

➔ How to Run an Xpert® Check

Cepheid® Self Help Article

Title: How to Run an Xpert® Check

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Solution:

Before starting Xpert® Check perform the GeneXpert and Infinity optics cleaning.

GeneXpert and Infinity Optics Cleaning

The procedure below describes the method for removing dust and tube debris from the surface of rod lenses of the excite. It also describes how to detect blocks for GeneXpert Dx and Infinity modules prior to performing the Xpert Check procedure.

Note This procedure applies only to GeneXpert 6-color modules.

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.
3. Locate the brush provided in the Xpert Check kit.

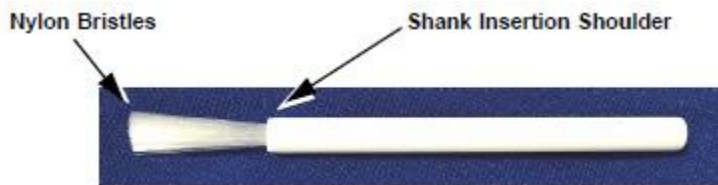


Figure 2-1. Lens Cleaning Brush (300-8330)

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

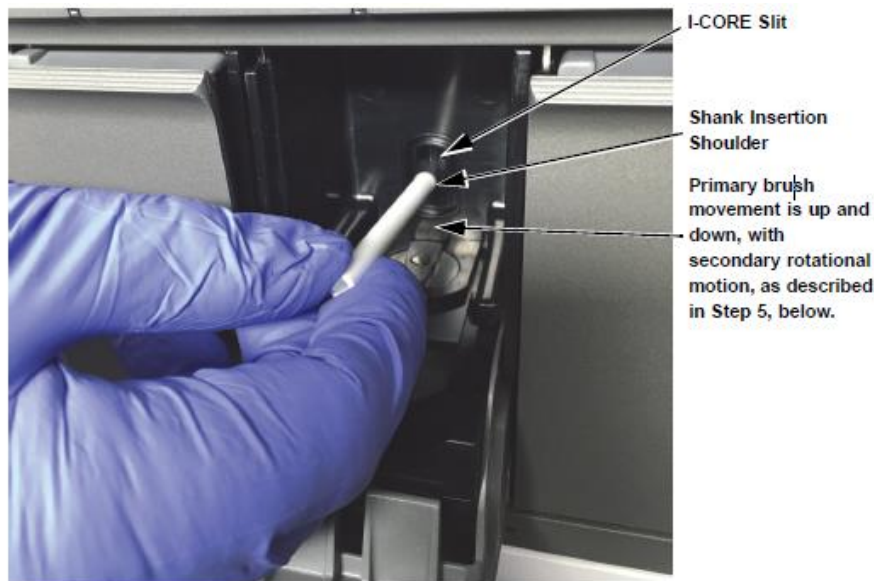
Note: Make sure that all the bristles are fully inserted (up to the shoulder of the plastic shank of the brush) so that it does not cause unnecessary damage to the brush.

Caution: Do not insert any objects into the I-CORE slit except the provided brush. Please note that 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.

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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 inward, then in up and down direction within the I-CORE slit. Brush rotation, even if it must 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, at 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, at 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.

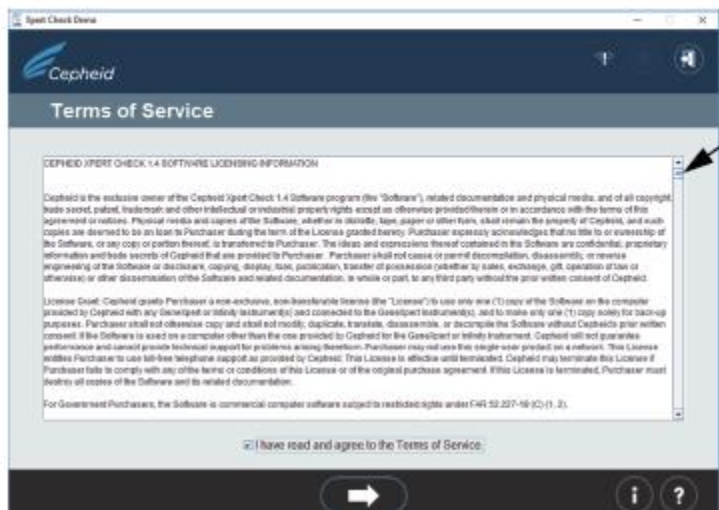
Data Collection Procedure: GeneXpert Dx and Infinity

Important: Before collecting data, be sure to prepare the system for checking. Internet-connected users should verify their system's connectivity status prior to beginning the Xpert Check process.

1. Place Software CD1 in the computer connected to the GeneXpert Dx. For the Infinity, connect the DVD drive following the instructions in the Infinity Operator Manual and insert the CD into the DVD drive.

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2. This step varies with the operating system installed on your computer:
 - **Windows XP:** On the computer desktop, right-click the **My Computer** icon and a drop-down menu will appear. Click **Explore**, then right-click on the applicable drive letter for your DVD drive. Select **Explore** 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.
 - **Windows 7, Windows 10:** 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. 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 click the check box (bottom of the screen) to verify that you have read and agree to the Terms of Service before continuing.



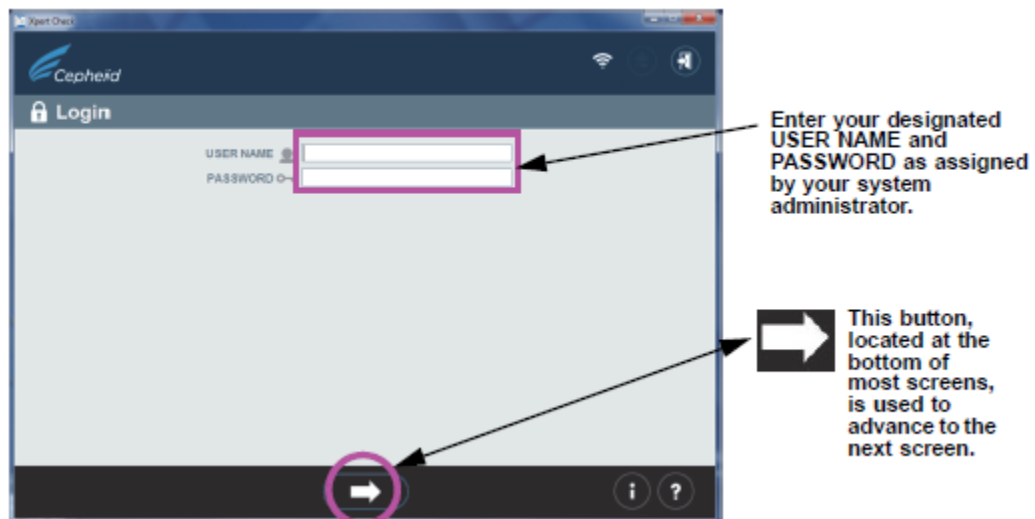
Scroll down to read the entire document.

Note: A copy of these Terms of Service is located on CD1.

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

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

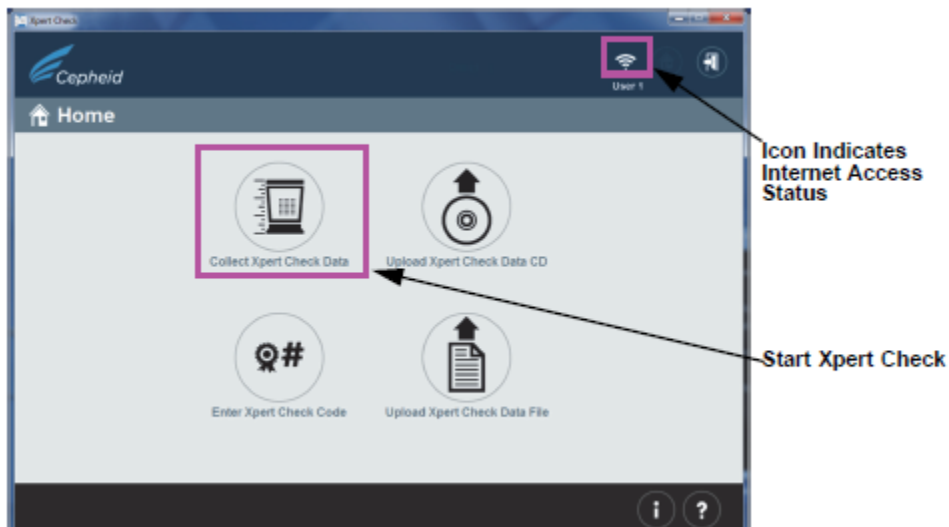
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6. Obtain a sufficient number of cartridges for the number of modules to be tested.

Important: Do not open cartridge packages until you are ready to scan the cartridge barcodes

7. Click the **Collect Xpert Check Data** icon on the Home screen. After a few seconds, the first Contact Information screen will appear.



8. When the first of two Contact Information screens appear, 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 that fields marked with "*" (at the right of the entry area) are mandatory fields.

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Xpert Check

Cepheid

User 1

Contact Information

Instrument Name My GeneXpert *

Serial Number # 123456 *

User User1 *

Institution Institution1 *

Laboratory Lab 1 *

Address 100 Main Street *

Address (line 2) Suite 202 *

City New York *

State/Province NY *

Postal Code 10001 *

Country USA *

Xpert Check

Cepheid

User 1

Contact Information

Email user1@institution.com *

Phone 408-400-XXXX *

Ext. X *

Mobile *

Service Provider L1531 *

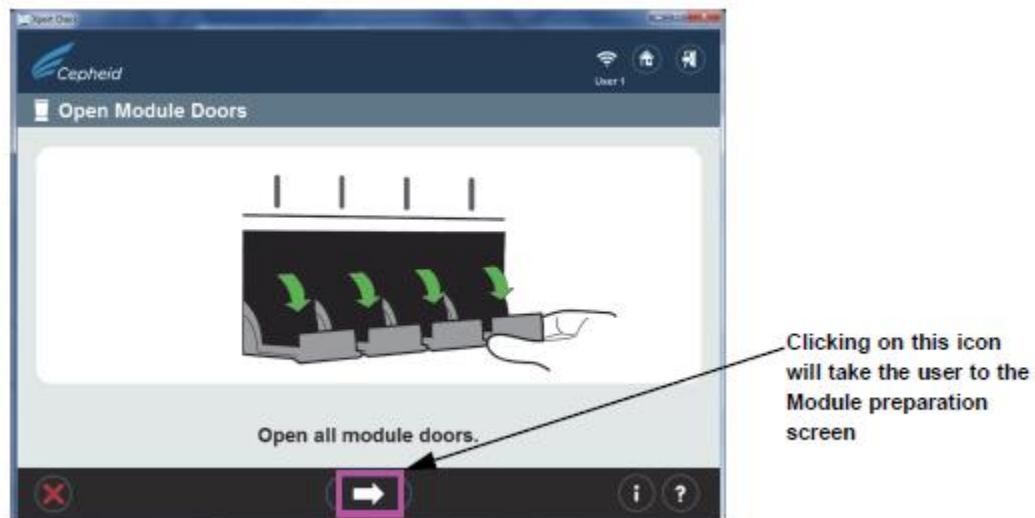
In this mandatory field, enter your Authorized Service Provider's ID code. The ID code is four characters, as described in the note below.

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

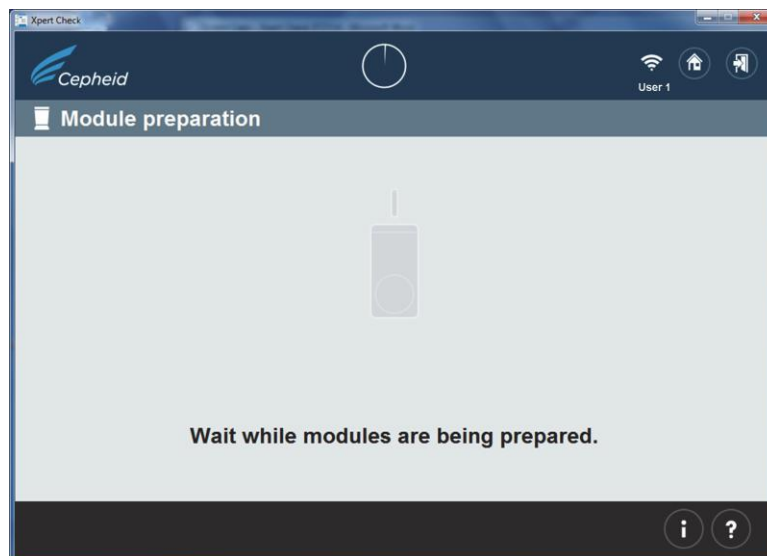
Clicking on this icon will take the user to the Open Module Doors screen

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

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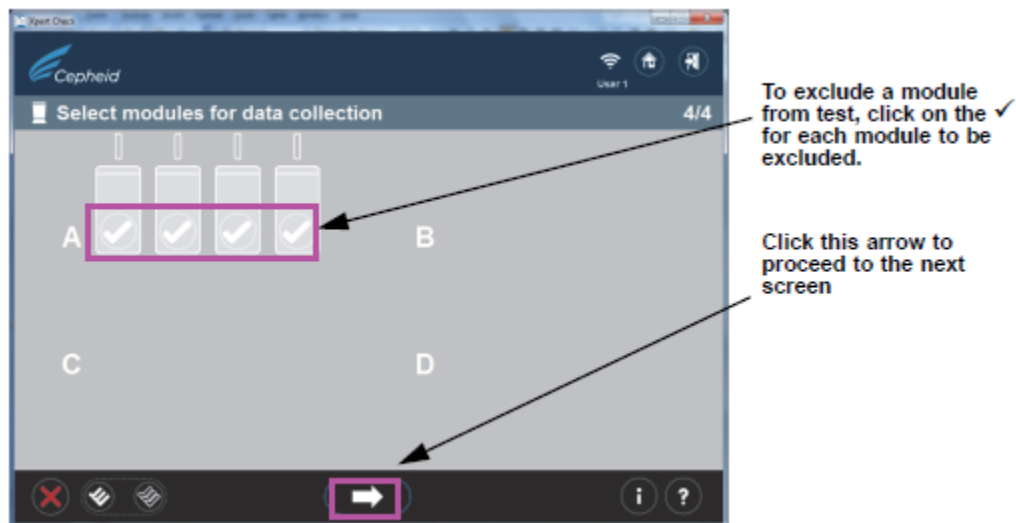
10. After opening all the module doors, click the forward arrow button at the bottom of the screen. The Module preparation screen may appear, showing the message **Wait while modules are being prepared.**



11. Follow the on-screen software instructions. By default, all detected modules will be marked as selected for checking. On this screen, the user can click on individual modules to exclude them from being checked, if required. The modules will disappear as they are excluded.

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

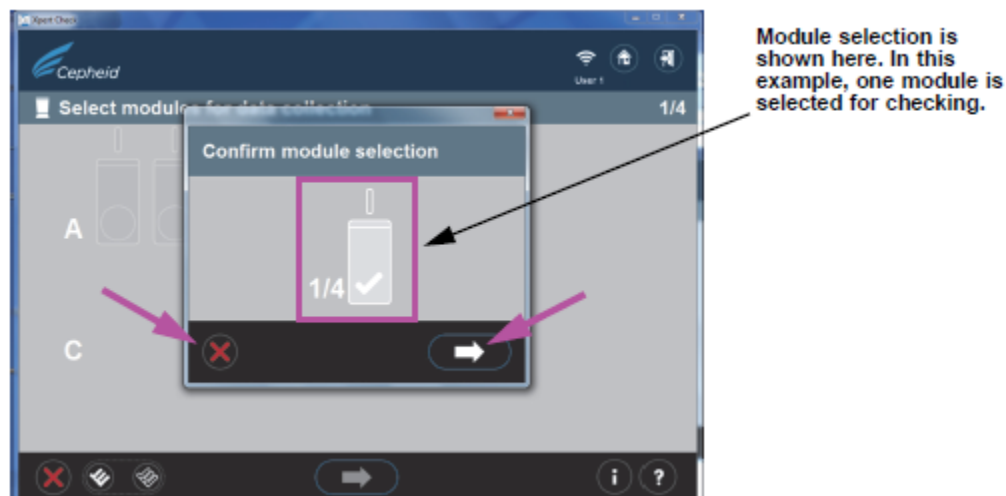
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Important:

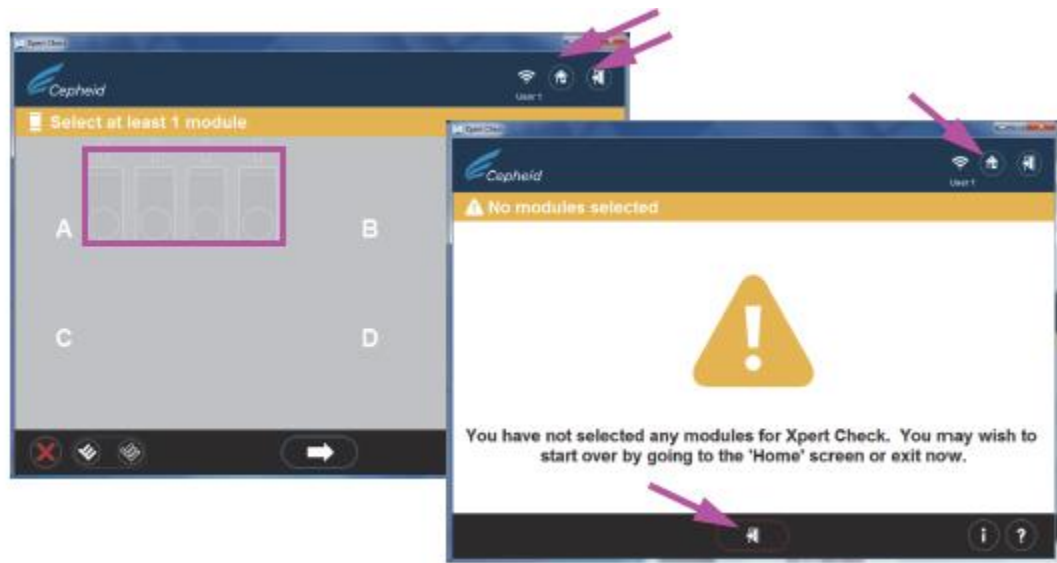
GX-XVI and Infinity systems only: When selecting modules on screen, make a note of which module lights are blinking on the system as you select each bank, to ensure cartridges are placed in the correct modules for testing.

12. After confirming the module selection shown, click the white arrow at the bottom of the screen overlay, to begin scanning cartridges. If the module selection shown is incorrect, click the red X at the bottom left corner of the screen to return to the Select Modules screen and change your selection.



13. 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. Follow the on-screen instructions to select a module, or start over by returning to the Home screen or exiting the program.

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14. 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.
15. 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 a refrigerated storage and immediately use the cartridge to run this test.

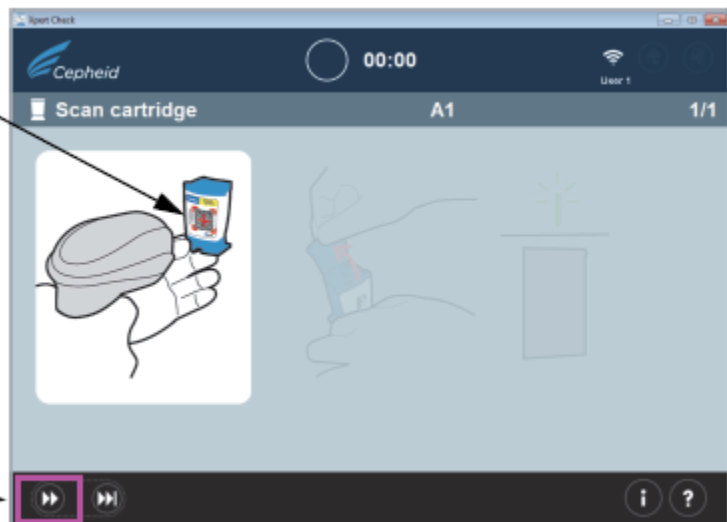
16. Scan the cartridge barcode. Do not substitute a cartridge with another after it's been scanned.

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. Click this icon to skip the cartridge just scanned.



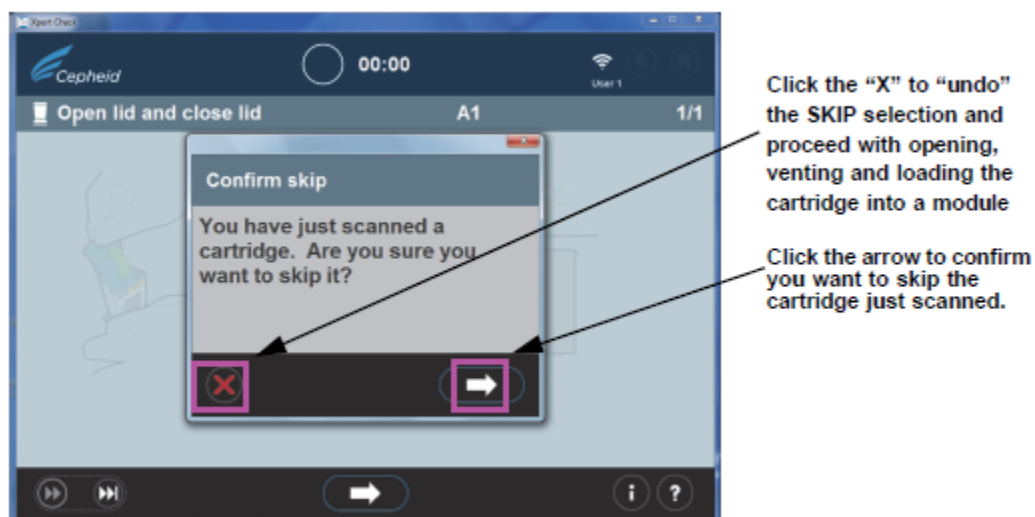
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A. After scanning the barcode of the cartridge, ensure you open (vent) the cartridge lid and then close it for each cartridge as directed by the software in [Step B](#) through [Step E](#) below.

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

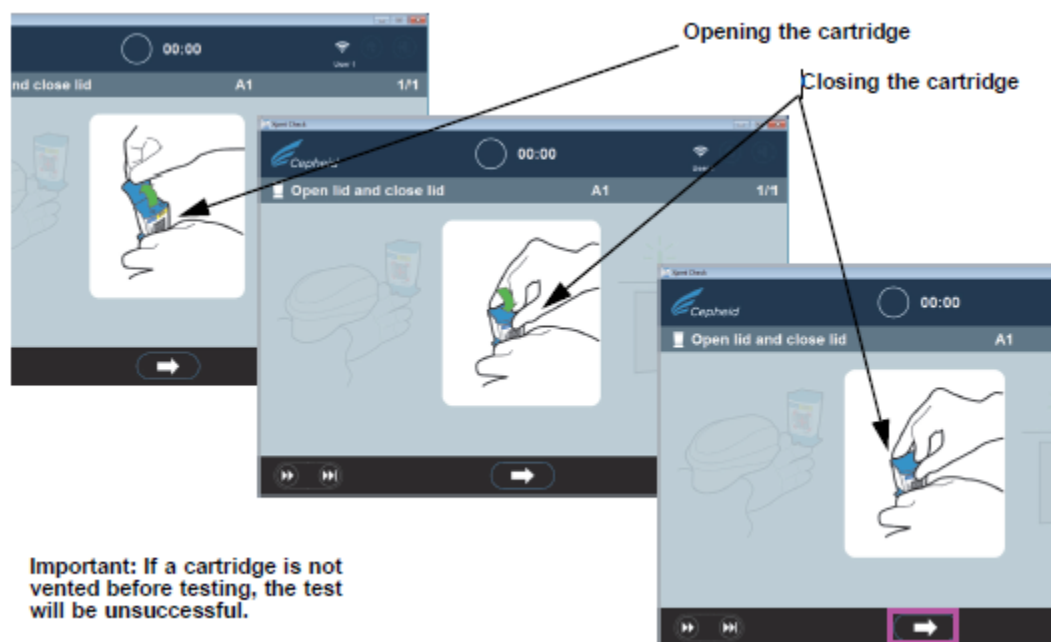
Note: After a cartridge barcode is scanned a green light will blink on the system above the module door where the cartridge is to be loaded.

Note: If, for some reason, you want to skip the cartridge just scanned, click the **SKIP** button at the bottom of the screen. An overlay will appear, asking for confirmation on skipping the cartridge. To SKIP the cartridge, click the forward arrow at the bottom of the confirmation screen. To proceed without skipping the cartridge, 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.



B. Venting the cartridge for two seconds is sufficient. This screen is animated, showing the cartridge lid being opened and closed. After venting, click the forward arrow at the bottom of the screen to continue.

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C. Close the cartridge lid and ensure the module door is fully opened to receive the cartridge.

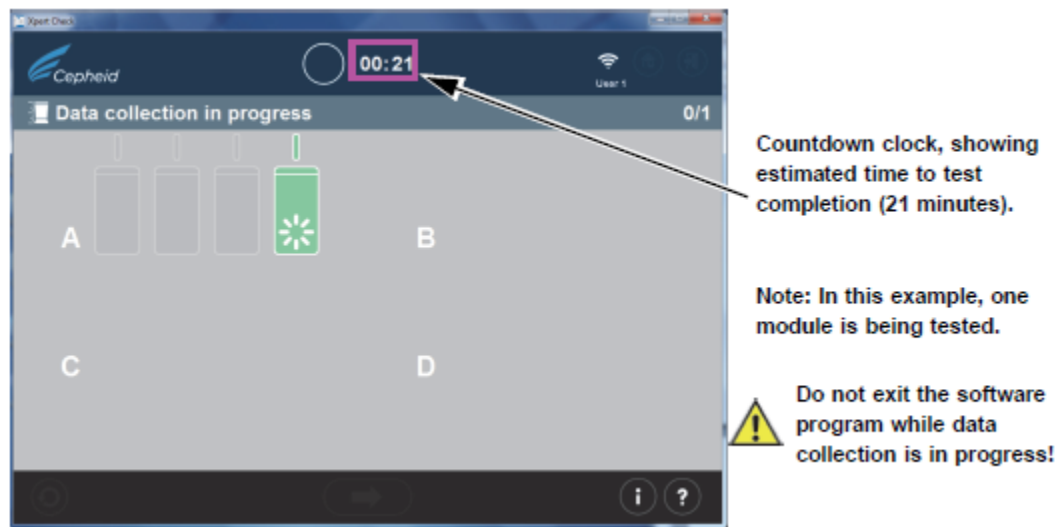
D. Load the cartridge into the module (with the cartridge reaction tube (tab) facing away from you), as directed by the animated software screens.

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, press 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.

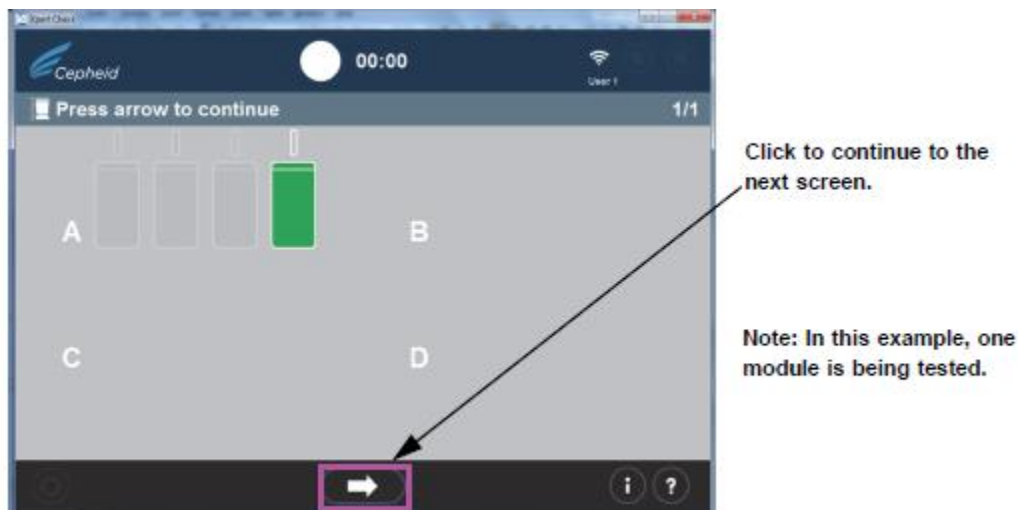
17. Checking will take approximately 20 minutes to complete after the final module has been loaded for testing. When checking begins, the data collection in progress screen appears.

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18. After test completion, the module door will open and the light above the module door will turn off. Screens similar to those shown below will appear. Press the right arrow to continue.

A. The figure below shows the completion of a successful Xpert® Check data collection.



B. If the test was unsuccessful, the screen shown below will appear, showing module status. A test retry must be performed. **Click the Retry** icon in the lower left-hand corner of the screen.

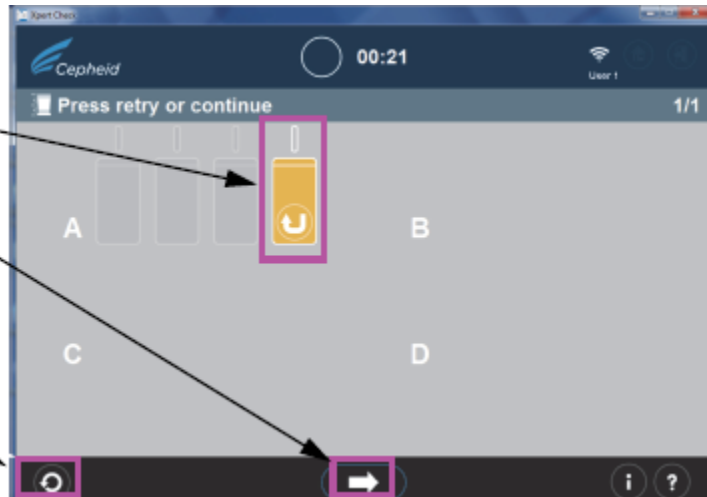
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Module test unsuccessful. Test must be rerun using either the same or a new cartridge, as instructed by the on-screen display.

Continue button. Click to proceed without retesting. See Figure 2-21.

Retry Icon. Click to retest the module.

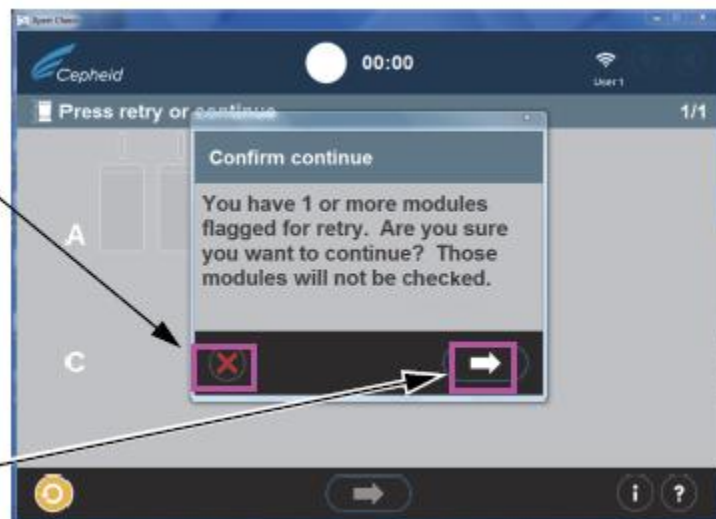
Note: In this example, one module is being tested.



C. If the **Continue** arrow at the bottom of the screen is pressed when there is an unsuccessful module test displayed, the Confirm continue screen will appear.

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

To continue without retesting the flagged module, click on the right arrow at the bottom of the Confirm continue screen.



You have the option to continue by pressing 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 19.

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, click the **Retry** icon and you will return to the Scan Barcode screen 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

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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.

19. After successful test completion and Xpert® Check data collection, click the forward arrow to display the screen shown below, if you have an active internet connection. However, if you have never been connected to the Internet, 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 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 at the beginning of this procedure to continue as a user without an internet connection.

