TAEUS® FLIP System User Guide - US

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ENDRA Life Sciences, Inc.

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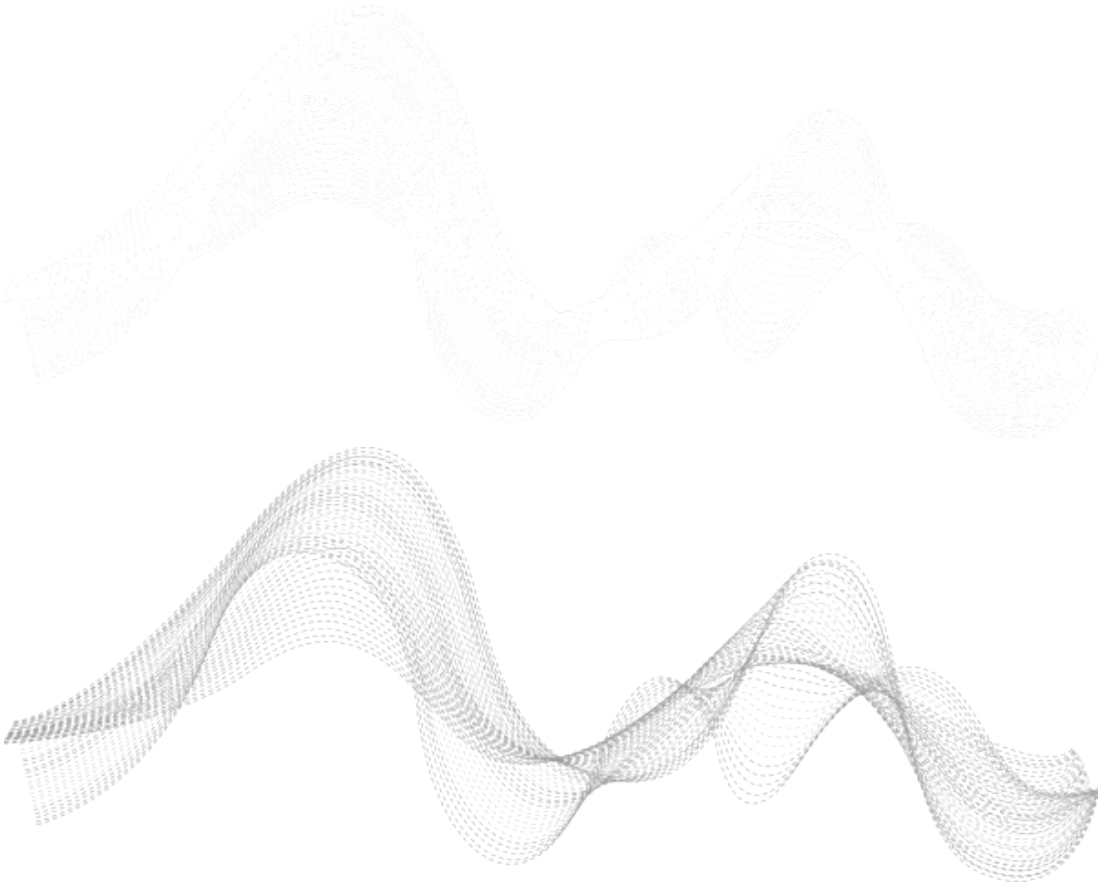

TAEUS® FLIP System User Guide - US

Part # EN5000

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Revision History

TAEUS® FLIP System User Guide - US

Part # EN5000

Revision History

ECO Number	Revision	Description
ECO-24-045	Rev. 1	Initial document release
ECO-25-002	Rev. 2	Addition of Investigational Device statement

Please verify that you are using the latest revision of this document. Visit https://docs.endrainc.com/ or scan the QR code below to download the latest documentation

Regulatory Information

Conformance Standards

The following classifications are in accordance with the IEC/EN 60601-1:

- According to 93/42/EEC Medical Device Directive, this is a Class IIa Medical Device
- According to IEC/EN 60601-1, Equipment is Class I, with BF Applied Parts
- According to CISPR 11, TAEUS® FLIP System is Class A, group 1 (commercial use only)
- Protection against electric shock:
- Class I ME EQUIPMENT, externally powered, type BF applied part (Probe)
- Protection against harmful ingress of water or particulate matter:
- FLIP Console IP20
- FLIP Probe IPX1 / IPX7
- FLIP Display IP43
- Two-pedal Footswitch IPX1
- Method(s) of sterilization:
- No sterilization is required
- Suitability for use in an OXYGEN RICH ENVIRONMENT:
- Not intended for oxygen-rich environments
- Mode of operation:
- Continuous

Original Documentation

- The original document was written in English

Important Notices

Investigational Device / To Be Used By Qualified Investigators Only
Instrument de recherche / Réservé uniquement à l'usage de chercheurs compétents

- It is essential that you read and understand all the information in this User Guide prior to using or maintaining the TAEUS® FLIP System.
- Do not attempt to setup the TAEUS® FLIP System alone. A trained ENDRA Life Sciences representative will setup the system. Contact service@endrainc.com if system re-location or disposal is required in the future.
- Do not modify any component of the TAEUS® FLIP System without authorization from ENDRA Life Sciences.
- This equipment may be used in hospitals, clinics and other institutions which are environmentally qualified. The use of this equipment in an inappropriate environment may cause some electronic interference to radios and televisions around the equipment.
- Precautions should be taken to ensure that the system is separated from strong sources of electromagnetic interference, such as strong transmitters, motors, etc. The system may fail to operate properly or display unexpected results if subject to large electromagnetic disturbances.
- Do not operate the TAEUS® FLIP System near life-support equipment (e.g., ventilators) which is sensitive to 434 MHz frequency.
- The TAEUS® FLIP System should not be used adjacent to or stacked with equipment other than specified in this user guide. If adjacent or stacked use is necessary, the TAEUS® FLIP System should be observed to verify normal operation in the configuration it will be used. Use of the TAEUS® FLIP System adjacent to or stacked with other equipment could result in improper operation.
- To avoid risk of electric shock, the system power must be supplied from a separate, properly rated supply mains with protective earth:
- A separate, grounded power outlet with an appropriate circuit breaker for ~100V, 60Hz, 1000VA.
- Under no circumstances should the AC power plug be altered, changed, or adapted to a configuration rated less than specified. Never use an extension cord or adapter plug.
- To ensure proper grounding of the system, connect to a "hospital grade" or "hospital only" grounded power outlet.
- The TAEUS® FLIP System should only be operated by qualified clinicians or other healthcare practitioners who have been trained by ENDRA Life Sciences. Contact ENDRA Life Sciences for training.

CHAPTER 1: Safety Precautions

This chapter describes the safety issues regarding the use and maintenance of the TAEUS® FLIP System.

ICON DESCRIPTION

Various levels of safety precautions may be found on the equipment and different levels of concern are identified by one of the following flag words and icons which precede the precautionary statement.

DANGER Indicates that a specific hazard is known to exist which through inappropriate conditions or actions will cause:

- Severe or fatal personal injury
- Substantial property damage.

WARNING Indicates that a specific hazard is known to exist which through inappropriate conditions or actions will cause:

- Severe or fatal personal injury
- Substantial property damage.

CAUTION Indicates that a potential hazard may exist which through inappropriate conditions or actions will cause:

- Minor injury
- Property damage.

NOTE: Indicates precautions or recommendations that should be used in the operation of the TAEUS® FLIP System, specifically:

- Maintaining an optimum system environment
- Using this Manual.
- Notes to emphasize or clarify a point.

HAZARD SYMBOLS

Potential hazards are indicated by the following icons:

ICON	POTENTIAL HAZARD	USAGE
	• Patient/user infection due to contaminated equipment	• Cleaning and care instructions • Glove guidelines
	• Electrical shock to user or patient	• Connections to rear panel of console
	• Patient injury or tissue damage from non-ionizing electromagnetic radiation.	• ALARA, the use of RF output following the 'as low as reasonably achievable' principle
	• Patient/user injury or adverse reaction from fire or smoke. • Patient/user injury from explosion and fire.	• Outlet guidelines

IMPORTANT SAFETY CONSIDERATIONS

The following topic headings (*Patient Safety*, *FLIP System Measurement Power Output,* and *Equipment and Personnel Safety*) are intended to make the equipment user aware of particular hazards associated with the use of this equipment and the extent to which injury can occur if precautions are not observed. Additional precautions may be provided throughout the manual.

WARNING Improper use can result in serious injury. The user must be thoroughly familiar with the instructions and potential hazards involving the TAEUS® FLIP System before attempting to use the device. Training assistance is available from ENDRA Life Sciences.

The equipment user should be familiar with these concerns and avoid conditions that could result in injury.

Disregarding information on safety is considered abnormal use.

Patient Safety

Usage Information

Equipment malfunction or incorrect settings can result in measurement errors or failure to detect details within the image. The equipment user must become thoroughly familiar with the equipment operation in order to optimize its performance and recognize possible malfunctions. Training is available through ENDRA Life Sciences.

WARNING Do not operate the TAEUS® FLIP System near life-support equipment (e.g., ventilators) which is sensitive to 434 MHz frequency.

Mechanical and Electrical Hazards

The use of a damaged FLIP Probe can result in injury or increased risk of infection. Inspect the FLIP Probe often for sharp, pointed, or rough surface damage that could cause injury or harm.

ELECTRICAL HAZARD

A damaged FLIP Probe can increase the risk of electric shock if conductive solutions come in contact with internal live parts. Inspect the FLIP Probe before each use for cracks or openings in the housing and holes that could allow liquid entry. Do not immerse the FLIP Probe in any solutions.

WARNING

The FLIP Probe is a sensitive instrument which can be damaged by rough handling. Take extra care not to drop the FLIP Probe and avoid contact with sharp or abrasive surfaces. A damaged housing or tether cable can result in patient injury. Avoid bending the tether cable beyond its natural bend radius while hanging. Inspect any part for damage if it has been dropped and contact service@endrainc.com.

TAEUS® FLIP System Measurement Power Output

CAUTION

Prolonged exposure to RF radiation can produce harmful effects in tissue and potentially result in patient injury. ENDRA has used the prinicple of ALARA (as low as reasonably achievable) in the development of the TAEUS® FLIP System.

The resulting pre-set TAEUS® FLIP System RF Measurement emissions are at safe levels when used as instructed.

Equipment and Personnel Safety

Related Hazards

WARNING This equipment contains dangerous voltages that are capable of causing serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact service@endrainc.com for information.

There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.

DANGER The concerns listed below can seriously affect the safety of equipment and personnel during an examination.

ELECTRICAL HAZARD

To avoid injury:

- Do not remove protective covers. No user serviceable parts are inside. Refer servicing to qualified service personnel.
- To assure proper grounding, connect the attachment plug to a suitable (hospital grade, where available) grounding outlet.
- Never use any adaptor or converter of a three-prong-to-two-prong type to connect with a mains power plug, as this could compromise proper grounding of the system.
- Do not sit on or place liquids on the console. Spilled liquid may contact live parts and increase the risk of shock.

CAUTION Do not use this equipment if a safety problem is known to exist. Have the unit repaired and performance verified by qualified service personnel before returning to use. Contact service@endrainc.com for information.

CAUTION To avoid injury or system damage, do not sit on or place any object or liquid on the Console cabinet.

CAUTION

- Do not scratch or press on the touchscreen Display Panel with any sharp objects, such as a pencil or pen, as this may result in damage to the panel.
- The touchscreen Display Panel may have defective pixels. These pixels may appear as a slightly light or dark area on the screen. This is due to the characteristics of the Display Panel itself, and not the product.
- The backlight of the touchscreen Display Panel has a fixed life span. When the screen becomes dark or begins to flicker, contact a qualified ENDRA Service Representative.

DEVICE LABELS

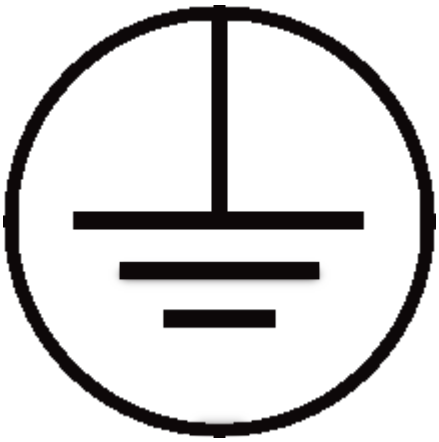
Label Icon Description

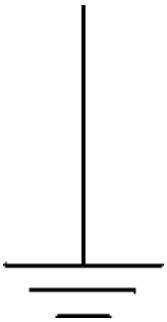
The following table describes the purpose and location of safety labels and other important information provided on the equipment.

Label/Icon	Purpose/Meaning	Location
	Manufacturer's name and address	Console, FLIP Probe, Display Panel
		
	Date of manufacture	Console, FLIP Probe, Display Panel
		

	Serial Number	Console, FLIP Probe, Display Panel
	Catalog Number	Console, FLIP Probe, Display Panel
Type/Class Label	Used to indicate the degree of safety or protection.	Console
	United States only Prescription Requirement label	Console, FLIP Probe, Display Panel
	WARNING: Non-ionizing radiation	Console
	No access for people with active implanted cardiac devices	Console
	No access for people with metallic implants	Console

	No sitting	Console
	Type BF Applied Part symbol is in accordance with IEC 60417-5333	FLIP Probe
	Type B Applied Part symbol is in accordance with IEC 60517-5333	Console
	"ATTENTION" - Consult accompanying documents is intended to alert the user to refer to the operator manual or other instructions when complete information cannot be provided on the label	Console, FLIP Probe
	"General Warning Sign"	FLIP Probe
	"Warning" - Dangerous Voltage (the lightning flash with arrowhead) is used to indicate electric shock hazards	Console

		
	"Mains OFF" indicates the power off position of the mains power breaker.	Rear of Console
	"Mains ON" indicates the power on position of the mains power breaker.	Rear of Console
	"OFF" indicates the power off position of the power switch. CAUTION: This Power Switch DOES NOT ISOLATE Mains Supply.	Front of Console
	"ON" indicates the power on position of the power switch. CAUTION: This Power Switch DOES NOT ISOLATE Mains Supply.	Front of Console
	"Protective Earth" indicates the protective earth (grounding) terminal	Console
	"Functional Earth" indicates the terminal to be used for connecting equipotential conductors when interconnecting (grounding) with other equipment.	Console

		
	This "WEEE" symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact ENDRA for information concerning the decommissioning of your equipment.	Console, FLIP Probe, Display Panel
	Connection terminal (USB-A) for optional footswitches.	Console
	Connection terminals for FLIP Probe.	Console
	Connection terminal (USB-A) for the touchscreen display monitor.	Console

CLASSIFICATIONS

The FLIP Probe is a TYPE BF APPLIED PART providing a required degree of protection against electric shock when in contact with the patient surface.

The FLIP Console provides an adequate degree of protection for a protectively earthed TYPE B APPLIED PART, which provides a specified degree of protection against electric shock when touched.

Table 1-1: Type B and BF Equipment

	Normal Mode	Single fault condition
Patient leakage current	Less than 100 µA	Less than 500 µA

EMC (Electromagnetic Compatibility)

The TAEUS® FLIP System intentionally radiates radio frequency energy. Observe other electronic medical equipment and non-medical devices in the vicinity during TAEUS® FLIP System activation for any possible adverse electromagnetic effects. Ensure adequate separation of electronic equipment based on observed reactions. There is no guarantee that interference will not occur in a particular location.

NOTE: If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measures:

- Reorient or relocate the affected device(s).
- Increase the separation between the equipment and the affected device.
- Power the equipment from a source different from that of the affected device.
- Consult the point of purchase or ENDRA service representative for further suggestions.

EMC Performance

All types of electronic equipment may emit electromagnetic energy, potentially interfering with other equipment. Interference is either radiated (transmitted through air), or conducted (via connecting cables, or conductive contact). The term EMC (Electromagnetic Compatibility) describes a device's susceptibility to electromagnetic influence from external sources and at the same time limiting its ability to affect other equipment via electromagnetic emission from itself.

Proper setup is required in order to achieve the full EMC performance of the product.

In case of issues related to EMC, please contact ENDRA service.

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment.

Unauthorized changes or modifications could affect the safe usage of the equipment.

CAUTION

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TAEUS® FLIP System, including cables specified by the manufacturer. Otherwise, degradation of the performance of the system could result.

Medical staff in charge of this equipment is required to instruct technicians, patients and other people who may be around this equipment to fully comply with the above regulation.

Notice upon Setup of Product

Separation distance and effect from fixed radio communications equipment

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast transmitter cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level as stated in the immunity declaration, the system should be observed to verify normal operation. If abnormal operation is observed additional measures may be necessary, such as re-orienting or relocating the system or using an RF shielded examination room may be necessary.

Declaration of Emissions

This system is suitable for use in the environment indicated in *Table 1-2*, below. The user must assure that it is used only in the electromagnetic environment as specified.

Table 1-2: Declaration of emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The system is intended for use in the environment specified below. The user of the system should ensure that it is used in such an environment.

Emission Type	Compliance	Electromagnetic Environment
RF Emissions CISPR 11	Group 1 when idle/not performing measurement	
	Group 2 when performing measurement	
RF Emissions CISPR 11>	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communications services. The user might take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC-61000-3-3	Complies	

Declaration of Immunity

This system is suitable for use in the environment indicated in *Table 1-3* below. The user must assure that the system is used according to the specified guidance and only in the electromagnetic environment listed.

Table 1-3: Declaration of Immunity

Immunity Type	Test Method	Achieved Professional Healthcare Facility Environment Compliance Level	EMC Environment and Guidance
Electrostatic Discharge	IEC-61000-4-2:2008	± 2, ± 4, ±8, ± 15 kV Air ± 8 kV for Contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Mains power quality should be that of a typical commercial and/or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the system be powered from a UPS or a battery. NOTE: UT is the A.C. mains voltage prior to application of the test level. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment. Separation distance to radio communication equipment must be maintained according to the method below. Interference may occur in the vicinity of equipment marked with the symbol: 
Radiated RF Immunity	IEC 61000-4-3:2006+AMD1:2007+AMD2:2010	3 V/m at 80 MHz to 2.7 GHz	
Immunity for proximity fields from RF wireless communications equipment	IEC 61000-4-3:2006+AMD1:2007+AMD2:2010	380 to 5800 MHz, 5 sec dwell	
Electrical Fast Transient/ Burst (Repetition frequency 100 kHz)	IEC 61000-4-4:2012	±2 kV at AC Power Lines	
Surge Transient	IEC 61000-4-5:2014+AMD1:2017	± 0.5 kV, ±1 kV, ±2 kV line-to-earth at AC/ DC Power Lines ± 0.5 kV, ±1 kV line-to-line at AC Power Lines	
Conducted Immunity on all ports	IEC 61000-4-6:2013	3Vrms at 150 kHz - 80 MHz AC/DC/Signal lines 6 Vrms at ISM bands between 150 kHz - 80 MHz	
Conducted Immunity on patient coupling port	IEC 61000-4-6:2013	150 kHz - 80 MHz and 480.0498 kHz at 3 Vrms and ISM Band at 6 Vrms, 10 sec dwell time.	
Power Frequency Magnetic Field	IEC 61000-4-8:2009	30 A/m; 50/60 Hz	
Voltage Dips and Interruptions	IEC 61000-4-11:2004+AMD1:2007	0%, 0.5 Cycle 0%, 1 Cycle 70% 25/30 Cycles at 50/60Hz	

		0% 250/300 Cycles (Interruption at 50/60Hz
Immunity to proximity magnetic fields	IEC 61000-4-39:2017	134.2kHz Pulse Modulation 2.1kHz 65A/m and 13.56MHz Pulse Modulation 50kHz 7.5A/m

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. If noise generated from other electronic equipment is near the FLIP Probe's center frequency, noise may appear on the image. Good power line isolation is required.

CHAPTER 2: Introduction

INTENDED USE

The ENDRA TAEUS® FLIP System is intended to be used as a non-invasive tissue characterization tool for the assessment of the presence of fatty tissue with a differing permittivity from that of normal tissue by emitting pulsed radio frequency (RF) energy from which a thermoacoustic response is received and analyzed.

The TAEUS® FLIP System is a non-invasive tissue characterization tool, when used in conjunction with conventional ultrasound, that computes a ThermoAcoustic-derived Absorption Parameter (TAAP) estimate and computes and displays a corresponding fat fraction estimate that provides tissue permittivity properties of the liver, where increasing levels of fatty tissue result in decreasing TAAP values.

NOTE: TAAP is a TAEUS® FLIP System defined term that is used to represent the estimated conductivity of the tissue region of interest (based on signals measured with the TAEUS® FLIP System).

USERS AND ENVIRONMENT

Users of the TAEUS® FLIP System are qualified clinicians or healthcare practitioners. Users should have at least a basic ultrasound knowledge, including location of the liver.

The TAEUS® FLIP System is used during an ultrasound exam, in healthcare facilities, primarily clinician exam offices, ultrasound suites, and ambulatory care facilities.

The TAEUS® FLIP System may be used with any ultrasound system that is capable of abdominal and, more specifically, liver imaging.

CONTRAINDICATIONS

The TAEUS® FLIP System should not be used:

- In patients with implanted electromechanical devices, such as life sustaining implants or devices.
- In patients with metal implants, screws, plates, stent, coil, shrapnel, mesh, etc.
- In patients with broken or injured skin in the right upper abdominal quadrant.
- In patients with subcutaneous fat at measurement location less than or equal to 6mm.
- In patients with a missing liver lobe.
- In patients with ascites, or peri-hepatic fat, in the measurement location.
- In patients with focal liver lesions or anatomical structures in the measurement location, as detected by ultrasound.
- In women who are pregnant, believe they may be pregnant, or are trying to become pregnant.

PRINCIPLE OF OPERATION

Thermoacoustics

Thermoacoustics is a scientific term describing the use of time-varying electromagnetic radiation to generate pressure waves in tissue. The waves may be detected with conventional ultrasound transducer arrays and used to create molecular-contrast signals related to the tissue composition or processed into measures presenting various tissue properties.

TAEUS® FLIP System Principle of Operation

The TAEUS® FLIP System uses RF excitation to generate a measureable response. The TAEUS® FLIP System transmits short radio pulses, using a small fraction of the energy used in MRI scans, which are differentially absorbed in tissue according to water and ion content (conductivity). The short radio pulses are converted by absorption in the tissue into acoustic pressure waves. The resulting signals are acquired by the system's ultrasound acoustic receiver, processed, and displayed to the user as a Thermoacoustic-derived Absorption Parameter (TAAP) value (representing estimated liver conductivity) after a complete scan (i.e., FLIP Preview Scan, FLIP Measurement Scan) has occurred.

TAEUS® FLIP System for Fatty Liver

In anatomical regions where the liver is in contact with muscle, such as the boundary between the intercostal muscle and the liver capsule, a strong thermoacoustic signal may be measured. The amplitude of this thermoacoustic signal is strongly dependent on the liver fat content. As the liver fat content increases, the differential in absorbed energy between the muscle and liver increases. This increased differential in absorbed energy between the muscle and liver increases. This increased differential results in an increase of the induced thermoacoustic signal. This relationship is shown in ***Figure 2-1***.

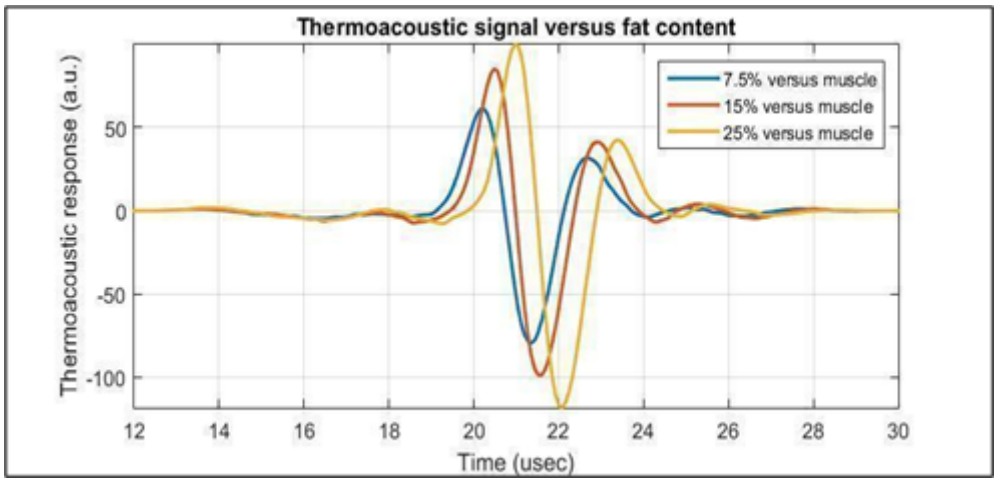


Figure 2-1: Thermoacoustic Signal Strength and Fat Content Relationship

TAEUS® FLIP System Signal Measurement and Processing

The algorithm used within the TAEUS® FLIP System uses the ratio of fat-to-muscle and muscle-to-liver signal amplitudes to estimate the conductivity of the liver tissue region. The signal amplitudes are generated from a single scan (i.e., FLIP Preview Scan, FLIP Measurement Scan) and are a function of the material properties (such as RF absorption) and the electric field present in the materials.

The RF absorption properties of fat and muscle are known and independent of the liver fat fraction, while the RF absorption properties of the liver and electric field distribution of the tissue are unknown. The electric field depends on the body habitus and the liver fat fraction. In order to estimate the unknown properties of the model, the TAEUS® FLIP System algorithm uses a simulated set of electric field models, which is derived from computational commercial simulation software (Ansys HFSS), performed for 175 different combinations of body habitus and liver fat.

The user input of fat/muscle and liver capsule boundary locations, obtained via ultrasound scan, define the body habitus and are used to obtain a subset of electric field models via interpolation. Thus, this subset of electric field models matches the current patient's body habitus and only depends on the liver fat.

The TAEUS® FLIP System estimates TAAP values and the corresponding liver fat fraction by acquiring thermoacoustic signals from the liver and overlying tissues (skin, fat, and muscle) and fitting a combination of electric field model and corresponding fat fraction to the recorded thermoacoustic signals.

TAEUS® FLIP SYSTEM: TECHNOLOGY AND COMPONENTS

The TAEUS® FLIP System combines a pulsed RF source, operating at a center frequency of 434 MHz, and an RF Applicator that delivers the RF energy efficiently into the tissue where a portion of the energy is absorbed and converted into an emitted acoustic response. The FLIP Probe's integrated ultrasound acoustic receiver records this response, and the TAEUS® FLIP System uses it to estimate the liver conductivity, referred to as TAAP. TAAP = conductivity/εOω, where εO is the permittivity of free space, and ω = 2πƒ (ƒ is the frequency of the RF excitation). For the TAEUS® FLIP System nominal parameters, TAAP = 41.42 x conductivity. Liver Conductivity is an electromagnetic tissue property that is strongly dependent on fat content.

The TAEUS® FLIP System enables the generation, display, and review of a TAAP value and fat fraction estimate (***Figure 2-2***) when used in conjunction with a commercially available B-mode ultrasound imaging system.

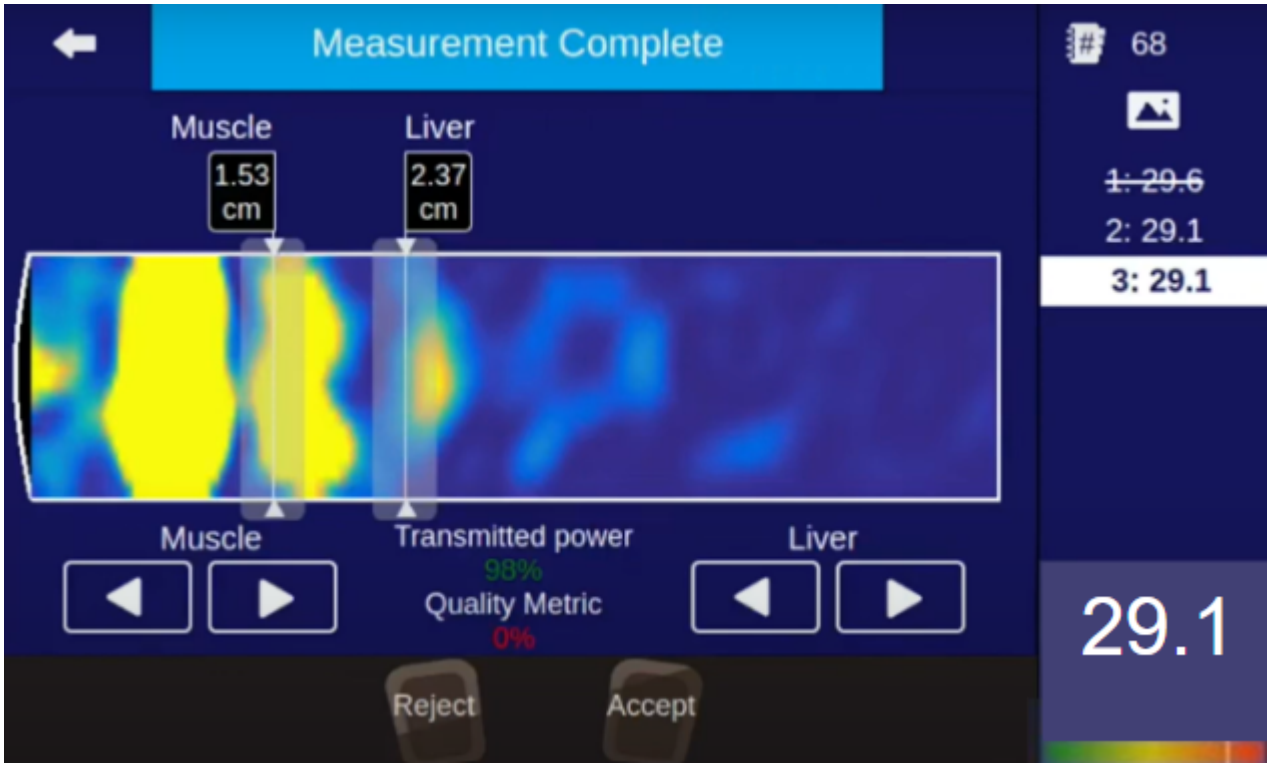


Figure 2-2: Representative GUI Display

The TAEUS® FLIP System consists of four primary components:

1. **FLIP Console**: A cart-mounted component that contains an RF source, power source, electronics, and software/firmware.

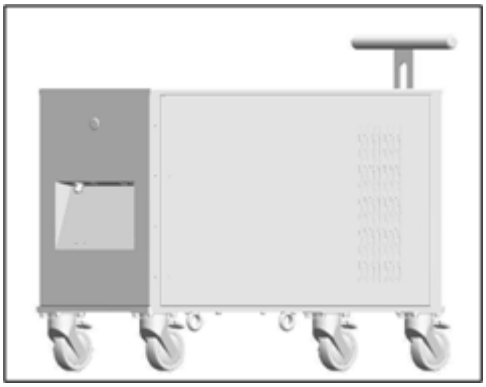


Figure 2-3: FLIP Console

2. **FLIP Probe**: A handheld component that includes a cable that connects to the FLIP Console, a patient-contacting RF applicator and ultrasound acoustic receiver, and electronics.

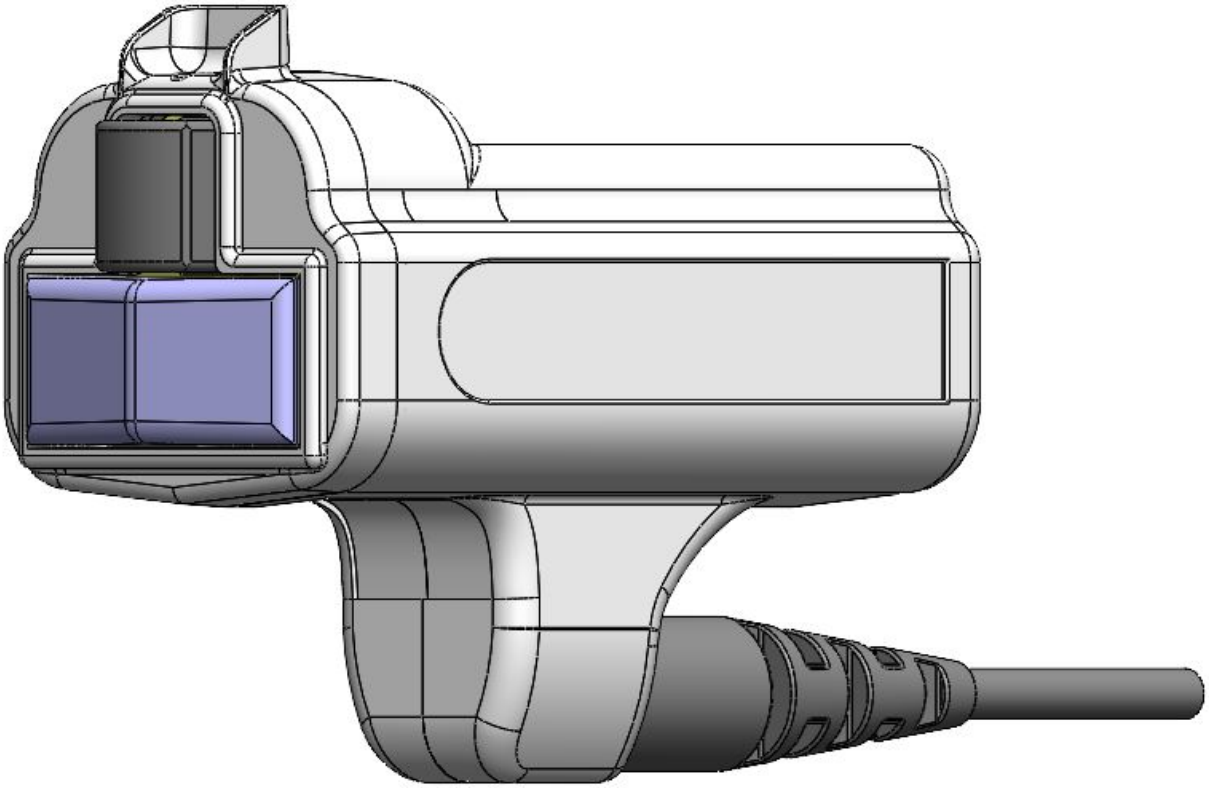


Figure 2-4: FLIP Probe

3. **FLIP Display**: A touchscreen monitor that is the graphical user interface and input device of the system.

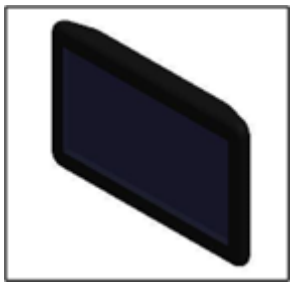


Figure 2-5: FLIP Display

4. **Two-pedal Footswitch**: A foot pedal that provides an alternative user input option for measurement acquisition (optional).

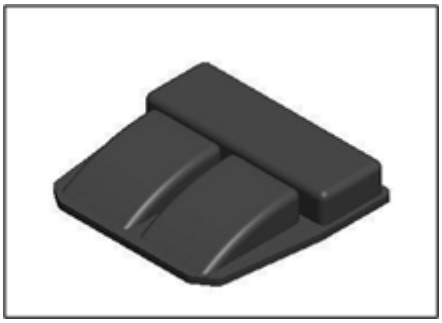


Figure 2-6: Two-pedal Footswitch, an optional component

NOTE: The TAEUS® FLIP System components are connected via four connection points:

1. FLIP Probe connection via HN and Lemo connectors on the FLIP Console connector alcove;
2. FLIP Display connection via USB-A connector on the FLIP Console connector alcove;
3. Two-pedal Footswitch connection via USB-A connector on the FLIP Console connector alcove; and
4. Main power connection via Mains inlet power connector on the FLIP Console chassis back panel

NOTE: The two USB-A ports on the FLIP Console are dedicated connectors for the FLIP Display and the Two-pedal Footswitch (optional). Users should not connect any other devices to these ports.

NOTE: The FLIP Display is not intended to be used to display images for diagnostic purposes.

NOTE: The Main Power switch on the rear of the FLIP Console is used to connect/disconnect the system to the building's mains. Leave sufficient space to access the Main Power switch on rear of FLIP Console, so that a means of isolating internal circuits from mains is readily accessible. An alternate method of isolating the system from mains is to unplug the device.

BASIC WORKFLOW

The TAEUS® FLIP System is intended to be used in conjunction with an ultrasound system. To complete a FLIP Study, the following steps occur:

- The anatomical measurement location is identified using a ultrasound system curved array probe and may be optionally marked on the patient for ease of repeat placement.
- Using a ultrasound system linear array probe, the distances from the patient's skin surface to the fat/muscle boundary and to the liver capsule, respectively, are measured in millimeters.
- The user switches to the TAEUS® FLIP System, first inputting the recorded measurement values ("Muscle" and "Liver"), as instructed by the TAEUS® FLIP System GUI.
- The user then performs FLIP Preview Scans and FLIP Measurement Scans, with quality checks, to complete the FLIP Study and generate a TAAP value and estimated fat fraction result for the patient.

Figure 2-7 outlines this workflow in greater detail.

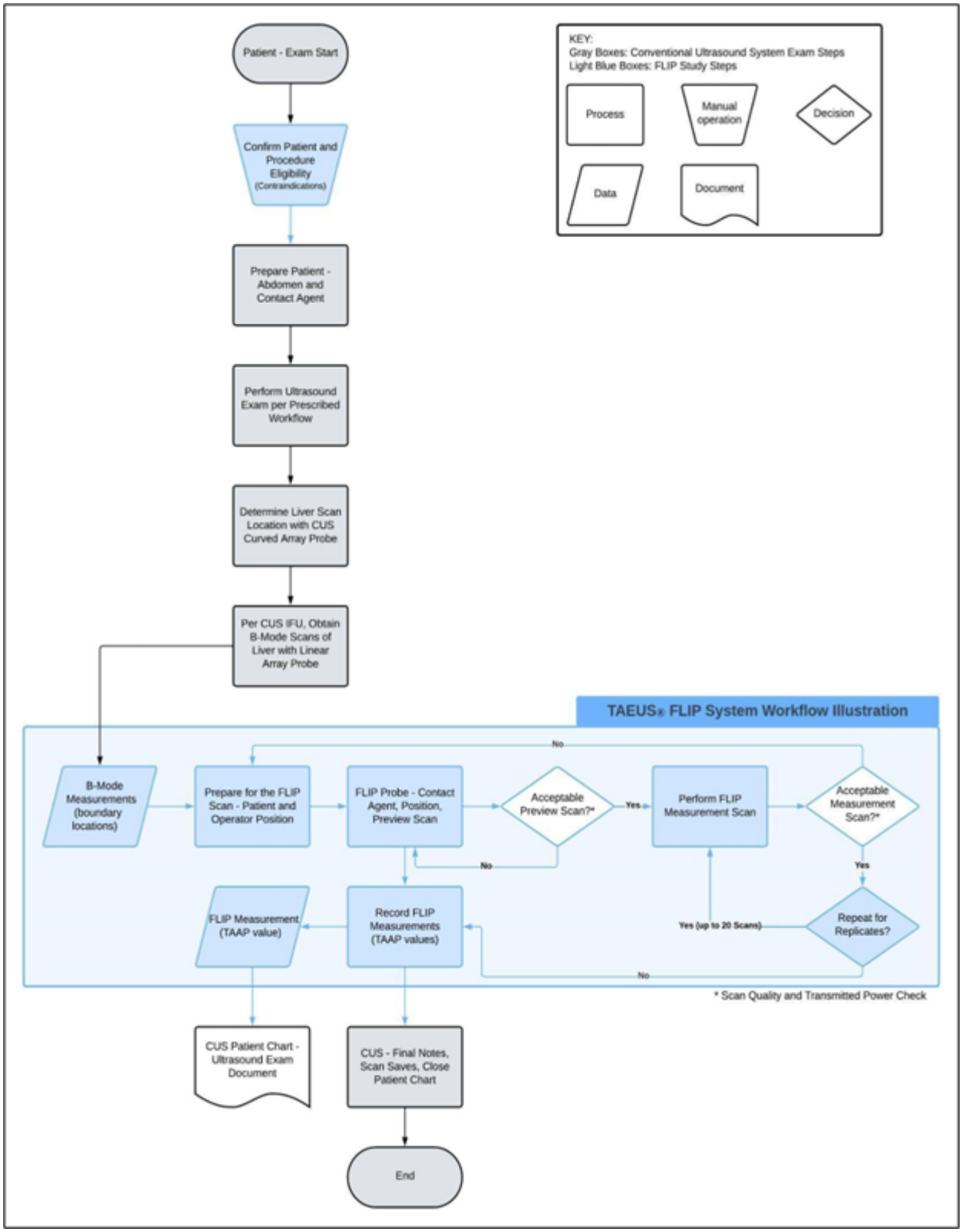


Figure 2-7: TAEUS® FLIP System Workflow

Specific instructions are provided in the following chapter.

CHAPTER 3: Operating Instructions

INTRODUCTION

This chapter describes how to use the TAEUS® FLIP System in conjunction with an ultrasound system.

Users should be familiar with all relevant operating procedures and clinical limitations before attempting to operate the ultrasound system.

NOTE: The TAEUS® FLIP System should only be operated by qualified and trained healthcare practitioners with at least basic ultrasound knowledge. Before use, users should read and understand this User Guide and be trained by ENDRA Life Sciences.

NOTE: The user is responsible for informing the patient about any warnings, hazards, precautions, contraindications, measures to be taken, and limitations of use as described in preceding chapters.

Interaction with the Ultrasound System

FLIP Measurements are derived from the thermoacoustic signals measured at the boundary between subcutaneous fat and the muscles within the intercostal space and the boundary between the intercostal muscles and liver capsule. B-mode images from an ultrasound system are used to determine:

- A suitable anatomical placement for the FLIP Probe
- The distance of the fat/muscle and muscle/liver interface from the skin surface

Accurate placement and B-mode measurements are both critical for obtaining FLIP Measurements of good quality.

A conventional curved array ultrasound system transducer should be used to determine a suitable region of interest (ROI) for the FLIP Probe. A linear array transducer, however, provides more contrast at shallower depths than a curved array, leading to better discrimination of the boundary between subcutaneous fat and muscles within the intercostal space. Users are advised to use a linear array probe to obtain more accurate B-mode measurements.

Factors for a Successful Measurement

In addition to accurate B-Mode measurements, quality FLIP Scans also depend on several other factors:

- Patient positioning
- Clinical positioning with respect to the patient
- Proper ultrasound system imaging technique and patient breath management
- Proper placement of the FLIP Probe on the patient
- Intercostal position confirmation
- Consistent and repeatable patient breath holding for scans
- Replication of a valid measurement

Materials and Equipment

The following materials and equipment are recommended for best results:

- Height-adjustable examination table or stretcher
- Height-adjustable scan chair for the user
- Pillow
- Permanent marker or surgical pen
- Curved array ultrasound system probe (for determining FLIP ROI)
- Linear array ultrasound system probe (for B-mode measurements)
- 45° body sponge (if available), for easier patient positioning

SYSTEM STARTUP/PREPARATION

Before powering up:

- Examine the FLIP Console main power cable for cuts or abrasions.
- Examine the full length of the FLIP Probe tether cable for cuts or abrasions.
- Examine the FLIP Probe enclosure for cracks.
- Inspect the FLIP Probe's patient-contacting surface for cracks, holes, sharp edges, and/or adhesive peeling or blistering.
- Check that the FLIP Probe is connected to the FLIP Console (visual confirmation).

ELECTRICAL HAZARD

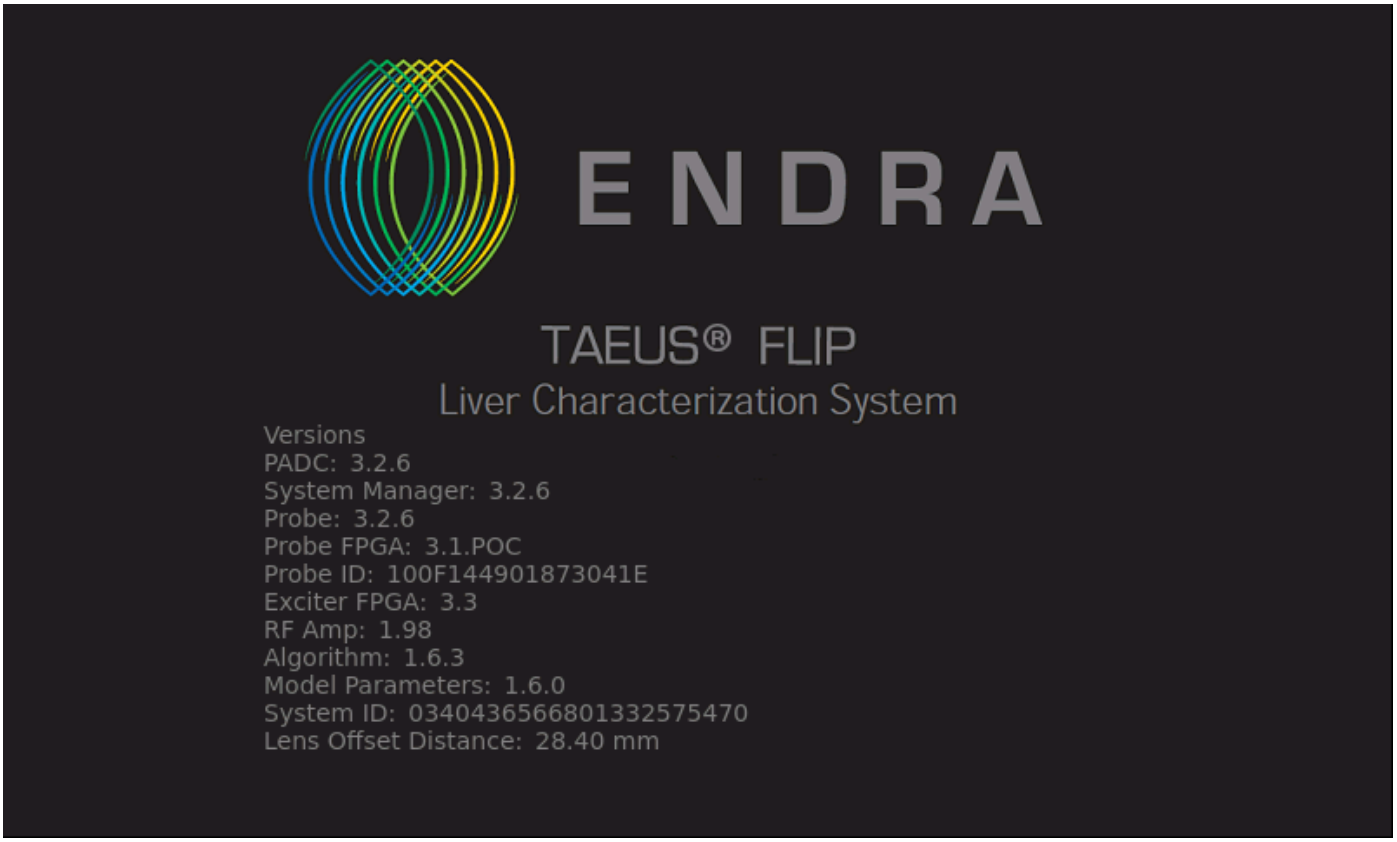
Do not operate the equipment if any defects are observed. Contact a qualified service person at service@endrainc.com for assistance.

If no defects are observed:

1. Press the flashing white Power button on the FLIP Console.

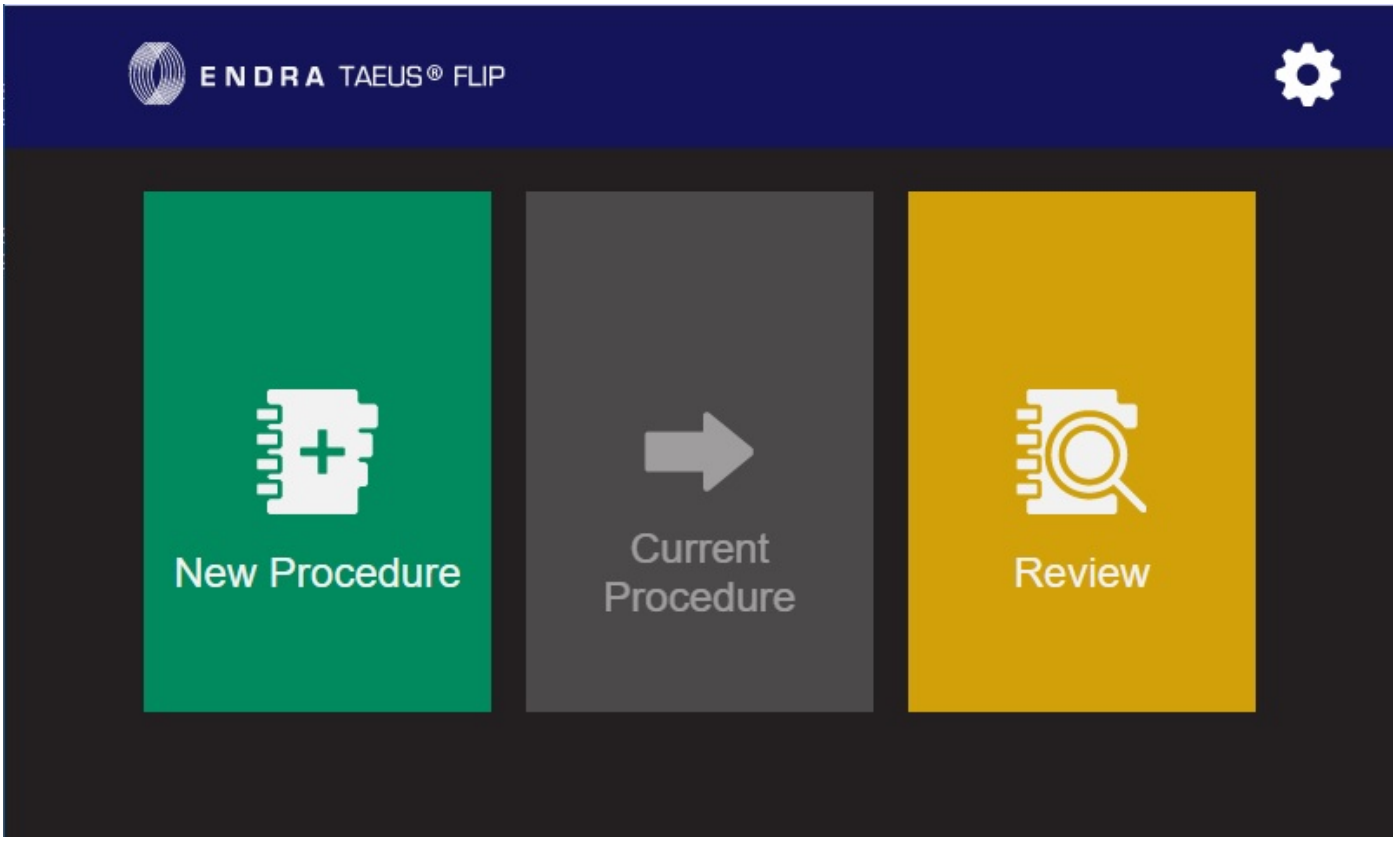
NOTE: If the Power button is not illuminated, ensure that the Main Power switch on the rear of the FLIP Console is turned on.

2. The TAEUS® FLIP splash screen will appear on the FLIP Display while the system performs various power-on system tests and initializes system components.



An LED indicator light on the FLIP Probe flashes blue during this process.

3. The **Idle** screen appears after a few seconds:



Available Operations:

New Procedure -- Press to initiate a FLIP Study with a new patient.
Current Procedure -- Press to resume a FLIP Study with current patient.
Review -- Press to view data from a previous FLIP Study.

NOTE: Only the **New Procedure** and **Review** options are available at start-up.

4. The TAEUS® FLIP System is now ready to operate as described below in **3.7 FLIP SCAN**.

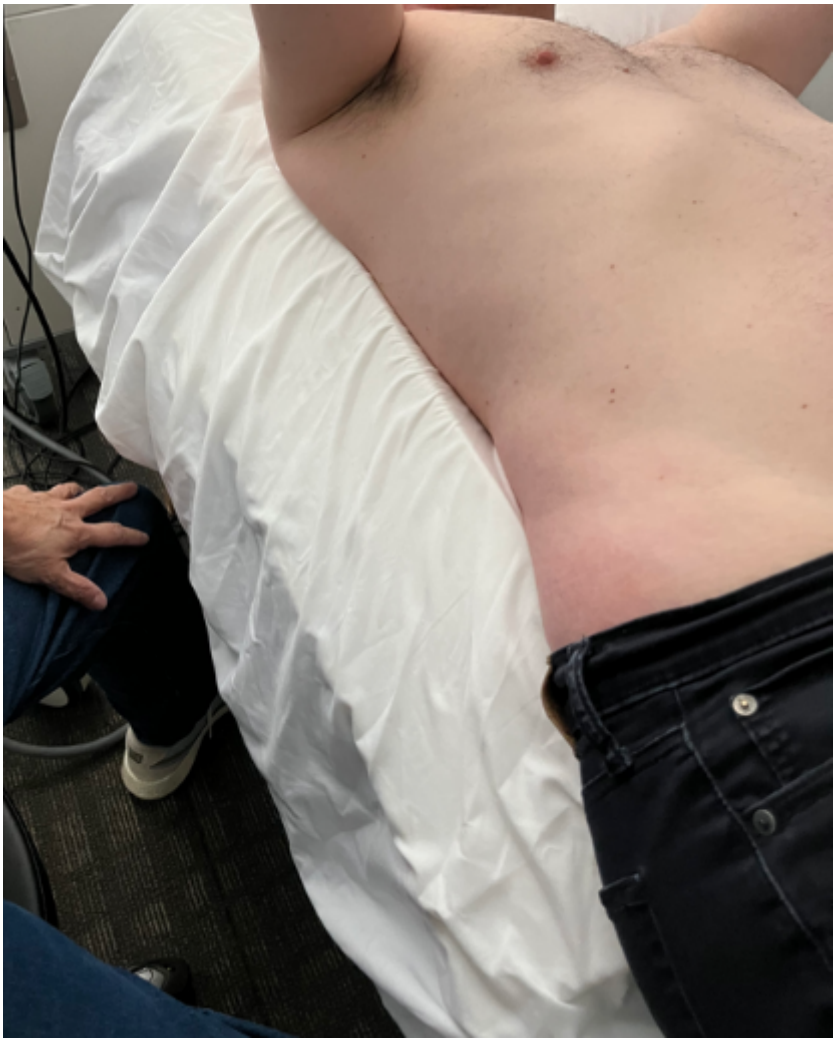
PATIENT PREPARATION

1. Review contraindications with the patient.
2. Enter patient information as instructed for the ultrasound system exam.

CAUTION Microwave energy should not be applied to persons wearing metallic jewelery or clothing containing metallic material. Hearing aids should be removed.

Patient Positioning

1. If available, place a 45° body sponge lengthwise on the examination table. This should be placed just below the patient's pillow.
2. Lie the patient on the examination table against the body sponge. Ensure the shoulders, chest, and body are resting on the sponge.
3. Roll the patient 45° away from the user.



User Positioning

1. Adjust the scan chair and examination table heights and location to allow the user to sit close to and at 45° to the table/patient, so that the user can see the FLIP Display easily.
2. Ensure adequate clearance for user knees and legs.
3. Adjust the (optional) Two-pedal footswitch or FLIP Display location to allow easy access and minimal movement when initiating a FLIP Measurement.
4. Rest the forearms against the body sponge or on the edge of the examination table for support while scanning. Arm abduction should not exceed 30°.

B-MODE IMAGE ACQUISTION WITH CURVED ARRAY - GUIDANCE

The curved array acquisition is used to determine a suitable anatomical placement for the FLIP Probe:

1. Per the ultrasound system instructions, configure the ultrasound system for B-Mode scanning.
2. Recommendations for location of the liver for ultrasound imaging is presented below. Refer to the ultrasound system instructions for more information:

   a. To locate the region for liver fatty tissue assessment, palpate the inferior edge of the xyphoid process, move laterally to the right upper quadrant (RUQ) and locate the intercostal space.

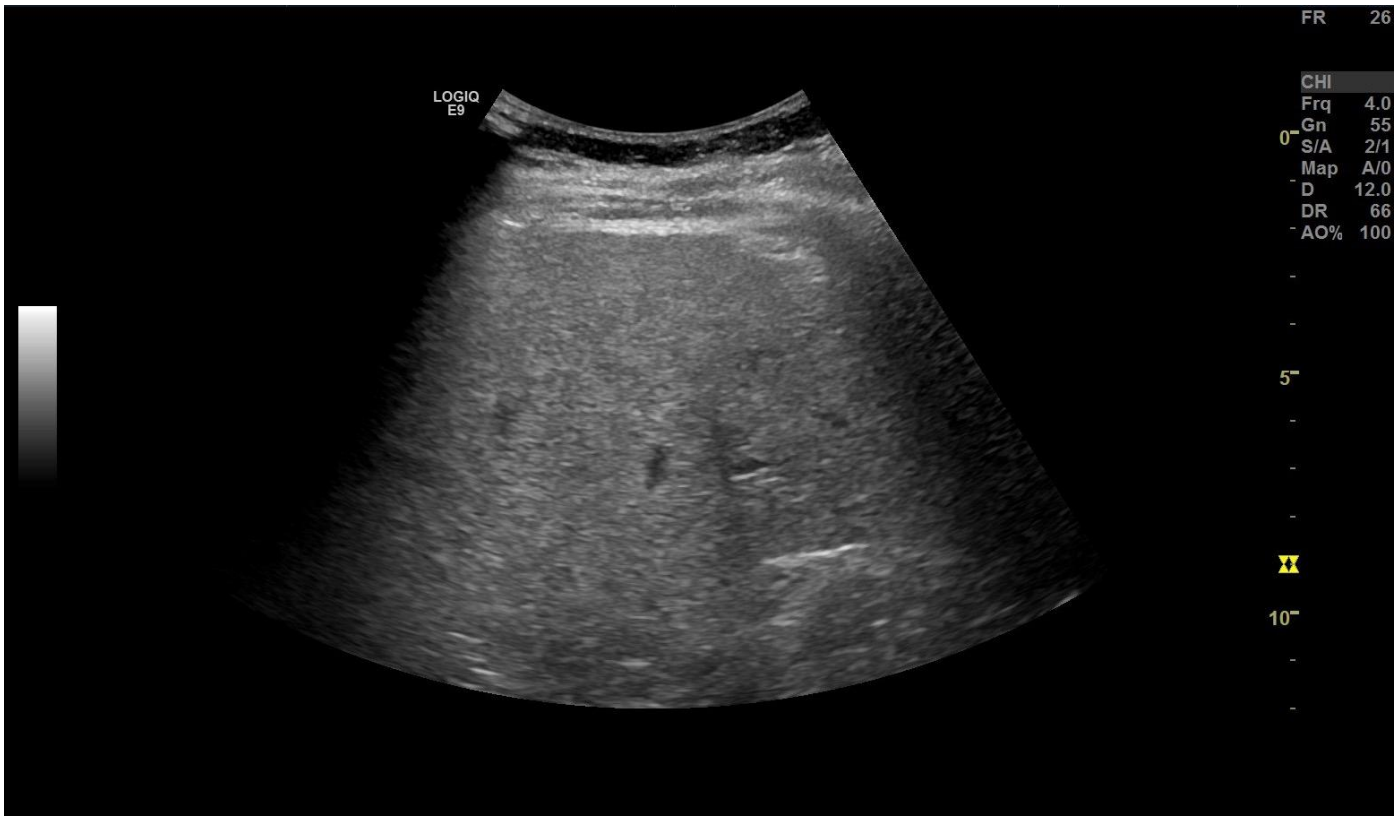
   b. Apply ultrasound gel to the scan area, per ultrasound system instructions.

   c. Do not tilt the ultrasound system probe while scanning. Hold the ultrasound system probe perpendicular to the patient contact surface.

   d. Ask the patient to exhale and then pause breathing. Scan 2-3 intercostal windows in the RUQ while breathing is paused.

   e. An appropriate B-Mode view shows clear delineation of the abdominal muscle/liver interface, with no lung, gall bladder or vessels in the field of view. The surface of the liver should be as parallel as possible with the probe.

   f. Freeze the B-Mode image.

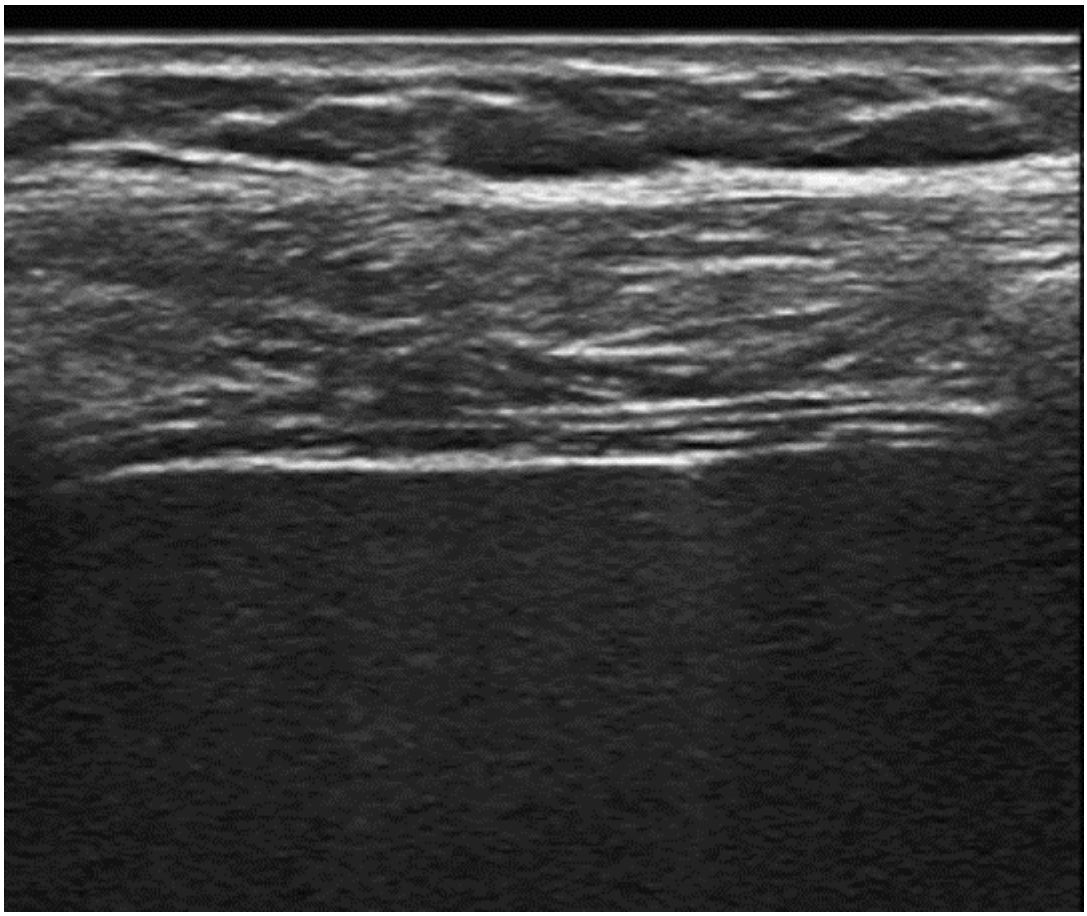


3. Before removing the ultrasound system probe, mark both ends of the probe with a surgical pen or permanent marker. This is where the FLIP Probe will be positioned for the thermoacoustic scan.

B-MODE IMAGE ACQUISITIONS WITH LINEAR ARRAY -- GUIDANCE

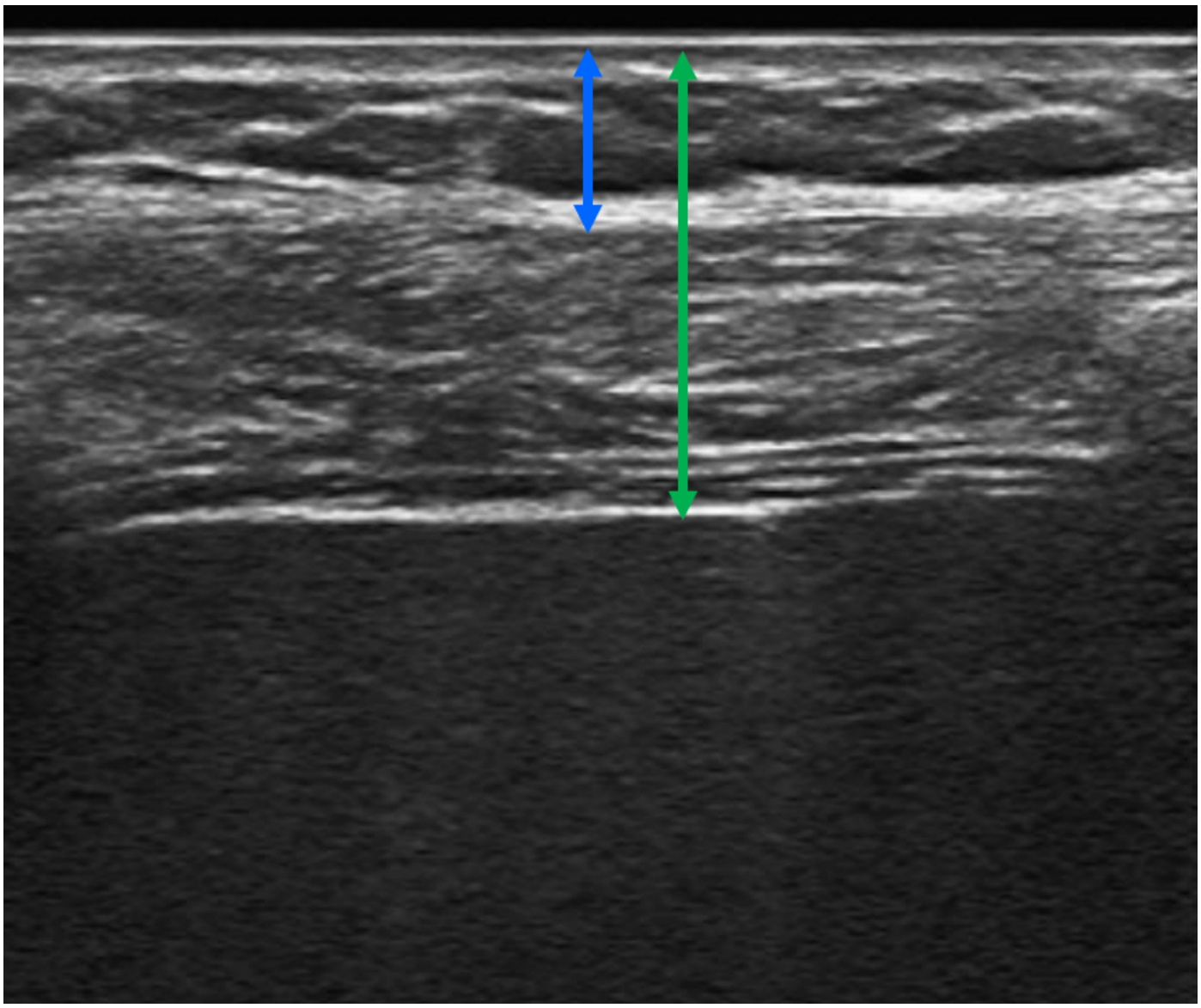
The linear array acquisition is recommended to determine the distance of the fat/muscle boundary and the liver capsule from the skin.

1. Place the linear array ultrasound system probe on the patient's abdomen so that it is in the same location and orientation as the curved probe was in, using the applied markings.
2. Ask the patient to exhale and then pause breathing.
3. Freeze the image.



BOUNDARY DETERMINATIONS

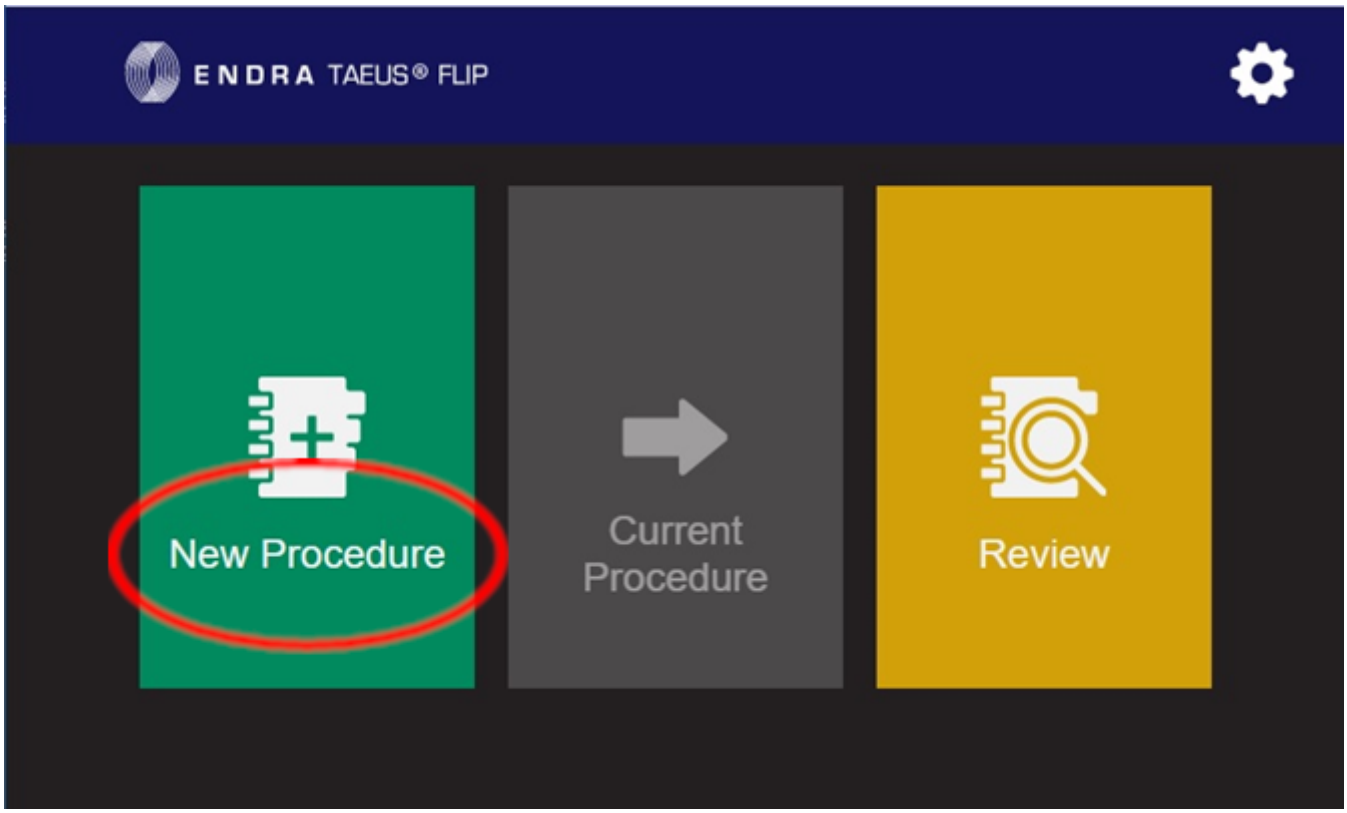
1. Measure the distance from the skin to the fat/muscle boundary (blue) and liver capsule (green).



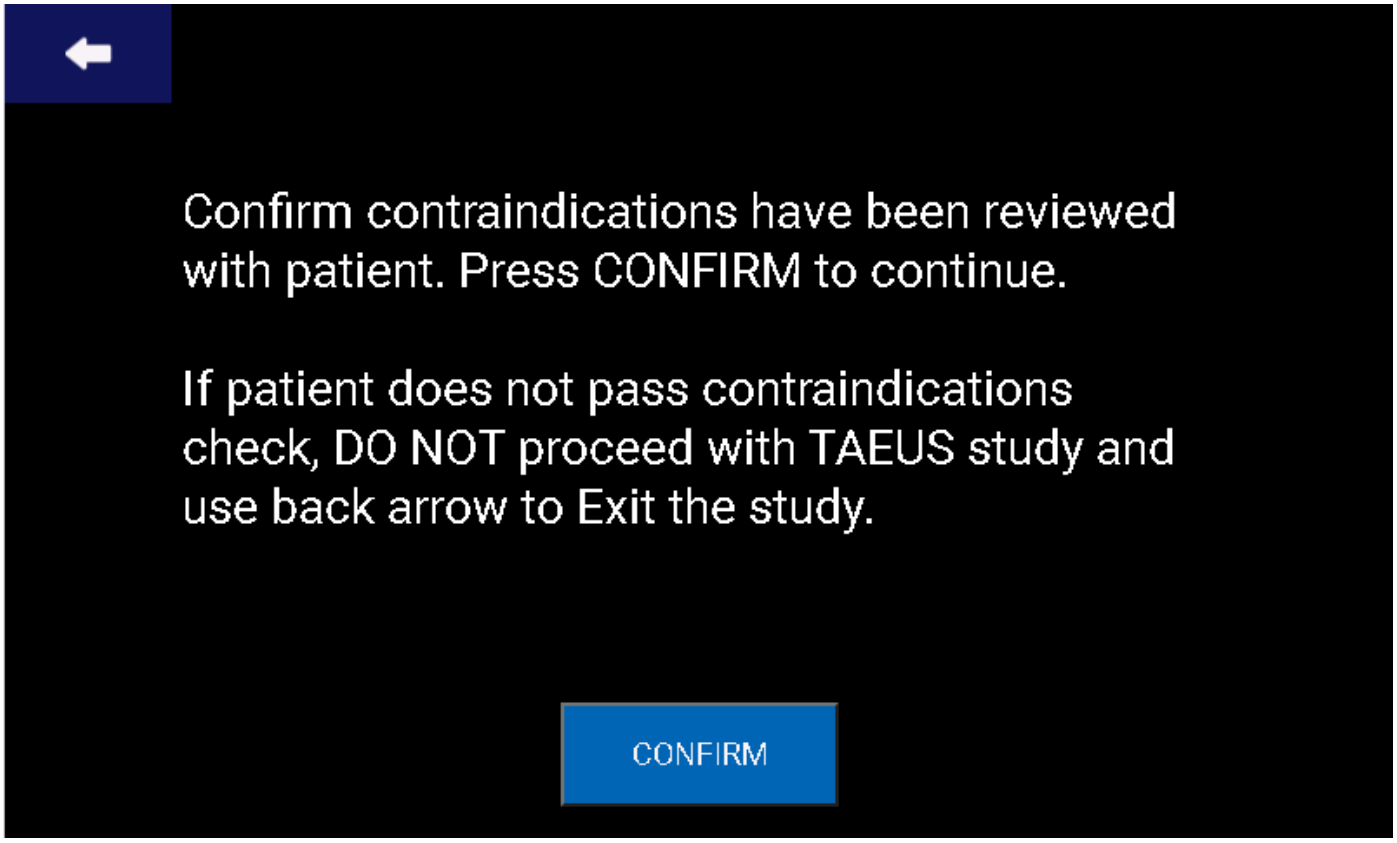
2. Record the two measurements.

FLIP SCAN - GUIDANCE

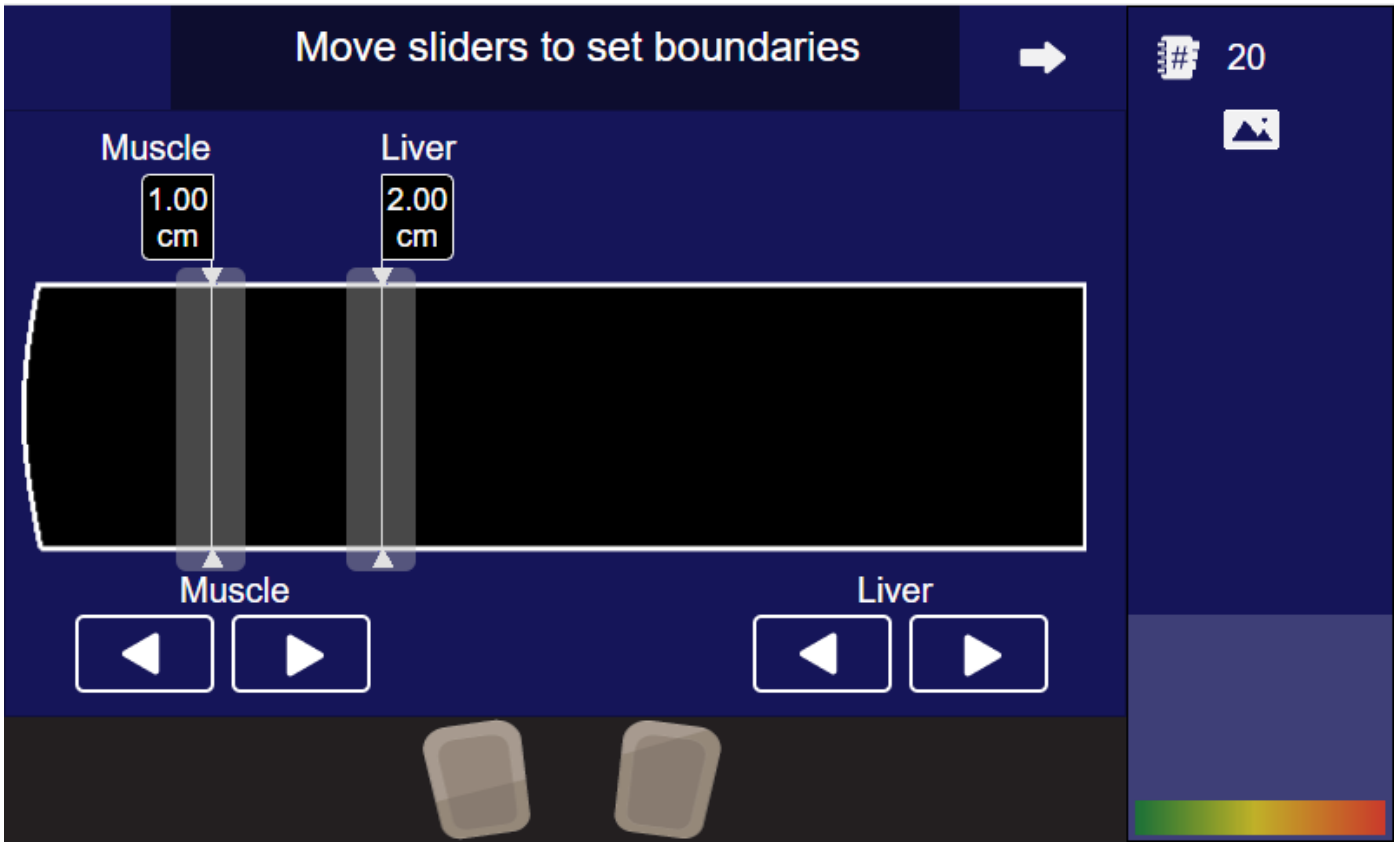
1. On the TAEUS® FLIP System ***Idle*** screen, press ***New Procedure***.



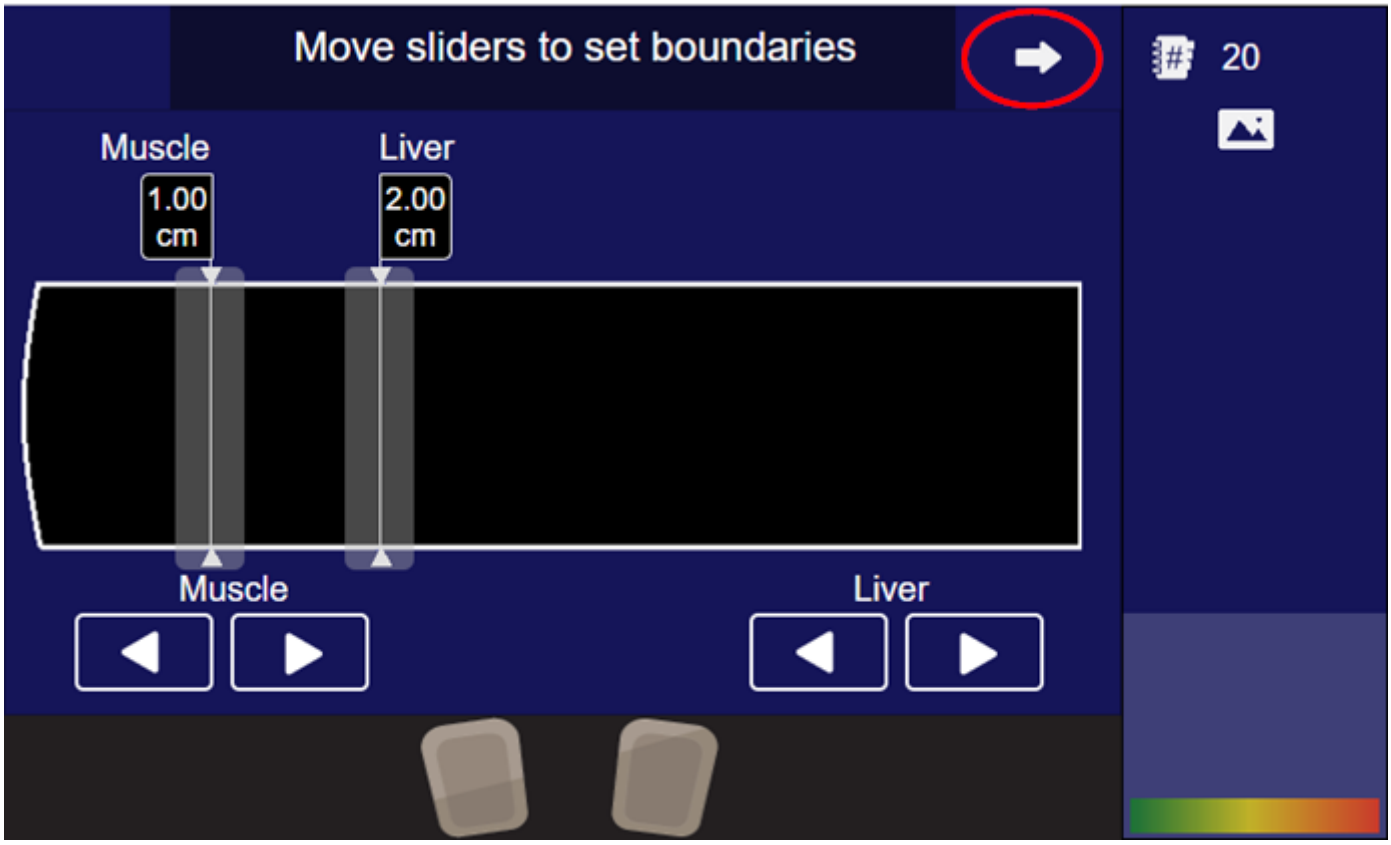
2. Before proceeding, confirm that all contraindications have been reviewed with the patient. Do not proceed if any apply.



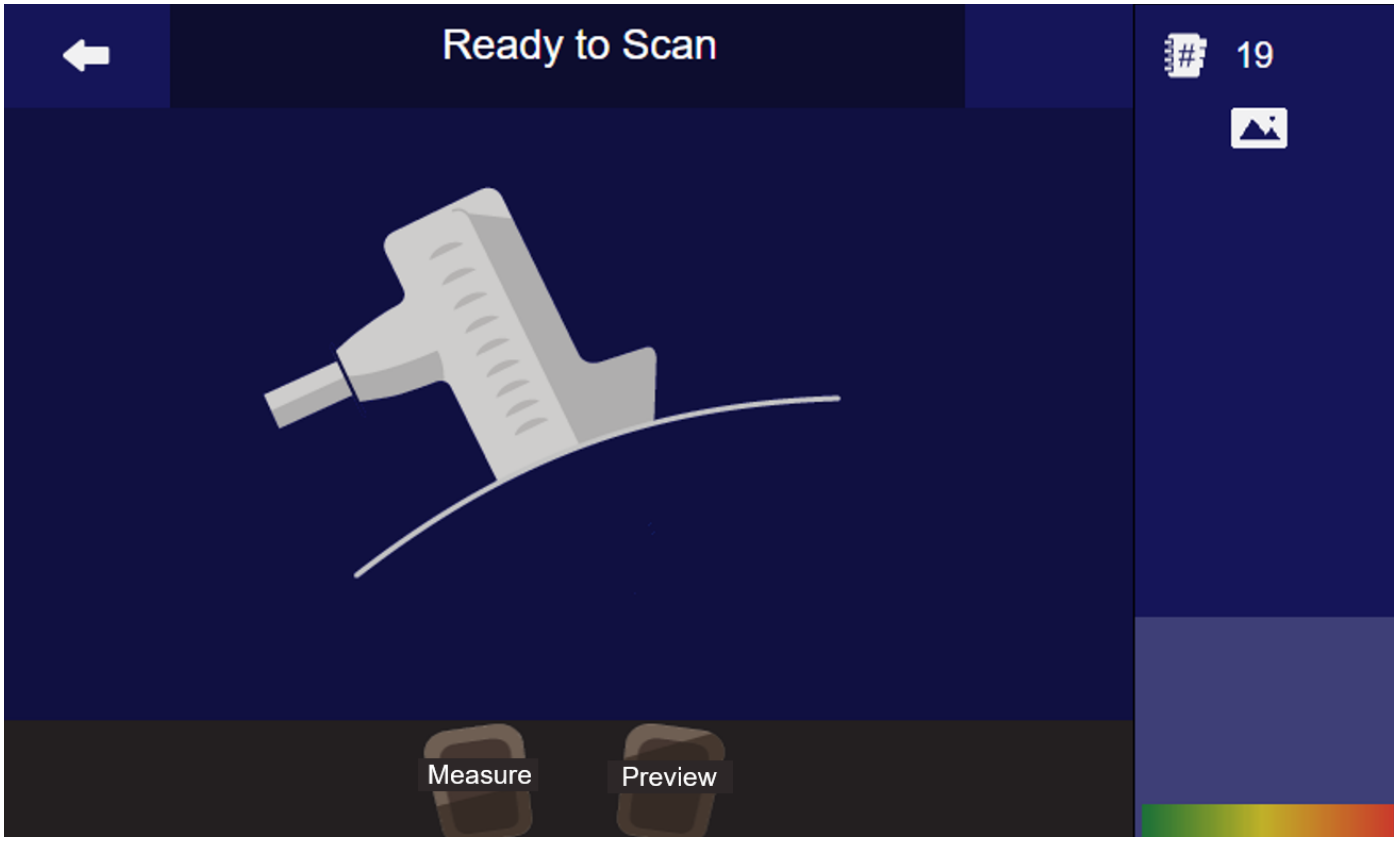
3. On the next screen, position each of the two slider bars so that the ***Muscle*** and ***Liver*** boundary values correspond to the fat/muscle boundary and liver capsule distance measurements, respectively, obtained with the ultrasound system. Press the arrow keys for fine positioning adjustments to move the slider bars.



4. Press the ***Arrow*** icon to proceed:



5. When the FLIP Probe has powered up, a ***Ready to Scan*** page appears and the LED indicator turns solid green:



6. Remove the FLIP Probe from its holder. Apply ultrasound gel as necessary.
7. For best results while scanning:
   - Hold the FLIP Probe firmly.
   - Apply even, medium pressure to ensure sufficient contact for the complete patient-contacting surface. Do not tilt the FLIP Probe.
   - Ensure the FLIP Probe is centered within the intercostal space.
   - Keep the FLIP Probe perpendicular to the skin.
   - Ensure that there is sufficient ultrasound gel under the FLIP Probe.
8. Place the FLIP Probe on the patient's abdomen so that it is in the same location as the ultrasound system probe was for the B-Mode acquisition. The applicator (blue extrusion on the patient contacting surface of the FLIP Probe) should be closer to the bowel so that both the transducer and applicator are intercostal and contacting the skin.
9. Ask the patient to exhale and then pause breathing.
10. Select ***Preview*** to take a FLIP Preview Scan. A ***Preview*** allows you to examine the thermoacoustic signal, for evaluation. The FLIP Probe LED indicator flashes green while data is acquired. An audio alert (short beep) sounds during RF emission.

    NOTE: A graphical representation of the optional, Two-pedal footswitch is displayed at the bottom of the touchscreen displays. Pressing one of these simulations will produce the same result as pressing a real footswitch, even if the system is not equipped with one.

    NOTE: During a FLIP Scan, an audio alert (long beep tone) sounds if any errors occur. See the *Troubleshooting* section below for more information.

    SAFETY NOTE: The TAEUS® FLIP System does NOT emit RF pulses when not in use (not scanning).

11. Evaluate the scan quality while keeping the FLIP Probe in its current position.

The graphic in the scan area window represents the raw thermoacoustic signal from the skin surface to a depth of approximately 5 cm. The two displayed lines correspond to the boundaries of intercostal muscle and liver capsule as they were input.

Thermoacoustic signals have the highest intensity where there is an change in the RF absoprtion between neighboring tissues: at the skin surface, at the fat/muscle boundary, and at the interface between intercostal muscle and liver capsule. An acceptable scan should have clear, vertical signals in these areas. The scan is unacceptable if:

- There is no signal at or near the expected boundaries
- There are multiple, low intensity signals at the expected boundaries

Anomalies such as these can result from poor FLIP Probe contact, incorrect ultrasound system probe positioning during B-Mode acquisition, or proximity to the lung, for example.

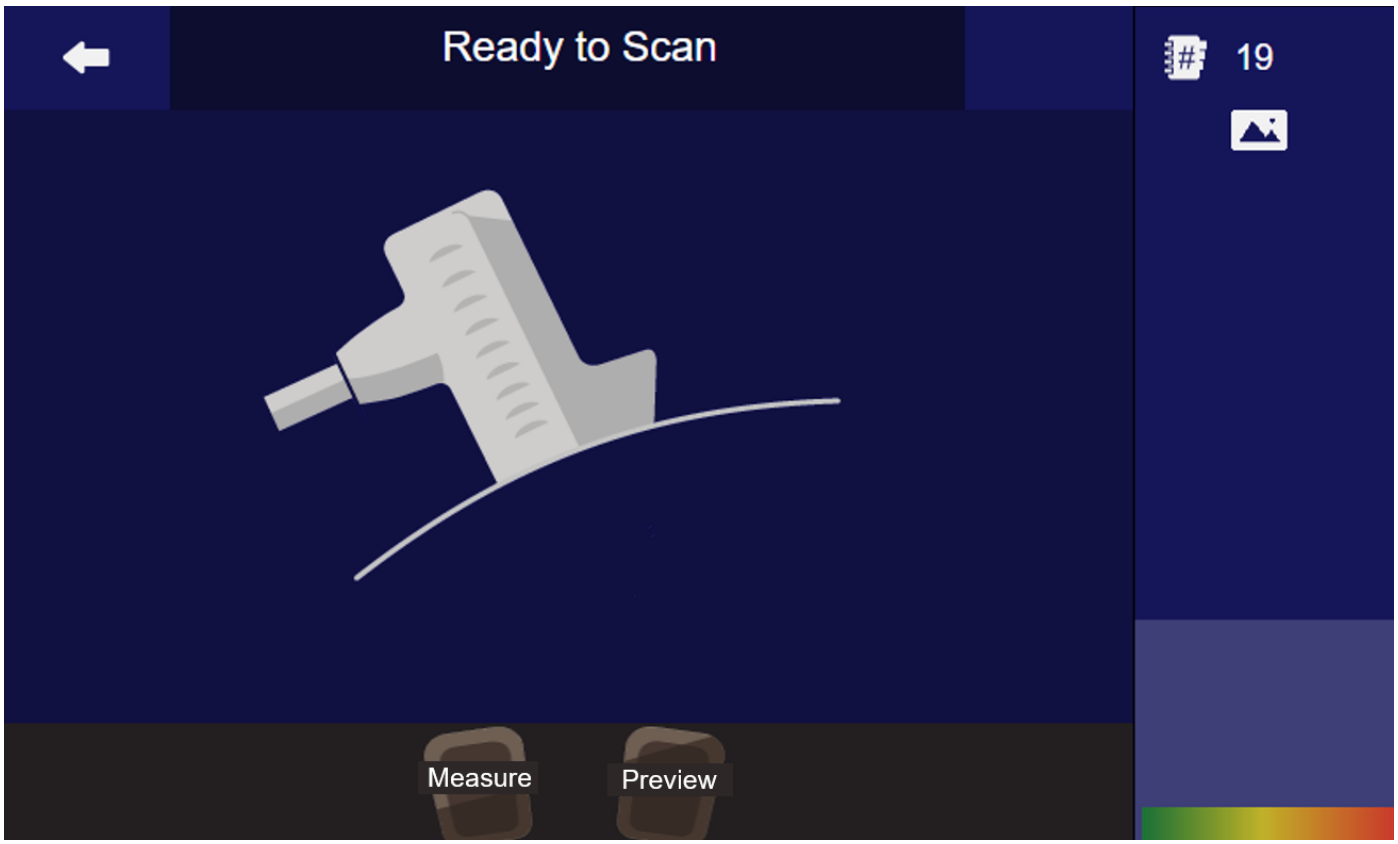
The **Transmitted Power** and **Scan Quality** metrics should also be used to determine whether a FLIP Scan with the current FLIP Probe position is acceptable. The **Transmitted Power** metric indicates effective FLIP Probe contact for the purpose of measurement. Values displayed in green (>95%) or yellow (80-95%) indicate excellent and good contact respectively. Values displayed in red (<80%) indicate poor FLIP Probe positioning. Adjust the FLIP Probe position and acquire another ***Preview*** Scan if the **Transmitted Power** is less than 80%.

The **Scan Quality** metric is a measure of the agreement between the FLIP Scan results and the inputted ultrasound system measurements. Values displayed in green (>80%) or yellow (50-75%) indicate excellent and good **Scan Quality** respectively. Values displayed in red (\<50%) indicate poor FLIP Probe positioning. Adjust the FLIP Probe position and acquire another ***Preview*** scan if the **Scan Quality** is less than 80%.

12. If the previous ***Preview*** scan was unacceptable, repeat Steps 7-12 until the **Transmitted Power** and **Scan Quality** parameters are both acceptable.
13. Once the ***Preview*** scan is acceptable,

    a. Keep the FLIP Probe in the same position

    b. Press the back ***Arrow*** to return to the ***Ready to Scan*** page.



    c. Ask the patient to exhale and then pause breathing.

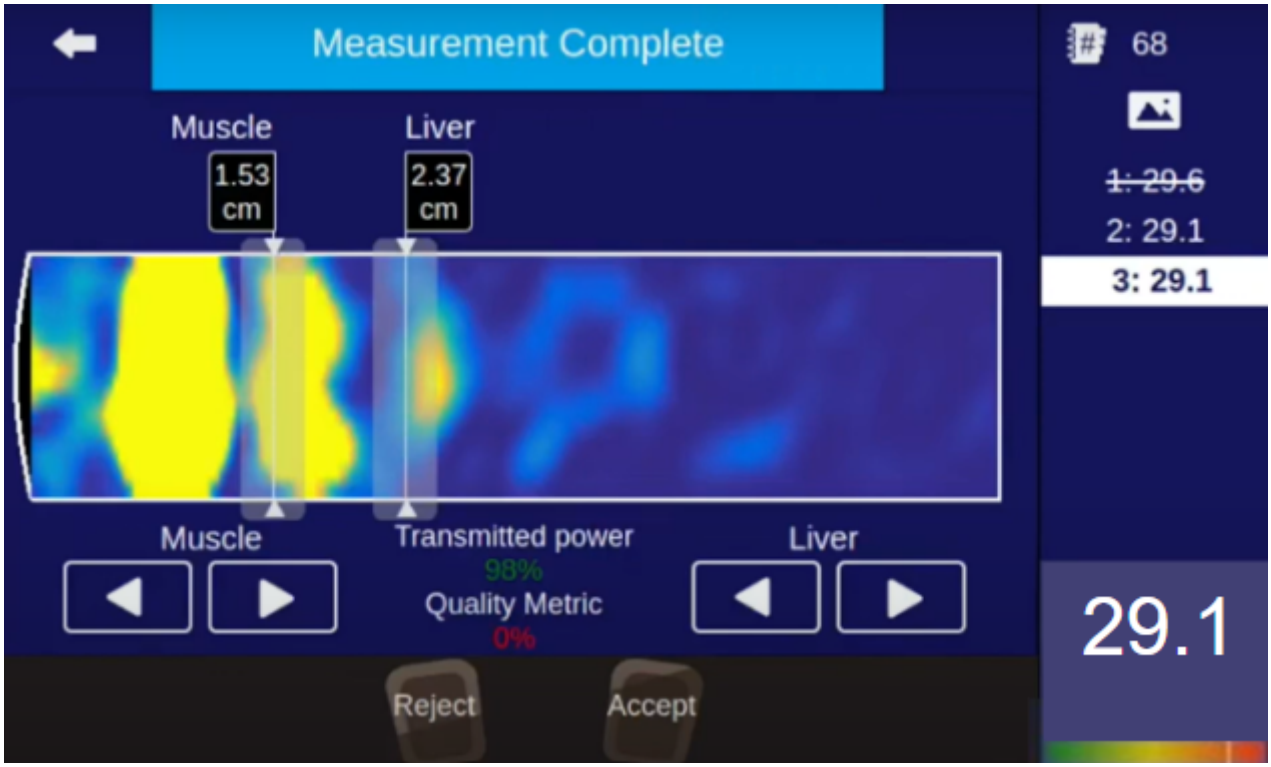
d. Select **Measure** to take a full FLIP Measurement Scan. The FLIP Probe LED indicator flashes green while data is acquired. An audio alert (short beep) sounds during RF emission.

NOTE: A graphical representation of the optional, Two-pedal footswitch is displayed at the bottom of the touchscreen displays. Pressing one of these simulations will produce the same result as pressing a real footswitch, even if the system is not equipped with one.

NOTE: During a FLIP Scan, an audio alert (long beep tone) sounds if any errors occur. See the *Troubleshooting* section below for more information.

SAFETY NOTE: The TAEUS® FLIP System does NOT emit RF pulses when not in use (not scanning).

14. A graphic displaying the thermoacoustic signal is shown when the FLIP Scan has completed, and the FLIP Probe indicator turns solid blue:



15. ***Reject*** the FLIP Measurement Scan if the **Transmitted Power** is less than 80% or **Scan Quality** is less than 80%. To reject the FLIP Scan, select ***Reject***. The user is returned to the ***Ready to Scan*** page. Reposition the FLIP Probe and acquire another FLIP Measurement Scan.

    NOTE: To ensure patient exposure to safe levels of RF emissions, scans are limited to a minimum inter-scan time interval. If the interval has not elapsed since the last measurement scan, a new FLIP Scan may not be initiated. The ***Ready to Scan*** page will automatically display when the timer reaches 0 sec. **NOTE:** Rejected FLIP Scan results are displayed in the right panel of the FLIP Display, with a strikethrough. If a FLIP Measurement Scan is mistakenly rejected, select the strikethrough text to accept the FLIP Measurement Scan.

16. If the FLIP Measurement Scan is acceptable, select ***Accept*** to save the scan data.
    The numerical measurement for the current scan, TAAP value, is displayed in the right panel of the FLIP Display, as are any previous or subsequent scans obtained from the same patient. The average TAAP value is displayed in the bottom right corner.

    NOTE: The calculations provided by the system are intended for use by qualified users. **NOTE:** If a FLIP Measurement Scan is mistakenly accepted, select the numerical value displayed in the right panel of the FLIP Display to reject the FLIP Measurement Scan. A rejected FLIP Measurement Scan will be displayed with a strikethrough.

17. Accepting the FLIP Measurement Scan returns the user to the ***Ready to Scan*** page if the inter-scan interval has elapsed since the start of the scan. Repeat the scanning procedure as described above for 5-10 measurements per patient. A maximum of 20 measurements is allowed.

RECORDING/PRESERVING FLIP MEASUREMENTS

Although FLIP Measurement Scans for a given FLIP Study are preserved and retrievable (see *Section 3-13* below), they should be recorded by hand before starting a new FLIP Study (***New Procedure***) or before turning the system off. At minimum, record the average TAAP value, the date, and the study number. A sequential study number is automatically generated with every new FLIP Study and displayed in the top right corner:

To start a new FLIP Study, follow the cleaning and disinfecting instructions below (*Section 3.10*), then repeat the instructions in *Sections 3.3 – 3.7* above.

AFTER EVALUATION

After completing all scans follow the cleaning and disinfecting instruction below after each patient and store the system in accordance with Environmental Requirements in this User Guide.

CLEANING AND DISINFECTING

CAUTION Inspect the FLIP Probe face or distal end for any visual damage or cracks before proceeding to the cleaning step. If any defects or damages are found on the FLIP Probe, do not use it.

WARNING Risk of Infection: ALWAYS clean and disinfect the ultrasound system probe and FLIP Probe between patients.

Adequate cleaning and disinfection between patients is necessary to prevent disease transmission. The FLIP Probe and ultrasound system probe must be thoroughly cleaned prior to disinfection. Recommended cleaning and disinfection is in addition to recommended weekly maintenance as detailed in *Section 4.2*.

To Clean:

- Inspect the FLIP Probe for any visual damage or cracks.
- Clean the FLIP Probe and any cords, housings, and other surfaces that were touched during the FLIP Study (i.e., the FLIP Display, FLIP Console, FLIP Console power switch) as described below:
- On the FLIP Probe, gently remove all ultrasound (coupling) gel by wiping with a soft, low lint cloth. Wipe the FLIP Probe distal end with one SONO Wipe™ or another TAEUS® FLIP System-compatible cleaning and disinfecting wipe listed in *Appendix C*. Using a second wipe, wipe the FLIP Probe remaining surfaces. Dispose of the cloth and wipes used. Visually inspect the FLIP Probe for any remaining soil and, if necessary, repeat this cleaning procedure until the FLIP Probe is visibly clean.
- Other surfaces that were touched during the FLIP Study should be cleaned with one SONO Wipe™ or another TAEUS® FLIP System-compatible cleaning and disinfecting wipe listed in *Appendix C*. Dispose of the wipe used. Visually inspect the surfaces touched during the FLIP Study for any remaining soil and, if necessary, repeat this cleaning procedure until the surfaces are visibly clean.
- Clean and disinfect the ultrasound system per the manufacturer's instructions.

To Disinfect:

Use SONO® Wipes or another TAEUS® FLIP System-compatible disinfectant wipe listed in *Appendix C* and follow the wipe manufacturer's instructions prior to using the disinfectant.

- Disinfect the FLIP Probe and any other surfaces that were touched during the FLIP Study as described below:
- On the FLIP Probe, wipe the distal end with one wipe and ensure the treated surface remains visibly wet for the wipe manufacturer's recommended contact time. Using a second wipe, disinfect the remaining FLIP Probe surfaces for the recommended contact time. After disinfection, remove any residual liquid with a clean, soft, low lint cloth, as needed. Dispose of the wipes and cloth used.
  NOTE: Pay special attention to seams, gaps, and recessed areas.
- Other surfaces that were touched during the FLIP Study should be disinfected with one wipe, ensuring that the treated surface remains visibly wet for the wipe manufacturer's recommended contact time. After disinfection, remove any residual liquid with a clean, soft, low lint cloth, as needed. Dispose of the wipe and cloth used.

NOTE: If wipes appear dry over contact time, use additional wipes as necessary and per wipe manufacturer instructions.

- Clean and disinfect the ultrasound system per the manufacturer's instructions.

SHUTDOWN PROCEDURE

1. Press the Power button on the FLIP Console.

2. Power down the ultrasound system as described in its User Guide.

TROUBLESHOOTING

ERROR MESSAGE	CAUSE	RESOLUTION
Failed to obtain VSWR status	Invalid signal from amplifier during contact-sensing.	Re-scan. User is returned to **Ready to Scan** page.
Low RF Power	Insufficient power to complete scan.	Ensure that there is sufficient contact between the FLIP Probe and the body. User is returned to **Ready to Scan** page.
Error during measurement, Re-Initiate Scan	System is unable to complete scan.	e-scan. User is returned to **Ready to Scan** page.
Parameter file not found An internal software error has occurred An unknown error occurred A software version mismatch error has occurred Signal detection error: adjust Probe and try again Scan not created Data not cached No depth values	System is unable to calculate or process a TAAP value.	Re-scan. User is return to **Ready to Scan** page. Contact service@endrainc.com if error persists.
Error during measurement, Re-Initiate Scan	System is unable to initiate scan.	User is returned to **Ready to Scan** page.
Disk Is Full	System is unable to store critical information.	Contact service@endrainc.com
Maximum Number of Scans Reached	The maximum number of FLIP Scans per FLIP Study/patient has been reached.	Start a New Procedure.
Replace clock battery	The voltage of the battery that controls the system clock is low or depleted.	Contact service@endrainc.com to have battery replaced.
System is in Service Mode. For service use only	System left in Service Mode	1. Navigate to the Idle screen. 2. Press the **Settings** icon. 3. Select **Turn off Service Mode.** Return to the Idle screen.
PADC did not start FLIP Probe did not start PADC error FLIP Probe error RF Error Exciter watchdog fired Exciter pulsing time timeout Exciter pulsing did not start Exciter pulse count error	System has detected an unrecoverable error.	Press **Shutdown** and re-start system. Contact service@endrainc.com if error persists.

Amp watchdog fired
Exciter poll error
Amp poll error
Unrecoverable Exciter Error, System Restart Required
Unrecoverable Amplifier Error, System Restart Required
Power Monitor Test Failed
FLIP Probe not available
An unrecoverable System error has occurred

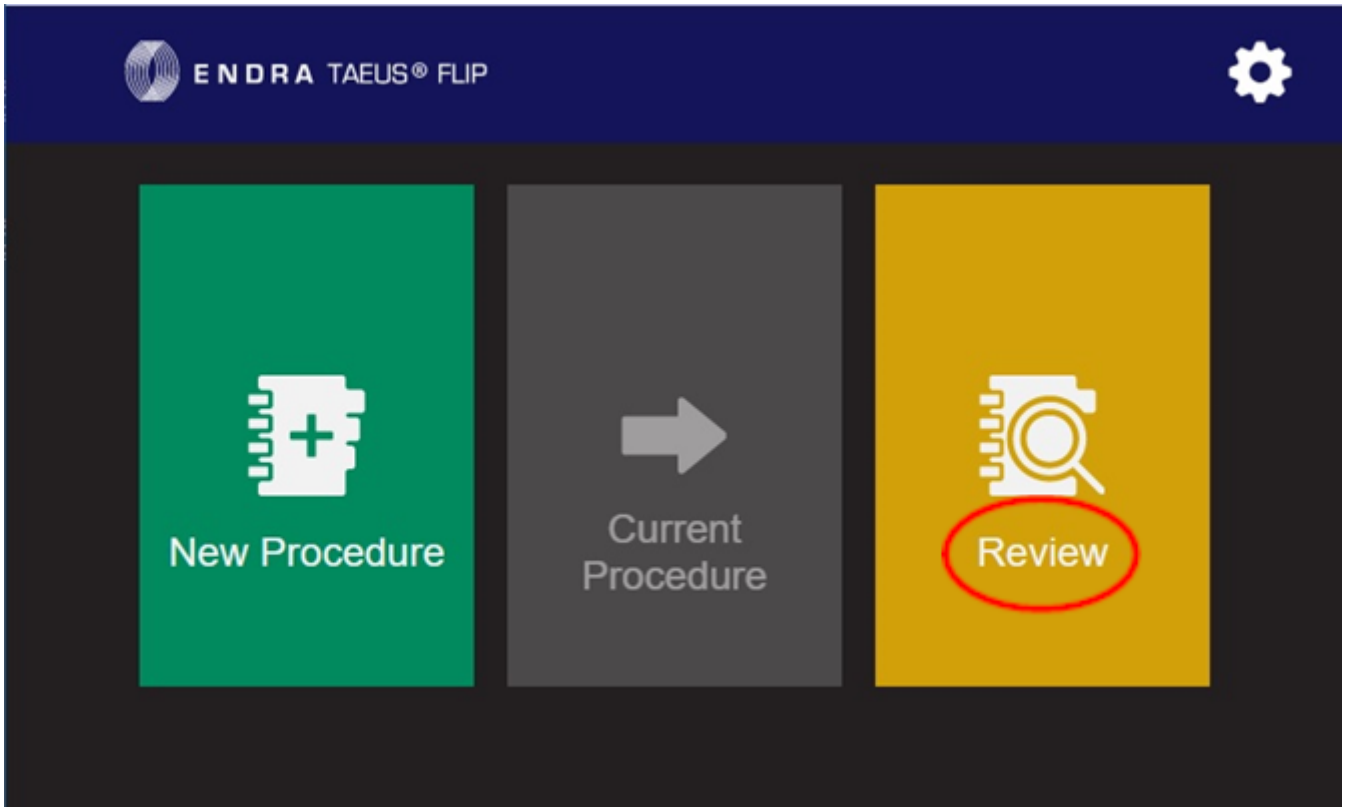
Contact service@endrainc.com in the event of any other system malfunction or change in its performance.

RETRIEVING PAST FLIP STUDIES

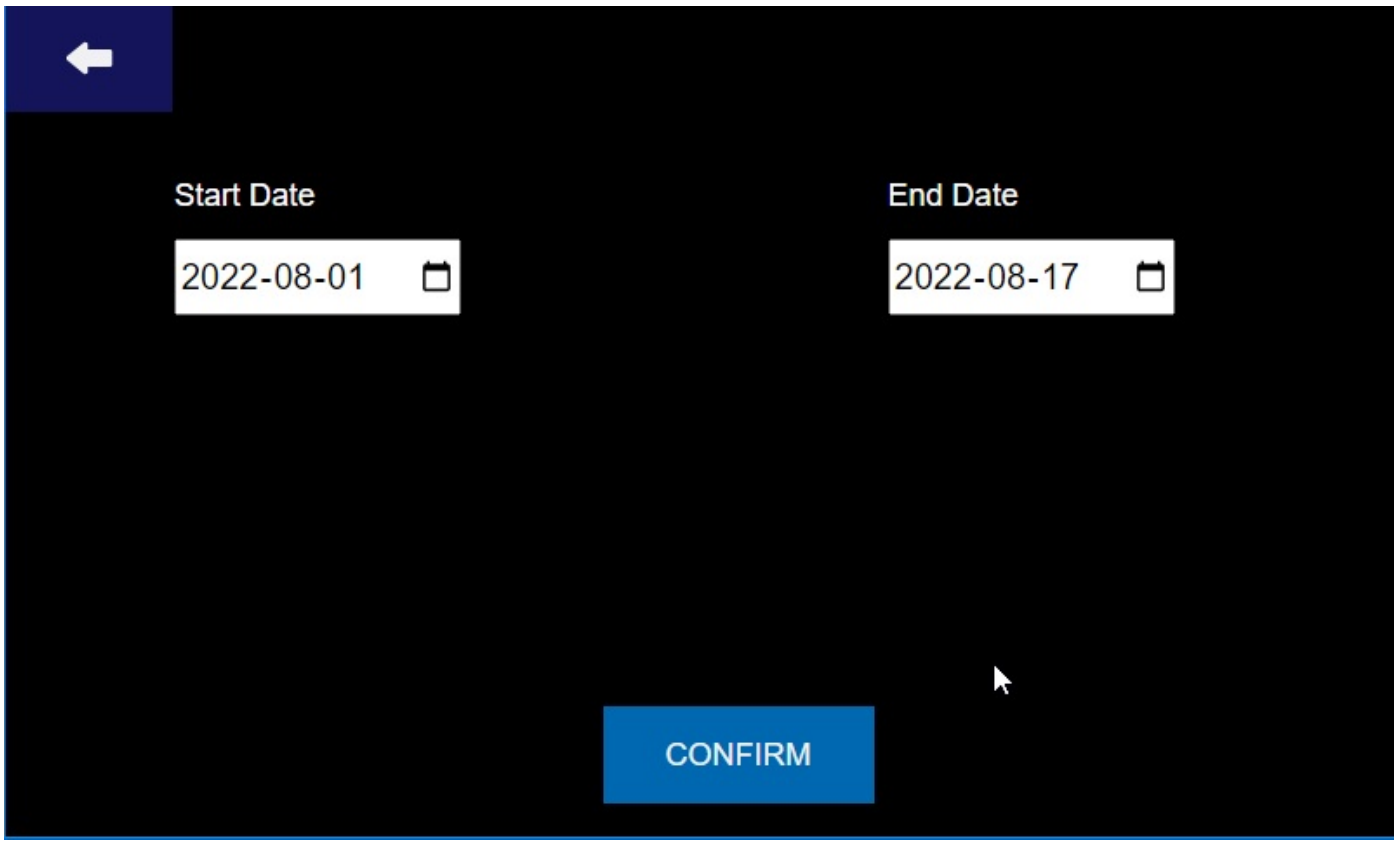
Measurements from individual FLIP Procedures are automatically saved to the TAEUS® FLIP System's internal storage system where they can be retrieved and displayed for downstream examination/review at later dates. They cannot be edited or appended.

To retrieve a past FLIP Study:

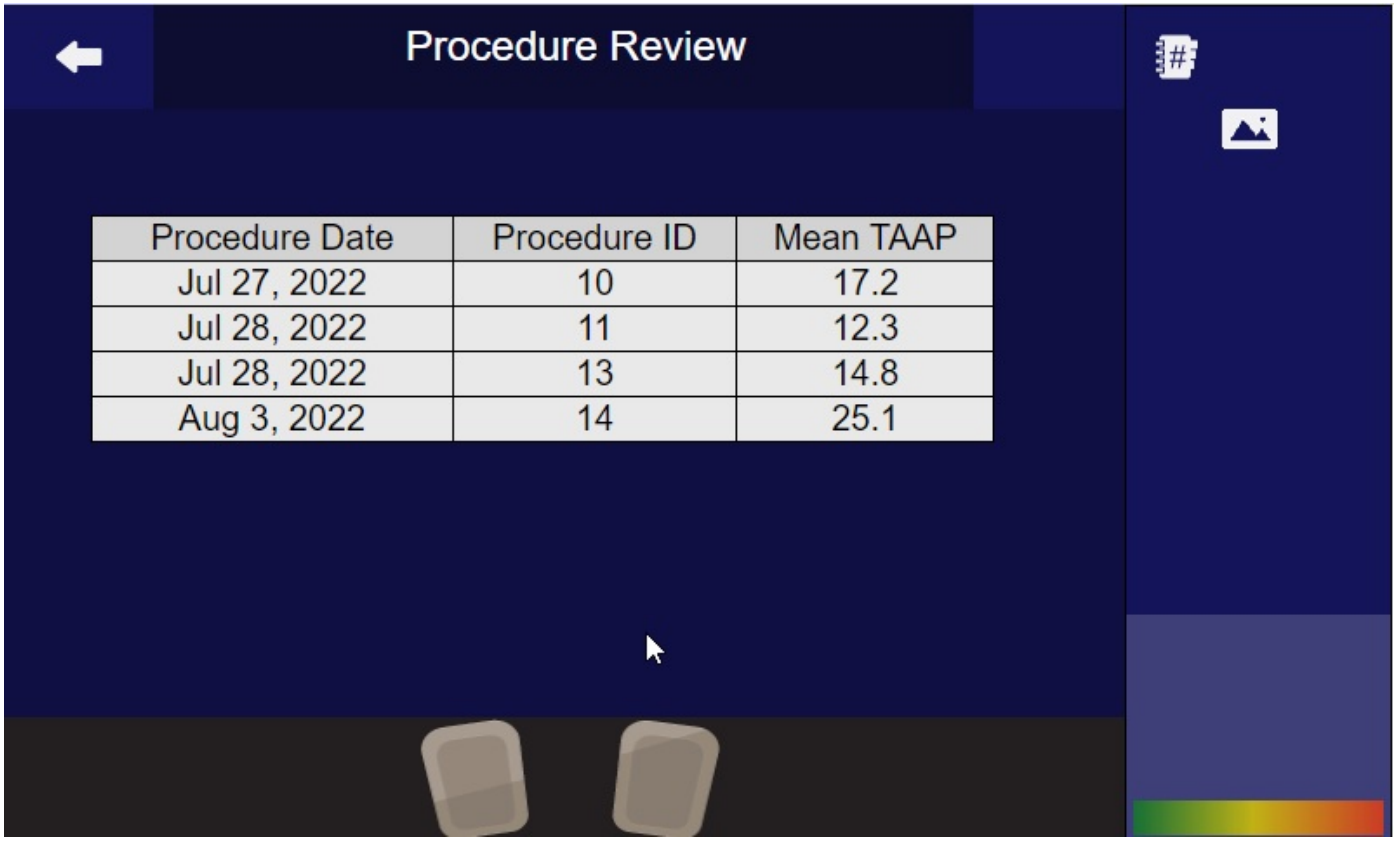
1. Press ***Review*** on the ***Idle*** screen:



2. Specify a range of dates to select from. Select a date on the left calendar for the **Start Date**, and a date on the right calendar for the **End Date**, then press ***Confirm*** to continue.



3. A scrollable list of FLIP Studies completed within the specified **Start** and **End** dates is displayed. The table specifies the date each procedure was performed, the study ID number, and the Mean TAAP value.



4. To display individual TAAP values for a given FLIP Study (i.e., from each individual scan), press the line in which the study is listed.

5. The tab displays the date the FLIP Study was performed. The study ID number, individual TAAP values, and the average TAAP value are displayed on the left side of the screen.

CHAPTER 4: Care and Maintenance

INSPECTING THE TAEUS® FLIP SYSTEM

Before powering up:

- Examine the FLIP Console main power cable for cuts or abrasions.
- Examine the full length of the FLIP Probe tether cable for cuts or abrasions.
- Examine the FLIP Probe enclosure for cracks.
- Inspect the FLIP Probe's distal end surfaces for cracks, holes, sharp edges, and/or adhesive peeling or blistering.

ELECTRICAL HAZARD

To avoid electrical shock hazard, do not remove panels or covers from the console. This servicing must be performed by qualified service personnel. Failure to do so could cause serious injury.
If any defects are observed or malfunctions occur, do not operate the equipment but inform a qualified service person. Contact service@endrainc.com for assistance.

WEEKLY MAINTENANCE

The TAEUS® FLIP System requires weekly care and maintenance to function safely and properly. Outer surfaces should be kept clean and free of dust.

CAUTION

System cleaning should be performed only when the system is shut down. Cleaning with the system turned on may be hazardous to the user and/or destructive to the system.

FLIP Console Maintenance

To clean the FLIP Console, wipe down the top, front, back, and both sides of the console cabinet with a cleaning and disinfecting wipe (e.g., SONO® Wipes). Note that the TAEUS® FLIP System should also be wiped down with cleaning and disinfecting wipes after each FLIP Study, as described in Chapter 3, Section 3.10.

FLIP Probe Maintenance

Inspect the full length of the FLIP Probe tether for wear or damage. Inspect the FLIP Probe housing and patient-contacting surface for wear or damage.

After inspection, wipe down the Tether and FLIP Probe with cleaning and disinfecting wipes (e.g., SONO® Wipes). One cleaning and disinfecting wipe may be used to wipe the FLIP Probe patient-contacting surface and a second wipe may be used to wipe the remaining surfaces. Note that the TAEUS® FLIP System should also be wiped down with disinfecting wipes after each FLIP Study, as described in Chapter 3, Section 3.10.

FLIP Display Maintenance

The FLIP Display touchscreen display panel and frame should be cleaned after each FLIP Study and as part of weekly routine maintenance.

Clean the FLIP Display per the manufacturer's instructions.

Two-pedal Footswitch Maintenance

The Two-pedal Footswitch should be cleaned after each FLIP Study and as part of weekly routine maintenance.

Clean the external surface of the Two-pedal Footswitch per the manufacturer's instructions.

WEEKLY PERFORMANCE VERIFICATION

The performance of the TAEUS® FLIP System should be tested on a weekly basis, using the TAEUS® FLIP System Check Phantom supplied by ENDRA Life Sciences. See the *EN5005 System Check* document for instructions.

REQUESTING SERVICE

The expected service life of the TAEUS® FLIP System is one year. Contact a qualified service representative at service@endrainc.com if any defects, malfunctions, or changes in performance are observed.

The FLIP Console, FLIP Probe, FLIP Display, System Check Phantom, and the Two-pedal Footswitch are field-replaceable.

NOTE: No service should be performed while the system is in operation with a patient.

APPENDIX A: System Specifications

NAME:

TAEUS® FLIP System

MODEL:

Europe: EN9000
North America: EN9001

MANUFACTURER:

ENDRA Life Sciences
3600 Green Ct., Suite 350
Ann Arbor, MI 48105-1570 USA
http://www.endrainc.com
Tel: +1-734-335-0468
E: info@endrainc.com

PHYSICAL DIMENSIONS:

Console

H x W x D:	Approx. 900 x 315 x 675 mm
Weight:	Approx. 100 kg

FLIP Probe

H x W x D:	150 x 120 x 75 mm
Cable length:	2438 mm ± 12.5mm
Weight:	Approx. 0.9 kg

Display Monitor

H x W x D:	300 x 500 x 75 mm
Weight:	0.35 kg
Resolution:	800 x 480
Diagonal:	> 170mm

FLIP PROBE:

RF Output

Applicator type:	Aperture antenna
Frequency:	433.92 MHz
Peak power:	4.4kW — 5.6kW (operating conditions), < 6.9kW (maximum)
Duty cycle:	≤ 0.15%
Energy (SAR):	2.9 W/kg — 3.7 W/kg (operating conditions), < 4.5 W/kg (maximum)
Measurement Average Power:	6.7 W — 8.4 W (operating conditions), < 10.4 W (maximum)

Ultrasound Transducer

Type:	16-Ch, receive only transducer
Frequency:	450 kHz ± 10%

ELECTRICAL REQUIREMENTS:

AC Power Requirements:	~100V, 60Hz, 1000VA

ENVIRONMENTAL REQUIREMENTS:

Operation

Room Temperature:	+15° — +30°C
Relative Humidity:	30 — 80%, noncondensing
Atmospheric Pressure:	70 — 106 kPa

Transport and Storage

Room Temperature:	-10° — +50°C
Relative Humidity:	30 — 80%, noncondensing
Atmospheric Pressure:	70 — 106 kPa

APPENDIX B: Contact Information

ADDRESS:

ENDRA Life Sciences
3600 Green Ct., Suite 350
Ann Arbor, MI 48105-1570
USA

TELEPHONE:

+1-734-335-0468

URL:

http://www.endrainc.com

E-MAIL (General):

info@endrainc.com

E-MAIL (Service):

service@endrainc.com

APPENDIX C: Compatible Cleaning/Disinfecting Products

The table below lists cleaning and disinfecting products that have been validated for use with the TAEUS® FLIP Imaging Probe (FLIP Probe). During compatibility testing, each of the listed products were used to clean and disinfect the patient-contacting surface of the FLIP Probe as described in *Chapter 3, Section 3.10* for reprocessing cycles representative of one year of use. The listed products did not cause unacceptable damage to the FLIP Probe's patient-contacting surface or adversely affected the FLIP Probe's performance as tested and described in *EN5005 TAEUS® FLIP System Check*.

PRODUCT NAME	MANUFACTURER	ACTIVE INGREDIENT(S)	CONTACT TIME[1]
SONO Wipes™	Advanced Ultrasound Solutions Inc.	Octyldecyldimethyl amonium chloride Dioctyldimethyl ammonium chloride Dideclidimethyl ammonium chloride Alkyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride	4 min

1. Always refer to manufacturer’s instructions to ensure appropriate contact times. ↩

Glossary

Term	Description
AFE	Analog Front-End
Exciter	A custom PCB module within the FLIP Console that synthesizes low amplitude RF pulses at a center frequency of 434 MHz
PADC	Processing and Display Computer – A computer which maintains the GUI and accepts acoustic data from the FLIP Probe for processing.
QR-Code	Short for "quick-response code". A type of two-dimensional matrix barcode.
RTC	Real-time Clock
SYSM	System Manager
TAAP	ThermoAcoustic derived Absorption Parameter
UTC	Coordinated Universal Time