Wireless Probe Type Ultrasound Scanner

BProbe

User's Guide

No.：SS-IFU-1501-03 Versions：A/2
Date：2021.12

1. Introduction

The Wireless Probe Type Ultrasound Scanner is the new generation instruments for bladder volume calculating with the outstanding feature of wireless.

Different from traditional ultrasound scanner with a cable connecting from probe to main unit, no cable appears at the end of the probe of the Scanner. The probe of a Scanner is highly integrated with ultrasound image processing, power management and a wireless signal provider to be connected by the main unit. Unlike traditional devices, the display part displays images through the iPad.The Probe contains a WiFi module that can be connected to the iPad. With the Probe be connected through WiFi and the App's running, enjoy your days of working without the trouble making by cables.

This manual is intended to provide a through 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 bladder volume calculating needs.

1.1. Signs and Meaning

Sign	Meaning
	Caution! Please consult the accompanying document.
	Consult the user manual
	Type BF applied part
IPN1N2	Degree of IP protection
	Non-ionizing electromagnetic radiation
	Manufacturer
	Date of manufacture
SN	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. SPECIALIST

1) Intended Use

The ultrasound system is intended for examining the adult, pregnant woman and children. It is mainly used for measuring urinary volume of bladder.

2) Contraindication

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

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

The basic equipment is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

3) Physical characteristics

Size	156 mm x 60 mm x 20 mm
Weight	450g

4) Environmental

	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

5) Electronic

Input:5Vd.c. 1A	
Battery Capacity： model（SNP-4200）	3.8Vd.c. 4200mAh
Continuous working time：	2 hours
Waterproof:	IPX5

6) Probe

Frequency:	2.6MHz
Display accuracy:	1ml
Measuring range:	20 – 999ml
Measuring accuracy:	20-99ml: ≤±10ml 100-999ml: ≤10%

7) Printer

Communication mode:	Bluetooth

8) Display

Display main unit:	iPad Series
Display Mode:	B-Mode
Gray Scale:	256 levels

9) other

Type of protection against electric shock	Internally powered
Degree of protection against electric shock	Type-BF applied part

Operation mode	Continuous working
Applied part	Probe

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

ITEMS	INCLUDED
scanner（4D Scan Wireless Ultrasound Probe）	√
USB Cable for Charging	√
Operators' Manual	√
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 to your local representative immediately to report the problem.

2.2. Installing

If the Bladder Scanner App is not installed in your iPad, Please Get it from App Store or from distributors freely.

To obtain software from Apple App Store, open the App Store on the iPad, enter bladerscanner in the search bar, and then click to install.

2.3. Starting probe

Figure 2-1 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 4.1.)

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.

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

The concave (4) is the place for loading pressure by thumb. Suitable pressure is applied to the probe so the probe can couple to body perfectly.

2.4. Wireless connection

When the probe is waiting for a wireless connection as described in previously, launch the Settings of iPad, turn on the Wi-Fi (if not on), Find the SSID of the probe. The SSID is like: “WB-1 GMBGBB001”, the suffix after “WB-1” 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 “WBPBGBB001” with

the prefix of “WBP”. It can be found on the surface of the probe.

After Wi-Fi is connected, launch the Bladder Scanner 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.

3. APP operation

3.1. Ultrasound scan

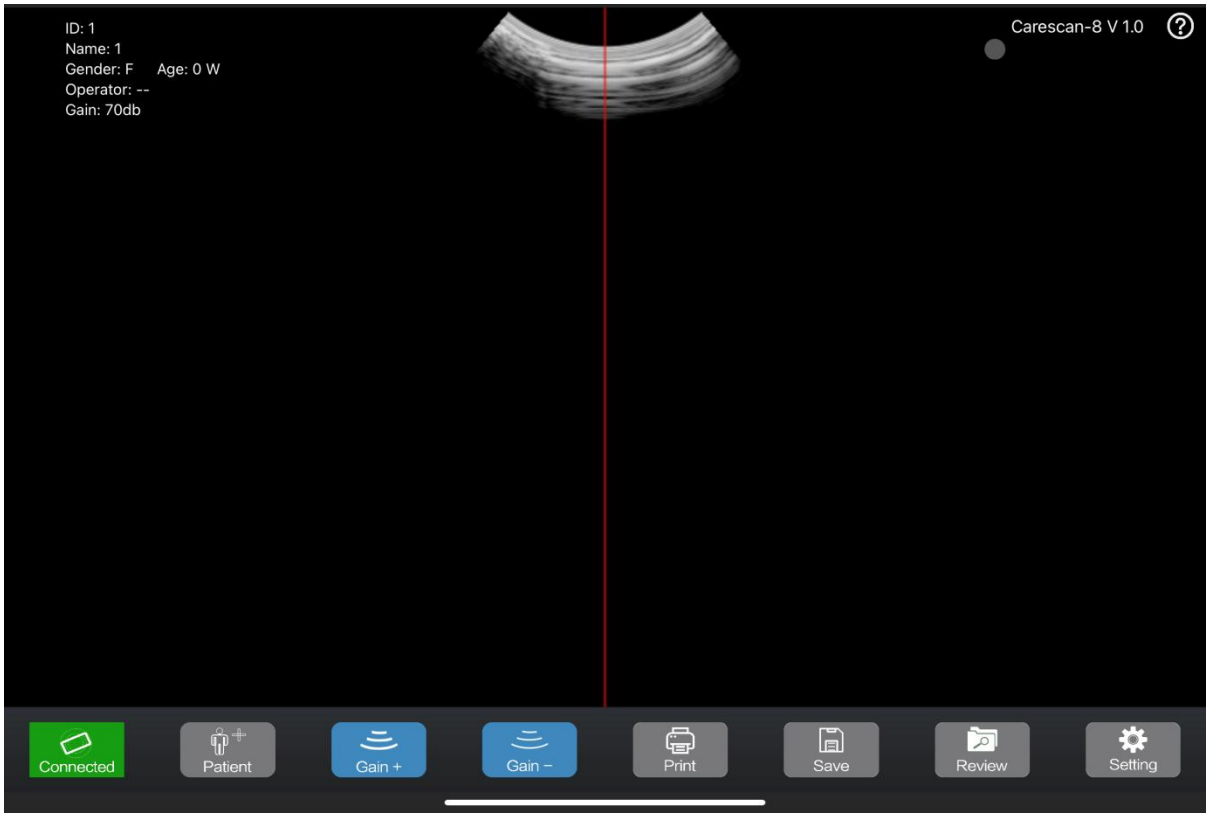

Figure 3-1 main menu

After the probe is connected, launch the App, the Main Screen will show similar in Figure 3-1. (No image is visible when the App is firstly launched.)

The probe connection status label(5) indicates the status of the connection between the probe and the main unit(like iPad).If the connection is well the label is green and prompt “ready” otherwise the label is gray and the prompt is”probe”.

There is a center indicate line (3) in the middle of the image area .
Touch the patient information area (2) to enter the patient interface to edit or create a new case. Please refer to section 3.2 for detail information.
Press the Run/Freeze Button to run and Freeze the probe. When the Image come to shown on the Image Area (1), the sample indicator (4) will turn green from gray if the proper image has been obtained(please refer to section 3.3 for detail information).
When the image is frozen, the 12 sections images and the calculating volume value will be shown on the screen. Users can press “print” (6)(please refer to section 3.4fordetailinformation)buttontoprintthecurrentresult.
Users can use the Save image button (7) to save the image and patient information, Review button(8) to review the stored images(please refer to section 3.5for detailinformation)..
Press the Setting button (9) to set the parameters, including gain and channel(pleaserefertosection3.6fordetailinformation).
Note: In all interfaces, if the button is blue means that the prompt operate is effective .if the button is gray indicates it is an invalid operate.

3.2. Patient information

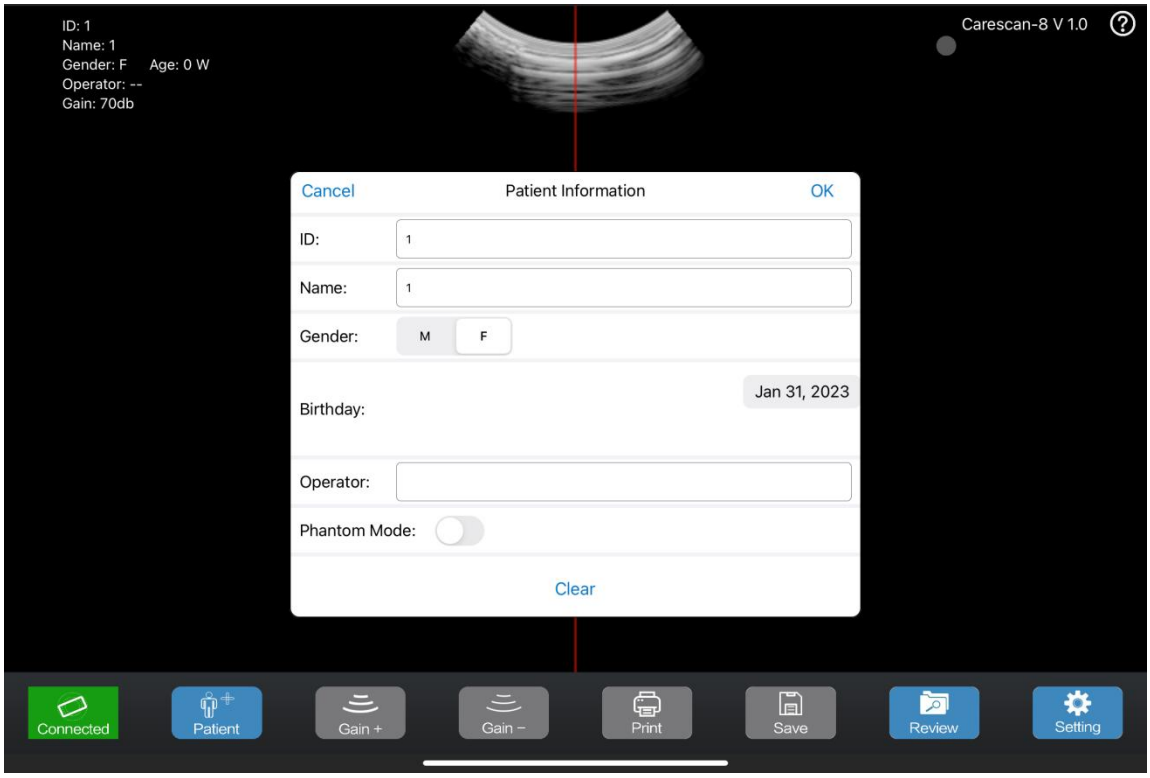

Figure 3-2 patient information

Touch the patient information area (2) (Figure3-1)to enter the patient interface ,then touch the boxes after the labels, the ID, Name, Gender, Age and the Operator can be input or chosen.

When you touch “Create New Case”, all the information will be cleared.

The Phantom Mode is default as closed.

After all the information has been set ,you can touch “OK” to save or “Cancel” to give up, then the patient information interface will be closed.

3.3. Scanning

3.3.1 Prepare probe

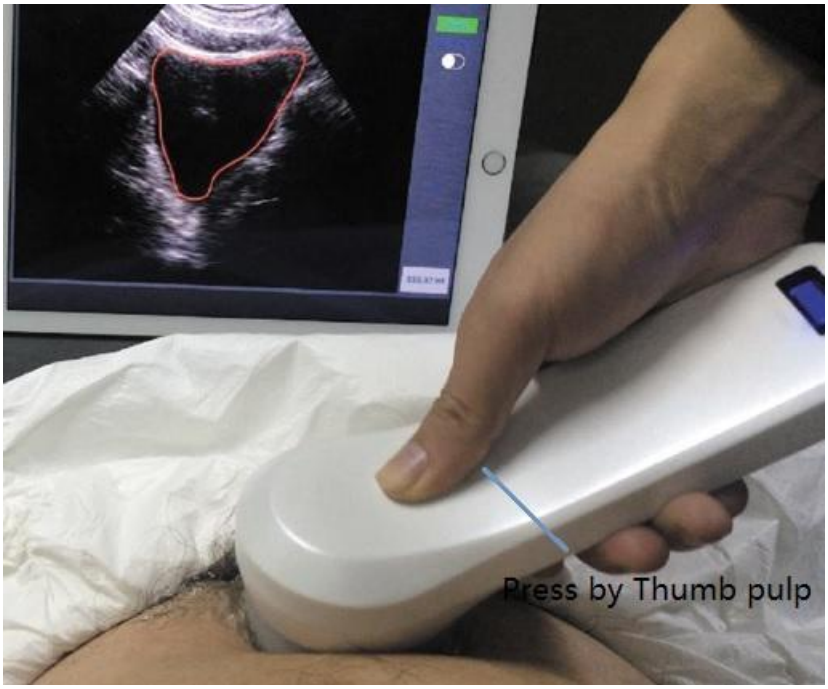

Figure 3-3 pre-Scanning

Before scanning, please use some acoustic gel on patient abdomen and place the probe. The thumb is place on the concave and the button can be pressed by thumb pulp. For good coupling between the probe and abdomen, Suitable pressure should be applied to probe by thumb.

3.3.1. Pre-scanning mode

Pre-scanning helps operator to locate bladder correctly to obtain accurate result. If the connection is done, press the Button once on the probe to start pre-scanning and the real-time B-mode ultrasound image displays on the screen.

When the mode is pre-scanning and the Bladder is in the center of image , the cycle ((4) Figure3-1) on the right upper will be green.

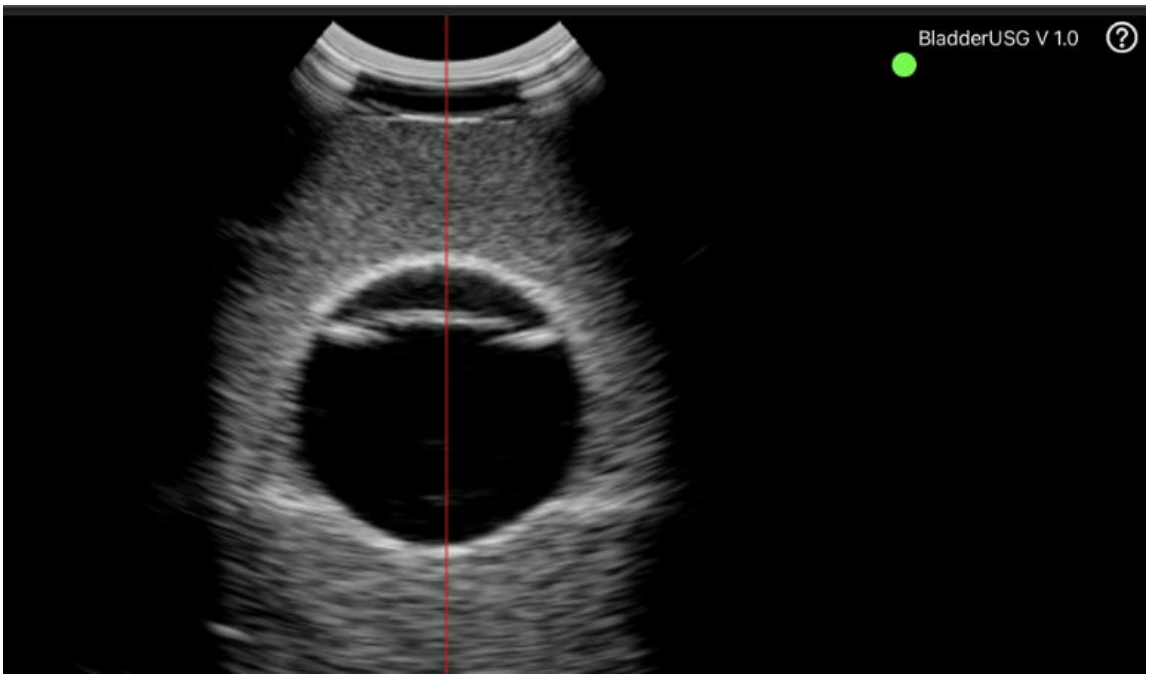

Figure 3-4 pre-Scanning

3.3.2. Scanning mode

When the cycle is green, press the button again to enter scanning mode. The device will obtain and deal with images. When the probe stops vibrating it means the scanning is finished. The 12 scanning images and the measurement result will be displayed on the screen (see Figure 3-3 scanning result menu).

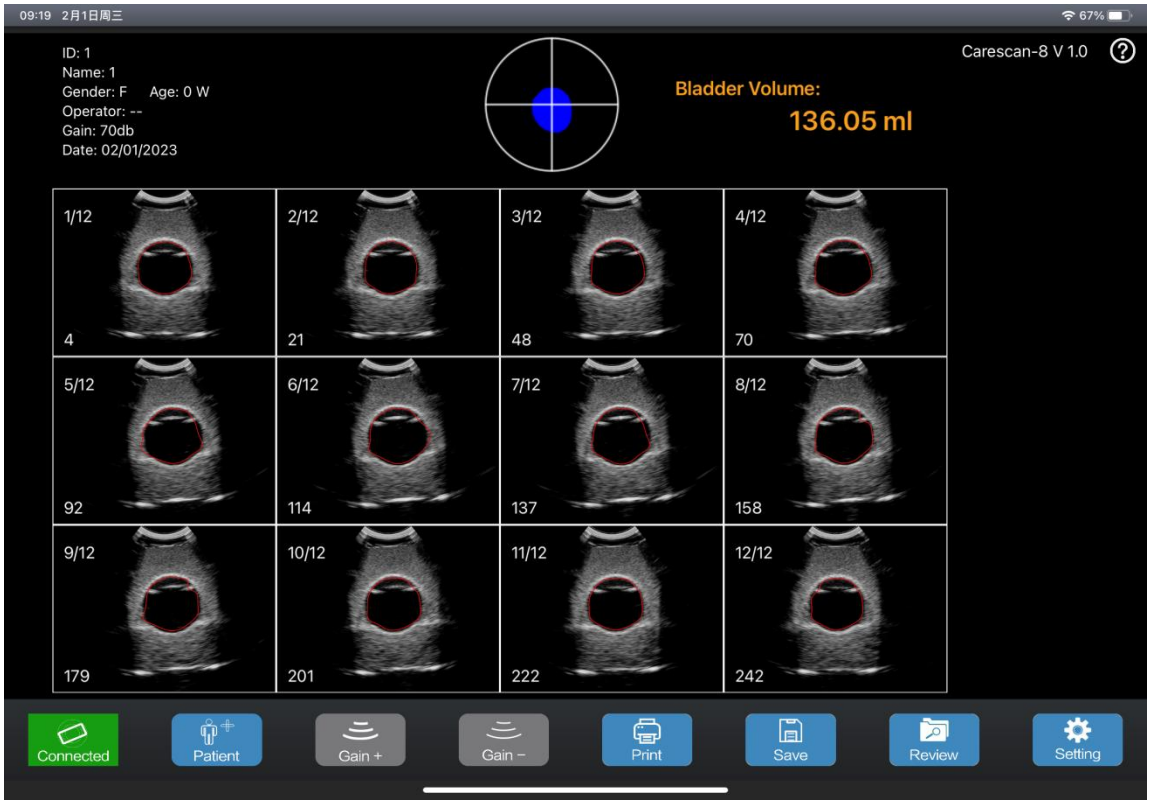

Figure 3-5 scanning result menu

On the scanning result menu, there are 12 section images. The serial number of the image is shown on the left upper of the single image. You can touch one single image to be full-screen to see the details, and swipe left/right to see the previous/next image and touch again shift back to total scanning result menu.

3.4. Print a case report

3.4.1. Reload a thermal paper roll

The Bluetooth printer uses the thermal paper roll, follow the steps to reload a roll:

Figure3-6 reload a paper roll

1) Turn off the printer;
2) Open the housing cover;
3) Take out the old roll(if have),put in a new one;
4) Pull the paper out 1cm off the housing and close the cover(there will be a creaking)
5) Try printing a case report to check if the paper roll was reloaded rightly.

Note: if the printer doesn't work rightly, please reload the roll.

3.4.2. Printer connection

Before you print the case report, you should connect the printer, named as "MPT-II-4" to the main unit by Bluetooth.

Turn on the printer, open the Bluetooth settings of the main unit, then connect the printer. The "power" LED will be red if the connection is well otherwise the LED will be red and blinking. The printed case report is shown as Figure3-5

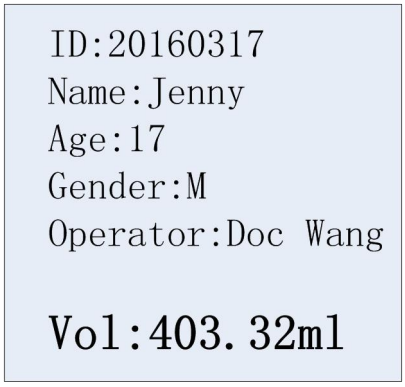

Figure3-7 printed case report

Note: if the printer is not used the POWER LED will be blinking between red and blue.

Note: if you charge the printer, the FEED LED will be blue and blinking.

3.5. Storage and Review the image

Press the button ”Save” to save the images and the patient information(including ID, Name etc) .The saved data can be recalled by touch the button “Review”

Note: Not only the scanning result menu can be stored but also a single picture in the menu.

When you touch “Review” button, there will be a small dialog box, as shown in Figure 3-6, then you can choose any photo you need to review.

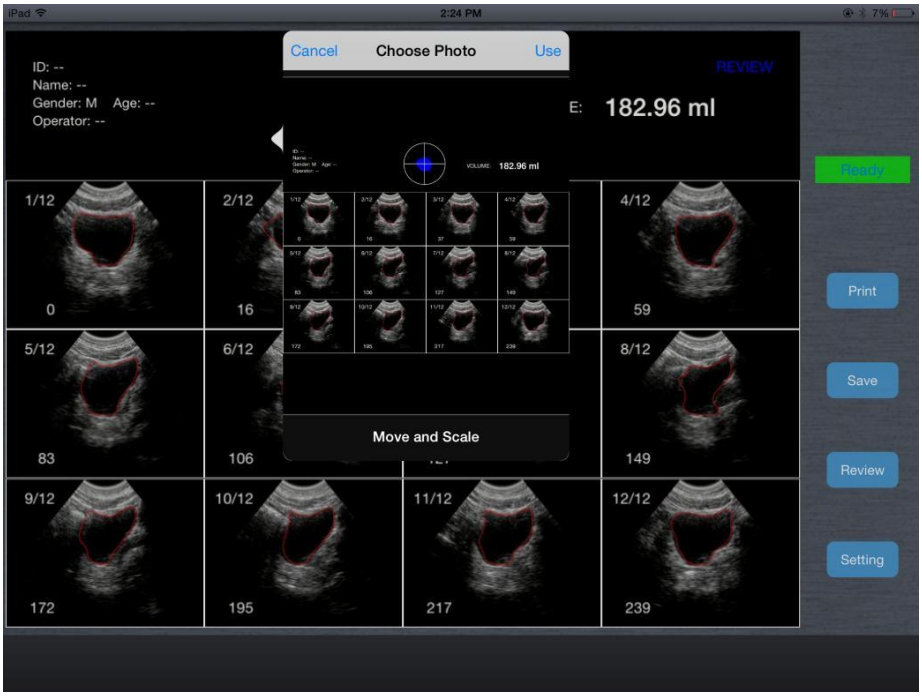

Figure 3-8 review menu

3.6. Set parameter

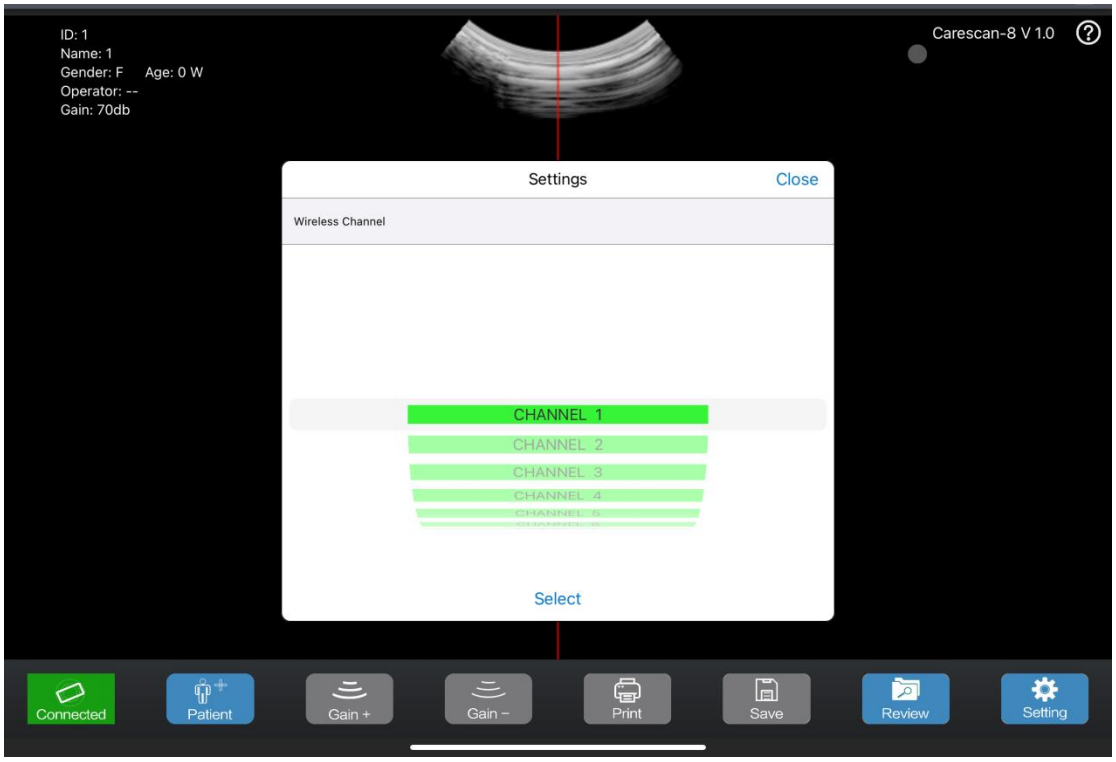

Figure 3-9 setting menu

1) Gain

When t a new gain is needed, the add and subtract button can used to change the gain from 30 to 105 dB

2) Wireless Channel

When the system is using in an environment where the Wi-Fi channel is crowded, 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.

4. Maintance

4.1. Battery Charge

When battery is low, it is necessary to recharge the probe. There are two charging methods you can take.

1) Charging with USB Cable

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 the left picture of Figure 4-1.

Figure 4-1 Charge the Probe

2) Wireless Charging

Applying power to the wireless charging pad, put the probe on the portable wireless charger as shown in the right picture of figure 4-1.if the relative position is right ,there will be a notification tone and the capacity indicator on the probe will be light.

When in charging, the battery indicator will be blinking and the grids indicate the capacity of the battery charged.

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. Cleaning and Disinfection

4.2.1 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

4.2.2 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.

4.3. 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.

4.4. Caution

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential 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 radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, 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 receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

PRECAUTION 1: 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.
PRECAUTION 2: The device shall be operated by professional physicians, and should wears gloves before use.

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.

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.

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.

5.1.1Electric 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.
- Warning against activation of transducer assembly intended for intra-corporeal use outside patient′s body if transducer assembly does not comply with emc requirements (may cause harmful interference with other equipment)
- 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.
- Do not place the multi-socket outlet on the floor.

- Do not connect other devices to multi-socket outlet; otherwise, the rated output power may be exceeded and failure may be resulted.
- The multi-socket outlet can only be used to provide power to the recommended peripheral devices of this system.
- Select the qualified multi-socket outlet with protective grounding, and ensure its maximum output power doesn't exceed the required one of this system.
- If the non-medical electric equipment connected to the system is powered by the movable multi-socket outlet with the isolation transformer, you should connect the plug of the system to the hospital-graded standard socket. Meanwhile, please consult the professional technician to ensure that the connection meets the safety requirements.
- The video printer should be connected to the cable provided by the manufacturer, otherwise, there is a danger of electric shock.
- It is recommended to connect this equipment to equipotential system. Use yellow and green equipotential grounding cables, one end is connected to position with symbol, and other end is connected to equipotential system. Use of potential equalization conductor together with a reference to requirements of IEC 60601-1 for Medical Electrical System.
- 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.
- Make sure the system is powered off and power cable is disconnected before cleaning the system. Otherwise, an electric shock may happen.
- 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 an 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 beding 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.

5.1.2Mechanical Safety

- Be careful when holding the device, for it is handhold, it may fall.
- Do not use shell cracking equipment.

Caution

- 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.

Warning

- Please make sure that the system is powered off and the power cable and the relevant accessories are disconnected before moving or transporting the system.
- 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

Warning

- 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.
- You should use the legally marketed rubber latex (probe sheath)when performing trans-esophagus or intracavitary exam, or biopsy exam. Please check the ingredient of the rubber latex on the package before purchasing the rubber latex. Contact with natural rubber latex may cause a severe anaphylactic reaction in persons sensitive to the natural latex protein. Refer to package labeling to check latex content and FDA's March 29,1991 Medical Alert on latex products
- Only the trained physicians or sonographers can handle the biopsy needle guides under ultrasound guidance. During the operation, the operator must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomforts, unnecessary risks or injuries to patient.
- 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.

Caution

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

5.2 Principles of Using Acoustic Power

Warning

- 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 theat 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 0.3dB cm^{-1} 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 cannot 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 Radiation

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

Emission Test	Compliance	Electromagnetic Environment and Guidance
RF emission CISPR 11	Group 1 Class A	The equipment use RF energy only for its internal function. Therefore, its RF emission is very low and not likely to cause any interference to nearby electronic equipment.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

5.3.2 Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment and 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%.
Electrical 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%UT (>95% dip in UT) for 0.5 cycle 40%UT (60% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles < 5%UT (>95% dip in UT) for 5 sec	< 5%UT (>95% dip in UT) for 0.5 cycle 40%UT (60% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles < 5%UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires contained operation during power mains interruptions, it is recommended for the equipment to 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 Minimum Distance BetweenBProbe and Mobile RF Equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment 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 $d = [\frac{3.5}{V1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E1}]\sqrt{P}$
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.	

IT Security or Wi-Fi

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:

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

		Operations	Storage and Transportation
Environmental Requirement	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

Transducer Model: Bprobe, SN: WBPBGBB004			Operating Mode: B mode					
Index label			MI	*TIS*			*TIB*	*TIC*
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
Maximum index value			0.47	0.037				N/A
Associated acoustic parameters	$p_{r.\alpha}$		0.81					
	P			3.39				N/A
	min *of* $[P_\alpha(Z_s), I_{ta.\alpha}(Z_s)]$							
	z_s							
	z_{bp}							
	z_b							
	z at max $I_{pi.\alpha}$		3.80					
	$d_{eq}(Z_b)$							
	f_{awf}		2.92	2.92				N/A
	Dim of A_{aprt}	X		1.29				N/A
		Y		1.30				N/A
Other information	t_d		0.56					
	prr		1250					
	p_r at max I_{pi}		1.19					
	d_{eq} at max I_{pi}							
	$I_{pi.\alpha}$ at max MI		25.61					
	Focal Length	FL_x						
		FL_y						
Operating control conditions	Fixed							

Transducer Model: Bprobe, SN: WBPBGBB004			Operating Mode: B+M mode					
Index label			MI	*TIS*			*TIB*	*TIC*
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
Maximum index value			0.47	0.037		0.029	0.11	N/A
Associated acoustic parameters	$p_{r.\alpha}$		0.81					
	P			3.39			3.41	N/A
	min *of* $[P_\alpha(Z_s),I_{ta.\alpha}(Z_s)]$					2.06		
	z_s					2.50		
	z_{bp}					2.19		
	z_b						3.45	
	z at max $I_{pi.\alpha}$		3.80					
	d_{eq} at z_b						0.34	
	f_{awf}		2.92	2.92		2.92	2.92	N/A
	Dim of A_{aprt}	X		1.29		1.29	1.29	N/A
		Y		1.30		1.30	1.30	N/A
Other information	t_d		0.56					
	prr		1250					
	p_r at max I_{pi}		1.19					
	d_{eq} at max I_{pi}						0.33	
	$I_{pi.\alpha}$ at max MI		25.61					
	Focal Length	FL_x				N/A		
		FL_y				4.10		
Operating control conditions	Fixed							

EC REP

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

CE 2862

Manufacturer:Guangzhou Sonostar Technologies Co., Ltd.

Address of facility:504#, C Building, #27 Yayingshi Road, Science Town, 510655 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Tel: 020-32382095

Fax: 020-62614030

Website: www.Sonostar .cn

E-mail:sonostar@sonostar.net