Cepheid OS v1.0 Release Notes

This document contains new information, known limitations, and clarifications not described in the *GeneXpert® System with Touchscreen Operator Manual*.

New Software

Cepheid OS is a new software release from Cepheid. Key features include:

- **Create Test Workflow** – The software uses a simplified workflow for running tests and determining test results.
- **Localization** – The software is available in the following languages: German, English, Spanish, French, Italian, Dutch, Polish, Portuguese, and Swedish.
- **New Hardware Support** – The software is compatible with the new GeneXpert System with Touchscreen.

Known Issues

Caution:

Cepheid recommends confirming that LIS uploaded results match GeneXpert test results after any changes to the GeneXpert or Host system, including (but not limited to) changes to the following:

- Cepheid OS version
- GeneXpert Assay Definition version
- GeneXpert Host Communication Settings
- Host middleware software or configuration changes
- LIS software or configuration changes

Create Test Issue

The test's host order cannot be changed after selecting and confirming the host order for a test. To remedy this, exit the Create Test workflow to re-select host order.

General Issues

1. During the print operation, if the user cancels printing or a printer is not connected, the user will receive a "printing was successful message" on the Cepheid OS. The user needs to verify that the printer is connected before performing print operation.
2. If a database backup is initiated while test results are being uploaded to a point-of-care data manager (POCDM), a test result may be sent to the POCDM more than once.
3. In the Host Communication Settings tab, if a port number larger than 2,147,483,647 is entered and the host communication protocol is switched, an error dialog appears.
4. The system is configured to open files with a single tap. Double tapping a file (for example, during assay import) may result in unintended navigation.
5. If tests are retrieved from an earlier GeneXpert software (GeneXpert Dx 5.3 and below) into Cepheid OS then the error messages of those tests will not translate into current language selected by user. Error messages will remain in the language that they were originally run in.