**Version 1** **February 2018**

# Rotor-Gene® Q MDx User Manual (US)

## US Version

For use with Rotor-Gene Q Software version 2.3.1 or higher

IVD

MAT 1113249EN

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**R5**

QIAGEN®

Sample & Assay Technologies

# Contents

# 1 Safety Information

Before using the Rotor-Gene Q MDx instrument, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

The following types of safety information appear throughout this manual.

| | |
|---|---|
| **WARNING**  | The term WARNING is used to inform you about situations that could result in **personal injury** to you or other persons.<br>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.<br>Details about these circumstances are given in a box like this one. |

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

## 1.1 Proper use

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|---|---|
| **WARNING**  | **Risk of personal injury and material damage** [W1]<br>Improper use of the Rotor-Gene Q MDx may cause personal injuries or damage to the instrument.<br>The Rotor-Gene Q MDx must only be operated by qualified personnel who have been appropriately trained.<br>Servicing of the Rotor-Gene Q MDx must only be performed by QIAGEN Field Service Specialists. |

Perform the maintenance as described in Section 9. QIAGEN charges for repairs that are required due to incorrect maintenance.

| | |
|---|---|
| **WARNING**  | **Risk of personal injury and material damage** [W2]<br>Rotor-Gene Q MDx is a heavy instrument. To avoid personal injury or damage to the instrument, take care when lifting. |

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| **WARNING**  | **Risk of personal injury and material damage** [W3]<br>Do not attempt to move the Rotor-Gene Q MDx during operation. |

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| **CAUTION**  | **Damage to the instrument** [C1]<br>Avoid spilling water or chemicals onto the Rotor-Gene Q MDx. Damage caused by water or chemical spillage will void your warranty. |

**Note**: In case of emergency, switch off the Rotor-Gene Q MDx at the power switch at the back of the instrument and unplug the power cord from the power outlet.

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| **WARNING**  | **Risk of personal injury and material damage** [W4]<br>Do not try to open the lid during an experiment, or while the Rotor-Gene Q MDx is spinning. Otherwise, if you overcome the lid lock and reach inside, you risk contact with parts that are hot, electrically live, or moving at high speed, and you may injure yourself and damage the instrument. |

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| **WARNING**  | **Risk of personal injury and material damage** [W5]<br>If you need to stop an experiment quickly, turn off the power to the instrument, then open the lid. Let the chamber cool before reaching inside. Otherwise you risk injury by touching parts that are hot. |

| | |
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| **WARNING**  | **Risk of personal injury and material damage** [W6]<br>If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. |

| | |
|---|---|
| **WARNING**  | **Risk of personal injury and material damage** [W7]<br>Loose paper underneath the Rotor-Gene Q MDx interferes with instrument cooling. It is recommended that the area beneath the instrument is kept free of clutter. |

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| **CAUTION**  | **Damage to the instrument** [C2]<br>Always use a locking ring on the rotor. This stops caps from coming off tubes during an experiment. If caps come off during an experiment, they may damage the chamber. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument** [C3]<br>Visually inspect and make sure the rotor is not damaged or deformed before each run. |

If you touch the Rotor-Gene Q MDx during an experiment, while you are charged with static electricity, in severe cases the Rotor-Gene Q MDx may reset. However, the software will restart the Rotor-Gene Q MDx and continue the experiment.

## 1.2 Electrical safety

Disconnect the line power cord from the power outlet before servicing.

| WARNING  | **Electrical hazard** [W8]<br>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.<br>Intentional interruption is prohibited.<br>**Lethal voltages inside the instrument**<br>When the instrument is connected to line power, terminals may be live, and opening covers or removing parts is likely to expose live parts. |
|---|---|

To ensure satisfactory and safe operation of the Rotor-Gene Q MDx, follow the advice below:

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

If the instrument becomes electrically unsafe, prevent other personnel from operating it, and contact QIAGEN Technical Services; the instrument may be electrically unsafe when:

- It or the line power cord appears to be damaged.
- It has been stored under unfavorable conditions for a prolonged period.
- It has been subjected to severe transport stresses.

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|---|---|
| **WARNING**  | **Electrical hazard** [W9]<br>The instrument has an electrical compliance label which indicates the voltage and frequency of the power supply as well as fuse ratings. The equipment should only be operated under these conditions. |

## 1.3 Environment

### Operating conditions

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| **WARNING**  | **Explosive atmosphere** [W10]<br>The Rotor-Gene Q MDx is not designed for use in an explosive atmosphere. |

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| **CAUTION**  | **Damage to the instrument** [C4]<br>Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.<br>The Rotor-Gene Q MDx must be located out of direct sunlight. |

## 1.4 Biological safety

Specimens and reagents containing materials from biological sources should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as *Biosafety in Microbiological and Biomedical Laboratories*, HHS (www.cdc.gov/od/ohs/biosfty/biosfty.htm).

### 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.

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|---|---|
| **WARNING**  | **Samples containing infectious agents** [W11]<br>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.<br>Always wear safety glasses, 2 pairs of gloves, and a lab coat.<br>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 Safety Data Sheets (SDSs) or OSHA,* ACGIH,† or COSHH‡ documents.<br>Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws. |

## 1.5 Chemicals

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|---|---|
| **WARNING**  | **Hazardous chemicals** [W12]<br>Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run.<br>Always wear safety glasses, gloves, and a lab coat.<br>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.<br>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).

### Toxic fumes

If working with volatile solvents or toxic substances, you must provide an efficient laboratory ventilation system to remove vapors that may be produced.

## 1.6 Waste disposal

Used consumables and plastic ware may contain hazardous chemicals or infectious agents. Such wastes must be collected and disposed of properly according to local safety regulations.

## 1.7 Mechanical hazards

The lid of the Rotor-Gene Q MDx must remain closed during operation of the instrument.

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| **WARNING**  | **Moving parts** [W13]<br>To avoid contact with moving parts during operation of the Rotor-Gene Q MDx, the instrument must be operated with the lid closed. |

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|---|---|
| **WARNING**  | **Risk of personal injury and material damage** [W14]<br>Open and close the lid of the Rotor-Gene Q MDx carefully to avoid trapping fingers or clothing. |

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|---|---|
| **CAUTION**  | **Damage to the instrument** [C5]<br>Make sure that the rotor and locking ring are installed correctly. If the rotor or locking ring show signs of mechanical damage or corrosion, do not use the Rotor-Gene Q MDx; contact QIAGEN Technical Services. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument** [C6]<br>The Rotor-Gene Q MDx must not be used if the lid is broken or if the lid lock is damaged.<br>Make sure that the rotor and locking ring are installed correctly.<br>Only use rotors, locking rings, and consumables designed for use with the Rotor-Gene Q MDx. Damage caused by use of other consumables will void your warranty. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument** [C7]<br>When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can block.<br>Allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on. |

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| **WARNING**  | **Moving parts** [W15]<br>In case of breakdown caused by power failure, remove the power cord and wait 10 minutes before attempting to manually open the lid. |

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| **WARNING**  | **Risk of overheating** [W16]<br>To ensure proper ventilation, maintain a minimum clearance of 10 cm (3.94 in.) at the sides and rear of the Rotor-Gene Q MDx.<br>Slits and openings that ensure the ventilation of the Rotor-Gene Q MDx must not be covered. |

## 1.8 Heat hazard

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| **WARNING**  | **Hot surface** [W17]<br>The Rotor-Gene Q MDx chamber can reach temperatures above 120°C (248°F). Avoid touching it when it is hot. |

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| **WARNING**  | **Hot surface** [W18]<br>When pausing a run, the Rotor-Gene Q MDx will not be cooled completely to room temperature. Exercise caution before handling the rotor or any tubes in the instrument. |

## 1.9 Maintenance

Perform the maintenance as described in Section 9. QIAGEN charges for repairs that are required due to incorrect maintenance.

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|---|---|
| **WARNING/ CAUTION**  | **Risk of personal injury and material damage** [W19]<br>Only perform maintenance that is specifically described in the user manual. |

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|---|---|
| **WARNING**  | **Risk of fire** [W20]<br>When cleaning the Rotor-Gene Q MDx with alcohol-based disinfectant, leave the Rotor-Gene Q MDx lid open to allow flammable vapors to disperse.<br>Only clean the Rotor-Gene Q MDx when the chamber components have cooled down. |

| | |
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| **WARNING/ CAUTION**  | **Risk of electric shock** [W21]<br>Do not disassemble the Rotor-Gene Q MDx instrument. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument housing** [C8]<br>Never clean the instrument housing with alcohol or alcohol-based solutions. Alcohol will damage the housing.<br>To clean the housing, use distilled water only. |

## 1.10 Symbols on the Rotor-Gene Q MDx

| Symbol | Location | Description |
|---|---|---|
|  | Near the sample chamber, visible when lid is open | Heat hazard — the temperature of the chamber can reach temperatures above 120°C (248°F) |
|  | Back of the instrument | Consult instructions for use |
|  | Type plate on the back of the instrument | CE mark for European conformity |
|  | Type plate on the back of the instrument | In vitro diagnostic medical device |
|  | Type plate on the back of the instrument | CSA listing mark for Canada and the USA |
|  | Type plate on the back of the instrument | Legal Manufacturer |
|  | Type plate on the back of the instrument | Waste Electrical and Electronic Equipment (WEEE) |
|  | Type plate on the back of the instrument | FCC mark of the United States Federal Communications Commission |
|  | Type plate on the back of the instrument | C-Tick mark for Australia (supplier identification N17965) |

| 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) |

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# 2 Introduction

Thank you for choosing the Rotor-Gene Q MDx. We are confident it will become an integral part of your laboratory.

Before using the Rotor-Gene Q MDx, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

## 2.1 About this user manual

This user manual provides information about the Rotor-Gene Q MDx in the following sections:

1. Safety Information
2. Introduction
3. General Description
4. Installation Procedures
5. Operating Procedures — Hardware
6. Operating Procedures — Rotor-Gene Q Software
7. Operating Procedures — Rotor-Gene AssayManager 1.0 and 2.1 Software
8. Access Protection
9. Maintenance Procedures
10. Optical Temperature Verification
11. Troubleshooting
12. Glossary

The appendices contain the following:

- Technical data
- FCC Declaration and information on disposal
- Rotor-Gene Q MDx instrument and accessories
- Liability clause

# 2.2 General information

## 2.2.1 Technical assistance

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

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

For technical assistance and more information, call one of the QIAGEN Technical Services Departments or local distributors (see back cover).

For up-to-date information about the Rotor-Gene Q MDx, visit http://www.qiagen.com/products/rotor-geneqmdx.aspx.

## 2.2.2 Policy statement

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

In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

## 2.2.3 Version management

This document is the *Rotor-Gene Q MDx User Manual (US)*, version 1.0, revision 5.

## 2.3 Intended use of the Rotor-Gene Q MDx

The Rotor-Gene Q MDx instrument, with Rotor-Gene Q software 2.3.1 or higher and/or Rotor-Gene AssayManager® version 1.0 or 2.1 software, is a real-time nucleic acid amplification and detection system which measures nucleic acid signals from amplified DNA using fluorescent detection.

The Rotor-Gene Q MDx instrument is intended for use with FDA cleared or approved nucleic acid tests in clinical laboratories.

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# 3 General Description

The Rotor-Gene Q MDx is an instrument that enables real-time PCR. It is highly suited for in vitro diagnostic applications.

The powerful and user-friendly Rotor-Gene Q software provides simplicity for beginners as well as an open experimental platform for advanced users.

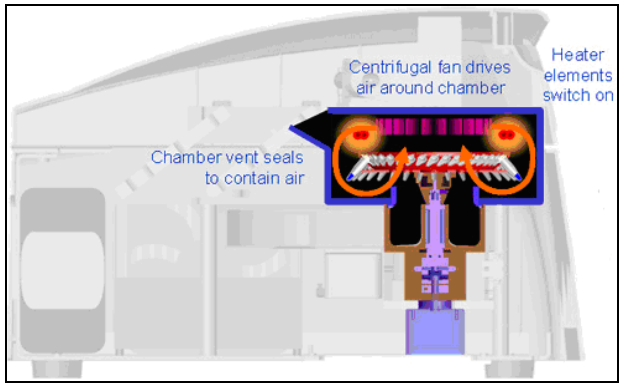

## 3.1 Thermal performance

The Rotor-Gene Q MDx uses a sophisticated heating and cooling design to achieve optimal reaction conditions. The unique rotary format ensures optimal thermal and optical uniformity between samples which is critical for precise and reliable analysis.

Samples spin continually at 400 rpm during a run. Centrifugation prevents condensation and removes air bubbles, but does not pellet DNA. In addition, samples do not need to be spun down prior to a run.

Samples are heated and cooled in a low-mass–air oven. Heating is achieved by a nickel-chrome element in the lid. The chamber is cooled by venting the air out through the top of the chamber while ambient air is blown up through the base.

### Heating




### Cooling

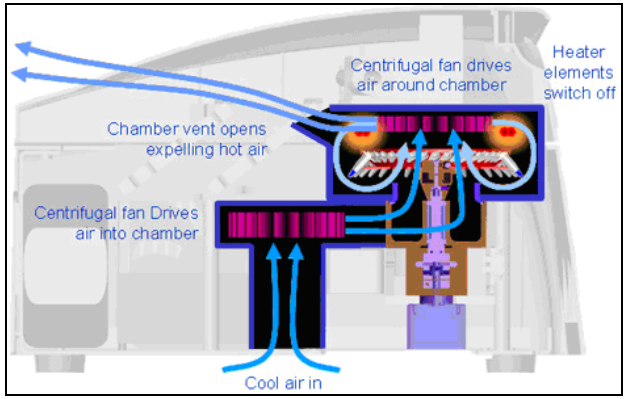



**Illustration of the heating and cooling system.**

## 3.2 Optical system

With a choice of up to 6 excitation sources* and 6 detection filters* combined with a short, fixed optical path, the Rotor-Gene Q MDx can be used for multiplex reactions, ensuring minimum fluorescence variability between samples and eliminating the need for calibration or compensation.

Samples are excited from the bottom of the chamber by a light-emitting diode. Energy is transmitted through the thin walls at the base of the tube. Emitted fluorescence passes through emission filters on the side of the chamber and is then collected by a photomultiplier. The fixed optical path ensures consistent excitation for every sample, which means that there is no need to use a passive internal reference dye such as ROX™.

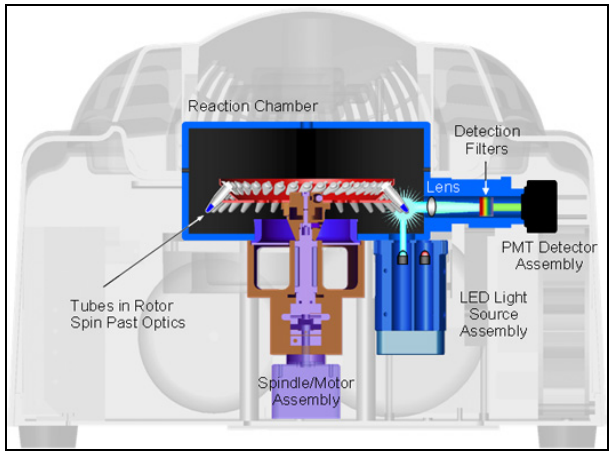



**Illustration of the optical system.**

* Red and HRM channels are not intended for use with FDA cleared or approved nucleic acid tests.

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# 4 Installation Procedures

## 4.1 Site requirements

The Rotor-Gene Q MDx instrument must be located out of direct sunlight, away from heat sources, and away from sources of vibration and electrical interference. Refer to Appendix A for the operating conditions (temperature and humidity). The installation site should be free of excessive drafts, excessive moisture, excessive dust, and not subject to large or frequent temperature fluctuations as may be present, for example, in the air flow of an air conditioning unit.

Refer to Appendix A for the weight and dimensions of the Rotor-Gene Q MDx instrument. Ensure that the workbench is dry, clean, vibration proof, and has additional space for accessories. For further information about required specifications of the workbench, contact QIAGEN Technical Services.

**Note**: It is extremely important that the Rotor-Gene Q MDx instrument is placed on a stable surface that is level and vibration-free. For guidance, refer to the operating conditions in Appendix A.

The Rotor-Gene Q MDx instrument must be placed within approximately 1.5 m (59 in.) of a properly grounded (earthed) AC power outlet.

| | |
|---|---|
| **WARNING**  | **Explosive atmosphere** [W10]<br>The Rotor-Gene Q MDx instrument is not designed for use in an explosive atmosphere. |

| WARNING | **Risk of overheating** [W16]<br>To ensure proper ventilation, maintain a minimum clearance of 10 cm (3.94 in.) at the sides and rear of the Rotor-Gene Q MDx.<br>Slits and openings that ensure the ventilation of the Rotor-Gene Q MDx must not be covered. |
|---|---|

## 4.2 AC power connection

### Power requirements

The Rotor-Gene Q MDx operates at:

- 100–240 V AC at 50–60Hz, 520 VA (peak)

Make sure that the voltage rating of the Rotor-Gene Q MDx is compatible with the AC voltage available at the installation site. Mains supply voltage fluctuations are not to exceed 10% of nominal supply voltages.

### Installation of AC power cord

Connect one end of the 3-conductor AC power cord to the socket located at the rear of the Rotor-Gene Q MDx instrument. Connect the other end to the AC power outlet.

## 4.3 PC requirements

A computer, with the required specifications for operating the Rotor-Gene Q MDx instrument is supplied as part of the instrument that is referred to as the “QIAGEN laptop” in the following text. In general, the following minimum requirements must be fulfilled.

**PC system requirements**

| Description | Minimum requirement |
|---|---|
| Operating system | Microsoft® Windows 7 Professional edition (32- and 64-bit) (Service Pack 2) |
| Processor* | Intel® Core™ 2 Duo 1.66 GHz or better |
| Main memory* | Minimum 1 GB RAM |
| Hard disk space* | Minimum 10 GB HDD |
| Graphics | Adapter and screen with at least 1200 x 800 pixels |
| Ports* | USB port or RS-232 serial port |
| DVD-ROM drive | 1 |
| Pointing device | Touchpad or mouse or equivalent is required |
| Bluetooth® | Must be switched off |
| PDF viewer, or similar | Must be installed; not part of the software installation packages |
| Power options | Never turn off hard disks, hibernate, or go to standby |

* When using Rotor-Gene AssayManager version 1.0 or 2.1 software, the following minimum PC requirements are different: Intel Core i3-380M processor, 4 GB RAM main memory, 250 GB hard disk space, USB port required.

## 4.4 Configuration for Windows 7 security

The laptop computer provided by QIAGEN for use with your Rotor-Gene Q MDx instrument have Microsoft Windows 7 pre-installed and are configured with a standard (non-administrative) Windows user account and with an administrator account. In routine usage of the system, the standard account should be used as Rotor-Gene Q software and the Rotor-Gene AssayManager version 1.0 or 2.1 is

designed to run without administrator rights. The administrator account shall only be used to install the Rotor-Gene Q or the Rotor-Gene AssayManager version 1.0 or 2.1 software and a virus scanner (please see chapter for anti-virus software). Use of the administrator account is indicated by a red desktop background. Please make sure, that you always log-in as standard-user for routine use.

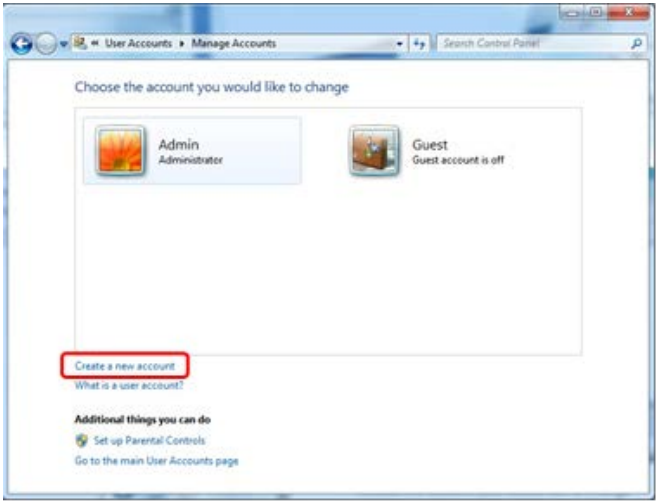
The default password for the administrator account is as follows: "Q1a#g3n!A6". Please change the administrator password after first login. Please make sure that the password is secure and does not get lost. There is no password for the operator account.

If your configuration is different and no non-administrative account is available, system administrators should setup an additional standard Windows user account to prevent access to critical system areas, such as "Program Files", "Windows" directory (e.g. access to installation or uninstallation functionality, including applications, operating system components, date/time settings, Windows updates, firewall, user rights & roles, anti-virus activation), or performance relevant settings like power saving.

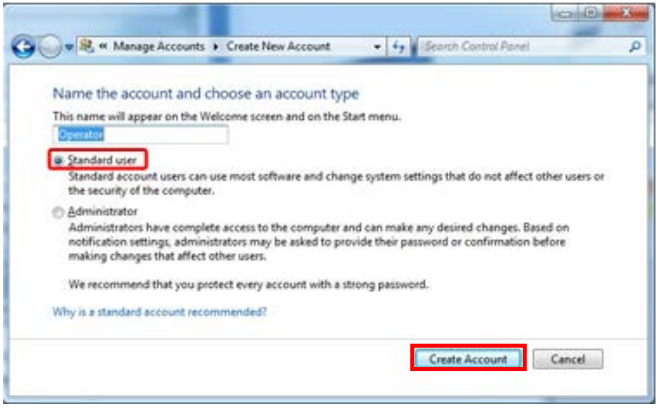
To create a standard user account in Windows 7, please follow these steps described in section "Creating a new user account".

1. Open the Windows control panel via the **Start** menu and select the **User Accounts/Manage Accounts.**

2. Chose **Create a new account.**




3. Name the account and select **Standard User** as the account type.




4. Click **Create Account**

## 4.5 Unpacking the Rotor-Gene Q MDx

The Rotor-Gene Q MDx is delivered with all the necessary components for setting up and running the instrument. The box also contains a list of all the components provided.

**Note**: Check this list for completeness to ensure that all the components are present.

**Note**: Check the instrument and delivered accessories for transport damage before installation.

The accessories box sits on top of the foam packing. The accessories box contains:

- *Rotor-Gene Q MDx Installation Guide (US)*
- CD (Rotor-Gene Q software)
- CD (*Rotor-Gene Q MDx User Manual (US)*)
- CD (*Rotor-Gene Q User Manual*)
- Loading Block 96 x 0.2 ml Tubes*

  * Not intended for use with FDA cleared or approved nucleic acid tests
- Loading Block 72 x 0.1 ml Tubes
- Rotor Holder (dismantled for safe transport)
- 36-Well Rotor (this rotor is red in color)*

  * Not intended for use with FDA cleared or approved nucleic acid tests
- 36-Well Rotor Locking Ring*

  * Not intended for use with FDA cleared or approved nucleic acid tests

The following items are packed on each side of the foam packing:

- USB and RS-232 serial cable
- International power cable set
- PCR Tubes, 0.2 ml (1000)*

  * Not intended for use with FDA cleared or approved nucleic acid tests
- Strip Tubes and Caps, 0.1 ml (1000)

Once all these components have been removed from the box, remove the foam packing on top of the Rotor-Gene Q MDx. Carefully remove the Rotor-Gene Q MDx from the box and unwrap the plastic cover. Open the lid by sliding it towards the back to access the reaction chamber.

The following items are already installed inside the Rotor-Gene Q MDx:

- A 72-Well Rotor (this rotor is blue in color)
- A 72-Well Rotor Locking Ring

A laptop computer is included with your Rotor-Gene Q MDx instrument.

Rotor-Gene AssayManager version 1.0 or 2.1 software is supplied on a separate installation DVD upon ordering.

Once you have unpacked the Rotor-Gene Q MDx, proceed with installation as described below.

## 4.6 Accessories

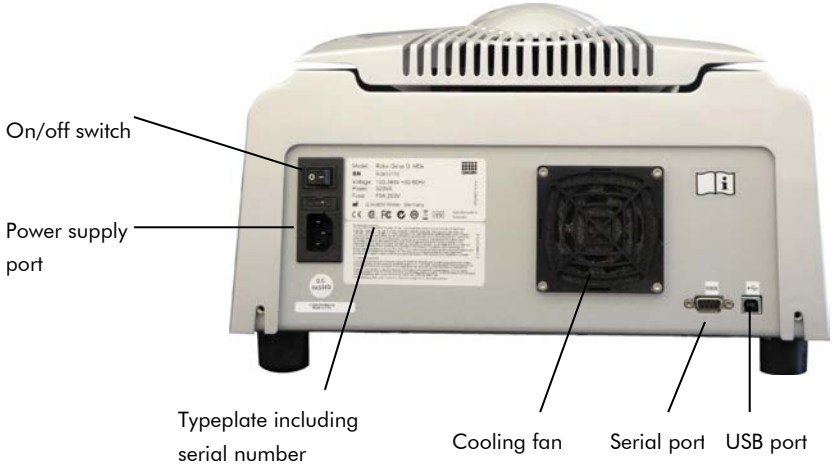
Accessories can be ordered separately for use with the Rotor-Gene Q MDx. For more details, see Appendix B.

## 4.7 Hardware installation

Once the Rotor-Gene Q MDx has been unpacked, proceed with installation as described below.

| CAUTION | **Damage to the instrument** [C7]<br>When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can block. Allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on. |
|---|---|

1. Place the Rotor-Gene Q MDx on a level and vibration-free surface.
2. Ensure that there is sufficient space behind the instrument for the lid to open fully.
3. Ensure that the power switch at the back of the instrument can be reached easily.
4. Do not obstruct the back of the instrument. Ensure that the power cord can be easily detached if required, to disconnect power to the instrument.
5. The Rotor-Gene Q software should be installed before the laptop computer is connected to the Rotor-Gene Q MDx. Please refer to Section 4.7, or the *Rotor-Gene Q MDx Installation Guide (US)* provided with the instrument, on how to install the Rotor-Gene Q software.
6. Connect the supplied USB cable or RS-232 serial cable to a USB or communications port on the back of the computer.
7. Connect the USB or RS-232 serial cable to the back of the Rotor-Gene Q MDx.
8. Connect the Rotor-Gene Q MDx to the power supply by connecting one end of the AC power cord to the socket located at the rear of the Rotor-Gene Q MDx and the other end to the AC power outlet.




**Note**: Connect the Rotor-Gene Q MDx to the computer with the USB or serial cables delivered with the instrument. Do not use other cables.

If you download software from the QIAGEN website on a different computer to the computer on which the software should have been installed, please make sure that the flash drive used to transfer the software is free of viruses. QIAGEN strongly recommends that you perform a virus scan using an up-to-date virus scanner on the flash drive to avoid software virus and/or malware contamination.

Note: Checksum confirmation is required to secure software integrity after web download has been successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded plug-in for Rotor-Gene AssayManager version 1.0 or 2.1 is started.

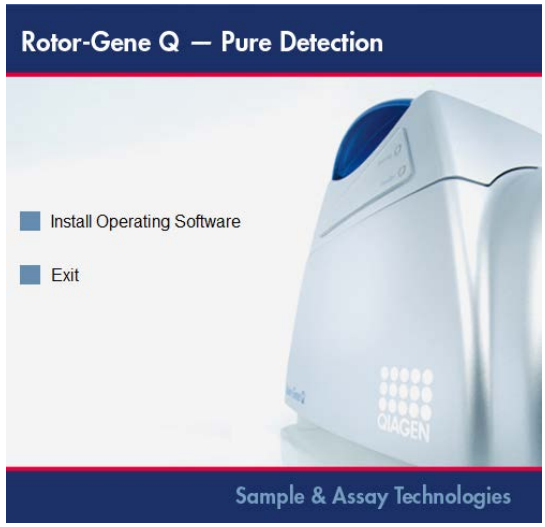
For detailed information on confirmation of software integrity during download and file transfer, please see the "QIAGEN software integrity verification process" description document, which is provided together with the software package on the QIAGEN webpage.

## 4.8 Rotor-Gene Q software installation

**Note**: Rotor-Gene Q software and Rotor-Gene AssayManager version 1.0 or 2.1 are software for routine testing in combination with Rotor-Gene Q MDx instruments. The two (2) types of software are used independently of each other but reside on the same computer. Refer to the specific assay Instructions for Use (Handbook) to determine the appropriate software to be used.

1. To install the Rotor-Gene Q software, insert the CD (Rotor-Gene Q software) delivered with the instrument into the CD/DVD drive of the computer.
2. Select "Install Operating Software" in the window that appears.

**Note**: Please refer to the *Rotor-Gene Q MDx Installation Guide (US)* provided with the instrument for easy installation and for guidance through the next steps of software installation.

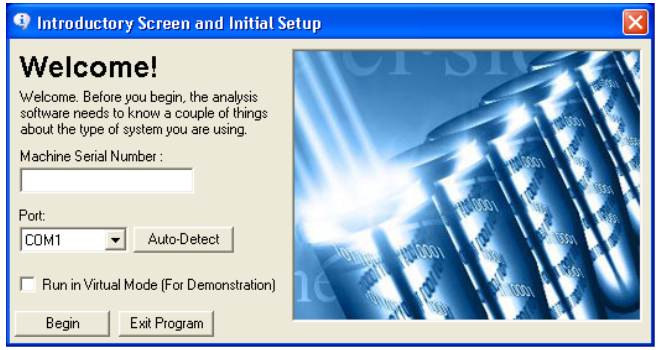



3. Once the Rotor-Gene Q software has been installed, a desktop icon will be created automatically.

4. Switch on the Rotor-Gene Q MDx by moving the toggle switch, located at the back on the right hand side, to the "**I**" position. A blue "Standby" light on the front of the Rotor-Gene Q MDx indicates that the instrument is ready for use.
   **Note**: When starting connected to a computer for the first time, the Rotor-Gene Q MDx will be recognized by the operating system and a number of messages will appear. Please refer to the *Rotor-Gene Q MDx Installation Guide (US)* provided with the instrument for guidance.

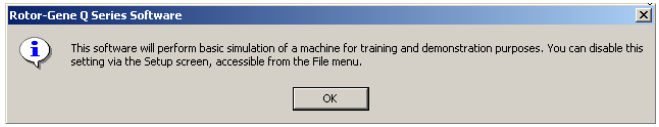
5. Double-click the Rotor-Gene Q Series Software desktop icon on your computer screen to initiate Rotor-Gene Q software.


6. A "Welcome" window appears the first time the Rotor-Gene Q software is started, but does not appear for subsequent Rotor-Gene Q software upgrades.




| | |
|---|---|
| Machine Serial Number: | Type in the serial number (7 digits), which can be found on the typeplate on the back of the Rotor-Gene Q MDx. |
| Port: | Choose either USB or serial cable. Select the appropriate communications port or click the "Auto-Detect" button. |
| "Auto-Detect": | When using this option, the corresponding USB or serial port will be detected automatically and displayed in the "Port" drop-down list. |
| Run in Virtual Mode (For Demonstration): | Checking this box allows installation of the Rotor-Gene Q software on a computer that is not connected to a Rotor-Gene Q MDx. The Rotor-Gene Q software is fully functional and can simulate runs.<br><br>**Note**: If this box is checked and a Rotor-Gene Q MDx is connected to the computer, the following message appears before the run starts: "You are about to run in Virtual mode". To perform a real run, the setup must be changed in the "Setup" window (see Section 6.3.1). |

"Begin": When all the information has been entered, click "Begin". Wait until initialization is finished, which may take a few seconds. If virtual mode was chosen the following message appears:

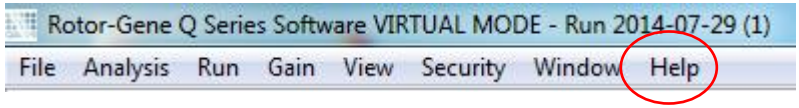



If the "Run in Virtual Mode" box is unchecked, the software initializes and opens automatically.

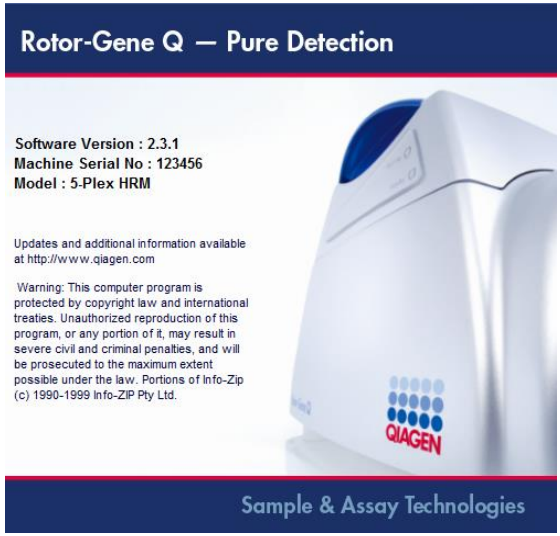
"Exit Program": Clicking on this button exits the program.

## 4.9 Rotor-Gene Q software version

To find the Rotor-Gene Q software version number, click on the "Help" button in the menu bar, then select "About This Software...".




The "About This Software..." window displays general information about the Rotor-Gene Q software, including the version of the Rotor-Gene Q software and the serial number and model of the instrument.




Rotor-Gene Q software may be freely copied for use within an organization that owns a Rotor-Gene Q MDx. Rotor-Gene Q software may not be copied and distributed to others outside the organization.

## 4.10 Rotor-Gene Q assay package installation

Assay packages contain the required files to run and analyze individual types of assays. A separate software installation is required for each assay package. The installation copies the required files to the system and creates one or more shortcuts on the desktop. The installation and use of each specific assay package is described in detail in the corresponding Instructions for Use (Handbook).

## 4.11 Installing Rotor-Gene AssayManager 1.0 or 2.1

See the "Rotor-Gene AssayManager 1.0 Core Application User Manual (US) IVD" in Part II of Volume 2 of the *QIAsymphony RGQ MDx (US) User Manual* or *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* for

information about installing the relevant Rotor-Gene AssayManager software.

## 4.12 Updating Rotor-Gene Q software

Software updates for Rotor-Gene Q software are available from the QIAGEN website at http://www.qiagen.com/products/rotor-geneqmdx.aspx . Online registration is necessary to download the software.

## 4.13 Additional software on connected computers

Rotor-Gene Q software manages time-critical processes during the PCR run and the data acquisition process. For this reason, it is important to ensure that no other processes use significant system resources and thus slow down the Rotor-Gene Q software. It is particularly important to pay attention to the points listed below.

System administrators are advised to consider any impact that a modification to the system may have on the resources before implementing it.

### 4.13.1 Virus scanners

QIAGEN is aware of the threat that computer viruses cause to any computer that exchanges data with other computers. Rotor-Gene AssayManager version 1.0 and 2.1 software is expected to be primarily installed in environments where local policies are in place to minimize this threat. However, QIAGEN recommends the use of a virus scanner. The selection and installation of an appropriate virus scanning tool is the customer's responsibility. QIAGEN has validated Rotor-Gene software and Rotor-Gene AssayManager version 1.0 and 2.1 with the QIAGEN laptop in combination with the following two virus scanners to show compatibility:

- Symantec Endpoint Protection V12.1.6
- Microsoft Security Essentials V4.10.209

Note: After installation of "Microsoft Security Essentials", you should check Windows updates are deactivated since the installation might activate this setting (please read chapter "Operating system updates").

Please refer to the product page on QIAGEN.com for the latest versions of anti-virus software that have been validated in combination with Rotor-Gene Q software and Rotor-Gene AssayManager version 1.0 and 2.1.

If a virus scanner is selected, make sure that it can be configured in a way that the database folder path can be excluded from the scan. Otherwise, there is the risk of database connection errors. Since Rotor-Gene AssayManager version 1.0 and 2.1 creates new database archives dynamically, it is required to exclude the folder path to the files and not single files. We do not recommend the use of virus scanners where only single files can be excluded, e.g. McAfee Antivirus Plus V16.0.5. If the computer is used in an environment without network access, please also make sure that the virus scanner supports offline updates.

To get consistent results after installation of a virus scanner, a system administrator should ensure the following:

- As explained above, the database folder path of the Rotor-Gene AssayManager 1.0 and 2.1 needs to be excluded from file scans which is as follows: C:\Program Files\Microsoft SQL Server\ MSSQL10_50.RGAMINSTANCE\MSSQL\DATA
- Updates to the virus database are not performed when the Rotor-Gene AssayManager 1.0 and 2.1 is in use.
- Please make sure that full or partial scans of the hard drive are disabled during real-time PCR data acquisition. Otherwise there is a risk of adverse impact on the performance of the instrument.

Please read the manual of your selected virus scanner for configuration details.

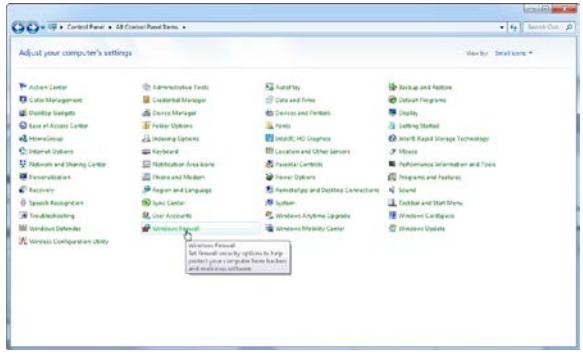
### 4.13.2 Firewall and networks

The Rotor-Gene Q software can run either on computers without network access, or can run in a network environment, if a remote database server is used. For networked operation, the firewall on the laptop computer provided by QIAGEN is configured in a way that inbound traffic is blocked for all ports, except those ones required to establish a network connection.

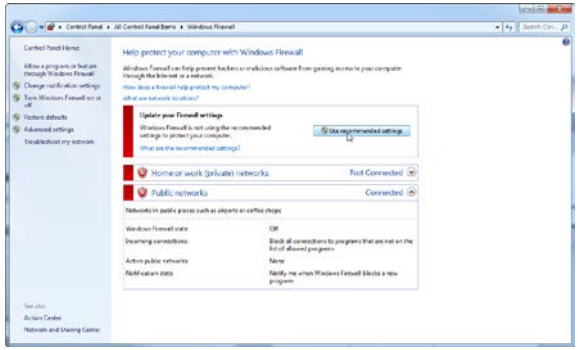
Please note that blocking incoming connections does not affect responses to requests triggered by the user. Outgoing connections are allowed as this may be required for retrieving updates.

If your configuration is different, QIAGEN recommends to configure the firewall in the same way as described above. To this end, a system administrator has to login and has to perform the following steps:

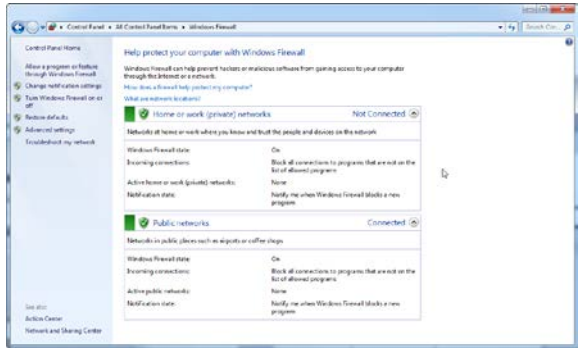
1. Open the “Control Panel” and select “Windows Firewall”.



2. Select “Use recommended settings”.

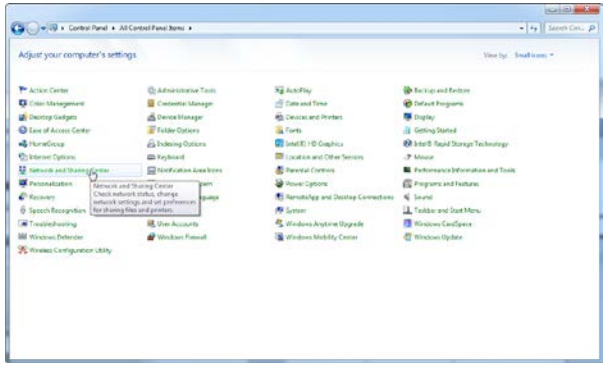



3. Check that the following settings are active:

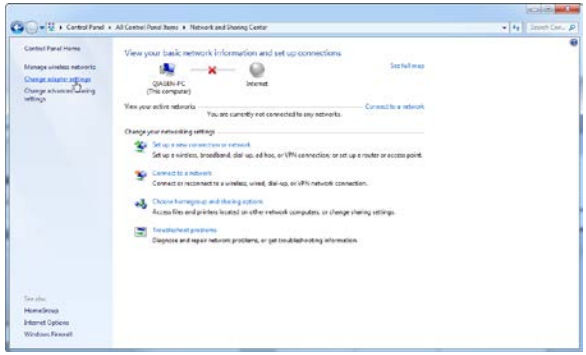



For security and reliability reasons cable-based network access should be used instead of Wi-Fi. The laptop computers provided by QIAGEN have a disabled Wi-Fi adapter. If your configuration is different, a system administrator must disable the Wi-Fi adapter manually and this can be performed as follows:

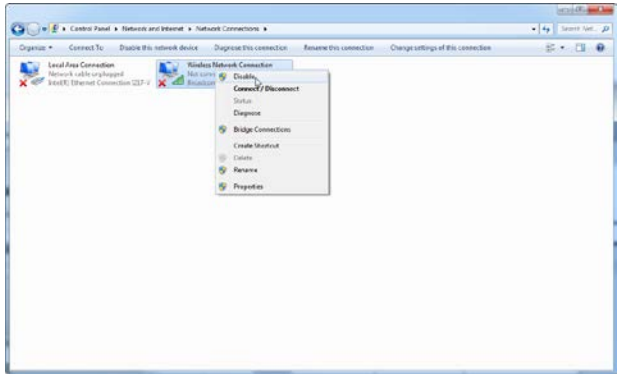
1. Open the “Control Panel” and select “Network and Sharing Center


Adjust your computer's settings

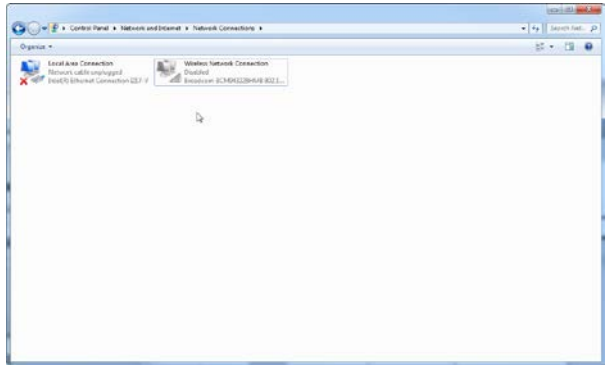
2. Select “Change adapter settings”.



3. Hover over “Wireless Network Connection”, press the right mouse button, and select “Disable” from the menu.



4. Check that the Wireless Network Connection is disabled.



## 4.13.3 System tools

Many system tools may use significant system resources even without any user interaction. Typical examples of such tools are:

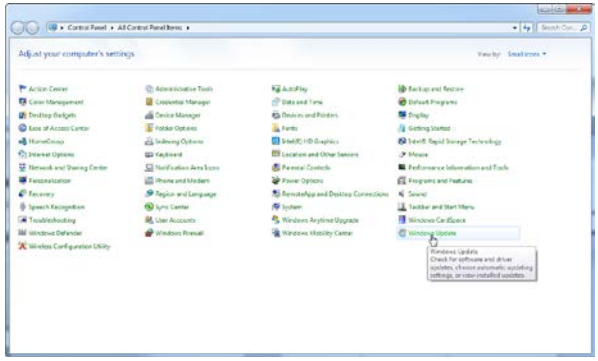
- File indexing, which is performed as a background task by many contemporary office applications
- Disk defragmentation, which often also employs a background task
- Any software that checks for updates on the internet
- Remote monitoring and management tools

**Note**: Due to the dynamic nature of information technology products and systems, this list may be incomplete. Tools may be released that are not known at the time of writing. It is important that system administrators take care that such tools are not active on the Rotor-Gene Q MDx during a PCR run.

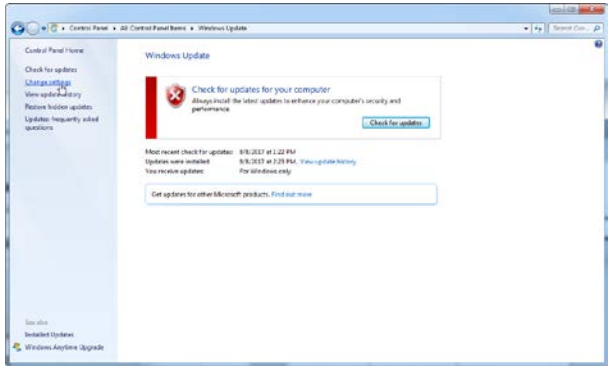
## 4.13.4 Operating system updates

The laptop computers provided by QIAGEN is configured in a way that automatic updates of the operating system are disabled. If your configuration is different, a system administrator must disable any automatic update process of the operating system which can be done by the following steps:

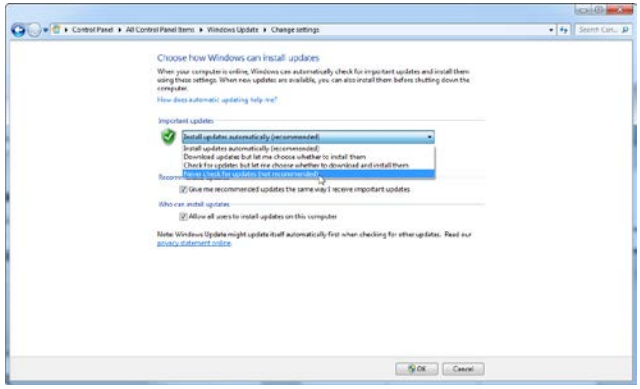
1. Open the “Control Panel” and select “Windows Update”.



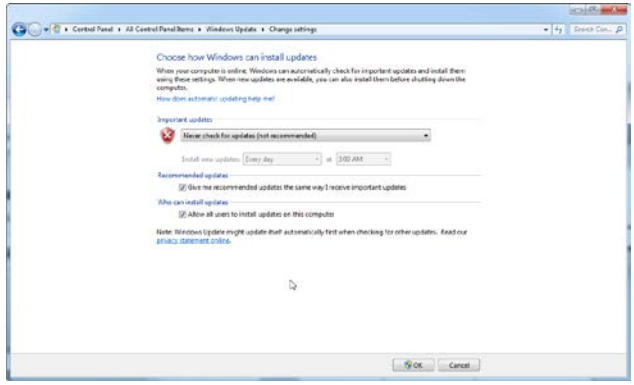
2. Select “Change settings”.



3. Select “Never check for updates”.




4. Check that option “Never check for updates” is active.




In the event that updates are required due to uncovered security vulnerabilities, QIAGEN provides mechanisms to install a defined set of validated Windows security patches either online (if internet connection is available on QIAGEN laptop), or as offline package, prepared on a separate computer with internet connection.

Please visit the product page on QIAGEN.com for more information.

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# 5 Operating Procedures — Hardware

This section describes operation of the Rotor-Gene Q MDx.

## 5.1 72-Well rotor

The 72-Well Rotor is blue in color. The 72-Well Rotor and 72-Well Rotor Locking Ring are used with Strip Tubes and Caps, 0.1 ml, which can be used for volumes as low as 20 µl. The caps provide a safe and reliable seal.

**Rotor specifications**

| Rotor type | Well capacity | Sample no. | Tube type | Recommended reaction volume |
|---|---|---|---|---|
| 72-Well Rotor | 100 µl | 72 | Strip Tubes and Caps, 0.1 ml | 20–50 µl |

| CAUTION | **Damage to the instrument** [C3]<br>Visually inspect and make sure the rotor is not damaged or deformed before each run. |
|---|---|

## 5.2 Manual reaction setup

**IMPORTANT**: Adequate controls should be used in each run to ensure reliable results.

**Note**: Refer to the specific assay Instructions for Use (Handbook) to determine the appropriate reaction setup to be used.

Reactions can be prepared using the Loading Block 72 x 0.1 ml Tubes (for Strip Tubes and Caps, 0.1 ml set up with a single-channel pipet), or the Loading Block 72 x 0.1 ml Multi-channel (for Strip Tubes and Caps, 0.1 ml set up with a multichannel pipet). Blocks are made of aluminum and can be precooled.

The Loading Block 72 x 0.1 ml Tubes (pictured) holds 18 Strip Tubes (4 x 0.1 ml) as well as up to eight 0.5 ml tubes, and up to sixteen 0.2 ml tubes. The procedure below describes the reaction setup for the 72-Well Rotor.

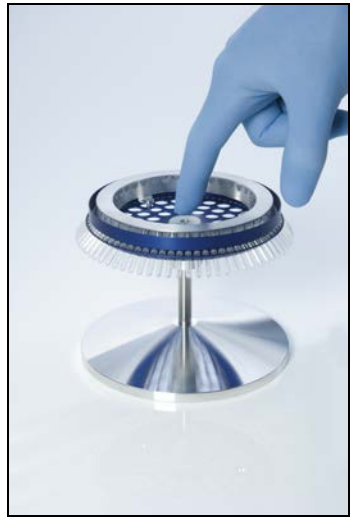
1. Place the Strip Tubes into the Loading Block and aliquot the reaction components.

2. Place the Caps securely on the Strip Tubes and visually inspect to confirm a tight seal.

3. Insert the Strip Tubes into the 72-Well Rotor, ensuring that each tube sits correctly in place in the correct orientation. Samples will not be optimally aligned over the detection system if not placed correctly in the rotor. This could result in a reduction in acquired fluorescence signal and detection sensitivity. A Rotor Holder that enables easy tube loading is provided with the instrument.

**IMPORTANT**: To achieve maximum temperature uniformity, each position in the rotor must contain a tube. Filling all positions in the rotor ensures even airflow to every tube. Keep a set of empty capped tubes available that can be used to fill any unused positions.

4. Insert the 72-Well Rotor Locking Ring onto the 72-Well Rotor by pushing the 3 locating pins through the outer holes of the rotor.
   The Locking Ring ensures that caps remain on tubes during a run.



5. Insert the assembly into the Rotor-Gene Q MDx chamber by clicking into place using the locating pin on the rotor hub. To remove, simply push down on the rotor hub to release and pull out.

6. Close the lid and select the icon on the computer desktop for the desired assay.

## 5.3 Automated reaction setup

See Volume 1 of the *QIAsymphony RGQ MDx (US) User Manual* and the specific assay Instructions for Use (Handbook) for instructions to use the QIAsymphony AS for automated reaction setup.

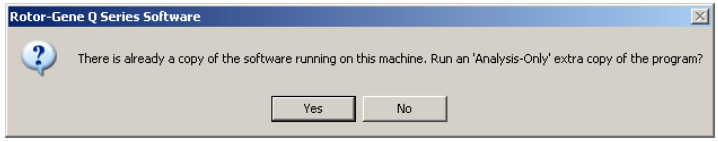
# 6 Operating Procedures — Rotor-Gene Q Software

**Note**: This chapter describes the Rotor-Gene Q software. See the "Rotor-Gene AssayManager 1.0 Core Application User Manual (US) IVD" in Part II of Volume 2 of the *QIAsymphony RGQ MDx (US) User Manual* or *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* for information about the relevant Rotor-Gene AssayManager software.

### Set up and perform run

A new run is started by double clicking on the template icon that is located on the desktop. More than one template icon may be available on the desktop, depending on the number of assay packages installed and the number of templates each assay package supports. Make sure that you select the right one according to the descriptions in the respective Instructions for Use (Handbook) for the assay you are using.

Ensure that no other instance of the software is running. If you get the following message box, press "No", close all other instances and try again.




The software starts up and presents the assay specific user interface. The procedure for entering sample data and performing the run is assay dependent. Please refer to the Instructions for Use (Handbook) for the assay you are using for further information on the workflow.

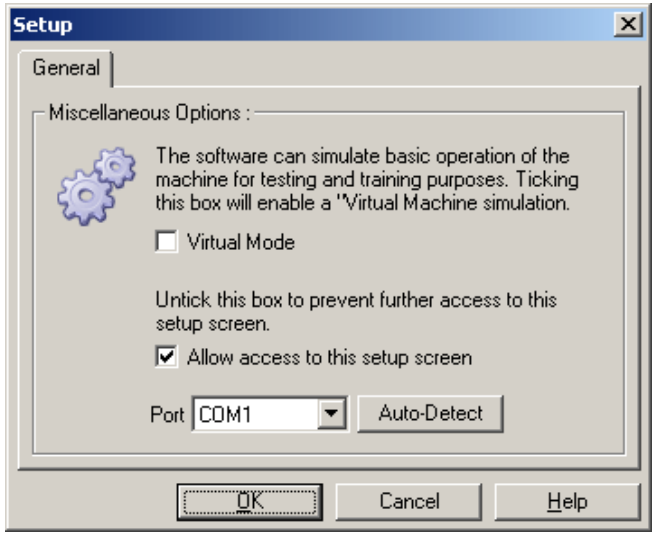
## 6.1 Analysis

The analysis is started automatically after the run is completed. As the analysis is assay dependent, please refer to the Instructions for Use (Handbook) for the assay you are using for more information on results and report files.

# 6.2 File menu

## 6.2.1 Setup

The initial setup of the Rotor-Gene Q MDx should be completed during installation. However, this option allows a change to the Rotor-Gene Q MDx connection setup, if this should be required after the initial installation.




Virtual Mode: Select this option if the software will be used without a connected Rotor-Gene Q MDx. The software retains all functions. This mode is useful for demonstration purposes, data analysis, and setting up templates.

Allow access to this setup screen: If this option is not checked during setup, this window can no longer be accessed. This security measure prevents users from altering the settings. To reestablish access, contact your distributor.

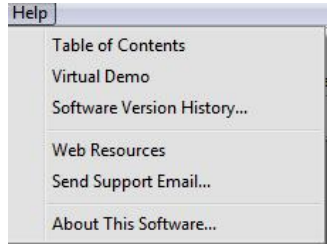
| | |
|---|---|
| Port: | Select the correct communication port to enable communications between the computer and the Rotor-Gene Q MDx. |
| Auto-Detect: | If you are unsure which port to select, click "Auto-Detect" to search for all available ports. |

## 6.3 Windows menu

This menu enables the windows to be tiled vertically or horizontally, or arranged in a cascade. Further options are accessible by clicking the arrow on the right of the "Arrange" button.

## 6.4 Help function

When using the Help button or Help menu the following drop-down menu will open:




| | |
|---|---|
| Table of Contents: | This accesses the Help function. |
| Virtual Demo: | This links to a QIAGEN webpage with an interactive demonstration of the software. |
| Software Version History: | This provides a brief overview of new features added since the previously installed software release. |

| | |
|---|---|
| Web Resources: | This opens a new browser window with a QIAGEN webpage that contains valuable latest information on Rotor-Gene Q MDx instruments and corresponding reagents. |
| About This Software…: | This provides information about the connected machine, the serial number of the Rotor-Gene Q MDx, and the software version. |

### 6.4.1 Send Support Email

The "Send Support Email…" option in the Help menu supports you by creating a support package that can be emailed to QIAGEN including all relevant information from a run. Press the "Save As" button, which will save all the information, for example, by copying it to a flash drive or across a network to a computer on which you have access to an email program.

# 1 Operating Procedures — Rotor-Gene AssayManager Software

For Rotor-Gene AssayManager software, see the "Rotor-Gene AssayManager 1.0 Core Application User Manual (US) IVD" in Part II of Volume 2 of the *QIAsymphony RGQ MDx (US) User Manual*.

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# 2 Access Protection

**Note**: This chapter describes access protection for Rotor-Gene Q software. See the "Rotor-Gene AssayManager 1.0 Core Application User Manual (US) IVD" in Part II of Volume 2 of the *QIAsymphony RGQ MDx (US) User Manual* or *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* for information about the relevant Rotor-Gene AssayManager software

Rotor-Gene Q software includes features that enable it to operate securely. When correctly configured, Rotor-Gene Q software can ensure the following:

- Access to the Rotor-Gene Q MDx and analysis software is restricted to user groups
- Modifications to run files are logged
- Unauthorized modifications are detected (signatures)
- Templates used to perform runs are logged
- Sample names are protected

### Integration with Windows security

To provide a strong level of accountability, Rotor-Gene Q software does not manage security internally. Accounts, groups, and passwords are all managed using the Windows built-in security model (Windows security). Integration allows the same password that provides access to network files and programs to control Rotor-Gene Q software access, leading to less administration. In larger organizations, for example, network administrators can easily remove access to ex-users due to the centralized security model.

For this reason, setting up Rotor-Gene Q software securely primarily involves configuration of the Windows security roles according to best practices.

### Prerequisites

The Rotor-Gene Q software must be installed with the "Force authentication through Windows domain" option.

**Note**: The Windows Security menu will not appear if you are logged into a Linux Samba domain. You must have either a local logon or a Windows server to use the security features.

## 2.1 User accounts

This section describes how to set up the system to run Rotor-Gene Q software securely.

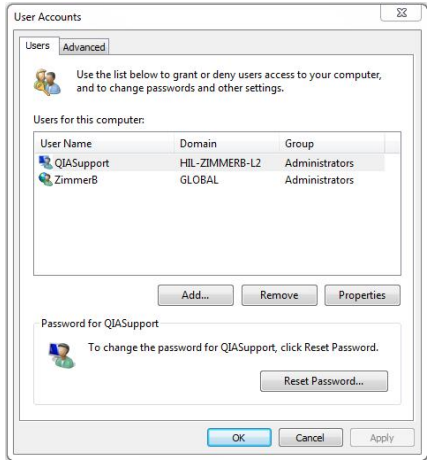
To use the security features, the software must be installed with the "Force authentication through Windows domain" option. This queries the Windows domain for your access level and credentials and is essential for providing the accountability and security features.

### 2.1.1 Creating a new user account

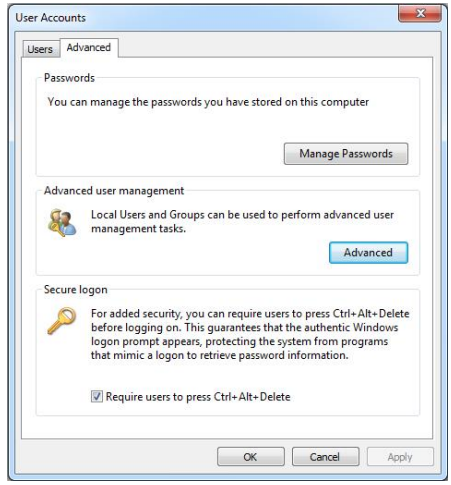
Create Windows user accounts for each user of the Rotor-Gene Q software. Windows user accounts enable to visibility of users in the report.

For each user, repeat the steps below until all accounts have been created.

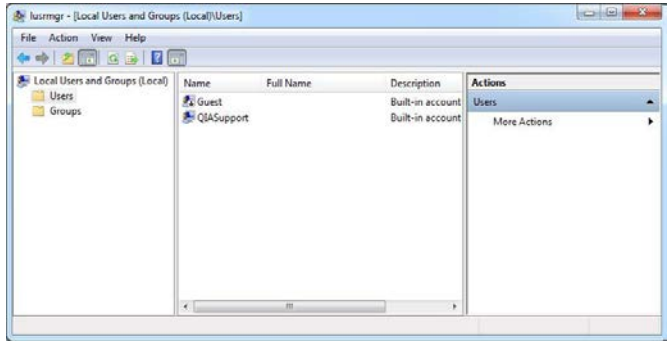
1. To create a new user, select "Start/Control Panel".
2. Double-click on "Users Accounts", then on "Manage User Accounts".



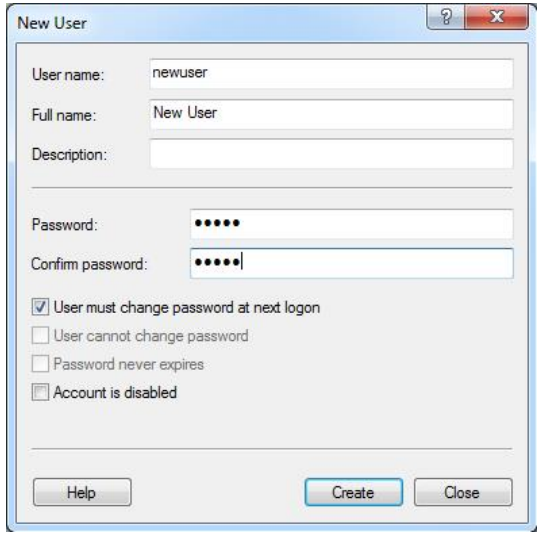
3. Click the “Advanced” tab, then click the “Advanced” button.




4. In the window that appears, select the “Users” folder. Right-click on the right-hand window and select “New User”.




5. Enter a username and password. By default, the user will be created with normal access privileges. This means they can run the software but not install new programs or change system settings.




6. Click "Create". You can now log on as this user.

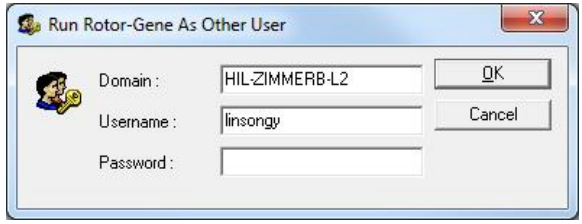
### 2.1.2 Assigning roles to each user

You should now assign roles to each user. Access is divided into the following options:

- Rotor-Gene Q Operator — can perform runs but cannot generate reports or perform analysis
- Rotor-Gene Q Analyst — can analyze run data and generate reports but cannot perform new runs
- Rotor-Gene Q Operator and Analyst — has the capabilities of both roles
- Administrator — can unlock sample names and perform all operations of Analysts and Operators
- None — access to the software is denied

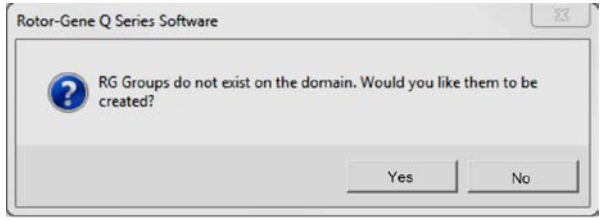
**To assign roles:**

1. Log in to Windows as an administrator, or use the "Rotor-Gene Q Software Login" icon to open the software and log in.

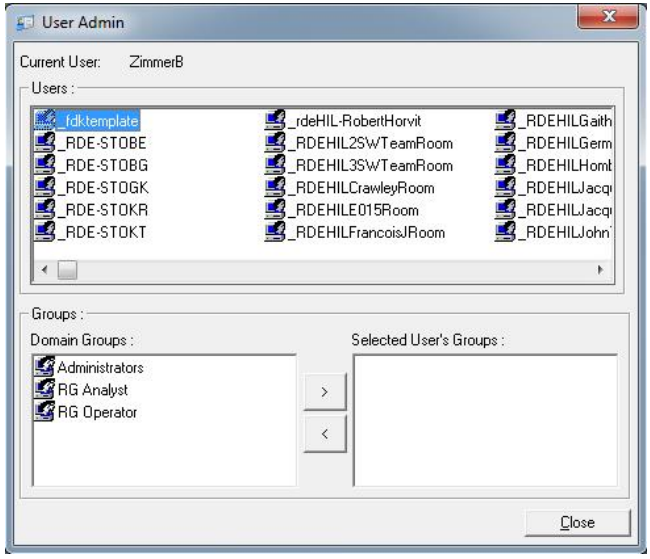



**Note**: To create the RG Groups with the Rotor-Gene Q software it is necessary to run the software with administrator rights. This is done by right-clicking on the desktop icon and choosing "Run as administrator" in the context menu.

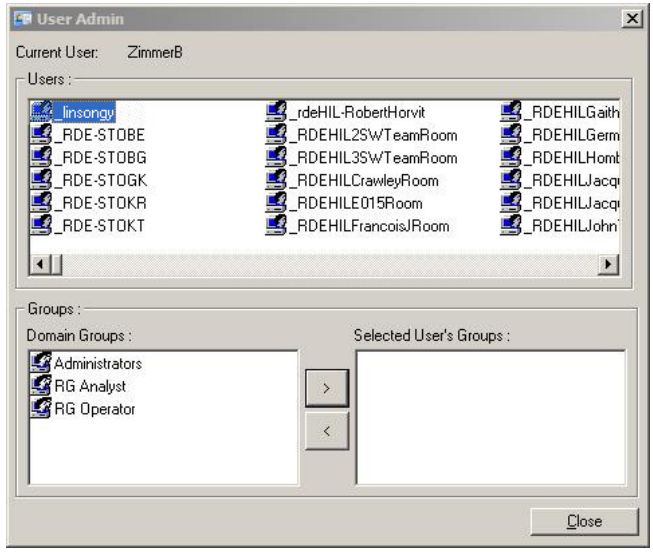
2. After the software is open, click on the "Security" menu. The first time the "Security" menu is accessed, Rotor-Gene Q software configures a number of system groups that will control access to the software.



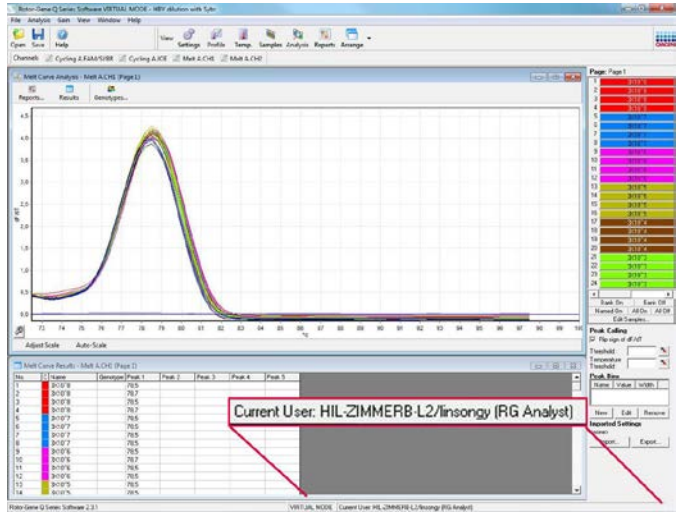

3. Click "Yes". The "User Admin" window appears. In the top panel, all the users of the computer are displayed. Some accounts are used by the system so they may be unfamiliar. The bottom pane shows the groups assigned to the user.




4. To assign a group to a user, select the user's name from the list. The bottom panel will update. If the user has no groups, they cannot launch the software. In the example below, we assign the user "linsongy" to the RG Analyst group by selecting the group on the left-hand side, then clicking the ">" button. Groups can be removed by selecting them, then clicking the "<" button.

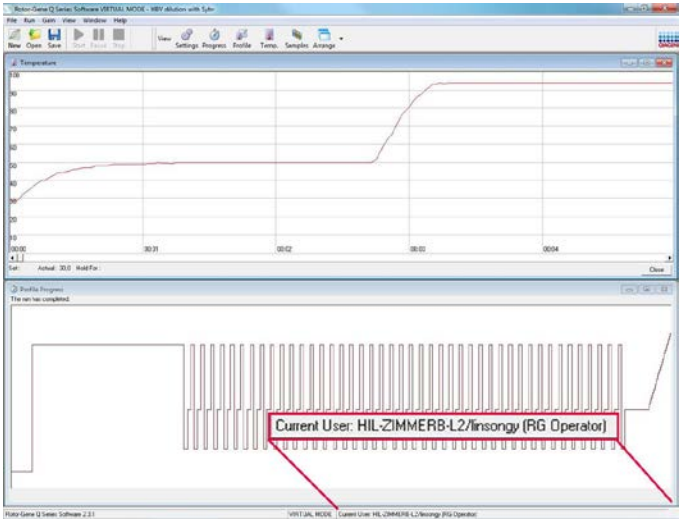



5. Now log in as this user. As an RG Analyst, the Run menu and "Profile" button are unavailable. However, existing files can be opened and analyzed, as shown in the screenshot below. The status bar indicates that the user "linsongy" is an RG Analyst.

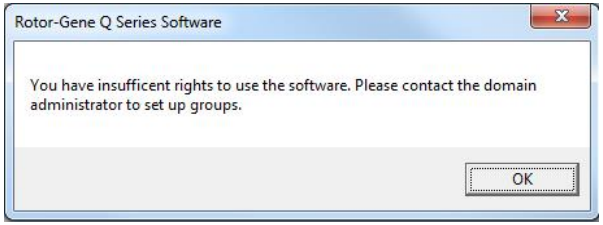



6. By logging in as an administrator again, RG Operator rights can be assigned to "linsongy" and the software

can be launched again. This time, the Analysis menu and “Reports” button are missing, and the Run menu is enabled. The status bar indicates that the user “linsongy” belongs to the RG Operator group.




7. If you log in as administrator and remove all groups from the user “linsongy”, the following message will appear when “linsongy” opens the software.




## 2.2 Running multiple users on the same computer

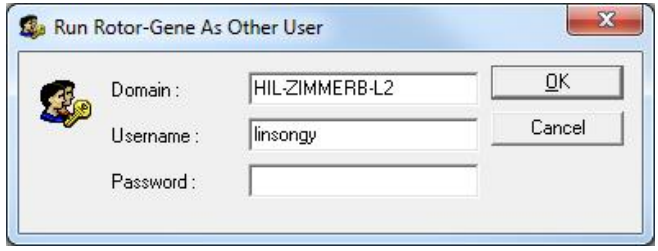
To use Rotor-Gene Q software with multiple users, all users need to have access rights to the Rotor-Gene Q software. The current user first has to log out of Windows. A different user can then log into Windows with their own account and access the Rotor-Gene Q software.

Should it be unfeasible for each user to log out of Windows repeatedly, a "lab user" Windows account can be created by the IT department. The "lab user" will be logged into Windows all the time and each Rotor-Gene Q MDx user can log into the Rotor-Gene Q software with their own credentials. However, the "lab user" Windows account should have no access rights to the Rotor-Gene Q software so no one can accidentally log into the Rotor-Gene Q software with the "lab user" Windows account.

**To set up multiple users:**

1. Using the "Rotor-Gene Q Software Login" icon, users can open their user account in the Rotor-Gene Q software.


2. Enter the username and password in the box that appears.




3. The domain is either the computer you are logging into or the name of your local network. Consult your network administrator if unsure which domain to enter in this field.

   **Note**: After logging in, all of the user files will be available for that user. Each user can save files in their own area. This ensures a high level of security.

**Note**: Each user should log out after their run has completed to prevent other users from performing a run in their name.

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# 3 Maintenance Procedures

Maintaining the working performance of the Rotor-Gene Q MDx is easy. Optical performance is maintained by ensuring that the lenses, located at both the emission and detection source, are clean. This is achieved by gently wiping a cotton tip applicator, moistened with ethanol or isopropanol,* over the lenses.

**Note**: Clean the lenses at least once a month, depending on usage. Wipe the rotor chamber at the same time.

Keep the work bench area clean and free from dust and sheets of paper. The air inlet of the Rotor-Gene Q MDx is at the bottom and loose material such as paper or dust may compromise performance.

To avoid dust build up, keep the lid of the Rotor-Gene Q MDx closed when the instrument is not in use.

If the rotor chamber becomes contaminated, it can be cleaned by wiping the surfaces with a lint-free cloth dampened (but not dripping) with a 0.1% (v/v) bleach solution.* Wipe the chamber with a lint-free cloth dampened with PCR-grade water to remove traces of bleach.

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* When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, consult the appropriate Safety Data Sheets (SDSs), available from the product supplier.

# 4 Optical Temperature Verification

Optical Temperature Verification (OTV) is a method that verifies the in-tube temperature in a Rotor-Gene Q MDx. While it is not required for the Rotor-Gene Q MDx, calibration of in-tube temperature can be a laboratory requirement. The OTV method provides a means for users to comply with this requirement, including if there are site specific calibration intervals. OTV is performed using a Rotor-Disc® OTV Kit (see Appendix B).

A short introduction to the OTV principle is given here. Performance of the OTV procedure is explained in the Rotor-Gene Q software. For a more detailed description of the OTV procedure, including a troubleshooting guide, please refer to the *Rotor-Disc OTV Handbook*.

**Note**: Rotor-Gene AssayManager version 1.0 and 2.1 software are not used for the OTV procedure.

## 4.1 OTV principle

OTV uses the optical properties of 3 thermochromatic liquid crystals (TLC)* as absolute temperature references. When heated, TLCs change from opaque to transparent at very precise temperatures (50°C, 75 °C, and 90 °C). TLCs do not themselves fluoresce. Therefore, it is necessary to cover the excitation source with a fluorescent insert so that the TLC transition points can be detected by the Rotor-Gene Q MDx optical system. TLCs that are below their transition temperature are opaque and reflect light. Some of the reflected light scatters towards the detector, increasing fluorescence. When the in-tube temperature reaches the TLC transition point, the TLC becomes transparent, and light passes through the sample rather than being reflected toward the detector, resulting in a decrease in fluorescence. The change in fluorescence is used to determine the precise transition temperature of each TLC. The transition

* When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, consult the appropriate Safety Data Sheets (SDSs), available from the product supplier.

temperature is compared with the temperature reported by the factory calibration file for the OTV Rotor-Disc to verify whether the Rotor-Gene Q MDx is within temperature specification.

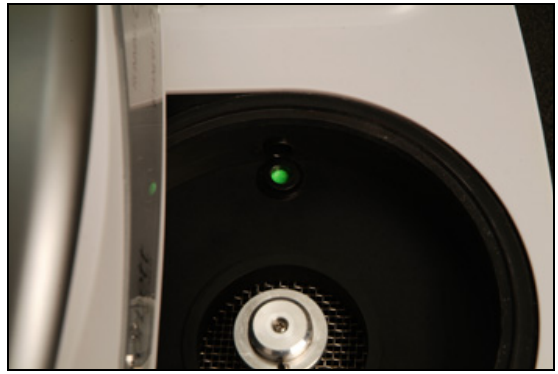
## 4.2 Rotor-Disc OTV Kit components

The following components are required to run an OTV:

- A Rotor-Disc OTV Kit, which includes:
  - Sealed Rotor-Disc 72 OTV Rotor (contains TLCs)
  - Fluorescent scatter plate insert (this insert is white for the Rotor-Gene Q MDx instruments)
  - A CD that contains the following files: OTV file with serial number (***.otv**); OTV test template file (***.ret**); OTV handbook (***.pdf**); Certificate of Conformity (***.pdf**); OTV Reference run (***.rex**)
  - Product Sheet
- Rotor-Disc 72 Rotor
- Rotor-Disc 72 Locking Ring

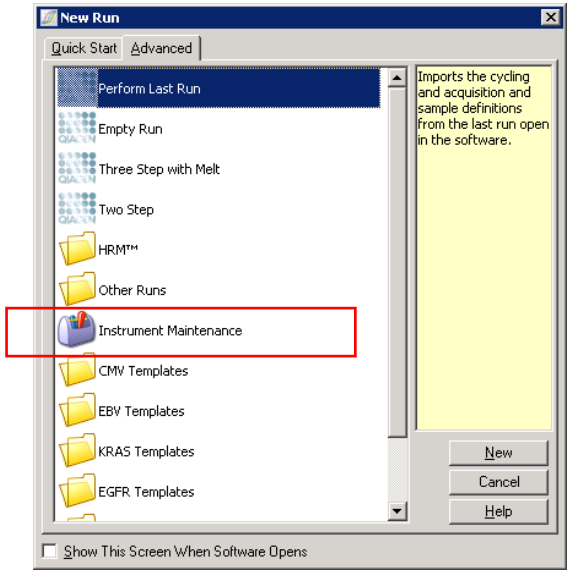
## 4.3 Running an OTV

1. Place the fluorescent insert over the emission lens in the bottom of the Rotor-Gene Q MDx chamber.
2. Place the OTV Rotor-Disc into a Rotor-Disc 72 Rotor. Secure using a Rotor-Disc 72 Locking Ring. Place the assembly into the Rotor-Gene Q MDx and click into place. Close the Rotor-Gene Q MDx lid.



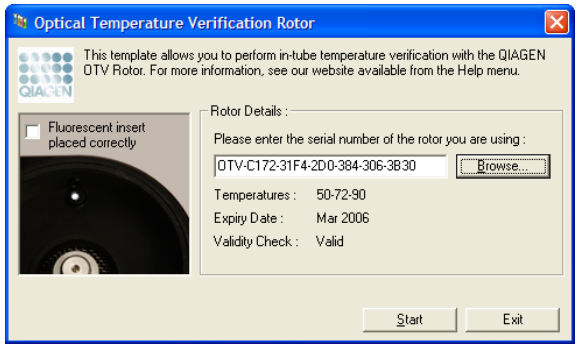
3. Access the Advanced wizard in Rotor-Gene Q software by selecting the “Advanced” tab in the “New Run” window. In the Advanced wizard, click on “Instrument maintenance” and then “OTV”.

**Note**: Rotor-Gene AssayManager version 1.0 and 2.1 software are not used for running an OTV.

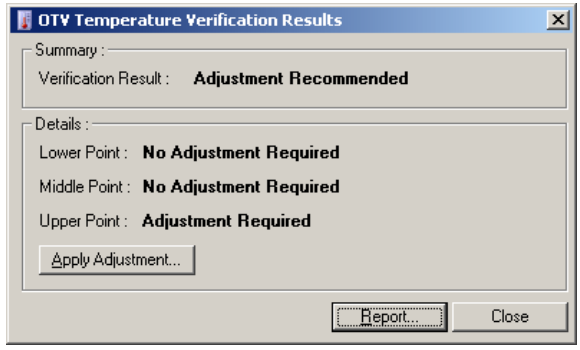



4. The wizard prompts for the OTV serial number. This number can be read from the label on the OTV Rotor-Disc or can be imported from the CD by clicking

on “Browse” and choosing the ***.otv** file provided on the CD. Once the number is entered, click “Start”.




5. The Rotor-Gene Q software then prompts for a filename for the run. Then the run begins.
6. The run performs a series of melts that determine the thermal characteristics of the Rotor-Gene Q MDx.




7. When the run is finished, the Rotor-Gene Q software indicates whether the Rotor-Gene Q MDx is within specification.

8. If adjustment is required, the user must click “Apply Adjustment”. This prompts the user to perform a verification run. After the verification run is complete, no adjustment should be required. If further adjustment is required, contact your distributor or QIAGEN Technical Service.
9. When the Rotor-Gene Q MDx is within specification, a report of the run can be reviewed and printed.

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# 5 Troubleshooting

## 5.1 Log Archives

The Rotor-Gene Q software keeps an unmodified record of each run, along with diagnostic information, in its Log Archive repository. By using the Help, Send Support Email option, you can send an email along with all the necessary diagnostic information to QIAGEN Technical Services (see Section 6.5.1).

To save disk space, only Log Archives of the 60 most recent runs are stored. Older run Log Archives will be overwritten as new run log archives are created.

## 5.2 General instrument errors

**Note**: This section provides information about general instrument errors when using Rotor-Gene Q software. See the "Rotor-Gene AssayManager 1.0 Core Application User Manual (US) IVD" in Part II of Volume 2 of the *QIAsymphony RGQ MDx (US) User Manual* or *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* for information about the relevant Rotor-Gene AssayManager software.

| Error message | Comments and suggestions |
|---|---|
| Can't open the serial port<COMPORT> | This error occurs on Rotor-Gene Q software startup if the software cannot communicate with the instrument via the configured COM port. This is commonly caused by faulty cables, loose cables, faulty serial ports, faulty USB ports, a USB driver problem, or a USB-to-serial converter driver problem.<br><br>Reconnect or replace the cable. Reinstall the appropriate drivers. Start the Rotor-Gene Q software in “Virtual Mode” and select “Setup/Auto-Detect button” from the “File” menu to reset the configured COM port. |
| Chamber Lid Open<br><br>Could not continue run; the chamber lid was opened during a run. Please reset the machine, and restart the software. | This error occurs when the Rotor-Gene Q software has detected the lid is open in the middle of a run.<br><br>Reset the machine and restart the Rotor-Gene Q software. |
| Chamber Lid Open<br><br>The instrument chamber lid is open. Please close the lid and then click Continue. | This error occurs when the user tries to start a run while the instrument lid is open.<br><br>Close the lid of the instrument chamber and then click “Continue”. |

| Error message | Comments and suggestions |
|---|---|
| Communication Corrupted | This error occurs when the data received from the instrument do not conform to the expected pattern.<br>Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument.<br>Please contact your distributor or QIAGEN Technical Services. |
| Communication Out Sequence<br>Instrument has received data from the machine that is out of sequence. | This error occurs when the data received from the instrument are not in the correct order.<br>Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument.<br>Please contact your distributor or QIAGEN Technical Services. |
| Communication Protocol Error<br>A communication protocol error occurred with this run. | This error occurs when the communication protocol configured in the firmware is not the same as the expected protocol.<br>Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the communication protocol or the instrument. |

| Error message | Comments and suggestions |
|---|---|
| Detector motor jam, stopped machine | This error can occur when the Rotor-Gene Q MDx is started immediately after delivery in cold climates.<br>In this case, allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on.<br>If the error persists, please contact your distributor or QIAGEN Technical Services. |
| Fatal Hardware Malfunction<br>The instrument detected that there was a fatal hardware malfunction. Do not attempt to re-use the machine until the machine has been serviced by your distributor. | This error occurs when the Rotor-Gene Q software has detected a fatal hardware malfunction and has activated a safe-protection procedure to turn off the machine.<br>Turn off the instrument immediately and contact your distributor or QIAGEN Technical Services. |
| Machine Error<br>This run was stopped as machine errors occurred that could not be recovered from. Please contact your distributor if this occurs again, attaching a support archive file. | This error occurs when the Rotor-Gene Q software has detected errors on the machine that could not be recovered from. The software has stopped the run.<br>Try another run. If the problem persists, contact your distributor or QIAGEN Technical Service and attach a support archive file. |

| Error message | Comments and suggestions |
|---|---|
| Machine Unplugged | |
| The instrument is not responding and failed with the message <ERROR MESSAGE >. This is an unrecoverable failure, please reset the instrument and restart the software. | This error occurs if the instrument does not communicate with the Rotor-Gene Q software after a defined timeout interval. It is often caused by an instrument fault or by excessive activity from the PC, which causes a packet to be lost.<br>Common Rotor-Gene Q software-related causes include processor-intensive tasks, such as anti-virus resident protection or anti-virus scheduled scans, wireless cards, or infrared cards.<br>Disable or uninstall the relevant processor-intensive software/task.<br>Reset the instrument and restart the Rotor-Gene Q software.<br>Please contact your distributor or QIAGEN Technical Services if the problem persists. |
| Machine Unplugged | |
| The instrument is not connected to your computer on <PORT NAME>. Reconnect the serial cable to the back of the computer and then click Continue. | This error occurs when the serial or USB communication to the instrument is lost.<br>Reconnect the serial or USB cable to the back of the computer and then click the “Continue” button. |

| Error message | Comments and suggestions |
|---|---|
| Object variable or with block variable not set | |
| | This error occurs on Rotor-Gene Q software startup if the default experiment template file has become corrupt. This may happen if the Rotor-Gene Q software/computer is shut down without exiting correctly, for example, during a power outage. |
| | Delete the file **C:\Program Files\Rotor-Gene Q Software\Templates\normal.ret** and then restart the software. |
| Rotor Speed Failure | |
| Time out while setting the rotor speed. | This error occurs when the Rotor-Gene Q software has attempted to set the rotor speed and failed to set the target speed within a time-out period. |
| | Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument. |
| | Please contact your distributor or QIAGEN Technical Services. |
| Serial Port In Use | |
| The serial port is currently being used by another application. Close any applications such as communications or synchronization software and then retry. | This error occurs when the Rotor-Gene Q software tries to connect to the machine on the configured COM port when the port is being used by another software. |
| | Close any applications such as communications or synchronization software and then retry. |

| Error message | Comments and suggestions |
|---|---|
| Shutdown timeout | |
| The instrument has exceeded the expected time to shutdown. Please reset the machine, and reset the software. | This error occurs when the Rotor-Gene Q software has issued shutdown command to shut down the instrument and the machine keeps sending data back after an expected grace period of time.<br>Reset the machine and restart the Rotor-Gene Q software. |
| Temperature Protection Activated | |
| The instrument detected that the chamber temperature increased above a safe level. It has therefore entered a self-protection mode. Please turn off the instrument and contact your distributor if the problem persists. | This error occurs when the Rotor-Gene Q software has detected the chamber temperature has increased to above a safe level and hence activated a safe-protection procedure.<br>Turn off the instrument immediately and contact your distributor or QIAGEN Technical Services. |
| Thermistor Is Open | |
| The instrument detected that the thermistor is open, and so to prevent damage to the machine, it has been turned off. Please contact your distributor if this occurs again. | This error occurs when the Rotor-Gene Q software has detected that the thermistor is open and therefore cannot read the temperature; the software has then activated a safe-protection procedure to turn off the machine.<br>Turn off the instrument immediately and contact your distributor or QIAGEN Technical Services. |

| Error message | Comments and suggestions |
|---|---|
| Unrecoverable errors occurred | |
| This run was stopped as machine errors occurred that could not be recovered from. Please contact your distributor if this occurs again, attaching a support archive file. | This error occurs in the middle of the run after the Rotor-Gene Q software has made all possible attempts to recover and failed.<br>Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument.<br>Please contact your distributor or QIAGEN Technical Services. |

## 5.3 Rotor-Gene AssayManager troubleshooting

See the "Rotor-Gene AssayManager 1.0 Core Application User Manual (US) IVD" in Part II of Volume 2 of the *QIAsymphony RGQ MDx (US) User Manual* or *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* for information about the relevant Rotor-Gene AssayManager software.

# 6 Glossary

| Term | Description |
|---|---|
| Acquisition | Acquisition is the collection of fluorescent data. Each acquisition (set of fluorescent data) from a channel is displayed in the software as unanalyzed data in a "Raw channel" window. This data can be analyzed using the options in the "Analysis" menu. |
| Channel | A channel consists of a light emitting diode (LED) with an excitation filter paired with an emission filter. The LED and excitation filter excite samples at a given wavelength. Fluorescence emitted by samples is passed through the emission filter, before being detected by a photomultiplier. |
| Gain | The Rotor-Gene Q MDx uses a photomultiplier to collect fluorescence photons and convert them to electronic signals. The gain is a setting that determines the sensitivity of the photomultiplier. If the gain is set too high, the signal is oversaturated. If the gain is set too low, it is not possible to differentiate signal from background noise. |
| Gain Optimization | Gain Optimization is a process that dynamically adjusts the gain setting, allowing an appropriate setting to be selected which results in optimal signal detection. |
| Loading Block | Loading Blocks are aluminum blocks available in different formats which are used to hold tubes during reaction setup. |
| Locking Ring | Locking Rings are metal rings that fit onto the rotor to prevent tubes and caps from coming loose during operation of the Rotor-Gene Q MDx. Loose caps and tubes could cause damage to the instrument. |
| Rotor | The metal rotor holds tubes in the Rotor-Gene Q MDx. It enables samples to spin in the instrument chamber and ensures that samples are correctly aligned with the optical system. The rotor is secured with a Locking Ring. |

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# Appendix A

## Technical data

QIAGEN reserves the right to change specifications at any time.

### Operating conditions

| | |
|---|---|
| Power | 100–240 V AC, 50–60Hz, 520 VA (peak)<br>Power consumption < 60 VA (standby)<br>Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages. |
| Fuse | F5A 250 V fuse |
| Heat dissipation/ thermal load | Average: 0.183 kW (632 BTU/hour)<br>Peak: 0.458 kW (1578 BTU/hour) |
| Overvoltage category | II |
| Air temperature | 18 to 30°C (64 to 86°F) |
| Relative humidity | 10–75% (noncondensing) |
| Altitude | Up to 2000 m (6500 ft.) |
| Place of operation | For indoor use only |
| Pollution level | 2 |
| Environmental class | 3K2 (IEC 60721-3-3)<br>3M2 (IEC 60721-3-3) |

## Transportation conditions

| | |
|---|---|
| Air temperature | –25°C to 60°C (–13°F to 140°F) in manufacturer's package |
| Relative humidity | Max. 75% (noncondensing) |
| Environmental class | 2K2 (IEC 60721-3-2) |

## Storage conditions

| | |
|---|---|
| Air temperature | 15°C to 30°C (59°F to 86°F) in manufacturer's package |
| Relative humidity | Max. 75% (noncondensing) |
| Environmental class | 1K2 (IEC 60721-3-1) |

## Mechanical data and hardware features

| | |
|---|---|
| Dimensions | Width: 370 mm (14.6 in.)<br>Height: 286 mm (11.3 in.)<br>Depth (without cables): 420 mm (16.5 in.)<br>Depth (door open): 538 mm (21.2 in.) |
| Weight | 12.5 kg (27.6 lb.) standard configuration |
| Capacity | Up to 72 samples per run using a 72-Well Rotor |
| Software | Rotor-Gene Q software, version 2.3.1 or higher, supplied on the installation CD provided |

## Thermal specifications

| Description | Specification |
|---|---|
| Temperature range | 35°C to 99°C (95°F to 210.2°F) |
| Temperature accuracy | ±0.5°C |
| Temperature resolution | ±0.02°C (smallest programmable increment) |
| Temperature uniformity | ±0.02°C (standard deviation) |

## Optical specifications

| Description | Specification |
|---|---|
| Excitation sources | High energy light-emitting diodes |
| Detector | Photomultiplier |
| Acquisition time | 4 seconds |

## FCC Declaration

The ''United States Federal Communications Commission'' (USFCC) (in 47 CRF 15. 105) declared that the users of this product must be informed of the following facts and circumstances.

''This device complies with part 15 of the FCC:
Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.''

"This Class B digital apparatus complies with Canadian ICES-0003.''

The following statement applies to the products covered in this manual, unless otherwise specified herein. The statement for other products will appear in the accompanying documentation.

**Note**: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and meets all requirements of the Canadian

Interference-Causing Equipment Standard ICES-003 for digital apparatus. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that the interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

Consult the dealer or an experienced radio/T.V. technician for help.

QIAGEN GmbH Germany is not responsible for any radio television interference caused by unauthorized modifications of this equipment or the substitution or attachment of connection cables and equipment other than those specified by QIAGEN GmbH, Germany. The correction of interference caused by such unauthorized modification, substitution or attachment will be the responsibility of the user.

## Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

In the European Union, the European Directive 2002/96/EC on WEEE requires proper disposal of electrical and electronic equipment when it reaches its end of life.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.

Recycling can be provided by QIAGEN upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements, and where a replacement product is being supplied by QIAGEN, free recycling of its WEEE-marked electronic equipment is provided.

To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

# Appendix B

## Rotor-Gene Q MDx instrument and accessories

| Product | Contents | Cat. no. |
|---|---|---|
| Rotor-Gene Q MDx (US) Platform | Real-time PCR cycler with 6 channels,* laptop computer, software, accessories, 1-year warranty on parts and labor | 9002035 |
| **QIAsymphony RGQ MDx System** | | |
| QIAsymphony RGQ MDx; Rotor-Gene AssayManager | QIAsymphony sample prep module; QIAsymphony assay setup module; Real-time PCR cycler with 6 channels (green, yellow, orange, red,* crimson, and HRM*); software for routine testing in combination with the QIAsymphony RGQ MDx instrument, laptop computer, software, accessories | 9002341 |
| **Accessories** | | |
| Strip Tubes and Caps, 0.1 ml (250) | 250 strips of 4 tubes and caps for 1000 reactions | 981103 |
| Strip Tubes and Caps, 0.1 ml (2500) | 10 x 250 strips of 4 tubes and caps for 10,000 reactions | 981106 |
| 72-Well Rotor | For holding Strip Tubes and Caps, 0.1 ml; requires Locking Ring 72-Well Rotor | 9018903 |
| Locking Ring 72-Well Rotor | For locking Strip Tubes and Caps, 0.1 ml, in the 72-Well Rotor | 9018904 |
| Loading Block 72 x 0.1 ml Tubes | Aluminum block for manual reaction setup with a single-channel pipet in 72 x 0.1 ml tubes | 9018901 |

* Red and HRM channels are not intended for use with FDA cleared or approved nucleic acid tests.

| Product | Contents | Cat. no. |
|---|---|---|
| Rotor-Disc OTV Kit | Kit for optical temperature verification of Rotor-Gene systems, includes a Rotor-Disc preloaded with thermochromatic liquid crystals, fluorescent inserts, CD with calibration files; requires Rotor-Disc 72 Rotor and Locking Ring or Rotor-Disc 72 Starter Kit | 981400 |
| Rotor Holder | Metal free-standing holder for assembling tubes and Rotor-Discs into rotors | 9018908 |

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

# Appendix C

## Liability clause

QIAGEN shall be released from all obligations under its warranty in the event repairs or modifications are made by persons other than its own personnel, except in cases where the Company has given its written consent to perform such repairs or modifications.

All materials replaced under this warranty will be warranted only for the duration of the original warranty period, and in no case beyond the original expiration date of original warranty unless authorized in writing by an officer of the Company. Read-out devices, interfacing devices and associated software will be warranted only for the period offered by the original manufacturer of these products. Representations and warranties made by any person, including representatives of QIAGEN, which are inconsistent or in conflict with the conditions in this warranty shall not be binding upon the Company unless produced in writing and approved by an officer of QIAGEN.

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| Document Revision History | |
|---|---|
| R5<br>02/2018 | This version has been updated to include Windows 7 and remove Windows XP as an operating system, and to include cyber security updates. |

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