

GeneXpert[®] Maintenance: GeneXpert Dx System



GeneXpert[®] System Maintenance: Training Agenda

- Why & when set maintenance should be completed
- Required tools
- How to order replacement filters & optics cleaning kit
- Daily, Weekly, Monthly, Quarterly & As Required Maintenance
- Annual Xpert Check
- Maintenance Log
- Operator Manual
- Technical Assistance

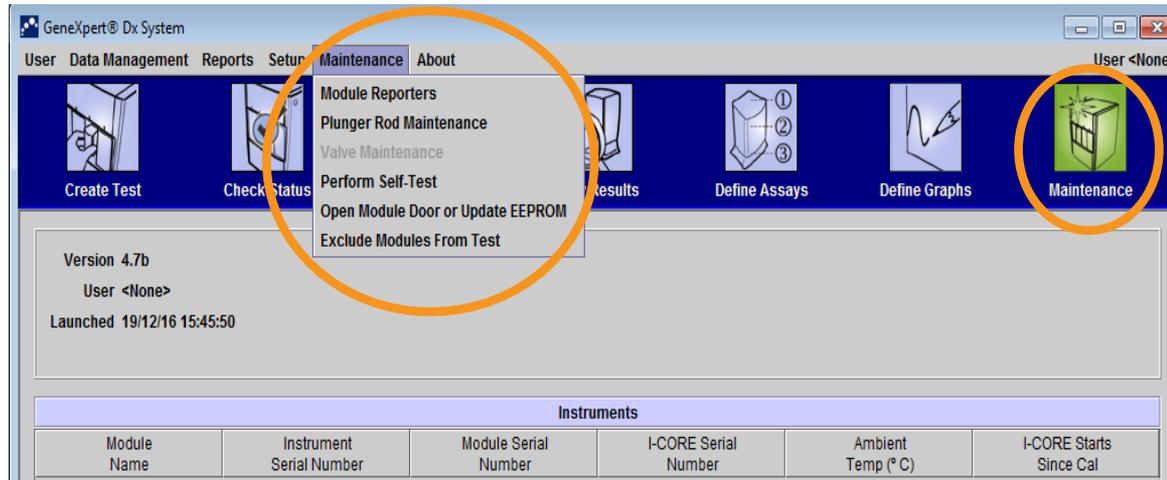
Overview of Maintenance Tasks

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 PreFilters	Weekly
Archive tests	Monthly
Purge tests	Monthly
Clean plunger rod and cartridge bay	Quarterly
Clean the instrument surfaces	Quarterly
Replace fan filters	Quarterly
Perform annual instrument maintenance	Annually
Clean I-CORE using I-CORE brush	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.

Maintenance of GeneXpert® System

- Preventative maintenance tasks:
 - Performed on regular basis by end-users: as necessary, daily, weekly, monthly, quarterly and yearly
 - Ensures performance of the system
 - Helps to avoid GeneXpert system malfunctions and errors



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 & Eye Protection
- Clean water & detergent
- Blank CD/Other External Device to save data



Required and Ordered from Cepheid

GeneXpert® System replacement fan filters	Description and Part Number (PN) GeneXpert® GX-IV Filter (PN 001-1537) GeneXpert® High Efficiency (HE) Filter Kit (P/N GX-HE-FILTERKIT) GeneXpert® GX-XVI R1 Filter (PN 001-1271) GeneXpert® GX-II (PN 001-1271) GeneXpert® GX-XVI R2 Filter (PN 001-1537)
GeneXpert® System Optics Cleaning Kit	Description and Part Number (PN) (PN 700-6519S) Contains the I-CORE brush and GX-IV filters 

Daily Maintenance Tasks



Daily Maintenance

1. Clean work area

(following your institution's guidelines)



3. Close all module doors



2. Remove and discard used cartridges



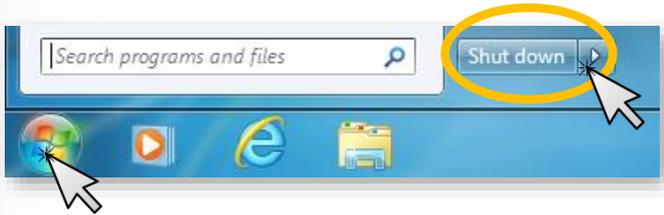
Weekly Maintenance Tasks



1. Reboot the system

- Reboot the GeneXpert[®] instrument and computer

1. Power down the GeneXpert computer



..... ..wait 2 minutes.....

3. Turn on the GeneXpert instrument



2. Power down the GeneXpert instrument



4. Turn on the on GeneXpert computer



US-IVD and CE-IVD. For *in vitro* diagnostic use.

Protecting your GeneXpert[®] Instrument

Whenever the GeneXpert instrument is not in use:

1. Power down the GeneXpert instrument
2. Protect the instrument with the GeneXpert dust cover, if available.

(provided with GX-IV in HBDC specific environments only)



Clean Fan Filters

- There are 2 styles of fan filters on the GX-II and GX-IV: under a filter guard & under a back panel
- Clean fan filters **weekly** if you operate in an area of high pollution, dust or smoke, otherwise **quarterly** is sufficient.



US-IVD and CE-IVD. For *in vitro* diagnostic use.

Cleaning 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

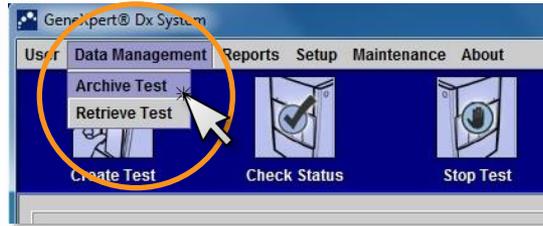
Monthly Maintenance Tasks



Archive and purge (delete) runs

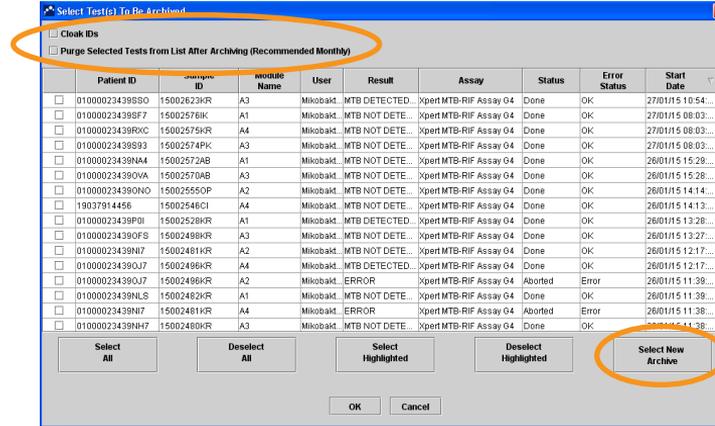
1

Choose Archive Test



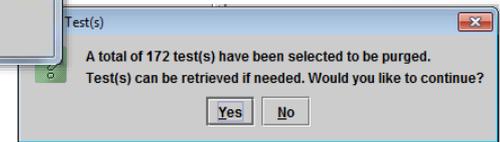
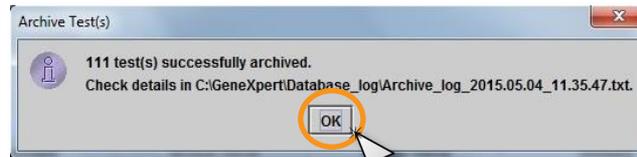
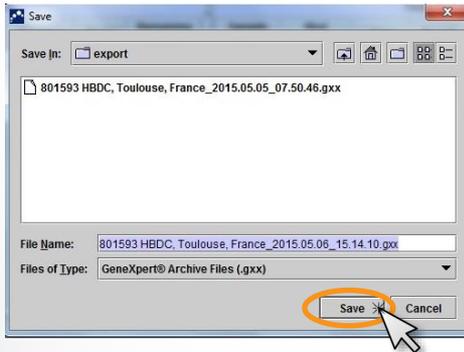
2

Select the runs with the button "Select New archive"
Check the appropriate boxes to purge the runs

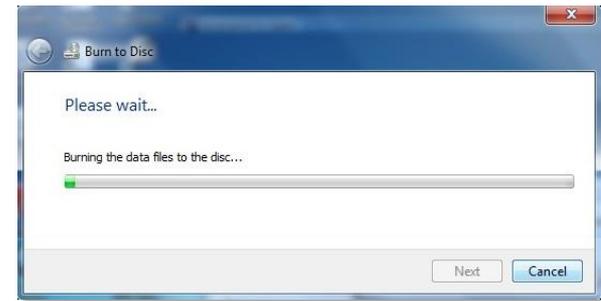
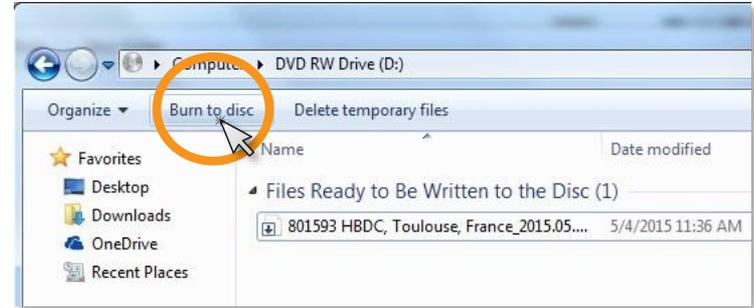
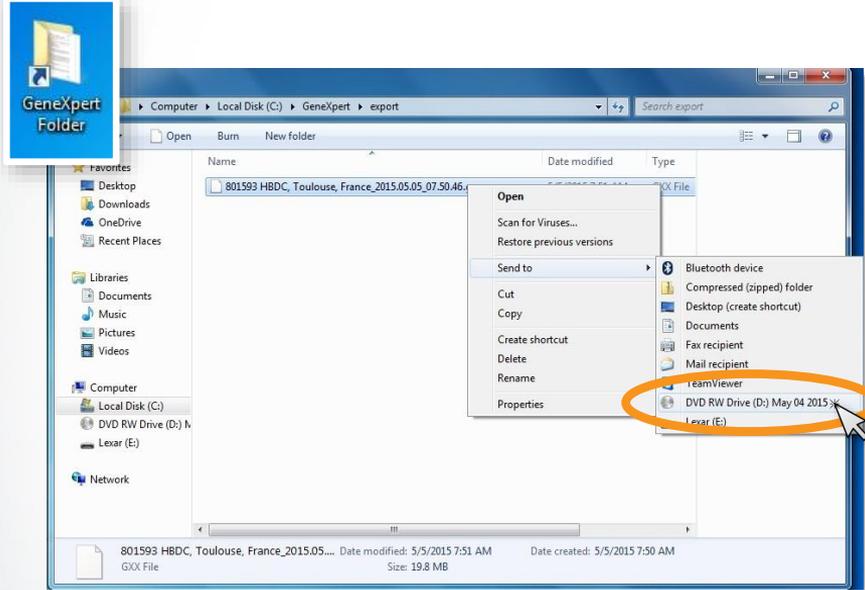


3

Name given automatically



Save data on an External Device



Quarterly Maintenance Tasks



Quarterly Maintenance

1. Clean instrument surfaces
2. Clean cartridge bays
3. Clean plunger rods



4. Replace fan filters



1. Cleaning the instrument surface

1. Shut down the GeneXpert® system before cleaning the surfaces.
2. Moisten a lint-free wipe with **70% ethanol** solution
3. Wipe all outside surfaces of the instrument
4. Wipe table surfaces around the instrument

Reminder:
• Wipe Surfaces
once with 70%
Ethanol

Use one lint-free wipe for the instrument and one for the work area

Discard used wipes according to your standard laboratory procedure



2. Cleaning the Cartridge Bay

- 3 x
1. Moisten a lint-free wipe with a 1:10 solution of household chlorine bleach
 2. Wipe the inside of the cartridge bay, the inside of the door and the top lip of the door
 3. Wait 2 minutes
 4. Moisten a lint-free wipe with 70% ethanol solution
 5. Wipe the parts described above with the ethanol solution

Change lint-free wipes frequently while wiping

Discard used wipes according to your standard laboratory procedure

- Reminder:**
- 3x Bleach
 - Wait 2 min. in between
 - 1x Ethanol

This procedure can be performed in case of spillage on the affected surfaces

US-IVD and CE-IVD. For *in vitro* diagnostic use.

2. Cleaning the Cartridge Bay

Wipe the inside of the cartridge bay, the inside of the door and the top lip of the door

Cartridge bay interior

Inside of the door

Top lip of the door



3. Cleaning the Plunger Rods

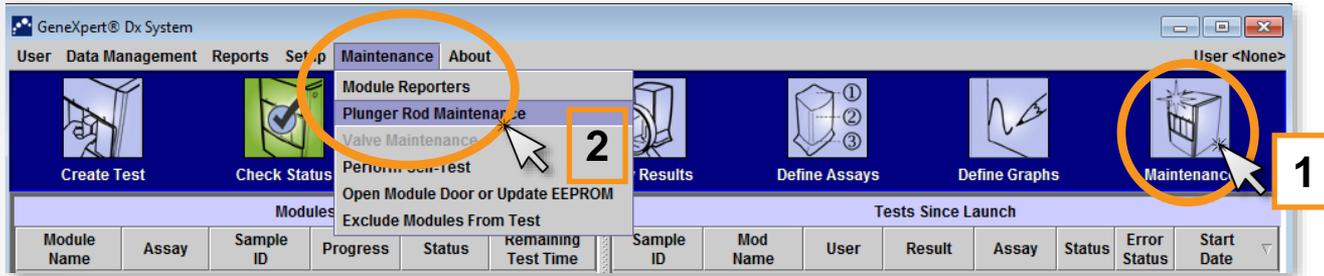
- 3 x
1. Moisten a lint-free wipe with a 1:10 solution of household chlorine bleach
 2. After the plunger rods are lowered, gently wipe the plunger rods
 3. Wait 2 minutes (never longer than 5 minutes)
 4. Moisten a lint-free wipe with 70% ethanol solution
 5. Wipe the plunger rod with the ethanol solution

Change lint-free wipes frequently while wiping

Discard used wipes according to your standard laboratory procedure

- Reminder:**
- 3x Bleach
 - Wait 2 min. in-between
 - 1x Ethanol

3. Cleaning the Plunger Rods



2

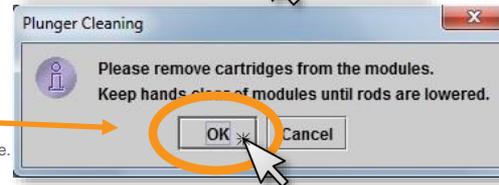
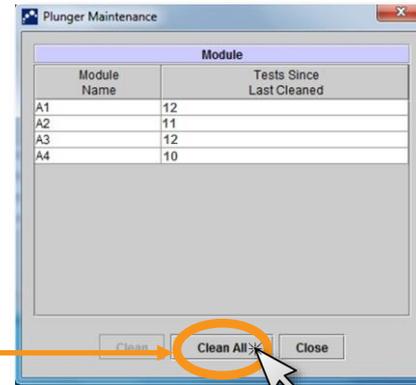
In the Maintenance menu select **Maintenance** then **Plunger Maintenance**

3

In the Plunger Maintenance window select **Clean All**

4

Follow the instructions in the dialog window and click **OK**



3. Cleaning the Plunger Rods

5

The plunger rods will be lowered in the selected modules. Wipe gently to remove any dust off the plunger rod

Plunger

Cartridge bay interior

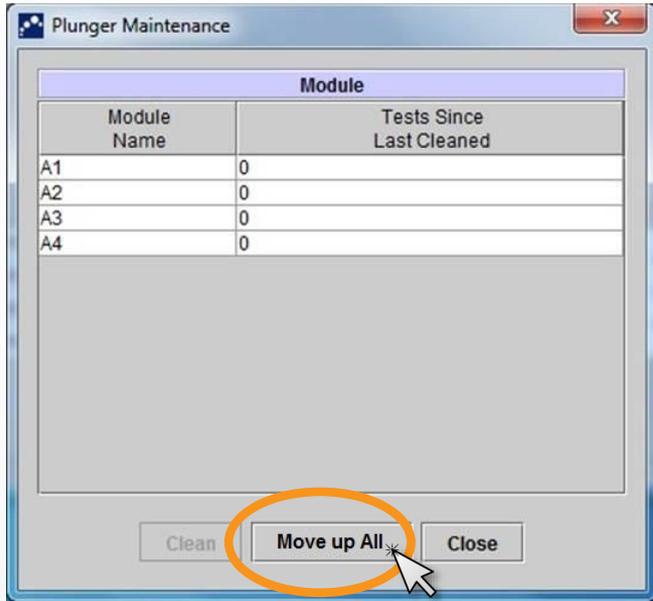
Top lip of the door



3. Cleaning the Plunger Rods

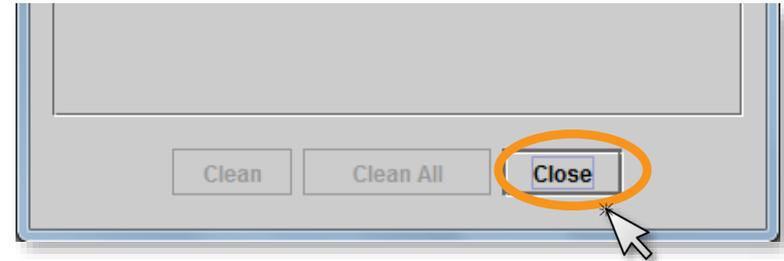
6

After cleaning the plungers select **Move Up All**
The plungers will return to their initial position



7

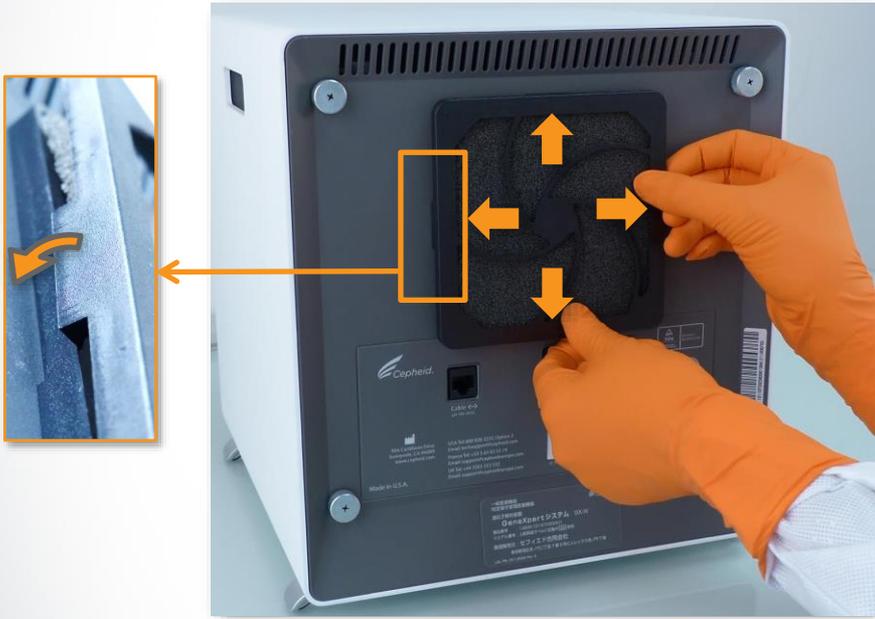
Select **Close**



4. Replacing the Fan Filters

Under a Filter Guard

Turn off the system



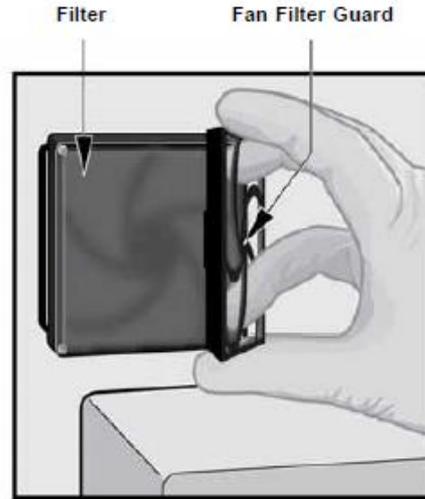
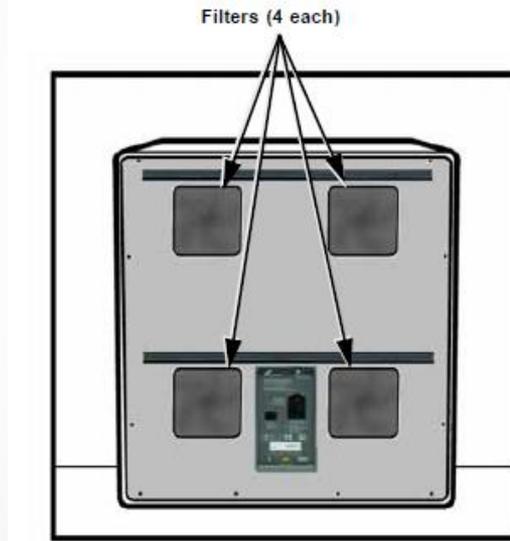
Unclip 4 clips one by one



4. Replacing the Fan Filters

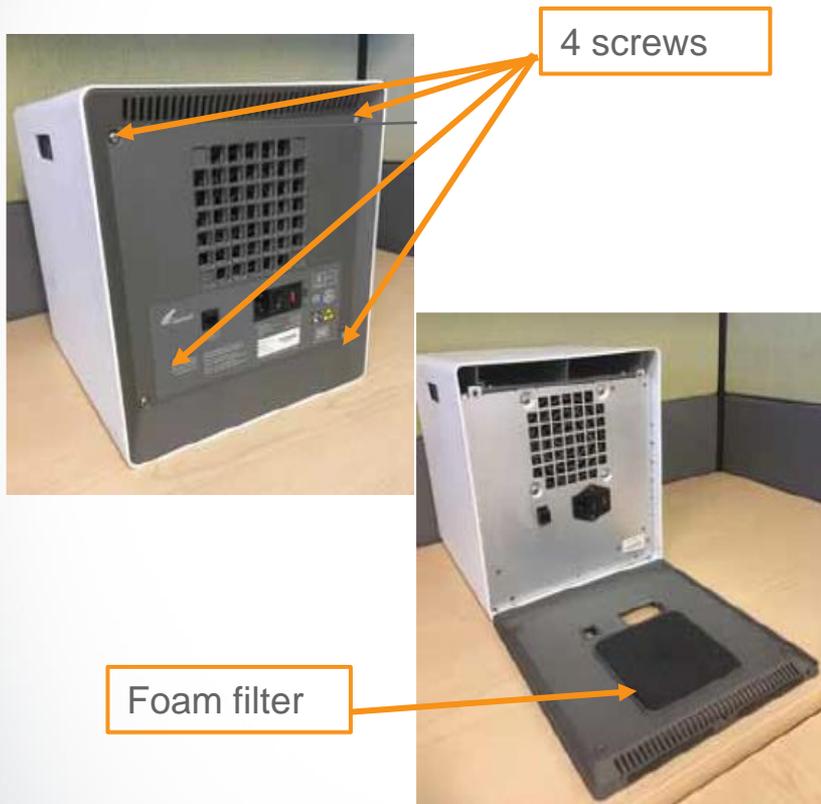
Under a Filter Guard

- 4 filters on a GX-XVI R2.



4. Replacing the Fan Filters

Under a Back Panel



- The instrument must be unplugged from all electrical outlets.
- Remove the 4 back panel screws using a Philips/star head screwdriver.
- Pull off the panel and remove the gray foam filter.
- Clean the filter with water & soap. Dry the filter between 2 paper towels. It must be completely dry before you re-insert it.

4. Replacing High Efficiency (HE) Filters*

- Only for specifically-configured GX-IV systems
- Prefilter replacement - once every 3 months (minimum)

Turn off the System



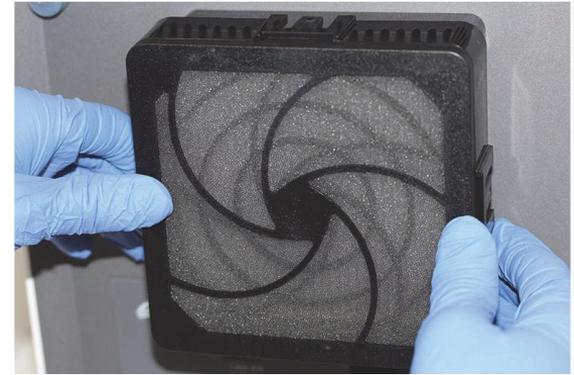
1

Remove the prefilter
retainer



2

Replace with a clean
prefilter



3

Place the prefilter on
top of the HE filter
retainer

* - HE filters are present on a limited number of systems and replacement should be performed by Cepheid personnel.
US-IVD and CE-IVD. For *in vitro* diagnostic use.

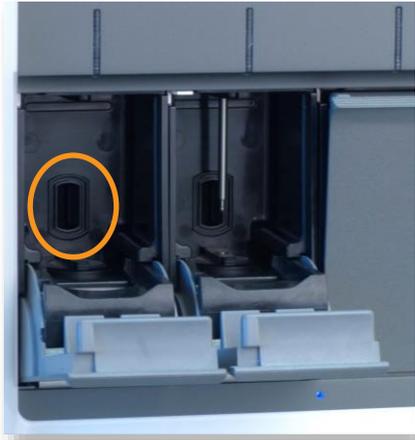
As-necessary Maintenance



As-necessary Maintenance

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

1. Clean I-CORE[®]



2. Print system log report

801593 HBDC, Toulouse, France 04/15/15 12:11:50

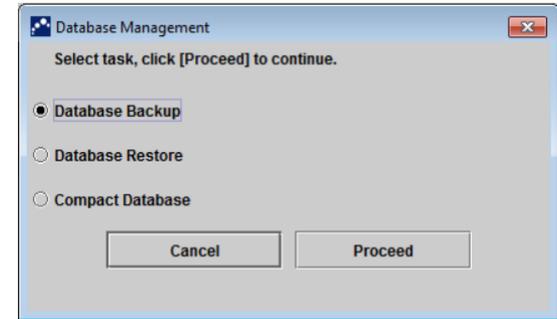
GeneXpert[®] Dx System
Installation Qualification Report

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

System Information

Software	Version	Status
GeneXpert [®] Dx System	4.0	Pass
Java Runtime Environment	1.7.0_04	Pass
GX_Utils.DLL	0.8.4.0	Pass
SQL Database	2008 R2 (SP2) - 10.50.4033	Pass
Database	gx_db 2.0.5.0	Pass
Operating System	Windows 7 6.1 Service Pack 1	Pass
CIT Plug-In	1	Pass

3. Back up database



Clean the I-CORE[®] module



Reminder:
• Dry brush

1. Wear laboratory gloves
2. Remove cartridges from the modules
3. Make sure that all the 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 sec

Note: Use one DRY brush per module

Annual Instrument Maintenance



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.
- Contact Cepheid Technical Support for further information about calibration checks.



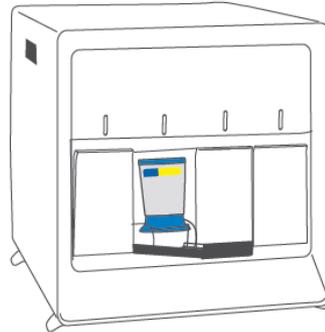
Xpert[®] Check

- Measures and confirms module performance
- Performed by Cepheid Authorized Personnel

STEP 1
OBTAIN KIT

STEP 2
CHECK MODULE PERFORMANCE

STEP 3
CONFIRM FUNCTIONALITY



Maintenance Log

GeneXpert® System Maintenance Log

Name of Institution
 GeneXpert Serial Number:
 Month and Year:
 Last Calibration Check Date:
 Installation Date:

- Instructions:
1. Enter the name of your institution, GeneXpert Serial Number, current Month and Year, Last Calibration Check date, and 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	<input type="checkbox"/>																														
Close all module doors	<input type="checkbox"/>																														
Discard used cartridges	<input type="checkbox"/>																														
Weekly Maintenance																															
Power down the GeneXpert instrument ¹ and Computer ¹	<input type="checkbox"/>																														
Clean Fan Prefilter ¹	<input type="checkbox"/>																														
Monthly Maintenance																															
Archive tests ²	<input type="checkbox"/>																														
Purge tests ²	<input type="checkbox"/>																														
Quarterly Maintenance																															
Clean plunger rod and cartridge bays ¹	<input type="checkbox"/>																														
Clean instrument surfaces ¹	<input type="checkbox"/>																														
Replace fan filters ¹	<input type="checkbox"/>																														
Replace fan prefilters ¹	<input type="checkbox"/>																														
Yearly Maintenance																															
Check annual instrument maintenance ¹	<input type="checkbox"/>																														
As Necessary																															
Print system log report ¹	<input type="checkbox"/>																														
Back up database ²	<input type="checkbox"/>																														
Clean I-CORE using I-CORE cleaning brush ¹	<input type="checkbox"/>																														
Technician Initials (Two Letters)	<input type="text"/>																														

¹ Refer to Chapter 9 (Service and Maintenance) in the Operator Manual for detailed procedure.
² Refer to Chapter 6 (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 System Operator Manual (P/N 302-4074, Rev. B)



For more information on Maintenance of GeneXpert[®] System

- **GeneXpert Operator Manual: Chapter 9**

9 Service and Maintenance

This chapter describes the basic maintenance procedures for the GeneXpert instrument and lists the possible problem or error messages you might encounter. The topics in this chapter are as follows:

- Section 9.1, Maintenance Tasks
- Section 9.2, Maintenance Log
- Section 9.3, Power Down the System
- Section 9.4, Guidelines for Cleaning and Disinfecting
- Section 9.5, Cleaning the Work Area
- Section 9.6, Close Module Doors
- Section 9.7, Discard Used Cartridges
- Section 9.8, Cleaning the Instrument Surfaces
- Section 9.9, Cleaning the Plunger Rods and Cartridge Bays
- Section 9.10, Cleaning the I-CORE
- Section 9.11, Cleaning and Replacing the Fan Filters
- Section 9.12, Annual Instrument Maintenance
- Section 9.13, Using Module Reporters
- Section 9.14, Performing a Manual Self-Test
- Section 9.15, Excluding Modules from Test
- Section 9.16, Generating the System Log Report
- Section 9.17, Replacing Instrument Parts
- Section 9.18, Repairing the Instrument
- Section 9.19, Troubleshooting

GeneXpert Dx System Operator Manual
302-4070, Rev. A August 2020

9-1

<http://www.cephheid.com/us/support/package-inserts/package-insert-entry-form>

Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
 - Product name
 - Lot number
 - Serial number of the System
 - Error messages (if any)
 - Software version and, if applicable, Computer Service Tag number
- Log your complaint online using the following link <http://www.cepheid.com/us/support> :
Create a Support Case



Thank You.



www.Cepheid.com