ENDRA LIFE SCIENCES

TAEUS® FLIP SYSTEM

ThermoAcoustic Enhanced UltraSound
Fatty Liver Imaging Probe

User Guide

ThermoAcoustic Enhanced UltraSound Fatty Liver Imaging Probe System (TAEUS® FLIP System) User Guide
Part # EN5001
Revision History

Date	Version	Change
October 2019	Rev. A	Initial version
December 2019	Rev. B	Revisions to Regulatory Information, Sections 3.3 (System startup), 3.8 (Post-scan operations), 4.2 (Weekly maintenance), Appendix A (FLIP Probe specifications) Revisions to Important Notices, warnings and precautions, Sections 3.10 (Troubleshooting), 4.2 (weekly maintenance), Appendix A Revisions to USB connections, FLIP Probe immersion limits.
December 2019	Rev. C	Revised CE number
November 2020	Rev. D	Revisions to warning/hazard symbols (ISO 7010 symbols), reprocessing instructions, user interface screens, environmental requirements. Revisions to Chapter 2, Introduction
July 2021	Rev. E	Revisions to TAAP value range, System RF output data per new performance enhancement report.
May 2023	Rev. F	Revisions to terminology and user interface screens. Clarification of operating instructions, error messages, and power requirements. Instructions for new Procedure Review and Usage Report. List of approved cleaning/disinfecting products.
December 2023	Rev. G	Clarification of operating instructions, revisions to user interface screens, implementation of integrated User Guide.
August 2024	Rev. H	Clarification of operating instructions, revisions to FLIP Probe images

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.

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This product complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices:

CE 2797

This product complies with the following North American safety standards:

ETL CLASSIFIED
C ETL US
LISTED
Intertek
5018124

CONFORMS TO:
AAMI STD ES60601-1
IEC STD 60601-1-6

CERTIFIED TO:
CSA STD C22.2#60601-1

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:
    - Console IP20
    - Probe IPX1, IPX7 (patient-contacting end)
    - Display and Probe Holder IP43 (monitor)
    - 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

This product complies with the requirements of the following standards and regulations:

- Council Directive 93/42/EEC concerning medical devices: the CE label affixed to the product testifies compliance to the Directive.
  The location of the CE marking is shown in Chapter 1 of this manual.
- International Electrotechnical Commission (IEC).
    - IEC/EN 60601-1 Medical Electrical Equipment, Part 1 General Requirements for Safety.
    - IEC/EN 60601-1-2 Electromagnetic compatibility - Requirements and tests.
    - IEC 60601-1-6 Usability.
- International Organization of Standards (ISO)
    - ISO 10993-1 Biological evaluation of medical devices.

Original Documentation

- The original document was written in English.

Important Notices

- 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 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 is approved, in terms of the prevention of radio frequency interference ("RFI"), to 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.
- The TAEUS® FLIP System should not be operated within 5 m of life sustaining equipment (e.g., ventilators).
- With the exception of a conventional ultrasound System (CUS), 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 ~100-240V, 50-60Hz, 1000VA as appropriate for country of use.
- 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 (HCPs) who have been fully trained by ENDRA Life Sciences. Contact ENDRA Life Sciences for training.
- The calculations provided by the System are intended for use by competent users, as an aid in the diagnosis and management of patients with fatty liver disease, as part of an overall assessment of the liver.

Table of Contents

CHAPTER 1: Safety Precautions

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

1.1 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 may cause:

- Severe personal injury
- Substantial property damage.

CAUTION — Indicates that a potential hazard may exist which through inappropriate conditions or actions will or can 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.

1.2 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
	• Risk of explosion if used in the presence of flammable anesthetics	• Flammable anesthetic
	• Patient/user injury or adverse reaction from fire or smoke. • Patient/user injury from explosion and fire.	• Outlet guidelines

1.3 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 TAEUS® FLIP examinations 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.

1.3.1 Patient Safety

1.3.1.1 Usage Information

The calculations provided by the System are intended for use by competent users, as an aid in the diagnosis and management of patients with fatty liver disease, as part of an overall assessment of the liver.

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. Added confidence in the equipment operation can be gained by establishing a quality assurance program.

WARNING

Do not operate TAEUS® FLIP within 5 m from life-sustaining equipment (e.g., ventilators).

1.3.1.2 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 tear protective barriers.

ELECTRICAL HAZARD

A damaged FLIP Probe can also 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 fully 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 or change the directional characteristics of the RF applicator. Avoid bending the tether cable beyond its natural bend radius while hanging (120 mm). Inspect any part for damage if it has been dropped.

1.3.2 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 principle of ALARA (as low as reasonably achievable) in the development of the TAEUS® FLIP System.

The resulting pre-set (**non-user adjustable**) TAEUS® FLIP System RF Measurement emissions are at safe levels when used as instructed.

1.3.3 Equipment and Personnel Safety

1.3.3.1 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 an ENDRA Service Representative 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.

EXPLOSION HAZARD Risk of explosion if used in the presence of flammable anesthetics.

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.

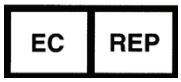
CAUTION

- 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.

1.4 DEVICE LABELS

1.4.1 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
Identification and Rating Plate 	Manufacturer's name and address	Console, FLIP Probe, Display Panel
Identification and Rating Plate 	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
	CE Mark	Console, FLIP Probe, Display Panel
	Authorized European Representative address	Console
	WARNING: Non-ionizing radiation	Console
	No access for people with active implanted cardiac devices	Console

Label/Icon	Purpose/Meaning	Location
	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 60417-5333.	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

Label/Icon	Purpose/Meaning	Location
	"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
ETL CLASSIFIED Intertek 5018124 CONFORMS TO: AAMI STD ES60601-1 IEC STD 60601-1-6 CERTIFIED TO: CSA STD C22.2#60601-1	ETL Listing Mark Monogram	Console, FLIP Probe, Probe and Display Holder(s)l

1.5 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 TAEUS® 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

1.6 EMC (Electromagnetic Compatibility)

This equipment generates, uses and radiates radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, this

product complies with emissions limits for a Class A, group 1 Medical Devices Directive as stated in EN 60601-1-2 when not performing a measurement. When scanning, TAEUS® FLIP complies with Class A, group 2. 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 service representative for further suggestions.

1.6.1 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 call your service personnel.

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.

1.6.2 Notice upon Setup of Product

1.6.2.1 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.

1.6.3 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 assure 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	

1.6.4 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 3Vrms and ISM Band at 6Vrms, 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+AMD1:2017	0%, 0.5 Cycle 0%, 1 Cycle 70% 25/30Cycles 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

2.1 INTENDED USE

The ENDRA ThermoAcoustic Enhanced Ultrasound System Fatty Liver Imaging Probe (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 the target internal structure by emitting a pulsed energy from which an acoustic response is received and analyzed.

The TAEUS® FLIP System is indicated for use as a non-invasive tissue characterization tool, as an adjunct to conventional Ultrasound Imaging Systems (CUS), by producing a ThermoAcoustic derived Absorption Parameter (TAAP) Measurement, that provides tissue permittivity properties of the liver, where increasing levels of fatty tissue result in decreasing permittivity measurements.

The TAEUS® FLIP System ThermoAcoustic derived Absorption Parameter (TAAP) may be used as an aid by healthcare practitioners in the diagnosis and management of adult patients with fatty liver disease, as part of an overall assessment of the liver.

NOTE: TAAP is a TAEUS® FLIP System Measurement defined term that is used to represent the estimated imaginary part of the complex relative permittivity of the tissue region of interest (the parameter measured with the TAEUS® FLIP System). For purposes of this User Guide, the terms “TAAP” and “Permittivity” are interchangeable and refer to the imaginary part of complex relative permittivity.

2.2 USERS AND ENVIRONMENT

Users of the TAEUS® FLIP System are qualified healthcare practitioners. Operators 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 CUS that is capable of abdominal and, more specifically, liver imaging.

2.3 CONTRAINDICATIONS

The TAEUS® FLIP System should not be used:

- In patients with implanted electromechanical devices, such as cardiac pacemakers, defibrillators or insulin pumps.
- 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 women who are pregnant or believe they may be pregnant.

2.4 PRINCIPLE OF OPERATION

2.4.1 Thermoacoustics

Thermoacoustics is a scientific term describing the use of a pulsed energy source – such as light or forms of electromagnetic radiation – to generate ultrasonic waves in tissue. The waves may be detected with conventional ultrasound equipment and used to create a high-contrast image of the tissue composition, or processed into measures that represent estimates of various tissue properties.

2.4.2 TAEUS® FLIP System Principle of Operation

As a RF-stimulated thermoacoustic System, the ENDRA's TAEUS® FLIP System transmits very 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 (salt) content. The radio pulses are converted by absorption in the tissue into ultrasound signals, which are detected by the ultrasound transducer and digital acquisition System. The detected ultrasound is processed into measurements. This principle is illustrated in ***Figure 2-1***.

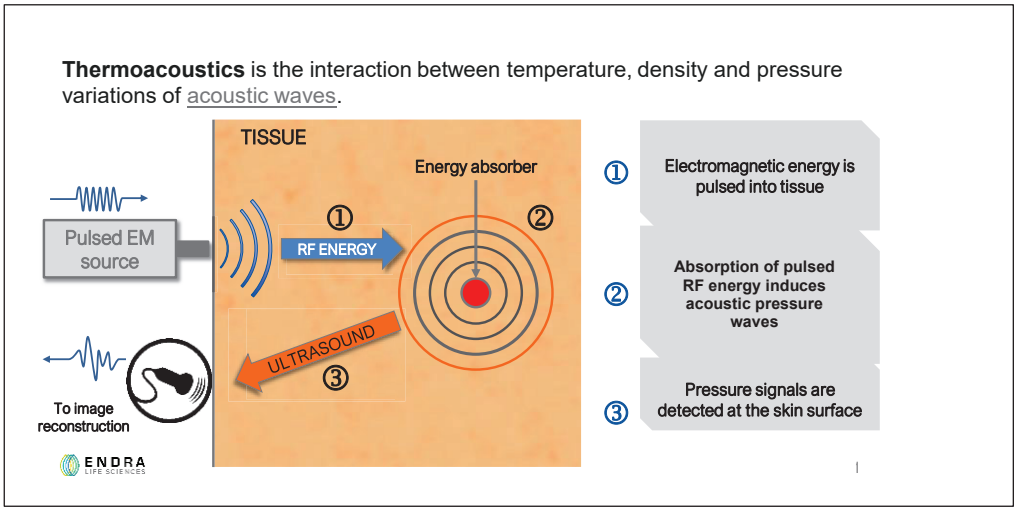


Figure 2-1. *TAEUS FLIP System Principle of Operation*

The TAEUS® FLIP System enables the generation, display and review of pre-set TAEUS® Measurements when used with a conventional ultrasound system (CUS) for identifying gross regions of interest. TAEUS® FLIP combines a pulsed RF source, operating at a nominal center frequency of 434 MHz and an RF Applicator that directs the RF energy efficiently into the tissue along a desired trajectory. The induced acoustic intensity ("response") is detectable with an ultrasound receiver integrated within the FLIP Probe.

TAEUS® FLIP processes the detected thermoacoustic pressure waves into the ThermoAcoustic-derived Absorption Parameter (TAAP). The TAAP value is a dimensionless number that compares the imaginary part of the complex relative permittivity of a material relative to the permittivity of a vacuum and is strongly

dependent on fat content. As the water and ions in lean tissue are replaced with increasing amounts of fat, its TAAP value decreases.

2.4.3 TAEUS® FLIP System TAAP Measurement and Performance

The TAEUS® FLIP System estimates TAAP values for fat fraction liver ranges through the generation of FLIP Metric (conductivity of the liver) estimates via the TAEUS® FLIP algorithm. The TAAP value estimates for fat fraction liver ranges have been compared to MRI-Proton Density Fat Fraction (MRI-PDFF) values, based on tissue-mimicking phantom models. ENDRA has completed this performance testing in two steps: a) Establish a correlation between MRI-PDFF fat fraction values and the imaginary part of the complex relative permittivity (TAAP estimates) with a bovine liver phantom model and liver-mimicking phantoms; b) Verify the TAAP estimates over a range of fat fractions, using a clinically representative four-layer phantom model.

2.4.3.1 Correlation of MRI-PDFF Fat Fraction to TAAP Estimates with Phantom Models

Studies conducted by ENDRA Life Sciences demonstrate an inverse correlation between the imaginary part of the complex relative permittivity and MRI-PDFF values measured from liver tissue phantoms with varying triglyceride concentrations (***Figure 2-2***) and allow for direct comparison between TAEUS® FLIP TAAP estimates and MRI-PDFF fat fractions for both the phantom model (room temperature) as well as clinical application (37° C).

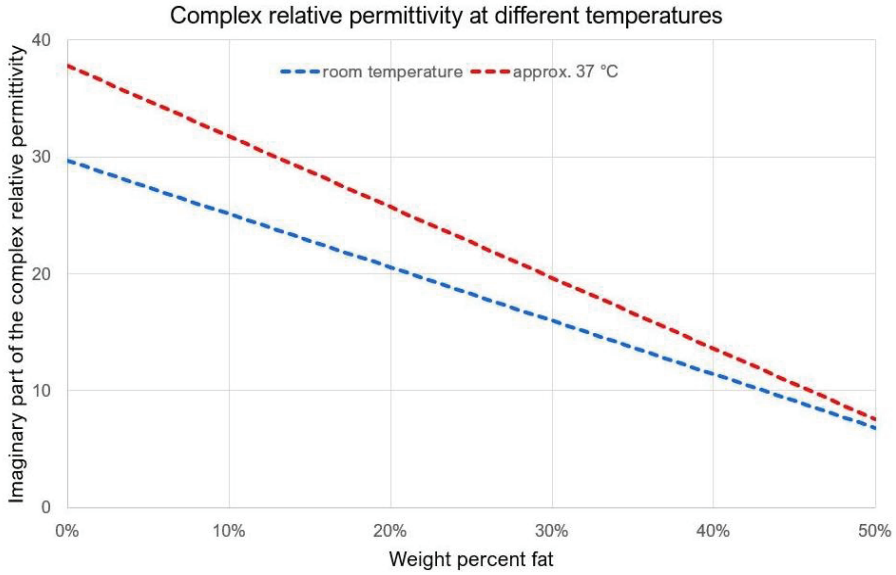


Figure 2-2. *Relationship between TAAP estimates and % Fat Fraction*

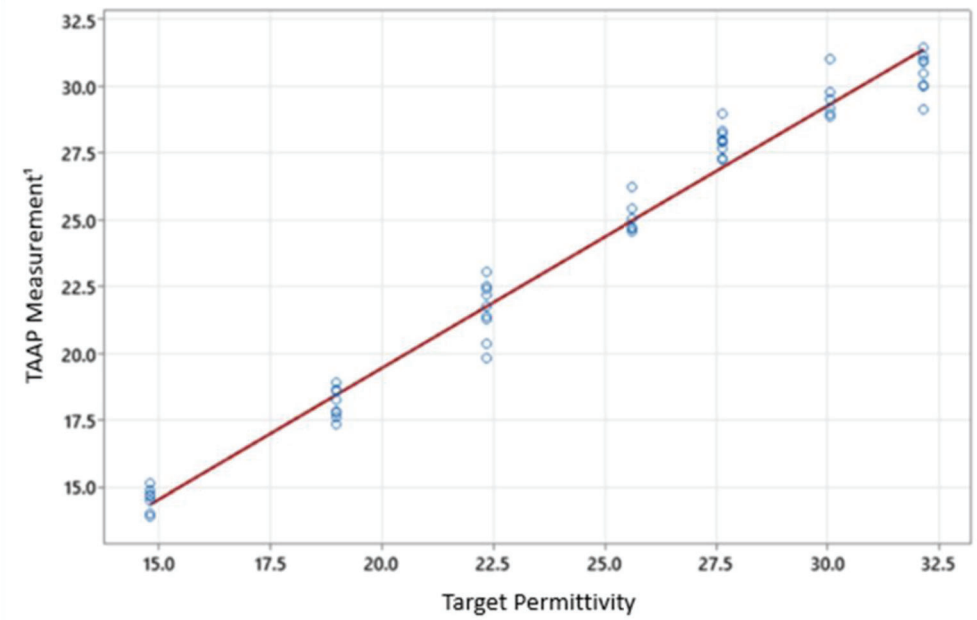
NOTE: The correlation shown above, between the TAAP value and the % Fat Fraction, is based on cross-correlations with bovine liver phantoms with varying fat fraction (peanut oil) and liver-mimicking phantoms, analogous to phantom validation of other modalities, such as those used with ultrasound and MRI-PDFF software.

2.4.3.2 TAAP Estimates for Liver Fat Fraction Range with a Clinically Representative Four-Layer Phantom Model

Based on a four layer (fat-muscle-liver) simulative model, the correlation of the TAAP value as a function of its Target Permittivity, based on that described above as compared to MRI-PDFF, is shown in the plot below for a range of liver fat fractions from 3% to 40%, with a range of Phantom fat layer thickness from 7 mm to 20 mm, and a nominal 10 mm thickness of muscle, representing a clinically significant range of fat and muscle layer thicknesses. The imaginary part of the complex relative permittivity (TAAP estimate) is inversely correlated to the fat fractions levels as determined by MRI-Proton Density Fat Fraction (MRI-PDFF) *(**Figure 2-2***).

Using a simulative phantom model, the TAEUS® FLIP bench performance testing confirmed that the TAEUS® FLIP System's TAAP values successfully fulfilled the predefined acceptance criteria with the 95% confidence intervals of the means falling within the specified Target Permittivity values (32.5 to 15.0), that correspond to a range of MRI-PDFF fat fractions from 3% to 40% (***Figure 2-3***).

Figure 2-3. *TAAP Measurement Results for a Range of Phantom Fat Fractions [Room Temperature]*



[1] TAAP Measurement is a unitless value estimated from the imaginary part of the complex relative permittivity, referred to for brevity as "Permittivity" in this Figure (x-axis).

Note that TAAP values are provided after a TAEUS® FLIP System Measurement to allow the user to record a numerical value for the patient session. A representative FLIP Scan

and TAAP Measurement is presented in ***Figure 2-4***; see Section 3 of this User Guide for more information on operation of the TAEUS® FLIP System. The FLIP System, with its TAAP values, is provided as an adjunct tool for liver characterization as an aid to qualified licensed healthcare practitioners and sonographers.

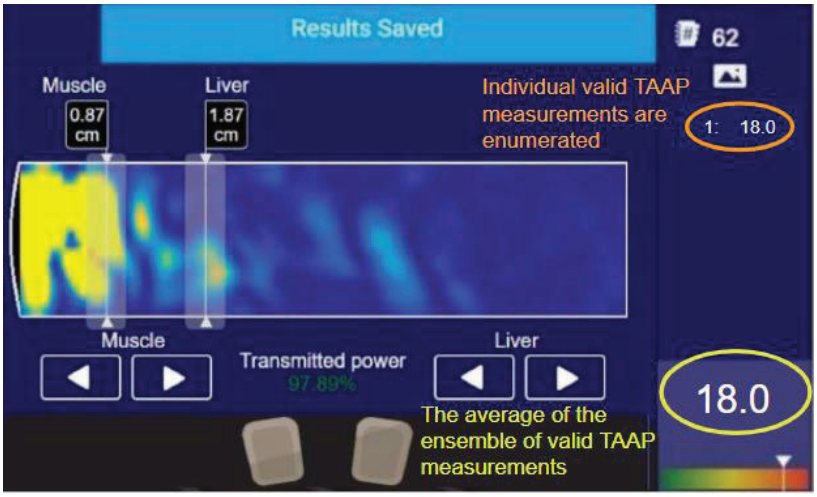


Figure 2-4. *Illustration of the TAAP Measurement User Displayed Graphic.*

2.4.4 TAEUS® FLIP System Clinical Performance

ENDRA has performed a clinical reproducibility and repeatability study as well as a comparison evaluation between TAEUS® FLIP measurements and MRI-PDFF fat fractions for a range of subjects with varying degree of fatty liver disease.

2.4.4.1 Intra- and Inter-Operator Variability

The intra-operator and inter-operator variability of the TAEUS® FLIP System, with User Guidance, showed no statistical difference demonstrating consistency in results by trained users. In addition, operators showed a statistically significant difference in FLIP Study results in comparing a healthy subject to a subject with moderate liver disease.

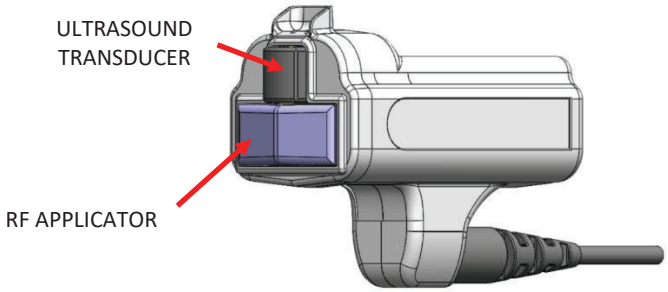
2.4.4.2 TAAP Estimates for Liver Fat Fraction Range vs. MRI-PDFF

TAEUS® FLIP estimates of liver fat fraction were obtained in a group of 24 subjects, at an investigational site, and compared to the subjects' MRI-PDFF scores of liver fat fraction. The BMI of the subjects included in the clinical study ranged from 24 to 42.9. No subjects were excluded for high BMI or liver fibrosis. TAEUS® FLIP metric estimates of liver fat fraction were highly correlated to MRI-PDFF scores of liver fat fraction, with a Pearson correlation coefficient of 0.78 (R^2 = 0.614).

2.5 SYSTEM COMPONENTS

The TAEUS® FLIP System consists of three primary components (***Figure 2-5***):

1. **TAEUS® System Console** (cart-mounted), containing an RF Source, Power Source, Electronics, and Firmware/Software.
2. **FLIP Probe** (handheld) – The handheld FLIP Probe consists of a proximal connector to the System Console, a cable, and the patient-surface contacting applicator, containing the RF applicator and US transducer, at the distal end. An LED display on the rear of the FLIP Probe indicates the current System status. A FLIP Probe Holder for a cart-mounted CUS Console is provided.



3. **Display Panel** – A seven-inch touchscreen monitor for entering data by the user and displaying System information. The Display Panel is connected to the TAEUS® Console via a USB-A cable and can be mounted to the side of a cart-mounted CUS monitor or to the detachable FLIP Probe Holder on the CUS console.

NOTE: The two USB-A ports on the TAEUS® System Console are dedicated connectors for the TAEUS® FLIP Display Panel and the optional, two-pedal footswitch. Designated Service personnel may optionally use one of these ports to connect a dedicated Service device for service activities; do not connect any other devices to these ports.

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

NOTE: The Main Power switch on the rear of the 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 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.

A two-pedal footswitch, which allows for hands-free operation of the TAEUS® FLIP while using the FLIP Probe, is provided as an optional accessory. If the footswitch is used, connection to the TAEUS® FLIP System Console is necessary to transfer information from the footswitch to the TAEUS® FLIP processing unit and is established by authorized service representatives during System setup.

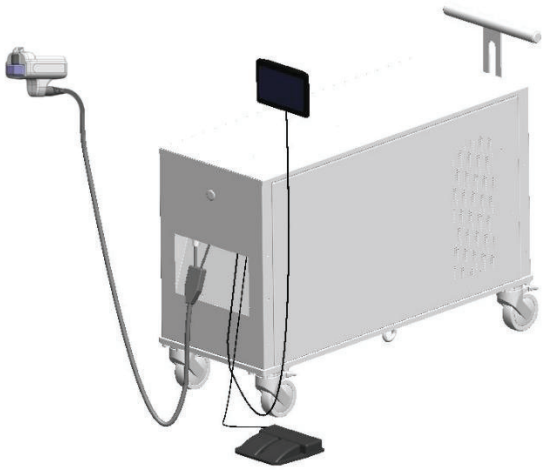


Figure 2-5. TAEUS® FLIP System.

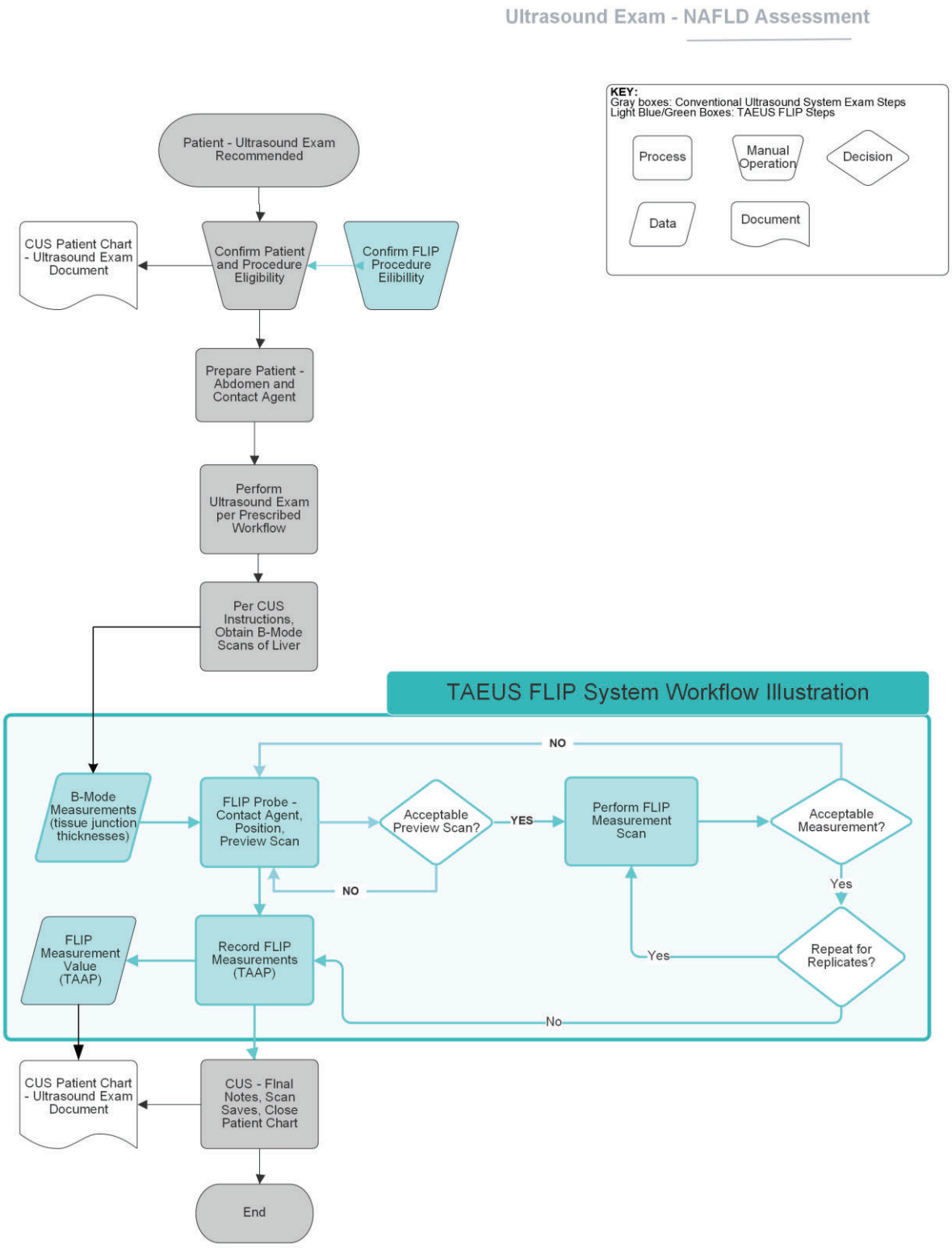
2.6 BASIC WORKFLOW

The basic procedure for obtaining TAEUS® FLIP measurements, when used with CUS, is as follows:

1. Prepare patient for exam
2. Per CUS Instructions, obtain B-Mode images with CUS
3. Per CUS instructions, on B-Mode image, measure distance from:
    a. skin surface to the boundary between subcutaneous fat and muscle
    b. skin surface to the boundary between intercostal muscle and liver capsule
4. Launch/Start TAEUS® FLIP System
5. Transfer boundary measurements to TAEUS® FLIP System
6. Perform FLIP Scan in same liver Region of Interest / position with FLIP Probe
7. Record FLIP TAAP [complex relative permittivity] measurements

A flowchart of the basic workflow is presented on the following page.

2.6.1 Workflow for TAEUS® Scan



Specific instructions are provided in the following chapter.

CHAPTER 3: Operating Instructions

3.1 INTRODUCTION

This chapter describes how to use the TAEUS® FLIP System in conjunction with a conventional ultrasound system (CUS).

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

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 operator 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.

3.1.1 Interaction with the CUS

FLIP Measurements (TAAP values) 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 a CUS 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 CUS 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.

3.1.2 Factors for a Successful Measurement

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

- Patient positioning
- Clinical positioning with respect to the patient
- Proper CUS 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 good measurement

3.1.3 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 operator
- Pillow
- Permanent marker or surgical pen
- Curved array CUS probe (for determining FLIP ROI)
- Linear array CUS probe (for B-mode measurements)
- 45° body sponge (if available), for easier patient positioning

3.2 SYSTEM STARTUP/PREPARATION

Before powering up:

- Examine the 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 console (visual confirmation).

ELECTRICAL HAZARD

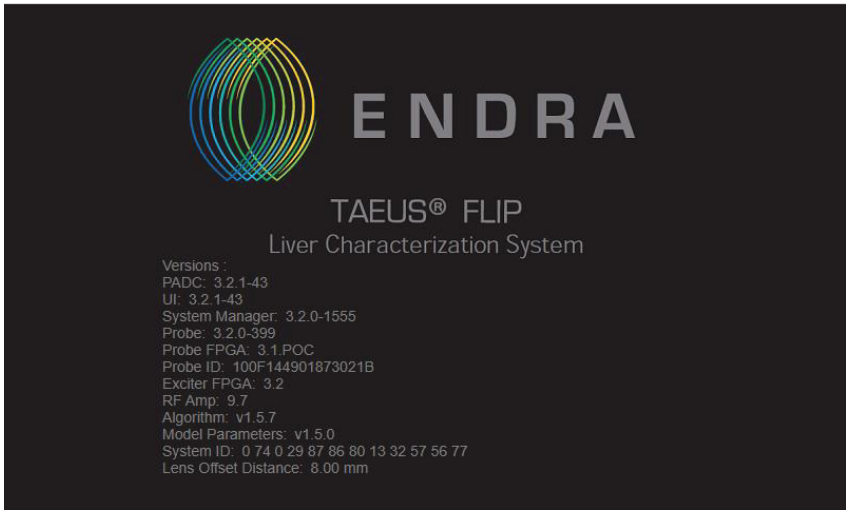
Do not operate the equipment If any defects are observed. Contact a qualified service person at service@endrainc.com for assistance.

If no defects are observed:

1. Press the flashing white Power button on the TAEUS® FLIP Console. A buzzer will sound as the System powers up.

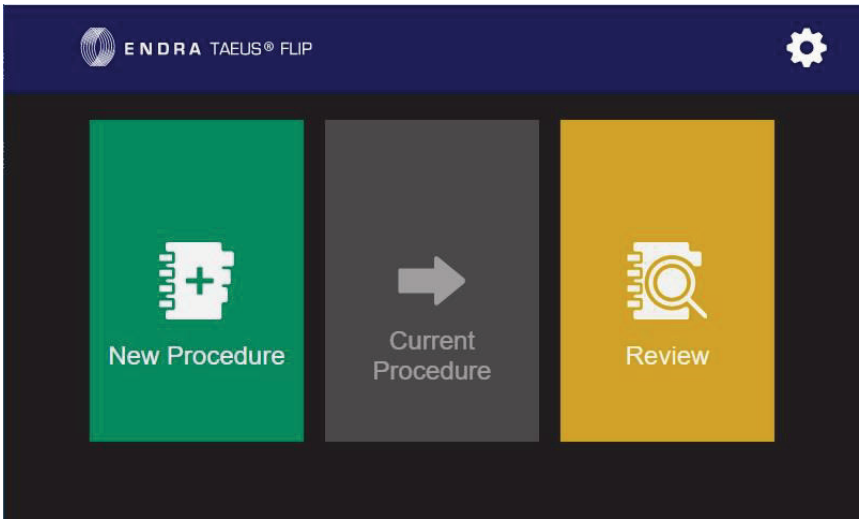
NOTE: If the Power button is not illuminated, ensure that the Main Power switch on the rear of the Console is turned on.

2. The TAEUS® FLIP splash screen will appear on the Display Panel 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 an exam with a new patient.

Current Procedure – Press to resume exam with current patient.

Review – Press to view data from a previous procedure.

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**.

3.3 PATIENT PREPARATION

1. Review contraindications with the patient.
2. Enter patient ultrasound data as instructed for the CUS procedure.

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

3.3.1 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 operator.

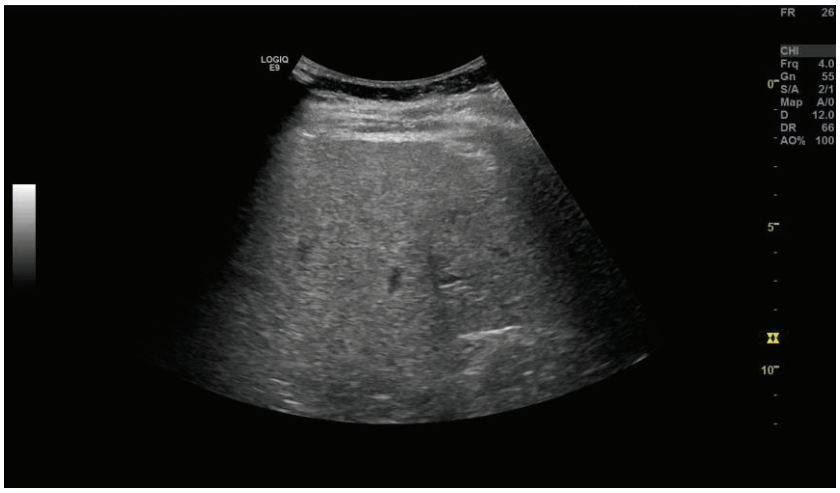
3.3.2 Operator Positioning

1. Adjust the scan chair and examination table heights and location to allow the operator to sit close to and at 90° to the table/patient.
2. Ensure adequate clearance for operator 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°.

3.4 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 CUS instructions, configure the CUS for B-Mode scanning.
2. Recommendations for location of the liver for ultrasound imaging is presented below. Refer to the CUS 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 CUS scan area, per CUS instructions.
    c. Do not tilt the CUS probe while scanning. Hold the CUS probe perpendicular to the patient contact surface.
    d. Scan 2-3 intercostal windows in the RUQ while the patient holds his/her breath. Compare images during expiration and inspiration to determine the most appropriate condition.
    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 CUS 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.

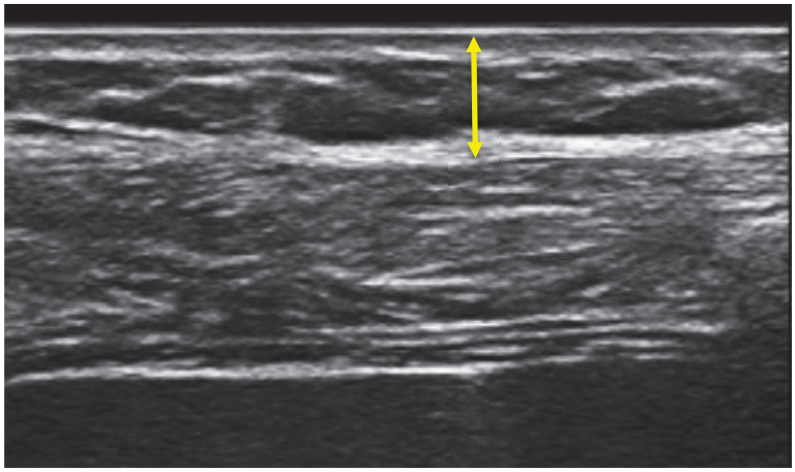
3.5 B-MODE IMAGE ACQUISITIONS WITH LINEAR ARRAY – GUIDANCE

The linear array acquisition is recommended to determine the distance of the fat/muscle and muscle/liver interface from the skin surface. Acquire a sagittal and a transverse image for comparison.

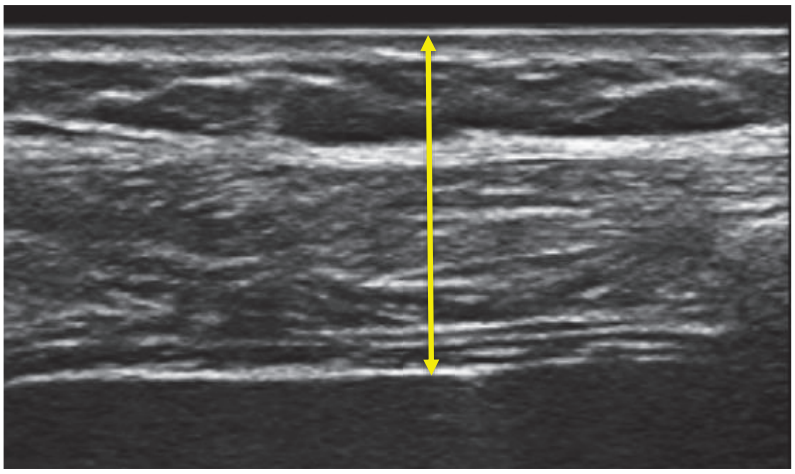
1. Place the linear array CUS probe on the patient's abdomen so that it is in the same location and orientation as the curved probe was in. Use the landmarks from the curved array CUS probe as a guide.
2. Have the patient hold their breath at the same point in the respiratory cycle they were in for curved array acquisition (i.e., expiration or inspiration).
3. Freeze the image.

3.6 BOUNDARY DETERMINATIONS

1. Compare the sagittal and transverse images and select the one in which the muscle and liver boundaries are the most clearly defined.
2. Measure the distance from the surface of the skin to the boundary between subcutaneous fat and muscle.



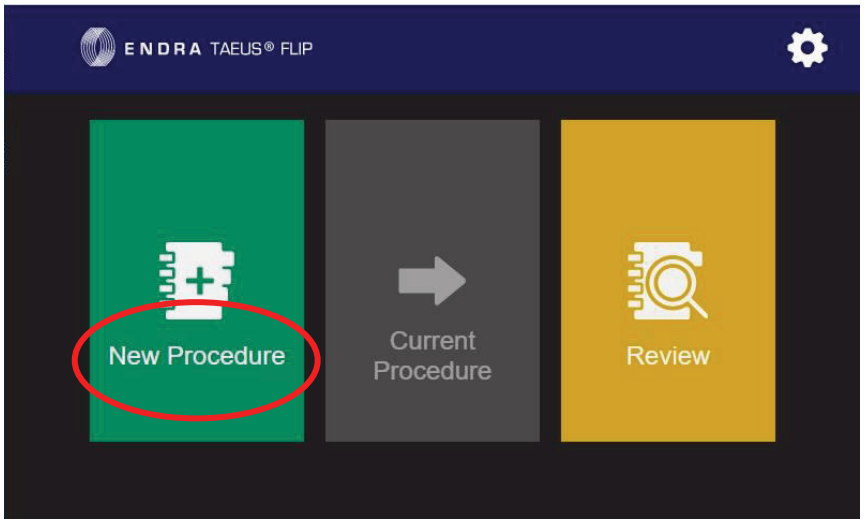
3. Measure the distance from the skin surface to the liver capsule.



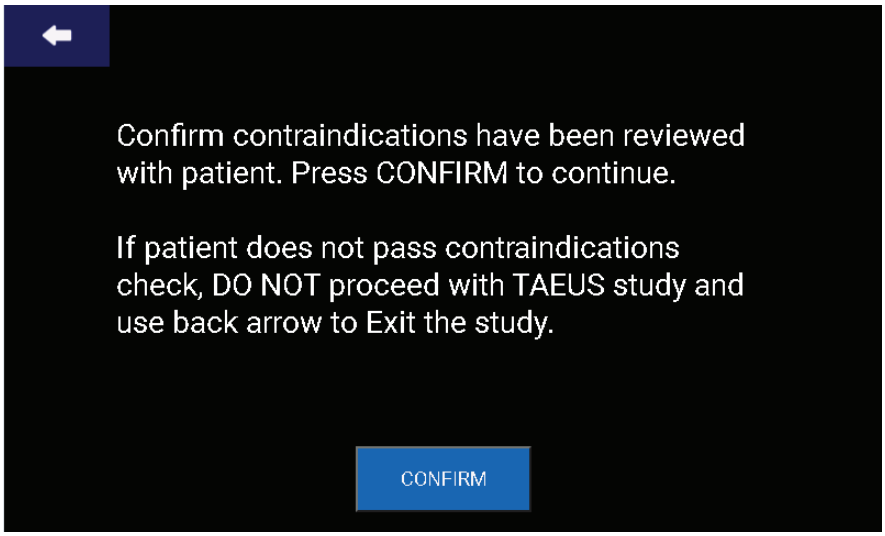
4. Record the two measurements.

3.7 FLIP SCAN - GUIDANCE

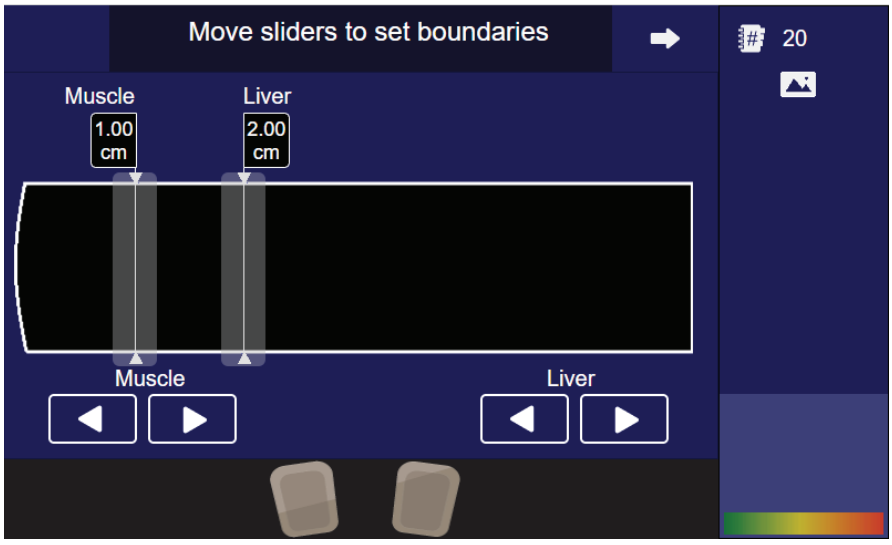
1. On the TAEUS® FLIP ***Idle*** screen, press ***New Procedure***.



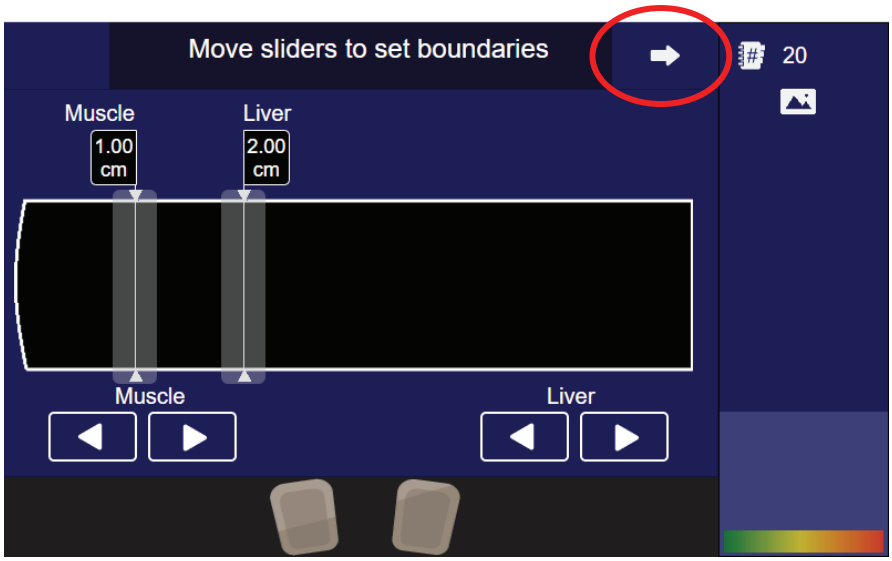
2. Before proceeding, confirm that all contraindications have been reviewed with the patient. Do not proceed if any apply.



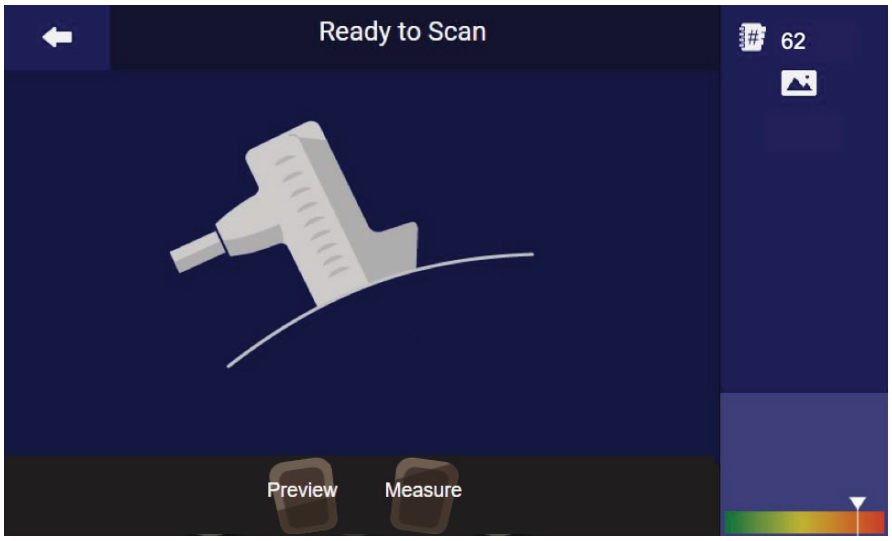
3. On the next screen, position each of the two slider bars so that the ***Muscle*** and ***Liver*** boundary values correspond to the distance measurements obtained with the CUS in *Section 3.6* above. Press the arrow keys for fine positioning adjustments to move the slider bars.



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



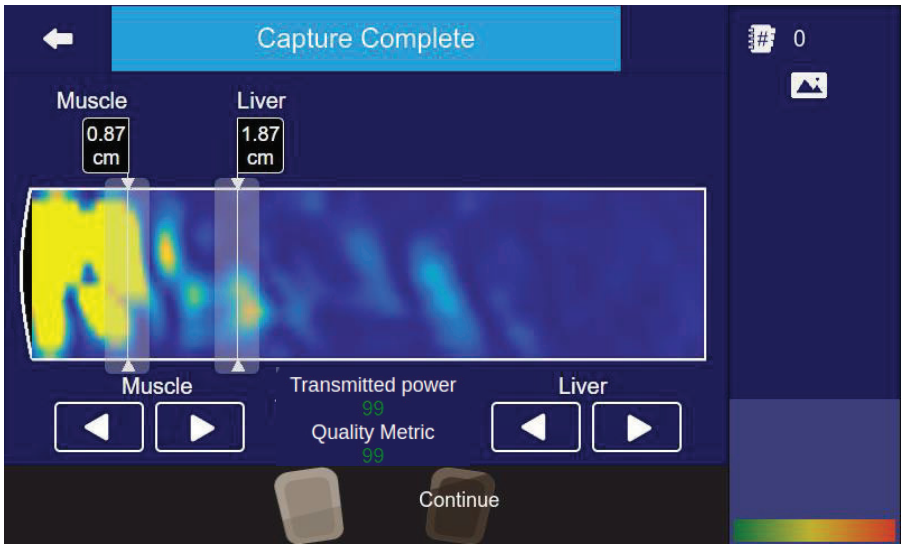
5. When the FLIP Probe has powered up, a ***Ready to Scan*** page appears and the LED indicator turns solid green:



6. Remove the FLIP Probe from its holder. Apply more ultrasound gel in necessary.
7. For best results while scanning:
    - Sit facing the FLIP Display.
    - Hold the FLIP Probe firmly with both hands.
    - Rest the forearm against the body sponge for support or rest the elbow on the edge of the examination table.

- Apply even, medium pressure to ensure sufficient contact for the complete patient-contacting surface. Do not tilt the FLIP Probe along its longitudinal axis.
- 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 and approximate orientation as the CUS probe was for the B-Mode acquisition. Line up the center of the FLIP ultrasound transducer (the small dark square) with the landmark made with the curved array CUS probe in Section 3.4.
9. Have the patient hold their breath at the same point in the respiratory cycle they were in for B-Mode acquisition (i.e., expiration or inspiration).
10. Press the ***Preview*** footswitch to acquire a short, 0.2 sec ***Preview*** scan. A ***Preview*** allows you to examine the thermoacoustic signal for evaluation purposes.



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.

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

    The graphic in the scan area window (signal localizer) represents the raw thermoacoustic signal from the skin surface to a depth of approximately 5 cm. The two lines correspond to the boundaries of intercostal muscle and liver capsule.

Thermoacoustic signals have the highest intensity where there is an change in the RF absoprtion between neighboring tissues: at the skin surface, at the interface between subcutaneous fat and intercostal muscle, 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:

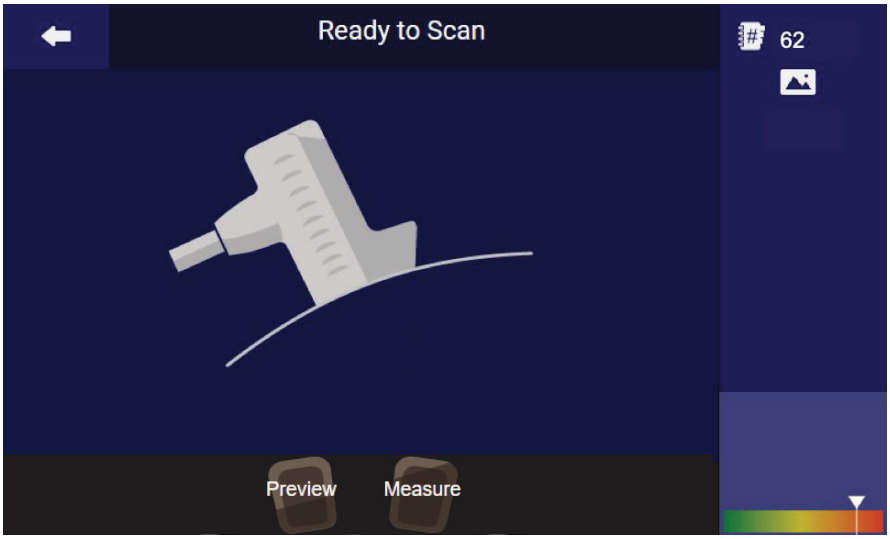
- There is no signal at or near the expected boundaries
- There are multiple, low intensity signals at the expected boundaries

Anomalies such as these can result from poor FLIP Probe contact, incorrect CUS probe positioning during B-Mode acquisition, proximity to the lung, or if the distance between the liver and muscle boundaries is greater than 12mm.

The **Transmitted Power** and **Scan Quality** parameters should also be used to determine whether a scan with the current Probe position is acceptable. The **Transmitted Power** parameter is an indicator of whether the contact is effective 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** parameter represents the likelihood of a scan to yield a true estimate of liver fat, as calculated from beamformed analysis of the amplitude and angle of the signals from the boundaries of the skin, subcutaneous fat, muscle, and liver. 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 50%.

12. Press the **Continue** footswitch to return to the ***Ready to Scan*** page.



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

14. Once the ***Preview*** scan is acceptable,

    a. Keep the FLIP Probe in the same position

    b. Have the patient hold their breath at the same point in the respiratory cycle they were in for the ***Preview*** scan

    c. Press the **Measure** footswitch to make a full ***FLIP Measurement***.

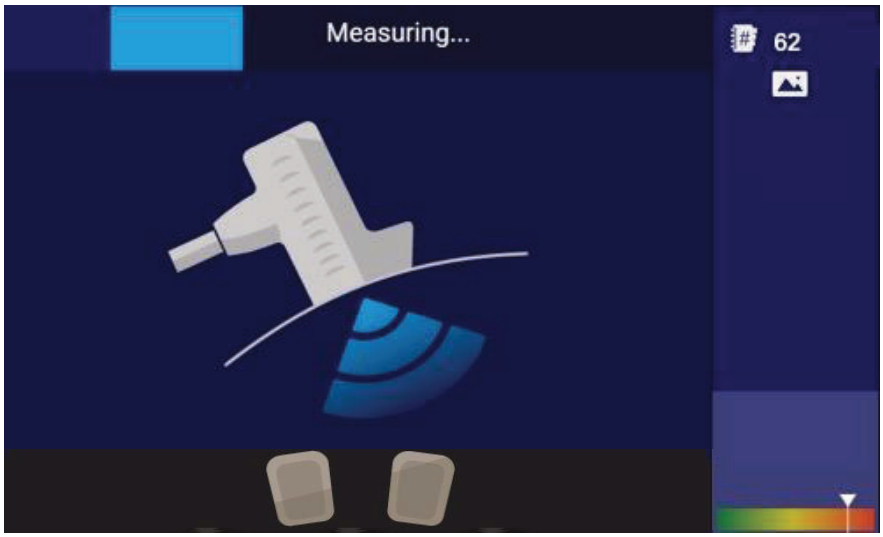
15. After pressing the footswitch, TAEUS® FLIP System checks that there is sufficient contact between the FLIP Probe and the body (***Searching for RF Signal***). An audio alert (long beep tone) sounds if any errors occur. See the *Troubleshooting* section below for more information.

    SAFETY NOTES:

    The TAEUS® FLIP System **does NOT emit RF pulses when not in use** (not scanning). Therefore, it is compatible with Ultrasound Systems that caution on RF use in near proximity.

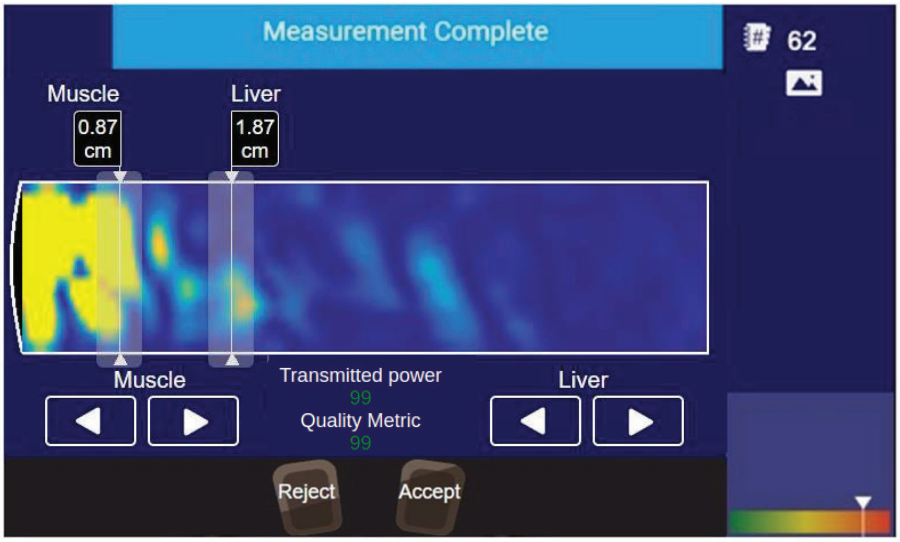
    As an additional safety feature, the System **checks to make sure that there is sufficient contact between the FLIP Probe and the patient**. If there is not sufficient contact, the FLIP Scan will not be initiated, and an error will occur.

16. When the checks have completed without errors, TAEUS® FLIP begins collecting the thermoacoustic signal:



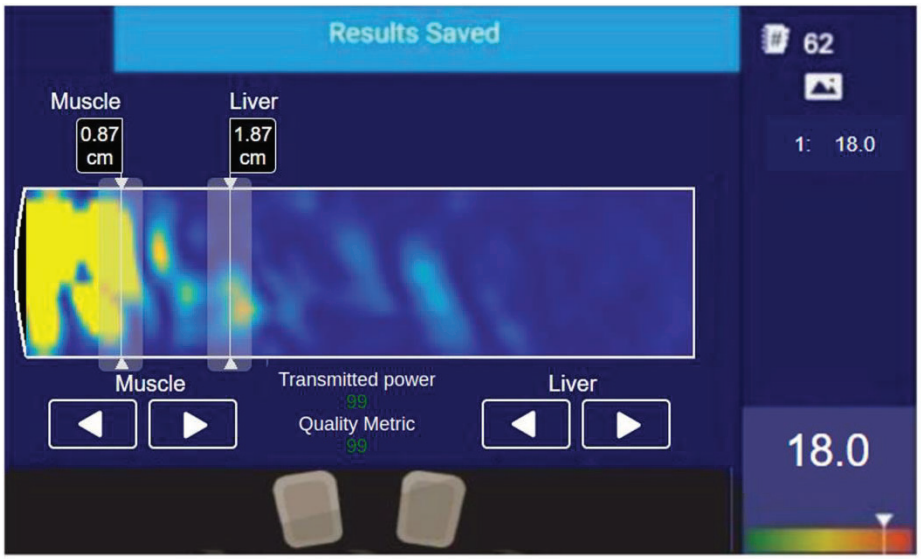
The LED indicator flashes green while data is acquired. An audio alert (short beep) sounds during RF emission.

17. A graphical signal localizer is displayed when the scan has completed, and the FLIP Probe indicator turns solid blue:



18. ***Reject*** the scan if the **Transmitted Power** is less than 80% or **Scan Quality** is less than 50%. To reject the scan, press ***Reject***. Data is discarded and the user is returned to the ***Ready to Scan*** page. Reposition the FLIP Probe and acquire another ***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 ***Preparing for Next Measurement*** screen will appear with a countdown timer. The ***Ready to Scan*** page will automatically display when the timer reaches 0 sec.



19. If the scan is acceptable, press the ***Accept*** footswitch to save the scan data.

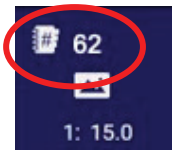
Numerical measurement for the current scan, estimated complex relative permittivity (+/- 3.5), referred to as the TAAP value, is displayed in the right panel, as are any previous or subsequent scans obtained from the same patient. The average TAAP value is displayed in the bottom right corner.

NOTE: The calculations provided by the System are intended for use by qualified users, as a tissue characterization tool to aid in the assessment of fatty liver tissue

20. Accepting the FLIP 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 up to 20 measurements per patient.

3.8 RECORDING/PRESERVING FLIP MEASUREMENTS

Although FLIP Measurements for a given procedure are preserved and retrievable (see *Section 3.13* below), they should be recorded by hand before starting a new patient exam (***New Procedure***) or before turning the System off. At minimum, record the average TAAP value, the date, and the procedure number. A sequential procedure number is automatically generated with every new FLIP Procedure and displayed in the top right corner:



Another way to preserve and/or document FLIP Measurements and to keep them associated them with a particular patient is to annotate and save the B-Mode image acquired with the CUS System.

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

3.9 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.

3.10 CLEANING AND DISINFECTING

CAUTION Once the patient has been scanned, inspect the FLIP Probe face or distal end for any visual damage or cracks before proceeding to the cleaning step.

To Clean:

- Wipe down the contact surface, cords, housings, and any other surface that was touched during the exam (i.e., the touchscreen display, console, console power switch, integrated Probe/Display holder) with SONO® Wipes or another TAEUS® System-compatible cleaning and disinfecting wipe listed in *Appendix C*.
- Perform cleaning and disinfection in accordance with the wipe manufacturer's instructions.
- Clean and disinfect the CUS probe per the manufacturer's instructions.

To Disinfect:

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

- Make sure the treated surface remains visibly wet for the manufacturer's recommended contact time, paying attention to seams, gaps, and recessed areas.

- Wipe down the contact areas, cords, housings, and any other surface that was touched during the exam (i.e., the touchscreen display, console, console power switch, integrated Probe/Monitor holder).
- After disinfection, remove any residual liquid with a clean, soft cloth, as needed.

3.11 SHUTDOWN PROCEDURE

1. Press the Power button on the TAEUS® FLIP console.

2. Power down the CUS as described in its User Guide.

3.12 TROUBLESHOOTING

ERROR MESSAGE	CAUSE	RESOLUTION
No Probe Contact	Poor RF signal.	Ensure that there is sufficient contact between the FLIP Probe and the body. User is returned to ***Ready to Scan*** page.
Timeout waiting for RF status	Pre-scan contact-sensing signal not received within specified time.	Ensure that there is sufficient contact between the FLIP Probe and the body. User is returned to ***Ready to Scan*** page.
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.
Incomplete Measurement	Probe loses contact with body while scan is in progress.	Re-scan. User is returned to ***Ready to Scan*** page.
Error during measurement, Re-Initiate Scan	System is unable to complete scan.	Re-scan. User is returned to ***Ready to Scan*** page.

ERROR MESSAGE	CAUSE	RESOLUTION
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 returned 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 20 scans per Procedure/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 home screen. 2. Press the ***Settings*** icon. 3. Select ***Turn off Service Mode.*** Return to home screen.

ERROR MESSAGE	CAUSE	RESOLUTION
PADC did not start Probe did not start PADC error Probe error PADC heartbeat lost Probe heartbeat lost RF Error Exciter watchdog fired Exciter pulsing time timeout Exciter pulsing did not start Exciter pulse count error Amp watchdog fired Exciter poll error Amp poll error Unrecoverable Exciter Error, System Restart Required” Unrecoverable Amplifier Error, System Restart Require Power Monitor Test Failed Probe not available An unrecoverable System error has occurred	System has detected an unrecoverable error.	Press **Shutdown** and re-start System. Contact service@endrainc.com if error persists.

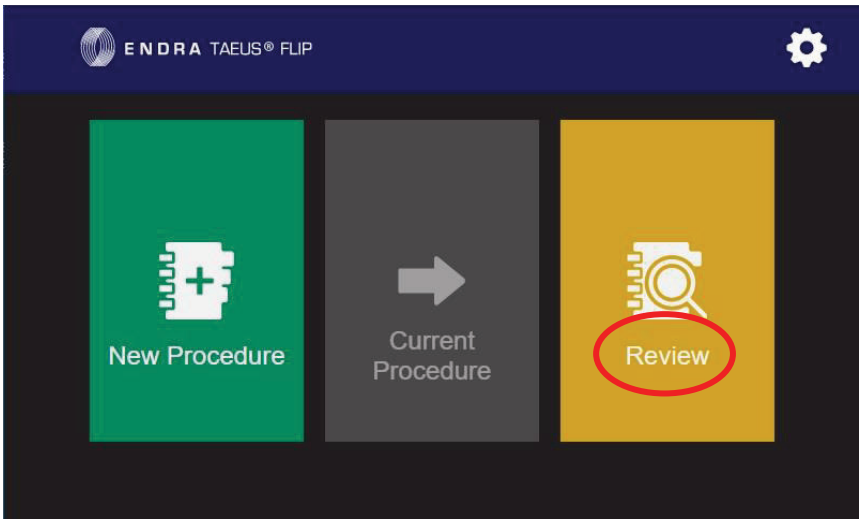
Contact service@endrainc.com in the event of any other System malfunction or change in its performance.

3.13 RETRIEVING PAST FLIP PROCEDURES

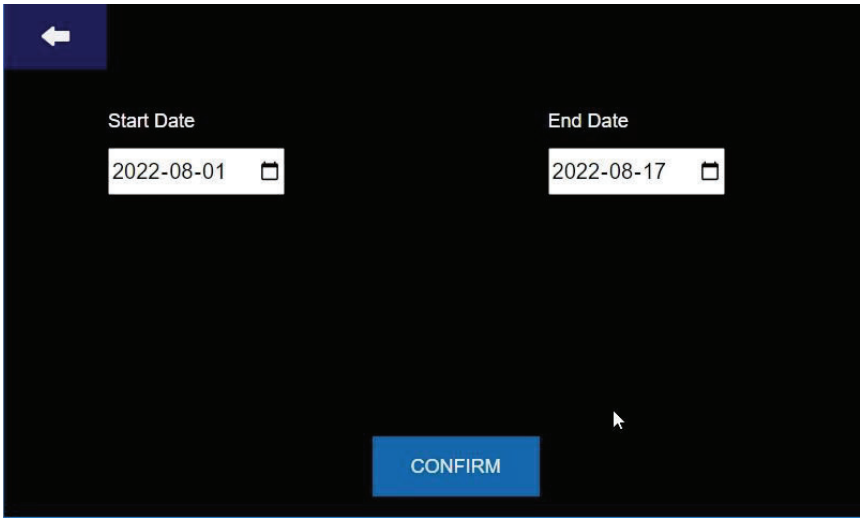
Measurements from individual FLIP Procedures are automatically saved to TAEUS® FLIP’s internal storage System where they can be retrieved and displayed for downstream examination/review at later dates. They cannot be edited or appended.

To retrieve a past FLIP Procedure:

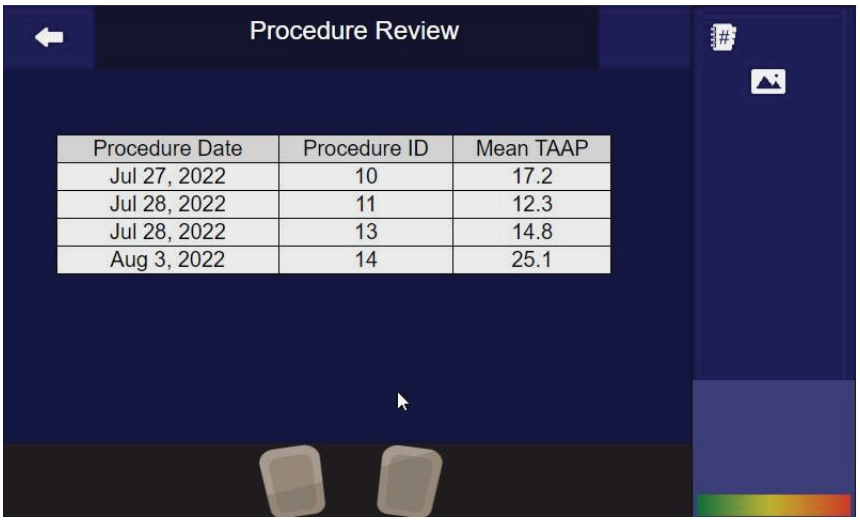
1. Press ***Review*** on the ***Idle*** screen:



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 Procedures completed within the specified **Start** and **End** dates is displayed. The table specifies the date each procedure was performed, the procedure ID number, and the Mean TAAP value.



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

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

CHAPTER 4: Care and Maintenance

4.1 INSPECTING THE TAEUS® FLIP SYSTEM

Before powering up:

- Examine the 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.

4.2 WEEKLY MAINTENANCE

The 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 and disconnected from the main power source. Cleaning with the System turned on may be hazardous to the operator and/or destructive to the System.

4.2.1 Console Cabinet

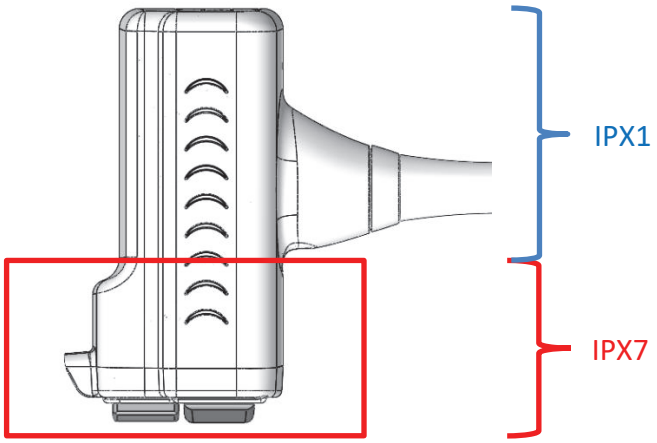
To clean the Console cabinet, wipe down the top, front, back, and both sides of the console cabinet with disinfectant SONO® Wipes or other TAEUS®-compatible wipes listed in *Appendix C.* Note that any surface that was touched during a FLIP scan should also be wiped down with disinfectant wipes as described in *Chapter 3, Section 3.10.*

4.2.2 FLIP Probe

After cleaning the Console cabinet, inspect the full length of the tether cable and the surface layer of the RF applicator for wear.

After inspection wipe down the Console tether cord and housing with SONO® Wipes or other compatible wipes. All components should also be wiped down following a TAEUS® scan as described in *Chapter 3, Section 3.10*.

Note that the FLIP Probe has two different levels of fluid ingress protection: The patient contacting face and all areas 4 cm back from it are immersible to a regulatory standard level IPX7. Visually, the FLIP Probe may be immersed up to its third grip feature, noted below. The remainder of the Probe including tether cable bend relief is drip resistant, rated to IPX1. These areas are protected against ingress so they can be wiped down with wetted wipes, as described above.



4.2.3 Display Panel

The touchscreen Display Panel and frame should be cleaned with disinfectant wipes after each TAEUS® exam and as part of weekly routine maintenance.

NOTE: Do not use alcohol (methyl, ethyl or isopropyl), thinner, benzene, or other abrasive cleaners.

NOTE: Do not get liquids on or inside the unit. If liquid does get inside, have a qualified service technician check it before you power it on again.

NOTE: Do not wipe the screen with a cloth or sponge that could scratch the surface.

4.2.4 Footswitch

Clean the external surface of the optional 2-pedal footswitch per the manufacturer's instructions. Clean by wiping the pedals and the electronics enclosure with a damp cloth. Alternately, a cloth dampened with rubbing alcohol (70% isopropanol) may be used, though any silk-screened graphics on the electronics enclosure may be damaged over time by effects of the solvent.

4.3 PERFORMANCE VERIFICATION

The performance of the TAEUS® FLIP should be tested on a weekly basis, using the TAEUS® FLIP SysCk Phantom supplied by ENDRA Life Sciences (Part #EN4010). See the *EN5005 System Check* document for instructions.

4.4 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 Console, FLIP Probe, Display Panel, Probe Holder, SysCk Phantom, and the optional 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
ThermoAcoustic Enhanced UltraSound Fatty Liver Imaging Probe System

MODEL:

Europe: EN9000
North America: EN9001

MANUFACTURER:

ENDRA Life Sciences
3600 Green Ct., Suite 350
Ann Arbor, MI 48105-1570 USA
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:	2235 mm +/-80mm
Weight:	< 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:	> 170 mm

FLIP PROBE:

RF Output

Applicator type:	Aperture antenna
Beam dimensions:	22 mm (azimuth) x 17 mm (elevation)
Frequency:	433.92 ± 0.6 MHz
Pulse rate:	400 Hz
Pulse width:	1.0 µs
Duration:	1.2 s
Peak power:	4.5kW - 5.5kW (operating conditions), <6.92kW (maximum)
Duty cycle:	0.04% (operating conditions), <0.15% (maximum)
Energy (SAR):	1.5 W/kg - 1.9 W/kg (operating conditions), < 2.35 W/kg (maximum)
Avg. radiated power:	1.8W - 2.2 W (operating conditions), <10.35 W (maximum)

Ultrasound Transducer

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

ELECTRICAL REQUIREMENTS:

AC Power Requirements: ~100-240V, 50-60Hz, 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:
www.endrainc.com

E-MAIL (General):
info@endrainc.com

E-MAIL (Service):
service@endrainc.com

AUTHORIZED REPRESENTATIVES:

EC REP

MedNet EC-REP GmbH
Borkstrasse 10
48163 Münster
Germany

MediMap Ltd.
2 The Drift
Thurston
Suffolk IP31 3RT
United Kingdom

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 a total of 250 reprocessing cycles (representative of one year of use). Each cycle consisted of gross cleaning of residual ultrasound gel with a soft, lint-free cloth, followed by cleaning and disinfection per the product manufacturer's instructions for general disinfection. None of the listed products caused unacceptable damage to the FLIP Probe's contact surface or adversely affected the Probe's performance as tested and described in *EN5005 TAEUS FLIP System Check*.

PRODUCT NAME	MANUFACTURER	ACTIVE INGREDIENT(S)	CONTACT TIME*
SONO Wipes™	Advanced Ultrasound Solutions Inc.	Octyldecyldimethyl ammonium chloride Dioctyldimethyl ammonium chloride Didecyldimethyl ammonium chloride Alkyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride	4 min
Clinell® Universal Wipes	GAMA Healthcare	Didecyldimethyl ammonium chloride	5 min
Mikrozid® AF Wipes	Schülke	Ethanol Propan-1-ol	5 min
WIP'ANIOS EXCEL Wipes	Laboratoires Anios	Didecyldimethyl ammonium chloride	5 min

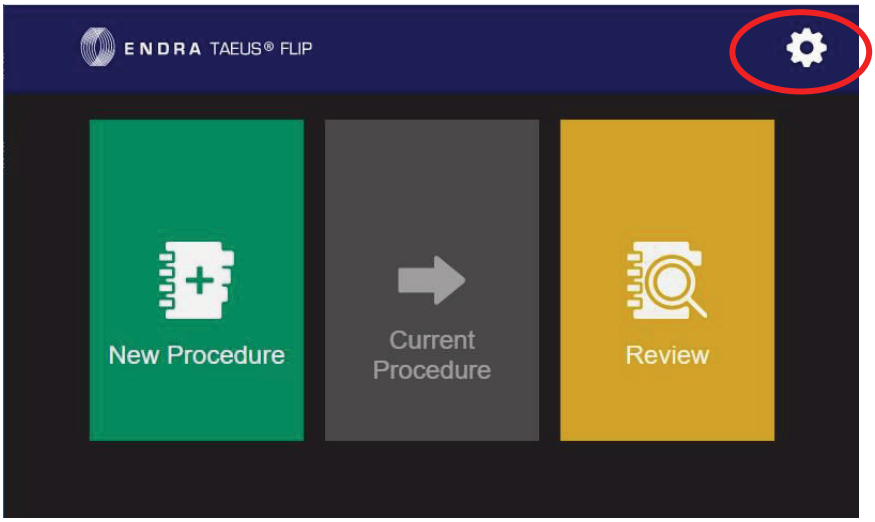
* Always refer to manufacturer's instructions to ensure appropriate contact times.

APPENDIX D: System Usage Report

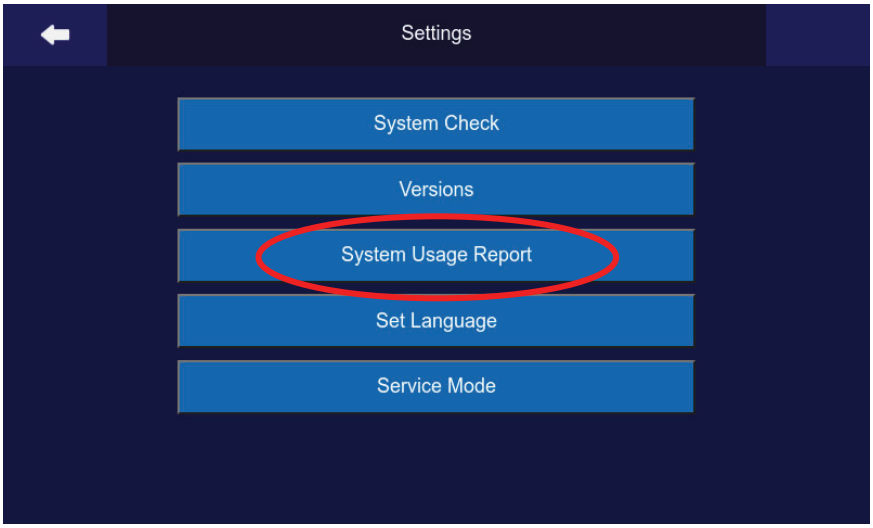
TAEUS® FLIP includes a mechanism to create and export a simple **System Usage Report** that summarizes usage statistics within a defined period of time.

To create a ***Usage Report***:

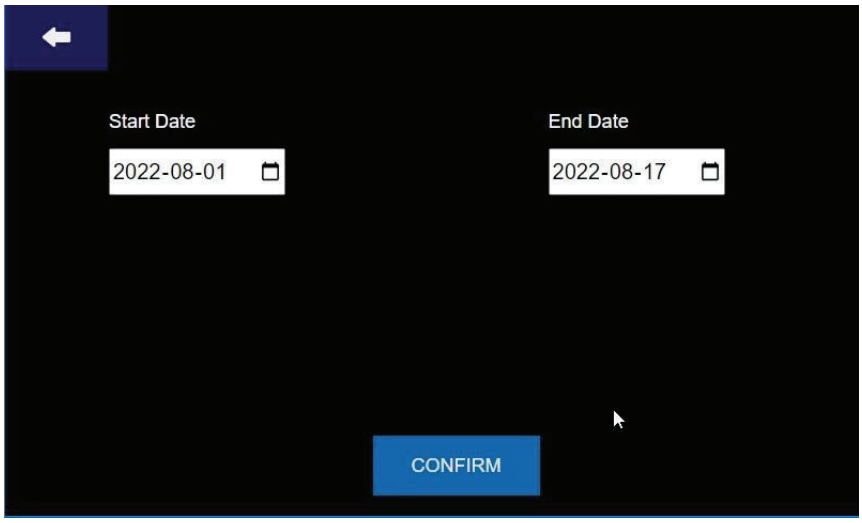
1. Click the ***Settings*** icon.



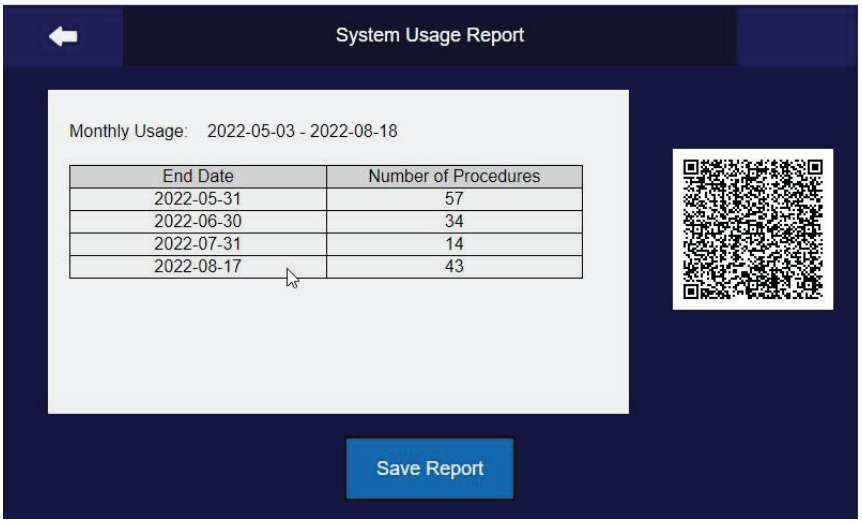
2. Select the ***System Usage Report*** option.



3. 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.



4. A scrollable list of FLIP Procedures completed within the specified **Start** and **End** dates is displayed. The table specifies the dates in which procedures were performed and the number procedures completed on those dates.

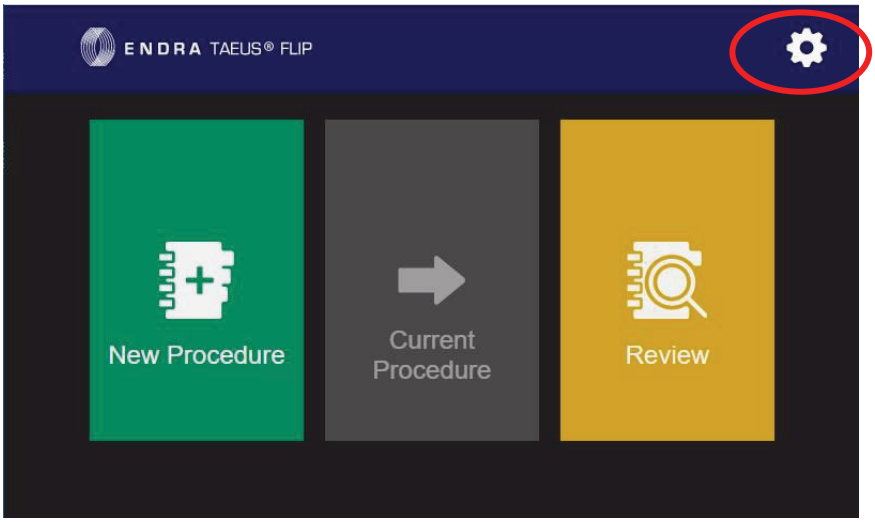


APPENDIX E: User Documentation Options

A copy of this User Guide may be accessed on the TAEUS® FLIP System.

To display the User Guide on the Display Panel:

1. Click the ***Settings*** icon.



2. Click the **Help/Info** icon.