# Diagnostic Ultrasound System

# Operating instruction

**Model: MX**

**Important statement!**

**Before using the product, you must carefully read and understand the content of this manual, and place the manual in a convenient place.**

**BMV UEM Eng CO., LTD**

Content

Introduction ..... 1
Warranty and Repair Service ..... 2
Operational Taboos: ..... 2
Intellectual Property Rights ..... 2
Product Information ..... 3
After-sales service company ..... 3
1. Safety precautions ..... 5
1.1 Safety classification ..... 5
1.2 Definition of symbols ..... 5
1.3 Security warning information ..... 6
1.5 Warning sign ..... 9
2. Product overview ..... 9
2.1 Scope of application ..... 9
2.2 Contraindications ..... 9
2.3 Product Specifications ..... 9
2.4 System configuration ..... 11
2.5 Symbol Description ..... 12
2.6 Introduction of various components of the product ..... 14
2.7 Control area ..... 15
2.8 Basic interface ..... 16
3. Basic introduction ..... 18
3.1 Working power supply ..... 18
3.2 Start Host/Close Host ..... 18
3.3 Device connection ..... 20
4. System settings ..... 21
4.1 Preset ..... 22
4.2 Case storage list ..... 26
4.3 Probe information ..... 26
5. Patient Information ..... 27
6. Image optimization ..... 27
6.1 Image mode ..... 27
6.2 Image parameter adjustment ..... 28
6.3 Parameter adjustment in mode B ..... 28
6.4 M mode image adjustment ..... 32

6.5 Image adjustment in Color mode (for Color Ultrasound model only) ..... 35
6.6 Image Adjustment in Power Mode (for COLOR Ultrasound models only) ..... 39
6.7 PW Mode Image Adjustment (for Color Ultrasound model only) ..... 42
7. Measure ..... 48
7.1 Routine measurement ..... 49
7.2 Application Measurement ..... 51
8. Cine playback, comment, body markers and report ..... 51
8.1 Cine Replay ..... 51
8.2 Comment ..... 53
8.3 Body markers ..... 53
8.4 Report ..... 54
9. Probe ..... 54
9.1 Probe Description ..... 54
9.2 Inspection and maintenance ..... 57
9.3 Cleaning and disinfection ..... 58
10. Puncture guidance ..... 61
10.1 Enter or exit puncture mode. ..... 61
10.2 Puncture guide line calibration ..... 61
11. Acoustic output instructions ..... 61
11.1 Biological Effects ..... 62
11.2 Use declarations with caution ..... 62
11.3 ALARA principle (As Low As possible to make, Reasonably Achievable) ..... 62
11.4 MI/TI ..... 63
11.5 Acoustic power setting ..... 64
11.6 Acoustic power control ..... 65
11.7 Acoustic output specification ..... 66
11.8 Measurement uncertainty ..... 68
11.9 References for acoustic power and its safety ..... 68
11.10 Transducer surface temperature ..... 69
12. EMC Declaration ..... 69

## Introduction

This instruction manual describes the operating procedures of the Diagnostic Ultrasound Systems . Please read and understand the contents of this manual carefully before use to ensure safe and correct operation of the product.

This manual has been prepared and interpreted by BMV.

BMV reserves the right to change the contents of this manual without prior notice.

**Important Notice!**

1. Copying or duplicating part or all of this manual without prior written permission is prohibited;

2. Modification of the software or hardware of the product is prohibited;

3. The product provides physicians with images and data needed for clinical diagnostic reference. Doctors are responsible for the diagnostic process. BMV is not responsible for the diagnostic process;

4. The warranty does not cover the following even during the warranty period:

(1) Damage or loss caused by incorrect installation or environmental conditions that do not meet the requirements;

(2) Damage or loss caused by charging power supply voltage exceeding the range specified for the product;

(3) Damage or loss occurring to instruments or parts not purchased from BMV or its authorized distributors or agents;

(4) Damage or loss caused by not using the product in the area in which it was originally purchased;

(5) Damage or loss caused by repair by persons not authorized by the Company;

(6) Damage or loss caused by force majeure such as fire, earthquake, flood or lightning;

(7) Damage or loss caused by mistake or rough use;

(8) Other failures not caused by the product itself.

5. The product may produce some waste or wearing parts etc. when used or after the expiration of the use period. Disposing of such waste will cause serious pollution or cross infection to the environment, It should be managed and disposed of in accordance with local laws and regulations and other relevant provisions, and should not be disposed of in the same way as normal waste products.

## Warranty and Repair Service

The standard warranty period for the product is 2 years, and the standard warranty period for major accessories is 1 year. The warranty period is counted from the "installation date" on the "Warranty Card" attached to the product, and the "Warranty Card" is the only proof for calculating the warranty period.

During the warranty period, the product can enjoy free after-sales service; but please note that, even during the warranty period, due to the reasons in the "Important Notices" on the previous page caused by the product needs to be repaired, the company will implement the charge maintenance service, you need to pay for the maintenance fee and accessories. After the expiration of the warranty period, we can provide paid repair services. Note: If you fail to pay or delay in paying for the repair service, BMV will temporarily suspend the repair service until you pay.

BMV declares that before use, you must familiarize yourself with the instruction manual, and strictly in accordance with the requirements of the instruction manual and operating methods for operation and use. BMV shall not be liable for any abnormalities or dangerous injury to persons or machines caused by operation, use, maintenance or storage not in accordance with the requirements of this manual, and shall not be liable for the safety, reliability and performance guarantee!

## Operational Taboos:

| | |
|---|---|
|  | ※ Do not modify the product, including the equipment components, software, internal wiring, etc. Modification of the product by the user may result in safety problems or degradation of system performance. All modifications must be done by our authorized personnel. |

## Intellectual Property Rights

The intellectual property rights of this manual and related products belong to BMV. No part of this manual may be reproduced, modified or translated by any person or organization without the written consent of BMV.

## Version Information

The version of this instruction manual is as follows:

- Version number: V1
- Release date: Dec 2024

## Product Information

Product Name：Diagnostic Ultrasound Systems

Model：MX

Registrant's name：BMV UEM Eng Co., Ltd

Registered address：Yinjin Building 701, Block 71, Xingdong Community, Xin'an Street, Bao'an District, Shenzhen, Guangdong Province 518133, P.R.China

Manufacturer's name: BMV UEM Eng Co., Ltd

Production address: Yinjin Building 701, Block 71, Xingdong Community, Xin'an Street, Bao'an District, Shenzhen, Guangdong Province 518133, P.R.China

Contact: +86-755-26564580

Lifetime: 5 years

## After-sales service company

Name：BMV UEM Eng Co., Ltd

Address：Yinjin Building 701, Block 71, Xingdong Community, Xin'an Street, Bao'an District, Shenzhen, Guangdong Province 518133, P.R.China

After-sales service telephone: +86-755-26564580

Warning:
Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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.

FCC Statement: 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.

FCC Radiation Exposure Statement:
The device complies with RF specifications when the device used at 0mm from your body-wom.Third-party belt-clips, holsters, and similar accessories used by this device should not contain any metallic components. Body-worn accessories that do not meet these requirements may not comply with RF exposure requirements and should be avoided.

The Highest Body-worn Reported Simultaneous Transmission SAR1-3 during testing is 0.16W/kg (separation distance -0mm)

# 1. Safety precautions

## 1.1 Safety classification

According to anti-shock type: internal power supply equipment;

According to the degree of shock resistance: BF type application part;

According to the degree of protection against harmful incoming liquids:

The product has a waterproof rating of IPX4 for the main unit and IPX7 for the probe;

as shown in the figure below:


In the presence of combustible anesthetic gas mixed with air (or oxygen, nitrous oxide) :

Equipment not suitable for use in the presence of combustible anesthetic gas mixed with air (or oxygen, nitrous oxide);

According to the working mode: continuous working equipment.

## 1.2 Definition of symbols

In this manual " Warning " " Be careful ", " Notice " is used to represent the relevant security and other important items, containing the righteous they are as follows. Before reading this manual, please carefully understand and remember the meaning of these words.

| Symbols and Vocabulary | Meaning |
|---|---|
| Warning  | Indicates a potentially dangerous situation that, if not avoided, may result in death or severe injury. |
| Be careful  | Indicates a potentially dangerous situation that, if not avoided, may cause mild or moderate injury. |
| Notice  | Represents dangerous conditions that may occur and, if not avoided, may cause damage to property. |

1.3 Security warning information

Please strictly abide by the following safety specifications when using in order to ensure the safety of patients and operators.

 Do not use the probe in the presence of combustible gas (e.g., anesthetic gas, hydrogen, etc.) or combustible liquid (e.g., ethanol, etc.), otherwise it may cause an explosion.

Warning 

1. Do not take apart the ultrasonic probe without authorization, which may cause electric shock.
2. An adapter that meets the relevant requirements of IEC 60601-1 must be used for charging, otherwise there may be a risk of electric shock when charging the ultrasonic system.
3. Use the probe with care. If the contact surface between the probe and the human body is scratched, stop using the probe immediately and contact the service representative. There is a risk of electric shock if a scratch probe is used.
4. The safety of the product must be checked before each use. Do not let the probe be hit, as the damaged ultrasonic probe may shock the patient.
5. Before ultrasound examination, please check the surrounding environment to ensure that it is safe to use in the environment. Do not operate the product in the presence of flammable or explosive liquids, vapors or gases such as oxygen or hydrogen.
6. The probe must be put on a sterile probe protective cover when conducting ultrasonic

cavity examination.

7. Do not immerse the interface and the above part of the ultrasonic probe into water or disinfectant. Because the ultrasonic probe interface does not have waterproof function, it will cause electric shock or abnormal probe function.
8. Before and after each inspection, it is necessary to ensure that the ultrasonic head is normal.
9. Please select the correct type of probe sound head according to the different parts of the inspection, do not use any probe that is not provided by the company.

Do not use any probe other than the one provided by the company, otherwise it will cause damage to the machine and the probe.

10. To ensure safety, charging of the system can only be done when the system is turned off, and charging is not allowed when the system is turned on.

Be careful

1. Precautions for clinical examination techniques:

The product should only be operated by qualified medical personnel.

This manual does not describe clinical examination techniques. The correct examination technique must be chosen based on professional training and clinical experience.

2. The product can not be used for a long time to examine pregnant women, fetuses and newborns.

3. In the process of ultrasound diagnostic examination, especially in the examination of pregnant women, fetuses and newborns, please follow the ALARA principle. To the extent satisfactory clinical charts are available, the low noise power should be reduced as far as possible.

4. Do not use incompatible couplings, disinfectants, probe protectors, probes, puncture racks, etc.

5. When using The product, you must wear sterile gloves to prevent infection.

6. Sterile ultrasonic couplant must be used in the operation. Use couplant that meet local regulatory requirements. In addition, it is important to properly manage and use ultrasonic

couplings to ensure that they do not become a source of infection.

7. Normal ultrasound examination, room temperature does not produce a risk of burns; however, if the ultrasound probe is placed in the same area for a long time, it may burn the user.

8. The material of the protective cover of the probe is natural rubber, use with caution if you are allergic to natural rubber.

9. The surface temperature of the probe used in the cavity should not rise above 43°C under single fault conditions.

Notice

1. In order to prevent abnormal probe function, please read the following safety precautions:

After each ultrasonic examination, the ultrasonic coupling agent on the probe surface should be thoroughly wiped. Otherwise, the ultrasonic coupling agent will solidify on the head mirror of the probe and affect the ultrasonic image quality.

2. Ambient requirements

Please use the product in the specified environment:

- Ambient temperature: 0℃ ~ 40℃
- Relative humidity: 30% ~ 85% (no condensation)
- Atmospheric pressure: 80 kPa ~ 1060kPa.

To prevent product damage, do not expose the product to the following environment:

- Where there is direct sunlight
- A place where the temperature changes dramatically
- Places where dust accumulates
- Places prone to vibration
- Places near heat sources

3. Multiple sterilizations can lead to a decrease in the safety and performance of the probe, which should be checked periodically.

### 1.5 Warning sign

Various markings are carried on the product to draw the user's attention to potential hazards. Symbols on warning signs indicate concerns about system security.
The instructions explain the meaning of these warning labels in detail. You must read the instructions carefully before using the system.

## 2. Product overview

### 2.1 Scope of application

The product is intended for use in Abdominal, Obstetrics, Gynaecology, Small Parts (breast, thyroid, etc), Peripheral Vascular, Urology

### 2.2 Contraindications

The product is not intended for use on burns, scalds, or areas of the body where there is damage to surface tissues; it is not intended for use on the eyes or any condition that may cause the sound beam to pass through the eyes; pregnant women, newborns, and infants should be examined for a controlled period of time.

### 2.3 Product Specifications

#### 2.3.1 Imaging mode

- B type imaging
- M type imaging
- C type imaging
- Power type imaging
- PW type imaging

2.3.2 Software version information

A) Embedded software version: V1

B) Control software version: Android platform software version: V2, the released version.

2.3.3 Power supply conditions

Charging port power input: DC 5V, 2A

Internal power supply: DC 7.4V

2.3.4 Environmental conditions

| | Operational environment | Storage and transportation environment |
|---|---|---|
| The environment temperature | 0℃～40℃ | -20℃～+55℃ |
| Relative humidity | 30%～85%(no condensation) | 30%～95%(no condensation) |
| The atmospheric pressure | 80kPa～106kPa | 70kPa～106kPa |

Warning

transport：

1. Do not use or store or transport the MX Diagnostic Ultrasound Systems outside the specified environmental conditions.

2. Please ensure that the product is firmly grasped in use, otherwise, the device may slip and harm users.

3. Ensure that the product runs in a dry environment. Sudden changes in temperature and humidity in the operating environment may cause liquid to condense on the circuit board, and there is a risk of short circuit.

4. Do not operate the product in the environment with flammable or explosive liquids, vapors or gases (such as oxygen or hydrogen). Equipment failure or a spark from a fan motor can

detonate these materials electronically.

A. Please ensure the environment before use. If flammable substances are detected in the environment, please do not plug in the power or turn on the system.

B. Real-time detection of the environment during use. Flammable substances are detected after the product is opened. Please do not attempt to turn off the device or unplug the power supply. Empty the area of air and ensure good ventilation, then turn off the power.

5. If the product malfunctions, please do not disassemble it privately to check it, please contact the after-sales service center or your sales representative.

6. The product is not suitable for areas with an altitude of more than 2000 meters.

2.3.5 Probe dimensions and weight

| Probe Model | Probe Type | Dimensions |
|---|---|---|
| C5-2Ks | Convex probe(big) | 170mm(L)×70mm(W)×30mm(H) |
| C5-2Fs | Convex probe(small) | 168mm(L)×58mm(W)×30mm(H) |
| C8-5Ks | Micro-Convex probe | 166mm(L)×58mm(W)×30mm(H) |
| L11-4Ks | Linear probe | 162mm(L)×58mm(W)×30mm(H) |

2.4 System configuration

Color Doppler ultrasound diagnostic system consists of mainframe, probe and control type software Android;

Configurable probe models are: C5-2Ks, C5-2Fs, C8-5Ks, L11-4Ks.

2.4.1 Standard configuration

Ultrasonic host machine (including probe, built-in battery)

Accessories: manual, hand-held toolbox.

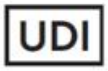
2.4.2 Optional

2.4.2.1 Optional probe

| Probe model | Probe type | Center frequency | Frequency range | Applicable parts |
|---|---|---|---|---|
| C5-2Ks | Convex probe(big) | 3.5MHz | 2.0~5.0MHz | The transcorporeal surface applies to: abdominal organs (liver, gallbladder, pancreas, spleen), gynecological and obstetrical organs (uterus, ovaries), urinary organs (kidneys, prostate, bladder) |
| C5-2Fs | Convex probe(small) | 3.5MHz | 2.5~5.0MHz | The transcorporeal surface applies to: abdominal organs (liver, gallbladder, pancreas, spleen), gynecological and obstetrical organs (uterus, ovaries), urinary organs (kidneys, prostate, bladder). |
| C8-5Ks | Micro-Convex probe | 6.5MHz | 5.0~8.0MHz | The transcorporeal surface applies to: abdomen in children, cranium in newborns |
| L11-4Ks | Linear probe | 7.5HMz | 6.0~10.0MHz | The transcorporeal surface applies to: carotid arteries |

2.5 Symbol Description

The following symbols are used in this equipment, and the following list explains their meanings.

| No. | Symbol | Description |
|---|---|---|
| 1 |  | Type BF Application Section<br>Description: All ultrasound probes belong to the BF-type application section. |
| 2 |  | This symbol indicates that please refer to the relevant contents of the manual to avoid safety accidents. |
| 3 |  | This symbol indicates the serial number of the product. |
| 4 |  | This symbol indicates the date of manufacture |
| 5 | IPX4 | This symbol indicates that the waterproof rating of the housing is IPX4. |
| 6 | IPX7 | This symbol indicates that the waterproof rating of the product is IPX7. |
| 7 |  | Manufacture date |
| 8 |  | Safety Warning Symbol. Before using the MX Diagnostic Ultrasound Systems , be sure to read the instructions carefully. |
| 9 |  | Non-Ionizing Radiation |
| 10 |  | Requires a separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive 20120/19/EU. |
| 11 |  | MR Unsafe – the system is not intended to be used within magnetic resonance (MR) environment. |
| 12 |  | Medical Device |
| 13 |  | It is the device identification assigned at the level of the device unit of use. |
| 14 | **Rx only** | Indicates the device is to be used under the supervision of a practitioner licensed by law to direct the use of such device according to FDA 21 CFR Part 801.109.<br>Caution: Federal law restricts this device to sale by or on the order of a Physician, or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device. |

2.6 Introduction of various components of the product


| Serial number | Name | Function |
|---|---|---|
| 1 | Probe | Emits ultrasound |
| 2 | Host body | Controlling the acoustic head |
| 3 | Control area | Operational control |
| 4 | Micro-USB interface | For connection to external adapted power supply |
| 5 | Handle | For moving the unit |

2.7 Control area

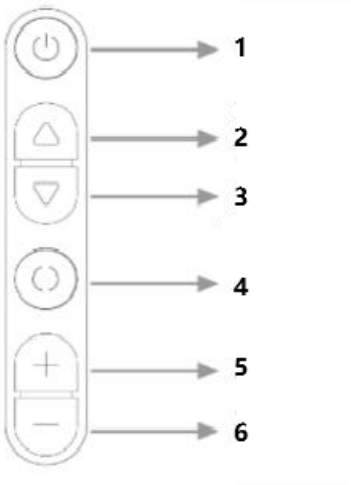



Fig 2.7 Control area

| No. | Key icon | Key name | Function |
|---|---|---|---|
| 1 | | Power/Freeze/ Defrost key | Long press: power on/off<br>Short press: Freeze/Defrost image |
| 2 | | (Depth) “ ▲”Key | Under the Gain/Depth menu: Increase the Depth; |
| 3 | | (Depth) “▼”Key | Under the Gain/Depth menu: Reduce the Depth;<br>Under parameters menu: select parameters |
| 4 | | Main Menu | 1.Switch image C mode<br>2.Save the image in frozen state |
| 5 | | (Gain) “+”Key | Under the Gain/Depth menu: Increase Gain;Under the parameters menu: increase the |
| 6 | | (Gain) “-”key | Under the Gain/Depth menu: Reduce the Gain;<br>Under the parameters menu: reduce the parameters |

## 2.8 Basic interface

The interface layout of the Android application is shown in the following figure:

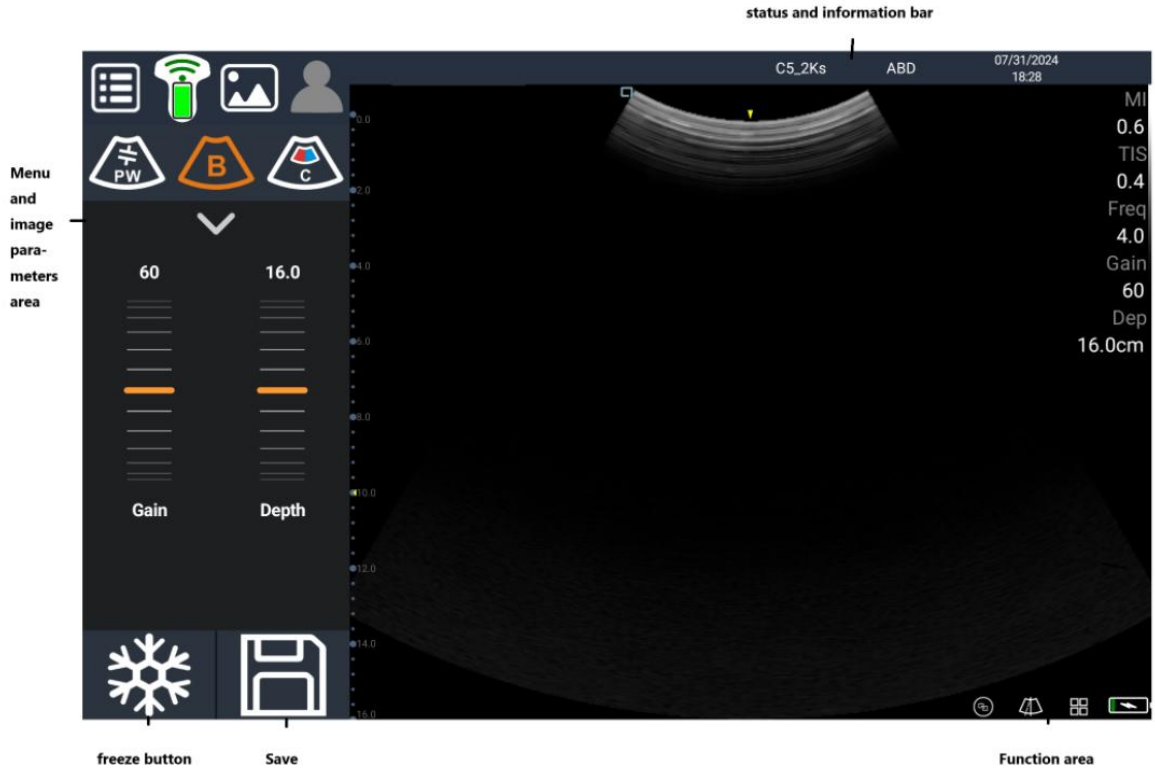



Fig 2.8.1 interface layout

- Status and information display area

The status and information display area includes system information viewing sign, probe signal and power, thumbnail, patient information, probe model, examination type, battery power, system time and other information.

- The system time

Display the current system time. Check time with image freezes when system freezes.

- Wireless signal strength indicator

Display the current probe signal strength that has been connected. There are 3 signal cells. The stronger the signal strength, the more stable the signal connection is. At the same time, the strength indicator mark also has the function of pressing Probe (Probe), click the mark  , the Probe selection dialog box will pop up.

- Probe model

Displays the currently used probe model or default probe model.

- Check the type

Displays the type of examination currently in use, such as abdomen.

- System information view flag 

Click this symbol, and a dialog box will pop up for the reader to view the probe ID of the connected probe, the battery level of the probe, the temperature of the probe, the firmware version of the probe, the WiFi firmware version and the application version.

- Probe battery level indicator  Device battery level indicator 

After connecting the probe, display the current power of the probe. Device battery level: The display device opens the application and displays the current battery level of the display device (phone/tablet).

Wifi band supports 2.4GHz and 5.2GHz/5.8G.

- Menu and image parameter display area

This area can be divided into left and right areas: left and right areas for the image parameter display area, the middle area for the image display area.

- Left image parameter display area

When the software is opened, it exists on the main screen, and its menu items will be different in the frozen and thawed state. When there are more menu items, you can slide to view all menu items. Click the corresponding item control item in the menu to pop up the menu for adjusting image parameters in each imaging mode.

- Image parameter display area on the right

The image parameters area displays the image parameters of the current active window. If the current active window has more than one imaging mode, the image parameters of each imaging mode are displayed respectively according to the imaging mode.

- Image display area

The image area displays the images of each mode, as well as the probe direction marker, time line (in M mode), coordinate axis (including depth axis and time axis), etc. At the same time, annotation information, measurement, and gray scale bar are also displayed here.

- Freeze/Defrost button area

The freeze/thaw button freezes/thaws the current active window.

# 3. Basic introduction

## 3.1 Working power supply

The MX Diagnostic Ultrasound Systems does not work when connected to an external power supply. The charging interface of the probe is connected through the charging power supply/line conforming to the standard requirements.

The external power supply system of the MX Diagnostic Ultrasound Systems must meet the following requirements:

Charging port power

input: DC5V, 2A

Internal power supply: DC7.4V

The internal power system shall meet the following requirements: When the battery is first used, there may be very little residual power in the battery and the battery needs to be charged first. Please do not disconnect the power when charging. Do not use non-product specific batteries. In the first three times of use, all the power in the battery should be used up and the charging time should be longer than the first charge, so as to maximize the activation of the battery and ensure the effective service time of the battery.

When the power is disconnected, the product will automatically switch to the battery power, the battery can last about 12 hours after full battery. The battery will have self-discharge phenomenon (about 1% a day), should maintain a full charge and discharge of the battery once a month. If not used for a long time, the battery will cause lack of power or even depletion because of long-term self-discharge, which is the inherent characteristics of lithium batteries, is a normal phenomenon. External power supply should be used at this time.

## 3.2 Start Host/Close Host

### 3.2.1 Start the host

Warning ⚠ :

1.Before opening the main engine, it is necessary to ensure that the connected probes are not

cracked or loose. Use of defective probes may result in electrical motors.

2.When loading and unloading the ultrasonic end of the probe, it is necessary to confirm that the probe is closed or frozen.

Be careful

In order to ensure the safe and effective work of the product, it is necessary to carry out routine inspection. As soon as an anomaly is detected, shut down the host and contact the service representative. If the main device with abnormal operation is used, the examination results will be inaccurate and even harm the patient and damage the probe itself.

Before starting the host machine, please carefully check or operate according to the following items:

| The serial number | Check the project |
|---|---|
| 1 | The temperature, humidity and atmospheric pressure shall meet the requirements of the conditions of use. |
| 2 | Probes must not be damaged or stained. |
| 3 | Clean the site and environment. |
| 4 | Clean and disinfect the probe. |

Open the main engine and check after opening the main engine. Long press the power button to open the main engine.

To check whether the host is normally started, check the probe after opening according to the following items:

| The serial number | Check the project |
|---|---|
| 1 | No abnormal sound, odor or overheating. |
| 2 | There shall be no obvious abnormal noise. |
| 3 | After the device is connected to the wireless signal emitted by the probe, check whether the probe surface is abnormally heated during use. |

Warning

1.Using an abnormally hot probe may burn a patient.

2.If any abnormal phenomena are found, the host is out of order. You should immediately shut down the host and contact a service representative.

3.2.2 Shut down the host

Long press the power button to turn off the host. The host needs to be shut down after normal use, or the user needs to shut down the host when some abnormal conditions occur.

After the ultrasonic examination, the ultrasonic coupling agent on the probe surface should be completely wiped, otherwise the coupling agent will solidify on the probe head mirror and affect the ultrasonic image quality.

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

3.2.3 Replacing the probe

Always perform loading and unloading operations on the probe when the main unit is off or frozen.

When installing the probe, align the probe connection end with the corresponding end of the main unit and carefully push it into place.

When removing the probe, your fingers can be pressed against the raised portion of the probe surface to pull the probe out carefully.

3.3 Device connection

3.3.1 WIFI Connection Methods

The following smart device connection methods apply to tablets, cell phones, and video glasses. It is recommended to prioritize the application of this connection method .

After The product is powered on and started, open the ultrasound APP software and click the "  " logo. Select the WiFi hotspot name corresponding to the current host, as in Figure 3.3.1 click to connect, or find the hotspot name under the WiFi list of the terminal device and enter the password (12345678) to connect.

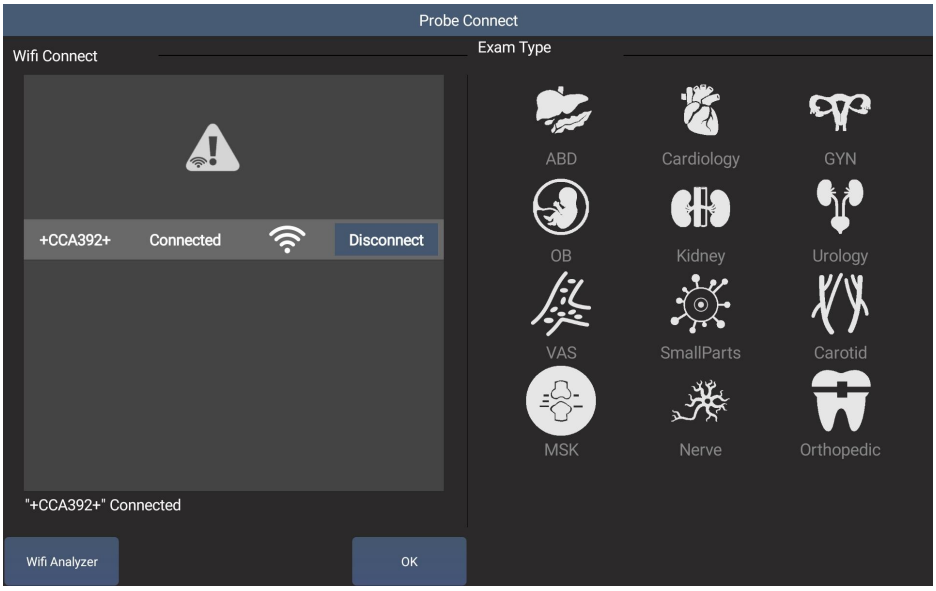



Fig 3.3.1

**Note:** 1 When there is no image display on WiFi connection, please restart the APP or ultrasound device.

2 The WiFi only supports one-to-one connection, when switching terminal devices, please disconnect the last connection first.

3 When WiFi has been occupied by other device connection, please restart the machine and quickly search for hotspot to connect.

## 4. System settings

Click the button  at the top left of the interface, and the preset menu will be displayed, as shown in Figure 4-1.

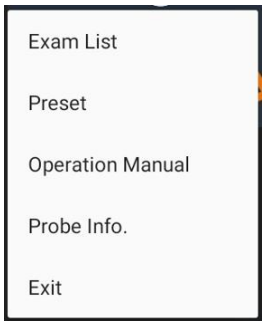
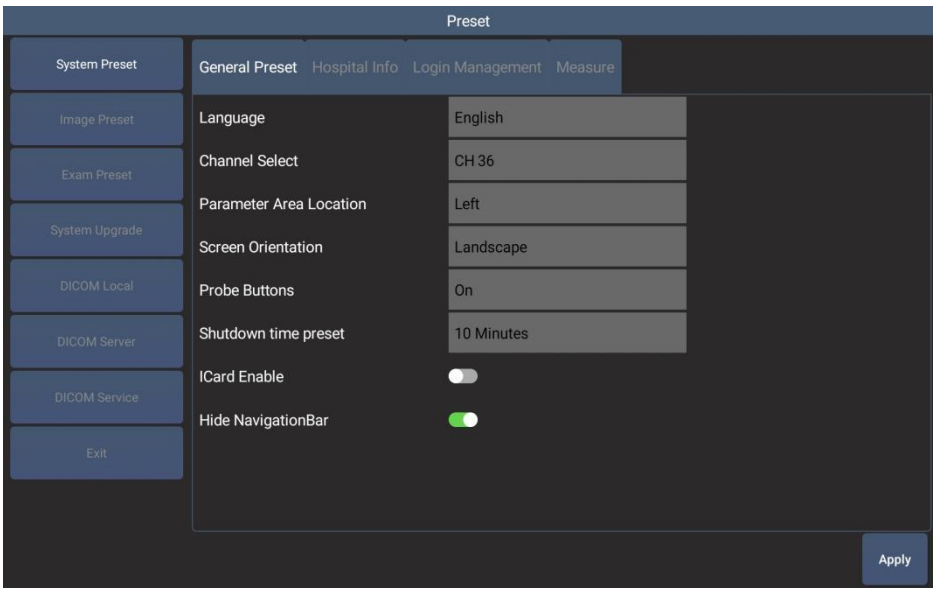



Fig 4-1

## 4.1 Preset

Through the system preset interface, system preset, image parameter preset, examination type preset, system upgrade and maintenance, DICOM connection. Comprehensive presetting, hospital information, login management, and measurement presetting are available.

### 4.1.1 System preset




| Name | Description |
|---|---|
| Language | Set the interface language of the system |
| Channel | Select different channels |
| Parameter Area | Set the interface parameters on the left and right |
| Screen Orientation | Select different screen orientation |
| Probe Keys | Host key switch |
| Shutdown Time Preset | Preset automatic shutdown in frozen state |

Hospital information

Fill in the hospital information. As in Figure 4.1.2

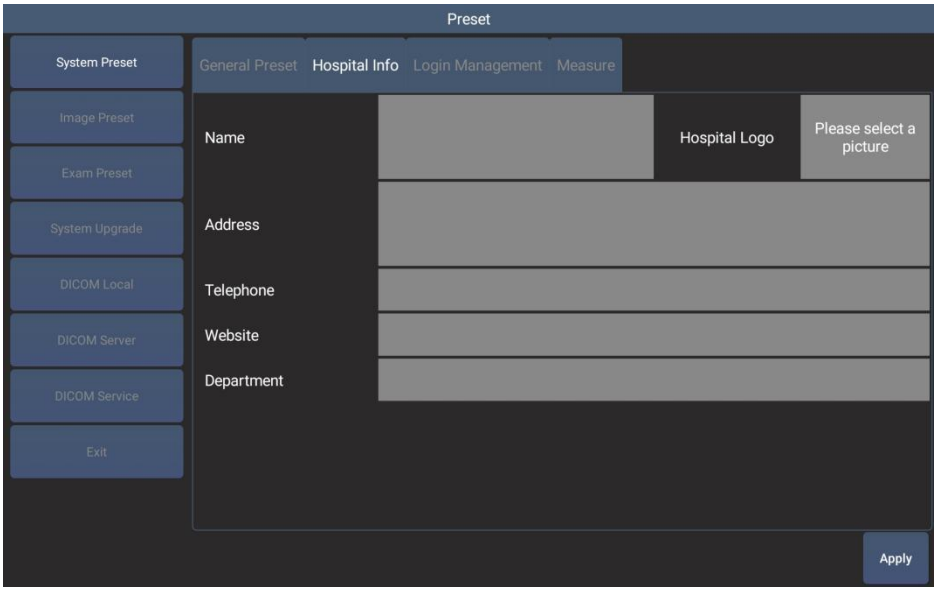



Fig 4.1.2

Login management

Set up personal physician information as in Figure 4.1.3

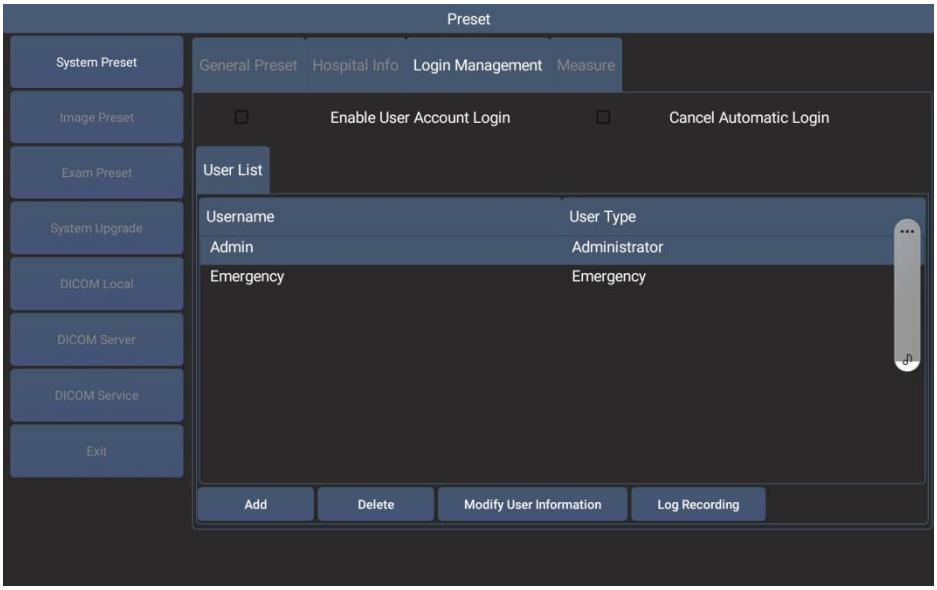



Fig 4.1.3

Measurement

Set up measurement items

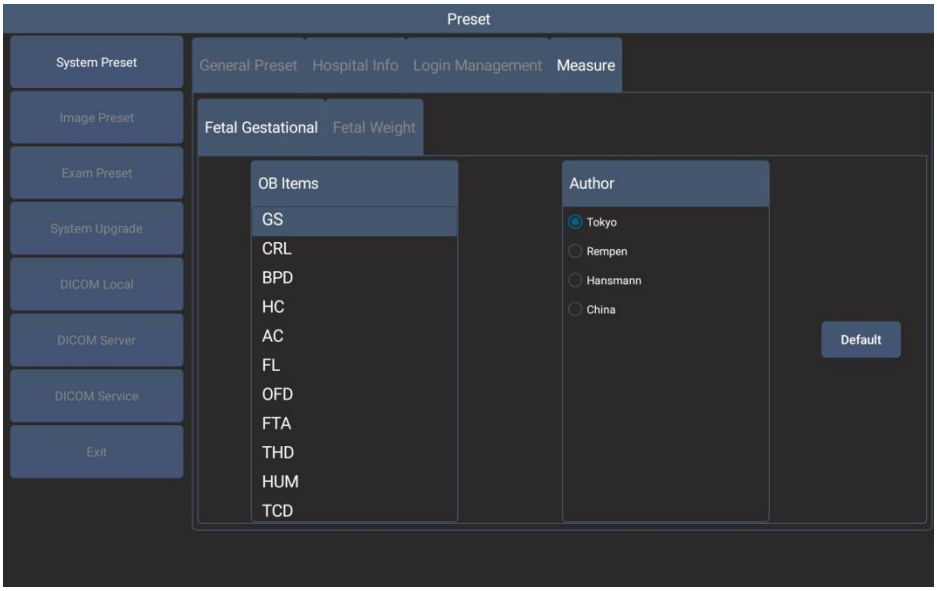



Fig 4.1.4

## 4.1.2 4.1.2 Image parameter presets

Preset the image measurement parameters for each mode, as shown in Figure 4.1.2

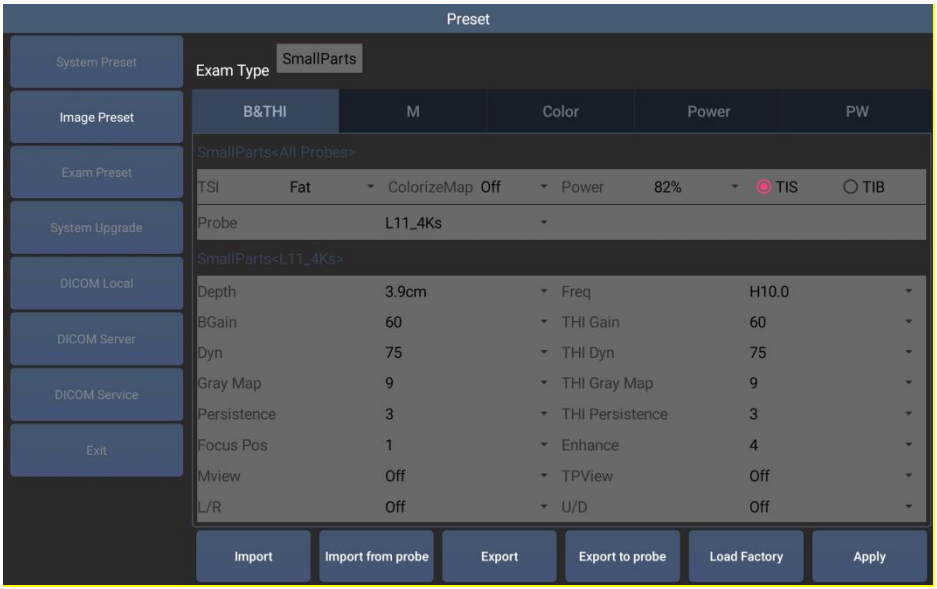



Fig 4.1.2

## 4.1.3 Inspection type presets

The different probe inspection types are preset, as shown in Figure 4.1.3.

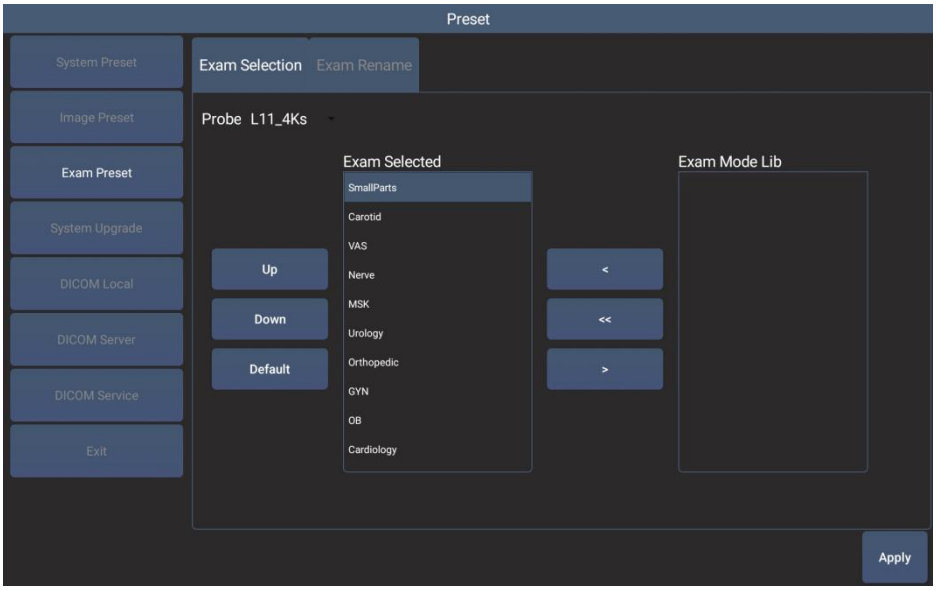



Fig 4.1.3

4.1.4 System Upgrade Maintenance

The permissions for the image function are opened for internal testing and use. as shown in Figure 4.1.4

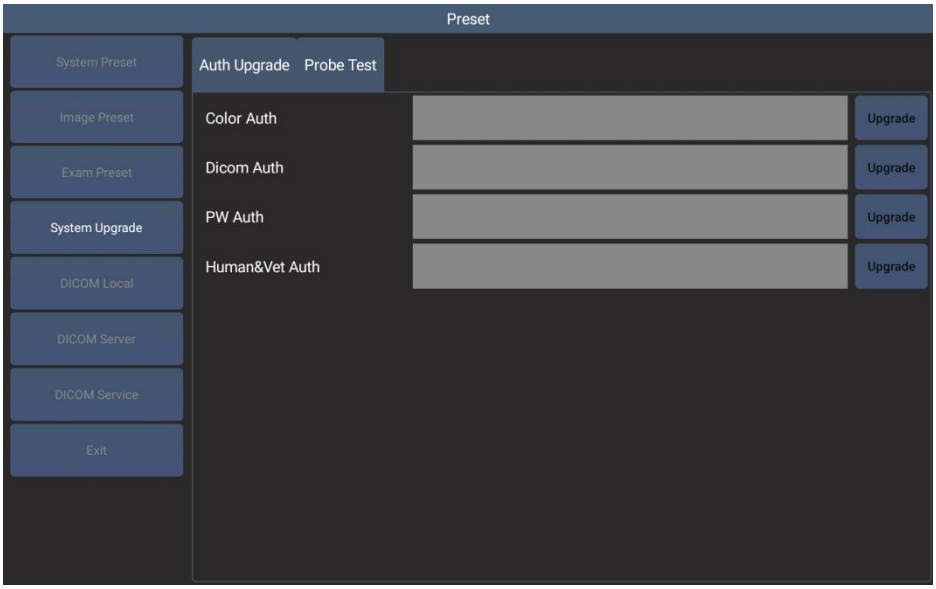



Fig 4.1.4

4.1.4 DICOM

Transfer the image information to the DICOM server. As in Figure 4.1.5

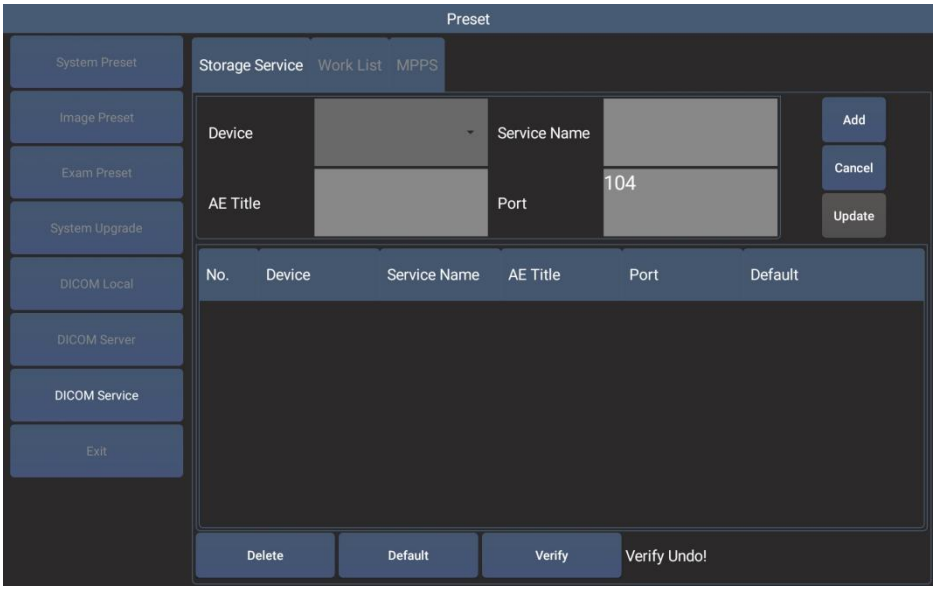



Fig 4.1.5

## 4.2 Case storage list

View patient case information. As in Figure 4.2

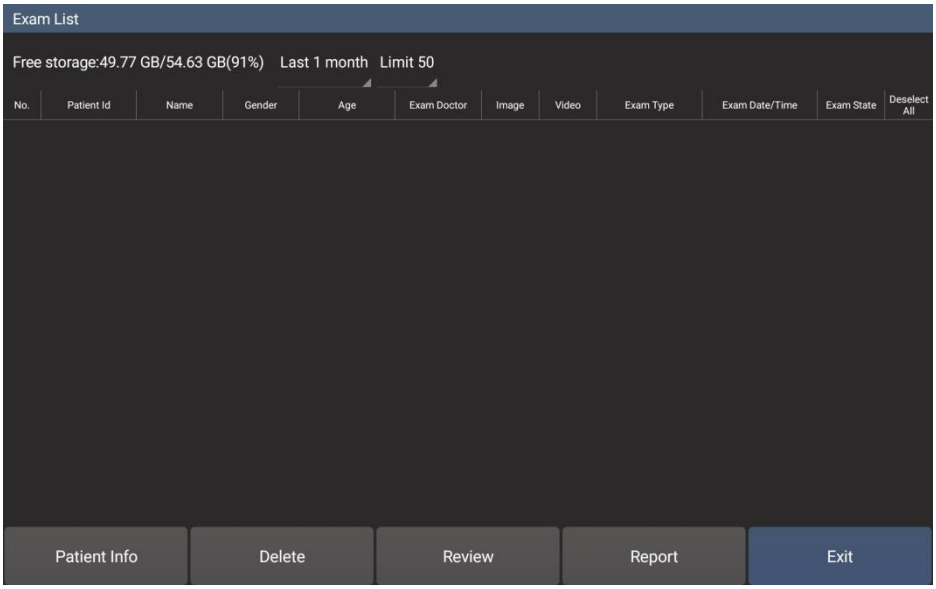



Fig 4.2

## 4.3 Probe information

View host, software information.

## 5. Patient Information

Before performing a patient examination, the user needs to enter relevant patient information and select the appropriate probe and subject for a more accurate and error-free patient examination.

Click the icon  to enter the patient information interface and enter the basic information of the patient, such as entering the patient's name, modifying the patient ID, and selecting the gender and date of birth. As in Figure 5.1.

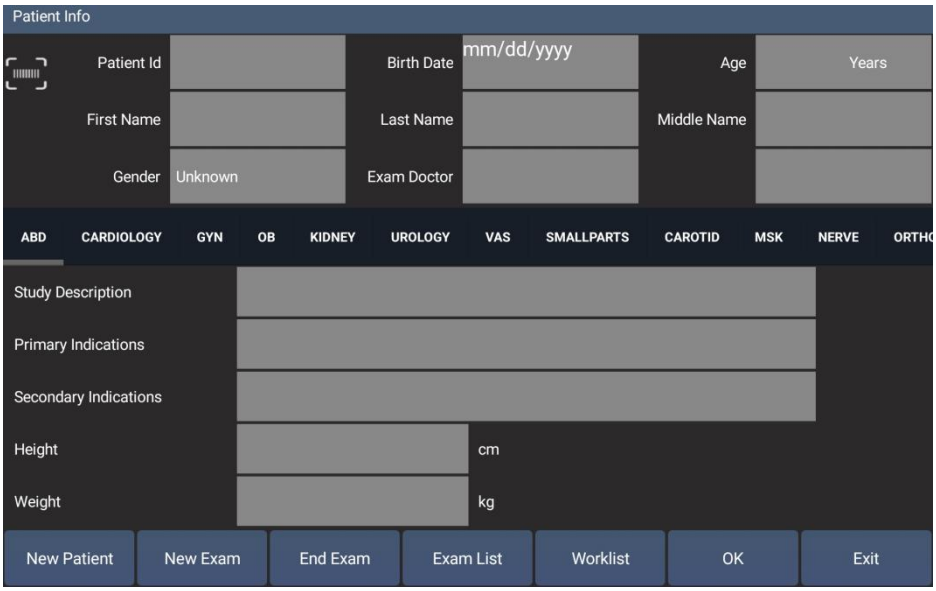



Fig 5.1

## 6. Image optimization

### 6.1 Image mode

| Model | instructions |
|---|---|
| 【B】 | Click to enter "B" image mode. |
| 【M】 | Click to enter M image mode. |
| 【Color】 | Click to enter the B+Color image mode. |
| 【Power】 | Click to enter B+Power image mode. |
| 【PW】 | Click to enter PW image mode. |

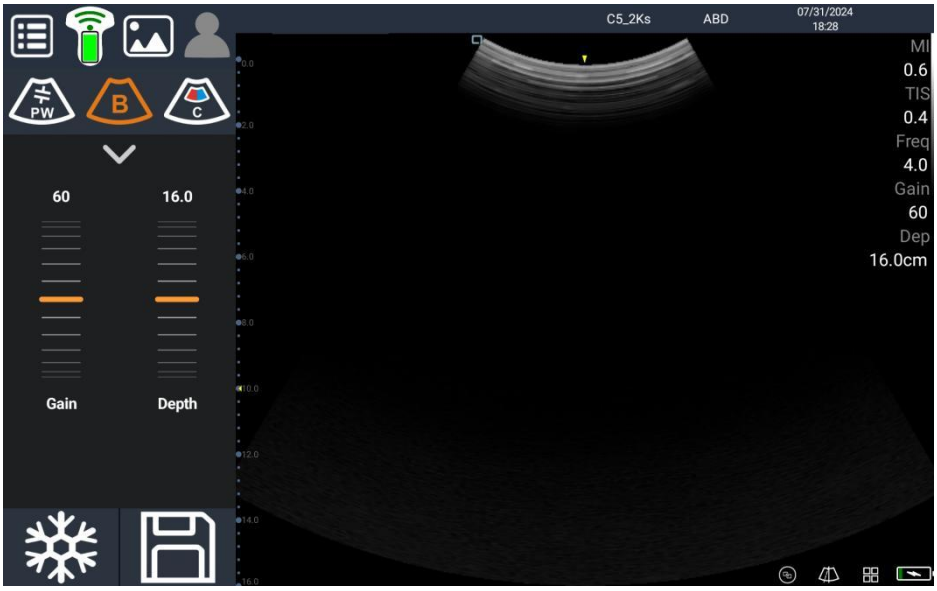
## 6.2 Image parameter adjustment

Before adjusting the image parameters to optimize the image, adjust the brightness of the monitor so that it is in the best working condition.

| Purpose | Optional operation |
|---|---|
| Change the image brightness | Adjust the gain and adjust the sound power<br>Adjust the TGC of the corresponding target area |
| Change the grayscale image effect | Adjusting dynamic range<br>Adjust the effect<br>Adjust frame correlation<br>Press [One-key Optimization] for One-key Optimization (Optional) |
| Improve the frame rate of grayscale images | Reduce the depth |
| Change the flow image display effect | Adjust color gain<br>Adjust color frequency<br>Adjust the deflection<br>Adjust the afterglow<br>Adjust the scale<br>Adjust the speed<br>Regulating wall filtering<br>Adjust color first |

## 6.3 Parameter adjustment in mode B

B mode is the most basic imaging mode, which shows the intensity of echo signal at the interface of a fault in the body by the brightness of light spots. The two-dimensional images of moving human soft tissue organs can be displayed in real time, so that the morphology, anatomical hierarchy and adjacent relationship of the organs can be clearly observed.




6.3.1 Image parameters of mode B

During B mode image scanning, the image parameter area located on the left side of the screen provides real-time parameter information, and the following parameters can be adjusted:

6.3.2 Image optimization in mode B

| Adjust the way | Parameters of the item |
|---|---|
| Control panel adjustment | Gain, depth |
| Software to adjust | Frequency, extended imaging, frame correlation, dynamic range, effects, focus, spatial composition, image enhancement, pseudo-color mapping, left-right flip, up-down flip, acoustic power, TGC, TSI |

1.Gain

- Description: The total gain of the image in 2D mode. The gain value is displayed in the image parameter area on the left of the screen in real time.
- Effect: The image brightness increases, you can see more echo signal, but also bring more noise.

2.Depth

- Description: it is used to adjust the depth of the image display. Different probes can adjust the depth range of the image. The depth value is displayed in the image parameter area on the left side of the screen.
- Effect: The greater the depth, the deeper and broader the observed tissue; The smaller the depth, the shallower the observed tissue. As the depth increases, the frame rate decreases.

3.One-click optimization

- Description: According to the organizational characteristics of the current scanning area, the image effect can be automatically adjusted and optimized.
- Effect: Automatically adjust and optimize the image

4.TGC

- Description: The attenuation caused by increasing tissue depth is compensated by piecewise adjustment of depth gain.
- Effect: By adjusting the signal gain within a specific depth range, the tissue image echoes evenly.

5.Frequency

- Description: the probe transmission frequency, can choose to adopt fundamental frequency or harmonic frequency. The frequency value is displayed in real time in the image parameter area on the left side of the screen. Fundamental wave or harmonic are divided into three frequency modes: "penetration", "conventional", "resolution".
- Effect: The higher the frequency, the better the near-field resolution, but the lower the penetration. Harmonics can enhance near - field resolution and reduce noise with low frequency and large amplitude.

6.Image enhancement

- Description: image optimization is achieved by enhancing the contour of the image to distinguish the boundary of the image.
- Effect: the larger the value, the more delicate the image, the more prominent the image contour.

7. Frame correlation

- Description: Image optimization is performed by stacking and averaging B images of

adjacent frames.

- Effect: Reduce image noise, optimize the image, make the image more delicate, may cause the loss of specific information.

8. Dynamic Range

- Description: Adjust the contrast of black and white images, compress or expand the gray scale display range.
- Effect: The larger the dynamic range, the darker the overall image, the less contrast, and the increased noise.

9. Focus position

- Description: Optimize the image at a specific depth by adjusting the position of the focus.
- Effect: The penetration and resolution near the focal point are higher than those outside the focal point.

10. Effect

- Description: Adjust black, white and gray scale contrast to optimize the image.

Impact: This feature is available for real-time, frozen, and cine playback images.

11. Spatial composition

- Description: Image optimization is performed by merging multiple frames from different deflection angles into a single frame.
- Effect: After opening the spatial composite, the image has the characteristics of speckle noise reduction and clear image, which improves the resolution of the ratio and more easily reveals the location of the lesion.

12. Extended imaging

- Description: Increase the scanning range of the probe.
- Effect: The scanning range of the probe expands, and the frame rate drops slightly.

13. Turn

- Description: Better viewing Angle can be obtained by changing the way the image is displayed. It can be flipped vertically up and down and horizontally left and right. The direction of the image can be identified by the "Q" mark on the screen, which is the default image direction in the upper left corner.
- Impact: This feature is available for real-time, frozen, and cine playback images.

14. Acoustic power

- Description: Adjust the power of the probe transmitting ultrasonic wave.
- Effect: When the acoustic power is increased, the overall brightness of the image is increased evenly, and the depth of detection is also increased. In clinical application, the appropriate acoustic power must be selected according to the actual situation and the "ALARA sound power principle".

15.TSI

- Description: Tissue feature imaging, select sound velocity according to tissue feature to make the image more typical. The MX wireless ultrasound diagnostic system provides four characteristic tissue optimizations: adipose, fluid, conventional, and muscular.

16. Pseudo color Spectrum

- Description: color difference is used instead of gray difference to image, that is, gray scale chromatographic.
- Effect: The MX wireless ultrasound diagnostic system offers four different pseudo-color maps for real-time, frozen, and cinematic playback images.

6.4 M mode image adjustment

M-mode adopts brightness modulation, and the brightness reflects the intensity of echo. The vertical direction represents the spatial position from shallow to deep, and the horizontal direction represents the time. It shows the curve of the distance of each layer of tissues in the body to the body surface (probe) changing with time, reflecting the one-dimensional spatial structure, so M-mode is mostly used to detect the heart.

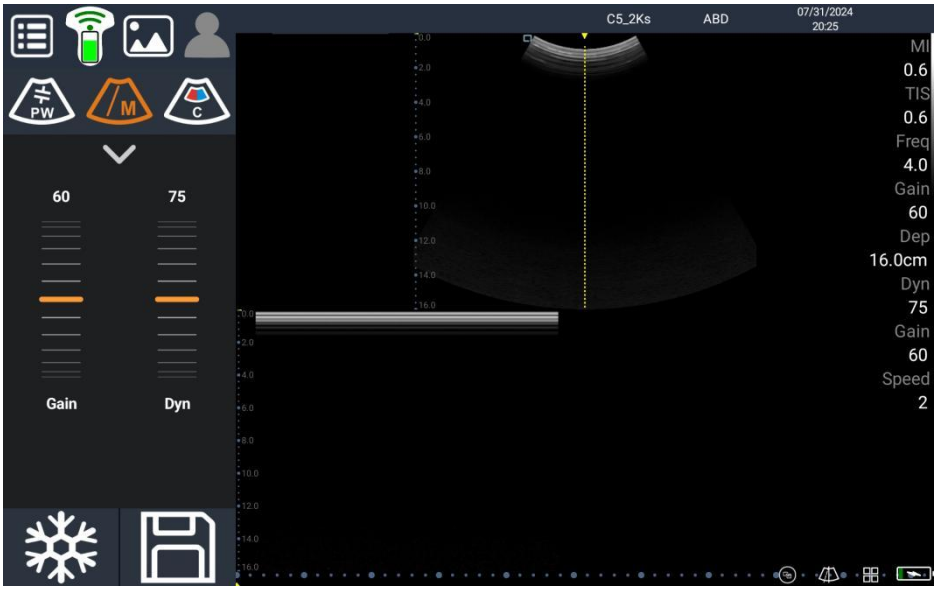



Fig 6.4

### 6.4.1 M mode image parameters

During the M mode image scanning, the image parameter area located on the left of the screen provides real-time parameter information, and the following parameters can be adjusted:

| Adjust the way | Parameters of the item |
|---|---|
| Control panel adjustment | Gain, depth |
| Soft key | Frequency, Dynamic Range, Time Signs, Scanning Speed, pseudo Color Spectrum, Effects, Line Correlation |

### 6.4.2 M mode image optimization

1. Gain

- Description: Adjust the gain of M image. The gain value is displayed in the image parameter area on the left side of the screen in real time.
- Effect: The image brightness increases, you can see more echo signal, but also bring more noise.

1. Depth

- Description: it is used to adjust the depth of the image display. The depth value is

displayed in the image parameter area on the left side of the screen.

- Effect: The greater the depth, the deeper and broader the observed tissue; The smaller the depth, the shallower the observed tissue, and the larger the depth, the lower the frame rate.

3. The frequency

- Description: the probe transmission frequency, can choose to adopt fundamental frequency or harmonic frequency. The frequency value is displayed in real time in the image parameter area on the left side of the screen. Fundamental wave or harmonic are divided into three frequency modes: "penetration", "conventional", "resolution".
- Effect: The higher the frequency, the better the near-field resolution, but the lower the penetration. Harmonics can enhance near - field resolution and reduce noise with low frequency and large amplitude.

4. Scan speed

- Description: Control the refresh speed of M mode. The scanning speed value is displayed in the image parameter area on the left side of the screen in real time.
- Effect: More detailed observations can be obtained, such as changing the scanning speed to detect anomalies in the cycle.

5. Dynamic Range

- Description: Adjust the contrast resolution of the image, compress or expand the gray scale display range. The dynamic range value is displayed in real time in the image parameter area on the left side of the screen.
- Effect: The larger the dynamic range, the darker the overall image, the less contrast, and the increased noise.

6. Pseudo color Spectrum

- Description: color difference is used instead of gray difference to image, that is, gray scale chromatographic.
- Impact: This feature is available for real-time, frozen, and cine playback images.

7. Effect.

- Description: Adjust black, white and gray scale contrast to optimize the image.
- Effectiveness: The MX wireless ultrasound diagnostic system provides 18 effects for

real-time, frozen and electroplayback images.

8. Time signs

- Description: Sets the display state of the time symbol on the M image.
- Effect: It is helpful to identify the cardiac cycle and find the characteristic lesions.

9. The line

- Description: Line correlation is the scan line processing of M image.
- Effect: Suppress noise and make image details clearer.

11. The acoustic power

- Description: Adjust the power of the probe transmitting ultrasonic wave.
- Effect: With the increase of acoustic power, the overall brightness of the image increases evenly, and the detectable depth also increases.

11. M line

- Description: Adjust the position of the M sampling line.

## 6.5 Image adjustment in Color mode (for Color Ultrasound model only)

Color flow Doppler is used to observe color flow and provide information about flow direction and velocity. In general, red indicates the flow to the probe, blue indicates the flow back to the probe; The brighter the color, the faster the blood flow, and the darker the color, the slower the blood flow.

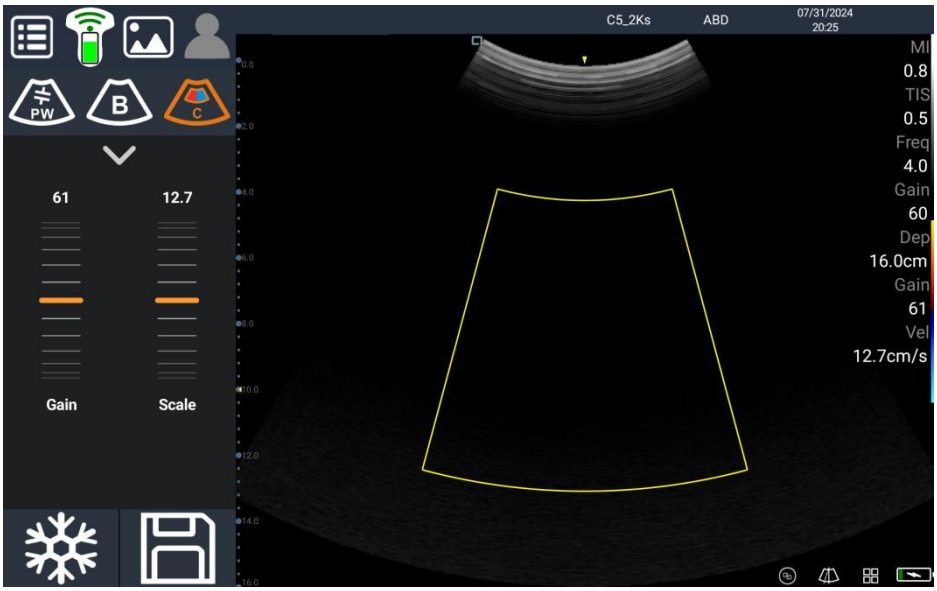



Fig 6.5

Warning

1. Color blood flow only has reference value for doctors, can not directly diagnose, and other machines are generally compared, or using non-ultrasonic means to diagnose.
2. The device cannot examine the fetus in Doppler mode for long periods of time.

6.5.1 Image parameters in Color mode

During C-mode image scanning, the image parameter area on the left side of the screen provides real-time parameter information, and the following parameters can be adjusted:

| Adjust the way | Parameters of the item |
|---|---|
| Control panel adjustment | Gain, rear sight |
| Soft key to adjust | Deflection, Wall Filter, Color Frequency, Afterglow, Mapping, Flip, Acoustic Power, Color Priority |

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

Since the Color mode is a superposition of two-dimensional (B) mode and Doppler mode, the two images change synchronously during magnification or depth adjustment.

6.5.2 Image optimization in Color mode

**Gain**

| | |
|---|---|
| Description | It is used to adjust the total sensitivity of the blood flow signal, and the gain value is displayed in real-time in the image parameter area on the left side of the screen. |
| Adjustment method | Android：Select the "Gain" button, the right slide gain increases, the left slide gain decreases;<br>Parameter Adjustable range: 0 to 100. |

| | |
|---|---|
| Impact | Gain is too large, will amplify the noise; Gain is too small, easy to lose blood flow signal. |

### Rear sight

| | |
|---|---|
| Description | Shows the velocity range of blood flow, which for the product is actually an adjustment of the detectable velocity range of blood flow. |
| Adjustment method | Android: Select the "Speed" button, swipe right to increase the speed, swipe left to decrease the speed;<br>Different probe speed adjustment range is different. |
| Effect | After adjustment, the color blood flow image can be displayed more clearly and accurately.<br>Low speed flow should be measured at a lower velocity range and high speed flow at a higher velocity range. |
| Impact | Aliasing is easy to occur when using lower velocity ranges to measure high velocity flow.<br>Too high a speed scale will cause the loss of small blood flow signals. |

### Deflection

| | |
|---|---|
| Description | Used to tilt color flow images left and right to get more information without moving the probe. |
| Adjustment method | Select [Deflection] button, click to adjust the left and right deflection;<br>Different probe deflection Angle is different. |
| Effect | Changing the incident direction of the beam in the color mode, thus changing the Angle between the beam and the direction of blood flow, is only effective for the linear array probe. |

### Wall filtering

| | |
|---|---|
| Description | Low frequency noise caused by blood vessel wall vibration can be filtered out so as to display the image information effectively. This function is used to adjust the cut-off frequency of the wall filtering in the product. |

| | |
|---|---|
| Adjustment method | Select the "Wall Filter" button, slide the wall filter to the right to increase, slide the wall filter to the left to decrease;<br>Parameter Value Range: 0 to 7. |
| Effect | High wall filtering may cause loss of blood flow signal. |

### Color frequency

| | |
|---|---|
| Description | Switches the probe frequency in Doppler mode. |
| Adjustment method | Select the "Frequency" button, swipe right to increase the frequency, swipe left to decrease the frequency;<br>The frequency range of different probes is different, which can be selected according to the need of probe depth and tissue characteristics. |
| Effect | The higher the frequency, the higher the resolution and sensitivity, but the lower the penetrating power. |

### Afterglow

| | |
|---|---|
| Description | The image is optimized by time smoothing. |
| Adjustment method | Select "Afterglow" button, swipe right to increase afterglow, swipe left to decrease afterglow;<br>Parameter adjustable range: 1 to 5. |

### Mapping

| | |
|---|---|
| Description | Color image display effect parameters, according to the need to switch different maps can get more comprehensive blood flow information. |
| Adjustment method | Click the [Atlas] button, and the tap button appears on the top. Click to select the tap.<br>Parameter adjustable range: V0 to V5. |
| Effect | This feature works with live, frozen, and cine playback images. |

### Flip

| | |
|---|---|
| Description | Set the display mode of color blood flow. After it is turned on, the color ruler will be turned over to change the display mode of blood flow on the image. |

| | |
|---|---|
| Adjustment method | Click the "Flip" button to adjust, and the button indicates the status of the switch. |
| Effect | This feature works with both live and frozen images. |

### Acoustic power

| | |
|---|---|
| Description | Adjust the ultrasonic power of the probe. |
| Adjustment method | Select [Sound power] button, swipe right to increase the power, swipe left to reduce the power;<br>Parameter adjustment range: 10% to 100%, step length is 6%. |
| Effect | With the increase of sound power, the overall brightness of the image increases evenly and the detectable depth also increases. |
| **Impact** | For clinical application, appropriate sound power must be selected according to the actual situation and the "ALARA sound power principle". |

### Color first

| | |
|---|---|
| Description | Used to set the level of blood flow display, choosing to preferentially display black and white or color blood flow. |
| Adjustment method | Select the "color first" button, swipe right to increase the priority, swipe left to decrease the priority;<br>Parameter adjustment range: 10% to 100%, step size is 10%. |
| Effect | When the gear value is large, color image is preferentially displayed; when the gear value is small, black and white image is preferentially displayed. |

6.6 Image Adjustment in Power Mode (for COLOR Ultrasound models only)

Energy Doppler mode is used to show the density and energy information of red blood cells in the blood flow within a certain period of time. It is represented by different brightness colors to provide the perfusion information of blood flow, but not the speed information.

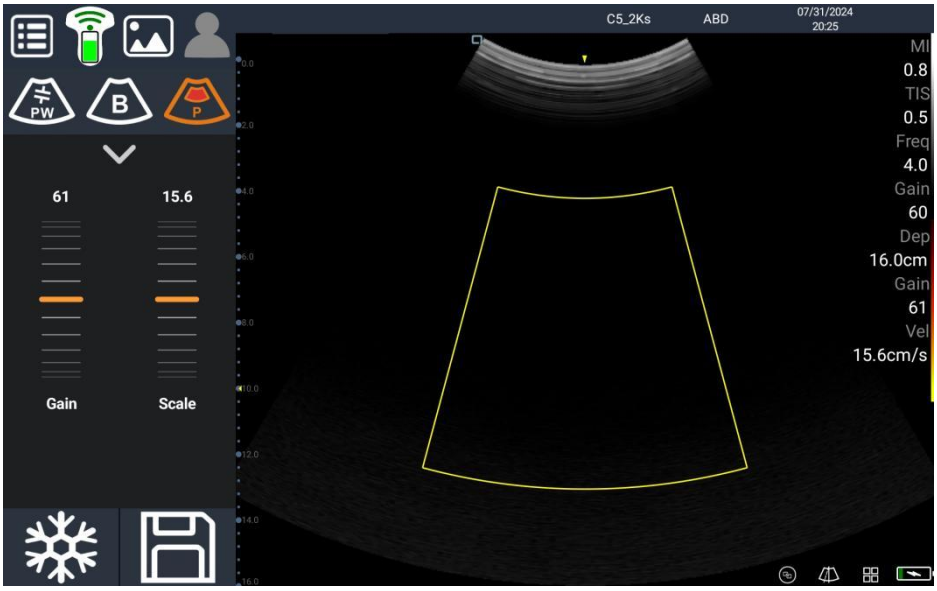



Fig 6.6

### 6.6.1 Image parameters in Power mode

During Power mode image scanning, the image parameter area on the left side of the screen provides real-time parameter information, and the following parameters can be adjusted:

| Adjust the way | Parameters of the item |
|---|---|
| Control panel adjustment | Gain, depth |
| Soft key to adjust | Speed, frequency, color priority, dynamic range, mapping, Wall filtering, acoustic power, afterglow |

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

Since the Power mode is a superposition of two-dimensional (B) mode and Doppler mode, the two images change synchronously during magnification or depth adjustment.

### 6.6.2 Image optimization in Power mode

Due to the same doppler Color imaging, most of the image parameter adjustment items in Power mode are the same as those in Color mode. Therefore, only the image parameters independently adjusted in Power mode are introduced below.

### Gain

| | |
|---|---|
| Description | The total sensitivity of blood flow energy signal is adjusted, and the gain value is displayed in the image parameter area at the top of the screen in real time. |
| Adjustment method | Select the "Gain" button, slide right gain increases, slide left gain decreases;<br>Parameter Adjustable range: 0 to 100. |
| Effect | Gain is too large, will amplify the noise; Gain is too small, easy to lose blood flow signal. |

### Mapping

| | |
|---|---|
| Description | Color image display effect parameters. |
| Adjustment method | Windows: Click the [Atlas] button, and the tap button appears on the top. Click to select the tap.<br>Parameter range: P0 to P3. |
| Effect | The energy map provides the perfusion information of the image and is sensitive to low speed flow. |

### Dynamic range

| | |
|---|---|
| Description | Controls how the echo intensity is converted into a color signal. |
| Adjustment method | Select the [Dynamic Range] key, swipe right to increase the gear, swipe left to decrease the gear;<br>Parameter adjustable range: 30 to 120. |
| Effect | After adjustment, it has greater sensitivity to low energy signals and increases the display range of signals. |

### Deflection

| | |
|---|---|
| Description | Used to tilt color flow images left and right to get more information without moving the probe. |
| Adjustment method | Select [Deflection] button, click to adjust the left and right deflection;<br>Different probe deflection Angle is different. |

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

## 6.7 PW Mode Image Adjustment (for Color Ultrasound model only)

The PW mode (i.e., the spectral Doppler mode) is used to provide information about the direction and velocity of the blood flow. The resulting spectrum represents time on the horizontal axis and doppler shift on the vertical axis.

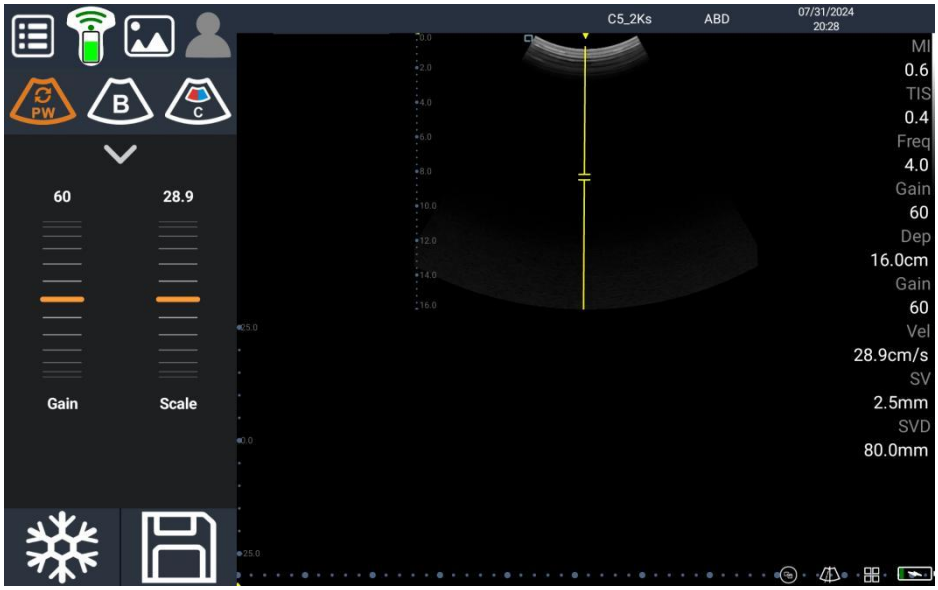



Fig 6.7

PW mode has distance gating function, can display a certain depth of local blood flow velocity, direction, properties.

| Be careful | **The timing of the PW image and THE B/C image is inconsistent, so the immovable probe changes the measurement position when entering the PW mode.** |
|---|---|

### 6.7.1 Image parameters in PW mode

During PW mode image scanning, the image parameter area on the left side of the screen provides real-time parameter information, which can be adjusted as follows:

| Adjust way | Parameters of the item |
| --- | --- |
| Control panel adjustment | Gain, depth |
| Soft key to adjust | Speed, baseline, deflection, fast correction angle, correction angle, flip, SV, wall filter, frequency, dynamic range, volume, tracing range, pseudo color spectrum, acoustic power, time marker, automatic calculation, automatic calculation parameters |

6.7.2 Image optimization in PW mode

**Gain**

| | |
| --- | --- |
| Description | Adjust the output signal size of the spectrum graph, and the gain value is displayed in the image parameter area on the left side of the screen in real time. |
| Adjustment method | Select the "Gain" button, slide right gain increases, slide left gain decreases;<br>Parameter Adjustable range: 0 to 100. |
| Effect | With the increase of gain, the image brightness increases, and more echo signals can be observed, but at the same time, more noise will be brought. |

**Speed**

| | |
| --- | --- |
| Description | Indicates the velocity range of blood flow, which for the product is actually a velocity adjustment. The speed value is displayed in real time in the image parameter area on the left side of the screen. |
| Adjustment method | Select the "Speed" button, swipe right to increase the speed, swipe left to decrease the speed;<br>Different probe speed adjustment range is different. |

| | |
|---|---|
| Effect | After adjustment, the color blood flow image can be displayed more clearly and accurately.<br>Low speed flow should be measured at a lower velocity range and high speed flow at a higher velocity range. |
| **Impact** | Aliasing is easy to occur when using lower velocity ranges to measure high velocity flow.<br>Too high a speed scale will cause the loss of small blood flow signals. |

### Baseline

| | |
|---|---|
| Description | The spectrum shows the region of zero velocity. |
| Adjustment method | Select "Baseline" button, swipe right to move baseline down, swipe left to move baseline up; Or hold the dot to the left of the baseline to move up and down.<br>Parameter adjustment range: -4 to 4. |
| Effect | According to the needs of different parts of the speed of detection, the blood flow display is clearer and aliasing is eliminated.<br>Positive values show a wider range of signals below the baseline, and negative values show a wider range of signals above the baseline. |

### Deflection

| | |
|---|---|
| Description | The Angle between the beam and the direction of blood flow is changed by changing the incident direction of the beam in PW mode. |
| Adjustment method | Select [Deflection] button, click to adjust the left and right deflection;<br>Different probe deflection Angle is different. |
| Effect | Get more information without moving the probe. |

### Quick correction Angle

| | |
|---|---|
| Description | The correction Angle is quickly adjusted with the step size of 60°, and the Angle value is displayed on the right side of the spectrum in real time. |

| | |
|---|---|
| Adjustment method | Select [Quick Angle correction] button, click to left and right Angle correction;<br>Parameter adjustable range: -60°, 0°, 60°. |
| Effect | This feature works with live, frozen, and cine playback images. |

### Correction Angle

| | |
|---|---|
| Description | Adjusting the measured speed and the actual speed as close as possible, is a kind of correction Angle.<br>When adjusting the Angle, the Angle value is displayed on the right side of the spectrum in real time. |
| Adjustment method | Select the "Correct Angle" button, slide the Angle clockwise to the right and counterclockwise to the left;<br>Parameter Adjustment range: -80° to 80°. |
| Effect | This feature works with live, frozen, and cine playback images. |

### Flip

| | |
|---|---|
| Description | After this function is enabled, the spectrum is flipped. |
| Adjustment method | Click the "Flip" button to adjust, and the button indicates the status of the switch. |
| Effect | This feature works with live, frozen, and cine playback images. |

### SV

| | |
|---|---|
| Description | Adjust the position and width of the pulse Doppler sampling volume door, and the current SV value is displayed in the image parameter area on the left side of the screen in real time. |
| Adjustment method | Select the [SV] button, swipe right to make SV bigger, swipe left to make SV smaller;<br>Parameter range: 0.5 mm to 20mm. |
| Effect | When the sampling gate is small, the results are more accurate. When the sampling gate is larger, the range of information obtained is larger. |

### Wall filtering

| | |
|---|---|
| Description | It is used to adjust the cutoff frequency of the wall filter in the system and filter the low-frequency noise caused by blood vessel wall vibration so as to display the image information effectively. The wall filter value is displayed in the image parameter area on the left side of the screen in real time. |
| Adjustment method | Select the "Wall Filter" button, slide the wall filter to the right to increase, slide the wall filter to the left to decrease;<br>Parameter Value Range: 0 to 7. |
| Effect | Could cause loss of signal of blood flow velocity. |

### Tracing range

| | |
|---|---|
| Description | Sets the doppler waveform range involved in the calculation. |
| Adjustment method | Click [Tracing range], automatically switch up, down and all cycles.<br>Parameter adjustment range: up, down and all. |
| Effect | This works for live, frozen, and cine playback images. |

### Automatic calculation and automatic calculation parameters

| | |
|---|---|
| Description | The spectrum Doppler waveform is recorded and the parameters are calculated. The results of automatic spectrum calculation will be displayed in the measurement result window in real time. |
| Adjustment method | Select the key of "Automatic calculation parameters" for adjustment, and the key indicates the status of the switch; |
| Effect | The heart rate value obtained by automatic spectrum calculation may have certain deviation. If you want to obtain accurate heart rate value, please choose manual measurement. |

### Scanning speed

| | |
|---|---|
| Description | Controls the refresh rate of PW mode. |

| | |
|---|---|
| Adjustment method | Select the "Scan Speed" button, swipe right to increase the gear, swipe left to decrease the gear; Windows: Click the "Scan Speed" button, the gear button appears above, click to adjust accordingly. Parameter adjustable range: 1 to 3. |
| Effect | Finer observations can be obtained, such as changing the scanning speed to detect anomalies in the cycle. |

### Time marker

| | |
|---|---|
| Description | Sets the display status of the time flag on a PW image. |
| Effect | The temporal information can help to accurately locate specific points and identify characteristic lesions within fluctuating cycles. |
| Impact | This feature works with live, frozen, and cine playback images. |

### Acoustic power

| | |
|---|---|
| Description | Adjust the ultrasonic power of the probe. |
| Adjustment method | Select [Sound power] button, swipe right to increase the power, swipe left to reduce the power; Parameter adjustment range: 10% to 100%, step length is 6%. |
| Effect | With the increase of sound power, the overall brightness of the image increases evenly and the detectable depth also increases. |
| Impact | For clinical application, appropriate sound power must be selected according to the actual situation and the "ALARA sound power principle". |

### Frequency

| | |
|---|---|
| Description | Switch the probe frequency in Doppler mode, and the frequency value is displayed in real-time in the image parameter area on the left side of the screen. |

| | |
|---|---|
| Adjustment method | Select the "Frequency" button, swipe right to increase the frequency, swipe left to decrease the frequency;<br>The frequency range of different probes is different, which can be selected according to the need of probe depth and tissue characteristics. |
| Effect | The higher the frequency, the higher the resolution and sensitivity, but the lower the penetrating power. |

### Dynamic range

| | |
|---|---|
| Description | Represents the amount of information that the echo intensity is transformed into the grayscale spectral graph. |
| Adjustment method | Select the [Dynamic Range] key, swipe right to increase the gear, swipe left to decrease the gear;<br>Parameter adjustable range: 24 to 72. |
| Effect | Corresponding to the adjustable contrast range of the image, the larger the dynamic range, the richer the layers displayed in the image, the more information, but the noise will also increase. |
| Impact | This feature works with live, frozen, and cine playback images. |

### Volume

| | |
|---|---|
| Description | Control and adjust the size of the output audio generated by the spectrum Doppler. |
| Adjustment method | Select the "Volume" button, swipe right to increase the volume, swipe left to decrease the volume;<br>Parameter adjustment range: 0 to 100. Step: 2. |
| Effect | Combined with audio signal, the flow state and nature can be more effectively judged. |

## 7. Measure

Measurement operations can be divided into routine measurement and application

measurement.

Be careful

1. Shut down during measurement, and all unsaved data will be lost.

2. During the measurement process, all measurement information on the image will be deleted once the frozen state is lifted.

3. The general mode change clears the general/applied measurements from the screen.

4. No meaningless measurements.

## 7.1 Routine measurement

### 7.1.1 2D routine measurement

2D routine measurement is suitable for routine measurement of 2D images. The measurement items are shown in the table below:

| Measuring project | Function |
|---|---|
| Distance | Measure the distance between two points on the ultrasound image. |
| Angle | Measure the included Angle between two intersecting planes on the ultrasonic image |
| Area | Measure the area and perimeter of a closed region on the ultrasound image. |
| Three Distance Volume | Measure the volume of the target object. |
| Recording length, | Measure the length of the upper curve of the ultrasonic image. |
| Recording area | The area and circumference of a closed curve region on the ultrasonic image were measured. |
| Length ratio | The length of two line segments in ultrasonic image is measured and the ratio is calculated. |
| Area ratio | The area of two closed regions on the ultrasonic image is measured and the ratio is calculated. |
| Histogram | The gray distribution of ultrasonic echo signal in a closed region of |

| | |
|---|---|
| | statistical ultrasound image was measured. |

7.1.2 M routine measurement

M Routine measurement items are shown in the table below:

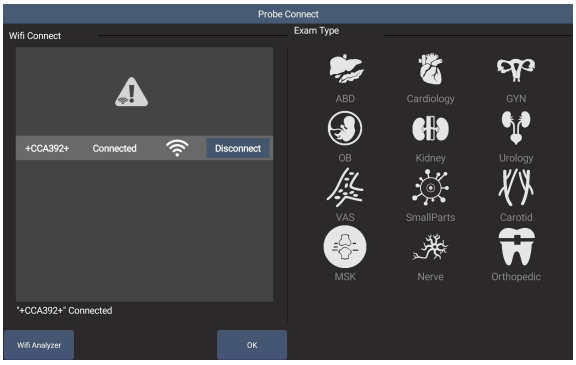
| Measuring project | Function |
|---|---|
| Distance | Measure the distance between any two points on a vertical line at a given time. |
| Time | Measure the time interval between two points on the M image. |
| Slope | Calculate the average slope between the two points by measuring the distance and time between them. |
| Heart rate | The time interval between 2 cardiac cycles was measured and heart rate was calculated on M cardiac images. |

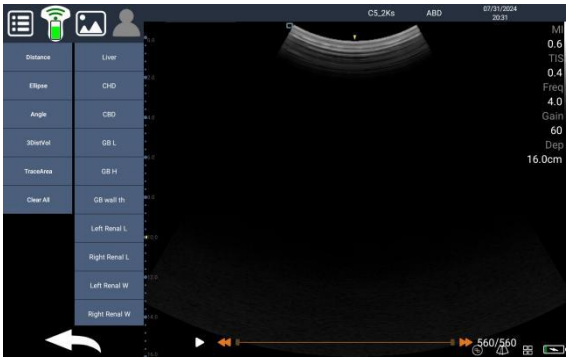
7.1.3 Doppler routine measurements

The PW routine measurement items are shown in the table below:

| Measuring project | Function |
|---|---|
| D Velocity | Measurement of velocity, pressure difference at a point on the Doppler spectral waveform on a Doppler image. |
| PS/ED | Measurement of velocity at the point of peak systole (PS) and end-diastole (ED) on the blood flow waveform in a Doppler image, and calculation of its pressure difference, resistance index RI, and ratio value S/D. |
| D tracing | Clinical indices such as velocity, differential pressure, and index are obtained by tracing the Doppler spectral waveform for 2 cycles. |

7.2 Application Measurement




The product provides measurement functions for the following applications:

- Routine measurements;
- Abdominal application software package;
- Obstetrics application software package;
- Gynecological applications package;
- Cardiac application software package;
- Small organ application software package;
- Neural Applications Software Package

## 8. Cine playback, comment, body markers and report

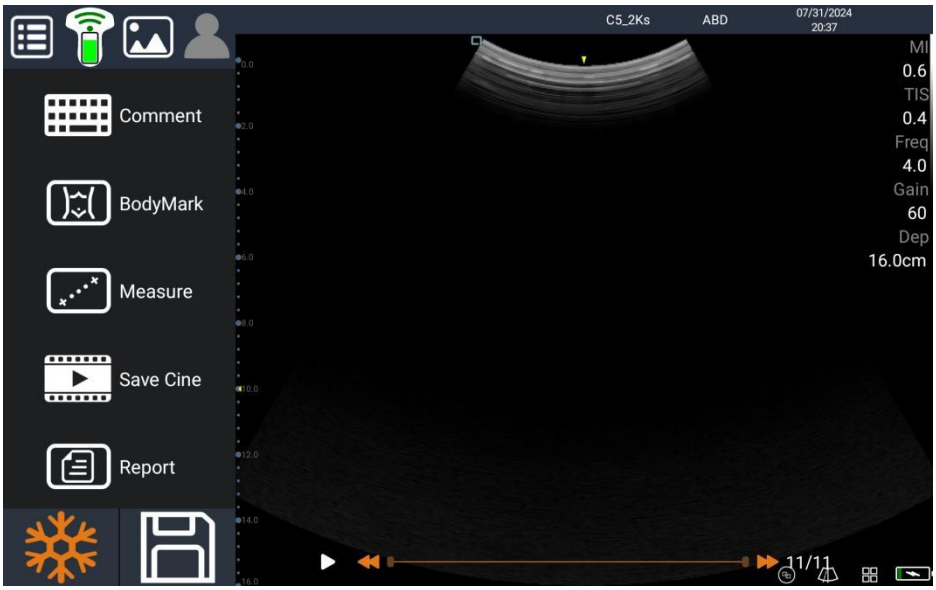
During image scanning, press the Freeze button to freeze the image. After the image freezes, the probe stops the sound output, and all images and image parameters remain unchanged. When the image is frozen, press the "Freeze" button to unfreeze the image, and the system will continue to scan the image.

8.1 Cine Replay

After the image freezes, the system supports cine playback and editing functions. At the same time, it supports enlarging, post-processing, measuring, annotation, adding body standard and other operations for the image of cine playback.

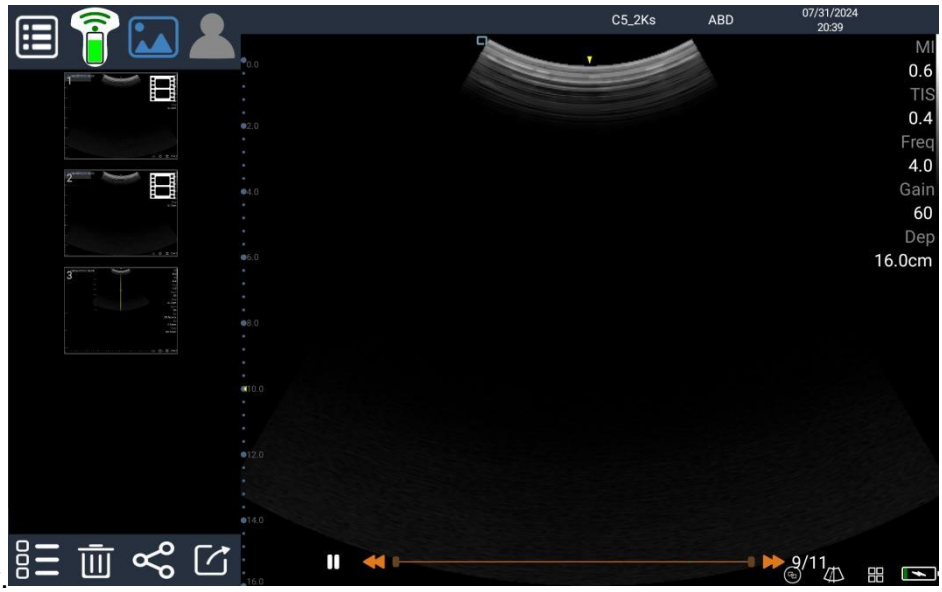
### 8.1.1 Linkage Cine Playback

Linkage cine playback is in B+M synchronous mode, the image is scanned and frozen, and then the B and M are synchronized in the time sequence during playback.



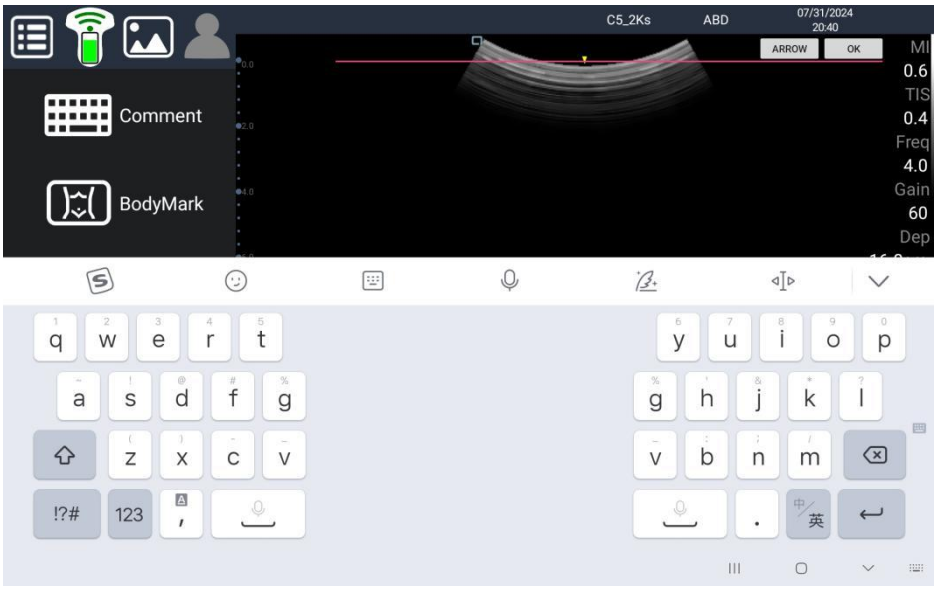

### 8.1.2 Save Cine

When the image is frozen, click the "Save cine" button in the soft key area. After the cine is saved, click on  to view locally.



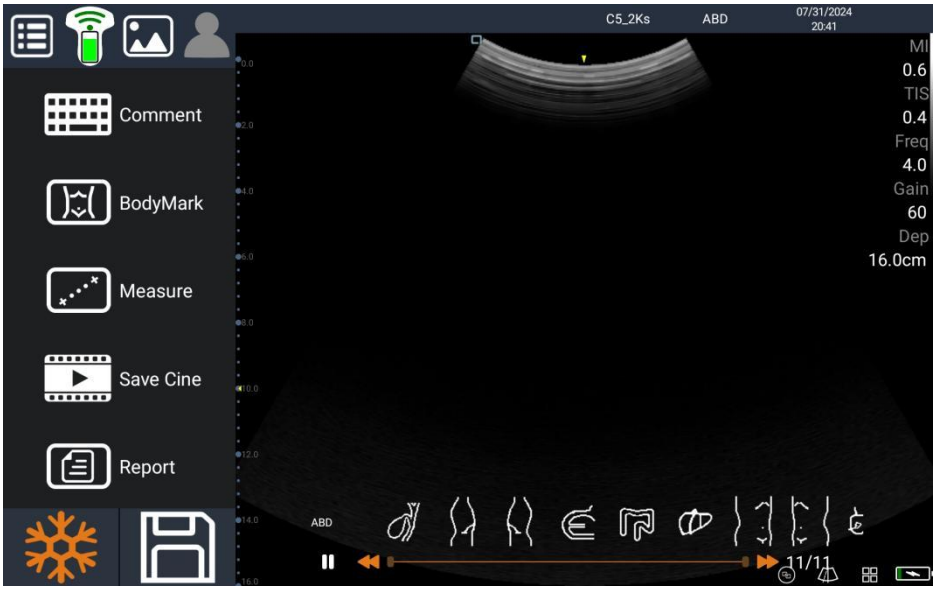
## 8.2 Comment

In the course of diagnosis, it is often necessary to add comment to the ultrasound image. The MX system supports two annotation types: typing characters and pointing arrows.



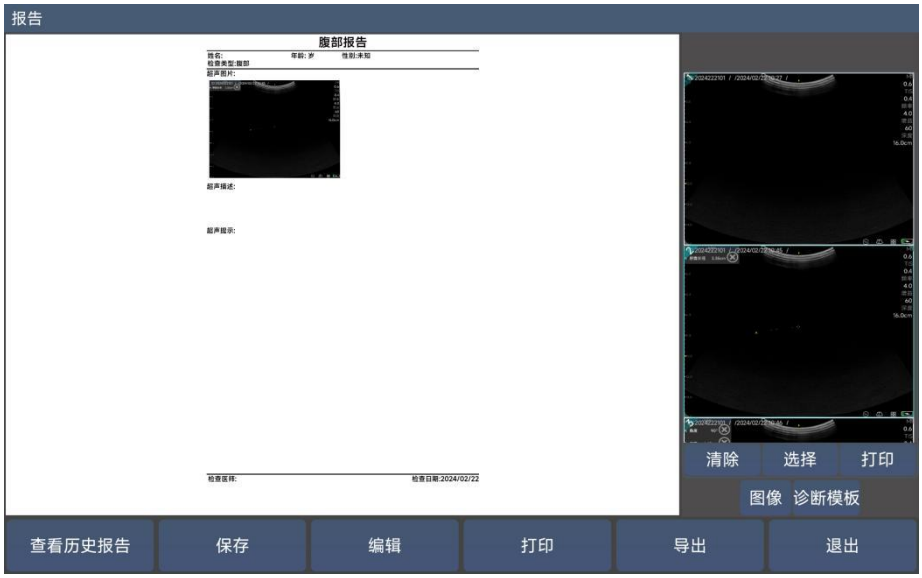

## 8.3 Body markers

The body markers indicate the position of the patient and the scanning direction of the probe, which play an auxiliary role in the image description.



8.4 Report

For routine measurements, no report is generated for the measurement results; for application measurements, a report is generated for the measurement results. The content of the measurement report mainly includes the basic information of the patient, the measurement calculation results, and the doctor's diagnosis results.




## 9. Probe

9.1 Probe Description

9.1.1 Probe type

L-linear array probe;
C-convex array probe;

9.1.2 Probe composition

The probe consists of a piezoelectric ceramic wafer, an acoustic focusing lens and a shell.

9.1.3 Probe performance index

The performance indicators of each probe are published as follows:

Sheet 9.1 Gray-scale imaging performance metrics

| No. | Performance metrics | Probe type | | | |
|---|---|---|---|---|---|
| | | C5-2Ks Convex transducer (big) | C5-2Fs Convex transducer (small) | L11-4Ks Linear transducer | C8-5Ks Micro-convex transducer |
| A | Probe Nominal Frequency (MHz) | 3.5 | 3.5 | 7.5 | 6.0 |
| B | Deviation of acoustic frequency from nominal frequency (%) | ±15 | ±15 | ±15 | ±15 |
| C | Maximum depth of sounding (mm) | ≥160 | ≥160 | ≥50 | ≥60 |
| D | Lateral resolving power (mm) | ≤2(depth≤80)≤3(80 ＜ depth≤130) | ≤2(depth≤80)≤3(80 ＜ depth≤130) | ≤2 (depth≤40) | ≤2 (depth≤50) |
| E | Axial resolving power (mm) | ≤1(depth≤80)≤2(80 ＜ depth≤130) | ≤2(depth≤80)≤3(80 ＜ depth≤130) | ≤1 (depth≤50) | ≤1 (depth≤60) |
| F | Blind zone (mm) | ≤3 | ≤3 | ≤3 | ≤3 |
| G | Slice thickness (mm) | ≤8 | ≤8 | ≤8 | ≤8 |
| H | Lateral geometric position accuracy (%) | ≤5 | ≤10 | ≤5 | ≤10 |
| I | Longitudinal geometric position accuracy (%) | ≤5 | ≤5 | ≤5 | ≤5 |
| J | Perimeter and area measurement deviation(%) | ±15 | ±15 | ±15 | ±15 |
| K | M-mode time display error (%) | ≤10 | ≤10 | ≤10 | ≤10 |

Sheet 9.2 Color Flow Imaging Performance Metrics

| No. | Performance metrics | Probe type | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | C5-2Ks Convex transducer (big) | | C5-2Fs Convex transducer (small) | | L11-4Ks Linear transducer | | C8-5Ks Micro-convex transducer | |
| A | Operating Frequency (MHz) | 2.0 | 3.5 | 2.5 | 3.5 | 6 | 7.5 | 5.0 | 6.5 |

| | | | | | |
|---|---|---|---|---|---|
| B | Detection depth (mm) | ≥120 | ≥120 | ≥40 | ≥40 |
| C | Position of the color blood flow image in relation to the grayscale image of the pipe in which it is located | Overlap. | Overlap | Overlap. | Overlap. |
| D | Blood flow direction requirement | It can be recognized correctly without overlapping. | It can be recognized correctly without overlapping. | It can be recognized correctly without overlapping. | It can be recognized correctly without overlapping. |

Sheet 9.3 Spectral Doppler Imaging Performance Metrics

| No. | Performance metrics | Probe type | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | C5-2Ks Convex transducer (big) | | C5-2Fs Convex transducer (small) | | L11-4Ks Linear transducer | | C8-5Ks Micro-convex transducer | |
| A | Operating Frequency (MHz) | 2.0 | 3.5 | 2.5 | 3.5 | 6.0 | 7.5 | 5.0 | 6.5 |
| B | Detection depth (mm) | ≥120 | | ≥120 | | ≥40 | | ≥40 | |
| C | Flow rate measurement error (%) | ±20 | | ±20 | | ±20 | | ±20 | |
| D | Accuracy of cursor position in Doppler sampling area | Outside of pipe, no flow rate display; center of pipe, maximum flow rate display. | | Outside of pipe, no flow rate display; center of pipe, maximum flow rate display. | | Outside of pipe, no flow rate display; center of pipe, maximum flow rate display. | | Outside of pipe, no flow rate display; center of pipe, maximum flow rate display. | |

### 9.1.4 Wear probe protection

A number of protective measures are necessary to minimize the spread of disease. In clinical practice, probe sheaths are beneficial in preventing transmission. It is strongly recommended to

The use of compliant sterile probe sheaths during endoluminal examinations.

Probe sheaths must be applied to the probe prior to examination of the body with an endocavity probe. Use a commercially recognized protective sleeve.

Be careful

1. To avoid infection, the probe protector should be used only once during the examination. Do not use a torn protective sleeve.
2. Probe sheaths are synthesized from natural latex and talc, which may cause allergies in

some people.

3. Do not use expired probe sheaths. Before using a probe sheath, check that the probe sheath is not expired.

Operation steps (for reference only)

1. Apply an appropriate amount of ultrasound coupling agent inside the protective sleeve or on the surface of the probe; if the coupling agent is not used, the image obtained will not be clear.

2. Ensure sterility when placing the probe into the protective cover of the probe. Pull the protective sleeve tightly to remove wrinkles and air bubbles, and be careful not to pull it over the head.

3. Secure the case with a string tie.

4. Check the case to make sure it is not torn.

9.2 Inspection and maintenance

9.2.1 Check

Frequently check the socket and sound window parts, if found damaged, blistering phenomenon, do not use, immediately replace or repair.

After cleaning and disinfecting (sterilizing) the host and probe each time, they shall be checked. If the above situation is found, please stop using it and replace or repair it immediately.

9.2.2 Probe Service Life

According to the design, production and other relevant documents of the manufacturer, the life of the probe is generally 5 years. The raw materials of the product will gradually age over time. If the product continues to be used beyond its life period, the performance may decline and the failure rate may increase significantly.

Warning

The manufacturer will not be responsible for the risks arising from the use of the product beyond its life.

9.2.3 Probe maintenance

Wipe the probe gently and thoroughly with a 3.4% saturated acetaldehyde solution with a soft damp hot cloth after each use. The probe is a valuable and vulnerable part. It is strictly prohibited to collide or drop. When suspending the diagnosis, it should be placed in the probe box and the instrument in a "frozen" state.

Medical ultrasonic coupling agent should be used in diagnosis.

Be careful

1. Probe repeated exposure to couplant for a long time may damage the probe.

2.Frequently check the probe housing for cracks to avoid immersion of liquid to damage internal components.

9.3 Cleaning and disinfection

The probe is the part that is in direct contact with the patient. In order to avoid infection, please clean and disinfect the probe (sterilization) according to the requirements after completing a test and closing the host machine.

Warning

1. The probe is not immersion proof (IPX7) equipment, can not be immersed in water;

2. Do not dip the probe plug into any liquid such as water or anti-virus solution; Immersion can cause shock or malfunction;

3. If the coupling agent is not completely removed after detection, the coupling agent will solidify and affect the image quality of the probe;

4. Do not put the probe in a high temperature environment (over 55℃) during cleaning and disinfection. High temperature may cause probe damage.

Notice

1. Wear antimicrobial gloves to prevent infection when cleaning or disinfecting;

2. After disinfecting, thoroughly clean the disinfecting residues with disinfecting water. Chemical residues will be harmful to human health.

3. If the effect of disinfection and sterilization solution is not guaranteed, please contact the manufacturer for product information.

1. Cleaning please follow the cleaning instructions on the manual:

A. Wear antimicrobial gloves to prevent infection.

B. Clean the probe with clean water to remove the attached stains. Soapy water can also be used, and polyurethane sponge can be used when cleaning. Avoid using a brush to avoid damaging the probe.

C. After cleaning the probe, use a sterile cloth or gauze to wipe moisture off the probe surface. Do not dry the probe by heating.

2. General disinfection

A. Use a medical cotton ball dipped in 75% medical-grade alcohol to gently wipe the probe back and forth.

B. Precautions for disinfectant: dilution and concentration, method of disinfection, and application process, please refer to the instructions on disinfectant concentration and method of disinfection in the instructions provided by the manufacturer;

C. After cleaning, wipe the probe dry with a germicidal cloth or tulle, and then let the alcohol on the surface of the probe evaporate naturally. Do not dry the probe.

Notice

1. The probe must be cleaned after each use;

2. Do not use a surgical brush to clean the probe. Even a soft brush may damage the probe. Only use a soft cloth.

Warning

1. Stay away from equipment with strong current and strong magnetic field;
2. Do not dip the probe into any type of liquid or detergent;
3. Any type of liquid is strictly prohibited to immerse the probe;
4. It is strictly prohibited to disinfect the probe by gas or heating;
5. Do not dip the probe socket into the solution. Although the probe surface is waterproof, it is limited to the probe head. Please be careful with coupling agent, detergent and disinfectant.
6. Probe failure, do not repair without authorization, must be sent to our company for repair.

Check the following items after cleaning and disinfection:

| Check the project | Check the method | Acceptance criteria |
|---|---|---|
| lens | Visually inspect the surface of the lens and the connection between the lens and the sound head housing | The surface of the lens shall not be damaged or cracked;There should be no cracks in the connection between the lens and the housing. |
| The shell | Visually inspect the surface of the enclosure | The surface of the shell shall not be damaged or cracked |
| Enclosure joint | Visually inspect housing connections | There should be no cracks or lack of glue at the connection of the shell |
| Residue | Visually inspect the surface of the probe, especially pits and narrow areas | No residual detergent or disinfectant |

## 10. Puncture guidance

10.1 Enter or exit puncture mode.

- Click "  " to enter or exit puncture mode.
- To turn on the puncture guidance function

Set up [Guidance Line] and select, according to the puncture needle, Line A, Line B and ALL.


10.2 Puncture guide line calibration

Place the puncture frame with the puncture needles placed, as well as the acoustic head, in the water;

Click [Calibrate] and adjust the "Position" and "Angle" with "+" and "-" to align the needle with the puncture guide line. After the alignment, save the calibrated puncture guide parameters.

## 11. Acoustic output instructions

This chapter focuses on the entire system (including the host, probes, accessories, and peripherals) and aims to provide the operator with important safety information about the acoustic output and how to control the irradiation time using the ALARA principle. In addition, this chapter also includes the information related to the real-time display of the acoustic output

of the MX Diagnostic Ultrasound Systems .
Please read this chapter carefully before using it.

## 11.1 Biological Effects

Ultrasound is generally considered safe for diagnosis. So far, there have been no reports of human injuries caused by ultrasound. Even so, we can't arbitrarily believe that all ultrasound is absolutely safe. Studies have proved that high intensity ultrasound is harmful to human tissues. In recent years, with the rapid development of ultrasound diagnostic technology, people have become more and more concerned about the application of ultrasound and the potential risk of biological effects caused by the diagnostic technology.

## 11.2 Use declarations with caution

Although it has not been confirmed that diagnostic ultrasound equipment causes biological effects in patients, it is possible to demonstrate the existence of biological effects in future applications. Therefore, we must use ultrasound carefully to play its clinical role, and avoid the use of high intensity ultrasound for a long time without obtaining the necessary clinical information.

## 11.3 ALARA principle (As Low As possible to make, Reasonably Achievable)

Ultrasound should be used in accordance with the ALARA principle, using the lowest level of energy that will not cause biological effects as far as possible while ensuring the availability of diagnostic information. The amount of ultrasonic energy depends on the output intensity and the duration of exposure. Different patients and clinical cases require different levels of ultrasound.
Not all tests can be done with ultra-low energy ultrasound. Extremely low energy ultrasound can only produce low quality images or weak Doppler signals, thus affecting the reliability of the diagnosis. However, using more sound power than is actually needed does not help improve the quality of the information for diagnosis, but rather increases the risk of biological effects.

The user must be responsible for the safety of the patient and use the ultrasound purposefully, that is, according to the ALARA principle to select the ultrasonic output power. Additional information on the ALARA principle and the potential biological effects of ultrasound can be found in the "Safety of Medical Ultrasound" document published by the American Institute for Ultrasound Medicine (AIUM).

## 11.4 MI/TI

### 11.4.1 Basic knowledge of MI and TI

The relationship between ultrasonic output parameters (such as frequency, acoustic pressure, acoustic intensity, etc.) and biological effects is not yet clear, but it is recognized that there are two inducements that can cause biological effects. One is thermal effect, refers to the absorption of ultrasonic tissue; The other is mechanical effects, including cavitation. The thermal index (Ti) is the index of temperature increase caused by thermal effects, and the mechanical index (Mi) is the index of mechanical effects. Ti and Mi indices reflect the situation of instantaneous output, without considering the cumulative effect of inspection time.
MI (Mechanical Index) : Mechanical effect is the result of the generation, increase, vibration and collapse of microbubbles in the tissue under the action of sound waves. This reaction is called cavitation effect. Mi indicates the probability of cavitation effect from sound pressure, and the value of MI is determined by dividing the peak negative pressure by the square root of the frequency. Therefore, the higher the frequency or the lower the peak negative pressure, the smaller the MI value, and the less likely the cavitation effect will be.

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

Where,

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

When the frequency is 1MHz and the peak negative pressure is 1MPa, the MI value is 1. Mi can be thought of as a threshold for the cavitation effect. In particular, MI should be set to a low value when both gas and soft tissue are present.

Ti (heat index) :

Ti is determined by the ratio of the total sound power to the sound power required to raise the tissue temperature by 1 ° C. In addition, different tissue structures have different temperature rises, so Ti is divided into three categories: TIS (soft tissue heat index), TIB (bone heat index), and TIC (skull heat index).

TIS: Application of soft tissue heat index, such as abdomen and heart.

TIB: Bone heat index applications, such as fetal (middle or third trimester), where the acoustic beam is focused at or near the bone.

TIC: Skull heat index applications such as pediatric and adult skulls. WFUMB (World Union of Ultrasound Medicine and Biology) states that exposure to a temperature rise of 4 ° C for 5 minutes may pose potential hazards to embryonic and fetal tissues.

The smaller the MI/ Ti, the lower the biological effect.

11.4.2 MI/TI display description

Ti and MI values are displayed in real time in the left-center position of the screen. The operator should monitor these index values during the inspection and ensure that the irradiation time and acoustic output values are kept as low as possible while valid diagnostic information is available.

Ti and MI values are displayed under any operating conditions and the step value does not exceed 0.2. Display precision is 0.1.

Notice

 If MI or TI display values exceed 1.0, be careful to follow the ALARA principle.

11.5 Acoustic power setting

Acoustic output adjustment Adjust the acoustic power according to the "Acoustic Power" item in the soft menu area at the bottom of the screen. When adjusted, the acoustic power level is displayed on the soft menu item and in the left-of-center position of the screen. The higher the numerical level of sound power, the greater the current acoustic output energy. When the image is frozen, no ultrasonic energy is output.

Default Settings indicate how the operator performs the check operation is the most important

factor in controlling the sound output.

The intensity level of the acoustic output depends on the scanning area. During fetal examination, be very careful to control the intensity of sound output.

For the MX wireless ultrasonic diagnosis system, users can preset the image parameters. Once the preset changes are made, the machine's original default Settings become invalid. Therefore, the user is responsible for changes to the default Settings.

Default setting range

| | |
|---|---|
| Acoustic output initial setting range | 10% to 100% |

The maximum acoustic output of each probe depends on the probe surface temperature rise in the selected mode and the acoustic output limits specified by the FDA.

Notice

 The system will automatically revert to the user preset when the machine is switched on, the probe is switched on, a new patient record needs to be filled in or the preset value is defaulted. In factory setting, acoustic power value is lower than user preset value. In accordance with the ALARA principle, the user can increase the acoustic power value through the corresponding soft menu, and can set the AP level in the preset.

The acoustic output of the system is in accordance with IEC 60601-2-37,Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, "Measurement Standard for acoustic Output of Diagnostic Ultrasonic Equipment (NEMA UD-2 2004)", The "Standard for Real Time Display of Thermal and Mechanical Index for Diagnostic Ultrasound Equipment" (AIUM and NEMA UD-3 2004) was measured and calculated. The published values of the acoustic output are shown in Appendix C.

## 11.6 Acoustic power control

The acoustic output ultimately depends on the system operator. Qualified operators should minimize the noise output under the premise of obtaining effective diagnostic images. There are three types of operational control associated with acoustic output control: direct control, indirect control, and receiver control.

1. Direct control

The MX wireless ultrasonic diagnostic system directly controls the acoustic output by adjusting the acoustic output through the "acoustic power" item in the soft menu area. However, in any mode, the maximum acoustic output should not exceed the acoustic output limit (MI limit of 2, TI limit of 6, ISPTA.3 limit of 720 mW/cm$^2$).

2. Indirect control

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

The operating mode determines whether the ultrasonic beam is in scanning or non-scanning mode, and the thermal effect is closely related to M, Doppler and Color modes. The acoustic attenuation of the tissue is directly related to the probe and its frequency changes.

Image depth is related to the effective aperture of the probe.

3. Receiver control

Receiver controls (such as gain, dynamic range, image processing, etc.) do not affect the acoustic output. Therefore, in image optimization, the receiver control class should be adjusted first to optimize the image, followed by direct control and indirect control.

## 11.7 Acoustic output specification

### 11.7.1 Attenuated acoustic output parameters

In order to determine the relevant acoustic output parameters, a method is needed to compare ultrasonic systems with different frequencies and different depth focusing. This method (also known as attenuation method) illustrates the effect of ultrasonic wave propagation through tissue by measuring the acoustic output in the tank. The average acoustic intensity attenuation value of 0.3dB /cm/MHz is usually adopted, that is, the ultrasonic intensity attenuation of ultrasonic emitted by the probe is 0.3dB /MHz for every 1cm propagated. The calculation formula is as follows:

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

Wherein, $I_{atten}$ is the attenuated acoustic intensity, $I_{water}$ is the acoustic intensity measured in the water tank (at the distance Z), $f_c$ is the center frequency of the ultrasonic wave (measured

in water), and Z is the distance from the probe. The attenuation acoustic pressure value formula is similar, but the attenuation coefficient is 0.15 dB/cm/MHz, which is half of the acoustic intensity. Because the pressure is proportional to the square of the pressure, the acoustic intensity coefficient is twice the acoustic pressure coefficient.
Although the attenuation coefficient of 0.3 dB/cm/MHz is much lower than that of any solid tissue in the human body, it can be regarded as the condition of fetal examination. In the first trimester of pregnancy, an ultrasound travels from the probe to the fetus, passing almost entirely through fluid, and fluid attenuation is very small. Therefore, the attenuation coefficient of 0.3dB /cm/MHz is much lower than the actual inspection.

11.7.2 Limits of acoustic output

In accordance with the requirements of FDA Track 3, the acoustic output limit is reduced (or attenuated), as shown in the table below. When any probe is used in any mode of operation, the maximum value of the acoustic output shall be within the limits listed in the table below.

FDA Track 3 Maximum Loudest Output Limits (Decay Value)

| application | $I_{spta.3}$ (mW/cm$^2$) | $I_{sppa.3}$ (W/cm$^2$) | | MI |
|---|---|---|---|---|
| Other parts (except eyeball) | 720 | ≤ 190 | or | ≤ 1.9 |

11.7.3 Differences between actual MI/ Ti values and displayed values

During operation, the system always displays the acoustic output parameters, the thermal index TI and the mechanical index MI. These parameters are indicators of the risk of thermal and mechanical effects from ultrasound. They indicate to the operator that a system setting may increase or decrease the likelihood of thermal or mechanical effects. To be more precise, these parameters are designed to implement the ALARA principle. When an operator changes a system control, the system displays the change in the acoustic output caused by the change. Heat index, however, is not the same as a rise in human temperature. First of all, in order to provide a single index, had to make several assumptions, simplify the problem is one of the assumptions mentioned attenuation method, for the human body most organizations actual values is much smaller (as in brush stroke muscle tissue or organ when attenuation is much higher than 0.3 dB/cm/MHz), for the organization's thermal properties

also will be simplified. Thus, when scanning a hyperperfused tissue (such as the heart or vascular system), a much lower thermal effect will be produced than the thermal index shown. The mechanical index is used to indicate the likelihood that a mechanical (cavitation) effect will occur. MI depends on the attenuation peak negative pressure and the center frequency. The actual peak negative pressure is affected by the actual attenuation, which in turn is caused by the organization between the probe and the focus. The attenuation of all solid tissues in the human body is higher than 0.3dB /cm/MHz, so the actual peak negative pressure value is lower than the displayed value and will vary with the scanning site.

For these reasons, the TI and MI display values are only used to assist the operator in implementing the ALARA principle during the ultrasound examination.

11.8 Measurement uncertainty

| | |
|---|---|
| $I_{spta}$ | 31.2% |
| $I_{sppa}$ | 30.4% |
| Center Frequency (Fc) | 2% |
| Total power (W) | 30.1%<br>(5.6% for scan mode and combination mode) |
| Peak Negative Pressure (Pr) | 15.5% |

11.9 References for acoustic power and its safety


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

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

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

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

(5) "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued by FDA in 2023.

(6) IEC 60601-2-37:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

11.10 Transducer surface temperature

According to the requirements of IEC 60601-2-37 clause 201.11, the surface temperature of the transducer is measured under the following two conditions: the transducer is in contact with the tissue mimicking material (Method B) and the transducer is suspended in the environment without Air circulation (Still Air).

The maximum surface temperature test results of the transducer are listed as follows:

| probe model | test results(Android) | |
|---|---|---|
| | The transducer contacts TMM (℃) | The transducer is suspended in a non-ventilated environment(℃) |
| C5-2Ks | 31.4 | 32.7 |
| C5-2Fs | 28.8 | 31.4 |
| C8-5Ks | 29.0 | 27.7 |
| L11-4Ks | 28.5 | 29.1 |

## 12. EMC Declaration

MX Diagnostic Ultrasound Systemss complies with EMC test standard IEC 60601-1-2 and MX Diagnostic Ultrasound Systems meets the relevant requirements of IEC 60601-1 and IEC 60601-2-37 standards for electromagnetic compatibility.

Warning

1. The use of improper accessories will reduce the product performance.
2. The adapter you choose shall meet the relevant requirements of IEC 60601-1-2
3. Equipment or system may be interfered by other equipment even if other equipment meets the transmission requirements of corresponding national standards.
4. The device should be away from RFID, MRI, diathermy, and electrocautery testing, wireless power transfer, 5G cellular and security equipment (such as electromagnetic

anti-theft system and metal detector). If the devices are near and are interfered by the concealed and undiscovered RF transmitter (for example, scanning mode changes or image disturbances affecting diagnosis), the user should immediately take mitigation measures, such as redirecting, repositioning or shielding the RF transmitter.

5.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.

"Harmful interference"is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Notice

1. Use of unspecified accessories, transducers and cables may cause MX Diagnostic Ultrasound Systems

Increased emission or reduced immunity of acoustic diagnostic system.

2. The MX Diagnostic Ultrasound Systems should not be used in close proximity or in a stack with other equipment. If it must be used in close proximity or in a stack, it should be observed and verified that it can operate normally under the configuration used

3. The MX Diagnostic Ultrasound Systems shall be specifically protected against EMC and shall be installed and maintained in an environment meeting the EMC information provided below.

4. The operation of the MX Diagnostic Ultrasound Systems under the condition that the physiological signal of the patient is lower than the minimum or minimum value specified by the product will lead to incorrect results.

5. Portable and mobile communication equipment will affect the performance of MX wireless ultrasound diagnostic system. See Tables 1, 2, 3 and 4 below. The user shall install and use the EMC information provided in the random file.

6. Portable and mobile radio frequency communication equipment may affect the MX Diagnostic Ultrasound Systems Avoid strong magnetic interference when using, such as

close to microwave oven, elevator, etc.

7. Transmission frequency band: 2412MHz ~ 2470MHz

8. Modulation type: DSSS /OFDM modulation

Frequency characteristics: 802.11b effective radiation

Power: TX power -- 18.0dBm@1DSSS

14.5 dBm @ 54 OFDM

Rx Sensitivity - 95.7dBm@1DSSS

74.0 dBm @ 54OFDM

9. Guidelines and manufacturer's statements are shown in the table below

Table 1:

| **Guidelines and Manufacturer's Statement - Electromagnetic Emission** | | |
|---|---|---|
| The MX Diagnostic Ultrasound Systems is intended to be used in the following specified electromagnetic environment, and the purchaser or user shall warrant that it is used in such electromagnetic environment: | | |
| Emission test | compliance | Electromagnetic Environments - Guidelines |
| RF emissions CISPR 11 | Group 1 | The MX Diagnostic Ultrasound Systems uses RF energy only for its internal functions. As a result, its RF emission is low and there is little chance of interference with nearby electronic devices |
| RF emissions CISPR 11 | Class A | The MX Diagnostic Ultrasound Systems is suitable for use in all installations, except home facilities and direct connection to the public low voltage power supply network used for demestic purpose. |
| Harmonic Emissions IEC 61000-3-2 | Class A | |
| Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3 | complies | |

Table 2

| **Guidelines and Manufacturer's Statement - Electromagnetic Immunity** | | | |
|---|---|---|---|
| Diagnostic Ultrasound Systems is intended to be used in the following specified electromagnetic environment, and the purchaser or user shall warrant that it is used in such electromagnetic environment: | | | |
| Immunity test | **IEC 60601 test level** | **Compliance level** | **Electromagnetic Environments - Guidelines** |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ±8 kV Contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air discharge | ±8 kV Contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air discharge | Floors should be wood, concrete or tile, and if covered with synthetic materials, the relative humidity should be at least 30% |
| Electrical fast Transient / burst IEC 61000-4-4 | ±2kV for the power cord ±1kV for input/output lines | ±2kV for the power cord ±1kV for input/output lines | **Mains power quality** should be of typical quality for use in commercial or hospital environments |
| Surge IEC 61000-4-5 | ±1 kV line(s) to line(s); ±1 kV line(s) to earth | ±1 kV line(s) to line(s); ±1 kV line(s) to earth | Mains power qualityshould be of typical quality for use in commercial or hospital environments |
| Voltage dips, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11 | 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70% UT for 25/30 cycle at 0° 0 % UT; 250/300 cycle | 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70% UT for 25/30 cycle at 0° 0 % UT; 250/300 cycle | Mains power quality shall be of quality typical for use in a commercial or hospital environment. If you require continuous operation during power mains interruptions, , it is recommended that the product use uninterruptible power supply or battery power supply |
| Power frequency (50/60 HZ) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic field shall have the level characteristics of the power frequency magnetic field typical of the site in a typical commercial or hospital environment |
| Note: UT refers to the AC network voltage before applying the test voltage. | | | |

Table 3

| Guidelines and Manufacturer's Statement - Electromagnetic Immunity | | | |
|---|---|---|---|
| The MX Diagnostic Ultrasound Systems is intended to be used in the following specified electromagnetic environment, and the customer or user shall warrant its use in such electromagnetic environment: | | | |
| **Immunity test** | **IEC 60601 test level** | **compliance level** | **Electromagnetic Environments - Guidelines** |
| Conduced RF IEC 61000-4-6 | 3 Vrms<br>0,15 MHz – 80 MHz<br><br>6 Vrms in ISMa and amateur radio bands between 0,15 MH and 80 MHz | 3 Vrms<br>0,15 MHz – 80 MHz<br><br>6 Vrms in ISMa and amateur radio bands between 0,15 MH and 80 MHz | Portable and mobile RF communication equipment should not be used in any part of the MX Diagnostic Ultrasound Systems , including cables, closer than the recommended isolation distance. The distance is calculated by a formula corresponding to the transmitter frequency.<br>Recommended isolation distance<br>$d = 1.2\sqrt{P}$<br>$d = 2\sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 10 V/m<br>80MHz - 2.7GHz | 10 V/m<br>80MHz - 2.7GHz | $d = 1.2\sqrt{P}$ 80 MHz～800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz<br><br>Where:<br>P -- the maximum rated output power of the transmitter as provided by the transmitter manufacturer in watts (W) according to the recommended isolation distance in meters (m)<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveyb , should be less than the compliance level in each frequency range .<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| Note 1 The formula for the higher frequency band is used at 80MHz and 800MHz frequencies.<br>Note 2 These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection by buildings, objects and the human body. | | | |

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

2. Over frequency range of 150KHz ~ 80MHz, the field strengths should be less than 3V/m.

Table 4

| The recommended seperation distance between portable and mobile radio-frequency communication equipment and the MX Diagnostic Ultrasound Systems | | | | |
|---|---|---|---|---|
| MX Diagnostic Ultrasound Systems is intended for use in electromagnetic environments where radiofrequency radiation harassment is controlled. Depending on the maximum rated power output of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitters) and the MX Diagnostic Ultrasound Systems as recommended below. | | | | |
| Rated maximum output power of the transmitter (W) | Separation Distance According to Frequency of Transmitter (m) | | | |
| | 150 kHz ~ 80 MHz $d = 1.2\ \sqrt{P}$ | 150 kHz ~ 80 MHz $d = 2\ \sqrt{P}$ | 80 MHz ~ 800 MHz $d = 1.2\ \sqrt{P}$ | 800 MHz ~ .5 GHz $d = 2.3\ \sqrt{P}$ |
| 0.01 | 0.12 | 0.2 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.64 | 0.38 | 0.73 |
| 1 | 1.2 | 2 | 1.2 | 2.3 |
| 10 | 3.8 | 6.4 | 3.8 | 7.3 |
| 100 | 12 | 20 | 12 | 23 |
| For the maximum transmitter output rating not listed in the table above,the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. If system image distortion occurs, it may be necessary to position system further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people | | | | |

Table 5.

Basic Performance Scanning Mode: The mode of operation of an ultrasonic diagnostic device, consisting of a series of ultrasonic pulses that produce scan lines that do not follow the same acoustic path.

| Scanning mode | parameter |
|---|---|
| B mode | Gain: adjustable from 0 to 100<br>Maximum loudest output: 10-100% adjustable<br>Depth:<br>-- C5-2KS probe ≥30cm<br>-- L10-4VC probe ≥14cm |
| M mode | |

**Names and contents of toxic and harmful substances or elements**

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

| Part name | Toxic and harmful substances or elements | | | | | |
|---|---|---|---|---|---|---|
| | Pb | Hg | Cd | Cr(VI) | PBB | PBDE |
| The internal wire | × | ○ | ○ | ○ | ○ | ○ |
| LCD | ○ | ○ | ○ | ○ | ○ | ○ |
| Button/knob | ○ | ○ | ○ | ○ | ○ | ○ |
| Shell (plastic) | ○ | ○ | ○ | ○ | ○ | ○ |
| shield | ○ | ○ | × | × | ○ | ○ |
| PCBA | × | ○ | ○ | ○ | ○ | ○ |

The following requirements:

○ : It means that the content of the toxic and harmful substances in all the homogeneous materials of the components is in the limit set by SJ/T11363-2006

× : denotes that the content of the toxic and harmful substance in at least one homogeneous material of the component exceeds the limit requirements specified in

**Acoustic output data**

Meaning of each symbol in the acoustic output table:

| symbol | Meaning |
|---|---|
| A | Acoustic attenuation coefficient |
| $A_{aprt}$ | -12dB output beam area |
| $D_{eq}$ | Equivalent pore diameter |
| $d_{eq}$ | Identical beam diameter |
| $f_{awf}$ | Acoustic operating frequency |
| $I_{pa}$ | Pulse mean acoustic intensity |
| $I_{pa,\alpha}$ | The average acoustic intensity of |
| Ipi | Pulse acoustic intensity integral |
| Ipi, α | Pulse acoustic intensity integral |
| Ita(z) | Time mean acoustic intensity |
| Ita, α(z) | Time mean acoustic intensity after |
| Izpta (z) | Spatial peak time mean acoustic |
| Izpta, α(z) | Spatial peak time mean acoustic |
| MI | Mechanical index |
| $P$ | The output power |
| $P_\alpha$ | Output power after attenuation |
| $P_1$ | Bounded output power |
| $pi$ | Pulsed acoustic pressure squared |
| $p_r$ | Peak sparse acoustic pressure |
| $p_{r.a}$ | The peak sparse acoustic |
| Prr | Pulse repetition rate |
| TI | Heat number |
| TIS | Soft tissue heat index |
| TIB | Heat index of bone |
| TIC | Cranial heat index |
| $z$ | The distance from the source to a |
| $z_b$ | The depth of the TIB |
| $z_{bp}$ | The depth of the breakpoint |
| $z_s$ | The depth of the TIS |