GeneXpert® System with Touchscreen GX II – GX IV
Installation Training

Speaker's Name
Date

302-8140 Rev. A February 2022

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Training Agenda

1. The Package
2. Environmental and Safety Requirements
3. System Installation and Set-Up
4. Powering Up the System and Cepheid OS Configuration
5. Data Collection
6. Discussion

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Training Objectives

The general objective of this module is to guide you through the installation of the GeneXpert® system with touchscreen.

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

- Consider environmental conditions for proper installation
- Install and configure the GeneXpert® system with touchscreen
- Communicate the required information to Cepheid, after installation

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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 version 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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The Package

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The Package

GeneXpert® System with Touchscreen

- Thermal and optical module(s)
- Touchscreen unit with integrated LED barcode scanner
- Simplified and intuitive Cepheid OS software
- USB Wi-Fi dongle for ethernet connection
- Padlock for instrument security

Cartridge

- Self-contained
- Disposable
- Assay Definition File

Required but Not Provided

- Assay Specific collection devices *(if applicable)*
- Assay Specific equipment *(if applicable)*
- Personal Protective Equipment
- Timer and Permanent marker

Recommended Accessories

- Line interactive or online UPS

Optional Accessories

- Batteries/Power generator
- Printer

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Environmental and Safety Requirements

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Define the Best Setting

Before installation, make sure that the GeneXpert® system will be:

- In a well-ventilated room
- In a temperature controlled (15° to 30°C) environment
- Not directly under an air conditioning vent or in direct sunlight
- Placed on a stable surface
- Provide at least 15–20 cm of clearance on each side of the instrument
- Near a power source (maximum 2 required; 1 when connection to the UPS)

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GeneXpert® System with Touchscreen Setup

Installation and Set-Up

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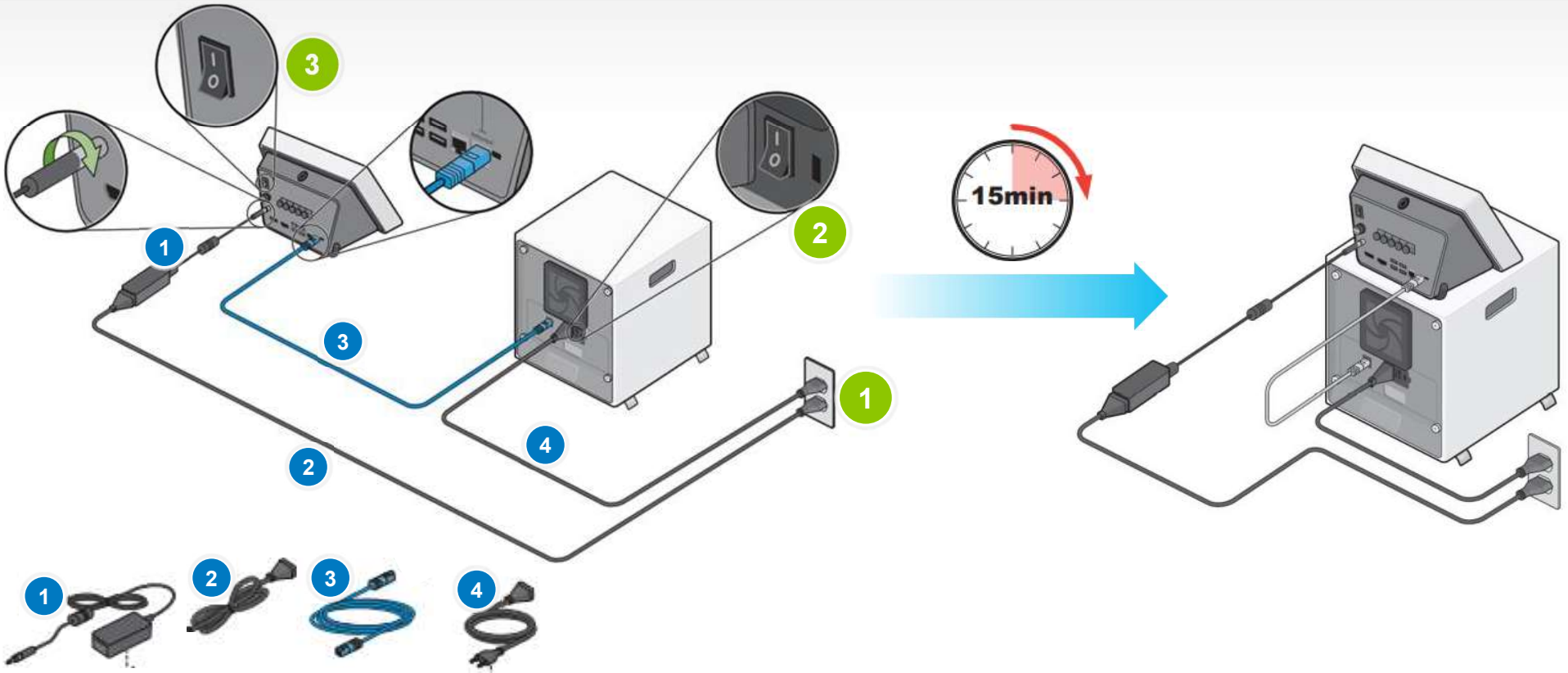
GeneXpert® System with Touchscreen Set Up

GX IV



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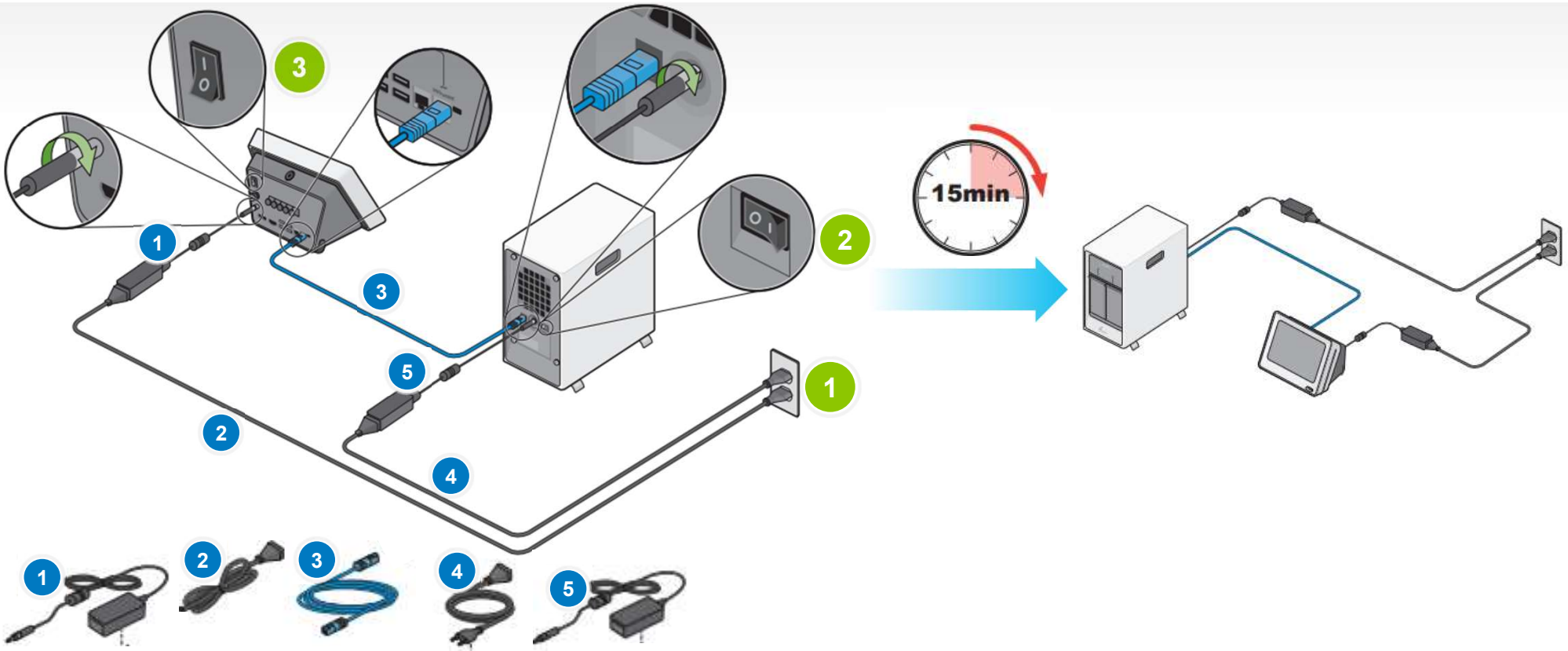
GeneXpert® System with Touchscreen Set Up

GX II



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UPS (Uninterruptible Power Supply)?

- An **uninterruptible power supply** is an electrical apparatus that provides emergency power when the input power source or mains power fails
- Support of a constant power supply prevents power interruptions, and power surges; Usage of a UPS reduces the risk of damage to the GeneXpert® instrument and repeat testing
- A UPS will provide near-instantaneous protection from input power interruptions, by supplying energy stored in batteries
- The on-battery run-time of most UPS is relatively short (only a few minutes) but sufficient to start a standby power source
- Line interactive or online UPS are highly recommended, particularly in areas prone to power outage and fluctuations

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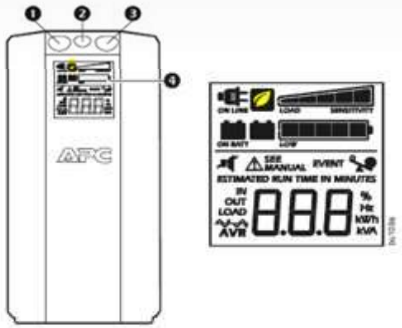
Set Up the GeneXpert® System with Touchscreen to the UPS

1. If the power-saving mode is ON, a 'leaf' will appear in the Display Interface panel.

Front panel

1. Mute button
2. Power On/Off button
3. Display button
4. Display interface



Power-Saving—Master and Controlled outlets are enabled, saving power when the master device goes into sleep or standby mode

2. Press **MUTE** and **DISPLAY** buttons at the same time for **2 seconds** to disable the power-saving feature. The leaf icon will darken (it will not be visible) and the UPS will beep once. Note: if the leaf icon is illuminated, the power-saving feature is still enabled.

UPS Model: APC Back-UPS Pro BR1500

- Cepheid P/N 850-0386 (North America)
- Cepheid P/N 850-0387 (International)
- UPS Install Instructions: 302-0697 Rev C

1. **Disable** the UPS power saving feature.

2. **Connect** instrument and touchscreen units via the power adapter into a master outlet.

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Wi-Fi Adapter Set Up

Wi-Fi adapter inserted into USB port

Ethernet cable inserted into Network port

1. **Insert** the USB Wi-Fi adapter into an available USB port at the back of the Touchscreen.
2. **Install** the necessary drivers, if prompted, using the CD in the adapter package. See the Connect a DVD Drive to the system instructions.
3. **Follow** the instructions provided by your network administrator to join your organization's wireless network.

Consult with your IT department/network admin for authorization to connect your GeneXpert® system with Touchscreen to your Wi-Fi network. They provide the required network connection details to establish the Wi-Fi connection.

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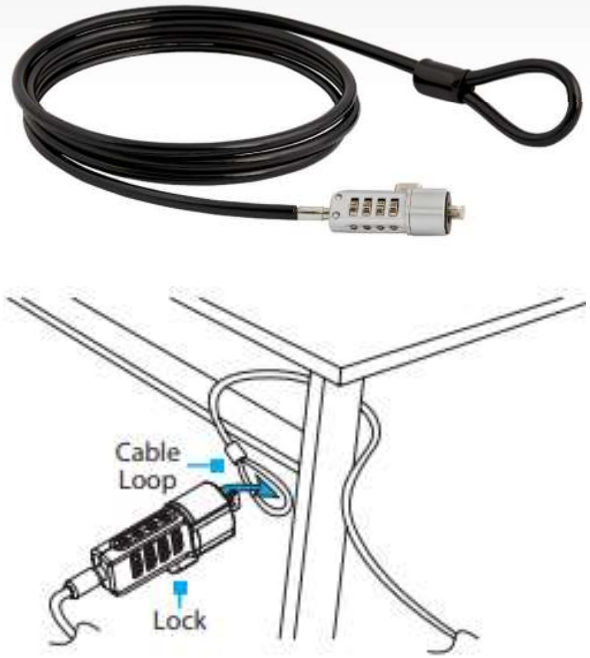
Touchscreen Lock Cable Installation

Installation



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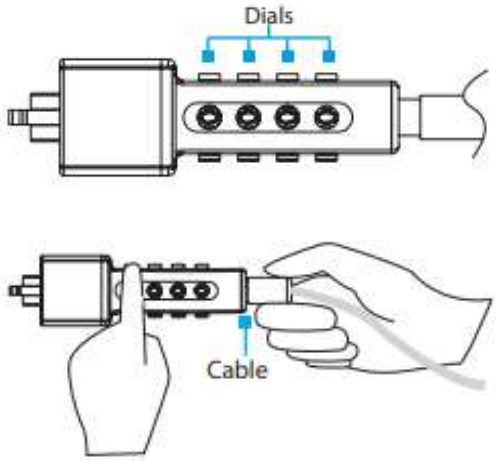
Touchscreen Lock Cable Set Up

Setting a New Combination

The factory preset lock combination is 0-0-0-0.

- For increased security, you should change the combination to a more secure series of numbers
  1. **Align** the numbers on the Dial using the default combination 0-0-0-0 (Guide Line).
  2. **Push** the cable in towards the lock and hold it in place.
  3. **Turn** the dials on the lock to the new combination that you want to set.
  4. **Release** the cable.
  5. **For added security**, turn the dials so that the combination isn't displayed in the combination display.



TIP: Write down the combination and keep it in a safe place.

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Powering Up the System & Cepheid OS Configuration

Power up the GeneXpert® System with Touchscreen

System Identification

User Management

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Start the GeneXpert® System with Touchscreen

1

Switch on the GeneXpert:
A blue light appears at the front of the system

2

Switch on the touchscreen unit:
A blue light appears on the top of the unit

3

Swipe on the left of the screen, then enter the login information:
Password: "cphd"
Must not be modified

If the unit requires to set up a new password, use **"cphd"**

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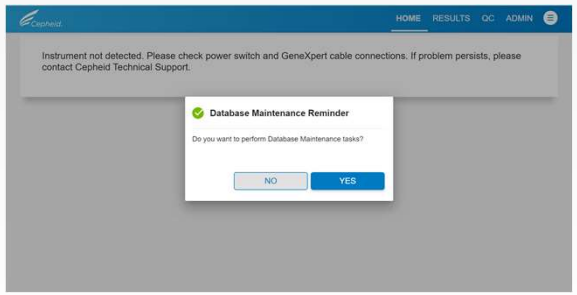
Verify Successful Start-up of the GeneXpert® System with Touchscreen

4

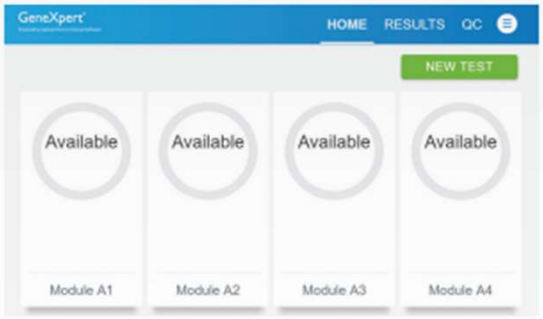
The Cepheid OS software starts automatically



Click NO

5

System verifies the modules availability



6

"WIN+M" to minimize your Cepheid OS app, and configure your Windows® operating system language and time zone

GeneXpert® System with Touchscreen Operator Manual

Chapter A.2 : Configure Windows® Language Settings

"For complete details on the GeneXpert® System, please refer to the GeneXpert® System Operators Manual"

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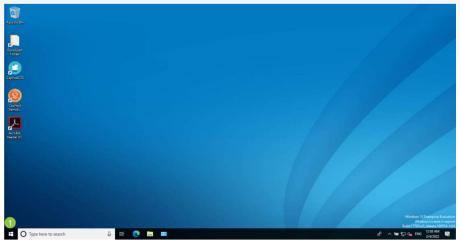
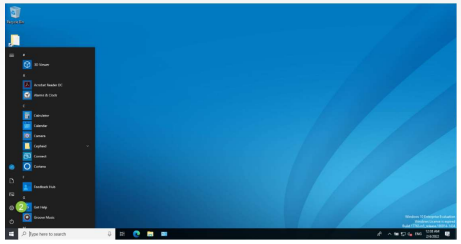
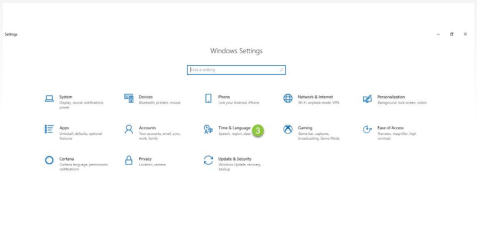
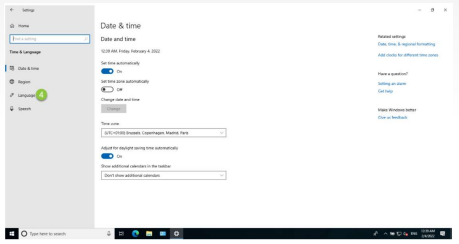
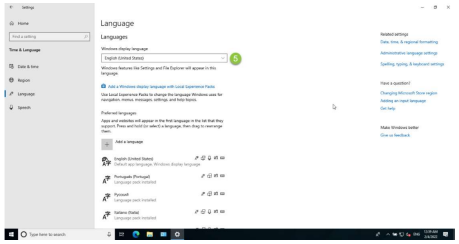
Configure your Windows® Operating System Language and Time Zone

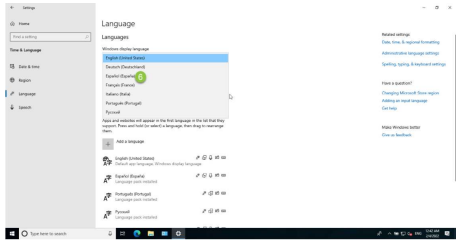


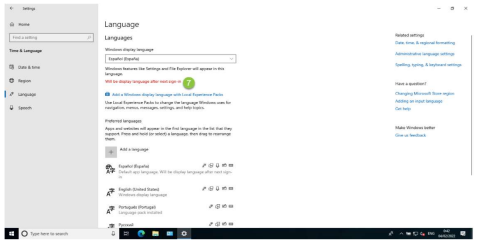


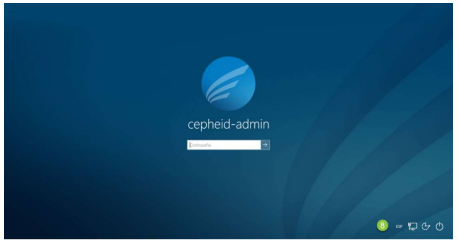












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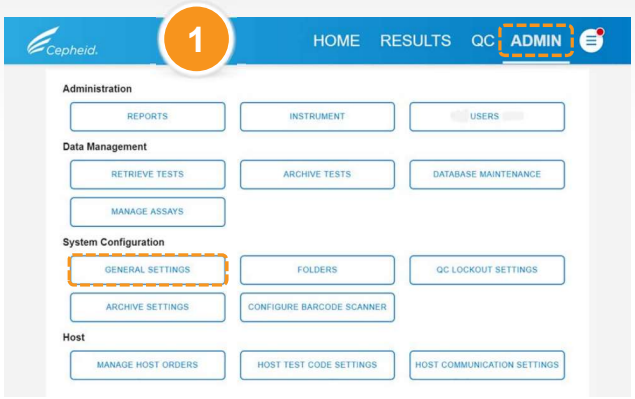
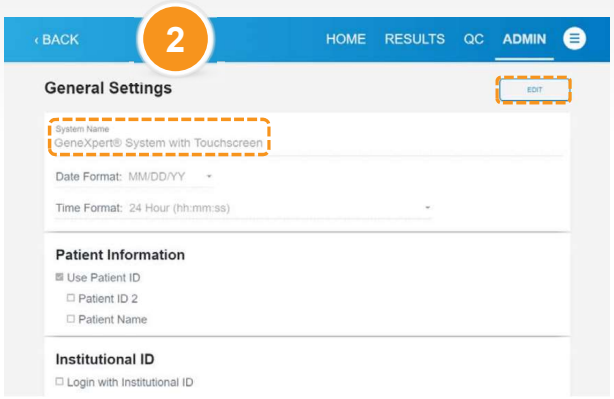
Cepheid OS Configuration

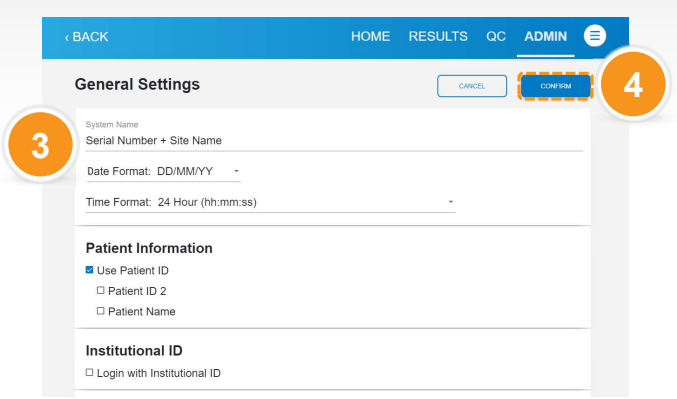
Identification of the GeneXpert® System with Touchscreen: Admin Profile



1. On the **HOME** screen select **ADMIN > GENERAL SETTINGS**



2. Tap **EDIT** to change any entries on this General Settings Screen



3. In the field « system Name » rename the system: Serial Number + Site Name recommended
4. Then tap **CONFIRM** to activate changes

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Cepheid OS Configuration

User Management Rules

User functions by roles:

User Role	Run Test	View Results	Perform Maintenance	Perform Administrative and System Functions
Basic	Yes	Yes	Limited	No
Administrator	Yes	Yes	Yes	Yes

- The first user created must be an ADMIN profile
- Requirements to add a validated user on User List:
  - Username: min 6 up to 128 characters
    + cannot contain: spaces, or these characters: | : * “ < > / \ ?
  - User Password: min 6 up to 128 characters + cannot contain: spaces

Note: User expiration date and permission level are received and managed by the Data Manager

- User Expiration Date: refers to the end of a one-year period after user certification
- User Permission Level: from 1 (Admin user) to 4 (Basic user)

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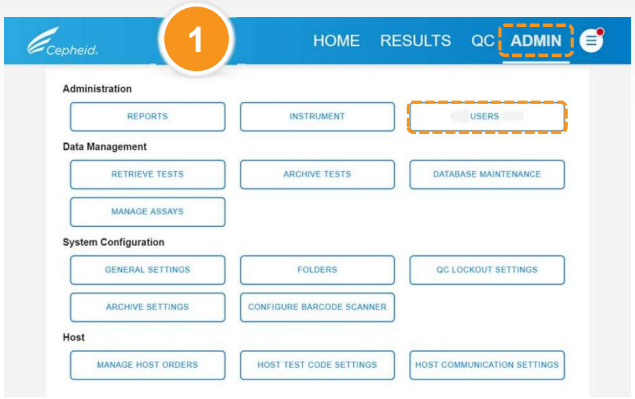
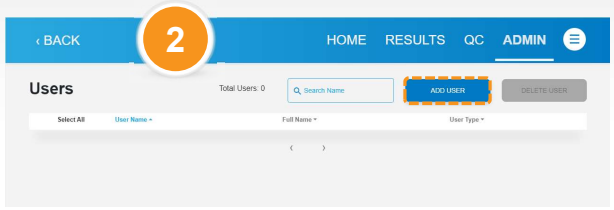
Cepheid OS Configuration

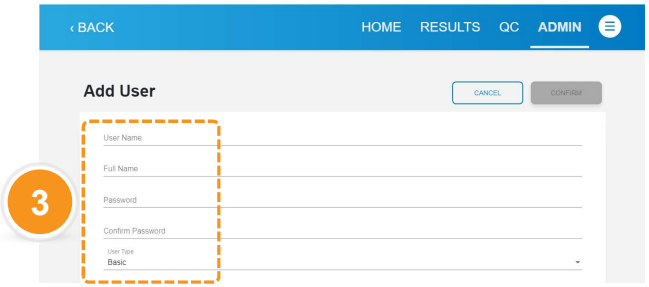
User Management: Add or Remove Users Locally (without Host Communication)



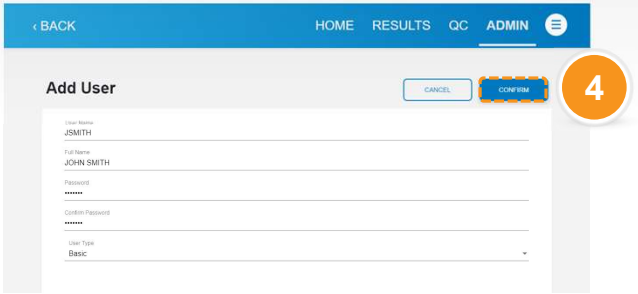
1. On the **HOME** screen select **ADMIN > USERS**



2. Tap **ADD USER**



3. Enter the User Name, the Full Name, Password of the user, Confirm the Password, and Select the User Type (Administrator for the first add; or Basic)



4. Then tap **CONFIRM** to activate changes

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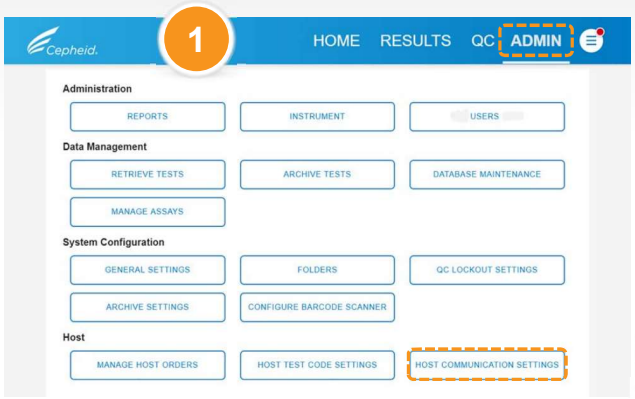
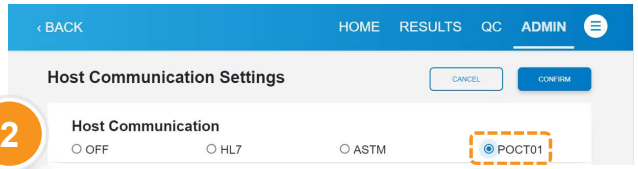
Cepheid OS Configuration

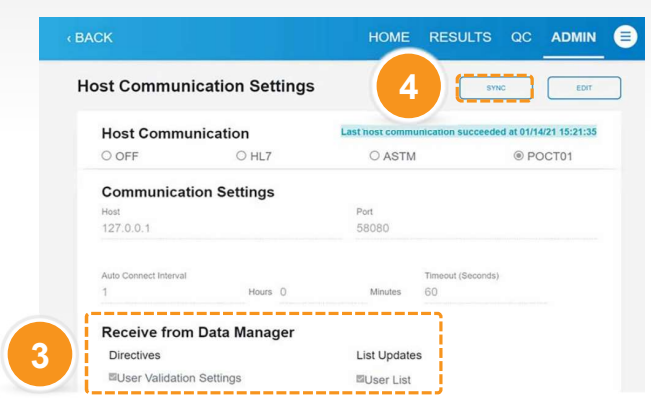
User Management: User Lists from Data Management System (DMS connection activated)



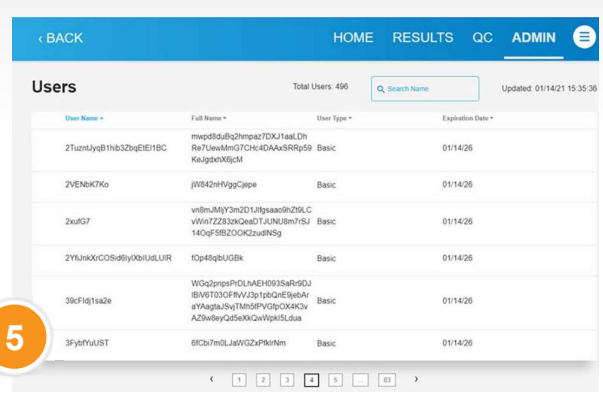
1. On the **HOME** screen select **ADMIN > HOST COMMUNICATION SETTINGS**



2. Tap **EDIT** and select POCTO1 protocol; check the DMS connection is successful



3. On the Receive from Data Manager part, tap **USER LIST** and **USER VALIDATION SETTINGS**
4. Then tap **SYNC** to update the user's list



5. Check the user's list is updated: On the **ADMIN** screen select **USERS** > the user list appears

Note: When users are added locally and the system is later connected to a Data Management (DM) system, those local users are removed when the user list is updated. If a user is added to a DM system and the instrument is later connected to the DM, the user list that then appears locally is the last list that was downloaded from the DM.

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Data to Collect and Send to Cepheid

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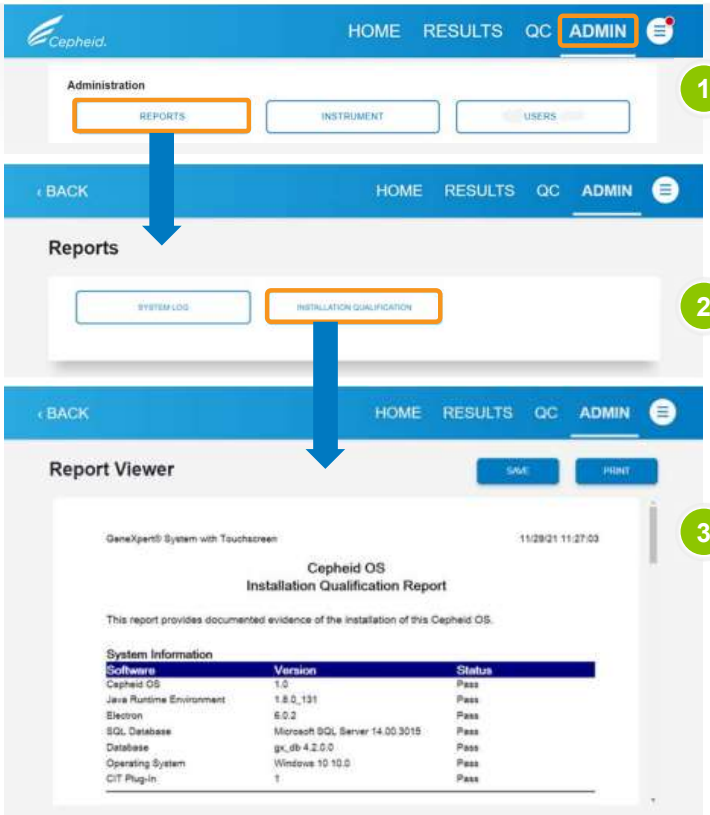
Documents to Save

- After the installation is complete, provide the following information to Cepheid Technical Service: serviceemea@cepheid.com



1. Site contact name
2. Email, physical address, and phone number of the contact
3. Generate the Installation Qualification Report, then save or print it

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Records

1. Sign and store the Installation Qualification report as proof of installation
2. Remember your login and password
3. Collect the touchscreen Service Tag Number

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Technical Assistance

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Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

Person in charge (name)	x
Phone number	x
Serial number of your GeneXpert® instrument	x
E-mail address	x
Address, City, Country	x
Serial number of your touchscreen unit	x
Installation date of the GeneXpert® system	xx/xx/xxxx
Description of the issue (software messages/codes)	x
Assay(s) used	x

When contacting Cepheid, please prepare this information in advance: www.cepheid.com/support

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Technical Assistance

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, 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
Othe 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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Thank You

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