



How to Apply the Cepheid® Xpert Check Code

Cepheid Self Help Article

Title: How to Apply the Cepheid® Xpert Check® Code

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Introduction: The Xpert Check® process consists of two phases. The first phase is the execution of module testing using the cartridges contained within the Xpert Check kit. The second phase consists of a Cepheid Quality Assurance (QA) 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.

For instruments that are internet-connected, the second phase is done automatically, and no user intervention is required. For instruments that are not internet-connected (or did not have internet connectivity at completion of phase one due to a down network, etc.), the user is required to send the Xpert Check data files to Cepheid. Once the QA Review is complete, Cepheid will send the user the code.

The solution below provides instructions on how to apply the Xpert Check code after receiving it from Cepheid.

Solution:

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 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 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.

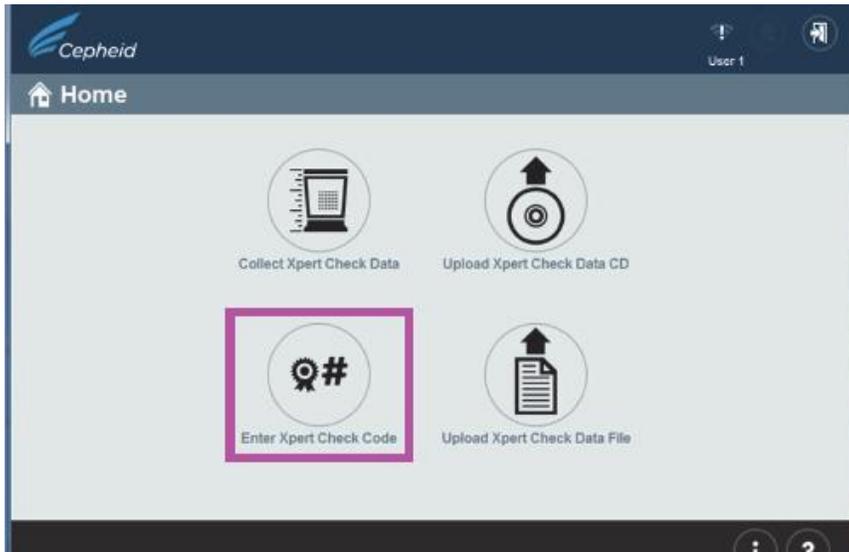
1. Exit the GeneXpert® GXDx or Xpertise software.
2. To finish the Xpert Check process, place the Xpert Check software CD in the DVD drive of the computer connected to the GeneXpert Dx instrument or in the kiosk computer for the Infinity.
3. Click on My Computer, then double-click on the applicable drive letter for your DVD drive. The files located on the CD will then be displayed. Find and double-click the XpertCheck.exe application/shortcut to launch the software.
4. Log in with your GeneXpert Dx or Infinity designated **USER NAME** and **PASSWORD**. After entering your login information, 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 or Xpertise

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software. If an Authorized Service Provider (ASP) or Field Service Engineer (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. Click on the Enter Xpert Check Code button. The Enter Xpert Check code screen will appear.



6. Enter your Xpert Check code as described below. In this step, there are various ways to enter the Xpert Check code. Your four options are listed below, beginning with the simplest (recommended) method.
 - A. **Option 1:** Use your scanner to input the barcode as follows: First, click on the icon located in the bottom center of the screen. The Xpert Check Code File (Figure 1) 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 1 for an example of an Xpert Check Code File.
 - B. **Option 2:** Print a copy of the Xpert Check 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 1 for an example of a Xpert Check Code File.
 - C. **Option 3:** Copy and paste the code string into the Enter code screen from the screen's display. The code string is visible on Figure 1.
 - D. **Option 4:** Type in the code string manually using the information on your screen or printed page. When you have successfully entered the code, click the forward arrow at the bottom of the screen to continue.

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

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Xpert Check Code File

Here is the Xpert Check code for the recent data collection of your modules for the system identified below.

Xpert Check data collection performed on 30 October 2018 15:02:31 PST

GX Instrument Name:	My GeneXpert
Cepheid System ID:	123456
Software Version:	Xh1.4
Data Collected By:	admin1
Institution Name:	Institution1
Laboratory Name:	Lab1
Street Address:	100 Main Street, Suite 202
City:	New York
State/Province:	NY
Postal Code:	10001
Country:	USA
Email:	user@institution.com
Facility Phone Number:	408 400-0000
Extension:	
Mobile:	
ASP Code:	US01

Scan or enter the Xpert Check code to complete the Xpert Check process.



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.

GeneXpert® Xpert Check Version: Xh1.4

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FIGURE 1 – Xpert Check Code File - Example

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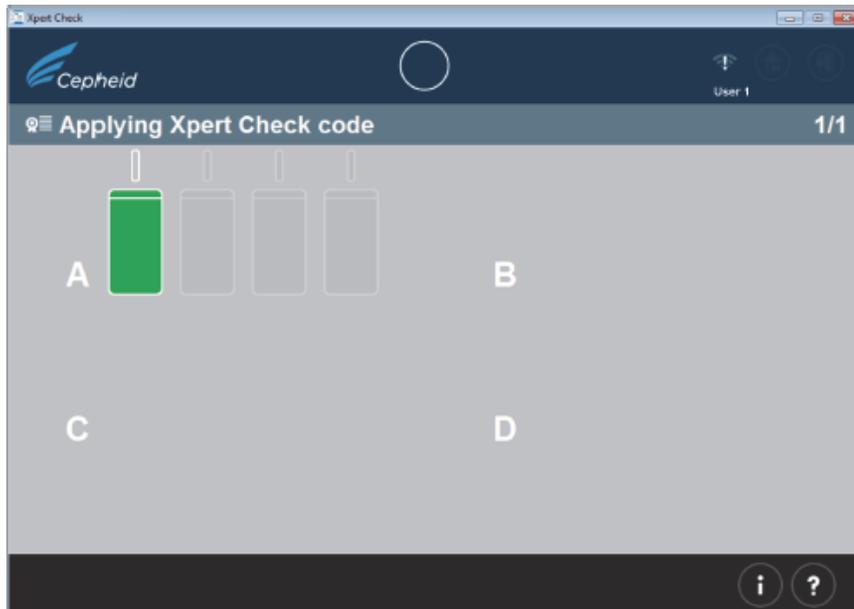


FIGURE 2 – Applying the Xpert Check code Screen Example

- 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 3.

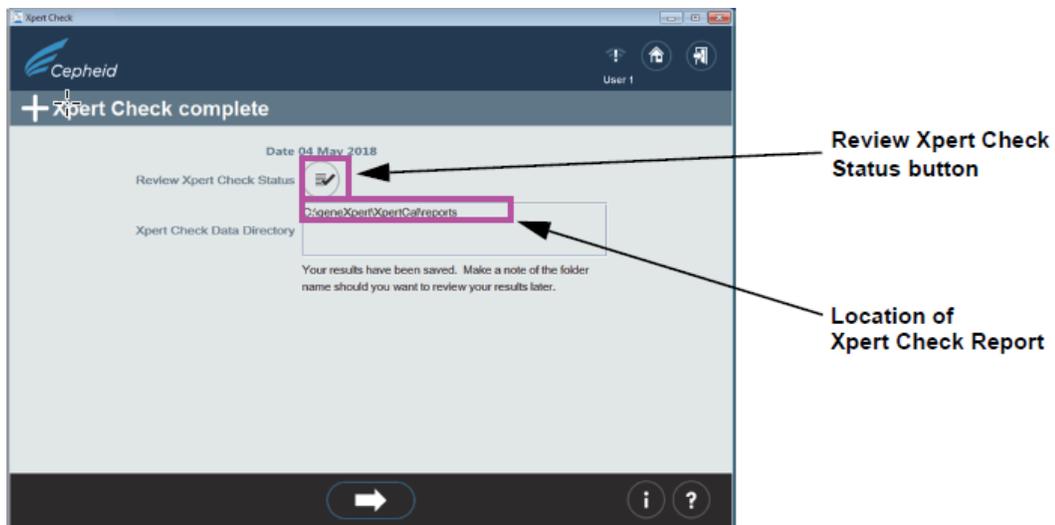


FIGURE 3 – Xpert Check complete Screen

- F. Click the Review Xpert Check Status button (see Figure 3).
- G. The Xpert Check status screen will appear. See Figure 4. In the Xpert Check status screen, the successfully checked modules are indicated by a + symbol on a green module.

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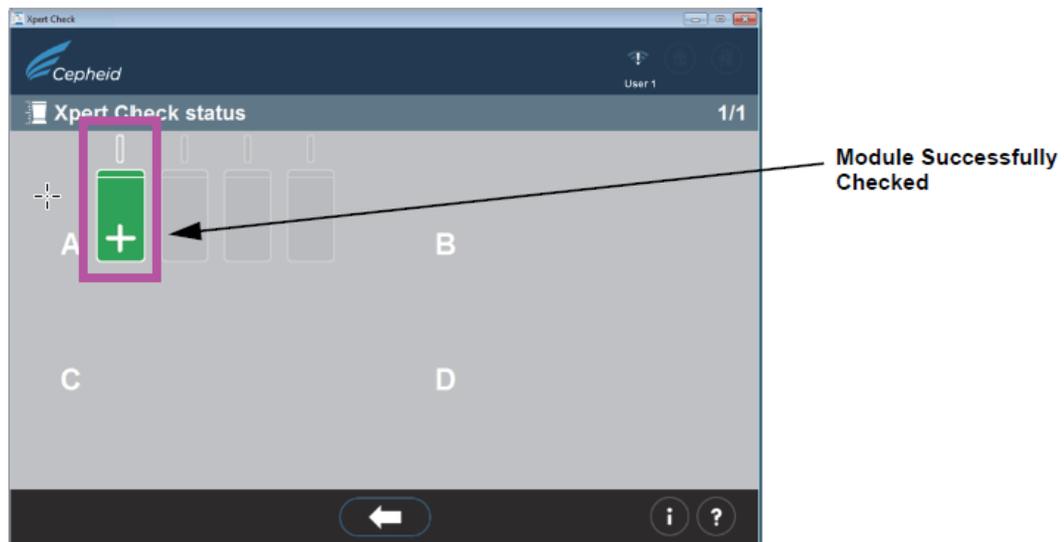


FIGURE 4 – Xpert Check status Screen

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 5 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 5. 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.

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Xpert Check Summary Report

Please Note:

Xpert Check data collection performed on 30 October 2018 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.

GX Instrument Name:	My 6Color
Cepheid System ID:	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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9. Return the system to normal operation.

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

A. **GeneXpert Dx**

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

- i. Restart your GeneXpert system and computer.
- ii. The system will be ready for full operation.

B. **Infinity-48S or Infinity-80**

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

- i. Restart the Xpertise software.
- ii. The system will be in Automation mode, ready for full operation.