

C10 Gen4Pro
Wireless Color Doppler
Pocket ultrasound system

Instruction Manual

(V1.1.2.10N)

IMPORTANT !

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

Beijing Konted Medical Technology Co., Ltd.

Contents

Introduce.....	I
Maintenance and repair service.....	II
Intellectual Property Statement.....	II
1 Safety precautions.....	1
1.1 Security classification.....	1
1.2 Security symbol.....	1
1.3 Safety warning information.....	3
14 WARNING Labels.....	3
2 Product overview.....	4
2.1Intended use.....	4
2.2 Contraindication.....	4
2.3 Product specifications.....	4
2.3.1 Imaging mode.....	4
2.3.2 Power condition.....	4
2.3.3 environment condition.....	5
2.3.4 Probe outline dimensions and weight.....	5
2.4 system configuration.....	6
2.4.1 Standard configuration.....	6
2.4.2 Components.....	6
2.5 Symbol description.....	6
2.6 Introduction of each component of the system.....	7
2.7 Control panel.....	8
3 Basic introduction.....	9
3.1 Install software.....	9
3.1.1 install software for iPhone iPad.....	9
3.1.2 install software for Android device.....	9
3.1.3 install software for windows device.....	9
3.2 Turn on / off probe.....	9
3.3 Probe and Terminal connnection.....	10
3.4 Basic interface.....	11
4 Detailed operation introduction.....	12
4.1 Introduction to all levels of menu.....	12
4.1.1 First level menu.....	12
4.1.2 Introduction to the two level menu.....	13
4.2 Operation introduction.....	13
4.2.1 B mode.....	13
4.2.2 BM mode.....	15
4.2.3 C mode.....	15
4.2.4 PW mode.....	17
5 Maintenance and inspect.....	18
5.1 Charge the probe.....	18

5.2	Replace the battery.....	18
5.3	Clean the probe.....	19
5.4	Wear probe protection sleeve.....	19
5.5	Storage.....	20
5.6	Inspect.....	20
5.7	Life circle.....	20

Production enterprise name: Beijing Konted Medical Technology Co., Ltd.

Registered address: 1F, Building 3, No. 27 Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District, Beijing, China

Production address: 1F, Building 3, No. 27 Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District, Beijing, China

Zip code: 102629

Tel: 8610-60219113

Fax: 8610-60219213

Customer service: Beijing Konted Medical Technology Co., Ltd.

Address: 1F, Building 3, No. 27 Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District, Beijing, China

Zip code: 102629

Tel: 8610-60219113

Fax: 8610-60219213

Introduce

This manual describes the operation of the ultrasonic diagnostic equipment. 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

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


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, KONTED 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:	<ol style="list-style-type: none">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 KONTED 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 Micro-USB interface or above in water or disinfectant. Because the Micro-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).




CAREF

UL:

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: <ul style="list-style-type: none"> ➤ 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: <ul style="list-style-type: none"> ➤ 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.

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, lungs, etc. when burned, burned or damaged in the surface of the human body, it can not be used in this part.

This product does not apply to the eye or any situation that may cause the sound beam to pass through the eye.

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: 3.7V

capacity: 4200mAh

2.3.3 environment condition

	work environment	Storage and transportation environment
ambient temperature	0°C ~ 35°C	0°C ~ +45°C
relative humidity	30% ~ 85% (No condensation)	30% ~ 95% (No condensation)
atmospheric pressure	70KPa ~ 106KPa	70KPa ~ 106KPa

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.

⚠ WARNING:

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.

2.3.4 Probe outline dimensions and weight

Linear array size: 158mm (L) * 58mm (W) * 18mm (thickness)

Net weight: 308g

Convex array size: 158mm (L) * 58mm (W) * 18mm (thickness)

Net weight: 308g

Micro Convex array size: 158mm (L) * 58mm (W) * 18mm (thickness)

Net weight: 308g

Endocavitary array size: 340mm(L)*58mm(W)*18mm(thickness)

Net weight: 315g

2.4 system configuration

The system is mainly composed of probe and application.

2.4.1 Standard configuration

- Main unit probe: 1 set
- Wireless charger: 1 set
- Plug: American Standard or British Standard Plug
- Accessory: Operation manual, warranty card, wrist strap


2.4.2 Components





Optional Transducer

Transducer model	Type of Transducer	Intended use	Applicable site
C10CT	Large convex transducer	Gynecology and obstetrics, abdominal kidney	body surface
C10RS	Micro convex transducer	Gynecology and obstetrics, abdominal kidney	body surface
C10CX	Linear array transducer	Small organ carotid artery	body surface
C10CS	Linear array transducer	Small organ carotid artery	body surface
C10RQ	Cavity transducer	Department of Obstetrics and Gynecology, urinary system	Via vagina

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.





Serial number	Symbol	Explain
2		Please refer to the instruction manual for this symbol to avoid accidents
3		This symbol represents the product serial number
4		This symbol represents the date of production
5	IPX 7	This symbol product as the IPX7 grade
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

2.6 Introduction of each component of the system



number	Name	Function
1	Control buttons	Freeze/Menu/choosing
2	Wifi connecting status	Wifi connected
3	Battery status	Battery charge/remaining display
4	Wireless charging	Face to wireless charger
5	Wrist scrap hole	Wrist scrap hole
6	Charging port	Charging with USB cable
7	SN	Serial number;password of this probe's wifi

2.7 Control panel

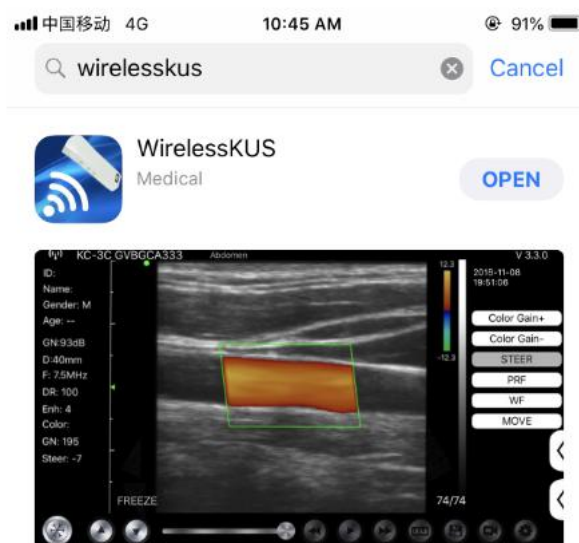
Control buttons	Button icon	Key name	Function
		Gain adjustment	Adjust the gain
		Menu button	Adjust the depth
		Power switch / freeze / thaw button	<ol style="list-style-type: none"> 1) When the probe is not turned on, press the key to open the probe; 2) When the probe is in the open state, press the 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.

3 Basic introduction

3.1 Install software

3.1.1 iPhone/iPad

Download the APP from app store, the name is the APP is WirelessKUS




3.1.2 Android device


You can get the android software from Google Play.The app name is kontedmed.
You can find the QR code named"android" in the homepage of website.
www.konted.cn

3.1.3 Windows device

You can get the windows software from KONTED website.

3.2 Turn on/off the probe

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

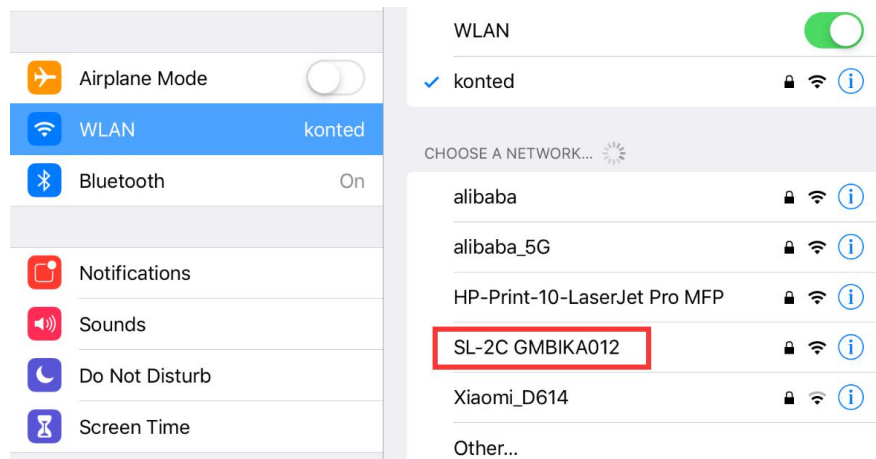
after ultrasonic examination, Press the power button  to turn off the probe,the indicator become black screen.

3.3 Probe and Terminal Wifi connection

The first time connection between the probe and the smart terminal device need to be entered the Wifi password.

After the first time connection, the device will be connected with the probe's wifi automatically.

Establish a connection between the ultrasound transducer and your IOS or Android device via WIFI. Turn on the ultrasound transducer and turn on the WIFI on your IOS or Android device. Search the list of networks for the SSID with the suffix SL,KC,KL...



This WIFI's password is the serial number of the probe, but it is the small letter not capital.

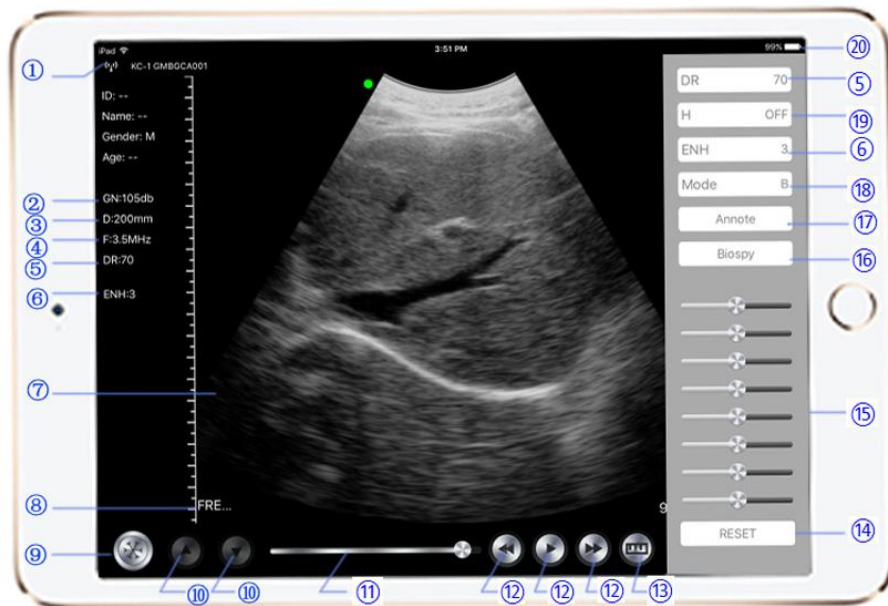
When the probe's WIFI connect with iPad successfully, The probe's status and software interface is as below:





3.4 Basic software interface

The application software interface layout as shown below:



- | | |
|--------------------------|--------------------|
| ① Wifi Connection Status | ⑪ Cine Loop Slider |
| ② Gain | ⑫ Cine Loop Play |
| ③ Depth | ⑬ Measurement |
| ④ Frequency | ⑭ Reset TGC |
| ⑤ Dynamic Range | ⑮ 8 Segments TGC |
| ⑥ Image Enhancement | ⑯ Biopsy |
| ⑦ Image Area | ⑰ Image Note |
| ⑧ Freeze/Live | ⑱ Mode B/BM |
| ⑨ Freeze/Live | ⑲ THI |
| ⑩ Gain adjustment | ⑳ Battery |

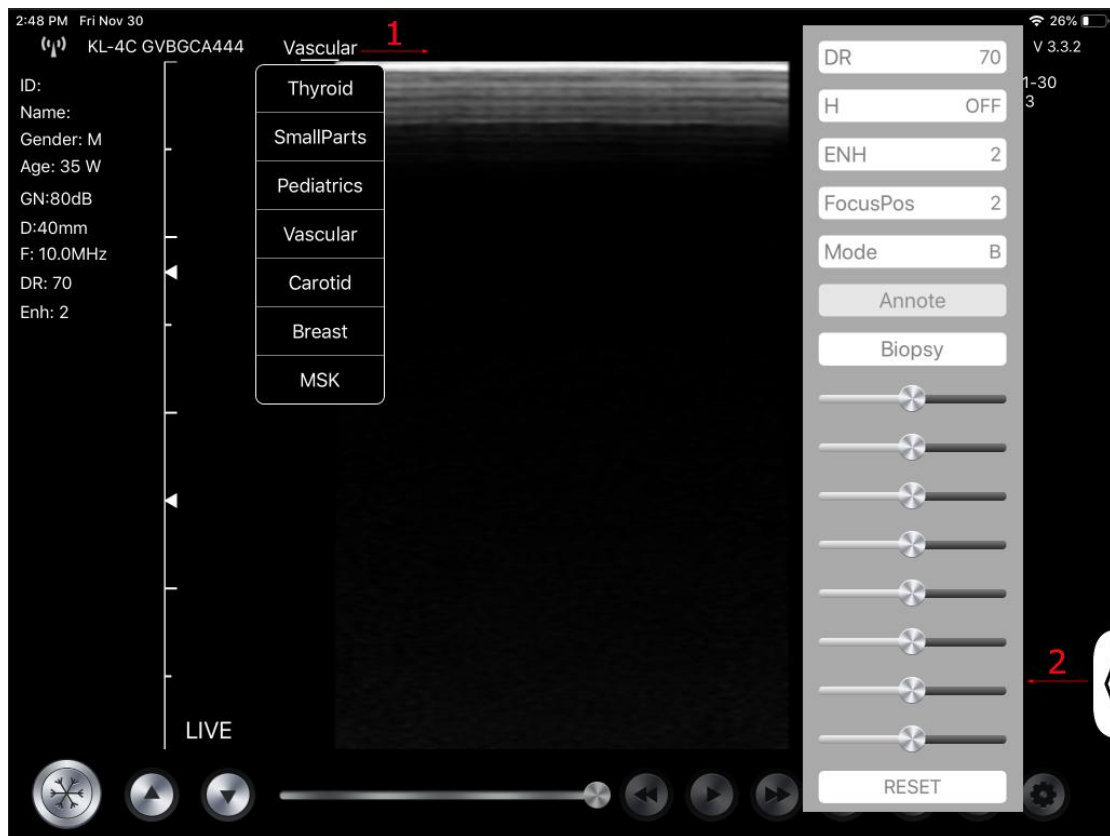
4 Detailed operation introduction

4.1 Introduction to all levels of menu

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

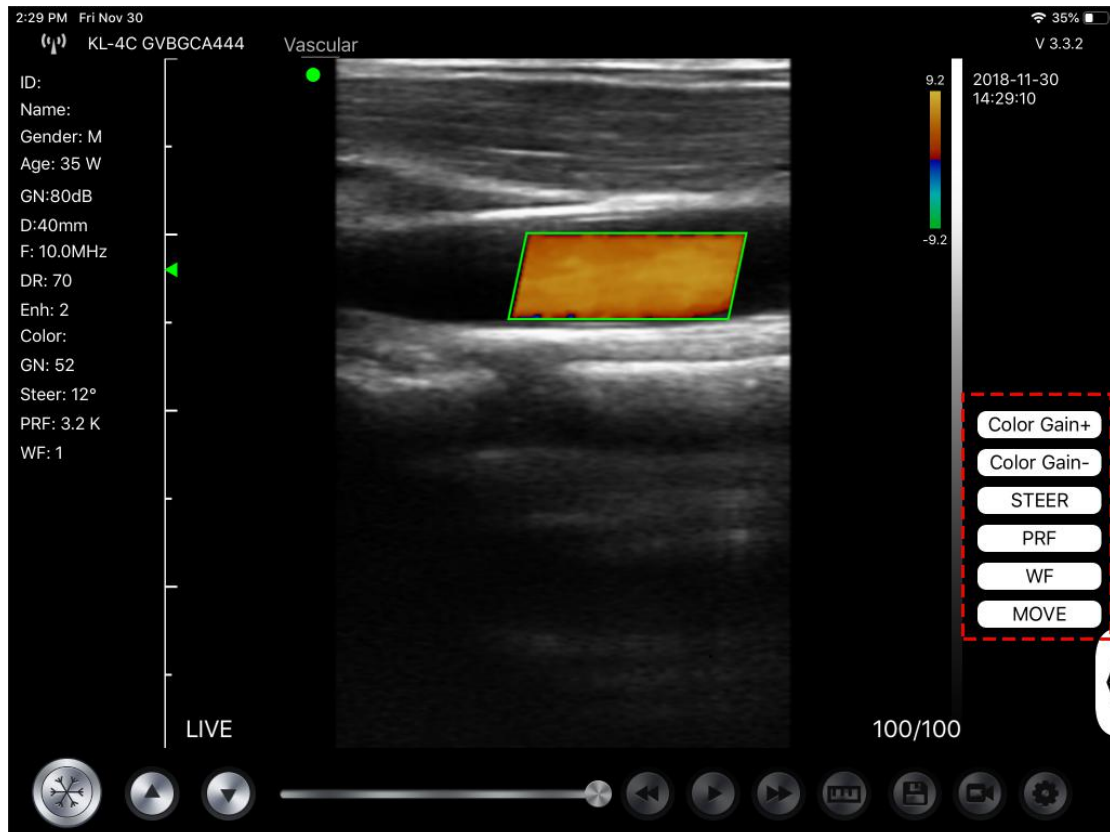
4.1.1 First level menu

1. Pre-setting button
2. Hidden menu for parameters



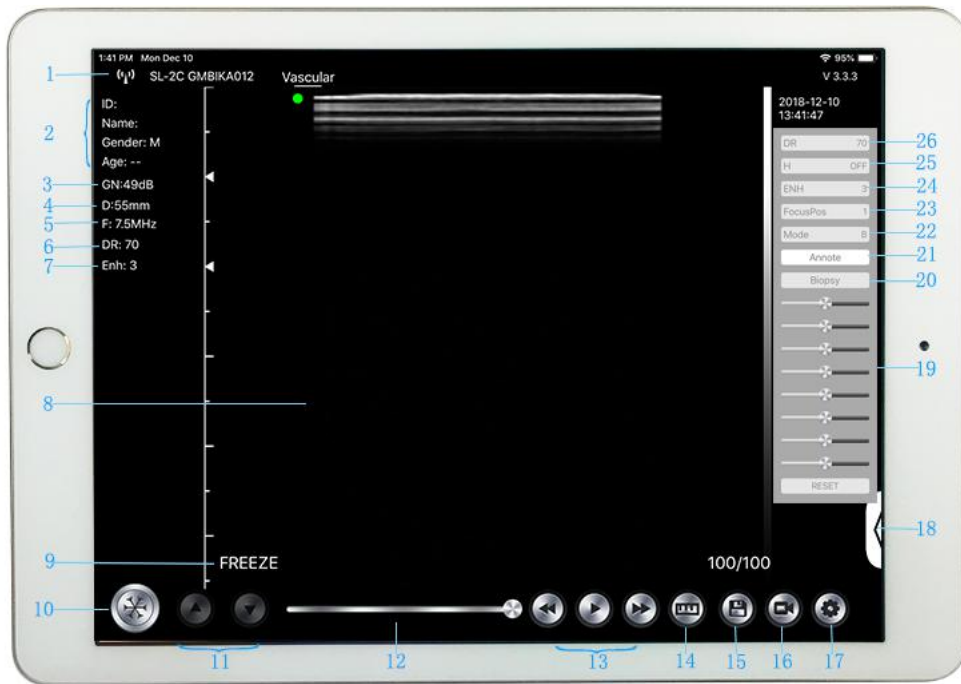
4.1.2 Introduction to the second level menu

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



- 1) Wifi connection status:if the probe's serial number showed, connected successfully
- 2) Patient information management: patient info entry
- 3) Gain: click 10) to increase or reduce the gain;or press up and down arrow button on the probe.
- 4) Depth:just slide the iPad's screen with your finger;or press menu button on the probe
- 5) Frequency: click 19) to change the frequency
- 6) Dynamic Range: click the hidden menu 5) to adjust the dynamic range of the image
- 7) ENH: click the hidden menu 6) to change the level of ENH.
- 8) Image area:image area
- 9) Freeze/Live status: to show the status
- 10) Freeze/Live button: after power on and connect with the probe,it will be showed Freeze status, press this button again, the status will be live
- 11) Gain adjust button
- 12) Movie Playback: Playback after the image is frozen
- 13) Movie Playback: Playback after the image is frozen
- 14) Measurement: distance / area / obstetric measurement(Length, Area, Circumference,GA(CRL,BPD,GS,FL,HC,AC)

When measuring, if you need to fine-tune the location of the measuring point, click the measuring point to make it turn green. The following button will appear on the lower right corner. Click the arrow to adjust and confirm by pressing the middle square button.

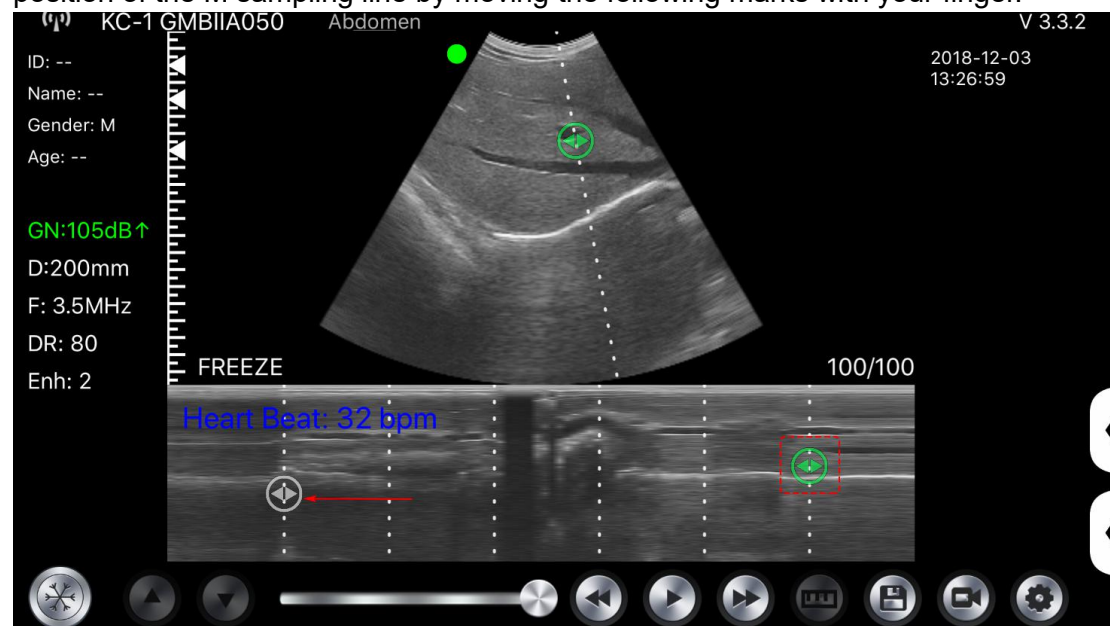
- After measuring, press the delete button to delete all the measurement results. If you want to delete a certain measurement, click on the X number to the right of the result on the result
- 15) Save Image: Save a single image
- 16) Save Image Video: Save entire image video
- 17) Settings: WIFI channel selection in order to avoid congestion
- 18) The second level menu button
- 19) 8 TGC
- 20) Puncture: Draw the puncture line for puncture guidance

The puncturing function includes two types of in-plane and out-of-plane puncturing. The in-plane puncturing can adjust the angle by the arrow button in the lower right corner of the image. The out-of-plane puncturing can adjust the depth and size of the blood vessel and automatically prompt the blood vessel depth and radius in the lower right corner of the image.

- 21) Comment: Enter a comment on the image
- 22) Image model: B, B/M, color, PW, PDI
- 23) FocusPos: click it to adjust focus 0-3
- 24) ENH:image enhancement from 0-4
- 25) THI: click it to change THI on/off
- 26) DR: Dynamic range

4.2.2 BM mode

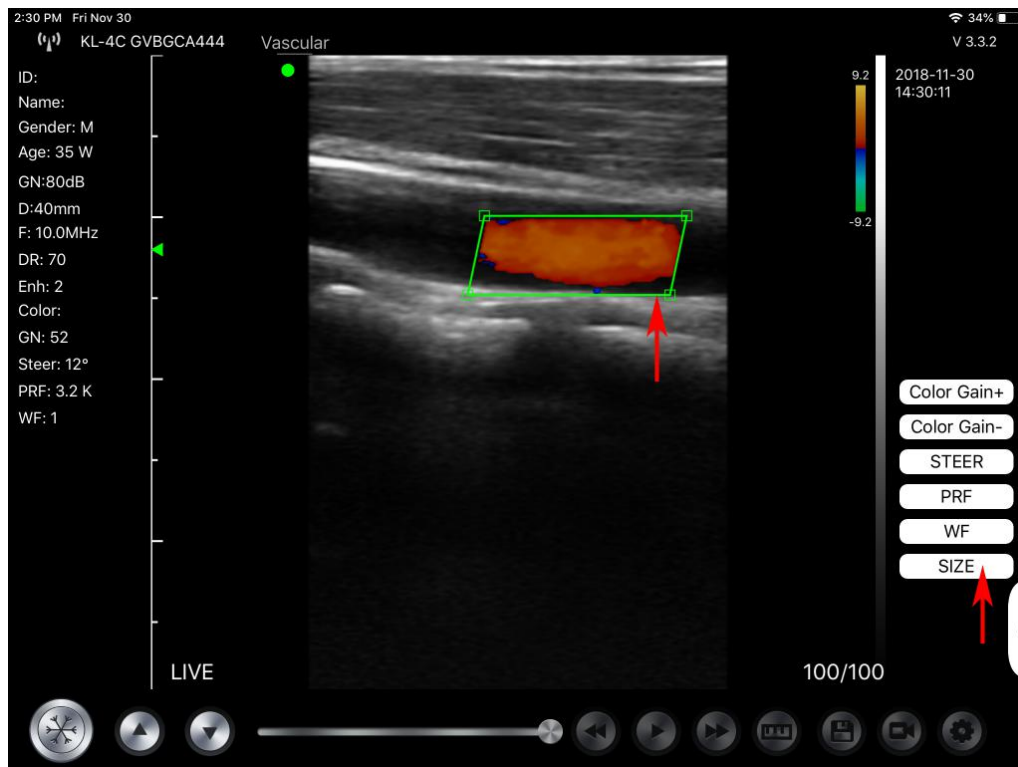
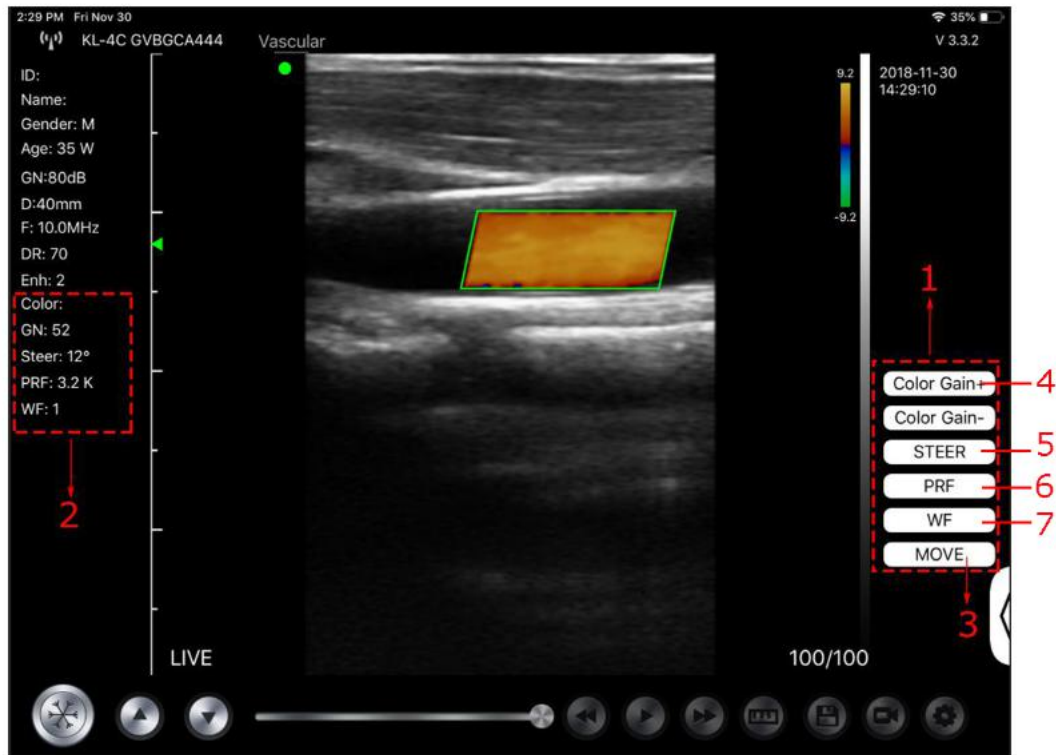
In BM mode, click the cursor two times, it will change green, you can adjust the position of the M sampling line by moving the following marks with your finger.



4.2.3 C mode

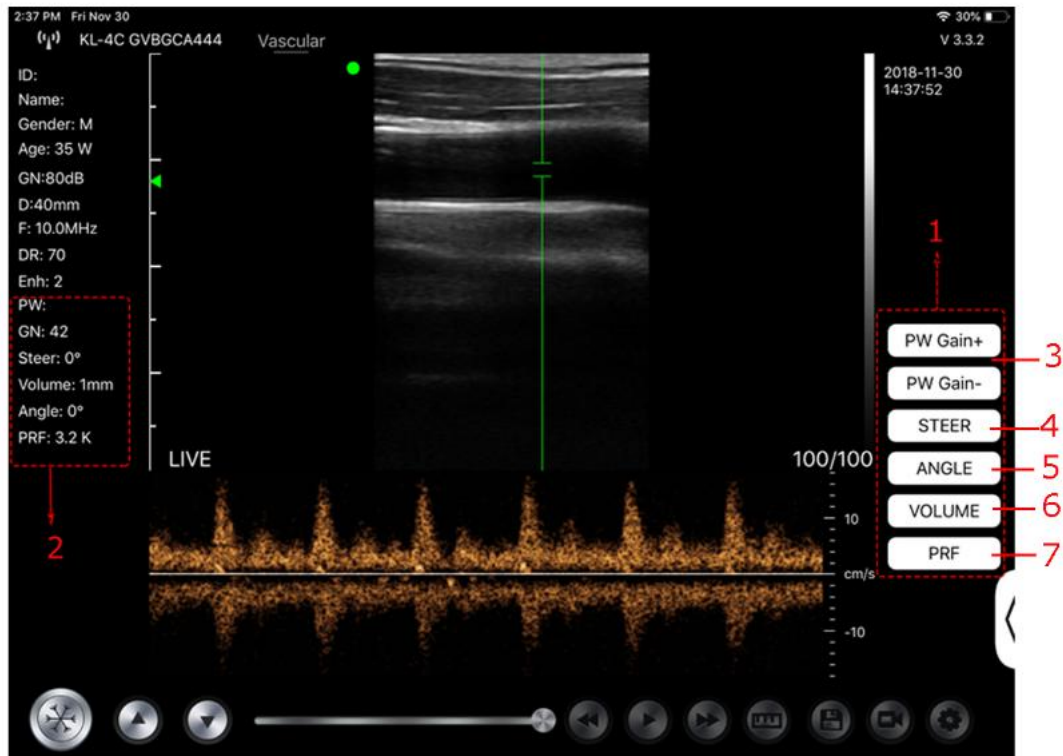
- 1). Second menu in color mode,click the buttons, the parameter will be changed
- 2). Parameters display area in color mode
- 3) Click this button,this button will be changed to button named"size",the***can be adjust the size in this status as below
- 4) Increase+ or reduce - the color gain
- 5) Steer: 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



5 maintenance and inspect

5.1 Charge the probe

Charge the probe when the battery is low(one cell battery). Pull out the rubber plug at the end of the probe and use a USB charging cable to connect the probe and the USB charger (or other USB port that can provide the power supply such as a charger) as shown below. When charging, the battery indicator flashes to indicate the current charge level. Konted 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. At this point unplug the USB charging cable and carefully insert the stopper to keep the probe waterproof.

The probe also has a wireless charging function, which can be charged by placing the probe on a wireless charging pad or a wireless charging pad



5.2 Replace the battery

Pull out the rubber plug at the end of the probe, unscrew the two screws, and then gently scrape the connection between the shell and the sound head with a thin blade to remove the glue, and then remove the shell of the wireless probe and then remove the battery Tape, remove the battery replacement.

5.3 Clean the probe

After the probe is used to clean the probe. The front of the probe can be rinsed directly with water or wiped with a damp cloth/ paper towel. Probes with IPX-5 waterproof rating can be rinsed with fresh water for a short period of time, but do not immerse the probe directly into the water (unless special instructions have been made prior to ordering to seal the USB charging port, etc.). For the probe is disinfected, can be wiped or sprayed on the probe with non-radiative disinfectant such as iodophor, and the operator should wear sterile sterile gloves.

Be careful:

1. **The probe must be cleaned after each use;**
2. **Do not use surgical brush to clean the probe, even if the use of soft brush may damage the probe, only use a soft cloth;**

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.

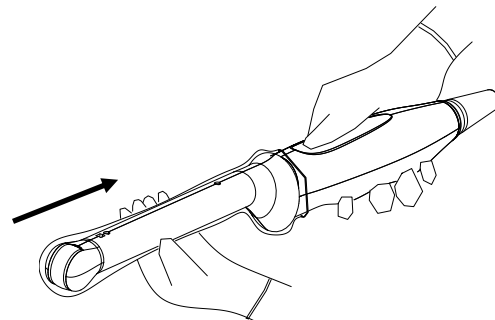
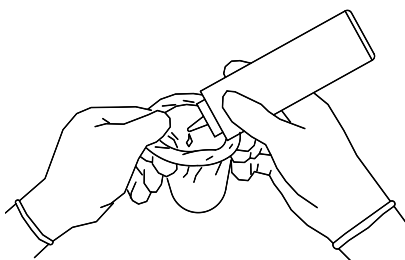
⚠️ CAREFUL:

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):

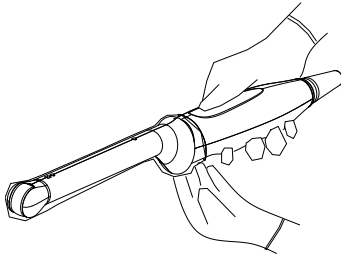
1. In the protective sleeve or inside the probe surface coated with an appropriate amount of coupling agent, without the use of coupling agent, the image is not clear.

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
------------------	---

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.
------------------	--