

GeneXpert[®] System with Touchscreen



Operator Manual
Cepheid OS version 1.0

IVD CE



In Vitro Diagnostic Medical Device

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GeneXpert System

“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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European Union Directives

The GeneXpert system with touchscreen has been designed and tested to conform to the laboratory equipment requirements of applicable regulatory agencies. A Declaration of Conformity is available by contacting Cepheid Technical Support. See the [Technical Assistance](#) section for more information

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	<i>Reference Guide and Quick Start Guide</i>
Instrument calibration standards	<i>Certificate of Calibration</i>
Assay-specific instructions for performing a specific test on a patient sample	The package insert for the assay
How to use the printer	The provided user guide from the manufacturer of the printer





To learn more about the different user roles on the system, see [User Functions by Roles](#).

1.3 Table of Symbols

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

Table 1. Symbols

Symbol	Description
	<i>In vitro</i> diagnostic medical device
	CE marking—European Conformity
	Do not reuse
	Consult instructions for use
	Manufacturer
	Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union.

Symbol	Description
	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.

1.4 Technical Support

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, the touchscreen serial number
- 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.

France	US
Telephone: +33 56 382 531	Telephone: +1 888 838 3222, Option 2
Email: support@cepheideurope.com	Email: techsupport@cepheid.com

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

1.5 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 Assistance section in the Preface for contact information.

1.6 LIS Uploads and Downloads

The GeneXpert System with Touchscreen running Cepheid OS 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 Assistance section in the Preface for the contact information.

Cepheid recommends to always confirm that LIS uploaded or downloaded results match GeneXpert System with Touchscreen running Cepheid OS results after any changes to the GeneXpert or host system, including, but not limited to, changes to the following:

Note

- Cepheid OS software version
 - GeneXpert assay definition files and version
 - GeneXpert host communication settings
 - Host middleware software or configuration changes
 - LIS software or configuration changes
-

1.7 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>.

1.8 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.

1.9 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.

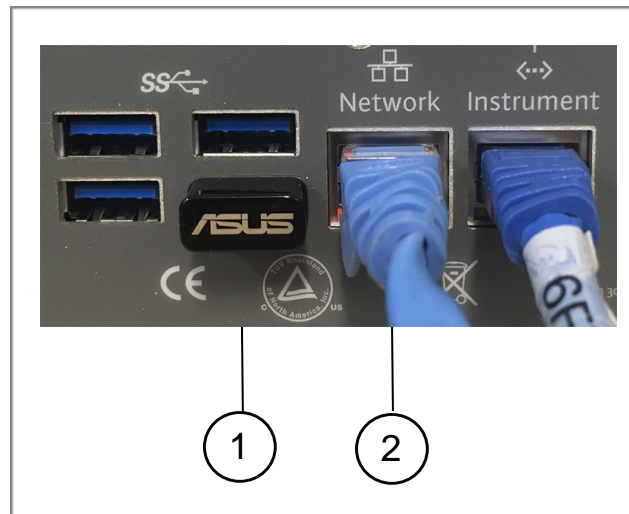


Figure 1. Wi-Fi Adapter and Ethernet Network Cable

Number	Description
1	Wifi adapter inserted into USB port
2	Ethernet cable inserted into Network port

1.9.1 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 2. 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 WiFi- connection.

1.9.2 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.

1.10 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 weight table in General 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.

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 or touchscreen. 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.

1.11 Windows User Accounts

The touchscreen is configured for a Cepheid user account. You must log on as the Cepheid user to operate the system. However, when logging on for the first time, use the following:

- User name: **Cepheid-Admin**
- Password: **cphd**

Caution







Do not change the Cepheid user profile. Changing the profile can cause loss of data during a test.

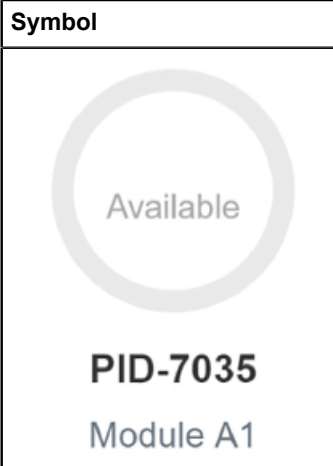



See [User Functions by Role](#) for a description of User Types and permissions for the Cepheid OS software.

1.12 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 3. Software Buttons, Icons and Symbols

Symbol	Definition
	HOME - Go to the Home screen.
	RESULTS - Displays a list of any tests previously run.
	QC - Navigates to the Quality Control page.
	User Menu - Displays system notifications (if any) and user options to Change a Password, Logout or Exit the software. Also provides an About selection to show the software version, Cepheid email addresses and a link to the complete software License.
	Available - Indicates a module that is available to run a test.
	Indicates a module with test in progress.

Symbol	Definition
	Indicates a module available after a test has completed (with Patient ID displayed).
	CANCEL TEST - Cancel a test being created (before the test starts running)
	Stop Test - Stops a test currently running.
	Report - Displays a PDF of the test shown onscreen (located on the Test Completed screen).

1.13 Cepheid Headquarters Locations

Corporate Headquarters

Cepheid
 904 Caribbean Drive
 Sunnyvale, CA 94089
 USA

Telephone: + 1 408 541 4191
 Fax: + 1 408 541 4192
www.cepheid.com

European Headquarters


Cepheid Europe SAS
 Vira Solelh
 81470 Maurens-Scopont
 France


Telephone: + 33 563 825 300
 Fax: + 33 563 825 301
www.cepheidinternational.com

2 Safety

2.1 Safety Information

Chapter 2 (Safety) in this manual provides important safety information that you should use when operating the GeneXpert System with Touchscreen running Cepheid OS. 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.




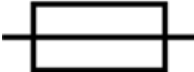

Caution  If the GeneXpert system with touchscreen is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Caution  **HEAVY OBJECT:** See the System Dimensions and Weights table in Appendix A 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 Electrical Symbols on the Touchscreen and Instrument

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

Table 1. Electrical Symbols on the GeneXpert system with touchscreen

Label	Description
	Indicates the ON position of the main instrument and touchscreen power switches.
	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.
	Indicates the rating of the fuse (such as 2.5A) protecting the unit.
	Indicates a location of the chassis ground connection.

2.4 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.

2.5 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.

2.6 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.

2.7 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.

2.8 Barcode Scanner

The barcode scanner (Cepheid PN 100-5961, Model Number N6600) contains an LED light source that has been tested and classified as "EXEMPT RISK GROUP" to the standard IEC 62471:2006.

3 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.

3.1 System Components

The touchscreen can be used with the GeneXpert II Instrument or the GeneXpert IV Instrument.

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 2. Touchscreen with GeneXpert II Instrument

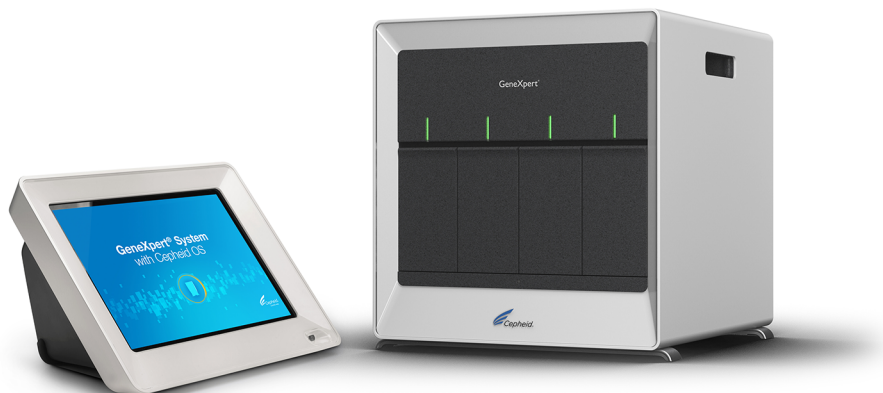


Figure 3. Touchsreen with GeneXpert IV Instrument

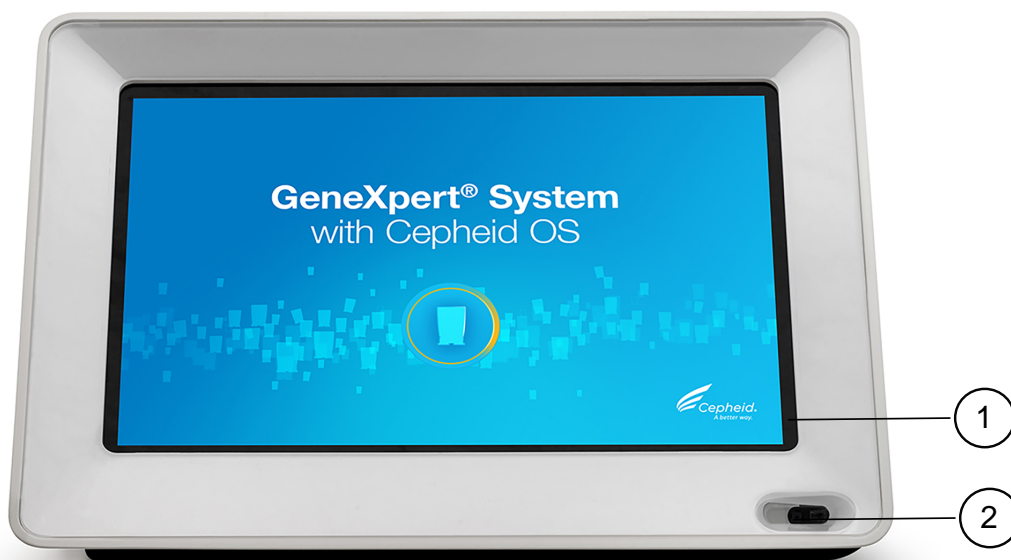


Figure 4. Touchscreen

Number	Description
1	Touchscreen user interface
2	LED barcode scanner



Figure 5. 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	Touchscreen locking cable

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

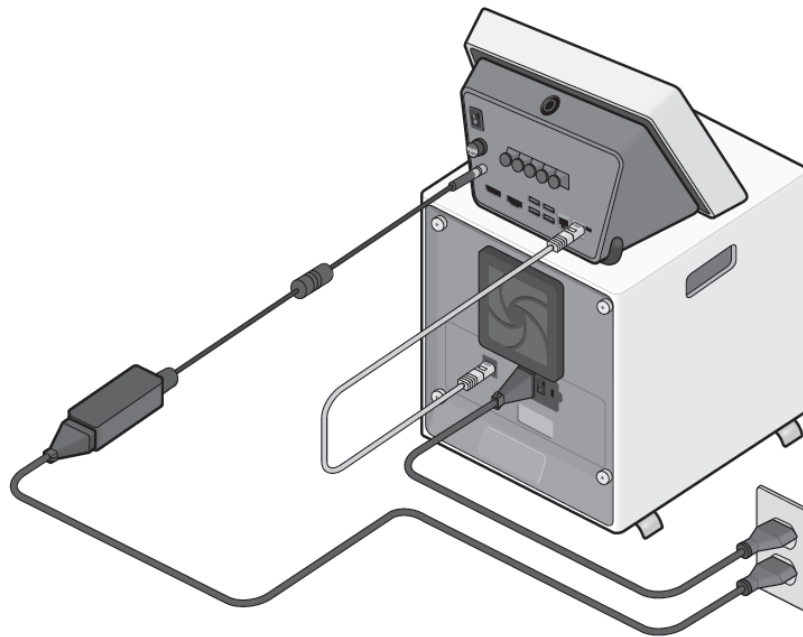


Figure 6. Power Cord and Connection Cable

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

3.2 Models of GeneXpert Instruments

Presently, two models of GeneXpert Instruments (GeneXpert II and GeneXpert IV) 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.

- The GeneXpert II instrument consists of two modules. Each module processes one sample.
- The GeneXpert IV instrument consists of four modules. Each module processes one sample.

3.3 6-Color and 10-Color Modules

A GeneXpert Instrument can have either 6-color or 10-color modules. A 10-color module can be identified by a blue stripe on the upper edge of the module door. The GeneXpert System with Touchscreen running Cepheid OS is equipped with a 10-color module; however, the touchscreen can also be acquired as an upgrade and is compatible with 6-color modules.



Figure 7. 6-Color and 10-Color Modules

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

3.4 Access the Software License Agreement

This section describes how to access the software license information.

1. From the Home screen, touch **User Menu**.

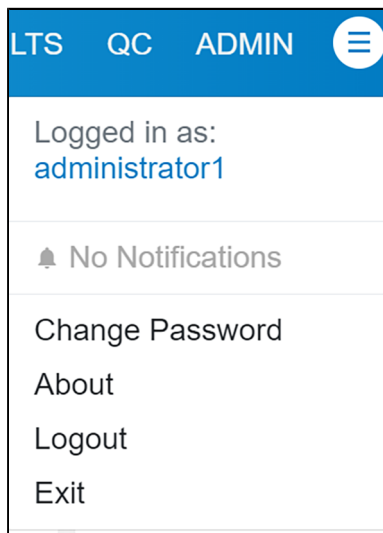


Figure 8. User Menu

2. On the User Menu, touch **About**.

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

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

3. On the About screen, touch **LICENSE** to view the software license agreement.

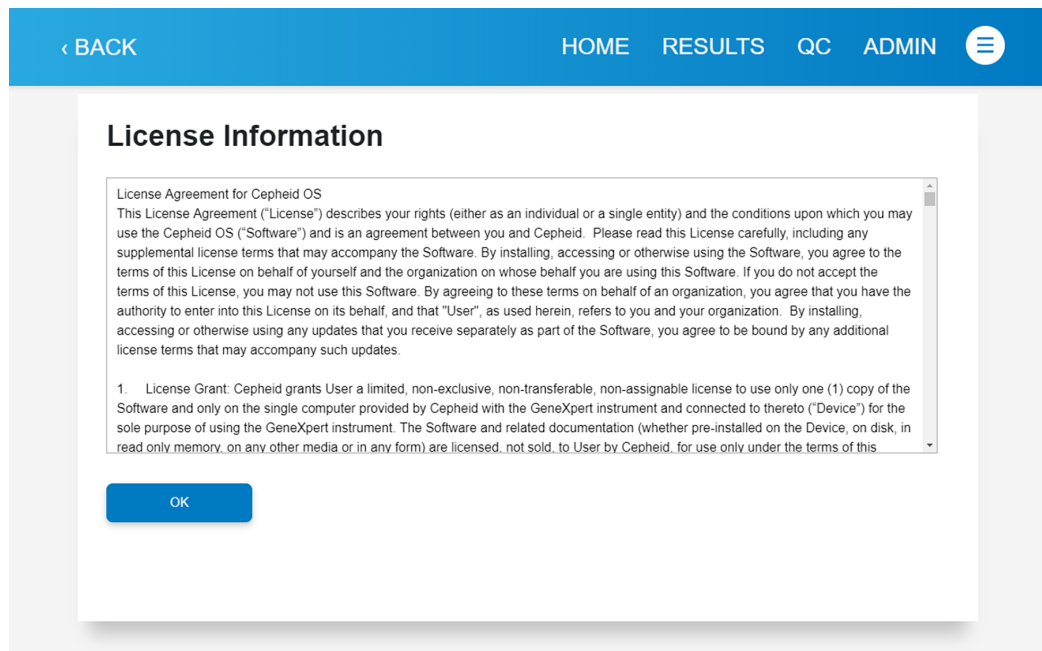


Figure 9. License Information Screen

3.5 Virtual Keyboard

The virtual keyboard appears onscreen when you are required to enter information, such as a Password, Sample ID or Patient ID.

Touch a screen entry field and the virtual keyboard appears.

To close the keyboard, touch the **X** in the upper right of the keyboard.

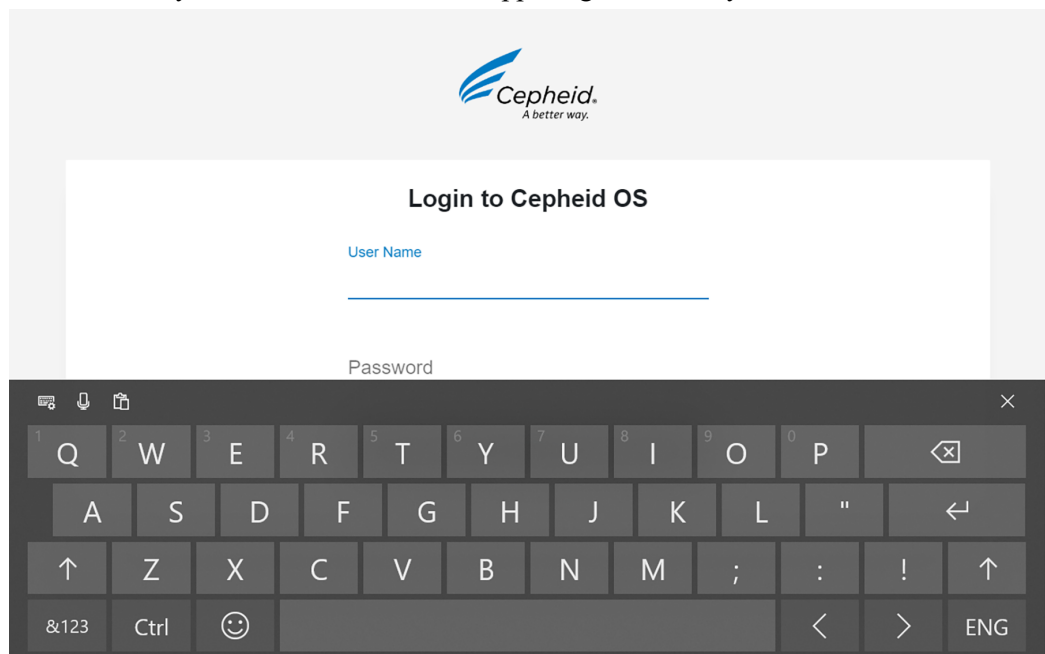


Figure 10. Virtual Keyboard

Note The virtual keyboard might cover or hide an input button such as **CONFIRM** or **OK**. Just touch the **X** button to close the keyboard.

3.6 Recommended Materials for Use with the System

- Uninterruptible Power Supply (UPS)
- Printer

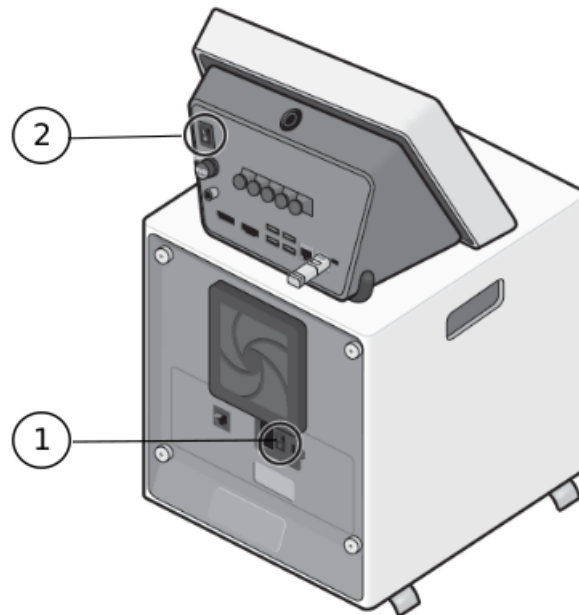
To order the printer or UPS, contact Cepheid. See the Technical Section section in the Introduction for contact information.

4 Starting the System

4.1 Start the GeneXpert system with touchscreen

To turn on the GeneXpert system with touchscreen:

1. Turn on the GeneXpert II or GeneXpert IV Instrument. The power switch is located on the back of the instrument. Press the switch to the **ON** (I) position.
2. Turn on the touchscreen. The power switch is located on the back of the touchscreen.



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

Note A blue push button at the top of the touchscreen can be used to restart the Windows software. It illuminates when the touchscreen power switch is turned on.

3. Wait for the system to boot. The Windows Opening screen appears. Swipe up anywhere on this screen, (as indicated by the dashed arrow) to display the login screen.
The computer is configured with two Windows accounts. The Cepheid-Admin account is for administrator tasks such as software updates, system configuration and normal operation; and the Cepheid-Techsupport account is for use only by Cepheid Technical Support.
4. On the Windows Login screen, touch **Cepheid-Admin**.

5. On the Cepheid-Admin login screen, enter the password **cphd** and touch the arrow to the right of the Password field.

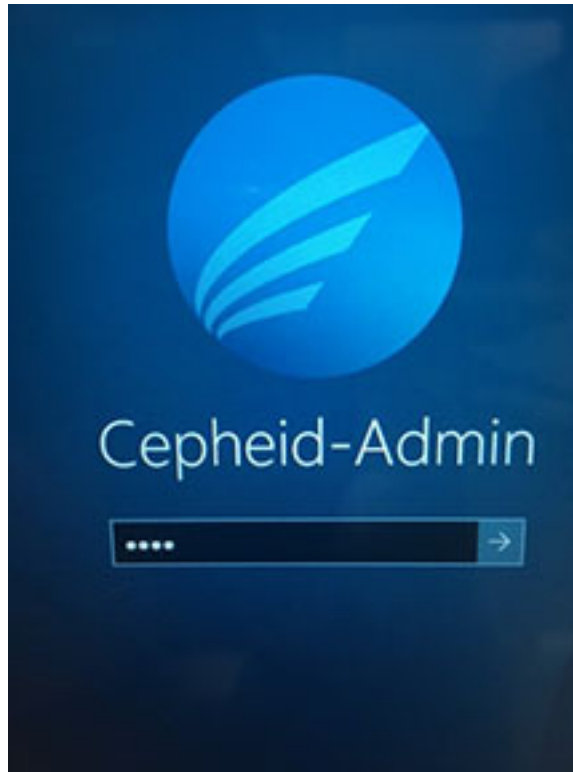


Figure 11. Administrator Sign On Screen

6. Touch the login field, and enter your user name and password.
7. Touch the arrow button at the right of the Confirm password field.

The software starts.

4.2 User Menu Functions

The User Menu icon is located in the upper right corner of the screen.

Touch **User Menu** and a drop-down menu appears. The drop-down menu identifies the user currently logged into the system, as well as notifications (if any). You can also touch: [Change Password](#) (of the logged-in user), [About](#) (details of the software), [Logout](#) (of the present user) and [Exit](#) (exits the software).

4.3 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**.

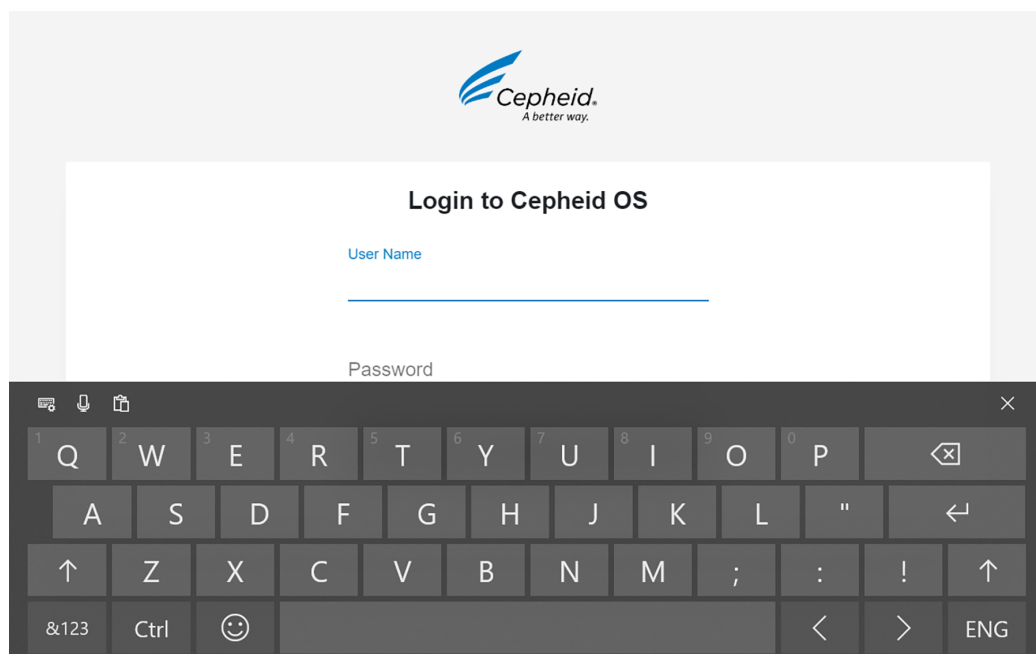


Figure 12. Login Screen

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 **New Test** button appears. The instrument is now initialized and ready to run tests.

4.3.1 Log In and Log Out

When multiple users are using the same system, user log in and log out may be required. Please see your system administrator for individual log in information.

On the HOME screen, touch **User Menu > Login**.

- If the Login with Institutional ID choice has not been selected by the administrator, login must be made using the virtual keyboard and the Login to Software screen displays.
- If the Login with Institutional ID choice has been selected by the administrator, login must be made using an ID card with barcode and the Scan Your ID Card to Continue screen displays.

4.3.2 Log In using the Virtual Keyboard

This section describes the steps necessary to log in manually, using the virtual keyboard on the touchscreen.

Note To login with an Institutional Login (barcode) see [Log In with an Institutional ID](#).

1. On the **User Menu**, touch **Login**. The virtual keyboard appears.
2. Enter your User Name.
3. Scroll down and enter your user Password.
4. When you are finished entering your User Name and Password, touch the **X** in the upper right of the virtual keyboard.
5. Touch **LOGIN** and the Home screen appears.

4.3.3 Log in with an Institutional ID

This section describes the steps necessary to log in using a barcode on an Institutional ID. To login using an Institutional ID, an administrator must first select that option in the General Settings screen.

Note To login manually, using the virtual keyboard, see [Log in Using the Virtual Keyboard](#).

1. After touching the Login entry on the User Menu, the Login - Scan Your ID Card screen displays if your administrator has previously selected the ID Card scanning option.
2. Using the integrated barcode scanner, scan your ID card. The Home screen appears.

4.4 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.

To change your own password, touch the **User Menu** icon. Touch **Change Password** on the drop-down menu. The Change Password screen appears.

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. On the Change Password screen, enter your Current Password. Touch **New Password** and enter your new password. Touch **Confirm New Password** and enter your new password a second time.

Note Passwords cannot contain spaces and the length should be between 6 and 32 characters.

2. When you are done, touch **Confirm** at the upper right of the screen, and you are returned to your previous screen and your new password is active.

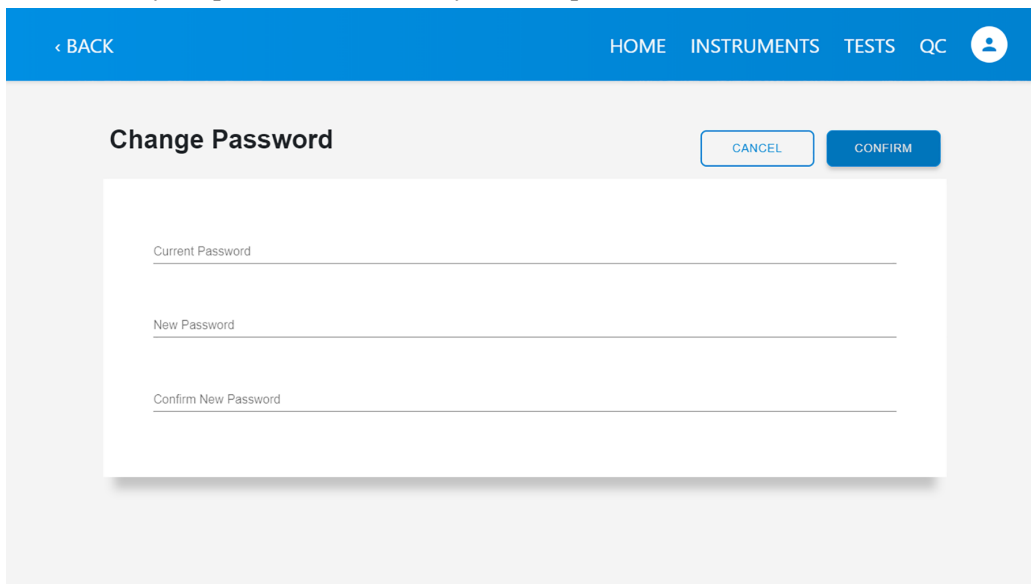


Figure 13. Change Password Screen

5 Running a Test

5.1 Run a Test

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

1. On the HOME screen, touch the **NEW TEST** button.

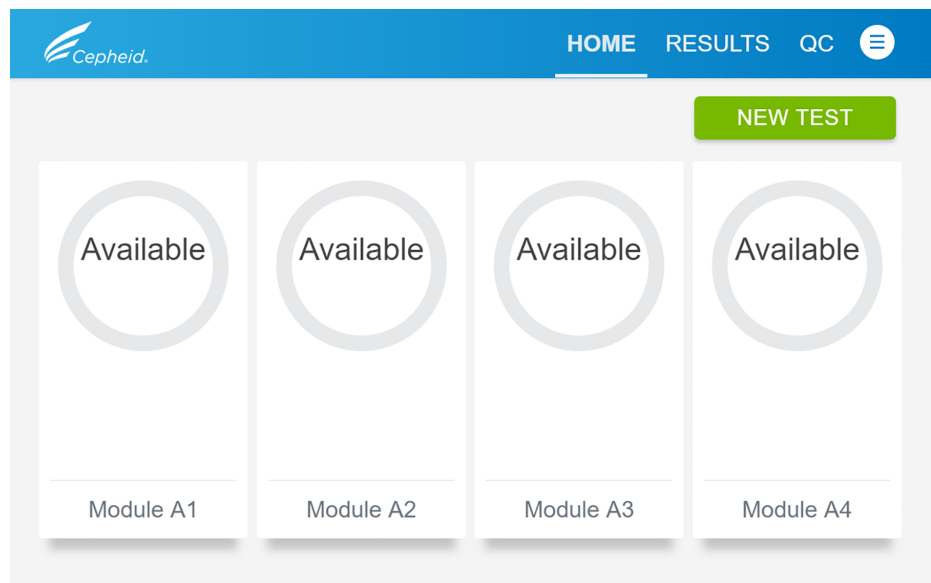


Figure 14. HOME Screen, NEW TEST Button

2. Enter a Patient ID. See [Options for Entering a Patient ID](#) for more information.
3. Enter a Sample ID. See [Section 3](#) for more information.
4. Scan cartridge barcode. Hold the cartridge about 10 cm (4 inches) away from the scanner.
5. After scanning, touch **CONFIRM**.

Note

For combinatorial assays select the correct test, and then touch **CONFIRM**. See [Select a Combinatorial Test](#) for more information.

6. If you are not logged in, the Enter Credentials to Continue screen appears. Enter your user name and password and click **LOGIN**.
7. The Cartridge Preparation screen appears. Watch video (if necessary) and touch **CONTINUE**.

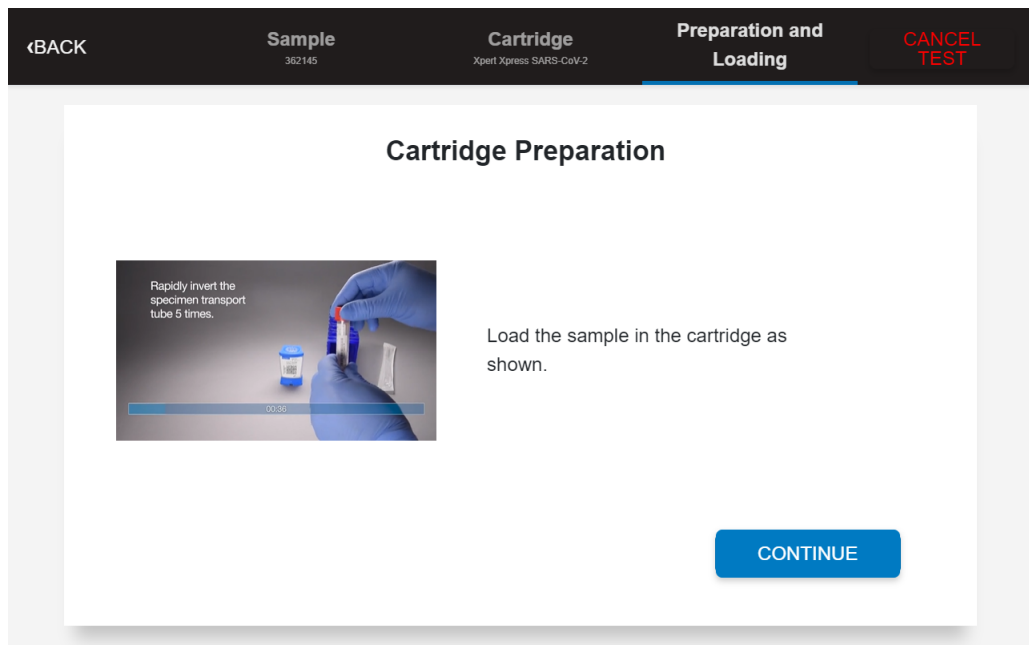


Figure 15. Cartridge Preparation

8. Load a cartridge into the module with a blinking green LED light and touch **CONTINUE**.
9. When the test completes, the Test Completed screen appears.
10. Remove the cartridge and dispose according to your institution's hazardous waste disposal guidelines.
11. Touch **Report** to view a test report.
12. Touch **Save** or **Print**.
13. Touch Home to return to the **HOME** screen.
14. Touch **RESULTS** to view the results of previously run tests.

5.2 Options for Entering the Patient ID

This section describes the method for entering the Patient ID into the system, either by scanning a barcode or entering the ID manually using the virtual keyboard.

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.

5.2.1 Scan the Patient ID

1. Scan the Patient ID barcode using the barcode scanner. Hold the sample about 10 cm (4 inches) away from the scanner slit on the front of the touchscreen. The scanner projects a green crosshair, which you should center on the barcode.
2. After a successful scan, the Confirm Patient Information screen appears. Verify the Patient ID is correct, then touch **CONTINUE**.

5.2.2 Enter a Patient ID Manually

1. Touch **Patient ID**.
2. Enter the Patient ID number using the virtual keyboard that appears on screen.
3. Verify the number you entered is correct and press **CONTINUE** and **CONFIRM**.

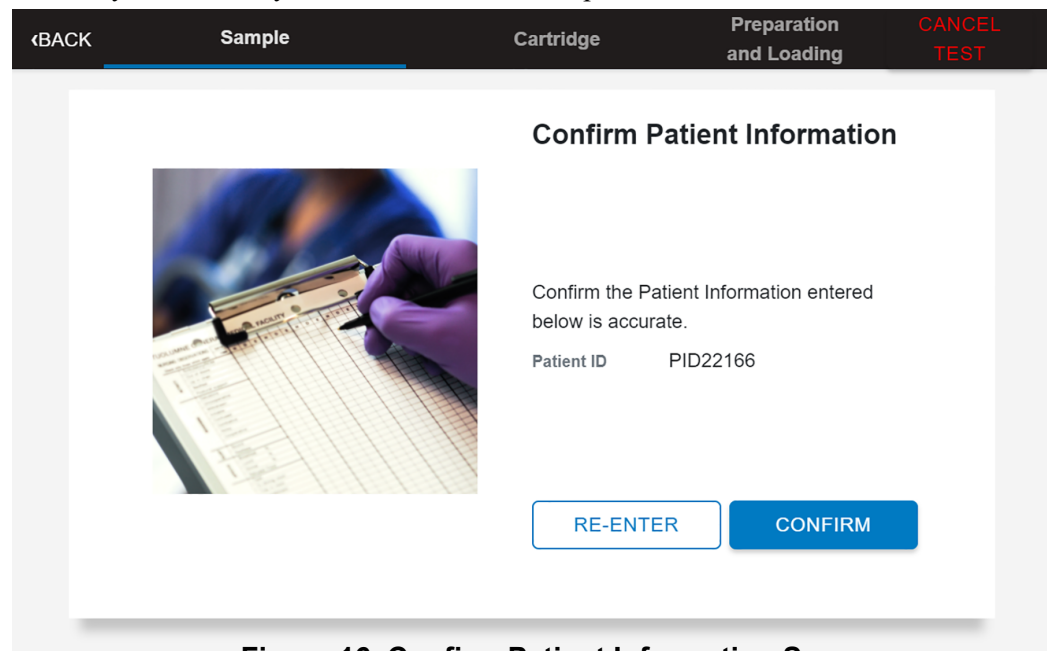


Figure 16. Confirm Patient Information Screen

5.3 Options for 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 random sample ID.

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 touchscreen.

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.

5.3.1 Scan the Sample ID

1. Scan the Sample ID barcode using the barcode scanner. Hold the sample about 10 cm (4 inches) away from the right side of the scanner.

Note

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

2. After a successful scan, the Confirm Sample ID screen appears. Verify that the Patient/Sample ID on the Confirm Sample ID screen matches the Sample ID on the sample. If it matches, touch **CONTINUE**.
3. If it does not match, touch the **RE-ENTER** button, which automatically clears the Sample ID. [Manually enter](#) the correct Sample ID.

5.3.2 Assign a Random Sample ID

You can assign a random sample ID instead of scanning or manually entering an existing sample ID.

1. When the Sample ID screen appears, touch **Continue** once.
2. On the Confirm Sample ID screen, note the auto-generated Sample ID.
3. Touch **Confirm** to accept the auto-generated Sample ID for your sample.

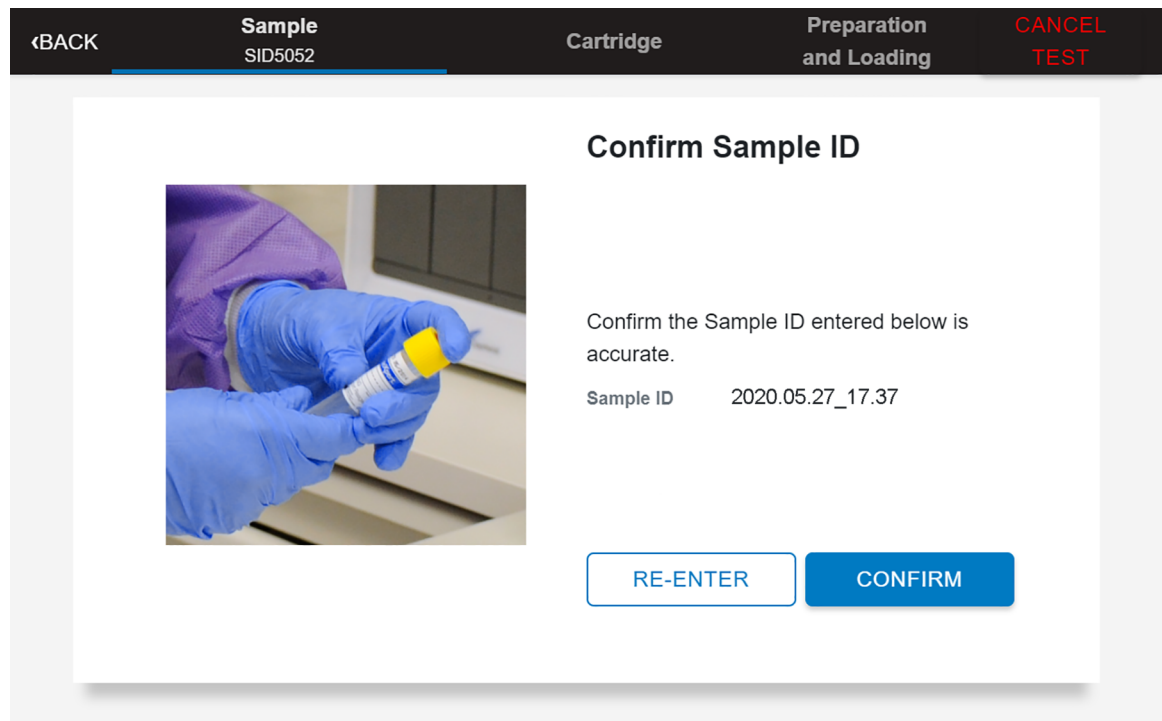


Figure 17. Confirm Auto-Generated Sample ID Screen

You can now scan your cartridge barcode.

5.3.3 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.
 - Touch **Clear** if it is not correct.
 - Touch **Continue** if it correct.

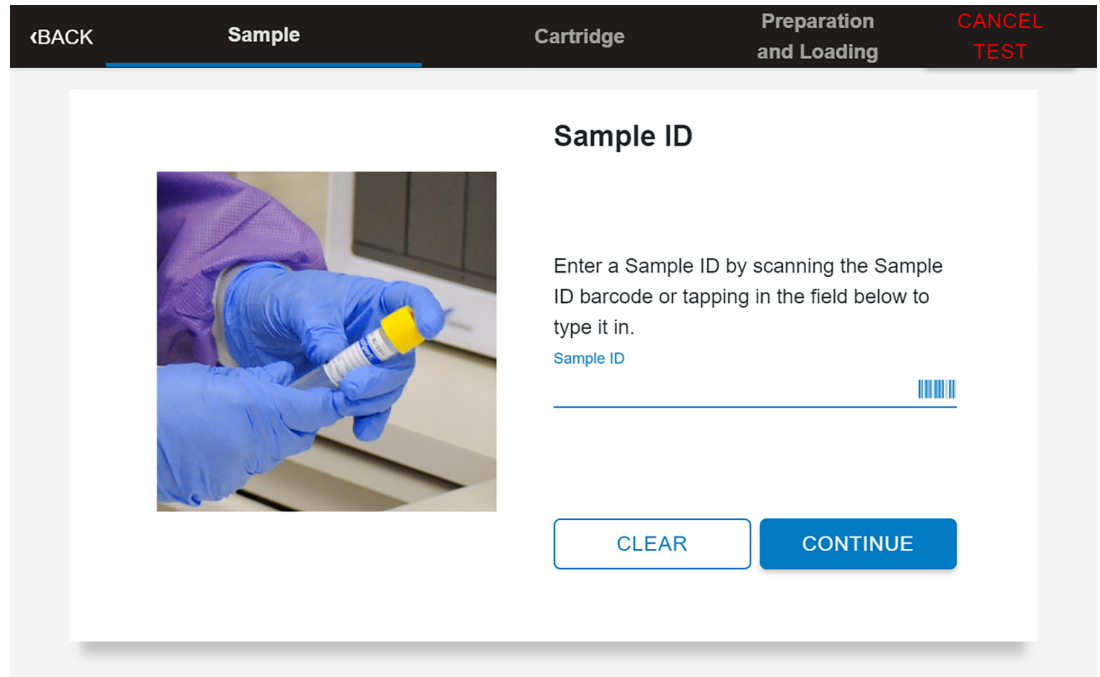


Figure 18. Sample ID Screen

4. On the Confirm Sample ID screen, touch **Confirm**.

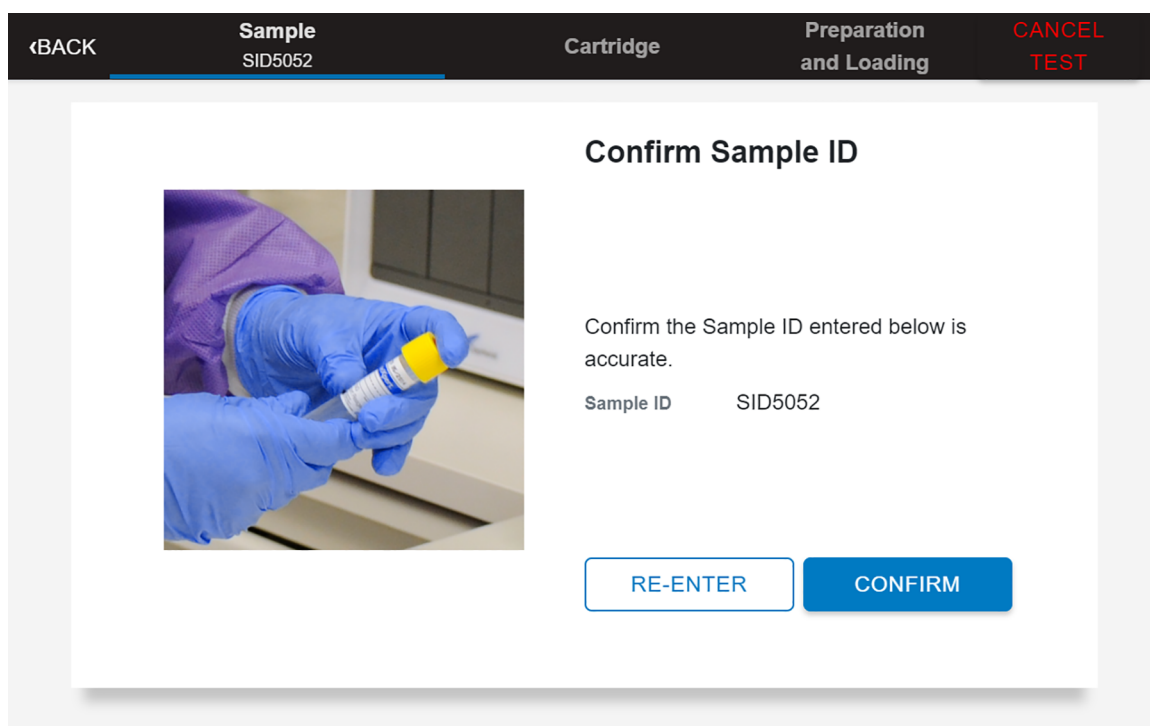


Figure 19. Confirm Sample ID Screen

5.4 Select a Combinatorial Test

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.

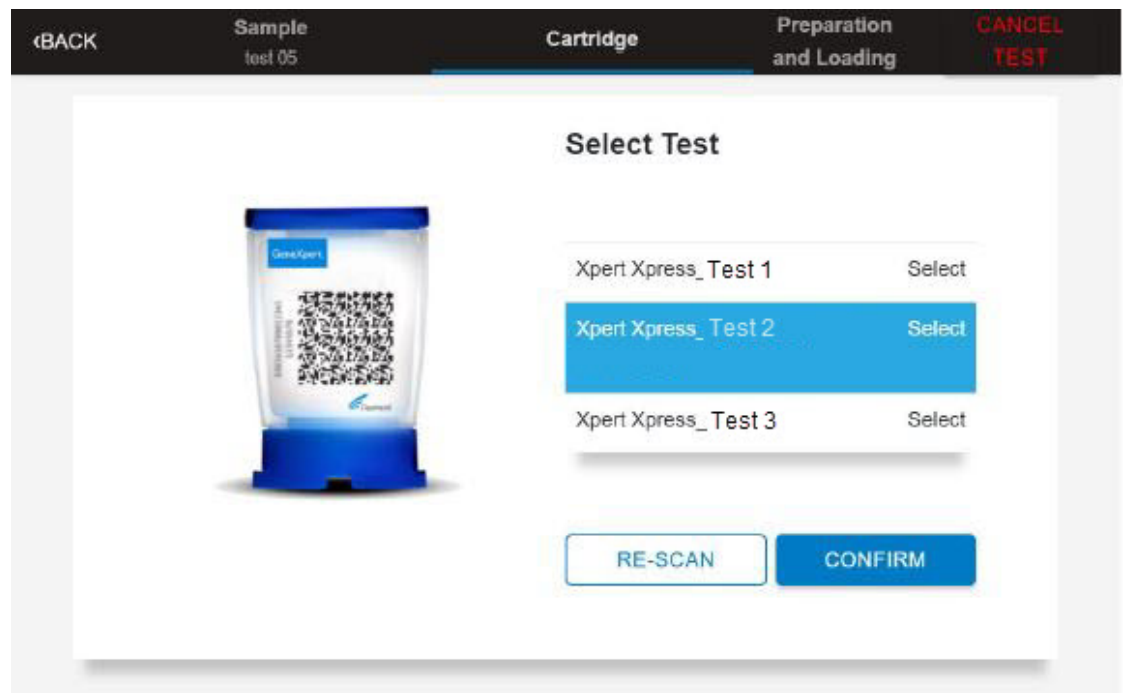


Figure 20. Select Test Screen for Combinatorial Assay

4. After scanning, verify that the correct cartridge has been scanned and that the assay name shown on the Confirm Test Information screen matches the assay name on the cartridge. If it does not match, touch **RE-SCAN** and scan the correct cartridge barcode.
5. Touch **CONFIRM**.

5.5 Scan the Cartridge Barcode

This section describes how to scan a cartridge barcode into the system.

Warning



In the following steps, cartridges should be kept upright when handling or scanning. Do not rotate or 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. Hold the cartridge about 10 cm (4 inches) 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 21. Scan Cartridge Barcode

3. After scanning, verify the correct cartridge has been scanned and touch **Confirm**.
4. If prompted, enter your user name and password. Press **Login**.
5. On the Cartridge Preparation screen, watch a cartridge preparation video (if necessary).
6. Prepare the cartridge according to the package insert/preparation video.

5.6 Load a Cartridge and Start a Test

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

1. After the cartridge has been prepared, touch **CONTINUE** on the Cartridge Preparation screen to halt the video clip. The Load Cartridge into Module screen will be display.
2. Open the instrument module door below the module with the flashing green light.
3. Place the cartridge on the module bay floor with the cartridge label facing out.
4. Press the module door closed. 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.

5. After the test has loaded, the Test Running screen appears, showing a blue circular graphic indicator at the right side of the screen to indicate the progress of the test.

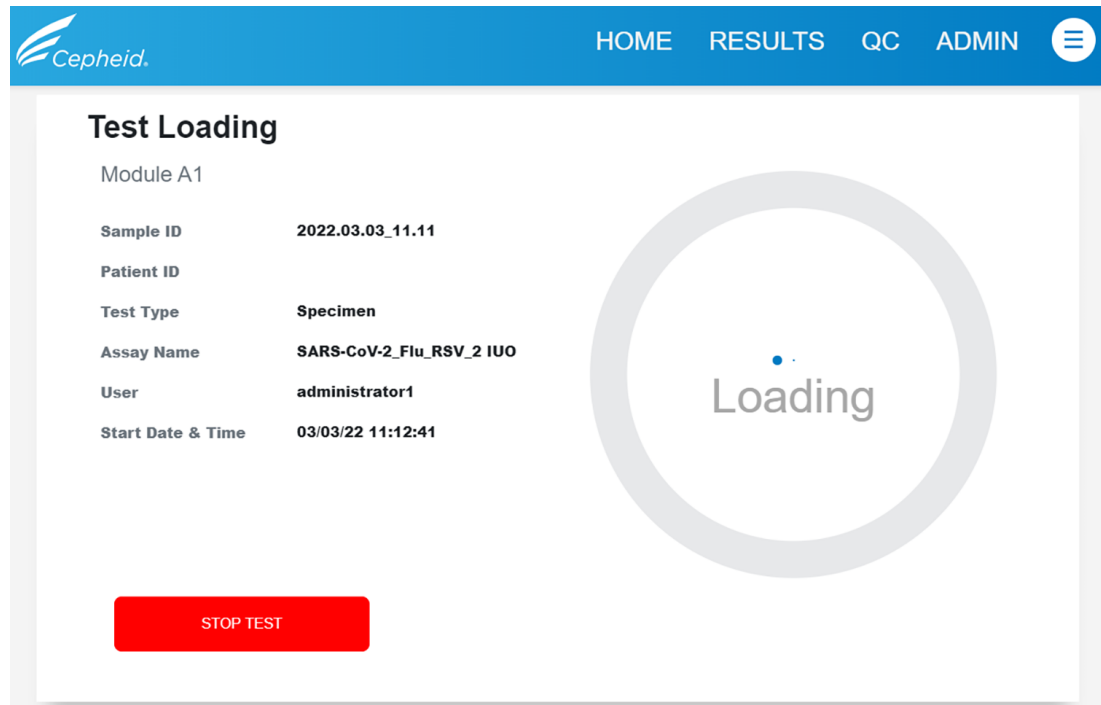


Figure 22. Test Running

Note At this point, another test can be started by returning to the Home screen.

6. When a test completes, the Test Completed screen appears.
7. Open the module door, remove the used cartridge, and properly dispose of the cartridge according to your institution's hazardous waste disposal guidelines.
8. The Test Completed screen shows results for the completed test.
9. To view a complete test report of the test just completed, touch the **REPORT** button on the Test Completed screen. The Report Viewer screen displays the report which can be saved, or printed to any wired or network printer.

5.7 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 instrument.

1. Touch the **HOME** button on the Test Running screen. The HOME screen appears.
2. Touch **NEW TEST** and perform the same steps required for a standard test, as described in [Load a Cartridge and Start a Test](#).

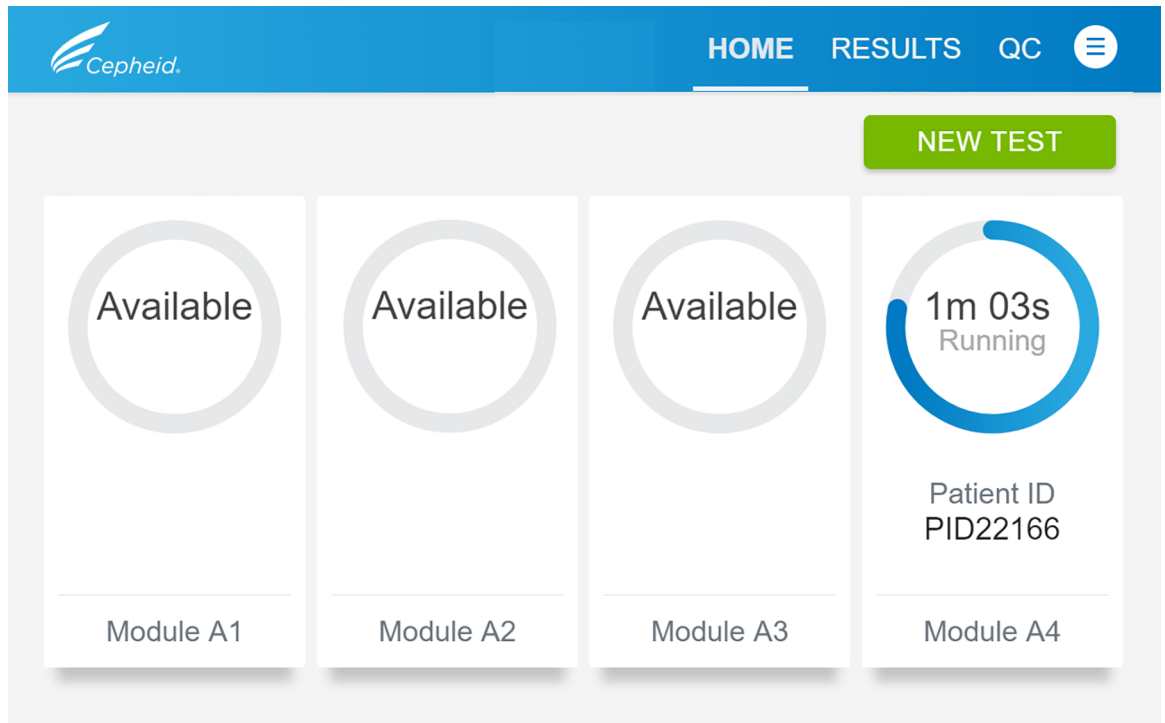


Figure 23. Home Screen, Showing Three Modules Available

3. Touch **HOME** and **NEW TEST** to start consecutive tests.
4. After a test has completed, the module icon text changes to Complete.

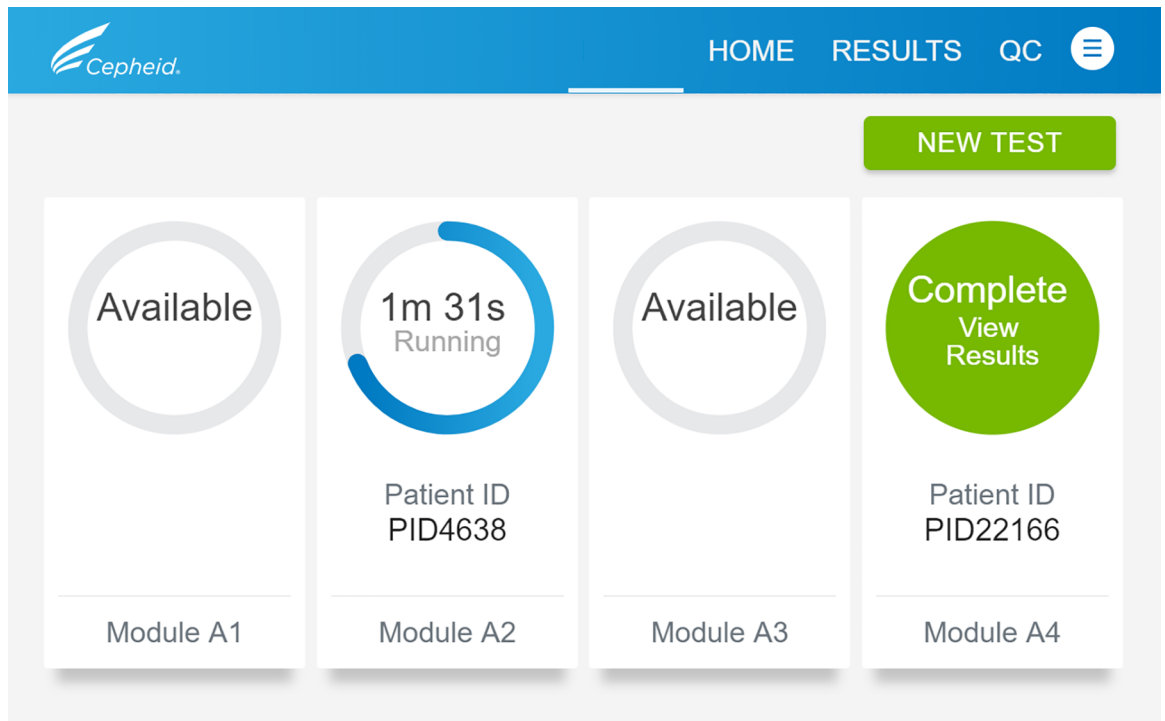


Figure 24. Home Screen, One Test Completed, Second Test Started

5.8 Operate with Host (LIS or POCT) 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 LIS connectivity, an Admin has additional capabilities for performing queries and managing host test orders.

Cepheid recommends to always confirm that LIS uploaded results match Cepheid OS software test results after any changes to the software or host system, including (but not limited to) changes to the following:

Caution

- Cepheid OS software version
 - The touchscreen Host Communication Settings
- Host middleware software or configuration changes**
- LIS software or configuration changes**
-

5.8.1 Create a Test with Host Connectivity

When host connectivity is enabled, the system periodically queries all test orders from the host. Depending on the Host Communication settings, test orders are automatically downloaded from the host when a test is initiated.

1. If configured, enter the Patient ID.
2. Enter the Sample ID.

Note

If there are test orders available from the host, there should be samples on hand for the tests ordered.

3. The system checks for a matching host order. If no order is found, the following screen appears.

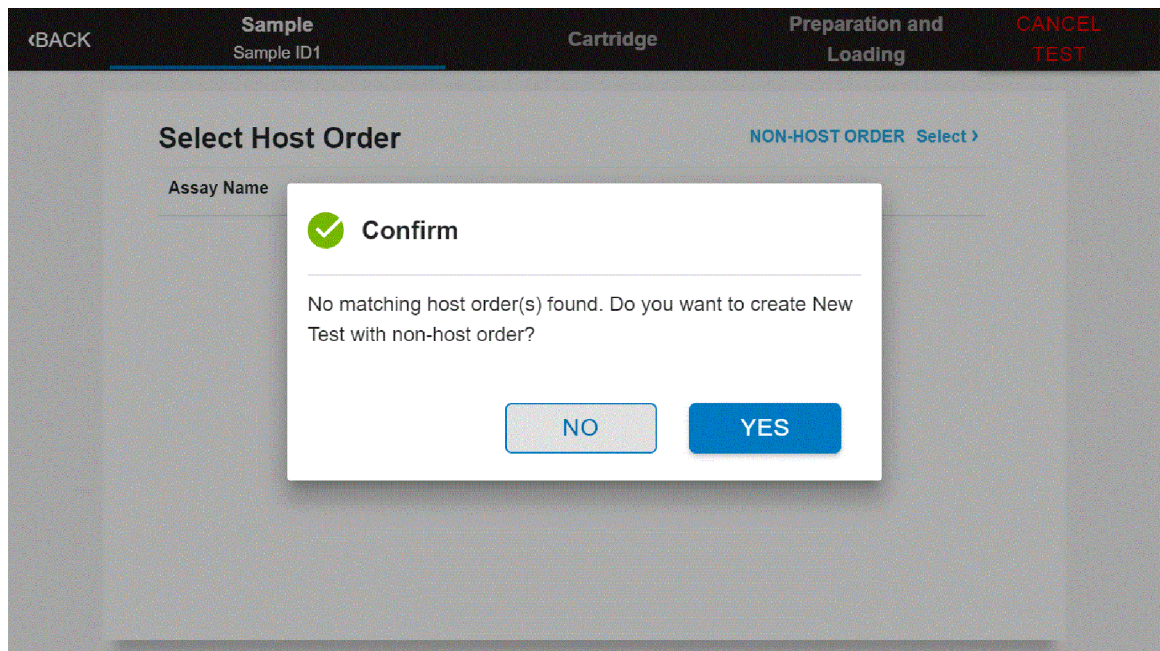


Figure 25. No Matching Orders Found

4. If you choose **NO**, you are returned to the Home screen. Start another test by touching the **NEW TEST** button. Perform the routine beginning with Step 1 of this procedure (scan a different Patient ID and Sample ID).
5. If you choose **YES**, then you can scan the cartridge and order a non-host order test.

Note The workflow in your laboratory determines how a test is created.

6. When you scan a Patient ID and a Sample ID, and the order is in the system, the Select Host Order screen appears, and the host order(s) appears on the screen.

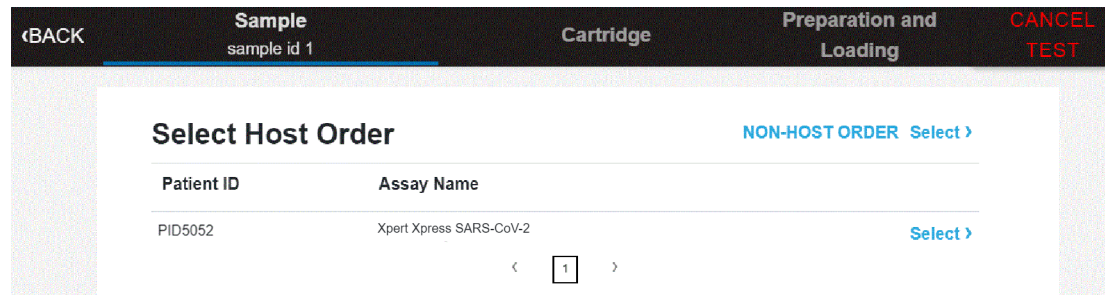


Figure 26. Select Host Order

7. Touch the **Select** button at the right of the host order. 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.
8. Insert the specimen and reagents into the cartridge according to the assay-specific package insert.
9. Load the cartridge and close the module door.

5.8.2 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 in the Test Information area of the View Result window.

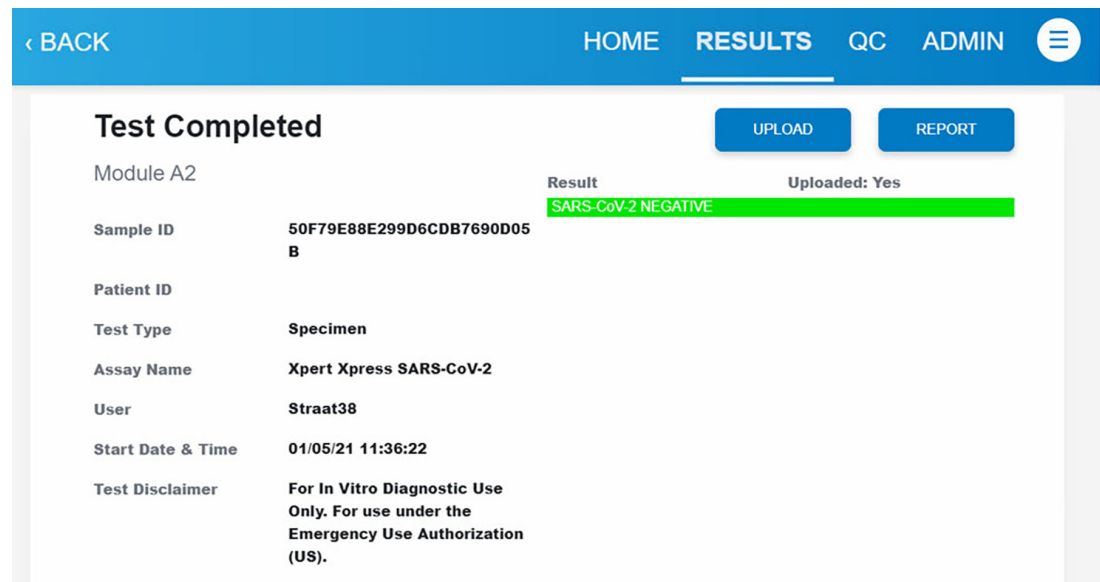


Figure 27. Test Upload Status

5.8.3 Manually Upload a Test Result to the Host

1. If a test has not been automatically uploaded, it can be manually uploaded by touching **UPLOAD** on the Test Completed screen. The individual test result is uploaded to the host.

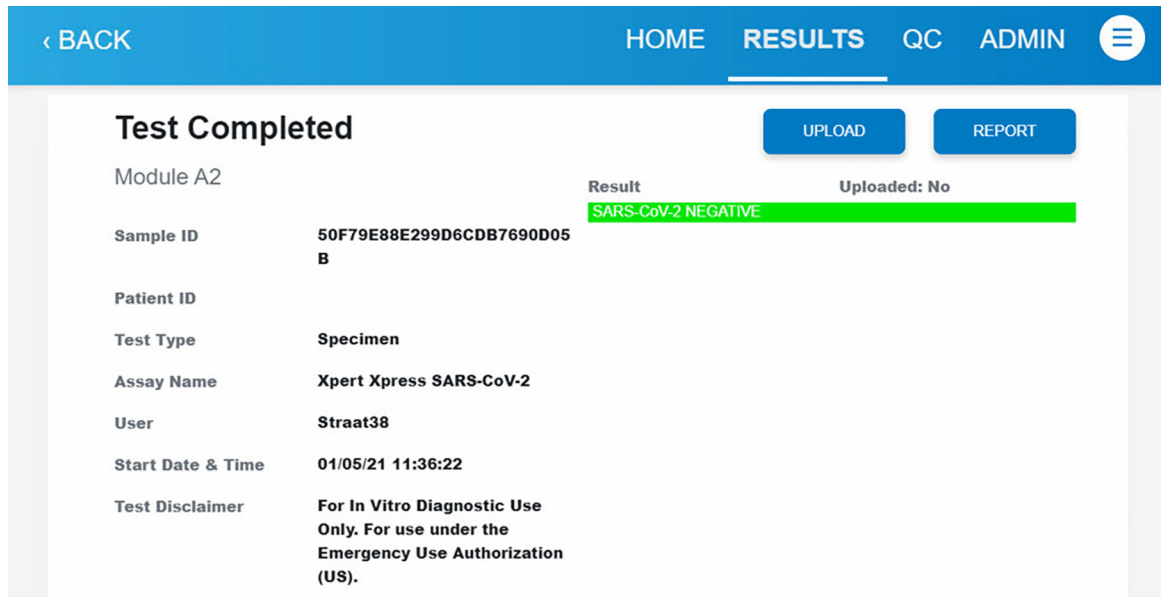


Figure 28. Test Completed Screen Showing UPLOAD Button

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

The possible host upload statuses are:

- Uploaded: No—this result has not been uploaded.
- Uploaded: Yes—this result has been received by the host.

Note If an attempt to exit the software is made while results are uploading, the software will alert the user.

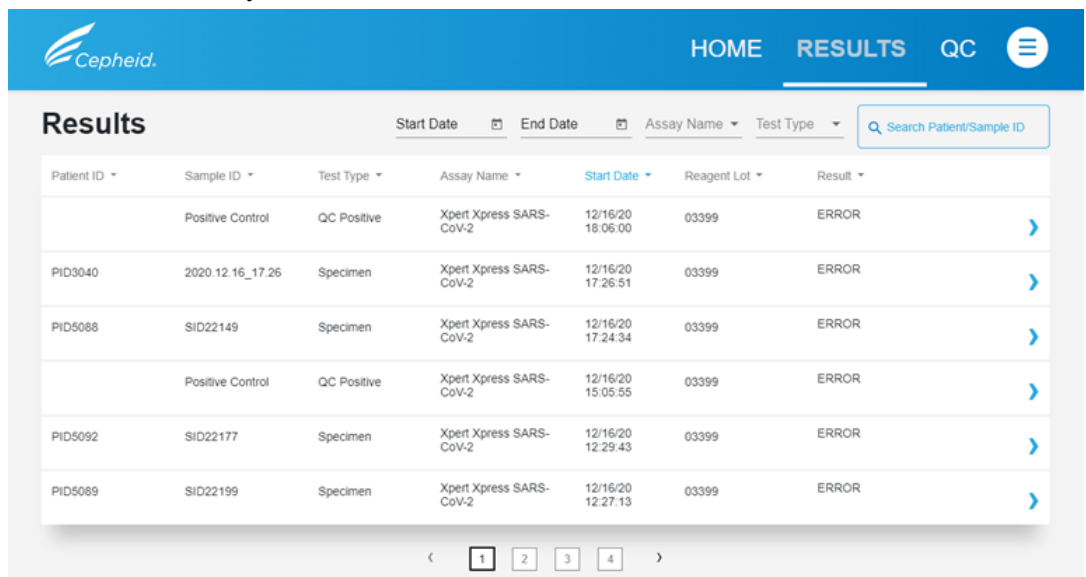
Note Each test can be uploaded individually from the Test Completed screen.

6 Managing Test Results

6.1 View Previous Test Results

This section describes how to view the results of previously run tests.

1. On the Home screen, touch **RESULTS**.
2. On the Results screen, tests are arranged by the date and time that a test was run. Touch the numbered page buttons at the bottom of the screen to navigate through the results if necessary.



Patient ID	Sample ID	Test Type	Assay Name	Start Date	Reagent Lot	Result
	Positive Control	QC Positive	Xpert Xpress SARS-CoV-2	12/16/20 18:06:00	03399	ERROR
PID3040	2020.12.16_17.26	Specimen	Xpert Xpress SARS-CoV-2	12/16/20 17:26:51	03399	ERROR
PID5088	SID22149	Specimen	Xpert Xpress SARS-CoV-2	12/16/20 17:24:34	03399	ERROR
	Positive Control	QC Positive	Xpert Xpress SARS-CoV-2	12/16/20 15:05:55	03399	ERROR
PID5092	SID22177	Specimen	Xpert Xpress SARS-CoV-2	12/16/20 12:29:43	03399	ERROR
PID5089	SID22199	Specimen	Xpert Xpress SARS-CoV-2	12/16/20 12:27:13	03399	ERROR

Figure 29. Results Screen

Note

The Patient ID column is configurable so that it can be visible or hidden, depending on the administrator's configuration. The filters on top of the column allow filtering by Start Date, End Date, Assay Name and Test Type, or by searching by the Patient or Sample ID number.

3. Touch the desired test results. The Test Completed screen appears and displays detailed information.
4. After viewing the results, touch the **HOME** button to return to the Home screen and run additional tests or touch the **RESULTS** button to return to the Results screen and view additional tests.
5. To interpret results for a specific assay, see the package insert provided in the assay kit.

7 Shutting Down the System

7.1 Log Out

1. Locate the User Menu icon, which is located in the upper right corner of any screen. In this example, the Home screen is shown.

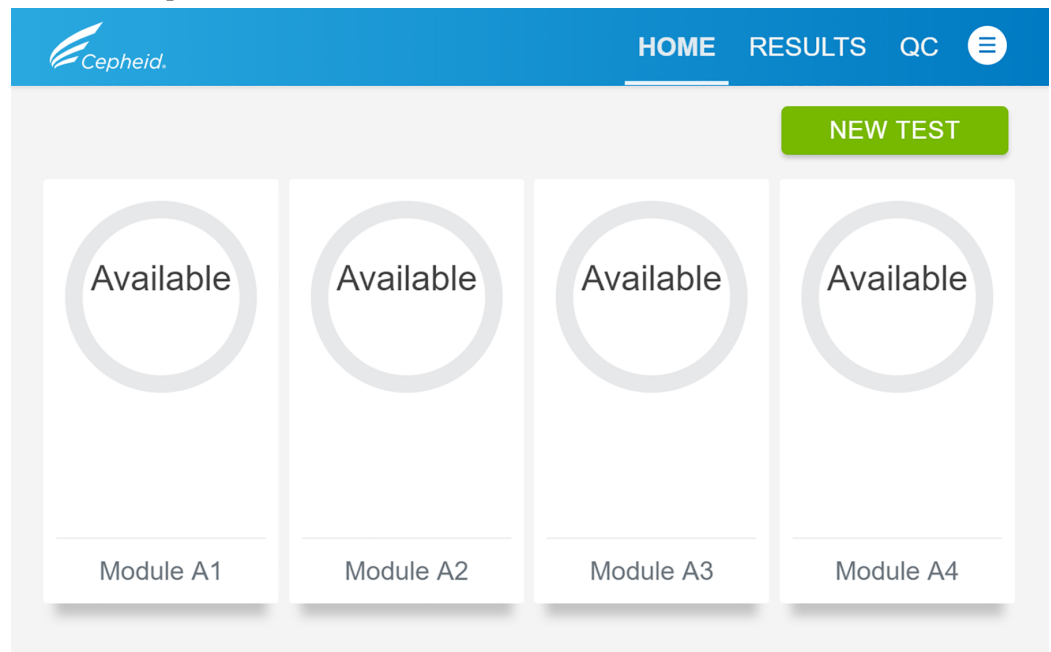


Figure 30. Home Screen - User Menu

2. Touch **User Menu** > **Logout**.

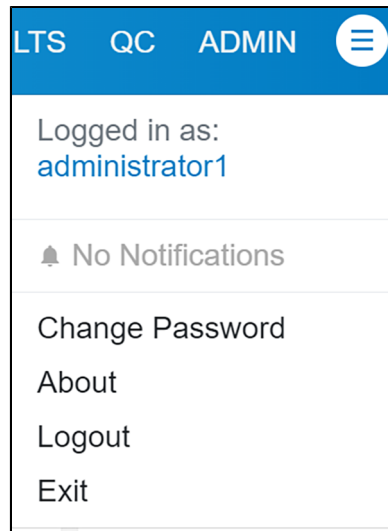


Figure 31. User Menu

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](#).

7.2 Exit the Software and Turn off the System

This section describes how to exit 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.

1. On the HOME screen, touch **User Menu** > **Exit**.

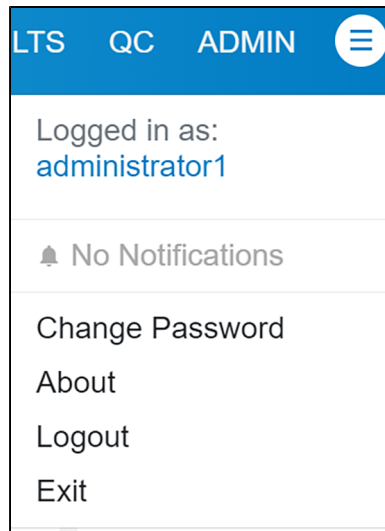


Figure 32. User Menu

2. A Confirmation screen appears. Select **Yes** to exit the software.
3. Touch Windows Start menu, touch Power icon, and select **Shut down**.
4. Wait about 10 seconds for Microsoft Windows to shut down (screen turns black) and press the power switch on the back of the touchscreen. The computer shuts down.
5. Press the power switch at the back of the GeneXpert II or IV Instrument. The instrument powers down.

The system is now shutdown.

8 Administration

8.1 Power Up the GeneXpert system with touchscreen

This section describes how to power up and log onto the GeneXpert system with touchscreen.

Note

The system may come up initially in the Cepheid-Techsupport account configuration. If so, touch the **Cepheid-Admin** button at the bottom of the screen.

Caution

You must log on using the preconfigured account. If you log on using a different user name and profile, the login will fail. Do not change the Cepheid user profile. Changing the profile can cause loss of data during a test.

1. Turn on the GeneXpert Instrument. The power switch is located on the back of the instrument. Press the switch to the **ON** (I) position.
After power has been turned on, the blue light on the front of the instrument illuminates.
2. Turn on the touchscreen. The power switch is located on the back of the touchscreen. Press the switch to the **ON** (I) position.
After power has been turned on, the blue light on the top of the touchscreen illuminates.
3. Wait for the system to boot. The Windows Opening screen appears. Swipe up anywhere on this screen to display the login screen.
The computer is configured with two Windows accounts. The Cepheid-Admin account is for administrator tasks such as software updates, system configuration and normal operation; and the Cepheid-Tech support account is for use only by Cepheid Technical Support.
4. On the Windows Login screen, touch **Cepheid-Admin**.
5. On the Cepheid-Admin login screen, enter the password and touch the arrow to the right of the Password field. The default password is "cphd" and must be changed upon initial login (as instructed by the software). After the password has been changed, enter the assigned password for future logins.

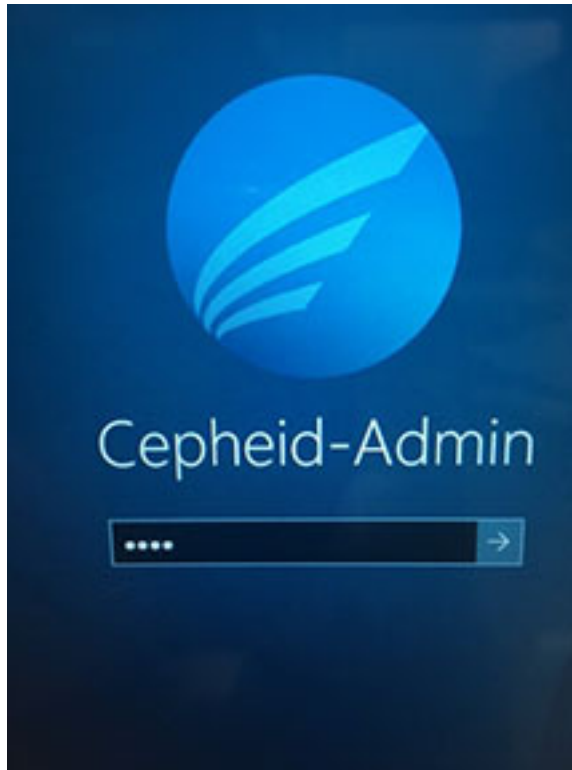


Figure 33. Administrator Sign In

6. Touch the arrow button at the right of the Confirm password field.
7. On the confirmation window, touch **OK** to complete the changing of password operation. The software launches.

The software starts.

8.1.1 Set the System Date and Time

To set or change the date and time:

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.
4. Touch **Time & Language**.
5. Touch **Date & Time**.
6. On the Date & Time screen you have two options for setting the date and time:
 - Automatically: Select your timezone. Touch **Adjust for daylight savings time automatically** if needed.
 - Manually: Touch **Change** and manually enter the Month, Day and Year. Then, scroll down and select the Hour, Minute and Second.

8.1.2 Rename Device

You can rename your GeneXpert system with touchscreen, if necessary.

1. Touch **Admin**, then **General Settings**.
2. Touch **Edit** and enter a new name in the System Name text entry box. Use system serial number or institutional naming protocol, etc.

8.1.3 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 window displays.
4. Touch **Devices**.
5. Touch **Printers and Scanners**.
6. Touch **Add a printer or scanner**.
7. Scroll to find the printer you want to connect the system to.
8. Touch **Add device**.
9. If your desired device did not display, touch **The printer I want isn't listed** and enter the network address.
10. Touch X to close the Windows Settings screen when finished.

8.2 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 HOME screen appears.

8.3 Administration Tasks

Administration functions available to an administrator are found under the Administration section and links to Reports, Instrument, and Users.

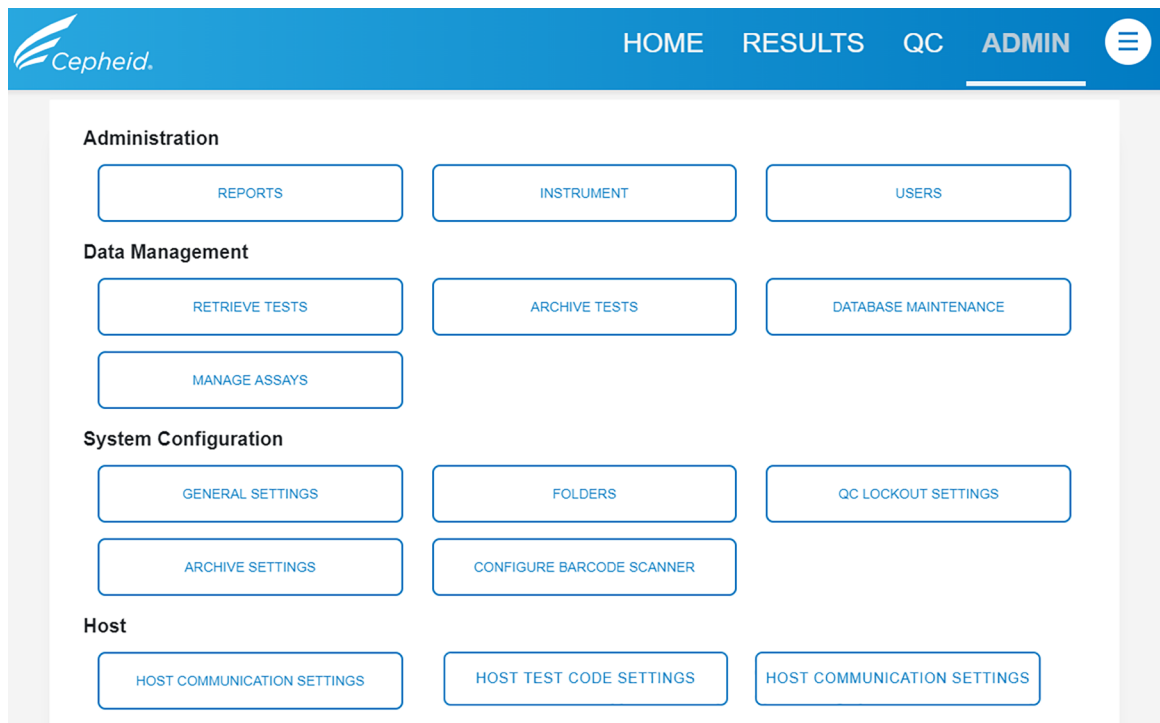


Figure 34. Administration Tasks Screen

8.3.1 Reports

When the Reports screen appears, **SYSTEM LOG** and **INSTALLATION QUALIFICATION** options are available.

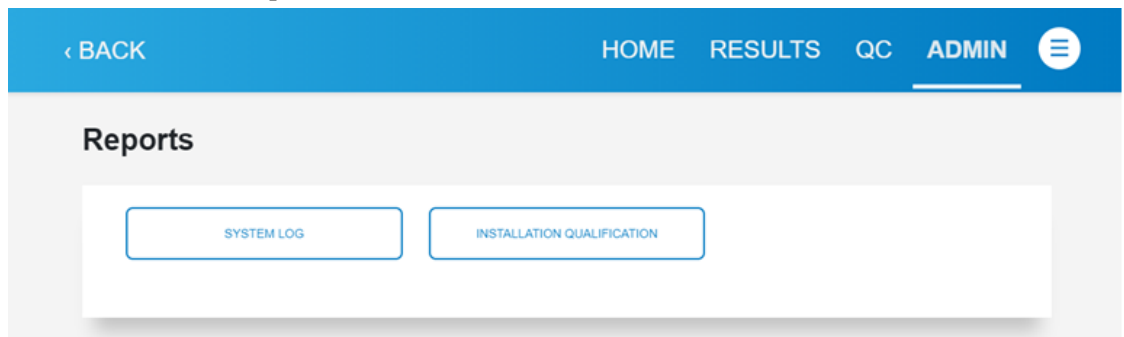


Figure 35. Reports Screen

8.3.1.1 Generate a System Log

On the Reports screen, touch **SYSTEM LOG**. The System Log screen appears.

The report shows the installed modules in the instrument, and the report can be used to provide incidents of instrument module self-tests and error to Cepheid when a module failure has been encountered.

1. Specify the following criteria to view the trends of interest:

Criteria	Options
Date Range	<ul style="list-style-type: none"> • All—Select to include all the records. • Date Range—Select to filter the records by specifying a range of dates. Entries older than one year are automatically removed.
Modules	<ul style="list-style-type: none"> • Currently Connected Modules—Displays modules that are connected to the system and are currently shown on the Instrument screen. This is the default option. • All Logged Modules—Displays all modules which have self-test or error entries in this system database within the last year. This allows Technical Support to obtain self-test/error entries for a module one-by-one, or by using one of the following buttons: • Select All—Selects every module shown in the table by checking all check boxes. • Select Individual Modules—Touch each module check box individually that you wish to include. • Deselect All—Deselect every module by clearing all check boxes.
Show	<ul style="list-style-type: none"> • Errors Only—Displays only error entries in the generated report file. • All Entries—Displays all self-test entries and error entries in the report.

2. To generate a report, touch **SYSTEM LOG** on the System Log screen.

The screenshot shows the 'System Log' interface. At the top, there is a navigation bar with 'BACK', 'HOME', 'RESULTS', 'QC', 'ADMIN', and a menu icon. Below the navigation bar, the title 'System Log' is displayed, and a 'SYSTEM LOG' button is visible in the top right corner. The main content area is divided into three sections: 'Date Range', 'Show', and 'Modules'. The 'Date Range' section has radio buttons for 'All' (selected) and 'Date Range', with 'Start Date' and 'End Date' fields below. The 'Show' section has radio buttons for 'Errors Only' (selected) and 'All Entries'. The 'Modules' section has radio buttons for 'Currently Connected Modules' (selected) and 'All Logged Modules'. Below this is a table with columns for 'Deselect All', 'Module Name', and 'Module Serial Number'. The table contains four rows of data, each with a checked checkbox, a module name (A1, A2, A3, A4), and a serial number (628907, 631805, 644020, 696595). At the bottom of the table, there is a pagination control showing '1'.

Figure 36. System Log Screen

3. The System Log Report appears. From this screen, scroll down to view the entire report, or touch the **Save** icon at the top of the screen to create a .pdf file of the report. Touch **Print** to send the report to the printer.

A dialog box appears, which enables a file to be saved to a specified location.

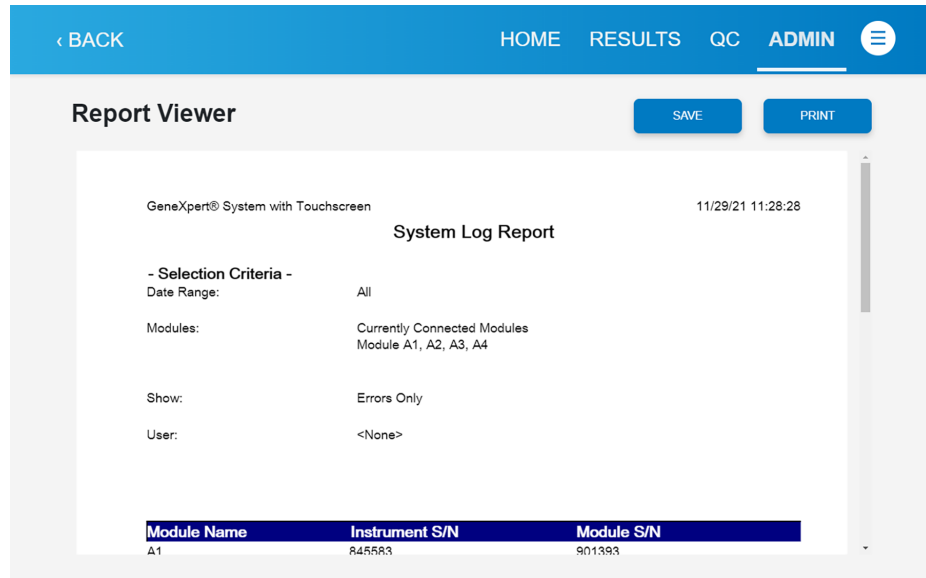


Figure 37. System Log Report

8.3.1.2 Generate an Installation Qualification Report

1. On the Reports screen, touch **INSTALLATION QUALIFICATION** and the Installation Qualification Report appears.

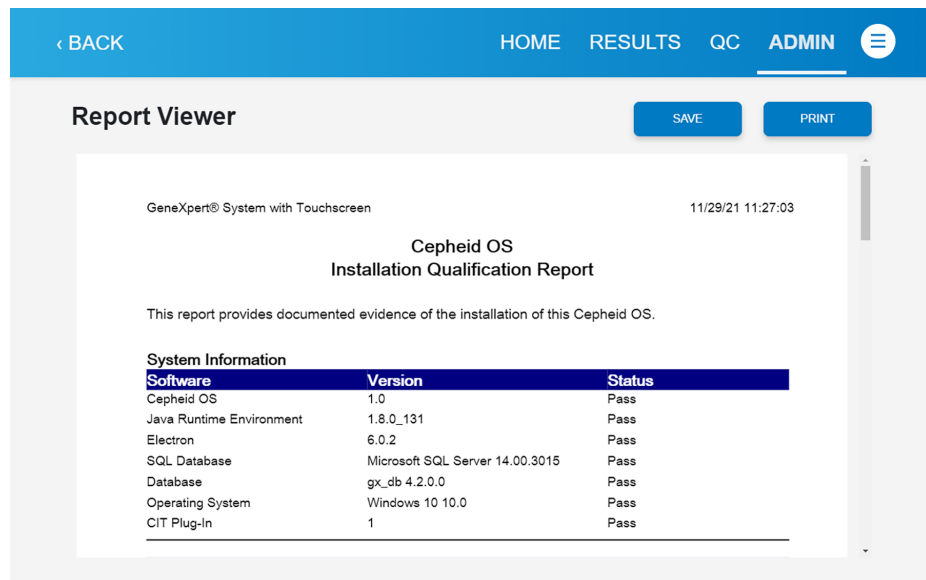


Figure 38. Installation Qualification Report

2. Touch **PRINT** to send a copy to the printer or to create a .pdf version of the file, or touch **SAVE** to save a copy.

Note

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.

8.3.2 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.

8.3.2.1 User Functions by Roles

The following table lists the functions that different user roles can perform.

Table 1. User Functions by Roles

User Role	Run Test	View Results	Perform Maintenance	Perform Administrative and System Functions
Basic	Yes	Yes	Limited	No
Administrator	Yes	Yes	Yes	Yes

8.3.2.2 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
- **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.

8.3.3 Instrument

On the Administration Tasks screen, touch **Instrument** to view the Instrument screen. The Instrument screen shows the available modules. Additional buttons on this screen allow the [exclusion of modules](#) from test or for [plunger rod maintenance](#).

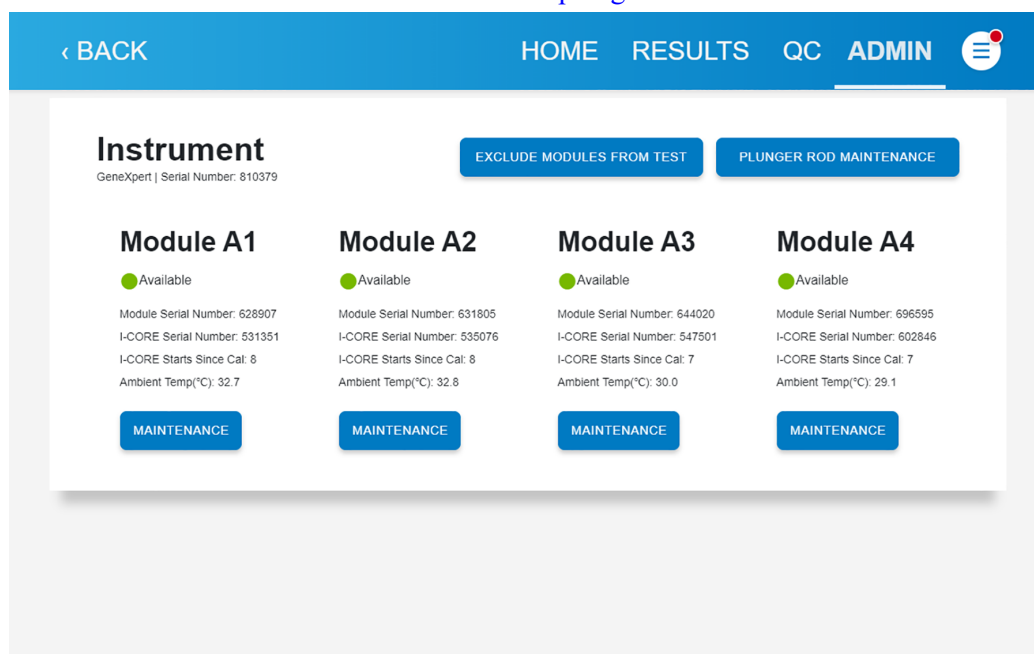


Figure 39. Instrument Screen

8.3.4 View User List

Prior to viewing the User List, if the user is list-managed by a Data Manager, 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 **ADMIN** from any user screen and the Administration Tasks screen appears.
2. Touch **HOST COMMUNICATION SETTINGS** and the Host Communications screen appears.
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.

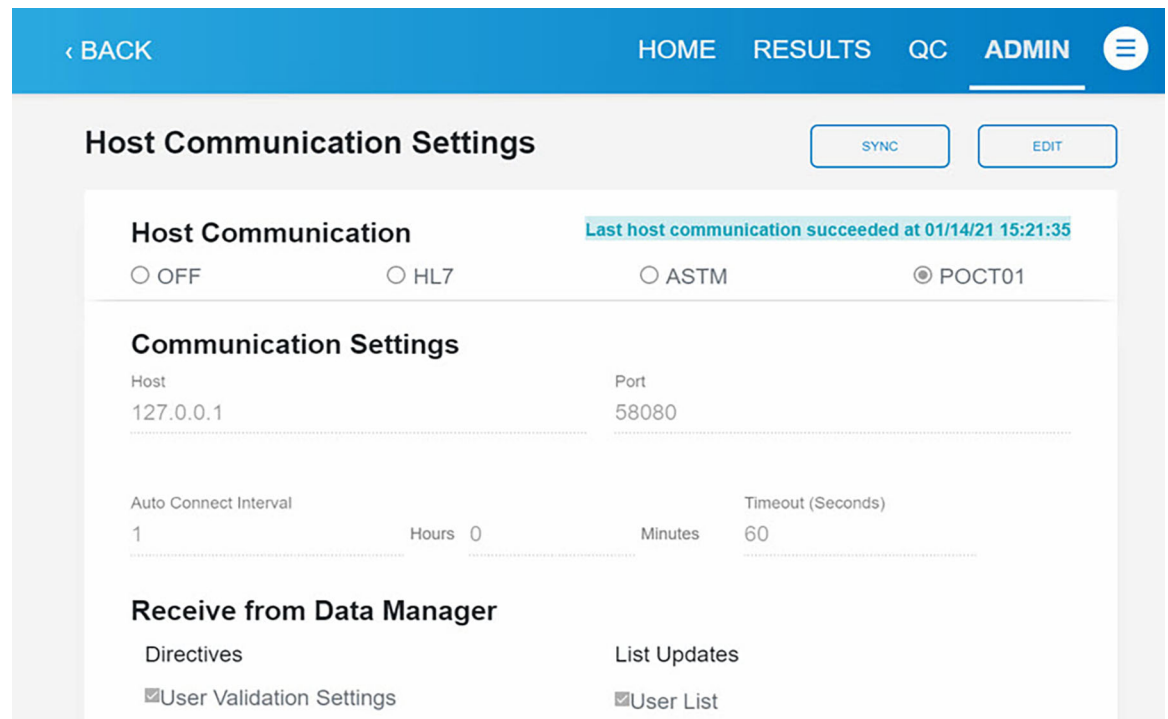


Figure 40. Host Communications Screen, Showing User List Selected

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.

- Return to the Administration screen, and touch **USERS**. 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.

User Name	Full Name	User Type	Expiration Date
2TuzntJyqB1hib3ZbqEtEI1BC	mwpd8duBq2hmpaz7DXJ1aaLDh Re7UewMmG7CHc4DAAxSRRp59 KeJgdxhX6jcM	Basic	01/14/26
2VENbK7Ko	jW842nHVggCjepe	Basic	01/14/26
2xufG7	vn8mJMijY3m2D1Jlfgsao9hZi9LC vWin7ZZ83zkQeaDTJUNU8m7rSJ 14OqF5fBZOOK2zudlNSg	Basic	01/14/26
2YfiJnkXrCOSid6lylXbiUdLUIR	fOp48qibUGBk	Basic	01/14/26
39cFlDj1sa2e	WGq2pnpsPrDLhAEH093SaRr9DJ IBiV6T03OFfvVJ3p1pbQnE9jebAr aYAagtaJSvjTMh5fPVGfpOX4K3v AZ9w8eyQd5eXkQwWpki5Ldua	Basic	01/14/26
3FybfYuUST	6fCbi7m0LJaWGXpPikrNm	Basic	01/14/26

Figure 41. Users Screen, Showing Active List of Users

8.4 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.

8.4.1 Add or Remove Users Locally (without Host Communication)

1. On the Administration Tasks screen, touch **USERS**.
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.

The screenshot shows the 'Add User' screen. At the top, there is a blue navigation bar with the following items: a back arrow and 'BACK', 'HOME', 'RESULTS', 'QC', 'ADMIN' (which is underlined), and a menu icon. Below the navigation bar, the title 'Add User' is displayed on the left, and 'CANCEL' and 'CONFIRM' buttons are on the right. The main form area contains the following fields:

- User Name: Admin user
- Full Name: Admin user
- Password: *****
- Confirm Password: *****
- User Type: Admin (with a dropdown arrow)

Figure 42. 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.

8.4.2 Add or Remove Users in Data Management System

1. From any screen, touch **ADMIN** to access the Administration Tasks screen.
2. On the Administration Tasks screen, touch **HOST COMMUNICATION SETTINGS**.
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.

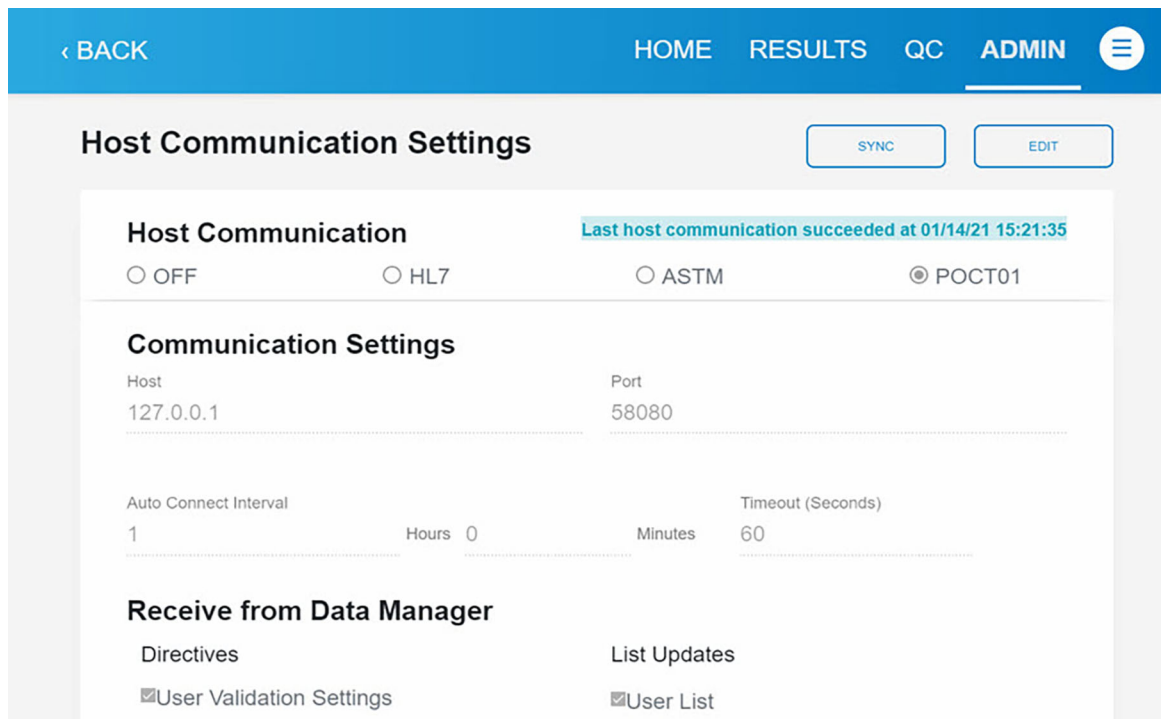


Figure 43. Host Communications Settings Screen Showing User Validation Settings Check Box

4. From any screen, touch **ADMIN** to access the Administration Tasks screen.
5. On the Administration Tasks screen, touch **USER VALIDATION SETTINGS**. The User Validation Settings screen appears, showing the active option selected. 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 touchscreen.

8.4.3 User Lists from Data Management System

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

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.

8.4.4 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. From any screen, touch **ADMIN** to access the Administration Tasks screen. When the screen appears, touch **HOST COMMUNICATION SETTINGS**. The Host Communication Settings screen appears.
2. 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.

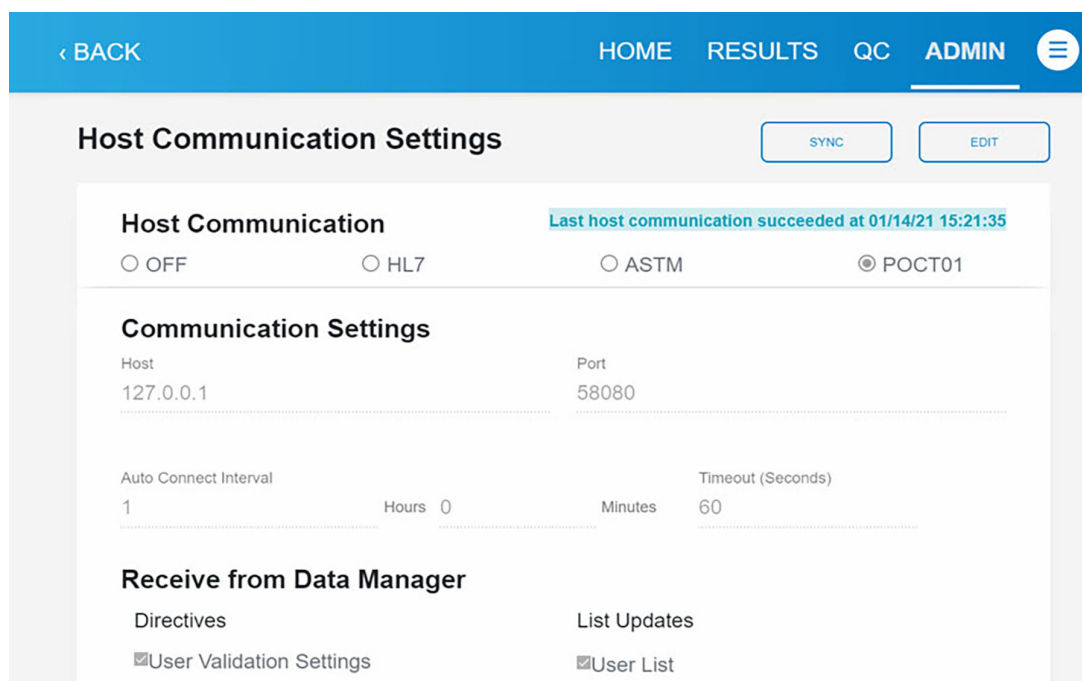


Figure 44. Host Communications Settings Screen Showing User Validation Settings Checked

Note

When POCT01 is selected on the Host Communication screen, the User Validation settings radio button appears, but it is grayed out. Select **User List** radio button to enable **User Validation Settings** on the Administration Tasks screen.

3. From any screen, touch **ADMIN** to access the Administration Tasks screen.
4. On the Administration Tasks screen, touch **USER VALIDATION SETTINGS**. The User Validation Settings screen appears, showing the active option selected.

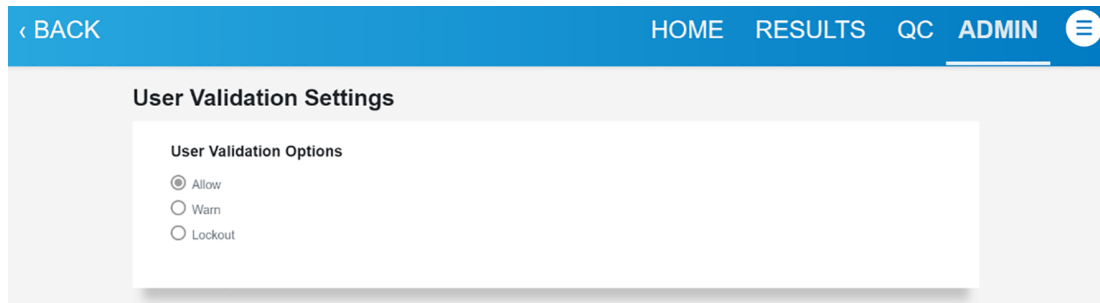


Figure 45. User Validation Settings Screen

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.

8.4.5 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.

8.5 Data Management Tasks

The ADMIN screen allows several Data Management tasks, including: Retrieve Tests, Archive Tests, Maintain Database and Manage Assays.

8.5.1 Retrieve Tests

1. On the ADMIN screen, touch **RETRIEVE TEST**.
The Open dialog box appears.

2. Select any archived files to retrieve, and then touch **Open**, or touch **Select All**.

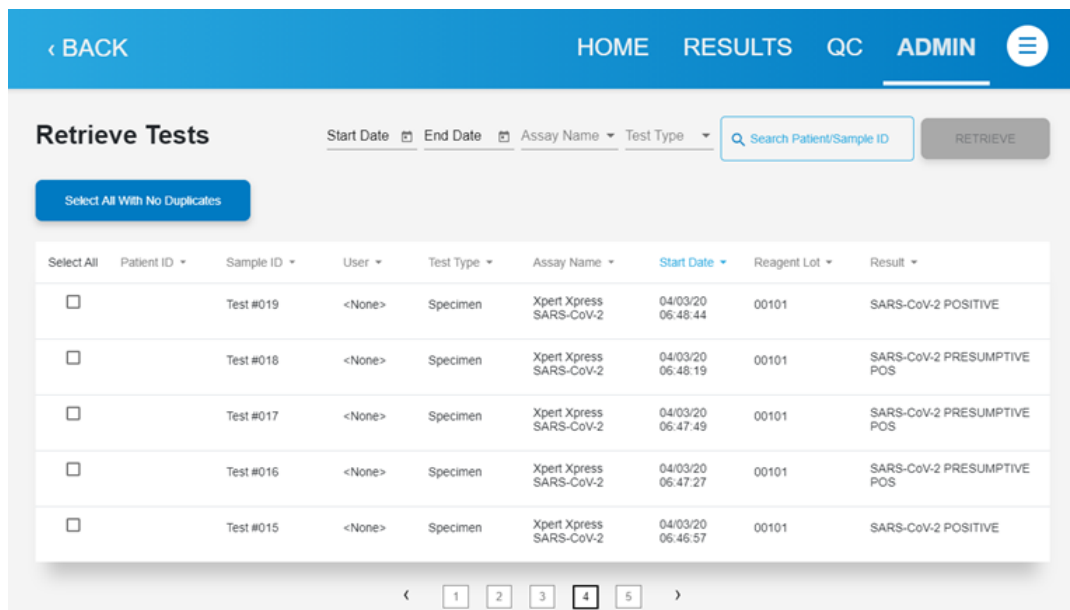


Figure 46. Retrieve Tests

If there are tests in the archive that already exist in the database, the Retrieve Test(s) dialog box indicates the number of duplicate tests. Touch **OK**.

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

The tests that already exist in the current database appear in red text.

4. Touch **RETRIEVE** to retrieve the selected test(s). A confirmation screen appears. Touch **YES** to continue with the retrieval.

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

8.5.2 Archive 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 safe-keeping 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.

1. On the Administration Tasks screen, touch **ARCHIVE TESTS**.
2. On the Archive Tests screen you can:
 - Cloak IDs—Select this check box if you want to send Cepheid Technical Support some data in question, 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. See [Purge Tests from the Database](#) for more information.

3. Select any tests to be included from the archive by touching the Check Box at the left of the test, or touch **Select All**.

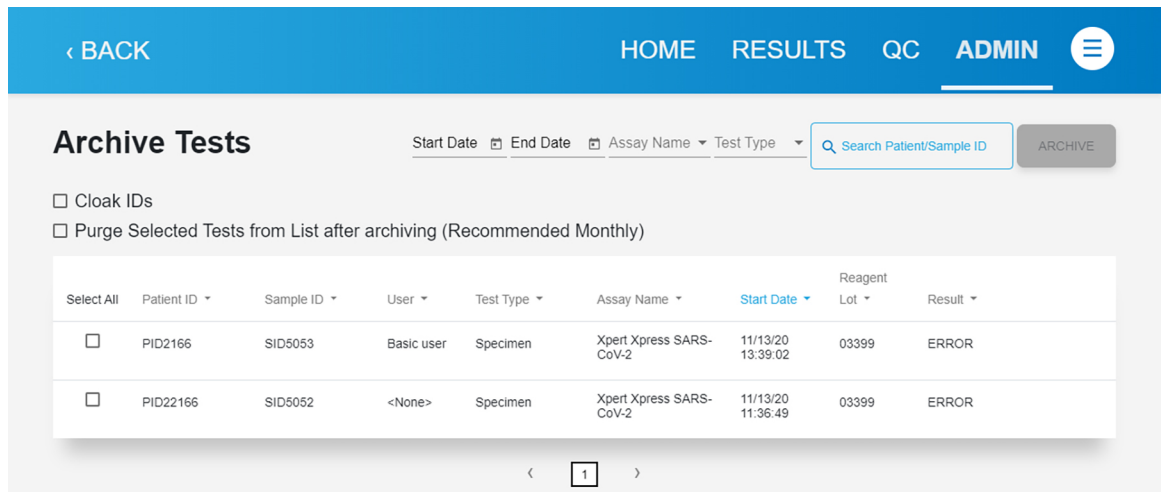


Figure 47. Archive Tests Screen

The screen will change to indicate the selected tests with a white check mark on a blue Check Box. The Select All button has now changed to Deselect All.

4. Touch **Archive**.
A confirmation box appears, showing the number of tests to be archived.
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.

8.5.3 Purge Tests from the Database

When tests have been archived, they have not been permanently deleted from the computer. Tests may be purged from the active database after they have been archived.

1. On the ADMIN screen, touch **ARCHIVE TESTS**.
2. Select **Purge Selected Tests from the List after archiving (Recommended Monthly)**.
3. Select the tests to be purged, or touch **Select All**.
4. Touch **Archive**.

The tests selected to be purged are removed from the archive database.

8.6 Database Maintenance

The database is a history file of previously-run tests, showing patient information, sample information, test type and results, system configuration, Assay Definition Files, User Administration, etc.

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 touchscreen 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 test is required.

Note

Database management cannot be performed while host communication is enabled. The user must disable host communication to perform database maintenance.

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

8.6.1 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.

To back up the database:

1. On the Database Maintenance screen, touch **DATABASE BACKUP**.

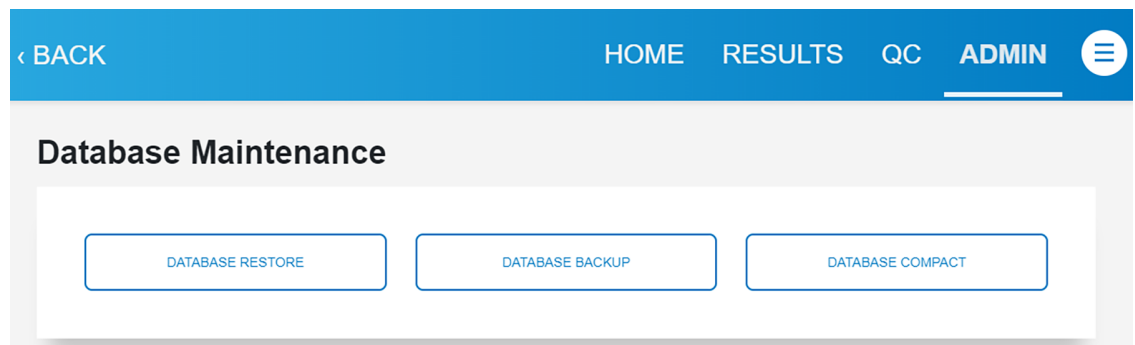


Figure 48. Database Backup

A screen appears with the default database filename.

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**.

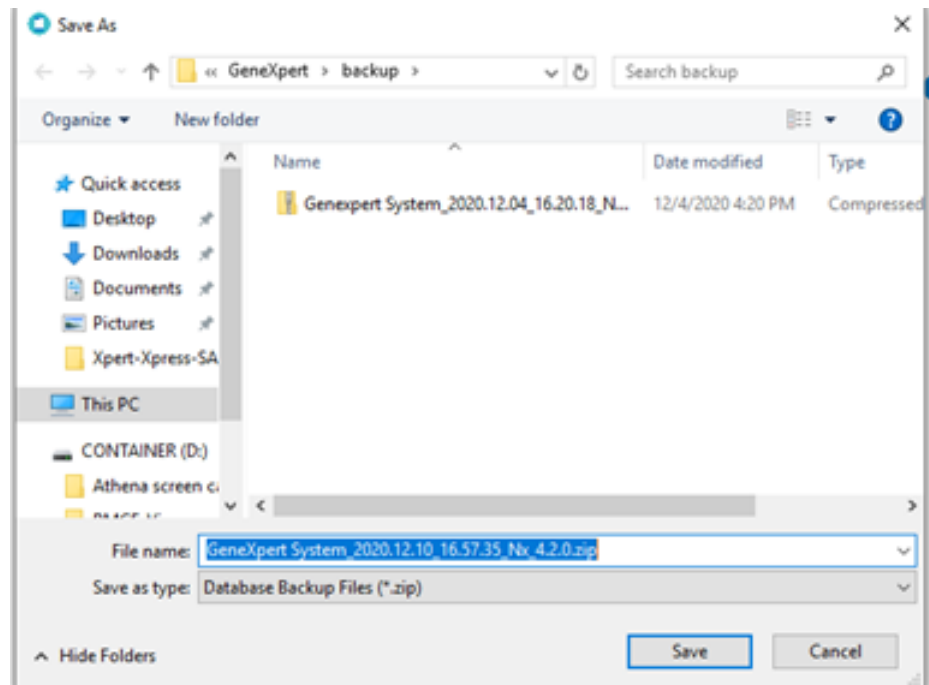


Figure 49. Database Backup Default Filename

The backup process creates a .zip file in the location you specified.

The default database backup location is the Backup folder which is located on the system touchscreen hard drive. To guard against loss of data, the files in the Backup folder should be periodically copied to a different computer or server. If the touchscreen is connected to a network, it is possible to back up the files directly to a server.

8.6.2 Restore the 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.

Caution



The database restore process overwrites the data in the current database. Do not restore a database unless the current database is corrupted or needs to be replaced.

1. On the Database Maintenance screen, touch **DATABASE RESTORE**.

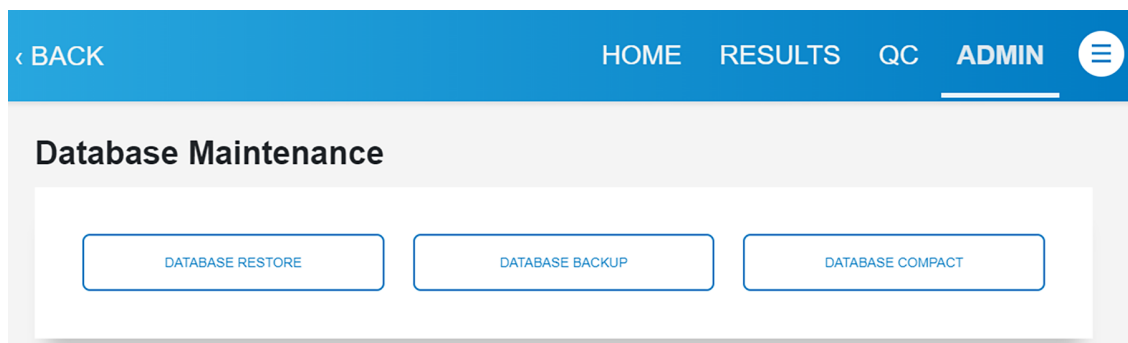


Figure 50. Database Restore

2. A screen appears, asking if you want to create a backup of your current database before proceeding. Choose **YES** or **NO**.
 - If you choose **NO**:
 - a. An advisory screen appears, stating “Database Restore will **OVERWRITE** your current database with a backup database.” Touch **CONFIRM** to acknowledge the message and continue.
 - b. A screen appears with a listing of database backup files. Select a database backup file from the available listings in the upper window, and it appears in the File name: field bottom of the screen.
 - c. Touch **Open** at the bottom of the screen. The Database restoration begins. When the restoration is complete, a message advises that the software will now shut down.

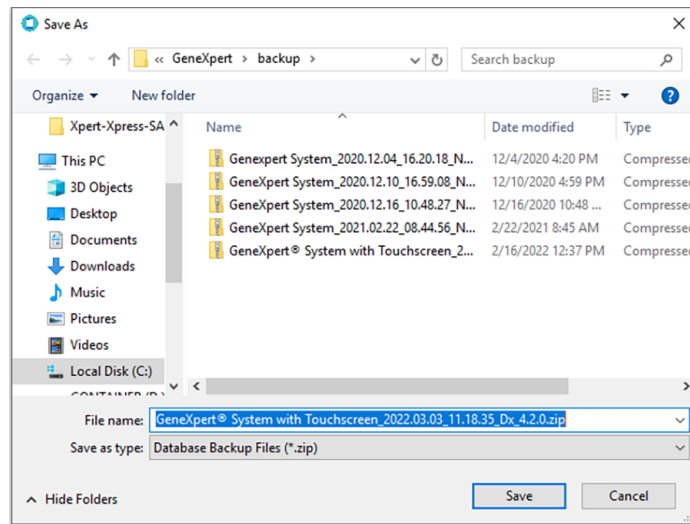


Figure 51. Database Backup File Folder

- If you choose **YES**:
 - a. A screen appears where you select a database backup file from the listings in the upper window. The file then appears in the File name field. Touch **Save**.
 - b. Database backup will begin, and when it is done an advisory screen appears stating that database backup is complete. Touch **OK** to continue.
 - c. A new advisory screen appears, stating that “Database Restore will **OVERWRITE** your current database with a backup database.” Touch **CONFIRM** to acknowledge the message and continue.
 - d. A new filename screen appears. Select a file from the backup listing, and touch **Open**. Navigate to the archive location and touch **Save**.
 - e. The Restore in Progress screen appears, and when it is complete, another information screen appears, with a message that the software will now shut down. Touch **OK** to confirm.

8.6.3 Compact the Database

Compact the database periodically to ensure efficient use of the space in the database and to save hard disk space.

To compact the database:

1. Select **Compact Database** on the Database Management window.
2. Click **Yes** on the confirmation dialog box.

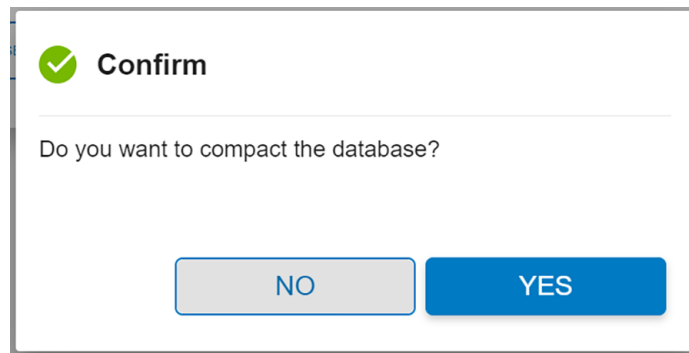


Figure 52. Compact Database Confirmation Screen

3. When the database compacting has completed, the Compact Database complete dialog box appears.
4. Click **OK**.

Note

In addition to compacting the database, you can also save space by purging tests from the database after archiving. For details on deleting archived tests, see [Purge Tests from the Database](#).

8.7 Manage Assays

An assay definition file 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.

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

8.7.1 Delete Assays

Caution



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

1. To delete an assay definition file, in the Manage Assays window, select the Check Box at the left corresponding to the assay to be deleted, and touch **DELETE ASSAY**.

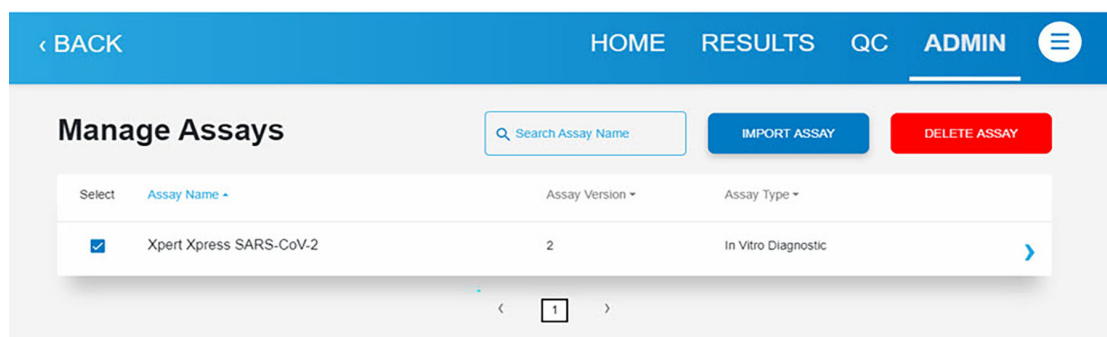


Figure 53. Manage Assays Screen Showing DELETE ASSAY Button

- On the Confirm message, touch **YES** to delete the assay definition file.
The assay definition file is deleted and removed from the list of assays.

8.7.2 Options for Importing Assay Definition Files

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

8.7.2.1 Connect a DVD Drive to the System

This section describes how to connect the DVD drive supplied with the system to import assay definitions from the CDROM.

- 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.

- Plug the DVD drive into one of the available USB ports on the rear of the touchscreen.
- Press the Eject button on the front of the DVD drive to open the door.
- The CDROM is located in the assay kit. Insert the assay definitions 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.
- 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.
- Disconnect the DVD drive from the touchscreen and store it and the cables to it in the event they are needed in the future.

8.7.2.2 Import Assay Definition File from CD

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

Note

Although in vitro diagnostic assay definitions can be imported, the Cepheid OS software does not allow the assay definitions to be modified.

1. On the Admin screen, touch **MANAGE ASSAYS** to import new assay definitions.
2. On the Manage Assays screen, touch **IMPORT ASSAY**.
3. Navigate to the DVD and to the folder containing ADF files. Locate and touch the assay definition (.gxa) file.
The assay name appears in the filename field.
4. Touch **Open** to import the file into the system.

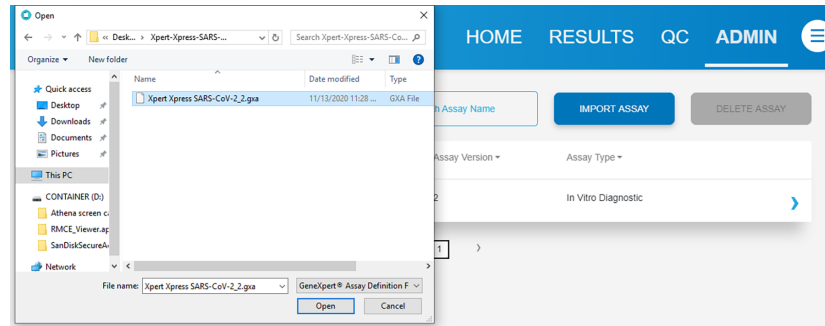


Figure 54. Import Assay

The new assay name and version number appear in the Assay list.

5. If you need to import additional assay definition files from the same CD, repeat Step 2-3.

Note

For combination assays that have multiple .gxa files, import only the assay definition files for assays that will be performed in your lab.

8.7.2.3 Download ADFs and Package Inserts from the Cepheid Website

To download assay definition files or package inserts 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 or package insert 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 and package inserts.
5. Read and follow the Assay Import Instructions to download the ADF and package insert 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.

8.8 System Configuration

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.

8.8.1 General Settings

On the General Settings screen, the Administrator can set the date and time format, Patient Information characteristics, Institutional ID login requirements, and audio reminder notifications.

Touching the check box to the left of Institutional ID will prompt the user to log in to the system using the barcode scanner, rather than entering a **User Name** and **Password** using the virtual keyboard.

Require Start Test Login determines if the Login screen appears when a new test is initiated. The user can select **Never**, **Always**, or choose **Start Test Login Timeout** and select a value in minutes from the drop-down menu.

To edit any entries on this screen, touch **EDIT**, make any desired changes and touch **CONFIRM** when you are finished.

The screenshot shows the 'General Settings' screen. At the top, there is a blue navigation bar with 'BACK', 'HOME', 'RESULTS', 'QC', and 'ADMIN' options. Below this, the title 'General Settings' is displayed with an 'EDIT' button to its right. The settings are grouped into sections:

- System Name:** GeneXpert® System with Touchscreen
- Date Format:** MM/DD/YY
- Time Format:** 24 Hour (hh:mm:ss)
- Patient Information:**
 - Use Patient ID
 - Patient ID 2
 - Patient Name
- Institutional ID:**
 - Login with Institutional ID

Figure 55. General Settings

8.8.2 Folders

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

1. To access this menu to make changes in the folder locations, touch the **FOLDERS** button on the Administration Tasks screen.
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.

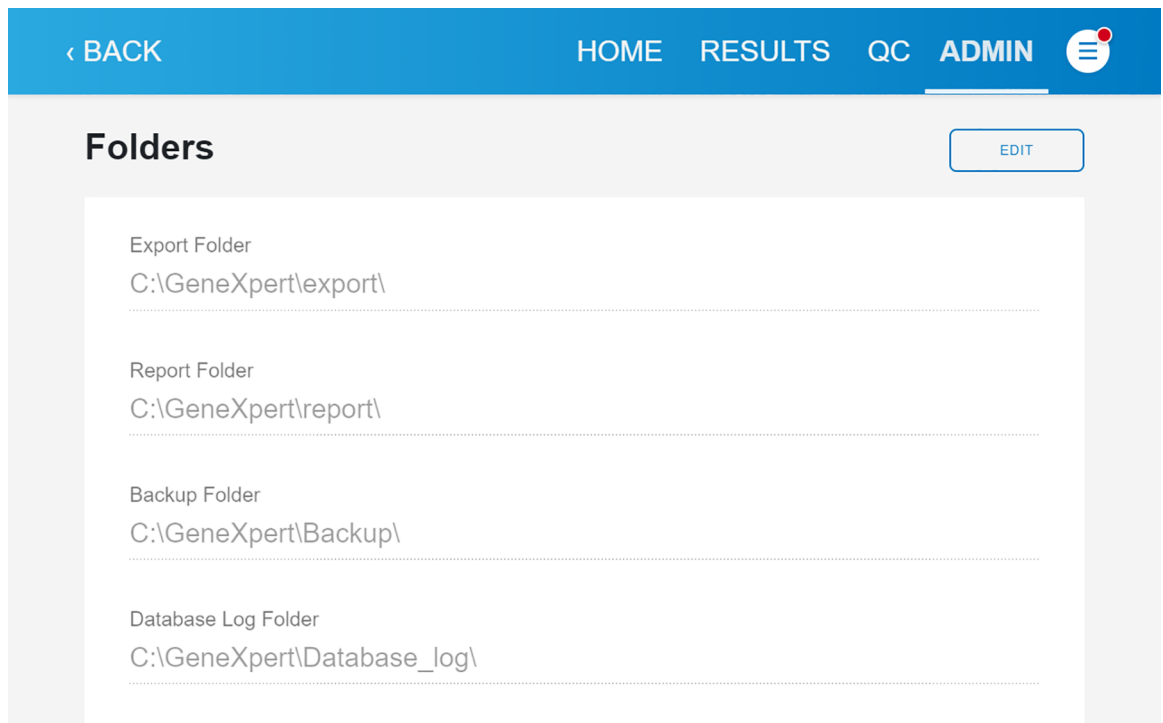


Figure 56. Folders Screen

8.8.3 Set QC Lockout Settings

The QC lockout feature allows an administrator to prevent a specific assay from running patient samples until the applicable Quality Controls (QC) test have been run and produce valid results. The QC test can be specified to be run at required intervals or at the beginning of a new lot of cartridges.

Use the QC Lockout Settings screen to change the settings for QC Lockout.

1. On the Admin screen, touch **QC LOCKOUT SETTINGS** to display the QC Lockout Settings screen.
2. Use the QC Lockout Settings screen to enable or disable QC Lockout for all assays, make any changes in the frequency of QC Lockout, choose between Assay-based or Reagent Lot-based lockouts, change the Lockout frequency setting, the reminder notification for the upcoming QC tests (in hours) and the expiration period of QC Notifications. Touch **EDIT**, and make any changes to the settings.
 - Under Quality Control Lockout, touch the **Enable QC Lockout for All Assays** check box to select Once, Daily, Weekly or Monthly from the Frequency drop-down menu.
 - Under Lockout Settings, choose **Assay Based** to the lockout of a specific assay.
 - Under Lockout Settings, choose **Reagent Lot Based** to lockout of each reagent lot.
 - Under Notification Settings, select the time interval from the Reminder for upcoming QC tests in hours drop-down menu.
 - To delete QC reminders: Under Expire QC Notifications, touch the check box, and then select the expiration time interval using the drop-down menu at Delete QC Reminders.

Figure 57. QC Lockout Settings Screen

3. Touch **CONFIRM** when you are finished.

8.8.4 Set Archive Settings

Use the Archive Settings screen to change the Archive Test Results time settings.

1. On the Admin screen, touch **ARCHIVE SETTINGS** to display the Archive Settings screen.
2. Choose between **Manually** and **Manually, with Reminder**. Choose the appropriate time interval for your organization.

Figure 58. Archive Settings

8.8.5 Configure the Barcode Scanner

Use the following section to scan a configuration barcode to configure the barcode scanner. On the Admin screen, touch **CONFIGURE BARCODE SCANNER** to display the Configure Barcode Scanner screen.

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

1. Print the matrix shown.



Figure 59. Configuration Data Matrix Barcode

2. Using the Configure Barcode Scanner screen, touch **ENABLE SCANNER**.
3. Scan the Configuration Data Matrix barcode printed, to reconfigure the scanner.

8.9 Host (LIS) Management and Settings

8.9.1 Manage Host Orders

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

1. On the Admin screen, touch **MANAGE HOST ORDERS** to display the Manage Host Orders screen.
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.
 - **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.

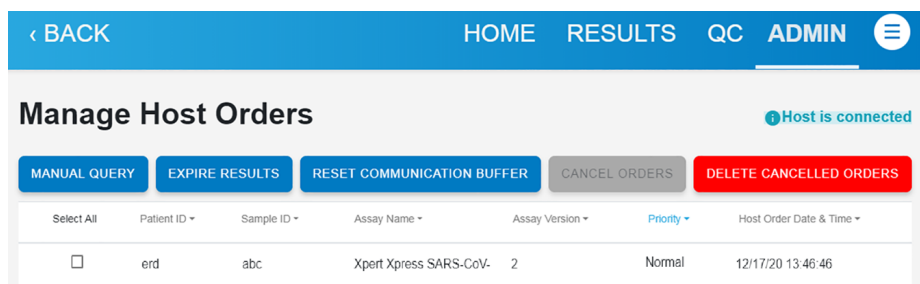


Figure 60. Manage Host Orders – Delete Cancelled Orders

8.9.2 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. On the ADMIN screen, touch **HOST TEST CODE SETTINGS** to display the Host Test Code Settings screen.

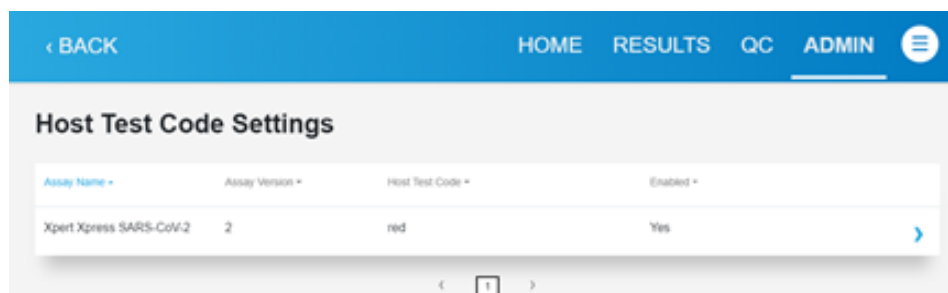


Figure 61. Host Test Code Settings

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 **CONFIRM** to save the changes. Close the screen.

8.9.3 Host Communication Settings

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

On the Admin screen, touch **HOST COMMUNICATIONS SETTINGS** to display the Host Communications Settings screen.

On the Host Communications screen, the administrator can enable or disable host LIS or Data Manager communication, set up communication settings including changing the host ID name, changing protocol between HL7 and ASTM, POCT01, and choose to run the touchscreen as either a server or client, as described below.

In addition, settings are provided for automatic host Query after Sample ID scan, automatic test order downloading and result uploading, and choosing instrument specimen identification.

The Host Communications screen also displays the server IP address and port settings. To change any of these setting, touch **EDIT**, 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.

When a Host is connected, the status in the right side of the screen displays in blue that a Host is Connected.

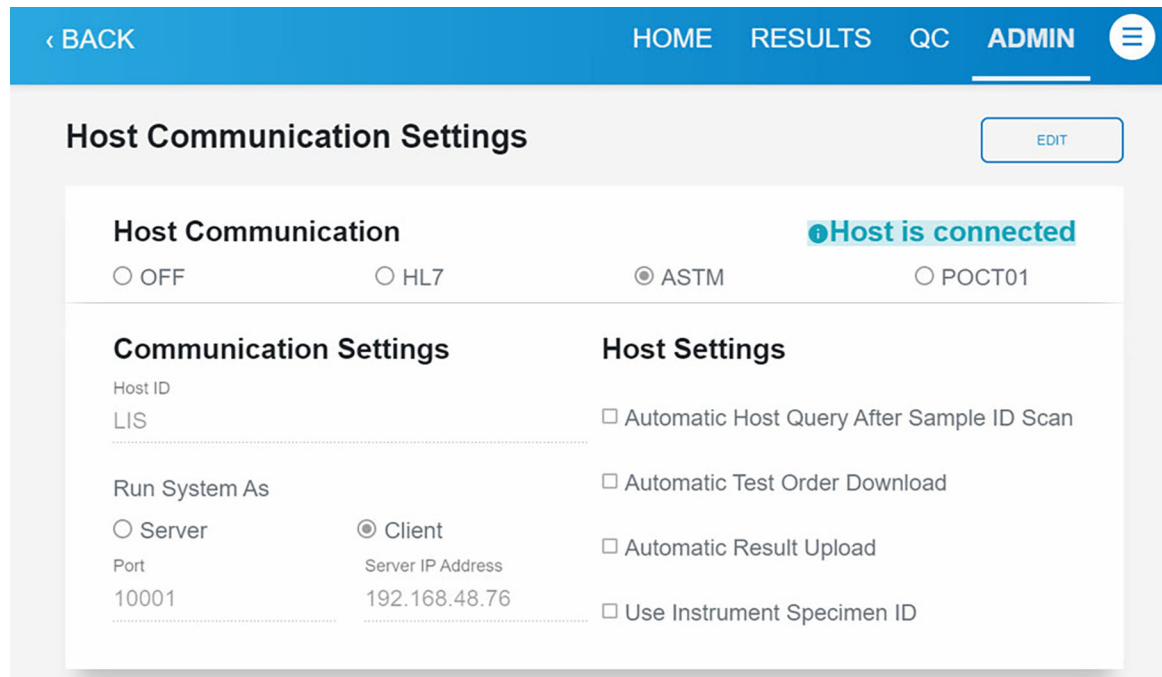


Figure 62. Host Communication Settings Screen Showing Host is Connected

If the Host is disconnected, the display appears in red stating that the Host is disconnected. If this is unexpected, please see [Troubleshoot the LIS Interface](#) or [Section 26. Troubleshoot the POCT Interface](#).

Figure 63. Host Communications Settings Screen Showing Host is Disconnected

Note If the LIS is being enabled on a new system, no assays are shown.

Caution  **Within the hospital or laboratory network, each system should have a unique system name, which is used for host communication. The System Administrator should control the process for defining system name.**

Host (LIS) Settings Descriptions

Use the following settings to configure the communication between the Cepheid OS software and a Laboratory Information System (LIS):

Host Communication

- **Enable Host Communication**—Select to enable the software connected to a host. Clear to disable the host communication.

Host Settings

- **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.

If the facility provides unique sample identification, this setting should be disabled.

- **Communication Settings**—Select or clear the following check boxes:
 - **Protocol**—Select HL7-compatible or ASTM-compatible protocol.

Note

HL7 or ASTM protocols can be used to connect to data manager software for test orders and result entry only.

- **Run As**—radio button with options: Server and Client (default).
 - **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.
-

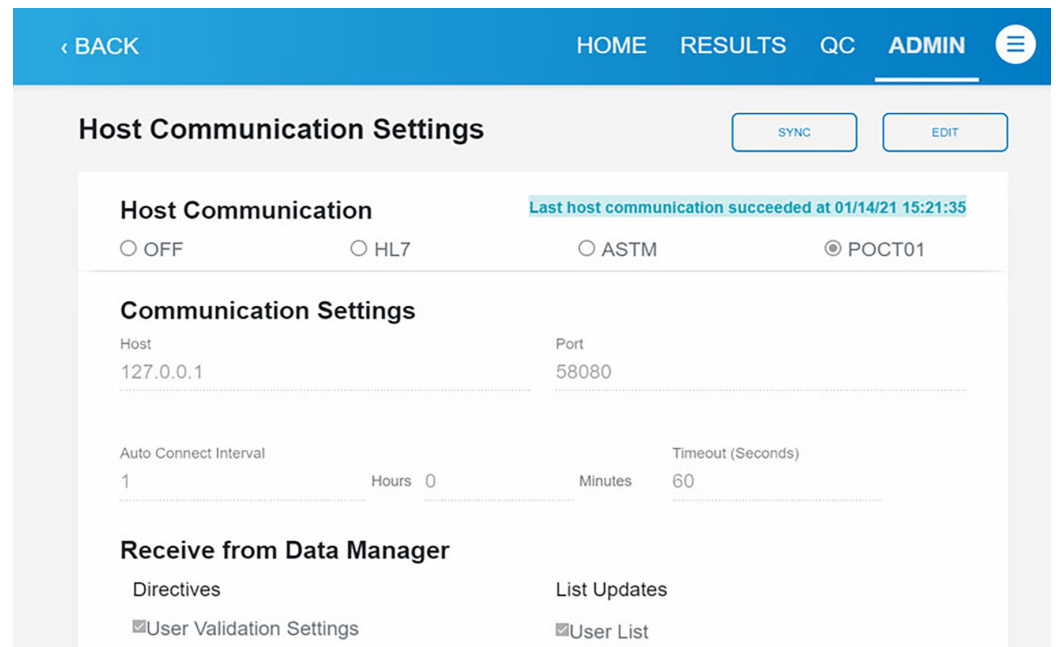
Important The network port that is dedicated for the GeneXpert IV Instrument should not be used for the host connection. The second NIC available on each touchscreen should be used to connect the touchscreen to the host.

- **Host ID**— 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.

Host (POCT) Communication Settings Descriptions

Use the following settings to configure the communication between the Cepheid OS software and a Laboratory Information System (LIS):

- **Host Communication**
 - **Enable Host Communication**—Select to enable the system software to connect 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.



Host Communication Settings

Host Communication: OFF HL7 ASTM POCT01

Last host communication succeeded at 01/14/21 15:21:35

Communication Settings

Host: 127.0.0.1 Port: 58080

Auto Connect Interval: 1 Hours 0 Minutes Timeout (Seconds): 60

Receive from Data Manager

Directives: List Updates:

User Validation Settings User List

Figure 64. Host Communication Settings Screen Showing Last Host Communication

- **Communication Settings**—Select or clear the following check boxes:
 - **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.

- **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 one hour. 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 (discussed below)** during normal operation; otherwise, you would have to re-download orders and re-upload results.

8.10 Operate with Host (LIS) Connectivity (Admin Only)

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 [Section 25. Troubleshoot the LIS Interface](#))

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:

Caution



- Cepheid OS software version
 - The touchscreen **Host Communication Settings**
 - Host middleware software or configuration changes
 - LIS software or configuration changes
-

8.10.1 Create a Test with Host Connectivity (Admin)

When host connectivity is enabled, the touchscreen periodically requests new orders, and test orders can be automatically downloaded from the host.

An Admin can perform manual queries of new orders from the Manage Host Orders screen and can also view new test orders from the Manage Host Orders screen which have been automatically downloaded from the host.

Any user can scan or manually enter the Sample ID to perform host query for orders for a specific Sample ID.

The workflow in your laboratory will determine how a test is created.

1. Select Host Order Screen.

When any user scans a sample and the order is in the system, the Select Host Order screen appears, and the host order appears on the screen.

- #### 2. Manage Host Orders Screen.
- To perform a manual query of Host Orders, touch **ADMIN** on the HOME screen, and the Administration Tasks screen appears. Touch **MANAGE HOST ORDERS** at the bottom of the screen, and the Manage Host Orders screen appears.

- **Patient ID**—Patient ID for each test order (If Use Patient ID is configured).
- **Sample ID**—Sample ID for each test order.
- **Assay Name**—Assay name for each test order.
- **Assay Version**—Assay version number for each test order.

- **Priority**—Indicates whether it is STAT priority or Normal priority.
- **Host Order Date & Time**—Date and Time downloaded by the host or created by the touchscreen as date and time received.
- **CANCEL ORDERS**—Flags a selected order for cancellation.
- **DELETE CANCELLED ORDERS**—Deletes the flagged order(s).
- **EXPIRE RESULTS**—Changes Upload - Pending and Review to Expired.
- **MANUAL QUERY**—Allows manual query of the host for any available new orders.

Note

To accept an order from the host, the test code for the assay must be set up by the host administrator. See [Set Host Test Code Settings](#) for details.

8.10.2 Create a Test by Selecting from a List of Test Orders Downloaded by the Host Automatically

1. In the Host Communication Settings tab of the System Configuration dialog, touch **Automatic Test Order Download** check box to select and enable this function.

Figure 65. Automatic Test Order Download Selected

The system periodically queries all test orders from the host. The period is fixed in the software as 1 minute.

Note

If there are test orders from the host, there should be samples on hand for the tests ordered.

2. On the Home screen, touch **NEW TEST**.
3. Scan or enter the optional Patient ID, Patient ID 2, Patient Name, if enabled.

Do not use the following symbols in this area: | @ ^ ~ \ & / : * ? " < > ' \$ % ! ; () -.

If invalid characters are manually entered or scanned, there will be a software notification to the user.

The Scan Sample ID Barcode screen appears.

4. Scan the Sample ID barcode on the specimen container using the barcode scanner.
5. The Select Host Order screen appears, showing the test order corresponding to the Sample ID scanned. Select the order by touching **Select** on the right side of the screen.

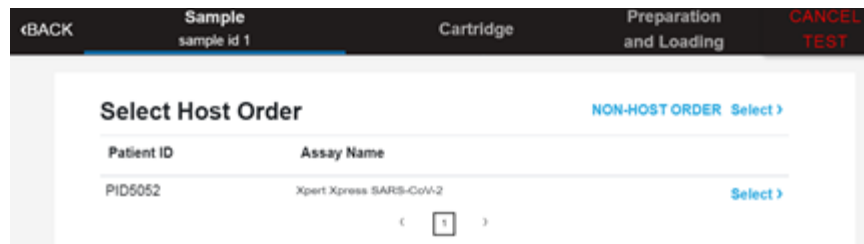


Figure 66. Select Host Order Screen

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.
7. The order for this Patient ID and Sample ID will be removed from the list of new orders.
8. Insert the cartridge with the specimen and reagents according to the assay-specific package insert.
9. Load the cartridge, and close the module door.

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.

8.10.3 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](#).

8.10.4 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.

The screenshot shows the 'Host Communication Settings' screen. At the top, there is a navigation bar with 'BACK', 'HOME', 'RESULTS', 'QC', and 'ADMIN' (selected), along with a menu icon. Below the navigation bar, the title 'Host Communication Settings' is displayed, with 'CANCEL' and 'CONFIRM' buttons to the right. The main content area is divided into three sections: 'Host Communication', 'Communication Settings', and 'Host Settings'. In the 'Host Communication' section, 'ASTM' is selected with a radio button. The 'Communication Settings' section includes 'Host ID' (ASTM Client), 'Run System As' (Client selected), and 'Port' (2222). The 'Host Settings' section includes 'Automatic Host Query After Sample ID Scan' (checked), 'Automatic Test Order Download' (unchecked), 'Automatic Result Upload' (unchecked), and 'Use Instrument Specimen ID' (unchecked).

Figure 67. Automatic Host Query Selected

2. On the Home screen, touch **NEW 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.

8.10.4.1 Abort a Query

It may be necessary to abort a query if you are experiencing technical difficulties or have a change in plans.

1. During the Manual Query, touch **MANUAL QUERY** and the application queries the LIS for all new orders.

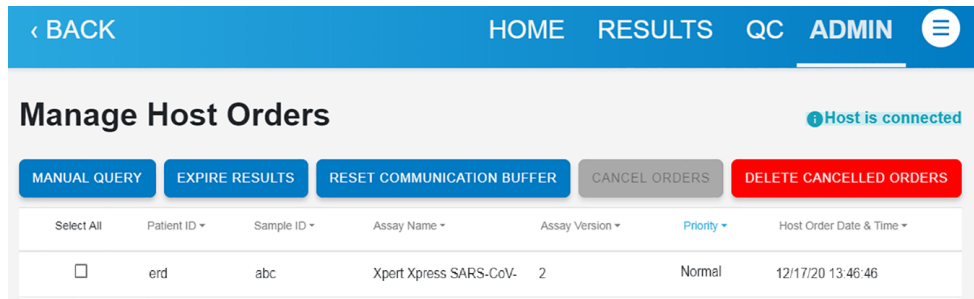


Figure 68. Manage/Abort Query

While the query is being performed, the button shall change to be **ABORT QUERY**. If the query completes normally, the database's LIS test orders shall be updated appropriately, with valid new orders being inserted and valid cancellations applied. The button shall return to **MANUAL QUERY** button.

2. You can touch the **ABORT QUERY** button to cancel the operation.

8.10.4.2 Delete a Host-downloaded Test Order

Occasionally, you may need to delete an order downloaded from the host.

1. Select individual orders from the Manage Host Orders screen using the check boxes at the left of the order, or Select All in the far left heading to select every order on the screen.
2. Touch the **CANCEL ORDERS** button.
3. A new screen appears. You have the option of deleting canceled host orders that are more than 6 days old, or deleting all canceled host orders. Select a delete option and touch **OK** or **CANCEL**.

8.11 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.

8.11.1 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.

8.11.2 Automatically Upload the Test Result to the Host

1. In the Host Communication Settings tab of the System Configuration dialog, touch **EDIT** and select the **Automatic Result Upload** check box so the result is uploaded as soon as the test is completed.

The screenshot shows the 'Host Communication Settings' dialog box. At the top, there are navigation tabs: BACK, HOME, RESULTS, QC, and ADMIN. Below the title bar, there are 'CANCEL' and 'CONFIRM' buttons. The main content area is divided into two columns: 'Communication Settings' and 'Host Settings'. In the 'Host Settings' column, the 'Automatic Result Upload' checkbox is checked, while other checkboxes like 'Automatic Host Query After Sample ID Scan', 'Automatic Test Order Download', and 'Use Instrument Specimen ID' are unchecked. The 'Communication Settings' column includes fields for Host ID, Run System As (Server/Client), Port, and Server IP Address.

Figure 69. Automatic Result Upload

2. After the test is completed, the result is automatically uploaded. The Upload Status is shown in the Test Information area of the View Result window.

The screenshot shows the 'Test Completed' screen. At the top, there are navigation tabs: BACK, HOME, RESULTS, QC, and ADMIN. Below the title bar, there are 'UPLOAD' and 'REPORT' buttons. The main content area displays test information for 'Module A2'. The 'Result' is 'SARS-CoV-2 NEGATIVE' (highlighted in green) and the 'Uploaded' status is 'No'. The test details include Sample ID, Patient ID, Test Type (Specimen), Assay Name (Xpert Xpress SARS-CoV-2), User (Straat38), Start Date & Time (01/05/21 11:36:22), and a Test Disclaimer.

Module A2		Result	Uploaded: No
Sample ID	50F79E88E299D6CDB7690D05 B	SARS-CoV-2 NEGATIVE	
Patient ID			
Test Type	Specimen		
Assay Name	Xpert Xpress SARS-CoV-2		
User	Straat38		
Start Date & Time	01/05/21 11:36:22		
Test Disclaimer	For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (US).		

Figure 70. Test Completed Screen Showing UPLOAD Button

8.11.3 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 Test Completed screen.

Touch **UPLOAD** on the Test Completed screen. 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. The possible host uploaded statuses are:

- **Uploaded: No**—this result has not been uploaded.
- **Uploaded: Yes**—this result has been received by the host.

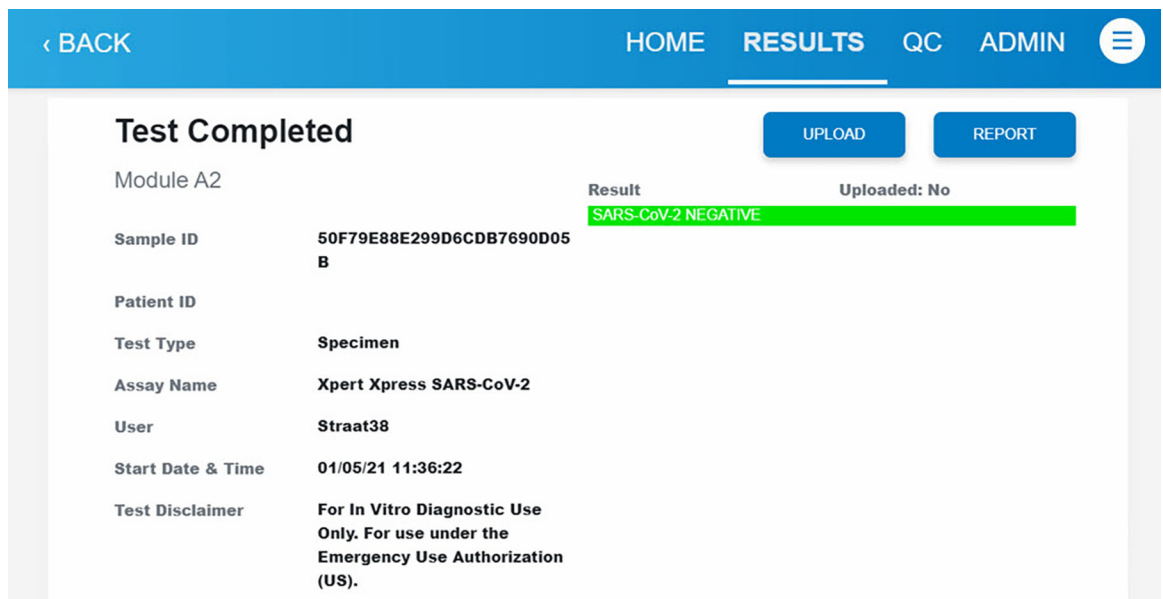


Figure 71. Test Completed, UPLOAD Button

8.12 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. It is essential for you to 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](#).

8.12.1 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.

8.12.2 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.

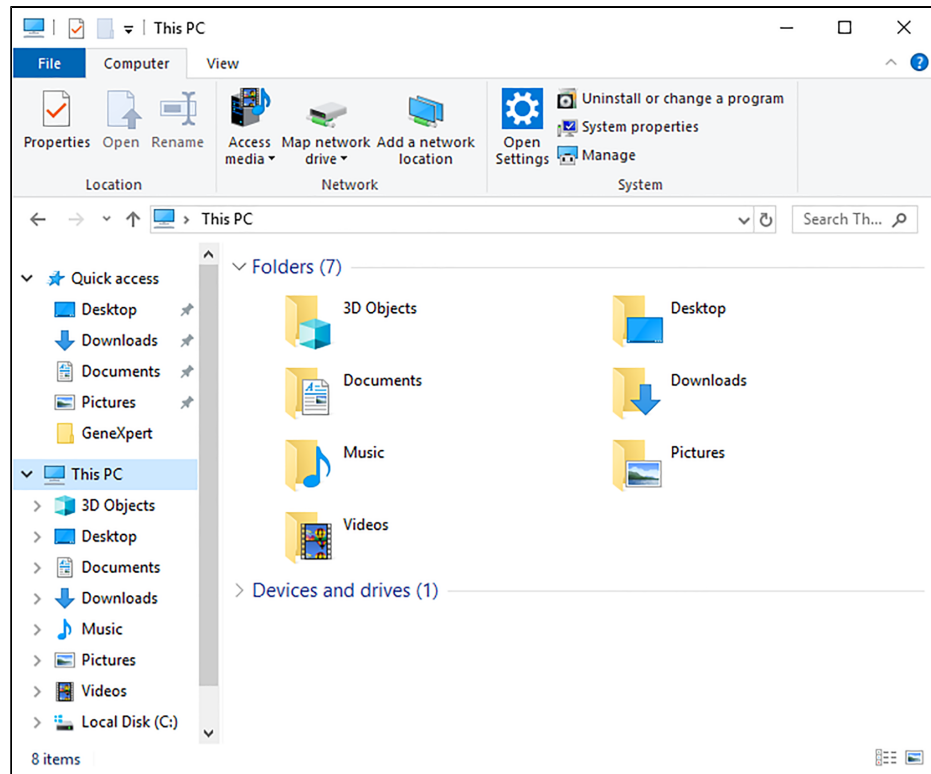


Figure 72. Start Menu with This PC Selected

3. When the menu appears, touch **Turn on BitLocker**.

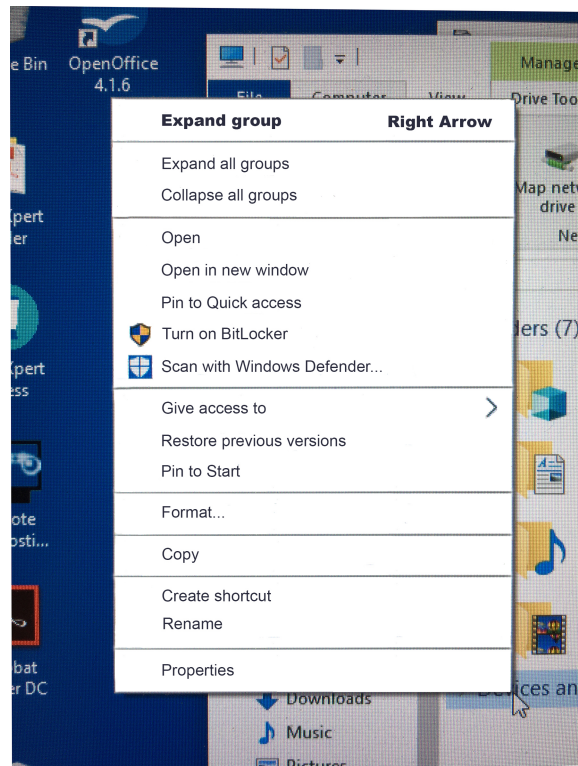


Figure 73. Select Turn On BitLocker

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.

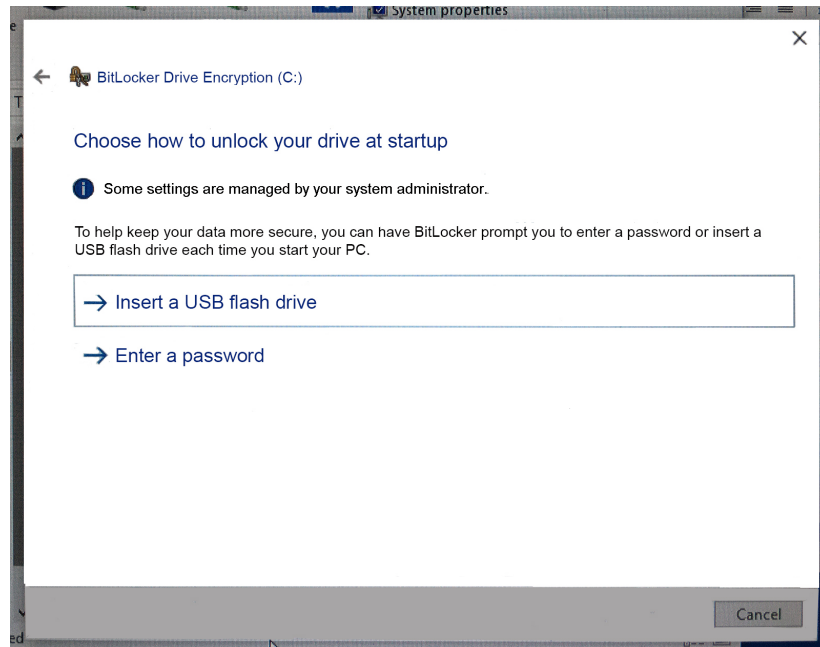


Figure 74. Choose Unlock Method for Flash Drive

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.

8.13 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.

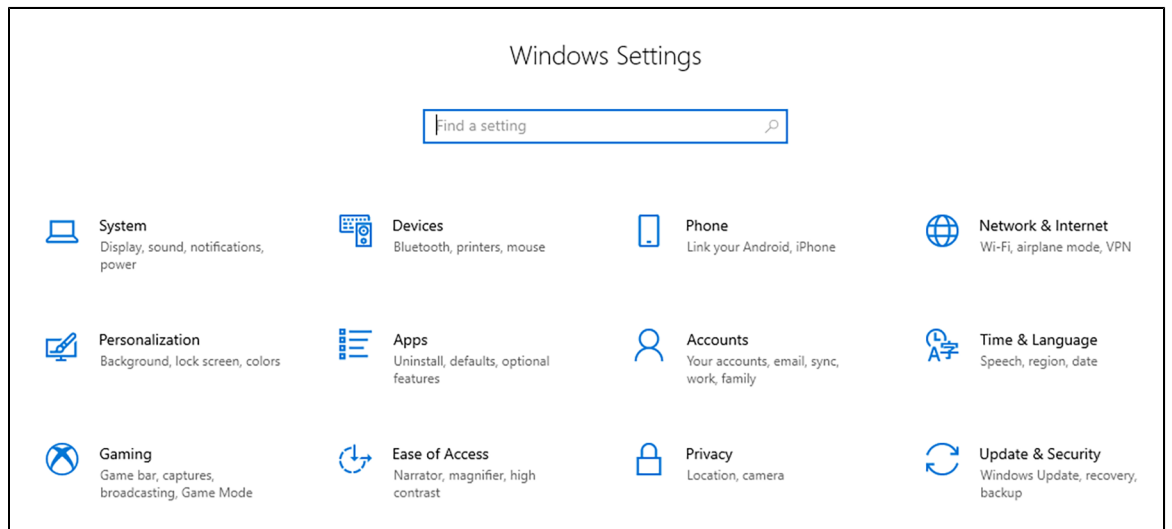


Figure 75. Windows Settings Screen

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.

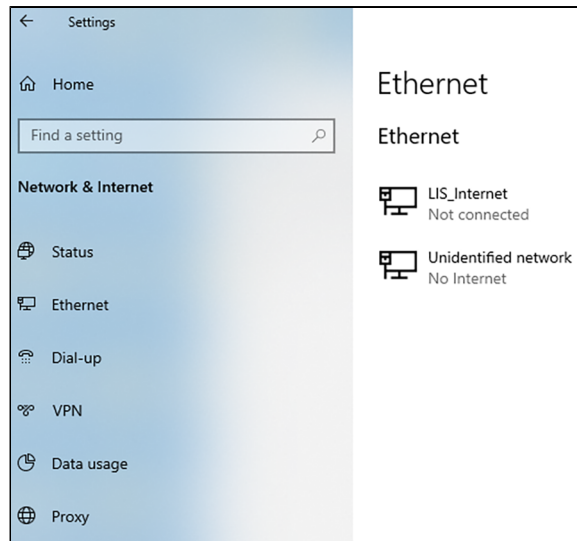


Figure 76. Network & Internet Screen

The Network Connections screen appears.

7. Touch and hold the **GeneXpert Connection** entry.
A drop-down menu appears.

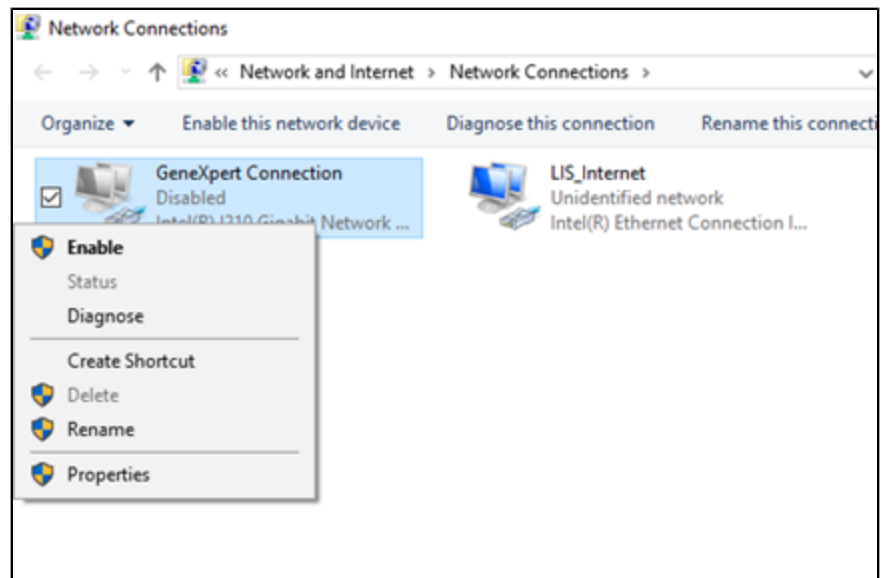


Figure 77. GeneXpert Connection Drop-down

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.

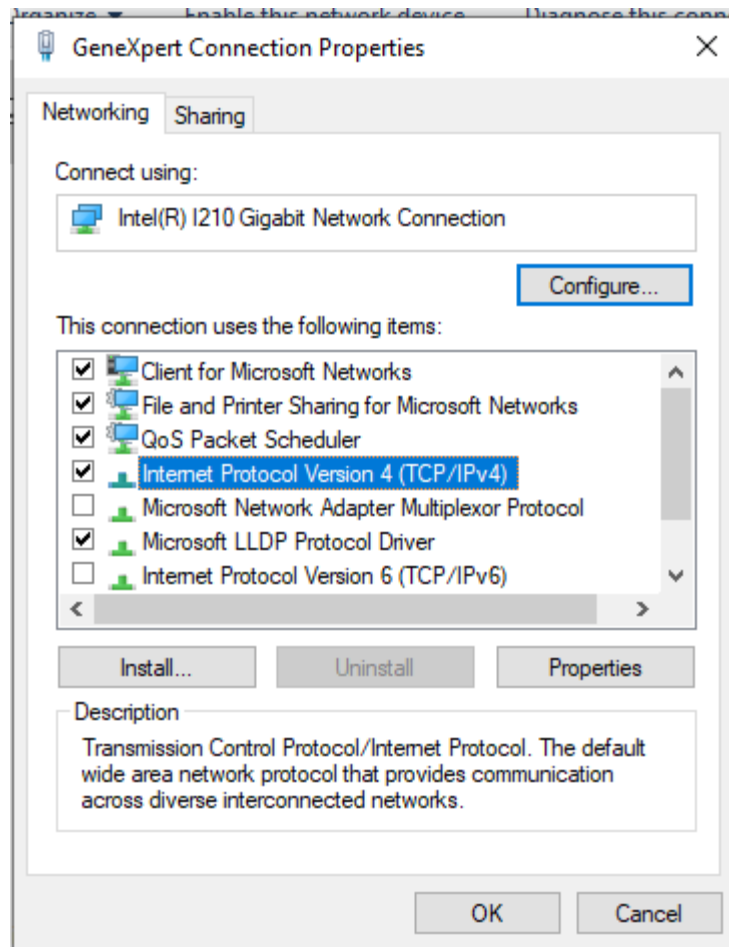


Figure 78. Connection Properties Screen

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.

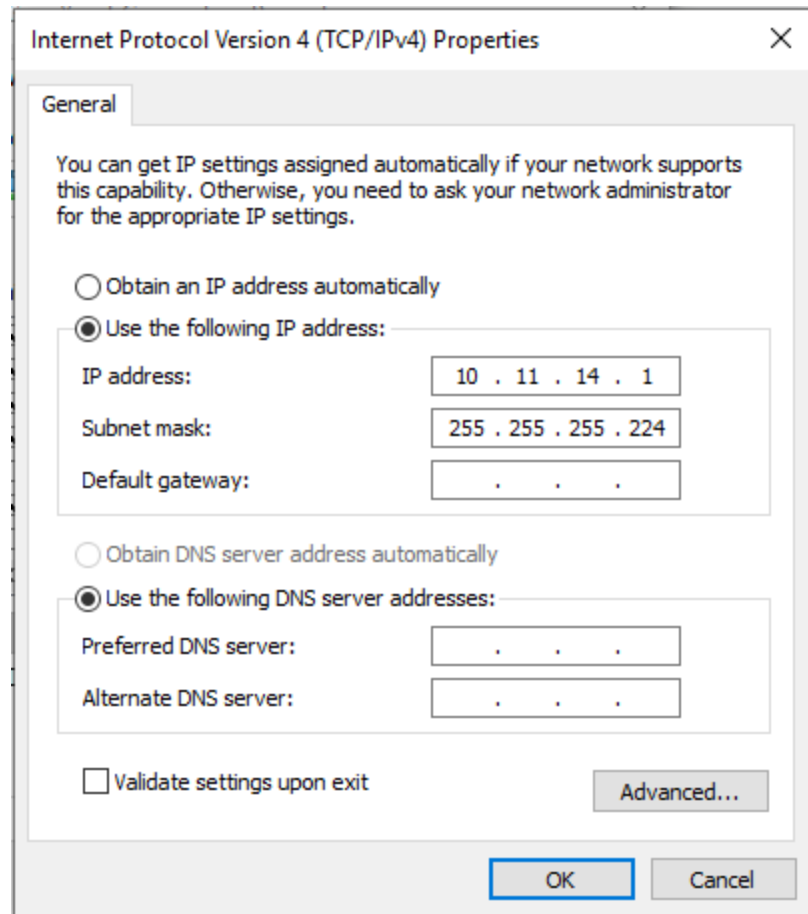


Figure 79. Internet Protocol Version 4 Properties Screen

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. Return to the Home screen and touch **User Menu** > **Exit** to exit the software.
15. Restart the system.

8.14 Connect to Cepheid C360

C360 Analytics is an intelligent remote medical device data system that provides data aggregations and analysis for monitoring epidemiology in a healthcare setting. These solutions help maximize the utility and application of Cepheid products by integrating several information management tools. Use the following procedure to connect to the Cepheid C360 network.

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 *C360 Analytics Quick Reference Guide* for details.

9 Maintenance

9.1 Error Handling

This section describes how to handle any errors that may occur when using the GeneXpert system with touchscreen. An example of an error that may occur is shown below.

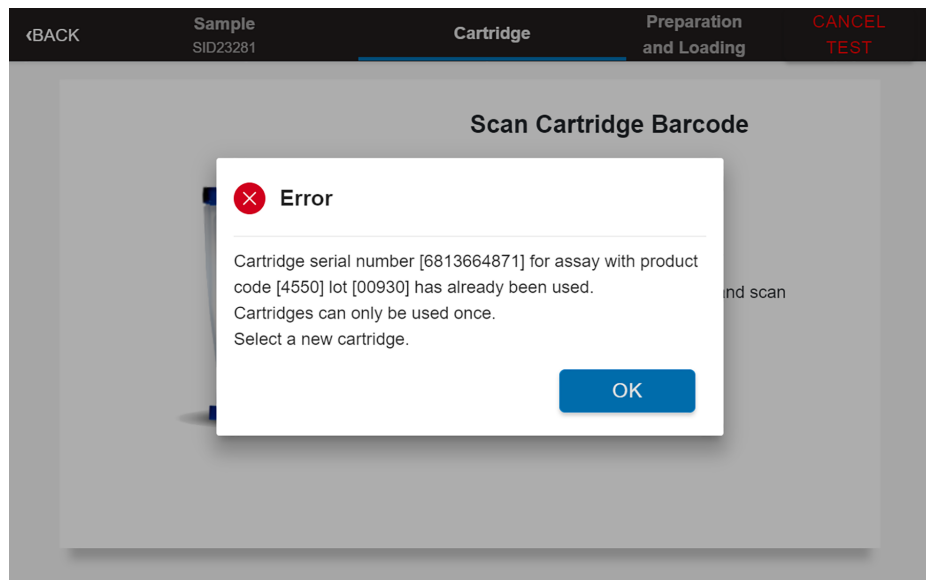


Figure 80. Error Example

If the Cartridge Already Used error screen is displayed, a cartridge with the same serial number has already been run on the system. Touch **OK** to repeat the test using a new cartridge and leftover specimen from the initial test.

For any error messages that may appear onscreen, follow the instructions on the screen.

9.2 Maintenance Tasks

Although the system is designed to prevent cross-contamination and ensure accurate results, the instrument can be checked and cleaned periodically as a precautionary measure. The table below lists the basic maintenance tasks that can be performed.

Table 1. Maintenance Tasks and Frequency

Task	Frequency	Section
Power down the GeneXpert system with touchscreen	Weekly	Power Down the System Weekly
Clean the fan filters	Weekly	Clean and Replace the Fan Filters
Clean the I-CORE module using the I-CORE Cleaning brush	As necessary	Clean the I-CORE® Module
Replace the fan filters	Quarterly	Clean and Replace the Fan Filter
Clean plunger rod and cartridge bay	Quarterly	Clean the Plunger Rods and Cartridge Bay
Clean the instrument and touchscreen surfaces	Quarterly	Clean the Instrument and Touchscreen Surfaces
Perform annual instrument maintenance	Annually	Annual Instrument Maintenance
Print system log report	As necessary	Generate the System Log Report

9.3 Maintenance Log

Complete the maintenance log daily or whenever maintenance tasks are performed on the system. Copies of this monthly log may be made to use, as required. There is an electronic version of this file available and can be used for monthly records. The electronic version of this file is a pdf file that can be filled in and saved using Adobe Reader or Adobe Acrobat.

GeneXpert® System with Touchscreen Maintenance Log

Name of Institution

GeneXpert Serial Number

Month and Year:

Last Calibration Check Date:

FAS Installation Date:

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.

	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
Daily Maintenance																															
Clean work area																															
Close all mobile 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 ¹																															
Yearly Maintenance																															
Check annual instrument maintenance ¹																															
As Necessary																															
Clean I-CORE using I-CORE ¹ cleaning brush																															
Print system log report ¹																															
Back up database ²																															
Technician Initials (Two Letters)																															



1. Refer to Chapter 9 (Service and Maintenance) in the Operator Manual for detailed procedure.
 2. Refer to Chapter 5 (Operating Instructions) in the Operator Manual for detailed procedure.
 These are minimum recommendations for cleaning. Your institution may require that maintenance be performed on a more frequent basis.
 Reference: GeneXpert GX Dx Operator Manual (P/N 302-5302, Rev. A)

9.4 Power Down the System Weekly

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.

1. To exit the software, touch **User Menu** > **Exit**.
2. Touch Windows Start menu, touch Power icon, and select **Shut down**.
3. Turn off the touchscreen.
4. Turn off the GeneXpert Instrument.
5. Wait two minutes.
6. Restart the system by turning on GeneXpert Instrument, then the touchscreen.

9.5 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.

Note

Do not to spray any cleaning fluids directly on the touchscreen or instrument. Begin by spraying the bleach/alcohol onto a clean wipe, then wipe the touchscreen or instrument.

- 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.

9.6 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.

9.7 Close Module Doors

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

9.8 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.


9.9 Clean the Instrument 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.

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. 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.

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.

9.10 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. Move the GeneXpert Instrument and wipe the table surfaces underneath and 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.

9.11 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.

9.12 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 **ADMIN** on the Home screen.
The Administration screen is displayed. This screen shows a menu of the various functions available to an administrator.
4. Touch **Instrument** to view the Instrument screen.
5. On the Instrument screen, touch **PLUNGER ROD MAINTENANCE**. The Plunger Rod Maintenance screen is displayed.

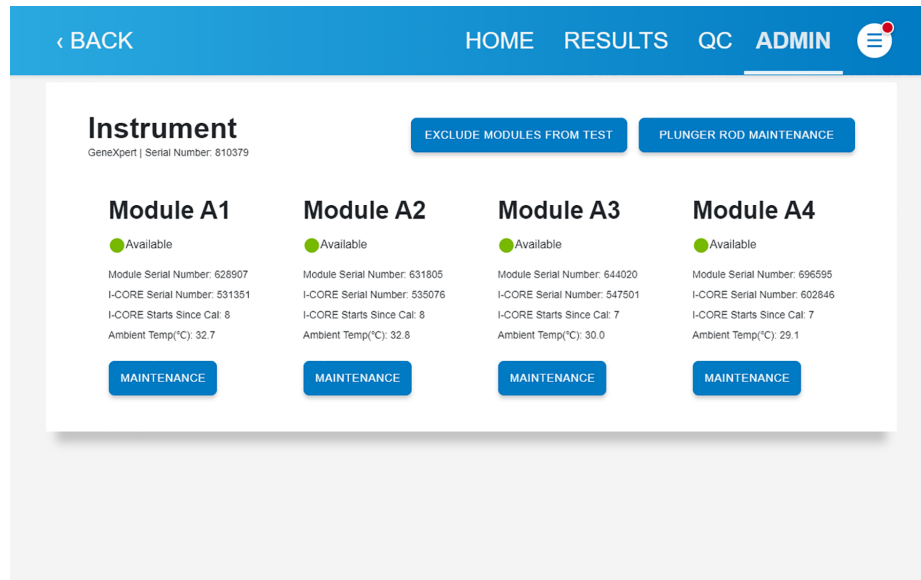


Figure 81. Instrument Screen

- 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.

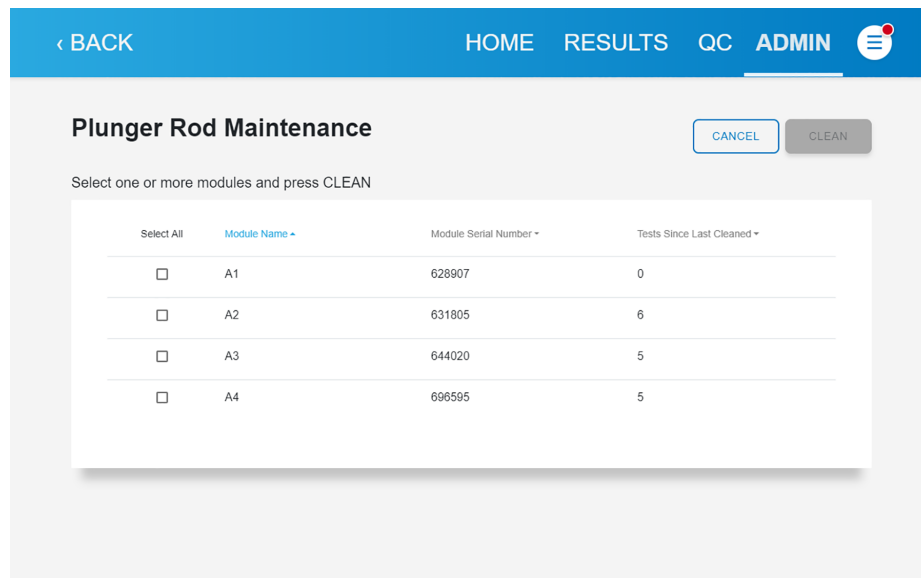


Figure 82. Plunger Rod Maintenance Screen

- 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.

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

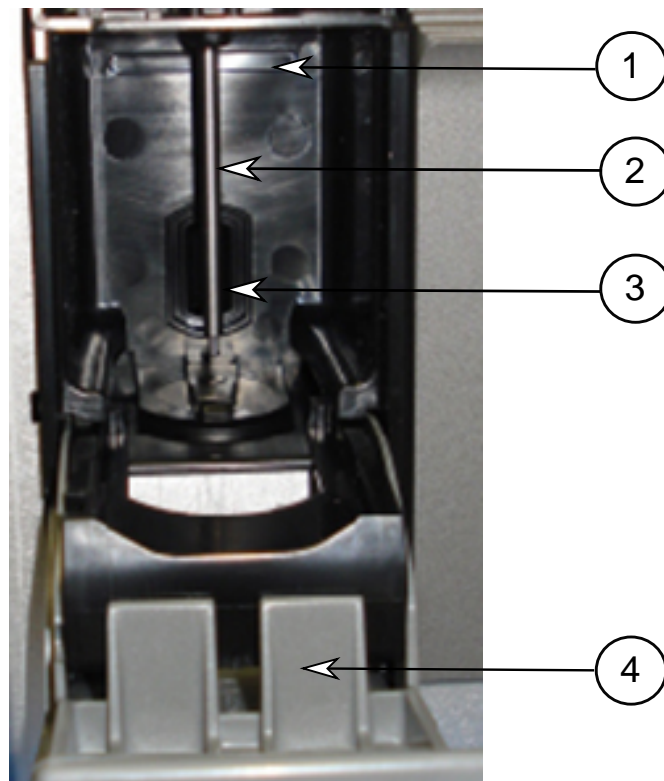


Figure 83. Plunger Rod Lowered into Cartridge Bay

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

Note Do not use a spray bottle to clean inside the cartridge bay. Getting bleach solution inside the I-CORE module can damage the module.

- 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.

- 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.
- 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 **HOME** to return to the HOME screen.

9.13 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.

Materials Required or Recommended for Cleaning:

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

Estimated Cleaning Time: 30 Seconds per module.

9.14 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.

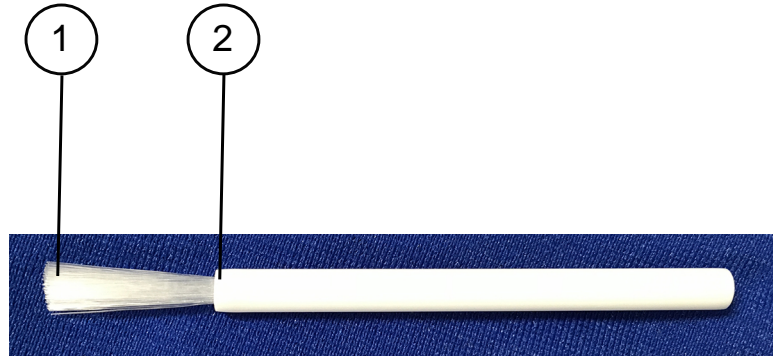


Figure 84. Lens Cleaning Brush (300-8330)

1	Nylon Bristles
2	Shank Insertion Shoulder

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



Figure 85. 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.

9.15 Clean and Replace the GeneXpert Instrument Fan Filter

Clean the fan filter weekly or more frequently, if necessary if you operate the instrument in an area with high pollution, dust or smoke. 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 Replacement Fan Filter Part Number: 001-1537
- 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. This procedure must be performed on a monthly basis.

1. Make sure all tests have finished running before attempting to move the instrument.
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.
5. Remove the dirty filter for cleaning.
6. Place a clean filter into the fan filter guard.
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 86. Fan Filter Guard

8. Press the bottom guard of the filter into place.

9. Clean the old 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 to use the following month, when you next remove the filter for cleaning.
11. In the maintenance log, fill in the date of the fan filter cleaning and keep it for your records.

9.16 Annual 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 Field Service Engineer with Administrator user permissions can perform calibration checks during annual maintenance. Contact Cepheid Technical Support for information about calibration checks. See the Technical Assistance section in the Preface for contact information.

9.17 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.

1. To view the Module Reporters of a particular module, go to the Instrument screen. Touch **MAINTENANCE** for the module desired. The Module Maintenance screen with Module Reporters appears.
2. The Module Reporter names are shown in the far-left column.

Module Maintenance

Module A1
● Available

Reporter Name	Calibration Status	Calibration Date	Calibration Concentration (nM)	Minimum Scalable Concentration (nM)	Maximum Scalable Concentration (nM)
Alx532	Valid	05/29/20	200	50.0	200.0
Alx647	Valid	05/29/20	200	50.0	200.0
CF1	Valid	05/29/20	800	200.0	800.0
CF6	Valid	05/29/20	400	100.0	400.0
FAM-2	Valid	05/29/20	300	75.0	300.0
TxR	Valid	05/29/20	400	100.0	400.0

Figure 87. Module Maintenance Screen, showing Module Reporters

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

9.18 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:

- Remove cartridges from the modules to be checked.
- Go to the Instrument screen. Touch **MAINTENANCE** for the module desired for the self-test (Module A1 is used in this example). The Module Maintenance screen appears.

Note If necessary, return to the Instrument screen to select and view a different module.

- Touch **SELF-TEST**. The Self-Test Confirm dialog box appears.

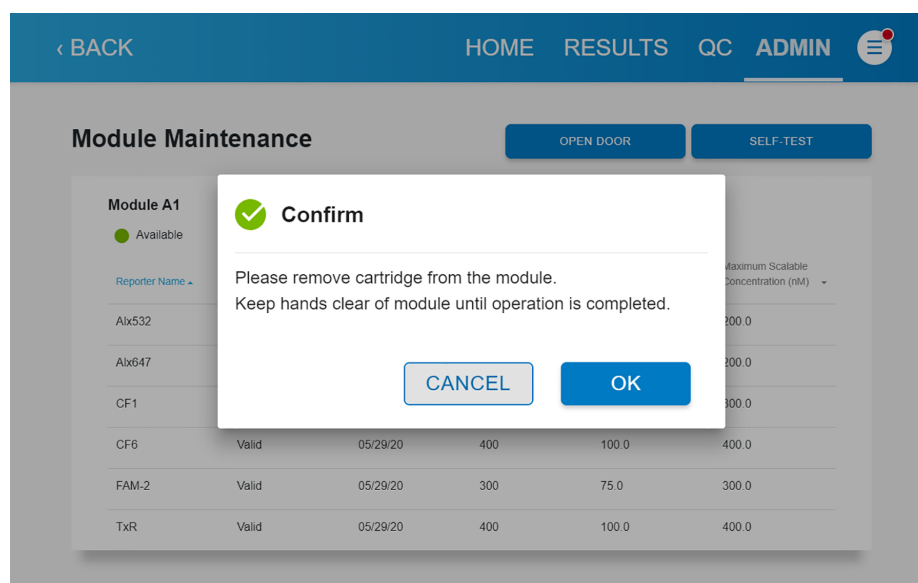


Figure 88. Self-Test Confirmation Dialog Box

4. Follow the instructions in the Self-Test Confirm dialog box and touch **OK**.
5. 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.

9.19 Exclude 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. Go to the Instrument screen. Touch **EXCLUDE MODULES FROM TEST**. The Exclude Modules from Test screen appears.
2. Select the module(s) to be excluded from test by touching the check box at the left of the desired module. The module is shown as Disabled. Press **CANCEL** to cancel changes.
3. Touch **CONFIRM** to save changes to the Exclude Modules From Test screen.

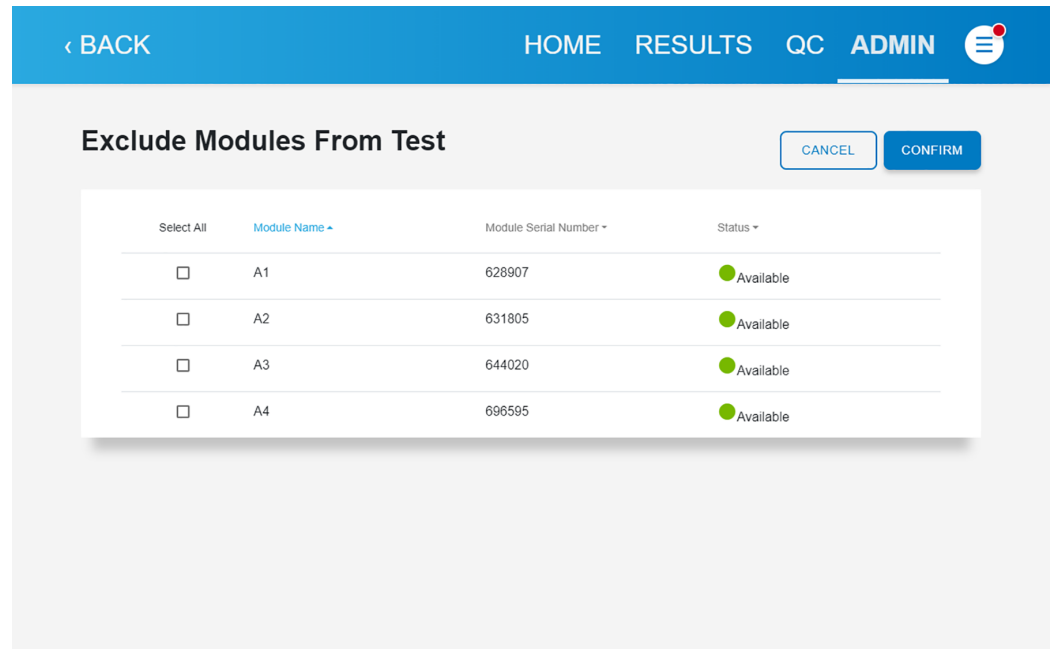


Figure 89. Exclude Modules From Test Screen

The Instrument screen appears.

4. Touch **HOME** to return to the HOME screen.

9.20 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.

9.21 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 100-3717EU or 100-3717UK). Check with Technical Support to confirm P/N for cord for your region.
- Power Supply Adapter, external (P/N 100-5519)
- Wi-Fi Adapter (P/N 800-0412)
- External DVDRW (P/N 800-0487)
- Fuse, (P/N 100-5986)
- Pad lock, (P/N 200-9165)

You can obtain the power cords and Ethernet cables from Cepheid. See the [Technical Assistance](#) section in the Preface for the contact information.

9.22 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.

9.23 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.

Table 2. Hardware Issues

Issue	Possible Cause	Solution
The system does not start.	The instrument is not connected to the power outlet.	Check the instrument power connections.
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.
Module(s) 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 the software and relaunch with the instrument powered on. Change the IP Address setting by performing the steps provided in Set IP Address .

Issue	Possible Cause	Solution
The cartridge is stuck inside the instrument module.	Module mechanical failure.	To remove the cartridge: <ul style="list-style-type: none"> ● Touch ADMIN at the top of any screen. ● On the Instrument screen, touch MAINTENANCE for the module you wish to access. ● On the Module Maintenance screen, touch OPEN DOOR to open the module door on the selected module. ● If the door does not open, cycle the instrument power down and repeat the steps above. ● If you still cannot remove the cartridge, contact Cepheid Technical support.
The instrument module red light is flashing.	Module mechanical failure.	Confirm no cartridge is in the module. Perform a self-test manually . If the error recurs, contact Cepheid Technical Support.
Unable to create a test.	Modules not available. No assay selected. The ambient temperature of the module is above 55 °C. Barcode is not detected.	Check that the modules are not disabled. Check that assay is selected. 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. Barcode reader may need reconfiguration. Check that the barcode reader is functional.

9.24 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.

9.25 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 3. LIS/System Configuration Problems

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.	<ul style="list-style-type: none"> • 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.

9.26 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 4. POCT System Configuration Issues

Issue	Possible Cause	Solutions
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Issue	Possible Cause	Solutions
The touchscreen is dropping the connection.	<p>The connection interval set up on the DM is connecting too quickly after previous communication, or</p> <p>The host connection was changed on the Host Communication screen, or</p> <p>The connection is routed over a different gateway, or</p> <p>The assigned port is being blocked on the network, or</p> <p>The assigned port is being blocked on the network, or</p>	<ol style="list-style-type: none"> 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.	<p>The device has not been added to the Data Manager, or</p> <p>Windows firewall is blocking the port, or</p> <p>The device is not physically connected to the wall Ethernet jack, or</p> <p>Host Communication settings are not correct on the touchscreen, or</p> <p>The serial number of the GeneXpert Instrument may have been entered in the DM incorrectly.</p>	<ol style="list-style-type: none"> 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 touchscreen to the DM.	<p>DM never sends a request observation message, or</p> <p>There is a computer Ethernet issue, or</p> <p>There is a network issue, or</p> <p>There are incorrect host communication settings.</p>	<ol style="list-style-type: none"> 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.	<p>The GeneXpert instrument(s) are in a DM group without an associated user list, or</p> <p>The instrument(s) are in a DM group without an associated user list, or</p>	<ol style="list-style-type: none"> 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 the touchscreen, or The DM is sending invalid User Validation settings.	<ol style="list-style-type: none"> 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 the touchscreen.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.

9.27 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.

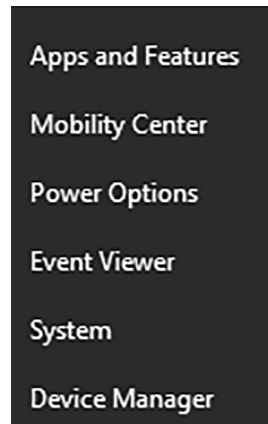


Figure 90. Windows Start Screen

3. The Event Viewer screen appears. To view logs:
 - a) Touch the folder **Applications and Services Logs** to expand the folder.

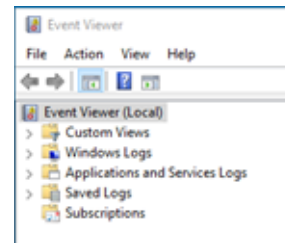


Figure 91. Applications and Services Logs Folder

- b) On the expanded folder view, touch and hold **GeneXpert Connectivity**.

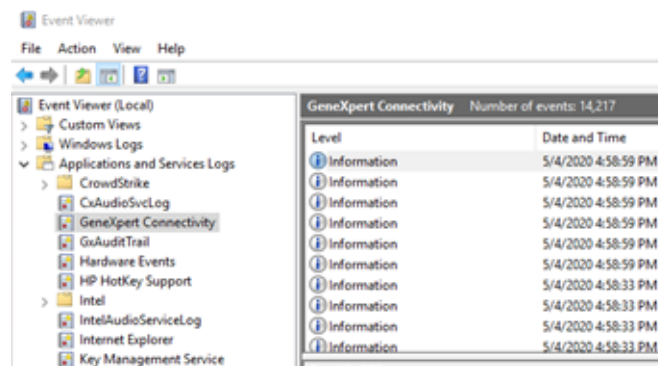


Figure 92. Applications and Service Logs Folder Expanded

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

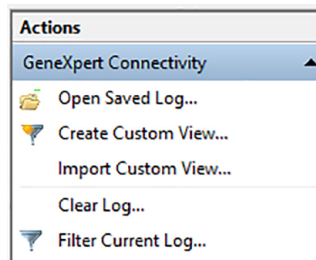


Figure 93. Filter Current Log

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 then 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**.

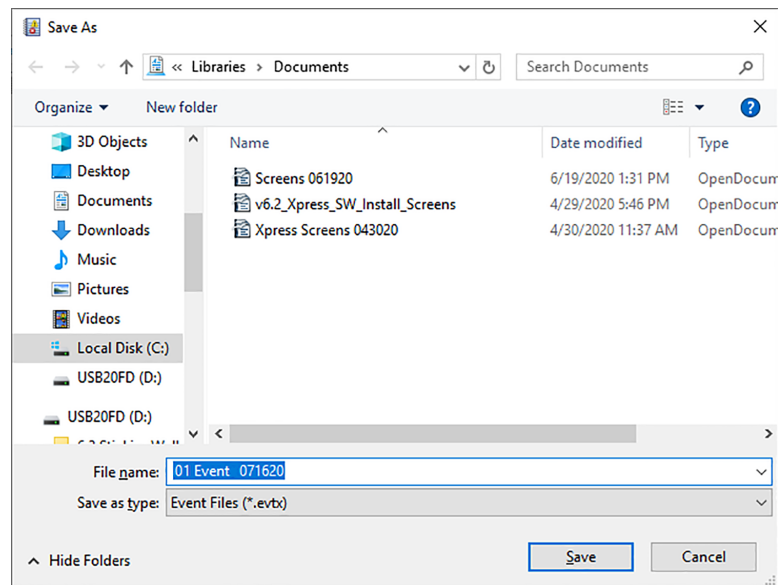


Figure 94. Save Event Log

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**.

9.28 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.

10 Performance Characteristics and Specifications

10.1 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.

10.2 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
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-II Instrument	16.3 cm(6.4 in)	30.7 cm(12.1 in)	29.7 cm(11.7 cm)	6.5 kg(15 lb)
Touchscreen	28 cm(11.1 in)	17 cm(6.75 in)	17.8 cm(7 in)	2.09 kg(4.6 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)

10.3 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.

10.4 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

10.5 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

10.6 European Union Directives

The GeneXpert system with touchscreen has been designed and tested to conform to the laboratory equipment requirements of applicable regulatory agencies. A Declaration of Conformity is available by contacting Cepheid Technical Support. See the [Technical Assistance](#) section for more information.

10.7 Hazardous Substances and Concentrations

{This is only useful for HTML publications.}

Product Name: GeneXpert system with touchscreen

Product Model Number: GX-TOUCHSCREEN, GX-II-1-TS-10C, GX-II-2-TS-10C, GX-IV-1-TS-10C, GX-IV-2-TS-10C, GX-IV-3-TS-10C, and GX-IV-4-TS-10C

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

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.

10.8 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	GeneXpert II	G	85	372	71
Cepheid	GeneXpert IV	G	100	489	83

10.9 Heat Output

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

11 Quality Controls

11.1 Quality Control

Quality Control tests can be run at any time. The lockout feature does not need to be enabled; however, the result is not saved in the QC Summary history.

Touch the **QC** button at the top of the screen to view the Quality Control screen, begin a quality control test, or to view the Quality Control Summary page.

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

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



Figure 95. 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.

Assay Name	Assay Version	Due Date & Time	Completion Date & Time	Status
Xpert Xpress SARS-CoV-2	1	05/25/20 14:39:31		Positive: Fail Negative: None
Xpert Xpress SARS-CoV-2	1	05/25/20 14:31:38	05/25/20 14:34:52	Positive: Pass Negative: Pass

Figure 96. Quality Control Summary Screen

11.2 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.

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.

11.3 Run a Quality Control Test

1. On the HOME screen, touch **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. In the following example, touch **RUN QC POSITIVE TEST**. The Sample ID screen appears.



Figure 97. Quality Control Screen

11.4 Run Positive or Negative Controls

You can enter run Positive or Negative Controls for quality control.

1. Touch the sample ID field to display the keyboard and enter **Positive Control** if running a positive control or **Negative Control** if running a negative control test.

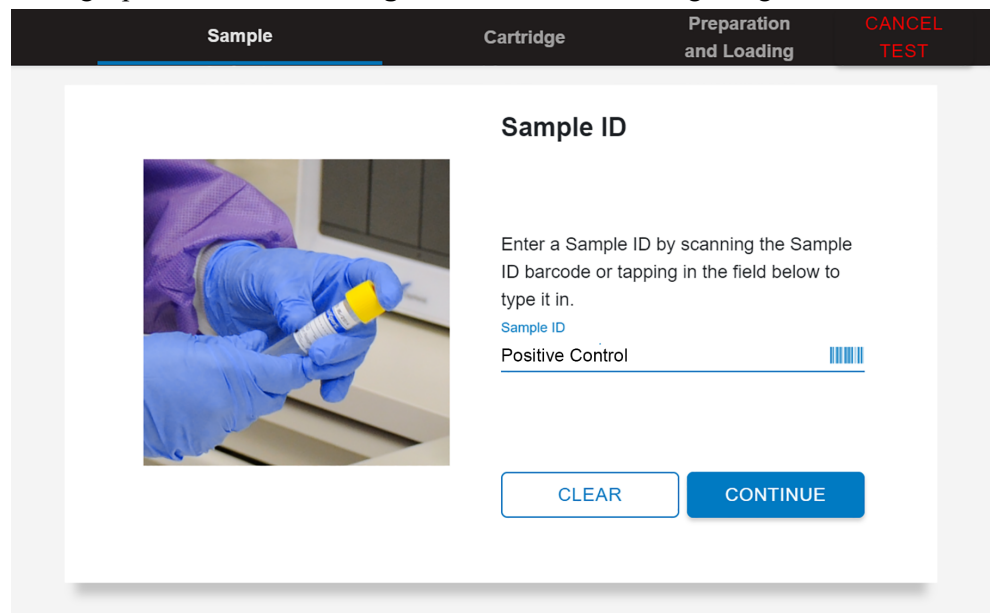


Figure 98. Sample ID Screen - Positive Control

2. Verify that the Sample ID on the Confirm Sample ID screen matches the Sample ID entered on the Sample ID screen (Positive Control or Negative Control). If it

matches, touch the **CONFIRM** button. If it does not match, touch the **RE-ENTER** button, re-enter the Sample ID and touch the **CONTINUE** button.

3. The Scan Cartridge Barcode screen appears.

Biological Risks



BIOLOGICAL RISKS: In the following steps, cartridges should be kept upright when handling or scanning. Do not rotate or tip the cartridge, because damage to the contents or injury to personnel may occur.

4. Scan the barcode. After scanning the barcode, the Confirm Test Information screen appears.

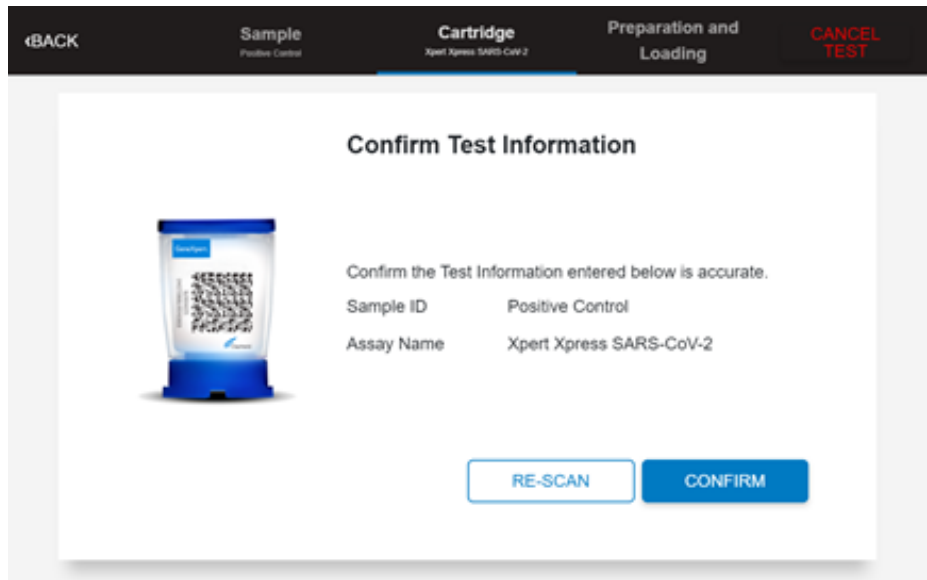


Figure 99. Confirm Test Information Screen

5. On the Cartridge Preparation screen, watch a video clip showing the cartridge preparation steps (if necessary).
6. Prepare the cartridge according to the directions shown in the video and in the assay package insert.
7. After the cartridge has been prepared, touch **CONTINUE** to halt the video clip.
8. When the Load Cartridge into Module screen is displayed, open the instrument module door below the module with the flashing green light.
9. Place the cartridge on the module bay floor. The cartridge label should face out. Make sure the cartridge sits level on the bay floor and is positioned at the heel of the bay.
10. Press the module door closed, ensuring that the door is completely closed. The door will latch and the flashing green light will turn solid green. As soon as the cartridge is loaded, the Test Loading screen will be displayed showing that the cartridge is being loaded.

Note

If necessary, touch the **STOP TEST** button to stop/cancel a test now, while it is loading, or later when the test is in progress. Note that you will not get a test result from a canceled test.

11. After the test has loaded, the Test Running screen appears, showing a blue circular graphic indicator at the right side of the screen, indicating the progress of the test and the time remaining until a test result is available.
12. When a test completes, the QC Test Result screen appears. The QC Test Result screen shows results for the completed QC tests.

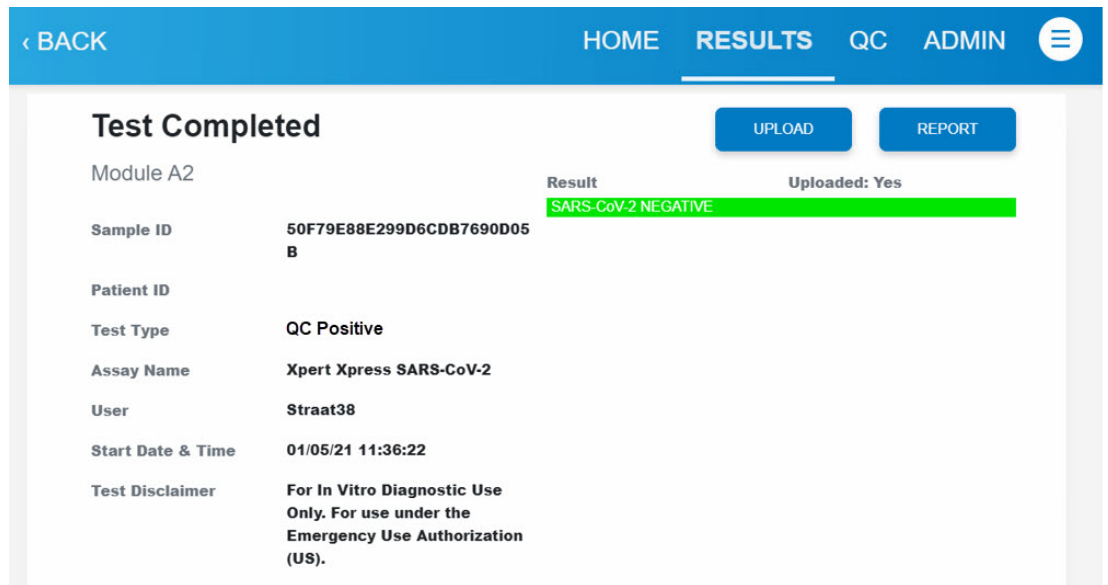


Figure 100. QC Test Result

13. Open the module door, remove the used cartridge, and properly dispose of the cartridge according to your institution's hazardous waste disposal policies.
14. Test the second control tube. In this example, the first test is with the positive control, therefore the second test is with the negative control.
15. To view a complete test report of the test just completed, touch **REPORT** on the QC Test Result screen.

The Report Viewer screen then appears, displaying the report which can be saved, or printed to any wired or network printer, as desired.

Note

If the option to print the results was selected, a screen indicating the print was successful will display.

16. After viewing and/or printing the test results, touch the **HOME** button to return to the Home screen. From the Home screen you can touch **RESULTS** to view the results of the tests previously run.

This completes the procedure for running a quality control test with the QC lockout enabled using the system.

If any error messages occur while running the test, see [Error Handling](#).

11.5 Upload a QC Result to the Host

QC results can be automatically uploaded to the host, depending on the settings for Automatic Result Upload. In addition, a QC result can be manually uploaded, as described in [Manually Upload a Test Result to the Host](#).

Note

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

A International Configuration Instructions

A.1 Introduction

This appendix provides instructions to configure the Cepheid OS software to display in a non-English language.

Important Use this document for new installations of the GeneXpert System with Touchscreen running Cepheid OS . For existing software installations, the touchscreen should be already configured for the correct language settings. Installing an update of the software does not change these settings. If you need assistance, contact Cepheid Technical Support. See the [Technical Assistance](#) section for contact information.

The information in this document applies only to configuring the touchscreen for a non-English language.

A.2 Configure Windows Language Settings

1. Log in to Windows using the Cepheid-Admin user account if 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 window displays.
4. On the Windows Settings window, touch **Time and Language**.
5. Touch **Language** on the left pane.
6. Touch **Add a Language**.
7. Scroll to find language or type it into the search bar.
8. Select the language and touch **Install**. Installation may take a few minutes.
9. In the Languages section of the Window, select the desired language from the drop-down menu.
10. Restart the touchscreen to allow the changes to be applied.
Once restarted, the screen displays a three-letter icon in the lower right corner to indicate the active language.

