GeneXpert®
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GeneXpert Dx 6.5 Installation Instructions

Cepheid®

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1 GeneXpert Dx v6.5 Upgrade and Installation Instructions

This document provides installation instructions and other information for GeneXpert Dx v6.5 software.

Note	This software installation instruction document assumes Microsoft Windows® 7 or Microsoft Windows® 10 has been installed and is properly configured on your system.
Important	**Use this document for new installations of GeneXpert Dx v6.5 Software or for upgrades to existing GeneXpert Dx software (v4.x and later) on Windows 7 and Windows 10 computers.**
Note	If upgrading from GeneXpert Dx software v2.1, contact Cepheid Technical Support for instructions. See Section 2.2, Technical Assistance for contact information.

The information in this document applies only to GeneXpert Dx software installation. Other than the topics described in this document, all other information for setting up, using and maintaining the GeneXpert Dx System is available in the *GeneXpert Dx Operator Manual*.

1.1 Before You Upgrade or Install the Software

The complete installation time will vary depending on whether or not you have GeneXpert Dx software installed on your computer. Software should be installed when there is a 1–2 hour time period when the system is not needed for testing and when there are no tests in process.

The software may require the support and verification from your lab LIS administrator. It is recommended to have these internal resources considered/allocated before beginning the installation process.

GeneXpert Dx 6.5 software must be installed by a system administrator. For more information on system administration, see Section 2.5 in the *GeneXpert Dx Operator Manual*.

Note	Some antivirus programs may block or interfere with installation of the GeneXpert Dx software. If installation is not successful, it may be necessary to temporarily disable any antivirus program on the PC in accordance with your institution's security policies and retry the GeneXpert Dx software installation.
Important	**The C360 Sync client can interfere with the installation of the GeneXpert Dx software. If C360 Sync or database processes are active, they must be stopped and shut down before starting the software installation.**

Verify Computer Minimum Requirements

- GeneXpert system computer supplied by Cepheid
- Operating System specifications:

Operating System	Minimum RAM	Minimum Available Disk Space
Windows® 7	4 GB	15 GB
Windows® 10	4 GB	15 GB

1.2 Turning On The Computer and Logging On

Use the following procedure to turn the computer on and log onto the computer.

1. Turn on the GeneXpert Dx System computer.

2. Wait for the system to boot.

   - On Windows 7, the Windows Account screen appears. See Figure 1.

   - On Windows 10, the Windows Lock screen appears. See Figure 2. Click anywhere on the screen to display the Windows Account and Password screen. See Figure 4.
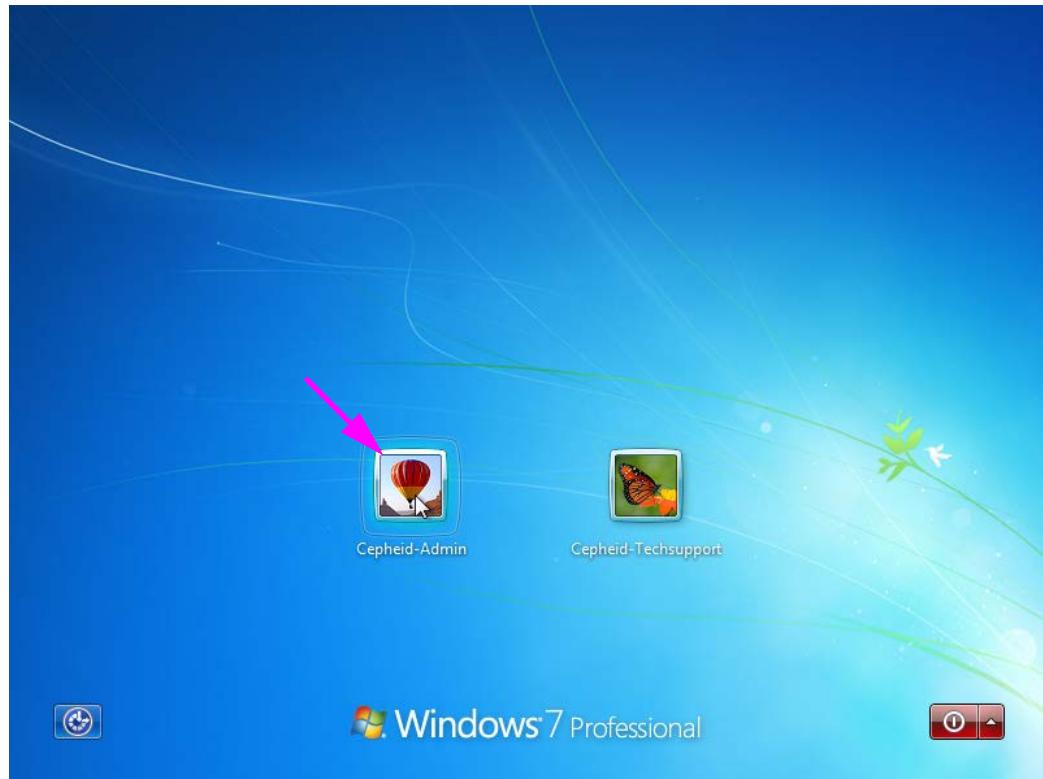
Figure 1. Windows 7 Account Screen
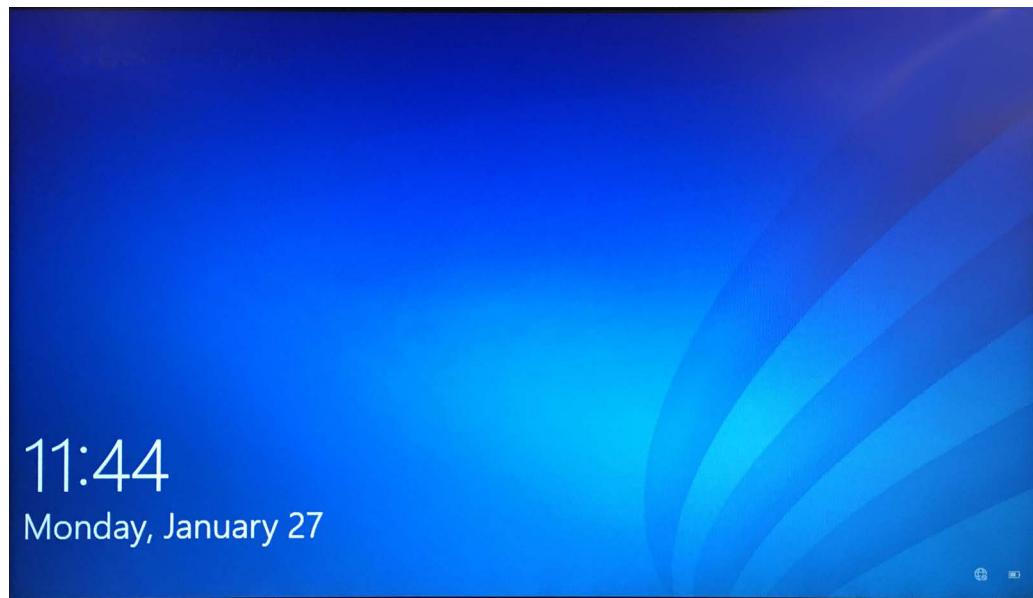
Figure 2. Windows 10 Lock Screen

3.   On the Windows Account screen, select the **Cepheid-Admin** user account (see Figure 1 and Figure 4).

   •   On Windows 7, The Windows Password screen appears. See Figure 3.

   •   On Windows 10, the Cepheid user account password field appears. See Figure 4.

The GeneXpert Dx System computer is configured with two Windows accounts. The **Cepheid-Admin** account is for administrator tasks such as software updates and system configuration; and the **Cepheid-Techsupport** account is for use only by Cepheid Technical Support. See Figure 1 and Figure 4.

Caution

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You must be logged on using the preconfigured Cepheid-Admin account. If you log on using a different user name and profile, the power management settings will be incorrect.

Figure 3. Windows 7 Password Screen
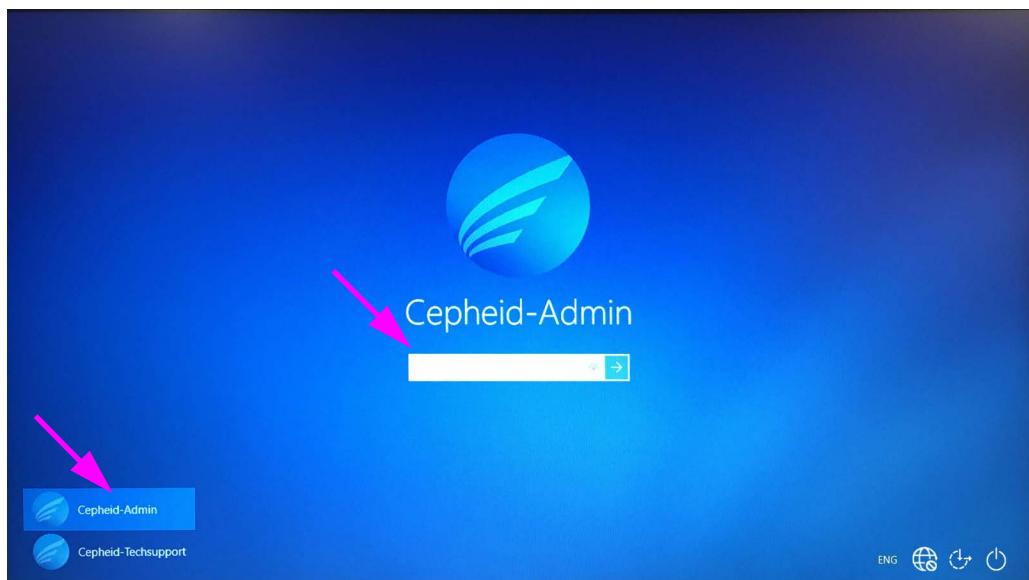
Figure 4. Windows 10 Account and Password Screen

4.   On the Windows Password screen (see Figure 3 and Figure 4), enter the system administrator password previously assigned.

5.   When GeneXpert Dx software starts, enter your password. The Database Management dialog box will be displayed, inquiring about backing up the database. Select **YES** to perform database management tasks. Perform a complete backup of the database.

For complete instructions about backing up the database, see Chapter 5 in the *GeneXpert Dx System Operator Manual*.
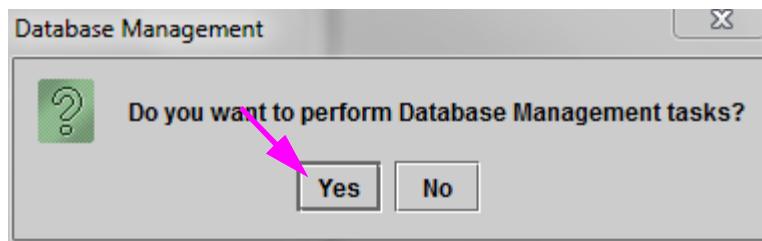
Figure 5. Backup Database Dialog Box

6. After the database has been backed up, exit the GeneXpert Dx software.

7. Quit any other applications that may be running on the computer.

8. Turn off all GeneXpert Dx instruments connected to the computer.

1.3   Connecting and Using the DVD Drive

The DVD drive can be either an external drive which must be connected to the system using a USB port, or an internal drive, already installed in the system.

1.3.1   Connecting an External DVD Drive to the GX Dx System

Connect the supplied external DVD drive to the GX Dx system as follows:

1. Locate the DVD drive. The DVD drive is shipped in the accessories box and is labeled as an item to save.Locate the DVD drive. The DVD drive is shipped in the accessories box and is labeled as an item to save (see Figure 6).

Figure 6. Provided DVD Drive, shown with Loading Door Open

2. Plug the DVD drive into one of the available USB ports on the system.

3. Press the **Eject** button on the front of the DVD drive to open the door.

4. Proceed with the installation of GeneXpert Dx 6.5 software. See Section 1.4.

1.3.2 Using the Internal DVD Drive in the GX Dx System

If a DVD drive is installed in the system, use the following procedure to access the drive.

1. Locate the DVD drive. The drive is installed on the GeneXpert Dx System computer but the location of the drive will vary:

   • On a desktop computer, the drive will be accessed from the front of the computer, and

   • on a laptop, the drive will be on the side of the laptop.

2. Press the **Eject** button on the front of the DVD drive to open the door.

3. Proceed with the installation of GeneXpert Dx 6.5 software. See Section 1.4.

1.4 Upgrade and Install Notes (Getting Started)

Note	The upgrade/update and installation instructions for v6.5 can vary, depending on whether or not you have GeneXpert Dx software installed on your computer.

If you Do Not Have GeneXpert Dx Software on the Computer:

Follow the instructions in Section 1.7, GeneXpert Dx 6.5 New Software Installation to install GeneXpert Dx Software v6.5.

If you Have GeneXpert Dx Software on the Computer:

Note	If GeneXpert Dx software is installed, instructions for installation can vary depending on the version of software installed on your computer, as described in this section. If you have GeneXpert Dx software installed on your system, the update to v6.5 may require 1-2 hours, depending upon the size of your GeneXpert Dx system's database.

Table 1. How to Update to v6.5 from Previous Software Versions

Existing Software Version	Instructions for Updating
v2.1 and below	Contact Cepheid Technical Support if you are upgrading your GeneXpert software as v6.5 does not support this direct upgrade path.See Section 2.2, Technical Assistance for contact information.
v6.x	Follow the instructions in Section 1.7.

Note	After you upgrade to v6.5, your older version of GeneXpert Dx Software will no longer be available. In addition, the GeneXpert Dx desktop shortcut to the older version will be updated to access the new v6.5 GeneXpert Dx Software. If the shortcut for the older version was renamed, a new shortcut will be installed and it is recommended that you delete the old shortcut.

1.5 Verifying if C360 Sync is Running

If C360 Sync is installed and running, it must be temporarily stopped before installing or upgrading GeneXpert software, to prevent a software installation failure. Follow the steps in this section to verify if you are running C360 Sync.

1. Examine the Windows desktop and look for the icon shown in Figure 7.

Figure 7. C360 Sync Icon

2. If you find the C360 Sync icon, it indicates that C360 Sync is running on your system and it must be stopped before you can install or upgrade GeneXpert software. Proceed with Section 1.6 to stop C360 Sync.

3. If you do not find the C360 Sync icon, it indicates that C360 Sync is not running on your system. Skip to Section 1.7 or Section 1.8 to install or upgrade your GeneXpert software,

1.6   Stopping C360 Sync

1.   From the Windows desktop, touch the **Search** icon, located near the bottom left corner of the screen (see Figure 8).
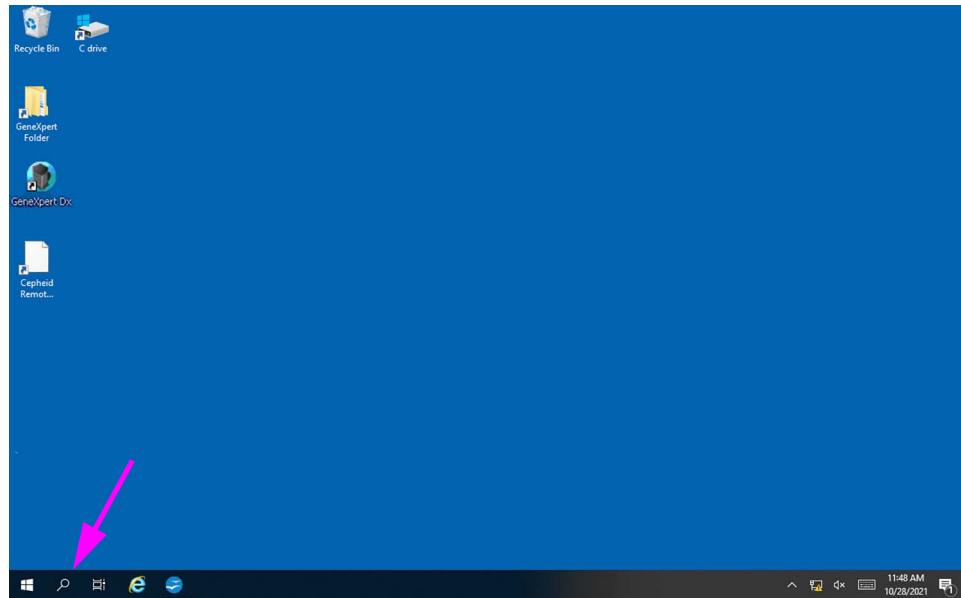
Figure 8. GeneXpert Desktop, showing the Search Icon

2.   When the Search screen appears, type **Services** in the search field at the bottom of the screen. The Services Search screen appears (see Figure 9).

3.   On the Services Search screen, click the right arrow on the Services Desktop app entry (see Figure 9).
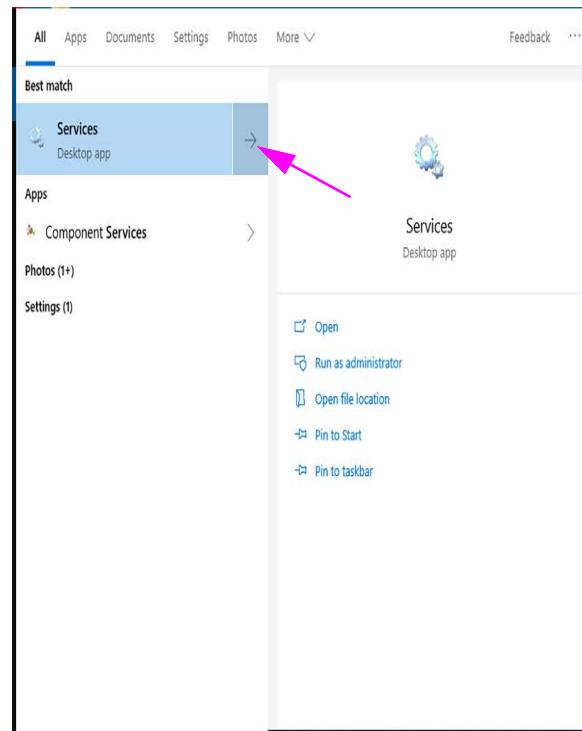
Figure 9. Services Search Screen

The Services (Local) screen appears (see Figure 10).

4.   On the Services (Local) screen, click the **Cepheid Reporter Daemon** entry, as shown in Figure 10.

Figure 10. Services (Local) Screen, showing Cepheid Reporter Daemon Selected

A drop-down menu appears (see Figure 11).

5.   Click **Stop** on this menu to halt C360 Sync (see Figure 11).
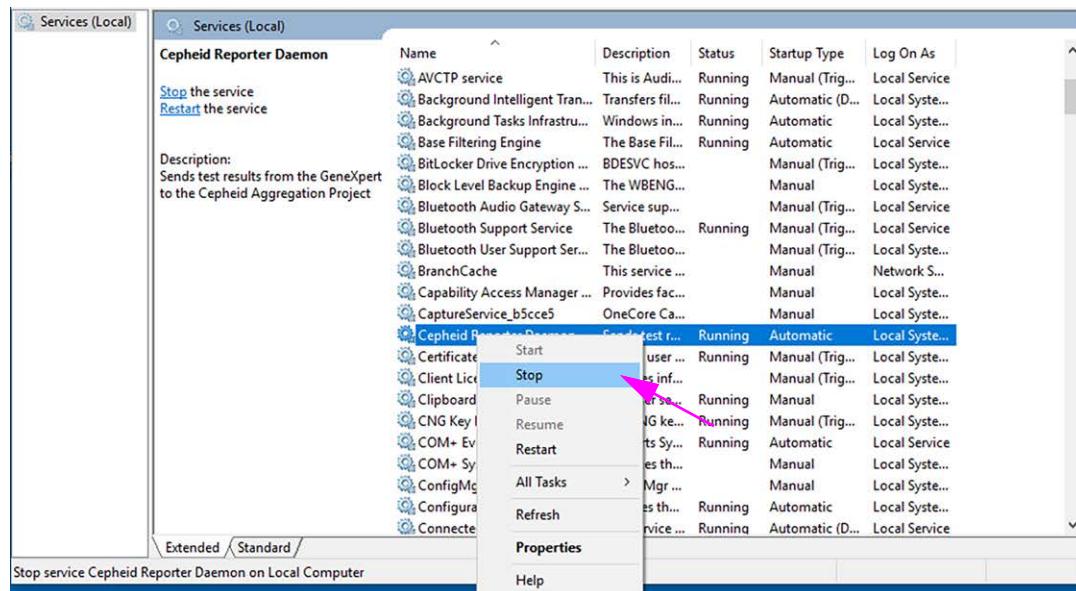
Figure 11. Services (Local) Screen, showing the Drop-down Menu

6. With C360 Sync stopped, proceed to Section 1.7 or Section 1.8 and continue with the software upgrade or installation.

1.7 GeneXpert Dx 6.5 New Software Installation

Important   **GeneXpert Software v6.0 and greater cannot be installed on Windows XP. If you are running GeneXpert Dx on a Windows XP computer, contact Cepheid Technical Support.**

This section provides instructions for new installations. To install the software:

1. Turn the computer on and log onto Windows as described in Section 1.2, (Step 1 through Step 4).

2. Insert the GeneXpert Dx 6.5 installation CD into the DVD drive.

    •   The CD is Auto Run-enabled and the setup application should start automatically. If it does not start automatically, click **Computer** to navigate to the DVD drive and double-click the **Setup** icon.

    •   An Auto Play dialog box may appear asking to run **setup.exe**. Click **Yes**.

    •   A User Account Control (UAC) message may also appear asking to allow **setup.exe** to make changes to this computer. Click **Yes**.

    •   If the Uninstall Adobe products message appears, click **Yes** to uninstall Adobe products that are incompatible with GeneXpert software.

3. When the Welcome window appears, read the instructions (see Figure 12), and then click **Next**. The Software License Agreement window appears (see Figure 13).

4. Read the license agreement, click **I accept the terms of the license agreement**, and then click **Next**. The Installation Type and Additional Functions window appears (see Figure 14).

5. Click **Typical** to install the typical set of software files on the computer.

Note	A typical installation will include SQL Express, MSXML, GeneXpert files, and Adobe Reader depending on what programs were already installed on the computer (i.e., the installer will recognize and skip any items that already exist on the computer).

6. When the installation is finished, the release notes will automatically open in Adobe Reader. Review or print the release notes and then close the window (see Figure 20).

Note	If prompted, accept the Adobe Reader license agreement.

7. The Installation Complete window appears and asks you to restart the computer (see Figure 21).

8. On the Installation Complete screen, select the radio button to the left of **Yes, I want to restart my computer now** and click the **Finish** button (see Figure 21). The Installation Complete window will close and the computer will restart.

This completes the installation of the GeneXpert Dx software. Remove the CD from the DVD drive. Keep the GeneXpert Dx 6.5 installation CD in a safe location. You may need the CD during System Recovery. Continue with Section 1.10 After the Installation.

1.8 Software Version 4.x, 5.x or 6.x Update Instructions

This section explains how to update from previous versions of GeneXpert Dx Software.

The GeneXpert Dx v6.5 installer will guide you through the process of installing the v6.5 update. During this process, your existing database will be updated to v6.5.

Before performing this update, please perform the following steps:

• Navigate to **Setup**>**System Configuration**.

• Take screenshots of all four tabs – **General**, **Archive Settings**, **Folders**, and **Host Communication Settings**.

• In the **Host Communication Settings** tab, click on the **Edit** button for each enabled assay listed in the Host Test Code section, and take a screenshot of the Assay Host Test Code and all Result Test Codes.

• Perform an archive and purge from the Data Management menu.

• Perform a database backup by following the instructions in the *GeneXpert Dx System Operator's Manual*.

• Please confirm that Cepheid Sync is not running in the system tray.

Note	If you are running C360 Sync on your system, before restoring the GeneXpert database or updating the GeneXpert database to the next version, verify that the Cepheid Reporter Daemon has stopped. See the Restoring a GeneXpert Database under the Tests tab in the *C360 Sync Quick Reference Guide* for detailed instructions about how to stop the Cepheid Reporter Daemon.
Important	**GeneXpert Software v6.0 cannot be installed on Windows XP. If you are running GeneXpert Dx on a Windows XP computer, contact Cepheid Technical Support.**

To update the software:

1. Turn the computer on and log on to Windows as described in Section 1.2, (Step 1 through Step 4).

2. Insert the GeneXpert Dx 6.5 installation CD into the DVD drive.

    • The CD is Auto Run-enabled and the setup application should start automatically. If it does not start automatically, click **Computer** to navigate to the DVD drive and double-click the **Setup** icon.

    • An Auto Play dialog box may appear asking to run **setup.exe**. Click **Yes**.

    • An antivirus software message may also appear asking to allow **setup.exe** to make changes to this computer. Click **Yes**.

    • If the Uninstall Adobe products message appears, click **Yes** to uninstall Adobe products that are incompatible with GeneXpert software.

3. The Welcome window appears. (see Figure 12).
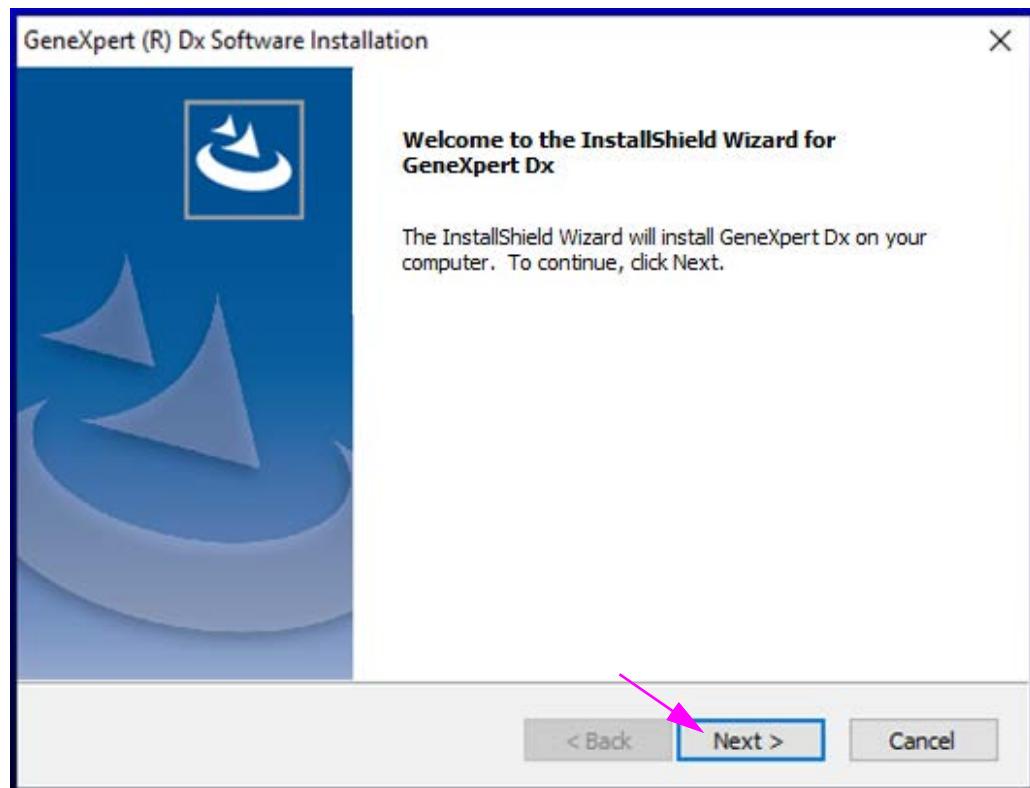
Figure 12. Welcome Window

4. Read the instructions in the Welcome window, and then click **Next**. The Software License Agreement window appears (see Figure 13).
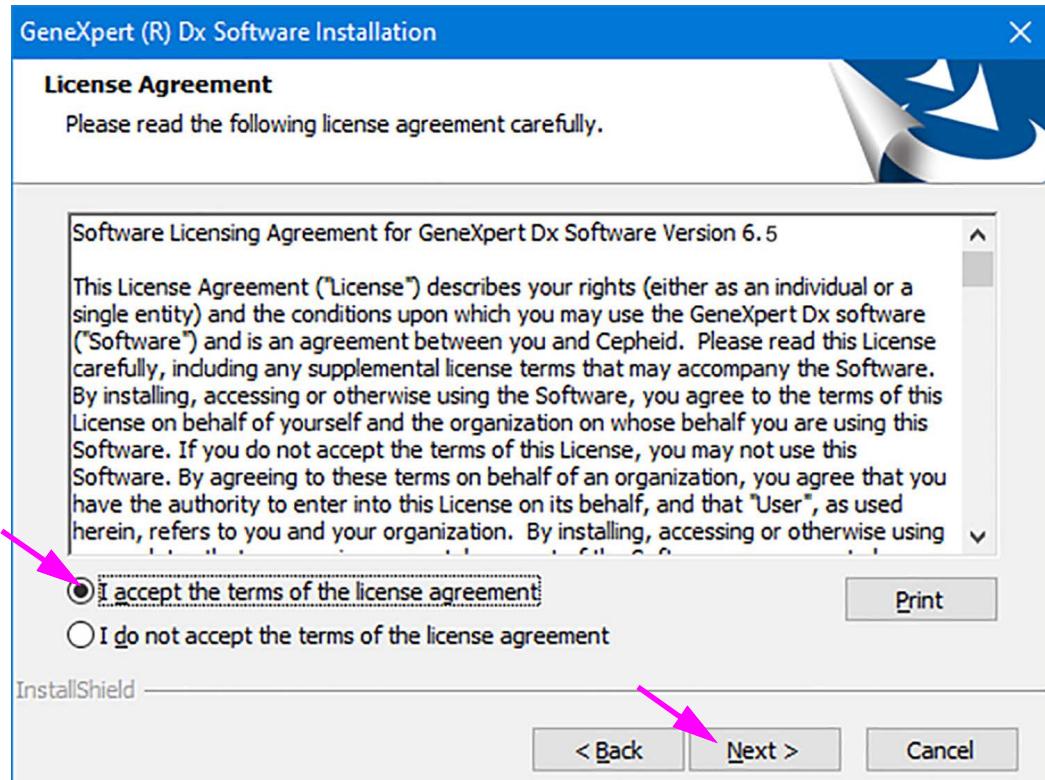
Figure 13. License Agreement

5. Read the license agreement, click **I accept the terms of the license agreement**, and then click **Next**.

6. The Installation Type and Additional Functions screen appears (see Figure 14).
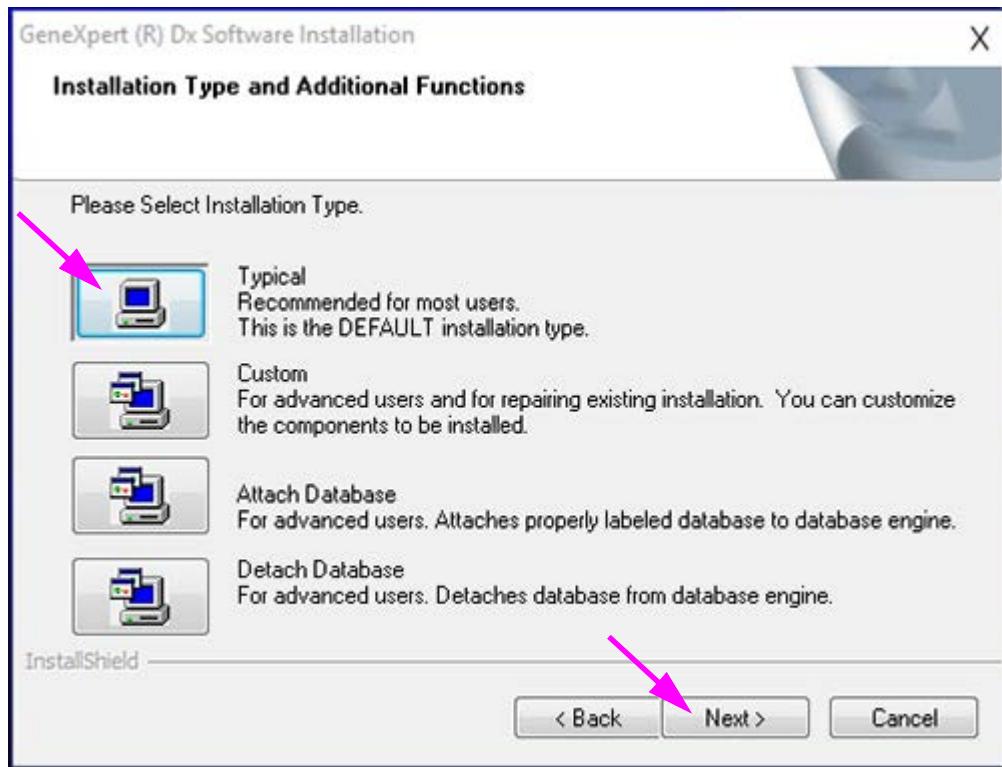
Figure 14. Installation Type and Additional Functions Screen

7.   Click **Typical** to install the typical set of software files on the computer.

Note	A typical installation will include SQL Express, MSXML, GeneXpert files, and Adobe Reader depending on what programs were already installed on the computer (i.e., the installer will recognize and skip any items that already exist on the computer).

A.   During installation, the prompt shown in Figure 15 may be displayed. Click **Yes** to uninstall incompatible software as required.
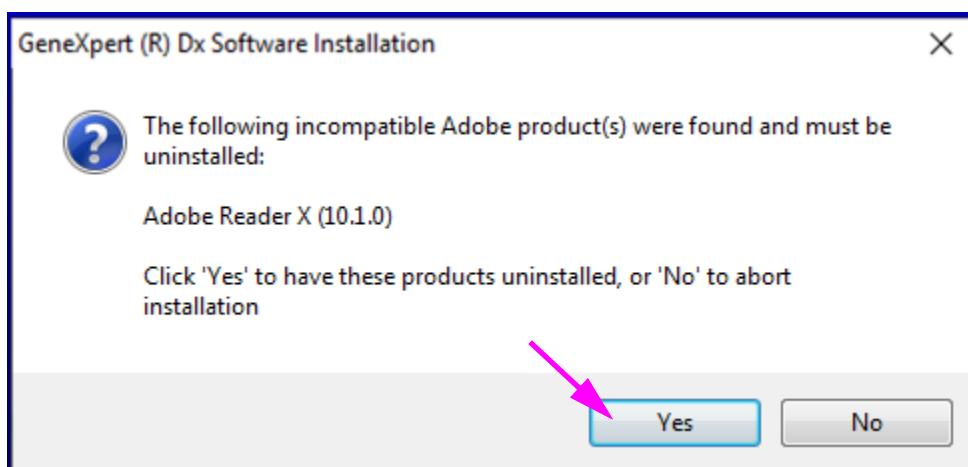
Figure 15. Incompatible Product(s) Uninstall Dialog Box

B.   If the SQL Server must be uninstalled, the prompt shown in Figure 16 will be displayed. Click **OK** to restart the computer.
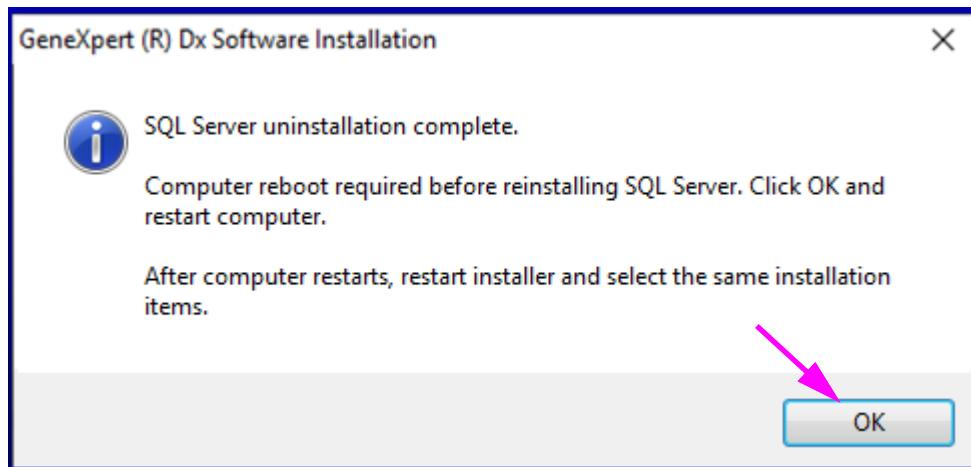
Figure 16. Restart Required Dialog Box

C.   After the computer restarts, restart the GeneXpert installer (Step 2) and select **Typical** installation (see Figure 14).

8.   A dialog box appears as shown in Figure 17. You need to uninstall the previous version of the GeneXpert Dx Software before installing the current version. Click **Yes** to this prompt and to the next confirmation prompt to uninstall the previous version of the GeneXpert Dx Software and all of its features.
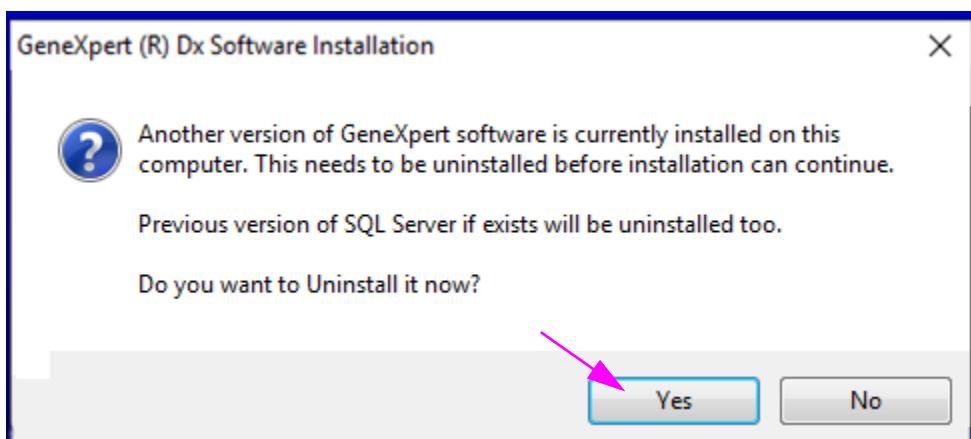
Figure 17. Uninstall Previous Version Dialog Box

9.   When the uninstall is finished, the Uninstall Complete window appears and asks you to restart the computer. See Figure 18.
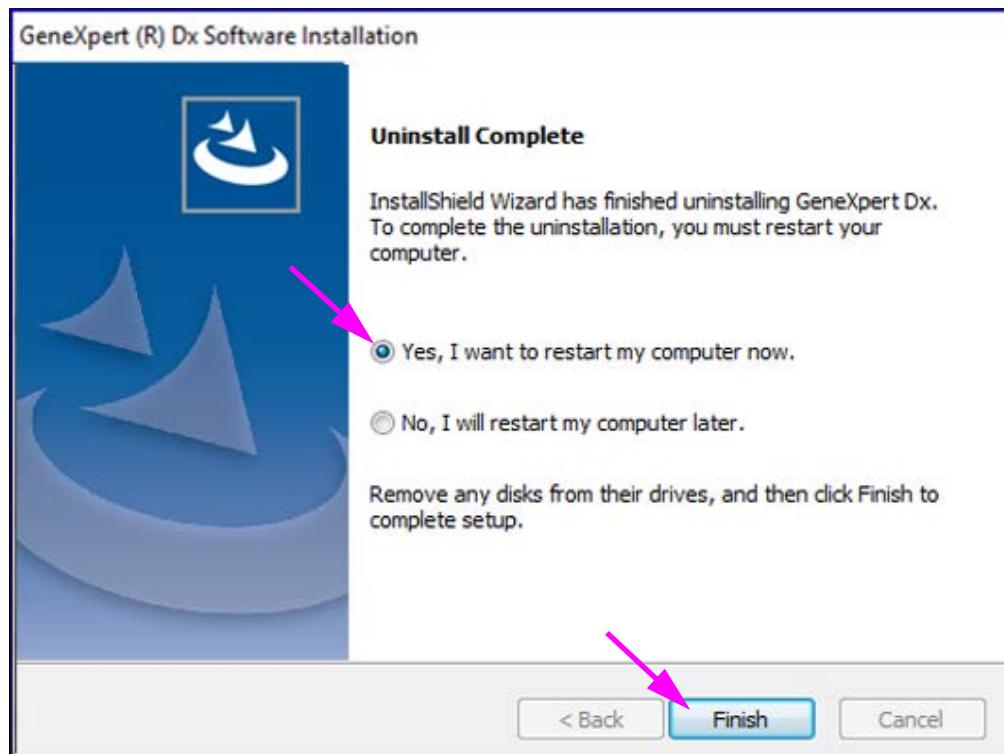
Figure 18. Uninstall Complete Window

10. On the Uninstall Complete window, select the radio button beside **Yes, I want to restart my computer now** and click the **Finish** button (see Figure 18). The Uninstall Complete window closes and the computer restarts.

11. After the computer restarts, restart the GeneXpert installer (Step 2) and select **Typical** installation (see Figure 14).

12. During the installation, several status screens appear. After opening various components, the following Setup Status window appears (see Figure 19), showing the installation progress.
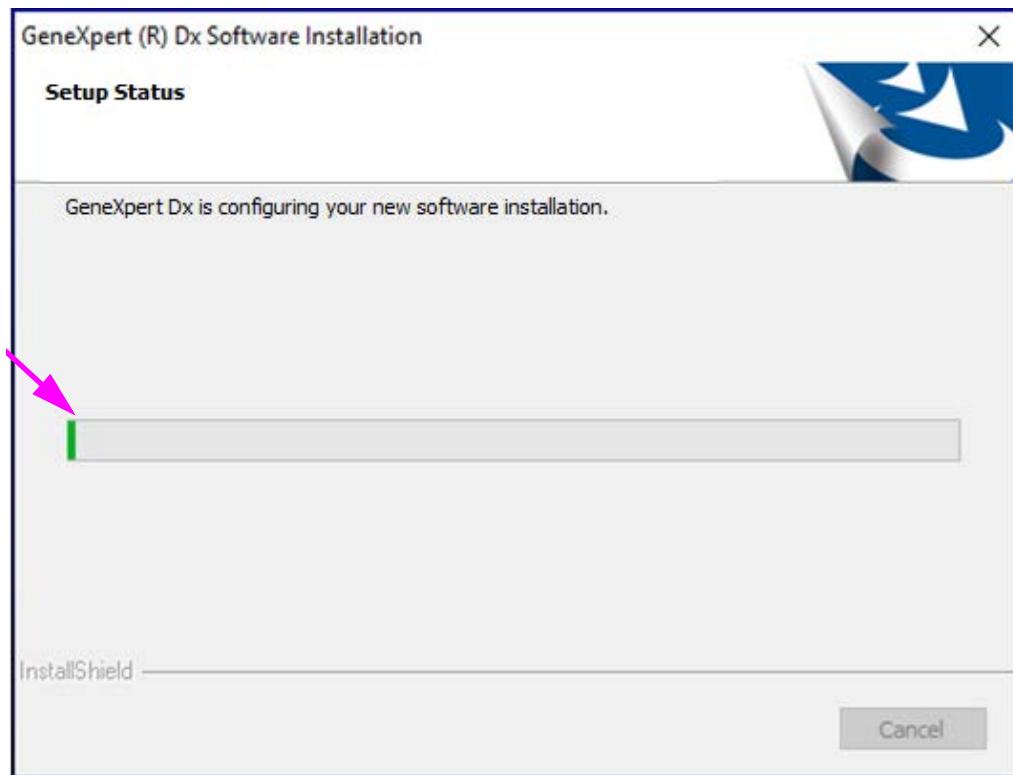
Figure 19. Setup Status Window

13. When the installation is finished, the Software Release Notes automatically opens in Adobe Reader. Review or print the release notes and then close the window (see Figure 20).

Note	If prompted, accept the Adobe Reader license agreement.

Note	The software release notes will be displayed in English. To view the release notes in other languages, open the appropriate language folder on the GeneXpert Operator Manual DVD and navigate to the release notes.
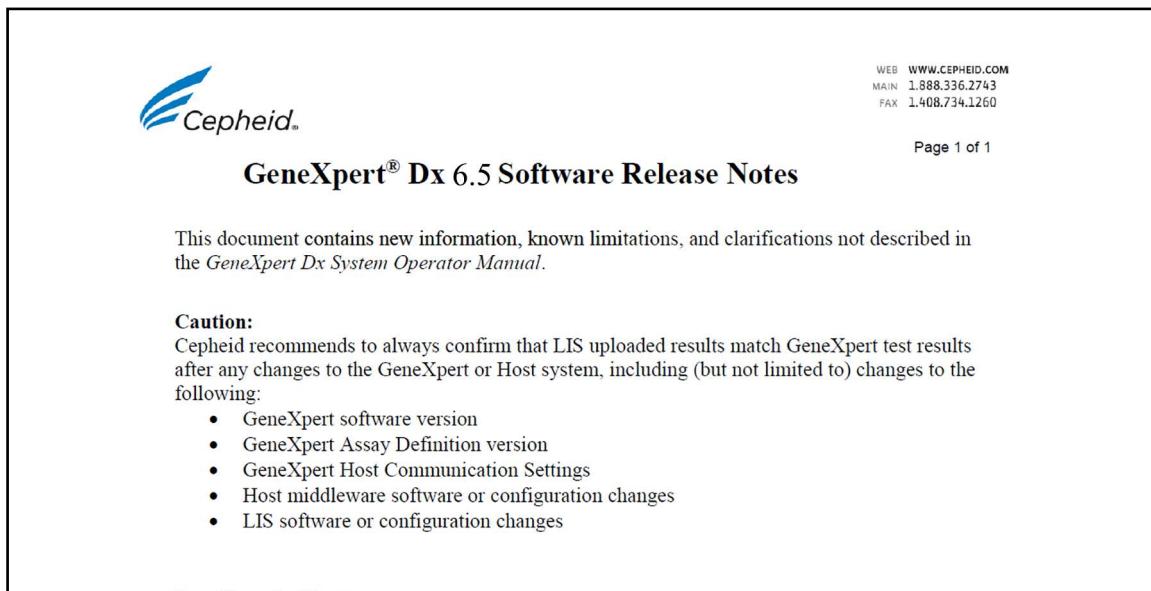
Figure 20. Release Notes Window

14. The Installation Complete screen appears and asks you to restart the computer (see Figure 21).
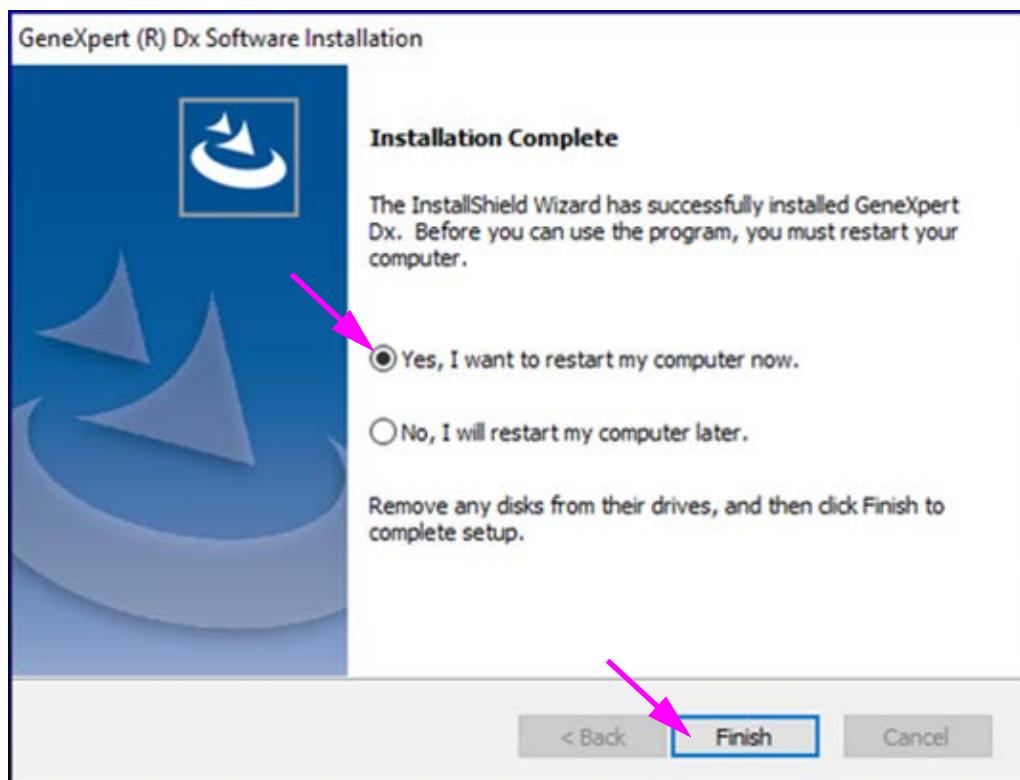
Figure 21. Installation Complete Window

15. On the Installation Complete window, select the radio button beside **Yes, I want to restart my computer now** and click the **Finish** button (see Figure 21). The Installation Complete window will close and the computer restarts.

This completes the installation of the GeneXpert Dx software. Remove the CD from the DVD drive. Keep the GeneXpert Dx v6.5 installation CD in a safe location. You may need the CD during System Recovery.

If an external DVD drive has been used and is no longer needed, disconnect it from the system and store the drive and associated cables for use in the future. (from section 2.16.2, Step 7 of Ops Manual)

You can also leave the DVD drive connected to the system, in case it is needed to reload any assay definition files (ADFs).

Note	If C360 Sync is present on your system and it was shut down prior to the GeneXpert Dx software installation, if must be restarted before launching the GeneXpert Dx software as described in Section 1.2 If C360 Sync is not installed on your system, skip to Section 1.10 to complete the software installation.

1.9 Restarting C360 Sync

After a software installation or upgrade, restart C360 Sync (if you stopped it previously) by navigating to the Services (Local) screen as described below.

1. From the GeneXpert desktop, touch the **Search** icon, located near the bottom left corner of the screen (see Figure 22).

Figure 22. GeneXpert Desktop, showing the Search Icon

2. When the Search screen appears, type **Services** in the search field at the bottom of the screen. The Services Search screen appears (see Figure 23).

3. On the Services Search screen, touch the right arrow on the Services Desktop app entry (see Figure 23).
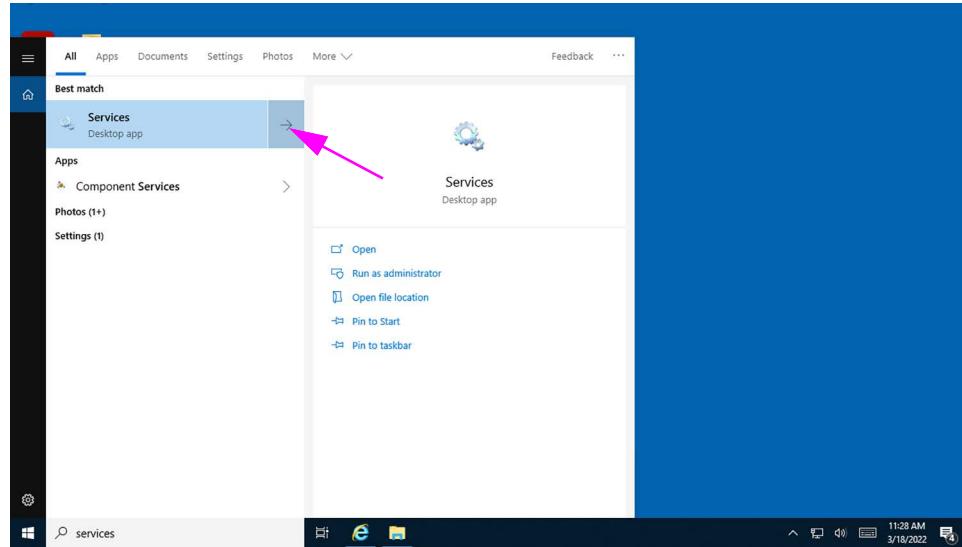
Figure 23. Services Search Screen

The Services (Local) screen appears (see Figure 24).

4. On the Services (Local) screen, touch the **Cepheid Reporter Daemon** entry (see Figure 24).
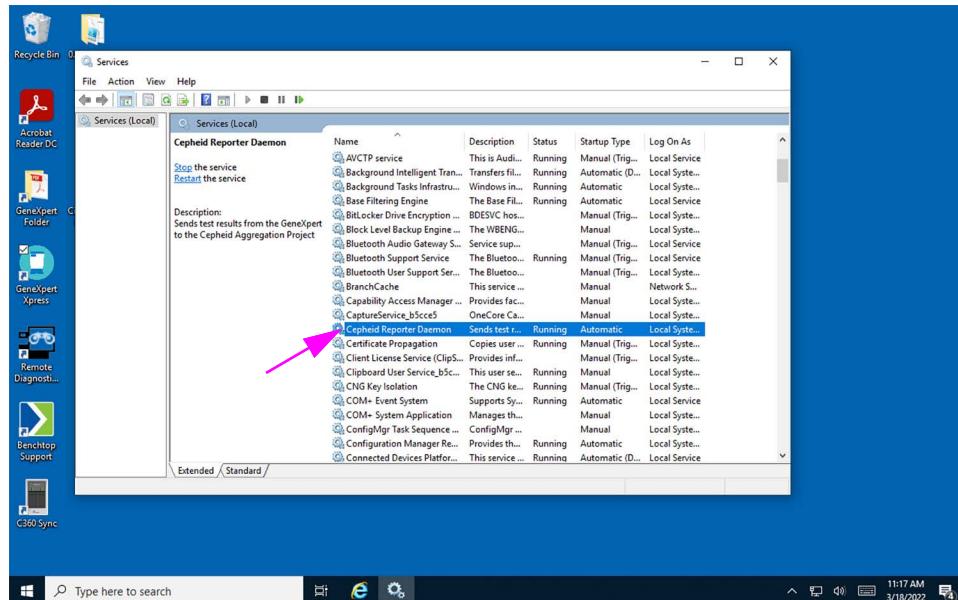
Figure 24. Services (Local) Screen, showing Cepheid Reporter Daemon Selected

A drop-down menu appears (see Figure 25).

5. Touch **Start** on this menu to launch C360 Sync (see Figure 25).
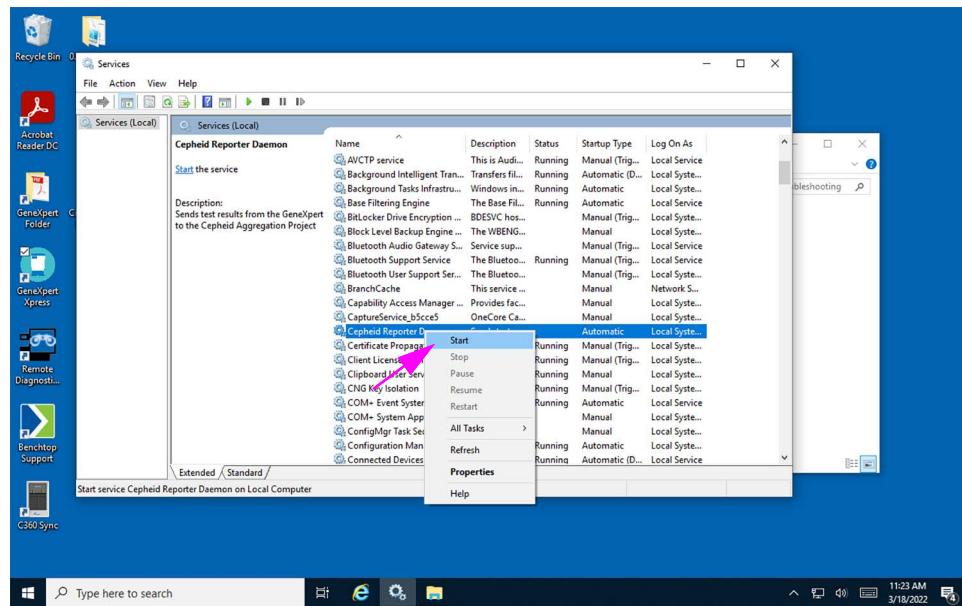
Figure 25. Services (Local) Screen, showing Start on the Drop-down Menu

1.10 After the Installation

1. Turn on the instrument.

2. Wait for the system to boot.

   • On Windows 7, the Windows Account screen appears. See Figure 1.

   • On Windows 10, the Windows Lock screen appears. See Figure 2. Click anywhere on the screen to display the Windows Account and Password screen. See Figure 4.

3. On the Windows Account screen, select the **Cepheid-Admin** user account (see Figure 1).

   • On Windows 7, the Windows Password screen appears. See Figure 3.

   • On Windows 10, the Cepheid user account password field appears. See Figure 4.

4. Enter the system administrator password previously assigned.

5. The software will start and the GeneXpert Dx Software Home screen will be displayed (see Figure 26).

| Note | If the software does not automatically start, double-click the GeneXpert Dx software icon on the desktop to start the GeneXpert Dx software application. |

When GeneXpert Dx software starts, enter your password. From the Data Management menu, retrieve the test results which you previously purged. Once the results are retrieved, exit the software. The Database Management dialog box appears, select **YES** to perform database management tasks and to compile a backup of the database.

Note	The module firmware update must be complete before the Database Management tasks can be performed. If you select YES to perform Database Management tasks while the module firmware is still booting or the firmware is being updated, you will see a message that you cannot complete the Database backup.

Caution

	Database backups made in one version of software cannot be restored to a different version of the software; therefore, perform database backups immediately after installing.

For complete instructions about backing up the database, see Chapter 5 in the *GeneXpert Dx System Operator Manual*.

Note	If you are performing a software upgrade from any previous GeneXpert Dx version, always back up the existing database using the GeneXpert Dx Software Database Management Menu.

6. To display and print the Installation Qualification report, perform the following steps: On the GeneXpert Software Home screen, click the **Reports** menu item. A drop-down menu will appear. From this menu, click the **Installation Qualification** entry (see Figure 26) to display the report.
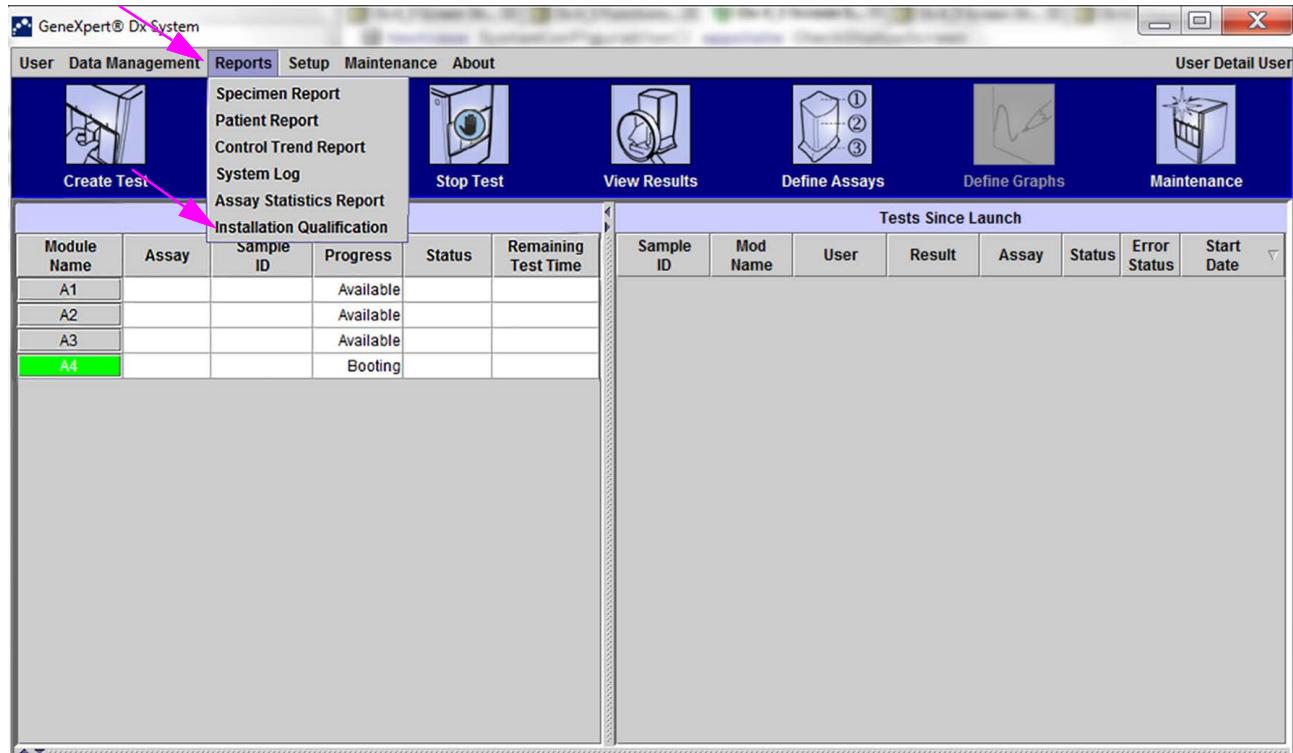
Figure 26. GeneXpert Home Screen showing the Reports Drop-Down Menu

7.   The Installation Qualification Report appears, displayed in Acrobat Reader (see Figure 27 and Figure 28). See Step 8 through Step 10 for instructions on printing and reviewing the report.

GeneXpert PC   06/20/22 13:04:15

GeneXpert® Dx System
Installation Qualification Report

This report provides documented evidence of the installation of this GeneXpert® Dx System.

System Information

Software	Version	Status
GeneXpert® Dx System	6.5	Pass
Java Runtime Environment	1.8.0_151	Pass
SQL Database	Microsoft SQL Server 14.00.3015	Pass
Database	gx_db 4.0.1.0	Pass
Operating System	Windows 10 10.0	Pass
CIT Plug-In	1	Pass

Instrument Information
Instrument A

Instrument S/N	Gateway Firmware
803488	2.0.18

Module Name	Module S/N	Module Firmware	Internal Temp °C	Status
A1	628676	3.3.3	31.6	Pass
A2	638430	3.3.3	30.8	Pass
A3	638964	3.3.3	30.0	Pass
A4	641366	3.3.3	30.7	Fail*

Fail* = Ambient temperature too high, incorrect model number or hardware error has been detected. Please generate a System Log with the list of errors for further troubleshooting.

Shaded Modules = Reporter is out of calibration.

Available Assays

Assay Name	Version	Assay Type
Xpert FII	1	In Vitro Diagnostic
Xpert FII & FV Combo	1	In Vitro Diagnostic
Xpert FV	1	In Vitro Diagnostic

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Figure 27. Installation Qualification Report—Page 1

GeneXpert PC   06/20/22 13:04:15

GeneXpert® Dx System
Installation Qualification Report

Installation of networked instruments complies with the setup requirements specified in the GeneXpert® Dx System Operator Manual, 'Installation' section.

_____   _____
Verified by   Date

This IQ is acceptable if all System Information and Instrument Information are listed as 'Pass'. All instrument modules that are listed as 'Pass' are available for use.

Acceptance: [   ] Acceptable   [   ] Not Acceptable

_____   _____
Performed by   Date

_____   _____
Reviewed and approved by   Date

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Figure 28. Installation Qualification Report—Page 2

8. Print the Installation Qualification report from Adobe Reader.

Note | The length of the report will depend upon the number of installed modules in the GeneXpert system and the number of assays installed on the system. See Figure 27 and Figure 28 for an example of a typical Installation Qualification printed report.

9. Review the following sections in the report to verify that the software is properly installed and set up:

   • **System Information**: Check that the Status column displays **Pass** in each row. See Figure 27.

   • **Instrument Information**: The report shows the instrument serial number, the firmware installed, and the status of each operational module. See Figure 27. If an **Out of Calibration** message or a **Not Available** message is shown, call Cepheid Technical Support. See the Section 2.2, Technical Assistance for the contact information.

     • **Gateway Information**: Provides gateway name, serial number, and firmware number (see Figure 27).

     • **Module Information**: Provides module name, serial number, firmware, internal temperature °C, and status (see Figure 27). There may be more than one page of module information depending upon your system configuration.

   • **Available Assays**: Check the assays in the list (see Figure 27). If the **No Assays** message is shown, see the instructions provided with your in vitro diagnostics assay kit and the *GeneXpert Dx System Operator Manual* for instructions on how to import assay definition files. If the **No Assays** message is shown after you import the assay definition files, call Cepheid Technical Support. See Section 2.2, Technical Assistance for contact information.

10. Sign the last page of the Installation Qualification Report (see Figure 28) and file a copy of the report for your records.

This completes the Installation Report verifying the integrity of the GeneXpert Dx software installation. Continue with Section 1.11, Operator Manual (on the next page).

1.11   Operator Manual

An updated *GeneXpert Dx Operator Manual* is provided in the software kit on a separate DVD. The new operator manual contains important information regarding changes to the software, maintenance procedures and other updates and should be copied to the desktop of the GeneXpert Dx system. After the software has been installed, copy the *GeneXpert Dx Operator Manual* from the Operator Manual DVD to the computer desktop.

1.   Exit the GeneXpert software.

2.   Insert the *GeneXpert Dx Operator Manual* DVD into the DVD drive.

3.   Double-click the DVD drive icon to display the Operator Manual DVD directory.

4.   Double-click the desired language folder.

5.   Double-click the *GeneXpert Dx Operator Manual* pdf file to open the file in Adobe Reader.

6.   Save the file to the desktop using the **Save As** command in Adobe Reader.

7.   Double-click the *GeneXpert Dx Maintenance Log* pdf file to open the file in Adobe Reader.

8.   Save the file to the desktop using the **Save As** command in Adobe Reader.

9.   Delete any old versions of the *GeneXpert Dx Operator Manual* and *GeneXpert Dx Maintenance Log* pdf files from the desktop.

10.   Remove the DVD from the computer DVD drive.

11.   Store all components provided in the 6.5 software upgrade kit in a safe location in case it is needed in the future.

This completes the installation of the GeneXpert Dx software.

1.12   Troubleshooting

Note   If installation was not successful, it may be necessary to temporarily disable any antivirus program on the PC in accordance with your institution's security policies and retry the GeneXpert Dx software installation.

The following errors indicate that the SQL database did not install properly.

- Error message **Unable to start SQL Express** during GeneXpert Dx software installation.

- Error message **[GeneXpert] database is not available** when starting the GeneXpert Dx software.

If either of these errors occur, contact Cepheid Technical Support for assistance. See Section 2.2, Technical Assistance for contact information.

2 Cepheid Locations and Assistance

2.1 Cepheid Headquarters Locations

Corporate Headquarters

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Telephone: + 1 408 541 4191

Fax: +1 408.541.4192

www.cepheid.com

2.2 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

*   Product name
*   Lot number
*   Serial number of the instrument
*   Error messages (if any)
*   Software version and, if applicable, Computer Service Tag number

Contact Information

United States	France
Telephone: + 1 888 838 3222	Telephone: + 33 563 825 319
Email: techsupport@cepheid.com	Email: support@cepheideurope.com

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