

Xpert[®] Calibration

REF **GXCAL-5**

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Xpert® Calibration (English)

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

Proprietary Name

Xpert Calibration

Common or Usual Name

Xpert Calibration

Intended Use

The Xpert Calibration kit is part of a calibration, verification, and hardware test system for 6-Color GeneXpert modules. The Xpert Calibration kit is used to recalibrate 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 calibration cartridge is used to calibrate a single module in conjunction with the Xpert Calibration Software.

Summary and Explanation

The GeneXpert (GX) module is the basis for all GeneXpert instrument systems worldwide. Each GX module requires recalibration after every 2,000 PCR tests or 1 year of utilization, whichever comes first.

The Xpert kit includes reagents for the optical recalibration 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 GX module.

The calibration process consists of two phases. The first phase is the execution of module testing using the cartridges contained within this kit. The second phase consists of Cepheid Quality Assurance Review, followed by the issuance of an activation code to enable each module's new calibration interval. **The Xpert calibration process is not complete until the activation code is applied to the system.**

Reagents and Instruments


Materials Provided

∇ The Xpert Calibration kit contains the following:

Xpert Calibration 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
PI CD	1 per kit
Data CD 2	1 per kit

Note: Safety Data Sheets (SDS) are available at www.cepheid.com/tests-and-reagents/literature/msds or www.cepheidinternational.com/tests-and-reagents/literature/msds.

Storage and Handling

- ±2 °C  • Store the Xpert Calibration cartridges at 2-28 °C.
- 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.
 - Lid must be opened (vented) prior to use of cartridge; however, no sample is required for calibration.
 - Discard all used and unused cartridges once the GX Calibration session is completed.

Note: Contents of cartridges are non-hazardous.

Materials Required but Not Provided

- GeneXpert Dx or Infinity System with Cepheid-supplied computer and barcode scanner.
- 6-color GeneXpert instrument.
- Xpert Calibration Software CD 1 (Xpert Cal 1.0 or higher)

Limitations

- For use only with 6-Color GeneXpert modules (running GeneXpert Dx software version 4.0 and above). 4-Color GeneXpert modules (including Bio-threat modules) and Dual-Cal modules cannot run Xpert Calibration and must be calibrated by Cepheid Service.
- Use of the Xpert Calibration 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.

Warnings and Precautions

- Follow your institution's safety procedures for working with chemicals.
- Do not add sample or other reagents to the Xpert Calibration cartridges.
- Do not use a cartridge that has a damaged reaction tube.
- Do not use cartridges from visibly damaged or compromised foil pouches.
- Contact Cepheid Customer Service for replacement of damaged kit contents.
- Do not use a cartridge if it is dropped.
- ⓧ Each single-use Xpert Calibration cartridge is used to process one test. Do not reuse spent cartridges.
- Do not open a cartridge package or break the lid seal until you are ready to perform testing.
- Allow the Xpert Calibration cartridge to come to room 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 Calibration 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.
- Once a cartridge barcode has been scanned, do not substitute another cartridge in place of the scanned cartridge.
- If using an internet-enabled Xpert Calibration, up-to-date anti-virus software must be installed on the desktop or laptop computer with updated virus definition files, prior to executing Xpert Calibration.
- Prior to running Xpert Calibration, ensure that the environmental operating temperature is within the correct limits (15 °C – 30 °C). Xpert Calibration 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 software. Do not proceed under these conditions.
- Xpert Calibration 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 Calibration Activation Code will expire if not applied within 30 days of completion of calibration.

Assistance and Contact Information

For a complete listing of Cepheid technical support, service support, sales support, and headquarters contacts, please see page 44 of this document.

Table 1. Software Buttons, Icons and Symbols































Symbol	Definition
	Information. Click on 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. Click on this icon to advance the display to the next screen.
	Continue to End. Clicking on this icon moves the user to the last screen.
	Exit. Exits the Xpert Calibration application.
	About. Brings up the About screen which brings up the name of the software, the software version number, copyright notice, etc.
	Home. Go to the Home screen.
	Repeat/Retry. Retry loading a calibration cartridge to attempt to calibrate 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 'Calibration Test' screen.
	Back. Clicking on 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.
	Un-selects all modules for calibration. If you only want to calibrate a few modules, you may deselect ALL of them, and then reselect only the ones you wish to calibrate. Used when an administrator or service engineer has logged in.
	Select all of the modules for calibration. The default setting for the system. Also used when an administrator or service engineer has logged in.

Table 1. Software Buttons, Icons and Symbols (Continued)

Symbol	Definition
	Connectivity Status. Indicates the GeneXpert is connected to the internet.
	Connectivity Status. Indicates the GeneXpert is not connected to the internet.
	Skip Current Module. Skip the current module and do NOT attempt to calibrate the current module. Used on the 'Load Calibration Cartridges' screen.
	Skip Current Module. Skip the current module and do not attempt to calibrate the current module. Used on the 'Load Calibration Cartridges' screen
	Skip Remaining Modules. Skip all the remaining modules and do NOT attempt to calibrate them. Used on the 'Load Calibration Cartridges' screen
	Indicates a module with a calibration test in progress.
	Indicates a completed module calibration test.
	Retest required. Indicates an incomplete calibration 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.

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Table 1. Software Buttons, Icons and Symbols (Continued)

Symbol	Definition
	Service required. Contact the Cepheid Authorized Service Provider (ASP). Module will no longer be available to run Xpert assays until serviced.
	Burn. Burn a CD containing the collected calibration information (for users without an active internet connection).
	Start Calibration Process. Leads the user through the calibration process.
	Enter Activation Code. Go to the 'Enter Activation Code' screen.
	Activation Status. Launch the Adobe® Reader® to review the calibration certificate on the 'Activation Status' screen.
	Upload Calibration Data from File. Go to the 'Upload Calibration from File' screen.
	Upload Calibration Data from CD. Go to the 'Upload Calibration from CD' screen.
	View Calibration Certificate PDF. Launches the Adobe Reader to view the calibration certificate.
	Read Calibration Code. Open a file to read the calibration code.
	Scan. Turn the barcode scanner on, and accept the next scanned input.
	View and Print. Launch the Adobe Reader so you can view and then print a PDF file.

System Preparation

Note: Prepare the system for calibration by following one of the three procedures listed in this section for the GeneXpert Dx, the Infinity-48, Infinity 48s or the Infinity-80.

GeneXpert Dx Preparation

1. Create an Admin level User Name and Password in the GeneXpert software if one does not exist. Xpert Calibration requires this logon credential to be established prior to starting.
2. Have your authorized Service Provider (ASP) ID code available before continuing to the next steps.
3. Exit the GeneXpert Dx software.
4. Go to Data Collection Procedure - Dx and Infinity on the next page of this document.

Infinity-48 Preparation

1. Create an Admin level User Name and Password in the GeneXpert software if one does not exist. Xpert Calibration requires this logon credential to be established prior to starting.
2. Have your authorized Service Provider (ASP) ID code available before continuing to the next steps.
3. Perform the steps in Appendix A in this document to put an Infinity-48 into **Manual** mode from **Automation** mode.
4. Go to Data Collection Procedure - Dx and Infinity on the next page of this document.

Infinity-48s or Infinity-80 Preparation

1. Create an Admin level User Name and Password in the GeneXpert software if one does not exist. Xpert Calibration requires this logon credential to be established prior to starting.
2. Have your authorized Service Provider (ASP) ID code available before continuing to the next steps.
3. Exit the Infinity System software.
4. Open the glass doors following the instructions in the *Infinity Operator Manual*.
5. Go to Data Collection Procedure - Dx and Infinity on the next page of this document.

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Data Collection Procedure - Dx and Infinity

Important: Before collecting data, be sure to prepare the system for calibration as described in the preceding section.

Internet-connected users should verify their system's connectivity status prior to beginning the Xpert calibration process.

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

Note: All screens displayed and reports generated in this program are in English only.

1. Place the Xpert Calibration Software CD 1 in the computer connected to the GeneXpert Dx instrument, or in the kiosk computer for the Infinity.
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 CD drive.

Select **Explore** from the drop-down menu, and the files located on the CD will then be displayed.

Find and right-click the **XpertCalibration.exe** application, and when the drop-down menu appears, click **Open** to launch the software.

- **Windows 7:** 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 CD drive.

Select **Open** from the drop-down menu, and the files located on the CD will then be displayed.

Find and right-click the **XpertCalibration.exe** application, and when the drop-down menu appears, click **Open** to launch the software.

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

3. The Terms of Service screen appears. Use the scroll bar to read through the entire document. You will be asked to click the check box (below the screen) to verify that you have read and agree to the Terms of Service before continuing. See Figure 1.



Scroll down to read the entire document.

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

Figure 1. Terms of Service Screen

4. After agreeing to the Terms of Service, the Login screen will appear. Log in with your GeneXpert Dx or Infinity designated 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 next screen (the Xpert Home screen). See Figure 2.

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

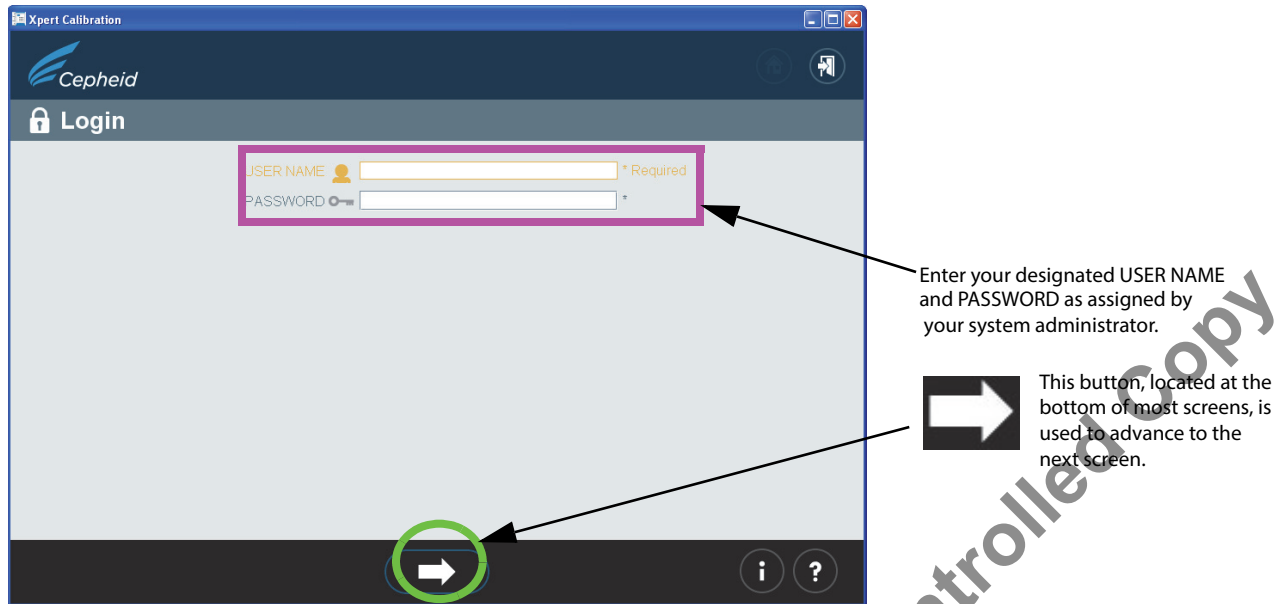


Figure 2. Xpert Calibration Login Screen

In case of a login error, the following screen will appear. See Figure 3.

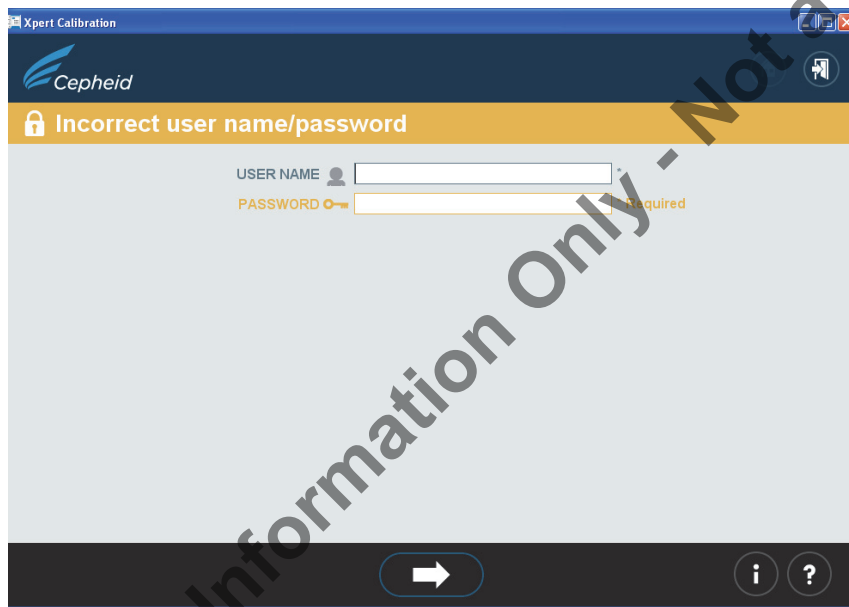


Figure 3. Login Error Screen

5. If a login error occurs, recheck the USER NAME and PASSWORD entries for errors. If necessary, reenter the information and retry. After entering your login information, click the forward arrow button at the bottom of the screen to advance to the next screen (the Xpert Home screen).
6. Obtain a sufficient number of cartridges for the number of module to be tested.

Important: Do not open cartridge packages until you are ready to scan the cartridge barcodes (in step 15).

Note: Only an Administrator can exclude (deselect) individual modules from this calibration test. 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 calibrating.

- Click the **Collect Calibration Data** icon on the **Home** screen (See Figure 4). After a few seconds, the first **Contact Information** screen (Figure 5) will appear.

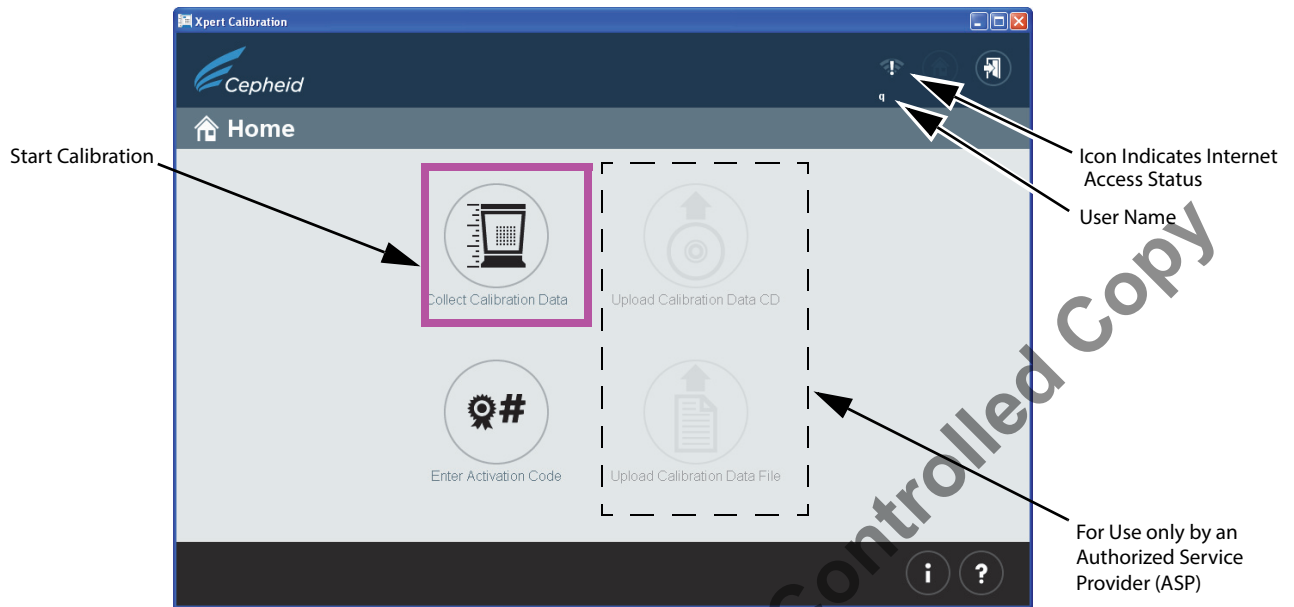


Figure 4. Home Screen

- When the first of two **Contact Information** screens appear (see Figure 5 and Figure 6), 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 “*” are mandatory fields.

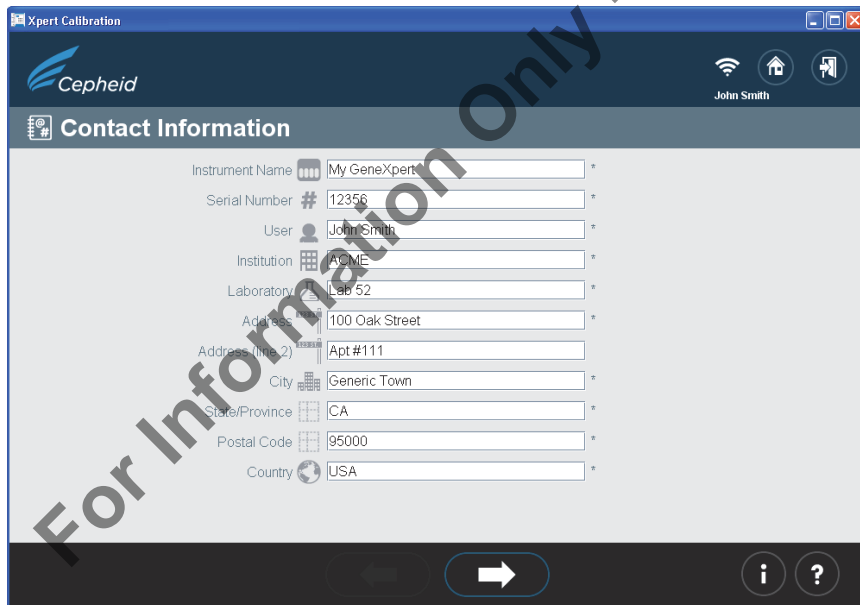


Figure 5. Contact Information Screen - Page 1

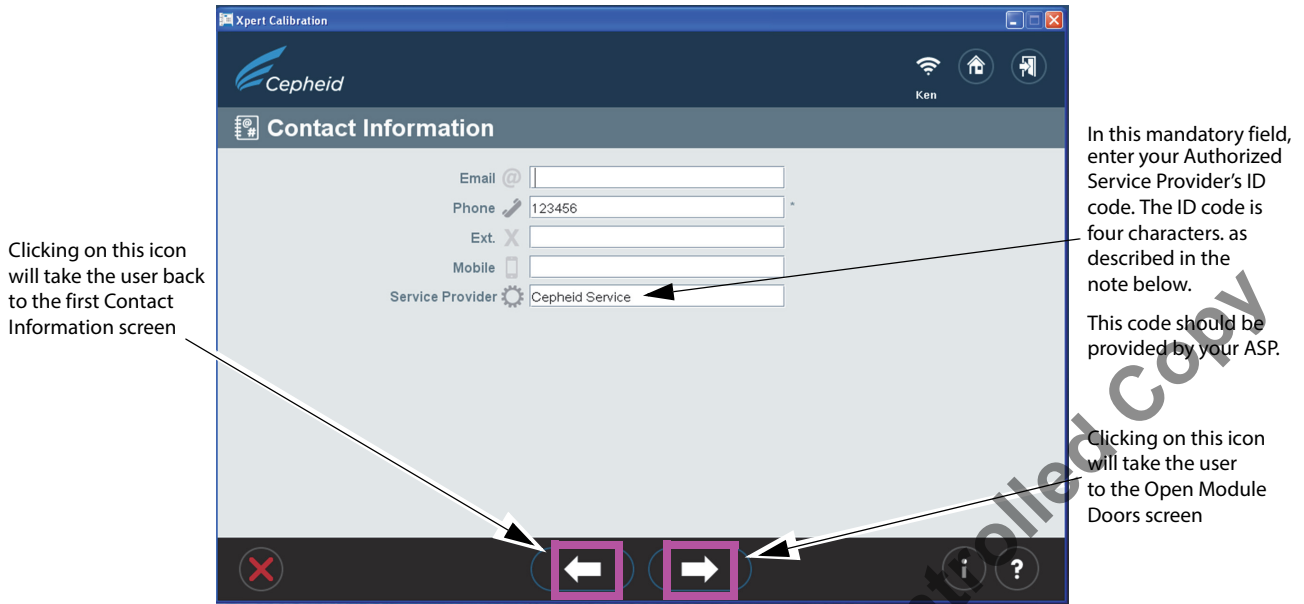


Figure 6. Contact Information Screen - Page 2

Note: The ASP-provided ID code for the Service Provider on the Contact Information screen consists of four characters. (As examples for the United States, use US, followed by two digits, such as US01, US28, etc.).

- 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. See Figure 7. Manually open all module doors to enable cartridge loading.

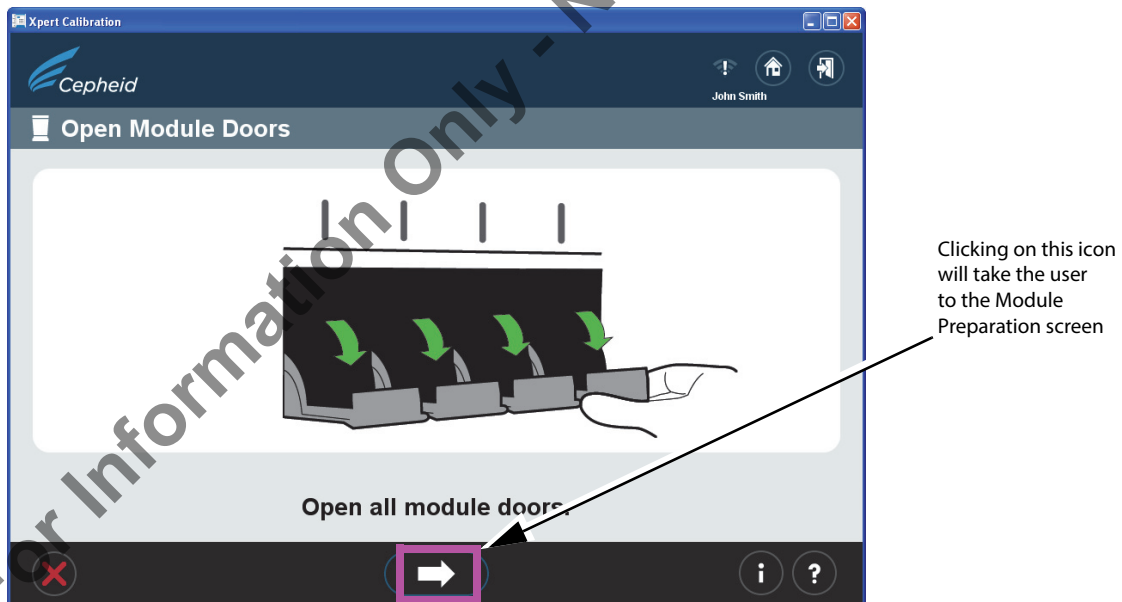


Figure 7. Open Module Doors Screen

- After opening all the module doors, click the forward arrow button at the bottom of the screen. The **Module Preparation** screen will appear briefly, showing the message, "Please, wait. Modules are being prepared." See Figure 8.

Important: Note that the **Module Preparation** screen may appear only briefly, with its length of visibility determined by the number of modules being calibrated. The next screen you see will be the screen shown in Figure 9, the **Select Modules** screen.

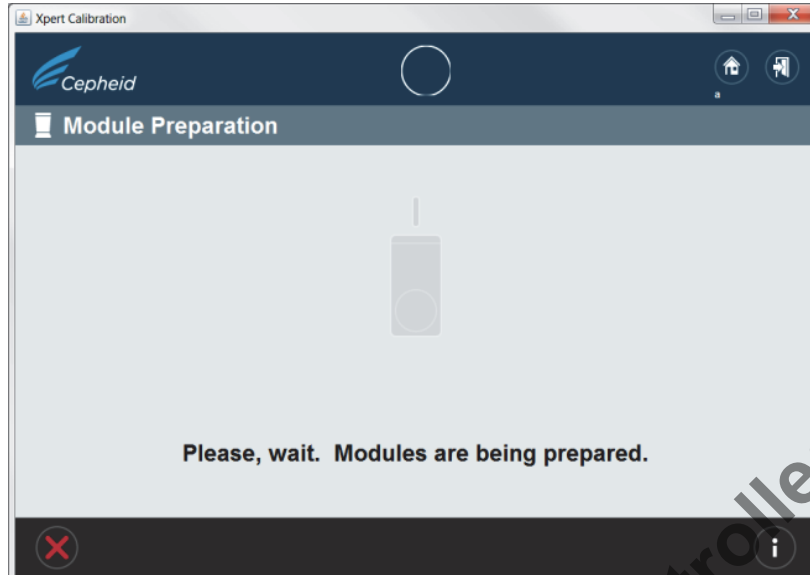
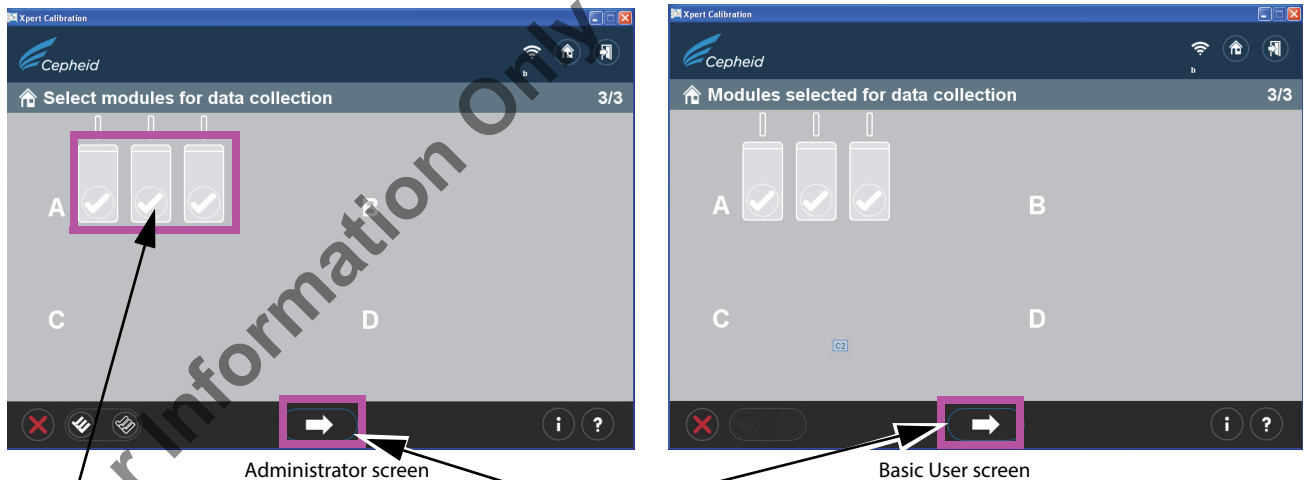


Figure 8. Modules Preparation screen

11. Follow the on-screen software instructions. By default, all detected modules will be marked as selected for calibration.

Note: A Basic User cannot deselect modules to exclude them from this calibration test. Only an Admin can click on individual modules to exclude them from calibration, if required. For excluded modules (not selected for calibration), the door position (open or closed) does not matter.

In Figure 9, two screens are displayed. The screen on the left shows the screen an Administrator would see in which individual modules can be deselected from calibration. The screen on the right shows the screen a Basic User would see where no deselection can be done. To move to the next screen, click the arrow at the bottom of the screen.



Admin Only: To exclude a module from test, click on the ✓ mark for each module to be excluded.

Click this arrow to proceed to the next screen

Note: Three modules have been selected for calibration testing in these two examples

Figure 9. Select Modules Screen - Administrator and Basic User Screens

Important: GX-XVI and Infinity systems only: When selecting modules on screen, note which module lights are blinking on the system as you select each bank.

12. After selecting the modules, click the arrow button at the bottom of the screen. If you are logged on as an Administrator, the Confirm module selection screen appears. See Figure 10. If you are logged on as a Basic User, this screen will not appear (Skip to step 13).

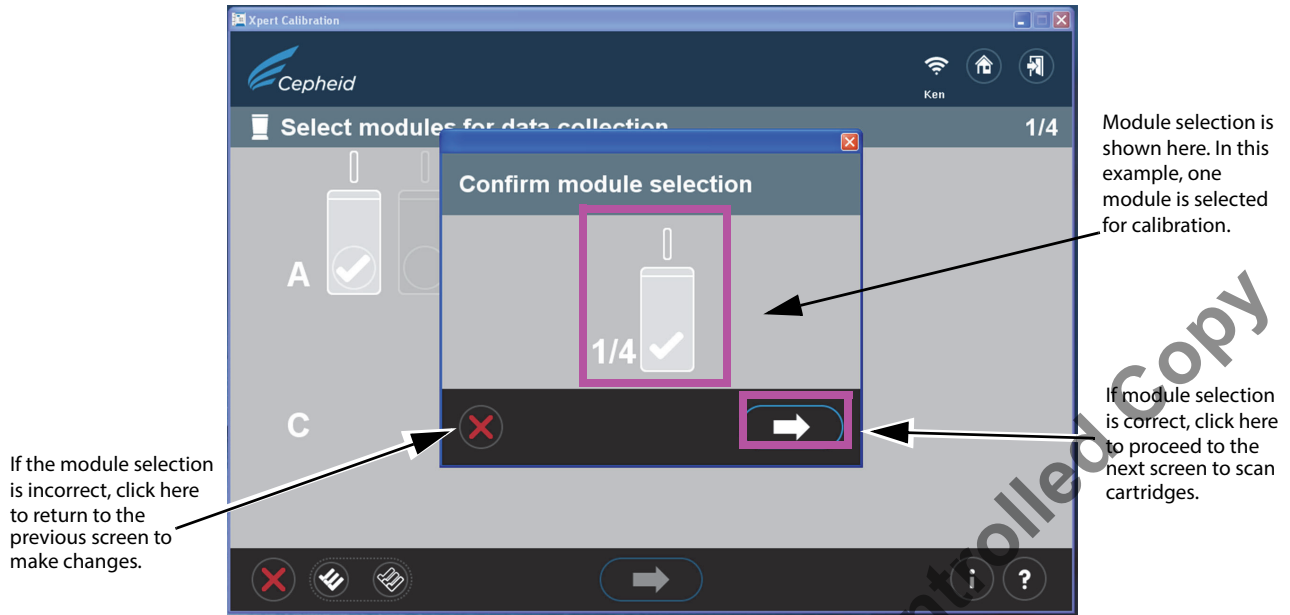


Figure 10. Confirm Module Selection Screen - Administrator Use Only

13. If all modules have been excluded in the above step by mistake, the following screen will appear (Figure 11), advising you to start over by returning to the **Home** screen or exiting the program.

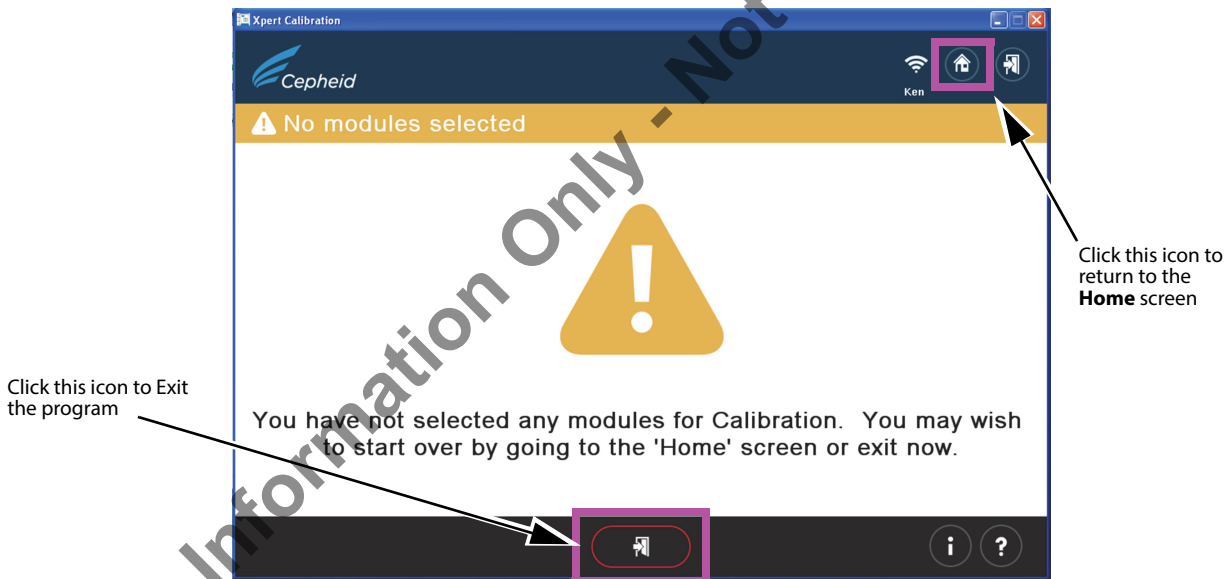


Figure 11. Error Screen - No Modules Selected

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 Calibration cartridge.

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

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

16. Scan the cartridge barcode. Figure 12 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 for a replacement cartridge, if necessary. If the barcode scanner is damaged, missing or incorrectly configured, contact your ASP for guidance.

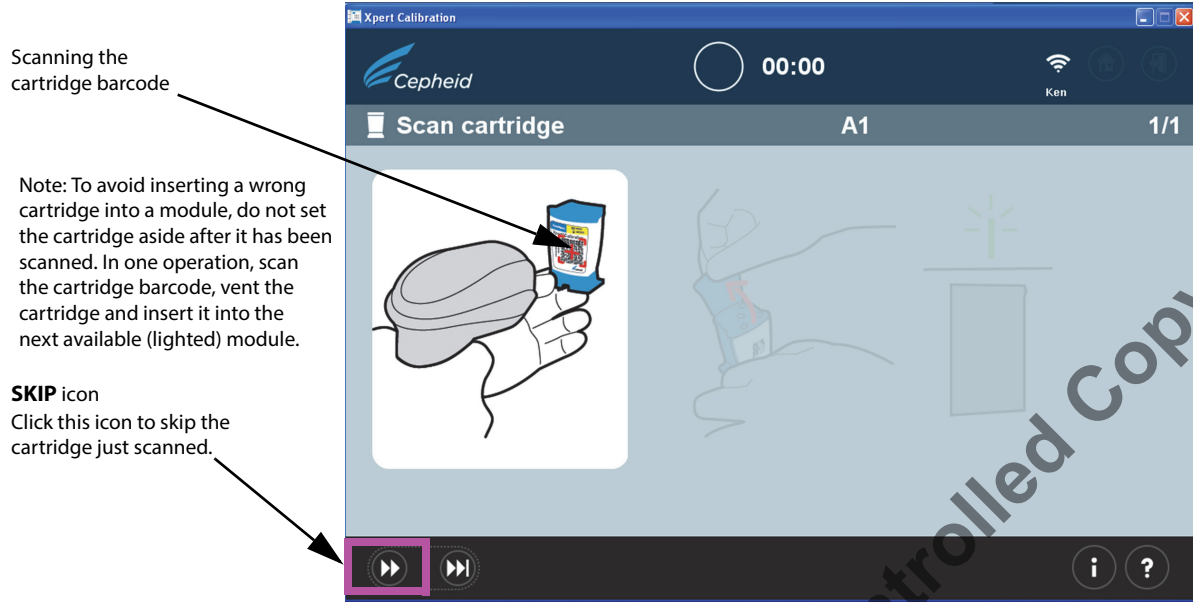


Figure 12. Scanning the Cartridge Barcode Screen

- 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 calibration kit provided.

Note: After a cartridge barcode is scanned a green light will blink on the system above the module door where the cartridge will 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, shown in Figure 13, will appear, asking for confirmation on skipping the cartridge. To **SKIP** the cartridge, click the forward arrow at the bottom of the 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.

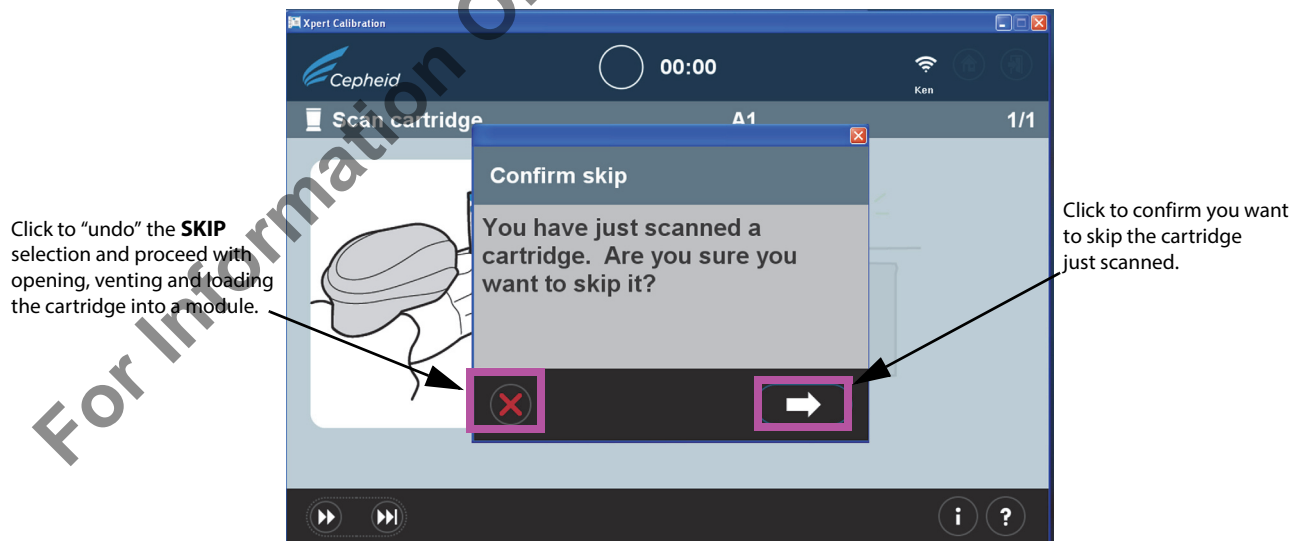


Figure 13. Confirm skip Screen

- b. Venting the cartridge (shown in Figure 14), 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.

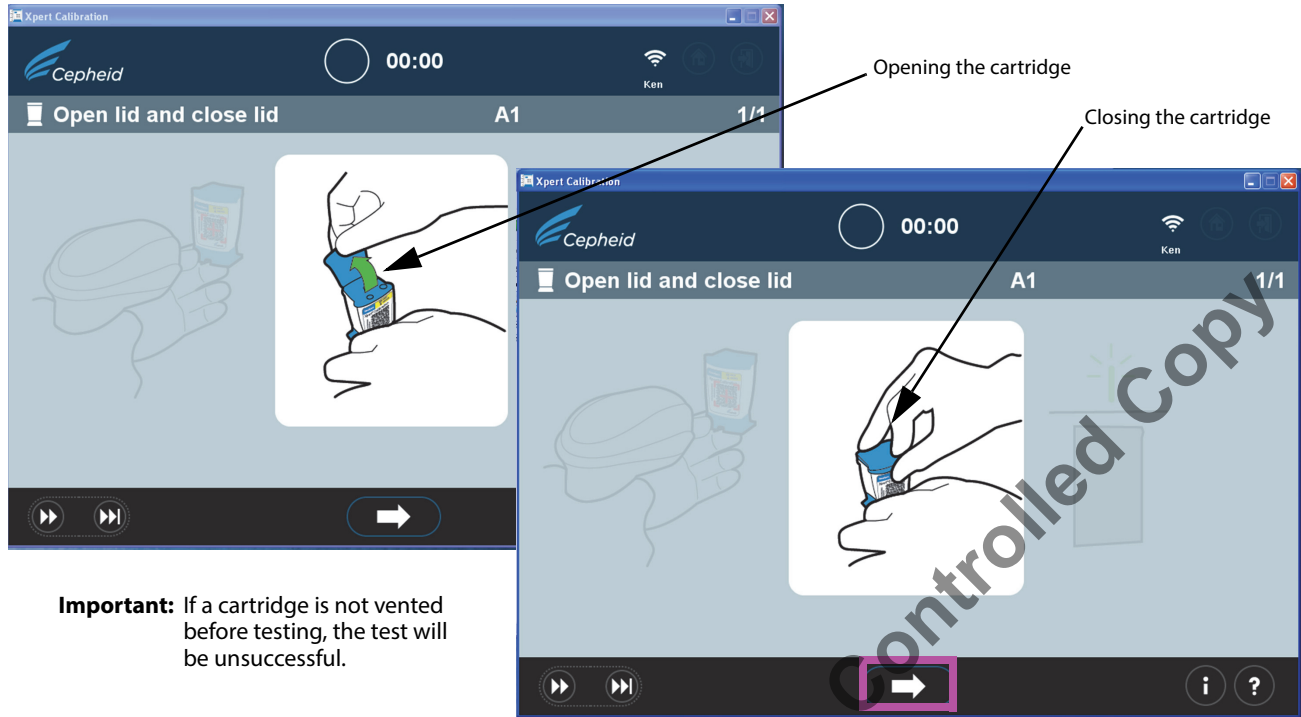


Figure 14. Venting the Cartridge by Opening and Closing the Cartridge Lid - Animated Screen

- 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 facing away from you), as directed by the software screens. See Figure 15.

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.

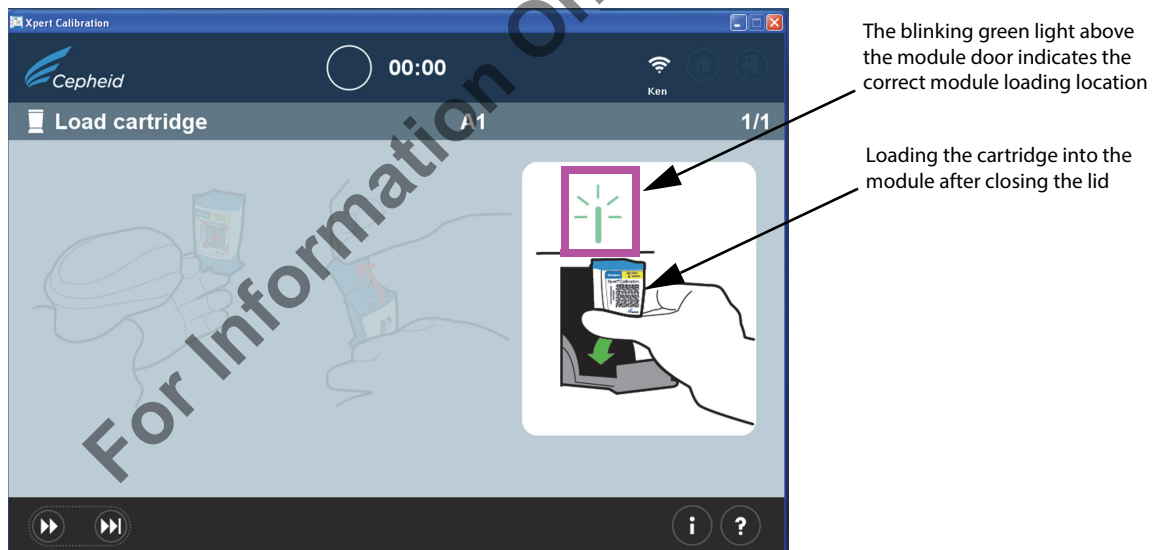


Figure 15. Loading the Cartridge into the Module

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, click the SKIP button at the bottom of the screen to abort testing that module and move on to the next module and continue testing.

Important: Be sure to remove the cartridge from a module whose door will not latch before proceeding. Notify your ASP 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.

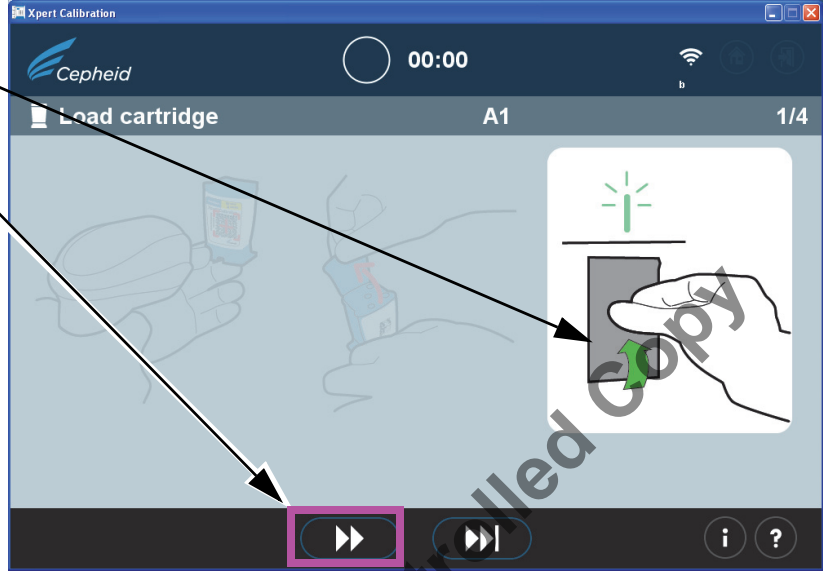


Figure 16. Loading the Cartridge into the Module - Animated Screen

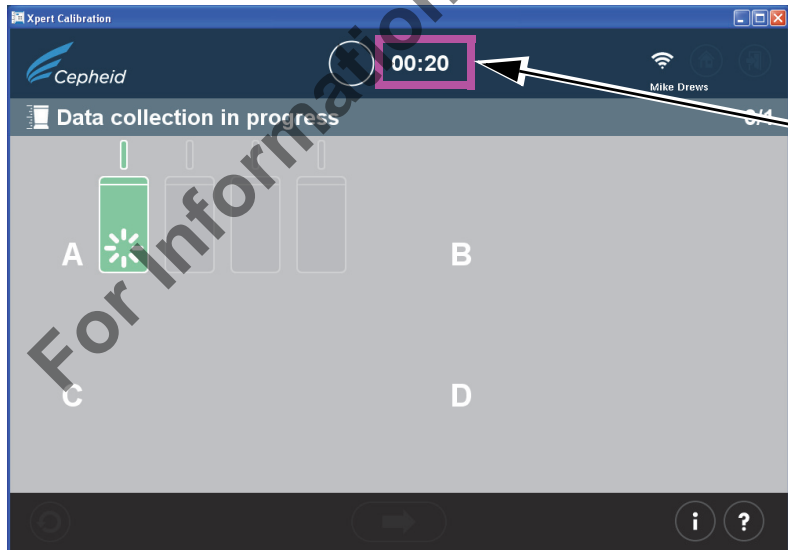
- e. If you are calibrating additional modules, continue by scanning the next cartridge. Place each individual scanned cartridge into the next selected open module, pressing the module door securely closed until it latches. **As each module door is closed and latched, data collection will automatically start on that specific module.** The blinking green light above the module will then become steady green, indicating that calibration testing 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 calibration test 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 so the module can be serviced.

- 17. Calibration will take approximately 20 minutes to complete after the final module has been loaded for testing. When the calibration test begins, the Data collection in progress screen appears, as shown in Figure 17.

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 18b through 18d.



Countdown clock, showing estimated time to test completion (20 minutes)

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


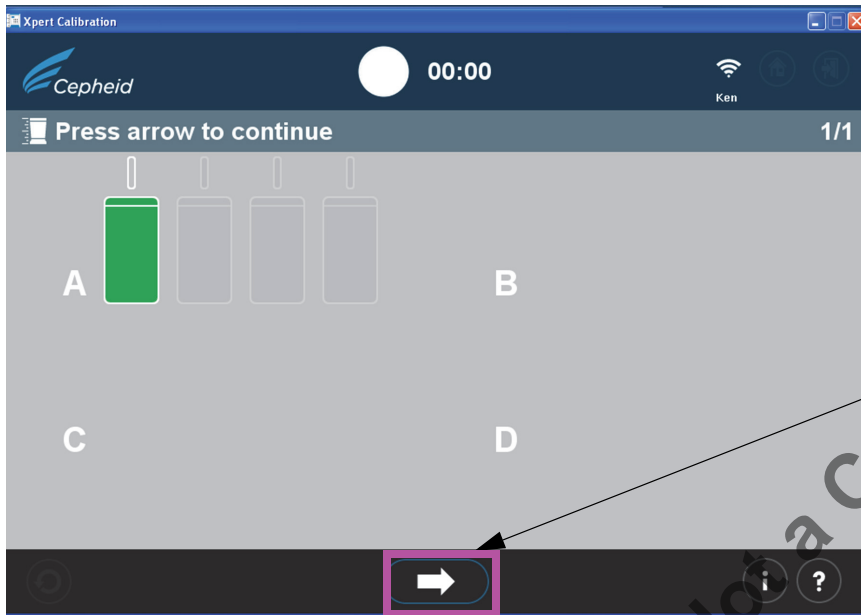
 Do not exit the software program while data collection is in progress!

Figure 17. Data Collection Screen

18. After test completion, the module door will open and the light above the module will turn off. Screens similar to those shown in Figure 18 or Figure 19 will appear. Press the right arrow to continue.

a. Figure 18 shows the completion of a successful calibration data collection.

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

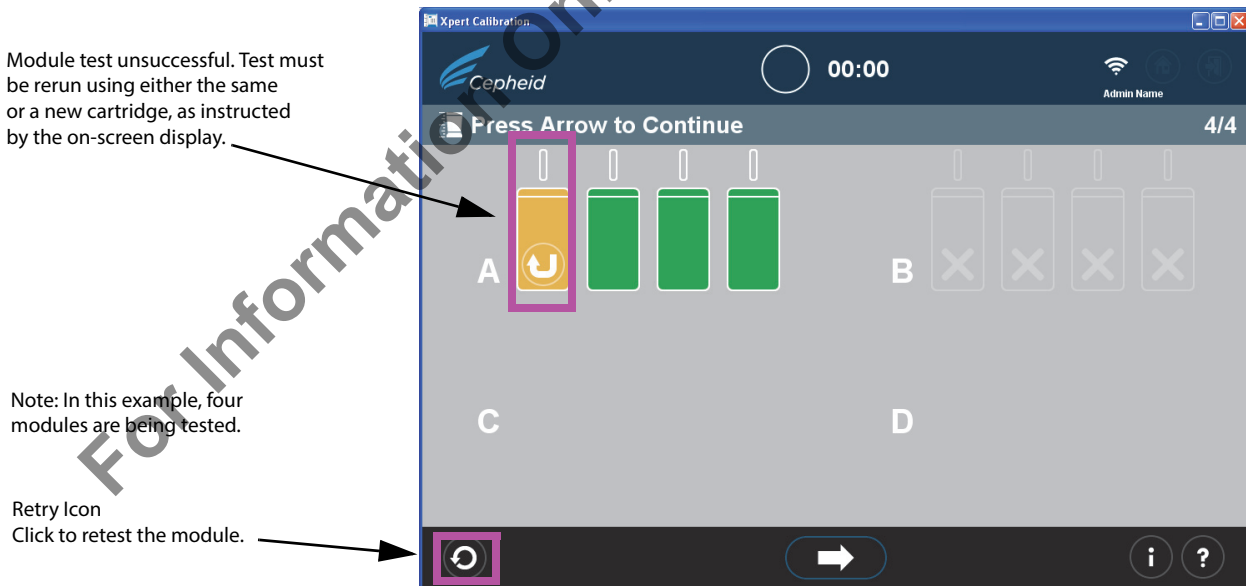


Click to continue to next screen.

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

Figure 18. Test Completion screen - Successful

b. For all users: If the test was unsuccessful, the screen shown in Figure 19 will appear, showing module status. A test retry must be performed. 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.

Note: In this example, four modules are being tested.

Retry Icon
Click to retest the module.

Figure 19. Test Completion Screen - Unsuccessful Module Calibration Example

c. If the arrow at the bottom of the screen is pressed when there is an unsuccessful module test displayed (as shown in Figure 19), the Confirm continue screen will appear. See Figure 20.

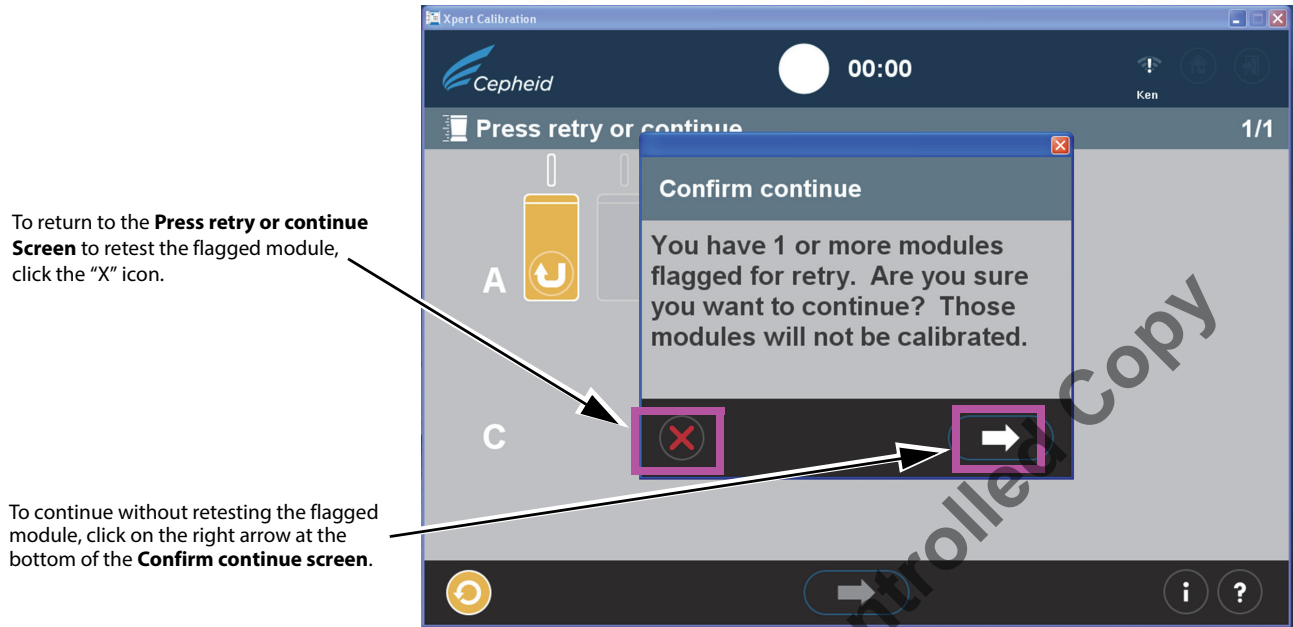


Figure 20. Confirm continue Screen Overlay

You have the option of continuing 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 calibration 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 on 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 19 at the bottom of the screen) appears, click the Retry icon and you will return to the Scan Barcode screen (Figure 12) to complete the retest on the affected module(s).

Note that the retest can be of two possible types:

- i. 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.
- ii. 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 Calibration cartridges. Please contact your ASP for additional Xpert Calibration cartridges. Rerun Xpert Calibration on any modules that were skipped.

Note: At the completion of the Xpert Calibration data collection process modules determined to require service will be flagged as locked to further use. Please contact your local ASP for further assistance in replacing modules requiring service. A module requiring service can be identified by this module icon:



19. After successful test completion and calibration data collection, click the forward arrow to display the screen shown in Figure 21, 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 calibration test, a **Download activation code error** screen (Figure 22) will appear instead, instructing you to write calibration data to data CD2 to send to your ASP. In this case, continue to step d (under step 25) 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 20), and the activation certificate should begin downloading, as shown in Figure 23.

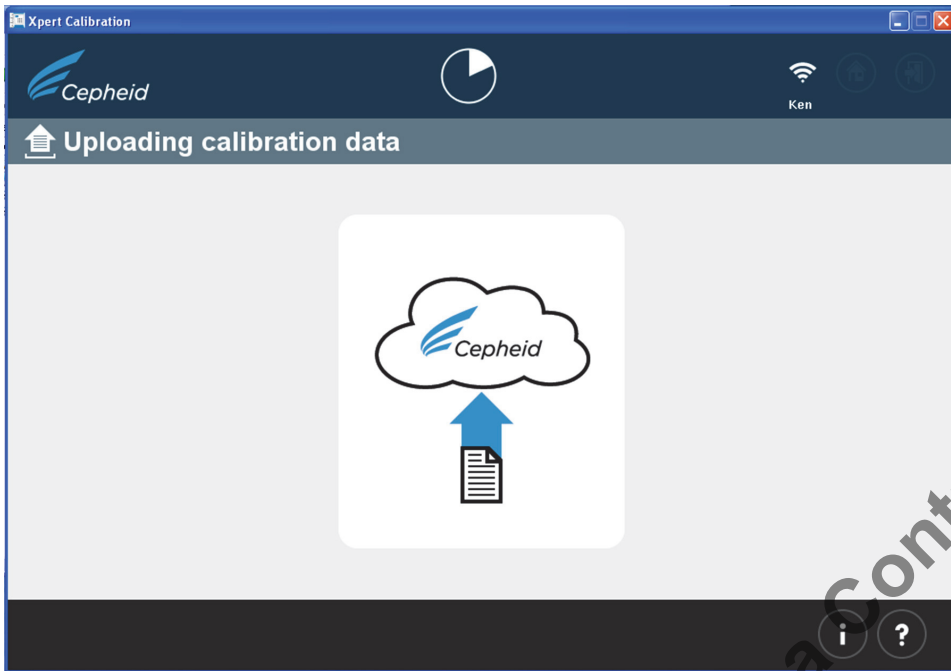


Figure 21. Uploading calibration data Screen

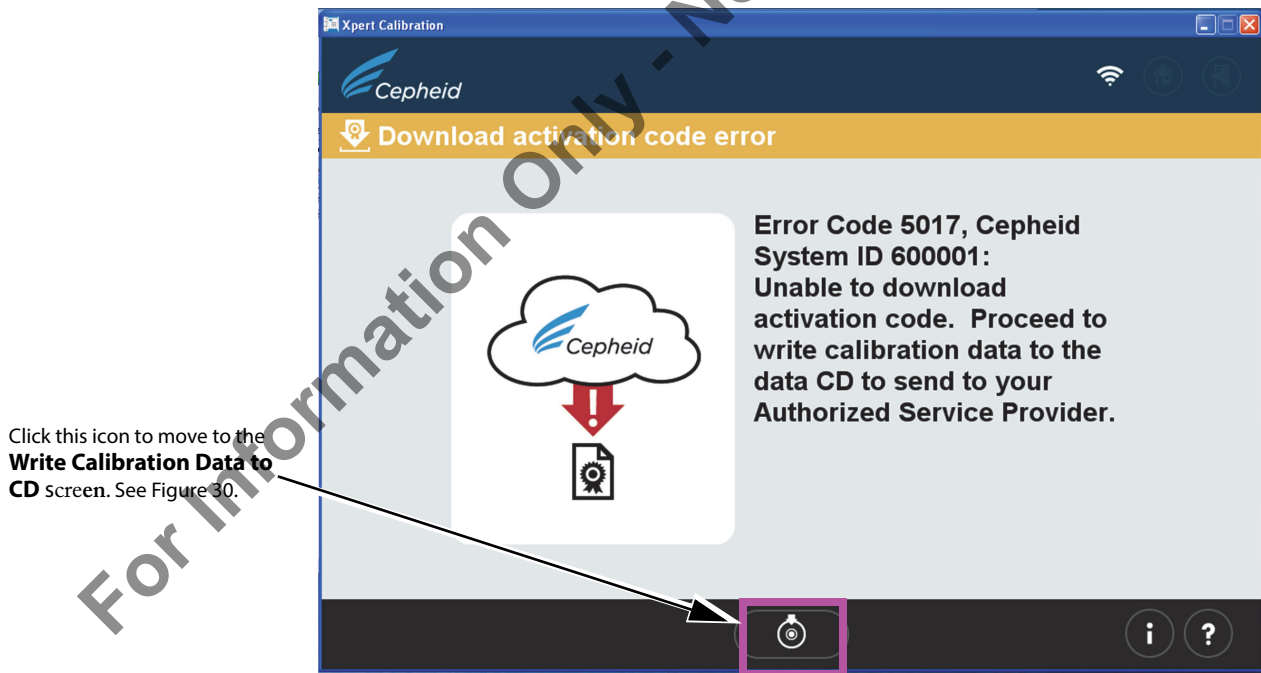


Figure 22. Download activation code error Screen

20. When the calibration data has finished uploading, a Quality Assurance check will be performed on the data. If the check is acceptable, the activation code certificate will automatically download. See Figure 23.

If the test is not acceptable, the affected module(s) will require service and will be locked to further use. Please contact Cepheid or your local ASP for further assistance.

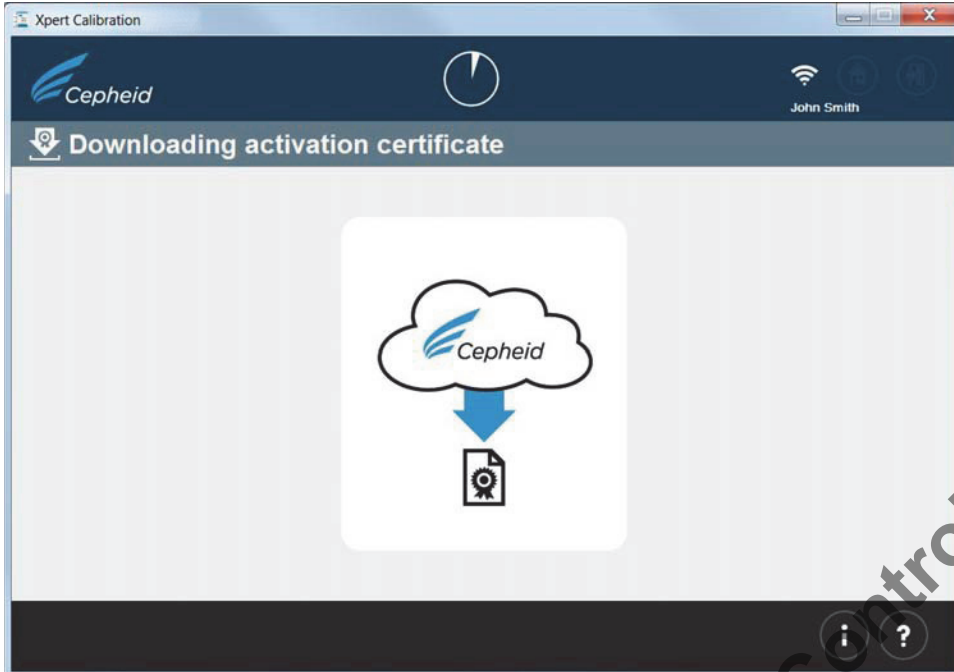


Figure 23. Downloading activation certificate Screen

21. After the Activation Code Certificate has downloaded, the Activation Code will be applied to each successfully tested module, and those modules will then be identified with a "+" symbol. See Figure 24.

As the activation code is applied to each module, a plus (+) symbol is added to the green module image.

Note: If the Service Required icon (see below) appears instead of the "+" sign on the green module, you must call your ASP for service.



You will no longer be able to use that module to run Xpert assays until the module is serviced.

Note: In this example, eight modules are being calibrated.

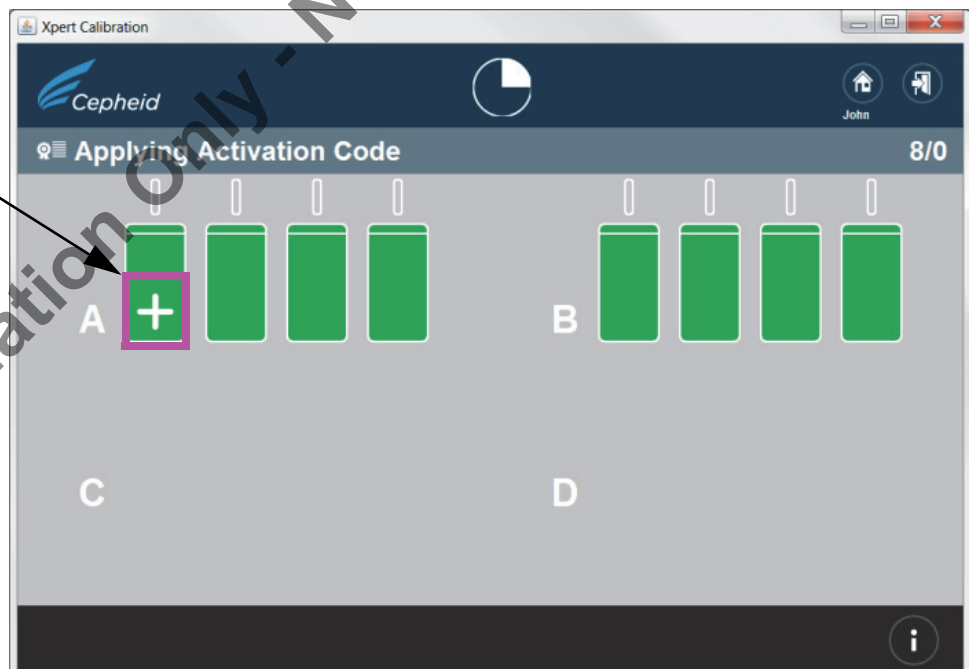


Figure 24. Applying Activation Code screen

Note: In the screen shown in Figure 24, some modules may display the service required icon or may be grayed out if they were skipped.

22. After all the activation codes have been applied to the successfully-tested modules (those green modules which appear with the plus symbols applied), the **Activation complete** screen will appear. See Figure 25. This screen shows the location of the Calibration Data report, which is available for review, if desired.

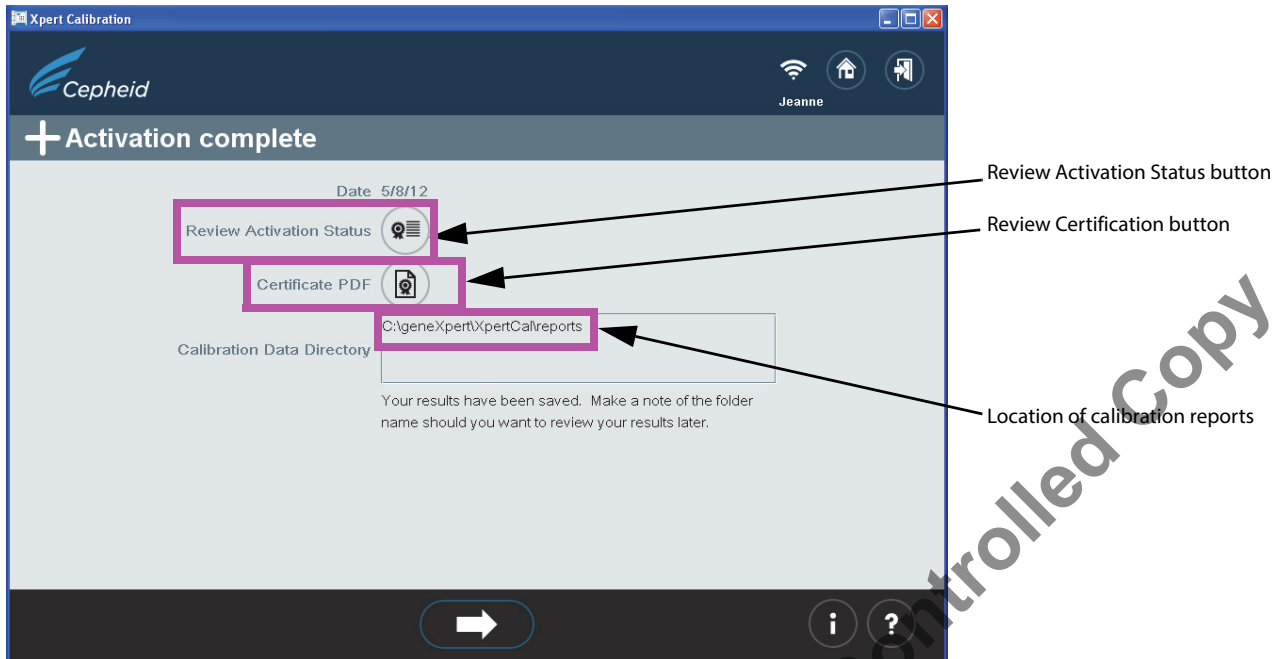


Figure 25. Activation complete screen

23. Remove and discard all calibration cartridges. Do not save partial kits (all unused cartridges must be discarded). When complete, click the Exit icon at the bottom of the screen to exit the program. See Figure 26.

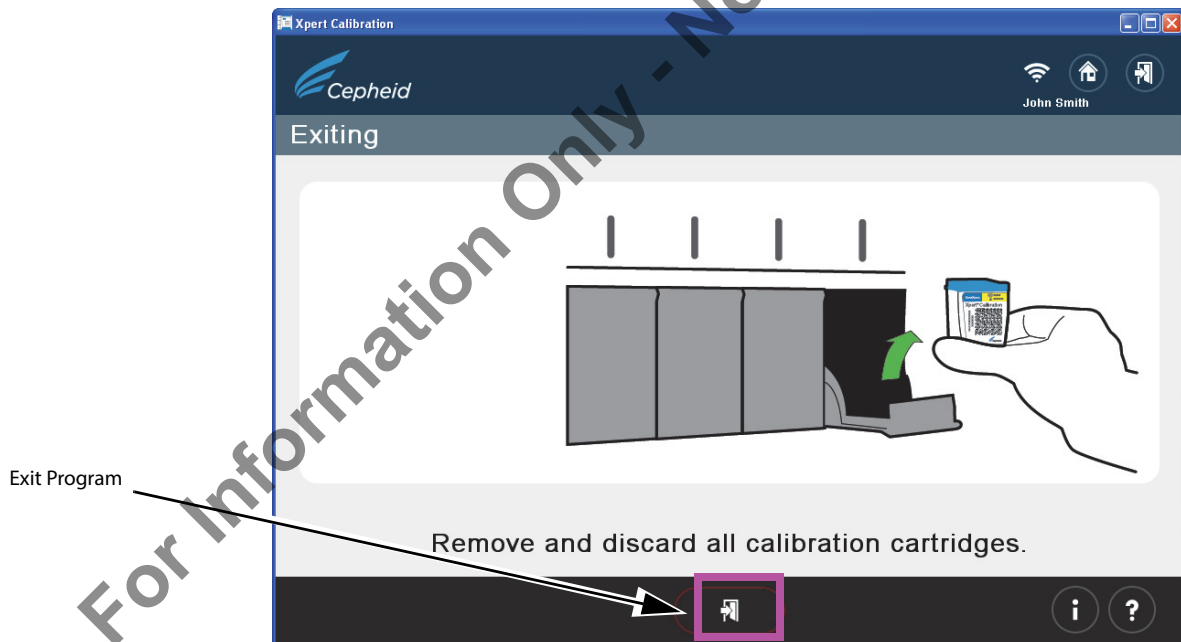
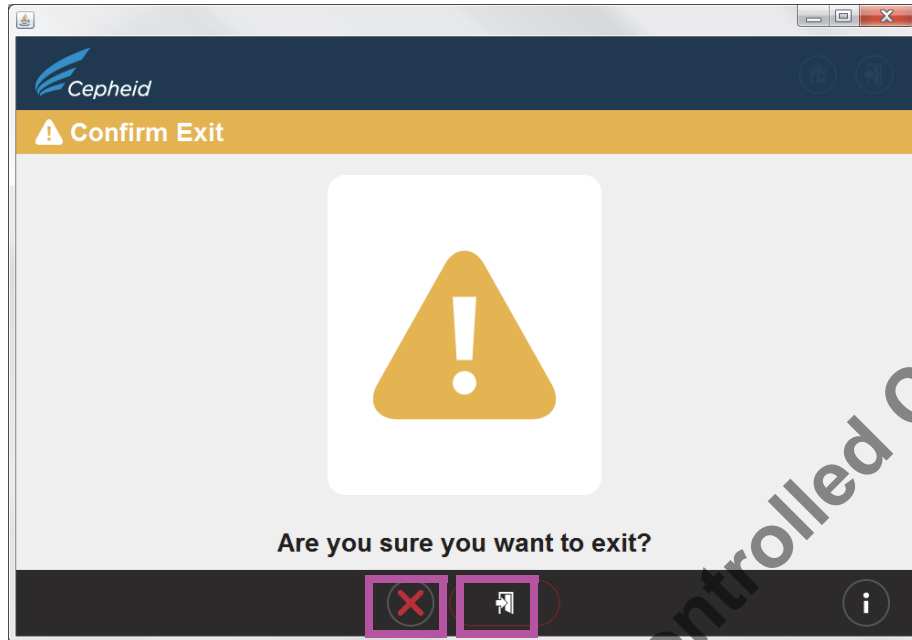


Figure 26. Exiting Screen

24. Note that in certain situations, the following screen may appear, asking for exit confirmation.



Click to abort the exit command

Click to confirm and exit the program

Figure 27. Confirm Exit screen

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

Note: Contact your Authorized Service Provider concerning modules requiring service.

Note: To view your calibration results, see step 22 and Figure 25, which shows the file path and location of calibration results and the certification PDF and the Calibration Summary report.

25. For Non-internet Connected Users:

For Non-internet connected users, you should have completed step 1 through step 16 to collect data before starting this section.

Note: See step 19 of this procedure section for internet-connected users.

- a. This section begins with the **Data collection in progress** screen, which is similar to the screen shown in Figure 17 for internet-connected users,

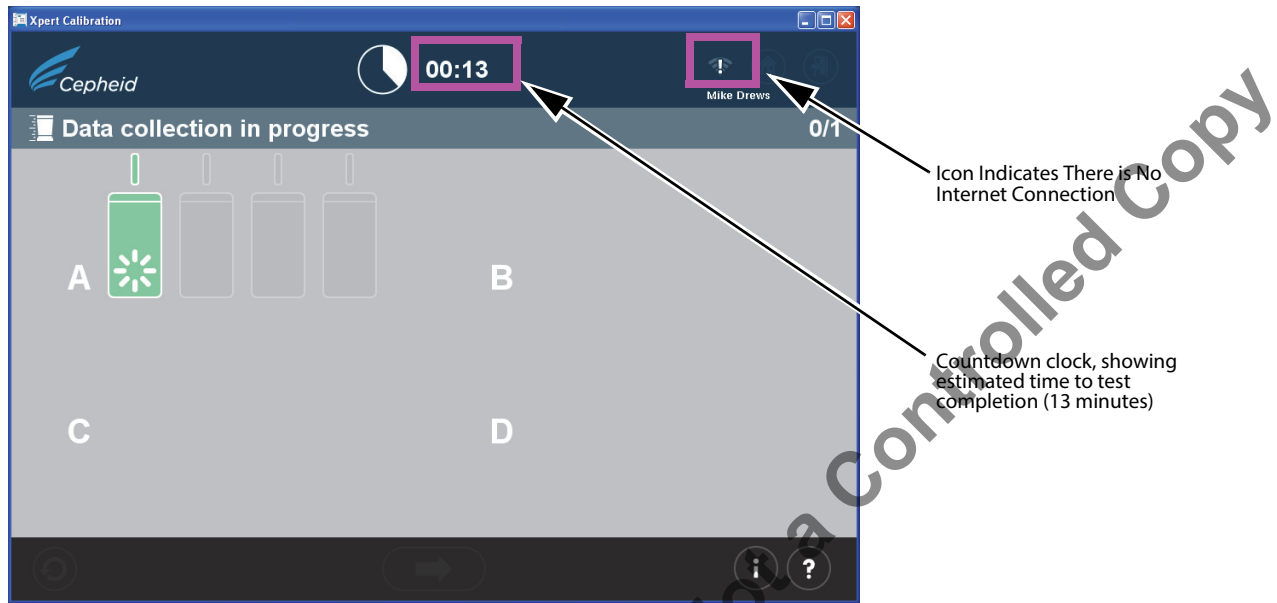


Figure 28. Data collection in progress Screen

- b. 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 29 will appear. Press the right arrow at the bottom of the screen to advance to the next screen.

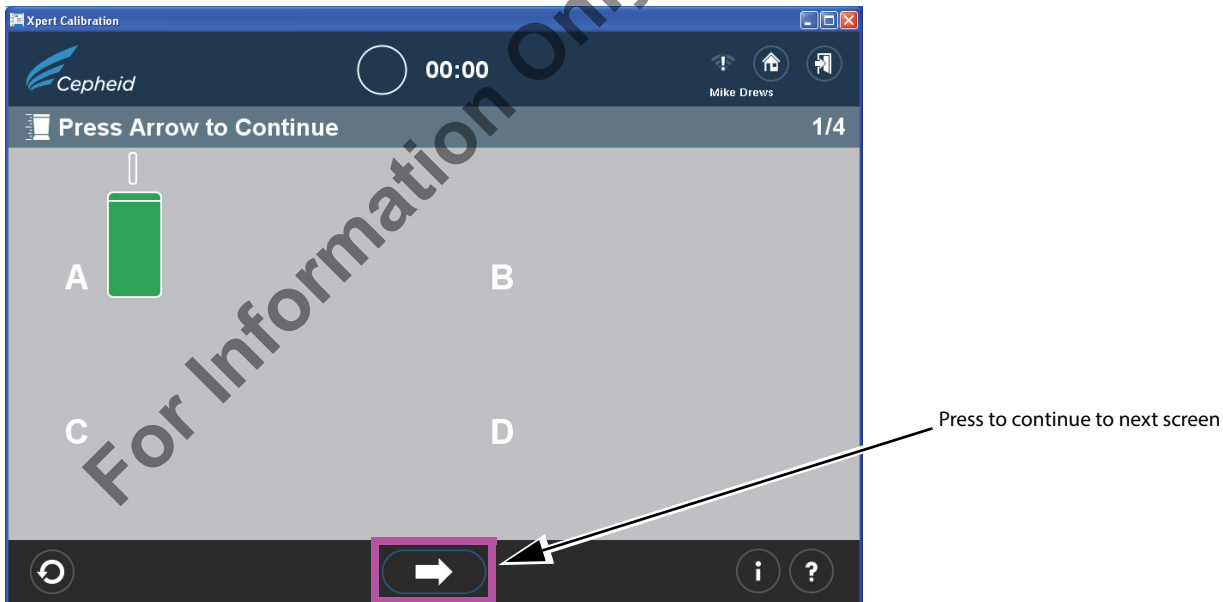


Figure 29. Test Completion screen - Successful

- c. When the Write calibration data to CD screen appears (Figure 30), you will be prompted to press the Eject button to remove the existing Xpert Calibration Software CD 1 so you can insert the blank Data CD 2.

Note: In the following step, use care in inserting the blank CD into the CDROM 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 lost your internet connection and received an error screen (Figure 22, resume your procedure beginning with the following step d., continuing through step 31.

- d. Insert the blank Data CD 2 into the computer and close the CD tray fully to ensure the CD will be recognized.

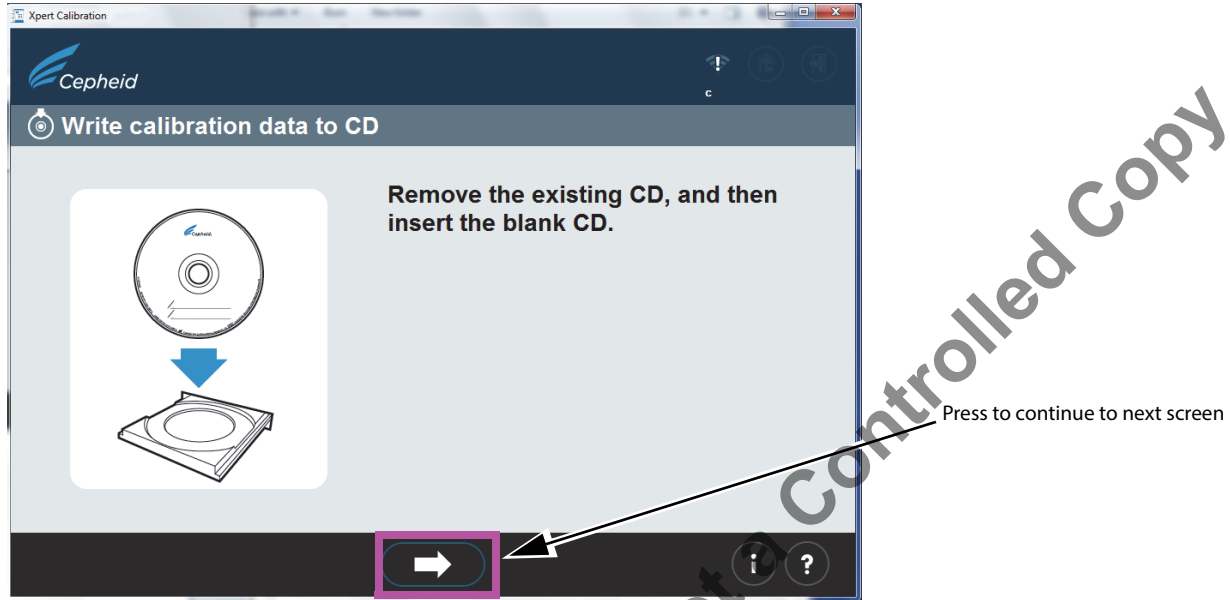


Figure 30. Write calibration data to CD screen - Step 1

26. After inserting the blank Data CD 2, the screen will change briefly, indicating the CD has been recognized. See Figure 31. 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.

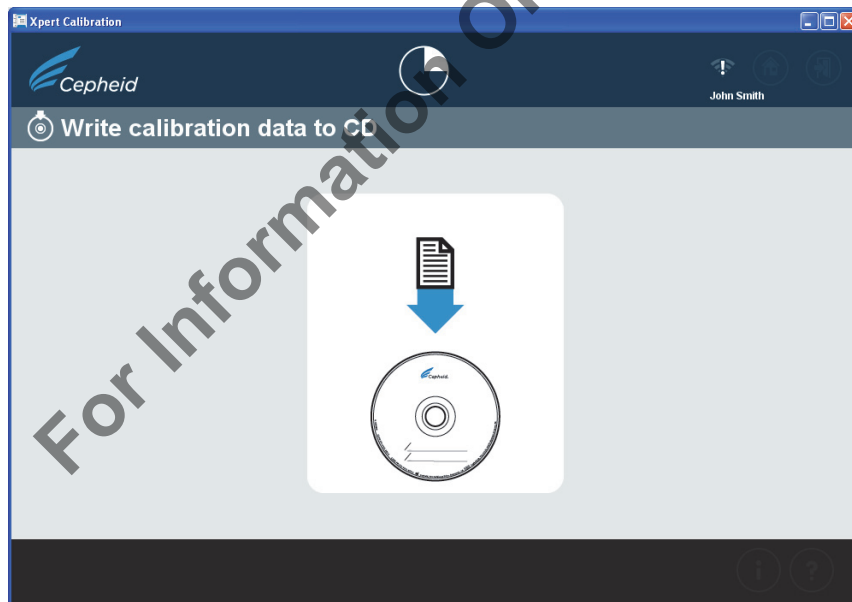


Figure 31. Write calibration data to CD screen - Step 2

- a. The CD Writing Wizard or Burn to Disc screen (Figure 32) will then appear as an overlay of the screen shown above, in Figure 31.
The next screens (Figure 32 through Figure 35) show the CD writing program screens as you progress through the writing process.
 - Windows® XP users: Follow the screens on the left side of the page.
 - Windows® 7 users: Follow the screens on the right side of the page.
- b. 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 click the **Next** button (as suggested on the screen) 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 click **Next**. See Figure 32.

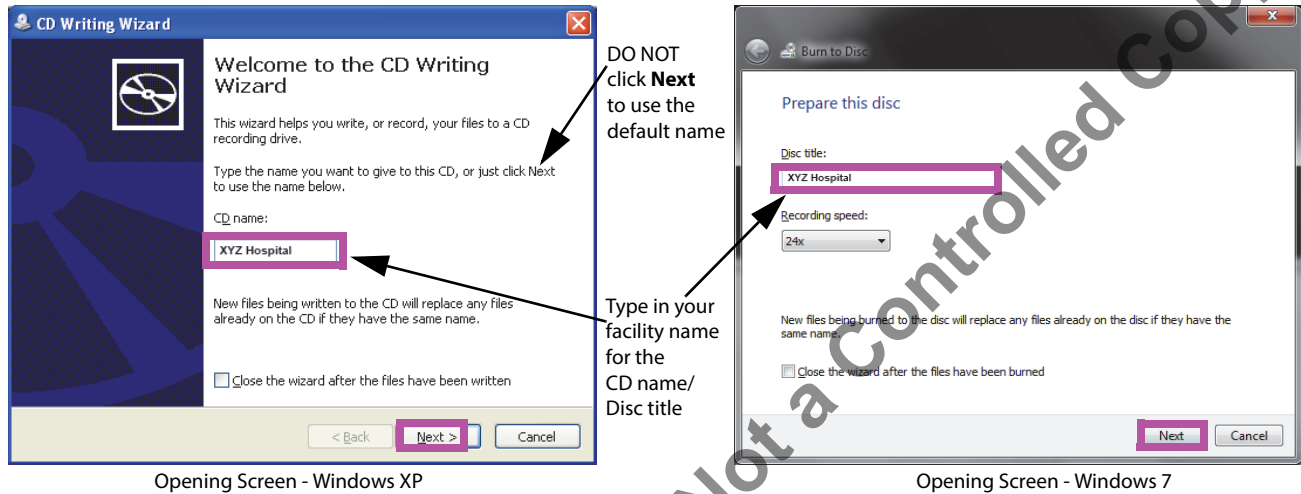


Figure 32. CD Writing Program - Opening Screen

- c. If the CD is not recognized, the screen shown in Figure 33 may appear, instead of the screen in Figure 34, 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 38.

Note: If you are unsuccessful with any part of the CD writing process, you may contact your ASP for assistance. It is safe for you to close the calibration software now because the calibration files have been saved to the hard drive and you will not lose data.

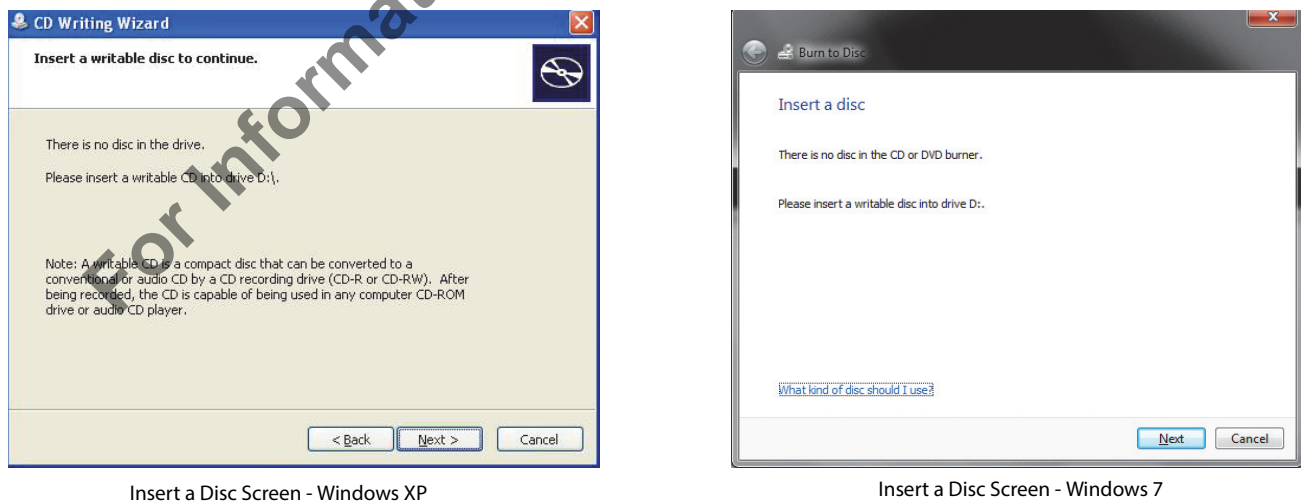
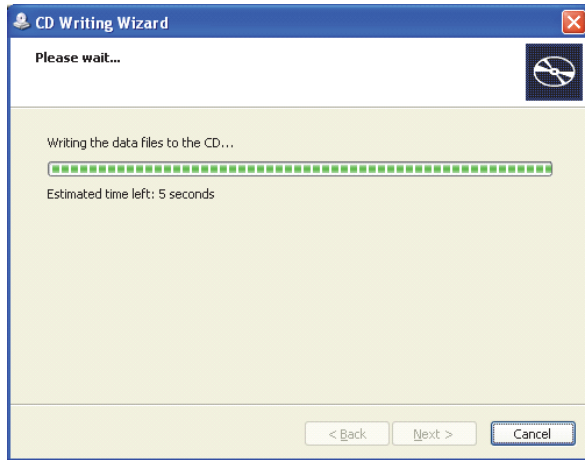
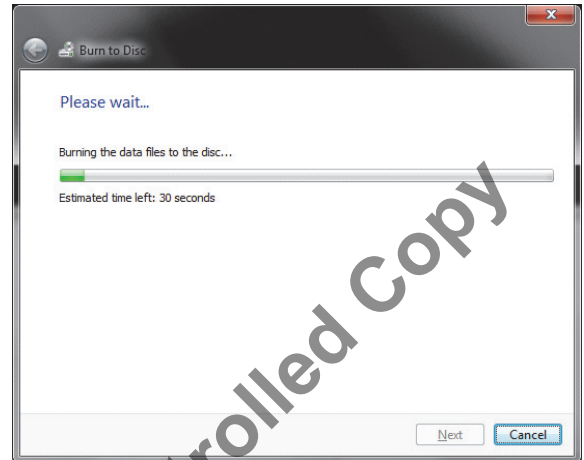


Figure 33. CD Writing program - Insert Writable Disk to Continue screen - Example

- d. After successful recognition and naming of the CD, click the **Next** button to continue. The writing process will begin automatically.
- e. During the writing/burning process, a progress bar will appear on the screen. See Figure 34.



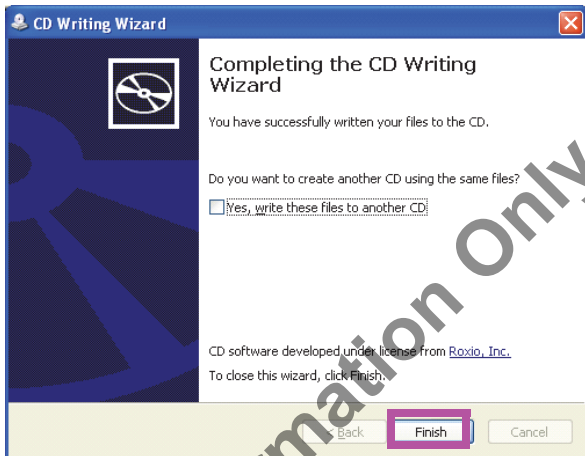
File Writing Progress Screen - Windows XP



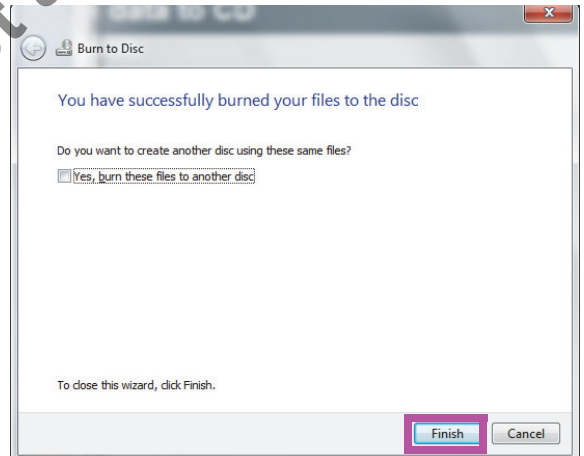
File Burning Progress Screen - Windows 7

Figure 34. CD Writing/Burning Progress screen

- f. When the writing of the CD is complete, the screen shown in Figure 35 will appear. Click the **Finish** button to exit the CD writing program.



Completion Screen - Windows XP



Completion Screen - Windows 7

Figure 35. CD Writing Completion screen

- g. On a Windows 7 machine, you may see the screen displayed in Figure 36 after a successful CD write. Click the **OK** button as many times as necessary for it to disappear before continuing.

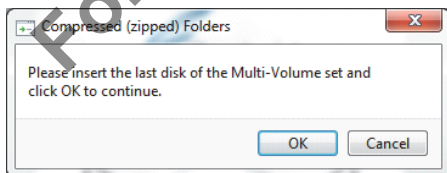


Figure 36. Final Screen from Windows 7 After CD Writing is Completed

- h. After clicking the **Finish** button on the CD writing screen, the **Send the CD to your Authorized Service Provider** Screen will appear (see Figure 37). Remove the completed calibration Data CD 2 from the disk drive and prepare the label, as described in step 29.

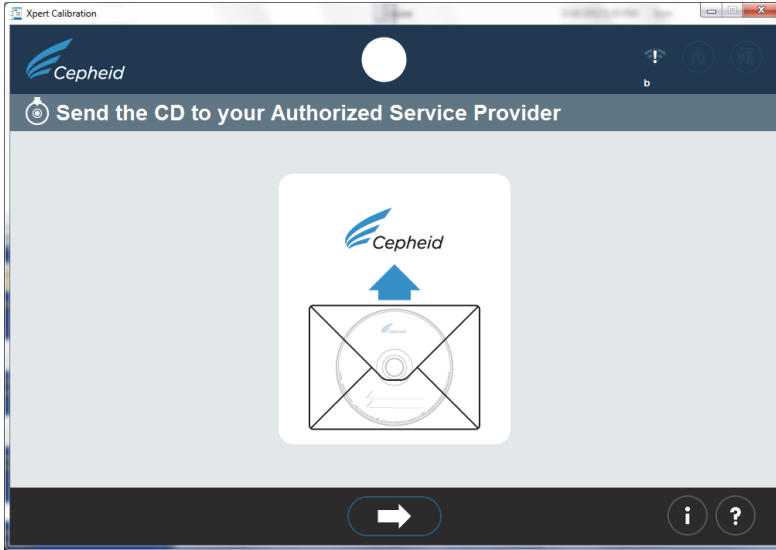


Figure 37. Send the CD to your Authorized Service Provider Screen

27. If a problem has occurred anytime during the CD writing process, an error code screen may appear. (See Figure 38).

- 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 press the **Retry** button.
- 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 for assistance, if necessary.

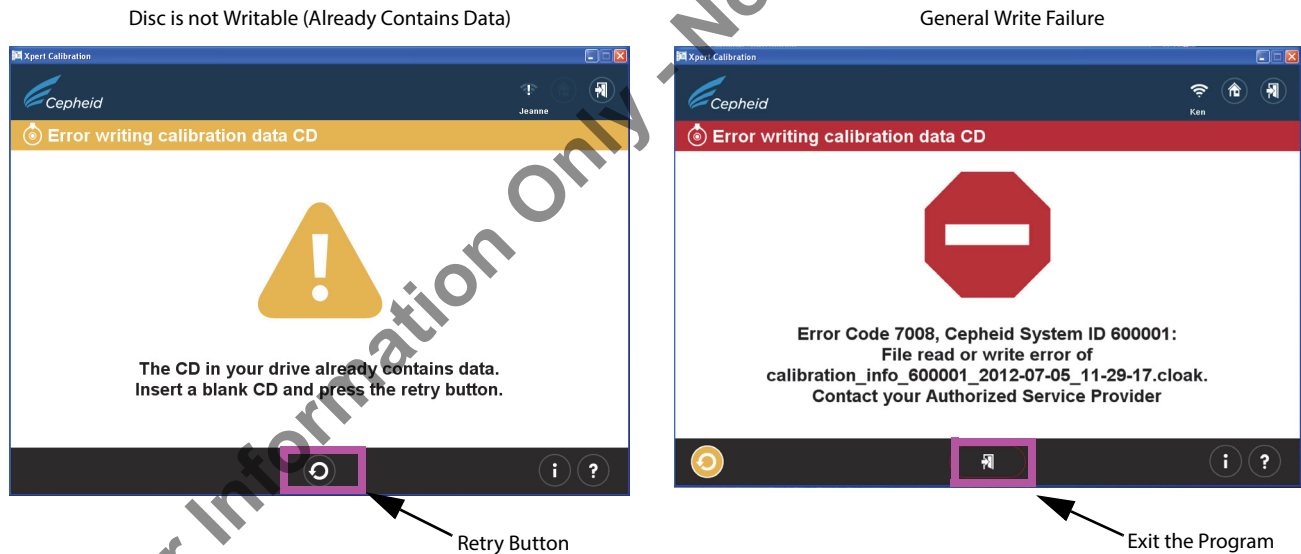


Figure 38. Error writing calibration data CD screens - Two Examples

28. After test completion, the **Exiting** screen will appear with the message to **Remove and discard all calibration cartridges** (see Figure 39).

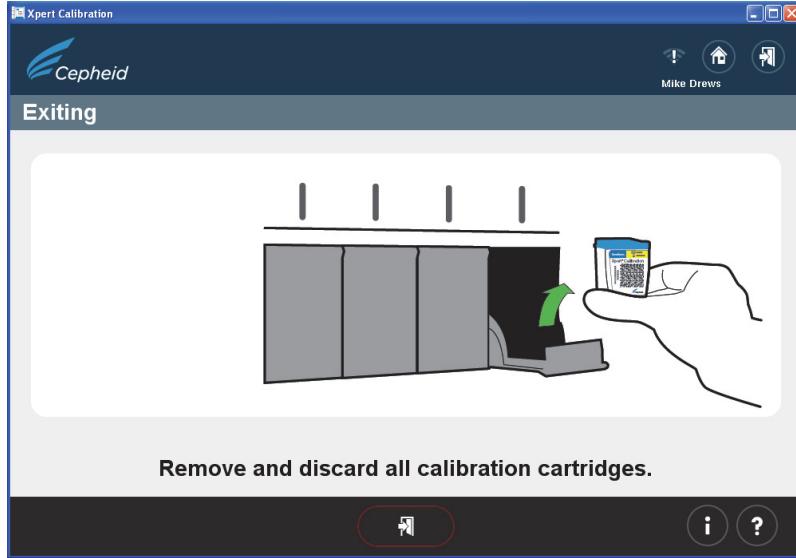
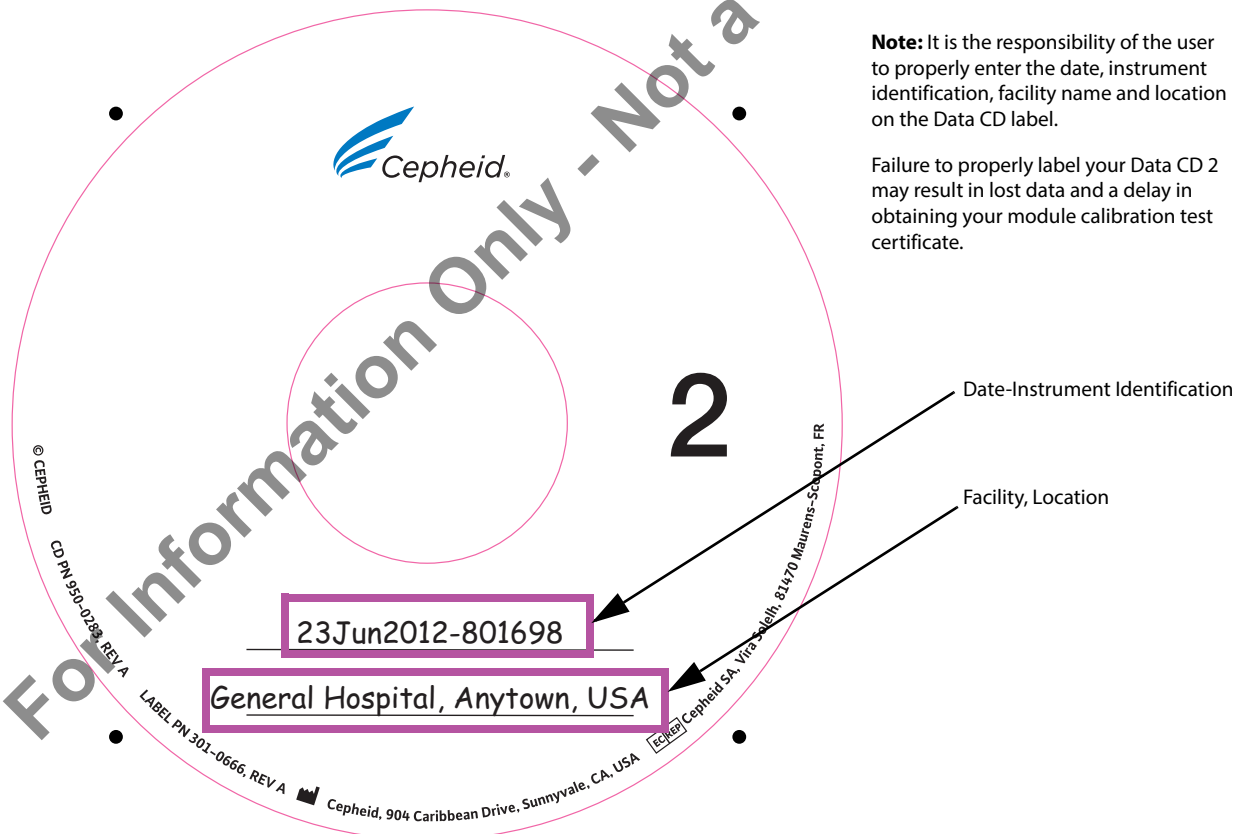


Figure 39. Exiting screen

29. Use a felt-tip pen to write on the label of the calibration Data CD 2 you've just created by writing the date, instrument identification and facility/location of the calibration test performed. See a label example in Figure 40.



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 2 may result in lost data and a delay in obtaining your module calibration test certificate.

Figure 40. Data CD 2 Labeling Example

30. You have the option to copy the `calibration_info.gxc` data file (located on the calibration CD just written) and E-mail the data file directly to your ASP instead of mailing the CD. If E-mail is not an option, place the calibration CD2 into the provided CD

shipping envelope and mail it to your local Authorized Service Provider (ASP) for data quality assurance checking and the issuing of your activation code. For US customer only, use the address at the end of this package insert: Attention Service Provider.

31. Your ASP will perform the quality assurance review and, if successful, send back your calibration activation code either by E-mail 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 Xpert Calibration Software CD 1. For users who E-mailed their file and have not shipped their Data CD 2: DO NOT discard your Data CD 2.

32. Restart your GeneXpert Dx or Infinity system and computer.

Note: You can continue to use your system and GeneXpert DX software while awaiting your activation code

Activation of Calibration for Non-internet Connected Users:

Note: Ensure the system is in the same configuration as when the calibration was run (i.e., no software updates or changes have been made and no new GX 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 Activation Code, new or modified modules will be ignored for the purposes of the Xpert Calibration activation process.

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

1. Exit the Gx Dx software.
2. To finish the calibration process, place Xpert Calibration Software CD 1 in the computer connected to the GeneXpert Dx instrument or in the kiosk computer for the Infinity.
3. Click on My Computer, then double-click on the applicable drive letter for your CD drive. The files located on the CD will then be displayed. Find and double-click the **XpertCalibration.exe** application to launch the software.
4. Log in with your GeneXpert Dx or Infinity designated USER NAME and PASSWORD (previously assigned to you by your system administrator). See Figure 2 for the **Login** screen.

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

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

5. Click on the **Enter Activation Code** button. See Figure 41. The Enter activation code screen will appear. See Figure 42.

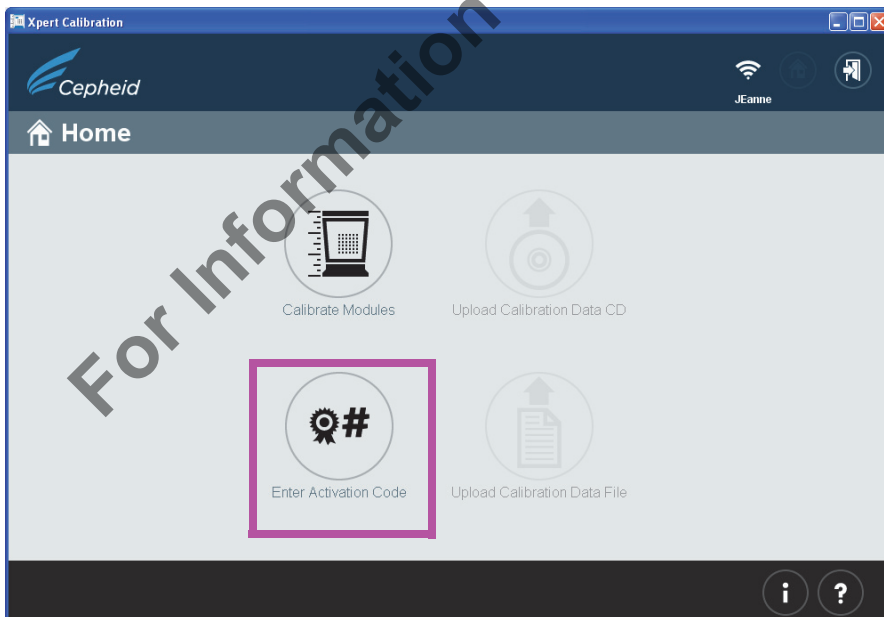


Figure 41. Home Screen, showing Enter Activation Code Button

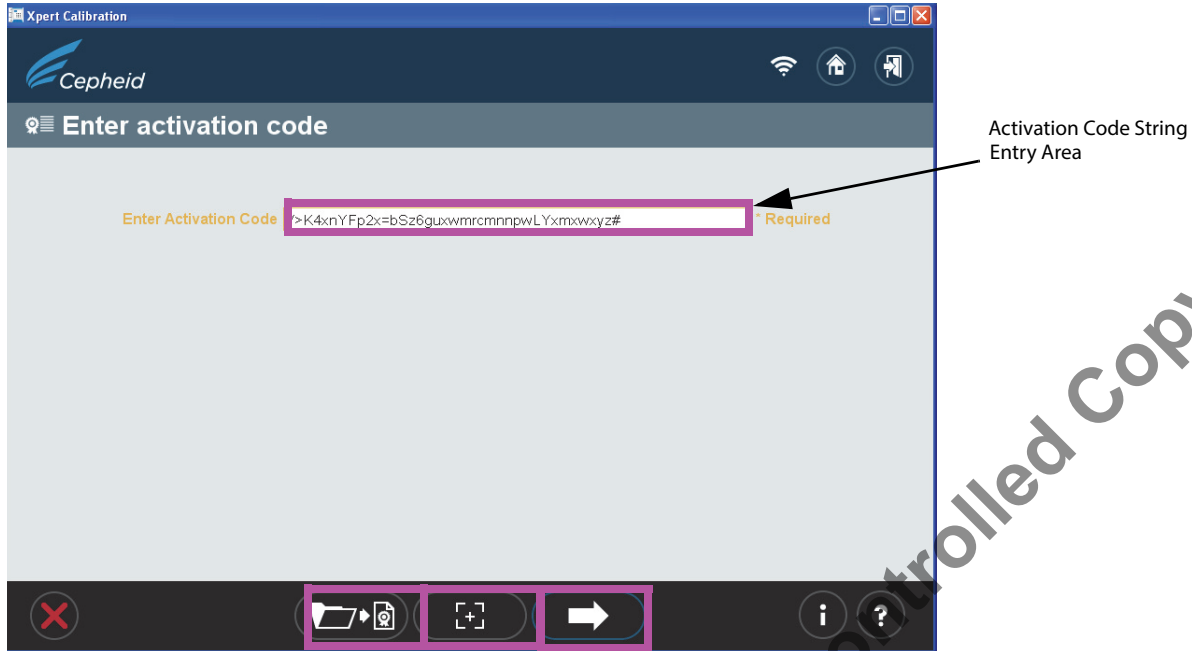



Figure 42. Enter activation code screen

6. Enter your activation code as described below.

In this step, there are various ways to enter the activation code. Your five options are listed below, beginning with the simplest (recommended) method.

- a. Use your scanner to input the barcode as follows: First, click on the  icon located in the bottom center of the screen. The Calibration Activation Code File (Figure 43) will appear on your screen. Position your scanner to scan the barcode on the Activation Certificate, using care to avoid any reflection on the monitor that may interfere with your scanner. See Figure 43 for an example of a Calibration Activation Code File.
- b. Print a copy of the Calibration Activation Code File and place the copy on a flat surface, facing up. Use your scanner to scan the barcode on the printed page. See Figure 43 for an example of a Calibration Activation Code File.
- c. Copy and paste the activation code string into the **Enter activation code** screen from the screen's display. The activation code string is visible on either Figure 42 and Figure 43.
- d. Type in the activation code string manually using the information on your screen or printed page.

When you have successfully entered the activation code, click the forward arrow at the bottom of the screen to continue. The **applying activation code** screen will appear. See Figure 44.



Xpert Calibration Activation Code File

Here is the activation code for the recent calibration data collection of your modules for the system identified below.

Calibration data collection performed on May 09 2012 08:20:31 PDT

GX Instrument Name:	GX-333
GX Instrument Serial Number:	12345
Software Version:	1.0.293Demo1_1.1
Data Collected By:	user1
Institution Name:	cepheid
Laboratory Name:	lab-333
Street Address:	333 main street, suite 333
City:	sunnyvale
State/Province:	ca
Postal Code:	95333
Email:	
Facility Phone Number:	408-400-3333
Extension:	
Cell Phone Number:	

Scan or enter the activation code to update the calibration in your instrument.



Barcode

VLx3-YnuY-KEHT-T?vW-4p&N-Krbm-pnp&-j@yP-wwwy-z#

Activation Code String

Figure 43. Calibration Activation Code File - Example

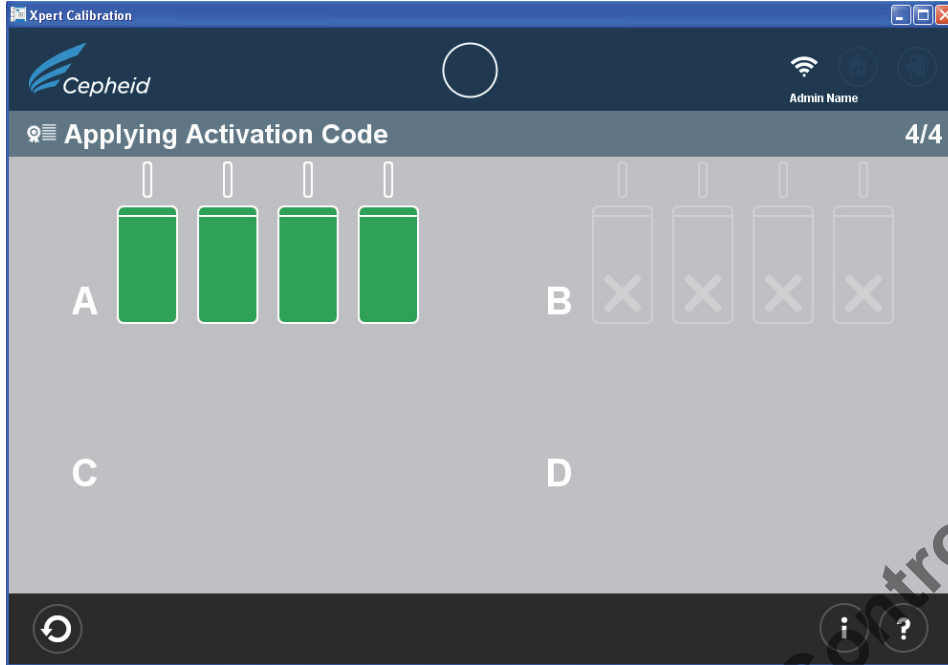


Figure 44. Applying Activation Code Screen Example

- e. After the activation code has been applied, the **Calibration Complete** screen will appear with the location of the Calibration Report displayed in the **Results Directory** area. Write down the file path and location of the Calibration Report file, as shown. See Figure 45.

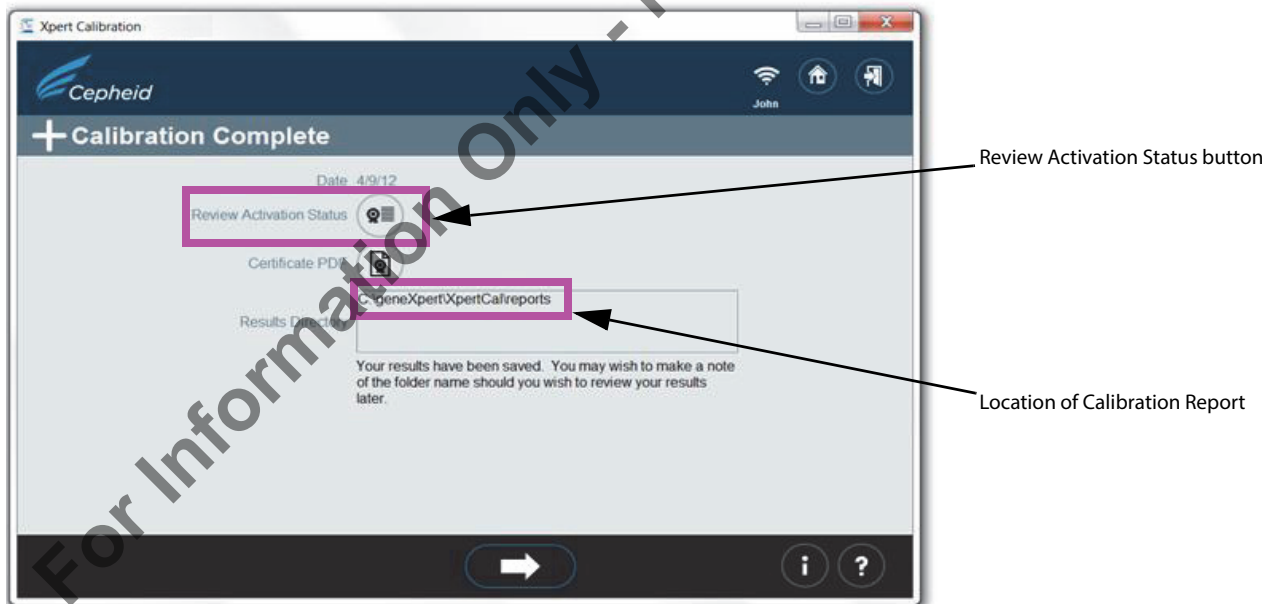


Figure 45. Calibration Complete Screen

- f. Click the **Review Activation Status** button (see Figure 45).
- g. The **Activation status** screen will appear. See Figure 46. In the **Activation status** screen, the successfully calibrated modules are indicated by a “+” sign on a green module.

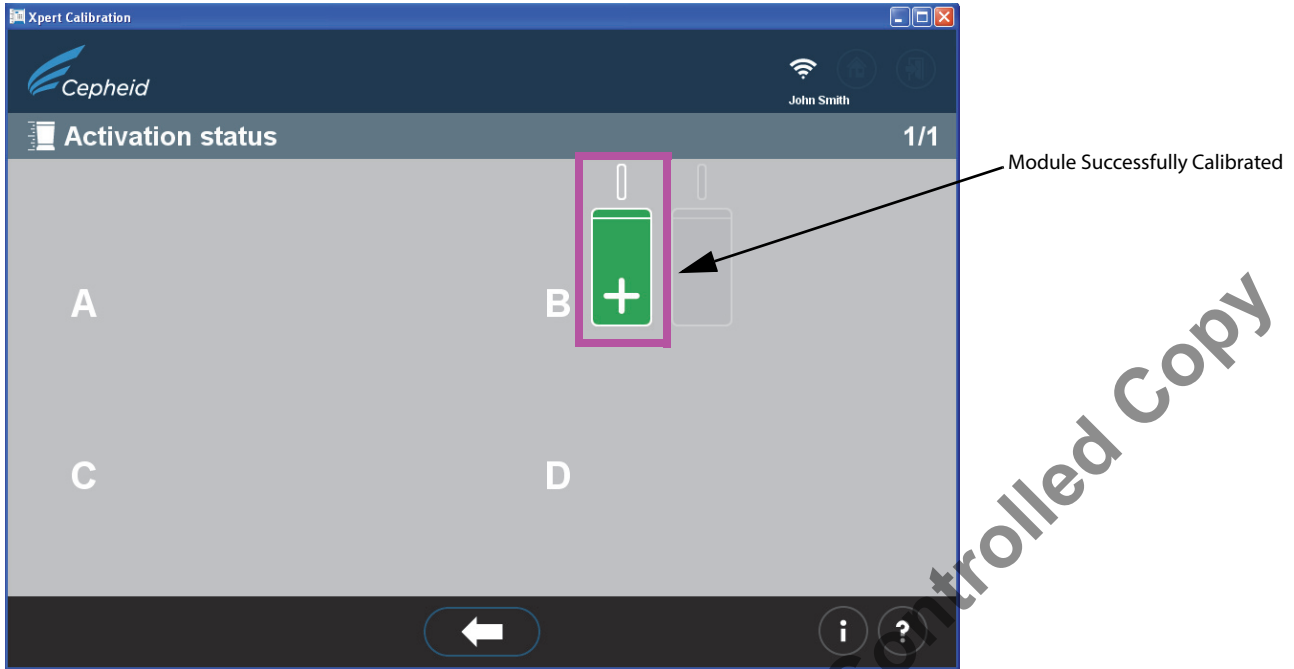


Figure 46. Activation Status Screen

Note: If the calibration certification has been lost or the copy on the computer was deleted, contact your ASP for assistance.

For Information Only - Not a Controlled Copy

7. Identify the generated Calibration Report file in the directory *C:\GeneXpert\Xpertcal\Reports*. Print, sign, and date the Calibration Certificate and for your records.
 - a. See Figure 47 for an example of a Calibration Certification.



GeneXpert® System Calibration Certification (Demo)

Congratulations! The following modules in your GeneXpert System have completed calibration:

Cepheid System ID:	12345
Calibration Date:	May 09 2012
Print Date and Time:	May 09 2012 08:22:03 PDT
Institution Name:	cepheid
Laboratory Name:	lab-333
Calibration Performed By:	user1
Calibration Expiration:	May 09 2013

Module Serial Numbers	
610942	610964

Each module listed above has undergone a multi-functional test of mechanical and electrical components, thermal verification and full optical calibration using current manufacturing specifications. Cepheid requires that the instrument be recalibrated after one year of use or at 2000 tests per instrument module, whichever comes first. Refer to Operator Manual for instructions.

Customer Name and Approver: _____

Customer Signature: _____

Function: _____

Date: _____

Cepheid
301-0776 Rev A

GeneXpert® Xpert Calibration Version: 1.1

Page 1 of 1

Figure 47. Calibration Certificate Example

8. Identify the generated Calibration Summary Report file in the directory *C:\GeneXpert\Xpertcal\Reports*.
 - a. See Figure 48 for an example of a Calibration Summary Report.

The Calibration Summary Report lists the modules that had an unsuccessful calibration test and require service. The listed modules will no longer be available to use until they have been replaced or repaired.

The modules requiring service are listed by serial number at the bottom of the form in Table 1. When requesting service, provide these listed serial numbers to your ASP.



Xpert Calibration Summary Report

No modifications were made to GeneXpert system.

Please Note:

Calibration data collection performed on 24 August 2012 12:46:16 CAT
 All modules that DID NOT pass calibration are listed in Table 1: Modules Requiring Service.
 Complete test results for each module are listed in Table 2: Detailed Test Results by Module.

GX Instrument Name:	RD2
Cepheid System ID:	467027
Data Collected By:	XXXX
Institution Name:	University
Laboratory Name:	Laboratory
Street Address:	997 York Blvd
City:	Sunnyvale
State/Province:	California
Postal Code:	94089
Country:	USA
Email:	mavu@gmail.com
Facility Phone Number:	5550098573
Extension:	8663
Mobile:	5550145510

Table 1: Modules Requiring Service

Module Serial Number	Requiring Service
602186	Requiring Service

Figure 48. Calibration Summary Report Example - Page 1

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, the Infinity-48, the Infinity 48s, or the Infinity-80.

GeneXpert Dx

1. Ensure all calibration cartridges and calibration CDs have been removed from the GeneXpert Dx.
2. Restart your GeneXpert system and computer. Follow the instructions in the *GeneXpert Dx System Operator Manual*.
3. The system will be ready for full operation.

Infinity-48

1. Ensure all calibration cartridges and calibration CDs have been removed from the Infinity-48.
2. Restart the Expertise software and switch the system from **Manual** mode back to **Automation** mode. Follow the instructions in the *GeneXpert Infinity System Operator Manual* for the Infinity-48.
3. The system will be ready for full operation.

Infinity-48s or Infinity-80

1. Ensure all calibration cartridges and calibration CDs have been removed from the Infinity-48s or Infinity-80.
2. Restart the Xpertise software. Follow the instructions in the *GeneXpert Infinity System Operator Manual*.
3. The system will be in **Automation** mode, ready for full operation.

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Information Key Screen:



Figure 49. Information Key Screen


Reasons to Repeat the Calibration with a new cartridge

If the onscreen instructions direct you to retest, repeat the test according to the instructions in step b. under step 18.

Reasons to Repeat the Calibration with the same cartridge

Software reports that the cartridge film seal was not broken. Remove original cartridge, rescan the cartridge barcode, open lid, close, and reinsert the cartridge. Restart the calibration for the affected module.

Application of Calibration Activation Code

 Calibration is not complete until the Cepheid-supplied activation code is applied to the system being recalibrated. Upon receipt of the Quality Assurance Activation Code from Cepheid, apply the activation code to your system using the Xpert Calibration Software to complete the calibration process and receive an updated calibration certificate.

Appendix A

Infinity-48 Preparation

Perform the following steps to put an Infinity-48 into Manual mode from Automation mode:

Note: For the following steps, the user should log in as one who has privileges to change the instrument's operation mode.

1. In the Xpertise Software Home workspace (Figure 50), press the **Setup** button.

The screenshot shows the Xpertise Software Home workspace. At the top, it says 'Xpertise Software' and 'David Jones'. Below that, there's a 'Welcome to GeneXpert Infinity System' message. The main area is a 'Message Log' table with the following data:

Type	Time	Subsystem	Message
i	07/14/09 10:12:42	System	Module H4: Performing Self-Test
i	07/14/09 10:12:42	System	Module A3: Performing Self-Test
i	07/14/09 10:12:42	System	Module A4: Performing Self-Test
i	07/14/09 10:12:42	System	Module K1: Performing Self-Test
i	07/14/09 10:12:43	System	Module K2: Performing Self-Test
i	07/14/09 10:12:43	System	Module K3: Performing Self-Test
i	07/14/09 10:12:43	System	Module K4: Performing Self-Test
i	07/14/09 10:12:45	System	Module G1: Performing Self-Test
i	07/14/09 10:12:45	System	Module G2: Performing Self-Test
i	07/14/09 10:12:45	System	Module G3: Performing Self-Test
w	07/14/09 10:13:21	Emergency Stop	Reminder 7202: Emergency Stop de-activated.
w	07/14/09 10:13:21	Glass Doors	Reminder 7223: Glass Doors are closed.
w	07/14/09 10:13:21	Glass Doors	Reminder 7221: Glass Doors are latched.
i	07/14/09 10:13:28	System	Full Automation Operating Mode
i	07/14/09 10:13:31	System	Welcome to GeneXpert Infinity System

Below the table are 'Preview PDF' and 'Clear' buttons. On the right side, there's a navigation menu with buttons for 'Orders', 'Results', 'Data Management', 'Setup', and 'Maintenance'. The 'Setup' button is highlighted with a pink box and an arrow.

Figure 50. Xpertise Software Home workspace Screen

2. The Setup menu appears. See Figure 51.

Xpertise Software

David Jones

Welcome to GeneXpert Infinity System

Message Log

Type	Time	Subsystem	Message
i	07/10/09 16:04:27	System	Module E1: Performing Self-Test
i	07/10/09 16:04:27	System	Module B1: Performing Self-Test
i	07/10/09 16:04:27	System	Module C1: Performing Self-Test
i	07/10/09 16:04:27	System	Module E2: Performing Self-Test
i	07/10/09 16:04:28	System	Module B2: Performing Self-Test
i	07/10/09 16:04:28	System	Module E3: Performing Self-Test
i	07/10/09 16:04:28	System	Module C2: Performing Self-Test
i	07/10/09 16:04:28	System	Module E4: Performing Self-Test
i	07/10/09 16:04:28	System	Module B3: Performing Self-Test
i	07/10/09 16:04:28	System	Module C3: Performing Self-Test
i	07/10/09 16:04:28	System	Module B4: Performing Self-Test
i	07/10/09 16:04:28	System	Module C4: Performing Self-Test
i	07/10/09 16:04:29	System	Module I1: Performing Self-Test
i	07/10/09 16:04:30	System	Module I2: Performing Self-Test
i	07/10/09 16:04:30	System	Module I3: Performing Self-Test

Preview PDF Clear

- User Administration
- User Type Configuration
- System Configuration
- Manage Assays
- Installation Qualification
- Change Operation Mode**
- Back

Figure 51. Setup Menu - Change Operation Mode Highlighted

- Press the **Change Operation Mode** button (Figure 51).

The **Change Operation Mode** workspace appears (Figure 52).

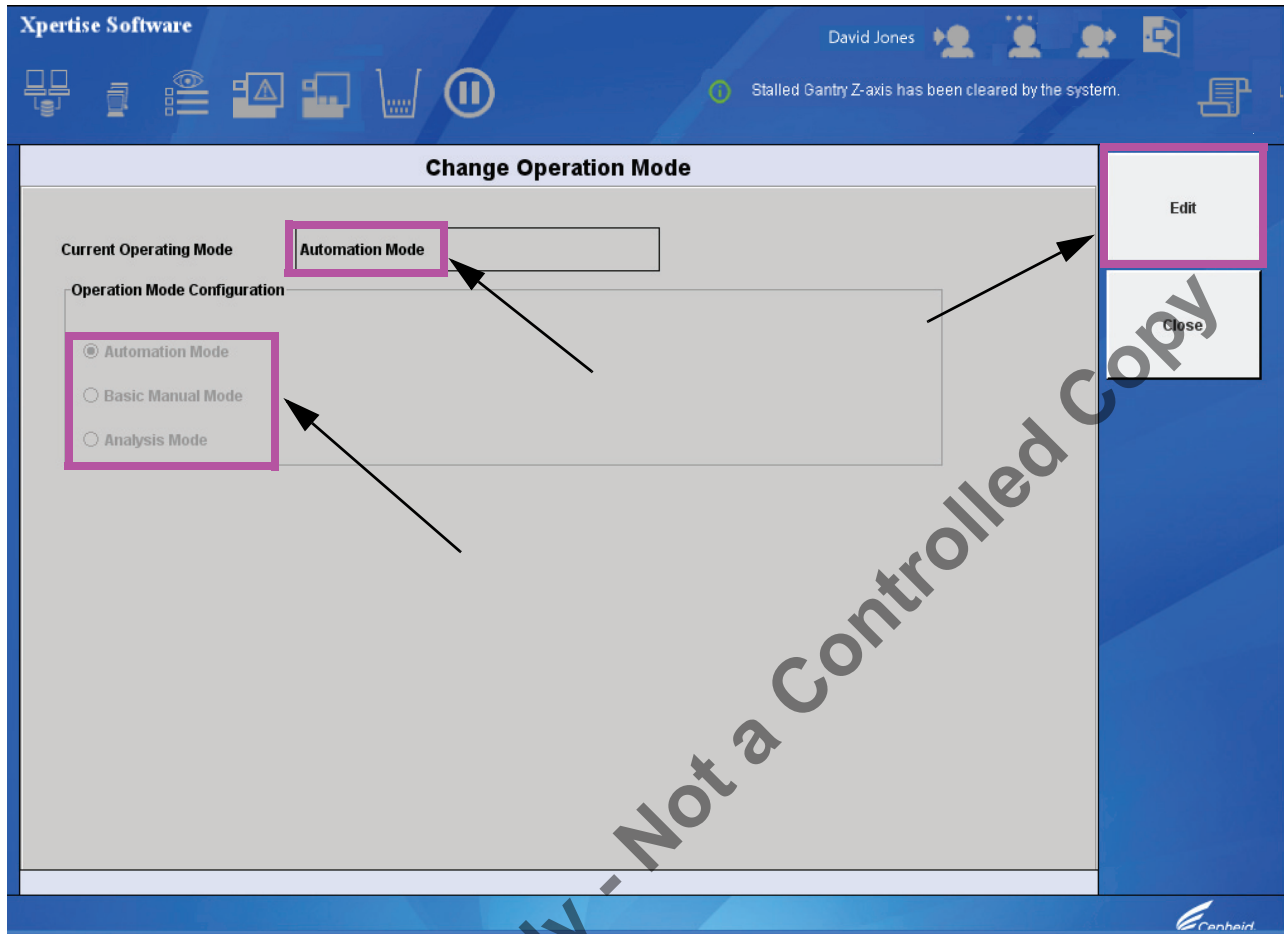


Figure 52. Change Operation Mode Workspace

The Change Operation Mode workspace allows you to change the operation mode.

Three radio buttons are displayed with the current operation mode saved in the database (Figure 52).

- Automation Mode (Default)
- Basic Manual Mode
- Analysis Mode (Disabled, user cannot select this setting.)

4. Press the **Edit** button (Figure 52).

The Change Operation Mode workspace is activated.

5. In the Change Operation Mode workspace, select **Basic Manual Mode** (Figure 53).

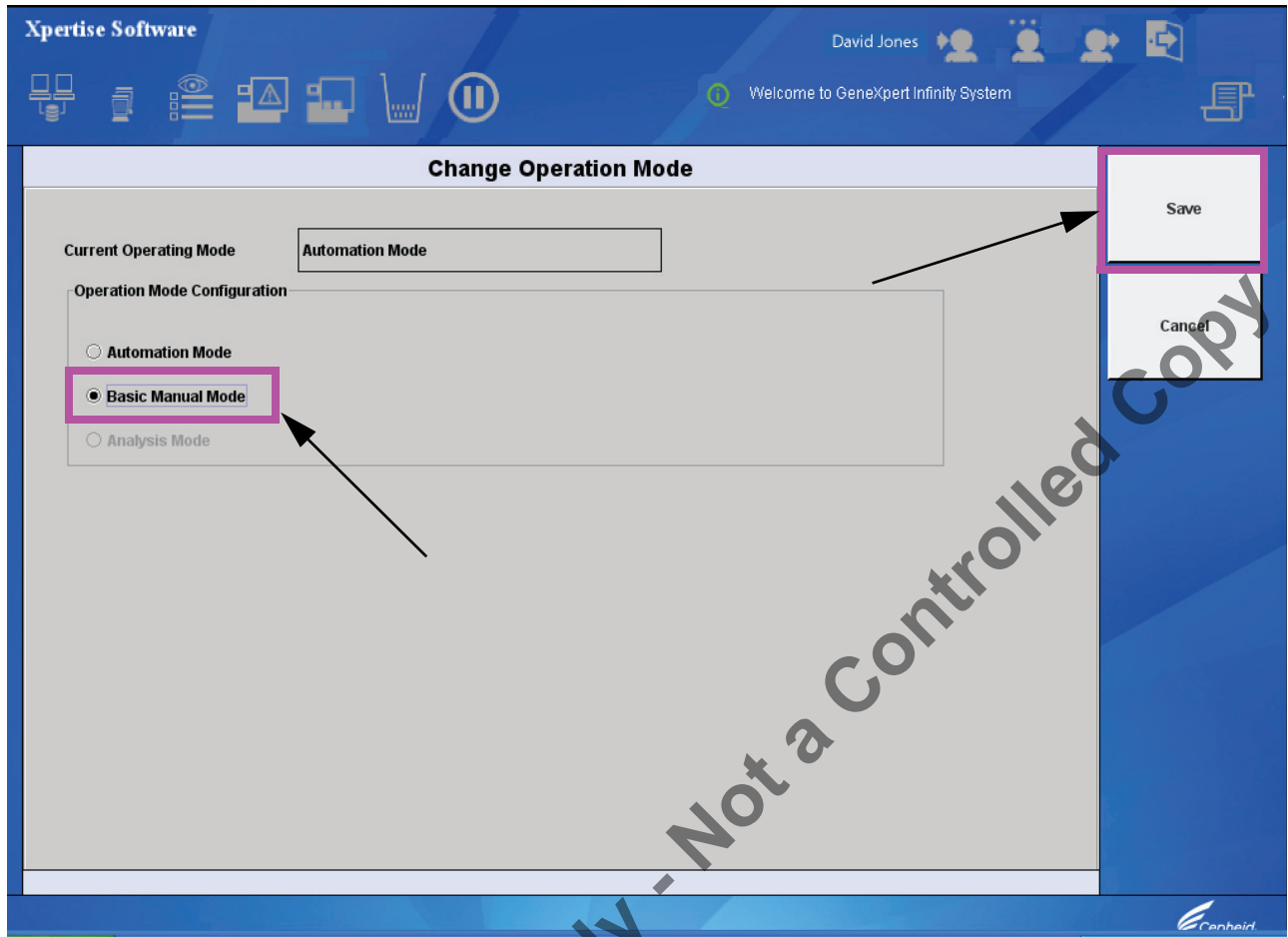


Figure 53. Change Operation Mode workspace – Selecting Basic Manual Mode

6. Press the **Save** button.

When there are outstanding orders pending, the Change Operation Mode dialog box will appear as shown in Figure 54; otherwise, it will appear as shown in Figure 55.

Confirmation Dialog Box for Changing to Manual Mode Appears (Figure 54).

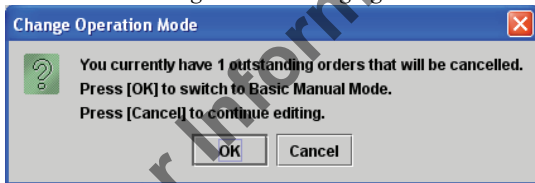


Figure 54. Change Operation mode dialog box - when outstanding orders are pending

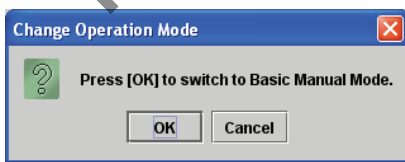


Figure 55. Change Operation dialog box—when no outstanding orders pending

7. For the dialog box for outstanding orders pending, click **OK** to go to the Leaving Automation mode workspace (Figure 54).
or
Click **Cancel** to continue editing.
8. For the dialog box for no outstanding orders pending, Click **OK**. Figure 55. The Leaving Automation Mode workspace appears (Figure 56).

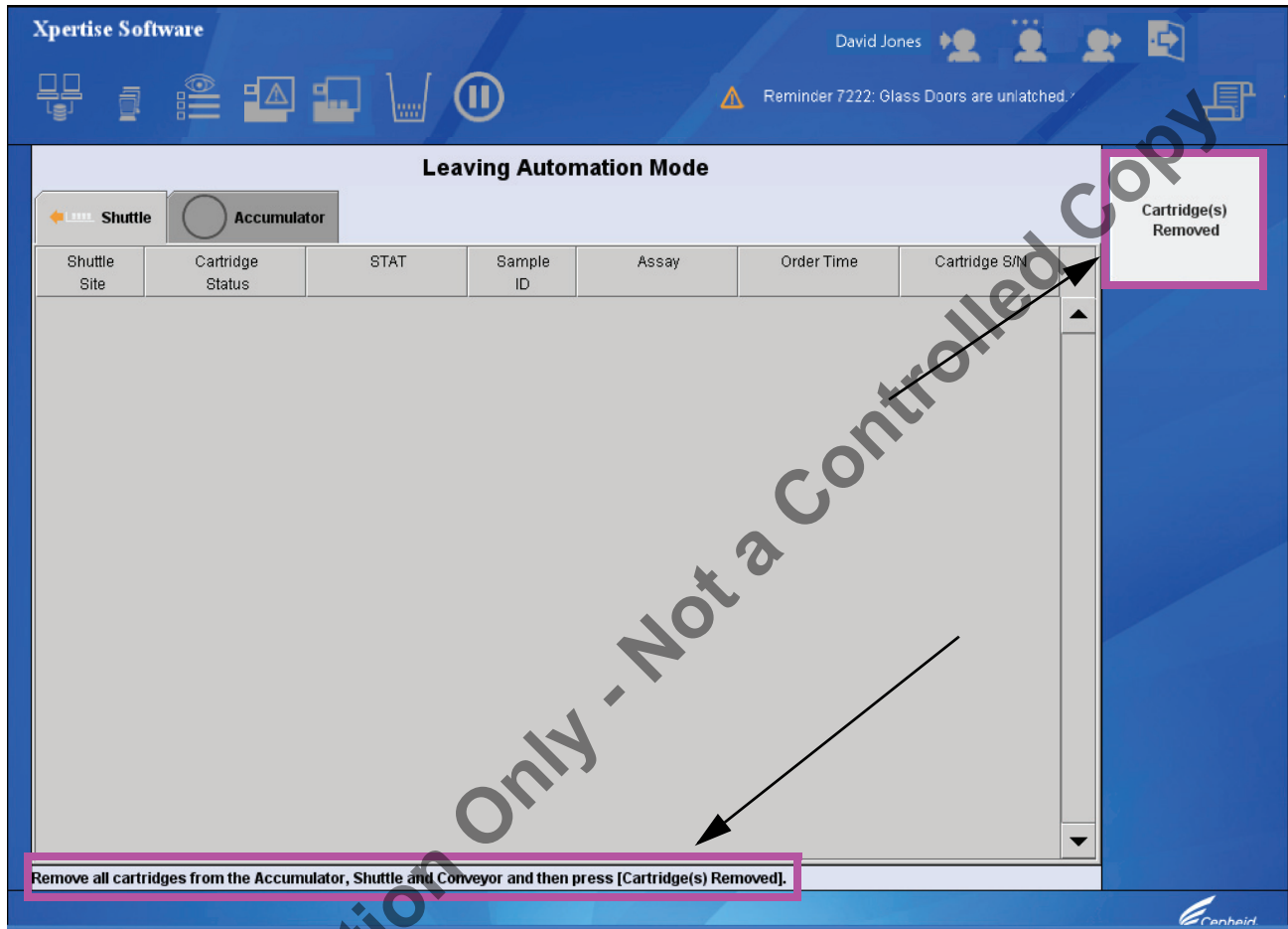


Figure 56. Leaving Automation Mode workspace

9. As stated at the bottom of the Leaving Automation Mode (Figure 56), open the glass doors, remove all cartridges from the Accumulator, Shuttle, and Conveyor and then press the **Cartridge(s) Removed** button. The Leaving Automation Mode dialog box appears (Figure 57).

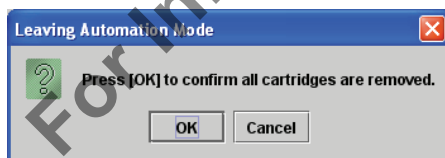


Figure 57. Leaving Automation Mode dialog box

10. Click the **OK** button (Figure 57).

The Change Operation Mode workspace appears (Figure 58) with the Current Operation Mode changed to Basic Manual Mode, and Basic Manual Mode icon present in the dashboard panel.

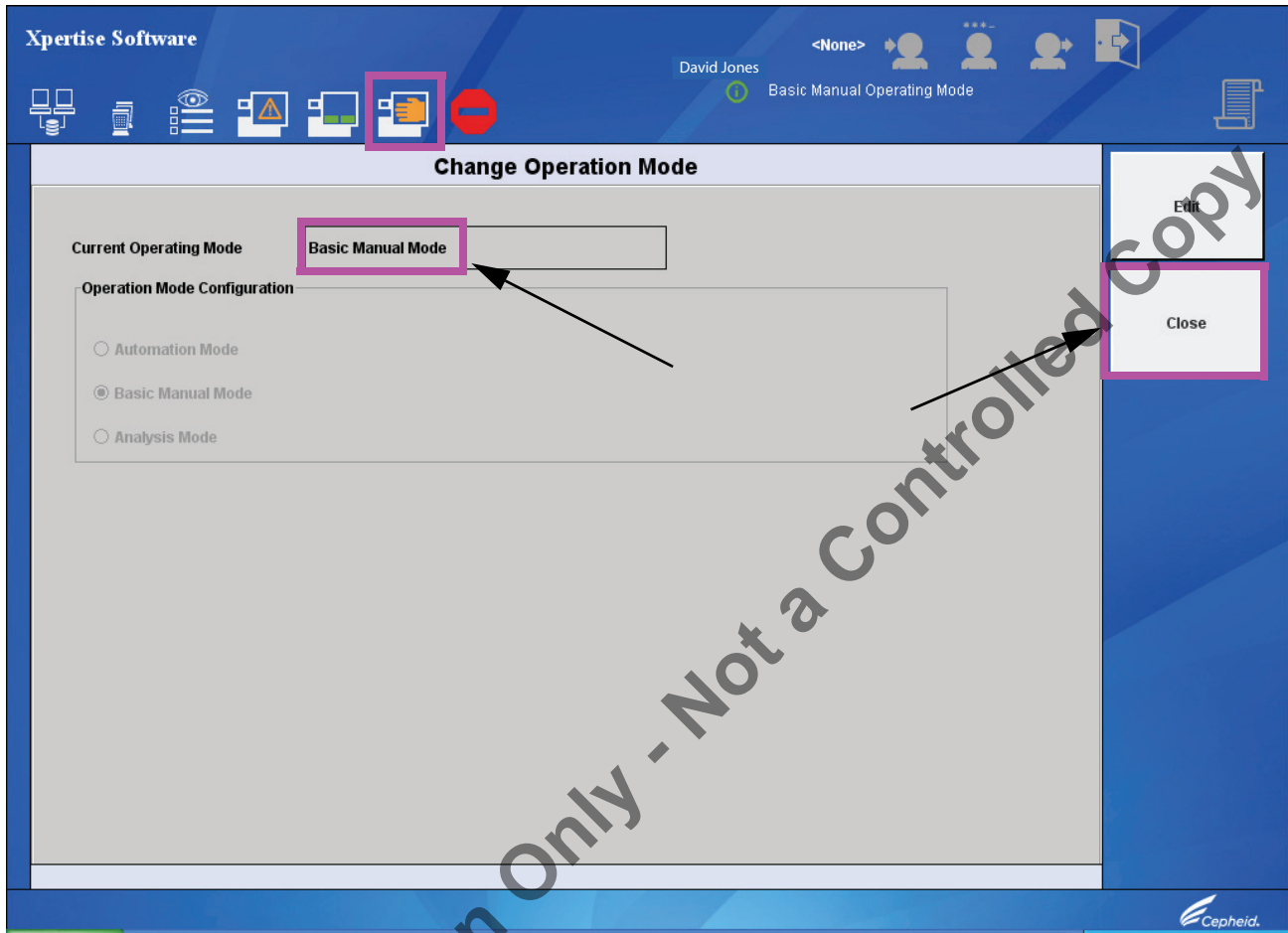


Figure 58. Change Operation Mode workspace indicating Basic Manual Mode

11. Press the **Close** button (Figure 58).

12. The Setup Menu appears (Figure 59).

The screenshot shows the Xpertise Software interface. At the top, the user is identified as David Jones, and the system is in Basic Manual Operating Mode. A navigation bar contains several icons, with the Manual Operation Mode icon (a hand holding a tool) highlighted with a red box. Below this is a Message Log table with columns for Type, Time, Subsystem, and Message. The log shows various system events, including self-tests for modules A1 through A4, waste container availability, emergency stop de-activation, air pressure status, glass door latching/unlatching, and the transition to Basic Manual Operating Mode. A sidebar on the right contains navigation buttons for User Administration, User Type Configuration, System Configuration, Manage Assays, Installation Qualification, Change Operation Mode, and a Back button. At the bottom of the message log, there are buttons for Preview PDF and Clear.

Type	Time	Subsystem	Message
i	09/23/10 07:54:59	System	Version 4.0a.22inf Demo
i	09/23/10 07:55:17	System	Module A1: Performing Self-Test
i	09/23/10 07:55:17	System	Module A2: Performing Self-Test
i	09/23/10 07:55:18	System	Module A3: Performing Self-Test
i	09/23/10 07:55:18	System	Module A4: Performing Self-Test
i	09/23/10 07:55:25	Waste Container	Waste Container available.
!	09/23/10 07:55:25	Emergency Stop	Reminder 7202: Emergency Stop de-activated.
i	09/23/10 07:55:28	Air Pressure	Air Compressor OK.
!	09/23/10 07:55:28	Glass Doors	Reminder 7223: Glass Doors are closed.
!	09/23/10 07:55:28	Glass Doors	Reminder 7221: Glass Doors are latched.
i	09/23/10 07:55:36	System	Full Automation Operating Mode
i	09/23/10 07:55:36	System	Welcome to GeneXpert Infinity System
!	09/23/10 07:56:08	Air Pressure	Error 6241: Air pressure below threshold.
!	09/23/10 07:56:08	Glass Doors	Reminder 7222: Glass Doors are unlatched.
i	09/23/10 07:56:37	System	Basic Manual Operating Mode

Figure 59. Setup menu showing Manual Operation Mode icon in dashboard

Important: After the system is changed to Manual Mode, ensure all available GX module doors are open and that all cartridges have been removed. Keep the module doors and glass doors open.

13. At this point, ensure the glass doors are open, and exit the Infinity software.
14. Go to Data Collection Procedure - Dx and Infinity on page 7 of this document.

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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

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Table of Symbols

Symbol	Meaning
	Catalog number
	Batch code
	Do not reuse
	Caution
	Consult instructions for use
	Manufacturer
	Contains sufficient for <n> tests
	Expiration date
	Control
	Temperature limitation
	Biological risks



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