Pocket Ultrasound System

Instruction manual

Model: P50

IMPORTANT !

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

GuangDong Youkey Medical Co., Ltd.

Contents

Introduction

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.

The company reserves the right to change the contents of the instruction manual without prior notice.

Important statement!

1. Any part 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 scanner can provide the doctor with the image and data needed for clinical diagnosis, and the doctor is responsible for the diagnostic 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 caused by components purchased from other company or its unauthorized distributor;
   (4) Damage or loss caused by using the scanner not in the original purchased place.
   (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 misuse;
   (8) Failure caused by other things, not the product itself.

Maintenance and repair service

Main unit is 2 years, and the probe head is 1 year. The warranty period from the product warranty card fill in the attached "date of installation" date, the warranty card is the only certificate calculation warranty period.

Within the warranty period, the product is provide with 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, the company will charge maintenance services, you need to pay the cost of maintenance and spare parts costs.

After the expiration of the warranty, the company can provide maintenance services.

It should be noted that if you do not pay or delay the payment of maintenance costs, the company 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 the company.

Intellectual Property Statement

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

Version information

The version of this instruction is as follows:
Version number: 1.0
Issue date: January 2021
Document No: JL-YF-57-1000-A(EN)-1.0

Product Information

Product name:Pocket ultrasound system

Product Model: P50

Name of the registrant: GuangDong Youkey Medical Co., Ltd.

Registered address: Unit 601,6/F,Block B,Building 1,B1 District,Hantian Technology City,Dongping Road,Pingxi Shanghai Village,Guicheng Street,Nanhai District,Foshan City,Guangdong Province,528200,China

Production enterprise name: GuangDong Youkey Medical Co., Ltd.

Production address (residence): Unit 601,6/F,Block B,Building 1,B1 District,Hantian Technology City,Dongping Road,Pingxi Shanghai Village,Guicheng Street,Nanhai District,Foshan City,Guangdong Province,528200,China

Contact photo: 0757-86258600

After-sales service unit:

Company Name: GuangDong Youkey Medical Co., Ltd.

Address: Unit 601,6/F,Block B,Building 1,B1 District,Hantian Technology City,Dongping Road,Pingxi Shanghai Village,Guicheng Street,Nanhai District,Foshan City,Guangdong Province,528200,China

After-sales service Tel: 0757-86258600

other:

Company website: www.youkeymedical.com

WeChat public number: Youkey

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 Main unit is IPX4;
- According to the working mode:
  Continuous working equipment.
- According to the degree of safety in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide:
  Equipment not suitable for use in the presence of a flammable anesthetic mixture with Air or with Oxygen or Nitrous Oxide.

1.2 Symbol definition

In this manual, "⚠DANGER", "⚠WARNING", "**CAUTION**"is used to indicate the safety and other important matters, and their specific meanings are as follows.

Symbols and vocabulary	Meaning
⚠**DANGER**	**Indicates that a hazardous situation may occur and, if not avoided, may result in death or serious injury.**
⚠**WARNING**	**Indicates that a potentially hazardous situation may occur and, if not avoided, may result in death or serious injury.**
CAUTION	**Indicates that the risk may occur, if not avoided, may cause property damage.**

1.3 Security symbol

Security symbol	Detailed description
	**Type BF application part** **Description: all the ultrasonic probes connected to the system are part of the BF application.**
	**"Be careful" indicates what should be noted. Be sure to read the instructions carefully before using the system.**
IPX4	**There is no harmful effect if the liquid is splashed into the shell from any direction.**
	**Non-ionizing electromagnetic radiation.**

1.4 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.

⚠DANGER	**Do not use the scanner in an environment containing combustible gas, such as an anesthetic gas, hydrogen, or flammable liquid, such as ethanol. It may cause an explosion.**

⚠WARNING	**1. Do not disassemble the ultrasonic probe, which may cause electric shock.** **2. Use the original power cable, or charging the scanner may cause 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. Use sterilized ultrasound cover when doing gynecology exam.** **7. Do not immerse the ultrasonic probe Type-C interface or above in water or disinfectant. Because the Type-C interface of the ultrasonic probe does not have a waterproof function, this may cause an electric shock or a probe malfunction.** **8. Make sure the transducer is in good status before and after each exam. The defective transducer may cause electric shock.** **9. Choose different transducer based on the exams. You can only use the transducer provided by the manufacturer.** **10. In order to ensure safety, the charging of the system can only be carried out in the state of shutdown, and the charging is not allowed under the power-on state.** **11. The Pocket ultrasound system does not support the contrast - enhanced sonography**

⚠ 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. **Do not scan fetal, newborn baby or pregnant woman for a long time.**
3. **Please follow the ALARA principle during ultrasonic diagnosis, especially in the examination of pregnant women, fetuses and newborns. The sound power can be reduced as much as possible when satisfactory clinical images can be obtained.**
4. **If the APP software fails during installation or use, please promptly provide feedback to the after-sales maintenance personnel to avoid misdiagnosis.**
5. **The APP software will be upgraded from time to time, and new updates will be submitted by the developer. If you want a better experience, please pay attention to download and upgrade.**
6. **Do not use incompatible coupling agents, disinfectants, probe protective cover, probe, puncture rack.**
7. **Sterile gloves must be worn to prevent infection when using ultrasonic probes.**
8. **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.**
9. **Normal ultrasound does not cause burns at room temperature; however, if the probe is placed in the same position for a long time, the patient may be burned.**
10. **The probe cover is made of natural rubber and is used with caution for natural rubber allergy.**
11. **During the examination, the temperature of the Transvaginal transducer lens surface should be lower than 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 cleaned. 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℃～ 37℃**
   - **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.**

1.5 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

Pocket Ultrasound System is intended for use by a qualified physician for ultrasound evaluation. Specific clinical applications and exam types include: Abdominal, Obstetrics, Gynaecology, Small Parts (breast, thyroid, etc), Peripheral Vascular, Urology.

2.2 Contraindication

Pocket Ultrasound System is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

2.3 Product specifications

2.3.1 Imaging mode

B mode

M mode

C mode

PW mode

Power mode

2.3.2 Software version information

a) Embedded software(Firmware) release version: 1.0.0

b) Controlled software(APP) release version:

- Android platform Software version: V1.0.0
- Windows Platform software version: V1.0.0.
- Get software from the USB flash disk with the unit.

2.3.3 Software running IT environment

Software Environment	
Network bandwidth	<500KBbps
Port	8080-8084
IP range	192.168.254.10-192.168.254.200
Operating system	WindowsXP/7/8/10 or Android5.0 or above
Antivirus software	1.Windows system is recommended to install the top anti-virus software, such software takes up less resources, runs smoothly, and does not conflict, enough to protect system security. 2.The general Android system brand equipment has built-in security procedures, no need to download; if the original system does not have its own security software, it is recommended to download some of the top anti-virus software to ensure system software security.
Antivirus frequency	It is recommended to perform anti-virus once a week to protect the system.

2.3.4 Power condition

Internal Battery (7.4V 1300mAh)
Charging power input: DC 5V/2A
Note: Can not work when charging.

2.3.5 Environment condition

	Work environment	**Storage and transportation environment**

Ambient temperature	0℃～37℃	-20℃～+55℃
Relative humidity	30%～85% (No condensation)	30%～93% (No condensation)
Atmospheric pressure	860hPa～1060hPa	700hPa～1060hPa

⚠ **WARNING：**	**Transportation:** **Do not use or store the system outside the specified environmental conditions.** **Working:** **1.Make sure the scanner is been held firmly, or it will drop and hurt the patient.** **2.Use the scanner 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. Do not use the scanner in an environment containing combustible gas, such as an anesthetic gas, hydrogen, or flammable liquid, such as ethanol. It may cause an explosion..** **A. If there are flammable substances in the environment, do not use the scanner.** **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 scanner, please contact the service center or your sales representative.**

2.3.6 Probe outline dimensions and weight

Net weight: 50g (R50) (C5-2Fs)

Convex array size: 53mm (L) * 28mm (W) * 38mm (thickness)

Net weight: 70g (R60) (C5-2Ks)

Convex array size: 73mm (L) * 28mm (W) * 38mm (thickness)

Net weight: 30g (L40) (L11-4Ks)

Linear array size: 55mm (L) * 28mm (W) * 30mm (thickness)

Net weight: 20g (L25) (L11-4Gs)

Linear array size: 41mm (L) * 28mm (W) * 30mm (thickness)

Net weight: 20g (R15) (C8-5Ks)

Microconvex array size：41mm(L)*28mm(W)*32mm(thickness)

Net weight: 50g (R10) (E10-4Ks)

Endocavitary array size：212mm(L)*41mm(W)*28mm(thickness)

2.4 system configuration

The system is mainly composed of main unit equipment, transduser and application (Android/Windows platform).

The configurable probe model is: C5-2Fs(Convex array), C5-2Ks(Convex array), L11-4Ks(Linear array), L11-4Gs(Linear array), C8-5Ks(Microconvex array), E10-4Ks(Endocavitary array).

2.4.1 Standard configuration

- Main unit: 1 set
- Appendix
  - Application
  - Operation manual

2.4.2 Components

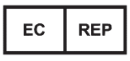
2.4.2.1 Optional Transducer

Transducer model	Type of Transducer	Intended use	Applicable site	Center frequency	Frequency range
C5-2Fs	Large convex transducer	Gynecology and obstetrics, abdominal kidney	body surface	3.5MHz	2.0~5.0MHz
C5-2Ks	Large convex transducer	Gynecology and obstetrics, abdominal kidney	body surface	3.5MHz	2.5~5.0MHz
C8-5Ks	Microconvex transducer	Gynecology and obstetrics, abdominal kidney	body surface	6.5 MHz	5.0~8.0MHz
L11-4Ks	Linear array transducer	Small organ carotid artery	body surface	7.5 MHz	6.0~11.0MHz

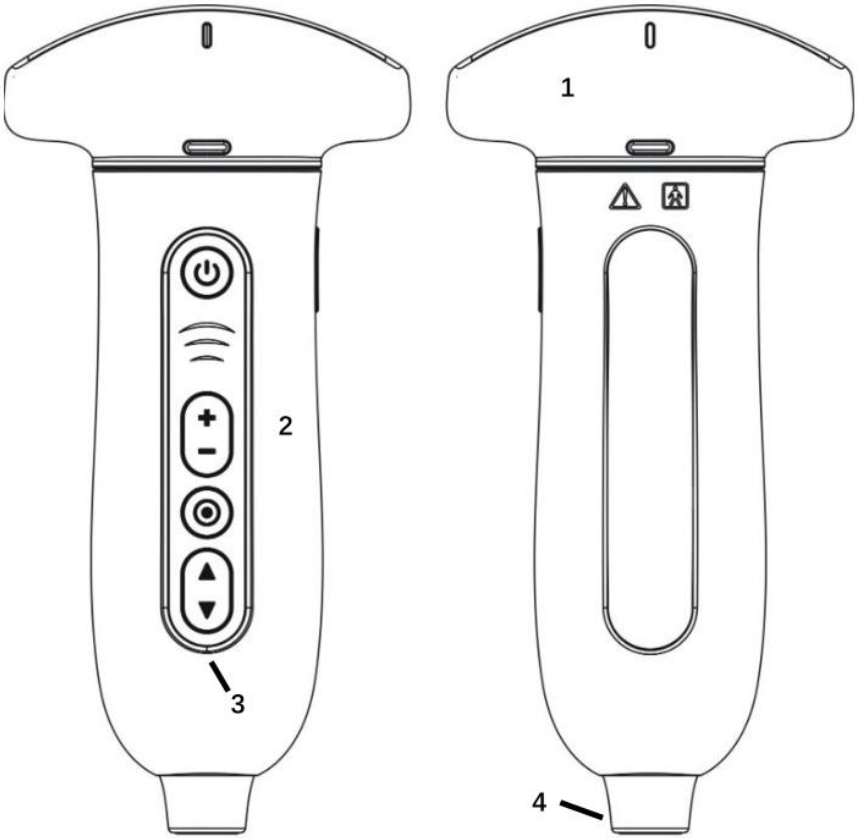
L11-4Gs	Linear array transducer	Small organ carotid artery	body surface	7.5 MHz	6.0~11.0MHz
E10-4Ks	Cavity transducer	Department of Obstetrics and Gynecology, urinary system	Via vagina	6.5 MHz	5.0~8.5MHz

2.5 Symbols description

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

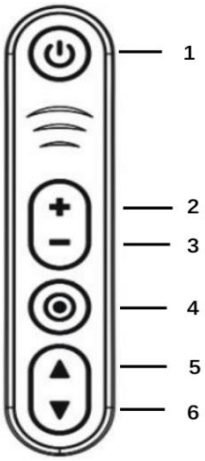
No.	Symbols	Description
1		Type BF application part All ultrasonic probes are part of the BF application.
2		Please refer to the instruction manual for this symbol to avoid accidents
3		This symbol represents the product serial number
4		This symbol represents the date of production
5	IPX4	There is no harmful effect if the liquid is splashed into the shell from any direction
6		CE mark
7		European Authorized Representative
8		Date of Production
9		No discard it at will is allowed.
10		To identify the country of manufacture of products
11		Indicates the item is a medical device
12		Indicates a carrier that contains Unique Device Identifier information.

2.6 Introduction of each component of the system



Serial number	Name	Function
1	Transducer	Transmit and receive ultrasound
2	Main Device	Scanning control and data processing
3	Control Panel	Operation control
4	Type-C interface	USB-C port for charging and data transferring

2.7 Control panel



2.7.1 Control area schematic

Serial number	Button icon	Key name	Function
1		Power switch / freeze / thaw button	1. Short press: power on / freeze / unfreeze scanner 2. Long press ⩾3s: power off the scanner. 3. Blue blinking, the scanner is in freezing status. 4. Blue solid, the scanner is in scanning status.
2		(Gain) “+”button	Increase Gain and Parameters
3		(Gain) “-”button	Decrease Gain and Parameters
4		Main menu button	1. Change scan mode. 2. Save image in freezing status 3. Battery light indication
5		(Depth) “▲”button	Increase Depth / Switch Parameters.
6		(Depth) “▼”button	Decrease Depth / Switch Parameters.

2.8 Basic interface

2.8.1 Android application interface

The interface layout diagram for the Android application is as follows:

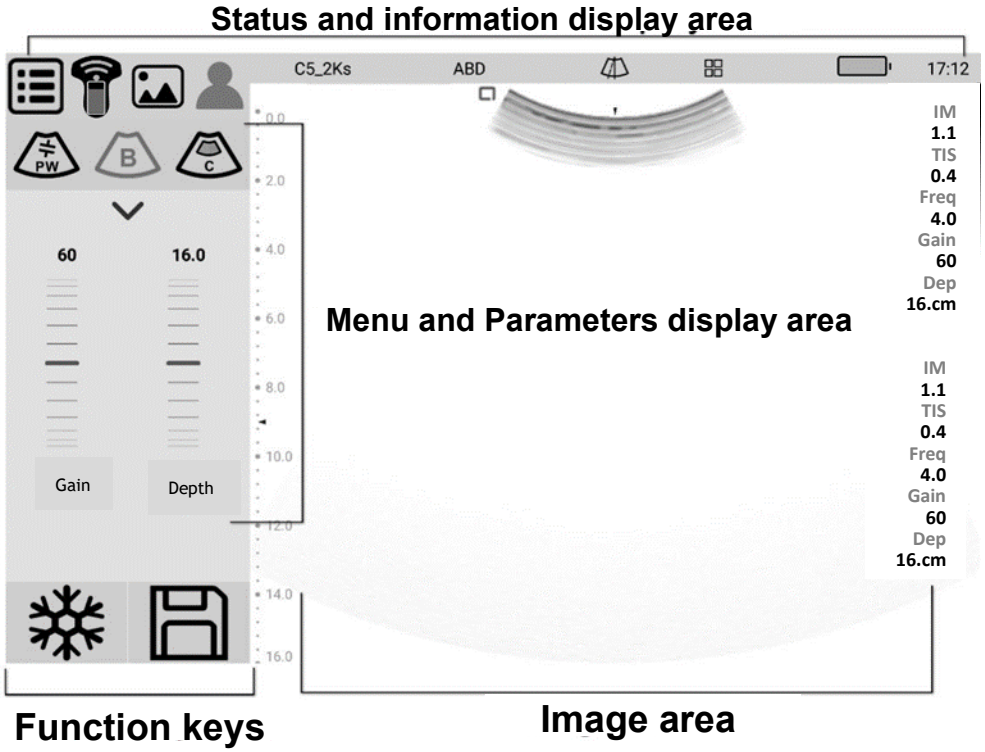


Figure 2.8.1 Interface layout diagram

Status and information display area

The status and information display area includes system menu, WiFi/USB connection sign, patient information management, probe type, inspection type, puncture line, battery charge and system time.

- System menu
  Contains pre-set, version information, operation manual.
- WiFi/USB connection sign
  Displays the current probe connection.When connected to a WIFI, the flag indicates signal strength， and you can also click to pop up the probe selection dialog box
- Probe type
  Displays the currently used probe model or the default probe model.
- Inspection type
  Displays the type of examination currently in use, such as abdomen, heart, etc., click to select the check mode.
- Guide line
  The system support 2 guide lines, when you toggle it on, you can adjust the position and angle of the guide line.

- Battery charge 
  Probe battery power (upper): after the probe is connected, the current probe is displayed.

  Device battery power (below): the display device opens the application and displays the current power of the display device (mobile phone / tablet).
- System time
  Displays the current system time. Check time as the image freezes when the system freezes.

Menu and Image Parameter display area

The areas can be divided into two parts: image mode switching area and image parameter adjustment area.

- 

B mode,click to switch to M mode, click back to B mode;
- 

Color mode, Click to enter Color mode, click again to enter Power mode;
- 

PW mode, Click to enter the pre-startup status of PW mode and click again to start / pause to get the spectrum. It's the same function as update.
- 
Drop-down menu flag, click to enter the corresponding image mode of all parameters adjustment.
- 

  Image parameter adjusting pulley: Slide up and down or click on the pulley to adjust the corresponding parameters.

Function shortcut key area

Contains freeze/unfreeze /saves image buttons


Freeze and unfreeze the clinical images


Save image button.

Image area

The image area displays images of each mode and probe direction markers, time lines (in M mode), PW sampling lines (PW mode), axes (including depth axes, time axes), etc., while annotating information and measuring, The gray bar also appears here.

2.8.2 Windows application interface

The interface layout diagram for the Windows application is as follows:

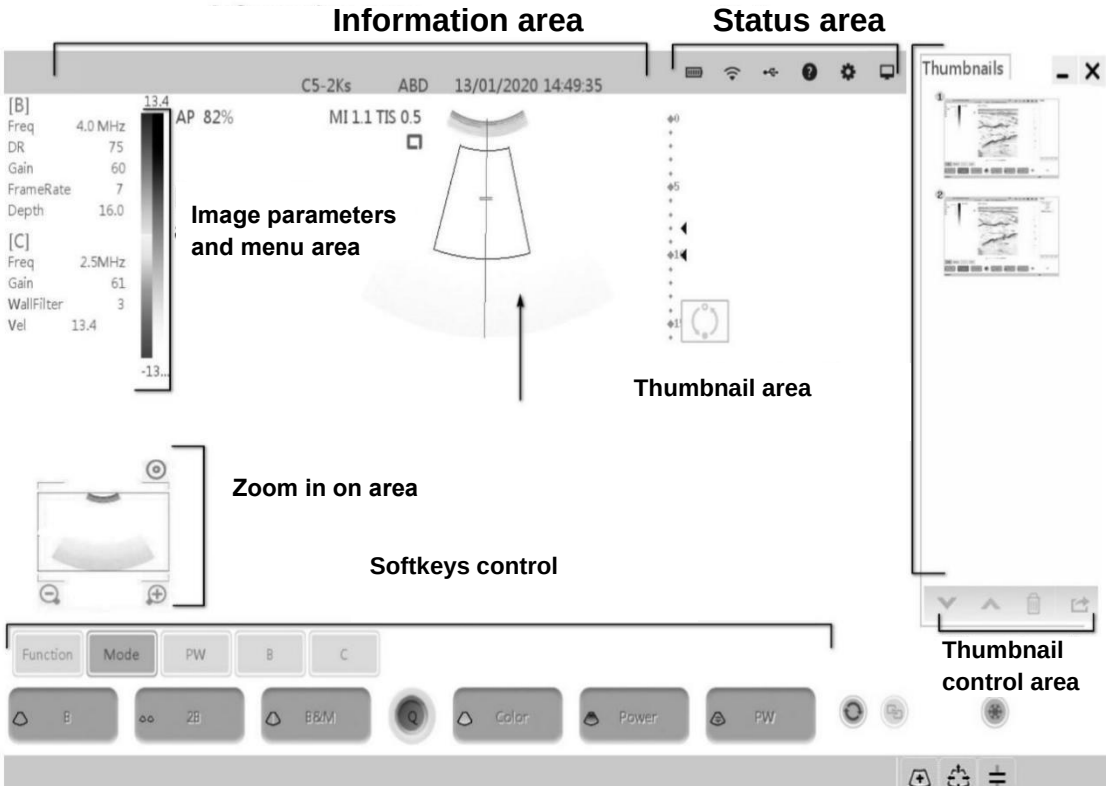


Figure 2.8.2 Interface layout diagram

Information area

The information area includes manufacturer identification, patient information, hospital name, probe type, current inspection type, date, inspection time, freezing mark, etc.

- Manufacturer identification
  Show the manufacturer's identity in the upper-left corner of the screen.
- Hospital name
  Show the hospital name. The hospital name setting path is [preset] [system preset][Hospital Information].
- Time
  Show the time, that is, the date and time of the system. The date and time and display format preset path is "[preset] [system preset] [composite preset]". Time as the image freezes when the system freezes.
- Freezing mark
  Freezing mark, ❄ Indicates that the current image is frozen.
- Patient information
  Show patient name, ID, sex, age. Patient information is entered through the “patient Information” dialog box or imported locally stored patient information data in the patient list page.
- Probe type
  Show the currently used probe model or the default probe model.
- Current inspection type

Shows the type of examination currently in use, such as the ABD.

Image parameters and menu area

Image parameters share this area with the menu. When a menu is not displayed on the screen, the area displays the image parameters of the current imaging modes.

- Menu area

  Menu pop-up overrides image parameters.

  Menu operation can be done by touch screen, cursor and multi-function knob.

  The opening and closing of the menu is controlled by the [function]→ [measure] button.

  The menu is divided into menu title bar, menu item and page turn button and so on.

- Image area

  The image area displays images of each mode and probe direction markers, time lines (M mode), PW sampling lines (PW mode), axes (including depth axes, time axes), etc., while annotating information, body marks, measurements, gray bar also appears here.

Zoom in on the image thumbnail area

After entering zoom-in mode, the area displays the thumbnail of the enlarged image, and the thumbnail box shows the current magnified area.

Thumbnail area

A thumbnail showing a stored image or movie under the current patient's examination.

Thumbnail control area

- Page turning: When you save an image with more than one page of thumbnail, click / button to turn down or up;
- Delete: Select one or more thumbnails, click to delete the image;
- Export: Select one or more thumbnails, click to export images to storage such as U disk.

Soft key control area

Soft key operation: click the Soft key directly to control.

【Function】

- Amplify Enter / exit image multiplication
- Comment Enter comment, import the information you want
- Body mark Enter the selection panel, select the body mark you need, change the scanner angle, then confirm or delete it.
- Measure Enter the Measure menu.
- Patient list Enter the Patient list
- Report Enter the Report
- Clear all Delete all comments on screen.
- Arrow Add arrow that can be used for dimensioning, not editable when arrow is yellow, click to blue the arrow，Then you can move the arrow position and adjust the arrow direction with the multi-function knob.
- Save parameters Save self-adjusted satisfactory parameter

Status bar

-  Probe battery power display

-  Wifi connection and exam mode choose interface .
-  Switching of input method
-  Probe USB connection and selection of check Typ
-  Electronic manual
-  System preset
-  Shows the current system for storage, print tasks, and exit the application.

2.9 Information security

2.9.1 Forget password

When the user forgets the password, the software can be reinstalled. At this time, the original password is cleared and a new password can be set.

2.9.2 User classification

User category		Permission division
Main user	Admin	Administrators, regular users and login passwords can be added/modified/deleted to view all patient information.
	Manager	Add/modify/delete common users and login passwords, browse all patient information
	Ordinary account	Can only manage patient information under this account
	First aid mode	No need to log in to the password, only the patient information under the account can be managed

2.9.3 Password setting

The user's login password is 12345678.
After selecting the save password and automatic login function, the user can log in without a password next time, but need to enter the password again every month to ensure the security of use.

2.10 Indicator light

Classification	Status indication	Features
	Flashing	Boot process

Power Indicator	Slow flash	Freeze
	Constantly bright	work
Battery level indicator	Two grids are always bright	More than 75% of electricity
	One grid is always bright (left)	50%~75% of electricity
	One grid is always bright (right)	25%~50% of electricity
	Slow flash	25% or less

3 Basic introduction

3.1 Working power supply

P50 Pocket Ultrasound System does not work when external Power supply is connected.

Connect to the Type-C interface of the probe by the charging power cord as required by the standard.

The external power supply system of P50 Pocket Ultrasound System must meet the following requirements:

Output: 5V 2A DC

internal electric source: 7.4V

Note:

- Please use power adapters and power cords that meet the requirements of the local regulations and use the power adapter to charge the DC 5V/2A adapter.
- The internal power supply system should meet the following requirements:
- The battery have self-discharge rate about 1% one day. You need to charge and discharge the scanner every month no mater you use it or not.
- When you charge the scanner, the scanner will be turned off automatically.

3.2 Turn on / off probe

3.2.1 Turn on probe

⚠ **WARNING:**	**1. Make sure the transducer is connected to the main unit firmly before you turn on the scanner.** **2. When handling the probe head, make sure that the probe is closed or frozen.**

⚠**CAREFUL:**	**Perform routine checks to make sure the scanner is working safely and efficiently. Turn off the scanner and contact with the local representative when you meet unusual situations.**

Check before Turn on the scanner.

Before Turn on the scanner, please carefully check or operate the following items:

Serial number	Inspection items
1	Temperature, humidity and atmospheric pressure shall meet the requirements for use.
2	The probe shall not be damaged or soiled.
3	Clean the site and the environment.
4	Probe cleaning and disinfection.

Press the power button to turn on the probe.

Check whether the probe is normally activated, refer to the following items to open the probe:

Serial number	Inspection items
1	There shall be no abnormal sound, smell or overheating.
2	There is no obvious abnormal noise.
3	Check if the transducer lens surface is overheat when connect the display device to the scanner.

⚠**WARNING:**	**1. The use of abnormal heating probes may burn patients.** **2. If any abnormality is found, the probe is faulty.Turn off the scanner immediately and contact the service representative.**

3.2.2 Turn off the probe

Long press the power button to turn off the scanner, the power light goes out.
After ultrasonic examination, the ultrasonic coupling agent on the surface of the probe should be completely erased. Otherwise, the coupling agent will be solidified on the probe head and affect the quality of the ultrasonic image.

Before and after each ultrasonic examination, the probe should be cleaned and disinfected.

3.2.3 Change the detachable transducer

Change the transducer when the scanner is in frozen or off status.

Attach the transducer to the main unit firmly.

Detach the transducer from the main unit gently.

3.3 Connection

3.3.1 Wifi Connection

After the machine starts, select the current scanner corresponding to the WiFi hot spot name, on the end device click to connect.

3.3.2 USB Connection

Windows: Install the Windows driver in SonoiQ folder , Connect the straight USB-C to the scanner USB-C port, connect the elbow USB-C to the Windows device and you will get images immediately.

Android: Connect the straight USB-C to the scanner USB-C port, connect the elbow USB-C to the Android device and you will get images immediately.

4 Detailed operation introduction

4.1 Image mode

Mode	Explain
【B】	Click to enter B mode.
【M】	Click to enter M mode.
【Color】	Click to enter Color mode.
【Power】	Click to enter Power mode.
【PW】	Click to enter PW mode.

4.2 Image parameter adjustment

Before adjusting the image parameters to optimize the image, adjust the brightness of the display so that it works best.

Purpose	Optional operation
Changing image brightness	Adjust gain Adjust sound power Adjust the TGC for the corresponding target area
Changing gray-scale image effect	Adjust dynamic range Adjust effect Adjust frame correlation Click [one key Optimization] to optimize one key
Increasing frame rate of Gray-scale Image	Reduce depth
Change the effect of blood flow image display	Adjust color gain Adjust color frequency Adjust of deflection Adjust afterglow Adjust scale Adjust speed Adjust wall filter Adjust color priority

4.3 Parameters adjustment for B mode

B mode is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude. To achieve the best possible image quality, properly adjust the display brightness, gain, depth settings, viewing angle, and exam type. Also, select an optimization setting that best matches your needs.

4.3.1 B mode image parameter

During B-mode image scanning, the image parameter area on the left side of the screen provides real-time parameter information, which allows you to adjust the following parameters:

Adjustment method	Parameter term
Control panel adjustment	Gain, depth, one-button optimization
SoftKey adjustment	Frequency, extended imaging, frame-related, dynamic range, effect, focus, spatial compounding, image enhancement, pseudo-color map, left and right turning, up and down, sound power, TGC, TSI

4.3.2 B mode image optimization

Gain

Resume The total gain of the image in the two-dimensional mode ， displays in real time on the image parameter area on the left side of the screen.

Effect By increasing the brightness of the gain image, more echo signals can be observed, but at the same time, there will be more noise.。

Depth

Resume For adjusting the depth of the image display, the range of image depth can be adjusted by different probes. The depth value is displayed in the image parameter area on the left side of the screen in real time.

Effect The deeper the depth, the wider the observed tissue; the smaller the depth, the shallower the observed tissue. When the depth increases, the frame rate decreases.

TGC

Resume The attenuation caused by increasing tissue depth is compensated and the depth gain is adjusted in different segments .

Effect By adjusting the signal gain in a specific depth range, the echo of the tissue image is uniform.

Frequency

Resume The emission frequency of the probe can be selected by fundamental frequency or harmonic frequency.

The frequency value is displayed in real time on the image parameter area on the left side of the screen. There are three frequency modes in the fundamental wave or the harmonic wave: "penetrating power", "conventional", and "resolution".

Effect The higher the frequency, the better the near-field resolution, but the penetration force decreases.

Harmonics can enhance the near-field resolution and reduce the noise with low frequency and large amplitude.

Persistence

Resume Improve the image quality by superposition of adjoin images.

Effect Better image quality, may loss details of the image.

Dynamic range

Resume Adjust the contrast of black-and-white images, compress or expand the gray-scale display range.

Effect The larger the dynamic range, the darker the overall image, the smaller the contrast, and the greater the noise.

Focus Position

Resume Optimize the image of a specific depth by adjusting the location of the focus.

Effect The penetration and resolution near the focal point are higher than those outside the focus.

Photographic enhancement

Resume By enhancing the contour of the image to distinguish the boundary of the image, the goal of optimizing the image is achieved.

Effect The larger the value, the finer the image, and the more prominent the image outline.

Cross Beam

Resume The image is optimized by merging multiple frames from different deflection angles into a single frame.

Effect After opening space recombination, the image has the characteristics of reduced speckle noise and clear image, which improves the contrast resolution and reveals the location of the lesion more easily.

L/R Flip, U/D Flip

Resume By changing the way the image is displayed to obtain a better viewing angle, the vertical flip up and down and the left and right horizontal flip can be carried out. The "Q" mark on the screen is used to identify the direction of the image, and the "Q" mark in the upper left corner is the default image direction of the system.

Effect This function is effective for real-time, frozen and movie playback images.

Acoustical Power

Resume Adjust the power of the probe to emit ultrasound.

Effect The louder power, the overall brightness of the image increases evenly, and the detectable depth also increases. In clinical application, the proper sound power must be selected according to the actual situation and the "ALARA sound power principle".

Gray Map

Resume Adjust the black and white grayscale contrast to optimize the image.

Effect This function is effective for real-time, frozen and movie playback images.

Expand mode

Resume Increase the scanning range of the probe.

Effect The probe's scan range expands and the frame rate drops slightly.

Colorize map

Resume Color difference is used instead of gray difference to image, that is, grayscale atlas colorization.

Effect P50 pocket ultrasound system provides four different pseudo-color maps, which are effective for real-time, frozen and movie playback images.

Biopsy

Resume Choose and set the biopsy guide.

TSI

Resume Tissue feature imaging, according to tissue features to select sound velocity, make the image more typical.

P50 pocket ultrasound system offers four characteristic tissue optimizations: fat, fluid, routine and muscle.

4.4 Parameters adjustment for M mode

Motion mode (M Mode) is an extension of B mode. It provides a trace of the B image displayed over time. A single beam of ultrasound is transmitted, and reflected signals are displayed as dots of varying intensities, which create lines across the screen. It reflects one-dimensional spatial structure, so M-mode is often used to detect the heart.

4.4.1 M mode image parameter

During M-mode image scanning, the image parameter area on the left side of the screen provides real-time parameter information, which allows you to adjust the following parameters:

Adjustment method	Parameter term
Control panel adjustment	Gain, depth
SoftKey adjustment	Frequency, dynamic range, time mark, scanning speed, pseudo-color map, effect, line correlation

4.4.2 M mode image optimization

Gain

Resume Adjust the gain of M mode ， displays in real time on the image parameter area on the left side of the screen.

Effect By increasing the brightness of the gain image, more echo signals can be observed, but at the same time, there will be more noise.

Depth

Resume For adjusting the depth of the image display, the range of image depth can be adjusted by different probes. The depth value is displayed in the image parameter area on the left side of the screen in real time.

Effect The deeper the depth, the wider the observed tissue; the smaller the depth, the shallower the observed tissue. When the depth increases, the frame rate decreases.

Frequency

Resume	The emission frequency of the probe can be selected by fundamental frequency or harmonic frequency. The frequency value is displayed in real time on the image parameter area on the left side of the screen. There are three frequency modes in the fundamental wave or the harmonic wave: "penetrating power", "conventional", and "resolution".
Effect	The higher the frequency, the better the near-field resolution, but the penetration force decreases. Harmonics can enhance the near-field resolution and reduce the noise with low frequency and large amplitude.

Scan speed

Resume	Control M mode refresh speed, scan speed value real-time display in the left side of the screen in the image parameter area.
Effect	More detailed observations can be obtained, such as changing the scanning speed to detect anomalies in the cycle

Dynamic range

Resume	Adjust the contrast of black-and-white images, compress or expand the gray-scale display range.
Effect	The larger the dynamic range, the darker the overall image, the smaller the contrast, and the greater the noise.

Acoustical Power

Resume	Adjust the power of the probe to emit ultrasound.
Effect	The louder power, the overall brightness of the image increases evenly, and the detectable depth also increases. In clinical application, the proper sound power must be selected according to the actual situation and the "ALARA sound power principle".

Colorize map

Resume	Color difference is used instead of gray difference to image, that is, grayscale atlas colorization.
Effect	P50 pocket ultrasound system provides four different pseudo-color maps, which are effective for real-time, frozen and movie playback images.

Gray Map

Resume	Adjust the black-and-white gray-scale contrast to optimize the image.
Effect	P50 pocket ultrasound system provides 18 effects, and is effective for real-time, frozen and cine-played images.

Time mark

Resume	Sets the display state of the time mark on the M image.
Effect	It is helpful to identify the cardiac cycle and find the characteristic lesions.

M Soften

Resume Line correlation is the processing of scan lines of M images.

Effect Suppress noise to make image details clearer.

M line

Resume Adjust the position of the M sampling line.

4.5 Parameters adjustment for Color mode

Color Doppler is used to observe the color blood flow and provide the flow direction and velocity information of the blood flow. In general, red indicates the blood flow to the probe, blue indicates the blood flow away from the probe, the brighter the color, the faster the blood flow, the darker the color, and the slower the blood flow rate.

⚠WARNING

1. **Color Doppler flow can only be used as a reference for doctors and can not be diagnosed directly. It is generally compared with other machines or diagnosed by non-ultrasonic means.**
2. **This device cannot perform long-term examination of the fetus in Doppler mode.**

4.5.1 Color mode image parameter

During C-mode image scanning, the image parameter area on the left side of the screen provides real-time parameter information, which allows you to adjust the following parameters:

Adjustment method	Parameter term
Control panel adjustment	Gain, depth
SoftKey adjustment	Velocity, deflection, Frequency, Color first, baseline, atlas, Wall filter, Sound Power, afterglow

The Color mode shares the probe sound power of the B mode ,When the acoustic power is adjusted, the sound power of the two imaging modes changes synchronously.

Because the Color mode is superimposed by two-dimensional (B) mode and Doppler mode, the two kinds of images change synchronously when magnifying or adjusting the depth.

4.5.2 Color mode image optimization

Gain

Resume To adjust the total sensitivity of the blood flow signal, the gain value is displayed in real time in the image parameter area on the left side of the screen.

Influence If the gain is too high, it will amplify the noise; if the gain is too low, it is easy to lose the blood flow signal.

Velocity

Resume Showing the velocity range of blood flow, for this product, is actually regulating the measurable range of blood flow velocity.

Effect After adjustment, the color blood flow image can be displayed more clearly and accurately.

A lower velocity range should be used to measure low velocity blood flow, and a higher velocity range should be used to measure high speed blood flow.

Influence Aliasing is easy to occur when measuring high-speed blood flow using a lower velocity range.

If the speed scale is too high, it will result in the loss of smaller blood flow signals.

Steer

Resume Used to tilt left and right color blood flow images to obtain more information without moving the probe.

Effect Changing the incident direction of the acoustic beam in color mode, thus changing the angle between the acoustic beam and the direction of blood flow, is only effective for the linear array probe.

Wall filter

Resume The low frequency noise caused by vessel wall vibration is filtered out to display the image information effectively. This function is used to adjust the cut-off frequency of the wall filter in P50 pocket ultrasonic system.

Effect May cause loss of blood flow signals.

Color frequency

Resume Toggles the probe frequency in Doppler mode.

Effect The higher the frequency, the higher the resolution and sensitivity, but the lower the penetration force.

Persistence

Resume	The B images of adjacent frames are averaged to optimize the images.
Effect	Reduce the image noise, optimize the image, make the image more delicate, may cause the loss of specific information.

Priority

Resume	Used to set the level of blood flow display, select the preferred black-and-white or color blood flow display.
Effect	Large value, priority display color image, small value, priority display black-and-white image.

Map

Resume	Color image display effect parameters, according to the need to switch different atlas can get more comprehensive blood flow information.
Influence	This function is effective for real-time, frozen and movie playback images.

Invert

Resume	Set the display mode of Color mode, turn over the color ruler when it is turned on, and change the display mode of blood flow on the image.
Influence	This function is effective for real-time, frozen and movie playback images.

Acoustical Power

Resume	Adjust the power of the probe to emit ultrasound.
Effect	The louder power increases the overall brightness of the image evenly, and the detection depth also increases.
Influence	In clinical application, proper sound power should be selected according to the actual situation and ALARA sound power principle.

4.6 Parameters adjustment for Power mode

Power Doppler mode is used to show the density and energy information of red blood cells in blood flow for a certain period of time, and to express it by color of different luminance, to provide perfusion information of blood flow, but not to provide information of velocity.

4.6.1 Power mode image parameter

During Power mode image scanning, the image parameter area on the left side of the screen provides real-time parameter information, which allows you to adjust the following parameters:

Adjustment method	Parameter term
Control panel adjustment	Gain, depth
SoftKey adjustment	Velocity, Frequency, Color first, dynamic range, atlas, Wall filter, Sound Power, afterglow

The Power mode shares the probe sound power of the B mode ,When the acoustic power is adjusted, the sound power of the two imaging modes changes synchronously.

Because the Color mode is superimposed by two-dimensional (B) mode and Doppler mode, the two kinds of images change synchronously when magnifying or adjusting the depth.

4.6.2 Power mode image optimization

Because of the same Doppler color imaging, most of the image parameter adjustment items in Power mode are consistent with Color mode. Therefore,the following is just a introduction of the image parameters independently adjusted in Power mode.

Gain

Resume Adjusting the total sensitivity of the blood flow energy signal, the gain value is displayed in real time in the image parameter area above the screen.

Effect If the gain is too high, it will amplify the noise; if the gain is too low, it is easy to lose the blood flow signal

Map

Resume Color image display effect parameters.

Effect The energy map provides perfusion information of the image and is sensitive to low-speed blood flow.

Dynamic range

Resume Controls how the echo intensity is converted into a color signal.

Effect After adjusting, it has greater sensitivity to the low energy signal, and increases the display range of the signal.

Steer

Resume Used to tilt left and right color blood flow images to obtain more information without moving the probe.

Effect Changing the incident direction of the acoustic beam in color mode, thus changing the angle between the acoustic beam and the direction of blood flow, is only effective for the linear array probe.

4.7 Parameters adjustment for PW mode

PW mode (spectral Doppler mode) is used to provide the information of blood flow direction

and velocity. The transverse axis of the spectrum pattern represents the time and the longitudinal axis indicates the Doppler frequency shift.

PW mode has the function of distance gating, which can show the velocity, direction and nature of local blood flow at a certain depth.

⚠CAREFUL	**The timing of PW mode is not consistent with that of B/C mode, so it is impossible to move the probe to change the position of measurement when entering PW mode.**

4.7.1 PW mode image parameter

During PW mode image scanning, the image parameter area on the left side of the screen provides real-time parameter information, which allows you to adjust the following parameters:

Adjustment method	Parameter term
Control panel adjustment	Gain, depth
SoftKey adjustment	Speed, baseline, deflection, quick correction angle, flip, SV, wall filter, frequency, dynamic range, volume, recording range, pseudo-color map, sound power, time mark, automatic calculation,automatic calculation parameters

4.7.2 PW mode image optimization

Frequency

Resume Switching the probe frequency in Doppler mode, the frequency value is displayed in the image parameter area on the left side of the screen in real time.

Effect The higher the frequency, the higher the resolution and sensitivity, but the lower the penetration force.

Trace Area

Resume Change the Trace Area between Above, Below and All.

Auto Calculation

Resume Set auto calculation on and off.

Auto Calculation parameters

Resume Set PS, ED, MD, PV, TAMAX, PPG, MPG, HR, VTI, RI, DT, AT, S/D, PI, D/S auto calculation parameters.

Automatic calculation and of parameters automatic calculation

Resume The spectrum Doppler waveform is recorded and the parameters are calculated. The results of the automatic spectrum calculation will be displayed in the measurement window in real time.

Influence The heart rate value obtained by automatic spectrum calculation may have some deviation. If you want to obtain accurate heart rate value, please choose manual measurement to obtain.

Dynamic range

Resume The amount of information that represents the conversion of echo intensity into grayscale gradient spectrum.

Effect Corresponding to the adjustable contrast range of the image, the larger the dynamic range, the richer the level of image display and more information, but the noise will also increase.

Influence This feature is valid for real-time, frozen, and movie playback images.

Audio

Resume Controls and adjusts the output audio size generated by spectrum Doppler.

Effect Combined with the volume signal, we can judge the blood flow state and nature more effectively.

Scanning speed

Resume Controls the refresh speed of PW mode.

Effect More detailed observations can be obtained, such as changing the scanning speed to detect anomalies in the period.

Acoustical Power

Resume Adjust the power of the probe to emit ultrasound.

Effect The louder power increases the overall brightness of the image evenly, and the detection depth also increases.

Influence In clinical application, proper sound power should be selected according to the actual situation and ALARA sound power principle.

Gain

Resume Adjusting the output signal size of the spectrum map, the gain value is displayed in the image parameter area on the left side of the screen in real time.

Effect By increasing the brightness of the gain image, more echo signals can be observed, but at the same time, there will be more noise.

Gray Map

Resume Adjust the black-and-white gray-scale contrast to optimize the image.

Effect Pocket ultrasound system provides 18 effects, and is effective for real-time, frozen and cine-played images.

Baseline

Resume The area where the speed is zero is shown on the spectrum map

Effect The requirements of the speed detected at different parts are adjusted, so that the display of the blood flow is more clear and the aliasing is eliminated. A positive value shows a larger range below the baseline and a negative value shows a larger range above the baseline.

Quick Angle

Resume The correction angle is adjusted rapidly by 60 degrees step, and the angle value is displayed on the right side of the spectrum map in real time.

Influence This feature is valid for real-time, frozen, and movie playback images.

Angle

Resume Adjusting the measurement speed and the actual speed as close as possible, is a kind of correction angle.
When adjusting the angle, the angle value is displayed on the right side of the spectrum map in real time.

Influence This feature is valid for real-time, frozen, and movie playback images.

SV

Resume Adjusting the position and width of the pulse Doppler sampling volume gate, the current SV value is displayed in real time in the image parameter area on the left side of the screen.

Effect When the sampling gate is small, the obtained result is more accurate, and when the sampling gate is large, the information range obtained is larger.

Wall filter

Resume It is used to adjust the cut-off frequency of the wall filter in P50 pocket ultrasonic system, and to filter the low frequency noise caused by the vibration of the vessel wall so as to display the image information effectively. Wall filter values are displayed in real time in the image parameter area on the left side of the screen.

Influence May cause Losing of signals about blood flow velocity.

PW Steer

Resume Change the incident direction of the acoustic beam in PW mode, so as to change the angle between the acoustic beam and the direction of blood flow.

Effect Get more information without moving the probe.

Time mark

Resume Sets the display state of the time flag on the PW image.

Effect It is helpful to accurately locate the time information of special points and identify the characteristic lesions in the fluctuation cycle.

Influence This feature is valid for real-time, frozen, and movie playback images.

Invert

Resume	Turn on this function to flip the spectrum.
Influence	This feature is valid for real-time, frozen, and movie playback images.

5 Measurements

The operation of measurement can be divided into conventional measurement and applied special measuring package.

⚠CAREFUL	1.	**All unsaved data will be lost by shutting down during the measurement process.**
	2.	**During the measurement process, all measurement information on the image will be deleted and the conventional measurement data will be lost once the frozen state is lifted.**
	3.	**A change in mode clears the conventional / applied special measurement data on the screen.**
	4.	**Don't do meaningless measurements.**

5.1 Conventional measurements

5.1.1 2D Conventional measurements

2D conventional measurements are suitable for regular measurements of 2D images such as B, Color, Power and so on. The items of measurement are as follows:

Measure item	Function
Distance	Measure the distance between two points on an ultrasonic image.
Angle	Measured the angle between the two intersecting planes on the ultrasonic image.
Area	Measure the area and perimeter of an enclosed area on an ultrasonic image.
Three distance volume	Measure the volume of the target object.
Recording length	Measure the length of a curve on an ultrasonic image.
Recording area	Measure the area and perimeter of a closed curve area on the ultrasound image.
Length ratio	Measure the length of the two lines on the ultrasonic image and calculate the ratio.
Area ratio	Measure the area of two enclosed areas on ultrasonic images and calculate the ratio.
Histogram	Measure the gray distribution of ultrasonic echo signal in a closed area of ultrasonic image.

5.1.2 Conventional measurements in M mode

M mode measurements are as follows:

Measure item	Function
Distance	Measure the distance between any two points on a vertical line at a given time.
Time	Measure the time interval between two points on the M image.
Gradient	The average slope between two points is calculated by measuring the distance and time of the two points.
Heart rate	On M cardiogram, the interval between two cardiac cycles was measured and the heart rate was calculated.

5.1.3 Conventional measurements in Doppler mode

PW mode measurements are as follows:

Measure item	Function
D speed	On Doppler images, the velocity and pressure difference at some point in the Doppler spectrum waveform are measured.
PS/ED	The velocity (PS) of the systolic peak point and the velocity (ED) of the end diastolic phase were measured on the blood flow waveforms in Doppler images and their pressure difference and resistance index RI, ratio were calculated.
D trace	The clinical parameters such as velocity, pressure difference, index and so on were obtained by depicting the Doppler spectrum waveforms of two cycles.

5.2 Special measuring package

This product provides the following application measurement capabilities:

- Conventional measurement
- Abdominal application measuring package
- Obstetrical application measuring package
- Gynecological application measuring package
- Cardiac application measuring package
- Small organ application measuring package
- Neural application measuring package

6 Cineloop/annotation/body mark

During image scanning, freeze the image by pressing the freeze key. After the image freezes, the probe stops the sound output, leaving all images and image parameters unchanged.
Image freeze state, press the freeze key will thaw the image, the system continues to scan the image.

6.1 Cineloop

After the image freezes, the system supports movie playback and editing functions. At the same time, it supports magnification, post-processing, measurement, annotation, adding body mark and so on.

P50 pocket ultrasound system supports manual playback and automatic playback; automatic and manual playback can be switched between each other.

6.1.1 Cineloop playback

The B mode and M mode cineloop will be played at the same pace.

6.1.2 Save Cineloop

In the image freeze state, click [Save Cine] in the Soft Key area. After you save the cineloop, you can view it locally.

6.2 Annotation

It is often necessary to add comments to ultrasound images during diagnosis. P50 pocket ultrasound system supports two annotation types: typing characters and indicating arrowheads.

6.3 Body mark

The body position of the probe and the position of the probe scanning direction are indicated by the body mark, which can help to explain the image.

7 Probe

7.1 Probe description

7.1.1 Probe type

L-Linear array probe
C-Convex array probe
E-Cavity probe

7.1.2 Probe composition

The transducer is composed of piezoelectric ceramic wafer, acoustic focusing lens and shell.

7.1.3 Probe performance index

The performance indicators of each probe are published as follows:

Table 1 Image performance Indexes

Mode	Order number	Project	Probe model				
			C5-2Fs	C5-2Ks	L11-4Ks	L11-4Gs	C8-5Ks
B/M	A	Probe nominal frequency (MHz)	3.5	3.5	7.5	7.5	6.5
	B	Deviation between acoustic working frequency and nominal frequency (%)	±15	±15	±15	±15	±15
	C	Maximum detection depth(mm)	≥180	≥170	≥60	≥60	≥60
	D	lateral resolution (mm)	≤2 (depth≤80) ≤3(80＜ depth≤130)	≤2 (depth≤80) ≤3(80＜ depth≤130)	≤2 (depth≤50)	≤1 (depth≤50)	≤2 (depth≤50)
	E	Azimuthal resolution (mm)	≤1 (depth≤80) ≤2(80＜ depth≤130)	≤1 (depth≤80) ≤2(80＜ depth≤130)	≤1 (depth≤60)	≤1 (depth≤60)	≤1 (depth≤60)

Mode	Order number	Project	Probe model									
			C5-2Fs		C5-2Ks		L11-4Ks		L11-4Gs		C8-5Ks	
	F	Fade zone(mm)	≤3		≤3		≤3		≤3		≤3	
	G	Slice thickness(mm)	≤8		≤8		≤8		≤8		≤8	
	H	Transverse geometric position precision(%)	≤10		≤10		≤5		≤10		≤10	
	I	Longitudinal geometric position precision(%)	≤10		≤10		≤5		≤5		≤5	
	J	Perimeter and area measurement deviation(%)	±15		±15		±15		±15		±15	
	K	M mode time display deviation(%)	≤10		≤10		≤10		≤10		≤10	
Color	L	Service frequency（MHz）	2.0	3.5	2.5	3.5	5.0	6.0	6.0	7.5	6.0	6.5
	M	Depth of investigation (mm)	≥120		≥120		≥40		≥40		≥40	
	N	Relationship between color blood flow image and gray-scale image of the pipe in which it is located	coincide		coincide		coincide		coincide		coincide	
	O	Blood flow direction requirement	It can be correctly identified and there is no aliasing.		It can be correctly identified and there is no aliasing.		It can be correctly identified and there is no aliasing.		It can be correctly identified and there is no aliasing.		It can be correctly identified and there is no aliasing.	
PW	P	Service frequency（MHz）	2.0	3.5	2.5	3.5	5.0	6.0	6.0	7.5	5.0	6.0
	Q	Depth of investigation(mm)	≥120		≥120		≥40		≥40		≥40	

Mode	Order number	Project	Probe model				
			C5-2Fs	C5-2Ks	L11-4Ks	L11-4Gs	C8-5Ks
	R	Velocity measurement deviation(%)	±20	±20	±20	±20	±20
	S	Accuracy of position of Vernier in Doppler sampling area	Near the wall of the vessel, no velocity indication; center of pipe, maximum velocity display	Near the wall of the vessel, no velocity indication; center of pipe, maximum velocity display	Near the wall of the vessel, no velocity indication; center of pipe, maximum velocity display	Near the wall of the vessel, no velocity indication; center of pipe, maximum velocity display	Near the wall of the vessel, no velocity indication; center of pipe, maximum velocity display

Table 2 Image performance Indexes

Mode	Order number	Project	Probe model	
			E10-4Ks	
B/M	A	Probe nominal frequency (MHz)	6.5	
	B	Deviation between acoustic working frequency and nominal frequency(%)	±15	
	C	Maximum detection depth(mm)	≥60	
	D	lateral resolution (mm)	≤2(depth≤50)	
	E	Azimuthal resolution (mm)	≤1(depth≤60)	
	F	Fade zone(mm)	≤3	
	G	Slice thickness(mm)	≤8	
	H	Transverse geometric position precision(%)	≤10	
	I	Longitudinal geometric position precision(%)	≤5	
	J	Perimeter and area measurement deviation(%)	±15	
	K	M mode time display deviation(%)	≤10	
Color	L	Service frequency（MHz）	6.0	6.5
	M	Depth of investigation (mm)	≥40	
	N	Relationship between color blood flow image and gray-scale image of the pipe in which it is located	coincide	
	O	Blood flow direction requirement	It can be correctly identified and there is no aliasing.	
PW	P	Service frequency（MHz）	5.0	6.0
	Q	Depth of investigation(mm)	≥40	
	R	Velocity measurement deviation(%)	±20	

Mode	Order number	Project	Probe model
			E10-4Ks
	S	Accuracy of position of Vernier in Doppler sampling area	Near the wall of the pipe, no velocity indication; center of pipe, maximum velocity display

7.2 Probe cover

In order to reduce the spread of the disease, it is necessary to take some protective measures. In clinic, we always use ultrasound probe cover to prevent infections.

It is strongly recommended that a qualified and bio-clean probe cover should be used when carrying out cavity inspection.

The probe has to wear a probe protection cover or before the probe is used to examine the human body. Please use the probe protection sheath accepted by the market.

⚠CAREFUL	**1. In order to avoid infection, the probe cover or sheath can be used only one time, and broken ones should never be used.** **2. The probe sheath, made of natural latex and talc, might cause allergic reactions to some people.** **3. Do not use expired probe covers. Check the expiration date of the probe covers before using it.**

Operation steps (for reference only):

1. Put coupling agent into the probe cover to get clear images.
2. Ensure sterility when the probe goes into the protective cover. Making the protective cover properly tense to avoid any wrinkles and bubbles, do not over pull the probe cover.
3. To fasten the probe cover with a string for safety concern.
4. Check the protective covers and ensure no broken ones.

7.3 Check up and maintenance

7.3.1 Check up

Please inspect the device carefully after the cleaning and disinfection completed and before starting to use. Only after the device is confirmed to be in good condition can it be put into use again. Otherwise, please consult the manufacturer for repair services or stop using it.

The specific check methods are as follows:

item	Inspection method	Acceptance criteria

Handle	Visually inspect handle cover, probe interface and Type-c interface	The handle cover shall not be damaged or cracked, and the interface shall be in good condition without deformation or foreign body blockage. It shall be fully dry and no liquid ingress.
Probe lens	Visually inspect the lens surface and the connection of the lens to the sound head cover	The surface of the lens shall not be damaged, cracked, scratched, bulged or discolored. The connection between the lens and the cover must not have
The cover of Probe	Visually inspect the surface of the probe cover	The surface of the shell shall not be damaged or cracked.
Seal ring	Visually inspect the circle of the sealing ring at the joint of the cover for	The sealing ring shall not be damaged, discolored and unglued.
The probe interface	Visually inspect the probe interface	The interface is in good condition without deformation and foreign body
Residue	Visually inspect the probe surface, especially pits and small areas	No residual medical ultrasonic gel, cleaning solution or disinfectant.

7.3.2 Service life

According to the device design requirement, the service life of the main unit is defined 5 years and the probe is defined 3 years. The raw materials of the device will gradually age during the life cycle. If the device continues to be used beyond its service life, the performance may degradation.

The abnormal use such as Impact and drop, incorrect cleaning and disinfection methods may shorten the actual service life of the device. Therefore, after each cleaning and disinfection and before starting the use, the device must be carefully inspected to confirm that the equipment is in good condition.

⚠ WARNING： The manufacturer will not be liable for any risk arising from continued use beyond the life of the product.

7.3.3 Probe maintenance

After each use of the probe, wipe the probe gently and thoroughly with a damp and hot soft cloth dipped in 3.4% saturated acetaldehyde solution.

The probe is a valuable and fragile part, collision or drop is strictly prohibited. When the diagnosis is suspended, it should be placed in the probe box and the instrument should be in a "frozen" state.

Medical ultrasonic coupling agent should be used in diagnosis.

⚠CAREFUL	**The probe might be damaged by repeated coupling agent over a long period of time.** **Check the probe housing frequently for cracks to avoid damaging the internal components，The immersion of the probe in water or liquid is forbidden .**

7.4 Cleaning and disinfection

According to the intended use, the probe is in direct contact with the patient. In order to avoid bacterial infection, after completing a test and turning off the equipment, please clean and disinfect the probe according to the requirements of the instructions. Although the handle does not directly contact the patient, it is an indirect transmission route of pathogenic microorganisms, and the handle needs to be cleaned and disinfected if necessary.

⚠WARNING：	1. Turn off the device after completing each examination, then clean and disinfect the probes as required. 2 The probe is a non-immersion device and can never be submerged in water. 3. It is forbidden to immerse the probe plug in a liquid such as water or an anti - virus solution. Immersion can cause an electric shock or malfunction. 4 If the coupling gel is not completely removed after each detection, it will solidify and reduce the image quality of the probe. 5. Do not place the probe in high temperature environment (over 55℃) during cleaning and disinfection. High temperature may cause the damage of the scanner.. 6. It is your responsibility to comply with the manufacturer's instructions and your institution's policy on cleaning and disinfecting medical equipment,Clean and disinfect your equipment in an appropriate manner.

CAUTION：	1. During cleaning or disinfection, please wear antibacterial gloves to prevent infection. 2. After disinfection, please use sterilizing liquid to thoroughly remove the residues. Chemical residue may be harmful to human body. 3. If you cannot confirm the efficacy of the disinfectant solution, contact the manufacturer for product information.

- Cleaning

Please follow the instructions on the manual:

a) Wear antibacterial gloves to prevent infection.

b) Preparing soapy water:

   i. Preparing soapy water .Take 25～30g soft soap，add 500～600mL distilled water(At room temperature), stirring evenly.

   ii. Rinsing the probe at least with 2L neutral soap water to remove all contaminant.

c) Wash the handle and probe with soapy water, remove attached stains, until no obvious stains are on the handle and probe.

d) Rinse with purified water 2~3 times to remove the soapy liquid on the handle and probe.

e) When cleaning the handle, the handle must be fully assembled with the probe to take advantage of the waterproof effect of the probe seal.

f) During the cleaning process, it is necessary to ensure that the socket of the probe is out of the liquid to prevent the probe from entering the liquid and damaging the probe

g) After cleaning the handle and probe, use a sterile cloth or gauze to wipe off the water on the handle and probe surface. It is forbidden to use heating way to dry the handles and probes.

h) Polyurethane sponge can be used for cleaning. But it is strictly forbidden to use a brush to clean to avoid damage to the handle and probe.

● Low-level disinfection

The low-level disinfection is only suitable for disinfection of probes and handles used on the body surface.

a) Use a medical cotton ball dipped in 75% medical grade alcohol to gently wipe the handle and probe back and forth, keeping the alcohol for 10 minutes.

b) When disinfecting the handle, the handle must be properly assembled with the probe to take advantage of the waterproof effect of the probe sealing ring.

c) After disinfection, dry the handle and probe with a sterile cloth or gauze, and then let the alcohol on the handle and probe surface evaporate naturally. It is forbidden to drying the handle and probe using heat.

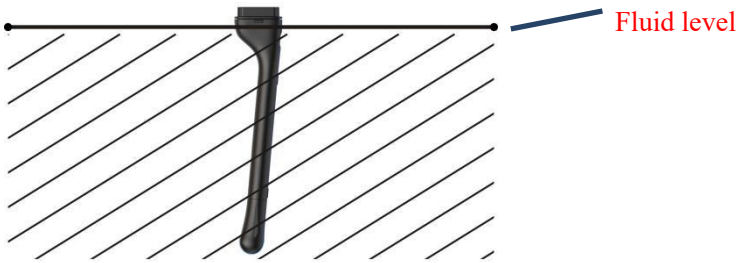
d) Check the handle and probe carefully, and use it only if they are in perfect condition. The specific inspection method shall be operated in accordance with the guidelines in 7.3.1.

e) Precautions for the disinfectant: For the dilution and concentration, disinfection method, and use process, please refer to the instructions on the concentration of the disinfectant and the disinfection method in the instructions for use provided by the manufacturer.

● High-level disinfection

For semi-critical use of transviginal probes, high-level disinfection methods must be used.

a) Immerse the probe in a 0.55% Phthalaldehyde disinfectant solution, and soak it at room temperature (18～26℃) for 12～45 minutes. During the disinfection process, it must be ensured that the liquid level does not exceed the fixed posts of the puncture frame on both sides of the probe.



Intracavity probe immersion level

b) After disinfection, immerse the probe in sterile water to clean and remove residual disinfectant. It needs to be soaked in sterile water 3 times, 1 minute each time, and replace with new sterile water after each soaking. During the cleaning process, make sure that the socket part of the probe is out of the liquid.

c) After cleaning, dry the probe with a sterile cloth or gauze, or place it in a well-ventilated area to let it dry completely. Do not dry the probe.

d) Check the probe carefully. Only the probe that is in perfect condition can be used. The specific inspection method is described in accordance with the guidelines in 7.3.1.

e) Precautions for disinfectant: For dilution and concentration, disinfection methods, and use process, please refer to the instructions for disinfectant concentration and disinfection method in the instructions provided by the manufacturer.

Declaration: the above cleaning and disinfection methods have been confirmed by professional testing institutions, which is safe and effective. The operator can rest assured to use.

⚠WARNING：	**1.** It is strictly prohibited to immerse the handle and probe (except the front end of the probe in the cavity) into any type of liquid or detergent. **2.** No liquid of any kind is allowed to enter the handle and probe. **3.** It is strictly forbidden to disinfect the handle and probe with gas or heating.

4. Do not immerse the probe socket in the solution, although the probe surface is waterproof but only the probe head. Please use medical ultrasonic couplant carefully and clean and disinfect the probe surface
5. Equipment failure, do not repair without authorization, must consult the company for after-sales service.

Caution ：

1. The probe must be cleaned after each use.
2. Probes should not be cleaned with a surgical brush. Even a soft brush may damage the probe. Use only soft material such as soft cloth, polyurethane sponge.
3 Multiple disinfection may lead to degradation of the safety and performance of the probe, and the probe performance should be checked regularly.
4 After disinfection, check whether the probe appearance is cracked or damaged. Include seals that are visibly corroded, discolored, dented, or cracked. If it is damaged, please stop using it and contact our customer service staff or your local representative.

7.5 Disassembly and assembly

When the operator needs to replace another type of probe to perform a new check on the patient or replace a sterilized probe for a new patient check during operation, the equipment needs to be disassembled and assembled.

The specific operation steps for disassembling and assembling equipment are as follows:

a） To make sure that the device is off or frozen, it is recommended to shut down the device.

b） Clean and disinfect the handle and probe. Please refer to section 7.4 Cleaning and Disinfection

c） Remove the handle and probe. When disassembling, pinch the protruding part of the probe shell surface with your fingers, and carefully pull out the probe. Remember: the disassembled probe and the disinfected probe should be placed separately to prevent the disinfected probe from being contaminated.

d） Disinfect the removed handle and probe. The disinfection operation is carried out separately in accordance with the guidelines for 7.4 low-level disinfection and high-level disinfection of cleaning and disinfection.

e） Assemble equipment. Align the connection end of the sterilized probe with the

corresponding port of the handle, and carefully push it into place. Remember: the handles and probes that have just been disinfected are allowed to be reassembled only after they are fully dried.

f） The equipment must be carefully inspected after assembly. The specific inspection shall be operated in accordance with the guidelines in 7.3.1.

g） The device can be used again only after that it is confirmed in perfect condition.

⚠WARNING：	
	1. Cleaning and disinfecting handle and probe must be very careful, avoid by all means into liquid! Otherwise, there is a risk of equipment damage, operator and patient electric shock.
	2. Do not reassemble the disassembled equipment until it is fully dried.
	3. It is forbidden to put the equipment into use before it is confirmed intact.

8 Puncture guide

8.1 Enter or exit puncture mode

- Under the Windows platform, in the SoftKey area, click B mode [Image Parameter Settings], and select [puncture (on / off)].

Set [Bracket] for quick calibration.

Set [guide line], depending on needle selection, A, B, and ALL.

Set [linetype], have thick, medium, thin.

⚠WARNING：	
	1. The guide leads must be calibrated before each puncture. **2. The frozen is not allowed at the time of puncture.** **3. If the puncture needle is not consistent with the position of the puncture guide lead, do not puncture.**

- Exit puncture guiding function
- The system is in the puncture status. Click[Exit] to exit the puncture status.

8.2 Puncture lead calibration

Put the biopsy guide and transducer Acoustical lens under water.

Make sure the rubber of the transducer is above the water.
Click [calibrate] to align the needle with the puncture guide line by adjusting the “position” “angle” “+” and“-”.

After coincident, save the calibrated puncture guide wire parameters.

9 Acoustic output description

The contents of this chapter for the entire system (including main unit , probe, accessories and peripherals), in order to provide relevant information to the operator output sound and how to use ALARA control principle of irradiation time and other important safety information. In addition, this chapter also includes information related to the system of acoustic output real-time display.

Please read this chapter carefully before use.

9.1 Biological effect

It is generally believed that the diagnosis with ultrasound is safe. So far, there is no any reports about ultrasonic cause bodily injury.

In spite of this, we can not arbitrarily believe all the ultrasonic is absolutely safe. Studies have shown that ultrasound with high intensity is harmful to human body.

In recent years, with the rapid development of ultrasound technology, people are increasingly concerned about the application of ultrasonic technique in diagnosis and may lead to the potential risk of biological effect.

9.2 Caution use declaration

Although there is no confirmation of diagnosis by ultrasonic instrument can cause the patient to produce biological effect, but there are still likely to prove the biological effects of existing applications in the future. So we must be careful to use ultrasound, exert their clinical effect in the premise to obtain the necessary clinical information, avoid long time using high intensity ultrasound the.

9.3 ALARA principle(As Low As Reasonably Achievable)

ALARA is the guiding principle for the use of diagnostic ultrasound. Sonographers and

other qualified ultrasound users, using good judgment and insight, determine the exposure that is “as low as reasonably achievable.” There are no set rules to determine the correct exposure for every situation.
The qualified ultrasound user determines the most appropriate way to keep exposure low and bioeffects to a minimum, while obtaining a diagnostic examination.
Users must be responsible for the safety of patients, to the use of ultrasonic, the output power of ultrasonic to choose according to the principle of ALARA.

Other information about the ALARA principle and the potential biological effects of ultrasound, can see the Research Institute of medical ultrasound (AIUM) published the "medical ultrasound safety" file.

9.4 MI/TI description

9.4.1 Basic knowledge of MI and TI

MI: An indication of the likelihood of mechanical bioeffects occurring: the higher the MI, the greater the likelihood of mechanical bioeffects.

TI: The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C under defined assumptions.

- MI (Mechanical index):

The mechanical effect is caused by the acoustic wave within the organization micro bubbles, increasing vibration and the results diabrosis, this reaction is called cavitation.

MI said the possibility of pressure cavitation effect, MI value is obtained by the square root of the peak negative pressure divided by the frequency. Therefore, the higher the frequency or peak negative pressure is low, the MI value is smaller, so the possibility of generating cavitation effect is smaller.

$$MI = \frac{P_{r,\alpha}}{\sqrt{f_{awf}} \times C_{MI}}$$

$$C_{MI} = 1\ (\mathrm{MPa} / \sqrt{\mathrm{MHz}})$$

When the frequency is 1 MHz and the peak pressure is 1 MPa, the MI value is 1 MI can be considered as a threshold for cavitation. When gas and soft tissue exist at the same time to set the MI value to the low value.

- TI (Thermal index):

TI is determined by the total acoustic power and the tissue temperature rise of 1 degrees Celsius required sound power ratio. In addition, the organizational structure of different temperature is different, so the TI is divided into three categories: TIS (soft tissue thermal index (TIB), and TIC (bone thermal index) skull thermal index).

- TIS: soft tissue thermal index applications, such as the abdomen and the heart
- TIB: the use of bone thermal index, such as the fetus (in late pregnancy), focused on or close to the focus of the acoustic beam in the bone
- TIC: Skull thermal index applications such as pediatric and adult skulls.

WFUMB (World Federation of ultrasound in medicine and Biology) statement: 5 minutes irradiation temperature rise of 4 degrees may cause potential harm to the embryo and fetal tissue.

The smaller the MI/TI, the lower the biological effect。

9.4.2 MI/TI display instructions

TI and MI display on the screen of centre. The operator should monitor these index values in the inspection process, and to ensure that in the premise of effective diagnostic information under the irradiation time and the output value is maintained at the lowest possible level.

The TI and MI values are displayed at any operating conditions, and the step value is not more than 0.2.

TI display items can be set in the prefab, open [the image preset parameter]"B/THI" page, you can see the acoustic output parameters preset, as shown below：

Here you can set the level of TI display items and power levels.

Display accuracy is 0.1.

Be careful	**If the MI or TI display values are greater than 1, please follow the ALARA principle carefully**

9.5 Sound power settings

Acoustical power adjustment

In the frozen state of the image, the ultrasonic energy is not output.

Default settings description

The operator is the most important factor to control the sound output.

The intensity level depends on the acoustic output in the scanning area. In the fetal examination, be especially careful control of acoustic output intensity.

In this system, the user can preset the image parameters. Once the preset change default settings for the original machine becomes invalid. Therefore, the user is responsible for the default settings.

Default setting range

Initial setting range of sound output	10% to 100%

The maximum acoustic output limit depending on the selected mode of the probe surface temperature rise and the provisions of the FDA acoustic output of each probe.

Be careful	When you turn on the scanner, change transducer, set a new patient, the system settings will be the default ones.. The user in accordance with the principle of ALARA and meet the FDA 510 (k) Guidance-Track3 limits, the user can through the corresponding increase in the sound power soft menu you can also set the AP value in the preset level.

The sound output system is based on EN 60601-2-37:2008+A1:2015, FDA 510 (K) GUIDANCE, the diagnostic ultrasound equipment acoustic output measurement standard (NEMA UD-2 2004) , diagnostic ultrasound equipment thermal and mechanical index real-time display standard (AIUM and NEMA UD-3 2004) were measured and calculated. For a definition of terms used in the acoustical output tables, see Appendix C.

9.6 Acoustic power control

Sound output depends on the system operator, the operator should obtain qualified under the premise of effective diagnostic image to reduce the acoustic output. There are three types of operation control and sound output control: direct control and indirect control and receiver control.

- Direct control

The system of direct control of acoustic output through the soft menu area [] sound power project adjusting acoustic output size. But in any mode of the acoustic output maximum value can not exceed the acoustic output limit (MI limit of 2 TI, the limit value is 6, ISPTA.3 limit of 720 mW/cm^2).

- Indirect control

Indirect control of acoustic output is mainly caused by the control of image related parameters. These include control operation mode, probe and frequency, focus, depth image and pulse repetition frequency (PRF).

The operating mode determines the ultrasonic beam is scanning and non scanning mode, the thermal effect with M, Doppler, Color are closely related.

The attenuation of the tissue is directly related to the change of the probe and its frequency. The image depth is related to the effective aperture of the probe.

- Receiver control

The receiver (such as gain control, dynamic range, image processing etc.) does not affect the sound output. Therefore, in image optimization, priority should be adjusted to optimize the image receiver control class, followed by direct control and indirect control.

9.7 Acoustic output description

9.7.1 Damping output parameter

In order to determine the relevant parameters of the acoustic output, compared to using a method of ultrasonic system for different frequencies and different depth of focus. This method (also called attenuation method) by measuring the acoustic output. In the water that ultrasonic wave propagation in tissues. Usually 0.3 dB/cm/ MHz average sound intensity attenuation, namely ultrasonic probe send each transmission of a 0.3 dB/MHz cm ultrasonic intensity attenuation, the calculation formula is as follows：

$$I_{atten} = I_{water} \times 10^{(-0.3/10 \times f_c \times z)}$$

9.7.2 Acoustic output limit

In accordance with the FDA requirements of Track 3, the acoustic output limits using the derating (or attenuation) method, as shown in the table below. The use of any probe in any mode of operation, the maximum acoustic output should be listed in the following table limits.

FDA 3 Track maximum sound output limit (attenuation)

Application	$I_{spta.3}$ (mW/cm^2)	$I_{sppa.3}$ (W/cm^2)	or	MI
Other parts (in addition to the eye)	720	⩽ 190		⩽ 1.9

9.7.3 The difference between the actual MI/TI value and the display value

Factors that contribute to display uncertainty

The net uncertainty of the displayed indices is derived by combining the quantified uncertainty from three sources: measurement uncertainty, system and transducer variability, and engineering assumptions and approximations made when calculating the display values.

Measurement errors of the acoustic parameters when taking the reference data are the

major source of error that contributes to the display uncertainty.

The displayed MI and TI values are based on calculations that use a set of acoustic output measurements that were made using a single reference ultrasound system with a single reference transducer that is representative of the population of transducers of that type. The reference system and transducer are chosen from a sample population of systems and transducers taken from early production units, and they are selected based on having an acoustic output that is representative of the nominal expected acoustic output for all transducer/system combinations that might occur. Of course every transducer/system combination has its own unique characteristic acoustic output, and will not match the nominal output on which the display estimates are based. This variability between systems and transducers introduces an error into displayed value. By doing acoustic output sampling testing during production, the amount of error introduced by the variability is bounded. The sampling testing ensures that the acoustic output of transducers and systems being manufactured stays within a specified range of the nominal acoustic output.

Another source of error arises from the assumptions.

9.8 Uncertainty of measurement

I_{spta}	31.2%
I_{sppa}	30.4%
center frequency (f_C)	2%
Total power (W)	30.1%（5.6% Scan mode and combination mode）
Peak negative pressure(pr)	15.5%

9.9 Reference literature for sound power and its safety

(1) “Bio-effects and Safety of Diagnostic Ultrasound” issued by AIUM in 1993

(2) “Medical Ultrasound Safety” issued by AIUM in 1994

(3) "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" issued by AIUM/NEMA in 2004

(4) "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004

(5) "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued by FDA in 2008.

(6) “Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment” issued by IEC in 2015.

9.10 Transducer surface temperature

EN 60601-2-37:2008+A1:2015 according to the requirements of clause 201.11, the transducer surface temperature was measured under two conditions: transducer suspension in the absence of air circulation environment (Still Air) and probe contact phantom (Method B).

The maximum surface temperature and maximum temperature rise of the transducer are listed below：

Transducer	Test method	Operation mode	Ambient (°C)	Initial temperature (°C)	Final Radiating Surface temp.(TF) and/or Temp.Rise (TR) (°C)
C5-2Fs	TMM	Normal(B+C+PW)	24.544	25.261	TF=30.020 TR=4.759
C5-2Fs	Still Air	Normal(B+C+PW)	24.612	24.612	TF=35.528 TR=10.916
C5-2Ks	TMM	Normal(B+C+PW)	24.590	24.539	TF=29.08 TR=4.541
C5-2Ks	Still Air	Normal(B+C+PW)	23.272	23.368	TF=32.995 TR=9.627
L11-4Ks	TMM	Normal(B+C+PW)	23.140	24.330	TF = 29.421 TR =5.091
L11-4Ks	Still Air	Normal(B+C+PW)	22.380	23.340	TF = 34.73 TR =11.390
C8-5Ks	TMM	Normal(B+C+PW)	24.656	25.740	TF = 31.553 TR =5.813
C8-5Ks	Still Air	Normal(B+C+PW)	23.731	23.838	TF = 38.376 TR =14.538
L11-4Gs	TMM	Normal(B+C+PW)	24.717	26.109	TF = 30.553 TR =4.444
L11-4Gs	Still Air	Normal(B+C+PW)	23.827	24.037	TF = 35.407 TR =11.37
E10-4Ks	TMM	Normal(B+C+PW)	24.801	24.658	TF = 28.094 TR =3.436
E10-4Ks	Still Air	Normal(B+C+PW)	24.747	24.275	TF = 33.943 TR =9.668

10 Electromechanical safety standards

The system complies with the EMC test standard EN 60601-1-2: 2006+A1:2013+AC:2014 +A12:2014 +A2:2020.

Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance-Collateral Standard. Electromagnetic Compatibility.

Requirements and Tests.

⚠ **WARNING**	**1. The use of inappropriate accessories will reduce the performance of the product.** **2. The selected adapter should meet the requirements of the EN 60601-1-2: 2006+A1:2013+AC:2014+A12:2014 +A2:2020** **3. The equipment or system may be interfered with by other equipment even if it meets the emission requirements of the corresponding national standards.**

Attention	**1.**	**The use of inappropriate accessories, transducers, and cables may cause the system to be launched with decreased immunity**
	2.	**This system can not be close to or in contact with other equipment, if it is necessary, it must ensure the normal operation of the system in use.**
	3.	**This system requires special protection against EMC, and the need for the installation and maintenance of EMC provided in the information environment to meet the following.**
	4.	**This system is lower than the minimum prescribed amplitude products or minimum operating conditions will lead to incorrect results in physiological signals of patients.**
	5.	**This equipment should not be used in close proximity or stacked with other equipment. If it must be used close to or stacked, it should be observed to operate properly in the configuration in which it is used.**
	6.	**Portable and mobile communication devices will affect the performance of the system. See table 1,2,3,4.**
	7.	**The user shall install and use according to the EMC information provided by the random file.**
	8.	**Portable and mobile RF communication equipment may affect the P50 pocket ultrasound system to avoid strong magnetic interference, such as near microwave ovens, elevators, etc.**
	9.	**Frequency band of emission：2412MHz～2470MHz** **Modulation type：DSSS modulate/OFDM modulate** **Frequency characteristic：802.11b/802.11g** **Effective radiated power：** **① TX power：** **— 18.0dBm@1DSSS** **— 14.5dBm@54OFDM** **② RX sensitivity** **— -95.7dBm@1DSSS** **— -74.0dBm@54OFDM**
	10.	**The guide and manufacturer's statement are detailed in the following table.**

Table 1

Electromagnetic launch guide and manufacturer statement		
This system can be used in a specified electromagnetic environment, users should ensure the use of electromagnetic environment in the following provisions.		
Radiation test	**Radiation test**	**Electromagnetic environment - Description**
RF launch CISPR 11	Group 1	This system uses RF energy inside the machine function only, so the RF emission is very low, not in the vicinity of the electronic equipment to produce any electromagnetic interference.
RF launch CISPR 11	Class B	The system is suitable for both home and direct connection to residential public low voltage power networks
Harmonic launch IEC 61000-3-2	Class A	
Voltage fluctuation / scintillation emission IEC 61000-3-3	accord	

Table 2

Electromagnetic disturbance guidance and manufacturer statement			
This system can be used in a specified electromagnetic environment, users should ensure the use of electromagnetic environment in the following provisions.			
Immunity test	**IEC 60601 Test level**	**Accord level**	**Electromagnetic environment - A Guide**
electrostatic discharge(ESD) IEC 61000-4-2	±6 kV Contact discharge； ±8 kV Air discharge	±6 kV Contact discharge； ±8 kV Air discharge	The ground must be made of wood, concrete or tile. If the floor is covered with synthetic material, the relative humidity is at least 30%
Electric fast pulse group(EFT) IEC 61000-4-4	±2 kV Power cord， ±1 kV I/OCable (length greater than 3 M）	±2 kV Power cord， ±1 kV I/OCable (length greater than 3 M）	The power quality of the network must be a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV Differential mode， ±2 kV common mode	±1 kV Differential mode， ±2 kV common mode	The power quality of the network must be a typical commercial or hospital environment

Voltage dips, short interruptions and voltage variations IEC 61000-4-11	<5% U_T (drop >95% U_T) 0.5cycle 40% U_T (drop 60% U_T) 5 cycle 70% U_T (drop30% U_T) 25cycle <5% U_T (drop >95% U_T) 5s	<5% U_T (drop >95% U_T) 0.5cycle 40% U_T (drop 60% U_T) 5 cycle 70% U_T (drop30% U_T) 25cycle <5% U_T (drop >95% U_T) 5s	The quality of the power supply network must be a typical commercial or hospital environment. If the system needs to be maintained during continuous operation in the power network interruption, we recommend the use of an uninterruptible power supply UPS power supply.
Power frequency magnetic field(50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field must conform to the characteristics of a typical commercial or hospital environment
Be careful： U_T is the AC voltage value before the test voltage is applied			

Table 3

Electromagnetic disturbance guidance and manufacturer statement			
This system can be used in a specified electromagnetic environment, users should ensure the use in the electromagnetic environment in the following provisions.			
Immunity test	**IEC 60601 Test level**	**Accord level**	**Electromagnetic environment - A Guide**
Conduction disturbance rejection IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	1 Vrms	Portable and mobile radio communication equipment must be from the equipment and / or system (including cable included) use any parts of the prescribed distance. This is based on the isolation distance transmitter frequency selection equation is calculated. The calculation formula is recommended isolation distance： $d = 3.5 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz

Radiated immunity IEC 61000-4-3	**10 V/m 80MHz – 2.7GHz**	**10 V/m**	Among them, P is the rated maximum output power of transmitter manufacturers, is a unit of Watt; D is the recommended distance, the units are in meters. Through the measurement of a electromagnetic field by RF transmitter in each frequency range of B must be less than meets the level。 Among them, P is the rated maximum output power of transmitter manufacturers, is a unit of Watt; D is the recommended distance, the units are in meters. Through the measurement of a electromagnetic field by RF transmitter in each frequency range of B must be less than meets the level. 
Be careful 1: In 80MHz-800MHz, using a higher frequency formula **Be careful 2: These guidelines do not apply in all cases. The material structure, objects and people can absorb and reflect electromagnetic waves, thus affecting the electromagnetic propagation**			
A. The radio base station (cellular and wireless) and ground mobile radio mobile phone antenna, receiver, field FM and am radio as well as TV broadcast is unable to use pure theory to accurately estimate. In order to evaluate the electromagnetic environment of fixed RF transmitter generates, should be taken into account. Electromagnetic field measurement method using field measured if the equipment operating environment more than the required RF level, it is necessary to observe the equipment to work properly. Once the abnormal situation, some measures should be taken, such as re placing the machine direction or move it to the environment. B. In the 150kHz-80MHz frequency range, the field strength should be less than 1V/m.			

Table 4

Recommended distance between this system and portable / mobile RF communication equipment	
This system can be used to control the electromagnetic environment in RF interference. In order to avoid the electromagnetic interference, customers or users should maintain the minimum distance between the proposed system and portable / mobile RF communication equipment. The following suggestions to keep the distance is calculated according to the maximum output power of communication equipment.	
Maximum rated	**Distance from the transmitter frequency**（m）

output power of transmitter（W）	150kHz -80MHz $d=\left[\frac{3.5}{1}\right]\sqrt{P}$	80MHz-800MHz $d=\left[\frac{3.5}{3}\right]\sqrt{P}$	800MHz-2.5GHz $d=\left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.11	0.37	0.74
1	3.50	1.17	2.34
10	11.07	3.69	7.38
100	35.00	11.67	23.34

If the rated maximum output power of the transmitter is not included in the values given above, can be estimated by using the corresponding column isolation distance equation. In the equation P is the nominal maximum output power of transmitter manufacturers are given, measured in watts.

If the system image severely disturbed affect diagnosis, it is necessary to set the device away from the noise source or install the external RF transmission power noise filter the noise reduced to an acceptable level.

Be careful 1 : In 80MHz-800MHz, using a higher frequency formula

Be careful 2: These guidelines do not apply in all cases. The material structure, objects and people can absorb and reflect electromagnetic waves, thus affecting the electromagnetic propagation.

Table 5

Fundamental characteristics

Scanning mode: the mode of operation of an ultrasonic diagnostic device, including a series of ultrasonic pulses that generate scanning lines that do not follow the same acoustic path.

Scanning mode	**Parameter**
B mode	**Gain：0-100 tunable** **Maximal acoustic output ： 10-100% tunable** **Depth：** — C5-2Fs probe≥30cm — C5-2Ks probe≥30cm — L11-4Ks probe≥14cm — L11-4Gs probe≥14cm — C8-5Ks probe≥14cm — E10-4Ks probe≥14cm
M mode	
C mode	
Power mode	
PW mode	

GuangDong Youkey Medical Co., Ltd.

Address: Unit 601,6/F,Block B,Building 1,B1 District,Hantian Technology City,Dongping Road,Pingxi Shanghai Village,Guicheng Street,Nanhai District,Foshan City,
Guangdong Province,528200,China

EC REP Share Info GmbH
Heerdter Lohweg 83, 40549 Düsseldorf, CE 0197 Germany

Appendix A Names and contents of toxic and hazardous substances or elements

Table：Names and contents of toxic and hazardous substances or elements

Toxic or hazardous substances or elements	Toxic or hazardous substances or elements					
	lead（Pb）	mercury（Hg）	cadmium（Cd）	Hexavalent chromium（Cr(VI)）	Polybrominated biphenyls（PBB）	Two phenyl ether（PBDE）
Internal wire rod	×	○	○	○	○	○
LCD	○	○	○	○	○	○
Button/Polybrominated biphenyls	○	○	○	○	○	○
Shell(Plastic cement)	○	○	○	○	○	○
Shield	○	○	×	×	○	○
PCBA	×	○	○	○	○	○

○：Said the content of toxic and harmful substances in all homogeneous materials in the parts of the SJ/T11363-2006 in the specified limits requires the following.

×：The toxic and harmful substances exceeded the limitation of SJ/T11363-2006 standard in the content of at least one of the homogeneous materials.

Appendix B Acoustic output data

The meaning of each symbol in the sound output table:

Symbol	Meaning
A	Acoustic attenuation coefficient
A_{aprt}	-12dBOutput acoustic beam area
D_{eq}	Equivalent pore diameter
d_{eq}	Equivalent sound beam diameter
f_{awf}	Sound working frequency
I_{pa}	Pulse average sound intensity
$I_{pa,\alpha}$	Average sound intensity after attenuation
I_{pi}	Impulsive sound intensity integral
$I_{pi,\ \alpha}$	Pulse sound intensity integral
$I_{ta}(z)$	Time average sound intensity
$I_{ta,\ \alpha}(z)$	Decay time average sound intensity
$I_{zpta}(z)$	Spatial peak time average sound intensity
$I_{zpta,\ \alpha}(z)$	Decay time space peak time average sound intensity
MI	Mechanical index
P	output power
P_α	Output power after attenuation
P_1	Bounded output power
p_i	Pulse sound pressure square integral
p_r	Peak sparse sound pressure
$p_{r.a}$	Peak sparse sound pressure
Prr	Pulse repetition frequency
TI	Thermal index
TIS	Soft tissue thermal index
TIB	Bone thermal index
TIC	Skull thermal index
Z	Distance from the sound source to the specified point
z_b	Distance from the sound source to the specified point
z_{bp}	Breakpoint depth

z_s	Depth for TIS

Probe: C5-2Fs Mode: B

Table 201.103		Transducer Model: C5-2Fs, Operating Model: B					
Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.94	*0.20*		*0.20*		*N/A*
Index component value			0.20	*N/A*	0.20	*N/A*	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	*1.56*					
	P (mW)		25.39		25.39		*N/A*
	P_{1x1} (mW)		14.03		14.03		
	Z_s (cm)			*N/A*			
	Z_b (cm)					*N/A*	
	z_{MI} (cm)	2.58					
	$z_{PII.\alpha}$ (cm)	2.58					
	F_{awf} (MHz)	2.76	2.76		2.76		*N/A*
Other Information	*Prr* (Hz)	7163.8					
	Srr (Hz)	22.53					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	23.10					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	33.44					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	53.52					
	$p_{r.}$ at z_{PII}(MPa)	1.99					
Operating control conditions	Focus(mm)	20	20	*N/A*	20	*N/A*	*N/A*
	Depth(mm)	30	30	*N/A*	30	*N/A*	*N/A*
	Frequency(MHz)	3.2	3.2	*N/A*	3.2	*N/A*	*N/A*

Probe: C5-2Fs Mode:M

Table 201.103		Transducer Model: C5-2Fs, Operating Model: M					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.00	0.34		0.31		N/A
Index component value			0	0.34	0	0.31	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.71					
	P (mW)		14.20		14.20		N/A
	P_{1x1} (mW)		N/A		N/A		
	Z_s (cm)			1.75			
	Z_b (cm)					1.85	
	z_{MI} (cm)	2.58					
	$z_{PII.\alpha}$ (cm)	2.58					
	F_{awf} (MHz)	2.93	2.93		2.93		N/A
Other Information	*Prr* (Hz)	7250.3					
	Srr (Hz)	N/A					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	30.04					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	73.56					

	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	120.24					
	$p_{r.}$ at z_{PII}(MPa)	2.01					
Operating Control conditions	Focus(mm)	20	20	20	20	20	N/A
	Depth(mm)	30	30	30	30	30	N/A
	Frequency(MHz)	3.2	3.2	3.2	3.2	3.2	N/A
	Speed	2	2	2	2	2	N/A

Probe: C5-2Fs Mode:B+C

Table 201.103		Transducer Model: C5-2Fs,Operating Model: B+C					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.94	0.29		0.29		N/A
Index component value			0.29	N/A	0.29	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.56					
	P (mW)		40.36		40.36		N/A
	P_{1x1} (mW)		22.30		22.30		
	Z_s (cm)			N/A			
	Z_b (cm)					N/A	
	z_{MI} (cm)	2.58					
	$z_{PII.\alpha}$ (cm)	2.58					
	F_{awf} (MHz)	2.76	2.26		2.26		N/A
Other Information	Prr (Hz)	7163.8					
	Srr (Hz)	22.53					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	23.10					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$or $z_{SII.\alpha}$(mW/cm^2)	42.18					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	65.74					
	$p_{r.}$ at z_{PII}(MPa)	1.99					
Operating control conditions	Focus(mm)	20	20	N/A	20	N/A	N/A
	Depth(mm)	30	30	N/A	30	N/A	N/A
	B Frequency(MHz)	3.2	3.2	N/A	3.2	N/A	N/A
	C Frequency(MHz)	2.0	2.0	N/A	2.0	N/A	N/A

Probe: C5-2Fs Mode:PW

Table 201.103		Transducer Model: C5-2Fs, Operating Model: PW					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.83	0.14		1.21		N/A
Index component value			0	0.14	0	1.21	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.25					
	P(mW)		25.33		25.33		N/A
	P_{1x1}(mW)		N/A		N/A		
	z_s(cm)			2.20			
	z_b(cm)					2.88	
	z_{MI}(cm)	3.08					
	$z_{PII.\alpha}$(cm)	3.08					
	f_{awf}(MHz)	2.26	2.26		2.26		N/A
Other Information	prr(Hz)	1695.4					
	srr(Hz)	N/A					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	95.67					

	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	149.8					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	330.85					
	$p_{r.}$ at z_{PII}(MPa)	1.85					
Operating control conditions	Focus(mm)	20	20	20	20	20	N/A
	Depth(mm)	30	30	30	30	30	N/A
	Frequency(MHz)	2.0	2.0	2.0	2.0	2.0	N/A

Probe: C5-2Fs Mode:B+P

Table 201.103		Transducer Model: C5-2Fs, Operating Model: B+P					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.94	0.31		0.31		N/A
Index component value			0.31	N/A	0.31	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.56					
	P(mW)		43.36		43.36		N/A
	P_{1x1}(mW)		23.96		23.96		
	z_s(cm)			N/A			
	z_b(cm)					N/A	
	z_{MI}(cm)	2.58					
	$z_{PII.\alpha}$(cm)	2.58					
	f_{awf}(MHz)	2.76	2.26		2.26		N/A
Other Information	prr(Hz)	7163.8					
	srr(Hz)	22.53					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	23.10					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	44.23					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	70.05					
	$p_{r.}$ at z_{PII}(MPa)	1.99					
Operating control conditions	Focus(mm)	20	20	N/A	20	N/A	N/A
	Depth(mm)	30	30	N/A	30	N/A	N/A
	B Frequency(MHz)	3.2	3.2	N/A	3.2	N/A	N/A
	C Frequency(MHz)	2.0	2.0	N/A	2.0	N/A	N/A

Probe: C5-2Ks Mode:B

Table 201.103		Transducer Model: C5-2Ks, Operating Model: B					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.12	0.35		0.35		N/A
Index component value			0.35	N/A	0.35	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.97					
	P(mW)		42.28		42.28		N/A
	P_{1x1}(mW)		23.36		23.36		
	z_s(cm)			N/A			
	z_b(cm)					N/A	
	z_{MI}(cm)	5.13					
	$z_{PII.\alpha}$(cm)	5.13					
	f_{awf}(MHz)	3.10	3.10		3.10		N/A
Other Information	prr(Hz)	7162.6					
	srr(Hz)	24.959					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	68.49					

	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	45.47					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	143.12					
	$p_{r.}$ at z_{PII}(MPa)	3.41					
Operating control conditions	Focus(mm)	20	20	N/A	20	N/A	N/A
	Depth(mm)	30	30	N/A	30	N/A	N/A
	Frequency(MHz)	3.3	3.3	N/A	3.3	N/A	N/A

Probe: C5-2Ks Mode:M

Table 201.103		Transducer Model: C5-2Ks, Operating Model: M					
Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.19	0.29		0.48		*N/A*
Index component value			0	0.29	0	0.48	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*2.11*					
	P(mW)		22.29		22.29		*N/A*
	P_{1x1}(mW)		*N/A*		*N/A*		
	z_s(cm)			4.00			
	z_b(cm)					4.47	
	z_{MI}(cm)	5.13					
	$z_{PII.\alpha}$(cm)	5.13					
	f_{awf}(MHz)	3.13	3.13		3.13		*N/A*
Other Information	*prr*(Hz)	7250.3					
	srr(Hz)	*N/A*					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	57.39					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	188.2					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	565.5					
	$p_{r.}$ at z_{PII}(MPa)	3.65					
Operating control conditions	Focus(mm)	20	20	20	20	20	*N/A*
	Depth(mm)	30	30	30	30	30	*N/A*
	Frequency(MHz)	3.3	3.3	3.3	3.3	3.3	*N/A*
	Speed	2	2	2	2	2	*N/A*

Probe: C5-2Ks Mode:B+C

Table 201.103		Transducer Model: C5-2Ks, Operating Model: B+C					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.12	0.40		0.40		N/A
Index component value			0.40	N/A	0.40	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.97*					
	P(mW)		49.93		49.93		*N/A*
	P_{1x1}(mW)		27.58		27.58		
	z_s(cm)			*N/A*			
	z_b(cm)					*N/A*	
	z_{MI}(cm)	5.13					
	$z_{PII.\alpha}$(cm)	5.13					
	f_{awf}(MHz)	3.10	2.29		2.29		*N/A*
Other	*prr*(Hz)	7162.6					
	srr(Hz)	24.959					

Information	n_{pps}	1						
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	68.49						
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	63.76						
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	177.72						
	$p_{r.}$ at z_{PII}(MPa)	3.41						
Operating control conditions	Focus(mm)	20	20	*N/A*	20	*N/A*	*N/A*	
	Depth(mm)	30	30	*N/A*	30	*N/A*	*N/A*	
	B Frequency(MHz)	3.3	3.3	*N/A*	3.3	*N/A*	*N/A*	
	C Frequency(MHz)	2.0	2.0	*N/A*	2.0	*N/A*	*N/A*	

Probe: C5-2Ks Mode:B+P

Table 201.103		Transducer Model: C5-2Ks, Operating Model: B+P					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.12	0.42		0.42		N/A
Index component value			0.42	N/A	0.42	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.97*					
	P(mW)		53.05		53.05		*N/A*
	P_{1x1}(mW)		29.31		29.31		
	z_s(cm)			*N/A*			
	z_b(cm)					*N/A*	
	z_{MI}(cm)	5.13					
	$z_{PII.\alpha}$(cm)	5.13					
	f_{awf}(MHz)	3.10	2.29		2.29		*N/A*
Other Information	*prr*(Hz)	7162.6					
	srr(Hz)	24.959					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	68.49					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	66.95					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	186.61					
	$p_{r.}$ at z_{PII}(MPa)	3.41					
Operating control conditions	Focus(mm)	20	20	*N/A*	20	*N/A*	*N/A*
	Depth(mm)	30	30	*N/A*	30	*N/A*	*N/A*
	B Frequency(MHz)	3.3	3.3	*N/A*	3.3	*N/A*	*N/A*
	C Frequency(MHz)	2.0	2.0	*N/A*	2.0	*N/A*	*N/A*

Probe: C5-2Ks Mode:PW

Table 201.103		Transducer Model: C5-2Ks, Operating Model: PW					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.98	0.25		1.17		N/A
Index component value			0	0.25	0	1.17	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.55*					
	P(mW)		*32.50*		*32.50*		*N/A*
	P_{1x1}(mW)		*N/A*		*N/A*		
	z_s(cm)			3.00			
	z_b(cm)					3.73	
	z_{MI}(cm)	3.80					
	$z_{PII.\alpha}$(cm)	3.80					
	f_{awf}(MHz)	2.53	2.53		2.53		*N/A*
Other	*prr*(Hz)	1695.4					
	srr(Hz)	*N/A*					

Information	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	116					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	235.3					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	456.6					
	$p_{r.}$ at z_{PII}(MPa)	2.16					
Operating control conditions	Focus(mm)	20	20	20	20	20	*N/A*
	Depth(mm)	30	30	30	30	30	*N/A*
	Frequency(MHz)	2.5	2.5	2.5	2.5	2.5	*N/A*

Probe: L11-4Ks Mode:B

Table 201.103		Transducer Model: L11-4Ks, Operating Model: B					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.37	0.078		0.078		N/A
Index component value			0.078	N/A	0.078	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.02*					
	P(mW)		3.68		3.68		*N/A*
	P_{1x1}(mW)		2.15		2.15		
	z_s(cm)			*N/A*			
	z_b(cm)					*N/A*	
	z_{MI}(cm)	0.68					
	$z_{PII.\alpha}$(cm)	0.68					
	f_{awf}(MHz)	7.65	7.65		7.65		*N/A*
Other Information	*prr*(Hz)	4848.6					
	srr(Hz)	13.696					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	110.23					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	11.73					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	16.92					
	$p_{r.}$ at z_{PII}(MPa)	1.24					
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*
	Frequency(MHz)	7.5	7.5	*N/A*	7.5	*N/A*	*N/A*

Probe: L11-4Ks Mode:M

Table 201.103		Transducer Model: L11-4Ks, Operating Model: M					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.40	0.11		0.07		N/A
Index component value			0.11	0	0	0.07	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.11					
	P(mW)		2.10		2.10		*N/A*
	P_{1x1}(mW)		*N/A*		*N/A*		
	z_s(cm)			*N/A*			
	z_b(cm)					1.65	
	z_{MI}(cm)	0.68					
	$z_{PII.\alpha}$(cm)	0.68					
	f_{awf}(MHz)	7.65	7.65		7.65		*N/A*
Other Information	*prr*(Hz)	4750					
	srr(Hz)	*N/A*					

	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	99.82					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	177.3					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	255.75					
	p_r at z_{PII}(MPa)	1.27					
Operating control conditions	Focus(mm)	5	5	5	5	5	*N/A*
	Depth(mm)	15	15	15	15	15	*N/A*
	Frequency(MHz)	7.5	7.5	7.5	7.5	7.5	*N/A*
	Speed	2	2	2	2	2	*N/A*

Probe: L11-4Ks Mode:B+C

Table 201.103		Transducer Model: L11-4Ks,Operating Model: B+C					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.37	0.21		0.21		N/A
Index component value			0.21	N/A	0.21	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.02*					
	P(mW)		12.26		12.26		*N/A*
	P_{1x1}(mW)		7.17		7.17		
	z_s(cm)			*N/A*			
	z_b(cm)					*N/A*	
	z_{MI}(cm)	0.68					
	$z_{PII.\alpha}$(cm)	0.68					
	f_{awf}(MHz)	7.65	5.67		5.67		*N/A*
Other Information	*prr*(Hz)	4848.6					
	srr(Hz)	13.696					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	110.23					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	49.77					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	81.28					
	p_r at z_{PII}(MPa)	1.24					
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*
	B Frequency(MHz)	7.5	7.5	*N/A*	7.5	*N/A*	*N/A*
	C Frequency(MHz)	6.0	6.0	*N/A*	6.0	*N/A*	*N/A*

Probe: L11-4Ks Mode:B+P

Table 201.103		Transducer Model: L11-4Ks, Operating Model: B+P					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.37	0.22		0.22		N/A
Index component value			0.22	N/A	0.22	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.02*					
	P(mW)		12.52		12.52		*N/A*
	P_{1x1}(mW)		7.32		7.32		
	z_s(cm)			*N/A*			
	z_b(cm)					*N/A*	
	z_{MI}(cm)	0.68					
	$z_{PII.\alpha}$(cm)	0.68					
	f_{awf}(MHz)	7.65	5.67		5.67		*N/A*
Other	*prr*(Hz)	4848.6					
	srr(Hz)	13.696					

Information	n_{pps}	1						
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	110.23						
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	45.37						
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	74.33						
	$p_{r.}$ at z_{PII}(MPa)	1.24						
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*	
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*	
	B Frequency(MHz)	7.5	7.5	*N/A*	7.5	*N/A*	*N/A*	
	C Frequency(MHz)	6.0	6.0	*N/A*	6.0	*N/A*	*N/A*	

Probe: L11-4Ks Mode:PW

Table 201.103		Transducer Model: L11-4Ks, Operating Model: PW					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.61	0.55		0.83		N/A
Index component value			0.55	0	0	0.83	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.46*					
	P(mW)		*20.07*		*20.07*		*N/A*
	P_{1x1}(mW)		*N/A*		*N/A*		
	z_s(cm)			*N/A*			
	z_b(cm)					1.65	
	z_{MI}(cm)	0.68					
	$z_{PII.\alpha}$(cm)	0.68					
	f_{awf}(MHz)	5.71	5.71		5.71		*N/A*
Other Information	*prr*(Hz)	4169.2					
	srr(Hz)	*N/A*					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	147.85					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	354.11					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	400.03					
	$p_{r.}$ at z_{PII}(MPa)	1.59					
Operating control conditions	Focus(mm)	5	5	5	5	5	*N/A*
	Depth(mm)	15	15	15	15	15	*N/A*
	Frequency(MHz)	6.0	6.0	6.0	6.0	6.0	*N/A*

Probe: L11-4Gs Mode:B

Table 201.103		Transducer Model: L11-4Gs, Operating Model: B					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.39	0.084		0.084		N/A
Index component value			0.084	N/A	0.084	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.08*					
	P(mW)		3.93		3.93		*N/A*
	P_{1x1}(mW)		2.30		2.30		
	z_s(cm)			*N/A*			
	z_b(cm)					*N/A*	
	z_{MI}(cm)	0.68					
	$z_{PII.\alpha}$(cm)	0.68					
	f_{awf}(MHz)	7.66	7.66		7.66		*N/A*
Other Information	*prr*(Hz)	4848.6					
	srr(Hz)	13.696					

	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	132.05					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	13.60					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	18.81					
	$p_{r.}$ at z_{PII}(MPa)	1.31					
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*
	Frequency(MHz)	7.5	7.5	*N/A*	7.5	*N/A*	*N/A*

Probe: L11-4Gs Mode:M

Table 201.103		Transducer Model: L11-4Gs, Operating Model: M					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.41	0.14		0.07		N/A
Index component value			0.14	0	0	0.07	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.13					
	P (mW)		2.25		2.25		*N/A*
	P_{1x1} (mW)		*N/A*		*N/A*		
	Z_s (cm)			*N/A*			
	Z_b (cm)					1.70	
	z_{MI} (cm)	0.68					
	$z_{PII.\alpha}$ (cm)	0.68					
	F_{awf} (MHz)	7.66	7.66		7.66		*N/A*
Other Information	*Prr* (Hz)	4750.1					
	Srr (Hz)	*N/A*					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$(W/cm^2)	115					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$or $z_{SII.\alpha}$(mW/cm^2)	204.2					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	292.7					
	$p_{r.}$ at z_{PII}(MPa)	1.29					
Operating control condition s	Focus(mm)	5	5	5	5	5	*N/A*
	Depth(mm)	15	15	15	15	15	*N/A*
	Frequency(MHz)	7.5	7.5	7.5	7.5	7.5	*N/A*
	Speed	2	2	2	2	2	*N/A*

Probe: L11-4Gs Mode:B+C

Table 201.103		Transducer Model: L11-4Gs,Operating Model: B+C					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.39	0.23		0.23		N/A
Index component value			0.23	N/A	0.23	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.08*					
	P (mW)		13.15		13.15		*N/A*
	P_{1x1} (mW)		7.69		7.69		
	Z_s (cm)			*N/A*			
	Z_b (cm)					*N/A*	
	z_{MI} (cm)	0.68					
	$z_{PII.\alpha}$ (cm)	0.68					
	F_{awf} (MHz)	7.66	5.67		5.67		*N/A*

Other Information	*Prr* (Hz)	4848.6						
	Srr (Hz)	13.696						
	n_{pps}	1						
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	132.05						
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	55.12						
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	87.88						
	$p_{r.}$ at z_{PII}(MPa)	1.31						
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*	
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*	
	B Frequency(MHz)	7.5	7.5	*N/A*	7.5	*N/A*	*N/A*	
	C Frequency(MHz)	6.0	6.0	*N/A*	6.0	*N/A*	*N/A*	

Probe: L11-4Gs Mode:B+P

Table 201.103		Transducer Model: L11-4Gs,Operating Model: B+P					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.39	0.24		0.24		N/A
Index component value			0.24	N/A	0.24	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.08					
	P (mW)		13.53		13.53		N/A
	P_{1x1} (mW)		7.91		7.91		
	Z_s (cm)			N/A			
	Z_b (cm)					N/A	
	z_{MI} (cm)	0.68					
	$z_{PII.\alpha}$ (cm)	0.68					
	F_{awf} (MHz)	7.66	5.67		5.67		N/A
Other Information	*Prr* (Hz)	4848.6					
	Srr (Hz)	13.696					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	132.05					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$or $z_{SII.\alpha}$(mW/cm^2)	56.34					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	90.15					
	$p_{r.}$ at z_{PII}(MPa)	1.31					
Operating control conditions	Focus(mm)	5	5	N/A	5	N/A	N/A
	Depth(mm)	15	15	N/A	15	N/A	N/A
	B Frequency(MHz)	7.5	7.5	N/A	7.5	N/A	N/A
	C Frequency(MHz)	6.0	6.0	N/A	6.0	N/A	N/A

Probe: L11-4Gs Mode:PW

Table 201.103		Transducer Model: L11-4Gs, Operating Model: PW					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.64	0.52		0.81		N/A
Index component value			0.52	0	0	0.81	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.52*					
	P (mW)		*19.12*		*19.12*		*N/A*
	P_{1x1} (mW)		*N/A*		*N/A*		
	Z_s (cm)			*N/A*			
	Z_b (cm)					1.70	
	z_{MI} (cm)	0.68					

	$z_{PII.\alpha}$ (cm)	0.68					
	F_{awf} (MHz)	5.67	5.67		5.67		*N/A*
Other Information	*Prr* (Hz)	4169.2					
	Srr (Hz)	*N/A*					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	153.35					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	403.35					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	453.6					
	$p_{r.}$ at z_{PII}(MPa)	1.61					
Operating control conditions	Focus(mm)	5	5	5	5	5	*N/A*
	Depth(mm)	15	15	15	15	15	*N/A*
	Frequency(MHz)	6.0	6.0	6.0	6.0	6.0	*N/A*

Probe:C8-5Ks Mode:B

Table 201.103		Transducer Model: C8-5Ks, Operating Model: B					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.56	0.11		0.11		N/A
Index component value			0.11	N/A	0.11	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.38*					
	P (mW)		6.93		6.93		*N/A*
	P_{1x1} (mW)		3.83		3.83		
	Z_S (cm)			*N/A*			
	Z_b (cm)					*N/A*	
	z_{MI} (cm)	1.72					
	$z_{PII.\alpha}$ (cm)	1.72					
	F_{awf} (MHz)	6.04	6.04		6.04		*N/A*
Other Information	*Prr* (Hz)	4848.4					
	Srr (Hz)	23.198					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	91.22					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	30.99					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	51.39					
	$p_{r.}$ at z_{PII}(MPa)	1.61					
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*
	Frequency(MHz)	6.5	6.5	*N/A*	6.5	*N/A*	*N/A*

Probe:C8-5Ks Mode:M

Table 201.103		Transducer Model: C8-5Ks, Operating Model: M					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.57	0.22		0.26		N/A
Index component value			0	0.22	0	0.26	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.42					
	P (mW)		7.50		7.50		*N/A*
	P_{1x1} (mW)		*N/A*		*N/A*		
	Z_S (cm)			1.74			
	Z_b (cm)					1.74	
	z_{MI} (cm)	1.72					

	$z_{PII.\alpha}$ (cm)	1.72					
	F_{awf} (MHz)	6.07	6.07		6.07		*N/A*
Other Information	*Prr* (Hz)	4750					
	Srr (Hz)	*N/A*					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	90.56					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	89.59					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	122.2					
	$p_{r.}$ at z_{PII}(MPa)	1.61					
Operating control conditions	Focus(mm)	5	5	5	5	5	*N/A*
	Depth(mm)	15	15	15	15	15	*N/A*
	Frequency(MHz)	6.5	6.5	6.5	6.5	6.5	*N/A*
	Speed	2	2	2	2	2	*N/A*

Probe:C8-5Ks Mode:B+C

Table 201.103		Transducer Model: C8-5Ks, Operating Model: B+C					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.56	0.19		0.19		N/A
Index component value			0.19	N/A	0.19	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.38*					
	P (mW)		13.27		13.27		*N/A*
	P_{1x1} (mW)		7.33		7.33		
	Z_s (cm)			*N/A*			
	Z_b (cm)					*N/A*	
	z_{MI} (cm)	1.72					
	$z_{PII.\alpha}$ (cm)	1.72					
	F_{awf} (MHz)	6.04	4.48		4.48		*N/A*
Other Information	*Prr* (Hz)	4848.4					
	Srr (Hz)	23.198					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	91.22					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	46.41					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	90.09					
	$p_{r.}$ at z_{PII}(MPa)	1.61					
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*
	B Frequency(MHz)	6.5	6.5	*N/A*	6.5	*N/A*	*N/A*
	C Frequency(MHz)	5.0	5.0	*N/A*	5.0	*N/A*	*N/A*

Probe:C8-5Ks Mode:B+P

Table 201.103		Transducer Model: C8-5Ks, Operating Model: B+P					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.56	0.20		0.20		N/A
Index component value			0.20	N/A	0.20	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.38*					
	P (mW)		14.19		14.19		*N/A*
	P_{1x1} (mW)		7.84		7.84		
	Z_s (cm)			*N/A*			
	Z_b (cm)					*N/A*	
	z_{MI} (cm)	1.72					
	$z_{PII.\alpha}$ (cm)	1.72					

	F_{awf} (MHz)	6.04	4.48			4.48		*N/A*
Other Information	*Prr* (Hz)	4848.4						
	Srr (Hz)	23.198						
	n_{pps}	1						
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	91.22						
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	47.99						
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	95.17						
	$p_{r.}$ at z_{PII}(MPa)	1.61						
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*	
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*	
	B Frequency(MHz)	6.5	6.5	*N/A*	6.5	*N/A*	*N/A*	
	C Frequency(MHz)	5.0	5.0	*N/A*	5.0	*N/A*	*N/A*	

Probe:C8-5Ks Mode:PW

Table 201.103		Transducer Model: C8-5Ks, Operating Model: PW					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.71	0.31		0.70		N/A
Index component value			0	0.31	0	0.70	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.58*					
	P (mW)		*20.44*		*20.44*		*N/A*
	P_{1x1} (mW)		*N/A*		*N/A*		
	Z_S (cm)			1.74			
	Z_b (cm)					1.74	
	z_{MI} (cm)	1.76					
	$z_{PII.\alpha}$ (cm)	1.76					
	F_{awf} (MHz)	4.97	4.97		4.97		*N/A*
Other Information	*Prr* (Hz)	4069.2					
	Srr (Hz)	*N/A*					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	96.28					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	303.1					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	381.75					
	$p_{r.}$ at z_{PII}(MPa)	1.99					
Operating control conditions	Focus(mm)	5	5	5	5	5	*N/A*
	Depth(mm)	15	15	15	15	15	*N/A*
	Frequency(MHz)	5.0	5.0	5.0	5.0	5.0	*N/A*

Probe: E10-4Ks Mode: B

Table 201.103		Transducer Model: E10-4Ks, Operating Model: B					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.67	0.18		0.18		N/A
Index component value			0.18	N/A	0.18	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.59*					
	P (mW)		12.20		12.20		*N/A*
	P_{1x1} (mW)		6.74		6.74		
	Z_S (cm)			*N/A*			
	Z_b (cm)					*N/A*	
	z_{MI} (cm)	1.65					
	$z_{PII.\alpha}$ (cm)	1.65					
	F_{awf} (MHz)	5.57	5.57		5.57		*N/A*

Other Information	*Prr* (Hz)	4850.3					
	Srr (Hz)	23.198					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	109.5					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	50.18					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	99.06					
	$p_{r.}$ at z_{PII}(MPa)	2.19					
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*
	Frequency(MHz)	6.5	6.5	*N/A*	6.5	*N/A*	*N/A*

Probe: E10-4Ks Mode: M

Table 201.103		Transducer Model: E10-4Ks, Operating Model: M					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.67	0.18		0.45		N/A
Index component value			0	0.18	0	0.45	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	1.59					
	P (mW)		6.60		6.60		*N/A*
	P_{1x1} (mW)		*N/A*		*N/A*		
	Z_s (cm)			1.75			
	Z_b (cm)					1.75	
	z_{MI} (cm)	1.65					
	$z_{PII.\alpha}$ (cm)	1.65					
	F_{awf} (MHz)	5.57	5.57		5.57		*N/A*
Other Information	*Prr* (Hz)	4749.9					
	Srr (Hz)	*N/A*					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	103.5					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	152					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)						
	$p_{r.}$ at z_{PII}(MPa)	287					
	$p_{r.\alpha}$at z_{MI} (MPa)	2.19					
Operating control conditions	Focus(mm)	5	5	5	5	5	*N/A*
	Depth(mm)	15	15	15	15	15	*N/A*
	Frequency(MHz)	6.5	6.5	6.5	6.5	6.5	*N/A*
	Speed	2	2	2	2	2	*N/A*

Probe: E10-4Ks Mode: B+C

Table 201.103		Transducer Model: E10-4Ks, Operating Model: B+C					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.67	0.28		0.28		N/A
Index component value			0.28	N/A	0.28	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.59*					
	P (mW)		20.53		20.53		*N/A*
	P_{1x1} (mW)		11.34		11.34		
	Z_S (cm)			*N/A*			
	Z_b (cm)					*N/A*	
	z_{MI} (cm)	1.65					
	$z_{PII.\alpha}$ (cm)	1.65					

	F_{awf} (MHz)	5.57	4.51		4.51		*N/A*
Other Information	*Prr* (Hz)	4850.3					
	Srr (Hz)	23.198					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	109.5					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	60.02					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	115.56					
	$p_{r.}$ at z_{PII}(MPa)	2.19					
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*
	B Frequency(MHz)	6.5	6.5	*N/A*	6.5	*N/A*	*N/A*
	C Frequency(MHz)	5.0	5.0	*N/A*	5.0	*N/A*	*N/A*

Probe: E10-4Ks Mode: B+P

Table 201.103		Transducer Model: E10-4Ks, Operating Model: B+P					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.67	0.30		0.30		N/A
Index component value			0.30	N/A	0.30	N/A	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.59*					
	P (mW)		25.29		25.29		*N/A*
	P_{1x1} (mW)		13.97		13.97		
	Z_S (cm)			*N/A*			
	Z_b (cm)					*N/A*	
	z_{MI} (cm)	1.65					
	$z_{PII.\alpha}$ (cm)	1.65					
	F_{awf} (MHz)	5.57	4.51		4.51		*N/A*
Other Information	*Prr* (Hz)	4850.3					
	Srr (Hz)	23.198					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	109.5					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	61.11					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	120.24					
	$p_{r.}$ at z_{PII}(MPa)	2.19					
Operating control conditions	Focus(mm)	5	5	*N/A*	5	*N/A*	*N/A*
	Depth(mm)	15	15	*N/A*	15	*N/A*	*N/A*
	B Frequency(MHz)	6.5	6.5	*N/A*	6.5	*N/A*	*N/A*
	C Frequency(MHz)	5.0	5.0	*N/A*	5.0	*N/A*	*N/A*

Probe: E10-4Ks Mode: PW

Table 201.103		Transducer Model: E10-4Ks, Operating Model: PW					
Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.75	0.32		0.71		N/A
Index component value			0	0.32	0	0.71	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	*1.67*					
	P (mW)		*21.22*		*21.22*		*N/A*
	P_{1x1} (mW)		*N/A*		*N/A*		
	Z_S (cm)			1.75			
	Z_b (cm)					1.75	
	z_{MI} (cm)	1.70					
	$z_{PII.\alpha}$ (cm)	1.70					

	F_{awf} (MHz)	4.97	4.97		4.97		*N/A*
Other Information	*Prr* (Hz)	4177.5					
	Srr (Hz)	*N/A*					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	101					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	311					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	428.36					
	$p_{r.}$ at z_{PII}(MPa)	2.30					
Operating control condition s	Focus(mm)	5	5	5	5	5	*N/A*
	Depth(mm)	15	15	15	15	15	*N/A*
	Frequency(MHz)	5.0	5.0	5.0	5.0	5.0	*N/A*

Legal manufacturer:

GuangDong Youkey Medical Co., Ltd.
Unit 601,6/F,Block B,Building 1,B1 District,Hantian Technology City,Dongping Road,Pingxi Shanghai Village,Guicheng Street,Nanhai District,Foshan City, Guangdong Province,528200,China

Production sites:
GuangDong Youkey Medical Co., Ltd.
Unit 601,6/F,Block B,Building 1,B1 District,Hantian Technology City,Dongping Road,Pingxi Shanghai Village,Guicheng Street,Nanhai District,Foshan City, Guangdong Province,52800,China

EC REP Share Info GmbH
Heerdter Lohweg 83, 40549 Düsseldorf, CE 0197 Germany