Cepheid
A better way.

Operator Manual

GeneXpert® System with Touchscreen

Running Cepheid OS version 2.1 Software

303-1468 Rev. A October 2023

In Vitro Diagnostic Medical Device

UK CA IVD CE

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“Agreement” means the agreement under which Customer acquired the Instrument.

“Customer” means the original party that acquired the Instrument from either Cepheid or its authorized third party, and not any subsequent purchasers or transferees.

“Instrument” means the GeneXpert instrument described in this manual.

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Cepheid warrants that the Instrument: (i) shall be free from defects in material and workmanship for a period of one year after shipment; (ii) conforms to Cepheid's published specifications for the Instrument; and (iii) is free of liens and encumbrances when shipped. Cepheid does not warrant any defects in any Instrument caused by: (a) improper use, installation, removal, or testing; (b) Customer's failure to provide a suitable operating environment for the Instrument; (c) use of the Instrument for purposes other than that for which it was designed; (d) unauthorized attachments; (e) unusual physical or electrical stress; (f) modifications or repairs performed by anyone other than Cepheid or a Cepheid authorized service provider; or (g) any other abuse, misuse, or neglect of the Instrument. Use of unapproved parts, reagents, or other materials with the Instrument will void any warranty and service contract between Cepheid and the Customer that pertains to the Instrument. This warranty extends to Customer only and not to Customer's customers or any other third party, is not transferrable. This warranty applies only to new Instruments.

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Revision History

Revision	Description
A	Initial Release

1 Introduction

1.1 Intended Purpose

1.1.1 Intended Use

The GeneXpert System with Touchscreen automates and integrates sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time Polymerase Chain Reaction (PCR). The system is suited for in vitro diagnostic applications that require hands-off processing of patient samples (specimens) and provides summarized and detailed test results data in tabular format. The GeneXpert Systems with Touchscreen are designed for the use of Cepheid Xpert® test applications.

1.1.2 Intended User/Environment

The GeneXpert system with touchscreen is intended to be used by laboratory professionals or specifically-trained healthcare users in a laboratory and near patient test setting as specified in the Cepheid Xpert test instructions for use.

1.2 About This Manual

The *GeneXpert System with Touchscreen Operator Manual* describes the user operation and maintenance of the GeneXpert system with touchscreen. Information is provided about safely using the system with the Cepheid OS software and performing maintenance. Information about the anti-virus software and its operation is also included.

Read the entire manual and become familiar with the safety information before you start to operate the system. Using the system without reading the manual can result in serious injury, damage to the system, invalid results, or loss of data.

This manual describes how to use, maintain, and administer the system. The audience for this manual is everyone who uses or administers the system.

To learn how to use other parts of the system and related products, locate the relevant publication in the following table.

For...	See...
How to install the system and abbreviated generic instructions for running a test for any approved assay	*Reference Guide* and *Quick Start Guide*
Instrument calibration standards	*Certificate of Calibration*
Assay-specific instructions for performing a specific test on a patient sample	The instructions for use (IFU) for the assay
How to use the printer	The provided user guide from the manufacturer of the printer
How to use the Uninterruptible Power Supply (UPS)	The provided user guide from the manufacturer of the UPS

To learn more about the different user roles on the system, see User Functions by Roles.

1.3 Technical Support

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument (located on the back of the GeneXpert instrument)
- Error messages (if any)
- Software version and, if applicable, the touchscreen serial number (located on the back of the touchscreen unit)
- Users should report serious incidents associated with the use of GeneXpert Instrumentation systems to Cepheid and the competent authority of the Member State in which the serious incident occurred.

United States Technical Support

Telephone: + 1 888 838 3222 and select Option 2.
Email: techsupport@cepheid.com

Contact information for other Cepheid offices is available on our website at www.cepheid.com under the **Support** tab. Select the **Contact Us** option.

See Generate Technical Support Package and Connect to Cepheid Technical Support for more information.

France Technical Support

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2 Safety

2.1 Safety Information

Read and understand the safety information thoroughly before you begin operating the system. Make sure you follow the precautionary statements presented in this guide:

Warning ⚠ **A warning indicates a possibility of adverse reactions, injury or death to the user or other persons if the precautions or instructions are not observed.**

Caution ⚠ **A caution indicates that damage to the system, loss of data or invalid results could occur if the user fails to comply with the advice given.**

Important **An important note highlights information that is critical for the completion of a task or the optimal performance of the system.**

Note A note identifies information that is useful for completion of a task or identifies information that applies only in special cases.

The warnings and cautions always use the same keyword but the icon may change to more clearly indicate the type of hazard.

2.2 Safety Introduction

This chapter describes the possible safety hazards found in the GeneXpert system with touchscreen. It is imperative that you follow the precautions in this chapter for safe operation.

Caution ⚠ **If the GeneXpert system with touchscreen is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.**

Caution ⚠ **HEAVY OBJECT: See Performance Characteristics and Specifications for the GeneXpert system with touchscreen weights. Use care when unpacking the touchscreen or GeneXpert Instrument. Do not attempt to lift the instrument without proper safety training and assistance. Lifting or moving the instrument without proper training and assistance can cause personal injury, damage the instrument, and void your warranty.**

2.3 Table of Symbols

The following symbols and icons are used in this manual and on the system labels:

Table 1. Symbols

Symbol	Description

Symbol	Description
	*In vitro* diagnostic medical device
	CE marking – European Conformity
	United Kingdom Conformity Assessed
	Importer
	Do not reuse
	Consult instructions for use
	Manufacturer
	Authorized Representative in the European Community
	United Kingdom Responsible Person
	Authorized Representative in Switzerland
	Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union.
	This type of warning label indicates a potential biological hazard risk. Biological samples such as tissues, body fluids, and blood of humans and/or animals have the potential to transmit infectious diseases. Follow your local, state/provincial, and national safety regulations for handling and disposing the samples.
	This type of warning label indicates that hazardous high voltage sections are present in the electrical system in the GeneXpert system with touchscreen. Do not remove covers with this warning label.
	This type of symbol indicates a Warning or Caution for which there is no other identified symbol. Read the instructions following the symbol to avoid injury or equipment damage.
	A heavy object warning indicates an object is heavy and that it is possible for personnel to be injured if they lift improperly. Follow instructions and observe proper lifting techniques or use lifting aids when lifting heavy objects.

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2.4 Electrical Symbols on the Touchscreen and Instrument

The electrical symbols used on the GeneXpert system with touchscreen are shown in the following table:

Table 2. Electrical Symbols on the GeneXpert system with touchscreen

Label	Description
I	Indicates the ON position of the main instrument and touchscreen power switches.
O	Indicates the OFF position of the main instrument and touchscreen power switches.
~	Indicates the designated instrument or touchscreen connector either receives or delivers alternating current or voltage.

Label	Description
	Indicates the rating of the fuse (such as 2.5A) protecting the unit.
	Indicates a location of the chassis ground connection.

2.5 Electrical Safety

Warning

ELECTRICAL HAZARD: Do not attempt to open or remove the touchscreen or GeneXpert Instrument covers. Doing so can expose you to electrical hazards and result in significant injury or death. If any liquid were to be spilled into the touchscreen or instrument, unplug the touchscreen and instrument and contact Cepheid Technical Support for instructions.

Warning

ELECTRICAL HAZARD: Do not replace the provided AC power cable with an inadequately rated substitute power cable.

The touchscreen and GeneXpert Instrument enclosures are designed to protect you from electrical shock hazards. Under normal operating conditions, you are protected from electrical shock hazards.

2.6 Biological Hazard Safety

Biological Risks

BIOLOGICAL RISKS: Treat all biological specimens, including used cartridges, as capable of transmitting infectious agents. Because it is often impossible to know what might be infectious, all biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical Laboratory Standards Institute.

2.7 Chemical Safety

Follow standard laboratory safety procedures for working with chemicals.

Biological Risks

BIOLOGICAL RISKS: Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per World Health Organization medical waste handling and disposal guidelines.

- Safety Data Sheets (SDS) for all reagents used with this system are available upon request from Cepheid Technical Support, and are available on Cepheid's websites (www.cepheid.com and www.cepheidinternational.com).
- Refer to the Cepheid website for additional environmental health and safety information on Cepheid products.

2.8 Environmental Data

- Recyclability of GeneXpert system with touchscreen: the WEEE mark is affixed to Cepheid electronic products.
- It is recommended to retain packaging materials. The materials may be useful for repackaging any items for re-shipment to Cepheid.
- Additional information on the above, including EU and country directives concerning packaging, energy consumption, RoHS, REACH, Prop. 65, etc. can be obtained by contacting Cepheid Technical Support: techsupport@cepheid.com.

2.9 Barcode Scanner Safety

The barcode scanner contains an LED light source that has been tested and classified as "EXEMPT RISK GROUP" to the standard IEC 62471:2006.

3 Performance Characteristics and Specifications

3.1 Instrument Classification

The GeneXpert system with touchscreen is:

- An Industrial Scientific Medical Device (ISM) instrument, medium-sized, for industrial and laboratory use.
- Designed for stationary operation.
- Intended for evaluating preprocessed biological material.

3.2 General Specifications

The GeneXpert system with touchscreen has the following specifications:

- **Dimensions and Weight** :

Table 1. System Dimensions and Weights

Component	Width	Height	Depth	Weight
Touchscreen	28 cm(11.1 in)	17 cm(6.75 in)	17.3 cm(7 in)	2.09 kg(4.6 lb)
GeneXpert-II Instrument	16.3 cm(6.4 in)	30.7 cm(12.1 in)	29.7 cm(11.7 in)	6.5 kg(15 lb)
GeneXpert-IV Instrument	28.2 cm(11.1 in)	30.5 cm(12 in)	29.7 cm(11.7 in)	11.4 kg(25 lb)
GeneXpert-XVI Instrument	53 cm (21 in)	65.8 cm (25.9 in)	33.8 cm (13.3 in)	57 kg (125 lb)

- **Power Supply** : Auto-ranging
- **Rated AC Voltage Range**: 100–240V~, 50-60Hz
- **Mains Supply Fluctuations**: Up to +/-10% of the nominal voltage
- **Transient Over-Voltages**: Up to 2500 V peak (impulse withstand category II)
- **Rated Current and Fuse Rating**:

Table 2. Rated Current and Fuse Rating

Instrument	Rated Current	Fuse Rating
GeneXpert II Instrument	1.5A @ 100V~ (AC Adapter Output 2.5A @24Vdc)	No serviceable fuse
GeneXpert IV Instrument	1.4A @ 100V~	250V~ T3A (IEC 60127 time-delay type)

3.3 Operational Environmental Parameters

Your laboratory must meet the following requirements:

- General Environment: Indoor only
- Pollution Degree: 2
- Operating Temperature: 15–30 °C
- Operating Temperature Required for Maximum Thermal Ramp Rates: 20–25 °C.
- Relative Humidity: 10%–90%, non-condensing

The GeneXpert system with touchscreen is designed for indoor use only. Place the GeneXpert system with touchscreen away from heat and air conditioning ducts. Do not place the instrument directly under an air vent or in direct sunlight. Always keep the instrument module doors closed when not in use.

3.4 Environmental Conditions - Storage and Transport

The required storage conditions are as follows:

- Temperature: -30 °C to +45 °C
- Humidity: 10%–95% relative humidity, non-condensing

3.5 Sound Pressure

The sound pressure specifications are as follows:

- Audible Sound Pressure Range: < 85 dB (reference level 20 µPa)
- Ultrasonic Sound Pressure Between 20kHz to 100kHz: < 94.5 dB SPL (reference level 20 µPa)
- Maximum Sound Pressure: Contained in the 40 kHz one-third octave bands

3.6 Hazardous Substances and Concentrations

Product Name: GeneXpert system

Product Model Number: .

Component Name	Hazardous Substances Name					
	(Pb)	(Hg)	(Cd)	(Cr^{6+})	(PBB)	(PBDE)
GeneXpert Disposable Cartridge	O	O	O	O	O	O
Cable Sub-Assemblies	O	O	O	O	O	O
Plastic Parts	O	O	O	O	O	O
Sheet Metal	O	O	O	O	O	O
Hardware (Screws, bolts, etc.)	O	O	O	O	O	O
Power Supply Sub Assembly	O	O	O	O	O	O
Printed Circuit Board Assemblies	X	O	O	O	O	O
Piezo Ultrasonic Transducer	X	O	O	O	O	O

Component Name	Hazardous Substances Name
This table is prepared in accordance with the provisions of SJ/T 11364-2014. O: Indicates that the toxic or hazardous substances contained in all of the homogeneous materials for this part is below the limit requirement in GB/T 26572. X: Indicates that the toxic or hazardous substances contained in at least one of the homogeneous materials used for this part is above the requirement in GB/T 26572.	

3.7 Product Energy Consumption Information

Supplier Name	Supplier Model Identifier	Energy Efficiency Class	On Mode Power Consumption (W)	Annual Energy Consumption (KWh)	Standby Power Consumption (W)
Cepheid	Touchscreen unit	G	22	149	N/A
Cepheid	GeneXpert II	G	85	372	71
Cepheid	GeneXpert IV	G	100	489	83
Cepheid	GeneXpert XVI	G	270	1168	170

3.8 Heat Output

Supplier Name	Supplier Model Identifier	BTU/hr
Cepheid	GeneXpert II	290
Cepheid	GeneXpert IV	341
Cepheid	GeneXpert XVI	921

3.9 Emissions and Immunity Compliance Results

The GeneXpert System with Touchscreen was tested according to the Test Specifications from EN 61326-1:2021; IEC 61326-1:2020; EN 61326-2-6:2021; IEC 61326-2-6:2020, and acceptance criteria from IEC 60601-1-2:2014 Ed .4+A1:2020

Basic Standard	Test Specifications	Applicable Ports	Test Mode and Configuration	Pass/Fail
CISPR 11	**Radiated Emission**	-	Normal Mode 230Vac 50Hz	Pass
CISPR 11	**Conducted Emission**	-	Normal Mode 230Vac 50Hz	Pass
IEC/EN 61000-4-2	**Electrostatic Discharge** ± 8 kV Contact Discharge ± 15 kV Air Discharge	Enclosure	Normal Mode 230Vac 50Hz	Pass
IEC/EN 61000-4-3	**Radiated Immunity** 3 V/m, 80 – 6000 MHz, 80% AM at 1 kHz and 9/27/28 V/m per Table 9 of IEC/EN 60601-1-2	Enclosure	Normal Mode 230Vac 50Hz	Pass
IEC/EN 61000-4-4	**Fast Transient/ Burst** ± 2 kV, 5/50 nsec pulse, 100 kHz repetition freq.	AC Power	Normal Mode 230Vac 50Hz	Pass
IEC/EN 61000-4-5	**Surge** 1.2/50 (8/20) µS ± 2 kV (line to earth) ± 1 kV (line to line)	AC Power	Normal Mode 230Vac 50Hz	Pass
		DC Power	-	Not Applicable
IEC/EN 61000-4-6	**Continuous Conducted RF** 80% AM (1 kHz) 3 Vrms, 0.15 – 80 MHz 6 Vrms in ISM Radio Bands	AC Power	Normal Mode 230Vac 50Hz	Pass
		DC Power	-	No test on DC power
IEC/EN 61000-4-8	**Power Frequency** **Magnetic Field** 30 Arms/m (50/60 Hz)	Enclosure	Normal Mode 230Vac 50Hz	Pass

Basic Standard	Test Specifications	Applicable Ports	Test Mode and Configuration	Pass/Fail
IEC/EN 61000-4-11	**Voltage dip** 0% during ½ cycle 0% during 1 cycle 40% during 5/6 cycles 70% during 25/30 cycles **Short Interruptions** < 5% during 250/300 cycles	AC Power	Normal Mode 120Vac 60Hz 230Vac 50Hz	Pass

4 Overview of the System

This section provides an overview of the GeneXpert system with touchscreen. It describes what the system does and what parts make up the system.

Caution

HEAVY OBJECT: See weight table in General Specifications for system component weights. Use care when unpacking the instrument. Do not attempt to lift the instrument without proper safety training and assistance. Lifting or moving the instrument without proper training and assistance can cause personal injury, damage to the instrument and void your warranty.

4.1 Windows User Accounts

The software is configured with three Cepheid user accounts. You must log on as the Cepheid administrator to set up the system. The three accounts are:

- **Cepheid-Admin**
- **Cepheid-Techsupport**
- **Kiosk**

4.2 System Components

The touchscreen can be used with the GeneXpert II, GeneXpert IV, or GeneXpert XVI Instrument. The Cepheid OS user interface supports the display of up to 16 modules.

The touchscreen includes an interface and a built-in scanner. The barcode LED scanner emits a bright green LED light from the front of the touchscreen when software prompts the user to scan barcodes.

Figure 1. Touchscreen with GeneXpert II, IV and XVI instruments

Figure 2. Touchscreen

Number	Description
1	Touchscreen user interface
2	LED barcode scanner

Figure 3. Rear of Touchscreen

Number	Description
1	Illuminated blue button used to restart the Windows software
2	Main Power switch
3	2.5A Fuse
4	24v DC In
5	Display Port Monitor Out
6	HDMI Monitor Out
7	USB 3.0 (4)
8	Network Ethernet Port
9	Instrument Ethernet Port
10	Instrument Ports
11	Kensington Lock

The touchscreen back panel includes ports for connecting system components and network cables.

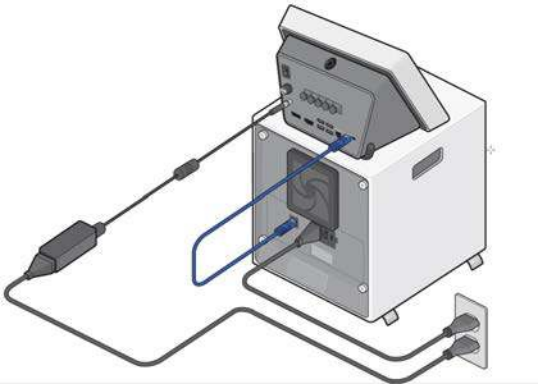


Figure 4. Power Cord and Connection Cable to GeneXpert IV Instrument

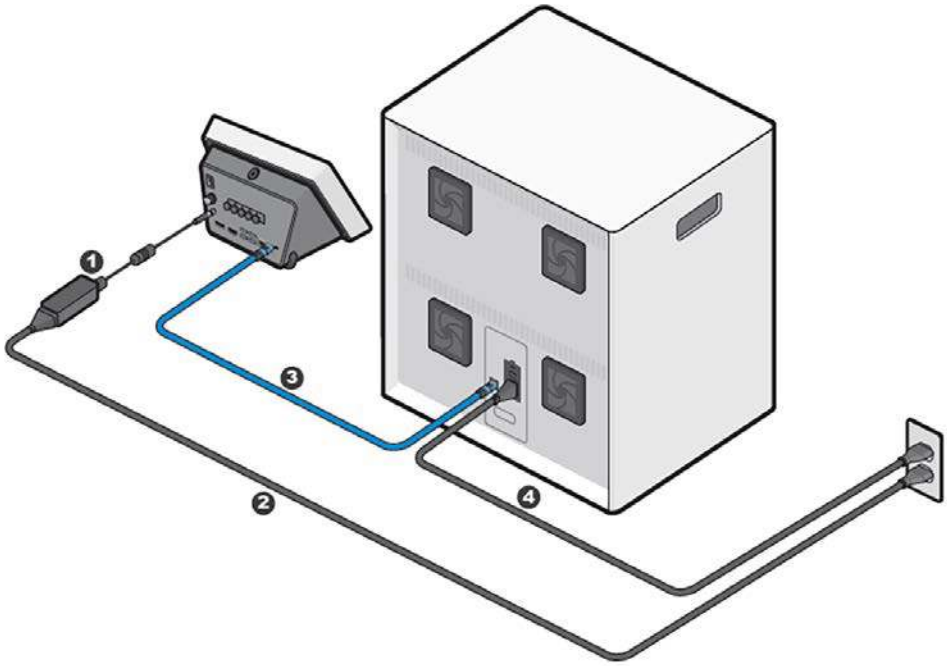


Figure 5. Power Cord and Connection Cable to GeneXpert XVI Instrument

See *Quick Start Guide* for information on connecting system components.

4.3 Models of GeneXpert Instruments

Presently, three models of GeneXpert Instruments (GeneXpert II, GeneXpert IV and GeneXpert XVI) are compatible with the touchscreen. The GeneXpert Instrument accepts the Xpert Cartridges that are loaded into the instrument, lyses the samples in the cartridges, releases the nucleic acids, and amplifies the target sequences. Because the system allows control of the modules independently, different samples can be processed using different assay definitions in the same instrument at the same time. Additional tests may be started when another test is in progress. Each module can process one sample at a time.

- The GeneXpert II instrument contains up to two modules.
- The GeneXpert IV instrument contains up to four modules.
- The GeneXpert XVI instrument contains up to 16 modules.

4.4 6-Color and 10-Color Modules

The GeneXpert system with a touchscreen is configurable with 6-color modules, 10-color modules, or a mixture of 6-color and 10-color modules. The blue band across the top of the module doors denotes 10-color modules.

Figure 6. 6-Color and 10-Color Modules

1	6-Color Module
2	10-Color Module (blue band)

4.5 Cartridges

Cartridges prepare the samples, capture the released nucleic acids, and amplify the target sequences for tests.

4.6 Access the Software License Agreement

If you need to access the software license information, including third-party software notices, for Technical Support or for information needed in writing lab protocols:

1. Touch ⋮ (more options menu) > **About**.

   The About screen shows the current software name and version, the POC serial number, and Cepheid technical support contact information.
2. On the About screen, touch **License** to view the software license agreement.

4.7 Access Instrument Serial Number

If you need to access the instrument serial number for Data Manager communication:

Touch ⋮ (more options menu) > **About**.

The About screen shows the current software version, the instrument serial number, and Cepheid technical support contact information.

Each system has its own unique serial number. The serial number may need to be entered into the Data Manager, to allow bi-directional communications.

4.8 Software Buttons, Icons, and Symbols

The following table is a short description of the most common buttons, icons and symbols encountered when using the Cepheid OS software.

Table 1. Software Buttons, Icons and Symbols

Symbol	Definition
	All modules - Touch to display all module bays.
	Error - Touch to display recent tests with errors.
	Completed test - Touch to display all completed tests.
	Available module - Touch to display all available module bays.
	Running module - Touch to display all tests in progress.
	Disabled modules - Touch to display all disabled module bays.
	More options and notifications menu - Touch to display list of systems settings and to view notifications.
Modules	**Modules** - Touch to go to the Modules screen.
Results	**Results** - Displays a list of any tests previously run.
Reports	**Reports** - From this screen you can view test statistics, system logs, and installation qualification reports.
Tasks	**Tasks** - Administrator can access tasks for quality control (QC), archiving and retrieving tests, maintaining database, generating a Tech Support package, managing host orders, and instrument maintenance.

4.9 Cepheid OS Software

The Cepheid OS software can accommodate a variety of applications. This section describes the software features that are for *in vitro* diagnostic use.

- **Administrative tasks**- Configure the system to accommodate the organization's preferences, define system users and set up permissions (access privileges), import

and delete *in vitro* diagnostic assay definition files, and manage the test data in the database.

- **Test tasks** - Create and start an *in vitro* diagnostic test, stop a test in progress, monitor a test in progress, view the test results, edit test information, and generate test reports.
- **Maintenance tasks** - Perform various maintenance tasks which include using the Module Reporters tool and Plunger controls for cleaning the module plungers, and performing a manual self-test.

4.10 Recommended Materials for Use with the System

- Uninterruptible Power Supply (UPS)
- Printer

To order the printer or UPS, contact Cepheid. See the Technical Support section in the Introduction for contact information.

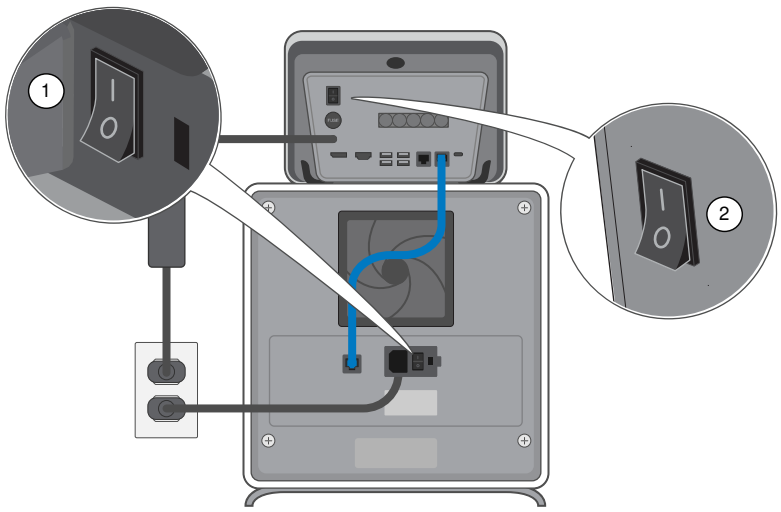
4.11 Power On GeneXpert System with Touchscreen

This topic describes routine start-up of the GeneXpert system with touchscreen.

Note Upon first start-up of the GeneXpert system with touchscreen, you are prompted to reset your login password and establish an Admin user account. See Initial Power Up of the GeneXpert System with Touchscreen for detailed steps about first start-up.

Note The power on sequence below is crucial for the touchscreen to connect with the GeneXpert Instrument.

1. Press the power switch on the back of the GeneXpert instrument.
2. Press the power switch on the back of the Turn on the touchscreenunit.



Number	Description
1	Power switch on GeneXpert IV (or GeneXpert II/ GeneXpert XVI) instrument
2	Power switch on touchscreen

Important **A blue push button at the top of the touchscreen can be used to restart the touchscreen. It illuminates when the touchscreen power switch is turned on. It does not power down the GeneXpert Instrument.**

3. Wait for the system to boot.

The software starts. After initial setup, the software auto-starts in kiosk mode.

4.12 Log In

1. Touch the **User Name** field and the virtual keyboard appears.
2. Enter your **User Name** and **Password**, then touch the **X**. The keyboard disappears.
3. Touch **Login**.

After logging in, you are asked to perform database tasks and if you want to archive tests. If you reply **No** to each of these questions, the Modules screen with the **Start Test** button appears. The instrument is now initialized and ready to run tests.

4.13 Log in with an Institutional ID

To login using an Institutional ID, an administrator must first select that option in the ⋮ > **Settings** > **Security** > **Authentication**.

Note To login manually, use the virtual keyboard.

On the Login screen, scan your ID card. Hold your ID approximately 1-3 inches (3-7 cm) from the scanner.

Figure 7. Login Screen

The Modules screen appears.

4.14 Change Your Password

The method for changing a password varies, depending on whether or not the system is connected to a Data Manager. If your system is not connected to a Data Manager, follow the procedure in this section.

Note If your system is connected to a Data Manager, a user password cannot be changed locally by either the user or an administrator. If a Data Manager is being utilized, contact the Data Manager administrator to request a password change.

1. Touch ⋮ > **Change Password**.
2. Enter your Current Password.
3. Touch **New Password** and enter your new password. Touch **Confirm New Password** and enter your new password a second time.

Note Passwords must be 8 to 32 characters in length and must include 3 of the following: 1 uppercase letter, 1 lower-case letter, 1 number or 1 special character.

4. Touch **Save**, then **OK**.

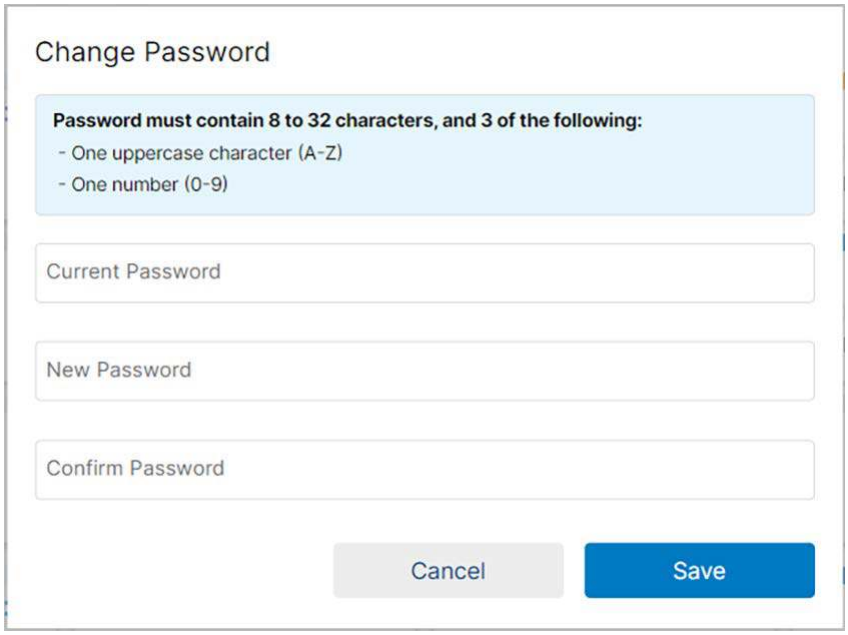


Figure 8. Change Password Screen

4.15 Log Out

1. Touch the ⋮ > **Logout**.

Note You should log out if you are going to be away from the system for an extended period of time. Logging out prevents the software from recording other users' activities under your account.

Note If you log off while a test is in progress, the system will finish the test and save the results.

Note A second user can start a separate test if a test is in progress. The first user must log off, the second user then will log in and start an additional test following the steps in Starting a Test While Another Test is Running.

4.16 Shut Down Software

1. On the Login screen, touch the power icon.
2. Select **Shut Down**.

Figure 9. Power - Shut Down

3. When you are logged into the software, you can touch ⋮ > **Shutdown** to shut down the Cepheid OS software.

4.17 Turn off the Touchscreen Unit and GeneXpert Instrument

This section describes how to shut down the software and power down the GeneXpert system with touchscreen.

Note Do not shut down the software and turn off the system if a test is running. Wait until the test finishes running.

Note When you log off of the system you may have trouble reconnecting to your network drives when you log in again. If this happens, a Network error displays. To reconnect, touch the error message, then touch the ✎ (Edit icon) and reenter your username and password for the Windows network drives.

1. Touch ⋮ > **Shutdown**.
2. A Confirmation screen appears. Select **Yes** to exit the software.
3. Wait about 10 seconds for Microsoft Windows to shut down (screen turns black) and press the power switch on the back of the touchscreen.

4. Press the power switch at the back of the GeneXpert II, IV or XVI Instrument. The instrument powers down.

4.18 Windows System Configuration

4.18.1 Access Windows Desktop

For operations in the Windows operating system, log out of Cepheid OS software.

Note Ensure all tasks run on the Cepheid OS application are complete before exiting. Otherwise, a system error may occur and the task(s) may fail.

1. Log in as administrator.
2. Touch ⋮ > **Exit** to exit Cepheid OS software.
3. Swipe up on the Windows screen and enter Cepheid-Admin password.

4.18.2 Configure Printer

1. Log into Windows using the Cepheid-Admin user account if you are not already logged in.
2. If the Cepheid OS software starts, exit the software.
3. Touch and hold the Windows Start icon and select Settings from the menu. The Windows Settings screen displays.
4. Touch **Devices**.
5. Touch **Printers and Scanners**.
6. Scroll to find the printer you want to connect the system to.
7. Touch **Add device**.
8. If your desired device did not display, touch **The printer I want isn't listed** and enter the network address.
9. Touch X to close the Windows Settings screen when finished.

4.18.3 Disk Encryption

This section provides information about enabling BitLocker Drive Encryption on the system.

BitLocker is an encryption system designed to prevent most offline attacks and malware. Use this feature to protect your data and keep confidential information secure. The procedure for Enabling BitLocker Drive Encryption in Windows 10 is included below.

Note Before you begin, please be aware that encrypting your entire hard disk can be a long process. You can use your computer while encryption takes place in the background, but you will eventually need to restart your computer. Save files frequently and plan accordingly.

Note Cepheid has validated BitLocker disk encryption on GeneXpert computers running Windows 10. Customers are responsible for enabling BitLocker and setting the recovery key.

Depending on whether or not your system has a Trusted Platform Module (TPM) installed, use one of the two procedures shown below: Disk Encryption for Systems without a Trusted Platform Module or Disk Encryption for Systems with a Trusted Platform Module.

4.18.3.1 Disk Encryption for Systems without a Trusted Platform Module

If your system does not include a Trusted Platform Module (TPM) chip, you cannot turn on BitLocker in Windows 10. You can still use encryption, but you need to use the Local Group Policy Editor to enable additional authentication at startup. Follow the steps in this section to set up encryption.

1. Touch and hold the Windows button. When the menu appears, touch **Run**. A dialog box opens. Touch the entry field and the virtual keyboard appears. In the Windows dialog box type **gpedit.msc** and touch **OK**.
2. Under Computer Configuration, expand **Administrative Templates**.
3. Expand **Windows Components**.
4. Expand **BitLocker Drive Encryption and Operating System Drives**.
5. On the right side, touch and hold **Require additional authentication at startup**.
6. Touch **Enabled**.
7. Touch to check the **Allow BitLocker without a compatible TPM (requires a password or a startup key on a USB flash drive)** option.
8. Touch **OK** to complete this process.

4.18.3.2 Disk Encryption for System with a Trusted Platform Module

If your system includes a Trusted Platform Module (TPM) , follow the steps in this section to set up encryption.

1. From the Windows desktop, touch **Start>Windows System>File Explorer>This PC**.
2. Under **Devices and drives**, touch and hold the disk or drive you want to encrypt.
3. When the menu appears, touch **Turn on BitLocker**.
4. The BitLocker configuration screen appears. Insert a flash drive into an open USB port.
5. Touch **Enter a password to unlock your drive**. This is important to ensure you can boot the system even if you lose the recovery key.

Note Cepheid recommends a password of 10 characters minimum with a combination of upper/lower case letters, numbers, and symbols.

6. Save the recovery key to the USB flash drive and print the recovery key.
7. Remove and safely store the USB flash drive. Archive the recovery key with your IT department.

Important **If Bitlocker is enabled, it is the customer's responsibility to maintain the recovery key if it is forgotten or misplaced. For more information, visit https://www.microsoft.com.**

8. Select by touching **New encryption mode**.

9. Touch to check the box next to **Run BitLocker system check**.
10. Restart your computer.
11. Enter your password when prompted.
12. After logging into Windows, you can check the status of encryption as follows:
    a) Touch **Start > File Explorer > This PC**. A padlock emblem now appears on the system drive.
    b) Touch and hold the drive to select it, then touch **Manage BitLocker**.
    c) Confirm the current status, which should be **C: BitLocker Encrypting**.

Note You can continue using your computer while encryption takes place in the background. You will be notified when it is complete.

Once BitLocker Encryption is finished, all content and communications are secured.

4.18.3.3 Set the IP Address for Instrument Communication

Note To perform the steps in this section, you must either be logged on as Cepheid-Admin or you need to enter the Admin password.

The touchscreen is already configured with the correct IP address when the system is shipped. If it needs to be reset:

1. Log onto the system as Cepheid-Admin or enter the Admin password when requested to do so.
2. On the Windows taskbar, touch the **Windows** icon.
3. Select the **Settings** icon (the gear).
   The Windows Settings screen appears.
4. Touch **Network & Internet**.
   The Network & Internet screen appears.
5. Touch **Ethernet** on the left panel.
6. Touch **Change Adapter Options** on the right panel.
   The Network Connections screen appears.
7. Touch and hold the **GeneXpert Connection** entry.
   A drop-down menu appears.
8. Select **Properties** from the drop-down menu.
   The Connection Properties Screen appears.
9. On the Connection Properties Screen uncheck the box next to Internet Protocol Version 6 (TCP/IPv6). Touch **Internet Protocol Version 4 (TCP/IPv4)**, and then touch **Properties**.
   The Internet Protocol Version 4 (TCP/IPv4) Properties screen appears.
10. On the Internet Protocol Properties screen, enter:
    a) IP Address: 10 . 11 . 14 . 1
    b) Subnet Mask: 255 . 255 . 255 . 224
11. After you have verified that all numbers are entered correctly, touch **OK** to close the Internet Protocol Version 4 (TCP/IPv4) Properties window.
12. Touch **Close** to close the GeneXpert Connection Properties window.
13. Touch the **X** in the right corner of the window to close the Control Panel window.

14. Restart the system.

4.18.3.4 Connect to Cepheid C360

Cepheid C360 is a web-based software application for administering Cepheid systems and visualizing aggregated, anonymized medical test data produced by Cepheid instruments. For more information about C360 administration, see *Cepheid C360 Administrative Features Operator Manual* and for more information about the data visualization tools, see *Cepheid C360 Data Visualization Features Operator Manual*.

1. Unpack the additional Ethernet cable.

2. If the Cepheid OS software is currently running, quit the software.

3. Confirm that the primary Ethernet connection from the touchscreen to the Instrument uses IP address 10.11.14.1.

4. Using the second Ethernet cable, connect the adapter to your network. By default, the IP address is assigned using DHCP.

Note If you wish to use a static IP address, contact your IT department for support in assigning the address for the LIS interface.

5. Log into the Cepheid C360 website to set up your system. Refer to the *Cepheid C360 Data-Visualization Features Operator Manual* for details.

5 Setting Up the System

5.1 Position Instrument on a Bench

This topic describes how to position the GeneXpert Instrument on a bench to ensure safety and proper functioning.

Caution

HEAVY OBJECT: See Performance Characteristics and Specifications for instrument weights. Use care when unpacking the instrument. Do not attempt to lift the instrument without proper safety training and assistance. Lifting or moving the instrument without proper training and assistance can cause personal injury, damage to the instrument, and void your warranty.

Place the instrument on a flat, level, stable surface in a sheltered environment.

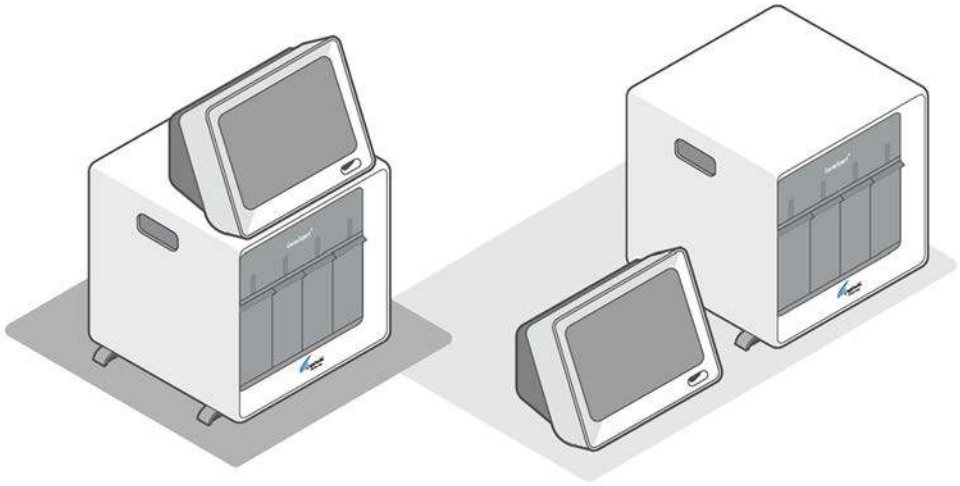


Figure 10. Touchscreen on top of GeneXpert IV or at Side

Avoid placing multiple instruments close together and avoid placing instruments near building ventilation.

Maintain at least 5 cm (2 inches) of clearance on each side of the instrument. Do not block the fan exhaust or air intake on the instrument. The lack of a proper ventilation can cause the instrument or touchscreen to malfunction.

Caution

Do not tip the instrument while running a test. This can cause the test to stop running.

Caution

Do not tip the instrument when there is a cartridge inside. Damage to the instrument can occur if the cartridge contents leak inside the instrument.

5.2 Connect Multiple Instruments

You can connect multiple GeneXpert instruments to the touchscreen unit. Multiple GeneXpert instruments connected to one touchscreen unit is considered to be one system. The Cepheid OS user interface supports the display of up to 16 modules.

1. First, insert the ethernet cable from the lower "Instrument" port to the upper, far right "Instrument" port on the touchscreen unit.
2. Insert the instrument ethernet cables into the top "Instrument" ports.
3. Apply ferrite beads to the additional instrument cords at the touchscreen end of the ethernet cables to reduce radio frequency emissions.
4. Insert the other ends of the ethernet cables into the GeneXpert instruments.

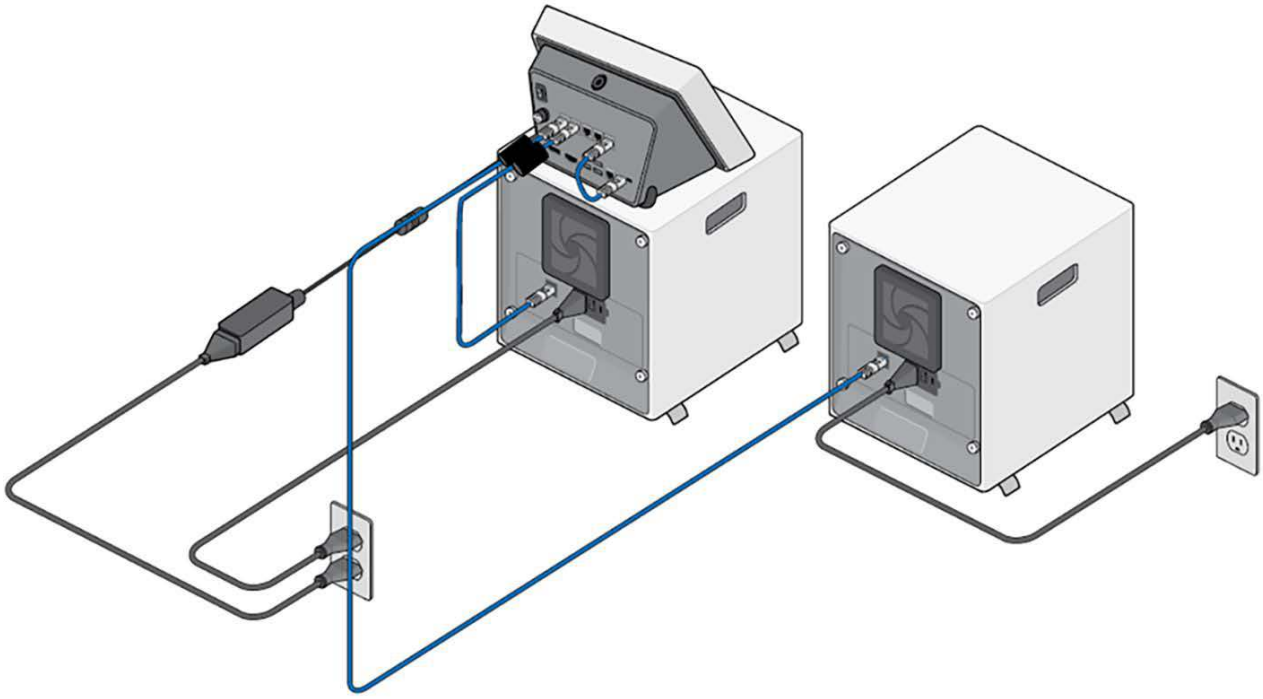


Figure 11. GeneXpert Instrument Connections

5.3 Manage Instruments

If you have multiple instruments connected to your touchscreen unit, you can edit the assigned letters of the instruments and identify which modules belong to which instrument.

1. Touch **Tasks** > **Instrument Maintenance** > **Manage Instruments**.

Figure 12. Instrument

2. Touch **Identify Instrument**.
   Green LED lights illuminate on the instrument the modules belong to.
3. Select the proper letter for the modules that are flashing. By default, GeneXpert XVI instruments have modules assigned A1-4, B1-4, C1-4, and D1-4.
4. Touch **Done**.

5.4 Instrument Network Connection

Caution

Do not change the Internet Protocol (IP) settings for the Ethernet connection to the "Instrument" port of the touchscreen. Changing the IP settings can cause system communication failure. Do not unplug the Ethernet cable from the touchscreen after starting the Cepheid OS software.

5.5 Network Connection Options

To connect the touchscreen to the Internet or intranet, you have two options:

- **Network port** – Insert an Ethernet cable into the network port at the back of the touchscreen.
- **USB port** – Insert a Wi-Fi adapter into a USB port at the back of the touchscreen. A Wi-Fi adapter is included in the accessories box that shipped with the touchscreen.

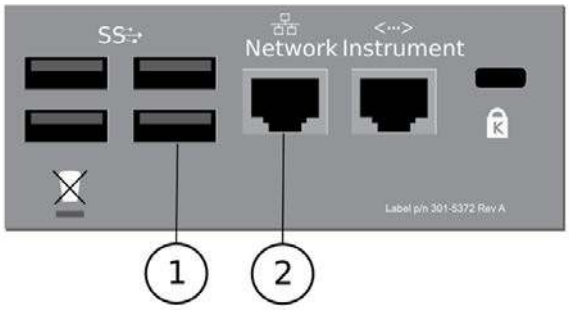


Figure 13. Wi-Fi Adapter and Ethernet Network Cable

Number	Description
1	Wi-Fi adapter is inserted into USB port
2	Ethernet cable is inserted into Network port

5.5.1 Wi-Fi Adapter

The USB Wi-Fi adapter is available as an accessory to enable Wi-Fi connectivity for your GeneXpert system with touchscreen when wired network connectivity is not available. The USB Wi-Fi adapter can be used for host communication, remote support and/or Cepheid C360 connectivity.

Table 1. Specifications

Specification	Details
Wi-Fi Adapter	Asus USB wifi key
Operating System Support	Windows 10
Operating Frequency	2.4 GHz/5GHz
Network Standards	IEEE 802.11a
	IEEE 802.11b
	IEEE 802.11g
	WiFi 4 (802.11n)
	WiFi 5 (802.11ac)
Security and Authentication	WPA2 PSK
	WPA2-Enterprise, EAP-TLS
	WPA2-Enterprise, PEAP/MSCHAPv2

Note The network speeds and bandwidth are based on current IEEE 802.11 specifications. Actual performance may be affected by network setup and other conditions.

Setup Tasks

1. Insert the USB Wi-Fi adapter into an available USB port at the back of the touchscreen.
2. Install the necessary drivers, if prompted, using the CD in the adapter package. See the Connect a DVD Drive to the System instructions.
3. Follow the instructions provided by your network administrator to join your organization's wireless network.

Note Consult with your IT department/network administrator for authorization to connect your GeneXpert system with Touchscreen to your Wi-Fi network. They provide the required network connection details to establish the Wi-Fi- connection.

5.5.2 Ethernet Network Connection

To connect the touchscreen to your institution's intranet or the Internet:

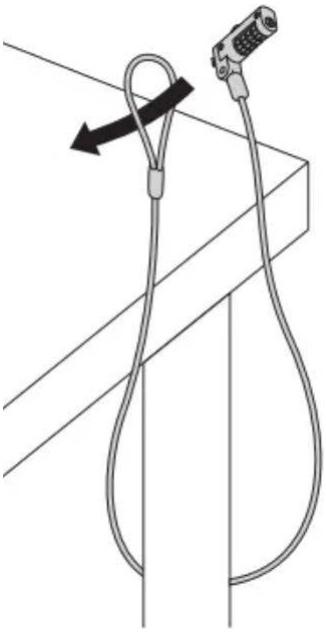
1. Insert an ethernet cable into the "Network" port at the back of the touchscreen.
2. Enter your user name and password, if necessary.

Note Contact your IT department for support if needed to establish connection to your institution's intranet or the Internet.

5.6 Secure Touchscreen Unit

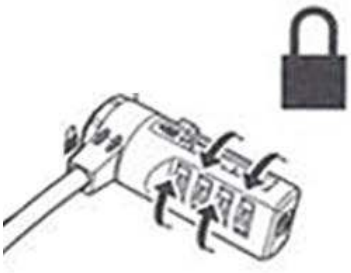
To physically secure the touchscreen unit:

1. Follow computer padlock (PN 200-7957) instructions to create a numeric code (password) for your lock.
2. Locate a table leg or other structure to secure the touchscreen unit to.
3. Wrap cable around that structure.



4. Insert key into the Kensington key port on the back of the touchscreen unit.

5. Turn the number dials to set the lock (disrupt the password).



6. To unlock, turn dials to the numeric code you created.

5.7 Software Installation

The system comes with the software pre-installed. If it is necessary to reinstall software or install a software update, contact Cepheid Technical Support. See the Technical Support section in the Introduction chapter for contact information.

5.8 Anti-virus Software

The touchscreen running Windows 10 ships with Windows Defender Anti-virus to protect against viruses that could cause data corruption or disrupt normal functionality. Because Windows Defender Anti-virus comes bundled with Windows 10 and is updated and maintained automatically with the operating system, Cepheid does not recommend using additional anti-virus software for the touchscreen running Windows 10.

Note If Bitlocker is enabled, it is the customer's responsibility to maintain the encryption key so that it is not forgotten or misplaced. For more information, visit https://www.microsoft.com.

5.9 LIS Uploads and Downloads

The GeneXpert system with touchscreen supports both LIS uploads and downloads, with or without the use of a Data Management system. See Operate with Host (LIS or POCT) Connectivity or Host (LIS) Management and Settings.

Please contact your local IT/LIS administrator first for assistance in configuring your system for LIS uploads/downloads.

For assistance, call Cepheid Technical Support. See the Technical Support section in the Introduction chapter for the contact information.

Note Cepheid recommends to always confirm that LIS uploaded or downloaded results match GeneXpert system with touchscreen results after any changes to the GeneXpert or host system, including, but not limited to, changes to the following: Cepheid OS software version, GeneXpert assay definition files and version, GeneXpert host communication settings, host middleware software or configuration changes, and LIS software or configuration changes.

5.10 Add Admin and Basic Users at First Start Up

Upon first start-up of a new GeneXpert system with touchscreen, follow the onscreen wizard to create the required administrator user.

1. On the Welcome to Cepheid OS screen:
   a) Select your preferred language.
   b) Select your time zone.
   c) Touch **Continue**.

Figure 14. Login to Cepheid OS Screen

2. Define an administrator user account and password.

Note Passwords must be 8 to 32 characters in length and must include 3 of the following: 1 uppercase letter, 1 lower-case letter, 1 number or 1 special character.

3. Touch **Add**.
4. Touch **Add User** and repeat steps to create additional admin users and basic users.

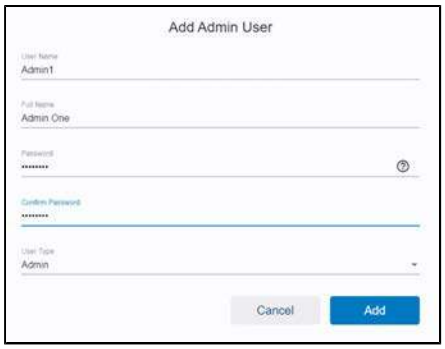


Figure 15. Add Admin User Screen

To add users with in your organization's data management system see Add or Remove Users in Data Management System.

5.11 Edit System Name

1. Touch **Tasks** > **Instrument**.

Figure 16. Tasks Instrument Screen

2. Touch (Edit) and enter the serial number of the instrument after your institution's name.
3. Touch **Save**.

5.12 Start Cepheid OS Software

1. After logging into Windows with administrator credentials, the Cepheid OS software launches and displays the Login screen.
2. Touch the **User Name** field, and the virtual keyboard appears.
3. Enter your User Name and Password in the provided fields, and then touch the **X** button at the far right of the keyboard. The keyboard disappears, and the Login button is visible.
4. Touch the **Login** button to complete the login process.

After login is complete, the Modules screen appears.

6 Running a Test

6.1 Import Assay Definition Files (ADFs)

You can import assay definition files (ADFs) from the CD included with your system or from the Cepheid website. See Import Test Definitions from the CD and Download ADFs and Package Inserts from the Cepheid Website for more information.

6.2 Prepare the Cartridge

Refer to the test instructions for use for specific cartridge preparation steps.

6.3 Run a Test

This section provides an example for running a test. Refer to the test instructions for use for specific instructions for the test you are using.

Note

Make sure you scan or type the correct Sample ID, PID, PID2, and Patient Name. The Sample ID, PID, PID2, and Patient Name are associated with the test results and shown in the Results window and on all reports. The following symbols cannot be used for Sample ID, PID, PID2, or Patient Name: | @ ^ ~ \ & / : * ' < > $ % ! ; ( ) -

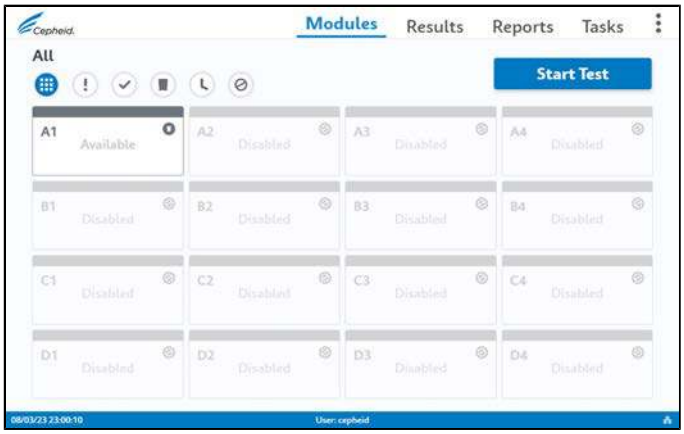


Figure 17. Modules Screen, Start Test Button

Table 1. Overview of Starting a Test

	Step	Detailed Information

	Step	Detailed Information
1	On the Modules screen, touch the **Start Test** button.	See additional topics: Create a Test with Host Connectivity; Start a Test while Another Test is Running and Create a Test by Selecting from a List of Host Orders
2	Input a Patient ID. Your software administrator can configure the software to use or not use the Patient ID field.	See Options for Entering a Patient ID and Show or Hide Patient ID Input Fieldfor more information.
3	Input a Sample ID.	See Options for Entering a Sample ID for more information.
4	Scan cartridge barcode. Hold the cartridge about 1-3 inches (3-7 cm) away from the scanner. After scanning, touch **Continue**.	For combinatorial assays select the correct test, and then touch **Continue**. See Select a Combinatorial Test for more information.
5	If prompted, enter your user name and password and touch **Login**.	See Log in Using the Virtual Keyboard and Log in with an Institutional ID.
6	On the Confirm screen, confirm all information was entered correctly. Touch **Confirm**.	See Confirm Test Information.
7	Load cartridge into the module with a blinking green LED light and close the door. The test starts immediately after the door is closed.	See Load a Cartridge and Start a Test.
8	When the test completes, remove the cartridge and dispose according to your institution's hazardous waste disposal guidelines.	See your institutions hazardous waste guidelines.
10	On the Results Summary screen, touch **View Report** to view a test report. Touch (download) or (print).	See View Test Results and Print Test Results.

6.4 Entering the Patient ID

If your software administrator has configured the software to require a patient ID, you can either scan or manually enter patient IDs.

The Patient ID has 1 to 32 characters that can include:

- Lowercase letters
- Uppercase letters
- Numbers
- Special characters except for : | : * “ < > / \ ?

The Patient ID barcode can be scanned using the integrated barcode scanner, or, if the barcode is unreadable or non-existent, the Patient ID number can be entered manually.

6.4.1 Scan the Patient ID

1. Scan the Patient ID barcode using the barcode scanner. Hold the sample 1-3 inches (3-7 cm) away from the scanner slit on the front of the system. The scanner projects a green crosshair, which you should center on the barcode.
2. After a successful scan, the verify the Sample ID is correct, then touch **Continue**.

6.4.2 Enter a Patient ID Manually

1. Touch the **Patient ID** field.
2. Enter the Patient ID number using the virtual keyboard.
3. Verify the information you entered is correct and press **Continue**.

6.5 Entering a Sample ID

This section describes the method for entering the Sample ID into the system, either by scanning a barcode, entering the ID manually using the virtual keyboard, or having the system assign a date/time stamp.

The Sample ID is a unique identifier that links the sample being processed to the patient that provided the sample

The Sample ID has 1 to 25 characters that can include:

- Lowercase letters
- Uppercase letters
- Numbers
- Special characters except for: | : * “ < > / \ ?

The Sample ID number can be scanned using the integrated barcode scanner, located on the front of the system.

If there is no barcode, or it cannot be scanned, enter the Sample ID number manually.

Alternatively, the system can assign a Sample ID instead of scanning it or entering it manually.

6.5.1 Scan the Sample ID

1. Scan the Sample ID barcode using the barcode scanner. Hold the sample 1-3 inches (3-7 cm) away from the right side of the scanner.

Note The barcode scanner projects a green beam that you center on the barcode. An audible beep confirms scanning success.

Note If the scan is not successful, an error message appears.

6.5.2 Assign a Date/Time Stamp for Sample ID

You can assign a date/time stamp for sample ID instead of scanning or manually entering an existing sample ID.

1. Touch **Enter**.
2. The auto-generated date/time stamp sample ID is visible on the Confirm step.

You can now scan your cartridge barcode.

6.5.3 Enter a Sample ID Manually

If there is no barcode, or the barcode does not scan, you can enter the Sample ID manually.

1. Touch the Sample ID entry area.
2. Enter the sample ID number via the virtual keyboard. Click **X** when finished.
3. Verify the Sample ID you typed is correct.
4. Touch **Continue** if it correct.

6.6 Scan the Cartridge Barcode

Warning

In the following steps, cartridges should be kept upright when handling or scanning. Do not tip the cartridge, because damage to the contents or injury to personnel may occur. Always pick up the cartridge by the body. Do not pick up the cartridge by the protruding reaction tube.

1. Select the appropriate cartridge for the sample you are testing.
2. Scan or manually input the cartridge serial number. If scanning, hold the cartridge about 1-3 inches (3-7 cm) away from the scanner. The scanner projects a green crosshair, which you center on the barcode. Scanning is complete when you hear an audible beep.

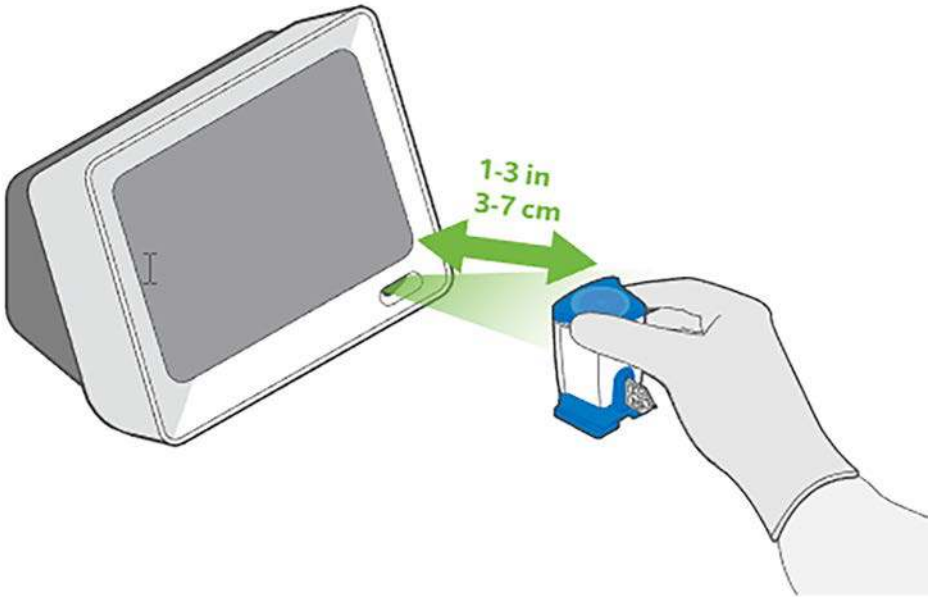


Figure 18. Scan Cartridge Barcode

3. After scanning, verify the correct cartridge name appears on screen and touch **Continue**.
4. If prompted, enter your user name and password. Press **Login**.

6.6.1 Select a Combinatorial Test (if necessary)

For combinatorial tests you need to select the correct test on the **Select Test** menu.

1. Select the appropriate cartridge for the sample.
2. Scan the cartridge barcode.
3. Make the appropriate test selection from the **Select Test** menu.

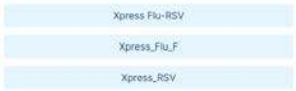


Figure 19. Select a Test to Run Screen

4. Touch **Next**.
5. After scanning, verify that the correct cartridge has been scanned and matches the assay name on the cartridge. If it does not match, touch **Cancel** and scan the correct cartridge barcode.
6. Touch **Confirm**.

6.7 Confirm Test Information

1. Confirm the test information you entered.

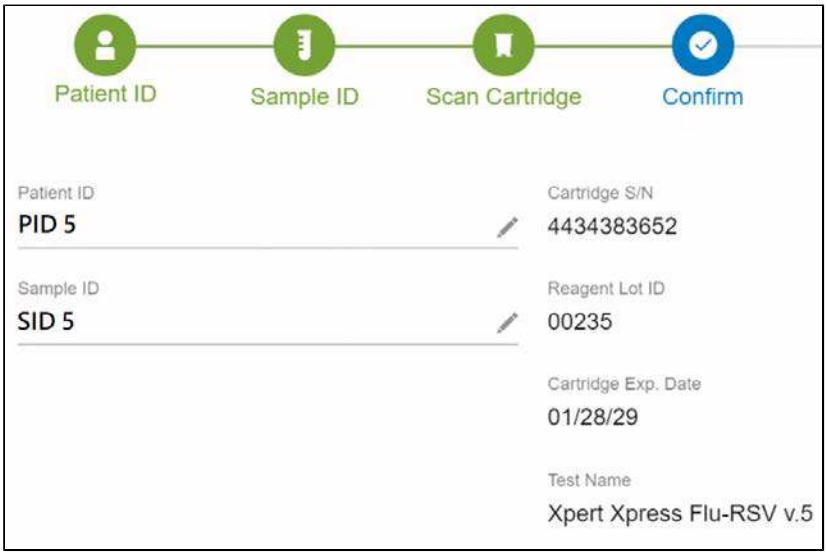


Figure 20. Confirm Screen

2. Touch (Edit) to change any data.
3. Touch **Confirm**.

6.8 Load a Cartridge and Start a Test

This section describes how to load a cartridge into an available module and start a test.

Note To ensure the accuracy of test results, be sure to use the same cartridge in the test. (Do not switch or substitute cartridges after scanning and other preparations have begun.)

1. Open the instrument module door below the module bay with the flashing green light.
2. Place the cartridge on the module bay ejector with the cartridge label facing out.

Figure 21. Cartridge Placement

3. Close the module door. The door will latch and the flashing green light will turn solid green and the Test Loading screen displays.

Note If necessary, touch the **STOP TEST** button to cancel a test while it is loading. Note that you will not get a test result from a canceled test.

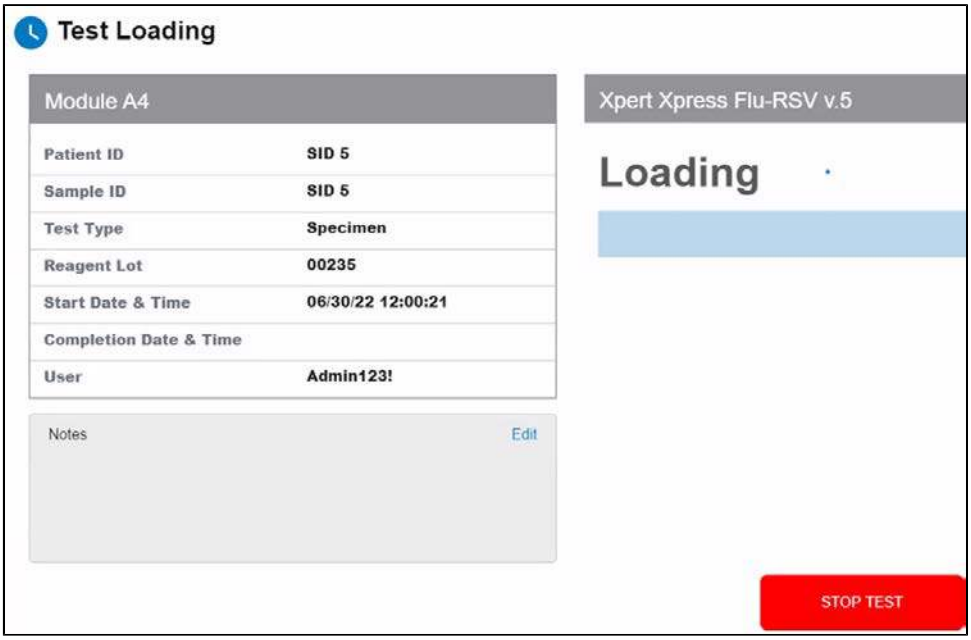


Figure 22. Test Loading Screen

4. After the test has loaded, the Test Running screen appears, showing a blue status bar to indicate the progress of the test.
5. When the test completes, the Results Summary screen appears.
6. Touch **Modules**. Your test pane is now green and has a green check mark denoting completion.

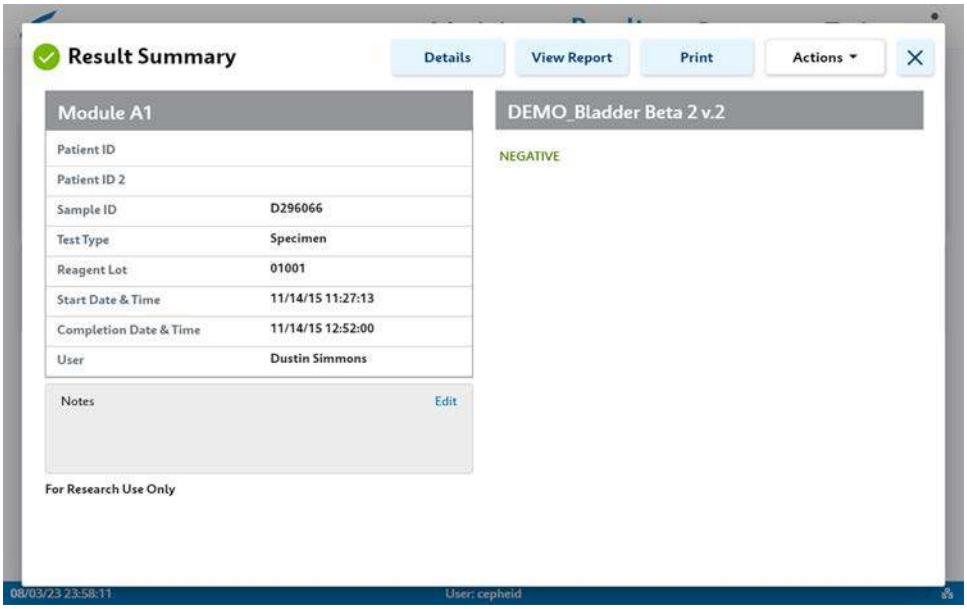


Figure 23. Completed Test Panel

7. When the test completes, the door opens. Remove the used cartridges, and properly dispose of the cartridges according to your institution's hazardous waste disposal guidelines.

6.9 Start a Test While Another Test is Running

Additional tests may be started when another test is in progress by following the steps in this section.

Note The total number of tests that can be running at one time is only limited by the number of available modules in the connected instruments.

1. Touch **Start Test** and perform the same steps required for a standard test, as described in Load a Cartridge and Start a Test.
2. Touch **X** on the Test Loading or Test Running screen.
3. Touch **Start Test** to start consecutive tests.
4. After a test has completed, the module icon text changes to Complete.

6.10 Operate with Host (LIS) Connectivity

This section provides instructions on how to use the system host interface to:

- Create a test from a downloaded test order and upload the result
- Upload a test result

Note Beyond the routines described in this section when operating with Laboratory Information System (LIS) connectivity, an administrator has additional capabilities for performing queries and managing host test orders.

Caution ⚠

Cepheid recommends confirming that LIS uploaded results match GeneXpert test results after any changes to the GeneXpert or host system, including (but not limited to) changes to the following: Cepheid OS software version, GeneXpert Assay Definition version, the GeneXpert Host Communication Settings, host middleware software or configuration changes, and LIS software or configuration changes.

6.11 Create a Test with Host Connectivity

When Automatic Test Order Download is checked, the system queries all test orders from the host. Test orders are then automatically downloaded from the host when a test is initiated.

1. Enter the Patient ID (optional).
2. Enter the Sample ID.
3. The system checks for a matching test order and displays it. If not found, a dialog box appears stating No Matching Host Order Found.
4. The Select Test Order screen appears. Check that the test type is appropriate and touch **Select**.

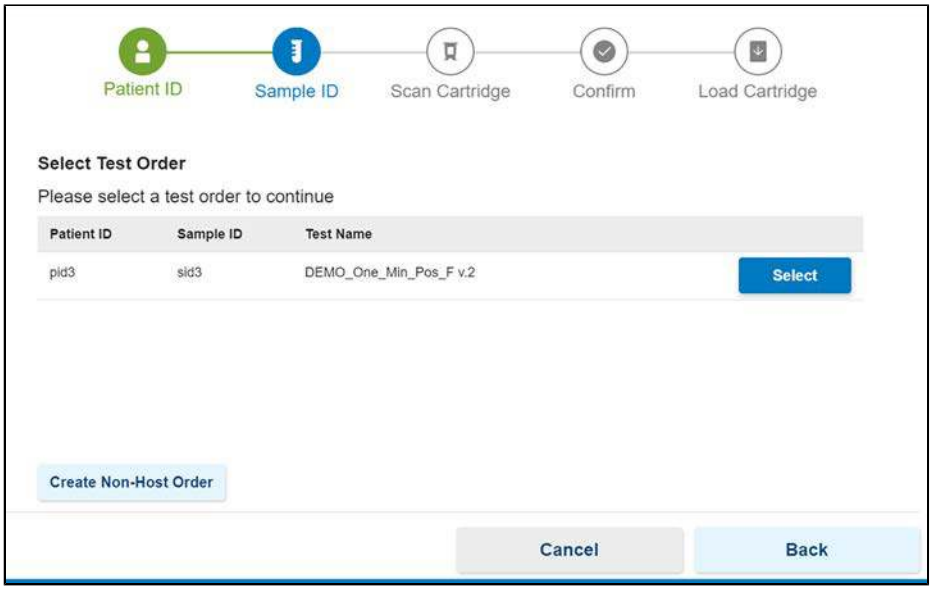


Figure 24. Select Test Order Screen

Note The test's host order cannot be changed after selecting and confirming the host order for a test. To remedy this, exit the Create Test workflow to re-select host order.

5. The Scan Cartridge Barcode screen appears and prompts you to scan the barcode on the cartridge. This prompt confirms that the correct assay will be run. The reagent lot ID, expiration date, and cartridge serial number are processed. This order will be removed from the list of new orders.
6. Insert the specimen and reagents into the cartridge according to the assay-specific package insert.
7. Load the cartridge and close the module door. The test runs.

7 Quality Controls

7.1 Quality Control Summary

Quality Control tests can be run at any time.

Touch the **Tasks** > **QC**.

The Quality Control screen provides the choice of viewing the summary page, running either a positive or negative test, or running a proficiency test.

To run a positive or negative test, touch the appropriate button on the screen. See Run a Quality Control Test.

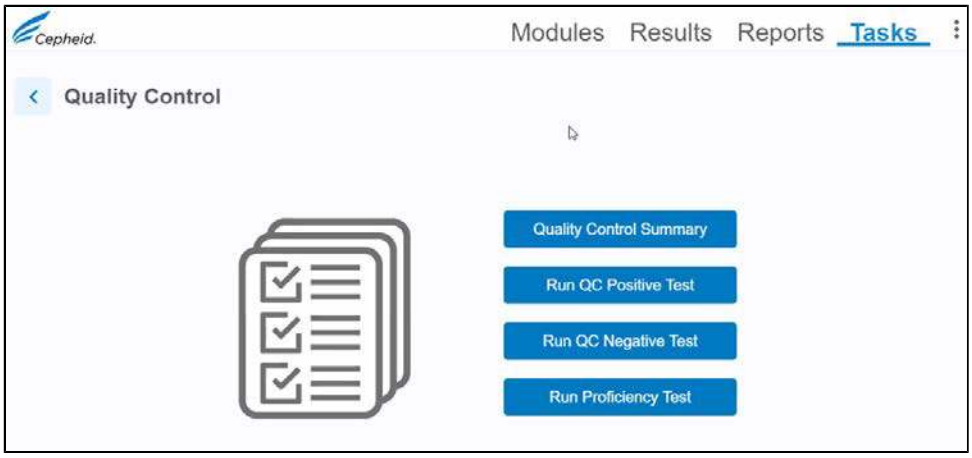


Figure 25. Quality Control Screen

The summary page displays important information about the QC status for assays.

Note

It is a good practice to check the Quality Control Summary screen each time you sign on to the system to see if any assays require a QC test during the work session.

Figure 26. Quality Control Summary Screen

7.2 Run a Quality Control Test

1. Touch **Tasks** > **QC**.
2. On the Quality Control screen, select either **Run QC Positive Test** or **Run QC Negative Test** for the control type to be tested.
3. Follow on-screen prompts to run the test.

7.3 Run a Proficiency Test

You can run a Proficiency Test from the Quality Control screen.

1. Touch **Tasks** > **QC** > **Run a QC Proficiency Test**.
2. Scan the proficiency test cartridge barcode and follow onscreen instructions to run the test.
3. Touch **Actions** to output the results as a PDF or CSV file.

7.4 Upload a QC Result to the Host

If your host is configured with HL7 or ASTM protocols, QC and proficiency test results are not automatically uploaded to the host. A QC result/proficiency test can be manually uploaded by touching **Upload** on the completed test screen.

If your host is configured with POCT protocol, QC and proficiency test results are uploaded automatically to the host.

Note If there are problems with host connectivity, see Host Communication Settings and User Lockout Problems.

8 Managing Test Results

8.1 View Test Report

You can view test results from three tabs: Results, Results Summary and Results Details.

1. On the Results screen, select the test or tests you want to view and touch **View Report**.

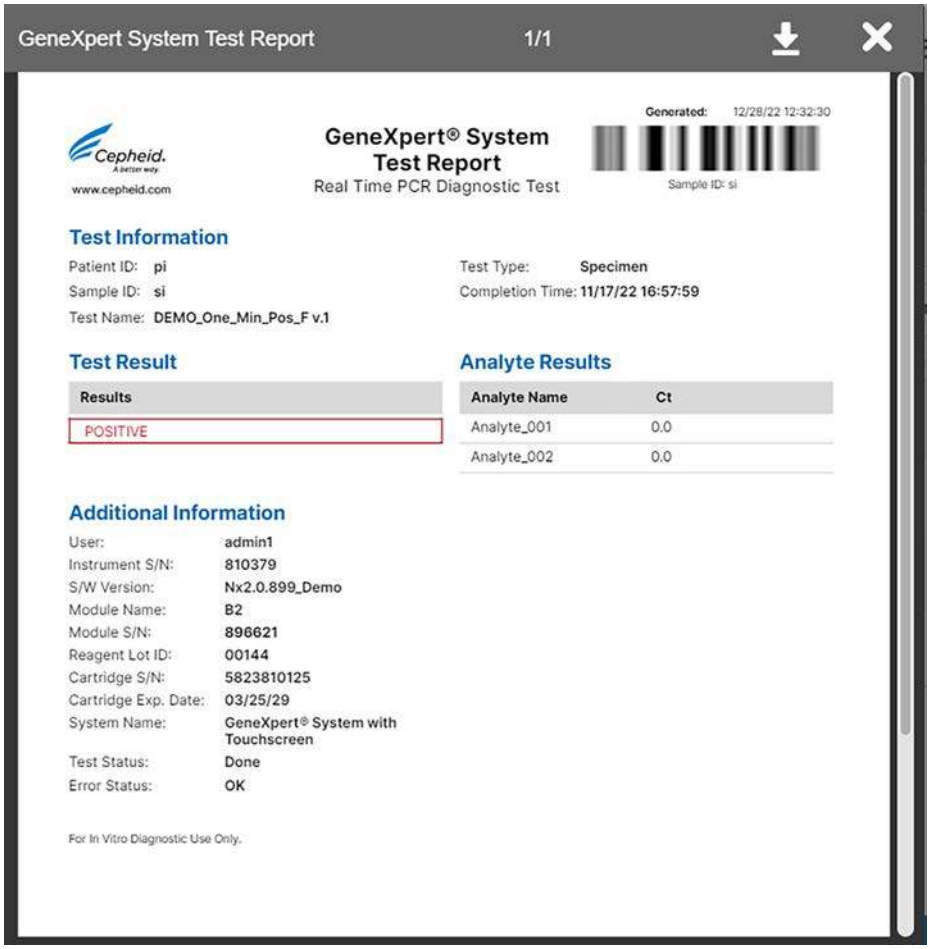


Figure 27. Report Viewer Screen

The Report Viewer screen appears.

Note Positive results are outlined with a box and negative results are not.

2. Touch (download) or (print) if needed.

8.2 Filter Test Results

This section describes how to filter different options to get a more specific selection of test results.

Note Multiple filters can be set at the same time for a more specific search.

Note Touch the **Reset Filters** button at any time to reset any filters.

Table 1. Filters

Filter	Description
Patient/Sample ID	To search for a specific patient or sample.
Select Date Range	To search for tests completed in a specific date range.
User ID	To search for tests completed by a specific user.
Reagent Lot	To search for tests with a specific lot number.
Test Name	To search for completed tests with a specific test name.
Test Type	To search for completed tests with a specific test type.
Upload Status	To search for completed tests with a specific upload status. Available only when the host is connected.

8.3 Result Details

The Result Details screen allows you to view results, print reports, enter notes and export CSV and PDF files.

- A navigation arrow allows you to return to the Result Summary page.
- **View Report** button allows you to view the report.
- **Print** allows you to print a report.
- **Actions** allows you to upload, export a PDF and export a csv file.

The Results Details page is divided into many sections and tabs, including:

Table 2. Result Details Page Overview

Field/Tab Name	Description
Patient ID	Patient identification name or number. This can be hidden from the report. See Show or Hide Patient ID on Test Report.
Sample ID	Sample identification name or number.
Completion Time	When the test completed.
Test Name	Automated test name.
Reagent Lot	Traceable lot number for the chemical reagents.
User	Name of the user who ran the test.
Notes	User-entered notes about the test. The field allows 512 character spaces for the note.
Analyte Result	Default tab displays analyte results, including Ct, end point, analyte, and probe check results.

Field/Tab Name	Description
Test Result	Displays up to 24 test results. Use page number navigation to see all test results.
Curves	Curve results displayed. You can remove curve by clicking on them in the legend. You can also maximize the page by clicking the maximize icon. You can minimize the page by touching the minimize icon
Details	Detailed view of results and probes.
History	Displays notes.
Info	Displays cartridge and system information.

8.4 Export Test Results as a CSV File

You can export your test results as a CSV file.

1. Touch the Results tab and select one or more test results to export as a CSV file.
2. On the **Actions** drop-down menu, select **Export as CSV**.

8.5 Print Test Results

Note You only see a print icon if your system is connected to a printer.

1. Touch **Results** tab.
2. Select test results.
3. Touch **View Report** to preview the report.

Note You can view multiple tests, if selected.

4. Touch to print the report.

8.6 Upload a Test Result to the Host

Note You cannot change the Patient ID, Patient ID 2, Patient Name, Sample ID, or the assay if it is selected from a host downloaded test order.

Test results can be uploaded to the host either automatically or manually.

1. After the test is completed, the result is automatically uploaded, as determined by the host communication settings.
2. The Upload Status is shown on the Results screen.

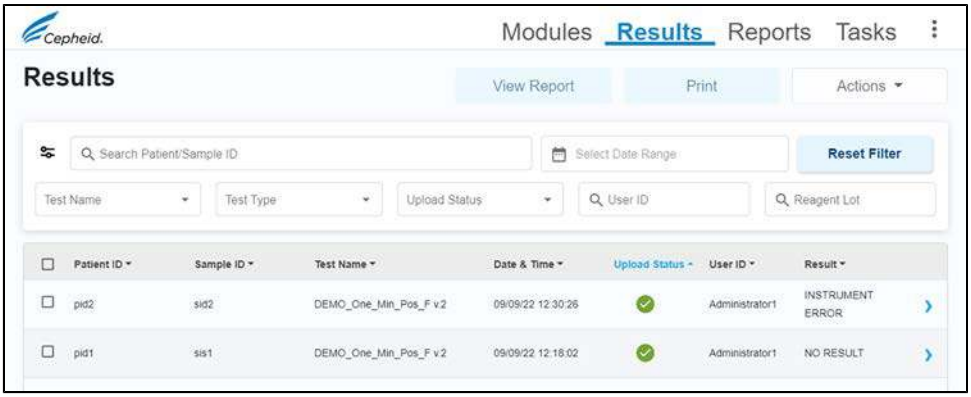


Figure 28. Test Upload Status

Possible upload statuses are:

Table 3. Upload Status Results

Upload Status Icon	Description
NA	
Upload-Pending	
Uploading	
Uploaded	
Review	
Expired	
Failed	

8.6.1 Automatically Upload the Test Result to the Host

1. Touch ⋮ > **Settings** > **Host** > **Host Communications**.
2. On the Host Communication Settings screen, touch **Change Settings** and select the **Automatic Result Upload** check box so the result is uploaded as soon as the test is completed.

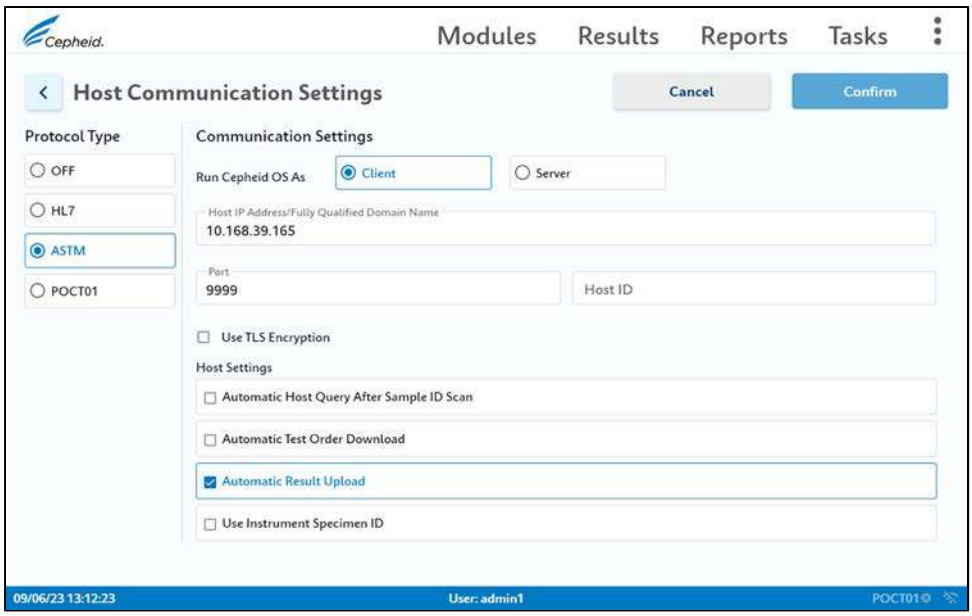


Figure 29. Automatic Result Upload

3. After the test is completed, the result is automatically uploaded.

8.6.2 Manually Upload a Test Result to the Host

1. If a test has not been automatically uploaded, it can be manually uploaded by touching **Actions** > **Upload** on the individual test results screen.

9 Tasks

9.1 Basic versus Administrator Tasks

Basic user and administrator functions are accessible from the Tasks screen.

Table 1. More Information About Administrator Tasks

Task	Description	Basic User	Admin User	More Information
QC	Options for running Quality Control tests	Yes	Yes	See Quality Controls.
Archive Tests	Options for archiving and purging tests	Yes, archive tests	Yes, archive and purge tests	See Archive and Purge Tests.
Retrieve Tests	Options for retrieving archived tests	No	Yes	Retrieve Tests.
Database Maintenance	Options for maintaining the database	Yes, database backup	Yes, back up, restore, reduce database file size	See Database Maintenance.
Instrument Maintenance	Options for instrument maintenance	Yes, view module reporters, plunger rod maintenance, manual self-test, manage instruments, disable modules from testing	Yes, plunger rod maintenance, manage instruments, use module reporters, manual self-test, disable modules from testing	See Maintenance chapter.
Tech Support Package	Options for generating a Technical Support Package	Yes	Yes	See Generate a Technical Support Package.

9.2 Retrieve Tests

The Retrieve Tests screen shows the tests previously run, with test information, including Patient ID, Sample ID, etc. By default, the most recent tests are displayed first. A search function is provided, to search by Patient or Sample ID.

1. Touch **Tasks** > **Retrieve Tests**.

2. Select any archived files to retrieve, and then touch **Open**.
3. A dialog box appears showing the number of tests being retrieved. Touch **OK**.
4. Select tests.
5. Touch **Retrieve** to retrieve the selected test(s). A confirmation screen appears. Touch **Confirm** to continue with the retrieval.

The selected tests are retrieved and a message appears and confirms that the tests are retrieved.

9.3 Database Maintenance

The database is a history file of previously-backed up tests, showing patient information, sample information, test type and results, system configuration, Assay Definition Files, User Administration, etc. It does not show tests that were archived or purged.

It is recommended that a database backup be created whenever there is a change to the system configuration. This file should be stored outside of the system in case of computer replacement and the backup would be restored onto the new computer.

These stored results can be managed by archiving to save storage space, purging (removal or deletion) if no longer needed, or restored from the archive if the original version of the database is required.

Note Database management cannot be performed while host communication is enabled. The user must disable host communication to perform database maintenance. Database Maintenance cannot be done while a test is running.

On the Database Maintenance screen the Administrator can perform database tasks, such as backing up the database or restoring the database from a backup.

Table 2. Database Maintenance Options

Operation	Description
Backup Database	You should back up the entire database periodically and store the backup on a different computer or on a different storage medium. **1.** Touch **Tasks** > **Database Maintenance** > **Backup Database** **2.** Select the folder in which you want to store the backup file, type a name for the backup file (or use the default file name), and then touch **Save**. **3.** A system backup success message appears. Touch **OK**.
Restore Database	You can restore the entire database using the backup database file. Because the restore process overwrites the data in the current database, first archive any test data to be retained, restore the database, and then retrieve the data from the archive file. **1.** Touch **Tasks** > **Database Maintenance**. **2.** Touch **Restore Database** to restore your system from a prior backup file. **3.** A screen appears, asking if you want to overwrite the current database before proceeding. Choose **OK** or **Cancel**.
Reduce Database Size	If you need more space for your hard drive, reduce the database file size periodically to save hard disk space. **1.** Touch **Tasks** > **Database Maintenance**. **2.** Select **Reduce Database Size** on the Database Management window. **3.** Click **Yes**, then **OK**, on the confirmation dialog box.

9.4 Generate Technical Support Package

When contacting Cepheid Technical Support for assistance, follow these steps to generate a Technical Support Package of information from your system. If your touchscreen unit is connected to the internet, the Technical Support representative can generate this package for you.

Note

The Tech Support Package may contain personal data and patient data. For the United States customers, if you submit protected health information (PHI) as defined under HIPAA to Cepheid, such PHI shall be processed by Cepheid pursuant to Business Associate Agreement ("BAA") located at https://www.cepheid.com/en_US/systems/business-associates-agreement. For customers outside of the United States, if you submit any personal data or patient related sensitive data to Cepheid, such data shall be processed by Cepheid pursuant to Technical Support and Maintenance - Data Processing Agreement located at https://www.cepheid.com/en/systems/data-processing-agreement . For all customers, you may refer to Cepheid's Privacy Policy for details on collection and use of personal data at https://www.cepheid.com/en_US/legal/Privacy.

Note

The touchscreen can also be used with a keyboard and mouse. Where instructions say "touch" note that you can use keyboard and mouse to "select" items.

1. Touch **Tasks** > **Technical Support Package**.
2. Select a date range for the past three months or the date range in which you experienced trouble with your system (whichever is longer) and touch **Apply**.
3. In the Support Categories drop-down, select appropriate category: **System Support**, **Test Support** or **Custom Support**.
   a) For a Custom Support package, select items to include.
4. Touch **Create Support Package**.
5. When package creation is complete, touch **Save** to save your support package and select a location for the folder.

Note

The package is saved to GeneXpert Export folder by default. However, you can choose an alternate location.

6. Touch **OK** on package completion screen.

For users who are not connected to the internet, you can transfer your data to a computer with Internet access and either upload the files to the Cepheid website, Support tab, (www.cepheid.com) or email them to techsupport@cepheid.com. However, there are file size limitations. Cepheid website portal and emails can accept a maximum file size of 2 GB. If the file exceeds 2 GB you would need to create multiple packages and send them individually (e.g. one email at a time).

10 System Configuration (Administrator)

10.1 Settings

System Configuration in the following section includes general system preference settings, folder path locations and naming, QC lockout settings, archive interval settings and configuring the barcode scanner. Some system configuration steps are done through Cepheid OS software and some are done through traditional Windows system configuration steps.

The Settings screen is accessible by touching ⋮ > **Settings**.

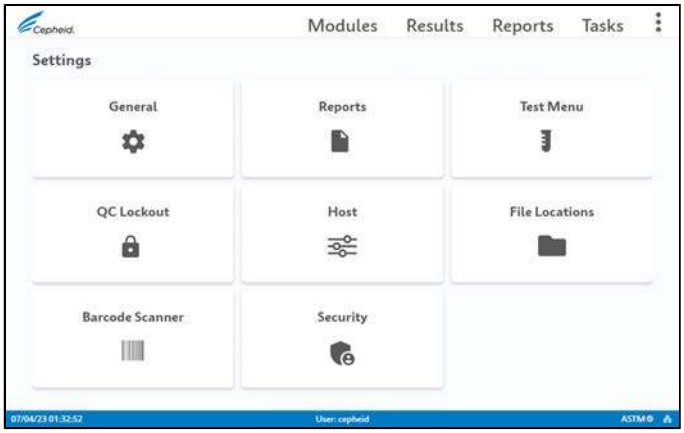


Figure 30. Settings Screen

Table 1. More Information About Settings

Settings	More Information
General	See General Settings.
Reports	See Reports.
Test Menu	See Manage Assay Definition Files (ADFs).
QC Lockout	See Set QC Lockout Settings.
Host	See Host Communications Settings and Set Host Test Code Settings
File Locations	See File Locations.
Barcode Scanner	See Configure Barcode Settings.
Security	See Security Settings.

10.2 General Settings

On the General Settings screen, the Administrator can set Patient Information characteristics.

To edit any entries on this screen, touch **Change Settings**, make any desired changes and touch **Confirm** when you are finished.

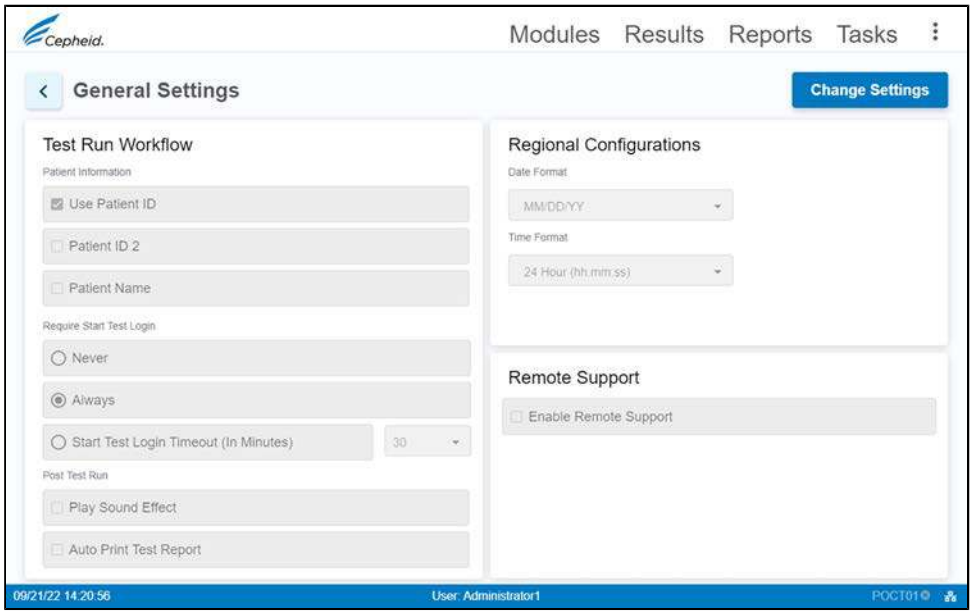


Figure 31. General Settings Screen

Table 2. General Settings Descriptions

Setting	Description
Use Patient ID	Patient information can be hidden or shown in the user interface, depending on your institution's privacy data guidelines.
Require Start Test Login	Configure system to require user login to start test. The administrator can select **Never**, **Always**, or choose **Start Test Login Timeout** and select a value in minutes from the drop-down menu.
Play Sound Effect	Configure system to play a sound effect when a test completes.
Auto Print Test Report	Configure system to print a test report automatically after test completion.
Regional Configurations	Set date and time formats.
Date Format	Set appropriate date format for your region.
Time Format	Set appropriate time format for your region.
Remote Support	**Enable Remote Support** allows you to request Cepheid Technical Support representatives to remotely access your system when help is needed.

10.3 Report Settings

The Report Settings screen allows you to configure report elements. The options enable you to customize the information displayed on test reports, ensuring that relevant information is included to meet your needs.

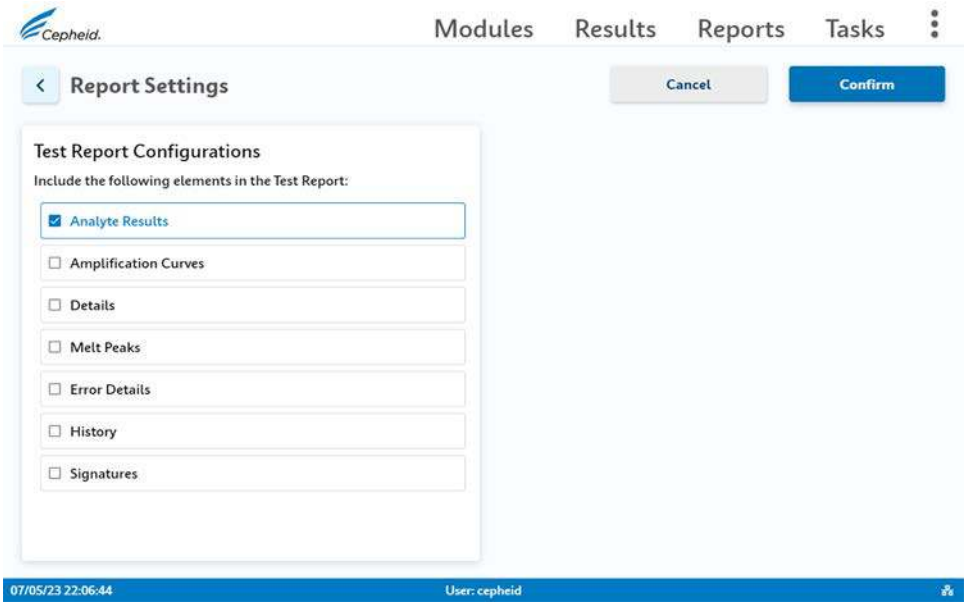


Figure 32. Report Settings

You can choose a variety of elements for your test reports.

Table 3. Report Settings Page Overview

Field/Tab Name	Description
Analyte Results	This element shows Ct and analyte results.
Amplification Curves	This element shows amplification curves.
Details	This element shows detailed view of results and probes.
Melt Peaks	This element shows melt peaks.
Error Details	This element shows error information.
History	This element shows notes.
Signatures	This element allows for reviewer sign-off.

10.4 Instrument Maintenance Settings

Touch **Tasks** > **Instrument Maintenance** to view the Instrument screen.

The Instrument screen shows the available modules. Additional buttons on this screen allow:

- The exclusion of modules from test.
- Plunger rod maintenance.
- Manage Instruments.

10.5 Reports

Touch the Reports tab to access **Test Statistics**, **System Log** and **Installation Qualification** options.

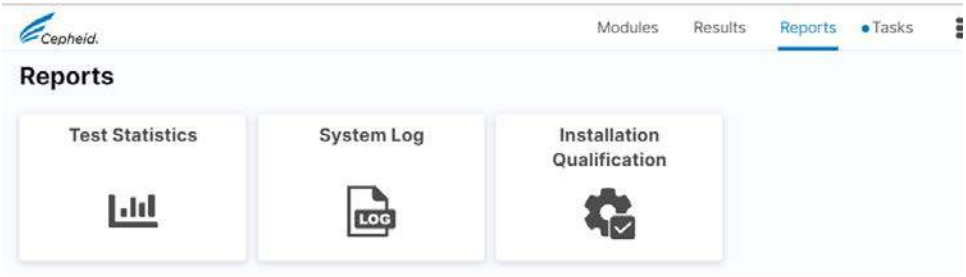


Figure 33. Reports Screen

Table 4. Reports Options

Report	Description
Test Statistics	You can create a test statistics report. **1.** Touch **Reports** > **Test Statistics**. **2.** Select information to include in your test statistics report, such as: Test Name, User, Lot Number, Date Range, Currently Connected Modules or All Logged Modules. **3.** Select test information and then touch **View Report** **4.** Optionally, you can touch**Export as PDF**.
System Log	You can create a System Log report. **1.** Touch **Reports** > **System Log**. **2.** Under Date Range, select All or enter a custom range. **3.** Under Display, select Errors or All Entries. **4.** Under Modules, select Currently Connected Modules or All Logged Modules. **5.** To generate a report, touch **View Report**.
Installation Qualification	You can create an Installation Qualification report. The Installation Qualification Report also shows the POC S/N. This POC S/N (POC Serial Number) is the unique identifier of your system, and is used by the POCT to communicate with your system when it is connected to a Data Manager.. **1.** Touch **Reports** > **Installation Qualification**. **2.** Touch to send a copy to the printer or to download and select a place to store file and touch **Save**.

10.6 Manage Assay Definition Files (ADFs) via Test Menu

An assay definition file (ADF) contains a series of programmed steps that the system uses to perform sample preparation, amplification and detection procedures. As described in this section, assay definition files can be imported by either using the CD that is supplied with the assay kit, or downloaded from the Cepheid website. ADFs are managed from the Test Menu screen.

Important **Please refer to your test Instructions for Use to identify the appropriate assay definition file to use.**

10.6.1 Options for Importing ADFs

You can import assay definition files (ADFs) from the CD included with your system or from the Cepheid website. See Import Test Definitions from the CD and Download ADFs and Package Inserts from the Cepheid Website for more information.

10.6.1.1 Import ADFs from CD

In vitro diagnostic assay definition files, ADFs, (.gxa/.nxa) are included on the CD that is shipped with the assay kit. This section describes how to import ADFs from a CD.

Note Although *in vitro* diagnostic ADFs can be imported, the Cepheid OS software does not allow the ADFs to be modified.

1. Locate the DVD drive. The DVD drive is shipped in the accessories box and is labeled as an item to save.

Note If the DVD drive has been misplaced and cannot be found, contact Cepheid Technical Support for assistance. See the Technical Support section in the Preface for the contact information.

2. Plug the DVD drive into one of the available USB ports on the rear of the touchscreen.
3. Press the Eject button on the front of the DVD drive to open the door.
4. The CDROM is located in the assay kit. Insert the ADFs CD into the DVD drive and close the DVD drive door. The green light on the front of the DVD drive will flash while the drive reads the CDROM.
5. When finished, remove the CD from the DVD drive and store the CD in a safe location in the event it is needed in the future.
6. Disconnect the DVD drive from the touchscreen and store it and the cables to it in the event they are needed in the future.
7. On the touchscreen, touch ⋮ > **Settings** > **Test Menu**.
8. On the Test Menu screen, touch **Import Test**.
9. Navigate to the DVD and to the folder containing the ADF files. Locate and touch the ADF (.gxa/.nxa) file.
   The test name appears in the filename field.
10. Touch **Open** to import the file into the system.
    The new test name and version number appear in the Test list.
11. If you need to import additional ADFs from the same CD, repeat Step 2-3.

Note For combination tests that have multiple .gxa/.nxa files, import only the ADFs for tests that will be performed in your lab.

10.6.1.2 Download ADFs from the Cepheid Website

To download assay definition files (ADFs) from the Cepheid website:

1. With an Internet capable computer, navigate to www.cepheid.com.
2. Under the Tests menu, select the product that you need to import the ADF for.
3. Scroll down to the Product Resources section.

4. Click **ADF Import Instructions** to download the complete set of instructions for downloading ADF files.
5. Read and follow the Assay Import Instructions to download the ADF and to install the ADF onto your system.

Note Assay Import Instructions are available in multiple languages.

Note If your system is connected to an LIS or HIS network, you must update your host test codes (after the assay definition file installation), in order to download tests to the system and/or upload test results from the system to the LIS or HIS network. See Update host test codes.

6. Extract the files from the compressed ZIP file downloaded from the website.

10.6.2 Delete Test Files (ADFs)

Caution 

Deleting test files from the system is a permanent operation. Ensure that the test files are no longer needed. If they are needed, they will need to be imported again from the test definitions CDROM or website.

1. Touch ⋮ > **Settings** > **Test Menu** and select the test file you want to delete.
2. Touch **Delete Test**.
3. On the Confirm message, touch **Yes** to delete the test file.
   The test file is deleted and removed from the list of tests.

10.7 Quality Control Lockout

If the QC lockout feature is enabled and required for new assay lots, the Quality Control Required message displays when a new lot is used. If the Quality Control Required message is displayed, touch the **OK** button to close the screen and then run QC for the selected assay and lot.

If the QC lockout feature is set so that QC must be run at regular intervals, reminders appear and indicate how long before the system locks out that particular assay. QC intervals are set by the system administrator. If the set time limit runs out and QC lots were not run, the system does not process any patient tests for the assay requiring QC until QC is completed. Acknowledge the reminder to close the reminder window to proceed. See Set QC Lockout Settings for more information.

You can also set QC Lockout by Reagent Lot for tests with basic or target-based organisms.

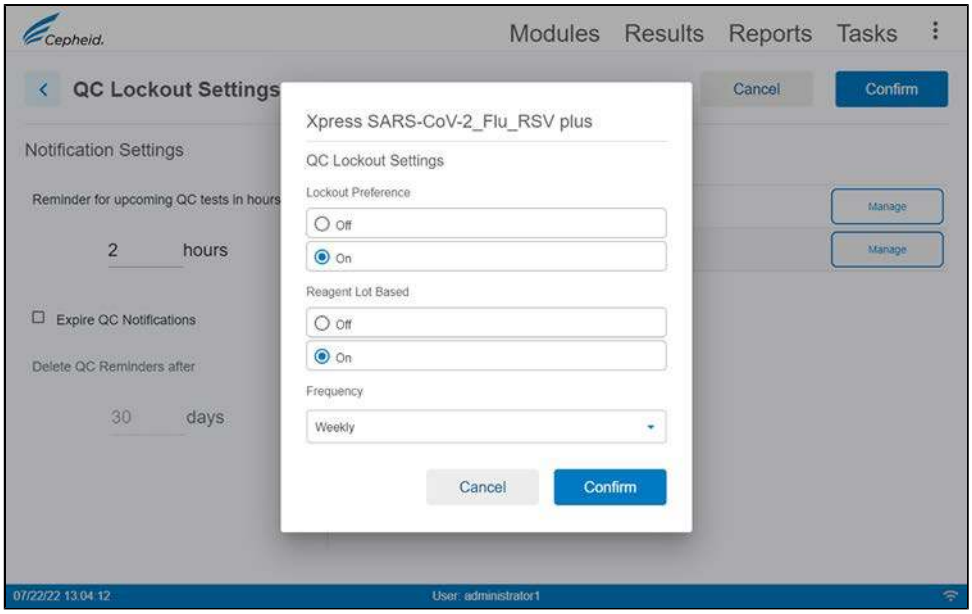


Figure 34. QC Lockout Settings Applied to Reagent Lot

You can apply QC Lockout to the individual tests in a combinatorial test, such as Flu/RSV.

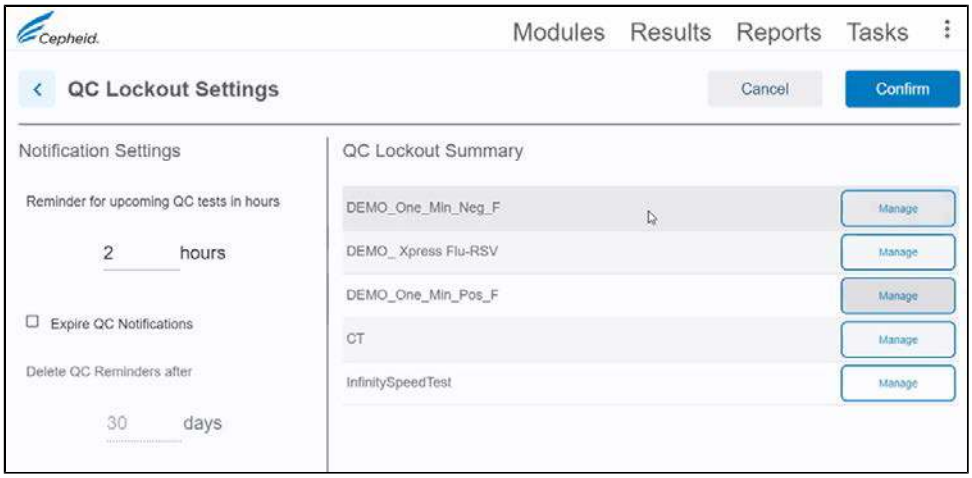


Figure 35. QC Lockout by Test for Combinatorial Test.

Note

You may continue running tests until the time limit runs out; however, allowing the time to run out may cause unexpected delays for urgent tests.

QC may also be required if the database has been restored. If the Database Restore Detected reminder is displayed, touch the **OK** button to close the reminder. Run QC for all active assays and lots.

10.8 Host (LIS) Management and Settings

10.8.1 Host Communication Settings

The Host Communications Settings screen displays the current communication settings which can be changed.

On the Host Communications screen, the administrator can:

- Enable or disable host LIS
- Enable or disable Data Manager communication
- Change the host ID name
- Change protocol between HL7, ASTM, and POCT01
- Run the touchscreen as either a server or client
- Enable or disable TLS encryption
- Set up automatic host Query after Sample ID scan
- Automatically download test orders
- Automatically upload results

To change any of these settings, touch **Change Settings**, make any changes, and touch **Confirm** when you are done. For assistance, call Cepheid Technical support. See the Technical Assistance section in the Preface for the contact information.

Table 5. Protocol Types

Protocol Type	Description
HL7	HL7 protocols can be used to connect to data manager software for test orders and result entry only.
ASTM	ASTM protocols can be used to connect to data manager software for test orders and result entry only.
POCT01	POCT01 protocols can be used to connect point of care software for user list and result entry only.

HL7/ASTM

Table 6. HL7/ASTM Communication Settings

Setting	Description
Host IP Address/Qualified Domain	Server IP address. Only integers and characters are allowed. The system only accepts valid IPv4 addresses (Format #.#.#.#). Required field.
Port	The port number is between 1024 to 65535 with default as blank. Entries in this field are always ASCII numeric. Required field.
Host ID	Host name. Type in a unique host name to identify an LIS or Data Management system (DM) that is connected to the touchscreen. The maximum number of characters is 20.

Table 7. HL7/ASTM Host Settings

Setting	Description

Setting	Description
Automatic Host Query After Sample ID Scan	Select to enable the touchscreen to query for test orders associated with the scanned or entered Sample ID.
Automatic Test Order Download	Select to enable the touchscreen to periodically query all test orders from the host.
Automatic Result Upload	As soon as the test is completed, the results are uploaded.
Use Instrument Specimen ID	Select to enable the touchscreen to generate a unique specimen ID, which is returned to the host. The Instrument Specimen ID is a unique ID for this sample. It should be stored in the host and used for future communication for this sample. This option is applicable if the facility does not provide unique sample identification. **Note** If the facility provides unique sample identification, this setting should be disabled.

POCT01

Use the following settings to configure the communication between the Cepheid OS software and POCT01:

- **Host Communication**
  - **Enable Host Communication**—Select to enable the software connected to a host. Clear to disable the host communication. The status of the last host communication is displayed on the right side of the screen. This status will state whether the communication was successful or unsuccessful.

Table 8. POCT01 Communication Settings

Setting	Description
Host	Type in an IP address, name or fully qualified domain name (FQDN) to identify a Data Management system (DM). The maximum number of characters is 20.
Port #	The port number is between 1024 to 65535 with default as blank. Entries in this field are always ASCII numeric. Required field. **Important** **The network port that is dedicated for the GeneXpert IV instrument should not be used for the host connection. The second NIC available on each touchscreen should be used to connect the touchscreen to the host.**

Table 9. POCT01 Host Settings

Setting	Description

Setting	Description
Auto Connect Interval	The Auto Connect Interval sets the time interval used by the touchscreen to automatically reach out to the Data Management System to receive data. The Auto Connect Interval default is 5 minutes. The interval range can be adjusted to between 5 minutes and 24 hours.
Timeout	The Timeout is how much time the touchscreen uses when attempting to communicate with the Data Management System. The Timeout default is 60 seconds, and the timeout range can be adjusted to between 30 and 60 seconds before the communication is terminated.
Receive from Data Manager	Select the following to receive data from the Data Management System: • **User Validation Settings**—When this is selected, the touchscreen can receive User Validation Settings from the Data Management System. • **User List**—When this is selected the touchscreen can receive the User List (which includes the name and expiration status of each user) from the Data Management system. The User List is automatically downloaded at the interval shown in the Auto Connect Interval field. To override this preset time interval and receive the User List on demand, touch the SYNC button on the Host Communication Settings screen

Important **Do not use Reset Communication Buffer during normal operation; otherwise, you would have to re-download orders and re-upload results.**

10.8.2 Enable TLS Encryption

Transport Layer Security (TLS) encryption secures data—such as sample ID, patient ID, and host details—when transferring from a customer workstation to hospital LIS server. The extra security protection does not slow down data transmission rate of speed.

Note When you integrate the Cepheid OS application and Active Directory/LDAP with TLS, your System Administrator must manually import the root CA certificate into the Windows certificate store on the touchscreen unit. TLS 1.1 and below versions are not supported. TLS 1.2 and 1.3 versions are supported.

1. Go to ⋮ > **Settings** > **Host** > **Host Communications**.
2. Touch **Change Settings**.
3. Select Protocol Type **HL7** or **ASTM**.
4. Input TLS-enabled server name or IP address in the Host IP Adress/Qualified Domain field.
5. Input TLS-enabled server port number in the Port field.
6. Input Host ID.
7. Select **Use TLS Encryption**.
8. Select Host Settings options.
9. Touch **Confirm**.
10. On the TLS Certificate screen, touch **Trust**.

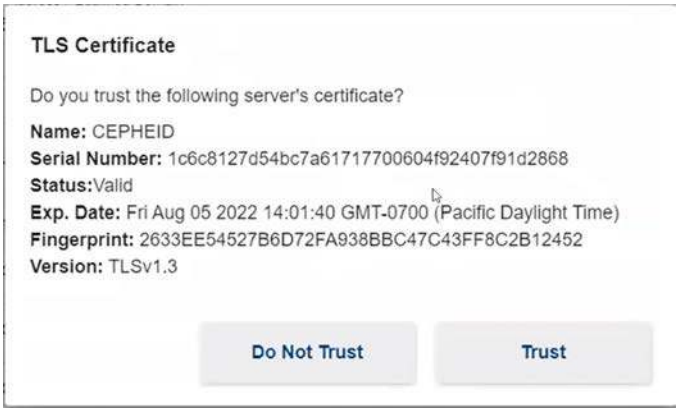


Figure 36. TLS Certificate Screen

11. Touch **Confirm**.
    The LIS Certificate Expiration Notification screen displays.
12. On the LIS Certificate Expire Notification screen, touch **OK**.

Figure 37. LIS Certificate Expire Notification Screen

Note View Settings is not displayed when basic user is logged in.

TLS Encryption Established appears on the Host Communication Screen. Sample ID, Patient ID, and host details data are now encrypted when transferred from customer workstation to the hospital LIS server.

10.9 Operate with Host (LIS) Connectivity

This section provides instructions on how to use the touchscreen host interface to:

- Create a test from a downloaded test order and upload the result (see Create a Test with Host Connectivity (Admin))
- Upload a test result (see Upload a Test Result to the Host)
- Troubleshoot Host Connectivity (see User Lockout Problems and Troubleshoot the LIS Interface)

Caution ⚠

Cepheid recommends to always confirm that LIS uploaded results match touchscreen test results after any changes to the touchscreen or host system, including (but not limited to) changes to the following: Cepheid OS software version, Host Communication Settings, Host middleware software or configuration changes, and LIS software or configuration settings.

10.9.1 Create a Test by Manually Requesting Test Orders and Selecting from the List of Test Orders

1. You can manually request new test orders from the host by touching the **Manual Query** button on the Manage Host Orders screen.
2. After orders are downloaded from the host, proceed as instructed in Create a Test by Selecting from a list of Test Orders.

10.9.2 Create a Test by Querying the Host with Sample ID

1. On the Host Communication Settings tab of the System Configuration dialog, touch the **Automatic Host Query After Sample ID Scan** check box to select and enable this function.
   When this function is checked and later, if a new test is started, when the Sample ID is scanned (or entered), the data manager will be queried. If an existing test order is found by the data manager, the test order will be automatically downloaded from the LIS to the system for processing.

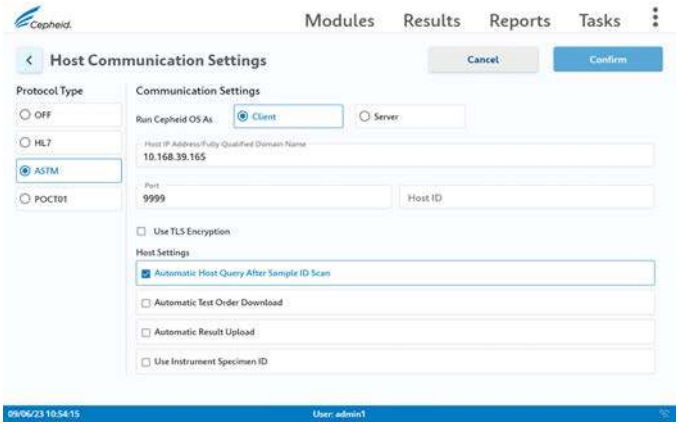


Figure 38. Automatic Host Query Selected

2. On the Modules screen, touch **Start Test**. Depending on the setup, the Scan Sample ID Barcode screen appears.
3. Scan the sample ID barcode on the specimen container.
4. Test orders for this Sample ID are downloaded from the host and are displayed in the Select Host Order screen which can be sorted by touching the header.

Note Other downloaded orders for different samples will not be displayed in the order table.

5. Select an order from the table. This will select the assay according to the test order.

Note If only one order matches the given Sample ID, this order will be automatically displayed.

6. The Scan Cartridge Barcode screen will automatically display a prompt to scan the barcode on the cartridge. This confirms that the correct assay will be run. Reagent lot ID, expiration date, and cartridge serial number are processed.
   The order for this Patient ID and Sample ID will be removed from the list of new orders.
7. Insert the cartridge with the specimen and reagents according to the assay-specific package insert.

8. Load the cartridge, and close the module door.

10.9.3 Cancel a Host Order

It may be necessary to cancel a host order if you are experiencing technical difficulties or have a change in plans.

1. Touch ⋮ > **Host** > **Manage Host Orders**.
2. Select the host order to be canceled.

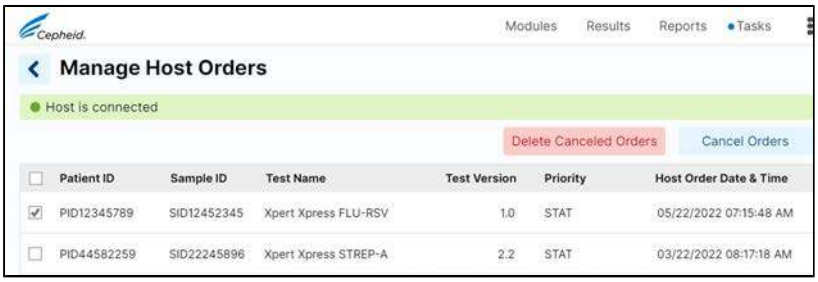


Figure 39. Delete Host Order

3. Touch **Cancel Orders**.
4. If the order needs to be deleted, touch **Delete Canceled Orders**.

10.10 Set Host Test Code Settings

Use the Host Test Code Settings screen for configuring the Host Test Codes used by your LIS system.

Note You cannot edit the test code for old versions of an assay. If you update the test code, the update will only apply to the new version of the assay; therefore, you must change the test code before upgrading an assay.

Important **Be careful to not use the same test code for tests from two different assays.**

1. Touch ⋮ > **Host** > **Manage Host Test Order** to display the Host Test Code Settings screen.

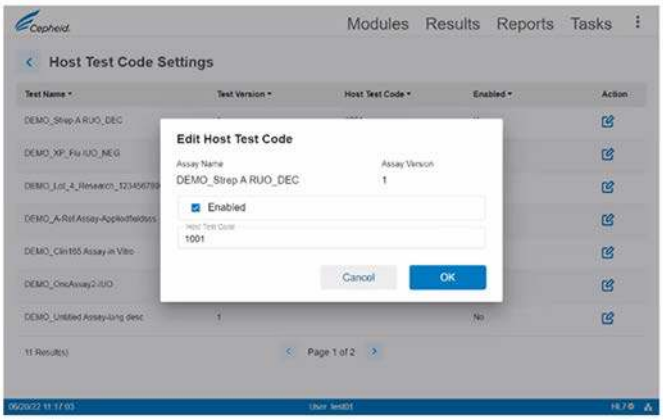


Figure 40. Host Test Code Settings

2. Use this screen to type in the test code that was entered into the host, so it can be translated into the touchscreen for test order processing and result reporting.
   - **Enabled** - Indicates if the assay has been set up for test order download and result reporting.
   - **Assay Name** - Assay name available for host connectivity.
   - **Assay Version** - Assay version available for host connectivity.
   - **Host Test Code** - The test code which the host used for download of test order and upload of test result.
3. Touch **OK** to save the changes. Close the screen.

10.11 Manage Host Orders

Use the Manage Host Orders screen to cancel or change the status of host orders.

1. Touch ⋮ > **Settings** > **Host** > **Manage Host Orders**.
2. On the Manage Host Orders screen, the administrator can perform a manual query of host orders, expired results (pending upload for tests that should no longer be uploaded to the host), reset the communications buffer (clear the data between the system and the host), cancel orders, and delete canceled orders.

Table 10. Host Order Status Options

Option	Description
MANUAL QUERY	Allows a manual query of the host for any new orders. During the manual query, the MANUAL QUERY button becomes the ABORT QUERY button. Wait until the query is completed or touch the ABORT QUERY button to cancel the operation.
EXPIRE RESULTS	Touch to change Upload - Pending and Review to Expired.
CANCEL ORDERS	Touch to flag the selected orders for cancellation.
RESET COMMUNICATION BUFFER	To clear the data between the system and the host. This is useful to remove data during host communication testing.
DELETE CANCELLED ORDERS	Touch to delete the flagged canceled orders. This is useful to remove redundant orders during host communication testing.

10.11.1 Configure Test Report

1. Log in as Administrator.
2. Touch ⋮ > **Settings** > **Reports**.
3. On the Report Settings screen, touch **Change Settings** and select the report sections you wish to change.

Table 11. Test Report Sections

Section Name	Description
Analyte Results	The analyte results for your report
Details	Test details for your report
Melt Peaks	Melt peaks for your report

Section Name	Description
Error Details	Error details for your report
History	History details for your report
Signatures	Signatures section for your report

4. Touch **Confirm**.

10.11.2 User Management

This section describes user roles, functions, requirements and how to view user list and how to add or change users on the system.

To access user management functions, touch ⋮ > **Settings** > **Security** > **User Management**.

10.11.2.1 User Name Requirements

When a new user is created, either locally or through a Data Manager, the User Name and Password must meet certain requirements.

If a user name does not meet the requirements shown in this section, the Cepheid OS software rejects that particular User. All other validated users are included on the User List. The Data Manager may sometimes refer to a User as an Operator.

- **User Name**: A user name is required. A user name should have a minimum of 6 characters and a maximum of 128 characters. The User name cannot contain spaces, and cannot contain any of the following characters: **| : * “ < > / \ ?**
- **User Password**: A user password is required, and cannot contain spaces. Passwords must be 8 to 32 characters in length and must include 3 of the following: 1 uppercase letter, 1 lower-case letter, 1 number or 1 special character.
- **User Expiration Date**: This date usually refers to the end of a one-year period after user certification was granted. User’s expiration date should not be empty when the user is being managed by a Data management system.

Note If users are managed locally (not through a Data Manager), a user expiration date is not required.

- **User Permission Level**: A user permission level should be entered as either 1 or 4
  - **Permission level 1**: is an Administrator User
  - **Permission level 4**: is a User
- **Name Duplication**: The User name should not be duplicated

Note The User ID and Institutional ID are the same when received from a data manager. A data manager sometimes refers to users as operators. When the operator information is received from a data manager, the user ID and the institutional ID are the same as when logging onto the touchscreen.

10.11.2.2 View User List

Prior to viewing the User List, if the user is list-managed by a Data Manager in POCT01 protocol, the list must be selected to be downloaded, using the settings on the Host Communication Settings screen. Use the steps in this section to set up that download.

1. Touch ⋮ > **Settings** > **Host** >**Host Communication Settings**.
2. Touch **Change Settings**.
3. At the bottom of this screen, touch the **User List** check box, under the Receive from Data Manager section. Checking this box tells the Data Manager to include the User List when it performs the next download.
4. Touch **Confirm**.

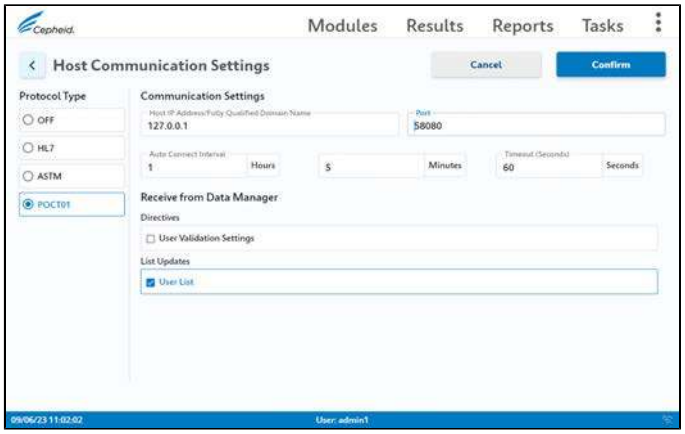


Figure 41. Host Communications Screen, Showing User List Selected

When the system is connected to a Data Manager, the user list cannot be managed on the local system. All user information must be added to the Data Manager by the system administrator, and the user list is automatically downloaded to the system.

5. Return to **Settings** and touch **Security** >**User Management**. The Users screen appears.
   The Users Screen displays User Name, Full Name, User Type and Expiration Date. If any user information needs to be updated it must be done on the Data Manager.

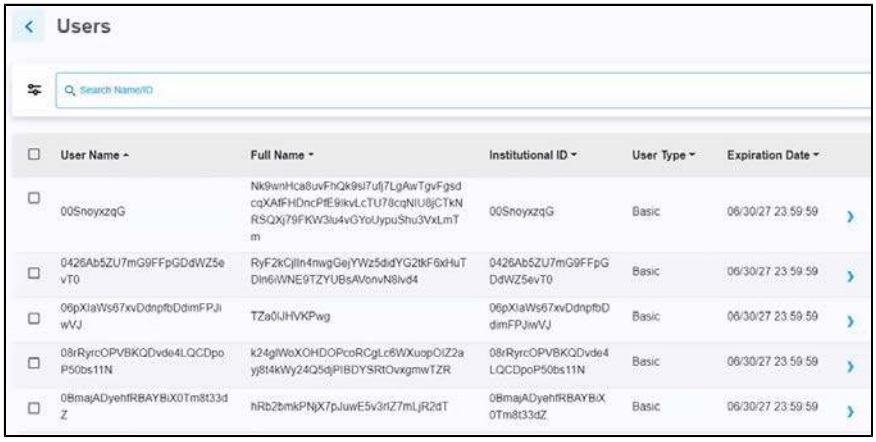


Figure 42. Users Screen, Showing Active List of Users

10.11.3 Add or Remove Users

This section describes how to add and remove users in the system, either locally or through a data management system.

Note When users are managed using a Data Management system, they cannot be managed locally on the system.

Important **When users are added locally and the system is later connected to a Data Management (DM) system, those local users are removed from the local list when the list is updated. A system administrator must add these users through the DM.**

10.11.3.1 Add or Remove Users Locally (without Host Communication)

1. Touch ⋮ > **Settings** > **Security** > **User Management**.
2. Touch **Add User**.
3. On the Add User screen, enter the full name and password of the user to be entered. Re-enter the password to confirm. Ensure the password conforms to the password requirements.
4. Enter the User type (Admin or Basic) from the drop-down menu. One administrator account is required at minimum.

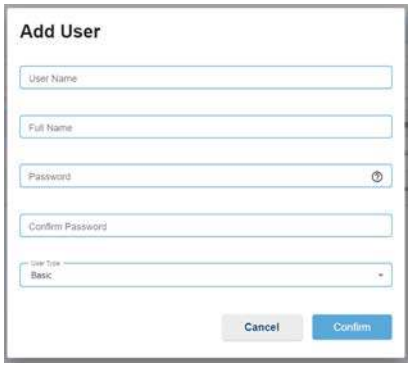


Figure 43. Add User Screen

5. When all user information on this screen has been entered, touch **Confirm**. Return to the Users screen. The added user now appears on screen.

Remove User

When logged in as Administrator, you can remove a user locally.

1. Touch ⋮ > **Settings** > **Security** > **User Management**.
2. Select the user you want to remove, then touch **Delete User**.
3. On the Confirm screen, touch **Yes**.

10.11.3.2 Add or Remove Users in Data Management System

1. Touch ⋮ > **Settings** > **Host** > **Host Communication Settings**.
2. Touch **Change Settings** and select **POCT01**.
3. To allow a system to receive User Validation Settings from a data manager, touch the User Validation Settings check box at the bottom of the screen. When this box is checked the touchscreen receives and stores User Validation Settings from the data manager.

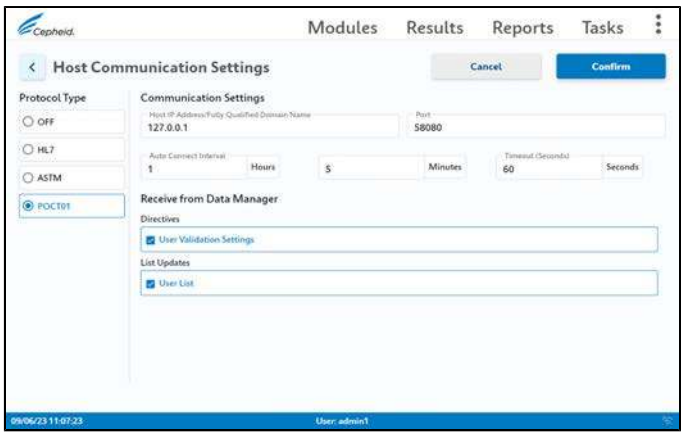


Figure 44. Host Communications Settings Screen Showing User Validation Settings Check Box

10.11.3.3 User Lists from Data Management System

This section explains the behavior when the system is configured to receive User Lists from a Data Manager in POCT01 protocol.

When using a data management system, all user additions and changes are done by the system administrator, remotely, using the Data Manager. Users cannot be added or changed locally.

Note If a user is added to a DM system and the touchscreen is later disconnected from the DM, the user list that then appears locally will be the last list that was downloaded from the DM.

Important **When users are added locally and the system is later connected to a Data Management (DM) system, those local users are removed when the user list is updated. It is necessary to have the system administrator add those users again, using the DM. If a user is added to a DM system and the instrument is later connected to the DM, the user list that then appears locally is the last list that was downloaded from the DM.**

10.11.3.4 Manage Users' Expiration Dates in a Data Management System

This section describes how to select and view User Validation Settings from a Data Manager. User Validation Settings allow a data manager to manage user's expiration dates, and the behavior the system uses when expired users are encountered, such as allowing an expired user to log on, warning an expired user, or locking out an expired user.

1. Touch ⋮ > **Settings** > **Host** > **Host Communication Settings**.
2. Touch **Change Settings**. To allow a system to receive User Validation Settings from a data manager, touch the **User Validation Settings** check box at the bottom of the screen. When this box is checked the system receives and stores User Validation Settings from the data manager.

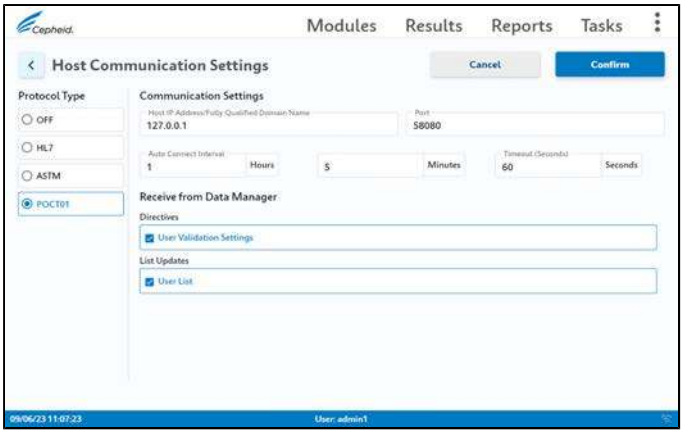


Figure 45. Host Communications Settings Screen Showing User Validation Settings Check Box

3. Touch ⋮ > **Settings** > **Security** > **User Validation**. The User Validation Settings screen appears, showing the active option selected.

Figure 46. User Validation Settings Screen

Note

The User Validation Options on the User Validation Settings screen can only be edited on the Data Manager. Locally, the Administrator can only view (not change) the User Validation Options that were sent from the Data Manager to the system. See User Validation Options for more information.

10.11.3.5 User Validation Options

User Validation Options information is sent to the system from the Data Manager, and this information manages the login access of the users. User login access is determined by their individual expiration dates, which is usually based on a user's credential status.

The three User Validation Options are:

- **Allow**: If the User Validation setting is set to Allow, anyone on the User List that was received from the Data Manager may log in, regardless of their expiration status. If a User on the User List is expired, they can still log in (based on how the system administrator has set it up). See the system administrator for additional information.
- **Warn**: If the User Validation setting is set to Warn, and a user who is expired attempts to log in, a message will appear, stating that they expired on a particular date, and asking if they still want to continue. The warning serves as a reminder

that the user needs to complete their compliance training, but if it is urgent they can continue. See the System Administrator for additional information.

- **Lockout**: When the User Validation setting is set to Lockout (the default setting) and an expired user attempts to login, the user receives an error message, informing them that they are not allowed to login to the system. See the System administrator for additional information.

Note The default User Validation setting is set to Lockout. This must be changed on the Data Manager if the Administrator wishes it changed to a different setting, such as Allow or Warn.

10.11.4 Upload a Test Result to the Host

Test results can be uploaded to the host either automatically or manually.

Note Be aware that only Patient Results, Quality Control Results, and Proficiency Test Results can be auto-uploaded when POCT01 or LIS are enabled.

10.11.4.1 Switching Protocols - Resulting Upload Behavior

This section describes the behavior when a user switches from one protocol to another (HL7/ASTM to POCT or from POCT to HL7/ASTM).

- If a test is run and HL7 or ASTM is turned off and then turned on:
  - If the test has a host code it can be manually uploaded.
  - If the host code is not defined, it cannot be uploaded to the LIS.
- If a test is run while HL7 or ASTM is turned on and then is switched to POCT01, the test result is automatically uploaded to the data manager.
- If a test is run with no protocol selected, and then POCT01 is switched on, the result can be manually uploaded but is not automatically uploaded.

10.11.4.2 Automatically Upload the Test Result to the Host

1. Touch ⋮ > **Settings** > **Host** > **Host Communications**.
2. On the Host Communication Settings screen, touch **Change Settings** and select the **Automatic Result Upload** check box so the result is uploaded as soon as the test is completed.

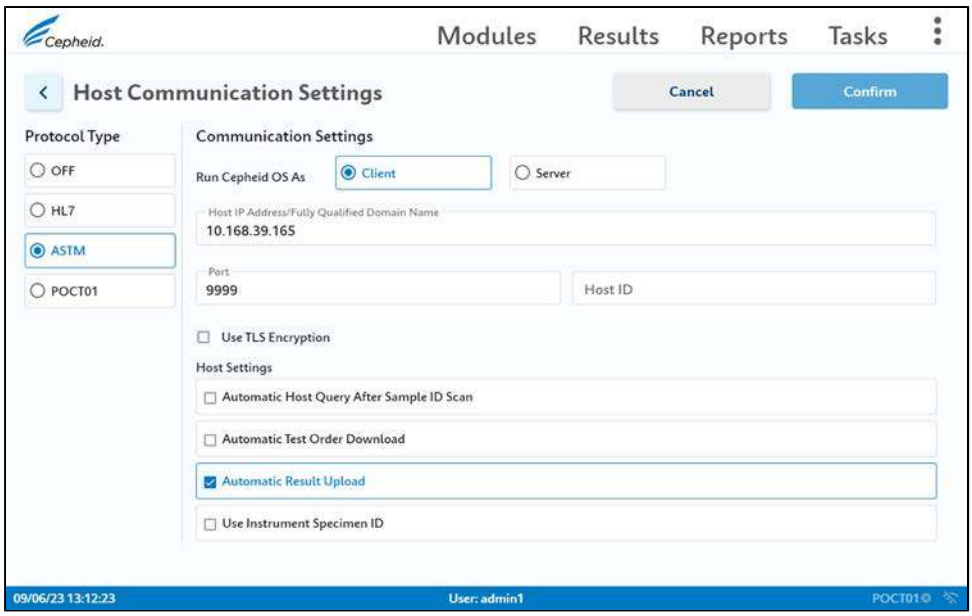


Figure 47. Automatic Result Upload

3. After the test is completed, the result is automatically uploaded.

10.11.4.3 Manually Upload a Test Result to the Host

Note You can manually upload a test result even if Automatic Result Upload is enabled.

Note If an attempt to exit the software is made with results in the uploading status, the software alerts the user.

Note Each test can be uploaded individually from the Results Summary screen.

On the Results Summary screen, touch **Actions** > **Upload**.
The individual test result is uploaded to the host, then on to the LIS. The test result then appears on the patient chart or record.

10.12 File Locations

10.12.1 Folders

The Folders screen displays the default location for the Export, Report, Backup and Database folders.

Note Network drives must be added from the Cepheid OS software to enable the storage of files from the software to the network drives.

Note If a network drive does not reconnect when a different user logs on, the login credentials to access the drive must be re-entered.

1. To access this menu to make changes in the folder locations, touch the ⋮ > **Settings** > **File Locations** > **Folders**.

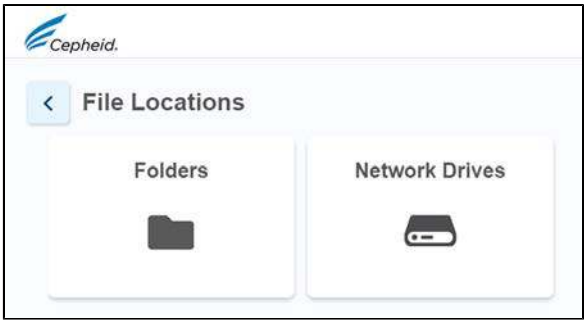


Figure 48. File Locations

2. To make changes to the default location for Export, Report, Backup or Database folders, touch **Edit** and make any changes to the default folder locations.
3. Touch **Confirm** when finished making changes.

10.12.2 Add a Network Drive

When logged in as a administrator user or basic user, you can add network drives to your touchscreen unit.

1. Touch ⋮ > **Settings** > **File Locations** > **Network Drives**.
2. Touch **Add Drive**.
   The Connect to a Shared Network Location screen displays.
3. In the Drive field, touch drop-down arrow and select a letter for your new network drive.
4. In the Server Path field, type or navigate to your network folder location.
5. Enter your user name and password.

10.13 Configure the Barcode Scanner

Use the following section to scan a configuration barcode to configure the barcode scanner.

Should it be necessary to reconfigure the scanner, perform these steps:

1. Print the matrix shown.

Figure 49. Configuration Data Matrix Barcode

2. Touch ⋮ > **Settings** > **Barcode Scanner**.

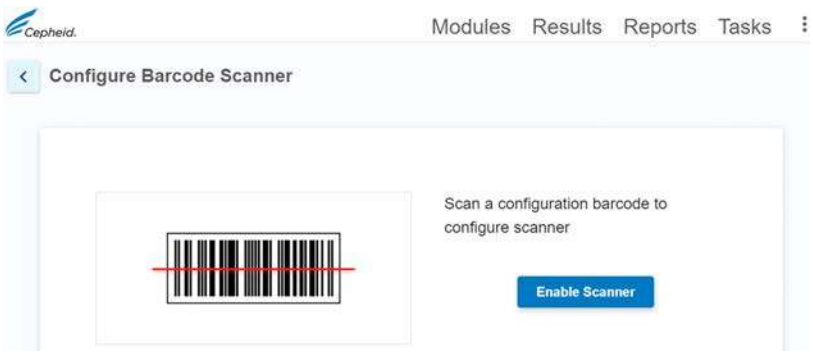


Figure 50. Configure Barcode Scanner Screen

3. Scan the Configuration Data Matrix barcode printed, to reconfigure the scanner.

10.14 Security Settings

10.14.1 Authentication Settings

With administrator user access, you can enable user authentication settings.

10.14.1.1 Enable User Login with Institutional ID

You can enable users to scan their identification badges to log in to Cepheid OS software.

1. Log in as administrator.
2. Touch ⋮ > **Settings** > **Security** > **Authentication Settings**.
3. Touch **Change Settings**.
4. Select **Login with Institutional ID** and touch **Confirm**.

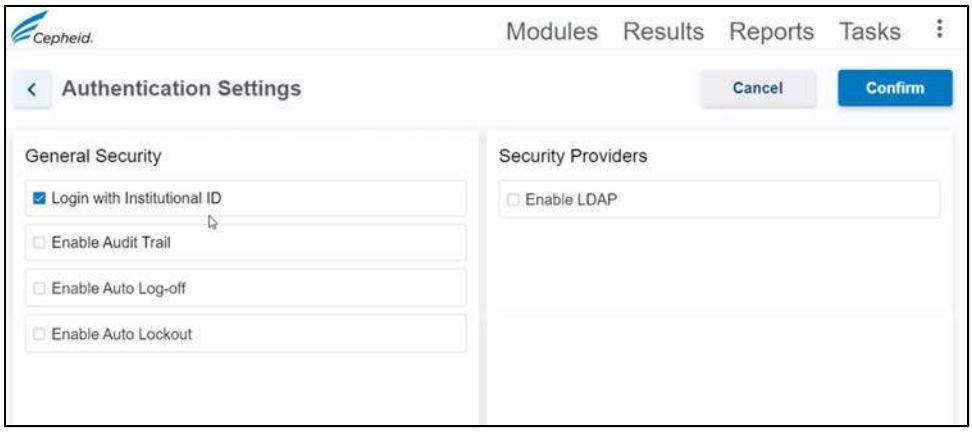


Figure 51. Authentication Settings Screen showing Login with Institutional ID Enabled

Now institutional users can log into Cepheid OS software by scanning their identification badges.

10.14.1.2 Enable Audit Trail

You can enable the audit trail Windows utility from Cepheid OS software.

1. Log in as administrator.
2. Touch ⋮ > **Settings** > **Security** > **Authentication Settings**.
3. Touch **Change Settings**.
4. Select **Enable Audit Trail** and touch **Confirm**.

Now user activity is recorded in the Event Audit Trail.

10.14.1.3 Enable Auto Log-off

You can configure automatic log-off for when a user is inactive on the system for an extended amount of time. Automatic log-off occurs after a defined period of inactivity to ensure the security and confidentiality of patient records and information.

1. Log in as administrator.
2. Touch ⋮ > **Settings** > **Security** > **Authentication Settings**.
3. Touch **Change Settings**.
4. Select **Enable Auto Log-off**.
5. Set the amount of minutes allowed for inactivity before automatic log off. The default is 15, but you can select between 15 and 500 minutes.
6. Touch **Confirm**.

Figure 52. Authentication Settings Screen showing Enable Auto Log-off

Now inactive users are logged out of Cepheid OS software automatically.

10.14.1.4 Enable Auto Lockout

You can configure automatic lockouts for when a user fails to enter a correct password. Auto Lockout Policy determines what happens when a user enters a wrong password. It ensures that an attacker cannot use brute force attack or dictionary attack to guess and crack the user's password.

1. Log in as administrator.
2. Touch ⋮ > **Settings** > **Security** > **Authentication Settings**.

3. Touch **Change Settings**.
4. Select **Enable Auto Lockout**.
5. Select the number of times the user can attempt password entry. The default setting is 5 times, but you can select between 3 and 10 times.
6. Set the lockout duration time, the amount of time a user remains locked out until the system allows the user to try again. The default setting is 30 minutes, but you can select between 15 and 60 minutes.
7. Touch **Confirm**.

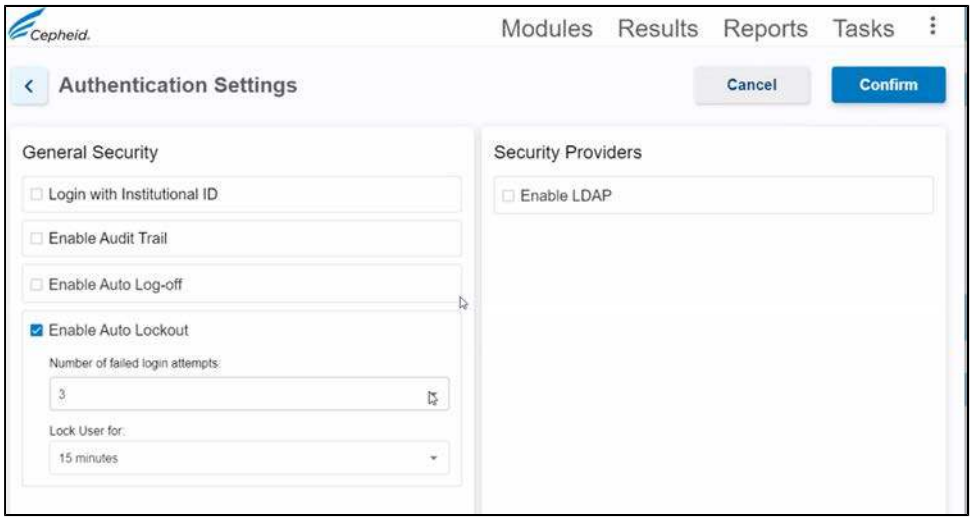


Figure 53. Authentication Settings Screen showing Enable Auto Lockout Enabled

Now users who enter the wrong password multiple times are locked out for a period of time.

10.14.1.5 Configure LDAP Authentication

Configuring Lightweight Directory Access Protocol (LDAP) Authentication allows Cepheid OS user accounts to be linked to a centralized directory system, such as Microsoft Active Directory, so that password validations can be managed in a central location. All users added while LDAP is enabled are labeled as Remote users in the Users window.

1. Log in as administrator.
2. Touch ⋮ > **Settings** > **Security** > **Authentication**.
3. Touch **Change Settings**.
4. Select **Enable LDAP**.
5. Enter the following:

Table 12. LDAP Settings

Setting	Description

Setting	Description
Host	Type in the address of the LDAP-enabled directory server.
Port	Type in the computer port on which the directory server is connected.
User ID Attribute	Type in the user ID attribute used to map unique directory users to a user name. For example, you might enter a user ID if your network uses the user ID attribute to identify users.
Base DN	Type in the base distinguished name (DN). A base DN is the point from where a server searches for users. An LDAP search for the user administrator starts at the base DN (dc=example,dc=com).
Bind DN	Type in the bind DN. The bind DN is a fully qualified identifier of an entity on an LDAP server of the account used to connect to the LDAP directory.
Password	Enter the password of the LDAP Bind DN account.
Enable TLS Authentication	Check this box to enable Transport Layer Security (TLS) encryption. TLS is a standard security technology for establishing an encrypted link between a server and a client. When the option is off, the system will transmit unencrypted information.

6. Touch **Confirm**.

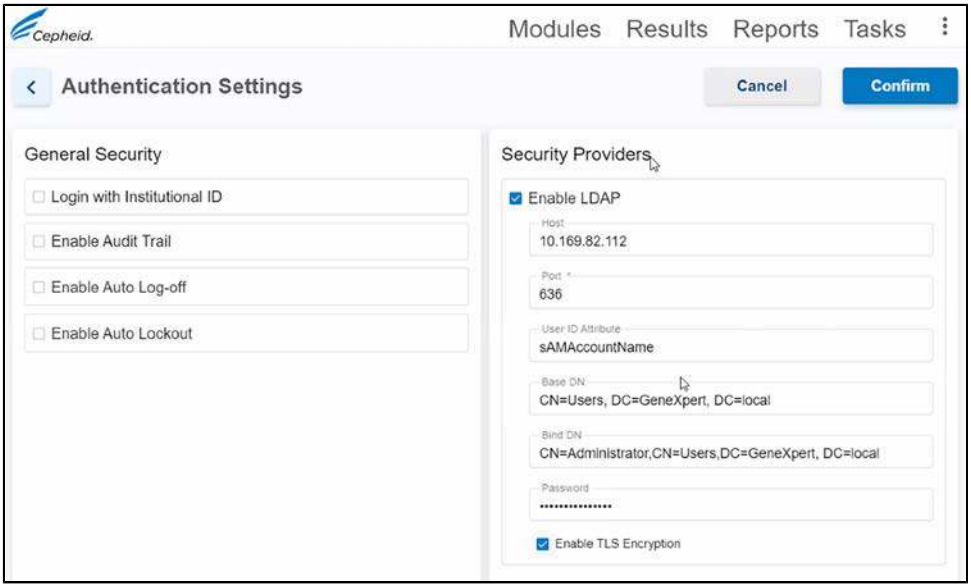


Figure 54. Authentication Settings Screen showing Enable LDAP

7. Touch **OK** on the Information screen.

Now all users added while LDAP is enabled are labeled as remote users and their logins are managed by the LDAP security feature.

10.14.1.6 Add Remote (Active Directory) Users

Once you enable LDAP authentication, you can add remote users via Active Directory.

1. Log in as administrator.
2. Enable LDAP. See Configure LDAP Authentication for detailed steps.
3. Touch ⋮ > **Settings** > **Security** > **User Management**.
4. Touch **Add User**.
5. Enter user name.

6. Select **Admin** or **Basic** user type.
7. Touch **Confirm**.

Figure 55. Add User while LDAP Authentication is Enabled

Users added when LDAP Authentication is enabled are listed as Remote users on the Users screen.

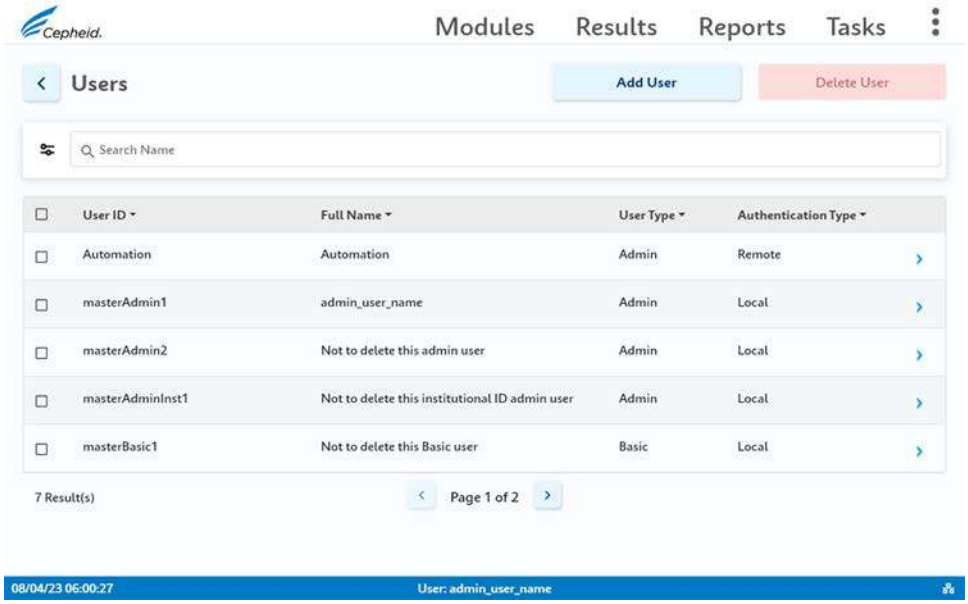


Figure 56. Remote Users

Note

Note If you want to further secure online data, select **Enable TLS Encryption**.

10.14.2 Connect to Cepheid Technical Support

This feature allows you to share your screen with Cepheid Technical Support when you contact them.

Note

If Remote Support window is hidden from view during connection with Cepheid Technical Support select ⋮ > **Get Remote Support** again and the window will reappear.

1. Touch ⋮ > **Get Remote Support**.

2. Touch **Enter a Session Key**.
3. Enter the session key provided by Cepheid Technical Support and touch **Next**.
4. Touch **Allow** so that Cepheid Technical Support can view your screen.

11 Maintenance

11.1 Maintenance Tasks

Although the system is designed to prevent cross-contamination and ensure accurate results, the instrument is checked and cleaned periodically as a precautionary measure. This chapter expands on the daily, weekly, monthly and quarterly tasks listed on your system maintenance log.

11.1.1 Maintenance Log

Complete the maintenance log as maintenance tasks are performed on the system. There is an Adobe PDF electronic version of this file available that can be used for monthly records.

GeneXpert® System with Touchscreen Maintenance Log

Month and Year:
Last Calibration Check Date:
FAS Installation Date:

Name of Institution GeneXpert Serial Number

Instructions:
1. Enter the name of your institution, GeneXpert Serial Number, current Month and Year, Last Calibration Check date, and FAS Installation Date in the fields above.
2. For each maintenance activity listed below check the box(es) under the day of the month that the activities were performed and enter your initials (2 characters maximum) in the bottom row.
3. Save the file after entering the data. We recommend saving one file each month for a complete record of activities.

Daily Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean work area																															
Close all module doors																															
Discard used cartridges																															
Weekly Maintenance																															
Power down the GeneXpert instrument[1]																															
Power down the touchscreen[1]																															
Clean instrument fan filters																															
Monthly Maintenance																															
Archive tests[2]																															
Purge tests[2]																															
Quarterly Maintenance																															
Clean plunger rod and cartridge bays[1]																															
Clean instrument surfaces[1]																															
Replace instrument fan filters[2]																															
Yearly Maintenance																															
Check annual instrument maintenance[2]																															
As Necessary																															
Clean I-CORE® Module using I-CORE[1] cleaning brush																															
Print system log report[1]																															
Back up database[2]																															
Technician Initials (Two Letters)																															

11.1.2 Guidelines for Cleaning and Disinfecting

Cleaning and disinfecting system components is crucial for proper system maintenance. Disinfection is a chemical reaction. As a chemical reaction, it is affected by many factors including the concentration of the disinfectant, contact time, temperature, nature of the microbes present, amount of organic residue, surface properties, etc. With any disinfectant, it is crucial that the entire area to be disinfected be in contact with the disinfecting solution.

Biological Risks

BIOLOGICAL RISKS: Wear disposable gloves, eye protection and other personal protective equipment (PPE) mandated by your institution's safety policies while performing this cleaning procedure. Wearing PPE prevents exposure to chemical and biologically hazardous materials.

Note Maintenance procedures may be performed more frequently according to your environmental conditions.

General guidelines for routine surface cleaning are:

- Use only 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol).

General guidelines for cleaning combined with disinfection are:

- Use a final concentration of 1:10 dilution of household chlorine bleach (used within 1 day of preparation).

Note Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.

Figure 57. Spray Cleaning Fluids on Wipe

- Use sufficient disinfectant (bleach solution) and spread the disinfectant evenly. The entire surface should be wet to completely disinfect the surface.
- Allow a minimum of two minutes contact time. More than eight minutes is not recommended.
- Remove remaining bleach residue with 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol).

Note Failure to remove bleach residue from the system may cause damage to the instrument components. Always perform a wipe down with ethanol after using bleach.

- Repeat the cleaning and disinfection with bleach three times (two minutes contact time for each bleach application) followed by a final wipe with ethanol to remove bleach residue.

Note An optical brush should be used for frequent I-CORE module cleaning depending on your environment. Please contact your local representative to determine the frequency of cleaning the optical lens. See Clean the Lens procedure for how to perform the optical cleaning.

11.2 Daily Maintenance

11.2.1 Clean the Work Area

Clean the work area daily using good laboratory practices to avoid contamination of specimens or reagents. Follow your institution's guidelines for cleaning the work area.

11.2.2 Close Module Doors

Check that all module doors are closed daily to avoid contamination of the modules.

11.2.3 Discard Used Cartridges

Discard used cartridges daily. Follow your institution's standard practices for disposal. See Biological Hazard Safety and Chemical Safety for additional information regarding cartridge disposal.

Important **Used cartridges may contain potentially infectious materials, as well as highly amplified PCR target(s). Do not open or attempt to alter any part of the cartridge for disposal.**

11.3 Weekly Maintenance

11.3.1 Power Down the System

The instrument and touchscreen should be powered down once per week to refresh the system. This action clears out unwanted temporary files and guards against computer memory corruption to prevent a malfunction of the system.

Note Do not shut down the software and turn off the system if a test is running. Wait until the test finishes running.

11.3.2 Clean the Instrument Fan Filters

Clean the fan filter weekly or more frequently, if necessary if you operate the instrument in an area with high pollution, dust or smoke. The fan filter is located on the back of the instrument. The materials needed for the procedure are as follows:

- Paper towels
- Water
- Disposable gloves

Note In order to minimize system downtime, Cepheid recommends that you have a spare fan filter available to swap with the dirty fan filter being cleaned. After removing the fan filter, it may be cleaned and re-used the next time that a fan filter is removed for cleaning.

Note The instrument and touchscreen must be powered down prior to performing the fan filter cleaning described below.

1. Make sure all tests have finished.
2. Turn off the GeneXpert Instrument and the touchscreen, following the instructions in Shut Down the System.
3. Reposition the instrument so the fan filter can be easily accessed.
4. Gently take the fan filter guard off by unsnapping the guard from the fan housing and set it aside for the remainder of the procedure for filter removal and cleaning.

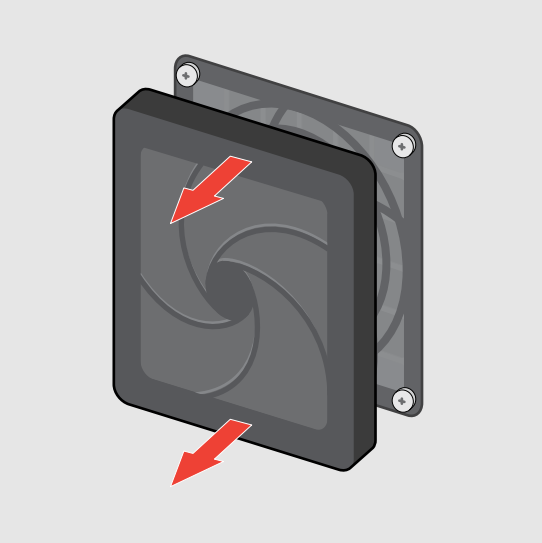


Figure 58. Fan Filter Guard Removal

5. Remove the dirty filter for cleaning.

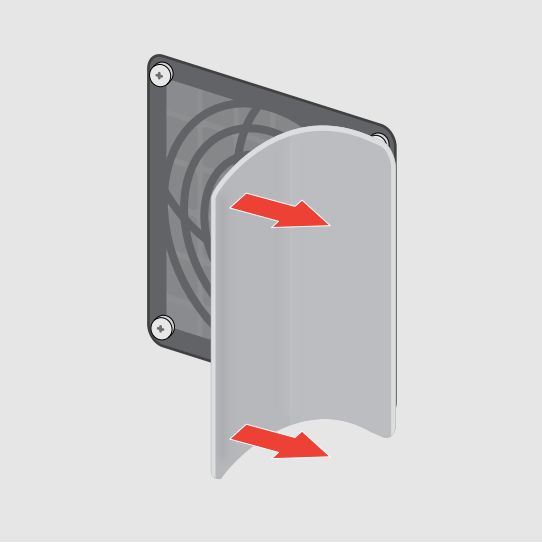


Figure 59. Dirty Foam Filter Removal

6. Place a clean filter into the fan filter guard.

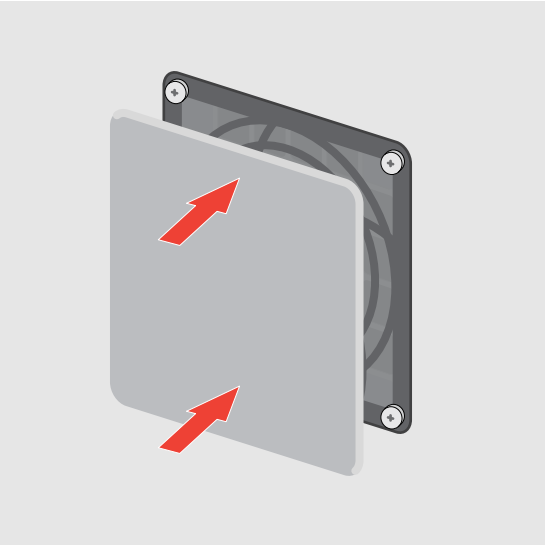


Figure 60. Clean Foam Filter Replacement

7. Position the fan filter guard and filter into place as a unit. Press the sides of the guard firmly onto the fan housing until the grip snaps securely onto the fan. Press the bottom of the guard until the grip snaps securely onto the fan.

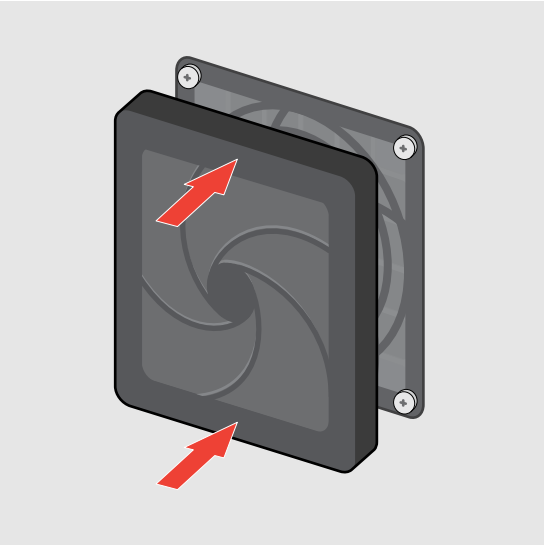


Figure 61. Fan Filter Guard Replacement

8. Press the bottom guard of the filter into place.
9. Clean the dirty filter by washing it. Place this cleaned filter between two paper towels and allow it to air-dry.
10. After the filter is dry, store it for use for the next cleaning interval.
11. In the maintenance log, fill in the date of the fan filter cleaning and keep it for your records.

11.4 Monthly Maintenance

11.4.1 Archive and Purge Tests

Archiving tests allows you to move your data and, if desired, free up space in the database. You can archive multiple tests at one time. In addition to serving as a data-retention mechanism, you can provide the archive files to Cepheid for analysis when troubleshooting. The archive process creates a copy of the test(s) and saves the data in an .nxx file.

Note The maintenance section outlines the minimum recommended archiving frequency. Ideally, you should archive your testing data on a routine basis (weekly or monthly). Routine archiving can help protect your data and minimizes the processing times to archive large batches of tests.

1. On the Tasks tab, touch **Archive Tests**.
2. All tests are selected by default. De-select any tests to be excluded from the archive by touching the Check Box at the left of the test.

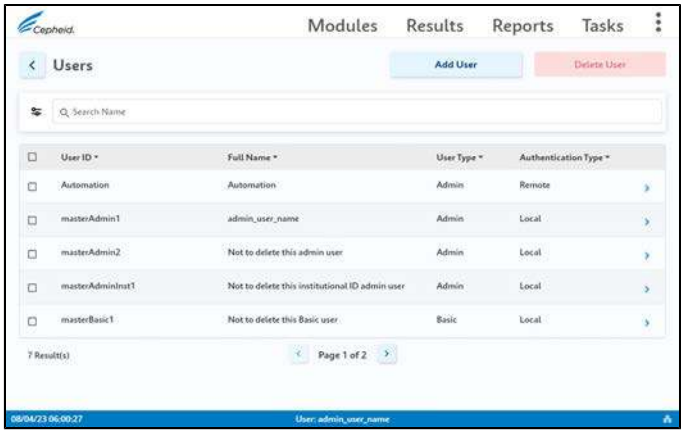


Figure 62. Archive Tests Screen

3. Touch **Archive**.
   A confirmation box appears, showing the number of tests to be archived.
4. On the Confirm Files to Archive screen you can:
   - Cloak IDs—Select this check box on the Confirm Files to Archive screen if you want to send data to Cepheid Technical Support, but want to hide patient-sensitive information.

Note You cannot trace a test result for a particular Patient ID if you cloak IDs.

   - Purge Selected Tests from list after archiving—Select to remove tests after archiving on the Confirm Files to Archive screen. See Purge Tests from the Database for more information.
5. Touch **OK** to begin the archiving process.

After archiving completes, an Information box appears, showing the number of tests archived and the archived file path. Touch **OK** to close the window.

11.5 Quarterly Maintenance

Note Shut down the GeneXpert system with touchscreen completely when cleaning the instrument and touchscreen surfaces.

Note Do not remove the instrument or touchscreen covers or use a vacuum cleaner inside the instrument or touchscreen at any time. Remove debris from exterior instrument and touchscreen surfaces using lint-free wipes or paper towels moistened with ethanol or bleach as described in the following procedure.

For routine cleaning of the instrument and touchscreen surfaces:

1. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.
2. Wipe all surfaces outside the instrument and touchscreen. Change lint-free wipes or paper towels frequently while wiping.
3. Wipe the table surfaces around the instrument. Change lint-free wipes or paper towels frequently while wiping.
4. Discard used wipes or paper towels according to your standard laboratory procedure.

11.5.1 Clean the Plunger Rods and Cartridge Bays

Before cleaning the plunger rods and cartridge bays, read Guidelines for Cleaning and Disinfecting.

Clean and disinfect the plunger rods and cartridge bays quarterly (every three months), in the event of a spill, or if a negative control yields a positive result.

Note Do not perform plunger rod maintenance when tests are in progress. If plunger maintenance is started while tests are in progress and a module where plunger maintenance is being performed (syringe rod lowered) becomes unavailable to complete the maintenance (raise syringe rod), the Cepheid OS software must be restarted after tests complete.

Note Perform the bleach wipe-down three separate times on the interior surfaces of the cartridge bay, allowing the bleach to remain on the surfaces for two minutes after each wipe. After the final two minutes, remove the bleach residue by thoroughly wiping the cartridge bay and plunger rod with ethanol.

Note Do not use 70% isopropyl alcohol for cleaning the cartridge bay and plunger rod. Isopropyl alcohol can degrade polycarbonate plastics.

The materials required for this procedure are:

- A final concentration of 1:10 dilution of household chlorine bleach (used within 1 day of preparation).
- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol).
- Lint-free wipes or paper towels
- Disposable gloves
- Eye protection

To clean the plunger rods and cartridge bays:

1. Put on disposable gloves, eye protection and other personal protective equipment (PPE) mandated by your institution's safety policies while performing this cleaning procedure. Wearing PPE prevents exposure to chemical and biologically hazardous materials.
2. Remove cartridges from the modules to be cleaned.
3. Touch **Tasks**.
4. Touch **Instrument Maintenance**.

5. On the Instrument screen, touch **Plunger Rod Maintenance**. The Plunger Rod Maintenance screen is displayed.

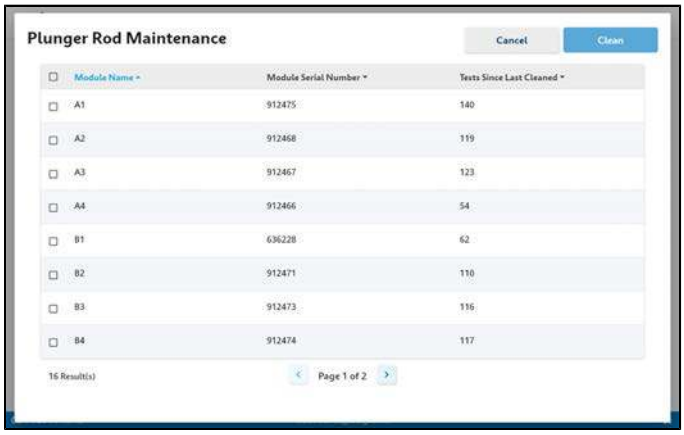


Figure 63. Instrument Screen

6. On the Plunger Rod Maintenance screen, touch the check box at the left of the module to be cleaned.

Note For efficient cleaning of the cartridge bays and plunger rods, choose **Select All**, which lowers all plunger rods, allowing the cleaning of all modules simultaneously.

7. After module selection is complete, touch **Clean**. A new screen appears with instructions to open the selected module door and remove any cartridges from the modules.

Note Keep hands clear of modules until the plunger rods are lowered.

8. After any cartridges have been removed, touch **Continue**. A new screen appears with instructions to clean the plunger rods and module bays.

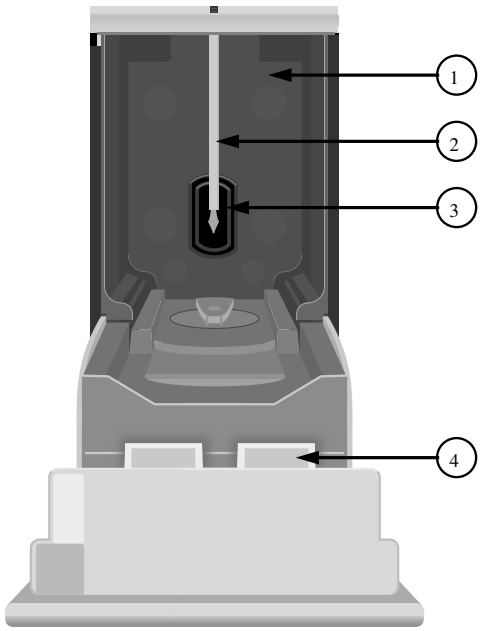


Figure 64. Plunger Rod Lowered into Cartridge Bay

1	Cartridge Bay
2	Plunger Rod (Lowered)
3	Slit for I-CORE Module
4	Instrument Module Door (Opened)

9. Clean the plunger rods and cartridge bays as follows:

a) Thoroughly moisten a lint-free wipe with a 1:10 solution of household chlorine bleach.

b) Vigorously wipe the plunger rod with the lint-free wipe. Wipe hard enough to remove the black debris that accumulates on the plunger rod.

Note Getting liquid inside the I-CORE module can damage the module. Do not touch the slit on the I-CORE module where the cartridge reaction tube is inserted.

Note Do not allow the bleach to remain on any surface for more than eight minutes.

c) Using the same lint-free wipe, wipe the walls, ceiling, corners and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door and discard the lint-free wipe.

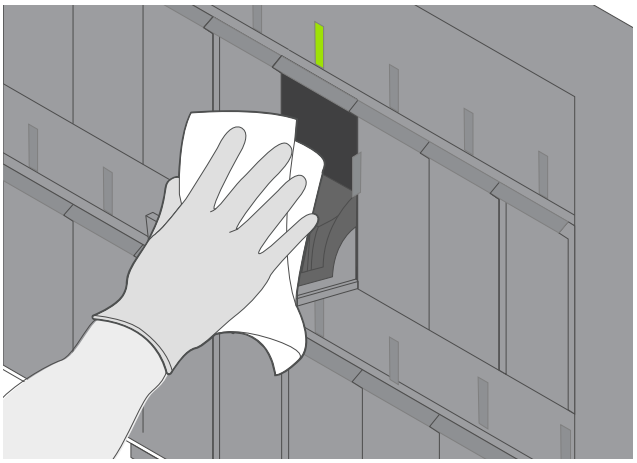


Figure 65. Wipe Module

d) Wait 2 minutes after wiping with the bleach solution.

e) Use a new lint-free wipe thoroughly moistened with the 1:10 bleach solution and wipe the plunger rod, walls, ceiling, corners and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door and discard the wipe.

f) Wait 2 minutes after wiping with the bleach solution.

g) Using another new lint-free wipe thoroughly moistened with the 1:10 bleach solution, wipe the plunger rod, walls, ceiling, corners and edges of the cartridge bay. Wipe the inside of the door and the top lip of the door and discard the lint-free wipe.

h) Wait 2 minutes after wiping with the bleach solution.

i) Thoroughly moisten a lint-free wipe with the 70% ethanol solution.

j) Use the lint-free wipe thoroughly moistened with the 70% ethanol solution to remove all residual bleach. Wipe the plunger rod, walls, ceiling, corners and

edges of the cartridge bay, then wipe the inside of the door and the top lip of the door and discard the lint-free wipe.

10. After the plunger rods and cartridge bays have been cleaned, return to the Plunger Rod Cleaning Instructions screen and touch **Complete**. The plunger rods move back up to the resting position.
11. Manually close the instrument module doors.
12. After the plunger rods complete their repositioning, the plunger rod cleaning complete advisory screen appears. Touch **OK** to acknowledge.
13. The Instrument screen appears. Touch **Modules** to return to the Modules screen.

11.5.2 Clean the System and Touchscreen Surfaces

Before cleaning the instrument and touchscreen surfaces, read Guidelines for Cleaning and Disinfecting.

The materials required for this procedure are:

- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol).
- A final concentration of 1:10 dilution of household chlorine bleach (used within 1 day of preparation).
- Lint-free wipes
- Disposable gloves
- Eye protection

Note Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.

Note The following disinfectant wipes and sprays may be used: Sani-cloth® AF3 Germicidal Disposable Wipes, Sani-cloth Plus® Germicidal Disposable Wipes, Clinell Universal Spray, Surfa'SAFE Premium spray, and WIP 'ANIOS EXCEL wipes.

Biological Risks **BIOLOGICAL RISKS: Use the bleach solution only in the event of a spill. Wipe down the affected surface(s) with bleach three separate times. Leave the bleach on the instrument and touchscreen surfaces for two minutes each time before wiping the surfaces with ethanol to remove the bleach residue.**

1. Put on disposable gloves, eye protection and other personal protective equipment (PPE) mandated by your institution's safety policies while performing this cleaning procedure. Wearing PPE prevents exposure to chemical and biologically hazardous materials.
2. Moisten the lint-free wipe with cleaning solution.

Note Do not spray liquids directly on the equipment.

3. Clean the instrument and touchscreen surfaces quarterly (every three months) with ethanol. All outside surfaces of the instrument and touchscreen housing should be cleaned including the top, sides, and outside doors of the module.

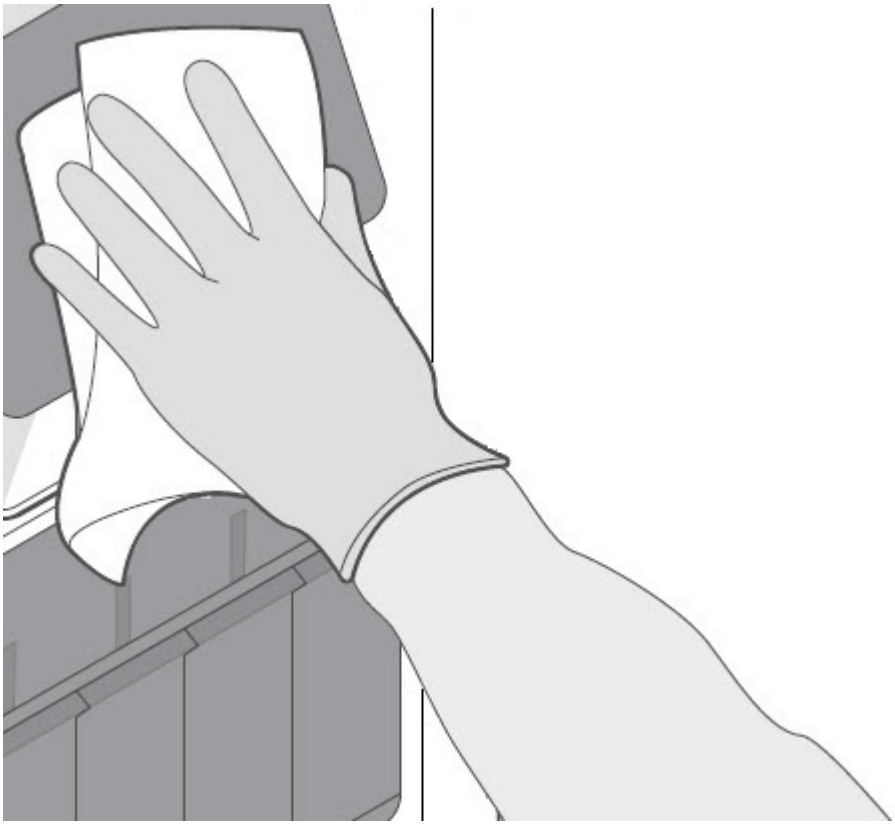


Figure 66. Wipe Screen

Biological Risks

BIOLOGICAL RISKS: Wear disposable gloves, eye protection and other personal protective equipment (PPE) mandated by your institution's safety policies while performing this cleaning procedure. Wearing PPE prevents exposure to chemical and biologically hazardous materials.

11.5.3 Replace the Instrument Fan Filters

Replace the fan filter quarterly, or more frequently if necessary. The fan filter is located on the back of the instrument. The materials needed for the procedure are as follows:

- GeneXpert II Replacement Fan Filter Part Number: 001-1271
- GeneXpert IV and XVI Replacement Fan Filter Part Number: 001-1537
- Disposable gloves

Note

The instrument and touchscreen must be powered down prior to performing the fan filter replacement described below.

1. Make sure all tests have finished.
2. Turn off the GeneXpert Instrument and the touchscreen, following the instructions in Shut Down the System.
3. Reposition the instrument so the fan filter can be easily accessed.
4. Gently take the fan filter guard off by unsnapping the guard from the fan housing and set it aside for the remainder of the procedure for filter removal.

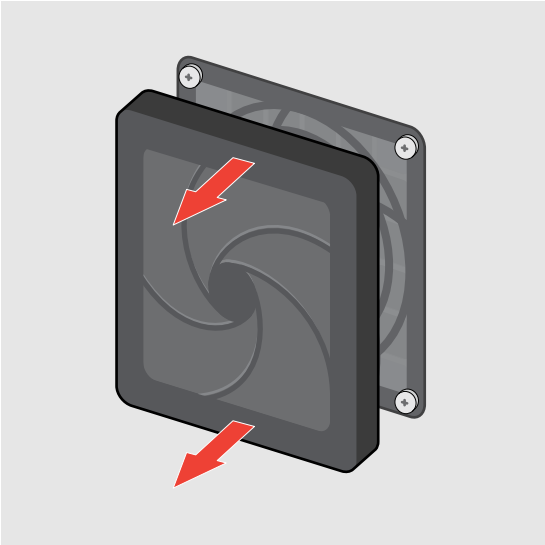


Figure 67. Fan Filter Guard Removal

5. Remove old filter.

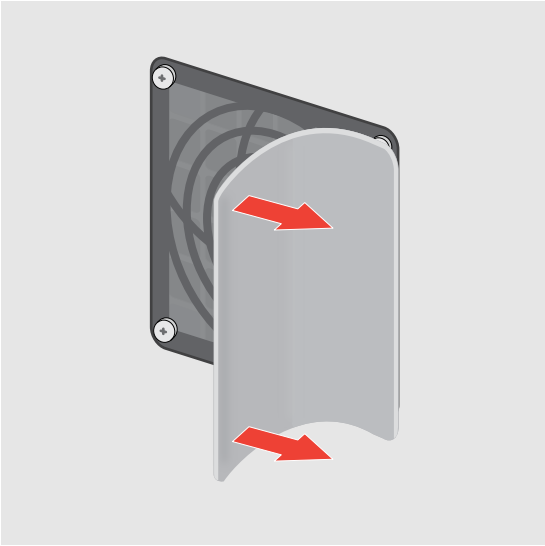


Figure 68. Old Foam Filter Removal

6. Insert new filter into the fan filter guard.

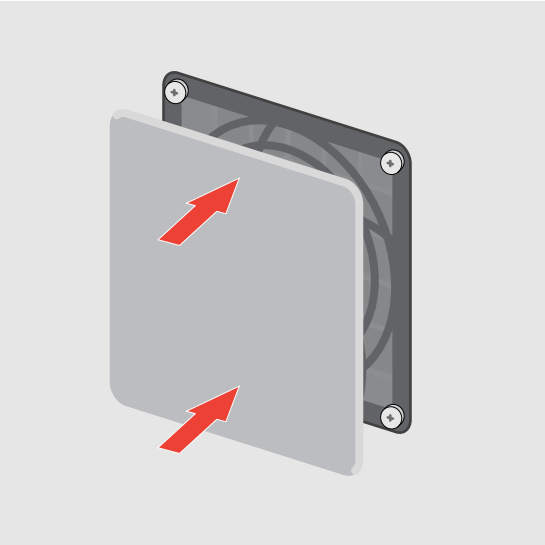


Figure 69. New Foam Filter Replacement

7. Position the fan filter guard and filter into place as a unit. Press the sides of the guard firmly onto the fan housing until the grip snaps securely onto the fan. Press the bottom of the guard until the grip snaps securely onto the fan.

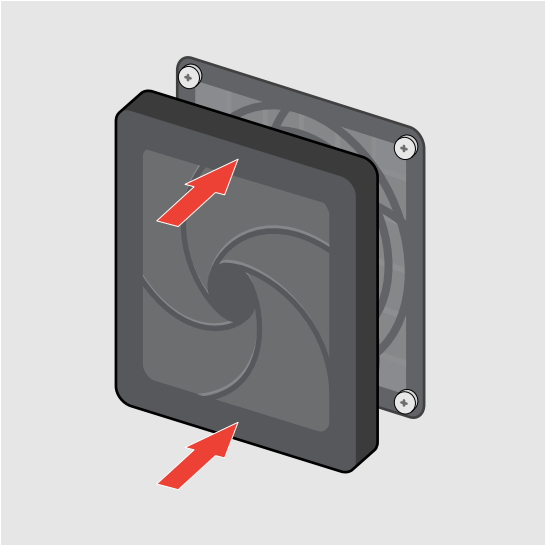


Figure 70. Fan Filter Guard Replacement

8. Press the bottom guard of the filter into place.
9. In the maintenance log, fill in the date of the fan filter replacement and keep it for your records.

11.6 Yearly Instrument Maintenance

Calibration of the instrument is not required during the initial system startup. Cepheid performs all of the necessary calibrations before the system is shipped. However, Cepheid recommends that the system be checked for proper calibration on an annual basis from the point of initial use. Based upon the usage and care of each system, calibration checks

may be recommended more frequently. The system is designed to measure module performance with the internal assay controls. In the event of a module replacement, the replacement module provided will have been calibrated prior to shipment.

A GeneXpert operator with Administrator user permissions or Cepheid Field Service Engineer can perform Xpert Check for annual maintenance. Contact Cepheid Technical Support for information about calibration checks. See the Technical Assistance section in the Preface for contact information.

11.7 As Necessary Maintenance

11.7.1 Clean the I-CORE® Module

Perform this I-CORE module cleaning procedure, as necessary. If you operate the system in an area with high pollution, dust or smoke, you will need to clean more frequently. This procedure describes the method for removing dust and tube debris from the surface of rod lenses of the excite and detect blocks for GeneXpert modules. See Xpert Check IFU for more detail.

Materials Required or Recommended for Cleaning:

- GX Cleaning Kit (700-6519S)
- Disposable gloves

Estimated Cleaning Time: 30 Seconds per module.

11.7.2 Generate the System Log Report

The System Log report can be used to provide incidents of instrument module self-tests and errors to Cepheid when a module failure has been encountered. See Generate a System Log for more information.

11.7.3 Back Up the Database

You should back up the entire database periodically and store the backup on a different computer or on a different storage medium. If the computer fails, you can restore the entire database using the backup copy.

Note You cannot back up the database while a test is running.

To back up the database:

1. Touch **Tasks** > **Database Maintenance** > **Backup Database**.
2. Select the folder in which you want to store the backup file, type a name for the backup file (or use the default file name), and then touch **Save**.
   The backup process creates a .zip file in the location you specified.
3. A system backup success message appears. Touch **OK**.

11.7.4 Clean Up Spills

Clean affected exterior instrument and touchscreen surfaces in the event of a spill.

To clean the affected instrument and touchscreen surfaces:

Note

If it is suspected that a spill has affected the interior of the instrument, do not remove any of the exterior instrument covers. Instead, shut down the instrument and contact Cepheid Technical Support for assistance.

1. Thoroughly moisten a lint-free wipe or paper towel with the 1:10 bleach solution.
2. Wipe affected surfaces on the instrument and touchscreen. Change wipes or paper towels frequently while wiping.
3. Allow the bleach solution to remain on the surfaces at least two minutes but no longer than eight minutes.
4. Repeat Step 1 through Step 3 two more times for a total of three times.
5. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.
6. Wipe affected surfaces on the instrument and touchscreen. Change wipes or paper towels frequently while wiping.
7. Discard used wipes or paper towels according to your standard laboratory procedure.

11.7.5 Clean the Lens

1. Select the module to be cleaned and manually open the door of the module.
2. If necessary, remove the cartridge from the module.

Biological Risks

BIOLOGICAL RISKS: Remove the cartridges from the GeneXpert instrument modules prior to cleaning. Failure to remove a cartridge could result in personnel being exposed to biological hazards and/or liquid biological materials spilling into the instrument and causing damage to the instrument.

3. Locate the brush provided in the GX Cleaning kit.

Figure 71. Lens Cleaning Brush (300-8330)

4. Wearing disposable gloves, insert the brush into the I-CORE module slit in a tilted manner up to the shank insertion shoulder.

Figure 72. Inserting the Cleaning Brush into the I-CORE Module Slit

5. Insert the brush into the I-CORE module slit completely up to the plastic shank (shoulder) of the brush. Hold the brush firmly in the I-CORE module slit, and perform cleaning of the rod lenses as described below. The entire cleaning process should take approximately 30 seconds per module.
   a) Begin by brushing from the top of the I-CORE module slit to the bottom, making sure to apply a uniform pressure when brushing from the top to the bottom of the I-CORE module slit. This will ensure that most of the tube debris and dust is brushed off from the surface of the lenses.
   b) Rotate the brush from left to right and back again, approximately 180°.
   c) Brush once more from the top of the I-CORE module slit to the bottom.
   d) Rotate the brush again from left to right and back again, approximately 180°.
   e) Finally, brush again from the top of the I-CORE module slit to the bottom.
6. When lens cleaning is complete, remove and discard the used brush and gloves as hazardous waste.

11.7.6 Use Module Reporters

Cepheid Technical Support may ask you to use the Module Reporters tool when investigating the source of possible module-related problems. The Module Reporters tool is also used to check the last date of calibration for the modules. It provides calibration information and other data.

To view the Module Reporters of a particular module:

1. Touch **Tasks** > **Instrument Maintenance**.
2. In the instrument row, touch blue arrow ❯ to access the instrument modules.
3. Touch **Maintenance** for the module desired. The Module Maintenance screen with Module Reporters appears.
4. The Module Reporter names are shown in the far-left column.

Figure 73. Module Maintenance Screen, showing Module Reporters

5. Return to the Instrument Maintenance screen to select and view a different module.

11.7.7 Perform a Manual Self-Test

Note No tests can be running in the system when performing a manual self-test.

The system automatically performs a self-test during startup. However, a self-test can be manually initiated on any of the modules to reset and check for hardware failure problems.

To start the self-test:

1. Remove cartridges from the modules to be checked.
2. Touch **Tasks** > **Instrument Maintenance**.
3. In the instrument row, touch blue arrow ❯ to access the instrument modules.
4. Touch **Maintenance** for the module to be tested.
5. Touch **Start Self Test**. The Module Maintenance screen appears.
6. Touch **OK** on the Self-Test Confirmation screen.

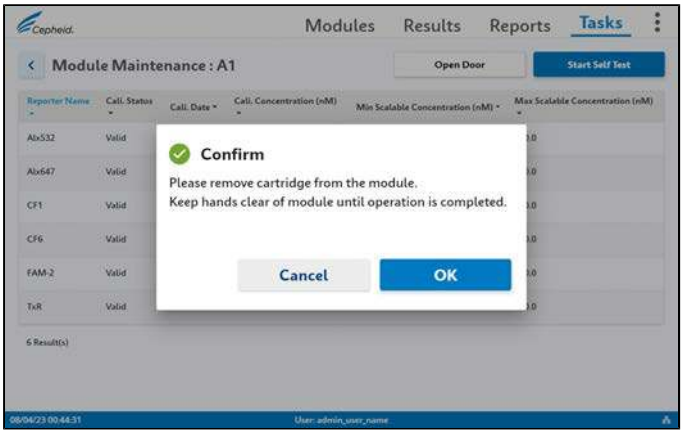


Figure 74. Self-Test Confirmation Screen

7. On the Test Complete screen, touch **OK**.

8. When the self-test finishes, the software changes the progress to Available, indicating the self-test passed. If a message appears indicating the self-test failed, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for the contact information.

11.7.8 Disable Modules from Testing

Modules may be excluded from testing, if desired, by following the instructions in this section. Modules that are excluded are listed as Disabled, and are not used by the system to run tests.

To exclude modules from a test:

1. Touch **Tasks** > **Instrument Maintenance.**
2. Touch the ❯ to see module information.
3. In the Active column, drag the slider to the left to disable a module from running tests.

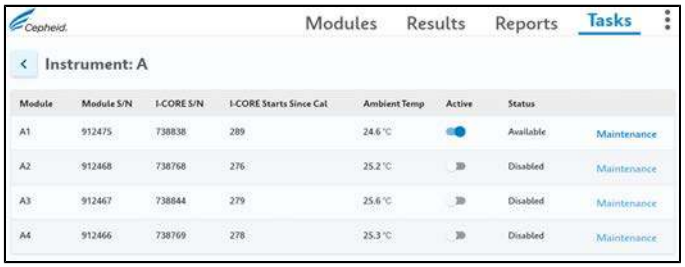


Figure 75. Included Column on Instrument Screen

11.7.9 Replace Touchscreen and Instrument Parts

Note Do not attempt to replace the power cord or Ethernet cable using non-approved parts. Using incompatible parts can damage the instrument, cause performance problems or cause loss of data.

You can replace the following GeneXpert system with touchscreen parts:

- Ethernet Cable, 6 feet (touchscreen to GeneXpert IV Instrument) (P/N 100-6091)
- Power Cord, 72 Inch (for GeneXpert IV Instrument) (P/N 100-1375). Check with Technical Support to confirm P/N for cord for your region.
- Power Supply Adapter, external (P/N 100-7125)
- Wi-Fi Adapter (P/N 800-0412)
- External DVDRW (P/N 800-0487)
- Fuse (P/N 100-5986)
- Pad lock (P/N 200-9165)
- Ferrite bead (P/N 100-7122)

You can obtain the power cords and Ethernet cables from Cepheid. See the Technical Support section in the Preface for the contact information.

11.7.10 Repair the Touchscreen or GeneXpert Instrument

Warning

ELECTRICAL HAZARD: Do not attempt to open or remove the touchscreen or GeneXpert Instrument covers. Doing so can expose you to electrical hazards and cause injuries or death.

Warning

ELECTRICAL HAZARD: Do not attempt to open the touchscreen or GeneXpert Instrument covers. Do not attempt to modify or repair the system. Improper repairs and incorrect part replacements can cause injury, damage the instrument, and void your warranty.

To protect your warranty and for proper operation, the system should be serviced only by an authorized Cepheid representative. If the system is not working correctly, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for the contact information. When you call Cepheid Technical Support, be prepared to supply the serial numbers of your system. You can find the serial number labels on the back side of the touchscreen and instrument.

12 Troubleshoot the System

This section lists the possible hardware problems you might encounter. To contact Cepheid Technical Support, see the Technical Assistance section in the Preface for the contact information.

12.1 User Lockout Problems

There may be an occasion when all users on site cannot log onto the system and are locked out. This can be the result of all available users forgetting their passwords, or a software malfunction. Whatever the reason, there is a "recovery user" option available as a remedy, by contacting Cepheid Technical Support. See the Technical Assistance section in the Preface for the contact information.

12.2 Hardware or Operation Problems

The table below lists the possible problems you might encounter. To contact Cepheid Technical Support, see the Technical Support topic in the Introduction chapter.

Table 1. Hardware or Operation Problems

Problem	Possible Cause	Solution
Windows or Cepheid OS software freezes.	Windows automatic update or large cache.	Press Blue button to start normal Windows shut down. This is the best way to prevent data loss in case of a system lock up.
Lose connection to network folders	User logs out of Windows.	Upon log in, touch network error message and touch (edit icon) and re-enter username and password for the Windows network drives.
Screen does not automatically light up after system power on.	Touchscreen is powered off.	Press power button on the back of the touchscreen to power on the screen.
The system does not start.	The instrument is not connected to the power outlet.	Check the instrument power connections.

Problem	Possible Cause	Solution
The cartridge is stuck inside the instrument module.	Module mechanical failure.	To remove the cartridge: **1.** In the Cepheid OS software, touch **Tasks** > **Instrument Maintenance**. **2.** Touch the instrument letter. **3.** On the Instrument screen, touch the row of the module with the stuck cartridge and touch**Maintenance**. **4.** Touch **Open Door**. **5.** Remove cartridge. If the door does not open, cycle through the instrument power and repeat the steps above.
Module not detected.	Network cable not connected or incorrect cable installed. Software launched before instrument turned on. The IP address is not assigned correctly.	Connect network cable (Cepheid P/N 700-0555). Exit software and relaunch with instrument powered on. Change IP Address Setting by performing the steps provided in Set the IP Address for Instrument Communication.
The instrument module red light is flashing.	Module mechanical failure.	Confirm no cartridge is in the module. Perform a self-test manually (see Perform a Manual Self Test). If the error recurs, contact Cepheid Technical Support.
Test report is not printed at the end of run.	Printer off line. Printer out of paper and/or toner.	Check: ● Printer online ● Paper present ● Toner OK
Unable to create a test.	Modules not available. No assay selected. Module not calibrated for reporters used in test. The ambient temperature of the module is above 55°C.	Check that assay is selected. Calibrate with assay dyes. Check that the modules are not disabled. Check module temperature in Maintenance screen. If your room is in the recommended temperature range and the module is above 55°C, contact Cepheid Technical Support.
Unable to start test.	Reporters out of calibration.	Check module reporters in maintenance window: ● Reporter for assay are present. ● Calibration status is valid.

12.3 Error Messages

Run-Time Errors

The table below lists errors that might appear during a test that is not aborted. Although the system was able to finish the test and save the results, some non-critical errors occurred and require attention. To contact Cepheid Technical Support, see the Technical Support section in the Introduction for the contact information.

Table 2. Errors that Occurred During a Test that is Not Aborted

Error Code	Error Message	Possible Causes	Solution
1001	The actual temperature n °C has drifted too far away from the setpoint of m °C. (n and m are temperature values that the software displays. The values can vary.)	A heater component or a related component failed. Environment temperature is too warm. Fan Failure.	Report the temperature value in the error message to Cepheid Technical Support. Check room temperature. Check fans are functional and fan filters are clean.
1002	The temperature difference of n °C exceeds the limit of m °C. The temperatures for heaters A and Bare p °C and q °C. (n, m, p, and q are temperature values that the software displays. The values can vary.)	The difference between the temperatures of the two thermistors has exceeded the acceptable difference of 5°C.	Call Cepheid Technical Support.
1004	The internal instrument temperature n °C was out of range of m1 °C to m2 °C (n, m1, and m2 are temperature values that the software displays. The values can vary.)	One or more of the following might have caused the error: • The ambient temperature is not within the required range. • The environmental conditions do not meet the requirements. • The ambient temperature sensor failed. • Broken or dirty fans	Check the following: • Verify the instrument has at least 5 cm (2 in) of clearance on each side. • Verify the laboratory environmental conditions meet the requirements specified in Operational Environmental Parameters. • Verify fans are moving. • Clean fan filters. If the instrument meets all the requirements and the error persists,call Cepheid Technical Support.
1005	Optic signal of n from detector #musing LED #p exceeded the limit of q. (n, m, p, and q are values that the software displays. The values can vary.)	One or more of the following might have caused the error: • The signal from the reporter is too high. • The module door is not closed properly. • A hardware component failed.	Try one or more of the following solutions: • Use a different cartridge. • Make sure the module door is closed completely. If the error recurs, call Cepheid Technical Support and provide the information presented in the error message.
1006	Detector #n dark signal of m exceeded the limit of p. (n, m, and p are values that the software displays. The values can vary.)	The detector or the electronics failed.	Call Cepheid Technical Support and provide the information presented in the error message.

Error Code	Error Message	Possible Causes	Solution
1007	The n V power supply was detected to be m V. (n and m are voltage values that the software displays. The values can vary.)	The power supply voltage is out of range.	Record the information in the error message. If the error recurs in multiple runs, call Cepheid Technical Support.
1017	The measured temperature of the optical system was n °C which was not within the acceptable range ofm1 °C to m2 °C. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	One or more of the following might have caused the error: • The optical block thermistor failed. • The ambient temperature is too high.	Rerun the test. If the error recurs, call Cepheid Technical Support.
1018	A valve positioning error of n count(s) was detected at the end of the run. (n is a value that the software displays. The value can vary.)	A valve component failed. Cartridge integrity compromised.	Rerun the test. If the error recurs, call Cepheid Technical Support
1096	Proceeded to Next Step #1: n, m,p, q (n, m, p, q values are assay specific)	Test specific cause. This code is reported as maximum pressure was reached in the assay. The high pressure leads the program to move to the next step. This will not influence the performance of the test or the test result.	For more information on the code number (message) contact Cepheid Technical Support.
1097, 1098, 1099, 1100	Proceeded to Next Step #2: n, m,p, q (n, m, p, q values are assay specific)	Test specific cause.	For more information on the code number (message) contact Cepheid Technical Support.
1125	Possible Insufficient Volume Error:n, m, p, q (n, m, p, q values are assay specific)	Possible Insufficient Volume	Rerun the test. If the error recurs, call Cepheid Technical Support.

Operation Terminated Errors

The table below lists errors that might appear when a test is aborted. To contact Cepheid Technical Support, see the Technical Support section in the Introduction chapter for the contact information.

Table 3. Errors that Might Appear When a Test is Aborted

Error Code	Error Message	Possible Causes	Solution

Error Code	Error Message	Possible Causes	Solution
2003	Module is already running a test with test ID n while performing command ID m. (m and n are ID numbers that the software displays. The number can vary.)	Software communication failed.	Call Cepheid Technical Support.
2005	Motion of the syringe drive was not detected. Detected motion started at position n ul and transferred m ul at valve position p with pressure q PSI. (n, m, p, and q are values that the software displays. The values can vary.)	One or more of the following items might have caused the error: ● A syringe stall was detected (module issue). ● Cartridge issue (Note if there is a time-sequence'pattern' for the error). ● Cartridge lid was not opened.	Try one or more of the following solutions: ● Use a new cartridge. ● Restart the system. ● Check for crystallization in the module and if required clean module per Operation Manual instructions. Monitor for one week after cleaning. ● If cartridge suspected, then note the Assay Name, Cartridge Serial Number, and Cartridge Lot Number. If the error persists, call Cepheid Technical Support.
2006	Valve motion was not detected. Valve started at position n. Last detected at position m. (n and m are values that the software displays. The values can vary.)	The valve drive failed. Improper interface between cartridge and valve body.	Try one or more of the following solutions: ● Open the module and reposition the cartridge. ● Use a new cartridge. ● Restart the system. If the error persists, call Cepheid Technical Support.
2008	Syringe pressure reading of f.f PSI exceeds the protocol limit of f.f PSI,command # [The command line number in the ADF] (f.f is a value that the software displays. The value can vary.)	One or more of the following items might have caused the error: ● The filter is clogged by debris in sample. ● Pressure sensor failed.	Try one or more of the following solutions: ● Retest sample per IFU using a new cartridge. ● Run a new cartridge with matrix only [no patient sample added](e.g., add to cartridge only'Sample Reagent' or 'SamplesTransport Medium' - if applicable). If the error persists, call Cepheid Technical Support. If possible, note the Test Name, Cartridge Lot Number, Sample Type, Cartridge Serial Number and Collection information for troubleshooting.
2009	Syringe pressure reading of f.f PSI is below the protocol limit of f.f PSI,command # [The command line number in the ADF] (f.f is a value that the software displays. The value can vary.)	The filter is clogged.	Try one or more of the following solutions: ● Use a new cartridge. ● Run a cartridge containing buffer only. If the error persists, call Cepheid Technical Support.

Error Code	Error Message	Possible Causes	Solution
2012	An inaccurate valve move to position n was detected. The valve was detected to stop at position m. (n and m are values that the software displays. The values can vary.)	A component of the valve drive failed.	Use a new cartridge. If the error persists, call Cepheid Technical Support.
2014	The digital temperature reading of n for Thermistor A/Thermistor B/Ambient Thermistor/Optic Thermistor was not within the acceptable range of m1 tom2. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	The heater A/heater B/ module's optical block thermistor failed.	Check the following: ● The ambient temperature. ● The internal temperature of the instrument. ● Two inches of clearance. ● If the ambient and internal temperatures are within the acceptable range and you continue to see the error message, call Cepheid Technical Support.
2016	The system was unable to find the valve home position.	The valve position sensor failed.	Perform self-test and try again with another cartridge. If the error persists, call Cepheid Technical Support.
2017	The door latch sensor is still on after a cartridge eject operation.	One or more of the following might have caused the error: ● A syringe component failed. ● The door or a related component failed. ● The door sensor failed.	To remove the cartridge: ● On the Maintenance menu, touch Open Module Door ● Select the module. ● Touch Open Door to open the module door. ● After you remove the cartridge, restart the system.
2022	Failed to get to desired temperature of n°C. The temperature reached m °C. (n and m are temperature values that the software displays. The values can vary.)	Environmental temperature is above or below the acceptable range.	Check the following: ● The ambient temperature ● The internal temperature of the instrument ● Two inches of clearance If the ambient and internal temperatures are within the acceptable range and you continue to see the error message, call Cepheid Technical Support.
2024	An ultrasonic horn failure occurred with n% duty cycle, m Hz and actual p%amplitude. Set point amplitude was q%. (n, m, p, and q are values that the software displays. The values can vary.)	The ultrasonic horn failed.	Use a new cartridge. If the problem persists, call Cepheid Technical Support.
2026, 2032	The ultrasonic horn current was detected to be out of the normal range.	The ultrasonic horn failed.	Call Cepheid Technical Support.

Error Code	Error Message	Possible Causes	Solution
2034	The optical signal from Detector n/LEDn did not reach the expected value. Expected value=m, Actual value=p. (n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: ● The LED is not working. ● The detector is not working. ● The associated circuit is experiencing problems.	Restart the test. If the error recurs, restart the system. If the error persists, call Cepheid Technical Support.
2035	An ultrasonic failure occurred with n%duty cycle, m Hz and actual p%amplitude. Set point amplitude was q%. (n, m, p, and q are values that the software displays. The values can vary.)	One or more of the following might have caused the error: ● Cartridge issue ● Dirt on the horn surface ● The ultrasonic horn failed.	Restart the test. If the error recurs, restart the system. If the error persists, call Cepheid Technical Support.
2096, 2097	Assay-Specific Termination Error #1: n,m, p, q (n, m, p, q values are assay specific)	Assay specific cause. Sample volume related. Refer to Package Insert for detail of error. In some cases the issue is: ● Cartridge related ● Pressure sensor failure	Rerun the test. Ensure correct sample volume added to new cartridge. Call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name,Cartridge Lot, Cartridge Serial Number and Module Serial Number(s) for the error(s).
2098, 2099, 2100	Assay-Specific Termination Error #3: n,m, p, q (n, m, p, q values are assay specific)	Assay specific cause.	Rerun the test. If the error recurs, call Cepheid Technical Support.
2125	Termination Error – Insufficient Volume:n, m, p, q (n, m, p, q values are assay specific)	Specified as a “Termination Error - Insufficient Volume” in the command sequence. ● Sample volume related ● Pressure sensor failure	Ensure correct volume added to cartridge. Retest sample per IFU using new cartridge. Call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name,Cartridge Lot, Cartridge Serial Number and Module Serial Number(s) for the error(s).
2126	Module was reset.	Intermittent power supply failure. Power supply cable or connector failure.	Restart the system. If problem persists, call Cepheid Technical Support.

Cartridge Loading Errors

The table below lists errors that might appear during a cartridge loading process. The cartridge loading error messages appear in the Check Status window. Because the software performs some self-test procedures during the loading process, some of the error messages that appear during loading process are identical to the self test error messages. To contact Cepheid Technical Support, see the Technical Support section in the Introduction for the contact information.

Table 4. Errors that Might Appear During the Cartridge Loading Process

Error Code	Error Message	Possible Causes	Solution
2011	Unable to initialize pressure sensor to n. Sensor value of m was obtained. (n and m are pressure values that the software displays. The values can vary.)	The force sensor failed.	Restart the test. If the error recurs, restart the system. If the error persists, call Cepheid Technical Support.
2018	Attempt to load a cartridge while the door is still closed.	One of the following might have caused the error: ● The valve motor failed. ● A syringe component failed. ● The door-latch sensor failed.	Restart the system. Open door. If the error recurs, call Cepheid Technical Support.
2025	One of the following messages is displayed: The system failed to find the plunger home position. Plunger moved down looking for ADC = n. ADC value m was detected and stall occurred. The system failed to find the plunger home position. Upward move with minimum force value of n was completed without reaching force value less than m. (n and m are values that the software displays. The values can vary.)	The plunger components or the force sensor failed.	To determine if the error is caused by a failed instrument module or a bad cartridge: ● Restart the test using the same cartridge and load it into the same instrument module. ● If the error recurs, restart the test using the same cartridge but load it into a different instrument module. If the test progresses successfully in the new module, the previous module requires repair. Call Cepheid Technical Support. ● If the error occurs in the second instrument module, restart the test using a new cartridge and load it into the original module. If the test progresses successfully, the previous cartridge was bad. If the error persists, call Cepheid Technical Support.
2037	The cartridge integrity test failed at valve position <n>. The pressure change of f.ff PSI did not exceed the requirement of f.f PSI. The pressure increased from f.f PSI to f.f PSI during the test.	One of the following may have caused the error: ● The reaction tube is missing from the cartridge. ● The cartridge has been damaged. ● The cartridge integrity test failed. ● Pressure sensor failure.	1. Remove the cartridge and inspect it for damage. 2. Rerun the test using a new cartridge. Call Cepheid Technical Support. If possible, note the Assay Name,Cartridge Lot Number, Cartridge Serial Number and Module Serial Number(s)for the error(s).

Self-Test Errors

The table below lists errors that might appear during the self-test process. The self-test error messages appear in the Check Status window. To contact Cepheid Technical Support, see the Technical Support section in the Introduction for the contact information.

Table 5. Error Messages that Might Appear During the Self-Test Process

Error Code	Error Message	Possible Causes	Solution
4001	A problem with the memory of the I-CORE was detected.	A hardware component failed.	Restart the system. Open door, select module, and update EEPROM. If the error persists, call Cepheid Technical Support.
4002	A problem with the main memory of the GeneXpert module was detected.	A hardware component failed.	Restart the system. If the error persists, call Cepheid Technical Support.
4003	A problem of the ultrasonic horn system was detected.	The ultrasonic drive circuitry failed.	Restart the system. If the error persists, call Cepheid Technical Support.
4004	Valve motion was not detected.	A component of the valve drive failed.	Remove any cartridges from the module, and then restart the system. Perform a self-test. See Perform a Manual Self Test. If the error recurs, call Cepheid Technical Support.
4006	Syringe drive movement was not detected.	The stall sensor failed during cartridge loading because: • The cartridge was not positioned correctly. • A component of the syringe drive failed.	Restart the system. If the error persists, call Cepheid Technical Support.
4008	The n-V power supply was detected to be m V. (n and m are voltage values that the software displays. The values can vary.)	Power supply failure.	Restart the system. If the error persists, call Cepheid Technical Support.
4009	Heater A operation was not verified. Measured temperature changed from n °C to m °C. (n and m are temperature values that the software displays. The values can vary.)	A heater A component failed.	Perform a self-test. See Perform a Manual Self Test. If the error recurs, call Cepheid Technical Support.
4010	Cooling fan operation was not verified. Measured temperature of n°C exceeded the limit of m °C. (n and m are temperature values that the software displays. The values can vary.)	A cooling component failed.	Make sure that the air vents are not blocked. The instrument must have at least 5 cm (2 in) of clearance on each side. Perform a self-test. See Perform a Manual Self Test. If the error recurs, call Cepheid Technical Support.

Error Code	Error Message	Possible Causes	Solution
4011	The reported dark value of n for detector m was too high. (n and m are values that the software displays. The values can vary.	The module door was not closed completely, or a hardware component failed.	Make sure the module door is closed completely. If the error recurs, record the value in the error message, and then call Cepheid Technical Support.
4012	Heater B operation was not verified. Measured temperature changed from n °C to m °C. (n and m are temperature values that the software displays. The value can vary.)	A heater B component failed.	Perform a self-test. See Perform a Manual Self Test. If the error recurs, call Cepheid Technical Support.
4013	An inaccurate valve move was detected. The valve was programmed to stop at position n but stopped at position m. (n and m are position values that the software displays. The values can vary.)	A valve error has occurred.	If a cartridge is found in the module, remove it. Perform a self-test. See Perform a Manual Self Test. If the error recurs, call Cepheid Technical Support.
4014	The optical signal from Detector n/LED n did not reach the expected value. Expected value = m, Actual value = p. (n, m, and p are optical signal values that the software displays. The values can vary.)	An optics component failed.	Call Cepheid Technical Support.
4015	The measured temperature of the optical system is n which was not within the acceptable range of m1 tom2. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	An optical block thermistor failed.	Restart the system. If the error recurs, call Cepheid Technical Support.
4016	GX module program corruption. Unable to continue the test	• Possible RAM failure • Possible EMI • Firmware defect	Call Cepheid Technical Support.
4017	The digital temperature reading of n for Thermistor A/Thermistor B/Ambient Thermistor/Optic Thermistor was not within the acceptable range of m1 to m2. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	The heater A/heater B/ module's/optical block thermistor failed.	Restart the system. If the error recurs, call Cepheid Technical Support.

Error Code	Error Message	Possible Causes	Solution
4019	The optical ramp test for LED n resulted in non-monotonic results at DAC setting of nnn. The reference detector readings were nnn and nnn.	LED is broken.	Restart the system. If the error recurs, call Cepheid Technical Support.

Post-Run Analysis Errors

The table below lists errors that might appear during the post-run analysis (data reduction) process. To contact Cepheid Technical Support, see the Technical Support section in the Introduction for the contact information.

Table 6. Data Reduction Errors

Error Code	Error Message	Possible Causes	Solution
5001	Unable to verify positive analyte [x]using curve fitting.* (x is the analyte name) * Note: With Error '5001' the 'Test Result' lists "Invalid" and not the word "Error".	• A component of the cartridge is defective, causing the positive growth curve to have an abnormal shape. • Too much sample was placed in the cartridge.	Rerun the test using a new cartridge and the correct amount of sample. If the error recurs, call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name,Cartridge Lot Number, Cartridge Serial Number and Module Serial Number(s) for the error(s).
5002, 5003, 5004, 5005	Failed to verify valid amplification curve for reporter. The shape factor of n was below the minimum of m.* (n and m are values that the software displays. The values can vary.) * Note: With Error the 'Test Result' lists "Invalid" and not the word "Error".	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Rerun the test using a new cartridge. If the error recurs, call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name, Cartridge Lot Number, Cartridge Serial Number and Module Serial Number(s) for the error(s).
5006	X probe check failed. Probe check value of n for reading number m was above the maximum of p. (x is the analyte name, n, m, and pare values that the software displays. The values can vary.)	One or more of the following might have caused the error: • An incorrect amount of reagent was inserted into the cartridge. • The reagent is defective. • Fluid transfer failed. • Module related.	Check the following: • Reagents are added to the cartridge correctly. • Cartridges were stored correctly. Rerun the test using a new cartridge following the Package Insert. If the error recurs, call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name,Cartridge Lot Number, Cartridge Serial Number and Module Serial Number(s) for the error(s).

Error Code	Error Message	Possible Causes	Solution
5007	X probe check failed. Probe check value of n for reading number m was below the minimum of p. (x is the analyte name, n, m, and pare values that the software displays. The values can vary.)	One or more of the following might have caused the error: ● An incorrect amount of reagent was inserted into the cartridge. ● The reagent is defective. ● Fluid transfer failed. ● The sample was processed incorrectly in the cartridge. ● Module related (possible dirty optics or calibration issue). ● Sample specific.	Check the following: ● Reagents are added to the cartridge correctly. ● Cartridges were stored correctly. Rerun the test using a new cartridge following the IFU. ● If the error persistently recurs: Clean module using optical brush (GX Cleaning Kit (700-6519)). See Guidelines for Cleaning and Disinfecting. ● If the error recurs, call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name, Cartridge Lot Number,Cartridge Serial Number and Module Serial Number(s) for the error(s).
5008	X probe check failed. Probe check delta value n between reading number m and reading number p was below the minimum of q. (x is the analyte name, n, m, and pare values that the software displays. The values can vary.)	One or more of the following might have caused the error: ● An incorrect amount of reagent was inserted into the cartridge. ● The reagent is defective. ● Fluid transfer failed.	Check the following: ● Reagents are added to the cartridge correctly. ● Cartridges were stored correctly. ● Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5009	X probe check failed. Probe check delta value n between reading number m and reading number p was above the maximum of q. (x is the analyte name, n, m, and pare values that the software displays. The values can vary.)	One or more of the following might have caused the error: ● An incorrect amount of reagent was inserted into the cartridge. ● The reagent is defective. ● Fluid transfer failed.	Check the following: ● Reagents are added to the cartridge correctly. ● Cartridges were stored correctly. ● Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5010	Unable to verify positive analyte [x]using curve fitting. X readings were available, but the minimum number of readings required is y. (x is the analyte name; y is a value software displays)	A component of the cartridge is defective, causing the positive growth curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.

Error Code	Error Message	Possible Causes	Solution
5011	Signal loss detected in the amplification curve for analyte [x]. n decrease in signal with m % decrease at cycle p. (X is the analyte name; n, m, and pare values that the software displays. The values can vary.	Usually occurs when a fluorescent signal is so high that it bleeds into another channel, causing the second signal to go into negative curve. In addition, the error could be due to the following: ● Sample related ● Module related ● Cartridge related	Refer to IFU for specific re-test procedures. Rerun the test using a new cartridge following the IFU.If the error recurs, call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name, Cartridge Lot Number, Cartridge Serial Number and Module Serial Number(s) for the error(s).
5013	Quantitative value is too large to represent in application or database.	The base quantitative value or quantitative value is too large to display.	If the error recurs, call Cepheid Technical Support.
5014	Quantitative value is below the lower calculation limit.	The quantitative value is less than 0.01.	If the error recurs, call Cepheid Technical Support.
5015	Failed to verify valid background slope for analyte [analyte name].The absolute value of the slope of f.f was above the maximum of f.f.* * Note: With Error ‘5015’ the ‘Test Result’ lists “Invalid” and not the word “Error”.	High slope in optical background region.	Rerun the test using a new cartridge following the IFU. If the error recurs, call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name,Cartridge Lot Number, Cartridge Serial Number and Module Serial Number(s) for the error(s).
5016	Failed to verify valid background error for analyte [analyte name]. The RMS error of f.f was above the maximum of f.f.* * Note: With Error ‘5016’ the ‘Test Result’ lists “Invalid” and not the word “Error”.	High RMS error in background region.	Rerun the test using a new cartridge following the IFU. If the error recurs, call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name,Cartridge Lot Number, Cartridge Serial Number and Module Serial Number(s) for the error(s).
5017	X probe check failed. Probe check value of n for reading number m was below the valid level of p.	● Cartridge issue. ● An incorrect amount of reagent was inserted into the cartridge. ● The reagent is defective. ● Fluid transfer failed. ● The sample was processed incorrectly in the cartridge.	Rerun the test using a new cartridge following the IFU. If the error recurs, call Cepheid Technical Support. If possible, note the following information for troubleshooting: Assay Name,Cartridge Lot Number, Cartridge Serial Number and Module Serial Number(s) for the error(s).
5018, 5019	Failed to verify valid probe check ratio for analyte [analyte name]. Probe check 1 = m, probe check 2 =n, ratio = f.ff greater than maximum f.ff.	Cartridge issue.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.

Communication Loss/Recovery Errors

Note

If module communication loss occurs after a test has been ordered and assigned to a module, but before the cartridge is loaded and the door is latched, an error message will appear that says not to proceed with loading the cartridge and latching the door. If the message instructions are followed, the cartridge may be resubmitted to another module. However, if the cartridge is loaded and the door latched, no result will be given when the test completes, and the cartridge should not be reused.

The table below lists communication errors that might appear while the module is idle, before the module door is latched or when starting the test (test is aborted). To contact Cepheid Technical Support, see the Technical Support section in the Introduction for the contact information.

Table 7. Communication Loss/Recovery Errors

Error Code	Error Message	Possible Causes	Solution
2120	Module X lost communication while module was idle.	Loose or faulty Ethernet cable between the touchscreen unit and the GeneXpert instrument.	Verify the Ethernet cable is connected properly between the touchscreen unit and the GeneXpert instrument. If the error recurs, call Cepheid Technical Support and provide the information presented in the error message.
2121	Module X lost communication before module door was latched.	Loose or faulty Ethernet cable between the touchscreen unit and the GeneXpert instrument.	Verify the Ethernet cable is connected properly between the touchscreen unit and the GeneXpert instrument. If the error recurs, call Cepheid Technical Support and provide the information presented in the error message.
2122	Module X lost communication while starting test, test aborted.	Loose or faulty Ethernet cable between the touchscreen unit and the GeneXpert instrument.	Verify the Ethernet cable is connected properly between the touchscreen unit and the GeneXpert instrument. If the error recurs, call Cepheid Technical Support and provide the information presented in the error message.
2124	Module X communication restored.	Communication restored from loose or faulty Ethernet cable between the touchscreen unit and the GeneXpert instrument.	Not applicable.

12.4 Troubleshoot the LIS Interface

This section lists the possible system configuration problems you might encounter. To contact Cepheid Technical Support, see the Technical Assistance section in the Preface for the contact information.

Table 8. LIS/System Configuration Problems

Problem	Cause	Solutions

Problem	Cause	Solutions
Cannot edit test code for old versions of an assay. If the LIS Administrator updates the test code, it will only apply to the new version of the assay.	Upgrade of assay to new version.	Change the test code prior to upgrade of assay.
Upload of test results shows incorrect System Name.	Incorrect system name.	• LIS interface to check for incorrect instrument system name. • LIS Administrator to control process for defining system name.
User error in selecting the assay when defining test codes.	User error in selecting the assay.	LIS Administrator to configure correct test code.

12.5 Troubleshoot the POCT Interface

This section lists some possible system configuration problems you might encounter, but you may encounter issues not listed here. To contact Cepheid Technical Support, see the Technical Assistance section in the Preface for the contact information.

Note See Access Windows Event Logs for POCT Troubleshooting for information on how to access the POCT communication log, which can aid in POCT communication troubleshooting issues.

Note See Perform Troubleshooting Remotely for information on how to perform troubleshooting steps remotely.

Table 9. POCT System Configuration Issues

Issue	Possible Cause	Solutions

Issue	Possible Cause	Solutions
The touchscreen is dropping the connection.	The connection interval set up on the DM is connecting too quickly after previous communication, or The host connection was changed on the Host Communication screen, or The connection is routed over a different gateway, or The assigned port is being blocked on the network, or The assigned port is being blocked on the network, or	**1.** Verify that POCT01 Protocol is enabled in Host Connectivity Settings. **2.** Check the Ethernet cable. Are both ends of the cable connected correctly? **3.** Check to see if other devices (other than GeneXpert Instrument) in your lab are having intermittent connectivity issues. **4.** Contact your IT department to see if there is a network problem. **5.** Check Windows Defender for malware. **6.** Verify if the DM has assigned the port to another connection. **7.** Check if the DM driver was updated, which could change configuration and cause an out of sync condition. **8.** Check if the DM driver was updated, which could change configuration and cause an out of sync condition.
The touchscreen states that communication is failing on the Host Communication screen.	The device has not been added to the Data Manager, or Windows firewall is blocking the port, or The device is not physically connected to the wall Ethernet jack, or Host Communication settings are not correct on the touchscreen, or The serial number of the GeneXpert Instrument may have been entered in the DM incorrectly.	**1.** Examine the host communication screen settings to ensure they are correct. **2.** Verify that the GeneXpert Instrument is on the network. **3.** Look in the DM software to see if the device has been added. **4.** Look in the DM software to make sure the GeneXpert Instrument serial number is correct. **5.** Review the event viewer logs to see if an error message indicates if the device is not set up in the DM. **6.** Review the event viewer logs and see if an error message matches the serial number on the DM. **7.** Confirm that the network cable is connected securely from the GeneXpert System to the wall jack. **8.** Confirm (with your IT network engineer's assistance) that the network jack is enabled. **9.** Confirm (with your IT network engineer's assistance) that the port for the POC DM is not blocked.
Test results from the touchscreen are not being sent by the touchscreento the DM.	DM never sends a request observation message, or There is a computer Ethernet issue, or There is a network issue, or There are incorrect host communication settings.	**1.** Check the Ethernet connection of your touchscreen. **2.** Ensure the Host Communication settings on the touchscreen are correct. **3.** Ensure the Host Communication settings on the touchscreen are correct.
One or more GeneXpert instruments are not getting updated user lists.	The GeneXpert instrument(s) are in a DM group without an associated user list, or The instrument(s) are in a DM group without an associated user list, or	**1.** Check that the group the GeneXpert Instrument is assigned to on the DM is associated with a user list **2.** Check that the DM is configured to send user lists to the GeneXpert user group.

Issue	Possible Cause	Solutions
User validation settings for **Lockout**, **Warn** and **Allow** are not showing up in the touchscreen.	The DM is not sending the validation settings, or There is no connection between the DM and thetouchscreen , or The DM is sending invalid **User Validation** settings .	**1.** See troubleshooting steps for issue No. 1 above. **2.** Review the Windows event viewer **User Validation Setting** error messages.
The user list is not showing all the expected users on the touchscreen.	Unsupported or invalid character for the user information.	Review the event viewer logs. See if there is an error message regarding the operator list.
The touchscreen shows that a result was sent but it is not showing in the EMR.	The DM has possibly sent a false result receipt acknowledgment to thetouchscreen.	**1.** Review event viewer logs and confirm that the DM sent a result receipt acknowledgment to the touchscreen. **2.** User needs to contact DM's support to determine why there was a false result receipt acknowledgment.
Manual Sync is not updating.	The user tries to manually sync when there is another conversation in progress.	**1.** Wait several seconds and try to manually sync again. **2.** See troubleshooting steps for problem No.1 above.
A device setting that a user expects to send to the touchscreen is not updating.	The system does not support that specific device setting.	Review windows event error logs for an expected device setting that is not enabled.
Host is disconnected.	The POCT settings are invalid.	**1.** Check device settings on the Host Communication screen. **2.** Check the error logs for an error that gives an invalid POCT01 setting error, and the reason why. **3.** Use troubleshooting steps Nos. 1 and 2.
Manual Upload of test result is not transmitting to the DM.	The result may have already been uploaded.	**1.** Verify if the host connection is working. **2.** Verify result upload status in system. **3.** Ask the POC LIS administrator to verify the result transmission received in DM.

12.6 Access Windows Event Logs for POCT Troubleshooting

This section describes how to access the POCT communication log that can aid in POCT communication troubleshooting issues.

To Access the Windows Event Logs:

1. Touch and hold the Windows **Start** button.
2. On the Start menu, touch **Windows Administrative Tools**, then **Event Viewer** to display the screen.

Note

It may take a short time for the Event Viewer to be fully loaded (screen shown below is fully loaded). During the loading time under Summary of Administrative Events, it will display reading data, please wait.

3. The Event Viewer screen appears. To view logs:
   a) Touch the folder **Applications and Services Logs** to expand the folder.
   b) On the expanded folder view, touch and hold **GeneXpert Connectivity**.

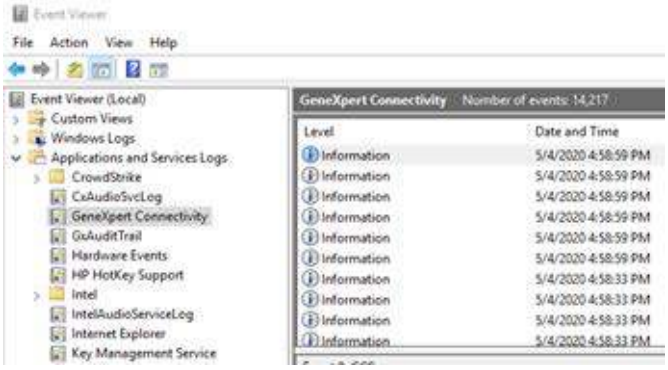


Figure 76. Applications and Service Logs Folder Expanded

   c) On the GeneXpert Connectivity screen, touch **Filter Current Log**.

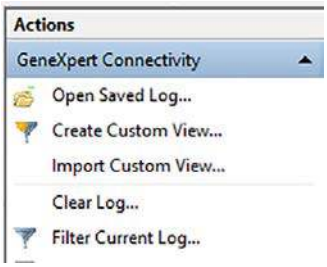


Figure 77. Filter Current Log

4. Configure the filter as desired.
5. Touch **OK**.
6. Touch and hold **GeneXpert Connectivity**.
7. Touch **Save Filtered Log File As...**
8. On the Windows Save As screen, locate the folder to save the file, and the enter a filename using the virtual keyboard (the keyboard appears when you touch the filename entry field).
9. Specify a desired location and filename, and touch **SAVE**.
10. On the Display Information prompt, touch Display Information for these languages.
11. Touch **OK**.
12. Touch and hold **GeneXpert Connectivity**.
13. Touch **Clear Filter**.

12.7 Perform Troubleshooting Remotely

If you need to remote into your device to perform troubleshooting, follow the steps below.

Note The following instructions assume that your device has been set up on the network by your IT department. Please contact your IT department if you need to connect devices to the network.

1. On the system, perform this one time set up:
   a) Navigate to **Setting** > **System** > **Remote Desktop**.
   b) Touch **Enable Remote Desktop** to turn it on.
   c) Touch **Confirm** when prompted.
   d) Optional Step: Under Advanced settings, touch Require computers to use Network Level Authentication to connect.
2. On an Administrator system, perform this first time setup per remote machine:
   a) In Windows Search, look up Remote Desktop Connection.
   b) Click to launch Remote Desktop Connection from the search result.
   c) Click **Show Options**. Perform the following steps:

      For Computer, either an IP address or computer name may be entered.

      For User name, enter the user name of the account you wish to access.

      Optional Step: Check mark **Allow me to save Credentials** so that this connection is saved for easy access at a later time.
   d) Click **Connect**.
   e) Enter the password of the remote machine.
   f) Click **Remember Me** to save the password.
   g) Click **OK**.
   h) You may be prompted by a Windows pop up message The identity of the remote computer cannot be verified. Do you want to connect anyways? Click **Yes**. Optionally you may also click the Check box for Don't ask me again for connections to this computer.
3. On an Administrator System, perform these steps on subsequent connects, after the first time setup:
   a) In Windows Search, look up "Remote Desktop Connection"
   b) Click to launch Remote Desktop Connection from search result.
   c) Select previously connected computers from the drop-down menu choices.
   d) Click **Connect**.
   e) Depending on if login credentials were saved on the initial set up, this should allow the administrator to be connected. Otherwise follow the on screen prompt similar to first time setup.