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QIAcuity® Safety Instructions and Quick-Start Guide

REF 911000, 911020, 911040, 911050

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Sample to Insight

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Introduction

Thank you for choosing QIAcuity. We are confident it will become an integral part of your laboratory. Before using QIAcuity, it is essential that you read this user manual carefully and pay 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.

About this user manual

This user manual provides information about QIAcuity in the following sections:

- Introduction
- Safety Information
- General Description
- Installation Procedures
- Maintenance Procedures
- Operating Plates
- Operating the QIAcuity Instrument
- Troubleshooting
- Technical Specifications
- Glossary
- Appendix A – Legal
- Appendix B — QIAcuity Accessories
- Document Revision History

A more detailed user manual (*QIAcuity User Manual*: **www.qiagen.com/HB-2717**) covering the operation of the Suite analysis software can be downloaded at **www.qiagen.com/QIAcuity**.

General information

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 QIAcuity 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, see our Technical Support Center at **www.qiagen.com/support/technical-support** or call one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit **www.qiagen.com**).

Policy statement

It is QIAGEN's policy to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time.

To produce useful and appropriate documentation, we appreciate your comments about this user manual. Contact QIAGEN Technical Services.

Intended use of the QIAcuity

QIAcuity systems are designed to determine absolute amounts of target DNA in a sample by using a digital PCR (dPCR) approach.

Digital PCR uses the procedure of end-point PCR but splits the PCR reaction into many single partitions in which the template is randomly distributed across all available partitions. After PCR, the target molecule is detected by measuring the fluorescence – either of sequence-specific DNA probes or of intercalating dyes – in all valid partitions. As the template is distributed randomly, Poisson statistics can be used to calculate the amount of target DNA per valid partition. The total amount of target DNA in all partitions of a well is then calculated by multiplying the amount of target DNA per partition with the number of valid partitions. Calculation of target concentration is determined by referring back to the volume in all analyzable partitions, that is, partitions that were filled with reaction mix. The total number of filled partitions is identified by a fluorescent dye, present in the reaction mix itself. Absolute quantification by dPCR eliminates the need of standard curves to determine amounts of target DNA in a given sample.

Aside from absolute quantification, the QIAcuity software provides analysis modules for mutation detection, genome editing analysis, copy number variation (CNV), and gene expression analysis.

QIAcuity systems are intended to be used only in combination with QIAGEN kits indicated for use with the QIAcuity systems for the applications described in the kit handbooks, such as QIAcuity Nanoplates and QIAcuity PCR Reagents.

If QIAcuity is used with products other than QIAGEN kits or QIAGEN assays designed for dPCR, it is the user's responsibility to validate the performance of such product combinations for any particular application.

The QIAcuity system is intended for use by professional users trained in molecular biological techniques and the operation of the QIAcuity system.

The QIAcuity system is intended for molecular biology applications. This product is not intended for the diagnosis, prevention, or treatment of a disease.

Requirements for QIAcuity users

This table covers the general level of competence and training necessary for transportation, installation, use, maintenance, and servicing of the QIAcuity systems.

Table 1. Requirements for QIAcuity users

Task	Personnel	Training and experience
Delivery	No special requirements	No special requirements
Installation	Laboratory technicians or equivalent	Appropriately trained or experienced personnel familiar with the use of computers and automation in general
Routine use (running protocols)	Laboratory technicians or equivalent	Appropriately trained or experienced personnel familiar with the use of computers and automation in general
Assay design and validation	Scientist or equivalent	Appropriately trained or experienced personnel familiar with molecular biological techniques
Dust filter replacement	Laboratory technicians or equivalent	Appropriately trained or experienced personnel familiar with the use of computers and automation in general
Preventive maintenance	QIAGEN service personnel or service technicians of an authorized agent	Trained and authorized by QIAGEN
Servicing	QIAGEN service personnel or service technicians of an authorized agent	Trained and authorized by QIAGEN

Safety Information

Before using the QIAcuity, it is essential that you read this user manual carefully and pay 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 in this manual.

WARNING

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

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 an 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.

Proper use

WARNING/ CAUTION

Risk of personal injury and material damage

Improper use of the QIAcuity may cause personal injuries or damage to the instrument. The QIAcuity must only be operated by qualified personnel who have been appropriately trained. Servicing of the QIAcuity must only be performed by a QIAGEN field service specialist.

Perform the maintenance as described in the "Maintenance Procedures" section. QIAGEN charges for repairs that are required due to incorrect maintenance.

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

The QIAcuity is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

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

Do not attempt to move the QIAcuity during operation.

CAUTION **Damage to the instrument**

Avoid spilling water or chemicals onto the QIAcuity. Damage caused by water or chemical spillage will void your warranty.

In case of emergency, power OFF the QIAcuity at the power switch located in the back of the instrument and unplug the power cord from the power outlet.

CAUTION **Damage to the instrument**

Only use QIAcuity-specific consumables with the QIAcuity. Do not use the plates without applied top seals. Damage caused by use of other consumables will void your warranty.

CAUTION **Damage to the instrument**

Do not drop objects into the instrument when the plate tray is ejected.

WARNING **Risk of explosion**

The QIAcuity is intended for use with reagents and substances supplied with QIAGEN kits or others that are outlined in respective Information for Use. Use of other reagents and substances may lead to fire or explosion.

CAUTION **Damage to the instrument**

Do not stack instruments and do not place items on top of the QIAcuity.

CAUTION **Damage to the instrument**

Do not lean against the touchscreen when it is pulled out.

Electrical safety

Note: 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.

WARNING **Damage to electronics**

Before powering ON the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING **Risk of electric shock**

Do not open any panels on the QIAcuity.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized Field Service Specialist.

To ensure satisfactory and safe operation of the QIAcuity, follow these guidelines:

- 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, power 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.
- Liquids come in contact directly with electrical components of the QIAcuity.

Environment

Operating conditions

WARNING **Explosive atmosphere**

The QIAcuity 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 QIAcuity must be located out of direct sunlight.

CAUTION **Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the QIAcuity.

Slits and openings that ensure the ventilation of the QIAcuity must not be covered.

Biological safety

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/labs/BMBL.html**).

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**

Samples used with the QIAcuity 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 (for example, a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe, and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Material Safety Data Sheets (MSDSs) or the OSHA1,* ACGIH,† or COSHH‡ documents.

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

* OSHA — Occupational Safety and Health Organization (United States of America)
† ACGIH – American Conference of Government Industrial Hygienists (United States of America)
‡ COSHH – Control of Substances Hazardous to Health (United Kingdom)

Chemicals

WARNING **Hazardous chemicals**

Some chemicals used with the QIAcuity may be hazardous or may become hazardous after completion of purification.

Always wear safety glasses, gloves, and a lab coat.

The responsible body (for example, a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe, and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Material Safety Data Sheets (MSDSs) or the OSHA1,* ACGIH,† or COSHH‡ documents.

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

* OSHA — Occupational Safety and Health Organization (United States of America)

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

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

Maintenance safety

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

Only perform maintenance that is specifically described in this user manual.

WARNING **Risk of fire**

Do not allow cleaning fluid or decontamination agents to come into contact with the electrical parts of the QIAcuity.

CAUTION **Damage to the instrument**

Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the QIAcuity.

CAUTION **Damage to the instrument**

Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the QIAcuity.

Radiation safety

WARNING **Risk of personal injury**

Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner.

Symbols on the QIAcuity

Symbol	Location	Description
CE	Type plate on the back of the instrument	CE mark for European Conformity
UKCA	Type plate on the back of the instrument	UKCA mark for UK Conformity
c SA us	Type plate at the back of the instrument	CSA listing mark for Canada and the USA
	Type plate on the back of the instrument	RCM mark for Australia and New Zealand

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	Waste Electrical and Electronic Equipment (WEEE) mark for Europe
	Type plate on the back of the instrument	Legal manufacturer
	Type plate on the back of the instrument	Consult instructions for use
	Type plate on the back of the instrument	See “Safety Information” section for risks
	Type plate on the back of the instrument	Date of manufacture
	On the drawer	Biological hazard – some samples used with this instrument may contain infectious agents and must be handled with gloves.

General Description

After manually loading and sealing the QIAcuity Nanoplate, the QIAcuity performs a fully automated processing of the QIAcuity Nanoplates, including all necessary steps of plate priming, sealing of partitions, thermocycling, and image analysis. Depending on the plate type, up to 8, 24, or 96 samples per plate can be analyzed. For high sensitivity applications, the QIAcuity Nanoplate 26K 8- or 24-well is available. The number of in-parallel processable plates depends on the instrument configuration (One, Four, Eight). The QIAcuity controls all integrated modules, including a robotic gripper for plate handling, a partitioning module, a PCR thermocycler, and a fluorescence imaging module.

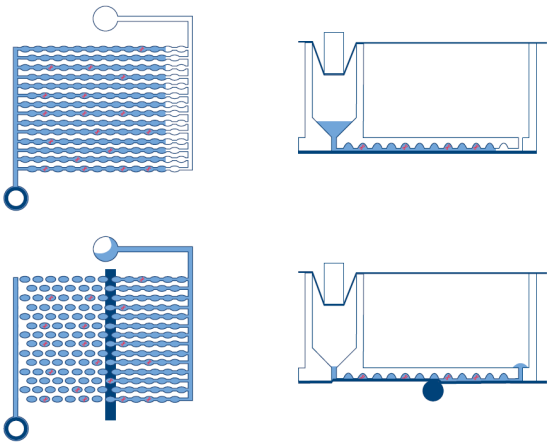
Setting up experiments and the analysis of results is done in the stand-alone QIAcuity Software Suite. The Software Suite and instrument software are able to communicate with each other over a direct connection or a network connection. Setting up an experiment is possible with the QIAcuity Software Suite as well as the instrument.

QIAcuity principle

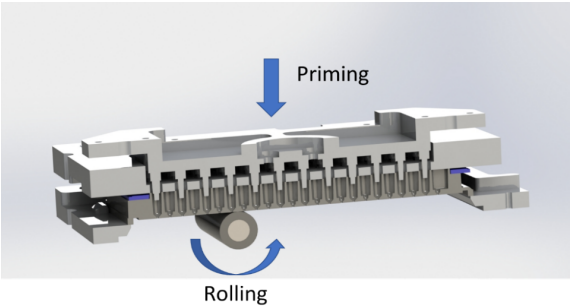
The QIAcuity is designed as a walk-away instrument that integrates and automates all plate processing steps. Only the plate preparation must be done manually before starting the run. This includes the pipetting of the target reagents and master mix in the input wells of the plate and the closing of the wells with the top-seal. Once this preparation is complete, the plate is placed in a free plate slot of the instrument tray. By reading the barcode of the plate, the instrument links the plate to the experiment previously defined in the software, and after pressing the **Play** button, all further steps are performed fully automated by the instrument.

The following process steps are done sequentially:

Partitioning: In the first module, the microchannels and partitions of the plate are filled with the target reagents and master mix previously pipetted into the wells. This is done by plunging the pins against the elastic top-seal and the input wells, which creates a peristaltic pressure that pumps the input well liquid into the microchannels and partitions. The connecting channels between the partitions are closed simultaneously by a pressure-controlled rolling process (see the following images).



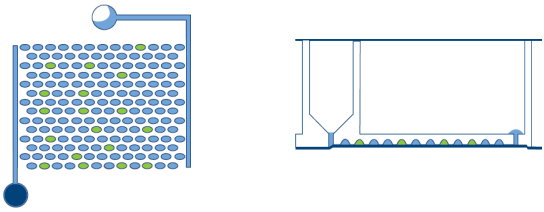
Scheme of filling and partitioning of a well.



Principle of priming and rolling to allow partitioning of the wells.

Thermocycling: In the second step, the module is a high-accuracy plate thermocycler that performs the polymerase chain reaction. The cycling profile can be set in the QIAcuity Software Suite or the instrument software. For more details on the thermal cycler specification, see the "11 Technical Specifications" section.

Imaging: The final process step is the image acquisition of all wells. The user can select the detection channels in the experiment setup. The partitions that contain a target molecule inside emit fluorescence and are brighter than the ones without target (see the following images). For more details and specifications on the imaging system, see the "Technical Specifications" section.

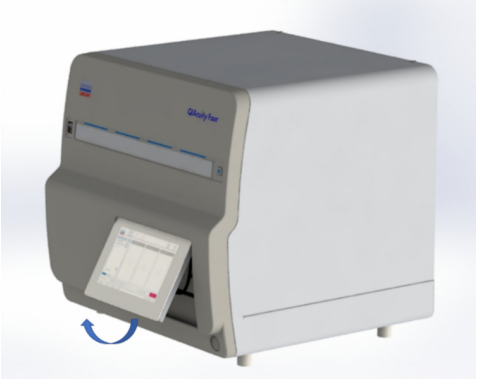


Scheme of positive (green) and negative (blue) partitions after imaging.

External features of QIAcuity

Touchscreen

The QIAcuity is controlled using a swivel-mounted touchscreen. To adjust the angle of the touchscreen, pull gently at the bottom edge. The touchscreen enables the user to see an overview of all plate slots and the corresponding process steps and remaining times. Additionally, it can be used to extend the plate tray, start/stop plate runs, set up experiments, etc.



Pulled out touchscreen.

Power switch

The main power switch is located at the back of the QIAcuity. To power ON the QIAcuity, turn the power switch to **I** and press the blue soft-switch button at the front of the instrument. The startup screen appears, and the instrument automatically performs initialization tests.

To conserve energy, the QIAcuity can be powered OFF when not in use. To power OFF the QIAcuity, press the blue front soft switch.

Important: After powering OFF the QIAcuity, wait for a few seconds before switching ON the instrument again. The system might fail to start if you do not allow the QIAcuity to rest for a few seconds before powering ON.

RJ-45 Ethernet port

The RJ-45 Ethernet port is located at the back of the instrument beside the power cord socket. It is used to connect the QIAcuity to a local area network via cable or to connect directly to the Software Suite computer, depending on the network configuration chosen.

USB ports

The QIAcuity has two USB ports that are located at the front of the instrument in the upper left corner. For the QIAcuity Four and Eight, a third slot for accessories is available behind the touchscreen in the upper right corner. To access this slot, extend the touchscreen as far as possible.

The USB ports allow a connection of the QIAcuity to a USB stick. Data files, such as support package, can be transferred via the USB port from the QIAcuity to the USB stick. The USB ports can also be used to plug in an external barcode reader or a keyboard.

Important: We recommend using QIAGEN USB sticks only to ensure full compatibility. If QIAGEN USB stick is not available, use a FAT32 or exFAT-formatted USB stick.

Important: Do not remove the USB stick while downloading or transferring data or software to or from the instrument.

Power cord socket

The power cord socket is located at the rear right of the QIAcuity and allows connection of the QIAcuity to a power outlet via the supplied power cord.

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.

WARNING **Damage to electronics**

Before powering ON the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING **Risk of electric shock**

Do not open any panels on the QIAcuity.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized Field Service Specialist.

Cooling air outlet

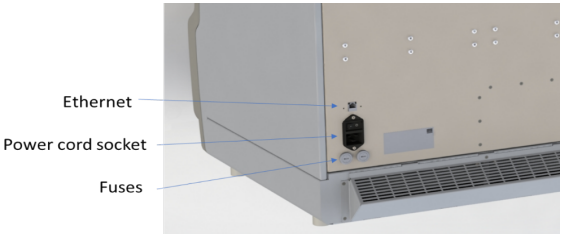
Cooling air outlets are located at the rear side of the QIAcuity and allow cooling of the internal components of the QIAcuity.

CAUTION

Risk of overheating

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the QIAcuity.

Slits and openings that ensure the ventilation of the QIAcuity must not be covered.



Back view of the QIAcuity Four and Eight.

External hand scanner

The QIAcuity Four and Eight instruments are equipped with a barcode scanner, which enables the user to scan the plate ID before loading. For QIAcuity One, a barcode scanner is available as accessory.

WARNING

Risk of personal injury

Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner.

Thermal cycler

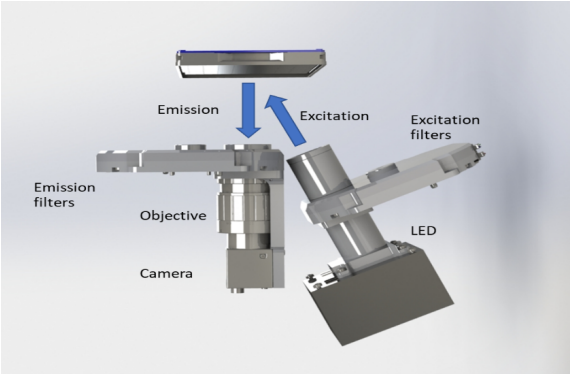
The thermal cycler of the QIAcuity is a plate thermocycler that features high speed and precision temperature control of the temperature cycling steps. Several Peltier elements are used for the temperature generation and control. For an optimal thermal contact between plate and thermocycler, the plate is clamped on the heating surface during cycling. The QIAcuity Eight features two thermocyclers that are operated in parallel.

The thermal cycler has the following specification:

Process temperature:	35–99°C
Ramp rate:	approx. 3.0°C/s
Accuracy:	±1°C
Homogeneity:	±1°C

Optical system

The optical system of the QIAcuity is a camera-based fluorescence microscopy system. The excitation source for the fluorescence dyes is a high-power white LED. This source in combination with a specific excitation filter is used to illuminate a whole well at a time. The fluorophores in the single partitions absorb that light and emit light that is being filtered by a detection filter, and collected and imaged through an objective lens on a CMOS-camera chip (see image below for a detailed overview of the components). QIAcuity instruments running under QIAcuity Software version 3.0 support dPCR assays up to 8 plex by using six optical channels for six standard dyes, and the additional use of two hybrid channels for LSS (Long Stokes Shift) dyes, which can be selected from five different hybrid channels. Starting from the QIAcuity Software version 3.1, the amplitude multiplexing option is available, enabling duplex assays using two amplicons in one channel supporting dPCR assays up to 12 plex. The QIAcuity One 2 plex offers only two detection channels. In addition to the target detection, channels are also used to detect the base fluorescence of the master mix, to determine the exact number of filled partitions and normalization of fluorescence data.



Scheme of the imaging module.

Available channels

Table 2. Available channels in QIAcuity

Channel	Excitation (nm)	Emission (nm)	Example fluorophores
Green	463–503	519–549	FAM™, EvaGreen®
Yellow	513–534	551–565	HEX™, VIC®
Orange	541–563	582–608	TAMRA™, Atto 550
Red	568–594	613–655	ROX™, Texas Red®
Crimson	588–638	656–694	Cy5®, Quasar 680
Far red	651-690	709-759	Cy5.5. Atto 680, Atto 700
Green / Yellow	463–503	551–565	DY-482XL (LSS G/Y)*
Orange / Red	541–563	613–655	DY-540XL (LSS O/R)*

* For Long Stokes Shift (LSS) dyes, the software provides generic dye names called "LSS" followed by the abbreviation of the used channel combination denoted by the first channel letters. For example, channel combination Green/Yellow is abbreviated as "LSS G/Y".

Installation Procedures

This section provides instructions on unpacking, packing, and installing the QIAcuity.

The installation procedure of the product is recommended to be carried out by a certified QIAGEN field service specialist. A person who is familiar with the laboratory and computer equipment should be present during the installation.

Site requirements

The QIAcuity must be located away of direct sunlight, away from heat sources, and away from sources of vibration and excessive electrical interference. Placing a QIAgility® instrument or an orbital shaker next to the instrument does not exceed this value. Refer to the "Technical Specifications" section for the operating conditions (temperature and humidity). Be aware that ambient temperatures of below 17°C (63°F) require an equilibration phase of approx. 30-60 min at the location where the instrument will be used before the instrument is powered on. The site of installation should be free of excessive drafts, excessive moisture, and excessive dust, and should not be subject to large temperature fluctuations.

Use a level workbench that is large enough and strong enough to accommodate the QIAcuity. Refer to the "Technical Specifications" section for the weight and dimensions of the QIAcuity. Allow at least 10 cm (5.9 in.) of free space behind and to the sides of the instrument for cooling and cabling.

Ensure that the workbench is dry, clean, and vibration-proof, and has additional space for accessories.

The QIAcuity must be placed within approximately 1.5 m of a properly grounded (earthed) AC power outlet. The power line to the instrument should be voltage-regulated and surge-protected. Ensure that the QIAcuity is positioned where it is easy to access the power connector and the power switch at the back of the instrument at all times, and that it is easy to power the instrument OFF and disconnect it.

Note: We recommend to plug the instrument directly into its own power outlet and not to share the power outlet with other lab equipment. Do not place the QIAcuity on a vibrating surface or near vibrating objects.

WARNING **Explosive atmosphere**

The QIAcuity is not designed for use in an explosive atmosphere.

CAUTION **Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the QIAcuity.

Slits and openings that ensure the ventilation of the QIAcuity must not be covered.

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

The QIAcuity is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

CAUTION **Damage to the instrument**

Direct sunlight may bleach parts of the instrument and cause damage to plastic parts. The QIAcuity must be located out of direct sunlight.

Power requirements

The QIAcuity operates at 100–240 V AC, 50/60 Hz, 1500 VA (max.)

Ensure that the voltage rating of the QIAcuity is compatible with the AC voltage available at the installation site. Main supply voltage fluctuations should not exceed 10% of nominal supply voltages.

WARNING **Damage to electronics**

Before powering ON the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

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.

Grounding requirements

To protect operating personnel, the National Electrical Manufacturers' Association (NEMA) recommends that the QIAcuity be correctly grounded (earthed). The instrument is equipped with a three-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.

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.

Installation of AC power cord

The AC power cord connects to the socket located at the rear of the QIAcuity, and the other end to the AC power outlet.

Unpacking the QIAcuity

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

The QIAcuity is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

Note: Before unpacking the QIAcuity, move the package to the site of installation and check that the arrows on the package point upward. In addition, check whether the package is damaged. In case of damage, stop here and contact QIAGEN Technical Services.

1. Cut the straps securing the packaging to the shipping pallet.
2. Open the top of the transportation box to remove the accessories set before lifting the box.
3. Remove the top and side protective black foam.
4. After the QIAcuity has been unpacked, a minimum of two people must lift the instrument. Lift the instrument by sliding your hands under both sides of the workstation and keeping your back straight.
5. **Important**: Do not hold the touchscreen display while unpacking or lifting the QIAcuity as it might damage the instrument.
6. Check if the packing list document is included after unpacking the QIAcuity.
7. Read the packing list to check that you have received all items. If anything is missing, contact QIAGEN Technical Services.
8. Check that the QIAcuity is not damaged and that there are no loose parts. If anything is damaged, contact QIAGEN Technical Services. Make sure that the QIAcuity has equilibrated to ambient temperature before operating it.

9. Retain the package in case you need to transport the QIAcuity in the future. Refer to "Packing the QIAcuity" for more details. Using the original package minimizes the possibility of damage during transportation of the QIAcuity.

Packing the QIAcuity

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

The QIAcuity is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

Note: Before transporting the QIAcuity, the instrument must first be decontaminated. Refer to the "Maintenance Procedures" section for more details. Then, prepare the instrument as follows:

1. Turn off the instrument and unplug the power cord.
2. Re-install the shipping fixation screw.
3. Prepare the packing material. Materials required are the cardboard carton, the pallet with foam blocks, and the foam lid.
4. Place the QIAcuity onto the pallet and put the black foam lid over the top of the instrument. Place the box onto the instrument.

   Important: When lifting the QIAcuity, slide your hands under both sides of the instrument and keep your back straight.

   Important: Do not hold the touchscreen display while lifting the QIAcuity, as this might damage the instrument.

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

The QIAcuity is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

Place the accessories into the black foam lid.

Important: The power cord must be packed in an air cushion bags.

5. Seal the outside edges of the carton with tape to protect against moisture.

   Note: Using the original package minimizes potential damage during transportation of the QIAcuity.

Installing the QIAcuity

This section describes important actions that must be performed before operating the QIAcuity. These actions include:

- Removal of the protective film from the QIAcuity touchscreen
- Removal of the shipping fixation screw
- Connection of the power cord to the back of the QIAcuity
- Powering ON the QIAcuity
- Removal of protective foam block of the drawer

Removing the protective film from the QIAcuity touchscreen

Carefully peel off the protective film from the QIAcuity touchscreen.

Removing the shipping fixation screw

Access the back of the instrument and remove the shipping fixation screw using a 4 mm hex wrench. Store the fixation screw in a safe place in case it is needed at a later point in time. The hole in the housing for the fixation screw shall be closed with the dust cap that is provided with the accessories of the instrument (cat. no. 9026772).

Back of QIAcuity.

Connecting the power cord to the back of the QIAcuity

1. Remove the power cord from the foam packing material on top of the QIAcuity.

   Note: Only use the power cord that is supplied with the QIAcuity.

2. Check that the voltage rating on the label found at the back of the QIAcuity matches the voltage available at the installation site.
3. Connect the power cord to the power inlet of the instrument and connect the cable to the wall power outlet.
4. Turn on the power switch at the back of the instrument.

WARNING **Damage to electronics**

Before powering ON the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

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.

Powering ON the QIAcuity

Check that the QIAcuity operates properly:

1. Ensure that the drawer of the QIAcuity is closed.
2. Power ON the QIAcuity using the blue front power switch.
3. The startup screen appears. The instrument automatically performs initialization tests.

   Note: The main power switch in the back must be switched on for the front power switch to work.

   Note: If ambient temperature is below 17°C (63°F), an equilibration phase of 30–60 min might be required. After the equilibration phase, the error can be cleared and the instrument is operational after restart.

4. If there is an initialization error, retry the initialization process by turning the instrument off and on again using the front power switch. If the problem persists, see “Troubleshooting the instrument and software“ section or contact QIAGEN Technical Services.

   Note: The instrument must be turned off at least once a week using the front power switch.

Removal of protective foam block of the drawer

Open the drawer of the QIAcuity instrument by pressing the physical button on the instrument or tapping Eject Tray on the instrument, and remove the protective foam. For QIAcuity Eight instrument, remove the foam of both drawers.

Operating Plates

In the QIAcuity plate-based system, one reaction mix per well is partitioned into a large number of individual partitions prior to the amplification step, resulting in one or very few templates being present in each partition. QIAGEN offers different plate types according to specific user needs.

Table 3. Plate types according to user needs

Plate type	Frame color	No. of wells	Input volume/well (µL)	No. of partitions	Partition volume (nL)
Nanoplate 26K 24-well	Blue	24	40	Approx. 26,000	Approx. 0.82
Nanoplate 26K 8-well	Light blue	8	40	Approx. 26,000	Approx. 0.82
Nanoplate 8.5K 24-well	White	24	12	Approx. 8500	Approx. 0.34
Nanoplate 8.5K 96-well	Gray	96	12	Approx. 8500	Approx. 0.34

Note that the QIAcuity Software Suite calculates with a partition volume of 0.82 or 0.34 nL, depending on Nanoplate type, in cases where the VPF (volume precision factor) has not been applied. If the VPF has been loaded to the software, the volume of each well is Nanoplate batch–specific calibrated and used for concentration calculation. Thus, the concentration calculated by the QIAcuity Software Suite will differ to concentration values calculated manually.

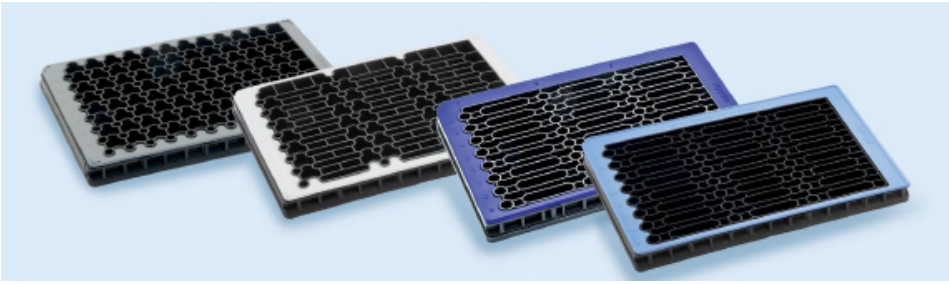


Image of Nanoplate 26K 24-well, Nanoplate 8.5K 24-well, and Nanoplate 8.5K 96-well.

QIAcuity Nanoplate 26K 24-well

For applications requiring high sensitivity, QIAGEN offers the 26K nanoplate. In this plate, one reaction mix is distributed over 4 wells and separated into approximately 26,000 partitions. The plate may be used for up to 24 samples and has a blue frame as distinction from the other plates.

The key applications of the 26K nanoplate are:

- Rare mutation detection
- Liquid biopsy

QIAcuity Nanoplate 26K 8-well

For applications requiring high sensitivity, QIAGEN offers the 26K nanoplate. In this plate, one reaction mix is distributed over 4 wells and separated into approximately 26,000 partitions. The plate may be used for up to 8 samples and has a light blue frame as distinction from the other plates.

The key applications of the 26K nanoplate are:

- Rare mutation detection
- Liquid biopsy

QIAcuity Nanoplate 8.5K 24-well

In this plate, one reaction mix is distributed in 1 well and separated into approximately 8500 partitions. The plate is recommended for applications using low input volumes and a small number of samples. The plate may be used for up to 24 samples and has a white frame as distinction from the other plates.

The key applications of the 8.5K nanoplate are:

- CNV detection
- NGS library quantification

QIAcuity Nanoplate 8.5K 96-well

In this plate, one reaction mix is distributed in 1 well and separated into approximately 8500 partitions. This plate is recommended for applications using low input volumes and a large number of samples. The plate may be used for up to 96 samples and has a gray frame as distinction from the other plates.

The key applications of this nanoplate are:

- CNV detection
- NGS library quantification

Reaction setup

Note: The QIAcuity reads fluorescence from the bottom of the nanoplate, which is covered with a seal. For best results, keep the foil clean and avoid damages such as scratches. Also, keep the barcode on the side of the nanoplate clean and intact. Ensure that you wear gloves when working with a nanoplate and do not apply force to it.

For better handling of the nanoplate, you can place it into the nanoplate tray that can be ordered as an accessory, see Appendix B — QIAcuity Accessories or the QIAcuity webpage on **www.qiagen.com**

To set up a plate, follow these steps:

1. Prepare your master mix according to your reaction setup. To prepare the reaction mix without sample, the QIAcuity PCR master mix has to be mixed with primers, RNase-free water, and optionally restriction enzyme and probes according to the kit manual. The final volume depends on the QIAcuity Nanoplate that is used (refer to Table 3).

Note: To prevent non-homogeneous reaction mixes, set up in a standard PCR pre-plate is required. The calculated reagent volumes must be pipetted into the PCR pre-plate, and then the sample added accordingly. For homogenous mixing of reaction mix, the pre-plate must be sealed, shortly vortexed, and briefly centrifuged.

Note: Enzymatic fragmentation of DNA larger than 20 kb ensures even distribution of template throughout the QIAcuity Nanoplate, which in turn leads to accurate and precise quantification. Therefore, adding a restriction enzyme depends on the template used. In case of enzymatic fragmentation using the recommended restriction enzymes, the pre-plate has to be incubated at room temperature (RT) for 10 min. Longer incubation does not lead to unspecific restriction and therefore has no impact on the result. Refer to the Application Guide on **www.qiagen.com** for the recommended restriction enzymes.

Important: Do not pipet master mix and sample separately into the nanoplate as this will lead to insufficient mixing.

2. Pipet each reaction mix from the pre-plate into a well of the nanoplate. If possible, use an electric one-channel pipette. To ensure bubble-free pipetting, we recommend to pipet 39 µL for Nanoplate 26K 8/24-well, and 11 µL for Nanoplate 8.5K 96/24-well of your prepared reaction mix to the bottom of the respective input well of the nanoplate. Ensure not to pipet into the output well instead of the input well.

   Note: To avoid damaging the optical surface and to reduce dust that will interfere with the imaging and analysis of results, we recommend placing the nanoplate into a nanoplate tray before pipetting the reaction mix into the nanoplate.

   Note: Do not centrifuge the nanoplate as this will lead to pre-priming and insufficient filling of the wells.

   Note: Do not vortex the nanoplate as this will lead to insufficient filling of the wells.

3. Apply the plate seal that comes with the nanoplates as follows to ensure good filling of the wells and to prevent evaporation and contamination:

a. The stiff plate seal consists of a plate seal and two protective sheets. The three-layered seal should not be folded. Remove the bottom white protective sheet carefully, and then center and align the plate seal (still containing the upper protective sheet) with the lower edge of the colored frame of row H. The seal should not overlap on any side more than 1 mm; otherwise, the nanoplate might not be processed by the instrument. In case the plate seal is incorrectly placed or the seal does not cover some parts of the nanoplate, carefully remove this seal and repeat the entire sealing step with a new one. Correct sealing of the nanoplate prevents samples from not being fully processed.

   Note: It is recommended to cover the plate with the top seal within 30 min after pipetting to prevent subsequent filling issues.

   Note: Keep the plate seals stored in a dry, darkened, and air-free environment by always completely closing them inside the provided storage bag in which they came, and storing them in the Nanoplate box.

b. After correct placement, the plate seal must be fixed with the Nanoplate roller in both the horizontal and vertical directions.

c. Afterwards, the upper protective sheet is removed from the bottom left corner. Hold the rubber seal in place on the plate corner with one finger while the upper transparent sheet is being pulled off. If the upper sheet is removed in another direction, the plate seal might loosen.

d. Use the Nanoplate roller with high force to fix the plate seal on the nanoplate by rolling at least three times forwards and backwards in a horizontal direction, and then three times forwards and backwards in the vertical direction over the edge of the plate. Roll over the plate seal covering the Nanoplate frame. The proper fixing of the plate seal is important for a good filling of the wells.

Note: For a properly sealed plate, the plate seal covers the whole structure, and no bubbles or strong depressions are visible, as this can also lead to poor filling.

4. The plate frame gives the option to mark the plate with a marker pen. Use the lane between the plate edge and the printed letters (next to column 1) as well as the mirrored portion (from column 12 to the plate edge) only. Marking the plate seal directly on top of each well is not recommended as it might lead to poor filling.

   Important: Do not mark the bottom side of the plate, as it is used to read fluorescence signals.

   Note: Ensure that overlapping parts of the plate seal are turned down and attached to the plate frame and that the barcode is not covered. Do not apply pressure to the either upper or lower plate seal.

5. For the transport of the Nanoplate to the QIAcuity instrument, the plate should be held at the side edges or on the tray horizontally. Make sure that the plate is transported to the QIAcuity smoothly without shaking or turning over the plate to ensure that the reaction mix remains at the bottom of the input well.

6. The plate can now be used to start a run.

   Note: Do not store the plate for more than 2 hours before the start of a run as this may lead to pre-priming of the reaction mix resulting in reduced number of analyzable partitions.

7. If the plate is kept in the dark, avoiding exposure to moving air (e.g., storage in a dark box), you can store the plate after the run for up to 1 week at room temperature or at 4°C. (**Note**: Storage time may be reduced from 1 week to shorter durations due to various factors, such as dye/probe stability, master mix, and previous imaging step/settings). Dispose the plates after 7 days at the latest. A plate can be re-imaged up to six times (seven total imaging steps).

Note: For improperly stored plates, the fluorescence intensity and plate seal integrity can be affected, which could lead to contamination of the laboratory. Store processed plates according to these guidelines or dispose of them properly after the process.

Operating the QIAcuity Instrument

The QIAcuity is operated through a touchscreen. Elements of the QIAcuity user interface are shown in the following table.

Table 4. QIAcuity interface elements

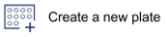
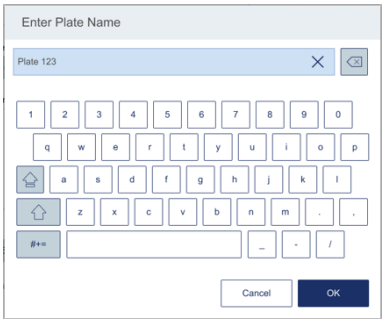
Button/Icon	Function
	Starts the run
	Stops the run
	Starts runs on all loaded plates
	Stops all runs
	Closes an open tray
	Ejects selected tray
	Displays an additional menu
	Enables the user to edit plate parameters
	Enables the user to create a new plate and specify its parameters
Text field	Enables to enter or edit a value using the on-screen keyboard
	Logs the user out

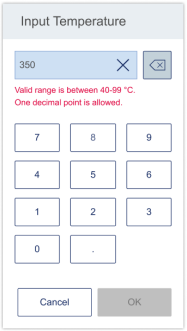
Table 4. QIAcuity interface elements (continued)

Button/Icon	Function
	Indicates whether the instrument is connected to a network
	Landing page with status of runs
	Configuration
	Tools

Entering text and numbers

To enter text or numbers, tap the corresponding field. An on-screen keyboard is displayed on the touchscreen.

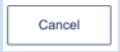




In some cases, the value required in a text field must meet a specific criterion. If required, the criteria are specified in the corresponding input window.

Note: For all text fields, a handheld scanner plugged into one of the USB ports can be used to scan 1D barcodes. Buttons and icons related to the on-screen keyboards are shown in the following table. An external keyboard can also be attached via USB port for data entry, if desired.

Table 5. On-screen keypad buttons and icons

Button/Icon	Function
	Removes one character to the left of the cursor
	Clears the field
	Enables the user to type one uppercase letter. After the letter is typed, the keyboard will show lowercase letters again.
	Switches to uppercase letters. Allows the user to type multiple uppercase letters. To return to lowercase letters, press the symbol again.
	Shows special characters
	Shows alphanumeric characters
	Confirms the input and closes the window
	Discards the input and closes the window

If the entered value is not correct, the border of the textbox changes to red and additional information about the field's requirements is shown. The input cannot be confirmed until the value entered in the box meets the requirements.

Turning on the instrument and logging in

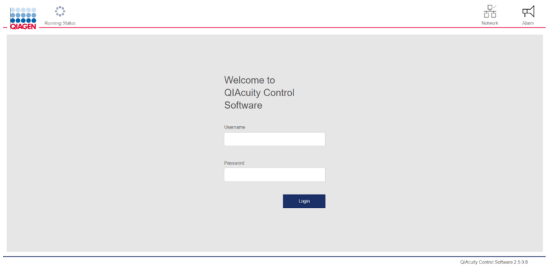
To turn on the instrument and log into the software, follow these steps:

1. Press the power button to turn on the QIAcuity.
2. The startup screen appears on the touchscreen, and the instrument automatically performs initialization tests. After the initialization setup, the Login window appears.
3. Enter your credentials in the “Username” and “Password” fields.

   Note: The “Username” field is case sensitive.

   Note: When connection to the Software Suite has not been established yet, log into the instrument using the following credentials:

   - **Login**: SetupUser
   - **Password**: 2#ConnectSuite



4. Tap **Login**.
5. The Home screen displays.

   Note: If the username does not match the password or if the username does not exist, an error message is displayed on the screen. Re-enter the correct credentials in the “Username” and “Password” fields.

Setting up a run

Before starting a run, at least one plate must be created, and its name, plate type, and dPCR parameters must be defined. We recommend that you define plates and their specific parameters (e.g., the run profile) using the QIAcuity Software Suite. For more information about setting up a plate using the QIAcuity Software Suite, refer to the "Operating the QIAcuity Software Suite" section. For creating a plate using the plate configurator of the instrument software, refer to "Plate configuration procedure" section of the *QIAcuity User Manual* (**www.qiagen.com/HB-2717**).

Setting up an experiment

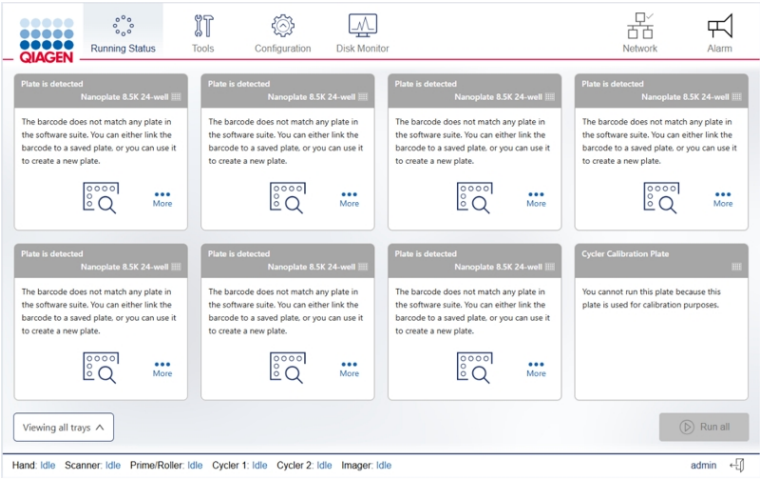
Note: A plate run can only be performed if the instrument is connected to the QIAcuity Software Suite through either a network or a direct cable connection to the QIAcuity Software Suite server.

Note: It is recommended to cover the plate with the top seal within 30 minutes after pipetting to prevent subsequent filling issues.

Loading the trays and starting a run

The Home/Running status screen shows the current status of the trays and the slots inside them. If there are no plates loaded in the instrument, the screen displays empty panes and each pane displays the **Plate is not loaded** label. You can load up to eight plates at one time with QIAcuity Eight, up to four plates at one time with QIAcuity Four, and one plate with QIAcuity One.

Note: Loading and unloading plates during a run is supported by QIAcuity Eight and QIAcuity Four. To learn more about continuous loading and unloading, refer to the "Continuous loading and unloading of plates" section.

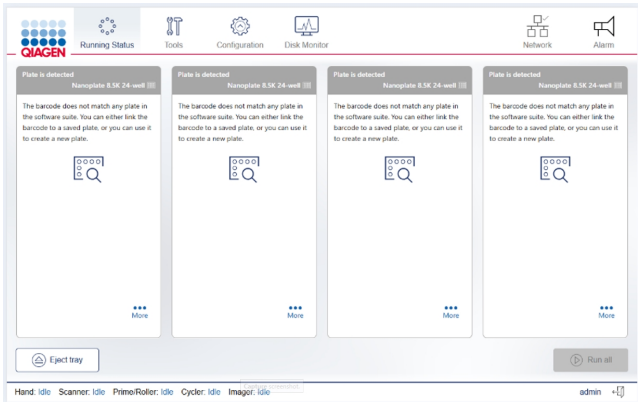


To load a tray and to start a run, follow these steps:

1. To eject a tray, press the physical button on the instrument or tap **Eject Tray** on the touchscreen.

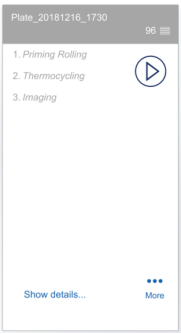
   Note: In QIAcuity Eight, you can select to eject either the upper or the lower tray from the list located below the panes.

2. Place a plate in one of the slots of the ejected tray. Ensure that the plate is placed in the correct orientation, facing the barcode toward the instrument and the QIAGEN lettering toward you. Also, ensure that the plate seal of the plate is intact and not overlapping any of the sides more than 1 mm. Repeat this step until all plates are loaded to the tray.



3. Tap **Close Tray** or press the physical button on the instrument to close the tray. Do not push the tray itself.

4. The instrument scans the barcodes on the plates. The instrument detects the availability of the plate and the label of the corresponding pane changes to **Plate is detected**. If the barcode matches to an existing experiment in the Software Suite, the loaded plate pane displays the defined run setup and can be started.



Note: In case the barcode does not match an existing plate in the Software Suite (e.g., if no barcode has been defined in the experiment setup), the plate can be assigned manually from the list of pre-defined plates without barcodes.

Note: If the plate is expired, a warning message displays, indicating the expiration date. User may continue with this plate at your own risk.

5. To view the details of the plate, tap **Show details** in the corresponding plate's pane.
6. When all plates are correctly labelled and the corresponding data are received from the QIAcuity Software Suite, start the run.
    - To start the run on all plates simultaneously without making any changes, tap **Run all**.
    - To start the run of an individual plate without making any changes, tap the **Run** icon on the plate's pane.

- To edit the parameters of a plate before starting a run, follow the steps described in the “Configuring a plate and starting a run” section.

Note: A run can only be started if the current user logged in has the appropriate rights.

Note: After a plate is loaded into the instrument, the QIAcuity sends a request to the Software Suite to lock the plate. This ensures that the plate is not modified by another user in the Software Suite while the plate is loaded and operated by an instrument. The plate is unlocked after it is unloaded from the instrument.

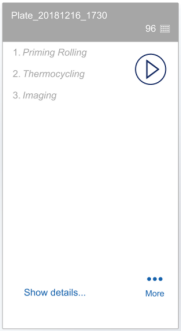
Configuring a plate and starting a run

User can configure a plate (in the Software Suite) before or after it has been loaded to the instrument.

Note: For configured plates loaded into instrument, only dPCR parameters can be changed; General Data cannot be edited. Changes are not allowed during the run.

To start the configuration of a plate that has been loaded into the instrument, follow these steps:

1. On the plate's pane, tap **More**.



2. Tap **Edit plate** or **Create a new plate** to proceed to the plate configurator.

   Note: The **Edit plate** button becomes available when a plate is loaded and the instrument successfully received the data from the Software Suite. The **Create a new plate** button is available when the plate's barcode is not found in the Software Suite database or when the QIAcuity cannot connect to the Software Suite.

3. Proceed to the "Plate configuration procedure" section.

To start the configuration of a plate that has not been loaded into the instrument, follow these steps:

1. On the Home (Running status) screen, tap **New Plate**.

   Note: The **New Plate** button is not available for single-plate instruments.

2. To input the barcode manually, tap the "Barcode" field. To scan the barcode using the external USB scanner, tap **Scan**.

3. Proceed to the "Plate configuration procedure" section.

Plate configuration procedure

To configure a plate and start the run, follow these steps:

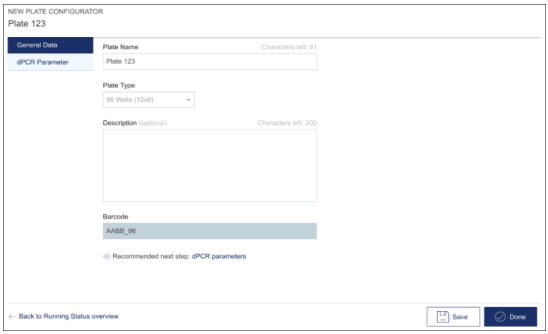
1. In the **General Data** section, enter the following information:

   - **Plate Name**: Enter the name of the plate.

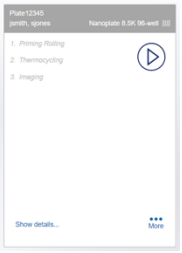
     Note: The plate type is automatically selected based on the scanned barcode.

   - **Description (optional)**: Provide a description for the plate.

Note: If you are editing an existing plate, you can only change the values in the **dPCR Parameters** section. The fields in the **General Data** section are disabled.



Note: If you are creating a plate, you are automatically assigned as an owner of a plate. Owners are displayed under plate name on running status page. Modifying owners of the plate is only possible by editing the plate in the Software Suite.



2. Tap **dPCR Parameters** to proceed with the next step.

   Note: Each step in dPCR parameters has its own tab. The **Priming**, **Cycling**, and **Imaging** tabs are mandatory.

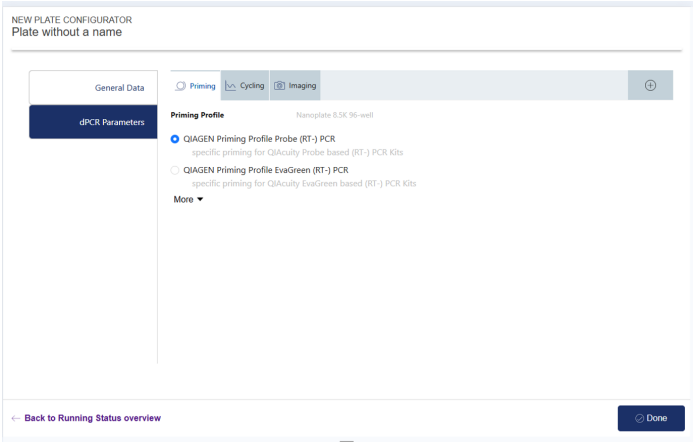
3. In the **Priming** tab, select the applicable priming profile. Starting with the QIAcuity software version 3.0:

   - To improve overall filling of all Nanoplate types: Two priming profiles are available for selection for probe-based and EvaGreen-based (RT-) reaction mixes.

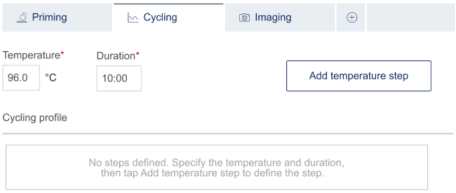
     Important: Nanoplates for those profiles must be sealed with the Nanoplate Seals.

   - To omit filling in the Priming process for all nanoplate types: One priming profile is dedicated to the plates sealed in an Automatic Plate Sealer called "No Priming" – available after pressing **More**.

     Important: Nanoplates sealed with the automatic plate sealing solution are already filled during that process.

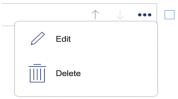


4. Perform the following steps in the **Cycling** tab:
    a. Enter your desired temperature in the “Temperature” field.
    b. In the “Duration” field, enter the cycling duration for the plate.
    c. Tap **Add temperature step**.

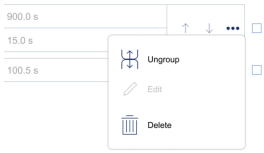


Note: The gradient cycling option can only be defined in the Software Suite.

5. If you want to modify the temperature steps, refer to these steps:
    - To edit or delete a temperature step, tap the **More** ••• icon, then tap **Edit** or **Delete**.



    - To group the temperature steps, check the corresponding boxes of more than one temperature step, then tap **Group**.
    - To ungroup a group of temperature steps, tap the **More** ••• icon, then tap **Ungroup**.



6. Perform the following steps in the **Imaging** tab:

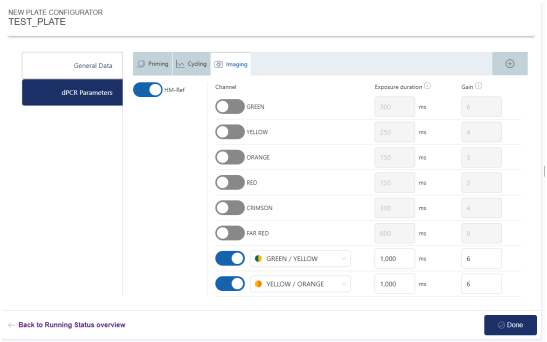
    a. In the **Imaging** tab, select the applicable channel, then enter the exposure duration and gain in the "Exposure duration" and "Gain" fields.

    b. On all QIAcuity instruments (excluding QIAcuity One, 2 plex), high multiplex experiments, up to 8-plex analysis, can be performed. Channels 6–8 (Far Red and the combinations of Green/Yellow, Yellow/Orange, Orange/Red, Red/Crimson, Crimson/Far Red) require the High-Multiplexing Reference channel of the new QIAcuity High Multiplex Kit. If any of the above channels is selected on the **Imaging** tab, the system will automatically enable the required High-Multiplexing Reference channel and the user cannot disable it. It is also possible to activate the High-Multiplexing Reference channel for standard channel usage.

    c. To include more steps in the run, tap the **Add** icon, then select the applicable step. Provide the required information for the step. Repeat this step if more steps are needed for the run. In total, nine steps can be performed per plate.

    d. Tap **Save** to save your progress or tap **Done** to save the run and go back to the Running Status window.

Note: If any required field is not completed, an error message is displayed, pointing out the missing information required in each field.



7. Start the run in the Running Status window:
    - To start the run on all plates simultaneously without making any changes, tap **Run all**.
    - To start the run of an individual plate without making any changes, tap the corresponding **Run** icon located on the plate's pane.

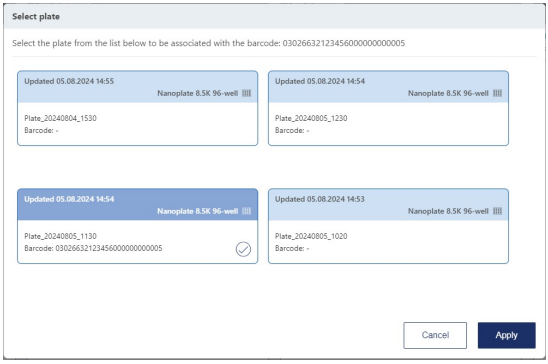
Linking a plate to a pre-defined plate without existing barcode

If the instrument cannot match the barcode on a loaded plate to a barcode that already exists in the Software Suite, the plate can be linked manually. Alternatively, a new plate can be created by following the steps in the “Configuring a plate and starting a run” section.

To link the barcode to a defined plate in the Software Suite that has no barcode defined, follow these steps:

1. Tap the **Link** icon.
2. In the Select Plate dialog box, select the plate that you want to link to the barcode of the loaded plate.

   Note: Only plates with a "Defined" status without a barcode assigned can be linked.



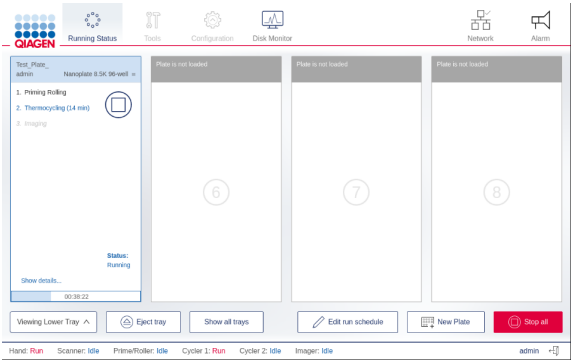
3. Tap **Apply**.

Tracking the run status

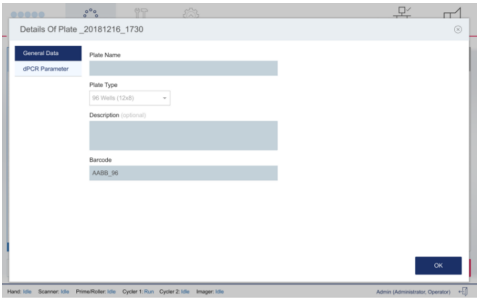
Once the run has started, the status of the run can be tracked. The plate that the QIAcuity is currently working with is distinguishable through the following elements:

- The Running status is displayed in the pane.
- The **Stop Run** button is available.
- A status bar with the remaining time is displayed.

The panel also shows all the steps within the run. The font color of the steps that are completed is black. When a step is in progress, its font color is blue. Pending steps are shown in light gray.



To view more details about the run, tap **Show details**. The dialog box appears containing information about the plate (in the **General Data** tab), as well as each step of the run (in the **dPCR Parameters** tab).



To view information about the individual steps of the run, tap **dPCR Parameters**, then tap the step that contains the details you want to view. The instrument shows the status of each step of the run and the remaining time of the current step. You can also view the parameters defined for each step.

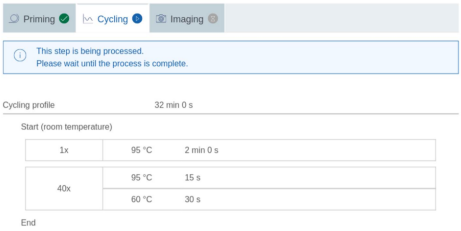
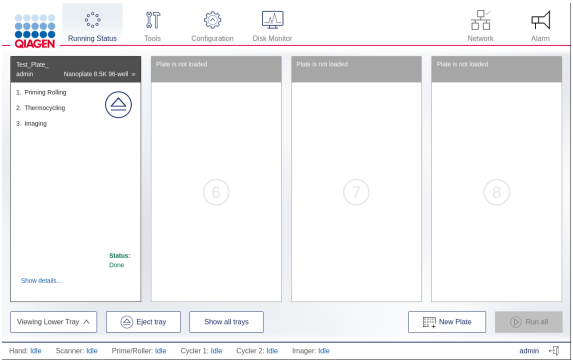


Table 6 shows the meaning of each status icon that is shown in the dPCR parameters step.

Table 6. dPCR step status icon

Icon	Status
	The step is successfully finished.
	The step is being executed.
	The step is pending, and its execution will start after the current step is done.
	The step failed.

When the run is finished, the status of the run changes to **Done** and the **Eject** button becomes available. To view the details about the run, tap **Show details**. To eject the plate, tap the **Eject** button.



Continuous loading and unloading of plates

Note: The **Continuous loading and unloading of plates** function is only available on the QIAcuity Eight and QIAcuity Four instruments. To unload a plate that is currently running in the QIAcuity One instrument, you need to abort the run. For more information, see the "Aborting a run" section.

On multi-plate instruments, user can load and unload plates while the instrument is running. User can load new plates, unload finished ones, or remove plates that are still in progress. To eject a tray, press the physical button on the instrument or tap **Eject tray** on the touchscreen. If any of the running plates are in the Imaging step, this process is paused. Once the changes in the tray are done, tap **Close tray** or press the physical button on the device to close the tray. The software checks the plates and displays the plate information on the screen. If any of the

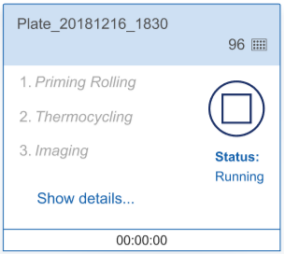
plates that were running before the tray was opened are missing, an error message appears and the run is stopped.

Note: If the slot where the new plate is placed is also used by a plate that is in a different module, an error message is shown on the screen and the new plate must be moved to a free slot. The drawer opens automatically, which can take up to 2 minutes. Move the plate and close the drawer to proceed.

Note: Depending on the time frame for unloading/loading of plates, the drawer opening might be delayed some time to finalize current movement steps.

Aborting a run

- If needed, a run can be stopped at any time. User can either abort all running plates or only a single running plate. To abort all runs on all plates, tap **Stop all**. Tap **OK** in the confirmation dialog box to proceed.
- To abort a single plate, tap the **Stop Run** icon on its pane. All aborted plates return to their loading position on the tray.
- To unload the plates from the instrument, tap the **Eject** button.

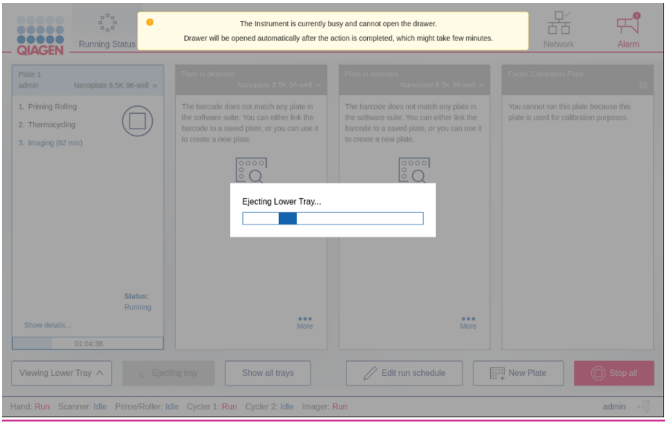


Aborting a plate during the priming/rolling step renders it unusable and the plate cannot be used and run again. A plate that has been aborted during the Thermocycling or Imaging step

can be used again. To rerun the plate, configure a run with only the remaining steps. See the “Rerunning a plate” section for more information.

Note: A run cannot be stopped during barcode scanning or when one or more trays are ejected.

Note: If the **Eject** button is tapped or the physical eject button on the instrument is pressed before the plate is returned to the tray, a warning message is displayed on the screen and the tray is ejected after the plate is transported to drawer.

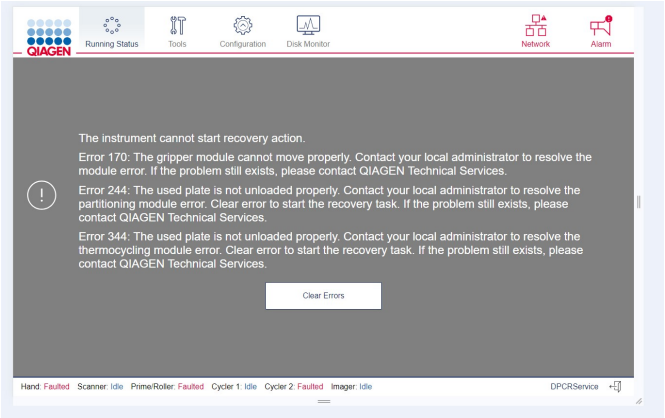


Error clearing

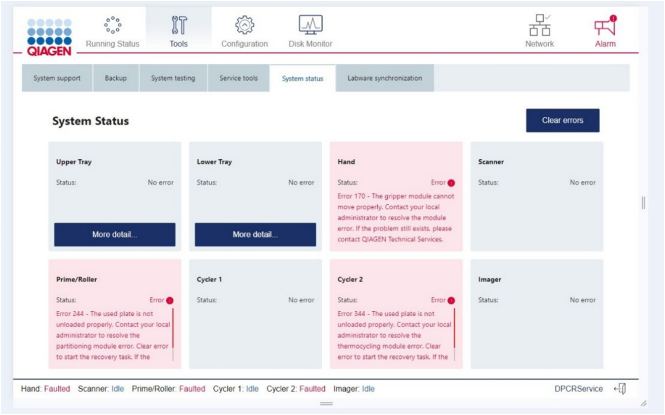
The Control Software provides an error-handling functionality to ensure that the software is in a defined state. It is designed to provide a streamlined and efficient way to manage potential system faults.

If an error appears on a specific module during the run, a notification will display under the “Alarm” notification box, for logged in users with appropriate permissions.

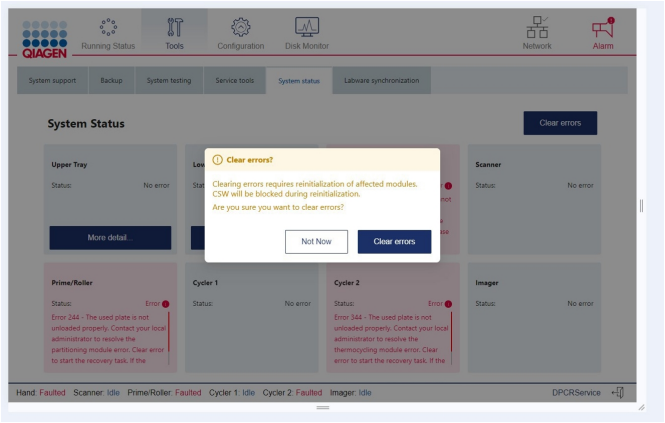
If the instrument was restarted after the error appeared during the run, a gray screen will display the list of errors that appeared and a **Clear errors** button to provide manual clearing of the errors without a need for instrument restart.



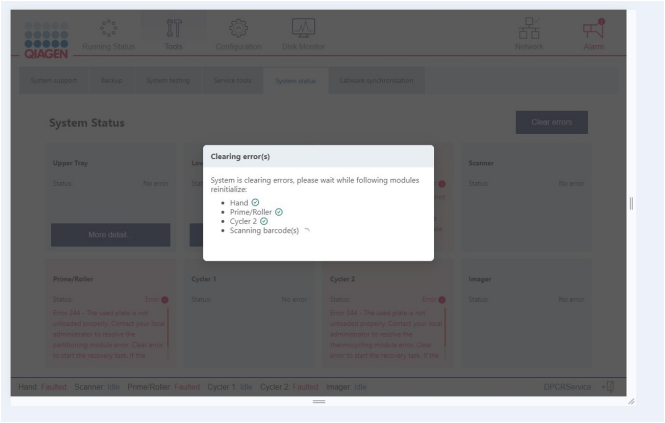
For a separate way to clear module-related errors, go to the **Tools** > **System status** panel and press the **Clear errors** button.



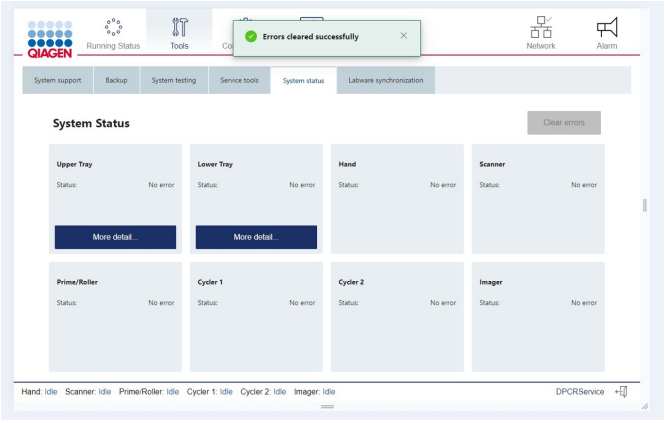
Confirmation is required after pressing the **Clear errors** button, as the process requires the affected modules to be reinitialized and the Control Software is blocked while this task occurs.



While the error clearing process occurs, information about the clearing status is displayed:



After the errors are cleared, an information message appears at the top of the screen, informing the user that the errors have cleared successfully. The errors no longer appear on the **System status** tab and under the "Alarm" notification box.



Automatic error clearing during the run

When Error 177 appears for the Hand, Primer, or Thermocycler module, it is currently thrown by the system and displayed on the "Alarm" notification page in the user interface (UI). Previously, this error stopped the run and the error must be manually cleared to resume operations. Rather than stopping the run immediately, the system will attempt automatic Hand positioning to retrieve the plate. The error will be eventually thrown and left for the user to be cleared after three unsuccessful attempts. This process reduces interruptions and enhances workflow continuity.

Rerunning a plate

If a plate failed or was aborted during the Thermocycling or Imaging step, it can be run again after adding new cycling or imaging steps. User can add the steps either through the instrument's plate configurator or in the Software Suite. To add steps using the built-in plate configurator, follow the steps in the "Plate configuration procedure" section. To use the Software Suite, refer to the "Setting up an experiment" section.

Note: To modify a plate that was already used, you must remove it from the instrument. This ensures that the plate is unlocked and ready for modifications in the QIAcuity Software Suite. If modifications are desired using the plate configurator on the instrument, load the plate again.

Editing the run schedule

Note: Editing the run schedule is only possible on QIAcuity Eight and QIAcuity Four and for those users having the appropriate permissions (see).

When a run starts, it is added to the run schedule and the **Edit schedule** button is shown on the screen. If the runs are started individually, they will be added to the schedule in the order which they were started by tapping the **Run**  icon on their respective panes. If all the runs are started at the same time, using the **Run All** button, there is a default order in which the plates are run.

In QIAcuity Eight, the run starts with the first slot in the upper tray and ends with the last slot in the lower tray. The slot numbers are presented in Table 7.

Table 7. Slot numbers the QIAcuity Eight

Tray	Slot numbers			
Upper	1	2	3	4
Lower	5	6	7	8

In QIAcuity Four, the run starts with slot number 1 and ends with slot number 4. The slot numbers are presented in Table 8.

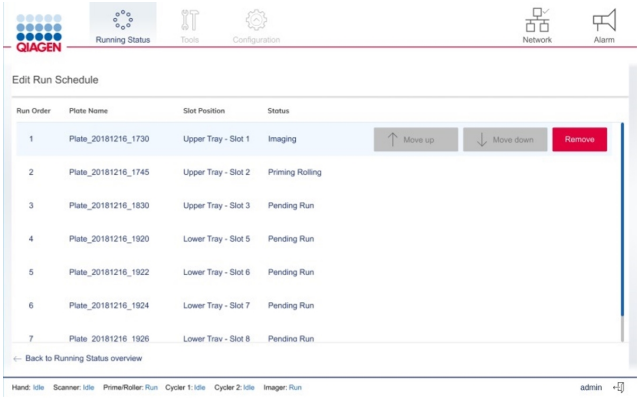
Table 8. Slot numbers of the QIAcuity Four

Slot numbers			
1	2	3	4

To edit the run schedule, follow these steps:

Note: Only runs that are not started yet (with Pending Run status) can be rearranged.

1. On the Running Status screen, tap **Edit run schedule**.

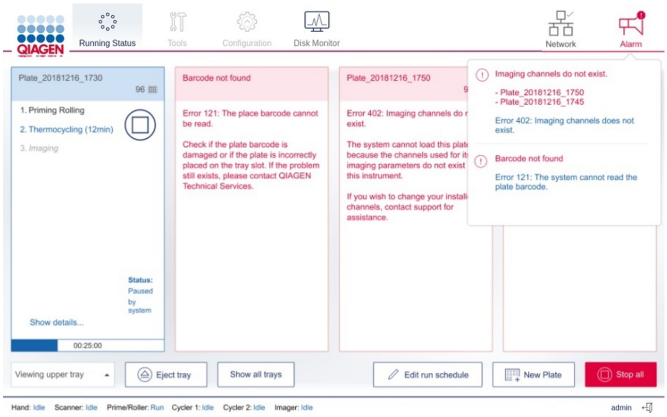


2. Tap the row corresponding to the plate to be moved.
3. Perform one of the following actions:
    - Tap **Move up** to move the plate run to an earlier position.
    - Tap **Move down** to move the plate run to a later position.
    - Tap **Remove** to cancel the plate run. Tap **Back to running status overview** to go back to the Running status window.

Viewing notifications

If the QIAcuity detects an error that affects the workflow of the instrument that the user can resolve, a notification displays on the screen.

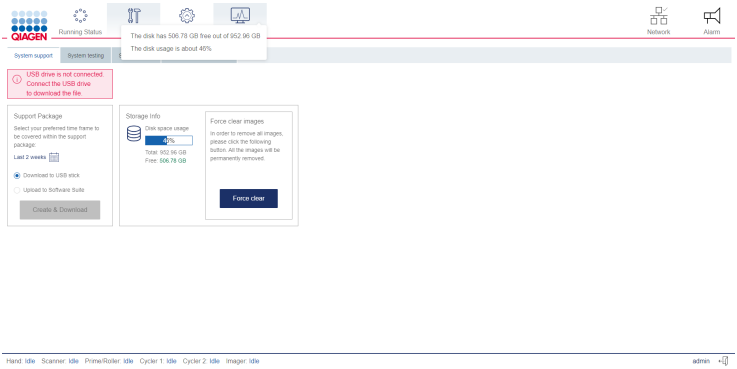
To view a list of all notifications and possible solutions to the errors, tap the **Alarm** icon. The last three errors are shown. If there are more than three errors, tap **View all** to view the full list of errors.



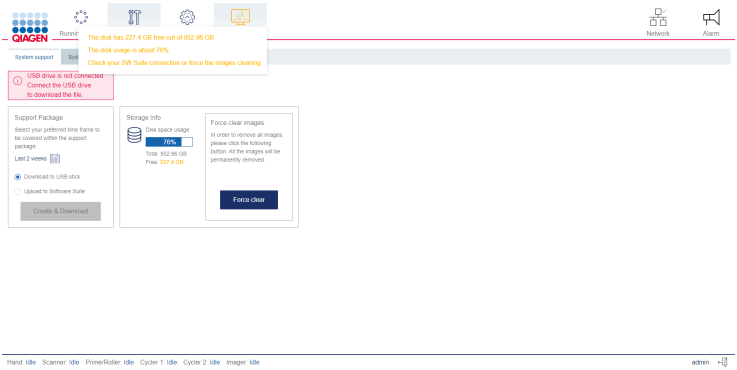
Disk monitoring

The **Disk Monitor** icon located in the header shows the real-time usage of the disk (free space and usage percentage). Depending on the space left, the information is shown in different colors. The **Disk Monitor** icon can appear as follows:

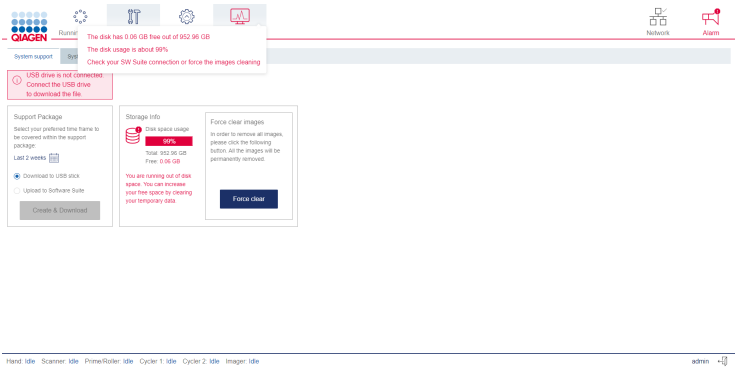
- **Blue** – When the disk occupation percentage is below 75% of the entire disk space



- **Yellow** – When the usage of the disk occupation rises above 75%



- **Red** – when the remaining free disk space is less than 4 GB (approx. 14%)



In case of Yellow and Red scenarios, additional information is shown to inform user about the actions that should be taken to regain disk space: forcing the clearing of images which have not been transferred to the Software Suite or setting up a connection with the Software Suite.

Logging out

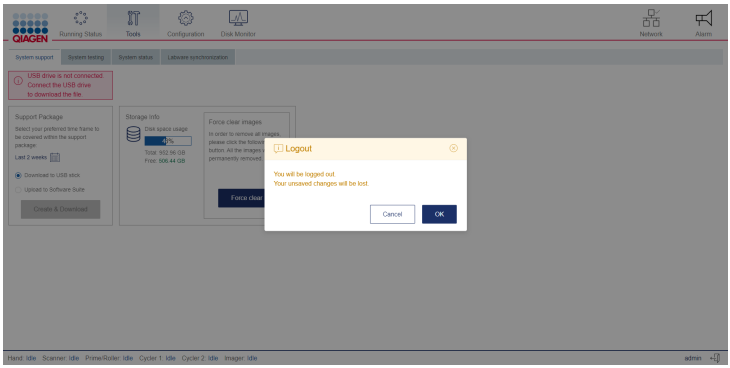
Note: If a run is processing, you can still access its status, even if you log out of the instrument. For more information, refer to "Automatic logout" section.

To log out of the instrument, follow these steps:

1. Tap the **Logout** icon located at the bottom right of the touchscreen.

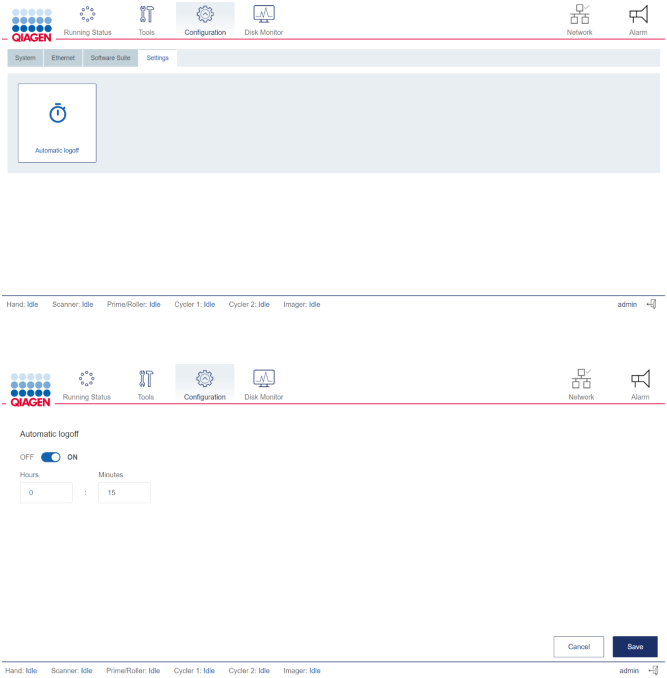
   Note: The **Logout** button is disabled when the instrument is being calibrated or when a tray is ejected. However, you can log out when a plate is running.

2. In the Confirmation dialog box, tap **OK** to confirm or tap **Cancel** to go back.



Automatic logout

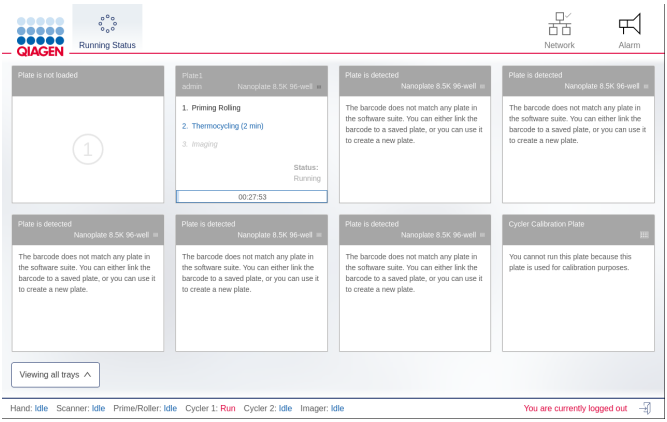
Users are automatically logged off after a default setting of a 15 minute period of inactivity. Time delay between user inactivity and log off can be configured manually or disabled under **Configuration** > **Automatic log off**. The maximum value that can be applied is 7 hours 59 minutes.



Note: For unsaved data, for example, during plate creation, an automatic log out will lead to loss of entries.

Accessing the run status when you are logged out

After logging out, the Login screen is displayed on the QIAcuity display. To view the run status of an ongoing run, tap **Running status**. The Running status screen is displayed in view-only mode. All functions are disabled. To perform any actions related to the run and the plates that are being processed, log into the instrument.



Maintenance Procedures

WARNING/ CAUTION

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual.

The following maintenance procedures must be carried out to ensure reliable operation of the QIAcuity:

1. Regular maintenance
2. Periodic maintenance

Optionally, these procedures may be performed to check and ensure the reliability of operation of the QIAcuity.

Select the cleaning agent according to the objective of the cleaning procedure, the sample material used, and the downstream assay.

WARNING

Risk of fire or explosion

When using ethanol or ethanol-based liquids on the QIAcuity, handle such liquids carefully and in accordance with the required safety regulations. If liquid has been spilled, wipe it off and allow flammable vapors to disperse.

Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment.

Cleaning agents

The following disinfectants and detergents are recommended for cleaning the QIAcuity.

Note: To use disinfectants different from those recommended, ensure that their compositions are similar to those described below.

General cleaning of the QIAcuity

1. Mild Detergents (e.g., Mikrozid® AF sensitive)
2. 25% ethanol

Disinfection

Ethanol-based disinfectants can be used for disinfection of surfaces (e.g., 25 g ethanol and 35 g 1-propanol per 100 g liquid or Mikrozid Liquid (Schülke & Mayr GmbH, cat. no. 109160)).

Disinfectants based on glyoxal and quaternary ammonium salt can be used (e.g., 10 g glyoxal, 12 g lauryl dimethyl benzyl ammonium chloride, 12 g myristyl dimethyl benzyl ammonium chloride, and 5–15% non-ionic detergent per 100 g liquid, Lysetol® AF [Gigasept Instru AF in Europe, cat. no. 107410, or DECON-QUAT® 100, Veltek Associates, Inc., in the USA, cat. no. DQ100-06-167-01]).

Removal of RNase contamination

RnaseZap® RNase Decontamination Solution (Ambion, Inc., cat. no. AM9780) can be used for cleaning surfaces. RnaseZap can also be used to perform decontamination by spraying the respective items.

Removal of nucleic acid contamination

DNA-ExitusPlus™ (AppliChem, cat. no. A7089,0100) can be used for cleaning surfaces. DNA-ExitusPlus can also be used to perform decontamination by spraying the respective items. DNA-ExitusPlus is very sticky and foamy. For this reason, after cleaning the items with DNA-ExitusPlus, user must clean the items with a wet cloth several times, or rinse them with running water, until the DNA-ExitusPlus is completely removed.

General instructions

1. Do not use spray bottles to spray cleaning or disinfectant liquids onto surfaces of the QIAcuity.
2. If solvents or saline, acidic, or alkaline solutions are spilled on the QIAcuity, wipe the spilled liquid away immediately.
3. Follow the manufacturer's safety instruction for handling cleaning agents.
4. Follow the manufacturer's instruction for soaking time and concentration of the cleaning agents.

   Important: Immersing for longer than the recommended soak time can harm the instrument.

   Note: Disinfection reagents shall be distributed equally on the instrument surface and drops shall be avoided.
5. Ensure that no liquid runs down the touchscreen. Liquid may be drawn through the dust protection sealing by capillary forces and cause malfunction of the display. To clean the touchscreen, moisten a soft lint-free cloth with water, ethanol, or a mild detergent and carefully wipe the display. Wipe dry with a paper towel.

CAUTION **Damage to the instrument**

Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the QIAcuity.

CAUTION **Damage to the instrument**

Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the QIAcuity. Take special care while cleaning the extended drawer that no liquid is spilled into the inside of the instrument.

WARNING **Risk of fire**

Do not allow cleaning fluid or decontamination agents to come into contact with the electrical parts of the QIAcuity. Take special care while cleaning the extended drawer that no liquid is spilled into the inside of the instrument.

WARNING **Risk of electric shock**

Do not open any panels on the QIAcuity.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized Field Service Specialist.

WARNING **Hazardous chemicals and infectious agents**

The plates may contain hazardous material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

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

Improper use of the QIAcuity may cause personal injuries or damage to the instrument. The QIAcuity must only be operated by qualified personnel who have been appropriately trained. Servicing of the QIAcuity must only be performed by a QIAGEN field service specialist.

WARNING **Risk of explosion**

When cleaning the QIAcuity with alcohol-based disinfectant, allow flammable vapors to disperse.

WARNING **Risk of fire or explosion**

When using ethanol or ethanol-based liquids on the QIAcuity, handle such liquids carefully and in accordance with the required safety regulations. If liquid has been spilled, wipe it off and allow flammable vapors to disperse.

WARNING **Toxic fumes**

Do not use bleach to clean or disinfect the QIAcuity.

WARNING **Toxic fumes**

Do not use bleach to disinfect used labware.

Servicing

Contact QIAGEN Technical Services or your local distributor for more information about flexible Service Support Agreements from QIAGEN.

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

Improper use of the QIAcuity may cause personal injuries or damage to the instrument. The QIAcuity must only be operated by qualified personnel who have been appropriately trained. Servicing of the QIAcuity must only be performed by a QIAGEN field service specialist.

Regular maintenance procedure of QIAcuity

Clean the instrument on a regular basis, especially if fluids have been spilled on the instrument. See “Cleaning agents“ section for the recommended cleaning agents that can be used to clean the QIAcuity instrument. All outer surfaces of the instrument, including the touch display, and the extended drawer can be cleaned.

Periodic maintenance

Air filter change

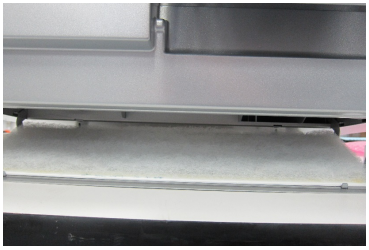
We recommend changing the air inlet filter of the instrument once per year. This will be part of an annual scheduled service visit. When operating the instrument in unusual dusty environments, a more frequent filter change might be necessary.

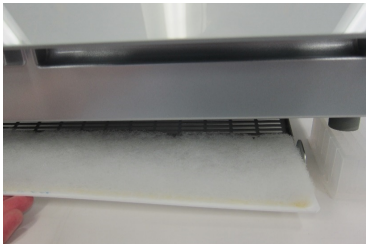
Note: Air filters can be ordered separately. See the "Ordering information" for more details.

Follow these steps for changing the air filter:

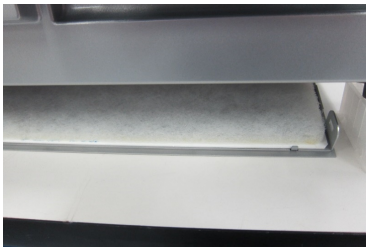
1. Turn off instrument and remove power cord.
2. Reach under the front of the instrument and push both buttons simultaneously.

3. Remove the filter from the swing-out filter compartment.





4. Replace with a new filter and push the compartment to the top to close.



Calibration of thermal cycler

The thermal cycler is designed to operate with the same specifications over the lifetime of the instrument. The cyclers are factory calibrated in production and the specification is controlled as part of the final instrument QC. This is part of the provided certificate of manufacture, where the SN of the calibrated module is referenced, and the passed calibration and temperature accuracy is checked. To ensure and verify the quality of the cycler, the calibration of the thermal cycler is part of an annual scheduled service visit.

Decontaminating the QIAcuity

If the QIAcuity is contaminated with infectious material, it should be decontaminated. If hazardous material is spilled on the outer surfaces or the plate trays of the QIAcuity, the user is responsible for carrying out appropriate decontamination. If damaged plates were used and the inside of the instrument is contaminated, contact QIAGEN Technical Services.

The QIAcuity should also be decontaminated before shipping (e.g., back to QIAcuity). In this case, a decontamination certificate must be completed to confirm that the decontamination procedure has been carried out.

To decontaminate the QIAcuity, follow the procedure in the "Disinfection" section, using the recommended disinfection agents.

Regular maintenance procedure for QIAcuity instrument software

The QIAcuity stores various information about the runs and plates used in the instrument. Images created during the runs are deleted automatically after they are transferred to the QIAcuity Software Suite. If the instrument is not connected to the Software Suite, the data are cached on the local storage until a connection to the Software Suite is established. Other plate information is saved on the local storage of the device as temporary data.

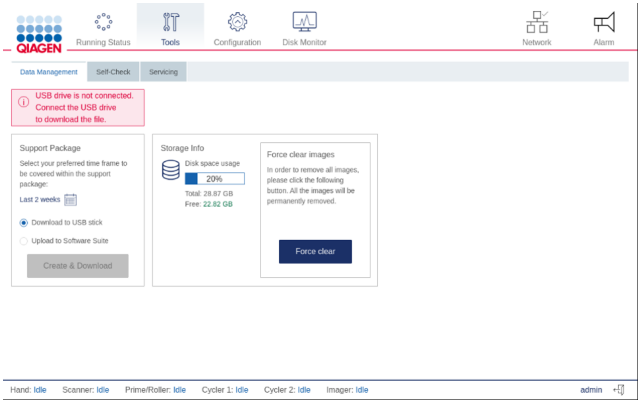
Deleting temporary data

You can remove temporary data from the instrument to save space on the local storage or to clear some space on the disk when the disk space becomes full. The current state of available storage is shown in the Storage Info pane and the below **Disk Monitor** icon (once clicked).

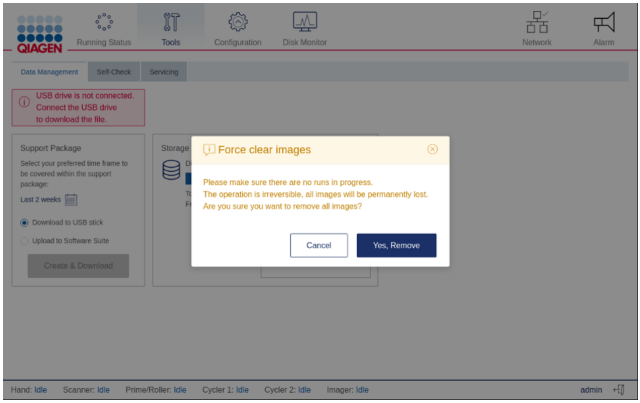
When the disk space is running low, a notification is shown to all users. Operators do not have permission to delete the temporary files, and they are instructed to contact their administrator.

1. Tap the **Tools** icon.

2. Tap **Data Management**.

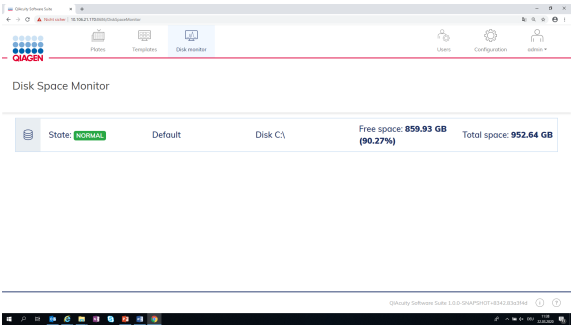


3. To clear the data, tap **Force clear images**. Click **OK** in the confirmation dialog box to delete the data. Images from the system and database will be removed.



Regular maintenance procedure for QIAcuity Software Suite

To monitor the space of your disk, click **Disk monitor** in the main toolbar. This shows an overview about the state of the disk, disk name, and disk path. It also shows the remaining free space and total space of your disk.



Disk monitor overview.

There are four different disk states possible regarding the availability of free space.

Table 9. Disk status

State	Meaning	Flag
Normal	No threshold has been reached.	None
Warning	Disk space reached the warning level, there is only disk space for a few runs left.	Yellow dot in disk monitor icon
Critical	No disk space left to store more run data.	Red dot in disk monitor icon
Unavailable	The disk is not available.	None

To free up disk space, user can export and delete used plates.

Note: It is recommended to check the free disk space on a regular manner and to archive or delete data appropriately.

Troubleshooting

General information

This section provides information about what to do if an error occurs while using the QIAcuity.

Contacting QIAGEN Technical Services

Whenever a QIAcuity error is encountered, ensure to have the following information at hand:

1. Software version
2. Sample input material
3. Detailed description of the error situation
4. Serial number of the instrument

This information will help you and your QIAGEN Technical Service Specialist to deal most efficiently with your issue.

Note: For most cases, to allow proper analysis of an error situation, the support package either from the instrument and/or the Software Suite is required.

Note: Information about the latest software and protocol versions can be found at **www.qiagen.com/QIAcuity**. In some cases, updates may be available for addressing specific problems.

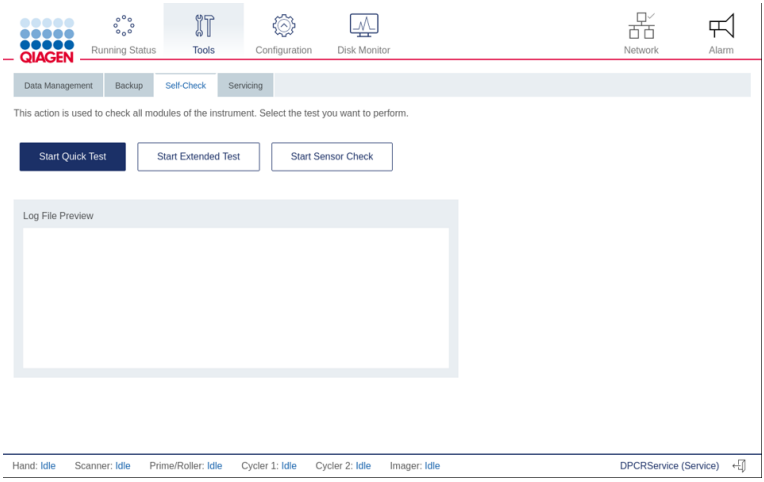
Performing a self-check on the QIAcuity instrument

The QIAcuity software can perform a self-check of the instrument to check the state of the device. There are two types of self-checks:

1. **Quick test**: This test does not include any hardware movement
2. **Extended test**: This test includes hardware movement. All modules return to their initial positions. If a plate is detected in the gripper, the plate is returned to the drawer.

To start a self-check, follow these steps:

1. Tap **Tools** .
2. Tap **Self-check**.
3. Tap **Quick Test** or **Extended Test** depending on the type of test you want to perform.
4. The instrument starts the test. The ongoing actions and their statuses are shown in the Log File Preview pane. The log from the test can be downloaded as part of a support package.



Troubleshooting the instrument and software

	Comments and suggestions
Installation and maintenance	
1. Instrument does not power on	Check if the power outlet is working properly and the correct voltage is applied. Check the correct connection of the power cable between power outlet and instrument power inlet. If the instrument fuses are blown, contact QIAGEN Technical Services.
2. Handler blocked	If the hand cannot move freely during initialization of the instrument, check if the transport locking screw was removed according to the installation procedure.
3. Overheating	If an overheating error is shown or the instrument shuts off during an operation, ensure correct ventilation of the instrument and correct environmental conditions according the installation section requirements. Ensure that the air filter is not clogged and exchanged on a regular basis.
Plate loading	
1. Plate presence/orientation	The instrument detects the proper orientation of the plate. Ensure that the barcode is pointed to the instrument back and the microstructures to the bottom.
2. Plate Seal presence	A missing Plate Seal is detected by the instrument. Ensure that always a closed plate with Plate Seal is loaded into the instrument. A run cannot be started if a plate seal is not detected by the instrument. Only use QIAGEN products for closing the plates.
3. Drawer blocking	If the drawer is retrieved and blocked, ensure that the plate is correctly loaded into the drawer and parallel to the base surface of the drawer.
4. Plate retrieving	If a plate could not be retrieved correctly in the instrument, ensure that the Plate Seal is applied properly and not overlapping more than 1 mm at the plate side surfaces. Check for any typographical error in the plate barcode of the experiment in the QIAcuity Software Suite.
5. Run cannot start	Check if the QIAcuity Software Suite is online.
Mechanical	
Frame of instrument is distorted (e.g., uneven, unstable or not level)	Ensure that the instrument is placed on a stable, flat and level surface as described in “Installing the QIAcuity” section.

	Comments and suggestions
Electronic	
1. Display does not turn on	Do not touch the display with excessive force or use corrosive chemicals to clean the display surface. Contact QIAGEN Technical Services for repair.
2. Error when copying files to USB	Power OFF the QIAcuity, wait for a few minutes, and power it ON again. Save the file (s) to the USB stick again. Check the USB stick on a PC to ensure it is functional. If the error persists, contact QIAGEN Technical Services.
3. USB device not detected	Power OFF the QIAcuity, wait for a few minutes, and power it ON again. Insert the USB stick into the USB port. Check the USB stick on a PC to ensure it is functional. If the error persists, contact QIAGEN Technical Services.
4. Login screen not visible when starting instrument	If the touchscreen does not display the login screen, but instead a software update message is shown, power OFF the QIAcuity and wait for a few minutes. Ensure that the USB stick is not inserted in the USB port. Power ON the QIAcuity again. The login screen should be visible. If the error persists, contact QIAGEN Technical Services.
5. Starting of instrument takes long	After Update of the instrument software the Firmware Update might be run in the background causing a long starting period (up to 60 min).
Application	
1. Images or analysis data cannot be viewed	Check the connection to the QIAcuity instrument.
2. Poor or no amplification	Check if the correct protocols and reagents have been used. Check if the reaction was set up correctly. Check the cycling and imaging conditions. Check if correct restriction enzyme was used when using gDNA as template material. Check the starting quality and quantity of the template. We recommend that you use QIAGEN kits for sample preparation.
3. No clear separation between positive and negative partitions	Check if the correct protocols and reagents have been used. Check if the reaction was set up correctly. Check the cycling and imaging conditions. Check if correct restriction enzyme was used when using gDNA as template material. Check the starting quality and quantity of the template. We recommend that you use QIAGEN kits for sample preparation.

		Comments and suggestions
4.	Images are saturated	Re-image the plate with 30% lower exposure duration (see also section Image quality control)
5.	Sample result is 0 copies/µL or infinite in absolute quantification	If your concentration is 0 copies/µL, although the sample is not an NTC, check the Histogram or 1D Scatterplot for this well. In case of having nearly only positive partitions in the well, a proper auto-threshold setting was likely not possible. Check also if the image of the well is too dark, and in case re-image the plate with 30% higher exposure time or gain settings.
6.	Sample results of replicates differ a lot	Check the images for blacked-out areas, that can occur, e.g., due to bad filling or areas of low amplification.
7.	High copy number in NTC	Check the images or signal map for dust or other particles. In case, wipe the plate with a lint-free tissue (optionally, use ethanol) and re-image the plate.
8.	Lower RFU of negative partitions in NTC/samples with low number of positive partitions	The signal intensity might be lower in images with high number of negative partitions. There is no influence on the result analysis, as the signal to noise is not affected.
9.	The confidence interval is wide	The number of valid partitions is low. Check the images for blacked-out areas that can occur, e.g., due to bad filling or areas of low amplification.
10.	Vertical stripes in the images	Re-image the plate for proper image analysis.
11.	Double positive or double negative signals	The double positive or double negative signals could have different root causes. One of the reasons for observing double signal bands could be suboptimal assay designs, such as cross-hybridization of probes to unspecific targets or secondary off-target amplification products. Besides assays-related causes, improper cross talk compensation could also be the root cause. An insufficient compensation or overcompensation of cross talk from neighboring channels could also result in extra signal bands. To determine the main root cause, re-image the plate with 30% less exposure times for affected channel. If double bands disappear or get much closer to each other after re-imaging, they are most likely to be caused by improper cross talk compensation rather than assay-related issues.
12.	Fetch error while accessing the Users list in User Management	If such error occurs, contact QIAGEN Technical Service to solve the issue.

		Comments and suggestions
Software		
1.	The QIAcuity Software Suite does not start	Check that the software is installed on the laptop. Check the operating system. The QIAcuity Software Suite can only be operated and Windows 10.
2.	Installation of QIAcuity Software Suite failed	Check the firewall settings on Windows and router to make sure that the following ports: 8080, 8687, 9595, 44321 are available and opened in the network.
3.	User cannot create new plate after rollback	During rollback Suite should be closed – if user forgot to close it then relog after rollback is needed
4.	Disc space is critical in the QIAcuity Software Suite	Delete plates from the plates overview.
5.	User forgot password	Administrator to log-in, change the password for the user. If administrator forgot the password, contact QIAGEN Technical Service.
6.	Communication error between QIAcuity instrument and software	This error occurs when the data received from the instrument does not conform to the expected pattern. Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument. Contact your distributor or QIAGEN Technical Service.
7.	Instrument software or Software Suite is unresponsive	Re-start the QIAcuity instrument or the notebook where the QIAcuity Software Suite is installed
8.	Startup of instruments displays an error	The required plate recovery task cannot be performed because there are no plate slots available in the tray. Remove all loaded plates before you proceed. Press **Restart** to start recovery.
9.	Error 205 or Error 32	The error can occur in different situations: (A) Make sure that the selected Plate type corresponds with the entered barcode, if manually entered. If not matching, it will lead to an error on the instrument (error 205). (B) Make sure that after the first successful suite connection, the instrument is restarted to allow automatic synchronization of labware files.
10.	Error 490	The error can occur after a plate was processed and a failure in image transfer to the Suite was detected. The Suite rejected a data package due to improper format. See if all images are available in the Suite. If you find images missing, add an additional imaging step to recover the data.

		Comments and suggestions
11.	Unidentified error occurs during upgrade	Check the log file for following entries: “Backup failed: Backup fail: There is not enough disk space for backup” or “Data size: x MB, free disk space: x MB”
13.	Error 300 during startup of instrument	The Thermocycle requires a minimum ambient temperature inside the instrument of 17°C. Thus, the Error 300 might occur in locations, where room temperature could sink below 17°C. If the Error 300 is raised during start up, when the instrument has been shut down for a longer period, a warm-up phase is required. Turn on the instrument for 30–60 min. After this time clear the Error and restart. The instrument should start without an Error. If the Error persists, contact QIAGEN Technical Services.
14.	Error 33	The error can occur if the instrument was shut down with plates loaded to all plate slots or an error occurred in a fully loaded instrument. During startup, the instrument starts a recovery sequence requiring a free slot in the drawer. Therefore, Error 33 is raised and asks you to unload at least 1 slot, clear the error, and restart.
15.	Empty running screen and CSW version 0.0.0.0 and no connection with Network and Software Suite	The error can occur very rarely after clearing errors and can be solved by restarting the instrument.
16.	Error 177	This error can occur when the teaching for the Hand was not performed properly and can occur for following modules: Drawer, Primer, and Thermocycler. Automatic positioning is implemented to prevent system from throwing the error, yet if it happens, the error needs to be cleared manually via **Tools** > **System status** > **Clear errors**. If the error keeps appearing, Hand teaching needs to performed by the FSE team member.

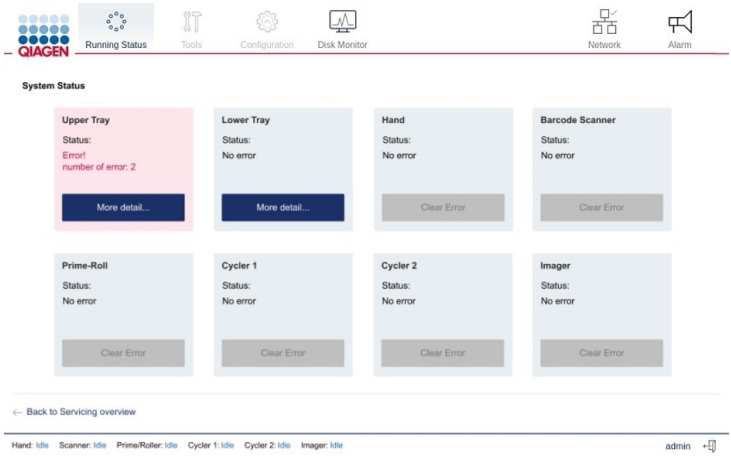
Accessing the system status and clearing errors

Note: Only administrators can access the instrument status.

The QIAcuity allows you to see the status of each of its modules. This is especially useful when a hardware error occurs. Details about errors that occurred on the instrument are shown in the **System Status** section. After viewing the information, administrators can clear errors and restart the instrument to initialize all the modules.

To access the System Status environment and clear errors, follows the steps below.

1. On the toolbar, tap **Tools**.
2. Tap **Servicing**.
3. In the Servicing tab, tap **System Status**.

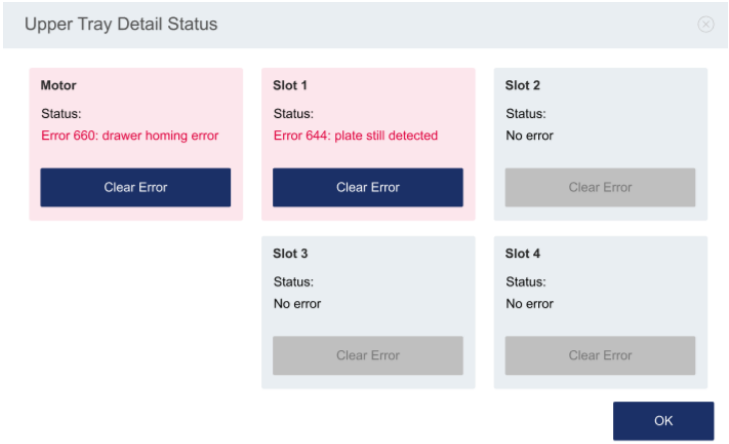


System status environment on the QIAcuity Eight after an error occurs.

4. To clear an error, tap **Clear error**.

5. If the error that occurred affects the tray(s), tap **More details**. To clear a tray-related error, tap **Clear error** in the dialog. The dialog box contains five items that can be cleared for each tray, such as motor and slot numbers (based on the instrument version).

   Note: In QIAcuity Eight, the **More details** button is located in the Upper Tray and Lower Tray panes. In the QIAcuity Four and QIAcuity One, the **More details** button is located in the Tray pane.



6. Restart the instrument. The instrument initializes and all modules are returned to their home positions.

   Note: If the affected module is not working after you cleared the error and restarted the instrument, contact QIAGEN Technical Services.

Technical Specifications

QIAGEN reserves the right to change specifications at any time.

Operating conditions

Power	100–240 V AC, 50/60 Hz, Mains supply voltage fluctuations are not to exceed 10% of nominal supply voltages. Maximum power consumption: QIAcuity One, 2plex: 1000 VA QIAcuity Four: 1000 VA QIAcuity Eight: 1500 VA
Fuse	2x T12A L 250 V
Overvoltage category	II
Air temperature	15–32°C (59.0–89.6°F)
Relative humidity	10–75% (non-condensing)
Altitude	Up to 2000 m (6500 ft.)
Place of operation	For indoor use only
Pollution level	2
Environmental class	3K21 (IEC 60721-3-3)

Transport conditions

Air temperature	–25°C to 60°C (–13°F to 140°F) in manufacturer's package
Relative humidity	5% to 85% (non-condensing)
Environmental class	2K11 & 2M4 (IEC 60721-3-2)
Ambient pressure	700 to 1060 hPa

Storage conditions

Air temperature	5°C to 40°C (41°F to 104°F) in manufacturer's package
Relative humidity	5% to 85% (non-condensing)
Environmental class	1K21 (IEC 60721-3-1)
Ambient pressure	700 to 1060 hPa

Mechanical data and hardware features

Dimensions Four/Eight	Width: 60 cm (23.6 in.) Height: 58 cm (22.8 in.) Depth: 65 cm (25.6 in.)
Dimensions One	Width: 38 cm (15.0 in.) Height: 45 cm (17.7 in.) Depth: 65 cm (25.6 in.)
Mass	QIAcuity One: 36.0 kg (79.4 lb.) QIAcuity Four: 43.0 kg (94.8 lb.) QIAcuity Eight: 55.0 kg (121.3 lb.) Accessories: 3.0 kg (6.6 lb.)
Thermal specifications	Process temperature: 35°C to 99°C Ramp rate: approx. 3.0°C/s Accuracy: ±1°C Homogeneity (over plate surface): ±1°C The QIAcuity Eight features two Thermocyclers that are operated in parallel

Optical specifications

The 2-plex version features the channels Green and Yellow and the 5-plex version all following channels:

Channel	Green	Yellow	Orange	Red	Crimson	Far red
Excitation in nm	463–503	513–534	541–563	568–594	588–638	651–690
Emission in nm	519–549	551–565	582–608	613–655	656–694	709–759

Excitation by high power white LED with average 4750 lumens

Image acquisition by CMOS camera with 6.3 MP

Capacity	Up to 96 samples per plate. Maximum plate capacity depends on the configuration (One, Four, Eight)
Touchscreen (Four/Eight)	10.1" LCD Touch, active area 218.0 x 136.6 mm, resolution 1280*800 HD
Touchscreen (One)	7.0" LCD Touch, active area 150.4 x 94.2 mm, resolution 1280*800 HD
Acoustic emission	QIAcuity One: Max. 57.4 dB (A) QIAcuity Four/Eight: Max. 54.6 dB (A)
USB drive	USB2.0 8GB Compatible OS: Windows 7 or later; Mac OS X 10.1 or later Operating temperature range: 0 to 35°C Operating humidity range: 10 to 90% (with no condensation) Storage temperature range: –20°C to 60°C (–4°F) to 140°F) Storage humidity range: 10 to 90% (with no condensation) Formatting: FAT32
Handheld scanner (optional)	Scan Pattern: Area Image (1280 x 80 pixel array) Motion Tolerance: Up to 89 cm/s (35 in/s) Print Contrast Ratio: 15% (minimum) Decode Capability: Reads standard 1D, 2D, Postal and stacked codes Resolution: 1D Linear: 0.102 mm/4 mils; PDF417: 0.127 mm/5 mils; Data Matrix: 0.195 mm/7.5 mils

Glossary

Glossary terms are listed in alphabetical order.

Term	Description
Acquisition	The collection of fluorescent data at the end of the run
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 the camera.
Confidence Interval	Indicates the range of values that is likely to contain the true parameter value
dPCR parameters	Parameters specifying a PCR run (e.g., number of cycles, temperature, acquisitions, etc.)
Environment	The QIAcuity Software Suite consists of several environments (e.g., "Plates", "Templates", "Analysis", "Report"). In these environments, certain tasks can be performed, such as setting up a run or analyze data.
Error code	A 3- or 4-digit number that indicates an error of the QIAcuity
Exposure duration	The length of time the samples are exposed to light during the florescence acquisition
Gain	A setting to amplify the fluorescence signal 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.
GUI	Graphical user interface
Initialization	An operation performed automatically when the QIAcuity is switched on or by initiating a self-check of the instrument, if required
Nanoplate	dPCR plate with several single partitions
Optical configuration	The optical configuration of a QIAcuity instrument is described by the available channels to detect fluorescence signals. The optical configuration differs between different types of the QIAcuity instruments.
Partition	Compartment in the Nanoplate where the PCR reaction takes place
Plate seal	Foil to be applied on top of the plate to prevent evaporation and contamination

Term	Description
Power switch	A button located at the front of the QIAcuity in the bottom-right corner It allows the user to switch the QIAcuity on and off; inner position is ON and outer position is OFF.
Priming	Filling of the partitions with the reaction volume
Rolling	Separation of the single partitions filled with the reaction volume
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
Touchscreen	The user interface that allows the user to operate the QIAcuity
VPF	Volume Precision Factor. The VPF specifies the exact cycled volume of a well within a Nanoplate and therefore further increases precision of concentration calculation in each well.

Appendix A – Legal

Declaration of conformity

Name and address of the legal manufacturer:

QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Germany

An up-to-date declaration of conformity can be requested from QIAGEN Technical Services.

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.

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.

California Proposition 65

WARNING

Using this product can expose you to chemicals including lead acetate, which is known to the state of California to cause cancer and DEHP, which is known to the State of California to cause birth defects and/or other reproductive harm. For more information, go to **www.P65Warnings.ca.gov**

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 — QIAcuity Accessories

For more information and an up-to-date list of available protocols, visit **www.qiagen.com**

Ordering information

Product	Contents	Cat. no.
QIAcuity One, 2plex Platform System FUL-13F*	One-plate digital PCR instrument for detecting up to 2 fluorescent dyes, notebook computer, Nanoplate Roller, USB flash memory, and QIAcuity Software Suite: includes installation, training, full agreement for 1 year with a 2 business day response time, and 1 preventive maintenance visit	911015
QIAcuity One, 5plex Platform System FUL-1*	One-plate digital PCR instrument for detecting up to 2 fluorescent dyes, notebook computer, Nanoplate Roller, USB flash memory, and QIAcuity Software Suite: includes installation, training, full agreement for 1 year with a 2 business day response time, and 1 preventive maintenance visit	911035
QIAcuity Four Platform System FUL-1*†	Four-plate digital PCR instrument for detecting up to 8 fluorescent dyes, notebook computer, barcode scanner, Nanoplate Roller, USB flash memory, and QIAcuity Software Suite; Includes installation, training, full agreement for 1 year with a 2 business day response time, and 1 preventive maintenance visit	911045
QIAcuity Eight Platform System FUL-1*†	Eight-plate digital PCR instrument for detecting up to 8 fluorescent dyes, notebook computer, barcode scanner, Nanoplate Roller, USB flash memory, and QIAcuity Software Suite: includes installation, training, full agreement for 1 year with a 2-business day response time, and 1 preventive maintenance visit	911055

Product	Contents	Cat. no.
QIAcuity, IQ/OQ product	Installation Qualification and Operational Qualification of QIAcuity provides documented verification that the instrument has been properly installed, and is operating according to the manufacturer's specifications. IQ/OQ Service is an on-site qualification service provided by a certified QIAGEN Service Specialist. This includes labor and travel	9245414
Barcode Hand Scanner, QIAcuity	Separate 2D barcode scanner for reading of QIAcuity Nanoplate IDs outside of the QIAcuity instrument	911106
Roller, QIAcuity	Nanoplate Roller for fixing the Nanoplate seal on QIAcuity Nanoplates	911105
Air Filter, QIAcuity One (1)	Replacement air inlet filter for QIAcuity One	9026699
Air Filter, QIAcuity Four/Eight (1)	Replacement air inlet filter for QIAcuity Four and QIAcuity Eight	9026700
QIAcuity Nanoplate 26k 24-well (10)	24-well dPCR Nanoplate with 26K partitions and 40 µL reaction volume per well, including Nanoplate seals	250001
QIAcuity Nanoplate 8.5k 24-well (10)	24-well dPCR Nanoplate with 8.5K partitions and 12 µL reaction volume per well, including Nanoplate seals	250011
QIAcuity Nanoplate 8.5k 96-well (10)	96-well dPCR Nanoplate with 8.5K partitions and 12 µL reaction volume per well, including Nanoplate seals	250021
QIAcuity Nanoplate 26k 8-well (10)	8-well dPCR Nanoplate with 26K partitions and 40 µL reaction volume per well, including Nanoplate seals	250031
Nanoplate Seals (11)	Nanoplate seal for sealing QIAcuity Nanoplates	250099
Nanoplate Tray (2)	Nanoplate Tray improving plate-handling during pipetting or carrying	250098

Product	Contents	Cat. no.
QIAcuity Probe PCR Kit (1 mL)	1 mL 4x concentrated QIAcuity Probe Mastermix, 2 x 1.9 mL Water	250101
QIAcuity Probe PCR Kit (5 mL)	5 x 1 mL 4x concentrated QIAcuity Probe Mastermix, 8 x 1.9 mL Water	250102
QIAcuity Probe PCR Kit (25 mL)	5 x 5 mL 4x concentrated QIAcuity Probe Mastermix, 4 x 20 mL Water	250103
QIAcuity EG PCR Kit (1 mL)	1 mL 3x concentrated QIAcuity EvaGreen Mastermix, 2 x 1.9 mL Water	250111
QIAcuity EG PCR Kit (5 mL)	5 x 1 mL 3x concentrated QIAcuity EvaGreen Mastermix, 8 x 1.9 mL Water	250112
QIAcuity EG PCR Kit (25 mL)	5 x 5 mL 3x concentrated QIAcuity EvaGreen Mastermix, 4 x 20 mL Water	250113

* Additional instrument and Service bundles are available.

† For all systems, Installation and Training is included but are additionally available as separate service offerings. For specific catalog numbers and additional information, visit **www.qiagen.com** or contact your local sales representative.

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** or can be requested from QIAGEN Technical Services or your local distributor.

Document Revision History

Revision	Description
April 2021	Initial release
July 2021	Removed reference to German and French translations of Safety Information section
May 2025	Content adjusted to Software Release 3.1

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