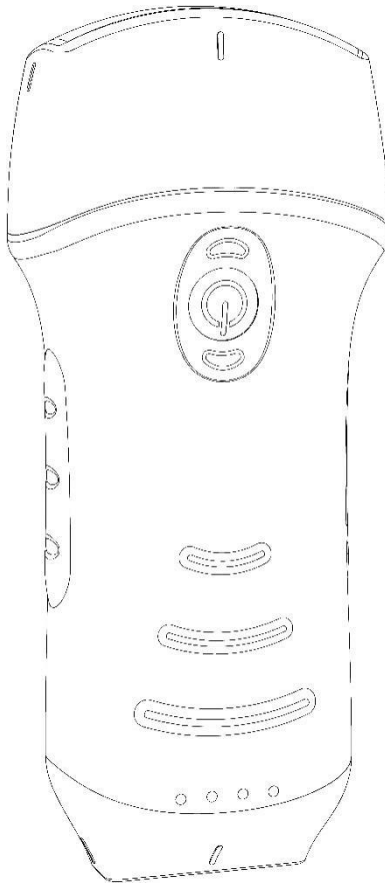


Pocket Ultrasound System C10

Instruction Manual

(V1.1N)



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:

Party B: SUNGO Cert GmbH,Add: Harffstr. 47, 40591 Düsseldorf, GermanyCE certificate



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 2018, first revised December 2019.

KONTED reserves the right to change the contents of the instruction manual without prior notice

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 system probe is IPX5;the probe head is IPX7
- 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.



WARNING:

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).



CAREFUL:

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: 0℃～ 35℃
 - 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.

Ultrasound Benefits

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

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、Paediatrics、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 in 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
PDI 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℃～40℃	0℃～+45℃
relative humidity	30%～85% (No condensation)	30%～95% (No condensation)
atmospheric pressure	70KPa～106KPa	70KPa～106KPa

WARNING:

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
- Plug: American Standard or British Standard Plug
- Accessory: Operation manual

2.4.2 Components

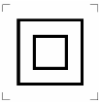
Transducer Type

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

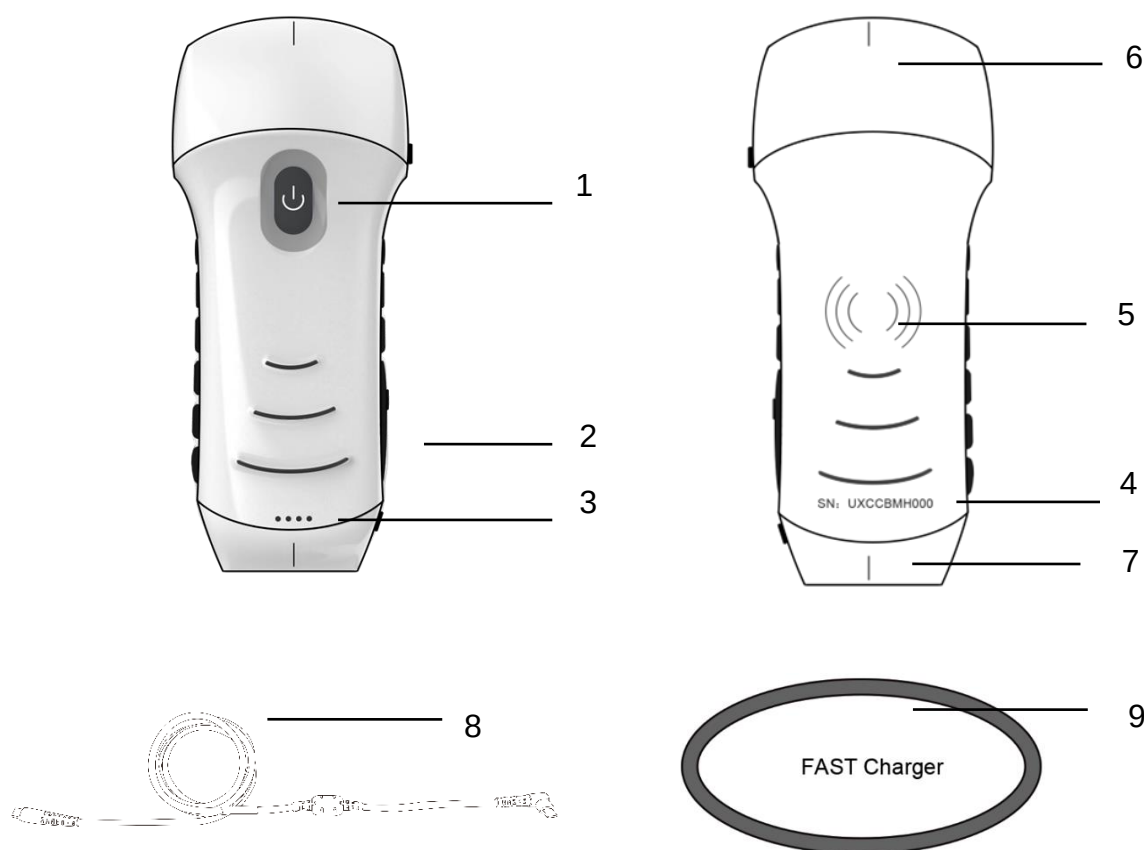
This device uses the following symbol identification, the following list shows its meaning.

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	IPX 7	The 7 indicates that the system is protected against the effects of immersion in water to depth between 15 cm and 1 meter.
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: Shanghai International Holding Corp. GmbH(Europe) Eiffestraße 80, 20537 Hamburg Germany
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

2.7 Control panel

Control buttons	Button icon	Key name	Function
		Power switch / freeze / thaw button	1) When the probe is not turned on, press the key to open the probe; 2) When the probe is in the open state, press the key to close the probe; 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)

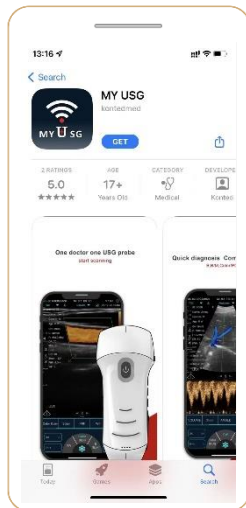
**Press the button and hold for 3 seconds to switch the scanning mode
(Convex array probe ↔ linear array probe)**

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	×	×

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.

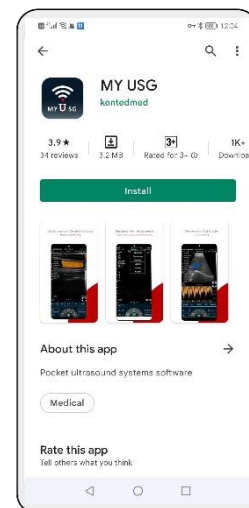
3.1.2 Android device

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
Smart phone	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: ≥4GB Wi-Fi: (802.11n/20MHz/5G) CPU: ≥1GHz, up to 3.6GHz, Inter i3/i5/i7 (Recommended Brand: Lenovo, HP, Dell, Acer, ASUS) It is recommended to use laptops manufactured after 2017.	Windows10 ,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

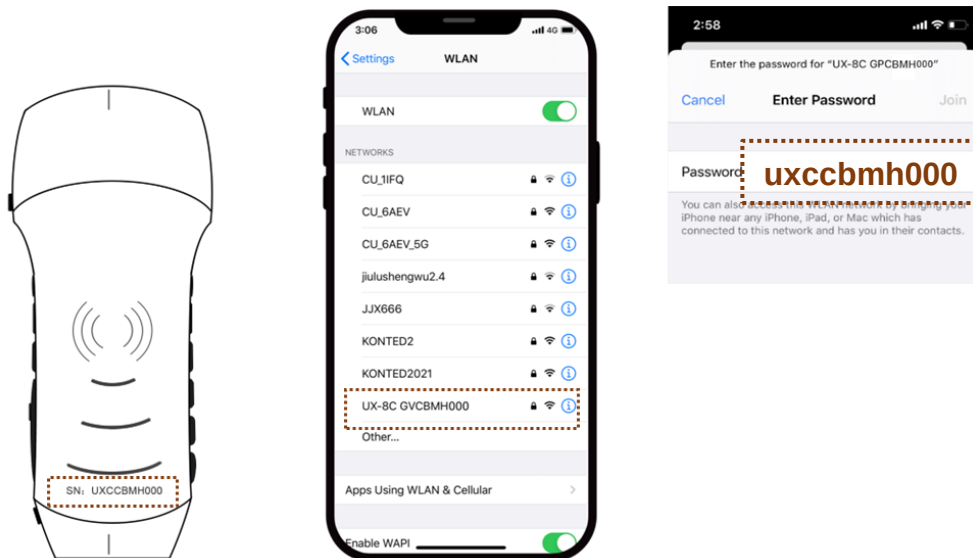
Press the power button  to turn on the probe, the indicator will show the battery icon.

after ultrasonic examination, Press the power button  and hold for 5 seconds to turn off the probe, the indicator become black screen.

3.3 Probe and Terminal connection

Wi-Fi connection:

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

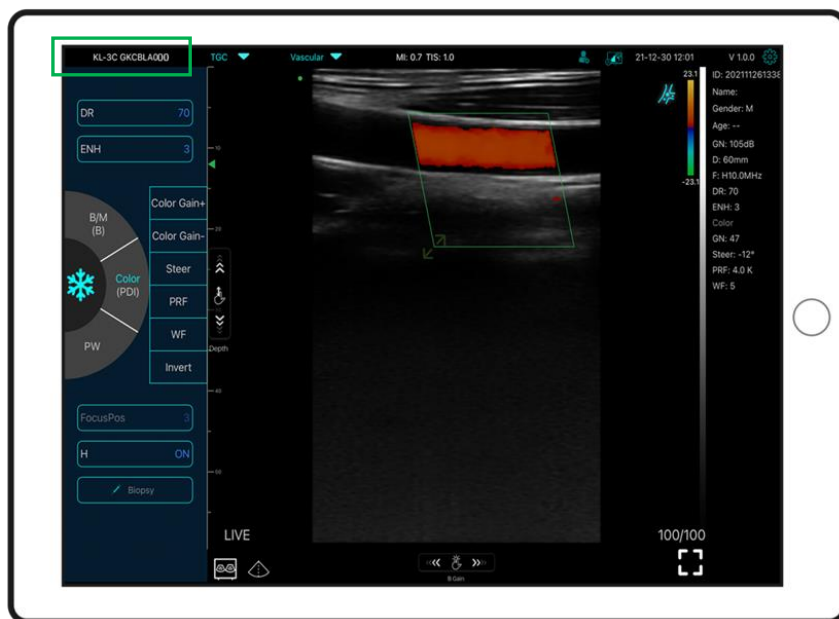
Enter the Wi-Fi password, this Wi-Fi password is the serial number of the probe, but it is the small letter not capital.

Step4:



To open the MY USG App on your mobile device's home screen, when the probe connect to your mobile device successfully, The "UX-8C *****A000" will be

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 change mobile device B to connect with the probe, please disconnect the probe from the mobile device A firstly. The probe only can be connected to one mobile device at the same time.

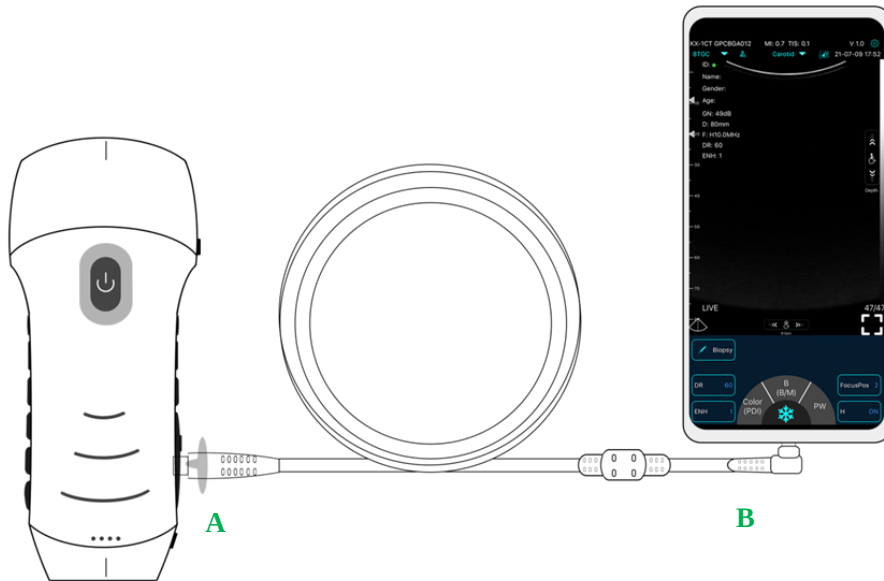
USB connection:

Step1:

Pull out the rubber plug on the right side of the probe.

Step2:

Connect the probe to your smart device by Type-C cable according to the picture above. 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.



Step3:



To open the MY USG App on your mobile device's home screen, when the probe connect to your mobile device successfully, The “ UX-8C *****A000” will be displayed on the App interface.



Android Devices	◀.....		Type-C
Windows PC (Win10)	◀.....		USB 2.0 / 3.0
IOS Devices	◀..... 		Apple Lightning / USB-C

Note:

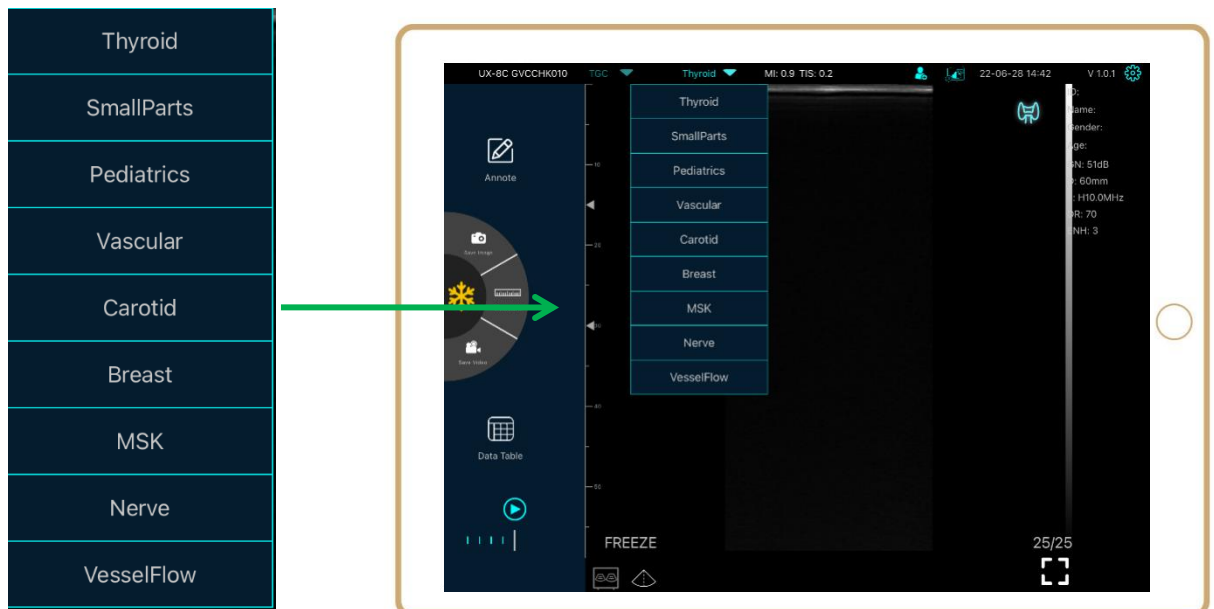
- If you connect the probe to your device successfully, but there is no image on the screen, please try to press the power button again.
- When the probe is connected to the device successfully, the probe charging indicator will automatically flash and charge the probe.
- The probe can be connected to an Android/Windows device via Type-C cable.
- iPad/iPhone only can be connected via Wi-Fi, not support Type-C cable connection.
- The probe can be used while charging.

3.4 Basic software interface

Convex array + Phased array mode:



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

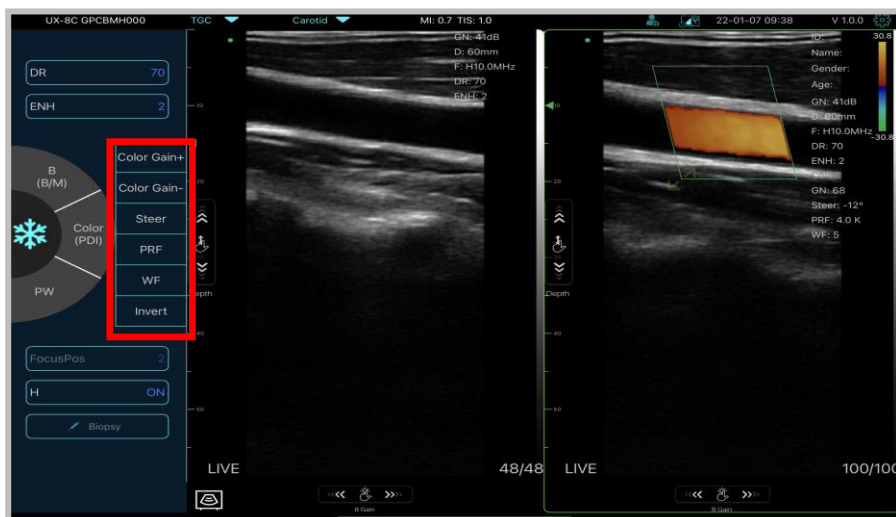
1. Preset button
2. Hidden menu for parameters



4.1.2 Introduction to the second level menu

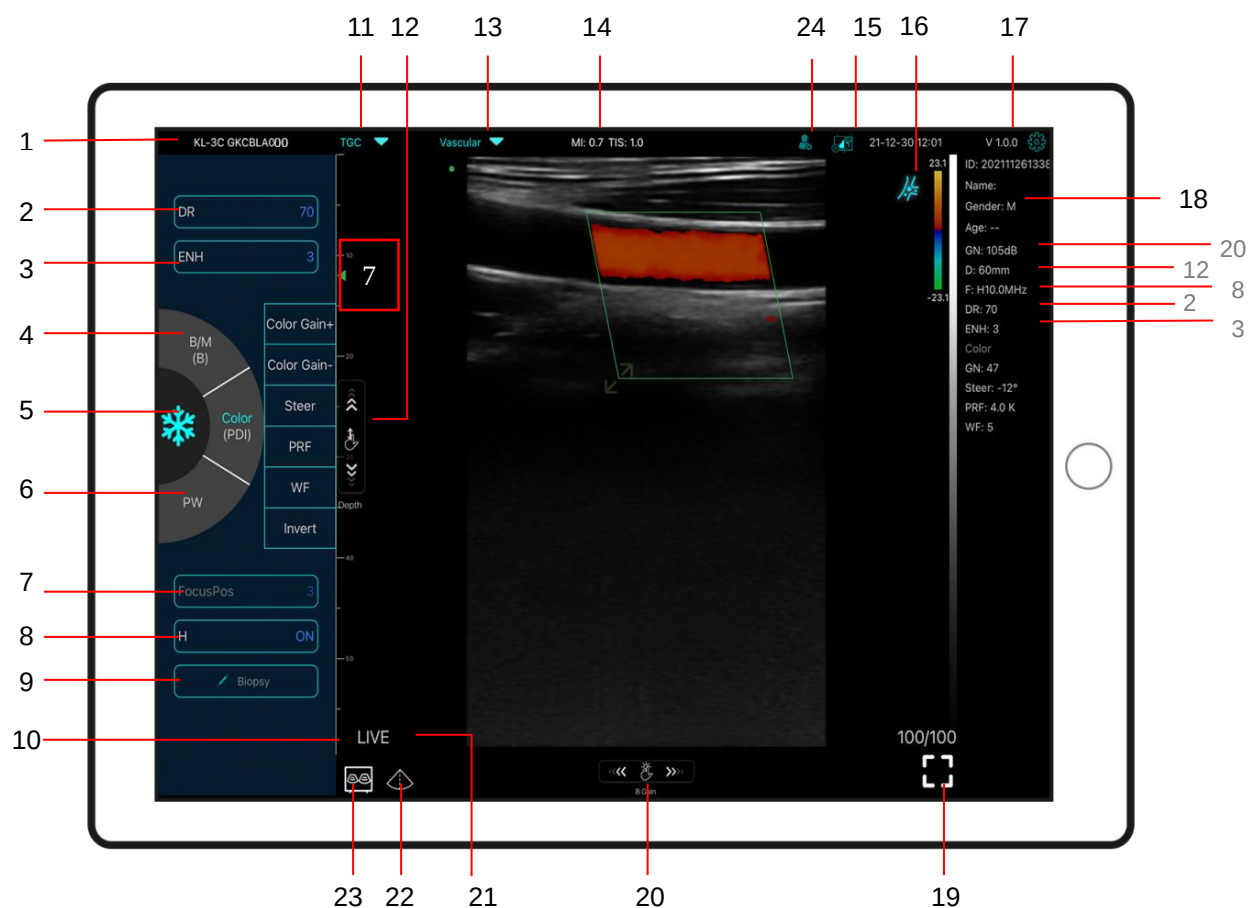
The 2 level menu is controlled by clicking on the corresponding item of the 1 menu.

This is the 2 level menu in Color mode.



4.2 Operation Introduction

4.2.1 B mode



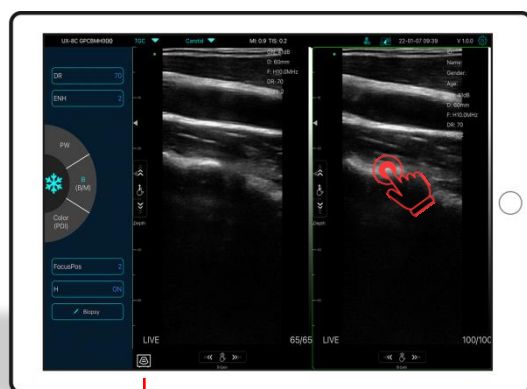
No Item Description

1	Serial number of probe	13	Preset selection
2	Dynamic Range (DR)	14	The Thermal Index (TI), Mechanical Index (MI), and Hz values
3	Imaging Enhance (ENH)	15	DICOM Procedures, uploading images to PACS
4	Mode: B↔B/M, Color↔PDI Dual click to switch scanning mode	16	Body Mark
5	Freeze/Live button	17	APP version number
6	Mode:PW	18	Show patient information
7	Focus Position	19	Full screen

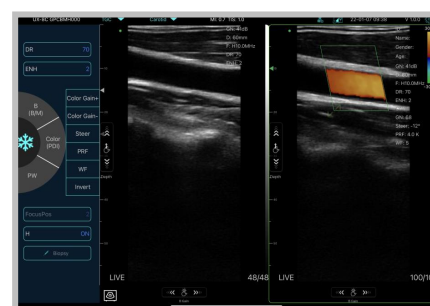
8	H: change scanning frequency(F)	20	B Gain (GN)
9	Biopsy Needle Guide line To invert the image horizontally or vertically. U/D flip, R/L flip	21	Live/freeze display
10	Depth Scale display	22	Mid-line
11	8 TGC: adjust gains of different depth	23	Dual screen display mode (only available for Apple ipad and android pad device)
12	Depth: adjust depth by swiping the button (D)	24	New patient & new report
23	Dual screen display mode		

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



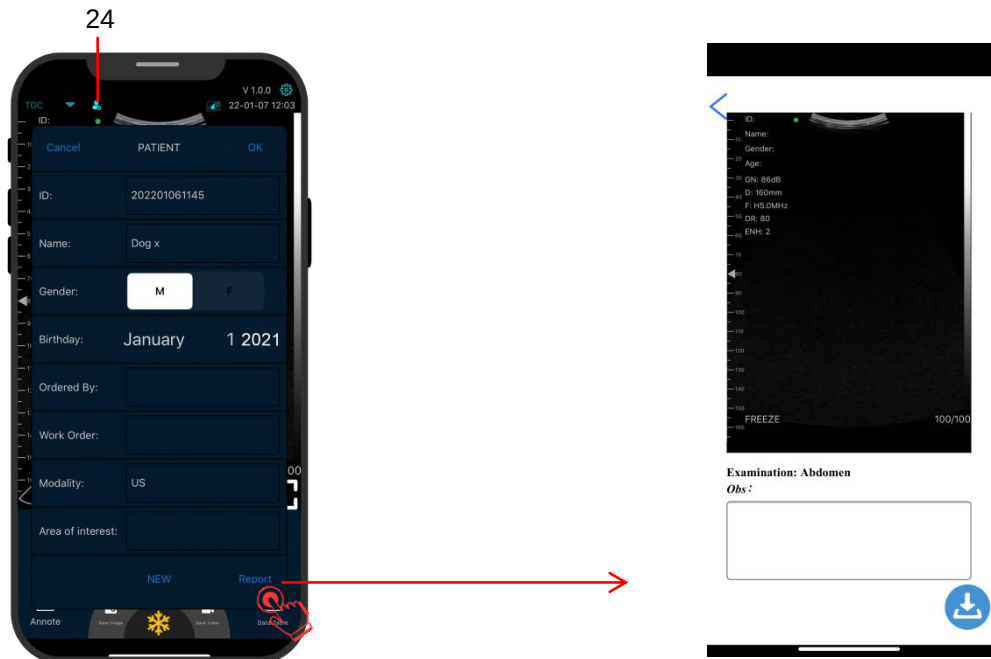
B+Color mode



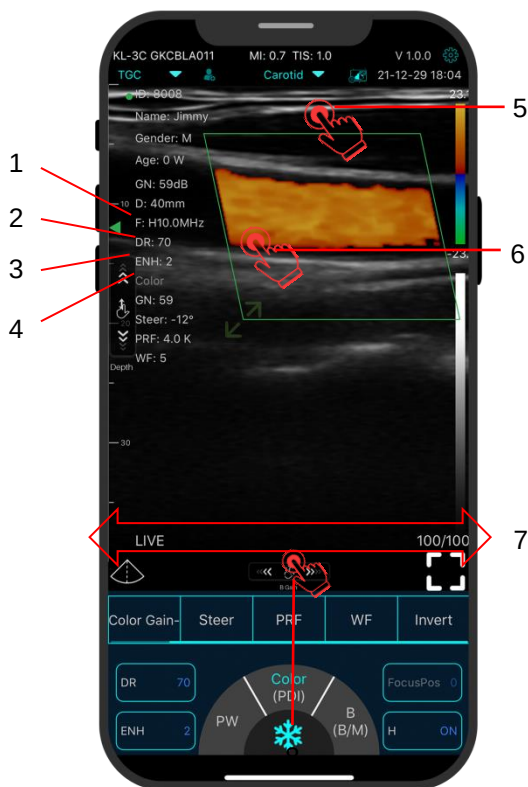
Color+PW mode

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 

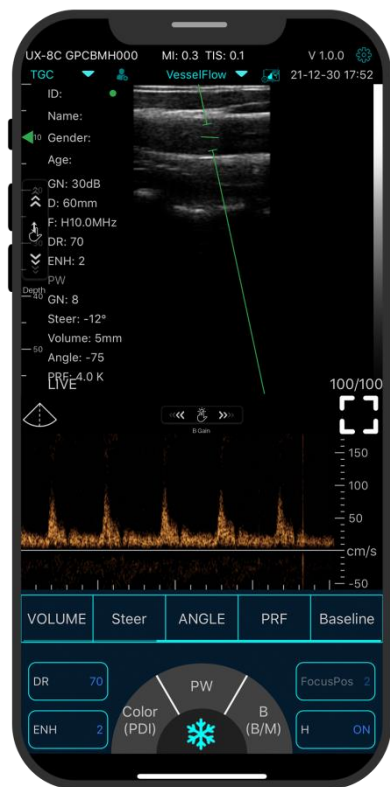


Color/PDI Mode



- | | | |
|---|--------------|--|
| 1 | GN | Color Gain $\pm$ |
| 2 | Steer | Click Steer Adjust the deflection angle of color ROI |
| 3 | PRF | Click PRF Adjust color pulse repetition frequency |
| 4 | WF | Click WF Adjusting the filtering frequency of a pulse wave or continuous wave Doppler low frequency signal |
| 5 | | Tap and drag the green box to move the Color ROI |
| 6 | | Use the arrows provided to adjust the angle and size |
| 7 | Invert | Color Red $\leftrightarrow$ Blue invert |
| 8 | | Slide the Color/PDI menu bar |
| | B | First select Color mode |
| | + | Then switch to PW mode |
| | Color | (only available for convex probe of dual head serial USG probe) |
| | + | |
| | PW | |
| | Mode | |
| 9 | GN | PW Gain $\pm$ |

PW Mode



- | | | |
|----|------------------|---|
| 10 | Steer | Click Steer Adjust the deflection angle of sampling line of linear array probe |
| 11 | Volume | Change the size of the sampling volume |
| 12 | Angle | Used to change the spectrum sampling line angle |
| 13 | PRF | Adjust color pulse repetition frequency |
| 14 | | Tap and drag the green line |
| 15 | Baseline | Move the velocity scale |
| 16 | | Slide the PW menu bar |
| 17 | Flow-mode ON/OFF | <p>Automatic blood flow measurement</p> <p>Step1: select vessel flow preset</p> <p>Step2: enter PW mode, produce a uniform spectrum</p> <p>Step3: click Flow mode ON</p> <p>Step4: Freeze the PW image then will show the result automatically (only available for linear probe of dual head serial USG probe)</p> |

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 Modes

Tap **No.22 (Mode)** to select the imaging modes:

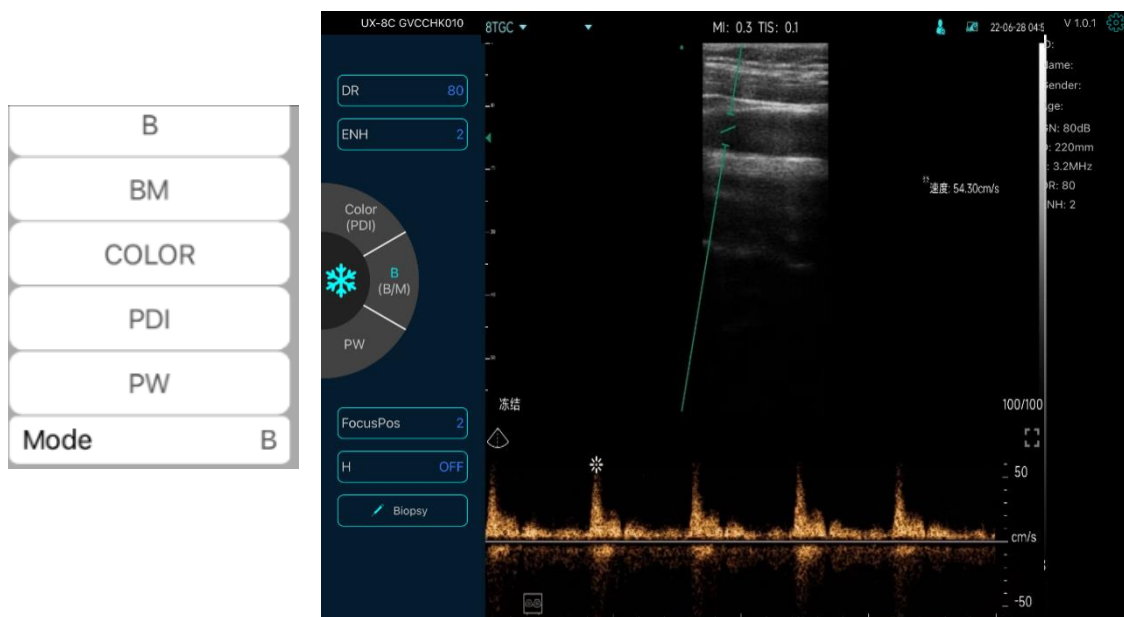
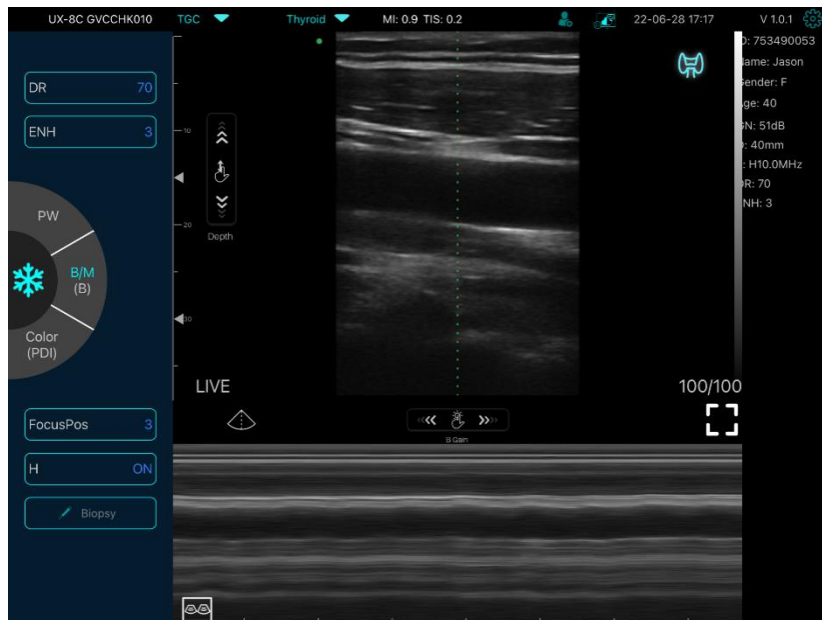


Image Adjustment

Requirement	Available Operations
To modify the brightness	Adjust No.10 Gain Adjust No.19 8TGC
To modify gray scale image effect	Adjust No.23 Focus Pos Adjust No.24 ENH Adjust No.25 H Adjust No.26 DR
Zoom	Adjust No.4 Depth

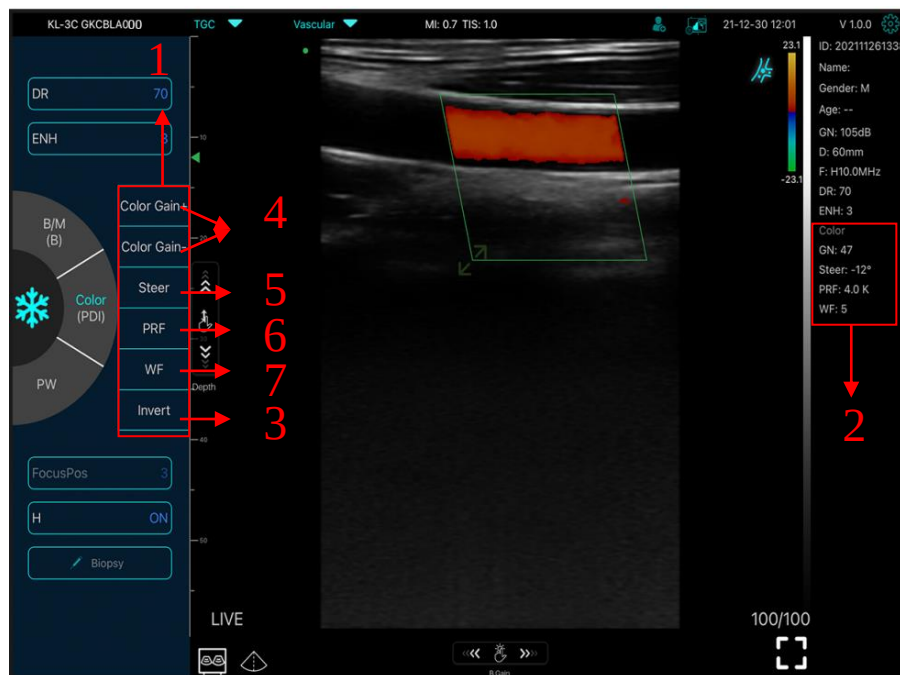
4.2.2 BM mode

In BM mode, click the cursor two times, it will change green, you can adjust the position of the M sampling line by moving the following marks with your finger.



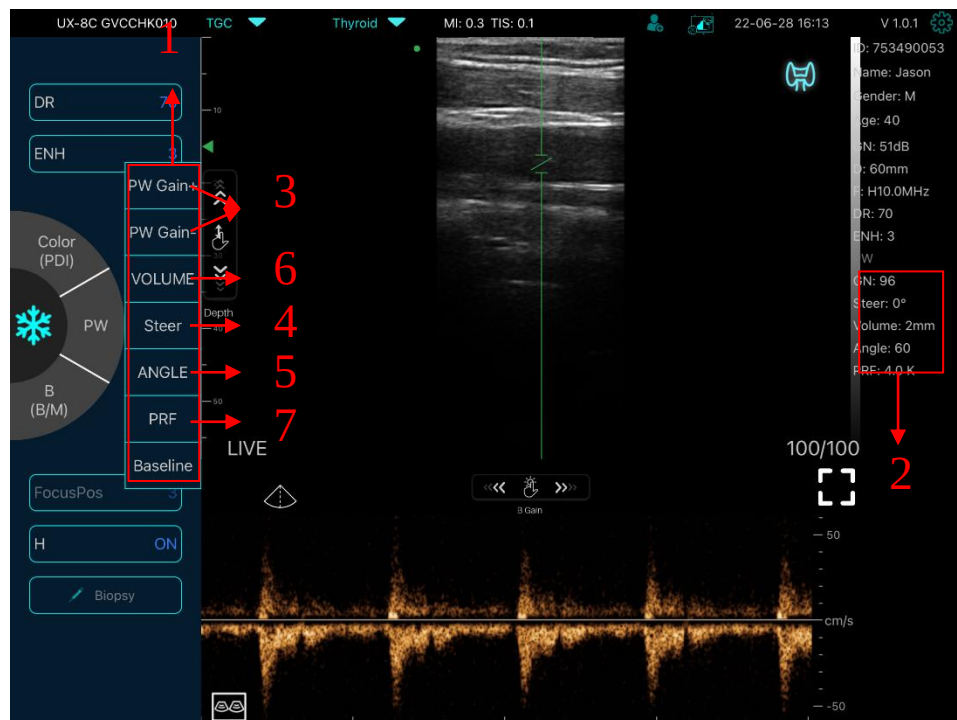
4.2.3 C mode

- 1). Second menu in color mode,click the buttons, the parameter will be changed
- 2). Parameters display area in color mode
- 3) Click this button,this button will be changed to button named"size",the***can be adjust the size in this status as below
- 4) Increase+ or reduce - the color gain
- 5) Steer: afterglow adjustment
- 6) PRF:Adjust color pulse repetition frequency
- 7) WF: adjusting the filtering frequency of a pulse wave or continuous wave Doppler low frequency signal



4.2.4 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: afterglow adjustment
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:Adjust color pulse repetition frequency



4.3 Measurements

General measurements refer to general measurements on images of B/C/PDI 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/PDI	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.

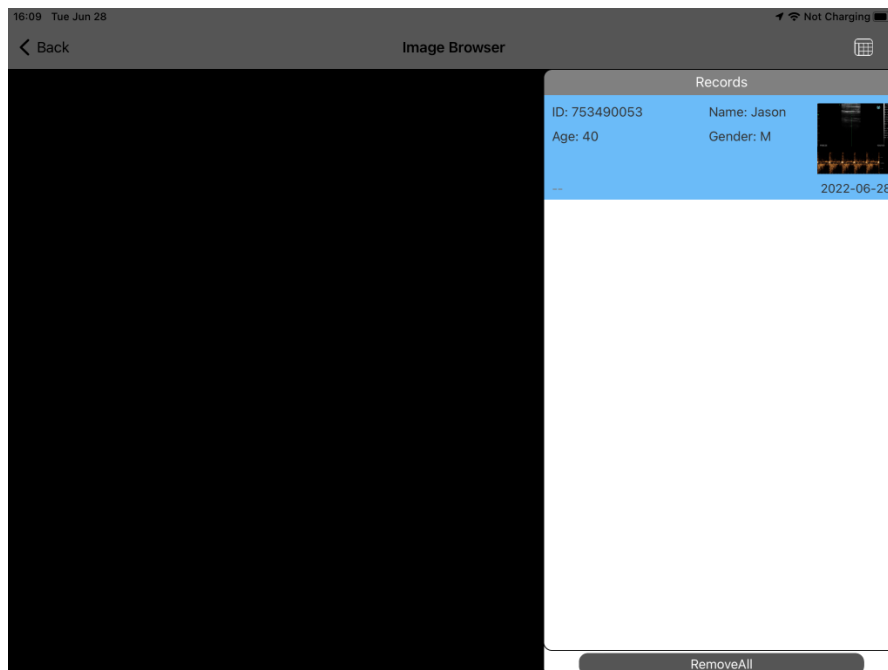
3. To delete a result, tap the result, then tap the **X** next to the corresponding numeric measurement display, and then tap Delete Line to confirm.

4.4 Patient's information and report

1. Click "ID" on the patient information enter the patient data input box.

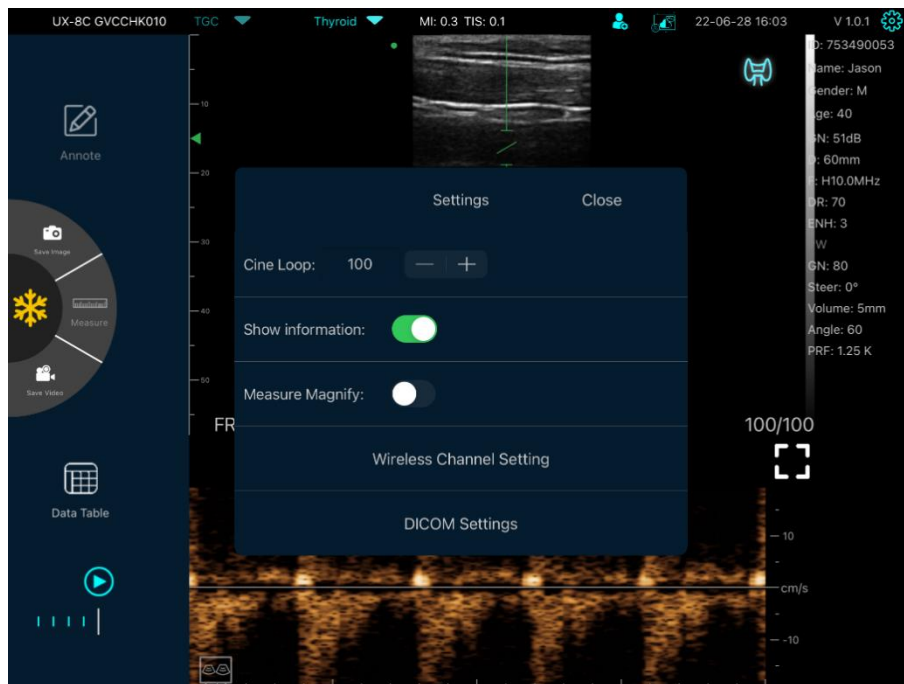
2. After editing the report, click  to save the report to the  Data Sheet .

Please swipe to the left to browse the pictures/videos and report.

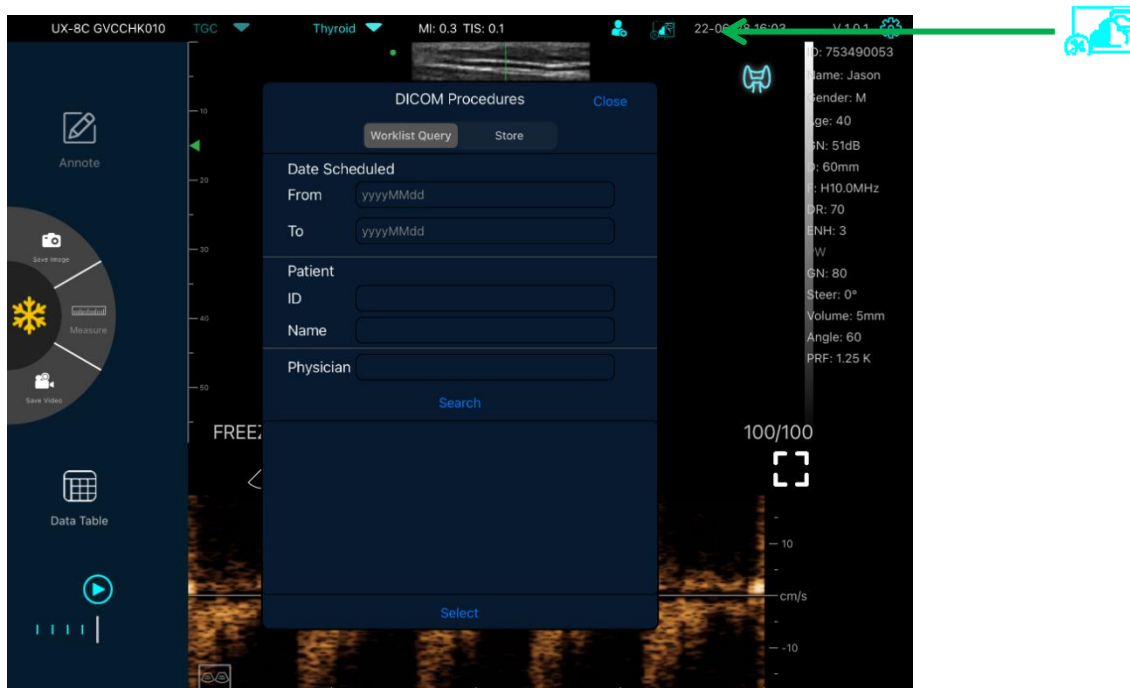


4.5 DICOM

1. Click setting , then press Dicom Settings.



2. Click , you can search and select patient info in the Worklist Query and Store.



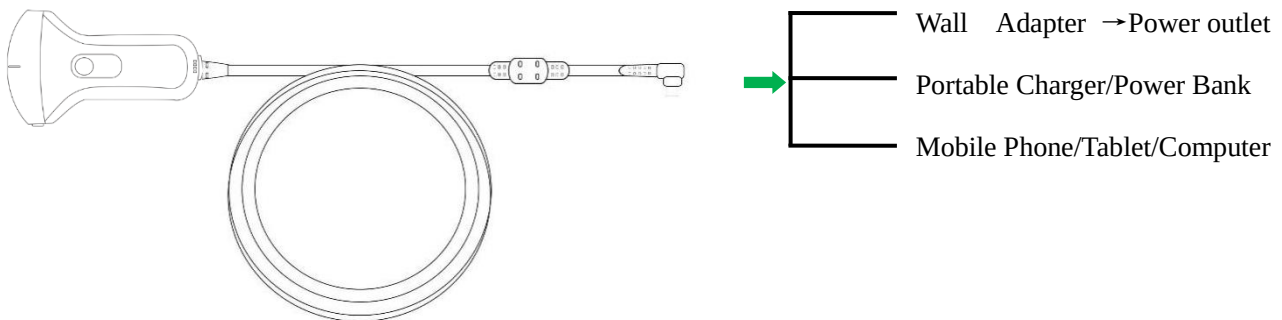
5 maintenance and inspect

5.1 Charging the probe

Charge the probe when the battery is low(one cell battery). When charging, the battery indicator flashes to indicate the current charge level. US suggest the probe should be charged when one cell battery showed. If the 4-cell battery indicator is on and the battery indicator stops blinking, the battery is fully charged.

Charging by USB cable:

1. Pull out the rubber plug at the end 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.



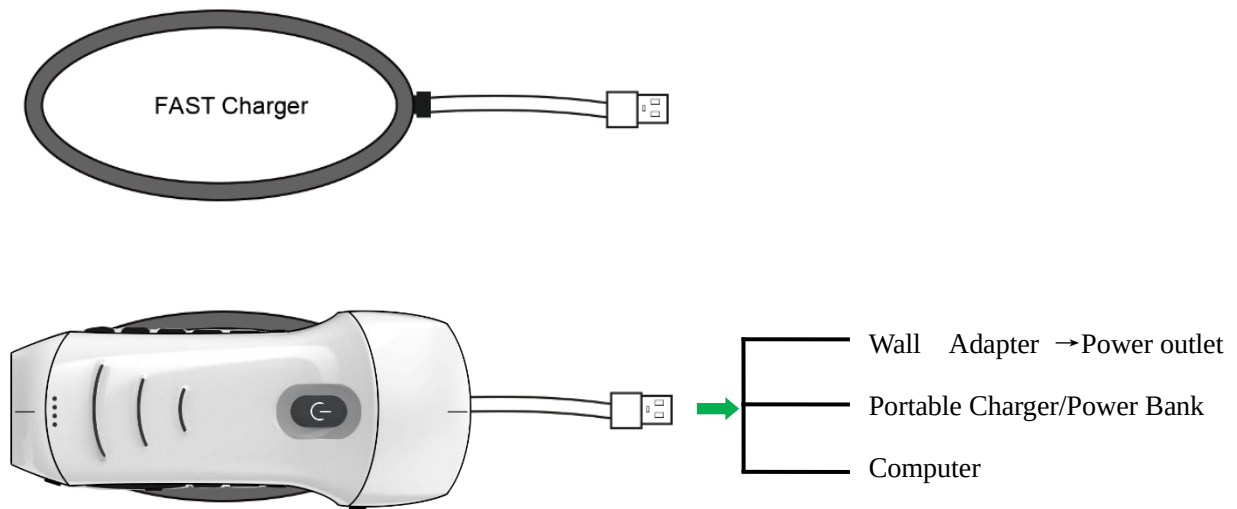
Note:

- You can perform imaging while the probe is charging by Power Bank. (Just connect the probe to mobile device by Wi-Fi)
- When you connect the probe to your Mobile phone/Tablet/PC by type-c cable, the probe will be charged automatically.

Charging by wireless charging pad:

The C10RL/C10UE/C10RQ 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:

- You can not perform imaging while the probe is charging by wireless charging pad.
- 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

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 of the coupling remaining 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 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 button for more than 3s 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 opens, the waterproof cap should be installed and returned.

2、 Use clean special wiping paper for ultrasonic instrument (the wiping paper shall be soft non abrasive disposable paper towel) or clean lint free soft cloth to wipe the acoustic head. Gently wipe the paper or soft lint-free cloth along the wide side of the vocal head to the other end (if the

wiping force is too large, it may cause the depression of the vocal head and make the machine unusable) . The wiping direction should be in accordance with the Repeated wiping is prohibited

in the same direction. If the sound head is also stained with coupling or other reagents, it should

also be wiped in the same way.

3、 During the wiping process, after each wiping from the beginning to the end, fold the special wipe

paper for ultrasonic instruments in half, and fold the wipe paper in half towards the side stained with coupling or other ultrasonic special colloid residues (Fold the stained side inside the wiping

paper).

4、 Ultrasound instrument special wipes or lint-free soft cloth should not be folded in half at most for

more than 4 times. If there is still coupling or other ultrasonic special colloids remaining on the ultrasonic probe part after wiping for the 4th time, you need to replace with new ultrasonic instrument special wipes, and repeat after replacement. The above steps are performed until the

coupling remaining in the vocal head is completely wiped.

- 5、 Use ultrasonic special wiping paper or lint free cloth dipped with enzyme containing detergent(the usage of specific cleaners should refer to the usage method of cleaner labels and instructions, and pay attention to whether the use time of detergent is within the warranty period of the product) to clean until there is no visible stain on the acoustic head and the acoustic head and its surroundings have been wiped.
- 6、 Rinse the probe with drinking water or softened filtered water (the water quality of tap water is too hard, there may be residual salt and alkali substances, 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 the vocal head with your hands until all the cleaning agents are rinsed. In principle, the rinsing time should not be less than 30s. During the rinsing process, water should be prevented from splashing on the fuselage. If any liquid enters the fuselage,it will cause irreversible damage to the electronic components of the machine.
- 7、 Use the special wipe paper for ultrasonic instruments or a clean lint-free soft cloth (The same lint free soft cloth used before is no longer used) to wipe the entire body and the vocal head, and wipe the residual water stains on the acoustic head until all the residual water stains on the body are wiped clean.
- 8、 Place the whole machine in the air with humidity $\leq 60\%$, temperature $\leq 40\text{ }^{\circ}\text{C}$ and $\geq 15\text{ }^{\circ}\text{C}$, fine particles $\leq 3.5\text{ }\mu\text{g}/\text{m}^3$ 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 whether the whole part of the fuselage is damaged, such as cracks, cracks, cracks or protruding sound head.In case of the above situations, stop using immediately and contact the local dealer or sales representative.

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: The compound double- chain quaternary ammonium salt with free safety content $\leq 2\%$ is mixed with purified water or softened filtered water. The

mixed quaternary ammonium salt content is 200mg / L-1000mg / L, which conforms to the alcohol disinfection solution of double chain quaternary ammonium salt) for spraying and disinfection . Install the mixed disinfectant reagent into a spray pot with spraying function, and use the spray pot to evenly spray the disinfectant on the surface of the ultrasonic probe and around the ultrasonic probe shell. (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, water-containing lanolin, etc.) Put the machine flat on the workbench for static disinfection, and the static time is 2min- 5min .

2、 Take a piece of special wiping paper for ultrasonic instrument, and spray it around the central

part of the wiping paper for 3-5 times with a spray pot equipped with quaternary ammonium salt

disinfectant to ensure that the area of the wiping paper containing disinfectant is $\geq 80\%$. Use wipes sprayed with disinfectant to wipe the machine, and ensure that all surfaces and gaps of the machine body are completely wiped and disinfected.

3、 Take a new piece of special wiping paper or clean lint free soft cloth for ultrasonic instrument,

wipe the whole body and the acoustic head again, and wipe it from the acoustic head to the body

until all the disinfection reagent residues on the body are wiped clean.

4、 Check whether there are residual stains or water stains on the body and sound head. If there are

still stains or water stains, repeat steps 2 and 3 until the stains on the body and sound head are

wiped off. If not, proceed to the next step directly.

5、 Place the wiped machine in the air with humidity $\leq 60\%$, temperature $\leq 40\text{ }^{\circ}\text{C}$ and $\geq 15\text{ }^{\circ}\text{C}$, and

fine particles $\leq 35\mu\text{g} / \text{m}^3$ 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 Wear probe protection sleeve

In order to reduce the spread of the disease, it is necessary to take some protective measures. In clinic, the probe sheath is conducive to prevent infection. Strongly recommended in accordance with requirements of the sterile transducer sheath cavity inspection.

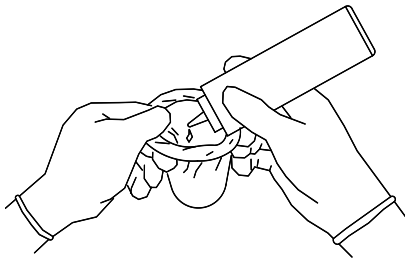
On the human body are examined using the probe to probe must be put on the probe set. Please use the protection cover market acceptance.

⚠ CAREFUL: 1. In order to avoid infection, in the inspection, the probe cover can only be used once.

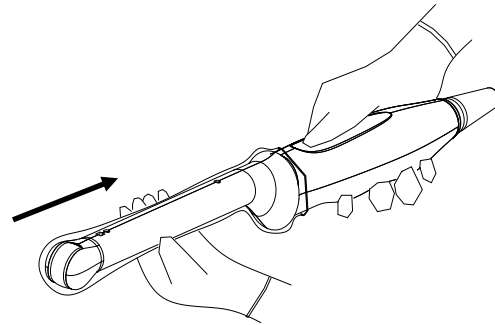
2. The probe sheath is made of natural latex and talc, which may cause allergic reactions in some people
3. Do not use expired probe sheath. Check the probe sheath for expiration before using the probe sheath

Operation procedure (for reference only):

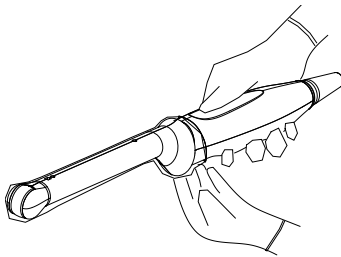
1. In the protective sleeve or inside the probe surface coated with an appropriate amount of coupling agent, without the use of coupling agent, the image is not clear.



2. To probe into the protective sleeve to ensure the sterility of the probe. The protective sleeve of the tension to remove wrinkles and bubbles, do not pull too far.



3. With the rope to ensure the protection of security.



4. Check the protective sleeve to ensure no damage

5.5 Storage

When not using the probe, please place the probe in a suitable package to avoid the impact of violent impact on the probe. And to avoid contact with the probe too high temperature (suitable storage temperature: 0 ° -40 °).

5.6 Inspect

Frequently check the probe cable, if found damaged, broken phenomenon, prohibit the use of immediate replacement or repair.

Regularly check the socket, the sound window parts, if found damaged, bubble phenomenon, prohibit the use of immediate replacement or repair.

Every time the main body and head of the probe to clean, disinfect (sterilization), are required to be checked, if found the above, please stop using, immediately replace or

repair.

⚠WARNING:	Equipment failure, Users are not allowed to repair without authorization. Product must be sent back to the company
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5.7 Life cycle

According to the manufacturer's design, production and other related documents, this type of product life is generally 5 years, it depends on using frequency, it is possible to be used 6-8 years. constituting the product material over time will gradually aging, continue to use the products beyond the life of the post, may cause performance degradation and failure rate is significantly high.

⚠WARNING:	The manufacturer will not be held responsible for the risks arising from the continued use of the product life cycle.
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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	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 connected to Mobile phone/tablet, but can work with laptop	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	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	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	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	1. Press and hold the probe's power Button for 15-20 seconds. 2. Charge the probe
App issues	
App can not turn on	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	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	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	1. Make sure you are using enough approved ultrasound gel. If quality does not improve. 2. If not work, contact Support
Image is not clear	1. Adjust the image parameters follow the page-24 2. Use enough ultrasound Gel.