Part No. MTI-RD-FDA-011

# Palmtop Ultrasound Diagnostic System

# MT10P/MT10

# User manual (V2)


**Mytech Intelligence(ShenZhen)Co., Ltd.**

Manufacturer's Address

Mytch Intelligence（Shenzhen）Co., Ltd.
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# Product information page

| | |
|---|---|
| Product name： | Palmtop Ultrasound Diagnostic System |
| Product modle: | MT10P、MT10 |
| Product waterproof Rate： | The protection class of the whole machine is IPX5<br>The protection class of the probe is IPX7 |
| Production date: | In Hand-held ultrasonic diagnostic instrument |
| Product life | 5years |
| Power Requirments: | Battery Nominal Voltage DC3.85V； Input Voltage DC5V； |
| Power input： | 5VA |
| The software edition： | V1 |
| Registrant&production enterprise： | Mytech Intelligence(ShenZhen)Co.,Ltd. |
| Address： | Room604, 605, 615 & 616, Block R3-B, Virtual University Park, No. 018, South 7th Gaoxin Road, Gaoxin Community, Yuehai Street, Nanshan District, Shenzhen |
| Production address： | Room604, 605, 615 & 616, Block R3-B, Virtual University Park, No. 018, South 7th Gaoxin Road, Gaoxin Community, Yuehai Street, Nanshan District, Shenzhen |
| Production license no. ： | |
| Postal code: | 518000 |
| Phone code： | |
| Fax： | |
| Email： | |
| After-sales service unit： | Mytech Intelligence(ShenZhen)Co.,Ltd. |
| Address： | Room604, 605, 615 & 616, Block R3-B, Virtual University Park, No. 018, South 7th Gaoxin Road, Gaoxin Community, Yuehai Street, Nanshan District, Shenzhen |
| Post code： | 518000 |
| Phone code： | |

Mytech Intelligence(ShenZhen)Co., Ltd. has the final interpretation of this instruction manual.

## Intended Use

Palmtop Ultrasound Diagnostic is intended for clinical ultrasound diagnosis.

## User responsibility

The user is responsible for ensuring that meets the following conditions:

1. Any person operating the device shall read and understand the entire contents of this user manual and other attached documents.
2. Any person who operates the device shall be authorized and shall be fully qualified after strict training.

## Warning

1. Please read this manual carefully before using this devicedevice.
2. This manual is only used as a reference for operation, repair and maintenance of the device.
3. Only qualified medical personnel can operate the device.
4. Only images approved by qualified medical personnel can be used for clinical diagnosis.
5. The acoustic power level described in this specification shall be below the maximum allowable value.
6. Do not use too high a power level, although regular ultrasound testing will not cause side effects.
7. Do not place or use flammable, explosive or combustible materials around the main engine.
8. Do not place any liquid material around the device.
9. Liquid immersion should be prevented during device disinfection/sterilization.
10. The maintenance of the device must be carried out by personnel approved by Mytech Intelligence (ShenZhen)Co., Ltd..
11. Do not modify the device. User modification will lead to safety hazards and degrade system performance. The system modification must be completed by a staff approved

by the company.

12. To ensure the accuracy of the user's use of this manual, the contents in this manual can be modified and updated without prior notice to the user based on software upgrades and new clinical findings.
13. Only qualified personnel could login and operate the software following to the instructions, so as to protect the product from being attacked by virus.

## FCC Compliance Statements

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

## Caution

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

## Note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

## RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The portable device is designed to meet the requirements for exposure to radio waves established by the FCC. These requirements set a SAR limit of 4 W/kg averaged over 10 gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the extremity, with 0mm separation.

## Intellectual property

1. Mytech Intelligence(ShenZhen)Co., Ltd. owns the intellectual copyright of all hardware, software and documents of the device.
2. Without permission, any unit, individual or institution shall not copy or copy any part of this manual in any form or by any means.
3. This manual is only used to operate and maintain the system. Mytech Intelligence(ShenZhen)Co.,Ltd. reserves the right not to disclose confidential information.
4. Mytech Intelligence(ShenZhen)Co., Ltd. Has the final right to interpret this non-public publication.

## The statement

1. Although the ultrasonic frequency, intensity, and duration of radiation used during examination with an

Palmtop Ultrasound Diagnostic Systemdo not have any harmful biological effects, it is still recommended to use a minimum acoustic output setting in order to produce satisfactory diagnostic information.

2. The software upgrade of the device supports the addition of new functions or modification of existing functions.Therefore, the contents in this manual can be updated and modified without notifying the user. Please refer to the purchased version.
3. The system functions differently depending on the user's purchase contract, so not all of the descriptions in this manual apply to your system.
4. Mytech Intelligence(ShenZhen)Co., Ltd. (hereinafter referred to as " Mytech Intelligence ") shall not be responsib

5. le for the improper use of the device.If all of the following requirements are met, Mytech Intelligence believes that it is responsible for the performance, reliability and safety of the instrument, and if not, it is not covered by Mytech Intelligence (ShenZhen)Co., Ltd.:
   a) Operate the device in accordance with this operation manual;
   b) The relevant electrical device conforms to the national standards and the operating environment meets the requirements of this operation manual;
   c) The improvement and maintenance shall be carried out by professional personnel recognized by Mytech Intelligence;
   d) All the parts involved in the maintenance and the accessories used shall be provided approved by Mytech Intelligence.

Directory

# Warning system

Any potential or real hazard to the patient or operator in normal use of the system will be dealt with by intien's smart alert system (after sales alert) in order to remove the hazard with the highest efficiency and the shortest time.

Therefore, if the user records to the device for any fault or features and/or the performance of the anomaly, and any use labels, insufficient and these conditions may lead to potential or real harm to the patient or operator, we invite users to apply the form below, or by containing the same data in the table below contains information to inform the company or the official distributor. All system-related data can be found on the nameplate. In this way, we will be able to take all necessary measures with the highest efficiency and in the shortest time.

**After-sales warning form**

To: Mytech Intelligence (ShenZhen)Co., Ltd.

Room604, 605, 615 & 616, Block R3-B, Virtual University Park, No. 018, South 7th Gaoxin Road, Gaoxin Community, Yuehai Street, Nanshan District, Shenzhen

518000

System/device name:……..

REF：…….

SN：……

Ppotential / Real hazard description…….

……...

Records and recommendations……

Contacts /department:…….

Address：……

Phone code：……

Tax:……..

Date:

Signature:

# 1 Product overview

## 1.1 Product introduction

MT10P/MT10 is a professional, innovative and multi-functional real-time high resolution handheld ultrasound diagnostic device.This product innovatively adopts the integrated design of wireless intelligent probe and host, which makes the product structure more compact and compact.The design of the handheld structure makes users more convenient, and the software of the product can be installed in mobile devices such as mobile phones and tablets by users themselves, which is convenient for users to use, but also enables many application scenarios that cannot be solved by traditional desktop ultrasound to be realized.

## 1.2 Product structure composition

Handheld ultrasound diagnostic device is composed of host, probe and software.The product appearance diagram is as follows (figure 1) :

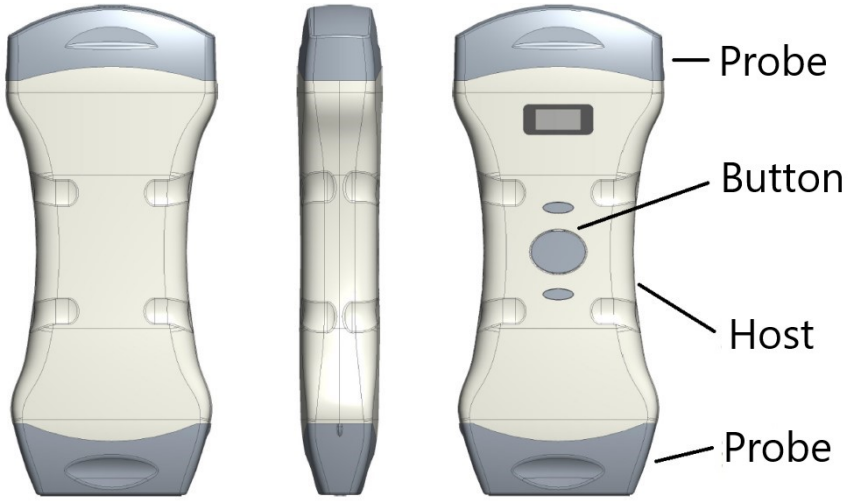



**FIG. 1 appearance of the product (the back, side and front of the diagnostic instrument)**

See table 1 for the type of probe used with diagnostic instrument.

See section 1.5 of this specification for detailed probe specifications and applications.

**Table 1 Probe type table**

| The serial number | Name | Type | Use for |
|---|---|---|---|
| 1 | Convex array probe | C 3-5 | Body surface |
| 2 | Linear array probe | L 5-7 | Body surface |

The integrated design of the probe and main machine.The display device can be configured by users themselves with WIFI smart display (laptops, tablets, mobile phones, etc., based on iOS or Android platform).The software can be downloaded from the client's official website.

The software model name of the product of handheld ultrasound diagnostic instrument (hereinafter referred to as diagnostic instrument) is Sky, and the release version is V1.The software can be installed on Android platform with version 6.0 or above or iOS platform with version 9.0 or above.

For detailed instructions on software installation, see the section "introduction to software 4".

## 1.3 Intended useuse

**Intended use** MT10P/MT10 Palmtop Ultrasound Diagnostic System is intended for clinical ultrasound diagnosis..

◎ The user shall use the device in accordance with local laws. Certain national/regional regulations prohibit the use of this device for specific purposes, such as gender identification.

◎ This device should not be used in the eye or in any situation that may cause the sound beam to pass through the eye.

## 1.4 Applicable people

- Age：unlimited
- Location: global
- Sex：: male and female
- Weight: all weight categories (recorded by BMI)
- Height: unlimited

## 1.5 Contraindication

This device should not be used in the eye or in any situation that may cause the acoustic beam to pass through the eye.

## 1.6 Service life

The service life of the product is Three years from the date of production.Please dispose of the electrical and electronic waste according to the local laws and regulations.

## 1.7 Probe information

Probe performance parameters are shown in table 2.

**Table 2 probe performance parameters**

| Probe model / Probe parameters | C3-5 | L7-10 |
|---|---|---|
| **Type** | **Convex array** | **The line array** |
| **Frequency range（MHz）** | 3-5 | 7-10 |
| **Central frequency（MHz）** | 3.5 | 7.5 |
| **Radius of curvature（mm）** | 60 | - |
| **Detection depth（mm）** | ≥190 | ≥60 |
| **Section thickness（mm）** | ≤5 | ≤5 |
| **M mode time display error** | ±5% | ±5% |
| **Detection depth of color flow imaging（mm）** | ≥120（frequency：2.5MHz） | ≥40（frequency：5.0MHz） |
| **Spectral doppler mode detection depth（mm）** | ≥120（frequency：2.5MHz） | ≥40（frequency：5.0MHz） |
| **Error of blood flow velocity reading（%）** | ±15 | ±15 |
| **Working mode** | B，B/M，PW，Color，PDI | B，B/M，PW，Color，PDI |
| **Use for** | Body surface | Body surface |
| **Application site** | Abdomen, gynecology, obstetrics and urinary system | Superficial tissues, small organs, peripheral vessels |

## 1.8 Operator requirement

MT10P/MT10 is a handheld ultrasound diagnostic device designed for qualified and trained professional operators. The operator must be a doctor or engineer with professional medical knowledge.Only qualified medical personnel may operate the device, including but not limited to the personnel listed below.The operator must read and understand this instruction before starting to use the device.

- □Ultrasonic inspector
- □Cardiologist
- □Obstetrician - pediatric medical obstetrician/expert
- □Radiologist and physician internist
- □System administrator and Customer service engineer

# 2 Safety information

## 2.1 Warning grading

Represents a specific danger situation known to exist that, if the conditions are unreasonable or improperly operated, will result in:

◎ Serious or fatal bodily injury

◎ The great destruction of property

◎ Fire

Represents a specific danger situation known to exist that, if the conditions are unreasonable or improperly operated, will result in:

◎ Serious personal injury

◎ The great destruction of property

Indicates that there is a potentially dangerous situation, if the conditions are unreasonable or improper operation, which may lead to:

◎ Minor personal injury

◎ Loss of property

◎ Missing data

Represents precautions or recommendations to be followed when operating an ultrasonic system, including:

◎ Maintain the best system environment

◎ A note to emphasize or clarify an operation point

## 2.2 Operation taboo

◎ Do not modify the host, probe or software of the device.User modification of device may result in safety issues or system performance degradation. All modifications must be made by a person approved by Mytech Intelligence (ShenZhen)Co., Ltd.

◎ Do not place or use flammable, explosive or combustible materials around the main engine.

◎ Do not place any liquid material around the device.

◎ Do not spray any liquid on the device.

◎ Once any conductive liquid penetrates into the live circuit components, it may cause a short circuit, which may cause a fire.

◎ If you accidentally spill the liquid on the host, please immediately power off and contact your Mytech Intelligence (ShenZhen)Co., Ltd.sales representative.

◎ Do not operate the device in an environment with flammable or explosive liquids, steam or gas (such as oxygen or hydrogen). Sparks generated by device failure may detonate these substances electronically.

◎ Donot used with high-frequency surgical device.

**Operators should pay attention to the following points to avoid such explosion hazards:**

1. If flammable substances are detected in the environment, do not turn on the power.
2. If flammable substances are detected after the system is turned on, immediately turn off the power and clean the flammable substances.

## 2.3 Notes

1） Keep the machine dry at all times, and avoid moving the machine quickly from a cold place to a warm place, otherwise condensation or water droplets may occur, causing a risk of short circuit.

2） There is no danger of burns during normal ultrasound examination, even if the probe surface temperature exceeds the patient's body temperature due to the difference in ambient temperature and inspection mode. To avoid burns, do not place the probe on the same part of the patient's body for a long time. As long as the diagnosis is satisfied, the examination time should be reduced as much as possible.

3） After using the probe, you must thoroughly remove the ultrasonic coupling agent from the surface and place the probe on a flat table. Otherwise, the moisture in the coupling agent may infiltrate the acoustic lens, adversely affecting the performance and safety of the probe.

4） When you need to discard this device system or any accessories, please contact my sales office, after-sales service department or representative office. Do not handle this device system without consulting the relevant department of the company. Our company will not be responsible for any damage caused by non-compliance with this provision.

5） With the extension of use time, the electrical and mechanical safety performance of the machine will be reduced (such as leakage current), and the image sensitivity and accuracy will also deteriorate. In order to ensure the normal performance of the machine, it is recommended to sign a maintenance and repair agreement to prevent accidents and misdiagnosis.

6） Non-professionals are not allowed to disassemble the device case without authorization.

7） When a fault occurs, the power supply should be cut off in time and the designated professional maintenance personnel or manufacturer should be notified.

8） The user must be a trained professional doctor. When using the device to diagnose the patient, the user must implement the detection and inspection of the patient according to the relevant safety regulations and rules to reduce the impact of ultrasound energy on the patient to Within acceptable levels. It should be avoided that the object / site / time or other abnormal usages beyond the inspection / diagnosis needs.

9） Protection of the transducer from high temperature hazards: the ultrasonic transducer that acts on the patient, the surface temperature should not exceed 43 ℃（GB9706.9—2008 42.3a）1）。In addition, when measured according to (22.3a) in IEC60601-2-37, the surface temperature rise should not exceed 27 ° C.

No air circulation test (no ultrasound transmission gel) Temperature rise Ambient temperature should be 23 ℃ ± 3 ℃. The initial temperature of the surface of the transducer assembly should be consistent with the ambient temperature. The temperature rise should not exceed 27 ° C.

10） In order to ensure the safety of patients, medical ultrasound transmission gel complying with YY 0299-2008 should be used.

11） The main body and the probe housing should be checked frequently, and if damaged, cracked or broken, they should be replaced immediately.

12） After the product is discarded, it should be disposed of in accordance with relevant national regulations.

## 2.4 Environmental security

The diagnostic instrument uses an internal battery for power supply. The internal battery is a lithium battery, which must be disposed of as special waste in accordance with applicable local regulations. This device must be treated as electronic and electrical waste, and should be disposed and recycled in accordance with local laws and regulations.

## 2.5 Electromagnetic compatibility

The design of this device can be used in the electromagnetic environment shown in the following table, in compliance with the YY 0505-2012 standard. The operator must ensure that this standard is followed when using this device.

Please install and use the product according to the content of the manual, otherwise it may cause the device's safety and electromagnetic compatibility performance to decrease unexpectedly. Our company assumes no responsibility for the risks.

In addition to the transducers and other accessories sold by the manufacturer of this system as spare parts for internal components, the use of unspecified accessories, transducers, etc. may negatively affect the EMC performance of the device and may cause Increase or decrease in use of machines.

This system should not be used close to or stacked with other device. If it must be used close to or stacked, it should be observed to verify normal operation in the configuration it is used in.

## Electromagnetic emission（Corresponding to IEC60601-1-2, respectively ）

| Guidelines and manufacturer's statement——Electromagnetic emission | | |
|---|---|---|
| The ultrasound diagnostic apparatus is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment: | | |
| Launch test | Compliance | Electromagnetic environment——guide |
| Radio frequency emission CISPR11 | 1group | This product uses radio frequency energy only for its internal functions. Therefore, its radio frequency emission is very low, and the possibility of causing interference to nearby electronic device is very small. |
| Radio frequency emission CISPR11 | Class A | This product is suitable for use in all facilities where non-domestic and residential residential public low-voltage power supply networks are not directly connected |
| Harmonic emission IEC61000-3-2 | Not applicable | |
| Voltage fluctuation / Scintillation launch IEC61000-3-3 | Not applicable | |

Portable and mobile RF communication device may affect the normal use of the product. The use of portable radio frequency communication device (including peripheral device such as antenna cables and external antennas) must not be more than 30cm away from any part of this product. Otherwise, the performance of the device may be reduced.

## Basic performance

The basic performance of this diagnostic device is:

- Does not display noise or artifacts on the waveform or distortion of the image or errors in the displayed values. These values cannot be attributed to physiological effects and may change the diagnosis.
- Does not display error values associated with the diagnosis to be performed.
- Does not produce unexpected or excessive ultrasound output.
- Unexpectedly high surface temperatures of sensor components will not be generated.

## Electromagnetic immunity（Corresponding to IEC60601-1-2, respectively）

| Guide and manufacturer's statement——Electromagnetic immunity | | | |
|---|---|---|---|
| The ultrasound diagnostic apparatus is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment: | | | |
| Immunity test | IEC60601 The test level | Coincidence detection level | electromagnetic environment——guide |
| electrostatic discharge IEC 61000-4-2 | ±6 kV contact discharge ±8 kV air discharge | ±6 kV contact discharge ±8 kV air discharge | The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30% |
| Electrical fast transient burst IEC 61000-4-4 | ±2 kV For the power cord ±1kV On the input/output line | Not applicable | The grid power supply should have the quality used in a typical commercial or hospital environment |
| Surge IEC 61000-4-5 | ±1 kV Wire to wire ±2 kV Line-to-earth | Not applicable | The network power supply should have the quality used in a typical commercial or hospital environment |
| Voltage dips, short interruptions and voltage changes on the power input line IEC 61000-4-11 | ＜5% $U_T$， For 0.5 cycle （ On $U_T$ ,> 95% sag ） 40% $U_T$， For 5 cycle（ On $U_T$ , a 60% drop ） 70%$U_T$， For 25 | Not applicable | The grid power supply should have the quality used in a typical commercial or hospital environment. If the user of the ultrasound system needs continuous operation during a power interruption, it is |

| | | | |
|---|---|---|---|
| | cycle<br>（On $U_T$ , a 60% drop）<br>＜5% $U_T$，For 5s<br>（On UT,> 95% sag） | | recommended that the ultrasound system use an uninterruptible power supply or battery power supply |
| power frequency magnetic field<br>（50Hz）<br>IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic field should have the characteristics of power frequency magnetic field level in a typical place in a typical commercial or hospital environment |
| Notes：$U_T$ refers to the AC grid voltage before applying the test voltage. | | | |
| Guide and manufacturer's statement——Electromagnetic immunity | | | |
| The ultrasonic diagnostic apparatus is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment: | | | |
| Immunity test | IEC 60601 immunity test level | Coincidence detection level | electromagnetic environment——guide |
| The radio frequency transmission<br>IEC 61000-4-6<br><br>radio-frequency radiation<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz ～ 80 MHz<br><br>3V/m<br>80 MHz ～ 2.5 GHz | Not applicable<br><br>3V/m | Portable and mobile RF communications device should not be used closer to any part of the ultrasound system than the recommended isolation distance, including cables. The distance should be calculated by the formula corresponding to the transmitter frequency.<br>Recommended isolation distance<br>$d = 1.2\sqrt{P}$<br><br>$d = 1.2\sqrt{P}$ 80 |

| | | | |
|---|---|---|---|
| | | | MHz～800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz～2.5GHz<br>in the formula：<br>*P* ——According to the maximum rated output power of the transmitter provided by the transmitter manufacturer, the unit is watt (W)；<br>*d* ——Recommended isolation distance in meters (m)。<br>The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field[a] and should be lower than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of device marked with the following symbol. |

Notes1：At the 80 MHz and 800 MHz frequency points, the formula for the higher frequency band is used.

Noyes2：These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

[a]The field strength of fixed transmitters, such as base stations for wireless (peak / cordless) phones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, cannot theoretically be accurately predicted. To assess the electromagnetic environment of fixed RF transmitters, surveys of electromagnetic sites should be considered. If the measured field strength of the ultrasonic diagnostic instrument is higher than the applicable RF compliance level above, the ultrasonic diagnostic instrument should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ultrasound system.

[b] In the entire frequency range from 150 kHz to 80 MHz, the field strength should be less than 3V / m.

## Recommended isolation distance between portable and mobile RF communication device and ultrasonic diagnostic device

（Corresponding to IEC60601-1-2 ）

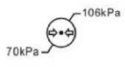
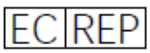
| Recommended isolation distance between portable and mobile RF communication device and ultrasonic diagnostic device | | | |
|---|---|---|---|
| Ultrasonic diagnostic device is expected to be used in an electromagnetic environment where radio frequency radiation disturbance is controlled. According to the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication device (transmitter) and the ultrasonic diagnostic device as recommended below | | | |
| Maximum rated output power of the transmitter W | Isolation distance corresponding to different frequencies of the transmitter /m | | |
| | 150 kHz~80 MHz $d = 1.2\sqrt{P}$ | 80 MHz~800 MHz $d = 1.2\sqrt{P}$ | 800 MHz~2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |
| For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column. Here P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W).<br>Notes1：At 80 MHz and 800 MHz frequency points, the formula for the higher frequency range is used.<br>Notes2：These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people. | | | |

# 2.6 Device labels and symbols

The symbols used for devices and labels are shown in table 3.

**Table3 Device label and description**

| No | label | implication /purpose |
|---|---|---|
| 1 |  | Warning: indicates that the user needs to consult the important warning information in the operating instructions. |

| No | label | implication /purpose |
|---|---|---|
| | | For example, warning messages and precautions that cannot appear on medical device products for many reasons. |
| 2 |  | BF type application parts. |
| 3 |  | Contains RF transmitters or external markings of device or device parts that use RF electromagnetic energy for diagnosis or treatment |
| 4 |  | Indicates that the user needs to consult the instructions |
| 5 | **IPX5** | The protection class of the whole machine is IPX5 |
| 6 | **IPX7** | The protection class of the probe is IPX7 |
| 7 |  | Electrical and electronic waste. Indicates that electrical and electronic device waste is not allowed to be treated as unsorted municipal waste and must be recycled or reused separately. If you want to scrap the device, please dispose of it according to local laws and regulations. |
| 8 |  | Fragile, handle with care. |
| 9 |  | Avoid rain and keep dry. |
| 10 |  | Recyclable packaging |
| 11 |  | The pollution control mark for electronic information products, where the number "3" in the mark is the environmental protection use period (in years). |
| 12 |  | Read instruction sign |
| 13 |  | Manufacturers:Mytech Intelligence(ShenZhen)Co.,Ltd. Manufacturer's address:Ruigu408, 2-10 Jinlong Avenue South, Shahu Community, Biling Street, Pingshan District, Shenzhen, China |
| 14 |  | Storage condition Environmental temperature: -20℃ ~ 40℃; |
| 15 |  | Storage condition relative humidity: 0% ~ 93% |
| 16 |  | Storage conditions atmospheric pressure: 70kPa ~ 106kPa |
| 17 |  | EU representative information |

| No | label | implication /purpose |
|---|---|---|
| 18 | CE | CE compliant marking |

## 2.7 Patient safety

◎ Please enter the patient's name and ID number accurately. Incorrect patient identification may lead to incorrect diagnosis.

◎ After the probe is disinfected and sterilized, chemical reagents or gases must be completely removed. The remaining chemical reagents or gases will not only harm the human body, but also may cause damage to the probe.

◎ This device should not be used for the eyes or any situation that may cause the sound beam to pass through the eyes.

◎ After each patient is checked, make sure that the probe and reusable accessories are cleaned and disinfected.

◎ When using a pacemaker, please use this system with caution.

◎ Normal ultrasound examination does not pose a risk of burns, even if the probe surface temperature exceeds the patient's body temperature. To avoid burns, do not place the probe on the same part of the patient's body for a long time.

## 2.8 Operator safety

◎ Only qualified clinicians or medical personnel familiar with ultrasound technology can perform scans on patients, and unauthorized personnel must not misuse the device. Only qualified doctors, medical personnel familiar with ultrasound technology, or sonic spectrum testers can scan patients. Unauthorized personnel are not allowed to use this device.

◎ If flammable substances are detected in the environment, do not plug in the power supply or start the device software.

◎ If flammable substances are detected, please evacuate the area and make the ventilation smooth before turning off the device.

◎ Do not open the case. If you open the case while the power is on, it may cause a short circuit or electric shock.

◎ Do not try to disassemble this product! There is a risk of electric shock when disassembling this product. Repairs, maintenance and internal system adjustments can only be performed by qualified Mytech Intelligence professionals.

◎ To prevent electric shock, turn off the power switch before cleaning the device.

◎ Risk of electric shock. Never try to disassemble the device yourself. Repairs and internal adjustments can only be carried out by professionals authorized by our company.

◎ Before cleaning the device, stop using the device to prevent electric shock.

◎ 。Do not modify this product, including system components, software, and cables. Modification of device by users may lead to safety problems and reduced system performance. All modifications must be completed by personnel approved by our company.

◎ Do not place liquid above the device. If conductive liquid penetrates into live circuit components, it may cause a short circuit and cause a fire.

◎ Do not operate the device in an environment with flammable or explosive liquids, vapors or gases such as oxygen or hydrogen.These can be triggered electronically by device failure or by sparks from a fan motor.

To avoid fatigue of the operator's hands, wrists or arms, please note the following:

◎ Keep your body in a balanced position during the scanning operation.

◎ During the operation, avoid repeated operation for a long time, and take regular breaks to relax the muscles.

◎ Do not hold the probe too hard to avoid operating in an uncomfortable posture and cause fatigue to the operator's hands, wrists, or arms.

## 2.9 Safety of host and probe

◎ Pay attention to safety during operation to prevent the main unit or probe from being damaged by hand slipping.

◎ Do not place liquids around the device to prevent liquids from entering the device. During the disinfection and sterilization process of the probe, prevent the disinfectant from invading the device.

◎ The content of the logo on the back of the device explains the electrical requirements of the device. Incorrect connection with the power supply will endanger the electrical safety of the system.

◎ After the device is dropped or immersed in liquid, please contact the manufacturer in time. Do not reuse it without the manufacturer's testing and maintenance.

## 2.10 As Low As Reasonably Achievable

When using ultrasound, the As Low As Reasonably Achievable should be implemented.

On the premise of obtaining diagnostic information, the lowest level of energy that will not cause biological effects should be used as much as possible. The amount of ultrasonic energy depends on the output energy and scanning time. The ultrasound intensity required by different patients and clinical cases is different. Not all inspections can be done by outputting very low energy ultrasound. Too low output energy will affect the B-mode image and Doppler mode spectrum quality; too high output energy will not improve the image quality, but will increase the risk of biological effects.

◎ When acquiring clinical information, the user must perform the ultrasound examination procedure with the lowest output level and radiation time according to the principle of being smaller and smaller.

## 2.11 Biological effects

In recent years, with the rapid development of ultrasound diagnostic technology, people are more and more concerned about the potential risks of ultrasound applications and diagnostic technologies in terms of possible biological effects. So far, although it is generally believed that diagnostic ultrasound is safe. No human injuries caused by ultrasound have been reported. Despite this, we cannot arbitrarily believe that all ultrasonic waves are absolutely safe. Related research has confirmed that high-intensity ultrasound is harmful to human tissues.

# 3 System preparation

## 3.1 Environmental requirements

◎ Keep the device dry at all times, and avoid moving the device quickly from a cold place to a warmer place, otherwise condensation or water droplets may occur, causing a risk of short circuit.

It is recommended to wait for 4 hours in a warm environment before switching on.

The environmental requirements for the operation/transportation and storage of the device are shown in table 4.

**Table4 Environmental requirements**

| Environmental characteristicsDevice Status | temperature | humidity | pressure |
|---|---|---|---|
| **operating state** | 5～30℃ | 10～85%（No condensation） | 700～1060 hPa |
| **storage stage** | -20～40℃ | ≤93% | 700～1060 hPa |

| | | | |
|---|---|---|---|
| **travel position** | -20～40℃ | ≤93% | 700～1060 hPa |

## 3.2 Biocompatibility and infection control

The probe must be cleaned properly before each inspection. For more information on probe cleaning and disinfection, please refer to the "9 Maintenance and Care" chapter.

Parts in contact with the patient's body

According to the design purpose, the probe and the host material in contact with the patient's body should meet the requirements of the applicable part of IEC60601-2-37 series "Biological Evaluation of Medical Devices". There have been no reports of negative effects on these materials.

Latex allergic patients

Due to reports of severe allergic reactions to latex, the US Food and Drug Administration (FDA) issued a warning about manufacturing latex products.

Mytech Intelligence 's probe and host do not contain latex.

## 3.3 Mobile / transport device

**operating steps**

1. Turn off the power switch;
2. Clean the head part of the probe;
3. Place the device in the packaging box for movement and transportation.

The packaged machine should be stored in a room free of corrosive gases and well-ventilated.

**transportation**

There are simple shock-absorbing measures in the box of this machine, suitable for aviation, railway, highway and ship transportation. During transportation, avoid rain and snow splashing, inversion and collision.

**keep in storage**

1. The machine should be stored in a dry and clean room.
2. The room should be well ventilated to avoid strong sunlight and corrosive gases.
3. If the storage period of the machine exceeds 6 months, the machine should be taken out of the packaging box, and after working for 4 hours after being energized, the instrument should be placed in the original packaging box in the direction shown on the packaging box.

## 3.4 Power and charging requirements

**built-in electronic ballast**

Lithium ion battery dc3.85v, 2800mAh.It can run continuously for more than 2 hours.

**Charging requirements**

Use a wireless charger to charge the scan tool.

The recommended wireless charger specifications are:

Input voltage: DC5V, 2A;

Output voltage：DC5V；

Maximum power: 5W。

◎ The charging current and charging voltage of the lithium ion battery cannot exceed the rated input current and voltage.

◎ Do not open the device and casing, and do not try to replace the battery to avoid the risk of electric shock due to loose cables.

◎ Do not disassemble the charger, as this may cause an electric shock hazard.

◎ Do not connect with non-medical electrical device that does not meet safety standards.

◎ Do not use the charger outdoors or in humid places.

◎ When the device is charging, please stop using the device. Only after the charging is completed, can it be used normally.

◎ If the device is not used for a long time, it should be charged with some electricity and stored in a dry, cool, and storage-friendly environment, and the battery should be charged every three months.

◎ Be sure to use the recommended charger to charge the battery. The use of other batteries or chargers may harm or damage the product and will render it useless.

◎ Exposing the product to an environment that is too hot or too cold may reduce the storage capacity and service life of the battery.

## 3.5 Open package

In order to prevent potential damage during transportation, this diagnostic instrument has been carefully packed. Before opening the package, please check whether the outer package is obviously damaged. If you find a defect or damage, please contact your local dealer.

After unpacking, please check whether the contents of the package are intact. The following items should be included:

1、Handheld Ultrasound Diasonograph；

2、Operating manual；

3、Qualification。

## 3.6 Connect the system

**Please check before starting**

1. Check whether there are cracks or loose screws in the device casing；
2. Check whether there are gaps or cracks in the probe part；
3. The device shell and probe part are normal before proceeding to the next operation。

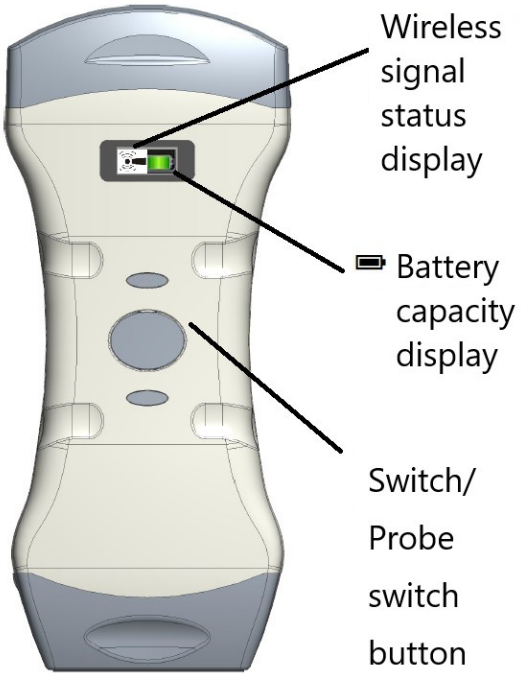
**Preparation Of Fittings**

1. Prepare a wireless charger for charging the host.
   For the recommended specifications of the wireless charger, please refer to the chapter "3.3 Power and Charging Requirements".
2. Prepare one tablet or smartphone for Android or iOS to install diagnostic software.
   The recommended tablet specification is：
   Screen：8 inch，Resolution: 1920x1200；
   CPU：Snapdragon 660 (or equivalent)；
   Memory：2GB RAM or above，32GB storage memory or above；
   Battery：5000MAH or above。

**Install software**

1. Install the APP on an android tablet or phone：Use WeChat or QQ to scan the back

| | |
|---|---|
| **APP** | cover QR code of this manual for installation.<br>2. Install the APP on an iOS iPad or iPhone：Open APP Store，Enter "Sky" in the search bar to find the software and download as well as install。 |
| **Turn on / off the host** | Press the power switch button to start the probe. After the probe is started, if you press the button shortly, you can achieve the freeze function； Press the button for about 3 seconds to switch the probe, that is, activate another probe； Press the button for about 5 seconds, the device shuts down。 |




**Picture 2 Product key and display diagram**

| | |
|---|---|
| **Wifi connection between host and display terminal** | The first connection between this diagnostic device and an intelligent display terminal device (tablet computer or smart phone) requires a Wifi password.<br>After the diagnostic instrument is powered on, open the device's LAN Wifi settings, you can find the Wifi name of the wireless probe in the Wifi list (generally starts with SX-, etc., and ends with the mantissa part of the probe serial number), click the Wifi and enter the password, password The last 7 digits of the lower case serial number of the WXP + probe. The serial number information can be found in the main body.<br>When the host is successfully connected to the intelligent display terminal, the system enters the ultrasound inspection interface by default. At this time, click the "Freeze" button to enter the ultrasound B mode real-time scanning mode. |
| **Please check after booting** | 1. Enter B mode, no abnormal noise, black screen or flicker in the image area；<br>2. Touch the surface of the probe by hand without abnormal heating；<br>3. The indicator of the freeze button of the host is displayed normally。 |

◎ If the probe becomes abnormally hot during use, it may burn the patient. If any abnormal phenomenon is found, it indicates that the machine is defective, please shut down immediately and contact your Mytech Intelligence sales representative.

◎ When the device is charging, please stop using the device. Only after the charging is completed, can it be used normally.

## 3.7 Charging device

When the battery is low, you need to charge the device. The wireless charger that meets the requirements recommended by our company must be used to charge the device. The recommended wireless charger specifications can be found in the "3.3 Power and Charging Requirements" chapter.

When using a wireless charger to charge the device, place the back of the system, that is, the body surface marked with the wireless charging symbol, on the charging surface of the wireless charger. When the scan tool is charging, the battery indicator will flash, showing the battery being charged. If all four power display symbols are lit and the power indicator stops flashing, it means that the battery is fully charged. At this time, the device can be removed from the wireless cha

◎ If the instrument is not used for a long time, it should be charged and discharged once a month.

◎ When the device is charging, it cannot be used. After the charging is completed, it can be used normally.

◎ The instrument contains a built-in lithium battery. The device should not be near or thrown into the fire source to avoid explosion.

◎ Users cannot replace the built-in lithium battery of the instrument by themselves, and the manufacturer must replace it.

# 4 Software introduction

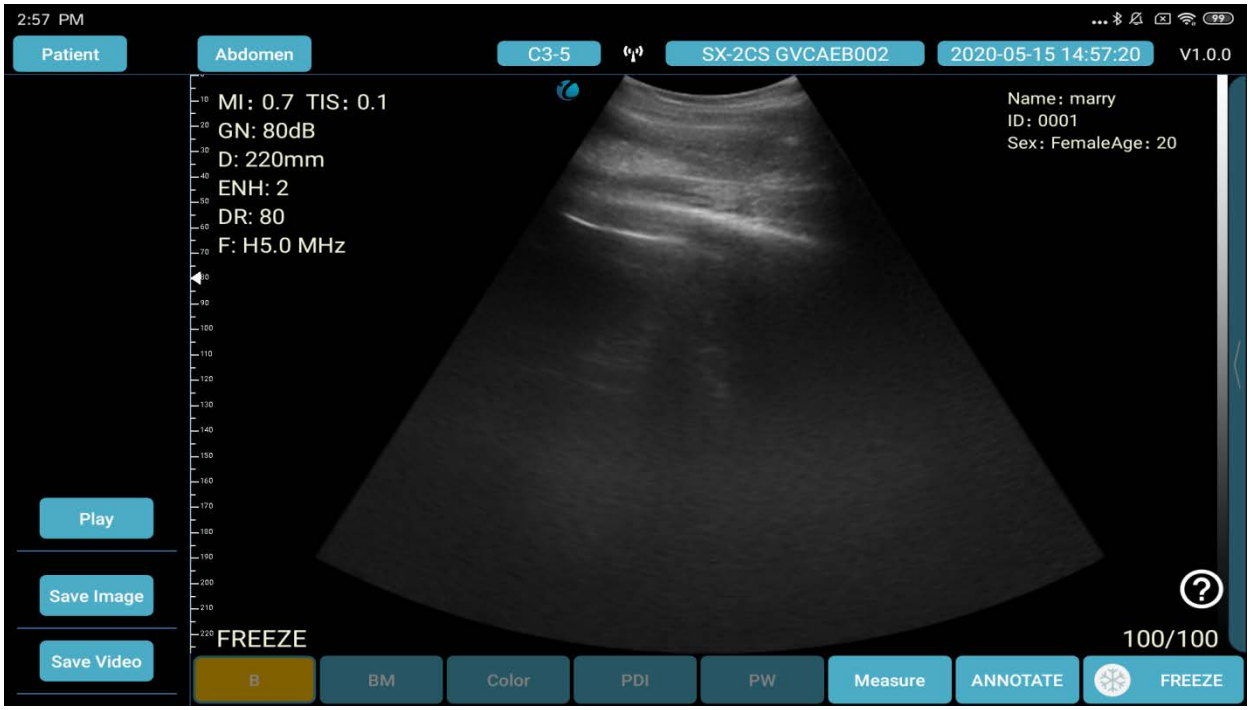
## 4.1 Enter the software APP interface

Click on the icon of the diagnostic instrument software APP that has been installed on the smart display terminal (tablet computer or smartphone)，like this“ 

”， After opening, the following boot interface will appear first on the display screen, including company logo icon information。

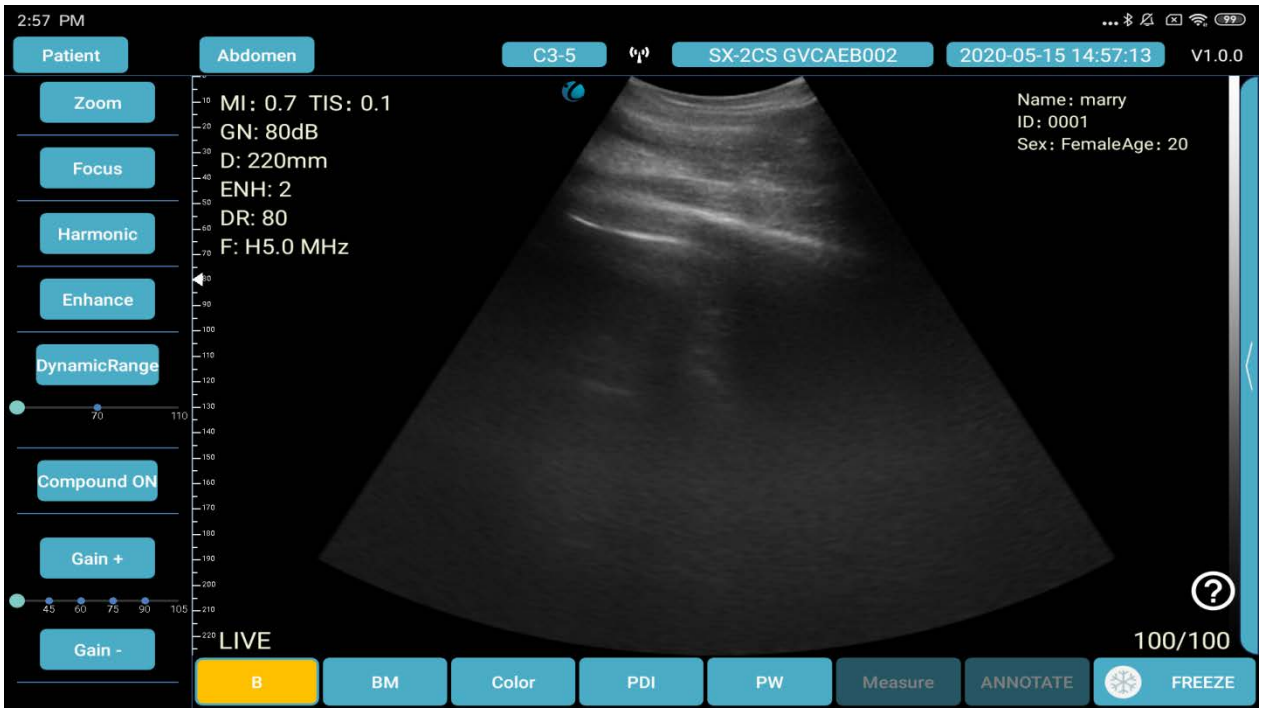

**Picture 3 startup logo picture**

After the startup Logo interface is briefly displayed, enter the operation interface of the diagnostic instrument software.As shown in the figure below.The default state is frozen.



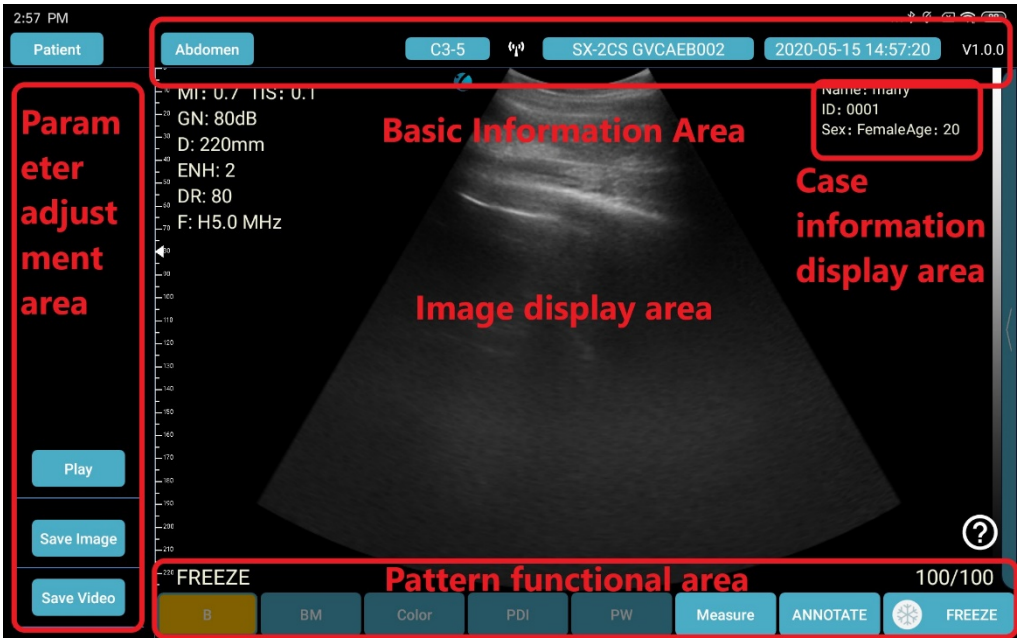

**Picture 4 Operation interface（Freeze mode）**

Click“ FREEZE ”button. When the frozen state is released, the system enters the real-time scanning state in the ultrasound B mode.




**Picture 5 Operation interface（Real-time scanning status）**

The functional area of the main interface of the software is divided as follows:



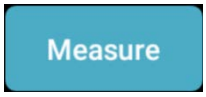
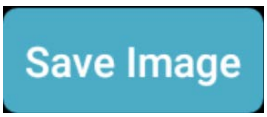
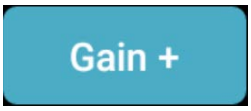
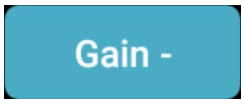
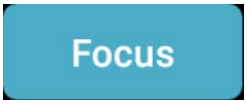

**Picture 6 Software interface function area division**

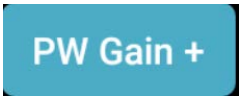
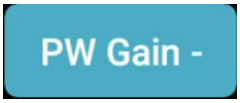
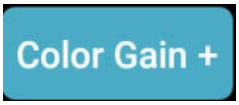
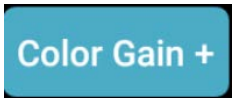
## 4.2 Software operation interface and function introduction

The icon function description of this device's software operation interface is shown in table 5.

**Table 5 Software button introduction**

| No | icon | functional description |
|---|---|---|
| 1 | Patient | Click to open the case information input interface. After the case information is saved, it will be displayed in the case information display area. |
| 2 | Abdomen | Displays the clinical application site selected for the current examination. For example, the thyroid gland will appear as; or the abdomen. |
| 3 | C3-5 | Displays the probe model selected for the current inspection. Such as C3-5. |
| 4 | SX-2CS GVCAEB002 | Display Wifi hotspot information of the currently connected host. |
| 5 | 2020-05-15 14:57:13 | Displays the date and time |

| | | |
|---|---|---|
| 6 |  | Click to switch to B mode imaging |
| 7 |  | Click to switch to BM mode imaging |
| 8 |  | Click to switch to Color mode for imaging |
| 9 |  | Click to switch to energy Doppler mode imaging |
| 10 |  | Click to switch to pulse Doppler mode imaging |
| 11 |  | Click to measure, including measurement sub-items such as distance / trajectory / angle |
| 12 |  | Enter a comment on the image |
| 13 |  | Images freeze and thaw |
| 14 |  | Save single image |
| 15 |  | Save the entire image video |
| 16 |  | Increase image gain |
| 17 |  | Reduce image gain |
| 18 |  | Adjust the detection depth of the image |
| 19 |  | Adjust the focus position of the image |

| | | |
|---|---|---|
| 20 |  | Click to enter harmonic imaging |
| 21 |  | Adjust the edge enhancement of the image |
| 22 |  | Adjust the dynamic range of the image |
| 23 |  | Cursor angle for changing blood flow direction |
| 24 |  | Device for adjusting filtering frequency of pulse wave or continuous wave Doppler low frequency signal |
| 25 |  | Adjust the color pulse repetition frequency that is the color range |
| 26 |  | In the color blood flow mode, the direction of the color sampling frame is changed; in the pulse Doppler mode, it is used to change the angle of the spectrum sampling line. |
| 27 |  | Change the size of the sampling volume |
| 28 |  | Change the baseline value |
| 29 |  | Increase pulse gain |
| 30 |  | Reduce pulse gain |
| 31 |  | Increase color flow gain |
| 32 |  | Reduce color flow gain |
| 33 |  | Increase energy Doppler gain |

| | | |
|---|---|---|
| 34 |  | Reduce energy Doppler gain |
| 35 | TGC function menu | Click "<" on the right side of the screen to pop up the menu, and adjust the TGC by sliding |
| 36 |  | Atlas of ultrasound teaching. Click the icon to pop up the content of the ultrasound teaching map. |

## 4.3 Patient information

**Describe**

Before the exam, please enter the new patient information.

**Operate**

1. Click the menu icon  , Open the menu to edit patient information;
2. Fill in the patient information on the screen one by one and save it after completion.

◎ Always know the correct identification of all patient data, and verify the accuracy of such data when entering the patient ’s name or ID number.

◎ Please ensure the confidentiality of patient data.

# 5 ScanAsyst

## 5.1 B Mode imaging

### 5.1.1 B Mode summarize

**Purpose** B mode, also known as 2D mode, is the default mode of the system and is used to display two-dimensional images and measurements related to soft tissue anatomy.

**Operate**

1. Long press the host switch to turn on the power; open the software and connect the host to the intelligent display terminal device;
2. Select the probe needed for inspection by pressing the button; Click the menu to create new patient information; Set reasonable parameters, cooperate with doctors and patients, and perform scanning;点击“ 

”， Freeze the image；
3. Measure and calculate data as needed；
4. Save the image and complete the inspection.

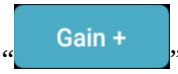
### 5.1.2 Optimize B mode image

**Optimize** During real-time scanning, on the left side of the image, the following parameters can be adjusted: gain, depth, focus position, image enhancement, dynamic range, 8-segment TGC.

#### B mode gain

**Describe** The B mode gain increases or decreases the amount of echo information displayed in the image. If enough echo information is produced, it has the effect of brightening and darkening the image.

**Operate**

In the left column of the image, click “ 

”or“ 

” to adjust the gain.

◎ For better image brightness, always optimize the B-mode gain before deciding whether to increase the sound power.

◎ If the image is still unclear after the gain is changed, try applying some couplant.

#### Image enhancement

**Describe** Image enhancement can enhance tissue structure, such as tissue edges / boundaries.

**Operate**

During real-time scanning in B mode, slide on the left side of the image 

to adjust the level of image edge enhancement;

◎ Image enhancement is only available in real-time mode, not in freeze or movie mode.

◎ If the image enhancement level is too high, the image grain will become larger, please use it with caution.

### Dynamic Range

**Describe** The increased dynamic range generates more signals (even noise), which makes the image appear brighter. The dynamic range is reduced and the weak signal display is darker.

**Operate**

When real-time scanning in B mode, click 

and slide to adjust the dynamic range.

◎ The small dynamic range (compression) value can suppress the weak signal (make the blood flow and cyst liquid tissue inside cleaner), but may make the image particles larger and less dense.

◎ Too high dynamic range may introduce noise.

### TGC

**Describe** TGC amplifies the return signal and corrects tissue attenuation. The TGC chutes are distributed in proportion to the corresponding image depth. When adjusting the TGC, the TGC menu can be pulled from the right side of the screen.

**Operate** During real-time scanning in B mode, click the "<" on the right side of the screen to pop up 

menu, and adjust the gain of the corresponding depth on the image by sliding.

## 5.2 Color flow model imaging

### 5.2.1 Color mode imaging

**Purpose** Color mode is an imaging mode in which blood flow velocity color coding is added to the B mode image. The qualitative information of red and blue color coding related to the relative speed and direction of fluid motion is added to the Color mode image.

**Operate**

1. Obtain a higher-quality B-mode image, and place the region of interest in the center of the B-mode image;

2. Click 

，Activate Color mode，The image area displays a default ROI window, and the depth of the color mode array element is located at the center of the ROI window;
3. Use your fingers to move the four ends of the ROI window, adjust the size of the ROI window, and press and hold the ROI window to move the position of the ROI window;
4. Optimize color blood flow parameters, such as color gain, to obtain high-quality Color mode images;
5. Click“ 

”，Freeze the image， The image can be measured；
6. Save the image after the measurement is completed and complete the inspection

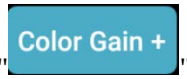
## 5.2.2 Optimize the image in Color mode

**Summarize** To obtain high-quality Color mode images, especially the blood flow on the scanning plane, like carotid imaging, ensure that the angle between the ultrasound beam and the blood flow direction is as small as possible, so that the most reliable and sensitive color blood flow During real-time scanning, on the left side of the image, the following parameters can be adjusted: gain, wall filtering, PRF, deflection angle, dynamic range, 8-segment TGC.

### Color Model gain

**Describe** Color mode gain enhances or reduces the overall Doppler signal. Too much gain will cause color noise, and insufficient gain will reduce the color flow information.

**Operate**

When scanning in Color mode in real time, click " 

" or " 

" to adjust the gain.

### Image enhancement

**Describe** Image enhancement can enhance tissue structure, such as tissue edges / boundaries.

**Operate**

When scanning in Color mode in real time, slide 

on the left side of the image to adjust the level of image edge enhancement;

◎ Image enhancement is only available in real-time mode, not in freeze or movie mode.

◎ If the image enhancement level is too high, the image grain will become larger, please use it with caution.

### Color PRF

**Describe** Pulse repetition frequency (PRF) is the reciprocal of the pulse repetition period (the time interval between two pulses being transmitted). Detection of high-speed blood flow requires a large PRF, otherwise it will cause color confusion. To detect low-speed blood

flow, a small PRF is required to keep low-frequency signals from being filtered out, so that low-speed blood flow can be detected.

**Operate**

When scanning in Color mode in real time, find 

on the left side of the image and click to select the appropriate PRF value.

◎ The adjustment range of PRF is limited to the scanning area. For example, a deep color ROI does not support high PRF.

### Color TGC

**Describe**

TGC amplifies the return signal and corrects tissue attenuation. The TGC chutes are distributed in proportion to the corresponding image depth. When adjusting TGC, the TGC curve will pop up automatically on the right side of the screen.

**Operate**

When scanning in Color mode in real time, click "<" on the right side of the screen to pop up the 

menu and adjust the gain of the corresponding depth on the image by sliding.

### Dynamic Range

**Describe**

The dynamic range is increased, generating more signals (even noise), which makes the image display brighter. The dynamic range is reduced and the weak signal display is darker.

**Operate**

When scanning in Color mode in real time, click 

and slide to adjust the dynamic range.

◎ The small dynamic range (compression) value can suppress the weak signal (make the blood flow and cyst liquid tissue inside cleaner), but may make the image particles larger and less dense.

◎ Too high dynamic range may introduce noise.

## 5.2.3 Power Doppler imaging

**Purpose**

Power Doppler imaging (PDI) is used to display the intensity (or energy) of the blood flow signal, not the blood flow rate. Since Doppler frequency shift information is not used, PDI is less prone to confusion and does not depend on the scanning angle.

When scanning in Color mode in real time, click 

to activate energy Doppler

imaging.

**Optimize** During real-time scanning, on the left side of the image, the following parameters can be adjusted: gain, wall filtering, PRF, deflection angle, dynamic range, 8-segment TGC.

# 5.3 Pulsed doppler mode imaging

## 5.3.1 Overview of PW mode

**Purpose** Color mode is an imaging mode in which pulse Doppler is added to the B-mode image. The user locates the blood vessel through the sampling gate, displays it on the B-mode ultrasound image, and can measure the blood flow at a fixed point. The flow velocity spectrum in the sampling gate is represented graphically on the Y axis and time on the X axis.

**Operate**

1. Get a higher-quality B-mode image
2. Click 

to activate the PW mode and place the spectrum sampling line at the position of the blood vessel of interest in the B mode image;
3. Adjust the sampling line angle, sampling solvent and other parameters to obtain high quality image signal;
4. Optimize PW mode parameters, such as adjusting PW gain, wall filtering, etc., to obtain high-quality PW mode images;
5. Click " 

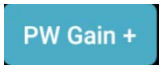
" to freeze the image and perform measurement operations on the image;
6. After the measurement is completed, save the image and complete the inspection.

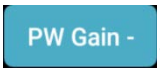
## 5.3.2 Optimize PW mode imaging

**Overview** During real-time scanning, on the left side of the image, the following parameters can be adjusted: gain, dynamic range, PRF, correction angle, sampling volume, deflection angle, baseline, 8-segment TGC.

### PW mode gain

**Describe** The PW mode gain enhances or reduces the overall Doppler signal. Too much gain will cause noise, and insufficient gain will reduce blood flow information.

**Operate** During real-time scanning in PW mode, click " 

" or " 

" to adjust the gain.

## Image enhancement

**Describe** Image enhancement can enhance tissue structure, such as tissue edges / boundaries.

**Operate**

In real-time scanning in PW mode, slide 

on the left side of the image to adjust the level of image edge enhancement;

◎ Image enhancement is only available in real-time mode, not in freeze or movie mode.

◎ If the image enhancement level is too high, the image grain will become larger, please use it with caution.

## PRF

**Describe** Pulse repetition frequency (PRF) is the reciprocal of the pulse repetition period (the time interval between two pulses being transmitted). Detection of high-speed blood flow requires a large PRF, otherwise it will cause color confusion. To detect low-speed blood flow, a small PRF is required to keep low-frequency signals from being filtered out, so that low-speed blood flow can be detected.

**Operate**

When scanning in real time in PW mode, find 

on the left side of the image and click to select the appropriate PRF value.

◎ The adjustment range of PRF is limited to the scanning area.

## TGC

**Describe** TGC amplifies the return signal and corrects tissue attenuation. The TGC chutes are distributed in proportion to the corresponding image depth. When adjusting TGC, the TGC curve will pop up automatically on the right side of the screen.

**Operate** During real-time scanning in PW mode, click "<" on the right side of the screen to pop up the 

menu, and adjust the gain of the corresponding depth on the image by sliding.

## Dynamic Range

**Describe** The dynamic range is increased, generating more signals (even noise), which makes the image display brighter. The dynamic range is reduced and the weak signal display is darker.

**Operate**

During real-time scanning in PW mode, click 

and slide to adjust the dynamic range.

◎ The small dynamic range (compression) value can suppress the weak signal (make the blood flow and cyst liquid tissue inside cleaner), but may make the image particles larger and less dense.

◎ Too high dynamic range may introduce noise.

## 5.4 B/M mode imaging

### 5.4.1 M mode Overview

**purpose**

The M mode is used to check the movement of tissues, and displays the amplitude change caused by the time change (for example, frame by frame) of a sound beam direction selected by the user. M mode is often used to view moving images of the heart.

**Operate**

1. Click 

to enter M mode;
2. Touch to move the sampling line to the area of interest, and touch to locate the sampling line;
3. Click 

to stop M imaging, the user can measure, calculate, save;
4. Click 

and exit B mode。

**Optimize**

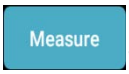
During real-time scanning, on the left side of the image, the following parameters can be adjusted: gain, depth, focus position, image enhancement, dynamic range, 8-segment TGC.

# 6 Measurement function

## 6.1 Distance (length) measurement

**Operating steps**

1. When the system enters the probe working mode, press the freeze button " 

" to freeze the image, and click " 

" to open the measurement submenu.

2. Click " 

" in the measurement submenu to start the length measurement.

3. Use your finger to select the position of the starting point and the ending point on the touch screen. The system automatically measures the distance between the two points and gives the measured value in the image area; the result is displayed in the upper right of the image in real time. The position of the selected point can be fine-tuned by clicking the " 
" four direction keys.

## 6.2 Angle measurement

**Operating steps**

1. When the system enters the probe working mode, press the freeze button " 

" to freeze the image, and click " 

" to open the measurement submenu;

2. Click " 

" in the measurement submenu to start angle measurement;

3. Use your finger to click on the touch screen to select the position of the starting point and the ending point. A straight line appears on the screen. Select a point outside the line to form another line, the system automatically measures the distance between the angles of the two lines, and gives the measured value in the image area； The result is displayed in real time at the upper right of the image. The position of the selected point can be fine-tuned by clicking the " 
" four direction keys.

## 6.3 Area/perimeter measurement

**Operating steps**

1. When the system enters the probe working mode, press the freeze button "

" to freeze the image, and click "


" to open the measurement submenu;

2. Click "


" in the measurement submenu to start the area / circumference measurement;

3. Use your finger to click on the touch screen to select three points. At this time, an ellipse connecting the three points appears on the screen. The system automatically measures the area and perimeter of the ellipse, and gives the measured value in the image area. The result is displayed in real time at the upper right of the image. The position of the selected point can be fine-tuned by clicking the "

" four direction keys.

## 6.4 Trajectory measurement

**Operating steps**

1. When the system enters the probe working mode, press the freeze button "


" to freeze the image. Click "


" to open the measurement submenu

2. Click "


" in the measurement submenu to start the measurement of the track;

3. Use your finger to draw the track of interest on the touch screen. At this time, the screen will display the figure formed by drawing the track, and automatically measure the area value of this figure, and display it in real time on the upper left of the image area. The position of the selected point can be fine-tuned by clicking the "

" four direction keys.

## 6.5 Speed measurement

**Operating steps**

1. When the system enters the probe working mode, press the freeze button "


" to freeze the image, and click "


" to open the measurement submenu.

2. Click "


" in the measurement submenu to start speed measurement;

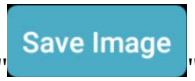
3. Use your finger to select the position of two parallel straight lines on the touch screen. At this time, the screen will automatically measure the speed value between the two parallel straight lines and display it in real time on the upper left of the image area. The position of

the selected point can be fine-tuned by clicking the "  " four direction keys.

# 7 Image storage

## 7.1 Image storage

**Operating steps** 1.Press the freeze button to freeze the image.

2. Click " 

" to save single image.

## 7.2 Video storage

**Operating steps** 1.Press the freeze button to freeze the image.

2.Click " 

" to save the entire image video.

# 8 Ultrasound Teaching Atlas

The handheld ultrasound diagnostic instrument includes the function of ultrasound teaching atlas. (Only for MT10P model)

## 8.1 Summarize

The name of this function on the diagnostic instrument is "Basic Ultrasonic Teaching Atlas of Ultrasound Project". Through simple and easy-to-understand language and intuitive legends, it introduces users how to use this product to search and scan the corresponding parts on the human body. Better meet the needs of clinical diagnosis.

## 8.2 How to use the teaching graph

**Operating steps**

1. When the system enters the real-time scanning working mode of the probe, click the "  " icon at the bottom right of the interface; the interface as shown in Figure 7 will pop up
2. At this time, you can use your finger to swipe up and down in the "teaching map" area of the touch screen interface to browse each page of the teaching map.
3. For the pages of interest in the teaching map, you can click the page to enlarge the page to full screen, as shown in Figure 8.
4. The enlarged map can be browsed and turned by clicking. Click on the left side of the image to turn the page forward; click on the right side of the image to turn the page backward.
5. To exit the zoomed-in teaching map interface, click the "  " symbol in the upper left corner to exit the full-screen state and return to the interface shown in Figure 8.
6. After using the teaching map, you can click on the blank area of the operation interface to return to the real-time scanning working mode of the probe.

# 9 Maintenance

## 9.1 Host maintenance

◎ The device should not be turned on and off frequently. If you need to turn it on again after shutting down, you have to wait 2 ~ 3 minutes.

◎ When the device is not used for a long period of time, the instrument should be cleaned and placed in the packaging box in the direction indicated by the packaging box, and stored in the warehouse. The use environment and storage environment of the device shall meet the environmental requirements of 3.1.

◎ Please do not open the inside of the plot without permission, nor do you want to shake or disassemble the parts.

◎ When the casing of the machine needs to be cleaned, it should be wiped with an alcohol cotton ball while it is turned off.

◎ If the instrument breaks down, please ask professional maintenance personnel approved by Jutian Wisdom to repair it.

## 9.2 Probe maintenance

### 9.2.1 Precautions

◎ When using this ultrasound probe, it is recommended to wear sterile gloves to prevent infection.

◎ Normal ultrasound examination, low temperature will not cause the risk of burns; however, if the ultrasound probe is placed in the same place for a long time, it may damage the patient.

◎ Do not try to split the probe and main unit. Splitting the probe may damage the probe. The user splitting the probe will invalidate the probe and host warranty.

◎ Probes and mainframes that have been dropped or impacted with objects should be used until they have been verified that the probes have not been damaged, otherwise do not use them.

◎ Never use an autoclave, ultraviolet rays, gamma rays, or gas, steam, or heating methods to sterilize the probe. These methods may permanently damage the probe.

◎ The probe is a non-watertight structure, and it is forbidden to immerse in any conductive liquid to avoid corrosion of the probe. The depth of the probe into the water must not exceed the probe's immersion line mark, and often check the probe shell for

cracks to avoid damage to internal components from entering the liquid.

◎ The damage caused by the improper use of the probe and the host, or the impact of foreign objects is not covered by the warranty.

◎ If the probe is cracked, cracked or damaged, do not use the probe and contact your Jutian wisdom sales representative.

◎ The user checks through visual inspection and manual operation to ensure that the entire surface of the probe is free of small holes, protrusions, damages or depressions.

◎ Please do not immerse the probe in the disinfectant longer than the time required by the manufacturer during high sterilization.

◎ It should be avoided that the probe is exposed to the air for a long time and emits sound waves, so as not to damage the probe.

## 9.2.2 Clean the probe

**Operate**

1. Disconnect the probe from the special software;;
2. Power off the host;
3. Check the probe and housing to ensure there are no cracks, cuts, tears or other signs of physical damage;
4. Prepare to clean the probe and wear sterile gloves;
5. Use a soft cloth or paper towel to wipe the coupling agent from the acoustic head;
6. Use a soft cloth soaked with soft detergent to gently wipe the stain on the probe;
7. Wipe the probe with a soft cloth soaked in neutral soapy water or warm water;
8. Wipe the probe with a soft cloth soaked in clean water until all soapy liquid is wiped;
9. Air dry or wipe the probe with a clean, dry soft cloth to dry。
10. After cleaning, please check the probe and the case。

◎ Do not clean or disinfect the probe when the main unit power is on。

◎ Do not use gasoline or other organic compounds to clean the probe。

◎ If body fluid is stuck to the probe, please disinfect it before cleaning.

◎ After each ultrasound examination, the ultrasonic coupling agent on the surface of the probe should be completely wiped off. Otherwise, the ultrasonic coupling agent will solidify on the acoustic lens of the probe and affect the quality of the ultrasonic image.

◎ Clean the probe regularly to ensure that the probe is working properly.

## 9.2.3 Probe disinfection

**Overview**

Ultrasonic probes can be disinfected with liquid chemical sterilants. The degree of disinfection is directly related to the time of exposure to disinfectant. Increasing the contact time has a better disinfection effect. In order to prevent the spread of disease and protect the safety of patients and medical personnel, the probe should be regularly disinfected with liquid chemical sterilant.

◎ The liquid chemical disinfectant in accordance with local regulations must be used to disinfect the probe.

◎ It is forbidden to immerse the whole main unit in liquids such as water and disinfectant, otherwise it may cause electric shock or probe failure.

◎ If using the disinfectant recommended in this manual, ensure that its concentration and probe immersion time meet the recommended conditions. Otherwise, it may damage the probe and invalidate the probe warranty. If the user has special purposes and requirements, please ensure that the configured solution concentration and probe immersion time are suitable for the clinical use of the probe.

◎ Before disinfecting the probe, please pay attention to the effective use date of the disinfectant, and prohibit the use of expired disinfectant.

◎ It is forbidden to use high-pressure steam to handle the probe or contact with ethylene oxide.

◎ It is forbidden to thermally disinfect the probe under any circumstances. If the temperature exceeds 66 ° C (150 ° F), the probe will be damaged.

◎ Do not allow any disinfectant to air dry on the probe.

**Operate**

1. Wear sterile gloves to avoid infection;
2. Clean the probe according to the cleaning steps in Section 8.2.2;
3. Disinfect the probe according to the method recommended in Table 6.

**Table 6 Recommended method for probe disinfection**

| Disinfectant | manufacturer | active ingredients | Active ingredient concentration | Contact Form | Duration of exposure |
|---|---|---|---|---|---|
| Glutaraldehyde disinfectant | YueXing | glutaraldehyde | 20.0g/L-25.0g/L | Wipe/soak | <60min |

4. Rinse thoroughly with sterile water to remove residual chemicals on the probe;
5. Use a sterile cloth or gauze to wipe off the moisture on the probe surface. It is forbidden to dry the probe by heating.

◎ Please refer to the instructions provided by the manufacturer regarding the concentration of disinfectant, disinfection method and dilution method.

◎ Please refer to the manufacturer's instructions for use of the activator.

◎ Glutaraldehyde is irritating to the skin and mucous membranes. Rubber gloves should be worn when contacting the glutaraldehyde solution to prevent splashing into the eyes or inhalation.

◎ Glutaraldehyde is irritating to the skin and mucous membranes. Rubber gloves should be worn when contacting the glutaraldehyde solution to prevent splashing into the eyes or inhalation.

**Reference**

1. Glutaraldehyde 3.1.8.1 in "Disinfection Technical Specification" (2002 edition).
2. GB 26372-2010《Hygienic standard for glutaraldehyde disinfectant》
3. Technical specification for the disinfection of ultrasonic diagnosis and treatment in medical institutions of henan province (trial) (yuwei medicine [2011] no. 186)
4. Tianjin Municipal Ultrasonic Diagnosis and Treatment Related Disinfection Technical Specifications (Trial)
5. WS/T 367-2012 technical specification for disinfection of medical institutions

## 9.3 Choose Ultrasonic Coupling Agent

**Overview**

During ultrasound examination, the air between the probe and the patient's skin will hinder the introduction of ultrasound to the human body. In order to obtain high-quality images, liquid needs to be transmitted to the medium to connect the probe to the patient's surface.

**Coupling agent performance requirements**

1. Low sound attenuation coefficient, good sound transmission；
2. The acoustic impedance is between the face material of the probe and the skin, matching well；
3. Low adhesion, easy to wipe off；
4. Does not contaminate clothes, leaving no traces after drying；
5. Moderate viscosity, not easy to dry；
6. Bright appearance, high transparency, no bubbles;
7. Good uniformity, free of particles or impurities, and does not block the nozzle during use;
8. Moderate moisturizing, not easy to dry;
9. Good stability, no color change, no change in consistency, no layering, no precipitation, no deterioration, no corruption;
10. Does not corrode or damage the probe, and does not irritate the skin.

◎ Please select a qualified ultrasonic coupling agent approved by the State Food and Drug Administration, and do not use expired or unqualified ultrasonic coupling agent.

◎ The quality of the coupling agent is closely related to the quality of the obtained acoustic image. The coupling agent of poor quality can cause the loss of ultrasound energy, reduce the resolution, blur the image, even irritate the skin and damage the probe.

◎ Because there is air between the probe and the skin, if the coupling agent is not used, the ultrasonic wave will return to the air and cannot enter the human body, which will affect the inspection effect and extend the inspection time.

◎ The use of expired or unqualified ultrasound coupling agents may cause misdiagnosis, misjudgment or damage to the patient's skin.

**Reference** YY 0299-2008 Medical ultrasound coupling agent

## 9.4 Security check

1. In order to ensure that the machine works normally, it is recommended to develop a maintenance and inspection plan, and regularly conduct safety inspections on the machine. If abnormal phenomena are found, please contact your sales representative.
2. If there is no image when starting up or there is a menu without image, please refer to Table 7 to deal with. If the fault still cannot be eliminated, please contact your sales representative.

**Table 7 Common failure causes and operation measures**

| Fault classification | Reason | Measure |
|---|---|---|
| The host cannot open | The built-in battery is low or the battery is damaged | Use a wireless charger to charge the device, the indicator light is orange to indicate charging. If the battery is damaged, please contact the manufacturer for replacement and repair. |
| The overall image quality is abnormal | 1. The check mode is incorrect;<br>2. Image post-processing settings are not normal； | 1. Set the inspection mode appropriately.<br>2. Adjust image post-processing settings or set to default values. |

# Addendum A　Sound output data

## A1：Explanation

The sound output display is located on the upper part of the system monitor.

Different pre-set values for different examination sites will have different MI and TIS values. Regardless of the settings, the values of MI and TIS output by the system are always less than 1, in line with national standards.

If any display value of MI or TI is greater than 1.0, please carefully follow the ALARA principle.

The sound intensity parameters usually generated by an ultrasound probe and their meanings are described as follows:

**Mechanical Index**

The mechanical index (MI) is used to predict the possibility of tissue damage due to the formation of air pockets. According to the FDA 510 (k) guidelines of September 9, 2008, the absolute maximum limit of MI is 1.9.

**Thermal index**

Thermal sensitivity index (TI) is a method to assess the increase in temperature of soft tissue or bone. The thermal index includes the following three categories:

• TIS：Soft tissue thermal index. The main TI category. Suitable for applications where bone imaging is not possible.

• TIB：Bone thermal index (bone located in the central area). Suitable for fetal applications.

• TIC：Skull thermal index (bone close to the surface). Suitable for transcranial applications.

Ispta

Ispta Refers to the time-averaged intensity of the spatial peak. The absolute maximum limit of Ispta is 720 mW / cm2, which was specified in the FDA 510 (k) principle of September 2008.

## A2：Probe maximum surface temperature

In compliance with the requirements of Part 42.3 of the standard IEC60601-2-37, the maximum surface temperature data of the probe used in this system are measured in the following two environments: placing the probe in static air and contacting the probe with human tissue materials.

| Probe model | The probe is in contact with the tissue-like phantom | Placed in static air |
|---|---|---|
| | Maximum surface temperature (℃) | Maximum surface temperature (℃) |
| C3-5 | ＜41 | ＜41 |
| L7-10 | ＜41 | ＜41 |

# A3：Acoustic output report form（IEC 60601-2-37）

This part is measured and calculated according to IEC 60601-2-37 "Medical Electrical Device Part 2-37: Special Requirements for the Safety of Ultrasonic Diagnosis and Monitoring Device".

Probe model： C3-5 Operating mode： B

| **Index Label** | | | **MI** | **TIS** | | **TIB** | | **TIC** |
|---|---|---|---|---|---|---|---|---|
| | | | | **At surface** | **Below surface** | **At surface** | **Below surface** | |
| Maximum Index Value | | | 0.93 | 0.48 | | 0.92 | | (a) |
| Index Component Value | | | | 0.48 | 0.48 | 0.92 | 0.48 | |
| Associated acoustic parameters | *p*r,α at *z*MI | (Mpa) | 1.45 | | | | | |
| | *P* | (mW) | | 15 | | 15 | | (a) |
| | *P*1x1 | (mW) | | 15 | | 15 | | |
| | *z*s | (cm) | | | # | | | |
| | *z*b | (cm) | | | | | # | |
| | *z*MI | (cm) | 4.1 | | | | | |
| | *z*pii,α | (cm) | 4.1 | | | | | |
| | *f*awf | (MHz) | 3.050 | 3.050 | | 3.050 | | (a) |
| Other information | prr | (Hz) | 1630.5 | | | | | |
| | *srr* | (Hz) | 8.5 | | | | | |
| | *n*pps | | 1 | | | | | |
| | *I*pa,α at *z*pii,α | (W/cm$^2$) | 29.6 | | | | | |
| | *I*spta,α at *z*pii,α or *z*sii,α | (mW/cm$^2$) | 1.18 | | | | | |
| | *I*spta at *z*pii or *z*sii | (mW/cm$^2$) | 1.68 | | | | | |
| | *p*r at *z*pii | (Mpa) | 2.556 | | | | | |
| Operating control conditions | Freq | (MHz) | 3.5 | | | | | |
| | Focus Position | (cm) | 4 | | | | | |
| | Depth | (cm) | 9 | | | | | |
| | Focus Num | | 1 | | | | | |
| (a) Intended use does not include cephalic so TIC is not computed # No data reported | | | | | | | | |

Probe model： C3-5 Operating mode： B/M

| Index Label | | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|---|
| | | | | At surface | Below surface | At surface | Below surface | |
| Maximum Index Value | | | 0.93 | 0.48 | | 0.92 | | (a) |
| Index Component Value | | | | 0.48 | 0.48 | 0.92 | 0.48 | |
| Associated acoustic parameters | *p*r,α at *z*MI | (Mpa) | 1.45 | | | | | |
| | *P* | (mW) | | 15 | | 15 | | (a) |
| | *P*1x1 | (mW) | | 15 | | 15 | | |
| | *z*s | (cm) | | | # | | | |
| | *z*b | (cm) | | | | | # | |
| | *z*MI | (cm) | 4.1 | | | | | |
| | *z*pii,α | (cm) | 4.1 | | | | | |
| | *f*awf | (MHz) | 3.050 | 3.050 | | 3.050 | | (a) |
| Other information | prr | (Hz) | 1630.5 | | | | | |
| | *srr* | (Hz) | # | | | | | |
| | *n*pps | | 1 | | | | | |
| | *I*pa,α at *z*pii,α | (W/cm$^2$) | 29.6 | | | | | |
| | *I*spta,α at *z*pii,α or *z*sii,α | (mW/cm$^2$) | 1.18 | | | | | |
| | *I*spta at *z*pii or *z*sii | (mW/cm$^2$) | 1.68 | | | | | |
| | *p*r at *z*pii | (Mpa) | 2.556 | | | | | |
| Operating control conditions | Freq | (MHz) | 3.5 | | | | | |
| | Focus Position | (cm) | 4 | | | | | |
| | Depth | (cm) | 9 | | | | | |
| | Focus Num | | 1 | | | | | |

(a) Intended use does not include cephalic so TIC is not computed # No data reported

Probe model： C3-5 Operating mode： C

| **Index Label** | | | **MI** | **TIS** | | **TIB** | | **TIC** |
|---|---|---|---|---|---|---|---|---|
| | | | | **At surface** | **Below surface** | **At surface** | **Below surface** | |
| Maximum Index Value | | | 0.86 | 0.35 | | 0.86 | | (a) |
| Index Component Value | | | | 0.35 | 0.35 | 0.86 | 0.35 | |
| Associated acoustic parameters | *p*r,α at *z*MI | (Mpa) | 1.339 | | | | | |
| | *P* | (mW) | | 11 | | 11 | | (a) |
| | *P*1x1 | (mW) | | 10 | | 10 | | |
| | *z*s | (cm) | | | # | | | |
| | *z*b | (cm) | | | | | # | |
| | *z*MI | (cm) | 4.31 | | | | | |
| | *z*pii,α | (cm) | 4.31 | | | | | |
| | *f*awf | (MHz) | 2.768 | 2.768 | | 2.768 | | (a) |
| Other information | prr | (Hz) | 3850 | | | | | |
| | *srr* | (Hz) | 8.12 | | | | | |
| | *n*pps | | 14 | | | | | |
| | *I*pa,α at zpii,α | (W/cm$^2$) | 48.3 | | | | | |
| | *I*spta,α at *z*pii,α or *z*sii,α | (mW/cm$^2$) | 4.932 | | | | | |
| | *I*spta at *z*pii or *z*sii | (mW/cm$^2$) | 7.897 | | | | | |
| | *p*r at *z*pii | (Mpa) | 1.861 | | | | | |
| Operating control conditions | Focus Position | (cm) | 4 | | | | | |
| | Depth | (cm) | 9 | | | | | |
| | PRF | (Hz) | 2.5K | | | | | |

(a) Intended use does not include cephalic so TIC is not computed # No data reported

Probe model： C3-5 Operating mode： PW

| Index Label | | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|---|
| | | | | At surface | Below surface | At surface | Below surface | |
| Maximum Index Value | | | 0.87 | 0.46 | | 1.41 | | (a) |
| Index Component Value | | | | 0.46 | 0.46 | 0.86 | 1.41 | |
| Associated acoustic parameters | *p*r,α at *z*MI | (Mpa) | 1.49 | | | | | |
| | *P* | (mW) | | 14 | | 14 | | (a) |
| | *P*1x1 | (mW) | | 13 | | 13 | | |
| | *z*s | (cm) | | | # | | | |
| | *z*b | (cm) | | | | | # | |
| | *z*MI | (cm) | 3.97 | | | | | |
| | *z*pii,α | (cm) | 3.97 | | | | | |
| | *f*awf | (MHz) | 2.231 | 2.231 | | 2.231 | | (a) |
| Other information | prr | (Hz) | 1980 | | | | | |
| | *srr* | (Hz) | # | | | | | |
| | *n*pps | | 1 | | | | | |
| | *I*pa,α at *z*pii,α | (W/cm$^2$) | 15.1 | | | | | |
| | *I*spta,α at *z*pii,α or *z*sii,α | (mW/cm$^2$) | 6.74 | | | | | |
| | *I*spta at *z*pii or *z*sii | (mW/cm$^2$) | 10.56 | | | | | |
| | *p*r at *z*pii | (Mpa) | 0.65 | | | | | |
| Operating control conditions | PRF | (Hz) | 2.5k | | | | | |
| | Focus Position | (cm) | 4 | | | | | |
| | Depth | (cm) | 9 | | | | | |

(a) Intended use does not include cephalic so TIC is not computed

# No data reported

Probe model： L7-10 Operating mode： B

| **Index Label** | | | **MI** | **TIS** | | **TIB** | | **TIC** |
|---|---|---|---|---|---|---|---|---|
| | | | | **At surface** | **Below surface** | **At surface** | **Below surface** | |
| Maximum Index Value | | | 0.87 | 0.38 | | 0.81 | | (a) |
| Index Component Value | | | | 0.38 | 0.38 | 0.81 | 0.38 | |
| Associated acoustic parameters | *p*r,α at *z*MI | (Mpa) | 1.85 | | | | | |
| | *P* | (mW) | | 13 | | 13 | | (a) |
| | *P*1x1 | (mW) | | 13 | | 13 | | |
| | *z*s | (cm) | | | # | | | |
| | *z*b | (cm) | | | | | # | |
| | *z*MI | (cm) | 0.92 | | | | | |
| | *z*pii,α | (cm) | 0.92 | | | | | |
| | *f*awf | (MHz) | 7.130 | 7.130 | | 7.130 | | (a) |
| Other information | prr | (Hz) | 7528.8 | | | | | |
| | *srr* | (Hz) | 11.5 | | | | | |
| | *n*pps | | 1 | | | | | |
| | *I*pa,α at *z*pii,α | ($W/cm^2$) | 32.0 | | | | | |
| | *I*spta,α at *z*pii,α or *z*sii,α | ($mW/cm^2$) | 1.08 | | | | | |
| | *I*spta at *z*pii or *z*sii | ($mW/cm^2$) | 1.63 | | | | | |
| | *p*r at *z*pii | (Mpa) | 3.556 | | | | | |
| Operating control conditions | Freq | (MHz) | 7.5 | | | | | |
| | Focus Position | (cm) | 0.6 | | | | | |
| | Depth | (cm) | 2 | | | | | |
| | Focus Num | | 2 | | | | | |

(a) Intended use does not include cephalic so TIC is not computed # No data reported

Probe model： L7-10 Operating mode： B/M

| **Index Label** | | | **MI** | **TIS** | | **TIB** | | **TIC** |
|---|---|---|---|---|---|---|---|---|
| | | | | **At surface** | **Below surface** | **At surface** | **Below surface** | |
| Maximum Index Value | | | 0.87 | 0.38 | | 0.81 | | (a) |
| Index Component Value | | | | 0.38 | 0.38 | 0.81 | 0.38 | |
| Associated acoustic parameters | *p*r,α at z*MI* | (Mpa) | 1.85 | | | | | |
| | *P* | (mW) | | 13 | | 13 | | (a) |
| | *P*1x1 | (mW) | | 13 | | 13 | | |
| | z*s* | (cm) | | | # | | | |
| | z*b* | (cm) | | | | | # | |
| | z*MI* | (cm) | 0.92 | | | | | |
| | z*pii*,α | (cm) | 0.92 | | | | | |
| | *f*awf | (MHz) | 7.130 | 7.130 | | 7.130 | | (a) |
| Other information | prr | (Hz) | 7528.8 | | | | | |
| | *srr* | (Hz) | # | | | | | |
| | *n*pps | | 1 | | | | | |
| | *I*pa,α at z*pii*,α | (W/cm$^2$) | 32.0 | | | | | |
| | *I*spta,α at z*pii*,α or z*sii*,α | (mW/cm$^2$) | 1.08 | | | | | |
| | *I*spta at z*pii* or z*sii* | (mW/cm$^2$) | 1.63 | | | | | |
| | *p*r at z*pii* | (Mpa) | 3.556 | | | | | |
| Operating control conditions | Freq | (MHz) | 7.5 | | | | | |
| | Focus Position | (cm) | 0.6 | | | | | |
| | Depth | (cm) | 2 | | | | | |
| | Focus Num | | 2 | | | | | |

(a) Intended use does not include cephalic so TIC is not computed # No data reported

Probe model： L7-10 Operating mode： C

| **Index Label** | | | **MI** | **TIS** | | **TIB** | | **TIC** |
|---|---|---|---|---|---|---|---|---|
| | | | | **At surface** | **Below surface** | **At surface** | **Below surface** | |
| Maximum Index Value | | | 0.53 | 0.21 | | 0.53 | | (a) |
| Index Component Value | | | | 0.21 | 0.21 | 0.53 | 0.21 | |
| Associated acoustic parameters | *p*r,α at *z*MI | (Mpa) | 1.319 | | | | | |
| | *P* | (mW) | | 8 | | 8 | | (a) |
| | *P*1x1 | (mW) | | 6 | | 6 | | |
| | *z*s | (cm) | | | # | | | |
| | *z*b | (cm) | | | | | # | |
| | *z*MI | (cm) | 0.62 | | | | | |
| | *z*pii,α | (cm) | 0.62 | | | | | |
| | *f*awf | (MHz) | 6.568 | 6.568 | | 6.568 | | (a) |
| Other information | prr | (Hz) | 7980 | | | | | |
| | *srr* | (Hz) | 9.09 | | | | | |
| | *n*pps | | 13 | | | | | |
| | *I*pa,α at zpii,α | (W/cm$^2$) | 45.26 | | | | | |
| | *I*spta,α at *z*pii,α or *z*sii,α | (mW/cm$^2$) | 4.641 | | | | | |
| | *I*spta at *z*pii or *z*sii | (mW/cm$^2$) | 7.592 | | | | | |
| | *p*r at *z*pii | (Mpa) | 1.551 | | | | | |
| Operating control conditions | Focus Position | (cm) | 0.6 | | | | | |
| | Depth | (cm) | 2 | | | | | |
| | PRF | (Hz) | 4.0K | | | | | |
| (a) Intended use does not include cephalic so TIC is not computed # No data reported | | | | | | | | |

Probe model： L7-10 Operating mode： PW

| Index Label | | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|---|
| | | | | At surface | Below surface | At surface | Below surface | |
| Maximum Index Value | | | 0.75 | 0.22 | | 1.21 | | (a) |
| Index Component Value | | | | 0.22 | 0.20 | 0.73 | 1.21 | |
| Associated acoustic parameters | *p*r,α at *z*MI | (Mpa) | 1.772 | | | | | |
| | *P* | (mW) | | 8 | | 8 | | (a) |
| | *P*1x1 | (mW) | | 7 | | 7 | | |
| | *z*s | (cm) | | | 0.55 | | | |
| | *z*b | (cm) | | | | | 0.85 | |
| | *z*MI | (cm) | 0.6 | | | | | |
| | *z*pii,α | (cm) | 0.6 | | | | | |
| | *f*awf | (MHz) | 6.621 | 6.621 | | 6.621 | | (a) |
| Other information | prr | (Hz) | 7930 | | | | | |
| | *srr* | (Hz) | # | | | | | |
| | *n*pps | | 1 | | | | | |
| | *I*pa,α at *z*pii,α | (W/cm$^2$) | 14.9 | | | | | |
| | *I*spta,α at *z*pii,α or *z*sii,α | (mW/cm$^2$) | 6.71 | | | | | |
| | *I*spta at *z*pii or *z*sii | (mW/cm$^2$) | 10.29 | | | | | |
| | *p*r at *z*pii | (Mpa) | 2.173 | | | | | |
| Operating control conditions | PRF | (Hz) | 4.0k | | | | | |
| | Focus Position | (cm) | 0.6 | | | | | |
| | Depth | (cm) | 2 | | | | | |

(a) Intended use does not include cephalic so TIC is not computed

# No data reported

# Addendum B：Pollution control of electronic information products

The "Administrative Measures on Pollution Control of Electronic Information Products" (No. 39) came into effect on March 1, 2007. According to the "Electronic Information Product Classification Notes", this diagnostic system belongs to the electronic information products of medical ultrasonic diagnostic instruments in the category of electronic applications. According to the requirements of the "Administrative Measures on the Pollution Control of Electronic Information Products" (No. 39), the toxic and hazardous substances or elements contained in the pollution control labels and products are described as follows:

**Symbol：**


In this diagnostic system, the pollution control signs of electronic information products are shown in the figure:

The number "3" in the mark is the environmental protection use period (in years), that is, the diagnostic system will not leak or mutate under normal use conditions within 3 years from the date of production. , Users use products will not cause serious pollution to the environment or cause serious damage to their personal and property.