Wireless Probe Type Ultrasound Scanner

CProbe

User's Guide

Prescription Statement "Caution: Federal law restricts this device to sale by or on the order of a physician".

A/0

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Section 1 INTRODUCTION

The Wireless Probe Type Ultrasound Scanner (Model: CProbe) 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 CProbe 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
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 TECHNICAL PARAMETERS

Display: iPad / iPhone Series
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: CProbe) 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.

1.4PRECAUTIONS & 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 3.6 SETTINGS), and then restart the probe.
- PRECAUTION 5: Prescription Use. The device shall be operated by professional physicians.
- PRECAUTION 6: The device shall be repaired by professional recognized by the manufacturer.

- PREACUTION 7: The device does not have shelf life. Its expected use lifeis 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.
- 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.
- 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.
- Changes or Modifications not expressly approved by the party responsible could void the user's authority to operate this device.
- 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.
- The device has been evaluated to meet general RF exposure requirement

Section 2 GETTING STARTED

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

Caution	Too high ultrasonic intensity and / or long exposure time may cause injury.
	Please do not apply the probe of this machine to the scope not covered in this manual.

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.

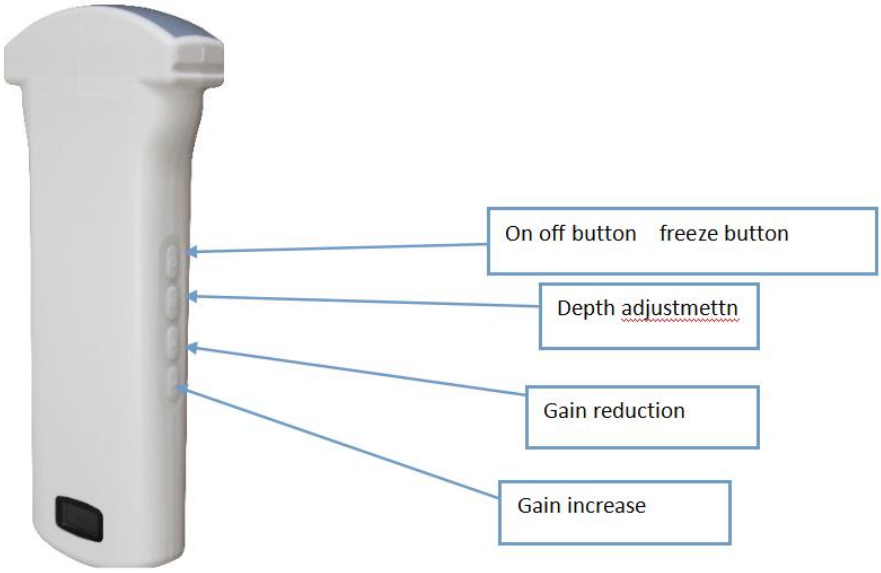
Items should be checked in order to ensure that all ordered items have been received. The following table lists the items which should be received with each particular system.

Table 2-1 Items List for The Wireless Ultrasound Scanner

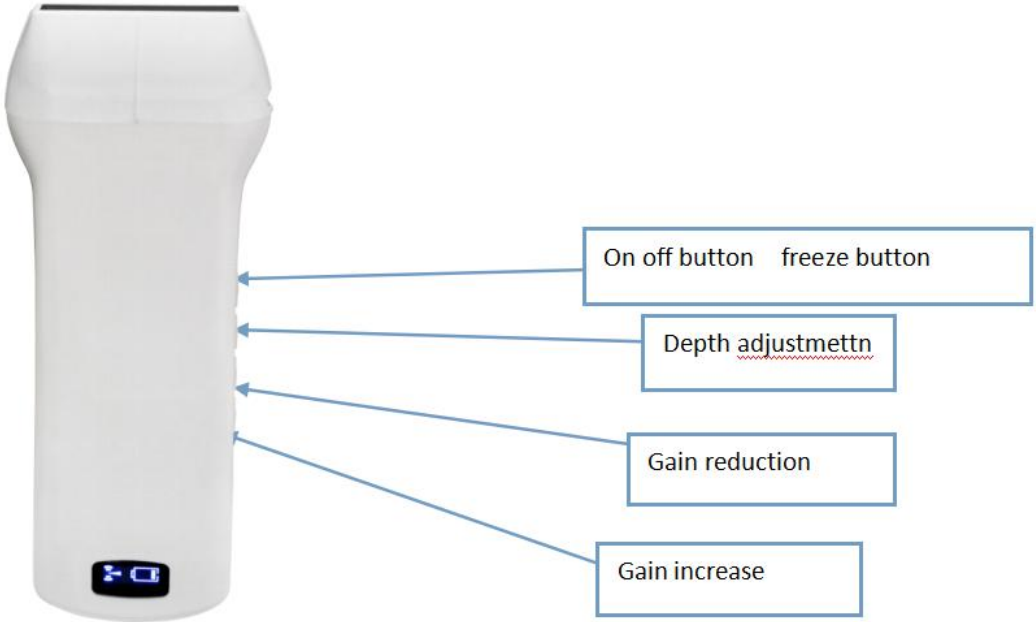
ITEMS	INCLUDED
Host(Including probe)	√
Manual	√
USB charging cable	√
Warranty Card	√
Power Adapter	Optional
Tablet	Optional

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.

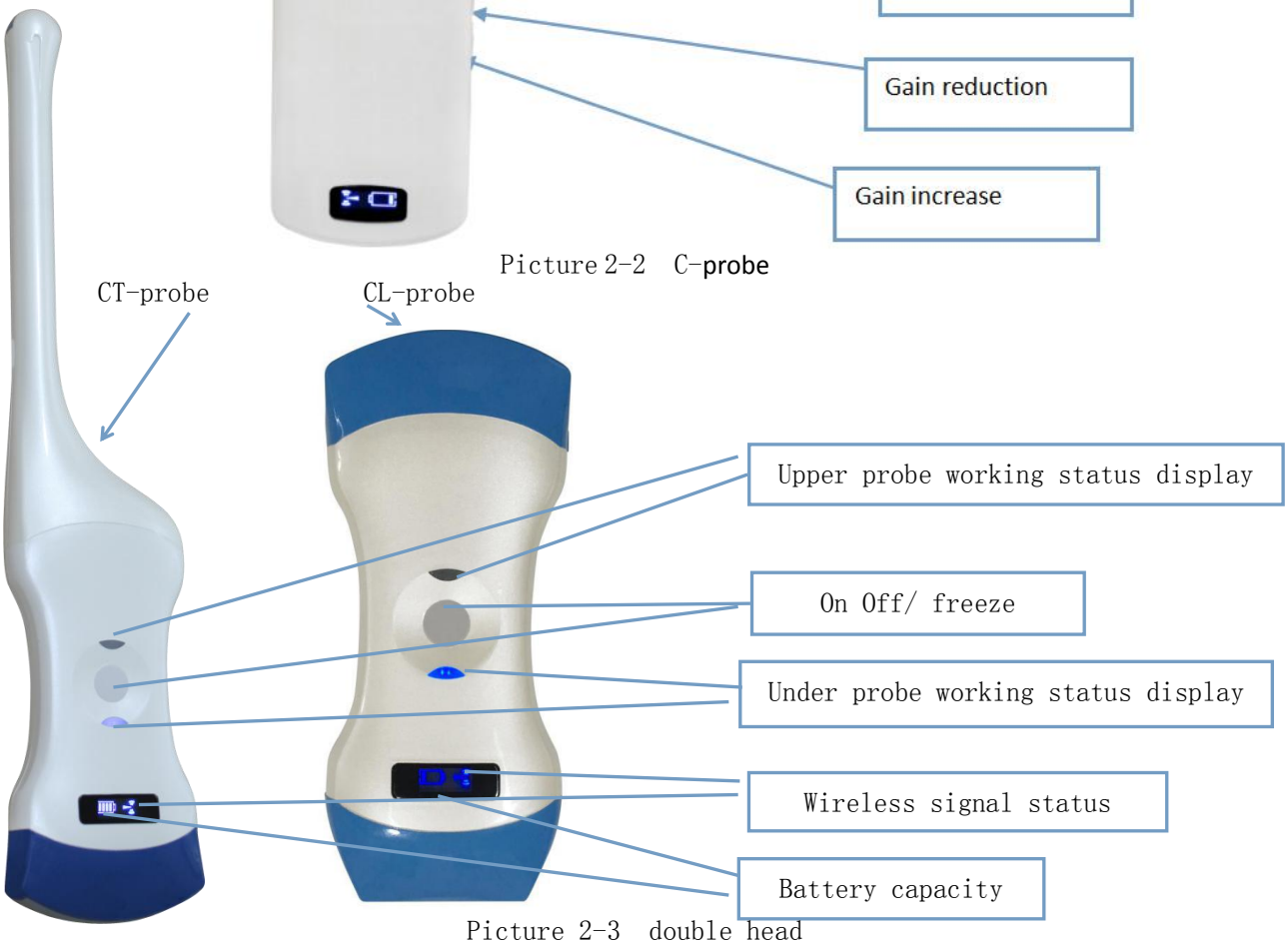
Product schematic diagram



Picture 2-1 L-probe



Picture 2-2 C-probe



Picture 2-3 double head

Switch the probe: press and hold the switch for three seconds
Working state display: indicator lamp indicates the position of the convex array to work with the convex array probe, and indicator linear array position to work with the linear array probe
Charging support: this probe only supports wireless charging.

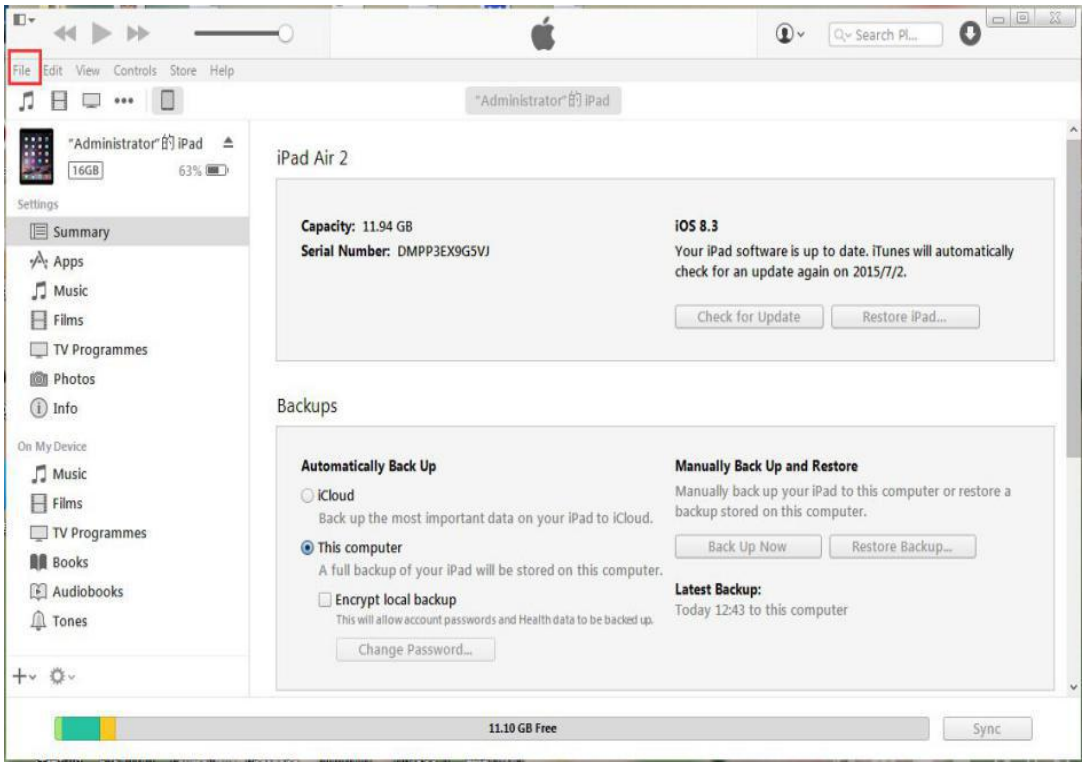
Picture 2-4 C-probe&L-probe

Picture 2-5double head(CT-probe&CL-probe)

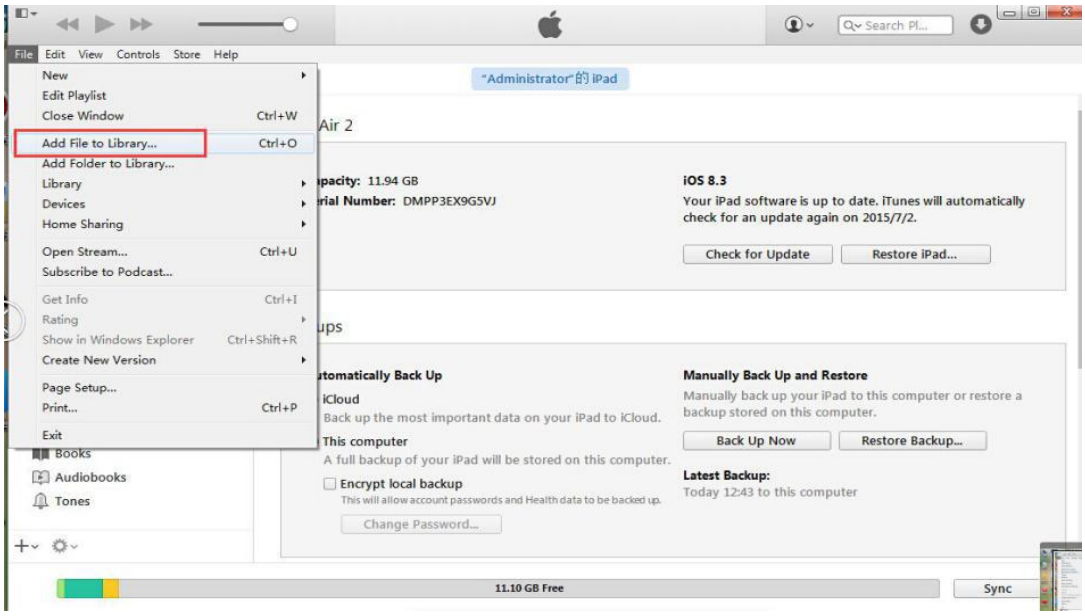
2.2 INSTALLING APP

The software is installed by computer after connecting iPad or iPhone to computer.
Before software installation, please make sure your computer has installed the Apple iTunes.

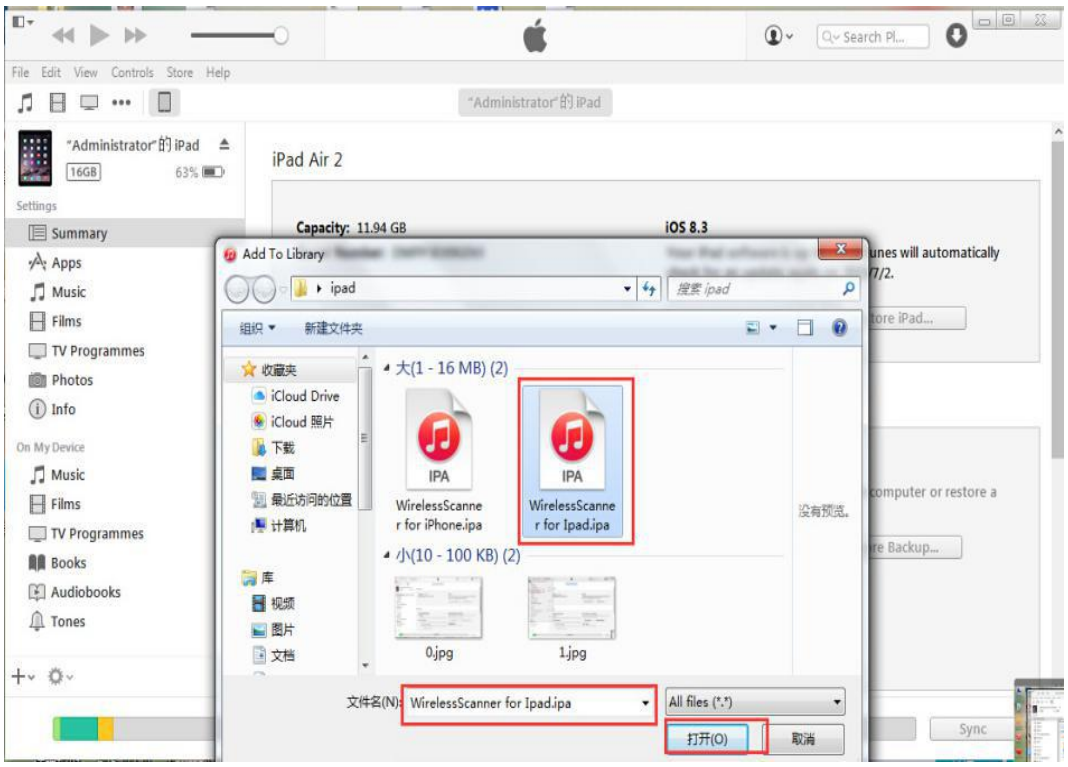
And please copy the wireless scanner Application to the computer disk. There are two separate applications, one for IPAD, another for IPHONE.



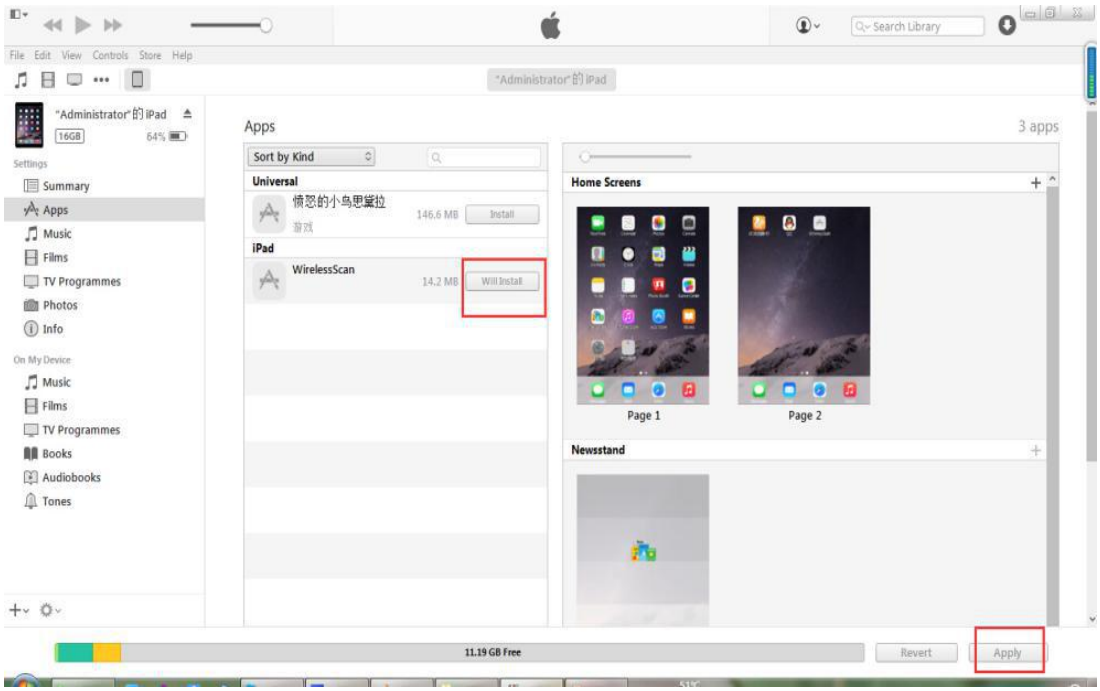
1) Connect the IPAD or IPHONE to your computer, Open iTunes, Choose File menu, marked with Red border.



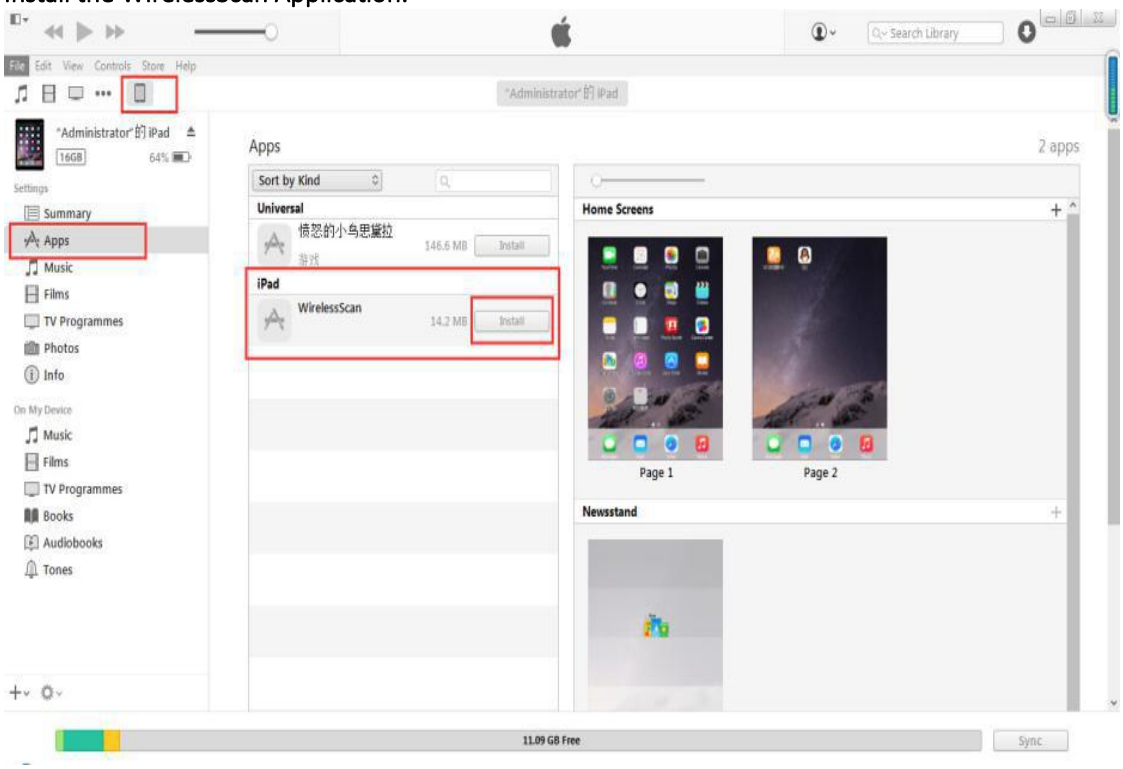
2)Choose menu Add File to Library...



3) Choose Application for IPAD or IPHONE, confirm it.



4)Choose IPAD, Enter into Apps menu, the Apps option would appear the added application. Choose Install the WirelessScan Application.



5) Click Install, the menu changes to Will Install, choose Apply. Startto install the application.

6) The wireless Scanner Application is installed successfully.

Note: if your system is iOS9, need to authorize at Settings - General - Profiles - tap on the Profile - tap on Trust button.

2.3 STARTING PROBE

2.3.1 Visual inspection

Before and after the ultrasonic visual inspection, check the probe surface or the fuselage sheath for abnormalities such as peeling, cracks, and bulging.

Waring	Abnormal probes can cause electric shock or injury to people. Therefore, once any abnormalities are found, you must immediately stop using the probe and contact Sonostar.

2.3.2 Probe cleaning

Ultrasonic probes should be cleaned and disinfected before and after ultrasound examination. Please refer to chapter “4 Cleaning and Disinfection”.

Caution	Probes that have not been cleaned or disinfected may cause bacterial and viral infections

2.3.3 Boot check

Please check the following before diagnosis

1. The probe should not be abnormally heated during use. The probe can be sensed by hand touching the probe, and if the temperature is significantly higher than the body temperature (or the probe surface temperature exceeds 40 ° C), the probe will be stopped.

Caution	If the operator places an abnormally hot probe on the surface of the patient’s skin, it may cause burns.

2. The ultrasound image must not be abnormal after power on, check whether the functions are normal, including software operation, button function, power, etc.

Caution	In the event of any of the above anomalies, the ultrasound imaging diagnostic apparatus may be defective, please contact SonoStar.

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.

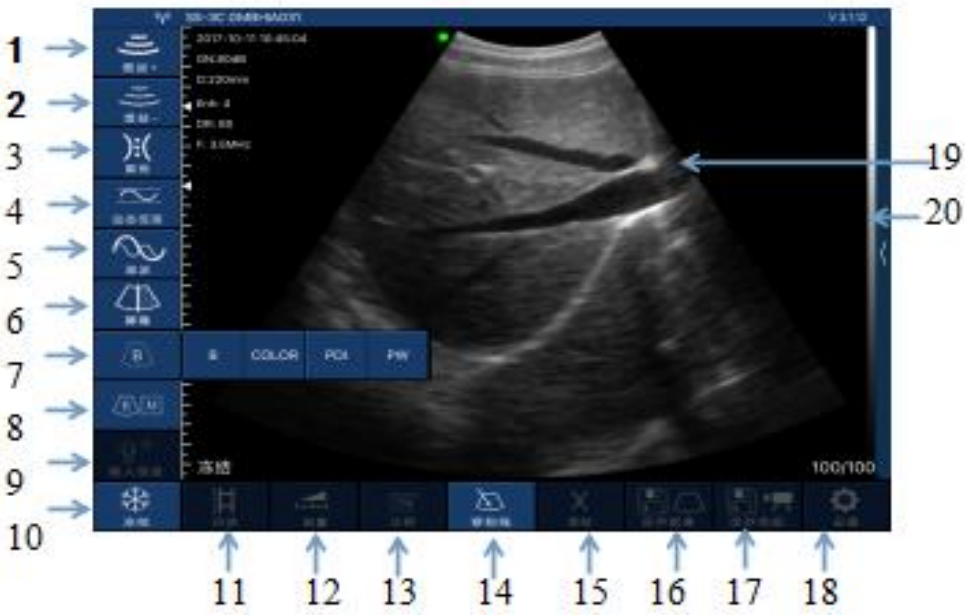
After Wi-Fi is connected, launch the WirelessScan App, after the connection from the app to the probe is confirmed, the Wireless Connection Indicator on the probe will be light with no blinking.

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 scanning

(1)
(2)
(3)
(4)



Main interface (Figure 3-1)

The meaning of each icon:

1.Gain +: increase image gain.

2.Gain -: reduce image gain.

3. Focus: adjust the focus position of the image.

4.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.Image mode: select image mode.

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.

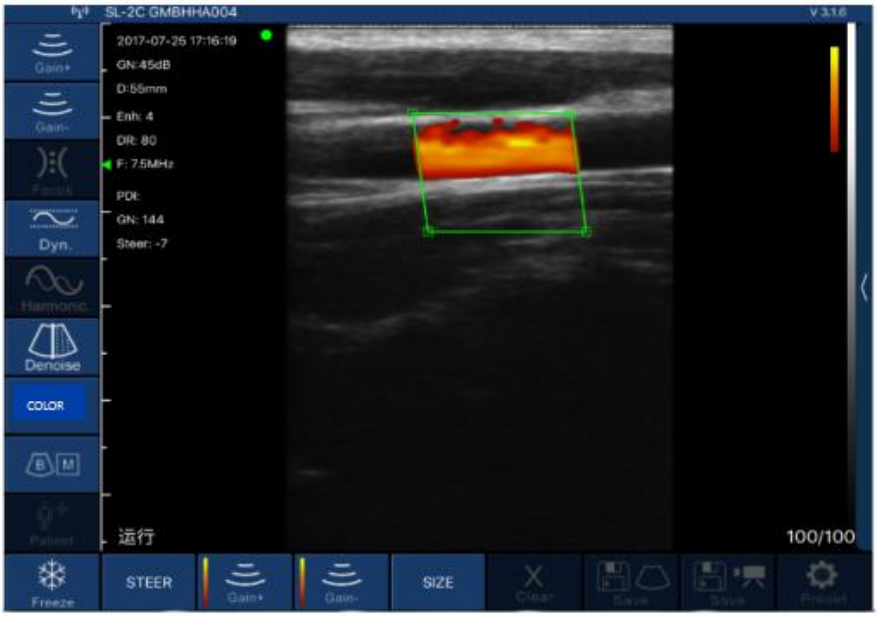
17. Save Image Video: save whole Image Video.

18.Setting: WIFI channel selection to avoid channel blocking.

19.Depth adjustment: change the depth of the image by sliding up and down the screen of the phone.

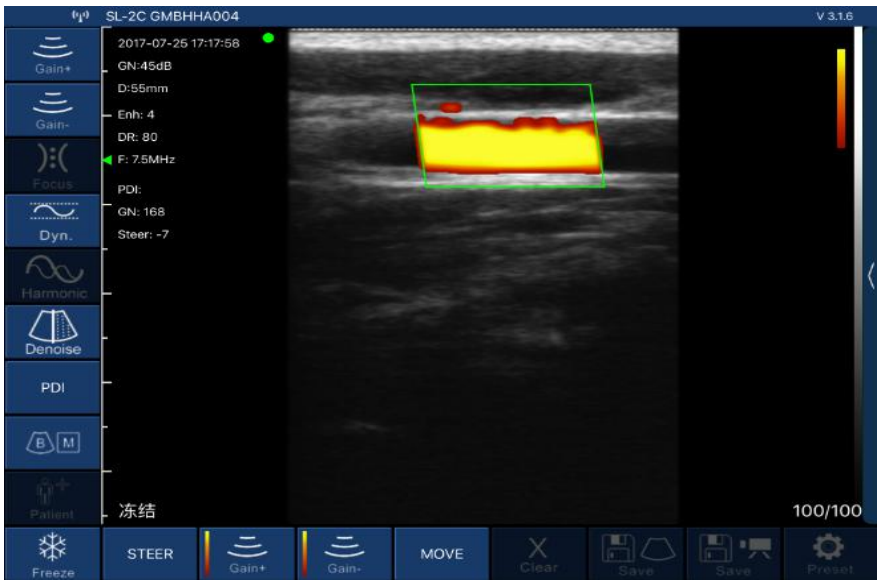
20. TGC (time gain compensation)the function menu pops up by clicking on the top of the right "<".

Mode introduction:



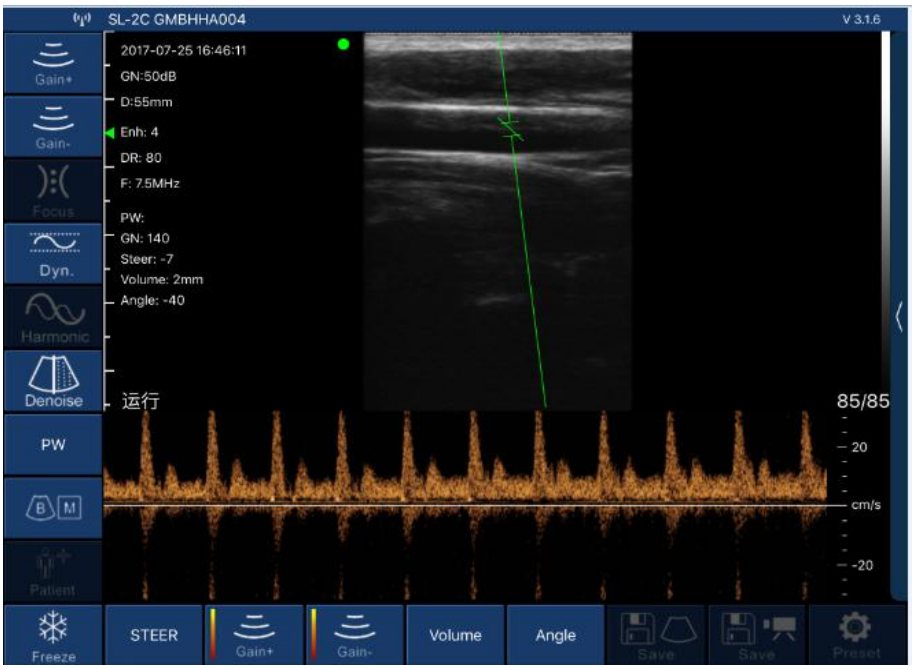
Picture 3-2 Color Doppler imaging mode

Color Doppler imaging mode, Picture 3-2:
1.Color sampling frame: change the direction of the color sampling frame.
2.Gain +: increase color blood flow gain.
3.Gain -: reduce color flow gain.
4.Move, Zoom: change the position and size of the color sampling frame by clicking and moving with your finger.



Picture 3-3 Energy Doppler imaging mode

Energy Doppler imaging mode, Picture 3-3:
1.Color sampling frame: change the direction of the color sampling frame.
2.Gain +: increase energy blood flow gain.
3.Gain -: reduce energy blood flow gain.
4.Move, Zoom: change the position and size of the color sampling frame by clicking and moving with your finger.



Picture 3-4 Pulse Doppler imaging mode

Pulse Doppler imaging mode, Picture 3-4:

1.Gain +: increase pulse gain.

2.Gain -: reduce pulse gain.

3.Deflection angle: used to change the angle of the spectrum sampling line in real-time scanning state.

4.Sampling frame: change the size of the sampling volume.

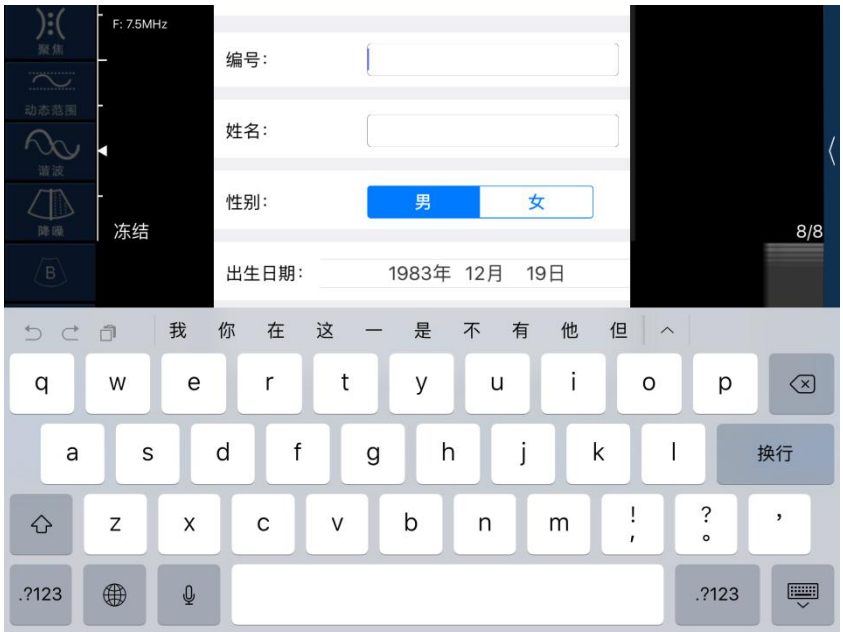
5.Correction angle: used to change the angle of the blood flow direction cursor.

3.3.2 Patient information input

Click on the software interface "Patient Information", thethe interface patient information will pop up as below Picture 3-5 shows:

Picture 3-5 Pop-up patient information interface

Enter the patient information in the number and name fields, click on the gender and click OK. The patient information is entered. If you make a mistake, you can click Cancel or create a new case.

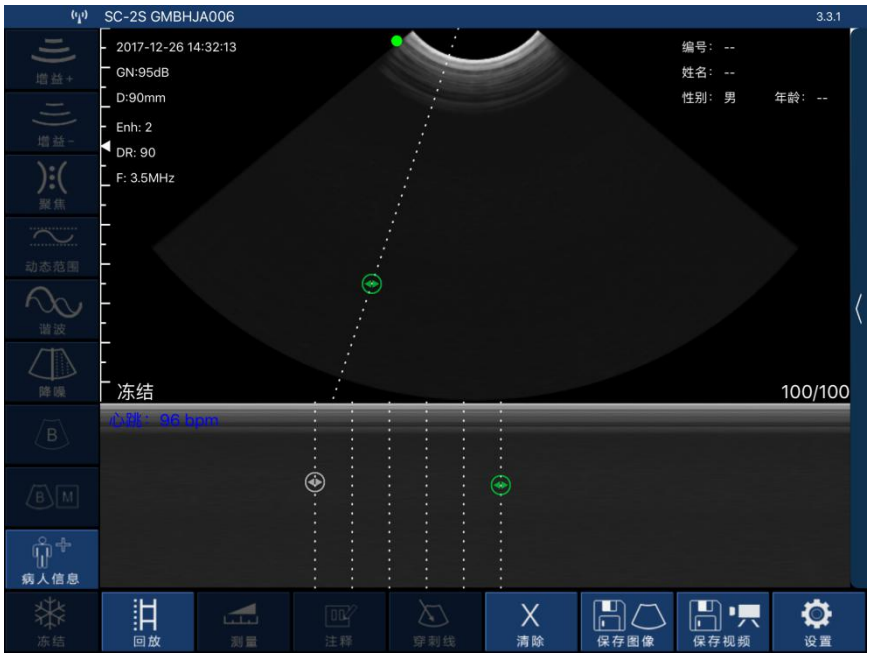


Picture 3-6 Patient Information Editing Interface

3.3.3 Data measurement

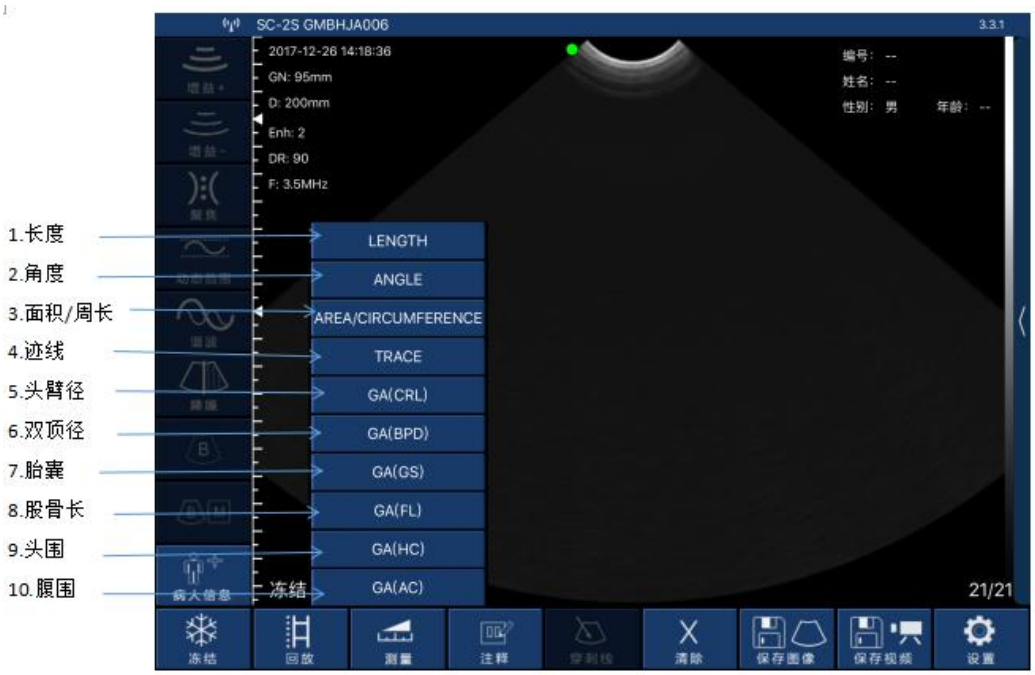
In B/M mode, the position of the sampling line can be adjusted by tapping the moving circle on the screen with your finger (as shown in Picture 3-7 below).

In the frozen state of B/M mode, click the M mode area, the moving circle can appear, the heart rate can be measured, and the default number of cardiac weeks is 5 weeks (five-segment, that isfive heartbeat intervals are taken and the average heart rate is calculated).



Picture 3-7 Measuring the heartbeat interface

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, 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.

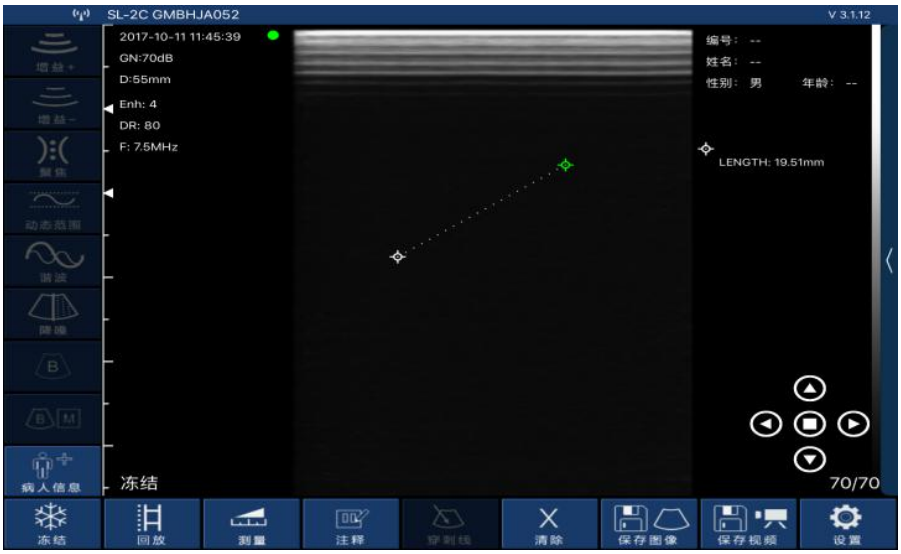
Select the "AREA/CIRCUMFERENCE" area/circumference measurement function, select the 3 o'clock position to be measured in the frozen screen and click on it. 3 moving points will appear on the screen, and 3 moving points will automatically form an elliptical trajectory. Click on the moving point to adjust 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.



Picture 3-10

Up to 4 sets of data can be measured in the same frozen screen. After the measurement, press “Clear X” to delete all measurement results. If you want to delete a measurement, click on the measurement data at the top right of the screen to display the result.

3-11， Within the same freeze frame, the measurement can be at most four sets of data. After finish the measurement, press the "remove X" can delete all measurements; if you want to delete one measurement, click measuring data result on the top right screen , immediately appear below as shown in figure 3 to 11, click "ⓧ" on the right side of the data, delete the measurement data.

Figure3-11 Delete part of the measurement data

3.3.4 Report download

Click on the ″patient information″ on the lower left of the software interface , then pop-up below patient information interface.

Figure 3-12 pop-up patient information interface.

Click on "report", pop up the interface below as shown in figure 3-13, click on the "tip" box, the user can input content in dialog box. Click on download icon " "on the lower right of the page, then the report can be downloaded. The report are stored automatically in the smart terminal display system (apple mobile phone, or tablet) photo album.

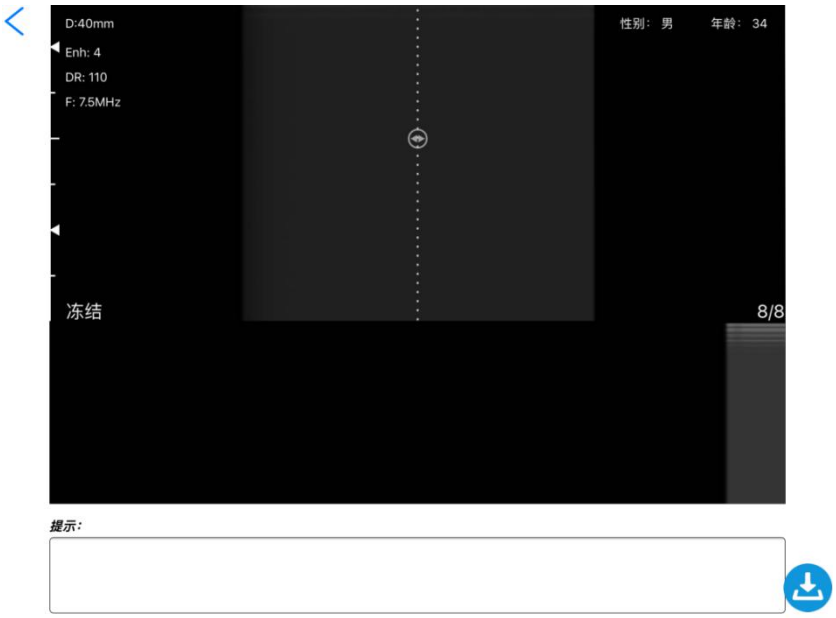


figure 3-13 patient information download interface

3.3.5image and vedio storage

3.3.5.1 Image storage

Click on "save image" on the bottom right in below interface (FIG. 3-14), then save the image displaying on the screen at the moment. The image is automatically stored in the smart terminal display system (apple mobile phone, or tablet) photo album.

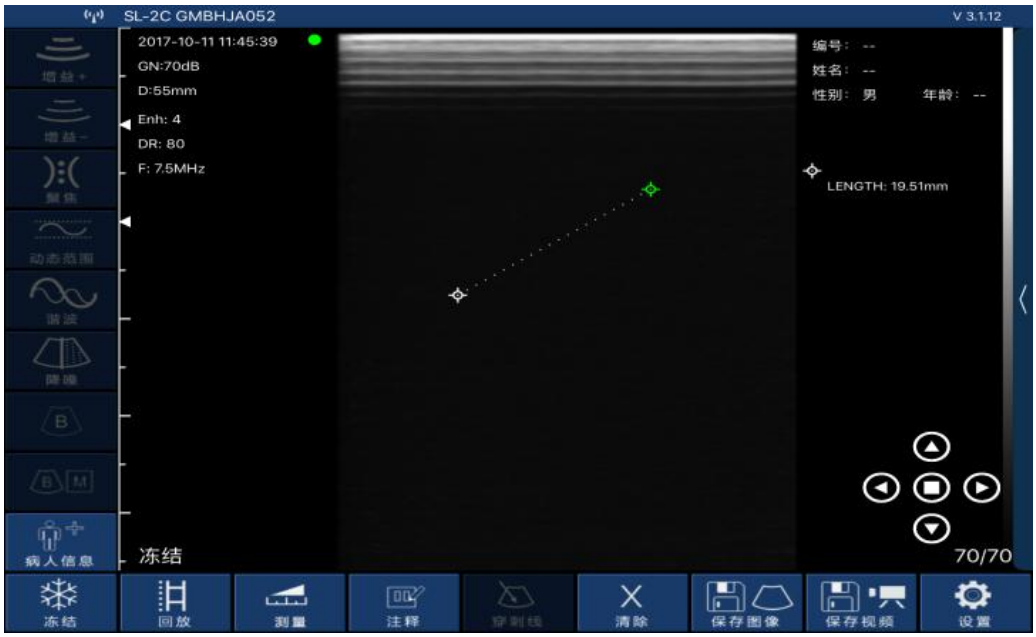


图 3-14

3.3.5.2 Vedio storage

Click on "save vedio" on the bottom right in above interface (FIG. 3-14), then the vedio starting from the operation within 100seconds are stored in the smart terminal display system (apple mobile phone, or tablet) photo album.

.

3.3.6 Image and vedio review

Open the photo album of the smart terminal display system (apple mobile phone, or tablet), then review the saved image and vedio.

3.3.7Replace the signal channel

In the WIFI crowded environment, the user can choose different WIFI channel for the probe. Press "set" key, then pop up the signal channel selection list (as showed in figure 3 to 15), click select channel. After 2 seconds, please restart the probe and connectwith intelligent terminal display screen according to 3.1 step .

Figure 3-15

Section 4 MAINTEANCE

4.1 PROBE CHARGING

When battery is insufficient, the probe needs charging. Pull out the rubber plug at the end of the probe, connect probe and the USB charger by USB cable as shown in figure 4-1. When charging, battery capacity indicator light is flashing. The grid shows the electricity sufficiency.

If all four grid light and light is not flashing, it indicates the battery is charged fully. When charging completed, please remove USB cable, then insert rubber plug into the probe end to avoid liquid and damage the instrument.

Figure 4-1 Charge the Probe

Caution	If the adapter power supply voltage is beyond the scope of instrument regulation adaptation (normal adapter output voltage is 5 V + / - 0.5 V), it shall not be used.
	Check the power cable, if any damage and fracture occur, power cable should be replaced immediately to meet the requirements.

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

The probe needs to be cleaned before using.

To clean the probe, Use a soft cloth dampened with isopropyl alcohol (or an appropriate hospital cleaning agent) to wipe the Probe until it is thoroughly cleaned.

If you use a detergent solution to clean the instrument, remove all residual detergent. Dry the instrument with a clean, soft cloth.

Alternatively, dampen a soft cloth in any glutaraldehyde-based hospital disinfectant solution such as Cidex. Wipe the instrument with the dampened cloth.

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

Thoroughly dry the instrument with a clean, soft cloth before using.

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.

4.5TROUBLE SHOOTING

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

Fault handling:

Ite	Failure Prolem	Solution
1	No response after press the power switch	Charging,check the power supply
2	Intelligent display can't connect probe WIFI	Check the WIFI signal channel is ready; test whether the WIFI password input is correct
3	Displayed on the screen with interference like snow	Check if other equipment started which cause electromagnetic interference,shut down the device or get far from the device.
4	The image not bright	Adjust brightness
5	Charging not work	Detect circuit and electrical outlet, check if the USB interface is damaged

4.6Disposal

*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.

4.7Proudct maintenance and protection

1, this product usage and storage conditions shall comply with the environmental conditions of section 1.5 in this manual.
2, The prouduct power suppy shall be in accordance with section 1.6 of this manual.
3, If Stop using this product for a long period of time, ensure charging at least twice a week, every time not less than 1 hour.
4, please do not open the probe cover for cleaning, shake or dismantle the components inside the probe.
5, Clean and wipe the probe cover by alcohol cotton,and should be operated in the power-off state.
6, this product should not be frequent startup and shutdown. After shutdown if needed to start up again, please wait at least 1 minute of time for boot operation.
7, if instrument malfunction occur,pls ask professional staff for maintenance.
8, probes are valuble and vulnerable part,any collision or drop is forbidden.
9, Suspended in the diagnosis process, please press the button for freeze.The system in the frozen statebenefit to probe for long-term use.
10,Apply the medical ultrasound coupling agent which complys with relevant standards when using the probe.
11, the structure of the probe is watertight, prohibit any conductive liquid immersionso as to avoid corrosion of the probe and the fuselage.
12,Probe into liquid shall not exceed the probe water lines, and regularly check for cracks in order to avoid liquid immersion and damage to internal components.
13,After each usage,please refer to chapter 4 of this manual for cleaning and disinfection.

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.

Warning

- 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.
- Please check and replace the battery periodically.
- 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 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 can not be used on 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 orprotrusions which may cause harm.
- Please read the instructions and then set and control the acoustic output levels.

Warning

- 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

Caution

- 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

- 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 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.

5.1.4 Cybersecurity

●In order to avoid database loss and damage, please back up the database regularly.

●The probe can be connected to mobile device IPad or IPhone by wireless local network. The software itself can not be connected to external network, the network the software is connected to is the local wireless network launched by the probe.

- During usage, if there is any software bug, the user can do feedback via company email: sonostar@sonostar.net, then the company will do analysis and modification according to the bug, if there is needs for update, there will be update notification via email to remind the user to do update.

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 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.

<table>
<tr><td>1</td><td colspan="3">Guidance and manufacturer’s declaration - electromagnetic emission</td></tr>
<tr><td>2</td><td colspan="3">The CProbe Wireless Probe Type Ultrasound Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of CProbe Wireless Probe Type Ultrasound Scanner should assure that it is used in such environment.</td></tr>
<tr><td>3</td><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>4</td><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The CProbe 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.</td></tr>
<tr><td>5</td><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">The CProbe 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.</td></tr>
<tr><td>6</td><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>7</td><td>Voltage fluctuations / flicker emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

5.3.2 Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The CProbe Wireless Probe Type Ultrasound Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the CProbe 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) IEC61000-4-2	±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 qualityshould 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 qualityshould be that of atypical commercial or hospital environment. If the user of the CProbe Wireless Probe Type Ultrasound Scanner requires continued operation during power mains interruptions, it is recommended that the CProbe 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.
NOTEU_T is the a.c. mains voltage prior to application of the test level.			

5.3.3 Recommended Separation Distance

The CProbe 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 CProbe 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 CProbe Wireless Probe Type Ultrasound Scanner as recommended below, according to the maximum output power of the communications equipment.

Note

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.	
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: CProbe, SN:WSPBGCA042			Operating Mode:Bmode					
Index label			MI	*TIS*			*TIB*	*TIC*
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
Maximum index value			0.65	0.16				N/A
Associated acoustic parameters	$p_{r.\alpha}$		1.17					
	P			13.31				N/A
	min of $[P_\alpha(Z_s), I_{ta.\alpha}(Z_s)]$							
	z_s							
	z_{bp}							
	z_b							
	z at max $I_{pi.\alpha}$		4.70					
	$d_{eq}(Z_b)$							
	f_{awf}		3.25	3.25				N/A
	Dim of A_{aprt}	X		1.29				N/A
		Y		1.30				N/A
Other information	t_d		0.73					
	prr		1250					
	p_r at max I_{pi}		2.10					
	d_{eq} at max I_{pi}							
	$I_{pi.\alpha}$ at max MI		42.30					
	Focal Length	FL_x						
		FL_y						
Operating control conditions	Depth(mm)		160	160				N/A
	Freq(MHz)		3.5	3.5				N/A

Transducer Model: CProbe, SN:WSPBGCA042			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			0.65	0.16		0.12	0.37	N/A
Associated acoustic parameters	$p_{r.\alpha}$		1.17					
	P			13.31			13.11	N/A
	min of $[P_\alpha(Z_s), I_{ta.\alpha}(Z_s)]$					7.68		
	z_s					2.40		
	z_{bp}					2.19		
	z_b						4.70	
	z at max $I_{pi.\alpha}$		4.70					
	$d_{eq}(Z_b)$						0.62	
	f_{awf}		3.25	3.25		3.25	3.25	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		0.73					
	prr		1250					
	p_r at max I_{pi}		2.10					
	d_{eq} at max I_{pi}						0.62	
	$I_{pi.\alpha}$ at max MI		42.30					
	Focal Length	FL_x				N/A		
		FL_y				5.00		
Operating control conditions	Depth(mm)		160	160		160	160	N/A
	Freq(MHz)		3.5	3.5		3.5	3.5	N/A

After-sale service

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