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Rotor-Gene[®] Q MDx Installation Guide (US)

For use with Rotor-Gene Q Software version 2.3.4 or higher



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Product Warranty and Satisfaction Guarantee

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A copy of QIAGEN terms and conditions can be obtained on request, and is also provided on the back of our invoices. If you have questions about product specifications or performance, please call QIAGEN Technical Services (see back cover or visit www.qiagen.com) or your local distributor.

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At QIAGEN, we pride ourselves on the quality and availability of our technical support. Our Technical Service departments are staffed by experienced scientists with extensive practical and theoretical expertise in sample and assay technologies and the use of QIAGEN products. If you have any questions or experience any difficulties regarding Rotor-Gene Q MDx instruments or QIAGEN products in general, please 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 or call one of the QIAGEN Technical Service departments or local distributors (see back cover or visit www.qiagen.com).

Introduction

About this installation guide

This guide provides an overview for installing Rotor-Gene Q MDx instruments.

Note: Please consult the *Rotor-Gene Q MDx User Manual (US)* for additional details regarding installation, such as site and AC power requirements. Pay particular attention to the safety information.

Information about Rotor-Gene Q MDx instruments is provided in the following sections:

- Unpacking the Rotor-Gene Q MDx
- Hardware Installation
- Installing Rotor-Gene Q Software
- Connecting the Laptop/Computer to the Rotor-Gene Q MDx
- Launching Rotor-Gene Q Software
- Rotor-Gene Q Software Assay Packages
- Launching Rotor-Gene AssayManager®
- Rotor-Gene AssayManager Assay Profiles and Plug-ins
- Additional Software on Computers Connected to Rotor-Gene Q MDx Instruments
- Updating Rotor-Gene Q Software and Rotor-Gene AssayManager Software

Unpacking the Rotor-Gene Q MDx

The Rotor-Gene Q MDx is delivered with all necessary accessories for instrument setup and for performing a run. A list of accessories is provided in the Rotor-Gene Q MDx box.

Note: Check the items on this list to ensure that all accessories are present.

Note: Check that the instrument and delivered accessories are free from transport damage before installation.

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

- *Rotor-Gene Q MDx Installation Guide (US)*
- CD (Rotor-Gene Q software)
- CD (*Rotor-Gene Q MDx User Manual [US]*)
- CD (*Rotor-Gene Q User Manual*)
- Loading Block 96 x 0.2 ml Tubes*
* Not intended for use with FDA cleared or approved nucleic acid tests
- Loading Block 72 x 0.1 ml Tubes
- Rotor Holder (dismantled for safe transport)
- 36-Well Rotor (this rotor is red in color)*
* Not intended for use with FDA cleared or approved nucleic acid tests
- 36-Well Rotor Locking Ring*
* Not intended for use with FDA cleared or approved nucleic acid tests

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

- USB and RS-232 serial cable
- International power cable set
- PCR Tubes, 0.2 ml (1000)*
* Not intended for use with FDA cleared or approved nucleic acid tests
- Strip Tubes and Caps, 0.1 ml (1000)

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

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

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

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

Rotor-Gene AssayManager software is supplied on a separate installation DVD upon ordering.

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

Hardware Installation

Note: 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 one hour before turning the instrument on.

1. Place the Rotor-Gene Q MDx on a level surface that is vibration free.

Note: Ensure that there is sufficient space behind the instrument for the lid to open fully.

Note: Ensure that the power switch at the back of the instrument can be easily reached.

Note: Do not obstruct the back of the instrument. Ensure that the power cord can be easily detached if required, to disconnect power to the instrument.

2. Install Rotor-Gene Q software and Rotor-Gene AssayManager, if applicable.

Install the Rotor-Gene Q software and connect the computer/laptop and instrument as described below.

Install Rotor-Gene AssayManager and plug-ins as described in the "Rotor-Gene AssayManager Core Application User Manual (US) IVD" in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

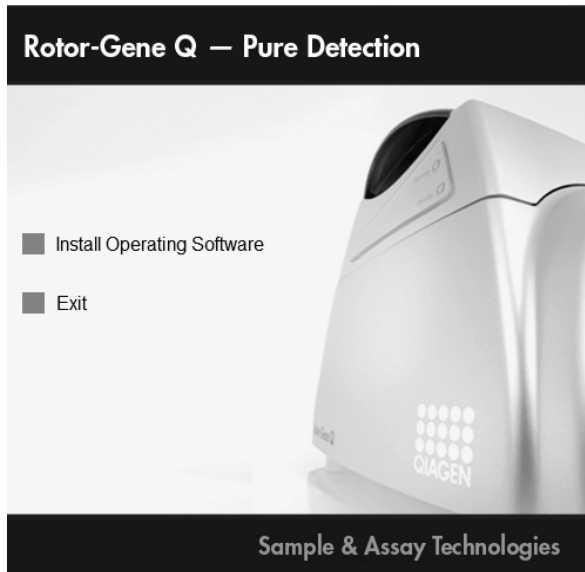
Installing Rotor-Gene Q Software

The Rotor-Gene Q MDx can be connected to a computer either via a USB interface (recommended) or via an RS-232 serial interface. Rotor-Gene Q software should be installed as described below before connecting the laptop computer to the Rotor-Gene Q MDx.

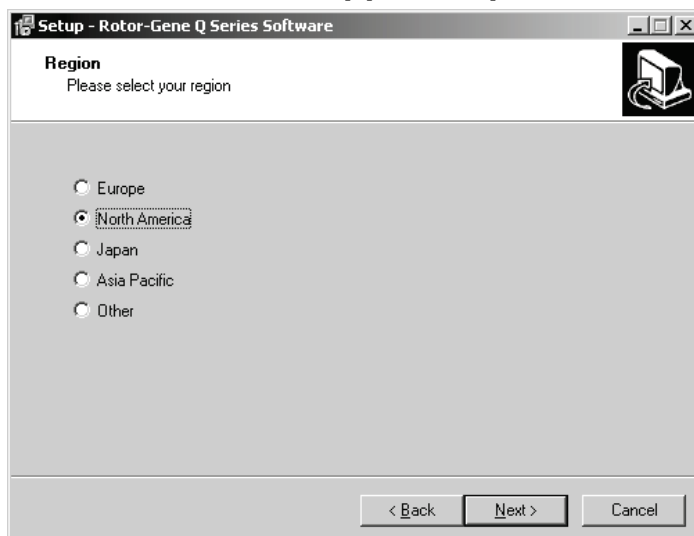
The Rotor-Gene Q software can be downloaded from the QIAGEN website and transferred to a virus-free removable storage (USB storage) and then transferred to the computer connected to the Rotor-Gene Q.

1. **Insert the Installation CD or removable storage into the computer. The software should launch automatically if using the CD-ROM. If it does not, browse to the CD-ROM in Windows® Explorer and double-click "autorun.hta". If using another form of removable storage, navigate to the device using Windows explorer and double-click the Rotor-Gene Q ".exe" file.**

2. Install the Rotor-Gene Q software by clicking “Install Operating Software” in the window that appears.

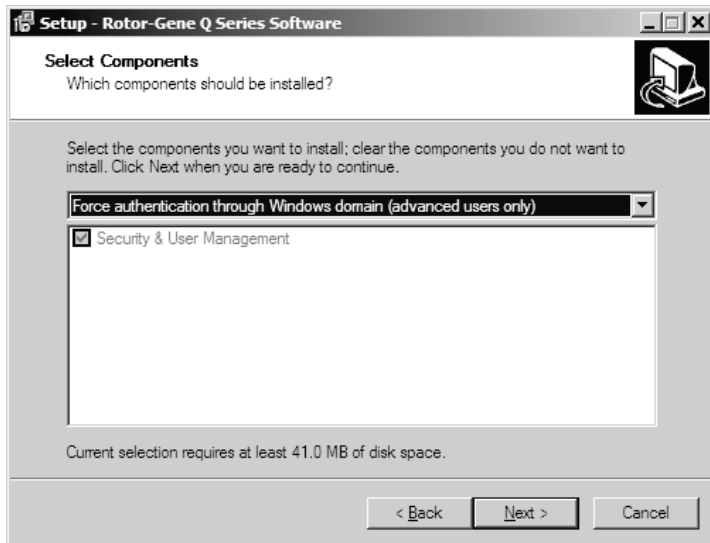


3. Click “Next”, then select “I accept the agreement” in the license agreement step, and click “Next” again.
4. In the “Region” window, select the region that will be used by the software to direct support requests to the right location.



5. Select the destination location where the Rotor-Gene Q software should be installed. For convenience, simply accept the suggested destination folder by clicking “Next”.
6. In the “Select Components” window you can select “Standard Installation” or “Force authentication through Windows domain (advanced users only)” via a drop-down list. Select “Force authentication through Windows domain (advanced users only)” if you want to use the advanced security features (see section on “Access Protection” in the *Rotor-Gene Q MDx User Manual (US)* for

more details). With this selection, the checkbox “Security & User Management” is automatically activated. Then click “Next”.



7. The setup wizard will now install the Rotor-Gene Q software. If the following message appears, click “Continue Anyway”.



8. After installation is completed, close the setup wizard by clicking “Finish”.

Connecting the Laptop/Computer to the Rotor-Gene Q MDx

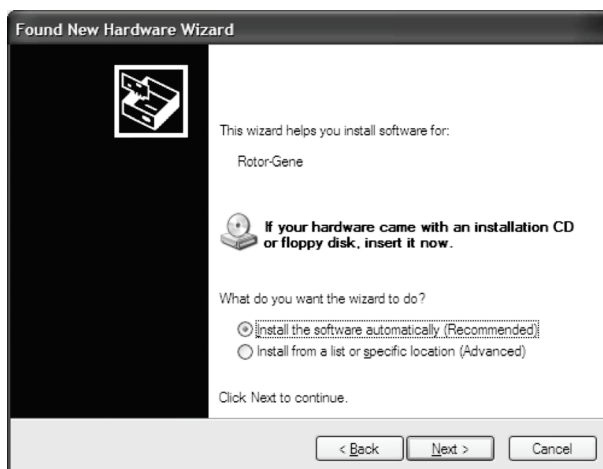
USB connection for Rotor-Gene Q software and Rotor-Gene AssayManager

We recommend connecting the laptop computer, which was delivered with your Rotor-Gene Q MDx, via the USB port.

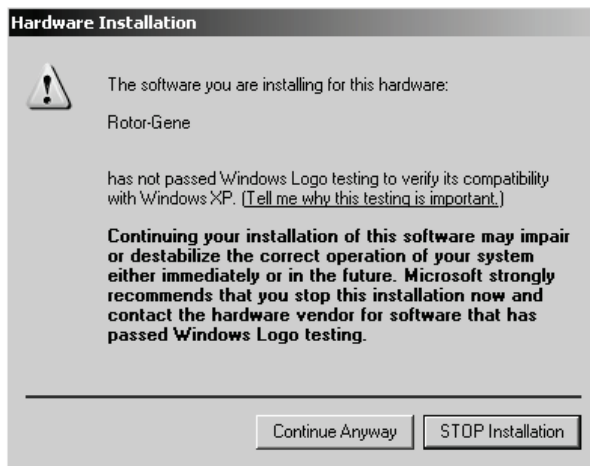
1. Connect one end of the provided USB cable to a USB port at the back of the computer. Connect the other end of the USB cable to the back of the Rotor-Gene Q MDx. Then connect the Rotor-Gene Q MDx to the power supply.
2. Switch on the Rotor-Gene Q MDx.
3. The following window appears. Select “No, not this time” and then click “Next”.



4. Select “Install the software automatically (Recommended)” and then click “Next”.



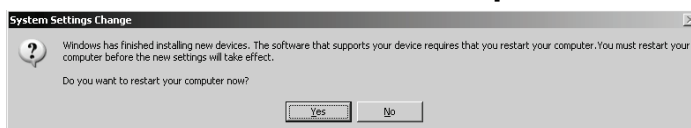
5. Click “Continue Anyway”.



6. Click “Finish”.



7. Click “Yes” to restart the computer.



8. After the computer has restarted, log in again and launch the Rotor-Gene Q software as described below.

RS-232 connection for Rotor-Gene Q software

- 1. Connect one end of the provided RS-232 serial cable to the serial port of your computer. Connect the other end of the RS-232 serial cable to the back of the Rotor-Gene Q MDx. Then connect the Rotor-Gene Q MDx to the power supply.**
- 2. Switch on the Rotor-Gene Q MDx.**
- 3. Start the Rotor-Gene Q software and launch the Rotor-Gene Q software as described below.**

Launching Rotor-Gene Q Software

1. Double-click the “Rotor-Gene Q Series software” desktop icon to launch the software. A message may appear with information. Click “Yes” to view a list of the latest changes or “No” to continue with the Rotor-Gene Q installation.
2. A “Welcome” window appears the first time the software is launched, but it does not appear for subsequent software upgrades.



3. Enter the serial number using numerical digits only (e.g., 0110123). You can find the serial number on the type plate located at the back of the instrument.
4. Click “Auto-Detect”. The corresponding USB or serial port will be detected and shown in the “Port” drop-down list.
5. Click “Begin” to work with the software.
6. Exit the Rotor-Gene Q software to install and work with Rotor-Gene assay packages.

Rotor-Gene Q Software Assay Packages

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

Launching Rotor-Gene AssayManager

To launch Rotor-Gene AssayManager, see the “Rotor-Gene AssayManager Core Application User Manual (US) IVD” in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

Rotor-Gene AssayManager Assay Profiles and Plug-ins

For more information on Rotor-Gene AssayManager assay profiles and plug-ins, see the “Rotor-Gene AssayManager Core Application User Manual (US) IVD” in Part II of Volume 2 of the *QIASymphony RGQ MDx (US) User Manual*.

Configuration for Windows 7 security

The laptop computers that are provided by QIAGEN for use with your Rotor-Gene Q MDx instrument have Microsoft® Windows 7 preinstalled and are configured with a standard (nonadministrative) Windows user account and with an administrator account. In routine usage of the system, the standard account shall be used, since Rotor-Gene Q software and the Rotor-Gene AssayManager version 1.0 or 2.1 are 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”). 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.

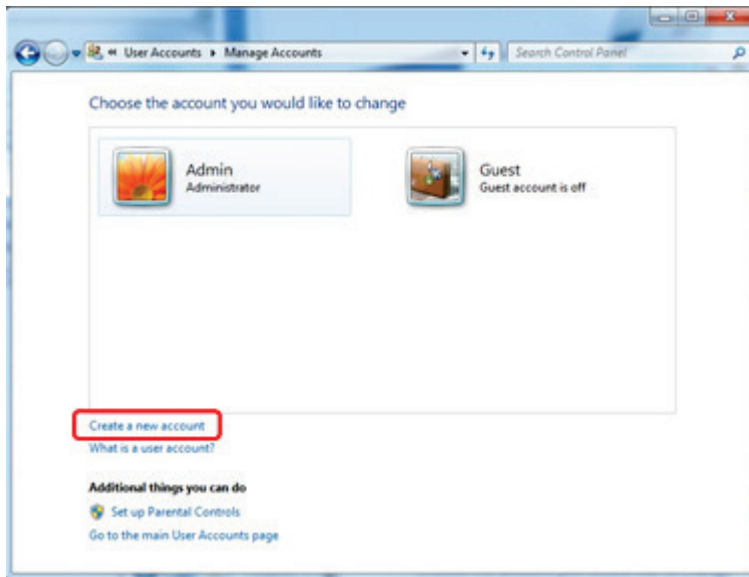
If the laptop Administrator password is lost, then we would advise you to contact Microsoft for support.

If your configuration is different and no nonadministrative 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 and roles, antivirus activation), or performance-relevant settings like power saving.

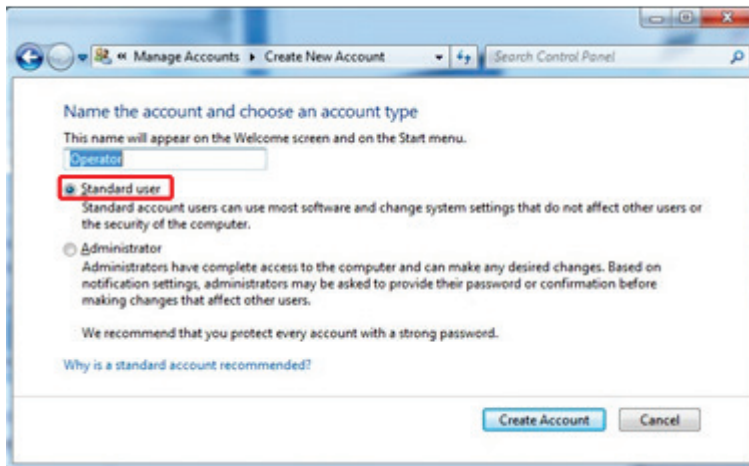
To create a standard user account in Windows 7, please follow these steps described in section “Creating a new user account”.

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”.

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.

Antivirus software

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

- Symantec® Endpoint Protection V12.1.6
- Microsoft Security Essentials V4.10.209¹

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

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. Since 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 the single files. We do not recommend the use of antivirus software where only single files can be excluded, e.g. McAfee Antivirus Plus V16.0.5. If the computer is used in an environment without network access, please also make sure that the 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.

¹ **Note:** After installation of "Microsoft Security Essentials", you shall check that Windows updates are deactivated since the installation might activate this setting (please read chapter "Operating system updates").

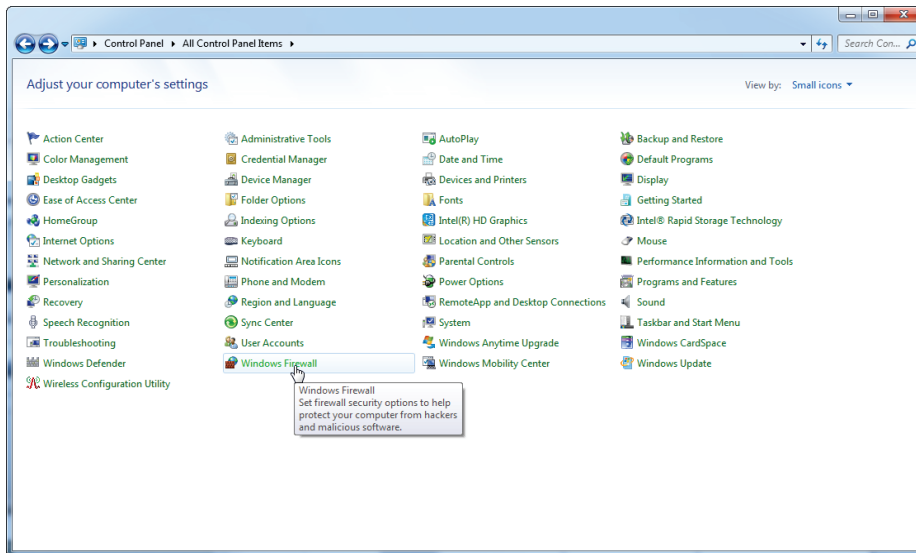
Firewall and networks

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 required to establish a network connection.

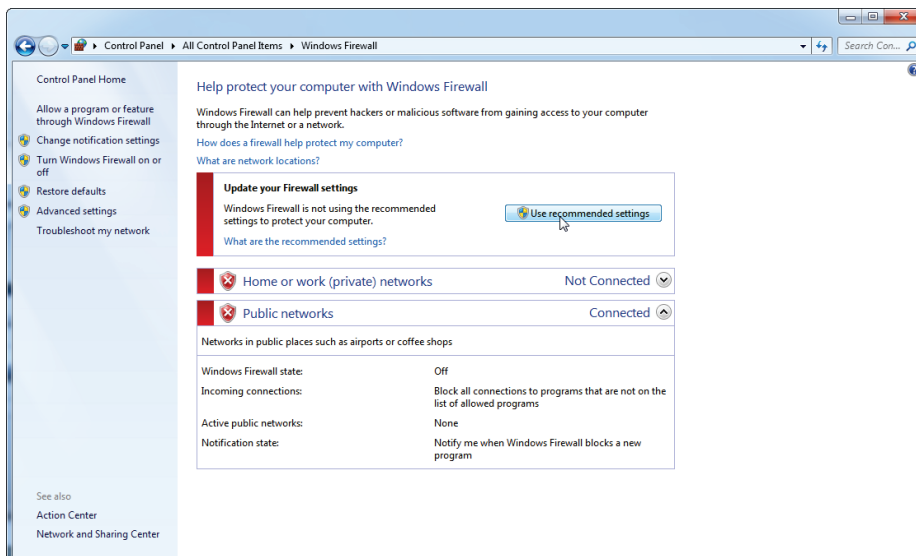
Please note that blocking incoming connections does not affect responses to requests triggered by the user. Outgoing connections are allowed because they may be required for retrieving updates.

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

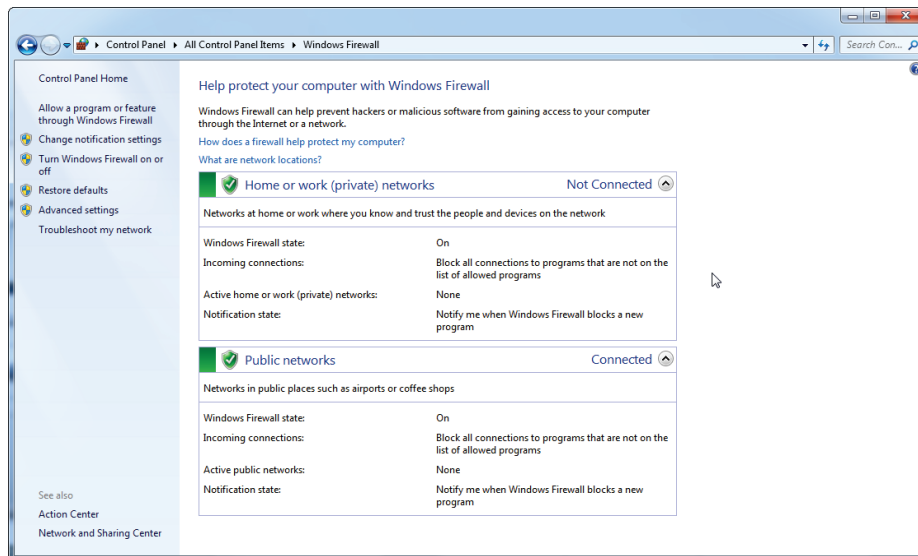
1. Open the Control Panel and select “Windows Firewall”.



2. Select “Use recommended settings”.

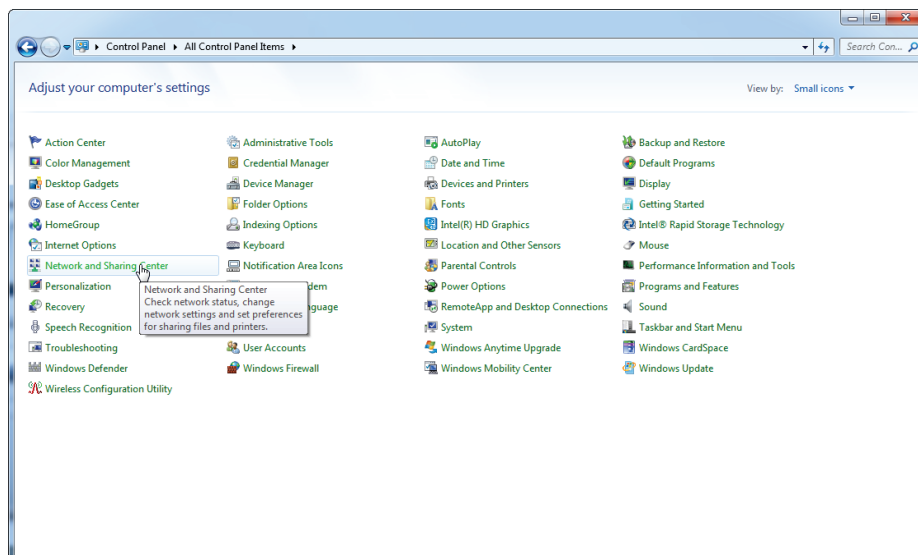


3. Check that the following settings are active:

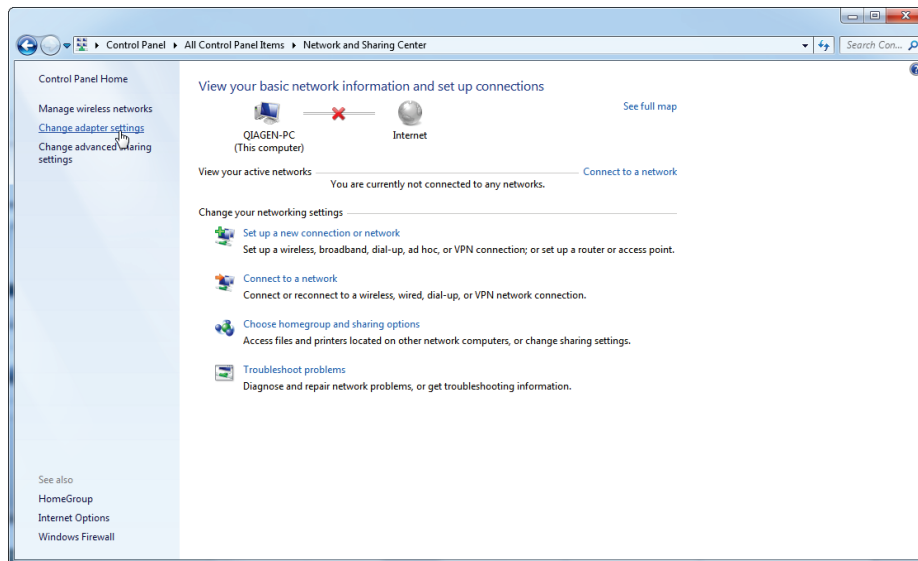


For security and reliability reasons, cable-based network access instead of Wi-Fi shall be used. The laptop computers that are provided by QIAGEN have a disabled Wi-Fi adapter. If your configuration is different, a system administrator must disable the Wi-Fi adapter manually. This can be done through the following steps:

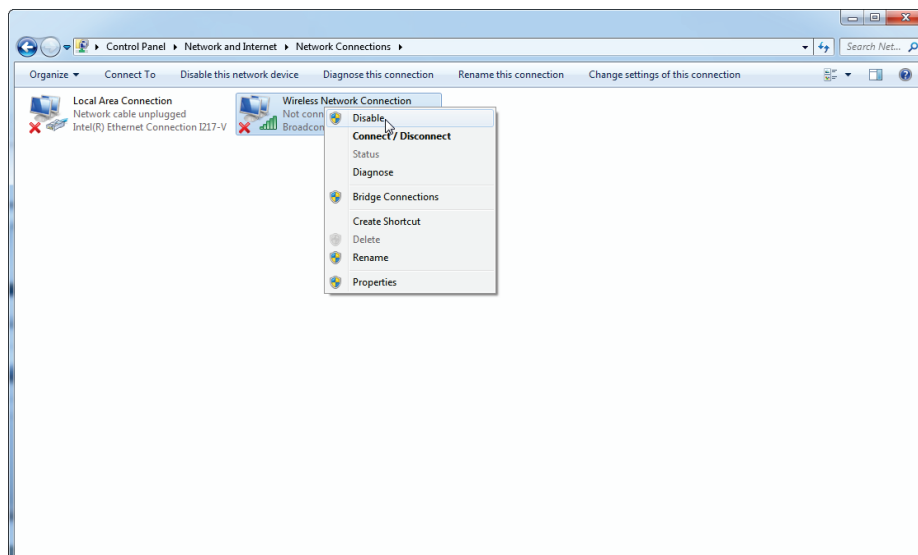
1. Open the Control Panel and select "Network and Sharing Center".



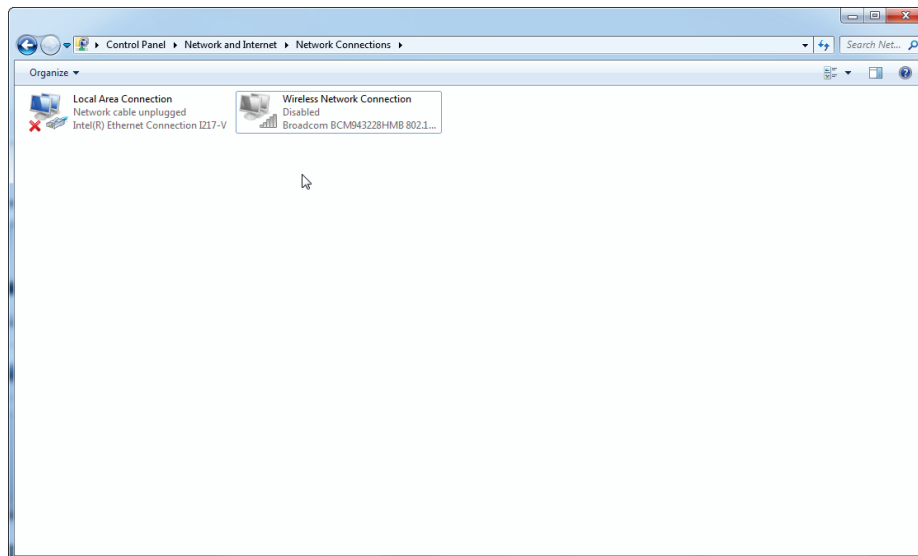
2. Select “Change adapter settings”.



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



4. Check that “Wireless Network Connection” is disabled.



System tools

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

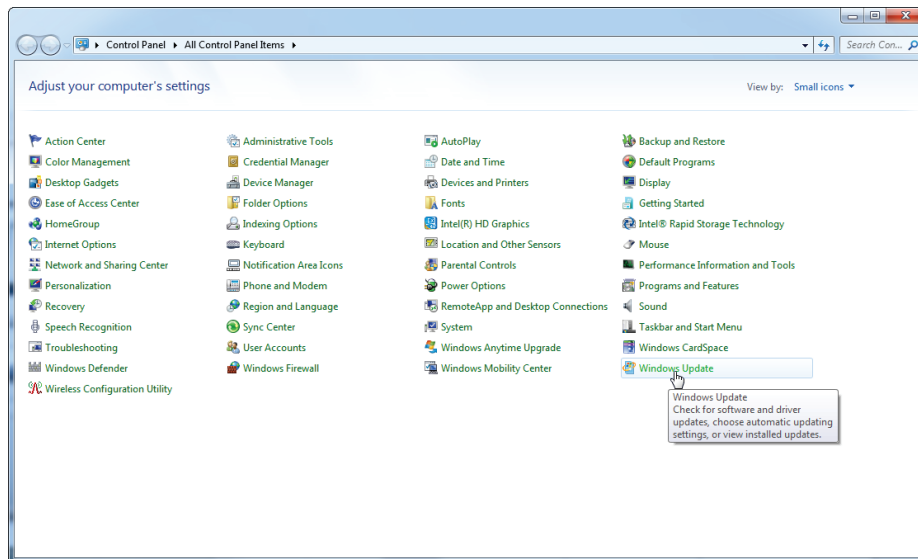
- File indexing, which is performed as a background task by many contemporary office applications
- Disk defragmentation, which often also employs a background task
- Any software that checks for updates on the internet
- Remote monitoring and management tools

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

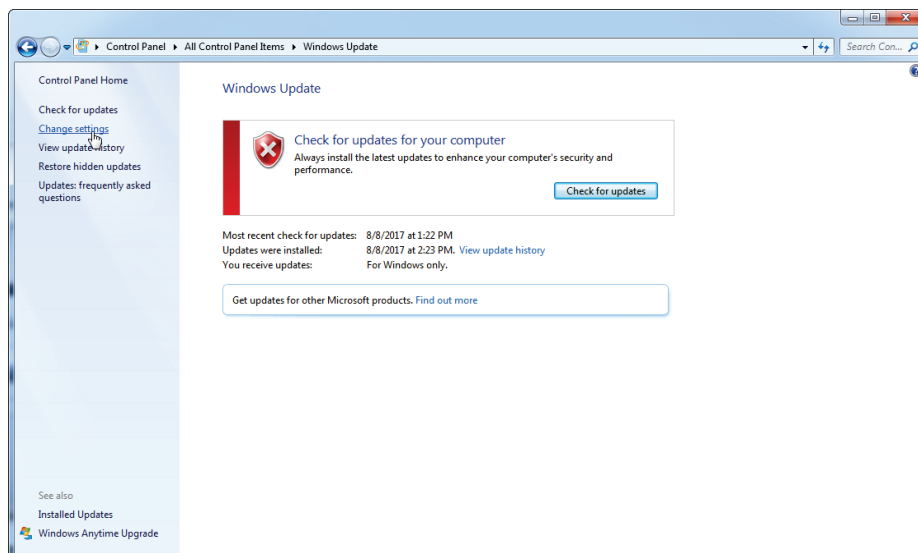
Operating system updates

The laptop computers provided by QIAGEN are configured such 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. This can be done through the following steps:

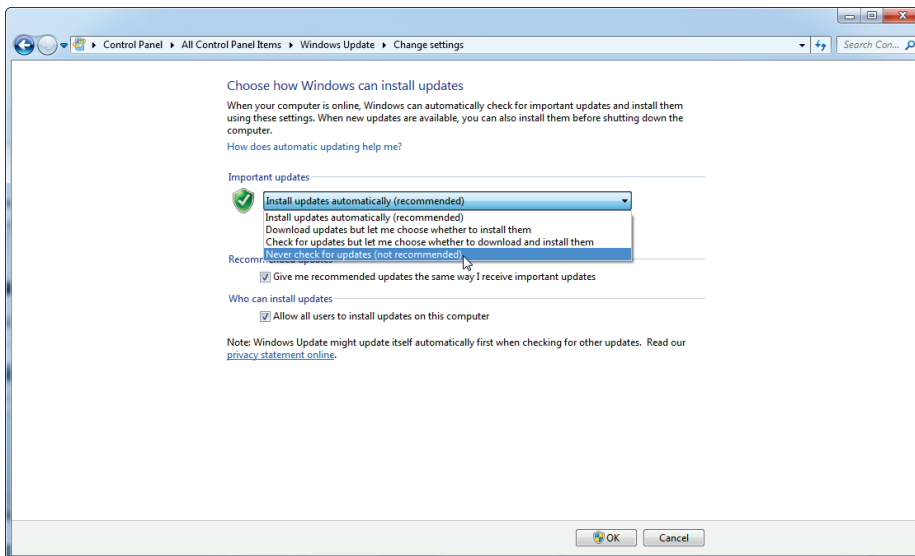
1. Open the Control Panel and select "Windows Update".



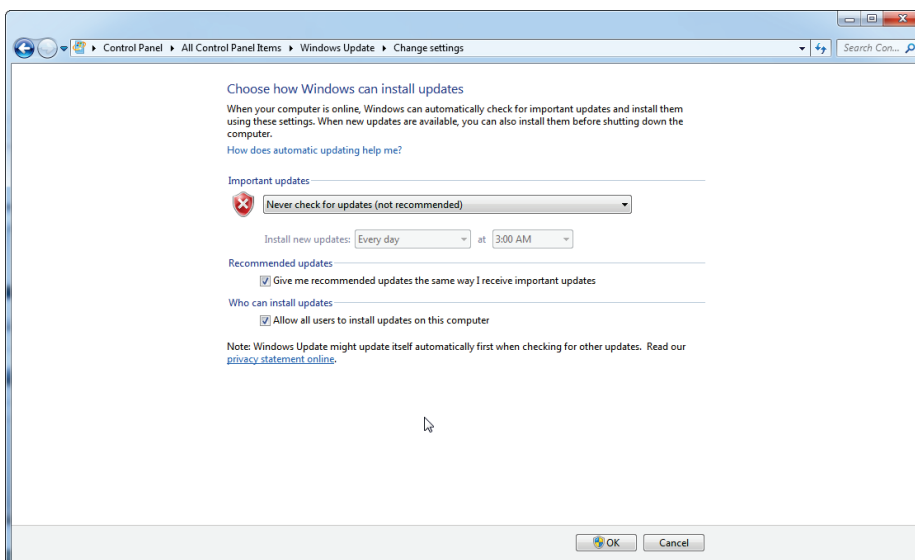
2. Select "Change settings".



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 7 or 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.

Updating Rotor-Gene Q Software and Rotor-Gene AssayManager Software

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

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.

Trademarks: QIAGEN®, Rotor-Gene®, Rotor-Gene AssayManager® (QIAGEN Group); Microsoft®, Windows® (Microsoft Corporation); Symantec® (Symantec Corporation).

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