QIAGEN GeneReader® User Manual



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1 Introduction

Thank you for choosing the GeneReader. We are confident it will become an integral part of your laboratory.

Before using the GeneReader, 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 GeneReader in the following sections:

- Introduction
- Safety Information
- General Description
- Installation Procedures
- Operating Procedures
- Maintenance
- Troubleshooting
- Technical Data
- Appendices
- Index

The appendices contain the following information:

- Declaration of Conformity
- License Terms
- Waste Electrical and Electronic Equipment (WEEE)
- FCC Declaration
- Liability Clause
- Bar codes
- GeneReader accessories

1.2 General information

1.2.1 Technical assistance

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

1.2.2 Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

1.3 Intended use of the GeneReader

The GeneReader is designed to perform next-generation sequencing (NGS) applications by integrating highly parallel fluorescence-based sequencing chemistry with detection of the corresponding fluorescent signals templates that have been clonally amplified using the GeneRead QIAcube®.

GeneReader software provides a wizard for setting up the sequencing, data storage management, and the functionality for base calling and generation of FASTQ files.

The GeneReader is intended to be used only in combination with QIAGEN kits indicated for use with the GeneReader for applications described in the respective QIAGEN kit product sheets or handbooks

The GeneReader is intended for use by professional users trained in molecular biological techniques and in the operation of the GeneReader.

1.4 Requirements for GeneReader users

The table below covers the general level of competence and training necessary for transportation, installation, use, maintenance and servicing of the GeneReader.

Task	Personnel	Training and experience
Transportation	No special requirements	No special requirements
Installation	QIAGEN Field Service Specialists only	
System relocation	QIAGEN Field Service Specialists only	
Routine use (running protocols)	Laboratory technicians or equivalent	Appropriately trained and experienced personnel familiar with use of computers and automation in general
Regular and monthly maintenance	Laboratory technicians or equivalent	Appropriately trained and experienced personnel familiar with use of computers and automation in general
Annual preventative maintenance and servicing	QIAGEN Field Service Specialists only	No special requirements

2 Safety Information

Before using the GeneReader, 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 the QIAGEN GeneReader User Manual.

WARNING



The term WARNING is used to inform you about situations that could result in **personal injury** to you or others.

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 an instrument or other equipment.

Details about these circumstances are given in a box like this one.

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

2.1 Proper use

WARNING

Risk of personal injury and material damage



Improper use of the GeneReader may cause personal injuries or damage to the instrument.

The GeneReader must only be operated by qualified personnel who have been appropriately trained.

Servicing of the GeneReader instrument must only be performed by a QIAGEN Field Service Specialist.

Perform the maintenance as described in Section 6. QIAGEN charges for repairs that are required due to incorrect maintenance.

WARNING

Risk of personal injury and material damage



The GeneReader is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone.

Contact QIAGEN Technical Services to relocate the instrument.

WARNING

Risk of personal injury and material damage



Do not attempt to move the GeneReader during operation.

WARNING

Risk of personal injury and material damage



Load flow cell only in accordance with step by step instructions provided by GeneReader software. Beware of moveable parts.

WARNING

Risk of personal injury and material damage



Do not stare into the beam of the flow cell bar code reader.

CAUTION

Risk of material damage



Avoid moving the workbench and causing vibrations to the GeneReader during operation to prevent disturbing sensitive optical measurements.

CAUTION

Damage to the instrument



Avoid spilling water or chemicals onto the GeneReader. Damage caused by water or chemical spillage will void your warranty.

CAUTION

Risk of material damage



Do not place any items on top of the instrument.

In case of emergency, power OFF the GeneReader using the power switch at the right, rear panel of the instrument and unplug the power cord from the power outlet.

CAUTION

Damage to the instrument



Only use QIAGEN consumables with the GeneReader. Damage caused by use of other types of consumables will void your warranty.

CAUTION

Damage to the instrument



Make sure that the flow cell is inserted in the correct position. Incorrect insertion of the flow cell can damage the instrument.

WARNING

Fire hazard



Empty the liquid waste bottle before each run and make sure to place it in the correct orientation back in the GeneReader instrument. Spilling of liquid-waste may cause an electrical short-circuit and fire.

2.2 Electrical safety

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

WARNING

Electrical hazard



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.

WARNING

Damage to electronics



Before powering ON the instrument make sure that the correct supply voltage is used.

Incorrect use of supply voltage may cause damage to electronics.

See specifications indicated on the type plate of the instrument.

WARNING

Risk of electric shock



Do not open any panels on the GeneReader.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual.

To ensure satisfactory and safe operation of the GeneReader, follow the advice below:

 The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).

- Place instrument in a location so that the power cord is accessible and can be connected/disconnected.
- Use only the power cord delivered by QIAGEN.
- Do not adjust or replace internal parts of the instrument.
- Do not operate the instrument with any covers or parts removed.
- If liquid has spilled inside the instrument, switch off the instrument, disconnect it from the power outlet and contact QIAGEN Technical Services.

If the instrument becomes electrically unsafe, prevent other personnel from operating it and contact QIAGEN Technical Services.

The instrument may be electrically unsafe when:

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

2.3 Environment

2.3.1 Operating conditions

WARNING

Explosive atmosphere



The GeneReader is not designed for use in an explosive atmosphere.

WARNING

Risk of explosion



The GeneReader is intended for use with reagents and substances supplied with QIAGEN kits. Use of other reagents and substances may lead to fire or explosion.

. . . .

Damage to the instrument

CAUTION



Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.

The GeneReader must be located out of direct sunlight.

2.4 Chemicals

WARNING

Hazardous chemicals



Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run. Always wear safety glasses, gloves, and a lab coat. The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Safety Data Sheets (SDSs) or OSHA,* ACGIH† or COSHH‡ documents.

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

2.5 Waste disposal

Used labware may contain hazardous chemicals. Such wastes must be collected and disposed of properly according to local safety regulations.

For more information about how to dispose of the GeneReader, see "Waste Electrical and Electronic Equipment (WEEE)", page 59.

^{*} 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).

WARNING

Hazardous chemicals and infectious agents



The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

2.6 Mechanical hazards

The door of the GeneReader must remain closed during operation of the instrument. Only handle the flow cell loading station when the flow cell door has been released by the software.

Note: Only power OFF the instrument if the process has been properly terminated by the software and the flow cell door is closed. Otherwise, the instrument could initialize with the flow cell door open.

WARNING

Moving parts



To avoid contact with moving parts during operation of the GeneReader, the instrument must be operated with the door closed.

If the door sensor is not functioning correctly, contact QIAGEN Technical Services.

WARNING

Risk of overheating



To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the GeneReader.

Slits and openings that ensure the ventilation of the GeneReader must not be covered.

2.7 Maintenance safety

WARNING

Risk of personal injury and material damage



Only perform maintenance that is specifically described in this user manual.

WARNING

Risk of fire



When cleaning the GeneReader with alcohol-based disinfectant, leave the GeneReader door open to allow flammable vapors to disperse.

CAUTION

Damage to the instrument



Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the GeneReader.

WARNING

Hot surface



Internal components of the instrument can reach very hot temperatures. Wait until the cool down cycle has finished before handling the flow cell to avoid skin burns.

2.8 Symbols on the GeneReader

Symbol	Location	Language	Description
	Inside instrument	-	Heat hazard – do not perform maintenance before the system has cooled down.
\triangle	On the instrument	-	Mechanical hazard – avoid contact with moving parts.
	On front of the instrument, open door	-	Mechanical hazard – avoid contact with moving parts.
A	Inside instrument	-	Electric shock hazard
CAUTION LASER RADIATION DO HOT STANS SHOW CLASS 2 LASER PRODUCT	On the instrument, right side panel	EN	This product contains a class 2 laser. Do not stare into the beam.
ATTENTION RAYONNEMENT LASER MYMAGEL ALARES CLARES 2 APPRAGEL ALARES CLARES 2	On the instrument, right side panel	FR	This product contains a class 2 laser. Do not stare into the beam.
	On front of the instrument, open door	-	This product contains a class 2 laser. Do not stare into the beam.
Z	Type plate on the right side panel	-	WEEE about the disposal of waste electrical and electronic equipment for Europe and rest of the world.
•••	Type plate on the right side panel	-	Legal manufacturer.
[]i	On the instrument, right side panel	-	Consult instructions for use.
DISCONNECT SUPPLY BEFORE SERVICING	On the instrument, right side panel	EN	Disconnect power supply before servicing.
SUSCOS TO STREET	Inside instrument	-	Earth (Ground)

Symbol	Location	Language	Description
CE	Type plate on the back of the instrument	-	CE mark for Europe
F©	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	-	RCM (former CTick) for Australia (supplier identification N17965)
25	Type plate on the back of the instrument	-	RoHS mark for China (the restriction of the use of certain hazardous substances in electrical and electronic equipment)
SN	Type plate on the back of the instrument	-	Instrument serial number

3 General Description

The QIAGEN GeneReader performs fully automated next-generation sequencing (NGS) by integrating highly parallel fluorescence-based sequencing chemistry with detection of the corresponding fluorescent signals on templates that have been clonally amplified using the GeneRead QIAcube.

The GeneReader system consists of the GeneReader instrument, the workstation, the GeneReader software and a handheld bar code scanner that connects to the workstation for scanning bar codes of kits and buffers, which are then automatically entered into the GeneReader software. The initial software installation is performed by a QIAGEN Field Service Specialist. There are two USB connections between the GeneReader instrument and workstation. The GeneReader system also comes with several accessories, listed in Section 4.1.

The GeneReader software provides a FASTQ file of sequence information that is ready for QCI Analyze, which automatically runs an optimized workflow for GeneReader panels and generates an analysis-ready report (VCF file).

3.1 QIAGEN GeneReader Sample to Insight® NGS workflow

The QIAGEN GeneReader Sample to Insight workflow provides a streamlined and standardized approach to next-generation sequencing, from sample preparation to the biological interpretation of sequencing data.

The majority of the workflow is automated, ensuring greater standardization and more accurate results.

QIAGEN Clinical Insight combines analytical tools and integrated human disease content, providing access to current and advanced interpretations of genomic data. QCI Analyze automatically sends samples through predefined workflows and provides a web-based result viewer. Afterwards, QCI Interpret (another web-based viewer) provides a biological interpretation solution.

3.2 GeneReader principle

The principle behind a sequencing run on the GeneReader is shown below in Figure 1. The workflow includes the following 6 processes: sequencing primer hybridization, flow cell preparation, reagents preparation, experiment set-up in QCI Analyze, flow cell loading and run start, and post-run maintenance wash. These procedures are described in detail starting on page 32 and the GeneReader sequencing chemistry is briefly described below. It consists of a unique terminator-dNTP sequencing-by-synthesis paradigm that ensures highly accurate and cost-effective NGS runs.

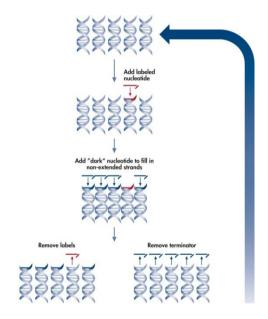


Figure 1. Principle behind sequencing run on the GeneReader.

After DNA library construction, DNA clonally amplified using the GeneRead QIAcube is immobilized via direct bead-slide interaction and exposed to a DNA sequencing primer to produce a high-density array on a GeneReader Flow Cell. To read out the sequence of each of the beads, the array of fragments is first subjected to reagents containing uniquely engineered DNA bases that include a removable fluorescent dye and an end cap. These bases attach themselves to the end of the growing strand of DNA in accordance with the base on the complementary strand. The array is scanned by a high-resolution electronic camera and the fluorescent output of each of the four dye colors at each array position is measured and recorded. The color indicates which base (A, C, G or T) was incorporated onto the DNA fragment from the previous step. Finally, the array is exposed to cleavage chemistry to break off the fluorescent dye and end cap that will then allow additional bases to be added. This cycle is then repeated on the GeneReader.

3.3 External features of the GeneReader



Front view

Side view (right side panel)

- 1 Status lights
- 2 Flow cell door
- 3 Hood
- 4 Fluidic drawer
- 5 USB port (hub workstation)
- 6 USB port (camera workstation)
- 7 Power switch
- 8 Power cord socket
- 9 Cooling air outlet (back of instrument)
 - Main Hood (QIAGEN service only)

3.3.1 Status lights

The status lights illuminate in the following pattern:

- When the instrument is not running the status lights are off.
- When a protocol is running normally, the green light is on.
- When a protocol is running, but a pause has been requested, or when a protocol is paused, the red light blinks.
- When a protocol has been stopped, aborted or an error has occurred, the red light is on.
- When the protocol has finished successfully, the green light blinks.

3.3.2 Flow cell door

Opening the flow cell door

Flow cells are inserted through the flow cell door. Opening the flow cell door is controlled by software.

Note: The flow cell door cannot be opened manually.

Closing the flow cell door

Push the flow cell door manually until the fastener snaps in place.

Note: The GeneReader will not work if the flow cell door is not locked.

3.3.3 Hood

Opening the hood

Opening the hood is controlled by software. The hood must be opened prior to opening the fluidic drawer.

Note: The hood can be manually released if the GeneReader loses power. Insert your hand, palm facing upward, and feel for the hole located approximately where the Main Hood meets the fluidic drawer. When your fingers are in the hole you will feel a lever on the right and by pulling slightly towards the front the hood will open.



Manually opening the hood

Closing the hood

The fluidic drawer must be closed (pushed all the way in until a clicking sound is heard) prior to manually pulling down the hood.

Note: The Main Hood on the left side of the instrument must only be opened by QIAGEN Field Service Specialists.

3.3.4 Fluidic drawer

Open the fluidic drawer to:

- Load or unload 1 liter wash bottles.
- Load or unload 50 ml tubes.
- Insert or remove the liquid waste bottle.
- Clean the cooling block, remove excessive condensation

- Clean the drawer
- Clean the dip stick
- Clean the waste level sensor surface

The fluidic drawer remains locked during a run.

Note: If the hood is closed, the fluidic drawer cannot be opened.

3.3.5 USB ports

The 2 USB ports are used to connect the GeneReader with the workstation. They are located on the right side panel of the instrument.

3.3.6 Power switch

The power switch is located on the right side panel of the GeneReader.

3.3.7 Power cord socket

The power cord socket is located on the right side panel of the GeneReader. It allows connection of the GeneReader to a power outlet via the supplied power cord.

3.3.8 Cooling air outlet

Cooling air outlets are on the right side and back of the GeneReader. They allow cooling of the internal components.

3.3.9 Workstation equipment

The GeneReader system is operated with a workstation.

The workstation specifications are listed in Section 8.3.

3.4 Internal features of the GeneReader



Internal view of the fluidic drawer

- 1 50 ml conical tubes in cooling compartment
- 3 Liquid waste bottle
- 2 One liter bottles for sequencing wash buffer or maintenance wash buffer

3.4.1 GeneReader Flow Cell

Sample is deposited into the GeneReader Flow Cell according to kit-specific instructions. The flow cell should be loaded into the GeneReader through the flow cell door with the bar code towards the left side of the GeneReader.



Loading the flow cell



View inside the flow cell door

CAUTION

Damage to the instrument



Make sure that the flow cell is inserted in the correct orientation. Incorrect insertion of the flow cell can damage the instrument.

Flow cell bar code reader

Upon loading of a flow cell, the flow cell bar code reader scans the bar code on the flow cell and provides the information to the GeneReader software. In the event that the flow cell has been inserted in the wrong orientation, an error message will occur.

4 Installation Procedures

4.1 System delivery and installation

The unpacking and installation of the GeneReader is performed by a certified QIAGEN Field Service Specialist. A person who is familiar with your laboratory and computer equipment should be present during the installation.

The following items are delivered:

- GeneReader instrument
- GeneReader User Manual
- Workstation
- GeneReader software (will be installed by QIAGEN Field Service during initial set up)
- Accessories: 1 international power cable set, 2 USB cables, 1 handheld bar code scanner, 1 waste container and 4 one liter bottles

Note: The computer required for data analysis is not provided. Refer to the QIAGEN Clinical Insight Analyze 1.0 User Manual for the required workstation specifications.

4.2 Site requirements

The GeneReader must be located out of direct sunlight, away from heat sources, and away from sources of vibration and electrical interference. Refer to Appendix A for the operating conditions (temperature and humidity). The site of installation should be free of excessive drafts, excessive moisture and dust, and not be subject to large temperature fluctuations.

Refer to Section 8 for the weight and dimensions of the instrument.

Use an appropriate workbench to accommodate the GeneReader. Ensure that the workbench is dry and clean, and has additional space for accessories. To accommodate the GeneReader instrument with the hood open, 125 cm (49.3 in.) minimum clearance above the workbench is required. Allow at least 10 cm (4 in.) of free space behind the instrument for cables and cooling of the instrument.

The GeneReader must be placed within approximately 1.5 m (59 in.) of a properly grounded (earthed) AC power outlet. The power line to the GeneReader should be voltage regulated and surge protected, and an uninterruptable power supply (UPS) is optional.

Note: Do not place the GeneReader instrument on a vibrating surface or near vibrating objects.

WARNING

Risk of overheating



To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the GeneReader.

Slits and openings that ensure the ventilation of the GeneReader must not be covered.

WARNING

Risk of personal injury and material damage



The GeneReader is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone.

4.3 AC Power and USB cable connections

4.3.1 Power requirements

The GeneReader operates at:

100-240 V AC, 50/60 Hz, max. 600 VA

The workstation operates at:

• 100-240 V AC, 50/60 Hz, max. 400 VA

Make sure that the voltage rating of the GeneReader and workstation are compatible with the AC voltage available at the installation site.

WARNING

Damage to electronics



Incorrect use of supply voltage may cause damage to electronics.

See specifications indicated on the type plate of the instrument.

4.3.2 Grounding requirements

To protect operating personnel, the National Electrical Manufacturers' Association (NEMA) recommends that the GeneReader 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 does not have a ground (earth) connection.

4.3.3 Installation of AC power cords, USB cables and workstation

IMPORTANT: Make sure that the GeneReader and workstation power switches are set to the OFF position.

Connect the power cords and USB cables as shown in the diagram below.

Note: It is recommended to plug the instrument and workstation directly into a shared line power outlet because the instrument and workstation are connected with 2 USB cables. This configuration results in less interference caused by ground loops.

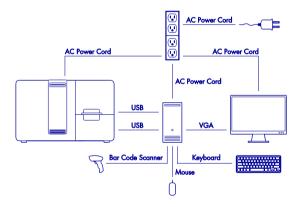


Diagram of cable connections

4.3.4 Installation of AC power cords, USB cables and workstation using an optional UPS

IMPORTANT: Make sure that the GeneReader and workstation power switches are set to the OFF position.

Connect the GeneReader and workstation to the UPS as shown in the diagram below. The UPS should be configured in such a way that a Windows® shutdown command is issued shortly before backup power is lost. The UPS should be able to supply the GeneReader and workstation with a maximum 1000 VA for the desired time.

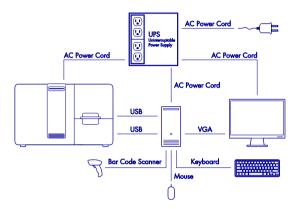


Diagram of cable connections using an optional UPS

4.4 Workstation requirements

The workstation, supplied with the GeneReader instrument, fulfills the requirements of the GeneReader software as detailed in the following table.

Workstation system requirements

Description	Minimum requirement
Operating system	Microsoff® Windows 7 Professional 64-bit (D/F/E/I)
Processor	Intel® Xeon® E5-1650
Main memory	3.20 GHz 6 Core/HP® Liquid Cooling Solution
Hard disk space	256 GB Solid Stat Drive
Graphic card	3x2 TB SATA 7200 rpm
Display	NVIDIA® Quadro® K2000 (2 GB GDDR5), PCIE x 16
Ports	Adapter and screen with at least 1920 x 1080 pixels

Adobe® Reader® software is preinstalled on the computer to view reports generated in PDF format.

4.5 Getting started

4.5.1 Powering ON the GeneReader and workstation

- Power ON the GeneReader using the power switch located on the right side panel of the GeneReader.
- 2. Power ON the workstation and monitor.
- 3. Log in to the system using your password.
- 4. Start the GeneReader software.

When the GeneReader software has been started, the following window will appear:



IMPORTANT: If virus scan software is installed on the GeneReader workstation, make sure that active scanning is not performed during a sequencing run.

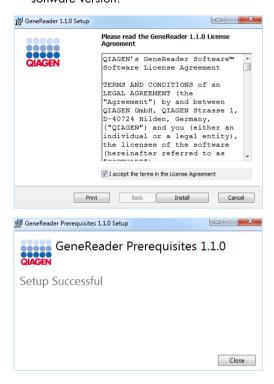
Note: After the instrument is powered ON and the software is running, the temperature regulation of the GeneReader starts. The specified temperature will be reached in 30 minutes.

4.5.2 Software upgrade

The GeneReader software is not preinstalled. QIAGEN Field Service will perform the installation. To upgrade software, follow the steps below:

- 1. Confirm that the following requirements are met before you begin the upgrade process:
 - a. A run is not being performed
 - b. There are no loaded flow cells on the instrument
 - c. The GeneReader software is closed
- 2. Create a folder named "Upgrade" on the desktop. Copy the GeneReaderInstaller zip file that is provided by QIAGEN to the newly created "Upgrade" folder.

- 3. Extract the GeneReaderInstaller zip file into the "Upgrade" folder by right-clicking the file and selecting Extract all... from the content menu.
- 4. Go to the "Upgrade" folder.
- 5. Go to the "GeneReaderInstaller" subfolder and run the setup.exe file.
- Follow the on-screen instructions to confirm all license agreements and install all parts of the software. The sequence of this process may differ depending on the existing and new software version.



- 7. The computer may require a restart after the installation is complete. Follow the on-screen instructions restart the computer.
- 8. The installer places a shortcut icon for starting the GeneReader software on the desktop. Another shortcut icon is created to start the software in service mode, but it is intended for service purpose only.
- Start the GeneReader software by clicking the GeneReader shortcut icon. If necessary, the GeneReader firmware updater appears. If this occurs click OK to perform a firmware update. This may take several minutes to finish.
- 10. After the firmware update is complete, wait until the software has finished the initialization and homing processes, and then close the GeneReader software.
- 11.Delete the "Upgrade" folder that was created on the desktop in step 2. The software is now ready for use.

5 Operating Procedures

Before proceeding, we recommend that you familiarize yourself with the features of the instrument by referring to the Section 3.

CAUTION

Damage to the instrument



Only use QIAGEN flow cells and consumables with the GeneReader. Damage caused by use of other types of flow cell or consumable will void your warranty.

CAUTION

Risk of material damage



Avoid moving the workbench and causing vibrations to the GeneReader during operation to prevent disturbing sensitive optical measurements.

5.1 Use of the GeneReader software

5.1.1 Start-up

During start-up, the software will perform a self-test and take an inventory of its own configuration files and any loaded flow cells and reagents. If flow cells are still loaded, you will be asked to unload them. Should a configuration file be missing, or any failure occur during the start-up procedure, contact QIAGEN Technical Services.

5.1.2 Software workflow

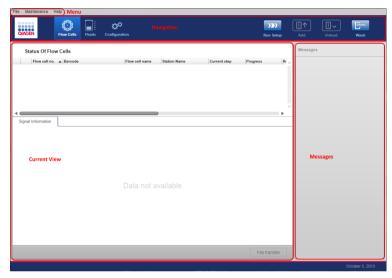
The GeneReader software provides a sample-to-result workflow, which includes the following stages:

- Definition of flow cell parameters, including optional multiplexing information
- Step-by-step loading instructions
- Sequence detection
- Generation of FASTQ data file

The software also provides step-by-step instructions for the maintenance wash that is part of routine GeneReader maintenance (see Section 6).

5.1.3 User interface

The GeneReader software is divided into four distinct areas (see image below). At the top, the menu offers access to general functionality. Below the menu bar, the navigation area contains quick links to the commonly used views and workflows. The main portion of the screen is devoted to the work area, which displays the current setup of flow cells and status of a protocol run, and on the right side the message area displays messages relating to protocol function, setup and errors.



Menu and navigation



Select File and Exit in the menu to close the GeneReader software. This cannot be done while a protocol is running or if any flow cells are still loaded.



Select Maintenance and the Manage Files command to start the Manage Files wizard, which can be used to clear space on the hard drive prior to starting a run. Any selected data for clearing will be permanently deleted. If data is still needed, make sure to create a proper backup on an external drive. Select Maintenance and the Service Archive command to create a service archive if requested by QIAGEN Technical Services.



Use the Help menu to access version and copyright information in the **About** dialog, and select Help to open the *GeneReader User Manual*.



The Flow Cells button displays the status of all flow cells inside the GeneReader. Refer to Section 5.1.4 for more information.



The Fluids button displays the status of all fluids in the main work area. Refer to Section 5.1.5 for more information.



The Configuration button opens the view for editing several configuration values. Refer to Section 5.1.6 for more information



Use the Run Setup command to open the workflow and to setup and start a run. Refer to the relevant QIAGEN kit handbook for more information.



Use the Add command to load flow cells during a run in staggered mode once the first cycle of sequencing is complete, and prior to 24 hours after the run has started. Refer to the relevant QIAGEN kit handbook for more information.



Use the Unload Flow Cell command to unload flow cells from the device.

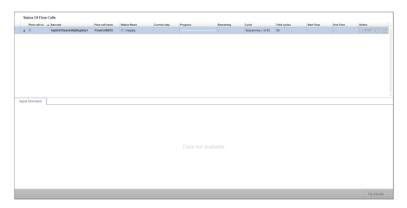
Refer to the relevant QIAGEN kit handbook for more information.



Use the Wash command to open the maintenance workflow. Refer to Section 6.1 for more information.

5.1.4 Status of Flow Cells view

Status of Flow Cells is displayed in the main work area and displays an overview of all flow cells loaded inside the instrument.



The current statuses of all loaded flow cells are shown, as well as estimations for remaining run times. In the Action column on the right-hand side of the screen, there are icons for performing specific actions regarding the particular flow cell. The icons may not be enabled if the action is not available for the current status of the flow cell.

■ STOP

The run can be interrupted by pressing the Stop icon. Be aware that the protocol does not stop immediately. The protocol will stop after the currently running process is complete. This button is available if the flow cell is running, after first cycle of sequencing is complete.



The Open Flow Cell Data Folder icon opens the run folder of the corresponding flow cell. This button is available if the flow cell is either finished or stopped, and the analysis is not currently running.



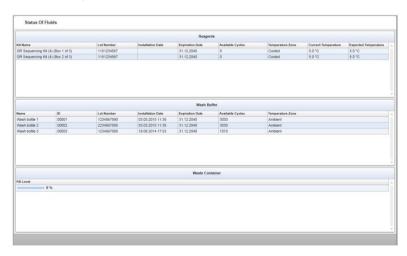
The Flow Cells Results icon opens the folder button that contains the analysis result data of the corresponding flow cell. This button is available if the flow cell is finished and the analysis is not currently running, but not if the flow cell was stopped.

Note: The number of cycles for a loaded flow cell will be slightly higher than the amount of cycles selected for sequencing. This is due to an extra cycle being required for lead/lag correction and to the additional cycles required to sequence the sample index when multiplexing is enabled.

To view flow cell details, press the (+) icon at the beginning of each row to display the current quality information for a run. By expanding the row of a flow cell, you can also view the multiplexing details.

5.1.5 Status of Fluids view

The Status of Fluids view is displayed in the main work area and provides an overview of all fluids currently loaded on the GeneReader.



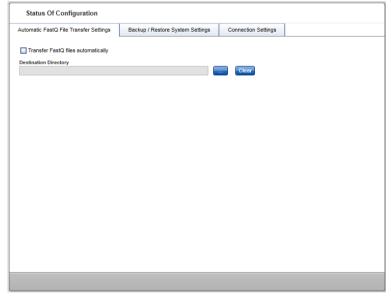
The screen is partitioned into three areas and provides information on the levels of reagents (top), wash bottles (middle) and the waste bottle (bottom). This view provides information only and does not allow the user to perform any actions.

5.1.6 Status of Configuration view

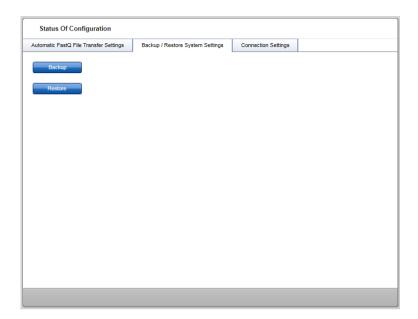
The Status of Configuration view provides the ability to edit several configuration settings. The view is divided into three areas (Automatic FastQ File Transfer Settings, Backup/Restore System Settings and Connection Settings) that are selected by tabs.

Automatic FastQ File Transfer Settings

The Automatic FastQ File Transfer Settings tab displays a checkbox to enable the automatic FastQ file transfer. The destination folder for the FastQ files can be specified using the "Destination Directory" field. Depending on the connections entered on the Connection Settings tab, these settings may not be editable.



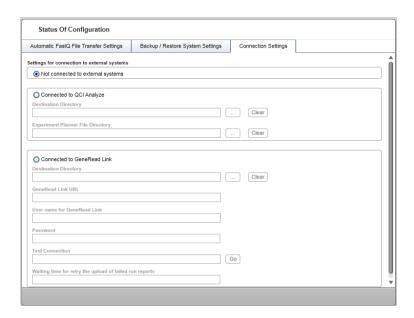
The Backup/Restore Systems Settings tab displays two buttons: one to save all GeneReader instrument settings to a Backup file and one to Restore the settings by loading a backup file that was previously saved. Backup and Restore may be disabled depending on the current state of the GeneReader instrument and software.



Connection Settings

The Connection Settings tab allows the setup of connections to external systems for experiment planning and analyses. Depending on the system used, there are three possibilities to select by marking the corresponding radio button

- Not connected to external system: Select this if there is no external system available.
- Connected to QCI Analyze: Select this if QCI Analyze is used as the experiment planning system. The user must provide the network share directory that the QCI Analyze experiment planner files will be stored, and the directory that the result data files will be saved to. For more information refer to the QIAGEN Clinical Insight Analyze 1.0 User Manual.
- Connected to GeneRead Link: Select this if GeneRead Link is used as the experiment planning system. The user must provide several configuration values: First, the network share directory that the result data files will be saved must be entered. Second, the URL, user name and password of the GeneRead Link server must be provided. By clicking the Go button it is possible to confirm that the connection to GeneRead Link is working. Third, the user must provide the time (in minutes) to wait for a retry if the data upload failed.



5.1.7 File handling

Required files

The GeneReader software performs an inventory of its own files and configuration upon start-up. If a message is shown about missing files, please contact QIAGEN Technical Services.

5.2 Workflow procedures

5.2.1 QCI Analyze web interface

QCI Analyze is a browser-based system for analyzing NGS data. Based on the capabilities of the Genomics Server and QIAGEN CLC bio algorithms, QCI Analyze can import NGS data, analyze it, display results for inspection and export result data in VCF format. In addition, it can connect directly to QCI for interpretation and reporting. For more information refer to the QIAGEN Clinical Insight Analyze 1.0 User Manual.

Intended use of QCI Analyze

QCI Analyze is intended for use in combination with the GeneReader by professional users trained in molecular biological techniques, and in the operation of the GeneReader.

QCI Analyze navigation

The QCI Analyze web interface contains several tabs for navigating the different steps of the analyses. It displays from left to right:

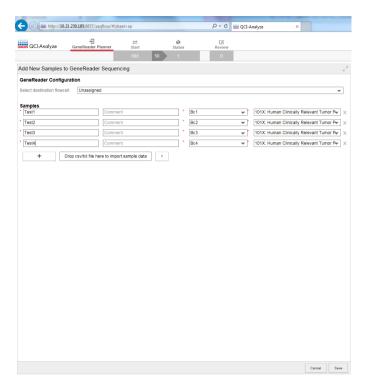
- GeneReader Planner tab: For importing samples in GeneReader.
- Start, Status and Review tabs: Three tabs that provide information on the main steps of the analysis. Numbers for each tab indicate how many samples are in or between each step.
- Interpret tab: For connecting to QCI for biological content interpretation.
- Administration tab: Visible only for administrators. This tab allows the addition of users and editing of groups. It also enables installation of connectors, plugins, and workflows, and their references.
- User button: For logging out of the system.
- Search function: For searching data by name or any other parameters already defined for the sample. A search tile will open once a search is started. All samples opened in the Status window are available for Review.

5.2.2 GeneReader Planner tab

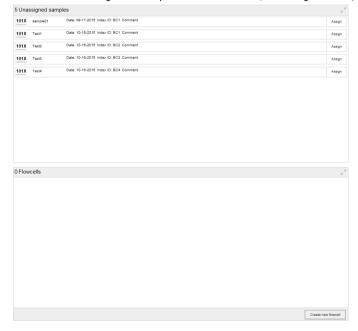
This tab is present as soon as you install the GeneReader plugin. The GeneReader tab is used to plan flow cells for sequencing on the GeneReader. Here, the user can add samples and sample information, including sample ID and choice of analysis workflow. The analysis workflow describes a CLC workflow that will be used to analyze the sample after sequencing is completed. The GeneReader and QCI Analyze exchange information dynamically to ensure that analysis starts automatically when sequencing is complete.

Add new samples to GeneReader Sequencing

- Type in the sample name. Select an index ID and analysis (usually described by a 4 character code such as "101x").
- 2. To add additional samples click the + button. Enter the name of the samples and define the index and analysis using the dropdown menu, or import information from a *.csv or *.txt file. When finished, save the sample information by clicking the Save button at the bottom of the window (see image below).



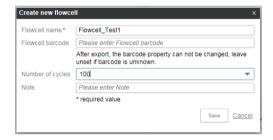
3. After a sample has been entered and saved, it will be displayed in the unassigned sample(s) tile until is it assigned to a particular flow cell (see image below).



Add flow cells

 Click Create new flowcell and enter the flow cell name, flow cell bar codes (if known), and the number of cycles.

Note: The flow cell bar code can be scanned automatically during loading, or manually using the handheld bar code scanner of the GeneReader.



2. When the flow cell entry process is complete, click Save to save the entered data.

Note: When locking the flow cell plan, it is also possible to create a printout by clicking Print. This provides a worksheet for reference when adding molecular indices to samples, and samples to a flow cell(s).

Note: Unlock the flow cell plan to make additional edits. Click on the window of an existing flow cell to the right of the parameters to display and print the associated sample(s) information.

Assign the samples to a particular flow cell

Note: The number of assigned samples is displayed in the flow cell tile area.

 To assign sample(s) to a flow cell, click Assign and select the appropriate flow cell. Click Save.



2. Move the cursor over the flow cell and right-click to display additional features such as Edit, Remove, Export and Lock. Undesired samples can be unassigned (Unassign), or the entire flow cell can be removed by clicking Remove.



3. Click Lock to save the entered data (flow cell plan) and prevent other QCI Analyze users from modifying the plan.

Note: When locking the flow cell plan, it is also possible to create a printout by clicking Print. This provides a worksheet for reference when adding molecular indices to samples, and samples to a flow cell(s).

Note: Unlock the flow cell plan to make additional edits. Click on the window of an existing flow cell to the right of the parameters to display and print the associated sample(s) information.

- 4. When the flow cell is ready to be loaded into the GeneReader for sequencing, Unlock the flow cell and Export the data (*.xml file format). The flow cell plan will be sent to the GeneReader software.
- 5. On the GeneReader, accept the flow cell plan and begin the sequencing process. When sequencing has been completed, the FASTQ files will begin analysis in QCI Analyze and appear in the Samples in analysis tile on the Start tab.

5.2.3 Loading and running the GeneReader

For instructions on loading and running the GeneReader refer to the relevant QIAGEN kit handbook.

Starting the GeneReader

- 1. Start-up the GeneReader software by clicking the icon. The GeneReader application will launch in approximately 45 seconds.
- 2. During start-up, the software will check for configuration files, perform a self-test and search for old flow cells.

5.2.4 Run finished

When the sequencing and analysis of all flow cells is completed, the Run Finished wizard will allow:

- Transfer of FASTQ files
- Viewing of result directory
- Unloading of flow cells and fluids
- A post-run prime or maintenance wash to be performed

Running the "Clean Disk" wizard

A run report is generated automatically after the analysis of the flow cells. A separate report is created for every flow cell in the run and it is saved to the flow cell directory within the run directory. The report contains sections on the run setup, the quality score distribution, data on bead quality and the sequence quality score, as well as multiplex data. Additionally, run reports contain any errors or warnings that may have been logged/reported during the course of the sequencing and analysis processes.

Log files

- The GeneReader software writes an EventLog.txt file to the folder:
 C:\ProgramData\QIAGEN\GeneReader\GeneReader. This log file contains warnings and errors and is intended to provide information in case of an issue. To prevent this log file from getting too large, a new log file is created once a month.
- During a run, a run-specific event log file is created within the run folder. Refer to this file for any issues that occurred during the execution of a sequencing protocol.
- When the analysis software is started, a flow cell report is generated as a PDF file and written to the path:

An example file is:

D:\QIAGEN\GRSData\2015_10_06_133222_SampleRun\FC_FC1_2c0sbgi977zjkqbktbg 1vuj71\Analyze\1510061332_2c0sbgi977zjkqbktbg1vuj71_FinalReport.pdf

6 Maintenance

This section describes routine and monthly maintenance procedures.

Note: Only use spare and other parts supplied by QIAGEN.

6.1 Maintenance wash

It is recommended to perform the following maintenance procedures to ensure reliable operation of the GeneReader:

- Routine maintenance A post-run prime must be performed if the GeneReader will be idle
 and/or a run has completed, and there are no additional runs immediately following
- Monthly maintenance Once a month or every 4 runs

Following these procedures ensures that the GeneReader is free of dust and helps prevent clogging of the fluidics system.

6.1.1 Routine maintenance

After a sequencing run has finished and the GeneReader will be idle, or no other sequencing run is planned, a post-run prime will prevent the formation of air pockets and the drying of reagent lines.

- 1. Open the GeneReader software. Click Run Setup.
- 2. Click Add Flow Cell and enter "PostRunPrime" as the flow cell name. Click Next.
- The hood will open. Load wash bottles containing ≥200 ml deionized (DI) water. Scan bar
 codes provided in Appendix B for wash buffers. The cursor will automatically move to the next
 wash bottle ID box.
- 4. Click Done and then Next.
- 5. Load 50 ml conical tubes containing 40 ml Dl water into the cooling compartment in positions 1, 2, 5, 6 and 8.
- 6. Click Add Reagent twice. Place the cursor in the top reagent ID box and scan the bar code provided in Appendix B for one of the kit reagents. Next, place the cursor in the second reagent ID box and scan the other provided kit reagent bar code.
- 7. Click Done and then Next. Close the hood and click Next.
- 8. The flow cell door will open. Load the priming flow cell. Close the flow cell door and click Next.

- 9. Instrument will now prime with water. Once complete, click Cancel. DO NOT select Start Run.
- 10.Leave all wash bottles and conical tubes on the instrument until the next run or maintenance wash is performed.

6.1.2 Monthly maintenance

To make sure reagent lines remain clear and to prevent buildup of material that could potentially clog the lines, a maintenance wash should be performed every 4 runs or once per month (whichever occurs first). The maintenance wash utilizes the maintenance wash buffer provided in the GeneRead Sequencing Buffer Q Kit (16) (cat. no. 185901). The steps below describe the maintenance wash procedure.

- If sequencing run has just completed, make sure that all flow cells are removed, reagents have been removed from the cooling compartment and discarded, and wash buffers are removed and stored at room temperature.
- 2. If software is not open, click the GeneReader software icon to open. GeneReader will scan for flow cells upon opening software. Remove if present
- 3. Click Wash in the navigation pane and the fluidic drawer will open.
- 4. Load 1 liter bottles containing ≥200 ml of DI water into positions 9 and 11 in the fluidic drawer
- Load 1 liter bottle containing 50 mL of Maintenance Wash Buffer into position 10 of the fluidic drawer.
- 6. Load 50 ml conical tubes containing 40 ml DI water into the cooling compartment in positions 1, 2, 5, 6 and 8.
- 7. Click Done when finished.
- 8. Click Next.
- Empty the waste bottle and dispose of the contents according to local safety regulations.Reload the empty waste bottle into the instrument. Close the hood and click Next.

IMPORTANT: Make sure to reload the waste bottle into the instrument in the correct orientation. An incorrect orientation may damage the instrument. Do not use force to close the hood. If blocked, check the waste bottle orientation and correct if necessary before retrying to close the hood.



10.Load the priming flow cell, close the flow cell door and click Next.



- 11. When the wash is complete, click Next.
- 12.Unload the priming flow cell, close the flow cell door and click Next.
- 13.Empty the waste bottle. When finished, close the hood and click Done.
- 14.Click Finish to close the wizard.
- 15.Repeat the maintenance wash procedure and leave all wash bottles and conical tubes containing DI water on the GeneReader, except replace Maintenance Wash Buffer in position 10 with 200 ml DI water.
- 16. After the final wash is complete, leave all wash bottles and conical tubes on the instrument until the next run or maintenance wash is performed.

6.1.3 Preparing the GeneReader fluidics lines for long-term storage

If the GeneReader instrument will be stored for a prolonged period of time, the fluidics lines must be emptied.

- 1. Fill all reagent containers and buffer bottles with ultra-pure water.
- 2. Perform a maintenance wash and wait until the run has finished.
- 3. Remove all buffer bottles and reagent containers from the instrument.
- 4. Run the maintenance wash protocol again (with no bottles or reagent containers) and wait until the run has finished.

The instrument will be free of liquids and can be stored in this state.

6.1.4 Monthly cleaning procedure

Thoroughly wipe the inside and outside of the GeneReader using the cleaning agents described in Section 6.2.1.

IMPORTANT: Do not use alcohol or alcohol-based disinfectants or detergents to decontaminate the GeneReader hood.

6.2 General cleaning procedures

6.2.1 Cleaning agents

The following disinfectants and detergents are recommended for cleaning the GeneReader instrument:

Mikrozid[®] Wipes (Schülke & Mayr GmbH; www.schuelke-mayr.com) – moistened with ethanol-based disinfectant for wiping alcohol-insensitive surfaces of the GeneReader instrument.

Mikrozid Sensitive Liquid (Schülke & Mayr GmbH; www.schuelke-mayr.com) – quaternary ammonium salt-based disinfectant for alcohol-sensitive surfaces (consists of 0.26 g quaternary ammonium compounds, benzyl-C12-C16-alkyldimethyl, chlorides; 0.26 g Didecyldimethyl-ammonium chloride and 0.26 g quaternary ammonium compounds, benzyl-C12-C14-alkyl[(ethylphenyl)methyl]dimethyl, chlorides per 100 g Mikrozid Sensitive Liquid).

IMPORTANT: Do not use alcohol or alcohol-based disinfectants to clean the GeneReader instrument hood. Exposure of the GeneReader hood to alcohol or alcohol-based disinfectants will cause surface cracking. Clean the GeneReader hood with distilled water or Mikrozid Sensitive Liquid only.

Note: If you would like to use different disinfectants from those recommended, ensure that their compositions are similar to those described above. A suitable alternative to Mikrozid Liquid is Incidin® Liquid (Ecolab; www.ecolab.com).

6.2.2 General instructions

- Do not use spray bottles to spray cleaning liquids onto surfaces of the GeneReader instrument.
 Spray bottles should only be used for items that have been removed from the instrument.
- If solvents or saline, acidic or alkaline solutions are spilled on the GeneReader, or if QIAGEN buffers splash the instrument door, wipe the spilled liquid away immediately.
- Follow manufacturer's safety instruction for handling cleaning agents.
- Follow manufacturer's instruction for concentration of the cleaning agents. Immersing for longer than the recommended soak time can harm the instrument.
- Do not use alcohol or alcohol-based disinfectants to clean the GeneReader hood. Exposing
 the GeneReader hood, Main Hood, and flow cell door to alcohol or alcohol-based
 disinfectants will cause surface cracking. Clean the GeneReader hood with distilled water or
 Mikrozid Sensitive Liquid only.

WARNING

Toxic fumes



Do not use bleach to disinfect used labware.

WARNING



Risk of electric shock

Do not open any panels on the GeneReader.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual.

WARNING

Hazardous chemicals and infectious agents



The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

WARNING

Risk of personal injury and material damage



Improper use of the GeneReader may cause personal injuries or damage to the instrument.

The GeneReader must only be operated by qualified personnel who have been appropriately trained.

Servicing of the GeneReader instrument must only be performed by a QIAGEN Field Service Specialist.

6.2.3 Servicing

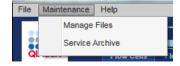
Contact QIAGEN Technical Services or your local distributor for more information about flexible Service Support Agreements from QIAGEN.

6.3 Cleaning the workstation hard disk

A sequencing run requires a large amount of memory on the computer hard drive. Therefore, the GeneReader software offers a Clean Disk Wizard to assist with backup tasks. To perform the clean disk process, additional free disk space for the backup is required, such as an external hard drive or network drive.

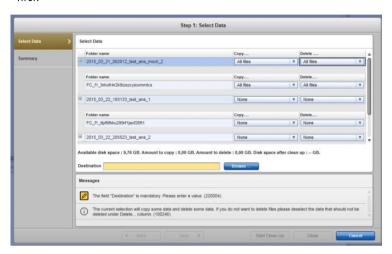
6.3.1 Procedure

1. Click Manage Files in the Maintenance menu to open the wizard. The wizard will display all previously run directories.

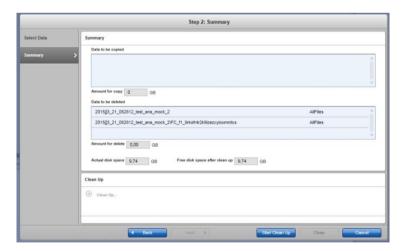


2. Select the folders you wish to backup by setting the respective action in the Copy ... column. If any folder is chosen for backup, the destination drive needs to be set. Select the folders to be cleaned up by setting the respective action in the Delete ... column.

IMPORTANT: It is possible to select folders for clean up without adding them to the list of files which will be backed up. Loss of data may occur if a manual backup has not been performed first!



3. The wizard will then display a summary of all copy and delete tasks as shown below. Check the estimated free disk space. You may return to the previous screen to change your settings by clicking Back.



7 Troubleshooting

This section provides information about what to do if an error occurs when using the GeneReader system.

If you need to contact QIAGEN Technical Services about an error, note the steps leading to the error and the information from any dialog boxes. This will help the QIAGEN Technical Service Specialist to resolve the error.

QIAGEN Technical Services may request a service archive file. The service archive wizard can be started by selecting Maintenance and Service Archive.

7.1 Hardware and software errors

7.1.1 Application module

Error message	Comments and suggestions
Cannot move the X or Y axis while the Z axis is not raised up.	Restart the GeneReader instrument. If the error occurs a second time, contact QIAGEN Technical Services.
Cannot move the Z axis while the following motors [{1}] are not at known safe positions.	Restart the GeneReader instrument. If the error occurs a second time, contact QIAGEN Technical Services.
Lowering flow cells into the stations failed.	Restart the GeneReader instrument. If the error occurs a second time, contact QIAGEN Technical Services.
The application cannot be closed because a run is ongoing.	Stop the run and unload all flow cells.
The application cannot be closed, because there are still flow cells in the instrument.	Unload all flow cells.

7.1.2 Clean Disk module

Error message	Comments and suggestions	
An error occurred while performing the operation. Please see the log for more details.	Verify that the destination path is still available and that you are running the software with the required permissions to write data there.	
Not all files that are selected for deletion are selected for backing up.	Verify that you wish to delete files without creating a backup.	
The destination drive is too small to copy the	Choose a destination drive with sufficient available space or copy less data.	

Error message	Comments and suggestions
The disk drive for the source and the destination is the same.	If the source and destination drives are identical, this wizard will not be able to release disk space.
The field "Destination" cannot contain any of the following characters: \/: * ? " <>	Correct the path name so that it does not include these characters.
The selected destination path does not exist.	Create the specified directories.
The selected destination path is too long to copy the selected files.	Choose a less nested destination path or rename the folders. The path may not exceed 255 characters in length.
The selected destination path is write protected.	Verify that you are running the software with the required permissions to write data to the selected path.

7.1.3 Fill fluids

Error message	Comments and suggestions
The data was not successfully saved to Configuration DynamicSettings.ini.	Verify that you are running the software with the required permissions to write data to the selected path.

7.1.4 Flow cells

Error message	Comments and suggestions
Cannot start a run because a maintenance wash has to be performed first.	Perform a maintenance wash.
Cannot start a run because there is not enough space on the hard drive to store run data.	Run the Clean Disk Wizard to free up disk space.
The wash cannot be started during a run.	Complete the run and unload process.
There are still flow cells on the carousel. Please unload these before starting a wash.	Unload all flow cells.
Validation of flow cell failed. Load the flow cell and ensure that the flow cell is placed correctly. Close the door to continue.	Verify that the flow cell orientation is correct and that the bar code is clean and undamaged. The bar code should be face up and to the left. Refer to the relevant QIAGEN kit handbook for more information.

7.1.5 Log module

Error message	Comments and suggestions
Severe warning: Time constraint for pausing the run was exceeded! Flow cell chemistry may be compromised, resulting in lower run-data quality.	Load flow cells within the given time frame.

7.1.6 Run module

Error message	Comments and suggestions	
An invalid flow cell is loaded.	Check that bar code is present on the flow cell.	
Error: Lowering flow cells into the stations failed. Is it ok to keep running the protocol?	Cancel the protocol and contact QIAGEN Technical Services.	
Error: There must be at least one flow cell loaded to run a protocol.	Use the Start Run Wizard to load flow cells and fluids before starting a run.	
Flow cell door is open.	Close flow cell door.	
No flow cell detected at the loader but flow cell <barcode> was expected to be there.</barcode>	Select Yes if this flow cell is at the loader. Select No to remove this flow cell from the inventory. Contact QIAGEN Technical Services if this message persists.	
The bar code reader found flow cell id <read barcode="">, but current inventory says the flow cell id should be <loadstation. chip.id="">.</loadstation.></read>	The flow cell door will reopen so the correct flow cell can be loaded. Contact QIAGEN Technical Services if this problem persists.	
The waste bottle is missing so the protocol cannot be run.	Load the waste bottle.	
Close the GeneReader Hood before continuing.	Close the hood.	

7.1.7 Start Run module

Error message	Comments and suggestions
The loaded reagent kit does not provide enough reagents to perform the run for the specified number of cycles.	Load a larger kit or modify the number of flow cell cycles.
This is not a known reagent kit and may not be used for a sequencing run.	Verify that you are using a GeneRead Sequencing Q Kit and contact QIAGEN Technical Services.

Error message	Comments and suggestions
This is not a valid barcode. Please re-scan the proper barcode from the reagent kit.	Verify that you are using a GeneRead Sequencing Q Kit and contact QIAGEN Technical Services.
This is not a valid barcode. Please re-scan the proper bottle from the wash kit.	Verify that you are using GeneRead Sequencing Wash Buffer and contact QIAGEN Technical Services.
Validation of flow cell failed.	Load the flow cell with bar code code> and ensure that the flow cell is loaded correctly. Close the flow cell door to continue. Do not use a priming flow cell.

8 Technical Data

Environmental conditions – operating conditions 8.1

100-240 V AC (±10%), 50/60 Hz Power

Max. 600 VA (GeneReader)

Max. 450 VA (workstation)

Overvoltage category

18 to 25°C (64 to 77°F) Air temperature Relative humidity 10-75% (noncondensing) Altitude Up to 2000 m (6500 ft.) Place of operation For indoor use only

Pollution level

3K2 (IEC 60721-3-3) Environmental class

Mechanical data and hardware features 8.2

93 cm (36.6 in.) Dimensions (hoods closed) Width:

Height: 61 cm (24.0 in.) Depth: 59 cm (23.2 in.)

Width: 93 cm (36.6 in.) Dimensions (hood open)

Height: 112 cm (44.1 in.) Depth: 59 cm (23.2 in.)

Width: Dimensions (Main Hood open) 93 cm (36.6 in.)

Height: 125 cm (49.3 in.)

59 cm (23.2 in.) Depth:

Weight 102 kg (224.9 lb.)

Up to 4 flow cells simultaneously Capacity

Workstation specifications (hardware and software) 8.3

Workstation 8.3.1

- Intel Xeon E5–1650 3.20 GHz 6 Core/HP Liquid Cooling Solution
- 32 GB (4x8) DDR3-1600 ECC
- 256 GB Solid Stat Drive 3x2 TB SATA 7200 rpm
- NVIDIA Quadro K2000 (2 GB GDDR5), PCI-E x 16
- Display resolution of 1920 x 1080 pixels, True Color (32 bit)
- 2x USB 3.0 Ports and 4x USB 2.0 Ports
- DVD drive
- Keyboard and mouse
- Monitor

• Handheld bar code scanner

8.3.2 Software

- Microsoft Windows 7 Professional 64-bit (D/F/E/I)
- GeneReader software

To view reports generated in PDF format, a PDF reader must be installed on the computer. Adobe Reader software can be downloaded at http://get.adobe.com/reader/.

Appendix A

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.

License Terms

The license terms for all software used with GeneReader, including QIAGEN software components, commercial software components and open source software components, are provided in the files licenses.rtf and Prerequisite.LicenseAgreements.rtf located on the GeneReader workstation under the following paths:

 $C: \label{local-constraint} C: \label{local-constraint} C: \label{local-constraint} Program Data \label{local-constraint} QIAGEN \label{local-constraint} Gene Reader \label{local-constraint} Idea \label{local-constraint} AGEN \label{local-constraint} C: \label{local-constraint} Program Data \label{local-constraint} QIAGEN \label{local-constraint} Gene \label{local-constraint} C: \label{local-constraint} Program Data \label{local-constraint} QIAGEN \label{local-constraint} Gene \label{local-constraint} Program \label{local-constraint} Gene \label{local-constraint} C: \label{local-constraint} Program \label{local-constraint} QIAGEN \label{local-constraint} Gene \label{local-constraint} G$

 $C: \label{likelihood} C: \label{likelihood} Prerequisite. License Agreements. rtf.$

Waste Electrical and Electronic Equipment (WEEE)

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

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

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



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

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

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/TV 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

Bar codes

Wash Buffer 9/10



8130062000109504709160010

TEC-IT.COM

Wash Buffer 9/10



81300620001095047091600164 TEC-IT.COM

Wash Buffer 11



81300640001095048091600112

TEC-IT.COM

GR Seq Q Buffers (4) Box 1 of 3



9802601160930210720150

TEC-IT.COM

GR Seq Q Add-Ons (4) Box 2 of 3



9802701160930210720 TEC:IT.COM

Appendix C

GeneReader accessories

Note: Only use accessories supplied by QIAGEN.

Product	Contents	Cat. no.
GeneReader System	Includes GeneReader instrument, workstation, USB cables, bar code scanner and international power cable set	9002312
Related Products		
GeneRead Sequencing Q Kit (1)	Includes reagents, add-ons and 1 flow cell supplied for 1 flow cell run on the GeneReader	185200
GeneRead Sequencing Q Kit (4)	Includes reagents, add-ons and 4 flow cells supplied for up to 4 flow cell runs on the GeneReader	185201
GeneRead Sequencing Buffer Q Kit (16)	Includes 800 ml each of wash buffers 9 and 10, and 1 L of wash buffer 11	185901
Related Products		
Handheld Bar Code Scanner NGS System		9022959
Waste Bottle NGS System		9243790
Workstation NGS System		9024359

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