SONOSCANNER
Premium Diagnostic Ultrasound

T-Lite and U-Lite Models

OPERATION MANUAL

Rev 5.0 – 03/2024

CE 0197

1.REGULATORY REQUIREMENT

This product complies with the regulatory requirements of the following:

Regulations/Standards	Scope
REGULATION (EU) 2017/745	European Regulation on Medical Device
2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)
2011/65/EU	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
IEC/EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC/EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC/EN 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC/EN 62366-1	Medical devices - Application of usability engineering to medical devices
EN ISO 14971	Medical devices - Application of risk management to medical devices
IEC/EN 62304	Medical device software - Software life-cycle processes
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes

This manual is a reference for the **U & T LITE ultrasound systems** and covers the following models :

MODEL	Unique Device Identifier
T LITE	37011046001160
T LITE PRO	37011046003218
U LITE EXP	37011046000484
U LITE PRO	37011046002914
U LITE SCP	37011046000002
U LITE SLP	37011046000170
U LITE SPA	37011046000248
U LITE SEP	37011046000316

2. TABLE OF CONTENTS

CHAPTER I
INTRODUCTION

1.GENERAL INFORMATION

Welcome. Thank you for choosing this ultrasound system from Sonoscanner. This device is specifically designed to help you run a wide variety of exams such as abdominal, obstetric, gynecologic, vascular...
Its wide range of imaging modes and its superior imaging system will help you make ever more accurate diagnostics over a broad range of clinical settings.

The Sonoscanner ultrasound systems are extremely secure and our network of official Sonoscanner distributors remains at your disposal to answer any question that you may have or to provide you with any help that you may need.

1.1.Manual Content

This manual contains a description of all the standards or on demand features. Some of the features described in this manual may not have been implemented on your device.

This manual is divided into nine (9) chapters. Each of these chapters covers a specific topic.

- **CHAPTER I** INTRODUCTION: contains the general information you need to know concerning your system.

- **CHAPTER II** SYSTEM SET UP AND PREPARATION FOR USE: tells you how to set up your system and prepare it for use.

- **CHAPTER III** GETTING STARTED: presents the recommended procedure to properly start an exam.

- **CHAPTER IV** IMAGING MODES AND ASSOCIATED SETTINGS: contains a detailed description on how to operate the available imaging modes and their associated settings.

- **CHAPTER V** MEASURES: explains how to perform measurements.

- **CHAPTER VI** SONOSCANNER PROBES: delivers information on the use, care, maintenance and safety of the Sonoscanner probes.

- **CHAPTER VII** SAFETY: describes all the safety considerations that you must be aware of before operating the system.

- **CHAPTER VIII** USER MAINTENANCE **CHAPTER VIII below** presents the recommended instructions for the care and maintenance of the device.

- **CHAPTER IX** ADVANCED CONFIGURATION: describes all the advanced configuration options for the system

1.2. How to use this manual

This manual contains all the necessary information so that you operate the system safely and effectively.
It is important that you take the time to read and understand all the instructions of this manual before attempting to use the device.

This manual is designed so that each chapter covers a specific topic, from the device safety considerations to its imaging modes and associated settings.

Information has been arranged to help you find information easily and quickly.

Keep this manual with the equipment. Do not hesitate to review its content if needed.

1.3. Contact Sonoscanner

If you need further information on the system, please contact your authorized Sonoscanner representative.

Sonoscanner
6, rue André Voguet
94200 Ivry-Sur-Seine
FRANCE
Tel : +33 (0)9 54 97 15 57
Email : contact@sonoscanner.com

1.4. Manual status

Rev 5.0
03 -2024

Electronic copies are available at academie.sonoscanner.com

1.5. ULTRASOUND BASIC PRINCIPLES

Ultrasound imaging, also called ultrasound scanning or sonography is a method used to obtain images from inside the human body through the use of high-frequency sound waves.
The creation of an ultrasound image is done in three steps:

Transmission of Mechanical High Frequency Waves (between 2 and 18 megahertz) by a piezoelectric transducer encased in a probe.
(Piezoelectricity is the ability of some materials to generate an electric potential including ultrasound wave in response to applied mechanical stress such as electric impulsion).
The ultrasound wave spread through the body and come into focus at a desired depth (determined by the frequency set by the practitioner). The ultrasound waves produce echoes where density changes occur : blood flow in organs, fetus in womb.
Echoes Reception: The echoes then return to the transducer that they make vibrate. The transducer converts those vibrations into electrical signals.
Interpretation of Echoes: The electrical signals are then amplified, processed and transformed into a digital image by several circuits (analog and digital) transforming the high frequency electrical signals into a series of digital image signals which are stored in memory.

It is important to note that each of the above three steps (transmission, reception, processing) are controlled by the computer.

After being stored, the computer is then able to display the images in real-time on the monitor.

2.INDICATIONS FOR USE

U Lite and T Lite models are Handheld Ultrasound system intended for use in environments where healthcare is provided by qualified and trained healthcare professionals.
It can therefore be used in different configurations, especially:
- In medical offices (general practitioner's office)
- In clinics & hospitals (incl. in emergency and critical care units)
- In a field hospital
It is used in imaging or examinations rooms.

The device is indicated for the visualization of structures and dynamic processes in the human body using ultrasound imaging and fluid flow analysis for diagnosis in the following clinical applications:

	U LITE SPA / SLP/ SEP/ SCP/ EXP	U LITE PRO	T LITE	T LITE PRO
Ophthalmic	×	✓	×	✓
Fetal	✓	✓	✓	✓
Abdominal	✓	✓	✓	✓
Pediatric	✓	✓	✓	✓
Small organ	✓	✓	✓	✓
Neonatal Cephalic	✓	✓	✓	✓
Adult Cephalic	×	✓	×	✓
Trans-rectal	✓	✓	✓	✓
Trans-vaginal	✓	✓	✓	✓
Musculo -skeletal (conventional)	✓	✓	✓	✓
Musculo-skeletal (superficial)	✓	✓	✓	✓
Cardiac Adult	✓	✓	✓	✓
Cardiac Pediatric	✓	✓	✓	✓
Gynecological	✓	✓	✓	✓
Peripheral Vessel	✓	✓	✓	✓
Urology (including prostate)	✓	✓	✓	✓

The Device should be used in compliance with law.
Some jurisdictions restrict certain uses such as gender determination(e.g., in India and China, the use of ultrasound-based diagnostic imaging technique to determine the gender of the fetus is strictly forbidden except when there is a medical necessity.)

The application fields are dependent on the selected probe.
Modes of operations include:
- B-Mode (B)
- M-Mode (M)
- Color Doppler (CD)
- Power Doppler (PD)
- Spectral Pulsed-Wave Doppler (PWD)
- Continuous Wave Doppler (CWD)
- Combined :(B+M; B+CD; B+ PD; B+PWD)

The device is a general-purpose ultrasound. It can therefore be used in different configurations, especially:
- in medical offices,
- in clinics,
- in hospitals.

It is used in imaging or examination rooms.
It can be used at the bedside. It is not intended for direct use in a sterile environment.

The Device is not compatible with the use of the HF surgery device or in an MRI system.

3. *INTENDED USER – PRESCRIPTION DEVICE*

This device with the associated probes is intended to be used by physicians and professional's sonographers with at least basic ultrasound knowledge.

Notification of Serious Incident
As a health care provider, you may report the occurrence of certain events to Sonoscanner Sarl, and possibly to the competent authority of the state in which the user and/or patient is established. These events include device related death and serious injury or illness. In addition, as part of our Quality Management System, Sonoscanner Sarl request to be notified of device failures or malfunctions.

For USA only
CAUTION : Federal law restricts this device to sale or use by or on the order of a physician.

4. ELECTROMAGNETIC COMPATIBILITY (EMC)

NOTE :	*This equipment generates, uses and can radiate 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 Group 1, Class A Medical Devices Directive as stated in EN 60601-1-2. However, there is no guarantee that interference will not occur in a particular installation*.

Electrical medical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
AII types of electronic equipment may characteristically cause electromagnetic interference with other equipment, transmitted either through air or connecting cables. The term Electromagnetic Compatibility (EMC) indicates the capability of the equipment to curb electromagnetic influence from other equipment, while at the same time not affecting other equipment with similar electromagnetic radiation.
Radiated or conducted electromagnetic signals can cause distortion, degradation, or artifacts in the ultrasound image which may impair the ultrasound unit's essential performance (see 'Electrical Safety' on page 2-8).
There is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:
• Re-orient or re-locate the affected device.
• Increase the separation between the unit and the affected device.
• Power the equipment from a source other than that of the affected device.
• Consult the service representative for further suggestions.

The manufacturer is not responsible for any interference or responses caused by the use of interconnecting cables other than those recommended, or by unauthorized changes or modifications to this unit. Unauthorized changes or modifications could void the user's authority to operate the equipment.
To comply with the regulations on electromagnetic interference, all interconnecting cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing or responding to radio frequency interference, in violation of the European Union Medical Device Regulation and FCC regulations.

Interference Caution

Use of devices that transmit radio waves near the system could cause it to malfunction.

Devices which intrinsically transmit radio waves such as cellular phones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, should preferably not be operated near the unit. Medical staff in charge of the system are required to instruct technicians, patients and other people who may be around the system to fully comply with the above recommendations.
Any electrical device can unintentionally emit electromagnetic waves. However, minimum device separation distances cannot be calculated for such unspecified electromagnetic radiation. When the ultrasound unit is

used adjacent to or in close proximity to other equipment the user should be attentive to unexpected device behavior which may be caused by such electromagnetic radiation.
The ultrasound unit is intended for use in the electromagnetic environment specified in the tables below.
The user of ultrasound unit should assure that the device is used in such an environment.

	The use of accessories and cables other than those specified, may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Device.
	The use of accessories and cables other than those specified, may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Device.
	The use of accessories and cables other than those specified, may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Device.
	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 Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”.
	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

4.1. Electromagnetic emissions

Guidance and manufacturer’s declaration – electromagnetic emissions.		
The Device is intended for use in the electromagnetic environment below. The customer or the user of the Device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emission EN55011	Group 1	The Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission EN55011	Class A	This system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: WARNING: This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the

		location.
Harmonic emission EN/IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN/IEC 61000-3-3	Complies	

NOTE :	*NOTE: The Device is a Class-A equipment suitable for use in a professional healthcare facility environment. The operator must assure that the system is used per the specified guidance and only in the electromagnetic environment listed above.*

4.2. Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic emissions.			
The Device is intended for use in the electromagnetic environment below. The customer or the user of the Device should assure that it is used in such an environment.			
Emissions test	**EN/IEC 60601 test level**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN/IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air Controlled shutdown with return to pre-disturbance condition after operator's intervention. (Power-on switch)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst EN/IEC 61000-4-4	±2 kV for power-supply lines	±2 kV for power-supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge EN/IEC 61000-4-5	±2 kV line(s) to line(s)	±2kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN/IEC 61000-4-11	0% UT; 0,5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycles	Compliance for all test levels.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ultrasound unit requires continued operation during power mains interruptions, it is recommended that the Device is powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field EN/IEC 61000-4-8	30 A/m 50 and 60 Hz	30 A/m 50 and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic emissions.		
The Device is intended for use in the electromagnetic environment below. The customer or the user of the Device should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms
Radiated RF and Proximity fields from RF wireless communications equipment IEC 61000-4-3	3 V/m; 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m; 80 MHz to 2.7 GHz 80% AM at 1 kHz
	385 MHz (18 Hz Pulse Modulation)	27 V/m
	450 MHz (FM +/ -5 kHz deviation 1 kHz sine or 18 Hz Pulse Modulation)	28 V/m
	710 MHz (217 Hz PM)	9 V/m
	745 MHz (217 Hz PM)	9 V/m
	780 MHz (217 Hz PM)	9 V/m
	810 MHz (18 Hz PM)	28 V/m

	870 MHz (18 Hz PM)	28 V/m
	930 MHz (18 Hz PM)	28 V/m
	1720 MHz (217 Hz PM)	28 V/m
	1845 MHz (217 Hz PM)	28 V/m
	1970 MHz (217 Hz PM)	28 V/m
	2450 MHz (217 Hz PM)	28 V/m
	5240 MHz (217 Hz PM)	9 V/m
	5500 MHz (217 Hz PM)	9 V/m
	5785 MHz (217 Hz PM)	9 V/m
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

4.3. Essential Performance

The essential performance of the Device is:

- The ability to display physiological images as input for diagnosis by qualified and trained healthcare professionals.
- The ability to display quantified data as input for diagnosis by qualified and trained healthcare professionals.
- The display of ultrasound indexes as aid for safe use of the Device.

5. MANUFACTURER

SONOSCANNER Sarl
6 rue André Voguet
94200 IVRY-SUR-SEINE
France
Email : contact@sonoscanner.com

Single registration number (SRN)
FR-MF-000002220

6. CONTACTING SONOSCANNER

If you need additional information, assistance or if you want to place an order, please contact your local Sonoscanner representative.

CHAPTER II
SYSTEM SET UP AND PREPARATION FOR USE

1.INTRODUCTION

We would like to remind you that the Device is a prescription device meaning that it can only be sold to or on the order of a physician. Only qualified personnel are authorized to perform ultrasound diagnostic imaging using the Device.
Do not hesitate to request additional training to your official Sonoscanner representative if needed.

To ensure optimal and safe performance of your system:
Maintain the device in a clean environment at all times. Turn off and disconnect the system before cleaning. Please refer to page VIII-2 for cleaning instructions.

Perform regular inspection on the system to detect possible defects or malfunctions.
Inspect the system and transducer to determine that it is free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact SONOSCANNER.

See page VIII-2 for detailed information on system inspection. If any defects are observed or malfunctions occur, do not try to service the system and instead secure the system and inform your local Sonoscanner representative.

2.PRODUCT DESCRIPTION

U-Lite / T Lite models are Handheld Ultrasound systems intended for use in environments where healthcare is provided by qualified and trained healthcare professionals.
It can therefore be used in different configurations, especially:
- In medical offices (general practitioner's office)
- In clinics & hospitals (incl. in emergency and critical care units)
- In a field hospital
It is used in imaging or examinations rooms.
It can be used at the bedside. It is not intended for direct use in a sterile environment.
U Lite / T Lite models are not compatible with the use of the HF surgery device or in an MRI system.

U Lite / T Lite models are indicated for the visualization of structures and dynamic processes in the human body using ultrasound imaging and fluid flow analysis for diagnosis in the following clinical applications:
• ophthalmic
• fetal/obstetric,
• gynecological,
• abdominal,
• pediatric,
• neonatal cephalic
• adult cephalic
• small organ,
• trans-vaginal,
• trans-rectal,
• cardiac adult & pediatric
• peripheral vascular,
• urology (including prostate)
• musculoskeletal (both conventional and superficial)

Modes of operations include:
• B-Mode (B)
• M-Mode (M)
• Color Doppler (CD)
• Power Doppler (PD)
• Spectral Pulsed-Wave Doppler (PWD)
• Continous Wave Doppler (CWD)
• Combined :(B+M; B+CD; B+ PD; B+PWD)

NOTE :	The application fields are dependent on the selected probe.

Operable probes:
• Multi-element probes (linear array, curved array, phased array)

The operation is designed for the specific clinical requirements and ensures simple and efficient handling. Vast ranges of measuring and evaluation programs, as well as many special functions enable comfortable working. The interface with interface software provides quick digital archiving of images and/or volume data sets on mass storage medium.

Under the provision of regular maintenance by authorized service personnel, the life expectancy is 5 years from the manufacturing date.

2.1. Biological safety

The biological effects of diagnostic ultrasound on the human body have not been entirely investigated yet. So far, no damages by ultrasound diagnosis are known, still the instrument should only be used by a medical doctor or under his supervision.
The ultrasound examination should be performed in as short of a time as possible and with the lowest transmit power available to enable diagnostic results (ALARA principle, **A**s **L**ow **A**s **R**easonably **A**chievable).
The Device permanently controls the emitted power and limits it according. to the maximum values set by the manufacturer. The occurring sound intensities depend on the respective probes. The declaration of sound field parameters acc. to IEC 61157 can be obtained from the manufacturer on request.

2.2. Bioeffects

One distinguishes between two acting mechanisms for the development of Bioeffects when exposing the human body to ultrasound waves: Heat Generation and Cavitation.
Heat generation: the ultrasound energy is absorbed by the tissue and warms it up, the amount of heat depending on the absorbed power and duration of exposure. A part of the heat is dissipated into the blood stream.
Cavitation: due to a strong negative pressure gas bubbles appear. The permanent change between gas and liquid phase constitutes strong local mechanical stress in the tissue. The degree of cavitation is influenced by the gas content and the superficial tension of the tissue resp. of body fluid.

3. TECHNICAL DESCRIPTION

You will find here below the technical parameters in which the device must be used, depending on the device model:

3.1.1. AC adapter for T-Lite Model:

Input tension: 100 - 240 VAC
Input Intensity: 1,4 - 0,7 A
Frequency range: 50 - 60 Hz
Output tension: 15 VDC
Output Intensity: 4A
The AC adapter is Class I.

3.1.2. AC adapter for U-Lite Model:

Input tension: 100 - 240 VAC
Input Intensity: 0,9 - 0,34 A
Frequency range: 47 - 63 Hz
Output tension: 5 VDC
Output Intensity: 5A
The AC adapter is Class I.

3.1.3. AC adapter for T-Lite Pro Model:

Input tension: 100 - 240 VAC
Input Intensity: 1,4 - 0,7 A
Frequency range: 50 - 60 Hz
Output tension: 15 VDC
Output Intensity: 4A
The AC adapter is Class I.

3.1.4. AC adapter for U-Lite Pro Model:

Input tension: 100 - 240 VAC
Input Intensity: 1,4 - 0,7 A
Frequency range: 50 - 60 Hz
Output tension: 15 VDC
Output Intensity: 4A
The AC adapter is Class I.

The device has type BF Applied Part: Those Applied parts are multi-element probes that can be connected/disconnected from the device (IPx0).
Degree of protection against harmful ingress of water:
Device parts and accessories: ordinary equipment (IPx0)
Overvoltage category: II
Degree of pollution: 2
Max Altitude of use: 2000m
Air pressure for use or non use: 700–1060 hPa

4. ENVIRONMENTAL REQUIREMENTS

You will find here below the environment parameters in which the device must be operated, stored and transported:

4.1.1. When being in operation

Temperature: 05°C; 28°C / 41°F; 82°F
Humidity: 30%; 80%

4.1.2. When being transported

Temperature: -10°C; 60°C / 14°F; 140°F
Humidity: 10%; 85%

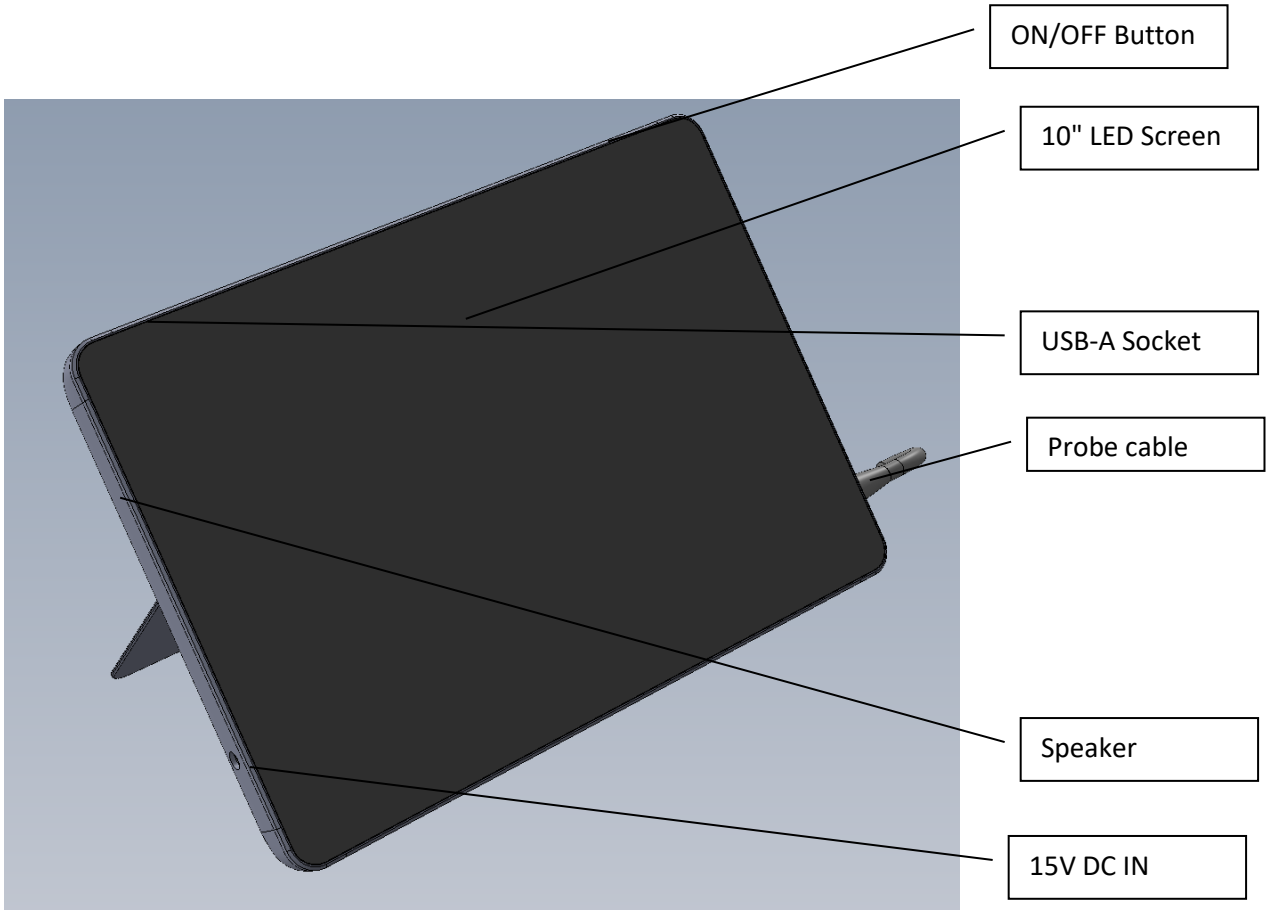
4.1.3. When being stored

Temperature: -10°C; 60°C / 14°F ; 140°F
Humidity: 10%; 85%

Do NOT operate immediately the system if it has been subject to major changes in temperature or humidity, or if there is any visible sign of condensation.

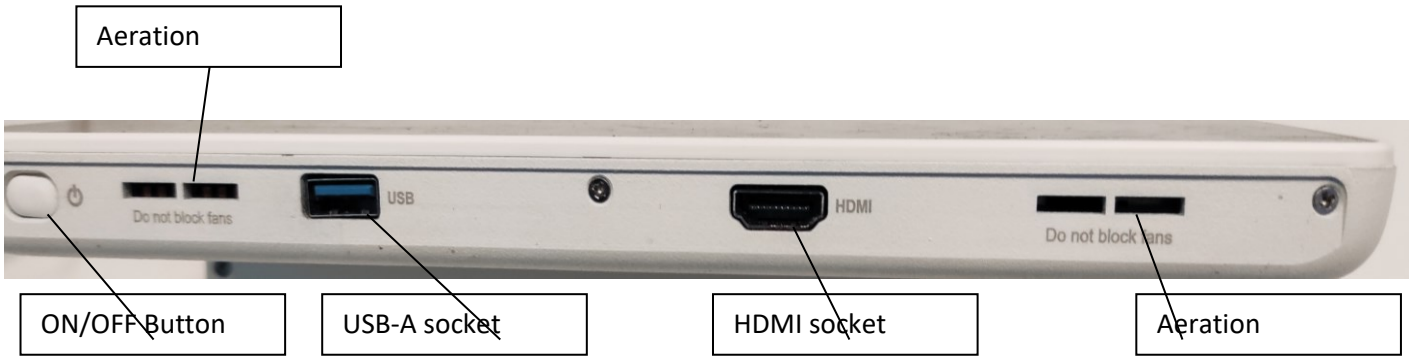
5.SYSTEM GRAPHICS

5.1.T-Lite Model External System Overview: Front side

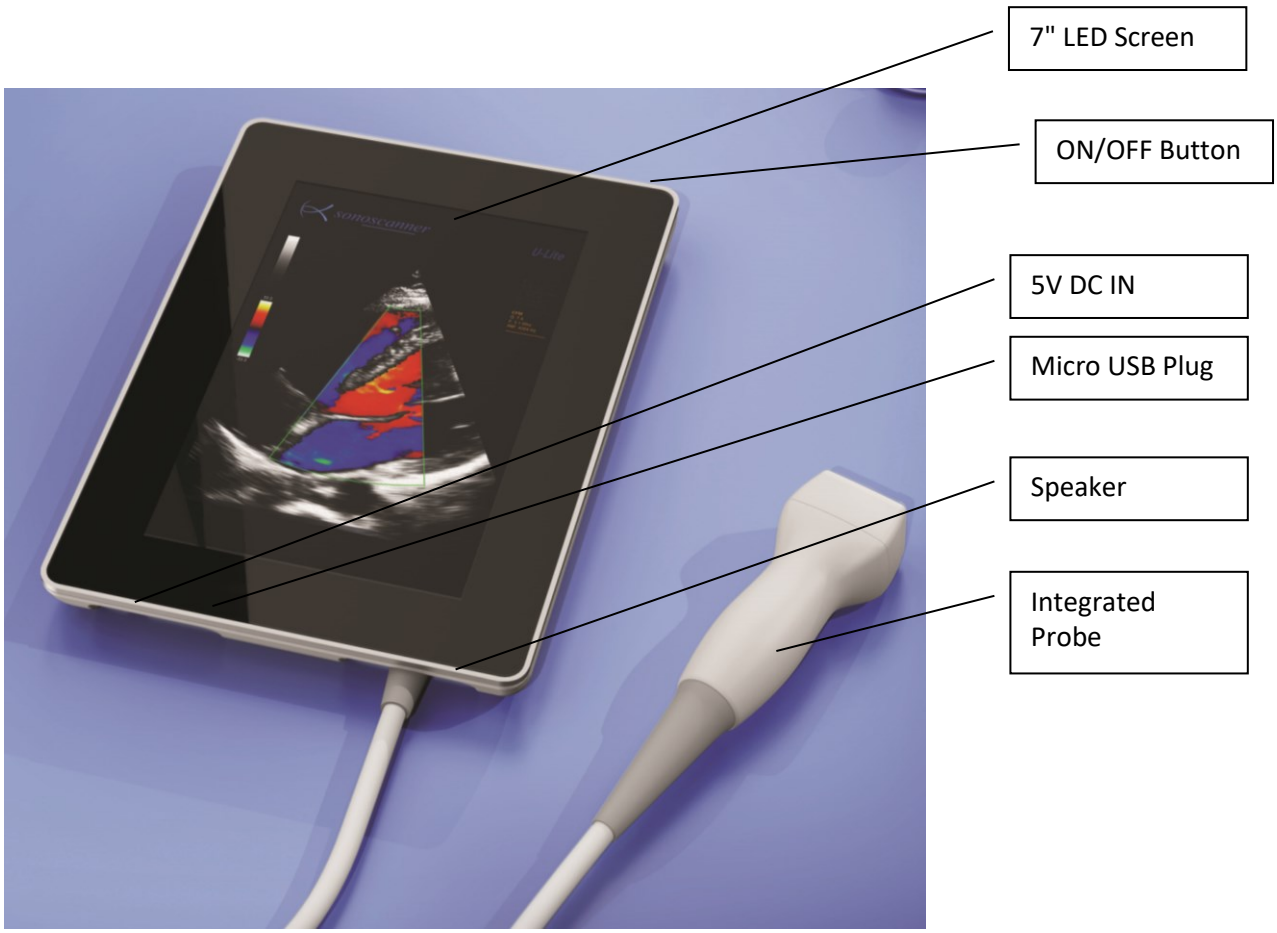


	Hearing damage may occur if speaker is used at an excessive volume. Refrain from setting the maximum volume delivered by the speaker for more than 5 minutes

5.2.T-Lite Model External System Overview

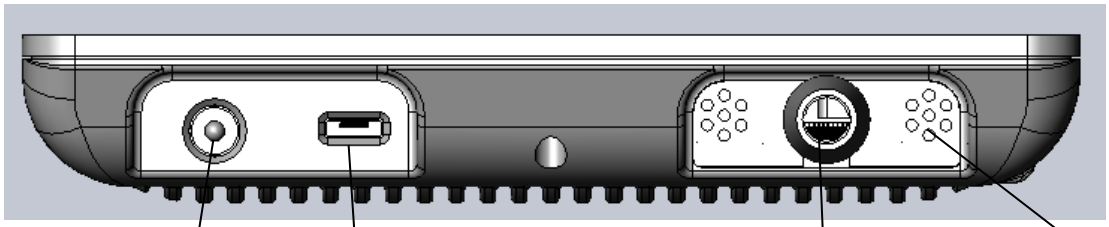


5.3. U-Lite Model External System Overview: Front side

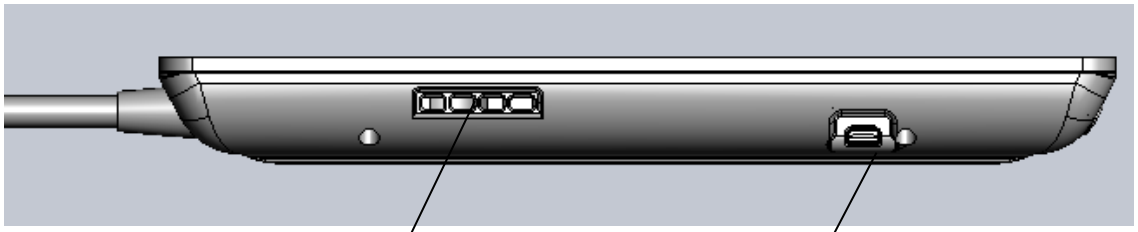


	Hearing damage may occur if speaker are used at an excessive volume. Refrain from setting the maximum volume delivered by the speaker for more than 5 minutes

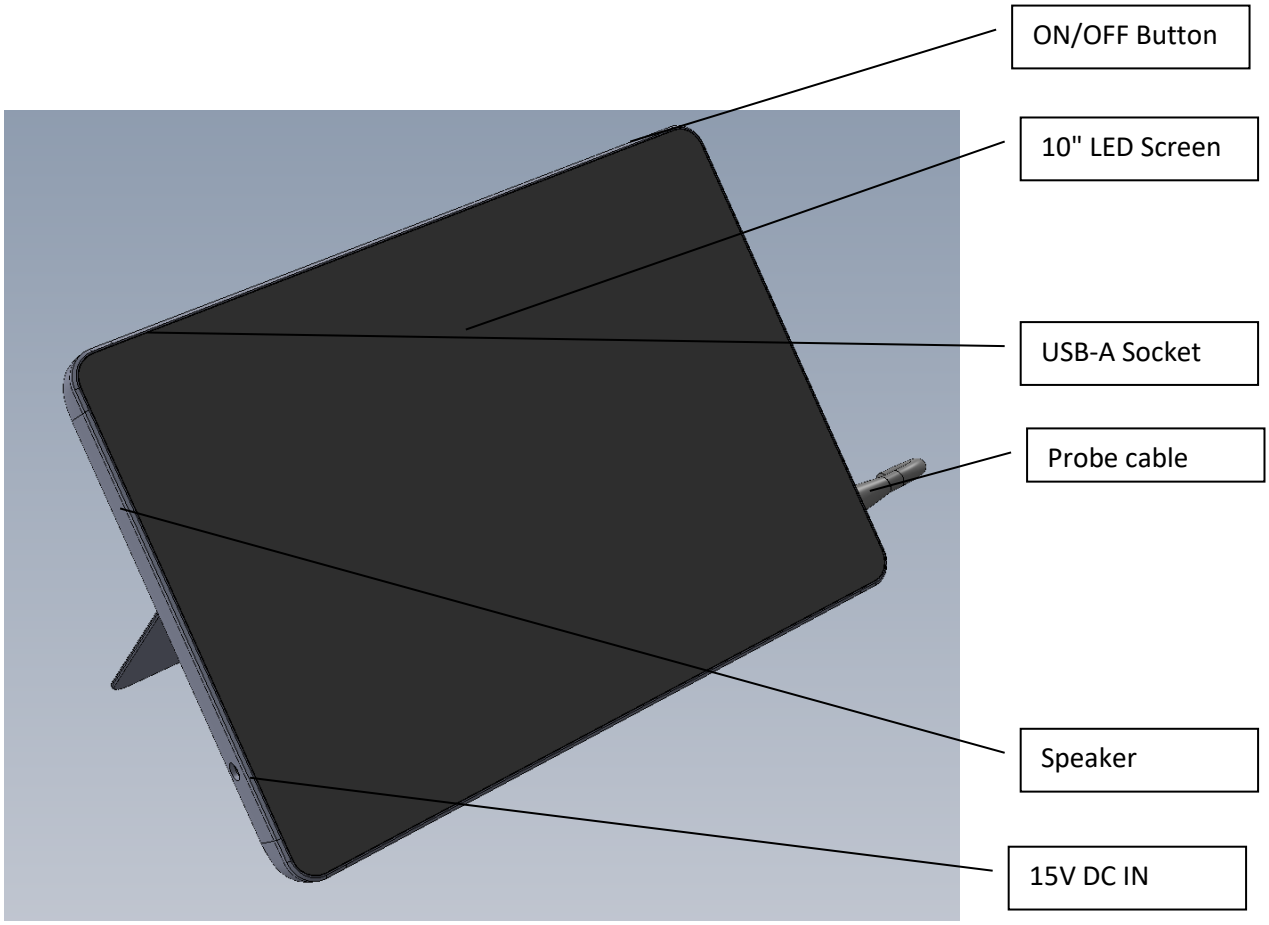
5.4. U-Lite Model External System Overview: Bottom Side



5.5. U-Lite Model External System Overview: Right Side

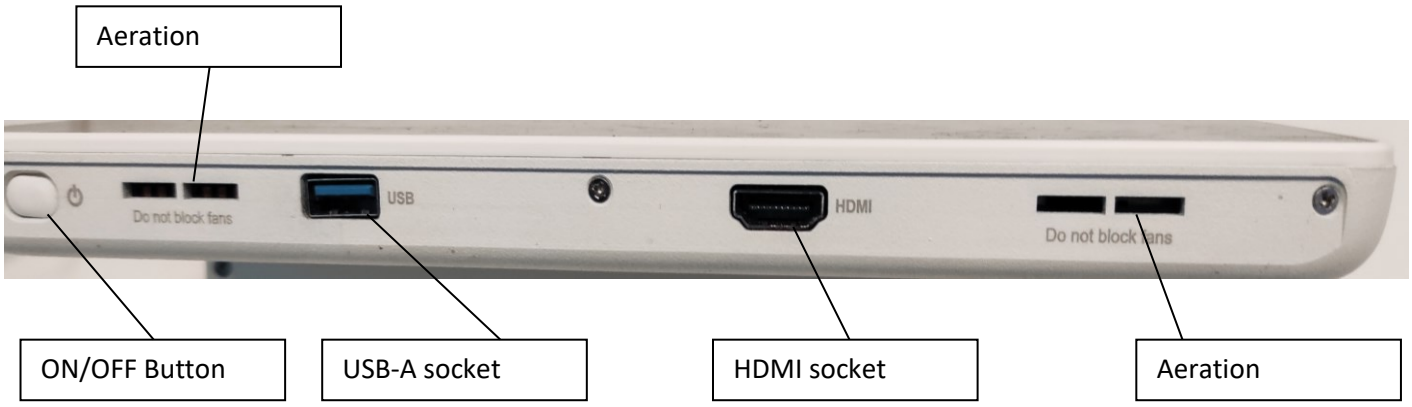


5.6. T-Lite Pro Model External System Overview: Front side

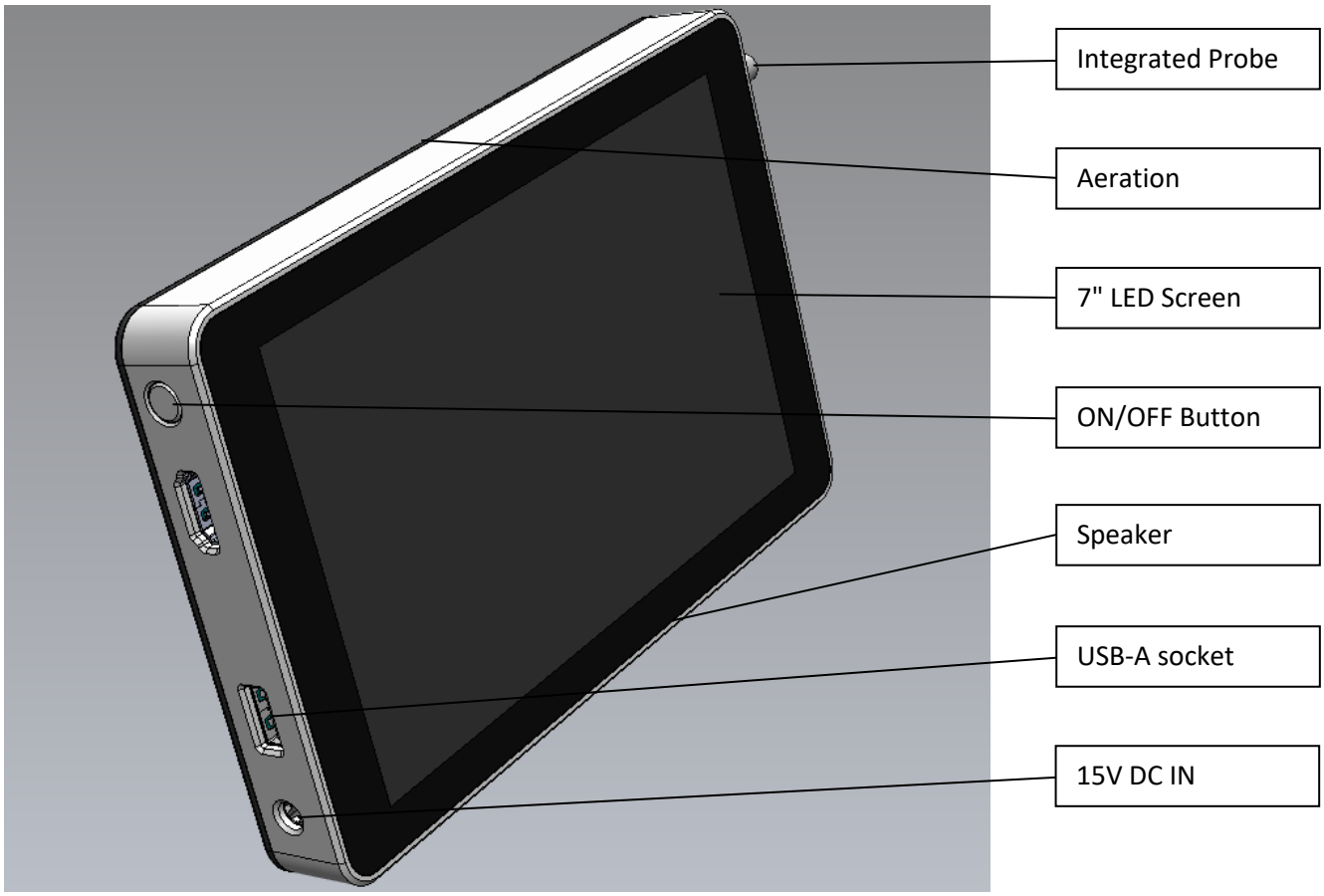


	Hearing damage may occur if speaker are used at an excessive volume. Refrain from setting the maximum volume delivered by the speaker for more than 5 minutes

5.7. T-Lite Pro Model External System Overview

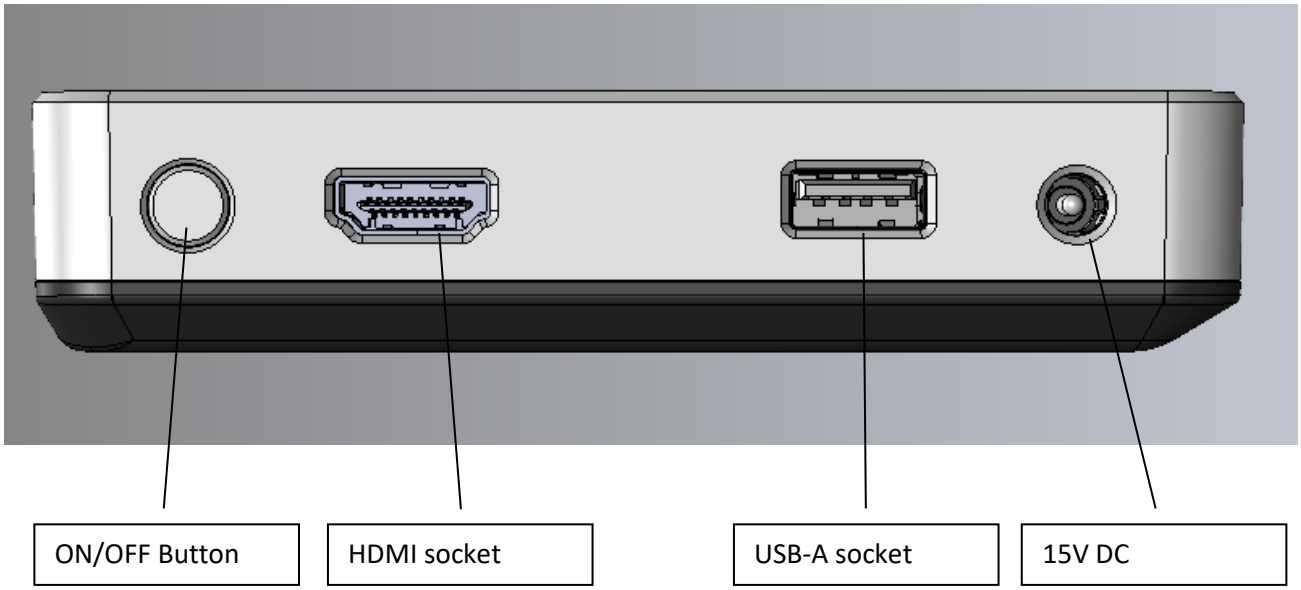


5.8. U-Lite Pro Model External System Overview: Front side



Hearing damage may occur if speakers are used at an excessive volume. Refrain from setting the maximum volume delivered by the speaker for more than 5 minutes

5.9. U-Lite Pro Model External System Overview



5.10. LCD DISPLAY MONITOR

T-Lite Model features a 10” LCD Screen high resolution.
U-Lite Model features a 7” LCD Screen high resolution.
T-Lite Pro Model features a 10.1” LCD Screen high resolution.
U-Lite Pro Model features a 7” LCD Screen high resolution.

NOTE :	The screen is calibrated from factory for ultimate results. It is recommended not to change its parameters except extreme needs.

6. *APPLIED PART*

The only part in contact with patient is the head of the probe.

II-1 Applied Part: Ultrasound Probe

It is a TYPE BF APPLIED PART providing a specified degree of protection against electric shock, with particular regard to allowable LEAKAGE CURRENT.

In order to assure optimal transmission of energy between the patient and the probe, a conductive gel must be applied on the probe lens.

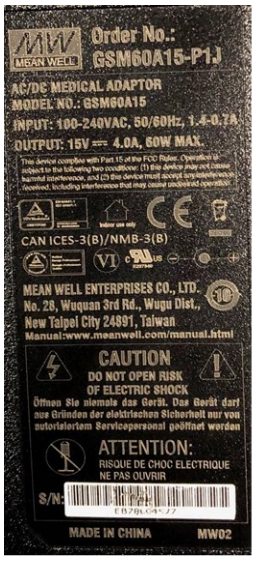
	Do not apply gel to the eyes. If there is gel contact to the eye, flush eye thoroughly with water.

Other parts of the Device shouldn't be in contact with the patient.

7.CONNECTING THE SYSTEM TO THE OUTLET

Connecting AC/DC Power to the Device, involves preliminary checks of the power cord, voltage level and compliance with electrical safety requirements.
The Device® is supplied by a specific power supply with the following specifications:

7.1.Power Supply AC Adapter

	GSM60A15 **Mean Well**	**GTM96600-6015-T3** **Glob Tek**	**MPU31-102** **SINPRO**
	- Input tension: 100 - 240 VAC - Input Intensity: 1,4 - 0,7 A - Frequency range: 50 - 60 Hz - Output tension: 15 VDC - Output Intensity: 4A - The AC adapter is Class I.	Input tension: 100 - 240 VAC Input Intensity: 1,5 A Frequency range: 50 - 60 Hz Output tension: 15 VDC Output Intensity: 4A The AC adapter is Class I.	Input :100-240 VAC Input Intensity :0.9 A-0.34 A Frequency range: 47-63Hz Output tension : 5VDC Output Intensity :5A The AC adapter is Class I.
			
T-Lite	✓	×	×
U-Lite EXP	×	×	✓
U-Lite SCP	×	×	✓
U-Lite SEP	×	×	✓
U-Lite SLP	×	×	✓
U-Lite SPA	×	×	✓
U-Lite Pro	✓	✓	×
T-Lite Pro	✓	✓	×

7.2. AC Adapter connection

1.) Ensure that the wall outlet is of appropriate type.

2.) Uncoil the power cable, allowing sufficient slack so that the unit can be moved slightly.

3.) Verify that the power cable is without any visible scratches or any sign of damage.

4.) Verify that the on-site mains voltage is within the limits indicated on the rating label on the bottom of the unit.

5.) Plug the power cord into the Device® AC connector. Be sure that nothing rests on the AC adapter's power cable and that the cable is not located where it can be tripped over or stepped on.

Use only the AC adapter and the power cord supplied by Sonoscanner. Failure to follow this guidance may void the warranty.

6.) Plug the power cord into the power outlet.

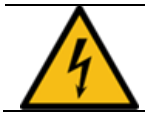
When you connect the power cord to the outlet, make sure that such outlet and power cord can easily be accessed: It is important that you can at any time disconnect the power cord either from the outlet or from the Device® and turn off the AC adapter

7.) Connect the Power Cable's other end (male plug) to a hospital grade mains power outlet with the proper rated voltage, and the unit is ready for Power ON/Boot Up.

When the adapter is working, do not hold it longer than 10 seconds

To avoid injury:

- To assure adequate grounding, connect the attachment plug to a reliable grounding outlet.
- Never use any adaptor or converter of a three-prong-to two prong type to connect with a mains power plug. The protective ground connection will loosen.



WARNING: To avoid the risk of electric shock, this device must be connected only to a supply network equipped with a protective ground.

8. DEVICE BATTERY

Each Device® is equipped with a Lithium-ion battery. When fully charged, the battery can give the system a total autonomy of up to 2h30 in scanning mode.
The battery provides power to the Device® when the system is not connected to an AC power source or when such power source stops feeding the system.

The battery level indicator is displayed on the screen:

- When the Device® is on battery mode, on the top right side of the control panel a battery indicator  gives the charge level. The green level indicates the available power of the battery.

- When fully green the battery is charged. When the indicator turns red  , the time of available power is less than 10 minutes.

The battery contains hazardous materials and should therefore not be disposed with common waste products. Follow national rules related to the disposal of chemical waste.

NOTE	This battery is specifically designed for use with the Device. Do not try to use batteries not authorized for use by Sonoscanner. Only authorized trained technicians are allowed to operate the battery itself

	**- Do not expose the battery to temperature over 60°C (140°F).** **- Charge the battery only when ambient temperature is between 05°C and 30°C (41°F and 86°F).** **- Discharge the battery when ambient temperature is between 05°C and 30°C (41°F and 86°F).** **- Do not use the battery if damaged** **- Do not try to alter or service the battery**

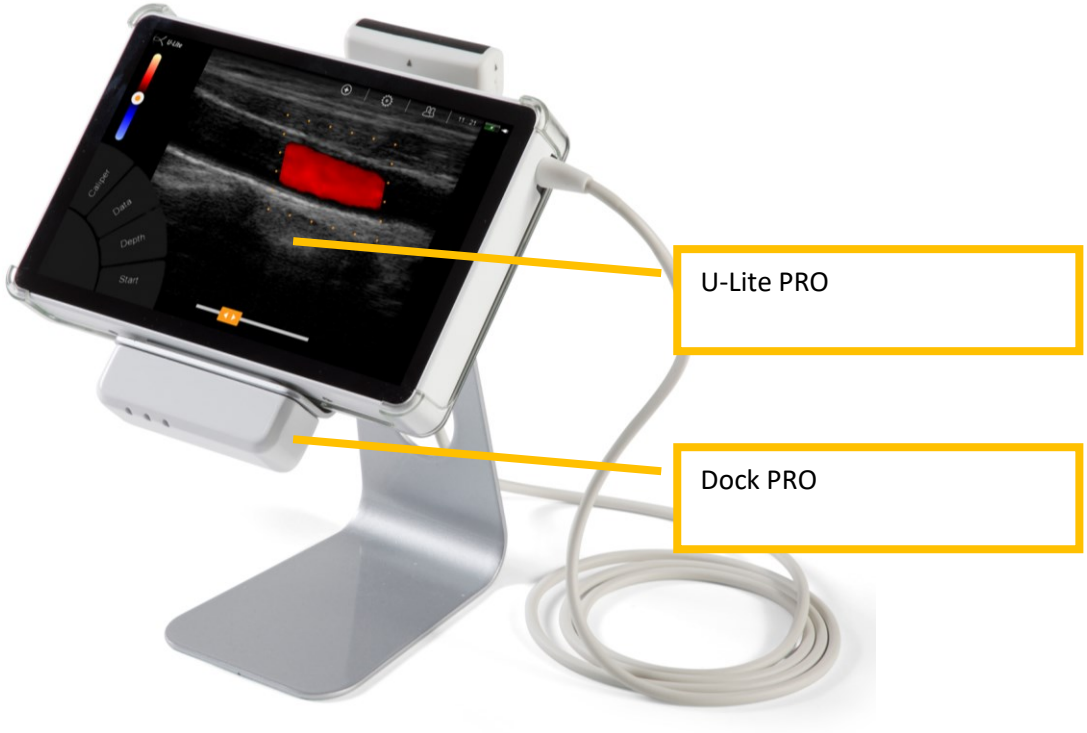
9. SUPPLIES

	**DO NOT** connect anything without approval by Sonoscanner Not all features or products described in this document may be available or cleared for sale in all markets. The following items have been verified to be compatible with the system:

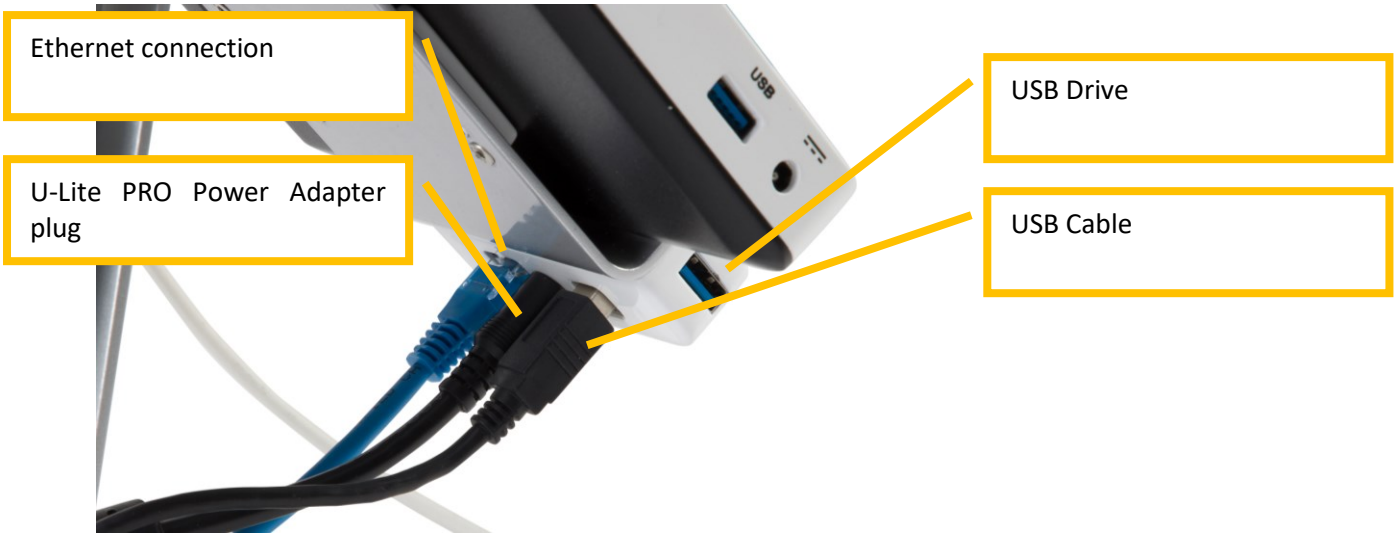
10. OPTIONAL ITEMS

Items	Units
Sony B/W Printer UP-D711MD	Each
Screen Eizo EV2450-BK	Each
Device Cart HD	Each
Device Cart Stand	Each
Dock PRO	Each
Device table stand	Each
Device transport Bag	Each
USB Keyboard	Each
USB Memory Stick	Each

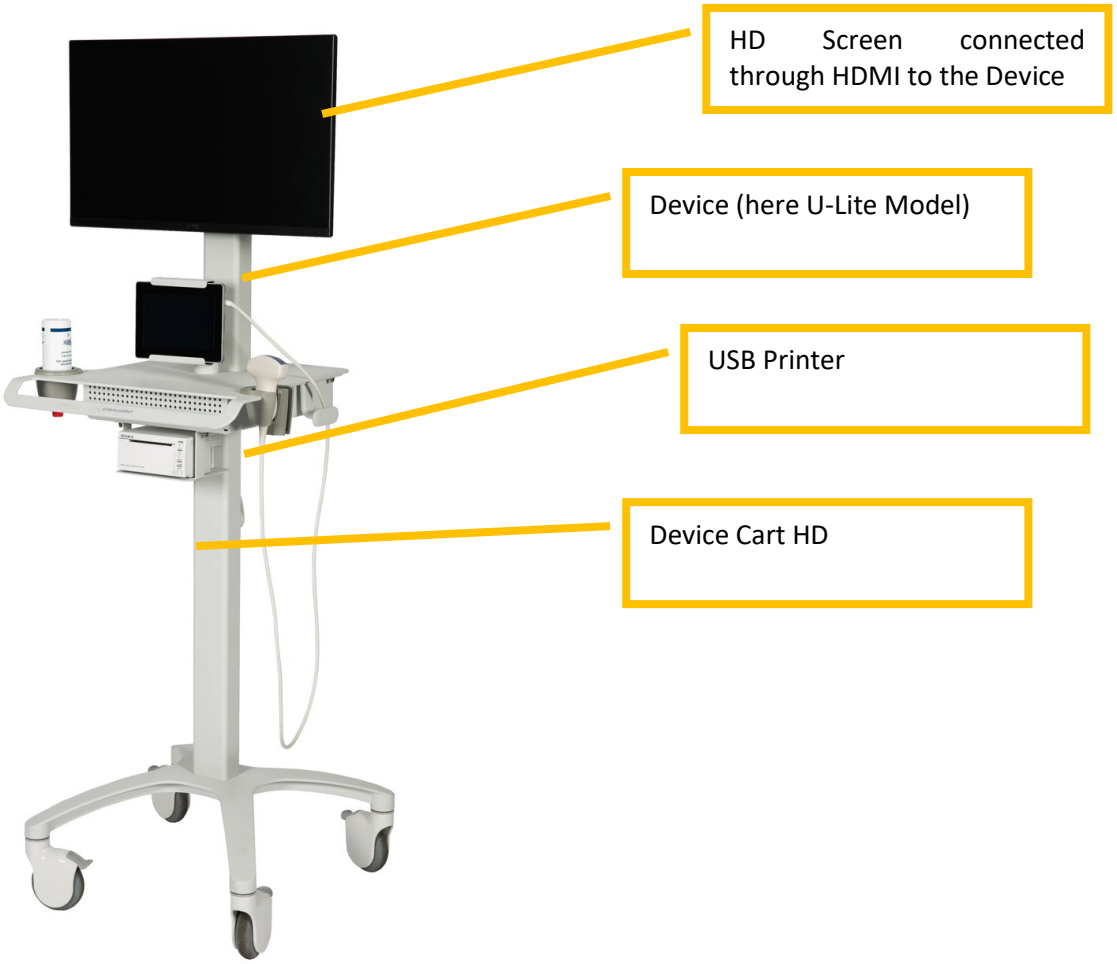
II-2 Dock PRO Overview



II-3 Dock PRO Connections



II-4 Device Cart HD



	DO NOT use Device Cart HD on a slope with more of 5° inclination
	DO NOT place additional weight on the Device Cart HD

If the Device Cart HD hasn't been delivered mounted by Sonsocanner authorized representative, mounting instructions are located inside the transport box of the cart. Please read carefully the instructions before assembly.

Device Cart HD Transport

Prior to moving the system, please make sure to follow the following instructions:

Make sure that the system is completely off.
Unplug the power cord from the scanner, the screen and from the power outlets.
Unplug the HDMI cable from the Device
Remove any item (Coupling gel, napkins…) to prevent them from falling during system transportation.
Turn the screen of 180° to have the following configuration:

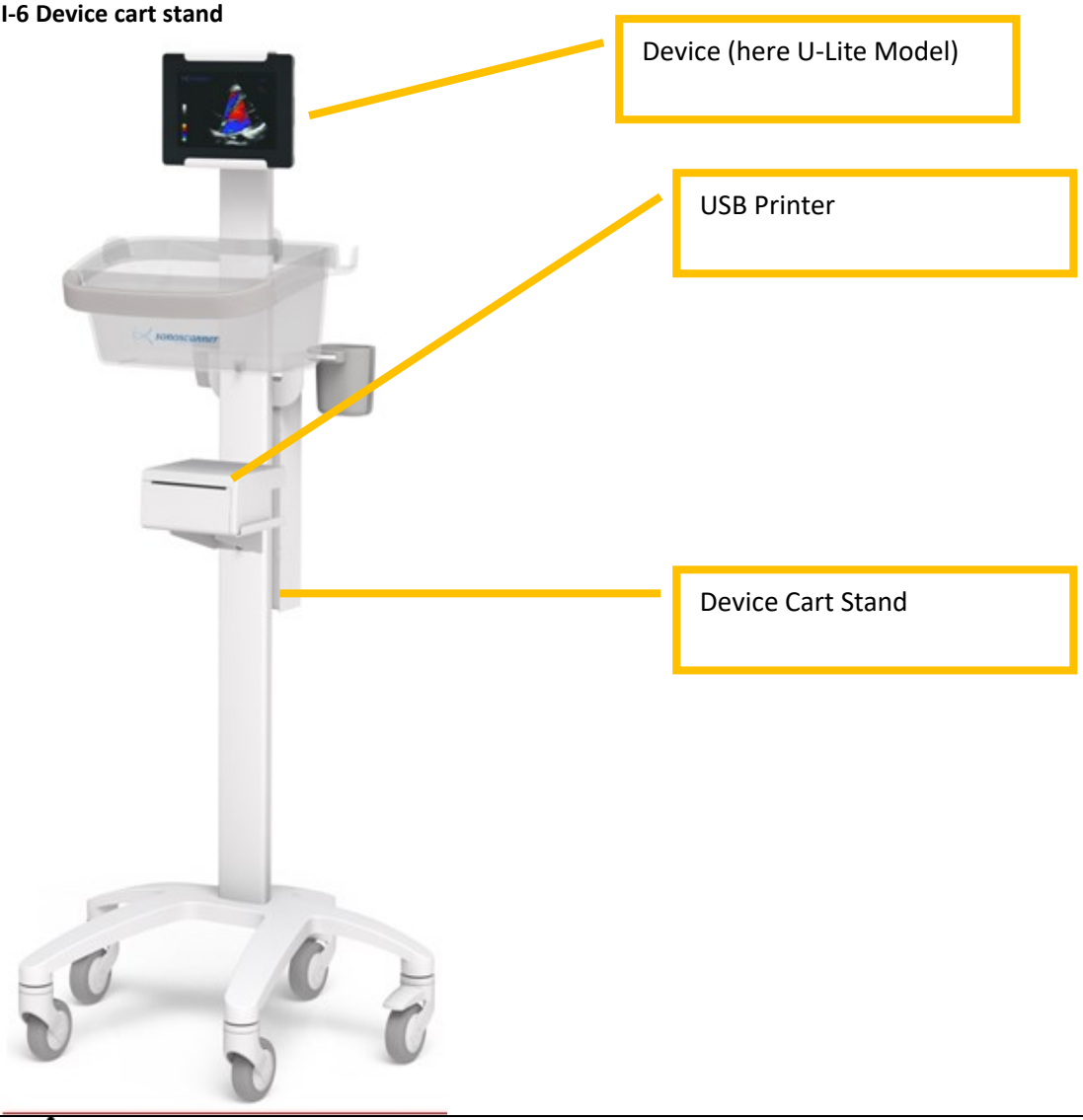
II-5 Device Cart HD Transport Configuration

Make sure that the brakes located on the wheels are on the off position. To put them on the off position, lift them using your feet.

When the above instructions have been fulfilled you can then move the system: Use the handle located in the front of the scanner to do so. To avoid equipment damage or injury, move the system with extra caution. Make sure the system does not hit walls or door frame.

Device Cart HD shall be moved carefully and can be moved only when in transport configuration

II-6 Device cart stand



DO NOT place equivalent of more than 3kg in the basket of the Device Cart Stand

If the Device Cart Stand hasn't been delivered mounted by Sonsocanner authorized representative, mounting instructions are located inside the transport box of the cart. Please read carefully the instructions before assembly.

Peripheral not to be used in the patient environment:
The Device has been verified for overall safety, compatibility and compliance with the following devices:
• Sony UP-D711MD B/W Printer or ZJ-5802LD
• Dell U2414H or Eizo EV2450-BK
The Device may also be used safely while connected to devices other than those recommended above if the devices and their specifications, installation, and interconnection with the system conform to the requirements of IEC/EN 60601-1-1.

The connection of equipment or transmission networks other than as specified in the user instructions can result in an electric shock hazard or equipment malfunction. Substitute or alternate equipment and connections requires verification of compatibility and conformity to IEC/EN 60601-1 by the installer. Equipment modifications and possible resulting malfunctions and electromagnetic interference are the responsibility of the owner.
General precautions for installing an alternate off-board, remote device or a network would include:
1. The added device(s) must have appropriate safety standard conformance and CE Marking.
2. There must be adequate mechanical mounting of the device and stability of the combination.
3. Risk and leakage current of the combination must comply with IEC/EN 60601-1.
4. Electromagnetic emissions and immunity of the combination must conform to IEC/EN 60601-1-2.

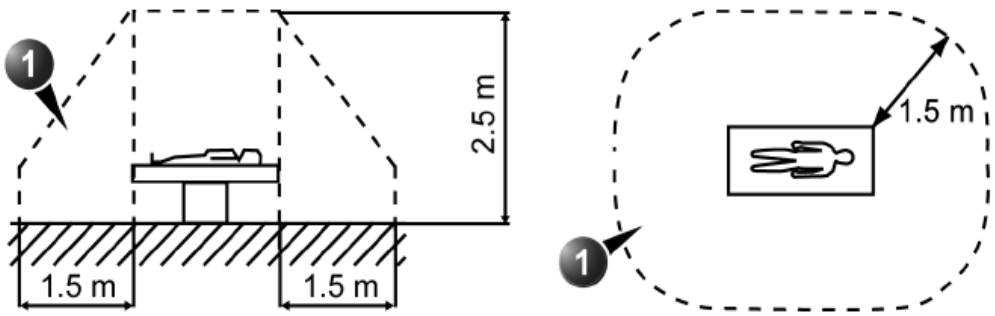
.

DO NOT use any power strip to connect the items. In case it is mandatory, very the leakage current and make sure the installation complies with IEC/EN 60601-1.

The devices connected to Device should stay out of the PATIENT ENVIRONMENT

DO NOT connect any probes or accessories without approval by Sonoscanner within the PATIENT ENVIRONMENT

II-7 Patient Environment



1. Patient environment

CHAPTER III
GETTING STARTED

1. GENERAL REMARKS

Installation, switching on for the first time and check-up of the system must only be performed by authorized persons.
The Device is delivered with recommended basic settings. These offer suitable conditions for a large number of applications. Depending on the user's experience these default settings can be changed and stored as new User Programs. Storing these programs or quick loading of new programs of a second user is done by Backups.

In the event the equipment has been brought from cold environment (stock room, airfreight) into a warm room, allow several hours for temperature balance and passing of condensation humidity before switching on the first time (risk of leakage current).

2. TURN UNIT ON

Press the switch located on the top side of the system for few seconds. A start-up screen will then appear on the LCD monitor. Please wait until this start-up screen disappears indicating that the scanner is ready for use. Do not attempt to use the scanner until it is fully up and running.

Press once on the **On/Off** key on the Operator Panel to boot the unit.
During a normal boot, you may observe that:

a.) The unit's ventilation fan starts.
b.) Power is distributed to the peripherals, Monitor, Ultrasound System, Computer.
c.) Computer and rest of scanner starts with the sequence listed in the next steps:
- Computer is turned ON and starts to load the software.
- The Start Screen is displayed on the monitor.
- The software initiates and sets up the front-end electronics and the rest of the instrument.
- As soon as the software has been loaded, a 2D screen is displayed on the screen, indicating that the system is ready.

NOTE	Total time used for start-up is typical ten seconds or less.

If you have just switched off the system, wait at least 3 seconds before turning the system back on

3.POWER OFF

3.1.Complete Power Down

First, make sure the system is completely up and running. Failure to give the system enough time to save/recover data may lead to loss of data or serious system failure.
Once you are sure that the system is fully up and running, simply press the button located on the top of the system for 15 seconds.

The Computer will Shutdown the device.

3.1.Disconnecting the system from the outlet

To disconnect the system from the outlet unplug the power cord from the AC connector. You can do so while the system is still up and running because the battery will automatically supply power to the system but it is however recommended to unplug the power cord from the AC connector when the system is completely off.

4.PROBES

The device has 1 active probe.

⚠	Prior to connecting or disconnecting a probe, freeze the image. It is not necessary to switch off the system. If a probe is disconnected while running (scan mode) a software error may occur. In this case switch OFF the system and, after an interval of 10 seconds, switch it ON again. (perform a reset).

Probes can be connected at any time, whether the unit is on or off.

4.1.To connect a probe

Before connecting the probe:

- Do a visual check of the probe pins and system sockets.
- Remove any dust or foam rests from the probe pins.
- Verify the probe and the probe cable for any visual damage.

Hold the probe connector horizontally with the cable pointing leftward.
Hold the two brackets on the probe connector at cable side
Align the connector with the probe port and carefully push into place.
A "click" is heard, signifying that the connector is at place

III-1 Lock on Probe connector, cable side

Position the probe cable so that it is not resting on the floor.

⚠	**Keep the probe cables away from the cart wheels.** **Do not bend the probe cable.**

When the probe is connected, it is automatically activated but it is not automatically selected. To select a probe, please follow the instructions listed below.

4.2. To select a probe

Press the "SCAN" button on the touch screen. The system will automatically recognize the probe and load its dedicated presets.

If the puncture line that appears on the LCD monitor does not correspond to the true puncture path of the selected probe, please stop operating the system, turn it off and contact your Sonoscanner authorized representative.

4.3. To disconnect a probe

1.) Freeze the image.

2.) Press the brackets on the connector.

3.) Remove the connector from the port.

4.) Ensure that the probe head is clean before placing the probe in its storage case.

4.4. Storing and transporting probes

We recommend that you store the probes and your Device, in their provided carrying case.

4.4.1. Storing:

Recommended steps to properly and safely store a probe in its carrying case:
Wind the probe cable around the foam circle. Make sure not to bend the cable too tightly
Carefully place the probe head in its dedicated area

4.4.2. Transporting:

Make sure that probes are protected against condensation when being stored or transported.

4.5. Probe environmental requirements

You will find here below the environmental parameters in which the Sonoscanner probes must be operated, stored and transported:

4.5.1. When being in operation

Temperature : 05°C ; 28°C / 41°F ; 82°F
Humidity: 30% ; 80%

4.5.2. When being transported

Temperature: -10°C ; 60°C / 14°F ; 140°F
Humidity: 10% ; 85%

4.5.3. When being stored

Temperature: -10°C ; 60°C / 14°F ; 140°F
Humidity: 10% ; 85%

CHAPTER IV
IMAGING MODES AND ASSOCIATED SETTINGS

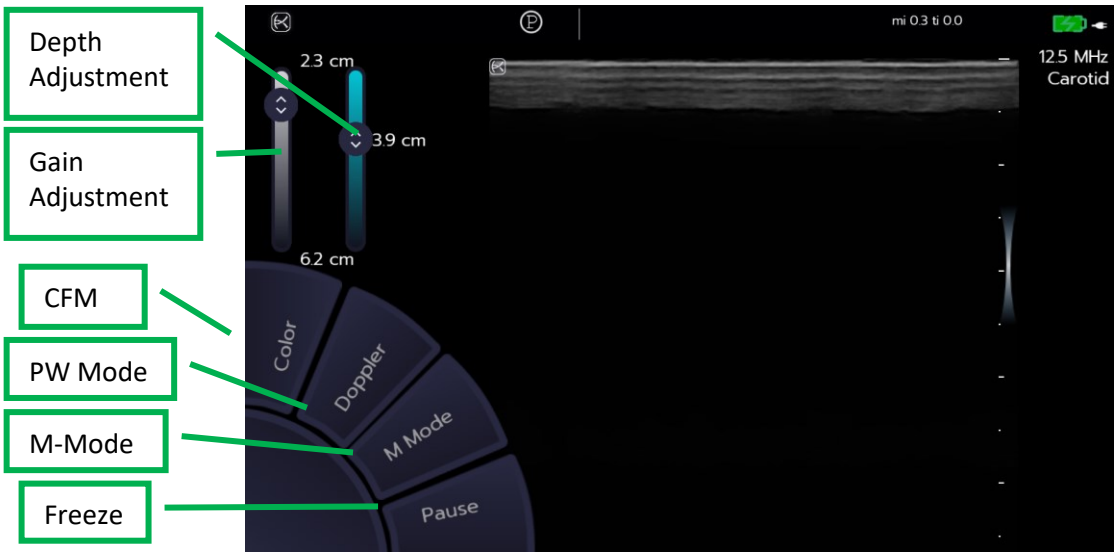
1.IMAGING MODES SELECTION

The following imaging modes are displayed on the touch panel:

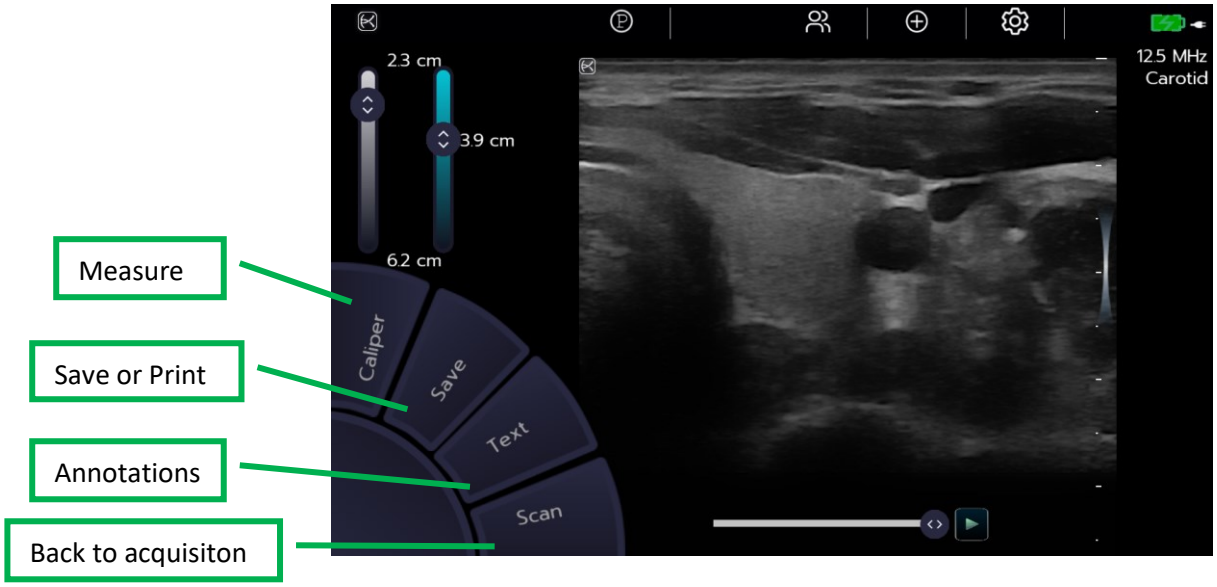
B Mode
Color Mode
Pulse Wave Doppler
Continuous Wave Doppler (For U-Lite PRO and T-Lite PRO only)
Power Doppler
Tissue Doppler
M-Mode

1.1.Device imaging modes selection

Note that all exams will start in B-Mode which is the default mode.



To freeze the image will give you access to other settings :

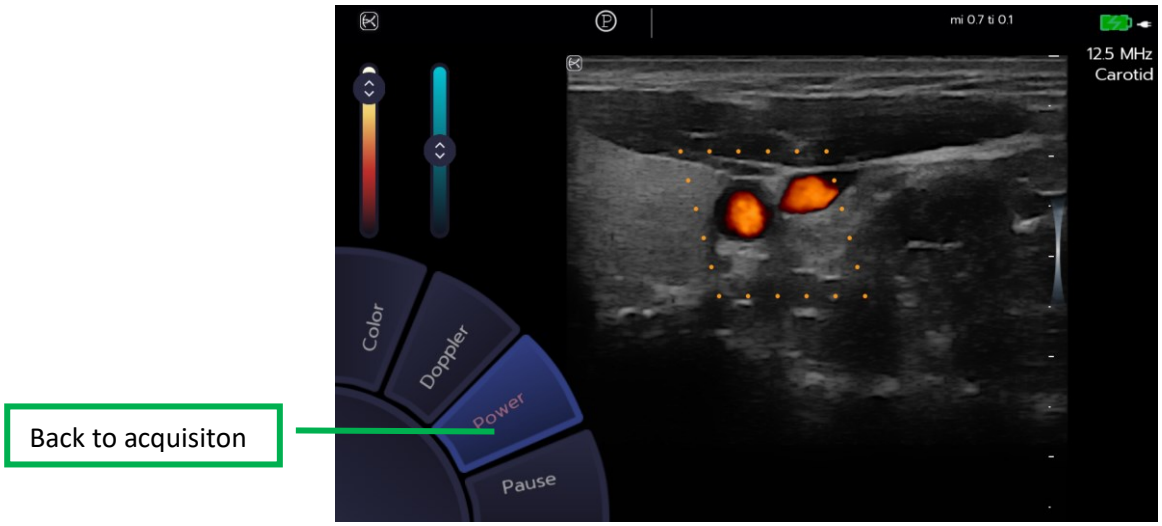


Each of the imaging modes can be activated by pressing its corresponding switch except for the power Mode:

1.1.1. Activating the Power Mode:

As displayed above, the **Color Mode** and **Power Mode** share the same switch.

To toggle between color mode and power mode, press the **Power** button.



1.1.2. Switching between DUPLEX/ SIMPLEX modes:

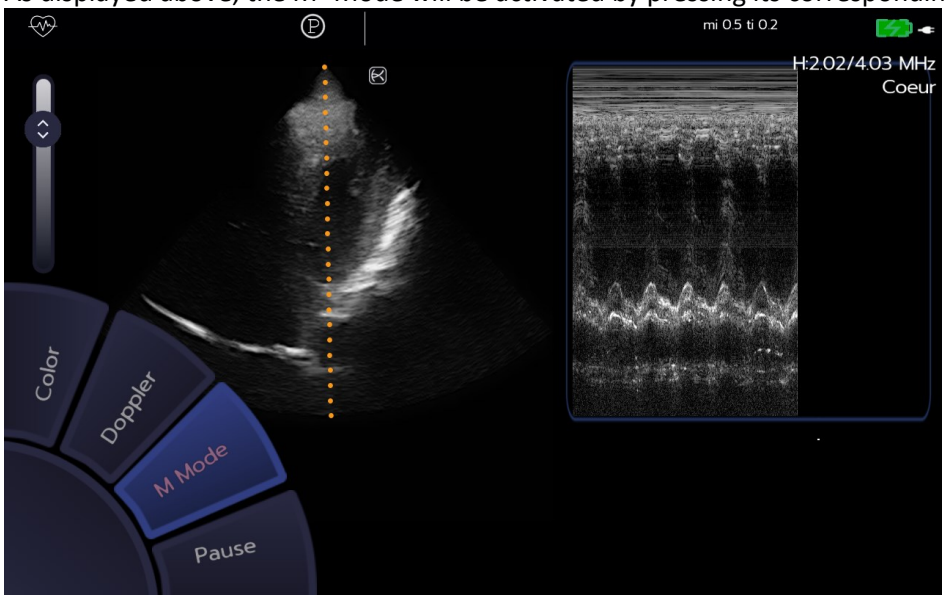
It is possible to activate PW from any other Mode. Depending on from where you are activating it, different modes are selected:

- If PW is pressed while in B Mode, it will automatically activate the DUPLEX mode, with B image and PW spectrum. Press PW once again to switch to simplex mode. Press PW once again to switch to DUPLEX mode.
-

If you want to switch from one imaging mode to another, simply press its corresponding switch. You will then return to BW image.

1.1.3. Activating the M- Mode:

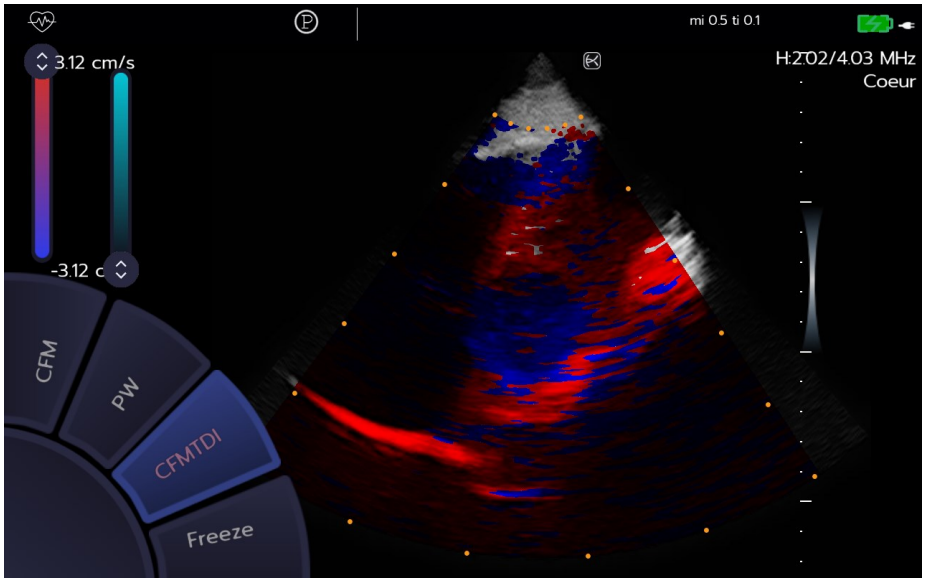
As displayed above, the M- Mode will be activated by pressing its corresponding switch.



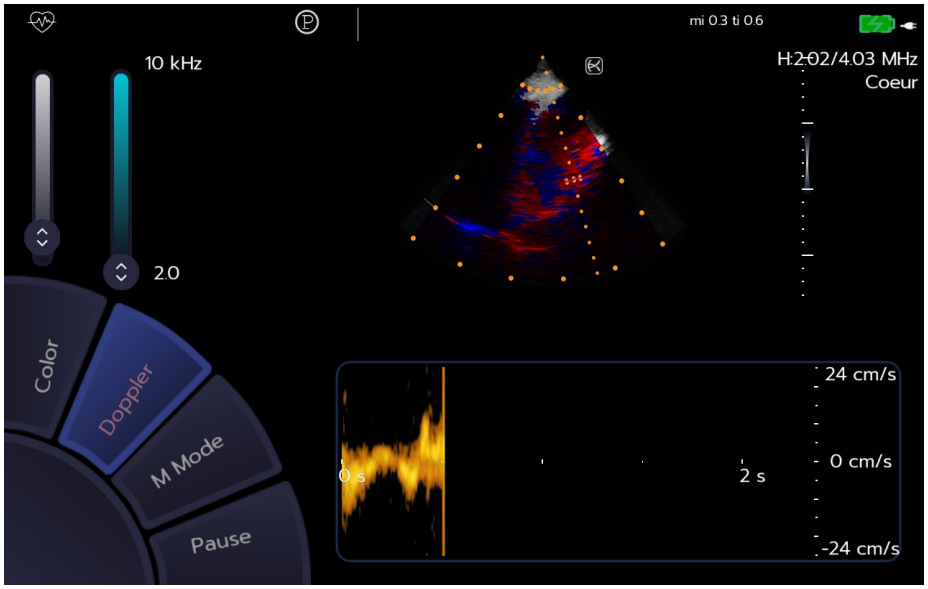
1.1.4. Activating the Tissue Doppler- Mode:

The Tissue Doppler Mode can be activated once the Color Doppler Mode is activated. There are two functions possible the Color Tissue Doppler or the Pulsed Wave Tissue Doppler. Pressing the TDI switch activates the Color Tissue Doppler. By pressing the PW switch from then, the PW Tissue Doppler will be activated.

TDI Color Mode:



TDI PW Mode:

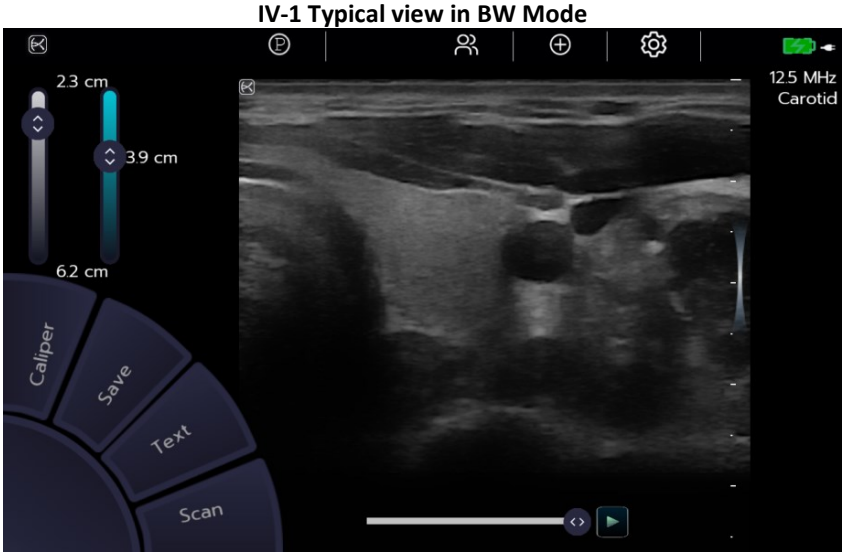

mi 0.3 ti 0.6
10 kHz
2.0
H:2.02/4.03 MHz
Coeur
Color
Doppler
M Mode
Pause
24 cm/s
0 cm/s
-24 cm/s
0 s
2 s

2.B MODE

Purpose: The B-Mode provides real time 2D images of the anatomical structure of soft tissue.

The ultrasound image is derived from the tissue echoes that return to the scan head.

IV-1 Typical view in BW Mode

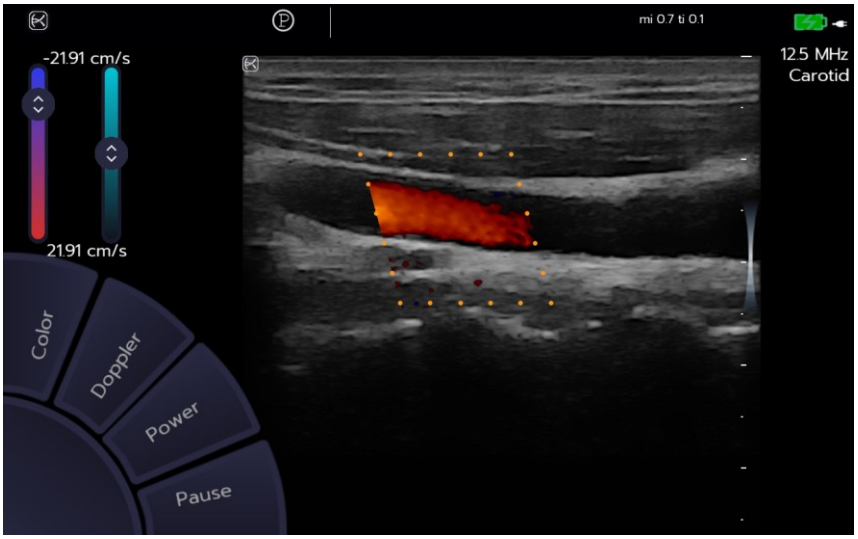


3.COLOR MODE

The color Mode (also called color Doppler, CFM or color flow mapping) displays color coded information about the direction and velocity of fluid in tissues within the B-Mode image.

This information is used to overlay a Color image onto the 2D grayscale scan image.
Color imaging helps you to locate blood flow disturbances. Color imaging also helps you to locate the sample volume for pulsed-wave Doppler spectral analysis.

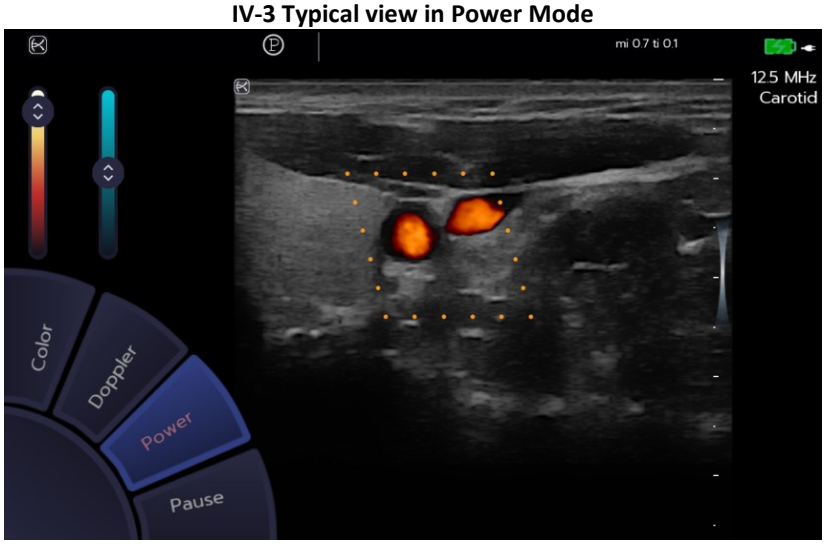
IV-2 Typical view in CFM Mode



4.POWER DOPPLER

Power Doppler also called power mode displays color flow based on the number of blood cells that are moving rather than their velocity.
Such imaging mode does not contain any directional information; it is therefore not subject to aliasing.

IV-3 Typical view in Power Mode



5.PULSE WAVE DOPPLER

The information delivered by the pulse wave (PW) mode is direction and speed of blood flow delivered through a frequency spectrum.

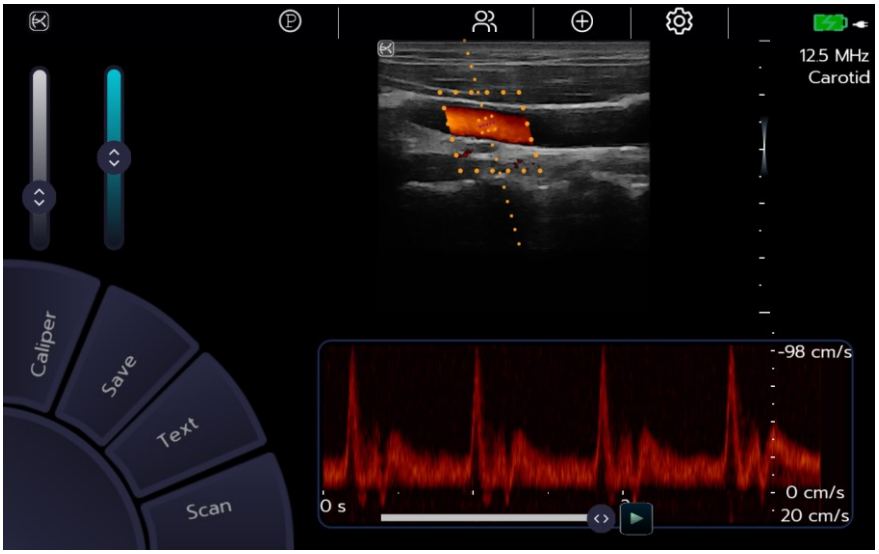
In PW Mode, short pulses of ultrasound waves are transmitted from the ultrasound probe just like in B-Mode. However in PW Mode, the receiving signals are processed to extract the difference in frequency between the transmitted and the receiving signals. Such difference in frequencies is caused by moving elements such as blood flow. The receiving signals are displayed:

Graphically on the monitor where the X axis represents time and the Y axis represents flow velocity in either a forward or reverse direction.

And

Audibly through the system speakers.

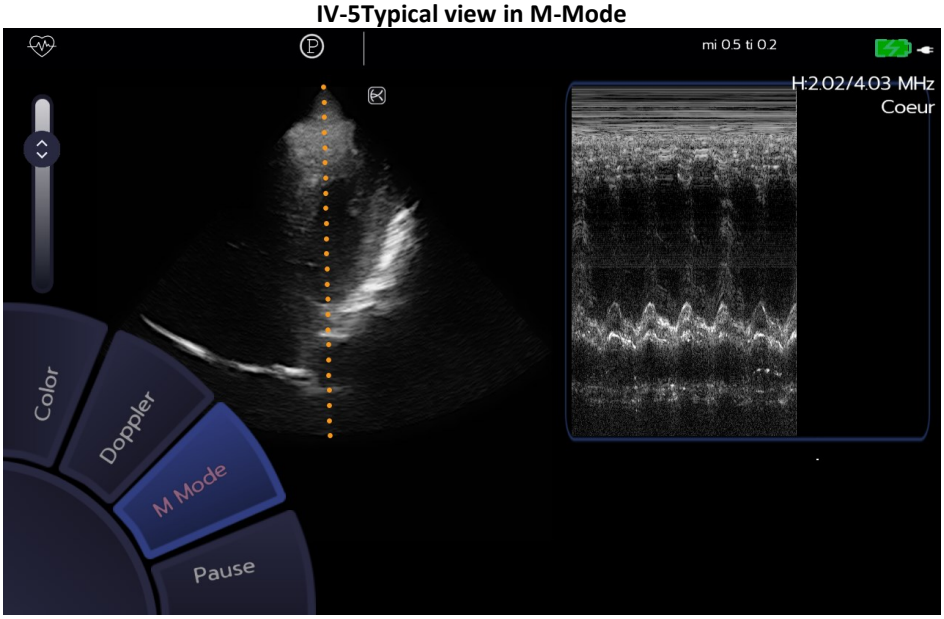
IV-4Typical view in PW Mode



6.M-Mode

M-Mode also called “M-Mode” displays the variation of the tissues vs time on a selected line of interest. You can choose this line by directly touching it.

IV-5Typical view in M-Mode



7.CONTINUOUS WAVE DOPPLER

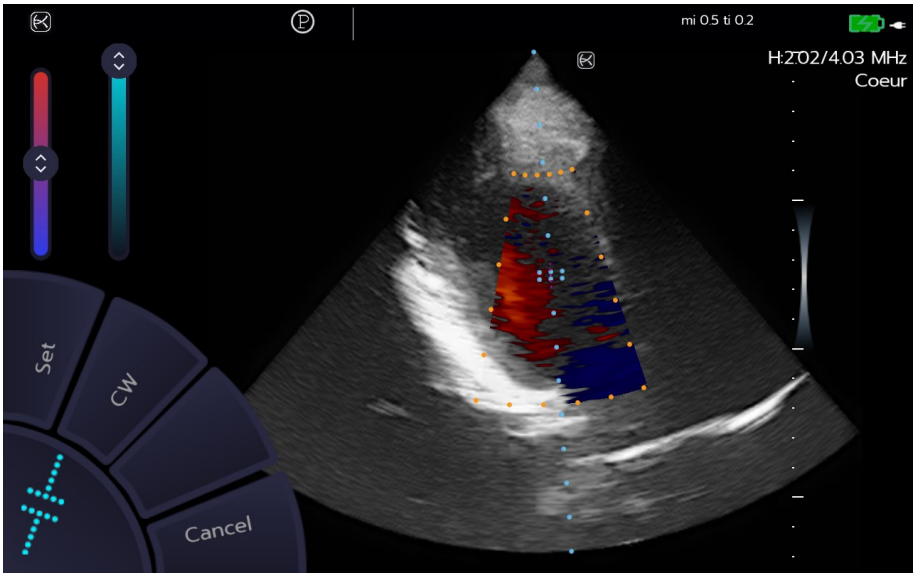
The information delivered by the continuous wave (CW) mode is direction and speed of blood flow delivered through a frequency spectrum.

In CW Mode, continuous impulses of ultrasound waves are transmitted from the ultrasound probe just like in B-Mode. However in CW Mode, the receiving signals are processed to extract the difference in frequency between the transmitted and the receiving signals. Such difference in frequencies is caused by moving elements such as blood flow. The receiving signals are displayed:

Graphically on the monitor where the X axis represents time and the Y axis represents flow velocity in either a forward or reverse direction.

And

Audibly through the system speakers.



8.Presets

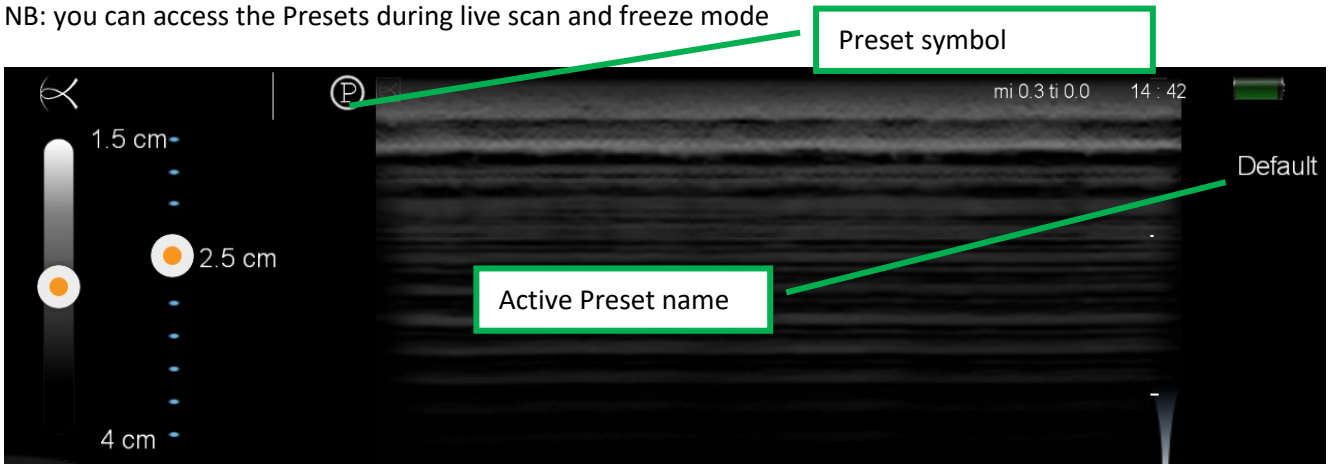
The system integrates optimized and stored settings known as “Presets”.
Those Presets allow the user to have an optimized image in most situations.
Those presets depend on each probes.

It is possible to:

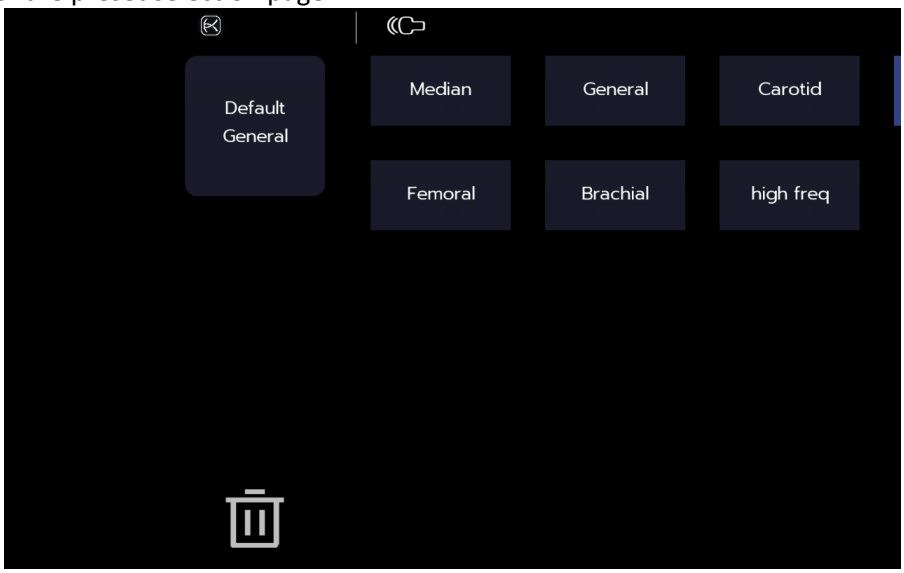
- Select the preset used
- Select the default Preset

8.1.Select the preset

Click on the “Preset” symbol “P”
NB: you can access the Presets during live scan and freeze mode



You will then enter the preset selection page.



In Orange is displayed the preset actually selected.
To select a new preset, click on it.
You will the get back to scanning page, with the preset and its parameters loaded.

8.1. Select the default preset

Enter the preset selection page.
Drag the preset you want to setup as default to the default box on the left of the screen.

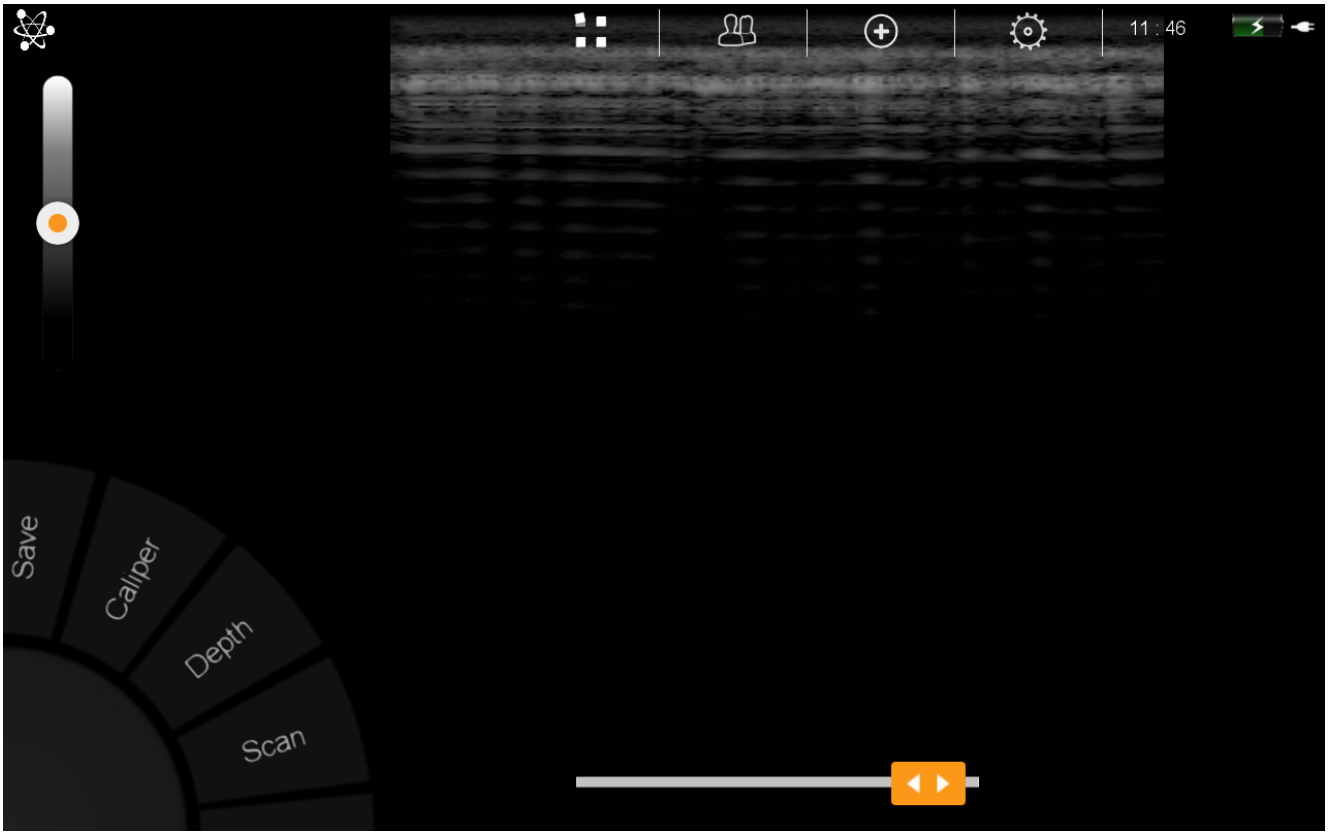
On startup of a new patient the system will then loads this default preset

CHAPTER V
MEASURES AND REVIEW

1.2D MODE MEASUREMENTS

1.1.Start a measure

To start a new measurement, make sure that the image is frozen. A scrolling bar should then appear at the bottom of the image and this one should be still.



Press the Caliper key to enter in Measurement mode (cf. Figure V-1).

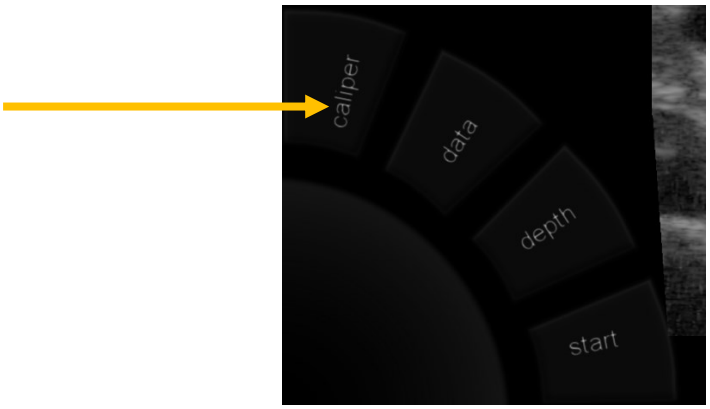


Figure V-1 - Functions when scanning is frozen

1.2. Distance

To measure the distance between two points once image has been frozen and selected:

1) Press the "caliper" button on the main display
2) A cursor appears on the screen.
3) Touch with the finger on the first location
4) Press the “next” button on the main display
5) Touch with the finger on the second location
6) Result of the measure appears on the screen.

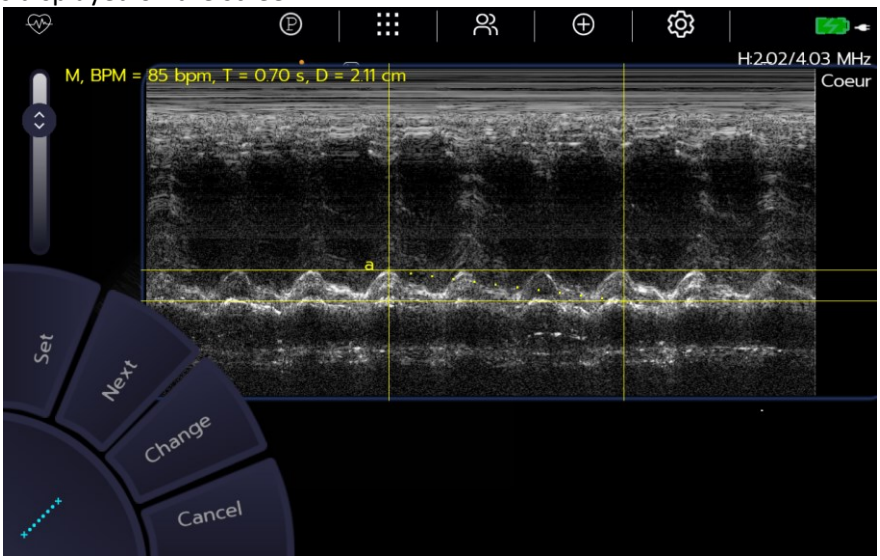
1.3. Circumference / Area

1) Press the "caliper" button on the main display
2) Press the “change” button on the main display
3) Select Ellipse
4) A cursor appears on the screen.
5) Touch with the finger on the first location
6) Press the “next” button on the main display
7) Touch with the finger on the second location, the end of ellipse long-axis
8) Press the “next” button on the main display
9) Touch the circle with the finger to change the ellipse short axis
10) Result of the measure appears on the screen.

2. *M Mode Measurement*

While scanning in M Mode and when image has been selected and frozen, it is possible to make measurements.

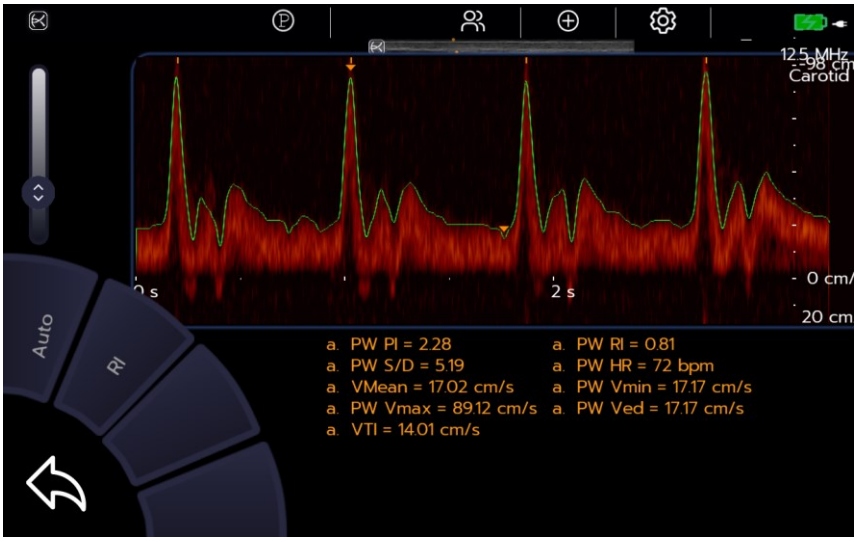
1) Make sure to have a nice M-Mode image
2) Press freeze
3) Press Caliper
4) Select the first point of the measurement and press set
5) Select the second point of the measurement and press set
6) Calculation is displayed on the screen



3.PW Mode Measurement

While scanning in PW Mode and when image has been selected and frozen, it is possible to make measurements.

1) Make sure to have a nice spectrum image with few cycles visible
2) Press freeze
3) Adjust the PW angle on the screen in order to have the angle parallel to the vessel
4) Press Caliper
5) Calculation is displayed on the screen



NOTE :	*The determination of the envelope curve requires a clear and low-noise recording of the Doppler spectrum. Otherwise the reliability of the displayed measurement results may not be ensured!.*

4.MEASUREMENT ACCURACY OF THE SYSTEM

Measurements must never be made in a hurry, accurate positioning of the measuring cross or measuring dots is necessary especially with area/circumference measurements.
Despite the high technical accuracy of the scan geometry and the measuring system of the Device equipment one must, however, be aware of inaccuracies caused by the ultrasound beam properties and the physiological properties of the scanned structures, tissues and fluids. For the reason of improved lateral resolution you should choose the proper scanhead for the depth range of the structure to be measured

System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.

4.1.2D Measurement Range and Accuracy

Measurement	Accuracy	Range
Axial Distance	≤ ± 3%	0 - 30.0 cm

Lateral Distance	≤ ± 3%	0 - 30.0 cm
Diagonal Distance	≤ ± 3%	0 - 40.0 cm
Area	< ±7%	0.1-720 cm2
Circumference	< ±5%	0.1-96 cm
Contour	< ±5%	0.1-96 cm

4.2.M Mode Measurement and Accuracy

Measurement	Accuracy	Range
Distance	≤ ± 3%	30.0 cm
Time	≤ ± 2%	0.02 to >4.0 s

4.3.PW & CW Mode Measurement and Accuracy

Measurement	Accuracy	Range
Velocity	≤ ± 12%	0.04 – 1.6 m/s
Time	≤ ± 2%	0.02 to >4.0 s

5.REVIEW AND STORAGE

During live scanning, acquired images are temporarily stored on the system's memory (image buffer). When the system's memory is full, the oldest images will be deleted and replaced by the newly acquired images.

5.1.Storage of images

Images for the current examination are stored in the system.

Pressing **Data** will store a single frame when in freeze (cf. Figure V-1).

5.2.Recall of stored data

Images stored on the device can be recalled for review.

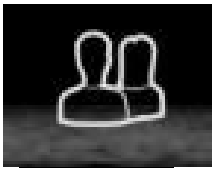


Figure V-2 - Data Review Icon

To recall stored data:

- Click on Data Review icon (cf. Figure V-2) to open the image review window (cf. Figure V-3)
- Click on the thumbnail of image to enlarge it.

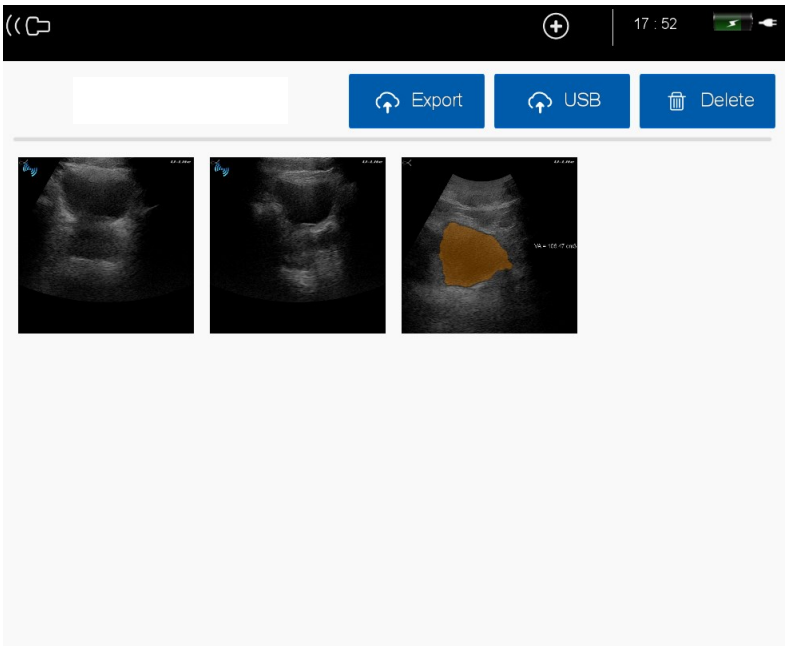


Figure V-3 - Image Review Window

6.Managing Patient Records

The Patient module offers tools for searching and managing patient exam records which are referred to in the system as Applications. Patient module enables you to search the worklist server for specific Applications, update patient information, create new studies, and save exams.
Each Application includes basic patient data, such as name, date of birth, height, and weight, as well as exam-specific information (exam type, purpose, notes, and any saved exam images or clips).
The specific information contained in a Application is based on the exam type. For example, the new study form for an obstetrics exam will look different from a new study form for a cardiac exam.

In Device, you can start scanning without entering any patient information. Device creates a temporary ID, and all the images are saved to that ID. Before submitting any images, you have to change the temporary ID to a patient name.

6.1.Create a new patient

From the Application menu, start exam. A pop-up show to enter patient information. When done completing the data, press start.
During an exam, tap the + icon to add a new patient and continue the study with this patient. The previous one will be automatically closed.

6.2.Accessing patient information

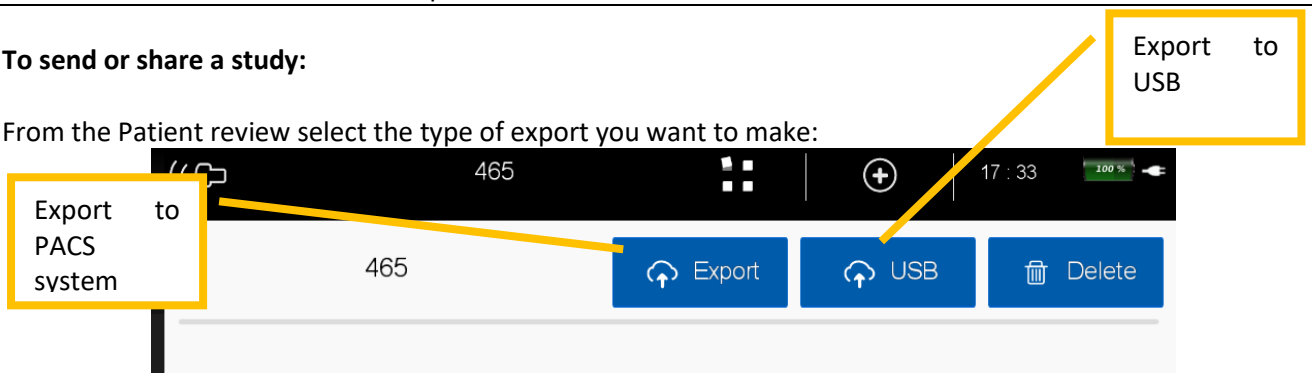
During an exam, tap the  icon to en enter the patient page

6.3.Sharing a study

	Do not disclose protected patient data in email. To protect patient data, take appropriate precautions when exporting patient data to a USB drive.

To send or share a study:

From the Patient review select the type of export you want to make:



Before selecting USB, make sure that a USB device is connected.
Before selecting PACS export, make sure that WIFI and PACS information are completed

Note: Through USB export: DICOM images are exported

7.AVAILABLE APPLICATIONS

All those measures and data are available on the Advanced App, which is the default app. Note that this device has a large range of applications, suitable for many specific uses.
Indeed to make it easier for physicians to use the device, we have created the concept of Applications or "APP" which defines the Imaging Modes available and the Measurements. An overview of those features is presented in the table below:

Applications Modes and Probes:

App	Available Modes				Recommended probes			
	B	M	Color	PW	Linear	Convex	Phased Array	Endocavitary
Advanced	x	x	x	x	x	x	x	x
Standard	x	x	x	x	x	x	x	x
Premium	x	x	x	x	x	x	x	x
Bladder	x					x		
Vascular	x		x	x	x			
Vascular access	x		x		x	x		x
OB	x	x	x	x		x		x
Physio	x		x	x	x	x		
Blue	x	x	x		x	x		
Anesthesia	x	x	x	x				
Dialysis	x		x	x	x	x		
Cardio	x	x	x	x			x	

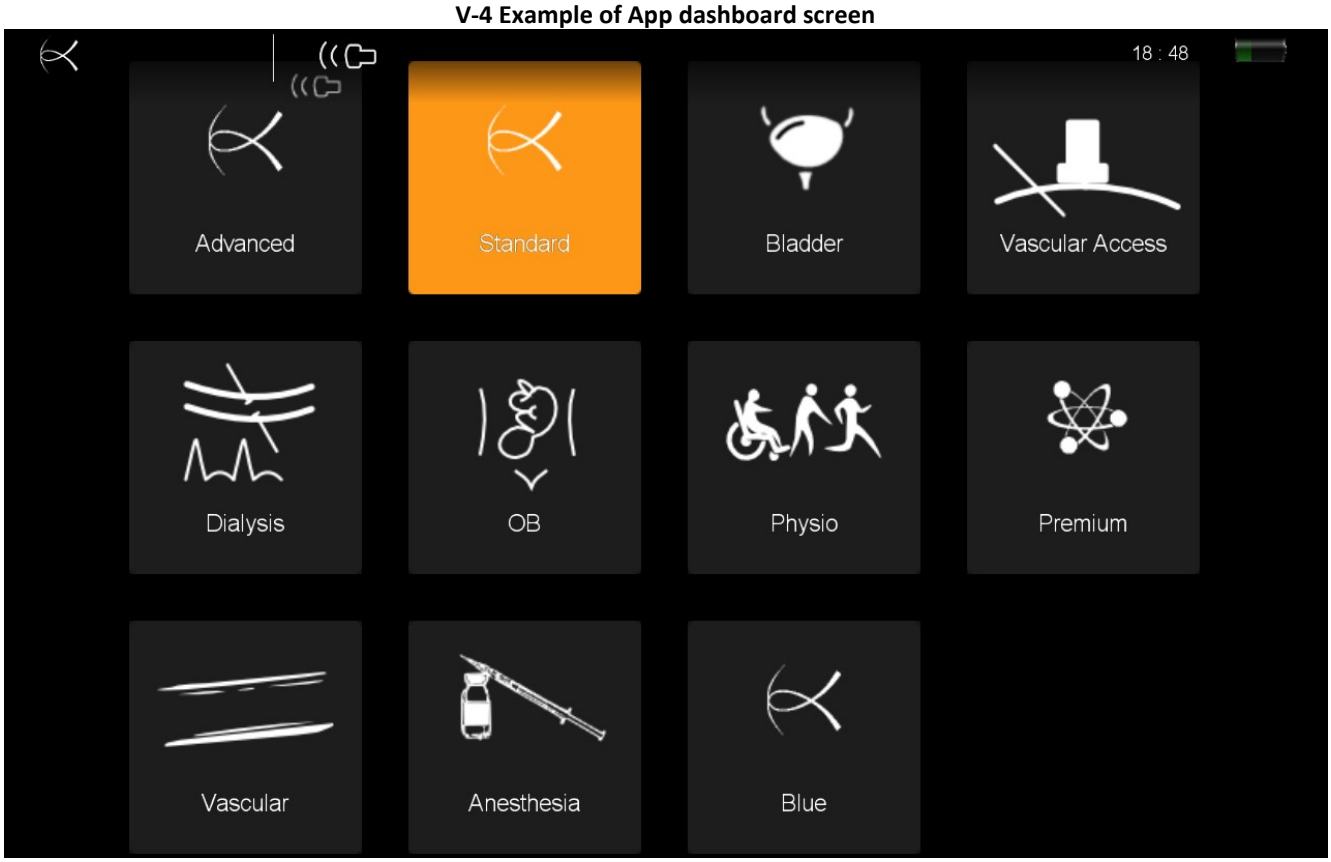
Applications Measures and Features:

App	Available Measures									
	2D	PW	M	Bladder Volume	Flow	IMT	Cardio	Storage	Needle Guide*	Needle Vision**
Advanced	x	x	x					x		
Standard	x	x	x							
Premium	x	x	x					x		
Bladder				x				x		
Vascular		x				x		x		
Vascular access	x							x	x	x
OB	x	x	x					x		
Physio	x	x						x		
Blue	x		x					x		
Anesthesia	x	x	x					x		
Dialysis					x			x		
Cardio	x	x	x				x	x		

* refer to Biopsy setup page VI-7 for detailed instructions
** just consists of green rendering instead of traditional grey

The available applications on the device are displayed on the dashboard:

V-4 Example of App dashboard screen



Standard : equivalent to Advanced app, but without Wi-Fi option and patient data

Biopsy : 4 and 6 cm depth available

7.1. Advanced: Usual controls and modes

This "App" is the one used to detail the different modes and controls in this manual. It is the "default" App.

7.2. Standard: Usual controls and modes without Patient data

This "App" is the same as the "Advanced App" without any patient data.

7.3. Physio: For MSK purposes

This "App" is the same as the "Advanced App" without the M-Mode.

7.4. Anesthesia: For Anesthesia purposes

This "App" is the same as the "Advanced App".

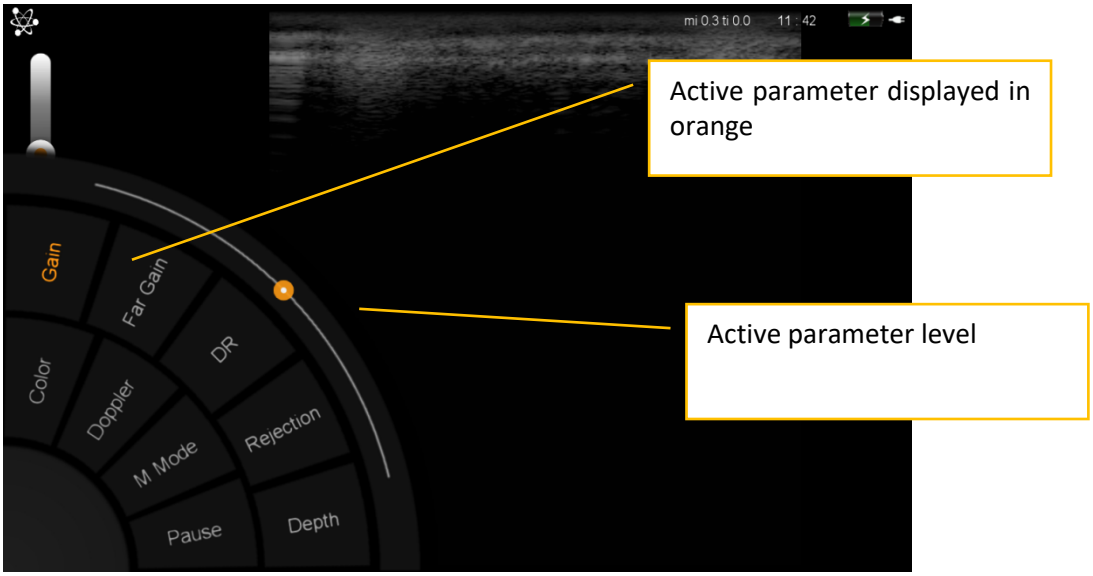
7.5. Blue: For Lung imaging purposes

This "App" is the same as the "Advanced App" without the PW-Mode.

7.6. Premium: Expert controls

This "App" is the based on the "Advanced App" and includes some more controls for expert users wishing to customize images.
The only change on this App from the Advanced App is the number of controls available

7.6.1. Controls available during scan:

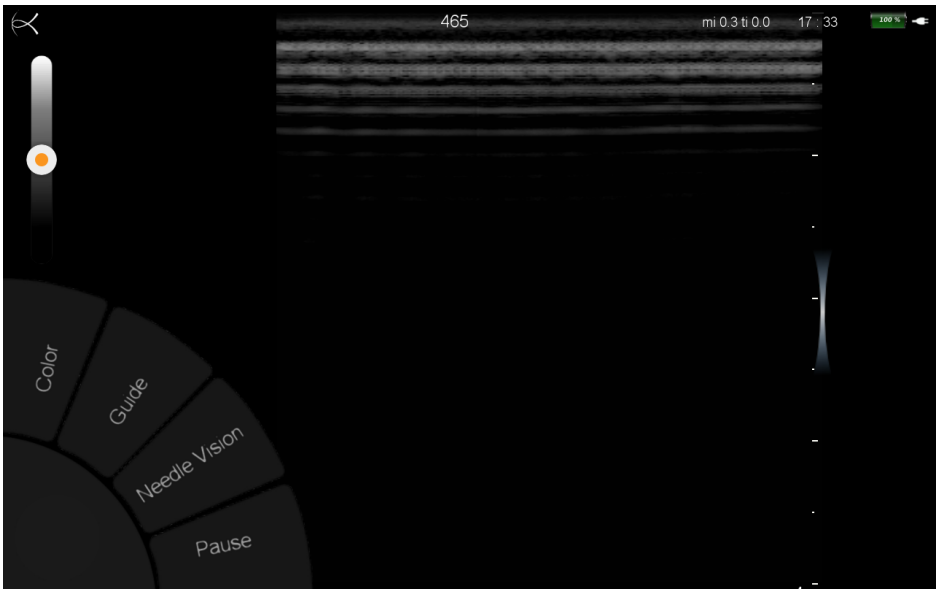


Gain: to adjust the overall gain
Far Gain: to adjust gain in the deeper zone of image
DR: to adjust the contrast of the image
Rejection: to adjust the rejection level of the low intensity echoes
Depth: to adjust the depth of scan

7.7. Vascular Access: For biopsy

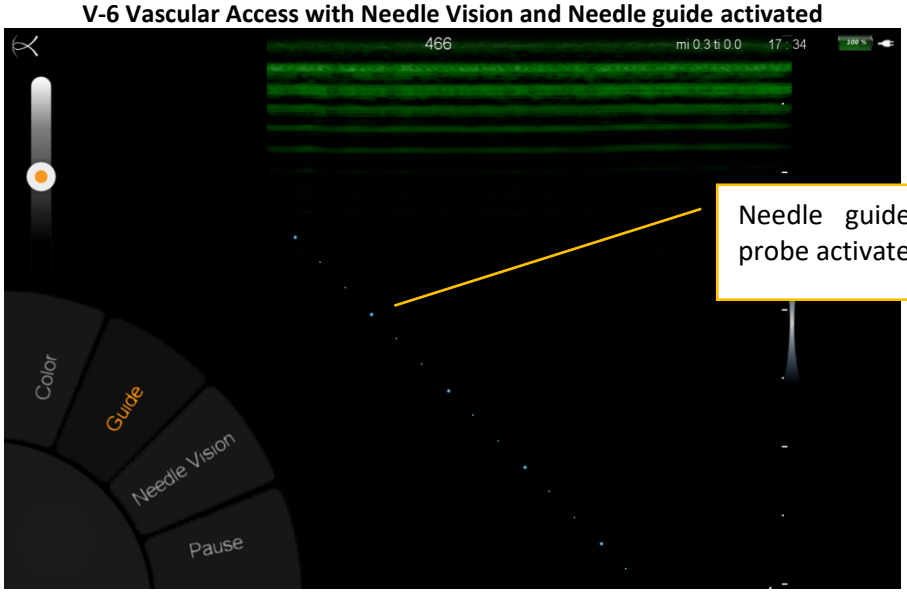
This "App" is intended to be used in case of biopsy procedure.

V-5 Vascular Access screen



This Application includes a display mode called "Needle Vision" which can be activated by pressing Needle Vision button. It consists of green scale rendering instead of traditional grey scale.
Depending on the probe used, a Needle Guide can be used. For more detailed info on biopsies, please refer to Biopsy setup page VI-7

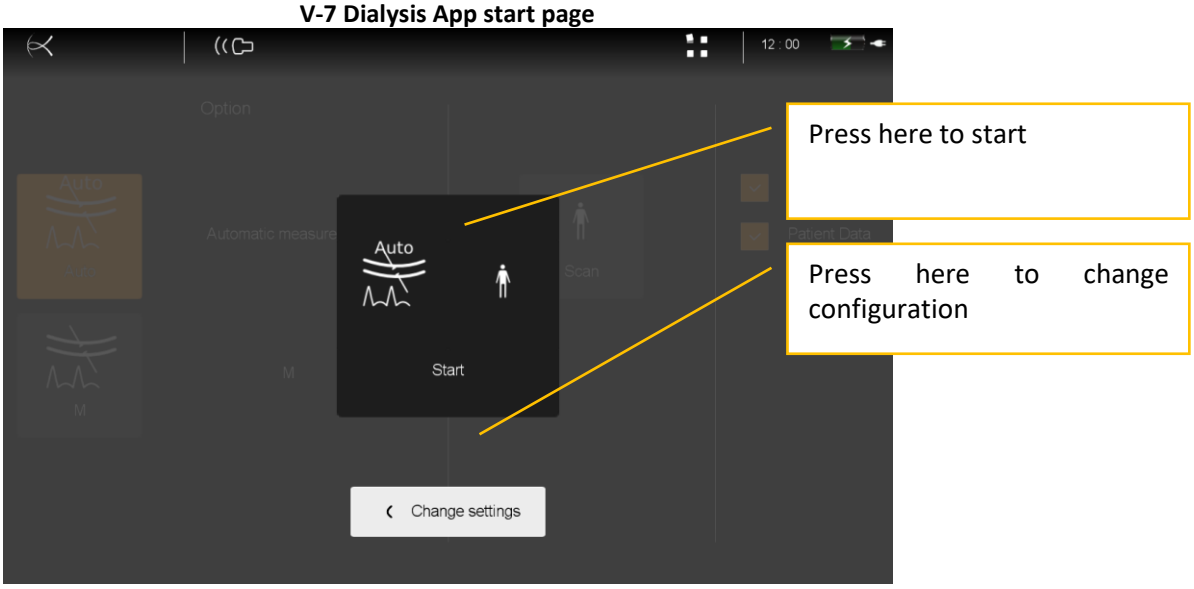
V-6 Vascular Access with Needle Vision and Needle guide activated



7.8. Dialysis: Estimates the blood flow

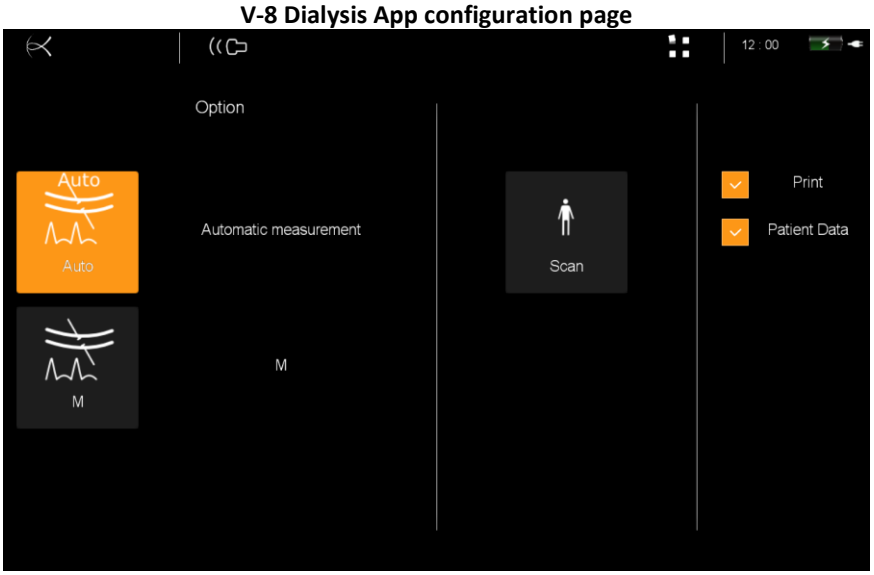
This "App" estimates the flow in a vessel using 2D measures and PW measures
When the system starts, the following screen appears:

V-7 Dialysis App start page



On the following page, It is possible to choose:
- the type of measurement used to calculate the flow.
- the patient type
- if printing is performed after confirmation of the assessment
- if a patient name is entered

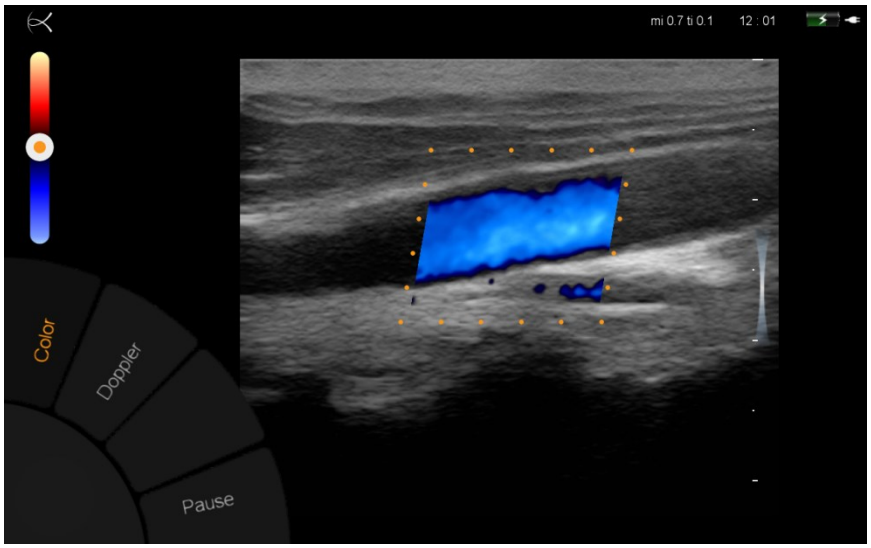
V-8 Dialysis App configuration page



7.8.1. Flow Calculation Auto:

The following procedure describes the flow measurement Auto.

1. Acquire a longitudinal scan of the artery and optimize the image.
2. Press Color.



3. Make sure to get a nice signal.
4. Press Doppler; The system will switch to PW Mode
5. After recording a few cycles of good PW trace, freeze the image
6. The measurement calculations are displayed in the Measurement result table

7. Both Diameter and PW measures can be redone if necessary

Flow Measure approval:

NOTE :	*Erroneous vessel diameter detection or wrong PW trace may lead to incorrect measurement results. The detection should be visually checked and edited if required.*

Since the flow measurements are done semi-automatically, the operator has to approve the detection by visual inspection before storing the results in worksheet and report.
1. If the diameter and traces are correct, approve the measurement by selecting "Validate" in the Measurement menu.

NOTE :	*Measurements that are not approved will not be saved.*

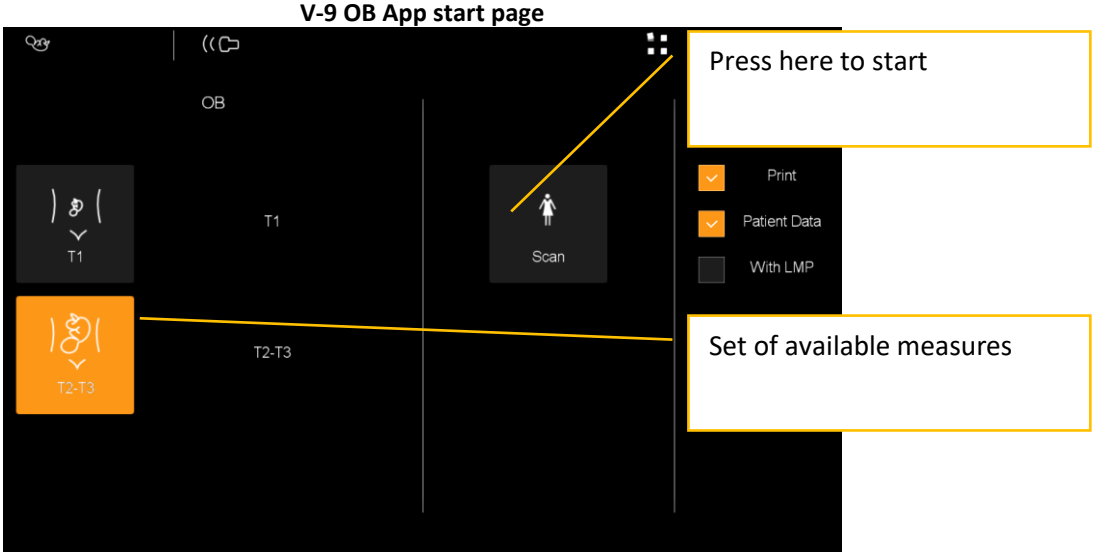
7.8.2. Manual Flow Calculation:

Procedure is the same as the Auto mode, except that vessel diameter has to be measured manually.

7.9. OB : computes standard biometry

This "App" allows calculation of standard fetal biometry. The measures are made according to 2D distance measurements procedure.

V-9 OB App start page



If "With LMP" is checked, user can input the LMP after typing patient's name:

V-10 LMP Input

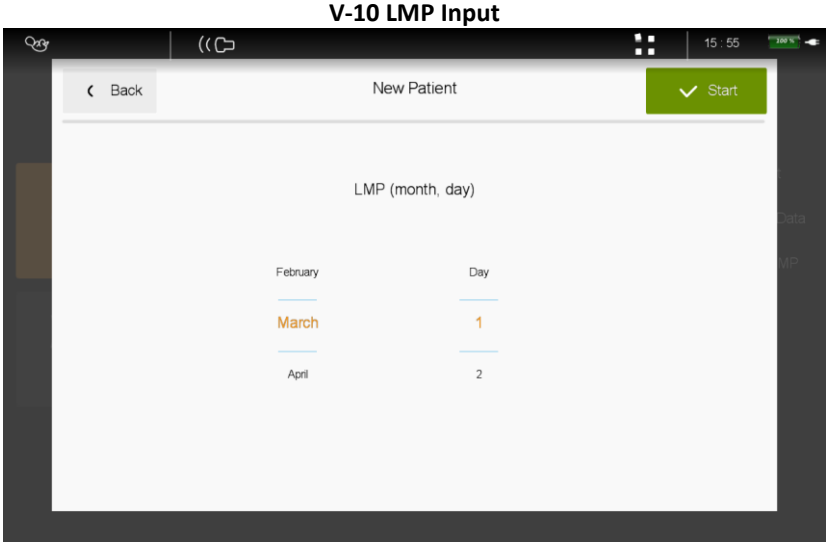


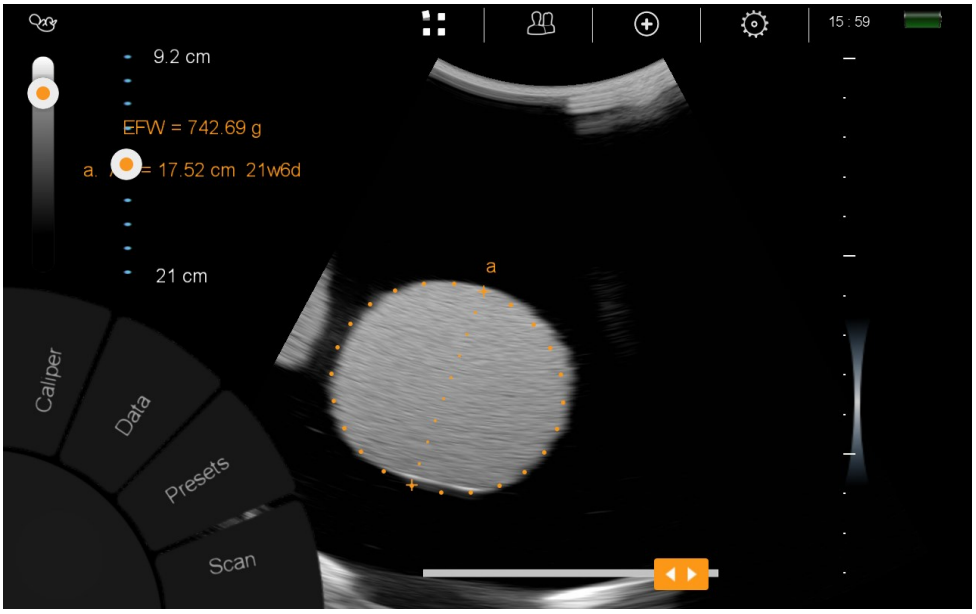
Table of the measures available depending on the set selected

Measure	T1	T2-T3	Author
CRL	X		
Gestational sac	X		
Yolk sac	X		
Cervical L	X		
Femur		X	Hadlock
BPD		X	Hadlock
HC		X	Hadlock
AC		X	Hadlock

EFW:

Once BPD, Femur FL, HC, AC are measured, the system computes the Estimated Fetal Weight using Hadlock formula:

EFW [g] = 10^(1.3596- (0.00386 * AC [cm] * FL[cm]) + (0.0064 * HC [cm]) + (0.00061 * BPD [cm] *AC [cm]) +(0.0424 * AC [cm]) + (0.174 * FL [cm]))

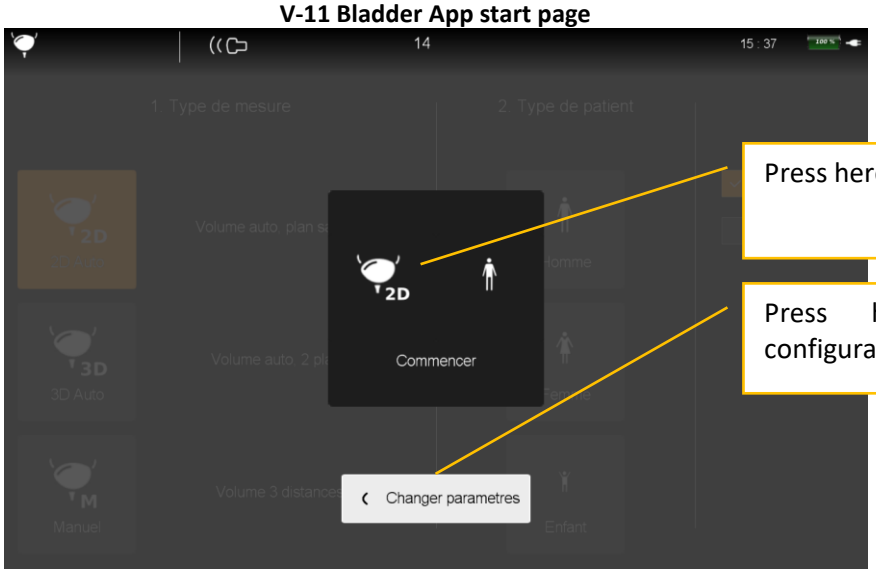


7.10. Bladder: Estimates bladder volume

This "App" estimates bladder volume on a B-mode image.

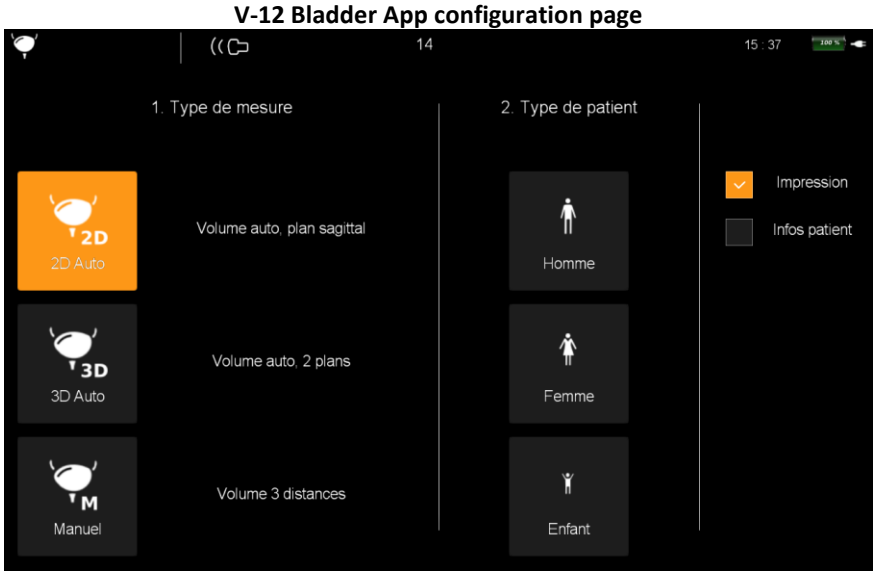
When the system starts, the following screen appears:

V-11 Bladder App start page



On the following page, it is possible to choose:
- the type of measurement used to calculate the volume of the bladder
- the patient type
- if printing is performed after confirmation of the assessment
- if a patient name is entered

V-12 Bladder App configuration page



7.10.1. Bladder Volume 2D:

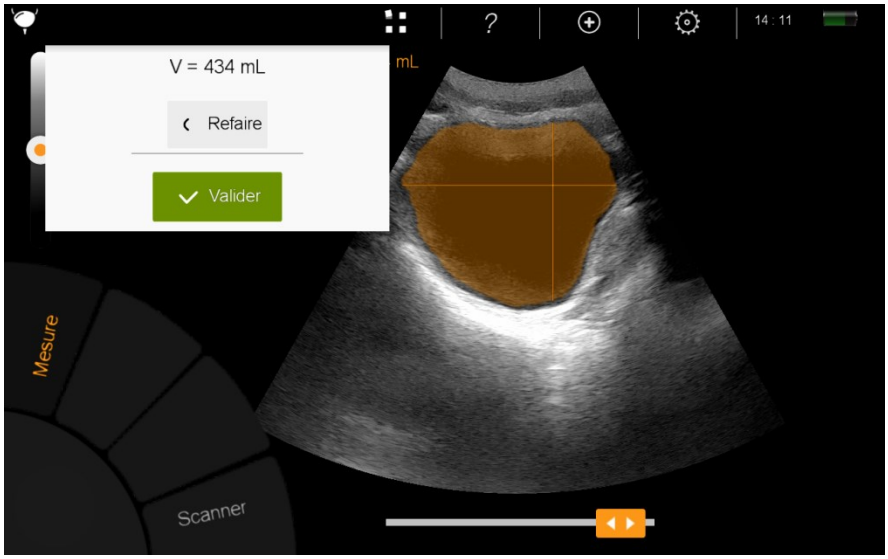
Bladder Volume 2D Estimation procedure

The following procedure describes the Bladder Volume 2D Estimation.

1. Acquire a sagittal scan of the bladder and optimize the image. The probe is placed on the midline, just above the pubis.

NOTE :	*The operator will ensure the correct position of the probe clearly identifying on the screen the typical image of the bladder.*

2. Adjust the position of the probe to maximize the surface visible bladder
3. Press Pause.
4. Click inside the bladder.
5. The estimated calculations are displayed in the result table



NOTE :	*The bladder volume calculated from a single scan is just an estimation based on the automatically detected diameters of the bladder. This estimation should only be used as an indicative value, as different bladders could have actual volumes different to the single plane estimation..*

Bladder Volume 2D approval:

NOTE :	*Erroneous contour detection of the bladder may lead to incorrect estimation results. The contour detection should be visually checked and edited if required.*

Since the bladder volume estimation is done semi-automatically, the operator has to approve the detection by visual inspection before storing the results in worksheet and report.
1. If the detection follows the bladder edges, approve the estimation by selecting "Validate" in the Measurement menu.

NOTE :	*Estimations that are not approved will not be saved.*

7.10.2. Bladder Volume 3D:

Bladder Volume 3D Estimation procedure

The following procedure describes the Bladder Volume 3D Estimation.
1. Acquire a sagittal scan of the bladder and optimize the image. The probe is placed on the midline, just above the pubis.

NOTE :	*The operator will ensure the correct position of the probe clearly identifying on the screen the typical image of the bladder.*

2. Adjust the position of the probe to maximize the surface visible bladder
3. Press Pause.
4. Click inside the bladder.
5. The estimated calculations are displayed in the result table
6. If the detection follows the bladder edges, approve the estimation by selecting "Validate" in the Measurement menu.
7. With respect to the sagittal position turn the probe by 90°.
8. Adjust the position of the probe to maximize the surface visible bladder.
9. Press Pause.
10. Click inside the bladder.
11. The estimation calculations are displayed in the result table
12. If the detection follows the bladder edges, approve the estimation by selecting "Validate" in the Measurement menu.

NOTE :	*The bladder volume calculated is an estimation which should only be used as an indicative value.*

Bladder Volume 3D approval:

NOTE :	*Erroneous contour detection of the bladder may lead to incorrect estimations. The contour detection at each step should be visually checked and edited if required.*

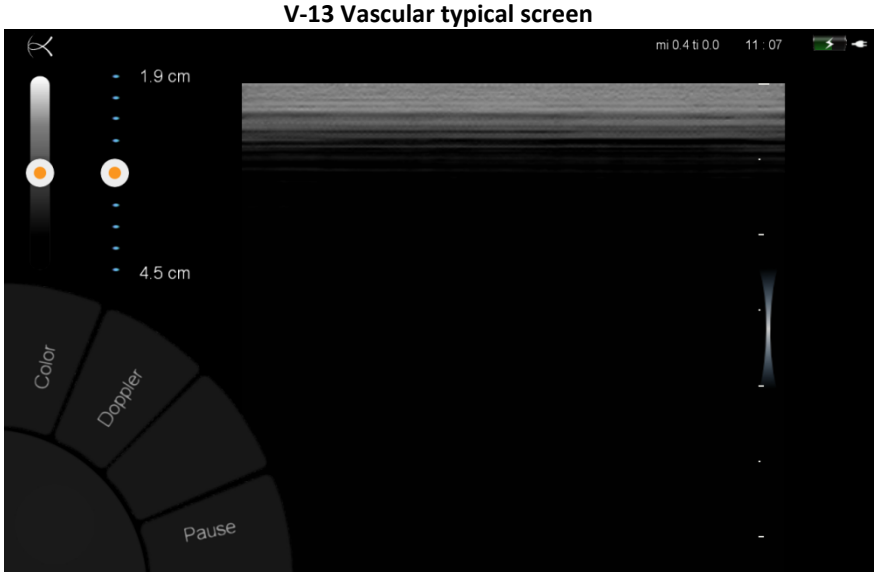
Since the bladder volume estimation is done semi-automatically, the operator has to approve the detection by visual inspection before storing the results in worksheet and report.
1. If the detection follows the bladder edges, approve the estimation by selecting "Validate" in the Measurement menu.

NOTE :	*Measurements that are not approved will not be saved.*

7.11. Vascular: **Estimates the IMT**

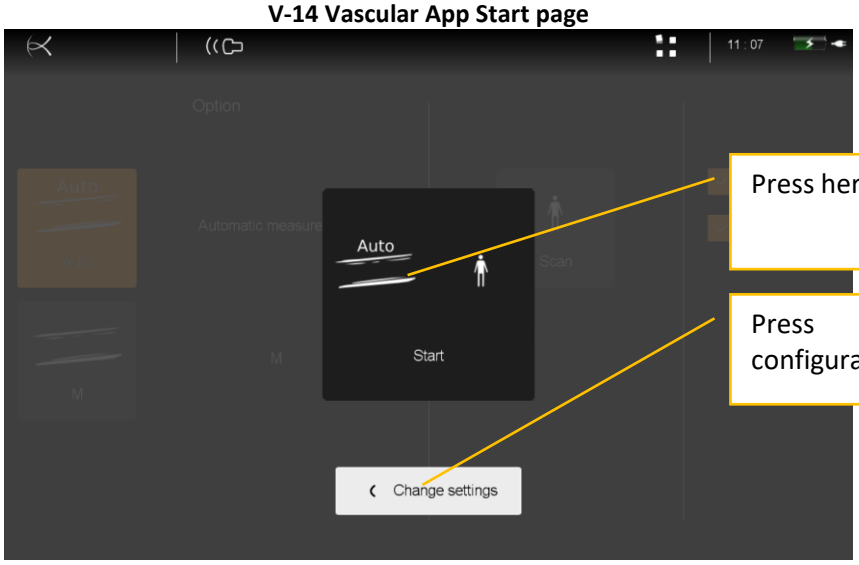
This "App" presents the same characteristics as the "Advanced App" including BMode, Color Doppler Mode and PW.

V-13 Vascular typical screen



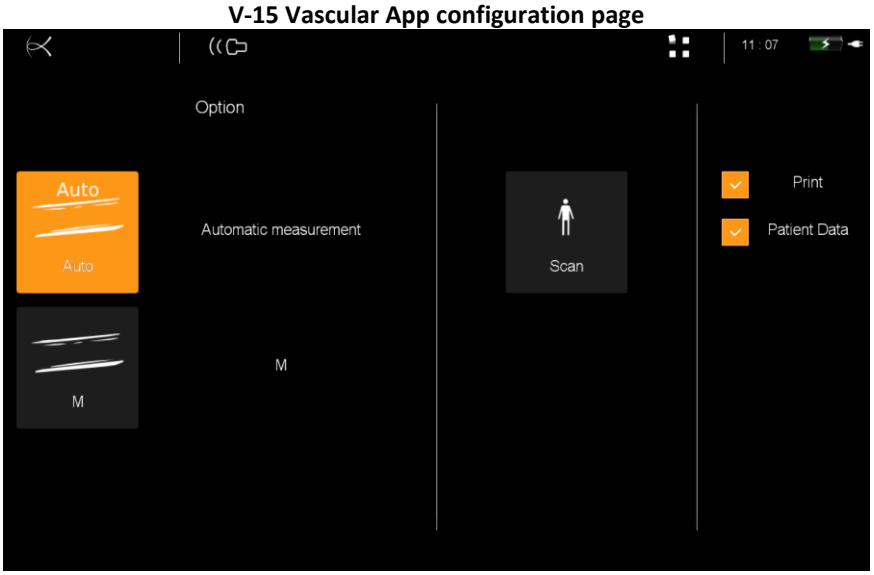
It also integrates measure of IMT.
When the system starts, the following screen appears:

V-14 Vascular App Start page



On the following page, It is possible to choose:
- the type of measurement used to calculate the IMT.
- if printing is performed after confirmation of the assessment
- if a patient name is entered

V-15 Vascular App configuration page



7.11.1. IMT (Intima Media Thickness) Auto:

The Intima-Media Thickness (IMT) is calculated based on automatic contour detection of the Intima and Media layers on a user-defined search region along the vessel wall. Multiple IMT measurements are made between pairs of intima and adventitia points along the wall. IMT can be measured both on the posterior and the anterior walls of the vessel. IMT should be done on 2D mode images, not on Color mode images.
The IMT measurement is available with linear probes only.

NOTE :	*Due to the physical properties of ultrasound imaging, the posterior IMT measurement is generally more accurate than the anterior IMT measurement*.

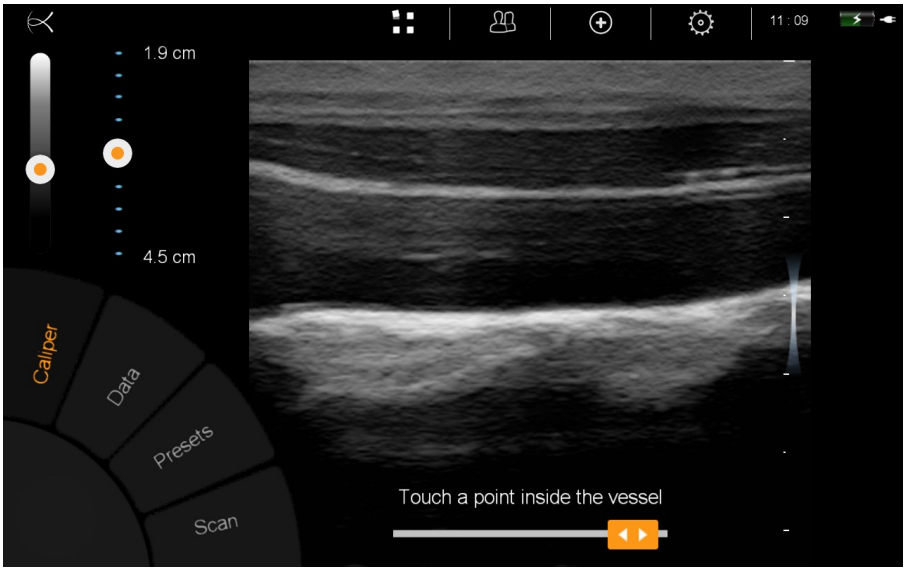
The following parameters are calculated:

- Average IMT

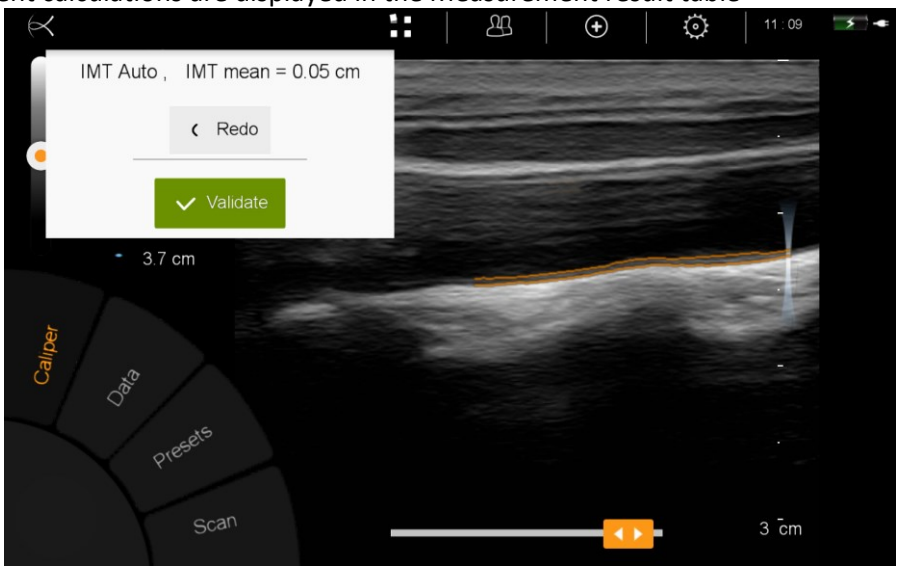
IMT Measurement procedure

The following procedure describes the IMT measurement Auto.

1. Acquire a longitudinal scan of the carotid artery and optimize the image.
2. Press Freeze.
3. Scroll to an end-diastolic frame where the intima layer is clearly visible.
4. Click inside the vessel.



5. The measurement calculations are displayed in the Measurement result table



6. If the contour is not optimal, click "Redo" to re-measure. If the contour is still not optimal, try to perform the IMT measurement on another frame, preferably close to the end diastole.

NOTE :	*The effect of an over-gained image is that the IMT interfaces are slightly thickened. As a result, the automatic IMT tracing may over-estimate the IMT thickness..*

IMT trace approval:

NOTE :	*Erroneous contour detection of the Intima and Media layers may lead to incorrect measurement results. The contour detection should be visually checked and edited if required.*

Since the IMT measurements are done semi-automatically, the operator has to approve the detection by visual inspection before storing the results in worksheet and report.

1. If the traces fit both layers of the posterior wall, approve the measurement by selecting "Validate" in the Measurement menu.

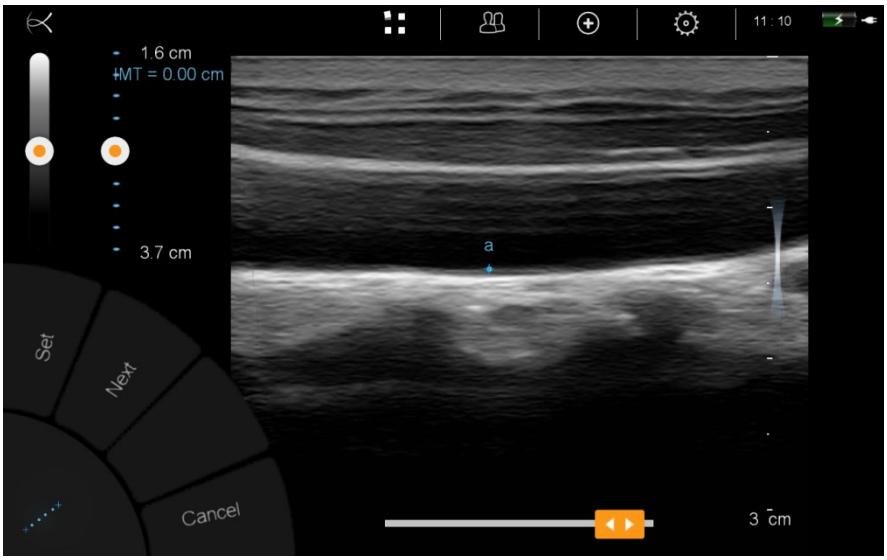
NOTE :	*Measurements that are not approved will not be saved.*

7.11.1. IMT (Intima Media Thickness) Manual:

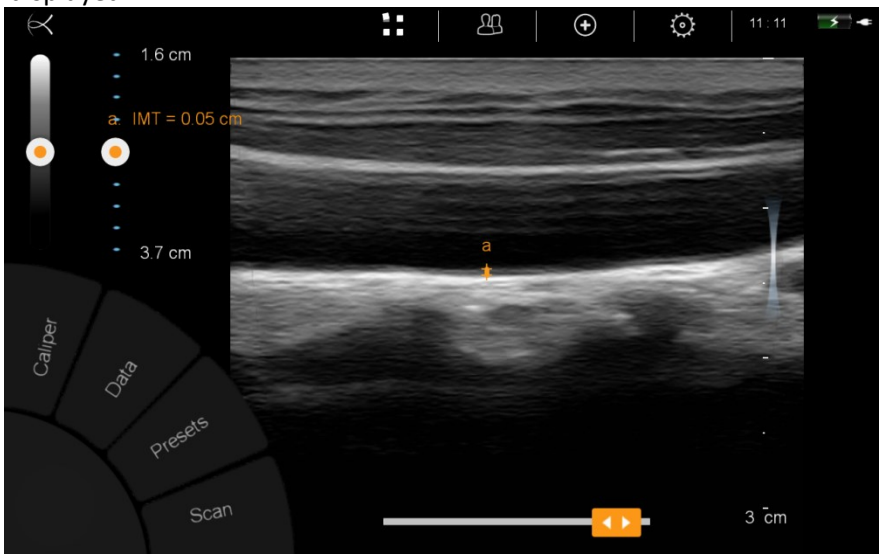
IMT Measurement procedure

The following procedure describes the IMT measurement Manual.

1. Acquire a longitudinal scan of the carotid artery and optimize the image.
2. Press Freeze.
3. Scroll to an end-diastolic frame where the intima layer is clearly visible.
4. Place the caliper on the upper side of the Intima
5. Press set



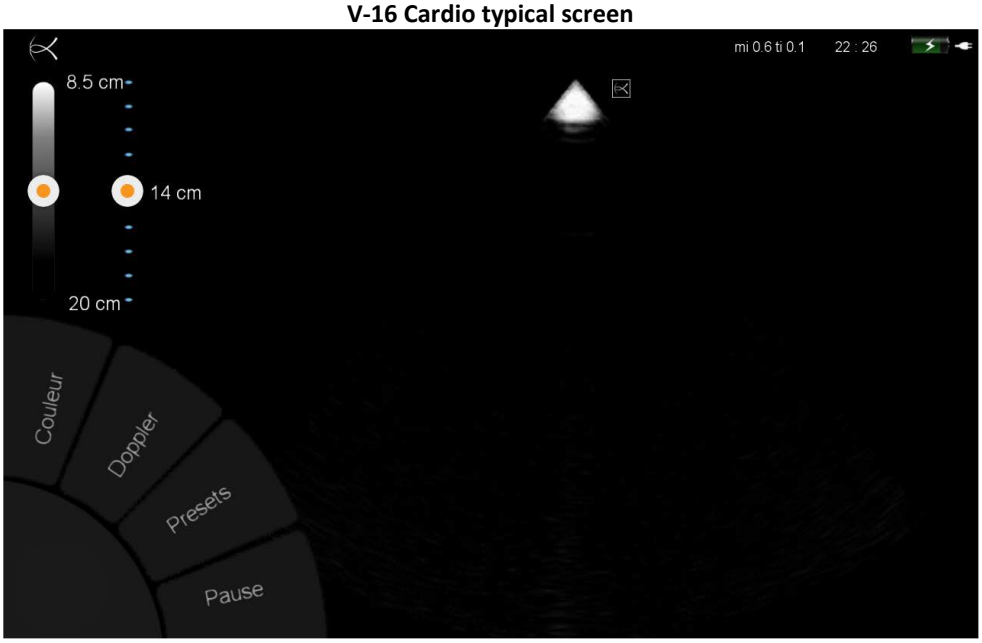
6. Move cursor to the bottom side of the intima
7. Press set
8. Measurement is displayed



7.12. Cardio: **Estimates basic cardio**

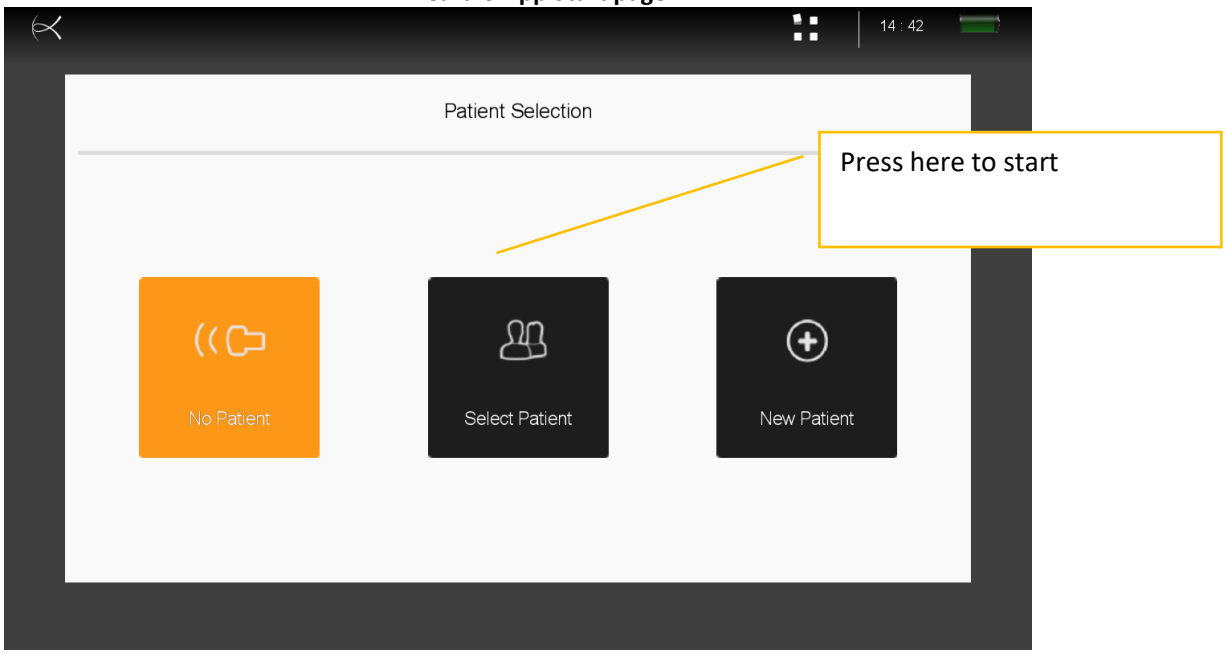
This "App" presents the same characteristics as the "Advanced App" including BMode, Color Doppler Mode and PW. It also includes specific parameters for those two modes known as Tissue Doppler

V-16 Cardio typical screen



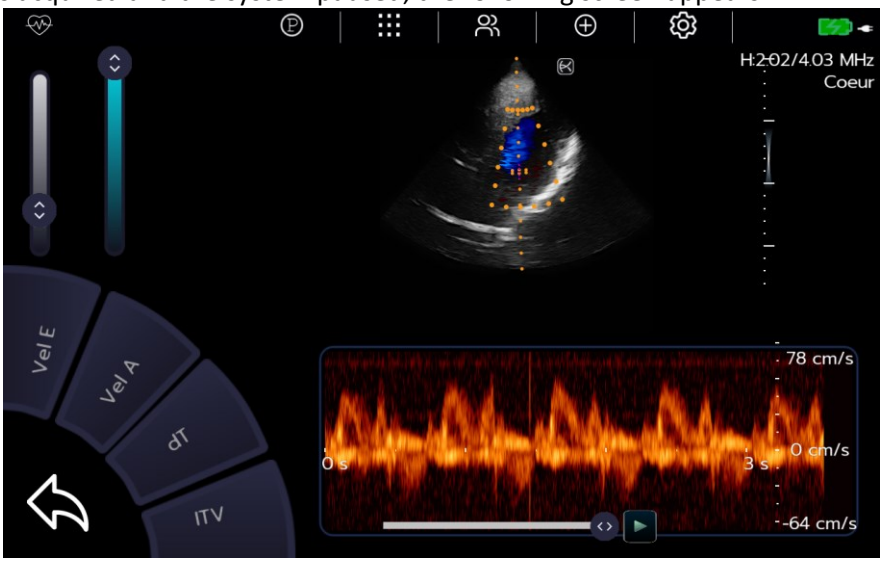
When the system starts, the following screen appears:

V-17 Cardio App Start page



7.12.1. Cardio PW Measurements:

Once a PW signal is acquired and the system paused, the following screen appears:

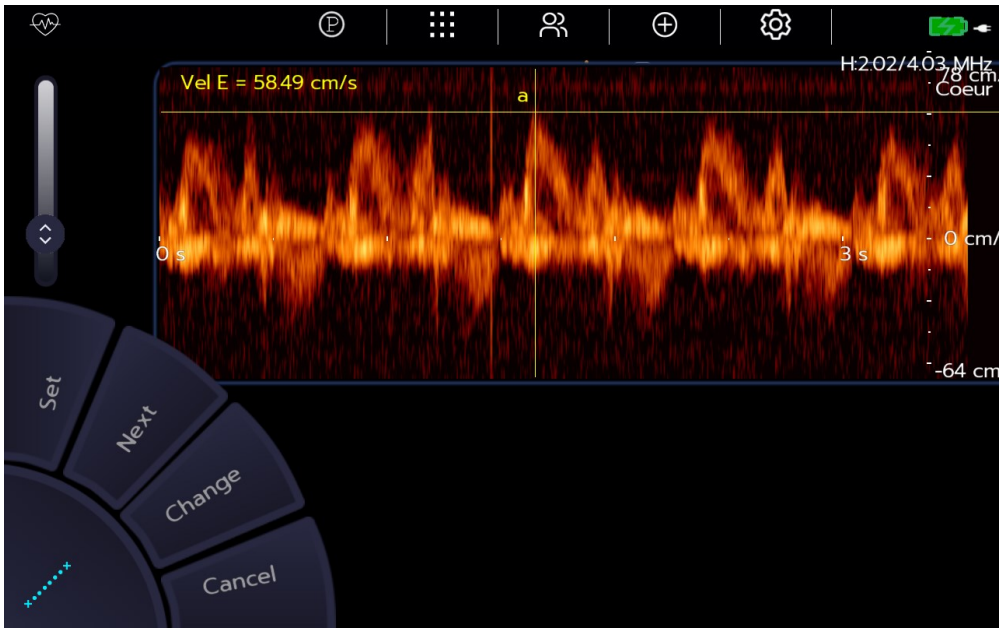


It is then possible to measure the followings items:
Vel E: Velocity of E wave
Vel E': Velocity of E' wave
Vel A: Velocity of E wave
Vel A': Velocity of A' wave
Vel S: Velocity of S wave
dT: deceleration Time
VTI

Velocities measurements in PW:

Select the Velocity you need to compute.
NB: make sure to adjust the spectrum and its baseline before proceeding with measurments.

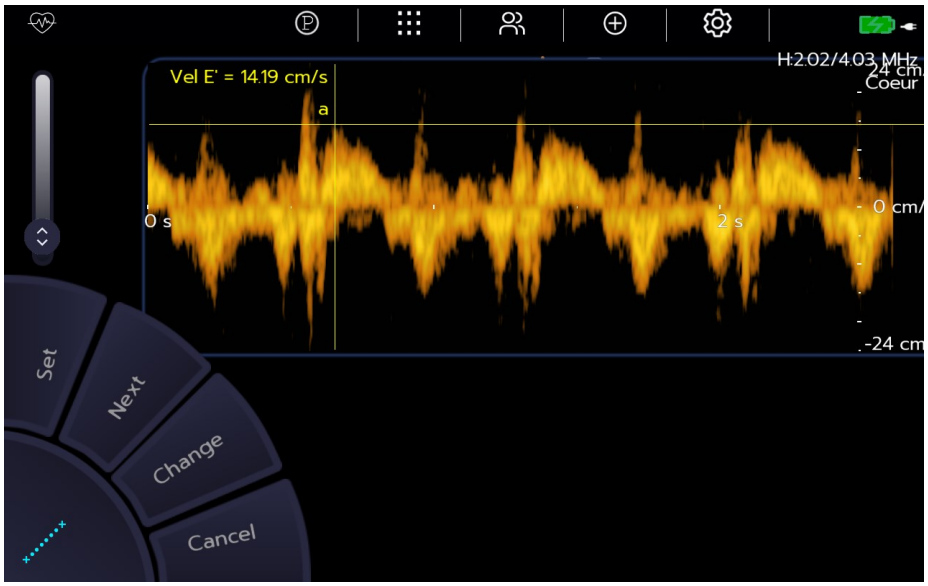
The PW display is then enlarged as follow. Place the cursor on the zone of interest and press "Set"



Velocities measurements in TDI PW:

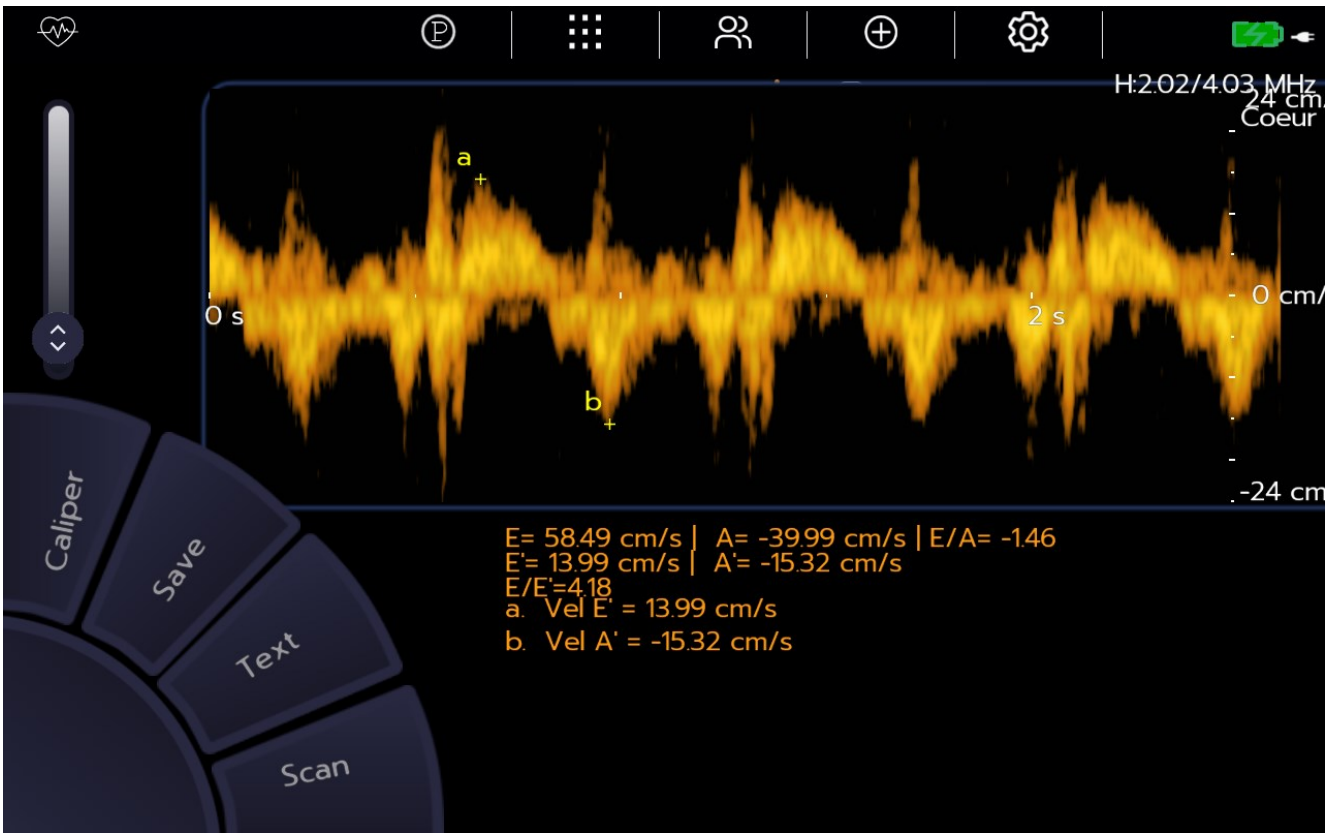
Make a TDI PW acquisition.

Select the Velocity you need to compute.



NB: make sure to adjust the spectrum and its baseline before proceeding with measurements.

The PW display is then enlarged as follow. Place the cursor on the zone of interest and press “Set”

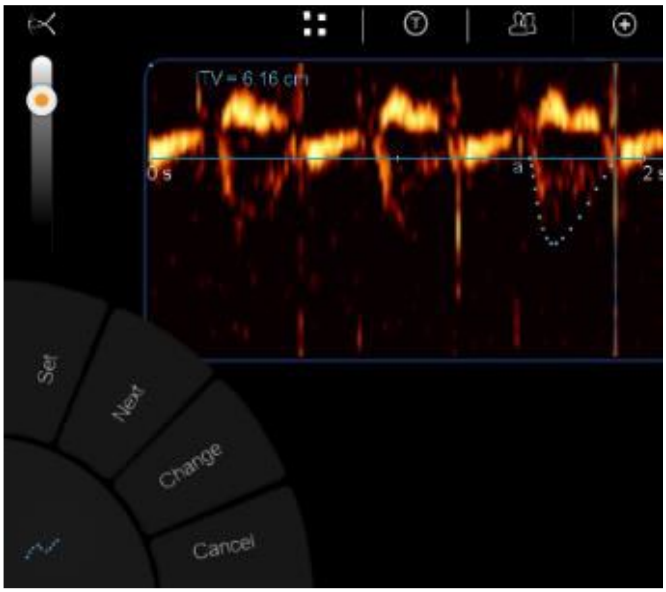


NB: if Vel E and Vel E' are calculated, the system computes Vel E/Vel E' and displays the result. if Vel A and Vel A' are calculated, the system computes Vel A/Vel A' and displays the result.

VTI measurement:

Once the PW acquisition is paused, press VTI.
NB: make sure to adjust the spectrum and its baseline before proceeding with measurments.

The PW display is then enlarged as follow. Place the cursor on the beginning of the wave and press "Set". Then place the cursor on the pick of the wave and press "Set". Finally place the cursor at the end of the wave and press "set". The system draws the VTI spline, computes the result and displays it.



If you need further information on the Device ® applications, please contact your authorized Sonoscanner representative.

CHAPTER VI
SONOSCANNER PROBES

1.PROBES SAFETY

1.1.Handling Precautions

Ultrasound probes are highly sensitive medical instruments that can easily be damaged by improper handling. Use care when handling and protect from damage when not in use.
DO NOT use a damaged or defective probe. Failure to follow these precautions can result in serious injury and equipment damage.
Transducer damage can result from contact with inappropriate coupling or cleaning agents.
Do not soak or saturate transducers with solutions containing alcohol, bleach, ammonium chloride compounds, hydrogen peroxide or incompatible solutions!
Avoid contact with solutions or coupling gels containing mineral oil or lanolin.
Inspect the probe prior to use for damage or degeneration to the housing, strain relief, lens and seal.

1.2.Watertightness

Attention: All probes labeled “IPX1” are watertight below the line represented in the figure below (probes for model Device).
All probes labeled “IPX7” are watertight up to a minimum of 5 cm above the probes strain relief.
If the probe is not explicitly marked as IPX1 or IPX7, only the scan head is watertight, and the rest of the probe is IPX0 according to IEC 60601-2-37.

1.3.Electrical Shock Hazard

The probe is driven with electrical energy that can injure the patient or user if live internal parts are contacted by conductive solution:
• **DO NOT** immerse the probe into any liquid beyond the immersion level. Never immerse the probe connector or probe adaptors into any liquid.
• **DO NOT** drop the probes or subject them to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the housing may result.
• Inspect the probe before and after each use for damage or degradation to the housing, strain relief, lens, and seal. A thorough inspection should be conducted during the cleaning process.
• **DO NOT** kink, tightly coil, or apply excessive force on the probe cable. Insulation failure may result.
• Electrical leakage checks should be performed on a routine basis by Sonoscanner Service or qualified hospital personnel.

1.4. Mechanical Hazard

A defective probe or excessive force can cause patient injury or probe damage:

• Observe depth markings and do not apply excessive force when inserting or manipulating intracavitary probes.

• Inspect probes for sharp edges or rough surfaces that could injure sensitive tissue.

• Avoid mechanical shock or impact to the transducer and do not apply excessive bending or pulling force to the cable.

1.5. Cable handling

Take the following precautions with probe cables:

- Keep free from wheels.
- Do not bend the cable acutely.
- Avoid crossing cables between probes.

1.6. Ergonomics

Probes have been ergonomically designed to:

- Handle and manipulate with ease.
- Connect to the system with one hand.
- Be lightweight and balanced.
- Have rounded edges and smooth surfaces.

Cables have been designed to:

- Connect to system with appropriate cable length.
- Stand up to typical wear with cleaning and using disinfectant agents, contact with approved gel, etc.

2. *LABELING (for probes used with model Device)*

Each probe is labeled with the following information:

- Brand name and address
- Probe serial number
- Year of Production
- IPX1 information
- Probe designation provided in the probe connector housing, so it is easily read before mounting on the system and is also automatically displayed on the screen when the probe is selected.

VI-1 Sonoscanner typical probe labels

3.PROBE USAGE

Please refer to page III-4 for detailed instructions on:

- **To connect a probe *page III-4***
- **To select a probe *page III-5***
- **To disconnect a probe *page III-5***
- **Storing and transporting probes *page III-5***

3.1.Coupling Gels

Do not use unrecommended gels (lubricants).
They may damage the probe and void the warranty.

Applying:
In order to assure optimal transmission of energy between the patient and probe, a conductive gel or couplant must be applied liberally to the patient where scanning will be performed.
Precautions:
Coupling gels should not contain ingredients which are known to cause probe damage.
Recommended CE marked coupling gels:

- Aquasonic® 100 from Parker
- Scan® from Parker

Never immerse the probe connector or probe adaptors into coupling gel.

When scanning in air (Ultrasound probe is not in contact with a human body or a phantom) most of the ultrasound energy is reflected at the lens - air surface and bounces back and forward between that interface and the transducer ceramics.
Already the smallest deviation from the ideal geometrical shape of the reflecting interfaces can cause irregularities in the reverberation pattern across the transducer surface. However, when the probe is coupled to the human skin or a phantom by using coupling gel most of the ultrasound energy passes the lens – skin interface and these small geometrical deviations will have a negligible effect on the ultrasound signal and image quality. Therefore variations of the reverberation pattern along the transducer cannot be used for judging image and transducer quality. The use of a tissue mimicking phantom is strongly recommended to assess image quality.

4.SPECIAL HANDLING INSTRUCTIONS

4.1.Using Protective Sheaths

	Probes are not delivered sterilely! **Before** the first usage, it is MANDATORY to clean and disinfect probes to avoid infections or disease transmissions!
	Protective barriers may be required to minimize disease transmission. Probe sheaths are available for use with all clinical situations where infection is a concern. Legally marketed, sterile probe sheaths must be used for intracavitary procedures. Use of legally marketed, sterile, pyrogen free probe sheaths is MANDATORY. **Instructions:** Custom-made sheaths are available for each probe. Each probe sheath kit consists of a flexible sheath used to cover the probe and cable and elastic bands used to secure the sheath
	Devices containing latex may cause severe allergic reaction in latex sensitive individuals. Refer to FDA's March 29, 1991 Medical Alert on latex products.
	**DO NOT** use pre-lubricated condoms as a sheath. In some cases, they may damage the probe. Lubricants in these condoms may not be compatible with probe construction.
	**DO NOT** use an expired probe sheath. Before using probe sheaths, verify whether the term of validity has expired.
	Probes must be **cleaned** and **disinfected** before they are replaced or disposed.

Recommended sheath: Latex-Free CIV-Flex™ Probe Covers from Civco

4.2. Using Biopsy Guides

	A biopsy must only be performed by physicians with adequate experience. Under all circumstances the necessary safety precautions and sterility measures have to be respected.
	• Every time before using a biopsy guide ensure its correct position and optimal fit on the probe. • Always use a straight needle for each biopsy procedure. • Before performing a biopsy ensure that the selected and displayed biopsy line corresponds to the biopsy needle guide mounted to the ultrasound probe (left/right). • The biopsy needle and the biopsy needle guide (and the bore inside) must be sterile.

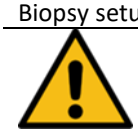
Caution
For detailed information on a biopsy guide, please contact the manufacturer of the biopsy guide.

Caution
Biopsy equipment is not sterile when delivered unless it is clearly labeled! If biopsy equipment is not sterile it is mandatory to clean and sterilize it before usage. For additional details please contact the legal manufacturer of the biopsy equipment..

Caution
Ensure the correct position and optimal fit every time before using a biopsy guide!

Caution
• Disposable biopsy guides: Single-use components must be disposed as infectious waste!
• Reusable biopsy guides must be sterilized before they are disposed!

Biopsy setup safety



Caution
• The default biopsy lines provided with the system software, must be verified at least once by the user. The procedure must be repeated if probes and/or biopsy guides are exchanged.
• Before performing a biopsy, prepare a water bath of approx. 47°C and make sure that the displayed biopsy line coincides with the needle track. Observe probe specific information on the temperature of the water bath.
• The needle used for water bath alignment must not be used for a biopsy performed on a patient.
• Depending on the needle stiffness/thickness and the elasticity and composition of the different tissue-types in the path of the biopsy needle, the actual needle track can deviate from the predicted biopsy line. The biopsy needle might bend and not follow a straight line.

Freehand biopsy

Caution
When performing a freehand biopsy, i.e. without a biopsy guide, it is the user's responsibility to use appropriate equipment. Ensure that the needle (especially the needle tip) is always visible in the ultrasound image during the whole biopsy procedure.

Caution
Always only use basic modes when performing a freehand biopsy..

Note A water bath alignment verification is also necessary before performing freehand biopsy procedures.

Reusable biopsy needle guides

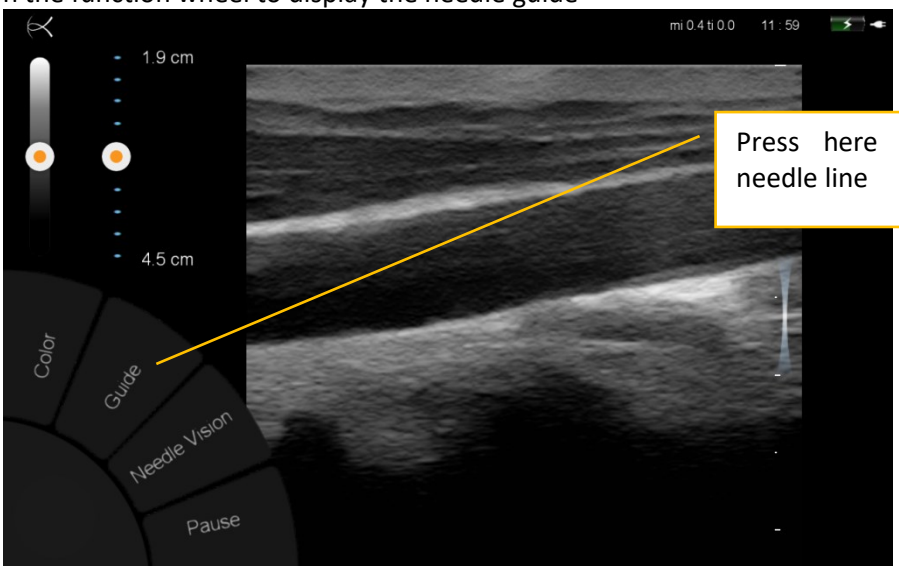
Caution
Cleaning and sterilization of reusable biopsy guides (for disposable biopsy guides, please refer to

enclosed manuals):
After each use, remove needle guide from transducer. Remove visible contaminants from needle guide surface thoroughly, using a small, soft instrument brush. Take special care of all narrow areas and tubes. Keep needle guide from drying out until complete cleaning can be accomplished. After that, soak needle guide for minimum of five minutes in neutral pH, low foaming enzymatic detergent.
While immersed, use instrument brush to remove trapped contaminants from surfaces, holes and tubes. If visible contaminants cannot be easily removed, repeat soaking procedure for an additional five minutes. Remove needle guide from cleaning solution and remove any remaining residue with dry wipe. Follow cleaning solution manufacturer's instructions for use and recommendations for concentration.

Sterilization for reusable biopsy needle guides:
Autoclaving (moist heat) 121˚C for 20 minutes (3 Pre-Vacuum-cycles) or 134˚C for 5 minutes.
Recommended minimum sterilization level SAL 10-6 .

4.2.1. Biopsy setup

1) Select the application including "Needle Guide function". Refer to AVAILABLE APPLICATIONS page V-8 for the complete list
2) Set the biopsy guide
3) Press "Guide" on the function wheel to display the needle guide



4.2.2. Available Biopsy guides

NOTE :	*The following recommended guides are manufactured by:* Aspen Surgical Products, Inc 6945 Southbelt Drive SE Caledonia, Michigan 49316, USA

Device with Endocavitary probe PR53	Biopsy 9000
	
	Needle diameters: >1.2mm , <1,6mm

	Material: Plastic Sterile packaged component Single-Use only! For detailed information, please contact the manufacturer : Aspen Surgical Products, Inc.

5. CARE AND MAINTENANCE

5.1. Inspecting Probes

After each use, inspect the probe's lens, cable, and casing. Look for any damage that would allow liquid to enter the probe. If any damage is found, the probe must not be placed into any liquid (e.g. for disinfection) and must not be used until it has been inspected and repaired/replaced by a Sonoscanner Service Representative

NOTE :	Keep a log of all probe maintenance, along with a picture of any probe malfunction.

5.2. Environmental Requirements

Probes should be operated, stored, or transported within the parameters outlined below.

	Ensure that the probe face temperature does not exceed the normal operation temperature range. Avoid temperatures above 50°C.

5.2.1. When being in operation

Temperature: 05°C ; 28°C / 41°F ; 82°F
Humidity: 30% ; 80%

5.2.2. When being transported

Temperature: -10°C ; 60°C / 14°F ; 140°F
Humidity: 10% ; 85%

5.2.3. When being stored

Temperature: -10°C ; 60°C / 14°F ; 140°F
Humidity: 10% ; 85%

6.PROBE INTRODUCTION

6.1.Available probes

The device supports up to 11 probes.

Transducer	Indications	Mode
PR50 Convex Probe 	Fetal, abdominal, pediatric, musculo-skeletal (conventional), other (gynecological), Urology (including prostate)	B, M, PWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR51 Linear 40mm Probe 	**Ophthalmic**, Pediatric, small organ (breast, testes, thyroid), Neonatal Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel	B, M, PWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR52 Linear 50mm Probe 	**Ophthalmic** ,Pediatric, small organ (breast, testes, thyroid), musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel	B, M, PWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR53 Endocavitary Probe 	Fetal, trans-rectal, trans-vaginal, other (gynecological), urology (including prostate)	B, M, PWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR54 Phased Array Probe 	Fetal, abdominal, pediatric, **Adult cephalic** musculo-skeletal (conventional), cardiac adult, cardiac Pediatric, other (gynecological), urology (including prostate)	B, M, PWD, **CWD**, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)

Transducer	Indications	Mode
PR55 Microconvex Probe 	Fetal, abdominal, small organ (breast, testes, thyroid, neonatal cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel, urology (including prostate)	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR56 Convex Probe Access 	Fetal, abdominal, Pediatrics, musculo-skeletal (conventional), other (Gynecological), Urology	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR57 Linear Probe Access 	**Ophthalmic** ,Pediatrics, small organ (breast, testes, thyroid), Neonatal Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR58 Microconvex Probe 	Fetal, abdominal, Pediatrics, small organ (breast, testes, thyroid), Neonatal Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel, urology (including prostate)	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR59 Convex Probe Single Crystal 	Fetal, abdominal, Pediatrics, musculo-skeletal (conventional), other (Gynecological), urology (including prostate)	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR60 Hockey Stick Probe 	Pediatrics, small organ (breast, testes, thyroid), Neonatal Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel,	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)

7. PROBE HANDLING AND INFECTION CONTROL

This information is intended to increase user awareness of the risks of disease transmission associated with using this equipment and provide guidance in making decisions directly affecting the safety of the patient as well as the equipment user.
Diagnostic ultrasound systems utilize ultrasound energy that must be coupled to the patient by direct physical contact. Depending on the type of examination, this contact occurs with a variety of tissues ranging from intact skin in a routine exam to recirculating blood in a surgical procedure.
The level of risk of infection varies greatly with the type of contact.
One of the most effective ways to prevent transmission between patients is with single use or disposable devices.
However, ultrasound transducers are complex and expensive devices that must be reused between patients. It is very important, therefore, to minimize the risk of disease transmission by using barriers and through proper processing between patients.

7.1. Probe Cleaning and Disinfecting Process

Adequate cleaning and disinfection are necessary to prevent disease transmission.
It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures in use.
High-level disinfection is recommended for surface probes and is required for endocavitary probes.
Additional to disinfection the use of sterile, legally marketed probe sheaths for intracavitary procedures is MANDATORY.
Ultrasound probes can be disinfected using liquid chemical germicides. The level of disinfection is directly related to the duration of contact with the germicide. Increased contact time produces a higher level of disinfection.

To clean and disinfect the probe after each use:
1. Remove the probe sheath, if appropriate.
2. Remove all coupling gel and other visible substances from the probe by wiping with a soft dry cloth. If necessary to remove material dried to the surface the cloth can be moistened with lukewarm water.
3. After each use, inspect the probe's lens, cable, and casing. Look for any damage that would allow liquid to enter the probe. If any damage is found, the probe must not be placed into any liquid (e.g. for disinfection) and must not be used until it has been inspected and repaired/replaced by a Sonsocanner Service Representative.
4. Prepare a solution of a suitable cleaning-disinfectant with the right concentration according to the manufacturer's instructions. Be sure to follow all precautions for storage, use and disposal.

Validated products for cleaning and disinfection of the probe

Product:	Concentration:	Minimum time:
Cidex	Undiluted	15 minutes
Sekusept Plus	4 %	15 minutes

1. Place the probe into the solution of cleaning-disinfectant. Make sure not to immerse the probe into the liquid beyond the immersion level given in the pictures below. Make sure that the probe is covered with the cleaning-disinfectant up to the immersion level during the complete disinfection time. Leave the probe in the solution for the specified time according to the manufacturer's instructions.

2. Scrub the probe as needed using a soft sponge, gauze, or cloth to remove all visible residue from the probe surface. Prolonged soaking or scrubbing with a soft bristle brush (such as a toothbrush) may be necessary if material has dried onto the probe surface.

3. Rinse the probe with enough clean, potable water to remove all disinfectant residues.

4. Use a soft cloth to clean the cable and the user section of the probe with the cleaning-disinfectant liquid. Make sure that the surface of the probe and cable is wetted thoroughly with the cleaning-disinfectant.

5. Allow probe to air dry completely.

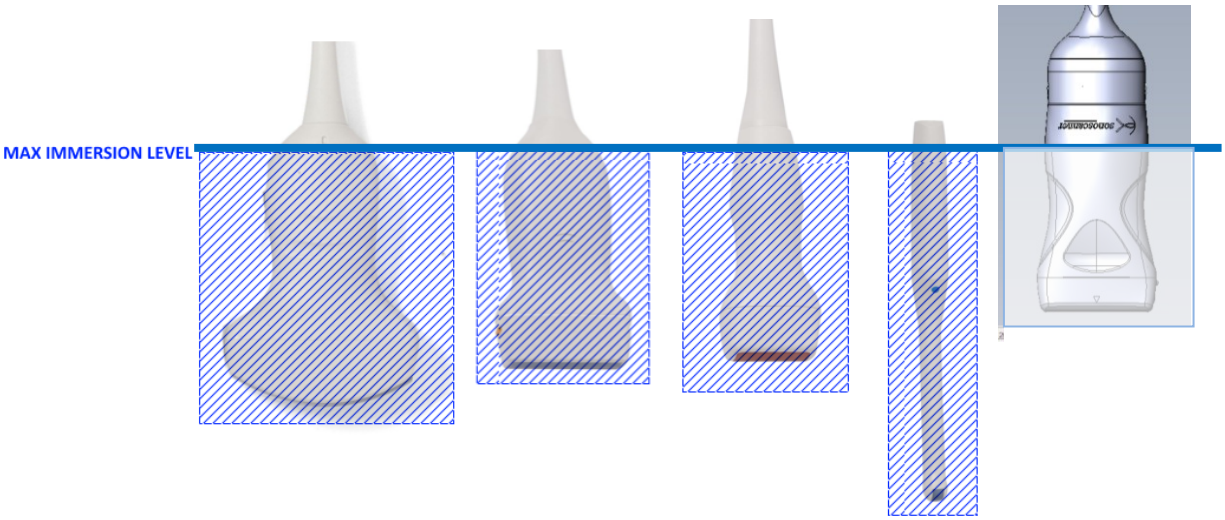
6. Inspect the probe prior to use for damage or degeneration to the housing, strain relief, lens and seal. Do not use a damaged or defective probe until it has been inspected and repaired/replaced by a Sonoscanner Service Representative.

7. Put a new sterile, legally marketed probe sheath over the probe prior to next use.

7.2. Planned Maintenance

The following maintenance schedule is suggested for the system and probe to ensure optimum operation and safety.

Do the Following	Daily	After Each Use	As Necessary
Inspect the Probes	X		X
Clean the Probes		X	X
Disinfect Probes		X	X



Make sure not to immerse the probe into the liquid beyond the immersion level.
Cable strain relief should not be immersed in water.

CHAPTER VII
SAFETY

The Device scanner system has been designed for utmost safety for patient and user. Read the following chapters thoroughly before you start working with the machine!
The manufacturer guarantees safety and reliability of the system only when all the following cautions and warnings are observed.

1.INDICATIONS FOR USE

This system is intended for use by a qualified and trained healthcare professionals for ultrasound evaluation in the following clinical applications:Image Acquisition for diagnostic purposes incl. measurements on acquired image.

clinical applications:	patient population:
Visualization of structures and dynamic processes in the human body using ultrasound imaging and fluid flow analysis for diagnosis in the following clinical applications: • ophthalmic • fetal/obstetric, • gynecological, • abdominal, • pediatric, • neonatal cephalic • adult cephalic • small organ, • trans-vaginal, • trans-rectal, • cardiac adult & pediatric • peripheral vascular, • urology (including prostate) • musculoskeletal (both conventional and superficial)	• Age: all ages (encl.embryos and fetuses) • Sex: male and female • Weight: all weight It can be used in different configurations, especially: - In medical offices (general practitioner's office) - In clinics & hospitals (incl. in emergency and critical care units) - In a field hospital It is used in imaging or examinations rooms. It can be used at the bedside. It is not intended for direct use in a sterile environment. The device is not compatible with the use of the HF surgery device or in an MRI system.

2.CONTRAINDICATIONS

The Device is not intended for:

• intra-operative use

Three probes are available for ophthalmic application (PR51, PR52, PR57) and U & T Lite PRO has predefined scanning settings optimized for ophthalmic clinical.
To avoid injury to the patient, select the Ophthalmic preset when performing an eye exam. The system will not exceed the lower acoustic energy limits for ophthalmic use only if the Ophthalmic preset is selected.
Be sure to use the appropriate probes and presets for eye scanning, and to use only MM, CMM and PW modes.

2.1.Warning labels used in the Operation Manual:

	General warning sign
	Describes important information that has to be read before proceeding.
	Describes precautions necessary to prevent the risk of disease transmission or infections.
	Describes precautions necessary to prevent the risk of injury through electric hazards.
	To warn of explosive materials Taking care when in the vicinity of or handling explosive materials
 Moving Hazard	To warn of moving mechanical parts Taking care to avoid mechanisms with parts which can come together in a crushing movement
 Mechanical Hazard	To warn of a closing motion of mechanical parts of equipment Taking care to avoid injury to hands when in the vicinity of equipment with closing mechanical parts

3. *IMPORTANT INSTRUCTIONS FOR SAFETY*

$\mathrm{R_x}$ *Only*	Federal law restricts this device to sale by or on the order of a physician!
	The use of the system outside the described conditions or intended use, and disregarding safety related information is considered as abnormal use. The manufacturer is not liable for damage caused by abnormal use of the device!
	The manual refers to probes that can be connected to the device. It might be possible that some probes are NOT available in some countries! Some features and options are not available in some countries!

	Handle carefully. A drop of more than 5 cm can cause mechanical damages.
 Explosion Hazard	This equipment must not be used in the presence of inflammable gases (e.g. anesthetic gases) => explosion hazard!
	The system must only be connected to a fully intact main socket with a grounded guard wire via an appropriate main cable. The ground wire must never be removed or disconnected.
	Only accessories explicitly recognized by the system manufacturer Sonoscanner may be used in connection with this ultrasound system
 Electrical Hazard	No covers or panels must be removed from the system (high-voltage risk). Only Sonoscanner-authorized personnel must perform service and repairs. Attempting do-it-yourself repairs invalidate warranty, and are an infringement to regulations and are inadmissible acc. to IEC 60601-1. Under the condition of regular maintenance by authorized service personnel a lifetime of **3 years** for the equipment and **3 years** for the probes may be expected.
	There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Operators are advised to identify latex-sensitive patients and be prepared to treat allergic reactions promptly. Refer to FDA Medical Alert MDA91-1.
	Before switching on check the device for cracks or damages.
	Not to be used in sterile environment!
	Do not cover the ventilation holes of the Device
	Modification of the Device by unauthorized personnel is strictly forbidden
	This equipment contains specified radio equipment that has been certified to the Technical Regulation Conformity Certification under the Radio Law.

4.ELECTRIC INSTALLATION

The system must be exclusively installed in medically used rooms. The equipment conforms with regulations for electrical safety (EN60601-1 and IEC 60601-1-2) and safety class IIa according to the MDR 2017/745 (EU) for use on human patients.
Probes are rated Type BF. Local safety regulations may require an additional connection between the potential equilibrium bolt and the building's grounding system.

Before switching on the first time, the local main voltage and frequency have to be checked against the values indicated on the Device nameplate located on the rear panel.
Only authorized personnel must perform any change to the system.
The minimum required house installation must have 16A

5.EXTERNAL CONNECTION OF OTHER PERIPHERAL DEVICE

External devices can be used only if CE marked and in compliance with related standards (EN 60601-1 or EN 60950). Do not plug any other external device

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all complete configurations shall comply with the valid version of the system standard IEC 60601-1.
Anybody connecting additional equipment to the signal input part or signal output part of ultrasound unit configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of IEC 60601-1.
If in doubt consult the technical service department or your local representative for Sonoscanner.
Other external devices, such as laser cameras, printers, VCRs and external monitors, usually exceed allowable leakage limits and, when plugged into separate AC outlets that are then connected to the unit, are in violation of patient safety standards.
Suitable electrical isolation of such external AC outlets may be required in order to meet UL60601-1 and IEC 60601-1 standards for electrical leakage.

6.SYMBOLS USED

Some symbols used with electrical medical equipment have been accepted as standard by IEC.
They serve for marking connections, accessories, and as warnings.

SYMBOL	STANDARD	TITLE	DESCRIPTION
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied.	Manufacturer	Indicates the medical device manufacturer as defined in EU regulation 2017/745
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied.	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	MDD 93/42/EEC MDR 2017/745	CE marking (incl. Notified Body ID)	Signifies European technical conformity..
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied.	Serial Number	Indicates the manufacturers' serial number so that a specific
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied.	Medical device	Indicates the item is a medical device.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied.	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE) WEEE Directive 2012/19/EU	Recycle: Electronic Equipment	Separate collection for electrical and electronic equipment DO NOT THROW IN TRASH.
	21 CFR 801.15 21 CFR 801.109	Prescription only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read
	ISO 15223-1, IEC 60601-1, ISO 7000-1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 7000/IEC 60417 Graphical symbols for use on equipment	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	IEC 60417 Graphical symbols for use on equipment	Direct current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals
	ISO 7010-P017	No pushing	To prohibit pushing against an object
	ISO 7010-W012	General warning symbol	Taking care regarding the hazard specified by the supplementary sign

	ISO 15223-1, IEC 60601-1	Attention: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 7010-W012	Warning electrical hazard	Taking care to avoid coming into contact with electricity
	ISO 7010-W009	Warning; Biological hazard	Taking care to avoid exposure to a biological hazard
	ISO 7000-0659	Biological risks	To indicate a reference to substances that may be hazardous to men, animals, plants, or the environment based on biological activity (for example, holding a virus)
IPX7	IEC 60601-1,	Degree of Ingress Protection Provided by Enclosure	Protected against the effects of temporary immersion in water.
IPX0		Degree of Ingress Protection Provided by Enclosure	
	ISO 15223-1 ISO 7000-2620	Storage humidity range	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1 ISO 7000-2621	Atmospheric Pressure	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1 ISO 7000-0632	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 7010-W002	Warning; Explosive material	To warn of explosive materials
	ISO 7010-W019	To warn of moving mechanical parts	To warn of moving mechanical parts
	ISO 7010-W024	Warning; Crushing of hands	To warn of a closing motion of mechanical parts of equipment
	ISO 15223-1	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process

7.REMARKS FOR SAFE USE

• Operator profile: Qualified physicians and professional sonographers with at least basic ultrasound knowledge.
• Get acquainted with the transducers and the ultrasound system: read the user manual thoroughly!
• Misinterpretation of an Ultrasound Image can lead to false diagnosis.
• Follow all safety instructions as well as the clinically adopted precautions and measures for hygiene.
• Any ultrasound transducers - irrespective of system and design - are sensitive to shock and shall be treated with care. Pay attention to cracks, which may allow conductive fluids to leak in.
• Only authorized personnel shall perform any type of repair. Never attempt to open a transducer or transducer connector. This will void the warranty!
• Avoid kinking, bending or twisting of probe cables and take care to guard them against mechanical stress (e.g., wheels or heels).
• The probes must not be exposed to mechanical shock (e.g., by dropping). Any damage caused in this will void the warranty!
• Have the scanner system and the transducers regularly checked (for faulty cables, housing, etc.) by authorized personnel!
• Damage to transducer or cable may lead to a safety hazard, therefore have them repaired immediately!
• Before plugging in or unplugging a transducer, activate the “FREEZE” mode!
• A specialist familiar with the handling and use of the system shall perform installation and first switch-on and check-up of the system.
• The user must have read and understood the user manual. The system must only be operated by trained and qualified personnel.
• For safety reason, avoid handling fluids in the vicinity of the system. Fluids leaking into the disk drive can damage the drive. Never remove the storage shelf above the probe connectors; it helps to protect the system from fluids.
• Trolley: never move the system with blocked wheels, but block the wheels in the proximity of stairs and ramps.
• The user manual must always be with the scanner system. It is the user’s duty to ensure this!
• Only probes conforming to type BF requirements may be used with the Device
• Do not install software on the system, that has not been released by Sonoscanner, as this may lead to errounous data transfer and thereby decrease system performance.

See the probe’s label. In case of doubt ask authorized service personnel.
• The Device has been tested for EMC and is compliant with EN 55011 group 1 class A and EN 60601-1-2. The Device system is approved for use in a residential district. It is expected that the user has medical experience and is well informed with the user manual.
• Main power quality should be that of a typical commercial and/or hospital environment. If the user requires continued operation during power main interruption, it is recommended that the system be powered from an uninterruptable power source (UPS).

There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Operators are advised to identify latex-sensitive patients and be prepared to treat allergic reactions promptly. Refer to FDA Medical Alert MDA91-1.

8. INSTRUCTIONS FOR USE

This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.
This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
Reorient or relocate the device.

Increase the distance between equipment.

Connect the equipment to an outlet on a circuit different from that to which the other device(s) are connected.

Consult the manufacturer or field service technician for help.

9. ENVIRONMENTAL CONDITIONS

Humidity: 30% to 80% RH, no condensation

Temperature: 05°C to 30°C resp. 41°F to 86°F Temperature: 05°C; 28°C / 41°F; 82°F

Light conditions: natural & artificial light source*

Barometric pressure: 700 to 1060 hPa

NOTE: * Bright light could impact readability of screen.

	In the event the equipment has been brought from a cold environment (stock room, airfreight) into a warm room, allow several hours for temperature balance and passing of condensation humidity before switching on for the first time.
	Do not operate the system in the vicinity of a heat source, of strong electric or magnetic fields (close to a transformer), or near instruments generating high frequency signals, such as HF surgery. These can affect the ultrasound images adversely.

10. CLEANING AND MAINTENANCE

Daily cleaning of the scanner, the probes and the probe holders from coupling gel, mineral oil, etc., is recommended; wet cloth and soap are allowed.

	Before cleaning the scanner switch it off. Do not use disinfection spray nor gas disinfection. Electric parts must be protected from drip water. Keep the screen clean. Dust and grime on the frame can cause irregular function! Check the main cable, transducer cables, plugs and sockets on a regular basis.

Have the system checked and serviced in regular intervals (once per year) by authorized service personnel. In case of total failure first check if main voltage is present. Mentioning any observations or failure symptoms to the service engineers is helpful.

11. DISPOSAL

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.

	Lithium battery included with this device. Do not puncture, mutilate or dispose of battery in fire. Replace only with same type recommended by the manufacturer. Dispose of used battery according to manufacturer's instructions and in accordance with your local regulations

12. MANUFACTURER RESPONSIBILITY

The manufacturer, assembler, importer or installer considers themselves responsible regarding safety, reliability and performance of the instrument under the following conditions:

- when assembling the system, when adding options, when new settings or modifications or repairs were performed by personnel authorized by themselves,
- also that the local electric installation complies with the national regulations, and that the equipment is only used according to the User Manual.

13. GENERAL INFORMATION ON ULTRASOUND POTENTIAL HAZARD

It is important to limit the acoustic output level during exams. However the acoustic output must reach a sufficient level so that the sonographer may be able to run an effective exam. As for all clinical settings, a compromise must be reached between the potential hazard (usually greater with fetus) due to exposure and the possible advantages that the diagnostic could provide. The chance of making a diagnostic error due to an insufficient acoustic output level must also not be neglected.

A cautious use is conceptualized with the **ALARA principle** (**As Low As Reasonably Achievable**). This principle must guide the sonographer when adjusting the parameters of the scanner prior to an exam. For more details, you can contact your local official ultrasound association or your local official Sonoscanner representative.

One of the main conclusions drawn on this topic was made by the AIUM (American Institute of Ultrasound Medicine):
Declaration made by the AIUM on clinical safety (*written on October 1982 and approved in March 1993*):
"Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:
There are no confirmed biological side-effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any that may be present.
The possible biological side-effects of ultrasound-based diagnostics are classified as non thermal (ex: cavitation) and thermal (increase of temperature). Conditions in which cavitation have occurred during test run on animals differ from the ones that apply during a standard ultrasound exam. This is why studies on ultrasound hazards have focused on thermal side-effects"

An increase of fetus tissue temperature to 41 degrees (105.8 Fahrenheit degrees) and beyond is considered as dangerous. But it is commonly believed that an increase of tissue temperature of no more than 1 degree Celsius (33.8 Fahrenheit degrees) may not lead to any biological side-effect.
In flexible tissue, a very concentrated beam requires an average intensity above 1000 mW/cm² (way above the FDA recommended maximum level). The real temperature increase resulting from a given I-zpta depends on the frequency level (high frequency tends to make the temperature increase greater), the intensity of the beam (less concentrated beam tends to carry less power and tends to reduce the range of temperature increase) and tissue perfusion (areas with a rich perfusion of blood will tend to scatter the effects of local temperature increase).

14. IN SITU CALCULATION OF INTENSITY

In order to evaluate the potential biological side-effects of ultrasound, it is necessary to calculate the intensity in tissues. Due to the weakening of the beam inside the body, the intensity in the tissue can be 10 to 100 times less powerful than what it would be if the test was done in water based environment. It is therefore important to take into account this fact when running test in water based environment (in-vitro type of test): the data must be lowered so that the scattering effect of the human body is taken into account.

The degree of attenuation of the ultrasound beam during its journey into the human body is determined by three factors:

The type of tissue on the beam trajectory
The acoustic frequency level
The distance between the point of origin and the tissue

The European norm 60601-2-37 requires applying the following mathematic formula when estimating the attenuation of ultrasound beam:

$I_t = I_w \, 10^{(-azf/10)}$

Where I_t is the estimated intensity in the tissue; I_w is the intensity measured in a water based environment from a distance Z in cm; a is the attenuation ratio expressed in dB/cm/MHz and f is the acoustic frequency level expressed in MHz of the ultrasound beam. The European norm explains that the attenuation ratio to be used in the above formula is the following:

a = 0,3 dB/cm/MHz

The use of such low attenuation ratio (way lower than the ratio usually applied on muscles, fat, liver…) is intentional and helps overestimate the intensity endured by the tissues during most exams.

For a number a reasons, the in situ intensity parameters are a good basis to compare the system' emissions. The maximal in situ parameters are a good indication of the worst possible conditions on the tissue given the propriety of the beam such as the acoustic frequency level and the focal depth. On the other side, the simple data measured in a water based environment do not involve any normalization ratio. Furthermore, decreasing the maximal data obtained in a water based environment could lead to greatly under-estimate the in situ maximal data. In general the in situ maximal data are observed in different environments and in different location from the ones observed in water based environment.

The highest in situ intensity value can only be obtained if the measuring values obtained in water based environment are intentionally lowered. The maximal in situ values determined by this method are indicated in the transducers' chart (page **Erreur ! Signet non défini.** to VII-44). Subdivided by functioning modes, by power settings, those data represent a cautious estimate of the worst possible conditions.

Prudent Use
Since no medical study has yet to prove whether or not ultrasound causes adverse effects, it is therefore important to observe the following instructions:

- Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

- Scan patients only if it is strictly necessary.

• Start scanning using low acoustic output level and increase it, only if it is strictly necessary to obtain a satisfactory image.

• If you switch from an application requiring high beam intensity, to one that requires a lower level, be sure to reset the levels before you scan. Especially if you are about to start fetal scanning.

• Take into account all the types of tissue that may be affected by the exam.

Acoustic Output Default Level
In order to assure that an exam does not start at a high output level, the transducers will start in the default setup when the scanner is turned back on. The default setup may be factory-defined or defined by the user. The default setup will depend upon the exam category and probe selected.
As part of the ALARA principle, these setups have been optimized to give the best compromise between low beam intensity and enough power to obtain the best possible image.

15. ELECTROMAGNETIC COMPATIBILITY PERFORMANCE

The DEVICE® is designed to be used in an electromagnetic environment where radiated Radio frequency disturbances are controlled. User can contribute to prevent electromagnetic interferences by keeping a minimal distance between the portable and mobile radio communications equipment (transmitters) and the DEVICE®, as recommended below, depending on the radio communications equipment's maximum power emission.

Output maximum transmitter power rated (W)	Separation distance depending on the transmitter frequency (m)		
	150KHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

If the transmitter's maximum power emission rated is not given above, the recommended separation distance *d* in meters (m) can be estimated by using the applicable equation with the transmitter frequency, with *p* the transmitter's maximum emission power in Watts (W), depending on the manufacturer.

NOTE 1: At 80MHz and 800MHz the higher frequency range is applied.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

16. INTERFERENCES

The Device® generates electromagnetic and/or radio frequency energy. It may therefore cause interference to other medical and non-medical devices. Although Device® complies with emissions limits for a Group 1, Class A Medical Devices Directive as stated in EN 60601-1-2 there is however no guarantee that electromagnetic or radio frequency interference will not occur.

Electromagnetic Interference

If the ultrasound scanner is affected by interference (simply look for interference by turning the Device® on and check if the image is distorted or not), one or more of the following corrective measures should be taken:
• Increase the distance between the Device® and the equipment at the origin of the interference
• Relocate or try to reorient the equipment at the origin of the interference
• Power the equipment from a source different from that of the equipment at the origin of the interference

If the interference cannot be suppressed, please consult your local Sonoscanner representative.

Consequence of electromagnetic interference on ultrasound diagnostic imaging: The electromagnetic interference can reduce the image depth. Therefore, in order to avoid having to repeat an ultrasound examination seen as a potential risk by the ALARA principle, please make sure that the Device® is not affected by such interference, before proceeding to an ultrasound exam.

Radio Frequency (RF) Interference
Do not use devices which transmit Radio frequency signals (cellular phones, radio controlled products), unless intended for use and approved for use with the Device®. At close range, those radio frequency devices may cause the ultrasound system to perform outside its published specifications.

Consequence of radio frequency interference on ultrasound diagnostic imaging:
An ultrasound scanner receives radio frequency signals for the purpose of its operation. That is why the transducers are designed to be very sensitive to frequencies within their signal frequency range (0.3MHz to 15MHz). Therefore the use of radio frequency equipment that operates within this frequency range can alter the quality of ultrasound imaging.
However there is no risk of confusion with physiological signals because the radio frequency interference will be converted into white lines on the ultrasound image.
In conclusion, even if the ultrasound scanner can be affected by radio frequency signals coming from communication equipment such as cell phones, it will remain safe and perform well.
However, we recommend you to instruct technicians, patients and other people who may be around this equipment to fully comply with the above instructions.

Sonoscanner is not responsible for any interference caused by unauthorized changes or modifications to the ultrasound scanner.

Before you use the scanner, make sure that all the ultrasound system safety requirements described above have been satisfied.

17. TRANSDUCER SAFETY CONSIDERATIONS

Ultrasound transducers are very sensitive devices which can easily be damaged. Manipulate the transducers with extra care; make sure it does not come into contact with sharp or abrasive surfaces. Do not drop them.
Using a damaged transducer (damaged casing, lens or cable) can produce harmful effects on patient such as injury or infection. Inspect probes daily for sharp or rough surface damage that could cause injury.
Always follow the ALARA (As Low As Reasonably Achievable) recommendation by minimizing exposure time and keeping ultrasound output level as low as possible.

 Electrical Hazard	The probe sockets contain terminals with 5V. Do not touch the patient while you are touching an uncovered socket.
	Make sure that the probes are free of cracks or openings as it could allow liquid entry, thus allowing such liquid to come into contact with internal live parts.
	When using high-frequency electrosurgical equipment, make sure not to leave any transducer in contact with the patient.

Before you use the scanner, make sure that all the transducer safety requirements described above have been satisfied.
Failure to comply with the above instructions will void the warranty.

18. OTHER SAFETY CONSIDERATIONS

	Do not subject the keyboard or any other parts of the scanner to heavy weights as they could be damaged or broken.
	Use protective barriers whenever possible. Thoroughly clean probes and reusable accessories after each patient examination and disinfect or sterilize. Follow sterile procedures when needed.

Before you use the scanner, make sure that all the other safety requirements described above have been satisfied.

19. PATIENT SAFETY

19.1. Patient Identification

Identification errors could result in an incorrect diagnostic that is why it is important that you include proper identification with all patient data (both recorded and printed data).

19.2. Diagnostic Information

It is very important that the Device® user becomes thoroughly familiar with the equipment in order to optimize its performance and recognize possible malfunctions. Any use of the Device® system by an unqualified user may lead to measurement errors or failure to detect details within the image due to equipment malfunction or incorrect settings.

20. SERVICE AND REPAIR

	Any service and repair made on Sonoscanner ultrasound system must be carried out by either the manufacturer or its authorized representatives. Sonoscanner reserves the right to disclaim all responsibility for the safety and performance of equipment serviced or repaired by other parties. Any equipment service and repair must be followed by a safety and performance check carried out by a qualified technician.

21. SECURITY SYSTEM

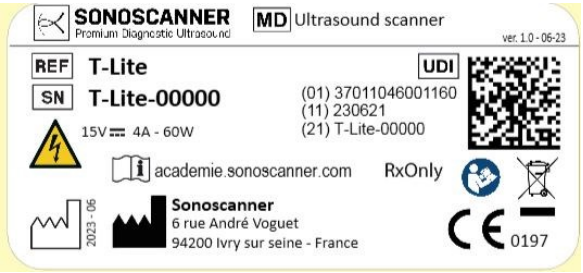
Sonoscanner cannot be held responsible for computer viruses from a network that may infect the Device®
Please perform a virus check on any external storage device (USB device or CD) before connecting it to the Device® ultrasound scanner.

- The system can be locked by a pin or password (see SECURE THE DEVICE page IX-2). No user will be able to access any data on the system without access to the pin or password
- Where the system has been stolen, no data will be accessible without the pin or password.
- Secure Wi-Fi protocols are supported, enabling data to be securely saved to remote storage.
- No internet ports are open. In the event a third party is able to access the system, they will not be able to access any data without the pin or password.
- This device has no listening ports open to the WLAN interface. A network entity cannot initiate a connection to the Device system from the WLAN
- No third party applications are able to be installed or run on the system, preventing malware and virus's.
- The Device USB port can only be used to export data to a USB memory stick.

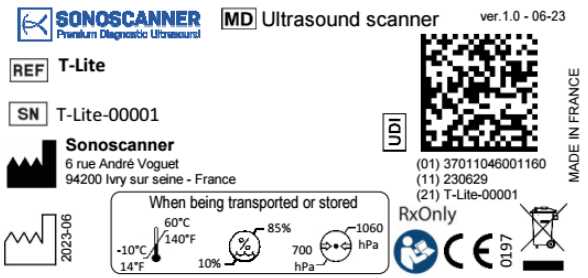
22. DEVICE LABELS

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

VII-1 Identification Plate for T-Lite Model

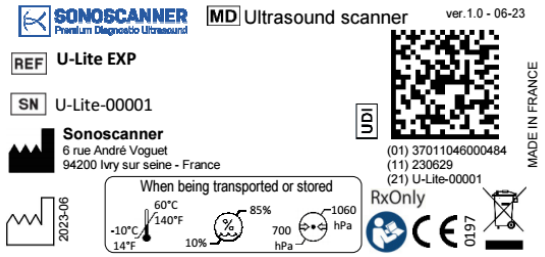


VII-2 T-Lite model transportation label



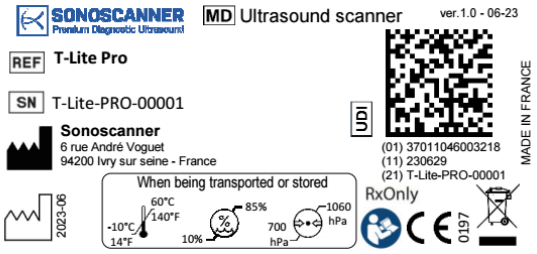
VII-3 Identification Plate for U-Lite Model

VII-4 U-Lite Model transportation label



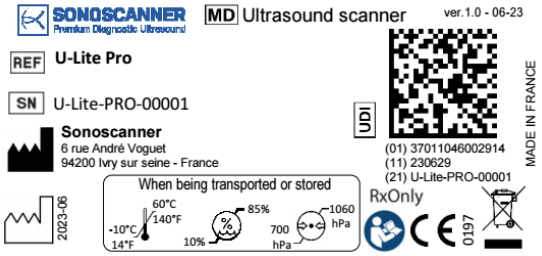
VII-5 Identification Plate for T-Lite Pro Model

VII-6 T Lite Pro Model Transportation label



VII-7 Identification Plate for U-Lite Pro Model

VII-8 U Lite Pro Model Transportation label



23. SOFTWARE REVISION LOCATION

For knowing the software revision look at the version number on bottom right of the screen.

24. TYPE BF EQUIPMENT

TYPE BF EQUIPMENT		
	NORMAL MODE	SINGLE FAULT CONDITION
Patient Leakage Current	Less than 100 microA	Less than 500 MicroA

25. ACOUSTIC OUTPUT

Studies revealed that there are two different ultrasounds effects that can affect the human body: one of them is made of the **Mechanical effect** due to the cavitation generated when the negative pressure of ultrasound reaches a certain limit. The other one is made of the **Thermal effects** generated by tissues absorbing ultrasound.
The levels of those two effects are represented by the following indexes: MI (Mechanical index) and TI (Thermal index).
The smaller those indexes are, the weaker the biological side-effects will be.

Results Display

Abbreviation	Measure	Description
MI	Mechanical index	Used for 2D scanning only
TIB	Thermal index, Bone at the beam center	Recommended when scanning second or third quarter pregnant women
TIS	Thermal index, Soft tissue located at the surface or at the beam center	Recommended when scanning soft tissue. Can also be used when scanning first quarter pregnant women, based on fetus position (PW Doppler)
TIC	Cranial Bone Thermal Index	The thermal index for applications, such as pediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body.

Definition and interpretation of the MI Index
The mechanical index (MI) is the peak rarefactional pressure (calculated by taking into account the attenuation effect of the tissue: α=0,3 dB/cm/MHz) divided by the square root of the acoustic work frequency f_{awf} (unit of measurement: MHZ) can be expressed through the following formula:

MI formula = $\frac{P_{r,a}}{\sqrt{f_{awf} \times C_{mi}}}$
Where C_{mi} = 1

The MI index provides a relative indication of the potential mechanical side effects especially with cavitation side effects

The standards set in the USA (FDA) recommend to limit the MI mechanical index to a value lower than 1,9.

Definition and interpretation of the TI index
The thermal index (TI) is the ratio total acoustic power divided by the acoustic power required to increase the tissue temperature by 1 degree Celsius. It indicates the highest expected temperature increase in degrees Celsius.

TIS (Thermal index of soft tissue) is related to the temperature increase when running abdominal, cardiac and peripheral vascular scanning,

TIB (Thermal index of bones) is related to the temperature increase of bones. This data can prove to be very important with fetal applications.

TIC (Cranial Bone Thermal Index) . Used when bone is near the skin surface as in transcranial examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue

The thermal index therefore helps assess the potential degree of temperature elevation when scanning. It is however an approximation. The real temperature increase can sometimes be superior to the one displayed.
The duration of exposure must also be taken into account: A fetus temperature increase is considered as potentially dangerous if this increase is applied for one hour and with a temperature increase of 2 degrees and for 15 minutes for a temperature increase of 3 degrees.

MI and TI values displayed
The values of the MI, TIS and TIB indexes are determined and displayed according to the measured acoustic power.
The accuracy of the display is rounded per 0.1 unit
The value of MI and TI are displayed all the time.

Parameters influencing the values of MI and TI
The value of MI/TI are affected by the transmission (or signals), conditions (emission frequency), tension applied to the piezoelectric elements, scanning conditions and the settings chosen by the user.
The output intensity is one of the parameters available when controlling the ultrasound signal leaving the transducers

Changing the Thermal Index Type

You can select the displayed TI. In Preferences select “security” and “system preferences”. Press next until the TI selection Menu. Tap it to select a different TI (Thermal Index) type displayed.

Maximum allowable output for MI, TI and ISPTA

The absolute maximum allowable output for Ophthalmic applications is:

- ISPTA less than or equal to 50 mW/cm2
- MI less than or equal to 0.23
- TI=Max (TIS_as,TIC) as less than or equal to 1

The absolute maximum allowable output for all other applications is:
- ISPTA less than or equal to 720 mW/cm2
- MI less than or equal to 1.9

Cautious use
The relative importance of the different indexes used to assess the biological risks depends on the conditions of use. The following chart summarizes the relative importance in setting low exposure indexes in diverse scanning situations.

Relative importance in setting low exposure indexes in diverse scanning situations		
	Of great importance	Of minor importance
Mechanical index	With contrast agents Cardiac scanning (lung exposure) Abdominal exposure (Intestine gases)	In the absence of gaseous body i.e.: in most tissue imaging situations
Thermal index	Quarter old Fetus scanning Fetal skull and spine Patient with fever In low irrigation tissue Ophthalmic scanning (requires a different risk assessment) If ribs or bones are exposed: TIB	In rich perfused tissue. i.e.: Liver, spleen. Cardiac scanning Vascular scanning

Fever
A temperature increase of one degree Celsius in a patient with fever may cause complications in certain circumstances; It may be safer to delay the investigation.

Acoustic Beam Management
The different modes described in the following charts are listed below:

B Mode: Mode using two dimensional images with shaded grey only.

Color Doppler Mode: Mode using simultaneously the color Doppler and the two dimensional imaging mode.

The Pulsed Wave Doppler (PW) Mode: Mode using the Pulsed Wave Doppler (PW) with B-Mode.

You can therefore be sure that each time you use the Pulsed Wave Doppler (PW), the estimated in situ beam will be similar to the typical maximal value corresponding to the worst conditions listed in the chart of the transducer being used, given the fact that this transducer is being used within the specified power range indicated for a Power Doppler Mode.

The maximum power ranges are indicated in the charts listed herein after.

Definitions

P^{ra} : Peak rarefactional pressure

P Accoustic power output, where the acoustic power output goes through a 1cm window.

$P_{\alpha}(z)$: Exit attenuated power at a “Z” depth

$I_{ta,\alpha}(z)$: Intensity peak, average in time and attenuated at a “Z” distance

Z_s : Related to TIS depth

Z_{bp} : Breaking point depth

Z_b : Related to TIB depth

D_{eq} Equivalent beam diameter

f_{awf} : Measured center frequency

A_{aprt} Beam area where the exit is at -12dB. Active opening of the elevation and azimuth planes.

t_d Impulse duration

prr Pulse repetition frequency

p_r at the maximum I_{pi} rarefaction pressure at the maximum pulse average Intensity (Isppa)

D_{eq} at the maximum I_{pi} Equivalent beam diameter at the maximum pulse average intensity (Isppa)

$I_{pa,\alpha}$ at the maximum MI Attenuated impulsion average intensity where MI is at its maximum

Acoustic Measurements of the Device model with Convex probe PR50 in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			1.90	0.21		0.21		1.06
Index Component Value				0.21	0.21	0.95	0.21	
Associated parameter	p_{ra} at Z_M	MPa	2.64					
	P	mW		125		125		138
	P_{1x1}	mW		20.30		20.30		
	z_s	cm			2.24			
	z_b	cm					4.50	
	z_{MI}	cm	1.68					
	$z_{PII\,\alpha}$	cm	1.68					
	f_{awf}	MHz	1.93	2.13	2.13	2.13	2.13	1.93
Other information	prr	Hz	8980					
	srr	Hz	47					
	n_{pps}		2					
	$I_{pa.\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	170.22					
	$I_{spta.\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	52.66					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	65.82					
	p_r at z_{pii}	MPa	2.95					
Operating Control Conditions	Preset		Abdo Deep Harm	General		General		Abdo Deep Harm
	Depth	cm	3.7	3.7		3.7		3.7
	Tx Freq	MHz	2.02	2.23		2.23		2.02

Acoustic Measurements of the Device model with Convex probe PR50 in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.65	0.15		0.15		0.36
Index Component Value				0.15	0.15	0.36	0.15	
Associated parameter	p_{ra} at Z_M	MPa	0.90					
	P	mW		33.91		33.91		33.91
	P_{1x1}	mW		10.78		10.78		
	z_s	cm			2.24			
	z_b	cm					4.50	
	z_{MI}	cm	6.95					
	$z_{PII\,\alpha}$	cm	6.95					
	f_{awf}	MHz	1.93	3.19	3.19	3.19	3.19	3.19
Other information	prr	Hz	3796					
	srr	Hz	7.99					
	n_{pps}		2					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	19.68					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	3.32					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	14.28					
	p_r at z_{pii}	MPa	1.42					
Operating Control Conditions	Preset		Abdo Deep Harm	General		General		General
	Depth	cm	15	15		15		15
	Tx Freq	MHz	2.02	2.23		2.23		2.23

Acoustic Measurements of the Device model with Convex probe PR50 in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.44	2.36		3.51		3.18
Index Component Value				2.36	1.57	3.18	3.51	
Associated parameter	p_{ra} at Z_M	MPa	0.77					
	P	mW		156.3		156.3		156.3
	P_{1x1}	mW		156.3		156.3		
	z_s	cm			2.87			
	z_b	cm					5.75	
	z_{MI}	cm	6.27					
	$z_{PII\,\alpha}$	cm	6.27					
	f_{awf}	MHz	3.17	3.17	3.17	3.17	3.17	3.17
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	24.49					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	264.04					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	1040.2					
	p_r at z_{pii}	MPa	1.54					
Operating Control Conditions	Preset		Abdo Deep Harm	Abdo Deep Harm		Abdo Deep Harm		Abdo Deep Harm
	Depth	cm	15.5	15.5		15.5		15.5
	Tx Freq	MHz	2.02	2.02		2.02		2.02

Acoustic Measurements of the Device model with Linear probe 40mm PR51 in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.74	0.05		0.05		0.11
Index Component Value				0.05	0.05	0.11	0.05	
Associated parameter	p_{ra} at Z_M	MPa	1.85					
	P	mW		5.27		5.27		5.27
	P_{1x1}	mW		1.73		1.73		
	z_s	Cm			0.86			
	z_b	Cm					2.00	
	z_{MI}	Cm	0.74					
	$z_{PII\,\alpha}$	Cm	0.74					
	f_{awf}	MHz	6.25	6.25	6.25	6.25	6.25	6.25
Other information	prr	Hz	12169					
	srr	Hz	80.1					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	137.29					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	16.47					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	22.66					
	p_r at z_{pii}	MPa	2.17					
Operating Control Conditions	Preset		lung	lung		lung		lung
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	6.25	6.25		6.25		6.25

Acoustic Measurements of the Device model with Linear probe 40mm PR51 in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.75	0.04		0.04		0.07
Index Component Value				0.04	0.04	0.07	0.04	
Associated parameter	p_{ra} at Z_M	MPa	1.94					
	P	mW		2.91		2.91		2.91
	P_{1x1}	mW		1.08		1.08		
	z_s	cm			0.65			
	z_b	cm					1.50	
	z_{MI}	cm	0.64					
	$z_{PII\,\alpha}$	cm	0.64					
	f_{awf}	MHz	6.60	14.97	14.97	14.97	14.97	14.97
Other information	prr	Hz	13287					
	srr	Hz	12.31					
	n_{pps}		12					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm²	95.73					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm²	13.79					
	I_{spta} at z_{pii} or z_{sii}	mW/cm²	19.79					
	p_r at z_{pii}	MPa	2.24					
Operating Control Conditions	Preset		vhFREQ	vhFREQ		vhFREQ		vhFREQ
	Depth	cm	1.30	1.30		1.30		1.30
	Tx Freq	MHz	15.6	15.6		15.6		15.6

Acoustic Measurements of the Device model with Linear probe 40mm PR51 in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.20	0.05		0.10		0.11
Index Component Value				0.05	0.04	0.11	0.10	
Associated parameter	p_{ra} at Z_M	MPa	0.51					
	P	mW		1.67		1.67		1.67
	P_{1x1}	mW		1.67		1.67		
	z_s	cm			0.82			
	z_b	cm					1.90	
	z_{MI}	cm	2.53					
	$z_{PII\,\alpha}$	cm	2.53					
	f_{awf}	MHz	6.61	6.61	6.61	6.61	6.61	6.61
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	6.72					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	28.23					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	89.49					
	p_r at z_{pii}	MPa	0.91					
Operating Control Conditions	Preset		carotid	carotid		carotid		carotid
	Depth	cm	3.3	3.3		3.3		3.3
	Tx Freq	MHz	6.25	6.25		6.25		6.25

Acoustic Measurements of the Device model with Linear probe 50mm PR52 in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			1.32	0.08		0.08		0.15
Index Component Value				0.08	0.08	0.15	0.08	
Associated parameter	p_{ra} at Z_M	MPa	3.65					
	P	mW		10.39		10.39		10.39
	P_{1x1}	mW		2.16		2.16		
	z_s	cm			1.25			
	z_b	cm					2.28	
	z_{MI}	cm	0.74					
	$z_{PII\,\alpha}$	cm	0.74					
	f_{awf}	MHz	7.59	7.59	7.59	7.59	7.59	7.59
Other information	prr	Hz	12169					
	srr	Hz	50.70					
	n_{pps}		2					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	459.77					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	22.84					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	33.65					
	p_r at z_{pii}	MPa	4.43					
Operating Control Conditions	Preset		Brachial	Brachial		Brachial		Brachial
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	7.81	7.81		7.81		7.81

Acoustic Measurements of the Device model with Linear probe 50mm PR52 in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.89	0.19		0.19		0.29
Index Component Value				0.19	0.19	0.29	0.19	
Associated parameter	p_{ra} at Z_M	MPa	1.95					
	P	mW		10.72		10.72		10.72
	P_{1x1}	mW		7.57		7.57		
	z_s	cm			1.03			
	z_b	cm					1.88	
	z_{MI}	cm	0.69					
	$z_{PII\,\alpha}$	cm	0.69					
	f_{awf}	MHz	4.79	15.18	15.18	15.18	15.18	15.18
Other information	prr	Hz	13021					
	srr	Hz	13.49					
	n_{pps}		10					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	66.56					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	84.98					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	2.18					
	p_r at z_{pii}	MPa	6.25					
Operating Control Conditions	Preset		Median	high freq		high freq		high freq
	Depth	cm	1.42	2.42		2.42		2.42
	Tx Freq	MHz	15.6	15.6		15.6		15.6

Acoustic Measurements of the Device model with Linear probe 50mm PR52 in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.22	0.16		0.21		0.25
Index Component Value				0.16	0.08	0.25	0.21	
Associated parameter	p_{ra} at Z_M	MPa	0.56					
	P	mW		5.30		4.47		4.47
	P_{1x1}	mW		5.30		4.47		
	z_s	cm			1.58			
	z_b	cm					1.88	
	z_{MI}	cm	2.51					
	$z_{PII\,\alpha}$	cm	2.51					
	f_{awf}	MHz	6.38	6.38	6.38	6.38	6.38	6.38
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	12.10					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	49.09					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	148.27					
	p_r at z_{pii}	MPa	0.98					
Operating Control Conditions	Preset		High freq	Femoral		High freq		High freq
	Depth	cm	2.42	5.14		2.42		2.42
	Tx Freq	MHz	6.25	6.25		6.25		6.25

Acoustic Measurements of the Device model with Endocavitary probe PR53 in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.61	0.04		0.04		0.08
Index Component Value				0.04	0.04	0.06	0.04	
Associated parameter	p_{ra} at Z_M	MPa	1.38					
	P	mW		2.86		2.86		3.93
	P_{1x1}	mW		1.30		1.30		
	z_s	cm			1.23			
	z_b	cm					2.50	
	z_{MI}	cm	0.74					
	$z_{PII\ \alpha}$	cm	0.74					
	f_{awf}	MHz	5.19	7.14	7.14	7.14	7.14	5.19
Other information	prr	Hz	12169					
	srr	Hz	55.31					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	71.61					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	7.56					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	9.85					
	p_r at z_{pii}	MPa	1.58					
Operating Control Conditions	Preset		Deep	newDEF		newDEF		Deep
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	5.68	7.81		7.81		5.68

Acoustic Measurements of the Device model with Endocavitary probe PR53 in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.39	0.02		0.02		0.04
Index Component Value				0.02	0.02	0.04	0.02	
Associated parameter	p_{ra} at Z_M	MPa	0.77					
	P	mW		1.17		1.17		1.50
	P_{1x1}	mW		1.06		1.06		
	z_s	cm			1.23			
	z_b	cm					2.50	
	z_{MI}	cm	1.45					
	$z_{PII\,\alpha}$	cm	1.45					
	f_{awf}	MHz	3.87	7.14	7.14	7.14	7.14	5.19
Other information	prr	Hz	10016					
	srr	Hz	12.92					
	n_{pps}		10					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	13.52					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	3.88					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	5.85					
	p_r at z_{pii}	MPa	0.93					
Operating Control Conditions	Preset		newDEF	newDEF		newDEF		Deep
	Depth	cm	4.0	4.0		4.0		6.9
	Tx Freq	MHz	3.90	7.81		7.81		5.68

Acoustic Measurements of the Device model with Endocavitary probe PR53 in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.16	0.09		0.10		0.16
Index Component Value				0.09	0.05	0.14	0.10	
Associated parameter	p_{ra} at Z_M	MPa	0.33					
	P	mW		4.31		4.31		2.55
	P_{1x1}	mW		4.31		4.31		
	z_s	cm			1.92			
	z_b	cm					3.90	
	z_{MI}	cm	5.47					
	$z_{PII\,\alpha}$	cm	5.47					
	f_{awf}	MHz	4.18	4.18	4.18	4.18	4.18	4.18
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	2.78					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	16.98					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	82.23					
	p_r at z_{pii}	MPa	0.72					
Operating Control Conditions	Preset		depth	depth		depth		newDEF
	Depth	cm	6.9	6.9		6.9		4.0
	Tx Freq	MHz	4.17	4.17		4.17		4.17

Acoustic Measurements of the Device model with Phased Array probe PR54 in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			1.46	1.61		1.61		4.42
Index Component Value				1.61	1.61	4.42	1.61	
Associated parameter	p_{ra} at Z_M	MPa	1.96					
	P	mW		167.6		167.6		167.6
	P_{1x1}	mW		167.6		167.6		
	z_s	cm			2.39			
	z_b	cm					4.00	
	z_{MI}	cm	1.68					
	$z_{PII\ \alpha}$	cm	1.68					
	f_{awf}	MHz	1.80	2.02	2.02	2.02	2.02	2.02
Other information	prr	Hz	8980					
	srr	Hz	112.2					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	83.7					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	95.5					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	117.6					
	p_r at z_{pii}	MPa	2.18					
Operating Control Conditions	Preset		Deep	HeartC		HeartC		HeartC
	Depth	cm	3.7	1.5		1.5		1.5
	Tx Freq	MHz	1.78	2.02		2.02		2.02

Acoustic Measurements of the Device model with Phased Array probe PR54 in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.56	0.38		0.38		0.75
Index Component Value				0.38	0.38	0.75	0.38	
Associated parameter	p_{ra} at Z_M	MPa	0.80					
	P	mW		36.6		36.6		36.6
	P_{1x1}	mW		36.6		36.6		
	z_s	cm			2.87			
	z_b	cm					4.81	
	z_{MI}	cm	5.55					
	$z_{PII\ \alpha}$	cm	5.55					
	f_{awf}	MHz	2.08	3.14	3.14	3.14	3.14	3.14
Other information	prr	Hz	6230					
	srr	Hz	13.08					
	n_{pps}		16					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	19.6					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	9.49					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	21.4					
	p_r at z_{pii}	MPa	1.20					
Operating Control Conditions	Preset		TransCranDOP	TransCranDOP		TransCranDOP		TransCranDOP
	Depth	cm	10.9	10.9		10.9		10.9
	Tx Freq	MHz	2.08	3.12		3.12		3.12

Acoustic Measurements of the Device model with Phased Array probe PR54 in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.40	0.80		1.59		1.66
Index Component Value				0.80	0.44	1.66	1.59	
Associated parameter	p_{ra} at Z_M	MPa	0.58					
	P	mW		81.0		81.0		81.0
	P_{1x1}	mW		81.0		81.0		
	z_s	cm			2.87			
	z_b	cm					4.81	
	z_{MI}	cm	7.21					
	$z_{PII\ \alpha}$	cm	7.21					
	f_{awf}	MHz	2.07	2.07	2.07	2.07	2.07	2.07
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	8.57					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	111.4					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	321.1					
	p_r at z_{pii}	MPa	0.96					
Operating Control Conditions	Preset		TransCranDOP	TransCranDOP		TransCranDOP		TransCranDOP
	Depth	cm	10.9	10.9		10.9		10.9
	Tx Freq	MHz	2.08	2.08		2.08		2.08

Acoustic Measurements of the Device model with Phased Array probe PR54 in CW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.40	0.80		1.59		1.66
Index Component Value				0.80	0.44	1.66	1.59	
Associated parameter	p_{ra} at Z_M	MPa	0.58					
	P	mW		81.0		81.0		81.0
	P_{1x1}	mW		81.0		81.0		
	z_s	cm			2.87			
	z_b	cm					4.81	
	z_{MI}	cm	7.21					
	$z_{PII\,\alpha}$	cm	7.21					
	f_{awf}	MHz	2.07	2.07	2.07	2.07	2.07	2.07
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa,\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	8.57					
	$I_{spta,\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	111.4					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	321.1					
	p_r at z_{pii}	MPa	0.96					
Operating Control Conditions	Preset		TransCranDOP	TransCranDOP		TransCranDOP		TransCranDOP
	Depth	cm	10.9	10.9		10.9		10.9
	Tx Freq	MHz	2.08	2.08		2.08		2.08

Acoustic Measurements of the Device model with MicroConvex probePR55 in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.60	0.02		0.02		0.04
Index Component Value				0.02	0.02	0.04	0.02	
Associated parameter	p_{ra} at Z_M	MPa	1.45					
	P	mW		3.18		3.18		3.30
	P_{1x1}	mW		0.88		0.88		
	z_s	cm			2.49			
	z_b	cm					5.24	
	z_{MI}	cm	0.74					
	$z_{PII\ \alpha}$	cm	0.74					
	f_{awf}	MHz	5.75	5.75	5.75	5.75	5.75	7.19
Other information	prr	Hz	12169					
	srr	Hz	101.4					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	70.18					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	5.44					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	7.30					
	p_r at z_{pii}	MPa	1.68					
Operating Control Conditions	Preset		General	General		General		near
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	6.25	6.25		6.25		7.81

Acoustic Measurements of the Device model with MicroConvex probePR55 in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.49	0.04		0.04		0.08
Index Component Value				0.04	0.04	0.08	0.04	
Associated parameter	p_{ra} at Z_M	MPa	0.86					
	P	mW		4.72		4.72		4.72
	P_{1x1}	mW		2.37		2.37		
	z_s	cm			1.44			
	z_b	cm					3.03	
	z_{MI}	cm	1.88					
	$z_{PII\,\alpha}$	cm	1.88					
	f_{awf}	MHz	3.04	7.19	7.19	7.19	7.19	7.19
Other information	prr	Hz	10016					
	srr	Hz	15.41					
	n_{pps}		12					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	13.8					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	6.70					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	10.39					
	p_r at z_{pii}	MPa	1.04					
Operating Control Conditions	Preset		near	near		near		near
	Depth	cm	4.4	4.4		4.4		4.4
	Tx Freq	MHz	3.125	7.81		7.81		7.81

Acoustic Measurements of the Device model with MicroConvex probePR55 in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.16	0.07		0.51		0.18
Index Component Value				0.07	0.04	0.18	0.51	
Associated parameter	p_{ra} at Z_M	MPa	0.28					
	P	mW		4.83		4.25		4.25
	P_{1x1}	mW		4.83		4.25		
	z_s	cm			2.49			
	z_b	cm					3.03	
	z_{MI}	cm	3.54					
	$z_{PII\ \alpha}$	cm	3.54					
	f_{awf}	MHz	3.06	3.06	3.06	3.06	3.06	3.06
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	1.70					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	18.8					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	39.7					
	p_r at z_{pii}	MPa	0.41					
Operating Control Conditions	Preset		near	General		near		near
	Depth	cm	4.4	7.6		4.4		4.4
	Tx Freq	MHz	3.125	3.125		3.125		3.125

Acoustic Measurements of the Device model with PR56: Convex Probe Access in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.79	0.07		0.07		0.19
Index Component Value				0.07	0.07	0.19	0.07	
Associated parameter	p_{ra} at Z_M	MPa	1.43					
	P	mW		24.7		24.7		24.7
	P_{1x1}	mW		4.26		4.26		
	z_s	cm			2.37			
	z_b	cm					4.50	
	z_{MI}	cm	1.68					
	$z_{PII\ \alpha}$	cm	1.68					
	f_{awf}	MHz	3.25	3.25	3.25	3.25	3.25	3.25
Other information	prr	Hz	8980					
	srr	Hz	120.0					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	67.0					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	11.2					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	16.4					
	p_r at z_{pii}	MPa	1.72					
Operating Control Conditions	Preset		Default	Default		Default		Default
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	3.125	3.125		3.125		3.125

Acoustic Measurements of the Device model with PR56: Convex Probe Access in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.30	0.08		0.08		0.14
Index Component Value				0.08	0.08	0.14	0.08	
Associated parameter	p_{ra} at Z_M	MPa	0.54					
	P	mW		12.3		12.3		12.3
	P_{1x1}	mW		5.25		5.25		
	z_s	cm			3.02			
	z_b	cm					5.74	
	z_{MI}	cm	5.22					
	$z_{PII\,\alpha}$	cm	5.22					
	f_{awf}	MHz	3.25	3.25	3.25	3.25	3.25	3.25
Other information	prr	Hz	4634					
	srr	Hz	14.4					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	9.59					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	2.36					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	8.85					
	p_r at z_{pii}	MPa	0.97					
Operating Control Conditions	Preset		Default	Default		Default		Default
	Depth	cm	11.8	11.8		11.8		11.8
	Tx Freq	MHz	3.125	3.125		3.125		3.125

Acoustic Measurements of the Device model with PR56: Convex Probe Access in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.23	0.38		0.45		0.49
Index Component Value				0.38	0.22	0.49	0.45	
Associated parameter	p_{ra} at Z_M	MPa	0.41					
	P	mW		28.4		28.4		28.4
	P_{1x1}	mW		25.3		25.3		
	z_s	cm			3.02			
	z_b	cm					5.74	
	z_{MI}	cm	7.66					
	$z_{PII\ \alpha}$	cm	7.66					
	f_{awf}	MHz	3.13	3.13	3.13	3.13	3.13	3.13
Other information	prr	Hz	8510					
	srr	Hz	66.5					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	6.88					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	47.8					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	250.3					
	p_r at z_{pii}	MPa	0.93					
Operating Control Conditions	Preset		Default	Default		Default		Default
	Depth	cm	11.8	11.8		11.8		11.8
	Tx Freq	MHz	3.125	3.125		3.125		3.125

Acoustic Measurements of the Device model with PR57: Linear Probe Access in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			1.05	0.08		0.08		0.09
Index Component Value				0.08	0.08	0.09	0.08	
Associated parameter	p_{ra} at Z_M	MPa	2.83					
	P	mW		8.0		8.0		8.0
	P_{1x1}	mW		2.36		2.36		
	z_s	cm			1.35			
	z_b	cm					3.00	
	z_{MI}	cm	0.74					
	$z_{PII\,\alpha}$	cm	0.74					
	f_{awf}	MHz	7.22	7.22	7.22	7.22	7.22	7.22
Other information	prr	Hz	12169					
	srr	Hz	107.7					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	251.2					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	38.7					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	56.0					
	p_r at z_{pii}	MPa	3.40					
Operating Control Conditions	Preset		Lung	Lung		Lung		Lung
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	7.81	7.81		7.81		7.81

Acoustic Measurements of the Device model with PR57: Linear Probe Access in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.49	0.11		0.11		0.11
Index Component Value				0.11	0.11	0.11	0.11	
Associated parameter	p_{ra} at Z_M	MPa	1.33					
	P	mW		7.52		7.52		7.52
	P_{1x1}	mW		3.57		3.57		
	z_s	cm			1.35			
	z_b	cm					3.00	
	z_{MI}	cm	1.89					
	$z_{PII\,\alpha}$	cm	1.89					
	f_{awf}	MHz	7.22	7.22	7.22	7.22	7.22	7.22
Other information	prr	Hz	8918					
	srr	Hz	23.5					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	55.2					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	21.0					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	46.6					
	p_r at z_{pii}	MPa	2.13					
Operating Control Conditions	Preset		Lung	Lung		Lung		Lung
	Depth	cm	3.8	3.8		3.8		3.8
	Tx Freq	MHz	7.81	7.81		7.81		7.81

Acoustic Measurements of the Device model with PR57: Linear Probe Access in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.17	0.10		0.12		0.11
Index Component Value				0.10	0.06	0.11	0.12	
Associated parameter	p_{ra} at Z_M	MPa	0.43					
	P	mW		3.18		3.18		3.18
	P_{1x1}	mW		3.18		3.18		
	z_s	cm			1.35			
	z_b	cm					3.00	
	z_{MI}	cm	2.73					
	$z_{PII\,\alpha}$	cm	2.73					
	f_{awf}	MHz	6.43	6.43	6.43	6.43	6.43	6.43
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	7.11					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	31.6					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	106.1					
	p_r at z_{pii}	MPa	0.79					
Operating Control Conditions	Preset		Lung	Lung		Lung		Lung
	Depth	cm	3.8	3.8		3.8		3.8
	Tx Freq	MHz	6.25	6.25		6.25		6.25

Acoustic Measurements of the Device model with PR58: Microconvex Probe in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			1.62	0.42		0.42		0.71
Index Component Value				0.42	0.42	0.71	0.42	
Associated parameter	p_{ra} at Z_M	MPa	3.33					
	P	mW		40.2		40.2		40.2
	P_{1x1}	mW		20.8		20.8		
	z_s	cm			1.34			
	z_b	cm					0.87	
	z_{MI}	cm	0.74					
	$z_{PII\ \alpha}$	cm	0.74					
	f_{awf}	MHz	4.25	4.25	4.25	4.25	4.25	4.25
Other information	prr	Hz	12169					
	srr	Hz	135.2					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	239.1					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	75.1					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	93.3					
	p_r at z_{pii}	MPa	3.71					
Operating Control Conditions	Preset		Blue Lung	BlueLung		BlueLung		BlueLung
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	4.17	4.17		4.17		4.17

Acoustic Measurements of the Device model with PR58: Microconvex Probe in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.76	0.48		0.48		0.67
Index Component Value				0.48	0.48	0.67	0.48	
Associated parameter	p_{ra} at Z_M	MPa	1.51					
	P	mW		26.7		26.7		26.7
	P_{1x1}	mW		25.8		25.8		
	z_s	cm			2.07			
	z_b	cm					1.46	
	z_{MI}	cm	2.06					
	$z_{PII\,\alpha}$	cm	2.06					
	f_{awf}	MHz	3.91	4.25	4.25	4.25	4.25	4.25
Other information	prr	Hz	9717					
	srr	Hz	10.3					
	n_{pps}		12					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	56.3					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	23.6					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	41.9					
	p_r at z_{pii}	MPa	1.99					
Operating Control Conditions	Preset		tf	BlueLung		BlueLung		BlueLung
	Depth	cm	4.8	13.9		13.9		13.9
	Tx Freq	MHz	3.9	4.17		4.17		4.17

Acoustic Measurements of the Device model with PR58: Microconvex Probe in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.31	0.45		0.45		0.96
Index Component Value				0.45	0.35	0.96	0.45	
Associated parameter	p_{ra} at Z_M	MPa	0.65					
	P	mW		22.1		22.1		22.1
	P_{1x1}	mW		22.1		22.1		
	z_s	cm			2.07			
	z_b	cm					1.46	
	z_{MI}	cm	2.99					
	$z_{PII\,\alpha}$	cm	2.99					
	f_{awf}	MHz	4.32	4.32	4.32	4.32	4.32	4.32
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	12.7					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	84.9					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	207.0					
	p_r at z_{pii}	MPa	1.02					
Operating Control Conditions	Preset		BlueLung	BlueLung		BlueLung		BlueLung
	Depth	cm	13.9	13.9		13.9		13.9
	Tx Freq	MHz	4.17	4.17		4.17		4.17

Acoustic Measurements of the Device model with PR59: Convex Probe Single Crystal in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.82	0.07		0.07		0.20
Index Component Value				0.07	0.07	0.20	0.07	
Associated parameter	p_{ra} at Z_M	MPa	1.49					
	P	mW		26.1		26.1		26.1
	P_{1x1}	mW		4.35		4.35		
	z_s	cm			2.20			
	z_b	cm					5.00	
	z_{MI}	cm	1.68					
	$z_{PII\ \alpha}$	cm	1.68					
	f_{awf}	MHz	3.29	3.29	3.29	3.29	3.29	3.29
Other information	prr	Hz	8980					
	srr	Hz	47.0					
	n_{pps}		1					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	116.1					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	24.0					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	35.1					
	p_r at z_{pii}	MPa	1.80					
Operating Control Conditions	Preset		Abdomen	Abdomen		Abdomen		Abdomen
	Depth	cm	3.7	3.7		3.7		3.7
	Tx Freq	MHz	3.47	3.47		3.47		3.47

Acoustic Measurements of the Device model with PR59: Convex Probe Single Crystal in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.34	0.07		0.07		0.14
Index Component Value				0.07	0.07	0.14	0.07	
Associated parameter	p_{ra} at Z_M	MPa	0.61					
	P	mW		11.7		11.7		11.7
	P_{1x1}	mW		4.44		4.44		
	z_s	cm			2.92			
	z_b	cm					6.64	
	z_{MI}	cm	6.19					
	$z_{PII\ \alpha}$	cm	6.19					
	f_{awf}	MHz	3.13	3.29	3.29	3.29	3.29	3.29
Other information	prr	Hz	6290					
	srr	Hz	8.85					
	n_{pps}		10					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	12.6					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	2.52					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	9.51					
	p_r at z_{pii}	MPa	1.19					
Operating Control Conditions	Preset		Abdomen	Abdomen		Abdomen		Abdomen
	Depth	cm	12.5	12.5		12.5		12.5
	Tx Freq	MHz	3.125	3.47		3.47		3.47

Acoustic Measurements of the Device model with PR59: Convex Probe Single Crystal in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.29	0.44		0.51		0.62
Index Component Value				0.44	0.27	0.62	0.51	
Associated parameter	p_{ra} at Z_M	MPa	0.51					
	P	mW		35.8		35.8		35.8
	P_{1x1}	mW		29.3		29.3		
	z_s	cm			2.92			
	z_b	cm					6.64	
	z_{MI}	cm	7.97					
	$z_{PII\,\alpha}$	cm	7.97					
	f_{awf}	MHz	3.14	3.14	3.14	3.14	3.14	3.14
Other information	prr	Hz	8189					
	srr	Hz	64.0					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	8.98					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	67.1					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	377.0					
	p_r at z_{pii}	MPa	1.20					
Operating Control Conditions	Preset		Abdomen	Abdomen		Abdomen		Abdomen
	Depth	cm	12.5	12.5		12.5		12.5
	Tx Freq	MHz	3.125	3.125		3.125		3.125

Acoustic Measurements of the Device model with PR60: Hockey Stick Probe in B Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.26	0.01		0.01		0.01
Index Component Value				0.01	0.01	0.01	0.01	
Associated parameter	p_{ra} at Z_M	MPa	0.86					
	P	mW		0.34		0.34		0.34
	P_{1x1}	mW		0.13		0.13		
	z_s	cm			0.55			
	z_b	cm					1.07	
	z_{MI}	cm	0.74					
	$z_{PII\ \alpha}$	cm	0.74					
	f_{awf}	MHz	10.6	10.6	10.6	10.6	10.6	10.6
Other information	prr	Hz	12169					
	srr	Hz	47.5					
	n_{pps}		2					
	$I_{pa.\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	25.0					
	$I_{spta.\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	1.31					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	2.25					
	p_r at z_{pii}	MPa	1.13					
Operating Control Conditions	Preset		NearM	NearM		NearM		NearM
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	12.5	12.5		12.5		12.5

Acoustic Measurements of the Device model with PR60: Hockey Stick Probe in Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.35	0.02		0.02		0.03
Index Component Value				0.02	0.02	0.03	0.02	
Associated parameter	p_{ra} at Z_M	MPa	0.89					
	P	mW		1.08		1.08		1.08
	P_{1x1}	mW		0.49		0.49		
	z_s	cm			0.55			
	z_b	cm					1.07	
	z_{MI}	cm	0.67					
	$z_{PII\ \alpha}$	cm	0.67					
	f_{awf}	MHz	6.44	10.6	10.6	10.6	10.6	10.6
Other information	prr	Hz	10942					
	srr	Hz	12.0					
	n_{pps}		12.8					
	$I_{pa\cdot\alpha}$ at $z_{PII\ \alpha}$	W/cm^2	27.8					
	$I_{spta\cdot\alpha}$ at $z_{PII\ \alpha}$ or $z_{sii\ \alpha}$	mW/cm^2	7.75					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	10.5					
	p_r at z_{pii}	MPa	1.03					
Operating Control Conditions	Preset		NearM	NearM		NearM		NearM
	Depth	cm	1.5	1.5		1.5		1.5
	Tx Freq	MHz	12.5 6.25	12.5 6.25		12.5 6.25		12.5 6.25

Acoustic Measurements of the Device model with PR60: Hockey Stick Probe in PW Mode

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.07	0.02		0.07		0.09
Index Component Value				0.02	0.01	0.08	0.07	
Associated parameter	p_{ra} at Z_M	MPa	0.18					
	P	mW		0.60		0.60		0.54
	P_{1x1}	mW		0.60		0.60		
	z_s	cm			0.59			
	z_b	cm					1.16	
	z_{MI}	cm	1.51					
	$z_{PII\,\alpha}$	cm	1.51					
	f_{awf}	MHz	6.36	6.36	6.36	6.36	6.36	6.36
Other information	prr	Hz	10016					
	srr	Hz	78.25					
	n_{pps}		128					
	$I_{pa\cdot\alpha}$ at $z_{PII\,\alpha}$	W/cm^2	1.13					
	$I_{spta\cdot\alpha}$ at $z_{PII\,\alpha}$ or $z_{sii\,\alpha}$	mW/cm^2	6.66					
	I_{spta} at z_{pii} or z_{sii}	mW/cm^2	12.93					
	p_r at z_{pii}	MPa	0.25					
Operating Control Conditions	Preset		Median	Median		Median		NearM
	Depth	cm	1.0	1.0		1.0		1.5
	Tx Freq	MHz	6.25	6.25		6.25		6.25

26. CONNECTIVITY & CYBERSECURITY

The user should disable the Wi-Fi prior to starting image acquisition and verify that the Wi-Fi should remain disabled during image acquisition.

26.1. Available protocols

Protocols	Available / disabled	Use
USB 3.1	Available	To send data to the usb stick/drive of a user.
Wifi (802.11ac)	Available	To send & receive data from trusted source in the network: Hospital PACS & SONOSCANNER update server.
HDMI	Available	To send digital video from the device to a monitor
Bluetooth 4.1	Disabled	/
4G	Disabled	/

WIFI	802.11 ac (Wi-Fi 5)
AP capacity	Single-user support (OFDM)
AP spatial streams	4
Band	5 Ghz
Maximum Data rate	6.9 Gbps
Maximum modulation	256 QAM
MU-MIMO	Downlink

26.2. Update protocols

Two protocols for update and patches are defined:

→ A physical update using a provided usb key and the device USB connector. This procedure is only performed by Sonoscanner engineers.
→ A network update using the latest version pushed on our secured servers.

26.3. User Site information and recommendations

→ To ensure safety, use an IT network that is isolated from the external environment by a firewall
→ The port for DICOM communication is used for outgoing communication to the network.
→ Anti-virus software is not installed on this device.
→ Room Access Control: Local procedures must be put in place to limit physical access to medical equipment, to prevent accidental, casual, or deliberate contact by unauthorized individuals.

→ System Access Controls: Access the system only through unique user password. Login credentials must not be disclosed.

→ Transmission Security: Clinical data transmitted over the network may not be encrypted. Add only trusted devices to the network. (We highly recommend the use of encrypted DICOM. If secure DICOM is not supported, then network security controls shall be implemented to protect integrity and confidentiality of data).

26.4. Dependency information

Not applicable.

26.5. Logs

The system logs any attempt to connect as administrator.
The system logs any attempt to change the application approved configuration (integrity control).

When security compromises (authorized connection, integrity default update) are detected, an error pop up message is displayed on the screen.

26.6. Behavior on security breach suspicion

In case of any doubt of cybersecurity issue on the device:

→ The system should be turned off.

→ The device should be returned to manufacturer for servicing.

CHAPTER VIII
USER MAINTENANCE

The user must ensure that safety inspections are performed at least every 12 months according to the requirements of the patient safety standard IEC 60601-1
Only authorized persons are allowed to perform the safety inspections mentioned above.
Technical descriptions are available on request.

To ensure that the unit constantly operates at maximum efficiency we recommend that the following procedures be observed as part of the customer's internal routine maintenance program. Sonoscanner reserves the right to disclaim all responsibility for the safety and performance of equipment serviced or repaired by unauthorized parties.

1.SYSTEM INSPECTION

If any defects are observed or malfunctions occur, DO NOT operate the equipment, and inform a qualified service person.

We recommend that you thoroughly inspect on a regular basis the following:

- The outer part of the system for any missing or loosing hardware
- The control panel and keyboard for any possible malfunction
- All the cables (transducer cables and power cables) for possible cuts
- The monitor and the wheels for any possible defect

To avoid electrical shock hazard, do not remove panels or covers from the unit.

2.SYSTEM CARE

In order to ensure a safe and optimal performance of the system, we recommend that you clean the screen and the rest of the working surface on a monthly basis.

2.1.LCD Monitor:

NOTE:	Never use thinner, benzene, alcohol (ethanol, methanol, or isopropyl alcohol), abrasive cleaners, or other strong solvents, as these may cause damage to the cabinet or LCD panel.

NOTE:	DO NOT scratch or press on the panel with any sharp objects, such as pencils or pens, as this may result in damage to the panel.

Clean the LCD surface with a soft cloth, such as cotton or lens paper.
If necessary, stubborn stains can be removed by moistening part of a cloth with water to enhance its cleaning power.

2.2.Prevention of static electricity interference:

Interference from static electricity can damage electronic components in the system. The following measures help to reduce the likelihood of electrostatic discharge:

- Wipe the LCD with lint-free tissue or a soft cloth dampened with anti-static spray on a monthly basis.
- Spray carpets with anti-static spray because constant walking on carpets in or near the scanning room may be a source of static electricity.

When cleaning any of the elements listed above, make sure not to spill nor spray any liquid as it could permanently damage part or all the system.

3.SYSTEM MALFUNCTION

In the event of error or system malfunction the user may contact authorized service personnel

4.SYSTEM DISPOSAL

The device must not be destroyed by incineration. Please return the device to your local Sonoscanner representative for disposal.

5.TROUBLESHOOTING

Device Troubleshooting

Problem	Possible Cause	Solution
Device has no power	Battery not charged	Charge the battery or connect the power adapter
	Battery defect or end of life	Contact Sonoscanner's representative Service Center
	Broken battery connection	Contact Sonoscanner's representative Service Center
	Main power is down.	Contact Sonoscanner's representative Service Center
	Temperature is outside the specified limits	Ensure the ambient temperature is within the specified limits
	Temperature of the device has been too high	Wait until the device cools down. It should reactiveate itself.
Parts of the image is missing when scanning.	Channels are missing	Contact Sonoscanner's representative Service Center
Noise when moving the probe cable	Defect probe cable	Contact Sonoscanner's representative Service Center
No image displayed when scanning	Defect probe	Contact Sonoscanner's representative Service Center

6.ACCESSORIES

6.1. Probes:

Device can be order with different configuration of probes:
Probes available :

PR50: Convex probe for Device
PR51: Linear probe 40mm for Device
PR52: Linear probe 50mm for Device
PR53: Endocavitary probe for Device
PR54: Phased Array probe for Device
PR55: MicroConvex probe for Device
PR56: Convex Probe Access
PR57: Linear Probe Access
PR58: Microconvex Probe
PR59: Convex Probe Single Crystal
PR60: Hockey Stick Probe

6.2. Adapter:

Device uses a specific power adapter. **Do not use other power adapter.**
To purchase another one, contact your local Sonoscanner representative.

References for T-Lite Model/T-Lite-Pro Model/U-Lite Pro Model:
Manufacturer: Meanwell
Product No: GSM60A15
Specification: Input :100-240V ~ 50-60Hz 1.4A-0.7A -Output: 15VDC 4A

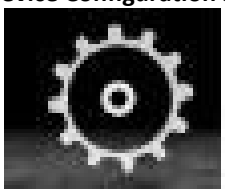
References for U-Lite Model:
Manufacturer: SINPRO
Product No: MPU31-102
Specification: Input :100-240V ~ 47-63Hz 0.9A-0.34A -Output: 5VDC 5A

References for T-Lite-Pro Model/U-Lite Pro Model:
Manufacturer: Globtek
Product No: GTM96600-6015-T3
Specification: Input :100-240V ~ 50-60Hz 1.5A - Output: 15VDC 4A

CHAPTER IX ADVANCED CONFIGURATION

You can change the Device ® configuration at any time when the acquisition is frozen by pressing the configuration switch :

IX-1 Device Configuration switch



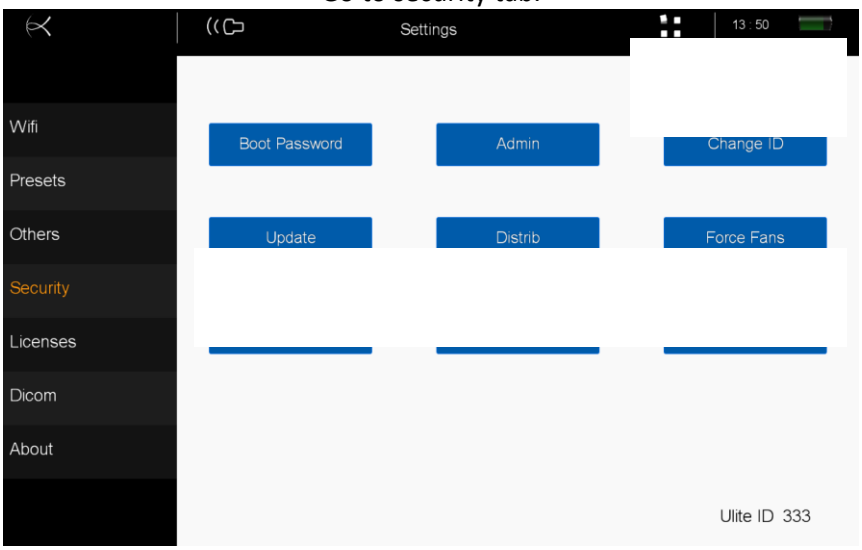
You then have access to several configuration tabs.

1. SECURE THE DEVICE WITH BOOT PASSWORD

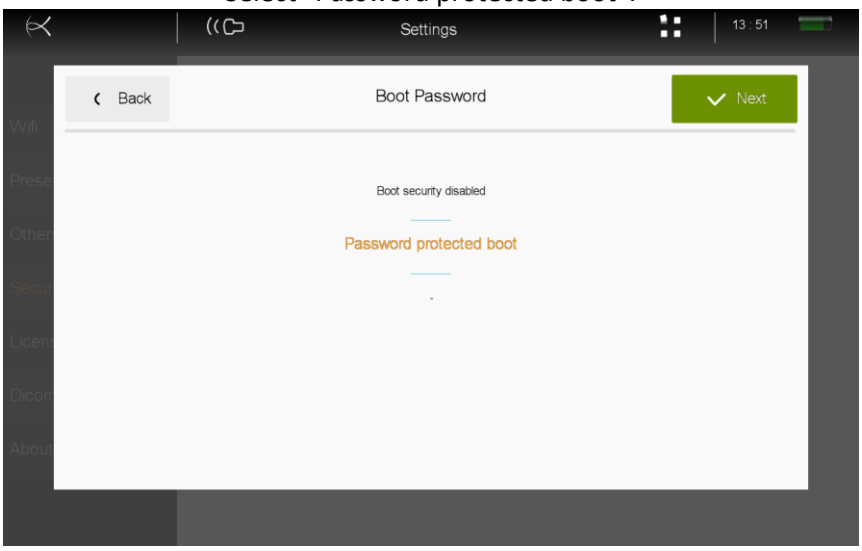
It is possible to secure access of your Device ® by adding a password. This password will be requested each time the systems starts. Therefore no access to the device or its data is possible without the password.

1.1. How to setup the password

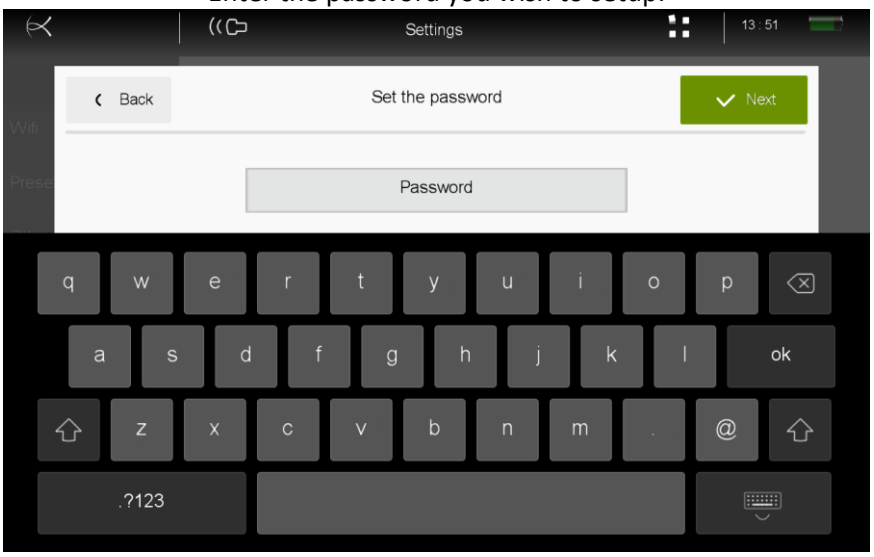
Go to security tab:



Select "Password protected boot":

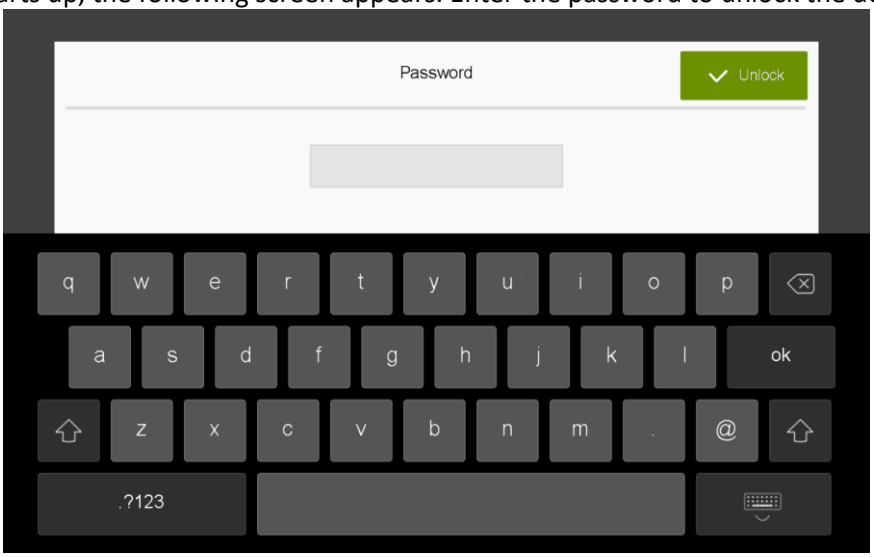


Enter the password you wish to setup:



1.2. Enter the password

Once the device starts up, the following screen appears. Enter the password to unlock the device.



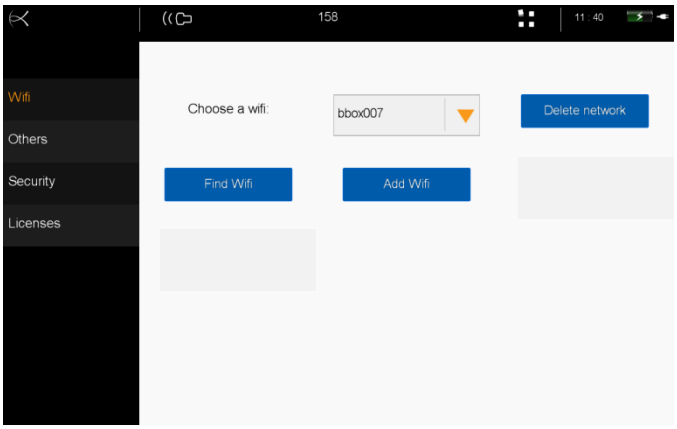
It is user sole responsibility to setup a password on his device to protect access to the device.

2. WIFI TAB

The device ® is connectable to a Wi-Fi network, to connect with your PACS or install upgrades

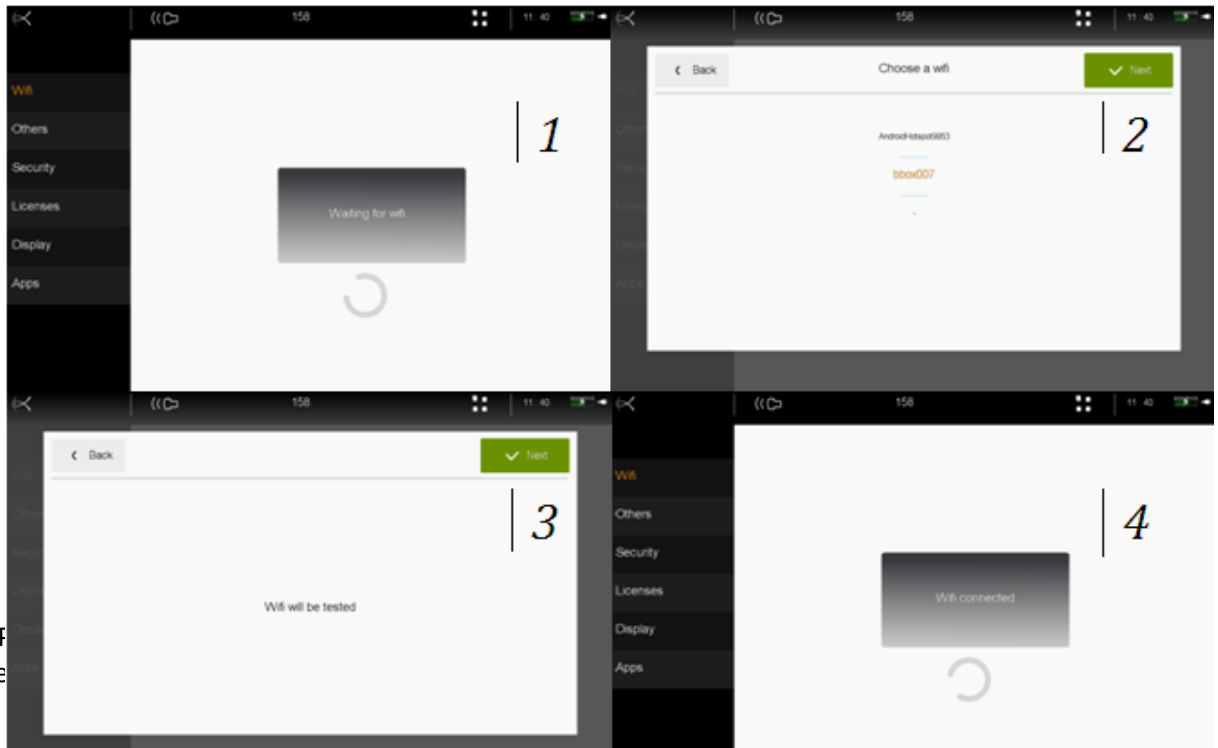
⚠	It is your responsibility to ensure that the security of your device and the protection of patient data meet your local security policies and regulatory requirements. Before e-mailing images and loops, consult your healthcare IT security department to ensure that you are in compliance with your department's specific policies and regulations regarding the handling of patient information.

⚠ The user should disable the Wi-Fi prior to starting image acquisition and verify that the Wi-Fi should remain disabled during image acquisition.



2.1. Device Wi-Fi connection procedure:

Click on the Wifi, look for networks or enter manually your network, enter the password and try the connection.



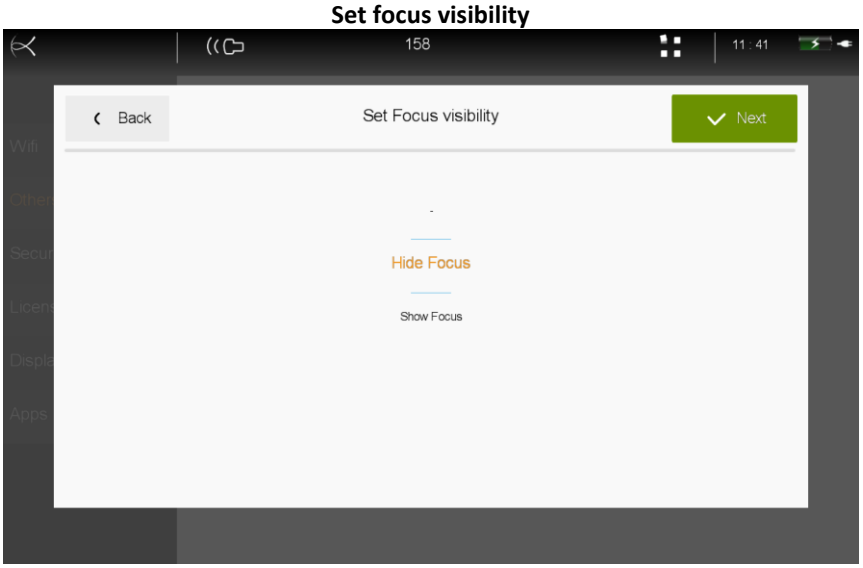
3. "OTHERS" TAB

This tab gives access to many settings, such as display preferences, system preferences, time setting, language, etc..

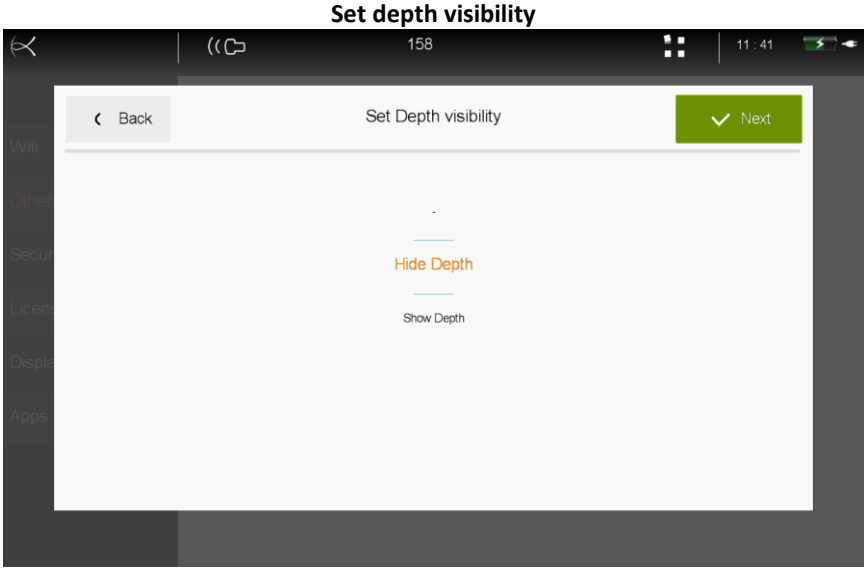
3.1. Display preferences

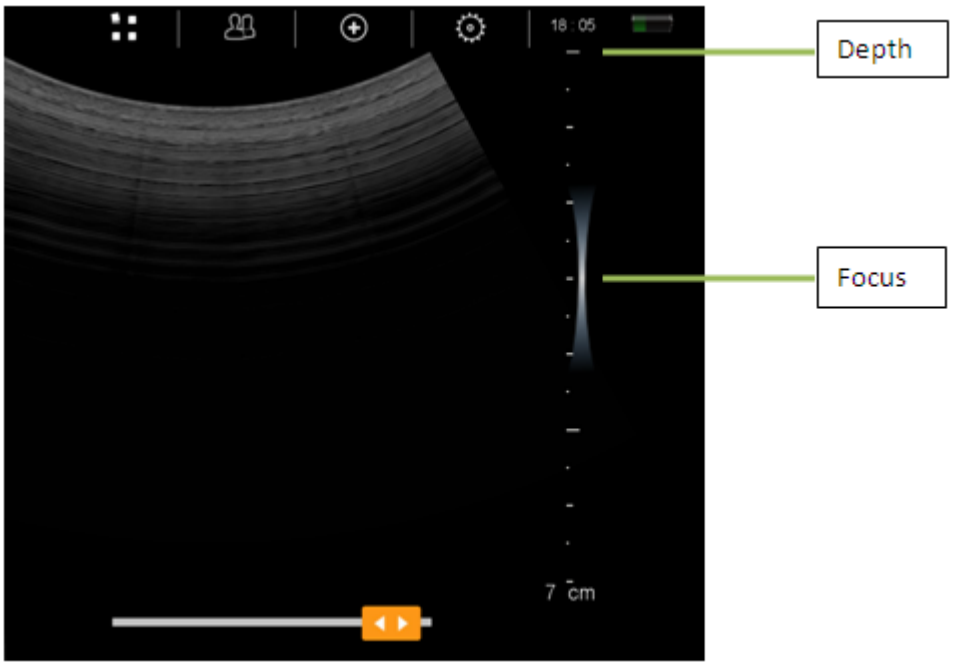
Display preferences tab gives access to the following settings:

Set focus visibility

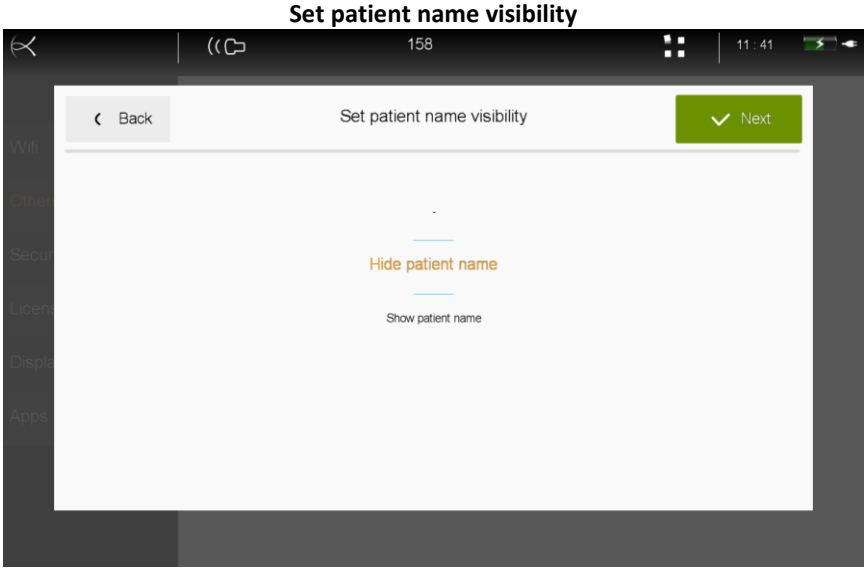


Set depth visibility



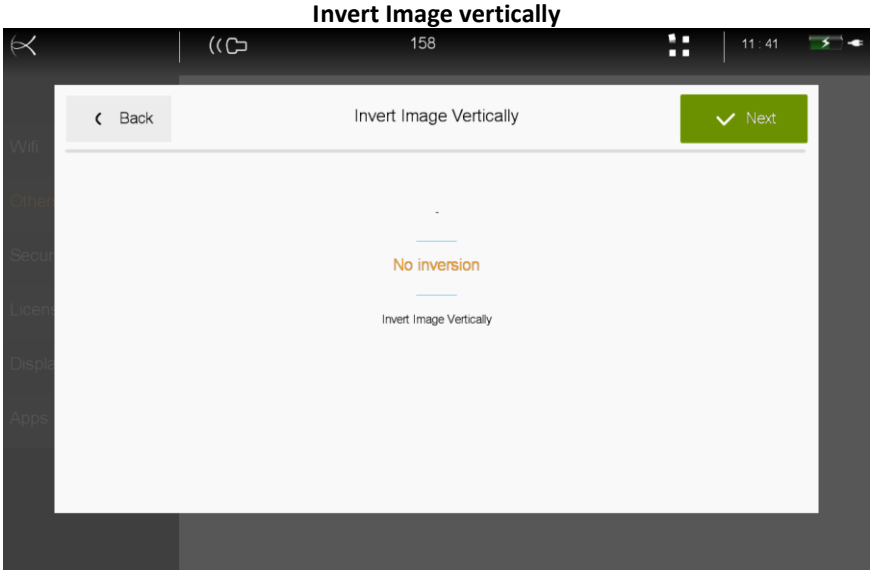


Set patient name visibility

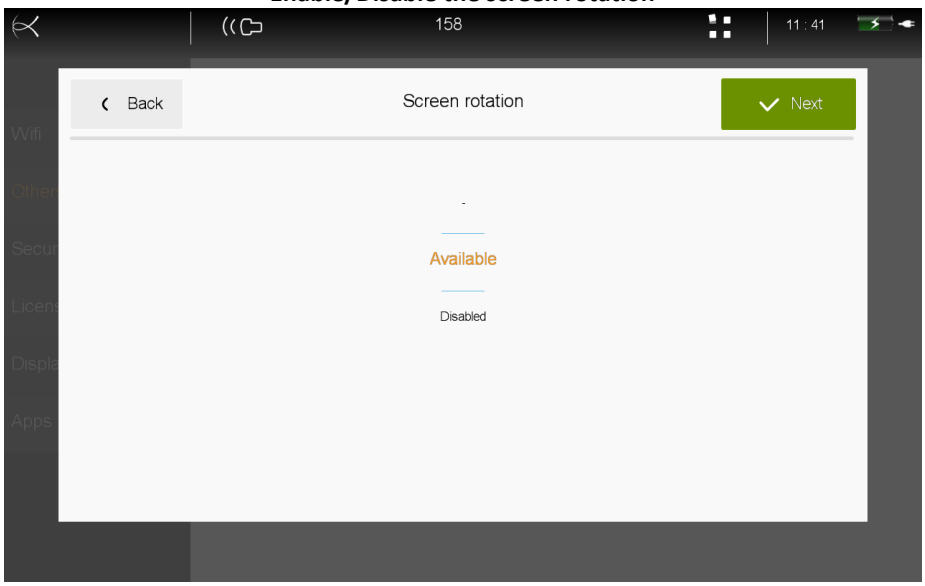


Set PW timescale

Invert Image vertically



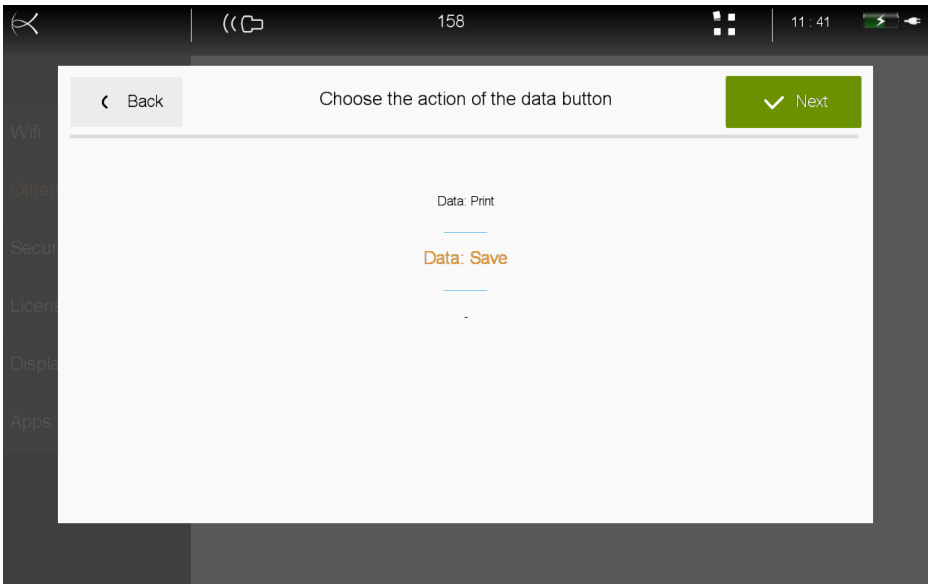
Enable/Disable the screen rotation



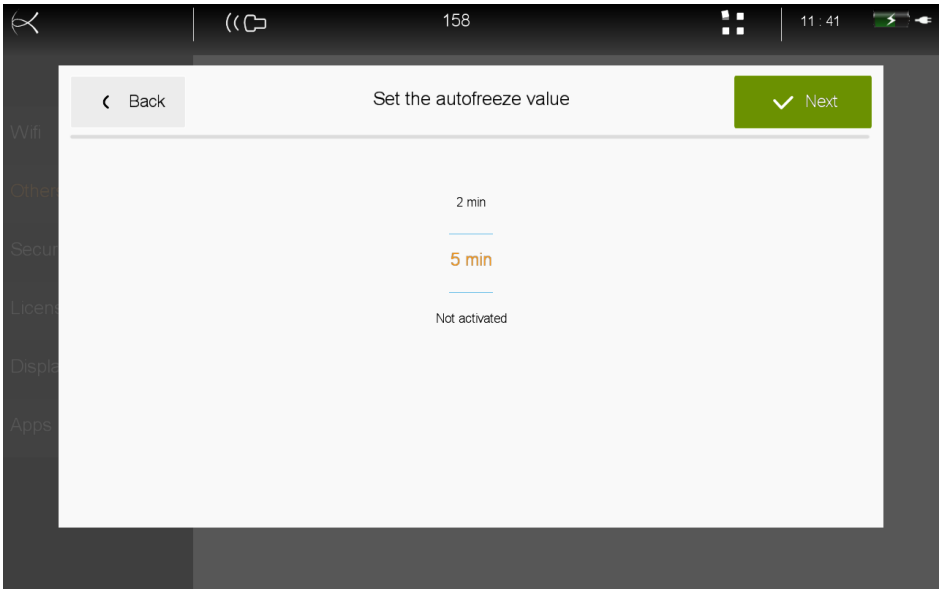
3.2. System preferences

System preferences tab gives access to the following settings:

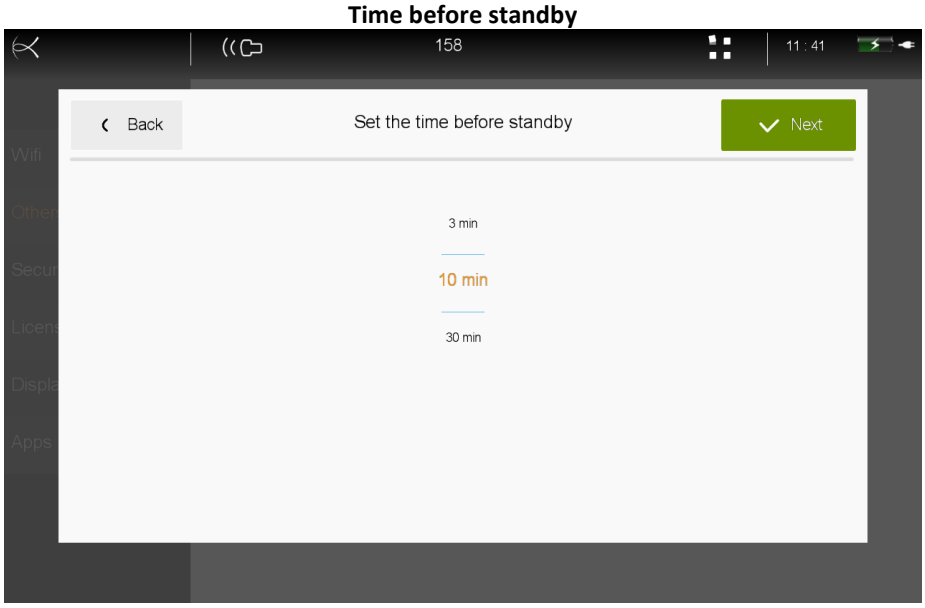
Data button action : Print or Save



Autofreeze value



Time before standby



3.3. Time Setting

You can set date and time in this tab.

3.4. Language

You can set language from this tab. Please note that you will need to restart the device

3.5. Printer

You can choose if the printer is either a text printer (for example with the Bladder app) a an image printer.

3.6. Factory Presets

Restore all presets.

3.7. Erase Data

Delete all patients and images already saved.

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