

Pocket Ultrasound System

Instruction Manual

(V1.2)



IMPORTANT !

Read and understand this manual before operating the equipment. After reading, keep this manual in an easily accessible place.

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Product: Pocket Ultrasound System

Model: C10

Authorized European Representative: SUNGO Europe B.V.



Introduce

This manual describes the operation of the Pocket Ultrasound System. In order to ensure the safe operation of the system, please read and understand the contents of the manual before using the system.

This specification is formulated and explained by KONTED.

This manual is published: December 2021, first revised December 2022.

KONTED reserves the right to change the contents of the instruction manual without prior notice. (Konted authorizes Mides Healthcare Technology GmbH to modify user manual)

Important statement!

1. The part or all of the contents of this manual shall not be copied or copied prior to the written permission;
2. It is forbidden to modify the software or hardware of this product;
3. The utility model can provide the doctor with the image and data needed for clinical diagnosis, and the doctor is responsible for the diagnosis process;
4. Quality assurance does not include the following, even within the warranty period:
 - (1) Damage or loss caused by improper installation or environmental conditions that do not meet the requirements;
 - (2) Damage or loss caused by the supply voltage exceeding the specified range;
 - (3) Damage or loss of equipment or components purchased not from KONTED or its authorized distributor or agent;
 - (4) There is no damage or loss caused by the use of this instrument in the initial purchase area;
 - (5) Damage or loss caused by maintenance of non-authorized personnel of the company;
 - (6) Damage or loss caused by force majeure such as fire, earthquake, flood or lightning;
 - (7) Damage or loss caused by error or rough use;
 - (8) Failure caused by other non product itself

5. FCC Caution:

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

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.

This radio is designed for and classified as “General population/uncontrolled Use”, the guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health.

Body and limbs operation; this device was tested for typical body and limbs operations kept 0mm for body worn. To maintain compliance with RF exposure requirements, use accessories that maintain a 0mm for body worn.

Note: 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.


Maintenance and repair service

The main warranty period is 18 months. The warranty period from the date when the product leave the factory. Within the warranty period, the product can enjoy free customer service; but please note that even in the warranty period, due to the reasons on the page "important statement" caused by the products need maintenance, KONTED will charge maintenance services, you need to pay the cost of maintenance and spare parts costs.

After the expiration of the warranty, KONTED can provide maintenance services. It should be noted that if you do not pay or delay the payment of maintenance costs, US will temporarily suspend maintenance services until you pay.

We hereby declare that you must familiarize yourself with the operating instructions before use and operate and use it in strict accordance with the requirements and methods of operation of the operating instructions. The company does not assume any responsibility for safety, reliability, and performance assurance due to any abnormality caused by operation, use, maintenance and storage in accordance with the requirements of this manual.

Operation taboo:

 **Danger** ※ Do not modify this equipment, including equipment components, software, cables and so on. User modifications may result in security problems or reduced system performance. All modifications must be completed by the personnel approved by KONTED.

Intellectual Property Statement



This specification and the intellectual property rights of the products are owned by KONTED. No individual or organization may copy, modify or translate any part of this manual without the written consent of KONTED.

1 Safety precautions

1.1 Security classification

- According to the type of anti electric shock:
Internal power supply, where the adapter is Class 1;
- According to the degree of anti electric shock:
Type BF application part;
- According to the protection degree of harmful liquid:
The ultrasound probe has protection class IP68
- According to the degree of safety in the presence of flammable anesthetic gas mixed with air (or oxygen, nitrous oxide two);
- According to the working mode:
Continuous working equipment.

1.2 Security symbol

Security symbol	Detailed description
	Type BF application part Description: all the ultrasonic probes are part of the BF application.
	"Be careful" indicates what should be noted. Be sure to read the instructions carefully before using the system.

1.3 Safety warning information

In order to ensure the safety of the patient and the operator, the following safety rules should be strictly observed in the use of the wireless ultrasonic probe.



WARN- ING:

1. Do not disassemble the ultrasonic probe, which may cause electric shock.
2. Use the power cord supplied with this unit; use only the power supply provided by US to supply power, the use of other specific power supply (such as UPS, etc.) on the ultrasonic probe power supply may bring the risk of electric shock.
3. Use the probe carefully, if the probe is scratched with the contact surface of the human body, immediately stop using the probe and contact the service representative. If you use a scratched probe, there is a risk of electric shock.
4. Every time you use the instrument must be checked for safety, do not let the probe by the impact of damaged ultrasound probe may cause the patient to be shocked.
5. Before performing an ultrasound check, check the surroundings to ensure safe use within the environment. Do not operate the unit in an environment with flammable or explosive liquids, vapors or gases such as oxygen or hydrogen.
6. Be sure to wear a sterile probe case on the probe when performing an ultrasonic chamber check.
7. Do not immerse the ultrasonic probe Type-C USB interface or above in water or disinfectant. Because the Type-C USB interface of the ultrasonic probe does not have a waterproof function, this may cause an electric shock or a probe malfunction.
- 8 Before and after each inspection, you must ensure that the ultrasound sound normal. A defective ultrasonic probe may cause the patient to be shocked.
- 9 If the head part of the probe does not comply with EMC requirements, it is forbidden to use the sound head for use in the body (as the device may be adversely affected by other equipment).



**CARE-
FUL:**

1. Matters needing attention in clinical examination technology:
 - This equipment can only be operated by qualified medical personnel.
 - This manual does not introduce a clinical examination technique. It is necessary to select the correct inspection techniques according to the professional training knowledge and clinical experience.
2. The equipment can not be checked for a long time.
3. Do not use incompatible coupling agents, disinfectants, probe protective cover, probe, puncture rack.
4. Sterile gloves must be worn to prevent infection when using ultrasonic probes.
5. You must use a sterile ultrasound coupling agent. Use a coupling agent that is in compliance with local regulatory requirements. In addition, it is necessary to properly manage and use the ultrasonic coupling agent to ensure that it does not become a source of infection.
6. The probe cover is made of natural rubber and is used with caution for natural rubber allergy.
7. For in vivo transducers in a single fault condition, the surface temperature rise shall not exceed 43 °C.

CAUTION: 1 In order to prevent abnormal probe function, read the following safety precautions:

After each ultrasonic examination, the ultrasonic coupling agent on the surface of the probe should be thoroughly erased. Otherwise, the ultrasonic coupling agent will be solidified on the probe head, which will affect the quality of the ultrasound image.

The probe should be cleaned and disinfected before and after each ultrasonic examination.

2 Ambient environmental requirements:

Please use the ultrasonic probe in the specified environment:


- ambient temperature: 0C ~ 40C
- relative humidity: 30% ~ 85% (No condensation)
- Atmospheric pressure: 70KPa ~ 106KPa .

To prevent damage to the ultrasonic probe, do not expose the probe to the following environment:

- Place where the sun shines
- A place where the temperature changes dramatically.
- A place filled with dust
- Easy to vibrate place
- Place near the heat source

3 Repeated disinfection will lead to the safety and performance of the probe, the performance of the probe should be regularly checked.

1.4 WARNING Labels

The system has a variety of identification to cause the user to pay attention to the potential danger. The symbol on the warning sign  indicates the precautions for system security.

The instructions explain in detail the meaning of these warning signs. Read the instructions carefully before using the system.

1.5 Ultrasound Benefits and Risks

Ultrasound is widely used because it provides many clinical benefits to the patient and has an excellent safety record. Ultrasound imaging has been used for over twenty years and there have been no known long-term negative side effects associated with this technology.

1.5.1 Ultrasound Benefits

- Portability
- Cost-effectiveness
- Multiple diagnostic uses
- Immediate results
- Safety record

1.5.2 Ultrasound Risks

Ultrasonic waves can heat the tissues slightly. It is normal that the probe may feel warm to the touch while charging. If you remove the probe from the charging pad before or immediately after charging is complete, it is recommended that you allow the probe to cool down before use. Since the system limits patient contact temperature and will not scan at or above 43° C (109° F), allowing the probe to cool down before use will optimize scan time performance.

2 Product overview

2.1 Intended use

It is designed to fulfill following intended uses:

- Obstetrics
- Gynaecology
- Abdominal
- Small Parts (breast, thyroid, testicle, etc.)
- Cardiology
- Peripheral Vascular
- Muscular-Skeletal
- Nerve
- Urology
- Orthopedic
- Angiography
- Physical Examinations
- Digestion
- Pediatrics
- Paracentesis

2.2 Contraindication

The product is not suitable for the examination of the organs containing gas, such as the stomach and intestines, etc. when burned, burned or damaged on the surface of the human body, it can not be used in this part.

2.3 Product specifications

2.3.1 Imaging mode

B mode

BM mode

C mode

PW mode

2.3.2 Power condition

External power adapter

Supply voltage AC : 100 - 240V

Power frequency : 50/60Hz

Output DC: 5V/2A

Internal battery

Voltage: 3.8V

Capacity: 2600mAh

2.3.3 Environment condition

	work environment	Storage and transportation environment
ambient temperature	0 C ~ 40 C	0 C ~ +45 C
relative humidity	30% ~ 85% (No condensation)	30% ~ 95% (No condensation)
atmospheric pressure	70KPa ~ 106KPa	70KPa ~ 106KPa



**WARN
-ING:**

Transport:

1. Do not use or store the system outside the specified environmental conditions.

Working:

1. Please ensure that the use of the equipment to master a solid, otherwise, equipment may hurt the patient fall.

2. To ensure that the equipment in a dry environment, the operation of environmental temperature and humidity changes, may lead to liquid condensation in the circuit board, there is the risk of short circuit.

3. Do not operate the unit in an environment with flammable or explosive liquids, vapors or gases such as oxygen or hydrogen. Equipment failure or fan motor sparks may be electronically detonated of these substances.

A. Please ensure that the environment before use, if the detection of flammable substances in the environment, please do not plug in the power or open the system.

B. Use the real-time detection environment to detect flammable substances after the system is turned on. Do not attempt to turn off the device or unplug the power supply. First empty the air in the area and ensure a smooth ventilation and then turn off the power.

4. If the system fails, please do not disassemble the view, please contact the service center or your sales representative.

2.4 system configuration

The system is mainly composed of probe and application.

2.4.1 Standard configuration

- Main unit probe: 1 set
- Type-C Cable: 1 set
- Wireless charger: 1 set
- Black handbag: 1 set
- Accessory: Operation manual












2.4.2 Components






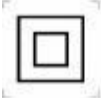


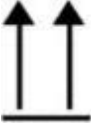
Transducer Type




Transducer model	Type of Transducer	Intended use	Applicable site	Wireless charging
C10	3 in 1 type	Gynecology and obstetrics, abdominal kidney , Small organ, carotid artery, Msk, Cardiac	body surface	√

2.5 Symbol description

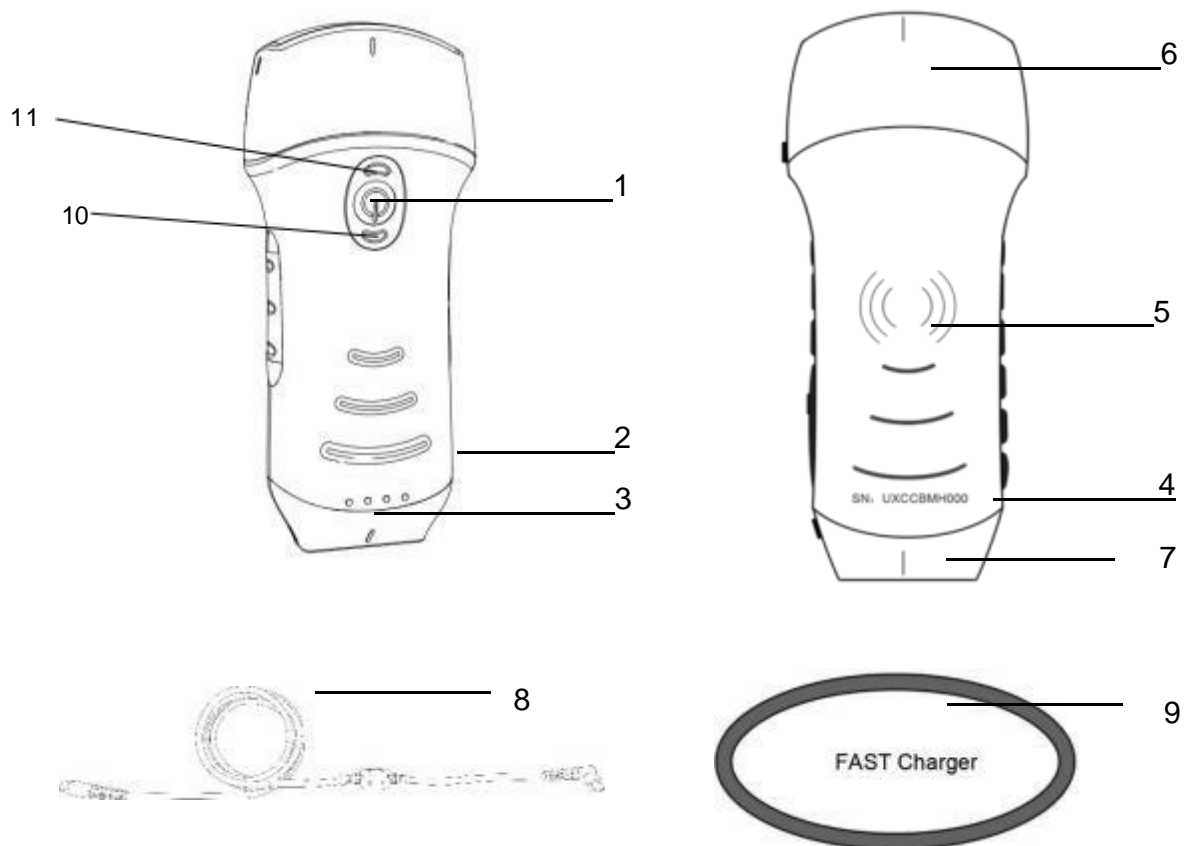
This device uses the following symbol identification, the following list shows its meaning.

Serial number	Symbol	Explain
1		Type BF application part explain: All ultrasonic probes are part of the BF application.
2		Please refer to the instruction manual for this symbol to avoid accidents
3		Indicates the product serial number
4		Indicates the manufacture.
5	IP68	IP68 means that the probe is dustproof and protected against damage after brief immersion in water (max. 1,5 m depth, up to 30 minutes)
6		Safety mark on behalf of the product has been in line with European standards for safety / health / environmental / health and other standards and directives
7		Indicates the date of manufacture.
8		Indicates that the device must be collected separately for disposal. Follow proper disposal procedures.
9		Authorized European Representative: SUNGO Europe B.V. Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
10		Indicates the reference or catalog number
11		Non- ionizing electromagnetic radiation
12		Model number

Serial number	Symbol	Explain
13		Country of manufacture
14		Importer
15		Distributor
16		Medical device
17		UDI
18		Power Voltage Frequency
19		Class II equipment
20		Away from the sunlight
21		Storage temperature limit
22		Upwards


Serial number	Symbol	Explain
23		Keep dry
24		Storage humidity limit
25		Stacking layer limit

2.6 Introduction of each component of the system



Number	Name	Function
1	Control buttons	Power switch / Freeze/Living button
2	USB Type-C port	Connect to Android/ Windows software / Charging with USB type-C cable
3	Battery status	Battery charge / remaining display
4	SN	Serial number; password of this probe's wifi
5	Wireless charging symbol	Face to wireless charger
6	Convex probe	Convex probe + Phased probe
7	Linear probe	Linear probe
8	Type-C cable	Connect to Android/ Windows software / Charging with USB type-C cable
9	Fast Charger	The wireless charging pad
10	Linear probe indicator lamp	The blue light indicates that the linear probe is active
11	Convex probe indicator lamp	The green light indicates that the convex probe is active

2.7 Control panel

Control buttons	Button icon	Key name	Function
		Power switch / freeze / thaw button	<ol style="list-style-type: none"> 1) When the probe is not turned on, press the key to activate the probe; 2) When the probe is in the open state, hold for 5 seconds to turn off the probe, the indicator become black screen. 3) When the probe is in the scanning state, press the key to freeze the screen image; 4) In the frozen state, press the button to thaw the screen image, the probe continues to scan the image. 5) Press and hold for 3 seconds to switch the scanning mode (Convex array probe/linear array probe)

Press the button and hold for 3 seconds to switch the scanning mode (Convex array probe ↔ linear array probe)

3 Basic introduction

3.1 Install software

3.1.1 iPhone/iPad

Download the iOS software from App store  on your Apple iPhone/iPad, the APP name is **MY USG**. The following lists the requirements:



Updates to the App and probe are handled through the Apple App Store.
Keep your mobile device's operating system and the App updated to ensure you have the most up-to-date version.

Apple Device	Requirement	Operating System
iPhone	Available for iPhone SE, iPhone 6s~iPhone12 pro Max	iOS version 11.0 or newer
iPad	iPad Air 1th/2th/3th, iPad 4th/5th/6th/7th/8th, iPad mini 3th/4th, iPad Pro 1th/2th/3th/4th	
PC	x	x

Note:

- MY USG App is available for download and use on an iPhone/iPad device, not support Apple PC.
- Do not use the MY USG App on a mobile device that does not meet minimum requirements. Using the APP on a mobile device that does not meet the minimum requirements may affect performance and image quality, possibly resulting in misdiagnosis.

3.1.2 Android device

Download the Android software from Google Play store . The App name is **MY USG**. The following lists the requirements:



Updates to the App and probe are handled through the Google play.
Keep your mobile device's operating system and the App updated to ensure you have the most up-to-date version.




Android Device	Requirement	Operating System
Smartphone	RAM≥2GB, ROM≥32GB	Android version 8.0 or newer
Smart Tablet	Wi-Fi: (802. 11n/20MHz/5G) USB connector type: Type-C	


3.1.3 Windows device

Please contact us to get the windows software installation package after receiving the probe. The following lists the requirements:

Windows Device	Requirement	Operating System
PC	RAM: ≥4 GB Wi-Fi: (802. 11n/20MHz/5G) CPU: ≥ 1 GHz, up to 3.6GHz, Inter i3/i5/i7 (Recommended Brands: Lenovo, HP, Dell, Acer, ASUS) It is recommended to use laptops manufactured after 2017.	Windows 10 ,64-bit or newer
Smart Tablet	RAM≥4GB, ROM≥ 16GB Wi-Fi: (802. 11n/20MHz/5G) USB connector type: Type-C	

3.2 Turn on/off the probe

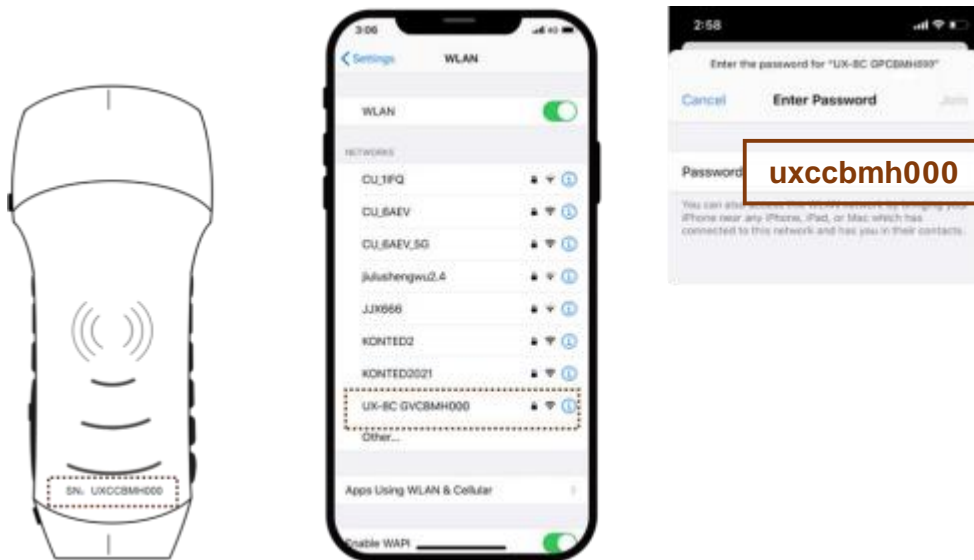
Press the power button  to turn on the probe, the indicator will show the battery icon.

After ultrasonic examination, press the power button  and hold for 5 seconds to turn off the probe, the indicators become a black screen.

3.3 Probe and Terminal connection

Wi-Fi connection:

The first-time connection between the probe and the smart terminal device must be entered with the Wi-Fi password. After the first-time connection, the device will be connected to the probe's Wi-Fi automatically.



Note:

password is the SN of the probe, but it is the small letter not capital.

Probe SN: uxccbmh000

Step1:

Turn on the ultrasound transducer and turn on the Wi-Fi on your iOS or Android device.

Step2:

Search the list of networks for the SSID with the suffix "UX-8C *****A000".


Step3:

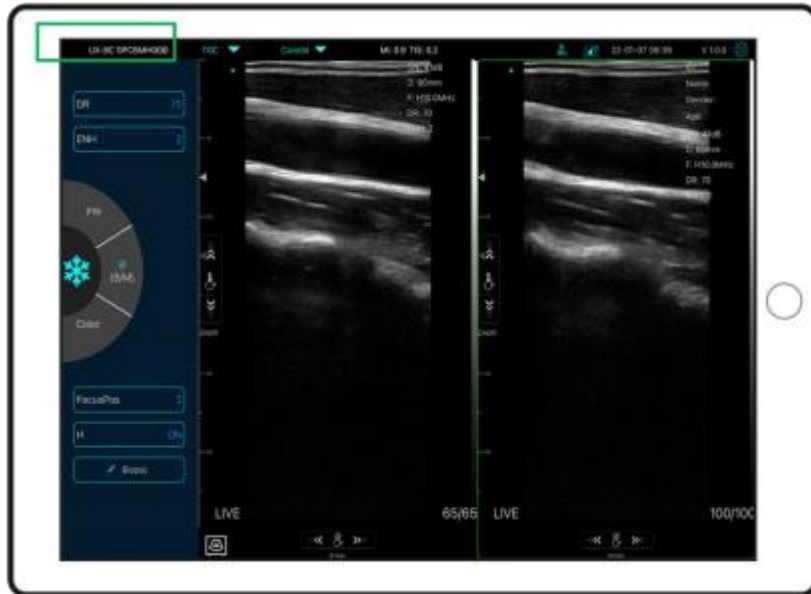
Enter the Wi-Fi password, this Wi-Fi password is the serial number of the probe, but in small letters, not capital.

Step4:

The Wi-Fi name is preceded by a " ✓ UX-8C *****A000 ", Indicates the connection is successful

Step5:

Open the MY USG App  on your mobile device's home screen, After, successful login, the "UX-8C * * * * * A000" will represent normal connection displayed on the App interface.



Note:

- If you connect the probe to your device successfully, but there is no image on the screen, please try to press the power button again.
- The password's letters must be input as small letters, not capital.
- When the probe is connected to mobile device A, if you want to connect mobile device B with the probe, please first disconnect the probe from mobile device A. The probe only can be connected to one mobile device at the same time.

3.4 Basic software interface

3.4.1 Convex array + Phased array mode:



3.4.2 Linear array mode:



4 Detailed operation introduction

4.1 Introduction to all levels of menu

The menu in this system is divided into first level, second level.

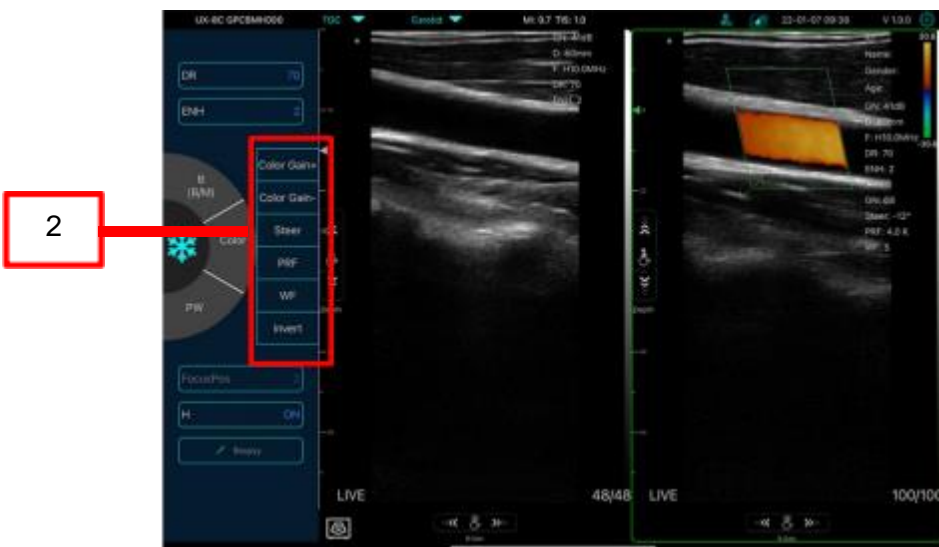
4.1.1 First level menu

1. Preset button
2. Hidden menu for parameters



4.1.2 Introduction to the second level menu

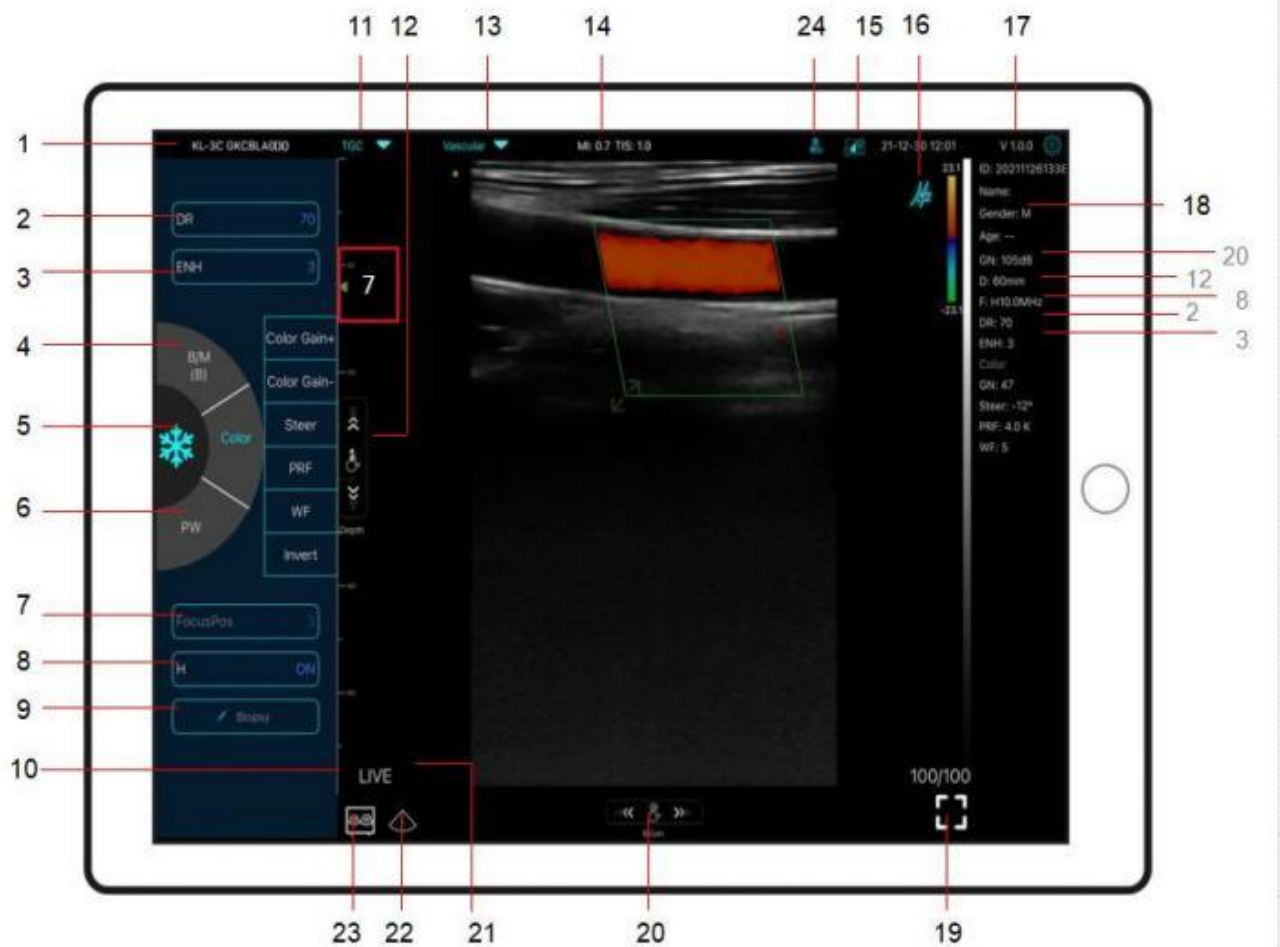
The 2 level menu is controlled by clicking on the corresponding item of the 1 menu. This is the 2 level menu in Color mode.



4.2 Operation Introduction



4.2.1 B mode

Live mode

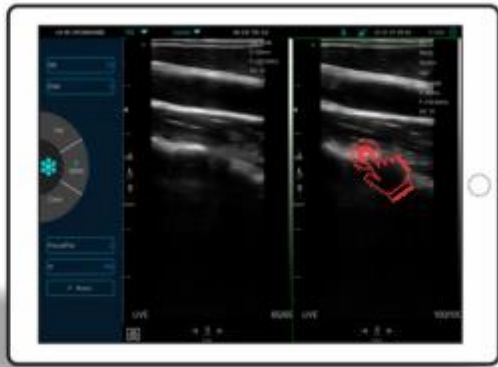


No	Item Description
1	Serial number of probe
2	Dynamic Range (DR)
3	Imaging Enhance (ENH)
4	Mode: B ⇌ B/M, Click to switch scanning mode
5	Freeze/Live button
13	Preset selection
14	The Thermal Index (TI), Mechanical Index (MI), and Hz values
15	DICOM Procedures, uploading images to PACS
16	Body Mark
17	APP version number

6	Mode:PW	18	Show patient information
7	Focus Position	19	Full screen
8	H: change scanning frequency(F)	20	B Gain (GN)
9	Biopsy Needle Guide line To invert the image horizontally or vertically. U/D flip, R/L flip	21	Live/freeze display
10	Depth Scale display	22	Mid-line
11	8 TGC: adjust gains of different depth	23	Dual screen display mode (only available for Apple iPad, Android tablet device and Windows Laptop/Tablet)
12	Depth: adjust depth by swiping the button (D)	24	New patient & new report

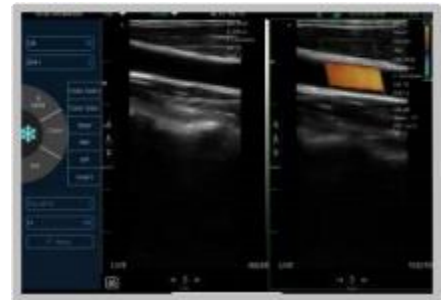
Click   button to switch the dual screen / single screen mode

Click the left/right screens to switch freely, and you can switch B/BM/Color/PW mode at the same time.

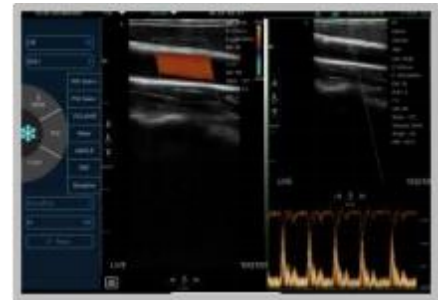


23

B+B mode





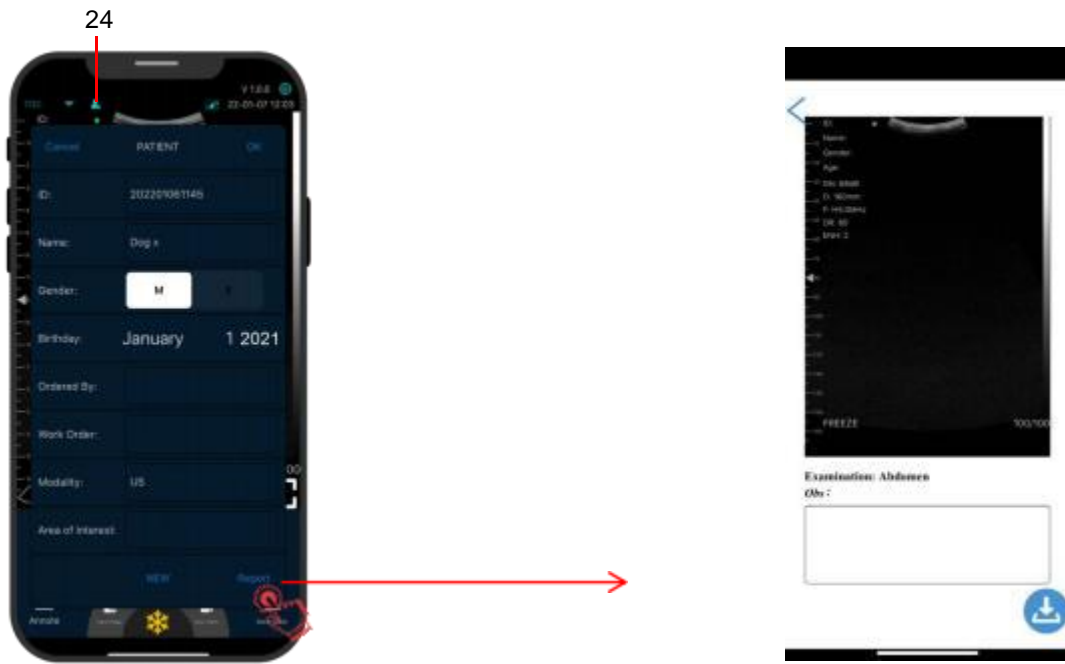
B+Color mode




Color+PW mode


24 New patient & new report


- Enter new patient info, click **OK**
- Scan now, then Freeze image
- Edit the report, click  to save the report to Data Table 





Freeze mode


- 1  add annotations on any frozen image


- 2  Save image, review the image in Data Table

- 3  Measurements

- 4  Save video, review the video in Data Table

- 5  Data Table

- 6  Auto cine review

- 7  Manual cine review

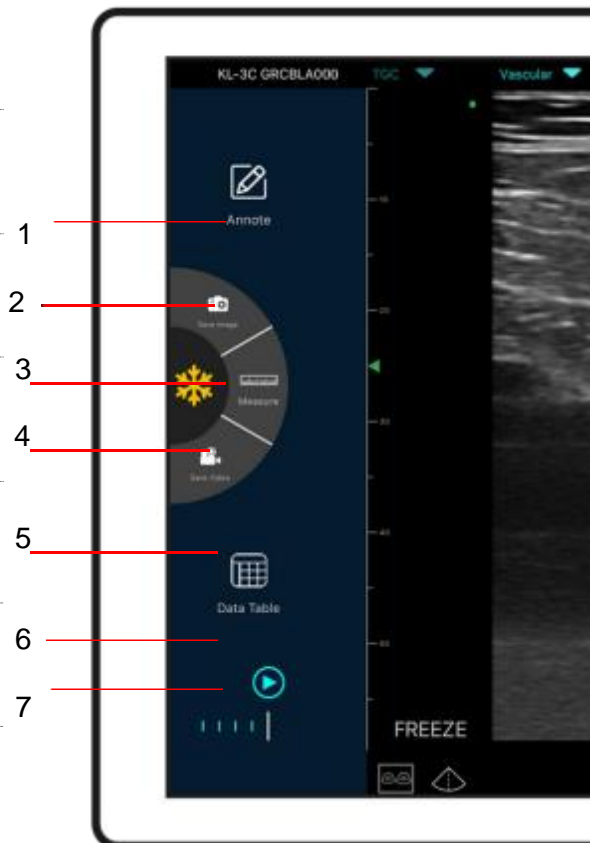




Image Browser Review image/video/report

Watch

① Click 5 **Date Table**

② Click 8  check record

③ Please swipe to the left to browse the images/videos and report.

Share

Sharing scanned files by other app

Printing image/report

Delete

Delete local files

The data table can store 500 files

Selecting Exam Present

Tap **No.31 (Abdomen)** to select the present:

Convex probe:

Abdomen
Gynecology
Obstetric
Cardiac
Urology
Kidney
Lung

Linear probe:

Thyroid
SmallParts
Pediatrics
Vascular
Carotid
Breast
MSK
Nerve
VesselFlow

Switching Between Imaging Mode

Tap **Color/PDI, B/B/M or PW** to select the desired imaging mode:

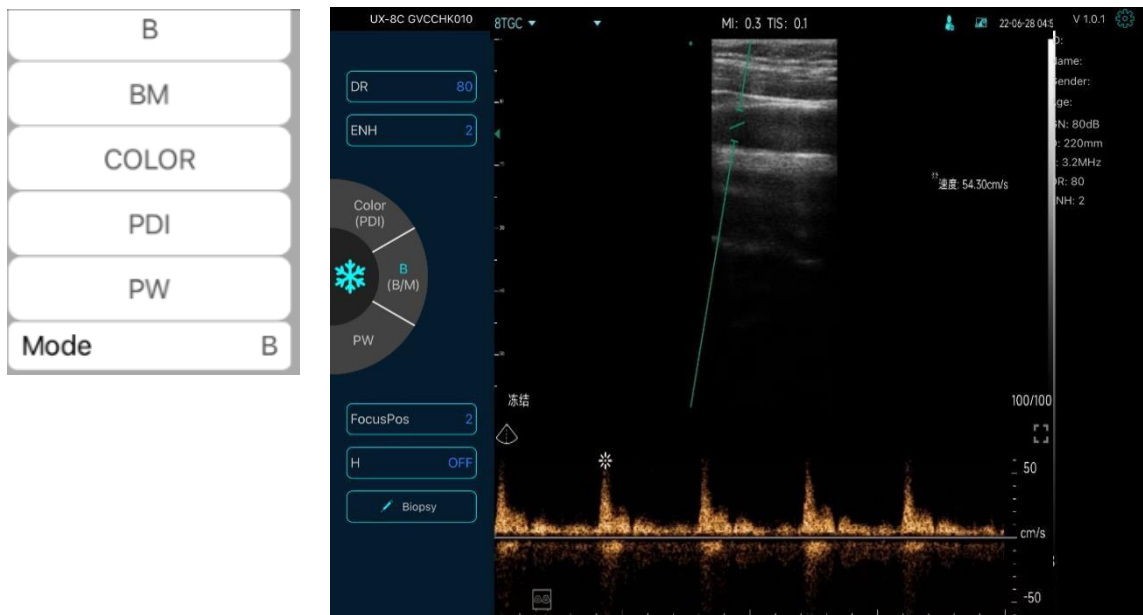


Image Adjustment

Requirement	Available Operations
To modify the brightness	Adjust No.20 Gain Adjust No.11 8TGC
To modify gray scale image effect	Adjust No.23 Focus Pos Adjust No.3 ENH Adjust No.8 H Adjust No.2 DR
Zoom	Adjust No.12 Depth

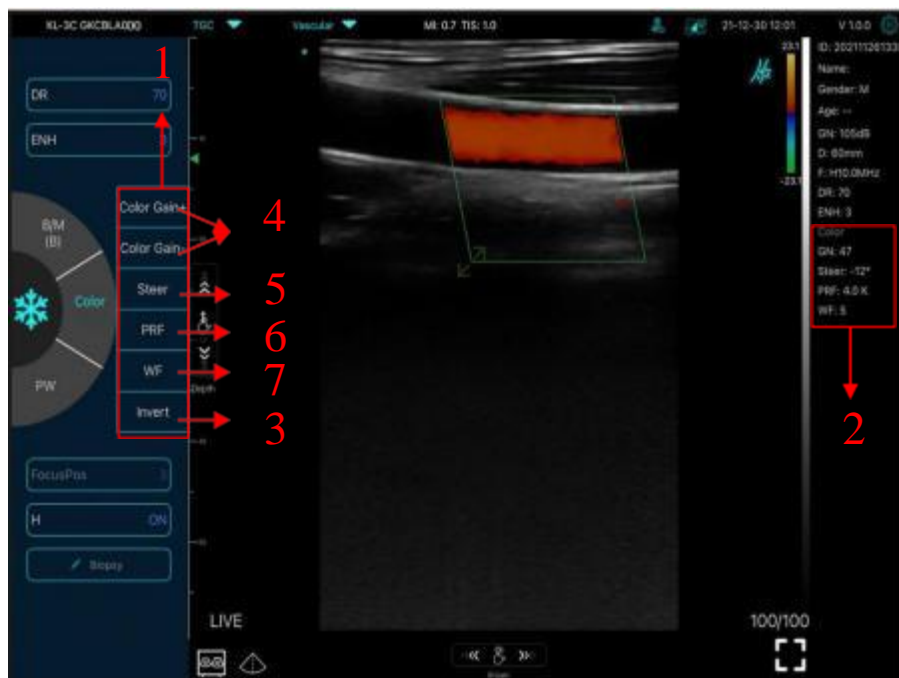
4.2.1 BM mode

In BM mode, you can adjust the position of the green M sampling line by moving the following marks with your finger.



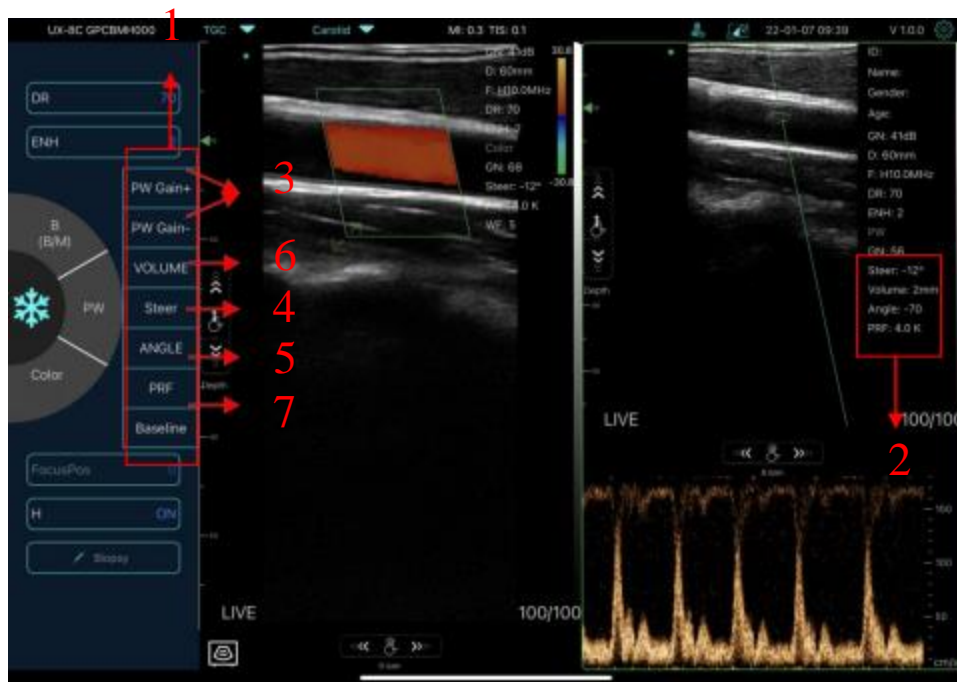
4.2.2 C mode

- 1) Second menu in color mode, click the buttons, the parameter will be changed
- 2) Parameters display area in color mode
- 3) Invert: to change the colors blue and red
- 4) Increase+ or reduce- the color gain
- 5) Steer: to adjust the deflection angle
- 6) PRF: to adjust color pulse repetition frequency
- 7) WF: adjusting the filtering frequency of a pulse wave or continuous wave Doppler low frequency signal



4.2.3 PW mode

- 1) Second menu in PW mode, click the buttons, the parameter will be changed
- 2) Parameters display area in PW mode
- 3) PW gain: Increase+ or reduce- the pulse gain
- 4) Steer: to adjust the deflection angle
- 5) Angle: real-time scanning state, used to change the spectrum sampling line angle
- 6) Sampling volume: change the size of the sampling volume
- 7) PRF: to adjust color pulse repetition frequency




4.3 Measurements

General measurements refer to general measurements on images of B/C mode, M mode, PW mode.

To perform a measurement:

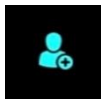
1. Tap  to freeze the image.

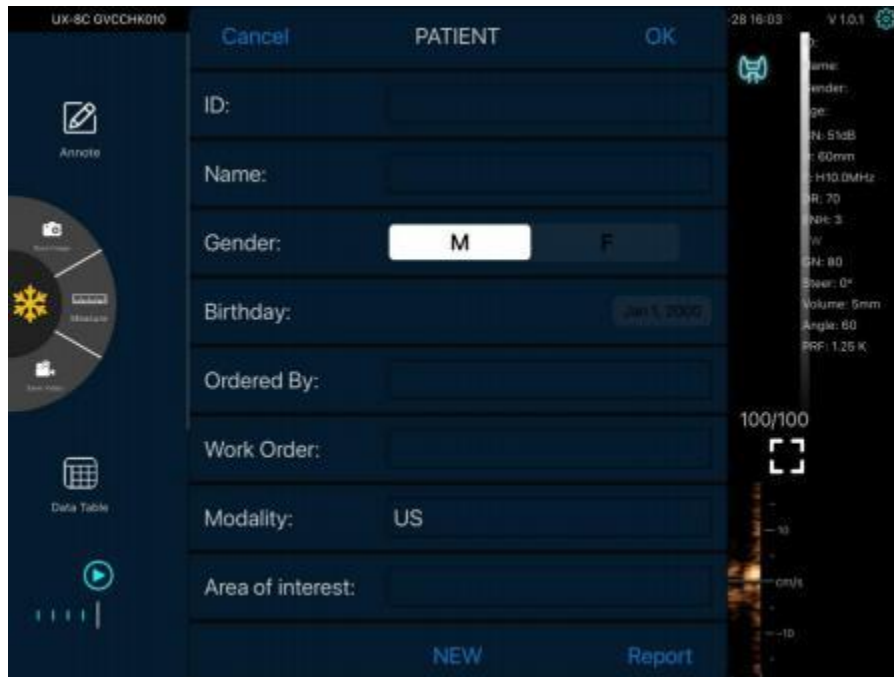
2. Tap  to access the measurement tools.

Mode	Measurement Tools	Available Operations
B/C	Length	Measures the length between two points of interest.
	Angle	The angle between two intersected planes
	Area/ Circumference	Measures the distance between two points of interest.
	Trace	Measures the length of a curve on the image
	Distance	Measures the distance between two points of interest.
	GA(CRL, BPD, GS, FL, HC, AC) EFW(BPD, FL)	Only for present: Obstetric
M	Heart Rate(5)	Measures the time of tow cardiac cycles and calculates the heart rate in M mode image.
	Time	The time interval between any two points.
	Distance	The vertical distance between two points.
PW	Velocity	Calculate the velocity of the point in Doppler spectrum wave.
	Heart Rate(2)	Measures the time of tow cardiac cycles and calculates the heart rate
	S/D	Calculate the PE/SD and RI
	Distance	The vertical distance between two points.

3. To delete a result, tap the result, then tap the "X" next to the corresponding numeric measurement display, and then tap Delete Line to confirm.

4.4 Patient's information and report

1. Click on  to enter the patient data input box.



UX-8C GVCCHK010

Cancel PATIENT OK

ID:

Name:

Gender: M F

Birthday:

Ordered By:

Work Order:



Modality: US

Area of interest:

NEW Report

Technical Specifications:

- Name:
- Gender:
- Age:
- Freq: 5148
- Depth: 60mm
- PRF: 110.0MHz
- SR: 70
- PRF: 3
- W:
- SN: 80
- Power: 0"
- Volume: 5mm
- Angle: 60
- PRF: 1.25 K

2. After editing the report, click  to save the report to the  Data Table. Please swipe to the left to browse the pictures/videos and report.

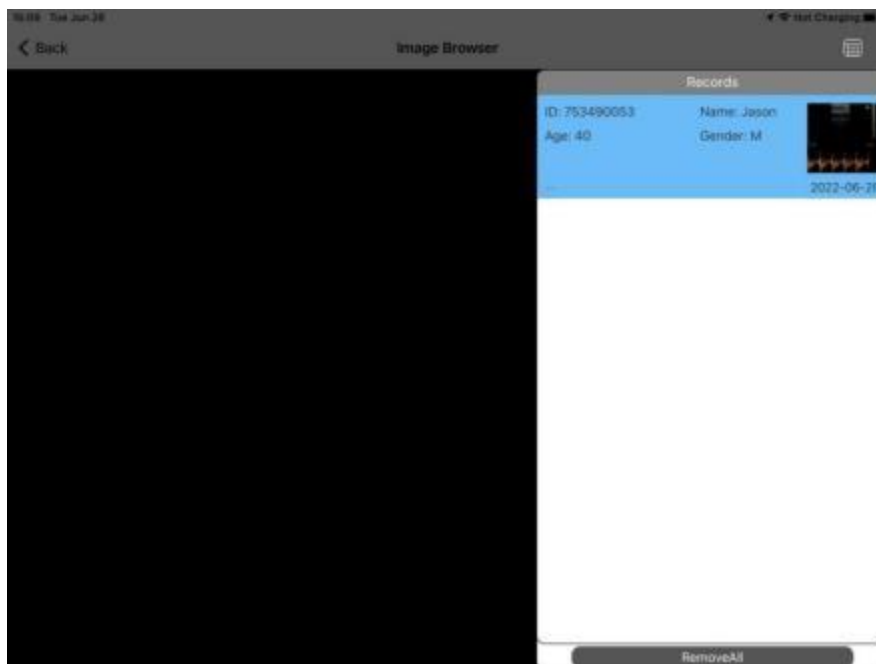



Image Browser

Records			
ID: 753490053	Name: Jason		
Age: 40	Gender: M		
			2022-06-28

RemoveAll


4.5 DICOM

DICOM is the digital imaging and communication standards. This system support related DICOM functions:

- DICOM Basic function: DICOM connection verify, DICOM storage.
- DICOM work list

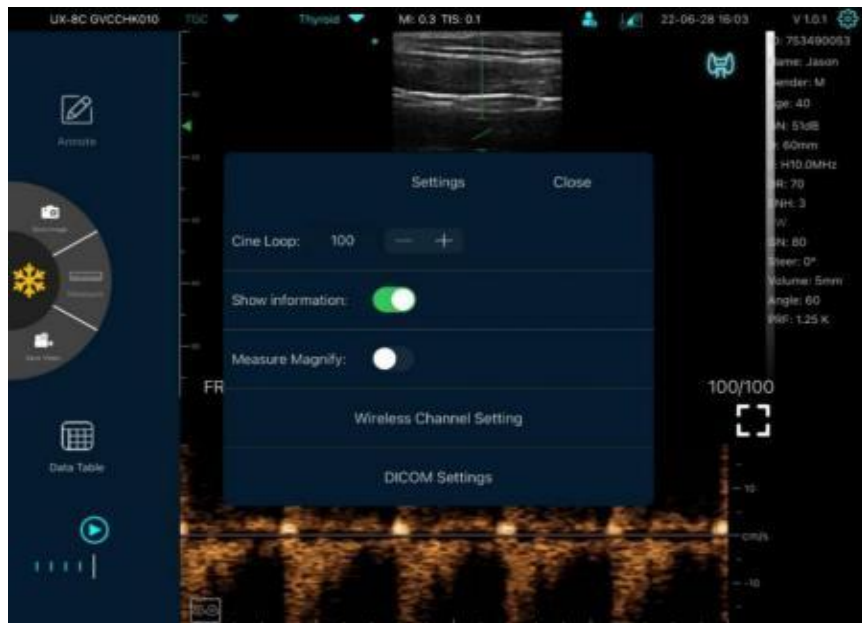
4.5.1. Dicom Setting

Step1:

Click setting  , then press DICOM Settings.


Step2:

- Connect mobile device with Workplace WiFi
- Fill in the DICOM1 - DICOM2 - Worklist information and tap Ping buttons to test run the Setups.
- If “success” messages appear, then the DICOM connection is completed.

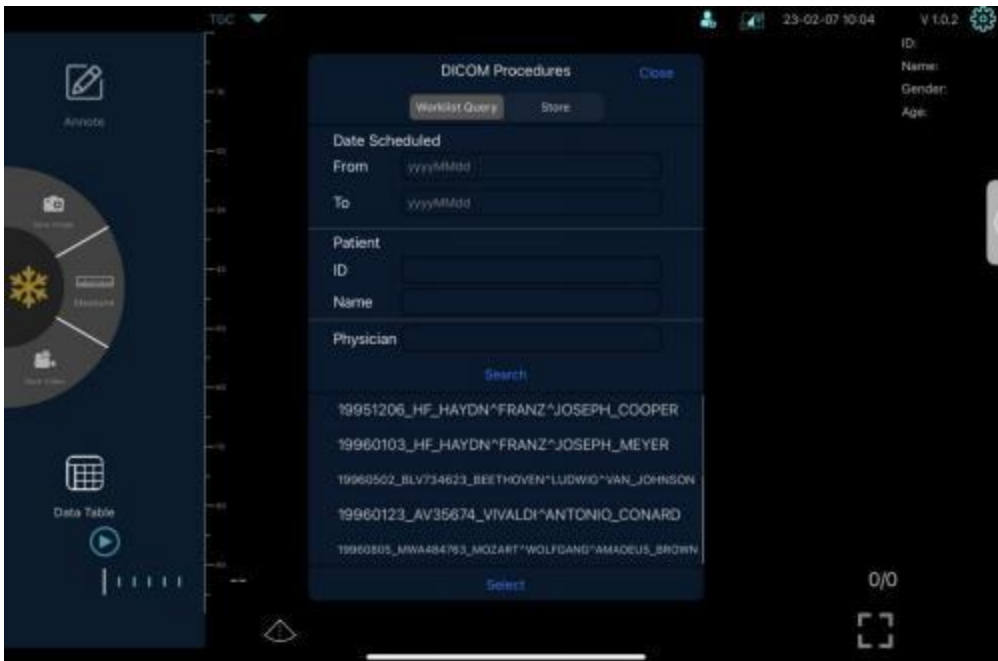


4.5.2. Dicom Procedures

After successfully connect to DICOM Worklist server with ultrasound system.

Click  you can search and query patient records from Worklist server, and then import the desired information to your system.

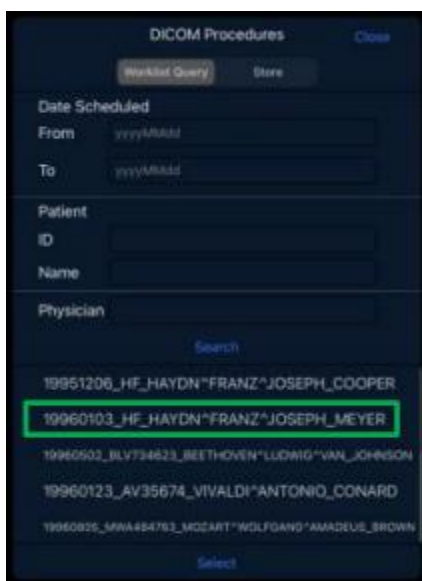
DICOM Store is used to send image(s) to DICOM store server for store.



Dicom worklist

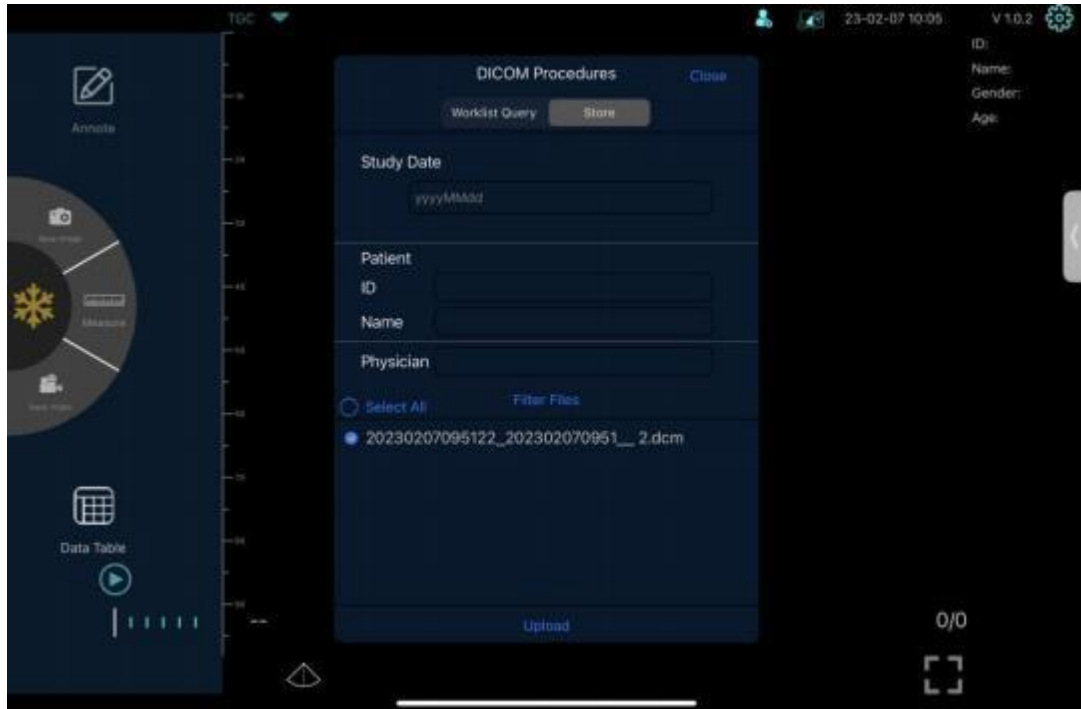
- Query patient information: Set query criteria among date Scheduled, Patient ID, Patient Name, physician.
- Click<Search> The scheduled patients, which meet the criteria, are displayed in the lower part of the screen.

Double-click or select one record, then click “Select” will display some information, and click “Use” to automatically fill in the APP case information form.

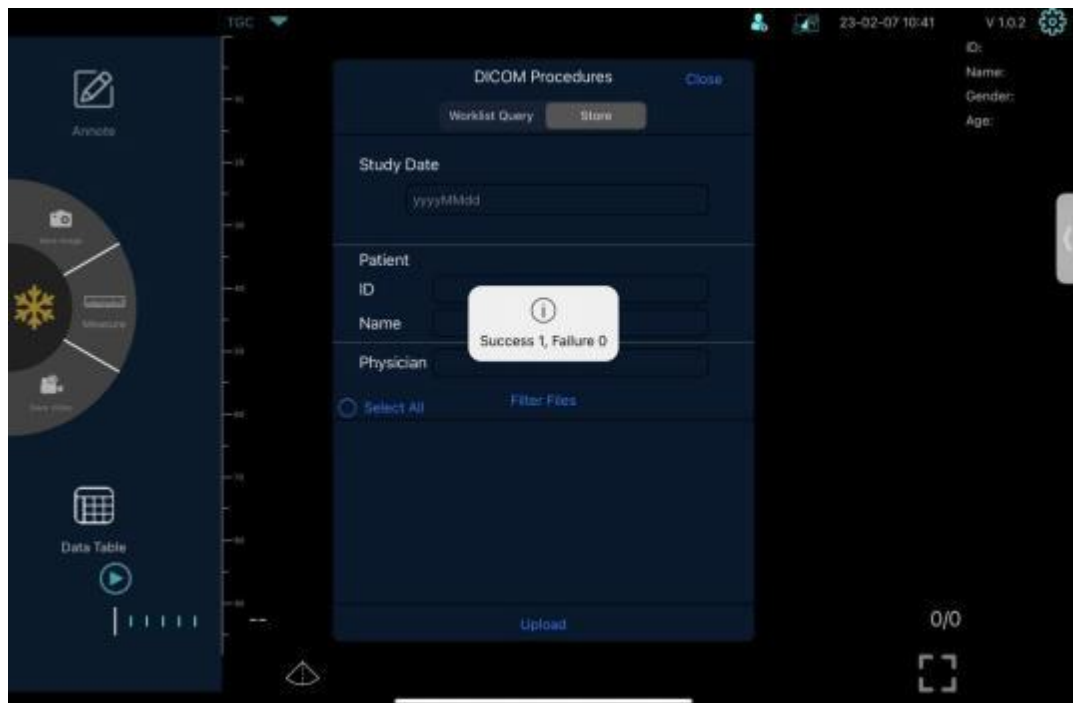


Dicom store

You can select a record and click “upload” it to Dicom store, then the “upload” is completed.



Successful upload interface is displayed “success” messages appear, as shown in the figure below. To prevent data loss, upload or backup data in time.



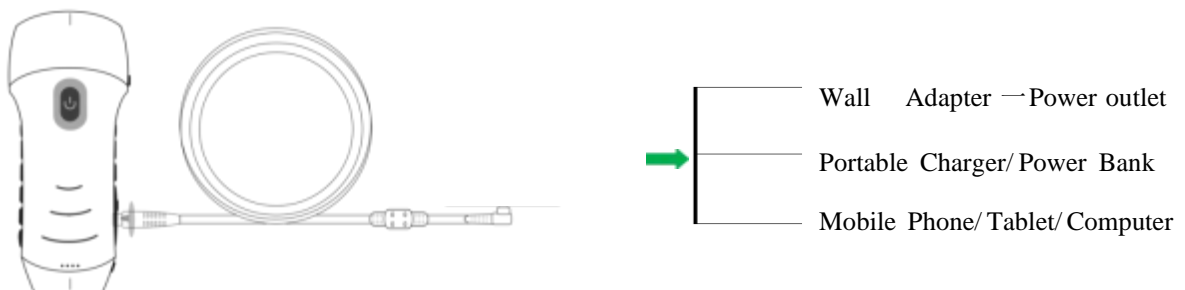
5 Maintenance and inspect

5.1 Charging the probe

Charge the probe when the battery is low (one battery indicator left). When charging, the battery indicator flashes to indicate the current charge level. We suggest the probe should be charged when only one battery indicator is lightning. If all 4 battery indicators are on and the battery indicator stops blinking, the battery is fully charged.

Charging by USB cable:

1. Pull out the rubber plug at the right-side of the probe.
2. Use our USB Type-C charging cable to connect the probe and wall adapter. (or other USB port that can provide the power supply such as a portable charger) as shown below.
3. Plug the wall adapter into a power outlet.



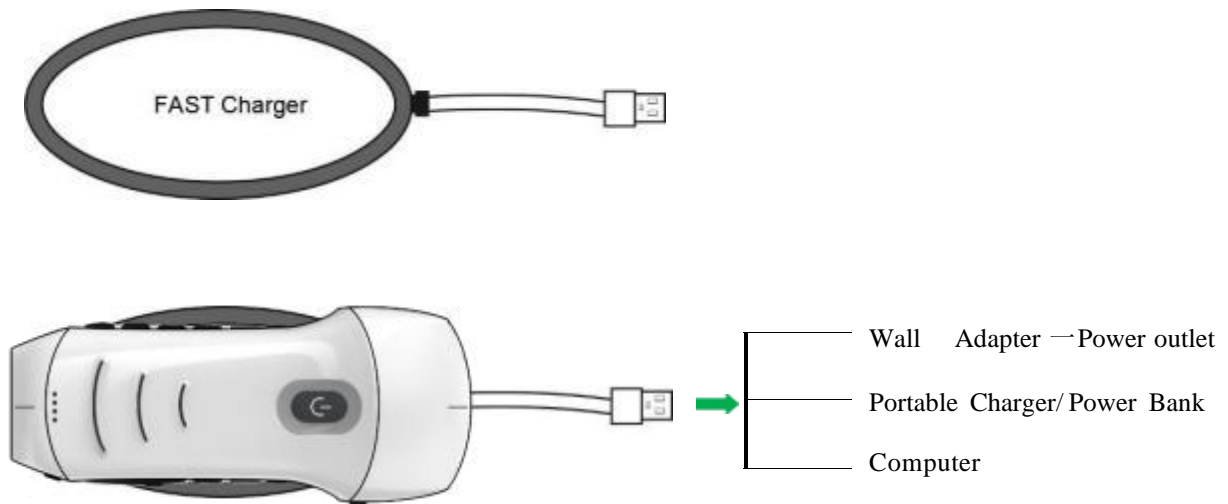
Note:

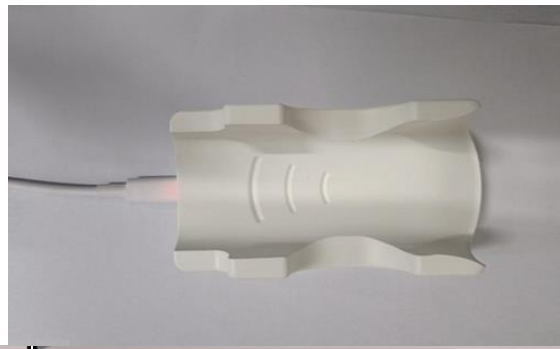
- The probe does not work during charging, and the charging cable has no data transmission
- When you connect the probe to your Mobile phone/Tablet/PC by type-c cable, the probe will be charged automatically.
- The power adapter shall use the European adapter, The standard is as follows
input: 100-240V \sim 50/60Hz 0.5A max
output : 5V $\overline{\text{---}}$ 2.4A

Charging by wireless charging pad:

The probe support wireless charging.

1. Disconnect the probe from your mobile device.
2. Connect the Micro USB cable to the wireless charging pad.
3. Connect the USB end of the cable to the wall adapter.
4. Plug the wall adapter into a power outlet.
5. Place the probe onto the white wireless charging pad.





Note:

- When the probe is charged through the wireless charging pad, it cannot work.
- Make sure to place the probe on the charging pad so that it lies flat on the charging pad on a flat surface. Do not hang the charging pad or hang the probe from the charging pad.
- Ensure that the probe is properly placed on the charging pad so that the probe's battery indicator flashes blue and the charger indicator light is blue.

CAUTION :



- 1** If the probe will not power on after charging, it could indicate a battery failure. Contact Support.
- 2** A non-medical grade power supply must be used outside of the patient environment so that it is at least 1.5 meters from the patient.
- 3** The probe battery should be charged at least monthly to ensure proper functionality.
- 4** It is normal that the probe may feel warm to the touch while charging. If you remove the probe from the charging pad before or immediately after charging is complete, it is recommended that you allow the probe to cool down before use. Since the system limits patient contact temperature and will not scan at or above 43°C (109°F), allowing the probe to cool down before use will optimize scan time performance.
- 5** If the battery charge is too low (25% or less), you may not be able to perform a study until the battery is recharged. Keep the battery fully charged whenever possible.

5.2 Replace the battery

The battery of USB&Wi-Fi probe can't be replaced. If the probe cannot be charged or the probe cannot be turned on, please contact us.

5.3 Cleaning and Disinfecting the probe

5.3.1 Cleaning the probe

The operation process is as follows:

The following cleaning methods shall be taken immediately after each complete test on the patient to avoid drying the remaining coupling gel on the probe, which is not conducive to the cleaning of the probe and to prevent the body and sound head from being corroded by coupling gel or other reagents. Before the cleaning or disinfection work begins, the operator should wear professional protective equipment such as goggles and gloves and check whether the instruments, equipment, materials, and environment used meet the requirements in advance.

1. Turn off the power of the ultrasound probe, press and hold the Power-button for more than 5s until the light goes out. For the specific operation process, please refer to the product instruction manual.
At the same time, check whether the waterproof cap of the charging port of the machine is installed and returned. If it is open, the waterproof cap should be installed and returned.
2. Use a clean hygienic paper (the wiping paper should be soft, non-abrasive disposable paper) or a clean, lint-free soft cloth to wipe the probe. Gently wipe the paper or soft, lint-free cloth along the wide side of the transducer to the other end (excessive wiping may cause pressure marks on the transducer and render the instrument unusable). The wiping direction should vary. Repeated wiping in the same direction should be avoided.
3. During the wiping process, fold the hygienic paper in half from the starting point to the endpoint after each wipe and fold the wiping paper in half in the direction of the side soiled with coupling or other ultrasonic special colloid residues (fold the soiled side into the wiping paper).
4. Hygiene paper or lint-free soft wipes should not be folded in half more than four times. If coupling or other ultrasound special colloids still remain on the transducer after the fourth wipe, you must use a new hygiene wipe and repeat the process after replacing it. The above steps are performed until the coupling medium has been completely wiped off the transducer.
5. Use tissue paper or a lint-free cloth soaked in an enzyme-containing detergent (detergents should be used as directed on the label and in the instructions for use) to clean the transducer until no visible stains remain and the transducer and its surroundings are completely clean. Pay attention to whether the use time of detergent is within the warranty period of the product.

6. Rinse the probe with drinking water or softened, filtered water (the water quality of tap water is too hard and may contain salt and alkali residues, which will cause different degrees of corrosion to the ultrasonic probe. For specific water quality requirements, please refer to AAMI TIR 34). During the process, keep wiping your hands over the transducer until all cleaning agents have been washed off. In general, the duration of the rinsing should not be less than 30 seconds. During the rinsing process, water should be prevented from splashing onto the shaft. If any liquid enters the shaft it will cause irreversible damage to the electronic components of the device.
7. Use a hygienic paper or a clean lint-free, soft cloth (the same lint-free soft cloth used before should not be used again) to wipe the entire case and both arrays, and wipe any remaining water spots from the arrays.
8. Place the entire device in the air with humidity $\leq 60\%$, a temperature $\leq 40\text{ }^{\circ}\text{C}$ and $\geq 15\text{ }^{\circ}\text{C}$ and a fine dust load $\leq 3.5\text{ }\mu\text{g}/\text{m}^3$. Ventilation and drying shall be carried out in a ventilated indoor environment, and the drying time should be $\geq 30\text{ s}$. Meanwhile, direct exposure to sunlight shall be avoided.
9. Check the entire housing for damage, such as cracks, fissures, breaks or a protruding array are visible. In case of the above situations, stop using immediately and contact the local dealer or sales representative.

5.3.2 Disinfecting the probe

The operation process is as follows:

Before the machine is sterilized, it should be ensured that the cleaning work has been carried out and the cleaning process is correctly followed. Operators should wear protective equipment such as professional goggles and gloves, and check whether the instruments, equipment, materials and environment used meet the requirements in advance.

1. Use alcohol disinfectants (For example: A mixture of quaternary ammonium compounds $\leq 2\%$ and purified or softened filtered water. The amount of quaternary ammonium compounds is 200mg - 1000mg / L, which is equivalent to an alcohol disinfectant solution of quaternary ammonium compounds for spraying and disinfection. Add the disinfectant mixture to a spray bottle and use it to spray the disinfectant evenly onto the surface of the ultrasound probe and around the ultrasound probe housing. (Quaternary ammonium salts should not be used in combination with soap or anionic surfactants, citrates, iodides, nitrates, potassium permanganate, salicylates, silver salts, tartrates and alkaloids, aluminum, sodium fluorescein, permanganate, hydrogen oxide, kaolin, hydrous lanolin, etc.) Lay the device for static disinfection flat on the workbench, the duration of static disinfection is 2 to 5 minutes.
2. Take a piece of hygienic paper and spray the middle part of the paper for 3-5 times with the disinfectant to ensure that the hygienic paper is $\geq 80\%$ wetted with disinfectant. Use hygienic wipes sprayed with disinfectant to wipe down the device, and ensure that all surfaces and gaps of the device are completely wiped and disinfected.
3. Take a new piece of hygienic paper or clean lint-free, soft cloth, wipe the whole housing and the arrays again, and wipe it from the arrays to the housing until all the disinfection reagent residues are removed.

4. Check whether there are still residues of water or other stains on the housing and the arrays. If water stains or other stains are still present, repeat steps 2 and 3 until the stains are wiped off the housing and arrays. If not, proceed directly to the next step.
5. Place the wiped device in an environment with humidity $\leq 60\%$, a temperature $\leq 40\text{ }^{\circ}\text{C}$ and $\geq 15\text{ }^{\circ}\text{C}$, and a fine dust load $\leq 35\text{ }\mu\text{g} / \text{m}^3$. The secondary ventilation and drying shall be carried out in a ventilated indoor environment, and the drying time shall be $\geq 2\text{ min}$. Meanwhile, direct exposure to sunlight shall be avoided.

5.4 Storage

When not using the probe, please store it in a suitable package to avoid the effects of violent shocks on the probe and to avoid exposing it to excessive temperatures (suitable storage temperature: 0 ° - 40 °C).

5.5 Inspect

Frequently check the probe cables, if you notice any damage, prohibit using the probe and arrange immediate replacement or repair.

Regularly check the socket and the array parts, if you notice any damage or bubble phenomenon, prohibit using the probe and arrange immediate replacement or repair.

Before each use, check whether the device and especially the transducer have been cleaned and disinfected (sterilization). If you find any of the above defects, stop using the device and arrange immediate replacement or repair.

WARNING:

Equipment failure, Users are not allowed to repair without authorization. Product must be sent back to the company

5.6 Life cycle

According to the manufacturer's design, production, and other related documents, this type of product life is generally 5 years, depending on use frequency, it can also be used for 6-8 years. The product material will gradually age over time, continue to use the products beyond the lifetime may cause performance degradation and a significantly higher failure rate.

WARNING:

The manufacturer will not be held responsible for the risks arising from the continued use of the product life cycle.

5.7 Troubleshooting

Here lists the troubleshooting issues and resolutions.

If you are unable to resolve an issue using Table- 1, please note the issue and report it to support for assistance.

Table- 1 Troubleshooting	
Connection issues	
Display the error password	<ol style="list-style-type: none"> 1. The SN number of the probe is the wifi password, re-enter the password, The password's letters must be input as small letters, not capital. 2. Try to connect to the probe with type-C cable.
The probe can not be connected to Mobile phone/tablet, but can work with laptop	<ol style="list-style-type: none"> 1. Please change the Wi-Fi channel with your laptop. 2. Try to connect the probe to your mobile phone again.
The probe can work by Wi-Fi, but can not work with Type-C	<ol style="list-style-type: none"> 1. The A-end and B-end of the cable can not be inserted reversely. The A-end must be fully inserted into the probe and the B-end must be fully inserted into the smart device. 2. Try to connect the probe with the other side of the type-C A port interface
Probe issues	
Probe can not be charged by cable	<ol style="list-style-type: none"> 1. The A-end must be fully inserted into the probe and the B-end must be fully inserted into the smart device. 2. Charge the probe for 1h with wireless charger. 3. If not work, pls contact support!
Can not turn on the probe	<ol style="list-style-type: none"> 1. Charge the probe for 30 minutes firstly 2. Try to turn on the probe again 3. If not work, pls contact support!
Can not turn off the probe	<ol style="list-style-type: none"> 1. Press and hold the probe's power Button for 15-20 seconds. 2. Charge the probe
App issues	
App can not turn on	<ol style="list-style-type: none"> 1. Delete and re-install the App 2. Update the App 3. Try to install the app to other mobile device
App crashes	
App opens but will not scan images	<ol style="list-style-type: none"> 1. Make sure the probe is connected successfully 2. Try to press the probe power button 3. Re-install and update the App 4. Charge the probe

Black screen or screen no longer updates	<ol style="list-style-type: none"> 1. Close the App and restart the App. 2. Unplug the probe from the mobile platform (mobile device) and reconnect.
Imaging issues	
Image degradation or occurrence of image artifacts	Make sure you are using the appropriate preset and the depth is appropriate for the anatomy being scanned.
Image quality degraded	<ol style="list-style-type: none"> 1. Make sure you are using enough approved ultrasound gel. If quality does not improve. 2. If not work, contact Support
Image is nor clear	<ol style="list-style-type: none"> 1. Adjust the image parameters follow the page-24 2. Use enough ultrasound Gel.

6 .Electromagnetic Compatibility

1. The product contains RF transmitters:



2. Note: The purchaser or user of the portable color ultrasonic diagnostic instrument should use the portable color ultrasonic diagnostic instrument in the electromagnetic environment specified in Table 1, 2, 3, and 4, otherwise the portable color ultrasonic diagnostic instrument may not work normally.
3. Note: Portable and mobile radio frequency communication equipment may affect the use of this portable color ultrasonic diagnostic instrument. When using this portable color ultrasonic diagnostic instrument normally, please use this device in the recommended electromagnetic environment.
4. The charging cable provided by our company must be used.
5. Warning: In addition to the charging connection cables provided by the company, the use of non- specified charging connection cables may lead to an increase in self-emission or a decrease in immunity.
6. This product is suitable for equipment and system requirements that intentionally receive radio frequency energy for its working purpose, and the receiving bandwidth is 20M.
7. This product is also suitable for equipment and system requirements that include RF transmitters, and the transmitting frequency is: transmitting frequency: 5GHz, frequency band: 4.9GHz~5.845GHz, receiving bandwidth 20 M, modulation type: MIMO-OFDM/DSSS/CCK, effective Radiation power: 14dBm.
8. In order to ensure the normal use of the portable color ultrasonic diagnostic instrument and ensure that its emission will not be increased and its immunity will not be reduced, please use the charging connection cable provided by our company.
9. Use of non-specified accessories with the portable color ultrasound system may result in increased emissions or reduced immunity of the equipment or system.
10. Warning: The portable color ultrasonic diagnostic instrument should not be stacked with other devices with the same or similar operating frequency. If it must be stacked, it should be observed to verify that it can operate normally under the configuration it uses.

11. The basic performance is:

- a) Shall not produce waveform noise, image artifacts or distortions, or display incorrect numerical values that could alter diagnostic results
- b) Shall not produce displays of incorrect numerical values related to the diagnostics performed
- c) Shall not produce unintended or excessive ultrasonic output
- d) Do not create unintended or excessive transducer component surface temperature rise
- e) When signal acquisition stops, acoustic output stops.

12. When the portable color ultrasonic diagnostic instrument is in normal use, it may cause electromagnetic interference to other diagnostic or therapeutic equipment. Please keep an appropriate distance from other equipment when using it, and carefully observe the correctness of the data during the use of the equipment.

13. Cable Information – none.

Table 1 for all devices and systems

Guidance and Manufacturer' sDeclaration – Electromagnetic Emissions		
Pocket ultrasound system is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is in this electromagnetic environment use:		
launch test	compliance	Electromagnetic Environment - Guidelines
Radio frequency emission GB 4824	Group 1	The pocket ultrasound system uses radio frequency energy only for its internal function. Therefore, it has low radio frequency emissions and is less likely to cause interference with nearby electronic equipment.
Radio frequency emission GB 4824	Class A	The pocket ultrasound system instrument is suitable for use in all facilities that are not directly connected to the public low-voltage power supply network for domestic and residential use.
Harmonic emission GB 17625. 1	Not applicable	
Voltage fluctuation/ flicker emission GB 17625.2	Not applicable	

Table 2 for all devices and systems

Guidance and Manufacturer' s Declaration - Electromagnetic Immunity			
The pocket ultrasound system instrument is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test level	Meet the level	Electromagnetic Environment - Guidance
Electrostatic discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or tile, and if floors are covered with synthetic material, then The relative humidity should be at least 30%.
Electrical Fast Transient Bursts GB/T 17626.4	±2 KV to power line ± 1 KV for input/output lines	Not applicable	/
surge GB/T 17626.5	± 1 kV line to line ±2 kV line to ground	Not applicable	/

and voltage changes on power input lines GB/T 17626. 1 1	<5%UT, last for 0.5 cycle (> 95% dip inUT) 40 % UT for 5 cycles (60% dip inUT) 70 % UT for 25 cycles (on UT, 30% dip) <5% UT, last for 5s (onUT , > 95% dip)	Not applicable	/
Power frequency magnetic field (50Hz/60Hz) GB/T 17626.8	3 A/m	3 A/m	/
Note: UT refers to the AC network voltage before the test voltage is applied.			

Table 3 for non-life support equipment and systems

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The pocket ultrasound system instrument is expected to be used in the following electromagnetic environment, and the purchaser or user of the portable color ultrasonic diagnostic instrument should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test level	Meet the level	Electromagnetic Environment - Guidelines
Radio frequency conduction GB/T 17626.6	3V (effective value) 150kHz~80MHz	3V (effective value)	Portable and mobile RF communications equipment should not be used closer to any part of the portable color ultrasound system, including cables, than the recommended separation distance. This distance should be calculated using the formula corresponding to the frequency of the transmitter. Recommended Separation Distance $d = 1.2 \sqrt{P}$
Radio frequency radiation GB/T 17626.3	3V/m 80MHz~2.5GHz	3V/m	80MHz~800MHz 800MHz~2,5GHz $d = 1.2 \sqrt{P}$ $d = 2.3 \sqrt{P}$ In the formula: P - the maximum output power rating of the transmitter provided by the transmitter manufacturer, in watts (W); dis the recommended separation distance in meters (m)

			<p>Field strengths from fixed radio frequency transmitters, as determined by an electromagnetic field survey, shall be lower than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with:</p> <p style="text-align: center;">▲</p>
<p>Note 1: At the 80MHz and 800MHz frequency points, the formula for the higher frequency band should be used.</p> <p>Note 2: These guidelines may not be appropriate in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<ul style="list-style-type: none"> - fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and television broadcasts, cannot be predicted for the electromagnetic environment of the radio frequency transmitter, the survey of the electromagnetic field should be considered. If the measured field strength in the location where the portable color ultrasonic diagnostic instrument is located is higher than the applicable RF compliance level above, the pocket ultrasound system instrument should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the direction or position of the portable color ultrasound diagnostic instrument. - In the entire frequency range from 150kHz to 80MHz, the field strength should be lower than 3V/m 			

Table 4 for non-life support equipment and systems

Recommended separation distance between portable and mobile RF communication equipment and pocket ultrasound system equipment			
<p>Pocket ultrasound system instrument is intended to be used in an electromagnetic environment where radiated RF disturbances are controlled. According to the maximum output power of the communication equipment, the purchaser or user of the pocket ultrasound system instrument can maintain the portable and mobile RF communication equipment (transmitter) through the following recommended</p> <p>The minimum distance between the pocket ultrasound system instrument and the portable color ultrasonic diagnostic instrument is to prevent electromagnetic interference.</p>			
Rated maximum output power of the transmitter / W	m of different frequencies of the transmitter		
	150 kHz~80 MHz $d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$ 80 MHz~800 MHz	$d = 2.3\sqrt{P}$ 800 MHz~2.5 GHz
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	twenty three
<p>For the rated maximum output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is provided by the transmitter manufacturer The maximum output power rating of the transmitter in watts (W).</p> <p>Note 1: At 80MHz and 800MHz, the formula for the higher frequency band is used.</p> <p>Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

7. Application of Acoustic Power

7.1 Safe Scanning Guidelines

- Ultrasound should only be used for medical diagnosis and only by trained medical
 - Diagnostic ultrasound procedures should be done only by personnel fully trained in the use of the equipment, in the interpretation of the results and images, and in the safe use of ultrasound (including education as to potential hazards).
 - Operators should understand the likely influence of the machine controls, the operating mode (e.g. B mode) and probe frequency on thermal and cavitation hazards.
 - Select a low setting for each new patient. Output should only be increased during the examination if penetration is still required to achieve a satisfactory result, and after the Gain control has been moved to its maximum value.
 - Maintain the shortest examination time necessary to produce a useful diagnostic result.
 - Do not hold the probe in a fixed position for any longer than is necessary. The frozen frame and Cine loop capabilities allow images to be reviewed and discussed without exposing the patient to continuous scanning.
 - Do not use endo-cavitary probes if there is noticeable self heating of the probe when operating in the air.
 - Although applicable to any probe, take particular care during trans- vaginal exams during the first eight weeks of gestation.
 - Take particular care to reduce output and minimize exposure time of an embryo or fetus when the temperature of the mother is already elevated.
 - Take particular care to reduce the risk of thermal hazard during diagnostic ultrasound when exposing: an embryo less than eight weeks after gestation; or the head, brain or spine of any fetus or neonate.
 - Operators should continually monitor the on-screen thermal index (TI) and mechanical index (MI) values and use control settings that keep these settings as low as possible while still achieving diagnostically useful results. In obstetric examinations, TIS (soft tissue thermal index) should be monitored during scans carried out in the first eight weeks after gestation, and TIB (bone thermal index) thereafter. In applications where the probe is very close to bone (e.g. trans-cranial applications), TIC (cranial bone thermal index) should be monitored.
- MI > 0.3 there is a possibility of minor damage to neonatal lung or intestine. If such exposure is necessary, reduce the exposure time as much as possible.
- MI > 0.7 there is a risk of cavitations if an ultrasound contrast agent containing gas microspheres is being used. There is a theoretical risk of cavitations without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.
- TI > 0.7 the overall exposure time of an embryo or fetus should be restricted in accordance with Table 2-2 below as a reference:
- TI > 0.7 the overall exposure time of an embryo or fetus should be restricted in accordance with Table 2-2 below as a reference:

TI	Maximum exposure time (minutes)
0.7	50
1.0	30
1.5	15
2.0	10
2.5	5

Table 2 - 2 Maximum recommended exposure times for an embryo or fetus

- Non-diagnostic use of ultrasound equipment is not generally recommended. Examples of non-diagnostic uses of ultrasound equipment include repeated scans for operator training, equipment demonstration using normal subjects, and the production of souvenir pictures or videos of a fetus. For equipment of which the safety indices are displayed over their full range of values, the TI should always be less than 0.5 and the MI should always be less than 0.3. Avoid frequent repeated exposure of any subject. Scans in the first trimester of pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs, nor should their production involve increasing the exposure levels or extending the scan times beyond those needed for clinical purposes.
- Diagnostic ultrasound has the potential for both false positive and false negative results. Misdiagnosis is far more dangerous than any effect that might result from the ultrasound exposure. Therefore, diagnostic ultrasound system should be performed only by those with sufficient training and education.

7.2 Understanding the MI/TI Display

Track-3 follows the Output Display Standard for systems that include fetal Doppler applications. The acoustic output will not be evaluated on an application-specific basis, but the global maximum de-rated I_{spta} must be $\leq 720 \text{ mW/cm}^2$ and either the global maximum MI must be ≤ 1.9 or the global maximum de-rated I_{sppa} must be $\leq 190 \text{ W/cm}^2$. An exception is for ophthalmic use, in which case the $TI = \max(TI_{s_as}, TIC)$ is not to exceed 1.0; $I_{spta.3} \leq 50 \text{ mW/cm}^2$, and $MI \leq 0.23$. Track-3 gives the user the freedom to increase the output acoustic power for a specific exam, and still limit output acoustic power within the global maximum de-rated $I_{spta} \leq 720 \text{ mW/cm}^2$ under an Output Display Standard.

For any diagnostic ultrasonic systems, Track-3 provides an Output Indices Display Standard. The diagnostic ultrasound systems and its operation manual contain the information regarding an ALARA (As Low As Reasonably Achievable) education program for the clinical end-user and the acoustic output indices, MI and TI.

The MI describes the likelihood of cavitations, and the TI offers the predicted maximum temperature rise in tissue as a result of the diagnostic examination. In general, a temperature increase of 2.5°C must be present consistently at one spot for 2 hours to cause fetal abnormalities. Avoiding a local temperature rise above 1°C should ensure that no thermally induced biologic effect occurs. When referring to the TI for potential thermal effect, a TI equal to 1 does not mean the temperature will rise 1 degree C. It only means an increased potential for thermal effects can be expected as the TI increases. A high index does not mean that bioeffects are occurring, but only that the potential exists and there is no consideration in the TI for the scan duration, so minimizing the overall scan time will reduce the potential for effects. These operator control and display features shift the safety responsibility from the manufacturer to the user. So it is very important to have the Ultrasound systems display the acoustic output indices correctly and the education of the user to interpret the value appropriately.

RF: (De-rating factor)

In Situ intensity and pressure cannot currently be measured. Therefore, the acoustic power measurement is normally done in the water tank, and when soft tissue replaces water along the ultrasound path, a decrease in intensity is expected. The fractional reduction in intensity caused by attenuation is denoted by the de-rating factor (RF),

$$RF = 10^{-0.1 a f z}$$

Where a is the attenuation coefficient in dB cm⁻¹ MHz⁻¹, f is the transducer center frequency, and z is the distance along the beam axis between the source and the point of interest.

De-rating factor RF for the various distances and frequencies with attenuation coefficient 0.3dB cm⁻¹ MHz⁻¹ in homogeneous soft tissue is listed in the following table. An example is if the user uses 7.5MHz frequency, the power will be attenuated by .0750 at 5cm, or 0.3x7.5x5=- 1 1.25dB. The De-rated Intensity is also referred to as „ .3” at the end (e.g. Ispta.3)

Distance (cm)	Frequency (MHz)			
	1	3	5	7.5
1	0.9332	0.8128	0.7080	0.5957
2	0.8710	0.6607	0.5012	0.3548
3	0.8128	0.5370	0.3548	0.2113
4	0.7586	0.4365	0.2512	0.1259
5	0.7080	0.3548	0.1778	0.0750
6	0.6607	0.2884	0.1259	0.0447
7	0.6166	0.2344	0.0891	0.0266
8	0.5754	0.1903	0.0631	0.0158

I"=I*RF Where I" is the intensity in soft tissue, I is the time-averaged intensity measured in water.

Tissue Model:

Tissue temperature elevation depends on power, tissue type, beam width, and scanning mode. Six models are developed to mimic possible clinical situations.

Thermal Model	Composition	Mode	Specification	Application	
1	TIS	Soft tissue	Unscanned	Large aperture (>1cm ²)	Liver PW
2	TIS	Soft tissue	Unscanned	Small aperture (<1cm ²)	Pencil Probe
3	TIS	Soft tissue	Scanned	Evaluated at surface	Breast color
4	TIB	Soft tissue and bone	Scanned	Soft tissue at surface	Muscle color
5	TIB	Soft tissue and bone	Unscanned	Bone at focus	Fetus head PW
6	TIC	Soft tissue and bone	Unscanned/scanned	Bone at surface	Transcranial

Soft tissue:

Describes low fat content tissue that does not contain calcifications or large gas-filled spaces.

Scanned: (auto-scan)

Refers to the steering of successive burst through the field of view, e.g. B and color mode.

Unscanned:

Emission of ultrasonic pulses occurs along a single line of sight and is unchanged until the transducer is moved to a new position. For instance, the PW, and M mode.

TI:

TI is defined as the ratio of the In Situ acoustic power (W.3) to the acoustic power required to raise tissue temperature by 1°C (Wdeg), TI = W.3/Wdeg.

Three TIs corresponding to soft tissue (TIS) for abdominal; bone (TIB) for fetal and neonatal cephalic; and cranial bone (TIC) for pediatric and adult cephalic, have been developed for applications in different exams. An estimate of the acoustic power in milli-watts necessary to produce a 1°C temperature elevation in soft tissue is:

$W_{deg} = 210/f_c$, for model 1 to 4, where f_c is the center frequency in MHz.

$W_{deg} = 40 K D$ for model 5 and 6, where K (beam shape factor) is 1.0, D is the aperture diameter in cm at the depth of interest.

MI:

Cavitation is more likely to occur at high pressures and low frequencies in pulse ultrasound wave in the tissue, which contains the bubble or air pocket (for instance, the lung, intestine, or scan with gas contrast agents). The threshold under optimum conditions of pulsed ultrasound is predicted by the ratio of the peak pressure to the square root of the frequency.

$MI = Pr^* / \sqrt{f_c}$

Pr^* is the de-rated (0.3) peak rare-fractional pressure in Mpa at the point where PII is the maximum, and f_c is the center frequency in MHz. PII is the Pulse Intensity Integral that the total energy per unit area carried by the wave during the time duration of the pulse. The peak rare-fractional pressure is measured in hydrophone maximum negative voltage normalized by the hydrophone calibration parameter.

Display Guideline:

For different operation modes, different indices must be displayed. However, only one index needs to be shown at a time. Display is not required if maximum MI is less than 1.0 for any setting of the operating mode, or if maximum TI is less than 1.0 for any setting of the operating mode. For TI, if the TIS and TIB are both greater than 1.0, the scanners need not be capable of displaying both indices simultaneously. If the index falls below 0.4, no display is needed. The display increments are no greater than 0.2 for index value less than one and no greater than 1.0 for index values greater than one (e.g. 0.4, 0.6, 0.8, 1, 2, and 3).

Display and Report

Located on the upper middle section of the system display monitor, the acoustic output display provides the operator with real-time indication of acoustic levels being generated by the system.

For Scan

Only display and report MI, and start from 0.4 if maximum MI > 1.0, display in increments of 0.2.

Below is a simple guideline for the user when TI exceeds one limit exposure time to 4(6-TI) minutes based on the „ National Council on Radiation Protection. Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms. Report No. 113 1992” .

Operator Control Features:

The user should be aware that certain operator controls may affect the acoustic output. It is recommended to use the default (or lowest) output power setting and compensate using Gain control to acquire an image. Other than the output power setting in the soft-menu, which has the most direct impact on the power; the PRF, image sector size, frame rate, depth, and focal position also slightly

affect the output power. The default setting is normally around 70% of the allowable power depending on the exam application mode. Controls Affecting Acoustic Output

The potential for producing mechanical bioeffects (MI) or thermal bioeffects (TI) can be influenced by certain controls.

Direct: The Acoustic Output control has the most significant effect on Acoustic Output.

Indirect: Indirect effects may occur when adjusting controls. Controls that can influence MI and TI are detailed under the bioeffect portion of each control in the Optimizing the Image chapter.

Always observe the Acoustic Output display for possible effects.

Best practices while scanning

HINTS: Raise the Acoustic Output only after attempting image optimization with controls that have no effect on Acoustic Output, such as Gain and TGC.



WARNING: Be sure to have read and understood control explanations for each mode used before attempting to adjust the Acoustic Output control or any control that can affect Acoustic Output.

Use the minimum necessary acoustic output to get the best diagnostic image or measurement during an examination. Begin the exam with the probe that provides an optimum focal depth and penetration.

Acoustic Output Default Levels

In order to assure that an exam does not start at a high output level, the system initiates scanning at a reduced default output level. This reduced level is preset programmable and depends upon the exam icon and probe selected. It takes effect when the system is powered on or New Patient is selected.

To modify acoustic output, adjust the Power Output level on the Soft Menu.

7.3 Acoustic output reporting table

Transducer Model: linear probe

Operating Model: B Mode

Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.31	0.15		0.15		N/A
Index component value			0.15	0.15	N/A	0.15	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	0.81					
	P (mW)		4.38		4.38		N/A
	$P_{1 \times 1}$ (mW)		4.38		4.38		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	0.54					
	$z_{pii.\alpha}$ (cm)	0.54					
	f_{awf} (MHz)	7.04	7.04		7.04		N/A
Other Information	p_{rr} (Hz)	4000.00					
	s_{rr} (Hz)	17.48					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm ²)	18.18					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm ²)	11.37					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	23.36					
	p_r at z_{pii} (MPa)	0.92					
Operating control conditions	Focus (mm)	9, 20	9, 20	9, 20	N/A	9, 20	N/A
	Depth (mm)	60	60	60	N/A	60	N/A
	Frequency (MHz)	7.5	7.5	7.5	N/A	7.5	N/A

NOTE: N/A indicates that there is no corresponding intended use or no data reported.

Notes:

(a) This index is not required for this operating mode. See section of the Output Display Standard

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: linear probe
 Operating Model: B + M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.31	0.151		0.157		N/A
Index component value			B:0.15 M:0.001	B:0.15 M:N/A	N/A	B:0.15 M:0.007	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	0.81					
	P (mW)		B:4.38 M:0.020		B:4.38 M:0.020		N/A
	$P_{1 \times 1}$ (mW)		B:4.38 M:N/A		B:4.38 M:N/A		
	z_s (cm)			N/A			
	z_b (cm)					1.14	
	Z_{MI} (cm)	0.54					
	$Z_{pii,\alpha}$ (cm)	0.54					
f_{awf} (MHz)	7.04		7.04		7.04		N/A
Other Information	pr_r (Hz)	B:4000.00 M:17.48					
	srr (Hz)	17.48					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$ (W/cm ²)	18.18					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$ (mW/cm ²)	11.44					
	I_{spta} at Z_{pii} or Z_{sii} (mW/cm ²)	23.45					
	p_r at Z_{pii} (MPa)	0.92					
Operating control conditions	Focus(mm)	9, 20	9, 20	9, 20	N/A	9, 20	N/A
	Depth(mm)	60	60	60	N/A	60	N/A
	Frequency(MHz)	7.5	7.5	7.5	N/A	7.5	N/A

NOTE: N/A indicates that there is no corresponding intended use or no data reported.

Notes:

- (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).
 - (b) This probe is not intended for transcranial or neonatal cephalic uses.
 - (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: linear probe

Operating Model: B+C Mode

Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.96	0.15		0.15		N/A
Index component value			B:0.07 C:0.08	B:0.07 C:0.08	N/A	B:0.07 C:0.08	
Acoustic Parameters	$\rho_{r,\alpha}$ at z_{MI} (MPa)	2.16					
	P (mW)		B:2.08 C:3.28		B:2.08 C:3.28		N/A
	$P_{1 \times 1}$ (mW)		B:2.08 C:3.28		B:2.08 C:3.28		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	1.14					
	$z_{pii,\alpha}$ (cm)	1.14					
	f_{awf} (MHz)	C:5.08		B:7.04 C:5.08		B:7.04 C:5.08	
Other Information	pr (Hz)	C:4000.00					
	srr (Hz)	8.33					
	n_{pps}	12					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	220.70					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ OR $z_{sii,\alpha}$ (mW/cm ²)	163.69					
	I_{spta} at z_{pii} OR z_{sii} (mW/cm ²)	243.33					
	p_r at z_{pii} (MPa)	2.64					
Operating control conditions	Focus (mm)	12	12	12	N/A	12	N/A
	Depth (mm)	60	60	60	N/A	60	N/A
	Frequency (MHz)	B:7.5 C: Fixed	B:7.5 C: Fixed	B:7.5 C: Fixed	N/A	B:7.5 C: Fixed	N/A
	PRF (kHz)	4.0	4.0	4.0	N/A	4.0	N/A

NOTE: N/A indicates that there is no corresponding intended use or no data reported.

Notes:

- (a) This index is not required for this operating mode. see section 4. 1.3. 1. of the Output Display Standard (NEMA UD-3).
- (b) This probe is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: linear probe

Operating Model: PW Mode

Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.01	0.24		0.82		N/A
Index component value			0.24	N/A	N/A	0.82	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.61					
	P (mW)		7.41		7.41		N/A
	$P_{1 \times 1}$ (mW)		N/A		N/A		
	z_s (cm)			N/A			
	z_b (cm)					1.14	
	z_{MI} (cm)	1.14					
	$z_{pii,\alpha}$ (cm)	1.14					
Other Information	f_{awf} (MHz)	6.66	6.66		6.66		N/A
	p_{rr} (Hz)	4000.00					
	s_{rr} (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	270.20					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	426.00					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	720.00					
p_r at z_{pii} (MPa)	3.39						
Operating control conditions	Focus(mm)	12	12	N/A	N/A	12	N/A
	Depth(mm)	60	60	N/A	N/A	60	N/A
	Frequency(MHz)	Fixed	Fixed	N/A	N/A	Fixed	N/A
	PRF(kHz)	4.0	4.0	N/A	N/A	4.0	N/A
	SV	1	1	N/A	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Transducer Model: convex probe

Operating Model: B Mode

Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.97	0.26		0.26		N/A
Index component value			0.26	0.26	N/A	0.26	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	1.62					
	P (mW)		39.78		39.78		N/A
	$P_{1 \times 1}$ (mW)		19.49		19.49		
	Z_s (cm)			N/A			
	Z_b (cm)					N/A	
	Z_{MI} (cm)	4.60					
	$Z_{pii,\alpha}$ (cm)	4.60					
	f_{awf} (MHz)	2.80	2.80		2.80		N/A
Other Information	pr (Hz)	3164.56					
	srr (Hz)	11.36					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$ (W/cm ²)	116.50					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$ (mW/cm ²)	2.65					
	I_{spta} at Z_{pii} or Z_{sii} (mW/cm ²)	6.26					
	p_r at Z_{pii} (MPa)	2.53					
Operating control conditions	Focus (mm)	60	60	60	N/A	60	N/A
	Depth (mm)	160	160	160	N/A	160	N/A
	Frequency (MHz)	3.2	3.2	3.2	N/A	3.2	N/A

NOTE: N/A indicates that there is no corresponding intended use or no data reported.

Notes:

(a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: convex probe

Operating Model: B+ M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.97	0.261		0.264		N/A
Index component value			B:0.26 M:N/A	B:0.26 M:0.001	N/A	B:0.26 M:0.004	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	1.62					
	P (mW)		B:39.78 M:0.14		B:39.78 M:0.14		N/A
	P_{1x1} (mW)		B: 19.49 M:N/A		B: 19.49 M:N/A		
	Z_s (cm)			3.50			
	Z_b (cm)					4.12	
	Z_{MI} (cm)	4.60					
	$Z_{pii,\alpha}$ (cm)	4.60					
	f_{awf} (MHz)	2.80	2.80		2.80		N/A
Other Information	pr (Hz)	B:3164.56 M: 1 1.36					
	srr (Hz)	11.36					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$ (W/cm ²)	116.50					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$ (mW/cm ²)	3.22					
	I_{spta} at Z_{pii} or Z_{sii} (mW/cm ²)	7.65					
	p_r at Z_{pii} (MPa)	2.53					
Operating control conditions	Focus (mm)	60	60	60	N/A	60	N/A
	Depth (mm)	160	160	160	N/A	160	N/A
	Frequency (MHz)	3.2	3.2	3.2	N/A	3.2	N/A

NOTE: N/A indicates that there is no corresponding intended use or no data reported.

Notes:

(a) This index is not required for this operating mode. see section 4. 1.3. 1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: convex probe

Operating Model: B+ C Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.97	0.24		0.24		N/A
Index component value			B:0.13 C:0.11	B:0.13 C:0.11	N/A	B:0.13 C:0.11	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.62					
	P (mW)		B:20.55 C: 19.28		B:20.55 C: 19.28		N/A
	$P_{1 \times 1}$ (mW)		B: 10.07 C:9.45		B: 10.07 C:9.45		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	4.60					
	$z_{pii.\alpha}$ (cm)	4.60					
	f_{awf} (MHz)	B:2.80	B:2.80 C:2.47		B:2.80 C:2.47		N/A
Other Information	p_{rr} (Hz)	1634.64					
	s_{rr} (Hz)	5.88					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	116.50					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ OR $z_{sii.\alpha}$ (mW/cm^2)	20.27					
	I_{spta} at z_{pii} OR z_{sii} (mW/cm^2)	46.14					
	p_r at z_{pii} (MPa)	2.53					
Operating control conditions	Focus(mm)	60	60	60	N/A	60	N/A
	Depth(mm)	160	160	160	N/A	160	N/A
	Frequency(MHz)	B:3.2 C: Fixed	B:3.2 C: Fixed	B:3.2 C: Fixed	N/A	B:3.2 C: Fixed	N/A
	PRF(kHz)	2.5	2.5	2.5	N/A	2.5	N/A

NOTE: N/A indicates that there is no corresponding intended use or no data reported.

Notes:

- (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).
- (b) This probe is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: convex probe

Operating Model: PW Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.90	0.46		2.67		N/A
Index component value			N/A	0.46	N/A	2.67	
Acoustic Parameters	$\rho_{r,\alpha}$ at Z_{MI} (MPa)	1.42					
	P (mW)		77.89		77.89		N/A
	$P_{1 \times 1}$ (mW)		N/A		N/A		
	Z_s (cm)			4.00			
	Z_b (cm)					4.52	
	Z_{MI} (cm)	4.84					
	$Z_{pii,\alpha}$ (cm)	4.84					
	f_{awf} (MHz)	2.49	2.49		2.49		N/A
Other Information	pr_r (Hz)	2500.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$ (W/cm^2)	87.25					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$ (mW/cm^2)	510.10					
	I_{spta} at Z_{pii} or Z_{sii} (mW/cm^2)	1175.00					
	ρ_r at Z_{pii} (MPa)	2.15					
Operating control conditions	Focus(mm)	60	N/A	60	N/A	60	N/A
	Depth(mm)	160	N/A	160	N/A	160	N/A
	Frequency(MHz)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	PRF(kHz)	2.5	N/A	2.5	N/A	2.5	N/A
	SV	1	N/A	1	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Notes:

(a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

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