

Summary

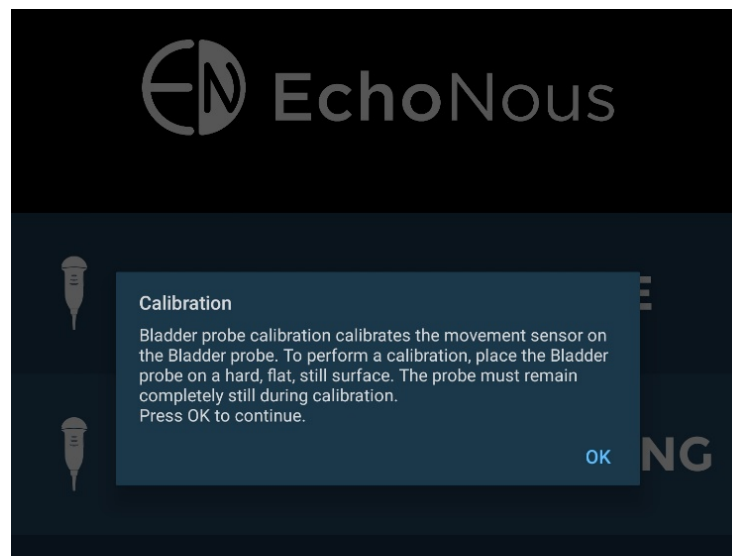
The EchoNous 4.4.0 system software update release is designed to mitigate an intermittent field issue that may result in corruption of the EchoNous Bladder Probe read-only memory (EEPROM). Corruption of the EEPROM then results in failure of the Bladder Probe to connect to the system. There is no safety risk associated with the failure – as this occurs at times other than scanning.

This document provides EchoNous / Signostics Sales and Clinical Support personnel and Biomedical Engineering customers with information on the Bladder Probe, Hub, S3 Samsung and system software version 4.4.0.

System Software v4.4.0 Update

The v4.4.0 system software features a software solution designed to reduce the incidence of Bladder Probe ‘failure to connect’ occurrences.

- ◇ The 4.4.0 software continues to store the probe calibration data in the tablet. This means that when a new (unknown) Bladder Probe is connected to the Tablet, the Tablet will require a calibration be performed before initial use.
- ◇ The request to calibrate will take the form of the image below.
 - The request to calibrate an unknown Bladder Probe will ‘time out’ after 10 seconds if the ‘OK’ is not pressed.
 - If the calibration requirement times out before pressing OK, back out of the menu and navigate to Three Dots -> Settings -> Maintenance -> Bladder Probe Calibration, follow instructions and tap OK.



- ◇ It will be possible to query identity and status of connected Probes and HUB through the three dots -> Settings -> Maintenance -> Probe Information menu.

Unaddressed Software Anomalies

The v4.4.0 system software does not address the following bugs discovered in the design and testing process.

- ◇ **Dead Samsung tablet not charging:** If the Samsung Tablet is allowed to reach a low-to-no charge status, the user may need to initially restore charge to the Tablet using an EchoNous-approved, medical-grade wall-wart charger.
 - Pay close attention to the charge status of the Tablet and re-charge when not in use.
 - Store the charger in the biomedical engineering lab for safekeeping.
- ◇ When using calipers in “Volume Measurement” menu (Ultrasound Imaging), deleting the calipers alone will not automatically refresh the volume estimation on the image.
 - Resolve by clicking anywhere on the scan image to update the measurement.
- ◇ Anonymized voluntary data upload feature to EchoNous for Research & Development purposes is suspended for this release.

Update Process

Over Wi-Fi

- ◇ If the Automatic Updates Check is enabled and the system is connected to the Internet, an update notification will appear. Follow the instructions on the device to download and install the update.
- ◇ If the Automatic Updates Check is not enabled, connect the device to the Internet using a secure Wi-Fi connection, then check for updates via Menu > Settings > Maintenance > Check for Updates. Follow the instructions on the device to download and install the update.

Using USB Flash Drive – Samsung Tablet

If the device cannot or will not connect to the Internet, contact Customer Support to assist with downloading and installing the software by means of a USB flash drive.

- ◇ Plug the USB Flash Drive directly into the tablet’s USB-C port.
- ◇ Navigate to Three dots -> Settings -> Maintenance -> Install from USB drive
- ◇ Follow on-screen instructions to install the update.
- ◇ Disconnect the HUB and then **switch OFF the tablet** by holding down the power button.
- ◇ Switch ON the tablet and wait for Uscan software to boot up. Once done, connect the HUB back and **WAIT FOR 30 secs** to re-install the HUB software.

If you have any questions regarding the update process contact EchoNous / Signostics customer support at 844-854-0800.