QIAcuity Safety Information and Installation Guide
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</tr>
</tbody>
</table>
Introduction

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, please 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 the policy of QIAGEN 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 guide. Please contact QIAGEN Technical Services.
About this guide

This safety and installation guide provides information about QIAcuity in the following sections:

- Intended use
- Safety Information
- General description
- QIAcuity Installation
- QIAcuity Software Suite Installation
- Connecting the QIAcuity Software Suite to the QIAcuity instrument
- Maintenance Procedures
- Troubleshooting
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 in 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 positive partitions. As the template is distributed randomly, Poisson statistics can be used to calculate the amount of target DNA per positive 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 positive partitions. Calculation of target concentration is determined by referring back to the volume in all analyzable partitions, i.e. partitions which were filled with reactions 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 such as QIAcuity Nanoplates and QIAcuity PCR Reagents for the applications described in the kit handbooks.

If the 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 combination 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. Competence level and training required for QIAcuity users**

<table>
<thead>
<tr>
<th>Task</th>
<th>Personnel</th>
<th>Training and experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery</td>
<td>No special requirements</td>
<td>No special requirements</td>
</tr>
<tr>
<td>Installation</td>
<td>Laboratory technicians or equivalent</td>
<td>Appropriately trained or experienced personnel familiar with use of computers and automation in general</td>
</tr>
<tr>
<td>Routine use (running protocols)</td>
<td>Laboratory technicians or equivalent</td>
<td>Appropriately trained or experienced personnel with use of computers and automation in general</td>
</tr>
<tr>
<td>Assay design and validation</td>
<td>Scientist or equivalent</td>
<td>Appropriately trained or experienced personnel familiar with molecular biological techniques</td>
</tr>
<tr>
<td>Dust filter replacement</td>
<td>Laboratory technicians or equivalent</td>
<td>Appropriately trained or experienced personnel familiar with use of computers and automation in general</td>
</tr>
<tr>
<td>Preventive maintenance</td>
<td>QIAGEN service personnel or service technicians of an authorized agent</td>
<td>Trained and authorized by QIAGEN</td>
</tr>
<tr>
<td>Servicing</td>
<td>QIAGEN service personnel or service technicians of an authorized agent</td>
<td>Trained and authorized by QIAGEN</td>
</tr>
</tbody>
</table>
Safety Information to Prevent Misuse and Personal and Material Damage

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 other persons. Details about these circumstances are given in a box like this one. |
| CAUTION | The term CAUTION is used to inform you about situations that could result in **damage to the instrument** or other equipment. Details about these circumstances are given in a box like this one. |

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

Proper use

| WARNING | **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. |

[W1]
Perform the maintenance as described in the Maintenance Procedures section. QIAGEN charges for repairs that are required due to incorrect maintenance.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of personal injury and material damage [W2]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of personal injury and material damage [W3]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not attempt to move the QIAcuity during operation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Damage to the instrument [C1]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Avoid spilling water or chemicals onto the QIAcuity. Damage caused by water or chemical spillage will void your warranty.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Damage to the instrument [C2]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Damage to the instrument [C3]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not drop objects into the instrument when the plate tray is ejected.</td>
</tr>
<tr>
<td><strong>WARNING</strong></td>
<td><strong>Risk of explosion</strong></td>
</tr>
<tr>
<td>-------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>![Warning Icon]</td>
<td>The QIAcuity is intended for use with reagents and substances supplied with QIAGEN kits or other than outlined in respective Instructions for Use. Use of other reagents and substances may lead to fire or explosion.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CAUTION</strong></th>
<th><strong>Damage to the instrument</strong></th>
<th>[C4]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Caution Icon]</td>
<td>Do not stack instruments and do not place items on top of the QIAcuity.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CAUTION</strong></th>
<th><strong>Damage to the instrument</strong></th>
<th>[C5]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Caution Icon]</td>
<td>Do not lean against the touchscreen when it is pulled out.</td>
<td></td>
</tr>
</tbody>
</table>
**Electrical safety**

**Note:** Disconnect the line power cord from the power outlet before servicing.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Electrical hazard</th>
<th>[W8]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warning Icon]</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intentional interruption is prohibited.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Lethal voltages inside the instrument</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Damage to electronics</th>
<th>[W9]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warning Icon]</td>
<td>Before powering ON the instrument, make sure that the correct supply voltage is used.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use of incorrect supply voltage may damage the electronics.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of electric shock</th>
<th>[W10]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warning Icon]</td>
<td>Do not open any panels on the QIAcuity.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Risk of personal injury and material damage</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Only perform maintenance that is specifically described in this user manual.</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Explosive atmosphere [W11]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The QIAcuity is not designed for use in an explosive atmosphere.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Damage to the instrument [C6]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.</td>
</tr>
<tr>
<td></td>
<td>The QIAcuity must be located out of direct sunlight.</td>
</tr>
</tbody>
</table>
**CAUTION**

**Risk of overheating** [C7]

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](http://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  

Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.

Always wear safety glasses, 2 pairs of gloves, and a lab coat.

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

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

---

**Chemicals**

---

**WARNING**

Hazardous chemicals  

Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run.

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

The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Safety Data Sheets (SDSs) or OSHA*, ACGIH†, or COSHH‡ documents.

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

---

* OSHA : Occupational Safety and Health Administration (United States of America).
† ACGIH : American Conference of Government Industrial Hygienists (United States of America).
‡ COSHH : Control of Substances Hazardous to Health (United Kingdom).
### Maintenance safety

<table>
<thead>
<tr>
<th>WARNING/CAUTION</th>
<th>Risk of personal injury and material damage [W14]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Only perform maintenance that is specifically described in this user manual.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of fire [W15]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not allow cleaning fluid or decontamination agents to come into contact with the electrical parts of the QIAcuity.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Damage to the instrument [C8]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the QIAcuity.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Damage to the instrument [C9]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the QIAcuity.</td>
</tr>
</tbody>
</table>

### Radiation safety

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of personal injury [W16]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hazard Level 2 laser light: Do not stare into the light beam when using handheld bar code scanner.</td>
</tr>
</tbody>
</table>
### Symbols on the QIAcuity

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Location</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="CE" /></td>
<td>Type plate on the back of the instrument</td>
<td>CE mark for European Conformity</td>
</tr>
<tr>
<td><img src="image" alt="CSA" /></td>
<td>Type plate at the back of the instrument</td>
<td>CSA listing mark for Canada and the USA</td>
</tr>
<tr>
<td><img src="image" alt="RCM" /></td>
<td>Type plate on the back of the instrument</td>
<td>RCM mark for Australia and New Zealand</td>
</tr>
<tr>
<td><img src="image" alt="RoHS" /></td>
<td>Type plate on the back of the instrument</td>
<td>RoHS mark for China (the restriction of the use of certain hazardous substances in electrical and electronic equipment)</td>
</tr>
<tr>
<td><img src="image" alt="WEEE" /></td>
<td>Type plate on the back of the instrument</td>
<td>Waste Electrical and Electronic Equipment (WEEE) mark for Europe</td>
</tr>
<tr>
<td><img src="image" alt="Legal" /></td>
<td>Type plate on the back of the instrument</td>
<td>Legal manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Instructions" /></td>
<td>Type plate on the back of the instrument</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="image" alt="Safety" /></td>
<td>Type plate on the back of the instrument</td>
<td>See chapter Safety Information for risks</td>
</tr>
<tr>
<td><img src="image" alt="Date" /></td>
<td>Type plate on the back of the instrument</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Biohazard" /></td>
<td>On the drawer</td>
<td>Biological hazard – some samples used with this instrument may contain infectious agents and must be handled with gloves.</td>
</tr>
</tbody>
</table>
General Description

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 24 or 96 samples per plate can be analyzed. For high sensitivity applications, the QIAcuity Nanoplate 26K 24-well is available. The number of in parallel processable plates depends on the instrument configuration. The QIAcuity controls all integrated modules, including a robotic gripper for plate handling, a partitioning module, a PCR thermocycler, and a fluorescence imaging module. For more information, refer to the QIAcuity User Manual on www.qiagen.com.

Figure 1. QIAcuity Four.
QIAGEN offers different instrument configurations. QIAcuity One as 2-plex and 5-plex version. QIAcuity Four and QIAcuity Eight always offer 5-plex analysis. This table shows the available channels provided in each instrument.

**Table 2. QIAcuity instrument configurations**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Available channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>QIAcuity One, 2-plex</td>
<td>Green, Yellow</td>
</tr>
<tr>
<td>QIAcuity One, 5-plex</td>
<td>Green, Yellow, Orange, Red, Crimson</td>
</tr>
<tr>
<td>QIAcuity Four</td>
<td>Green, Yellow, Orange, Red, Crimson</td>
</tr>
<tr>
<td>QIAcuity Eight</td>
<td>Green, Yellow, Orange, Red, Crimson</td>
</tr>
</tbody>
</table>
QIAcuity Installation

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.

Installation environment

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. A vibration amplitude of the lab bench of 6mm/s² shall not be exceeded. Placing a QIAgility or an orbital shaker next to the instrument does not exceed this value. Refer to Appendix A – Technical Data for the operating conditions (temperature and humidity). 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 Appendix A – Technical Data for the weight and dimensions of the QIAcuity. Allow at least 15 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 another lab equipment. Do not place the QIAcuity on a vibrating surface or near vibrating objects.

<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
<th><strong>Explosive atmosphere</strong> (W8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warning Icon]</td>
<td>The QIAcuity is not designed for use in an explosive atmosphere.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CAUTION</strong></th>
<th><strong>Risk of overheating</strong> (C7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Caution Icon]</td>
<td>To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the QIAcuity.</td>
</tr>
<tr>
<td></td>
<td>Slits and openings that ensure the ventilation of the QIAcuity must not be covered.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
<th><strong>Risk of personal injury and material damage</strong> (W2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warning Icon]</td>
<td>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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CAUTION</strong></th>
<th><strong>Damage to the instrument</strong> (C6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Caution Icon]</td>
<td>Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.</td>
</tr>
<tr>
<td></td>
<td>The QIAcuity must be located out of direct sunlight.</td>
</tr>
</tbody>
</table>
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**  
(W9)

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**  
(W5)

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 3-conductor AC power cord that, when connected to an appropriate AC power outlet, grounds (earths) the instrument. To preserve this protection feature, do not operate the instrument from an AC power outlet that has no ground (earth) connection.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Electrical hazard (W5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warning Icon]</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.
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 hood
- Removal of the shipping fixation screw
- Connection of the power cord to the back of the QIACuity
- Powering ON the QIACuity.

Removing the protective film from the QIACuity hood

Carefully peel off the protective film from the QIACuity hood and the touch screen.

Removing the shipping fixation screw

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

3. Connect the power cord to the power inlet on the instrument, and connect the cable to the wall power outlet.

4. Turn on the power switch at the back of the instrument.

---

<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
<th><strong>Damage to electronics</strong></th>
</tr>
</thead>
</table>

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.
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.
   
   The startup screen appears. The instrument automatically performs initialization tests.
   
   **Note:** The main power switch in the back must be switched on as well.

3. If there is an initialization error, retry the initialization process by turning the instrument off and on again. If the problem persists, see Troubleshooting the instrument and software or contact QIAGEN Technical Services.
   
   **Note:** The instrument must be turned off at least once a week.
QIAcuity Software Suite Installation

The QIAcuity Software Suite is designed to work with Windows 10 operating system. The following browsers are supported in the QIAcuity Software Suite:

- Mozilla Firefox (version 64.0.2 or later)
- Microsoft Edge (version 44.17763.1.0 or later)
- Google Chrome (version 71.0.3578.98 or later)

The QIAcuity Four and Eight instruments are supplied with a notebook, the QIAcuity One instrument can be optionally supplied with a notebook. See the following table for the recommended notebook requirements.

Table 3. Recommended notebook requirements

<table>
<thead>
<tr>
<th>Description</th>
<th>Recommended requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating system</td>
<td>Microsoft® Windows® 10 Professional Edition (64 bit)</td>
</tr>
<tr>
<td>Processor</td>
<td>x64 compatible processor with 4 physical cores and 2.5GHz</td>
</tr>
<tr>
<td>Main memory</td>
<td>16 GB RAM</td>
</tr>
<tr>
<td>Hard disk space</td>
<td>At least 500 GB</td>
</tr>
<tr>
<td>Graphics</td>
<td>At least 1920 x 1080 pixels</td>
</tr>
<tr>
<td>Interface</td>
<td>USB port, 1Gbps cable Ethernet</td>
</tr>
</tbody>
</table>

The QIAcuitySuite.msi package needed for the installation of the QIAcuity Software Suite is provided on the USB drive that comes with the QIAcuity. Alternatively, you can download the QIAcuitySuite.msi package from www.qiagen.com.
Installing the QIAcuity Software Suite

To install the QIAcuity Software Suite on the notebook, follow these steps:

1. Before you begin the installation process using the QIAcuity Setup Wizard, turn off the standby/hibernation settings in the Windows configuration:
   1a. Right-click the Windows start menu and select **Power Options**.
   1b. Click change plan settings next to your current power plan.
   1c. Select **Never** in the **Put the computer to sleep** field.
   1d. Click **Save changes**.
   1e. Go to **Advanced Settings > Sleep**.
   1f. Set the **Hybrid sleep** field to **Off**.
   1g. Click **Apply**.

2. Locate the **QIAcuitySoftwareSuite.exe** file and double-click it. The installation process starts. Click **Next**.
3. Check the **I accept the terms in the License Agreement** box in the End-User License Agreement window and click **Next**.
4. Click **Next** in Destination Folder window.
5. Click **Install** to start the installation.

6. In the prompt window asking you if you allow changes to your device, click **Yes**.
Note: During installation, some command line windows may appear in the foreground. Do not close any of them.
7. When the installation is completed, click **Finish**.

8. In the local host site that says the site is not secure, click **Details**.
9. Click **Go on to the webpage**.

You are directed to the QIAcuity Software Suite login screen.
For more information on upgrading or uninstalling the QIAcuity Software Suite refer to the QIAcuity user manual on www.qiagen.com

Establish a connection between the QIAcuity instrument and the QIAcuity Software Suite

The QIAcuity instrument needs to be connected to the QIAcuity Software Suite to enable the exchange of data. This also enables the QIAcuity Software Suite to set up plates, analyze results, and monitor the status of runs in real time. For this, the QIAcuity instrument and the QIAcuity Software Suite may be connected via an Ethernet cable between the QIAcuity and the notebook where the QIAcuity Software Suite is running.
Figure 2. The QIAcuity instrument and QIAcuity Software Suite are connected via Ethernet cable. Alternatively, both the QIAcuity instrument and the computer running the QIAcuity Software Suite can be connected to a LAN (local area network). This configuration allows the QIAcuity notebook or a separate computer to work as a server to which multiple clients can be connected. The QIAcuity Suite server instance and QIAcuity clients need to be connected through a network.

Figure 3. The QIAcuity instrument(s) and QIAcuity Software Suite are installed to a network, allowing multiple clients to access the QIAcuity instrument(s) via a single QIAcuity Suite server.
Configuring an Ethernet connection between the QIAcuity instrument and the QIAcuity Software Suite

To establish a connection, the instrument and the notebook must be connected to the LAN (local area network). For 10 users accessing the system in parallel, the requirement is a minimum data connection speed of 10Mbit/s for a setup via network.

**Note:** Please make sure that the QIAcuity instrument is connected to the LAN. Any other configurations are not supported by QIAGEN.

If you are unsure about your network infrastructure, please consult with your local IT.

**Note:** Only users with Administrator role can modify the network configuration. We recommend to consult your network administrator when configuring the network. For communication with QIAcuity Software Suite, the outbound TCP port 443 (https) is used. Pinging the network is also supported.

Follow the steps below to configure the notebook running the QIAcuity Software Suite.

1. Go to the **Control Panel** app.
2. Click **Network and Internet** (if not available proceed to the next step).

3. Click **Network and Sharing Center**.

4. On the left pane, click **Change adapter settings**.

5. Right-click the ethernet network adapter and select **Properties**.

7. Select **Obtain an IP address automatically**. If your organization does not provide DNS details, select **Obtain DNS server address automatically** as well. Click **OK**, then **Close**.
Optional: You can check if the addresses have been assigned properly by following the steps below.

1. From your Home screen, click the Search icon. Enter `cmd` and press the Enter key.

2. Wait for the command line window to open. Enter `ipconfig` command.

   Address should be visible under the ethernet interface name for which modifications were made.
Follow the steps below to configure the QIAcuity instrument.

1. On the toolbar, tap **Configuration**.

2. Select the Ethernet tab.
3. Check the **DHCP enabled** box. If you check this box, the IP address and MAC address fields are disabled. The assigned IP and MAC addresses of device are displayed in the **IP address** and **MAC address** fields.

4. Tap **Save**.
Configuring a direct cable connection between the QIAcuity instrument and the QIAcuity Software Suite

**Note**: Before you start, ensure that the QIAcuity instrument and the notebook are connected with an Ethernet cable.

Follow the steps below to configure the notebook running the QIAcuity Software Suite.

1. Go to the **Control Panel** app.

![Control Panel app screenshot](image)
2. Click **Network and Internet** (if not available proceed to the next step).

![Network and Internet](image)

3. Click **Network and Sharing Center**.

![Network and Sharing Center](image)  
**View network status and tasks**  
**Connect to a network**  
**View network computers and devices**

4. On the left pane, click **Change adapter settings**.

![Change adapter settings](image)

5. Right-click the ethernet network adapter and select the **Properties** option.

6. Select **Internet Protocol Version 4 (TCP/IPv4)** and click **Properties**: 
7. Select **Use the following IP address**. Enter the following information:

- **IP address**: Enter 192.168.1.1.
- **Subnet mask**: Enter 255.255.255.0.
- **Default gateway**: Enter 192.168.1.254.
- **Preferred DNS server**: Enter the DNS server address.
- **Alternative DNS server**: Enter the alternative DNS server address.

  **Note**: If the **Preferred DNS server** and **Alternative DNS server** fields are left blank, the connection is showed as unknown.

8. Click **OK**, then click **Close**.
Optional: You can check if the addresses have been assigned properly by following the steps below.

1. From your Home screen, click the Search icon. Enter `cmd` and press the `Enter` key.
2. Wait for the command line window to open. Enter `ipconfig`.
   Address should be visible under the ethernet interface name for which modifications were made.
Follow the steps below to configure the QIAcuity instrument.

1. On the toolbar, tap **Configuration**.

2. Select the Ethernet tab.

3. Ensure that the DHCP enabled box is not checked. Enter the following information:
   - **IP address**: Enter 192.168.1.2.
   - **Subnet mask**: Enter 255.255.255.0.
   - **Gateway**: Enter 192.168.1.1.
4. Tap **Save**.

Configuring the connection to the QIAcuity Software Suite in the QIAcuity instrument software

The QIAcuity instrument needs to be connected to the QIAcuity Software Suite to enable the exchange of data. To establish a connection, the instrument and the device in which the QIAcuity Software Suite is running must be connected to the same network.

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

To connect the instrument to the QIAcuity Software Suite:

1. The Network Icon represents the connection between the QIAcuity Software Suite and the Instrument. When the icon is red, the connection is not established.
2. On the Home screen, tap **Configuration**.

3. Tap the Software Suite tab.
4. Enter the URL in the **Software Suite URL** field. The Suite URL has the following format:

   https://<IP address of Suite Server>:8687/instrument/v0/

**Note**: To get the IP address of the Suite Server, the instrument must be connected to the Suite Server. From your Home screen, click the Windows icon and navigate to **Command Prompt**, or enter `cmd` in the **Search** field. A command line window appears. Enter `ipconfig` to view the network settings.

If you do not want to configure proxy settings, ensure that the “Do not use a proxy” box is checked. Then, tap **Test** to test the connection.
Note: An error message displays if the URL you entered is invalid. Tap OK to close the error message, then re-enter the correct URL in the Software Suite URL field.
5. If you want to configure the proxy settings in your network configuration, clear the **Do not use a proxy** box and enter the following information:

- **Proxy Server**: Enter the proxy server address.
- **Proxy Port**: Enter the port address.
- **User Name**: Enter the username.
- **Password**: Enter the password.

6. Tap **Save**.
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:

- Regular maintenance
- 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:** If you want to use disinfectants different from those recommended, ensure that their compositions are similar to those described below.

**General cleaning of the QIAcuity:**

- Mild Detergents (e.g., Mikrozid® AF sensitive)
- 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 for e.g. 10 g glyoxal, 12 g lauryldimethylbenzylammonium chloride, 12 g myristyldimethylbenzylammonium chloride, and 5–15% nonionic 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, you 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

- Do not use spray bottles to spray cleaning or disinfectant liquids onto surfaces of the QIAcuity.
- If solvents or saline, acidic, or alkaline solutions are spilt on the QIAcuity, wipe the spilt liquid away immediately.
- Follow manufacturer’s safety instruction for handling cleaning agents.
- Follow 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

- 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.
<table>
<thead>
<tr>
<th><strong>CAUTION</strong></th>
<th><strong>Damage to the instrument</strong></th>
<th>[C10]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean QIAcuity.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CAUTION</strong></th>
<th><strong>Damage to the instrument</strong></th>
<th>[C11]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
<th><strong>Risk of fire</strong></th>
<th>[W24]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
<th><strong>Risk of electric shock</strong></th>
<th>[W24]</th>
</tr>
</thead>
</table>
|  | Do not open any panels on the QIAcuity.  
**Risk or personal injury and material damage**  
Only perform maintenance that is specifically described in this user manual. |  |

<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
<th><strong>Hazardous chemicals and infectious agents</strong></th>
<th>[W24]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The plates may contain hazardous material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.</td>
<td></td>
</tr>
</tbody>
</table>
**WARNING**

**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.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of personal injury and material damage</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warning Icon]</td>
<td>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.</td>
</tr>
</tbody>
</table>

Regular maintenance procedure of QIAcuity

Clean the instrument on a regular basis, especially if fluids have been spilled on the instrument. See Cleaning agents for the recommended cleaning agents you can use 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 that you change 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.
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. 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 spilt 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, please contact QIAGEN Technical Services.

The QIAcuity should also be decontaminated before shipping (e.g., back to QIAGEN). 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 section Disinfection, 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 is 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.
Note: Only administrators can delete data from the instrument.

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 Space Monitor](image)

**Figure 4. Disk monitor overview.**

There are four different disk states possible regarding the availability of free space.
### Table 4. Disk status

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

To free up disk space, you can export and delete used plates. Refer to QIAcuity User Manual for more information about exporting and deleting plates.
Troubleshooting

General information

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

Contacting QIAGEN Technical Services

Whenever you encounter a QIAcuity error, ensure that you have the following information at hand:

- Software version
- Sample input material
- Detailed description of the error situation
- 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 suite is required. For more information about support packages, see Creating a support package.

**Note:** Information about the latest software and protocol versions can be found at [www.qiagen.com/MyQIAcuity](http://www.qiagen.com/MyQIAcuity). 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:

- **Quick test**: This test does not include any hardware movement
- **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.

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. For more information about support package, see Creating a support package.
Creating a support package

Creating a support package with the QIAcuity instrument software

You can create a support package in case of an error. The support package can be uploaded to the Software Suite or saved to a USB drive.

To create a support package and upload it to the Software Suite, follow the steps below. The QIAcuity Software Suite will combine the support package from the instrument and the Software Suite.

1. On the toolbar, tap **Tools**.
2. Tap **Data Management**.

![Data Management screen](image)

3. In the Support package pane, select **Upload to Software Suite**.
4. To set the timeframe of the support package, tap **Set timeframe**. The default timeframe is the last two weeks.
5. Tap the applicable option for your preferred timeframe.
- Tap **Today** to create a support package for the current day.
- Tap **Last week** or **Last 2 weeks** to select either the last week or the last two weeks.
- To set a custom timeframe, tap **From** and select a start date from the calendar. Then, tap **To** and select an end date from the calendar.

6. Tap **Apply** to save the changes.

![Set Support Package Timeframe](image)

**Figure 5. Set Support Package Timeframe dialog box.**

7. Tap **Create download**.

A progress bar is shown. To cancel the download, tap the progress bar. Once the download is complete, a notification is displayed.
To create a support package and save it on a USB drive, follow the steps below.

1. On the toolbar, tap **Tools**.
2. Tap **Data Management**.
3. Connect a USB drive to the instrument. Wait for the device to detect the USB drive. A notification is displayed once the drive is connected.
4. In the Support Package pane, Select Download to USB drive.

5. To set the timeframe of the support package, tap Set timeframe. The default timeframe is the last two weeks.

6. Tap the applicable option for your preferred timeframe.
   - Tap Today to create a support package for the current day.
   - Tap Last week or Last 2 weeks to select either the last week or the last two weeks.
   - To set a custom timeframe, tap From and select a start date from the calendar. Then, tap To and select an end date from the calendar.

7. Tap Apply to save the changes.
8. Tap **Create download**.

A progress bar is shown. To cancel the download, tap the progress bar. Once the download is complete, a notification is displayed, and the USB drive can be removed from the instrument.
Creating a support package with the QIAcuity Software Suite

1. Select a plate in the plate overview.

2. Click the left side of the screen on Support Package.
   
   A new window pops up, where you can specify what kind of support package you want to generate and from which time frame.
Note: The standard package includes the log files and a combined image view of all wells. The extended package includes the log files and the raw images of each single well. By clicking on the calendar symbol, you can define the time frame from which the support package shall be generated. Click **Download** to download the support package as zip file.
## Troubleshooting the instrument and software

### Comments and suggestions

<table>
<thead>
<tr>
<th>Installation and maintenance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a) <strong>Instrument doesn’t power on</strong></td>
<td>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, please contact QIAGEN Technical Services.</td>
</tr>
<tr>
<td>b) <strong>Handler blocked</strong></td>
<td>If the hand can’t move freely during initialization of the instrument, please check if the transport locking screw was removed according to the installation procedure.</td>
</tr>
<tr>
<td>c) <strong>Overheating</strong></td>
<td>If an overheating error is shown or the instrument shuts off during an operation, please ensure correct ventilation of the instrument and correct environmental conditions according to the installation chapter requirements. Please ensure that the air filter is not clogged and exchanged on a regular basis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Plate loading</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a) <strong>Plate presence/orientation</strong></td>
<td>The instrument detects the proper orientation of the plate. Please ensure that the barcode is pointed to the back of the instrument and the microstructures to the bottom.</td>
</tr>
<tr>
<td>b) <strong>Plate Seal presence</strong></td>
<td>A missing Plate Seal is detected by the instrument. Please ensure that a closed plate with Plate Seal is always 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.</td>
</tr>
<tr>
<td>c) <strong>Drawer blocking</strong></td>
<td>If the drawer is retrieved and blocked, please ensure that the plate is correctly loaded into the drawer and parallel to the base surface of the drawer.</td>
</tr>
</tbody>
</table>
Comments and suggestions

da) Plate retrieving
   If a plate couldn’t be retrieved correctly in the instrument, please
   ensure that the Plate Seal is applied properly and not overlapping
   more than 1 mm at the plate side surfaces.

e) Plate barcode cannot be linked to
   an experiment; or
   Plate barcode cannot be read
   Check for any typo in the plate barcode of the experiment in the
   QiAcuity Software Suite.

f) Run cannot start
   Check if the QiAcuity Software Suite is online.

Mechanical

a) 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.

b) Scratches appear on the
   instrument
   Always use the cleaning products as described in Maintenance
   Procedures. Do not use bleach or ethanol, as they can damage the
   surface of the instrument.

Electronic

a) 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.

b) 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.

c) 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
Comments and suggestions

a) Images or analysis data cannot be viewed
Check the connection to the QIAcuity instrument.

b) 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.

c) 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.

d) 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.

e) Error displayed when inserting the USB stick into a Windows PC
Ignore the message. In most cases, no scan is needed; use the USB stick as usual. Do not reformat the USB on a Windows PC. This will lead to complete data loss on the USB stick, and it can no longer be used with the QIAcuity.

f) Starting of instrument takes long
Depending on precondition, start could take up to 5 minutes until the software of the instrument has been started and Login screen is displayed.
## Comments and suggestions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Suggestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>d)</strong> Images are saturated</td>
<td>Re-image the plate with 30% lower exposure duration (see also section Image quality control)</td>
</tr>
<tr>
<td><strong>e)</strong> Sample result is 0 copies/µl or infinite in absolute quantification</td>
<td>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 you have nearly only positive partitions in the well, a proper auto-threshold setting was likely not possible. Please 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.</td>
</tr>
<tr>
<td><strong>f)</strong> Sample results of replicates differ a lot</td>
<td>Check the images for blacked-out areas, that can occur e.g. due to bad filling or areas of low amplification (see section Image corrective measures)</td>
</tr>
<tr>
<td><strong>g)</strong> High copy number in NTC</td>
<td>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.</td>
</tr>
<tr>
<td><strong>h)</strong> Lower RFU of negative partitions in NTC/samples with low number of positive partitions</td>
<td>The signal intensity might be lower in images with high number of negative partitions. There’s no influence on the result analysis, as the signal to noise is not affected.</td>
</tr>
<tr>
<td><strong>i)</strong> The confidence interval is wide</td>
<td>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 (see section Image corrective measures)</td>
</tr>
<tr>
<td><strong>j)</strong> Vertical stripes in the images</td>
<td>Please re-image the plate for proper image analysis</td>
</tr>
<tr>
<td>Comments and suggestions</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>k) Double positive or double negative signals</strong></td>
<td>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 crosstalk compensation could also be the root cause. An insufficient compensation or overcompensation of crosstalk 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 crosstalk compensation rather than assay-related issues.</td>
</tr>
</tbody>
</table>

**Software**

<table>
<thead>
<tr>
<th>a) The QIAcuity Software Suite does not start</th>
<th>Check that the software is installed on the laptop. Check the operating system. The QIAcuity Software Suite can only be operated on Windows 7 and Windows 10.</th>
</tr>
</thead>
<tbody>
<tr>
<td>b) Disc space is critical in the QIAcuity Software Suite</td>
<td>Delete plates from the plate overview.</td>
</tr>
<tr>
<td>c) User with role Operator forgot password</td>
<td>Administrator to log-in, new operator can be created. If administrator forgot the password, contact QIAGEN Technical Service.</td>
</tr>
</tbody>
</table>
Comments and suggestions

d) 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.
   Please contact your distributor or QIAGEN Technical Service.

e) Instrument software or Software Suite is unresponsive
   Re-start the QIAcuity instrument or the notebook where the QIAcuity Software Suite is installed.

f) 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.

g) Error 205
   The error can occur in different situations:
   
   A) Please 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) Please make sure that after the first successful suite connection, the instrument is restarted to allow automatic synchronization of labware files.
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, follow the steps below.

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

![System Status Environment](image)

**Figure 6.** 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 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.

<table>
<thead>
<tr>
<th>WARNING/ CAUTION</th>
<th>Risk of personal injury and material damage [W1]</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="warning_icon.png" alt="Warning Icon" /></td>
<td>Only perform maintenance that is specifically described in this user manual.</td>
</tr>
</tbody>
</table>
The following maintenance procedures must be carried out to ensure reliable operation of the QIAcuity:

- Regular maintenance
- 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.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of fire or explosion [W1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warning Symbol]</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.
Appendix A – Technical Data

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: 1000VA
QIAcuity One, 5plex: 1000VA
QIAcuity Four: 1000VA
QIAcuity Eight: 1500VA

Fuse 2x T12A L 250V

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**: 700hPa to 1060hPa

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**: 700hPa to 1060hPa
# Mechanical data and hardware features

| Dimensions | Width: 60 cm (23.6 in.) | 
| Four/Eight | Height: 58 cm (22.8 in.) | 
|            | Depth: 65 cm (25.6 in.)  | 

| Dimensions | Width: 38 cm (15.0 in.) | 
| One        | 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:

<table>
<thead>
<tr>
<th>Channel</th>
<th>Green (excitation in nm)</th>
<th>Yellow (excitation in nm)</th>
<th>Orange (emission in nm)</th>
<th>Red (emission in nm)</th>
<th>Crimson (emission in nm)</th>
</tr>
</thead>
</table>

Excitation by high power white LED with average 4750 lumens
Image acquisition by CMOS camera with 6.3MP

Capacity

Up to 96 samples per plate. Maximum plate capacity depends on the configuration (One, Four, Eight)

Touchscreen

(One) 7.0” LCD Touch, active area 150.4 x 94.2 mm, resolution 1280*800 HD

(Touchscreen) 10.1” LCD Touch, active area 218.0 x 136.6 mm, resolution 1280*800 HD

Acoustic emission

QIAcuity One: Max. 51.0dB(A)
QIAcuity Four/Eight: Max. 53.0dB (A)

USB drive

USB2.0 8GB
Compatible OS: Windows 8, Windows 7, Windows Vista, Windows XP (SP3 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 to 60°C (–4 to 140°F)
Storage humidity range: 10 to 90% (with no condensation)
Formatting: FAT32
<table>
<thead>
<tr>
<th>Handheld scanner (optional)</th>
<th>Scan Pattern: Area Image (1280 x 800-pixel array)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Motion Tolerance: Up to 89 cm/s (35 in/s)</td>
</tr>
<tr>
<td></td>
<td>Print Contrast Ratio: 15% (minimum)</td>
</tr>
<tr>
<td></td>
<td>Decode Capability: Reads standard 1D, 2D, Postal and stacked codes</td>
</tr>
<tr>
<td></td>
<td>Resolution: 1D Linear: 0.102 mm/4 mils; PDF417: 0.127 mm/5 mils; Data Matrix: 0.195 mm/7.5 mils</td>
</tr>
</tbody>
</table>
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

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.
Declaration list of China RoHS (SJT 11364-2014)

The environmental friendly use period of the QIAcuity instruments is 25 years. The marking for the Restricted Use of Hazardous Substances in Electronic and Electrical Products (SJT 11364-2014) is shown in Table 21.
<table>
<thead>
<tr>
<th>Part Name - 部件名称</th>
<th>Toxic or Hazardous Substances and Element - 有毒或有害的物质成分</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lead (Pb)</td>
</tr>
<tr>
<td>Plastics - 塑料</td>
<td></td>
</tr>
<tr>
<td>Enclosure/Plastics parts - 外壳/塑料部件</td>
<td>○</td>
</tr>
<tr>
<td>Mechanical units - 机械部分</td>
<td></td>
</tr>
<tr>
<td>Chassis/Moving parts - 底盘/可动部分</td>
<td>○</td>
</tr>
<tr>
<td>Shielding/apertures/covers - 罩/光圈/盖</td>
<td>○</td>
</tr>
<tr>
<td>Electrical Units - 电器部分</td>
<td></td>
</tr>
<tr>
<td>PCBs a. components/Sensors - 印刷电路板部分/传感器</td>
<td>X</td>
</tr>
<tr>
<td>Power supply - 电源</td>
<td>X</td>
</tr>
<tr>
<td>Cables - 电缆</td>
<td></td>
</tr>
<tr>
<td>Connecting cables - 连接电缆</td>
<td>○</td>
</tr>
<tr>
<td>Motors - 电机</td>
<td></td>
</tr>
<tr>
<td>Motors/Pumps/Fans - 电机/泵/风扇</td>
<td>○</td>
</tr>
<tr>
<td>Optical Parts - 光学部件</td>
<td></td>
</tr>
<tr>
<td>Part Name - 部件名称</td>
<td>Toxic or Hazardous Substances and Element - 有毒或有害的物质成分</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Lead (Pb)</td>
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<td>Plastics - 塑料</td>
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<tr>
<td>Enclosure/Plastics parts - 外壳/塑料部件</td>
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<tr>
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<td></td>
</tr>
<tr>
<td>Chassis/Moving parts - 底盘/可动部分</td>
<td>○</td>
</tr>
<tr>
<td>Filter, Lenses - 滤光器/镜头</td>
<td>○</td>
</tr>
<tr>
<td>Heating Unit - 加热装置</td>
<td></td>
</tr>
<tr>
<td>Thermocycler - 散热片</td>
<td>○</td>
</tr>
</tbody>
</table>

Note: This table is prepared in accordance with the provisions of SJ/T 11364.
O: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in GB/T 26572.
X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part may be above the limit requirement in GB/T 26572.
O: 代表用于此部件的所有同类型的包含该种有毒或者有害物质的材料均在GB/T 26572的规定界限以下
X: 代表用于此部件的至少一种此类型的包含该种有毒或者有害物质的材料可能在GB/T 26572的规定界限以上
## Document Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2021</td>
<td>Initial release</td>
</tr>
<tr>
<td>July 2021</td>
<td>Removed reference to German and French translations of Safety Information section</td>
</tr>
</tbody>
</table>
Limited License Agreement for QIAcuity

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

1. The product may be used solely in accordance with the protocols provided with the product and this handbook and for use with components contained in the kit only. QIAGEN grants no license under any of its intellectual property to use or incorporate the enclosed components of this kit with any components not included within this kit except as described in the protocols provided with the product, this handbook, and additional protocols available at www.qiagen.com. Some of these additional protocols have been provided by QIAGEN users for QIAGEN users. These protocols have not been thoroughly tested or optimized by QIAGEN. QIAGEN neither guarantees them nor warrants that they do not infringe the rights of third-parties.

2. Other than expressly stated licenses, QIAGEN makes no warranty that this kit and/or its use[s] do not infringe the rights of third-parties.

3. This kit and its components are licensed for one-time use and may not be reused, refurbished, or resold.

4. QIAGEN specifically disclaims any other licenses, expressed or implied other than those expressly stated.

5. The purchaser and user of the kit agree not to take or permit anyone else to take any steps that could lead to or facilitate any acts prohibited above. QIAGEN may enforce the prohibitions of this Limited License Agreement in any Court, and shall recover all its investigative and Court costs, including attorney fees, in any action to enforce this Limited License Agreement or any of its intellectual property rights relating to the kit and/or its components.

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