

GeneXpert
Powered By CEPHEID INNOVATION

Xpert[®] Omni SARS-CoV-2

Instructions for Use

For Use Under an Emergency Use Authorization (EUA) Only



REF OMNISARS-COV2-10

IVD

For Use with GeneXpert Omni System



For use under an Emergency Use
Authorization (EUA) Only

IVD

302-4579, Rev. A November 2020

Trademark, Patents, and Copyright Statements

Cepheid[®], the Cepheid logo, GeneXpert[®], and Xpert[®] are trademarks of Cepheid.
AccuPlexTM is a trademark of SeraCare Life Sciences.

THE PURCHASE OF THIS PRODUCT CONVEYS TO THE BUYER THE NON-TRANSFERABLE
RIGHT TO USE IT IN ACCORDANCE WITH THIS INSTRUCTIONS FOR USE. NO OTHER
RIGHTS ARE CONVEYED EXPRESSLY, BY IMPLICATION OR BY ESTOPPEL.
FURTHERMORE, NO RIGHTS FOR RESALE ARE CONFERRED WITH THE PURCHASE OF
THIS PRODUCT.

Copyright © Cepheid 2020. All rights reserved.

Xpert® Omni SARS-CoV-2

For use under the Emergency Use Authorization (EUA) only.

1 Proprietary Name

Xpert® Omni SARS-CoV-2

2 Common or Usual Name

Xpert Omni SARS-CoV-2

3 Intended Use

The Xpert Omni SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens (such as nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and/or nasal wash/aspirate) collected from individuals suspected of COVID-19 by their healthcare provider.

Testing of nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and nasal wash/aspirate specimens using the Xpert Omni SARS-CoV-2 test run on the GeneXpert Omni System is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform high or moderate complexity tests.

Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the Xpert Omni SARS-CoV-2 test is intended for use by qualified laboratory personnel specifically instructed and trained in performing tests using the GeneXpert Omni System. The Xpert Omni SARS-CoV-2 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Xpert® Omni SARS-CoV-2

4 Summary and Explanation

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.¹ Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.²

The Xpert Omni SARS-CoV-2 test is a molecular *in vitro* diagnostic test that aids in the detection of SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The Xpert Omni SARS-CoV-2 test contains primers and probes and internal controls used in RT-PCR for the *in vitro* qualitative detection of SARS-CoV-2 RNA in upper respiratory specimens.

5 Principle of the Procedure

The Xpert Omni SARS-CoV-2 test is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from SARS-CoV-2. The Xpert Omni SARS-CoV-2 test is performed on GeneXpert Omni System.

The GeneXpert Omni System automates and integrates sample preparation, nucleic acid extraction, reverse transcription, and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays. The system consists of an instrument and mobile device. The system requires the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the *GeneXpert Omni System Operator Manual*.

The Xpert Omni SARS-CoV-2 test includes reagents for the detection of RNA from SARS-CoV-2 in nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and/or nasal wash/aspirate specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert Omni instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab specimen and/or nasal wash/aspirate specimen is collected and placed into a viral transport tube containing 3 mL transport medium or 3 mL of saline. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Omni SARS-CoV-2 cartridge.

Xpert® Omni SARS-CoV-2

The Xpert Omni SARS-CoV-2 cartridge is loaded onto the GeneXpert Omni System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

6 Reagents and Instruments

6.1 Materials Provided

The Xpert Omni SARS-CoV-2 kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

Xpert Omni SARS-CoV-2 Cartridges with Integrated Reaction Tubes	10
Bead 1, Bead 2, and Bead 3 (freeze-dried)	1 of each per cartridge
Lysis Reagent	1.5 mL per cartridge
Binding Reagent	1.5 mL per cartridge
Elution Reagent	3.0 mL per cartridge
Disposable Transfer Pipettes	10-12 per kit
Quick Reference Instructions	1 per kit
Flyer	1 per kit
Directions to locate the product insert on www.cepheid.com	

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

7 Storage and Handling

- Store the Xpert Omni SARS-CoV-2 cartridges at 2-28°C.
- Do not open a cartridge lid until you are ready to perform testing.
- Do not use a cartridge that is wet or has leaked.

8 Materials Required but Not Provided

GeneXpert Omni System: Omni instrument with Omni instrument software version 1.2 or higher and mobile device with Omni mobile application version 1.2 or higher

9 Materials Available but Not Provided

SeraCare AccuPlex™ Reference Material Kit, catalog number 0505-0126 (Order Code CEPHEID)

10 Warnings and Precautions

10.1 General

- For *in vitro* diagnostic use.
- For emergency use only.
- Positive results are indicative of presence of SARS-CoV-2-RNA.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- Performance characteristics of this test have been established with nasopharyngeal swab specimens only. The performance of this assay with other specimen types or samples has not been evaluated.
- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be handled using standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention³ and the Clinical and Laboratory Standards Institute.⁴
- Follow safety procedures set by your institution for working with chemicals and handling biological specimens.
- Consult your institution's environmental waste personnel on proper disposal of used cartridges, which may contain amplified material. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions should check the hazardous waste disposal requirements within their respective countries.

10.2 Specimens

- Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see Section 12 Specimen Collection, Transport, and Storage). Specimen stability under shipping conditions other than those recommended has not been evaluated.

10.3 Assay/Reagent

- Do not open the Xpert Omni SARS-CoV-2 cartridge lid except when adding specimen.
- Do not use a cartridge that has been dropped after removing it from the packaging.
- Do not shake the cartridge. Shaking or dropping the cartridge after opening the cartridge lid may yield non-determinate results.
- Do not place the sample ID label on the cartridge lid or on the barcode label on the cartridge.
- Do not use a cartridge with a damaged barcode label.
- Do not use a cartridge that has a damaged reaction tube.

Xpert® Omni SARS-CoV-2

- Each single-use Xpert Omni SARS-CoV-2 cartridge is used to process one test. Do not reuse processed cartridges.
- Each single-use disposable pipette is used to transfer one specimen. Do not reuse disposable pipettes.
- Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.
- Wear clean lab coats and gloves. Change gloves between the handling of each specimen.
- In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels. Then, thoroughly clean the contaminated area with a 10% freshly prepared household chlorine bleach. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. Or, follow your institution's standard procedures for a contamination or spill event. For equipment, follow the manufacturer's recommendations for decontamination of equipment.
- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

11 Chemical Hazards^{5,6}

- **Signal Word:** Warning
- **UN GHS Hazard Statements**
 - Harmful if swallowed.
 - May be harmful in contact with skin.
 - Causes eye irritation.
- **UN GHS Precautionary Statements**
 - **Prevention**
 - Wash hands thoroughly after handling.
 - **Response**
 - Call a POISON CENTER or doctor/physician if you feel unwell.
 - If skin irritation occurs: Get medical advice/attention.
 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - If eye irritation persists: Get medical advice/attention.

12 Specimen Collection, Transport, and Storage

Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequate specimen collection, improper specimen handling and/or transport may yield a false result. See Section 12.1 for Nasopharyngeal Swab Collection Procedure, Section 12.2 for Oropharyngeal Swab Collection Procedure, Section 12.3 for Nasal Swab Collection Procedure, Section 12.4 for Mid-turbinate Swab Collection Procedure, and Section 12.5 for Nasal Wash/aspirate Procedure.

Nasopharyngeal, nasal, and mid-turbinate swabs and nasal wash/aspirate specimens can be stored at room temperature (15–30 °C) for up to 8 hours and refrigerated (2–8 °C) up to seven days until testing is performed on the GeneXpert Omni System. For oropharyngeal swab specimen transport and storage requirements and additional information, refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) using the link provided below:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>.

12.1 Nasopharyngeal Swab Collection Procedure

1. Insert the swab into either nostril, passing it into the posterior nasopharynx (see Figure 1).

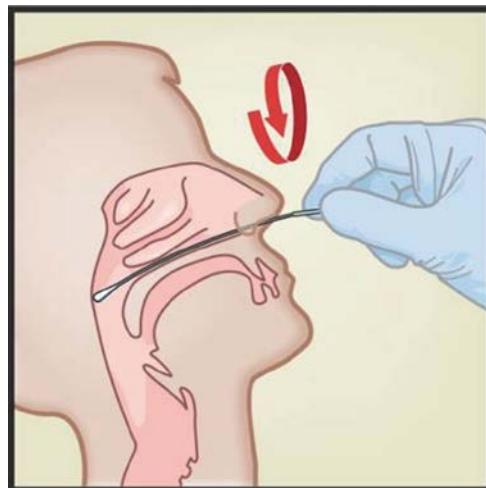


Figure 1. Nasopharyngeal Swab Collection

2. Rotate swab by firmly brushing against the nasopharynx several times. Remove and place the swab into the tube containing 3 mL of viral transport medium or 3 mL of saline.
3. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.2 Oropharyngeal Swab Collection Procedure

1. Swab the posterior pharynx, tonsils, and other inflamed areas. Avoid touching the tongue, cheeks, and teeth with the swab when collecting specimens.
2. Remove and place the swab into the tube containing 3 mL of viral transport medium or 3 mL of saline. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.3 Nasal Swab Collection Procedure

1. Insert a nasal swab 1 to 1.5 cm into a nostril. Rotate the swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril (see Figure 2).



Figure 2. Nasal Swab Collection for First Nostril

2. Repeat on the other nostril with the same swab, using external pressure on the outside of the other nostril (see Figure 3). To avoid specimen contamination, do not touch the swab tip to anything other than the inside of the nostril.

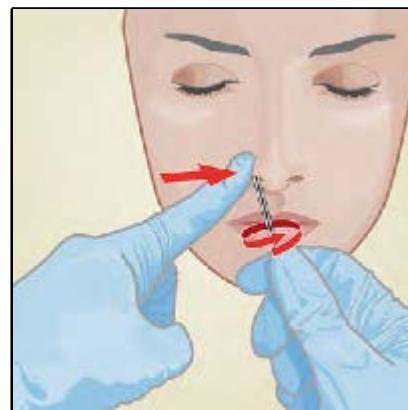


Figure 3. Nasal Swab Collection for Second Nostril

Xpert® Omni SARS-CoV-2

3. Remove and place the swab into the tube containing 3 mL of viral transport medium or 3 mL of saline. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.4 Mid-Turbinate Swab Collection Procedure

1. Insert the mid-turbinate swab into either nostril, passing it into the mid-turbinate area (see Figure 4).

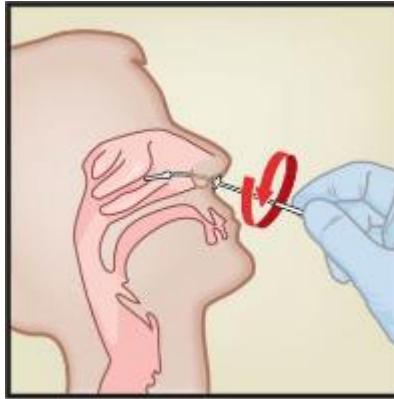


Figure 4. Mid-turbinate Swab Specimen Collection

2. Rotate swab by firmly brushing against the mid-turbinate area several times.
3. Remove and place the swab into the tube containing 3 mL of viral transport medium or 3 mL of saline.
4. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.5 Nasal Wash/Aspirate Procedure

Using a clean transfer pipette, transfer 600 µL of the sample into the tube containing 3 mL of viral transport medium or 3 mL of saline and then cap the tube.

13 Procedure

13.1 Starting the Test

1. Turn on the Omni instrument. Press in and hold the red power button on the back of the Omni instrument for 2 seconds.

Note It takes about two minutes to start up the instrument. During this time, the instrument performs a self-test procedure that includes opening and closing the cartridge door. When the instrument is ready, the white flashing activity light illuminates.

2. Turn on the mobile device. Press and hold the power button on the right side of the mobile device.
3. Swipe the mobile device home screen to unlock the mobile device.
4. In the Launcher application, tap the **Omni** icon to start the Omni mobile application (see Figure 5). The Cepheid login screen appears.

Xpert® Omni SARS-CoV-2

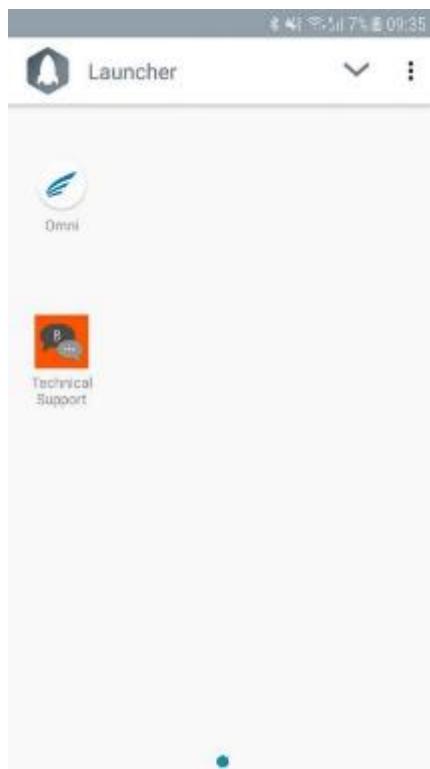


Figure 5. Omni Application

5. On the Cepheid login screen, tap **LOGIN**.
6. Tap in the **User Name** field and use the keyboard to type in your user name. Figure 6 shows an example of a user name typed into the field (e.g., my.institution01@gmail.com).



Figure 6. User Name and Password Fields

7. Tap in the **Password** field, type the password, and tap the forward arrow next to the Password field to enter login information (see Figure 6). The Home screen appears.
8. Verify that the instrument icon appears at the bottom of the screen as shown in Figure 7.

Xpert® Omni SARS-CoV-2



Figure 7. Example of an Omni Instrument Connected to Mobile Device

9. On the Home screen, tap the **Start New Test** icon (see Figure 8). The Patient ID screen appears.



Figure 8. Start New Test Icon on Home Screen

10. Tap in the **Patient ID** field and use the keyboard to type in the Patient ID.
 11. Scroll down to locate the forward arrow and tap the forward arrow at the bottom of the Patient ID screen. The Sample ID screen appears.
- Note** You can enter additional patient information (patient date of birth, patient name, patient gender, and patient address) in fields on the Patient ID screen, if pre-configured by your institutional administrator.
12. Enter the Sample ID by manually entering or scanning or randomly generating a sample ID (see Figure 9):
 - **Manual Entry:** Tap the **Enter Sample ID** icon, then type the Sample ID in the **Sample ID** field. OR
 - **Barcode Scan:** Tap the **Scan Sample Barcode** icon. Aim the rear camera of the mobile device at the Sample ID barcode on the sample container. When the mobile device recognizes the barcode, a beep sounds, and the Sample ID appears in the **Sample ID** field. OR
 - **Generate ID:** Tap the **Generate Sample ID** icon. A random ID generator generates the Sample ID in the **Sample ID** field that you can record on the sample container or test order.

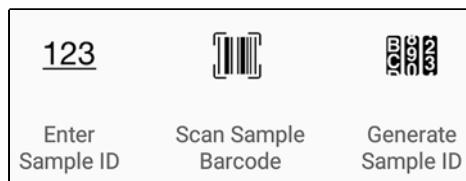


Figure 9. Sample ID Icons

Xpert® Omni SARS-CoV-2

Note You can enter additional sample information (test type, sample type description, and notes) in fields on the Sample ID screen.

13. Scroll down to locate the forward arrow and tap the forward arrow at the bottom of the Sample ID screen.
14. Using the screen animation on the mobile device as a guide, put the back of the mobile device close to the GeneXpert cartridge label to read the NFC tag embedded in the cartridge label (see Figure 10). **DO NOT** hold the reaction tube located at the back of the cartridge. When the mobile device reads the cartridge, it emits a single beep.

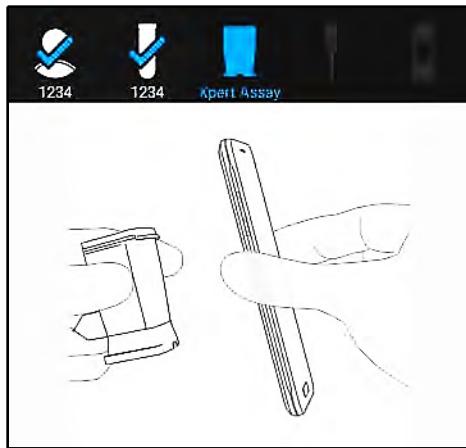


Figure 10. Scan Cartridge with Mobile Device

15. Verify that the correct cartridge was scanned and that the assay name shown on the screen matches closely with the assay name on the cartridge.

Note The assay name shown in the Assay Name field may not match exactly the assay name on the cartridge which may be abbreviated.

16. Scroll down to locate the forward arrow and tap the forward arrow at the bottom right of the screen. Animation on the screen appears as a guide to help you load the sample into the cartridge.

Xpert® Omni SARS-CoV-2

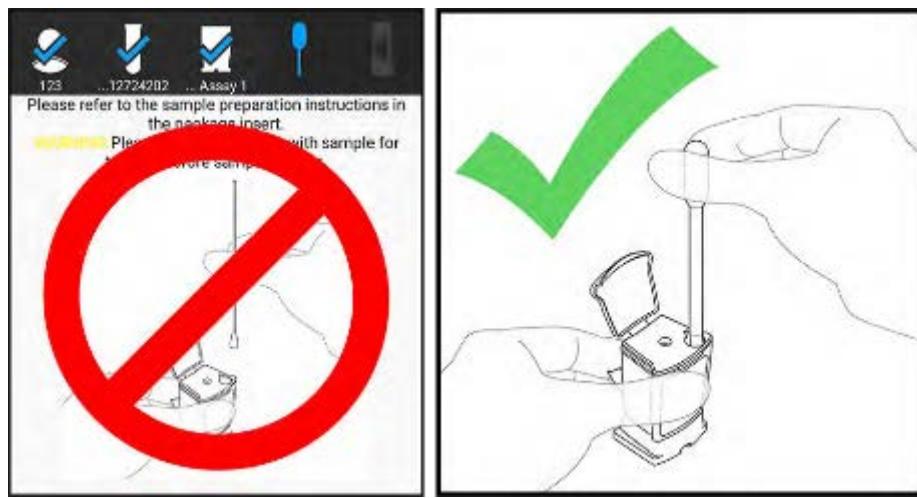


Figure 11. Loading Sample into Cartridge

Warning

- DO NOT ADD swab to cartridge.
- DO NOT USE swab to add sample to the cartridge as shown on the screen.
- Only use the transfer pipette to add directly to large sample chamber (see Section 13.2).

13.2 Preparing the Cartridge

Note Important: Start the test within 30 minutes of adding the sample to the cartridge.

1. Check the specimen transport tube is closed.
2. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open the cap on the specimen transport tube.
3. Open the cartridge by lifting the front of the cartridge lid.
4. Remove the transfer pipette from the wrapper.
5. Squeeze the top bulb of the transfer pipette **completely until the top bulb is fully flat**. While continuing to hold the bulb fully flat, place the pipette tip in the specimen transport tube (see Figure 12).

Xpert® Omni SARS-CoV-2

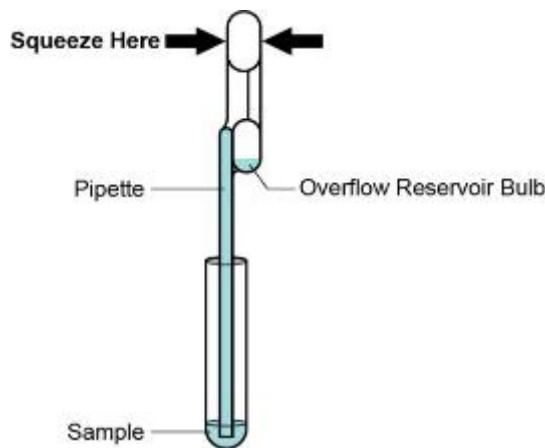


Figure 12. Transfer Pipette

6. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette to fill the pipette before removing from the tube. After filling pipette, excess sample will be seen in the overflow reservoir bulb of the pipette (see Figure 12). Check that the pipette does not contain bubbles.
7. To transfer the sample to the cartridge, squeeze the top bulb of the transfer pipette **completely until the top bulb is fully flat** to empty the contents of the pipette ($300 \mu\text{L}$) into the large opening (Sample Chamber) in the cartridge shown in Figure 13. Some liquid may remain in the overflow reservoir. Dispose of the used pipette.

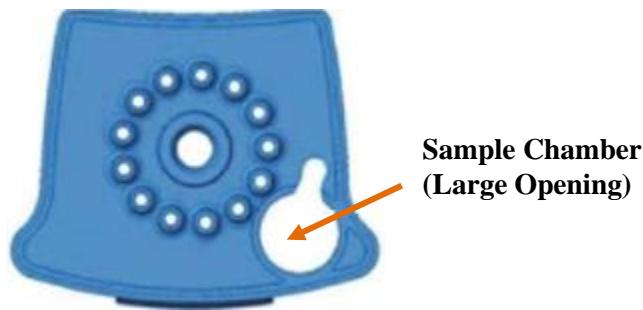


Figure 13. Xpert Omni SARS-CoV-2 Cartridge (Top View)

Note Dispense the entire volume of liquid into the sample chamber. False negative results may occur if insufficient sample is added to the cartridge.

8. Close the cartridge lid.

Xpert® Omni SARS-CoV-2

13.3 External Controls

External controls described in Section 9 are available but not provided and may be used in accordance with local, state, and federal accrediting organizations, as applicable.

To run a control using the Xpert Omni SARS-CoV-2 test, perform the following steps:

1. Mix control by rapidly inverting the external control tube 5 times.
2. Open the cap on the external control tube.
3. Open the cartridge lid.
4. Using a clean transfer pipette, transfer one draw of the external control sample (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Figure 13.
5. Close cartridge lid.

13.4 Loading Cartridge on the GeneXpert Omni

1. Scroll down to locate the forward arrow and tap the forward arrow at the bottom of the screen.
2. Tap the **instrument** icon. The door to the GeneXpert Omni instrument opens.

- Note** Wait until the door is fully open and all moving parts have stopped before inserting the cartridge. This wait time allows the loading mechanism to move into the correct position to receive the cartridge. Loading the cartridge prematurely can cause damage to the loading mechanism.
3. With the cartridge label facing the operator, load the cartridge onto the cartridge platform. Gently push the cartridge in place to allow the instrument to pull the cartridge. Remove hands immediately from instrument after loading cartridge. The door will close automatically, the test starts, and the screen shows the test is starting (see Figure 14). The screen changes to the test in process and the time remaining (see Figure 15). When the test completes, the instrument door opens, and the screen provides the test result. At the bottom of the screen, tap **Print Result**.

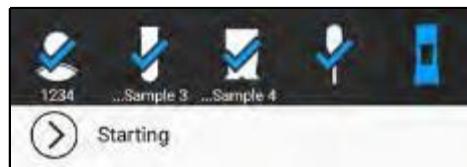


Figure 14. Test Starting Screen

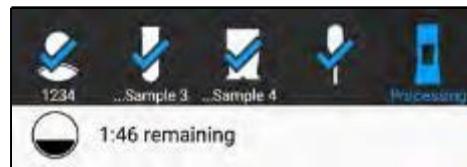


Figure 15. Test in Progress Screen

Xpert® Omni SARS-CoV-2

- Note** Do not try to manually open the instrument door at any time. Damage to the door mechanism can occur if the door is manually operated.
- Note** Do not move the instrument once a test has started. Invalid test results can occur if the instrument is moved during processing.
- Note** Do not tip the instrument when a test is running. In addition to causing an error and possible invalid test results, damage to the instrument can occur if the cartridge contents leak or spill into the interior of the instrument.
4. Remove the cartridge and dispose of the cartridge and gloves according to your institution's hazardous waste policies.

14 Viewing Results

1. On the Home screen, tap the **View Results** icon (see Figure 16).



Figure 16. View Results Icon

The test results performed today are listed with the most recent test at the top (see Figure 17).

View Results	
Test ID	Date
1536684222967	2018-09-11 09:47 AM
First	Last
Xpert Assay 3	
1536605661822	2018-09-10 11:56 AM
Nom Cognome	
Xpert Assay 1	
ORG DETECTED	
1536605216135	2018-09-10 11:49 AM
Fornamn Apelito	
Xpert Assay 3	
6789	2018-09-10 11:41 AM
Primo Segundo	
Xpert Assay 2	
ORG NOT DETECTED	
12345	2018-09-10 11:34 AM
First	Last
Xpert Assay 1	
ORG DETECTED	
1536094010000	2018-09-04 01:48 PM
null null	
Xpert Assay 1	

Figure 17. View Results Screen

2. To view the list of results for a different time period, tap one of the result period options shown at the top of the screen (see Figure 18).



Figure 18. Select Result Period

3. Tap a listed test to view more information about the test and print the test result by tapping **Print Result** at the bottom of the screen. If results are not displayed, make sure that:
 - Omni instrument is turned on.
 - Mobile device is within 30 meters (100 feet) of the Omni instrument.

15 Quality Control

15.1 Internal Controls

Each cartridge includes a Sample Processing Control (SPC) and Probe Check Control (PCC).

Sample Processing Control (SPC) – Ensures that the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.

Probe Check Control (PCC) – Before the start of the PCR reaction, the GeneXpert Omni System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the validated acceptance criteria.

15.2 External Controls

External controls should be used in accordance with local, state, and federal accrediting organizations as applicable.

16 Interpretation of Results

The results are interpreted automatically by the GeneXpert Omni System and are clearly shown in the **View Results** screen. The Xpert Omni SARS-CoV-2 test provides test results based on the detection of two gene targets according to the algorithms shown in Table 1.

Xpert® Omni SARS-CoV-2

Table 1. Xpert Omni SARS-CoV-2 Possible Results

Result Text	N2	E	SPC
SARS-CoV-2 POSITIVE	+	+/-	+/-
SARS-CoV-2 POSITIVE	+/-	+	+/-
SARS-CoV-2 NEGATIVE	-	-	+
INVALID	-	-	-

See Table 2 to interpret test result statements for the Xpert Omni SARS-CoV-2 test.

Table 2. Xpert Omni SARS-CoV-2 Results and Interpretation

Result	Interpretation
SARS-CoV-2 POSITIVE	<p>The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are detected.</p> <ul style="list-style-type: none"> • The SARS-CoV-2 signal for the N2 nucleic acid target or signals for both nucleic acid targets (N2 and E) have a Ct within the valid range and endpoint above the minimum setting. <p>OR</p> <ul style="list-style-type: none"> • The SARS-CoV-2 signal for the E nucleic acid target has a Ct within the valid range and endpoint above the minimum setting. Additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management. NOTE: Specific target information can be accessed through the C360 portal, https://c360.cepheid.com. Refer to the GeneXpert C360 user's manual for additional instructions. • SPC: NA; SPC is ignored because coronavirus target amplification occurred. • Probe Check: PASS; all probe check results pass.
SARS-CoV-2 NEGATIVE	<p>The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected.</p> <ul style="list-style-type: none"> • The SARS-CoV-2 signals for two nucleic acid targets (N2 and E) do not have a Ct within the valid range and endpoint above the minimum setting. • SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting. • Probe Check: PASS; all probe check results pass.

Xpert® Omni SARS-CoV-2

Result	Interpretation
INVALID	SPC does not meet acceptance criteria. Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test according to the Retest Procedure (Section 17.2). <ul style="list-style-type: none">• SPC: FAIL; SPC and SARS-CoV-2 signals do not have a Ct within valid range and endpoint below minimum setting• Probe Check – PASS; all probe check results pass
ERROR	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test according to the Retest Procedure (Section 17.2). <ul style="list-style-type: none">• SARS-CoV-2: NO RESULT• SPC: NO RESULT• Probe Check: FAIL; all or one of the probe check results fail. <p>Note: If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range, no sample added, or by a system component failure.</p>
NO RESULT	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test according to the Retest Procedure (Section 17.2). A NO RESULT indicates that insufficient data were collected. For example, the operator stopped a test that was in progress. <ul style="list-style-type: none">• SARS-CoV-2: NO RESULT• SPC: NO RESULT• Probe Check: NA (not applicable)

The Xpert Omni SARS-CoV-2 test includes an Early Assay Termination (EAT) function, which will provide earlier time to results in high titer specimens if the signal from the target nucleic acid reaches a predetermined threshold before the full 45 PCR cycles have been completed. When SARS-CoV-2 titers are high enough to initiate the EAT function, the SPC amplification curve may not be seen and its results may not be reported.

17 Retests

17.1 Reasons to Repeat the Assay

If any of the test results mentioned below occur, repeat the test once according to instructions in Section 17.2, Retest Procedure.

- An **INVALID** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.
- An **ERROR** result could be due to, but not limited to, Probe Check Control failure, system component failure, no sample added, or the maximum pressure limits were exceeded.

Xpert® Omni SARS-CoV-2

- A **NO RESULT** indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress, or a power failure occurred.

If an External Control fails to perform as expected, repeat external control test and/or contact Cepheid for assistance.

17.2 Retest Procedure

To retest a non-determinate result (**INVALID**, **NO RESULT**, or **ERROR**), use a new cartridge.

Use the leftover sample from the original specimen transport medium tube or new external control tube.

1. Follow Section 13 to initiate test using the Omni instrument and mobile device and follow the steps below to prepare a retest of the sample or external control.
2. Put on a clean pair of gloves. Obtain a new Xpert Omni SARS-CoV-2 cartridge and a new transfer pipette.
3. Check the specimen transport tube or external control tube is closed.
4. Mix the sample by rapidly inverting the specimen transport medium tube or external control tube 5 times.
5. Open the cap on the specimen transport tube or external control tube.
6. Open the cartridge lid.
7. Using a clean transfer pipette (supplied), transfer sample (one draw) to the large opening (Sample Chamber) on the cartridge (see Figure 13).
8. Close the cartridge lid.

Xpert® Omni SARS-CoV-2

18 Limitations

- Performance of the Xpert Omni SARS-CoV-2 test has only been established in nasopharyngeal swab. Use of the Xpert Omni SARS-CoV-2 test with other specimen types has not been assessed and performance characteristics are unknown.
- Oropharyngeal, nasal swabs, mid-turbinate swabs, nasal wash/aspirate specimens are considered acceptable specimen types for use with the Xpert Omni SARS-CoV-2 test but performance with these specimen types has not been established.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if inadequate numbers of organisms are present in the specimen.
- As with any molecular test, mutations within the target regions of Xpert Omni SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- As the E gene target of the Xpert Omni SARS-CoV-2 test detects other coronaviruses in the B lineage, *Betacoronavirus* genus, including SARS-CoV, the presence of these viruses may cause a false positive result for detection of SARS-CoV-2. None of these other coronaviruses is known to currently circulate in the human population. Additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV or other Sarbecovirus currently unknown to infect humans.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- This test has not been FDA cleared or approved.
- This test has been authorized by FDA under an EUA for use by authorized laboratories.
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

19 Conditions of Authorization for the Laboratory

The Cepheid Xpert Omni SARS-CoV-2 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

However, to assist clinical laboratories using the Xpert Omni SARS-CoV-2 (referred to in the Letter of Authorization as “Your Product”), the relevant Conditions of Authorization are listed below.

- Authorized laboratories^a using this product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
 - Authorized laboratories using this product will use this product as outlined in the Xpert Omni SARS-CoV-2 Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Xpert Omni SARS-CoV-2 test are not permitted.
 - Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
 - Authorized laboratories that receive this product will notify the relevant public health authorities of their intent to run this product prior to initiating testing.
 - Authorized laboratories using the Xpert Omni SARS-CoV-2 test will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA Reporting@fda.hhs.gov) and Cepheid (+1 888 838 3222 or techsupport@cepheid.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
 - All operators using this product must be appropriately trained in RT-PCR techniques and use appropriate personal protective equipment when handling this kit, and use this product in accordance with the authorized labeling.
 - Cepheid, authorized distributors, and authorized laboratories using this product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- a. The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate or high complexity tests” as “authorized laboratories.”

Xpert® Omni SARS-CoV-2

20 Performance Characteristics

20.1 Clinical Evaluation

The performance of the Xpert Omni SARS-CoV-2 test on the GeneXpert Omni System was evaluated using archived clinical nasopharyngeal (NP) swab specimens in universal transport media (UTM) or viral transport medium (VTM). A total of 52 known SARS-CoV-2 positive and 52 SARS-CoV-2 negative NP swab specimens, were tested with Xpert Omni SARS-CoV-2 in a randomized and blinded fashion.

All 52 SARS-CoV-2 positive specimens were collected during the COVID-19 pandemic in the US and had previously been characterized as positive for SARS-CoV-2 by an EUA RT-PCR test. All of the 52 SARS-CoV-2 negative NP swab specimens were collected at least one year before the onset of the COVID-19 pandemic in the US and are expected to be negative for SARS-CoV-2.

The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the results of the Xpert Omni SARS-CoV-2 test relative to the expected results. Results of these 104 archived clinical NP swab specimens are shown in Table 3. The PPA was 100.0% (95% CI: 93.1% - 100%) and the NPA was 100.0% (95% CI: 93.1% - 100%).

Table 3. Xpert Omni SARS-CoV-2 Performance Results

		Expected Results		
Xpert Omni SARS-CoV-2		Positive	Negative	Total
	Positive	52	0	52
	Negative	0	52	52
	Total	52	52	104
PPA		100% (95% CI: 93.1% - 100%)		
NPA		100% (95% CI: 93.1% - 100%)		

Xpert® Omni SARS-CoV-2

21 Analytical Performance

21.1 Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical limit of detection (LoD) of the Xpert Omni SARS-CoV-2. The LoD was estimated with limiting dilutions of heat-inactivated SARS-CoV-2 virus (USA WA1/2020) using two lots of reagents in viral transport medium. The LoD of the assay was estimated using heat-inactivated SARS-CoV-2 virus diluted in nasopharyngeal swab clinical matrix (Table 4).

Table 4. LoD Determination Using USA WA1/2020 Strain Using One Reagent lot

Concentration (copies/mL)	Assay Positives / Replicates	Assay Positive Hit Rate (%)	E Positives / Replicates	E Mean Ct	E Hit Rate (%)	N2 Positives / Replicates	N2 Mean Ct	N2 Hit Rate (%)
0	0/22	0	0/22	0.0	0	0/22	0	0
12.5	5/22	22.7	0/22	0.0	0	5/22	42.3	22.7
25	13/22	59.1	2/22	40.2	9.1	13/22	41.6	59.1
35	14/21 ^a	66.7	1/21	42.5	4.8	13/21	41.7	61.9
50	20/22	90.9	3/22	42.6	13.6	19/22	41.7	86.4
100	19/22	86.4	3/21 ^b	38.5	14.3	18/22	41.1	81.8
125	21/22	95.5	8/21 ^b	39.8	38.1	21/22	40.5	95.5
150	21/21 ^a	100	10/20 ^b	40.4	50.0	21/21	40.8	100
350	22/22	100	19/21 ^b	36.8	90.5	22/22	38.6	100
500	22/22	100	21/21 ^b	35.8	100.0	22/22	38.1	100

a. One test gave INVALID overall result with INVALID for E and N2 target.

b. One test gave INVALID result for E target and positive result for N2 target.

Verification of the estimated LoD claim was performed on one reagent lot in replicates of 22 prepared in pooled NP swab clinical matrix. The LoD is the lowest concentration (reported as copies/mL) of heat-inactivated SARS-CoV-2 virus samples that can be reproducibly distinguished from negative samples $\geq 95\%$ of the time with 95% confidence. The claimed LoD is 400 copies/mL (Table 5).

Table 5. Limit of Detection of the Xpert Omni SARS-CoV-2

Strain	Concentration (copies/mL)	Positives/Replicates	E Hit Rate (%)	E Mean Ct	N2 Hit Rate (%)	N2 Mean Ct
SARS-CoV-2 USA WA1/2020	400	22/22	100	36.1	100	38.8
	0	0/22	0	-	0	-

Xpert® Omni SARS-CoV-2

21.2 Analytical Reactivity (Inclusivity)

The inclusivity of Xpert Omni SARS-CoV-2 was evaluated using *in silico* analysis of the assay primers and probes in relation to 110,206 SARS-CoV-2 (as of October 21, 2020) sequences available in the GISAID gene database for two targets, E and N2.

For the E target, 214 matching sequences were excluded due to ambiguity codes, which reduced the total to 109,992 sequences. Xpert Omni SARS-CoV-2 had 99.14% match to the sequences with the exception of 926 sequences that had a single mismatch and 21 sequences with additional mismatches.

None of these mismatches are predicted to have a negative impact on the performance of the assay.

For the N2 target, 211 matching sequences were excluded due to ambiguity codes, which reduced the total to 109,995 sequences. Xpert Omni SARS-CoV-2 had 97.29% match to the sequences with the exception of 2,919 sequences that had a single mismatch and sixty-three sequences with two or more mismatches.

None of these mismatches are predicted to have a negative impact on the performance of the assay.

21.3 Analytical Specificity (Exclusivity)

An *in silico* analysis for possible cross-reactions with all the organisms listed in Table 6 was conducted by mapping primers and probes in the Xpert Omni SARS-CoV-2 test individually to the sequences downloaded from the GISAID database. E primers and probes are not specific for SARS-CoV-2 and will detect Human and Bat SARS-coronavirus. No potential cross reactivity with other organisms listed in Table 6 is predicted based on the *in silico* analysis.

Table 6. Xpert Omni SARS-CoV-2 Analytical Specificity Microorganisms

Microorganisms from the Same Genetic Family	High Priority Organisms
Human coronavirus 229E	Adenovirus (e.g. C1 Ad. 71)
Human coronavirus OC43	Human Metapneumovirus (hMPV)
Human coronavirus HKU1	Parainfluenza virus 1-4
Human coronavirus NL63	Influenza A
SARS-coronavirus	Influenza B
MERS-coronavirus	Influenza C
Bat coronavirus	Enterovirus (e.g. EV68) Respiratory syncytial virus Rhinovirus <i>Chlamydia pneumoniae</i> <i>Haemophilus influenzae</i> <i>Legionella pneumophila</i> <i>Mycobacterium tuberculosis</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus pyogenes</i>

Xpert® Omni SARS-CoV-2

Microorganisms from the Same Genetic Family	High Priority Organisms
	<i>Bordetella pertussis</i>
	<i>Mycoplasma pneumoniae</i>
	<i>Pneumocystis jirovecii</i> (PJP)
	Parechovirus
	<i>Candida albicans</i>
	<i>Corynebacterium diphtheriae</i>
	<i>Legionella non-pneumophila</i>
	<i>Bacillus anthracis</i> (Anthrax)
	<i>Moraxella catarrhalis</i>
	<i>Neisseria elongata</i> and <i>N. meningitidis</i>
	<i>Pseudomonas aeruginosa</i>
	<i>Staphylococcus epidermidis</i>
	<i>Staphylococcus salivarius</i>
	<i>Leptospira</i>
	<i>Chlamydia psittaci</i>
	<i>Coxiella burnetii</i> (<i>Q-Fever</i>)
	<i>Staphylococcus aureus</i>

22 References

1. Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/index.html>. Accessed February 9, 2020.
2. bioRxiv. (<https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1>). Accessed March 3, 2020.
3. Centers for Disease Control and Prevention. *Biosafety in Microbiological and Biomedical laboratories* (refer to latest edition). <http://www.cdc.gov/biosafety/publications/>
4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline*. Document M29 (refer to latest edition).
5. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on the classification labeling and packaging of substances and mixtures amending and repealing, List of Precautionary Statements, Directives 67/548/EEC and 1999/45/EC (amending Regulation (EC) No 1907/2007).
6. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z).

23 Cepheid Headquarters Locations

Corporate Headquarters

Cepheid
904 Caribbean Drive
Sunnyvale, CA
94089 USA

Telephone: + 1 408 541 4191
Fax: + 1 408 541 4192
www.cepheid.com

European Headquarters

Cepheid
Europe SAS
Vira Solelh
81470 Maurens-Scopont
France

Telephone: + 33 563 825 300
Fax: + 33 563 825 301
www.cepheidinternational.com

24 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tagnumber

United States

Telephone: + 1 888 838 3222
Email:
techsupport@cepheid.com

France

Telephone:+ 33 563 825 300
Email:
support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website:
www.cepheid.com/en/CustomerSupport.

Xpert Omni SARS-CoV-2

25 Table of Symbols

Symbol	Meaning
	Catalog number
	<i>In vitro</i> diagnostic medical device
	Do not re-use
	Batch code
	Consult instructions for use
	Manufacturer
	Country of manufacture
	Contains sufficient for <n> tests
	Expiration date
	Temperature limitation
	For prescription use only
	Near Field Communication (NFC) (label with NFC embedded tag)
	Near Field Communication (NFC) product



Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA
Phone: +1 408 541 4191
Fax: +1 408 541 4192



For use under Emergency Use Authorization (EUA) Only

Quick Reference Instructions for Xpert® Omni SARS-CoV-2 and GeneXpert Omni System



For use under the Emergency Use Authorization (EUA) only



The user should be trained in the procedure. Wear the appropriate protective attire for your safety when handling patient samples. Clean testing surfaces according to your institution's policy. This test is only for nasopharyngeal, oropharyngeal, nasal, and mid-turbinate swab or nasal wash/aspirate specimens for laboratory settings to perform high and moderate complexity tests.

Read the complete Quick Reference Instructions before performing the test. For assistance, call Cepheid Technical Support at (888) 838-3222.

I. Storage and Handling and Warnings

Storage and Handling	Warnings
<ul style="list-style-type: none"> Wear gloves. Change gloves between processing each sample. Store the Xpert Omni SARS-CoV-2 cartridges at 2-28°C. 	<ul style="list-style-type: none"> DO NOT try to manually open or close the instrument door at any time. DO NOT move the mobile device more than 30 meters (~100 feet) from the instrument. DO NOT use a cartridge that is wet or has leaked. DO NOT use a cartridge that has been dropped. DO NOT open a cartridge lid until you are ready to perform testing. DO NOT shake or tilt the cartridge after adding the sample. DO NOT reuse disposable pipettes or cartridges. DO NOT turn off, unplug, move or tip the instrument while a test is in progress as this will stop the test. DO NOT use a cartridge that has a missing or damaged reaction tube.

Refer to Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control Testing. Refer to the GeneXpert Omni Reference Guide for a description of instrument, mobile device, and key to commonly used icons.

II. How to Start the Software

1 Start Software. a. Put on a pair of clean gloves. b. Turn on the GeneXpert Omni instrument by holding the power button for at least 2 seconds. c. An instrument self-test will run for about 2 minutes. d. Turn on the mobile device. Swipe mobile device screen to unlock. e. Tap the Omni icon to start the Omni mobile application. 	2 Login. a. Tap the LOGIN icon. b. Tap the User Name icon and enter user name. c. Tap Password icon and enter password. d. Tap the forward arrow next to the Password field. The Home screen appears. e. Verify the instrument icon appears at the bottom of the Home screen. 	3 How to Access Instructions for Use (optional). a. Tap the Information icon then select Assay Dashboard from the drop down menu. b. Follow the instructions on the documentation home page to open and read the instructions for use for the Xpert Omni SARS-CoV-2 test.
---	--	--

III. How to Test a Patient Specimen

Before you begin:

- Refer to the package insert for more information.
- Read through this entire Quick Reference Instructions before beginning a test.
- Start the test within 30 minutes of adding the specimen to the cartridge.
- The recommended environmental operating conditions for Xpert Omni SARS-CoV-2 are 15-30°C, 20-80% relative humidity.

1 Start a Test on the Mobile Device. a. If needed, tap Home icon at top of screen to go to Home screen. b. Tap the Start New Test button on the Home screen. 	2 Enter Patient Information. Scroll down to Tap Forward Arrow. 	3 Choose to Manually Enter, Scan or Generate the Sample ID. Enter Test Type and Sample Type description. Scroll down to Tap Forward Arrow. 123 Enter Sample ID Scan Sample Barcode Generate Sample ID To scan sample barcode, aim the rear camera of the mobile device at barcode. A beep sounds and the Sample ID will appear in the Sample ID field. 	4 Scan Cartridge. a. Place the back of the mobile device close to the GeneXpert cartridge label. The cartridge should be aimed to the center back of the mobile device. b. Verify the correct cartridge has been scanned: Xpert Omni SARS-CoV-2.
5 Mix Specimen. a. Check that the specimen transport tube cap is closed. b. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open the cap on the specimen transport tube. c. Open the cartridge lid. 	6 Fill Pipette with Sample. a. Remove the transfer pipette from wrapper. b. Squeeze the top bulb of the pipette completely until the top bulb is fully flat . While continuing to hold the bulb fully flat, place the pipette tip in the specimen transport tube. c. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly to fill the pipette with sample before removing from the tube. It is okay if liquid goes into the overflow reservoir. 	7 Transfer Sample to Cartridge. a. Squeeze the top bulb of the pipette completely until it is fully flat to empty the contents of the pipette into the large opening (Sample Chamber). Some liquid may remain in the overflow reservoir. Dispose of the used pipette. Note: DO NOT ADD swab to the cartridge as shown below. 	8 Loading/Unloading Cartridge and Viewing Results. a. Tap the instrument icon. 12345 ...pleD103 ... Assay 1 Ready Test is ready. Please select an Omni below. b. An instrument self-test will run then the instrument door automatically opens. c. Load the cartridge on instrument as shown below. d. Remove hands immediately from instrument after loading cartridge. The door will close automatically. When the test is done, the door will open. e. Result is displayed. At the bottom of the screen, tap Print Result . f. Dispose of the cartridge and gloves.
NOTE: Refer to the Package Insert for information on reviewing past results.			

IV. How To Start a New Test

a. Put on a new pair of clean gloves.



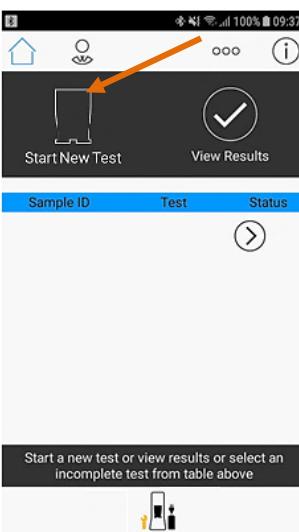
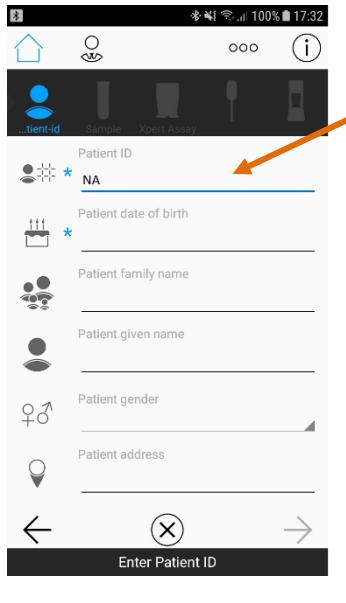
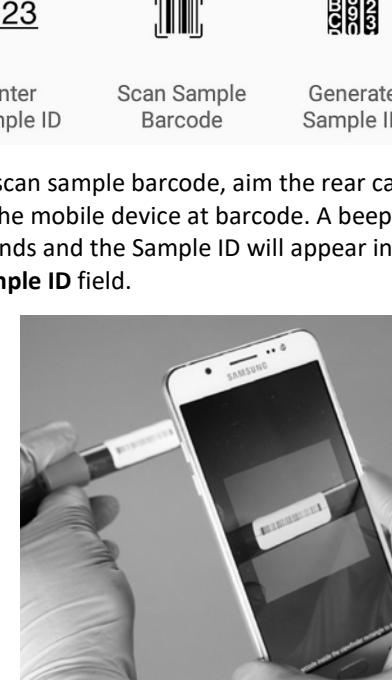
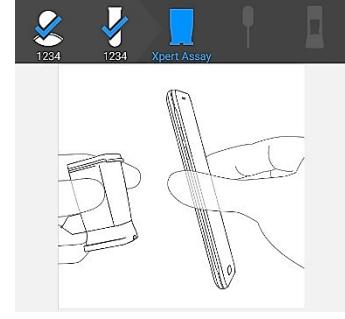
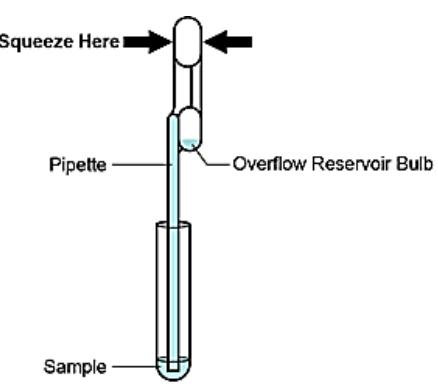
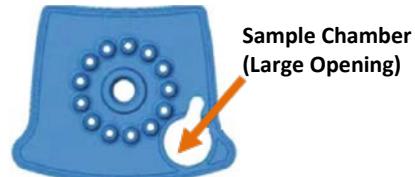
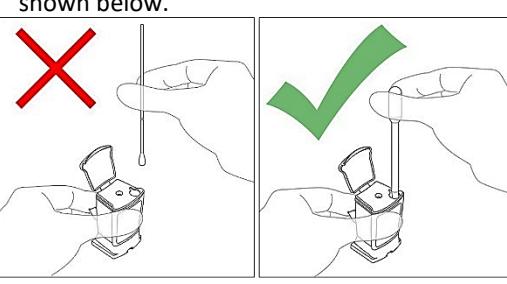
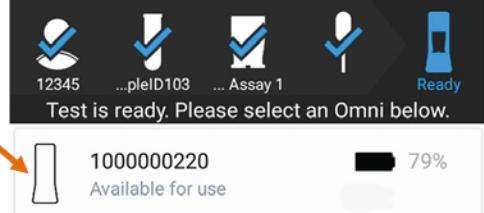
b. Tap Home icon at top of screen.

c. To start a new test, follow the test procedure above, starting with Step 1.

V. How to Run External Controls – Positive and Negative Controls

It is recommended that external controls (SeraCare AccuPlex™ Reference Material Kit, catalog number 0505-0126) be tested at the frequency noted below.

- Each time a new lot or a new shipment of Xpert Omni SARS-CoV-2 is received.
- Each time a new operator is performing the test.
- When problems are suspected or identified.
- Per your institution's standard Quality Control (QC) procedures.

<p>1 Start a Test on Mobile Device.</p> <p>a. If needed, tap Home icon at top of screen to go to Home screen.</p> <p>b. Tap the Start New Test icon on the Home screen.</p>  <p>Start a new test or view results or select an incomplete test from table above 00000875</p>	<p>2 Enter "NA" for Patient ID. Scroll Down to Tap Forward Arrow.</p> 	<p>3 Choose to Manually Enter, Scan or Generate the Sample ID. Scroll down to Tap Forward Arrow.</p> <p>123 Scan Sample Barcode Generate Sample ID</p> <p>To scan sample barcode, aim the rear camera of the mobile device at barcode. A beep sounds and the Sample ID will appear in the Sample ID field.</p>  	<p>4 Scan Cartridge.</p> <p>a. Place the back of the mobile device close to the GeneXpert cartridge label. The cartridge should be aimed to the center back of the mobile device.</p>  <p>b. Verify the correct cartridge has been scanned: Xpert Omni SARS-CoV-2.</p>
<p>5 Mix External Control.</p> <p>a. Check that the external control tube cap is closed.</p> <p>b. Mix external control tube by rapidly inverting the external control tube 5 times. Open the cap on the external control tube.</p> <p>c. Open the cartridge lid.</p> 	<p>6 Fill Pipette with External Control.</p> <p>a. Remove the transfer pipette from wrapper.</p> <p>b. Squeeze the top bulb of the pipette completely until the top bulb is fully flat. While continuing to hold the bulb fully flat, place the pipette tip in the external control tube.</p> <p>c. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly to fill the pipette with the external control before removing from the tube. It is okay if liquid goes into the overflow reservoir.</p> 	<p>7 Transfer External Control to Cartridge.</p> <p>a. Squeeze the top bulb of the pipette completely until it is fully flat to empty the contents of the pipette into the large opening (Sample Chamber). Some liquid may remain in the overflow reservoir. Dispose of the used pipette.</p>  <p>Note: DO NOT ADD swab to the cartridge as shown below.</p>  <p>b. Close the cartridge lid.</p> <p>c. Tap the forward arrow at the bottom right of the screen to move to the next screen.</p>	<p>8 Loading/Unloading Cartridge and Viewing Results.</p> <p>a. Tap the instrument icon.</p>  <p>b. An instrument self-test will run then the instrument door automatically opens.</p> <p>c. Load the cartridge on instrument as shown below.</p>  <p>d. Remove hands immediately from instrument after loading cartridge. The door will close automatically. When the test is done, the door will open.</p> <p>e. Result is displayed. At the bottom of the screen, tap Print Result</p> <p>f. Dispose of the cartridge and gloves.</p>

 NOTE: Refer to the Package Insert for information on reviewing past results.

VI. Possible Results

Result	Interpretation
SARS-CoV-2 NEGATIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected.
SARS-CoV-2 POSITIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are detected.
INVALID	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test with a new cartridge.
ERROR	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test with a new cartridge.
NO RESULT	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test with a new cartridge.

NOTE: If an incorrect result is provided for the external control, repeat the external control run. If repeated control runs do not produce the expected results, contact Cepheid Technical Support.

Warnings

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA
Tel: +1 408 541 4191
Fax: +1 408 541 4192

Technical Support
888-838-3222 option 2
techsupport@cepheid.com
<http://www.cepheid.com/us/support>

GeneXpert® Omni System



Operator Manual

IVD



For use under an Emergency Use
Authorization (EUA) Only

302-4220, Rev. B November, 2020

Table of Contents

Warnings	6
Legal Information.....	7
1 Introduction.....	21
1.1 About This Manual.....	21
1.2 Safety Information.....	21
1.3 Table of Symbols.....	22
1.4 Technical Support.....	22
1.5 Addresses.....	24
2 Overview of the Omni System.....	25
2.1 System Overview.....	25
2.2 Instrument Overview.....	27
2.2.1 Features On the Front of the Instrument.....	28
2.2.2 Features On the Back of the Instrument.....	30
2.3 Software Overview.....	31
2.3.1 Software Used By the Omni System.....	31
2.3.2 GeneXpert Omni Mobile Application Overview.....	33
2.3.3 Omni Mobile Application User Interface Overview.....	36
2.3.4 User Accounts and Privileges.....	41
2.4 Opening the Omni System Documentation.....	43
3 Preparing To Run a Test.....	45
3.1 Positioning Instruments On the Bench.....	45
3.2 Turning On the Instrument.....	46
3.3 Turning On the Mobile Device.....	46
3.4 Starting the Omni Mobile Application.....	46
3.5 Logging In As a Registered User.....	49
3.6 Logging In As a Guest User.....	50
3.7 Managing the System When It Is Idle.....	51
4 Running a Test.....	53
4.1 Entering Patient Information.....	53
4.2 Options for Entering the Sample ID.....	54
4.2.1 Entering a Sample ID Manually.....	55
4.2.2 Scanning the Sample ID With the Barcode.....	55
4.2.3 Generating a Random Sample ID.....	57
4.3 Loading the Cartridge and Running the Test.....	57
4.4 Canceling a Test Before It Starts.....	61
4.5 Stopping a Test That Is Running.....	61
5 Managing Test Results.....	63
5.1 Viewing Stored Test Results.....	63

Table of Contents

5.2 Searching for Test Results.....	64
5.3 Selecting a Printer.....	64
5.4 Printing Test Results.....	65
5.5 Downloading Test Results to the Mobile Device.....	66
5.6 Uploading Test Results To C360 Analytics.....	67
5.7 Receiving Test Results via SMS Text Message.....	68
6 Shutting Down the System.....	69
6.1 Shutting Down the Instrument Using the Power Button.....	69
6.2 Shutting Down the Instrument Using the Mobile Device.....	70
6.3 Logging Off the Omni Application.....	71
6.4 Closing the Omni Mobile Application.....	71
6.5 Shutting Down the Mobile Device.....	72
7 Administrative Tasks.....	73
7.1 Adding an Omni Instrument.....	73
7.2 Disconnecting an Omni Instrument.....	75
7.3 Changing the Lab To Which the Mobile Device Is Assigned.....	76
7.4 Changing a Password for Another Lab User.....	77
7.5 Manually Syncing Data With C360 Admin.....	79
7.6 Installing Software Updates.....	79
7.7 Configuring a Laboratory Information System.....	79
7.7.1 Enabling the Host Configuration Screen.....	80
7.7.2 Configuring the Omni System as an LIS Client.....	80
7.7.3 Configuring the Omni System as an LIS Server.....	82
7.7.4 Disabling Host Communications.....	83
7.7.5 Manually Uploading Test Results To an LIS.....	83
7.7.6 Configuring the Test Code Settings.....	84
7.7.7 Troubleshooting Host Connectivity.....	86
8 Maintenance and Troubleshooting.....	89
8.1 About Cleaning and Disinfecting.....	89
8.1.1 Cleaning and Disinfecting the Instrument Surfaces.....	89
8.1.2 Performing Weekly and Monthly Maintenance.....	90
8.2 Handling An Instrument That Has Tipped Over.....	95
8.3 Error Messages and Troubleshooting.....	95
8.4 Performing a Manual Self-Test.....	97
8.5 Troubleshooting Sample Barcode Scanning.....	99
8.6 Troubleshooting Wireless Connections.....	102
8.7 Troubleshooting Instrument Power Problems.....	102
9 Performance Characteristics and Specifications.....	105
9.1 System Classification.....	105
9.2 Physical Specifications.....	105
9.3 Electrical Specifications.....	106
9.4 Wireless Technologies Used By the Instrument.....	106
9.5 Wireless Technologies Used By the Mobile Device.....	108
9.6 Operational Environmental Parameters.....	109
9.7 Environmental Conditions for Storage and Transport.....	109

9.8 Sound Pressure.....	109
9.9 Product Energy Consumption Information.....	110
9.10 Regulatory Directives.....	110
9.11 Data Security.....	110
10 Quality Controls.....	113
10.1 About Instrument Calibration.....	113
10.2 Internal Quality Controls.....	113
10.3 External Quality Controls.....	114
11 Safety Reference.....	115
11.1 General Safety Information.....	115
11.2 Instrument Battery Safety.....	116
11.3 Environmental Information.....	116
A Appendix - Icon Definitions.....	119

Warnings

- This product has not been FDA cleared or approved;
- This product has been authorized by FDA for use with the Xpert Omni SARS-CoV-2 test under an Emergency Use Authorization (EUA);
- This product has been authorized only for use with the Xpert Omni SARS-CoV-2 test for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Legal Information

GeneXpert Omni Instrument Limited Warranty

The following section constitutes the specific terms of the warranty for the GeneXpert Omni Instrument (“Instrument”) unless otherwise specified in the purchase agreement under which GeneXpert Omni Instrument was purchased.

“Customer” means the original party that purchased the Instrument from either Cepheid or its authorized third party, and not any subsequent purchasers.

Cepheid warrants that (i) the Instrument is free from defects in material and workmanship, (ii) the Instrument conforms to Cepheid's published specifications, and (iii) the Instrument conforms to the labeling claims that accompany the Instrument. This warranty is for a period of 12 months from the date of shipment to the Customer (the Warranty Period). During the Warranty Period, if the Instrument's hardware is found to be defective or if the Instrument is found to be non-conforming under item (ii) or (iii) above, Cepheid will repair or replace it, at a site determined by Cepheid at Cepheid's expense. This warranty extends to Customer only and not to any other parties, except as agreed to in writing by Cepheid and applies only to new Instruments manufactured by Cepheid.

Cepheid does not warrant any defects in the Instrument caused by (i) improper installation, removal or testing, (ii) Customer's failure to provide a suitable operating environment for the Instrument, (iii) use of the Instrument for purposes other than that for which it was designed, (iv) unauthorized attachments, (v) unusual physical or electrical stress, (vi) modifications or repairs done by other than Cepheid or a Cepheid authorized service provider, or (vii) any other abuse, misuse, or neglect of the Instrument. The Instrument is designed and certified with applicable regulatory authorities as part of an integrated instrument/reagent/consumable system. Use of unapproved parts, reagents or other materials with the Instrument will void any warranty and any service contract between Cepheid and the Customer that pertains to the Instrument.

OTHER THAN ANY EXPRESS WARRANTY PROVIDED HEREIN THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THE FACE HEREOF, AND CEPHEID DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, REGARDING THE PRODUCT, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. CEPHEID AND ITS DIRECTORS, OFFICERS, EMPLOYEES AND AGENTS SHALL HAVE NO LIABILITY FOR GENERAL, CONSEQUENTIAL, INCIDENTAL OR SPECIAL DAMAGES ARISING FROM A DEFECT IN THE INSTRUMENT. FURTHERMORE, CEPHEID SHALL HAVE NO STRICT LIABILITY, PRODUCTS LIABILITY OR NEGLIGENCE LIABILITY, WHETHER ACTIVE OR PASSIVE, AS TO THE CUSTOMER.

Customer's exclusive remedy for any defective or non-conforming Instrument is limited to the repair or replacement of any defective Instrument. If Cepheid cannot or does not repair or replace a defective or non-conforming Instrument, Cepheid will remove same and return the purchase price. If Cepheid cannot or does not repair or replace any defective or non-conforming Instrument or if Customer's exclusive remedy fails of its essential purpose, Cepheid's entire liability shall in no event exceed the purchase price for any defective or non-conforming Instrument.

GeneXpert Omni Software License

Cepheid is the exclusive owner of the GeneXpert Omni System software and GeneXpert Omni mobile application (the "Software" and any updates thereto, related documentation, and all copyright, trade secret, patent, trademark and other intellectual or industrial property rights therein. By accessing or using the Software, you agree to the terms of this Software License Agreement ("License") for yourself and on behalf of your organization. If agreeing to these terms on behalf of an organization, you agree that you have the authority to enter into this License on its behalf, and that "User", as used herein, refers to you and your organization. User expressly acknowledges that no title to or ownership of the Software, or any copy or portion thereof, is transferred to User. The ideas and expressions thereof contained in the Software are confidential and proprietary information of Cepheid that are provided to User for limited use under this License. User shall not cause or permit decompilation, disassembly, or reverse engineering of the Software or disclosure, copying, display, loan, publication, transfer of possession (whether by sales, exchange, gift, operation of law or otherwise) or other dissemination of the Software and related documentation, in whole or part, to any third party without the prior written consent of Cepheid.

License Grant: Cepheid grants User a non-exclusive, non-transferable license (the "License") to use only one (1) copy of the Software or updates (except to the extent such updates are accompanied by new or additional terms, in which case those different terms apply prospectively and do not alter User's rights relating to pre-updated Software) on the mobile device provided by Cepheid to the User connected to the Instrument. Unless otherwise allowed by Cepheid in writing, User may not distribute or make the Software available over a network where it could be used by multiple devices at the same time. Cepheid may terminate this License if User fails to comply with any of the terms or conditions of this License or of the original purchase agreement. If this License is terminated, User must destroy all copies of the Software and its related documentation. This License does not supersede, amend, or modify any additional terms agreed to by the User.

For Government Customers, the Software is commercial computer software subject to restricted rights under FAR 52.227-19 (C) (1, 2).

NO OTHER RIGHTS ARE CONVEYED EXPRESSLY, BY IMPLICATION OR BY ESTOPPEL. FURTHERMORE, NO RIGHTS FOR RESALE ARE CONFERRED WITH THE PURCHASE OF THIS PRODUCT.

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE SOFTWARE IS PROVIDED "AS IS" AND "AS AVAILABLE" WITHOUT ANY WARRANTY AND CEPHEID DISCLAIMS ANY LIABILITY ATTRIBUTABLE TO USER'S USE OF THE SOFTWARE OR IN CONNECTION WITH THE SOFTWARE WEBSITE TO THE FULLEST EXTENT ALLOWED BY LAW.

Trademark and Copyright Statements

Cepheid, the Cepheid logo, GeneXpert, I-CORE, and Xpert are trademarks of Cepheid, registered in the U.S. and other countries. Cepheid 360 and GeneXpert Omni are trademarks of Cepheid.

All other trademarks are the property of their respective owners.

This Manual contains information protected by copyright. No part of this Manual may be photocopied or reproduced in any form without prior written consent from Cepheid.

Copyright © Cepheid 2020. All rights reserved.

Customer must not alter or remove any labels, signs, symbols, serial numbers, copyright, patent, trademark, trade secret, proprietary and/or other legal notices contained on or in this Manual, the GeneXpert Omni Instrument, GeneXpert Omni Software, and related documentation.

Disclaimers

All examples (printouts, graphics, displays, screens, etc.) are for information and illustration purposes only and shall not be used for clinical or maintenance evaluations. Data shown in sample printouts and screens do not reflect actual patient names or test results. Labels depicted in the manual may appear different from actual product labels. Cepheid makes no representations or warranties about the accuracy and reliability of the information contained in the GeneXpert Omni Operator Manual. The information was developed to assist the user with the operation of the GeneXpert Omni system. Updates to this GeneXpert Omni Operator Manual may be issued periodically and should be maintained with this original manual.

Part 15 Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Warning

This product can expose you to chemicals including Nickel (Metallic) which is known to the State of California to cause cancer. For more information, go to www.p65warnings.ca.gov.

THIRD PARTY SOFTWARE ATTRIBUTIONS

Certain third-party software integrated and/or redistributed with the Software require certain attributions, which are set forth below.

1) SwiftDecoder

SwiftDecoder™ decoding software licensed by Honeywell Scanning and Mobility;
Patent: hsmpats.com

2) Free and Open-Source Licensing Information

This section contains licensing information relating to Cepheid's use of free and open-source software with or within the Software (collectively, "FOSS"). Any terms, conditions, and restrictions governing the use or distribution of FOSS that are not contained within the license(s) governing use and distribution of the FOSS (the "FOSS Licenses") are offered and imposed by Cepheid alone. The authors, licensors, and distributors of the FOSS have disclaimed all warranties relating to any liability arising from the use and distribution of the FOSS.

This document identifies the FOSS packages used, the FOSS Licenses that Cepheid believes govern those FOSS packages, and, where available, a link to or contact information for the author or source of the FOSS package. Cepheid has also attempted to reproduce the copyright notices and licensing information for the distributed FOSS packages, as provided in the FOSS packages. While Cepheid has sought to provide complete and accurate licensing information for each FOSS package, Cepheid does not represent or warrant that the licensing information provided herein is correct or error-free. Recipients of the Software should investigate the identified FOSS packages to confirm the accuracy of the licensing information provided herein. Recipients are also encouraged to notify Cepheid of any inaccurate information or errors found in this document.

Certain FOSS Licenses, such as the GNU General Public License, GNU Lesser (or Library) General Public License, and Mozilla Public License (whether or not these licenses apply to Cepheid's use of FOSS with or within the Software), require that Cepheid make available to recipients the source code corresponding to FOSS binaries distributed under those licenses. Recipients who would like to receive a copy of such source code should submit a request to Cepheid by email at Cepheid.legal@cepheid.com or by post at:

Cepheid

Attn: Cepheid Legal - FOSS Source Requests

904 Caribbean Drive

Sunnyvale, CA 94089

In submitted requests, please specify: the FOSS packages for which you are requesting source code; the Cepheid application and version number with which the requested FOSS package is distributed; an email address at which Cepheid may contact you regarding the request (if available); and the postal address for delivery of the requested source code.

The free and open-source software packages identified below are arranged by the applicable license(s).

Apache License, Version 2.0

Jetty

Google Guava

SQLite JDBC Driver

Zebra Crossing

Retrofit

OkHttp

Joda Time for Android
Android Annotations
Apache Commons
FasterXML
Spring-security-crypto
Gson
Apache Http component package
Android Logging Log4j
Log4j
Gradle

Apache License
Version 2.0, January 2004
<http://www.apache.org/licenses/>

TERMS AND CONDITIONS FOR USE, REPRODUCTION, AND DISTRIBUTION

1. Definitions.

"License" shall mean the terms and conditions for use, reproduction, and distribution as defined by Sections 1 through 9 of this document.

"Licensor" shall mean the copyright owner or entity authorized by the copyright owner that is granting the License.

"Legal Entity" shall mean the union of the acting entity and all other entities that control, are controlled by, or are under common control with that entity. For the purposes of this definition, "control" means (i) the power, direct or indirect, to cause the direction or management of such entity, whether by contract or otherwise, or (ii) ownership of fifty percent (50%) or more of the outstanding shares, or (iii) beneficial ownership of such entity.

"You" (or "Your") shall mean an individual or Legal Entity exercising permissions granted by this License.

"Source" form shall mean the preferred form for making modifications, including but not limited to software source code, documentation source, and configuration files.

"Object" form shall mean any form resulting from mechanical transformation or translation of a Source form, including but not limited to compiled object code, generated documentation, and conversions to other media types.

"Work" shall mean the work of authorship, whether in Source or Object form, made available under the License, as indicated by a copyright notice that is included in or attached to the work (an example is provided in the Appendix below).

"Derivative Works" shall mean any work, whether in Source or Object form, that is based on (or derived from) the Work and for which the editorial revisions, annotations, elaborations, or other modifications represent, as a whole, an original work of authorship.

For the purposes of this License, Derivative Works shall not include works that remain separable from, or merely link (or bind by name) to the interfaces of, the Work and Derivative Works thereof.

"Contribution" shall mean any work of authorship, including the original version of the Work and any modifications or additions to that Work or Derivative Works thereof, that is intentionally submitted to Licensor for inclusion in the Work by the copyright owner or by an individual or Legal Entity authorized to submit on behalf of the copyright owner. For the purposes of this definition, "submitted" means any form of electronic, verbal, or written communication sent to the Licensor or its representatives, including but not limited to communication on electronic mailing lists, source code control systems, and issue tracking systems that are managed by, or on behalf of, the Licensor for the purpose of discussing and improving the Work, but excluding communication that is conspicuously marked or otherwise designated in writing by the copyright owner as "Not a Contribution."

"Contributor" shall mean Licensor and any individual or Legal Entity on behalf of whom a Contribution has been received by Licensor and subsequently incorporated within the Work.

2. Grant of Copyright License. Subject to the terms and conditions of this License, each Contributor hereby grants to You a perpetual, worldwide, non-exclusive, no-charge, royalty-free, irrevocable copyright license to reproduce, prepare Derivative Works of, publicly display, publicly perform, sublicense, and distribute the Work and such Derivative Works in Source or Object form.

3. Grant of Patent License. Subject to the terms and conditions of this License, each Contributor hereby grants to You a perpetual, worldwide, non-exclusive, no-charge, royalty-free, irrevocable (except as stated in this section) patent license to make, have made, use, offer to sell, sell, import, and otherwise transfer the Work, where such license applies only to those patent claims licensable by such Contributor that are necessarily infringed by their Contribution(s) alone or by combination of their Contribution(s) with the Work to which such Contribution(s) was submitted. If You institute patent litigation against any entity (including a cross-claim or counterclaim in a lawsuit) alleging that the Work or a Contribution incorporated within the Work constitutes direct or contributory patent infringement, then any patent licenses granted to You under this License for that Work shall terminate as of the date such litigation is filed.

4. Redistribution. You may reproduce and distribute copies of the Work or Derivative Works thereof in any medium, with or without modifications, and in Source or Object form, provided that You meet the following conditions:

(a) You must give any other recipients of the Work or Derivative Works a copy of this License; and

(b) You must cause any modified files to carry prominent notices stating that You changed the files; and

(c) You must retain, in the Source form of any Derivative Works that You distribute, all copyright, patent, trademark, and attribution notices from the Source form of the Work, excluding those notices that do not pertain to any part of the Derivative Works; and

(d) If the Work includes a "NOTICE" text file as part of its distribution, then any Derivative Works that You distribute must include a readable copy of the attribution notices contained within such NOTICE file, excluding those notices that do not pertain to any part of the Derivative Works, in at least one of the following places: within a

NOTICE text file distributed as part of the Derivative Works; within the Source form or documentation, if provided along with the Derivative Works; or, within a display generated by the Derivative Works, if and wherever such third-party notices normally appear. The contents of the NOTICE file are for informational purposes only and do not modify the License. You may add Your own attribution notices within Derivative Works that You distribute, alongside or as an addendum to the NOTICE text from the Work, provided that such additional attribution notices cannot be construed as modifying the License.

You may add Your own copyright statement to Your modifications and may provide additional or different license terms and conditions for use, reproduction, or distribution of Your modifications, or for any such Derivative Works as a whole, provided Your use, reproduction, and distribution of the Work otherwise complies with the conditions stated in this License.

5. Submission of Contributions. Unless You explicitly state otherwise, any Contribution intentionally submitted for inclusion in the Work by You to the Licensor shall be under the terms and conditions of this License, without any additional terms or conditions. Notwithstanding the above, nothing herein shall supersede or modify the terms of any separate license agreement you may have executed with Licensor regarding such Contributions.

6. Trademarks. This License does not grant permission to use the trade names, trademarks, service marks, or product names of the Licensor, except as required for reasonable and customary use in describing the origin of the Work and reproducing the content of the NOTICE file.

7. Disclaimer of Warranty. Unless required by applicable law or agreed to in writing, Licensor provides the Work (and each Contributor provides its Contributions) on an "AS IS" BASIS, WITHOUT WARRANTIES OR CONDITIONS OF ANY KIND, either express or implied, including, without limitation, any warranties or conditions of TITLE, NON-INFRINGEMENT, MERCHANTABILITY, or FITNESS FOR A PARTICULAR PURPOSE. You are solely responsible for determining the appropriateness of using or redistributing the Work and assume any risks associated with Your exercise of permissions under this License.

8. Limitation of Liability. In no event and under no legal theory, whether in tort (including negligence), contract, or otherwise, unless required by applicable law (such as deliberate and grossly negligent acts) or agreed to in writing, shall any Contributor be liable to You for damages, including any direct, indirect, special, incidental, or consequential damages of any character arising as a result of this License or out of the use or inability to use the Work (including but not limited to damages for loss of goodwill, work stoppage, computer failure or malfunction, or any and all other commercial damages or losses), even if such Contributor has been advised of the possibility of such damages.

9. Accepting Warranty or Additional Liability. While redistributing the Work or Derivative Works thereof, You may choose to offer, and charge a fee for, acceptance of support, warranty, indemnity, or other liability obligations and/or rights consistent with this License. However, in accepting such obligations, You may act only on Your own behalf and on Your sole responsibility, not on behalf of any other Contributor, and only if You agree to indemnify, defend, and hold each Contributor harmless for any liability incurred by, or claims asserted against, such Contributor by reason of your accepting any such warranty or additional liability.

END OF TERMS AND CONDITIONS

MIT Licenses

SLF4J

Twilio SDK

Android-gif-drawable, version 1.2.1

Jenkins

Copyright (c) 2004-2017 QOS.ch

All rights reserved.

Permission is hereby granted, free of charge, to any person obtaining a copy of this software and associated documentation files (the "Software"), to deal in the Software without restriction, including without limitation in the rights to use, copy, modify, merge, publish, distribute, sublicense, and/or sell copies of the Software, and to permit persons to whom the Software is furnished to do so, subject to the following conditions:

The above copyright notice and this permission notice shall be included in all copies or substantial portions of the Software.

THE SOFTWARE IS PROVIDED "AS IS", WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT. IN NO EVENT SHALL THE AUTHORS OR COPYRIGHT HOLDERS BE LIABLE FOR ANY CLAIM, DAMAGES OR OTHER LIABILITY, WHETHER IN AN ACTION OF CONTRACT, TORT OR OTHERWISE, ARISING FROM, OUT OF OR IN CONNECTION WITH THE SOFTWARE OR THE USE OR OTHER DEALINGS IN THE SOFTWARE.

BSD

SQLCipher Community Edition

Copyright (c) 2008-2020 Zetetic LLC

All rights reserved.

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

- Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
- Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.

- Neither the name of the ZETETIC LLC nor the names of its contributors may be used to endorse or promote products derived from this software without specific prior written permission.

THIS SOFTWARE IS PROVIDED BY ZETETIC LLC "AS IS" AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL ZETETIC LLC BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

Internet Systems Consortium (ISC)

ORMLite

This document is part of the ORMLite project.

Permission to use, copy, modify, and/or distribute this software for any purpose with or without fee is hereby granted, provided that this permission notice appear in all copies.

THE SOFTWARE IS PROVIDED "AS IS" AND THE AUTHOR DISCLAIMS ALL WARRANTIES WITH REGARD TO THIS SOFTWARE INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS. IN NO EVENT SHALL THE AUTHOR BE LIABLE FOR ANY SPECIAL, DIRECT, INDIRECT, OR CONSEQUENTIAL DAMAGES OR ANY DAMAGES WHATSOEVER RESULTING FROM LOSS OF USE, DATA OR PROFITS, WHETHER IN AN ACTION OF CONTRACT, NEGLIGENCE OR OTHER TORTIOUS ACTION, ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF THIS SOFTWARE.

The author may be contacted via <http://ormlite.com/>.

Oracle Binary Code License Agreement for the Java SE Platform Products and JavaFX

JDK 1.8.0_121

<https://www.oracle.com/technetwork/java/javase/documentation/index.html>

ORACLE AMERICA, INC. ("ORACLE"), FOR AND ON BEHALF OF ITSELF AND ITS SUBSIDIARIES AND AFFILIATES UNDER COMMON CONTROL, IS WILLING TO LICENSE THE SOFTWARE TO YOU ONLY UPON THE CONDITION THAT YOU ACCEPT ALL OF THE TERMS CONTAINED IN THIS BINARY CODE LICENSE AGREEMENT AND SUPPLEMENTAL LICENSE TERMS (COLLECTIVELY "AGREEMENT"). PLEASE READ THE AGREEMENT CAREFULLY. BY SELECTING THE "ACCEPT LICENSE AGREEMENT" (OR THE EQUIVALENT) BUTTON AND/OR BY USING THE SOFTWARE YOU

ACKNOWLEDGE THAT YOU HAVE READ THE TERMS AND AGREE TO THEM. IF YOU ARE AGREEING TO THESE TERMS ON BEHALF OF A COMPANY OR OTHER LEGAL ENTITY, YOU REPRESENT THAT YOU HAVE THE LEGAL AUTHORITY TO BIND THE LEGAL ENTITY TO THESE TERMS. IF YOU DO NOT HAVE SUCH AUTHORITY, OR IF YOU DO NOT WISH TO BE BOUND BY THE TERMS, THEN SELECT THE "DECLINE LICENSE AGREEMENT" (OR THE EQUIVALENT) BUTTON AND YOU MUST NOT USE THE SOFTWARE ON THIS SITE OR ANY OTHER MEDIA ON WHICH THE SOFTWARE IS CONTAINED.

1. DEFINITIONS. "Software" means the software identified above in binary form that you selected for download, install or use (in the version You selected for download, install or use) from Oracle or its authorized licensees and/or those portions of such software produced by jlink as output using a Program's code, when such output is in unmodified form in combination, and for sole use with, that Program, as well as any other machine readable materials (including, but not limited to, libraries, source files, header files, and data files), any updates or error corrections provided by Oracle, and any user manuals, programming guides and other documentation provided to you by Oracle under this Agreement. The Java Linker (jlink) is available with Java 9 and later versions. "General Purpose Desktop Computers and Servers" means computers, including desktop and laptop computers, or servers, used for general computing functions under end user control (such as but not specifically limited to email, general purpose Internet browsing, and office suite productivity tools). The use of Software in systems and solutions that provide dedicated functionality (other than as mentioned above) or designed for use in embedded or function-specific software applications, for example but not limited to: Software embedded in or bundled with industrial control systems, wireless mobile telephones, wireless handheld devices, kiosks, TV/STB, Blu-ray Disc devices, telematics and network control switching equipment, printers and storage management systems, and other related systems are excluded from this definition and not licensed under this Agreement. "Programs" means (a) Java technology applets and applications intended to run on the Java Platform, Standard Edition platform on Java-enabled General Purpose Desktop Computers and Servers; and (b) JavaFX technology applications intended to run on the JavaFX Runtime on JavaFX-enabled General Purpose Desktop Computers and Servers. "Java SE LIUM" means the Licensing Information User Manual – Oracle Java SE and Oracle Java Embedded Products Document accessible at <http://www.oracle.com/technetwork/java/javase/documentation/index.html>. "Commercial Features" means those features that are identified as such in the Java SE LIUM under the "Description of Product Editions and Permitted Features" section.

2. LICENSE TO USE. Subject to the terms and conditions of this Agreement including, but not limited to, the Java Technology Restrictions of the Supplemental License Terms, Oracle grants you a non-exclusive, non-transferable, limited license without license fees to reproduce and use internally the Software complete and unmodified for the sole purpose of running Programs. **THE LICENSE SET FORTH IN THIS SECTION 2 DOES NOT EXTEND TO THE COMMERCIAL FEATURES. YOUR RIGHTS AND OBLIGATIONS RELATED TO THE COMMERCIAL FEATURES ARE AS SET FORTH IN THE SUPPLEMENTAL TERMS ALONG WITH ADDITIONAL LICENSES FOR DEVELOPERS AND PUBLISHERS.**

3. RESTRICTIONS. Software is copyrighted. Title to Software and all associated intellectual property rights is retained by Oracle and/or its licensors. Unless enforcement is prohibited by applicable law, you may not modify, decompile, or reverse engineer Software. You acknowledge that the Software is developed for general use in a variety of information management applications; it is not developed or intended for use in

any inherently dangerous applications, including applications that may create a risk of personal injury. If you use the Software in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle disclaims any express or implied warranty of fitness for such uses. No right, title or interest in or to any trademark, service mark, logo or trade name of Oracle or its licensors is granted under this Agreement. Additional restrictions for developers and/or publishers licenses are set forth in the Supplemental License Terms.

4. DISCLAIMER OF WARRANTY. THE SOFTWARE IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. ORACLE FURTHER DISCLAIMS ALL WARRANTIES, EXPRESS AND IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

5. LIMITATION OF LIABILITY. IN NO EVENT SHALL ORACLE BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, OR DAMAGES FOR LOSS OF PROFITS, REVENUE, DATA OR DATA USE, INCURRED BY YOU OR ANY THIRD PARTY, WHETHER IN AN ACTION IN CONTRACT OR TORT, EVEN IF ORACLE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. ORACLE'S ENTIRE LIABILITY FOR DAMAGES HEREUNDER SHALL IN NO EVENT EXCEED ONE THOUSAND DOLLARS (U.S. \$1,000).

6. TERMINATION. This Agreement is effective until terminated. You may terminate this Agreement at any time by destroying all copies of Software. This Agreement will terminate immediately without notice from Oracle if you fail to comply with any provision of this Agreement. Either party may terminate this Agreement immediately should any Software become, or in either party's opinion be likely to become, the subject of a claim of infringement of any intellectual property right. Upon termination, you must destroy all copies of Software.

7. EXPORT REGULATIONS. You agree that U.S. export control laws and other applicable export and import laws govern your use of the Software, including technical data; additional information can be found on Oracle's Global Trade Compliance web site (<http://www.oracle.com/us/products/export>). You agree that neither the Software nor any direct product thereof will be exported, directly, or indirectly, in violation of these laws, or will be used for any purpose prohibited by these laws including, without limitation, nuclear, chemical, or biological weapons proliferation.

8. TRADEMARKS AND LOGOS. You acknowledge and agree as between you and Oracle that Oracle owns the ORACLE and JAVA trademarks and all ORACLE- and JAVA-related trademarks, service marks, logos and other brand designations ("Oracle Marks"), and you agree to comply with the Third Party Usage Guidelines for Oracle Trademarks currently located at <http://www.oracle.com/us/legal/third-party-trademarks/index.html>. Any use you make of the Oracle Marks inures to Oracle's benefit.

9. U.S. GOVERNMENT LICENSE RIGHTS. If Software is being acquired by or on behalf of the U.S. Government or by a U.S. Government prime contractor or subcontractor (at any tier), then the Government's rights in Software and accompanying documentation shall be only those set forth in this Agreement.

10. GOVERNING LAW. This agreement is governed by the substantive and procedural laws of California. You and Oracle agree to submit to the exclusive jurisdiction of, and venue in, the courts of San Francisco, or Santa Clara counties in California in any dispute arising out of or relating to this agreement.

11. SEVERABILITY. If any provision of this Agreement is held to be unenforceable, this Agreement will remain in effect with the provision omitted, unless omission would frustrate the intent of the parties, in which case this Agreement will immediately terminate.

12. INTEGRATION. This Agreement is the entire agreement between you and Oracle relating to its subject matter. It supersedes all prior or contemporaneous oral or written communications, proposals, representations and warranties and prevails over any conflicting or additional terms of any quote, order, acknowledgment, or other communication between the parties relating to its subject matter during the term of this Agreement. No modification of this Agreement will be binding, unless in writing and signed by an authorized representative of each party.

SUPPLEMENTAL LICENSE TERMS

These Supplemental License Terms add to or modify the terms of the Binary Code License Agreement. Capitalized terms not defined in these Supplemental Terms shall have the same meanings ascribed to them in the Binary Code License Agreement. These Supplemental Terms shall supersede any inconsistent or conflicting terms in the Binary Code License Agreement, or in any license contained within the Software.

A. COMMERCIAL FEATURES. You may not use the Commercial Features for running Programs, Java applets or applications in your internal business operations or for any commercial or production purpose, or for any purpose other than as set forth in Sections B, C, D and E of these Supplemental Terms. If You want to use the Commercial Features for any purpose other than as permitted in this Agreement, You must obtain a separate license from Oracle.

B. SOFTWARE INTERNAL USE FOR DEVELOPMENT LICENSE GRANT. Subject to the terms and conditions of this Agreement and restrictions and exceptions set forth in the Java SE LIUM incorporated herein by reference, including, but not limited to the Java Technology Restrictions of these Supplemental Terms, Oracle grants you a non-exclusive, non-transferable, limited license without fees to reproduce internally and use internally the Software complete and unmodified for the purpose of designing, developing, and testing your Programs.

C. LICENSE TO DISTRIBUTE SOFTWARE. Subject to the terms and conditions of this Agreement and restrictions and exceptions set forth in the Java SE LIUM, including, but not limited to the Java Technology Restrictions and Limitations on Redistribution of these Supplemental Terms, Oracle grants you a non-exclusive, non-transferable, limited license without fees to reproduce and distribute the Software, provided that (i) you distribute the Software complete and unmodified and only bundled as part of, and for the sole purpose of running, your Programs, (ii) the Programs add significant and primary functionality to the Software, (iii) you do not distribute additional software intended to replace any component(s) of the Software, (iv) you do not remove or alter any proprietary legends or notices contained in the Software, (v) you only distribute the Software subject to a license agreement that: (a) is a complete, unmodified reproduction of this Agreement; or (b) protects Oracle's interests consistent with the terms contained in this Agreement and that includes the notice set forth in Section H, and (vi) you agree to defend and indemnify Oracle and its licensors from and against any damages, costs, liabilities, settlement amounts and/or expenses (including attorneys' fees) incurred in connection with any claim, lawsuit or action by any third party that arises or results from the use or distribution of any and all Programs and/or Software. The license set forth in this Section C does not extend to the Software identified in Section G.

D. LICENSE TO DISTRIBUTE REDISTRIBUTABLES. Subject to the terms and conditions of this Agreement and restrictions and exceptions set forth in the Java SE LIUM, including but not limited to the Java Technology Restrictions and Limitations on Redistribution of these Supplemental Terms, Oracle grants you a non-exclusive, non-transferable, limited license without fees to reproduce and distribute those files specifically identified as redistributable in the Java SE LIUM ("Redistributables") provided that: (i) you distribute the Redistributables complete and unmodified, and only bundled as part of Programs, (ii) the Programs add significant and primary functionality to the Redistributables, (iii) you do not distribute additional software intended to supersede any component(s) of the Redistributables (unless otherwise specified in the applicable Java SE LIUM), (iv) you do not remove or alter any proprietary legends or notices contained in or on the Redistributables, (v) you only distribute the Redistributables pursuant to a license agreement that: (a) is a complete, unmodified reproduction of this Agreement; or (b) protects Oracle's interests consistent with the terms contained in the Agreement and includes the notice set forth in Section H, (vi) you agree to defend and indemnify Oracle and its licensors from and against any damages, costs, liabilities, settlement amounts and/or expenses (including attorneys' fees) incurred in connection with any claim, lawsuit or action by any third party that arises or results from the use or distribution of any and all Programs and/or Software. The license set forth in this Section D does not extend to the Software identified in Section G.

E. DISTRIBUTION BY PUBLISHERS. This section pertains to your distribution of the JavaTM SE Development Kit Software ("JDK") with your printed book or magazine (as those terms are commonly used in the industry) relating to Java technology ("Publication"). Subject to and conditioned upon your compliance with the restrictions and obligations contained in the Agreement, Oracle hereby grants to you a non-exclusive, nontransferable limited right to reproduce complete and unmodified copies of the JDK on electronic media (the "Media") for the sole purpose of inclusion and distribution with your Publication(s), subject to the following terms: (i) You may not distribute the JDK on a stand-alone basis; it must be distributed with your Publication(s); (ii) You are responsible for downloading the JDK from the applicable Oracle web site; (iii) You must refer to the JDK as JavaTM SE Development Kit; (iv) The JDK must be reproduced in its entirety and without any modification whatsoever (including with respect to all proprietary notices) and distributed with your Publication subject to a license agreement that is a complete, unmodified reproduction of this Agreement; (v) The Media label shall include the following information: "Copyright [YEAR], Oracle America, Inc. All rights reserved. Use is subject to license terms. ORACLE and JAVA trademarks and all ORACLE- and JAVA-related trademarks, service marks, logos and other brand designations are trademarks or registered trademarks of Oracle in the U.S. and other countries." [YEAR] is the year of Oracle's release of the Software; the year information can typically be found in the Software's "About" box or screen. This information must be placed on the Media label in such a manner as to only apply to the JDK; (vi) You must clearly identify the JDK as Oracle's product on the Media holder or Media label, and you may not state or imply that Oracle is responsible for any third-party software contained on the Media; (vii) You may not include any third party software on the Media which is intended to be a replacement or substitute for the JDK; (viii) You agree to defend and indemnify Oracle and its licensors from and against any damages, costs, liabilities, settlement amounts and/or expenses (including attorneys' fees) incurred in connection with any claim, lawsuit or action by any third party that arises or results from the use or distribution of the JDK and/or the Publication; ; and (ix) You shall provide Oracle with a written notice for each Publication; such notice shall include the following

information: (1) title of Publication, (2) author(s), (3) date of Publication, and (4) ISBN or ISSN numbers. Such notice shall be sent to Oracle America, Inc., 500 Oracle Parkway, Redwood Shores, California 94065 U.S.A , Attention: General Counsel.

F. JAVA TECHNOLOGY RESTRICTIONS. You may not create, modify, or change the behavior of, or authorize your licensees to create, modify, or change the behavior of, classes, interfaces, or subpackages that are in any way identified as "java", "javax", "sun", "oracle" or similar convention as specified by Oracle in any naming convention designation.

G. LIMITATIONS ON REDISTRIBUTION. You may not redistribute or otherwise transfer patches, bug fixes or updates made available by Oracle through Oracle Premier Support, including those made available under Oracle's Java SE Support program.

H. COMMERCIAL FEATURES NOTICE. For purpose of complying with Supplemental Term Section C.(v)(b) and D.(v)(b), your license agreement shall include the following notice, where the notice is displayed in a manner that anyone using the Software will see the notice:

Use of the Commercial Features for any commercial or production purpose requires a separate license from Oracle. "Commercial Features" means those features that are identified as such in the Licensing Information User Manual – Oracle Java SE and Oracle Java Embedded Products Document, accessible at <http://www.oracle.com/technetwork/java/javase/documentation/index.html>, under the "Description of Product Editions and Permitted Features" section. I. SOURCE CODE. Software may contain source code that, unless expressly licensed for other purposes, is provided solely for reference purposes pursuant to the terms of this Agreement. Source code may not be redistributed unless expressly provided for in this Agreement.

J. THIRD PARTY CODE. Additional copyright notices and license terms applicable to portions of the Software are set forth in the Java SE LIUM accessible at <http://www.oracle.com/technetwork/java/javase/documentation/index.html>. In addition to any terms and conditions of any third party opensource/freeware license identified in the Java SE LIUM, the disclaimer of warranty and limitation of liability provisions in paragraphs 4 and 5 of the Binary Code License Agreement shall apply to all Software in this distribution.

K. TERMINATION FOR INFRINGEMENT. Either party may terminate this Agreement immediately should any Software become, or in either party's opinion be likely to become, the subject of a claim of infringement of any intellectual property right.

L. INSTALLATION AND AUTO-UPDATE. The Software's installation and auto-update processes transmit a limited amount of data to Oracle (or its service provider) about those specific processes to help Oracle understand and optimize them. Oracle does not associate the data with personally identifiable information. You can find more information about the data Oracle collects as a result of your Software download at <http://www.oracle.com/technetwork/java/javase/documentation/index.html>.

For inquiries please contact: Oracle America, Inc., 500 Oracle Parkway,
Redwood Shores, California 94065, USA.

Last updated 21 September 2017

//END OF GENEXPERT OMNI SOFTWARE LICENSING INFORMATION//

1 Introduction

This section provides general information about the manual as well as related GeneXpert® Omni System documents and contact information.

1.1 About This Manual

This manual describes how to use, maintain, and administer the GeneXpert® Omni Instrument and mobile device. The audience for this manual is everyone who uses or administers the GeneXpert® Omni System.

To learn how to use other parts of the Omni System and related products, locate the relevant publication in the following table.

For...	See...
How to configure the Cepheid C360 Admin web application	<i>Cepheid C360 Admin Manual</i>
How to review and analyze Omni data uploaded to the Cepheid C360 Analytics application	<i>Cepheid C360 Analytics Institution Admin Manual</i>
How to install the Omni System and abbreviated generic instructions for running a test for the Xpert Omni SARS-CoV-2 assay	<i>GeneXpert Omni Reference Guide</i>
Assay-specific instructions for performing a specific test on a patient sample	The package insert for the assay
How to use the general features of the mobile device, such as how to charge it	The provided quick setup guide from the manufacturer of the phone
How to use the printer	The provided user guide from the manufacturer of the printer

To learn more about the different user roles on the Omni System, see Section 3.4.

1.2 Safety Information

About This Topic

This topic explains the meanings of the safety notices used throughout this manual.

Before Using the Omni System

Before using the Omni System for the first time, carefully read the Section section in addition to the following explanation of the different types of notices.

Types of Notices

Warning

A warning indicates the possibility of adverse reactions, or serious or fatal injury, to you or others if the precautions or instructions are not observed.

Caution

A caution indicates that damage to the system, loss of data or invalid results could occur if the user fails to comply with the advice given.

Important

An important note highlights information that is critical for the completion of a task or the optimal performance of the system.

Note

A note identifies information that is useful for completion of a task or identifies information that applies only in specific cases.

Warnings and cautions have a symbol followed by a keyword that describes the type of safety notice, and then a statement describing the hazard.

1.3 Table of Symbols

This topic explains the meaning of each symbol found in this manual and on the instrument label located on the bottom of the instrument. A table of the icons used in the GeneXpert Omni Mobile Application is provided in the appendix of this manual.

Caution

To prevent liquid spills, make sure there is no cartridge in the instrument before turning it over to look at the label.

Symbol	Meaning
	Warning or caution
	<i>In vitro</i> diagnostic medical device
	Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union
	Manufacturer
	Biological risks
	Consult instructions for use
	Indicates there is an internal lithium ion battery inside the unit
	cTUVus certification mark
	Indicates on the rating plate that the equipment is suitable for direct current only to identify relevant terminals

1.4 Technical Support

This topic provides contact information for technical support as well as the information to gather before making contact.

Before Contacting Us

Gather the following information before contacting Cepheid® Technical Support:

- The product name: GeneXpert® Omni System.
- The mobile device Hardware ID and Omni Application software version (see below).
- Any error messages you encountered and/or notes you have that describe the problem.
- The assay name and lot number located on the assay kit box and GeneXpert Cartridge label (if you think the problem is assay related).
- The serial number of the GeneXpert® Omni Instrument.

You will find the serial number on the label attached to the back of the instrument.

For example, the serial number in the following image is 1000000103.



Locating the Hardware ID and Software Versions

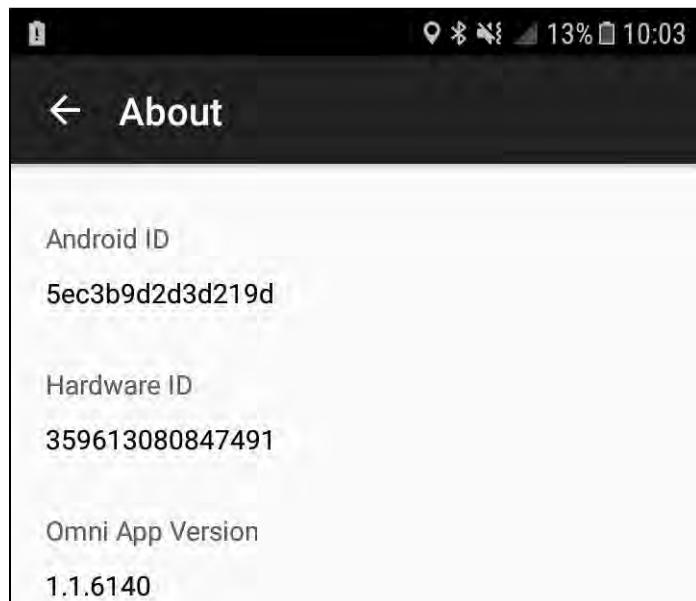
In the GeneXpert® Omni Mobile Application on the mobile device:

1. Tap the information icon at the top right of the screen.



2. Tap **Help**.
3. Tap **About**.

The following image shows a Hardware ID followed by the Omni Mobile Application version.



United States

Telephone: + 1 888 838 3222
Email: techsupport@cepheid.com

Contact information for all Cepheid Technical Support offices is available on our website:
www.cepheid.com/en/CustomerSupport.

1.5 Addresses

Corporate Headquarters

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Telephone: + 1 408 541 4191
Fax: + 1 408 541 4192
www.cepheid.com

Manufacturer Address



Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089-1189
USA
Phone: +1.408.541.4191
Fax: +1.408.541.4192
www.cepheid.com

2 Overview of the Omni System

This section provides an overview of the GeneXpert® Omni System. It describes what the system does and explains the different parts that make up the system. It also explains some concepts that are important to know before starting.

To learn how to set up the system, see the printed copy of the *GeneXpert Omni Reference Guide* in the shipping package.

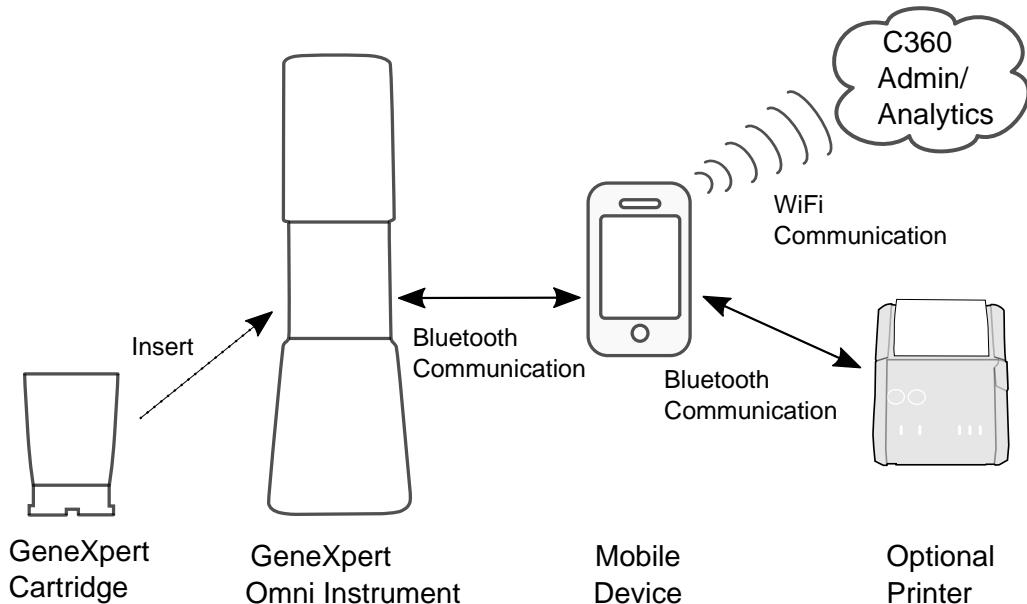
2.1 System Overview

This topic explains what the GeneXpert Omni System does and describes how the different components of the system work together.

Intended Use

The GeneXpert Omni System, for use with the Xpert® Omni SARS-CoV-2 assay, 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).

System Description



Each of the following sections describes a component in the above diagram.

GeneXpert Cartridge

GeneXpert Cartridges are included with the Xpert Omni SARS-CoV-2 assay kits.

GeneXpert Omni Instrument

1. The GeneXpert Omni automates and integrates sample preparation, nucleic acid extraction and amplification, and detection of the target sequence in clinical specimens using real-time PCR assays. The GeneXpert Omni requires the use of the assay-specific single-use disposable cartridges (provided separately) that hold the PCR reagents and host the PCR process. Each module contains a syringe drive for dispensing fluids (i.e., the syringe drive activates the plunger that works in concert with the rotary valve in the cartridge to move fluids between chambers), an ultrasonic horn for lysing cells or spores, and a proprietary I-CORE® thermocycler for performing real-time PCR and detection. To eliminate test-to-test contamination, all fluids including amplicons, are contained within the disposable cartridge and does not come in direct contact with the instrument. Each instrument has an integrated NFC antenna within the I-CORE to recognize cartridges containing a Near Field Communication (NFC) tag for cartridge recognition.
2. The GeneXpert Omni instrument is capable of running on battery power via an internal battery, or while plugged into an external power source.
3. GeneXpert Omni instrument software sends the test results to C360 Analytics for storage.
4. GeneXpert Omni instrument software uses short message service (SMS) text message to provide test results to preconfigured destination phone numbers

Mobile Device

The mobile device is a handheld computer. In the GeneXpert Omni System, it provides the following functions:

1. Allows the user to submit test orders.
2. Allows the user to view the results of the tests ordered.
3. Allows the user to add and remove instruments to and from the mobile device.
4. Allows the user to add either Bluetooth printer or a Wi-Fi printer.
5. Allows the user to perform various operations on the instruments like open door, close door, self-test, instrument maintenance.
6. Allows the user to print test report.
7. Allows the user to view the GeneXpert Omni System operator manual and instructions for use for IVD tests.
8. Allows the user to install new assay definition files, mobile device software updates and instrument software updates.
9. Synchronizes with C360 Admin to download new user information, new assay definition files, mobile device software updates and instrument software updates. Uploads to C360 Admin audit trail information, instrument information and printer information.

Note

In the images of the mobile device used in this manual, the model of mobile device may not exactly match the model you are using, but the described procedures are identical.

C360 Admin

C360 Admin is a web-based software application used with the GeneXpert Omni System and accessed like a website from any computer.

C360 Admin is used to:

1. Perform routine administration of user accounts and passwords for all GeneXpert Omni Systems in the institution.
2. Automatically log the events taking place on all Omni instruments in the institution.
3. Provide the following: software updates, the Omni user's manual, assay definition file updates, and the instructions for use for IVD tests from Cepheid to the Omni mobile device (a Cepheid task).

Note

The software and assay definition files will later be installed by the user from the mobile device to the assigned Omni instruments at a time of the user's choosing.

For more information, see *Cepheid C360 Admin Manual*.

C360 Analytics

This is an application which is hosted on a server on the internet and is intended to provide data aggregation and analysis for monitoring epidemiology. This application provides the following functions to the GeneXpert Omni System:

1. Acts as a data store for all the test results from the GeneXpert Omni System.
2. Allows the administrative user (Admin user) or non-administrative user (Reader) to retrieve the test result data for analysis for monitoring epidemiology in a healthcare setting.

LIS Interface (not included in the picture)

The GeneXpert Omni System interacts with the LIS system unidirectionally. The mobile device only sends results to the LIS system. It sends the information in an unencrypted form. The GeneXpert Omni System supports the ASTM and HL7 protocols.

SMS Interface (not included in the picture)

The GeneXpert Omni System can be configured to send test results via an SMS text message to pre-configured phone numbers. The instrument software at the end of every test run will send the test result to the Twilio cloud server. Twilio will forward the test results via the SMS text message to final destination phone numbers.

For more information, see Cepheid C360 Analytics manual

Printer (optional)

Test results can be printed on paper using the printer provided with the Omni System. The printout can be stored in the patient's file and used to aid communication with the patient. Test results can also be:

- Viewed directly on the mobile device screen.
- Automatically sent by text message to phone numbers previously set up in C360 Admin.

Note

The printer is an accessory and not formally part of the GeneXpert Omni System.

2.2 Instrument Overview

This section describes the features on the front and back of the GeneXpert® Omni Instrument.

2.2.1 Features On the Front of the Instrument

This topic describes the features on front of the instrument including the door, cartridge bay, and activity light.

Feature Descriptions



Feature Number	Description
1	Door covering the cartridge bay
2	Activity light indicating instrument status
3	Instrument label and internal battery charge level lights

Activity Light

The activity light can only be seen when the instrument is on and the light is active. When on, the light emits a small rectangle of white light through the case just below the door, as shown in the following image.



The following table explains the different activity light states.

Activity Light State	Instrument Status
Off	Either: <ul style="list-style-type: none"> • The system is off • The system is on but the instrument is performing a self-test
On: Solid white	A test is running.
On: Slow pulse with brightness slowly increasing from off to full brightness in 2.5 seconds	The instrument is either waiting for the cartridge or loading the cartridge.
On: Rapid flash	The instrument is in an error state. Check the Omni Mobile Application on the mobile device for details.
On: Slow flash	Either the instrument is idle and ready, or the system is booting up.

Cartridge Bay

In the following image, the instrument door is open revealing the cartridge bay.



The vertical opening on the back wall of the cartridge bay is where the cartridge reaction tube protrudes into the core of the instrument. The rails at the base of the cartridge bay guide the cartridge during loading, as shown in the following image.



2.2.2 Features On the Back of the Instrument

This topic describes the features on the back of the instrument, including the Technical Support information label, the power button and the communication ports.

Feature Descriptions



Feature Number	Description
1	Ventilation grille
2	Technical Support information label
3	Instrument serial number label

Feature Number	Description
4	Power console with power button and USB-C ports

Power Console Detail

The following image shows the power console in more detail.



The red power button is used to turn the instrument on and turn the instrument off. The two identical USB-C ports are used to connect the power cable.

Important Ensure you plug in the USB-C connector from the power supply provided for the instrument and not the power supply provided for the mobile device.

See the *GeneXpert Omni Reference Guide* to learn how to connect the power cable.

2.3 Software Overview

This section provides an overview of the GeneXpert Omni System software. It includes more detailed descriptions of the GeneXpert Omni Mobile Application and the user roles that govern who can perform which tasks.

2.3.1 Software Used By the Omni System

This topic describes the software components used with the GeneXpert Omni System.

Many software components are needed for the Omni System to work. Because the Institution Admin will occasionally need to install new and upgraded software, you do need to be aware of some of the components described in this topic. Contact Cepheid Technical Support if you have difficulty installing updates.

Android Operating System

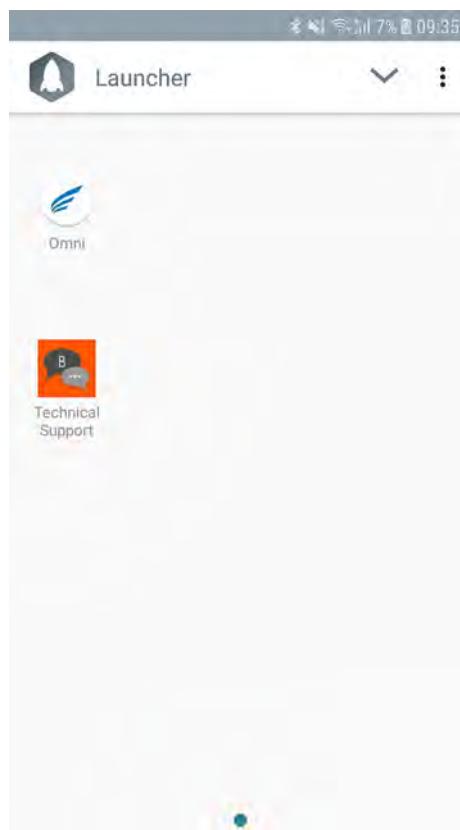
The mobile device uses the Android operating system. Access to the operating system is restricted, but you can use the Android operating system settings to:

- Connect to a Wi-Fi network
- Change the screen brightness

Launcher Application

The mobile device provides access to only those applications and operating system functions needed to run the Omni System. This means that the mobile device cannot be used as a phone or to access the internet through a browser.

Access to applications and operating system functions is managed through the Launcher application, which opens after swiping on the mobile device's home screen. The Launcher application home screen is shown in the following image.



Through the Launcher application, you can access the GeneXpert Omni Mobile Application and a Technical Support application. Use the Technical Support application if instructed to by a Cepheid Technical Support representative.

GeneXpert Omni Mobile Application

The GeneXpert Omni Mobile Application is the mobile device app you use to enter patient information, select a test, run the test, and see the test results. The application is also used by the Institution Admin to set up the Omni System and manage all of the instruments in your lab. Lastly, the Omni Mobile Application is also used to download software updates from, and upload patient test data to, C360 Admin. Much of this manual describes how to use the Omni Mobile Application.

GeneXpert Omni Instrument Software

The GeneXpert® Omni Instrument Software installed on the instrument controls the instrument, automates and integrates sample preparation, nucleic acid extraction and amplification, and detection of the target sequence in clinical specimens using real-time PCR assays. The GeneXpert Omni Instrument Software sends the test results to C360 Analytics for storage. The GeneXpert Omni Instrument Software uses short message service (SMS) text message to provide test results to preconfigured destination phone numbers.

C360 Admin

The C360 Admin web application delivers various software updates to the mobile device, including the Assay Definition Files needed to perform a run. When setting up a new Omni System, you must connect the mobile device with C360 Admin to install the needed software.

As well as delivering updates, C360 Admin has an administrative function. A designated person in your organization uses C360 Admin to set up and manage the collection of Omni Systems purchased by your organization.

C360 Admin and the mobile device communicate in both directions through a Wi-Fi network. Any setup choices made directly on the mobile device are pushed to C360 Admin whenever you sync the two.

For more information, see *Cepheid C360 Admin Manual*

Assay Definition Files

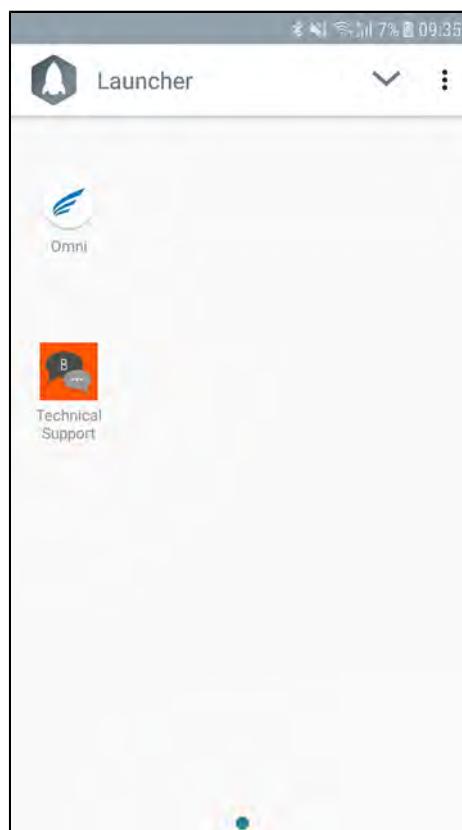
The settings specific to a test are stored in Assay Definition Files (ADFs) that the Institution Admin downloads to the mobile device from C360 Admin and then installs on the instrument.

2.3.2 GeneXpert Omni Mobile Application Overview

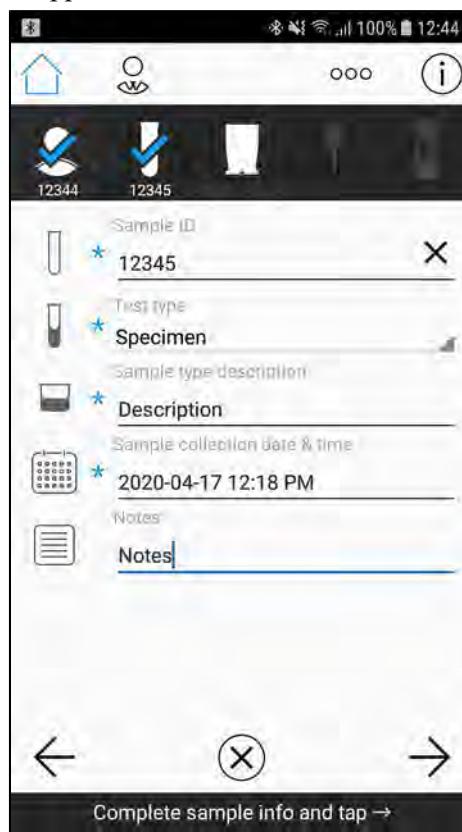
This topic describes the GeneXpert Omni Mobile Application and explains what it is used for.

Introduction

The GeneXpert Omni Mobile Application is the Cepheid mobile device app that runs the GeneXpert Omni Instrument. The application starts when you tap the Omni icon on the Launcher application screen shown in the following image.



An example Omni Mobile Application screen is shown below:



The Omni Mobile Application controls the instrument and runs the following workflows and procedures:

- Installation workflow
- Login workflow
- Test workflow
- General Lab Assistant procedures
- Maintenance procedures
- Troubleshooting procedures
- Administrative procedures

Each of these items is described in more detail below.

Installation Workflow

After performing the initial setup that connects the mobile device to the internet, the Institution Admin runs the installation workflow. During the installation workflow the Institution Admin:

- Tests whether the mobile device is connected to the internet with Wi-Fi communication
- Enters their C360 Admin username and password
- Associates the mobile device with lab information previously setup in C360 Admin
- Connects the mobile device to one instrument using built-in Bluetooth wireless communication
- Installs one or more assays (Assay Definition Files) onto the instrument
- Optionally installs a printer

See the *GeneXpert Omni Reference Guide* for the initial setup and installation instructions.

Login Workflow

The login workflow is followed every time a user logs in to the Omni Mobile Application.

Test Workflow

The test workflow runs an assay for a patient sample.

Before starting the test workflow in the Omni Mobile Application, the Lab Assistant collects a specimen from the patient and prepares the sample. Instructions for this procedure are provided in the package insert for the Cepheid Xpert® Omni SARS-CoV-2 assay.

Next, in the Omni Mobile Application the Lab Assistant:

- Enters information about the patient, such as the name, patient ID and date of birth
- Enters information about the sample by scanning a barcode or manually entering the sample ID on the sample collection vessel
- Uses the mobile device to read the data on the GeneXpert Cartridge NFC tag
- Adds the sample to the cartridge
- Loads the cartridge into the Omni Instrument, which starts the test

In this workflow, information about the sample collected from the patient, information about the patient, and information about the cartridge used for the test are associated together in the Omni Mobile Application database.

At the end of the test, the result displays on the screen.

General Lab Assistant Procedures

Outside of the main workflows, Lab Assistants can use the Omni Mobile Application to:

- View and print previous test results
- Upload test data and system information such as error messages to C360 Platform
- Turn the Omni Instrument on and turn the Omni Instrument off

Maintenance Procedure

The maintenance procedures take you through the process of cleaning the plunger rod and cartridge bay.

Self-Test Troubleshooting Procedure

You can use the self-test troubleshooting procedure at any time to check for instrument hardware failure problems.

Administrative Procedures

The Institution Admin can use the Omni Mobile Application to perform administrative procedures such as:

- Managing passwords
- Managing connections to instruments
- Setting up a connection to an LIS

2.3.3 Omni Mobile Application User Interface Overview

This topic gives an overview of the GeneXpert Omni Mobile Application user interface. This is helpful for understanding the organization of the software and identifying the landmarks that help you navigate around.

Omni Mobile Application Menu Bar

Many screens have a menu bar at the top with the same four icons, as shown in the following image.



The icons are named in the following table and covered in more detail below.

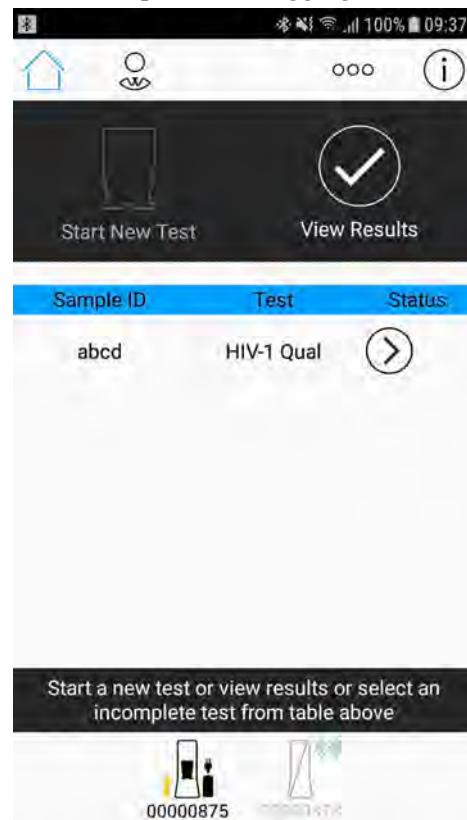
Icon	Description
	Home screen
	User screen
	More options screen

Icon	Description
(i)	Information menu

The three screen icons turn blue when you tap them to load their related screen. In the example image above, the home screen icon is blue because the home screen is being displayed.

Home Screen

The home screen is the screen that opens after logging in.

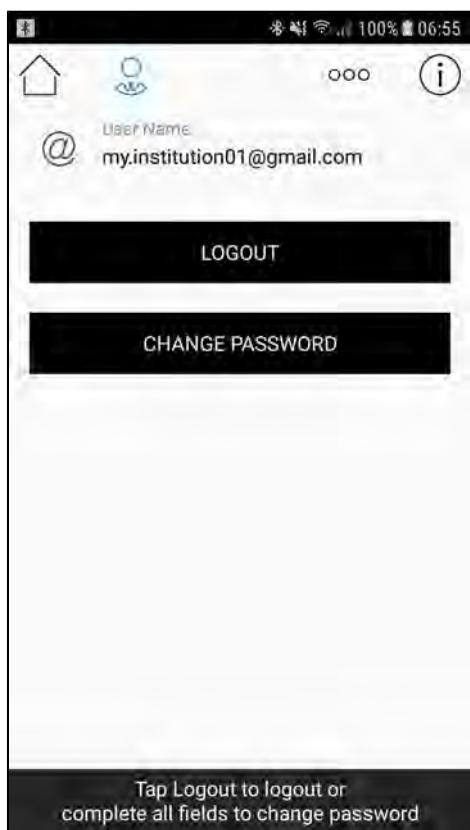


From the home screen you can:

- Start the test workflow by clicking **Start New Test**
- Navigate to a page to view the test results stored on the connected instruments by tapping **View Results**
- See a list of the tests currently running on the connected instruments and the status of the test
- See which instruments are currently connected along with a summary of their current status (the icons at the bottom of the screen)

User Screen

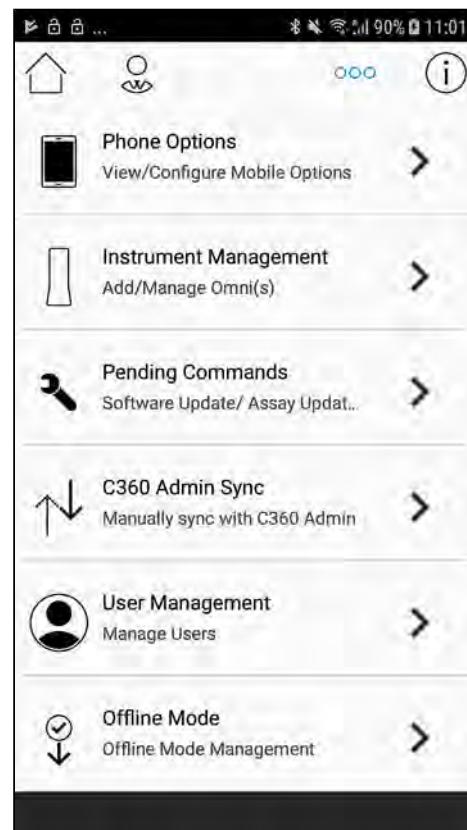
The user screen shown below is where you perform tasks related to your C360 Admin credentials.



On this screen you can login, view your user name, logout, and change your password.

More Options Screen

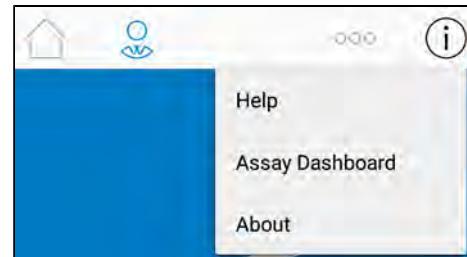
The more options screen shown below is where you perform configuration and administrative tasks unrelated to the installation and test workflows.



Information Menu

The information menu has three links that allow you to:

- Access the user documentation
- See the assays that are installed
- View the software version information



Test Workflow

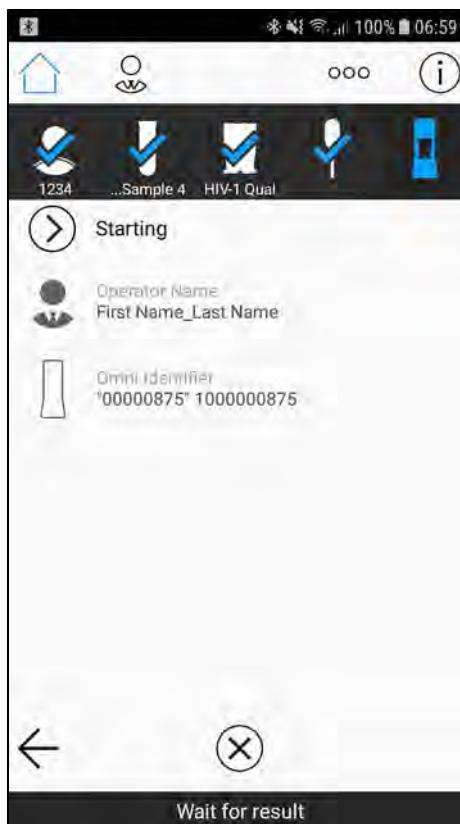
After starting a test, you are taken through a workflow with the following screens that display in sequence:

- Patient information screen
- Sample ID screen
- Scan cartridge screen
- Load sample screen
- Select instrument and start the test screen

As you progress through the workflow, the step you are on is indicated by the step icon in the area below the application menu. The icon turns from white to blue for the current step.

Completed steps are indicated by a blue check mark on the white icon.

In the following example, the first four icons have checkmarks and are therefore complete. The fifth icon is blue and indicates that you are currently on the step for selecting the instrument and starting the test.



Navigation arrows at the bottom of the screen either take you back to the previous screen or move you on to the next screen. The X icon or red octagon icon at the bottom of the screen are used to cancel or stop a test.

Detail Screens

The GeneXpert Omni Mobile Application includes many screens that show more detail related to a parent screen. Some of these detail screens are for reference only, and others have lists and checkboxes that you can select to perform tasks. For example, the following detail screen shows a list of instruments that are available to be connected.



To navigate back to the parent screen from a detail screen, click the back arrow at the top left of the screen.

2.3.4 User Accounts and Privileges

This topic explains how user roles control which tasks you can perform on the GeneXpert Omni System.

Every person using the GeneXpert Omni System is assigned a user account with a username and password for logging in. Each user account is assigned a user role. The user role defines access privileges on the Omni System, just like the access privileges you may have on your organization's computer network.

User Role Descriptions

The Omni System has the user roles described below.

Institution Admin

Institution Admin users have the highest level of privileges and can perform all tasks on the system. They can run tests, assign instruments to labs, add labs and manage user accounts.

Laboratory Admin

Laboratory Admin users have the same privileges as Institution Admin users on the mobile device except that they are restricted to managing users and seeing results related to their laboratory.

For information about how the Laboratory Admin and Institution Admin user roles are different in C360 Admin, see the *Cepheid C360 Admin Manual*.

Lab Assistant

Lab Assistant users can run patient tests, view test results, print test results, sync mobile devices with Cepheid C360 Platform and change their own password in C360 Admin.

Guest

Guest users can log in to mobile devices and run tests if enabled by the Institution Admin, but they cannot login to C360 Admin.

Epidemiologist

Epidemiologist users typically work for international organizations such as the World Health Organization. The Institution Admin can assign epidemiologists the Epidemiologist user role, giving permission to view test results uploaded to C360 Analytics. Epidemiologist users cannot run patient tests, but they can change their own password in C360 Admin.

User Role Summary Table

The following table summarizes the tasks that different C360 Admin user roles can perform on the mobile device and instrument. For information about the tasks that these user roles can perform in C360 Admin, see the *Cepheid C360 Admin Manual*.

Task	Institut Admin	Lab Admin	Lab Assist	Guest User
Run a test	Yes	Yes	Yes	Yes
View results	Yes (all)	Yes (all)	Yes (all)	Yes (own)
Run maintenance	Yes	Yes	Yes	No
Add an instrument	Yes	Yes	Yes	No
Remove an Instrument	Yes	Yes	Yes	No
Manually sync with C360 applications	Yes	Yes	Yes	No
Offload results from instruments	Yes	Yes	Yes	No
Upload results to C360 Analytics	Yes	Yes	Yes	No
Run a self-test	Yes	Yes	Yes	No
Change own password	Yes	Yes	Yes	Yes
Change other users password who are not Administrators	Yes	Yes	No	No
Add a printer/configure a printer	Yes	Yes	Yes	No
Install assays	Yes	Yes	Yes	No
Install/upgrade software	Yes	Yes	No	No

Reset site	Yes	Yes	No	No
Restart the application	Yes	Yes	Yes	Yes
Identify the instrument with a blinking light	Yes	Yes	Yes	Yes
Open/close the instrument door	Yes	Yes	Yes	Yes
Set instrument unavailable for test run	Yes	Yes	Yes	No
Restart the instrument	Yes	Yes	Yes	Yes
Shutdown the instrument	Yes	Yes	Yes	Yes
Edit Guest user information	Yes	Yes	No	No
View the Help	Yes	Yes	Yes	Yes
Wipe the instrument database	Yes	Yes	No	No
Backup the instrument database	Yes	Yes	No	No
Restore the instrument database	Yes	Yes	No	No

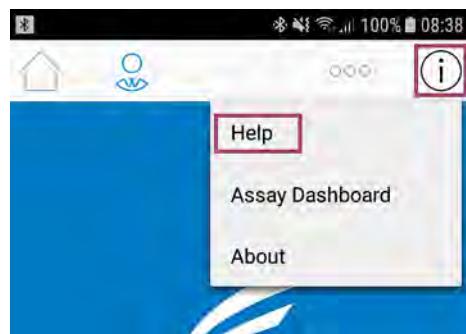
Note

A user role of *Basic User* that appears in some screens on the mobile device is the same as the *Lab Assistant* user role in C360 Admin described in the table above. The user role of *Admin* on the mobile device has the same privileges on the mobile device as the C360 Admin *Institution Admin* and *Laboratory Admin* user roles in the above table.

2.4 Opening the Omni System Documentation

This topic provides instructions for opening the GeneXpert Omni System documentation on the mobile device. The topic is intended for customers reading a PDF format version of this guide.

1. From the mobile device Home screen, tap the information menu icon and then tap **Help**.



2. Follow the instructions on the documentation home page to open this manual or the package insert for the Xpert Omni SARS-CoV-2 assay.

3 Preparing To Run a Test

This section explains how to position the GeneXpert® Omni Instrument on the bench, start the system, and log in. These instructions assume you have previously set up the GeneXpert® Omni System using the *GeneXpert Omni Reference Guide*.

3.1 Positioning Instruments On the Bench

This topic describes how to position GeneXpert® Omni Instrument on the bench in a way that minimizes problems.

Important **Wireless enabled mobile devices can cause communication loss between the instrument and mobile device during an Xpert® assay test run. Please ensure such mobile devices are not within 30 cm (12 in.) of the instrument or other mobile devices when a test is running.**

Ensure the Instrument is On a Stable Sheltered Surface

Always place the instrument on a flat, level, stable surface in a sheltered environment.

For improved stability, keep the instrument seated in the instrument base stand as shown in the printed unpacking instructions provided in the shipping box.

Avoid Placing Instruments Close Together

The GeneXpert Omni Instrument reads information stored on an electronic NFC (Near-Field Communication) chip built into each GeneXpert Cartridge label.

Caution

 **To minimize NFC interference, place instruments at least 13cm (5 inches) apart. Avoid placing GeneXpert Cartridges within 13cm (5 inches) of the front or side of the instrument at door height.**

At least 5 cm (2 in) of clearance on each side of the instrument is needed to ensure adequate ventilation.

Avoid Placing Instruments Near Vents

Do not place instruments close to the vents of other instruments or air handling units.

Avoid Tipping the Instrument

Caution

 **Do not tip the instrument while running a test. This can trigger a sensor that stops the run.**

Caution

 **Do not tip the instrument when there is a cartridge inside. Damage to the instrument can occur if the cartridge contents leak inside the instrument.**

3.2 Turning On the Instrument

This topic explains how to turn on the GeneXpert Omni Instrument using the power button. See also Section 1.

1. Without tipping the instrument, turn it around to view the back.
2. Press in and hold the red power button for 2 seconds.



It takes about two minutes to start up the instrument. During this time, the instrument performs a self-test procedure that includes opening and closing the cartridge door. When the instrument is ready, the white flashing activity light illuminates.

3.3 Turning On the Mobile Device

This topic explains how to turn on the mobile device.

1. Fully charge the mobile device using the supplied USB charging cable and the facilities main power.
2. Press and hold the power button on the right side of the mobile device.

The power button is illustrated in the provided quick setup guide for the mobile device.

3.4 Starting the Omni Mobile Application

This topic explains how to start the GeneXpert® Omni Mobile Application.

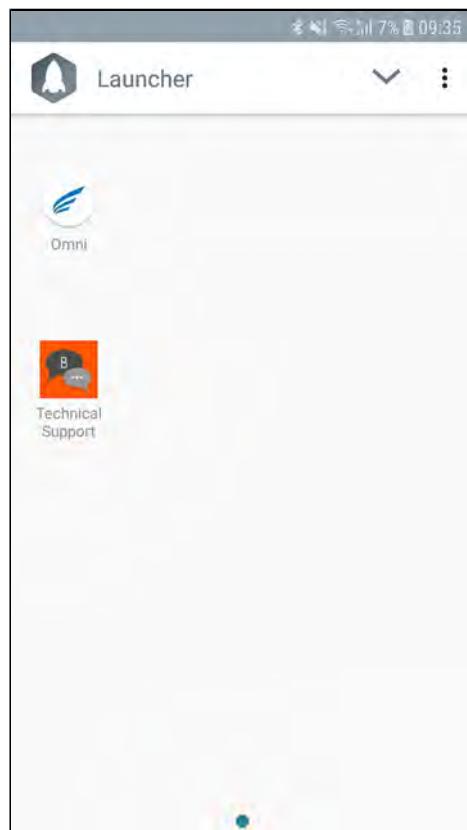
1. Using a finger, swipe the mobile device home screen in any direction.



Note

The "Emergency calls only" link at the top of the home screen does not activate the ability to make phone calls.

-
2. In the Launcher application, tap the Omni icon to start the Omni application.



The Cepheid login screen opens.



3.5 Logging In As a Registered User

This topic explains how to log in to the GeneXpert Omni Mobile Application as a registered user.

A registered user is someone with an account in C360 Admin set up by your organization's Institution Admin. If you are not a registered user, you can still use the GeneXpert Omni System by logging in as a guest user.

1. On the Cepheid login screen, tap **LOGIN**.



2. Tap in the **User Name** field and use the keyboard to type in your user name.
Contact the person assigned the Institution Admin role if you do not know your assigned password.

The following image shows a user name typed into the field

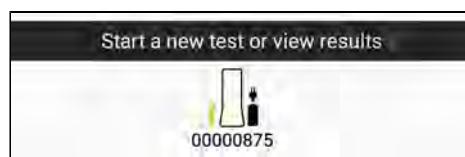


Note

Fields with an asterisk (*) are required. Your institution policy set by your Institution Administrator determines some of the fields that are required.

3. Tap in the **Password** field, type your password, and tap the adjacent arrow to login.

4. In the Omni Mobile Application home screen, verify that the instrument icon appears at the bottom of the screen as shown in the following example.



The instrument is now initialized and ready to run tests.

3.6 Logging In As a Guest User

This topic explains how to log in to the GeneXpert Omni Mobile Application as a guest user. This option is only available if it is turned on in C360 Admin by the Institution Admin.

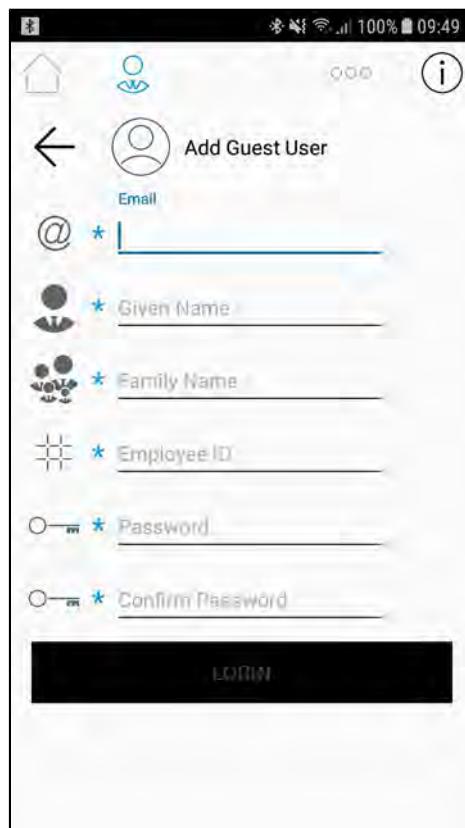
Guest users are temporary users who need to run tests and view results but have not been added to the list of users in C360 Admin.

After a guest user account is created, no further permission is required to log onto the system. The guest user account is valid with no time limit on usage, allowing guest users to log in every day without creating a new account each time. The guest login account can be used across multiple mobile devices and is not confined to one particular device.

1. On the Login screen, tap **GUEST USER**.



2. Tap in the Email field and use the keyboard to enter the email address suggested by your organization.



3. In a similar way, complete the other fields on the screen.

Use the Employee ID suggested by your organization.

The password must contain at least eight characters with at least one character from three of the following four character types:

- Lowercase letters
- Uppercase letters
- Numeric characters
- Special characters (~ ! @ # \$ % ^ & * _ - = + , . / < > ? ; ' : " [] \ { } |)

4. Tap **LOGIN**.

3.7 Managing the System When It Is Idle

This topic describes what to do with the GeneXpert Omni System when it will not be used for a while.

- If the GeneXpert Omni Instrument or mobile device is running on AC power, leave it powered on.
- If the instrument or mobile device is running on battery power, power it down or plug it into an AC power outlet.

4 Running a Test

This section gives the workflow for running a test.

4.1 Entering Patient Information

This topic explains how to add the necessary patient information before running a test. This is needed to associate the patient with the test in the GeneXpert® Omni Mobile Application.

When setting up the GeneXpert® Omni System, your organization's Institution Admin decided which fields on the patient information screen are required. The required fields are marked with an asterisk (*). You can also enter information into fields that are not required.

Important After entering information, you can still update it until the test run is complete. Use the back and forward arrows at the bottom of the screen to navigate between screens.

The following procedure assumes you will enter information for every field.

1. On the home screen, tap **Start New Test**.



2. Tap in the **Patient ID** field and use the keyboard to type in the Patient ID as shown in the following example.



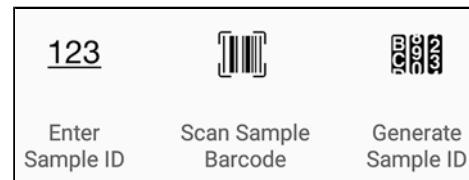
The Patient ID has 1 to 32 characters that can include:

- Lowercase letters
 - Uppercase letters
 - Numbers
 - Special characters except for the following: “ : * < >.
3. Tap the **Patient date of birth** field, select the patient's date of birth from the calendar, vertically scrolling the fields as needed, and tap **OK**.
 4. Tap the **Patient family name** field and enter the patient's last name.
 5. Vertically scroll the screen and tap the **Patient given name** field and enter the patient's first name.
 6. Tap the **Patient gender** field and select the gender from the list.
 7. Tap the **Patient address** field and enter the patient's address.
 8. Tap the now active **Forward-Arrow** at the bottom right of the screen.

4.2 Options for Entering the Sample ID

This topic describes the options for entering a Sample ID, which is needed to associate the sample-containing vessel with the test in the GeneXpert® Omni Mobile Application.

After entering patient information on the previous screen, you are presented with three options for entering the Sample ID, as shown in the following image.



If a Sample ID barcode label is available, you can select the **Scan Sample Barcode** option. Alternatively, you can manually enter a Sample ID (**Enter Sample ID** option) or let the software generate a Sample ID for you (**Generate Sample ID** option).

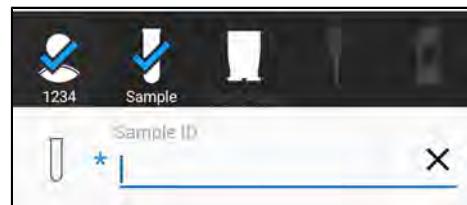
Note A Sample ID is always required. This field cannot be left empty.

The next three topics give the instructions for each of these options.

4.2.1 Entering a Sample ID Manually

This topic explains how to enter a Sample ID manually. Use this option if the barcode is unreadable or if there is no barcode and a Sample ID is available.

1. In the Sample ID options screen tap **Enter Sample ID**.
2. Tap in the **Sample ID** field and use the keypad to type in the Sample ID.



3. Carefully verify the Sample ID on the screen against the Sample ID on the sample label to make sure they match.

If needed edit the text using the keypad.

Caution

To avoid errors it is important to verify the Sample ID on the screen.



4. Tap in the **Test type** field and select one of the options.
5. Tap in the **Sample type description** field and enter a description following guidance from your organization about the type of information to add here.
6. Tap in the **Notes** field and enter any additional notes.
7. Tap the forward arrow at the bottom of the screen.

If a required field is not completed, the arrow will be gray and inactive.

4.2.2 Scanning the Sample ID With the Barcode

This topic explains how to enter a Sample ID by scanning the Sample ID barcode using the camera on the mobile device.

1. On the Sample ID options screen, tap **Scan Sample Barcode**.
2. Aim the rear camera of the mobile device at the barcode to scan it, as shown in the following image.

While looking at the screen, overlay the barcode with the crosshairs and hold the mobile device still.



Important The entire sample barcode must be visible through the camera.



When the mobile device recognizes the barcode, a beep sounds and the sample ID shows in the **Sample ID** field.

If the barcode is not read, try again up to two times, waiting for up to 30 seconds each time. If the barcode is still not read, either enter the sample ID manually or see Section 5.

3. After scanning the barcode, carefully verify the Sample ID on the screen of the dialog box against the Sample ID on the sample label to ensure they match.

Caution



To avoid errors it is important to verify the sample ID on the screen.

4. Tap **CONFIRM**.
5. Tap in the **Test type** field and select an option.
6. Tap in the **Sample type description** field and enter a description following guidance from your organization about the type of information to add here.

7. Tap in the **Notes** field and enter any additional notes.
8. Tap the forward arrow at the bottom of the screen.
If a required field is not completed, the arrow will be gray and inactive.

4.2.3 Generating a Random Sample ID

This topic explains how to enter a Sample ID using a random ID generator. Choose this option if neither a sample barcode nor sample ID are available.

1. On the Sample ID options screen, tap **Generate Sample ID**.
A random alphanumeric text value is entered into the Sample ID field.
2. If required, record the Sample ID on the sample container or test order.
3. Tap in the **Test type** field and select one of the options.
4. Tap in the **Sample type description** field and type a description following guidance from your organization about the type of information to add here.
5. Tap in the **Notes** field and enter any additional notes.
6. Tap the forward arrow at the bottom of the screen.
If a required field is not completed, the arrow will be gray and inactive.

4.3 Loading the Cartridge and Running the Test

This topic explains how to read the GeneXpert Cartridge NFC tag, load the sample, load the cartridge and run the test.

Caution



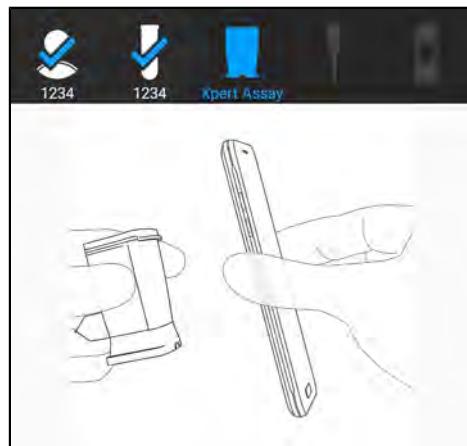
The instrument ensures a GeneXpert Cartridge can only be used once. Cartridges are single-use only. Adding a patient sample to a previously-used cartridge will result in loss of the sample.

Caution



If instrument communication loss occurs after selecting the instrument to use for the test but before the cartridge is loaded and the door is closed, an error message will appear. The error message will advise you to not load the cartridge and to close the door. If the message instructions are followed, a different instrument can be selected to run the cartridge (if more than one instrument is connected). However, if the cartridge is loaded and the door closed when instrument communication loss occurs, no result will be given when the test completes. Also, you will not be able to reuse the cartridge.

1. Using the screen animation as a guide, place the back of the mobile device close to the cartridge label to read the NFC tag embedded in the label.



While doing this, do not hold the reaction tube located at the back of the cartridge, which should be kept clean.

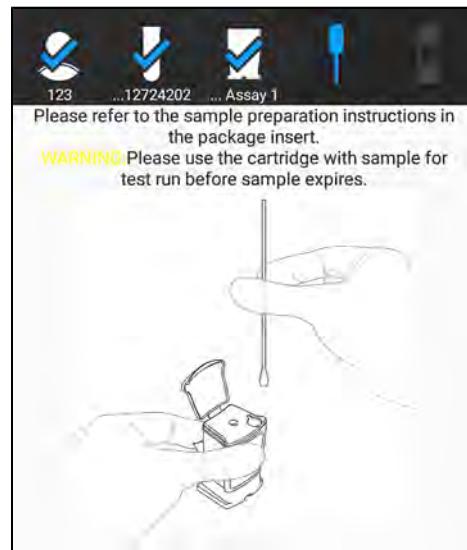


The mobile device emits a single beep when the NFC tag is read.

When the NFC tag is read, the mobile device determines whether the cartridge has expired or previously been run. In these cases, an error message will appear on the screen indicating that the cartridge cannot be used.

If the NFC tag is not read, contact Cepheid Technical Support.

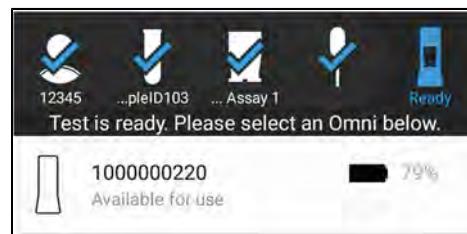
2. In the screen, verify that the correct cartridge was scanned: Xpert Omni SARS-CoV-2.
3. If the correct cartridge was scanned, tap the forward arrow at the bottom right of the screen to move to the next step.
4. Prepare the sample following the instructions in the package insert for the Xpert Omni SARS-CoV-2 assay.
5. Open the cartridge lid and load the sample using the animation on the screen as a guide.



Note See the package insert for information about sample expiration.

6. Close the cartridge lid.
7. Tap the forward arrow at the bottom right of the screen to move to the next screen.
8. Tap the serial number of the instrument connected to the mobile device.

In the following example, the serial number is 1000000220.



The door to the instrument opens.

Caution



Wait until the door is fully open and all moving parts have stopped before inserting the cartridge. This wait time allows the loading mechanism to move into the correct position to receive the cartridge. Loading the cartridge prematurely can cause damage to the loading mechanism.

9. With the cartridge label facing out, place the cartridge into the instrument so the side rails of the cartridge just enter the receiving tracks of the cartridge bay.
10. Using both hands, press the cartridge gently into the instrument.



The loading mechanism will pull the cartridge inside the instrument, and the instrument door will close.

Caution



Do not try to manually open or close the instrument door at any time. Damage to the door mechanism can occur if the door is manually operated.

Caution



Do not move the instrument once a test has started. Invalid test results can occur if the instrument is moved during processing.

Caution



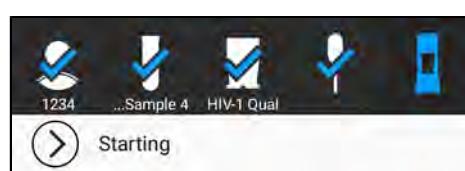
Do not tip the instrument when a test is running. In addition to causing an error and possible invalid test results, damage to the instrument can occur if the cartridge contents leak or spill into the interior of the instrument.

Important

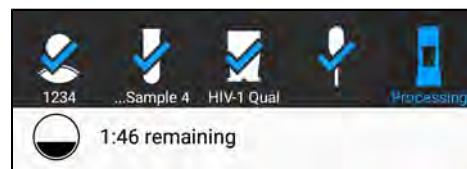
It is possible to modify or edit patient information after a test has started, but any editing must be completed before the test finishes. To edit patient information, use the back arrow to return to the patient entry screens. After making modifications, use the forward arrow to return to the test in progress screen.

Once the door is closed, the test request is sent to the instrument and the test begins.

The screen initially indicates that the test is starting, as shown in the following image.



Then, the last workflow icon indicates that the test is processing and the screen displays the hours and minutes remaining until the test completes.



While a test is running, do not:

- Move the instrument
- Run other applications on the mobile device
- Change the date and time

Note

If an error message appears, see Section 3 for troubleshooting help.

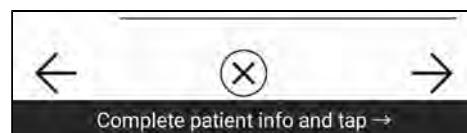
When the test completes, the last test workflow icon shown in the image above is blue and it indicates that the test is complete. The instrument door opens and the screen provides the test result.

11. Confirm that the test result is either positive or negative (ORG DETECTED or ORG NOT DETECTED).
If the result is NO RESULT or ERROR, repeat the test with a new cartridge.
12. Remove the cartridge and dispose of the cartridge according to your institution's hazardous waste policies.
Cartridges cannot be reused.
13. Close the instrument door.

4.4 Canceling a Test Before It Starts

This topic explains how to cancel a test while still entering data and before loading the cartridge. You might do this if you no longer need to perform the test.

Tap the "X" icon near the bottom of the screen.



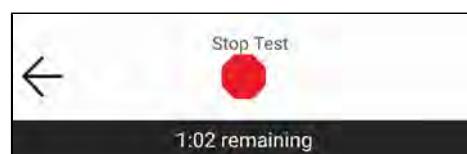
4.5 Stopping a Test That Is Running

This topic explains how to stop a test after loading a cartridge.

Important Stopping a test that is running will prevent delivery of the test result.

After a test starts running, the icon at the bottom of the screen changes from an "X" (**Cancel Test**) to a red "stop sign" (**Stop Test**).

1. Tap the **Stop Test** icon to stop a test that is running.



2. Tap **YES** in the confirmation dialog box.

There will be a short delay until the test stops, then the home screen displays.

5 Managing Test Results

This section explains how to view test results, print test results and push test results to C360 Analytics.

5.1 Viewing Stored Test Results

This topic explains how to list, sort, and view the test results stored on one or more GeneXpert® Omni Instruments. The instruments must be connected before you can list the results.

1. On the Home screen, tap **View Results**.



The test results performed today are listed with the most recent test at the top.

Test Sample 5		2019-08-07 02:45 PM
PATIENT NAME NOT SUPPLIED		
DEMO MTB-RIF Ultra RUO		
MTB DETECTED LOW		
RIF Resistance DETECTED		
Test Sample 4		2019-08-06 04:01 PM
PATIENT NAME NOT SUPPLIED		
DEMO MTB-RIF Ultra RUO		
MTB DETECTED VERY LOW		
RIF Resistance NOT DETECTED		
Test Sample 3		2019-06-14 03:29 PM
PATIENT NAME NOT SUPPLIED		
DEMO MTB-RIF Ultra RUO		
MTB NOT DETECTED		
Test Sample 2		2019-06-08 04:00 PM
PATIENT NAME NOT SUPPLIED		
DEMO MTB-RIF Ultra RUO		
MTB Trace DETECTED		
RIF Resistance INDETERMINATE		
Test Sample 1		2019-04-08 04:56 PM
PATIENT NAME NOT SUPPLIED		
DEMO MTB-RIF Ultra RUO		
ERROR		
Tap a test to view the result		

2. To view the list of results for a different time period, tap one of the following options at the top of the screen.



3. Tap a listed test to view more information about the test and print the test result.

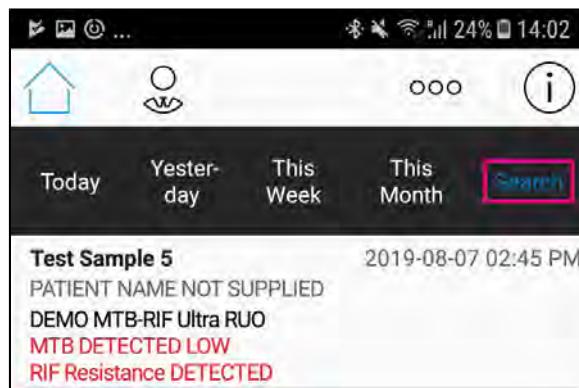
If you cannot see any results, make sure the:

- Instrument is on
- Mobile device is within 30 meters (100 feet) of the instrument

5.2 Searching for Test Results

This topic explains how to locate particular test results by entering search criteria.

1. On the home screen, tap **View Results**.
2. Tap **Search**.



3. Select a field you want to search on.

The selected field has a green flashing cursor and green underline.



4. Enter the text or date you want to retrieve test results for.
5. Optionally, select and enter criteria for additional fields.
6. Scroll down and tap **SEARCH**.

The subset of results that meet your search criteria are listed on the screen.

5.3 Selecting a Printer

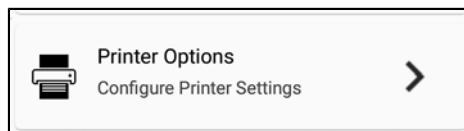
This topic explains how to select a previously connected printer so you can use it for printing test results.

The GeneXpert® Omni System can be used with two printer models — a Bluetooth model and a wired/Wi-Fi model. Instructions for installing a printer that you can then connect to are given in the *GeneXpert Omni Reference Guide*.

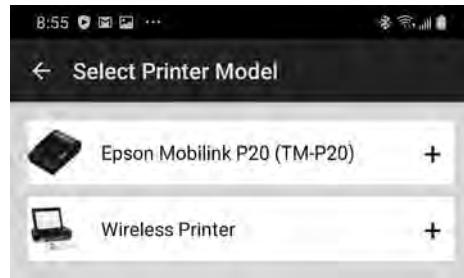
1. Tap the more options icon.



2. Scroll down and tap **Printer Options**.



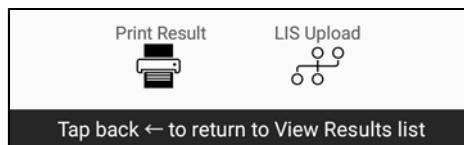
3. Tap one of the listed printers to select it for use.



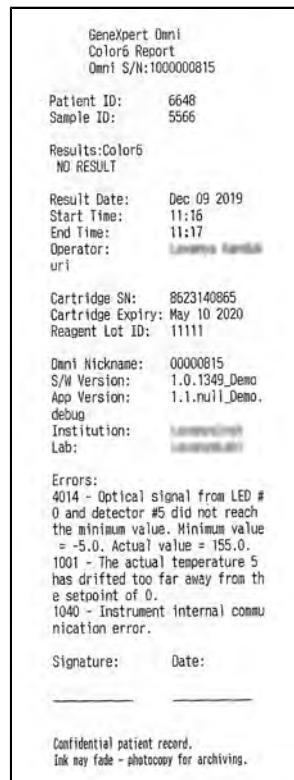
5.4 Printing Test Results

This topic explains how to print test results on the printer.

1. Display the screen listing the details of the test result you want to print.
2. At the bottom of the screen, tap **Print Result**.



The test result prints, as shown in the following example.



The bottom of the printout contains error information and a place for signature approval.

Note The format of the printout varies with the printer model used.

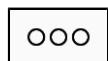
5.5 Downloading Test Results to the Mobile Device

This topic explains how to download test results from connected GeneXpert Omni Instruments to the mobile device.

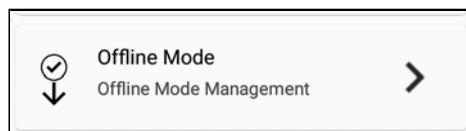
The test results are stored on the instrument. The results can be encrypted by the mobile device and pushed to Cepheid C360 over a Wi-Fi network. If there is no network access at the testing site, you can download the anonymized test data to the mobile device for storage. Then, when you are in a location where there is network access, you can upload the test data to C360.

During the download and upload processes you will never be able to see the actual test data. You will only see the number of test results that are being downloaded and uploaded.

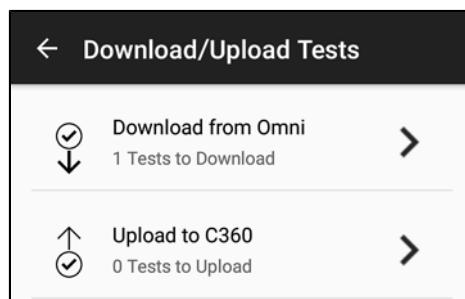
1. Tap the more options icon.



2. Tap **Offline Mode** at the bottom of the screen.



3. Tap **Download from Omni**.



The screen indicates how many tests there are to download.

4. Tap **DOWNLOAD**.

The test results on all connected instruments begin downloading to the mobile device. The download time depends on the number of instruments connected to the mobile device and the number of tests to download.

When the test results have downloaded, the screen changes to gray.

5. Tap the back arrow in the top left of the screen twice to return to the more options screen.

5.6 Uploading Test Results To C360 Analytics

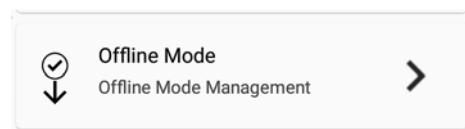
This topic explains how to upload test results stored on the mobile device to C360 Analytics. Before uploading test results to C360 Analytics, you must first have downloaded the test results to the mobile device.

You do not need an instrument for this procedure.

1. Ensure you are in a location with Wi-Fi access to the internet.
2. Tap the more options icon.



3. Tap **Offline Mode** near the bottom of the screen.



The number of tests available for uploading displays in the screen.



4. Tap **Upload to C360**.

5. Tap **UPLOAD**.

The test results begin uploading to C360. The upload time depends on the number of tests to upload. When the test results have uploaded, the screen changes to gray.

6. Tap the back arrow at the top left of the screen twice to return to the more options screen.

5.7 Receiving Test Results via SMS Text Message

This topic explains the requirements for sending patient test results by SMS text message to a health care worker's mobile phone.

Your Institution Admin can set up the ability for select people to receive text messages containing patient test results. Typically these messages are sent to the mobile phones of healthcare workers who communicate test results to patients. Instructions for setting up this capability are given in the *Cepheid C360 Admin Manual*.

For SMS messages to be sent, the Omni instrument that ran the test needs to be connected to the mobile device and the mobile device needs to have an active Wi-Fi connection.

6 Shutting Down the System

This section explains how to shut down the GeneXpert® Omni Instrument and mobile device.

6.1 Shutting Down the Instrument Using the Power Button

This topic explains how to the GeneXpert Omni Instrument using the power button located on the back.

Before starting, ensure there is no GeneXpert® Cartridge in the instrument.

Caution



Do not tip the instrument with a cartridge inside. Damage to the instrument can occur if the cartridge contents leak or spill into the interior of the instrument.

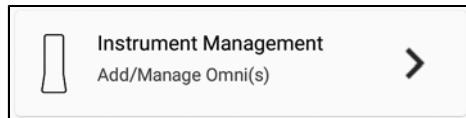
Note

When turning off the instrument using the power button on the back of the instrument, the USB-C charger cable can either be plugged in or not.

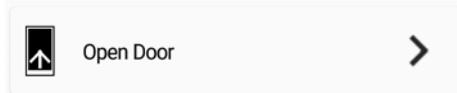
1. Tap the more options icon.



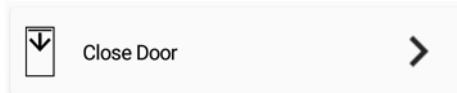
2. Tap **Instrument Management**.



3. In the list of connected instruments, tap the instrument you want to shut down.
4. Ensure there is no cartridge in the instrument and that the door is closed.
 - a) If the door is closed and you need to see if there is a cartridge in the instrument, scroll down and tap **Open Door**.



- b) Tap **YES** in the dialog box, and then tap **OK**.
The door opens.
- c) If there is a cartridge in the instrument, remove it.
- d) Tap **Close Door**.



- e) Tap **YES** in the dialog box, and then tap **OK**.
5. On the back of Omni instrument, press and hold the red power button for 2 seconds.



The shutdown sequence begins and will take several seconds.

Note

If the instrument does not start to shut down after holding the button for 2 seconds, repeat the button press for 10 seconds which cuts power to the instrument immediately without saving any unsaved data.

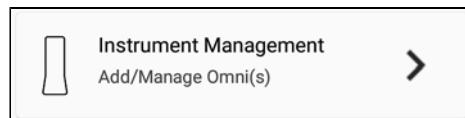
6.2 Shutting Down the Instrument Using the Mobile Device

This topic explains how to shut down the GeneXpert Omni Instrument using the GeneXpert Omni Mobile Application on the mobile device.

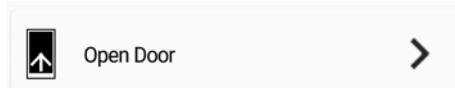
1. Tap the more options icon.



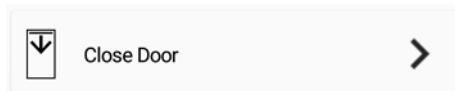
2. Tap **Instrument Management**.



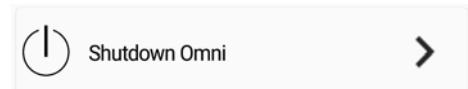
3. In the list of connected instruments, tap the instrument you want to shut down.
4. Ensure there is no cartridge in the instrument and that the door is closed.
 - a) If the door is closed and you need to see if there is a cartridge in the instrument, scroll down and tap **Open Door**.



- b) Tap **YES** in the dialog box, and then tap **OK**.
The door opens.
- c) If there is a cartridge in the instrument, remove it.
- d) Tap **Close Door**.



- e) Tap **YES** in the dialog box, and then tap **OK**.
5. Tap **Shutdown Omni**.



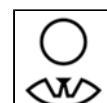
6. Tap **OK** in the dialog box.
The instrument shuts down.

6.3 Logging Off the Omni Application

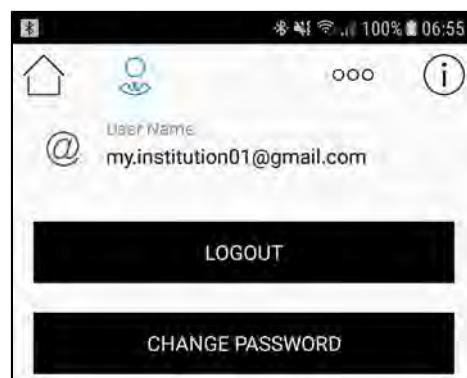
This topic explains how to log off the GeneXpert Omni Mobile Application on the mobile device. You might do this before shutting down the GeneXpert Omni System or after you have finished running tests when others may still need to use it.

If a test is running when you log off, the test will continue and you can view the result when you log back on.

1. Tap the user icon.



The user icon turns blue to indicate the user information screen is now active.



2. Tap **Logout** and then tap **YES** in the dialog box.

6.4 Closing the Omni Mobile Application

This topic explains how to close the GeneXpert Omni Mobile Application when you have finished running tests.

If a test is running when you exit the application, the instrument will continue to run the test and the result will be available when you restart the application and log on.

1. Press the mobile device Recents button to display the open applications.

The Recents button is shown in the provided quick setup guide for the mobile device.

2. Tap the **X** on the Omni window.



The application closes.

6.5 Shutting Down the Mobile Device

This topic explains how to shut down the mobile device, which can be done at any time.

After shutting down the mobile device, any connected instruments will continue to run tests already started. You will be able to retrieve the test results after turning the mobile device back on and logging in to the GeneXpert Omni Mobile Application. Previous instrument connections should re-establish automatically, provided the instruments are located nearby.

1. Press and hold the power button on the side of the mobile device.

The power button is shown in the provided quick setup guide for the mobile device.

2. Tap **Power Off**.



7 Administrative Tasks

This section covers the tasks that can only be performed by the Institution Admin and Laboratory Admin user roles.

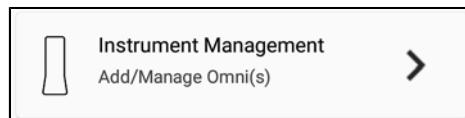
7.1 Adding an Omni Instrument

This topic explains how the Institution Admin can associate a GeneXpert® Omni Instrument with a laboratory using the GeneXpert® Omni Mobile Application on the mobile device. Instruments associated with a laboratory appear as icons at the bottom of the home screen. Associating an instrument with a laboratory allows you to use the instrument for running tests.

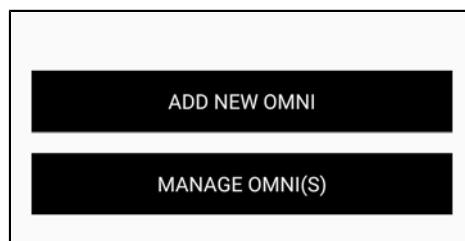
1. Tap the more options icon.



2. Tap **Instrument Management**.



3. Tap **ADD NEW OMNI**.



When the search for nearby instruments is complete, the screen lists the available instruments as shown in the following example.



4. Select the checkbox for the instrument to connect.

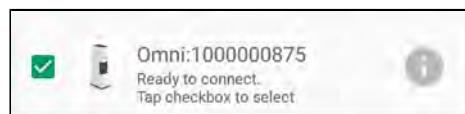
To identify your instrument, turn the instrument around and read the serial number printed on the label near the power button. In the following example, the serial number is 1000000103.



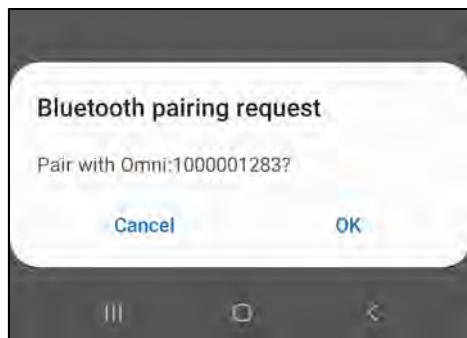
Note

If your instrument is not listed, tap **NOT SEEING OMNI?** to repeat the instrument search, then select the checkbox.

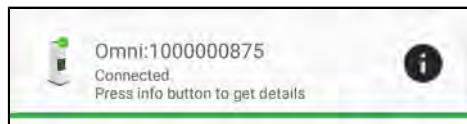
The following image shows a selected instrument.



5. Tap **CONNECT TO OMNI(S)**.
6. Tap **OK** in the Bluetooth pairing request dialog box.



The mobile device takes several seconds to connect to the selected instrument. The icon for the connected instrument has a green checkmark and a 'completed' green progress stripe, as shown in the following image.



7. Tap **DONE ADDING OMNI(S)**.
8. Tap the back arrow at the top of the screen and tap the home icon to return to the home screen.

An instrument icon for the newly added instrument shows at the bottom of the screen. For a list of the icons and what they mean, see Icon Definitions.



7.2 Disconnecting an Omni Instrument

This topic explains how the Institution Admin can remove the association between a GeneXpert Omni Instrument and a laboratory.

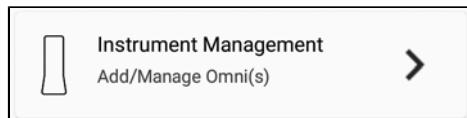
Instruments may be disconnected from a laboratory for the following reasons:

- An instrument may be needed by another laboratory, which requires the Omni to be disconnected from one laboratory and then added to another laboratory. For more information, see Changing the Lab To Which the Mobile Device Is Assigned.
- An instrument may be defective and need to be disconnected for servicing.

1. Tap the more options icon.

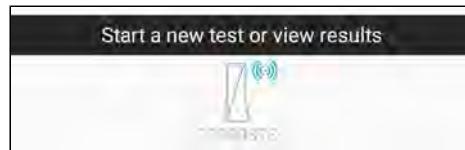


2. Tap **Instrument Management**.



3. Tap the instrument to disconnect.
4. Scroll down and tap **Disconnect Omni**.
5. Tap **YES** in the dialog box to disconnect the instrument.
6. Return to the more options screen by tapping the back arrow at the top of the screen and then tap the home screen icon.
7. Verify the instrument is disconnected by viewing the instrument icons at the bottom of the home page.

The following example shows the recently connected instrument 878 now disconnected.



7.3 Changing the Lab To Which the Mobile Device Is Assigned

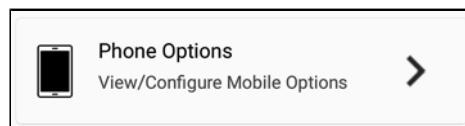
This topic explains how the Institution Admin can change the laboratory to which a mobile device is assigned. The laboratory assignment is made during initial setup as described in the *GeneXpert Omni Reference Guide*. However, you may later decide to use the mobile device in a different lab.

In this procedure, you first disconnect all instruments and delete the current lab assignment. Then, you return to the setup workflow to assign a different lab to the mobile device.

1. Disconnect all instruments from the mobile device whether they are currently connected or were recently connected.
2. Tap the more options icon.



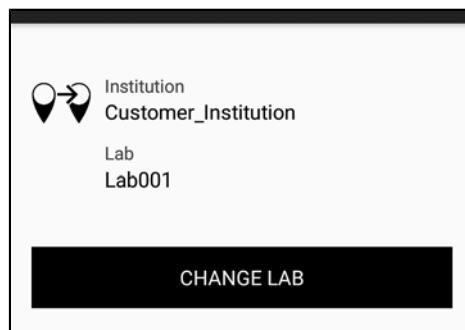
3. Tap **Phone Options**.



4. Tap **Lab Location**.



5. Tap **CHANGE LAB**.



6. Tap **OK** in the dialog box to confirm you want to remove the lab assignment.
7. To assign a different laboratory to the mobile device, follow the instructions in the **Welcome** screen as described in the *GeneXpert Omni Reference Guide*.



7.4 Changing a Password for Another Lab User

This topic explains how the Institution Admin can change a password for another user.

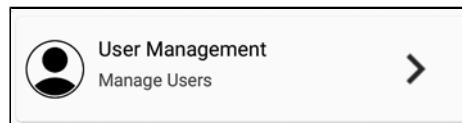
Note

All users can change their own passwords. This procedure is for an Institution Admin to change the password for someone else.

1. Tap the more options icon.



2. Tap **User Management**.



3. Tap the user in the list.

User Management			
@	Inst	Admin	Admin
instadmin@n... jassist@nym...	Jay	Assistant	Basic
labadmin@n... my.institution...	lab	admin	Admin
omniuser.tes... test.user@in...	First Name	Last Name	Admin
test.user@in...	Test	User	Basic

4. Tap **CHANGE PASSWORD**.
5. Type the new password into the **New password** field and then type the same password again in the **Confirm new password** field.

A screenshot of a mobile application interface titled "Change password for my.institution...". It shows three input fields: "New password", "Confirm new password", and "Your password". Each field has a placeholder text and a password strength indicator icon. Below the fields is a large "SAVE" button.

6. Type your Institution Admin password in the **Your password** field.
7. Tap **SAVE**.

The password change will take effect on the next automatic sync with C360 Platform, which occurs every hour. If you want the password change to happen immediately, perform a manual C360 sync. Note that syncing with C360 requires an active Wi-Fi connection.

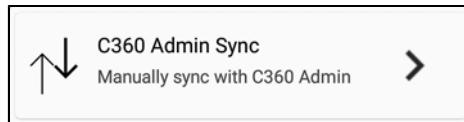
7.5 Manually Syncing Data With C360 Admin

The data in the mobile device is automatically synced with C360 Admin every hour. This topic explains how the Institution Admin can sync the data immediately.

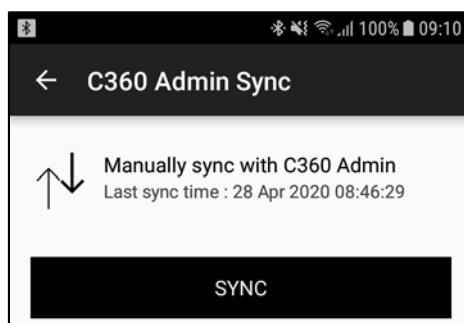
1. Tap the more options icon.



2. Tap **C360 Admin Sync**.



3. Tap **SYNC**.



The syncing process will take some time, depending on the speed of your network connection.

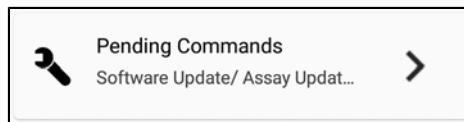
7.6 Installing Software Updates

The GeneXpert Omni System system uses a variety of software components that may occasionally need to be updated. This topics explains how the Institution Admin can download and install these updates.

1. Tap the more options button.



2. Tap **Pending Commands**.



3. If one or more software updates are listed, tap an item and follow the onscreen instructions for installation.

7.7 Configuring a Laboratory Information System

This section explains how the Institution Admin can configure the GeneXpert Omni System to enable test data uploads to a Laboratory Information System (LIS) connected to the institution network.

The hospital's IT department controls the LIS system. When the GeneXpert Omni System is brought into the hospital, the system can be set up as the Client or Server for a Wi-Fi connection.

The LIS Configuration screen displays the current communication settings, which can be changed if needed. On the LIS Configuration screen, the administrator can:

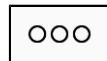
- Enable or disable host communication
- Set up communication settings including:
 - Changing the host ID name
 - Changing protocol between HL7 and ASTM

Important Within the hospital or laboratory network, each GeneXpert Omni System should have a unique system name, which is used for host communication. The LIS host administrator should control the process for defining system names.

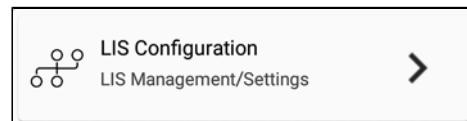
7.7.1 Enabling the Host Configuration Screen

This topic explains how the Institution Admin can make the Host Configuration screen editable. This is a prerequisite for changing the LIS configuration options.

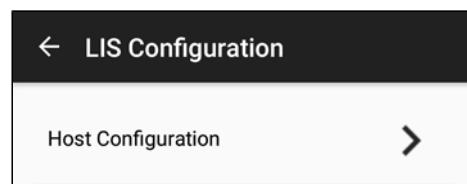
1. Tap the more options icon.



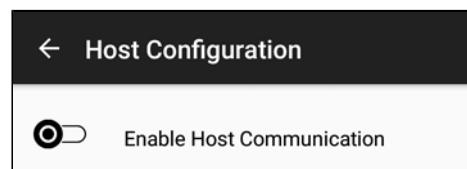
2. Scroll down and tap **LIS Configuration**.



3. Tap **Host Configuration**.



4. To make this screen editable, drag the **Enable Host Communication** slider to the right.



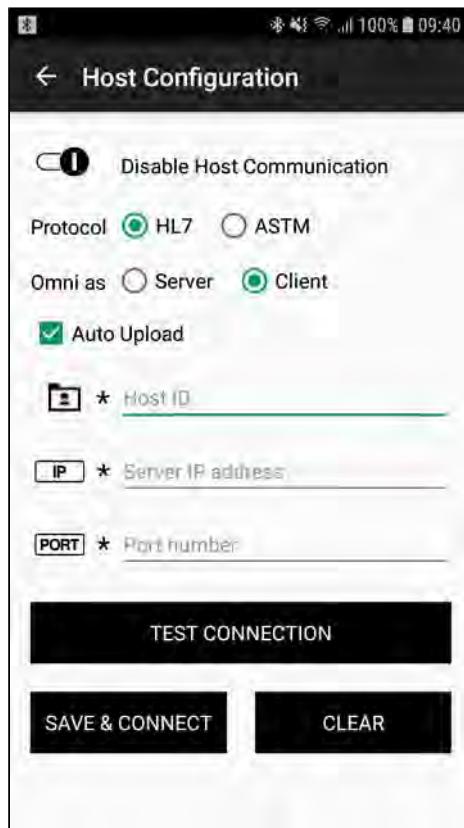
5. In the dialog box, tap **YES**.

7.7.2 Configuring the Omni System as an LIS Client

This topic explains how the Institution Admin can configure the GeneXpert Omni System as a client when setting up an LIS.

For this procedure, you may need to coordinate with your organization's IT department, which should be managing the LIS system. Also, ensure you have first made the settings editable.

When the GeneXpert Omni System is used as a client (using a Wi-Fi connection), the Hospital's LIS (or LIS middleware) will be the server. When a test completes, the GeneXpert Omni System sends a request to the server asking that test results be uploaded. Usually, the system is configured to upload results automatically (Auto Upload), but the results can also be uploaded manually. Edit the Host Configuration screen shown below as described in this procedure.



1. Select or clear the following check boxes:
 - a) **Protocol:** Select **HL7** or **ASTM**.
 - b) **Omni as:** Select **Client**.
 - c) **Auto Upload:** In Client Mode, when this entry is checked, the results are uploaded as soon as the test is completed.
If Auto Upload is not selected, test results must be uploaded manually.
2. Complete these required fields:
 - a) **Host ID:** Type in a unique host name to identify an LIS or Data Management System (DMS) that is connected to the GeneXpert Omni System. The maximum number of characters is 20. If invalid characters are entered (*, /, etc.), a pop-up advisory will appear.
 - b) **Server IP address:** Obtain the LIS host IP address and enter it manually in this field. The GeneXpert Omni System can upload test results and the LIS host can request results. The action can originate from either the Omni System or the LIS host. The IP address is usually furnished by the IT department, and the Administrator will have this information.

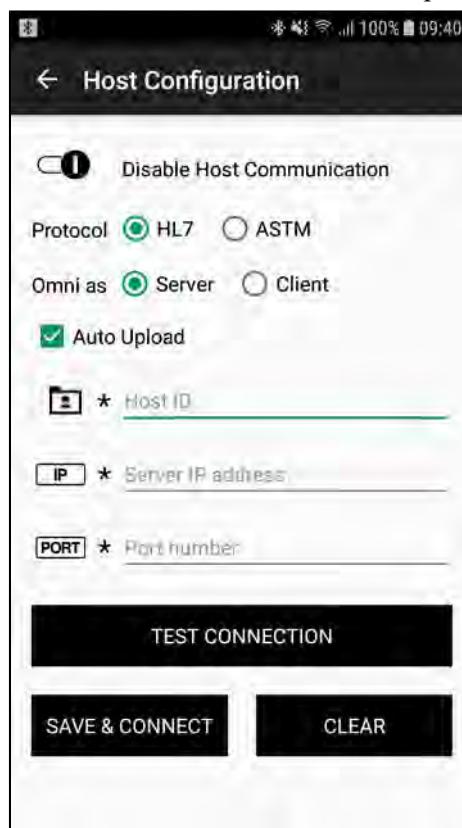
- c) **Port** number: Obtain the Port Number from the IT department and type it in here. The port number should be between 1024 and 48151.
3. Complete the setup:
 - a) Tap **TEST CONNECTION**, which verifies if the information you've entered is correct.
 - b) Tap **SAVE & CONNECT** to save your entries.
If you need help, contact Cepheid Technical support.

7.7.3 Configuring the Omni System as an LIS Server

This topic explains how the Institution Admin can configure the GeneXpert Omni System as a server when setting up an LIS.

For this procedure, you may need to coordinate with your organization's IT department, which should be managing the LIS system. Also, ensure you have first made the settings editable.

When the Omni System is used as a server, as a test finishes the Omni System pushes the test results to the client (Hospital's LIS server). This push is either manual or automatic depending on the Auto Upload check box set in the Host Configuration screen. Edit the Host Configuration screen shown below as described in this procedure.



1. Select or clear the following check boxes:
 - a) Protocol: Select **HL7** or **ASTM**.
 - b) Omni as: Select **Server**

- c) **Auto Upload:** In Server Mode, when this entry is selected the results are uploaded as soon as the test is completed. Usually, Auto Upload is selected, unless there is a specific reason not to.
If Auto Upload is not selected, you must upload individual test results manually.
2. Complete these three required fields:
- Host ID:** Type in a unique host name to identify an LIS or Data Management System (DMS) that is connected to the GeneXpert Omni System. The maximum number of characters is 20. If invalid characters are entered (*, /, etc.) a pop-up advisory will appear.
 - Server IP address:** This is grayed-out in Server Mode. Because the GeneXpert Omni System is the server, the IP address is assigned (populated for you when you enter Wi-Fi mode) to your system, and cannot be changed. This is the IP address from which you will upload test results. Only integers and characters are allowed. The system only accepts valid IPv4 addresses (Format xxx.xxx.xxx.xxx, where xxx is a number from 0 - 255). The Server IP address is automatically assigned by the network.
 - Port number:** The port number should be a number between 1024 and 48151 with default as blank. Entries in this field will always be ASCII numeric. Obtain the Port Number from IT and enter it manually here.

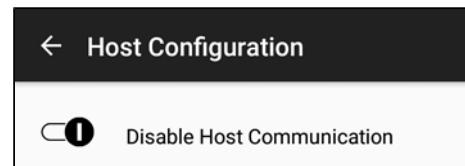
3. Tap **SAVE**.

In Server mode you cannot test the connection. If you need help, contact Cepheid Technical Support.

7.7.4 Disabling Host Communications

This topic explains how the Institution Admin can disable host communications.

In the Host Configuration screen slide the **Disable Host Communication** slider to the left.



7.7.5 Manually Uploading Test Results To an LIS

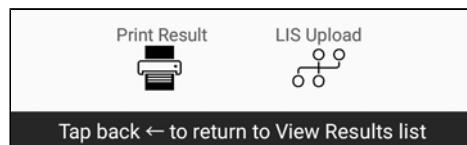
This topic explains how the Institution Admin can manually upload test results to an LIS. Follow these instructions if your GeneXpert Omni System is not configured for auto upload.

1. Select a stored test result.

The screen should look similar to the example below.



2. Scroll down and tap **LIS Upload**.



7.7.6 Configuring the Test Code Settings

This topic explains how the Institution Admin can configure the Test Code settings for the Xpert® Omni SARS-CoV-2 assay used by the LIS system.

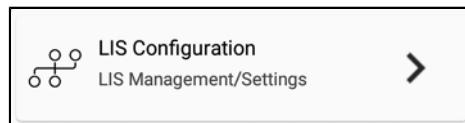
After completing the LIS Configuration, the Test Code settings will be configured for the assays used by the LIS system. The Test Codes are determined and assigned by the LIS Host Administrator.

A test code is a unique entry that identifies each instrument and the Xpert Omni SARS-CoV-2 assay being run on that instrument. When a test is being run, the test can then be identified as originating from a specific location and assay type, as determined by the assay test code.

1. Tap the more options icon.

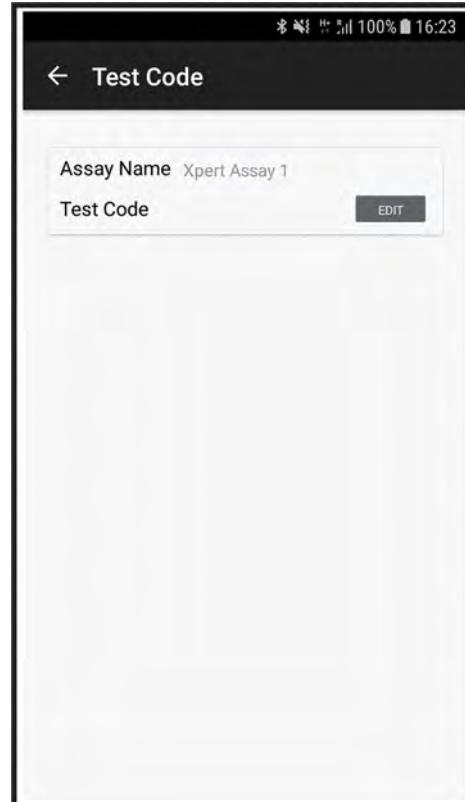


2. Scroll down and tap **LIS Configuration**.



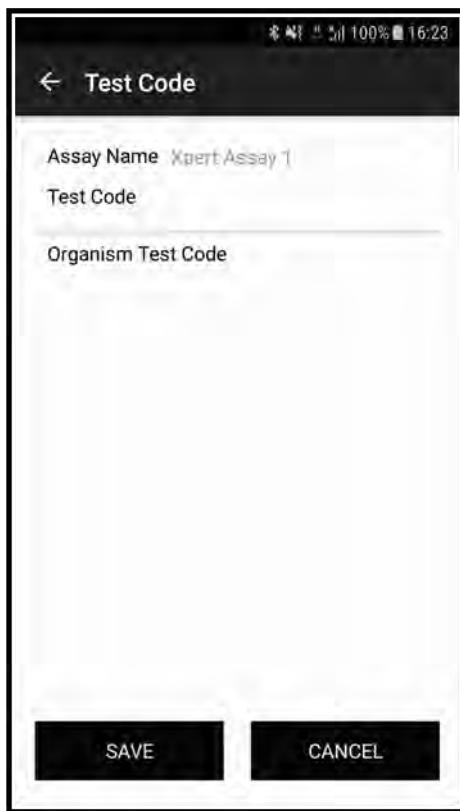
3. Tap **Test Code.**

There is a test code listed for every installed assay.



4. Tap **EDIT to the right of the Test Code you wish to edit.**

This screen allows the LIS Host Administrator to type in the test code that was entered into the host, so it can be translated into the Omni System for test result reporting.



5. Enter the new test code.

Note

You cannot edit the test code for the old version of an assay definition file. If you update the test code, the update will only apply to the new version of the assay definition file. Therefore, you must change the test code before upgrading to a new assay definition file. Be careful to not use the same test code for tests from two different assay definition files.

6. Tap **SAVE** to save the changes and close the screen.

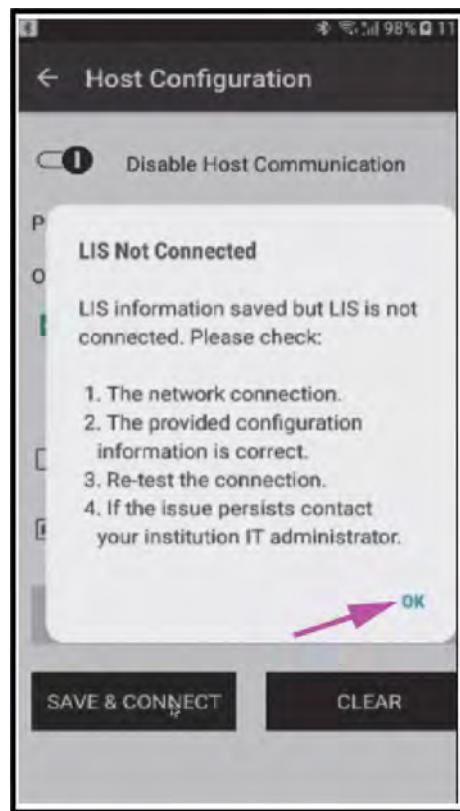
If you need help, contact Cepheid Technical support.

7.7.7 Troubleshooting Host Connectivity

This topic provides general information for the Institution Admin about troubleshooting host connectivity.

If there are problems with host connectivity, such as the error shown in the image below, check your IP address to ensure that the IP address has not changed.

An IP address may change if the mobile device is re-started, so verify the IP address if it is not working. We recommend making a note of the IP address upon start up (or when re-starting) for future reference.



8 Maintenance and Troubleshooting

This section provides instructions for maintaining and troubleshooting the GeneXpert® Omni System.

8.1 About Cleaning and Disinfecting

This topic provides general information about cleaning and disinfecting the GeneXpert Omni System, and summarizes the maintenance tasks to perform at regular intervals.

About Cleaning and Disinfecting

For proper system maintenance it is essential to clean and disinfect the instrument.

Cleaning is the removal of liquids, deposits, dust, and so on. Disinfection is the inactivation of biological materials.

Disinfection is affected by many factors including the concentration of the disinfectant, contact time, temperature, nature of the microbes present, amount of organic residue, surface properties, and so on. With any disinfectant, it is crucial that the entire area to be disinfected is in contact with the disinfecting solution.

Cleaning Maintenance Schedule

Although the GeneXpert Omni System is designed to prevent cross-contamination and ensure accurate results, follow the cleaning maintenance schedule in the table below.

Task	Frequency
Clean and disinfect the instrument surfaces	Weekly
Clean and disinfect the cartridge bay	Weekly
Clean and disinfect the plunger rod	Monthly

8.1.1 Cleaning and Disinfecting the Instrument Surfaces

This topic explains how to clean and disinfect the GeneXpert Omni Instrument surfaces weekly and in the event of a spill. Before cleaning and disinfecting the instrument surfaces, read about cleaning and disinfecting.

In this procedure you will clean and disinfect all outside surfaces of the instrument, including the top, sides, and door.

The materials required for this procedure are:

- A fresh 1:10 dilution of household bleach or commercially pre-diluted bleach solution that contains at least 0.5% sodium hypochlorite.
- 70% ethanol or denatured ethanol (for example 60% ethanol, 5% isopropanol and 5% methanol)

Caution	<p> Do not use isopropyl alcohol for cleaning inside the instrument because it can degrade materials.</p>
	<ul style="list-style-type: none">• Soft, lint-free wipes or paper towels• Disposable gloves• Eye protection• Lab coat
Warning	<p> The instrument must be unplugged and turned off before cleaning the instrument surfaces.</p>
Caution	<p> Biological and Chemical Hazard: Wear disposable gloves, eye protection, and other personal protective equipment mandated by your institution's safety policies while performing this cleaning procedure. Wearing personal protective equipment prevents exposure to hazardous chemical and biological materials.</p>
	<p>To clean the instrument surfaces:</p> <ol style="list-style-type: none">1. Verify there is no cartridge inside the instrument.2. Shut down and unplug the instrument.3. Thoroughly moisten a lint-free wipe or paper towel with the bleach solution.4. Wipe the outside surfaces of the instrument. They should be visibly wetted.5. Wait for a minimum of 2 minutes.6. Repeat steps 3 to 5 two more times for a total bleach exposure time of 6–8 minutes.
Caution	<p> Do not allow the bleach to remain on any surface for more than 8 minutes.</p>
	<ol style="list-style-type: none">7. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol or denatured alcohol.8. Wipe all outside surfaces of the instrument to remove any residues from the bleach solution. Change the lint-free wipes or paper towels frequently while wiping.9. Wipe all surfaces on the mobile device with bleach and alcohol in the same way.
Note	<p>You do not need to shut down the mobile device.</p>
	<ol style="list-style-type: none">10. Move the instrument and wipe the table surfaces underneath and around the instrument with bleach and alcohol in the same way.11. Discard the used lint-free wipes or paper towels according to your standard laboratory procedure.

8.1.2 Performing Weekly and Monthly Maintenance

This topic explains how to clean and disinfect the cartridge bay and plunger rod for routine maintenance of the GeneXpert Omni Instrument and when there is a spill.

The first part of the procedure is the same for both cleaning operations, but you select the weekly option to clean and disinfect the cartridge bay and the monthly option to clean and disinfect the plunger rod. Every month, perform both the monthly procedure and weekly procedure to clean the cartridge bay and plunger rod.

Before you start, read about cleaning and disinfecting. For this procedure, the instrument must remain on and connected to the mobile device.

Materials required:

- A fresh 1:10 dilution of household bleach or commercially pre-diluted solution that contains at least 0.5% sodium hypochlorite.
- 70% ethanol or denatured ethanol (60% ethanol, 5% isopropanol and 5% methanol).

Caution



Do not use isopropyl alcohol for cleaning the cartridge bay and plunger rod. Isopropyl alcohol can degrade components inside the system.

- Soft lint-free wipes or paper towels
- Disposable gloves
- Eye protection
- Lab coat

Biological Risks



Biological and Chemical Hazard: Wear disposable gloves, eye protection and other personal protective equipment mandated by your institution's safety policies while performing this cleaning procedure. Wearing personal protective equipment prevents exposure to potentially hazardous chemical and biological materials.

Important

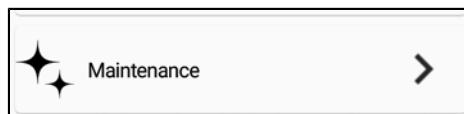
Do not run tests while cleaning the GeneXpert Omni Instrument. Do not shut down the software if a test is running — wait until the test finishes running and the cartridge is removed.

To clean and decontaminate the instrument plunger rod or cartridge bay:

1. From the home screen, tap the icon at the bottom of the screen for the instrument you want to clean.

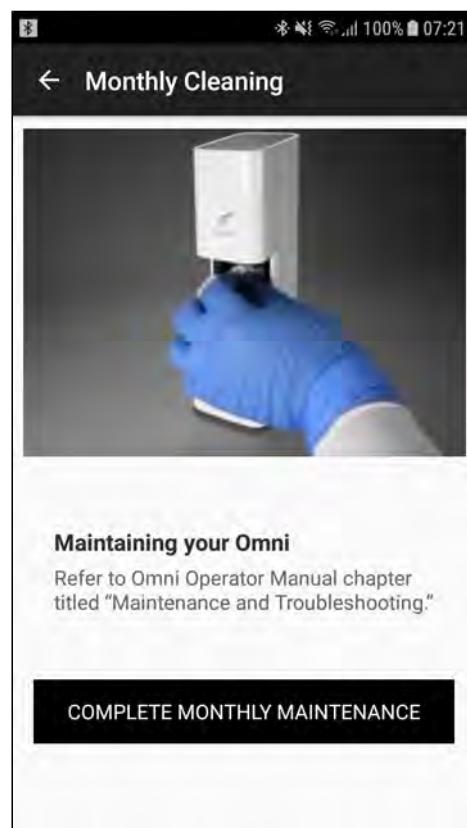


2. Near the bottom of the screen, tap **Maintenance**.



3. To clean and decontaminate the plunger rod, tap **START MONTHLY MAINTENANCE**.

The instrument door opens, the plunger rod inside the cartridge bay moves down, and the mobile device screen plays a video of the procedure.



4. Use the video along with the following image and instructions to clean the plunger rod.



Number	Description
1	Cartridge bay
2	Plunger rod
3	Slit that accommodates the cartridge's reaction tube
4	Cartridge cam
5	Valve drive

- Thoroughly moisten a lint-free wipe with the bleach solution.
- Wipe the plunger rod with the lint-free wipe, using only enough force to remove debris from the plunger rod. Pay special attention to the cut-out area at the tip of the plunger rod because this area will often contain debris that is not easily removed. Discard the used wipe and allow the bleach solution to remain on the plunger rod for a minimum of 2 minutes.

Caution

Avoid getting bleach or alcohol into the slit that accommodates the cartridge's reaction tube because these solutions can damage the optics and electronics.

- Repeat steps a and b two more times for a total bleach exposure time of 6–8 minutes.

Caution

Do not allow the bleach to remain on any surface for more than 8 minutes.

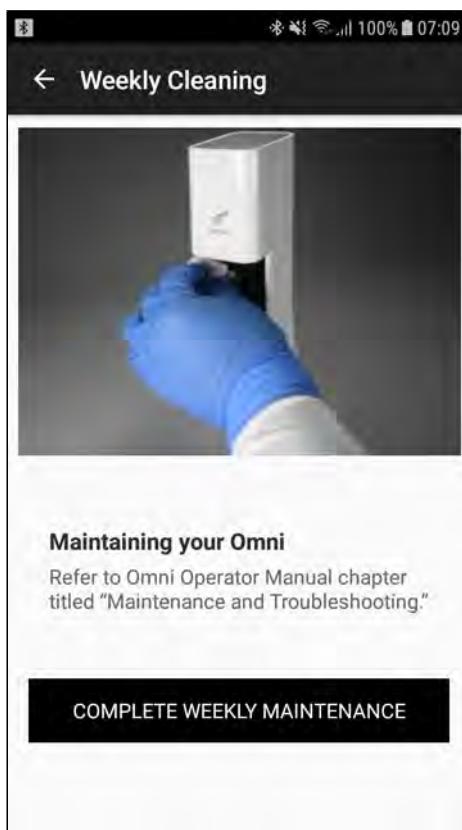
- Thoroughly moisten a lint-free wipe with the 70% ethanol or denatured ethanol.
- Wipe the plunger rod to remove residual bleach, then discard the wipe.

5. Tap COMPLETE MONTHLY MAINTENANCE.

The plunger rod moves back to its resting position and the door closes.

6. To clean and disinfect the cartridge bay, tap **START WEEKLY MAINTENANCE**.

The instrument door opens and the mobile device screen plays a video of the procedure.



7. Use the video along with the following instructions to clean and disinfect the cartridge bay.
 - a) Thoroughly moisten a lint-free wipe with the bleach solution.
 - b) Wipe the cartridge bay walls, ceiling, floor (including the valve drive, and cams) and lip of the door. These areas should be visibly wetted. Discard the used wipe and allow the bleach solution to remain on the cartridge bay surfaces for a minimum of 2 minutes.

Caution



Avoid getting bleach or alcohol into the slit that accommodates the cartridge's reaction tube because these solutions can damage the optics and electronics.

- c) Repeat steps a and b two more times for a total bleach exposure time of 6–8 minutes.

Caution



Do not allow the bleach to remain on any surface for more than 8 minutes.

- d) Thoroughly moisten a lint-free wipe with the 70% ethanol or denatured ethanol.
- e) Wipe all of the same areas to remove residual bleach and discard the lint-free wipe.

8. Tap **COMPLETE WEEKLY MAINTENANCE**.

The door closes.

9. Tap the back arrow at the top of the screen twice to return to the home screen.

8.2 Handling An Instrument That Has Tipped Over

This topic explains how to handle the situation where a GeneXpert Omni Instrument has tipped over, including how to clean up spills.

To Do First

First carefully turn the instrument back upright and remove any cartridge.

Handling Exterior Spills

If there is spilled liquid on the outside of the instrument, follow the protocol for cleaning and disinfecting the instrument surfaces.

Handling Internal Spills

Important **Do not remove the instrument covers or open the cartridge door.**

If you think liquid has leaked inside the instrument, including inside the cartridge bay:

1. Shut down the instrument.
2. Follow the protocol for cleaning and disinfecting the instrument surfaces.
3. Place the instrument inside a plastic bag and then place that bag inside a second plastic bag.
4. Place the instrument upright on a flat surface away from the work area.
5. Contact Cepheid Technical Support.

8.3 Error Messages and Troubleshooting

This topic gives general guidance for handling equipment malfunctions and error messages appearing on the mobile device screen.

Review the Error Message

If the mobile device or instrument malfunctions, review any error message for an explanation and guidance (see below).

If there is no error message or if you are unable to recover after following the instructions in the message, contact Cepheid Technical Support.

All error messages are uploaded to C360 Admin where they can be reviewed by the Institution Admin.

Types of Error Messages

Error messages may appear on the mobile device during normal system operation. You may see error messages for the following types of errors.

Run-time Errors:

Run-time errors may appear during a test that is not aborted. Although the system was able to finish the test and save the results, some non-critical errors occurred and require attention.

Run-time errors can be caused by an environmental temperature that is too warm, the failure of an instrument fan, a heater component or hardware component failure or an instrument door that is not properly closed. In addition, various assay-specific causes (such as maximum pressure reached in the assay) can lead the program to move to the next step.

Operation Terminated Errors:

Operation terminated errors may appear during a test that is aborted.

Cartridge Loading Errors:

Cartridge loading errors may appear during the cartridge loading process. Because the software performs self-test procedures during the loading process, some of the error messages that appear during the loading process are identical to the self-test error messages.

Self-Test Errors:

Self-test errors may appear during the self-test process.

Communication Loss/Recovery Errors:

Communication loss/recovery errors may appear while the module is idle, before the instrument door is closed or when starting the test (test is aborted).

Viewing Error Details

Use the following steps to view more information about an error:

1. Tap the more options icon.



2. Tap **Instrument Management**.
3. Tap the instrument displaying the error to view.
4. Tap **View Errors**.
5. Tap the error to view.

The screen displays possible causes and solutions.

In the following example, the error code listed in the screen (1005), can help Cepheid Technical Support troubleshoot the problem.



8.4 Performing a Manual Self-Test

This topic explains how to manually perform a GeneXpert Omni Instrument self-test for troubleshooting purposes.

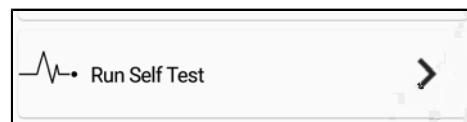
The GeneXpert Omni System automatically performs a self-test during startup. You can also manually perform a self-test on any connected instrument to reset and check for hardware failure problems.

1. Remove any Xpert® cartridge from the instrument to be checked.
2. Tap the icon at the bottom of the screen for the connected instrument to test.

In the following image, there is only one connected instrument.

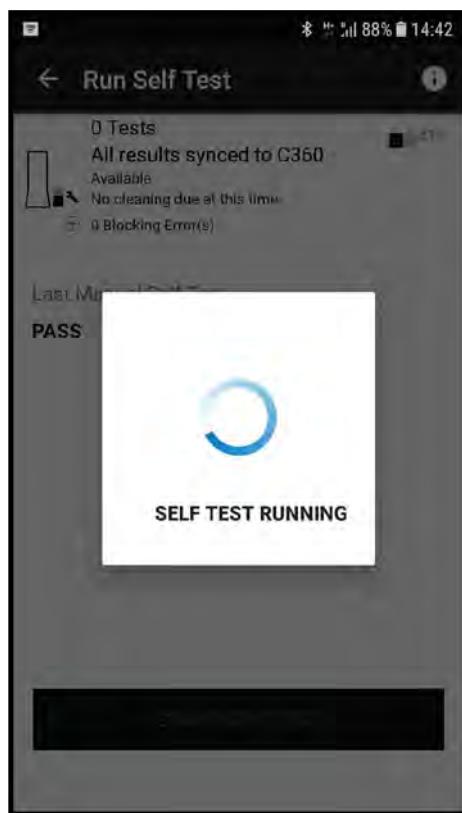


3. Tap **Run Self Test**.



4. Tap **START SELF TEST**.

The self-test begins.



- When the self-test finishes, tap **OK**.

The self-test result appears on the screen.



A pass notification indicates the self-test passed. If the message indicates the self-test failed, contact Cepheid Technical Support.

6. Click **OK** to close the dialog box.

8.5 Troubleshooting Sample Barcode Scanning

This topic provides solutions to sample barcode scanning problems.

The mobile device includes high-quality barcode scanning software. If you are unable to read the barcode label on a sample within 30 seconds, try the following solutions in the order given. If you are still having problems after trying these solutions, contact Cepheid Technical Support.

Ensure the Camera Lens is Clean

Wipe the camera lens with a soft cloth to remove any dirt or liquids and repeat the barcode scan.

Ensure the Barcode Image Is in Focus and Free From Glare

While scanning, ensure you hold the mobile device the correct distance away from the sample for the barcode to be in focus. The typical scanning distance is roughly 15 cm (6 inches), although smaller labels may need to be held closer to the camera. Ensure the entire barcode is within the camera view. Also, ensure there is good, even light falling on the barcode and there is no reflected glare from the sun or other strong point of light.

Ensure the Barcode is Clean and Well Printed

Dirty labels, and barcodes that are smudged or improperly printed, may not be successfully read by the scanner.

If the problem could be caused by surface dirt, try wiping the label and rescanning. As different label stock is made from different materials with different surface coatings, and printing inks also differ, you may need to experiment to find the best way to wipe the label clean without smudging the barcode ink.

If the problem could be caused by poor printing quality or smudged ink, review the following examples.

The following example barcode has minor print defects, but it could still be read and yielded an ISO/ANSI grade D decodability rating using a barcode verifier. Provided the lines have sufficient width and spacing, barcodes with minor print defects can still be read. However, we recommend testing with a barcode verifier to ensure printed barcodes receive an ISO/ANSI decodability grade of C or better.



The following example barcode has smudges that could cause unreliable decoding.



Barcodes with minor smudging can still be read. However, with more severe smudging like this, the scanner may be able to focus on the barcode but still be unable to decode it. This barcode label yielded an ISO/ANSI decodability grade F (fail) using a barcode verifier.

When a barcode cannot be decoded by a reader, the software stalls without indicating that the barcode cannot be read.

Ensure the Barcode Symbology Is Supported

Different symbologies can be used to convert text into a barcode. Contact the group in your organization responsible for generating barcodes and ensure they used one of the symbologies in the following table with the suggested line width. Note that 1 mil equals 0.001 inches.

Symbology	Supported Barcode Narrow Bar Width
ITF (Interleaved 2 of 5) (with check characters - see note below)	≥ 0.178 mm (7 mils)
Code 128, 128A, 128B, 128C	≥ 0.127 mm (5 mils)
Code 93	≥ 0.127 mm (5 mils)
Code 39 (with check characters - see note below)	≥ 0.127 mm (5 mils)
QR	≥ 0.254 mm (10 mils) (X Dimension)
DataMatrix	≥ 0.254 mm (10 mils) (X Dimension)

Caution



Using barcodes that do not meet the standards described above may return incorrect barcode values. The barcode ANSI/ISO grade should be C or better.

Code 39 and ITF barcodes must be printed with check characters to prevent barcode read failure. If the option is available, barcodes should be printed with a bearer bar as shown in the example below.

Important

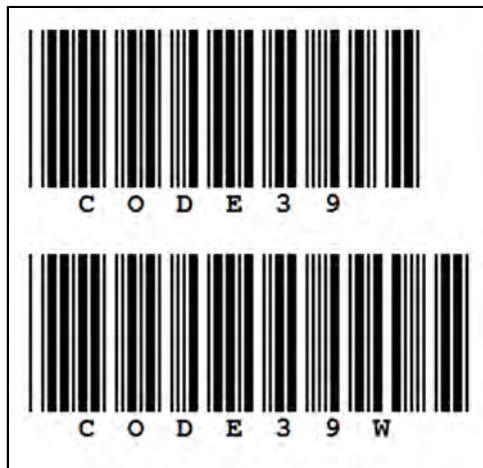


We have successfully tested barcodes with the symbologies and line widths given in the table. However, as printers vary in how they print barcodes, you may need to try printing labels with a line width thicker than suggested. The following image shows line widths that are 4 mils, 5 mils and 7 mils.



Review Check Character Use

If Code 39 symbology bar codes are generated with check characters, we recommend including the check characters in the human-readable portion of the barcode. This is because the software will return the check characters if present in the barcode symbols. The following image shows barcodes with and without check characters. In this case 'W' is the check character set by the barcode generator.



A label without a check character will not be decoded by the mobile device software. If this appears to be the cause of the barcode read problem, discuss it with the person who generates the barcode labels. If scanning labels without check characters is necessary, contact Cepheid Technical Support.

Test Labels With a Barcode Verifier

To further troubleshoot problems with barcode scanning, you can use a barcode verifier.

Barcode verifiers test how easy it will be for a scanner to read the barcodes printed by your printer on your label stock. Verifiers assess edge contrast, the widths of bars and spaces, the presence of white patches on the dark bars and black patches in the spaces, reflectance, and so on.

After a barcode is scanned by a barcode verifier, the verifier software gives the barcode a grade. Two common grading systems are the ANSI and ISO/IEC grading systems. The possible grades are A, B, C, D and F. Grade A denotes the highest quality, grade D denotes the lowest readable quality, and grade F means the barcode could not be read.

In addition to providing a grade, a barcode verifier may give a description of any problems detected.

8.6 Troubleshooting Wireless Connections

This topic describes problems that can occur with wireless connections and explains how to handle them.

Slow Data Transfer

As microwave ovens and some fluorescent lighting use the same 2.4 GHz spectrum as Wi-Fi and Bluetooth, it is possible for a nearby microwave oven or lighting to cause data transfer to slow down. If you encounter a problem trying to connect the mobile device to Wi-Fi or a GeneXpert Omni Instrument, you can try to connect again. If still not successful, contact Cepheid Technical Support.

Mobile Device Loses Connection With the Instrument During a Test

Even though the mobile device has lost connection with the instrument, the test is still in progress and will be completed. The test result is retained by the instrument and will be displayed on the mobile device once the connection has been re-established. If the mobile device does not automatically reconnect with the instrument after the test refer to the instructions for connecting the mobile device in the *GeneXpert Omni Reference Guide*.

Mobile Device Loses Connection with C360

If the mobile device loses its connection with the Wi-Fi connection, follow the instructions in the *GeneXpert Omni Reference Guide* to enable Wi-Fi. If that does not work, contact Cepheid Technical Support.

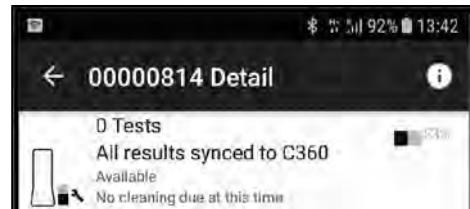
8.7 Troubleshooting Instrument Power Problems

This topic describes power-related problems that can occur with the GeneXpert Omni Instrument and suggests ways to resolve them.

Internal Battery Is Not Charging

For the instrument's internal battery to be charged by the mains power, the instrument's internal temperature must be below 45°C. If the temperature measured near the instrument is around 40°C or more and the mobile device indicates that the internal battery is not charging, look for a warning in the GeneXpert Omni Mobile Application (code 1704). If you see the warning, try to charge the battery again in a cooler environment.

You can see the internal battery charge level on the instrument detail screen, as shown in this example.

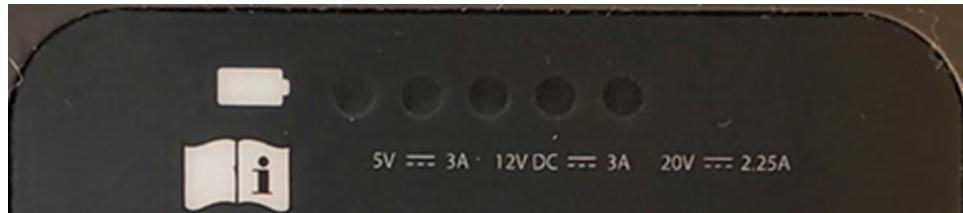


The Instrument Does Not Turn On

If the instrument does not turn on, the internal battery may be fully discharged.

To check the charge level of the internal battery:

1. Ensure there is no cartridge in the instrument.
2. Turn the instrument upside down and press the red power button on the back of the instrument.
3. Look for blue LED lights next to the battery icon on the instrument label. In the following image, the lights are not lit.



9 Performance Characteristics and Specifications

This section provides the performance characteristics and specifications for the GeneXpert® Omni System.

9.1 System Classification

This topic lists the general characteristics of the GeneXpert Omni System.

The GeneXpert Omni System is:

- Designed for stationary operation
- Intended for use worldwide
- Intended for evaluating preprocessed biological material

9.2 Physical Specifications

This topic provides the physical characteristics and clearance requirements of the GeneXpert Omni System.

GeneXpert Omni Instrument Dimensions and Weight

- Height: 9.3 in. (23.6 cm)
- Width: 3.0 in. (7.7 cm)
- Depth: 4.2 in. (10.7 cm)
- Weight: 2.40 lbs (1.09 kg)

GeneXpert Omni Instrument Clearance Requirements

Provide the following clearances on each side of the instrument for user access and ventilation.

- Back: 12.0 in. (30 cm)
- Left Side: 6.0 in. (15 cm)
- Right Side: 6.0 in. (15 cm)
- Front: 12.0 in. (30 cm)

Do not block the fan exhaust and intake on the back side of the instrument. The lack of proper ventilation can cause the instrument to malfunction.

Mobile Device Dimensions and Weight

For the dimensions and weight of the Cepheid validated mobile device, follow the instructions in the provided quick setup guide to obtain the user manual for the device.

9.3 Electrical Specifications

This topic provides the electrical specifications for the GeneXpert Omni System.

Omni Instrument

Item	Specification
Line Voltage	100 – 240Vac
Frequency	50 – 60 Hz ±0.5%
Power Consumption at maximum current	45 W
Power Supply Fluctuation	Up to ± 10% of the nominal voltage
Transient Over-Voltage	Up to 2500V peak (impulse withstand category II)
AC Adapter Output	3.0 A @ 5VDC (when charging mobile device) 2.25 A @ 20VDC (when charging instrument) 3.0 A @ 9VDC 3.0 A @ 15VDC
USB-C port	20 VDC (power adapter input) 15 VDC 5 VDC (when charging the phone)

Mobile Device

For the electrical specifications of the mobile device, follow the instructions in the provided quick setup guide to obtain the user manual.

9.4 Wireless Technologies Used By the Instrument

This topic provides specifications related to the wireless technologies used by the GeneXpert Omni Instrument.

Introduction

The GeneXpert Omni Instrument uses the following wireless technologies:

Technology	Used to communicate with...
Bluetooth	The mobile device
Wi-Fi	C360 Admin via a network set up in your building
Near Field Communications (NFC)	The NFC tag on each cartridge

Important As microwave ovens and some fluorescent lighting use the same 2.4 GHz spectrum as Wi-Fi and Bluetooth, it is possible for a nearby microwave oven or lighting to cause data transfer to slow down. If you encounter a problem trying to connect the mobile device to Wi-Fi or an instrument, you can try to connect again. If still not successful, contact Cepheid Technical Support.

FCC Part 15 compliance information is included in the Legal information section.

Bluetooth Technology

- Bluetooth version: 4.1
- RF frequency: 2.4 Ghz
- Maximum output power: 11.7 dBm
- Maximum range: 30m (100 feet) radius

The Bluetooth communication with the instrument is not encrypted.

Wi-Fi Technology

- Applicable standards: IEEE 802.11a, 802.11b, 802.11.g, and 802.11.n.
- RF frequency: 2.4 GHz
- Maximum output power: 17.3 dBm

The instrument has Wi-Fi capability, but Wi-Fi is not enabled and not accessible to the user.

NFC Technology

The assay cartridge has an NFC tag that stores information about the assay. The GeneXpert Omni Instrument reads the cartridge NFC tag at the start of a test run and verifies certain information. This is for quality control to ensure the correct cartridge is loaded for the test. Once the test starts, the instrument also writes a small piece of data to the cartridge NFC tag to indicate that the cartridge has been used. This prevents the cartridge from being used twice.

- Applicable standards: ISO/IEC 18092 / ECMA-340
- RF frequency: 13.56 MHz
- Maximum range: 4 cm (1.5 inches)

FCC RF Radiation Exposure Statement

The Wi-Fi and Bluetooth chipset are certified by the FCC as a single-modular transmitter. The mobile device complies with Part 15 of the FCC rules.

Caution



The Wi-Fi and Bluetooth chipset included with the mobile device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure limits. This transmitter must not be colocated or operating with any other antenna or transmitter.

Other Wireless Products

Note

Any Bluetooth-capable phone can pair with the Omni Instrument, but only the Cepheid validated mobile device with the GeneXpert Omni Mobile Application configured by Cepheid is able to control the instrument.

9.5 Wireless Technologies Used By the Mobile Device

This topic provides specifications related to the wireless technologies used by the mobile device.

Introduction

The Cepheid validated mobile device uses the following wireless technologies:

Technology	Used to communicate with...
Bluetooth	The instrument
WiFi	C360 Admin via a network set up in your building
Near Field Communications (NFC)	The NFC tag on each cartridge

Each technology is covered in more detail in the following sections.

Bluetooth Technology

- Bluetooth version: 4.1
- RF frequency: 2.4 GHz
- Maximum output power: 17.3 dBm
- Maximum range: 30m (100 feet) radius

See Section 6 if you are having a problem with the Bluetooth connection.

The Bluetooth communication with the instrument is not encrypted.

Wi-Fi Technology

- Applicable standards: 802.11b, 802.11g, Wi-Fi 4 (802.11n)
- RF frequency: 2.4 GHz
- Maximum output power: 16.5 dBm

Wi-Fi is not used to connect with the instrument it is only used to connect with C360.

See Section 6 if you are having a problem with the Wi-Fi connection.

NFC Technology

The Xpert® Omni SARS-CoV-2 assay cartridge has an NFC tag that stores information about the assay. During the workflow for running a test, you use the mobile device to read the information stored on the tag. The Omni Mobile Application then automatically enters the assay information into the screen.

- Applicable standards: ISO/IEC 18092 / ECMA-340
- RF frequency: 13.56 MHz
- Maximum range: 4 cm (1.5 inches)

FCC RF Radiation Exposure Statement

The Wi-Fi and Bluetooth chipset are certified for the FCC as a single-modular transmitter. The mobile device complies with Part 15 of the FCC rules.

Other Wireless Products

Other Bluetooth devices can pair with the mobile device. Examples are Bluetooth printers and headphones. However, these devices are unable to control the GeneXpert Omni Mobile Application configured by Cepheid, which controls the instrument.

9.6 Operational Environmental Parameters

This topic lists the operational requirements of the GeneXpert Omni System. Your environment must meet these requirements:

General environment	Indoor use only
Pollution degree	2
Operating temperature	15 – 30 °C (59 – 86 °F)
Ambient humidity	20% – 80%, non-condensing
Altitude	1 – 2000m (1 – 6560 feet)

Consult your facilities department regarding ventilation requirements for the level of heat output in your laboratory.

Place the Omni instrument away from heat and air conditioning ducts and do not place the instrument directly under an air vent or in direct sunlight. Do not place the instrument in direct sunlight. Always keep the instrument door closed when not in use.

9.7 Environmental Conditions for Storage and Transport

This topic lists the environmental storage conditions for the GeneXpert Omni System.

The conditions are:

Temperature	0 – 45 °C (32 – 113 °F)
Ambient Humidity	16 – 90%, non-condensing
Altitude	1 – 2000m (1 – 6560 feet)

Caution

Instrument damage may occur in temperatures below 0 °C (32 °F).



9.8 Sound Pressure

This topic describes the sound pressure requirements of the GeneXpert Omni System.

The sound pressure specifications are as follows:

Audible Sound Pressure Range	< 85 dB (reference level 20 µPa)
-------------------------------------	----------------------------------

Ultrasonic Sound Pressure Between 20kHz to 100kHz	< 110 dB SPL (reference level 20 µPa) with a maximum in the 40 kHz one-third octave bands
Maximum Sound Pressure	Contained in the 40 kHz one-third octave bands

9.9 Product Energy Consumption Information

This topic provides general product energy consumption information for the GeneXpert Omni System.

Omni Instrument

The energy consumption is as follows:

Supplier Name	Cepheid
Supplier Model Identifier	GeneXpert Omni
Energy Efficiency Class	G
On Mode Power Consumption (BTU/Hr)	29
Standby Power Consumption (W)	4.5
Annual Energy Consumption (kWh)	29

Omni Mobile Device

The energy consumption for the mobile device is as follows:

Supplier Name	Samsung
Supplier Model Identifier	A20
Energy Efficiency Class	G
On Mode Power Consumption (W)	1.0
Standby Power Consumption (W)	0.1
Annual Energy Consumption (kWh)	1.7

9.10 Regulatory Directives

The GeneXpert Omni System has been designed and tested to conform to the laboratory equipment requirements of applicable regulatory agencies.

9.11 Data Security

This topic explains how the GeneXpert Omni System protects patient privacy.

Privacy and security have been incorporated into the Omni System design, which adheres to regulatory standards relating to:

- Access control
- Transfer, handling and storage of electronic Protected Health information (ePHI) and sensitive data
- The use of secure coding practices and routine assessments of our products for known security vulnerabilities

Data stored in the GeneXpert Omni System may contain PHI (Protected Health Information) and PII (Personally Identifiable Information), such as patient names and test results. Safeguards have been implemented to protect privacy and integrity of data that includes PHI and PII. Safeguards include:

- Encryption at rest and in-transit
- Multi-factor authentication
- Role Based Access
- Strong password policy enforcement

Consult your facilities security officer to ensure internal compliance with all applicable laws and regulations.

10 Quality Controls

This section provides information about calibration and quality controls.

10.1 About Instrument Calibration

This topic describes how the instrument is calibrated.

The GeneXpert® Omni Instrument does not require calibration during the initial system setup because Cepheid performs the necessary calibrations before shipping.

The system uses internal assay controls to measure instrument performance. In the event of an instrument failure, the replacement instrument provided will have been calibrated before shipping.

10.2 Internal Quality Controls

This topic describes the types of quality control testing performed.

The GeneXpert® Omni System automatically performs internal quality control for each sample. During each test, the system uses one or more of the following controls that must be positive to report a negative test result:

Sample-Processing Control (SPC)

Helps ensure that a sample was correctly processed. The sample-processing control, which is included in the cartridge, is processed with the sample and detected by PCR.

Internal Control (IC)

Helps verify the performance of the PCR reagents and the absence of significant inhibition that would prevent PCR amplification.

Endogenous Control (EC)

Normalizes targets and/or helps ensure sufficient sample is used in the test. The endogenous control is from the test sample.

In addition to the controls, the system performs a probe check during the first stage of the test. A probe check verifies the presence and the integrity of the labeled probes. A probe-check status of **Pass** indicates that the probe check results meet the acceptance criteria.

Lastly, the system performs a series of internal diagnostic self-tests to confirm the functional integrity of all subsystems.

10.3 External Quality Controls

External quality controls may be used in accordance with local, state, or federal accrediting organizations, as applicable.

11 Safety Reference

This section provides safety information.

11.1 General Safety Information

This topic provides general information about electrical, chemical and biological safety hazards.

Safety Symbols

The section describing the instrument label includes descriptions of the safety symbols used on the instrument.

Electrical Safety

The GeneXpert® Omni Instrument operates on low voltage DC current supplied by the internal battery and there are no hazardous voltages inside.

An AC adapter is provided to charge the internal battery.

Warning



To prevent possible electrical overheating or fires when using multiple power strips, do not daisy-chain the power strips.

Caution



Do not connect instruments together with USB-C cables.

Biological Risks



Biological Safety

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

Chemical Safety

Warning



This product can expose you to chemicals, including Nickel (Metallic) which is known to the State of California to cause cancer. For more information, go to www.p65warnings.ca.gov.

Safety Data Sheets (SDSs) for all reagents used with this system are available upon request from Cepheid Technical Support and are available on Cepheid's websites (www.cepheid.com and www.cepheidinternational.com).

Refer to the Cepheid website for additional environmental health and safety information on Cepheid products.

11.2 Instrument Battery Safety

This topic describes important safety information about charging and maintaining the instrument's internal battery.

Safety Procedures

The GeneXpert® Omni Instrument uses a lithium ion battery for power. Follow standard laboratory safety procedures for working with lithium ion batteries.

Temperature Range for Battery Charging

The instrument prevents the battery from being charged when the internal temperature lies outside the 0–45 °C range. This is because charging outside this range might:

- Cause the battery to become hot
- Harm the performance of the battery
- Reduce the battery's life expectancy

Precautions

The battery is a hermetically sealed metallic case containing chemicals and construction materials that could be hazardous if released. These chemical and materials are not hazardous when used according to the recommendations of the manufacturer.

Under normal conditions of use where the battery integrity is maintained and the seals remain intact, the electrode materials and liquid electrolyte are not exposed to the outside. Risk of exposure occurs only in cases of abuse (mechanical, thermal, or electrical) that lead to the rupture of the battery container. Rupture may lead to electrolyte leakage, the reaction of electrode materials with moisture/water, or battery vent/explosion/fire, depending upon the circumstances.

Caution

Do not short-circuit, puncture, incinerate, crush, immerse, force-discharge or expose the battery to temperatures above the declared operating temperature range of the instrument.

Accidental Electrolyte Release Measures

If accidental release of electrolyte occurs, remove personnel from the area until fumes dissipate. Use water to thoroughly wash skin that has come into contact with the electrolyte. Use sand or earth to absorb any exuded material. Seal the leaking battery and contaminated absorbent material in a plastic bag and dispose of it as Special Waste in accordance with local regulations and standard laboratory safety procedures.

11.3 Environmental Information

This topic provides information about recycling the GeneXpert Omni System and its packaging materials.

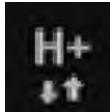
- Recyclability of GeneXpert Omni System: the WEEE mark is affixed to Cepheid electronic products.
- Please retain all packaging materials. The materials may be useful for repackaging any items for re-shipment to Cepheid.

- Additional information on the above, including EU and country directives concerning packaging, energy consumption, RoHS, REACH, Prop. 65, etc. can be found on the Cepheid website.

A Appendix - Icon Definitions

This topic explains the icons used in the GeneXpert Omni Mobile Application on the mobile device.

Icon	Icon Name	Description
	Admin Login	Cepheid Admin use only. Please do not tap.
	Apps Not Available	This icon is shown on the Settings menu, and provides configuration details about applications on the mobile device which are not available to the user.
	Assay or Self-Test Completed, with Result	This icon, which appears on the test completion screen, shows a test that has been successfully run and completed. The test name (assay name or test type) and result usually appears to the right of this icon.
	Back	This back-arrow icon is used throughout the Omni application as a navigation tool at the top of the screen. Tapping on this icon takes the user to the page last viewed.
	Back	This Back-arrow icon is used throughout the Omni application as a navigation tool at the bottom of the screen. Tapping on this icon takes the user to the previous page.
	Battery Charging, shown 60%	There are several icons estimating the instrument battery level while charging. This one shows the battery at 60%
	Battery Level, Full	This icon shows the instrument battery at full power.
	Battery Level Low	There are several icons estimating the instrument battery charge. The icon turns red (as shown) when the charge is critically low (20%)
	Mobile Device Charge Remaining	Located at the top of the mobile device screen, this number indicates the remaining battery charge available on the mobile device.

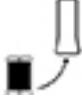
	Bluetooth	This icon is shown on the Settings menu, and provides Bluetooth configuration details.
	Cancel Entry	This icon is used in several places in the application. Tapping the icon can cancel a setup routine or cancel another entry just selected.
	Cancel Test	This icon is used to cancel a test that has been selected, but not yet started.
	Cartridge Entry Completed	When initiating a new test, a Test Progress bar appears near the top of the mobile device screen. This icon, with a checkmark, indicates that the cartridge entry portion of the test creation has been completed.
	Cartridge Bay Open	This icon has multiple functions. It can indicate that a test has been ordered, and the cartridge bay is open and waiting for the cartridge to be loaded, or that the test is complete and the cartridge has been ejected, but not yet removed for disposal.
	Cellular Connection - Active	Located at the top of most mobile device screens, shows that the cellular network connection is active.
	Cellular Signal Strength	This icon represents the strength of the cellular signal. Upright bars usually indicate signal strength, with more bars displayed equaling a stronger signal.
	Change Lab Site	This icon is located on the Site Network Configuration screen in the <i>Omni Quick Reference Guide</i> . Tap this icon to change the site.
	Cleaning/Maintenance	This icon, can be tapped to initiate a cleaning process on the selected Omni.
	Close the Door of the Selected Omni	This icon, shown on the Omni Details screen near the bottom of the screen, can be tapped to close the cartridge loading door of the selected Omni.
	Date	This icon, on the Search Test Results screen, is shown on the Select date range line. Tap this entry to select a date range from the screen that appears.

	Device Details	This icon is shown on the Settings menu, and displays information about the mobile device configuration.
	Disconnect the Selected Omni	This icon is located on the View Omni status screen, and is placed at the far right of the menu bar near the bottom of the screen. Tap this icon to disconnect the selected Omni instrument from the mobile device.
	Down Arrow	This icon is located on the launcher screen, near the top of the screen. Tap this icon to gain access to the Settings and Admin icons
	Download Test Results from Omni	This icon is active when there is no Wi-Fi or cellular connection available. First, tap this icon to download test results from an Omni instrument to the mobile device. Later, you can travel to an area where network connectivity is available, and upload the test results from the mobile device to C360, without the need to bring an Omni along for the upload.
	Email Address	This icon is found in multiple places to indicate email address entry.
	Enter Address or Lab Location	The icon appears on various screens to indicate the entry area for an address or location of a lab.
	Error Resolution Suggestions	This icon appears on a detailed view of an error screen. Possible suggestions for clearing the error will appear at the right of the icon.
	Expiration Date	This icon, shows the expiration date of the scanned sample.
	Forward	This forward-arrow icon is used throughout the Omni application as a navigation tool. Tapping this icon takes the user to the next page to be viewed, or completes an entry on the page being viewed.
	Generate Sample	When choosing sample entry options during the creation of a new test, tapping this icon generates a random sample ID number (used if the sample barcode is unavailable or unreadable).

A Appendix - Icon Definitions

	Guest User-Add	This icon identifies the Add Guest User configuration screen, and is shown in the heading at the top of the screen.
	Help	This icon is shown on the Settings menu, and displays help information about the mobile device.
	Home	Located at the top (or bottom) of most mobile device screens, tapping this icon will take the user to the Home screen.
	Host ID	This icon indicates a user entry identifier to define which mobile device information is being received from.
	Identify Omni	This icon is located on the View Omni status screen, on the menu bar at the far left. Tapping this icon at the bottom of the screen, causes the selected Omni to self-identify, by slowly blinking a white light on the front of the Omni.
	Information - About	This icon appears in several places. The icon can display information available for the user. Tap the icon to display information.
	IP Address	This icon, identifies the IP address of the server the Omni System is connected to.
	LIS Communication Disabled/Enabled	This toggle switch on the Host Communication screen, enables or disables LIS communication.
	LIS Configuration Icon	This icon, located by tapping on the More Options icon, allows the user to configure the LIS communication.
	Lot Number	This icon, on the Load Sample Step screen (during test set up) shows the Lot number of the scanned sample.
	Maintenance	This icon signifies that a maintenance task is due on that Omni.
	Maintenance Pending	This icon indicates the maintenance status.
	Mobile Device-Details	This icon is located on the tools menu bar. Tap this icon to display and/or configure the Site Network Configuration screen

	Mobile Device-Information	Tapping this icon will display information about the mobile device.
	More Options	This icon is located near the top of the mobile device Home screen. Tapping this icon will display the More Options menu, allowing the user to make further choices.
	Not Available	This icon, indicates a function or service that is currently not available. Shown here on the mobile device, the icon indicates that cellular connectivity is unavailable.
	Notification-Assay Installation	This icon identifies a task that is due to be performed, such as installing an assay update. Tap this icon to begin the assay update process.
	Notification-Mobile Device Update Message	This icon identifies a task that is due to be performed, such as installing a mobile device application update. Tap this icon to begin the update process.
	Notification-Omni SW Update	This icon identifies a task that is due to be performed, such as installing an Omni software update. Tap this icon to begin the update process.
	Notification Task Complete	This icon identifies a task that is has been successfully completed. This icon appears at the far right of the notification message.
	Number	This icon appears on various screens to indicate a numeric entry.
	Obtain One-Time Passcode	This icon appears on the user login screen, to the right of the entry area for the administrator's email address. Tap this icon to initiate system activation, and it causes a one-time pass code to be sent to the administrator's email for usage during initial site login.
	Omni-Available	This icon, usually at the bottom of the mobile device screen, shows an Omni instrument that is connected and available (no cartridge loaded).

	Omni-Available-Battery Charge Level Indicated	This icon appears at the bottom of the Home screen. It indicates an Omni that has no cartridge loaded, and is available for running a test. The indicator at the right of the Omni shows the remaining charge available on the Omni battery.
	Omni-Blocking Error	This icon, usually displayed on an Omni at the bottom of the mobile device screen, indicates that the Omni can not run a test. When the tools menu is displayed, tapping on the Omni icon on the tool menu bar will display additional information about the problem.
	Omni Data Backup	This icon, found on the Instrument Detail screen, backups the Omni data to the mobile device.
	Omni Data Restore	This icon, found on the Instrument Detail screen, screen, restores the Omni data from the Mobile Device.
	Omni Data Wipe	This icon, found on the Instrument Detail screen, screen, will delete the data on the Omni.
	Omni Enabled/Disabled	This icon, is a toggle switch usually displayed on an Omni at the bottom of the mobile device screen, to enable or disable an Omni.
	Omni Launch	Icon appears on the Launcher screen, Tap to start the Omni application.
	Omni Name	This icon, shown on the Omni Details screen, shows the name (or other designation) of the selected Omni.
	Omni-Non-Blocking Error	This icon, usually displayed on an Omni at the bottom of the mobile device screen, indicates that the Omni requires attention. The Omni will still run a test. When the tools menu is displayed, tapping on the Omni icon on the tool menu bar will display additional information about the problem.
	Omni Not Connected or Unavailable	This icon shows an Omni which is unavailable or not connected to the mobile device. Usually it is shown as the result of lost communication with the mobile device.

	Omni Processor Busy	This icon may be seen if the application is shut down during maintenance.
	Omni has a Cartridge Loaded/ Processing Test	This icon has various functions. The icon can appear on the middle of the Add Omni screen to initiate the addition of an Omni to the site; or it can be shown at the bottom of the screen to show a connected Omni that has a cartridge loaded. This icon also appears on the More Options menu; tapping the icon will initiate the addition of an Omni to the site.
	Omni Requires Service (Yellow Wrench)	This icon shows an Omni which is available, but requires service (the yellow wrench icon to the left of the Omni indicates service is required). Tap the tools icon to navigate to the selected Omni, which will then display a detailed maintenance screen.
	Omni Self Test	This icon, shown on the Omni Details screen near the bottom of the screen, can be tapped to initiate a Omni self-test on the selected instrument.
	Omni-Test Completed	When running a new test, a Test Progress bar appears near the top of the mobile device screen. This icon, with a checkmark, indicates that the test has been completed.
	Omni is Busy	This icon, primarily displayed on the Instrument Management screen, indicates the Omni is busy with a task.
	Omni is Connected and Available	This icon, primarily displayed on the Instrument Management screen, indicates the Omni is connected and available.
	Omni with a Blocking Error	This icon, primarily displayed on the Instrument Management screen, indicates the Omni has an error preventing the Omni from being used.
	Omni with a Non-Blocking Error	This icon, primarily displayed on the Instrument Management screen, indicates the Omni has an error, but can still be used.
	One-Time Passcode-Enter	This icon appears on the user login screen, to the left of the line for the one-time pass code (emailed to the administrator) to be entered.

A Appendix - Icon Definitions

	Open the Door of the Selected Omni	This icon, shown on the Omni Details screen near the bottom of the screen, can be tapped to open the cartridge loading door of the selected Omni.
	Other Information for Test-Enter	This icon is located on the Sample Information screen, and is located to the left of a line near the center of the screen. Tap on this line to enter any additional information (i.e., blood, sputum) about the specimen being used in the test.
	Password	This icon appears on the user login screen, to the left of the line for the user's password to be entered. This icon is also found twice on the Add Guest User screen, at the left of the line where the guest must enter a password and again when they must retype the password to confirm it. The two passwords typed on the Add Guest User screen must match identically.
	Patient Entry Completed	When initiating a new test, a Test Progress bar appears near the top of the mobile device screen. This icon, with a checkmark, indicates that the patient entry portion of the test creation has been completed. When the icon is present without a checkmark, it indicates that the entry is not complete.
	Patient Entry-ID Number	This icon is used on the Patient Information Entry screen to designate a patient's ID (Identification) number. Also, this icon, on the Search Test Results screen, can be tapped, to enter the patient's ID number.
	Patient Entry-Given (First) Name	This icon is used in various places, usually to indicate an entry area for a username. Used on the Patient Information Entry screen to designate a patient's given (first) name.
	Patient Entry-Select Date of Birth	This icon is used on the Patient Information Entry screen to designate a patient's birth date. Also, this icon, on the Search Test Results screen, is shown on the Select patient date of birth line. Tap this entry to select a date from the screen that appears.
	Patient Entry-Select Gender	This icon is used on the Patient Information Entry screen to designate a patient's gender.

	Port Number	This icon indicates the port number.
	Power Off Mobile Device	After clicking the power button on the right side of the mobile device, a screen appears with this icon at the top. Tap this icon to continue the power down sequence.
	Power Off Mobile Device-2	After clicking the power button on the right side of the mobile device, a screen appears with a Power Off mobile device icon displayed. Tap that icon and this final Power off icon appears. Tapping this icon completes the power off sequence.
	Previous Screen	This icon, located on the face of the mobile device at the bottom right, can be tapped to show the previous screen displayed on the mobile device.
	Print	This icon, when shown on the tools menu bar, can be tapped to select a printer. When this icon appears at the bottom of a Test Result screen, tap to print the test result on a connected printer.
	Recents	This icon, located on the face of the mobile device at the bottom left, can be tapped to display the applications that are currently open on the mobile device.
	Reload Launcher	This icon is shown on the Launcher screen. Tap this icon to reload the launcher on the mobile device.
	Required Field	This icon, found on screens such at the Patient information screen, indicate that the information for that field is required.
	Reset Password	To reset an Omni User's password, begin at the Site Network Configuration screen. Tap the User icon to display a list of active Omni users. Tap on the line containing the desired user. On the resulting screen, this icon will be displayed at the bottom. Tap this icon to reset the password of the user displayed on the screen.
	Restart Mobile Device	After clicking the power button on the right side of the mobile device, a screen appears with this icon in the center of the screen. Tap this icon to abort the power down sequence and restart the mobile device.

	Restart Omni Application	This icon, shown on the Omni Details screen near the bottom of the screen, can be tapped to restart the Omni application on the selected instrument.
	Sample Barcode-Scan	When choosing sample entry options during the creation of a new test, tapping this icon activates the mobile device camera to scan a barcode.
	Sample ID-Enter	When choosing sample entry options during the creation of a new test, tapping this icon allows a sample ID number to be entered manually (used if the sample barcode is unreadable).
	Sample ID-Enter Manually	When initiating a new test, after choosing the Enter Sample ID option on the Sample screen, the Enter Sample ID screen appears. This icon appears on the left of the manual entry line.
	Sample Prep-Completed	When initiating a new test, a Test Progress bar appears near the top of the mobile device screen. This icon, with a checkmark, indicates that the sample preparation entry portion of the test creation has been completed. When the icon is present without a checkmark, it indicates that the entry is not complete.
	Sample Prep-In Progress	When initiating a new test, a Test Progress bar appears near the top of the mobile device screen. This icon indicates that the sample preparation entry portion of the test creation is being performed. When this icon is displayed in white, it indicates the sample preparation step is ready (and waiting) to be performed.
	Sample-Entry Completed	When initiating a new test, a Test Progress bar appears near the top of the mobile device screen. This icon, with a checkmark, indicates that the sample entry portion of the test creation has been completed. When the icon is present without a checkmark, it indicates that the entry is not complete.

	Scan Cartridge	This icon appears on the progress menu bar when a test is being set up, to show the cartridge entry section of the set-up process is waiting to be completed. This icon turns blue when the cartridge is ready to be scanned.
	Select Date Range	This icon is located on the Search Test Results dialog screen. When searching for test results, you can specific a range of dates by tapping this icon and choosing a date range from the calendar.
	Settings Menu Access	Tap the Down-Arrow icon on the launcher screen to display this icon. Then, tap this icon to display the Settings menu.
	Shutdown	This icon, shown on the Omni Details screen near the bottom of the screen, can be tapped to shut down the Omni application on the selected instrument. After tapping this icon you will be asked to confirm your selection.
	Slide Switch On-Off	This icon is shown on the Wi-Fi screen and is used to turn Wi-Fi On or Off by sliding the switch.
	SMS sharing icon	This SMS sharing icon is displayed on an error screen. After the Omni sends an error result to the SMS recipient, a checkmark will appear at the right of this icon, indicating the message was successfully sent.
	Specimen Type-Select From Menu	This icon is located on the Select Test screen, and is located to the left of a line near the center of the screen. Tap on this line to select specimen information (from the drop-down menu) about the test to be run.
	Start New Test	This icon appears on the Omni Home screen. Tap this icon to initiate a new test.
	Starting Test	This icon is used to show an assay test that is starting. This icon, when shown on an Omni self-test screen, will initiate the self-test when it is tapped.
	Stop Test	This red icon, shown when an assay test is being run, can be tapped to stop the test.

A Appendix - Icon Definitions

	System Information	This icon, shown on the Omni Details screen, shows information including the current software version number of the selected Omni.
	Sync-Start, Information or Error	This synchronization icon has a few uses, and various functions, depending on where it is used in the application. Tapping on the icon will bring up a screen where you can initiate a synchronization routine.
	Technical Support Contact Icon	This icon appears on the Launcher screen. Tap to start the application to initiate a live chat session with Cepheid Technical Support.
	Test Completion, Date and Time	This icon, which appears on the test completion screen, shows the date and time of a test that has been successfully run and completed. The test date and time of completion appears to the right of this icon.
	Test Error	This icon indicates there was an error while running the test.
	Test, No Results	This icon indicates that the test has no results and has been aborted.
	Test Notes-Enter	This icon is located on the Select Test screen, and is located to the left of a line near the bottom of the screen. Tap on this line to enter any additional notes (optional) about the test to be run.
	Test Time Remaining	This icon, shown onscreen when an assay test is being run, identifies the time remaining on the test (time shown to the right of this icon). When the circle is completely dark, the test is complete.
	Time Out	This icon, found on the Phone Options page after tapping the More Options Icon, allows the user to set the length of time the mobile device is idle before timing out.

	Upload Test Results to C360	This icon is located on the View Omni status screen, on the menu bar near the bottom of the screen. This icon is active when there is no Wi-Fi or cellular connection available. First, download test results from an Omni to the mobile device. Later, you can travel to an area where network connectivity is available, and tap this icon to upload the test results from the mobile device to C360, without the need to bring an Omni along for the upload.
	User, Username or User First Name	This icon is used in various places, usually to indicate an entry area for a username. This icon is used on the User Management screen to designate a User's given (first) name. This icon is also found on the tools menu bar, and, when tapped, displays patient configuration information. If the icon is blue, the user area is active.
	User Information	This icon is shown on the Settings menu, and provides detailed information about a selected user.
	User Level	This icon appears on the Users screen, in the list of users associated with the site. The icon is in the heading of the column identifying the user level (Basic, Admin, etc.) of each of the users, at the far right of the screen.
	User or Patient Family (Last) Name	This icon is used in various places, such as the Patient Information Entry screen. The icon designates a patient's family (last) name or user last name.
	View Results	This icon appears on the Omni Home screen. Tap this icon to view a test previously test run on the site.
	Wi-Fi	This icon appears at the top of the mobile device screen and shows the type of connection in use (Cellular or Wi-Fi)
	Wi-Fi Password Protected	This icon is shown on the Wi-Fi screen and is shows a Wi-Fi Network connection that is protected by a password (locked out).



GeneXpert® Omni

Reference Guide

IVD

In Vitro Diagnostic Medical Device

For use under Emergency Use Authorization (EUA) Only

Table of Contents

Using This Document	2
Warnings	2
Powering the Omni System On or Off	3
Log In to the Omni Application	3
Commonly Used Icons	4
Enable Wi-Fi	5
Install Assay(s)	6
Start and Test	7
Maintenance	9
Troubleshooting	10
Technical Assistance	11



Using This Document

1

Numbered green circles indicate step sequence.



Orange outline indicates a button to tap.



Arrows are used to point out information.



Warnings

- This product has not been FDA cleared or approved;
- This product has been authorized by FDA for use with the Xpert® Omni SARS-CoV-2 test under an Emergency Use Authorization (EUA);
- This product has been authorized only for use with the Xpert Omni SARS-CoV-2 test for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

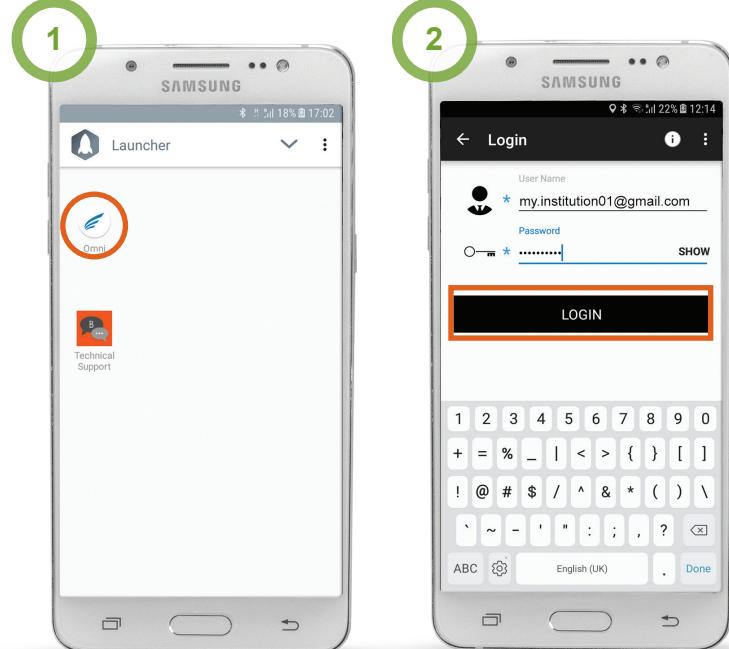


Powering the Omni System On or Off

1. If the Omni instrument is not on, press and hold the power button on the back of the instrument for 2 seconds. **It may take up to 30 seconds before the activity light on the front of the instrument illuminates**, indicating the instrument is on. Press the button again for 2 seconds to turn the instrument off.
2. To turn the mobile device on or off, press the power button on the side for 2 seconds.
3. Wait a few seconds for the lock screen to load. Swipe up to unlock the mobile device.

NOTE: Phone models may vary in color or appearance, but will have the same functions.

Log In to the Omni Application





Commonly Used Icons

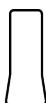
General Use Icons



Cepheid Application Launch



Required Field



Instrument Available



Instrument Error



Instrument with Cartridge



More Options Menu



Home



Remote Support Tool



Information Menu

To see the Package Inserts and the Operator Manual, tap Information Menu, then:

Tap Assay Dashboard to access Assay Instructions/Package Insert.

Tap Help to access the Operator Manual.

Running a Test Icons



Start a New Test



Stop Test



Scan Cartridge



Patient ID



View Results

Battery Icons (Example)



Instrument Battery (<20%)



Instrument Battery (full)



Instrument Battery (charging 60%)



Instrument with Full Battery and Plugged in

Mobile Device Buttons

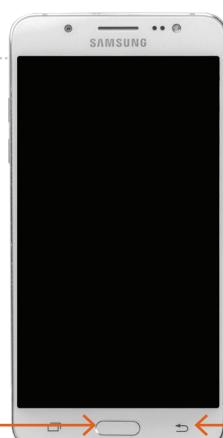
Maintenance Icons



Maintenance Due



Instrument Maintenance



Volume Button
Power Button

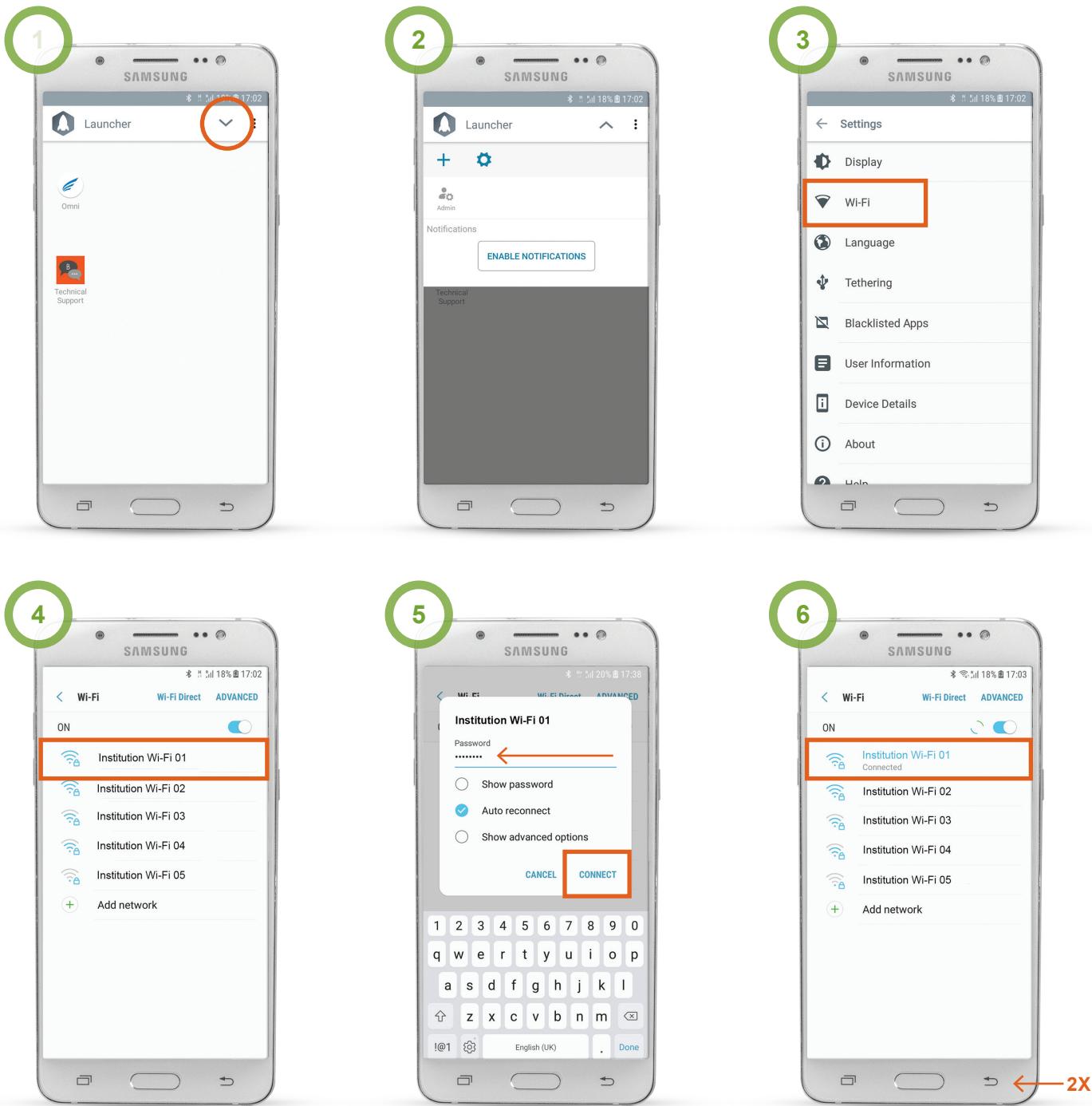
Home Button

Mobile Device Back Navigation Button

©2020 CEPHEID. ALL RIGHTS RESERVED



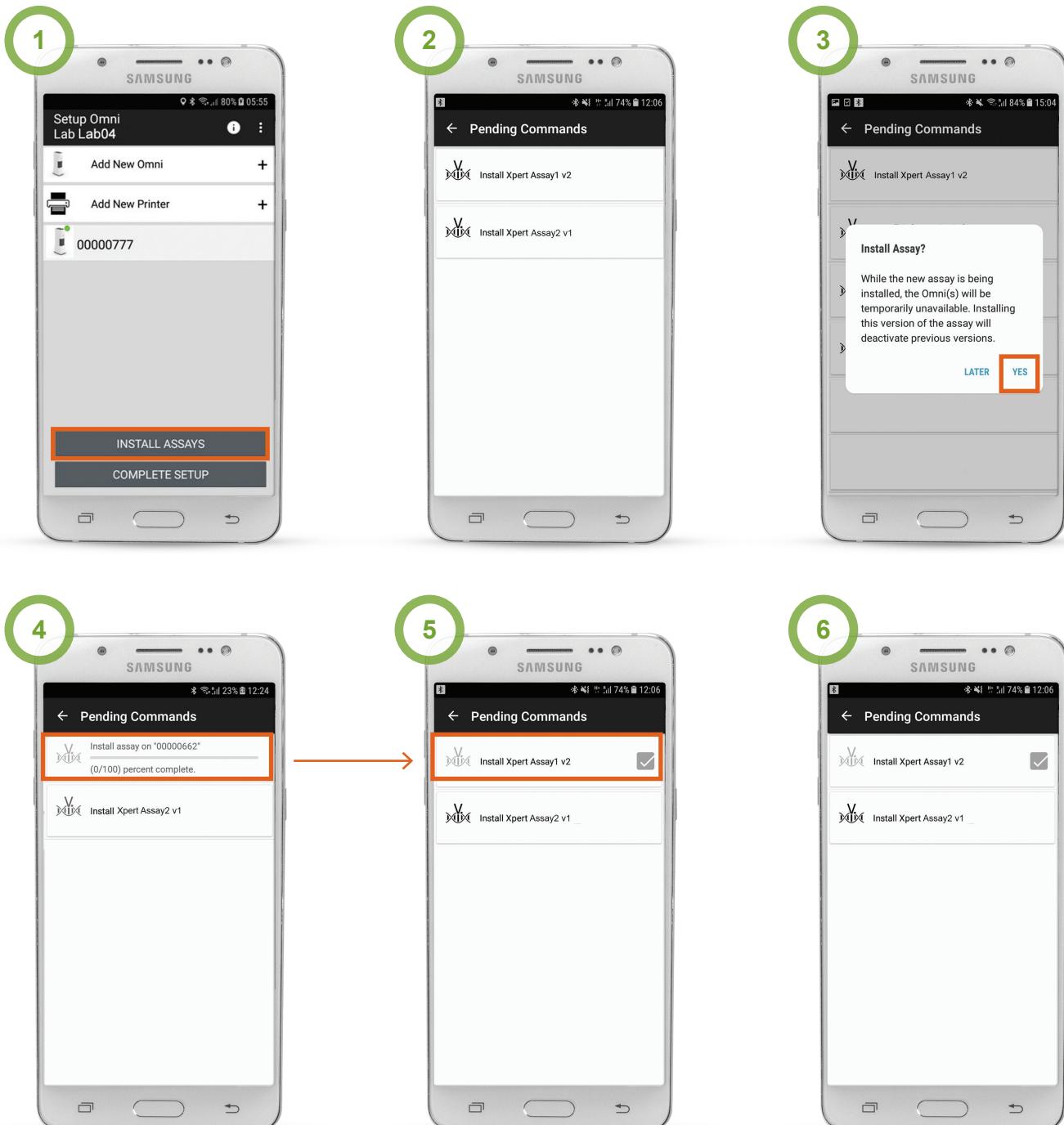
Enable Wi-Fi



When connected to Wi-Fi, tap the back navigation button on the mobile device twice to reach the Launcher page.



Install Xpert Omni SARS-CoV-2 Assay



Tap the arrow at the top of the screen again to return to the Setup Omni screen.



Assay Installation Complete.

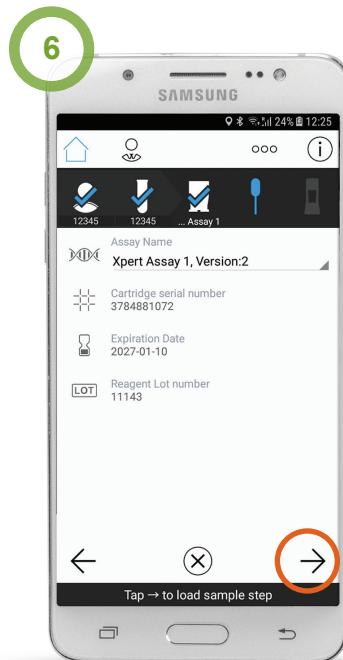
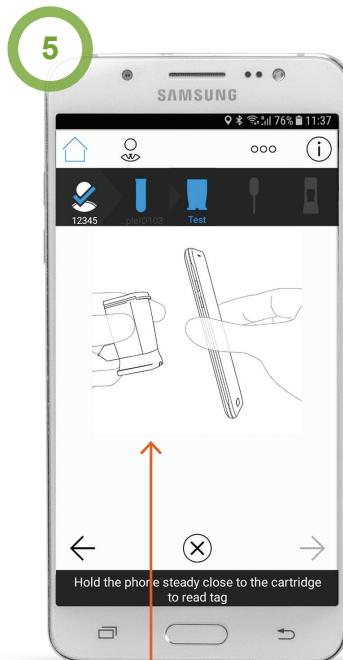
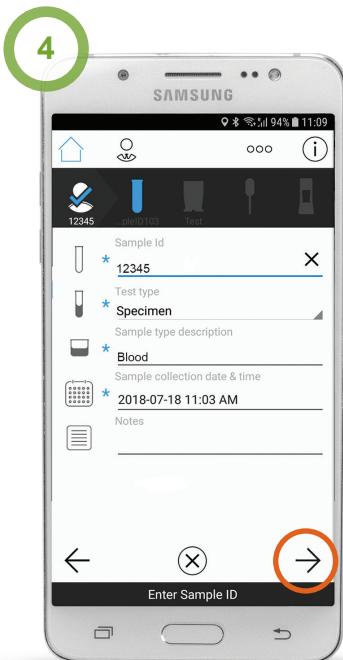
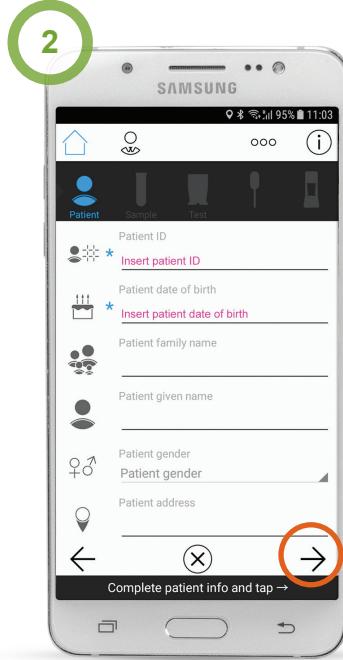
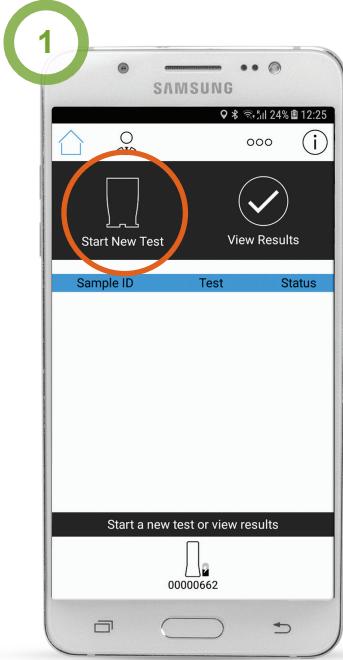


Start and Test

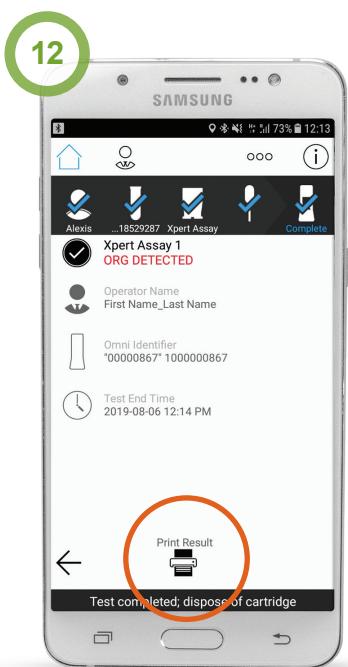
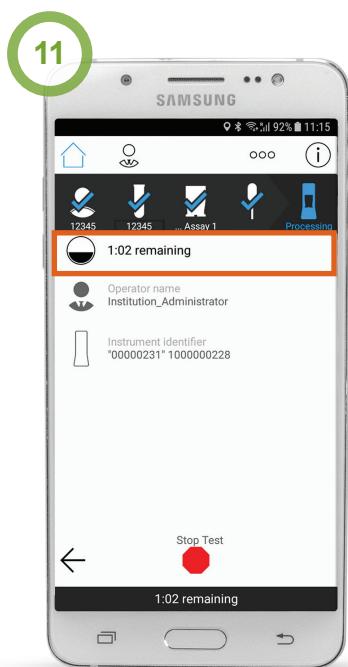
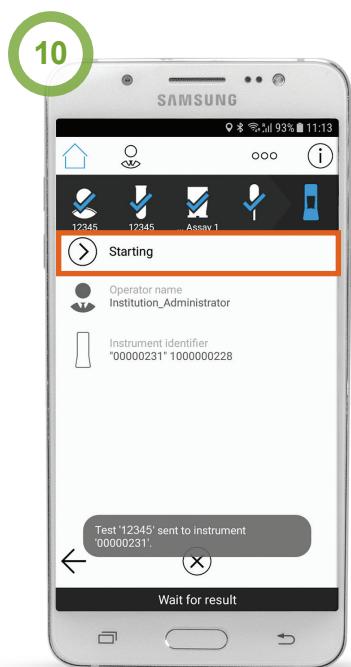
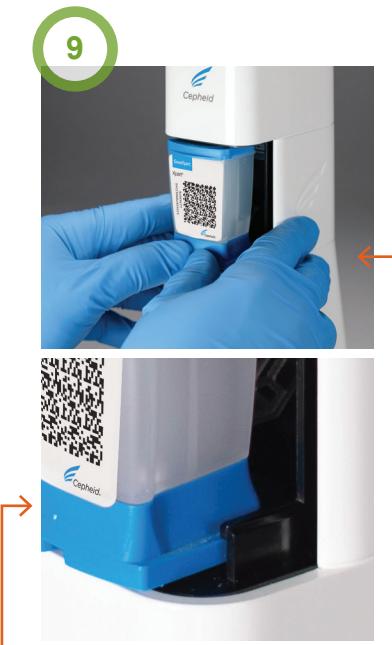
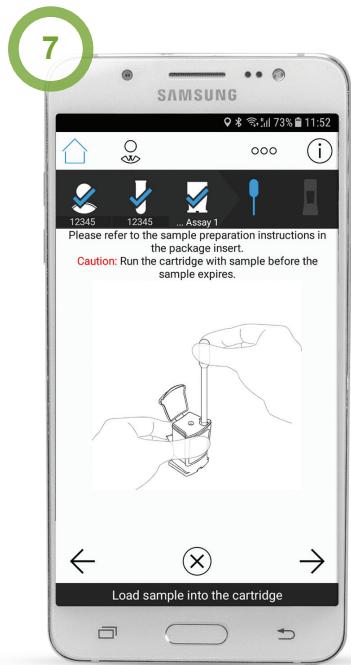
IMPORTANT: Read the assay instructions for information on preparing the cartridge and for time limitations to start the test. Tap the “” icon to access the Package Insert for the Xpert Omni SARS-CoV-2 assay.

CAUTION: Do not move or tip the instrument when a test is running. In addition to possible invalid test results, damage to the instrument can occur if the cartridge contents leak or spill into the interior of the instrument.

NOTE: Fields marked with a blue asterisk * are required.



Keep the cartridge upright, avoid touching the reaction tube and slowly bring the cartridge to the back of the mobile device to scan the NFC tag.



Remove and dispose of the cartridge according to your institution's hazardous waste policies.



Test Completed.



Maintenance

i **IMPORTANT:** The instructions provide a summary from the GeneXpert Omni Operator Manual and are for reference only. For complete and detailed instructions, refer to the Information Menu icon to access the operator manual (see page 4).

! **CAUTION:** Do not spray directly inside the Omni Instrument.



Materials Required:

- 70% ethanol or denatured ethanol
- 1:10 dilution of household bleach (0.5% final chlorine concentration)
(1:10 dilution = 1 measure of bleach + 9 measures water)
- Lint free wipes
- Institution mandated Personal Protection Equipment (PPE)

Procedure:

1. Tap the Maintenance Due icon.
2. Tap the Instrument Maintenance icon

NOTE: Change lint free wipe after cleaning each instrument or as needed

Weekly:

Clean the Instrument surfaces

1. Unplug and power down the Omni instrument
2. Moisten a lint-free wipe with 70% ethanol or denatured ethanol.
3. Wipe all outside surfaces of the instrument.
4. Wipe all surfaces on the mobile device.
5. Wipe the table surfaces underneath and all around the instrument.

Clean Cartridge Bay

1. Tap Start Weekly Cleaning.
2. Moisten a lint-free wipe with a 1:10 dilution of household chlorine bleach. Wipe entire cartridge bay interior with diluted bleach 3 times allowing the bleach to remain for 2 minutes each time.
3. Moisten a lint free wipe with 70% ethanol or denatured ethanol.
4. Wipe the entire cartridge bay interior with the ethanol solution to remove bleach residue.
5. Tap the Weekly Cleaning Complete button.

Monthly:

Clean Plunger Rod and Cartridge Bay

1. Tap Start Monthly Cleaning.
2. Wait for the Plunger Rod to lower
3. Moisten a lint-free wipe with a 1:10 dilution of household chlorine bleach. Wipe plunger rod and entire cartridge bay interior with diluted bleach 3 times allowing the bleach to remain for 2 minutes each time.
4. Moisten a lint free wipe with 70% ethanol or denatured ethanol.
5. Wipe the plunger rod and entire cartridge bay interior with the ethanol solution to remove bleach residue.
6. Tap the Monthly Cleaning Complete button.





Troubleshooting

Refer to the GeneXpert Omni Operator Manual for detailed instructions and for a complete list of error messages.

Problem	Possible Cause	Solution
No Instrument connected to Mobile Device	Instrument out of Range	Keep the Mobile Device and Omni within 30 meters (100 feet)
	Bluetooth Tethering off	Ensure Mobile Device Bluetooth Tethering is on
Instrument will not turn ON	No power	<ol style="list-style-type: none">1. Press the power button for at least 2 seconds2. Plug the Omni into a power outlet
Mobile Device not connected to Internet	No Wi-Fi service	<ol style="list-style-type: none">1. Wi-Fi not available2. Enter correct Wi-Fi password
Unable to install assays or perform updates	Not able to download assay from C360	Mobile Device not connected to Internet, see above
	Role used does not have correct privileges	Login as Institution Admin or Lab Admin
	Instrument has experienced an error	Restart the instrument
Cartridge is being ejected from the instrument	Battery Level is very low	Verify that the instrument is plugged into the charger and is charged at least 10% and before starting a test
	Cartridge loading error	Retry with the same cartridge and if problems persist, try a different cartridge
	NFC reading failure	Try a different cartridge
Cartridge does not scan after multiple tries	NFC reading failure	Try a different cartridge
Instrument door will not open	Cartridge stuck in instrument	<ol style="list-style-type: none">1. Use Open Door function2. Restart the instrument
Unable to view results	Instrument and Mobile device are too far apart and/or not connected	Check that the instrument is on and Mobile device is within 30 meters (100 feet) of the Omni.
The printer will not connect (Bluetooth Printer)	Printer communication was lost	<ol style="list-style-type: none">1. Verify that Bluetooth is enabled and the printer is ON2. Tap the More Options icon3. Select printer icon and select the printer4. Restart printer
The printer will not connect (Wi-Fi Printer)	Printer not connected	<ol style="list-style-type: none">1. Verify that Wi-Fi is enabled and the printer is ON2. Verify that Mobile Hotspot is On (if using Hotspot)3. Tap the More Options icon4. Select printer icon and select the printer5. Restart printer

Please contact Technical Support if the suggested solutions do not resolve the problem. See the Technical Support contact information on the back cover of this guide.



Technical Assistance

Before Contacting Cepheid Technical Support, collect the following information:

- Product name
- Cartridge and reagent lot number
- Serial number of the system
- Error messages (if any)
- Software version

Log a support ticket online: <http://www.cepheid.com/us/support>

Contact Information

United States

TELEPHONE: +1 888 838 3222
EMAIL: techsupport@cepheid.com

France

TELEPHONE: +33 563 825 319
EMAIL: support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.



CEPHEID
904 CARIBBEAN DRIVE
SUNNYVALE, CA 94089
USA
PHONE: +1.408.541.4191
FAX: +1.408.541.4192

CORPORATE HEADQUARTERS

904 Caribbean Drive
Sunnyvale, CA 94089 USA

TOLL FREE +1.888.336.2743
PHONE +1.408.541.4191
FAX +1.408.541.4192

EUROPEAN HEADQUARTERS

Vira Solelh
81470 Maurens-Scopont France

PHONE +33.563.82.53.00
FAX +33.563.82.53.01
EMAIL cepheid@cepheideurope.fr

www.Cepheidinternational.com

©2020 Cepheid. All rights reserved.

302-2370 Rev. B NOVEMBER 2020