



Wireless Probe Type Ultrasound Scanner **UProbe-C & UProbe-L**

User's Guide

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Section 1 INTRODUCTION

The Wireless Probe Type Ultrasound Scanner (Model: Uprobe-C 、 Uprobe-L) is the new generation instruments for ultrasonography with the outstanding feature of wireless.

Different with traditional ultrasound scanner with a cable connecting from probe to main unit, no cable appears at the end of the probe of the Scanners. The probe of the Scanner is highly integrated with ultrasound image processing, power management and a wireless signal provider to be connected by the main unit. The main units different with traditional devices are now changed to be any iPad from Apple Inc or Apple iPhone. The probe acts as a Wi-Fi Access Point and can be connected by iPad or iPhone. With the probe be connected through WiFi and the App is running, enjoy your days of working without the trouble making cables.








This manual is intended to provide a thorough overview of the Scanner and should be carefully read before starting operating the device.


Thank you for your trust in us to provide for your ultrasonography needs.



Figure 1.1 UProbe-C Wireless Probe Type Ultrasound Scanner

1.1 Signs and Meaning

Sign	Meaning
	Caution! Please consult the accompanying document.
	Consult the user manual
	Type BF applied part
IPN ₁ N ₂	Degree of IP protection
	Non-ionizing electromagnetic radiation
	Manufacturer
	Date of manufacture
	Serial number

	Keep dry
IPX5	Prevent the water from the nozzle from invading in all directions and cause damage to the electrical apparatus.

1.2 TECHNICAL PARAMETERS

Display: iPad / iPhone Series
 Probe: 3.5MHz (convex)/7.5MHz(line)

Operation frequency	3.5MHz	7.5MHz
Depth	≥160mm	≥60mm
Measurement Accuracy	Lateral Resolution: ≤3 (Deep≤80) ; ≤4 (80<Deep≤130) Axial Resolution: ≤2 (Deep≤80) ; ≤3 (80<Deep≤130)	Lateral Resolution: ≤2 (Deep≤40) Axial Resolution: ≤1 (Deep≤50)

Display Mode: B Mode, B+M Mode
 Gray Scale: 256 levels
 Battery last: > 3 hours
 Size: 104mm x 50mm x 22mm
 Weight: ≈308g

	Operations	Storage and Transportation
Relative Humidity	25% to 80%, non-condensing	25% to 93%, non-condensing
Ambient Temperature	5°C to +40°C	-20°C to +55°C
Atmospheric Pressure	700hPa to 1060hPa	700hPa to 1060hPa

Electronic:
 Input:5Vd.c. 1A
 Battery Capacity: modle (SNP-4200) 3.8Vd.c. 4200mAh
 continuous working time: 2hour
 Waterproof: IPX5

1.3 INDICATIONS FOR USE

The Wireless Probe Type Ultrasound Scanner (Model: UProbe) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.

Contra-indication:

The basic equipment is not suitable for injuries or acute inflammatory site inspection, to avoid cross infection.

The diagnosis, the basic equipment is not suitable for gas containing organs such as lung, stomach and intestine.

The Diagnostic Ultrasound System is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

1.4 PRECAUTIONS & WARNINGS

- PRECAUTION 1: Read the user manual carefully before operating the device, be familiar with the equipment and operation procedures, and strictly implement; the company is not responsible for the damage caused by the improper use of the machine and the resulting potential adverse consequences;
 - PRECAUTION 2: The instrument must work in a clean environment, should avoid direct sunlight, extreme temperature changes, dust, near heat sources, high humidity places, do not place anything on top of the instrument.
 - PRECAUTION 3: The device shall be operated in undisturbed conditions so as to avoid data transmission interruption.
 - PRECAUTION 4: When there is wireless channel congestion, switch the channel (Refer to Section 3.5 SETTINGS), and then restart the probe.
 - PRECAUTION 5: Prescription Use. The device shall be operated by professional physicians, and should wears gloves before use.
 - PRECAUTION 6: The device shall be repaired by professional recognized by the manufacturer.
 - PRECAUTION 7: The device does not have shelf life. Its expected use life is 10 years. After 10 years, though the device still works normally, it is recommended to have it checked by the manufacturer.
 - PRECAUTION 8: Useless components shall be disposed according to local regulations.
 - PRECAUTION 9: Be careful when holding the device, for the device is handheld, it may fall.
 - PRECAUTION 10: Pay attention: the words “Insufficient Storage Space” will appear on the interface to remind the user to clean up space when storage space will be insufficient.
 - PRECAUTION 11: Put on a condom that meets the medical qualification for use, dispose the used condom in the medical waste recycling box after use, and then disinfect and clean the probe according to Section 4.3.
- WARNING 1: The device is not explosion-proof. Do not use it in inflammable and explosive environment (such as in the presence of anesthetic gas, oxygen or hydrogen,etc.);
- WARNING 2: Instrument is not waterproof, do not spill water or other liquids on the instrument.

WARNING: The user and/or patient should be reported “any serious incident that has occurred in relation to the device” to the our company and the competent authority of the Member State.

Section 2 GETTING STARTED

FOR YOUR PROTECTION, please read these safety instructions completely before applying power to, or operating the system.

2.1 UNPACKING

The Scanner is carefully packed to prevent damage during shipment. Before unpacking, please note any visible damage to the outside of the shipping containers.

Items should be checked in order to ensure that all ordered items have been received. The following table lists the items which should be received with each particular system.

Table 2-1 Items List for The Wireless Ultrasound Scanner

ITEMS	INCLUDED
scanner (C-Probe/L-Probe)	√

USB Cable for Charging	✓
The Wireless Ultrasound Scanner Users' Guide	✓
APP	✓
IPad	Optional

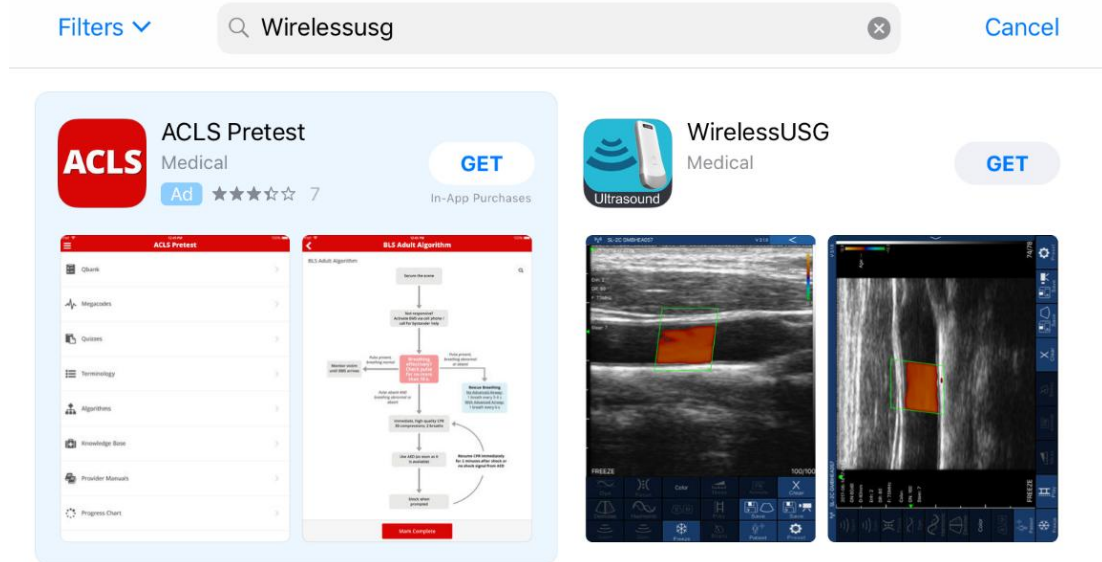
Each item should be examined for any noticeable defects or damage that may have occurred during shipment although it is packed carefully. If any defect or damage exists, please contact your local representative immediately to report the problem.

2.2 INSTALLING APP

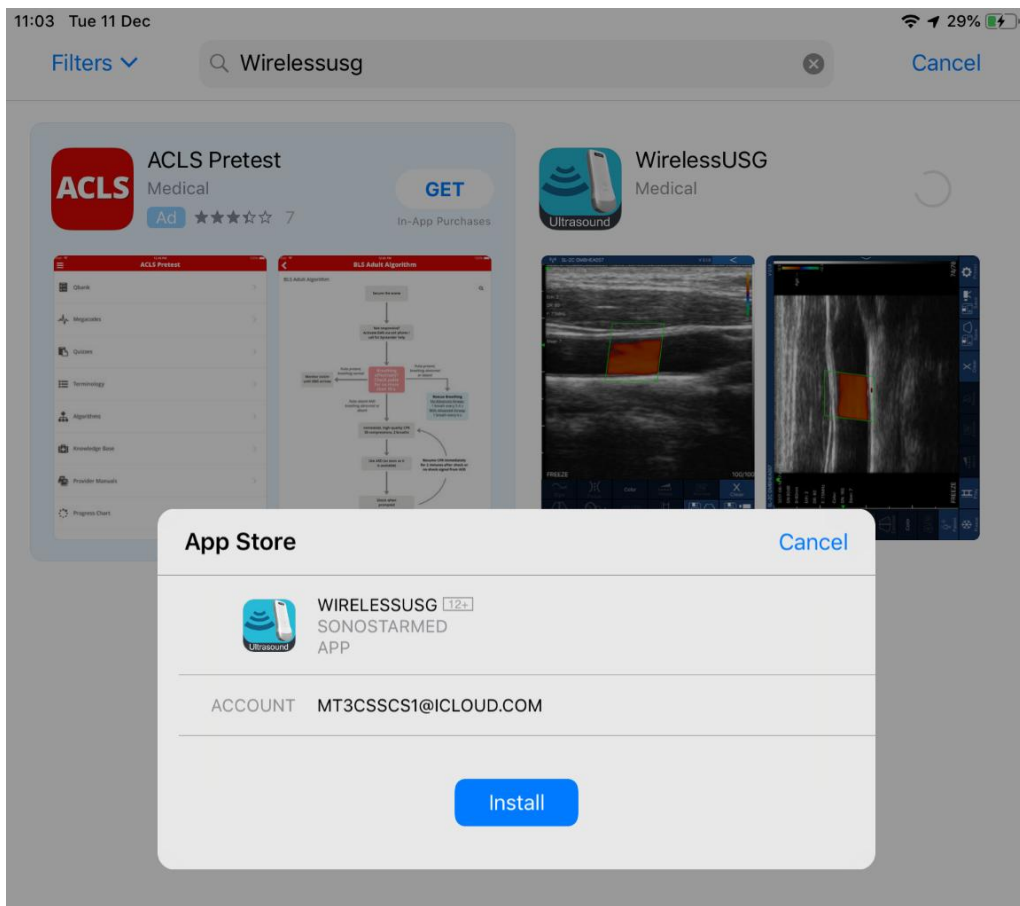
Open the App Store on the iPad or the iPhone, type "Wireless USG" in the search bar.

11:02 Tue 11 Dec

29%



Find the software and download and install it.



2.2.2 Method 2

Using the two-dimensional code scanning software to scan the two-dimensional code below, you can get the download link of APP for installation.



2.3 STARTING PROBE

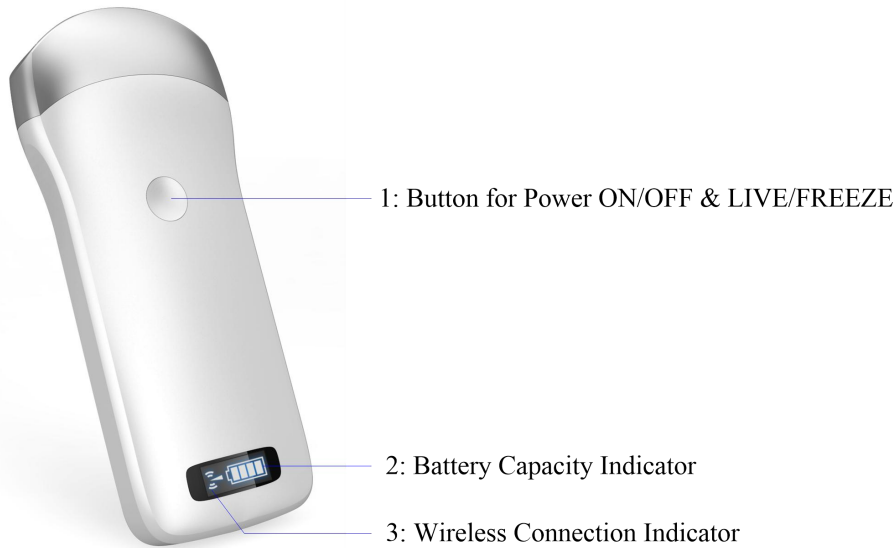


Figure 2-1 The Wireless Ultrasound Probe

The Wireless Connection Indicator and the Battery Capacity Indicator on the probe may be invisible before the probe is turned on.

Press the button to turn on the probe. The Battery Capacity Indicator will be light to indicate the capacity of the battery. The four grids of the indicator imply the battery capacity. (Probe charging will be described in section 4.)

Seconds after the probe turned on, the Wireless Connection Indicator will be light and blinking to notice that the probe is ready for a wireless connection from the iPad or iPhone.

The probe can be turned off by hold down the button for seconds. When the probe is off, the indicators will be turned off.

2.4 WIRELESS CONNECTION

When the probe is waiting for a wireless connection as described in previously, launch the Settings of iPad or iPhone, turn on the Wi-Fi (if not on), Find the SSID of the probe. The SSID is like: "SS-1 GMBFCA001", the suffix "GMBFCA001" is a code generated from Serial Number. Connect to the SSID with the password same as the Serial Number (in lower case). The Serial Number is in the form like "WSPBFCA001" with the prefix of "WSP". It can be found on the surface of the probe.

After Wi-Fi is connected, launch the WirelessScan App, after the connection from the app to the probe is confirmed, the Wireless Connection Indicator on the probe will be light with no blinking.

Every connection steps are done. The operations of using the system to finish ultrasonography task will be described in the next section.

Section 3 APP OPERATIONS

3.1 ULTRASOUND SCAN

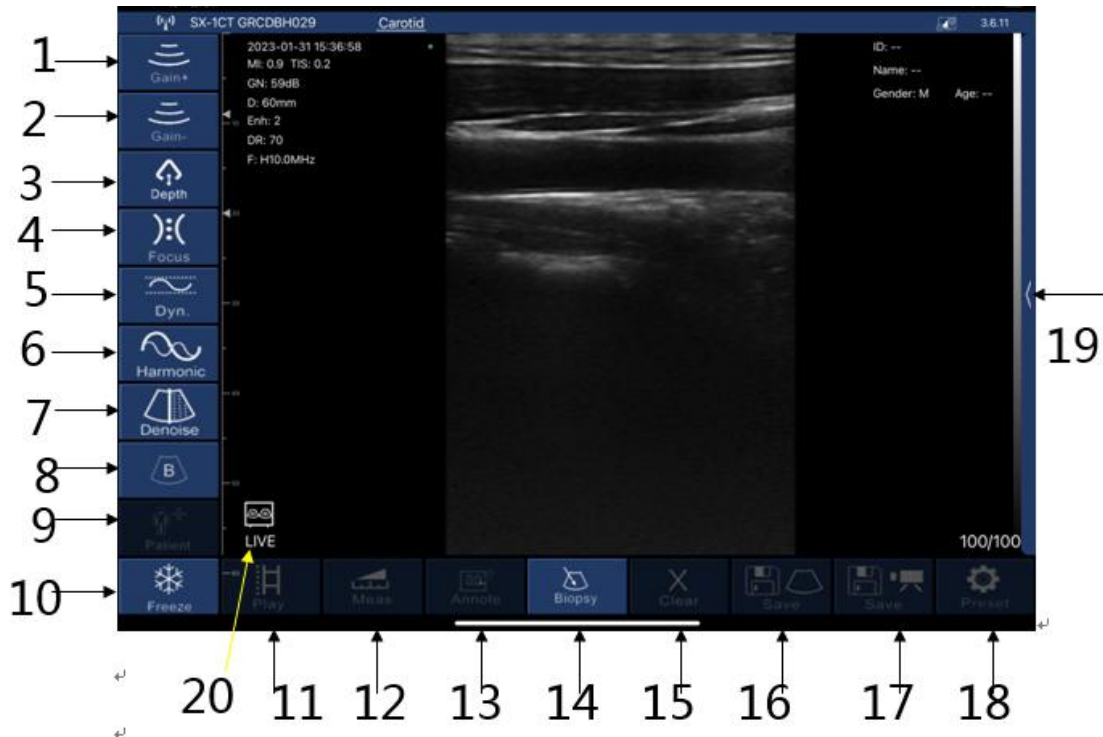
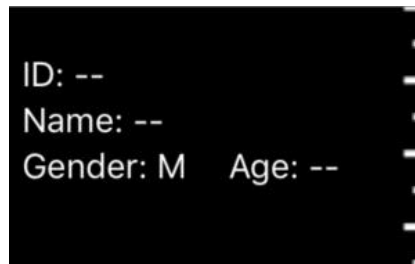


Figure 3-1 Main Screen

1. Transmission Gain +: increase image gain.
2. Transmission Gain -: reduce image gain.
4. Focus: adjust the focus position of the image.
5. Dynamic range: adjust the dynamic range of the image.
5. Frequency: can change the working frequency of the probe.
6. Noise reduction: used to eliminate low-level echoes caused by noise.
7. Noise reduction, image processing
8. Image mode: B mode, B / M mode, Color Doppler mode (COLOR), Energy Doppler mode (PDI), Pulse Doppler (PW).
9. Patient information management: patient information input.
10. Freeze/ operate: image freeze and thaw.
11. Movie playback: replay after the image freezes.
12. Measurement: distance / area / obstetrical measurement.
13. Note: enter a comment on the image.
14. Puncture: draw a puncture line for puncture guidance.
15. Delete measurements and notes: delete measurement results and notes on images.
16. Save the image: save a single image.
17. Save Image Video: save whole Image Video.
18. Setting: WIFI channel selection to avoid channel blocking.
19. TGC (time gain compensation) the function menu pops up by clicking on the top of the right "<".
- 20 BB Dual B mode

3.2 ENTER PATIENT INFORMATION

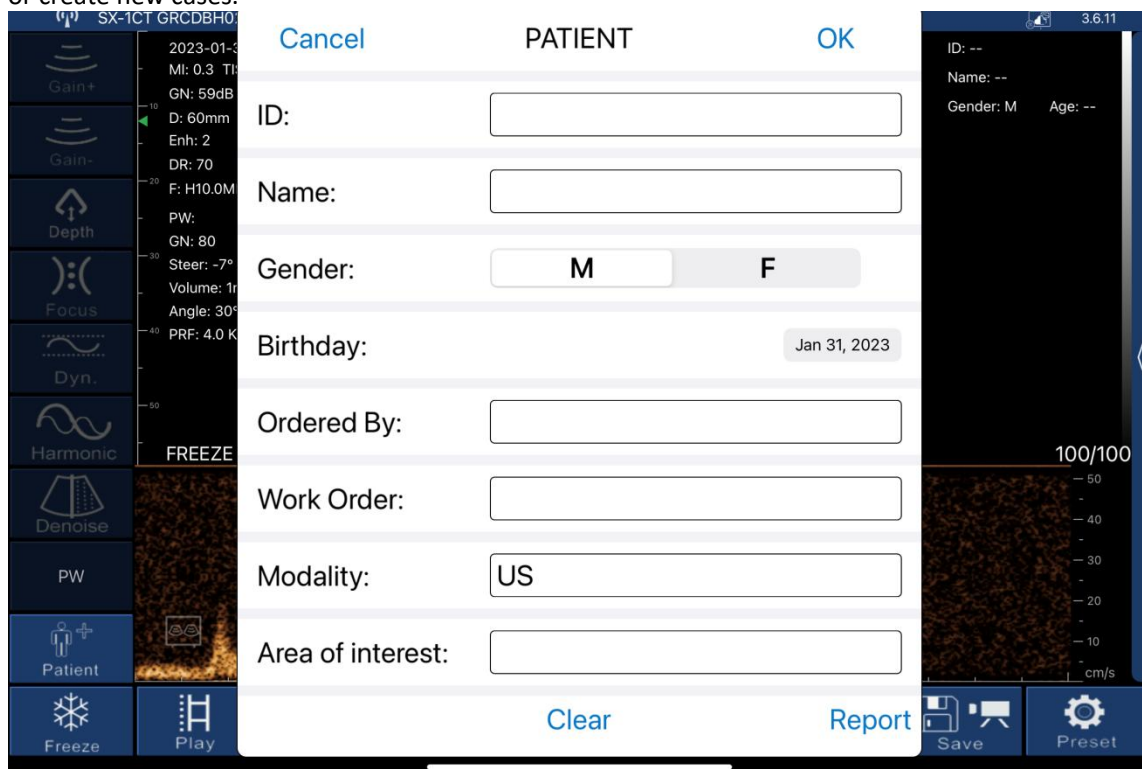
First, click on the top right of the ultrasonic software interface with your finger



Pop-up screen



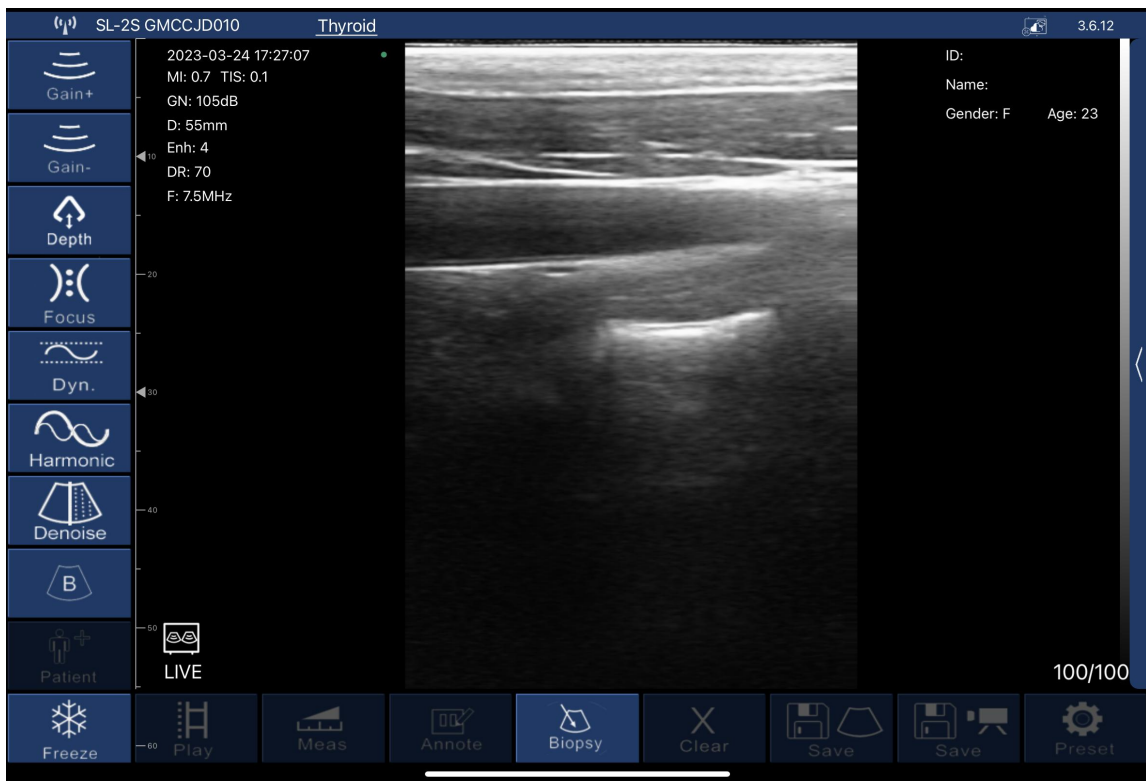
In ID, enter the name of the patient information bar, click on sex selection, picture mode, and then click OK, the patient information will be entered, if an input error, you can click again to modify or create new cases.



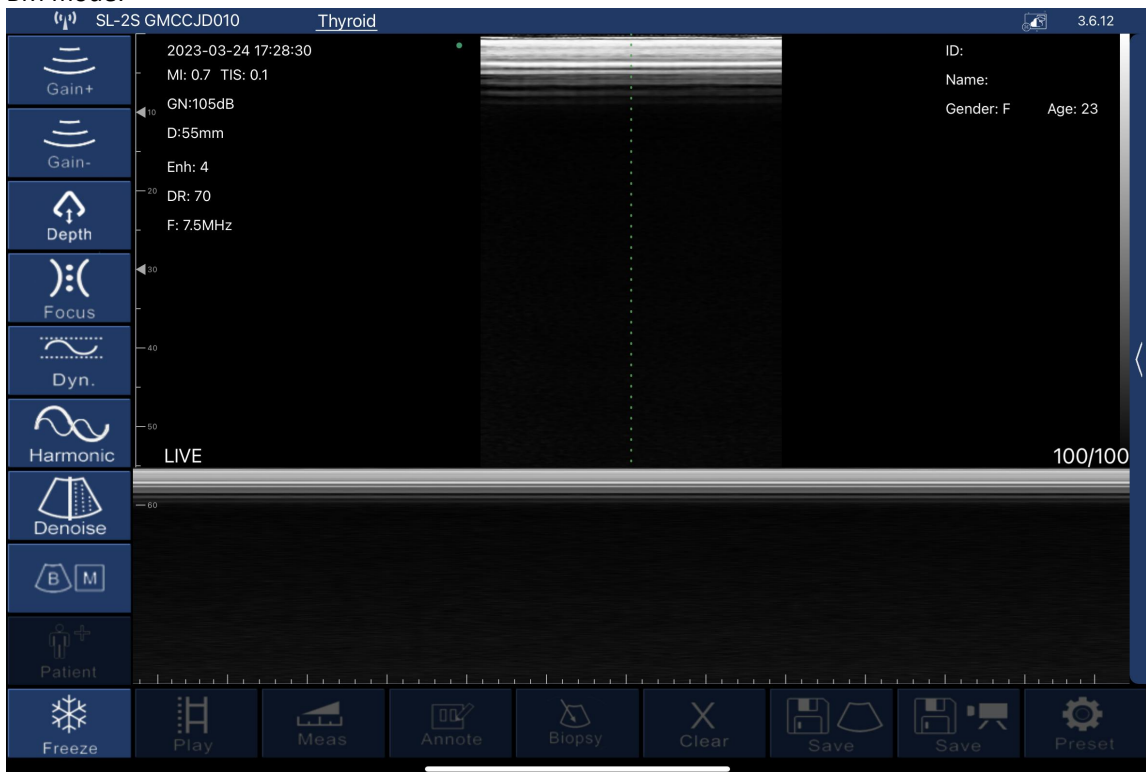
3.3 SELECT THE IMAGE MODE

Enter patient information section can select the image mode, select B mode or BM mode, you can enter different modes, as shown:

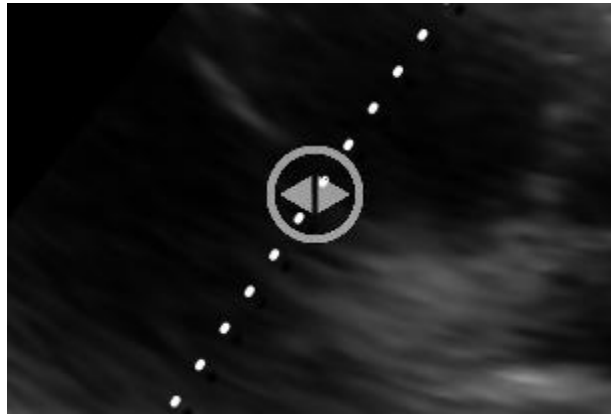
B mode:



BM mode:

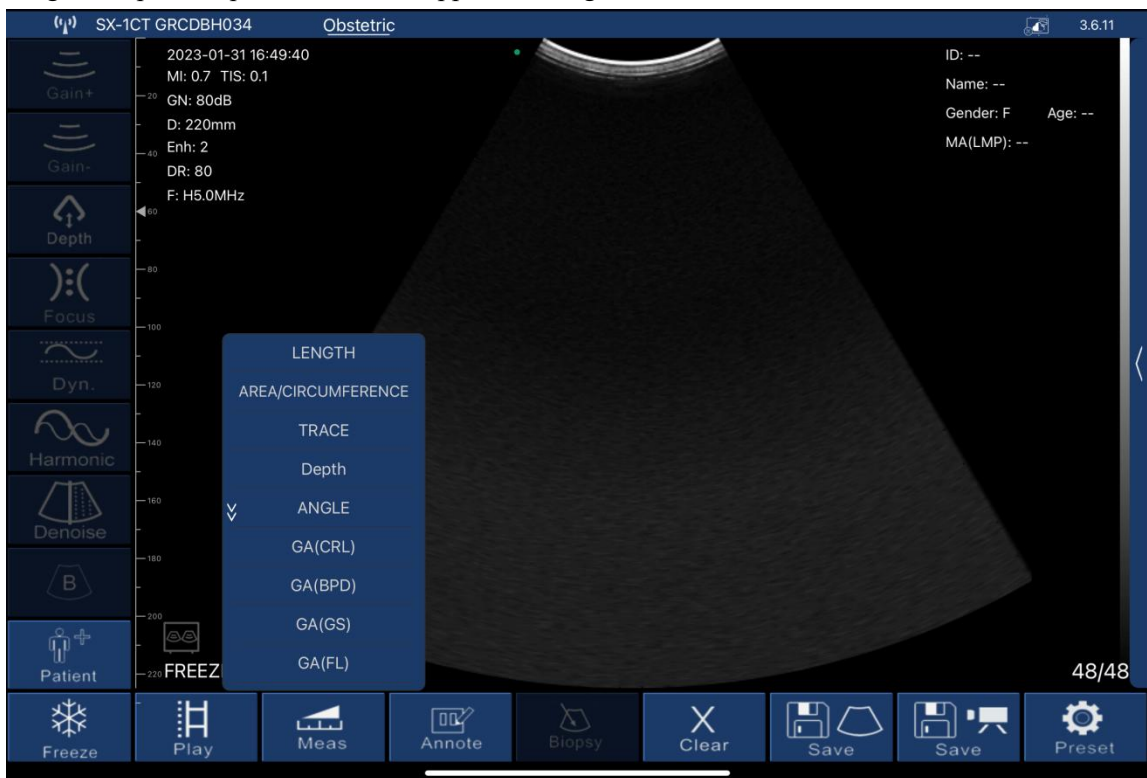


In the BM mode, by clicking with your finger to move here, you can adjust the position of M sample lines:



3.4 MEASURING

Click “Measure” in the B mode freeze state, and then the ten measurement functions of the screen shown in Picture 3-8 will pop up. Users should select the appropriate measurement function according to the product probe model, the applicable range and the data to be measured.



Picture 3-9 Measurement function

After selecting the “LENGTH” length measurement function, click on the two points to be measured in the frozen screen, the measurement trajectory will appear, click the moving point on the trajectory line (as shown in the middle of Figure 3-7), move the trajectory, and adjust the length. The size of the real-time measurement data is displayed at the top right of the screen. Among them, GA (CRL), GA (BPD), GA (GS), and GA (FL) are measured in the same manner.

Select the "AREA/CIRCUMFERENCE" area/circumference measurement function, select the 3 o'clock position to be measured in the frozen screen and click on it. 3 moving points will appear on the screen, and 3 moving points will automatically form an elliptical trajectory. Click on the moving point to adjust the measurement position, and the measured data will be displayed in real time on the upper right of the screen. Among them, GA (HC) and GA (AC) are measured in the same way.

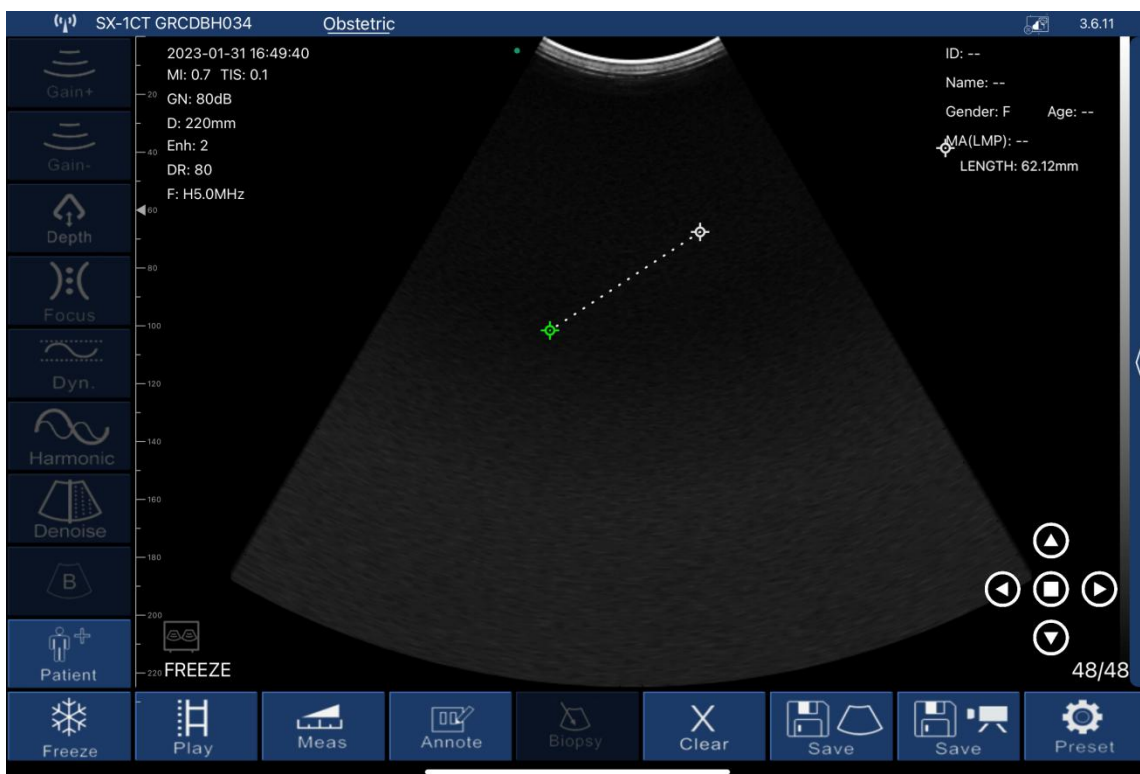
Select the “ANGLE” angle measurement function to measure the angle. You can select the 3

o'clock position to be measured in the frozen screen and click it will appear 3 moving points on the screen. 3 moving points will automatically form an angle. Click the moving point to adjust the measuring angle. The measured data is displayed in real time on the upper right.

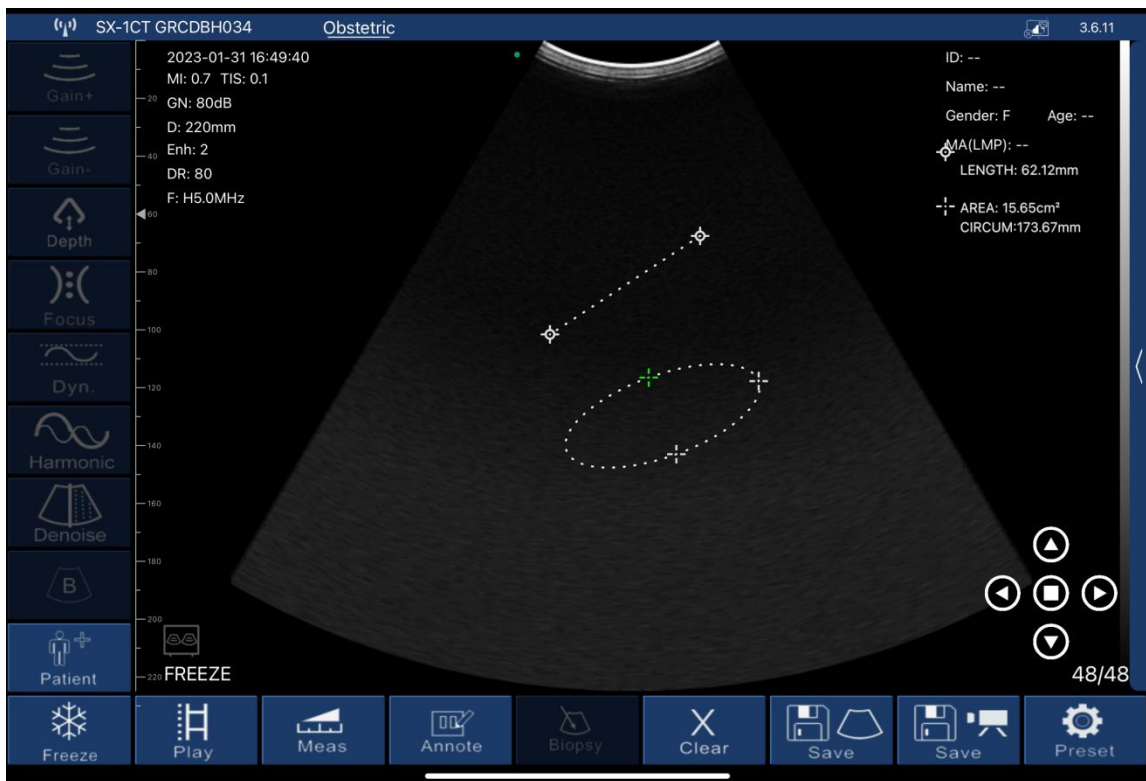
After selecting the “TRACE” track area measurement function, you can measure the irregular position area of the edge, and draw the edge on the screen with your finger to get the area size. The final measured data is displayed at the top right of the screen.

Note: Measurement functions GA (CRL), GA (BPD), GA (GS), GA (FL), GA (HC), and GA (AC) are only available for obstetrics.

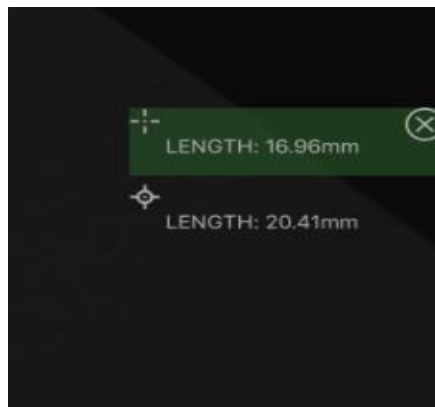
The above measurement functions can be fine-tuned using the virtual trackball of the screen. During the measurement, you can click on the generated measurement point, and the virtual trackball that appears (as shown in the lower right corner of Figure 3-10) can be fine-tuned according to the direction of the measurement point.



Note: When measuring other data, such as area, in addition to finger click, the size can also be adjusted by the virtual scroll ball.



Click on the right data (X), Measurement data can be deleted:



3.5 STORAGE OF IMAGES

When image is showing in image area, Save Image Button (11) can be pressed to save the image to the album of the iPad.

By pressing the Browse Stored Image Button (12), users can select a stored image and show it on the image area.

The stored images can be exported with same method as photos exporting using iTunes or other equivalent methods.

3.6 SETTINGS

If users hold the probe on the right hand, and want to operate the software by the left hand, the software provides settings to adjust the interface.

Press the settings button(14), settings screen will appear as Figure 3-5 below.

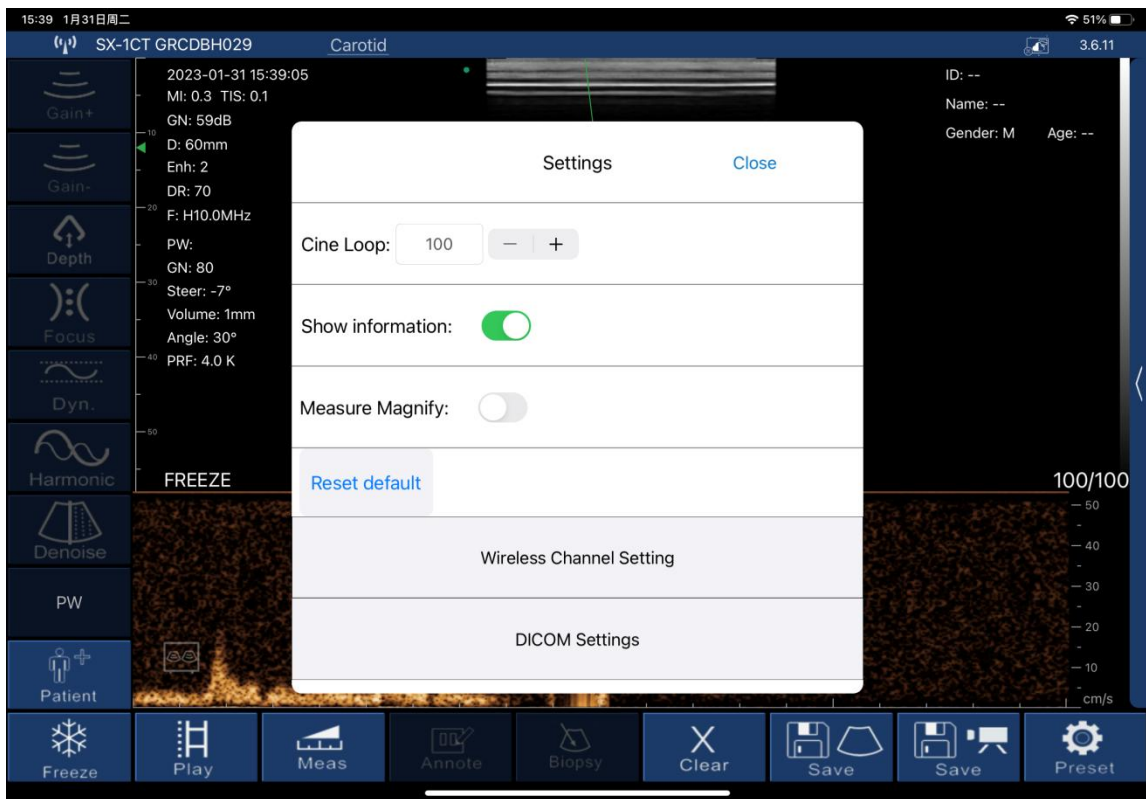


Figure 3-2 Settings Screen

Switch ON/OFF the Left Hand Operation to adjust the screen to convenience operators.

When the system is using in an environment where the WiFi channel is crowd, a new channel can be selected for the probe by pick a channel from the picker and tap Select button. After 2 seconds, please restart the probe to make the new channel available and the user also have to reconnect the probe with a different SSID.

Section 4 MAINTENANCE

4.1 PROBE CHARGING

When battery goes down, it is necessary to recharge the probe. Pull the insertion at the end of the probe, then connect the USB Charger and USB Cable with the probe to charge the probe as shown in figure 4-1. When in charging, the battery indicator will be blinking and the grids indicate the capacity of the battery charged.



Figure 4-1 Charge the Probe

If four grids all light and the indicator not blinking means the battery is fully charged. Unplug the USB cable and the insertion should be carefully plugged to make the probe able to keep out water.

4.2 WATERPROOF IPAD

A waterproof bag is provided by local repository. Users can use it to protect the iPad when it is used in humidity or dirty fields.

4.3 CLEANING AND DISINFECTION

4.3.1 Precaution and warnings

When cleaning and disinfecting:

- Follow the procedures in the order they are described in this guide, without skipping steps.
- Follow the manufacturer's instructions, recommendations, and guidelines for cleaners and disinfectants, as well as your regional regulations.
- Check expiry dates, concentration, and efficacy of the chemicals used.
- Wear the appropriate personal protective equipment (PPE), such as eyewear and gloves, as recommended by the chemical manufacturer.

- Repeated use and cleaning over the course of the scanner 's life may deteriorate its cleanliness.
- Using incompatible solutions to clean the scanner may damage its surface.
- Cleaning or disinfecting the scanner while the battery is installed may cause the battery to short-circuit and overheat, causing an electric shock or burn.

WARNING: During an emergency where the scanner is used to examine multiple patients in a short period of time, the lack of proper cleaning and disinfecting between patients may spread infections to other patients and users.

Put on a condom that meets the medical qualification for use, dispose the used condom in the medical waste recycling box after use, and then disinfect and clean the probe

4.3.2 Cleaning and Disinfection the probe

1. Thoroughly dry the instrument with a clean, soft cloth before using.
2. To clean the probe, Use a soft cloth dampened with 75%Alcohol to wipe the Probe until it is thoroughly cleaned.
3. To remove all traces of disinfectant solution, wipe the instrument with a clean soft cloth dampened in sterile water or potable tap water. Wiping the device three separate times to remove all residual disinfectant is recommended.
4. Verify that all gel, particulate matter, and bodily fluids have been removed.
5. Dispose the soft cloth and the instrument used to insert the cloth.

4.4 STORAGE

When not in use, it is recommended that the equipment should be put in the case. While stored, the equipment should be protected from temperature extremes.

4.5 TROUBLE SHOOTING

Inspect: check if the probe and the scanner is properly connected.

Fault handling:

Serial number	problem	Solution method
1	No response after pressing the power switch	Check wires and plugs
2	Display on the screen to show the band or snowflake like interference	1.Check if any other device is started 2.Check the electric field or magnetic field in the surrounding environment.
3	The image area is dark.	1.adjusting brightness

4.6 Disposal

*Warning: products should not be discarded at will.

-Battery recycling meets local requirements.

-Recycling of waste electrical and electronic products should comply with local laws and regulations.

WARNING: The user and/or patient should be reported “any serious incident that has occurred in relation to the device” to the our company and the competent authority of the Member State.

Section 5 Safety

The operation safety is the most important concern of the designer . To ensure the safety and efficiency of the system, the operator should read carefully about this chapter before using the system.

5.1 Safety Instructions

Read and understand all precautions in this manual before using the system.

Keep this manual with the system at all times. Periodically review the procedures for operation and safety precautions.

To maintain the performance and safety of the system, electric and mechanical safety inspections for the system should be performed periodically by professional technicians in less than 6 months.



- Do not use the system in the applications other than those listed in the intended use. Otherwise, it may result in system damage or serious injury.
- This equipment can only be used for diagnosis, cannot be used for treatment.

5.1.1 Electric Safety

- The biocompatibility of this product has been verified, in normal circumstances, it will not bring harm to the operator or patient.

- No modification of this equipment is allowed.
- If any operator requests more information such as circuit diagrams, parts list and product descriptions, for repairs carried out by qualified technical personnel, please contact us.
-
- Please check and replace the battery periodically, please use batteries as power supply when there is any problem with protective earthing
- Warning: Class I equipment, to avoid the risk of electric shock, the equipment must only be connected to a supply mains with protective earth.
-
- The video printer should be connected to the cable provided by the manufacturer, otherwise, there is a danger of electric shock.
-
- Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure. If carelessly pour any water onto the system, immediately stop using the ultrasound system and contact Service Representative immediately.
- Only use the probes provided by the manufacturer. Otherwise, the ultrasound system cannot be performed, and an accident such as a fire may result in the worst case.
- The machine that are not serviced or maintained while in use with the patient.
-
- The outer surface of the portions of transducer assembly which is intended to be inserted into a PATIENT should be checked to ensure that there are no unintended rough surfaces, sharp edges or protrusions which may cause harm.
- Please read the instructions and then set and control the acoustic output levels.



- Only qualified physicians or sonographers can perform ultrasound scanning on human body for medical diagnosis.
- The system can only be maintained by the person authorized or trained by the manufacturer.
- The transducer is treated as the applied part.
- Do not operate this system in an atmosphere containing flammable gases or liquids such as anesthetic gases, hydrogen, and ethanol, because there is a danger of explosion.
- Do not use this system at the same time with other equipment such as electric knife, defibrillator, and other high-frequency therapy equipment. Otherwise, there is danger of electric shock.
- keep the system dry, avoid being transported to the field with a great temperature change to prevent condensation or water droplets from resulting in short circuit
- Connect the earth conductor before powering on the system, Disconnect the grounding cable after powering off the system. Otherwise, there is a danger of electric shock.

5.1.2 Mechanical Safety



- Be careful when holding the device, for it is handheld, it may fall.



- Do not use this system in the strong electromagnetic field. Using the system in the improper environment may result in malfunction or damage.
- Only the peripherals and accessories (such as probes, peripherals or cables) provided or recommended by the manufacturer can be used. Using other devices or accessories may degrade the system performance and even cause an electrical shock.



- Place the system on a level desk.
- The plug is used as disconnect to the mains supply, do not to position the machine so that it is difficult to operate the disconnection device.
- Do not place the system on a tilted plane with the angle larger than 10°. Otherwise, the system will fall off to cause system damage or personal injury.

5.1.3 Accessories Safety

- You should use the legally marketed medical ultrasound couplants. Please check the user instruction carefully before using it, please manage and use the ultrasound couplants correctly to prevent it being polluted.



- Disconnect the probe from the system after freezing an image or powering off the system. Otherwise, the system or the probe could be damaged.



- Use the probe carefully. If any part of the transducer surface is scratched, immediately stop using the probe. Otherwise, there is a danger of electric shock.
- After disinfecting the accessories, chemicals must be washed out from the accessories. Remaining residual chemicals or gases could not only result in damage to the accessories but also can be harmful to human bodies.

5.2 Principles of Using Acoustic Power



- Perform ultrasound procedures prudently under the guidance of the ALARA (as low as reasonably achievable) principle. Expose the patient to the lowest practical transmit power levels in the shortest possible period to achieve a satisfactory diagnosis.
- The operator should notice the effect of the heat on the patient body when the exam is performed around the bones and the nearby soft tissues which can transform the ultrasound energy to heat energy. Take special care to the fetal whose bones are growing.

5.2.1 Biological Safety

Diagnostic ultrasound is recognized as being safe, but the risk of biological effects exists when using it in high exposure levels and long exposure times. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient.

5.2.2 Mechanical and Thermal Indices

The ultrasound system displays two parts: thermal Index (TI) and Mechanical Index (MI). The MI/ TI value of the machine is real time displayed at the upper right corner, regarding how to change TI display type, please choose: **Preset** → [System Preset] → [TI].

■ Meaning of MI/TI

Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies with tissue type. The potential mechanical bioeffects varies with peak pressure and ultrasound frequency. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. There is no specific MI value that means that a mechanical effect is actually occurring. The MI should be used as guide for implementing the ALARA principle.

The TI value informs the operator about the conditions that might lead to an increase in temperature at surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. That is, the TI value informs the operator about the potential temperature rise in body tissue. It is an estimate of temperature increase in body tissue with specific properties. The actual amount of an temperature rise is influenced by factor such as tissue type, vascularity, mode of operation and others. The TI value should be used as a guide for implementing the ALARA principle. Depending on the examination and type of tissue involved, TI could be one of three types.

Soft Tissue Thermal Index (TIS) is used when imaging soft tissue only, it provides an estimate of potential temperature rise in soft tissue.

- Bone Thermal Index (TIB) is used when bone is near the focus of the image as in the third cropester OB examination, it provides an estimate of potential temperature rise in the bone or adjacent soft tissue.
- Cranial Bone Thermal Index (TIC) is used when bone is near the skin surface as in transcranial examination, it provides an estimate of potential temperature rise in the bone or adjacent soft tissue.

■ Precision of MI/TI

TI and MI values are displayed in real time on the screen. The operator should observe these index values during examinations and ensure that exposure time and output values are maintained at minimum amounts needed for effective diagnosis. The MI and TI precision is 0.1.

5.2.3 Acoustic Output Statement

5.2.3.1 The Influencing Factors of Acoustic Uncertainty

When estimating accuracy of displayed numerical values, many factors are considered:

- The probe changeability

- The system changeability
- Changeability and accuracy of measurement
- Possible operating conditions and testing numbers needed to obtain displayed result accuracy of the diagnostic system
- Whether the display accuracy depends on specific system combination, mode combination , probe component and launch mode combination, or all of above
- Algorithm accuracy of the system software used to calculate the MI/TI
- Approximation engineering method used in real time computation

5.2.3.2 Differences between Actual and Displayed MI and TI

For many assumptions used in the process of measurement and calculation, actually they are conservative. For most organizations path, high estimate is made in the measurement and calculation process of tissue exposure intensity. For example, using attenuation coefficient $0.3\text{dB cm}^{-1}\text{ MHz}^{-1}$ much lower than the actual human tissue attenuation coefficient, choosing conservative values of tissue characteristic. Therefore, displayed MI and TI values should be relative information for reference, they serve to indicate to the operator whether a particular setting of the system increases or decreases the possibility of Thermal or Mechanical effect, used to help the operator be careful to use ultrasonic diagnostic system and follow the ALARA principle, these values can not be equal to actual values.

5.2.3.3 Uncertainty of Measurement

Sound pressure is the most basic data of sound field measurement, and other sound field parameters can be deduced from sound pressure, so when analysing measurement uncertainty, only take sound pressure for analysis and uncertainty of other parameters can be deduced from the sound pressure.

Measurement uncertainty mainly include repeated measurement uncertainty and the system uncertainty, the system uncertainty is an order of magnitude higher than repeated measurement uncertainty, so the main analysis is the system uncertainty. Mainly decided by the following factors:

1. The sensitivity of hydrophone:According to hydrophone calibration report provided by ONDA company, the maximum allowable error of sound pressure for hydrophone is plus or minus 12%;
2. Scope: according to agilent DSO6502A specifications, its effect on the sound pressure is plus or minus 2%;
3. Temperature: effect of the thermocouple on sound pressure error is plus or minus 4%;

Above all uncertainty components are not related, synthetic standard uncertainty of sound pressure is :plus or minus 13%.

5.2.4 Operator Control Property

There are three types of operation control related to the generation of mechanical/thermal effect: direct control and indirect control, receiver control. Qualified operator should try to cut down the acoustic output in the premise of effective diagnostic images.

■ Direct control The direct control of the acoustic output of this system is adjusting voltage size. But its maximum acoustic output shouldn't be more than displayed acoustic output limit in any modes.

■ Indirect control

The controls that indirectly affect output are many imaging parameters. These are operating modes, frequency, focal point number/position, image depth and pulse repetition frequency (PRF)(By adjusting the [Scale] of the toolbar).

The operating mode determines whether the ultrasound beam is scanning or non-scanning. Thermal effect is closely connected to M Mode, PW Doppler and Color Mode.

Acoustic attenuation of tissue is directly related to transducer frequency.

The focal point number and position is related to active aperture of transducer and beam width.

For the pulse repetition frequency(PRF)(By adjusting the [Scale] of the toolbar), the higher the PRF,

the more acoustic output power increased over a period of time.

■ The receiver control

The receiver control does not affect the acoustic output, including gain, dynamic range, and image processing, etc. Therefore, in the image optimization, should adjust the receiver control to optimize images firstly, the second are through direct control and indirect control.

When acquiring images, it is recommended to use the default (or as low as possible) acoustic output location, and use the gain control to compensate. The default setting is commonly 70% of maximum allowed acoustic output value, which will not cause harm to the operator, and for the probe is the most effective value

5.2.5 Acoustic Power Settings

The ultrasound system has been preset the parameters for each exam mode with different probes before shipment. When the ultrasound system is powered on, a new patient is created or the application mode is changed, the system will retrieve the default settings. You can also reset the parameters.

5.2.6 ALARA

It is required to practice ALARA when using ultrasound energy. Practicing ALARA ensures that the total energy level is controlled below a low level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is controlled by output intensity and total radiation time. The output intensity necessary for examinations differs depending on the patient and clinical case.

Not all examinations can be performed with an extremely low level of acoustic energy. Controlling the acoustic level at an extremely low level leads to low-quality images or insufficient Doppler signals, adversely affecting the reliability of the diagnosis. However, the sound power which is used greater than the actual needs does not contribute to improving the quality of diagnostic information either, it will increase the risk of biological effects.

The operator must take responsibility for the safety of patients.

5.3 Electromagnetic Compatibilities

Electromagnetic compatibilities are the abilities of the system or equipment to operate normally in the electromagnetic environment and not to radiate any electromagnetic interruptions to any other objects which are in the same environment.

This system is designed in accordance with the current EMC requirement. And the ultrasound image will degrade instantly if the system is used in the electromagnetic field environment. If the degradation of the image is found, it is recommended to inspect the operation environment to confirm the radiation source.

5.3.1 Electromagnetic Emission

This system is applicable for the following environment. You should use this system under the suggested environment.

1	Guidance and manufacturer's declaration - electromagnetic emission		
2	The UProbe-C Wireless Probe Type Ultrasound Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of UProbe-C Wireless Probe Type Ultrasound Scanner should assure that it is used in such environment.		
3	Emission test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The UProbe-C Wireless Probe Type Ultrasound Scanner 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. The UProbe-C Wireless Probe Type Ultrasound Scanner is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

5.3.2 Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The UProbe-C Wireless Probe Type Ultrasound Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the UProbe-C Wireless Probe Type Ultrasound Scanner should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient \ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input output lines	±2 kV for power supply lines ±1 kV for input output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	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 IEC 61000-4-11	< 5%U _T (>95% dip in U _T) for 0.5 cycle 40%U _T (60% dip in U _T) for 5 cycles 70%U _T (30% dip in U _T) for 25 cycles < 5%U _T (>95% dip in U _T) for 5 sec	< 5%U _T (>95% dip in U _T) for 0.5 cycle 40%U _T (60% dip in U _T) for 5 cycles 70%U _T (30% dip in U _T) for 25 cycles < 5%U _T (>95% dip in U _T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the UProbe-C Wireless Probe Type Ultrasound Scanner requires continued operation during power mains interruptions, it is recommended that the UProbe-C Wireless Probe Type Ultrasound Scanner be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	U _T is the a.c. mains voltage prior to application of the test level.		

5.3.3 Recommended Separation Distance

The UProbe-C Wireless Probe Type Ultrasound Scanner is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the UProbe-C Wireless Probe Type Ultrasound Scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the the UProbe-C Wireless Probe Type Ultrasound Scanner as recommended below, according to the maximum output power of the communications equipment.



If the system has generated the interference (confirmed by powering on and off the system), you or the qualified service personnel should solve the problem by following the steps as below:

- Reposition the affected system.
- Place this system further away from the affected system.
- Supply power to this system in other ways other than the way used currently.
- Contact the manufacturer as soon as possible.

Rated Maximum Output Power of Transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E1} \right] \sqrt{P}$
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

Appendix A Specifications

Complied Standards

EN 60601-1 (IEC 60601-1), Medical electrical equipment Part 1: General requirements for basic safety and essential performance, Class I, BF, continuous operation EN 60601-2-37:2008 (IEC 60601-2-37:2007), Medical Electrical Equipment Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment EN 60601-1-2:2007 (IEC 60601-1-2: 2007), Class A

Safety Types

Type of protection against electric shock Internally powered

Degree of protection against electric shock Type-BF applied part

Operation mode Continuous working

Installation and operation type Portable Equipment

Degrees of protection against harmful liquid IPX5

Degree of safety of application The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Operating system requirements

IOS 9.0 and above version.

IPad is the Wi-Fi signal transmitted by the Wi-Fi module of the scanner. It is a local area network, not connected to the Internet, but only used for signal and data transmission.

The information using wifi communication is as follows:

IT Security or Wi-Fi

Working frequency band (MHz)	2400-2483.5
Receiving frequency (MHz)	2412-2462
Modulation type	802.11b/g/n
Frequency characteristic	Suitable for short-distance micro-power wireless communication equipment
Effective radiated power	8mW

Environmental Requirement

	Operations	Storage and Transportation
Relative Humidity	25% to 80%, non-condensing	25% to 93%, non-condensing
Ambient Temperature	5°C to +40°C	-20°C to +55°C
Atmospheric Pressure	700hPa to 1060hPa	700hPa to 1060hPa
Max. Altitude	3000m	3000m

Appendix B Acoustic Output Data

These data are acquired through the test report of IEC 60601-2-37.

Transducer Model: Uprobe-C, Operating Model: B mode

Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.78	0.17		0.17		N/A
Index component value			0.17	0.17	N/A	0.17	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	1.36					
	P (mW)		11.56		11.56		N/A
	P_{1x1} (mW)		11.56		11.56		
	Z_s (cm)			N/A			
	Z_b (cm)					N/A	
	Z_{MI} (cm)	5.18					
	$Z_{PII,\alpha}$ (cm)	5.18					
	f_{awf} (MHz)	3.01	3.01		3.01		N/A
Other Information	p_{rr} (Hz)	1266.30					
	s_{rr} (Hz)	6.82					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $Z_{PII,\alpha}$ (W/cm ²)	83.94					
	$I_{spta,\alpha}$ at $Z_{PII,\alpha}$ or $Z_{SII,\alpha}$ (mW/cm ²)	1.20					
	I_{spta} at Z_{PII} or Z_{SII} (mW/cm ²)	2.93					
	p_r at Z_{PII} (MPa)	2.33					
Operating control conditions	Display focus(mm)	30, 50, 70	30, 50, 70	30, 50, 70	N/A	30, 50, 70	N/A
	Display depth(mm)	90	90	90	N/A	90	N/A
	Working frequency(MHz)	3.5	3.5	3.5	N/A	3.5	N/A
	Display focus number	3	3	3	N/A	3	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Transducer Model: Uprobe-C, Operating Model: B+M mode

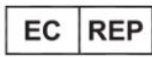
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.78	0.17		0.26		N/A
Index component value			B:0.17 M:N/A	B:0.17 M:0.07	N/A	B:0.17 M:0.26	
Acoustic Parameters	$p_{r. \alpha}$ at Z_{MI} (MPa)	1.36					
	P (mW)		B:11.56 M:10.88		B:11.56 M:10.88		N/A
	$P_{1 \times 1}$ (mW)		B:11.56 M: N/A		B:11.56 M: N/A		
	Z_s (cm)			4.00			
	Z_b (cm)					4.80	
	Z_{MI} (cm)	5.18					
	$Z_{PII. \alpha}$ (cm)	5.18					
	f_{awf} (MHz)	3.01	3.01		3.01		N/A
Other Information	p_{rr} (Hz)	1266.30					
	s_{rr} (Hz)	B:6.82					
	n_{pps}	B:1					
	$I_{pa. \alpha}$ at $Z_{PII. \alpha}$ (W/cm^2)	83.94					
	$I_{spta. \alpha}$ at $Z_{PII. \alpha}$ or $Z_{SII. \alpha}$ (mW/cm^2)	45.59					
	I_{spta} at Z_{PII} or Z_{SII} (mW/cm^2)	133.43					
	p_r at Z_{PII} (MPa)	2.33					
Operating control conditions	Display focus(mm)	30, 50, 70	30, 50, 70	30, 50, 70	N/A	30, 50, 70	N/A
	Display depth(mm)	90	90	90	N/A	90	N/A
	Working frequency(MHz)	3.5	3.5	3.5	N/A	3.5	N/A
	Display focus number	3	3	3	N/A	3	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Transducer Model: Uprobe-L, Operating Model: B mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.94	0.03		0.03		N/A
Index component value			0.03	0.03	N/A	0.03	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.39					
	P (mW)		0.90		0.90		N/A
	P_{1x1} (mW)		0.90		0.90		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	1.02					
	$z_{PII,\alpha}$ (cm)	1.02					
	f_{awf} (MHz)	6.49	6.49		6.49		N/A
Other Information	p_{rr} (Hz)	1266.30					
	s_{rr} (Hz)	6.82					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	202.40					
	$I_{spta,\alpha}$ at $z_{PII,\alpha}$ or $z_{SII,\alpha}$ (mW/cm ²)	2.49					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	4.29					
	p_r at z_{PII} (MPa)	3.00					
Operating control conditions	Display focus(mm)	8, 15	8, 15	8, 15	N/A	8, 15	N/A
	Display depth(mm)	20	20	20	N/A	20	N/A
	Working frequency(MHz)	7.5	7.5	7.5	N/A	7.5	N/A
	Display focus number	2	2	2	N/A	2	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Transducer Model: Uprobe-L, Operating Model: B+M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.94	0.05		0.11		N/A
Index component value			B:0.03 M:0.02	B:0.03 M: N/A	N/A	B:0.03 M:0.11	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	2.39					
	P (mW)		B:0.90 M:0.89		B:0.90 M:0.89		N/A
	P_{1x1} (mW)		B:0.90 M: N/A		B:0.90 M: N/A		
	Z_s (cm)			N/A			
	Z_b (cm)					1.02	
	Z_{MI} (cm)	1.02					
	$Z_{PII,\alpha}$ (cm)	1.02					
	f_{awf} (MHz)	6.49	6.49		6.49		N/A
Other Information	p_{rr} (Hz)	1266.30					
	s_{rr} (Hz)	B:6.82					
	η_{pps}	B:1					
	$I_{pa,\alpha}$ at $Z_{PII,\alpha}$ (W/cm^2)	202.40					
	$I_{spta,\alpha}$ at $Z_{PII,\alpha}$ or $Z_{SII,\alpha}$ (mW/cm^2)	54.37					
	I_{spta} at Z_{PII} or Z_{SII} (mW/cm^2)	86.25					
	p_r at Z_{PII} (MPa)	3.00					
Operating control conditions	Display focus(mm)	8, 15	8, 15	8, 15	N/A	8, 15	N/A
	Display depth(mm)	20	20	20	N/A	20	N/A
	Working frequency(MHz)	7.5	7.5	7.5	N/A	7.5	N/A
	Display focus number	2	2	2	N/A	2	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							



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