GeneXpert® Edge Software

Cepheid Training Centre

302-0567 Rev. B May 2022

Agenda Title

1 | Intended Use

2 | Starting the System

3 | GeneXpert Software

4 | Managing User

5 | GeneXpert Edge Software

6 | Q & A

IVD. In vitro diagnostic medical device. May not be available in all countries.

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Training Objectives

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

- Configure the GeneXpert® software

- Configure the GeneXpert® Edge software

- Prepare a cartridge and run the test

- Report and print the various software generated results

- Perform basic troubleshooting

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Intended Use

- The GeneXpert® Edge system is an in vitro diagnostic device intended for use with Cepheid Xpert® test kits. The GeneXpert® Edge system 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 designed for hands-off processing of patient samples (specimens) and provides both summarized and detailed test results data in tabular and graphic formats.

- The GeneXpert® Edge system is intended to be used by **laboratory professionals** or **specifically-trained healthcare users** in a **laboratory and near patient test settings** as specified in the Cepheid® Xpert® test instructions for use.

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Software Installation

- The GeneXpert® Edge System comes with the GeneXpert® Software & GeneXpert® Edge software pre-installed.

- The GeneXpert® Edge software is a Simplified UI(User Interface) to run tests.

- It uses GeneXpert® DX Database.

- GeneXpert® Edge software 1.0 is exclusively for running and view tests.

- Key features included is a Video guidance for cartridges Preparation

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Starting up the system

Starting the Software and Instrument

1. Put on a clean pair of gloves.

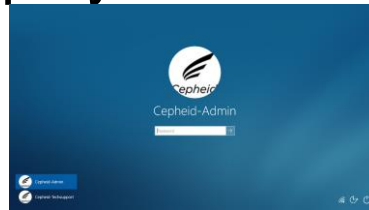2. Turn on the GeneXpert® Edge Instrument.

3. Turn on the tablet computer. The Windows® screen will display.

4. Swipe up on the lock screen.

5. The Windows login screen will display. Touch the Password field to display the keyboard. Enter the password.

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Starting the Software and Instrument continued

6. Touch the arrow button at the right of the password entry area to log in.

7. The Welcome Screen appears after the software initializes. Touch the TOUCH HERE TO BEGIN button.

8. The VIEW PREVIOUS TESTS button will display. The RUN NEW TEST button will appear on the Home screen within 3 minutes

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GeneXpert® Software

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GeneXpert® Software

- All configuration activities are performed on GeneXpert® Software prior to creating tests in GeneXpert® EDGE

  – Create/Define Users

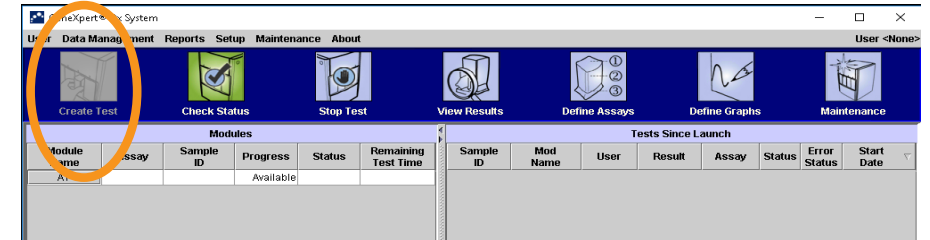 – Install ADF

  – System configuration

  – Access to Reports
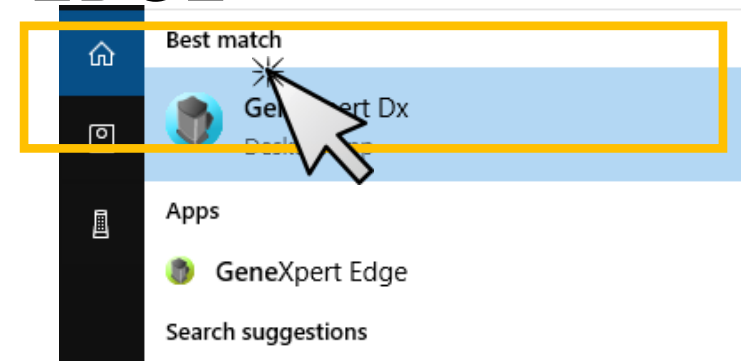
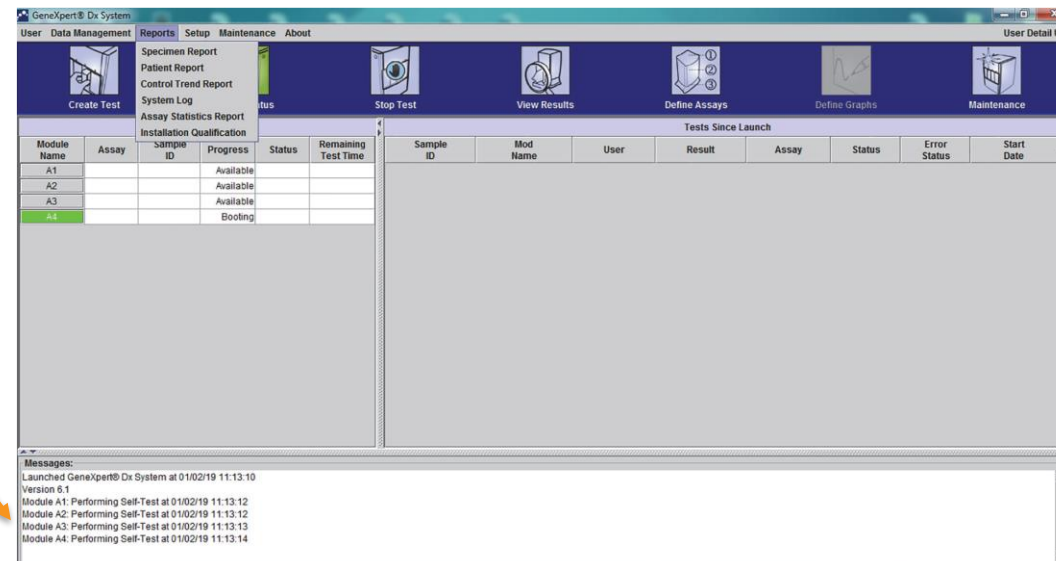 ➢ including Installation Qualification Report, System log

  – LIS Settings

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Important Reminders !

- **Create Test is disabled in GeneXpert Software**

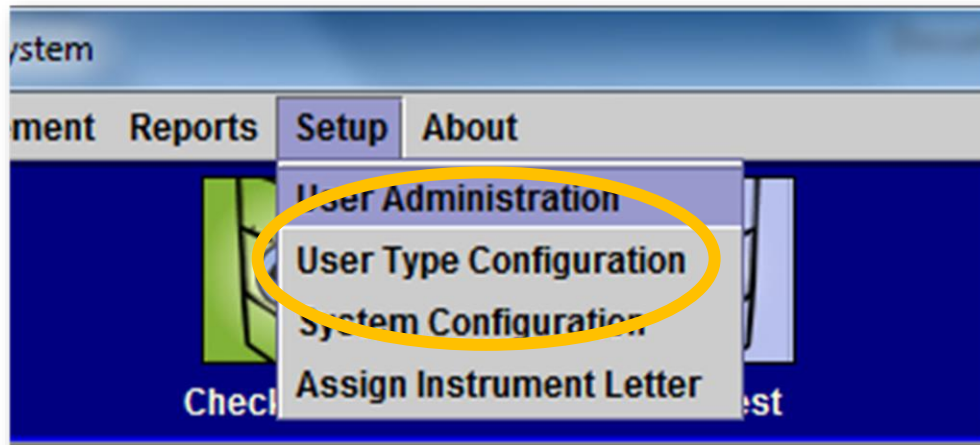- GeneXpert Software version is displayed at the bottom of the Check status screen

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Managing Users

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Edit user type configuration

Define access rights to the software

1

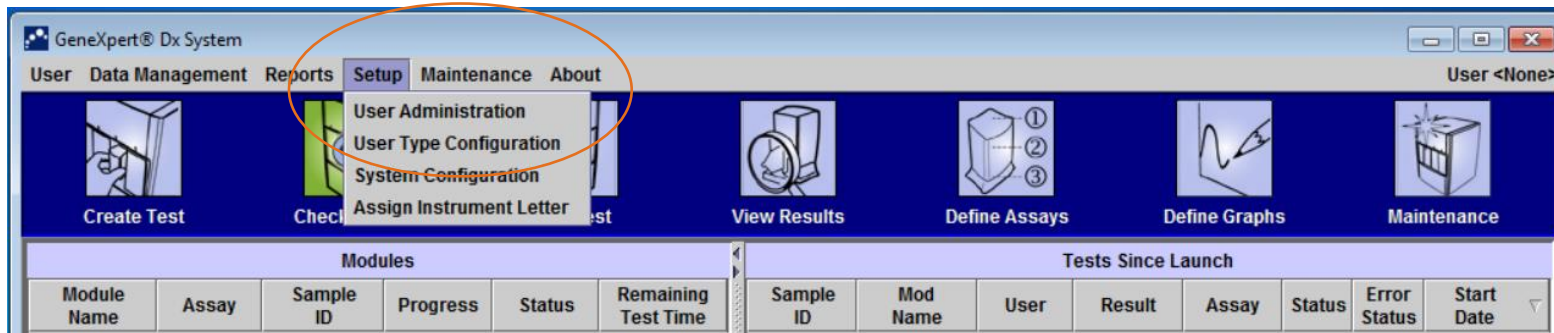**2** Edit user configuration by selecting or deselecting

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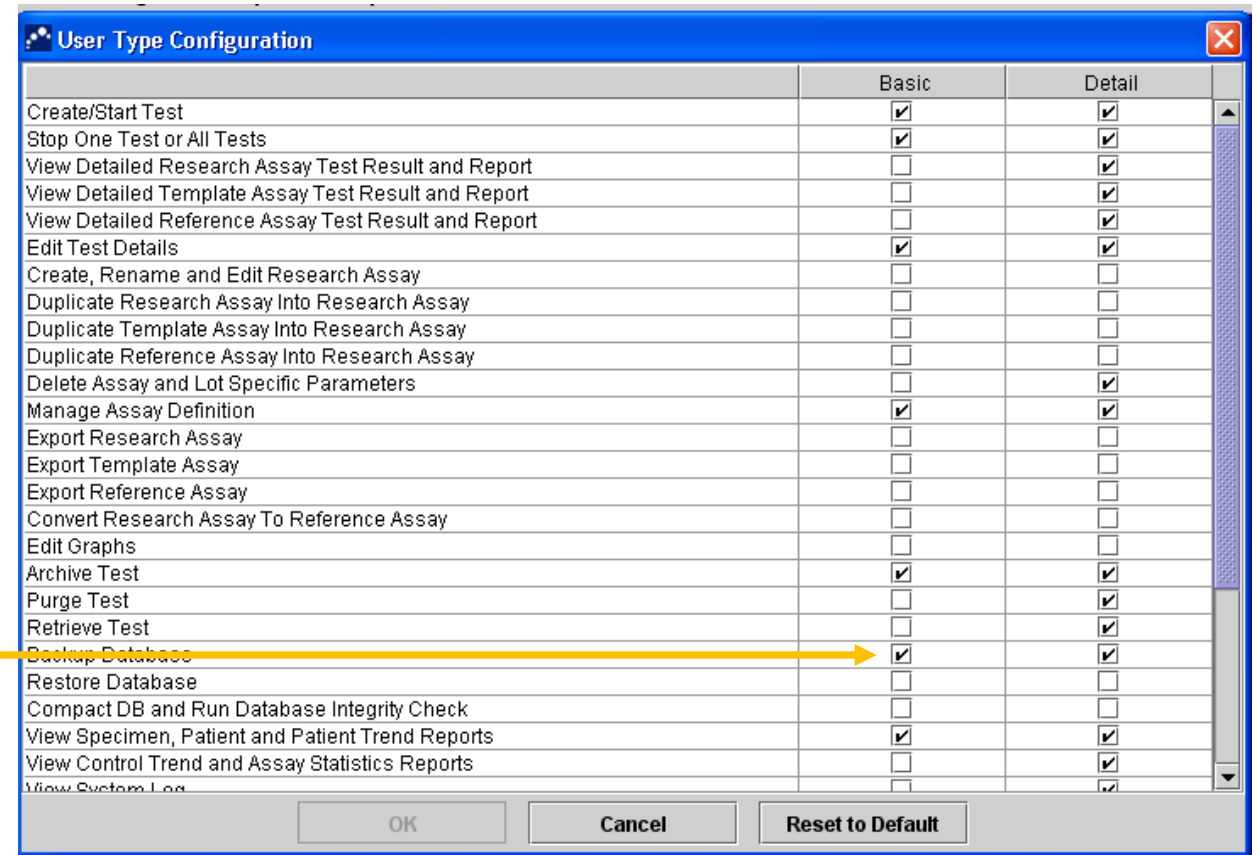
Adding new users

Create an Administrator Account ("Admin")

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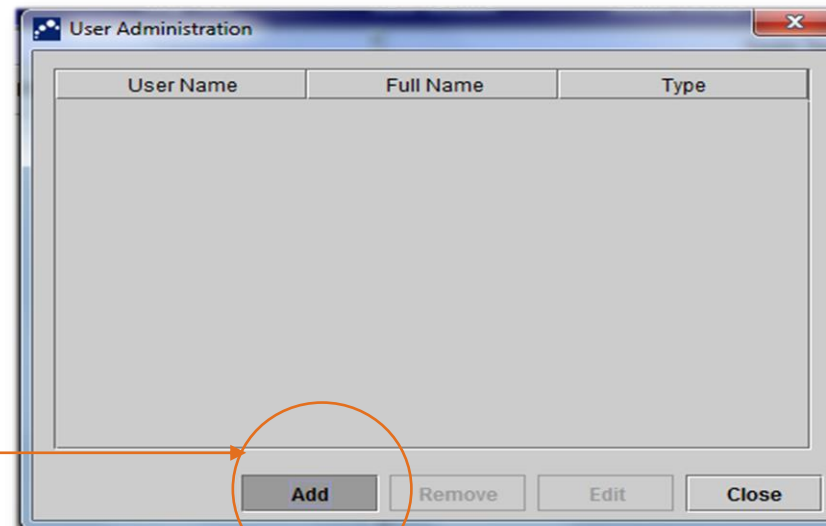# Create an Administrator Account ("Admin")

Define the person in the lab that will have full access to the software

*The first account to be created **must be an Admin account**. There can be more than one Administrator account per system*
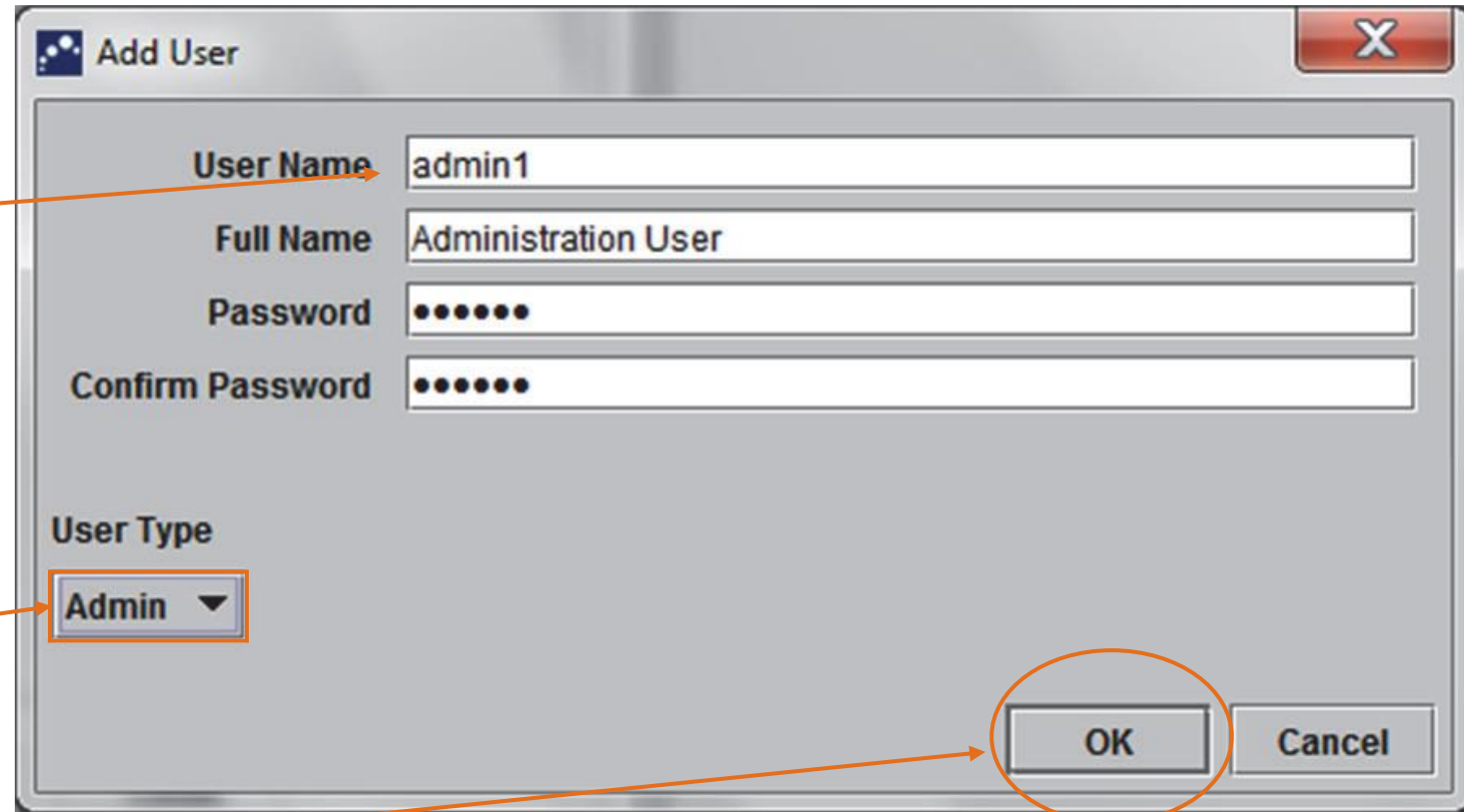
1 | **Setup → User Administration**

2 | Click **Add**

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Create an Administrator Account ("Admin")

3 Enter the Username and Password

4 Choose the User type (**Admin**)

5 Click **OK**

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Create an Xpress Account

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Create an Xpress Account

1 Setup → User Administration

2 Click **Add**

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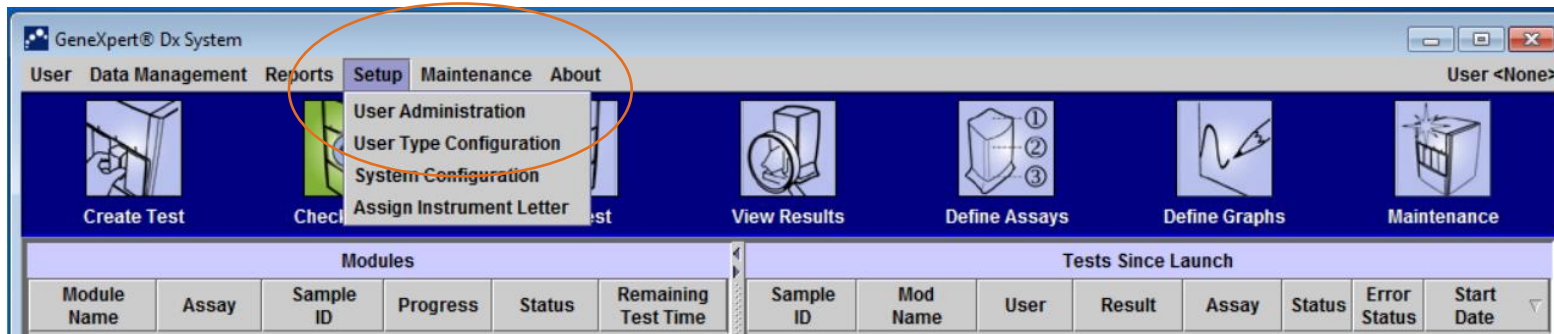
Cepheid
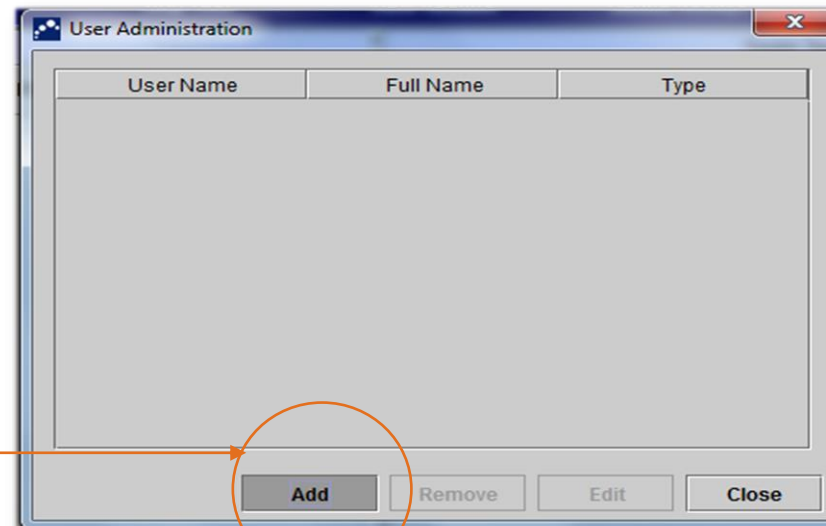
Create an Xpress Account

Password and username must be between 6-10 characters

3 Enter the Username and Password

4 Choose the User type (Xpress)

5 Click on OK

Edit User

User Name   xpress
Full Name   Xpress User
Password   ••••••
Confirm Password ••••••

User Type

Xpress ▼

Basic
Detail
Admin
Xpress

OK   Cancel

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Editing User Profile

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How to edit user profile

1 Select the user to be edited from the user administration list.
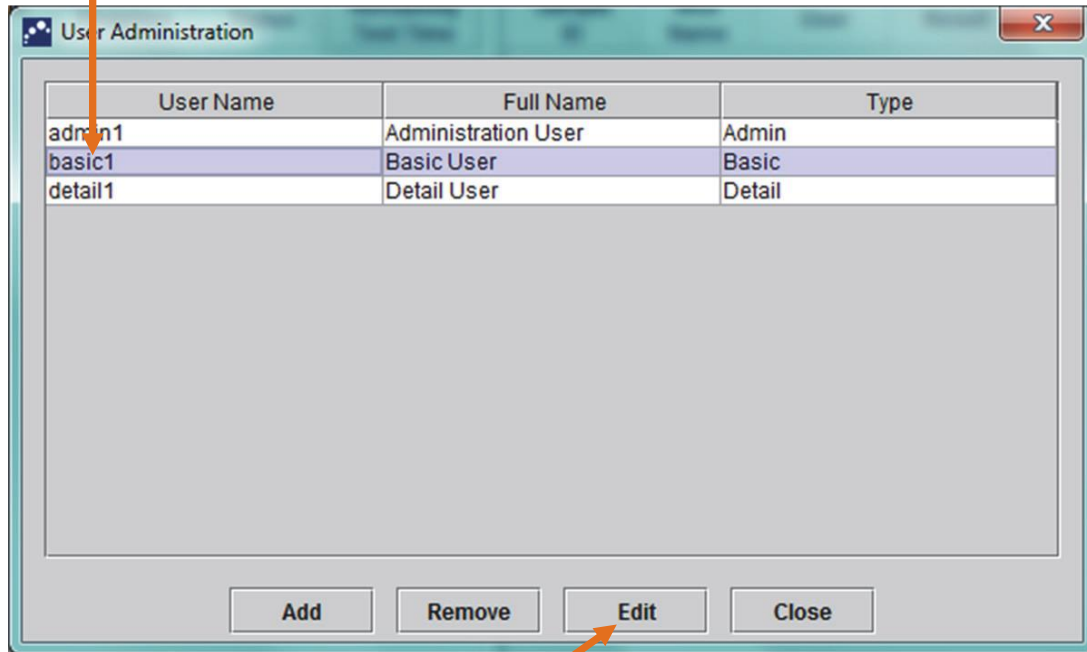
2 Click on **Edit**

3 Revise the information, as desired, and then click **OK** to save the changes and close the Edit User dialog box.

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Removing Users
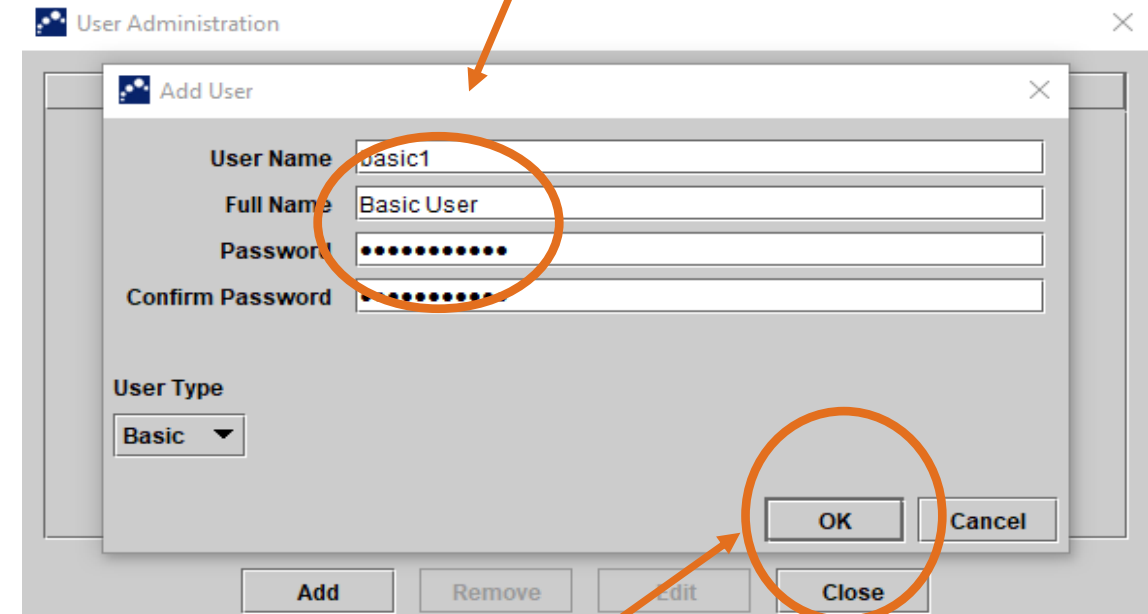
IVD. In vitro diagnostic medical device. May not be available in all countries.

How to remove users

1 Click to select the user to be removed
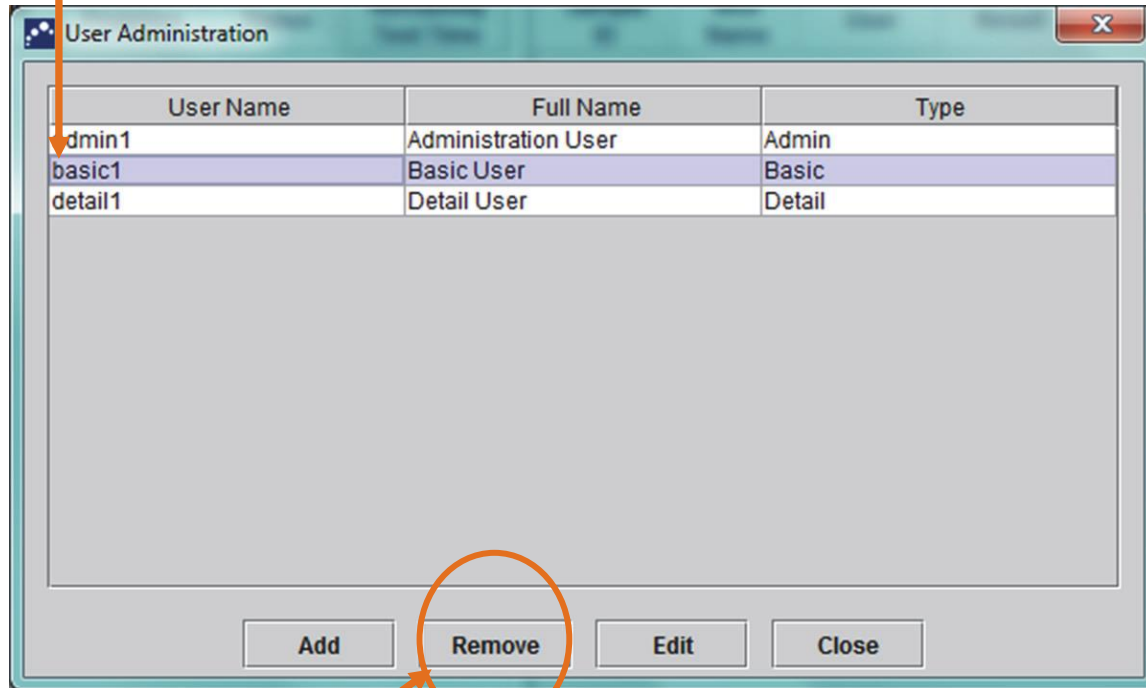
2 Click on **Remove**

3 To remove additional users, repeat Step 1 and Step 2. If you are done removing users, click **Close**

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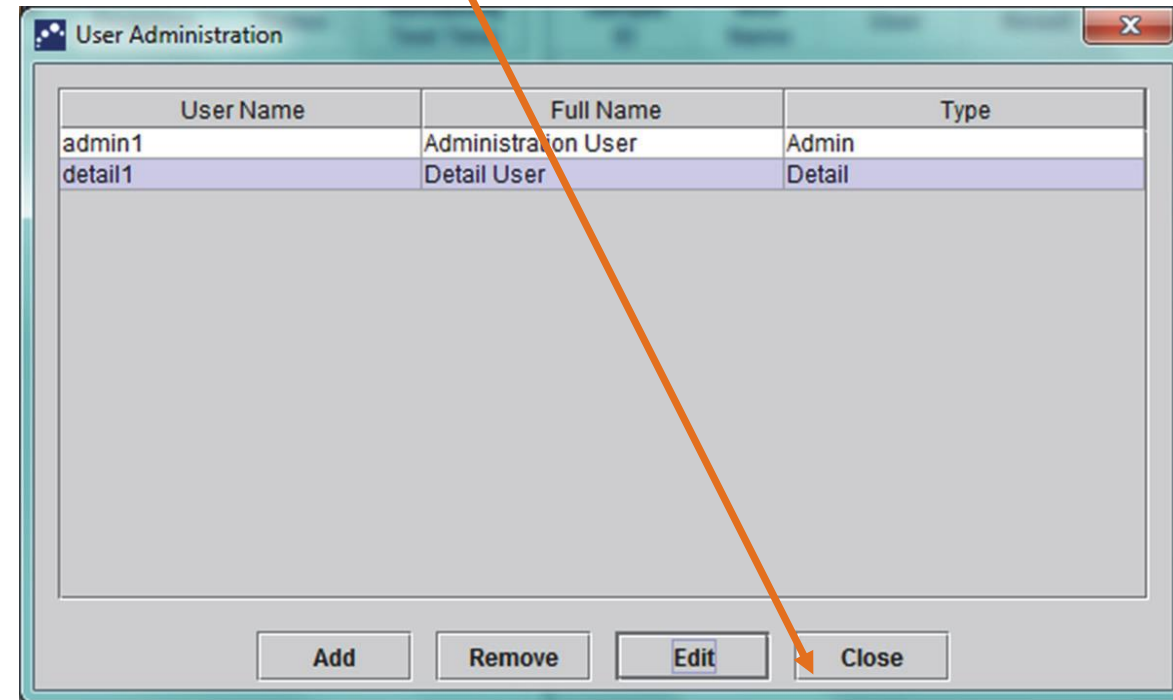
Enabling Login for GeneXpert® Edge Users

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Create an Xpress Account

Define the person (s) will only have access to the GeneXpert® Edge software. This user cannot access the GeneXpert software

1

2 Click on «Add»

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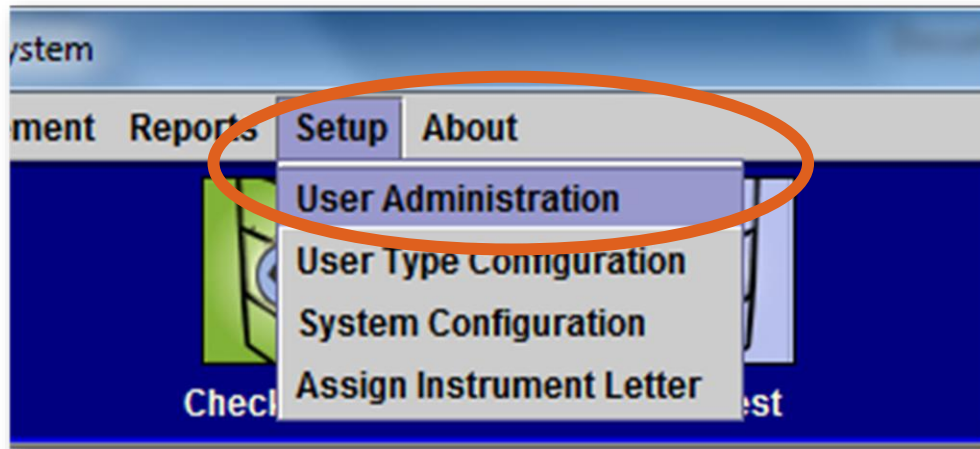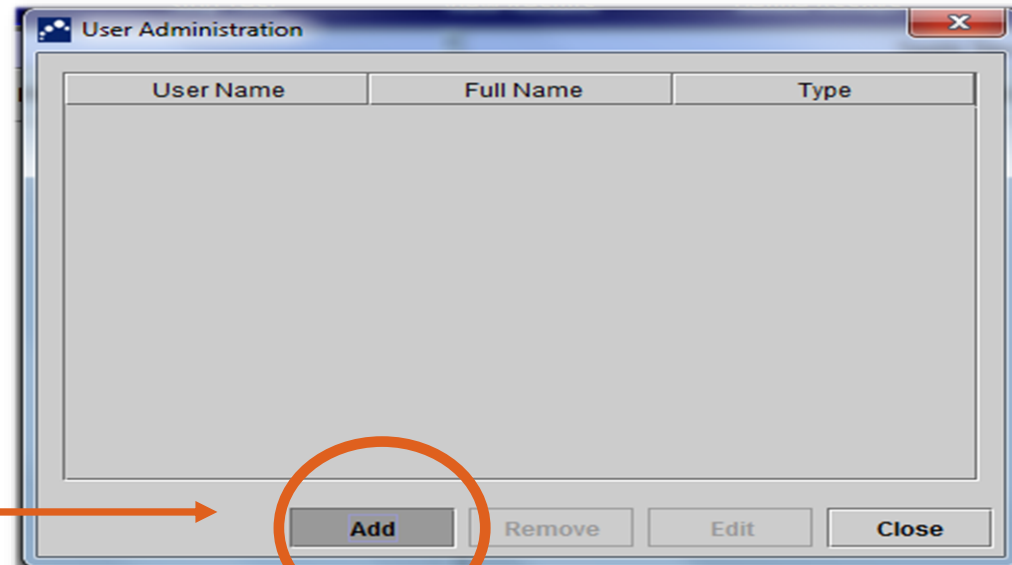
Enable user log-in

The default setting does not require a login for GeneXpert®
Edge users.
If login is required, the configure the system as such

1 Go to System Configuration> Xpress
settings
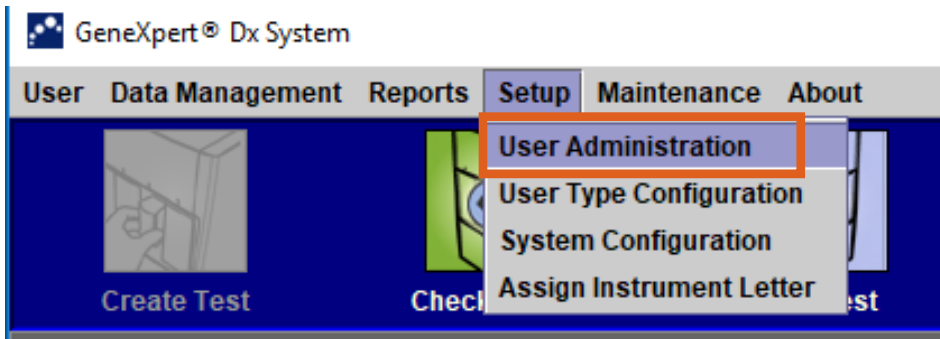
2

Tick box to allow
log-in for
GeneXpert ®
Edge software

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Host Communication Settings

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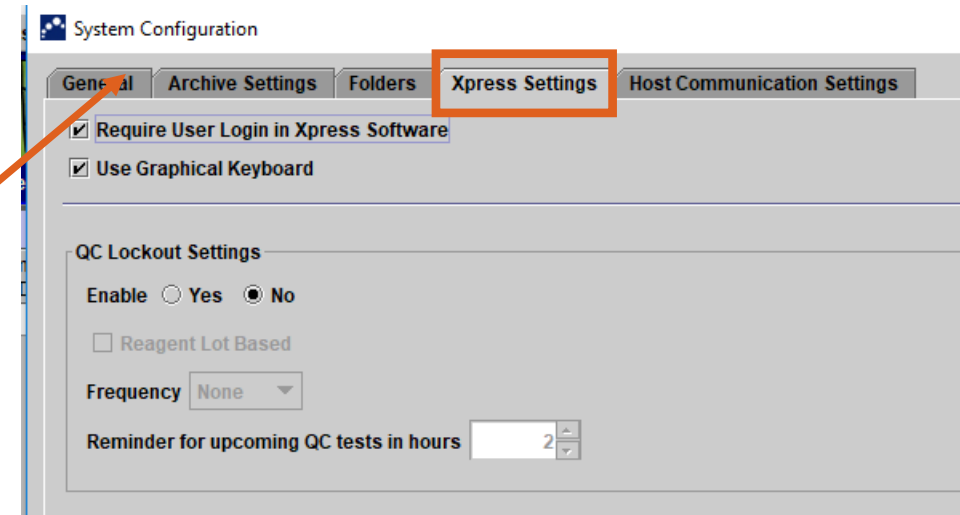
Host Communication Settings

- To configure the GeneXpert ® Edge software for a Laboratory Information System (LIS) interface connection, contact Cepheid Technical Support.

- See the Technical Assistance section in the Preface for contact information

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GeneXpert® Edge 1.0 System Software

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GeneXpert® Edge Software Overview

- **GeneXpert® Edge 1.0** software

- Requires **GeneXpert® Software** in the background

- Compatible with Windows 10

- Languages Supported: English ONLY

- GeneXpert® Edge and GeneXpert® folder shortcuts on Desktop

- Computer is Configured to Auto Launch GeneXpert® Edge Software

- Video Guidance for Cartridge Preparation included during create test process

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Start-up

- Please wait a little – the Edge software will start automatically

If the software does not open automatically, double click the icon on the desktop

GeneXpert Edge

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Create a test

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Create a new test

1 Welcome To Touch Screen Edge System

TOUCH HERE TO BEGIN

2 RUN NEW TEST

VIEW PREVIOUS TESTS

Module available

A1
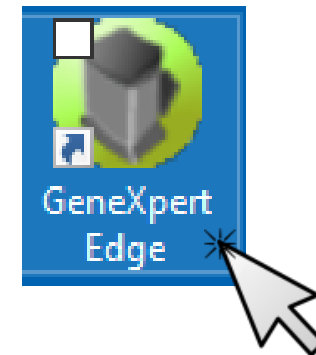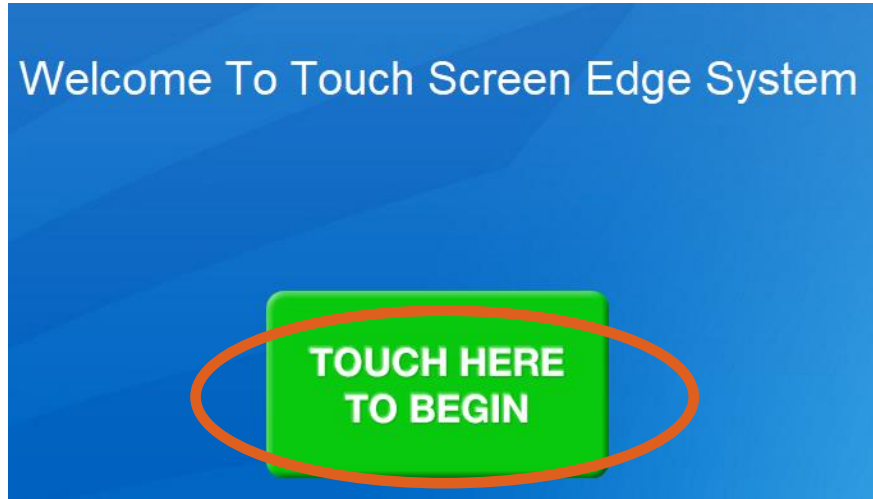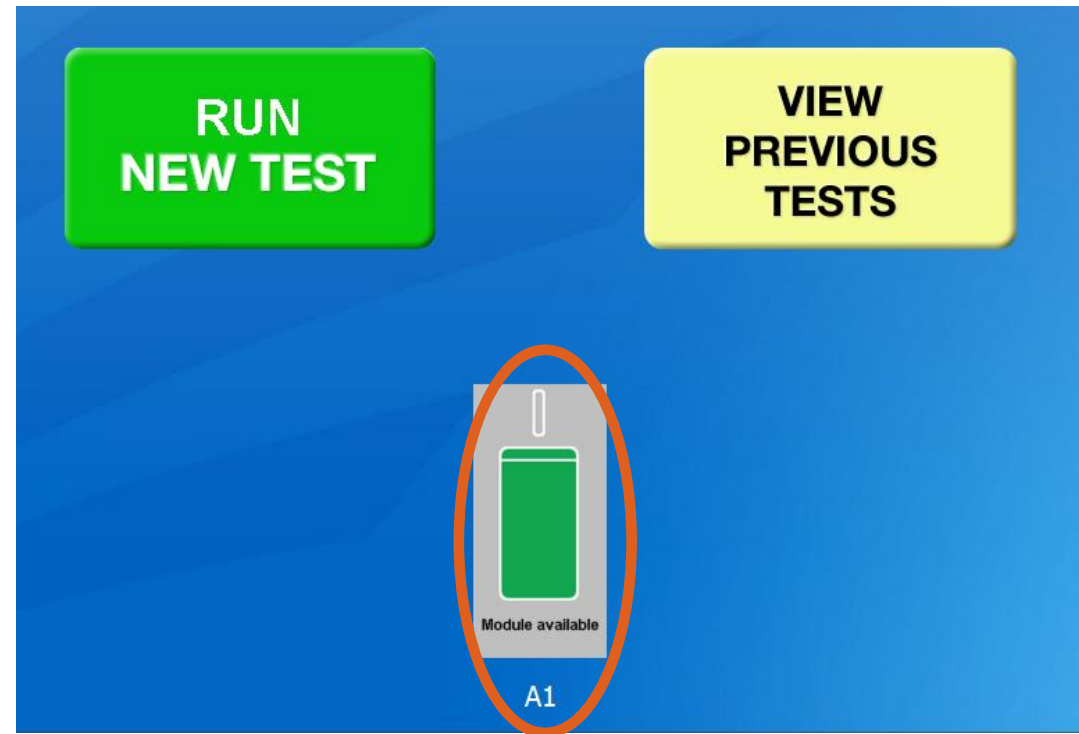
Make sure that your module is available and connected

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Create a Test

1
RUN NEW TEST

2 Click YES if Sample/Patient ID barcode is available

Click NO and enter it manually

3 Scan sample ID

Patient/Sample ID is successfully scanned when you hear the beep

Check information and confirm to proceed

4
Please confirm if you have entered the correct Patient/Sample ID?

662698701197

Scan cartridge barcode

5
Select the appropriate cartridge and press the trigger, as shown, to scan the barcode.

Cartridge barcode is successfully scanned when you hear the beep

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Create a Test

6

Please confirm that the selected Assay (Test) is correct?

Xpert MTB-RIF Assay G4

YES   **NO**

7

Patient/Sample ID

3401551882096

Assay

Xpert MTB-RIF Assay G4

Please refer to the package insert for specific sample and cartridge preparation instructions

CONTINUE

Watch the video and follow the cartridge preparation steps

8

Load the cartridge and close the module door

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Monitoring Progress

You can monitor the progress of your test. Time is displayed in minutes

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View and print results

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View results

Display shows: Patient/Sample ID, Assay and Start Date plus Time

Double-click on a result line to view a specific result

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Print Results

3

Patient/Sample ID	Cartridge S/N
12345a99	7143473072

Assay

Xpert HIV Qual

Result

HIV-1 DETECTED

Start Time

06/04/18 09:05:23

Test Disclaimer

For In Vitro Diagnostic Use Only.

4 Ensure that your printer is connected and select print results **5**

PRINT RESULT

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Exiting the software

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How to Exit Edge Software

Do NOT exit the software whilst a test is running

1

EXIT ⊗

2

GeneXpert® EDGE SOFTWARE   **Exit**

Are you sure you want to exit the software?

YES   NO

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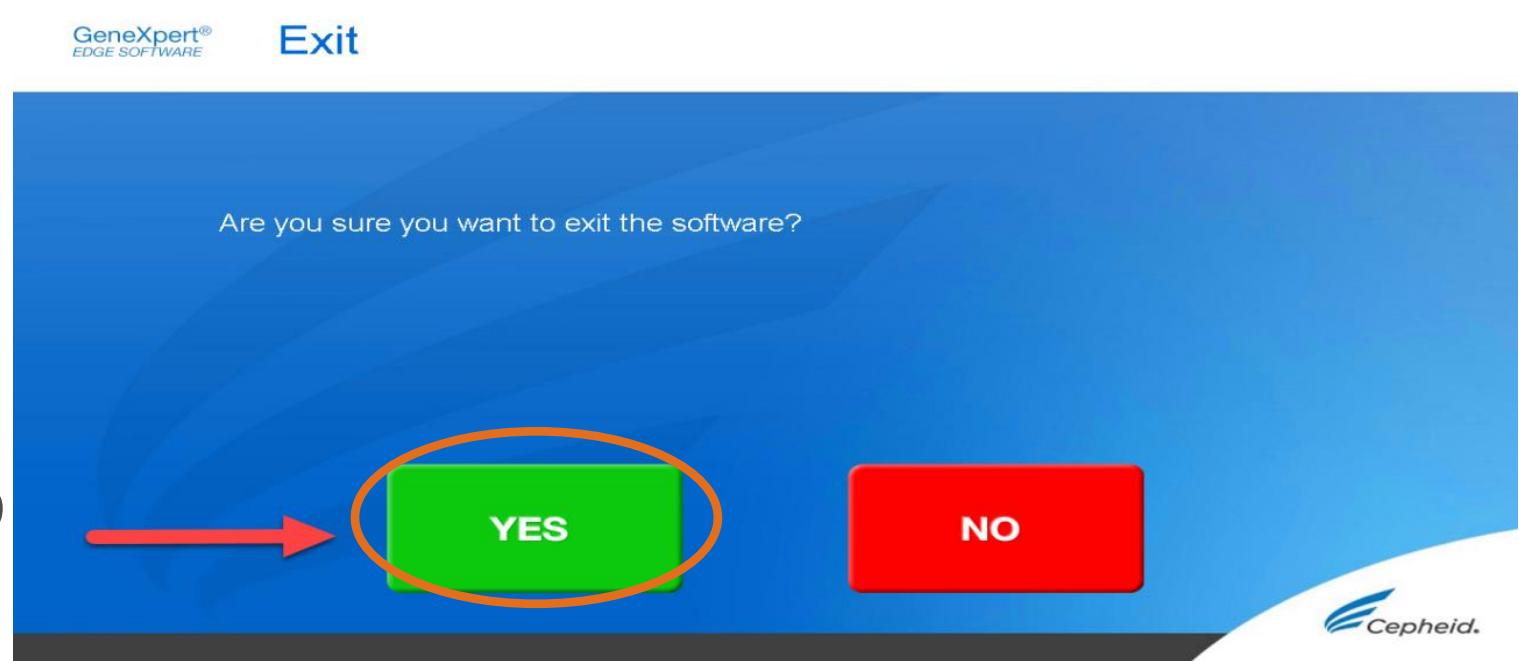
Select Yes to confirm and exit the software

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Troubleshooting

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NO RESULT/INVALID

Repeat the test by following the retest procedure

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Technical assistance

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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 using the following link *http://www.cepheid.com/us/support* - *Create a Support Case*

Region	Telephone	Technical Support Email
US	+ 1 888 838 3222	techsupport@cepheid.com
Australia and New Zealand	+ 1800 107 884 (AU) + 0800 001 028 (NZ)	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
India, Bangladesh, Bhutan, Nepal, and 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
Belgium, Netherlands and Luxembourg	+33 563 825 319	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

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Information on GeneXpert Edge System

- **GeneXpert® Edge User Manual**

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Thank You

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