SonoStar

Wireless Probe Type Ultrasound Scanner
BProbe

User's Guide

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Section 1 INTRODUCTION

The Wireless Probe Type Ultrasound Scanner (Model: BProbe) 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 bladder volume calculating needs.

Figure 1.1 BProbe Wireless Probe Type Ultrasound Scanner

1.1Signs and Meaning

Sign	Meaning
	Caution! Please consult the accompanying document.
	Consult the user manual

	Type BF applied part
	Class II equipment
IPN1N2	Degree of IP protection
	Non-ionizing electromagnetic radiation
	Manufacturer
	Date of manufacture
SN	Serial number
	Keep dry
IPX1	There is no harmful effect on vertically falling water droplets.
IPX7	The device can be immersed in water within a depth of 1 meter for up to 30 minutes without damage.
MD	Medical device Indicates the item is a medical device.
UDI	Unique device identifier Indicates a carrier that contains unique device identifier information This symbol may be used when multiple date carriers are present on the label. If used, this symbol shall be placed adjacent to the unique device identifier carrier.
REF	Catalogue number Indicates the manufacture's catalogue number so that the medical device can be identified
	WEEE Directive: 2002 / 96 / EC waste electrical and electronic equipment

	Model number Indicates the model number or type number of a product This symbol shall be accompanied by the model number of the product adjacent to the symbol.
	Country of manufacture To identify the country of manufacture of products In the application of this symbol, the"CC" shall be replaced by either the two-letter country code or the three-letter country code defined in ISO3166-1 The date of manufacture may be added adjacent to this symbol.

1.2TECHNICAL PARAMETERS

1.2.1 General performance

1) Product configurations

The Wireless Probe Type Ultrasound Scanner consists of a scanner, IPAD, charging cable, software.

2) Intended Use

The Wireless Probe Type Ultrasound Scanner (Model: BProbe) is mainly used for measuring urinary volume of bladder.

3) Intended User

Wireless Probe Type Ultrasound Scanner should be operated by professional medical staffs, includes physicians, nurses, therapists or other relevant staffs with medical science.

4) Intended patient

Adult and children, including pregnant women.

5) Contraindication

This device is not suitable for the examination of the site of injury or acute inflammation.

6) Physical characteristics

Dimension：156 (L) x 60 (H) x 20(D)(mm)

Weight：450g

7) Environmental

Item	Operations	Storage and Transportation
Relative Humidity	25% to 80%, non-condensing	25% to 93%, non-condensing
Ambient Temperature	5°C to +35°C	-20°C to +55°C
Atmospheric Pressure； Altitude	700hPa to 1060hPa； ≤3000m	700hPa to 1060hPa; ≤3000m

8) Mmeasurement accuracy of BProbe

Type	BW（black and white）
Frequency	2.6MHz
Display accuracy	1ml
Measuring range	20 – 999ml
volume accuracy	20-99ml: ≤±10ml 100-999ml: ≤10%
Scanning Radius	80°
Display Mode	B
Application	Urology

9) Electronic

Input:5Vd.c. 1A

Battery Capacity：modle（SNP-4200） 3.8Vd.c. 4200mAh

continuous working time： 2hour

Waterproof: Main unit: IPX1; Acoustic head: IPX7

Security classification

According to the type of anti-electric shock:

Internal power supply;Class II charging equipment；

According to the degree of anti-electric shock:

Type BF application part;

According to the protection degree of harmful liquid:

Main unit: IPX1; Acoustic head: IPX7

According to the degree of safety in the presence of flammable anesthetic gas mixed with air (or oxygen, nitrous oxide two):

Cannot be used in the presence of flammable anesthetic gas mixed with air or oxygen or nitrous oxide;

According to the working mode: Continuous working equipment.

10) The specification of Charging cable

Type	Micro USB 5P
Maximum input power	9V/2A
Specifications	1m

11) The specification of IPAD/APP operating environment requirements

Hardware	· Processor: Apple A8X; tri-core · Processor frequency: 1.5 GHZ · System memory: 2GB · Storage capacity: 32GB · WIFI: 802.11a /b/g/n/ac · Dual-band (2.4G Hz and 5G Hz)
Software	· Operating system: IOS 9.0 or above · Supported software: SmartUS.ipa

1.3 INDICATIONS FOR USE

The Wireless Probe Type Ultrasound Scanner (Model: BProbe) is mainly used for measuring urinary volume of bladder.
Contraindications: This device is not suitable for the examination of the site of injury or acute inflammation.Patients with open skin or wounds in the supra pubic region.Patients with ascites.

1.4 PRECAUTIONS & WARNINGS

- PRECAUTION 1: Read the user manual carefully before operating the device, be familiar with the equipment and operation procedures, and strictly implement; the company is not responsible for the damage caused by the improper use of the machine and the resulting potential adverse consequences;
- PRECAUTION 2: The instrument must work in a clean environment, should avoid direct sunlight, extreme temperature changes, dust, near heat sources, high humidity places, do not place anything on top of the instrument.
- PRECAUTION 3: The device shall be operated in undisturbed conditions 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, and should wears gloves before use.
- 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 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 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 will be insufficient.

- WARNING 1: The device is not explosion-proof. Do not use it in an 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.

- The probe should be turned off when it is not in use. The probe can be safely stopped by pressing the power button for a long time.
- 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 requirements.
- Patients using cardiac pacemakers are guided by doctors' suggestions.
- Warning: Charging the battery by the operator is at least 1.5 meters away from patients; this product can't operate during charging.
- During equipment use, maintenance and upkeep cannot be carried out.
- Ensure that you are aware if the patient has any of the following conditions, which may affect ultrasound transmission and the accuracy of the exam:
- A catheter in the bladder-The presence of a catheter may affect the accuracy of the bladder volume measurement, but the measurement may still be dinically useful (example: detecting a blocked catheter).

  Previous supra pubic or pelvic surgery-Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.

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

Section 2 GETTING STARTED

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

Caution	The over-high ultrasonic intensity and/ or overtime exposure may cause injury.
	Please do not apply the probe of this device to the indication of use not covered in this manual.
	This product is identified as a type BF applied part.

2.1 Configuration And Equipment

2.1.1UNPACKING

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.

ITEMS	INCLUDED
scanner（BProbe）	√
Manual	√
USB Cable for Charging	√
IPad	Optional

Table 2-1 Items List for The Wireless Ultrasound Scanner

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.

The accessories include manual, USB Cable for Charging and IPad.

2.1.2 STARTING PROBE

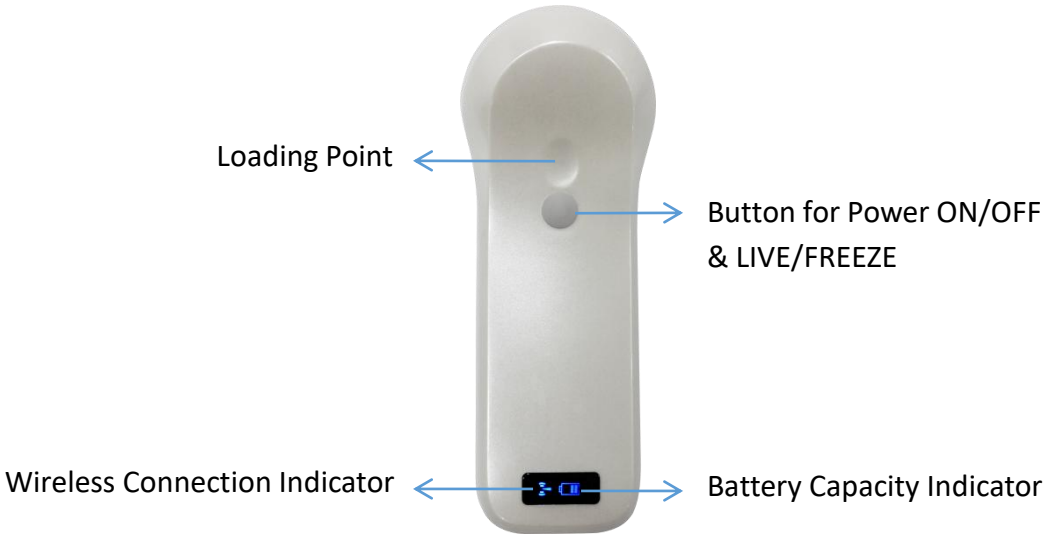


Figure 2-1 Wireless Ultrasound Probe

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

Press the button to turn on the probe. The Battery Capacity Indicator will be light to indicate the capacity of the battery. The four grids of the indicator imply the battery capacity. (Probe charging will be described in section 4.1.)

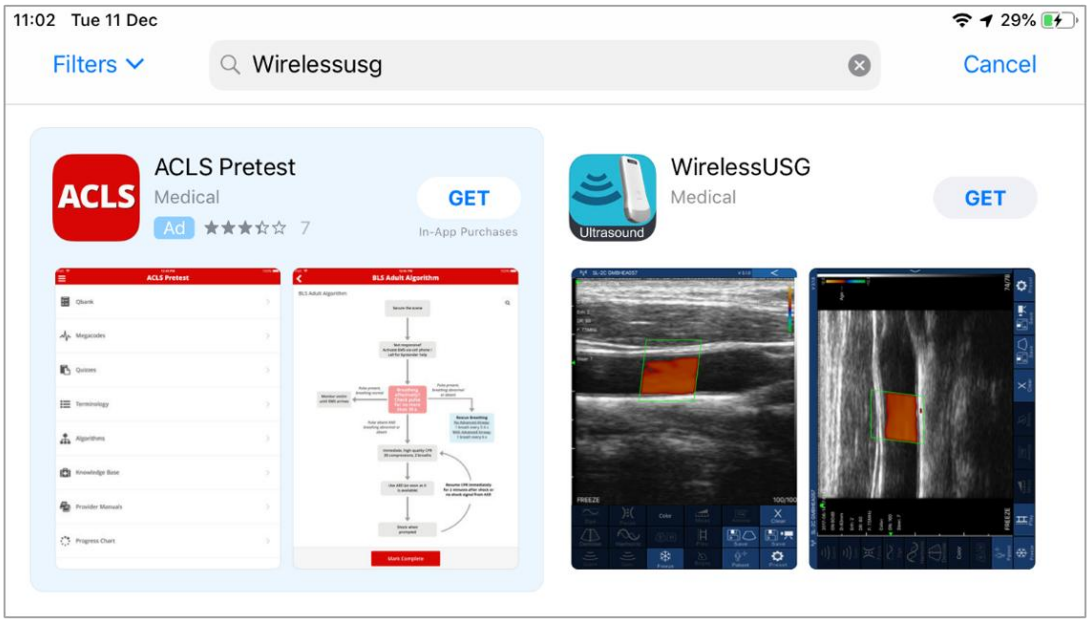
Seconds after the probe turned on, the Wireless Connection Indicator will be light and blinking to notice that the probe is ready for a wireless connection from the iPad.

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

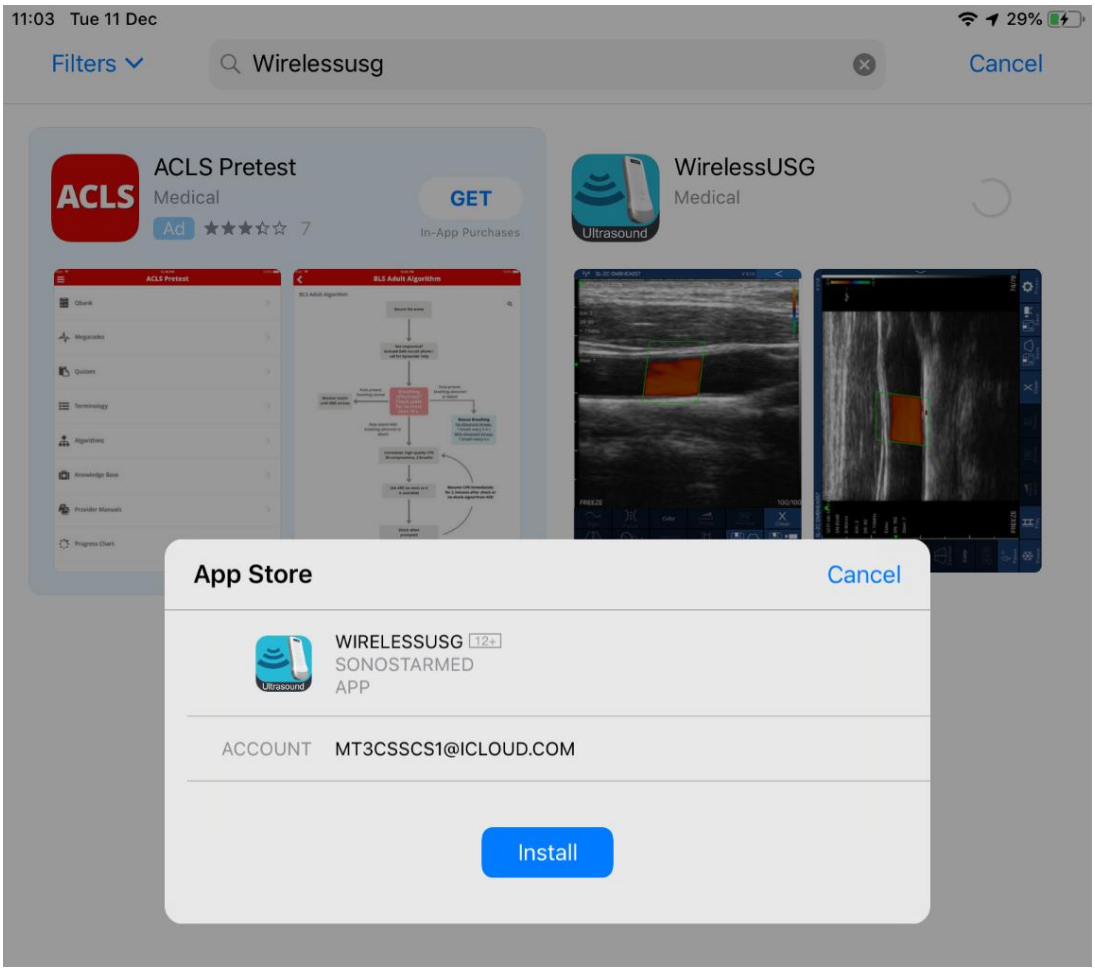
The concave (4) is the place for loading pressure by thumb. Suitable pressure is applied to the probe so the probe can couple to body perfectly.

2.2 INSTALLING APP

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



Find the software and download and install it.



2.2.2 Method 2

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

2.3 STARTING PROBE

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 the 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 should stop using.

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 On-Off Button for 3 seconds 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 is 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 5 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 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 of “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 step is done. The operations of using the system to finish the ultrasonography task will be described in the next section.

Section 3 APP OPERATIONS

3.1 ULTRASOUND scanning

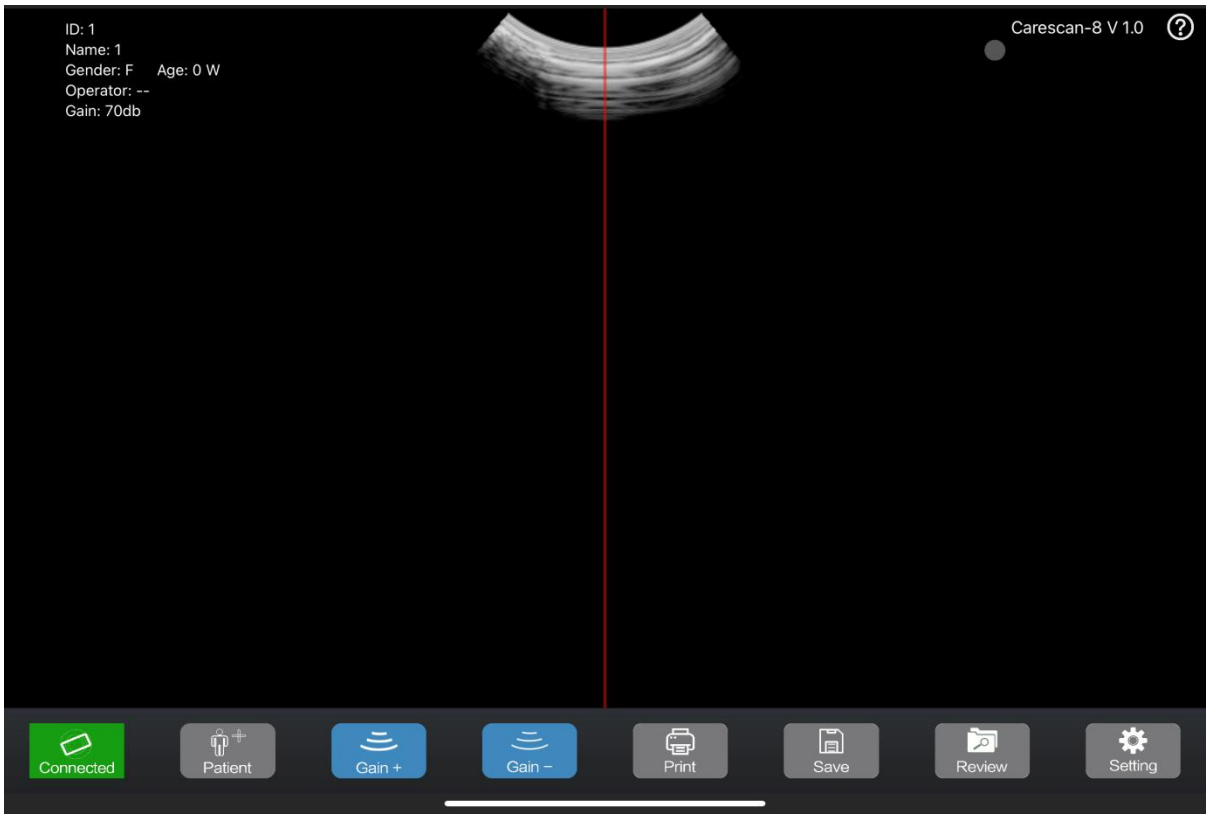


Figure 3-1 main menu

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

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

There is a center indicate line (3) in the middle of the image area .

Touch the patient information area (2) to enter the patient interface to edit or create a new case. Please refer to section 3.2 for detail information.

Press the Run/Freeze Button to run and Freeze the probe. When the Image come to shown on the Image Area (1), the sample indicator (4) will turn green from gray if the proper image has been obtained(please refer to section 3.3 for detail information).

When the image is frozen, the 12 sections images and the calculating volume value will be shown on the screen. Users can press “print” (6) (please refer to section3.4 for detail information)button to print the current result.

Users can use the Save image button (7) to save the image and patient information, Review button(8) to review the stored images(please refer to section 3.5for detail information)..

Press the Setting button (9) to set the parameters, including gain and channel(please refer to section3.6 for detail information).

Note: In all interfaces, if the button is blue means that the prompt operate is effective .if the button is gray indicates it is an invalid operate.

3.2Patient information

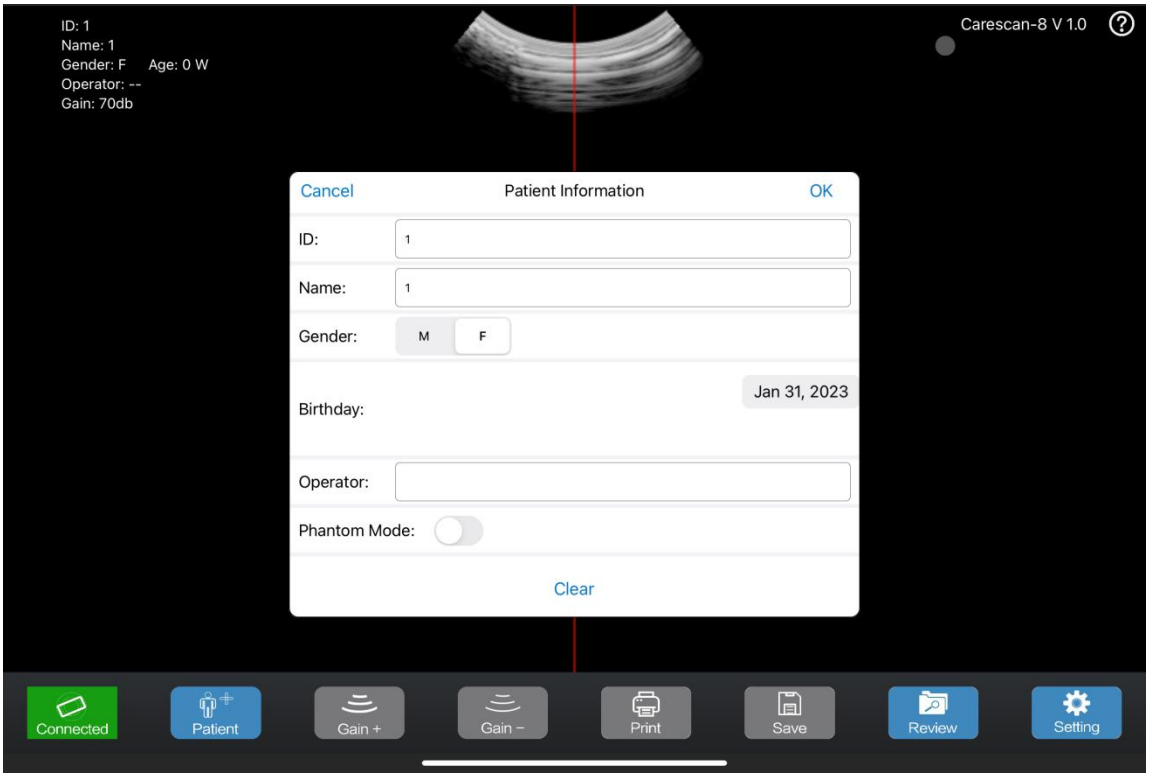


Figure 3-2 patient information

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

chosen.

When you touch “Create New Case”, all the information will be cleared. The Phantom Mode is default as closed.

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

3.3 Scanning

3.3.1 Prepare probe

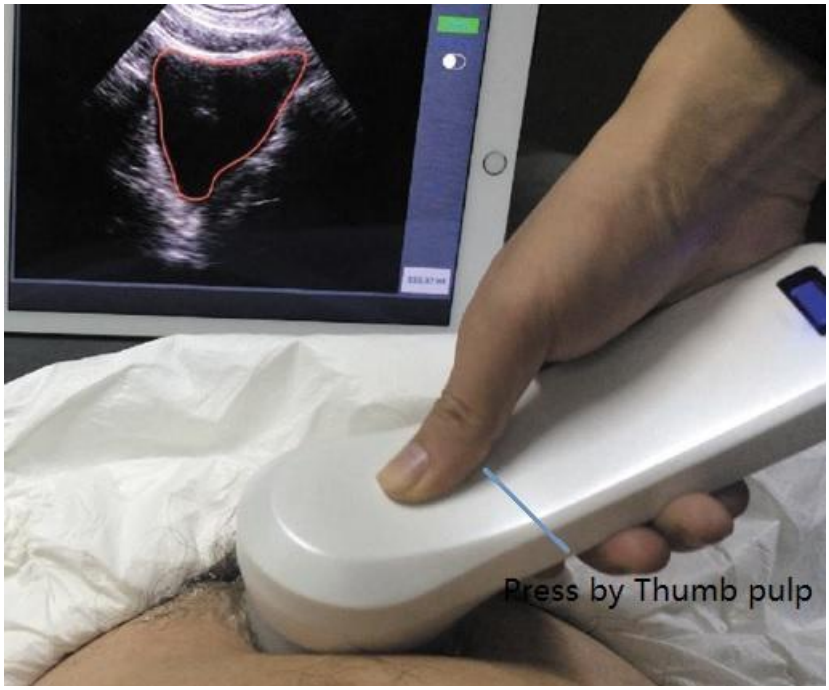


Figure 3-3 pre-Scanning

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

3.3.2 Pre-scanning mode

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

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

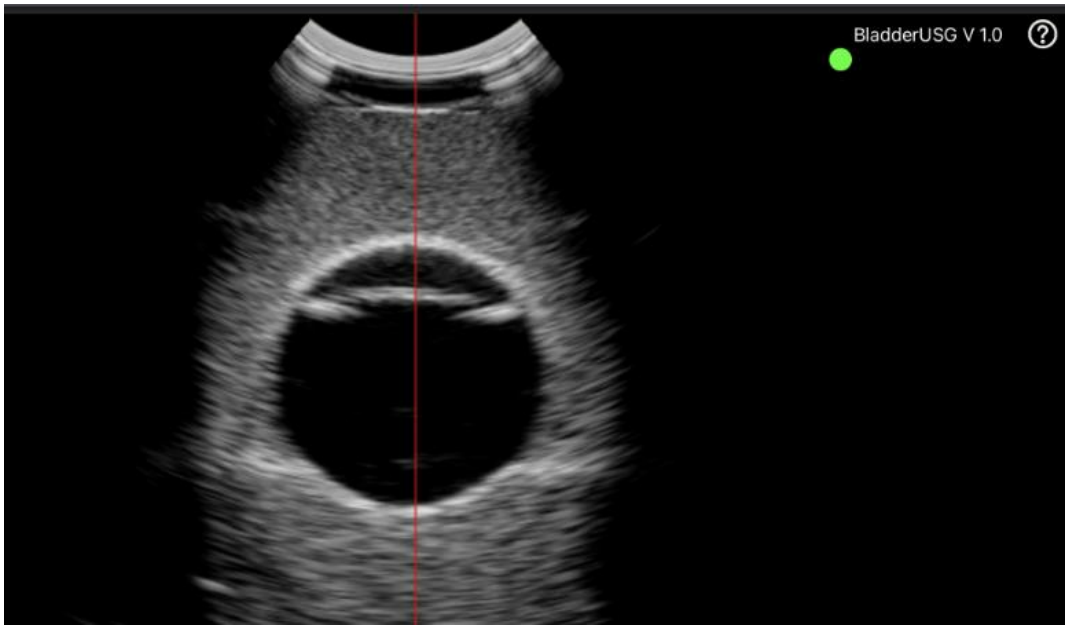


Figure 3-4 pre-Scanning

3.3.3 Scanning mode

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

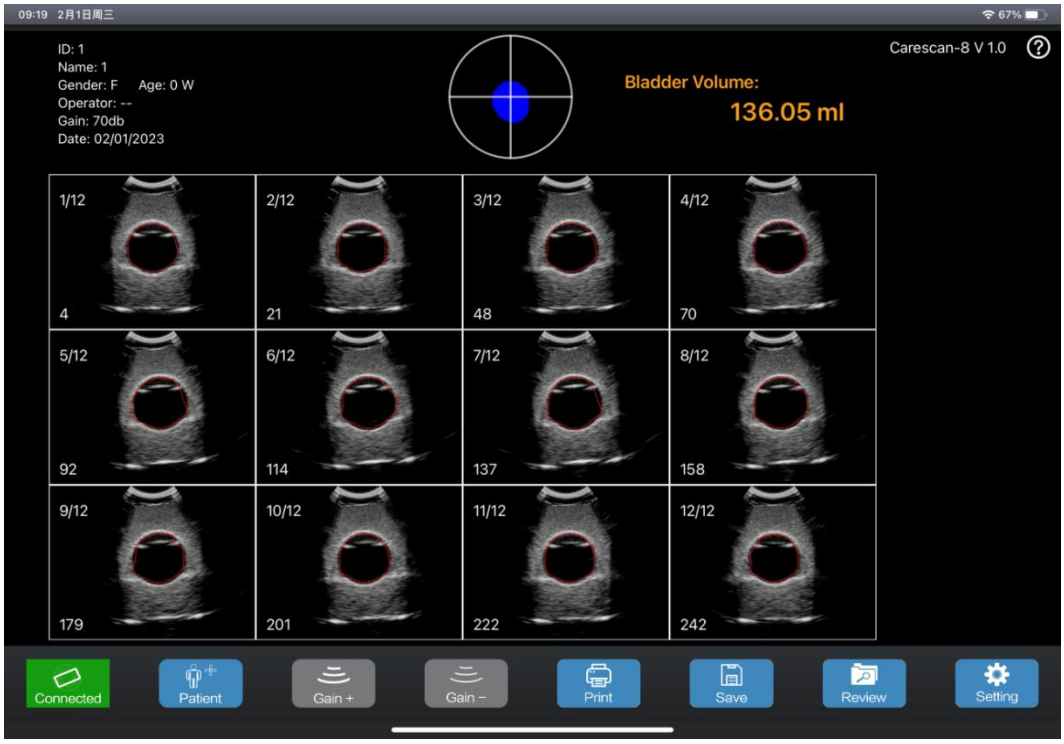


Figure 3-5 scanning result menu

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

3.4.Storage and Review the image

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

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

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

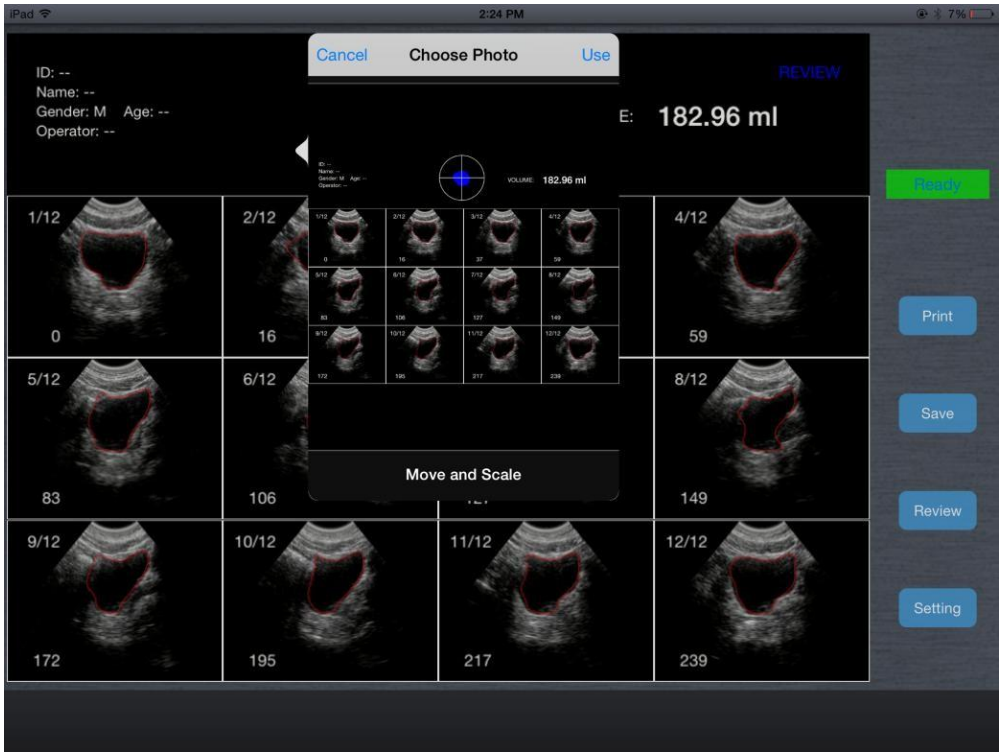


Figure 3-6 review menu

3.5. Set parameter

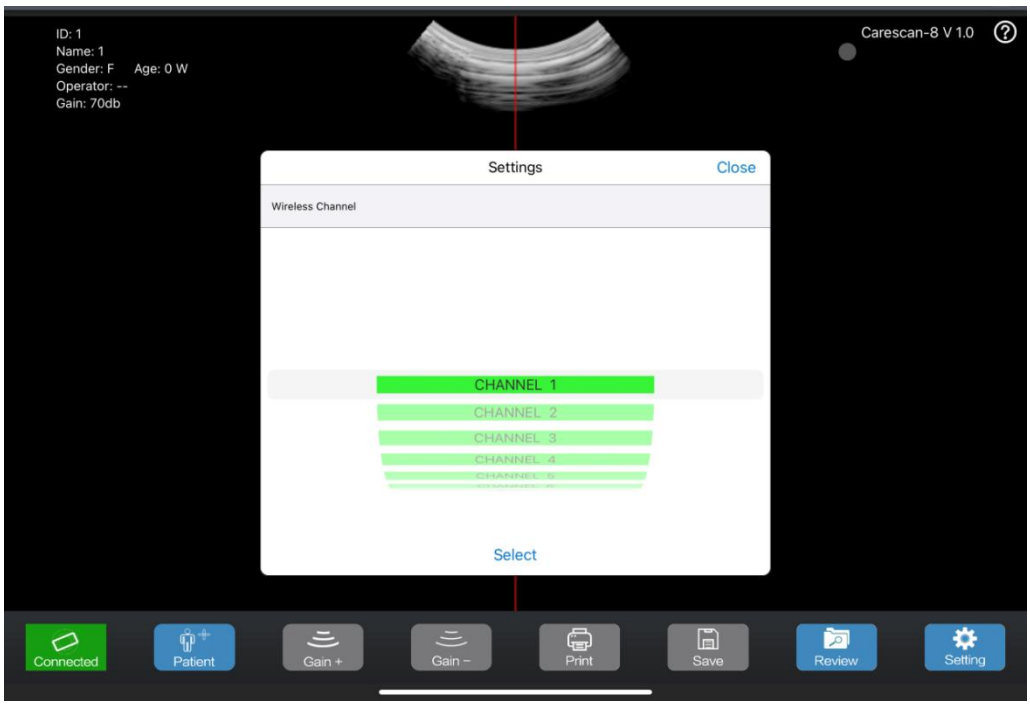


Figure 3-7 setting menu

1) Gain

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

2) Wireless Channel

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

Section 4 MAINTEANCE

4.1 PROBE CHARGING

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

Figure 4-1 Charge the Probe

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

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.
	The device should be charged using a charging adapter that comply with IEC60601-1 or IEC 62368.

4.2 WATERPROOF IPAD

We will provide a waterproof bag if you using iPad as the accessory. Users can use it to protect the iPad when it is used in humidity or dirty fields.

- The manufacturer not providing iPad and iPhone, the user should configurate this accessory by themselves.

4.3 CLEANING AND DISINFECTION

4.3.1 Precaution and warnings

When cleaning and disinfecting:

• Follow the procedures in the order they are described in this guide, without skipping steps.

• Follow the manufacturer's instructions, recommendations, and guidelines for cleaners and disinfectants, as well as your regional regulations.

• Check expiry dates, concentration, and efficacy of the chemicals used.

• Wear the appropriate personal protective equipment (PPE), such as eyewear and gloves, as recommended by the chemical manufacturer.

• Repeated use and cleaning over the course of the scanner’s life may deteriorate its cleanliness.

• Using incompatible solutions to clean the scanner may damage its surface.

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

4.3.2 Cleaning and Disinfection the probe

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

2. To clean the probe, Use a soft cloth dampened with 75%Alcohol to wipe the Probe until it is thoroughly cleaned.

3. To remove all traces of disinfectant solution, wipe the instrument with a clean soft cloth dampened in sterile water or potable tap water. Wiping the device three separate times to remove all residual disinfectant is recommended.

4. Verify that all gel, particulate matter, and bodily fluids have been removed.

5. Dispose the soft cloth and the instrument used to insert the cloth.

4.4 STORAGE

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

4.5 TROUBLE SHOOTING

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

Fault handling:

Ite	Failure Problem	Solution
1	No response after press the power switch	Charging,check the power supply
2	Intelligent display can't connect scanner 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

4.6 Disposal

Warning: products should not be discarded at will.

-Battery recycling meets local requirements.

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

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

4.7 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 in accordance with section 1.2 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 scanner cover for cleaning, shake or dismantle the components inside the scanner.

5, Clean and wipe the scanner 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, pleas ask professional staff for maintenance.

8, scanners are valuable 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 states benefit to scanner for long-term use.

10, Apply the medical ultrasound coupling agent which complies with relevant standards when using the scanner.

11, the structure of the scanner is watertight, prohibit any conductive liquid immersion so as to avoid corrosion of the scanner 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 4.3 of this manual for cleaning and disinfection.

14, 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.

15, When the product is damaged due to impact drop, it should contact after-sale for maintenance and calibration. Detailed contact information can be found after-sale.

16,Before each use of the product, check the surface of the probe for cracks. If there are cracks, they can be sent back to the after-sales service for inspection and maintenance.

17,Conduct a one-time performance check on the product every year, which can be calibrated or the image accuracy can be checked through body film.

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.

● Do not use the system in the applications other than those listed in the intended use. Otherwise, it may result in system damage or serlous 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 by after-sale. When the continuous working time of batteries is less than 2 hours, you can contact after-sales for battery replacement.

● Replacing batteries requires professional trained technicians to use specialized tools. Untrained personnel replacing batteries may cause hazards such as overheating, fire, and explosion.

● Replacing batteries requires unscrewing the shell screw with a special screwdriver, carefully opening the shell, then taking out the old batteries directly, installing new batteries, and sealing the edges with glue when reinstalling the machine.

● 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 or protrusions which may cause harm.

Warnin

● 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

● Please read the instructions and then set and control the acoustic output levels.

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.

Warnin

● 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 Probe Safety

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

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

● Use the probe carefully. If any part of the transducer surface is scratched, immediately stop using the probe. Otherwise, there is a danger of electric shock.

● After disinfecting the accessories, chemicals must be washed out from the accessories. Remaining residual chemicals or gases could not only result in damage to the accessories but also can be harmful to human bodies.

5.1.4 Cybersecurity

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

● The scanner 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 scanner.

● 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.

Connection security

When connecting smart devices, Scanner provides a Wi-Fi 802.11n local area network. IPad can only be accessed using WPA (Wi-Fi Protected Access) or WPA2 (WiFi Protected Access II) as a security protocol to protect this network.

For information on setting up wireless network security, please refer to the documentation of your network device.

For security purposes, only the preset security password can be used to connect to WiFi.

The scanner can only be connected to one iPad device, successfully locking your smart

device.

The following behaviors may bring new risks to patients, operators, and third parties. Your organization is responsible for identifying, analyzing, evaluating, and controlling these risks:

Change network configuration.

Medical device network security information:

1、The product uses a local area network, which is not connected to the external network when working. The platform used by the software is the IOS system developed by Apple, which has similar security features and protection mechanisms. These security features include face ID, Touch ID, password protection, data encryption and so on, which have strong security and protection mechanism. Apple regularly updates its operating system to fix known vulnerabilities and enhance security performance. At the same time, Apple also strictly controls the applications on the App Store through the audit mechanism to prevent the emergence of malware.

2、As a separate LAN, the scanner will not be affected by external network attacks. If there is a network error, just restart the scanner, and the scanner WIFI will automatically reconnect with the tablet. If the tablet is attacked by the network, just restart the tablet or restore the factory settings.

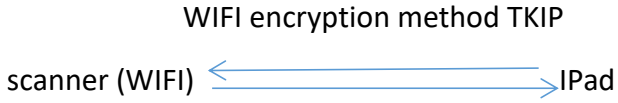
3、The software is put on the Apple APPSTORE. If you need to restore the program, you only need to download it again in Apple Mall, and the saved data needs to be backed up by Apple ICLOUD cloud.

4、The IFU provides the software download link and guides the installation tutorial. For details, please refer to the relevant IFU,section 2.2INSTALLING APP.

5、The device will establish a separate local area network, which needs WIFI password to log in, and the scanner can only be connected to the tablet terminal one-to-one, so there are no network security risks such as stealing information or being attacked by the external network.

6、The network port relationship for receiving/sending data is as follows: the scanner establishes WIFI connection with the IPad, and uses wireless WiFi port to connect with the IPad. The scanner data is transmitted to the APP, and the APP transmits control parameters to the scanner, and the image data will be displayed on the IPad terminal.

7、Network diagram



8. If there are security vulnerabilities in software operating environment, Apple will regularly upgrade and maintain it. Just pay attention to the related upgrades and vulnerability patches prompted by the scanner. Log files are kept by the scanner, and users can use the scanner to authenticate and authorize users. The recovery equipment can be operated according to the scanner provided by Apple.

IT Security or Wi-Fi

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

The information using wifi communication is as follows:

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

5.2 Principles of Using Acoustic Power

● Perform ultrasound procedures prudently under the guidance of the AL ARA (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.

The materials used for the contact between the probe head and the patient are RTV and ABS. If the patient experiences redness or other reactions after contact, immediate cessation of use is required.

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 scanner 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, scanner component and launch mode combination, or all of above

●Algorithm accuracy of the system software used to calculate the MI/TI

●Approximation engineering method used in real time computation

5.2.3.2 Differences between Actual and Displayed MI and TI

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

5.2.3.3 Uncertainty of Measurement

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

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

1. The sensitivity of hydrophone:According to hydrophone calibration report provided by ONDA company, the maximum allowable error of sound pressure for hydrophone is plus or minus 12%;

2. Scope: according to agilent DSO6502A specifications, its effect on the sound pressure is plus or minus 2%;

3. Temperature: effect of the thermocouple on sound pressure error is plus or minus 4%;

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

5.2.3.4 Accuracy of the displayed acoustic output

Parameter	Displayed acoustic output accuracy	Measurement uncertainty B-mode and Color doppler mode
Pressure, MI	±25%	±15%
Power, TI	±50%	±30%

Accuracy of the displayed acoustic output = (Measured value - Acoustic output display value) / Acoustic output display value * 100%

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 scanner 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 scanners before shipment. When the ultrasound system is powered on, a new patient is created or the application mode is changed, the system will retrieve the default settings. You can also reset the parameters.

5.2.6 ALARA

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

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

The operator must take responsibility for the safety of patients.

5.3 Electromagnetic Compatibilities

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

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

5.3.1 Electromagnetic Radiation

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

Emission Test	Compliance	Electromagnetic Environment and Guidance
RF emission CISPR 11	Group 1 Class A	The equipment use RF energy only for its internal function. Therefore, its RF emission is very low and not likely to cause any interference to nearby electronic equipment.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker Emissions IEC61000-3-3	Not Complies	

5.3.2 Electromagnetic Immunity

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment and Guidance**

Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transient \ burst IEC 61000-4-4	±2 kV for power supply Lines ±1 kV for input output lines	±2 kV for power supply Lines ±1 kV for input output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5%UT (>95% dip in UT) for 0.5 cycle 40%UT (60% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles < 5%UT (>95% dip in UT) for 5 sec	< 5%UT (>95% dip in UT) for 0.5 cycle 40%UT (60% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles < 5%UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires contained operation during power mains interruptions, it is recommended for the equipment to be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

5.3.3 Recommended Minimum Distance Between BProbe and Mobile RF Equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and

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.			

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

mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communications equipment.

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.

5.4 Secrecy

The confidentiality guarantee of information is as follows:

The scanner does not contain patient identification information.

When the scanner is connected to a wireless network, it encrypts and stores WiFi passwords.

The data transmitted between the scanner and the app on the iPad is transmitted through an encrypted local area network.

The image needs to be logged into the iPad system to be viewed, so the image data is confidential.

If there are no images exported to the iPad's image library, the app will store these images.

5.5 Integrity

The integrity of the transmitted data is guaranteed as follows:

Authenticated encryption can prevent malicious users from intercepting and modifying data. Integrity checks ensure the integrity and validity of the received data. If any data is incomplete or invalid, it will be discarded.

The TCP channel used through Wi-Fi ensures the correct transmission of data.

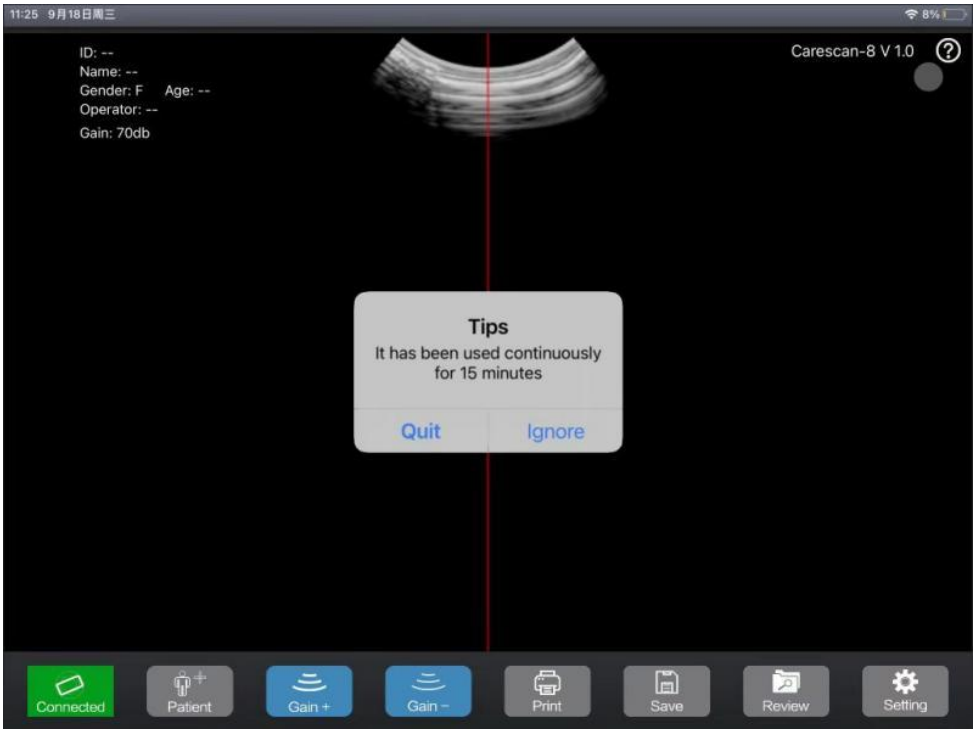
5.6 Availability

If Wi-Fi connection cannot be achieved (such as excessive radiation or electromagnetic interference in the environment), please use other channels or switch to a different usage environment.

5.7 Tips for probe head operating temperature observation:

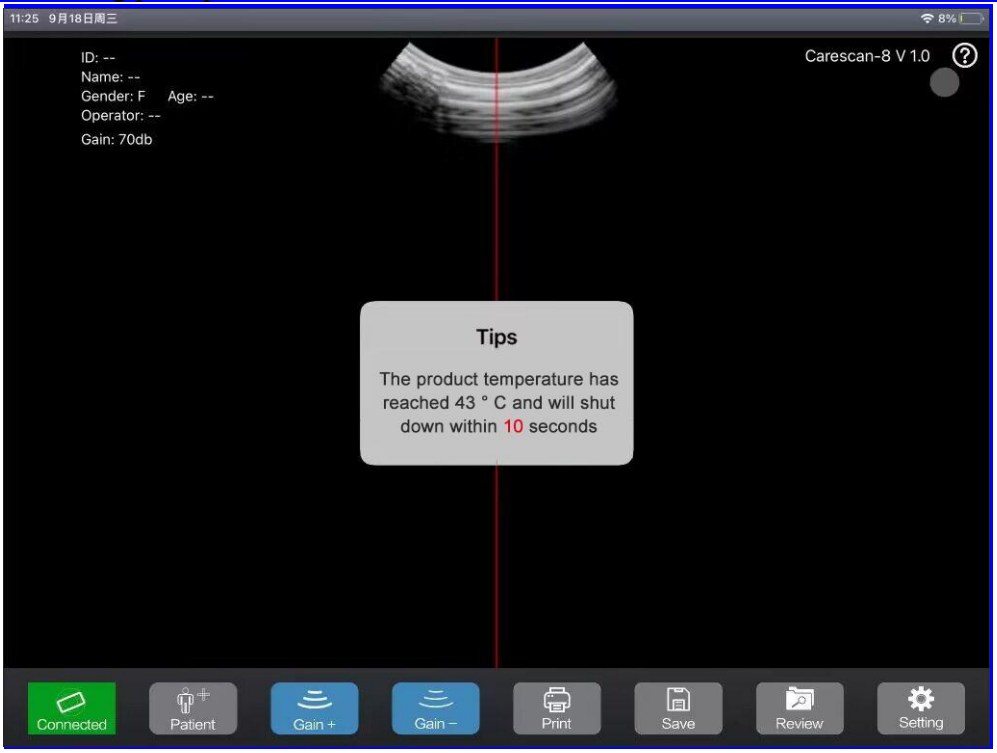
If the surface temperature of the ultrasonic probe exceeds 43° C, it may cause discomfort or pain to the human body, and there may be unforeseeable injuries such as burns, cell damage, edema, etc. Therefore, it is necessary to limit its continuous use time to ensure that its surface temperature is within a safe range.

When the probe is connected to the mobile phone tablet device, for 15 minutes, the software will pop up, as shown in the figure below:



The operator chooses whether to exit the software according to the current temperature of the probe sound head. If the probe sound head temperature exceeds 43 ° C, click Quit to exit the software, if not over 43 ° C, click Ignore and continue working.

Once the system detects that the surface temperature of the probe reaches 43 ℃, the software will give the following prompt and the machine will be forced to shut down after 10 seconds.



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	Main unit: IPX1 Acoustic head: IPX7	
	Degree of safety of application	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.	
Operating system requirements	IOS 9.0 and above version.		
Environmental Requirement		Operations	Storage and Transportation
	Relative Humidity	25% to 80%, non-condensing	25% to 93%, non-condensing
	Ambient Temperature	5°C to +35°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: BProbe, Operating Model: B mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.39	0.11		0.11		N/A
Index component value			0.11	0.11	N/A	0.11	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	0.69					
	P (mW)		9.99		9.99		N/A
	P_{1x1} (mW)		7.86		7.86		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	4.33					
	$z_{PII.\alpha}$ (cm)	4.33					
	f_{awf} (MHz)	3.07	3.07		3.07		N/A
Other Information	*prr* (Hz)	1594.00					
	srr (Hz)	9.09					
	n_{pps}	3					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	20.93					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$ (mW/cm^2)	2.53					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	5.16					
	$p_{r.}$ at z_{PII} (MPa)	1.09					
Operating control conditions	Display focus(mm)	Fixed	Fixed	Fixed	N/A	Fixed	N/A
	Display depth(mm)	Fixed	Fixed	Fixed	N/A	Fixed	N/A
	Working frequency(MHz)	Fixed	Fixed	Fixed	N/A	Fixed	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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