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Rotor-Gene® Q MDx User Manual (US)

US Version; for use with Rotor-Gene Q Software version 2.3.5 or higher

IVD

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Sample to Insight

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1   Introduction

Thank you for choosing the Rotor-Gene Q MDx (cat. nos. 9002035 or 9002036). 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.

1.1   About this user manual

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

1. Introduction
2. Safety Information
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15. Document Revision History

1.1.1 Technical assistance

At QIAGEN®, we pride ourselves on the quality and availability of our technical support. Our Technical Services departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding 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, 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**).

1.1.2 Policy statement

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

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

1.2 Intended use of the Rotor-Gene Q MDx

The Rotor-Gene Q MDx instrument, with Rotor-Gene Q software version 2.3.5 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.

1.3　Requirements for Rotor-Gene Q MDx users

The table below covers the general level of competence and training necessary for delivery, installation, use, maintenance, and servicing of the Rotor-Gene Q MDx.

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

2   Safety Information

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.

The following types of safety information appear throughout this manual:

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

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

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

2.1   Proper use

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

WARNING/ CAUTION	**Risk of personal injury and material damage** [W2]
	The Rotor-Gene Q MDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone.

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

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

In case of emergency, power OFF the Rotor-Gene Q MDx at the power switch located at the back of the instrument and unplug the power cord from the power outlet.

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

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

WARNING/ CAUTION	Risk of personal injury and material damage	[W6]
⚠️	If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.	

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

CAUTION	Damage to the instrument	[C2]
⚠️	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]
⚠️	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.

2.2 Electrical safety

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

WARNING	**Electrical hazard** [W8]
	Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.
	Intentional interruption is prohibited.
	Lethal voltages inside the instrument
	When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

To ensure satisfactory and safe operation of the Rotor-Gene Q MDx, follow 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 Rotor-Gene Q MDx.

WARNING	**Electrical hazard** [W9]
	The type plate of the instrument indicates the voltage and frequency of the power supply as well as fuse ratings. The equipment should only be operated under these conditions.

2.3   Environment

Operating conditions

WARNING	Explosive atmosphere	[W10]
⚠️	The Rotor-Gene Q MDx is not designed for use in an explosive atmosphere.	

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

2.4   Biological safety

Samples 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 (**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	[W11]
☣️	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.	

* 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).

2.5 Chemicals

WARNING ⚠	**Hazardous chemicals** [W12]
	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 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.

2.6 Waste disposal

Used consumables and plasticware may contain hazardous chemicals or infectious agents from the purification process. Such hazardous wastes must be collected and disposed of properly according to local safety regulations.

For more information about how to dispose of the Rotor-Gene Q MDx, see Appendix A – Technical data, Electronic Equipment .

2.7 Mechanical hazards

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

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

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

* 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).

CAUTION	**Damage to the instrument** [C5]
⚠️	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]
⚠️	When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can stall. Allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on.

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

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

2.8   Heat hazard

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

WARNING	**Hot surface** [W18]
⚠️	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.

2.9 Maintenance safety

Perform the maintenance as described in Section 8, page 64. QIAGEN charges for repairs that are required due to incorrect maintenance.

WARNING/ CAUTION ⚠	**Risk of personal injury and material damage** [W19] Only perform maintenance that is specifically described in this user manual.

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

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

CAUTION ⚠	**Damage to the instrument housing** [C7] Never clean the instrument housing with alcohol or alcohol-based solutions. Alcohol will damage the housing. To clean the housing, use distilled water only.

2.10 Symbols on the Rotor-Gene Q MDx

Symbol	Location	Description
⚠ (heat hazard)	Near the sample chamber, visible when lid is open	Heat hazard — the temperature of the chamber can reach temperatures above 120°C (248°F)
(consult IFU)	Back of the instrument	Consult instructions for use
IVD	Type plate on the back of the instrument	In vitro diagnostic medical device
CSA cUS	Type plate on the back of the instrument	CSA listing mark for Canada and the USA
(factory)	Type plate on the back of the instrument	Legal manufacturer
(WEEE)	Type plate on the back of the instrument	WEEE mark for Europe
FC	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	See warnings and precautions.

3 General Description

The Rotor-Gene Q MDx is an innovative instrument that enables high-precision real time PCR and is highly suited for in vitro diagnostic applications, in combination with QIAGEN IVD-marked kits.

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

3.1 Rotor-Gene Q MDx principle

3.1.1 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.
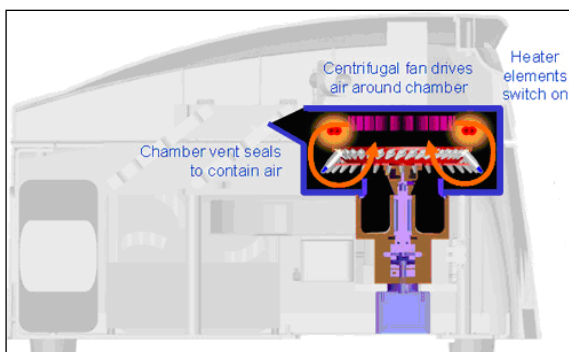
Heating
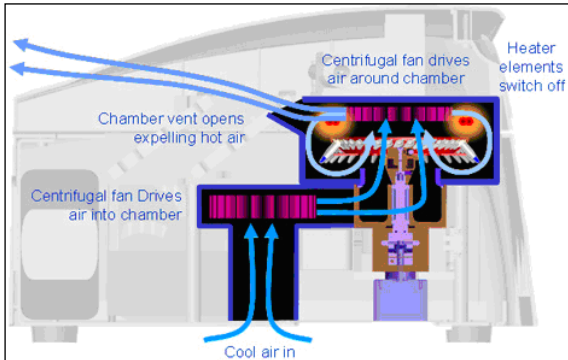
Illustration of the heating and cooling system.

3.1.2   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™*.
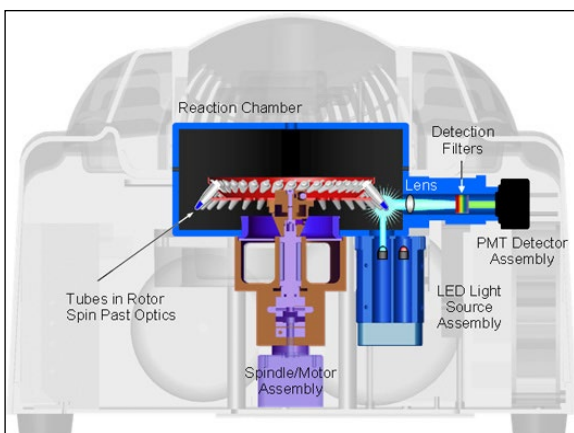
Illustration of the optical system.

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

Available channels

Channel	Excitation (nm)	Detection (nm)	Examples of fluorophores detected
Blue	365 ± 20	460 ± 20	Marina Blue®, Edans Bothell Blue, Alexa Fluor® 350, AMCA-X, ATTO 390
Green	470 ± 10	510 ± 5	FAM®, SYBR® Green I, Fluorescein, EvaGreen®, Alexa Fluor 488
Yellow	530 ± 5	557 ± 5	JOE™, VIC®, HEX™, TET™, CAL Fluor® Gold 540, Yakima Yellow®
Orange	585 ± 5	610 ± 5	ROX, CAL Fluor Red 610, Cy®3.5, Texas Red®, Alexa Fluor 568
Red*	625 ± 10	660 ± 10	Cy5, Quasar® 670, LightCycler® Red640, Alexa Fluor 633
Crimson	680 ± 5	712 high pass	Quasar 705, LightCycler Red705, Alexa Fluor 680
High resolution melt (HRM)*	460 ± 20	510 ± 5	SYBR Green I, SYTO®9, LC Green®, LC Green Plus+, EvaGreen

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

Note: QIAGEN kits indicated for use with the Rotor-Gene Q MDx instruments are optimized with respect to certain dye combinations. Please refer to the corresponding kit handbooks for more information.

3.2   External features of the Rotor-Gene Q MDx
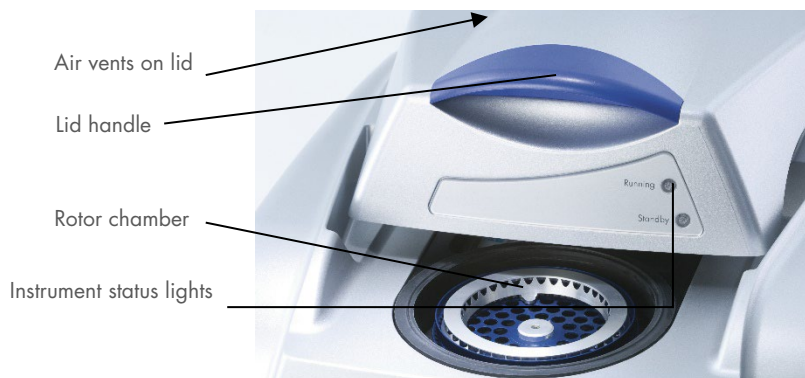
3.2.1   Air vents on the lid

The Rotor-Gene Q MDx has vents on the rear of the instruments lid. These vents allow the instrument to vent heat from the chamber during operation. Blockage or insufficient clearance around the vents can impact the performance of the instrument.

3.2.2   Lid handle

The lid handle is used to slide the lid of the instrument back. This handle is not intended to support the weight of the instrument and should not be used to lift the instrument.

3.2.3 Rotor chamber

The rotor chamber is where rotors are loaded and undergo the programmed heating and cycling steps.

3.2.4 Instrument status lights

There are two status lights on the Rotor-Gene Q MDx. The standby light indicates that the instrument is not in use. The running light flashes when the Rotor-Gene Q MDx is in use.

3.3 Internal features of the Rotor-Gene Q MDx

Internal view of the Rotor-Gene Q chamber

1	Rotor hub	2	Optical lens

3.3.1 Rotor hub

The rotor hub holds the rotor in place within the instrument.

3.3.2 Optical lens

Optical lens were the excitation diode light is focused on the tubes.

4   Installation Procedures

4.1   Installation environment

4.1.1   Site requirements

The Rotor-Gene Q MDx instruments must be located out of direct sunlight, away from heat sources, and away from sources of vibration and electrical interference. Refer to Appendix A – Technical data on page 78 for the operating conditions (temperature and humidity). The installation site should be free of excessive drafts, excessive moisture, and excessive dust, and should not be subject to large temperature fluctuations.

Refer to Appendix A – Technical data — for the weight and dimensions of Rotor-Gene Q MDx instruments. Ensure that the workbench is dry and clean, 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. Refer to operating conditions – see Appendix A – Technical data.

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]
	The Rotor-Gene Q MDx instrument is not designed for use in an explosive atmosphere.

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

4.1.2   AC power connection

Power requirements

The Rotor-Gene Q MDx operates at 100–240 V AC at 50–60Hz, 520 VA (peak).

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

Grounding requirements

To protect operating personnel, QIAGEN recommends that the Rotor-Gene Q MDx be correctly grounded (earthed). The instrument is equipped with a 3-conductor AC power cord that, when connected to an appropriate AC power outlet, grounds (earths) the instrument. To preserve this protection feature, do not operate the instrument from an AC power outlet that has no ground (earth) connection.

Installation of AC power cord

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

4.2   PC requirements

The laptop computer, optionally supplied with the Rotor-Gene Q MDx, fulfills the requirements of the Rotor-Gene Q software detailed in the following table:

PC system requirements

Description	Minimum requirement
Operating system	Microsoft Windows 10 Professional edition (64 bit)
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
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

* Microsoft Windows 10 Professional edition is required to run the Rotor-Gene Q software with security features (see "Configuration for Windows 10", Section 6.3.1). Security features are not available if the Home edition of Windows 10 is used.

† 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.

4.3   Configuration for Windows security

The laptop computers that are provided by QIAGEN for use with your Rotor-Gene Q MDx instrument have Microsoft Windows 10 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 shall be used, because 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 — the one with the red desktop background – shall only be used to install the Rotor-Gene Q or the Rotor-Gene AssayManager version 1.0 or 2.1 software and an antivirus software (please see section on "Antivirus software", page 30). Using the administrator account is indicated by a red desktop background. Please make sure that you always log in as standard user for routine use.

Q1a#g3n!A6 is the default password of the administrator account. 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 contained, system administrators shall set up 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, antivirus activation) or performance-relevant settings like power saving.

To create a standard user account in Windows 10, please follow these steps described in section "Creating a new user account":

Open the Windows control panel via the Start menu and select "User Accounts" and then "Manage Accounts".

1. Choose **Create a new account**.
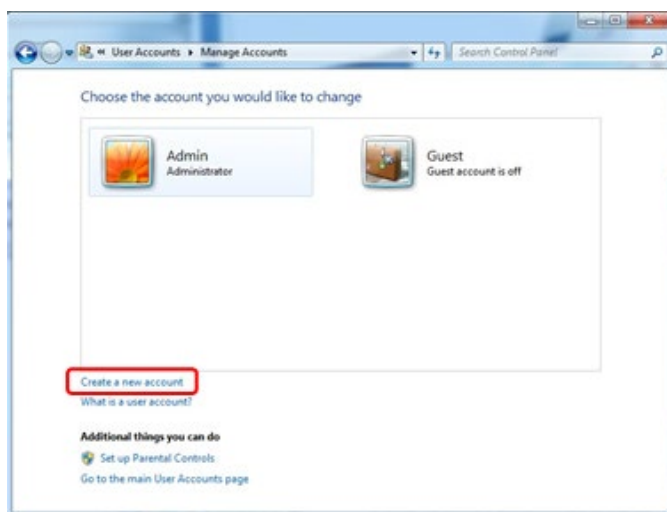
2. Name the account and select **Standard User** as the account type.
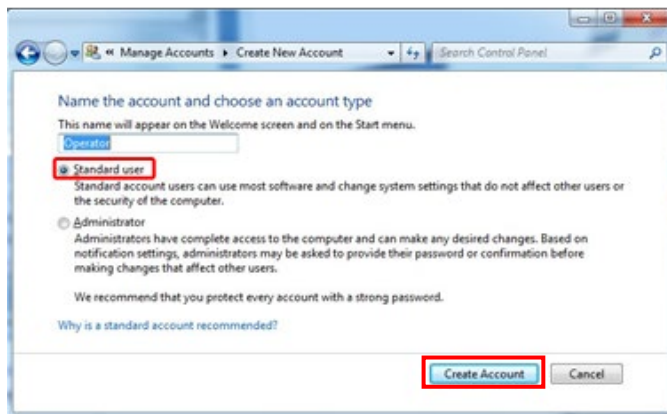
3. Click **Create Account**.

4.4   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 that the instrument and delivered accessories are free from 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*
● Loading Block 72 x 0.1 ml Tubes
● Rotor Holder (dismantled for safe transport)
● 36-Well Rotor (this rotor is red in color)*
● 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)*
- 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 toward the back to access the reaction chamber.

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

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

A laptop computer may be included in the packaging, depending on your order details.

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

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

4.5   Parts and components

Additional parts and components can be ordered separately for use with the Rotor-Gene Q MDx.

For more details, see Appendix C – Rotor-Gene Q MDx Products, Accessories, and Consumables.

4.6   Hardware installation

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

CAUTION	Damage to the instrument [C6]
⚠️	When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can stall. Allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on.

Proceed as follows:

1. Place the Rotor-Gene Q MDx on a level 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. Connect the USB cable or RS-232 serial cable, which was supplied with the instrument, to a USB or communications port on the back of the computer.

6. Connect the USB or RS-232 serial cable to the back of the Rotor-Gene Q MDx.

7. And then connect the Rotor-Gene Q MDx to the power supply. Connect one end of the AC power cord to the socket located at the rear of the Rotor-Gene Q MDx and the other end to the AC power outlet.
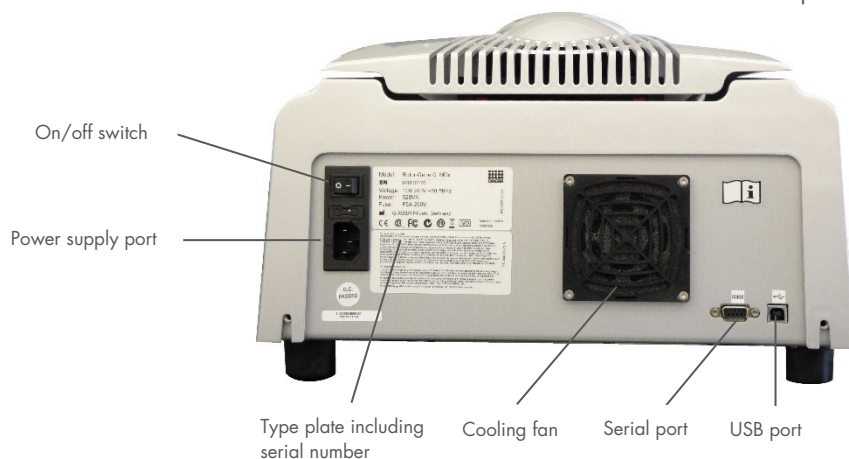
Note: Only connect the Rotor-Gene Q MDx to the computer with the USB and serial cables delivered with the instrument. Do not use other cables.

If you download software from the QIAGEN website (**www.qiagen.com**) 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 antivirus software 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.

4.7　Software installation

1. To install the Rotor-Gene Q software, insert the CD (software) delivered with the instrument into the CD drive of the computer.

2. Select **Install Operating Software** in the window that appears.

   Note: Please refer to the *Rotor-Gene Q Installation Guide* provided with the instrument for easy installation and to guide you through the next steps of software installation.
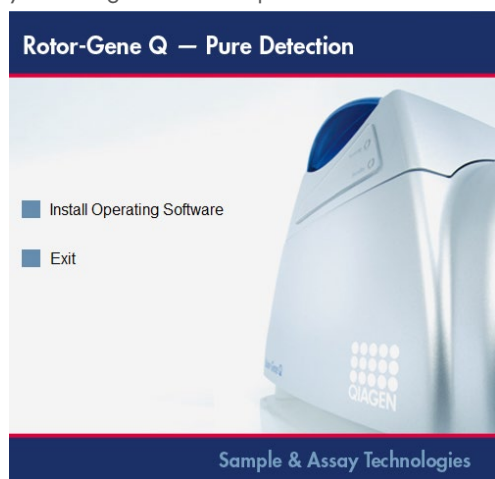
3. Once the software has been installed, a desktop icon will be created automatically.

4. Switch on the Rotor-Gene Q MDx by moving the switch, located at the back on the left-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 Installation Guide* provided with the instrument (CD and printed edition) for guidance.

5. Double-click the **Rotor-Gene Q Series Software** desktop icon to initiate the software.

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

Machine Serial Number:	Type in the serial number (7 digits), which can be found 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 software is fully functional and can simulate runs.
	Note: If this box is checked and a Rotor-Gene Q MDx is connected to the computer, the following message appears before the run starts: "You are about to run in Virtual mode". To perform a real run, the setup must be changed in the "Setup" window (see Section 6.2.1).
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:
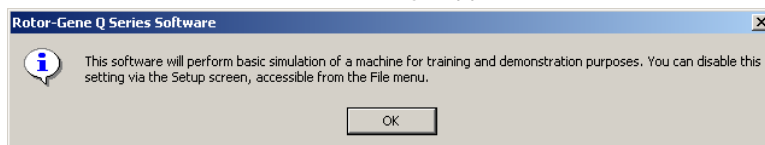
If the "Run in Virtual Mode" box is unchecked, the software initializes and opens automatically.

Exit Program: Clicking on this button exits the program.

4.8   Rotor-Gene Q Software version

To find out the software version installed on your laptop computer, click **Help** then **About This Software...**.
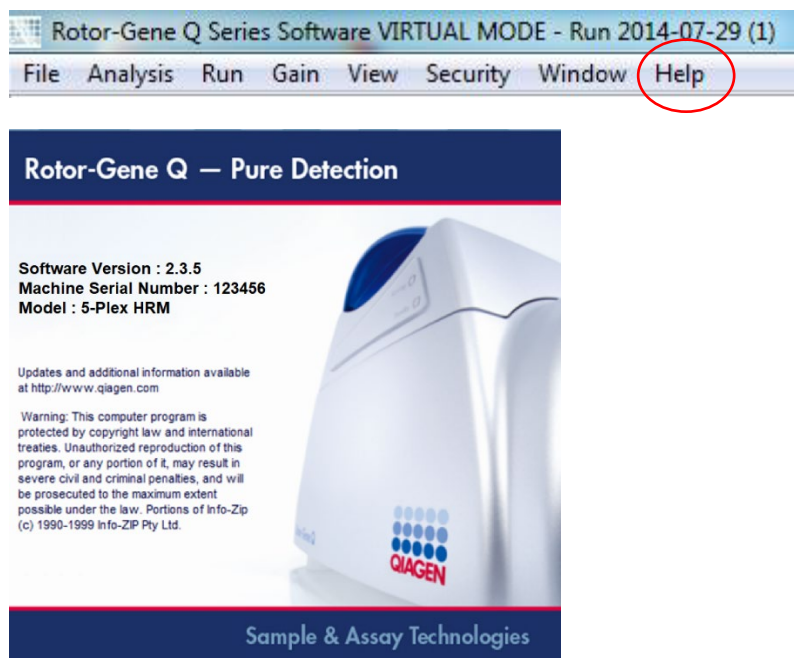
This window displays general information about the software, including the version of the software and the serial number and model of the instrument.

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

4.9   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).

4.10 Installing Rotor-Gene AssayManager 1.0 or 2.1

See the *Rotor-Gene AssayManager 1.0 Core Application User Manual* or the *Rotor-Gene AssayManager v2.1 Core Application User Manual* for information about installing the relevant Rotor-Gene AssayManager software.

4.11 Updating Rotor-Gene Q software

Software updates for Rotor-Gene Q software are available from the QIAGEN website.. Online registration is necessary to download the software.

4.12 Additional software on computers connected to Rotor-Gene Q MDx instruments

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.

4.12.1 Antivirus software

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

4.12.2 Microsoft Defender Client Version 4.18.2005.5 Antivirus software

If an antivirus software 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. Because Rotor-Gene AssayManager versions 1.0 and 2.1 create 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 antivirus software where only single files can be excluded, for example, McAfee® Antivirus Plus V16.0.5. If the computer is used in an environment without network access, please also make sure that the antivirus software supports offline updates.

To get consistent results after installation of an antivirus software, a system administrator should ensure the following:

- As explained above, the database folder path of the Rotor-Gene AssayManager 1.0 and 2.1 (**C:\Program Files\Microsoft SQL Server\ MSSQL10_50.RGAMINSTANCE\MSSQL\DATA**) needs to be excluded from file scans.
- Updates to the virus database are not performed when the Rotor-Gene AssayManager 1.0 or 2.1 is in use.
- All 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 antivirus software for configuration details.

4.12.3 Firewall and networks

The Rotor-Gene Q software can run either on computers without network access or 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 configuring the firewall in the same way as described above. To this end, a system administrator must login and perform the following steps:

1. Open the **Control Panel** and select **Windows Firewall**.
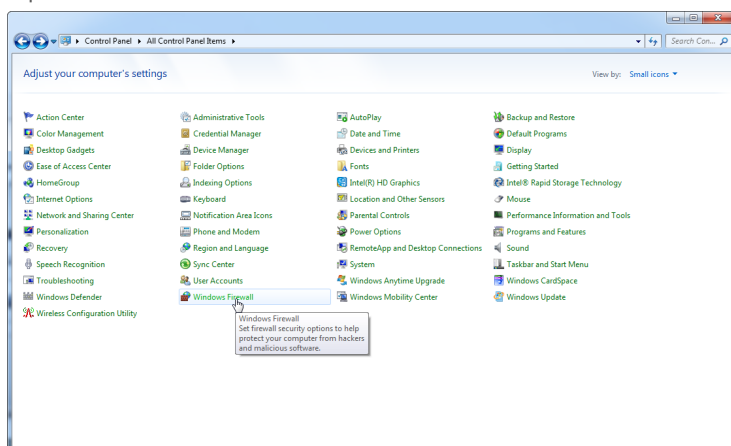
2. Select **Use recommended settings**.
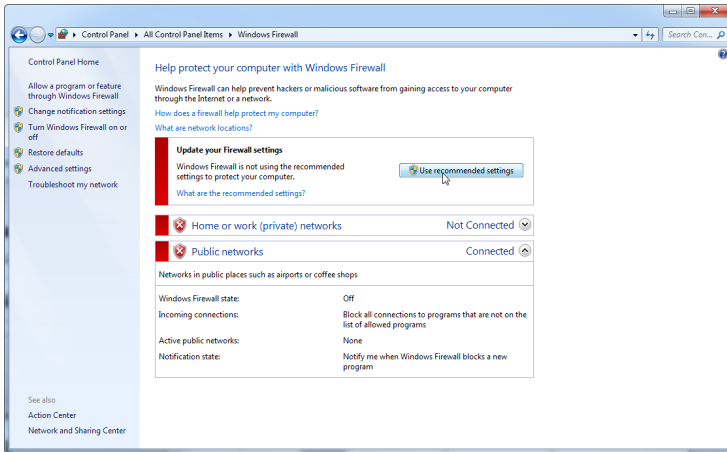
3. Check that the following settings are active:
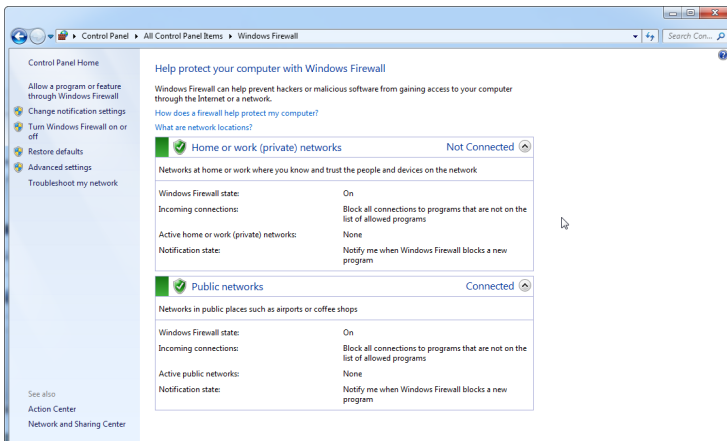
For security and reliability reasons cable-based network access shall be used instead of Wi-Fi. The laptop computers that are provided by QIAGEN have a disabled Wi-Fi adapter. If your configuration is different, a system administrator must disable the Wi-Fi adapter manually; this can be done through the following steps:

1. Open the **Control Panel** and select **Network and Sharing Center**.
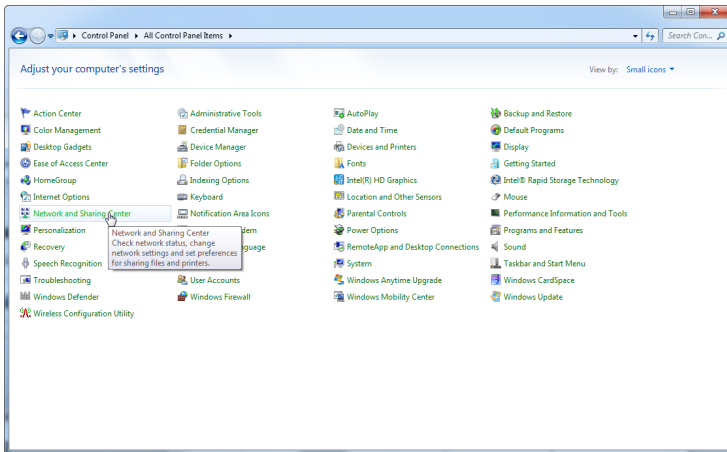
2. Select **Change adapter settings**.
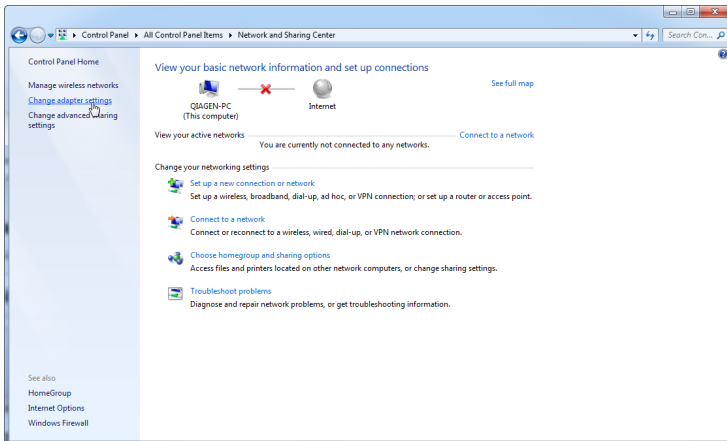
3. Hover over **Wireless Network Connection**, press the right mouse button, and select **Disable** from the context menu.
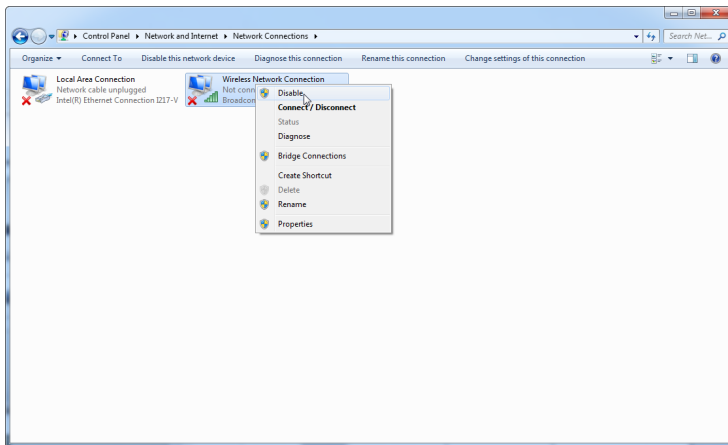
4. Check that the Wireless Network Connection is disabled.
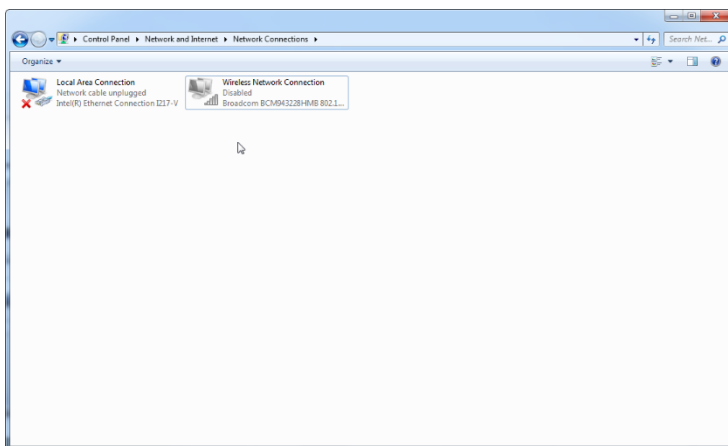
4.12.4 System tools

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

Please be aware that, due to the dynamic nature of the IT world, this list may not be complete and tools may be released that are not known at the time of writing. It is important that system administrators take care that such a tool is not active during a PCR run.

4.12.5 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**.
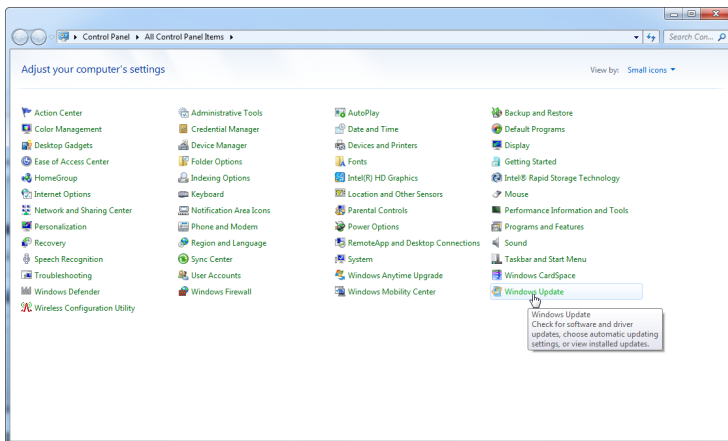
2. Select **Change settings**.
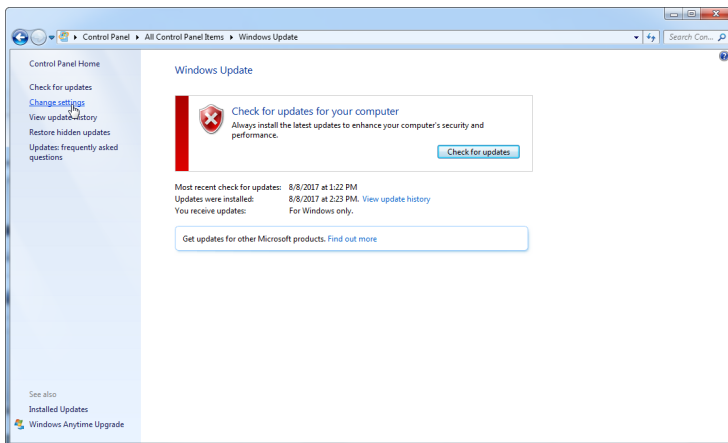
3. Select **Never check for updates**.
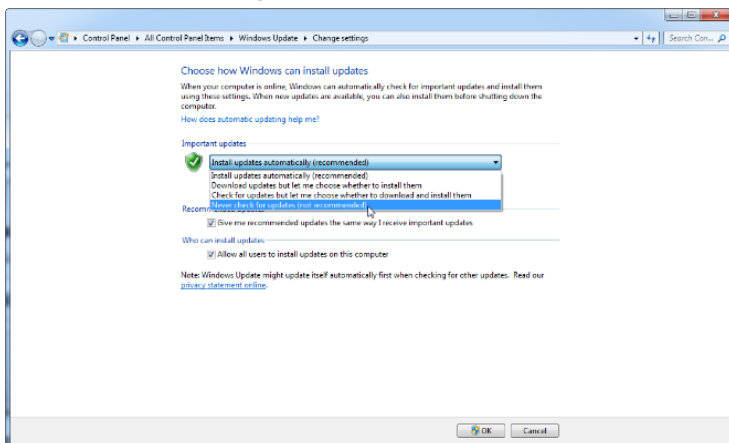
4. Check that the "Important updates" option **Never check for updates** is active.
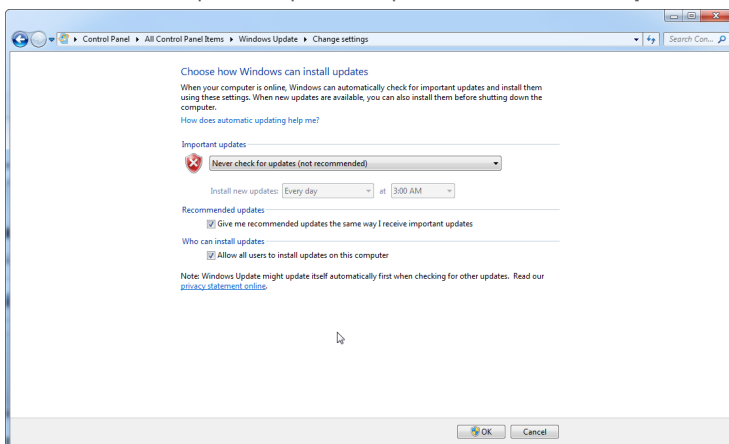
QIAGEN designed the QIAGEN System Updater to facilitate Windows updates in a controlled manner. The QIAGEN System Updater is only for use with your QIAGEN laptop computer, in conjunction with Microsoft Windows 10.

The QIAGEN System Updater will only allow Windows updates after they have been tested and verified with QIAGEN software. Windows security updates provided by the QIAGEN System Updater will ensure that your system is performing as intended.

The QIAGEN System Updater and the corresponding instructions for use can be downloaded from **www.qiagen.com**. The instructions for use will provide a guide for the installation and usage of the QIAGEN System Updater.

5   Operating Procedures — Hardware

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

5.1   72-Well Rotor

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

Rotor specifications

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

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

5.2   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.

5.3   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.
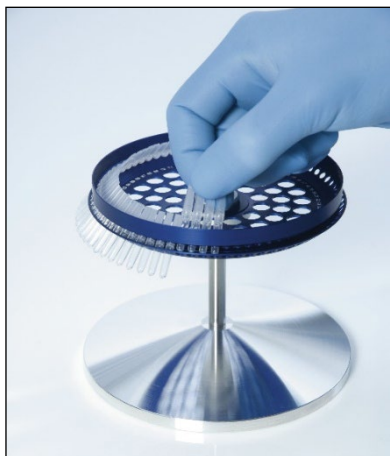
Important: To achieve maximum temperature uniformity, each position in the rotor must contain a tube. Filling all positions in the rotor ensures even airflow to every tube. Keep a set of empty capped tubes available that can be used to fill any unused positions.

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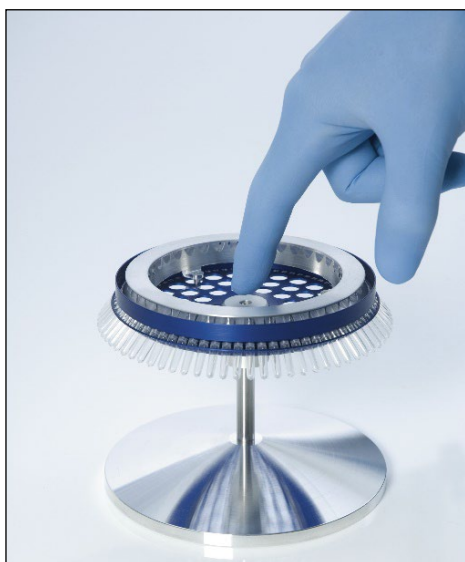
5. Insert the assembly into the Rotor-Gene Q MDx chamber by clicking into place using the locating pin on the rotor hub. To remove, simply push down on the rotor hub to release and pull out.

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

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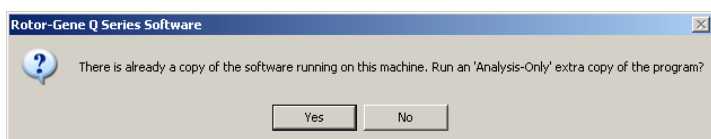
The software starts up and presents the assay specific user interface. The procedure for entering sample data and performing the run is assay dependent. Please refer to the Instructions for Use (Handbook) for the assay you are using for further information on the workflow.

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.
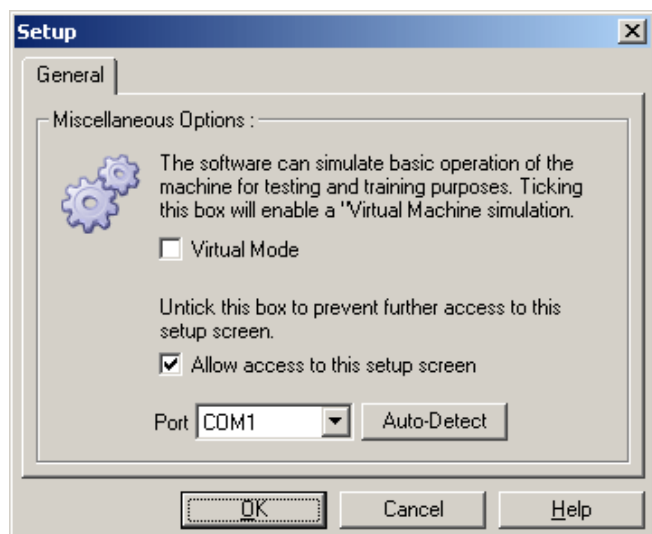
Virtual Mode:	Select this option if the software will be used without a connected Rotor-Gene Q MDx. The software retains all functions. This mode is useful for demonstration purposes, data analysis, and setting up templates.
Allow access to this setup screen:	If this option is not checked during setup, 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   Access protection for Rotor-Gene Q software

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

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

Integration with Windows security

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

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

Prerequisites

To use security, you must be running Windows 10 Professional edition. The security features cannot be used with Windows 10 Home edition, because the Home editions do not have the fine-grained access model used by the software. The software must be installed with the "Force authentication through Windows domain" option.

Note: The 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.
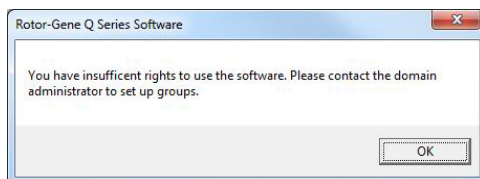
6.3.1 Configuration for Windows 10

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.

Running as Administrator

Many users run their computers as an administrator, with no password. While this is convenient, it makes it impossible to determine who is using the computer. This eliminates accountability and prevents many Rotor-Gene Q software security measures from activating. When running as an administrator, all the software features are enabled. Therefore, running as an administrator ensures that users who do not need security features can access all the software features.

Creating a new user account

Create a user account for each user of the software by repeating the steps below until all accounts have been created:

1. To create a new user, select **Start**, enter "Computer Management", press Enter and navigate to "Local Users and Groups" on the left side.
2. In the window that appears, select the **Users** folder. Right-click on right-hand window and select **New User**.
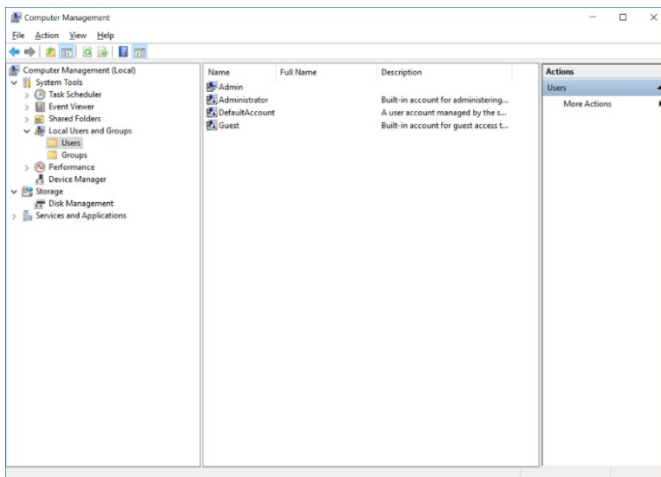
3. Enter a username and password. By default, users will be created with normal access privileges. This means they can run software but not install new programs or change system settings.

4. Click **Create**. You can now log on as this user.

Assigning Roles to each user

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

- 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

Note: In Microsoft Windows 10, it is not possible to create user groups with the Rotor-Gene Q software. The domain administrator needs to work within the domain to create groups and assign users to specific groups. Run menu is enabled. The status bar indicates that the user "linsongy" belongs to the RG Operator group.

6.3.2 Running multiple users on the same computer

To use the Rotor-Gene Q software with multiple users, create a user account that does not have access to the Rotor-Gene Q software. Log into Windows using this account, so that users cannot anonymously access the Rotor-Gene Q MDx 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

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

1. Using the **Rotor-Gene Q Software Login** icon, users can open their user account in the Rotor-Gene Q software.
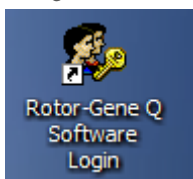
2. Enter the username and password (mandatory) in the box that appears.
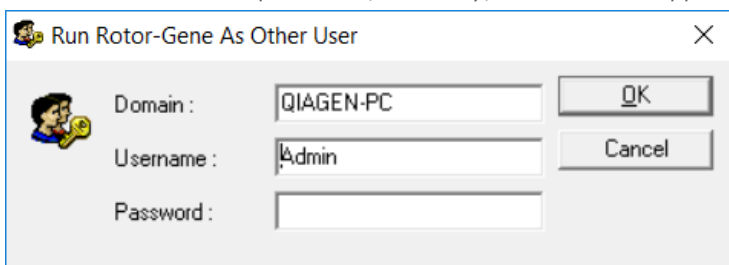
3. The domain is either the computer you are logging into or the name of your local network, together with the hostname. Consult your network administrator if unsure which domain to enter in this field.

   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 been completed, to prevent other users from performing a run in their name.

6.3.3 Audit Trails

Every time a file is saved by a user, the user's details are recorded in "Run Settings" under the **Messages** tab as Security Audit Trail Summary and Security Audit Trail Detail.
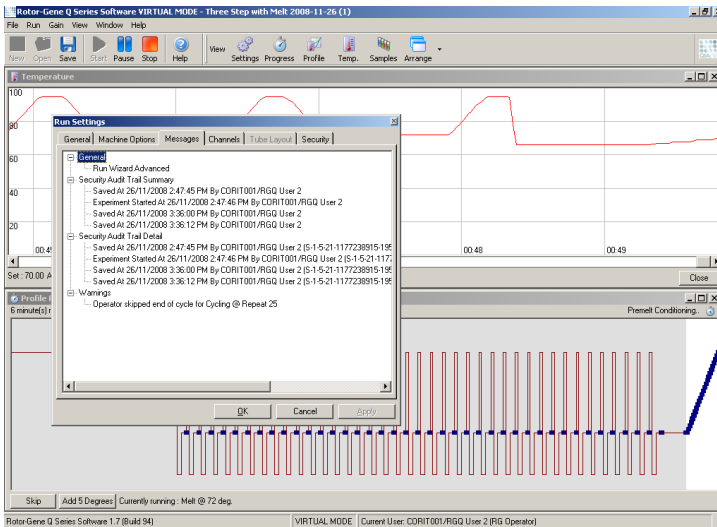
This can be used to monitor who has modified the contents of a file. The Security Audit Trail Detail contains more detail, such as the unique identifier of the user. This identifier is important to prevent users from creating an account with the same name on another computer and thereby impersonating another user. With this identifier, although usernames can still be the same, the account IDs will be different.

The identifier for the account CORIT001/RGQ User 2, S-1-5-21-1177238915-195, is shown in the details.
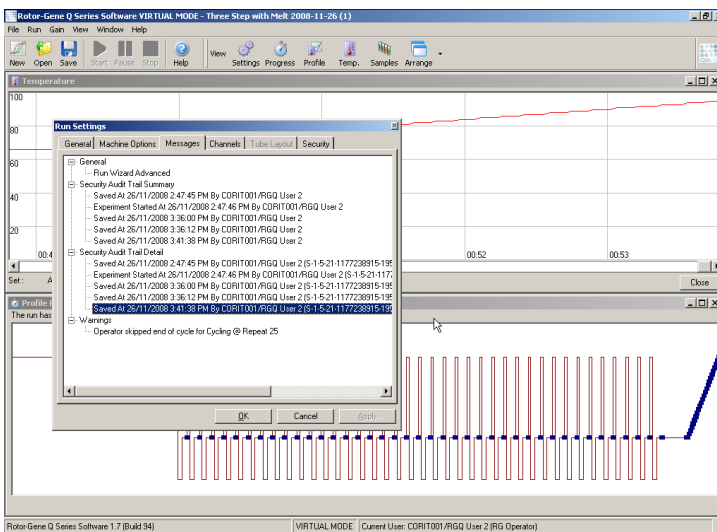
6.3.4 Run Signatures

The audit trail is stored in the Rotor-Gene Q run file. To avoid any unwanted modification of these files, they should be kept in a safe location accessible only by designated Windows accounts. However, if files are stored in a shared area, Run Signatures provide extra security. The screenshot shows the **Security** tab in Run Settings for a file with a Run Signature.
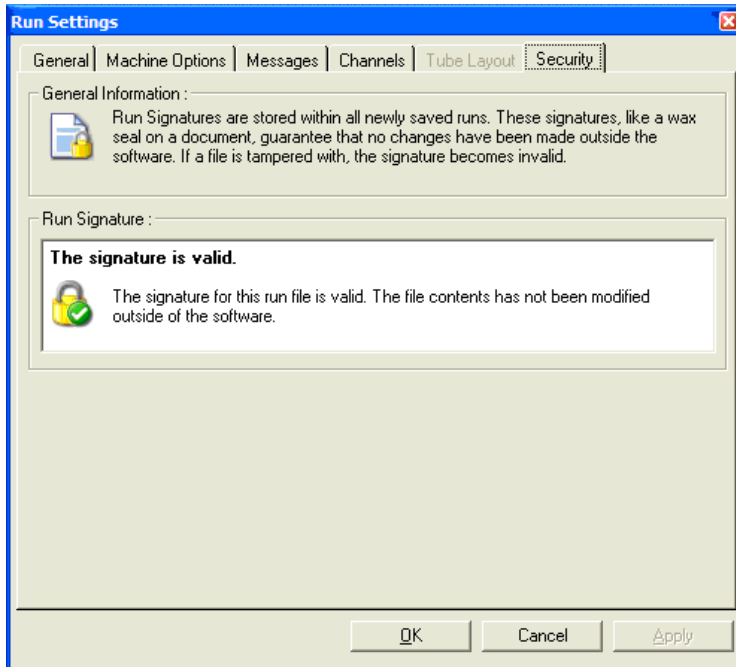
The Run Signature is a long series of characters that is generated every time the file is saved; it is linked to the contents of the file. For example, the signature for this file is 517587770f3e2172ef9cc9bd0c36c081. If the file is opened in Notepad and an edit is made (e.g., the run date is changed to three days earlier), the following message appears when the file is reopened:
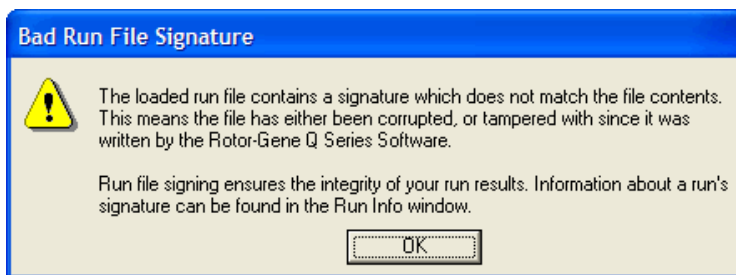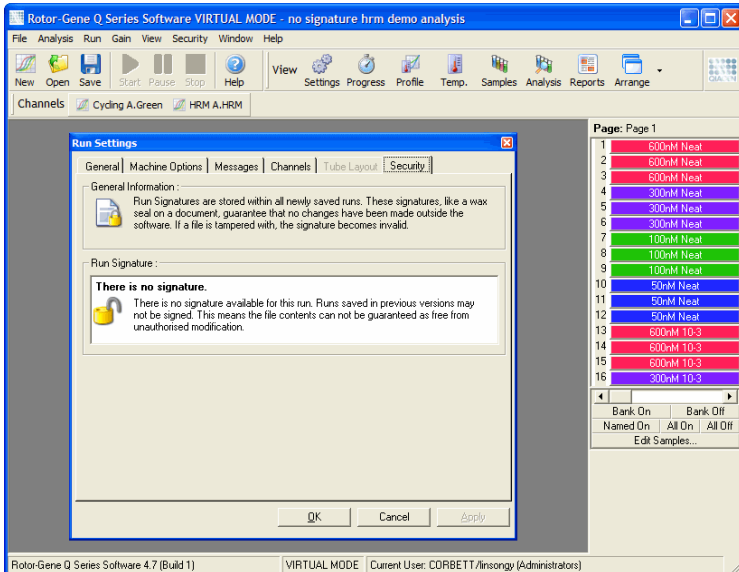
Note: If files are e-mailed, the encryption process can invalidate the signature. To avoid this, zip the file before e-mailing.

6.3.5   Sample locking

It is important to ensure that sample names are not accidentally or intentionally changed once a user has started a run. For this reason, the Rotor-Gene Q software provides sample locking. Sample names can be locked by any user but can only be unlocked by an administrator. For users who run their computers in administrator mode, this option is of limited value. To use this option, the computer must be configured securely, as described in the previous sections.

Note: If you wish to lock samples, do not run the software as an administrator. Create an account with RG Operator and RG Analyst groups, and keep the administrator password secret. Users will then require authorization from the administrator to unlock files.

When using the Advanced wizard, samples can by locked before starting a run by clicking **Finish and Lock Samples**.
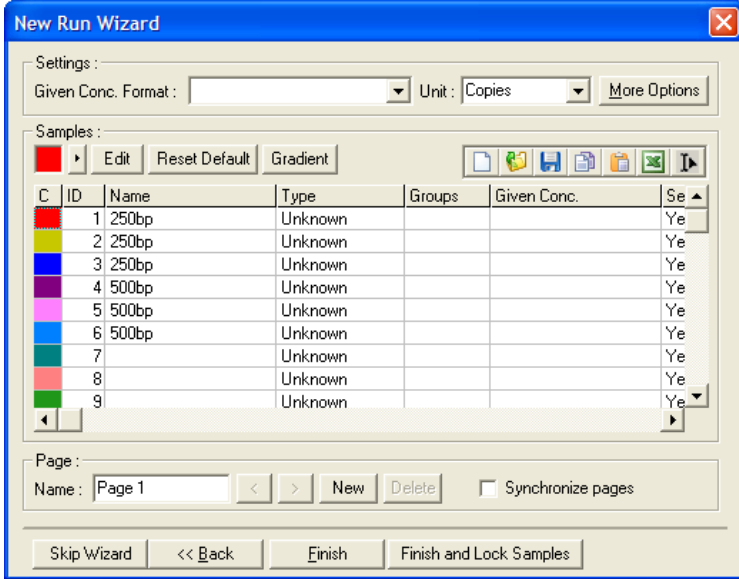
The following warning will appear. Click **Yes** to confirm.
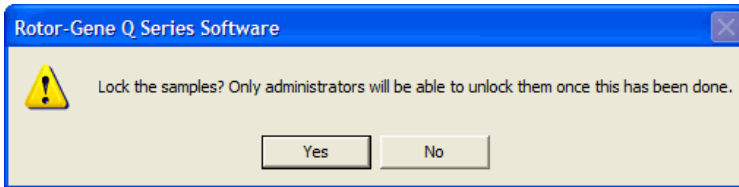
Once the samples are locked, it will not be possible to edit samples in the "Edit Samples" window.
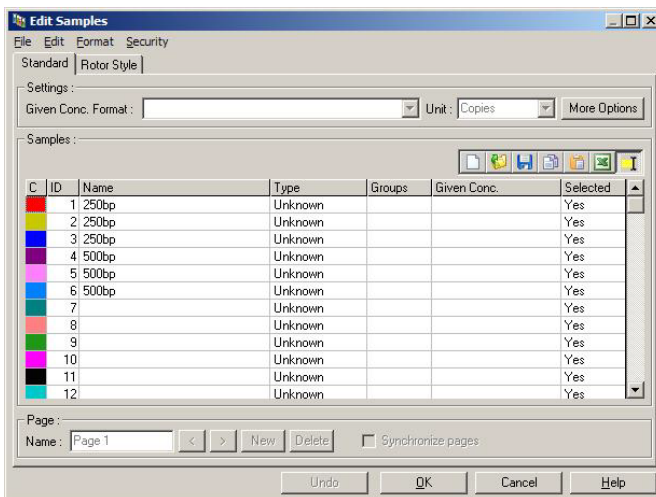
Samples can also be locked and unlocked in the "Edit Samples" window. However, only an administrator can unlock samples once they have been locked.
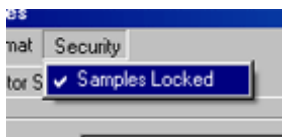
Any unauthorized change to the file will invalidate the Run Signature.

6.3.6 Locked templates

It is currently not possible for the user to create read-only template files using the Rotor-Gene Q software. However, if desired, it can be specified as a requirement that all runs should be performed using a specific template file. In order to ensure read-only access to this template, it should be stored on a network drive where users cannot modify data. Users can still run and modify their own profiles, while the template on a network drive such as this is protected. In order to track which template has been used, the Rotor-Gene Q software stores the name of the template file that was run. This information can be accessed by clicking the **Settings** button, which then enables the "Run Settings" window to be displayed. The template information is stored in "Other Run Information".
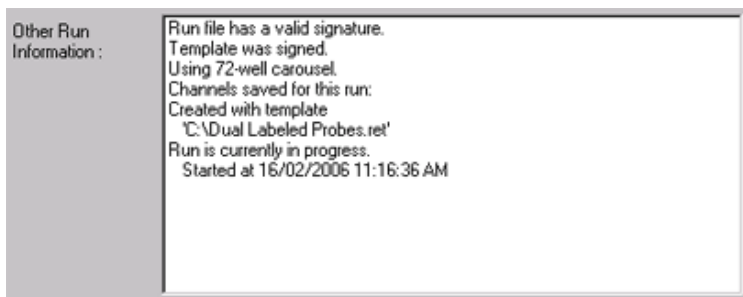
6.4 Gain menu

Click on the Gain menu to view the gain settings for the current run. This sets the gain of the specified channel before a run. Gain settings are retained from the last run. These can be modified if the run has not yet started or is still in the initial cycles. Use the up/down arrows next to each text field to modify the fields. Then click **OK**.

The gain can be changed during the initial cycles. A red line will be drawn in the appropriate channel, showing where the gain was changed. Cycles before the gain change will be excluded from analysis.
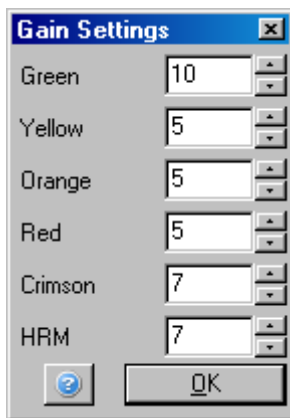
6.5 Window menu

This menu enables the windows to be tiled vertically or horizontally or arranged in a cascade. To access further options, click the arrow on the right of the **Arrange** button.

6.6 Help function

When using the Help button or Help menu, the following drop-down menu will open:
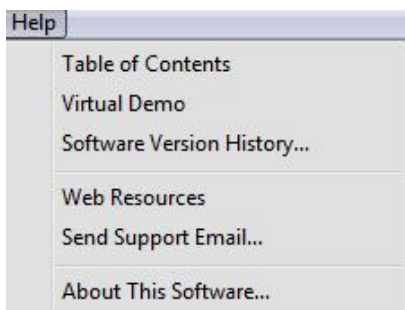
Table of Contents:	This provides access to the Help function.
Virtual Demo:	This links to a QIAGEN Web page with an interactive demonstration of the software.
Software Version History…:	This gives a brief overview of new features added since the previously installed software release.
Web Resources:	This opens a QIAGEN webpage in a new browser window, with 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.

6.6.1   Send Support EMail
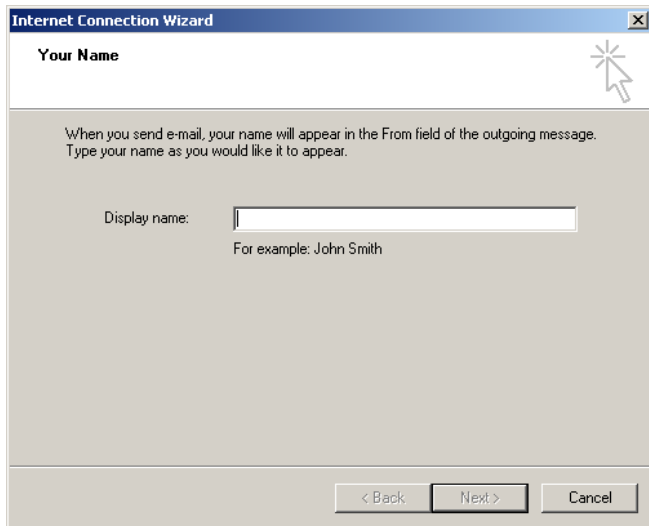
The Send Support Email option in the Help menu allows you to send to QIAGEN a support-request e-mail that includes all relevant information from a run.

The **Save As** option will save all the information to a file that you can copy into a disk or across a network, in case you do not have access to e-mail on the computer running the Rotor-Gene Q MDx.

If you use the support email function on the laptop computer provided optionally with the Rotor-Gene Q MDx (country dependent) for the first time, you have to configure your e-mail settings.
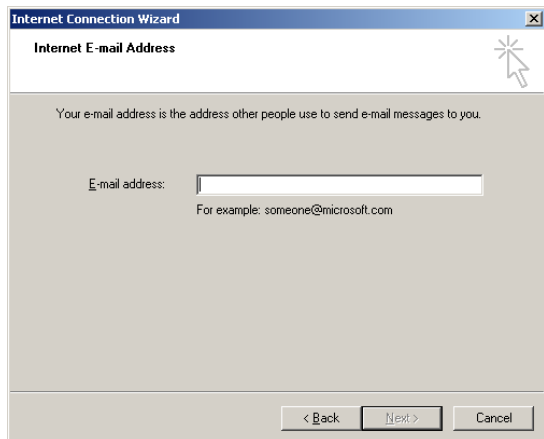
Configure the EMail Settings

Click the option **Send Support Email…**. The following window will open:

1. Type in your name and click **Next**. The "Internet E-mail Address" window will open.

2. Type in your e-mail address and press **Next**. The "E-mail Server Names" window will open.
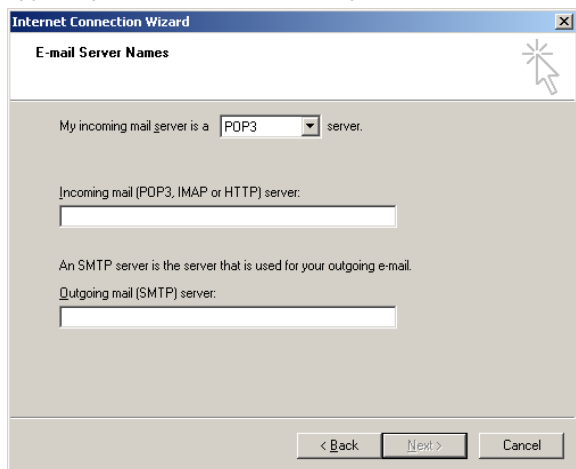
3. Select the type of mail server for incoming mails, and specify the server names for incoming and outgoing e-mails. Then press **Next**. The window "Internet Mail Logon" will open.
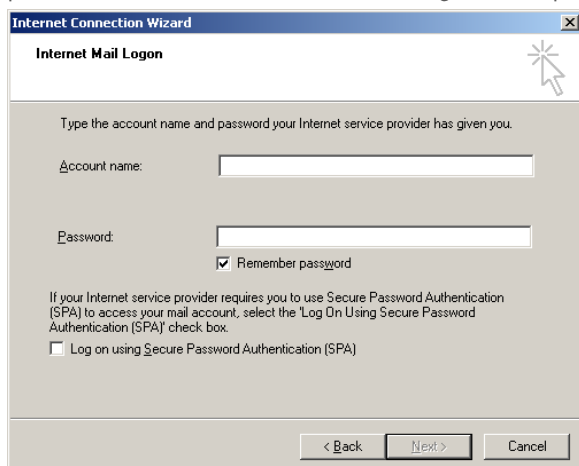
4. Enter your e-mail account name and password if your server uses secure password authentication. Then click **Next**. The "Congratulations" window will open.
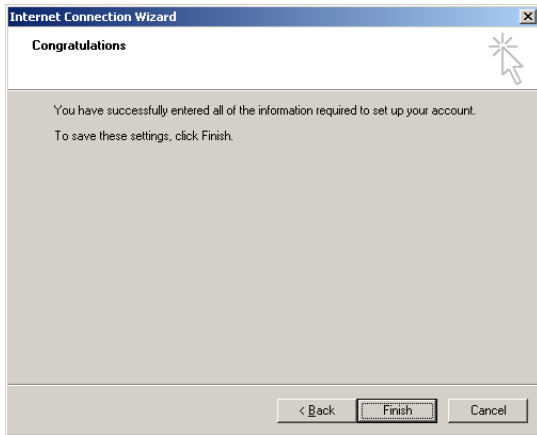
5. Confirm with **Finish** to complete the e-mail account setup.

Setting up in Outlook

1. Open "Outlook Express" from the Start menu (**Start** > **All programs** > **Outlook Express**).
2. Select **Tools**, and then **Options**. The window below appears.
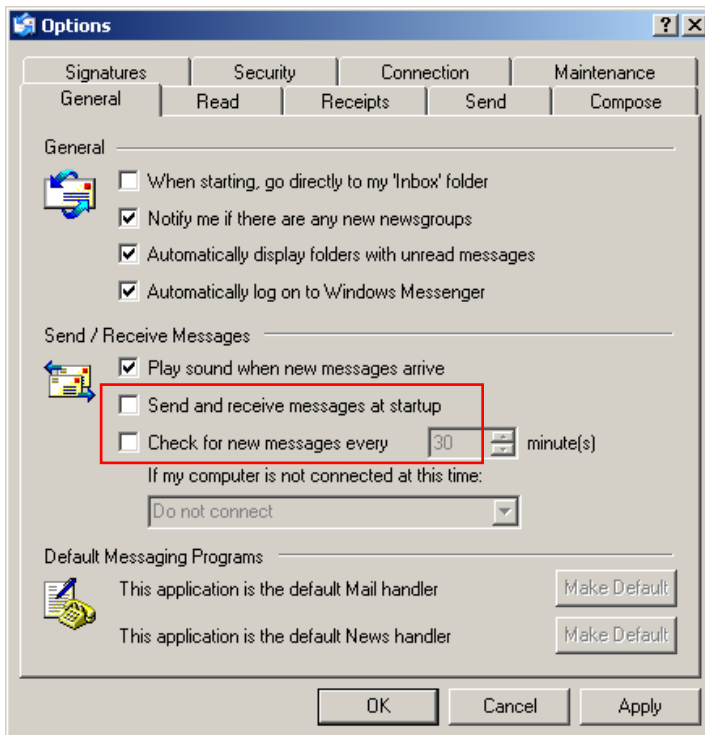
Important: To avoid any retrieval of e-mails during PCR runs, disable the default entries in the "Send/Receive Messages" screen.

3. Disable "Send and receive messages at startup".

4. Disable "Check for new messages every x minute(s)".

5. Confirm changes with **OK**.

6.7   Operating Procedures — Rotor-Gene AssayManager Software

See the *Rotor-Gene AssayManager 1.0 Core Application User Manual* or the *Rotor-Gene AssayManager v2.1 Core Application User Manual* for information about the relevant Rotor-Gene AssayManager software.

7 Additional Functions

7.1 Opening a second run

While performing a run, it is possible to open and analyze runs that were performed earlier. Several functions, such as **New** or **Start Run** buttons, are not activated in the second window. A new run can be started from the first window once the first run has finished.

7.2 Scaling options

To access "Adjust Scale", click on **Adjust Scale...** at the bottom of the main window, or right-click on the graph and select **Adjust Scale...** on the menu that appears. A scale can be manually entered in the window that appears.
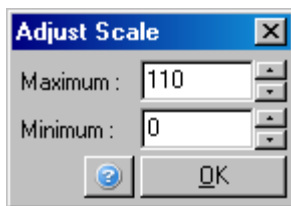
To access "Auto-Scale", click on **Auto-Scale...** at the bottom of the main window, or right-click on the graph and select **Auto-Scale...** on the menu that appears. "Auto-Scale" attempts to fit the scale to the maximum and minimum readings in the data.

To access "Default Scale", click **Default Scale...** at the bottom of the main window, or right-click on the graph and select **Default Scale...** on the menu that appears. "Default Scale" resets the scale to display from 0 to100 fluorescence units.

7.3   Exporting graphs

7.3.1   Picture export

The following steps describe how to save an image:

1. Right-click on the image and select **Export** from the menu that appears.

2. The "Export Dialog" window appears. Select the desired format from the "Format" list.
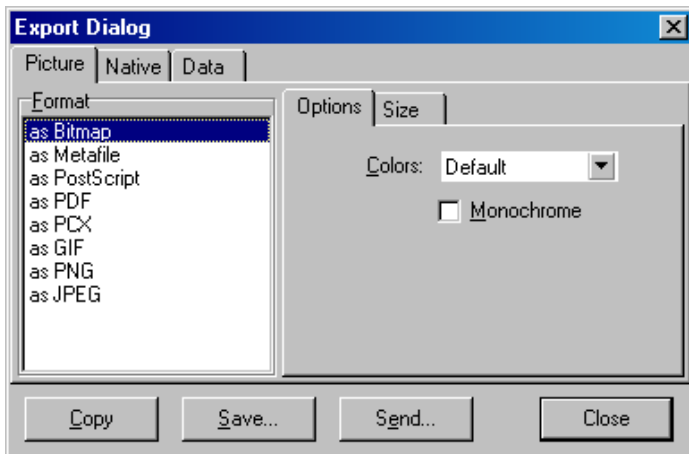
3. Select the **Size** tab and specify the desired size.
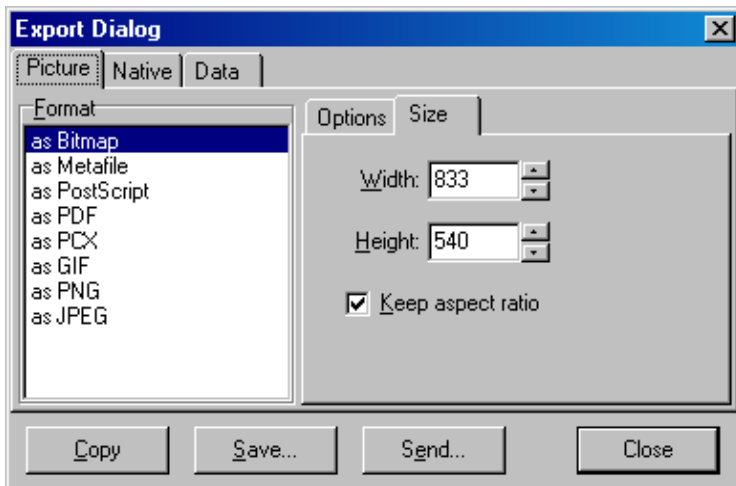
4. Check the "Keep aspect ratio" checkbox to keep the image in the correct proportion when adjusting its size.

5. Click "**Save**", and then select a file name and location for the file in the dialog box that appears.

If a higher resolution image is required, we recommend either increasing the size of the image until it meets your requirements or saving the graph as a metafile (***.emf**, ***.wmf**). This is a vector-based format that can be opened in software such as Adobe® Illustrator®, allowing the user to create an image of any resolution.

Native format export

Graphs in the Rotor-Gene Q software use the third party TeeChart® component developed by Steema software. To save a graph in native format, select the **Native** tab in the "Export Dialog" window (see previous screenshot), and then click **Save**. Native format is the standard TeeChart file format. This allows the user to use TeeChart Office from Steema software. TeeChart Office is available as freeware and is installed as part of the Rotor-Gene Q software package. To access the software, click on the TeeChart icon on the desktop.

TeeChart Office enables manipulation of exported graphs, including changing colors of curves, adding annotations, changing fonts and adjusting data points.
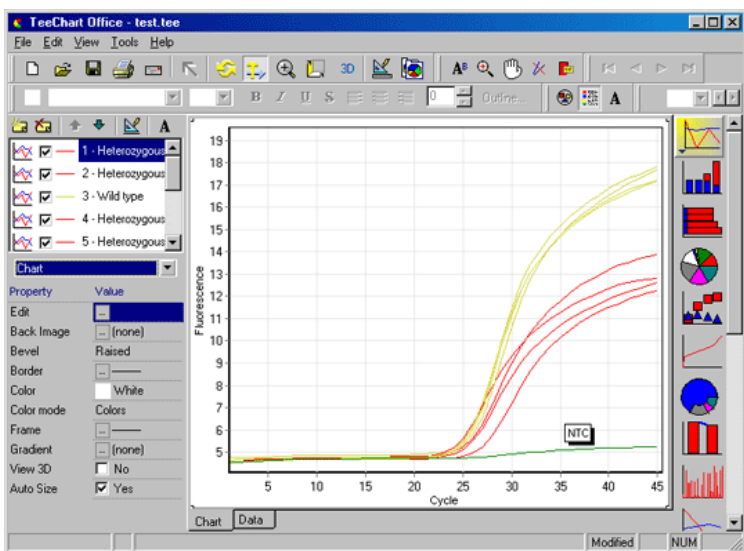
Data export

To export data in various formats, select the **Data** tab in the "Export Dialog" window. The exported file contains the raw data points used in the graph.
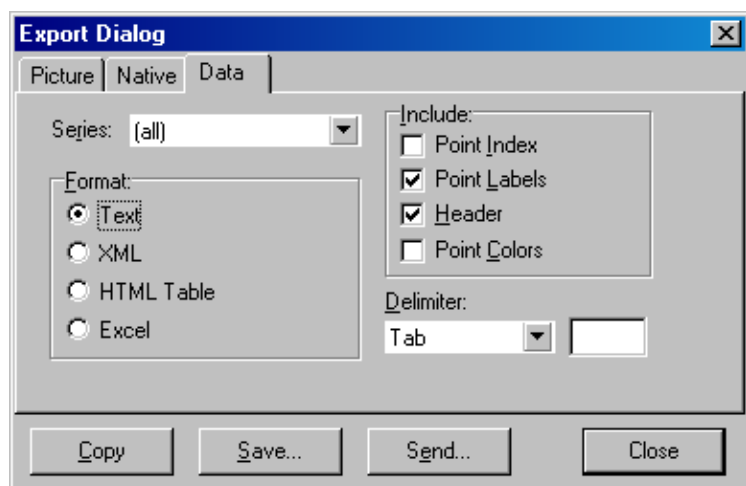
Exporting raw data and analysis data can also be performed by selecting **Save As** under the **File** menu (see Section 6.2).

7.4   Spanner/Wrench icon

The spanner/wrench icon appears at the bottom left of the main window. Clicking on the spanner/wrench icon enables several options. These options can also be accessed by right-clicking on the graph.
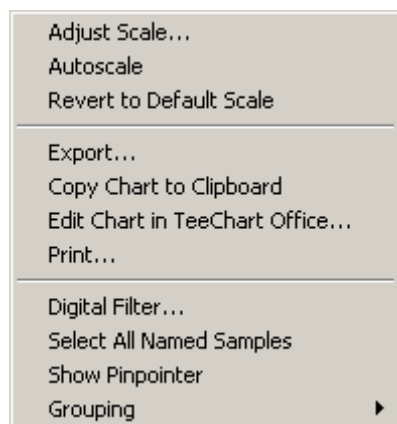
Adjust Scale, Autoscale…, Revert to Default Scale:	See Section 7.2.
Export…:	This saves the graph in a variety of formats (see Section 7.3).
Copy Chart to Clipboard:	This copies the graph image to the clipboard.
Edit Chart in TeeChart Office…:	This opens the graph directly in TeeChart Office for editing (see Section 7.3).
Print…:	This prints the graph.
Digital Filter…:	This modifies the currently selected digital filter on the graph. The digital filter smoothes data using a sliding window of points.
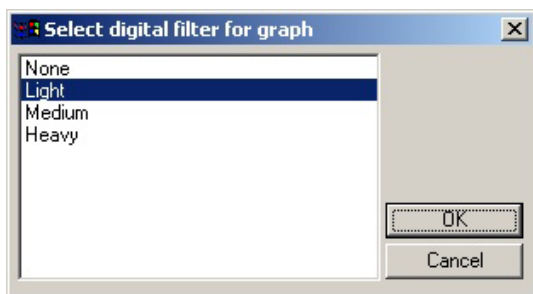
Show Pinpointer:	This opens a window that displays the exact coordinates of the mouse pointer position.
Grouping:	This visually groups samples that have identical names. This can be useful on full rotor runs. Selecting this option does not affect calculated values.

7.5 Selected area options

An area of a graph can be selected by clicking and holding the left mouse button and dragging the mouse pointer. The following options appear:
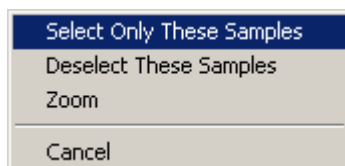
Select Only These Samples: Samples outside the selected area are deselected.

Deselect These Samples: All samples in the selected area are deselected.

Zoom: This zooms in on the selected area of the graph. Click the **Default Scale** button to zoom out.

8   Maintenance Procedures

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

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

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

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

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

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

9 Optical Temperature Verification

Optical Temperature Verification (OTV) is a method that verifies the in-tube temperature in a Rotor-Gene Q MDx. Validation of in-tube temperature can be an important procedure in certified laboratories. OTV is performed using a Rotor-Disc OTV Kit (see Appendix C – Rotor-Gene Q MDx Products, Accessories, and Consumables).

In the following sections, only a short introduction to the OTV principle is given. Performance of the OTV procedure is explained in the Rotor-Gene Q MDx 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.

9.1 OTV principle

OTV uses the optical properties of three 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 toward the detector, increasing fluorescence. When the in-tube temperature reaches the TLC transition point, the TLC becomes transparent and light passes through the sample rather than being reflected toward the detector, resulting in a decrease in fluorescence. The change in fluorescence is used to determine the precise transition temperature of each TLC. The transition temperature is compared with the temperature reported by the factory calibration file for the OTV Rotor-Disc to verify whether the Rotor-Gene Q MDx is within temperature specification.

9.2 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 (Rotor-Gene 3000 instrument or Rotor-Gene Q/6000 instruments)
  - A CD that contains the following files: OTV Rotor serial number and expiry date file (*.**txt**); OTV test template file (*.**ret**); Product Sheet (*.**pdf**); factory calibration file (*.**rex**)
  - Product Sheet
- Rotor-Gene Series Software Version 1.7 or above, which contains the easy-to-use OTV Rotor wizard
- Rotor-Disc 72 Rotor
- Rotor-Disc 72 Locking Ring

* 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.

9.3   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.
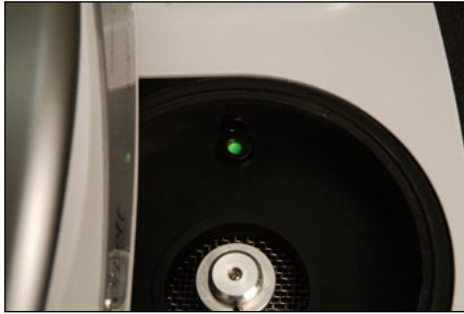
3. Access the Advanced wizard by selecting the **Advanced** tab in the "New Run" window. In the Advanced wizard, click on **Instrument maintenance** and then **OTV**. The wizard prompts for the OTV serial number. This number can be read from the label on the OTV Rotor-Disc or can be imported from the CD by clicking on **Browse** and choosing the **.otv** file provided on the CD. Once the number is entered, click **Start**.
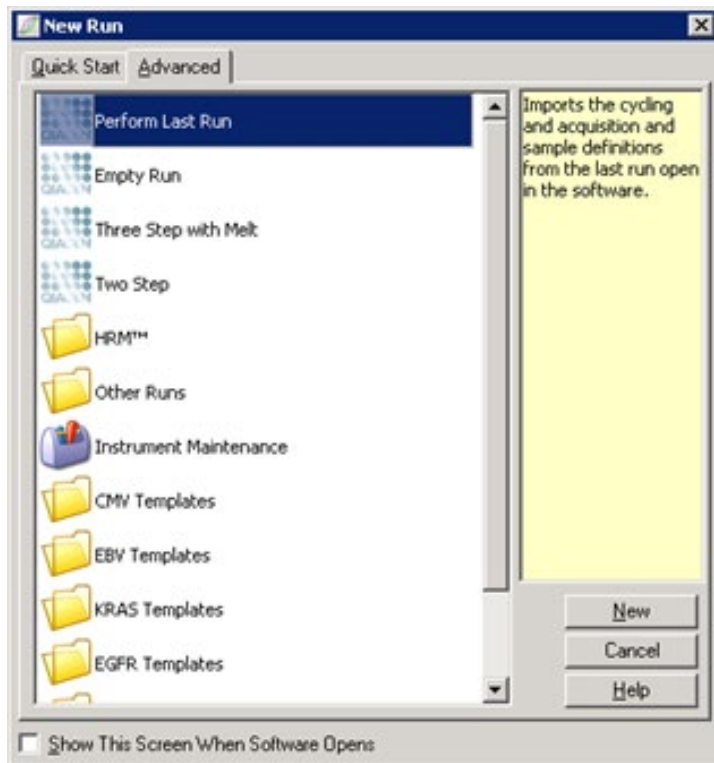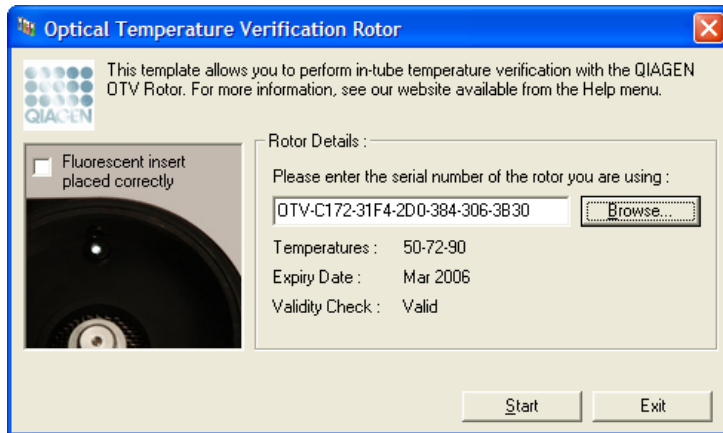
4. The software then prompts for a file name for the run. Then the run begins.

5. The run performs a series of melts that determine the thermal characteristics of the Rotor-Gene Q MDx.
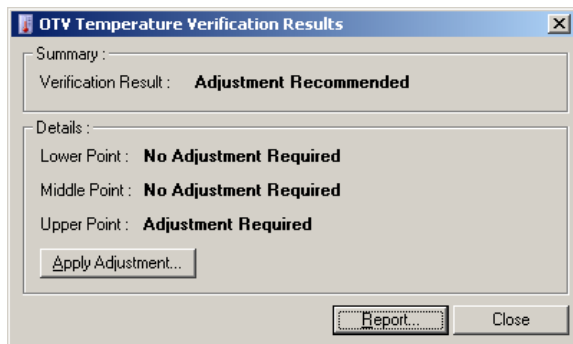
6. When the run is finished, the software indicates whether the Rotor-Gene Q MDx is within specification.

7. If adjustment is required, the user should 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.

8. When the Rotor-Gene Q MDx is within specification, a report of the run can be reviewed and printed.

10 Troubleshooting

10.1 Log archives

The software keeps an unmodified record of each run, along with diagnostic information, in its Log Archive repository. By using the Help, Send Support Email option, you can send an e-mail along with all the necessary diagnostic information to QIAGEN Technical Service (see Section 6.6.1).

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.

10.2 General instrument errors

	Comments and suggestions
Can't open the serial port<COMPORT>	This error occurs on 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. Reconnect or replace the cable. Reinstall the appropriate drivers. Start the software in "Virtual Mode" and select **Setup/Auto-Detect** button from the File menu to reset the configured COM port.
Chamber lid open 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 software has detected the lid is open in the middle of a run. Reset the machine and restart the software.
Chamber lid open 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. Close the lid of the instrument chamber and then click **Continue**.
Communication corrupted	This error occurs when the data received from the instrument do 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 Services.

Communication out of sequence

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.

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.

Communication protocol error

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.

Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the communication protocol or the instrument.

Detector motor jam, stopped machine

This error can occur when the Rotor-Gene Q MDx is started immediately after delivery in cold climates.

In this case, allow the instrument to acclimatize to room temperature for at least an hour before turning the instrument on.

If the error persists, please contact your distributor or QIAGEN Technical Services.

Fatal hardware malfunction

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 software has detected a fatal hardware malfunction and has activated a safe-protection procedure to turn off the machine.

Turn off the instrument immediately and contact your distributor or QIAGEN Technical Services.

Machine error

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 software has detected errors on the machine that could not be recovered from. The software has stopped the run.

Try another run. If the problem persists, contact your distributor or QIAGEN Technical Services and attach a support archive file.

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 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.

Common software-related causes include processor-intensive tasks, such as antivirus resident protection or antivirus scheduled scans, wireless cards, or infrared cards.

Disable or uninstall the relevant processor-intensive software/task.

Reset the instrument and restart the software.

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.

Reconnect the serial or USB cable to the back of the computer and then click the "Continue" button.

Object variable or with block variable not set

This error occurs on software startup if the default experiment template file has become corrupt. This may happen if the 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 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 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.

Shutdown timeout

The instrument has exceeded the expected time to shutdown. Please reset the machine, and reset the software.

This error occurs when the software has issued shutdown command to shut down the instrument and the machine keeps sending data back after an expected grace period of time.
Reset the machine and restart the 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 software has detected the chamber temperature has increased to above a safe level and hence activated a safe-protection procedure.
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 software has detected that the thermistor is open and therefore cannot read the temperature; the software has then activated a safe-protection procedure to turn off the machine.
Turn off the instrument immediately and contact your distributor or QIAGEN Technical Services.

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 software has made all possible attempts to recover and failed.
Further investigations are required by a QIAGEN Field Service Specialist to diagnose the problem with the instrument.
Please contact your distributor or QIAGEN Technical Services.

Rotor-Gene AssayManager troubleshooting

See the *Rotor-Gene AssayManager 1.0 Core Application User Manual* or the *Rotor-Gene AssayManager v2.1 Core Application User Manual* for information about the relevant Rotor-Gene AssayManager software.

10.3 Rotor-Gene Q software messages

The following is a list of use, warnings and other messages that may appear in the Rotor-Gene Software during hardware and software operation. Any part of the message that is variable, for example, characteristic error descriptions, are given in brackets (e.g., "< ERROR DESCRIPTION >").

	Message text
General message	
1	A raw channel already exists for this page. If you would like to recreate this page, you must first delete the raw channel via the **Options** button, and then try again.
2	A serious problem has occurred which requires shutting down the software. After you click **OK**, your current work will be saved, and the machine will be turned off, if possible. If this problem persists, please contact your distributor.
3	Cannot delete this page. There must always be at least one sample page.
4	Can't connect to instrument on serial port <COMPORT>. Check the machine is correctly plugged into the back of the computer, then retry
5	Can't open the serial port <COMPORT> to connect to the instrument. Check you do not have any communications software open, then retry.
6	Could not save to run because some data on the form was invalid. Please check your entries then try again.
7	Couldn't save file. Confirm the disk has enough space and that it is free of errors.
8	E-mail application could not be started. Confirm that it has been correctly installed on your computer.
9	Encountered an error during run: <ERROR DESCRIPTION>. The run will continue, and a message will be logged in the messages tab of Run Info.
10	Instrument was not detected. Please ensure you have correctly connected the instrument, and that the instrument is turned on.
11	Logging is currently disabled due to a previous error. Archived logs cannot be viewed until the software has been restarted.
12	Not all samples could be normalized as the fluorescent level was too low.
13	Only runs performed with the same rotor as the current run may be imported.
14	Please note that log files for the current run will not be available until it has completed.
15	Please type valid number of times to repeat. It should be more than 0.
16	Problem encountered while updating log data. Logging has been disabled, but will be reenabled on the next run.
17	Run file signing ensures the integrity of your run results. Information about a run's signature can be found in the Run Info window.

	Message text
18	Sample ID is locked. Cannot paste over locked samples.
19	TeeChart Office has not been installed on this computer. Please re-install the Rotor-Gene software.
20	The COM port configured for the instrument is not selected. You must select a COM port.
21	The loaded run file contains a signature which does not match the file contents. This means the file has either been corrupted, or tampered with since it was written by the Rotor-Gene software.
22	The loaded run file has no signature. The contents of this file cannot be guaranteed.
23	The Machine serial number is not valid. Serial numbers must be at least 6 digits long.
24	The machine will now be cooled to <TEMPERATURE> degrees. The chamber and surfaces will still be very hot when opening the machine. Please exercise due caution and wear protective gloves if touching any of the surfaces or tubes.
25	The regional settings for your computer are conflicting. Ensure your currency and numeric decimal placeholders are matching.
26	The serial number entered in the welcome screen <SERIAL NUMBER1> does not match the serial number stored in the attached machine <SERIAL NUMBER2>. The computer's serial number has now been updated to match the connected machine.
27	There was a problem communicating with the communication board. You should reboot the computer and then retry.
28	There was a timeout attempting to talk to the instrument. Check it is correctly plugged in.
29	This feature cannot be used in virtual mode.
30	This profile file was created in a more recent version of the Rotor-Gene software. Certain aspects may not load correctly.
31	This run file was created in a more recent version of the Rotor-Gene software. Certain aspects of the run may not load correctly.
32	This sample file was created in a more recent version of the Rotor-Gene software. Certain aspects may not load correctly.
33	This software will perform basic simulation of a machine for training and demonstration purposes. You can disable this setting via the Setup screen, accessible from the File menu.
34	This template was created in a more recent version of the Rotor-Gene software. Certain aspects of the template may not load correctly.
35	Unable to load this sample file as tube layouts do not match. Load these samples before starting the run.
36	Unable to open communications with the machine because another application is already using <COMPORT>. Check you do not have any applications running that use the same serial port, then retry.
37	Unrecoverable errors were encountered while attempting to load the file. The file was not loaded.

	Message text
38	You cannot stop the program while the run is in progress.
39	You have insufficient rights to use the software. Please contact the domain administrator to set up groups.
40	You must have performed a quantitation analysis to export samples.
41	You must select a COM port before continuing.
42	Your run could not be saved to its default location. On the following window, select an alternative location to save your run.
43	Your settings have been saved. Click **OK** to close the software.
44	You must select a rotor before continuing.
45	You cannot start the run until you tick the checkbox to confirm that the locking ring has been attached.

Autogain adjustment messages

46	Manual gain adjustment uses the channels you have defined in your profile. As you have not defined any acquisition points in your profile, you cannot perform manual gain adjustment.
47	The temperature you entered was not saved because it was outside the range of the machine. Enter a valid temperature.

Editor messages

48	Please enter a valid group code. Group codes must be a maximum of 5 characters, and contain no spaces or commas.
49	Please enter a valid group name. Group names cannot contain commas or be empty.

Optical denature calibration messages

50	Unable to set as optical denature point due to calibration failure. Please enter a valid number of seconds to hold. It should be a positive value.
51	A melt peak could not be detected during Optical Denature Calibration. This may be because the incorrect tube was selected for calibration, or that an inappropriate chemistry was used for this sample. A timed step profile was run instead.

OTV messages

52	You must enter a valid OTV serial number to perform the run.
53	This temperature verification file has been corrupted. Please uninstall and re-install the Rotor-Gene software to correct this error.
54	This run file is not correctly signed. Results cannot be displayed.
55	You cannot start until you tick the checkbox to confirm that the fluorescent insert has been placed correctly.
56	This rotor has expired. Please contact your distributor to obtain a replacement.

Security menu messages

57   Could not open the Windows user/group manager.

58   Could not create groups.

59   Cannot modify access of inbuilt accounts.

Analysis menu

60   You have only selected one channel for analysis. To select multiple channels, drag a rectangle around the channels you wish to display in the analysis selection window.

61   You have selected multiple channels for analysis. This analysis technique only allows single channels to be analyzed.

Concentration measurement messages

62   Concentration Measurement performs auto-gain optimization on the first rotor position. Ensure you have your highest concentration standard in the first rotor position.

End-point analysis messages

63   To use end-point analysis you must have positive and negative controls in each channel. To define these controls click **OK**.

64   You have not defined any positive controls. You must define positive controls for each channel you are analyzing.

65   You have not defined any negative controls. You must define negative controls for each channel you are analyzing.

66   You have not defined any NTC controls. You must define NTC controls for each group.

Melt analysis messages

70   The genotypes cannot be defined until bins have been placed. Please define all bins and then try again.

71   You must enter an abbreviation for <GENOTYPE NAME> genotype.

Scatter plot analysis messages

72   Scatter plot analysis requires exactly 2 channels to be selected. To select multiple channels, drag a rectangle around the channels you wish to display in the analysis selection window, or click while holding the SHIFT key on each channel.

Quantitation analysis messages

73   The auto-find threshold feature requires that you have defined at least 2 selected standards. To set this up, right-click on the sample list and select **Edit Samples...**

11 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.
Bins	In a melt analysis, bins are set to define a region where a melt peak is expected to occur. Genotypes can be defined based on the presence of peaks in certain bins or in combinations of bins.
CE-IVD	Compliance with the in vitro diagnostic medical device European Directive 98/79/EC.
Channel	A channel consists of a light emitting diode (LED) with an excitation filter paired with an emission filter. The LED and excitation filter excite samples at a given wavelength. Fluorescence emitted by samples is passed through the emission filter, before being detected by a photomultiplier.
Gain	The Rotor-Gene Q MDx uses a photomultiplier to collect fluorescence photons and convert them to electronic signals. The gain is a setting that determines the sensitivity of the photomultiplier. If the gain is set too high, the signal is oversaturated. If the gain is set too low, it is not possible to differentiate signal from background noise.
Gain Optimisation	Gain Optimisation is a process that dynamically adjusts the gain setting, allowing an appropriate setting to be selected which results in optimal signal detection.
Loading Block	Loading Blocks are aluminum blocks available in different formats which are used to hold tubes or Rotor-Discs during reaction setup. Rotor-Disc Loading Blocks are also used with the Rotor-Disc Heat Sealer to heat seal Rotor-Discs.
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 or Rotor-Discs 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.
Rotor-Disc	Rotor-Discs are circular plates of vertically oriented reaction wells. Rotor-Disc formats for 72 and 100 reactions are available. Rotor-Discs are sealed using Rotor-Disc Heat Sealing Film and the Rotor-Disc Heat Sealer.
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.
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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) Power consumption 60 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages.
Fuse	F5A 250 V fuse
Heat dissipation/ thermal load	**Average**: 0.183 kW (632 BTU/hour) **Peak**: 0.458 kW (1578 BTU/hour)
Overvoltage category	II
Air temperature	18–30°C (64–86°F)
Relative humidity	10–75% (noncondensing)
Altitude	Up to 2000 m (6500 ft.)
Place of operation	For indoor use only
Pollution level	2

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

Mechanical data and hardware features

Dimensions	Width: 370 mm (14.6 in.) Height: 286 mm (11.3 in.) Depth (without cables): 420 mm (16.5 in.) Depth (door open): 538 mm (21.2 in.)
Weight	12.5 kg (27.6 lb.) standard configuration
Capacity	Up to 100 samples per run using a Rotor-Disc 100

Thermal specifications

Temperature range	35–99°C (95–210.2°F) (50–99°C [122–210.2°F] for cycling applications)
Temperature accuracy	±0.5°C (calibrated using Rotor-Disc OTV procedure)
Temperature resolution	±0.02°C (smallest programmable increment)
Temperature uniformity	±0.02°C

Optical specifications

Excitation sources	High energy light-emitting diodes
Detector	Photomultiplier
Acquisition time	4 s

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.

Electronic Equipment Disposal

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. 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.

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.

Liability Clause

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

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

Appendix B — Mathematical Techniques

This appendix describes the mathematical techniques used in more detail.

Quantitation

Calculated concentrations are obtained from a simple linear regression model, with the known values the log concentrations (x) and the experimental values the C_T values (y).

The log concentrations and C_T values of the standards are used to construct a model in the form:

y = Mx + B

Confidence intervals for calculated concentrations

We use the following confidence interval $100(1-\alpha)\%$ for an estimate of a new observation x0 from the standard curve:

$$\frac{Y_0 - \hat{\beta}_0}{\hat{\beta}_1} \pm \frac{S}{\hat{\beta}_1}(1 + \frac{1}{n} + \frac{(x_0 - \bar{x})^2}{S_{xx}})^{\frac{1}{2}} t_{n-2,\alpha/2}$$

This is the confidence interval for the concentration of a single unknown.

Suppose now we have k further observations at x = x0 and we denote their average by $\bar{Y}_0$. Then,

$$\bar{Y}_0 \sim N(\beta_0 + \beta_1 x_0, \frac{\sigma^2}{k})$$

and arguments similar to above give:

$$\frac{Y_0 - \hat{\beta}_0}{\hat{\beta}_1} \pm \frac{S}{\hat{\beta}_1}(\frac{1}{k} + \frac{1}{n} + \frac{(x_0 - \bar{x})^2}{S_{xx}})^{\frac{1}{2}} t_{n-2,\alpha/2}$$

This formula determines how confidence intervals for concentrations of replicate unknowns are determined.

For estimation of standards, a tighter confidence interval can be obtained:

$$\frac{Y_0 - \hat{\beta}_0}{\hat{\beta}_1} \pm \frac{S}{\hat{\beta}_1}\left(\frac{1}{n} + \frac{(x_0 - \bar{x})^2}{S_{xx}}\right)^{\frac{1}{2}} t_{n-2,\alpha/2}$$

The implication of this formula is that adding replicates to an standard individual concentration reduces the width of the interval for all estimates, as n is increased. Adding a large number of replicates to an unknown reduces its uncertainty to that of a single standard. The extra replicates reduce the uncertainty due to the unknown not forming part of the linear model.

Confidence intervals for C_T values

We assume that error in replicate C_T values is linear and normally distributed.

We therefore use the One-Sample t Confidence Interval. Let μ be the mean value for a replicate's C_T values $(x_0 \ldots x_{n-1})$. Then, a $100(1-\alpha)\%$ confidence interval for a C_T value μ is:

$$\left(\bar{x} - t_{\alpha/2,n-1} \cdot \frac{s}{\sqrt{n}}, \ \bar{x} + t_{\alpha/2,n-1} \cdot \frac{s}{\sqrt{n}}\right)$$

We would like to thank Peter Cook from the Mathematics department of the University of NSW, Sydney, Australia, whose help was invaluable in verifying the mathematical approaches used.

Appendix C – Rotor-Gene Q MDx Products, Accessories, and Consumables

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

Ordering Information

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
Rotor-Gene Q MDx (US) System	Real-time PCR cycler with 6 channels,* laptop computer, software, accessories, 1-year warranty on parts and labor, installation and training	9002036
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
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.

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

Document Revision History

Date	Description of changes
11/2023	Removal of information regarding Windows 7 and non-applicable software and analysis sections. Update to the wording in the intended use
09/2018	This version has been updated to include Windows 10 as an operating system.

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