in.
310011	Error occurred during report generation. Retry report generation.
310015	Failed to create file {0}.
350005	Failed to generate report.
350010	Failed to generate audit trail report.
350011	File {0} not found.
350013	Failed to create file {0}.
350015	The import of the report profile failed. Reason: {0}
350016	The export of the report profile failed. Reasons: {0}
350018	The resource has an invalid document format. Contact QIAGEN Technical Services.
350019	Failed to delete the report profile.

Error ID	Error text
350023	The report profile version {0} does not match with the current Rotor-Gene AssayManager version {1}. Update your report profile version.
350034	Selected report profile is already deleted. Select another report profile.
390022	Could not find a matching assay profile in the database for the given experiment. Select another experiment.
390028	The experiment {0} assay {1} is locked by user {2}.
390029	The assay is locked by user {0}.
390030	The lock for experiment {0} assay {1} was lost. Close the assay and open it again.
390038	Selected assay already released The assay {0} of experiment {1} has already been released. The approval cannot be started. The assay data can be found in the archive environment.
390039	Report generation failed. Reason: {0}
390040	Failed to create support package. Reason: {0}
390052	Failed to create log file. Reason: {0}
390054	Copy operation is cancelled. Selected cell(s) should be contiguous.
430000	The channel {0} does neither have gain nor auto gain. The run cannot be started.
430001	The required channel {0} on the selected cycler could not be found. The run cannot be started.
430012	The run could not be started on the cycler with the serial number {0}. Make sure the lid is closed.
430020	Persisting the experiment failed. See error log for details.
430021	Unknown error during run profile execution.

Error ID	Error text
430023	The merged contains a wrong acquisition type: {0}. Expected {1}. The run cannot be started.
430024	Within one cycle, the runProfileEntryIndex must not change. The run cannot be started.
430030	The run was stopped. For more information see experiment error log.
430031	The application cannot be closed. Release all instruments before closing the application.
430032	The cycler with the serial number {0} cannot be modified in the current state. The current cycler state is: {1}. Contact QIAGEN Technical Services.
430033	The optical configuration with the ID '{0}' is not supported by the system. Select another optical configuration.
430035	The optical configuration does not match with a previously connected instrument with this serial number. Check the combination of serial number and optical configuration of the cycler and remove potentially wrong configured cycler from the cycler list.
430039	The number of tubes configured in the samples exceeds the capacity of the rotor. Reduce the number of tubes for that rotor.
430041	The analysis of experiment {0} failed.
430042	Enter a valid password.
430043	This user is deactivated. Contact your local administrator.
430050	This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed.
430051	An error occurred during the initialization of the device. Reinitialize the cycler.

Error ID	Error text
430053	The run cannot be stopped. Switch off the cyclor, switch it back on again, and restart the application.
470003	An Experiment with this name already exists in the database.
470018	The chosen experiment name has already been used in the meantime. Select a different experiment name.
470021	The work list has been removed by another user in the meantime. Check available work lists.
470086	The list of experiment names is not yet initialized. This could lead to a database connection error. Check the database connection or contact QIAGEN Technical Services.
470087	Sample ID is not valid. Sample IDs for this assay must be unique.
470095	The data from slot '{0}' in QIAsymphony AS result file '{1}' cannot be imported to a work list.
470110	Error occurred during report generation. Retry report generation.
470111	Failed to create file {0}.
470116	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
470118	Paste operation is cancelled. Selected cell(s) must be editable for pasting.
470119	Pasting failed. The selected target area is smaller than the clipboard entry. Select a different target area or reduce data to be copied.
470121	Paste operation is cancelled. Selected cell(s) must be contiguous.
470122	Paste operation is cancelled. Selected cell(s) must be contiguous.
470123	Paste operation is cancelled. Select some cell(s)

Error ID	Error text
470124	Selected work list locked The work list {0} has been locked for editing by user {1} since the table has been updated. The work list cannot be accessed.
470128	There is not enough space for the information to be pasted.
470129	The database is full. Approve and release experiments in the Approval dialog to allow new runs.
470131	The work list {0} has already been created in the meantime. Select a different work list name.
470134	The run cannot be started. The assay profile(s) contained in the work list might have been deactivated or the work list settings have been changed.
510000	Fatal exception error occurred during command execution: {0} Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510001	Fatal exception error occurred during command execution: {0} Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510003	Cycler-device generated an error with error code {0}. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510004	Device was disconnected. Reconnect the device and retry.
510005	Fatal exception error occurred during Optical Temperature Verification (OTV) run: {0} Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510006	Fatal exception error occurred during assay profile execution: {0} Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.



Error ID	Error text
510007	Reset cycler status failed. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510008	Fatal exception error occurred during command execution. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510010	Update of OTV-calibration failed!
510011	The air temperature has gone over 140° C. Check if the heater or the thermistor are working properly. Contact QIAGEN Technical Services
510012	A communication error occurred. Contact QIAGEN Technical Services.
510013	The machine's detector motor jammed. Contact QIAGEN Technical Services.
510014	The communication with the cycler was lost. Switch off the cycler, switch it back on again. If error persists, contact QIAGEN Technical Services.
510018	The rotor has stalled or stopped.
510019	The machine's source motor jammed. Contact QIAGEN Technical Services.
510020	The cycler is taking too long to reach temperature. This can affect the assay performance.
510021	The temperature measurement thermistor has gone open circuit. Contact QIAGEN Technical Services.
510022	Undefined error. Switch off the cycler, switch it back on again, and restart the application. If the error persists, contact QIAGEN Technical Services.

Error ID	Error text
510023	An unexpected exception occurred during the run. Switch off the cycler, switch it back on again, and restart the application. If the error persists, contact QIAGEN Technical Services.
510028	The requested rotor is not configured for this device. Check the rotor configuration and retry.
550016	Schema validation failed: {0}
550033	The run template does not contain any cycling parameters
550034	The run profile must only contain "Cycling" and "Hold" steps. Check the run profile and the assay profile for consistency.
550036	The loaded rex-file contains a melt step. The assay profile does not allow melt steps. Check the rex-file and the assay profile for consistency.
550070	Failed to generate report. Reason: {0}
550073	Failed to launch the application {0}. Reason:
550188	Run profile must contain at least 7 cycles in the "Cycling" entries.
550199	Enter a valid password.
550200	This user is deactivated. Contact your local administrator.
550212	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
550215	Paste operation is cancelled. Selected cell(s) must be contiguous.
550216	Paste operation is cancelled. Selected cell(s) must be editable for pasting.
550217	Paste operation is cancelled. Select some cell(s).
550218	Paste operation is cancelled. Selected cell(s) must be contiguous.

Error ID	Error text
550219	Pasting failed. The selected target area is smaller than the clipboard entry. Select a different target area or reduce data to be copied.
550229	There is not enough space for the information to be pasted.
550231	This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed.
550233	The release was not performed.
550237	The release was not performed but data was saved.
570016	Schema validation failed: {0}
570017	Quantitation template could not be loaded. File reading failed. Check Rotor-Gene .qut-file and retry.
570018	Quantitation template could not be loaded. The file does not contain all mandatory fields. Create a file where all fields including the threshold are set.
570033	The run template does not contain any cycling parameters
570034	The run profile must only contain "Cycling" and "Hold" steps. Check the run profile and the assay profile for consistency.
570036	The loaded rex-file contains a melt step. The assay profile does not allow melt steps. Check the rex-file and the assay profile for consistency.
570070	Failed to generate report. Reason: {0}
570073	Failed to launch the application {0}. Reason:
570202	Enter a valid password.
570203	This user is deactivated. Contact your local administrator.

Error ID	Error text
570220	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
570222	Paste operation is cancelled. Selected cell(s) must be contiguous.
570223	Paste operation is cancelled. Selected cell(s) must be contiguous.
570224	Paste operation is cancelled. Selected cell(s) must be editable for pasting.
570225	Pasting failed. The selected target area is smaller than the clipboard entry. Select a different target area or reduce data to be copied.
570226	Paste operation is cancelled. Select some cell(s).
570229	There is not enough space for the information to be pasted.
570231	This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed.
570233	The release was not performed.
570237	The release was not performed but data was saved.
670016	The number of messages in the audit trail table to print exceeds {0} messages. Adjust the filter settings.
670018	File {0} not found.
670020	An error occurred during report generation. Retry report generation.
1010000	The access to the selected file or folder is denied. Select a different file or folder.
1010001	File not found. Check the file name and repeat the procedure.
1010002	The entered file name is invalid. Enter a valid file name without invalid characters, i.e. /   ? * " < >.

Error ID	Error text
1010003	File path must be less than 260 characters. Path too long: {0}.
1010004	Reserved Device Name {0} is a reserved device name and cannot be used for a folder. Enter a different folder name.
1010005	The directory {0} does not exist. Select an existing directory.
1010010	Folder {0} could not be created. Either the permission was denied, or a folder with this name already exists. Enter a different folder name.
1010012	{0} This file exists with Read Only attributes. Use a different file name.
1010013	Cannot create a new folder at the currently selected path. Directory path must be less than 248 characters.
1010016	User name is unknown or password is incorrect. Enter user name and password again.
1010018	Invalid user name or password. Enter user name and password again.
1010027	The new password has been used before. Use a different one.
1010028	Invalid password. The old password for the user is incorrect.
1010029	Invalid user name or password. Enter user name and password again.
1010031	The entered name is reserved. It cannot be used as folder name. Enter a different folder name.
1010032	The entered folder name is invalid. Enter a valid folder name.
1010033	This user is deactivated. Contact your local administrator.
1010035	The new password must be different from the previous {0} passwords. Enter a unique password.
1010037	Enter a valid PIN.

Error ID	Error text
1010039	QIAGEN service file could not be loaded. Unauthorized access to the file system or a memory resource. Contact your local administrator.
1010040	QIAGEN service file could not be loaded. Signature is not valid. Contact QIAGEN Technical Services.
1010041	QIAGEN service file could not be loaded. The resource provided has an invalid document format. Contact QIAGEN Technical Services
1010042	QIAGEN service file could not be loaded. The file was not found. Contact QIAGEN Technical Services.
1010043	QIAGEN service file could not be loaded. Signature is not valid. Contact QIAGEN Technical Services.
1010044	{0} is not accessible. Directory not found. Check the network connection or create a new directory.
1010046	This user was deactivated because the old password has been entered wrong too many times. Contact your local administrator. The current session will be closed.
1010047	Could not log-in to the application. The database connection is lost. Contact your local administrator.
1010050	This user was deactivated because the password has been entered wrong too many times. Contact your local administrator.
1010054	Invalid name. Do not use special characters. Especially the following characters are not acceptable: / > < " : *   ? \
1010055	A specified {0} name is a reserved name. Select a different name.
1010057	The password must not contain whitespaces.
1010058	The entered file name is invalid. File name must be less than 256 characters.

Error ID	Error text
1110000	Login error. Unknown user name or invalid password. Repeat login procedure.
1110007	Verification failed. No signature was found in the XML file. Retry with an originally signed XML file.
1110008	Verification failed: More than one signature was found for the XML file. Retry with an originally signed XML file.
1110009	File not found.
1110010	The folder you selected is not available or does not have memory space left. The access is denied. Select a different folder.
1110011	Signature could not be validated.
1110012	Signature not found.
1110014	The resource has an invalid document format. Contact QIAGEN Technical Services.
1110015	File not found.
1110016	Signature could not be validated.
1110017	The resource has an invalid document format. Contact QIAGEN Technical Services.
1110018	Signature not found.
1110019	The folder you selected is not available or does not have memory space left. The access is denied. Select a different folder.

## 9 Abbreviations and File Endings

**Note:** Further information can be found in the "Glossary", page 812.

### 9.1 Abbreviations

APS	Assay Parameter Set
AUDAS	Automatic Data Scan
CAL	Calibrator
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
COC	Cut-off control
CT	Cycle threshold
EC-	Negative extraction control
EC+	Positive extraction control
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
GUI	Graphical User Interface
IC	Internal control
LIMS	Laboratory Information Management System
LOQ	Limit of quantification
NTC	No template control
OTV	Optical Temperature Verification
PCR	Polymerase chain reaction
PC	Positive control
R	Root extracted from R2
R2	Correlation coefficient
QS	Quantitation standard
S	Test sample
UDT Mode	User Defined Test Mode of operation



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## 9.2 File endings

- \*.iap Rotor-Gene AssayManager Assay Profile file
- \*.irp Rotor-Gene AssayManager report file
- \*.iwl Rotor-Gene AssayManager work list
- \*.rex Rotor-Gene Q experiment file format used by the Rotor-Gene Q software


## 10 Glossary

Term	Description
Acquisition	Acquisition is the collection of fluorescent data during a PCR run. Each acquisition step is related to a certain channel and a certain cycling step.
Administrator	User role which has the permissions to configure the software, add and delete assay profiles, report profiles, and to manage cyclers and users.
Amplification plot	Plot showing one or more amplification curves.
Analysis	See "PCR analysis".
Analysis parameters	Parameters to define the different analysis steps (e.g., fluorescence thresholds, allowed ranges of C <sub>T</sub> values).
Anomaly	Deviation from an ideal amplification curve (e.g., peaks, baseline dips, or rising/decreasing plateaus).
Application	Used here as a synonym for Rotor-Gene AssayManager.
Approval (approve)	The process by which the approver reviews sample results. After approval, the experiment can be released so that the related information can be printed into a report or submitted to a LIMS.
Approver	User role which gives the user the right to release sample results.
APS	See "Assay Parameter Set".
Archive (noun)	Part of the experiment repository that contains experiments with completely released sample results.

Term	Description
Assay	General molecular biology test (term used here for real-time PCR assays). In the context of the Rotor-Gene AssayManager software the term "assay" defines the collection of all samples (including external controls) and their corresponding sample results that are related to one assay performed in one run.
Assay and sample analysis	Analysis step that contains various rule based checks to create the final results for each sample by incorporating all targets (including the internal control and the external controls).
Assay developer	Role for a developer for developing assay profiles in UDT Mode. Closed Mode assays are developed and validated by QIAGEN.
Assay Parameter Set (APS)	File from QIAsymphony. The combination of an Assay Definition with additional parameters defined (e.g., number of replicates and assay standards). In Integrated run mode, it is also connected to the Assay Control Set.
Assay profile	Consists of general information, e.g., about cycling compatibility, structural information about targets and samples, a run profile, and an analysis profile.
Assay status	The assay status describes whether run and analysis were successful or failed. Reasons for failed can be "run failed", "run stopped", or "assay invalid" (according to failed analysis rules).
AUDAS	See "Automatic Data Scan" (AUDAS)".
Audit trail	A record of user actions.

Term	Description
Automatic Data Scan (AUDAS)	AUDAS is the name for the analysis step of the real-time PCR analysis that tests each curve for anomalies. Curves with anomalies are flagged as invalid. Unproblematic anomalies can be flagged by a warning flag that does not lead not to an invalid result.
Auto-lock (verb)	Locks the application after a predefined time without any user interaction to prevent misuse. Started runs are neither interrupted nor impacted if a user logs out, another user starts a new session, or if the application is locked (automatically or manually).
Auto-lock timer	The auto-lock timer locks the application after a predefined time without user interaction.
Bar code	See "QIAGEN kit bar code".
CFR	Code of Federal Regulations. See "FDA CFR Title 21 Part 11".
Channel	A channel consists of a light-emitting diode (LED) with an excitation filter paired with an emission filter. The LED and excitation filter excite samples at a given wavelength. Fluorescence emitted by samples is passed through the emission filter, before being detected by a photomultiplier.
CLIA	Clinical Laboratory Improvement Amendments.
CLIA compliant password rules	<p>According to CLIA, a password must contain at least:</p> <ul style="list-style-type: none"> <li>● 8 characters</li> <li>● 2 upper case characters</li> <li>● 2 lower case characters</li> <li>● 2 numeric characters</li> <li>● 2 special characters</li> </ul>

Term	Description
Closed Mode of operation	In Closed Mode of operation only validated QIAGEN assays can be processed. The user does not have permission to modify the assay profile.
Computer	In Rotor-Gene AssayManager the term "computer" is used for a notebook or a PC, not a server.
Core analysis	This term describes a part of the analysis comprising the normalization, $C_T$ value calculation, and (for quantitative assays) the quantification. This analysis is identical to the analysis used by the Rotor-Gene Q software.
Core application	The Rotor-Gene AssayManager software consists of different components working together. The core application is complemented by different plug-ins that contain assay type-specific, analysis-specific options. The core application is mandatory for working with Rotor-Gene AssayManager. At least one plug-in must be installed.
$C_T$	See "Cycle threshold ( $C_T$ )".
Curve	Unprocessed (raw data) or processed data measured by an acquisition with the cycler in a series of an assay-specific number of cycles. Technically, the curve is a discrete series of fluorescence measurements. However, these measurements are typically connected and displayed as a curve. A curve corresponds to one target of a specific sample.
Cycle threshold ( $C_T$ )	Fractional cycle at which a curve reaches a predefined normalized fluorescence threshold.
Cycler	See "Rotor-Gene Q MDx Cycler".
Cycler verification	General term for a maintenance method to check whether the device works properly.

Term	Description
Date picker	Calendar icon  to help with selecting the required date. Alternative to entering the date manually.
Default name	Automatically generated name for a newly created work list or an experiment. The pattern for the generated name is defined in the Configuration environment.
EC-	Sample type (external controls): Negative extraction control.
EC+	Sample type (external controls): Positive extraction control.
Euate	Purified nucleic acids from a sample.
Environment	The Rotor-Gene AssayManager software consists of several environments ( <b>Setup</b> , <b>Approval</b> , <b>Archive</b> , <b>Service</b> , <b>Configuration</b> , and <b>Cycler</b> ). In these environments, certain tasks can be performed, such as setting up a run.
Error	See "System error".
Experiment	The process composed of a PCR run and a PCR analysis yielding test results.
Experiment data	All data that are collected during an experiment: work list, assay profiles, raw data, processed data, logs, assay status, approvals, release status, sample result, and comments.
Experiment status	The 3 states of an experiment are initialized, run performed, and run failed.
Expiration date	Every kit has an expiration date. If a kit has expired, QIAGEN will not guarantee that the kit performs according to its specification anymore.
Expiry date	Used here as a synonym for expiration date.
Export	The process of transferring any kind of data from Rotor-Gene AssayManager to an external destination.

Term	Description
External controls	Collection of standards and controls (such as the quantitation standard, the negative control, or the positive control) defined by an individual assay profile. External controls are always located in other tubes than the test samples of the assay.
External control result	Assay-dependent final test outcome of an external control summarizing all corresponding target results.
External source/external destination	Location outside of the Rotor-Gene AssayManager software.
FDA	Food and Drug Administration is an agency of the United States Department of Health and Human Services responsible for the safety regulation of most types of foods, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products, and cosmetics.
FDA CFR Title 21 Part 11	FDA CFR Title 21 Part 11 regulations define the criteria for considering electronic records and electronic signatures to be trustworthy, reliable, and equivalent to paper records.
Flag	Annotation that may occur during the run or the analysis.
Global settings	Global settings are stored in the database and affect all clients using this database. These settings can be configured in the <b>Configuration</b> environment.
GUI	Graphical User Interface.
*.iap	File extension for a Rotor-Gene AssayManager Assay Profile.
IC	See "Internal control (IC)".
Import	The process of transferring any kind of data from an external source into Rotor-Gene AssayManager.

Term	Description
Internal control (IC)	A standard reaction that is run simultaneously with the sample within the same tube and detected by a certain acquisition. It is used to verify that the PCR process was successfully performed and has not been inhibited. Technically, the IC is one of the targets of an assay and is present in the test sample tubes as well as in the external control tubes. In some assays the internal control is located in a different tube than the test. In such cases the "internal" control can be tested with the same sample but in a separate tube.
Invalid result	A result of a sample or target gets the status INVALID if it is not possible to identify a specific result, such as "Signal detected" or "No signal", without a doubt.
*.irp	File extension for a Rotor-Gene AssayManager report profile.
*.iwl	File extension for a Rotor-Gene AssayManager work list.
Kit	A kit is a box with reagents sold by QIAGEN to perform a biological application. In the context of Rotor-Gene AssayManager, a kit contains all reagents to perform a PCR run with eluates. PCR kits can contain master mix components, positive and negative controls, etc.
Kit bar code	See "QIAGEN kit bar code".
Kit information	A kit is labeled with, among others, the following information: material number, lot number, and expiration date.
LIMS	Laboratory Information Management System. If configured, Rotor-Gene AssayManager exports results in a file to be read by a LIMS.
Local settings	Local settings are stored on the local computer and affect no other clients using the same database (in comparison



Term	Description
	to the global settings). These settings can be configured in the "Configuration" environment.
Lock (verb)	Make the application inaccessible for other users without logging out. Started runs are neither interrupted nor impacted if a user logs out, another user starts a new session, or if the application is locked (automatically or manually).
Locking ring	Locking rings are metal rings that fit onto the rotor to prevent tubes and caps from coming loose during operation of the Rotor-Gene Q MDx. Loose caps and tubes could cause damage to the instrument.
Log file	Log of the technical software behavior that can be interpreted by the QIAGEN Technical Services.
Lot number	Part of the kit information.
Material number	Part of the kit information.
Mode	See "Closed Mode of operation". See "User Defined Test Mode of operation".
Mode of operation	See "Closed Mode of operation". See "User Defined Test Mode of operation".
Normalization	In this context, normalization is an analysis step used for curve preprocessing prior to CT value calculation and the quantitation. It includes typically a smoothing of the curves and a removal of the background noise by subtracting the baselines.
NTC	No template control.
Operator	User role with the rights to perform a PCR run and to view the results. (An operator is not allowed to approve.)

Term	Description
Optical configuration	The optical configuration of a Rotor-Gene Q MDx cyclers is described by the available excitation diodes that excite the fluorescence and the emission filters letting pass the emitted light. It can be read out from the firmware.
Optical Temperature Verification	Optical Temperature Verification (OTV) is a method that verifies the in-tube temperature in a Rotor-Gene Q MDx. While it is not required for the Rotor-Gene Q MDx, calibration of in-tube temperature can be a laboratory requirement. The OTV method provides a means for users to comply with this requirement, including if there are site-specific calibration intervals. OTV calibration can be performed with the Rotor-Gene Q software but not with Rotor-Gene AssayManager.
OTV	Optical Temperature Verification.
PC	Sample type (external controls): Positive control.
PCR	Polymerase chain reaction.
PCR analysis	Processing of the raw PCR data, for example, by applying AUDAS, normalization, CT value calculation, quantification, and assay and sample analysis algorithms to obtain a quantitative or qualitative result.
PCR run	PCR process performed in a thermocycler (e.g., the Rotor-Gene Q MDx). In this context, PCR is always a real-time PCR.
Plug-in	A plug-in allows Rotor-Gene AssayManager to support a specific type of assays. Plug-ins may not be available in all countries.
Processed curve	Raw data that have been changed during PCR analysis.
Processed data	Collection of processed curves.

Term	Description
QIAGEN kit bar code	Identifies the QIAGEN kit. The bar code consists of the material number (7 digits), the expiry date (6 digits), and the lot number (4–10 digits).
QIAlink	Middleware at QIAGEN to support specific LIMS systems. Contact QIAGEN Technical Services for details.
QIASymphony	QIAGEN platform for automatic sample preparation and assay setup.
QS	Sample type (external controls): quantitation standard.
Qualitative result	Information whether a signal has been detected for a target or not or whether the target is invalid.
Qualitative result	Information whether a signal has been detected for a target or not or whether the target is invalid.
Quantification	Analysis step to determine the initial concentration of a target.
Quantitative result	Information of the initial target concentration of a result.
Quantitation standard	Reference sample with a given target concentration used for quantification.  <b>Note:</b> In the Rotor-Gene Q software the term “quantitation” may be used instead of the term “quantification”.
R	Root extracted from $R^2$
$R^2$	Correlation coefficient: The correlation coefficient is a statistical parameter to measure the fit of the data points to the regressed line. In general, the standard curve should have an $R^2$ value $\geq 0.990$ . The individual limit for the $R^2$ value can be defined in the assay profile.

Term	Description
Raw curve	Unprocessed fluorescence data measured in one tube on one channel by the cycler in a series of an assay-specific number of cycles.
Raw data	Collection of unprocessed amplification curves.
Reaction volume	Volume of liquid in the PCR tubes.
Real-time PCR	PCR with real-time monitoring of the reaction products.
Regression line	In this context, a regression line is a linear function derived from a regression analysis between the $C_T$ values and given concentrations of quantitation standards. It is also known as the standard curve. See "Standard curve".
Release	The process of publishing previously approved sample results by generating a report and optionally transferring the data to a LIMS.
Release status	The release status is the status of an assay that can be "not released" and "fully released".
Renewal interval	Days until a password must be renewed.
Replicate	See "Sample replicate".
Report	Summary of sample results (external control results are always included) of one assay as a secure *.pdf-file. The file cannot be manipulated.
*.rex	File extension for a Rotor-Gene Q MDx experiment file format used by Rotor-Gene Q software.
Role	User rights are summarized in a certain role: administrator, approver, operator, assay developer, and super user are available.
Rotor	The metal rotor holds tubes in the Rotor-Gene Q MDx. It enables samples to spin in the instrument chamber and

Term	Description
	ensures that samples are correctly aligned with the optical system. The rotor is secured with a locking ring.
Rotor-Gene Q MDx Cyclers	The real-time PCR cyclers supported by Rotor-Gene AssayManager.
Rotor-Gene Q Software	Open mode software to control the Rotor-Gene Q MDx cycler and to analyze the acquired data
Rotor type	See "Rotor".
Row selector	Specific table column to select complete rows.
Run	See "PCR run".
Run parameters	Parameters specifying a PCR run (e.g., number of cycles, temperature, acquisitions, rotor type, tube volume, etc.).
Run profile	Set of all run parameters. It is part of the assay profile.
S	Sample type: test sample.
Sample	Test sample or external control to be analyzed.
Sample ID	Identifier of a sample. The sample ID must not be empty and must consist of 1–40 characters.
Sample information	Annotations describing one sample. It contains sample ID, reaction volume, sample volume, sample type, flags set by an upstream platform, and process history.
Sample replicate	One sample split on several tubes to do the same test in parallel in order to get an estimate for the variance
Sample result	General term for test result and external control result.
Sample result status	The sample result status describes a qualitative result by different assay-dependent states corresponding to a test result or an external control result.

Term	Description
Sample type	A sample can be of the following types: test sample (S) or one of the following external controls: quantitation standard (QS), no template control (NTC), positive control (PC), negative extraction control (EC-), and positive extraction control (EC+). Not all assays include all types of external controls. This is assay dependent.
Sample volume	Volume of the initial amount of material for the sample preparation procedure.
Service user	User role that has all necessary permissions to maintain the software at customer site. The service user has no permission to approve analysis results.
Session	Contains all user actions from login until logout.
Standard curve	A standard curve is a linear function derived from a regression analysis between the C <sub>T</sub> values and given concentrations of quantitation standards.
Super User	The super user has all available permissions of all available roles as a convenient way to grant all permissions to one user.
Support package	Information wrapped up in a *.zip file to be sent via an email program to QIAGEN Technical Services to inform QIAGEN what went wrong at the customer's site and how to help the customer. The support package can be created in the <b>Approval</b> and in the <b>Archive</b> environment.
System error	Technical errors (e.g., process errors, software malfunctions, cyclor errors) that are not acceptable. User interaction is required.  <b>Note:</b> Do not confuse with invalid results.
Target	Specific DNA sequence (or RNA before reverse transcription step) to be amplified during the PCR.

Term	Description
Target result	The result of the analysis of one target for one specific sample.
Test	Synonym of assay.
Test sample	Unknown sample to be tested with an assay.
Test sample result	Assay-dependent final test outcome of an assay for one test sample summarizing all corresponding target results.
Threshold	Predefined fluorescence value used to calculate the cycle threshold ( $C_T$ ) of a curve.
Tube	Small container for liquids, in which the PCR reaction takes place. A sample can be split over multiple tubes.
UDT Mode	See "User Defined Test Mode (UDT Mode)".
Upstream process	From the PCR point of view, the upstream process consists of the sampling, the sample disruption, the purification, and the assay setup.
Upstream status	Status which is set by QIAasymphony system. It can be "valid", "unclear", or "invalid". For FDA cleared or approved nucleic acid tests, samples with an "invalid" or "unclear" upstream status are processed as if they are "invalid".
User Defined Test Mode (UDT Mode)	This is the mode of operation for assays that are created and validated by a user of Rotor-Gene AssayManager software.
User role	See "Role".
Validation error	An error that occurs due to a missing or invalid user input. User interaction is required.
Verification	See "Cycler verification".

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Term	Description
Warning	A situation could be optimized by further input. User interaction is possible, but not mandatory.
Work list	Sample information for all samples to be analyzed and a reference to an assay profile for each sample. When using an upstream platform, the work list contains flags as well.

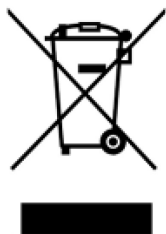


## Appendix A

### Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users in the European Union.

The European Directive 2002/96/EC on WEEE requires proper disposal of electrical and electronic equipment when it reaches its end of life. The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local legislation. The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.



QIAGEN accepts its responsibility in accordance with the specific WEEE recycling requirements and, where a replacement product is being supplied by QIAGEN, provides free recycling of its WEEE-marked electronic equipment in Europe. If a replacement product is not being purchased from QIAGEN, recycling can be provided upon request at additional cost. To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

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# Appendix B

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The following section lists the license texts displayed during installation. These texts are also available in the Rotor-Gene AssayManager v1.0 software.

### **QIAGEN's Rotor-Gene AssayManager v1.0**

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## WiX

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# QIASymphony® RGQ MDx (US) User Manual

## Volume 2, Part III

Rotor-Gene Q MDx Installation Guide (US)

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# 1 Introduction

## 1.1 About this installation guide

This guide provides an overview for installing Rotor-Gene® Q MDx instruments.

**Note:** Please consult the *Rotor-Gene Q MDx User Manual (US)* (Part I of Volume 2 of the *QIAsymphony RGQ MDx (US) User Manual*) for additional details regarding installation, such as site and AC power requirements. Pay particular attention to the safety information.

Information about Rotor-Gene Q MDx instruments is provided in the following sections:

- Unpacking the Rotor-Gene Q MDx
- Hardware Installation
- Installing Rotor-Gene Q Software
- Connecting the Laptop/Computer to the Rotor-Gene Q MDx
- Launching Rotor-Gene Q Software
- Rotor-Gene Q Software assay packages
- Launching Rotor-Gene AssayManager version 1.0
- Rotor-Gene AssayManager assay profiles and plug-ins
- Additional software on computers connected to Rotor-Gene Q MDx instruments
- Updating Rotor-Gene Q software and Rotor-Gene AssayManager software

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## 2 Unpacking the Rotor-Gene Q MDx

The Rotor-Gene Q MDx is delivered with all necessary accessories for instrument setup and for performing a run. A list of accessories is provided in the Rotor-Gene Q MDx box.

**Note:** Check the items on this list to ensure that all accessories are present.

**Note:** Check that the instrument and delivered accessories are free from transport damage before installation.

The accessories box is on top of the foam packing. The accessories box contains:

- Rotor-Gene Q MDx Installation Guide (US)
- CD (Rotor-Gene Q software)
- CD (Rotor-Gene Q MDx User Manual (US))
- CD (Rotor-Gene Q User Manual)
- Loading Block 96 x 0.2 ml Tubes\*
  - \* Not intended for use with FDA cleared or approved nucleic acid tests
- Loading Block 72 x 0.1 ml Tubes
- Rotor Holder (dismantled for safe transport)
- 36-Well Rotor (this rotor is red in color)\*
  - \* Not intended for use with FDA cleared or approved nucleic acid tests
- 36-Well Rotor Locking Ring\*
  - \* Not intended for use with FDA cleared or approved nucleic acid tests

The following items are packed on each side of the foam packing:

- USB and RS-232 serial cable
- International power cable set
- PCR Tubes, 0.2 ml (1000)\*
  - \* Not intended for use with FDA cleared or approved nucleic acid tests
- Strip Tubes and Caps, 0.1 ml (1000)

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Once all these components have been removed from the box, remove the foam packing on top of the Rotor-Gene Q MDx. Carefully remove the Rotor-Gene Q MDx from the box and unwrap the plastic cover. Open the lid by sliding it towards the back to access the reaction chamber.

The following items are already installed inside the Rotor-Gene Q MDx:

- 72-Well Rotor (this rotor is blue in color)
- 72-Well Rotor Locking Ring

A laptop computer is included with your Rotor-Gene Q MDx instrument.

Rotor-Gene AssayManager® version 1.0 software is supplied on a separate installation DVD.

Once you have unpacked the Rotor-Gene Q MDx, proceed with instrument hardware installation, as described below.

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## 3 Hardware Installation

**Note:** When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can block. Allow the instrument to acclimatize to room temperature for at least one hour before turning the instrument on.

1. Place the Rotor-Gene Q MDx on a level surface that is vibration free.

**Note:** Ensure that there is sufficient space behind the instrument for the lid to open fully.

**Note:** Ensure that the power switch at the back of the instrument can be easily reached.

**Note:** Do not obstruct the back of the instrument. Ensure that the power cord can be easily detached if required, to disconnect power to the instrument.

2. Install Rotor-Gene Q software and Rotor-Gene AssayManager.

Install the Rotor-Gene Q software and connect the computer/laptop and instrument as described below.

Install Rotor-Gene AssayManager and plug-ins as described in the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.



## 4 Installing Rotor-Gene Q Software

The Rotor-Gene Q MDx can be connected to a computer either via a USB interface (recommended) or via an RS-232 serial interface. Rotor-Gene Q software should be installed as described below before connecting the laptop computer to the Rotor-Gene Q MDx.

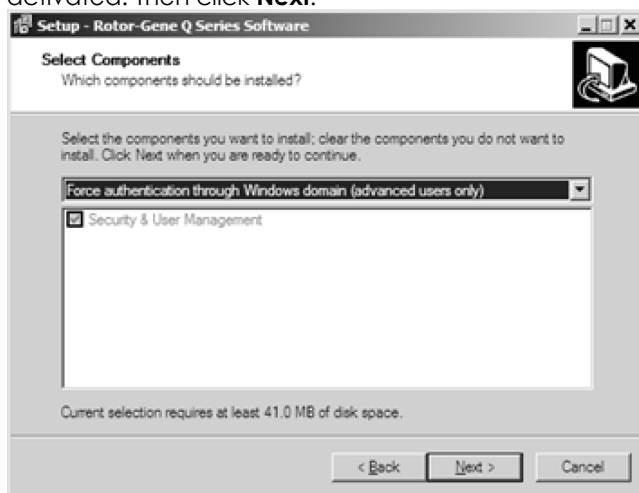
1. Insert the Installation CD into the CD drive of the computer. The software should launch automatically. If it does not, browse to the CD-ROM in Windows Explorer and double-click **autorun.hta**.
2. Install the Rotor-Gene Q software by clicking **Install Operating Software** in the window that appears.



3. Click **Next**, then select **I accept the agreement** in the license agreement step, and click **Next** again.
4. In the **Region** window, select the region that will be used by the software to direct support requests to the right location.



5. Select the destination location where the Rotor-Gene Q software should be installed. For convenience, simply accept the suggested destination folder by clicking **Next**.
6. In the **Select components** window you can select **Standard Installation** or **Force authentication through Windows domain (advanced users only)** via a drop-down list. **Select Force authentication through Windows domain (advanced users only)** if you want to use the advanced security features (see Section 8 "Access Protection" in Part I of Volume 2 of the *QIAAsymphony RGQ MDx (US) User Manual* for more details). With this selection, the checkbox **Security & User Management** is automatically activated. Then click **Next**.



7. The setup wizard will now install the Rotor-Gene Q software. If the following message appears, click **Continue Anyway**.



8. After installation is completed, close the setup wizard by clicking **Finish**.

## 5 Connecting the Laptop/Computer to the Rotor-Gene Q MDx

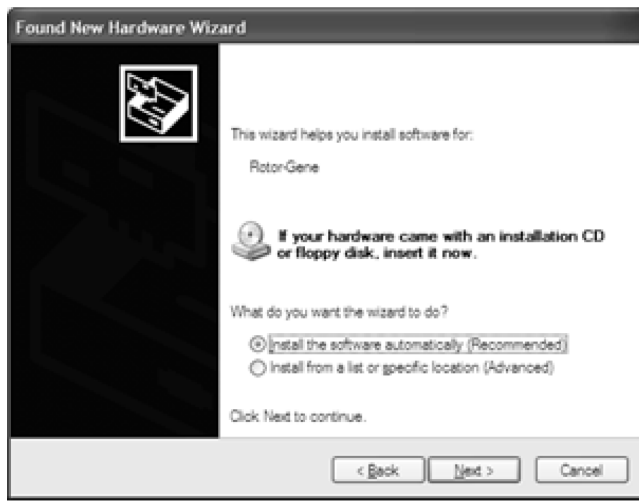
### 5.1 USB connection for Rotor-Gene Q software and Rotor-Gene AssayManager

We recommend connecting the laptop computer delivered with your Rotor-Gene Q MDx via the USB port.

1. Connect the USB cable provided to a USB port at the back of the computer.  
Connect the USB cable to the back of the Rotor-Gene Q MDx. Then connect the Rotor-Gene Q MDx to the power supply.
2. Switch on the Rotor-Gene Q MDx.
3. The following window appears. Select **No, not this time** and then click **Next**.



4. Select **Install the software automatically (Recommended)** and then click **Next**.



5. Click **Continue Anyway**.



6. Click **Finish**.



7. Click **Yes** to restart the computer.



8. After the computer has restarted, log in again and launch the Rotor-Gene Q software as described below.

## 5.2 RS-232 connection for Rotor-Gene Q software

1. Connect the RS-232 serial cable provided to the serial port of your computer. Connect the RS-232 serial cable to the back of the Rotor-Gene Q MDx. Then connect the Rotor-Gene Q MDx to the power supply.
2. Switch on the Rotor-Gene Q MDx.
3. Start the Rotor-Gene Q software as described in "Launching Rotor-Gene Q Software", page 905.

## 6 Launching Rotor-Gene Q Software

1. Double-click the **Rotor-Gene Q Series software** desktop icon to launch the software.  
A message may appear with information. Click **Yes** to view a list of the latest changes or **No** to continue with the Rotor-Gene Q installation.
2. A **Welcome** window appears the first time the software is launched, but does not appear for subsequent software upgrades.



3. Enter the serial number using numerical digits only (e.g., 0110123). You can find the serial number on the type plate located at the back of the instrument.
4. Click **Auto-Detect**. The corresponding USB or serial port will be detected and shown in the **Port** drop-down list.
5. Click **Begin** to work with the software.
6. Exit the Rotor-Gene Q software to install and work with Rotor-Gene assay packages.

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## 7 Rotor-Gene Q Software Assay Packages

Rotor-Gene Q software assay packages contain the required files to run and analyze individual types of assays. A separate software installation is required for each assay package. The installation copies the required files to the system and creates one or more shortcuts on the desktop. The installation and use of each specific assay package is described in detail in the corresponding Instructions for Use (Handbook) for the assay you are using.



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## 8 Launching Rotor-Gene AssayManager

See the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

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## 9 Rotor-Gene AssayManager Assay Profiles and Plug-ins

See the *Rotor-Gene AssayManager Core Application User Manual (US) IVD* in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

### 9.1 System tools

Many system tools may use significant system resources even without any user interaction. Typical examples of such tools are:

- File indexing, which is performed as a background task by many contemporary office applications
- Disk defragmentation, which often also employs a background task
- Any software that checks for updates on the internet
- Remote monitoring and management tools

**Note:** Due to the dynamic nature of information technology products and systems, this list may be incomplete. Tools may be released that are not known at the time of writing. It is important that system administrators take care that such tools are not active on the Rotor-Gene Q MDx during a PCR run.

### 9.2 Operating system updates

See Section 4.11.4 Operating system updates on page 517.

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## 10 Updating Rotor-Gene Q Software and Rotor-Gene AssayManager version 1.0 Software

Software updates are available from QIAGEN at **[www.qiagen.com/products/rotor-geneqmdx.aspx](http://www.qiagen.com/products/rotor-geneqmdx.aspx)** for Rotor-Gene Q software and **[www.qiagen.com/products/rotor-geneassaymanager.aspx](http://www.qiagen.com/products/rotor-geneassaymanager.aspx)** for Rotor-Gene AssayManager software. Online registration is necessary to download the software.

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Document Revision History	
R2 12/2018	This is revision 2 of the "QIAAsymphony RGQ MDx (US) User Manual, vol. 1 and 2 for use with software version 5.0". This version has been updated to include Windows 10 and remove mention of Windows XP as an operating system as well as to include cyber security updates and changes to software versions.

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