



**DrSono Wireless Ultrasound**

**User Manual**

# DRSONO

## User's Manual

**Rev. 1.00**

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

## Content

Section 1 INTRODUCTION .....	1
1. Signs and Meaning .....	2
2. Technical Parameters .....	2
2.1 Indications For Use .....	3
2.2 Precautions&Warnings .....	3
Section 2 GETTING STARTED .....	4
2.1 Unpacking .....	4
2.2 Installing APP .....	6
2.3 Starting Probe .....	6
2.4 Wireless Connection .....	7
Section 3 APP OPERATIONS .....	7
3.1 Ultrasound Scanning .....	7
3.2 Mode Introduction .....	9
3.3 Patient Information Input .....	12
3.4 Data Measurement .....	13
3.5 Report Download .....	16
3.6 Image and Video Storage .....	18
Section 4 Maintenance .....	20
4.1 Wireless Charging .....	20
4.2 Cleaning And Disinfection .....	20
4.3 Storage .....	21
4.4 Troubleshooting .....	21
4.5 Disposal .....	21
4.6 Product Maintenance and Protection .....	21
Section 5 SAFETY .....	22
5.1 Safety Instructions .....	22
5.2 Principles of Using Acoustic Power .....	25
5.3 Electromagnetic Compatibilities .....	29
Appendix A. Specification .....	33

# Section 1 INTRODUCTION

The Wireless Probe Type Ultrasound Scanner is the new generation instrument for ultrasonography with the outstanding feature of wireless.

Different from traditional ultrasound scanners 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 central units different from traditional devices are now changed to be any iPad from Apple Inc or Apple iPhone. The probe is a WiFi Access Point and can be connected by Android Phone / Tablet/ iPad / iPhone / Windows PC. With the probe connected through WiFi and the App is running, enjoy your working days without the trouble making cables.

This manual is intended to provide a thorough overview of the Scanner. It should be carefully read before to operate the device.

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

# 1. Signs and Meaning

Sign	Meaning
	Caution! Please consult the accompanying document
	Consult the user manual
	Type BF applied part
IPN <sub>1</sub> N <sub>2</sub>	Degree of IP protection
	Non-ionizing electromagnetic radiation
	Manufacturer
	Date of manufacture
	Serial number
	Keep dry
IPX5	Prevent the water from the nozzle from invading in all directions and cause damage to the electrical apparatus.

## 2. Technical Parameters

Display: iPad / iPhone Series/Android Phone/Tablet/Windows PC

Gray Scale: 256 levels

Battery last: > 3 hours

Size: 104mm x 50mm x 22mm

Weight: ≈270g

	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: model (SNP-4200) 3.8Vd.c. 4200mAh

continuous working time : > 3 hours

Waterproof: IPX5

## 2.1 Indications For Use

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

## 2.2 Precautions&Warnings

- PRECAUTION 1: Read the user manual carefully before operating the device, be familiar with the equipment and operation procedures, and strictly implement them; 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, and should avoid direct sunlight, extreme temperature changes, dust, near heat sources, and high humidity places. Do not place anything on top of the instrument.
- PRECAUTION 3: The device shall be operated in undisturbed conditions to avoid data transmission interruption.
- PRECAUTION 4: When there is wireless channel congestion, switch the channel (Refer to Section 3.6 SETTINGS) and restart the probe.
- PRECAUTION 5: Prescription Use. Professional physicians shall operate the device.
- PRECAUTION 6: The device shall be repaired by a professional recognized by the manufacturer.
- PRECAUTION 7: The device does not have a shelf life. Its expected use life is 10 years. After ten years, though the device still usually works, it is recommended to have it checked by the manufacturer.

- PRECAUTION 8: Useless components shall disposed of 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 is insufficient.
- WARNING 1: The device is not explosion-proof. Do not use it in inflammable and explosive environments (such as in the presence of anesthetic gas, oxygen or hydrogen, etc.);
- WARNING 2: Do not allow the interior of the product to be exposed to, or immersed in, liquid. Otherwise, fire, electric shock, injury, or damage to the product may occur.

## Section 2 GETTING STARTED

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

<b>Caution</b>	The too high ultrasonic intensity and/or prolonged 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 packs to prevent damage during shipment. Before unpacking, please note any visible damage to the outside of the shipping containers.

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

**Table 1-1 Items List for The Wireless Ultrasound Scanner**

ITEMS	INCLUDED
Host(Including probe)	√
User's Manual	√

Power Adapter	√
Quality Inspection Certificate	√
Velvet Bag	√

Each item should examine for any noticeable defects or damage that may have occurred during shipment, although it is packs carefully. If any defect or injury exists, please get in touch with your local representative immediately to report the problem.

Product Schematic Diagram



	Items	Descriptions
1	Linear On/Off Indicator	Indicate Linear Array's Activation Status
2	Power On/Off & Freeze	Power ON/OFF: Press the button for about 5 sec. Freeze: Press the button for about 1 sec.
3	Convex On/Off Indicator	Indicate Convex Array's Activation Status
4	Wireless Signal Status	Show Wireless Signal Status
5	Battery Level Indicator	Indicate Battery Level

Switching the probes of Double Heads: Press the ON/OFF button and hold it for 3~4 seconds, then the working Probe will change from one probe to the other.

Working state display: indicator light indicates the position of the convex array to work with the convex array probe and the indicator linear array position to work with the linear array probe.

Turning off the power of Double Heads: Press the ON/OFF button and hold it for 6~7 seconds.

Charging: this Double Heads Probe only supports wireless charging, full charging time is around 2 hours.

## 2.2 Installing APP

### Software Installation Method

For iOS Devices: Go to the Apple App Store.

For Android Devices: Go to the Google Play Store.

Search for "WirelessUSG Flash," then click the install button. The app will install on your device.

Open it to start scanning.

## 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.

<b>Warning</b>	Abnormal probes can cause electric shock or injury to people. Therefore, once abnormalities are found, you must immediately stop using the probe and contact us.
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### 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".

<b>Caution</b>	Probes that have not been cleaned or disinfected may cause bacterial and viral infections.
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### 2.3.3 Boot Check

Please check the following before diagnosis.

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), will stop the probe.

<b>Caution</b>	If the operator places an abnormally hot probe on the surface of the patient's skin, it may cause burns.
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1. The ultrasound image must not be abnormal after power on; check whether the functions are standard, including software operation, button function and ability.

<b>Caution</b>	In the event of any of the above anomalies, the ultrasound imaging diagnostic apparatus may be defective, and please get in touch with DRSONO.
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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 lit to indicate the battery's capacity. The four grids of the indicator imply the battery capacity. (Probe charging will be described in section 4.)

Seconds after the probe is turned on, the Wireless Connection Indicator will be lit and blink to notice that the probe is ready for a wireless connection from the iPad/iPhone/Android Phone/Tablet /Windows PC.

The probe can be turned off by holding down the button for seconds. When the probe is off power, 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/iPhone/Android Phone/Tablet/Windows PC, turn on the WiFi (if not on), and Find the SSID of the probe. The SSID is like: "SS-1 GMBFCA001"; the suffix "GMBFCA001" is a code generated from the Serial Number. Connect to the SSID with the password the same as the Serial Number (in lowercase). The Serial Number is in the form of "WSPBFCA001" with the prefix "WSP". It can be found on the surface of the probe. After WiFi 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 light up with no blinking. Every connection step is done. The operation of the system to finish ultrasonography will be described in the next section.

# Section 3 APP OPERATIONS

## 3.1 Ultrasound Scanning



Main Interface (Image 3-1)

The meaning of each icon:

1. Gain +: increase image gain.
2. Gain - : reduce image gain.
3. Depth : choose the scanning depth penetration. You can also change the depth of the image by sliding up and down the screen of the phone/tablet.
4. Focus: Adjust the focus position of the image.
5. Dynamic range: Adjust the dynamic range of the image.
6. Harmonic : can change the working frequency of the probe.
7. Denoise : noise reduction can eliminate low-level echoes caused by noise.
8. Image Mode: Select image mode, B mode, B / M mode, Color Doppler mode (COLOR), Energy Doppler mode (PDI), Pulse Doppler (PW).
9. Patient :It's for patient information management; the patient information is showing at the top right corner.
10. Freeze/Scan: Image freeze and scan.
11. Play: Movie playback, replay after the image freezes.
12. Meas: It's for distance/area/obstetrical measurement.
13. Annote: Enter a comment on the image.
14. Biopsy: Draw a puncture line for biopsy image guidance.
15. Clear: Delete measurement results and notes on images.
16. Save Image: Save a single scanning image in JPG format.

- 17. Save Image Video: Save the scanning video.
- 18. Preset: WIFI channel selection to avoid channel blocking.

19: TGC  (time gain compensation) the function menu comes out by clicking on the top of the right "<".

## 3.2 Mode Introduction

### 3.2.1 Color Doppler Imaging Mode, Image 3-2

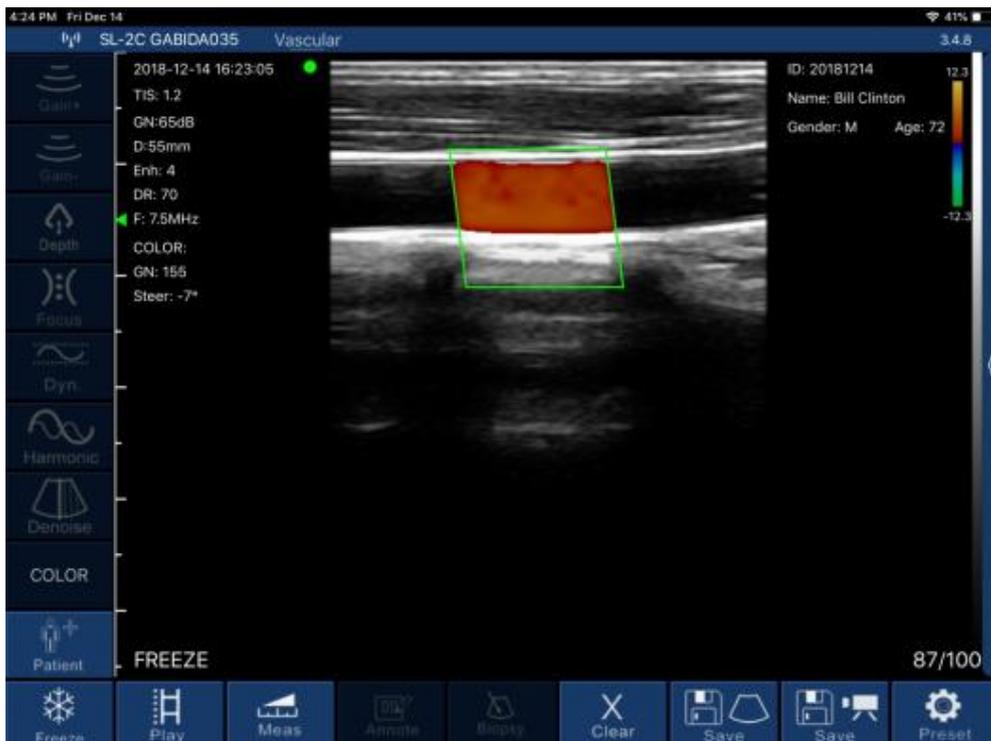


Image 3-2 Color Doppler Imaging Mode

- 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.

### 3.2.2 Energy Doppler Imaging Mode, Image 3-3

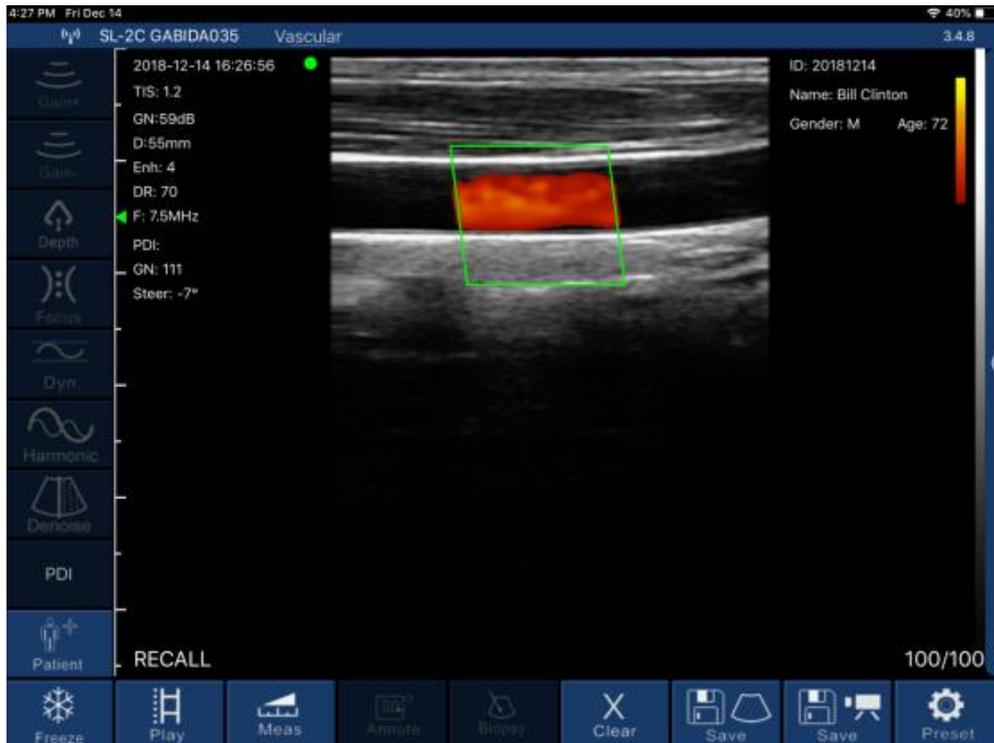


Image 3-3 Energy Doppler Imaging Mode

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.

### 3.3.3 Pulse Doppler Imaging Mode, Image 3-4



Image 3-4 Pulse Doppler Imaging Mode

1. Gain +: increase pulse gain.
  2. Gain -: reduce pulse gain.
  3. Deflection angle: used to change the angle of the spectrum sampling line in a real-time scanning state.
  4. Sampling frame: change the size of the sampling volume.
- Correction angle: used to change the angle of the blood flow direction cursor.

### 3.3 Patient Information Input

5. Click on the software interface "Patient" button, then the patient information interface will show up as below Image 3-5 :

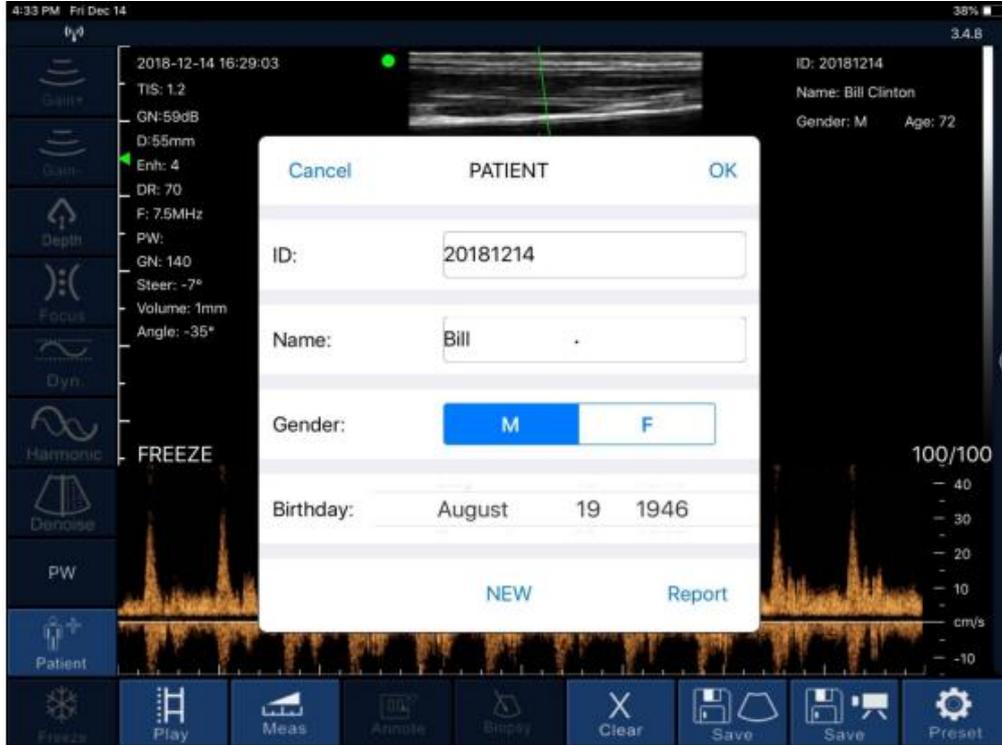


Image 3-5 Patient Information Interface

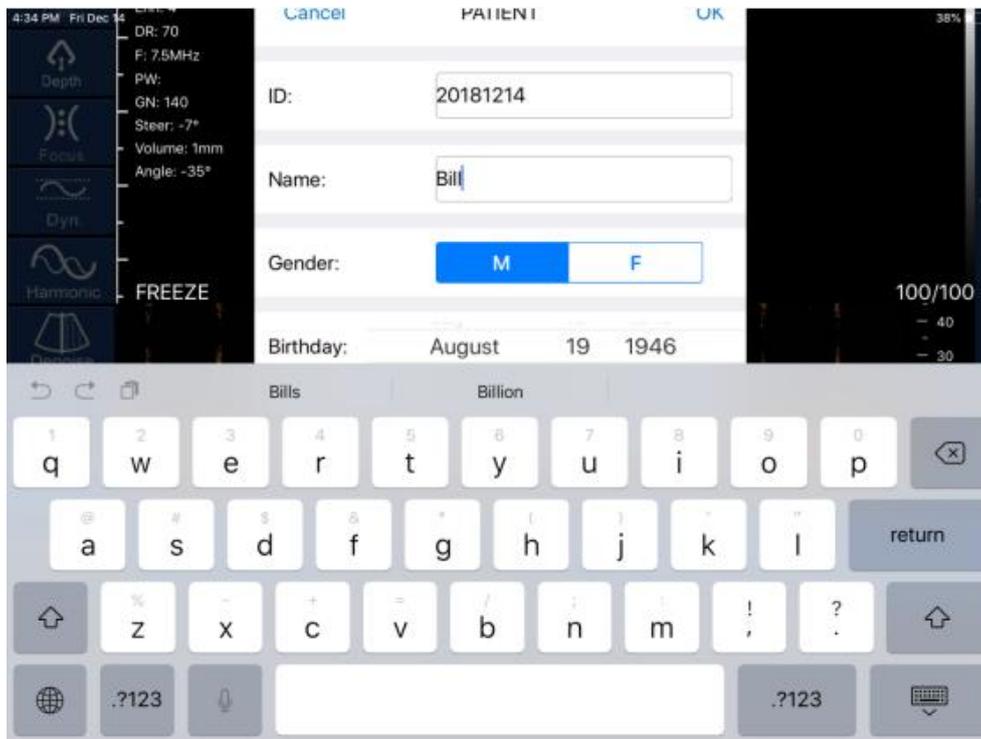


Image 3-6 Patient Information Editing Interface

Input the Patient ID and Patient Name, then choose the gender and click OK. The patient information is finished. If you make a mistake, click cancel or create a new case.

### 3.4 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 Image 3-7).

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

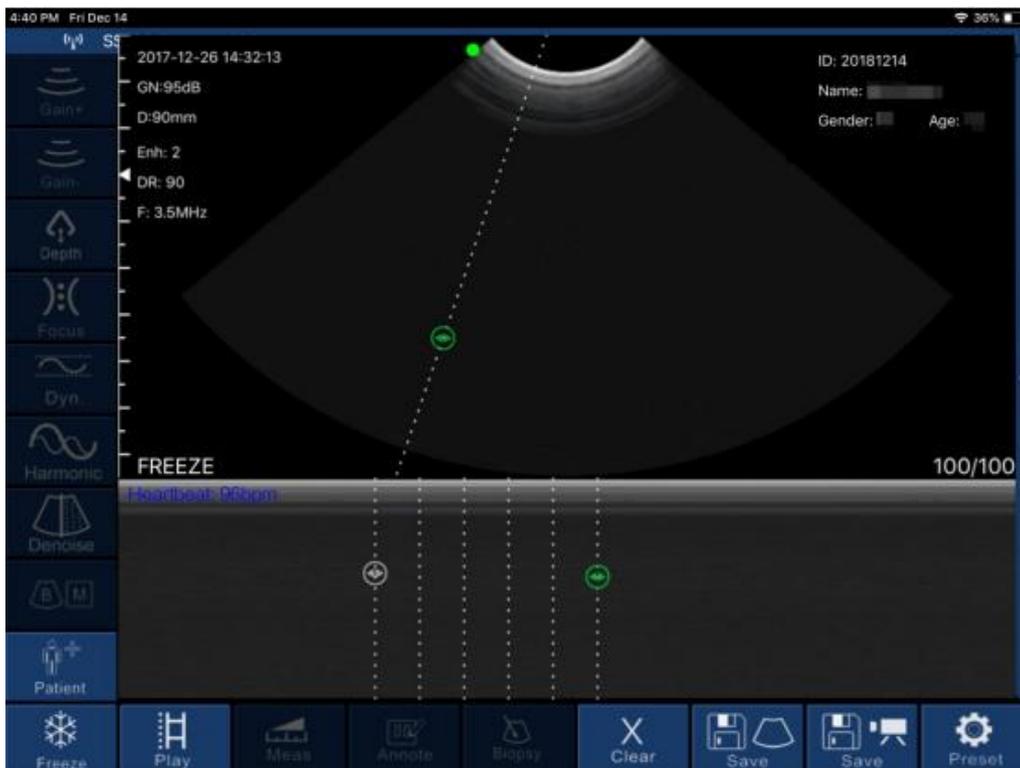


Image 3-7 Measuring the Heartbeat Interface

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



Image 3-9 Measurement Function

After selecting the “LENGTH” length measurement function, click on the two points to be measured on the frozen screen, the measurement trajectory will appear, click the moving point on the trajectory line (as shown in the middle of Image 3-7), move the course, 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 on the frozen screen and click on it. Three 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 similarly. 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 three moving points on the net. Three 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 estimated 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. The virtual trackball that appears (as shown in the lower right corner of Image 3-10) can be fine-tuned according to the direction of the measurement point.



Image 3-10

Up to 4 sets of data can be measured on the same frozen screen. After the measurement, press “Clear X” to delete all measurement results. If you want to delete a size, 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 data sets. After finishing the size, press the “Clear X” can delete all size; if you want to delete one size, click the measuring data result on the top right screen, immediately appear below as shown in

Image 3-11, click "  " on the right side of the data, and delete the measurement data.

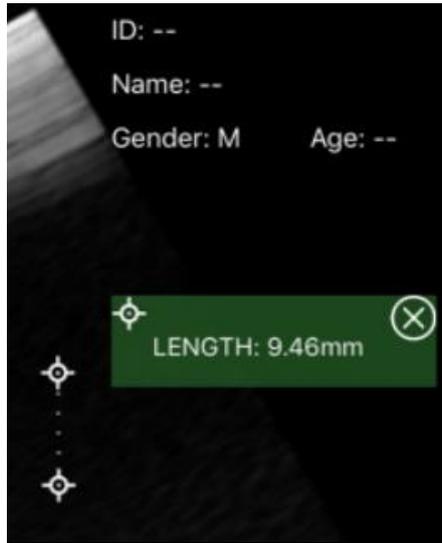


Image 3-11 Delete Part of the Measurement Data

### 3.5 Report Download

Click on the "Patient" on the lower left of the software interface, then comes out the patient information interface as below.

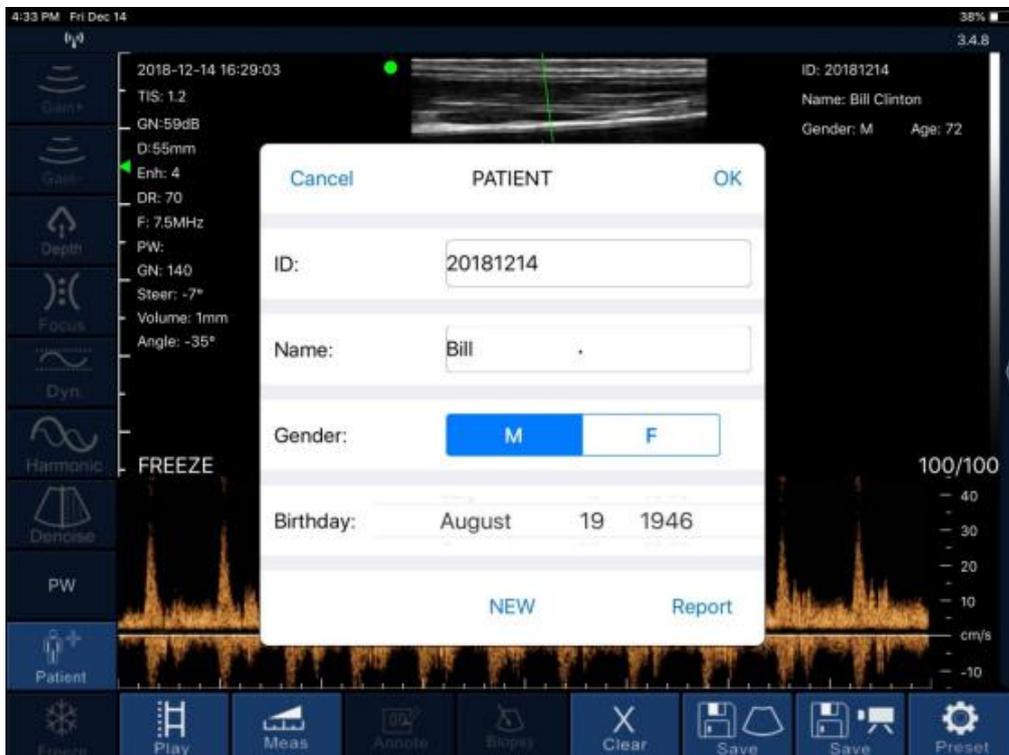


Image 3-12 Patient Data

Click on "Report", and come out of the interface below, as shown in the Image 3-13, click on the remark box, and the user can input content in a dialog box. Click on the download icon "  " on the lower right of the page, then the report can be downloaded. The information is stored automatically in the smart terminal display system (apple mobile phone or tablet) photo album.

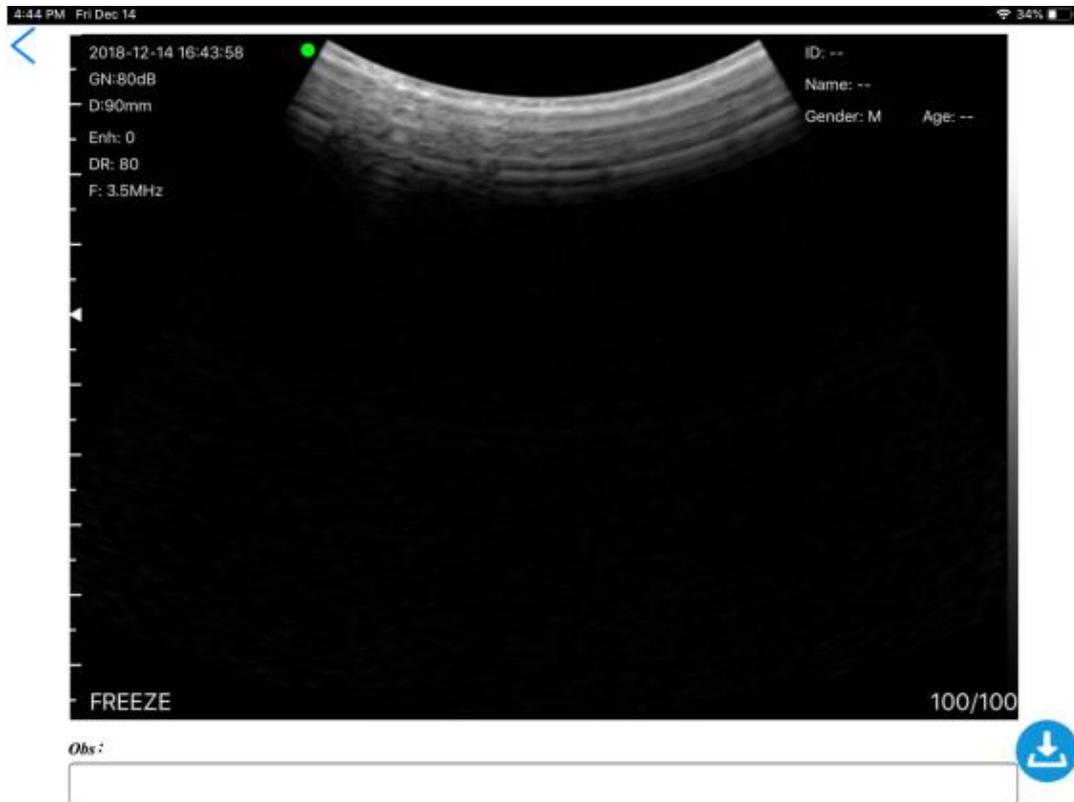


Image 3-13 Patient Information Download Interface

### 3.6 Image and Video Storage

#### 3.6.1 Image Storage

Click on "  " on the bottom right in the below interface (Image. 3-14), then save the image displaying on the screen at the moment. The image is automatically stored in the intelligent terminal display system (iPad/ iPhone/Android Phone/Tablet/Windows PC) photo album.



Image 3-14

#### 3.6.2 Video Storage

Click on "  " on the bottom right in the above interface (Image3-14). Then the video starting from the operation within 100seconds is stored in the intelligent terminal display system (iPad/iPhone/Android Phone/ Tablet/Windows PC) photo album.

#### 3.6.3 Image and Video Review

Open the photo album of the smart terminal display system (iPad/ iPhone/Android Phone/Tablet/Windows PC), then review the saved image and video.

### 3.6.4 Replace the Signal Channel

In the crowded WIFI environment, the user can choose different WIFI channels for the probe. Press the "Preset" button, then the signal channel selection list comes out ( as shown in Image 3-15), and click select channel. After 2 seconds, please restart the probe and connect with the intelligent terminal display screen according to the 3.1 step.

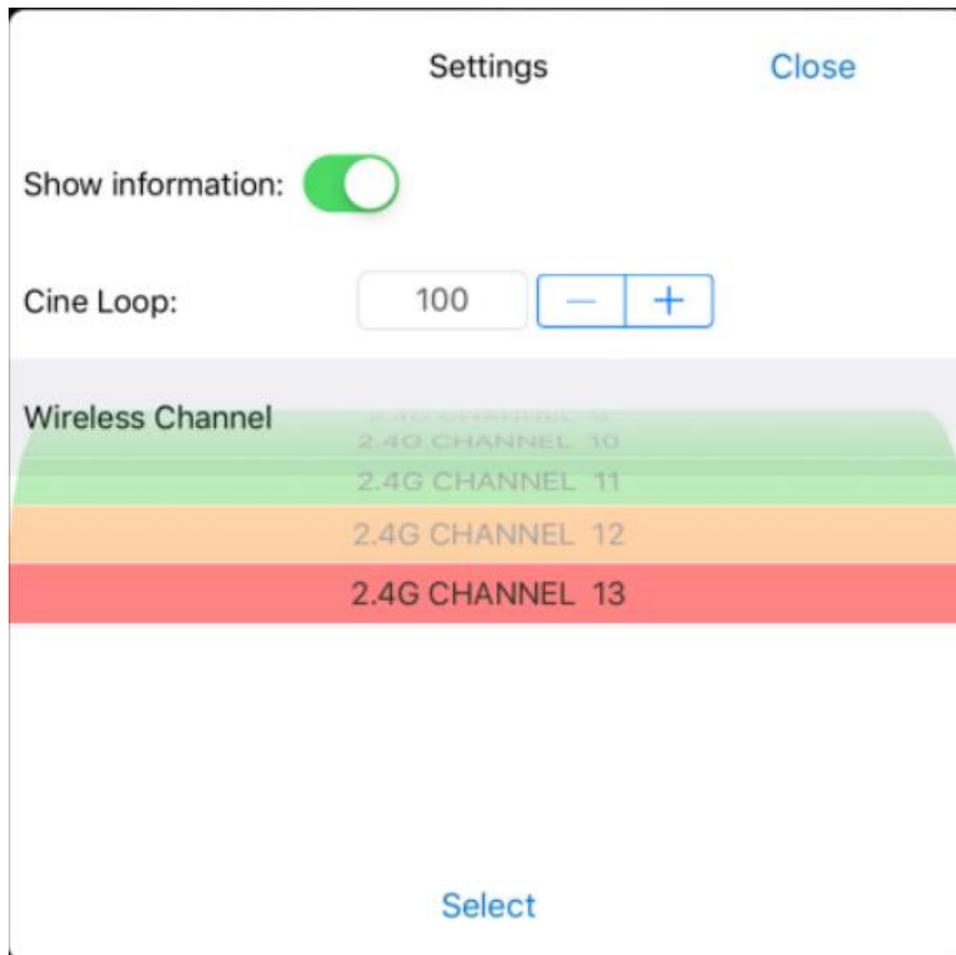


Image 3-15

## Section 4 MAINTENANCE

### 4.1 Wireless Charging

Plug one end of the USB cable into the wireless charging pad. Place the search on the wireless charging pad. The probe lights up and starts charging after 1~2 seconds. Ensure the probe is centered on the wireless charging pad. For efficient charging, place the probe, place the probe within seven mm left and right from the center of the wireless charging pad. If it is significantly out of the range, it may be unstable or not charge.



Image 4-1 Wireless Charging with wireless charging pad

#### Warnings:

- ★ It should not be used if the adapter power supply voltage is outside the adaptive range of the appliance (Normal Adapter's output voltage:  $5V \pm 0.5V$ ).
- ★ Check the condition of the power cable first. If the power cable is damaged or broken, replace the new one immediately.

### 4.2 Cleaning And Disinfection

The probe needs to be cleaned before use.

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 wet cloth.

To remove all traces of disinfectant solution, wipe the instrument with a clean soft cloth, dampened in sterile water or potable tap water. Brushing the device three

separate times to remove all residual disinfectant is recommended. Thoroughly dry the instrument with a clean, soft cloth before using.

### 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 Troubleshooting

Inspect: Check if the probe and the host are connected correctly. Fault handling:

Ite	Failure Problem	Solution
1	No response after the press the Power ON/OFF button	Charging, check the power supply
2	Intelligent display can't connect probe WIFI	Check that 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 is not bright	Adjust brightness
5	Charging not work	Detect circuit and electrical outlet, check if the USB interface is damaged

### 4.5 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.

### 4.6 Product 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 product power supply shall be by section 1.6 of this manual.

3. If you stop using this product for an extended 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, shaking, or dismantling the components inside the probe.
5. Clean and wipe the probe cover with alcohol cotton, and it should be operated in the power-off state.
6. This product should not be frequently startup and shutdown. After shutdown, if needed to start up again, please wait at least 1 minute of time for the boot operation.
7. If instrument malfunction occurs, please ask professional staff for maintenance.
8. Probes are valuable and vulnerable parts; any collision or drop is forbidden.
9. Suspended in the diagnosis process; please press the button for freeze. The system in the frozen state benefit from probing for long-term use.
10. Apply the medical ultrasound coupling agent, which complies with relevant standards when using the probe.
11. the structure of the probe is watertight, prohibiting any conductive liquid immersion so 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 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

Operation safety is the most crucial 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 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, and cannot be used for treatment.

### 5.1.1 Electric Safety

- The biocompatibility of this product has been verified; in normal circumstances, it will not harm 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 get in touch with us.
- Please check and replace the battery periodically.
- Warning: Class I equipment must only be connected to a supply mains with protective earth to avoid the risk of electric shock.
- Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure. If carelessly pour any water onto the system, immediately stop using the ultrasound system and contact the 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 is not serviced or maintained can not be used on the patient.
- The outer surface of the portions of the 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 that 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 the human body for medical diagnosis.
- The system can only be maintained by the person authorized or trained by the manufacturer.
- The transducer is treated as the applied part.

- Do not operate this system in an atmosphere containing flammable gases or liquids such as anesthetic gases, hydrogen, and ethanol because there is a danger of explosion.
- Do not use this system simultaneously with other equipment such as an electric knife, defibrillator and other high-frequency therapy equipment. Otherwise, there is a danger of electric shock.
- Keep the system dry. Avoid bedding transported to the field with a significant temperature change prevent condensation or water droplets from resulting in short circuits.
- Connect the earth conductor before powering on the system. Disconnect the grounding cable after powering off the system. Otherwise, there is a danger of electric shock.

### 5.1.2 Mechanical Safety



#### **Caution!:**

- Be careful when holding the device, for if it is handheld, it may fall.
- Do not use shell-cracking equipment.
- Do not use this system in a 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 an angle larger than  $10^{\circ}$ . Otherwise, the system will fall off causing 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, and please manage and use the ultrasound couplants correctly to prevent it from being polluted.

**Caution!:**

- Disconnect the problem 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 a mobile device iPad or iPhone by a wireless local network. The software itself can not be connected to an external network; the network the software is connected to is the local wireless network launched by the probe.

## 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 heat's effect on the patient's 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 of the fetus 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 at high exposure levels and long exposure times. Thus ultrasound should be used in a prudent manner to provide medical benefits 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 the TI display type, please choose: Preset → [System Preset] → [TI].

- Meaning of MI/TI

Mechanical bioeffects are threshold phenomena that occur when a certain output level is exceeded. The threshold level varies with tissue type. The potential mechanical bioeffects vary with peak pressure and ultrasound frequency. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. There is no specific MI value that means that a mechanical effect is occurring. The MI should be used as a guide for implementing the ALARA principle. The TI value informs the operator about the conditions that might lead to an increase in temperature at the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. 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 temperature rise amount is influenced by factors 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 the bone is near the focus of the image, as in the third crop ester OB examination; it provides an estimates 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 the 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 a 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

They are conservative for many assumptions used in the process of measurement and calculation. For most organizations path, a high estimate is made in the size and calculation process of tissue exposure intensity. For example, using an attenuation coefficient for  $0.3\text{dB cm}^{-1}\text{ MHz}^{-1}$ , much lower than the actual human tissue attenuation coefficient, choosing conservative values of tissue characteristics. 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 good field measurement, and other proper field parameters can be deduced from proper pressure, so when analyzing measurement uncertainty, only take sound pressure for analysis and fate of different parameters can be deduced from the sound pressure.

Measurement uncertainty mainly includes repeated measurement uncertainty and the system uncertainty, system uncertainty is an order 32 of a magnitude higher than repeated measurement uncertainty, so the main analysis is system uncertainty. Mainly decided by the following factors:

1. The sensitivity of hydrophone: According to the 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 generating mechanical/thermal effects: direct control and indirect control, receiver control. Qualified operators should try to reduce the acoustic output on the premise of compelling diagnostic images.

- Direct control

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

#### ■ 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. The 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 are related to the 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 some time.

#### ■ The receiver control

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

When acquiring images, using the default (or as low as possible) acoustic output location is recommended, and using the gain control to compensate. The default setting is commonly 70% of the maximum allowed acoustic output value, which will not cause harm to the operator, and for the probe is the 33most practical value.

### **5.2.5 Acoustic Power Settings**

The ultrasound system has 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 accumulates. The total energy is controlled by output intensity and real radiation time. The output intensity necessary for examinations differs depending on the patient and clinical case. Not all examinations can be performed with a shallow level of acoustic energy. Controlling the acoustic level at a shallow level leads to low-quality images or insufficient Doppler signals, adversely affecting the reliability of the diagnosis. However, the sound power used more significant 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 generally in the electromagnetic environment and not to radiate any electromagnetic interruptions to any other objects in the same domain.

This system is designed by the current EMC requirement. And the ultrasound image will degrade instantly if the system is used in the electromagnetic field environment. Suppose the degradation of the image is found; IN that case, it is recommended to inspect the operation environment to confirm the radiation source.

### 5.3.1 Electromagnetic Emission

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

1	Guidance and manufacturer's declaration - electromagnetic emission		
2	The CProbe Wireless Probe Type Ultrasound Scanner is intended for use in the electromagnetic environment specified below. The customer or the CProbe Wireless Probe Type Ultrasound Scanner user should assure that it is used in such environment.		
3	Emission test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	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.
5	RF emissions CISPR 11	Class B	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.
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

### 5.3.2 Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The CProbe Wireless Probe Type Ultrasound Scanner is intended for use in the electromagnetic environment specified below. The customer or the CProbe Wireless Probe Type Ultrasound Scanner user 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	$\pm 6$ k V contact $\pm 8$ kV air	$\pm 6$ k V contact $\pm 8$ kV 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 I E C 61000-4- 4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input output lines	$\pm 2$ kV for power supply lines $\pm 1$ kV for Input-output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge I E C 61000-4- 5	$\pm 1$ k V differential mode $\pm 2$ k V common mode	$\pm 1$ k V differential mode $\pm 2$ k V 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 cycles $40\%$ 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	( $>95\%$ 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 an 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 I E C 61000-4- 8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a familiar commercial or hospital environment.
NOTEUT is the a.c. Mains voltage before 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 disturbances are controlled. The customer or the user of the CProbe Wireless Probe Type Ultrasound Scanners can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CProbe Wireless Probe Type Ultrasound Scanner, as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation distance according to the frequency of the 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.



**Note!:**

Suppose the system has generated the interference (confirmed by powering on and off the system); In that case, 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 ways other than currently used.
- Contact the manufacturer as soon as possible.

# Appendix A. Specification

Complied Standard		
EN/IEC 60601-1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance, BF, Non-continuous operation	
EN/IEC 60601-2-37:2015	Medical Electrical Equipment Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment	
EN/IEC 60601-1-2:2014	Electromagnetic Compatibility Requirements and tests, Class A	
Circumstance		
Operation	Ambient Temperature	5°C ~ +35°C
	Relative Humidity	25% ~ 80%, Non-Condensing
	Atmospheric Pressure, Max. Altitude	700hPa ~ 1060hPa, 3000m
Storage / Shipping	Ambient Temperature	-20°C ~ +55°C
	Relative Humidity	25% ~ 93%, Non-Condensing
	Atmospheric Pressure, Max. Altitude	700hPa ~ 1060hPa, 3000m
Safety		
Type of protection	Internal-Power Type, 3.8 VDC / 4,200 mA h	
against electric shock	Type BF Applied Parts	
Degree of protection	Non-continuous operation Operating mode: 1:2 duty cycle (ON: 5 min / OFF: 10min)	
against electric shock	Hand-Held Type	
Degrees of protection against harmful liquid	IPX1	

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.
<b>Wireless Parameters</b>	
WI-FI Type	2.4G Band
Supported Type	IEEE 802.11n(HT20)
Modulation	IEEE 802.11n:OFDM
Channel Number	11 Channel for 20 MHz bandwidth (2,412~2,462 MHz)
Channel Separation	5 MHz
Wireless Power	10 mW/MHz or below
<b>Common Technical Parameters</b>	
Description	- Display: Tablet PC or Mobile Phone which supports by iOS 8.0 or above, Android OS 7.0 or above, Windows System.
Element	192
Dimension & Weight	159 mm × 69 mm × 29 mm, 250g
Array Type	Electronic array R60 / L40
Probe Type	Convex array probe, Linear array probe
Mode	B, B/M, Color, PDI, PW
Frequency	3.2/5 MHz Convex, 7.5/10 MHz Linear
Depth	Convex 90 mm~305 mm, Linear 20~80 mm
Measurement	[Common] Length, Area, Angle, Velocity, HR, S/D, Depth [For Obstetrics] GA(CRL), GA(BPD), GA(GS), GA(FL), GA(HC), GA(AC), EFW(BPD), EFW(FL)
Application	Abdomen, Obstetrics, Gynecology, Peripheral Vessel, Superficial Organ
Image Frame Rate	18f/s
Battery Operation Time	2.5 hours
Charging Mode	Wireless Charging



## User Manual

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