NATIONAL TB PROGRAMME, MYANMAR

GeneXpert Instrument Maintenance

National TB Reference Laboratory

Version-1

Table of Contents

1. Scope

This SOP describes maintenance and service of GeneXpert instrument. This applies to laboratory staff involved in GeneXpert MTB/RIF testing.

2. Definitions and abbreviations

SH – Sodium Hypochlorite
SOP – Standard Operating Procedure
STLS – Senior Tuberculosis Laboratory Supervisor

3. Personnel pre-qualifications

3.1. Tasks and responsibilities

Laboratory technician has to take responsibilities for Disinfection of the instrument and Preparation of disinfectant solutions according to SOP.

3.2. Training

Education level of laboratory staff should be adequate to perform the assigned tasks.

The training should be:

- Given before a staff member takes up tasks
- Strictly supervised by STLS
- Adapted to take account of new or changed conditions
- Repeated periodically

Basic knowledge

- TB symptoms and transmission; infection control measures
- Good laboratory practices
- Hygiene

Laboratory safety (biological, chemical, electrical and fire hazards, etc)

- Use of personal protective equipment
- Disinfection/decontamination

Related procedures

- Procedure for preparation of disinfectants

4. Procedure

4.1. Principle

Proper functioning and safe operating of GeneXpert system requires regular disinfection of the instrument surfaces and parts of it that potentially come into contact with the infectious materials like the cartridge bay interior and the plunger rod. Calibration of the instrument modules has to be done annually or after 2000 run/module. Archiving of the results secures the data from possible lost.

4.2. Equipment and materials

- GeneXpert instrument
- Goggles
- Gloves
- Laboratory coat
- Cotton swabs
- Paper towels

4.3. Reagents and solutions

- 1 % Sodium hypochlorite solution that can be freshly prepared from household bleach by diluting 10 times, which is also called 10% bleach solution.
- 70% ethanol

4.4. Frequency of maintenance

1. **Daily** → Discard cartridges and clean the bench-work
2. **Weekly** → Re-start the GeneXpert instrument, then computer
3. **Monthly** → Disinfect the instrument surfaces, clean fan filter, disinfect the cartridge bay, disinfect the plunger rods, clean the module PCR slot, archive the results and save them on CD
4. **Annually** → Calibrate every module or after 2000 runs/module whichever comes first

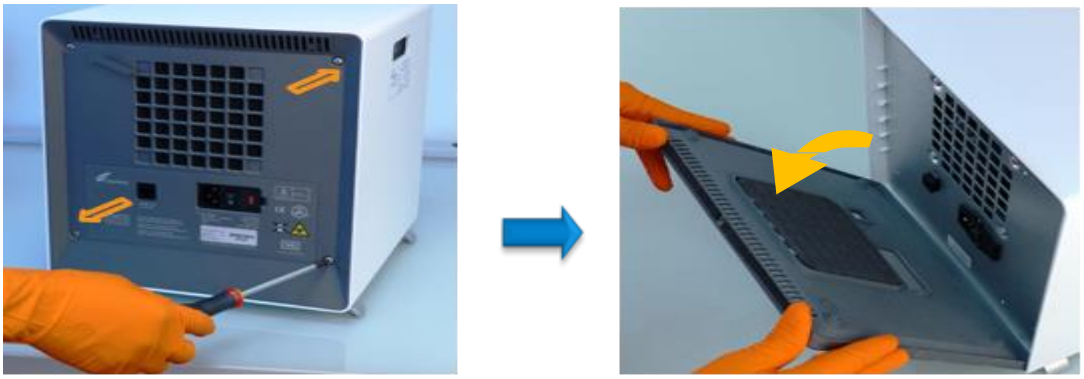
4.5. Disinfection of the instrument surfaces

1. Moisten a lint-free paper towel with 1% Sodium Hypochlorite solution and then wipe the instrument surfaces thoroughly with that paper towel
2. Wait 10 minutes
3. Moisten a lint-free paper towel with 70% ethanol solution and then wipe the instrument surfaces with that paper towel
4. Repeat the cleaning one more time by doing the steps 1,2, and 3 again.
   (Make sure that the solutions are not spilled on the AC power components and computer)

4.6. Cleaning the fan filter

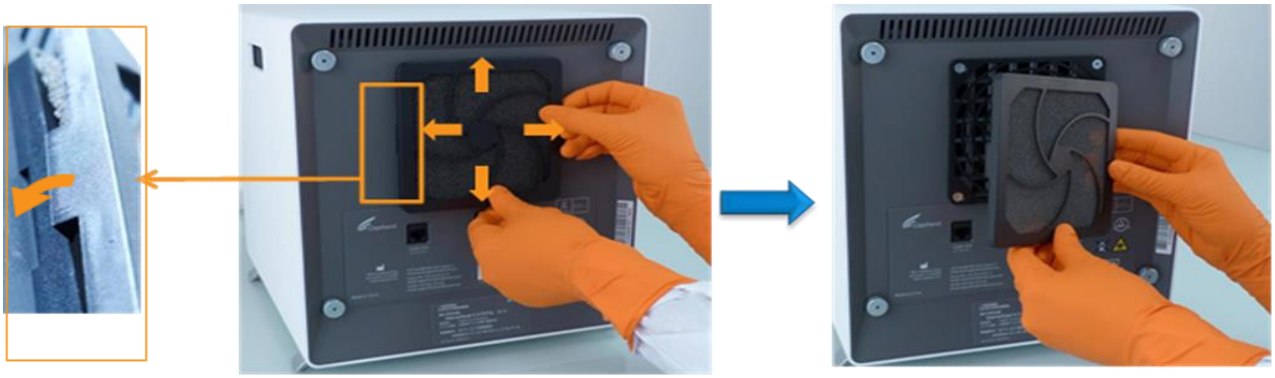
(When filter is positioned behind the back panel)

1. Turn off the System and remove the 4 screws on the rear grey panel
2. Tilt back the panel



(When filter is positioned on the outside)

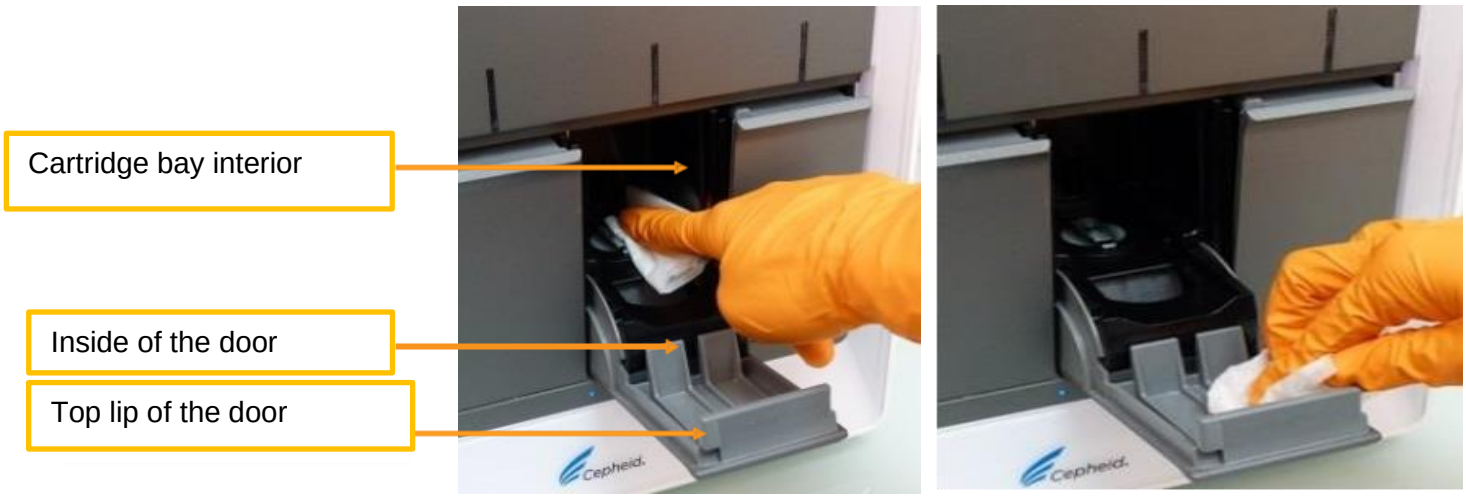
1. Turn off the System
2. Unclip 4 clips one by one



3. Remove the filter (sponge)
4. Wash the filter with water and soap
5. Dry it between 2 paper towels (Must be completely dry before putting it back)

4.7. Disinfection of cartridge bay

1. Moisten a lint-free cotton swab with 1% Sodium Hypochlorite solution and wipe the surfaces inside the cartridge bay, the inside of the door and the top lip of the door with that swab. (Do not touch the slit on the I-CORE module into which the cartridge reaction tube is inserted. Getting liquid inside of the I-CORE module can damage the module)
2. Wait 10 minutes
3. Moisten a lint-free cotton swab with 70% ethanol solution and wipe the same surfaces with that swab
4. Repeat cleaning by doing step 1,2,3.
5. Close module door



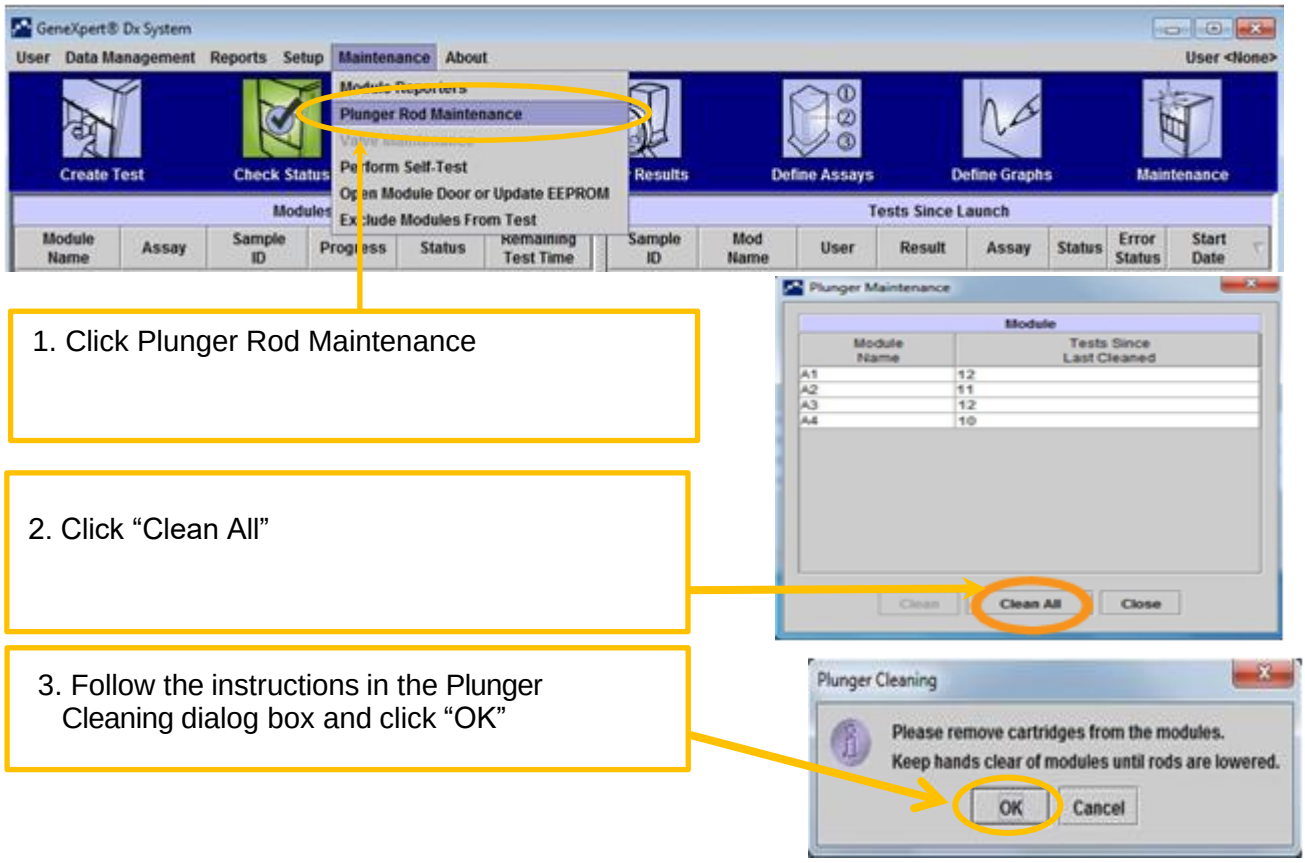
4.8. Disinfection of plunger rod

Remove cartridges from the modules you want to clean and use a fresh swab for each plunger rod

1. In the GeneXpert Dx System window, click Plunger rod Maintenance on the Maintenance menu. Plunger Maintenance dialog box appears.

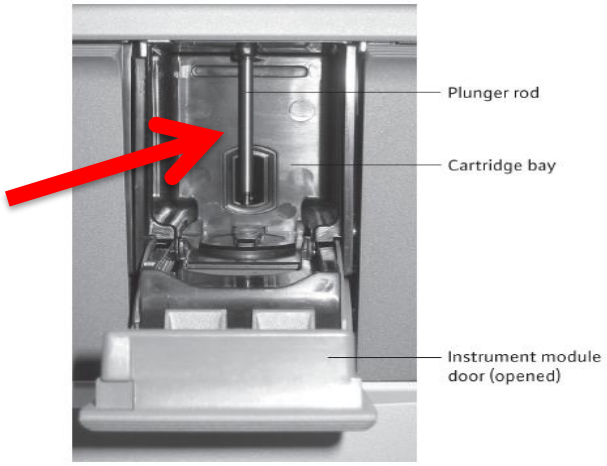
2. In Plunger Maintenance dialog box, select the module you want to clean, and then click Clean. If you want clean all modules, select Clean All.

3. When the Plunger Cleaning dialog box appears, follow the directions in the Plunger Cleaning dialog box, then click OK



4. Plunger rod in the selected module lowers into the cartridge bay. At the same time, Clean button changes to Move Up button (if you clicked Clean All button, plunger rods of each and every module lower and then change to Move Up All)

5. Moisten a lint-free cotton swab with 1% sodium hypochlorite solution and wipe the plunger rods with that swab.

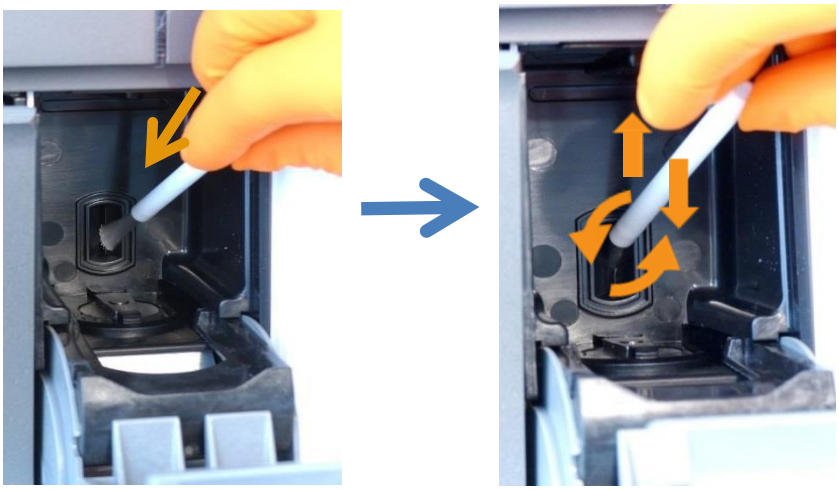


6. Wait 5 minutes
7. Moisten a lint-free cotton swab with 70% ethanol solution and wipe the plunger rods with that swab.

8. Repeat cleaning 2 times more by doing the steps 5,6 and 7.
9. Click Move Up (or Move Up All) in Plunger Maintenance dialog box so that plunger rod moves back up to its resting position
10. Click Close button to dismiss the Plunger Maintenance dialog box

4.9. Cleaning module PCR tube slot

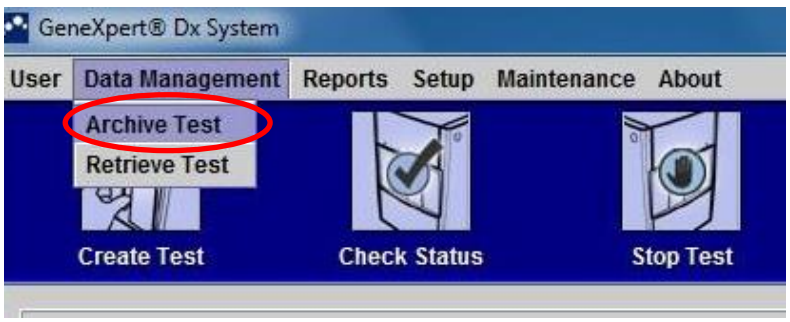
1. Remove any cartridge from the module
2. Insert the brush bristles completely in PCR slot. (Use one dry brush for one PCR slot)
3. Brush inside PCR slot with several up and down movements, twisting the brush between thumb and forefinger
4. Clean every module for at least 30 seconds
5. After cleaning, brushes are washed with 70%ethanol and keep dry for next time.



5. Archival of results

(Test data should be archived monthly or once in three months)

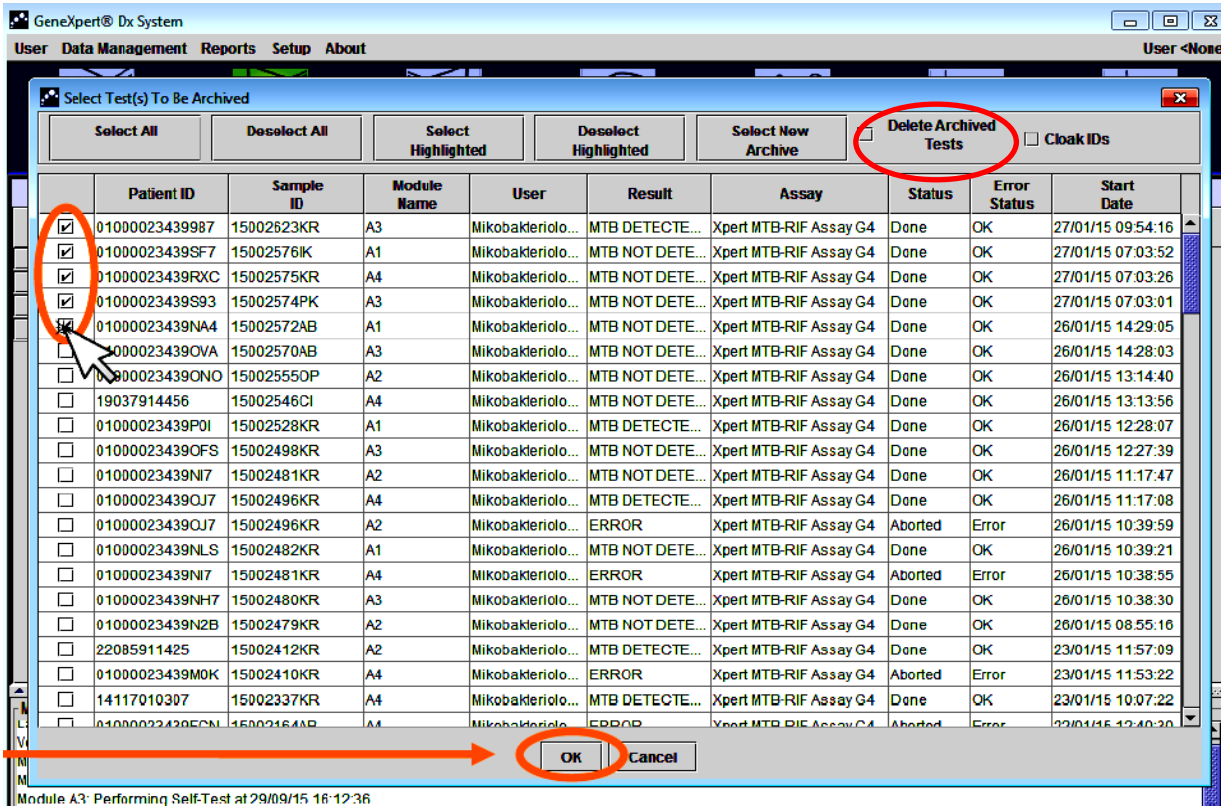
1. Click on the Data Management menu in the GeneXpert Dx System window



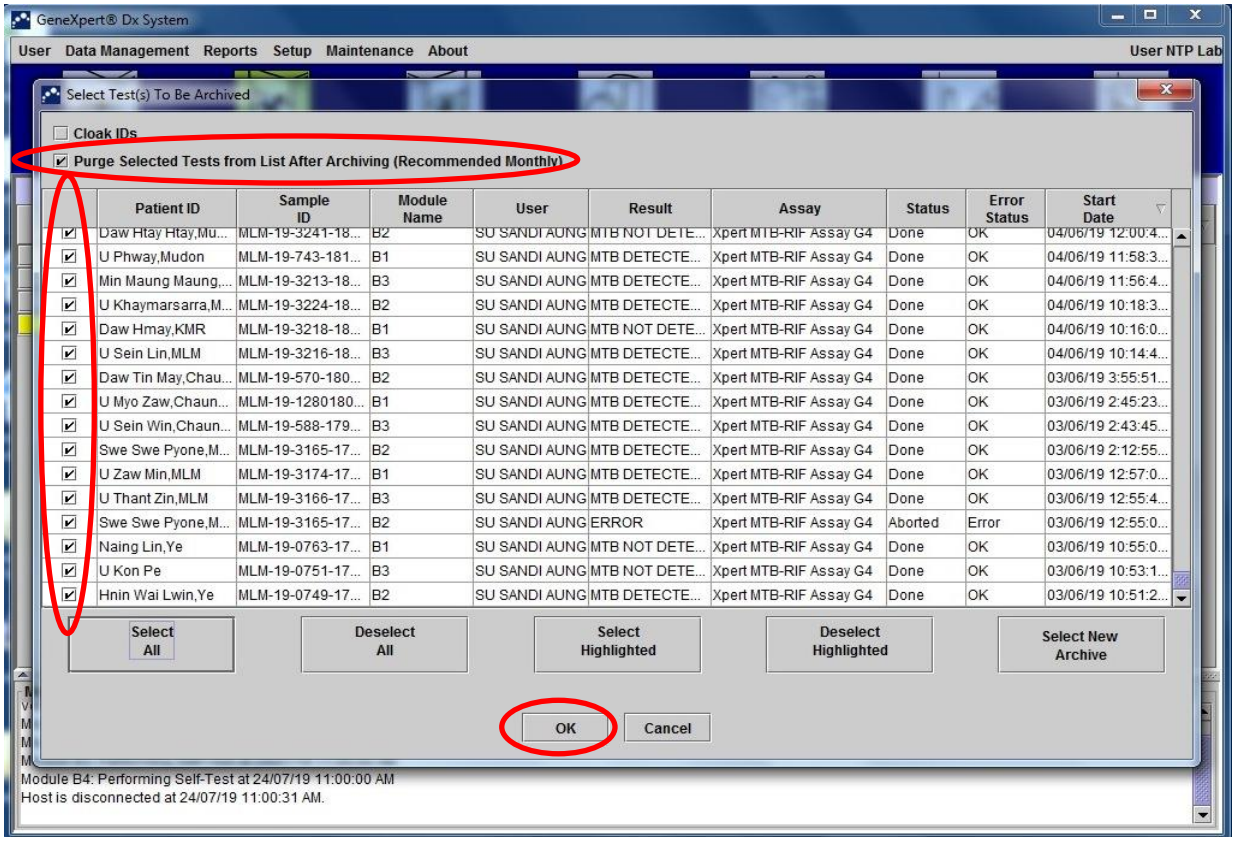
2. Click on “Archive test”. An archive test dialog box appears (see picture on next page)
3. Select the tests you want to archive when archive test dialog box appears

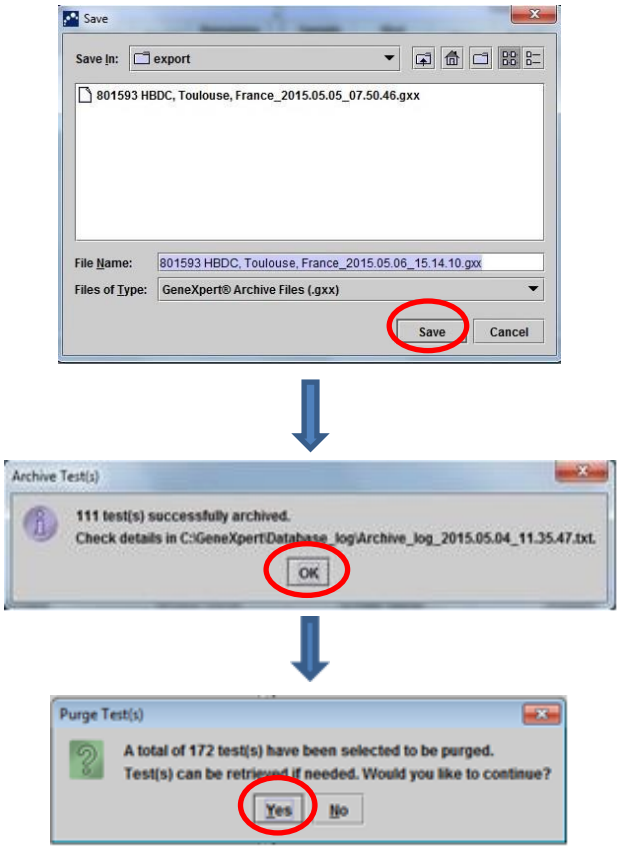
4. Tick “Delete Archived Test” in version 4.0 or Tick on “Purge Selected test on list after archiving” in version 4.6 and then click “OK” button

(You need to delete the data after its archiving. File name will be given automatically and proceed to do so. You can change the name)



(OR)



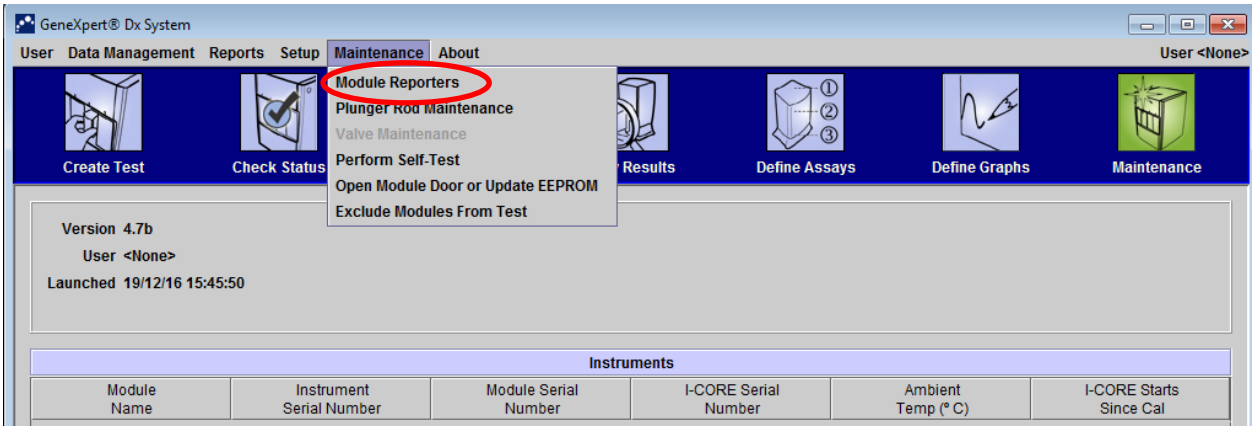


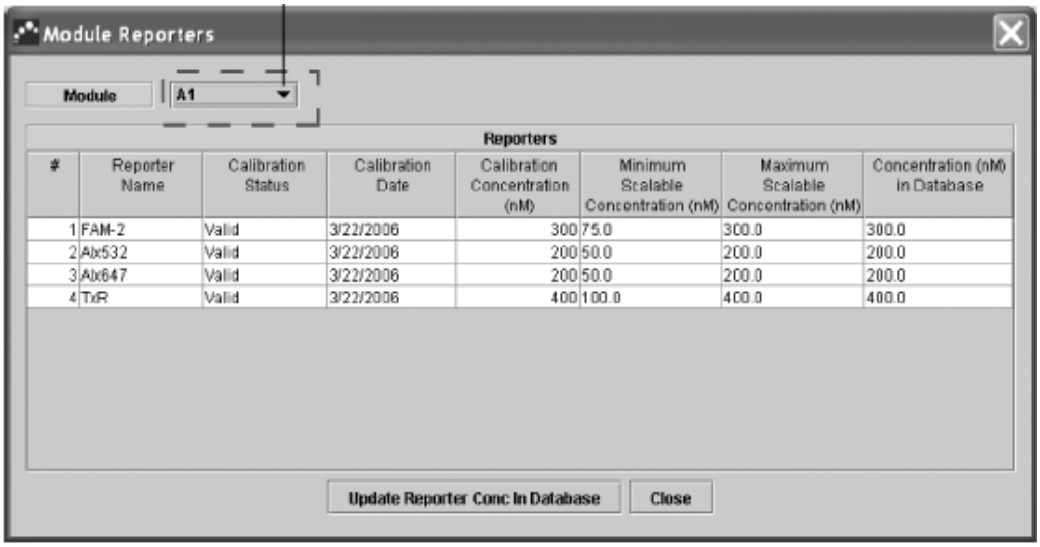
6. Xpert Check of modules (Calibration)

Calibration with Xpert® Check required after a year (annual calibration) or 2,000 runs/module
Full maintenance process must be done before performing Xpert® Check.

Calibration can be done in two mode of operation. There are ONLINE MODE (Internet Connected Systems) in which Xpert Check Code is automatically download and OFFLINE MODE (Non-Internet Connected Systems) in which Xpert Check code has to be manually loaded

1. In the GeneXpert Dx System window, click on “Maintenance”
2. And then click on “Module Reporters”. (Module Reporters window appear and last date of calibration for every module can be seen)

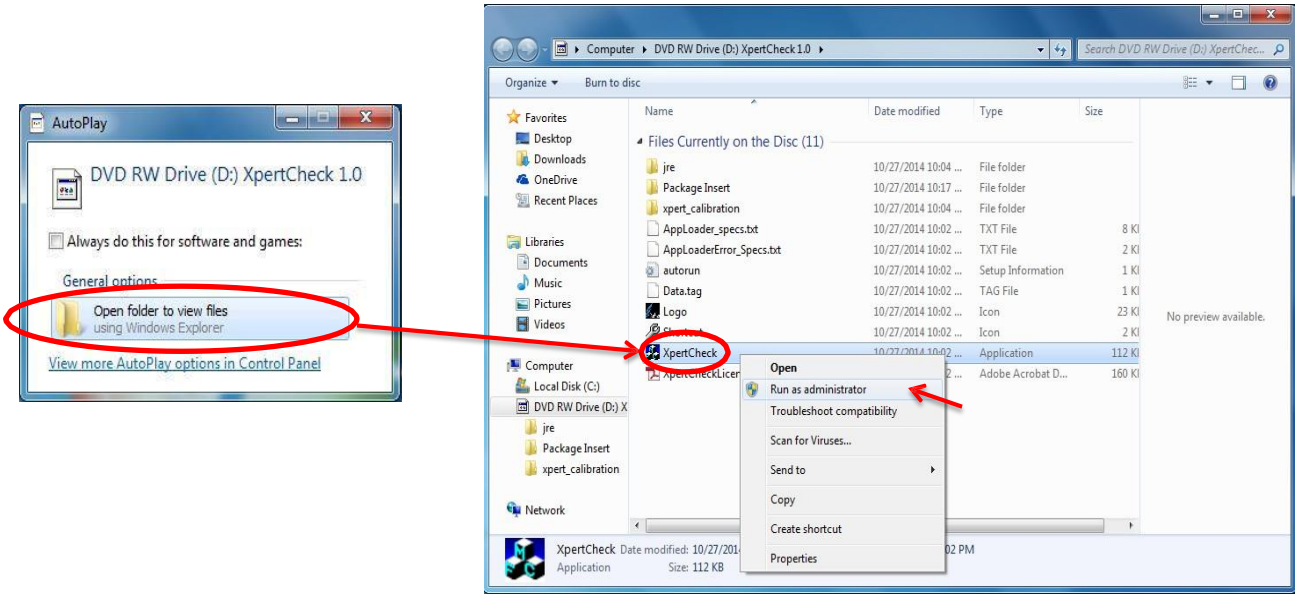




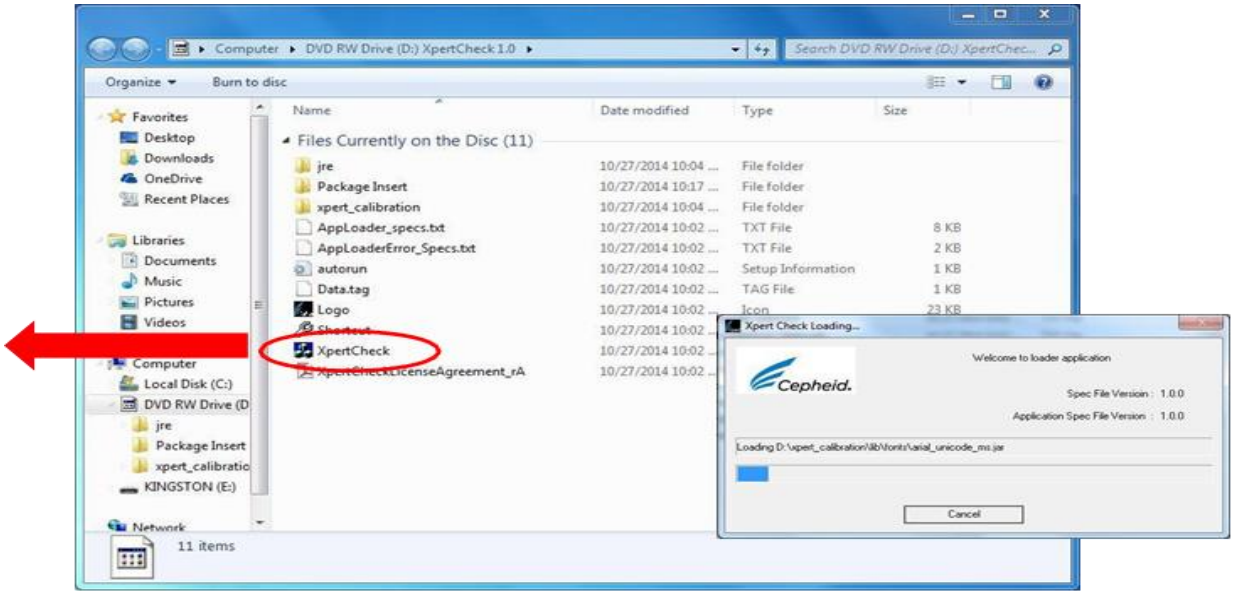
Note: If one or more modules are problem, contact customer support via hotline number to arrange for a date of sending: +33.5.63.82.53.19 or email address: support@cepheideurope.fr. It is necessary to indicate the serial number of the instrument.

6.1. The Xpert Check Process (Calibration Process)

1. Close the GeneXpert DX software
2. Put CD (CD1) on the D drive of your computer
3. "Autoplay" window appears, and then select "open folder to view files"
4. Right click on the application "XpertCheck" and select "Run as administrator

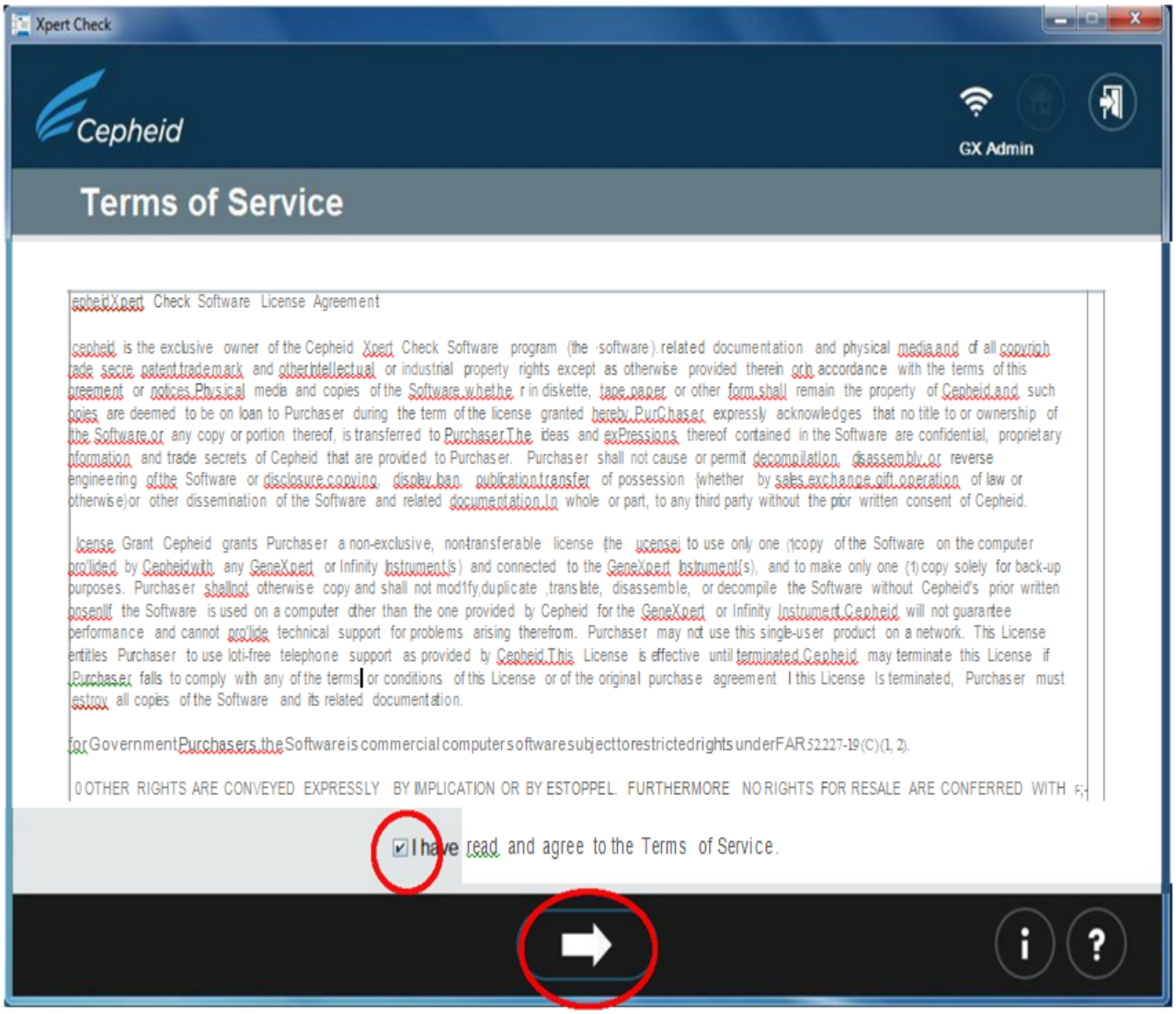


(The XpertCheck software will be installed on the computer hard drive C automatically. A shortcut "XpertCheck" will then appear on the GX computer desktop)

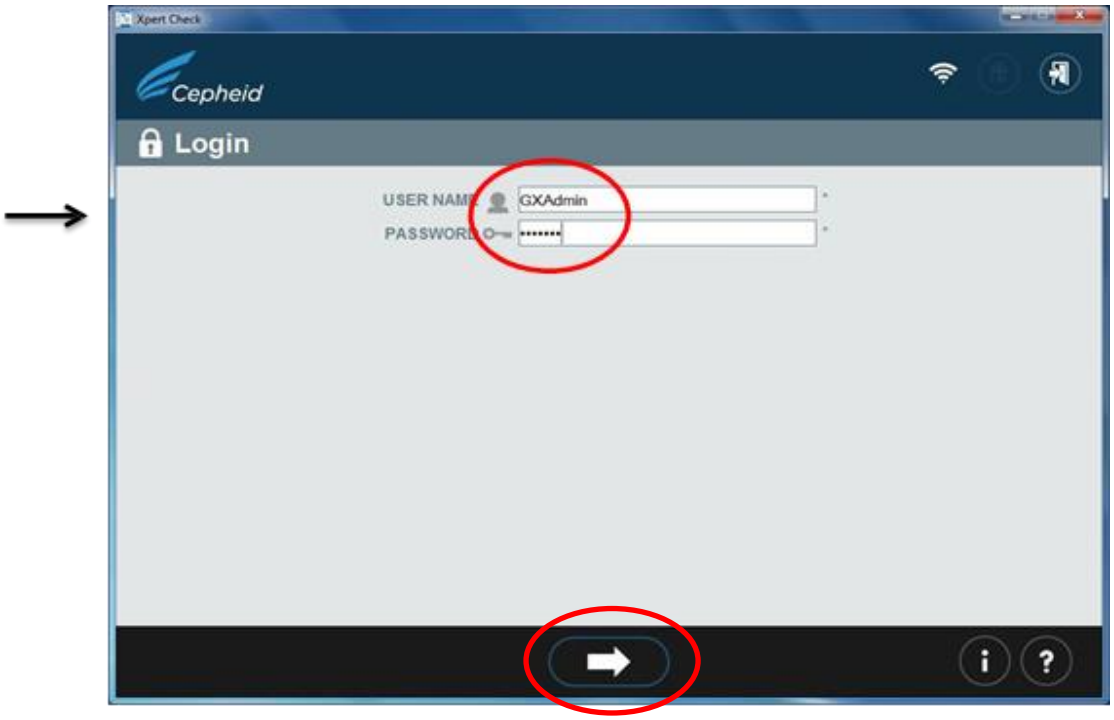


5. Double click on XpertCheck icon on the GX computer desktop

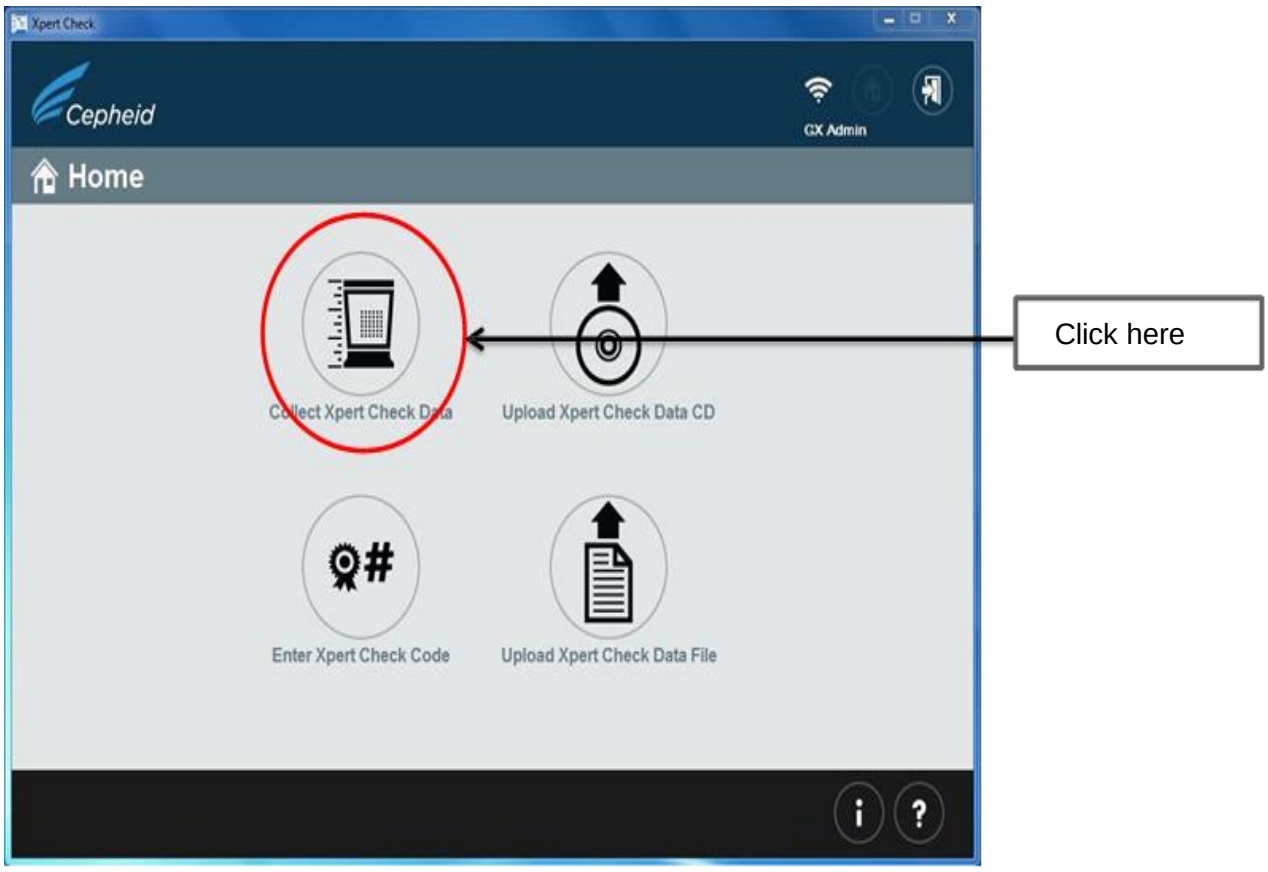
6. Accept the terms of service by ticking “I have read and agree to the Terms of Service” and click on the arrow

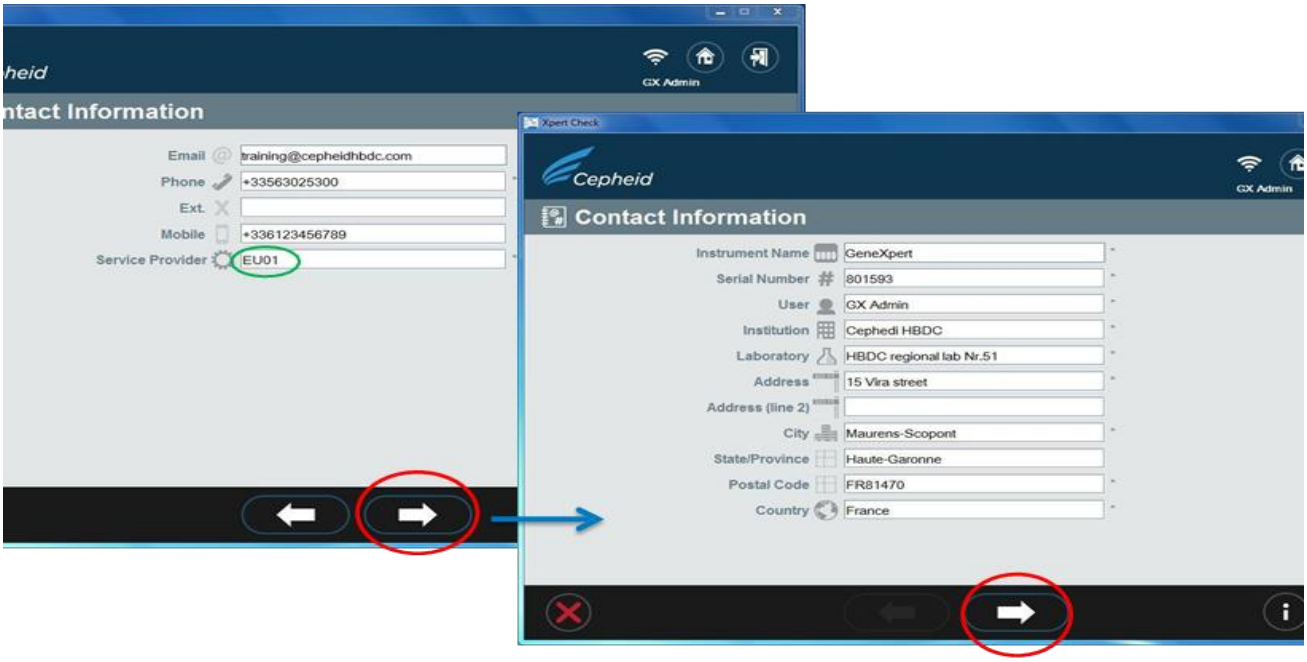


7. Log on to the software using your user name and password and then click on the arrow

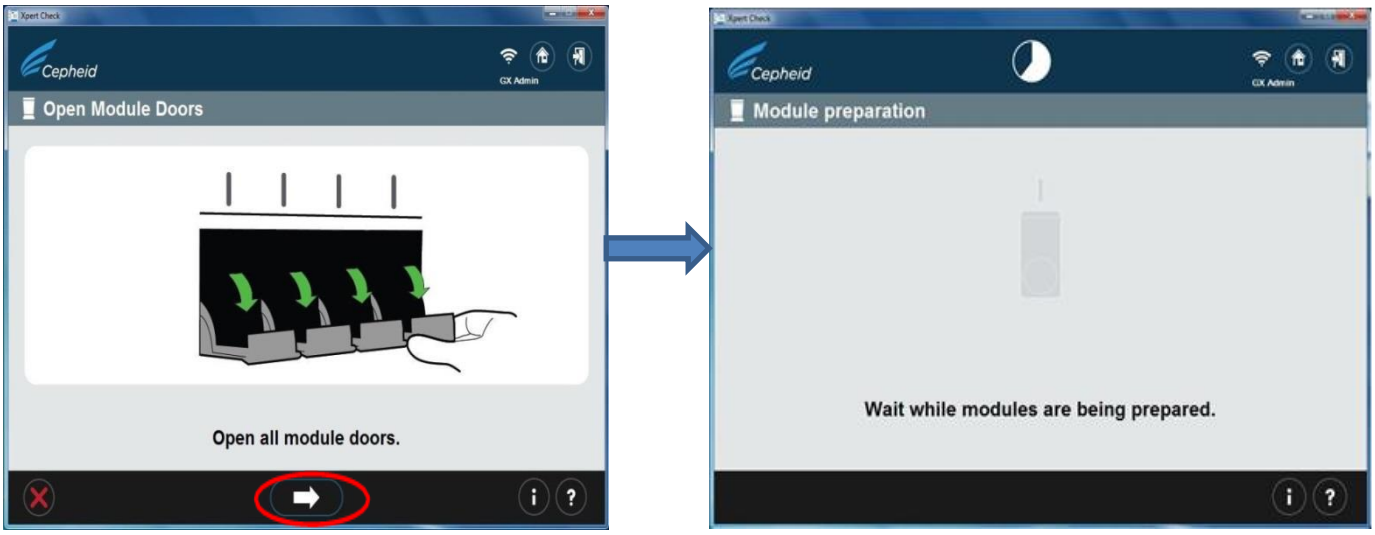


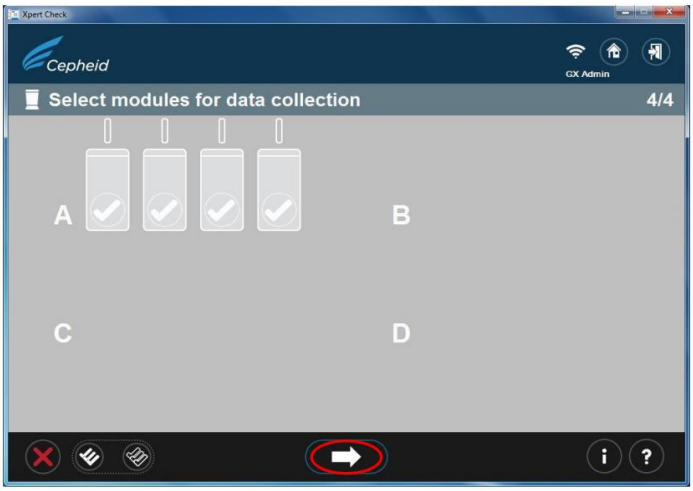
8. Click on "collect Xpert Check data" and then fill in two dialog boxes of "Contact Information" one after one by clicking on the arrow. **(Service Provider code for Myanmar: ME02)**





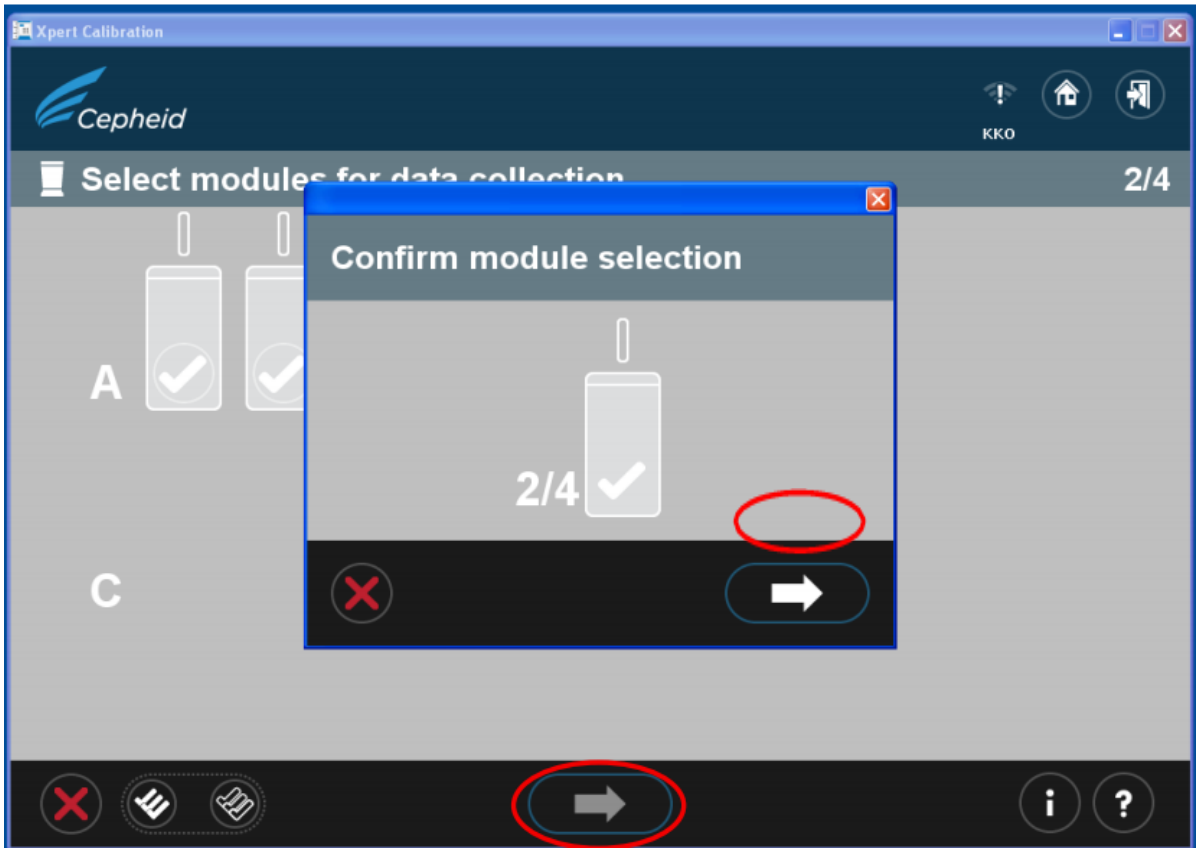
9. Open all module door and then click on the arrow. (Check that lights on modules turn green)





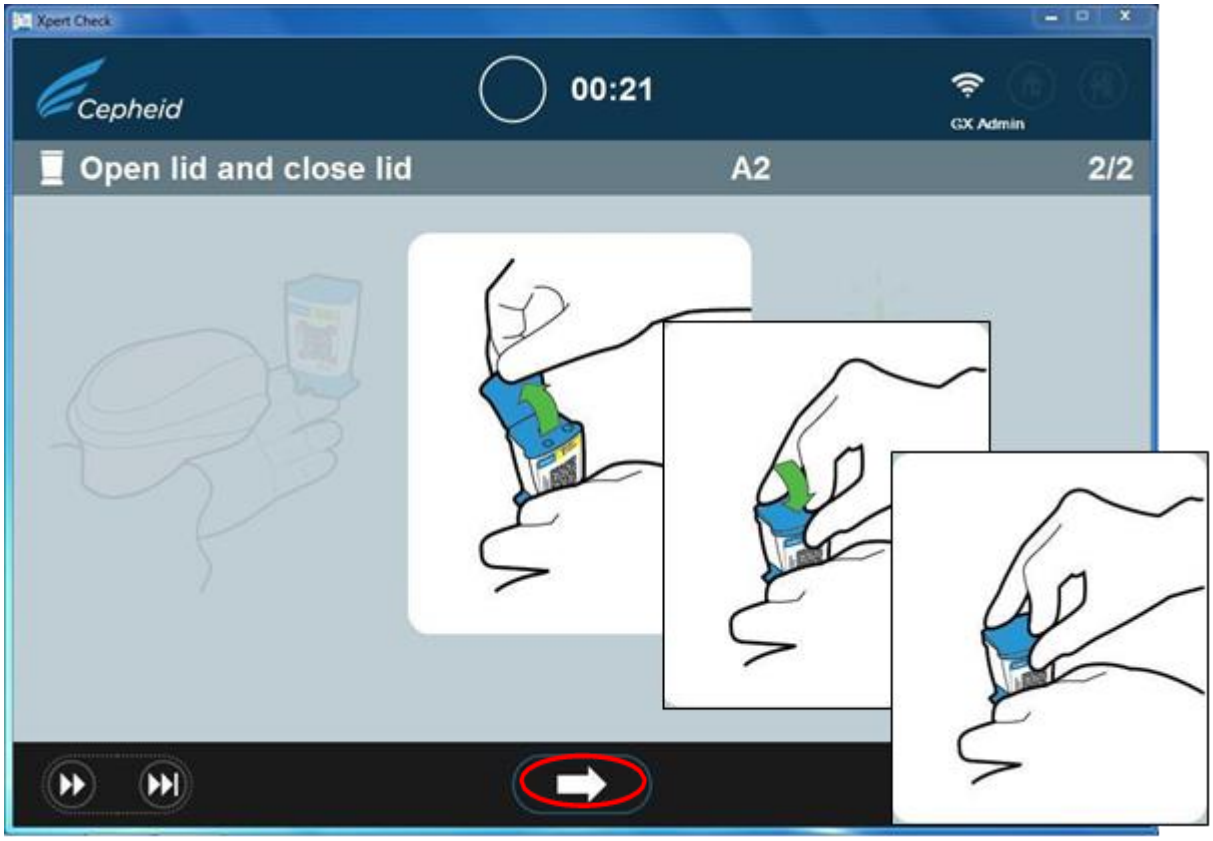
(All modules are selected by default)
(If you want to calibrate one module only, click on the other modules to exclude them and then click on the arrow)

10. “Confirm modules selection dialog box” will appears and then click on the arrow.

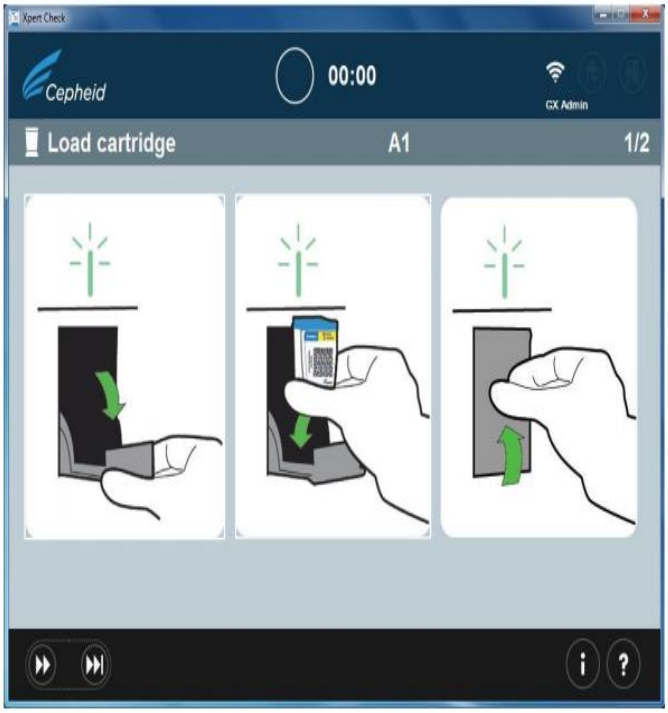


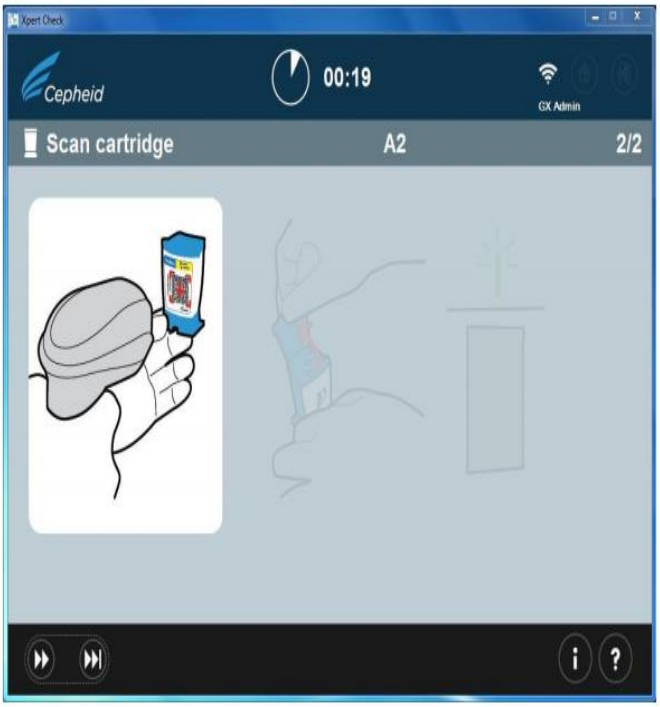
11. Scan Xpert Check cartridge barcode. (Verify that the “Caps Lock” key is not activated)

12. Open and close the lid to vent cartridge and then click on arrow

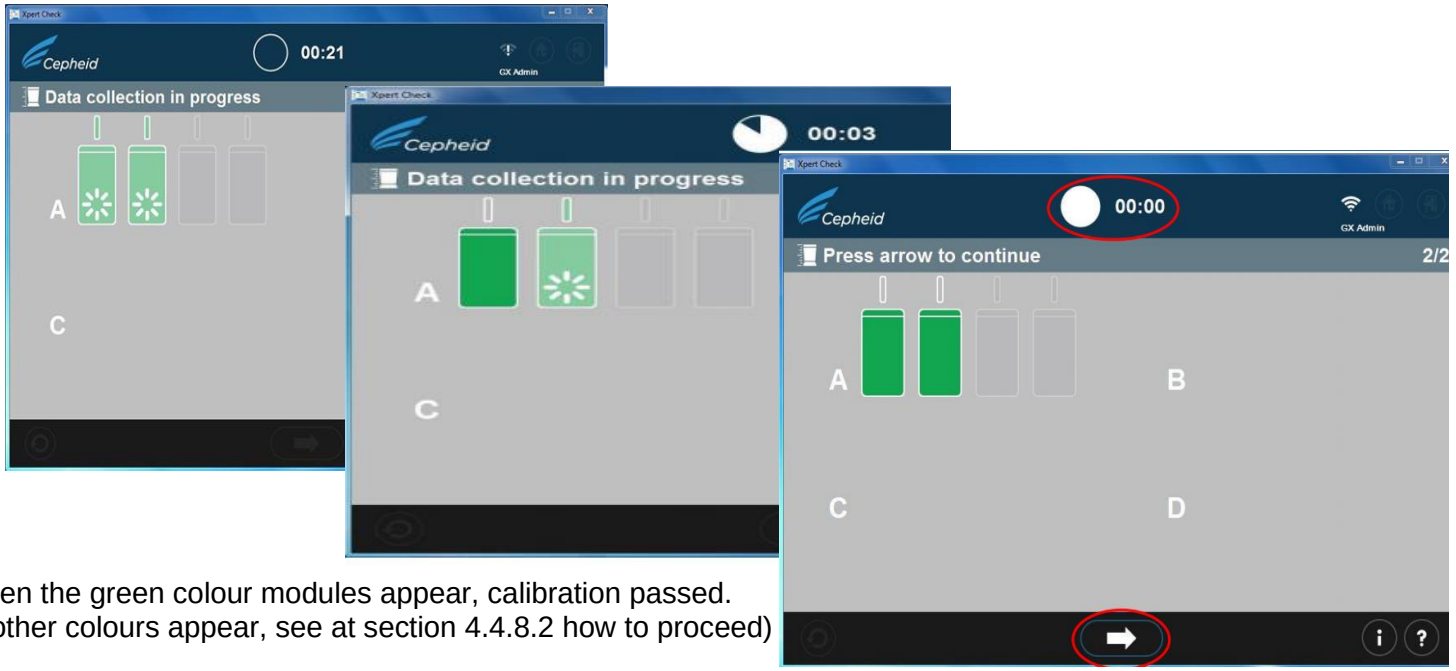


13. Load cartridge in module with blinking green light and close door and continue same process with other modules to calibrate





14. Check in progress will last 21 min. When completed, click on the arrow
(Do not exit the software while data collection is in progress!)

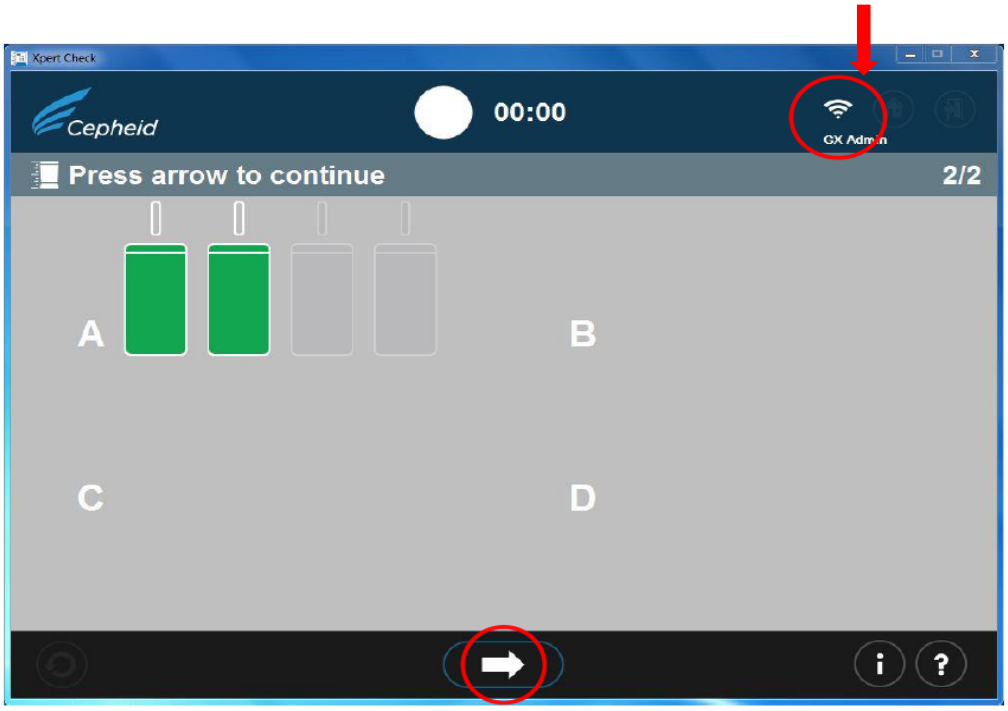


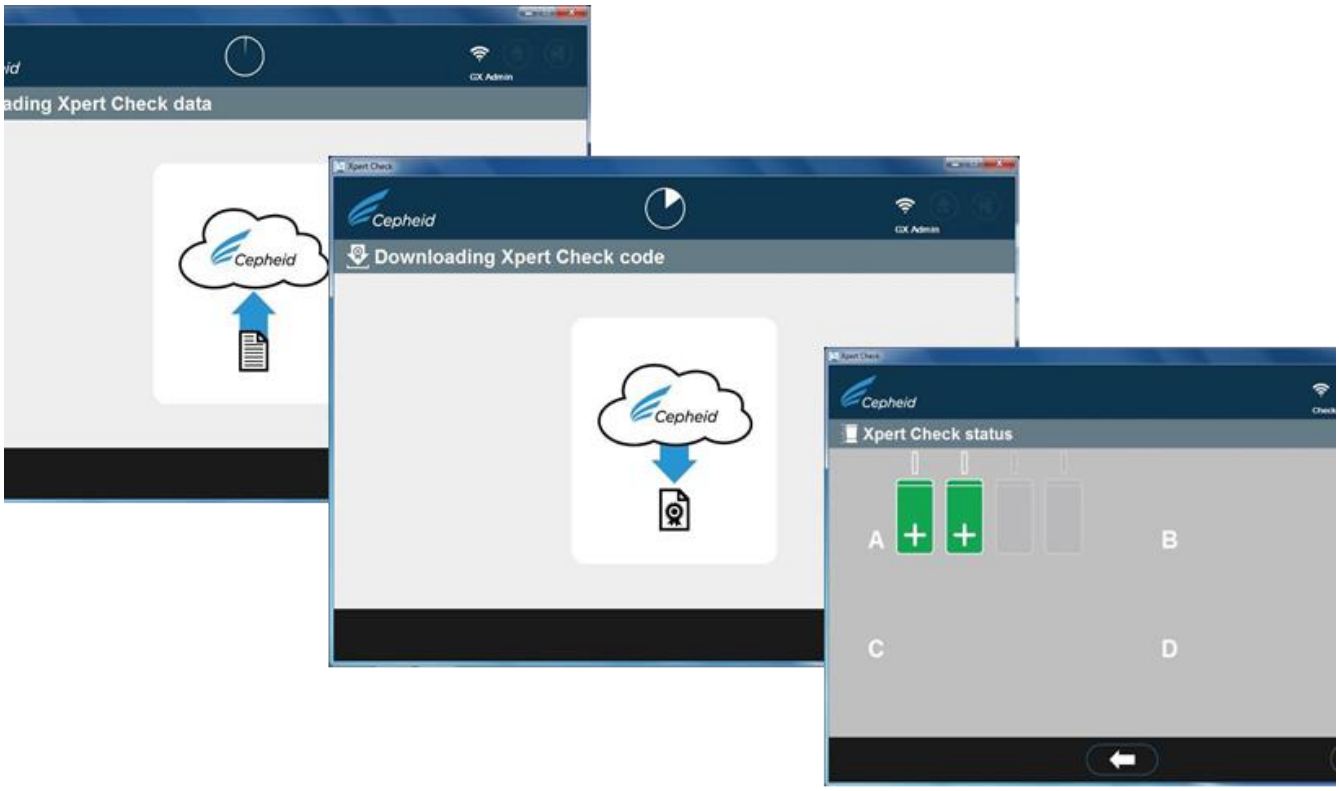
When the green colour modules appear, calibration passed.
(If other colours appear, see at section 4.4.8.2 how to proceed)

6.1.1. Online data processing (Online Mode)!

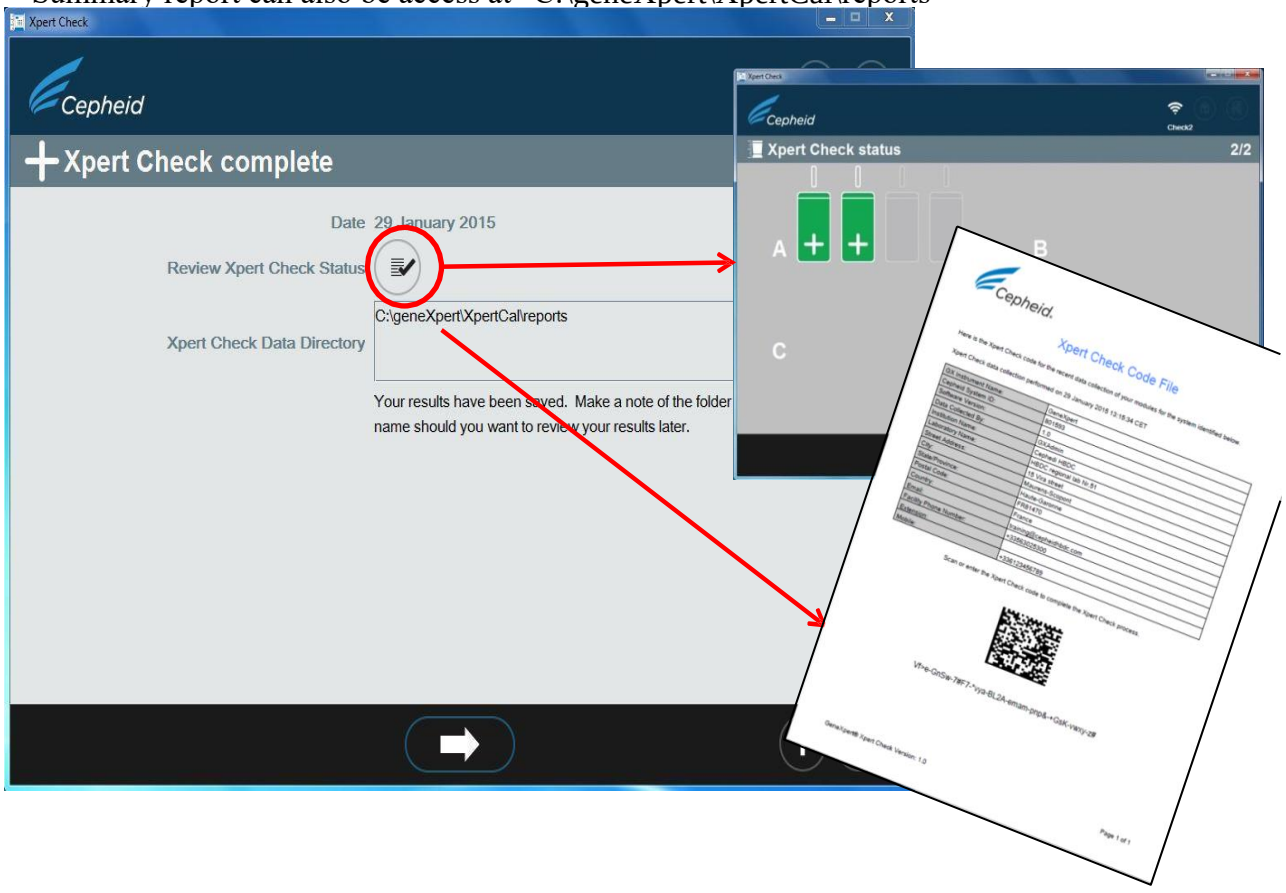
(The Genexpert must have access to a functional internet connection)

1. Check the connection icon and then click on arrow (Xpert Check data uploaded, Check code downloaded and applied automatically. A screen appears very briefly: Modules marked with A +)

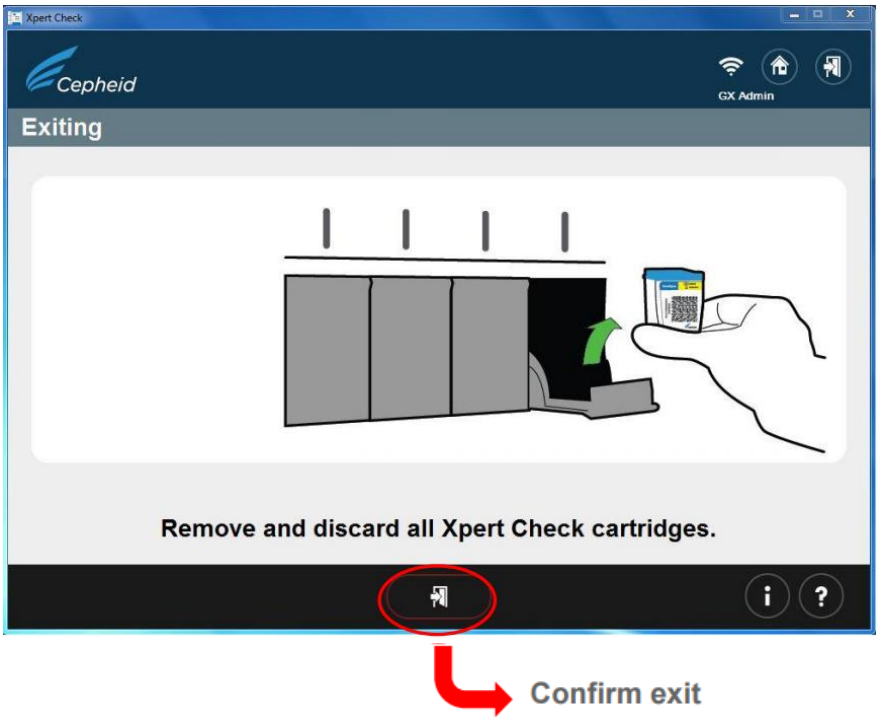




2. Review the Xpert check status by clicking on "Review Xpert Check status icon " Summary report can also be access at "C:\geneXpert\XpertCal\reports"



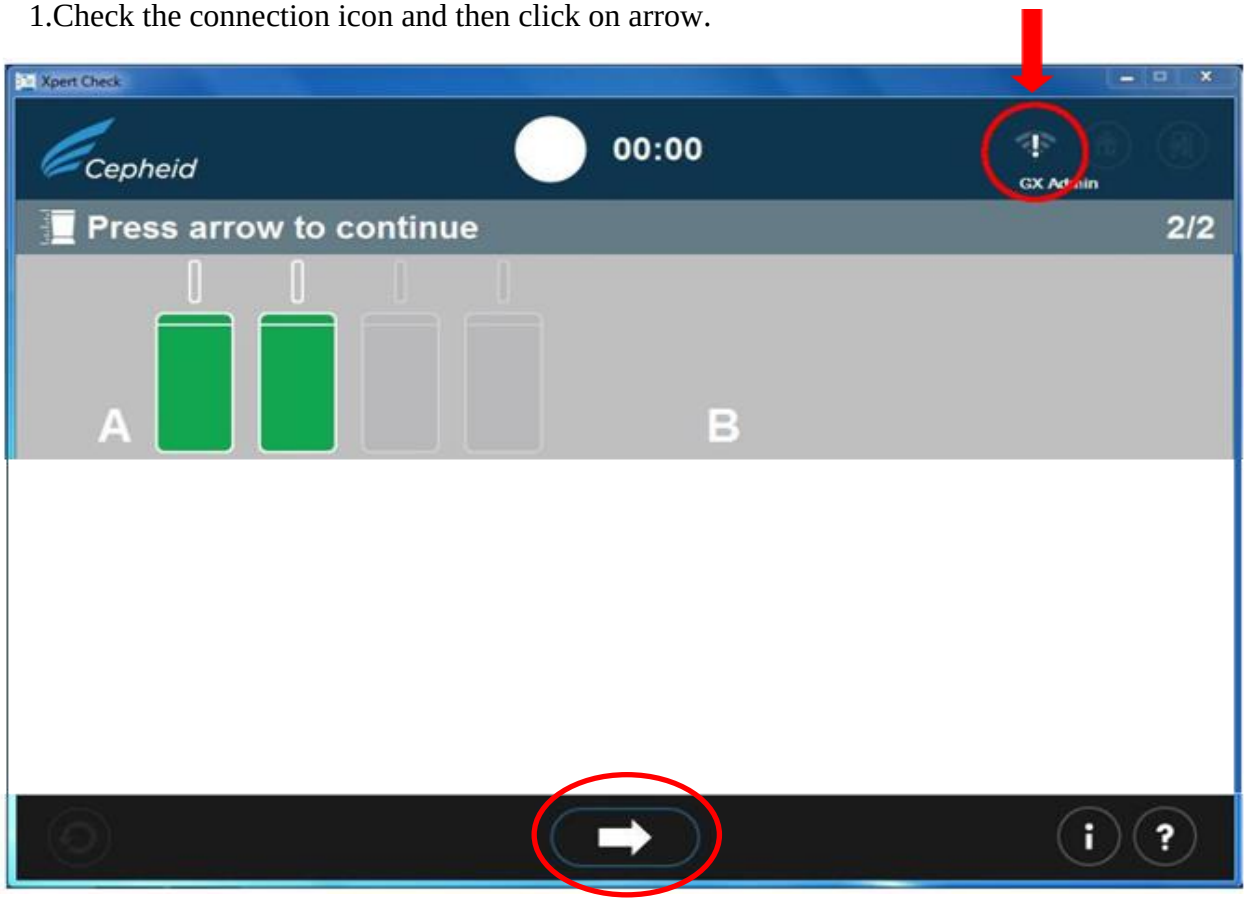
3. Remove and discard all Xpert Check cartridges and then click confirm exit button. Then, the Xpert Check software window shuts down



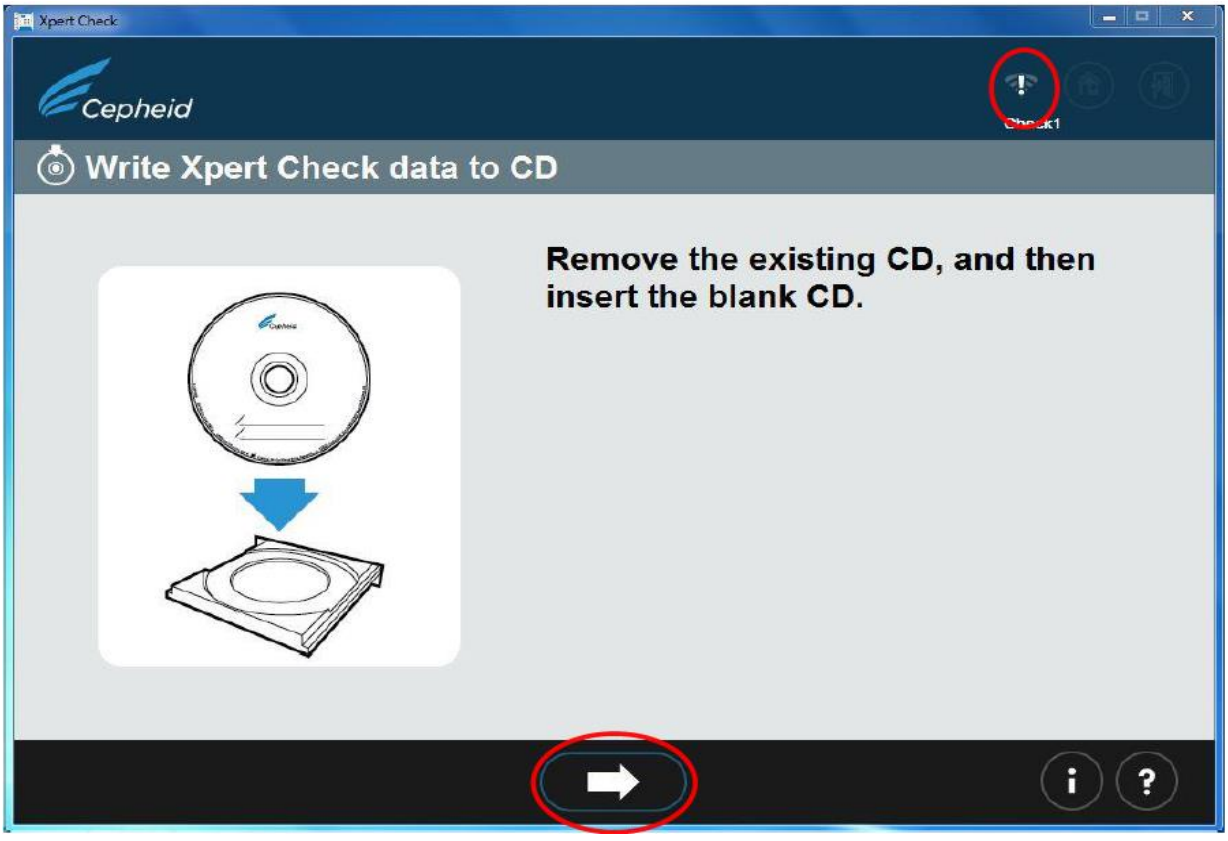
4. After an online Xpert Check, the XpertCheck code and summary report gets downloaded

6.1.2. Offline data processing (Offline Mode)!

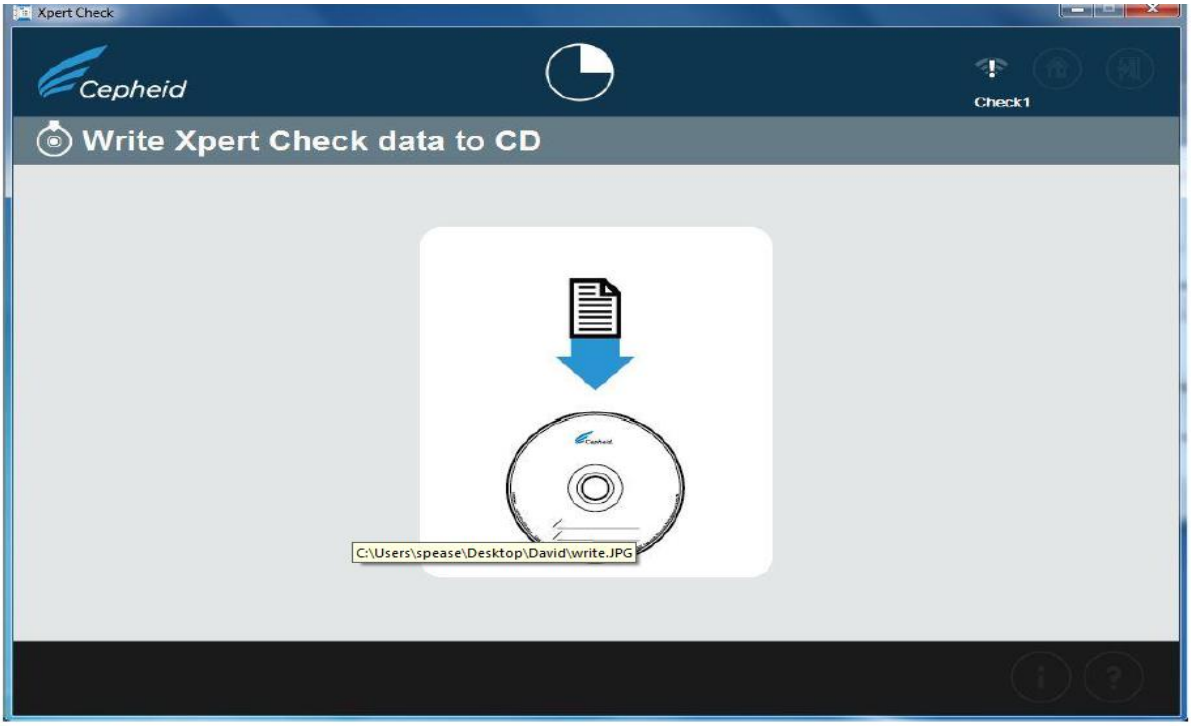
1.Check the connection icon and then click on arrow.



2. Remove the existing CD (CD 1), insert the blank CD (CD 2) and then click on arrow

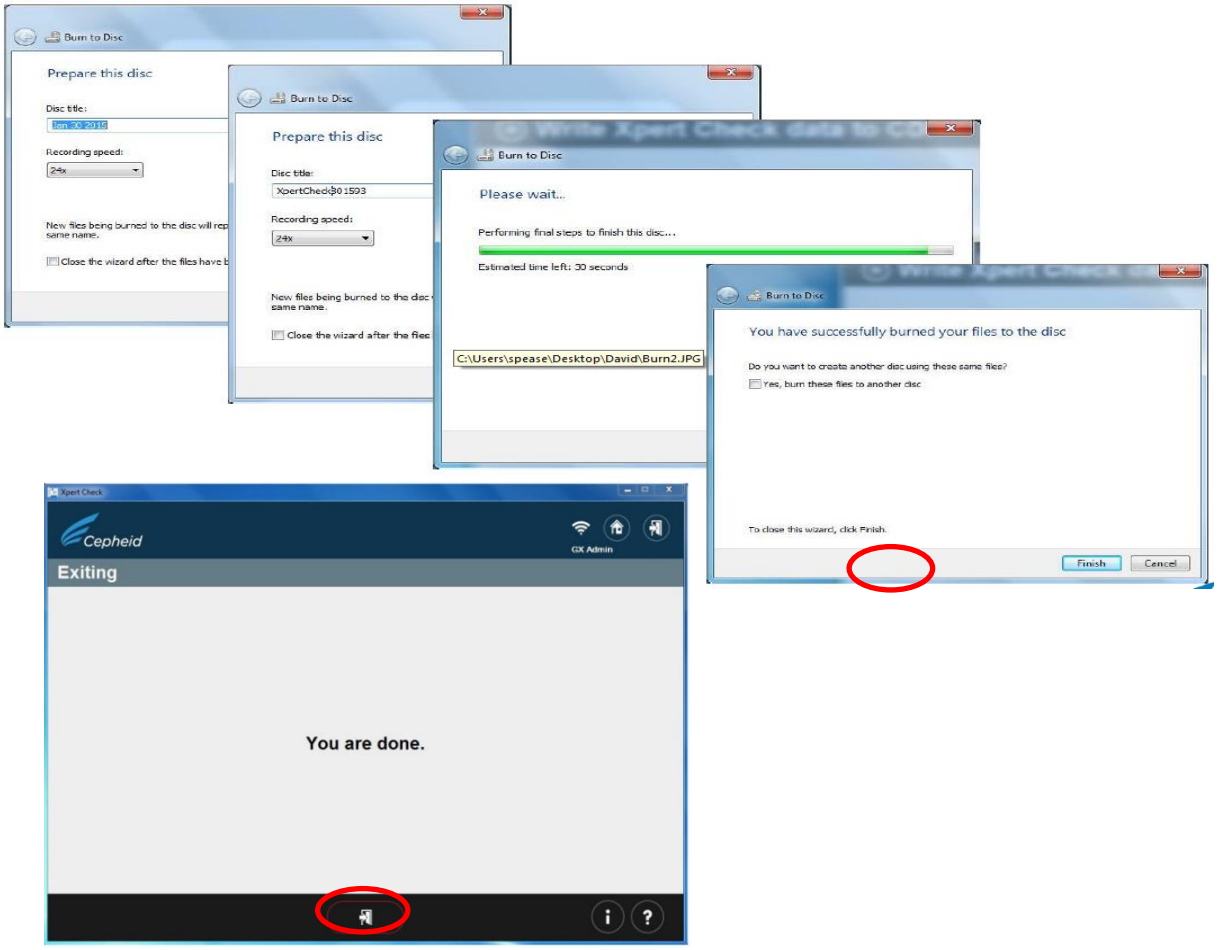


3. The machine will automatically write Xpert Check data to CD



NOTE: the .gxc file can be found in C:/GeneXpert/XpertCal

4. Click Buring the CD



5. Identify your CD with a permanent marker with Date, GX serial number, and Name of lab.
6. Email .gxc file from CD to Cepheid by email to xpertcal.dubai@cepheid.com
   (NOTE: the .gxc file can be found in C:/GeneXpert/XpertCal. While waiting for the Check code from Cepheid, feel free to use the system in the meantime)
7. Print the pdf file, which was returned the Check code by email from Cepheid.
   If you are running Assays, please wait until they are finished to scan the Xpert Check code
   (NOTE: Check code must be entered within 45 days after performing the Xpert Check !!!)

Cepheid.

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 29 January 2015 14:50:39 CET

GX Instrument Name:	GeneXpert
Cepheid System ID:	801593
Software Version:	1.0
Data Collected By:	GXAdmin
Institution Name:	Cepheid HBDC
Laboratory Name:	HBDC regional lab Nr.51
Street Address:	15 Vira street
City:	Maurens-Scopont
State/Province:	Haute-Garonne
Postal Code:	FR81470
Country:	France
Email:	training@cepheidhbdc.com
Facility Phone Number:	+33563025300
Extension:	
Mobile:	+336123456789

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

Vam&-3Dbh-FpNe-HNHc-A=Sb-qgbm-pnpC-p2eM-xwxy-z#

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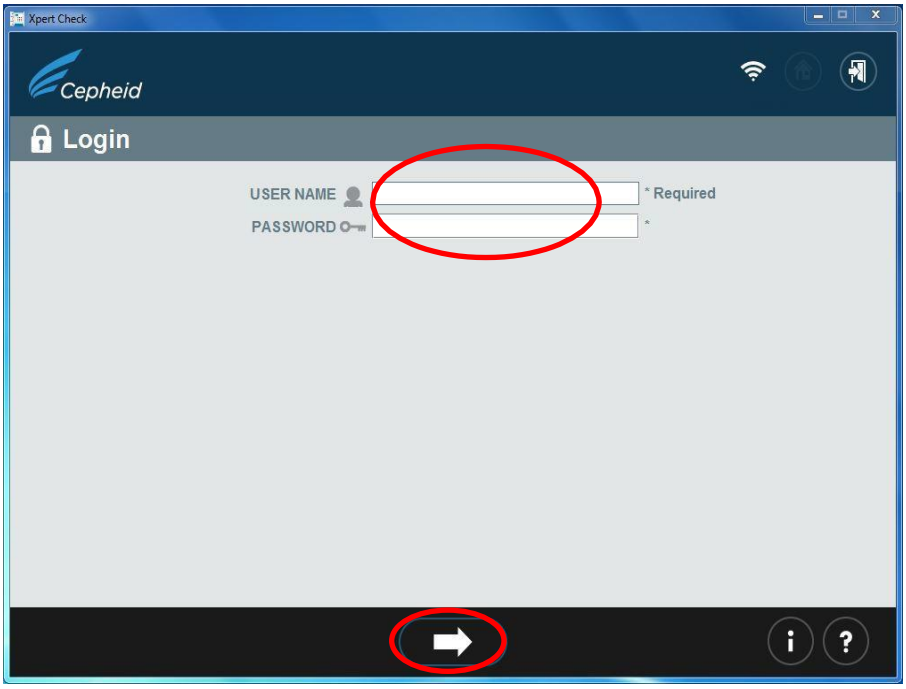
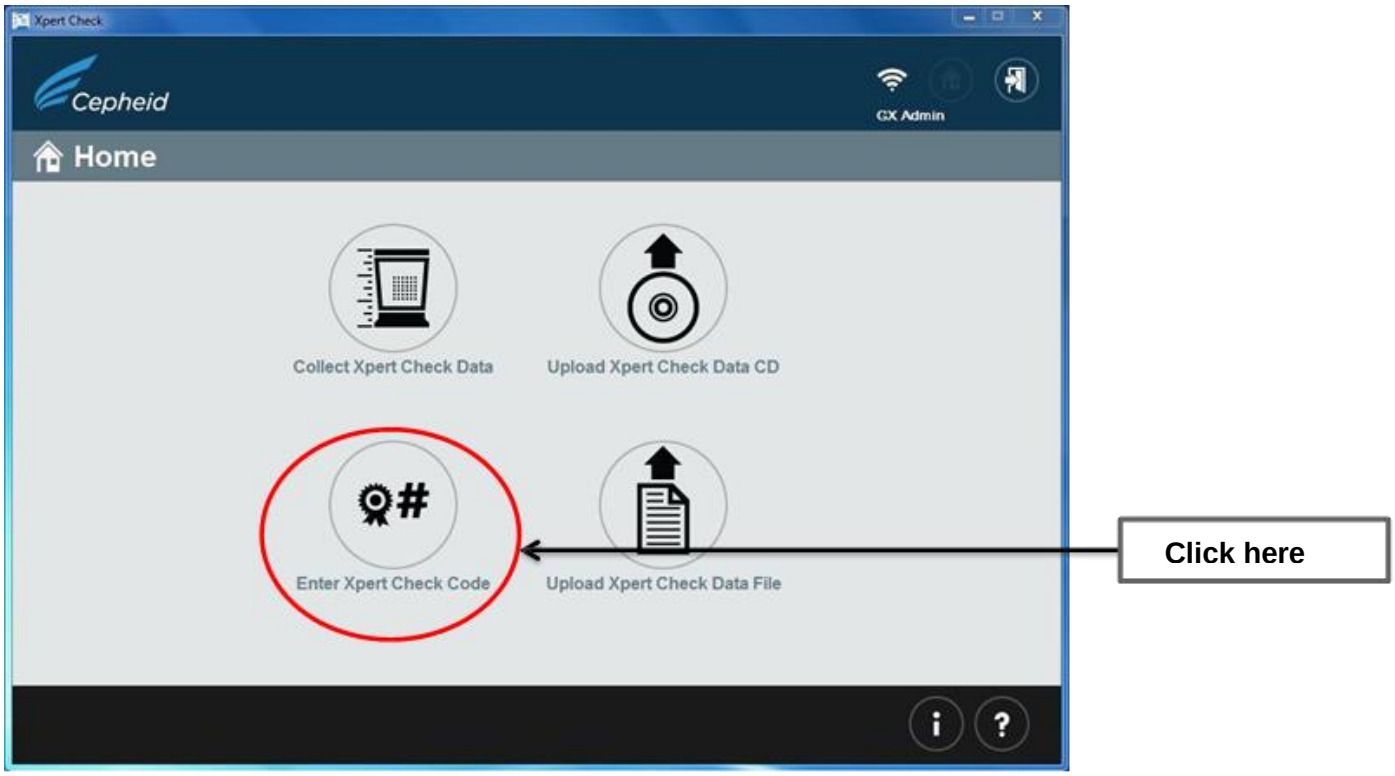
8. Close the GeneXpert DX software
9. Double click on the XpertCheck icon to open the Xpert Check Software 

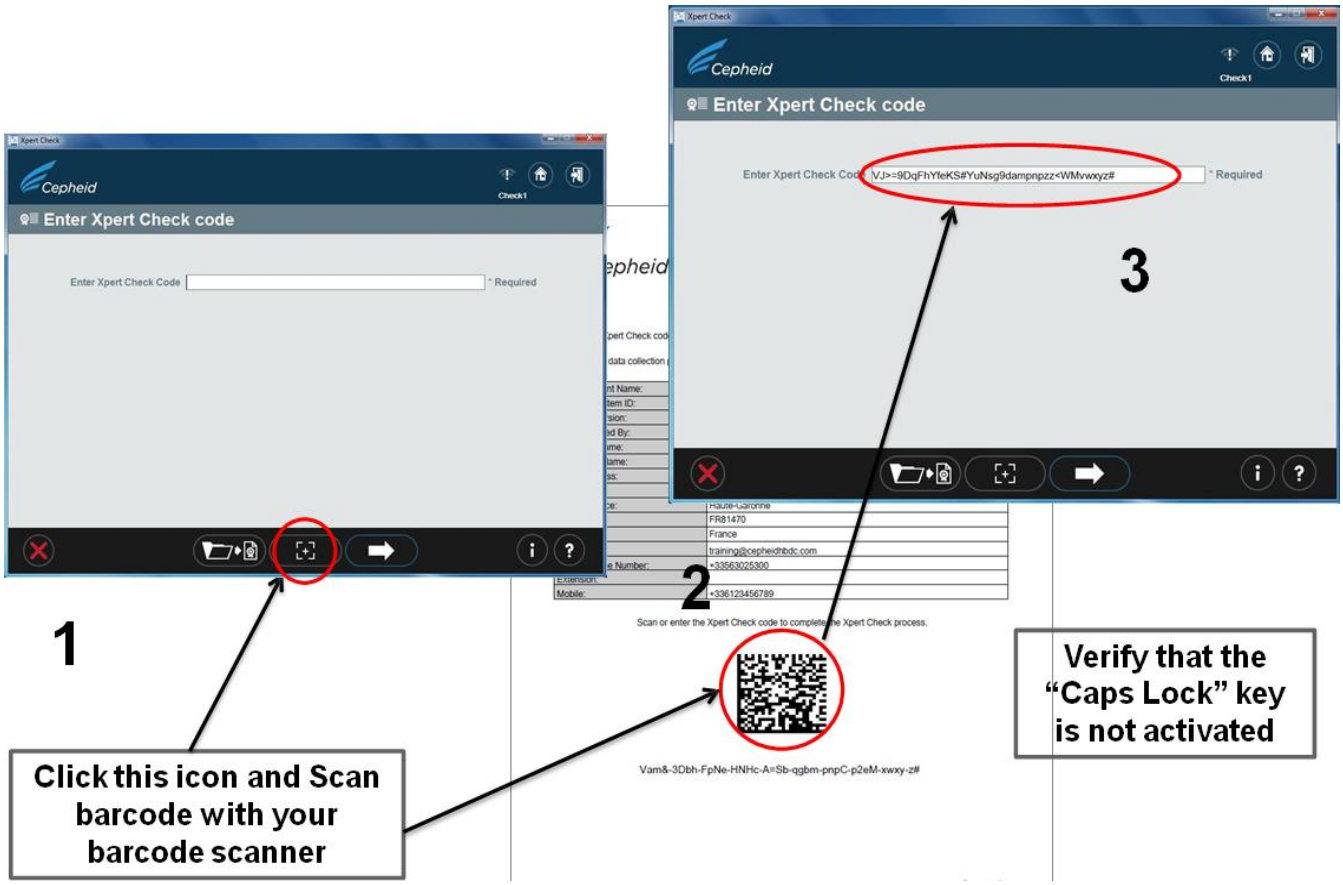
10. Log on to the software using your user name and password and then click on the arrow.If you do not have any access, you first need to create a username and password on the geneXpert software refer to page13.



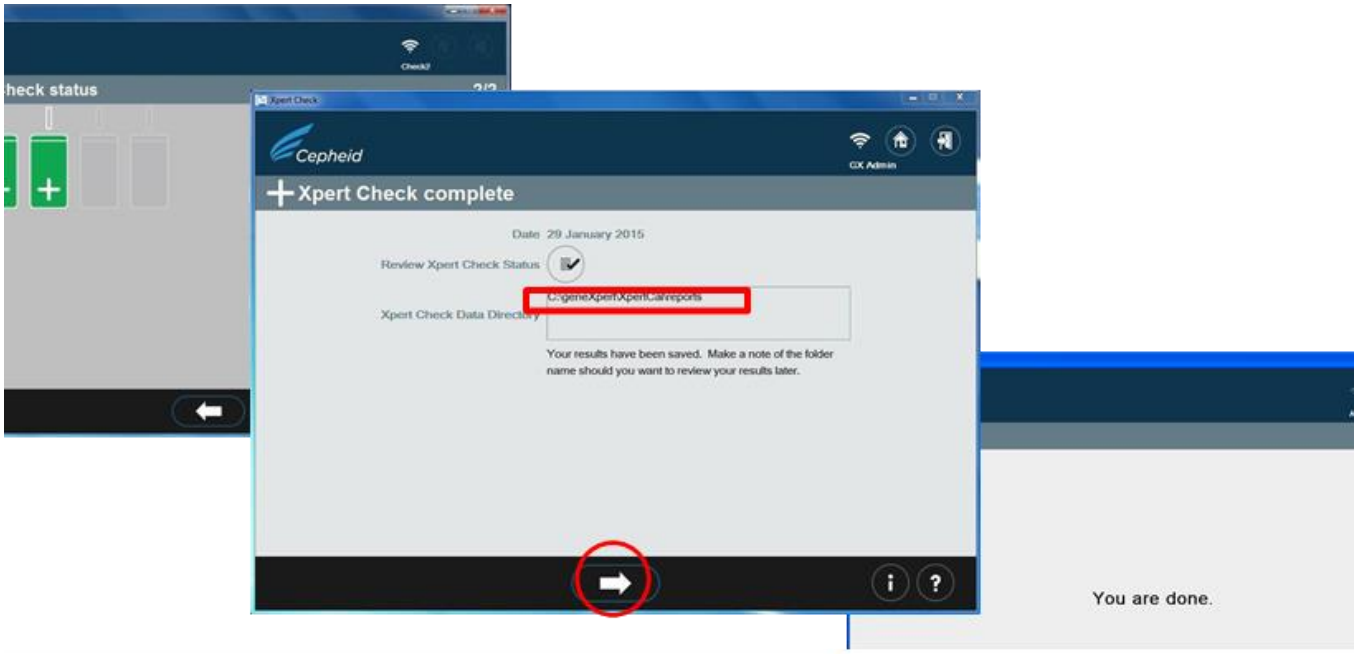
11. Click on Enter Xpert Check Code



12. Scan the barcode on Xpert Check file with the barcode scanner.



A screen appears very briefly: Modules marked with A +



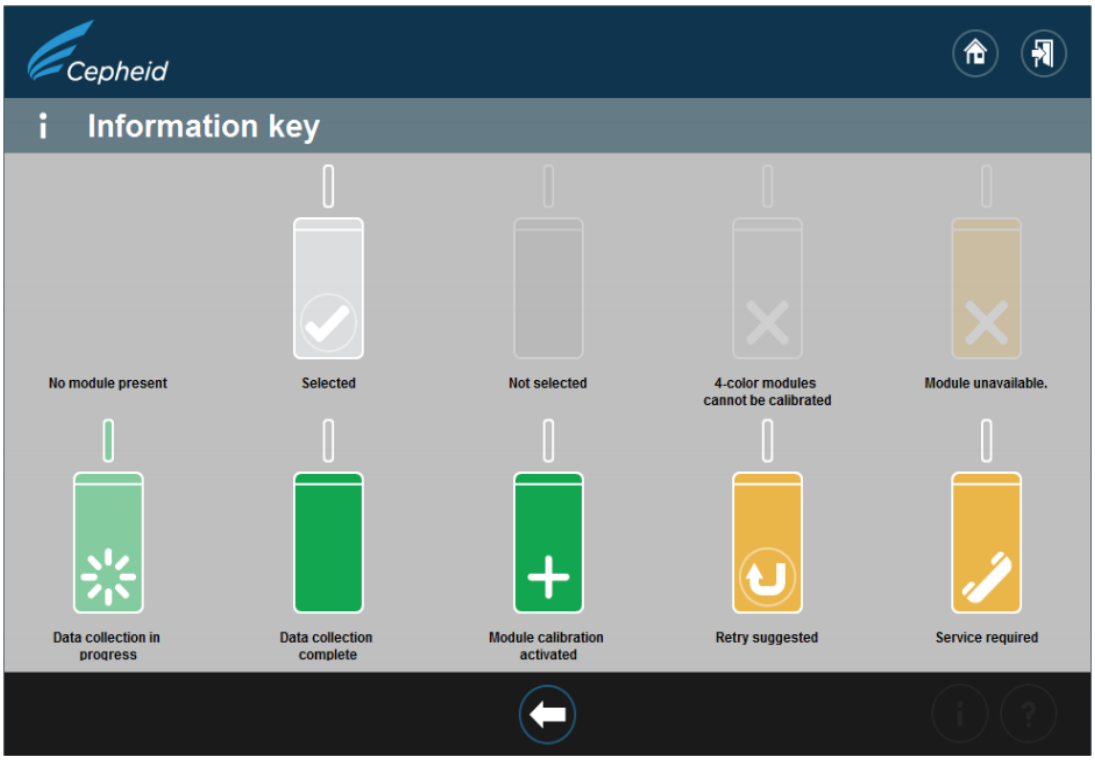
Code is applied and Xpert Check is complete

Summary report will be available in C:\GeneXpert\Xpertcal\Reports

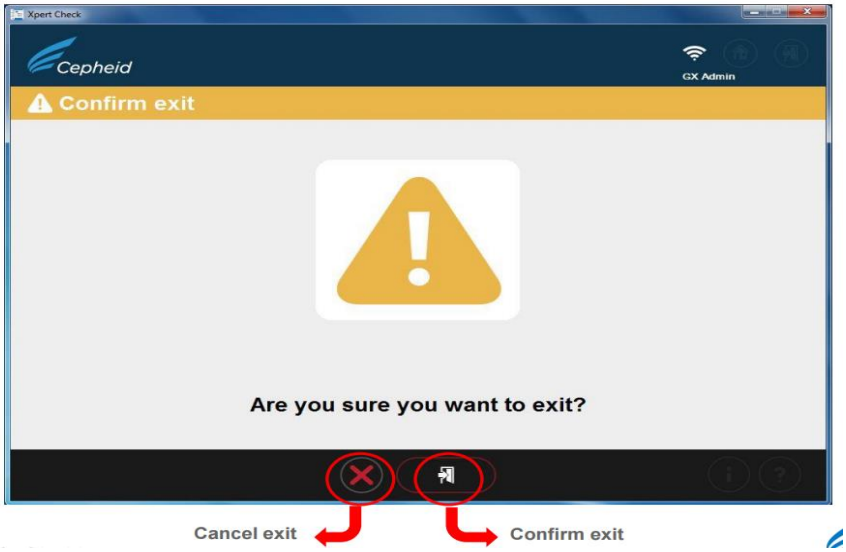
(Activation code must be scanned through the Xpert-check software within 45 days after the Xpert-check has been complete. Please not that after 45 days, the activation code expires and Xpert-check will have to be run again.)

6.2. Xpert Check Information Key

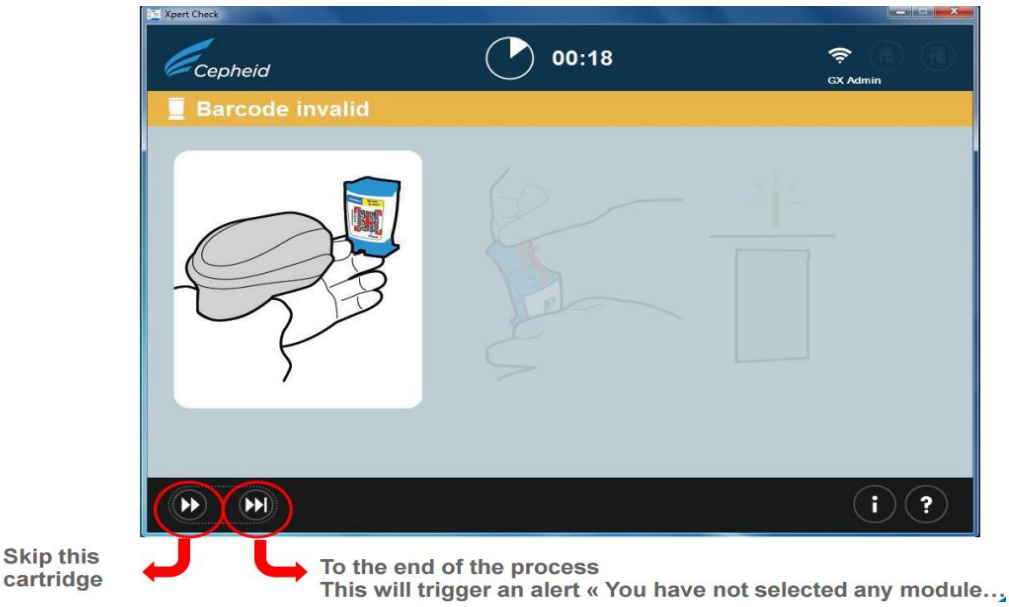
(1) Alert figure for calibration status



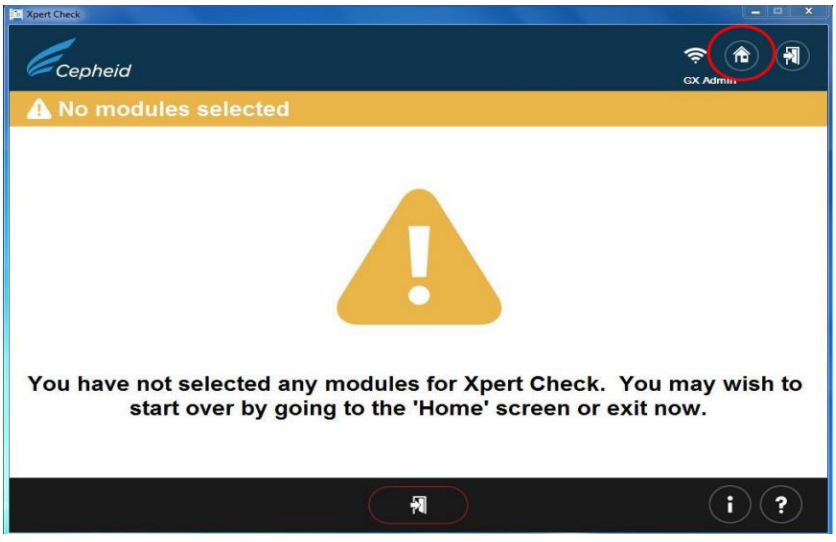
(2) Involuntary exit



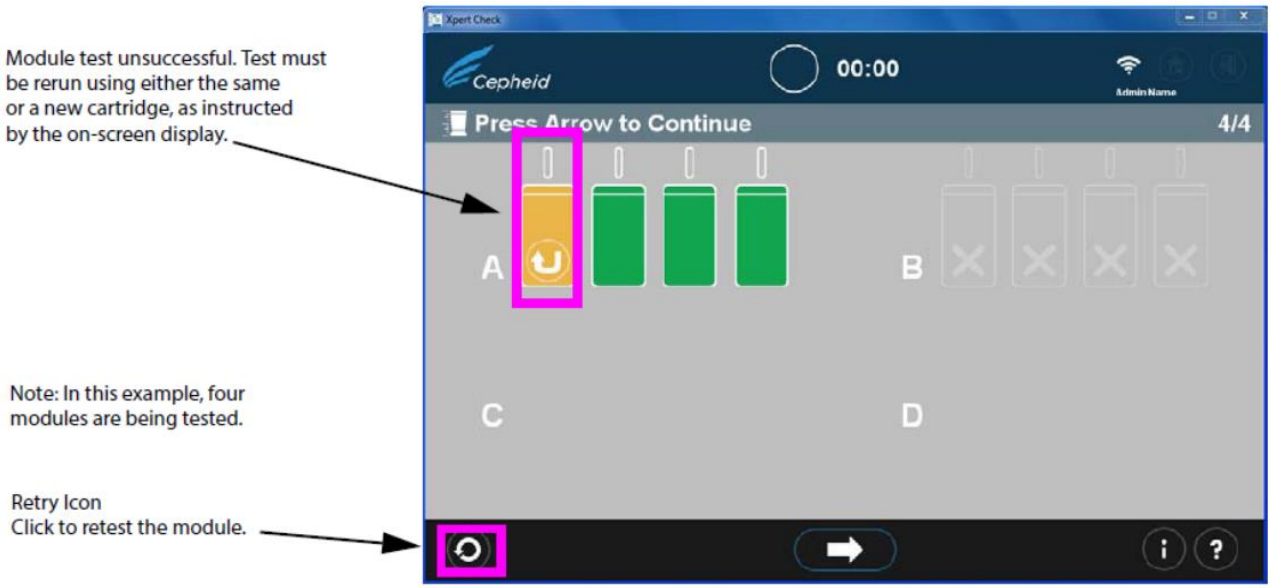
(3) Invalid Barcode



(4) Barcode scanning triggered and skipped



(5) Module test unsuccessful

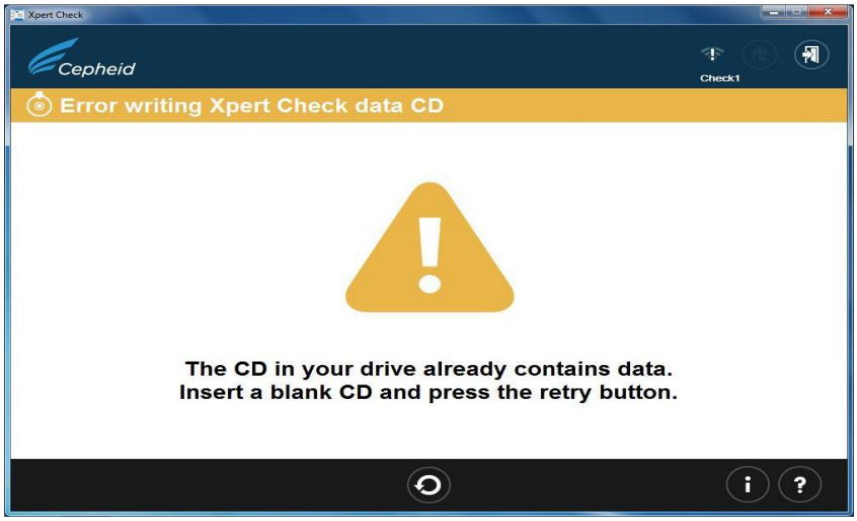


"Retry with the same cartridge": A message may appear telling you to vent the cartridge, rescan it, and put
it back in the module.
"Retry with a new cartridge": If the cartridge was defective, or had already been used, you will be asked to
scan a new cartridge.

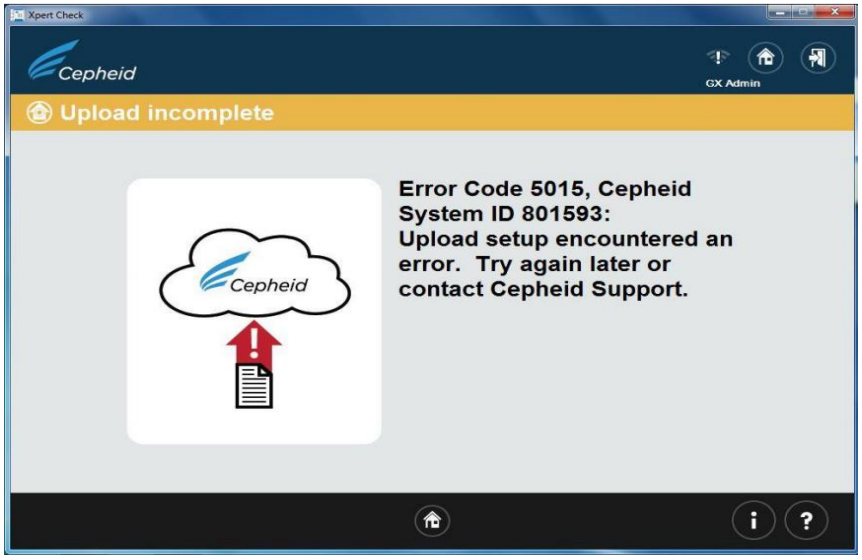
(6) Failed Module

• If any of the series of the Check tests fails, the module will fail.
• A module requiring service will be flagged with a specific module icon
• At the completion of the Xpert Check data collection process, modules requiring service will be flagged
•After the Xpert Check Code file has been downloaded, the code will be applied to each successfully tested module, the "Service Required" icon will appear instead of the " + "for failed module
• Failed modules will NOT be locked out and will still be available for use, while you are waiting for the replacement modules
Identify the Serial Number of the failed module
• At the bottom of the Failed Module Report generated by the Xpert Check software
• Contact Cepheid Technical Support at support@cepheideurope.com (Based in Europe) or techsupport@cepheid.com (based in USA), for further assistance in replacing modules requiring service:

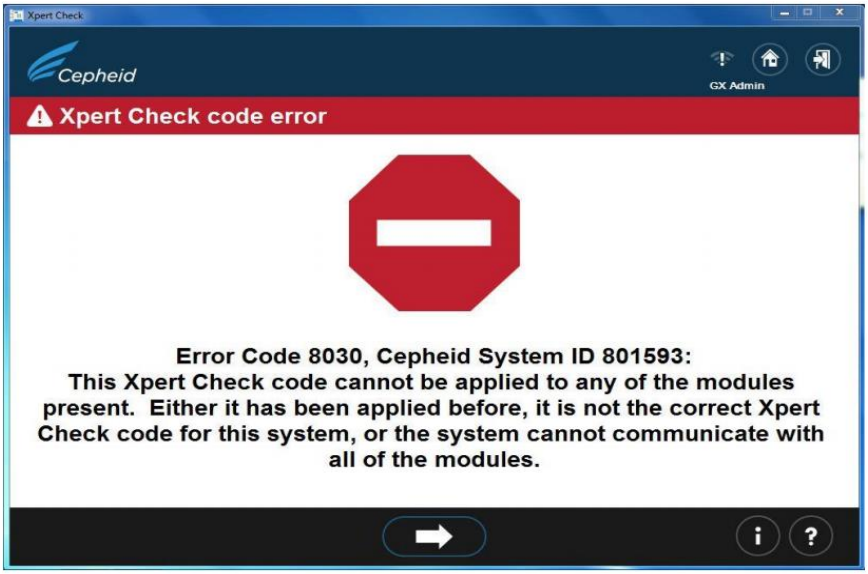
(7)When the CD refuses to be burnt



(8) When the upload did not succeed (internet issue)



(9) When the Xpert code can't be applied



7. Taking out stuck cartridge

1. *Make sure that the door is actually not opened. (Sometimes it is not visible, and it could be hard to open)*
2. Try gently to open.

   Note: DO NOT BREAK THE DOOR.

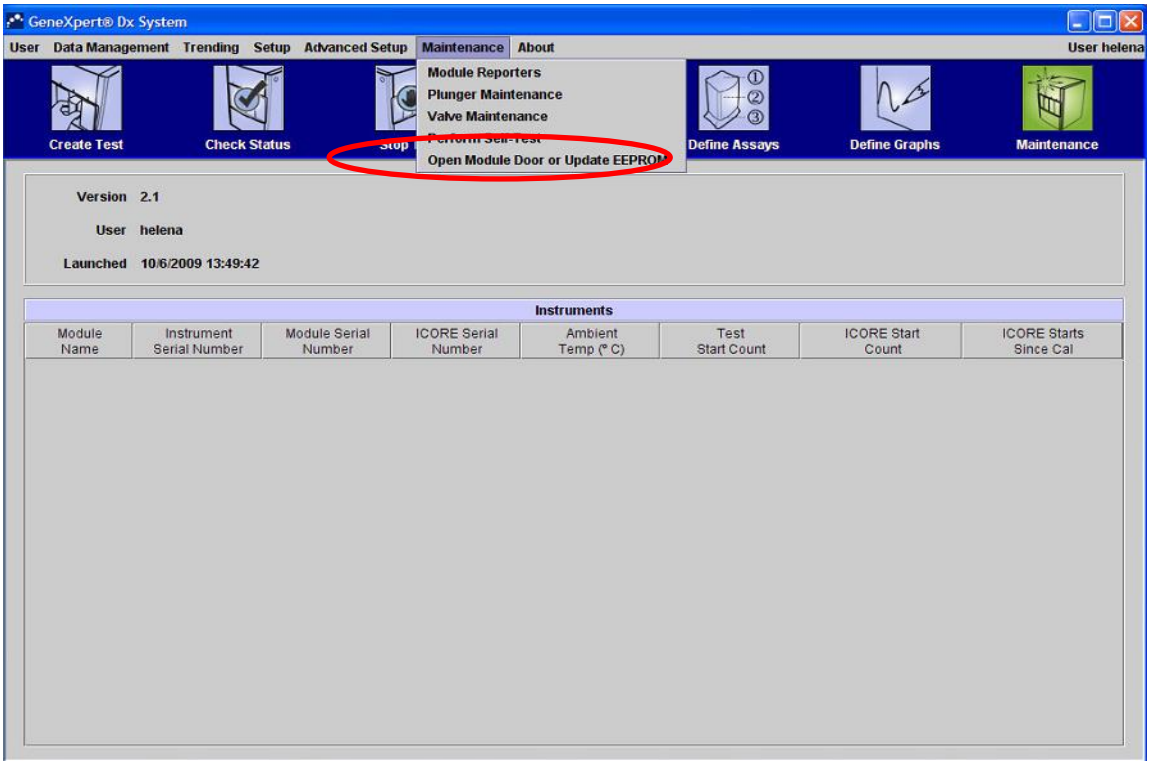
Reasons of Stuck cartridge

1. Software problem
2. Plunger rod problem
3. Ultrasonic horn problem

7.1. Software problem

1st solution:

1. Choose in the main menu "**Maintenance"** on Maintenance Screen
2. Select "**Open Module Door or Update EEPROM"**



2nd solution:

1. Close and open the software.

   Note: When the software is reopened, the module will reinitialize itself, by putting the valve and the syringe in correct position. That could help to open the door.

3rd solution:

1. If it still does not help, turn off system and restart both GeneXpert and Software.

4th solution

The GeneXpert System automatically performs a self-test during startup. However, you can initiate a self-test manually on any of the modules to reset and check for hardware failure problems.

1. Click **perform Self test on** the maintenance screen, under **main menu- Maintenance**.
2. Follow the instructions in the Self-Test dialog box and click **OK**.

When the self-test finishes, the software changes the progress to "Available", indicating the self-test passed. If the message indicates the self-test failed, contact Cepheid Technical Support.

Note: Turn the instrument off and remove the cartridge manually if nothing of the above works

7.2. Plunger rod problem

5th solution:

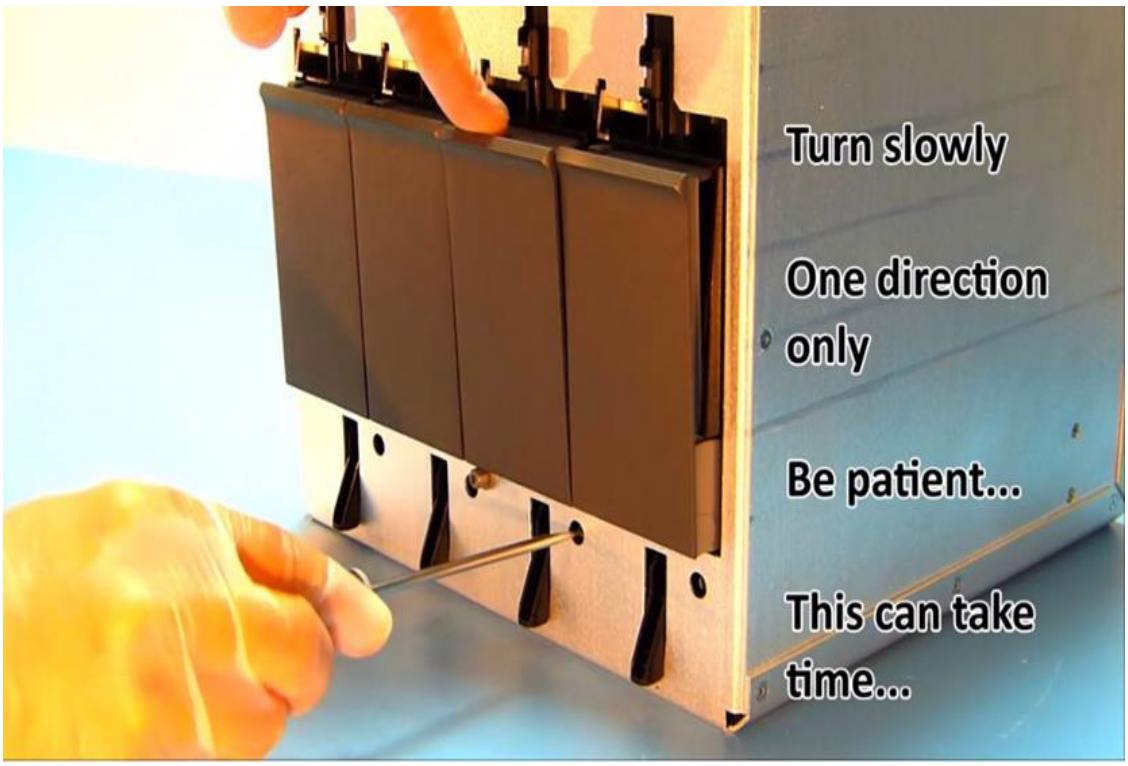
Disconnect the instrument from electrical sources and the computer. Open up the cover of the GeneXpert (Place the machine at table edge and remove three screws from each side of the base. Apart the body from the cover by pushing the body from the front side)

1. *Try to screw the plunger back to "Up" position by turning the screw in the "Up" direction and try to open the door and it solve the problem.*

7.3. Ultrasonic horn problem

6th Solution

1. Turn particular screw slowly in one direction (must be e patient)
2. Module door will open in the correct direction and it solves the problem.



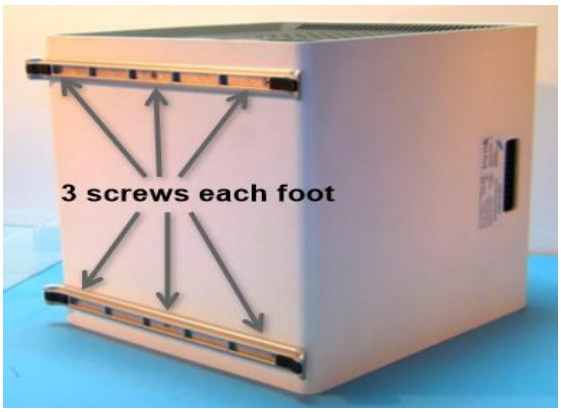
8. Module replacement

The important things keep in mind

- Do not rush
- Do not use excessive force
- Avoid touching electrical parts
- Wear glove
- Remove the used cartridges
- Disinfect and decontaminate the modules (refer to maintenance procedure)

Removing the old module

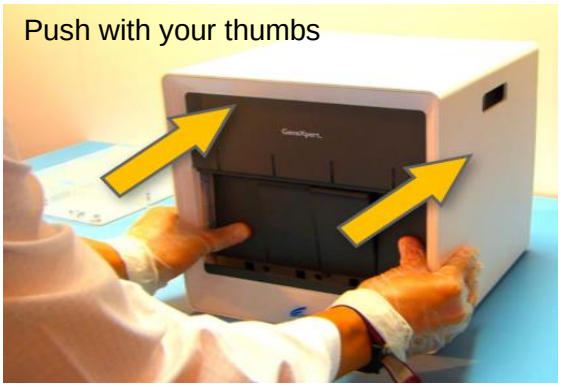
1. Switch off the computer, Gene Xpert instrument and then remove the cables
2. Carefully place the Gene Xpert on its Front surface

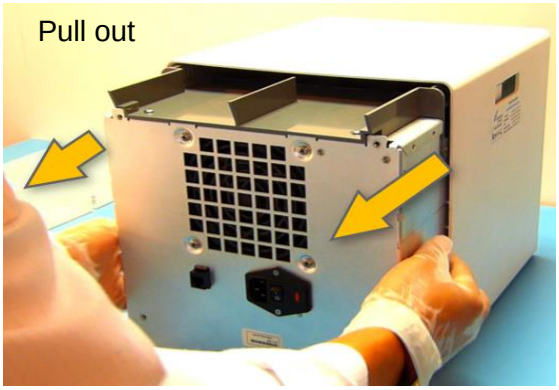


3. Remove the 3 screws at each foot on the Base
4. Remove the 4 screws at the Rear surface of instrument

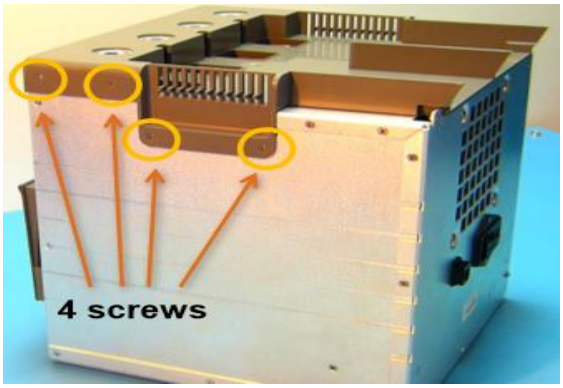
5. Remove the back cover of the Rear surface

6. Remove the filter. (wash and let it dry before reassembling)
7. Apart instrument's body from the cover by pushing the front side

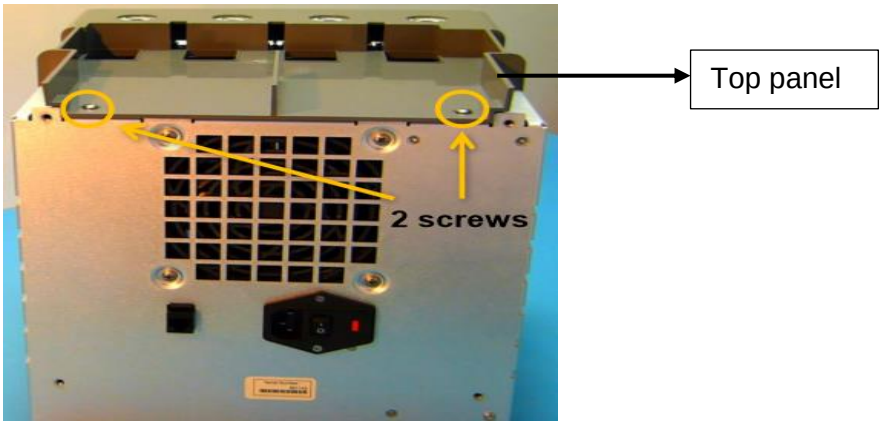




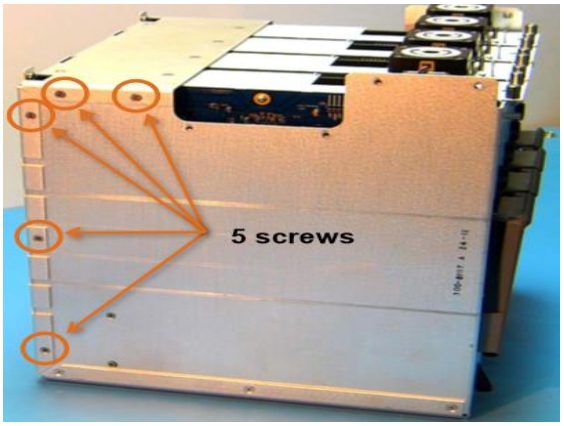
8. Remove the 4 screws from each side of instrument



9. Remove the 2 screws on the top panel to take away it



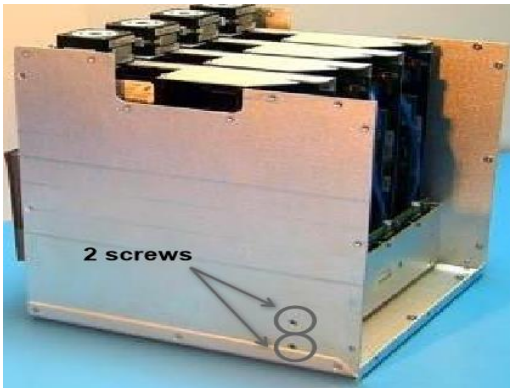
10. Remove the 5 screws on each side of metallic frame



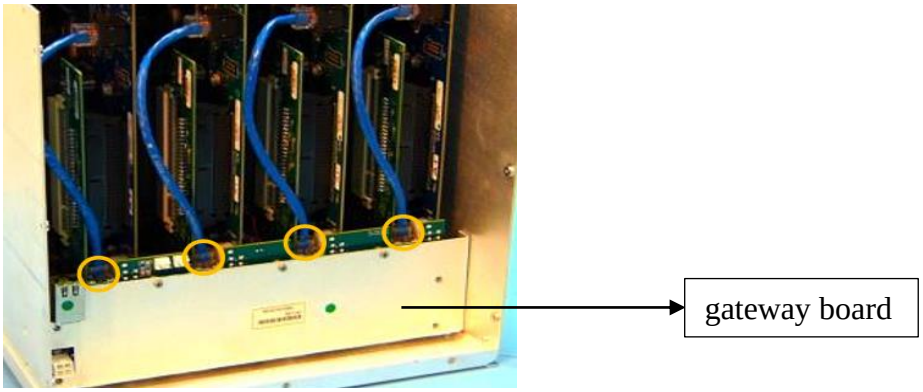
11. Remove the 3 screws on the rear-bottom part of the metallic frame

12. Disconnect the 3 cables to remove the metallic frame.

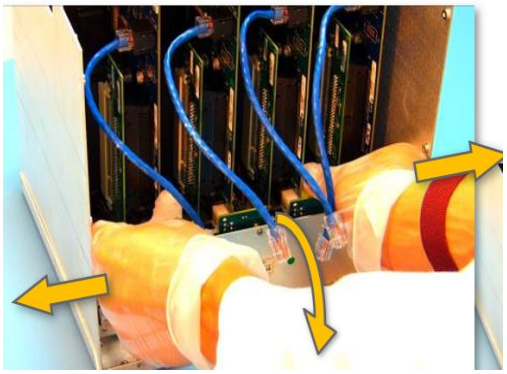
13. Remove the 2 screws from the holes at each side of metallic frame, that hold the gateway board



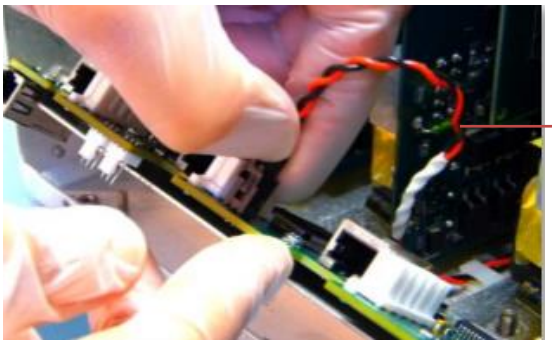
14. Disconnect the 4 blue coloured cables from gateway board.



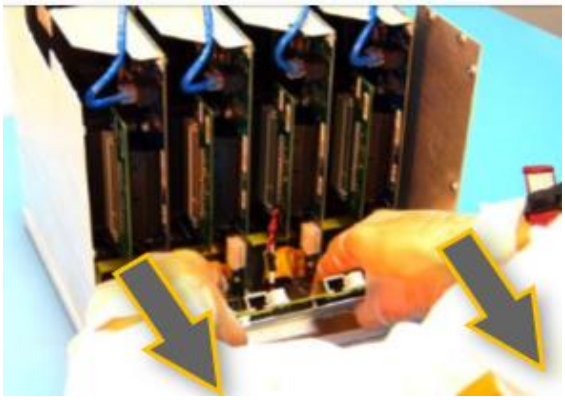
15. Pull a little the gateway board from the instrument with thumb while spreading the metallic Frame. (Do not touch electrical parts)



16. Disconnect the red/black cable from gateway board.

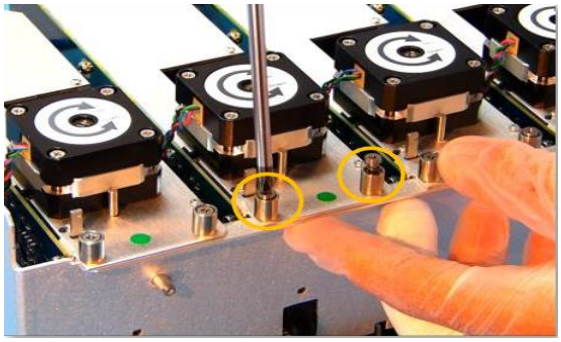


17. Carefully take the whole gateway board out while spreading the metallic Frame.



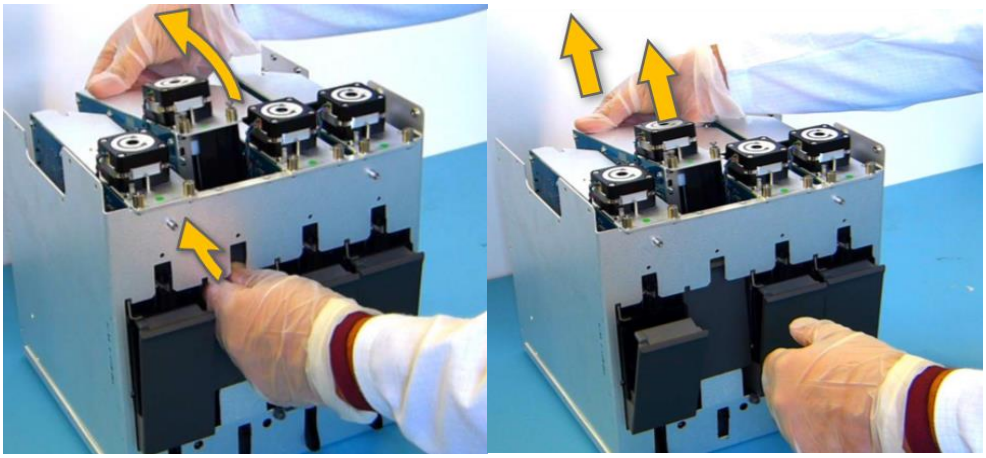
18. Choose the right modules that will be replaced
(Do not place your fingers in the hole of upper surface of each module)

19. Untighten the 2 screws at the top of selected module. (Do not remove them)



20. Remove the nut on the rear bottom part of selected module to take it out.

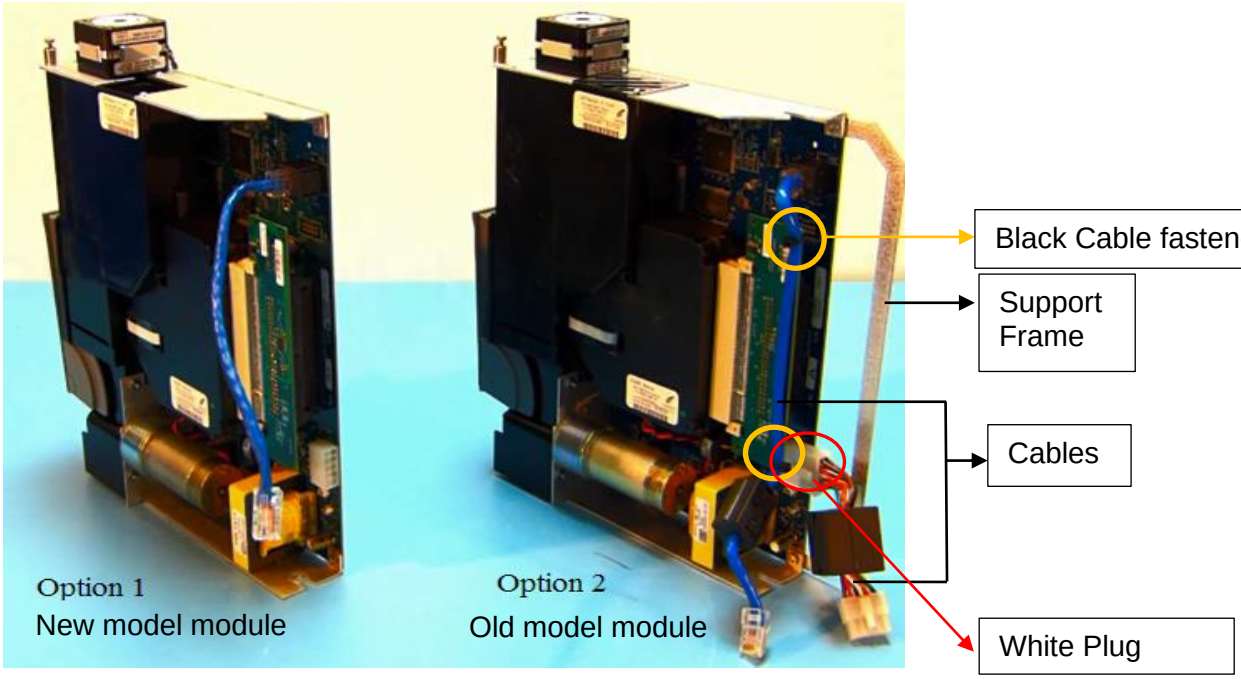
21. Remove the modules slowly by following the movement. (Avoid touching the electrical parts)



Replacing the new modules

22. Observe the new module to make sure it is OK.

According to instrument model, there are two options of procedure for replacing new module

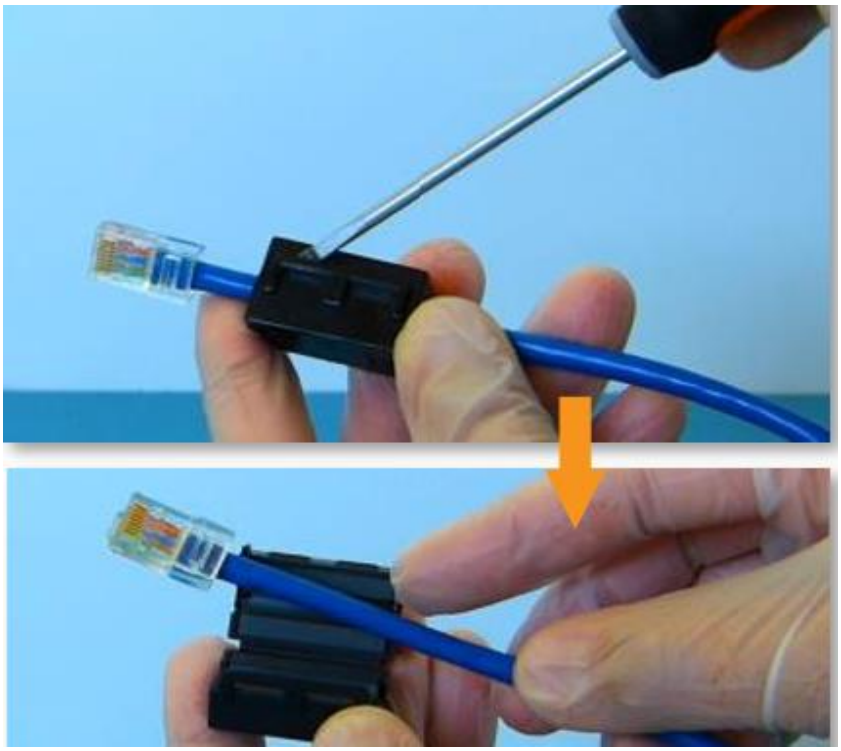


Option 1: In new model instrument, module doesn't have support frame and attached cables

If your instrument is entitled with Option 1, skip the steps of Option 2

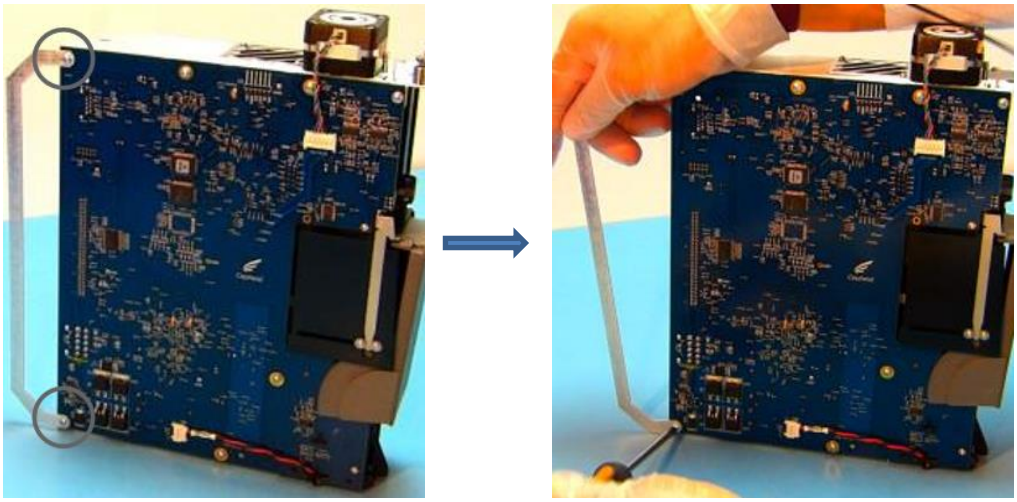
Option 2: In old model instrument, module has support frame and attached cables. Perform the following steps

a. Remove the top cable fastener and the bottom one
b. Remove the blue cable and the white plug
c. Carefully remove the ferrite snap



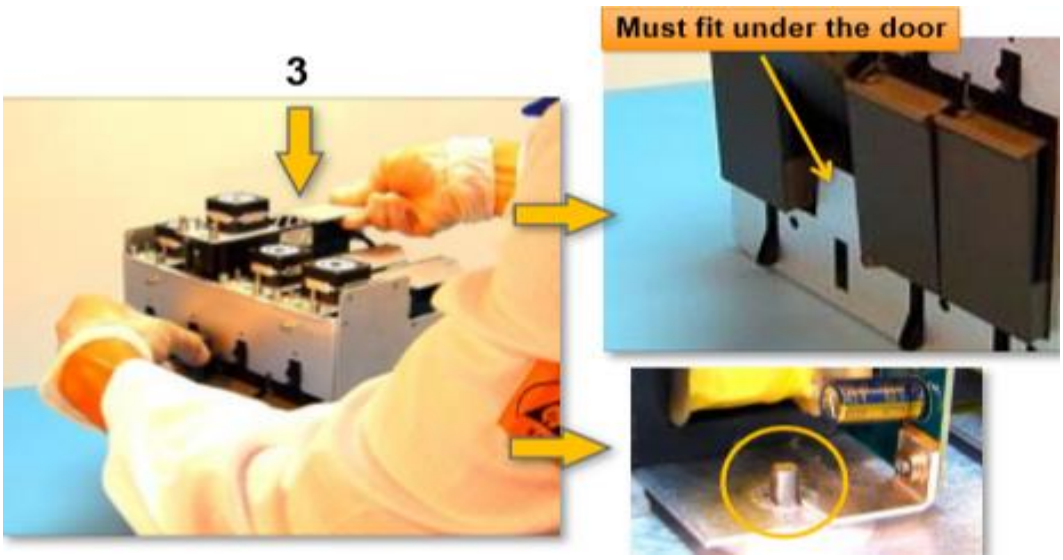
d. Insert back the blue cable on the new module

e. Remove the 2 screws at both ends of metallic frame and discard the metallic frame

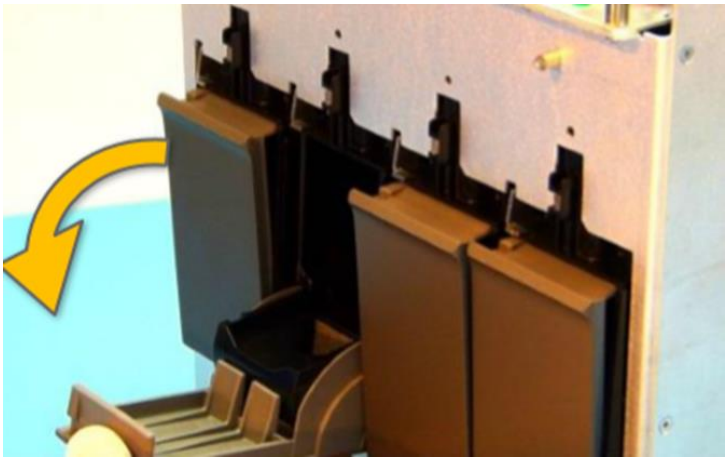


f. Put back these 2 screws

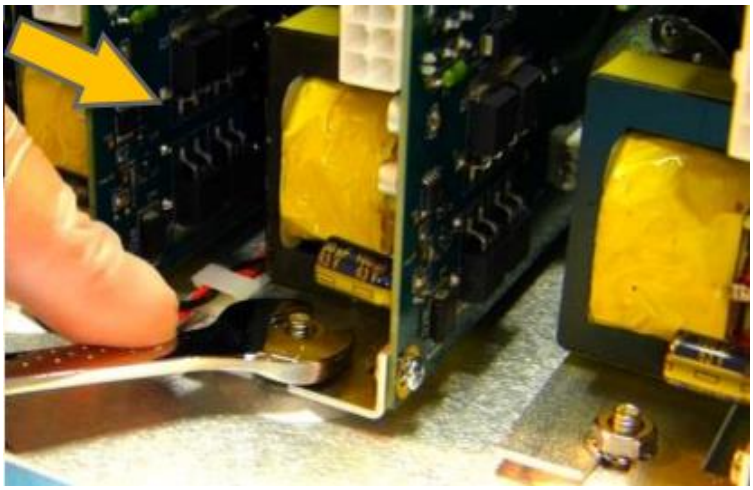
23. Allocate new module slowly by following the movement



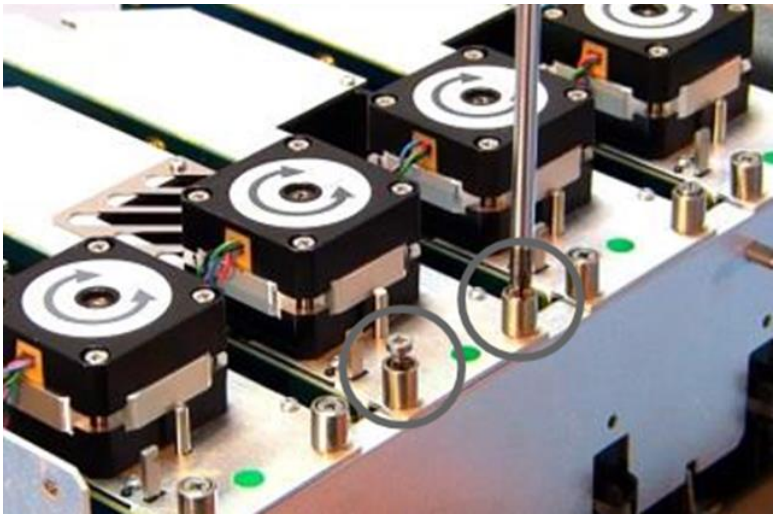
24. Check the module Door



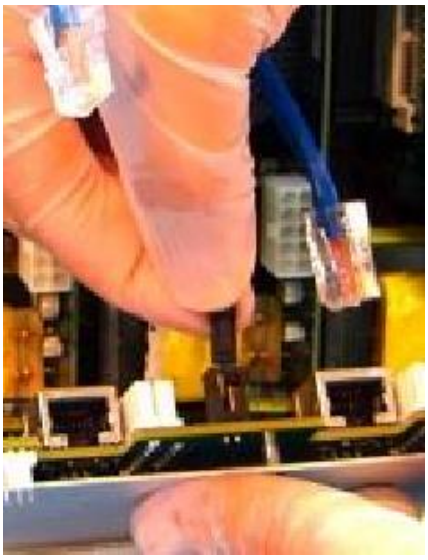
25. Put back one nut on the rear bottom part of instrument to fit module (Do not overtighten)



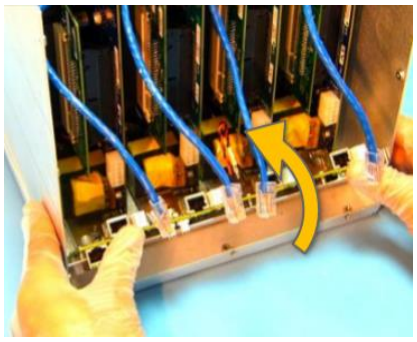
26. Put back 2 screws at the top of new module (Do not overtighten)

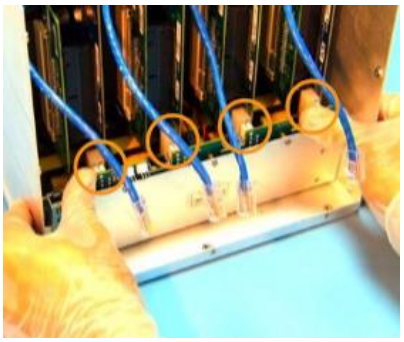


27. Connect the red/black cable to gateway board

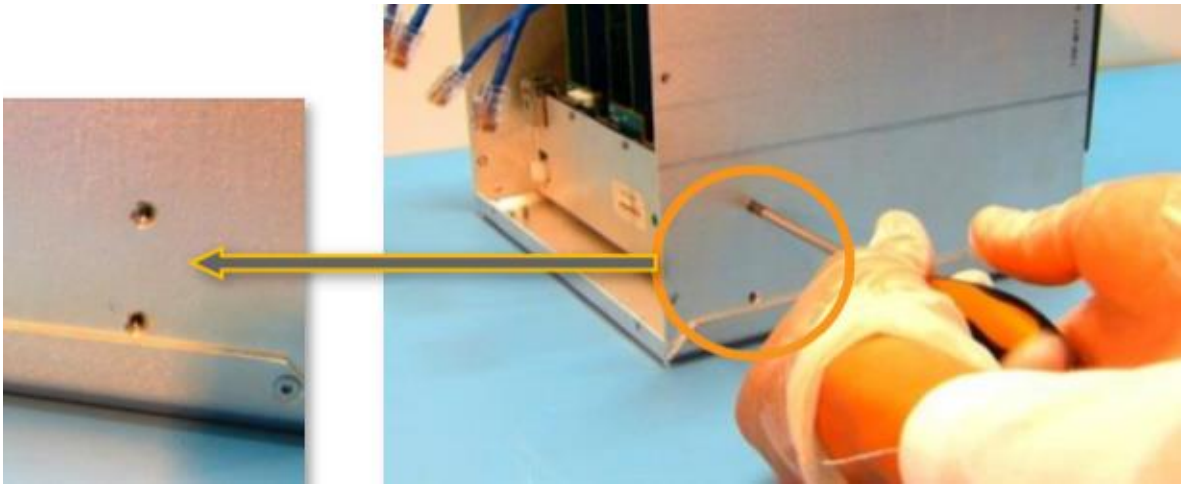


28. Put back the gate way board in the bottom part of instrument by sliding and tilting while spreading metallic frame (The white connectors of instrument and gateway board must be corresponded and press these for getting proper connection. Don’t touch the electrical parts of gateway board)



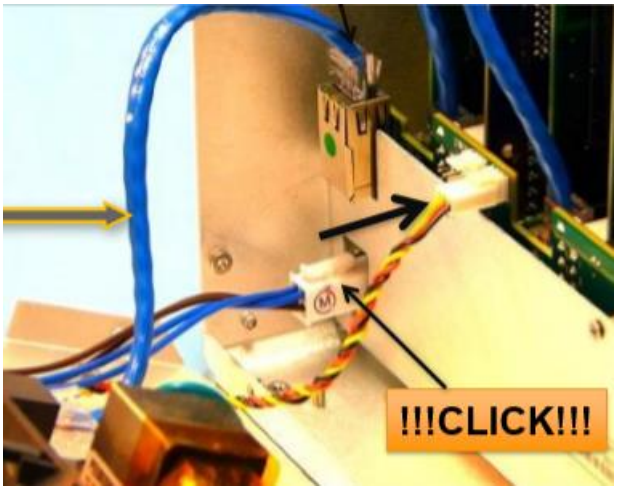


29. Replace the two screws on both sides of metallic frame for holding the gateway board

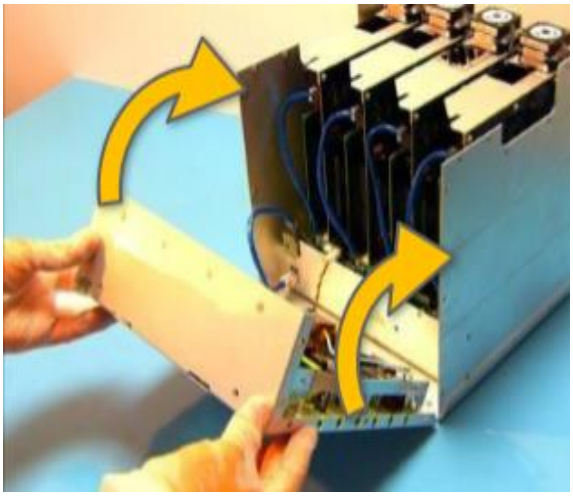


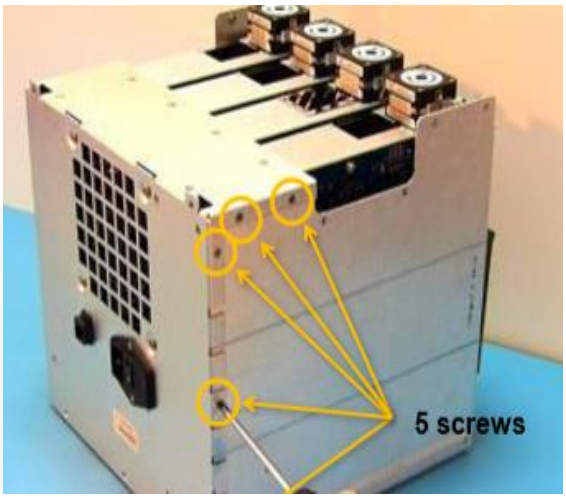
30. Connect the 4 blue connection cables in place

31. Connect the 3 cables from metallic frame to the corresponding parts of gateway board

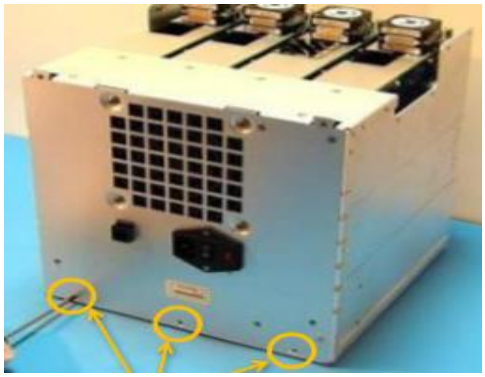


32. Put back the metallic frame. Put back the 5 screws on each side (Do not overtighten)

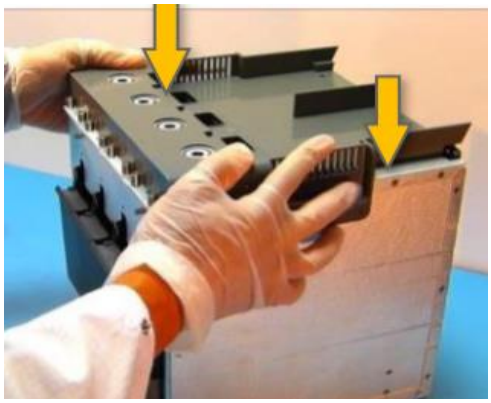




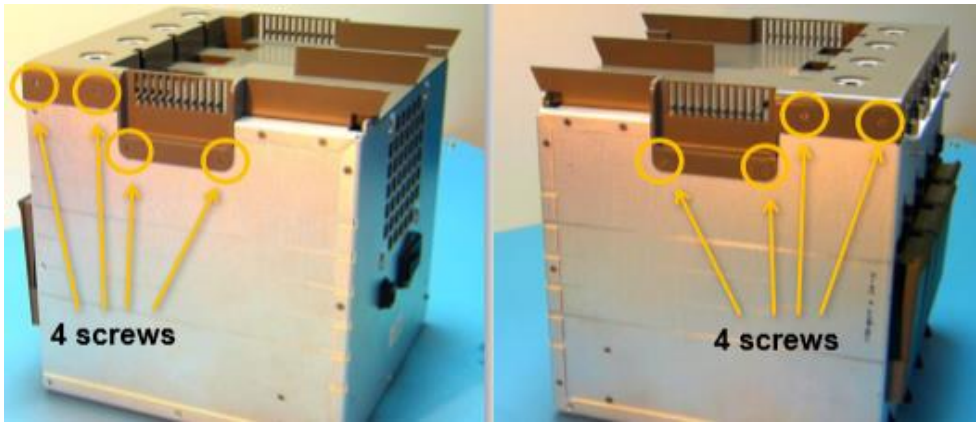
33. Put back the 3 screws on the back bottom part



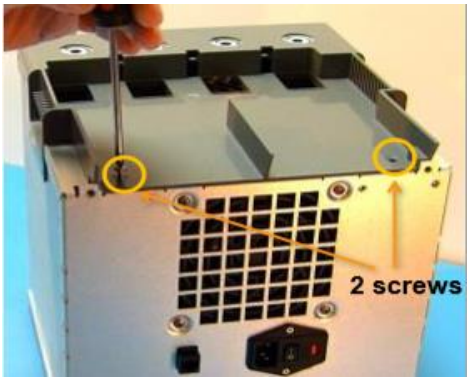
34. Put back the top panel



35. Put back the 4 screws on each side

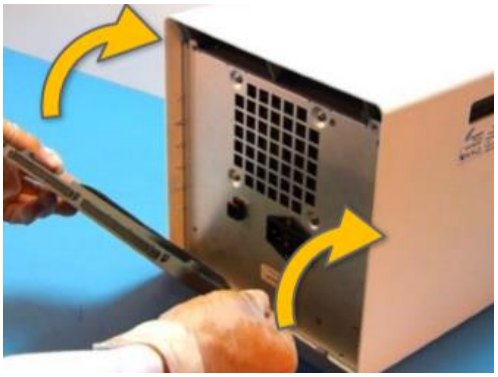


36. Put back the 2 screws on the top panel

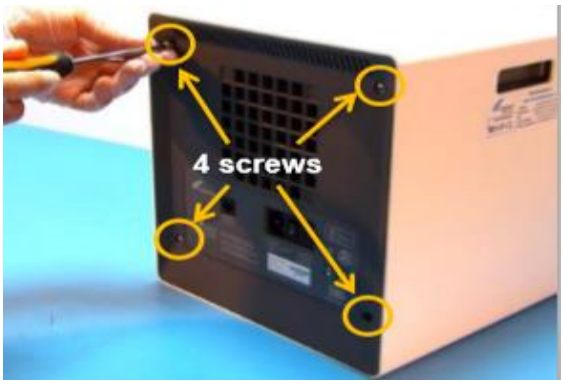


37. Put back machine into the cover by following the movement

38. Put back the filter and check the filter is in place



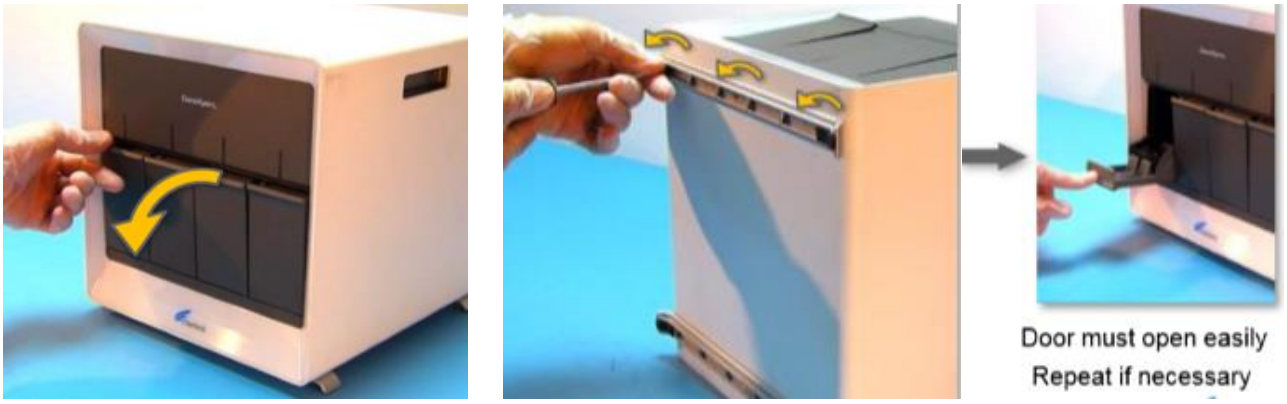
39. Put back the 4 screws at the back cover



40. Accurately place the Gene Xpert on its front surface

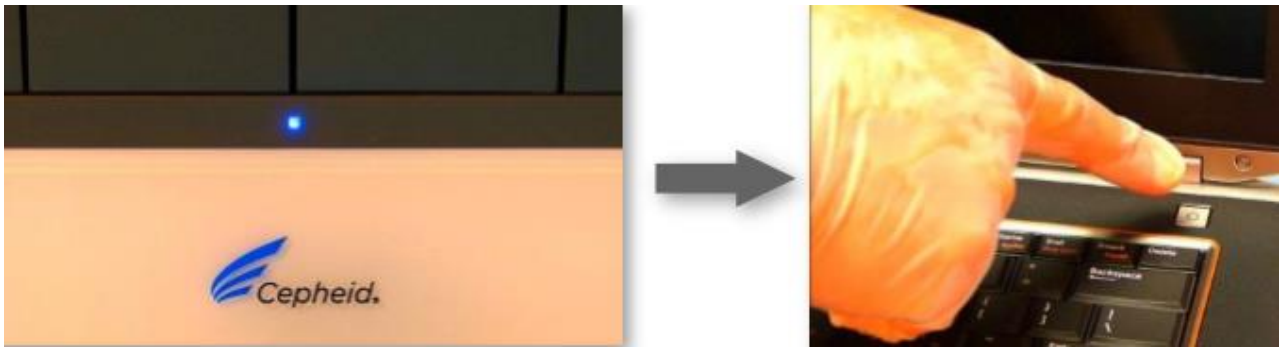
41. Put back the 3 screws on each foot and check the door

42. If a fraction persists or a door would not open, loosen all screws of the front foot

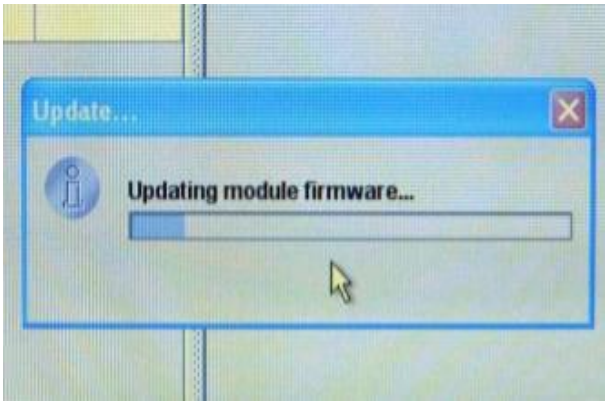


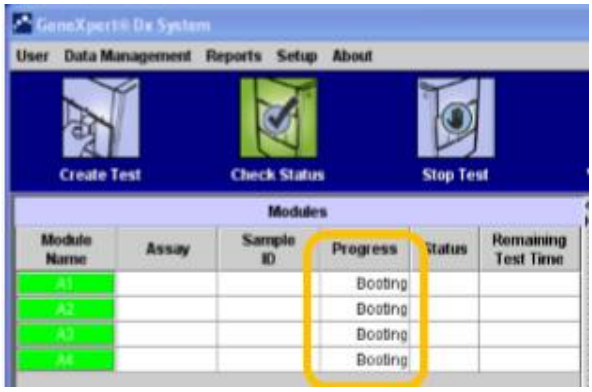
43. Reconnect the 2 cables to get running condition.

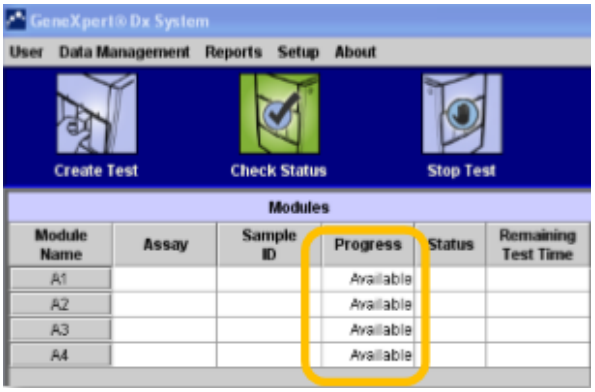
44. Switch on first you GeneXpert® then the computer



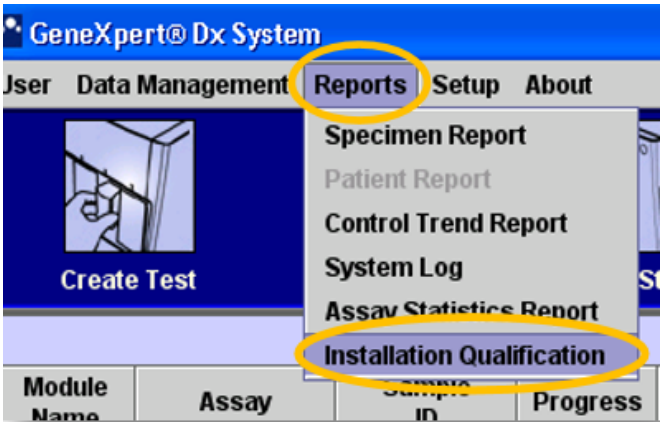
45. Wait for while







46. Click on “Report” and then click on “Insttallation Qualification” and generate the IQ report.



47. Save this report and send the file with contact name, phone number, email address and physical address of the GeneXpert ® to training@cepheidhbdc.com

9. Recording

- Record in the maintenance log sheets after doing it

10. Waste management

- Dispose of the used paper towel, swabs and disinfectants according to standard laboratory procedure

11. References

- Cepheid GeneXpert GXMTB/RIF-10. Package insert; 300-6252 Rev. D, September 2010
- Procedure for preparation of disinfectants
- Procedure for use and maintenance of personal protective equipment
- Service and Maintenance, 9-22 GeneXpert Dx Operator Manual, Software Version 4.6,301-0045, Rev. E December 2014 Cepheid GeneXpert GXMTB/RIF:

For the related procedures refer to websites:
TBCARE I http://www.tbcare1.org/publications/toolbox/lab/
STOP TB http://www.stoptb.org/wg/gli/documents.asp
Global Laboratory Initiative (GLI) http://www.gliquality.org/

Annex

GeneXpert User Maintenance Check-List

Installation Date	
Machine Serial Number	

Month	
Year	

Module Number	1	2	3	4	Date
Module Serial Number					
Replacement Module s/n (1st)					
Replacement Module s/n (2nd)					
Replacement Module s/n (3rd)					

Please write your initials in the boxes when done

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																															
Discard used cartridges																															
Keep module doors upright																															
Room Temperature (°C)																															

WEEKLY MAINTENANCE	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5
Power Down GeneXpert instrument and Computer					

MONTHLY MAINTENANCE	
Archive and delete tests- Save on CD	
Clean Fan Filters	
Clean module PCR slots	
Clean cartridge bays and plunger rods	
Clean instrument surfaces	

YEARLY MAINTENANCE	Accomplish	Up coming
Perform Xpert Check		
User Name		
Supervisor Name		

Gene Xpert Site Assessment Form

Demographic Information and HR	
GeneXpert Machine Location	
GeneXpert Room Location	1. TB Lab 2. General Lab
Contact Person Name	
Contact Person's Phone Number	
Machine Maintenance	
Calibration Date / Xpert Check Date (Last Time)	----/---- /-------
Air-condition Status	1. Good 2. Need to Repair 3. Need to replace
Last time maintainance date (Air Con)	----/---- /-------
Gene Xpert Accesssary & Laboratory Equipment	
Gene Xpert Printer	1. Functioning 2. Not Functioning
Refrigerator	1. Yes, Functioning, 2. Yes, Not Functioning, 3. No
Votex Mixer	1. Yes, Functioning, 2. Yes, Not Functioning, 3. No
Timer	1. Yes, Functioning, 2. Yes, Not Functioning, 3. No
Thermometer	1. Yes, Functioning, 2. Yes, Not Functioning, 3. No
Safely & Waste Measurement	
Fire extinguishers (if Yes, Please specify the expire date)	1. Yes (If yes, Date: --- / ---- / --------) 2. No
Exhaust Fun (if not functions, please filled no)	1. Yes, Functioning, 2. Yes, Not Functioning, 3. No
Gene Xpert Maintanace Kit	
Brush	1. Yes 2. No
Fun Filter	1. Yes 2. No
5% sodium hypochlorite & 70% Ethanol ဖျော်ရည်	1. Yes 2. No
Last time maintainance date	Date: ___ / ____ / _____
Machine Maintainance Sheet / Record	1. Yes 2. No
UV Light (UVGI) တပ်ဆင်ထားခြင်း ရှိ/မရှိ	1. Yes, Functioning, 2. Yes, Not Functioning, 3. No
Plastic bag for waste /Autoclave Bags / လိမ္မော်ရောင်အိတ်	1. Yes 2. No
Waste Bin (အမှိုက်ပုံး)	1. Yes 2. No
Can access Incinerator If not, how to manage waste disposal	1. Yes 2. No ______________________________ ______________________________
N95	1. Yes 2. No
Report Copy of Monthly Gene Xpert Report	1. Yes 2. No

Remark:_ _

_ _

2025