

# **Digital Handheld Probe-type Ultrasound System**

## **User Manual**

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## Foreword

### Product Information:

Respected users, thanks for using Digital Handheld Probe-type Ultrasound System produced. Please read the contents before operating to ensure the safety and correct operation on this machine, so that you can quickly grasp the performance of the equipment and use. Please keep this manual in a safe place for easy access.

Product name: Digital Handheld Probe-type Ultrasound System

Product model:

Registration producer:

Address: Tel: Zip code:

Manufacture address:

Date of manufacture: See product label

Version No.: V.

### Warning:

For the safe and correct operation of this equipment, to extend its life and ensure the safety of users and patients, the user must totally understand its function, operation and maintenance methods. Please read the contents before operating this machine, and please note the following requirements:

1. This system must be used only by qualified medical professionals.
2. The formulas and databases in this manual are for reference only.
3. In order to use the equipment safely, please strictly follow the instructions in this manual.
4. Although the amount of radiation caused by the use of ultrasonic diagnosis has no effect on the human body, avoid unnecessary ultrasonic energy to the human body as far as possible.
5. DO NOT allow the operator to contact the patient, the live parts of the ultrasound system or other devices.
6. In terms of safety, it is the operator's responsibility to understand the hazards of the equipment and to take appropriate action to ensure that the patient receives the minimum risk while obtaining the necessary diagnostic information.
7. If anything goes wrong with the machine, please immediately shut down and contact the company or its authorized agents.

### Statement :

The device provides software upgrades. as the system improve and update,the software will also be updated.Therefore, contents of this manual are subject to change without prior notice.

The configurations and functions are different for different models in different sales regions.The features described in this manual and the displayed operation interface may not be supported or different from your system. Please refer to the actual device configuration.

Do not make any kind of commitment to this manual, including (but not limited to) implied warranties of fitness for a particular purpose.

If There are replacement parts and scrap machine ,please classify ,recycle or dispose them according to the local laws, regulations and environmental requirements.

**After purchasing this product, the customer has full responsibility for the maintenance and management of the product.**

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

)Damage or loss due to misuse or abuse.

)Damage or loss caused by Acts of God, such as fire, earthquake, flood, lightning and so on.

)Damage or loss caused by failure to meet the specified conditions for this system,such as inadequate power supply,improper installation or environmental conditions.

)Damage or loss due to use of the system outside the region where the system was originally sold.

)Damage or loss involving the system purchased from a source other than our company or its authorized agents.

.DO NOT make changes or modifications to the software or hardware of this system.

.In any case, manufacturer shall not be liable for any problems, damages or losses caused by improper re-installation, alteration or repair by unqualified or unauthorized service people.

.The purpose of this system is to provide physicians with data for clinical diagnosis.

.The physician is responsible for the results of diagnostic procedures. Manufacturer shall not be liable for the results of diagnostic procedures.

.Important data must be backed up on external memory media.

.Manufacturer shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.

.This manual contains warnings regarding foreseeable potential dangers, but you shall also be continuously alert to dangers other than those indicated.



.Manufacturer shall not be liable for damage or loss resulting from negligence or ignorance of the precautions and operating instructions described in this operator's manual.

.If a new manager takes over this system, be sure to hand over this user's manual to the new manager.

## **copyright:**

.the hardware and software of this system are protected by intellectual property rights.

.Manufacturer owns the intellectual property rights to this product and this manual .

.No individual or organization may copy, modify, or translate any part of this manual without the prior written permission of Manufacturer.

.This manual serves only as a reference for operation and maintenance of the equipment.

.Manufacturer reserves all right in final explanation of this manual.

## **Warranty and maintenance services**

The warranty is months. If the warranty period is not consistent with the above standard warranty or another agreement in your contract with the seller, please consult manufacturer services and confirm. If the manufacturer can't confirm, you may need to confirm with the seller timely.

Warranty period starts from the written "installation date" on the "warranty card" attached to products. "Warranty card" is the only certificate to calculate the warranty period

In order to safeguard your rights and interests, Please urge the installer return the card to manufacturer within days from the data of installing the device. If the warranty card you purchased is not returned to manufacturer on time, the warranty period will be extended from days according to the "Product Code" marked on the box.

During warranty period, the products can enjoy free after-sales service. However, please note that, even during the warranty period, when the product needs repair due to the following reasons, the manufacturer will charge maintenance services, and you need to pay for maintenance and accessories.

1. Malfunction or damage caused by improper use or human behavior.
2. Malfunction or damage caused by unstable or out-of-range power input
3. Malfunction or damage caused by force majeure, such as fire, earthquake and so on.
4. Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
5. Others not caused by instrument or part itself

Manufacturer can provide paid reparation service after the expiry of warrant.

If you do not pay or delay to pay the fees for maintenance services, manufacturer will suspend maintenance services until you pay the bill.

**After-sales Service Center**

Manufacturer :

Address:

Postal code :

Website:

Tel:

Fax:

# Chapter 1 Safety Regulations

This chapter describes the important safety measures that should be taken before using Digital Handheld Probe-type ultrasound system, and also indicates the equipment's compliance standards. In order to ensure the safety of patients and operators before using this machine, please read the following safety regulations.



► Do not modify this product, including system components, software, and cables. If users modify this equipment, it may cause security problems and system performance degradation. All modifications must be made by professional approved by manufacturer.



► This system is not waterproof designed. DO NOT use this system in any place where water or any liquid leakage may occur.

► Do not place the liquid above the device. if the conductive liquid into the charged circuit components may cause a short circuit, resulting in a fire.

► If water is accidentally sprayed on or into the system, power off the system immediately and contact Manufacturer Customer Service Department or agents.

► Do not operate this equipment in an environment with flammable or explosive liquids, vapors, gases such as oxygen and hydrogen. Malfunction or the spark generated by the fan motor may detonate this materials electronically.

► Do not place the probe on the chemical environment (such as corrosion, degradation, pollution) to avoid damaging the device / probe by the strong acids and bases .

The operator shall pay attention to the following points in order to avoid the danger of explosion:

)If there is a flammable substance in the environment, do not plug in the power supply or boot the device software

)Do not attempt to shut down the device or unplug the power if flammable substance is detected in the environment after the system turned on.

)If there is a flammable substance in the environment, please empty the area of the air before shutting down the device.

)DO NOT open the cover. Short circuit or electric shock may be caused when the system hardware is exposed and powered on.



C CAUTION

► Always keep the system dry. Avoid transporting this system quickly from a cold place to a warm place; otherwise condensation or water droplets may form resulting in a short circuit and possible electric shock.

► If a fault occurs. Please contact manufacturer Customer Service Department or agents .Do not try to solve it by yourself.

## 1.1 Meaning of Signal Words



D DANGER

Indicate extremely hazardous situations that, if not avoided, will result in the following situations.:

- Death or serious injury;
- Heavy property loss;
- Fire.



W WARNING

Indicate potential hazardous situations that, if not avoided, could result in:

- Minor or severe bodily injury, even life-threatening;
- Heavy property loss.



Indicate a potentially hazardous situation that, if not avoided, may result in:

- ▶ Minor personal injury;
- ▶ Property loss;
- ▶ Data missed.



Indicate a potentially non-compliance situation that, if not avoided, may result in:

- ▶ Abnormal equipment;
- ▶ Invalid operation.

## 1.2 Identification Label and Host Label:



Product name: Digital Handheld Probe-type ultrasound system

Product model:

Voltage: DC  $V_{\pm}$ .V

Power consumption: VA

Serial Number:

Registration producer:

Address:

Tel:


Zip code:


Production license No.:

Registration certificate No.:

Product technical requirements No.:

Lifespan:

Other details please refer to the specification: 

 Manufacturing data:

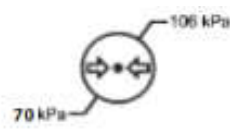
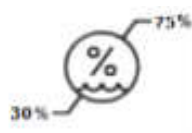
### Package marks:

Product name: \_\_\_\_\_

Product model: \_\_\_\_\_

Dimension: \_\_\_\_\_

Net: Gross:



Address:

After sales service:

Tel:

Website:

## Qualification certificate

Certificate	
Product name:	<u>Digital Handheld Probe-type</u> <u>Ultrasound System</u>
Product model:	_____
Serial Number:	_____
Ex -factory Date:	_____
Censor:	_____
Manufacture address:	
Address:	
After sales service:	
Tel:	
Website:	

## Warranty card

# Warranty Card

(Original)

Product name : Digital Handheld Probe-type ultrasound system	Product model:
Serial Number:	Manufacturer:
Address:	
Date of Installation:	Tel:
warranty period: twelve months	Zip code:

Dear Consumers,

In order to provide you with excellent after-sales service, Please complete the warranty registration, and return the copy of this card to our company for a half of month from the date of purchase. we would like to keep your particulars on file so that can trace the quality of this product. Otherwise it may affect timely warranty service which is your required .

if you have any other request, please enclose a separate letter. Thank you for your cooperation!

statement:

.Users will enjoy free maintenance with the warranty card within the specified period.

.This warranty shall not extend to:

.Can not produce warranty card or number does not match;

.Malfunction or damage caused by improper use or man-made failure;

.Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.;

.Malfunction or damage caused by force Acts of God ,such as fire and earthquake;

.The company is responsible for life-long maintenance without the warranty period.

## Warranty Card

(Original)

NO -----

**\*\*In order to provide you with excellent after-sales service, Please complete the warranty registration, and return the copy of this card to our company\*\***



product model:	Name: (stamp)	
Serial Number:	Address:	
Signing date:	Name of dean:	
Installer:	Departments:	Operator:
Warranty period:	Tel:	Zip code:





Probe:

All probes are attached to the shell with a data of working frequency and a raised dot. The dot indicates the direction.

The raised edge corresponds to the "  " mark on the scan screen. The "  " mark indicates the direction of the scanning probe.

Notes:

If the probe parameters or specifications are changed, please consult the company's after-sales service department or refer to the latest instructions.

### 1.3 Safety Classification

According to the type of electroshock proof:

Class II equipment.

According to the degree of electroshock proof:

Type-B applied part.

According to the degree of protection against harmful ingress of water

The grade is IPX.

According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:

Not AP/APG.

Whether the the device have application to discharge part of the protective effect of defibrillation.

The device does not have an application part that protects against defibrillation effects.

According to the mode of operation:

Continuous operation mode.

### 1.4 Patient Safety



W WARNING

► Please keep the correct identification of all patients' data, and verify the accuracy of such data when entering the patient's name or ID number. Make sure that all data and the patients' identification provided in the print are correct. Identifying errors may result in incorrect diagnosis.

► Make sure that the confidentiality of patients' information data.

► After accessories disinfecting, the chemical reagent or gas must be completely removed. The residual chemical reagent or gas will not only cause damage to the accessories, but also harm the human body.



- ▶ DO NOT use this system in the presence of flammable gases (e.g., anesthetic gas, hydrogen) or flammable liquids such as ethanol, otherwise it may cause an explosion.
- ▶ There may be a risk of electric shock if any lighting, monitor, or visual indicator remains open after the device turned off.
- ▶ Be careful of biological hazards when performing inspection procedures. Prevent the spread of the disease.
- ▶ This system does not apply to the eye examination and the examination may cause the beam passes through the eye .
- ▶ This device is used with caution in patients with burns, scalds or other external skin lesions.
- ▶ The device can not check the fetus for a long period.
- ▶ This device may cause blurred images if the patient has too much gas in the gastrointestinal tract.
- ▶ After examination of each patient, the probe and reusable accessories should be thoroughly clean, and carried out disinfection or sterilization if necessary.
- ▶ The device may be less likely to interfere with the pacemaker. However, since the device will produce a high frequency electrical signal, the operator should be aware of the risks associated with this interference.
- ▶ Normal ultrasonic examination does not present a risk of burns, even when the surface temperature of the probe exceeds the body temperature of a patient due to the different environmental temperature and inspection mode. DO NOT keep the probe on the same region of the patient for a long time to avoid being burned. Apply the probe only for a period of time required for the purpose of diagnosis .
- ▶ Any accessory (such as gel) must meet be qualified.

## 1.5 Operator Safety

Commands:

This system must be used only by qualified doctor, medical staff who is familiar with the ultrasonic technology and wave spectrum of testers. Unauthorized persons can not use this device.



Incorrect operation may result in the risk of injury to the operator. It is only permitted by service people or authorized by the manufacture to open the equipment shell. Do not attempt to disassemble the device by yourself.

- ▶ Risk of electric shock. DO NOT attempt to disassemble the device by yourself. Maintain and adjustment should be done by service people from or authorized by manufacturer.

- ▶ Before cleaning the device, remove the device from the computer to prevent electric shock.

- ▶ To avoid causing the damage of operators' hand, wrist or arm, Please note the following matters:

- › Keep the body in a balanced position during the scanning operation.

- › During the operation, relax muscles regularly to avoid prolonged repetitive operation.

- › DO NOT over-tighten the probe to avoid operating in an uncomfortable position, which may result in the damage of operators' hand, wrist or arm.

## 1.6 Probe Safety



- ▶ If probe is dropped or collided with other hard objects, DO NOT use it until the leakage test has verified that the electrical safety is not impaired.

- ▶ Never immerse the probe into liquids such as water or disinfectant to clean because it is not waterproof. Immersion may cause electric shock or malfunction.

- ▶ Using the probe with caution, damage to the probe may increase the risk of electric shock. Please check frequently whether there are cracks or openings in the shell, holes inside or around the sound lens, or other damage to resulting in water flow into probe.

- ▶ If contact surface of the probe is scratched, immediately stop using it and contact the sales office or distributor. If use a scratched probe, there is a risk of electric shock.

- ▶ Avoid excessive bending the probe cable to



prevent the probe electrical safety from the damage caused by the cracks or damage of the probe shell, or cable breaking or exposure.

► DO NOT disinfect the probe with steam, heat, or liquid sterilization, which can cause permanent damage to the probe.

► DO NOT connect or disconnect the active probe during real-time scanning, Probe could be plug in/out with power on under freezing condition or after existing ultrasound system.

► Repeated disinfection will reduce the probe safety function, please check the probe's performance periodically.

## 1.7 Electrical Safety



► The ultrasonic equipment must use the auxiliary computer with a USB port.

► When the this device and high-frequency equipment (such as surgical electrodes) is used at the same time, the malfunction of surgical equipment or damaged probe lens may cause surgical electrodes to burn the patient.

► The probe and heart rate display waveform panels must be removed from the patient before electric defibrillation.

► The system uses high-frequency signals, and the pacemaker can interfere with these signals. Users should be aware of potential hazards and should immediately turn off the device if they are found or suspected of interfering with the pacemaker operation.

► All input / output terminals of this device can only be connected with the equipment complying with GB.. If the device is connected with the equipment complying with other relevant national standards, the whole system should conform to GB..

► All components of this device and all accessories must be disposed of in accordance with local environmental

regulations at the end of lifetime .

► All repairs must be made by our company. So the device is not equipped with the corresponding circuit diagram. If the customer has this need, please contact your local dealer.

## **1.8 Electromagnetic Compatibility and Risk Warning**

This user manual includes the following information:

Through the electromagnetic compatibility test, diagnostic system fits the National standards of YY- and GB.-.

Please strictly observe the following requirements, or it may cause electromagnetic interference to other devices or reduce the therapeutic apparatus of anti-electromagnetic interference, or even the loss of basic performance.

This product belongs to A class equipment of the I group GB- , so it should not be used in household and can not be directly connected with the device used in residential low voltage power grid facilities.

Instructions of portable and mobile RF communications equipment may affect medical electrical equipment: The Portable and mobile RF communication equipment may affect the normal operation of the device,so ensure to meet a certain distance between the communication equipment and this device. Specific requirements are in table .

3)The length of USB cable should not be longer than . meters. If the cable is with breakdown, please contact our company for repair or replacement, otherwise,may cause excessive electromagnetic interference. If fthere is damage, please contact our company in time. Don't repair or replacement of components without permission, otherwise it may cause excessive amounts of electromagnetic interference.

4)Caution: Using the accessories, probes and cables which against the regulations except the probe or cable sold by the manufacturer of the device or system as spare parts for internal components may result in increasing equipment and system emissions or reducing the immunity.

Caution: Equipment or system should not be used in close to and stacked with other equipment. If it is essential, should observe and verify that it can operate normally in this configuration.

Basic performance

In normal situation, detect whether the host work properly, check the probe detection depth which should meet the technical requirements( ..): Convex array probe should be deeper than or equal to mm.

Test method: start the system, minutes later, test by using human body ultrasonic simulation phantom.

Electromagnetic compatibility statement **In table 1 - table 4**

## Digital Handheld Probe-type Ultrasound System Electromagnetic Statement

Table 1


Guide and manufacturer's statement - electromagnetic emission		
The Digital Handheld Probe-type Ultrasound System intends to be used in the following electromagnetic environment, the purchaser or user shall ensure that it is used in the electromagnetic environment		
Launch Experiment	Compliance	Electromagnetic Environment - Guide
Radio frequency Emission GB	set	The digital handheld probe-type ultrasound system uses RF energy only for its internal function. So its RF emission is very low, and the possibility of interference with electronic devices is very small
Radio frequency emission GB	Class A	The digital handheld probe-type ultrasound system is suitable for using in all non - domestic and not directly connected to all facilities of the residential public low-voltage power supply network
Harmonic emission GB .	Inapplicability	
Voltage fluctuation/Scintillation emission GB .	Inapplicability	

Table 2

Guide and manufacturer's statement - electromagnetic immunity			
The digital handheld probe-type ultrasound system intends to be used in the following electromagnetic environment, the purchaser or user shall ensure that it is used in the electromagnetic environment			
Immunity Test	IEC Test Level Guide	Coincidence Level	Electromagnetic Environment - Guide
Electrostatic discharge GB/T .	± kV contact discharge ± kV air discharge	± kV contact discharge ± kV air discharge	The ground shall be wood, concrete or ceramic tile. If the ground is covered with synthetic material, the relative humidity should be at least %
Electrical fast transient burst GB/T .	± kV to power line ± kV input and output lines	± kV to power line	The network power supply should have the quality that is used in a typical commercial or hospital environment
Electrical surges GB/T .	± kV line to line ± kV line to ground	± kV line to line ± kV line to ground	The network power supply should have the quality that is used in a

			typical commercial or hospital environment
Voltage dips, voltage interruptions and voltage variations GB/T.	$< \%U_t (> \% \text{ dip in } U_t) \text{ for } . \text{ cycles}$ $\%U_T (\% \text{ dip in } U_T) \text{ for } \text{ cycles}$ $\%U_T (\% \text{ dip in } U_t) \text{ for } \text{ cycles}$ $< \%U_T (> \% \text{ dip in } U_t) \text{ for } \text{ seconds}$	$< \%U_T \text{ for } . \text{ cycles}$ $\%U_T \text{ for } \text{ cycles}$ $< \%U_T \text{ for } \text{ seconds}$	The network power supply should have the quality that is used in a typical commercial or hospital environment. If the user of the Digital Handheld Probe-type Ultrasound System needs continuous operation during an electric power outage, it is recommended that the Digital Handheld Probe-type Ultrasound System uses the uninterruptible power supply or batteries
Power frequency magnetic field (/Hz) GB/T .	A/m	A/m	In the event of malfunction, it may be necessary to keep the digital handheld probe-type ultrasound system away from the power frequency magnetic field or install a magnetic shield in the field. And the power frequency magnetic field in the expected installation site shall be measured to meet the requirements below the coincidence level.
Note: $U_T$ refers to the AC grid voltage before the voltage is applied			

Table 3

Guide and manufacturer's statement - electromagnetic immunity			
The Diagnostic System intends to be used in the following electromagnetic environment, the purchaser or user shall ensure that it is used in the electromagnetic environment			
Immunity Test	IEC Test Level Guide	Coincidence Level	Electromagnetic Environment - Guide
Radio frequency conduction GB/T . Radio frequency radiation GB/T .	V( Effective value) kHz~ MHz V/m MHz~. GHz	V( Effective value) V/m	<p>Portable and mobile radio communication equipment should not be closer to any part of the Digital Handheld Probe-type Ultrasound System including cable than recommended isolation distance.The distance should be calculated using the formula corresponding to the transmitter frequency.</p> <p>Recommended isolation distance</p> $d = \sqrt{\frac{P}{4\pi f}}$ <p>d=. kHz~MHz d=. kHz~MHz</p> <p>In the formula: P--Maximum output rated power of transmitter supplied by transmitter manufacturer,in watts (W) as the unit; d--Recommended isolation distance , in Meter (m) as the unit.</p> <p>The field strength of a fixed RF transmitter is determined by the investigation of the electromagnetic field<sup>a</sup> , and each frequency range<sup>b</sup> should be lower than the coincidence level.</p> <p>Interference may occur near the device marking the following symbol.</p> 
<p>Note : In the MHz and MHz frequency, the higher frequency band should be used.</p> <p>Note : These guides may not be appropriate for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and the human body.</p>			
<p><sup>a</sup> Fixed transmitter field strength in theory can not be accurately predicted, Such as: wireless (cellular phone / cordless) and ground mobile radio base station, amateur radio, FM radio and television broadcasting etc.In order to assess the electromagnetic environment of fixed RF transmitters, electromagnetic site survey should be taken into account. If the measured field strength of the Digital</p>			



Handheld Probe-type Ultrasound System is higher than the RF compliance level, the Digital Handheld Probe-type Ultrasound System should be observed to verify its normal operation. If observed performance is abnormal, supplemental measures may be necessary, such as reorienting the direction or location of the Digital Handheld Probe-type ultrasound system.

<sup>b</sup> The field strength should be less than V / m over the whole frequency range of KHz to MHz.

Table 4

Recommended separation distance between portable and mobile radio-frequency communication equipment and Digital Handheld Probe-type Ultrasound System			
Digital Handheld Probe-type Ultrasound System intend to be used in a controlled electromagnetic environment for RF radiation disturbance. Based on the maximum output power of the communication device, the purchasers or users of the Digital Handheld Probe-type Ultrasound System can maintain the minimum distance between the portable and mobile RF communication devices (transmitters) and the Digital Handheld Probe-type Ultrasound System to prevent electromagnetic interference			
Transmitter maximum rated output power W	Isolation distance corresponding to different frequency of transmitter /m		
	KHz~ MHz d=.	MHz~ MHz d=.	MHz~. GHz d=.
.	.	.	.
.	.	.	.
.	.	.	.
.	.	.	.
.	.	.	.
For transmitters maximum ratings not listed above, the recommended separation distance in meters (m) as a unit, can be determined by the corresponding transmitter frequency bar formula, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in Watt (W) as a unit.			
Note: In the MHz and MHz frequency, the higher frequency band should be used.			
Note: These guides may not be appropriate for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and the human body.			

Table 5

S/N	Description	Cable Length (m)	Whether to shield
	USB cable	.	Yes

## 1.9 ALARA principle

Using ultrasound should follow ALARA principle(As Low As Reasonably Achievable). On the premise of obtaining diagnostic information, use the lowest level energy that does not lead to biological effects as far as possible. Ultrasonic energy depends on the intensity

of output and exposure time. Besides, different patients and clinical cases require different intensity of ultrasound. Not all inspections can be done by using ultra-low ultrasound energy. The ultra-low energy ultrasound can only produce low quality images or weak doppler signals, thereby affecting the reliability of the diagnosis. However, using the sound power which is greater than actual need does not help to improve the diagnostic information quality, but will increase the risk of biological effects.

When obtaining clinical information, the user should perform the ultrasonic inspection procedure with the lowest output level and irradiation time according to the principle of small size (ALARA) when a satisfactory clinical diagnosis map is available.

### **1.10 Safety Statement**

Although it has been proved that ultrasonic frequency, intensity, and radiation time have no harmful biological effects on scanning, we recommend that please use the lowest sound output setting in order to produce satisfactory diagnostic information.

See Appendix A for acoustic output data of this device.

### **1.11 Biological Effect**

Recently, With the rapid development of ultrasonic diagnostic technology, people are more and more concerned about the biological effects of potential risks which may be resulted by the application of ultrasound and diagnostic techniques. So far, it is generally believed that ultrasound diagnosis is safe. There have also been no reports of any human injury caused by ultrasound. In spite of that, we can not arbitrarily believe that all of the ultrasound is absolutely safe, because some researches have confirmed that high-intensity ultrasound is detrimental to human tissue.

## Chapter 2 System Composition and Characteristics

### 2.1 Appearance



### 2.2 System Composition

Digital handheld probe-type ultrasound system consists of probe, USB cable and exclusive software ( version V.) .

The element is 80 ; the central frequency is 3.5 MHz ; the radius of curvature is R = 60mm ; element distance is 0.78mm; the scan mode is electronic convex array scan.

#### 2.2.1 Product Model

Model:

#### 2.2.2 Performance Index

Dimension: x x mm

USB length: mm

N/W: g

Power supply: DCV, VA

Working and storage conditions

Working environment

Ambient temperature: +°C~+°C;

Relative humidity: ≤%;

Atmospheric pressure: hPa~hPa

Storage environment

Ambient temperature:  $-^{\circ}\text{C} \sim ^{\circ}\text{C}$ ;

Relative humidity:  $\leq\%$ ;

Atmospheric pressure: hPa $\sim$ hPa

### **2.3 Intended Use**

The product can be applied to all clinical departments of each big hospital, primary medical unit and first aid unit for rapid emergency inspection (e.g., emergency room, ICU, ambulance, wild aid) and basic examination (e.g., ward inspection, fetal monitoring, musculoskeletal rehabilitation inspection, fracture judgment, hospital medical examination, grassroots unit inspection, supply inspection, inspection and family planning inspection and family doctor on-site checking); as well as anaesthetic puncture intervention, PICC catheter, visual guidance of various surgeries, blood vessels checking in injection and infusion, etc. By application of mobile intelligent terminals, it can also realize intelligent medical services since it can provide remote medical service by uploading images, medical data, etc.

### **2.4 Contraindication**

It is an unobtrusive ultrasound imaging product with no contraindications in clinical use. The product cannot be used directly on burned, scald or injured surface tissue of human body, but can be used after disinfection and physical isolation of the probe and wire.

The computer connected to this product shall not be used for other purpose. It is recommended that a pure version system should be installed, and no other application software should be installed except for that of the product.

### **2.5 Target Group**

Adults, teenagers, and pregnant women.

### **2.6 Lifetime**

Five years.

## Chapter 3 Basic Principles and Main Technical Indicators

### Indicators

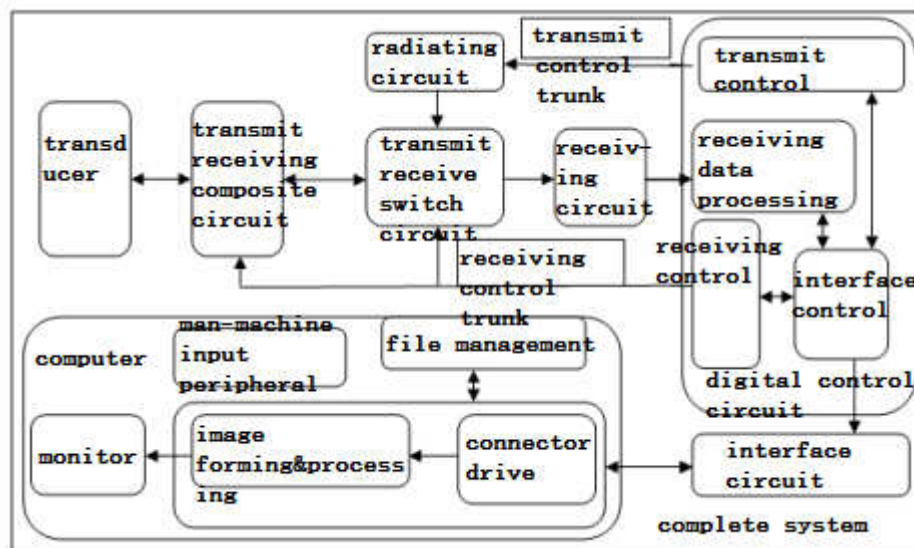
#### 3.1 Basic Principle

##### 3.1.1 System Principle

The system includes image collecting(probe head) and image processing(exterior intelligent terminals).

After receiving instruction issued by the intelligent terminal, the probe will form ultrasound beams of different scanning modes. The beams are passed to the transducer (sound head) via the transmitting circuit, the radiating receiving switch circuit, and the radiating receiving composite circuit, and then the transducer will convert the electrical signals into mechanical wave and transmit it to the scanned organ to form ultrasonic launch. When the transducer received ultrasound, it realizes ultrasonic receiving (or collection) of the converted electrical signals via the radiating receiving composite circuit, the radiating receiving switch circuit and the transmitting circuit. The collected electrical signals will be transmitted to the intelligent terminal via the interface circuit after simple synthesis and storage processing.

##### 3.1.2 System Composition Diagram



#### 3.2 Main Technical Indicators

The performance of the probe shall be in accordance with Table .

Table 1 Requirements of ultrasound system

Performance indicator	Probe type and standard frequency
Standard frequency	. MHz
Probe frequency error	Deviation of the sound working frequency from standard frequency shall $\leq \pm\%$
Probe type	convex, $R \geq \text{mm}$
Scanning depth, mm	$\geq$
Axial resolution, mm	$\leq (\text{depth} \leq)$ $\leq (< \text{depth} \leq)$
Lateral resolution, mm	$\leq (\text{depth} \leq)$ $\leq (< \text{depth} \leq)$
Accuracy of geometric position (%)	lateral $\leq$ , longitudinal $\leq$
Blind region (mm)	$\leq$
Slice thickness (mm)	$\leq$
Error of perimeter/area (%)	$\leq \pm$
Time error of M mode (%)	$\leq$
Distance error of M mode (%)	$\leq$

### 3.3 Power Supply Voltage Adaptability

The device shall work normally if USB output voltage is  $\text{DCV} \pm .V$ .

### 3.4 Continuous Working Time

$\geq 8 \text{ h}$ .

### 3.5 Sound Output Parameters

The sound output parameters of the diagnostic equipment shall be tested according to GB16846—2008. If the conditions are not met, the information shall be published in the form of technical specifications, operating instructions and other background information. The sound output parameters of this ultrasonic probe do not meet the requirement of being exempted from the promulgation conditions and are hereby promulgated(Appendix A).

### 3.6 Intelligently terminals requirements

This device consists of image collecting(probe head) and image processing(intelligent

terminals). Intelligent terminals include normal PC and mobile terminals.

### **3.6.1 Lowest configuration of normal PC terminals**

- a) GPU:  $\geq 1.4\text{GHz}$
- b) RAM:  $\geq 2\text{G}$
- c) Hardware capacity:  $\geq 320\text{G}$
- d) Monitor resolution:  $1024*768$  or higher
- e) One USB3.0 port
- f) Operating system: Windows 7, Windows 8, Windows 10.

### **3.6.2 Recommended brands and models**

Lenovo(E), HP(G), Dell(E), Asus(MCD), Samsung(RL-Z), and Jumper(EZPAD MINI).

## **Chapter 4 Installation and Instructions**

### **4.1 Using Conditions and Environmental Requirements**

- 1) Power supply:  $DCV \pm V$ ;
- 2) Ambience temperature:  $+^{\circ}C \sim +^{\circ}C$ ;
- 3) Relative humidity:  $\leq \% (^{\circ}C)$  ;
- 4) Atmosphere pressure: 860hPa $\sim$ 1060hPa;

5) The screen shall be far away from strong electric field, high magnetic field equipment and high pressure equipment, as well as flammable, explosive, strong corrosive materials; and direct sunshine shall be avoided. Sunshine shall be avoided indoors, beneficial for image observation, ventilating, moisture proof and dust proof).

### **4.2 Appearance Requirements**

Surface of the device should be clean and uniform in color; there should be no significant scratches, grease dirt and damage. DO NOT allow foaming, peeling, cracking and whitening.

### **4.3 Depth Requirement of Probe Immersion**

Waterproof range: IPX. Any conducting liquid is forbidden to avoid probe corrosion. Depth can't exceed mm when acoustic window immerses water.

### **4.4 Unpack and Check**

After unpacking, check if the random accessories are complete according to "packing list", and whether the host and the accessories are deformed or damaged. If necessary, raise the host and make appropriate "shake" action to check whether there are internal "loose" parts. If you find any problems, please contact the agent immediately. Install it after confirming that there is no shipping damage.

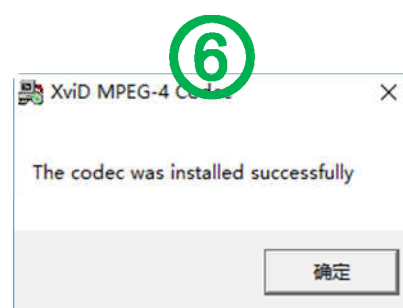
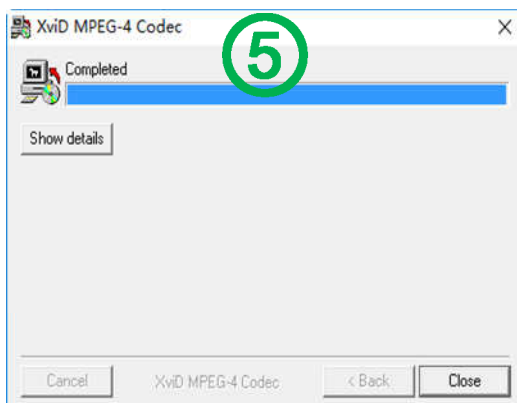
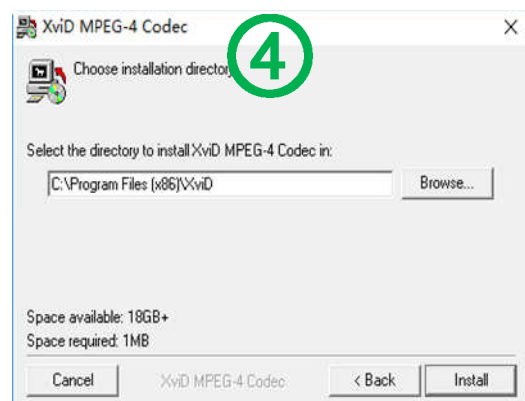
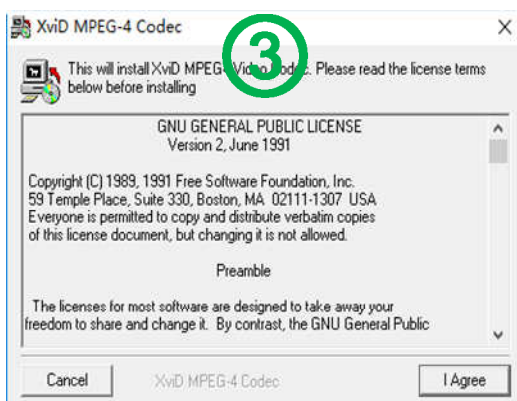
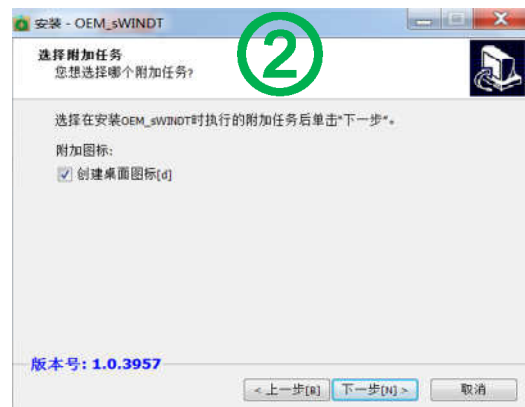
### **4.5 Software Installation**

An example of Windows installation. It is suggested that the computer is only for ultrasound use.



Please install pure application system, and uninstall antivirus software before ultrasound software installation.

Start the installation by clicking “sWINDT”. Run the program as an administrator.



1.Click “Next” and choose the default path as the installation. Then there will be decoder installation interface.

2.Click “IAgree”.

3.Click “Install”.

4.Installation completed.

5.Click “Close” to close decoder installation interface. Drive installation guide will be displayed automatically.

6.Click “Next” to install.

7.Click “Finish” after installation.

8.Whether run “sWINDT”.

#### 4.6 Instructions of Startup & Shutdown

Check the following items before startup.

No.	Items	Inspection Method
	The power supply conforms to standard USB output power (DCV $\pm$ .V )	Asking for information/ investigation /testing
	The probe and connecting cable shall not be damaged, scratch and fall off; and the joint connection is without loose and no crack.	Visual inspection
	To ensure that USB connection is not on abnormal phenomena (such as scratches, cracks)	Visual inspection
	Cleaning and sterilizing the probe	Visual inspection
	Temperature, humidity and atmospheric pressure shall meet the requirements of use conditions	Temperature / humidity measurement
	Condensation phenomenon can not occur	Visual inspection

⚠Warning: If any quality problem, contact our marketing dept, after-sales dept, or agents.

#### 4.7 Connect/disconnect the probe

**⚠Caution:**

Close the software before plugging in/out the probe, otherwise it will cause faults easily.  
Place the probe on a flat surface before plugging in/out the probe, in this case it will protect the probe from falling down resulting in damage.

**⚠Warning:**

Close the software before plugging in/out the probe, otherwise it will cause faults easily.  
Place the probe on a flat surface before plugging in/out the probe, in this case it will protect the probe from falling down resulting in damage.

#### 4.8 Connect Intelligent Terminals

Turn on the intelligent terminal, and connect USB cable. Enter the software interface by clicking desktop icon.

Check whether there is abnormal heating when the probe is working.

⚠Warning: Using abnormal probe may burn the patient.

Follow next steps to check:

Check image to make sure of that there is no abnormal phenomena(abnormal noise, flicker,etc).

Also check following items:

No.	Item	Method
	Abnormal sound, odd flavor, or overheating not allowed	Visual/Hear
	No error information	Visual
	No obvious abnormal noise, discontinuously displaying or black area in mode B	Visual
	Surface of acoustic lens is not overheating(check by hand)	By hand

	No black line or interference in the image area.	Visual
--	--	--------

⚠Warning: If any abnormal phenomena, it means defaults. Shut down the system and contact our marketing dept, after-sales dept, or agents immediately.

## 4.9 Diagnosis

Smear ultrasound gel on the diagnostic part of patients, let the probe contact the part , then an image will be shown on the monitor. Different tangent planes will be displayed by changing probe angle and gradient. Select proper image as the basis of diagnosis. If gain is not good enough, adjust it to get best image.

### 4.10 Restart if with faults

When following abnormal situation occur, reconnect the device by exiting/open software:

Always show error information on the screen.

Abnormal screen displaying.

Operate abnormally.

⚠Warning: Daily maintenance or check is essential to run safely and effectively. Check device status before booting. Once there is abnormal circumstance, close software immediately and contact our marketing dept, after-sales service dept, or agents. Using abnormal system will do harm to patients and device.

⚠Warning: DO Not use a probe without clearance and sterilization. Residual chemical reagent or gas will do harm to a probe and patients.

### 4.11 Instructions

1) Avoid electric shock when installing and moving device.

Always keep dry. It is forbidden to move device from a cold place to a warm place rapidly, otherwise there will be phenomenon of condensation or water drops resulting in short circuit.

2) Normal ultrasound diagnosis will not burn patients, even probe temperature is higher than patients' temperature because of ambient temperature and diagnostic modes. In order to avoid burning, don't place the probe on the same scanning body part too long. Shorten the scanning time asap under the condition of meeting diagnostic judgment.

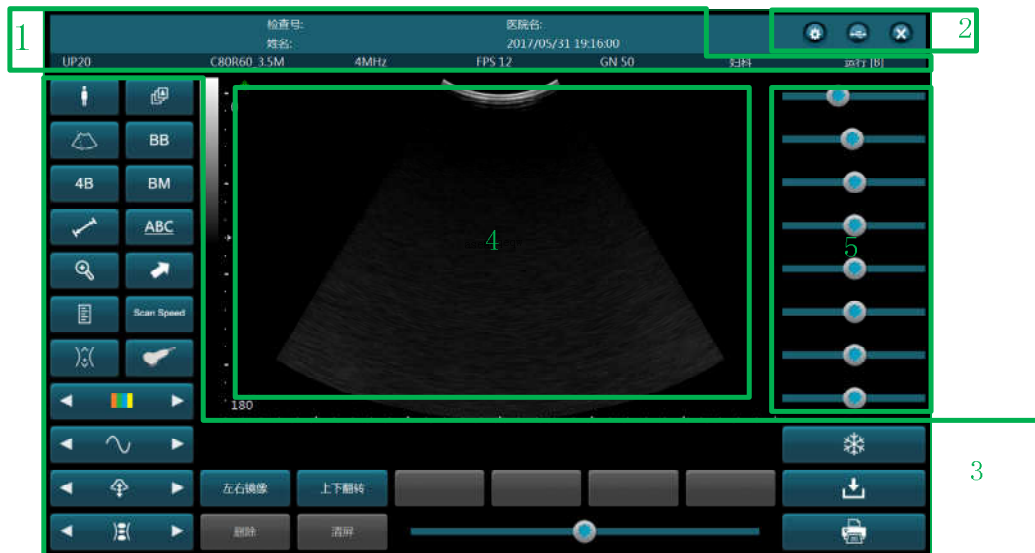
3) Don't plug in/out a probe without closing software, or it will cause system damage or

electric shock.

- 4) Don't turn off when printing, saving, or using data, or it will cause the process completed abnormally.
- 5) Clear out gel thoroughly and place a probe on a flat surface after using the probe. Otherwise water in the gel may immerge acoustic lens, which will have bad influence of performance and safety.
- 6) To protect data safety, save patient files to external storage medium. In this case, it can avoid data loss because of system defaults.
- 7) When discarding the device or any accessory, please contact our sales office, after-sales dept or representative office. Our company will not be responsible for any responsibility if customers dispose product without without authorization.
- 8) With the time of use, the performance of electric and machinery safety will reduce(such as leak current), as well as sensitivity and precision will be less and less. It is suggested that sign a maintenance agreement to avoid accident and misdiagnose.

## Chapter 5 Functions

### 5.1 Main Interface



- 1.Information display information
- 2.Setup, configuration, close area
- 3.Function button area
- 4.Image area
- 5.TGC adjustment area

#### 5.1.1 Function Keys Area

Including all functional operation keys. Click the left mouse button to operations.

#### 5.1.2 Image Area

Including the two-dimensional image and a gray scale display bar.

#### 5.1.3 Information Display Area

Including product model, probe model, working condition (freeze or operation) of the probe, working frequency of the probe, image transmit frame frequency, hospital name, patient information, date & time, and company logo.

#### 5.1.4 TGC Regulation Area

8 TGC

### 5.2 Function Keys



Patient file button. Click this button to enter the interface of new medical record construction and medical records management.



Medical records browse button. Click this button to browse persisted medical records.



B mode and puncture guiding line switch button;



B/B mode;



B mode;



BM mode and M mode switch button;



Access to range measurement;



Access to text annotation;



Access to arrow annotation;



Access to zoom mode;



Access to preset and image processing;



Load the scan speed selection button;



Access to body mark selection;



Access to the probe selection interface to select probe or position;



Pseudo color selection;



Frequency



Refresh



	Depth		Access to setting
	Focus		Delete the last mark or measurement
	Access to report editing		Clear all marks and measurement
	Save image		Freeze

## 5.3 Brief Introduction to Functions

### 5.3.1 Interface Language

- ▶ Chinese and English are optional

### 5.3.2 On-screen Display

- ▶ Probe information, display mode, depth, focus, body mark, probe direction signs, patient information, name of hospital, measurements, date, scale, M sampling line (BM mode), probe frequency, frame rate, total gain, menu and notes.

Save Image

Movie Save and Playback

### 5.3.3 Display Mode

- ▶ B, B/B, 4B, B/M and M as shown below

### 5.3.4 Display Depth

- ▶ 90-240mm continuously adjustable

### 5.3.5 Focus Point

- ▶ The focus point is up and down continuously adjustable

### 5.3.6 Frequency Conversion

- ▶ Adjustable Frequency Conversion

### 5.3.7 Scan Speed

- ▶ Scan speeds adjustable

### 5.3.8 Local Zoom

- ▶ amplification factors adjustable (real-time B mode)

### 5.3.9 Display gray-scale

- ▶ Gray-scale

### 5.3.10 Total Gain

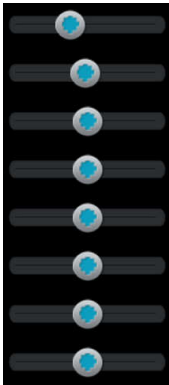
- ▶ The value range of overall gain is from to .The greater the gain value, the brighter the image, whereas the image will be darker.



- ▶ Drag the progress bar rightward to increase the gain and drag it leftward to decrease the gain.
- ▶ The current total gain value is shown as "Gn" on the top of the main interface.

#### 5.3.11 TGC

TGC refers to the depth segmented gain compensation curve. Adjust the slider manually to regulate the present depth segment by segment.



- ▶ This system supports 8 segments of TGC.
- ▶ When the image is frozen, the gain adjustment does not display.

#### 5.3.12 Image Post-processing

- ▶ Frame Correlation
- ▶ Brightness
- ▶ Contrast
- ▶ Gamma
- ▶ Sharpen
- ▶ Edge enhancement
- ▶ Linear correlation
- ▶ Smoothness
- ▶ Intelligent noise reduction
- ▶ Upside down
- ▶ Left-right mirror
- ▶ Pseudo-color

#### 5.3.13 Preset

<	帧相关	2	>
<	亮度	0	>
<	对比度	1	>
<	伽玛	0	>
<	锐化	0	>
<	边缘增强	0	>
<	线相关	4	>
<	平滑	0	>
<	智能降噪	4	>
预设		关闭	

- Click *Preset*. In the dialog box of preset, the present post-processing parameters can be saved to files.
- Click *Preset*. In the dialog box of preset, it's able to load preset and set rapidly the image style.

#### 5.3.14 Pseudo-color

- types of pseudo-colors in total are available.

#### 5.3.15 DICOM

- Support saving and sending image in Dicom (dcm) format.

#### 5.3.16 Static image

- Save image at any time (image format subjects to setting)

#### 5.3.17 Cineloop

In the image acquisition process, the system will automatically save finally collected multiple frames in the internal list, after freezing, the user is allowed to play images in the list looping or by single frame, and this function is called the movie playback.



- ▶ Press down the “Freeze” button to call the movie operation dialog box automatically.
- ▶ The system supports saving frames maximumly.
- ▶ Click “Play” to access the movie playback status.
- ▶ Click “Pause” to stop playing images temporarily.
- ▶ Click “Start Frame” to select a start point of playback from the movie playback scrollbar.
- ▶ Click “End Frame” to select an ending point of playback from the movie playback scrollbar.
- ▶ Click “Save Movie” to save the present movie into the avi file in the disk.
- ▶ Click “Browse” to check all movie files under the present medical record.

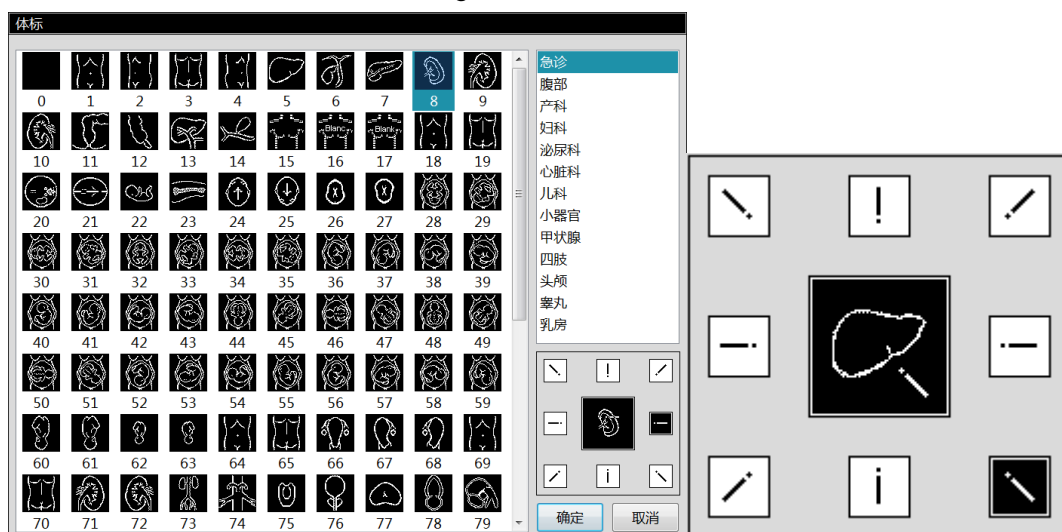
### 5.3.18 Probe Switch

- ▶ The system supports two probes: convex array and linear array.
- ▶ Click to switch probe and select the inspection area.
- ▶ In case of pull and plug probes in the freeze process, press unfreeze to switch automatically.

⚠ **Caution: before pull or plug probes, must freeze image or exit the software, otherwise it's easy to break down.**

### 5.3.19 Body Mark

Body mark refers to the inspection body position of patient and the inspection location of probe, which is used to comment on images.



- ▶ The body mark library is grouped according to functional parts of human body, including

abdominal, obstetrical, gynecology, urology, cardiology, pediatrics, small organs, thyroid, arms and legs, head, testis, breast, etc.

- ▶ The first image in the list is blank, select that image means delete the body mark.
- ▶ After a body mark is selected, it's able to add probe position on that image and can adjust the probe location.
- ▶ The first image is black, which means body mark will be deleted if choosing it.


### 5.3.20 Annotation

- ▶ Click the annotation button to access the annotation status.
- ▶ Move mouse to the annotation point, and click the mouse to popup the dialog box of Annotation Input.
- ▶ Input annotation and click "Confirm" to finish.

▶

⚠ Warning: the annotation added must be correct. A wrong annotation may result to misdiagnose!

### 5.3.21 Arrow

- ▶ Click the arrow button  to access the arrow annotation status.
- ▶ Move the mouse to the first endpoint of the arrow, click the mouse and up-spring it.
- ▶ Move the mouse to the second endpoint of the arrow, click the mouse and up-spring it to finish the arrow annotation.
- ▶ The arrow annotation function is usually used together with the annotation function.

▶

⚠ Warning: the direction of arrow must be correct. A wrong arrow may result to misdiagnose!

### 5.3.22 System Settings

- ▶ See 5.4

### 5.3.23 Medical Record Management

- ▶ See 5.5


### 5.3.24 Measurement and Calculation

- ▶ See 5.6

### 5.3.25 Print Report

- ▶ See 5.7

## 5.4 System Settings

Click  at the upper right corner of the screen to access to settings.

### 5.4.1 Basic Settings

- ▶ Hospital name: add hospital name to the medical record automatically.
- ▶ Language: select Chinese or English accordingly.
- ▶ Date: select the format of dd/mm/yy or yy/mm/dd according to custom.
- ▶ Image format: bmp, jpg, png, tif and dicom
- ▶ Movie frames: Effective in real-time acquisition status, and is selectable ( frames, frames, frames and frames) as required.

### 5.4.2 Obstetrics list preset

Item	Left Column	Right Column
1	AC	Hadlock82
2	BOD	Hadlock90
3	BPD	Hansmann79
4	Cereb	Hansmann86
5	Clav	Jeanty82
6	CRL	Merz91
7	FL	Tokyo96_1
8	FTA	Tokyo96_2
9	GS	Korean
10	HC	Sonotech
11	HC/AC	
12	HL	
13	OFD	
14	TAD	

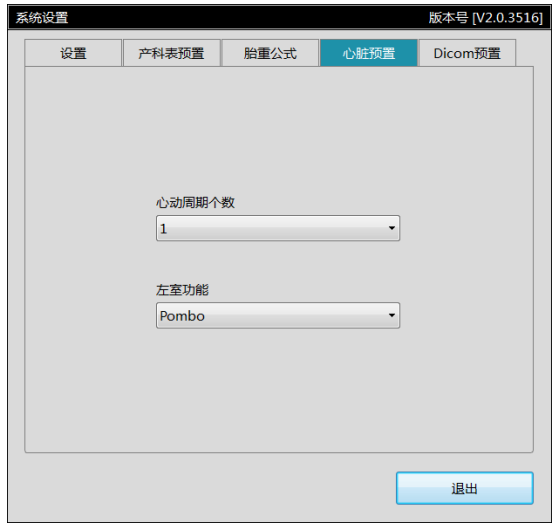
- ▶ Hospital name: choose a proper obstetrics list according to regions or races. This system supports the following obstetrics list (subject to the actual model): abdominal girth (AC), biparietal diameter (BPD), brachiocephalic diameter (CRL), femur length (FL), breast diameter (THD), gestational sac (GS), occipitofrontal diameter (OFD), humerus length (HL), tibia (TL), ulna (UL), head circumference (HC), transverse trunk diameter (TAD), anteroposterior trunk diameter (APTD), transverse trunk (FTA), vertebral length (LV).

### 5.4.3 Fetal Weight Formula



- types of viviparity calculation formula is optional. Proper choice can be made according to requirements.

### 5.4.4 Heart Preset



- Cardiac cycle number: refers to the number of adjacent valleys or peaks in measuring the heart rate.
- Left ventricular function: formula used in calculating functions of the heart and the left ventricular.

### 5.4.5 Dicom Settings

- Dicom title, IP address and port number settings. Can use Ping to check whether the IP is blocked or not.

## 5.5 Patient File Management

Click the button “Patient” at the left side of the main interface to enter the medical record interface.

### 5.5.1 New Patient File

- Automatically generated ID (when use the AQ code scan function and succeed, the ID is the the ID card information).



- ▶ Name, age, address, height, weight, serum and hospitalization can be inputted.
- ▶ Gender, referral department and doctors are optional.
- ▶ The last menstrual period and the oviposit date can be adjusted and modified (if the gender is female).
- ▶ Click Close to close the current medical record.
- ▶ Click new medical record after enter the patient information will save the medical record and return to the main interface.
- ▶ Click exit will exit directly without saving data.

### 5.5.2 Patient Case Management

Click  to enter.



检查号	姓名	性别	年龄	诊断医师
2016030310001	病历1号	男		


- ▶ There are two ways to search records: inspection number and name. Input the corresponding patient's name or inspection number according to the selected mode, the items found will be listed automatically.
- ▶ Click the "View/Modify Cases" will switch to the medical record interface for modified operation.
- ▶ Select medical record, click "Open Medical Record" to go back to the main interface, and the medical record displayed is the selected one.
- ▶ Select medical record, click "Delete Records", the patient's medical records, image files and video files will be deleted.

⚠Warning: the target and image measured must be correct, and the measurement area must be effective, otherwise it may result to misdiagnose!

## 5.6 Measurement and Calculation

⚠Warning: 1. In measurement, once unfreeze or the inspection mode is changed, all scale on the image will be cleared, and the basic measured data will lose.  
2. Close the system, all data will lose.

### 5.6.1 Measurement Menu

Click  to enter the measurement mode  
Convex:



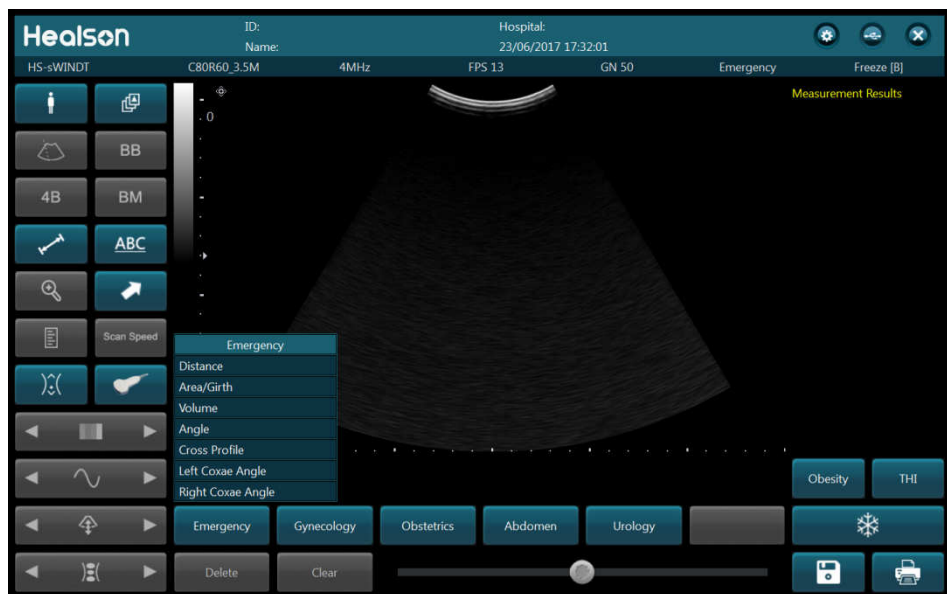
Linear:



### 5.6.2 Measurement Symbol

- ▶ LW/H: distance, in mm (millimeter)
- ▶ G: perimeter, in mm (millimeter)
- ▶ A: area, in cm (square centimeter)
- ▶ Vol: volume, in ml (milliliter)
- ▶ HR: Heart rate
- ▶ Slope: slope
- ▶ T: time, in s (second)
- ▶ GA: gestational age
- ▶ EDD: expected date of confinement

### 5.6.3 Emergency case measurement



#### 5.6.3.1 Comparison table

Mode	Measurement Items	Measureme nt Method
Emergency B mode	Distance	
	Area/perimeter	
	Volume	
	Angle	
	Cross-section diagram	
	Left hip angle	
	Right hip angle	
Emergency M mode	Distance	Distance
	Time	Distance
	Slope	Distance
	Heart rate	Distance

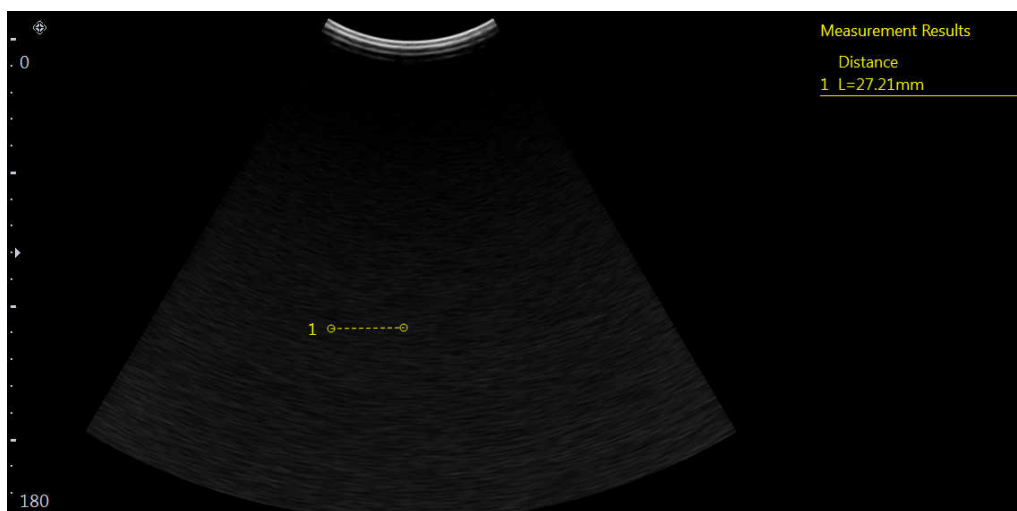
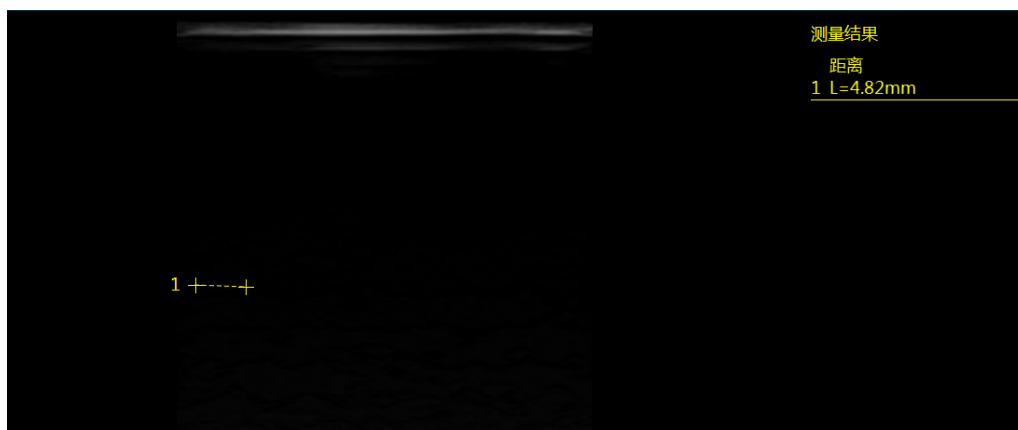
### 5.6.3.2 Measurement Method

#### Distance

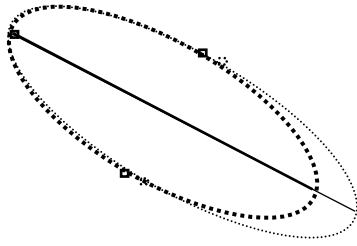
Under the measurement mode, select distance to measure;

Move mouse to the start point of measurement, press down the mouse to fix the start point;

Move mouse to the end point of measurement, and press down it to fix the end point.

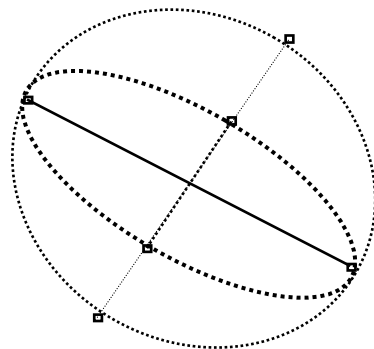


Area/perimeter



#### Confirm an axis

Move the cursor to the starting point of an elliptical axis, press down the key to confirm, then move the cursor to the end of that axis and press down the button to confirm.



#### Confirm another axis

Move the trackball to change axis length and press down the button to confirm.

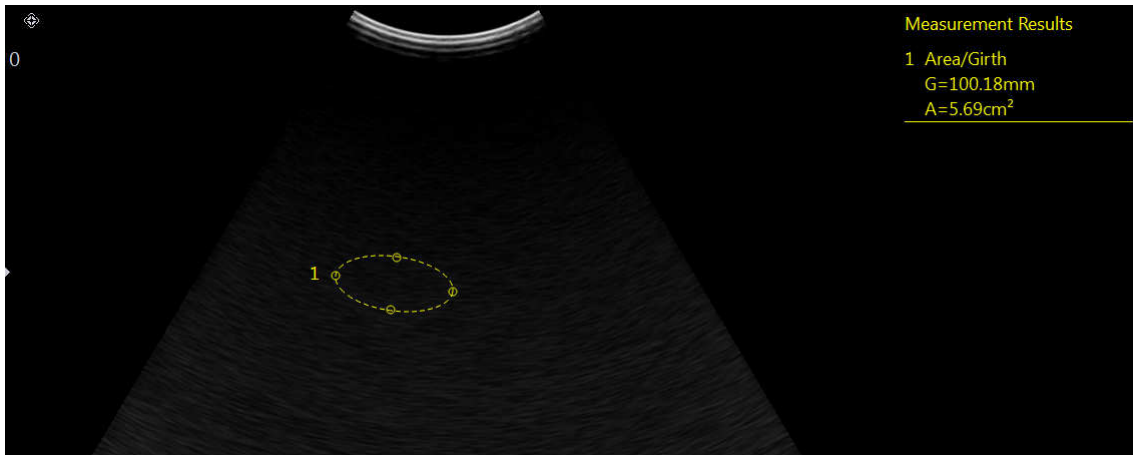
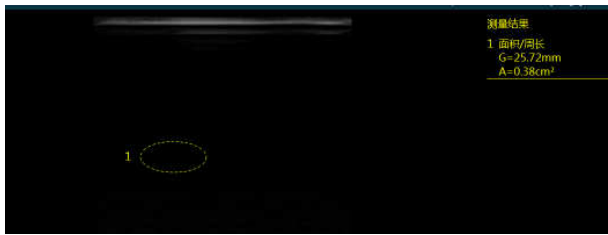
### Operation steps:

Under the measurement mode, select the emergency area/perimeter to enter the area/perimeter status;

Move the cursor to one end of the elliptical axis, and press down the mouse to fix the start point of that axis;

Move the cursor to the other end of the elliptical axis, and press down the mouse to fix the end point of that axis;

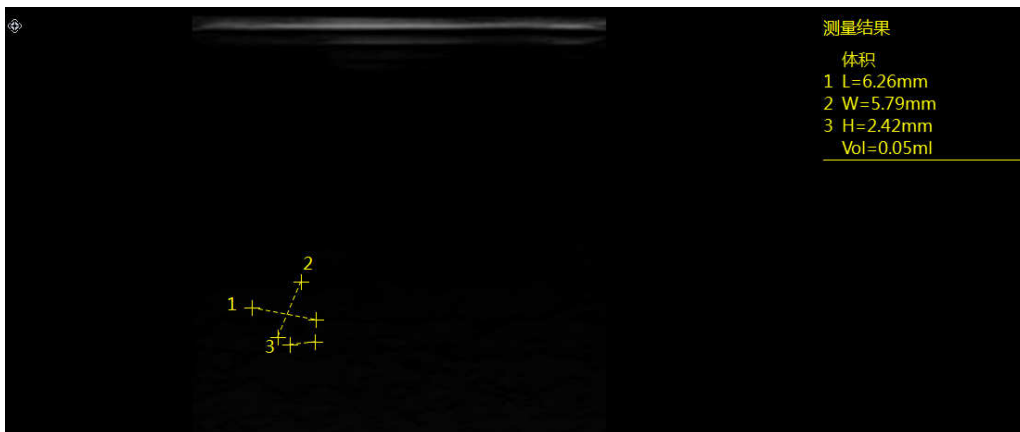
Move the mouse to change the length of another axis of the ellipse.

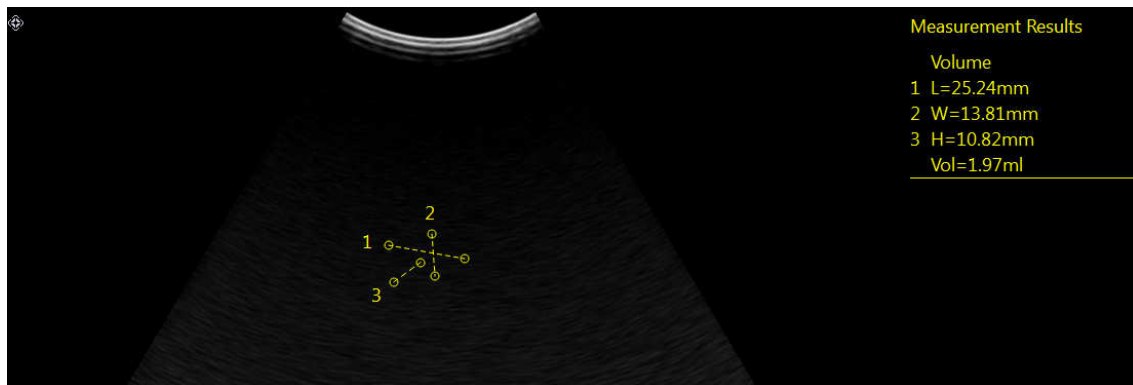


## Volume

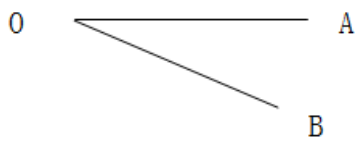
The volume is composed of three distances, and the usage is the same as the “Distance Measurement”.

The three distances are length, width and height respectively, wherein each data measured is displayed in the right data field, and the volume data is gained after complete the three measurements (as shown in the figure).





## Angle



## Steps:

Under the measurement mode, click Emergency to select angle and enter the angle measurement status;

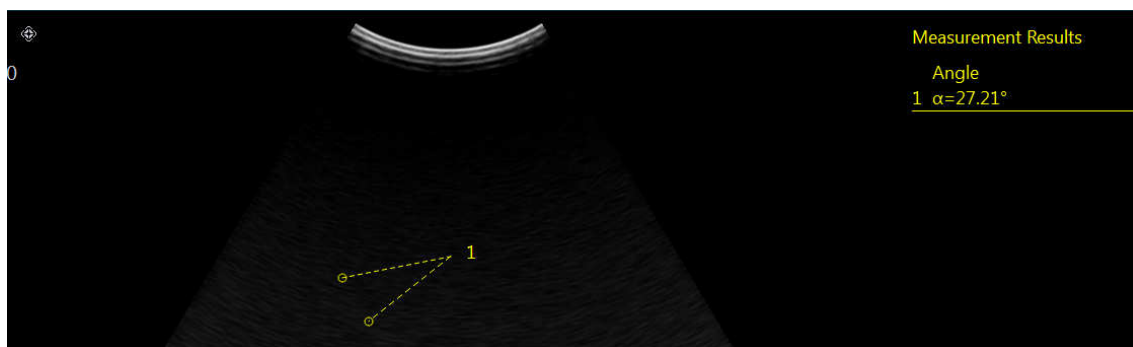
Move the mouse to locate the cursor to point A, and press down the mouse to get the cursor “+” at the ultrasound image zone and fix the point A;

Move the mouse to locate the cursor to point O, and press down the mouse to fix the point;

Move the mouse to locate the cursor to point B, and press down the mouse to fix the point;

Thus getting the OAB (line OA and line OB) angle.





### Cross-section Diagram

Refer to the area/perimeter

### Left/Right hip angle

#### Steps:

Under the measurement mode, click Emergency to select the left/right hip angle and enter the angle measurement status;

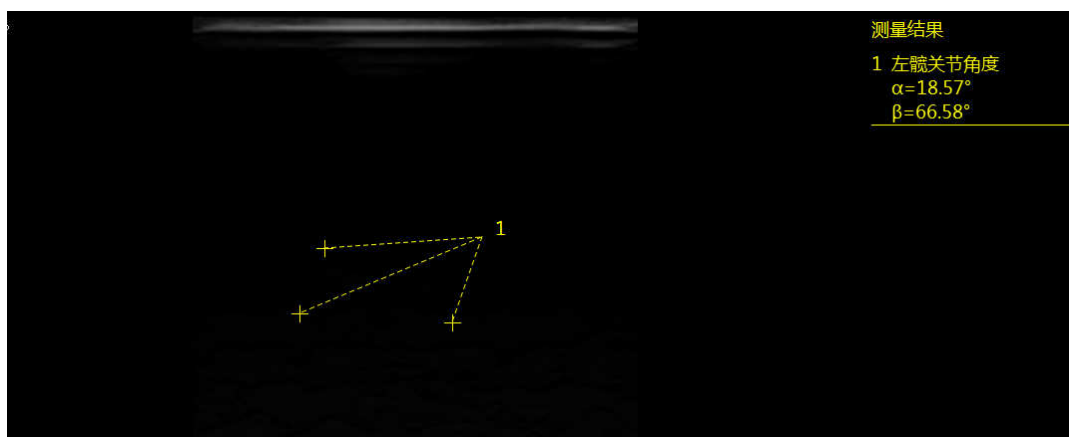
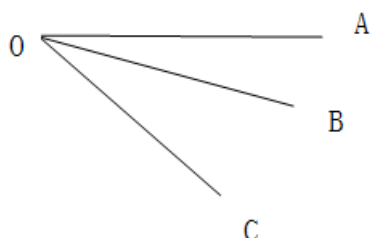
Move the mouse to locate the cursor to point A, and press down the mouse to get the cursor “+” at the ultrasound image zone and fix the point A;

Move the mouse to locate the cursor to point O, and press down the mouse to fix the point;

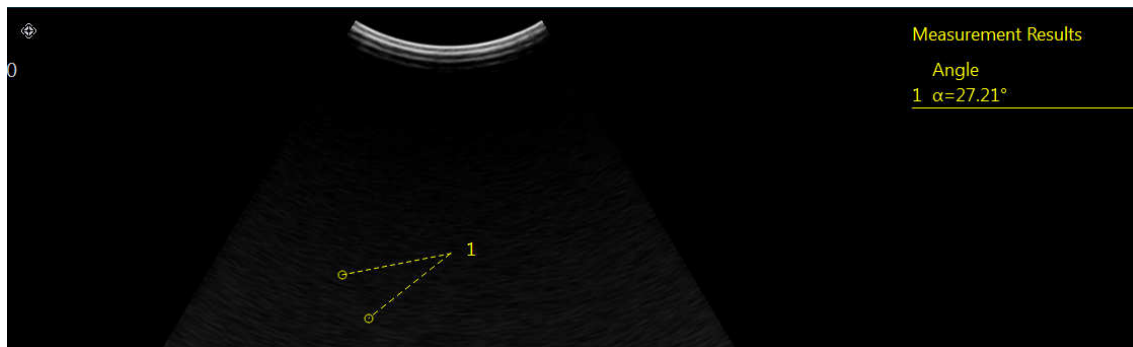
Move the mouse to locate the cursor to point B, and press down the mouse to fix the point;

Move the mouse to locate the cursor to point C, and press down the mouse to fix the point;

Thus getting the OAB (line OA and line OB) angle and the OAC (line OA and line OC) angle.







### M distance

#### Steps:

Access to measurement under mode BM, and click Emergency to choose Heart Rate;

Move to measure the start point, and press down the mouse to fix it;

Move the mouse to the end point and press down the mouse to fix it.

M time

Refer to M distance

M slope

Refer to M distance

Heart rate measurement

Refer to M distance

## 5.6.4 Professional Measurement

### 5.6.4.1 Classification

- ▶ Convex array probe: abdominal, gynecology, obstetrics and urology
- ▶ Linear array probe: small organs, blood vessel, and muscle

► Comparison Table

Position	Measurement Items	Measurement Methods
Abdomen	Right Liver Lobe Volume	Volume
	Left Liver Lobe Volume	Volume
	Intrahepatic bile duct	Distance
	Hepatic portal vein	Distance
	Cystic mass	Volume
	Solid lesions	Volume
	Pancreatic head	Distance
	Pancreatic body	Distance
	Pancreatic tail	Distance
	Cystic mass	Volume
	Solid lesions	Volume
	Gall bladder	Distance
	Gall bladder ball	Distance
	Common Bile Duct	Distance
	Intrahepatic bile duct	Distance
	Stone	Volume
	Polyp	Volume
	Spleen volume	Volume
	Spleen index	Distance
	Splenic artery	Distance
	Splenic vein	Distance
	Cystic mass	Volume

	Solid lesions	Volume
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Position	Measurement Items	Measurement Methods
gynecology	Uterine volume	Volume
	Uterine body and neck	Double Distance
	Uterine neck major axis	Distance
	Right dominant follicle	Double Distance
	Left dominant follicle	Double Distance
	Right ovarian volume	Volume
	Left ovarian volume	Volume
	Intimal thickness	Distance
	Uterine neck line	Distance
	Cyst	Volume
	Mass	Volume
	Breast	Volume

Position	Measurement Items	Measurement Methods
obstetrics	AC	Area/Perimeter

	BPD	Distance
	CRL	Distance
	FL	Distance
	THD	Distance
	GS	Distance
	OFD	Distance
	HL	Distance
	TL	Distance
	UL	Distance
	HC	Area/Perimeter
	TAD	Distance
	APTD	Distance
	FTA	Area/Perimeter
	LV	Distance
	NT	Distance
	Amniotic fluid Index	
	Fetal Heart Rate	

	Growth Curve	
	Physiology score	

Position	Measurement Items	Measurement Methods
Urology	Left kidney volume	Volume
	Left kidney ureter	Distance
	Left kidney sinus renalis echo area	Area/Perimeter
	Left kidney sinus renalis echo free area	Area/Perimeter
	Left kidney cystic mass	Volume
	Left kidney solid lesions	Volume
	Right kidney volume	Volume
	Right kidney ureter	Distance
	Right kidney sinus renalis echo area	Area/Perimeter
	Right kidney sinus renalis echo free area	Area/Perimeter
	Right kidney cystic mass	Volume
	Right kidney solid	Volume

	lesions	
	Prostate volume	Volume
	Bladder volume	Volume
	Residual urine sample	Volume

Position	Measurement Items	Measurement Methods
Small Organs	Left thyroid	Volume
	Right thyroid	Volume
	Thyroid isthmus	Distance
	Thyroid cystic mass	Volume
	Thyroid solid lesions	Volume
	Maxillofacial parotid gland	Volume
	Maxillofacial lymph gland	Area/Perimeter
	Maxillofacial tuberculosis	Area/Perimeter
	Maxillofacial lymphoma	Area/Perimeter
	Maxillofacial abscess	Area/Perimeter
	Maxillofacial cystic hygroma	Area/Perimeter

	Prostate transition zone	Volume
	Prostate central zone	Volume
	Prostate peripheral zone	Volume
	Prostate anterior fiber matrix region	Volume
	Prostate cystic mass	Volume
	Prostate solid lesions	Volume
	Left testis	Volume
	Right testis	Volume
	Left epididymis	Volume
	Right epididymis	Volume
	Spermatic cord	Distance
	Vaginal sac	Volume

Position	Measurement Items	Measurement Methods
Small Organs	Right common carotid artery %STA	Double Area
	Right common carotid artery %STD	Double distance
	Right common carotid artery blood area	Area/Perimeter
	Right common carotid artery blood distance	Distance
	Right internal carotid %STA	Double Area
	Right internal carotid %STD	Double distance
	Right internal carotid blood area	Area/Perimeter
	Right internal carotid blood distance	Distance
	Right external carotid artery %STA	Double Area
	Right external carotid artery %STD	Double distance
	Right external carotid artery blood	Area/Perimeter



	area	
	Right external carotid artery blood distance	Distance
	Left common carotid artery %STA	Double Area
	Left common carotid artery %STD	Double distance
	Left common carotid artery blood area	Area/Perimeter
	Left common carotid artery blood distance	Distance
	Right internal carotid %STA	Double Area
	Right internal carotid %STD	Double distance
	Right internal carotid blood area	Area/Perimeter
	Right internal carotid blood distance	Distance
	Left external carotid artery %STA	Double Area
	Left external carotid artery %STD	Double distance
	Left external carotid artery blood area	Area/Perimeter


	Left external carotid artery blood distance	Distance
	Tip %STA	Double Area
	Tip %STD	Double distance
	Tip blood area	Area/Perimeter
	Tip blood distance	Distance
	Heart rate	Distance

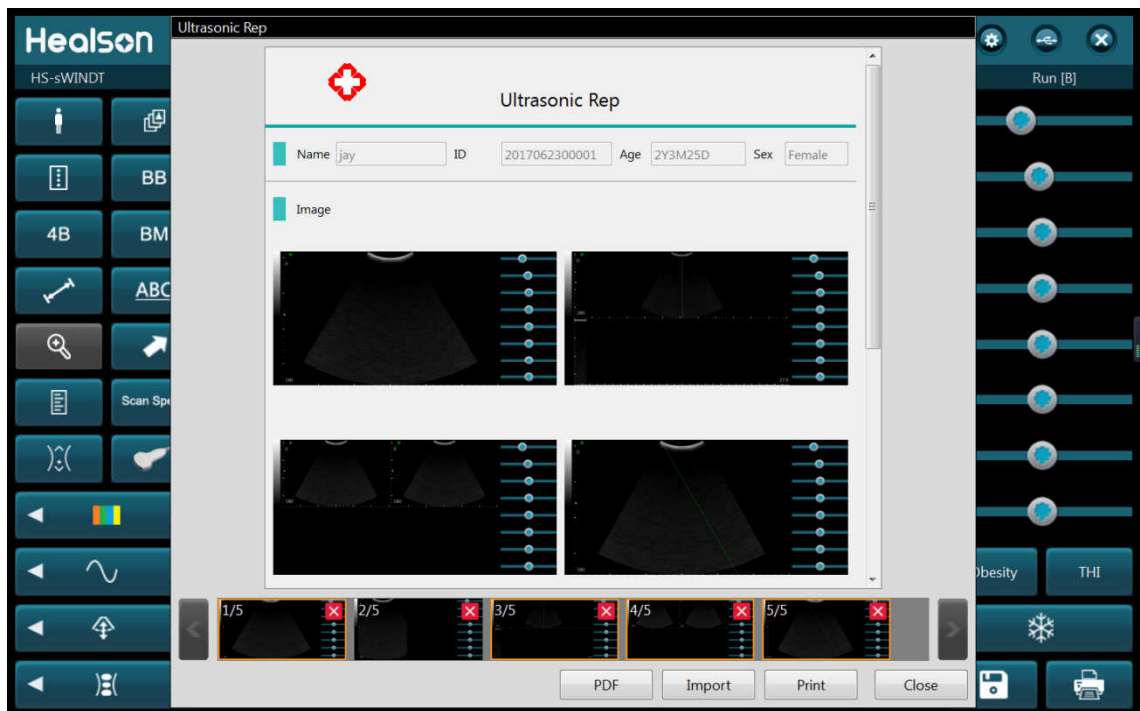
#### 5.6.4.2 Measurement Method

Refer to common measurement

### 5.7 Print Report

#### 5.7.1 Report Interface

Press "Print"  button to enter the report edit interface.



### **5.7.2 Report Edit Function**

In the report editing interface, it's able to show the ultrasound images saved, edit and input the inspected result, save report in PDF format, select, edit and save all kinds of report templates, and print diagnosis report.

### **5.7.3 Report Input**

Character input: it's able to use character key of a standard keyboard to input characters when edit the "Inspection Result" and the "Ultrasonic Conclusion" boxes.

Use "Load Report" to load a proper report template and edit the report quickly.

### **5.7.4 Image Input**

Below the ultrasonic inspection report, as shown in figure ., preserved images of the patient is included, only need to move the mouse and click the left key to select the image to print it.

### **5.7.5 FDF Save**

The medical record can be saved to the local machine.

### **5.7.6 Load Report**

Click "Load Conclusion", a list will pop up in the screen, all configured report templates of the inspection area are listed, in which the user can choose in accordance with the inspection, click left key of the mouse on the selected template, content of the selected template will displayed respectively in two corresponding edit boxes, and then click "Select Template" after completion.



### 5.7.7 Edit Model

The user can enrich their own template library through this operation.

If a template in need is not found from Select Report Template or Add Report Template, one can click the button “New” at the lower left corner as shown in figure . to add what report template you need. Edit and then click "Save" button.

### 5.7.8 Print

Click the “Print” button to print the medical record.

## Chapter 6 Tablet Software Introduction

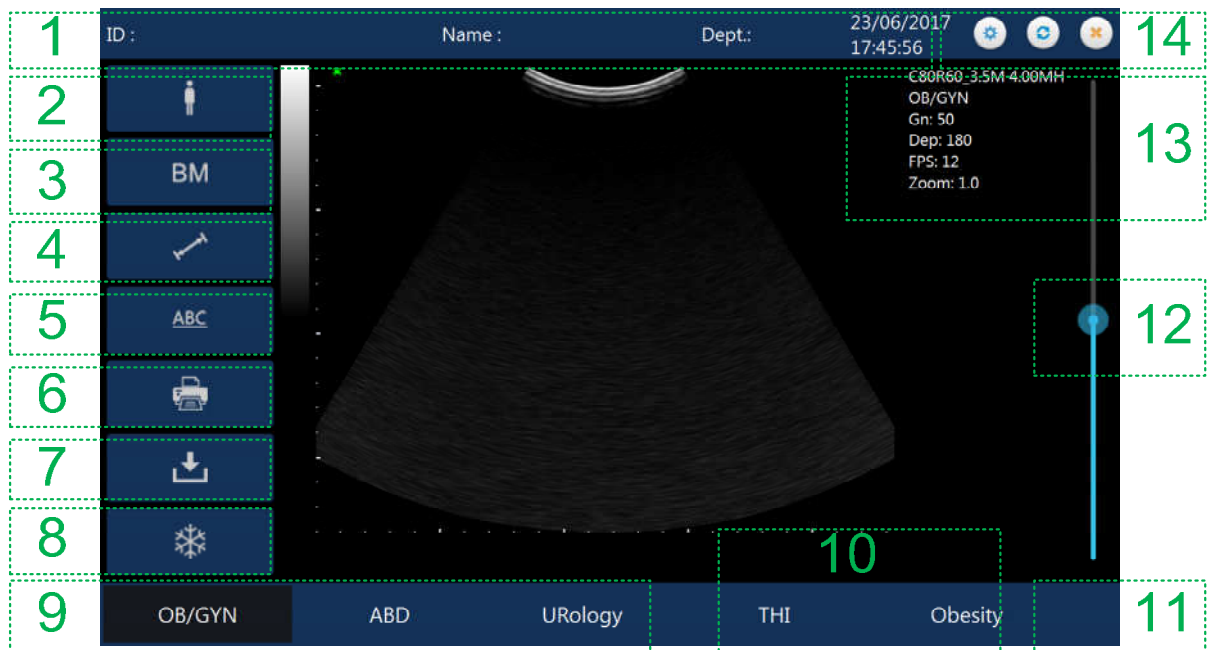
### 6.1 Operation interface key function introduction

Description	Function
Setup	Access to setup interface. Edit hospital name, language, date format, frame, image format, and OB formula preset, fetal weight.
Exit	Exit software

Refresh	Dispose software functions
Patient	Access to patient case interface, and edit case information.
Browse	Check images and movies of patient cases.
B	Access to B Mode
BM	Access to B/M Mode
Measurement	Access to measurement mode
Annotation	Annotation on an image
Arrow	Arrow on image after Freeze
Depth	90-240mm adjustable
Delete	Delete latest measurement data, annotation, and arrow.
Freeze	Freeze image.
Save	Save images in real time or Freeze status.
Print	Access to report interface. Save a report in PDF format. Choose, edit, and save multiple report templates, and print diagnostic report.
Total gain	Adjust total gain

## 6.2 Main Interface

Click the icon, and enter main interface(an example of using convex). See figure5



- 1 ID/Name/Dept/Date/Time
- 2 Patient
- 3 B/BM
- 4 Measurement
- 5 Annotation
- 6 Print a report
- 7 Save
- 8 Freeze
- 9 Convex: OB/GYN, urology  
Linear: Vascular/MSK/Small parts
- 10 THI/Obesity(Convex)
- 11 Battery power
- 12 Gain adjustment
- 13 Software running status including probe information, frequency, gain, depth, FPS,and Zoom.
- 14 System setup/software refreshing/close

## 6.3.Function Introduction

### 6.3.1 Language

- English/Chinese

### **6.3.2 Screen Display**

- ▶ Probe information, mode, depth, focus, body mark, probe direction, patient information, hospital name, measurement value, date, scaleplate, M sample line(BM mode), frequency, FPS, total gain, menu, annotation.

### **6.3.3 Mode**

- ▶ B, B/B, B/M, 4B

### **6.3.4 Depth**

- ▶ Continuously adjustable. Slide up increasing depth and slide down decreasing depth in real time.

### **6.3.5 Focus depth**

- ▶ Automatic

### **6.3.6 Frequency**

- ▶ Automatic

### **6.3.7 Zoom**

- ▶ Touch zoom

### **6.3.8 Gray**

- ▶ 256

### **6.3.9 Total gain**

0-100dB. Higher value, higher brightness. Lower value, Lower brightness.

- ▶ Increase gain by moving progress bar to the right, and decrease gain by moving progress bar to the left.
- ▶ Recent value is "Gn50".

### **6.3.10 TGC**

- ▶ 8TGC。



### 6.3.11 Image post processing

Automatic

### 6.3.12 DICOM

- ▶ Save and send image in Dicom(dcm) format.






### 6.3.13 static image

- ▶ Save an image at any time(image format refers to setup)

### 6.3.14 Cineloop

In the image acquisition process, the system will automatically save finally collected multiple frames in the internal list, after freezing, the user is allowed to play images in the list looping or by single frame, and this function is called cineloop.




- ▶ Maximum 512 frames.
- ▶ Press down the “Freeze” button to call the movie operation dialog box automatically.
- ▶ Click  to access the movie playback status.
- ▶ Click  to stop playing images temporarily.
- ▶ Click  to watch the last frame.
- ▶ Click  to watch the next frame.
- ▶ Click  to save the present movie into the avi file in the disk.


### 6.3.15 Probe Switch

- ▶ The system supports two probes: convex and linear probe.
- ▶ In case of pulling and plug probes in the freeze process, press unfreeze to switch automatically.


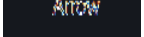
**⚠Caution: before pull or plug probes, must freeze image or exit the software, otherwise it's easy to break down.**


### 6.3.16 Annotation

- ▶ Click  to access the annotation status
- ▶ Move mouse to the annotation point, and click the mouse to popup the dialog box of Annotation Input.
- ▶ Input annotation and click “Confirm” to finish.

 Warning: the annotation added must be correct. A wrong annotation may result to misdiagnose!

### 6.3.17 Arrow

- ▶ Click  to access annotation: the arrow button  to access the arrow annotation status.
- ▶ Move the mouse to the first endpoint of the arrow, click the mouse and up-spring it.
- ▶ Move the mouse to the second endpoint of the arrow, click the mouse and up-spring it to finish the arrow annotation.
- ▶ The arrow annotation function is usually used together with the annotation function.

 Warning: the direction of arrow must be correct. A wrong arrow may result to misdiagnose!

## 6.4 System Settings

Set up dept name, time, language, and date format. Detailed operation steps is as followings:

## 6.4.1 Access to dialog box



## 6.4.2 Menu Layout

Scroll the mouse to the selected point.

## 6.4.3 Department

After inputting department information, click “Close” to save, then it will display in main interface and report.

## 6.4.4 Freeze automatically

Freeze automatically when running a few time. It can be classified with 5 minutes, 10 minutes, 15 minutes, 30 minutes, and never freeze.

## 6.4.5 Language

English/Chinese

## 6.4.6 Date Format

dd/MM/yy or yy/MM/dd

## 6.4.7 Movie Frame

64/128/256/512 frame adjustable.

## 6.4.8 Image Format

Bmp/jpg/png/tif/dcm

## 6.4.9 Dicom

Set up DICOM IP address.

## 6.4.10 Using Habit Setup

Left Hand Mode: menu on the left of image area

Right Hand Mode: menu on the right of image area

## 6.4.11 About

Manufacturer information, version information, etc.

## 6.5 Patient Case Management

ID	Name	Sex	Age	Doctor
2017062300002	jay	Male	25	张医生
2017062300001	病历一号	Female	54	张医生

### 6.5.1 New Patient File

Check no. : Check number automatically generated by the system.

Name: Input name in the input box (required).

Age: Input the age in the input box.

Gender: Click a drop-down box to choose male, female, unknown.

Doctor: Click a drop-down box to choose a doctor or built a new doctor.

After input is complete, click the new records, and click the save records and display in the main interface.

### 6.5.2 Open the patient file

Click patient file record box, and click the medical record, then back to the main interface, done.

### 6.5.3 Save the patient file

1. In the Patient Record Box, click to select the medical record you want to modify.
2. Make changes in the left patient information input box.
3. Click to save the medical records, done.

### 6.5.4 Delete the medical records.

1. Select medical record.
2. Click "*Delete Records*", the patient's medical records, image files and video files will be deleted.
- 3.3. At the same time of deleting the medical record, the deleted medical records will no longer show the medical display box.

### 6.5.5 Cancel

Back to the main interface

### 6.5.6 Search

1. There are two ways to search for a medical record: check number and name.
2. Select the search method, and enter the corresponding patient's name or check the number to find.

### 6.5.7 Medical records show

1. Show the existing medical records.
2. Under the search function is displayed in line with the search words or ID of the medical records.


### 6.5.8 Medical records resource show


1. Display the pictures and movies of the selected medical records.
2. Double-click the resource (picture or video) to access the browsing function.

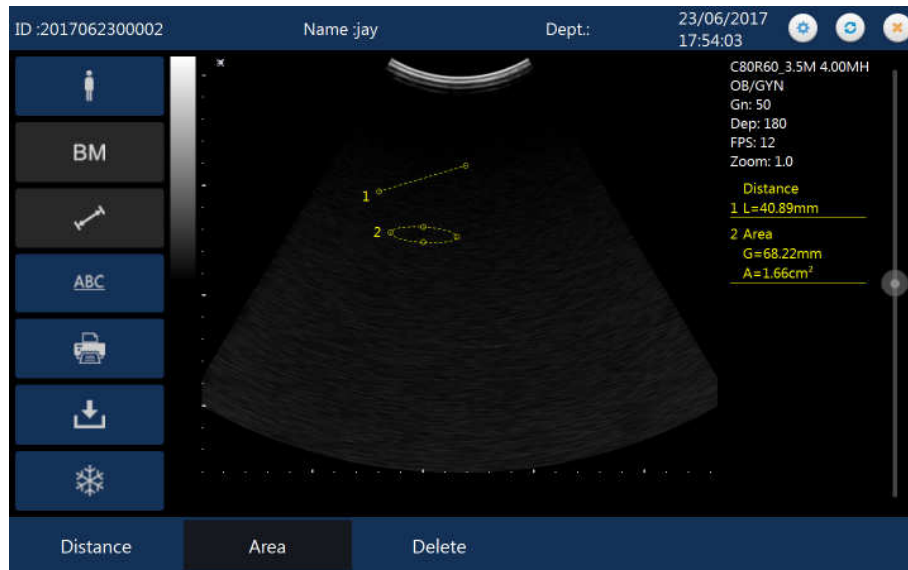
### 6.5.9 Browsing

1. A picture or video of showing a medical record.
2. You can play pictures or video.

## 6.6 Measurement

 Warning: the annotation added must be correct. A wrong annotation may result to misdiagnose!
--

 Caution: 1. Unfreeze or mode changed, all measurement and data will be lost. 2. Shutdown system will lose all data.
--

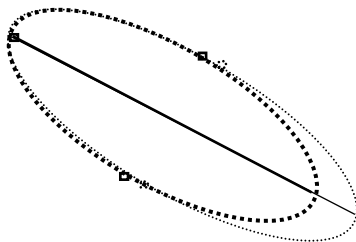


### 9-5-1 B mode measurement

#### 6.6.1 Distance

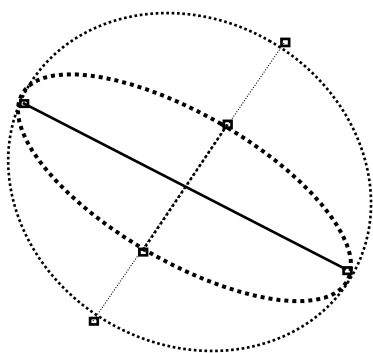
1. Under the measurement mode, select distance to measure;
2. Move mouse to the start point of measurement, press down the mouse to fix the start point;
3. Move mouse to the end point of measurement, and press down it to fix the end point.

#### 6.6.2 Area Measurement



Confirm an axis

Move the cursor to the starting point of an elliptical axis, press down the key to confirm, then move the cursor to the end of that axis and press down the button to confirm.



Confirm another axis  
Move the trackball to change axis length and press down the button to confirm.

### Operation steps:

1. Under the measurement mode, select the emergency area/perimeter to enter the 2.
2. Area status;
3. Move the cursor to one end of the elliptical axis, and press down the mouse to fix the start point of that axis;
4. Move the cursor to the other end of the elliptical axis, and press down the mouse to fix the end 5. point of that axis;
6. Move the mouse to change the length of another axis of the ellipse.

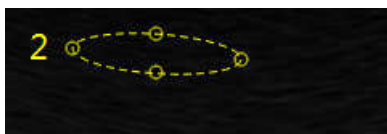
## 6.6.3 Heart Rate Measurement

Select heart rate measurement under BM mode.

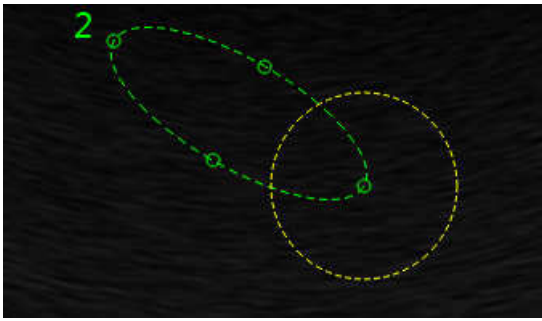
Move the cursor to the starting point(crest or trough), and press mouse to fix (crest or trough).

Move the cursor to the starting point(crest or trough) nearby, and press mouse to fix (crest or trough).


### 6.7 Measurement Location Change

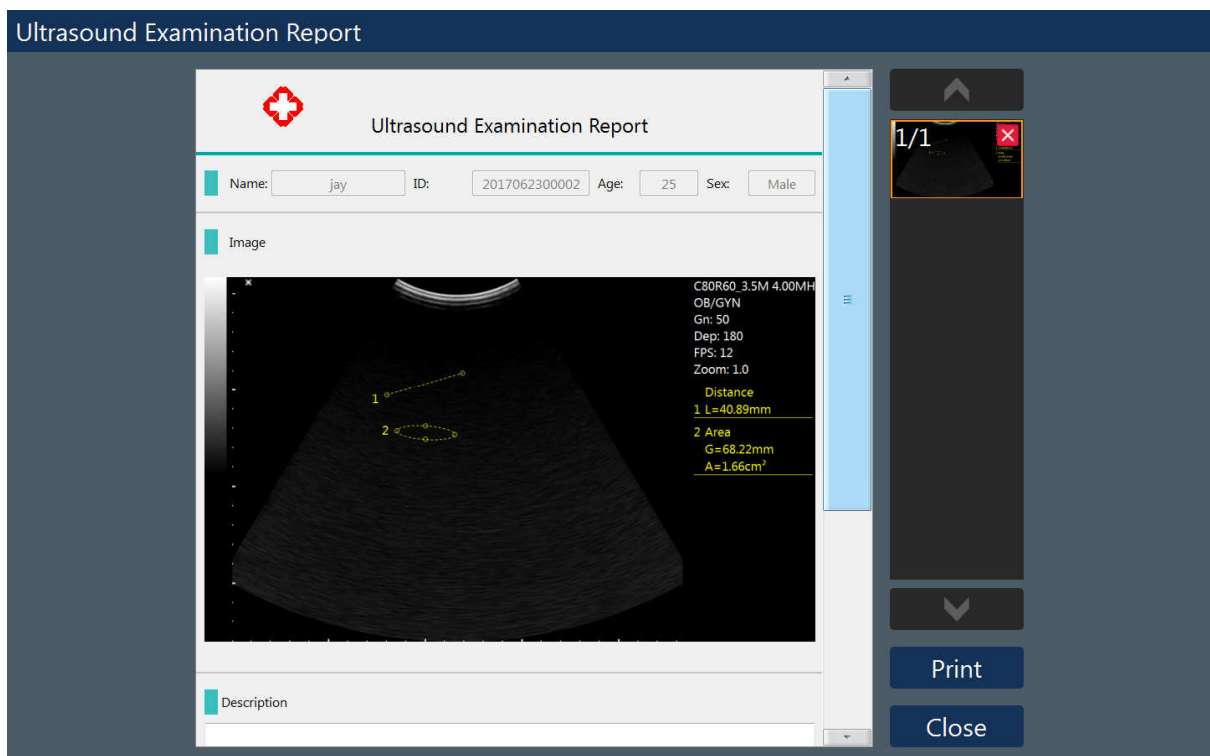


After measurement completed, click fixed icon to adjust it. As the following picture showed:



## 6.8 Print

Click  access to report interface.



### 6.8.1 Report Edit Function

In the report editing interface, it's able to show the ultrasound images saved, edit and input the inspected result, save report in PDF format, select, edit and save all kinds of report templates, and print diagnosis report.



### 6.8.2 Report Input

Character input: it's able to use character key of a standard keyboard to input characters when edit the "Inspection Result" and the "Ultrasonic Conclusion" boxes.

Use "Load Report" to load a proper report template and edit the report quickly.

### 6.8.3 Image Input

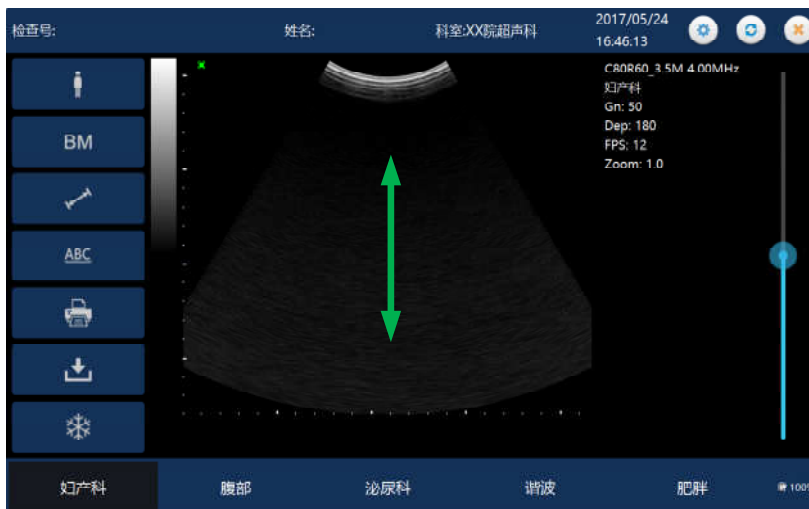
Below the ultrasonic inspection report, as shown in figure ., preserved images of the patient is included, only need to move the mouse and click the left key to select the image to print it.

### 6.8.4 Print

Click the "Print" button to print the case.

## 6.9 Zoom in

Fingers are away from zoom area gradually.As the picture shows;



## Chapter 7 Maintenance

The maintenance of the system should be done by both the customer and the service

engineer together. After purchase of this product, the user has full responsibility for the system maintenance.

## 7.1 Power Supply Check

- Power supply should be checked frequently, and if the computer USB voltage is beyond regular range (to the power adapter is  $DCV5\pm0.5V$ ) , DO NOT use the system.
- Check the power cable and probe cable and replaced immediately if find any damage or crack.

## 7.2 Safety Instructions

- Ensure power off then install or unplug the probe.
- Non-professional personnel shall NOT open the machine cover.
- In the event of failure, the power supply should be promptly cut off and inform the designated professional maintenance personnel or manufacturer.

- Protection of ultrasound energy output:

Users must be trained professional doctors. When they use the machine to diagnose patients, they must obey the safety rules to decrease the influence of the ultrasonic energy to an acceptable level. The object / site / time or other non - normal usage beyond the inspection / diagnosis needs to be avoided.

- Put the probe back to holders and press [Freeze] button if stop using to avoid overheating and extend lifetime.
- The probe can not be used as a guide to ultrasonic lithotripsy equipment, and the high intensity ultrasonic energy will damage the probe.

- Transducer overheating protection:

Surface temperature of ultrasonic transducer should NOT exceed  $43^{\circ}\text{C}$  (Test conditions in GB.—GB9706.9—2008 42.3.a) . In addition, according to ( GB. 9706.9—2008- 42.3 .a) in the measurement, the surface temperature rise should not exceed  $27^{\circ}\text{C}$ .

General experiment information is shown in following table

Transducer type→ experiment↓		In vitro use	Non in vitro use
a) Simulated condition test	A) temperature re	The test mold temperature shall be maintained at not less than $33^{\circ}\text{C}$ and not more than $43^{\circ}\text{C}$ .	The test mold temperature shall be maintained at not less than $37^{\circ}\text{C}$ and not more than $43^{\circ}\text{C}$ .

	B)	The initial temperature of the test mold and the transducer interface should be same with the environment temperature, which should be $23^{\circ}\text{C}\pm 3^{\circ}\text{C}$ . The temperature rise should NOT be more than $10^{\circ}\text{C}$ .	The initial temperature of the test mold and the transducer interface should be same with the environment temperature, which should be $23^{\circ}\text{C}\pm 3^{\circ}\text{C}$ . The temperature rise should NOT be more than $6^{\circ}\text{C}$ .
a) No air flow test (without coupling agent)	temperature rise	The environment temperature should be $23^{\circ}\text{C}\pm 3^{\circ}\text{C}$ . The initial temperature of the transducer component surface should be same with the environment temperature. The temperature rise should NOT be more than $27^{\circ}\text{C}$ .	

Be careful if the surface temperature of the transducer is more than  $43^{\circ}\text{C}$ , so as to avoid harm to the patients.

- Use medical ultrasound gel which is conform to YY0299-2008 standard to ensure patients' safety.
- Check the cable and the shell frequently and replace immediately if find any damage or crack.
- Method of treatment of the disposed device should be down by relevant provision (without environment pollution or harmful substance) or disposed as scrap.

### 6.3 Probe Maintenance

•DO NOT drop or hit the probe. Especially the lens surface can't contact with sharp objects. Put transducers back to holders and press [Freeze] button if stop using to avoid overheating and extend lifetime.

•DO NOT add gasoline, salad oil and any other chemical solvent composition into medical ultrasound gel.

•Check the shell frequently in case of crack for immerging because probe is the immersion type equipment.

•Shall not remove the plug and socket, so as to avoid the bad contact caused by image

line, once the probe connected with computer.

- DO NOT pull sensor cable transmission line emphatically when use tthe probe, otherwise it will cause the connector at the sheath extrusion and disconnection fault.

#### Cleaning, Disinfection and Sterilization of Probe

- Clean, disinfect and sterilize probe every time after using.
- In order to avoid damage the probe, obey the following rules when cleaning, disinfecting and sterilizing probe.

a) Temperature limit: 0℃～65℃

b) DO NOT use organic solvent to clean probe;

c) DO NOT use steam high pressure to process probe or contact with ethylene oxide.

d) DO NOT soak transducers more than 1 hour.

- **clean**

a) Use wet mull to clean probe surface after using;

b) Use mull or tampon with cleaning agent (e.g. neutral soap water) to clean the dirty probe first, and then use mull with water to clean the cleaning agent;

c) Use clean and dry mull to dry transducers after cleaning.

- **disinfection and sterilization**

a) Use special liquid chemical disinfectants to disinfect and sterilize probe, like Glutaraldehyde solution(the concentration is 2 % , PH7.5 ~ 8.5) or Bromogeramine solution(the concentration is 2 % , PH7.5~8.5).

b) Use sterile water to clean disinfectant solution and use dry mull to dry probe after the disinfection is completed.

- The probe is not specially sterilized before delivery. When used, it is necessary to carry out disinfection according to the relevant safety regulations.

Clean, disinfect and sterilize probe after using, so as to diagnose the following patient. Put probe back to holders.

#### **Attention:**

- DO NOT clean probe surface with organic diluent.
- DO NOT use overdue disposable sterile protective sleeve.

- DO NOT immersion the transducer into water to clean it.
- Seal up cleaning, disinfection and sterilization waste to protect the environment.

## 7.4 Daily Maintenance of Products

- Check power frequently, and DO NOT use the device with impropriety power.
- Use soft, dry mull to clean device. DO NOT use dripping cloth to wipe device.
- There should be at least 1 hour working time of the power supply and functional check time every month. DO NOT deposit the device without power more than 6 months.
- Contact the professional service people if fail to repair and give a brief introduction of equipment fault state.

# Chapter 8 Simple fault check and elimination

## 8.1 Check

- Check whether the computer power is normal and check whether the probe USB plug is plugged into the computer USB port and has a good contact.

## 8.2 Trouble Shooting

- Trouble Shooting (shown in the following table)

number	Fault	Methods of Trouble Shooting
1	Open system software and prompt device configuration fails.	1. Check computer output-voltage; 2. Check the probe into the USB port;
2	The screen is disturbed by intermittent line and snow.	1. Check whether there is high power equipment running around; 2. Check whether the system is disturbed by electromagnetic field around; 3. Check that the plug of the probe is in good contact with the USB port.
3	Image on the screen is not clear.	1. Adjust GAIN;

		<p>2. Adjust Brightness and Contrast;</p> <p>3. The near field image is not clear. Adjust the top 3 of 9 sliders which are below the GAIN</p> <p>4. The far field image is not clear. Adjust the bottom 3 of 9 sliders which are below the GAIN.</p>
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## **Chapter 9 Transportation and Storage**

### **9.1 Transportation**

After the product has been packaged, it is permissible to transport the product using conventional means of transportation or to transport it in the manner stipulated in the contract, but avoid exposure, rain and snow splash, severe vibration and mechanical collision.

### **9.2 Storage**

a) This machine should be placed in dry and clean rooms. The environment temperature:  $-5^{\circ}\text{C} \sim +40^{\circ}\text{C}$ , relative humidity  $< 80\%$  ( $20^{\circ}\text{C}$ ), the atmospheric pressure:  $800\text{hPa} \sim 1060\text{hPa}$ . Make sure of the good aeration, and avoid strong sunshine and corrosive gas.

b) If store this machine in packing case over three months, please take it out and turn it on for at least four hours before putting back according to the direction indicated on the packing case. The storage should be same with 12.2a)。

Equipment storage is valid for 12 months. If the equipment has been stored for more than the period of validity, open the package and check the equipment according to the factory inspection requirements and pack up it again after checked out.

## **Chapter 10 Service Guide**

### **10.1 Maintenance Service**

1) When the device is out of work, please check it in accordance with the seventeenth chapter "simple Troubles & Trouble Shooting ". Ensure that all part of the device is connected correctly, no loosening and contacted well.

2) Please contact with manufacturer. if the trouble can't be solved by yourselves. We will give replay to you in 24 hours.

### **10.2 Warranty Provisions**

1) Coverage: Host.

2) Period:

(1) From the date of delivery within one year, due to host quality problems and host failure, you will enjoy free maintenance.

(2) From the date of delivery within three months, due to accessory quality problems, you will enjoy free maintenance.

(3) From the date of delivery within one month, the host has a serious quality problem, and the maintenance can not be resolved, free replacement.

3) Free maintenance conditions:

(1) Fill in < Warranty registration receipt card > and send it to us.

(2) Be maintained by the maintenance service department of our company.

(3) Within the warranty period.

### **10.3 Out of Free Maintenance Coverage**

In the following conditions, the company shall not be responsible for all losses caused by such phenomena, and shall not provide free maintenance:

(1) Trouble as a consequence of incorrect operation and maintenance, or as a consequence of artificial damage or disassembly, installation, adding and reducing of component and repair at other places;

(2) Trouble as a consequence of incorrect operation and maintenance in defiance of the steps of the User's Manual.

(3) Man-made appearance damage or scratch.

### **10.4 European Representative**

Name: Prolinx GmbH

Add: Brehmstr. 56, 40239, Duesseldorf

Tel: 0049 2131 4051968-0

Fax: 0049 2131 4051968-9

Contact Person Mr. Nianzhuang Liu



**10.5 Our company is responsible for maintenance of troubles which are out of free maintenance coverage, and charge in accordance of the provisions.**

## Appendix 1: Sound output of probe announcement

display mode: B

probe type: Convex array 3.5MHz

Index name		MI	TIS			TIB	TIC
			scan ner	scannerless		scann erless	
				Aaprt≤1cm <sup>2</sup>	Aaprt> 1cm <sup>2</sup>		
Maximum index value		0.93	0.01	-	-	-	-
Related acoustic parameters	Pra(Mpa)	1.73					
	P(mW)		5.8	-		-	-
	Pa(Zs) and I <sub>ta</sub> ,α(Zs) minimum (mW)				-		
	Zs(cm)				-		
	Zbp(cm)				-		
	Zb(cm)					-	
	At maximum I <sub>pi.α</sub> Z(cm)	1.07					
	deq(cm)						
	fawf(MHz)	3.44	3.44	-	-	-	-
	Aaprt diameter X (CM)		0.80	-	-	-	-
	Aaprt diameter Y (CM)		1.00	-	-	-	-
Other information	td(μsec)	0.52					
	pr <sub>r</sub> (Hz)	3788					
	Pr at maximum I <sub>pi</sub> (Mpa)	1.96					
	Deq at maximum I <sub>pi</sub> (cm)					-	
	I <sub>pa,α</sub> at maximum MI (W/cm <sup>2</sup> )	29.57					
Operation and control conditions	Focus number	1	1				
	Focus setting	D0	D0				
	frequency (MHz)	3.5	3.5				

display mode: M

probe type : Convex array 3.5MHz

Index name		MI	TIS			TIB	TIC
			sca nner	scannerless		scan nerle ss	
				Aaprt≤1cm <sup>2</sup>	Aaprt>1cm <sup>2</sup>		
Maximum index value		0.95	-	0.05	-	0.51	-
Related acoustic parameters	Pra(Mpa)	1.76					
	P(mW)		-	2.9		2.9	-
	Pa(Zs) and Ita,α(Zs) minimum (mW)						
	Zs(cm)						
	Zbp(cm)						
	Zb(cm)					1.07	
	Z (CM) at the maximum lpi.	1.07					
	deq(cm)					0.01	
	fawf(MHz)	3.44	-	3.44	-	3.44	-
	Aaprt diameter X (CM)		-	0.80	-	0.80	-
	Aaprt diameter Y (CM)		-	1.00	-	1.00	-
Other information	td(μsec)	0.52					
	prr(Hz)	3788					
	Pr at the maximum lpi (Mpa)	2.00					
	deq at the maximum lpi(cm)					0.01	
	lpa,αat the maximum MI (W/cm2)	29.91					
Operation and control conditions	Focus number	1		1		1	
	Focus setting	D0		D0		D0	
	frequency (MHz)	3.5		3.5		3.5	

display mode: BM

probe type : Convex array 3.5MHz

Index name		MI	TIS			TIB	TIC
			scan ner	scannerless		scanne rless	
				Aaprt≤1cm <sup>2</sup>	Aaprt> 1cm <sup>2</sup>		
Maximum index value		0.95	0.01	0.05	-	0.51	-
Related acoustic parameters	Pra(Mpa)	1.76					
	P(mW)		2.9	2.9		2.9	-
	Pα(Zs) and Ita,α(Zs) minimum (mW)						
	Zs(cm)						
	Zbp(cm)						
	Zb(cm)					1.07	
	Z (CM) at the maximum lpi.	1.07					
	deq(cm)					0.01	
	fawf(MHz)	3.44	3.44	3.44	-	3.44	-
	Aaprt diameter X (CM)		0.80	0.80	-	0.80	-
	Aaprt diameter Y (CM)		1.00	1.00	-	1.00	-
	Other information	td(μsec)	0.52				
prf(Hz)		3788					
Pr at the maximum lpi (Mpa)		2.00					
deq at the maximum lpi(cm)						0.01	
lpa,αat the maximum MI (W/cm2)		29.9 1					
Operation and control conditions	Focus number	1	1	1		1	
	Focus setting	D0	D0	D0		D0	
	frequency (MHz)	3.5	3.5	3.5		3.5	