



GeneXpert® System with Touchscreen Maintenance Training

Speaker's Name
Date

For Use with GeneXpert® Systems with Touchscreen

302-8141 Rev. A February 2022

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

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Training Agenda

- 1 Maintenance Schedule
- 2 Required Materials and Good Laboratory Practice
- 3 Maintenance Tasks: Daily, Weekly, Monthly, Quarterly, As Necessary, Annually
- 4 Resources Documentation: Maintenance Log & Operator Manual
- 5 Technical Assistance



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Training Objectives

At the end of the training, users will be able to:

- Properly handle the GeneXpert® system maintenance procedures
- Follow proper laboratory safety precautions
- Replace filters and use optics cleaning kit
- Follow daily, weekly, quarterly, and as required maintenance
- Track the daily, weekly, quarterly, annually maintenance traceability
- Find all the details of maintenance procedures in the Operator Manual
- Contact technical support for assistance



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The Cepheid Solution

GeneXpert® System with Touchscreen

- Thermal and optical module(s)
- Touchscreen Unit
- Integrated LED barcode scanner
- Simplified and intuitive Cepheid OS software



Required but not provided

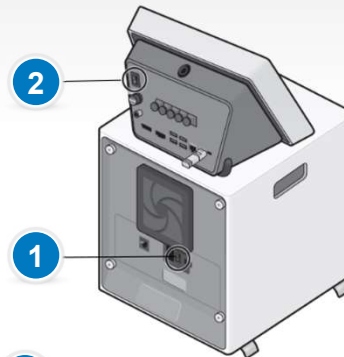
- Assay Specific collection devices (*if applicable*)
- Assay Specific equipment (*if applicable*)
- Personal Protective Equipment
- Line interactive or online UPS
- Timer and permanent marker

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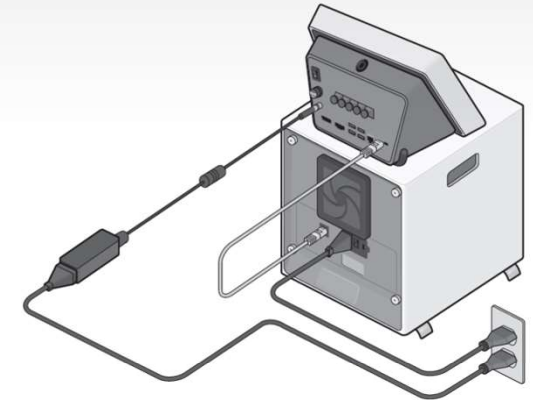
Overview of GeneXpert® System and Touchscreen Components



- 1 Touchscreen user interface
- 2 LED barcode scanner



- 1 Power switch on GeneXpert® instrument
- 2 Power switch on Touchscreen unit



Power Cord and Connection Cable

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Intended Use

- The GeneXpert® system with touchscreen running Cepheid OS version 1.0 automates and integrates sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time Polymerase Chain Reaction (PCR).
- The system is suited for *in vitro* diagnostic applications that require hands-off processing of patient samples (specimens) and provides summarized detailed test results data in tabular format.
- The GeneXpert® system with touchscreen running Cepheid OS 1.0 is designed for use with Xpert® assay applications.
- The GeneXpert® system with touchscreen is intended to be used by trained users in accordance with the test environment specified in the assay instructions for use.



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Maintenance Schedule

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Overview of Maintenance Tasks

Task	Frequency*
Clean work area	Daily
Close all module doors	Daily
Discard used cartridges	Daily
Power down the GeneXpert® instrument	Weekly
Power down the GeneXpert® computer	Weekly
Clean fan filters	Weekly
Archive tests	Monthly
Purge tests	Monthly
Clean plunger and cartridge bay	Quarterly
Clean the instrument surfaces	Quarterly
Replace fan filters	Quarterly
Perform annual instrument maintenance	Annually
Clean I-CORE module	As necessary
Print system log report	As necessary
Back up database	As necessary

* Maintenance procedures may be performed more frequently according to your environmental conditions.

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Maintenance of GeneXpert® System with Touchscreen

Preventative maintenance tasks:

- Performed on regular basis: as necessary, daily, weekly, quarterly (by end-users), and annually (by Cepheid)
- Ensures performance of the system
- Helps to avoid GeneXpert® system with touchscreen malfunctions and errors

GeneXpert® System with Touchscreen Maintenance Log		Month and Year:																														
		Last Calibration Check Date:																														
		FAS Installation Date:																														
<input type="text"/> Name of Institution <input type="text"/> GeneXpert Serial Number																																
Instructions: 1. Enter the name of your institution, GeneXpert Serial Number, current Month and Year, Last Calibration Check date, and FAS Installation Date in the fields above. 2. For each maintenance activity listed below check the box(es) under the day of the month that the activities were performed and enter your initials (2 characters maximum) in the bottom row. 3. Save the file after entering the data. We recommend saving one file each month for a complete record of activities.																																
Daily Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Clean work area																																
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Quarterly Maintenance																																
Clean plunger rod and cartridge bays ¹																																
Clean instrument surfaces ¹																																
Replace instrument fan filters ¹																																
Yearly Maintenance																																
Check annual instrument maintenance ¹																																
As Necessary																																
Clean I-CORE using I-CORE ¹ cleaning brush																																
Print system log report ¹																																
Back up database ²																																
Technician Initials (Two Letters)																																

1. Refer to Chapter 9 (Service and Maintenance) in the Operator Manual for detailed procedure.
 2. Refer to Chapter 5 (Operating Instructions) in the Operator Manual for detailed procedure.
 These are minimum recommendations for cleaning. Your institution may require that maintenance be performed on a more frequent basis.
 Reference: GeneXpert GX Dx Operator Manual (P/N 302-5302, Rev. A)





Required Materials and Good Laboratory Practice

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Required and NOT Supplied Tools/Products

- Use a final concentration of 1:10 dilution of household chlorine bleach used within 1 day of preparation (final chlorine concentration of 0.5%)



- 70% ethanol solution or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol)



- Lint-free wipes/non-cotton swabs



- PPE: Disposable gloves and eye protection



BIOLOGICAL RISKS: Wear disposable gloves, eye protection and other personal protective equipment (PPE) mandated by your institution's safety policies while performing this cleaning procedure. Wearing PPE prevents exposure to chemical and biologically hazardous materials.

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Required and Ordered from Cepheid

Product	Description and Part Number (PN)
GeneXpert® System Replacement Fan Filters	GeneXpert GX-IV Filter PN 001-1537
	GeneXpert GX-II PN 001-1271
GeneXpert® System Optics Cleaning Kit	Contains the I-CORE® module brush and GeneXpert® GX-IV filters (PN 700-6519S)



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Good Laboratory Practice Review

Personnel Protective Equipment (PPE)

- Wear clean lab coats, safety glasses, and gloves
- Change gloves between processing samples

Lab Bench Area

- Clean work surfaces routinely with:
 - ✓ 1:10 dilution of household bleach*
 - ✓ 70% ethanol solution
- After cleaning, ensure work surfaces are dry

*Final Active Chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.



- Store specimens and sample away from kit to prevent contamination

Specimens, Samples, and Kits Storage

- Use filtered pipette tips when recommended
- Follow the manufacturer's requirements for calibration and maintenance of equipment

Equipment

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Maintenance Tasks

*Daily, Weekly, Monthly, Quarterly,
As Necessary, Annually*

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Daily Maintenance Tasks

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Daily Maintenance

1



Clean work area.
(Following your institution's guidelines)

2



**Remove and discard
used cartridges.**

3



**Close all
module doors.**

Biological
Risks



BIOLOGICAL RISKS: Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per World Health Organization medical waste handling and disposal guidelines.

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Weekly Maintenance Tasks

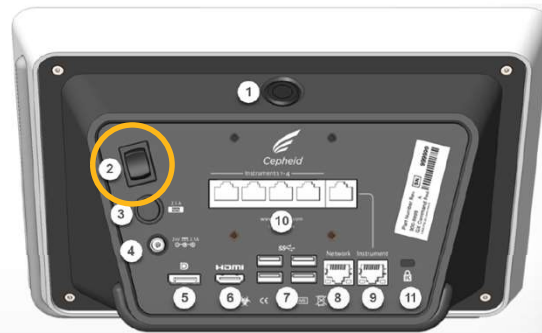
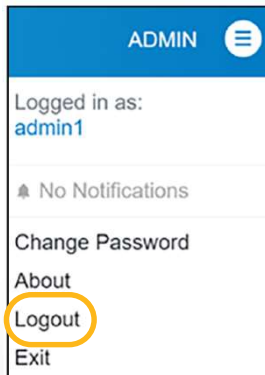
1. *Reboot the system*
2. *Clean up fan filter*

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1. Reboot the System

Power down the GeneXpert® instrument and touchscreen unit

1. On the HOME screen select **User Menu > Exit**
2. Tap **YES** to exit the software, Tap Windows® **Start menu**, Tap **Power** icon, and select **Shut down**.
3. Wait 10 seconds for Windows to shut down.
4. Then press the power switch on the back of the touchscreen unit, the computer shuts down.
5. Press the power switch of the GeneXpert® instrument, the instrument powers down.



...wait 2 minutes...

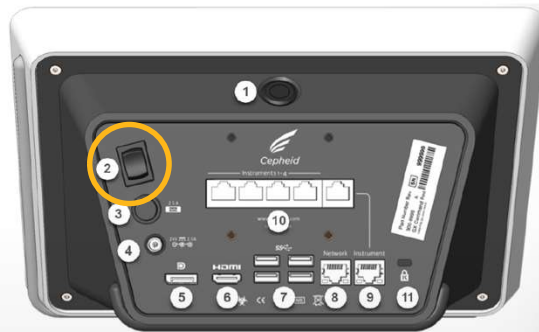
Windows® is a registered trademark of Microsoft Corporation
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1. Reboot the System

Power up the GeneXpert® instrument and touchscreen

..... *...after 2 minutes...*

1. Power up the GeneXpert® instrument.
2. Power up the touchscreen unit.
3. The Windows® opening screen appears.
4. Swipe up anywhere to display the login screen.
5. Select the **Cepheid-Admin** and enter the password (**cphd**), then tap the arrow.



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2. Clean Fan Filters

- **Clean** the fan filter **weekly**, or more frequently, if you operate the instrument in an area with high pollution, dust, or smoke.
- **Replace** the fan filter **quarterly**, or more frequently if necessary.
- The fan filter is located on the back of the instrument.



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2. Clean Fan Filters

1



Remove and replace the filter with a clean filter.

2



Wash the filter with running water and detergent.

3



Clean the old filter by washing it. Place this cleaned filter between two paper towels and allow it to air-dry.



Monthly Maintenance Tasks

Archive and purge tests

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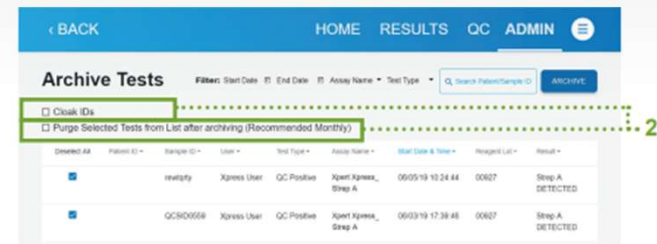
Archive and Purge (Delete) Tests

1



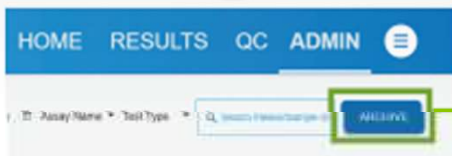
Tap the **ADMIN** button and touch **ARCHIVE TESTS**.

2



Tap **Select All** or select individual tests to be archived or removed. To remove selected files, check **Purge Selected Tests from List after Archiving**.

3



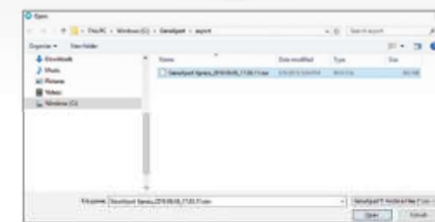
Tap **ARCHIVE**: Confirm files to be archived and save files.

4



Confirm with **OK** to begin archiving process.

5



Confirm with **OK** to close the window.

Archive and Purge (Delete) Tests

6



If **Purge Selected Tests** was checked, confirm the selection by touching **Yes**. Then tap **OK**.

7

Backup archived data file to an external location per your institutional practices.

Quarterly Maintenance Tasks

1. *Clean instrument surfaces*
2. *Clean the plunger rods and the cartridge bays*
3. *Replace the fan filters*

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1. Clean the Instrument and Touchscreen Surfaces

Clean the instrument and touchscreen unit surfaces with 70% ethanol

- 1 Shut down the GeneXpert® system before cleaning the surfaces.
- 2 Moisten a lint-free wipe with 70% ethanol solution.
- 3 All outside surfaces of the instrument and touchscreen housing should be cleaned including the top, sides, and outside doors of the module.

- Use one lint-free wipe for the instrument and one for the work area
- Discard used wipes according to your standard laboratory procedure



Reminder: Wipe surfaces once with 70% ethanol



2. Clean the Plunger Rods and Cartridge Bays

- 1 Tap the **ADMIN** button on the Home screen and login.
- 2 Tap the instrument button.
- 3 Tap **PLUNGER ROD MAINTENANCE**.
- 4 Select the modules that require maintenance with the tick box.
- 5 Tap **CLEAN**.

The first screenshot shows the 'ADMIN' button highlighted in the top navigation bar. Below it, the 'INSTRUMENT' button is highlighted in the 'Administration' section.

The second screenshot shows the 'PLUNGER ROD MAINTENANCE' button highlighted in the 'Instrument' section. Below it, four modules (A1, A2, A3, A4) are listed, each with a 'MAINTENANCE' button.

The third screenshot shows the 'Plunger Rod Maintenance' screen with a table of modules. The 'SELECT' column has checkboxes for each module, and the 'CLEAN' button is highlighted.

Select All	Module Name	Module Serial Number	Tests Since Last Cleaned
<input type="checkbox"/>	A1	628907	0
<input type="checkbox"/>	A2	631805	6
<input type="checkbox"/>	A3	644020	5
<input type="checkbox"/>	A4	666595	5

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2. Clean the Plunger Rods and Cartridge Bays

6

Moisten a lint-free wipe with a 1:10 solution of **household chlorine bleach**.

7

Wipe plunger rod and entire cartridge bay interior.

8

Wait 2 minutes.

9

Moisten a lint-free wipe with **70% ethanol or denatured ethanol**.

10

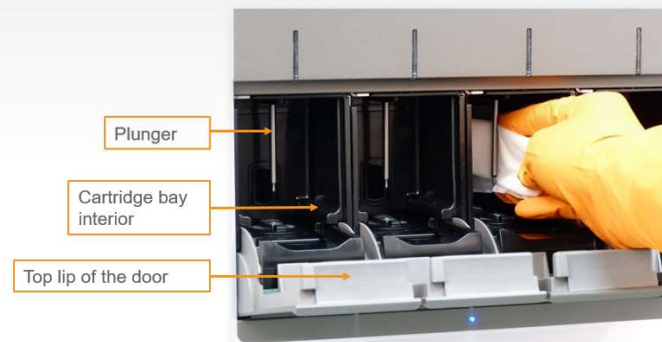
Wipe plunger rod and entire cartridge bay interior with the ethanol solution to remove bleach residue.

11

Tap **COMPLETE** to raise the plunger rods.

12

Tap **OK** to acknowledge and **HOME** to return at the **HOME** screen.



Reminder:

- **3x bleach**
- **Wait 2 minutes in between**
- **1x 70% ethanol**

Note: Change lint-free wipes frequently while wiping. Discard used wipes according to your standard laboratory procedure. [This procedure can be performed in case of spillage on the affected surfaces.](#)

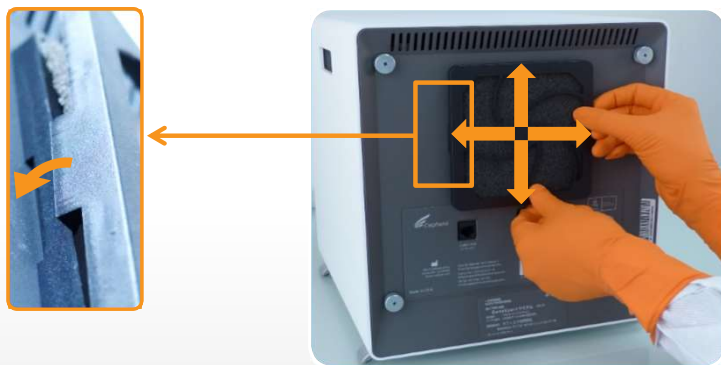


3. Replace the Fan Filters

1 Position the instrument so the fan filter can be easily accessed.

2 Gently take the fan filter guard off by unsnapping the guard from the fan housing and set it aside for the remainder of the procedure for filter removal and cleaning.

3 Place a clean filter into the fan filter guard.



4 Position the fan filter guard and filter into place as a unit.

5 Press the sides of the guard firmly onto the fan housing until the grip snaps securely onto the fan.

6 Press the bottom of the guard until the grip snaps securely onto the fan.





As Necessary Maintenance

1. *Clean up spills*
2. *Clean the I-CORE® module*
3. *Save or print system log report*
4. *Backup the database*

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1. Clean Up Spills on Exterior Instrument and Touchscreen Unit Surfaces

- 3x {
- 1 Moisten a lint-free wipe with a 1:10 solution of household chlorine bleach.
 - 2 Wipe affected surfaces on the instrument, surfaces, and bench.
 - 3 Wait 2 minutes.
 - 4 Moisten a lint-free wipe with 70% ethanol solution of denatured ethanol.
 - 5 Wipe plunger rod and entire cartridge bay interior with the ethanol solution to remove bleach residue.



Reminder:

- 3x bleach
- Wait 2 minutes in between
- 1x ethanol

Note: Change lint-free wipes frequently while wiping.
Discard used wipes according to your standard laboratory procedure.

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2. Clean the I-CORE[®] Module

- 1 Wear laboratory gloves.
- 2 Remove cartridges from the modules.
- 3 Make sure that all bristles are fully inserted (up to the shoulder of the plastic shank of the brush).
- 4 Brush the inside of the slot with up and down movements.
- 5 Rotate the brush for approx. 180° and back, then repeat the previous step 2 times.
- 6 Clean each module for at least 30 seconds.



Reminder:

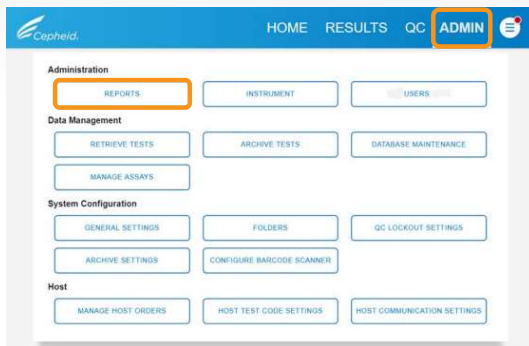
- **Dry brush**

Note: Use one DRY brush per module.

Note: If you operate in an area with a high level of dust or air pollution, please ensure to clean the optics monthly.

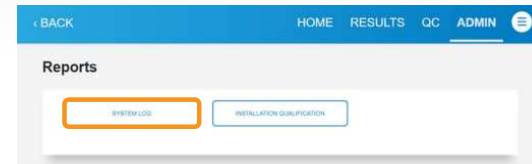
3. Edit and Save or Print System Log Report

1



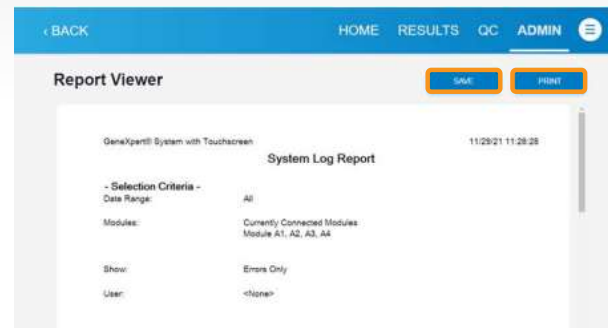
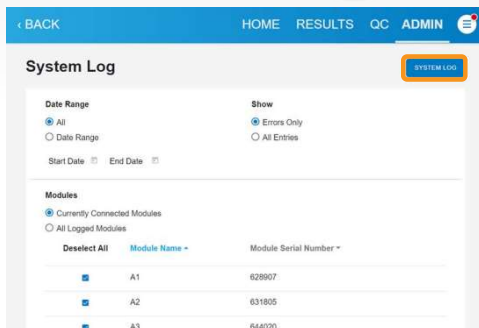
Tap the **ADMIN** button and touch **REPORTS**.

2



Tap **SYSTEM LOG** on the Reports screen.

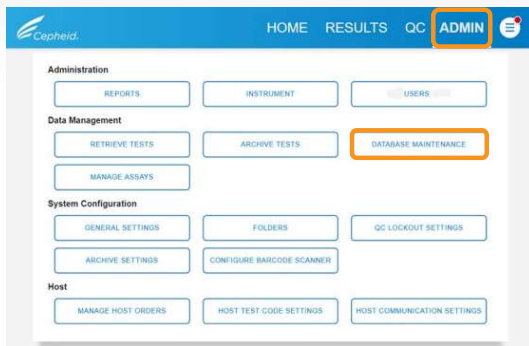
3



Tap **SYSTEM LOG** on the screen to generate the report, and tap on **SAVE** or **PRINT**.

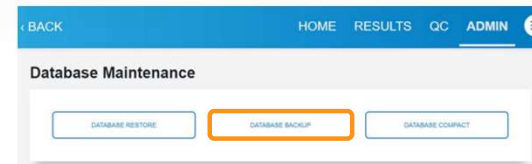
4. Back Up the Database

1



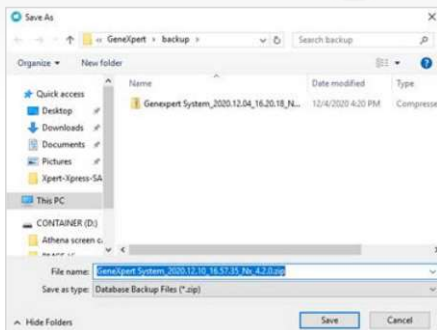
Tap the **ADMIN** button and tap **DATABASE MAINTENANCE**.

2



Tap **DATABASE BACKUP** on the database maintenance screen.

3



Select the folder in which you want to store the backup file, and then tap **Save**.



Annual Instrument Maintenance

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Annual Instrument Maintenance

- Calibration is performed before a system is shipped.
- Xpert[®] Check is performed annually by Cepheid Authorized Personnel.
- Replacement modules are calibrated prior to shipment from the Cepheid Repair Center, a calibration report is provided for each new module installed in the GeneXpert[®] system.

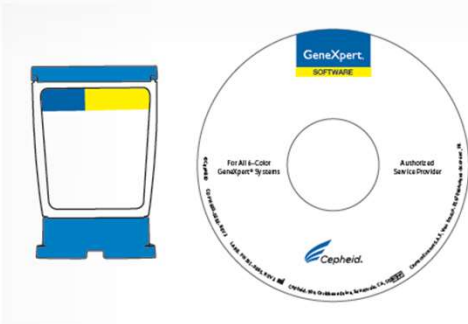


➔ **Contact Cepheid Technical Support for further information about calibration checks.**

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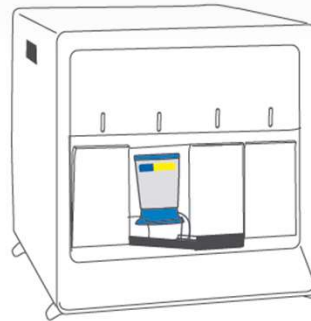
Xpert[®] Check

1



Obtain kit.

2



Check module performance.

3



Confirm functionality.

- Measures and confirms module performance

- Performed by Cepheid Authorized Personnel

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Resources Documentation

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Operator Manual GeneXpert® System with Touchscreen

Maintenance tasks are detailed
in chapter 9: “Maintenance”

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GeneXpert® System with Touchscreen



Operator Manual
Cepheid OS version 1.0

IVD CE



In Vitro Diagnostic Medical Device

302-5302, Rev. A
March 2022



Maintenance Log

GeneXpert® System with Touchscreen Maintenance Log		Month and Year:																														
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GeneXpert Serial Number		FAS Installation Date:																														
<p>Instructions: 1. Enter the name of your institution, GeneXpert Serial Number, current Month and Year, Last Calibration Check date, and FAS Installation Date in the fields above. 2. For each maintenance activity listed below check the box(es) under the day of the month that the activities were performed and enter your initials (2 characters maximum) in the bottom row. 3. Save the file after entering the data. We recommend saving one file each month for a complete record of activities.</p>																																
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Technical Assistance

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Technical Assistance

Before contacting Cepheid Technical Support, collect the following GeneXpert® information:

Product name	X
Lot number	X
Serial number of your GeneXpert® System (on back panel)	X
Software version and, if applicable, Touchscreen Unit Service Tag number	X
Error messages (if any)	X

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Log your case online using the following link:
<http://www.cepheid.com/en/support>

→ Create a Support Case

- Contact local technical support

Region	Telephone	Email
US	+ 1 888 838 3222	techsupport@cepheid.com
Australia and New Zealand	+ 1800 130 821 + 0800 001 028	techsupportANZ@cepheid.com
Brazil and Latin America	+ 55 11 3524 8373	latamsupport@cepheid.com
China	+ 86 021 5406 5387	techsupportchina@cepheid.com
France	+ 33 563 825 319	support@cepheideurope.com
Germany	+ 49 69 710 480 480	support@cepheideurope.com
Spain	+ 34 919 90 67 62	support@cepheideurope.com
Portugal	+ 351 800 913 174	support@cepheideurope.com
India, Bangladesh, Bhutan, Nepal, Sri Lanka	+ 91 11 48353010	techsupportindia@cepheid.com
Italy	+ 39 800 902 567	support@cepheideurope.com
South Africa	+ 27 861 22 76 35	support@cepheideurope.com
United Kingdom	+ 44 3303 332 533	support@cepheideurope.com
Other European, Middle East, and African countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com
Other countries not listed	+ 1 408 400 8495	techsupport@cepheid.com





Thank You

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