GeneXpert®

Powered By   CEPHEID INNOVATION

Xpert Check Instructions for Use

REF   **XPERTCHECK-CE-5**

Cepheid®

In Vitro Diagnostic Medical Device   UK CA   IVD C€   302-6125, Rev. C 2024-04

Revision History

Description of changes: 302-6125, Rev B to C

Purpose: Updated EU Importer address

Section	Description of Change
Preface	Updated EU Importer address

Preface

About This Document

The *Xpert Check Package Insert* provides instructions on running Xpert Check software for checking module performance.

Safety Information

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

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

Highlights information that is critical for the completion of a task or the optimal performance of the system.

Note

Identifies information that applies only in special cases.

Related Documents

For other information outside the scope of this document, see the following publications:

* *GeneXpert Dx Operator Manual*

* *GeneXpert Xpress User's Guide*

* *GeneXpert Infinity Operator Manual*

Cepheid Headquarters Locations

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Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name

- Serial number of the instrument

- Error messages (if any)

- Software version and, if applicable, Computer Service Tag number

Contact Information

United States

Telephone: + 1 888.838.3222
Email: techsupport@cepheid.com

France

Telephone: + 33 563.825.319
Email: support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.

Report serious incidents associated with the product to Cepheid and the competent authority of the member state in which the serious incident occurred.

Table of Symbols

Symbol	Meaning
REF	Catalog number
IVD	*In vitro* diagnostic medical device
LOT	Batch code
(do not reuse symbol)	Do not reuse
(warning triangle)	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.
(consult symbol)	Consult instructions for use
(manufacturer symbol)	Manufacturer
CC	Country of manufacture
Σ	Contains sufficient for \<n\> tests
(hourglass symbol)	Expiration date
CONTROL	Control
CE	CE marking - European Conformity
EC REP	Authorized representative in the European Community
(importer symbol)	Importer
CH REP	Authorized representative in Switzerland
UK CA	United Kingdom Conformity Assessed
UK REP	United Kingdom Responsible Person
(temperature symbol)	Temperature limitation
(biohazard symbol)	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.

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1 Introduction

Important   **Read and understand this entire document before performing the data collection procedure.**

1.1 Proprietary Name

Xpert® Check

1.2 Common or Usual Name

Xpert Check

1.3 Intended Purpose

1.3.1 Intended Use

Xpert® Check is part of a check, verification, and hardware test system for GeneXpert® modules. Xpert Check is used in GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity systems. Xpert Check is used to check the optical system, verify the thermal system and perform a series of system-level tests to ensure full system functionality within Cepheid's instrument servicing specifications. One Xpert Check cartridge is usually used to check a single module in conjunction with the Xpert Check software. In certain cases where a retest is required, multiple cartridges may be necessary to test a module.

1.3.2 Intended User/Environment

Xpert® Check is intended to be performed by trained users where a GeneXpert System is installed.

1.4 Summary and Explanation

The GeneXpert module is the basis for all GeneXpert instrument systems worldwide. Cepheid recommends that the system be checked for proper operation on an annual basis. Based upon the usage and care of each system, checks may be recommended more frequently. The system is designed to detect module issues with the internal assay controls.

Xpert Check is an accessory to GeneXpert systems. Xpert Check includes reagents for the optical checking and performance verification of the module. Probe Check Controls (PCCs) verify reagent rehydration, PCR tube filling in the cartridge, probe integrity, and reagent stability. Thermal performance is verified via proprietary thermal probe chemistries, and module hardware performance is tested and verified by a suite of subsystem-specific tests which exercise all critical elements of the GeneXpert® module.

The Xpert Check process consists of two phases. The first phase is the execution of module testing using the cartridges. The second phase consists of a Cepheid Quality Assurance Review, followed by the issuance of an Xpert Check code to complete the Xpert Check process. **The Xpert Check process is not complete until this code is applied to the system**.

1.5   Reagents and Instruments

1.5.1   Materials Provided

The Xpert Check kit contains the following:

Table 1-1. Kit Contents

Description	Quantity
Xpert Check cartridges with integrated reaction tubes	**5 per kit**
Each cartridge contains the following materials:	
• Bead 1	**1 per cartridge**
• Reagent 1	**1.0 mL per cartridge**
I-CORE Lens Cleaning Brush	**4 per kit**
PI/Software (P/N 950-0413)	**1 per kit**
Data CD	**1 per kit**

Note   Safety Data Sheets (SDS) are available at www.cepheidinternational.com under the **SUPPORT** tab.

Note   The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and postmortem testing. During processing, there was no commingling of the material with other animal materials.

1.5.2   Storage and Handling

•   Store the Xpert Check cartridges at 2-28 °C. Wait at least 10 minutes after removal from cold storage before using, to allow a cartridge to reach ambient temperature.

•   Use the cartridge within 48 hours of opening the foil pouch.

•   Discard cartridges that have been removed from their foil-wrapped pouches outside of the approved usage interval.

- Do not use cartridges that have passed the expiration date.

- Do not open a cartridge lid until you are ready to perform testing.

- The cartridge lid must be opened (vented) prior to use of the cartridge; however, no sample is required for testing.

- Discard all used and unused materials, including cleaning brushes and cartridges once the Xpert Check session is completed.

Note   Contents of cartridges are non-hazardous.

1.5.3 Materials Required but Not Provided

- GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity System with Cepheid-supplied computer and barcode scanner.

- GeneXpert instrument.

1.6 Limitations

- For use with GeneXpert modules (running GeneXpert Dx software version 4.0 and above or GeneXpert Xpress software version 6.2 and above). 4-color GeneXpert modules (including Bio-threat modules) and Dual-Cal modules cannot run Xpert Check and must be tested by Cepheid Service.

- Use of the Xpert Check kit does not guarantee that the GeneXpert instrument will be free of hardware failures, nor does it take the place of a Cepheid Service Agreement.

1.7 Warnings and Precautions

After January 14, 2020, Microsoft will no longer provide security updates or support for PCs running Windows 7. It is recommended that you upgrade to Windows 10.

Important

**Please contact:
https://www.microsoft.com/en-us/microsoft-365/windows/end-of-windows-7-support for Windows 7 support information.**

In addition, please contact your local Cepheid Technical Support if you have questions about using Windows 7.

- Even though Xpert Check cartridges do not contain hazardous chemicals, you should always follow your institution's safety procedures for working with chemicals.

- Do not add a sample or other reagents to the Xpert Check cartridges.

- Do not use a cartridge that has a damaged reaction tube.

- Do not use cartridges from visibly damaged or compromised foil pouches.

- Contact your local Cepheid Technical Support office for replacement of damaged kit contents.

- Do not use a cartridge if it is dropped.

②
- Each single-use Xpert Check cartridge is used to process one test. Do not reuse spent cartridges.

- Each cleaning brush is intended for use in a single module. Do not re-use brushes in multiple modules.

- Do not open a cartridge package or break the lid seal until you are ready to perform testing.

- Allow the Xpert Check cartridge to come to ambient temperature prior to use if it has been placed in cold storage. Wait at least 10 minutes after removal from cold storage before using.

- Do not store single cartridges. Cartridges left over from an Xpert Check session, including pouched/unopened cartridges should be discarded along with spent cartridges.

- Do not use cartridges whose shelf life has expired. The system will detect expired cartridges and abort the test.

- Follow your institution's environmental waste procedures/consult your institution's environmental waste personnel for proper disposal of cartridges. If necessary, reference the WHO's [World Health Organization's] waste handling and disposal guidelines for the proper disposal of cartridges.

- Once a cartridge barcode has been scanned, do not substitute another cartridge in place of the scanned cartridge.

- If using an internet-enabled Xpert Check, it is recommended that up-to-date anti-virus software be installed on the desktop or laptop computer with updated virus definition files, prior to executing Xpert Check.

- Prior to running Xpert Check, ensure that the environmental operating temperature is within the correct limits (15 °C–30 °C). Xpert Check will render a system's modules unavailable if the internal temperature is above 40 °C. The internal temperature can be verified in the Maintenance section of the GeneXpert Dx, GeneXpert Infinity or GeneXpert Xpress software. Do not proceed under these conditions.

- Xpert Check expects the same computer to be used throughout the entire process. The computer installed with the GeneXpert system should be used, and not another computer from a different GeneXpert system.

- The Xpert Check code will expire if not applied within 45 days of completion of running Xpert Check.

1.8 Chemical Hazards

According to the Globally Harmonized System for Classification and Labeling (GHS) and the Classification, Labeling and Packaging (CLP) Regulation, this material is not considered hazardous.

1.9 Assistance and Contact Information

For a complete listing of Cepheid technical support, service support, sales support, and headquarters contacts, please see Technical Assistance, in the Preface of this document.

1.10 Software Buttons, Icons and Symbols

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Information. Touch or click this icon to obtain additional information. Displays the Information Key workspace screen which has an explanation of the various module icon displays.
	Continue. This icon is located at the bottom of most screens. Touch or Click this icon to advance the display to the next screen.
	Continue to End. Touching or clicking this icon moves the user to the last screen.
	Exit. Exits the Xpert Check application.
	About. Brings up the About screen which shows the name of the software, the software version number, copyright notice, etc.
	Home. Go to the Home screen.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Repeat/Retry. Retry loading an Xpert check cartridge to attempt to check a module that has had an unsuccessful test of a minor nature or if the cartridge has not been vented by the user. Used on the 'Check Test' screen.
	Back. Touching or clicking this icon takes the user to the previous screen.
	Cancel. Cancel the current operation. In most cases this will mean going back to the previous screen. In some cases, it may mean going back to the screen before the one that started the current operation.
	Select none of the modules for check. Deselects all modules for checking. If you only want to check a few modules, you may deselect ALL of them, and then reselect only the ones you wish to check.
	Select all of the modules for checking. The default setting for the system.
	Connectivity Status. Indicates the system is able to reach the Xpert Connectivity Center.
	Connectivity Status. Indicates the system is not able to reach the Xpert Connectivity Center.
	Module unsupported for Xpert Check. Skip the current module and do NOT attempt to check the current module.
	Module selected for Xpert Check. Module will be included when Xpert Check is run.

Table 1-2. Software Buttons, Icons and Symbols
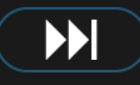
Symbol	Definition
▶▶	**Skip Current Module.** Skip the current module and do not attempt to Xpert Check the current module. Used on the 'Load Xpert Check Cartridges' screen.
▶▶|	**Skip Remaining Modules.** Skip all the remaining modules and do NOT attempt to Xpert Check them. Used on the 'Load Xpert Check Cartridges' screen.
	Module not selected for Xpert Check. Module will not be included when Xpert Check is run.
	Module unavailable for Xpert Check. Module will not be included when Xpert Check is run.
	Indicates a module with data collection in progress.
	Indicates data collection complete.
	Retest required. Indicates an incomplete Xpert Check data collection. A message will notify the user that the test must be rerun. A further message will indicate if the existing cartridge can be reused for the test or if a new cartridge must be used.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Service required. Contact the Cepheid Authorized Service Provider (ASP) or your local Cepheid Technical Support office.
	Lost communication. Contact the Cepheid Authorized Service Provider (ASP) or your local Cepheid Technical Support office.
	Burn. Burn a CD containing the collected Xpert check information (for users without an active internet connection).
	Collect Xpert Check Data. Leads the user through the Xpert Check data collection process.
	Enter Xpert Check code. Go to the 'Enter Xpert Check Code' screen.
	Xpert Check Status. Go to the Xpert Check Status screen to review Xpert Check status.
	Upload Xpert Check Data File. Go to the 'Upload Xpert Check Code Data File' screen.
	Upload Xpert Check Data CD. Go to the 'Upload Xpert Check Code Data CD' screen.
	Write Xpert Check Code. Write an Xpert Check Code to a file.
	Read Xpert Check Code. Open a file to read the Xpert Check code.
	Scan. Turn the barcode scanner on, and accept the next scanned input.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	View and Print. Launch the Adobe Reader so you can view and then print a PDF file.

2 Procedure

2.1 System Preparation

Note	Prepare the system for Xpert Check by following one of the four procedures listed in this section for the GeneXpert Dx, GeneXpert Xpress, the GeneXpert Infinity-48s, or the GeneXpert Infinity-80.

Important	**Authorized Service Providers (ASPs) who perform Xpert Check but won't be on-site when the Xpert Check code numbers come back (non-internet connection sites), should leave the user name and password for the users to log in later to enter the codes (see section 2.3.2).**

2.1.1 GeneXpert Dx Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.

2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.

3. Exit the GeneXpert Dx software.

4. Go to Section 2.2, GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity Optics Cleaning.

2.1.2 GeneXpert Xpress Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert Xpress software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.

2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.

3. Exit the GeneXpert Xpress software.

4. Go to Section 2.2, GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity Optics Cleaning.

2.1.3 GeneXpert Infinity-48s or GeneXpert Infinity-80 Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.

2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.

3. Exit the GeneXpert Infinity System software.

4. Open the glass doors following the instructions in the *GeneXpert Infinity System Operator Manual*.

5. Go to Section 2.2, GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity Optics Cleaning.

2.2 GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity Optics Cleaning

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 Dx, GeneXpert Xpress and GeneXpert Infinity modules prior to performing the Xpert Check procedure.

Materials Required or Recommended for Cleaning

• I-CORE Lens Cleaning brush (Quantity of four Included in the Xpert Check kit)

• Disposable gloves

Estimated Cleaning Time: 30 Seconds per module.

2.2.1 I-CORE® Lens Cleaning Procedure

1. Select the module to be checked and manually open the door of the module.

2. If necessary, remove the cartridge from the module.

Biological Risks

Remove the cartridge from the GeneXpert 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 Xpert Check kit (see Figure 2-1).

Nylon Bristles   **Shank Insertion Shoulder**

Figure 2-1. I-CORE Lens Cleaning Brush

Note

The brush is designed so that it will easily insert into the I-CORE slit and make contact with the rod lenses of the excite and detect blocks.

Biological Risks

Make sure you wear disposable gloves for the cleaning process. Wearing gloves prevents you from being exposed to biologically hazardous materials.

4. Wearing disposable gloves, insert the brush into the I-CORE slit in a tilted manner up to the shank insertion shoulder, as shown in Figure 2-2.

Note

Make sure that all the bristles are fully inserted (up to the shoulder of the plastic shank of the brush) so that it does not cause unnecessary damage to the brush.

Caution

Do not insert any objects into the I-CORE slit except the provided brush. Inserting any other object may damage the I-CORE.

Caution

Do not apply any solution (such as ethanol or bleach) onto the brush bristles. The brush must be completely dry when inserting it into the I-CORE slit.

Important

The brush is intended for single-use and should not be used on more than one module. Use a new brush for each module to be cleaned.

I-CORE Slit

Shank Insertion Shoulder

Primary brush movement is up and down, with secondary rotational motion, as described in Step 5, below.
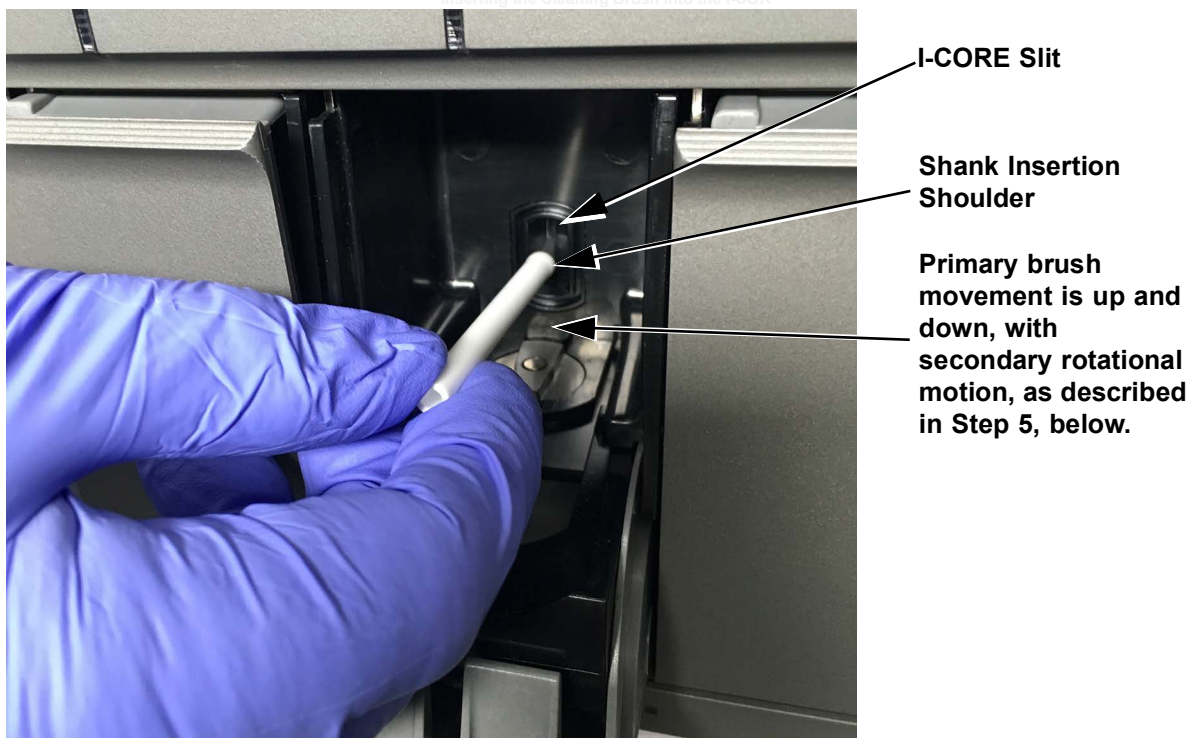
Figure 2-2. Inserting the Cleaning Brush into the I-CORE Slit

5. Insert the brush into the I-CORE slit completely up to the plastic shank (shoulder) of the brush. Hold the brush firmly in the I-CORE slit, and perform cleaning of the rod lenses as described below. The entire cleaning process should take approximately 30 seconds per module.

Note	Cleaning is done by moving the brush in an up and down direction within the I-CORE slit. Brush rotation, even if it has to be done, is not the main action that results in optics cleaning.

> A. Begin by brushing from the top of the I-CORE slit to the bottom, making sure to apply a uniform pressure when brushing from the top to the bottom of the I-CORE 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 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 slit to the bottom.

6. When lens cleaning is complete, remove and discard the used brush and gloves as hazardous waste.

Important	**Dispose of gloves and brushes according to your institution's safety policies and procedures for hazardous waste.**

7. Proceed to Section 2.3, Data Collection Procedure: GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity.

2.3 Data Collection Procedure: GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity

Important	**Before collecting data, be sure to prepare the system for checking as described in Section 2.1, System Preparation.** **Internet-connected users should verify their system's connectivity status prior to beginning the Xpert Check process.**

Note	Throughout this procedure, when making an onscreen button or icon selection, use the touchscreen on the GeneXpert Xpress system by touching the button or icon with your finger. When using the GeneXpert Dx or GeneXpert Infinity system, use a mouse to select, by clicking the desired button or icon.

Note	Use care in inserting CD1 into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

1. Place Software CD1 in the computer connected to the GeneXpert Dx. For the GeneXpert Dx system using an external DVD drive and for the GeneXpert Xpress and GeneXpert Infinity systems, connect the DVD drive following the instructions in the *GeneXpert Dx Operator Manual*, the *GeneXpert Xpress User's Guide* or the *GeneXpert Infinity System Operator Manual*, and insert the CD into the DVD drive.

2. For a GeneXpert Xpress system, follow the procedure in Step A; for GeneXpert Dx and GeneXpert Infinity, follow the procedure in Step B.

   A. **GeneXpert Xpress** On the computer desktop, touch and hold the **Computer** icon and a drop-down menu will appear. Touch **Open**, then touch and hold the applicable drive letter for your DVD drive.
   Touch **Open** from the drop-down menu, and the files located on the CD will then be displayed.
   Find, touch and hold the **XpertCheck.exe** application, and when the drop-down menu appears, touch **Run** to install as administrator. When the software has been installed, a "wrench" icon will appear on the desktop.

Note	The software may take some time to load from the CD.

   B. **GeneXpert Dx and GeneXpert Infinity:** On the computer desktop, right-click the **Computer** icon and a drop-down menu will appear. Click **Open**, then right-click on the applicable drive letter for your DVD drive.
   Select **Open** from the drop-down menu, and the files located on the CD will then be displayed.
   Find and right-click the **XpertCheck.exe** application, and when the drop-down menu appears, click **Run** to install as Administrator. When the software has been installed, a "wrench" icon will appear on the desktop.

Note	The software may take some time to load from the CD.

3. Depending on your system, either touch or double-click the "wrench" icon to launch the Xpert Check program.

4. The Terms of Service screen appears first. Use the scroll bar to read through the entire document. You will be asked to select (touch or click) the check box (bottom of the screen) to verify that you have read and agree to the Terms of Service before continuing. See Figure 2-3.

Note	The Xpert Check software runs on Windows 7 or Windows 10. The screens shown in this manual are from Xpert Check software running on Windows 7. Screens for Xpert Check software running on Windows 10 will be similar.

Important	**After January 14, 2020, Microsoft will no longer provide security updates or support for PCs running Windows 7. It is recommended that you upgrade to Windows 10.** **Please contact:** **https://www.microsoft.com/en-us/microsoft-365/windows/end-of-windows-7-support for Windows 7 support information.** **In addition, please contact your local Cepheid Technical Support if you have questions about using Windows 7.**
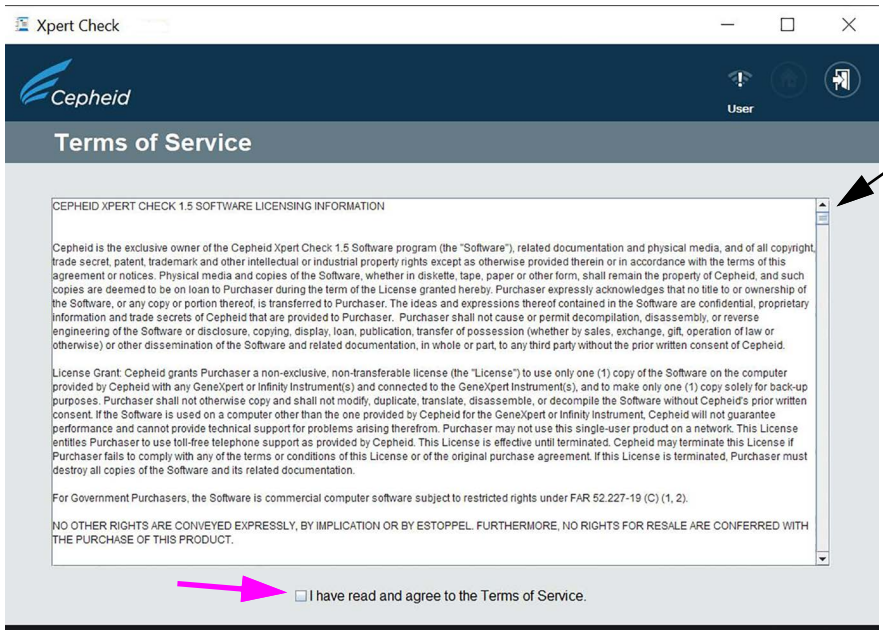
Figure 2-3. Terms of Service Screen

5. After agreeing to the Terms of Service, the Login screen will appear. Log in with your GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity designated Administrator level **USER NAME** and **PASSWORD** (previously assigned to you by your system administrator). After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the Xpert Check Home screen. See Figure 2-4.

Note	On the GeneXpert Xpress system, touching any field for inputting usernames, passwords, text, etc., will cause a virtual keyboard to appear for data entry. To close the keyboard, touch the **X** key in the upper right corner of the keyboard.

Note	The user name and password are the same ones you used for the GeneXpert Dx, GeneXpert Xpress or GeneXpert Xpertise software.

Enter your designated USER NAME and PASSWORD as assigned by your system administrator.

This button, located at the bottom of most screens, is used to advance to the next screen.
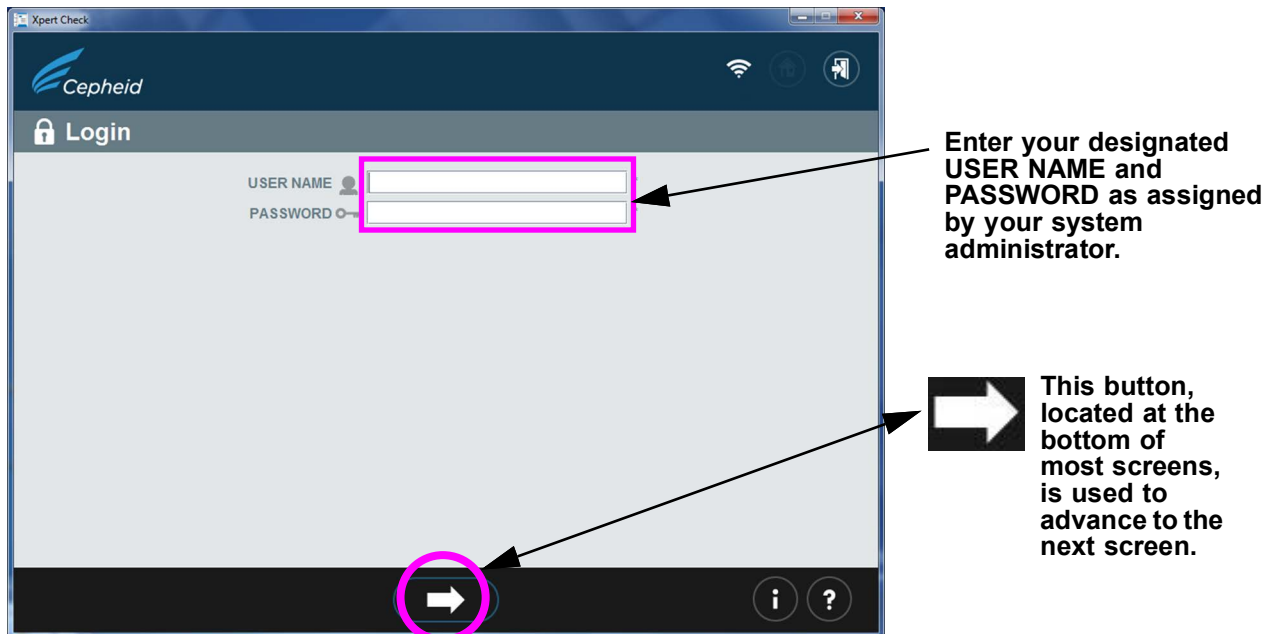
Figure 2-4. Xpert Check Login Screen

In case of a login error, the following screen will appear. See Figure 2-5.
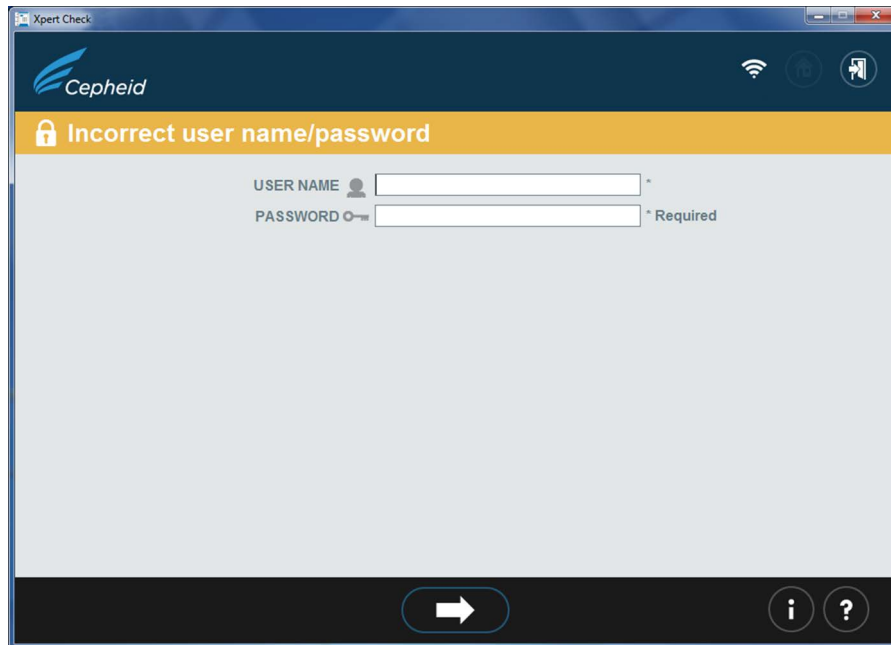
Figure 2-5. Login Error Screen

6. If a login error occurs, examine the **USER NAME** and **PASSWORD** entries for errors. If necessary, reenter the information and retry. After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the Xpert Check Home screen.

7. Obtain a sufficient number of cartridges for the number of modules to be tested.

Important	**Do not open cartridge packages until you are ready to scan the cartridge barcode (in Step 17).**

Note	When determining the number of cartridges that will be needed for this test, the user should be aware of the number of modules that they will be checking.

8. Touch or click the **Collect Xpert Check Data** icon on the Home screen (See Figure 2-6). After a few seconds, the first Contact Information screen (Figure 2-7) will appear.
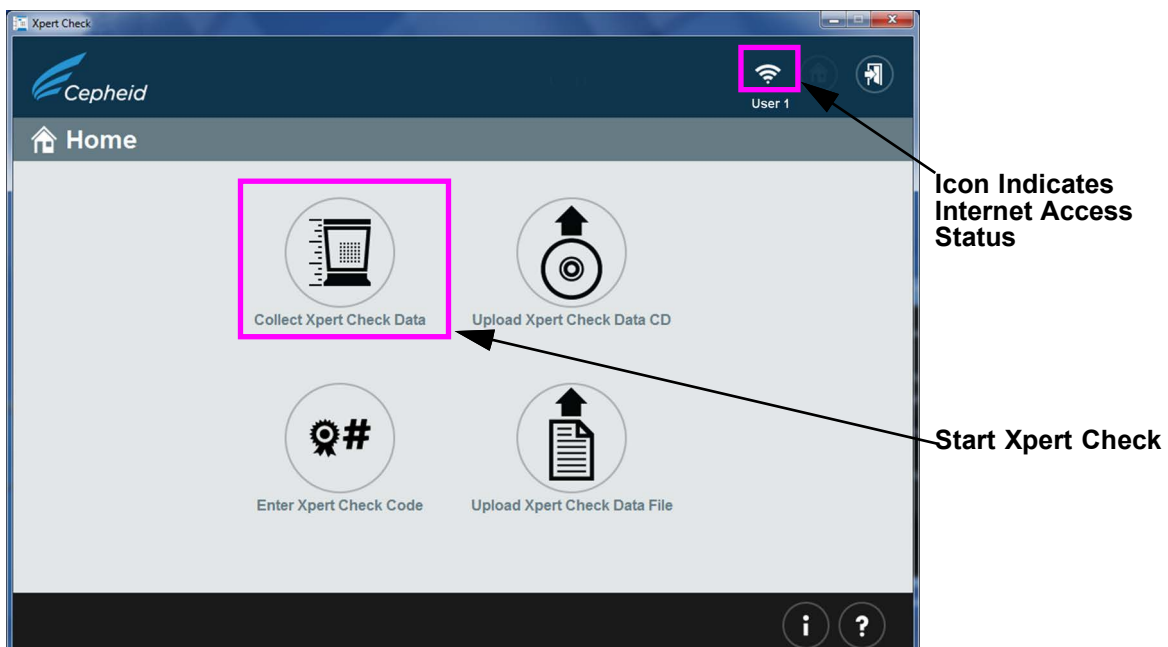
Figure 2-6. Home Screen

9. When the first of two Contact Information screens appear (see Figure 2-7 and Figure 2-8), fill out the fields in the two screens. Use the large navigation arrows at the bottom of the screens to move between the two screens.

Note	GeneXpert Xpress: When you touch a field, an onscreen keyboard appears for entering data.

Note that fields marked with "*" (at the right of the entry area) are mandatory fields.
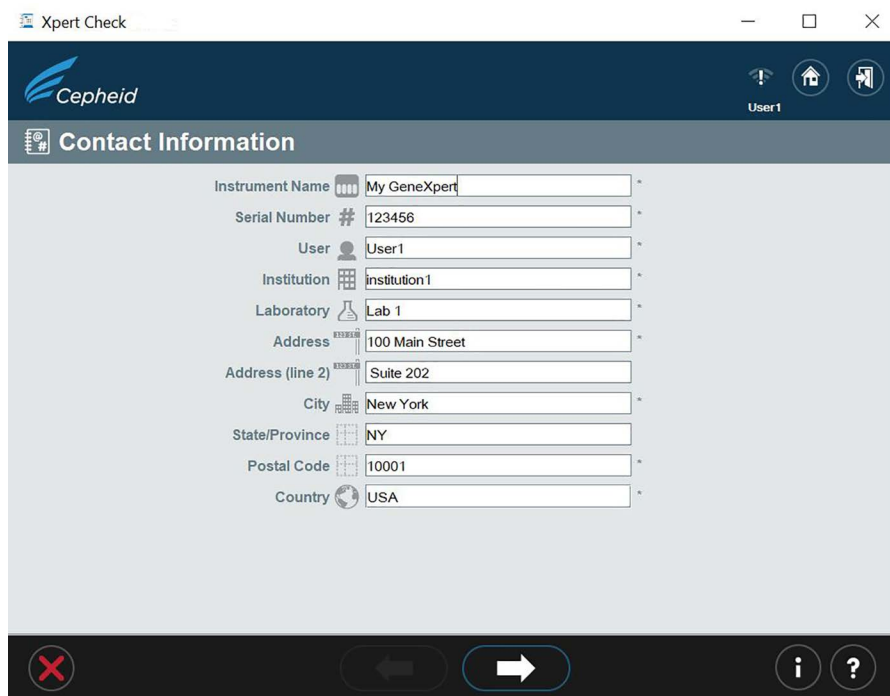
Figure 2-7. Contact Information Screen - Page 1
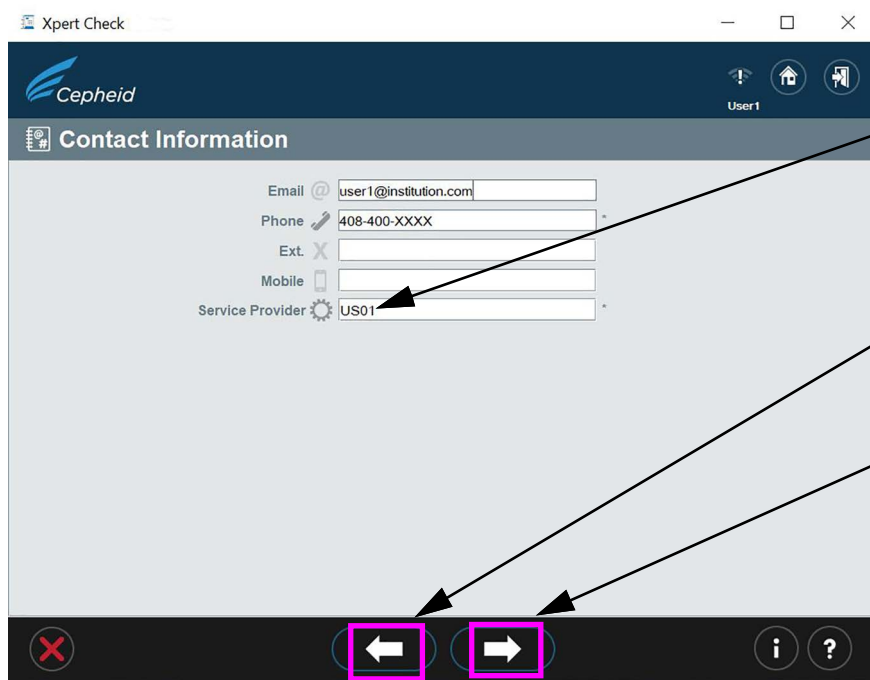
In this mandatory field, enter your Authorized Service Provider's ID code. The ID code is four characters, as described in the note below.

Clicking on this icon will take the user back to the first Contact Information screen

Clicking on this icon will take the user to the Open Module Doors screen

Figure 2-8. Contact Information Screen - Page 2

Note	The ASP-provided ID code for the Service Provider on the Contact Information screen consists of four characters. (As examples: US01, 1203, etc.)

10. When all information has been entered, touch or click the forward arrow button at the bottom of page 2 of the Contact Information screen. The Open Module Doors screen will appear. See Figure 2-9. Manually open all module doors to enable cartridge loading.
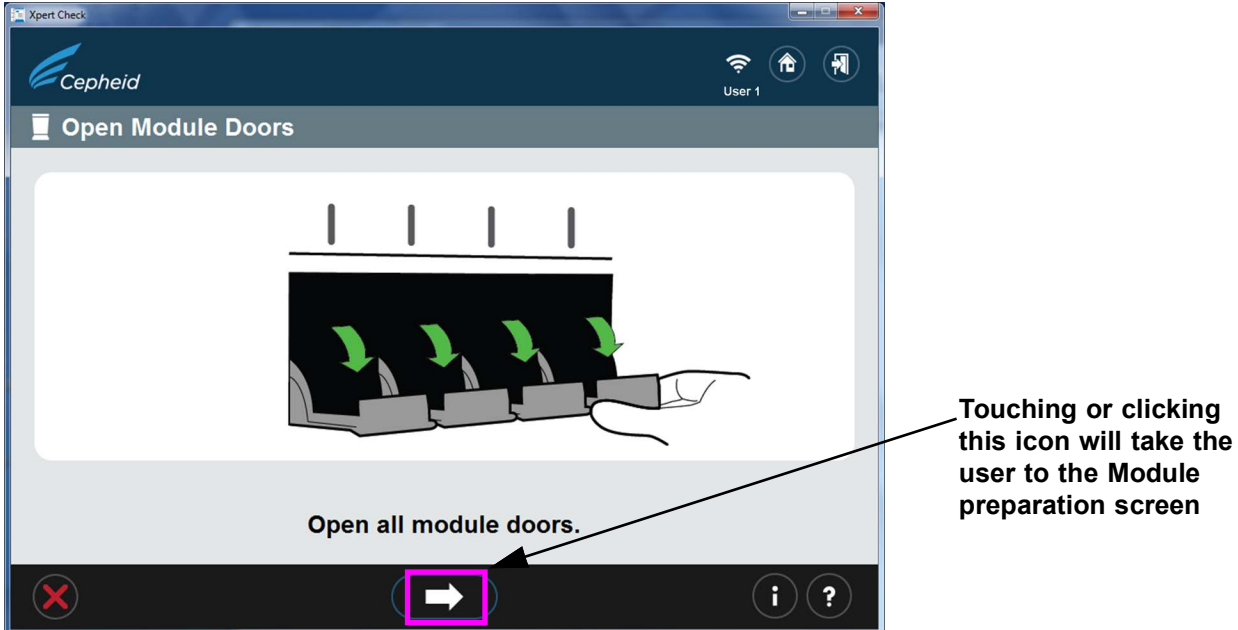
Figure 2-9. Open Module Doors Screen

11. After opening all the module doors, touch or click the forward arrow button at the bottom of the screen. The Module preparation screen may appear, showing the message **Wait while modules are being prepared.** (See Figure 2-10.)

Important	Note that the Module preparation screen will appear only if the firmware in the modules is not 3.0.3. The screen indicates that the software is upgrading/downgrading the firmware to the modules. The next screen you see will be the screen shown in **Figure 2-11**, the Select Modules screen.
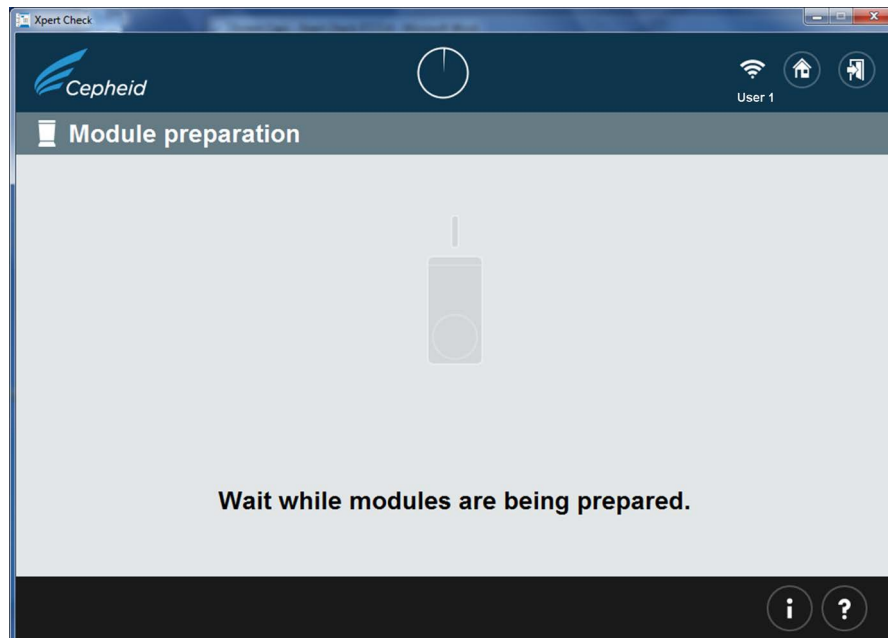
Figure 2-10. Module preparation Screen

12. Follow the on-screen software instructions in Figure 2-11. By default, all detected modules will be marked as selected for checking.

On this screen, the user can touch or click individual module icons to exclude the modules from being checked, if required. The module icons will disappear as they are excluded.

Note	For excluded modules (not selected for checking), the door position (open or closed) does not matter.

To exclude a module from test, touch or click on the ✓ for each module to be excluded.

Touch or click this arrow to proceed to the next screen
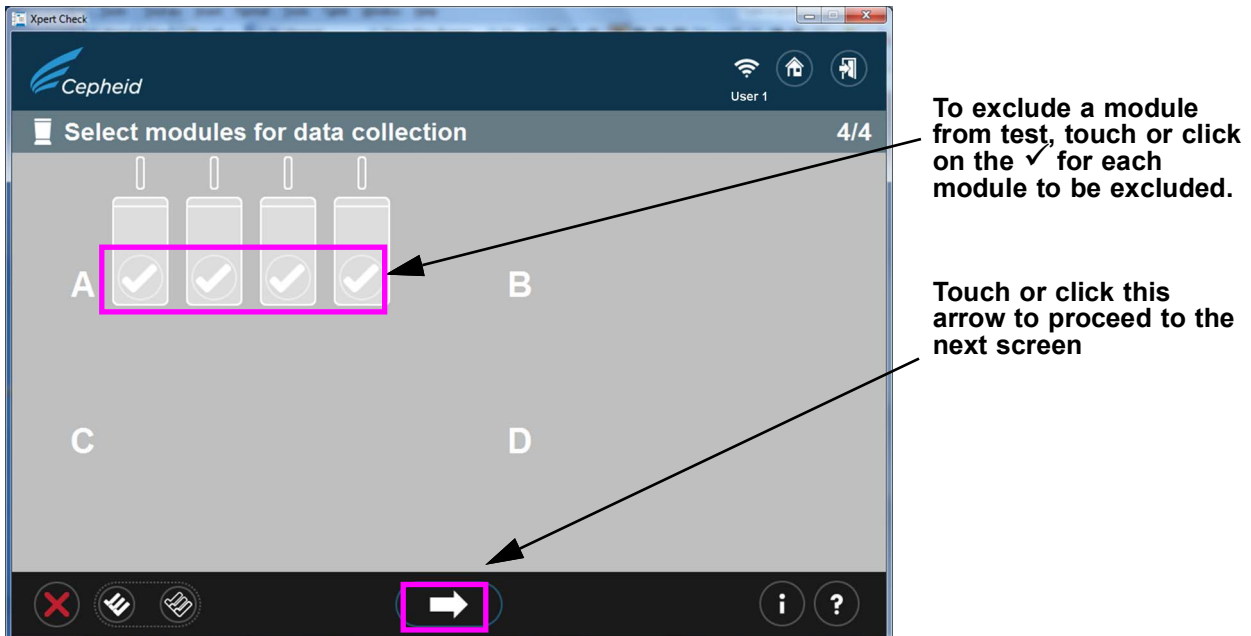
Figure 2-11. Select modules for data collection Screen

Important	GeneXpert-XVI and GeneXpert Infinity systems only: When selecting modules on screen, make a note of which module lights are blinking on the system as you select each bank, to ensure cartridges are placed in the correct modules for testing.

13. After confirming the module selection shown in Figure 2-11, touch or click the white arrow at the bottom of the screen overlay, to begin scanning cartridges. If the module selection shown is incorrect, touch or click the red **X** at the bottom left corner of the screen to return to the Select Modules screen and change your selection. See Figure 2-12.
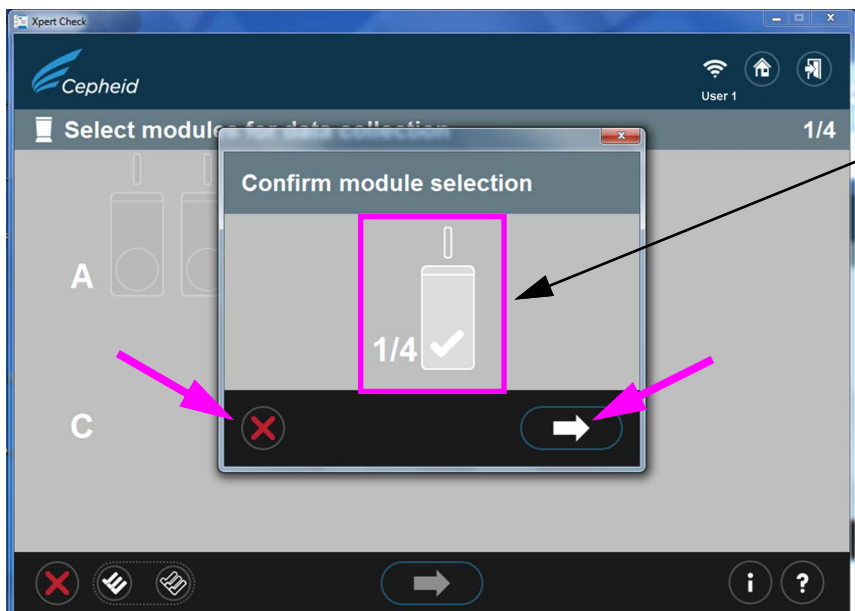
Figure 2-12. Confirm module selection Screen

14. In case of an error in the preceding step, in which either no modules have been selected, or all modules have been excluded, one of the following screens will appear (Figure 2-13). Follow the on-screen instructions to select a module, or start over by returning to the Home screen or exiting the program.
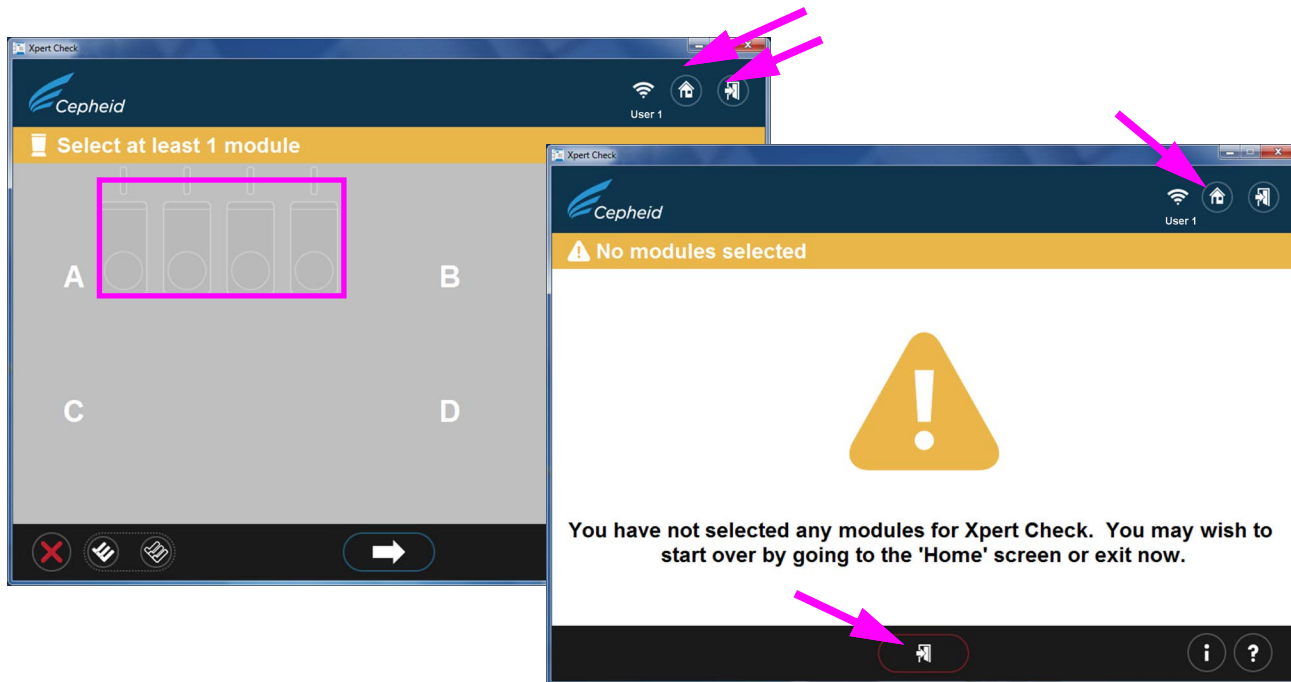
Figure 2-13. Error Screen Examples

15. After confirming your module selection, you will advance to the Scan cartridge screen, where you will be prompted to scan the barcode on the Xpert Check cartridge.

Note	Verify you have enough cartridges on hand to perform the check procedure for the desired number of modules.

16. Remove the test kit cartridge from the package for the module you've previously selected, opening only one cartridge at a time.

Important	**Allow the cartridge to reach ambient temperature before proceeding. Do not remove a cartridge from refrigerated storage and immediately use the cartridge to run this test.**

17. Scan the cartridge barcode. Figure 2-14 shows a cartridge barcode being scanned. Do not substitute a cartridge with another after it's been scanned.

Note	If the barcode cannot be scanned, skip the cartridge and contact your ASP or local Cepheid Technical Support office for a replacement cartridge, if necessary. If the barcode scanner is damaged, missing or incorrectly configured, contact your ASP or local Cepheid Technical Support office for guidance.

Scanning the cartridge barcode

Note: To avoid inserting a wrong cartridge into a module, do not set the cartridge aside after it has been scanned. In one operation, scan the cartridge barcode, vent the cartridge and insert it into the next available (lighted) module.

SKIP button: Touch or click this icon to skip the cartridge just scanned.
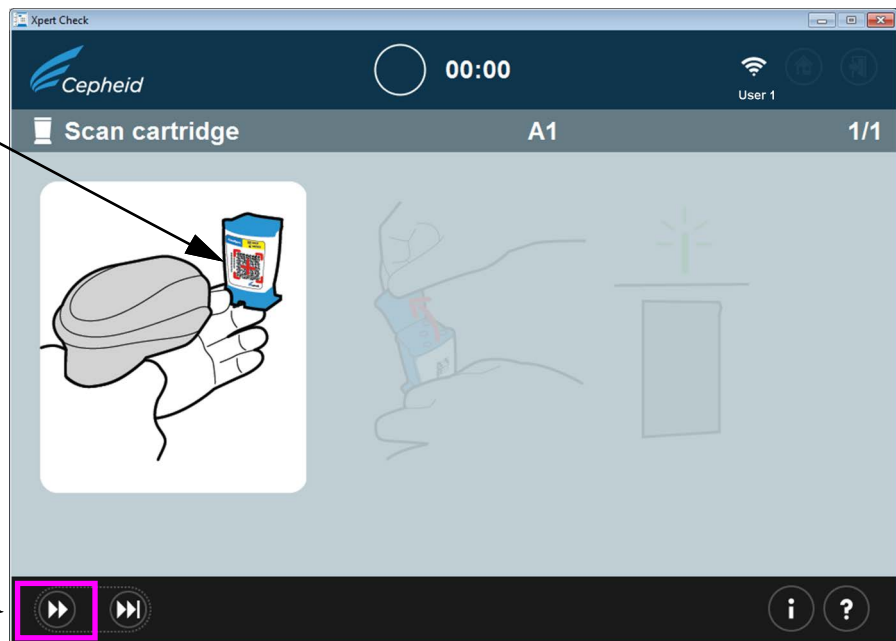
Figure 2-14. Scanning the Cartridge Barcode Screen

A. After scanning the barcode of the cartridge, ensure you open (vent) the cartridge lid and then close it for each cartridge as directed by the software in Step B through Step E below.

Important	**Do Not add a sample or reagent to the cartridge. Use ONLY the cartridges in the Xpert Check kit provided.**

Note	After a cartridge barcode is scanned a green light will blink on the system above the module door where the cartridge is to be loaded. (See Figure 2-17.)

Note	If, for some reason, you want to skip the cartridge just scanned, touch or click the **SKIP** button at the bottom of the screen. An overlay, shown in Figure 2-15, will appear, asking for confirmation on skipping the cartridge. To SKIP the cartridge, touch or click the forward arrow at the bottom of the confirmation screen. To proceed without skipping the cartridge, touch or click the **X** icon at the left bottom corner of the screen. You are urged to rescan a cartridge (or substitute a new cartridge if necessary) to ensure a module is not skipped.

Figure 2-15. Confirm skip Screen

B.   Venting the cartridge (shown in Figure 2-16), for two seconds is sufficient. This screen is animated, showing the cartridge lid being opened and closed. After venting, touch or click the forward arrow at the bottom of the screen to continue.

Opening the cartridge

Closing the cartridge
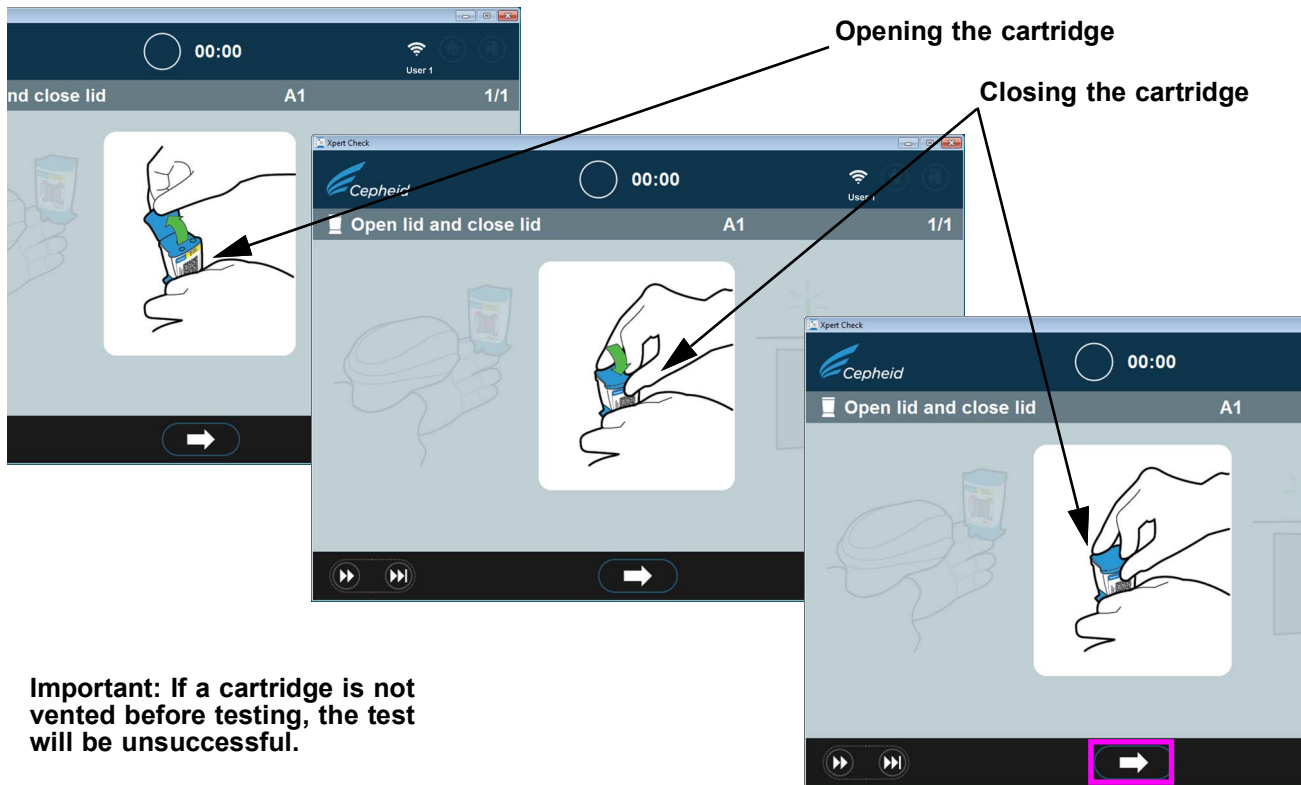
Important: If a cartridge is not vented before testing, the test will be unsuccessful.

Figure 2-16. Venting the Cartridge by Opening and Closing the Cartridge Lid - Animated Screen

> C. Close the cartridge lid and ensure the module door is fully opened to receive the cartridge.
>
> D. Load the cartridge into the module (with the cartridge reaction tube (tab) facing away from you), as directed by the animated software screens. See Figure 2-17.

Note	Be sure to load scanned cartridges in sequence in the next available module. This will avoid loading cartridges in the wrong location or leaving modules empty.

The blinking green light above the module door indicates the correct module loading location

Load the cartridge into the module.

Press firmly on the module door after loading the cartridge, ensuring the door is fully latched.

If a module door will not close and latch, touch or click the SKIP button at the bottom to abort testing the module and move on to the next module to continue testing.

Important: Be sure to remove the cartridge from a module whose door will not latch before proceeding. Notify your ASP or local Cepheid Technical Support office of the malfunctioning module door latch so it can be serviced.

Note that the door on a module without a cartridge loaded will not latch. That door can be left in the open position when running the other loaded modules.

Figure 2-17. Loading the Cartridge into the Module

E. If you are checking additional modules, continue by scanning the next cartridge. Place each individually scanned cartridge into the next selected open module, pressing the module door securely closed until it latches. **As each module door is closed and latched, data collection will automatically start on that specific module.** The blinking green light above the module will then become steady green, indicating that checking has started.

Important	If a module door is not closed completely (until it latches) after loading a cartridge, the screen will continue to display a message to insert a cartridge, and the check will not run. If you are unable to close and latch a module door after several tries, touch or click the SKIP button at the bottom of the screen to skip the module with the faulty door and move ahead. Notify your ASP or local Cepheid Technical Support office so the module can be serviced.

18. Checking will take approximately 20 minutes to complete after the final module has been loaded for testing. When checking begins, the Data collection in progress screen appears, as shown in Figure 2-18.

Important	If necessary, a retest of a previously run module may be started without waiting for the present module to complete its test, as described in steps 19b through 19d.

Countdown clock, showing estimated time to test completion (21 minutes).

Note: In this example, one module is being tested.

⚠ Do not exit the software program while data collection is in progress!
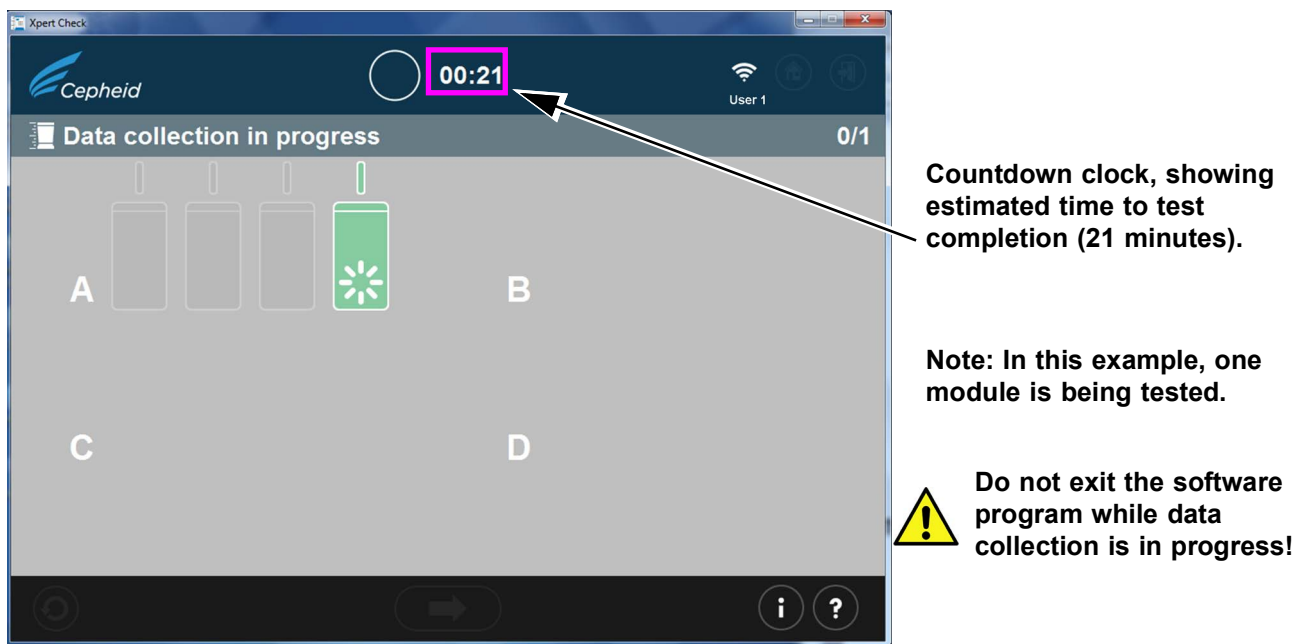
Figure 2-18. Data Collection Screen

Important	If you do not have an internet connection, skip to section 2.2.1 for the remainder of this procedure. If you have an internet connection, continue with step 19.

19. After test completion, the module door will open and the light above the module door will turn off. Screens similar to those shown in Figure 2-19 or Figure 2-20 will appear. Touch or click the right arrow to continue.

   A. Figure 2-19 shows the completion of a successful Xpert Check data collection.

   When the test is complete, touch or click the forward button at the bottom of the screen to begin uploading Xpert Check test results to the Xpert Connectivity Center.

Important	When uploading test results, especially multiple files, verify the selected folder destination is correct.
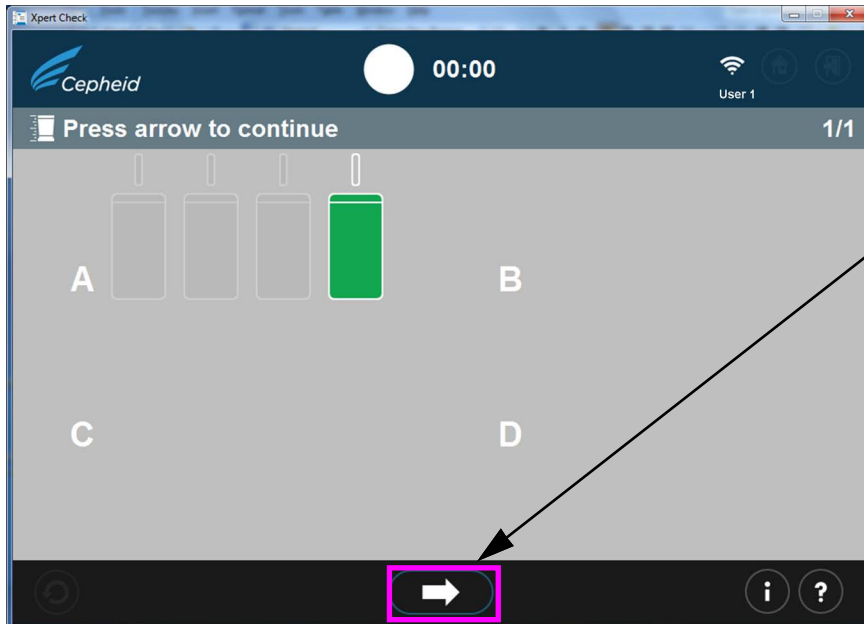
Touch or click to continue to the next screen.

Note: In this example, one module is being tested.

Figure 2-19. Test Completion Screen - Successful

B. If the test was unsuccessful, the screen shown in Figure 2-20 will appear, showing module status. A test retry must be performed. Touch or click the **Retry** icon in the lower left-hand corner of the screen.

Module test unsuccessful. Test must be rerun using either the same or a new cartridge, as instructed by the on-screen display.

Continue button. Touch or click to proceed without retesting. See **Figure 2-21**.

Retry Icon: Touch or click to retest the module.

Note: In this example, one module is being tested.

Figure 2-20. Test Completion Screen - Unsuccessful Module Checking Example

C. If the **Continue** arrow at the bottom of the screen is pressed when there is an unsuccessful module test displayed (as shown in Figure 2-20), the Confirm continue screen will appear. See Figure 2-21.

To return to the Press retry or continue Screen to retest the flagged module, touch or click the X icon.

To continue without retesting the flagged module, touch or click the right arrow at the bottom of the Confirm continue screen.
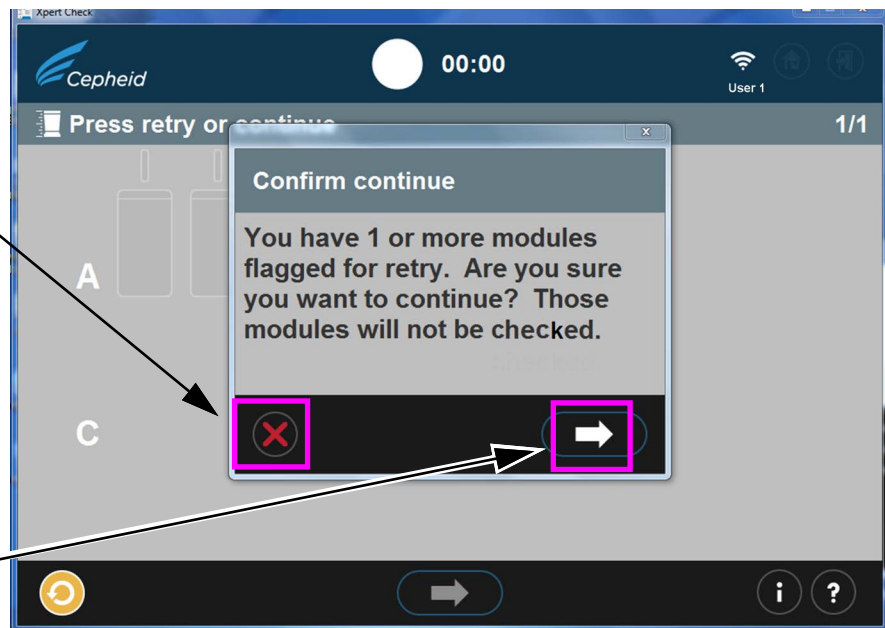
Figure 2-21. Confirm Continue Screen Overlay

You have the option of continuing by touching or clicking the right arrow on the Confirm continue screen overlay. Choosing this option will result in the flagged module not being retested, and you will begin uploading check data as described in Step 20.
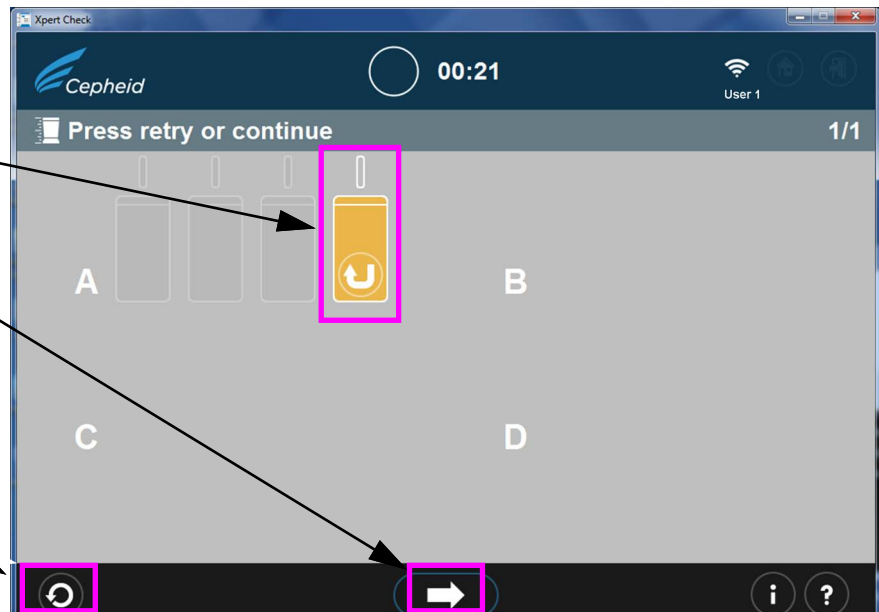
Another option is to return to the Press retry or continue screen to Retry (retest) the flagged module by clicking the red **X** icon at the bottom left of the Confirm continue screen. The Retry procedure is described in Step D which follows.

D.   If the Retry icon (shown above in Figure 2-21 at the bottom of the screen) appears, touch or click the Retry icon and you will return to the Scan Barcode screen (Figure 2-14) to complete the retest on the affected module(s).

Note that the retest can be of two possible types:

1)   Retry with the same cartridge: For example, a message may appear telling you to vent the cartridge, rescan it, and put it back in the module.

2)   Retry with a new cartridge: If the cartridge was defective, or had already been used, you will be asked to replace it by scanning the barcode on a new cartridge, venting it, and loading it into the module.

Note	During the course of running retests, modules may need to be skipped if the user runs out of Xpert Check cartridges. Please contact your ASP or local Cepheid Technical Support office for additional Xpert Check cartridges. Rerun Xpert Check on any modules that were skipped.

Note	At the completion of the Xpert Check data collection process, modules determined to require service will be flagged with an orange module icon (See Figure 2-20). Please contact your local ASP or local Cepheid Technical Support office for further assistance in servicing or replacing modules.

20.   After successful test completion and Xpert Check data collection, touch or click the forward arrow to display the screen shown in Figure 2-22, if you have an active

internet connection. However, if you have never been internet connected, or have lost your functioning internet connection sometime during the Xpert Check test, a Download Xpert Check code error screen or an Upload incomplete error screen (Figure 2-23) may appear instead, instructing you to write Xpert Check data to a data CD to send to your ASP or local Cepheid Technical Support office. In this case, continue to the instructions beginning at Step 4 (under Section 2.3.1) of this procedure to continue as a user without an internet connection.

| **Note** | With a functioning internet connection, the system should proceed normally (with Step 21), and the Xpert Check code should begin downloading, as shown in Figure 2-24. |
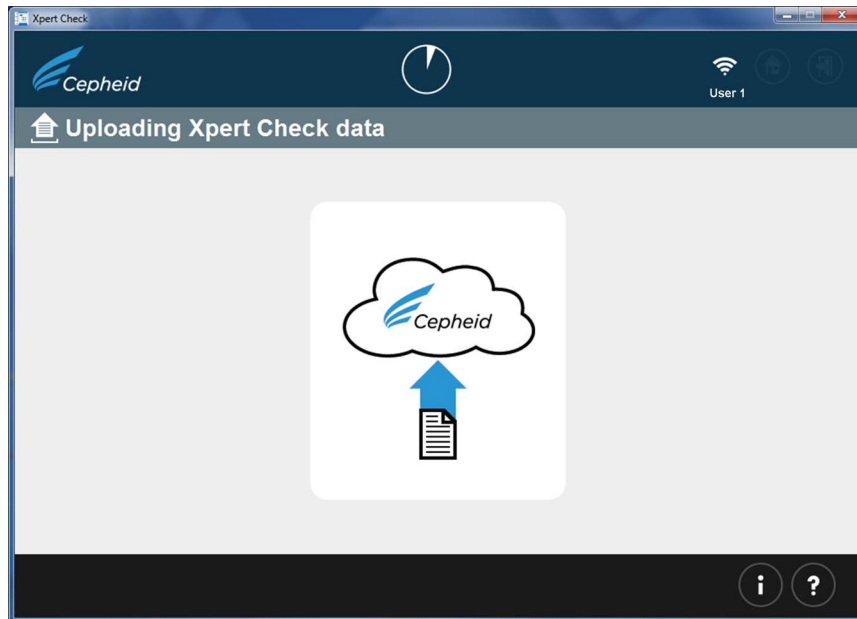
Figure 2-22. Uploading Xpert Check Data Screen

Touch or click this icon to move to the Write Xpert Check Data to CD screen. See Figure 2-31.
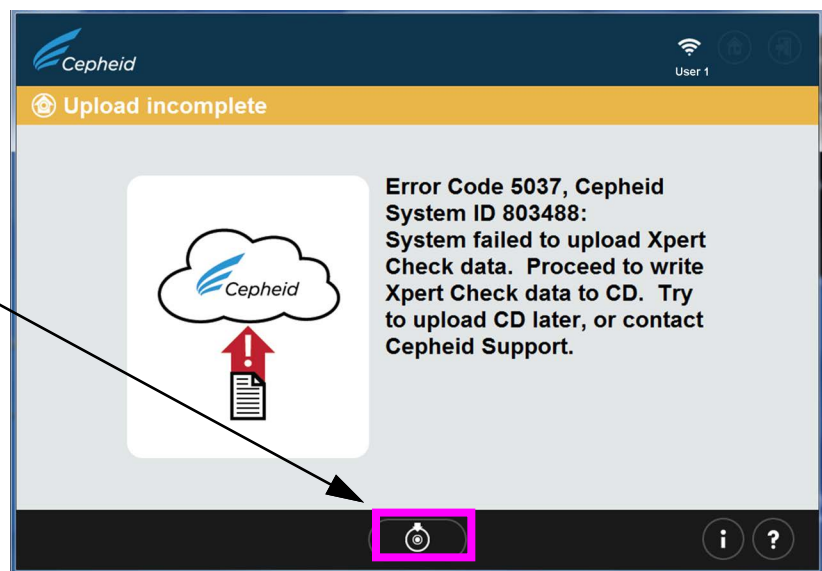
Figure 2-23. Upload incomplete Error Screen

21. When the Xpert Check data has finished uploading, a Quality Assurance check will be performed on the data. If the check is acceptable, the Xpert Check code will automatically download. See Figure 2-24.

     If the test is not acceptable, the affected module(s) will require service or replacement and will be flagged with an orange icon. Please contact Cepheid or your local ASP or the local Cepheid Technical Support office for further assistance.
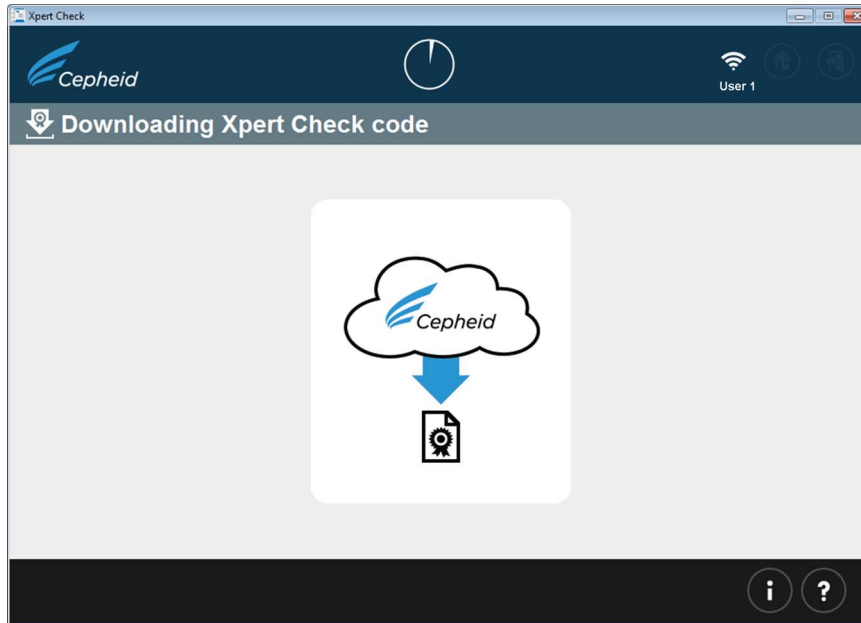
Figure 2-24. Downloading Xpert Check code Screen

22. After the Xpert Check test results have downloaded, the Xpert Check code will be applied to each successfully tested module, and those modules will then be identified with a **+** symbol. See Figure 2-25. As shown here, one module is being checked.

After the Xpert Check code is applied to each module, a plus (+) symbol is added to the green module icon.

Note: If this Service Required icon (at left) appears instead of the "+" symbol on a checked module, call your ASP or local Cepheid Technical Support office for service.
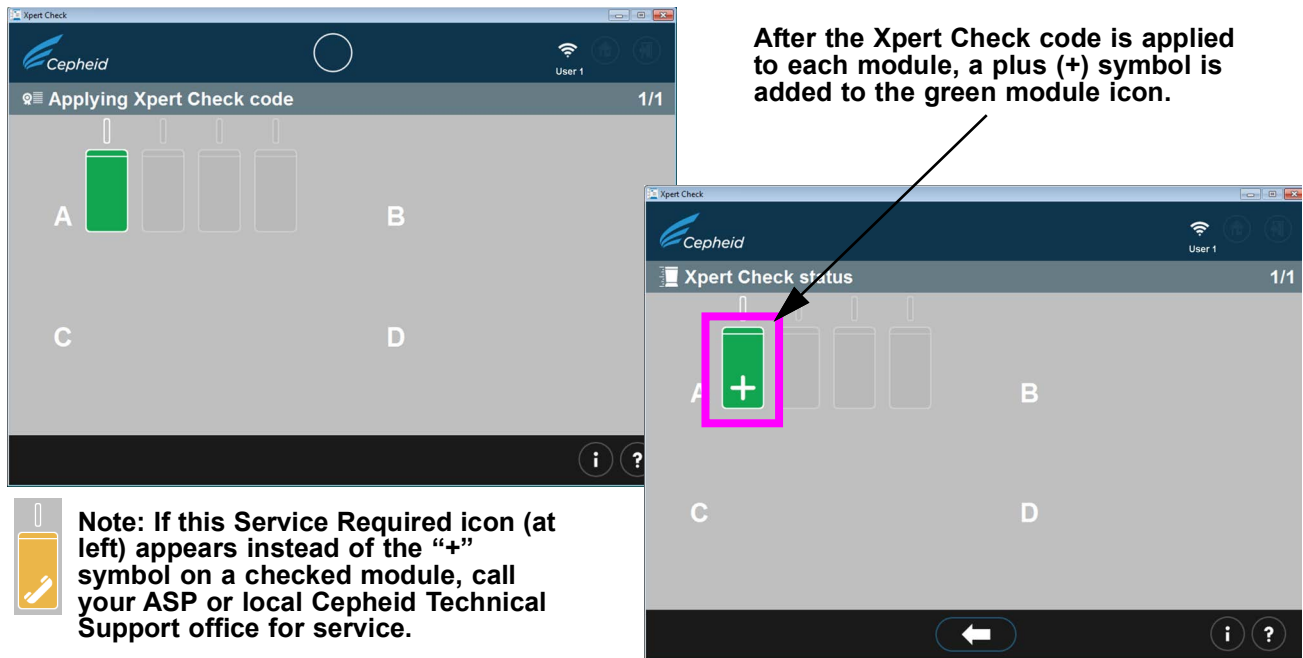
Figure 2-25. Applying Xpert Check code Screen

Note | In the screen shown in Figure 2-25, some modules may display the service required icon or may be grayed out if they were skipped.

23. After all the Xpert Check codes have been applied to the successfully-tested modules (those green modules which appear with the plus symbols applied), the Xpert Check complete screen will appear. See Figure 2-26. This screen shows the location of the Xpert Check Data report, which is available for review, if desired.

Review Xpert Check Status button

Location of Xpert Check reports
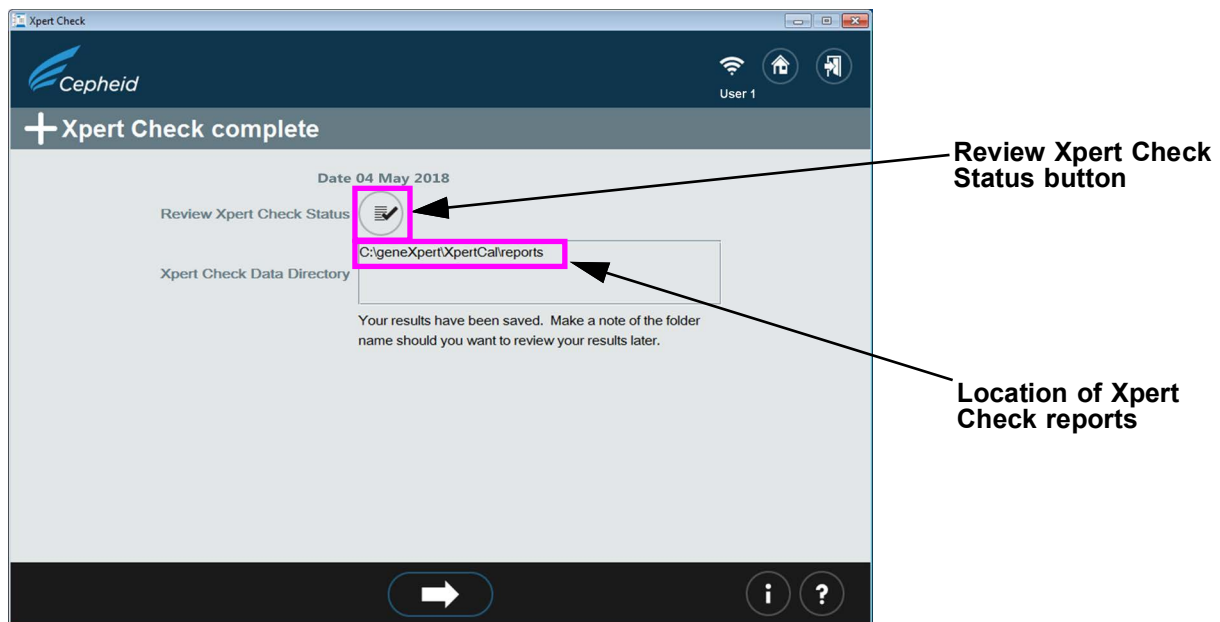
Figure 2-26. Xpert Check complete Screen

24. Remove and discard all Xpert Check cartridges. Do not save partial kits (all unused cartridges must be discarded).When complete, click the **Exit** icon at the top or bottom of the screen to exit the program. See Figure 2-27.

Touch or click to exit the program with a confirmation (see Figure 2-28).

Touch or click to exit the program immediately, without confirmation.
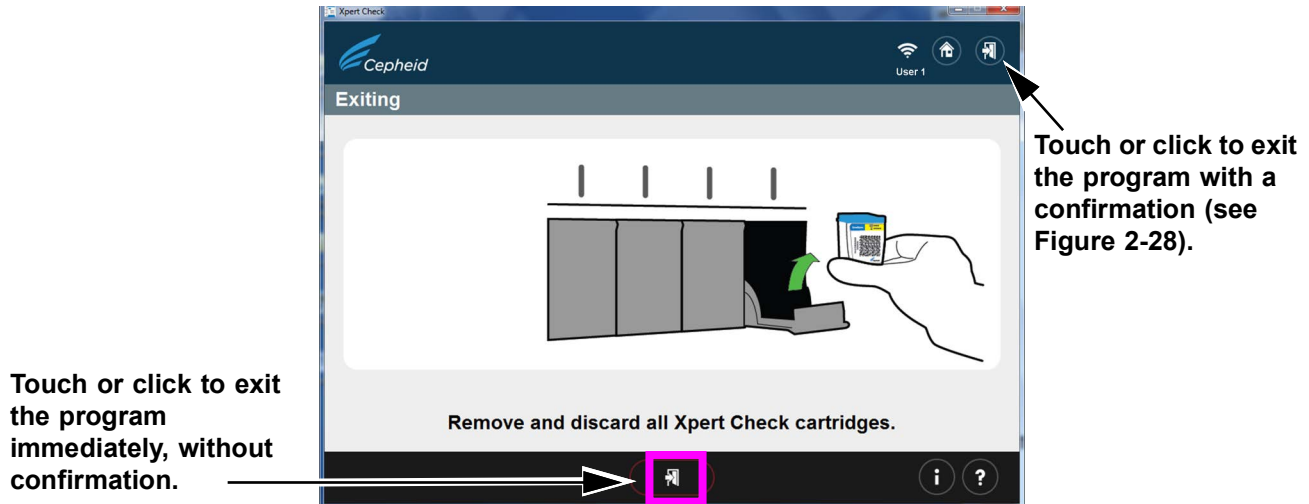
Figure 2-27. Exit the Program

25. The screen shown in Figure 2-28 appears only if you touch or click the exit arrow in the upper right of the screen.
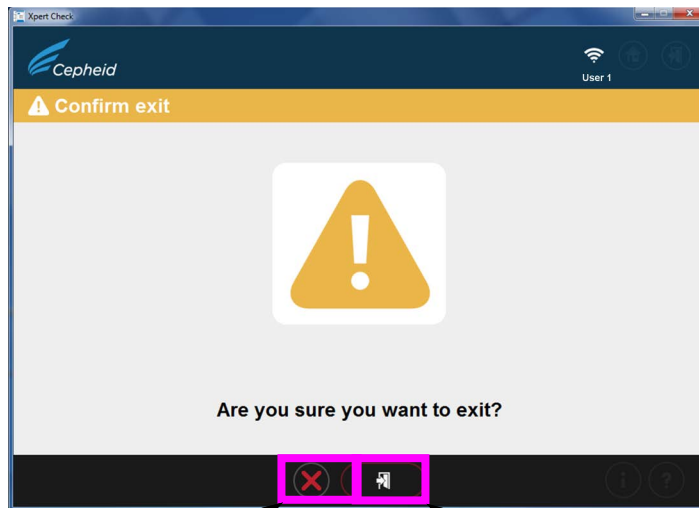
Touch or click to abort the exit command   **Touch or click to confirm and exit the program**

Figure 2-28. Confirm exit Screen

This completes the Xpert Check Test for an internet-connected user.

Note	Contact your Authorized Service Provider or the local Cepheid Technical Support office concerning modules requiring service.
Note	To view your Xpert Check results, see Step 23 and Figure 2-26, which shows the file path and location of Xpert Check results and the Xpert Check Summary report.

2.3.1 Xpert Check Completion For Non-internet Connected Users

For Non-internet connected users, you should have completed Step 1 through Step 19 of Section 2.3 to collect data before starting this section.

1. This section begins with the Data collection in progress screen, which is similar to Step 18 in Section 2.3, and the screen shown in Figure 2-18 for internet-connected users.

Icon Indicates There is No Internet Connection

Countdown clock, showing estimated time to test completion (18 minutes)

Figure 2-29. Data collection in progress Screen

2. After test completion, the module door will open and the light above the module will turn off. A screen similar to that shown in Figure 2-30 will appear. Touch or click the right arrow at the bottom of the screen to advance to the next screen.
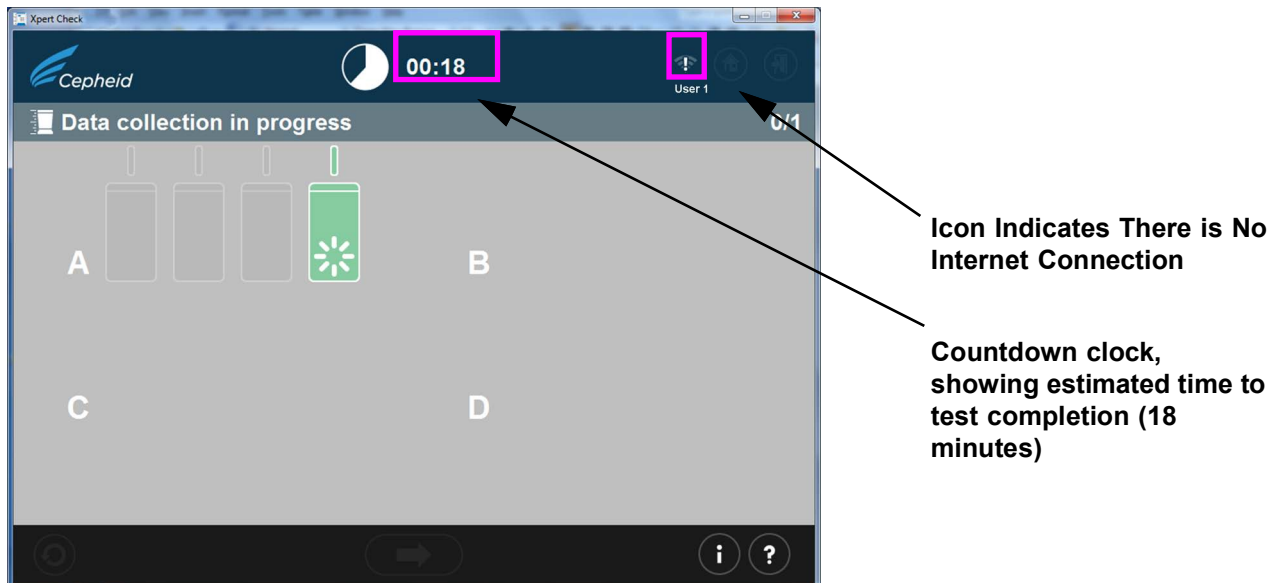

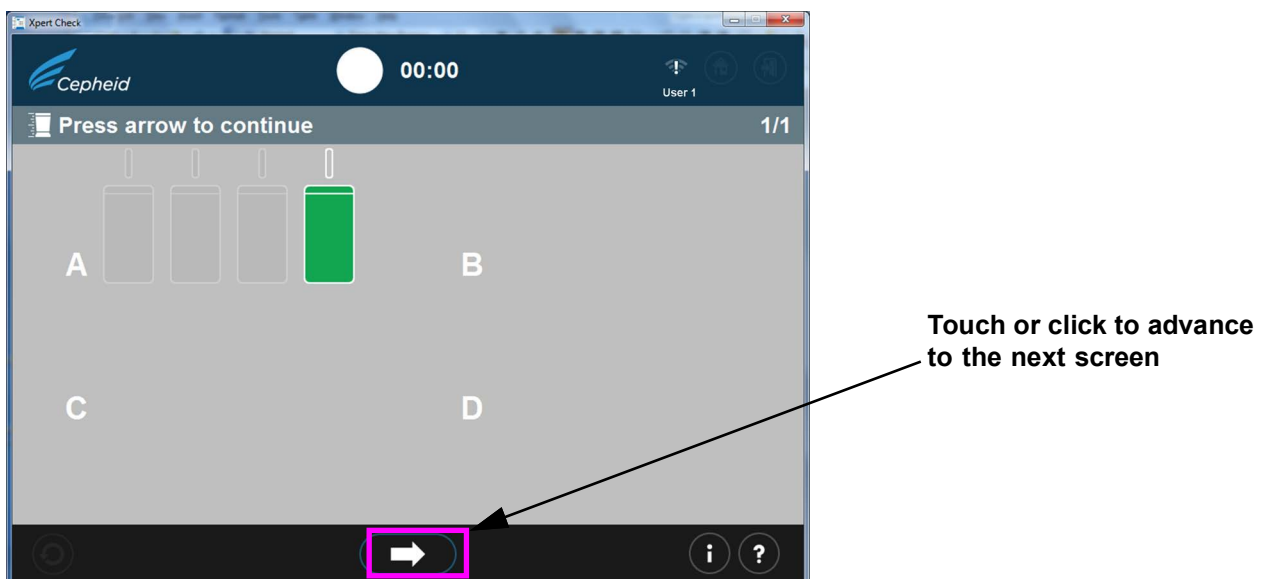**Touch or click to advance to the next screen**

Figure 2-30. Test Completion screen - Successful

3. When the Write Xpert Check data to CD screen appears (Figure 2-31), you will be prompted to press the **Eject** button on the DVD drive to remove the existing Xpert Check Software CD so you can insert the blank data CD.
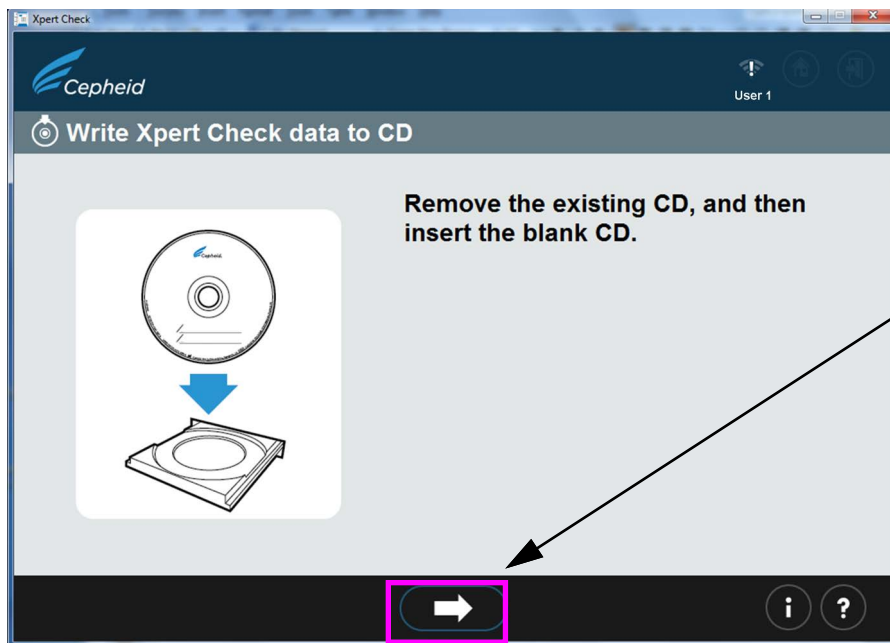
Note	In the following step, use care in inserting the blank CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.
Important	**If you have been running this test as an internet-connected user and then lose your internet connection and received an error screen (Figure 2-23), resume your procedure beginning with the following Step 4, continuing through Step 12.**
Note	In the following step, pause for 10 seconds after CD insertion and cancel any wizards that auto-open before touching or clicking the forward arrow to proceed. When you either close the wizard or have waited enough time to ensure that a wizard will not auto-open, touch or click the forward button to proceed. This will launch the Windows CD burning screens that the Xpert Check program opens.

4. Insert the blank CD into the DVD drive of the computer and close the DVD drive tray fully to ensure the CD will be recognized.

   Pause to allow the launch of any possible CD wizard programs. If wizard programs launch, close them before touching or clicking the forward button to proceed.

Figure 2-31. Write Xpert Check data to CD Screen - Step 1

5. After inserting the blank CD, the screen will change briefly, indicating the CD has been recognized. See Figure 2-32. This screen will remain displayed until the CD writing process is complete.

Note	It is not necessary for the user to locate the file to write because that process is automatic.
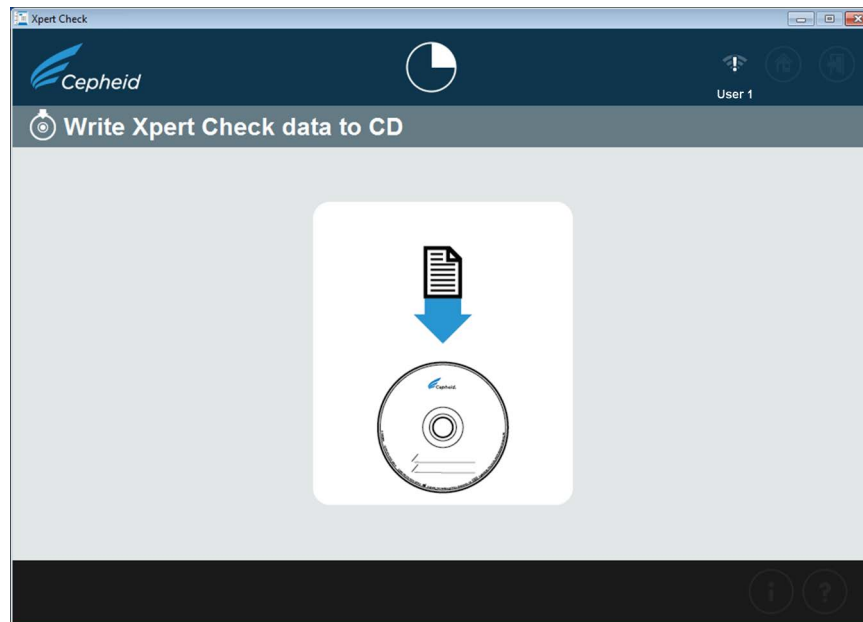
Figure 2-32. Write Xpert Check data to CD screen - Step 2

6.   The CD Writing Wizard or Burn to Disc screen (Figure 2-34) will then appear as an overlay of the screen shown above, in Figure 2-32.

The next screens (Figure 2-33 though Figure 2-37) show the CD writing program screens as you progress through the writing process.

- Windows® 7 users: Follow the screens on the top of the figure.

- Windows®10 users: Follow the screens at the bottom of the figure.

A.   On the first screen, after successful recognition of the blank CD, you will be asked to provide a name for the CD that you will be writing. DO NOT simply touch or click the **Next** button to continue the writing process with the default name that appears. Instead, type in your facility's name, such as "XYZ Hospital," in the space provided and touch or click **Next**. See Figure 2-33.

**Type in your facility name
for the CD name/Disc title**
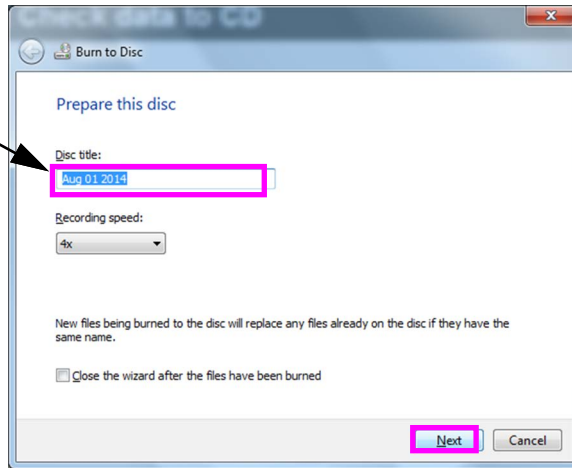
Opening Screen - Windows 7
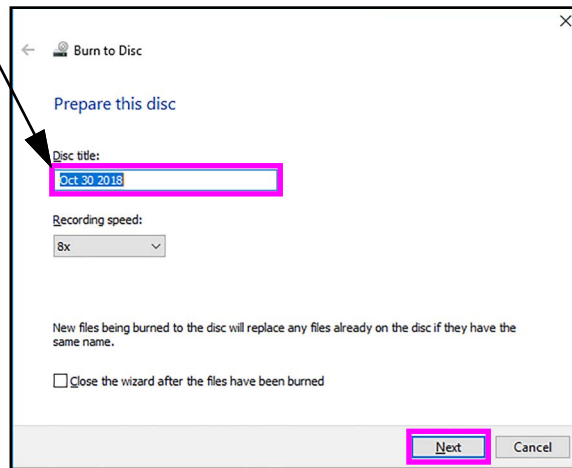
Opening Screen - Windows 10

Figure 2-33. CD Writing Program - Opening Screen

B.   If the CD is not recognized, the screen shown in Figure 2-34 may appear, instead of the screen in Figure 2-35, asking you to insert a writable disc to continue. Writable discs, in this case, are CDs on which you can store files. Writable discs can only be written to once, meaning that once any files are copied to the disc, they are there permanently.

A disc that has data on it is not considered to be a writable disc and will result in an error screen, as shown in Figure 2-39.

Note   If you are unsuccessful with any part of the CD writing process, you may contact your ASP or local Cepheid Technical Support office for assistance. It is safe for you to close the Xpert Check software now because the Xpert Check files have been saved to the hard drive and you will not lose data.
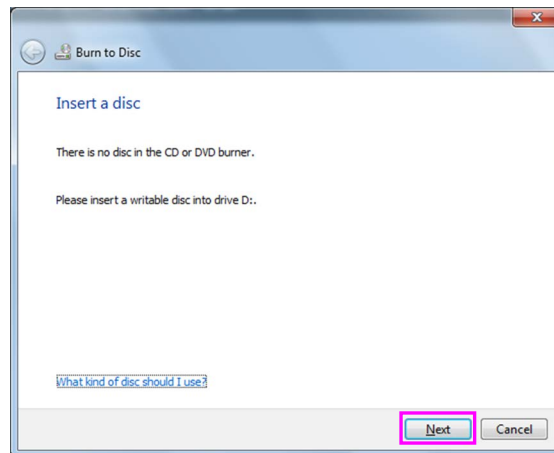
Insert a Disc Screen - Windows 7
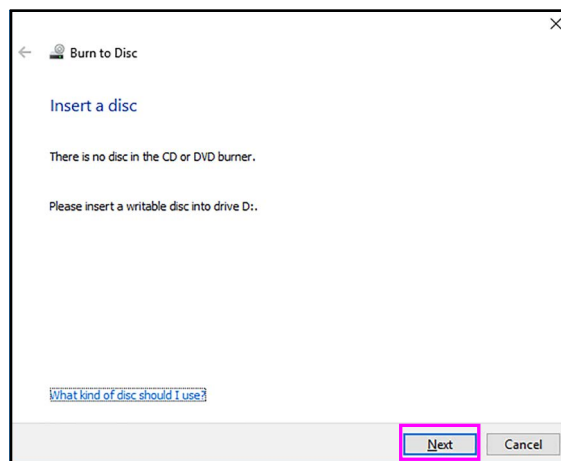
Insert a Disc Screen - Windows 10

Figure 2-34. CD Writing program - Insert a writable disk to continue Screen - Example

  C. After successful recognition and naming of the CD, touch or click the **Next** button to continue. The writing process will begin automatically.

  D. During the writing/burning process, a progress bar will appear on the screen. See Figure 2-35.
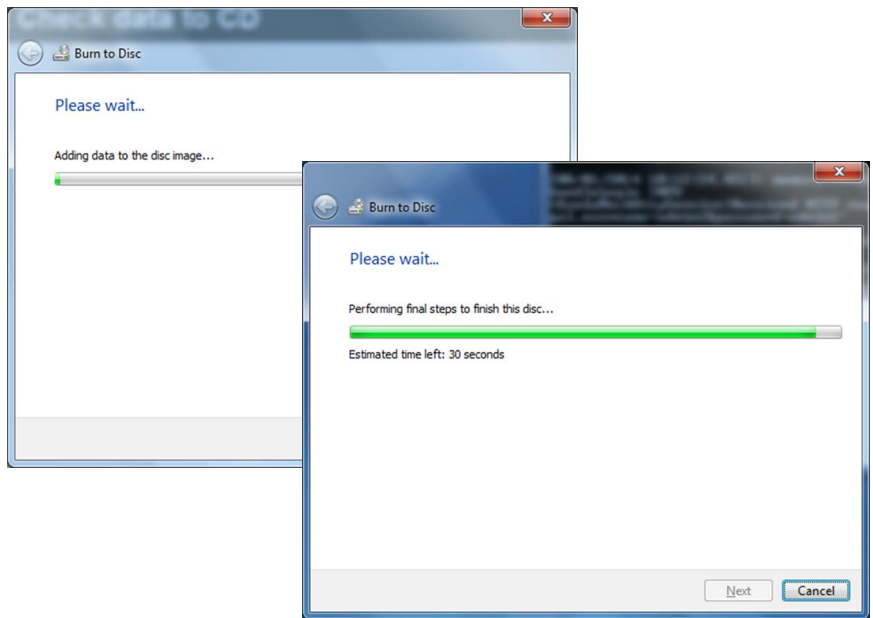
File Burning Progress Screens - Windows 7
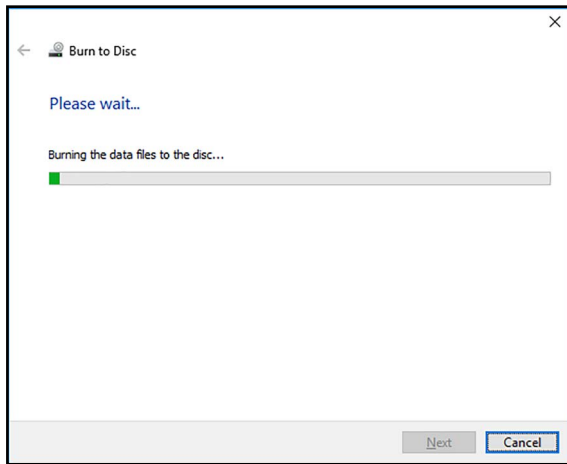
File Burning Progress Screen - Windows 10

Figure 2-35. CD Writing/Burning Progress Screen

E.   When the writing of the CD is complete, the screen shown in Figure 2-36 will appear. Touch or click the **Finish** button to exit the CD writing program.
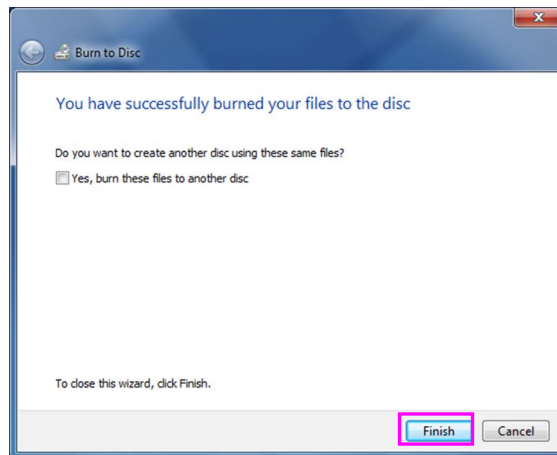
Completion Screen - Windows 7
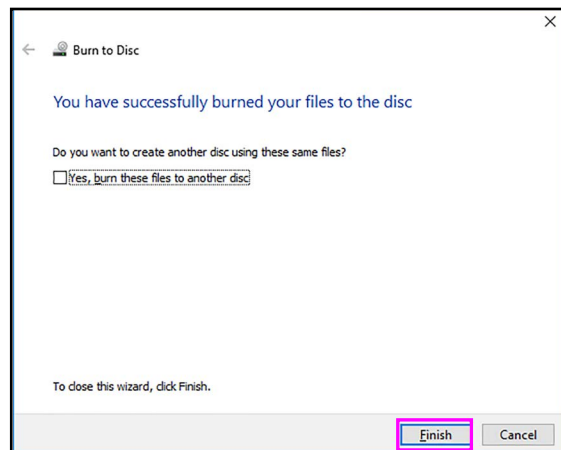
Completion Screen - Windows 10

Figure 2-36. CD Writing Completion Screen

F. On a Windows 7 computer, you may see the screen displayed in Figure 2-37 after a successful CD write. Touch or click the **OK** button as many times as necessary for the screen to disappear, before continuing.
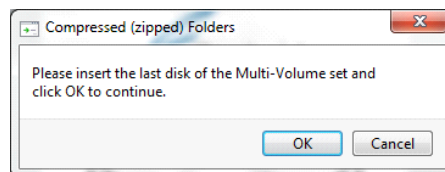
Figure 2-37. Final Screen from Windows 7 After CD Writing has Completed

7. After touching or clicking the **Finish** button on the CD writing screen, the Send the CD to your Authorized Service Provider Screen will appear (see Figure 2-38). Remove the completed Xpert Check data CD from the disk drive and prepare the label, as described in Step 10.

Touch or click to proceed to the next screen, prior to shutdown.
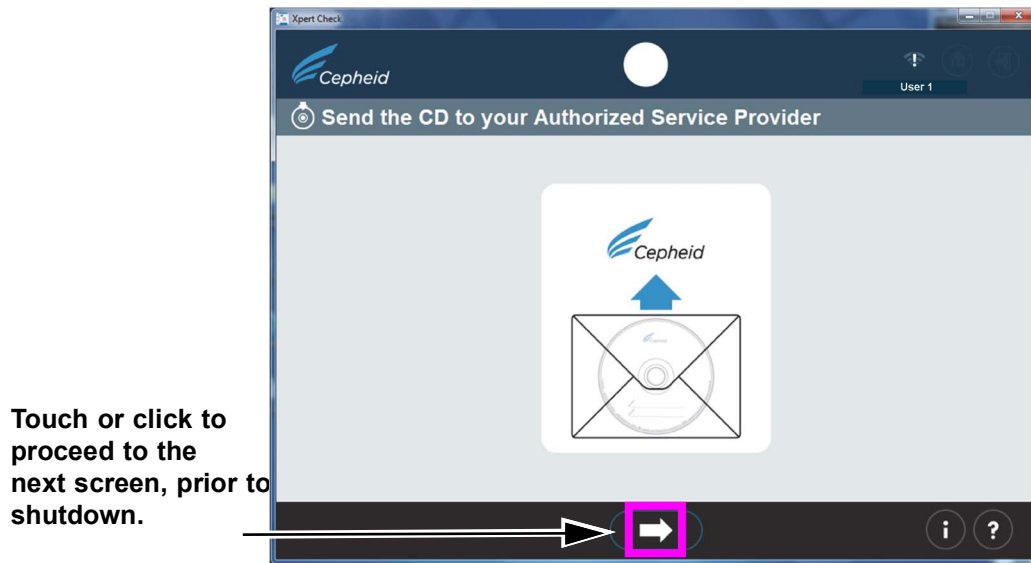
Figure 2-38. Send the CD to your Authorized Service Provider Screen - Step 3

8. If a problem has occurred anytime during the CD writing process, an error code screen may appear. (See Figure 2-39).

- If a CD you have inserted already contains data as shown in the error screen below at the left, remove the CD and insert a blank CD, and then touch or click the **Retry** icon.

- In the case of a read or write error, the screen shown at the right may appear and you must exit the program. Contact your ASP or the local Cepheid Technical Support office for assistance, if necessary.

Disc is not Writable (Already Contains Data)   **General Write Failure**
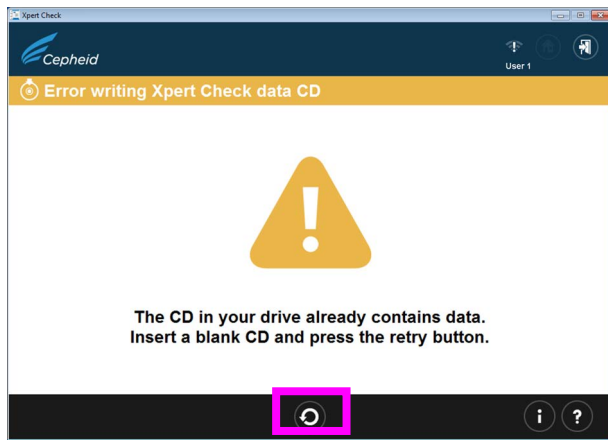
Retry Button
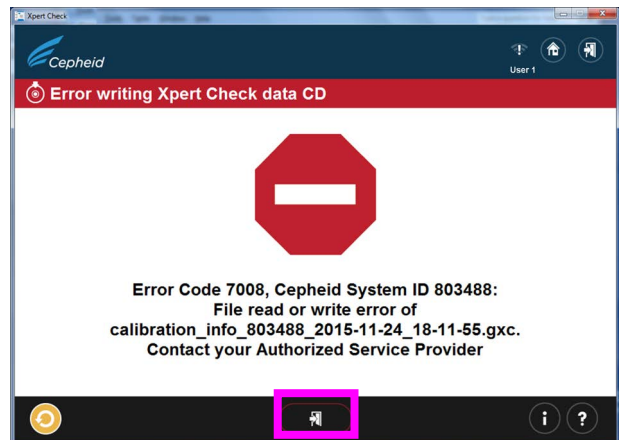
Exit the Program

Figure 2-39. Error writing Xpert Check data CD Screens - Two Examples

9. After test completion, the Exiting screen will appear with the message **Remove and discard all Xpert Check cartridges** (see Figure 2-40).

Touch or click to exit the program.
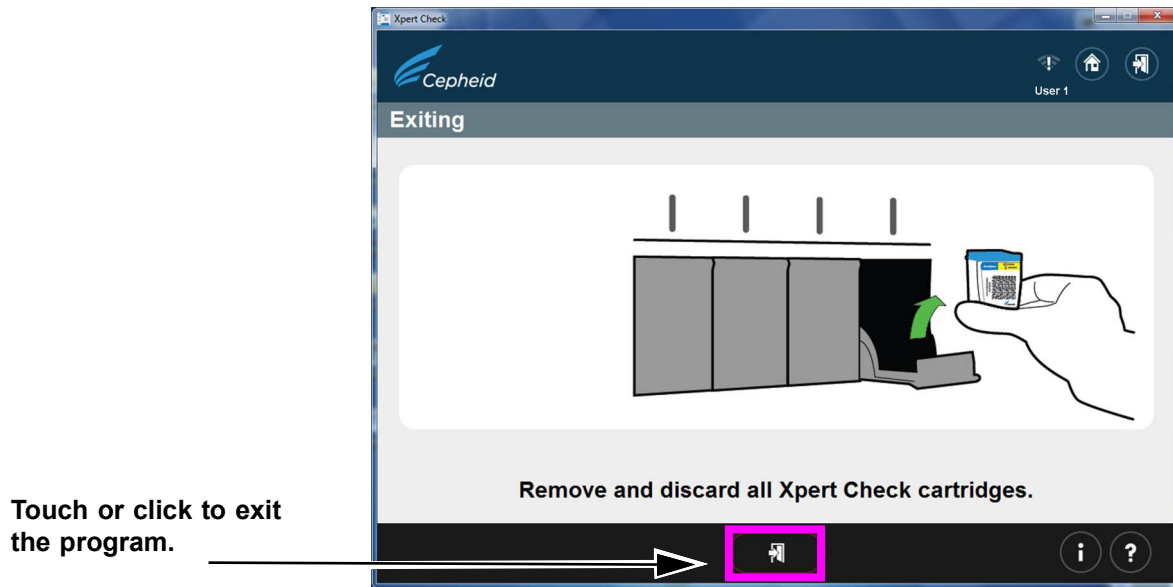
Figure 2-40. Exiting Screen

10. Use a felt-tip pen to write on the label of the Xpert Check data CD you have just created by writing the date, instrument identification and facility/location of the test performed. See a label example in Figure 2-41.

Note: It is the responsibility of the user to properly enter the date, instrument identification, facility name and location on the Data CD label.

Failure to properly label your Data CD may result in lost data and a delay in obtaining your module Xpert Check code test.

Date-Instrument Identification

Facility, Location

Figure 2-41. Data CD Labeling Example

11. You have the option to copy the calibration_info.gxc data file (located on the Xpert Check data CD just written) and Email the data file directly to your ASP or the local Cepheid Technical Support office instead of mailing the CD. If Email is not an option, place the Xpert Check CD2 into the provided CD shipping envelope and mail it to your local Authorized Service Provider (ASP) or the local Cepheid Technical Support office for data quality assurance checking and the issuing of your Xpert Check code.

12. Your ASP or the local Cepheid Technical Support office will perform the quality assurance review and, if successful, send back your Xpert Check code either by Email or regular mail, depending on what method you have previously set up with them.

Note Discard all remaining materials from the kit. DO NOT save unopened kit pouches for later use. DO NOT discard your Software CD. For users who Emailed their file and have not shipped their data CD: DO NOT discard your Data CD.

13. Restart your GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity system and computer.

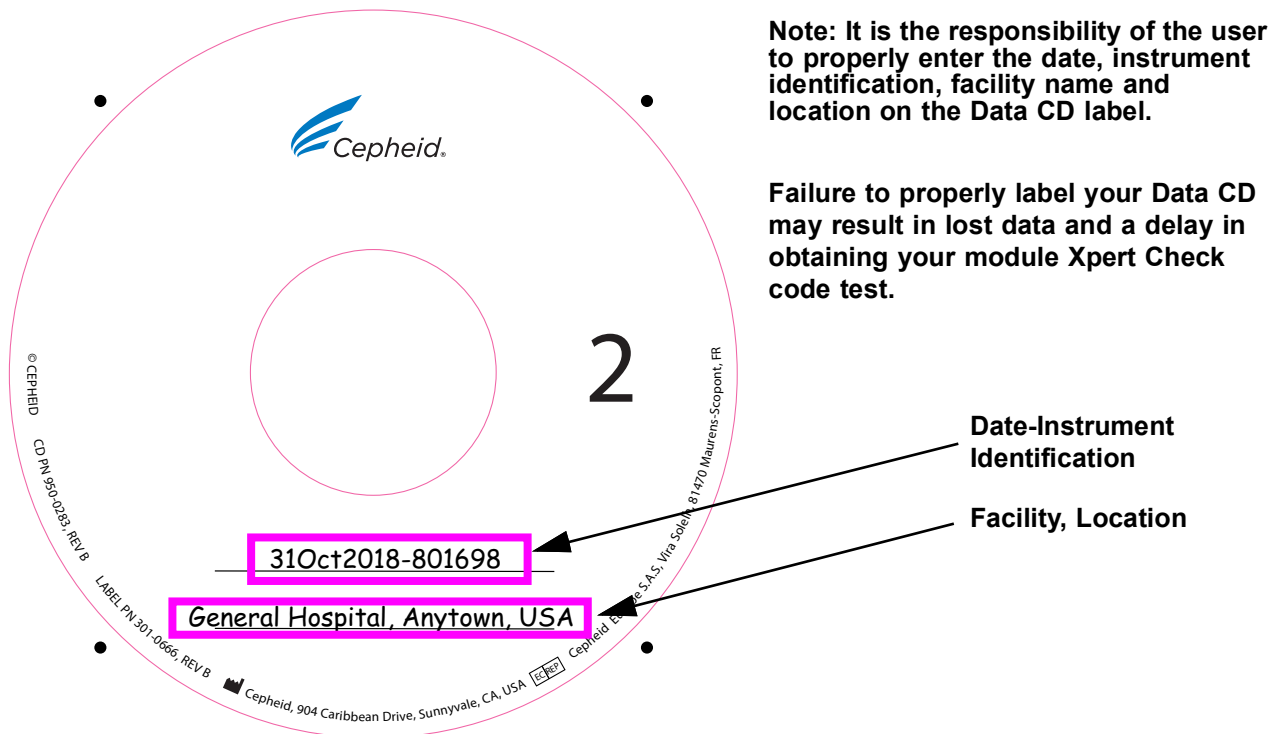**Note** You can continue to use your system while awaiting your Xpert Check code.

2.3.2 Obtaining the Xpert Check Code for Non-Internet Connected Users

Note Ensure the system is in the same configuration as when Xpert Check was run (i.e., no software updates or changes have been made and no new GeneXpert systems have been moved to or from this computer). In the case of any module servicing and/or replacement that may occur between data collection and application of the Xpert Check Code, new or modified modules will be ignored for the purposes of the Xpert Check testing process.

Note In the following step, use care in inserting the CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

1. Exit the GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity software.

2. To finish the Xpert Check process, place the Software CD in the DVD drive of the computer connected to the GeneXpert Dx or GeneXpert Xpress instrument or in the kiosk computer for the GeneXpert Infinity.

3. Touch or click on My Computer, then touch and hold or double-click on the applicable drive letter for your DVD drive. The files located on the CD will then be displayed. Find and touch and hold or double-click the **XpertCheck.exe** application/ shortcut to launch the software.

4. Log in with your GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity designated **USER NAME** and **PASSWORD** (see the IMPORTANT note in Section 2.1). Also see Figure 2-4 for the Login screen.

   After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the next screen (the Xpert Check Home screen).

Note	The user name and password are the same ones you used for the GeneXpert Dx, GeneXpert Xpress or Xpertise software. If an ASP (FSE) previously performed Xpert Check and is not now on site, the user name and password should have been provided for this step to enter the code. If the user name or password are not now available, contact your ASP or your local Cepheid Technical Support office.

5. Touch or click the **Enter Xpert Check Code** button. See Figure 2-42. The Enter Xpert Check code screen will appear. See Figure 2-43.
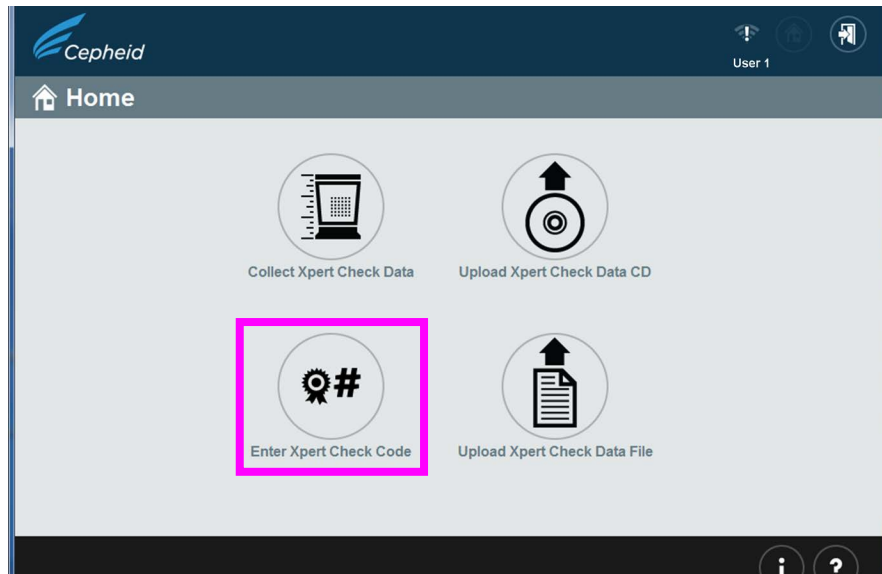

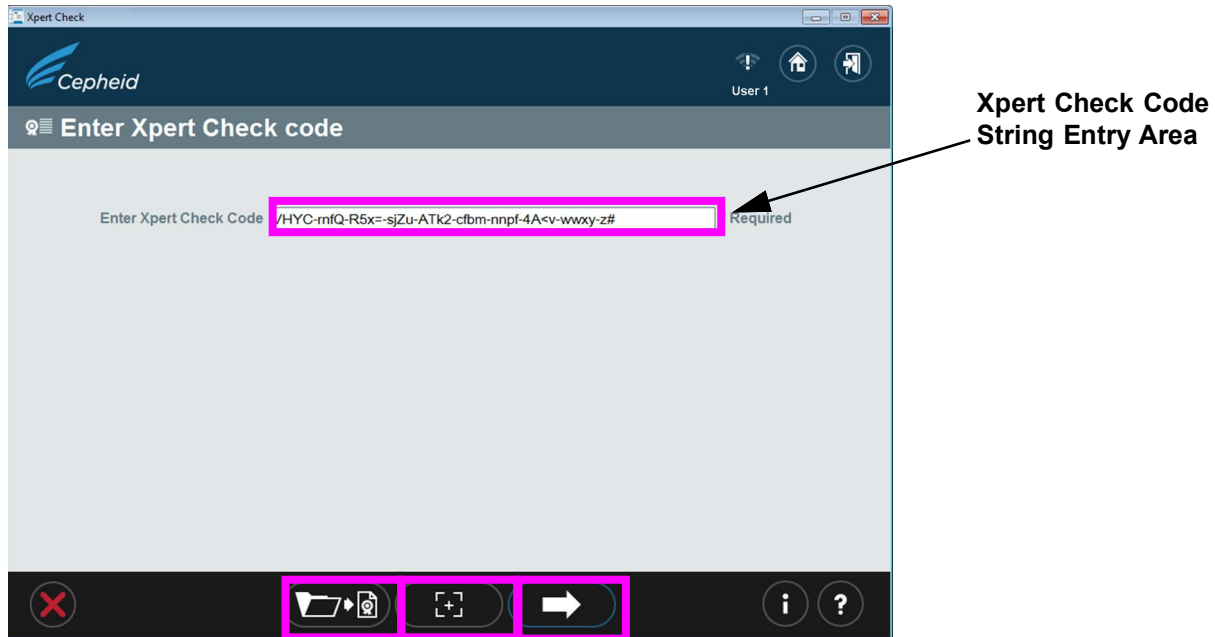**Figure 2-42. Home Screen, showing Enter Xpert Check Code Button**

Figure 2-43. Enter Xpert Check code Screen

6. Enter your Xpert Check code as described below.

    In this step, there are various ways to enter the Xpert Check code, depending on your system. Your four options are listed below.

    A. Option 1 (For GeneXpert Dx or GeneXpert Infinity systems only): Use your scanner to input the barcode as follows: First, click the icon located in the bottom center of the screen. The Xpert Check Code File (Figure 2-44) will appear on your screen. Position your scanner to scan the barcode on the Code form, using care to avoid any reflection on the monitor that may interfere with your scanner. See Figure 2-44 for an example of an Xpert Check Code File.

    B. Option 2 (For all systems): Print a copy of the Xpert Check Code File and use your scanner to scan the barcode on the printed page. See Figure 2-44 for an example of an Xpert Check Code File.

    C. Option 3 (For GeneXpert Dx and GeneXpert Infinity systems only): Copy and paste the code string into the Enter code screen from the screen's display. The code string is visible on Figure 2-44.

    D. Option 4 (For all systems): Type in the code string manually using the information on your screen or printed page.

    When you have successfully entered the code, touch or click the forward arrow at the bottom of the screen to continue. The Applying Xpert Check code screen will appear. See Figure 2-45.

Figure 2-44. Xpert Check Code File - Example

Figure 2-45. Applying Xpert Check code Screen Example

    E.   After the Xpert Check code has been applied, the Xpert Check Complete screen will appear with the location of the Xpert Check Report displayed in the **Xpert Check Data Directory** area. Write down the file path and location of the Xpert Check Report file, as shown. See Figure 2-46.

Figure 2-46. Xpert Check complete Screen

    F.   Touch or click the **Review Xpert Check Status** button (see Figure 2-46).

    G.   The Xpert Check status screen will appear. See Figure 2-47. In the Xpert Check status screen, the successfully checked modules are indicated by a **+** symbol on a green module.
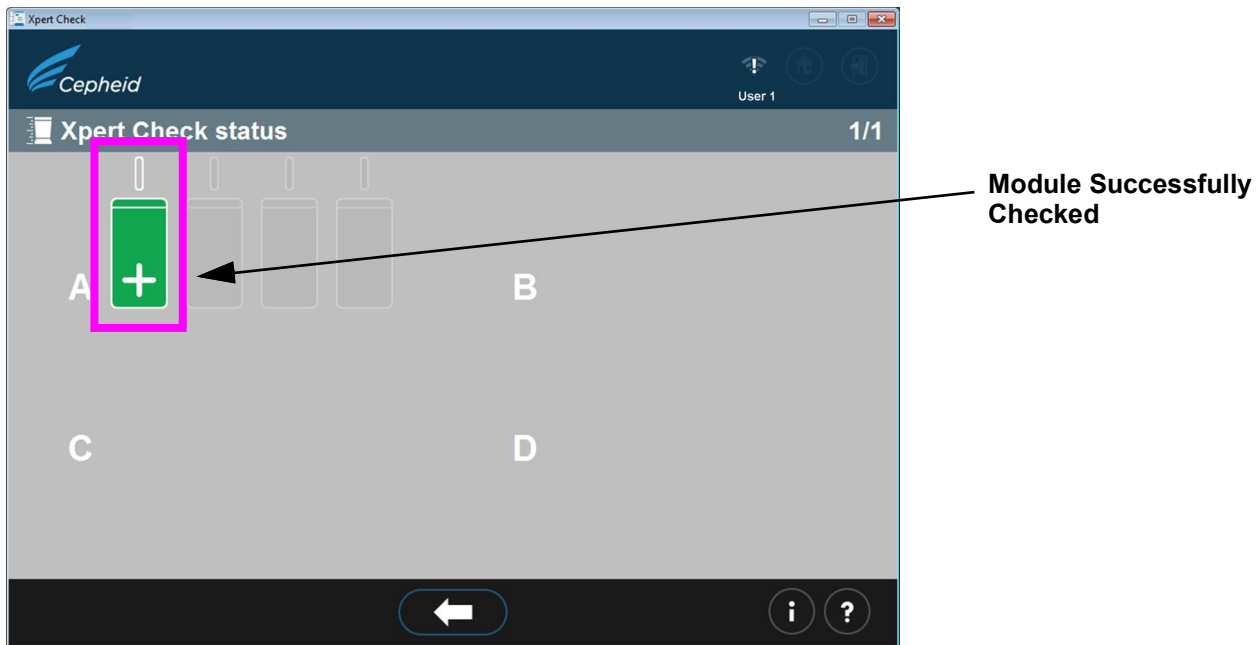
Figure 2-47. Xpert Check status Screen

Note	If the Xpert Check report on the computer has been deleted, contact your ASP or the local Cepheid Technical Support office for assistance.

7. Identify the generated Xpert Check Report file in the folder **C:\GeneXpert\XpertCal\Reports**.

8. Identify the generated Xpert Check Summary Report file in the folder **C:\GeneXpert\XpertCal\Reports**.

   A. See Figure 2-48 for an example of a Xpert Check Summary Report.

   The Xpert Check Summary Report lists the modules that had an unsuccessful test and require retesting or service.

   The modules requiring retesting or service are listed by serial number in Table 1 on the form in Figure 2-48. When requesting service, provide these listed serial numbers to your ASP or the local Cepheid Technical Support office.

   Gateway information is provided in Table 2 of the form.

<div style="border: 1px solid black; padding: 20px;">

<p align="center">

Cepheid®
</p>

<p align="center" style="color: #4a90d9; font-size: large;">Xpert Check Summary Report</p>

Please Note:

<table>
<tr><td>
Xpert Check data collection performed on 30 September 2020 09:37:04 PDT
All modules that DID NOT pass Xpert Check are listed in Table 1: Modules Requiring Service.
Gateway Informations are provided in Table 2.
Complete test results for each module are listed in Table 3: Detailed Test Results by Module.
</td></tr>
</table>

GX Instrument Name:	My 6Color
Instrument Serial Number:	12345
Data Collected By:	User1
Institution Name:	Institution1
Laboratory Name:	Laboratory Sunnyvale
Street Address:	123 Main Street
City:	Sunnyvale
State/Province:	CA
Postal Code:	90001
Country:	USA
Email:	User1@Institution1.com
Facility Phone Number:	408-400-XXXX
Extension:	
Mobile:	
ASP Code:	US03

Table 1: Modules Requiring Service

Module Serial Number / Location	Module Status
639563/A2	Skipped and Retest required
639565/A1	Requiring Service

Table 2: Gateway Information

Gateway Serial Number	MAC Address
804471	00:21:38:00:2E:1B
804470	00:21:38:00:2E:1A

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</div>

<p align="center">**Figure 2-48. Xpert Check Summary Report Example - Page 1**</p>

Xpert Check Summary Report

Table 3: Detailed Test Results by Module Serial Number

The column header will show Module Serial Number, followed by (Location / Cartridge Lot).

If a module undergoes multiple tests, the Module Serial Number will be shown as Module Serial Number : Cartridge -Test Run.

Test	639565 (A1/00402)
Cartridge Load	pass
Module Tests	pass
Ambient Temperature	pass
Motherboard EEPROM	pass
ICORE EEPROM	pass
+12V Power Supply	pass
-12V Power Supply	pass
+24V Power Supply	pass
Valve Drive	pass
Valve Label Dropouts	pass
Valve Home Integrity	pass
Valve Timing	pass
Valve Drift	pass
Pump Drive	pass
Ultrasonic	pass
ICORE Heater	pass
ICORE Fan	pass
Force Sensor	pass
Optical Check	fail
EBF Value	pass
Probe Check	fail

1. Cepheid recommends that system performance should be evaluated annually using Xpert Check.

2. Cepheid declares that the I-CORE modules in the GeneXpert® Instrument were checked using an Xpert Check product. NIST traceable qualification standards are used to control the parameters for the fluorescence standards of concentration, brightness, and spectrum. Cepheid products are manufactured, quantified and controlled under a Quality System compliant with ISO 13485 and QSR requirements.

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Figure 2-49. Xpert Check Summary Report Example - Page 2

2.4 Return System to Normal Operation

Note

Return the system to normal operation by following one of the three procedures listed in this section for the GeneXpert Dx, GeneXpert Xpress, the GeneXpert Infinity 48s, or the GeneXpert Infinity-80.

2.4.1 GeneXpert Dx

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Dx.

1. Restart your GeneXpert system and computer. Follow the instructions in the GeneXpert Dx System Operator Manual.

2. The system will be ready for full operation.

2.4.2 GeneXpert Xpress

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Xpress.

1. Restart your GeneXpert Xpress system. Follow the instructions in the GeneXpert Xpress User's Guide.

2. The system will be ready for full operation

2.4.3 GeneXpert Infinity-48s or GeneXpert Infinity-80

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Infinity-48s or GeneXpert Infinity-80.

1. Restart the Xpertise software. Follow the instructions in the *GeneXpert Infinity System Operator Manual*.

The system will be in Automation mode, ready for full operation.
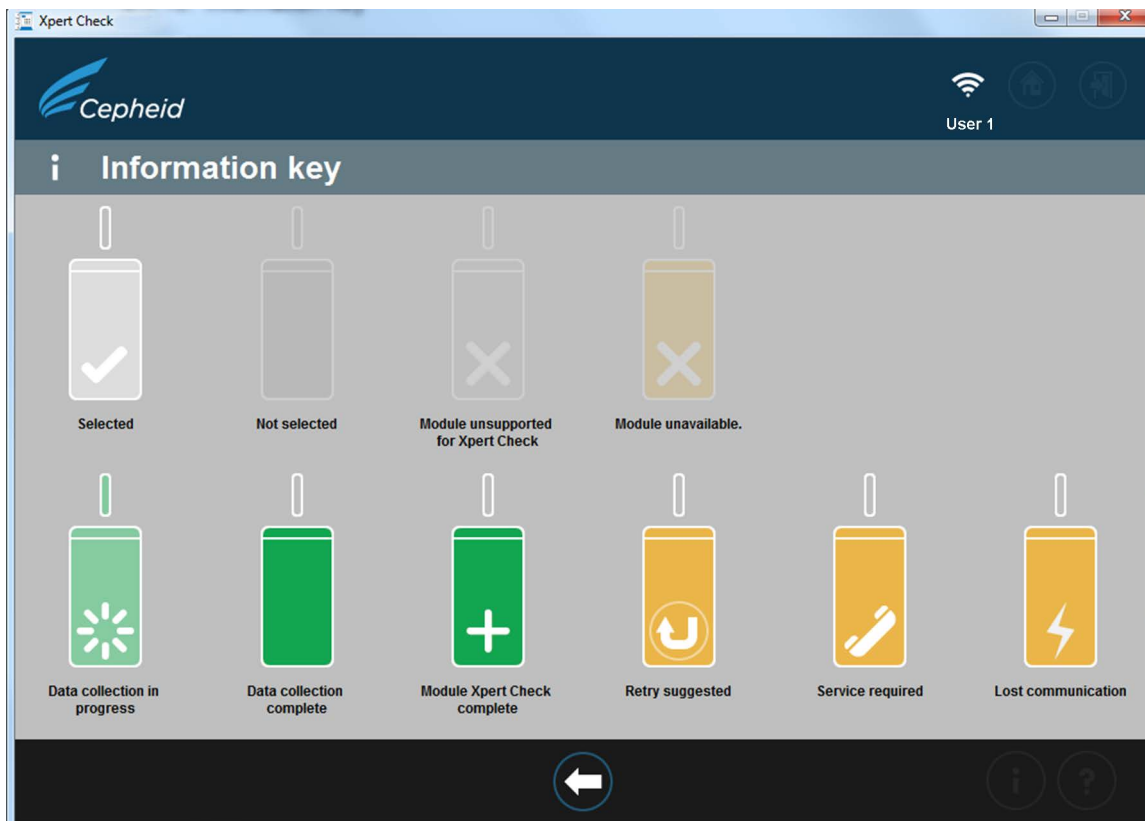
2.5   Information Key Screen

Figure 2-50. Information key Screen

2.5.1   Reasons to Repeat Xpert Check with a New Cartridge

If the onscreen instructions direct you to retest, repeat the test according to the instructions in Step B. on page 2-19.

2.5.2   Reasons to Repeat Xpert Check with the Same Cartridge

If software reports that the cartridge film seal was not broken, remove the original cartridge, rescan the cartridge barcode, open the lid, close the lid, and reinsert the cartridge. Restart the Xpert Check procedure for the affected module.

2.5.3   Application of Xpert Check Code

Xpert Check is not complete until the Cepheid-supplied Xpert Check code is applied to the system being tested. Upon receipt of the Quality Assurance Xpert Check Code from Cepheid, apply the code to your system using the Xpert Check Software to complete the Xpert Check process.