Wireless Ultrasound Scanner User Manual

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Table

Preface

Dear customers, thank you for purchasing Free5 ultrasound guidance system. Before using this product, please read the contents of this manual carefully so that the product can be used properl After reading, please keep this manual carefully so that you can refer to it whenever you need it.

Product Name: Wireless Ultrasound Scanner Specification Model: Free5

Production License: Guangdong Food and Drug Administration pro No.20173015

Product Features

This product uses advanced ultrasound imaging an technology, can be widely used in emergency, outpatient, bedside, bl rehabilitation and other fields, as a screening and guidance tool, Provide a visualization tool to clinical.

Security Classification

According to the type of electric shock prevention: Belongs to class II equipment;

According to the degree of protection against electric shock: Belongs to the BF type application part.

Safety Warning Message

This user manual always uses the following graphics. Symbols indicate safety pre important notices and familiarize yourself with these symbols and their meanings before product.

Symbol	Content
⚠**Warnings!**	"Warnings" is used to indicate that it will result in serious personal inj significant property damage without notice.
⚠**Cautions!**	"Cautions" is used to indicate that it can result in minor persona property damage without notice.
⚠**Attentions!**	"Attentions" is to remind users of installation, operation and maintenance, which is important but no danger.

Safety Labels, Markings and Symbols Instructions

Position	Item No.	Graphics	Content

Medical device part	**1**		Power Switch
	2		USB Port
	3		BF Type
	4		Reference User Manual
	5		Do not Discard
	6		Non-ionizing Radiation
	7		Series Number
	8		Date Of Manufacture
	9		Period Of Use
Software Part	**10**		Patient Information Setting
	11		B Mode/C Mode/M Mode
	12		Display Depth Adjustable
	13		Gain Adjustable
	14		Run/Freeze
	15		Center Line
	16		Wireless Ultrasound Scanner Battery Power
	17		Mobile Terminal Battery Power
	18		Play/Back Bar
Package Section			

Other Safety Information Instruction

1. This product can not be used in the presence of flammable and explosive gases;

2. Pls. read it carefully before using the power cord, power adapter, the host and the probe shell and make sure the completeness of them so as not to cause harm to the human body;

3. Do not put this product in a violent oscillation environment so as to avoid damage to the probe or product internal structure at any time;

4. It is necessary to unplug the power adapter and turn off the power switch for the product routine maintenance;

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Chapter One Overview

1.1 Introduction

1.1.1 Manual Introduction

1. This manual introduces the wireless ultrasound scanner, which is a visual guidance diagnostic device developed by US

2. This manual contains the necessary and sufficient information to ensure safe operation coherence of the device and should be read conveniently;

3. The manual consists of independent chapters, and some sections repeat. Each chapter is written to provide users with convenience, consistency and ease of reading;

4. If you have any questions in the procedure, please contact US Customer Service or Designated Service Provider.

1.1.2 System Introduction

The wireless ultrasound system is excellent in quality, stable and reliable, completely different from traditional portable medical ultrasound, with high-end and convenient touch operation. Can be widely used in emergency, outpatient, bedside, blood vessels, anesthesia, rehabilitation fields, as a screening and guidance tool, Provide a visualization tool to clinical.

The system consists of wireless probe and mobile terminal software.

1.2 Function Introduction

1. Set handhold Medical ultrasound system Bottom hardware parameter;

2. Send control commands to the bottom of handhold medical ultrasound system, image freeze, display range, image depth and so on.

3. Diagnostic image display and measure: Include different model image display and patient's focus of Infection acreage and length measure.

4. Entry patient information such as patient clinic number, name, age and date;

5. Storage Patient Information;

6. System basic setting, such as brightness, time, date.

1.3 Indication

This product provides ultrasound images for variety clinical ultrasound examinations and puncture guidance.

1.4 Contraindications

This product is forbidden used in eye.

Chapter Two Structure And Working Principle

2.1 Structure

This product combines all ultrasonic function in a probe:

- ◆ Wireless ultrasound probe;
- ◆ Software;

Optional Accessories:

- ◆ Puncture trestle;

2.2 Working Principle

Wireless Scanner is a miniaturized, professional and intelligent product. It integrates the ultrasonic circuit into the probe, then wirelessly connected to the display terminal. Convex, Linear and Micro-convex is widely applied in abdominal, gynecological and urological and ultrasound puncture guidance.

Image 2-1 Wireless Ultrasound System Working Principle

Chapter Three Product Technical Specifications

3.1 Power Adapter

Input voltage: 100-240VAC,50/60Hz

Output voltage: DC 5V

The maximum output current: 3.0A

3.2 Software Mobile Terminal

Work Platform: Mobile phone, Tablet;

Work System: Android5.0 Above;

Operation Interface: Chinese and English;

3.3 Wireless Ultrasound Probe

Probe Type: Convex, Linear

Work Mode: B mode, C mode, M mode

Quiescent Power Consumption: ≤2W

Dynamic Power Consumption: 2.8W □ 4.5W

Work Time: Internal battery can support 4 hours of continuous operation under B model.

Chapter Four Product instructions

4.1 Wireless ultrasound probe operation instructions

4.1.1 Turn on/Turn off

Turn on: Long press power button for 5 seconds, turn on the main unit.

Turn off: Long press power button for 5 seconds, turn off the main unit.

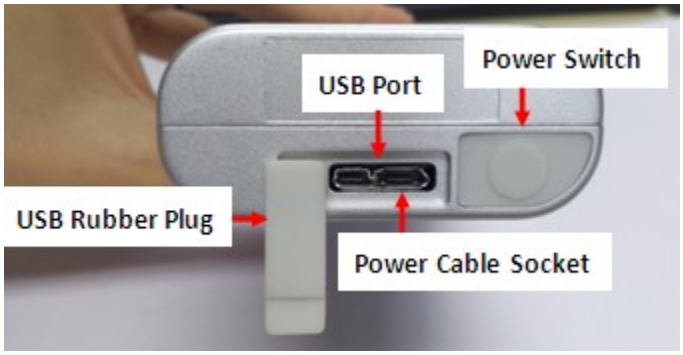


Image 4-1 Input instructions

4.1.2 Wireless ultrasound probe connect with mobile terminal

After start the probe, open WiFi on mobile terminal, the wireless probe blinker turn into blue color from green color, it indicates successful connect with WiFi.

⚠Attention! After WiFi successful connected ,wireless probe only can be used with mobile terminal.

4.1.3 Wireless probe charge operation

Open the end of wireless probe USB plug rubber, pick power adapterwith power cable, plug one side of power cable into powe adapter, another side plug into the end of wireless probe USB port (As Image 4-1 power cable socket).

⚠Attention! This product USB port is USB 3.0

4.1.4 Wireless probe button Instruction

There is "run/freeze button on interface, when "run/freeze button, it can switch between "run/freeze" button.

4.2 Mobile Terminal Interface Operation Instruction

⚠Attention! At first download "Free5"software package in website, then install it in mobile terminal.

4.2.1 Home page Interface

Home page interface: It is the main interface of system, also it is the entrance of all module. As image 4-2 shows.

Home page interface include below module:

1) Wi-Fi Icon: Enter WiFi Start Setting Interface
2) Setting: Enter ultrasound tab setting Interface

3) Ultrasound connecting: Enter Ultrasound Work Interface
4) Company profile: Check company introduction
5) Study Manual: Product manual
6) Online consultation: Connect with professional to consult remotely
7) Medical Library: Clinical ultrasound related books, case
8) First page: Back to first page
9) Ultrasound Image: Check patient case
10) Ultrasound Mall: Check our company product information
11) My: Enter personal user interface

4.2.2 Ultrasound Optional Setting interface

Ultrasound Parameter setting Interface: It is a setting interface before enter ultrasound wor Interface, it can set parameter, for example hospital nar achievebest hitialization.Click“home Page” upper rightConner“setting” then can enter“Ultrasound Parameter Setting Interface”. As image 4-3 shows.

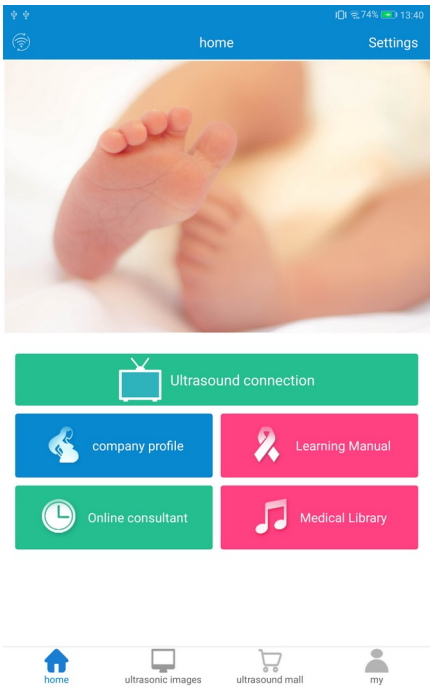


Image 4-2 Home Page interface

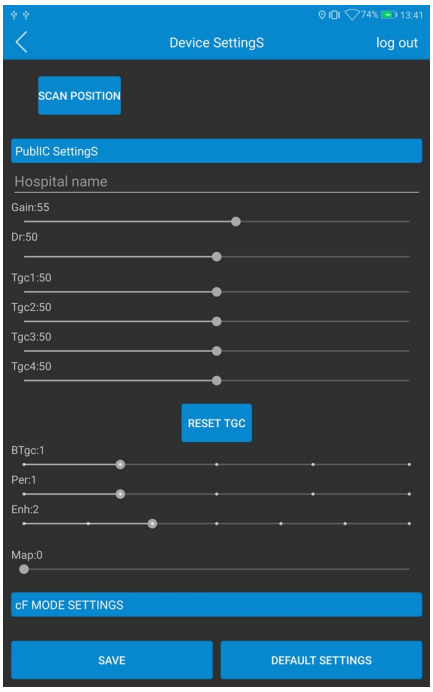


Image 4-3 Ultrasound Setting interface

4.2.3 Ultrasound Working Interface

Ultrasound Working Interface: It is the Core interface of this system, can edit Patient information, display diagnosis image, measure image, save clinic picture and video. As Image 4-4 shows.

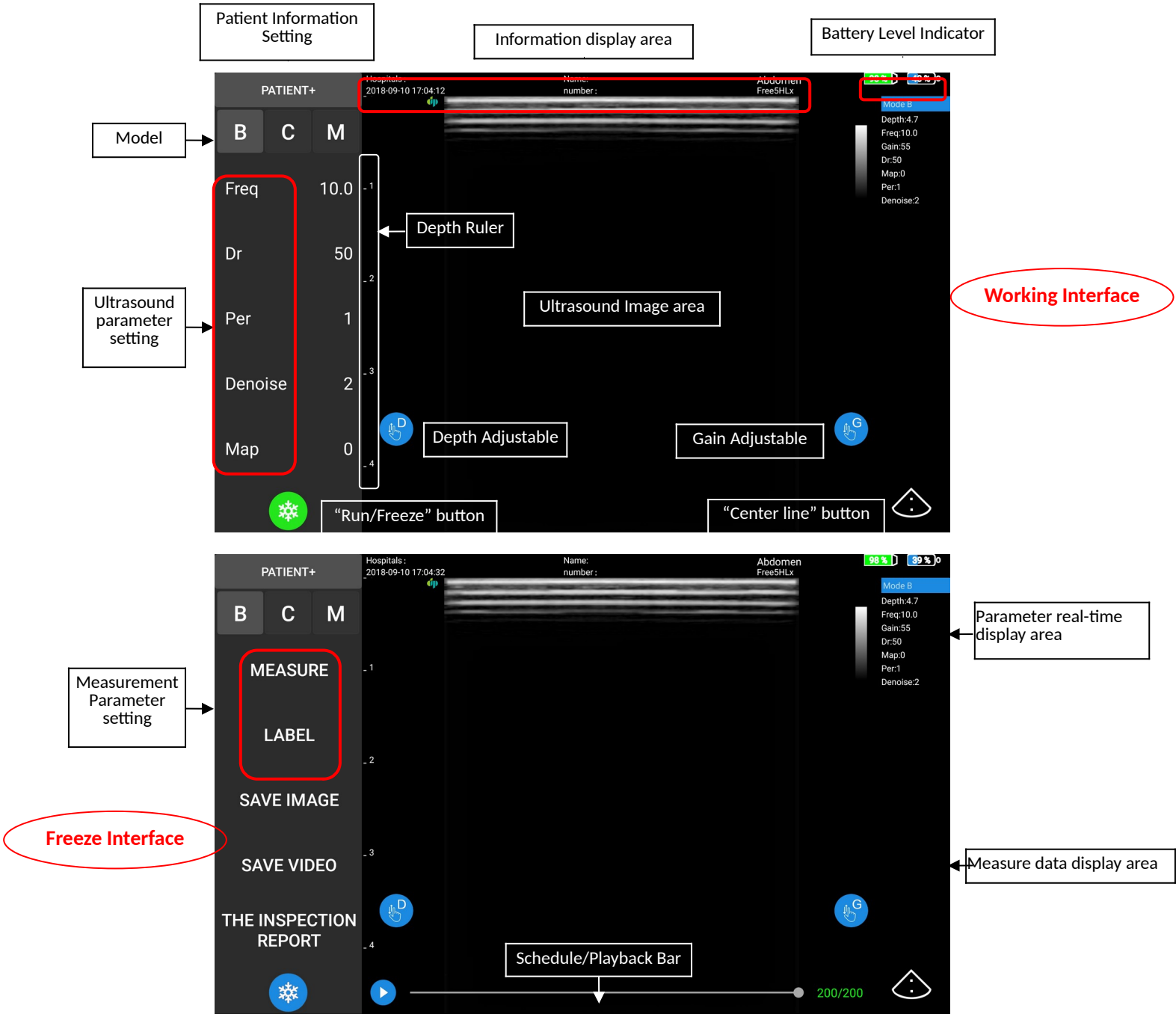


Image 4-4 Ultrasound Interface

1. Patient Information Setting: Click Upper left corner PATIENT+, can edit patient information. As Image 4-5 shows.

2. B Model/C Model: Click Upper left "B" or "C", can enter "B Mode" or C "Mode". As Image 4-6, Image 4-7 shows.

There are measure, label, Dual etc. functions.

1) Click "measure", Choose related shape, press to the measurement data display in "measurement data area".

2) Click "Label" can make label to ultrasound image.

3) Double Click“B” or “C”, you can enter“Dual” function,UltrasonicImage appear another layer image. As Image 4-8 shows.

3. Ultrasound parameter setting: In “Ultrasound Working Interface”, you can choose ultrasound adjustable parameter. Choose the parameter need to set, then slide up and down in the ultrasound scan area.

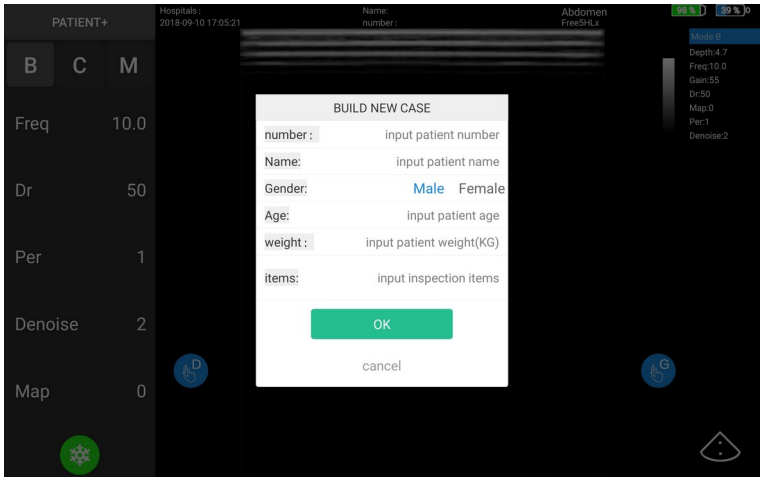


Image 4-5 Patient Information Setting

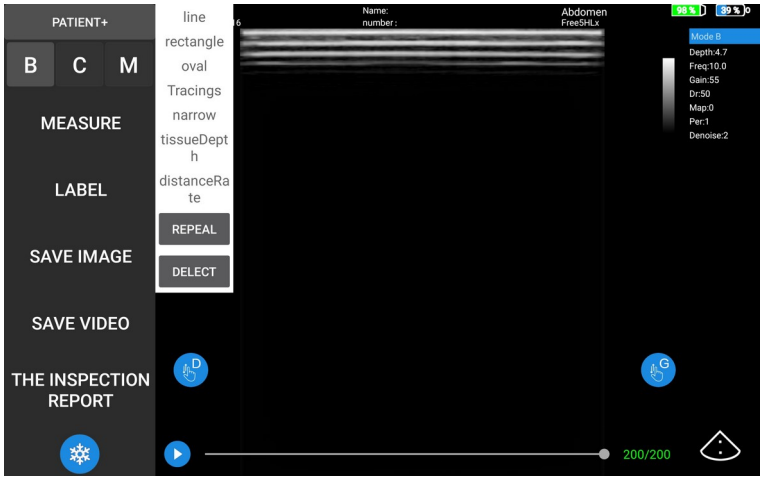


Image 4-6 B Model

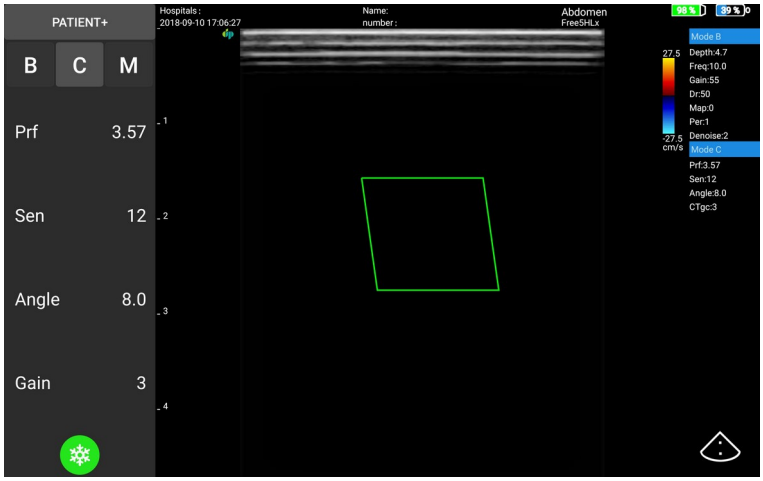
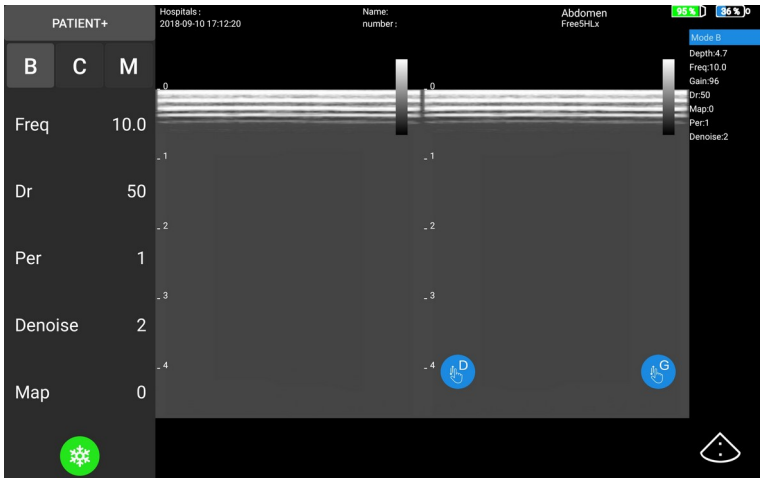


Image 4-7 C Model



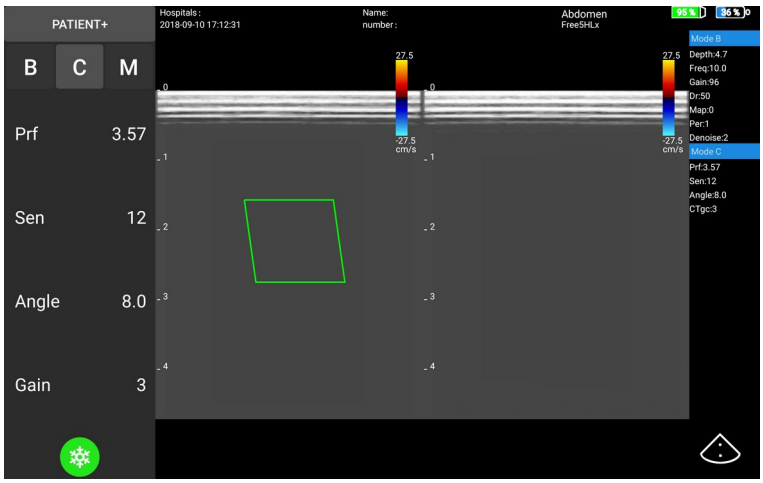


Image 4-8 B/C Model “Dual” Function

4. “Depth Adjustable”, “Gain Adjustable”, “Center Line”, “Run/Freeze” est. parameter adjustable.

1) “Depth adjustable” operation: Left side touch up and down, then can adjust measurement depth.

2) “Gain adjustable” operation: Right side slide  up and down, then can adjustable overall gain of image. In “ultrasound working area” slide left and right, then can adjustable segmented gain of image in “ultrasound working area”. As Image 4-9shows:

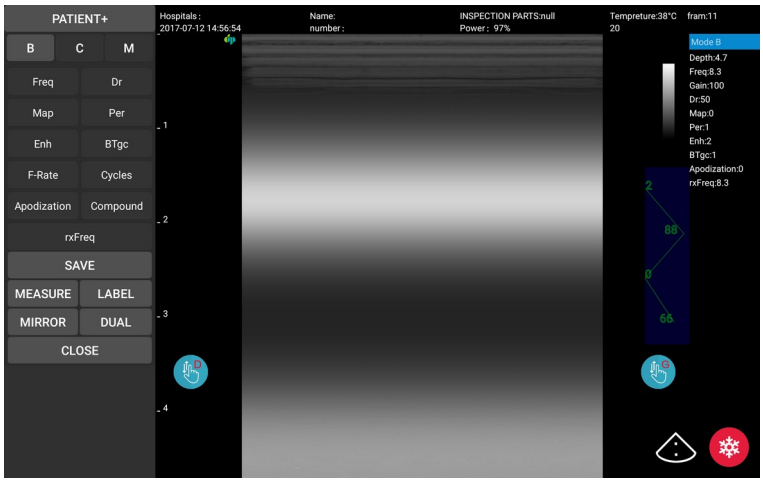


Image 4-9 Image adjustable segmented

3) “Center line” Operation: There are 3 types “Center Line”, They are: point distance 5mm center line, point distance 1mm center line, Gridlines. Click Icon  image, appear point distance 5mm center line; Click Icon  image, appear point distance 1mmcenter line; Click Icon  image, appear Gridlines (point distance 1mm), Click Icon  Image, then return back default interface. As Image 4-10, image 4-11, image 4-12 shows.

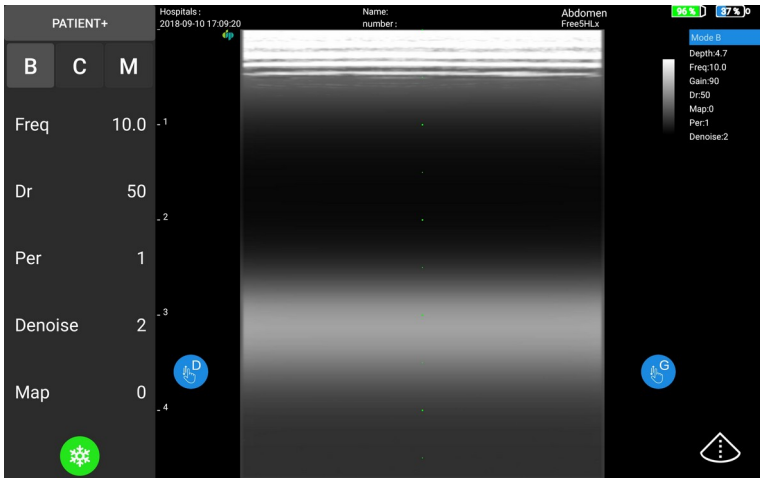


Image 4-10 Point distance 5mm Center Line

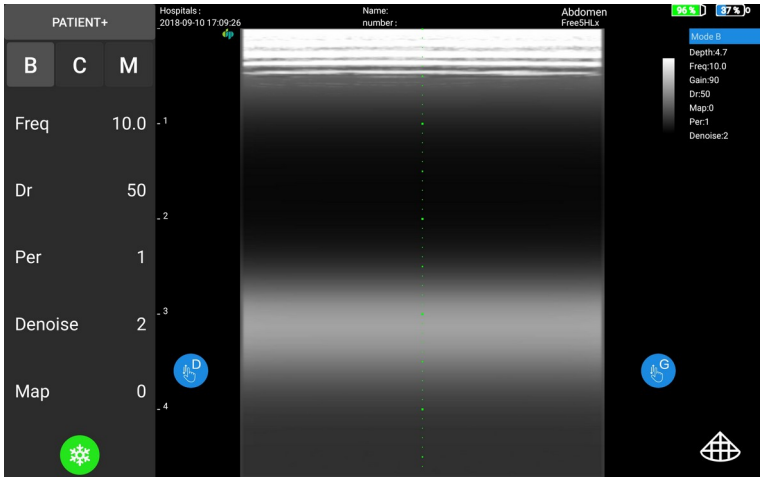


Image 4-11 Point distance 1mm Center Line

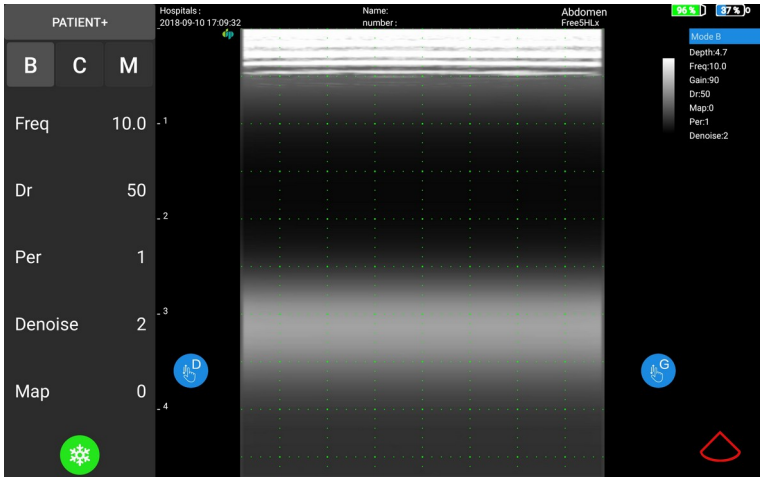


Image 4-12 Gridlines type center line

4) "Run/Freeze" operation: Green icon represent running status, Blue icon represent freeze status. When the image in freeze status, in the bottom of screen appears Playback bar. (As Image 4-4). In freeze status, system automatic recording 200 frames image before frozen (but not save automatically). "playback bar" can check any frame image before frozen. Stop in any frame of image, click "save" button, then can save picture, long press on 2 second can save the video.

4.2.4 Ultrasound Image Interface

Ultrasound Image Interface: In this interface, you can check patient case in the list, it shows the patient information that edit by doctor. In this page there is a search function, you can get c patient information quickly by this function. As Image 4-13, Image 4-14 shows.

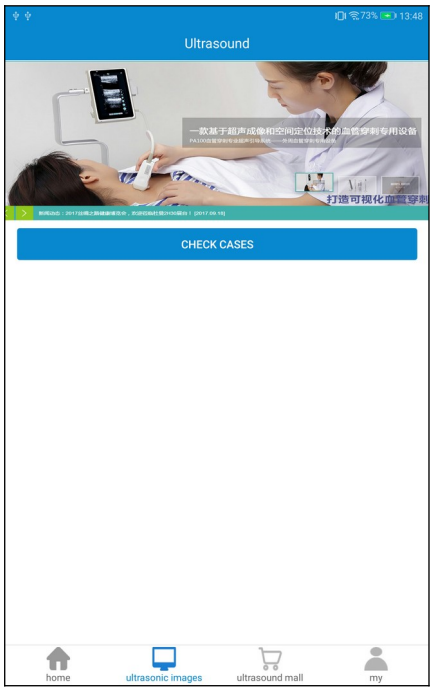


Image 4-13 Ultrasound Image Interface Image 4-14 Patient Case List

Enter patient case details page, you can check the picture and the video be saved during Ultrasound scan. As Image 4-15 shows.

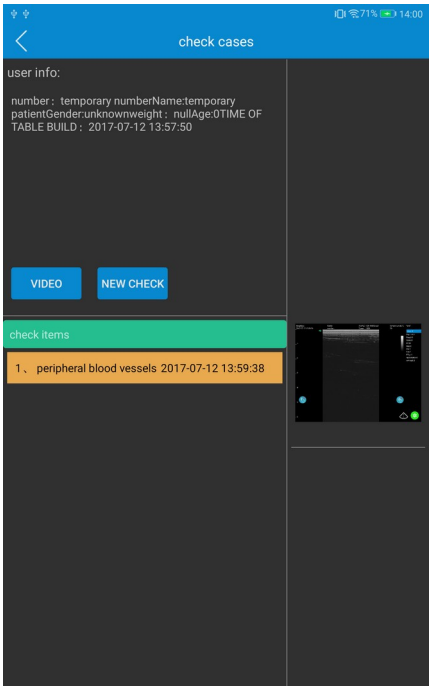
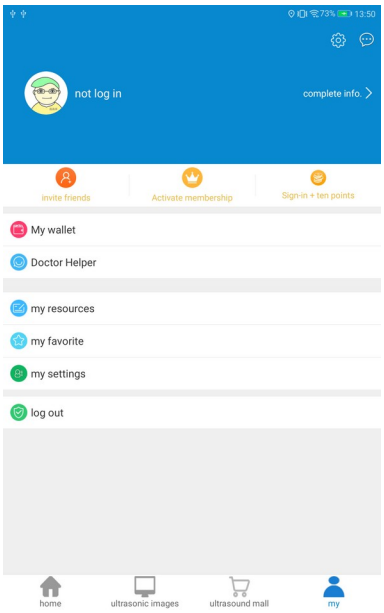
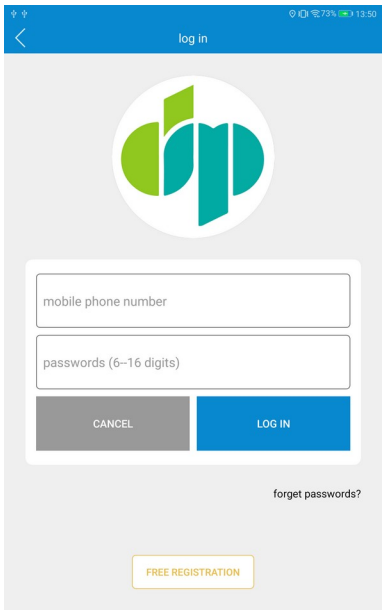


Image 4-15 Patient Case Details

4.2.5 Personal User Interface

Personal User Interface: It is system user center page, Include registration, Log on, Clear Cac software version upgrade act Function. As Image 4-16 shows.





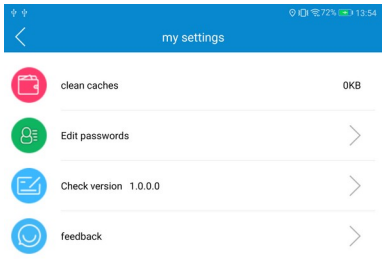


Image 4-16 User Center Page

Chapter Five Transportation and storage

5.1 Transportation Requirement

Environment Requirement

Environment Temperature: -20℃～+55℃;

Relative Humidity: 10%～93% (Not Condense);

Atmospheric pressure: 700hPa～1060hPa;

Notes Term Instruction:

This product package meets the requirements of air, railway, road and shipping transportation, but should avoid rain and snow splashing, violent collision and strong sunlight transportation.

5.2 Storage requirement

Environment Requirement

Environment Temperature: -20℃～+55℃;

Relative Humidity: 10%～93% (Not Condense);

Atmospheric pressure: 700hPa～1060hPa;

Notes Term Instruction:

- The product should be placed indoors and keep good ventilation in the room;
- Avoid Long-term exposure by strong daylight or contact with corrosive gases;
- Storage off the ground and wall ≥10cm place;
- Stacking layer ≤10 layers;
- Storage battery requirements: 60%～80%;
- When storage period than 6 months, should taken out from warehouse and check, make sure working well and battery power meets storage requirements then Re-storage.

Chapter Six Daily Maintenance Instruction

6.1 Proper Use Of The Probe

In order to Increase the life of the probe and get the best performance possibility, be carefully when operating the probe, please observe the following notes:

- Avoid dropping the probe on the floor or hitting it with other hard object surface, incorrect operating Will affect their performance.
- When the probes are not in use, they should be storage on the stand.
- Do not heat the probe.

 Warning：	Don't use the probe with damage, in case Cause serious consequences, It will harm the life or health of the operator or patients.

When use on patients with or suspected of having creutzfeldt, If the probe protection failure or the probe is directly contact with the meninges or any intracranial tissue of creutzfeldt-Jakob disease, the probe should be destroyed. At present, there isn't effective way to eliminate such probe contamination.

6.2 Probe Clean/Maintenance

After inspection, Turn off wireless scanner and clean the ultrasound probe according request. As below providing cleaning, disinfection and sterilization according <Medical institution disinfection technical specifications>.

 warning：	Forbidden put the probe wire or connector in the solvent as this may cause electric shock or probe fault.

 cautious：	Pay attention to the inspections and maintenance, Be sure to check for cracks in the probe section (transducer assembly) that is allowed to immerse in the conductive liquid.

Notes：	Avoid overheating the probe (over 55°C) during temperature may cause the probe deformed or damaged.

- ❖ In order to keep the main unit and probe clean, it should be clean at least 1 time with soft cloth dampened with warm water. Never use paint thinner, ethylene oxide, or other organic solvents, and also not use probe surface to clean, otherwise this can damage the probe film. It is not allow disinfectant or water to infiltrate into the probe system.

- After cleaning the probe, use a sterile cloth or gauze to wipe off the moisture on the probe. Forbidden drying the probe by heating.

Chapter Seven Additional Safety Information

7.1 Electromagnetic compatibility

Free5 Series wireless ultrasound scanner belongs to ultrasonic device, the process of transmitting/receiving ultrasonic signals may be affected by electromagnetic waves in the surrounding environment. When it appears electromagnetic interference, the Technicians need to estimate the impact of image quality degradation on usage.

If electromagnetic interference is caused to other devices due to using this product and affects the normal use of other devices, users can try to below methods to solve this case:

◆ Increase the gap between our device with other device;

◆ Connect with after service staff of Guangdong US to ask for help.

Notes!	1) Free5 series wireless ultrasound scanner according YY0505 standard electromagnetic compatibility regarding request; 2) Users should install and use the equipment according to the electromagnetic compatibility information provided by the random document; 3) Portable and mobile RF communication devices may affect the performance of the Free5 wireless ultrasound scanner, avoiding strong electromagnetic interference during use, such as near cell phone, microwave oven etc. 4) The guide and the manufacturer's statement are detailed in the attachment.

 Warning!	1) Free5 series wireless ultrasound scanner should not be used or stacked with other equipment, if you must approach or stack, it should be observed that the function properly work in the configuration it uses. 2) Class A equipment is intended for use in industrial environments. Due to the conducted disturbances and radiated disturbances of the Free5 series of w scanners, it may be potentially difficult to ensure electromagnetic compatibility in other environments.

RF Parameter

Item	Description
Working Frequency Band	2.412GHz-2.472GHz
Transmit Power	<20dBm
Protocol	IEEE 802.11 b/g/n

Table 7-1

Guide And Manufacturer's Statement - Electromagnetic Emissions - For All Equipment And Systems

Guide and manufacturer's statement–Electromagnetic interference		
Free5 series wireless ultrasound scanner is intended to be used in the electromagnetic environment specified below. The purchaser or user of this should ensure that it is used in such an electromagnetic environment.		
Emission test	Compliance	Electromagnetic environment - Guide
Radio frequency emission GB 4824	1 Group	The Free5 Series Wireless Ultrasound Scanner uses RF energy for internal functions only. Therefore, its RF emissions is very low and the possibility of interference to nearby electronic devices is low.
Radio frequency emission GB 4824	C1ass B type	The Free5 Series Wireless Ultrasound Scanner is suitable for use in all facilities that are not directly connected to home and public low voltage power supply networks for residential homes.
Harmonic emission GB17625.1	Not applicable	
Voltage fluctuation/Flashing emission GB 17625.2	Not applicable	

Table 7-2

Guide And Manufacturer's Statement - Electromagnetic immunity - For All Equipment And Systems

Guide and manufacturer's statement–Electromagnetic immunity			
Free5 series wireless ultrasound scanner is intended to be used in the electromagnetic environment specified below. The purchaser or user of this should ensure that it is used in such an electromagnetic environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guide
Electrostatic discharge (ESD) GB/T 17626.2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	The floor should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst (EFT) GB/T 17626.4	Not applicable		

Surge GB/T 17626.5	Not applicable		
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	Power frequency magnetic field should have the characteristics of the power frequency magnetic field in commercial typical place or hospital environment.

Table 7-3

Guide And Manufacturer's Statement - Electromagnetic immunity – For Non-living support devices and systems

Guide and manufacturer's statement–Electromagnetic immunity			
Free5 series wireless ultrasound scanner is intended for use in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in such an electromagnetic environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guide
Radio frequency conduction GB/T 7625.6 Radio frequency radiation GB/T 7626.3	3Vrms (150 kHz to 80 MHz) 3V/m (80MHz to 2.5GHz)	3Vrms 3V/m	Portable and mobile RF communications equipment should not be closer to the product than the recommended isolation distance. Suggestion Isolation distance d = $\left[\frac{3.5}{V_1}\right]\sqrt{P}$ d = $\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz d = $\left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.5GHz Here “p” is the maximum transmitter Rated output power provide by manufacturer, the unit is wall(w), d is recommend isolation distance, unit is meter (m). The field strength of fixed RF transmitter is determined by surveying the electromagnetic field ,and each frequency range b should be lower than the compliance level.

			Interference may occur near devices marked with the following symbols. 
1. At frequencies of 80 MHz and 800 MHz, adopt higher range frequency. 2. This guide is not suitable in all situations. Electromagnetic propagation is affected by building, object, absorption of the human body and Reflection.			
1. Fixed launch airports, such as: wireless (cellular/cordless) phones and ground mobile radio base stations, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts and television broadcasts, the field strength is theoretically inaccurate It is foreseen that in order to assess the electromagnetic environment of a fixed RF transmitter, an electromagnetic field survey should be performed. If the field strength at the location where the product is located is higher than the RF compliance level for the above application, the product should be observed to verify that it is functioning properly. Additional measures may be necessary if abnormal performance is observed, such as reorienting or locating the product. 2. Since electromagnetic wave propagation is affected by environment, the conditions given in the guidelines may not be suitable for all situations.			

Table 7-4

Recommended isolation distance between portable and mobile RF communications equipment with Free5 series wireless ultrasound scanner - For Non-living support devices and systems

Recommended isolation distance between portable and mobile RF communication with Free5 series wireless ultrasound scanner.			
Free5 series wireless ultrasound scanner is intended for use in the electromagnetic environ specified below. The purchaser or user of this should assure that it is used in such an electrom environment.			
Transmitter maximum Rated output power/w	Corresponding distance to different frequencies transmitter/m		
	150kHz～80MHz d=$1.2\sqrt{P}$	80MHz～800MHz d=$1.2\sqrt{P}$	800MHz～2.5GHz d=$2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
Regarding Transmitter Rated maximum output power listed in above form, recomm Isolation distance d, in meters(m), can be determined by the formula in the corresponding transmitter			

frequency column, here “p” is the maximum transmitter Rated output power provide by manufacturer, the unit is wall(w).

Mark:

1. At frequencies of 80 MHz and 800 MHz, adopt higher range frequency.
2. This guide isn't suitable all situations, Electromagnetic propagation affected by building, object, Absorption of the human body and Reflection.

7.2 Waste or disposal pollution control management

This product shouldbe pay attention to the image quality at the end of its service life. If the image quality is found to be degraded, distributor.

Chapter Eight After Service Guarantee

This product is worldwide quality assurance. You may dial the Global Service Hotline at +86 4006-782-532 when the product purchased by any organization authorized by US in the world professional customer service personnel of US will solve your problems.

Product failure during the warranty period, according to the US service personnel on the need to return and repair, please send the whole machine back to my company or the specified company in the local country. To be repaired, US Products will be sent back to you.

⚠Attentions!

The following conditions are not covered by the warranty:

1. This commitment applies only to the operation of the device in line with the conditions specified in the manual, please make sure that the device is only used in the recommended range of the manual;

2. This promise does not apply to damage to device due to accident, misuse, abuse, drop, attempt to modify or change any part of the device;

3. US is not responsible for damage caused by other device or by unauthorized connection to other device;

4. When problems occur with your US product during the warranty period, notify US or the local specified service providers about the device model number, purchase date, and nature of the problem.

⚠Warnings!

1. The maintenance of this product need to be authorized by our company professionals;

2. The power adapter is a special part of the product, users do not use other power alternative, otherwise it may cause damage to the product, the resulting loss will not be covered by the warranty;

3. This manual provides instructions for using the Free5 series wireless ultrasonic scanner. For more information, contact your local Authorized Distributor.

4. To meet the requirements of the relevant laws and regulation continuously improve the finished product, improve the clinical value responsibility. The company reserves the right to update the product with the ri notifying customers, hoping to get users' understanding, thank you for your support again!

Free5 wireless ultrasound scanner has a 8-year service life.