

TAEUS® FLIP SYSTEM

ThermoAcoustic Enhanced UltraSound
Fatty Liver Imaging Probe

System Check

TAEUS® FLIP System Check

Part # EN5005

Revision History

Date	Version	Change
November 2020	Revision A	Initial version
August 2021	Revision B	Care and handling instructions, screenshots
May 2023	Revision C	Update GUI screenshots

Please verify that you are using the latest revision of this document.



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INTRODUCTION

This System Check protocol establishes that the TAEUS® FLIP System is operating within its design specifications and is able to make accurate/reliable thermoacoustic measurements. The protocol measures the signal-to-noise performance (SNR) of the system, from production of radio frequency pulses to receiving and capturing ultrasound signals. The test checks RF output from Exciter, Amplifier and Applicator, and checks that signals of correct amplitude are received by the Receiver, PCB and PAD processor. Data are then uploaded to ENDRA engineers for performance analysis and evaluation. This system check should be performed at installation and weekly thereafter, as part of a recommended routine maintenance procedure.

MATERIALS

The following materials are required to perform the test protocol:

- TAEUS® FLIP SysCk Phantom (part # EN4010)
- TAEUS® FLIP SysCk Probe Holder (part # EN4014)
- Ultrasound gel
- SONO® Wipes or other TAEUS® FLIP-compatible cleaning and disinfecting wipes. See *Appendix C* in the *EN5001 TAEUS® FLIP User Guide* for a list of compatible wipes.
- Mobile phone with a QR Read function (camera or application)

CARE AND HANDLING

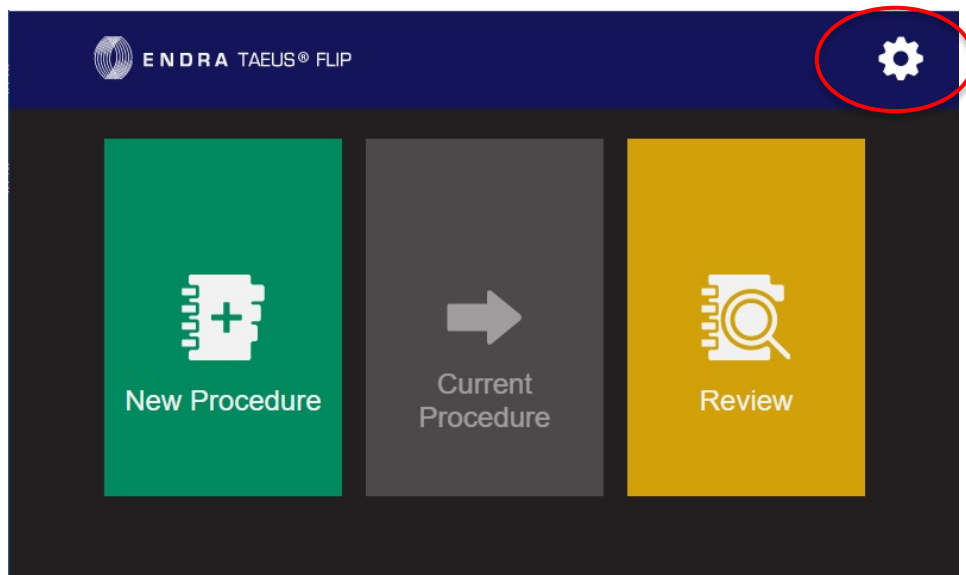
With proper care, the TAEUS® FLIP SysCk Phantom will withstand years of weekly use. Below are some guidelines to follow:

- The scanning surface is the most important part of the phantom to protect. It can withstand the scanning pressure exerted during the System Check procedure as described below, but DO NOT press on the surface with your fingernails or any other sharp objects. If the scanning surface becomes damaged, seal the phantom in an airtight container and contact service@endrainc.com.
- Clean the phantom with TAEUS® FLIP-compatible cleaning and disinfecting wipes. Avoid solvent-based or abrasive cleaning agents.
- For longest life, the phantom should be stored at room temperature and should not be subjected to excessively hot or cold temperatures. Never allow the phantom to freeze. The most accurate measurements will be made when the ambient temperature is between +19 and +24°C.
- Always store the phantom with its removable storage cover attached, and in its air-tight carry case.
- Zerdine®, the SysCk Phantom material, will desiccate over time if the phantom is not stored properly. Contact service@endrainc.com if there is a noticeable change in the phantom.

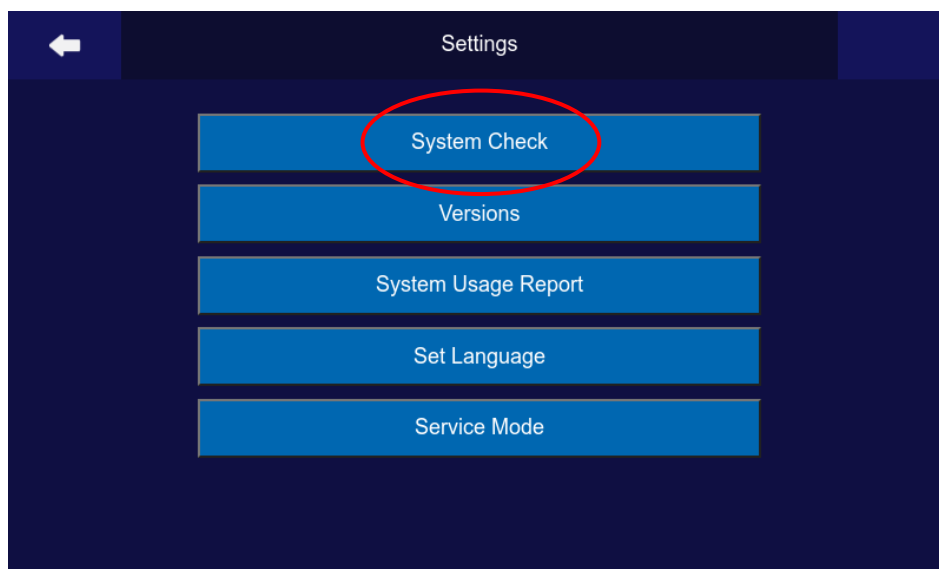
- Inspect the phantom for damage regularly, before use.
- At least once a year, weigh the phantom and compare it to the original weight listed on its label. Contact service@endrainc.com if the phantom has lost more than 2% of its original weight as stated on the phantom label, or if the scan surface appears depressed.

PROCEDURE

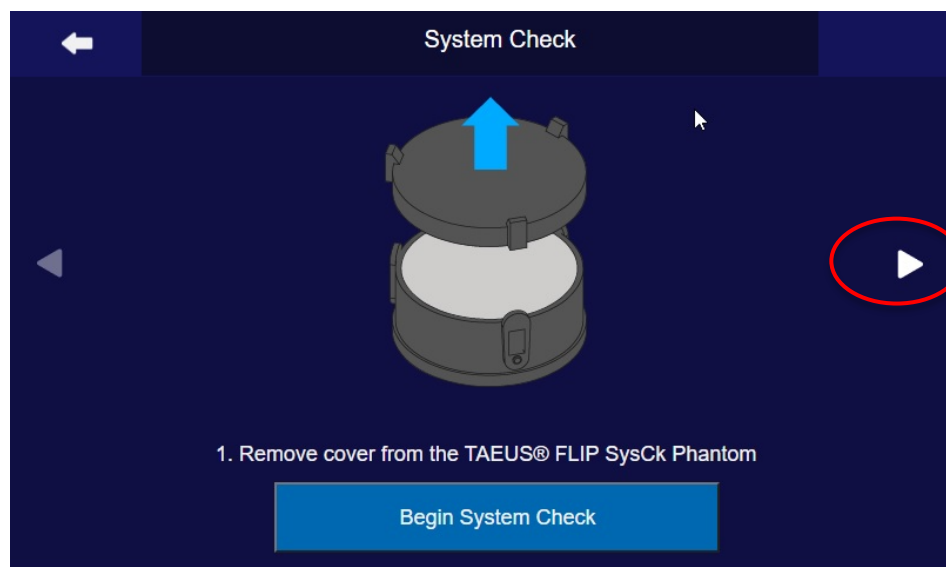
1. Ensure that the room temperature is between +19 and +24°C
2. Place the phantom on a non-metallic working surface close to the TAEUS® FLIP system.
3. Power up the TAEUS® FLIP system.
4. When the Idle screen appears, press the **Settings** icon:



5. On the **Settings** screen, press **System Check**:

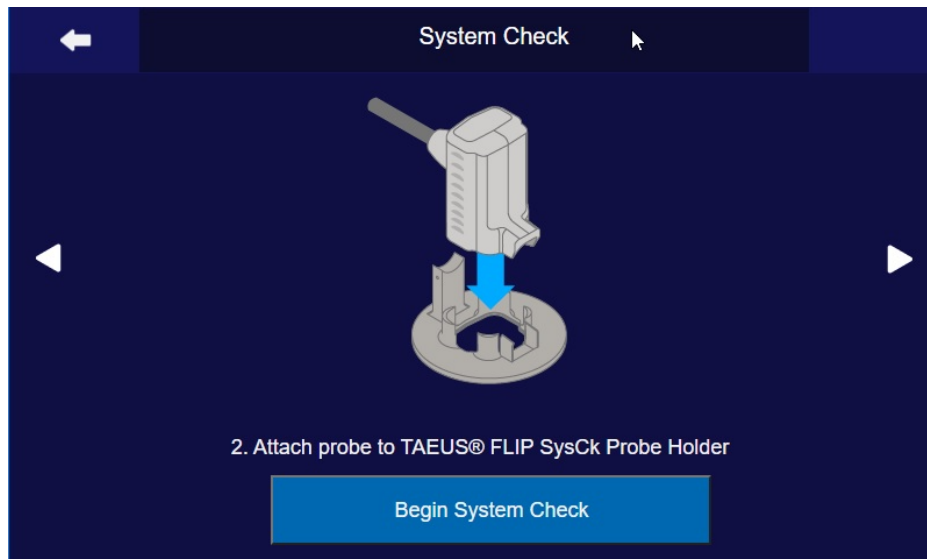


6. Remove the cover of the phantom and inspect its surface for damage. Ensure that the surface is free of debris and has been wiped with a TAEUS® FLIP-compatible wipe. Press the **Next** arrow to proceed to the next instructional image, or press **Begin System Check** if the phantom and FLIP Probe are already prepared (see Note below).

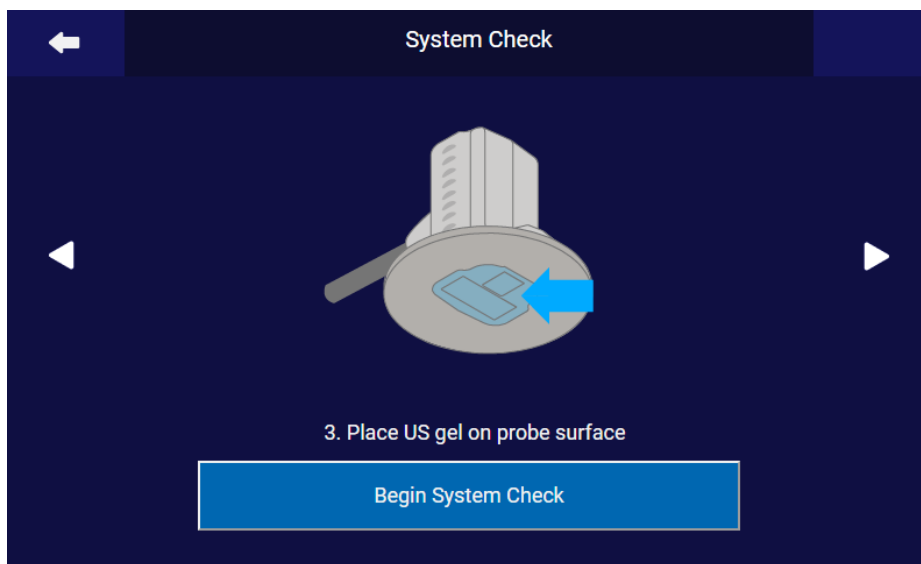


NOTE: A set of instructional images are provided which describe how to prepare the phantom and FLIP Probe for the System Check. New users can scroll through these preparatory instructions with the **Next** and **Previous** arrow keys before starting the scan. Experienced users may simply press **Begin System Check** once the preparations have been completed, without scrolling through the instructional images.

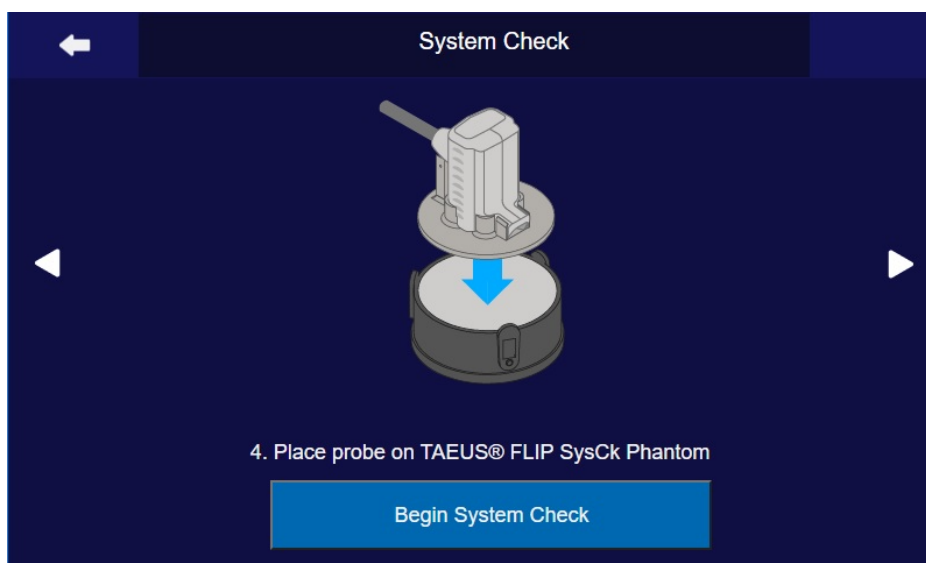
7. Attach the FLIP Probe to the Probe Holder. The Probe Holder helps ensure proper contact of the probe on the phantom surface without probe motion caused by the operator. Ensure that:
 - a) the plastic tabs are fully engaged
 - b) the FLIP Probe is held firmly in the holder.
8. Press **Next** arrow to proceed to the next instructional image.



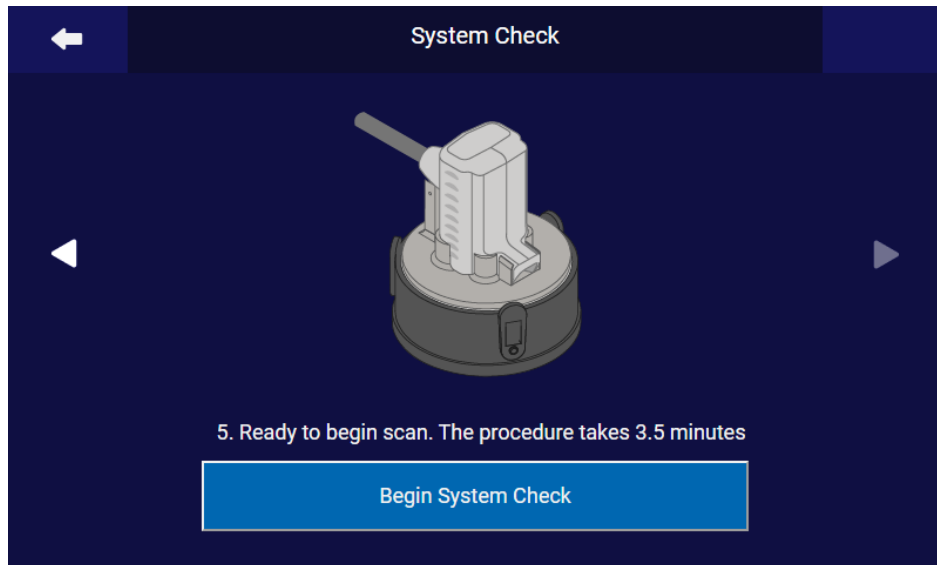
9. Place approximately 15ml of ultrasound gel on the probe's phantom contact surface. Press **Next** arrow to proceed to the next instructional image.



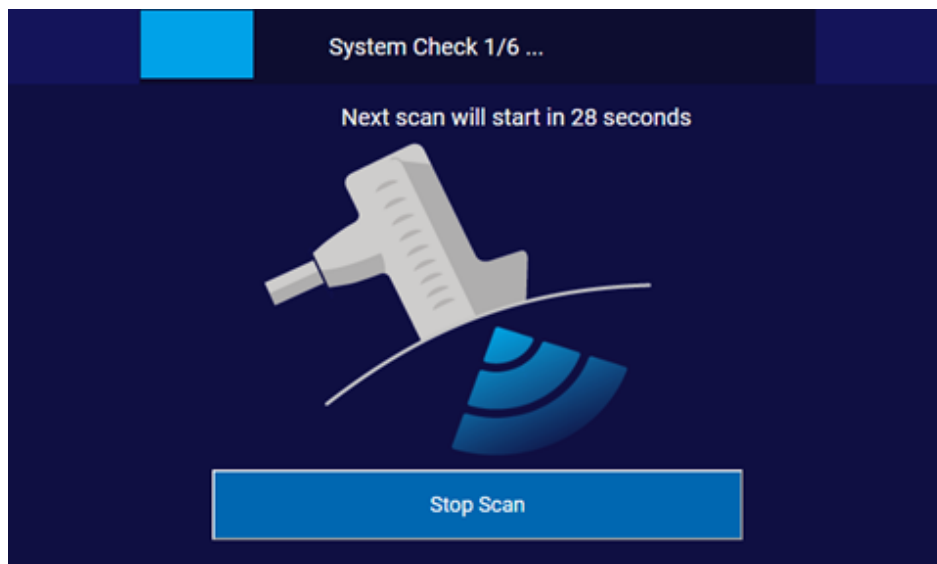
10. Place probe/holder assembly firmly on the phantom. Re-seat the probe in the holder once or twice while the holder is in position to spread the gel and ensure good contact between the probe and phantom surface.



11. Press **Begin System Check** to proceed with data acquisition. Do not move or hold the probe/holder assembly while the scan is in progress.

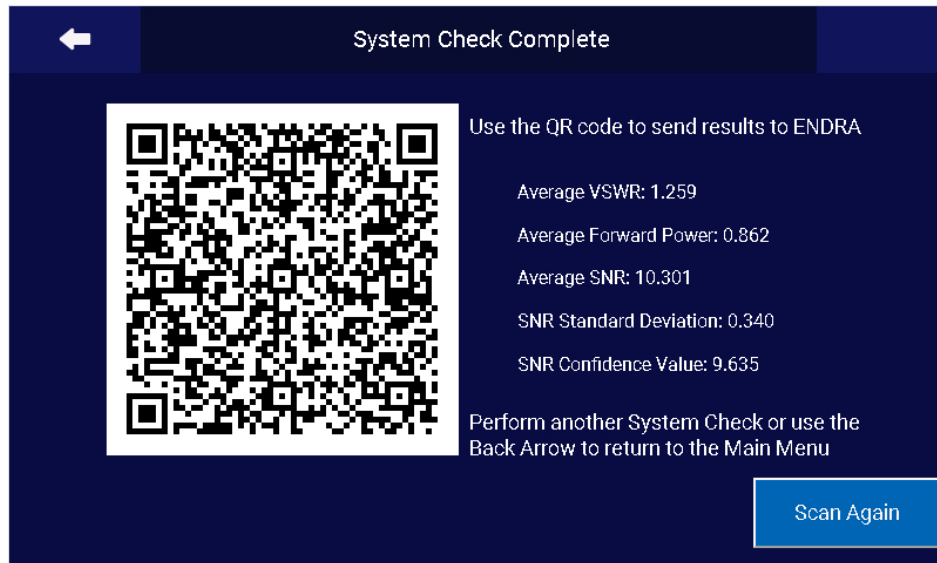


12. Six consecutive scans are automatically acquired. The total scan time is approximately 3.5 minutes.

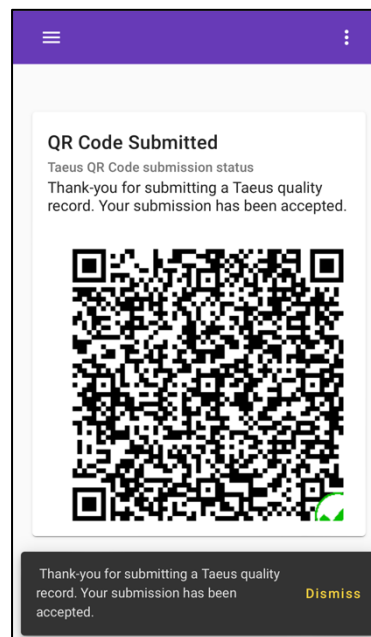


Should it be necessary to abort the test while it is in progress (e.g., if the probe is accidentally moved), press **Stop Scan** and start again.

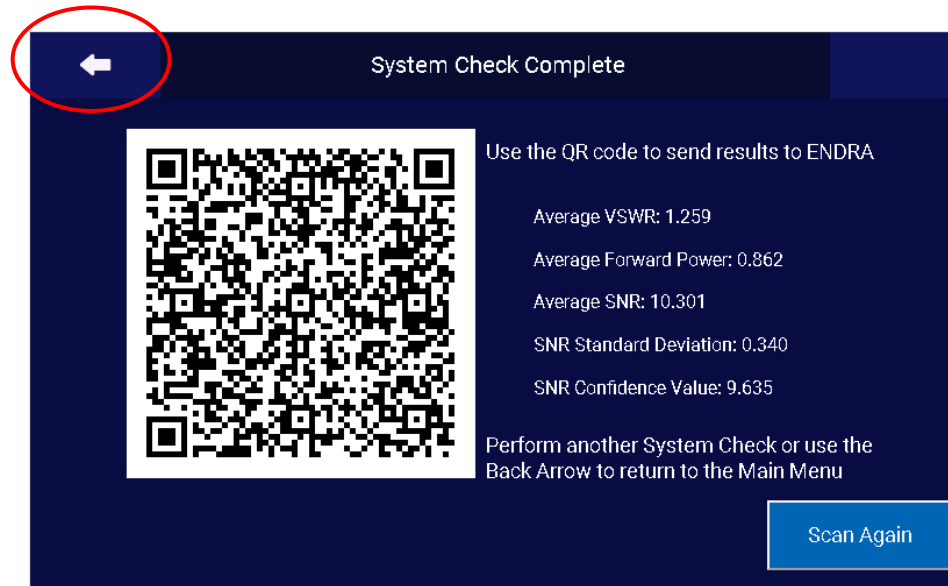
13. A set of summary statistics is displayed when all six scans in the System Check have completed, along with a test-specific QR Code.



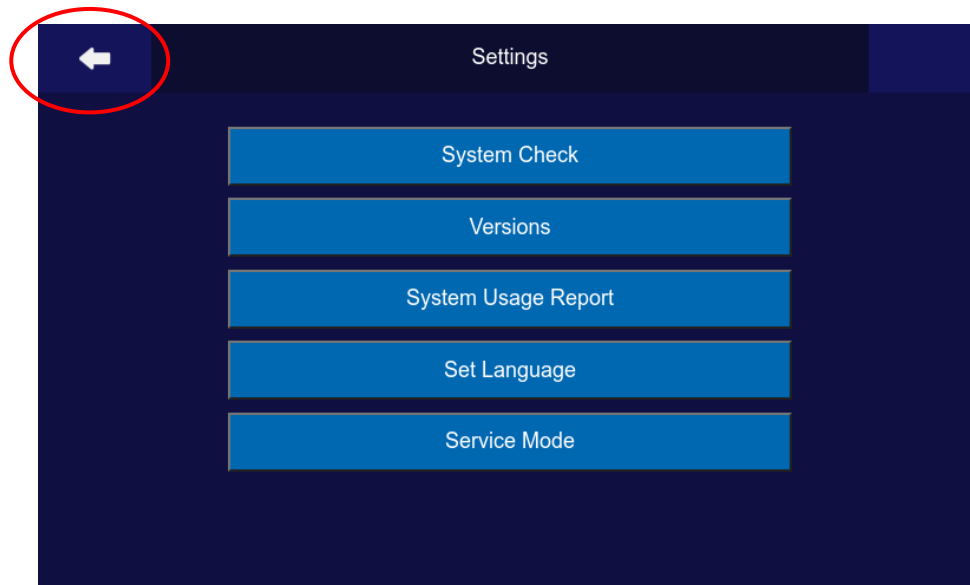
14. Scan the QR code with your mobile phone's camera and tap the yellow **quality.endra.com** link that appears. Data from all six scans are automatically uploaded to ENDRA Life Sciences for evaluation and analysis.



15. The SNR value will be greater than or equal to 10 if the system is operating within specification. A poor SNR (< 10) may be due to inadequate positioning of the probe, too little gel, or too much gel. If the SNR value is below 10 perform the following steps:
 - a. Clean the probe and the phantom surface as described below.
 - b. Re-apply gel, then press **Scan Again**.
 - c. If the SNR is still below 10 after one or two re-scans, contact ENDRA Service prior to use.
16. When all data have been acquired and uploaded, press the **Back** arrow in the top left corner to return to the **Settings** menu screen.



17. Press the **Back** arrow again to return to the **Idle** screen.



CLEANING UP

When the System Check is complete, carefully remove the FLIP Probe from the Probe Holder. Clean the FLIP Probe and SysCk Phantom with a FLIP-compatible wipe. Refer to wipe manufacturer's instructions prior to use. Wipe down the contact surface of the phantom, cords, housings, and any other surface that was touched during the System Check (e.g., the touchscreen display, console, console power switch, integrated Probe/Monitor holder). Inspect the contact surface of the FLIP Probe for wear after cleaning as well.

NOTE: Alcohol-based wipes may erase some of the print on the product label.

Replace the cover on the phantom and return it to storage as described in the *Care and Handling* section above.