

May 2019

Rotor-Gene AssayManager® v2.1 MDx Quick-Start Guide

For installation and setup of Rotor-Gene AssayManager v2.1



R3

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Installing Rotor-Gene AssayManager v2.1

This Quick-Start Guide summarizes instructions for the installation and setup of Rotor-Gene AssayManager v2.1. Before using Rotor-Gene AssayManager v2.1, it is essential that you read "Getting Started" in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* (available as a .pdf file on the QIAGEN website) carefully and pay particular attention to the safety information.

Rotor-Gene AssayManager v2.1 uses a database (Microsoft® SQL Server® Express) to store all data. The database can be installed locally or on a remote system. The Microsoft SQL Server database provides backup and restore mechanisms. For detailed information about backup and restore instructions, refer to the "Maintenance" section in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

Most screenshots in this document were created using Windows® 7. If there is no difference between Windows 7 and Windows 10, no additional screenshots were created for Windows 10. A separate description has been added only where the behavior differs between the operating system versions.

Rotor-Gene AssayManager v2.1 can be installed with 3 different configurations:

Task/configuration	Description
Install on stand-alone computer*	<ul style="list-style-type: none">• A user with local system administration privileges installs the database (Microsoft SQL Server Express) including initial data, the Rotor-Gene AssayManager v2.1 application, and at least one Rotor-Gene AssayManager v2.1 plug-in on a computer.• The user is completely guided by the installation wizard and will be prompted for input, if necessary.
Set up a stand-alone computer,* which is connected to a network, and install Rotor-Gene AssayManager v2.1 on additional computers* connected to the first	<ul style="list-style-type: none">• Proceed as described in "Install on stand-alone computer*".• The computer* is connected to the local area network.• Rotor-Gene AssayManager v2.1 and at least one Rotor-Gene AssayManager v2.1 plug-in is installed on one or multiple computers by a user with local administration privileges. During installation the user is prompted for connection to the database, which has to be provided by the database administrator.

* The term "computer" is used to describe a notebook or a PC, and not a server.

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Task/configuration	Description
Use existing database server and install Rotor-Gene AssayManager v2.1 on additional computers*	<ul style="list-style-type: none"><li data-bbox="555 506 1155 625">• A user with all required database administration privileges uses the installation wizard to install only a new database instance including initial data on an existing database server.<li data-bbox="555 634 1155 910">• The database administrator is responsible for checking whether the database server fulfills the Rotor-Gene AssayManager v2.1 requirements. The administrator is also responsible for performing all database administration tasks necessary to back up the system before installation. Furthermore, the database administrator must guarantee the functionality of the system after the successful installation or a failed installation.<li data-bbox="555 919 1155 1098">• Rotor-Gene AssayManager v2.1 and at least one Rotor-Gene AssayManager v2.1 plug-in are installed on additional computers by a user with local administration privileges. During installation the user is prompted for connection to the database, which has to be provided by the database administrator.

* The term "computer" is used to describe a notebook or a PC, and not a server.

Note: It is not possible to install Rotor-Gene AssayManager v2.1 on a computer or an existing database server which already has Rotor-Gene AssayManager v1.0 installed on it.

Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. In addition, Rotor-Gene AssayManager v2.1 does not replace Rotor-Gene AssayManager v1.0.

Minimum computer requirements

A computer with the required specifications for operating the Rotor-Gene® Q MDx instrument and Rotor-Gene AssayManager v2.1 is supplied as part of the Rotor-Gene Q MDx instrument. This computer is referred to as the “QIAGEN laptop” in the following text. In general, the following minimum requirements must be fulfilled to run Rotor-Gene AssayManager v2.1.

Minimum computer requirements

System	Requirements
Display	1024 x 768 pixel resolution or higher
Supported operating systems	Windows 7 Professional (32- or 64-bit) with service pack 1 Windows 10 with version 1709 or newer (32- or 64-bit)
Disk space	250 GB
Processor	Intel® Core™ i3-380M Processor or higher
Memory	4 GB RAM recommended
USB interface	1–4 USB 2.0 ports or higher. Contact www.qiagen.com for details regarding a USB hub, if necessary
Pointing device	Touchpad or mouse or equivalent is required
Bluetooth®	Has to be switched off
PDF viewer or similar	Already installed
Power options	Never turn off hard disks, hibernate or go to standby

Note: Rotor-Gene AssayManager v2.1 consists of different components working together. The core application v2.1 is complemented by different plug-ins that provide assay type specific analysis and visualization of results. The core application v2.1 is mandatory for working with Rotor-Gene AssayManager v2.1. At least one plug-in must be installed. Optionally, additional plug-ins can be installed. Plug-ins may not be available worldwide. See www.qiagen.com/rotor-gene-assaymanager-21-us for details.

Note: A stable power connection is required. Unstable power connections can cause loss of data.

General download and installation instructions

If you download software from the QIAGEN website on a different computer to the one on which the software is to be installed, please make sure that the flash drive used to transfer the software is free of viruses. QIAGEN strongly recommends a virus scan is performed using an up-to-date virus scanner on the flash drive to avoid 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 software is started.

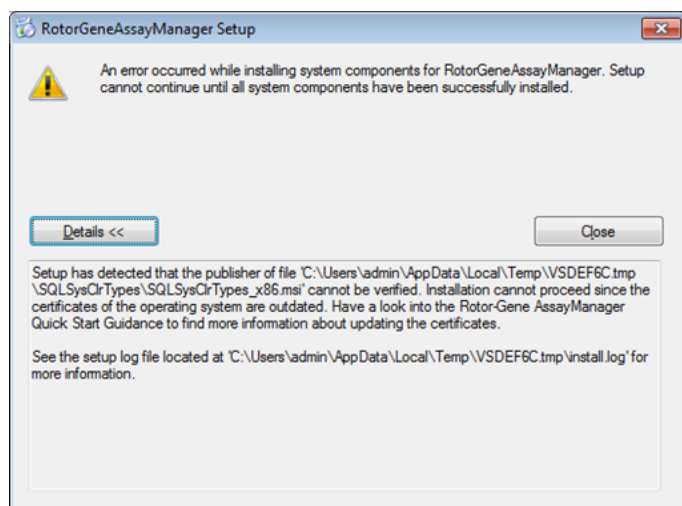
For detailed information on confirmation of software integrity during download and file transfer, please check the “*QIAGEN software integrity verification process*” description document, which is provided together with the software package on the QIAGEN webpage.

Outdated certificates on Windows 7

All installation packages contained in the Rotor-Gene AssayManager v2.1 installer are signed with validated certificates, trusted by Microsoft. This validity is checked by the operating system for every new program which shall be installed on the system. To be able to verify the validity of installer packages, the operating system maintains a list of trusted root certification authorities which is updated automatically by the so-called “automatic root update mechanism” introduced by Microsoft during the lifetime of Windows 7.

If your operating system or the list of trusted root certification authorities is in an outdated state, Microsoft cannot verify the validity of the pre-requisite packages, installed by the Rotor-Gene AssayManager v2.1 installer. This will result in the following error message during installation: “Setup has detected that the publisher of file ‘...’ cannot be verified. Installation cannot proceed since the certificates of the operating system are outdated.” (See screenshot below.)

Note: The error message is only shown if you click on the **Details <<** button.



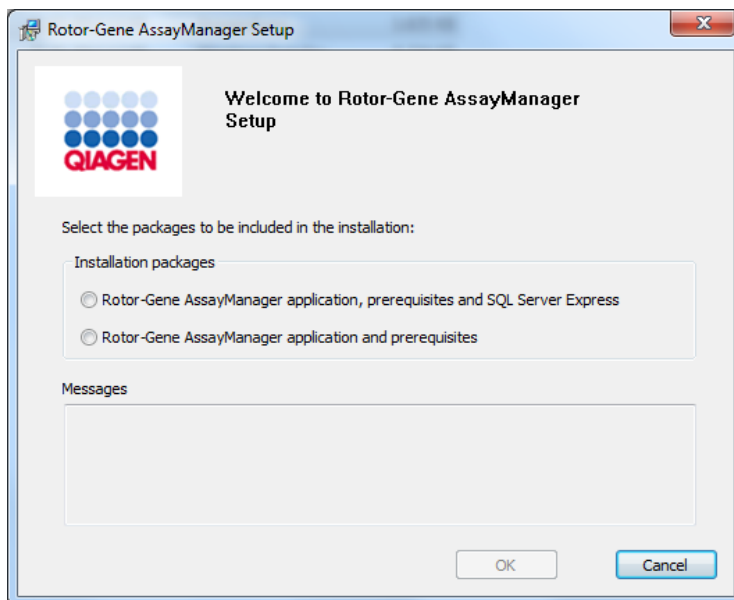
Visit the QIAGEN website for updates and instructions to solve this problem.

Installation instructions for core application v2.1

Note: Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. In addition, Rotor-Gene AssayManager v2.1 does not replace Rotor-Gene AssayManager v1.0.

1. Check if the instructions described in sections “General download and installation instructions” (for Windows 10 operating systems) and “Outdated certificates on Windows 7” (for Windows 7 operating systems) need to be performed.
2. Start the installation of Rotor-Gene AssayManager v2.1 by double-clicking on **setup.exe**.

The setup wizard automatically opens the **Rotor-Gene AssayManager Setup** window.

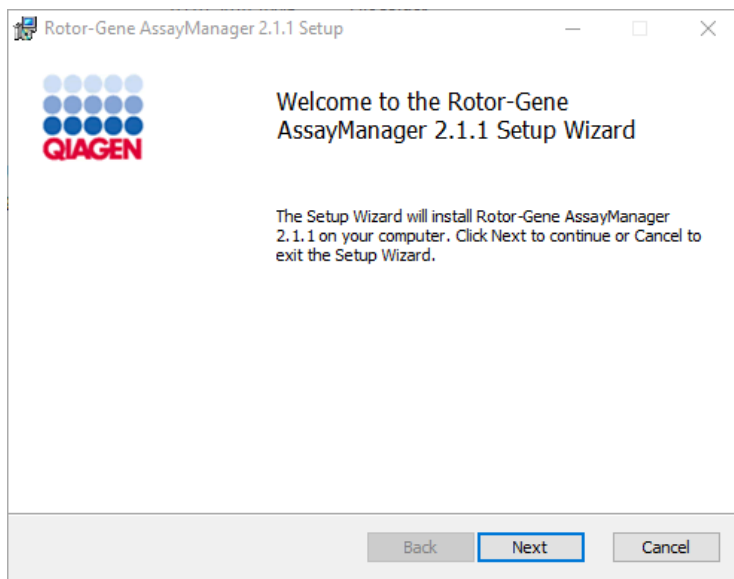


Note: Rotor-Gene AssayManager v2.1 requires a Microsoft SQL Server 2014 Express instance with mixed mode authentication and TCP/IP network protocol activated for installation. The installation process depends on whether Microsoft SQL Server 2014 Express is already installed or should be installed on the local system, or whether Rotor-Gene AssayManager v2.1 will be installed with a remote connection to an existing SQL Server on an external system. Details about the different installation configurations can be found in “Getting Started” in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

3. Select the required installation packages and click **OK**. Follow the instructions to set up the software.

Rotor-Gene AssayManager v2.1 uses several software packages provided by third parties. If the packages are not available on the computer, these software packages are automatically installed at the beginning of the Rotor-Gene AssayManager v2.1 setup. Follow the instructions if necessary.

Note: Depending on the software packages installed, a reboot of the system may be required before proceeding with the setup. After the reboot, the installation procedure is resumed automatically.



4. Follow the steps of the wizard. Details can be found in the "Getting Started" section of the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

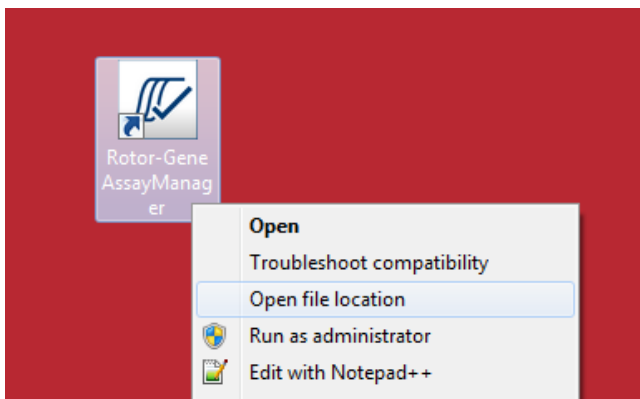
After the core application v2.1 is installed successfully, continue with the plug-in installation.

Note: Rotor-Gene AssayManager future updates will be provided on the QIAGEN webpage.

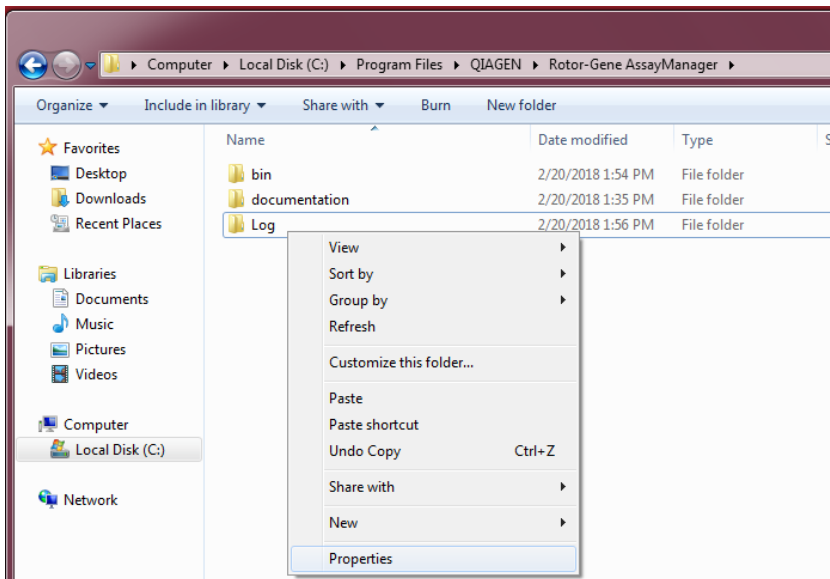
Setting up properties for log folder

If you are using Rotor-Gene AssayManager v2.1 in a multi-user windows environment, you must manually set up permissions for the "log" folder after installing Rotor-Gene AssayManager. Otherwise it will not be possible for Rotor-Gene AssayManager to create new log files if the Windows user is changed.

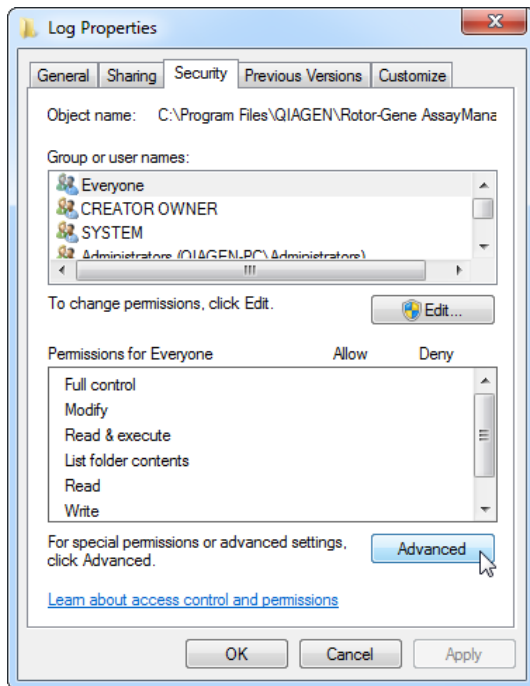
1. Log in as Administrator, right click on the Rotor-Gene AssayManager icon and select **Open file location**.



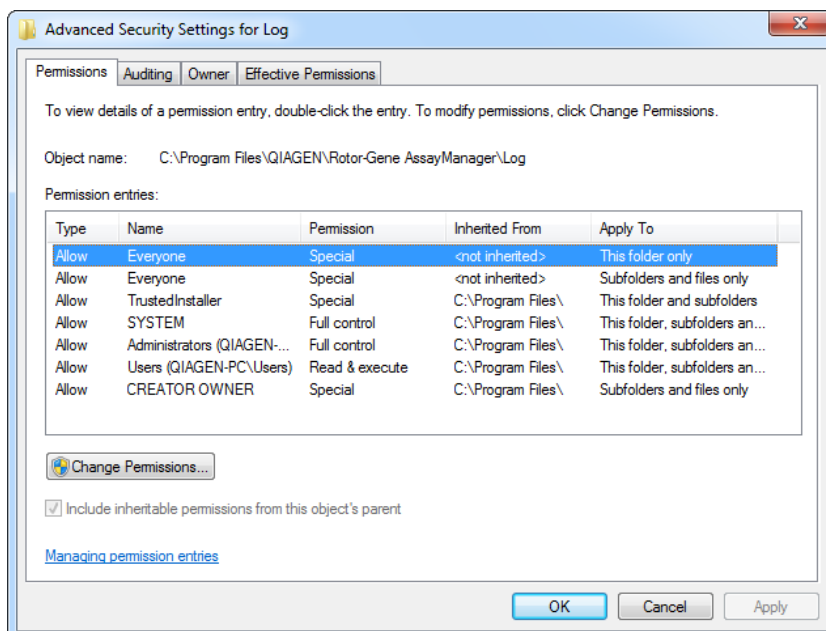
2. The file explorer will open the Rotor-Gene AssayManager/bin folder. Navigate up one folder to the Rotor-Gene AssayManager top folder. Right-click on the **Log** folder and select **Properties**.



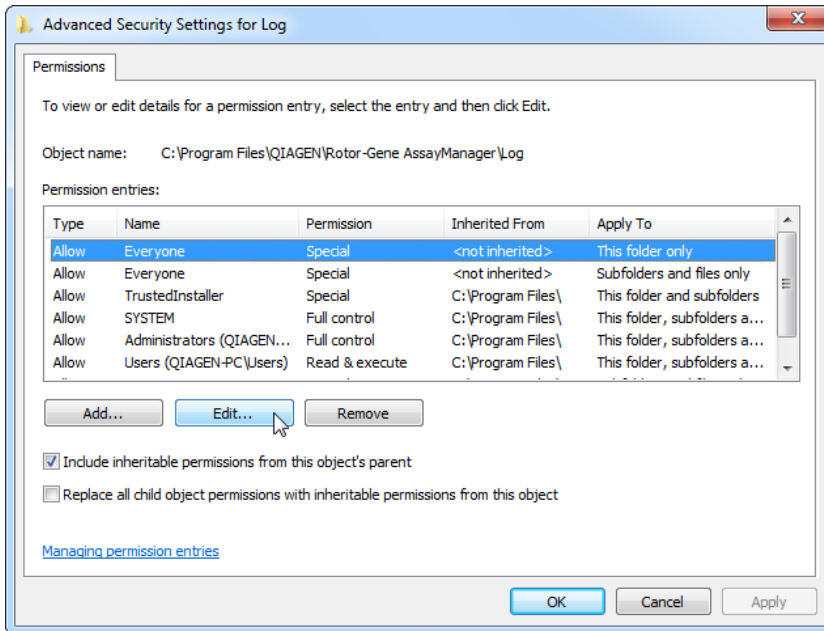
- In the new dialog box, click on the **Security** tab and then select the **Advanced** button.



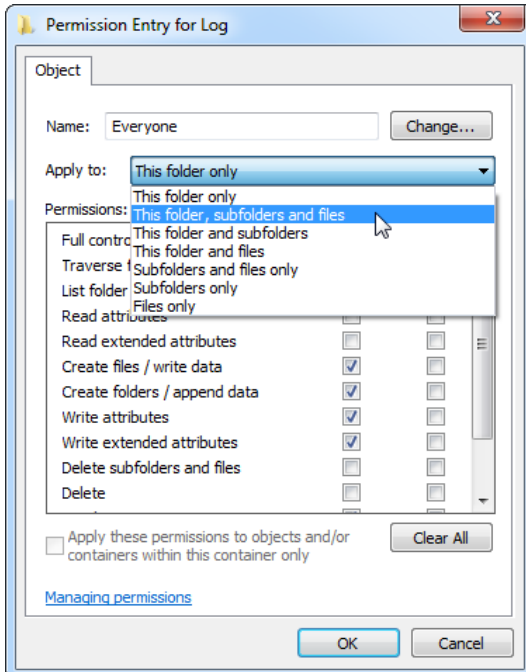
- In the new dialog box, click on **Change Permissions....**



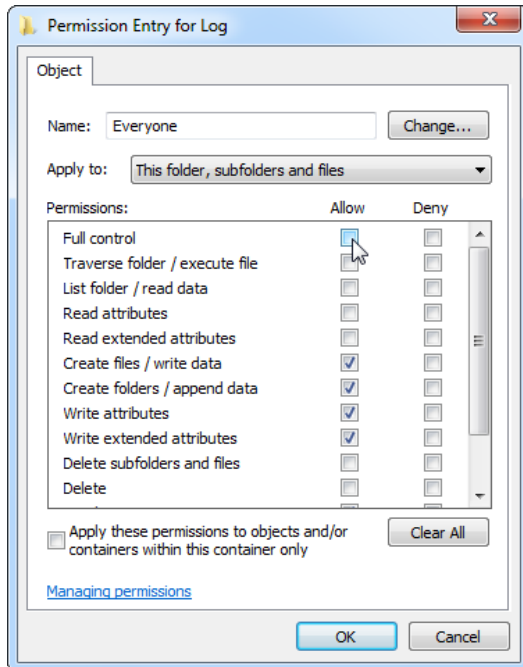
5. Select the user with the name **Everyone** and click on **Edit**.



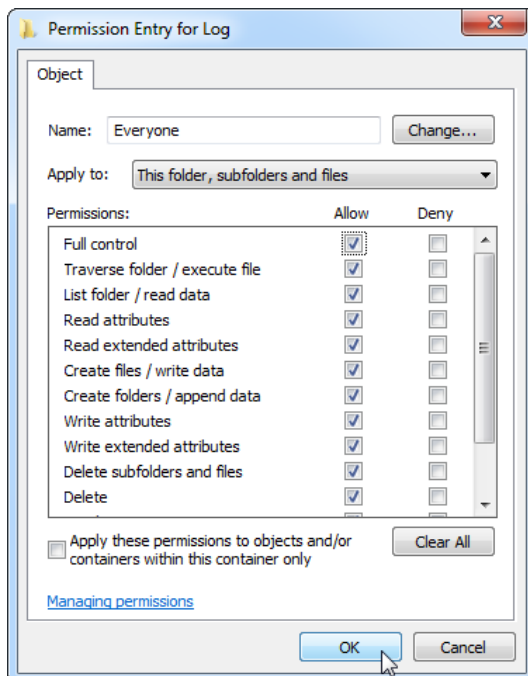
6. Select the entry **This folder, subfolders and files** from the drop-down menu **Apply to**.



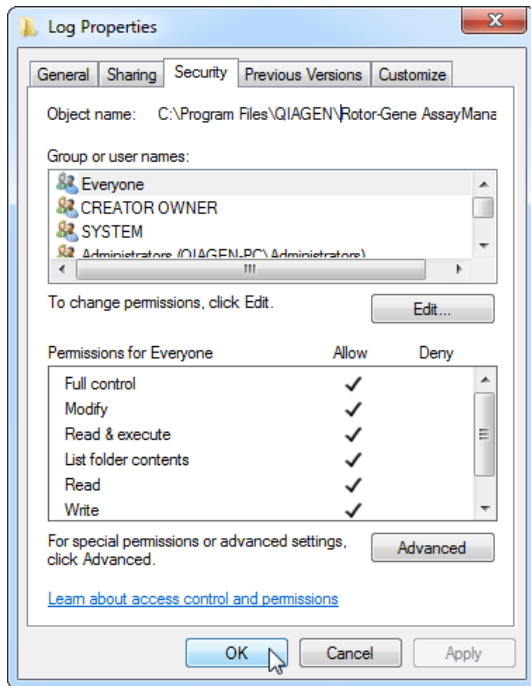
7. Click on the checkbox **Full control** in the column under **Allow**.



8. Afterwards, **Allow** should be checked for all permissions. Confirm this dialog and close the window by pressing on **OK**.



9. Close the remaining dialogs with a click on the **OK** button as well. The last dialog box should look like the one below. (User “Everyone” has full control.)



Installation instructions for a plug-in

At least one plug-in must be installed for the use of Rotor-Gene AssayManager v2.1.

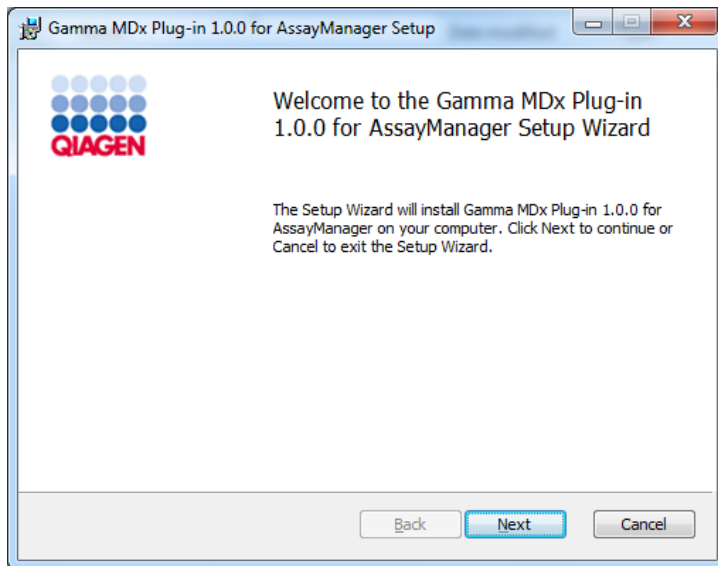
Note: Plug-ins for Rotor-Gene AssayManager v1.0 are not compatible with Rotor-Gene AssayManager v2.1.

Note: Checksum confirmation is required to secure software integrity after web download is successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded plug-in is started.

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

Note: The installation of the Gamma MDx Plug-in is taken as an example for the installation of any plug-in.

1. Double-click on **RGAM_Gamma_MDx_Plug-in.Installation.V1_0_0.msi** to start the Gamma MDx Plug-in setup wizard.
2. Click **Next** to proceed. Follow the instructions to set up the software.



3. Select the features to be installed.

Follow the steps of the wizard. Details can be found in the “Getting Started” section of the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

Getting started

For a detailed description of Rotor-Gene AssayManager v2.1, refer to “Basic Concepts and General Software Usage” in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* (available by clicking **User Manual** during the Rotor-Gene AssayManager v2.1 installation process).

To run Rotor-Gene AssayManager v2.1, a license key file is required. Please consult the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* or www.qiagen.com/rotor-gene-assaymanager-21-us for information on how to obtain a license.

There are two types of licenses available:

- The trial license

The trial license is limited to a certain period of time. It can be used on any computer where Rotor-Gene AssayManager v2.1 is installed.

- The regular license

The regular (perpetual) license can only be used with a dedicated computer. It cannot be transferred between computers. The customer is requested to create a file containing information which clearly identifies a specific computer. This information is incorporated into the "license key" which is sent back to the customer later on.

1. Launch Rotor-Gene AssayManager v2.1 from the Windows start menu by selecting **QIAGEN/Rotor-Gene AssayManager** or by double-clicking the icon on the desktop.



2. Enter user ID "admin" and password "admin". Select the mode from the **Mode** drop-down list and click **OK**.

A screenshot of the Rotor-Gene AssayManager 2.1.1 login dialog box. The window has a light blue header with the QIAGEN logo on the left and the text "Rotor-Gene AssayManager 2.1.1" on the right. Below the header, there are three input fields: "User ID" with a blue text box, "Password" with a white text box, and "Mode" with a dropdown menu currently showing "Closed". At the bottom right of the dialog, there are two buttons: "OK" and "Cancel".

Explanation of modes:

Closed mode The **Closed** mode is reserved only for validated assay profiles that have been preconfigured by QIAGEN. These assay profiles are signed by checksum and can only be modified by QIAGEN as part of the development and validation procedure of assays.

User Defined Test mode The **User Defined Test** mode uses assay profiles created by laboratory users who predefine assay parameters using standard Rotor-Gene Q software. The UDT mode allows run and analysis of homebrew or third-party assays as well as self-developed assays.

Note: The UDT mode is not intended for use with FDA cleared or approved nucleic acid tests

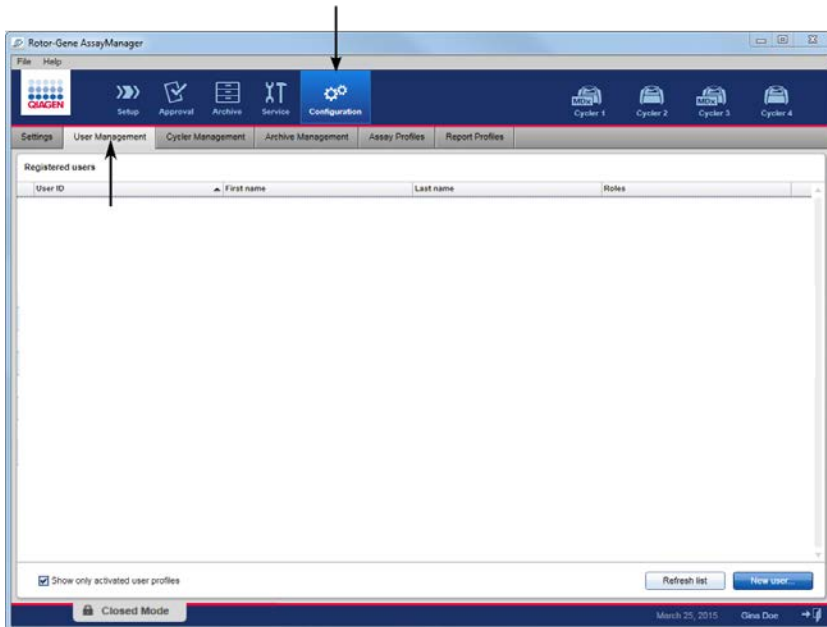
Note: For usage of the User Defined Test mode (UDT mode) functionalities, a compatible UDT mode plug-in is required to be installed. A log-in in UDT mode without installation of the corresponding plug-in will give you no access to administrative tasks and you can neither perform experiments nor any analysis.

3. Enter a new, secure password.
4. Create a license file via the **Generate key file** button for each computer on which Rotor-Gene AssayManager v2.1 has been installed and submit it to QIAGEN to receive a license key.
5. After receiving your computer-specific Rotor-Gene AssayManager v2.1 license key, archive the license key locally on your computer.

Note: Make sure that the license key always exists on the respective computer where Rotor-Gene AssayManager v2.1 is installed. It is strongly recommended that the system administrator archives the Rotor-Gene AssayManager v2.1 license key in a protected location where access for standard (non-administrator) user accounts is not permitted. In addition, the storage location of Rotor-Gene AssayManager v2.1 license key should not be changed.

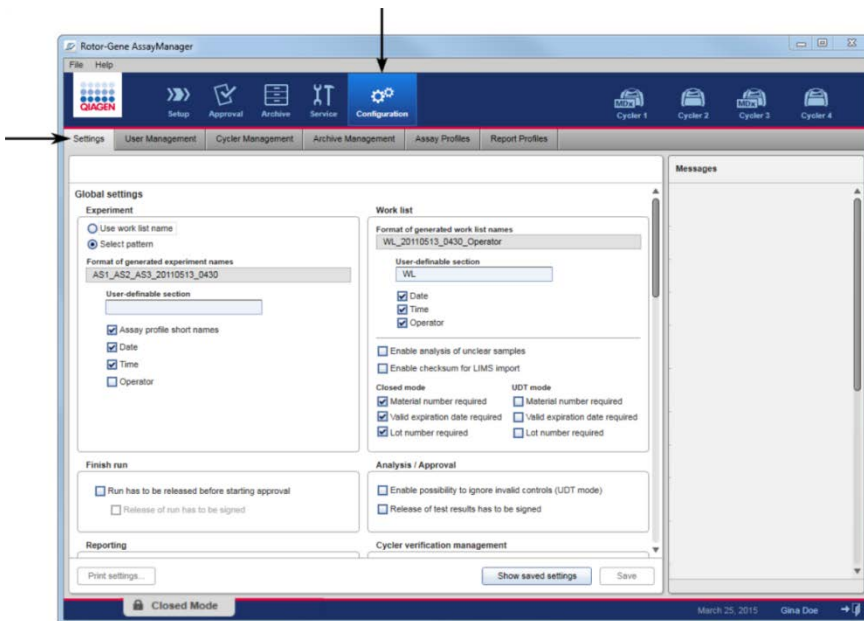
6. After the Rotor-Gene AssayManager v2.1 license key is stored securely, start the software and select the **License** entry in the **Help** menu. Click on **Browse** to locate and load the provided license file.

7. Open the **User Management** tab in the **Configuration** environment, and create user accounts.



For more details, see the section "Managing Users" of the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

8. Open the **Settings** tab, and configure the settings for Rotor-Gene AssayManager v2.1.



For more details, see "Settings" in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

Additional software on connected computers

Rotor-Gene AssayManager v2.1 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 AssayManager v2.1 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.

Configuration for Windows security

The laptop computers that are provided by QIAGEN for use with your Rotor-Gene Q MDx instrument have Microsoft Windows 7 or 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 should be used as Rotor-Gene AssayManager v2.1 is designed to run without administrator rights. The Administrator account should only be used to install the Rotor-Gene AssayManager v2.1 software and a virus scanner (please see section “Anti-virus scanners”). Use of the Administrator account is indicated by a red desktop background. Please make sure you always log in as a standard user for routine use.

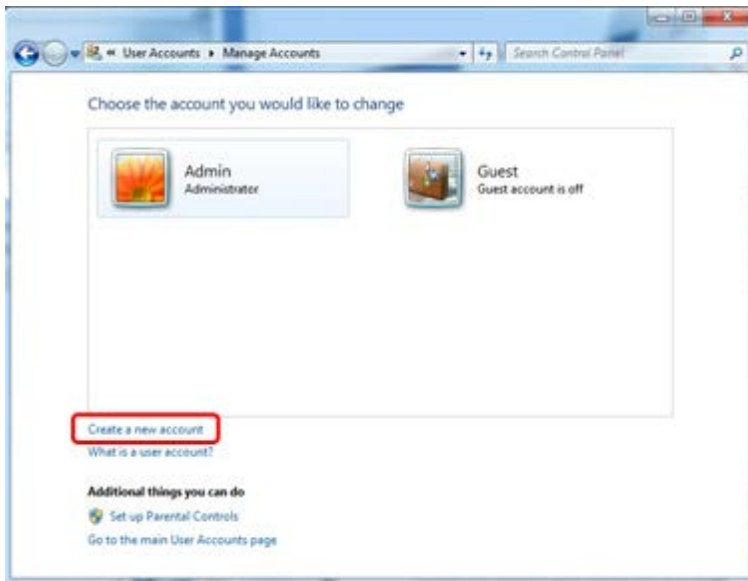
The default password of the Administrator account is as follows: “Q1a#g3n!A6”. Please change the Administrator password after first login. Please make sure that the password is secure and does not get lost.

There is no password for the operator account.

If your configuration is different and no non-administrative account is available, a system administrator should setup an additional standard Windows user account to prevent access to critical system areas, such as “Program Files”, “Windows” directory (e.g. access to installation or uninstallation functionality, including applications, operating system components, date/time settings, Windows updates, firewall, user rights and roles, anti-virus activation), or performance relevant settings like power saving. Multiple users can then be configured within the Rotor-Gene AssayManager v2.1 user management.

Creation of standard user account for Windows 7

1. To create a standard user account, please follow these steps: Open the Windows control panel via the **Start** menu and select the **User Accounts/Manage Accounts**.
2. Choose **Create a new account**.



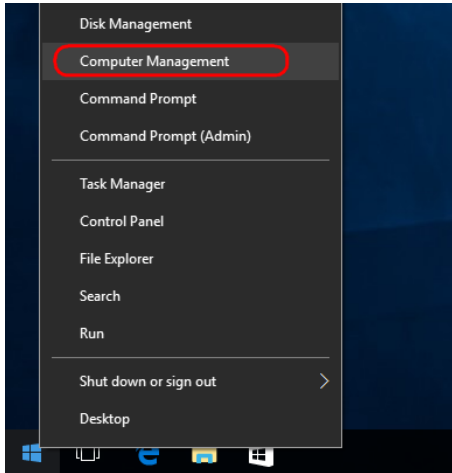
3. Name the account and select **Standard user** as the account type.



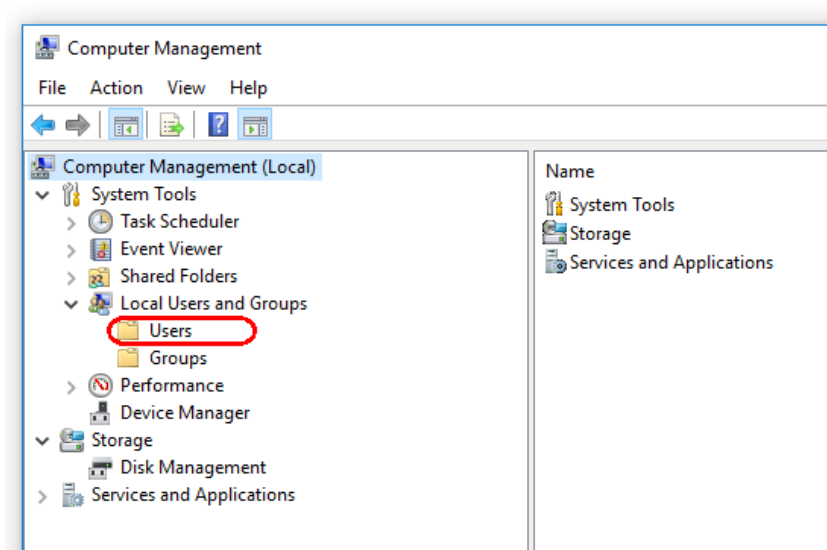
4. Click **Create Account**.

Creation of standard user account for Windows 10

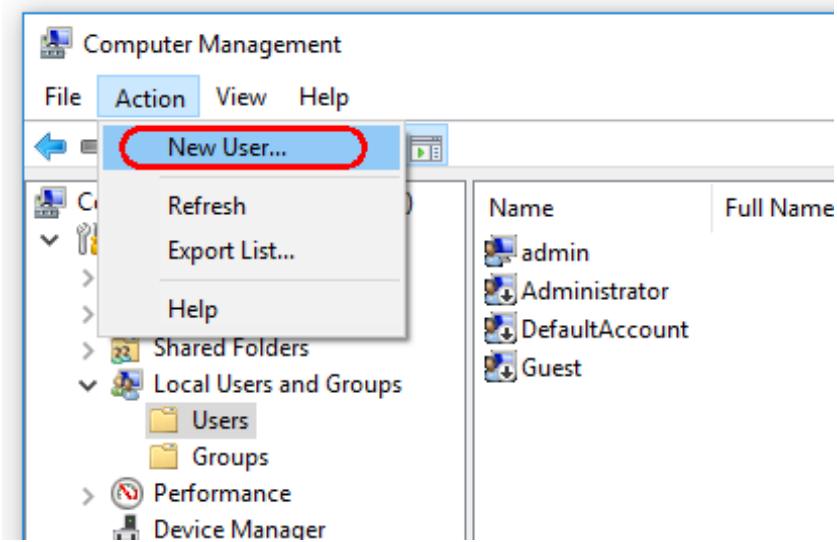
1. Right-click on the Windows-button and select **Computer Management**.



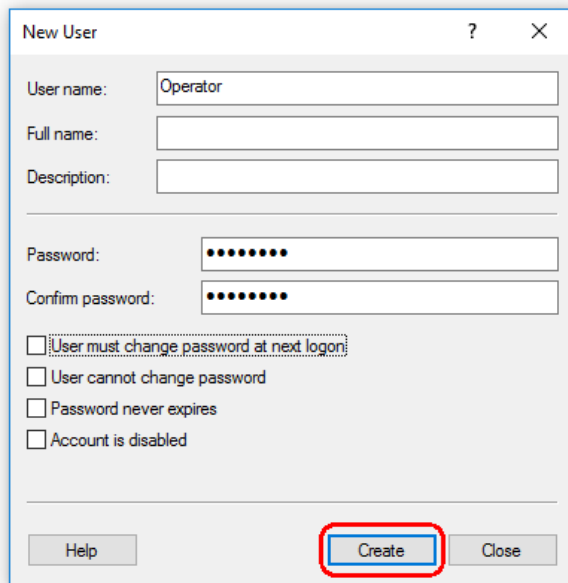
2. Expand **Local Users and Groups** and then **Users**.



3. While the section **Users** is highlighted, click **Action** and select **New User...**



4. Name the account, set a password (optional) and click **Create**.



Anti-virus scanners

Please refer to the product page on www.qiagen.com for the latest versions of anti-virus software that have been validated in combination with Rotor-Gene AssayManager v2.1.

QIAGEN is aware of the threat that computer viruses cause to any computer that exchanges data with other computers. Rotor-Gene AssayManager v2.1 software is expected to be primarily installed in environments where local policies are in place to minimize this threat. QIAGEN recommends the use of an anti-virus scanner. The selection and installation of an appropriate virus scanning tool is the customer's responsibility. However, QIAGEN has validated the Rotor-Gene AssayManager with the QIAGEN laptop in combination with the following two virus scanners to show compatibility:

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

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

If a virus scanner is selected, make sure that it can be configured in a way that the database folder path can be excluded from the scan. Otherwise, there is the risk of database connection errors. Since Rotor-Gene AssayManager v2.1 creates new database archives dynamically, it is required to exclude the folder path to the files and not single files. We do not recommend the use of virus scanners where only single files can be excluded, e.g. McAfee® Antivirus Plus V16.0.5. If the computer is used in an environment without network access, please also make sure that the virus scanner supports offline updates.

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

- As explained above, the database folder path of Rotor-Gene AssayManager v2.1 needs to be excluded from file scans which are as follows, depending on the Microsoft SQL server version which initially created the database:
 - **C:\Program Files\Microsoft SQL Server\MSSQL10_50.RGAMINSTANCE\MSSQL\DATA**
 - **C:\Program Files\Microsoft SQL Server\MSSQL12.RGAMINSTANCE\MSSQL\DATA**
- Updates to the virus database are not performed while the Rotor-Gene AssayManager v2.1 is in use
- Please make sure that full or partial scans of the hard drive are disabled during real-time PCR data acquisition. Otherwise there is a risk of adverse impact on the performance of the instrument.

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

Firewall and networks

Rotor-Gene AssayManager v2.1 can be run either on computers without network access if the database is located on the same computer that controls the Rotor-Gene MDx instrument, or can run in network environments 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 the ports required to establish a network connection. Please note that blocking incoming connections does not affect responses to requests triggered by the user such as updating anti-virus definition files or connecting Rotor-Gene AssayManager v2.1 to the centralized database server. Outgoing connections are allowed as this may be required for retrieving updates or when Rotor-Gene AssayManager v2.1 is configured to work with a centralized database server. For security and reliability reasons in such cases, a cable-based local area network instead of wireless network connections should be used.

If your configuration is different, QIAGEN recommends to configure the firewall in the same way as described above and to disable the Wi-Fi adapter manually. To this end, a system administrator will need to login and perform the steps described in the *Rotor-Gene AssayManager v2.1 Core Application User Manual*.

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 computer while Rotor-Gene AssayManager v2.1 is performing a PCR run.

Operating system updates

The laptop computer provided by QIAGEN is configured in a way that automatic updates to the operating system are disabled. If your configuration is different, a system administrator must disable any automatic updates to the operating system. This can be performed by following the steps described in the Rotor-Gene AssayManager v2.1 MDx Core Application User Manual.

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

Please visit the product page on www.qiagen.com for more information.

Database backup tool and maintaining the database

Important: It is important to back up the database as this will mean you can recover the data from your last back up if there is a computer failure.

Note: It is not possible to back up the content of the computer's hard disc directly to create a backup copy of the database.

The Rotor-Gene AssayManager (RGAM) Backup Tool software has been specifically developed for use with Rotor-Gene AssayManager software. The RGAM Database Backup Tool is software for automatic backup creation of the Rotor-Gene AssayManager database (Microsoft SQL Server Express) using Windows Task Scheduler. The RGAM Database Backup Tool has the functionality to restore previously created backup files automatically. For maintaining the database, download the RGAM Database Backup Tool software from the QIAGEN webpage. Please refer to the RGAM Database Backup Tool User Manual for further information.

FAQ

Question	Answer
How can I uninstall a plug-in?	For regulatory reasons, plug-ins cannot be uninstalled. In case you want to uninstall a plug-in, the core application must be uninstalled together with the plug-in.
Why is Rotor-Gene AssayManager v2.1 unable to communicate with the cyclers?	Check the cable connection between Rotor-Gene Q MDx and the computer. The USB cable might be loose or faulty. Reconnect or replace the cable. Only use cables and accessories supplied by QIAGEN. Switch off the Rotor-Gene Q MDx and switch it back on again. Restart Rotor-Gene AssayManager v2.1.
Why does Rotor-Gene AssayManager v2.1 not start?	a) Microsoft Windows 7 or 10 is not installed Rotor-Gene AssayManager v2.1 can only be operated with Windows 7 or 10. If you are running a different version of Windows, then this software will not start. b) No plug-in installed Rotor-Gene AssayManager v2.1 consists of the core software and plug-ins with application specific components. Besides the core software, at least one plug-in must be installed to be able to use Rotor-Gene AssayManager v2.1.

Revision History

Revision	Description
R3, 05/2019	<p>Updated the following parts for the new Rotor-Gene AssayManager 2.1.1 version:</p> <ul style="list-style-type: none">● Added support and descriptions for Windows 10● Added prerequisites for the installation of Rotor-Gene AssayManager on Windows 10 systems● Added creation of Windows 10 user accounts● Updated and extended description of recommended virus scanner settings

For further support with technical difficulties, please contact QIAGEN Technical Services at www.qiagen.com.

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