CHISON

Value Beyond Imaging

Digital Color Doppler Ultrasound System

SonoAir 70

Operation Manual

V1.0

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CHUM SonoAir -003

CHISON Medical Technologies Co., Ltd.

Regulatory Requirement

CE 0197 This product conforms to the essential requirements of the Medical Device Directive 93/42/EEC. Accessories without the CE mark are not guaranteed to meet the Essential Requirements of the Medical Device Directive.

This manual is a reference for the SonoAir 70. Please verify that you are using the latest revision of this document. If you need the latest revision, cont act your distributor.

Statement

1. No part of this manual may be reproduced, modified, copied or reprinted, in whole or in part, without written permission from CHISON.
2. The contents of this manual are subject to change without prior notice and without our legal obligation.
3. Before operating the system, please read and understand this manual. After reading, keep this manual in an easily accessible place. If you have any question or doubt, please contact CHISON's authorized service engineer.
4. CHISON’s Warranty only cover material and parts costs for repair, but does not cover any labor cost or onsite service cost at end user's side.
5. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
6. A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Meaning of the signal words

In this manual, the warning words NOTE, CAUTION and WARNING are used for regarding safety and other important instructions. Please understand their meanings clearly before reading this manual. The words and their meanings are defined as follows:

Warning words	Meaning
⚠**NOTE**	Indicates information of interest to users of the equipment as to exceptional conditions or operating procedures and make the system work in good condition.
⚠**WARNING**	Indicates an imminently hazardous situation which can not be avoided will result in death, serious injury to the user or damage to the system.
⚠**CAUTION**	Indicates a potentially hazardous situation which can not be avoided, may result in death, serious injury to the user or make the system misoperation.

Important information

⚠**CAUTION**

1. The device can only be sold to qualified medical institutions or doctors.

2. The users shall have got the qualification, and shall comply with the local laws and regulations, the local religion and customs, etc.

3. The users should read the operation manual carefully before operating the devices. Turning on the device means the users have read the operation manual and accept the listed cautions, warnings, and notes in the manuals. If the users disagree and cannot accept the cautions, the users can ask for returning the device.

⚠NOTE

1. It is the customer's responsibility to maintain and manage the system after delivery.

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

a. Damage or loss due to misuse or abuse with system and probes, for example, drop the probe, the liquid or the metal part fall into the system.

b. Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.

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

d. Damage or loss caused by non-approved transportation by CHISON.

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

f. Damage or loss involving the system purchased from a source other than CHISON or its authorized agents.

3. Do not make changes or modifications to this system and probes. The System modified or repaired by people other than CHISON's qualified service engineers, CHISON shall not be liable for the system.

4. The system is to provide physicians with data for clinical diagnosis. It is the physician's responsibility for diagnostic procedures. CHISON shall not be liable for the results.

5. This manual contains warnings regarding foreseeable potential dangers, but user shall always be alert to dangers other than those indicated as well. CHISON shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions described in this operation manual.

6. Important data must be backed up on external memory media. CHISON shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.

7. Please put this manual with the system to ensure operator and manager can reach it at any time. Due to negligence not following operation manual, CHISON shall not be liable for the results.

8. LCD display screen may have some dark or light dots, it is normal for the LCD. It does not mean that LCD screen is defective.

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Chapter 1 Introduction

This manual contains necessary information for safe system operation.
Read and understand all instructions in this manual before operating the system. Always keep this manual with the equipment, and periodically review the procedures for operation and safety precautions.

1.1 System Overview

Indications for Use

The SonoAir Series Digital Color Doppler Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), B/M, M, B+CFM, B+CPA (PD), B+DPD, B+PW, B+CFM+D (PW), B+CPA (PD)+D (PW), TDI and Fusion Harmonic Imaging modes. The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified clinician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Adult Cephalic, Cardiac Adult, Musculo-skeletal (Conventional, Superficial), Peripheral Vascular, Trans-vaginal and Urology.

Contraindication

The system is NOT intended for ophthalmic use or any use that causes the acoustic beam to pass through the eye.

1.2 Contact Information

For additional information or assistance, please contact your local distributor or the appropriate support resource shown below:

CHISON website	www.chison.com
Service Support	CHISON Medical Technologies Co., Ltd. Tel:0086-0510-85311707 Fax: 0086-0510-85310726 E-mail: service@chison.com.cn
Placing an Order	CHISON Medical Technologies Co., Ltd. Tel: 0086-0510-8531-0593/0937 Fax: 0086-0510-85310726 Email: export@chison.com.cn
Manufacturer	CHISON Medical Technologies Co., Ltd. No.3 Changjiang South Road, Xinwu District, Wuxi, 214028 Jiangsu, P.R. China

US Agent	Mr. Marco Mu, 2219 Rimland Drive, Suite 301, Bellingham, Barkley Villiage Bellingham, Washington, 98226, UNITED STATES Phone: 360-3257028, Fax: 360-9253199 Email: us.agent@mid-link.net MID-LINK INTERNATIONAL CO., LTD

⚠*CAUTION*

Federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.

Chapter 2 System Safety

2.1 Safety Overview

This section discusses the measures to ensure the safety of both the operator and patient. To ensure the safety of both operator and patient, please read the relevant details in this chapter carefully before operating this system. **Disregarding the warnings or violation of relevant rules may result in personal injury for operator or patient, or even loss of life.**

Users should observe the following precautions:

1. This system complies with Type BF general equipment, and the IEC standard.
2. Do not modify this system in any way. Necessary modifications must be made only by the manufacturer or its designated agents.
3. This system has been fully adjusted at the factory. Do not adjust any fixed adjustable parts.
4. In the event of a malfunction, turn off the system immediately and inform the manufacturer or its designated agents.
5. The power cable of the system should only be connected to a grounded power socket. Do not remove the ground cable for any reason.
6. Only connect this system, either electronically or mechanically, with devices that comply with the EN60601-1 standard. Recheck the leakage current and other safety performance indices of the entire system to avoid potential system damage caused by leakage from a current superposition.
7. The system does not incorporate any specialized protective measures in the event it is configured with high-frequency operation devices. The operator should use caution in these types of applications.
8. The system should be installed only by personnel authorized by the manufacturer. Do not attempt to install the system by yourself.
9. Only an authorized service engineer may perform maintenance to the transducers and adapter, etc.
10. Only a qualified operator, or someone under qualified supervision, should use the system.
11. Do not use this system in the presence of flammable substances, otherwise an explosion may occur.
12. Do not continuously scan the same part of a patient or expose the patient to prolonged scanning; otherwise it may harm the patient.
13. When using the system for ultrasound testing, use only qualified ultrasound gel that complies with system standards.
14. Do not unplug probe when the system is in active operation. Always go to EXAM screen when need to remove the probe.
15. To prevent from arm or neck injury, the operator should not stay at the same position for too long during patient scanning without taking break.
16. Do not put liquid on top of the main unit.

⚠*NOTE*

- *The system has built-in screen saver to avoid the tic mark on the display. It is not recommended to constantly turn on and off the unit.*
- *To dispose of this product properly, please call your local service department.*

2.2 Electrical Safety

Type of protection against electric shock

- **Class II Equipment**

Term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conitions.

⚠*NOTE*

The mains supply shall be cut off after disconnecting the power line and the net power.

Degree of protection against electric shock

- **Type BF Applied part (for Probes marked with BF symbol)**

TYPE BF APPLIED PART providing a specified degree of protection against electric shock, with particular regard to allowable LEAKAGE CURRENT.

Level of protection against harmful ingress of water

- Parts of probe intended to be immersed in normal use meet the requirements of watertight equipment (IPX7)
- The IP classification of main unit and the type-C probe connection port is Ordinary Equipment (IPX0)

The Equipment is not suitable for use in the presence of a flammable anesthetic mixed with air (with oxygen or with oxide)

- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Safety level when used in the presence of FLAMMABLE ANAESTHETIC MIXED WITH AIR (or WITH OXYGEN or WITH NITROUS OXIDE):

The Equipment is not suitable for use in the environment with FLAMMABLE ANAESTHETIC MIXED WITH AIR (or WITH OXYGEN or WITH NITROUS OXIDE).

Conduction Interference

Image quality will effect by conducted disturbance. Please do not use the effected image. And put system in a simpler electromagnetic compatibility environment to start working. If conducted disturbance occurred, stop using it and change the position for acquiring a better image.

⚠***WARNING***

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Mode of operation

Continuous Operation

For maximum safety, always follow these guidelines**:**

Proper grounding of the system is critical to avoid electrical shock. For protection, ground the chassis with a three-wire cable and plug, and plug the system into a hospital-grade, three-hole outlet.

- Do not remove or circumvent the grounding wire.
- Do not remove the protective covers on the system. These covers protect users from hazardous voltages. Cabinet panels must remain in place while the system is in use. A qualified electronic technician must make all internal replacements.
- Do not operate this system in the presence of flammable gases or anesthetics.
- All peripheral devices (unless certified as medical grade) that are connected to the system must be powered through the electrical outlet through an optional isolation transformer.

Notice upon Installation of Product

Separation distance and effect from fixed radio communications equipment: field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast transmitter cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ultrasound system is used exceeds the applicable RF compliance level as stated in the immunity declaration, the ultrasound system should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the ultrasound system or using an RF shielded examination room may be necessary.

- Use either power supply cords provided or designated by CHISON. Products equipped with a power source plug should be plugged into the fixed power socket which has the protective grounding conductor. Never use any adaptor or converter to connect with a power source plug (e.g. three-prong-to-two-prong converter).
- Locate the equipment as far away as possible from other electronic equipment.
- Be sure to use only the cables provided by or designated by CHISON. Connect these cables following the installation procedures (e.g. wire power cables separately from signal cables).
- Lay out the main equipment and other peripherals following the installation procedures described in this manual.
- Portable RF communications equipment (including peripherals such as antenna cables and externalantennas) should be used no closer than 30 cm (12 inches) to any part of this medical system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment couldresult.

Notice against User Modification

The user should never modify this product.

User modifications may cause degradation in Electrical Safety. Modification of the product includes changes in**:**

- Cables (length, material, wiring, etc.)
- System configuration/components

User modifications may cause degradation in EMC performance. Modification of the product includes changes in**:**

- Cables (length, material, wiring, etc.)
- System installation/layout
- System configuration/components
- Securing system parts (cover open/close, cover screwing)

Essential performance

- The image of the host is clearly displayed, the key function is normal, and the host can respond normally.
- Free from noise on a waveform or artefacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.
- Free from the display of incorrect numerical values associated with the diagnosis to be performed.
- Free from the display of incorrect safety-related indications.
- Free from the production of unintended or excessive ultrasound output.
- Free from the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature.
- Free from the production of unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.

2.3 Labels

Labels on main unit

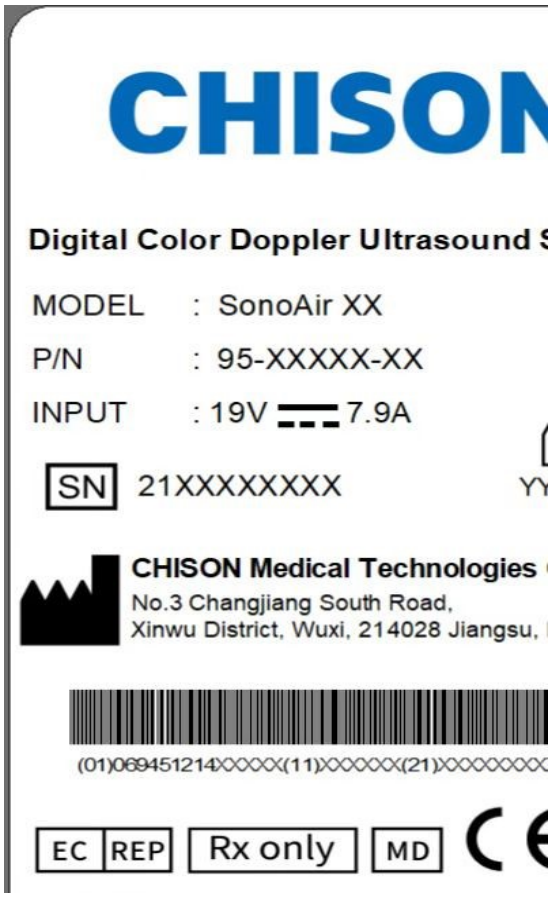


Fig. 2-1 SonoAir 70 Label

Labels on transducers

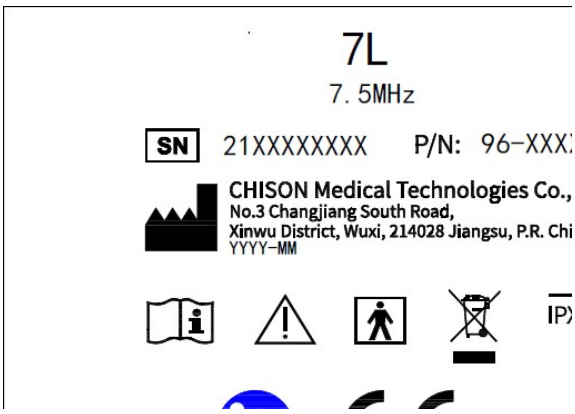


Fig. 2-2 7L Label

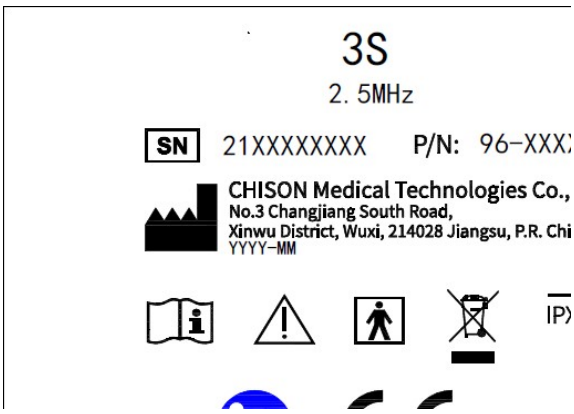


Fig. 2-3 3S Label

Fig. 2-4 3C Label

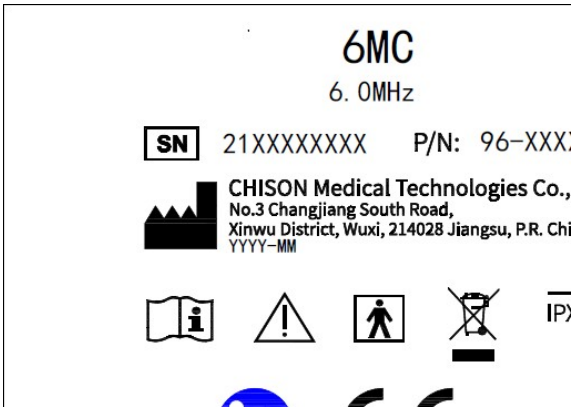


Fig. 2-5 6MC Label

Fig. 2-6 6E Label

2.3.1 Symbols on Label

 This mark indicates that this product contains a limited amount of hazardous substances in the Chinese Standard GB/T 26572-2011 "Limited Requirements for Restricted Substances in Electrical and Electronic Products". The numbers in the logo are the environmental protection use period of the product, indicating that under the normal use conditions, the harmful substances will not leak or be abrupt. The use of the product will not cause serious pollution to the environment or cause personal or property serious damage, the term unit is year.	 WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE): This symbol is used for Environment Protection, it indicates that the waste of electrical and electronic equipment must not be disposed as unsorted waste and must be collected separately. Please contact your local Authority or distributor of the manufacturer for information concerning the decommissioning of your equipment.
 Do not use the following devices near this equipment**:** cellular phone, radio receiver, and mobile radio transmitter, radio controlled toy, etc. Use of these devices near this equipment could cause this equipment to perform outside the published specifications. Keep power to these devices turned off when near this equipment.	 Caution, consult accompanying documents. This symbol advises the reader to consult the accompanying documents for important safety related information such as warnings and pre-cautions that cannot be presented on the device itself.
 Refer to instruction manual.	 The CE mark of Conformity indicates this equipment conforms with the Council Directive 93/42/EEC.
 (01)069451214XXXXX (11)XXXXXX (21)XXXXXXXXXX This symbol indicates the UDI of the device, (01) is followed by the UDI-DI code of the device, (11) is followed by the manufacturing date of the device, (21) is followed by the serial number of the device.	

EC REP AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.	SN This symbol is followed by the serial number of the device.
CN This symbol indicates the country of manufacture of products is china, and this symbol is followed by the manufacturing date of the device in the form YYYY-MM.	 MANUFACTURER: This symbol is accompanied by the name and the address of the manufacturer.
 Scan the QR code for model info and serial number.	Rx only This symbol indicates that in the united states of America, Federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.
 Direct current To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	IPX7 Protection against the effects of immersion
 Refer to instruction manual/booklet.	MD This symbol indicates the item is a medical device
 This symbol is accompanied by the name and the address of the importing entity	

2.3.2 Other Device Labels

The following table describes the purpose of safety labels and other important information provided on the equipment.

Table 2-1: Symbol Icons

Icon	Meaning

	Type-BF applied part

2.4 Patient Environmental Devices

Left side:

- 1 LAN port
- 1 DC IN port
- 2 USB ports
- 1 HDMI port

Right side:

- 4 Probe connection ports

Acceptable Devices

The Patient Environmental devices shown above are specified to be suitable for use within the PATIENT ENVIRONMENT.

⚠CAUTION

- *DO NOT connect any probes or accessories without approval by CHISON within the PATIENT ENVIRONMENT.*
- *DO NOT touch patient and devices without IEC/EN 60601-1 approval to avoid the leakage current risk within the PATIENT ENVIRONMENT.*

Unapproved Devices

⚠CAUTION

- *DO NOT use unapproved devices.*
- *If devices are connected without the approval of CHISON, the warranty will be INVALID.*
- *The system can't be used with HF surgical equipment; otherwise the burns to patient may occur.*

Any device connected to this system must conform to one or more of the requirements listed below**:**

- IEC standard or equivalent standards appropriate to devices.
- The devices shall be connected to PROTECTIVE EARTH (GROUND).

⚠CAUTION

Unsafe operation or malfunction may occur. Use only the accessories, options and supplies approved or recommended in these instructions for use.

Peripheral used in the patient environment

The system may be used safely while connected to devices other than those recommended if the devices

and their specifications, installation, and interconnection with the system conform to the requirements of IEC/EN 60601-1.

Adapter is considered as a part of ME equipment.

The connection of equipment or transmission networks other than as specified in the user instructions can result in an electric shock hazard or equipment malfunction. Substitute or alternate equipment and connections require verification of compatibility and conformity to IEC/EN 60601-1 by the installer. Equipment modifications and possible resulting malfunctions and electromagnetic interference are the responsibilities of the owner.

General precautions for installing an alternate off-board, remote device or a network would include**:**

- The added device(s) must have appropriate safety standard conformance and CE Marking.
- There must be adequate mechanical mounting of the device and stability of the combination.
- Risk and leakage current of the combination must comply with IEC/EN 60601-1.
- Electromagnetic emissions and immunity of the combination must conform to IEC/EN 60601-1-2.

Peripheral used in the non-patient environment

The system has been verified for compatibility, and compliance for connection to a local area network (LAN) via a wire LAN, provided the LAN components are IEC/EN 60601-1 compliant.

General precautions for installing an alternate off-board, remote device or a network would include**:**

- The added device(s) must have appropriate safety standard conformance and CE Marking.
- The added device(s) must be used for their intended purpose having a compatible interface.

⚠*CAUTION*

Make sure using ONLY the dedicated USB disk or removable media to save or back up data. Before connecting to the ultrasound system, make sure using the latest antivirus software on the USB disk or removable media to clean any virus. It is user's responsibility to ensure the USB disk or removable media is virus-free. Improper use of USB disk or removable media may cause the virus infections of system and eventually malfunction may occur. Such malfunction may impact the stability, effectiveness and safety of the system and probes, and users should immediately stop using the system and probes until CHISON authorized engineer has checked the system and confirm the effectiveness and safety of the system and probes.

⚠*CAUTION*

Use only secure Local Area Network connection. Don't connect the ultrasound system to Internet. Make sure your hospital's firewall software is configured correctly, thus blocking incoming connection requests from Internet. Improper use of network connection may cause the virus infections of system and eventually malfunction may occur.

2.5 Biological Safety

This product, as with all diagnostic ultrasound equipment, should be used only for valid reasons and should be used both for the shortest period of time and at the lowest power settings necessary (ALARA - As Low As Reasonably Achievable) to produce diagnostically acceptable images. The AIUM offers the following guidelines**:**

Clinical Safety Quoted from AIUM

Approved March 26, 1997

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:
There are no confirmed biological effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any that may be present.

Heating: Elevating tissue temperature during obstetrical examinations creates medical concerns. At the embryo development stage, the rise in temperature and the length of time exposed to heat combine to determine potential detrimental effects. Exercise caution particularly during Doppler/Color exams. The Thermal Index (TI) provides a statistical estimate of the potential temperature elevation (in centigrade) of tissue temperature. Three forms of TI are available**:** Soft Tissue Thermal Index (TIS), Bone Thermal Index (TIB) and Cranial Bone Thermal Index (TIC).

Soft Tissue Thermal Index (TIS). Used when imaging soft tissue only, it provides an estimate of potential temperature increase in soft tissue.
Bone Thermal Index (TIB). Used when bone is near the focus of the image as in the third trimester OB examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.
Cranial Bone Thermal Index (TIC). Used when bone is near the skin surface as in transcranial examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.

Cavitations: Cavitations may occur when sound passes through an area that contains a cavity, such as a gas bubble or air pocket (in the lung or intestine, for example). During the process of cavitations, the sound wave may cause the bubble to contract or resonate. This oscillation may cause the bubbles to explode and damage the tissue. The Mechanical Index (MI) has been created to help users accurately evaluate the likelihood of cavitations and the related adverse effects.
MI recognizes the importance of non-thermal processes, cavitations in particular, and the Index is an attempt to indicate the probability that they might occur within the tissue.

2.6 Scanning Patients and Education

The Track-3 or IEC60601-2-37 output display standard allows users to share the responsibility for the safe use of this ultrasound system. Follow these usage guidelines for safe operation**:**

- In order to maintain proper cleanliness of the probes, always clean them between patients.
- Always use a disinfected sheath on all EV/ER probes during every exam.
- Continuously move the probe, rather than staying in a single spot, to avoid elevated temperatures in one part of the patient's body.
- Move probe away from the patient when not actively scanning.
- Understand the meaning of the TI, TIS, TIB, TIC and MI output display, as well as the relationship between these parameters and the thermal/cavitation bio effect to the tissue.
- Expose the patient to only the very lowest practical transmit power levels for the shortest possible time to achieve a satisfactory diagnosis (ALARA - As Low As Reasonably Achievable).

2.6.1 Safe Scanning Guidelines

- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.
- Diagnostic ultrasound procedures should be done only by personnel fully trained in the use of the equipment, in the interpretation of the results and images, and in the safe use of ultrasound (including education as to potential hazards).
- Operators should understand the likely influence of the machine controls, the operating mode (e.g. B mode) and probe frequency on thermal and cavitation hazards.
- Select a low setting for each new patient. Output should only be increased during the examination if penetration is still required to achieve a satisfactory result, and after the Gain control has been moved to its maximum value.
- Maintain the shortest examination time necessary to produce a useful diagnostic result.
- Do not hold the probe in a fixed position for any longer than is necessary. The frozen frame and Cine loop capabilities allow images to be reviewed and discussed without exposing the patient to continuous scanning.
- Do not use endo-cavitary probes if there is noticeable self heating of the probe when operating in the air. Although applicable to any probe, take particular care during trans- vaginal exams during the first eight weeks of gestation.
- Take particular care to reduce output and minimize exposure time of an embryo or fetus when the temperature of the mother is already elevated.
- Take particular care to reduce the risk of thermal hazard during diagnostic ultrasound when exposing**:** an embryo less than eight weeks after gestation; or the head, brain or spine of any fetus or neonate.
- Operators should continually monitor the on-screen thermal index (TI) and mechanical index (MI) values and use control settings that keep these settings as low as possible while still achieving diagnostically useful results. In obstetric examinations, TIS (soft tissue thermal index) should be monitored during scans carried out in the first eight weeks after gestation, and TIB (bone thermal index) thereafter. In applications where the probe is very close to bone (e.g. trans-cranial applications), TIC

(cranial bone thermal index) should be monitored.

MI> 0.3 there is a possibility of minor damage to neonatal lung or intestine. If such exposure is necessary, reduce the exposure time as much as possible.

MI> 0.7 there is a risk of cavitations if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitations without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.

TI> 0.7 the overall exposure time of an embryo or fetus should be restricted in accordance with Table 2-2 below as a reference:

TI	Maximum exposure time (minutes)
0.7	60
1.0	30
1.5	15
2.0	4
2.5	1

Table 2-2: Maximum recommended exposure times for an embryo or fetus

- Non-diagnostic use of ultrasound equipment is not generally recommended. Examples of non-diagnostic uses of ultrasound equipment include repeated scans for operator training, equipment demonstration using normal subjects, and the production of souvenir pictures or videos of a fetus. For equipment of which the safety indices are displayed over their full range of values, the TI should always be less than 0.5 and the MI should always be less than 0.3. Avoid frequent repeated exposure of any subject. Scans in the first trimester of pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs, nor should their production involve increasing the exposure levels or extending the scan times beyond those needed for clinical purposes.
- Diagnostic ultrasound has the potential for both false positive and false negative results. Misdiagnosis is far more dangerous than any effect that might result from the ultrasound exposure. Therefore, diagnostic ultrasound system should be performed only by those with sufficient training and education.

2.6.2 Understanding the MI/TI Display

Track-3 follows the Output Display Standard for systems that include fetal Doppler applications. The acoustic output will not be evaluated on an application-specific basis, but the global maximum de-rated Ispta must be ≤ 720 mW/cm^2 and either the global maximum MI must be ≤ 1.9 or the global maximum de-rated Isppa must be ≤ 190 W/cm^2. An exception is for ophthalmic use, in which case the TI=max (TIS_as, TIC) is not to exceed 1.0; Ispta.3 ≤50mW/cm^2, and MI ≤ 0.23. Track-3 gives the user the freedom to increase the output acoustic power for a specific exam, and still limit output acoustic power within the global maximum de-rated Ispta ≤ 720 mW/cm^2 under an Output Display Standard.

For any diagnostic ultrasonic systems, Track-3 provides an Output Indices Display Standard. The diagnostic ultrasound systems and its operation manual contain the information regarding an ALARA (As Low As Reasonably Achievable) education program for the clinical end-user and the acoustic output

indices, MI and TI. The MI describes the likelihood of cavitations, and the TI offers the predicted maximum temperature rise in tissue as a result of the diagnostic examination. In general, a temperature increase of 2.5°C must be present consistently at one spot for 2 hours to cause fetal abnormalities. Avoiding a local temperature rise above 1°C should ensure that no thermally induced biologic effect occurs. When referring to the TI for potential thermal effect, a TI equal to 1 does not mean the temperature will rise 1 degree C. It only means an increased potential for thermal effects can be expected as the TI increases. A high index does not mean that bio effects are occurring, but only that the potential exists and there is no consideration in the TI for the scan duration, so minimizing the overall scan time will reduce the potential for effects. These operator control and display features shift the safety responsibility from the manufacturer to the user. So it is very important to have the Ultrasound systems display the acoustic output indices correctly and the education of the user to interpret the value appropriately.

RF: (De-rating factor)

In Situ intensity and pressure cannot currently be measured. Therefore, the acoustic power measurement is normally done in the water tank, and when soft tissue replaces water along the ultrasound path, a decrease in intensity is expected. The fractional reduction in intensity caused by attenuation is denoted by the de-rating factor (RF),

RF=10 (-0.1 a f z)

Where a is the attenuation coefficient in dB cm-1 MHz-1, f is the transducer center frequency, and z is the distance along the beam axis between the source and the point of interest.

De-rating factor RF for the various distances and frequencies with attenuation coefficient 0.3dB cm-1 MHz-1 in homogeneous soft tissue is listed in the following table. An example is if the user uses 7.5MHz frequency, the power will be attenuated by .0750 at 5cm, or 0.3x7.5x5=-11.25dB. The De- rated Intensity is also referred to as '.3' at the end (e.g. Ispta.3).

Distance	**Frequency (MHz)**			
(cm)	1	3	5	7.5
1	0.9332	0.8128	0.7080	0.5957
2	0.8710	0.6607	0.5012	0.3548
3	0.8128	0.5370	0.3548	0.2113
4	0.7586	0.4365	0.2512	0.1259
5	0.7080	0.3548	0.1778	0.0750
6	0.6607	0.2884	0.1259	0.0447
7	0.6166	0.2344	0.0891	0.0266
8	0.5754	0.1903	0.0631	0.0158

I'=I*RF Where I' is the intensity in soft tissue, I is the time-averaged intensity measured in water.

Tissue Model:

Tissue temperature elevation depends on power, tissue type, beam width, and scanning mode. Six models are developed to mimic possible clinical situations.

	Thermal Models	Composition	Mode	Specification	Application
1	TIS	Soft tissue	Unscanned	Large aperture (>1cm^2)	Liver PW
2	TIS	Soft tissue	Unscanned	Small aperture (<1cm^2)	Pencil Probe
3	TIS	Soft tissue	Scanned	Evaluated at surface	Breast color
4	TIB	Soft tissue and bone	Scanned	Soft tissue at surface	Muscle color
5	TIB	Soft tissue and bone	Unscanned	Bone at focus	Fetus head PW
6	TIC	Soft tissue and bone	Unscanned/scanned	Bone at surface	Transcranial

Soft tissue:

Describe low fat content tissue that does not contain calcifications or large gas-filled spaces.

Scanned: (auto-scan)

Refers to the steering of successive burst through the field of view, e.g. B and color mode.

Unscanned:

Emission of ultrasonic pulses occurs along a single line of sight and is unchanged until the transducer is moved to a new position. For instance, the PW, and M mode.

TI:

TI is defined as the ratio of the In Situ acoustic power (W.3) to the acoustic power required to raise tissue temperature by 1°C (Wdeg), TI=W.3/Wdeg.

Three TIs corresponding to soft tissue (TIS) for abdominal; bone (TIB) for fetal and neonatal cephalic; and cranial bone (TIC) for pediatric and adult cephalic, have been developed for applications in different exams.

An estimate of the acoustic power in milli-watts necessary to produce a 1°C temperature elevation in soft tissue is:

Wdeg=210/fc,for model 1 to 4, where fc is the center frequency in MHz.

Wdeg=40 K Dfor model 5 and 6, where K (beam shape factor) is 1.0, D is the aperture diameter in cm at the depth of interest.

MI:

Cavitation is more likely to occur at high pressures and low frequencies in pulse ultrasound wave in the tissue, which contains the bubble or air pocket (for instance, the lung, intestine, or scan with gas contrast agents). The threshold under optimum conditions of pulsed ultrasound is predicted by the ration of the

peak pressure to the square root of the frequency.

MI=Pr'/sqrt(fc)

Pr' is the de-rated (0.3) peak rare-fractional pressure in Mpa at the point where PII is the maximum, and fc is the center frequency in MHz. PII is the Pulse Intensity Integral that the total energy per unit area carried by the wave during the time duration of the pulse. The peak rare- fractional pressure is measured in hydrophone maximum negative voltage normalized by the hydrophone calibration parameter.

Display Guideline:

For different operation modes, different indices must be displayed. However, only one index needs to be shown at a time. Display is not required if maximum MI is less than 1.0 for any setting of the operating mode, or if maximum TI is less than 1.0 for any setting of the operating mode. For TI, if the TIS and TIB are both greater than 1.0, the scanners need not be capable of displaying both indices simultaneously. If the index falls below 0.4, no display is needed. The display increments are no greater than 0.2 for index value less than one and no greater than 1.0 for index values greater than one (e.g. 0.4, 0.6, 0.8, 1, 2, and 3).

Display and Report

Located on the upper middle section of the system display monitor, the acoustic output display provides the operator with real-time indication of acoustic levels being generated by the system.

For Scan

Only display and report MI, and start from 0.4 if maximum MI > 1.0, display in increments of 0.2.

Below is a simple guideline for the user when TI exceeds one limit exposure time to 4(6-TI) minutes based on the 'National Council on Radiation Protection. Exposure Criteria for Medical Diagnostic Ultrasound**:** I. Criteria Based on Thermal Mechanisms. Report No.113 1992'.

Operator Control Features:

The user should be aware that certain operator controls may affect the acoustic output. It is recommended to use the default (or lowest) output power setting and compensate using Gain control to acquire an image. Other than the output power setting in the soft-menu, which has the most direct impact on the power; the PRF, image sector size, frame rate, depth, and focal position also slightly affect the output power. The default setting is normally around 70% of the allowable power depending on the exam application mode.

Controls Affecting Acoustic Output:

The potential for producing mechanical bio effects (MI) or thermal bio effects (TI) can be influenced by certain controls.

Direct: The Acoustic Output control has the most significant effect on Acoustic Output.

Indirect: Indirect effects may occur when adjusting controls. Controls that can influence MI and TI are detailed under the bio effect portion of each control in the Optimizing the Image chapter.

Always observe the Acoustic Output display for possible effects.

Best practices while scanning

HINTS: Raise the Acoustic Output only after attempting image optimization with controls that have no effect on Acoustic Output, such as Gain and STC.

⚠*WARNING*

- *Be sure to have read and understood control explanations for each mode used before attempting to adjust the Acoustic Output control or any control that can affect Acoustic Output.*
- *Use the minimum necessary acoustic output to get the best diagnostic image or measurement during an examination. Begin the exam with the probe that provides an optimum focal depth and penetration.*

Acoustic Output Default Levels

In order to assure that an exam does not start at a high output level, the system initiates scanning at a reduced default output level. This reduced level is preset programmable and depends upon the exam icon and probe selected. It takes effect when the system is powered on or New Patient is selected. To modify acoustic output, adjust the Power Output level on the Soft Menu.

2.7 Device Instructions of Cybersecurity Controls

2.7.1 Software Integrity Control

The following controls are in place to assure that the device software will maintain its integrity from the point of origin to the point at which that device leaves the control of the manufacturer.

- The system goes through a security self-test at startup, some key files for security checks to ensure that the system starts normally.
- The system supports the recovery function. This function will restore the system to the original state.

The following controls are in place to assure that the device software will be protected from malware from the point of origin to the point at which that device leaves the manufacturer's control point.

- Installing OS Updates Immediately

Whenever an update appears on the screen, consider installing an operating system update immediately to avoid virus and malware attacks.

- The device software doesn't provide any entrance for executing third party application.
- Never trust an unknown computer

The device connect computer with USB port.Do not plug the device into an unknown computer.

- Install anti-virus software and use firewall and scan device regularly with antivirus software.
- Keep network safe

Set a strong network access password, and do not open public Wi-Fi connections, use WPA, WPA2 encryption or the latest WPA3 encryption. Don't open email attachments from unknown people or companies, don't click links in unsolicited emails, do not download suspicious apps, etc.

2.7.2 Device Instructions of Cybersecurity Controls

The following are device instructions for use related to recommended cybersecurity controls appropriate for the intended use environment.

- Install anti-virus software and use firewall before connecting the device with wifi.
- Install anti-virus software and use firewall before connecting the device with DICOM server.
- Limit access to device software through the authentication of users by user name and password. Ownership of a device is assigned to one user at a time.
- To protect the patient information, the system should hide the critical patient information when exporting the image and cine. And the hidden function is configurable.
- Image and cine data contains no patient or user-identifying information. If want to encrypt this data, please connect to a network that uses an encryption protocol.
- The software uses private custom format to store patient data and can not be recognized by general tools.
- Connect the network only to run the DICOM functions or transmission function, otherwise disconnect the network.
- When connecting the device with wifi, use a network that supports Wi-Fi 802.11n. We recommend that

secure this network using WPA (Wi-Fi Protected Access) or WPA2 (Wi-Fi Protected Access II) as security protocol.

2.8 Insturctions to the Intruded Device

The following are instructions to protect your device prior to the device leaving your control.

- Back up the patient data.
- Verify the patient data on the device with anti-virus software.
- Recovery the system to the original state.
- Recovery the patient data to the system.

Chapter 3 Preparing the System for Use

3.1 Site Requirement

3.1.1 Operation Environment Requirement

The following environmental conditions are within system tolerances for operation:
Strong radiation sources or powerful electromagnetic waves (e.g. Electro-magnetic waves from radio broadcasting) may result in image ghosting or noise. The system should be isolated from such radiation sources or electromagnetic waves.

Environment / Parameter	Operation	Transportation & Storage
Temperature	10℃ ~ 40℃	-10℃ ~ 50℃
Relative Humidity	30% ~ 75%	≤80%, non-condensing
Atmosphere Pressure	700hPa ~ 1060hPa	700hPa ~ 1060hPa

⚠NOTE

While the temperature of environment is between 0℃ to 38℃, the system can work continuously in normal. If the temperature of environment is over 38℃ , the system can detect the temperature and stop working while overheating.

3.1.2 Electrical Requirements

Adapter power supply voltage: AC100-240V～±10%, 47-63Hz

Main system power input: ≤150W

Battery type: U726467PHVG-4S1P: 70Wh

Power consumption: 150VA

⚠WARNING

Maintain a fluctuation range of less than ±5%, otherwise the system may be damaged.

⚠NOTE

- *Please follow the outlined power requirements. Only use power cables that meet the system guidelines—failure to follow these procedures may produce system damage.*
- *Battery*

To avoid the battery bursting, igniting, or fumes from the battery; causing equipment damage, observe the following precautions: Do not immerse the battery in water or allow it to get wet. Do not put the battery into a microwave oven or pressurized container. If the battery leaks or emits an odor, remove it from all

possible flammable sources. If the battery emits an odor or heat, is deformed or discolored, or in a way appears abnormal during use, recharging or storage, immediately remove it and stop using it.

In storage，battery must be charged every three months to 40%～60% capacity.

Build in Battery specification:

Battery Model	U726467PHVG-4S1P
Capacity	nominal capacity : 4600mAh
Related Voltage	15.4V
Standard charge Voltage	17.6V
Discharge closing voltage	12.0V
Discharge time	≥5h/0.2C
Standard charge current	920mA（0.2C）
Maximum continuous discharge current	4600mA（1C）
Battery structure	4S1P
Cycle life	≥500 80% capacity
Charging time	≈6H/920mA（0.2C）
Operating temperature	0-60℃
Storage temperature	-20℃~35℃
Battery status indicator	NC

3.1.3 Battery Handling Instructions

⚠*CAUTION*

Read and observe the following warnings and precautions to ensure correct and safe use of Li-ion batteries.

- *Do not immerse the battery in water or allow it to get wet.*
- *Do not use or store the battery near sources of heat such as a fire or heater.*
- *Do not use any chargers other than those recommended.*
- *Do not reverse the positive (+) and negative (-) terminals.*
- *Do not connect the battery directly to wall outlets or car cigarette-lighter sockets.*
- *Do not put the battery into a fire or apply direct heat to it.*
- *Do not short-circuit the battery by connecting wires or other metal objects to the positive (+) and negative (-) terminals.*
- *Do not pierce the battery casing with a nail or other sharp object, break it open with a hammer, or step on it.*
- *Do not strike, throw or subject the battery to sever physical shock.*
- *Do not directly solder the battery terminals.*
- *Do not attempt to disassemble or modify the battery in any way.*

- *Do not place the battery in a microwave oven or pressurized container.*
- *Do not use the battery in combination with primary batteries (such as dry-cell batteries) or batteries of different capacity, type or brand.*
- *Do not use the battery if it gives off an odor, generates heat, becomes discolored or deformed, or appears abnormal in any way. If the battery is in use or being recharged, remove it from the device or charger immediately and discontinue use.*
- *Do not use or store the battery where is exposed to extremely hot, such as under window of a car in direct sunlight in a hot day. Otherwise, the battery may be overheated. This can also reduce battery performance and/or shorten service life.*
- *If the battery leaks and electrolyte gets in your eyes, do not rub them. Instead, rinse them with clean running water and immediately seek medical attention. If left as is, electrolyte can cause eye injury.*

3.1.4 Hardware requirements

The digital color doppler ultrasound system includes the transducer, software and main uint.
The minimum requirements for main unit are as follows:
IEC 62638-1 compliant
IEC 55032 compliant
CPU: i3-1005G1, Dual-Core
Memory: Support 4GB/8GB
Storage: Not less than 128G
Touch Pad
Touch interface
802.11abgn+acR2+ax MIMO 2x2 (up to 160MHz channel support)
Bluetooth® 5.2
Fingerprint
Operating System: Ubuntu -20.04.2.0-desktop-amd64.iso
LCD: 14.1”IPS 1920 x 1080
Interface: Type C, USB 3.0

3.1.5 Programming Language Requirements

Operation System: Ubuntu 20.04
Programming Environment: QtCreator

3.2 System Specifications

3.2.1 Console View

Fig. 3-1 SonoAir 70 Console View

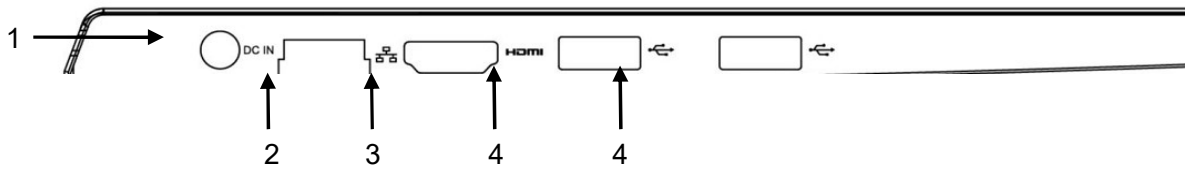


Fig. 3-2 System Left Side View

1. DC IN 2. LAN Port 3. HDMI 4. USB Port

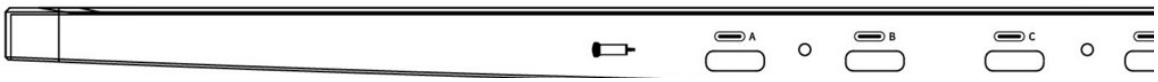


Fig. 3-3 System Right Side View

A/B/C/D Port: Probe Connection Port

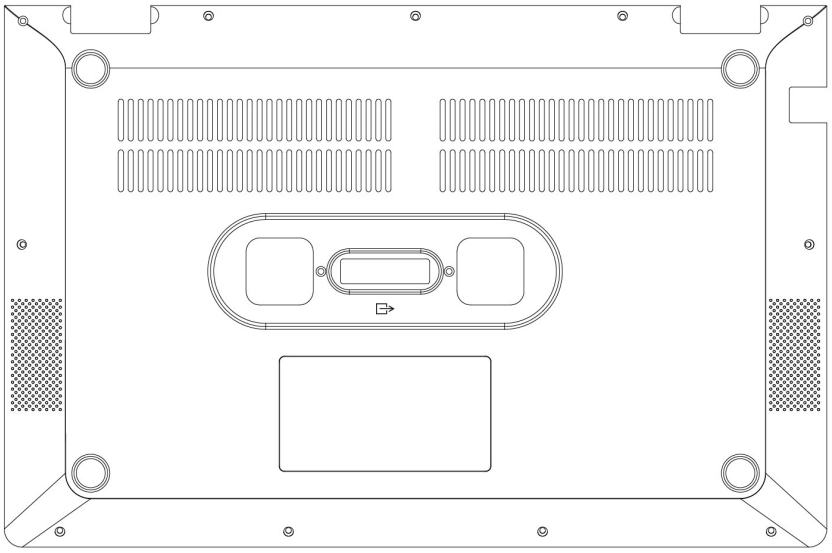


Fig. 3-4 System Bottom Panel View

3.2.2 Physical Specification

Dimensions of main unit (approx.): 330mm (Length) × 220mm (Width) × 30mm (Height)

Net weight of main unit (approx.): 2.1kg (No probe included)

3.2.3 System Components

Component	SonoAir 70
Control Panle	Standard
14.1〃 LCD Touch Screen	Standard
Built-in Lithium Battery	Standard
Internal Hard Disk (≥128GB)	Standard
Power Adapter	Standard
USB 3.0 × 2	Standard
Number of Probe Socket	4

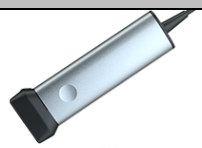
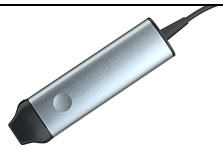
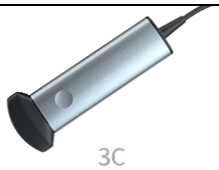
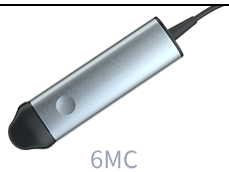
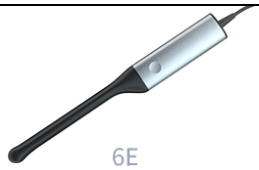
3.2.4 System Configuration

The system configures with the following functions:

B Mode	Biopsy	Bodymark
B/B Mode	Full Screen	Auto IMT
4B Mode	SonoZoom	HDMI
B/M Mode	SonoRemote (Option)	Cine Loop
M Mode	Zoom (Option)	Save and Recall
CFM Mode	Depth	Print
PW Mode	Freeze/Unfreeze	DICOM (Option)
CPA (PD) Mode	Focus	Screen Protector
DPD Mode	Parameters Adjustment	Image Browsing
2D Steer	TGC	Report Management
B/BC (Option)	Gain	Patient Management
Triplex	Chroma	Archive Management
Quadplex	X-contrast	Multilingual Interface Display
Intell. Doppler (Option)	Compound	Touch Function
Extended	AIO	Standby
Trapezoidal	SRA	WiFi
Super Needle	Q-image	Bluetooth
Super Needle+ 1.0	Human Measurement Package (Option)	Fingerprint Recognition

3.2.5 Accessories

① Transducers

Overview	Information	Application
 7L	Linear probe: 7L (4.5-10MHz)	Carotid, Thyroid, Scrotum, Breast, MSK, Nerve, Appendix, Vascular, Superficial, PED
 3S	Phased probe: 3S (1.5-3.5MHz)	Cardiac, CardiacDifficult, Abdomen, Lung, TCD, FAST
 3C	Convex array probe: 3C (1.8-4MHz)	Abdomen, OB, UT&Ovary, Renal, Urology, Lung, Lumbar, FAST
 6MC	Micro convex probe: 6MC (4.3-9.5MHz)	PED-ABD, Vascular, Cardiac
 6E	Intracavity convex probe: 6E (4.3-9.5MHz)	Early Pregnancy, Pelvic, UT&Ovary, Prostate

② AC/DC adapter

Adapter specifications:

Adapter Model	MANGO150S-19AB
Input	100-240V～, 50/60Hz, 2.0-1.0A
Output	19V⎓7.9A

3.2.6 Trolley TR3000

The trolley is used for SonoAir Series. You can adjust the height of the trolley to fit you when you standing or sitting. Casters with lock prevent the trolley moving effectively and make you focus on your patient.

Fig. 3-5

3.2.6.1 Components

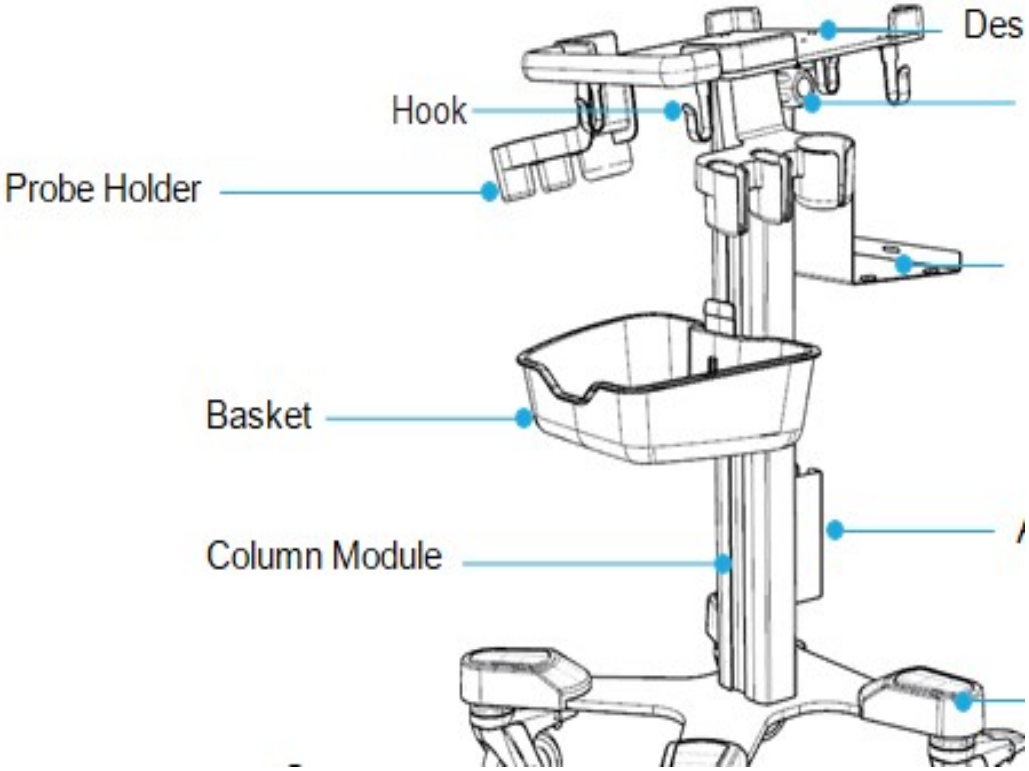


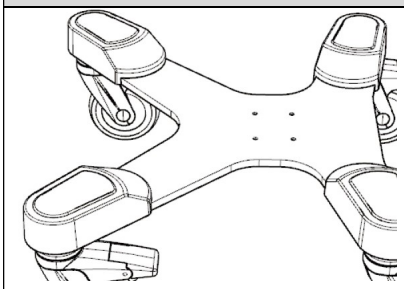
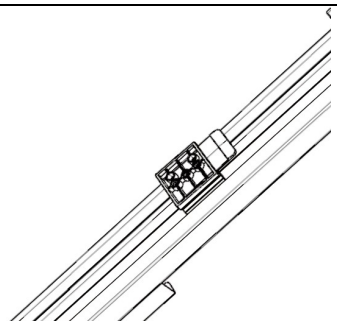
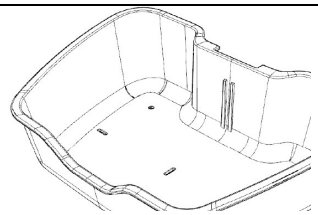
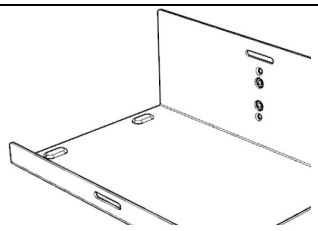
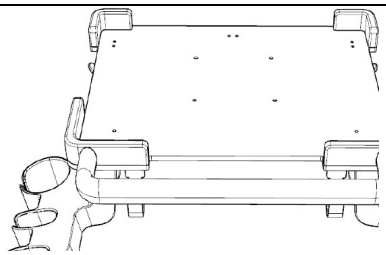
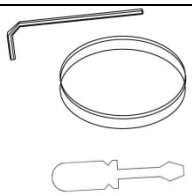
Fig. 3-6

3.2.6.2 Physical Specifications

Dimensions of main unit (approx.): 500mm*480mm*1150mm

Weight (approx.): 16kg

3.2.6.3 Components List

Item	Name	Quantity	Remark
	Base Module	1	
	Column Module	1	
	Basket	1	
	Printer Shelf	1	
	Desktop Module	1	
	Tool Kit	1	Including： 1 screw driver 1 hex wrench 1 rubber band

NOTE: *Check the quantity of the parts before installation.*

3.2.6.4 Recommend Optional Accessory

Component.	Manufacturer	Model No.	Technical data
Printer	SONY ELECTRONICS INC	UP-897MD	100-240V, 50/60Hz, 1.5A-0.8A
Printer	Mitsubishi Electric Corp. Kyoto Works	CP31W	AC 120V,1.7A AC220-240V,1.0A, 50/60Hz
Printer	Mitsubishi Electric Corp. Kyoto Works	CP30W	AC 120V,1.7A AC220-240V,1.0A, 50/60Hz
Printer	Mitsubishi Electric Corp. Kyoto Works	P93W	100-240V, 50/60Hz, 1.5A-0.8A

3.2.6.5 Caution

⚠CAUTION:

1) Do not tilt the trolley more than 5 degree angle.

2) Do not modify this equipment without authorization of the manufacturer.

3) Parts without permission of the manufacturer cannot be used with the trolley without permission of the manufacturer.

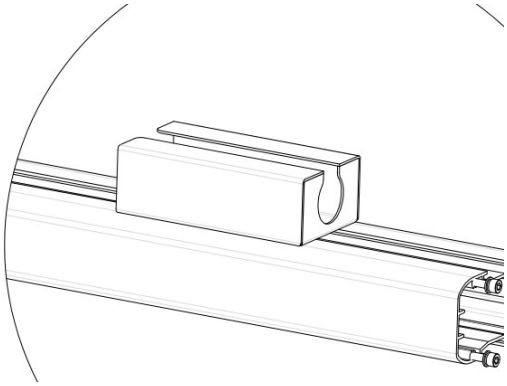
3.2.6.6 Installation Steps

- **Connect the base module and the column module**

  A: Remove the 4 M5 screws installed on the column first.

  B: Insert the column module into the base module with care.

  C: Lay down the cart carefully and fix the 4 M5 screws onto the column by using the attached hex wrench.



A

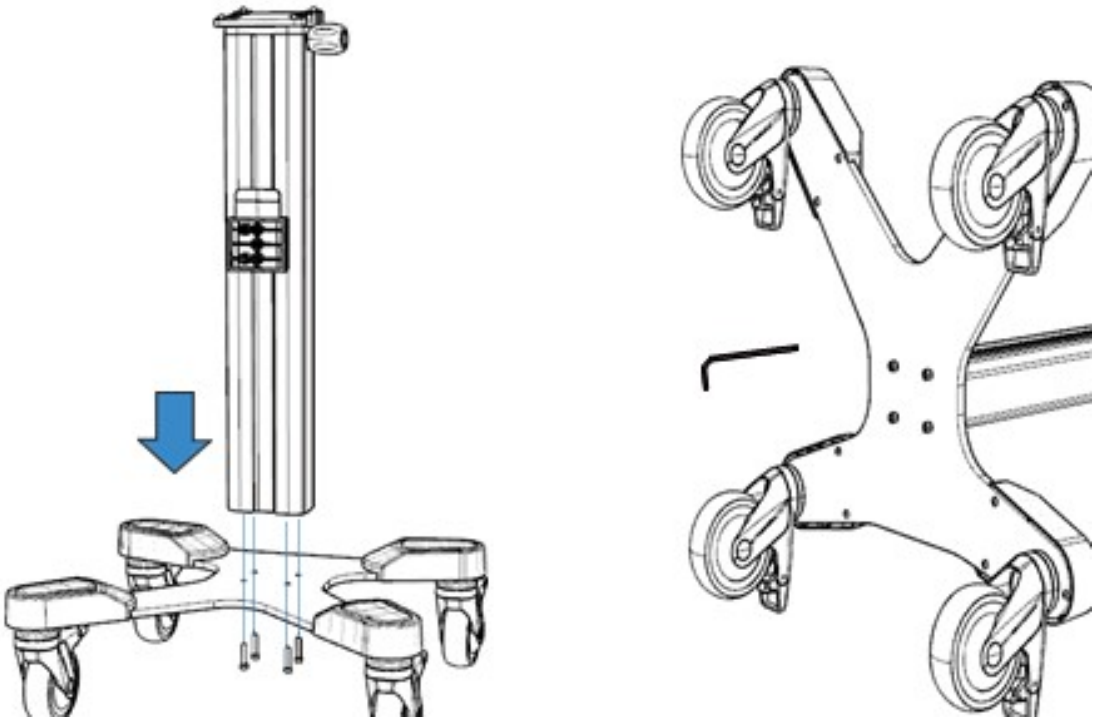


Fig. 3-7

⚠NOTE:

1) When installing, pay attention that the front and back of the column must be consistent with the front and back of the base.

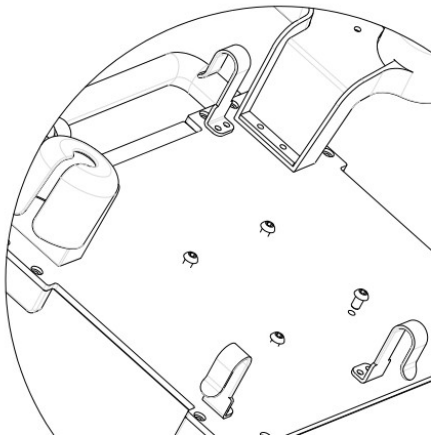
2) *The side with the largest angle between the casters is the back for the base, and the opposite side is the front side.*
3) *The one side with basket hanger is the front side of the column and the opposite is the back side.*

➢ Connect the column module and the desktop module

A: Remove the 4 M6 screws installed on the desktop first.

B: Place the desktop module onto the column to align the holes.

C: Secure the desktop and the column with 4 M6 screws by using the hex wrench.



A

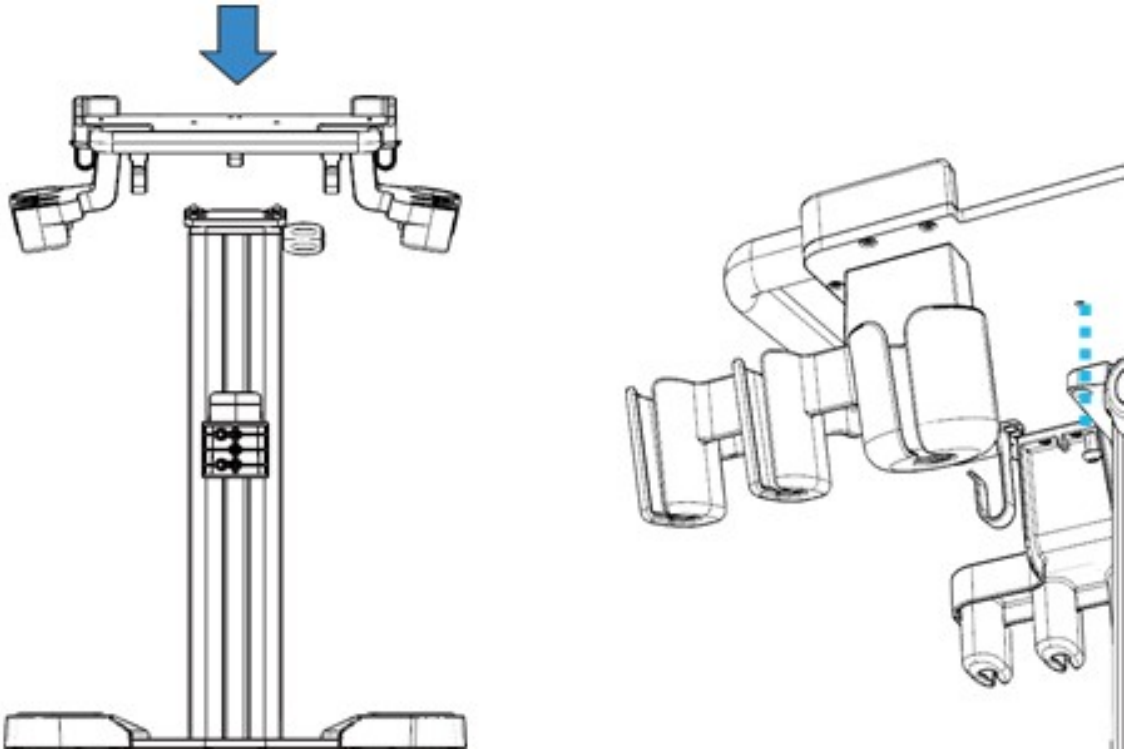


Fig.3-8

➢ Install the basket and the printer shelf

A: Insert the basket into the slider in the front of the column.

B: Fix the printer shelf onto the slider at the back of the column by using the screw driver.

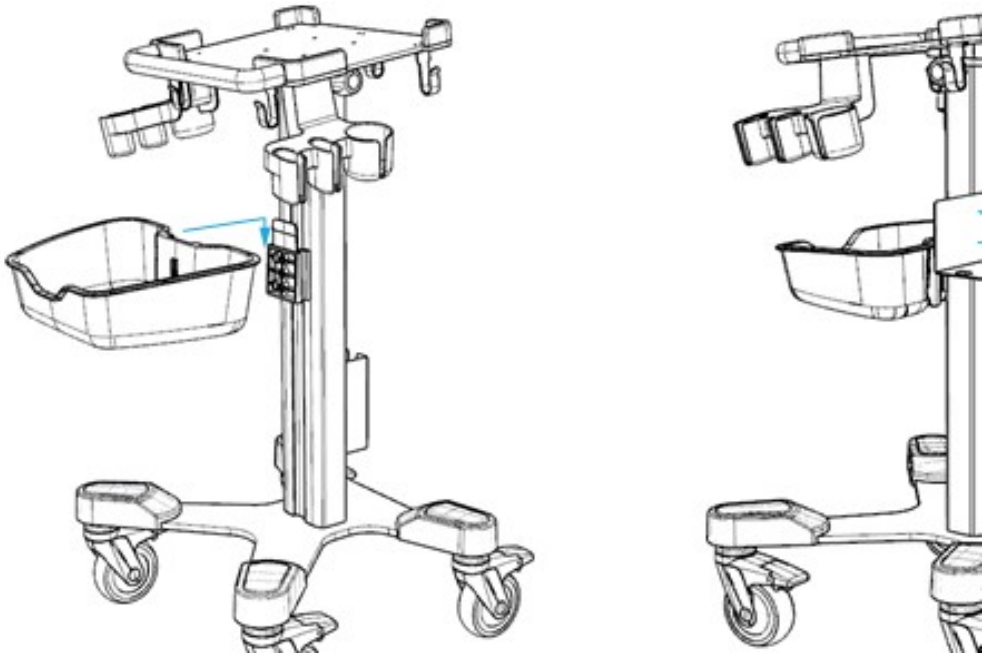
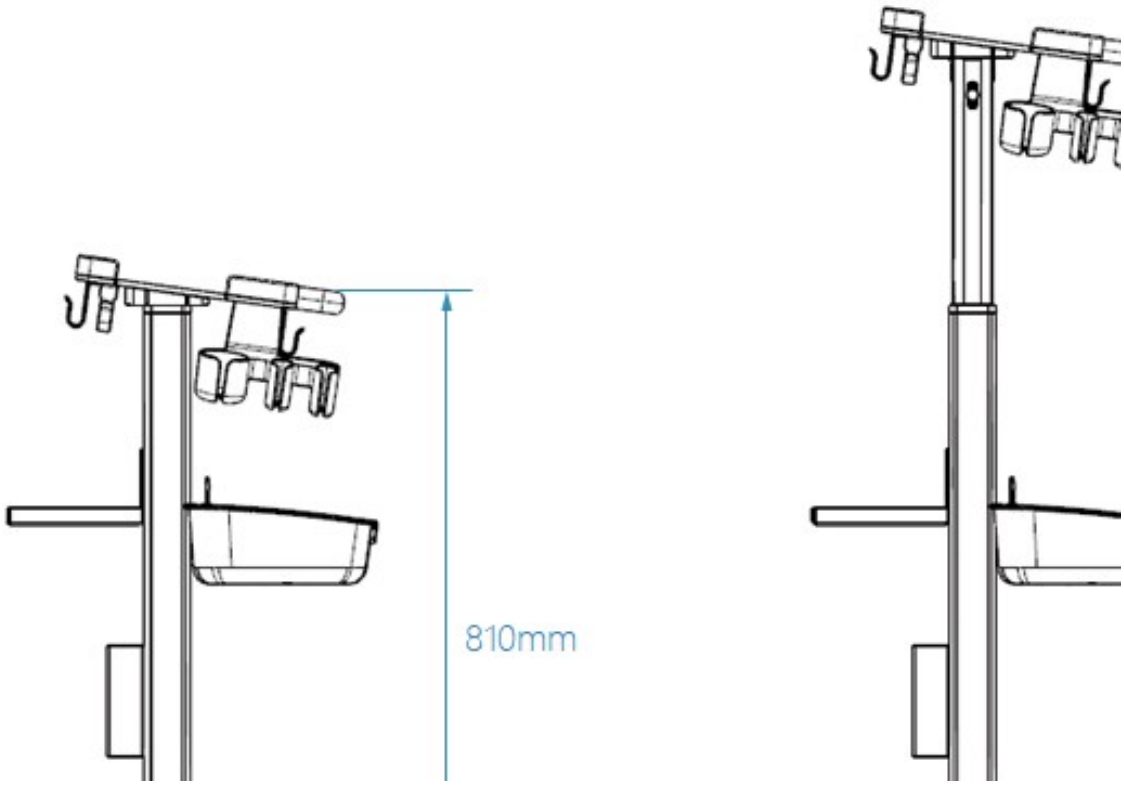


Fig. 3-9

➢ Column height adjustment

The column can be adjusted by the knob manually and the adjustable height is 300mm.



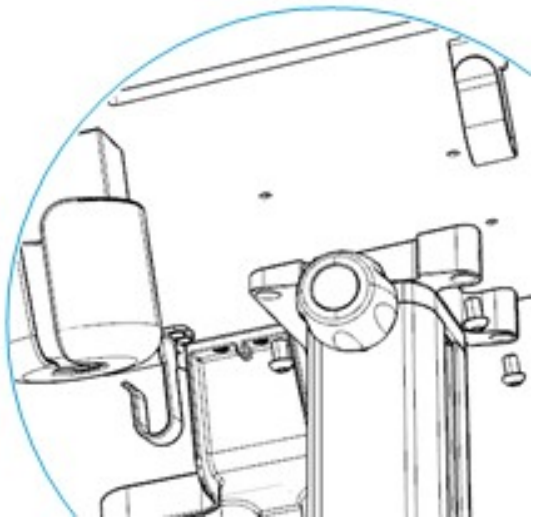


Fig. 3-10

To achieve the most comfortable operating experience, the column height is adjustable.

Operation Procedures:

1. Loose the knob manually first.
2. Hold the desktop by two hands and pull up or push down to increase or decrease the column height.
3. Lock the knob manually to secure.

⚠CAUTION:

1) Please be aware of crushing of hands when adjust the column height.

2) Fix the SonoAir with the rubber band on the desktop in case of possible drop.

3) This trolley only fits for SonoAir series ultrasound system manufactured by CHISON.

3.3 System Positioning & Transporting

◆ **Moving the System**

When moving or transporting the system, take the precautions described below to ensure maximum safety for personnel, the system and other equipment.

◆ **Before Moving the System**

● Press  (see 【SWITCH】 key in Section 4.4 Function Key Introduction) for more than 4 seconds, system will be forced to shut down and completely switch off.

● Disconnect all cables from off-board peripheral devices (external printer, etc.) from the console.

⚠*NOTE*

● *To prevent damage to the power cord, DO NOT pull excessively on the cord or sharply bend the cord*

while wrapping it.

- *Store all probes in their original cases or wrap them in soft cloth or foam to prevent damage.*
- *Replace gel and other essential accessories in the appropriate storage case.*
- *Ensure that no loose items are left on the console.*

◆ **When Moving the System**

Carry the system with hand, or put the system on the cart to move it.

⚠NOTE

Walk slowly and carefully when moving the system.

Do not let the system strike walls or doorframe.

◆ **Transporting the System**

Use extra care when transporting the system in a vehicle. After preparing the system as described above, take the following additional precautions**:**

- Only use vehicles that are suitable for transport of the system.
- Before transporting, place the system in its original storage carton.
- Load and unload the system to a vehicle parked on a level surface.
- Load the unit abroad the vehicle carefully. Keep the unit still and upright.
- Drive carefully to prevent damage from vibration. Avoid unpaved roads, excessive speeds, and erratic stops or starts.

3.4 Powering the System

3.4.1 Acclimation Time

After being transported, the unit requires one hour for each 2.5ºC increment if its temperature is below 10ºC or above 38ºC.

3.4.2 Connecting the Electric Power

After making sure that the AC power supply in hospital is in normal status, and this AC voltage type matches to the power requirements indicated on the label of system, then please connect the plug of power cord to the DC IN port in the left side of the control panel, and connect the other end of power cord to the AC power supply socket in hospital.

Please use the power cable provided by the manufacturer, other type of power cable is not allowed.

⚠CAUTION

Connecting the system to the wrong AC power supply may cause damage to the system and danger to the operators.

3.4.3 Power On

Please be sure to plug in power adapter to power on for the first time. Press  , system boots up.

3.4.4 Power Off

Press  and system pops up dialog box. Click “Shutdown”. Then system powers off.

Or long press  for a few seconds, system will be forced to shut down.

3.4.5 Standby

Press  , and system pops up dialog box. Select “Standby” to enter into the standby status.

3.5 Probe Installation and Disassembly

⚠CAUTION

- *Only power supply at “turn off” state, can install/take down the probe, otherwise, it will damage the main unit and the probe.*
- *When installing and disassembling probe, please keep the probe in a safe environment to prevent it from accidentally falling and thus cause damage.*
- *Please only use the probes provided by manufacturer for this model, other types of probes are not allowed to use with this system! Otherwise, it may cause damage to the system and the probe.*

3.5.1 Probe Installation

⚠CAUTION

Before connecting the probe, please carefully check the probe lens, probe cable and probe connector to see whether there is anything abnormal, such as cracks, falls off. Abnormal probe is not allowed to connect to the main unit; otherwise there is possibility of electricity shock.

- Vertically insert the probe TYPE-C connector into either of the A/B/C/D probe connection port on the right side of the control panel.
- Check the locked probe with one hand to make sure that it’s not loose, and it’s securely connected.

3.5.2 Probe Disassembly

- Pull out the TYPE-C connector vertically from the main unit gently.

Chapter 4 Control Panel

4.1 Overview of Display Area

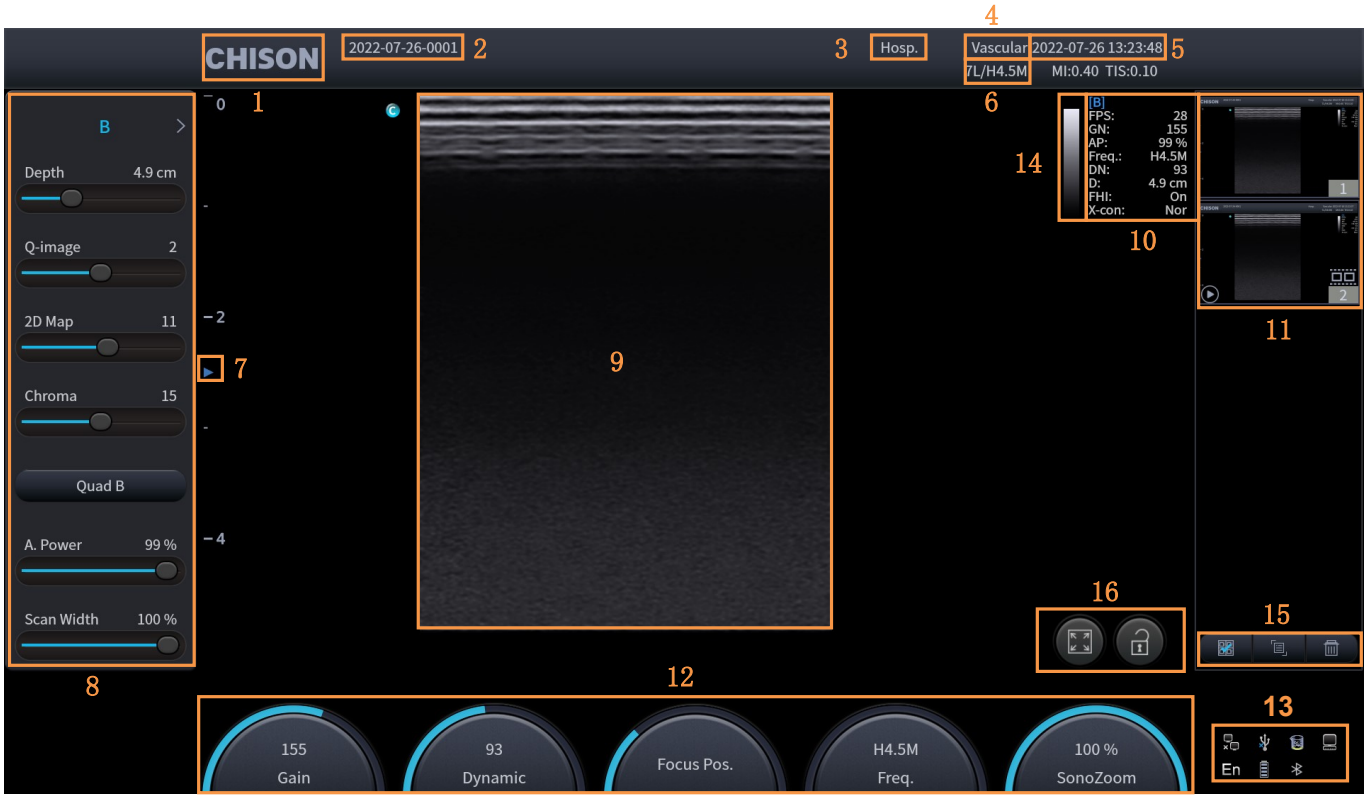
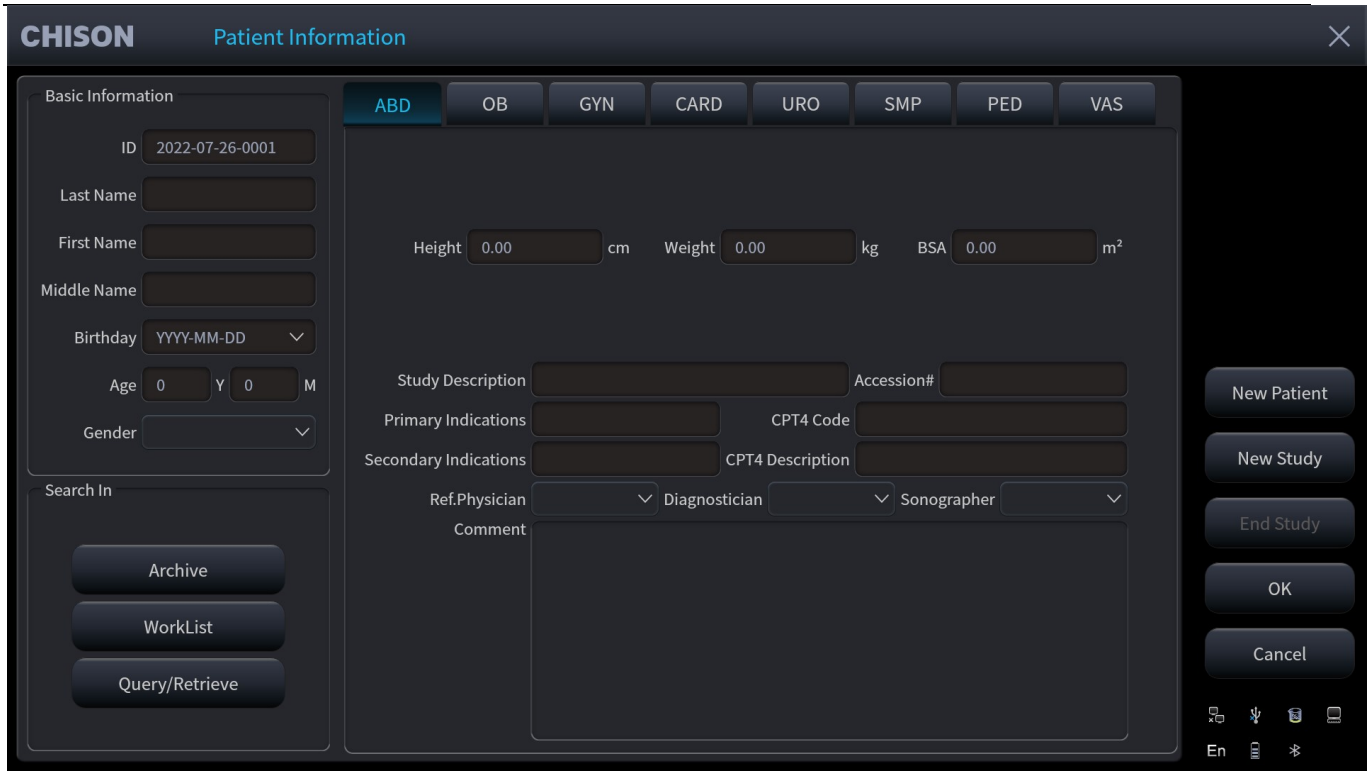


Fig. 4-1 Display Interface

1	Logo	2	Patient ID
3	Hospital Name	4	Current Preset
5	Date and Time	6	Current Probe Type and Frequency
7	Focus	8	Mode Menu Area
9	Image Area	10	Mode Image Parameter Area
11	Thumbnail Area	12	Image Parameter Control Area
13	System Status Information Area	14	Gray-scale Strip
15	Thumbnail Operating Area	16	Full Screen & Screen Lock

4.2 Start a New Exam

Press  to display the patient screen.



Function Buttons on Patient screen**:**

[Archive]: Operation on the patient information which has already existed.

[Worklist]: Recall patient information in worklist. And need to activate the DICOM function.

[Query/Retrieve]: Recall patient information for examination.

[New Patient]: Create a new patient information identity.

[New Study]: Choose exam applications (OB, GYN, CARD and so on) for the current patient.

[End Study]: End patient's exam item.

[OK]: Save patient's information.

[Cancel]: Cancel the operation of new patient's information.

Operation Methods:

1. Move the cursor by touchpad to the position of inputting character. Press【ENTER】key then the soft keyboard pops up. Input patient information by soft keyboard.
2. Use the touchpad and the【ENTER】key to switch between different input options**:** ID, patient's name, birthday (It can be automatically calculated when inputting age), age (It can be automatically calculated when inputting birthday), and gender.
3. Select the exam items, and input the regular inspection information.
4. After inputting the required information, click on the **[OK]** button to save the patient's information, the system will return to the B mode.
5. To recall information of the previous patient, you can use the Archive or Worklist to recall patient's information to exam.

⚠*CAUTION*

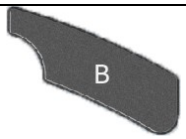
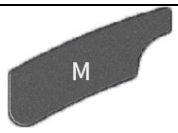
Creating a diagnostic record, you should check the accuracy of the patient's information before saving

measurement or image; otherwise, it will be stored in the wrong patient records. After checking the patient, press【END】to save the patient's information in the system.

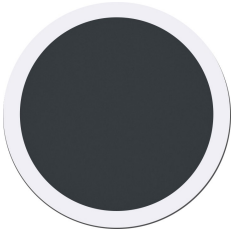
4.3 Control Panel Appearance

4.4 Function Key Introduction

Key icon	Key's name	Function description
	【SWITCH】key	Turn on or off the device.
	【SonoRemote】	Press this key to enter into SonoRemote interface.
	【Intell. Doppler】	In active CFM mode or PW preview mode, press this button to enter Intelligent Doppler.
	【PATIENT】key	Set up a new patient data, input name and other information.
	【PROBE】key	Select probe. Only connected probe can be selected.
	【EasyView】Key	File management of system, you can view and

Key icon	Key's name	Function description
		edit the patient's data.
	【SETUP】Key	Get in or out the system setting page.
	【REPORT】Key	Produce/Save/Recall an examination report.
	【END】Key	Finish the current exam.
	【PRINT 1】Key 【PRINT 2】Key	PRINT1: print the screen image by video printer connected to the system. PRINT2: print the report by printer connected to the system (Only report page works). Or print the image in the scanning page; Or print the image in the review page.
	【B】Key	Display B mode.
	【C】Key	Display CFM mode.
	【PW】Key	Display PW mode.
	【M】Key	Display B/M mode.
	【PD】Key	Display CPA mode.
	【AIO】Key	Optimize the image automatically.
	【CW】Key	
	【CINE】Key	Save the current cine loop.
	【IMAGE】Key	Save the current image.
	【FREEZE】key	Freeze or unfreeze the current image.

Key icon	Key's name	Function description
	【BODYMARK】key	Add bodymark to the image.
	【ARROW】key	Add arrows icon to the image area.
	【ANNOTATION】key	Add annotations in the image area on the screen.
	【CLEAR】key	Clear all the measurement lines, body mark, and annotations.
	【CAL】key	Activate measurement package under corresponding scanning mode.
	【MEASURE】key	Activate fast measurement function under corresponding scanning mode.
	【CURSOR】key	Press to display cursor.
	【Single】Key	This key's function is the same as 【B】Key. Display single B mode image.
	【Dual】Key	Display dual mode.
	【L/R INVERT】Key	Invert the image from left and right.
	【U/D INVERT】Key	Invert the image from up and down.
	【ENTER】key	This multifunction key works with touchpad. The function switches with the unit status. Such as, set the cursor position, body mark position, comment position, toggle touchpad function, selected the menu, and confirm the input.

Key icon	Key's name	Function description
	【UPDATE】key	This multifunction key works with touchpad. The function switches with the unit status. Such as, call the annotation and back in measuring.
	【SK】Key	Parameter control key. Change the image parameters of the corresponding mode. Totally 5 groups of such keys are included in the control panel listed from left to right: SK1, SK2, SK3, SK4, SK5. To increase parameter value, press the upward arrow; to decrease parameter value, press the downward arrow.
	【Mode Parameter Selection】key	Adjust the parameters in corresponding mode menu. Press up or down button to select parameter. Press left or right button to adjust the value of the selected parameter.
	【TOUCHPAD】	Position calipers in measurement. Position 'mouse' cursor for exam mode selection. Position the M mode, PW cursor. Select EXAM mode. Position and re-size the Color Region of Interest (CROI). Position and re-size the Doppler Sample Volume Gate. Control digital cine review frames.

4.5 Image Parameter Area

Display information about application, frequency, mode, depth, gain and etc.

4.6 Cine Control

No.	Item	Description
<1>		Press and slide on the processing bar to view frames.
<2>	Current/Total	The number corresponds to the current frame and total frame.

4.7 System Status Information

4.7.1 Information Area Indicating System Status in LCD Screen

From left to right, up to down: cable network, USB, hard disk, task queue, input method, battery gauge, blue tooth

- Cable network**:** show the present situation of cable network; press this icon to show the IP address of current system.

Wi-Fi Operation Procedures:

1. Press cable network icon on SonoAir, “Network” dialog prompt displays.
2. Click “Enable Wi-Fi” to scan for Wi-Fi signal.
3. Choose the needed Wi-Fi and click.
4. “Wi-Fi Network Authentication Required” dialog prompt displays. Check the Wi-Fi name and input the password. And then click “OK” on SonoAir. The connection is enabled.
5. To Disconnect, click on the Wi-Fi name again in the “Enable Wi-Fi” interface. Detailed Wi-Fi network information will appear. Click “Disconnect” to disable.

- USB**:** show whether this system connects USB flash disk or not, press this icon to show USB safely remove interface.
- Hard disk**:** press this icon to show the capacity of disk that used to save data or USB flash disk in current system.
- Task queue**:** press this icon to show task and its situation. To terminate the task, delete, and so on.
- Input method**:** press this icon to switch between uppercase and lowercase characters.
- Battery gauge**:** show the connecting situation of the battery, just press this icon to show the present State of charge and discharge, remaining electric quantity and available time.
- Bluetooth**:** press this icon to show the detail of Bluetooth, scan, connecet or disconnect to other Bluetooth devices.

Bluetooth Operation Procedures:

1. Turn on the Bluetooth function of the peripheral device.
2. Press Bluetooth icon on the SonoAir, “Bluetooth Detail” dialog prompt appears. SonoAir automatically scans for the Bluetooth devices.
3. Choose the right device and tick “Paired” on SonoAir.

4. “Bluetooth Pairing Request” shows on the selected Bluetooth device.
5. Click “Pair” on the device to connect it to SonoAir.
6. To disconnect, tick “Paired” again on SonoAir to release the pairing.

4.7.2 Indicator Light on Control Panel

Left to right: Adapter connection indicator, charging indicator, standby indicator

- Adapter connection indicator**:** When the system is connected to an adapter and the adapter is powered, the light is green and steady on. Otherwise, it goes out.
- Charging indicator**:** Yellow light flashes (breathing light effect) when the power is lower than 10%. Yellow light is steady on when power is 10%-95% and green light is steady on when power is more than 95%.
- Standby indicator**:** When the system is in standby state, the indicator is green and steady on; otherwise, it is off.

Chapter 5 Imaging

This chapter will introduce image display modes and the operation of image control and adjustment.

5.1 Select Scan Mode

5.1.1 The Probe Identification

The system default automatically identifies the current probe type when the probe is inserted. Press  to switch the probe.

⚠NOTE

Please connect or disconnect the probe only after the system is frozen in order to ensure stability and extend the service life of the probe.

5.1.2 Mode Selection

In probe selection interface, probe and clinical application selection page is displayed, you can choose needed probe and inspection part and then press to enter into the default B mode, start scan detection.

⚠NOTE

The system has been set clinical application preset before leaving factory, each probe has its own preset. For *the detailed operation steps of the clinical application preset of the probe, please refer to Chapter 8.5.4 Scanning Mode Preset Edit.*

5.1.3 B Mode

Press 【B】 key to display the single B mode image, B mode is the basic mode for two-dimensional scanning and diagnosis.

5.1.4 2B Mode

Press 【Dual】key to display double B mode images side by side. One image is in real-time status; the other is in frozen status. The real-time image has start scan marker and ruler marker. Press 【Dual】 key in 2B mode, the original active image is frozen while the original frozen image is activated.

In frozen status, Press【Dual】key to choose a B mode image to be activated when unfreezing the image.

⚠NOTE

This function is also available in CFM mode, CPA mode and DPD mode.

5.1.5 4B Mode

In B mode, press 【4B Mode】 in the B menu, the image which is activated will be displayed at the upper

left side of the screen. Press 【4B Mode】 continuously will freeze and activate the upper right image, lower left image, and lower right image in order.

Press  on the control panel to do the left/right invert for current activated image. Press the 

on the control panel to do the up/down invert for current activated image. It will go back to B Mode if press【B】key again.

NOTE

1. *This function is also available in CFM mode, CPA mode and DPD mode.*
2. *There is only one image could be activated at one time.*

5.1.6 B/M and M Mode

Press 【M】key, a sample line displays in B image area. Press【M】key again to enter into B/M mode, a real time B mode image and a real-time M mode image will be displayed at the same time. The sample line in the B mode image area indicates the active sample position for M image on the B image area. Move the sampling line by touchpad. Press【M】 key again to enter into M mode. A real time M mode image displays in the image area.

5.1.7 CFM Mode

CFM is a Doppler mode intended to add color-coded qualitative information concerning the relative velocity and direction of fluid motion within the B mode image.

CFM is useful to see flow in a broad area. It allows visualization of flow in the CROI, whereas Doppler mode provides spectral information in a smaller area. CFM is also used a stepping stone to Doppler mode. You can use CFM to locate flow and vessels prior to activating Doppler.

In CFM mode, move in the touchpad to change the position of sampling box. Press SK3 for **[STEER]** to adjust the angle of color sampling box (if current probe is linear probe). Press 【ENTER】 key to fix the position of color sampling box. Adjust the size of color sampling box by moving in the touchpad. Press 【ENTER】 key again and move in the touchpad to change the color sampling position again. Press SK1 for **[Gain]** to adjust the gain of CFM.

Exam Procedure:

- Follow the same procedure as described under B mode to locate the anatomical area of interest.
- After optimizing the B mode image, add Color Flow.
- Move the color region of interest CROI as close to the center of the image as possible.
- Optimize the color flow parameters so that a high frame rate can be achieved and appropriate flow velocity can be visualized.
- Press【FREEZE】key to hold the image in cine memory.
- Record color flow image as necessary.

CFM Scanning Hints:

- **PRF:** increase/decrease the PRF on the color bar. Imaging of higher velocity flow requires increased velocity scale values to avoid aliasing.
- **Wall Filter:** affect low flow sensitivity versus motion artifact
- **Color Map:** allow you to select a specific color map. It shows the direction of the flow and highlights the higher velocity flows.
- **Color Gain:** amplify the overall strength of echoes processed in the CROI.
- **Persistence:** affect temporal smoothing and color Doppler 'robustness'.

5.1.8 CPA (PD) Mode

Power Doppler Imaging (PD) is a color flow mapping technique used to map the strength of the Doppler signal coming from the flow rather than the frequency shift of the signal. Using this technique, the ultrasound system plots color flow based on the number of reflectors that are moving, regardless of their velocity. PD does not map velocity; therefore it is not subject to aliasing.

Press【PD】key to enter into the CPA mode.

5.1.9 DPD Mode

In PD mode, press **[DPD]** item on the touch screen to enter into DPD mode.

To switch from DPD to PD mode, press【PD】key directly in the control panel, or press SK5.

5.1.10 PW Mode

Doppler is intended to provide measurement data concerning the velocity of moving tissues and fluids. PW Doppler lets you examine blood flow data selectively from a small region called the Sample Volume. The X axis represents time while the Y axis represents velocity in either a forward or reverse direction. PW Doppler is typically used for displaying the speed, direction, and spectral content of blood flow at selected anatomical sites.

PW Doppler can be combined with B mode for quick selection of the anatomical site for PW Doppler examination. The site where PW Doppler data is derived appears graphically on the B mode image (Sample Volume Gate). The Sample Volume Gate can be moved anywhere within B mode image.

PW mode Exam Procedure:

- Get a good B mode image. Press【C】key to help locate the vessel you wish to examine.
- Press【PW】key to display the sample volume cursor and gate.
- Position the sample volume cursor by moving in the touchpad. Press 【ENTER】 key, adjust the sample volume gate size through moving in the touchpad. Press【ENTER】key again, the position can be set again.
- Press【UPDATE】key to display PW Doppler spectrum and the system will run in combined B+Doppler mode. The Doppler signal can be heard through the speakers.
- Optimize the PW Doppler spectrum as necessary.

- Ensure that the sample line is parallel to the blood flow.
- Press【FREEZE】key to hold the trace in cine memory and stop imaging.
- Perform measurements and calculations, as necessary.
- Record results with your recording devices.
- Press【FREEZE】key to resume imaging.
- Repeat the above procedure until all relevant flow sites have been examined.
- Replace the probe in its respective holder.

While entering Duplex mode for the first time, the Doppler spectrum is not activated. The Doppler Sample Volume appears in the default position, and the B mode image or 2D (either B or Color) mode are active. Moving in the touchpad will change the Sample Volume position. Press the【ENTER】key to toggle the touchpad function between Sample Volume Gate position and size. Press the 【UPDATE】key after the Sample Volume Gate is defined to activate the Spectral Doppler mode. Press the【UPDATE】key for second time to toggle back to 2D (B or Color) update and deactivate the Spectral Doppler.

Doppler mode Scanning Hints:

The best Doppler data will be got when the scanning direction is parallel to the direction of the blood flow; when the scanning direction is perpendicular to the anatomic target, you can get the best B mode image, so you should keep the balance as you don't usually get both an ideal B mode image and ideal Doppler data simultaneously.

PRF: adjust the velocity scale to accommodate faster/slower blood flow velocity. Velocity scale determines pulse repetition frequency.

Wall Filter: remove the noise caused by vessel or heart wall motion at the expense of low flow sensitivity.

Baseline: adjust the baseline to accommodate faster or slower blood flows to eliminate aliasing.

Angle: optimize the accuracy of the flow velocity. It estimates the flow velocity in a direction at an angle to the Doppler vector by computing the angle between the Doppler vector and the flow to be measured. This is special useful in vascular applications where you need to measure velocity.

Doppler Gain: allow you to control the background information of spectral.

Sweep Speed: control speed of spectral update.

Doppler Sample Volume Gate Position and Size (Touchpad and ENTER)

Move the sample volume on the B mode's Doppler cursor. The gate is positioned over a specific position within the vessel.

- To move Doppler cursor position, move in the touchpad left or right until positioned over the vessel.
- To move sample volume gate position, move in the touchpad up or down until positioned inside the vessel.
- To size sample volume gate, press【ENTER】 key to switch touchpad function from sample volume gate positioning to sizing, then move in the touchpad to change sample volume gate size.

5.1.11 B/BC Mode

This mode can display an active Color mode image at the left side of the screen and a real-time B mode

image at the right side of the screen. In real-time C mode, choose **[B/BC]** in the C Menu and click on this item to turn on/off this function.

5.1.12 2D Steer

2D Steer is available for linear probes. It can steer the beam to obtain the left or right image and enlarge the area without to rotate the probes.

In B mode, press **[Advance]** option in the left side menu column, choose **[2D Steer]**.

5.1.13 Trapezoidal

Trapezoidal image is available for linear probes. In B mode, press **[Advance]** option in the left side B menu column, then choose **[Trapezoidal]**.

5.1.14 Triplex

While in B mode, press【C】key once and【PW】key twice to access the B+Doppler+Color mode, click **[Triplex]** on the touch screen in the D menu to enter the Triplex active mode.

While in B mode, press【PD】key once and【PW】key twice to access the B+Doppler+CPA mode, click **[Triplex]** on the touch screen in the D menu to enter the Triplex active mode.

While in DPD mode, press【PW】key twice to access the B+Doppler+DPD mode, click **[Triplex]** on the touch screen in the D menu to enter the Triplex active mode.

5.1.15 Quadplex

While in B mode, press【C】key once and【PW】key twice to access the B+Doppler+Color mode, click **[Quadplex]** on the touch screen in the D menu to enter B mode, CFM mode, PW mode and real-time measurement mode at the same time.

While in B mode, press【PD】key once and【PW】key twice to access the B+Doppler+CPA mode, click **[Quadplex]** on the touch screen in the D menu to enter B mode, CPA mode, PW mode and real-time measurement mode at the same time.

While in DPD mode, press 【PW】 key twice to access the B+Doppler+DPD mode, click **[Quadplex]** on the touch screen in the D menu to enter B mode, DPD mode, PW mode and real-time measurement mode at the same time.

5.1.16 Extended

Extend is short for Convex Array Extended.

In B mode, click **[Advance]** to select **[Extend]** to expand the image display area.

5.1.17 Biopsy and Super Needle

1. How to enter into Biopsy

In B mode, press **[Advance]** option in the left side menu column to open advanced menu. Then click “Biopsy” option to activate this function to show or hide the biopsy line.

⚠CAUTION

Please confirm the biopsy line before using biopsy function. The biopsy tool provided by CHISON must be used for this diagnostic ultrasound instrument. Otherwise, the accuracy of biopsy cannot be guaranteed.

2. How to adjust the biopsy

After the biopsy line shows, press the【ENTER】key to activate the adjustment function of biopsy line, horizontal moving in the touchpad can adjust biopsy line angle, vertical moving in the touchpad can adjust the biopsy line start point, press the【UPDATE】key to set the default biopsy line position. Press the【ENTER】key again to end the edition.

3. Super Needle, Super Needle+ and Needle Angle

Super needle is used for enhance the needle image in the B mode image.

Super Needle+ function can adjust the needle angle automatically.

Needle Angle function allows user to adjust the needle angle manually.

After turning on the super needle, super needle+ and needle angle function will be activated and user can adjust the needle angle to optimize the image for needle only.

5.1.18 Intell. Doppler

Intell. Doppler is short for Intelligent Doppler.

Ultrasound imaging system displays tissue imaging in B mode, and Doppler mode can analyze blood flow data. Pulse Doppler can quantitatively measure blood flow in a vessel if the diameter of the vessel and the Angle (Doppler Angle) between the ultrasound beam and the direction of blood vessel flow are known. In current clinical practice, these parameters are manually determined by the examiner. However, due to inaccuracies and variability, manual determination is time consuming and a source of error in blood flow measurements. In order to overcome these problems, an intelligent Doppler method based on image processing algorithm is proposed. The system confirms the position of Doppler sampling gate, steering angle and Angle according to the blood vessel Angle and center point of the algorithm.

In active CFM mode or PW preview mode, press  to activate Intelligent Doppler.

5.1.19 SonoRemote

SonoRemote is equal to Ultra Remote in the system.

The SonoRemote function is based on cloud audio and video synchronization technology. It could build high-quality two-way audio and video communication between the ultrasound device and computer, which makes the remote consultation process to be immersive. This function is divided into two parts: the ultrasound side and the computer side, two sides could perform real-time audio and video communication when they are connected. And the ultrasound image is displayed on the computer in real time through screen sharing.

The SonoRemote function is suitable for remote assisted diagnostics, training of ultrasound device and remote technical support.

Press  to enter into SonoRemote interface.

5.1.20 Full Screen

Full screen can be used in both real-time and frozen status, which is to display the image area in full screen. There are two forms of full-screen display: full-screen display contains images and patient information; full-display displays images in full screen only.

Press  on the touchscreen to display images with patient information in full screen. Press  again to display image in full screen only without patient information.

User can carry out various relevant measurements on the enlarged image, and save figures or movies at the same time. The annotation and bodymark functions can also be used normally. In the full screen state, press the button【Full Screen】 on the touchscreen again to return to the normal image interface. The figures and movies saved in the previous full-screen state will be displayed at the thumbnail area.

5.1.21 Screen Lock

Screen lock is to lock the touchscren in case of misoperation.

Press  , then it is unable to operate by touchscreen. User can not make any operations through the touchscreen. But control panel works. Press it again to unlock.

5.2 Functional Description of Parameter Adjustment

5.2.1 Adjust Parameters by Keys on Control Panel

Parameters' Name	Function Description
L/R Invert	Press  , the displayed image can be reversed in left/right direction.
U/D Invert	Press  , the displayed image is reversed in up/down direction.
AIO	Press the【AIO】key to automatically optimize the image.

5.2.2 Adjust Parameters by SK Keys and Menu

5.2.2.1 B Image Parameters Adjustment

Parameters' Name	Function Description
Adjust Parameters by SK Keys	
Gain	Adjust B image gain. In real-time status, press SK1 or directly drag it left/right/upwards/downwards on the touch screen to adjust.

Parameters' Name	Function Description
Dynamic	Adjust B image dynamic range. In real-time status, press SK2 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Focus Pos.	Adjust focus position. In real-time status, press SK3 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Freq.	Adjust the frequency of the tranducer. In real-time status, press SK4 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Zoom	Zoom the B image. In real-time status, press SK5 or directly drag it left/right/upwards/downwards on the touch screen to adjust. Minimum 60% and maximun 100%. 5% is adjustable each time.
Adjust Parameters by B Menu	
FHI	In real-time status, click it on the touch screen to turn it on/off.
A. Power	Acoustic power means the acoustic power transmitting from the probe. In real-time status, click it on the touch screen to adjust.
Q-image	Optimize B image to improve image quality and make the image more delicate. In real-time status, click it on the touch screen to adjust.
Depth	Adjust B image depth. In real-time status, click it on the touch screen to adjust.
Scan Width	Adjust scan width of B image; frame rate will be fast if scan width is small. In real-time status, click it on the touch screen to adjust.
Chroma	Adjust B image chroma. In real-time status, click it on the touch screen to adjust.
2D Map	Adjust B image gray-scale curve. In real-time status, click it on the touch screen to adjust.
Persistence	Increase/decrease the contrast resolution of B image. In real-time status, click it on the touch screen to adjust.
Compound	In real-time status, click it on the touch screen to turn it on/off. The SRA can't be edited after the Compound is on.
SRA	In real-time status, click it on the touch screen to turn it on/off. It can be on or off while Compound is off or on.
Density	Adjust the image density, high or low. In real-time status, click it on the touch screen to adjust.

Parameters' Name	Function Description
Smooth	Smoothness function is used for restraining the image noise and performing axial smooth processing to make the image smoother. In real-time status, click it on the touch screen to adjust.
X-contrast	Adjust the X-contrast. This function can optimize the contrast of ultrasound images of different tissues by improving the signal-to-noise ratio and improve the image quality. In real-time status, click it on the touch screen to adjust.
Edge Enhance	Edge enhancement is used for enhancing the image outline. In this way the user can view the tissue structure more clearly. In real-time status, click it on the touch screen to adjust.
4B Mode	Click to activate the Quad B mode in B mode. Please refer to the Section 5.1.5 for details.
Rotation	The B image can be rotated 0-270 degrees. In real-time status, click it on the touch screen to adjust.
Gamma	Adjust B image gamma value. In real-time status, click it on the touch screen to adjust.
Advance	Click to open the B mode advanced menu.
Adjust Parameters by Advanced Menu	
Trapezoidal	Turn on/off the trapezoidal function. Linear probe only.
2D Steer	Steer the beam transmitted by the transducer. Linear probe only.
Biopsy	Show/Hide biopsy line.
Super Needle	Turn on/off the super needle function.
Needle Angle	After super needle function is activated, needle angle can be set.
Center Line	Show/Hide center line.

5.2.2.2 B/M Image Parameters Adjustment

Parameters' Name	Function Description
Adjust Parameters by SK Keys	
Gain	Adjust M image gain. In real-time status, press SK1 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
2D Map	Adjust M image gray-scale curve. In real-time status, press SK2 or directly drag it left/right/upwards/downwards on the touch screen to adjust.

Parameters' Name	Function Description
Chroma	Adjust M image chroma. In real-time status, press SK3 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Display	Adjust the scale display of B image and M image: 2:1; 1:1; 2:1. In real-time status, press SK4 or directly click it on the touch screen to adjust.
Speed	Adjust scanning speed of M image. In real-time status, press SK5 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Adjust Parameters by M Menu	
Layout	Adjust B/M image display in up and down direction or left and right direction. In real-time status, click it on the touch screen to adjust.

5.2.2.3 CFM Image Parameters Adjustment

Parameters' Name	Function Description
Adjust Parameters by SK Keys	
Gain	Adjust CFM image gain. In real-time status, press SK1 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
PRF	Adjust PRF value, adjustment range depends on probe. In real-time status, press SK2 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Steer	Adjust angle of sampling box of blood flow under the linear transducer. In real-time status, press SK3 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Color Map	Adjust CFM image color map. In real-time status, press SK5 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Adjust Parameters by CFM Menu	
Baseline	Adjust the color of the blood flow. In real-time status, click it on the touch screen to adjust.
Wall Thre.	Adjust wall threshold. In real-time status, click it on the touch screen to adjust.
Persistence	Improve the current color. In real-time status, click it on the touch screen to adjust.
Color Invert	Realize the color reversal of blood flow. In real-time status, click it on the touch screen to adjust.

Parameters' Name	Function Description
Density	Adjust the image density, high or low. In real-time status, click it on the touch screen to adjust.
Blood Eff.	Choose different blood effection. In real-time status, click it on the touch screen to adjust.

5.2.2.4 PW Image Parameters Adjustment

Parameters' Name	Function Description
Adjust Parameters by SK Keys	
Gain	Adjust PW spectrum gain. In real-time status, press SK1 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
PRF	Adjust PRF value, adjustment range depends on probe. In real-time status, press SK2 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Baseline	Adjust the position of baseline. In real-time status, press SK3 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Display	Adjust the scale display of B image and PW spectrum: 2:1; 1:1; 2:1. In real-time status, press SK4 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Speed	Adjust scanning speed of PW spectrum. In real-time status, press SK5 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Adjust Parameters by PW Menu	
Chroma	Adjust the chroma. In real-time status, click it on the touch screen to adjust.
Dynamic	Adjust the dynamic range of the spectrum. In real-time status, click it on the touch screen to adjust.
2D Map	Adjust the color of spectrum. In real-time status, click it on the touch screen to adjust.
Audio	Adjust audio of Doppler. In real-time status, click it on the touch screen to adjust.
Steer	Adjust angle of sampling box of blood flow under the linear transducer. In real-time status, click it on the touch screen to adjust.
SV	Adjust the size of the sample volume gate. In real-time status, click it on the touch screen to adjust.

Parameters' Name	Function Description
Quick Angle	Quickly adjust the angle of the sample volume gate. In real-time status, click it on the touch screen to adjust.
Angle	Adjust the angle of the sample volume gate. In real-time status, click it on the touch screen to adjust.
Wall Filter	Change wall filtering. In real-time status, click it on the touch screen to adjust.
Spectrum Enhance	Adjust the brightness of the spectrum. In real-time status, click it on the touch screen to adjust.

5.2.2.5 PD Image Parameters Adjustment

Parameters' Name	Function Description
Adjust Parameters by SK Keys	
Gain	Adjust PD image gain. In real-time status, press SK1 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
PRF	Adjust PRF value. Adjustment range depends on probe. In real-time status, press SK2 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Steer	Adjust angle of sampling box of blood flow under the linear transducer. In real-time status, press SK3 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Persistence	Increase/decrease the contrast resolution of PD image. In real-time status, press SK4 or directly click it drag it left/right/upwards/downwards on the touch screen to adjust.
DPD	Switch between PD mode and DPD mode. In real-time status, click it on the touch screen to adjust.
Adjust Parameters by PD Menu	
Wall Thre.	Adjust wall threshold. In real-time status, click it on the touch screen to adjust.
Density	Change images density. In real-time status, click it on the touch screen to adjust.
Blood Eff.	Choose different blood effection. In real-time status, click it on the touch screen to adjust.

5.2.2.6 DPD Image Parameters Adjustment

Parameters' Name	Function Description
Adjust Parameters by SK Keys	
Gain	Adjust DPD image gain. In real-time status, press SK1 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
PRF	Adjust PRF value. Adjustment range depends on probe. In real-time status, press SK2 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Steer	Adjust angle of sampling box of blood flow under the linear transducer. In real-time status, press SK3 or directly drag it left/right/upwards/downwards on the touch screen to adjust.
Persistence	Increase/decrease the contrast resolution of DPD image. In real-time status, press SK4 or directly click it drag it left/right/upwards/downwards on the touch screen to adjust.
PD	Switch between DPD mode and PD mode. In real-time status, click it on the touch screen to adjust.
Adjust Parameters by DPD Menu	
Baseline	Adjust the color of the blood flow. In real-time status, click it on the touch screen to adjust.
Wall Thre.	Adjust wall threshold. In real-time status, click it on the touch screen to adjust.
Density	Change images density. In real-time status, click it on the touch screen to adjust.
Color Invert	Realize the color reversal of blood flow. In real-time status, click it on the touch screen to adjust.
Blood Eff.	Choose different blood effection. In real-time status, click it on the touch screen to adjust.

5.2.2.7 Utility Menu

In frozen status, press 【Utility】 in the Freeze menu. Utility Menu displays.

Each mode described in the above lists shares the same utility menu.

Parameters' Name	Function Description
Full Screen	In frozen status, click it on the touch screen to show the frozen image in full

Parameters' Name	Function Description
	screen. At this time, full-screen display contains images and patient information. Press  on the touch screen, a full-display image without patient information displays in full screen.
Post Process	Chroma: In frozen status, adjust B image chroma.
	2D Map: In frozen status, adjust B image gray-scale curve.
	Gamma: In frozen status, adjust B image Gamma parameters.
	B Rejection: In frozen status, adjust B image gray scale inhibition parameters.
Slide Show	Some DEMO images are stored for demonstration when the system leaves factory. DEMO images will be displayed in slideshow mode. In frozen status, click it to enter into slide show function. Operation procedures: Autoplay: DEMO images begin to autoplay when this function is activated. Manual play: Touch the screen, the control bar appears in the lower right corner of the screen. Click  in the control bar to stop the slide show. Then click  or  to manual play the image one by one. Click  for autoplay. Adjust the play speed: when the slide show is paused，choose the wanted speed in the dropdown list box of speed. Exit: Click  in the control bar to exit the function. ⚠***NOTE*** The DEMO images in the slide show are built-in in the system. User can not delete or add them and make other management operations.

5.3 After Capturing the Image

5.3.1 Adding Annotation

5.3.1.1 Overview

The comment is to enter text or symbols on the image.

- **Enter COMMENT:** Press【ANNOTATION】key to enter into comments status.
- **Exit COMMENT:** Press【ANNOTATION】key again or【FREEZE】key to exit.

Comment means input the words or symbols on images for making explanation. To add comments, user

can input directly through the soft keyboard or using the default comments.

The default comments are classified by examination mode as follows**:**

Classification	Function Description
Abdomen	Abdomen, general anatomy term
Obstetrics	Anatomy term of Obstetrics
Gynecology	Anatomy term of Gynecology
Cardiology	Anatomy term of Cardiology
Small Parts	Anatomy term of Small Parts
Urology	Anatomy term of of Urology
Vascular	Anatomy term of Vascular
Pediatrics	Anatomy term of Pediatrics

5.3.1.2 Input and Edit Comments

◆ Input Characters

Operation**:**

1. Press【ANNOTATION】key, then system will go into the comment process; or input characters with alphanumeric keyboard, the system will enter into comments status too.
2. Move the cursor to the position where needs to comment.
3. Input characters at cursor position by soft keyboard then press【ENTER】key to confirm.
4. Press【ANNOTATION】key again or【FREEZE】key to exit.

◆ Input Comment Library Characters

Operation**:**

1. In comment status, move the cursor by touchpad to image area to edit.
2. Press the SK5 for **[Font size]** to adjust font size of comments, the range is 10~20.
3. Click the needed comments from the comment library displayed in the left column to add comment.

◆ Edit Comments

Operation:

1. In comment status, move the cursor by touchpad to the comment, press【ENTER】key to activate it.
2. Press **[BACK]** key on the soft keyboard to delete unnecessary characters. Input the desired characters.
3. Press【ENTER】key to confirm.

5.3.1.3 Move Comments

Operation:

1. In comment status, move the cursor by touchpad to the comment, press【ENTER】key to activate it.
2. Move in the touchpad to place the comment to target area.
3. Press【ENTER】key again to confirm the new position.

5.3.1.4 Delete Comments

◆ **Delete Characters**

In comment status, move the cursor by touchpad to the comment that needs to be deleted, then press 【ENTER】key, it will display "|" on the screen. Press **[BACK]** key on the soft keyboard to delete unnecessary characters.

◆ **Delete Single Comment**

Activate the comment that needs to be deleted, press【CLEAR】key to delete.

◆ **Delete All Contents of the Comment**

Don't activate the single comment; press【CLEAR】key to delete all characters that have been input.

⚠CAUTION

Press【CLEAR】key will delete the measurement and body mark at the same time.

5.3.1.5 Set the Position of Default Comment

Operation**:**

Press the upward arrow in SK3 to shift between **[Home Pos. Load]**/ **[Home Pos. Set]**. SK2 function goes with the SK3.

1. When SK3 is for **[Home Pos. Load]**, SK2 is for **[Load]**. Click **[Load]** to move the comment to the initial position.
2. When SK3 is for **[Home Pos. Set]**, SK2 is for **[Set]**. Click **[Set]** to set the initial position.

5.3.2 Adding BodyMark

5.3.2.1 General Description

The body mark indicates patient's examination position and the direction of probe scan on the image.

Body marks are divided into**:** Abdomen, Obstetrics, Gynecology, Cardiology, Small Organs, Urology, Vessel, Nerve, Rapid Scan, each has different body mark. Each type of body mark automatically is corresponding to current examination mode.

5.3.2.2 Body Mark Operation

Operation**:**

1. Press【BODYMARK】key to enter into the body mark status.
2. Select the body mark that you need in the right body mark column. A body mark image appears in the lower left corner of the image area. If the desired body mark is not in the current interface, move up or down in the bodymark column in the touchscreen to select.
3. A blue icon around the bodymark shows the position of the probe. By moving in the touchpad, it can be adjusted to the desired position. The direction of the probe can be adjusted by pressing【UPDATE】key.
4. Press【ENTER】key, the position of the body mark can be adjusted by moving in the touchpad. Press

【ENTER】key again to fix the position.

5. Press【BODYMARK】key again to exit and the body mark is fastened to the screen.
6. Press【FREEZE】key to exit and to delete the bodymark.

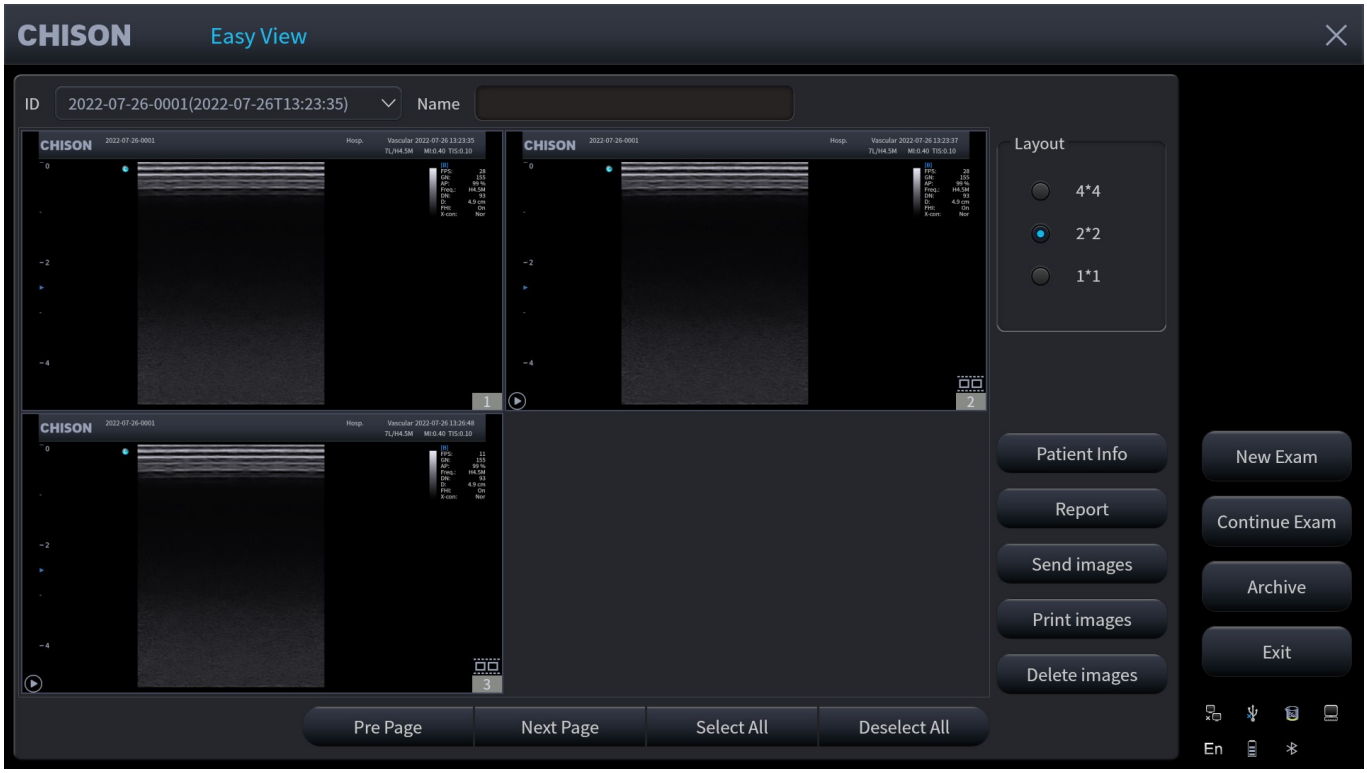
5.3.3 Adding Arrow

Operation**:**

1. Press【ARROW】to display arrow in the image area.
2. Move the arrow by touchpad.
3. Press【ENTER】key to fix the positon of the first arrow. To add more arrows, repeat step 2 and step 3.
4. Press【ARROW】key again to exit the arrow setting.
5. Press【CLEAR】key can delete all the arrows input.

5.4 Image Browse

Press【EasyView】Key to enter image information browsing interface.

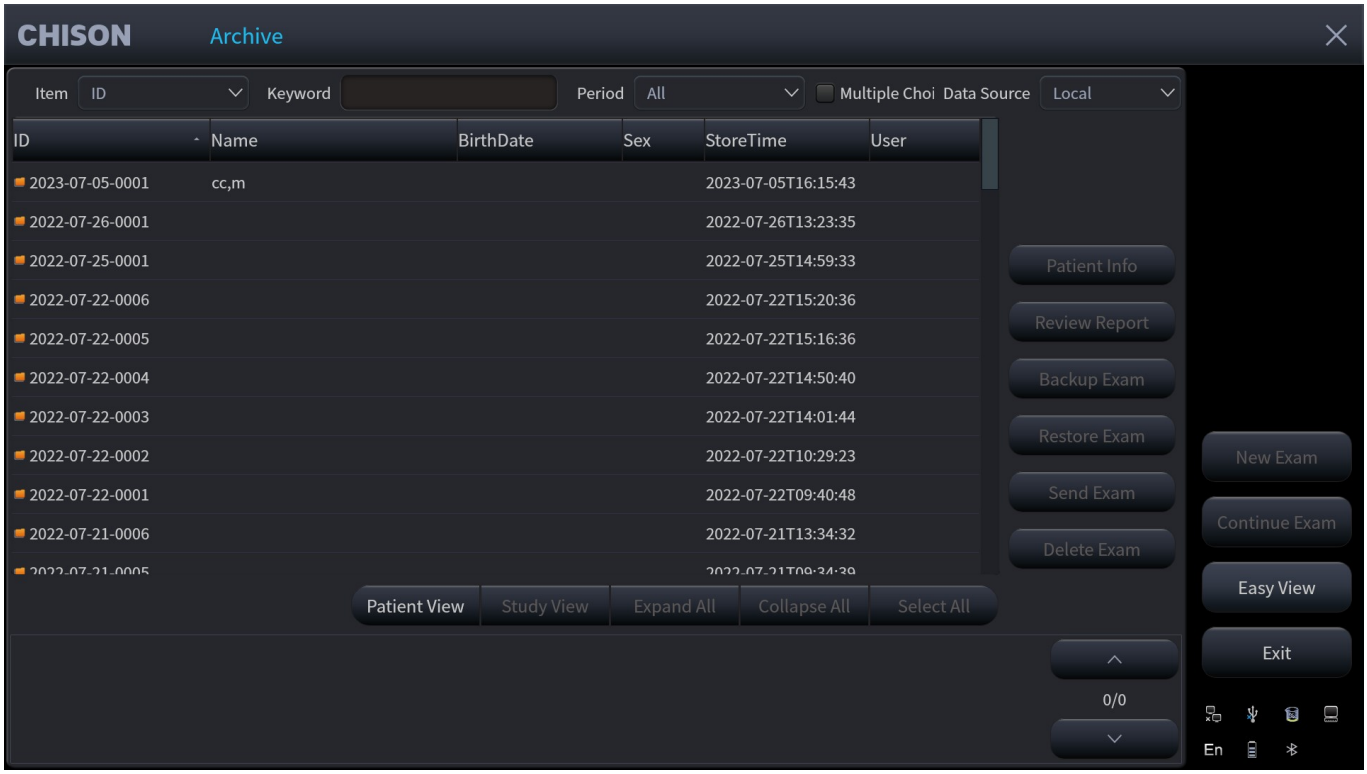


- **ID:** ID of current patient.
- **Name:** Current patient's name.
- **Layout:** Select the format to display the images.
- **Patient Info:** Enter into current patient's information interface.
- **Report:** Enter into current patient's report interface.
- **Send images:** Send image to USB hard disk, DICOM storage and print.
- **Print images:** print the image which be chosen, it will be printed as the arrangement set.
- **Delete images:** Delete selected image.

- **Pre page:** Page up.
- **Next page:** Page back.
- **Select All:** Select all the images of this patient.
- **Deselect All:** Cancel to select all the images of this patient.
- **New Exam:** Exit current examination and open a new dialog box.
- **Edit Archive:** Edit the current archive.
- **Archive:** Open up archive management interface.
- **Exit:** Turn off image browsing interface.

5.5 Archive Management

Archive management can search for patient's information which has been stored in system. Pres【EasyView】key and click **[Archive]** to open archive management interface. All process can be opened up by moving cursor.



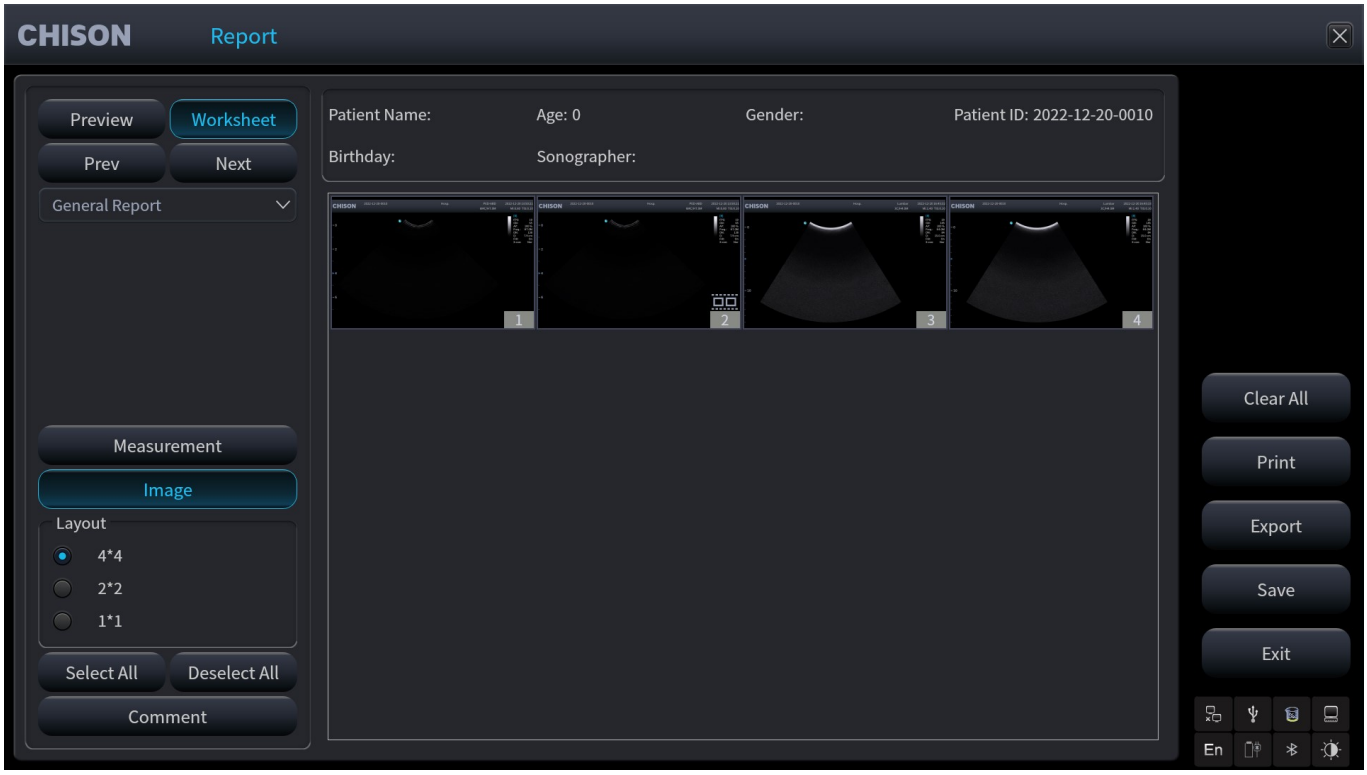
- **Item:** Type selection, select Patient's ID or Name.
- **Keyword:** Search for key words.
- **Period:** Time filter, select today, one week, one month, three months, six months, recent one year and all.
- **Multiple Choice:** Multiple choice.
- **Data Source:** Path choice, select hard disk or U disk.
- **Patient info:** Enter into patient's information interface.
- **Review Report:** Enter into report interface.
- **Backup Exam:** Select examination information to USB hard disk.
- **Restore Exam:** Recover examination information from USB hard disk.

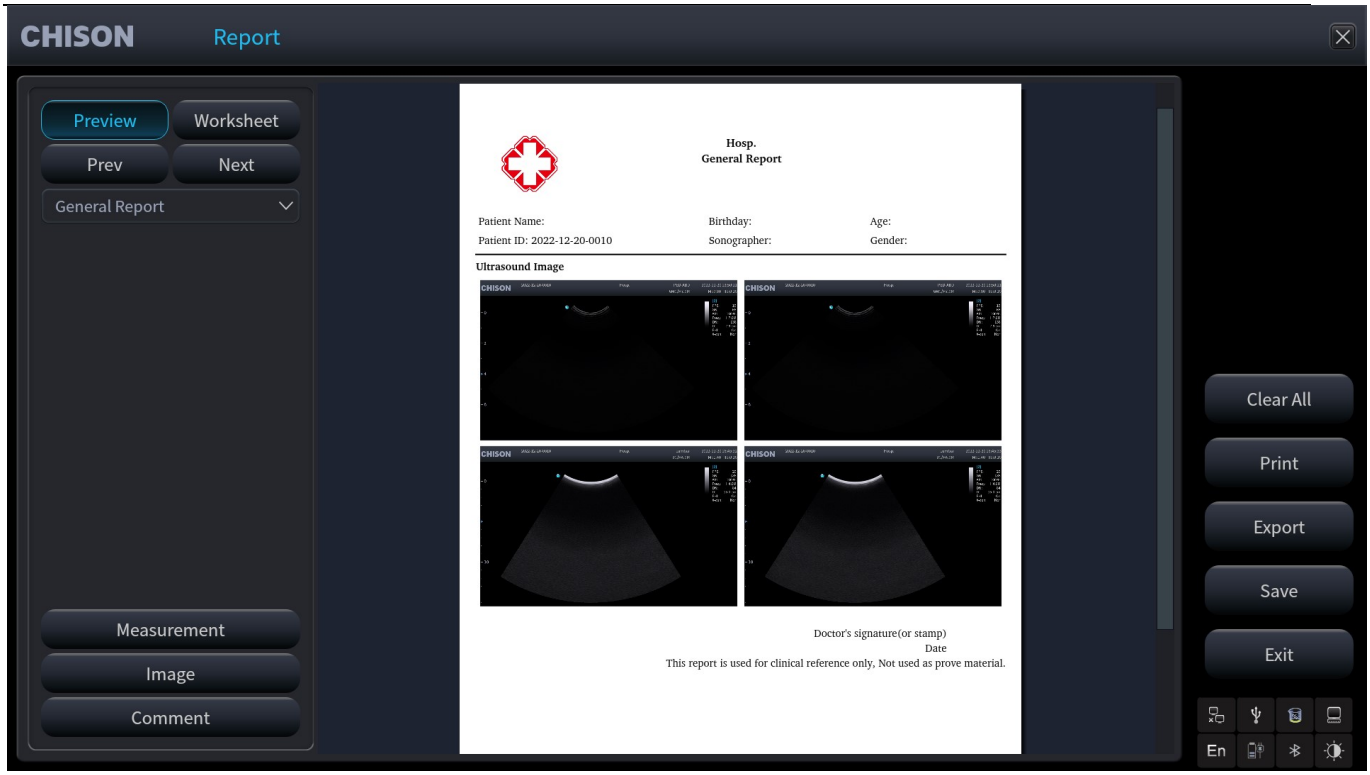
- **Send Exam:** Send selected examination information remotely to USB hard disk or DICOM Storage/Print (Need to activate the DICOM).
- **Delete Exam:** Delete selected examination information.
- **Patient View:** Change display mode of information.
- **Study View:** Change different display mode of information.
- **Expand All:** Select Patient View, it will display sub-directory.
- **Collapse All:** Exit sub-directory.
- **Select All:** Select all examination information.
- **New Exam:** Exit current patient's examination.
- **Continue Exam:** Exit archive management interface and go on checking current patient.
- **Easy View:** Exit archive management interface and open up image browsing interface.
- **Exit:** Exit archive management interface and go on checking current patient.

5.6 Report

Press【REPORT】key to enter into report interface and the system pops up the report page of the current exam mode. Report Worksheet displays in default. Move cursor to the images and press【ENTER】key to add the selected images into the report preview page. The report can be saved and printed. It is convenient for the doctor to view and edit the patient's information.

Report type contain general report, abdomen report, obstetric report, gynecology report, cardiology report, vascular report, LE vein report, LE Artery report, urology report, smallpart report, ORTH report, pediatrics report, TCD report. Choose the required report type in the dropdown list in the left report type selection column.





- **Preview:** Preview the report for the current exam.
- **Worksheet:** Display the corresponding contents in the worksheet area when click the Measurement/ Image/ OB Graph/ Comment.
- **Prev:** In an image layout, click to display images in the previous page if more than 1 page exists.
- **Next:** In an image layout, click to display images in the next page if more than 1 page exists.
- **Report Title:** Report options, different kinds of report can be selected, such as General, OB/GYN etc.
- **Measurement:** Click to enter into Measurement. Choose the measurement result you want to display in the report.
- **Image:** Choose image layout displayed in report.
- **Select All:** Press this key to add all the images on the right side into the report.
- **Deselect All:** Delete all the images added into the report.
- **OB Graph:** Under OB report, click to review the fetal production graph.
- **Comment:** Click to enter into Comment. Choose the comment you want to display in the report.
- **Clear All:** Clear all the data including the selected status of the image, the result of the measurement etc.
- **Print:** Print the report with image.
- **Export:** Export the PDF report to the U disk.
- **Save:** Save the report in system.
- **Exit:** Press this key to exit the report function.

5.7 DICOM

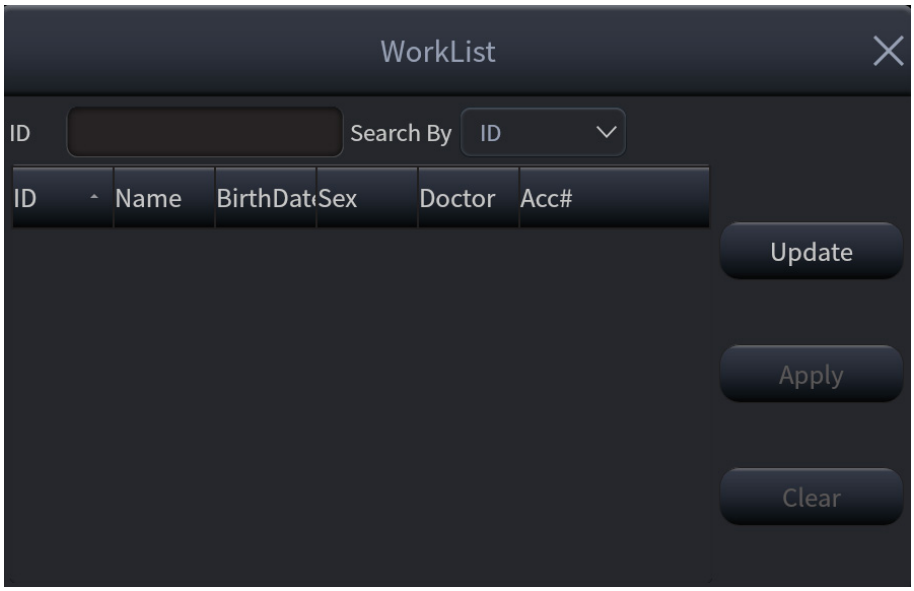
DICOM includes DICOM Storage, DICOM Worklist, DICOM Print and DICOM SR. If DICOM is to be applied, please make sure DICOM has been activated. In the system page of setting interface, you can

check whether DICOM is open or not. If you want to activate DICOM, please contact with CHISON.

There must be DICOM SCP server which has been installed with PACS or other relative DICOM server software.

5.7.1 DICOM Worklist

Press **[Worklist]** button in Patient Interface, pop up the following dialog box.



- **ID:** input ID or some characters, fuzzy query needs server.
- **Search By:** select term, ID or name.
- **ID:** display the ID of patients.
- **Name:** display the names of patients.
- **BirthDate:** display the birth date of patients.
- **Sex:** display sex of patients.
- **Doctor:** display names of doctors.
- **Acc#:** display the accession number of patients.
- **Update:** press this button to do search operation.
- **Apply:** select the searched patient, press this key to input all this patient information into the new patient interface.
- **Clear:** clear all searched content.

5.7.2 DICOM Storage

Check the “Send while saving” in setting, then DICOM stores when saving cine and images. Press send button in archive or freeze interface. Select DICOM Storage in left, choose DICOM server and press Export button to DICOM storage. Enter Task Queue and watch or edit DICOM process.

5.7.3 DICOM SR

Press [**Send DICOM SR**] button in report interface, this task is added into Task Queue.

5.7.4 DICOM Print

DICOM Print operation is the same as DICOM storage.

Chapter 6 Measurement and Calculation

Main contents of this chapter:

Normal calculation and measurement on B mode image, B/M mode image, PW mode image. The system can enter into corresponding measurement mode depends on current exam mode, and enter into the corresponding report depends on the measurement mode.

Default measurements according to the exam modes have been built into the system. Please refer to the chapter of preset settings when making modificaionts to the measurement.

⚠CAUTION

Please select the most appropriate ultrasound images, measurement tools and measurement methods for measurements according to your diagnosis needs. The final measurement results must be determined and verified by a physician. Measurement accuracies are affected by many non-technical factors, for example operator's experience, patient's status. Please do not only use the ultrasound measurement results as the sole basis for diagnosis, please always use other clinical information to do integrated diagnostics.

6.1 Keyboard for Measurement

◆【Touchpad】

Touchpad is used to move the cursor, main functions are as follows:

1. Before starting a measurement, use the touchpad to choose the menu options.
2. After starting a measurement, move the cursor by touchpad, during the measurement, the cursor should not be moved out image area.
3. During the Ellipse method measurement, use touchpad to change the length of short axis.
4. Update the moving of the measurement results, change the position of the measurement result by touchpad.

◆【ENTER】key

During the measurement, the functions of【ENTER】key are as follows:

1. When cursor is on the menu, press the key to choose the options and start the measurement.
2. During the measurement, press the key to anchor the start point and end point.

◆【UPDATE】key

1. During the measurement,【UPDATE】key is used to switch the start point and end point, long axis and short axis when the measurement is not finished.
2. During the distance measurement, press【UPDATE】key to fix the start point, when the end point is not fixed, press【UPDATE】key to switch the start point and end point.

3. During the Ellipse measurement, when fix the long axis, but the short axis is not fixed, press 【UPDATE】key to switch the long axis and short one.

◆【CLEAR】key

Press【CLEAR】key to delete all the measurement results, comments and traces.

6.2 Fast Measurement

This system uses 【MEASURE】key for rapid measurement. In each display mode, users can freely choose the item to be measured on the touch screen during the measure.

6.2.1 Enter into Fast Measurement

Press【MEASURE】key to enter into the fast measurement state.

6.2.2 Exit Fast Measurement

In the measurement state, press the【MEASURE】key again or press the【FREEZE】key to exit the quick measurement.

6.2.3 B Mode Fast Measurement

The following measurement items are available by pressing SK1 or clicking directly on the touchscreen.

◆ Distance

Measurement steps:

1. In B mode, press the【MEASURE】key to enter into fast measurement.
2. Press **[Distance]** item at the bottom on the touchscreen, it will display a “+” icon.
3. Move the “+”icon by touchpad to fit the one point of the line. Press【ENTER】key to fix the start point and the cursor can be moved to the next position.
4. Press【UPDATE】key can change the activated point, and fit the other point of the line.
5. Move the cursor to the end-point, press【ENTER】key again to complete the measurement.
6. After the measurement, the result will display in the measurement results area.
7. Repeat the steps from 2 ~ 5 to start next “Distance” measurement.

◆ Angle

Measurement steps:

1. Switch to **[Angle]** item by clicking the Distance option on the touchscreen or by pressing SK1. A “+” icon displays.
2. Line1 measurement starts. Refer to the steps from 3~ 5 in the Distance measurement above.
3. Line2 measurement starts. Refer to the steps from 3~ 5 in the Distance measurement above.
4. After the measurement, the result of the angle will be displayed on the screen.

◆ Ratio (Distance)

Calculate the ratio of the 2 distances through 2 distances measurement. Refer to distance measure above.

The following measurement items are available by pressing SK2 or clicking directly on the touchscreen.

◆ Trace

Measurement steps:

1. In B mode, press the【MEASURE】key to enter into fast measurement.
2. Press SK2 for **[Trace]** item on the menu; it will display a "+" icon.
3. Use the touchpad to move the cursor, press【ENTER】key to set the start point.
4. Use the touchpad to trace the perimeter of the object to be measured, and press the【ENTER】key to set the end point. The end point and the starting point of the trace will be automatically connected with a straight line.
5. The area and the circumference of the shape will be calculated. With the movement of the cursor, the result will appear on the right side of the screen, and will change along with the moving of the trace.
6. To get the multiple data, repeat the same steps to create other distance pairs.

◆ Trace_L

Measurement steps:

1. Switch to **[Trace L]** item by clicking the Trace option on the touchscreen or by pressing SK2. A "+" icon displays.
2. Use the touchpad to move the cursor, press【ENTER】key to set the start point.
3. Use the touchpad to trace the perimeter of the object to be measured, and press the【ENTER】key to set the end point.
4. The circumference of the shape will be calculated.

◆ Trace_L auto

Measurement steps:

1. Switch to **[Trace L auto]** item by clicking the Trace option on the touchscreen or by pressing SK2. A "+" icon displays.
2. Use the touchpad to move the cursor, press【ENTER】key to set the start point.
3. Move the cursor to next point and press【ENTER】key until the last point.
4. The circumference of the shape will be calculated.

◆ Ellipse

Measurement steps:

1. Switch to **[Ellipse]** item by clicking the Trace option on the touchscreen or by pressing SK2. It will display a “+” icon.
2. Move the icon to the starting point of measurement by the touchpad. Press 【ENTER】key to set the beginning point.
3. The second icon appears. Use the touchpad to change the length of axis of the ellipse. Press 【ENTER】key to fix the length.
4. Use the touchpad to change the length of the other axis of the ellipse. When fix the long axis, but the short axis is not fixed, press【UPDATE】key to switch the long axis and short one. Press【ENTER】to confirm. The value of area and circumference is shown in the measurement result area on the right.

◆ Auto Cubic Spline

This function is used to measure the cardiology item, which is used to calculate the circumference and area.

Measurement steps:

1. Switch to **[Auto Cubic Spline]** item by clicking the Trace option on the touchscreen or by pressing SK2. It will display a “+” icon.
2. Move the cursor to a point and press【ENTER】key to set the start point, then move the cursor to next point and press【ENTER】key until the last point.
3. The circumference and area of the chosen area will display on the measurement result area.

◆ Ratio (Area)

Calculate the ratio of the 2 areas through 2 areas measurement. Refer to ellipse measurement above.

The following measurement items are available by pressing SK3 or clicking directly on the touchscreen.

◆ Volume (3Distances)

Measurement steps:

1. Press **[Volume(3Distances)]** item at the bottom on the touchscreen; it will display a “+” icon.
2. The next measure steps are the same as the Distance measurement.
3. After the measurement of 3 lines is finished, the result will display in the measurement results area.

◆ Volume (2Distances)

Switch to **[Volume(2Distances)]** item by clicking the Volume option on the touchscreen or by pressing SK3. It will display a “+” icon. Calculate the volume of the object through 2 distances measurement. Refer to distance measure above.

◆ Volume (1Distance)

To enter into this item, please refer to the above method. Calculate the volume of the object by one line. Refer to distance measure above.

◆ Volume (1Ellipse)

To enter into this item, please refer to the above method. Calculate the volume of the object through 1 ellipse measurement. Refer to ellipse measure above.

◆ Volume (1Ellip1Dis)

To enter into this item, please refer to the above method. Calculate the volume of the object through 1 distance and 1 ellipse measurement. Refer to ellipse and distance measure above.

6.2.4 B/M Mode Fast Measurement

The following measurement items are available by pressing SK1 or clicking directly on the touchscreen.

◆ M Distance

Measurement steps:

1. In B/M mode, press the【MEASURE】key to enter into fast measurement.
2. Press **[M Distance]** item at the bottom on the touchscreen; it will display a "+" icon.
3. Use the touchpad to move the cursor, press【ENTER】key to fix it.
4. One dotted line and second cursor will appear on the screen.
5. Move the cursor by moving in the touchpad to the end point in the dotted line vertically, press the【ENTER】key to confirm.
6. The measurement result will appear on the screen automatically.

◆ Time

Measurement steps:

1. Switch to **[Time]** item by clicking the MDistance option on the touchscreen or by pressing SK1. It will display a "+" icon with a dotted vertical line in the M image area.
2. Move the icon by touchpad to the start point and press【ENTER】key to confirm.
3. The second icon appears. Move on the touchpad to drag it to the end point. The distance between the two straight lines stands for time you want to measure. You can drag the active straight line to anywhere you want to change the measured time.
4. Press【UPDATE】key to activate the two straight lines in turns and drag them to change the distance between them. The measurement result will be displayed on the result area.

◆ Heart Rate

Heart rate is used to calculate the number of heart beats per minute from cardiac image.

Measurement steps:

1. Switch to **[Heart Rate]** item by clicking the MDistance option on the touchscreen or by pressing SK1. It

will display a “+” icon with a dotted vertical line in the M image area.

2. The measurement steps are the same as Time.

3. After the above measurement, the calculated heart rate result is displayed in the measurement result area.

◆ Velocity

Measurement steps**:**

1. Switch to **[Velocity]** item by clicking the MDistance option on the touchscreen or by pressing SK1. It will display a “+” icon with two blue dotted crossed line in vertical and horizontal direction in M image area.

2. Move the icon by touchpad to the start point and press【ENTER】key, the starting point and the removable cursor display, drag cursor to the end point.

3. Press【ENTER】key again, measurement completes, the result displays in the region of measurement.

◆ Other Measurement Items

These listed items share the same measure steps as those in the B mode fast measurement:

Distance, Angle, Distance, Ratio (Distance), Trace, Trace_L, Trace_L auto, Ellipse, Auto Cubic Spline, Ratio (Area), Volume (3 Distances), Volume (2 Distances), Volume (1 Distance), Volume (1 Ellipse), Volume (1 Ellipse 1 Distance).

6.2.5 PW Mode Fast Measurement

The following measurement items are available by pressing SK1 or clicking directly on the touchscreen.

◆ Auto

Measurement steps:

1. In PW mode, press the【MEASURE】key to enter into fast measurement.
2. Press the **[Auto]** item on the menu to activate this function.
3. The system will finish the trace of spectrum automatically. The cursor “+” will appear on the screen.
4. Move the cursor by touchpad to choose a start point of one cycle, press【ENTER】key to confirm.
5. The second cursor “+” will appear on the screen automatically, move the cursor to the end point of current cycle, and press【ENTER】key to fix.
6. The measurement results and the other calculated parameters will appear on the screen automatically.

◆ Manual

Measurement steps:

1. Switch to **[Manual]** item by clicking the Auto option on the touchscreen or by pressing SK1. It will display a “+” icon with two dotted crossed line in the M image area.

2. Move in the touchpad to select the start point of the one cycle and press【ENTER】key to fix it.

3. Move in the touchpad along the spectrum and press【ENTER】key to complete.

4.The measurement results will be displayed on the monitor and calculate other values of parameters.

The following measurement items are available by pressing SK1 or clicking directly on the touchscreen.

◆ Peak

Measurement steps:

1. Press **[Peak]** item at the bottom on the touchscreen to bring up the sample marker.
2. Move the marker to the measurement start point through the touchpad, press【ENTER】key, velocity and pressure of the current point will appear on the screen automatically.
3. Go on to measure Vd, after getting the result, the system will calculate S/D, RI, Time automatically.

◆ Other Measurement Items

These listed items share the same measure steps as those in the B mode fast measurement:

Angle, Distance, Ratio (Distance), Trace, Trace_L, Trace_L auto, Ellipse, Auto Cubic Spline, Ratio (Area), Volume (3 Distances), Volume (2 Distances), Volume (1 Distance), Volume (1 Ellipse), Volume (1 Ellipse 1 Distance).

Heart Rate measurement in PW mode is the same as that in B/M mode fast measurement.

6.3 B Mode Measurement Package

This system uses【CAL】key for measurement package. In each display mode, users can freely choose the item to be measured on the touch screen during the measure.

6.3.1 General Measurement Methods

◆ Circumference/Area (Ellipse)

Measurement steps:

1. In B mode, press the【CAL】key to enter into measurement package.
2. Press **[Circumference/Area (Ellipse)]** item in the left measurement column. At this time, a mark "+" will appear on the screen.
3. Move in the touchpad to anchor the first mark and press【ENTER】key to fix it.
4. The second mark will appear on the screen. Move in the touchpad to change the length of the long axis of the ellipse. Press【ENTER】key to confirm the length.
5. Move in the touchpad to change the length of another axis of the ellipse and press 【ENTER】 key to fix it. The value of the area and perimeter will be displayed on the right side of the screen.
6. To get the multiple data, repeat the same steps.
7. Press【CAL】key to exit.

◆ Histogram (Ellipse Histogram)

Histogram is used to calculate the gray distribution of the ultrasound echo signals within a specified area. Elliptic histogram measurement is to measure the desired area by an enclosed ellipse. The result is shown in the form of histogram.

Histogram can only be measured on frozen images.

Measurement steps**:**

1. Press【FREEZE】to freeze the image.

2. Choose **[Histogram (Ellipse Histogram)**] option in the general measurement.
3. Measure the histogram by ellipse. The method is the same as ellipse measurement.

The horizontal axis represents the gray scale of the image ranging from 0 to 250.

The vertical axis represents the distribution ratio of each gray scale. The value shown on the top of vertical axis represents the percentage of the maximally distributed gray in the whole gray distribution.

◆ Profile

Profile is used to measure the gray distribution of the ultrasound signals in the vertical or horizontal direction on a certain profile (section).

This measurement is only available in the frozen mode.

Measurement steps**:**

4. Press【FREEZE】to freeze the image.
5. Press【CAL】key. Choose **[Profile]** option in the general measurement.
6. Draw a straight line at the measuring position. The method is the same as that to measure distance.
7. The calculated result of the profile will be displayed on the screen.

The horizontal (or vertical) axis represents the projection of the profile line on the horizontal direction.

The vertical (or horizontal) axis represents the gray distribution of the corresponding points on the profile line.

◆ Other Measurement Items

These listed items share the same measure steps as those in the B mode fast measurement except for the way to enter into the measure item:

Distance, Volume (3 Distances), Volume (2 Distances), Volume (1 Distance), Volume (1 Ellipse), Volume (1 Ellipse 1 Distance), Ratio (Distance), Ratio (Area), Angle.

6.3.2 B General Measurement

Click【CAL】key in B mode and select general measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
General Measurement	Distance	cm	Refer to Distance Meas.	
	Circumference/Area (Ellipse)	Area:cm^2 Circumference: cm	Refer to Ellipse Meas.	
	Volume(3Distances)	ml	Refer to Distance Meas. Formula: $V=(\pi/6)*D1*D2*D3$	D1, D2, D3: Distance
	Volume(2Distances)	ml	Refer to Distance Meas. Formula: $V=(\pi/6)*D1*D2^2$	D1: the longer distance D2: the shorter distance
	Volume(1Distance)	ml	Refer to Distance Meas. Formula: $V=(\pi/6)*D1*D1*D1$	D1: Distance
	Volume(1Ellipse)	ml	Refer to Ellipse Meas. Formula: $V=(\pi/6)*A*B*B$	A: Long Axis B: Short Axis
	Volume(1Ellip1Dis)	ml	Refer to Distance and Ellipse Meas. Formula: $V=(\pi/6)*A*B*M$	A: Long Axis B: Short Axis M: Distance
Ratio	Ratio(Distance)	%	Refer to Distance Meas. Formula: R=D1/D2	D1: First Distance D2: Second Distance
	Ratio(Area)	%	Refer to Ellipse Meas. Formula: R=A1/A2	A1: First Area A2: Second Area
Angle	Line 1 Line 2	deg	Refer to Distance Meas.	Angle Range: 0°~ 180°
Histogram (Ellipse Histogram)			Refer to Histogram Meas.	
Profile			Refer to Profile Meas.	

6.3.3 B Abdomen Measurement

Press【CAL】key in B mode and select abdomen measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Distance		cm	Refer to Distance Meas.	
CBD				
GB wall				
Liver Length				
Aorta	Height	cm	Refer to Distance Meas.	
	Width	cm	Refer to Distance Meas.	
	StD%	%	Refer to Distance Meas. Formula: ((D1-D2)/D1)*100%	D1: Length of Normal D2: Length of Stenosis
	StA%	%	Refer to ellipse Meas. Formula: ((A1-A2)/A1)*100%	A1: Area of Normal A2: Area of Stenosis
	Vessel Area(Ellipse)	cm^2	Refer to Ellipse Meas.	
	Vessel Distance	cm	Refer to Distance Meas.	
Spleen	Length Height Width	cm	Refer to Distance Meas. Formula: V=(π/6)*L*H*W	L: Length H: Height W: Width
Renal Volume (Right/Left)	Length Height Width	cm	Refer to Distance Meas. Formula: V=(π/6)*L*H*W	L: Length H: Height W: Width
Lliac (Right/Left)	Height	cm	Refer to Distance Meas.	
	Width	cm	Refer to Distance Meas.	
	StD%	%	Refer to Distance Meas. Formula: ((D1-D2)/D1)*100%	D1: Length of Normal D2: Length of Stenosis
	StA%	%	Refer to ellipse Meas. Formula:((A1-A2)/A1)*100%	A1: Area of Normal A2: Area of Stenosis
	Vessel Area(Ellipse)	cm^2	Refer to Ellipse Meas.	
	Vessel Distance	cm	Refer to Distance Meas.	

6.3.4 B OB Measurement

Press【CAL】key in B mode and select OB measurement.

Meas. Menu	Submenu	Unit	Meas. Method	Comment

Meas. Menu	Submenu	Unit	Meas. Method	Comment
Distance		cm	Refer to Distance Meas.	
GS				Formula to choose: CFEF, Campbell, Hadlock, Hansmann, Korean, Merz, Shinozuka
CRL				Formula to choose: Hadlock, Hansmann, Korean, Nelson, Osaka, Rempen, Robinson, Shinozuka
BPD				Formula to choose: Bessis, CFEF, Campbell, Chitty, Hadlock, Hansmann, Jeanty, Johnsen, Korean, Kurtz, Merz, Osaka, Rempen, Sabbagha, Shinozuka
HC(Ellipse)		cm	Refer to Ellipse and Trace Meas.	Formula to choose: CFEF, Campbell, Chitty, Hadlock, Hansmann, Johnsen, Korean, Merz
AC(Ellipse)		cm	Refer to Ellipse and Trace Meas.	Formula to choose: CFEF, Campbell, Hadlock, Hansmann, Korean, Merz, Shinozuka
FL		cm	Refer to Distance Meas.	Formula to choose: Bessis, CFEF, Campbell, Chitty, Doubilet, Hadlock, Hansmann, Hohler, Jeanty, Johnsen, Korean, Merz, Osaka, Shinozuka
Fetal Biometry	YS	cm	Refer to Distance Meas.	
	OFD			Formula to choose: Hansmann, Korean
	APD			Formula: Bessis
	TAD			Formula: CFEF
	FTA(Ellipse)			Formula: Osaka
	SL			
	APTD			Formula: Hansmann
	TTD			Formula: Hansmann
	ThC			
Fetal Long Bones	Humerus	cm	Refer to Distance	Formula to choose: Jeanty, Korean, Merz, Osaka
	ULNA			Formula: Jeanty
	Tibia			Formula to choose: Jeanty, Merz
	RAD			

Meas. Menu	Submenu	Unit	Meas. Method	Comment
	FIB			
	CLAV			Formula: Yarkoni
Fetal Cranium	CEREB	cm	Refer to Distance Meas.	Formula to choose: Chitty, Hill
	CM			
	NF			
	NT			
	OOD			Formula: OOD
	IOD			
	NB			
	Lat Vent			Formula: Tokyo
	HW			
OB Others	LtKid	cm	Refer to Distance Meas.	
	RtKid			
	LtRenalAP			
	RtRenalAP			
	LVWrHEM			
	MAD			
AFI	AFI1	cm	Refer to Distance Meas.	AFI=AFI1+AFI2+AFI3+AFI4
	AFI2			
	AFI3			
	AFI4			
CX_L		cm	Refer to Distance Meas.	

6.3.4.1 Twins and Multiple Births Measurement

1. In the new patient OB page, choose the number of gestations from one to four.
2. In the OB measurement menu, press on **[Fetus A]** title bar to switch between babies, which could measure the babies separately.

6.3.4.2 EDD (estimated date of delivery) Estimation

- **Calculating EDD by LMP (Last menstrual period)**

1. In the new patient OB page, update the LMP input box.
2. Choose the LMP from the date dialog box or input the LMP date directly.
3. The calculated EDD value will appear in the result measurement area of OB page.

- **Calculating EDD by BBT (Basal body temperature)**

1. In the new patient OB page, update the Ovul.Date input box and input the bbt date.
2. The method is the same as the LMP method.

6.3.4.3 Growth Curves

Function**:** Growth curves comparison is used to compare the measured data of the fetus with the normal growth curve in order to judge whether the fetus grows normally.

Measurement steps**:**

1. Finish the measurement of the OB item and get into the report page.
2. Click **[OB Graph]** to display the growth curve, and check it to show the growth curve on report.
3. Click **[X]** icon on the dialog box to exit.

⚠**Tips:** The abscissa of growth curves is the gestational weeks calculated according to the LMP in patient information.

6.3.5 B Pediatrics and Orth Measurement

Press【CAL】key in B mode and select pediatrics measurement.

6.3.5.1 HIP Angle

HIP function is used for evaluating the fetal hip growth. In order to make calculation, three lines need to be added on the image, which is to conform to the fetal anatomic structure. The system will calculate and display two angles for doctor's reference.

Measurement steps**:**

1. Choose **[HIP Angle]** menu item, and click it to enter into measurement.
2. Three crossed blue lines display. Move in the touchpad to show the "+" icon.
3. Place the icon close to one line or on the line and press【ENTER】key. Then this line is activated and can be moved.
4. Move the line to the target measurement region and press【ENTER】key to fix.
5. Fix another 2 lines as the steps above. The measurement result of the angle appears.

⚠***CAUTION***

D 3 shows bias line between protruding of conjunction and acetabular bone.

D 2 shows direct line between osileum and acetabular bone.

D 1 shows base line between cotyle, joint purse, gristle periosteum and ilium.

β is the angle between D1 and D 2 (acute angle). α is the angle between D 1 and D 3 (acute angle).

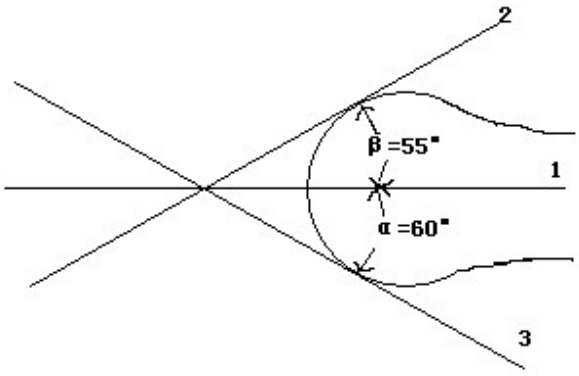


Fig. 6-1 HIP angle

6.3.6 B Vascular Measurement

Press【CAL】key in B mode and select vascular measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
IMT (Auto)	IMT Max IMT Min IMT Mean IMT Std	cm	Refer to Distance Meas.	
IMT (Manual)	IMT	cm	Refer to Distance Meas.	
Distance	Distance	cm	Refer to Distance Meas.	
Circumference/Area	Ellipse	Area:cm^2 Perimeter: cm	Refer to Ellipse Meas.	
	Trace		Refer to Manual Trace Meas.	
Volume	Volume(1Ellipse)	ml	Refer to Distance Meas.	
	Volume(1Ellip1Dis)	ml	Refer to Distance and Ellipse Meas. Formula: V=(π/6)*A*B*M	A: Long Axis B: Short Axis M: Distance
Ratio	Ratio(Distance)	%	Refer to Distance Meas. Formula: R=D1/D2	D1: First Distance D2: Second Distance
	Ratio(Ellipse)	%	Refer to Ellipse Meas. Formula: R=A1/A2	A1: First Area A2: Second Area
	Ratio(Trace)	%		

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
%Stenosis	%Stenosis(Dis)	%	Refer to Distance Meas.	
	%Stenosis(Area)	%	Refer to Ellipse Meas.	
Angle	Line 1 Line 2	deg	Refer to Distance Meas.	Angle Range: 0°~ 180°

6.3.7 B GYN Measurement

Press【CAL】key in B mode and select GYN measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Distance		cm	Refer to Distance Meas.	
UT	UT_L	cm	Refer to Distance Meas.	
	CX_L			
	UT_W			
	UT_H			
Cervix Vol.	Length/ Height/ Width	ml	Refer to Distance Meas. Formula: V=(π/6)*L*H*W	L: Cervix_Length H: Cervix_Height W: Cervix_Width
ENDO		cm	Refer to Distance Meas.	
Ovary	Volume Length/ Height/ Width (Left/Right)	ml	Refer to Distance Meas. Formula: V=(π/6)*L*H*W	L: Ovary_Length H: Ovary_Height W: Ovary_Width
Follicle	(Left/Right) Follicle length	cm	Refer to Distance Meas.	
	(Left/Right) Follicle height	cm	Refer to Distance Meas.	
	(Left/Right) Follicle width	cm	Refer to Distance Meas.	

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
	Follicle Volume	ml	Formula of 2 distance V=（π/6）*A*B^2 Formula of 3 distance V=（π/6）*L*H*W	2distance A: the longer distance B: the shorter distance 3distance L: follicle length H: follicle height W: follicle width

6.3.8 B Small Parts Measurement

Press【CAL】key in B mode and select small parts measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Distance		cm	Refer to Distance Meas.	
Thyroid	Left Volume Right Volume	ml	Refer to Distance Meas. Formula: V=(π/6)*L*H*W	L: Thyroid Length H: Thyroid Heigh W: Thyroid Width
Angle	Line 1 Line 2	deg	Refer to Distance Meas.	Angle Range: 0°～180°
Ratio	Distance 1 Distance 2	%	Refer to Distance Meas. Formula: R=D1/D2	D1: First Distance D2: Second Distance
Volume (3 Distances)	Distance 1 Distance 2 Distance 3	ml	Refer to Distance Meas. Formula: V=(π/6)*D1*D2*D3	

6.3.9 B Urology Measurement

Press【CAL】key in B mode and select urology measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Kidney Volume (Left/Right)	Length Height Width	ml	Refer to Distance Meas. Formula: V=(π/6)*L*H*W	L: Kidney_L H: Kidney_H W: Kidney_w

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Bladder	Vol.(L*W*H) Vol.(Biplane)	ml	Refer to Distance Meas. Formula: V=0.497*L*H*W	L: Bladder _L H: Bladder _H W: Bladder _w
Prostate	Length Height Width	ml	Refer to Distance Meas. Formula: V=(π/6)*L*H*W	L: Prostate _L H: Prostate _H W: Prostate _w
Residual	Length Height Width	ml	Refer to Distance Meas. Formula: V=0.7*L*H*W	L: RVU_L H: RVU_H W: RVU_w

6.3.10 B LE Vein Measurement

Press【CAL】key in B mode and select LE Vein measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
ABSENT (Right/Left)		cm	Refer to B Distance Meas.
BAKERS CYST (Right/Left)		cm	Refer to B Distance Meas.
SYNOVIAL CYST (Right/Left)		cm	Refer to B Distance Meas.
Ex.Iliac (Right/Left)		cm	Refer to B Distance Meas.
CFV (Right/Left)		cm	Refer to B Distance Meas.
SFV (Right/Left)		cm	Refer to B Distance Meas.
Deep Femoral (Right/Left)		cm	Refer to B Distance Meas.
Peroneal (Right/Left)		cm	Refer to B Distance Meas.
Gastrocnemius (Right/Left)		cm	Refer to B Distance Meas.
Saphenofemoral Junction (Right/Left)		cm	Refer to B Distance Meas.
GSV (Right/Left)	GSV Thigh GSV Leg	cm	Refer to B Distance Meas.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
GSV Perf (Right/Left)	GSV Perf Thigh GSV Perf Leg	cm	Refer to B Distance Meas.
Ant Thigh Tributary (Right/Left)		cm	Refer to B Distance Meas.
Post Thigh Tributary (Right/Left)		cm	Refer to B Distance Meas.
AAGSV (Right/Left)	AAGSV Thigh AAGSV Leg	cm	Refer to B Distance Meas.
PAGSV (Right/Left)	PAGSV Thigh PAGSV Leg	cm	Refer to B Distance Meas.
Saphenopopliteal Junction (Right/Left)		cm	Refer to B Distance Meas.
SSV (Right/Left)		cm	Refer to B Distance Meas.
ACC Perf (Right/Left)	ACC Perf Thigh ACC Perf Leg	cm	Refer to B Distance Meas.
Giacomini-(V. of G.) (Right/Left)		cm	Refer to B Distance Meas.
Intersaphenous vein(s) (Right/Left)		cm	Refer to B Distance Meas.
Superfic. Access (Right/Left)	Superfic. Access of SSV Superfic. Access of GSV-thigh Superfic. Access of GSV-leg	cm	Refer to B Distance Meas.
Lateral Venous (Right/Left)	Lateral Venous System-high Lateral Venous System-leg	cm	Refer to B Distance Meas.
Ant Mid Tributary (Right/Left)		cm	Refer to B Distance Meas.
Post Mid Tributary (Right/Left)		cm	Refer to B Distance Meas.
Ant Leg Tributary (Right/Left)		cm	Refer to B Distance Meas.

Meas. Menu	**Submenu**	**Unit**	**Meas. Method/ Meas. Formula**
Post Leg Tributary (Right/Left)		cm	Refer to B Distance Meas.
Popliteal (Right/Left)		cm	Refer to B Distance Meas.
Post Tibial (Right/Left)		cm	Refer to B Distance Meas.
SSV Perf (Right/Left)		cm	Refer to B Distance Meas.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
LE Venous Mapping (Right/Left)	CFV FV Mid POP DUPP GSV AAGSV GSV Below the SFJ GSV GSV At the Knee GSV Below the Knee Truncal GSV SSV Below SPJ SSV Gastrocnemius Soleal DVT SVT Hunterain Perforator Dodd's Perforator Boyd's Perforator Cockett's Perforator Tributary Out of Fascia Baker's Cyst Not Visualized S/P ABL. Recanilized Partially Recanilized Calf Thigh Within Normal Limits Non Compressible With Augmentation	cm	Refer to B Distance Meas.

6.3.11 B LE Artery Measurement

Press【CAL】key in B mode and select LE Artery measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
Ex.Iliac (Right/Left)		cm	Refer to B Distance Meas.
Common Femoral (Right/Left)		cm	Refer to B Distance Meas.
Profunda Femoris (Right/Left)		cm	Refer to B Distance Meas.
Spf Femoral (Right/Left)		cm	Refer to B Distance Meas.
Popliteal (Right/Left)		cm	Refer to B Distance Meas.
Ant Tibial (Right/Left)		cm	Refer to B Distance Meas.
Dorsalis Pedis (Right/Left)		cm	Refer to B Distance Meas.
Post Tibial (Right/Left)		cm	Refer to B Distance Meas.
Peroneal (Right/Left)		cm	Refer to B Distance Meas.
Graft (Right/Left)		cm	Refer to B Distance Meas.
LE Arterial Mapping (Right/Left)	CFA DFA SFA POP PTA Dist ATA Dist Peroneal Occluded Not Visualized	cm	Refer to B Distance Meas.

6.3.12 B TCD Measurement

Press【CAL】key in B mode and select TCD measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
ICA (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	ICA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	ICA Vessel Dis	cm	Refer to B Distance Meas.
CS (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	CS Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	CS Vessel Dis	cm	Refer to B Distance Meas.
MCA (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	MCA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	MCA Vessel Dis	cm	Refer to B Distance Meas.
ACA (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	ACA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	ACA Vessel Dis	cm	Refer to B Distance Meas.
PCA (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	PCA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	PCA Vessel Dis	cm	Refer to B Distance Meas.
ACOA (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	ACOA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	ACOA Vessel Dis	cm	Refer to B Distance Meas.
PCOA (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	PCOA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	PCOA Vessel Dis	cm	Refer to B Distance Meas.
OA (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	OA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	OA Vessel Dis	cm	Refer to B Distance Meas.
Vertebral A (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	Vertebral A Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	Vertebral A Vessel Dis	cm	Refer to B Distance Meas.
BA	StA%	%	Refer to B Ellipse Meas.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
(Right/Left)	StD%		Refer to B Distance Meas.
	BA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	BA Vessel Dis	cm	Refer to B Distance Meas.
PICA (Right/Left)	StA%	%	Refer to B Ellipse Meas.
	StD%		Refer to B Distance Meas.
	PICA Vessel Area(Ellipse)	cm^2	Refer to B Ellipse Meas.
	PICA Vessel Dis	cm	Refer to B Distance Meas.

6.3.13 B Cardiology Measurement

Press【CAL】key in B mode and select cardiology measurement.

NOTE

Input the BSA when create a new patient.

Meas. Menu	Submenu	Meas. Method/ Meas. Formula	Comment
Teichholz	LVIDd LVIDs	Refer to Distance Meas. Formula: EDV=(7*LVIDd^3)/(2.4+LVIDd) ESV=(7*LVIDs^3)/(2.4+LVIDs) SV=|EDV-ESV| CO=SV*HR/1000 EF=SV/EDV*100 FS=(LVIDd-LVIDs)/LVIDd*100 SI=SV/BSA CI=CO/BSA	
Single Plane	EDV(A2C/A4C) ESV(A2C/A4C)	Refer to Volume of A4CTrace method Formula: SV=|EDV-ESV| CO=SV*HR/1000 EF=SV/EDV*100 SI=SV/BSA CI=CO/BSA	
Simpson BP	EDV(A2C) ESV(A2C) EDV(A4C) ESV(A4C)		

Meas. Menu	Submenu	Meas. Method/ Meas. Formula	Comment
Modi Simpson	LVLd LVLs LVAMd LVAMs LVAPd LVAPs	Refer to Distance Meas. & Ellipse Mea. Formula: EDV= $\frac{LVLd}{9} \times (4 \times LVAMd + 2 \times LVAPd + \sqrt{LVAMd \times LVAPd})$ ESV= $\frac{LVLs}{9} \times (4 \times LVAMs + 2 \times LVAPs + \sqrt{LVAM}$ SV=|EDV-ESV| CO=SV*HR/1000 EF=SV/EDV*100 SI=SV/BSA CI=CO/BSA	
Cube	LVSd LVIDd LVPWd IVSs LVIDs LVPWs	Refer to Distance Meas. Formula: EDV=$LVIDd^3$ ESV=$LVIDs^3$ SV=|EDV-ESV| CO=SV*HR/1000 EF=SV/EDV*100 FS=(LVIDd-LVIDs)/LVIDd*100 SI=SV/BSA CI=CO/BSA	
Bullet Volume	LVLd LVLs LVAMd LVAMs	Refer to Distance Meas. Formula: EDV=(5/6.0)*LVLd*LVAMd ESV=(5/6.0)*LVLs*LVAMs SV=|EDV-ESV| CO=SV*HR/1000 EF=SV/EDV*100 SI=SV/BSA CI=CO/BSA	
Gibson	LVIDd LVIDs	Refer to Distance Meas. Formula: EDV=π/6*(0.98*LVIDd+5.9)*LVIDd*LVIDd ESV=π/6*(0.98*LVIDs+5.9)*LVIDs*LVIDs SV=|EDV-ESV| CO=SV*HR/1000 EF=SV/EDV*100 FS=(LVIDd-LVIDs)/LVIDd*100 SI=SV/BSA CI=CO/BSA	

Meas. Menu	**Submenu**	**Meas. Method/ Meas. Formula**	**Comment**
Mitral Valve	MV Diam MV Area LA/AO	Refer to Distance Meas. & Ellipse Mea. Formula:LA/AO=LAD/AOD	
Aortic Valve	AV Diam AV Area	Refer to Distance Meas. & Ellipse Mea.	
Pulmonary Valve	PV Diam PV Area		
Tricuspid Valve	TV Diam TV Area		
LVOT	LVOT Diam LVOT Area		
RVOT	RVOT Diam RVOT Area		
RV/LV	RVIDd LVIDd	Refer to Distance Meas. Formula:RV/LV=RVIDd/LVIDd*100	
RA/LA	RA LA	Refer to Trace Meas. Formula:RA/LA	
AO/LA	AO LA	Refer to Distance Meas. Formula: AO/LA	
PISA	PISA MR(Rad, Als Vel) PISA AR(Rad, Als Vel) PISA TR(Rad, Als Vel) PISA PR(Rad, Als Vel)	Refer to Distance Meas. Formula:Flow Rate=2π*Rad*Rad*Als Vel	
LV Mass	Cube(LVSd, LVIDd, LVPWd)	Refer to Distance Meas. Formula: LV Mass=1.04*((LVSd+ LVIDd+ LVPWd)^3- LVIDd^3)-13.6 LV Mass Index=LV Mass/BSA	
	A-L(LVAd sax Epi, LVAd sax Endo, LVLd apical)	Refer to Distance Meas. & Ellipse Mea. Formula: $1.05 \times \frac{5}{6}\left\{\left[LVAd\ sax\ Epi \times \left(LVLd\ apical + \sqrt{\frac{LVAd\ sax\ Epi}{\pi}} - \sqrt{\frac{LVAd\ sax\ Endo}{\pi}}\right)\right] - (LVAd\ sax\ Endo \times LVLd\ apical)\right\}$	

Meas. Menu	Submenu	Meas. Method/ Meas. Formula	Comment
	T-E(LVAd sax Epi, LVAd sax Endo, a, d)	Refer to Distance Meas. & Ellipse Mea. Formula: $1.05\pi \times \left\{(b+t)^2\left[\frac{2(a+t)}{3}+d-\frac{d^3}{3(a+t)^2}\right]-b^2\left(\frac{2a}{3}+d-\frac{d^3}{3a^2}\right)\right\}$	
Qp/Qs	AV Diam PV Diam	Refer to Distance Meas.	
IVC	IVC Ins IVC Exp	Refer to Distance Meas. Formula: IVC Ins/IVC Exp	

6.4 B/M Mode Measurement Package

At real-time status, click【M】key to enter into prepare mode, click 【M】key again to enter into B/M mode, then press【CAL】key to enter into B/M mode measurement package.

6.4.1 General Measurement Methods

The general measurement items in B/M mode measurement package are Distance, Time, Heart Rate and Velocity. Please refer to the measure steps in B/M mode fast measurement except for the way to enter into the measure item.

6.4.2 General Measurement in B/M mode

Press【CAL】key in B/M mode and select general measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Distance		cm	Refer to M Distance Meas.	
Time		s	Refer to M Time Meas.	
Velocity		cm/s	Refer to M Velocity Meas.	
Heart Rate		bpm	Refer to M Time Meas.	

6.4.3 B/M Cardiology Measurement

Press【CAL】key in B/M mode and select cardiology measurement.

Meas. Menu	Submenu	Meas. Method/ Meas. Formula	Comment
Distance		Refer to M Distance Meas.	
Time		Refer to M Time Meas.	
Slope		Refer to M Velocity Meas.	

Meas. Menu	**Submenu**	**Meas. Method/ Meas. Formula**	**Comment**
Heart Rate			
Teichholz			
Left Ventricle	Cube(LVSd, LVIDd, LVPWd, LVSs, LVIDs, LVPWs)	Refer to M Distance Meas. Formula: EDV=LVIDd^3 ESV=LVIDS^3 SV=|EDV-ESV| CO=SV*HR/1000 EF=SV/EDV*100 FS=(LVIDd-LVIDs)/LVIDd*100 SI=SV/BSA CI=CO/BSA	
	Teichholz(LVIDd, LVIDs)	Refer to M Distance Meas. Formula: EDV=7*LVIDd^3/(2.4+ LVIDd) ESV=7*LVIDs^3/(2.4+ LVIDs) SV=|EDV-ESV| CO=SV*HR/1000 EF=SV/EDV*100 FS=(LVIDd-LVIDs)/LVIDd*100 SI=SV/BSA CI=CO/BSA	
	Gibson(LVIDd, LVIDs)	Refer to M Distance Meas. Formula: EDV=π/6*(.98*LVIDd+0.59)*LVIDd^2 ESV=π/6*(1.14*LVIDs+4.18)*LVIDs^2 SV=EDV-ESV CO=SV*HR/1000 EF=SV/EDV*100 FS=(LVIDd-LVIDs)/LVIDd*100 SI=SV/BSA CI=CO/BSA	
	IVSd/LVPWd	Refer to M Distance Meas.	
Mitral Valve	EPSS		
	MV E Amp		
	MV A Amp		
	MV D-E Exc Dist	Refer to M Velocity Meas.	
	MV E-F Slope		
	MV D-E Slope		
	A-C Int Slope		
	E Duration	Refer to M Time Meas.	

Meas. Menu	Submenu	Meas. Method/ Meas. Formula	Comment
	A Duration	Refer to M Time Meas.	
Aortic Valve	AOD	Refer to M Distance Meas.	
	Ao Sinus Diam		
	Ao Asc Diam		
	Ao Arch Diam		
	Ao Desc Diam		
	LVOT Diam		
	LAD		
	LVPEP/LVET	Refer to M Time Meas.	
	AA	Refer to M Distance Meas.	
Tricuspid Valve	RVOT Diam		
	RA Diam		
	D-E Exc Dist	Refer to M Velocity Meas.	
	E-F Slope		
	A-C Int Time		
Pulmonary Valve	RVPEP	Refer to M Time Meas.	
	RVET	Refer to M Time Meas.	
	A wave Amp	Refer to M Distance Meas.	
	B-C Slope	Refer to M Velocity Meas.	
RV/LV	RVIDd LVIDd	Refer to M Distance Meas.	
LV Mass			
TAPSE			
VP			

6.4.4 Other Measurement in B/M Mode

B/M Abdomen, OB, GYN, Urology, Small Parts, Pediatric, Vascular and Orth measurement refer to general measurement in B/M mode.

6.5 PW Mode Measurement Package

Press【PW】key to enter into PW mode, and then press【CAL】key to enter into PW mode measurement package.

⚠NOTE

- *In order to get accurate result, the PW image must be clear and high quality.*
- *Insure that you have fixed the cursor at the exact place of cardiac systole and diastole.*

6.5.1 General Measurement Methods

◆ **StD%**

Measure the diameter reduction ratio of vessel.

Measurement steps**:**

1. Select **[StD%]** in the left measurement column. A cursor “+” will appear on the screen.
2. Move the cursor to the point of outside wall of the vessel and press【ENTER】key to fix it. The method to measure the diameter of the outside wall of the vessel is the same as “Distance” in genera measurement in B mode.
3. When the diameter of outside wall of the vessel is finished, the cursor “+” will appear on the screen again. Measure the diameter of the stenosis area.
4. The value of diameter and StD will be displayed in the result window.

◆ StA%

Measure the area reduction ratio of vessel.

Measurement steps**:**

1. Select **[StA%]** in the left measurement column. A cursor “+”will appear on the screen.
2. Move the cursor to the point of outside wall of the vessel and press【ENTER】key to fix it. The method to measure the area of the outside of the vessel is the same as “Area-Ellipse” in genera measurement in B mode.
3. When the area of outside of the vessel is finished , the cursor “+”will appear on the screen again. Measure the area of the stenosis area.
4. The value of area and StA will be displayed in the result window.

◆ Velocity

Measurement steps**:**

1. Select **[Velocity]** in the left measurement column.
2. A cursor “+” will appear on the PW image area. Move the cursor “+” to the place where need to be measured and press【ENTER】key to fix it.
3.The value of velocity and pressure will appear on the screen.

◆ Trace (Auto Trace)

Measurement steps**:**

1. Select **[Trace (Auto Trace)]** in the left measurement column.
2. The system will finish the trace of spectrum automatically. Move in the touchpad to select the start point of the one cycle and press【ENTER】key to fix it.
3. A second cursor “+” will appear, and move it to the end point of the cycle by touchpad, press【ENTER】key to fix it.
4. The measurement results will be displayed on the screen and calculate other values of parameters.

◆ Other Measurement Items

These listed items share the same measure steps as those in the corresponding mode fast measurement

except for the way to enter into the measure item:

Distance: Please refer to the Distance measurement in B mode fast measurement.

Peak: Please refer to the Peak measurement in PW mode fast measurement.

Heart Rate: Please refer to the Heart Rate measurement in B/M mode fast measurement.

6.5.2 PW General Measurement

Press【CAL】key in PW mode and select general measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Velocity		cm/s	Refer to PW Velocity Meas.	
Distance		cm	Refer to B Distance Meas.	
Peak	Vs	cm/s	Refer to PW Slope Meas.	
	Pressure(s)	mmHg	Formula: Pressure=4*Vs*Vs/10000	
	Vd	cm/s	Refer to PW Slope Meas.	
	Pressure(d)	mmHg	Formula: Pressure=4*Vd*Vd/10000	
	SD		Formula: SD=Vs/Vd	
	RI		Formula: SD=(Vs-Vd)/Vs	
	Time	s	Refer to PW Time Meas.	
Trace<AutoTrace>	Vs	cm/s	Refer to PW Slope Meas.	
	Pressure(s)	mmHg	Formula: Pressure=4*Vs*Vs/10000	
	Vd	cm/s	Refer to PW Slope Meas.	
	Pressure(d)	mmHg	Formula: Pressure=4*Vd*Vd/10000	
	VMean	cm/s	Refer to PW Slope Meas.	
	Pressure(VMean)	mmHg	Formula: Pressure=4*VMean*VMean/10000	
	TVI	cm		
	SD		Formula: SD=Vs/Vd	
	RI		Formula: SD=(Vs-Vd)/Vs	
	PI		Formula: SD=(Vs-Vd)/VMean	
	HR(Single wave)	bpm		
StD%	Distance1	cm	Refer to B Distance Meas.	
	Distance2	cm	Refer to B Distance Meas.	
	StD%	%	Formula: StD%=((D1-D2)/D1)*100%	D1:Distance 1, D2:Distance 2
StA%	Area1	cm^2	Refer to B Ellipse Meas.	

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
	Area2	cm^2	Refer to B Ellipse Meas.	
	StA%	%	Formula: StA%=((A1-A2)/A1)*100%	A1:Area1,A2:Area2
ICA/CCA	ICA	cm/s	Refer to PW Velocity Meas.	
	Pressure(ICA)	mmHg	Formula: Pressure=4*ICA*ICA/10000	
	CCA	cm/s	Refer to PW Velocity Meas.	
	Pressure(CCA)	mmHg	Formula: Pressure=4*CCA*CCA/10000	
	ICA/CCA		Formula: ICA/CCA	
Volume Flow	Diam	cm	Refer to B Distance Meas.	
	TVI	cm		
	Time	s	Refer to PW Time Meas.	
	HR(Single wave)	bpm		
	SV	ml	Formula: SV=0.785*Diam*Diam*|TVI|	
	CO	l/min	Formula: CO=SV*HR(Single wave)/1000	
Heart Rate		bpm	Refer to B/M Heart Rate Meas.	

6.5.3 PW OB Measurement

Press【CAL】key in PW mode and select OB measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Umb A, Aorta, Descending Aorta, Uterine Artery, Pulmonary Artery, MCA, Duct Veno,	Vs	cm/s	Refer to PW Trace Meas.	
	Pressure(Vs)	mmHg	Formula: Pressure=4*Vs*Vs/10000	
	Vd	cm/s	Refer to PW Trace Meas.	
	Pressure(Vd)	mmHg	Formula: Pressure=4*Vd*Vd/10000	
	TAMAX	cm/s	Refer to PW Trace Meas.	
	Pressure(TAMAX)	mmHg	Formula: Pressure=4*TAMAX*TAMAX/10000	
	VTI	cm		
	SD		Formula: SD=Vs/Vd	
	RI		Formula: SD=(Vs-Vd)/Vs	
	PI		Formula: SD=(Vs-Vd)/VMean	
FHeart Rate		bpm	Refer to B/M Heart Rate Meas.	

6.5.4 PW GYN Measurement

Press【CAL】key in PW mode and select GYN measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Umb A, MCA, Uterin A, Fetal AO	Vs	cm/s	Refer to PW Trace Meas.	
	Pressure(s)	mmHg	Formula: Pressure=4*Vs*Vs/10000	
	Vd	cm/s	Refer to PW Trace Meas.	
	Pressure(d)	mmHg	Formula: Pressure=4*Vd*Vd/10000	
	VMean	cm/s	Refer to PW Trace Meas.	
	Pressure(VMean)	mmHg	Formula: Pressure=4*VMean*VMean/10000	
	TVI	cm		
	SD		Formula: SD=Vs/Vd	
	RI		Formula: SD=(Vs-Vd)/Vs	
	PI		Formula: SD=(Vs-Vd)/VMean	
	HR(Single wave)	bpm		
Heart Rate		bpm	Refer to B/M Heart Rate Meas.	

6.5.5 PW Cardiology Measurement

Press【CAL】key in PW mode and select cardiology measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
Velocity		cm/s	Refer to PW Velocity Meas.
Acceleration		cm/s^2	Refer to PW Slope Meas.
Time		s	Refer to PW Time Meas.
Heart Rate		bpm	Refer to B/M Heart Rate Meas.
ED/PS	ED PS	cm/s	Refer to PW Velocity Meas. Formular:RI=(ED-PS)/ED
Mitral Valve	MV E Vel	cm/s	Refer to PW Velocity Meas. Formular:MV E PG=4*MV E Vel*MV E Vel/10000 E/Ea=MV E Vel/Ea
	MV A Vel	cm/s	Refer to PW Velocity Meas. Formular:MV A PG=4*MV A Vel*MV A Vel/10000 E/A=MV E Vel/MV A Vel A/E=MV A Vel/MV E Vel

	MV VTI		Refer to PW Trace Meas. Formular:MV PGmax=4*MV Vmax*MV Vmax/10000 MV PGmean=4*MV Vmean*MV Vmean/10000 MV SV=0.785*MV Diam*MV Diam*|MV VTI| MR Fraction=MR Flow/MV SV*100
	MVA(PHT)		Formular:MV PHT=(-1)*0.3*VPeak/Slope MVA PHT=220/MV PHT/1000
	MVA(VTI)		Formular: MV(VTI)=π*|LVOT VTI*LVOT Diam*LVOT Diam|/MV VTI/4
	MV E Dur	s	Refer to PW Time Meas.
	MV A Dur	s	
	MV DecT	s	
	MR Vmax	cm/s	Refer to PW Velocity Meas. Formula:MR PGmax=4*MR Vmax*MR Vmax/10000
	MR VTI		Refer to PW Trace Meas. Formula:MR PGmax=4*MR Vmax*MR Vmax/10000 MR PGmean=4*MR PGmean*MR PGmean/10000
	dp/dt		Formula:dp/dt=32/Time
	IVRT	s	Refer to PW Time Meas.
	IVCT	s	
Aortic	AV Vmax	cm/s	Refer to PW Velocity Meas. Formular:AV PGmax=4*AV Vmax*AV Vmax/10000
	AV VTI		Refer to PW Trace Meas. Formular:AV PGmax=4*AV Vmax*AV Vmax/10000 AV PGmax=4*AV Vmean*AV Vmean/10000 AV SV=0.785*AV Diam*AV Diam*|AV VTI| AR Fraction=AR Flow/AV SV*100
	AVA(VTI)		Formular: AVA(VTI)=π*|LVOT VTI*LVOT Diam*LVOT Diam|/AV VTI/4
	LVOT Vmax	cm/s	Refer to PW Velocity Meas. Formular: LVOT PGmax=4*LVOT Vmax*LVOT Vmax/10000
	LVOT VTI		Refer to PW Trace Meas. Formular: LVOT PGmax=4*LVOT Vmax*LVOT Vmax/10000 LVOT PGmax=4*LVOT Vmean*LVOT Vmean/10000
	LVPEP	s	Refer to PW Time Meas.
	LVET	s	
	AR Vmax	cm/s	Refer to PW Velocity Meas. Formular:AR PGmax=4*AR Vmax*AR Vmax/10000

	AR VTI		Refer to PW Trace Meas. Formular:AR PGmax=4*AR Vmax*AR Vmax/10000 AR PGmean=4*AR Vmean*AR Vmean/10000
	AR DecT	s	Refer to PW Time Meas.
	AR PHT		
Tricuspid Valve	TV Vmax	cm/s	Refer to PW Velocity Meas. Formular:TV PGmax=4*TV Vmax*TV Vmax/10000
	TV E Vel	cm/s	Refer to PW Velocity Meas. Formular:TV E PG=4*TV E Vel*TV E Vel/10000
	TV A Vel	cm/s	Refer to PW Velocity Meas. Formular: TV A PG=4*TV A Vel*TV A Vel/10000 E/A=TV E Vel/TV A Vel A/E=TV A Vel/TV E Vel
	TVA(VTI)		Formular: TVA(VTI)=π*|RVOT VTI*LVOT Diam*LVOT Diam|/TV VTI/4
	RVSP		Formular: TR PGmax=4*TR Vmax*TR Vmax/10000 RVSP=RAP+4*TR Vmax*TR Vmax/10000
Pulmonary Valve	RVOT Vmax		Refer to PW Velocity Meas. Formular: RVOT PGmax=4*RVOT Vmax*RVOT Vmax/10000
	RVOT VTI		Formular: RVOT PGmax=4*RVOT Vmax*RVOT Vmax/10000 RVOT PGmean=4*RVOT Vmean*RVOT Vmean/10000
	PV Vmax	cm/s	Refer to PW Velocity Meas. Formular: PV PGmax=4*PV Vmax*PV Vmax/10000
	PV VTI		Formular:PV PGmax=4*PV Vmax*PV Vmax/10000 PV PGmean=4*PV Vmean*PV Vmean/10000
	PVA(VTI)		Formular: PVA(VTI)=π*|RVOT VTI*LVOT Diam*LVOT Diam|/PV VTI/4
	MPA Vmax	cm/s	Refer to PW Velocity Meas. Formular: MPA PGmax=4*MPA Vmax*MPA Vmax/10000
	RPA Vmax	cm/s	Refer to PW Velocity Meas. Formular: RPA PGmax=4*RPA Vmax*RPA Vmax/10000

	LPA Vmax	cm/s	Refer to PW Velocity Meas. Formular: LPA PGmax=4*LPA Vmax*LPA Vmax/10000
	RVPEP	s	Refer to PW Time Meas.
	RVET	s	
	RAEDP		Formular:PR PGmax=4*PR Vmax*PR Vmax/10000 RAEDP=RAP+4*PR Vmax*PR Vmax/10000
	PR Vmax		Refer to PW Velocity Meas. Formular:PR PGmax=4*PR Vmax*PR Vmax/10000
	PR VTI		Formular:PR PGmax=4*PR Vmax*PR Vmax/10000 PV PGmean=4*PR Vmean*PR Vmean/10000
	PR PHT		
Pulmonary Vein	PVein S Vel		Refer to PW Velocity Meas.
	PVein D Vel		
	PVein A Vel		
	PVein A Dur		Refer to PW Time Meas.
	PVein S VTI		Refer to PW Trace Meas.
	PVein D VTI		
PISA	MR,AR,TR,PR		Refer to PW Trace Meas. Formular:EROA=|Flow Rate/Vmax| Flow=EROA/VTI Fraction=Flow/SV*100
Qp/Qs	AV VTI		Refer to PW Trace Meas. Formular:AV SV=0.785*AV Diam*AV Diam/|AV VTI| CO=AV SV*AV HR/1000
	PV VTI		Refer to PW Trace Meas. Formular:PV SV=0.785*PV Diam*PV Diam/|PV VTI| CO=PV SV*PV HR/1000 Qp/Qs Qp-Qs
Tei Index	IRT		Refer to PW Time Meas.
	ICT		
	ET		Refer to PW Time Meas. Formular:Tei Index=(ICT+IRT)/ET
TDI	MV medial (Sa,Ea,Aa,ARa, DRa)		Refer to PW Velocity Meas. & Slope Meas.
	MV lateral (Sa,Ea,Aa,ARa)		

6.5.6 PW Vascular Measurement

Press【CAL】key in PW mode and select vascular measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
Subclavian A, CCA, Bulb, ICA, ECA, Vertebral A, General Measurement	Vs	cm/s	Refer to PW Slope Meas.
	Pressure(Vs)	mmHg	Formula: Pressure=4*Vs*Vs/10000
	Vd	cm/s	Refer to PW Slope Meas.
	Pressure(Vd)	mmHg	Formula: Pressure=4*Vd*Vd/10000
	TAMAX	cm/s	Refer to PW Slope Meas.
	Pressure(TAMAX)	mmHg	Formula: Pressure=4*VMean*VMean/10000
	VTI	cm	
	SD		Formula: SD=Vs/Vd
	RI		Formula: SD=(Vs-Vd)/Vs
	PI		Formula: SD=(Vs-Vd)/VMean
	Time	s	
	HR	bpm	
ICA/CCA	ICA	cm/s	Refer to PW Velocity Meas.
	CCA	cm/s	Refer to PW Velocity Meas.
Volume Flow	Diam	cm	Refer to PW Distance Meas.
	VTI	cm	
	Time	s	Refer to PW Time Meas.
	HR	bpm	
	SV	ml	Formula: SV=0.785*Diam*Diam*|VTI|
	CO	l/min	Formula: CO=SV*HR/1000
Heart Rate		bpm	Refer to B/M Heart Rate Meas.

6.5.7 PW LE Vein Measurement

Press【CAL】key in PW mode and select LE Vein measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
Ex.Iliac (Right/Left)		cm	Refer to B Distance Meas.
CFV (Right/Left)		cm	Refer to B Distance Meas.
SFV (Right/Left)		cm	Refer to B Distance Meas.
Deep Femoral (Right/Left)		cm	Refer to B Distance Meas.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
Post Tibial (Right/Left)		cm	Refer to B Distance Meas.
Peroneal (Right/Left)		cm	Refer to B Distance Meas.
Gastrocnemius (Right/Left)		cm	Refer to B Distance Meas.
Saphenofemoral Junction (Right/Left)		cm	Refer to B Distance Meas.
GSV (Right/Left)	GSV Thigh GSV Leg	cm	Refer to B Distance Meas.
Ant Thigh Tributary (Right/Left)		cm	Refer to B Distance Meas.
Post Thigh Tributary (Right/Left)		cm	Refer to B Distance Meas.
AAGSV (Right/Left)	AAGSV Thigh AAGSV Leg	cm	Refer to B Distance Meas.
PAGSV (Right/Left)	PAGSV Thigh PAGSV Leg	cm	Refer to B Distance Meas.
Saphenopopliteal Junction (Right/Left)		cm	Refer to B Distance Meas.
SSV (Right/Left)		cm	Refer to B Distance Meas.
Giacomini-(V. of G.) (Right/Left)		cm	Refer to B Distance Meas.
Intersaphenous vein(s) (Right/Left)		cm	Refer to B Distance Meas.
Superfic. Access (Right/Left)	Superfic. Access of SSV Superfic. Access of GSV-thigh Superfic. Access of GSV-leg	cm	Refer to B Distance Meas.
Lateral Venous (Right/Left)	Lateral Venous System-high Lateral Venous System-leg	cm	Refer to B Distance Meas.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
Ant Leg Tributary (Right/Left)		cm	Refer to B Distance Meas.
Post Leg Tributary (Right/Left)		cm	Refer to B Distance Meas.
GSV Perf (Right/Left)	GSV Perf Thigh GSV Perf Leg	cm	Refer to B Distance Meas.
SSV Perf (Right/Left)		cm	Refer to B Distance Meas.
ACC Perf (Right/Left)	ACC Perf Thigh ACC Perf Leg	cm	Refer to B Distance Meas.
Popliteal (Right/Left)		cm	Refer to B Distance Meas.
Ant Tributary (Right/Left)		cm	Refer to B Distance Meas.
Post Tributary (Right/Left)		cm	Refer to B Distance Meas.
Post Mid Tributary (Right/Left)		cm	Refer to B Distance Meas.
Ant Mid Tributary (Right/Left)		cm	Refer to B Distance Meas.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
LE Venous Mapping (Right/Left)	CFV FV Mid POP DUPP GSV AAGSV GSV Below the SFJ GSV GSV At the Knee GSV Below the Knee Truncal GSV SSV Below SPJ SSV Gastrocnemius V Soleal V DVT SVT Hunterain Perforator Dodd's Perforator Boyd's Perforator Cockett's Perforator Tributary Out of Fascia Baker's Cyst Not Visualized S/P ABL. Recanilized Partially Recanilized Calf Thigh Within Normal Limits Non Compressible With Augmentation	cm	Refer to B Distance Meas.

6.5.8 PW LE Artery Measurement

Press【CAL】key in PW mode and select LE Artery measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
Ex.Iliac (Right/Left)		cm	Refer to B Distance Meas.
Common Femoral (Right/Left)		cm	Refer to B Distance Meas.
Profunda Femoris (Right/Left)		cm	Refer to B Distance Meas.
Spf Femoral (Right/Left)		cm	Refer to B Distance Meas.
Popliteal (Right/Left)		cm	Refer to B Distance Meas.
Ant Tibial (Right/Left)		cm	Refer to B Distance Meas.
Dorsalis Pedis (Right/Left)		cm	Refer to B Distance Meas.
Post Tibial (Right/Left)		cm	Refer to B Distance Meas.
Peroneal (Right/Left)		cm	Refer to B Distance Meas.
Graft (Right/Left)		cm	Refer to B Distance Meas.
LE Arterial Mapping (Right/Left)	CFA DFA SFA POP PTA Dist ATA Dist Peroneal Occluded Not Visualized	cm	Refer to B Distance Meas.

6.5.9 PW TCD Measurement

Press【CAL】key in PW mode and select TCD measurement.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
ICA (Right/Left)	Vs Pres(Vs)	cm/s mmHg	

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula
CS (Right/Left)	Vd	cm/s	
	Pres(Vd)	mmHg	
MCA (Right/Left)	RI		
	S/D		
ACA (Right/Left)	Accelerate		
	HR	bpm	
PCA (Right/Left)			
ACOA (Right/Left)			
PCOA (Right/Left)			
OA (Right/Left)			
Vertebral A (Right/Left)			
BA (Right/Left)			
PICA (Right/Left)			

6.5.10 Other Measurement in PW Mode

PW Abdomen, Urology, Small parts, Pediatric and Orth measurement refer to PW general measurement.

Chapter 7 Cine-Memory

This chapter introduces the theory of saving images in Cine-Memory and the operation of image playback in Cine-Memory.

7.1 The Principle of Cine Storage

In real image status, the image can be stored in the movie memory in chronological order, maximum frames can be set. The maximum number of frames of the film storage can be set, please refer to Chapter 8.1.2.

If the movie memory is full, the recent frame saved into memory, the previous frame removed out from memory. Therefore, there are always the latest images in the storage. All the images in Cine-Memory can be played back manually or automatically.

Fig. 7-1 Cine loop indicate diagram

7.2 Manual Playback

Press【FREEZE】 key to freeze image, pop cine playback bar, at this time, move in the touchpad to play by hand.

7.3 Automatic Playback

After freezing image, press SK1 for **[Play/Pause]** or directly click this button on the touchscreen to play, press it again to stop.

7.4 Loop Range

Move the slider to the frame interested. Press【ENTER】key to set the loop start position. Go on moving the slider to another interested frame and press 【ENTER】key to set the loop end position. The loop range is settled.

Press SK2 for **[Reset Ranges]** to reset the loop range to maximum.

7.5 Play Speed

Press SK3 for **[Play Speed]** to set the play speed.

7.6 Save and Recall Image

Press 

to save current image, the image will be displayed in the thumbnail area of the screen. If you need to recall images that have been stored, move cursor to needed image, press【ENTER】key to recall it; or you can recall archived patient's information to recall image, please refer to Archive chapter.

7.7 Save and Recall Cine

In freeze status, press 

to save cine, then it will be displayed in the thumbnail area of the screen. Move cursor to needed cine, press【ENTER】key to recall cine.

7.8 Send Image

After recalling the images, press  in thumbnail operating area. Then press  to send images to USB flash disk, net storage, DICOM storage and print.

Hint1**:** Activate the DICOM before DICOM storage and print.

Hint2**:** Click the "Cine transform to AVI" to save the cines to AVI.

Chapter 8 Setup

This chapter introduces the operation to make settings to the system.

The setting function is used to set up working environment and status, parameters of each examination mode. The settings are stored in the memory of the system and will not get lost even after the system is switched off. When the system is switched on, it will work automatically with the status which is required by the operator.

During the setting, all operation relies on moving in the touchpad to required function key position or directly touching the screen to operate.

8.1 General Setup

Press 【SETUP】 key to enter system setting interface. User can make user-defined setting. Click [**X**] in the right corner of the title bar to exit the system setting interface.

8.1.1 General Interface

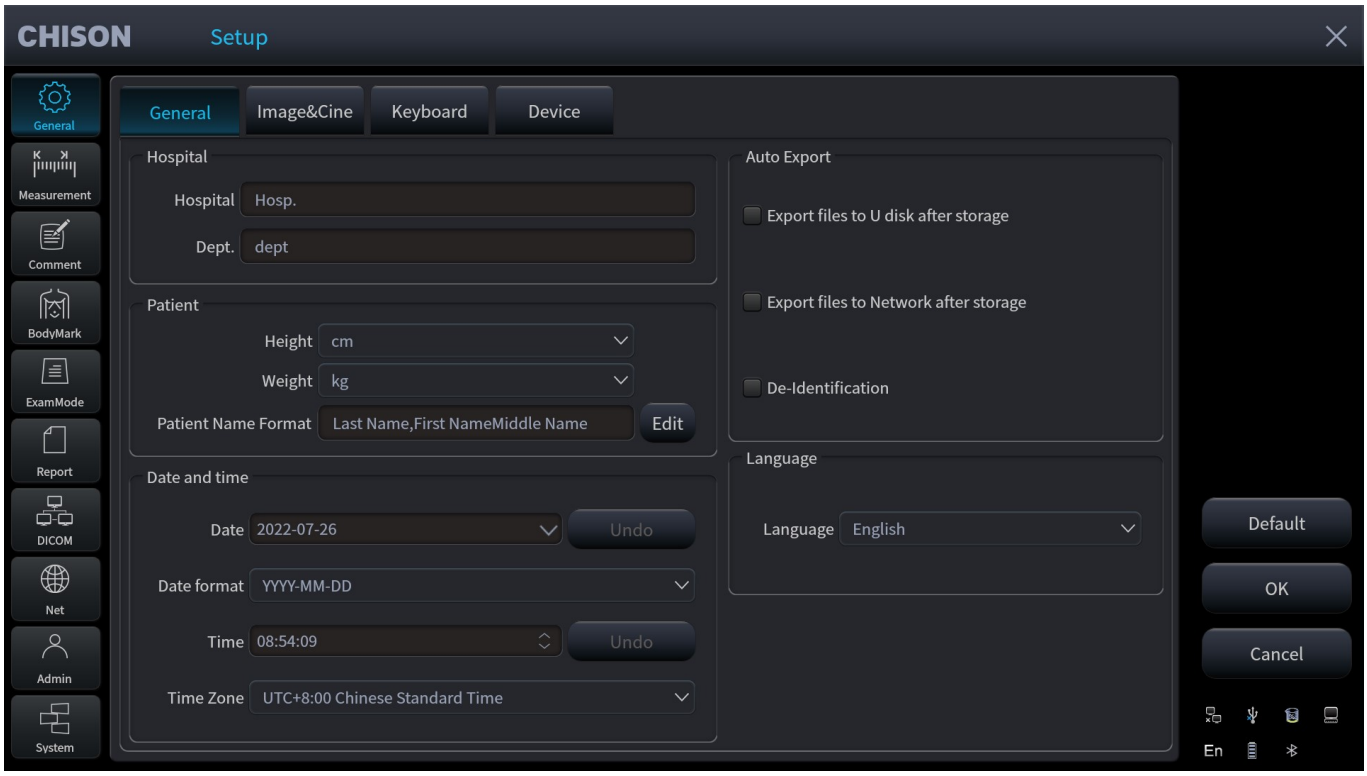


Fig. 8-1

- **Hospital:** Input the hospital name and department name.
- **Patient:** Set up patient's height, weight, name format.
- **Date and time:** Set up the system date (calendar format). Date format can be changed by format setting. Set up date format: Year/Month/Date, Month/Date/Year, Date/Month/Year. Set up the working clock of the system. Set up the time zone.

- **Language:** Select the language of operation interface (Simplified Chinese, English and so on).
- **Auto Export:** Select to export files to U disk or Network after storage. Activate the De-Indentification function.

8.1.2 Image & Cine Interface

User can select Image&Cine option to set the screen type, parameters of image, cine or image area. See the following for detailed description.

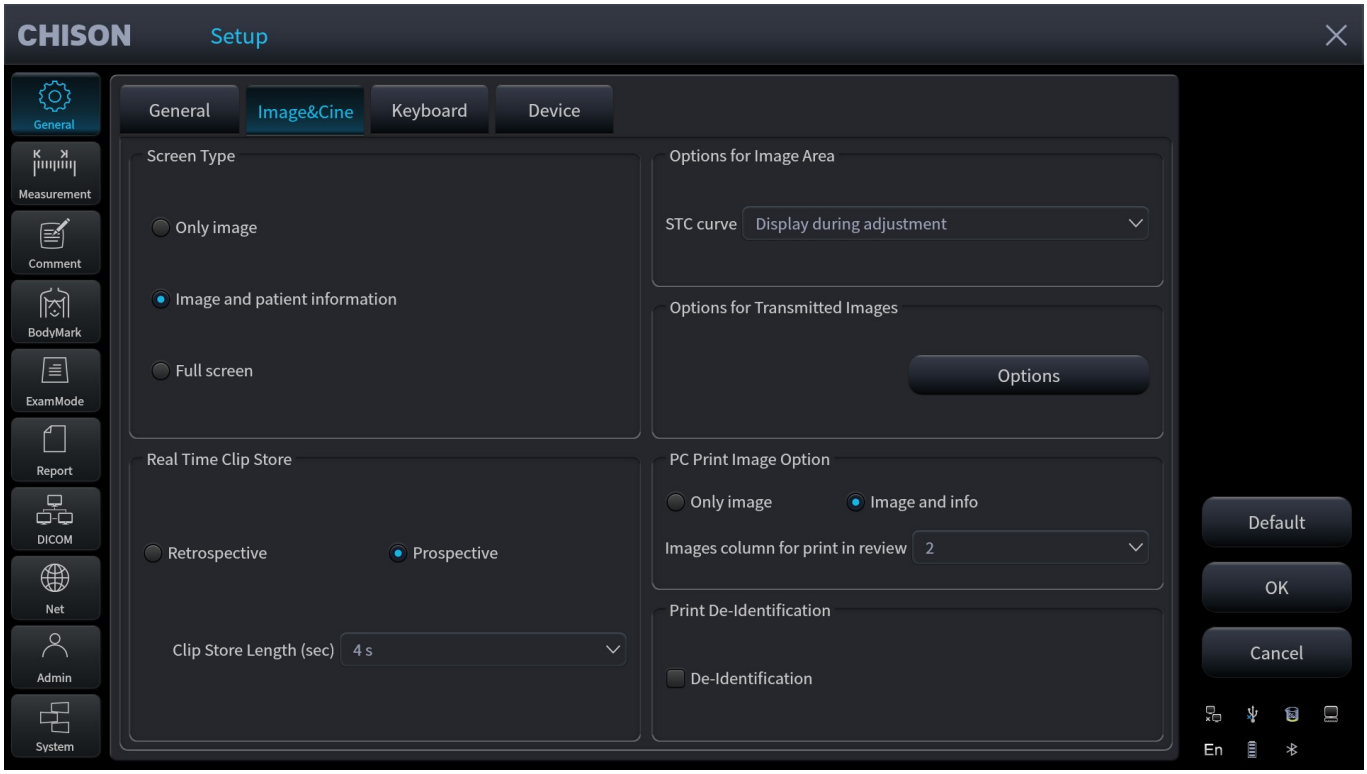


Fig. 8-2

- **Screen Type:** Set the content which screen picture contain**:** only picture, image and patient information, full screen.
- **Real Time Clip Store:** Set the default time to save the cine. The number of frames is at its maximum when setting the time to the maximum 200s.
- **Options for Image Area:** Set the STC curve, including display during adjustment, always diaplay, always hide and display for 1 to 8 seconds.
- **Options for Transmitted Images:** Click “Options” button to open the setting box. Adjust the parameters of transmitted images**:** brightness, contrast, and gamma and select the need image type.
- **PC Print Image Option:** Including print area and image column in the image preview interface.
- **Print De-Indentification:** Set up not to show the identification of the patient when printing the image. This dialog box can be set to pop up every time before printing.

8.1.3 Keyboard Interface

Users can set the different functions for number keys and other optional buttons according to the using habits.

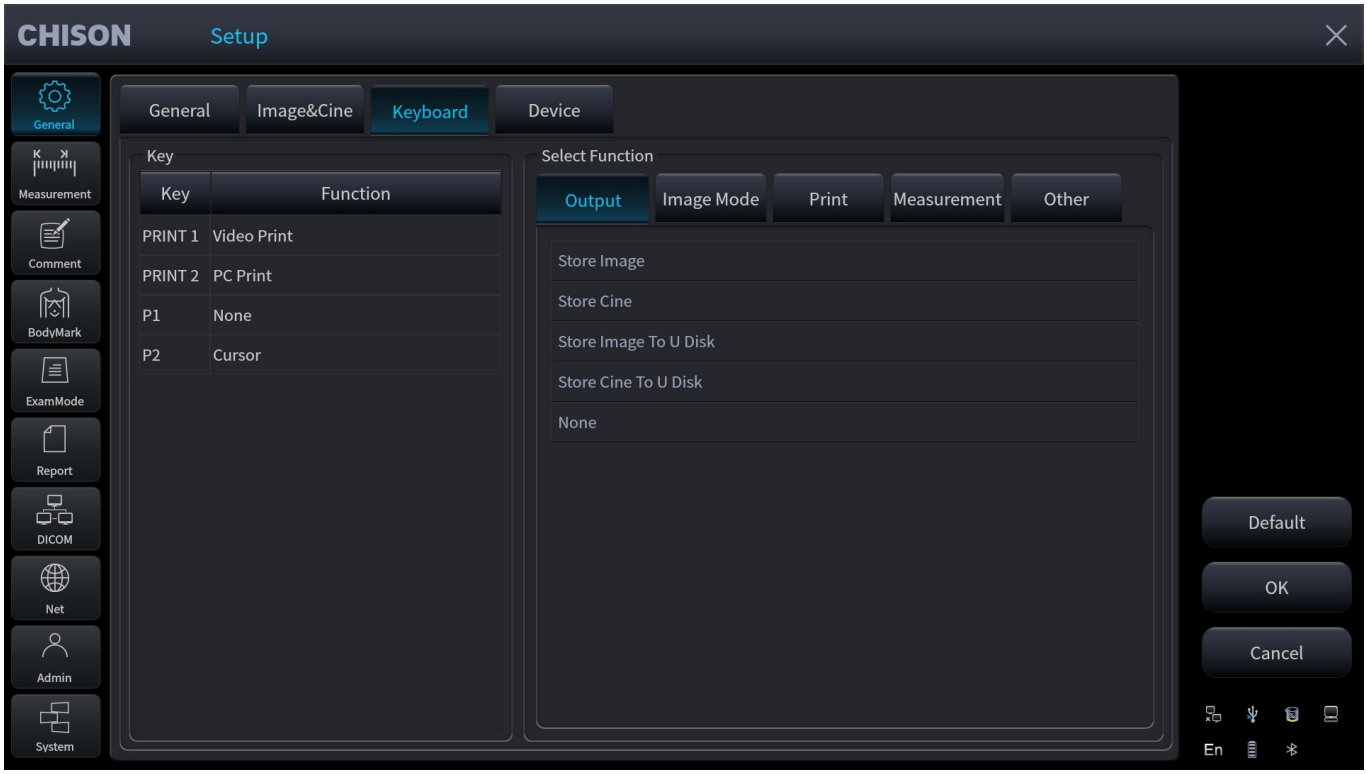


Fig. 8-3

- **Key:** Display the settable number keys and buttons.
- **Function:** Settable functions for corresponding settable number keys and buttons.
- **Select Function:** Set key function options, output, image mode, print, measurement and other.

8.1.4 Device Interface

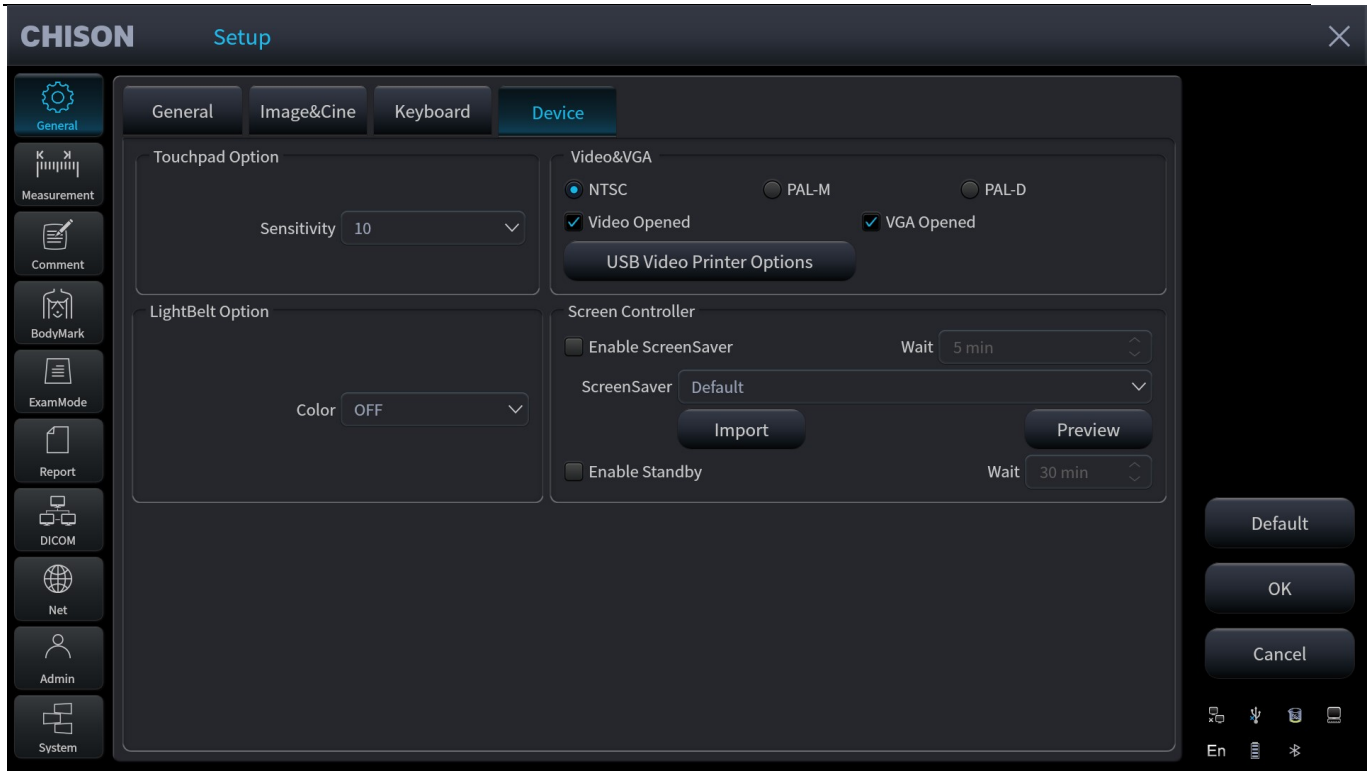


Fig. 8-4

- **Touchpad Option:** Set up sensitivity of touchpad.
- **LightBelt Option:** Set up the color of the lightbelt around the touchpad.
- **Video&VGA:**

  Choose the video data: NTSC, PAL-M and PAL-D.

  Video opened: Tick to open this function.

  VGA opened: Tick to open this function.

  USB Video Printer Options is to adjust the parameters of video printer: Dark, Light, Sharpness, Gamma. Select the parameters need to adjust. Move the slider of the parameter directly on the touchscreen to change the parameter. press [√] button to confirm the adjustment.
- **Screen Controller:** Enable screen saver, setup the wait minute. User can custom screen saver images. A custom picture named "screensaver" in JPG, PNG, BMP format with size not exceed 512 * 384 pixels can be imported into the system. Enable standby, set up the wait interval.

8.2 Measurement Setup

Measurement includes general measurement setting and measurement formula setting.

8.2.1 General Interface

General settings can only change the display of measurement unit.

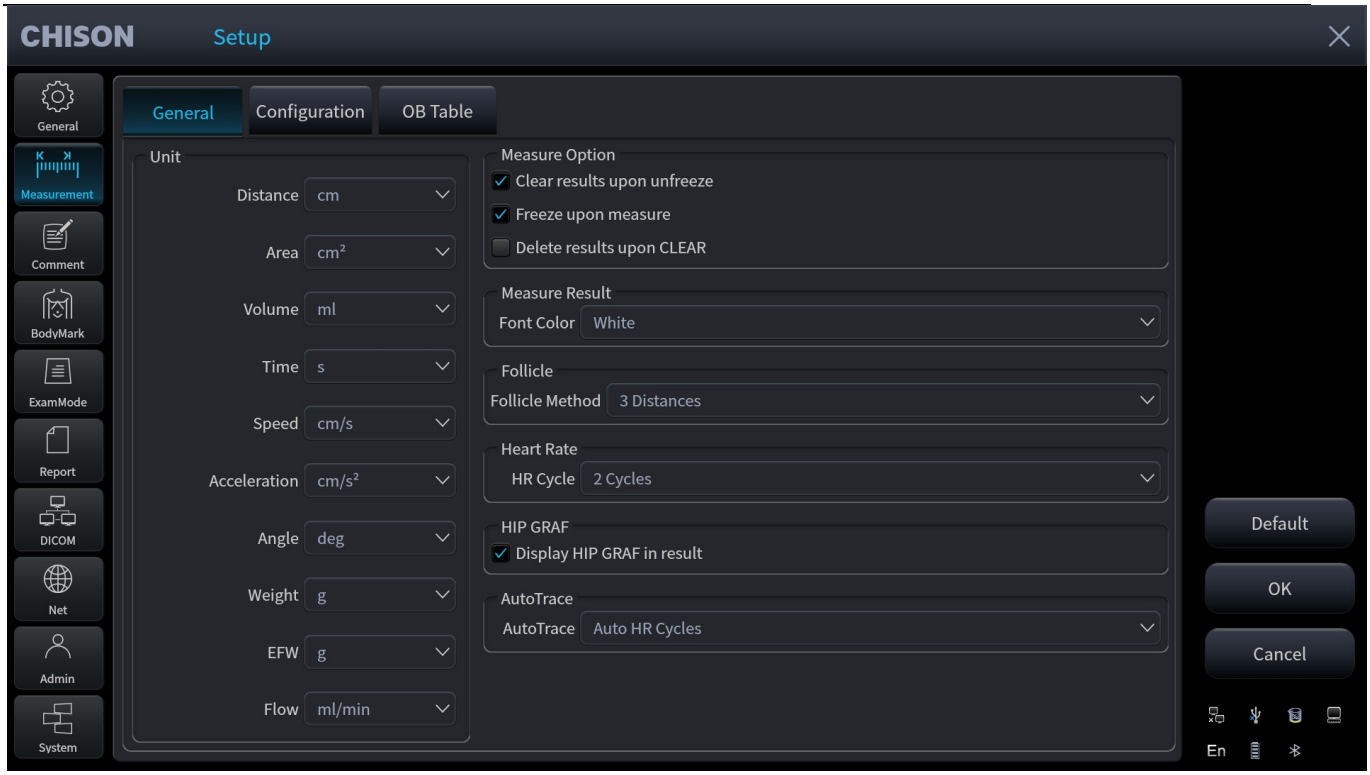


Fig. 8-5

- **Unit:** Display the unit of all measurement items.
- **Measure Option:** Select clear results upon unfreeze, freeze upon measure, delete results upon 【CLEAR】key.
- **Measure Result:** The color of the result font is alternative, including yellow/white/orange/green.
- **Follicle:** Ways to measure follicle, you can choose two distances or three distances.
- **Heart Rate:** Cycle options for calculating the number of heart beats per minute of cardiac image.
- **HIP GRAF:** Select to display HIP GRAF in result or not.
- **AutoTrace:** Auto HR cycles and manual HR cycles are available.

8.2.2 Configuration Interface

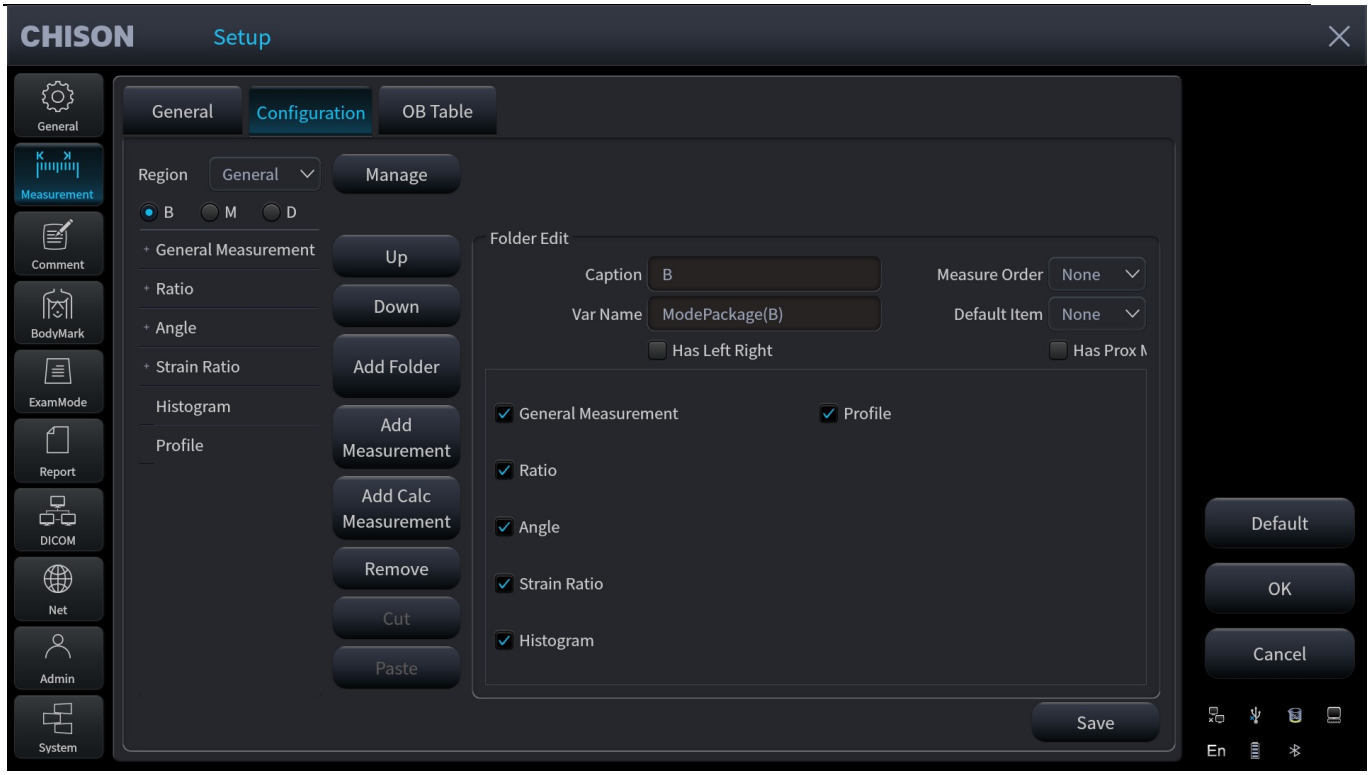


Fig. 8-6

- **Region:** Pull down and select needed measurement menu.
- **Manage:** Pop up packages manager to add, modify, delete, change marshalling sequence in measurement menu.
- **B, M, D:** Display measurement of each Exam mode.
- **Up:** Press this button to move selected measurement term up.
- **Down:** Press this button to move selected measurement term down.
- **Add Folder:** Add a measurement item. In the left column, when the term is fold there is “+” otherwise “-”.
- **Add Measurement:** Add a measurement item for a term in the right column. There is selected item and detailed parameter.
- **Add Calc Measurement:** Add a calc item for a measurement term.
- **Remove:** Remove selected measurement term or item.
- **Default:** Restore all measurement term as factory setting.
- **Save:** Save measurement item modifications that users did.
- **Cut:** Select to cut the measurement option you want to paste.
- **Paste:** Paste the measurement option you have cut.

Folder Edit content description

Caption	Display names of all items that dispaly in measurement menu.

Var Name	The name of built-in selected measurement menu, user don't need to modify while display order according to the names.
Measure Order	None**:** Disable rule, Repeated**:** Repeat this item, Next**:** measure by sequence.
Default Item	After choosing the Repeat and Sequential, choose one measurement or calculation to activate the measurement rule.
Has Left Right	Display Left and Right in the mode measurement package.
Has Prox Mid Distal	Display Prox, Mid, Distal in the mode measurement package.

8.2.2.1 Interface Description-Measurement Calculation

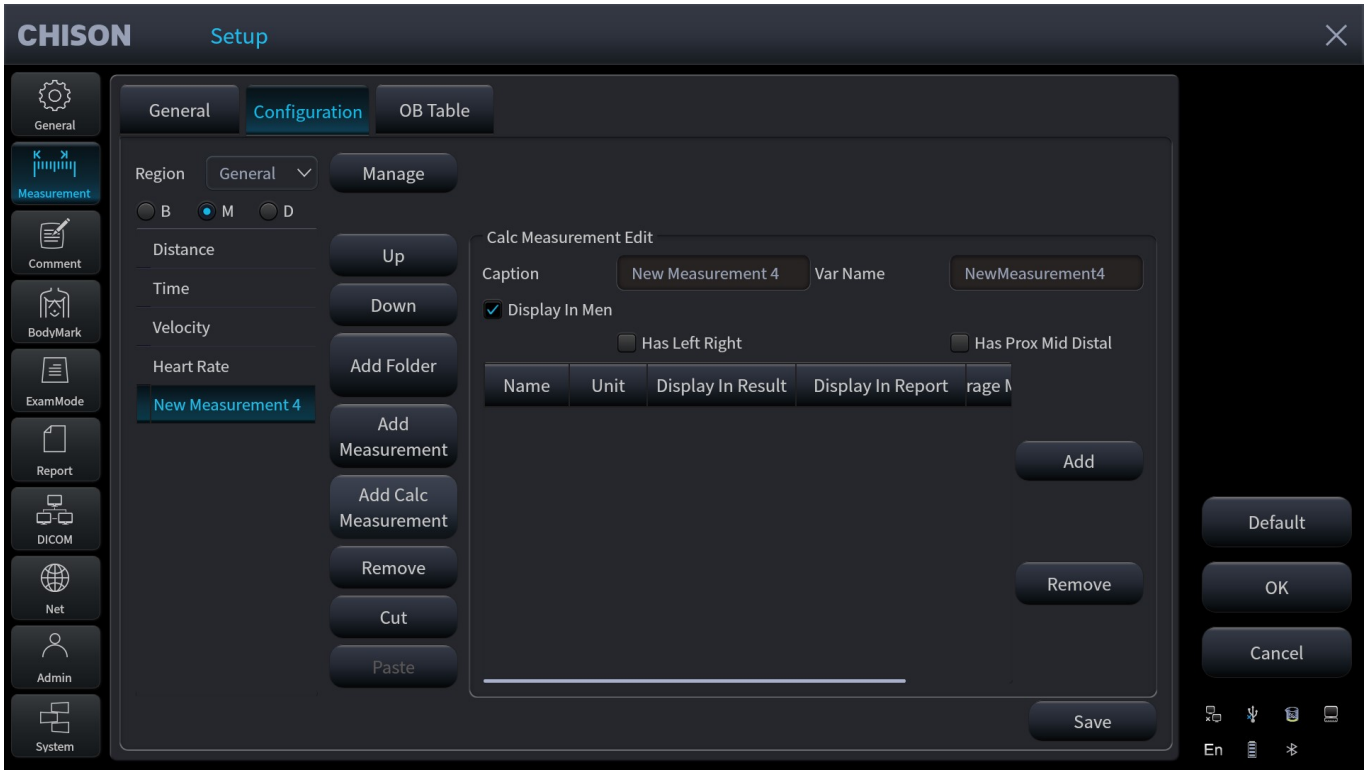


Fig. 8-7

Calc Measurement Edit content description

Caption	Display the name of selected term that is display names in the measurement menu.
Var Name	The name of built-in selected measurement menu, user don't need modify while display order according to the names.
Display In Menu	Check the required item and it will display on the measurement menu. The item without checking will not display on the measurement menu.
Name	Needed measurement operation of specific measurement and calculation.
Unit	Data unit which measurement operation produces.
Display In Result	Whether display in the result or not.
Display In Report	Whether display in the report or not.
Average Method	The average rule of data.
Add	Press this button to pop up interface to add measurement operation.
Remove	Press this button to delete selected measurement operation.

8.2.2.2 Create Measurement Operation

Press **[Add Measurement]** button to go into Measurement Edit page. And press **[Add]** button in this page, the following dialog box pops up.

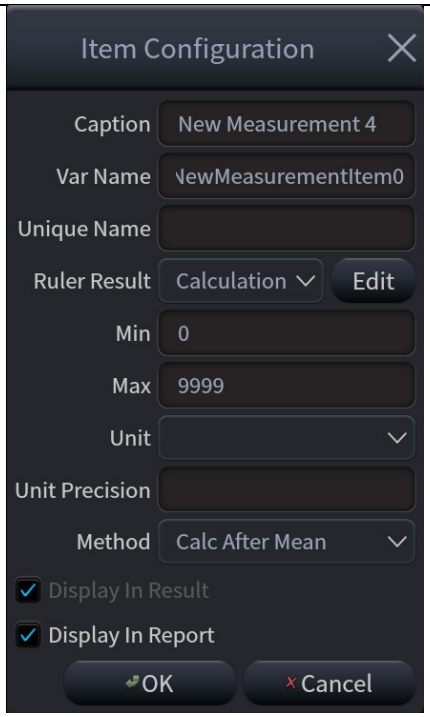


Fig. 8-8

Operation content description of creating new measurement

Caption	Display the name of selected term that displays in the measurement menu.
Var Name	The name of built-in selected measurement menu, user don't need modify while display order according to the names.
Unique Name	Built-in code, user doesn't need to modify.
Ruler Result	Needed measurement operation of specific measurement and calculation.
Edit	Enter into interface to edit formula when selecting calculation item.
Min	The minimum value displays in result zone and report.
Max	The maximum value displays in result zone and report.
Unit	Data unit which measurement operation produces.
Unit Precision	Set unit precision value.
Method	The average rule of data.
Display In Result	Selected by default by the system. It is a must-have option.
Display In Report	Whether display in the report or not.

8.2.2.3 Formula Edit

It is necessary to enter into the following interface when creating measurement operation except OB.

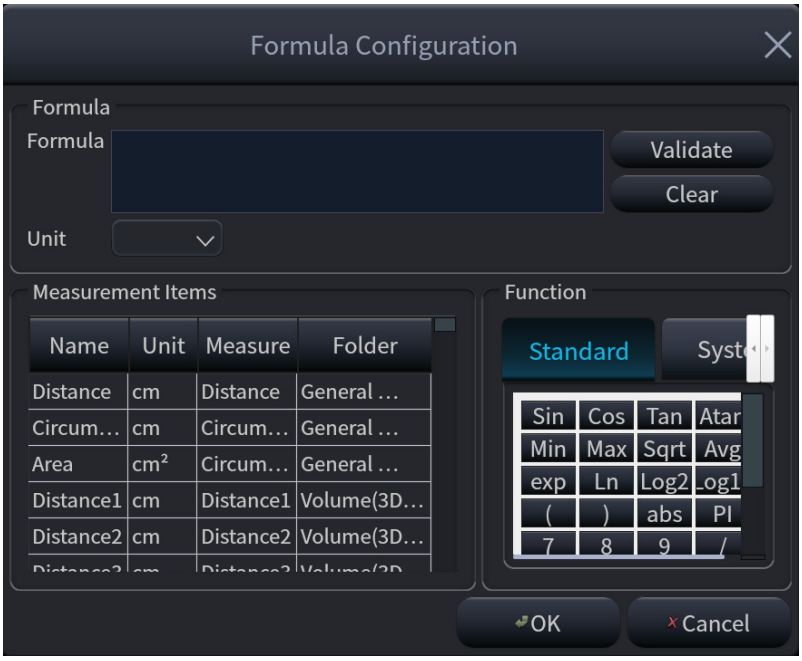


Fig. 8-9

- **Formula:** Edit formula in input box via soft keyboard and built-in formula.
- **Validate:** Press this button to check whether the formula is right or not after editing formula.
- **Clear:** Clear the content in the input box.
- **Unit:** Select the unit of calculation consequence.
- **Measurement Items:** Display all available measurement operation in the measurement menu.
- **Function:** Built-in formula, number input and some parameters that system needs such as BSA, SPSA etc.
- **Cancel:** Cancel editing formula and close the interface.
- **OK:** Save edited operation and close the interface.

8.2.3 OB Table Interface

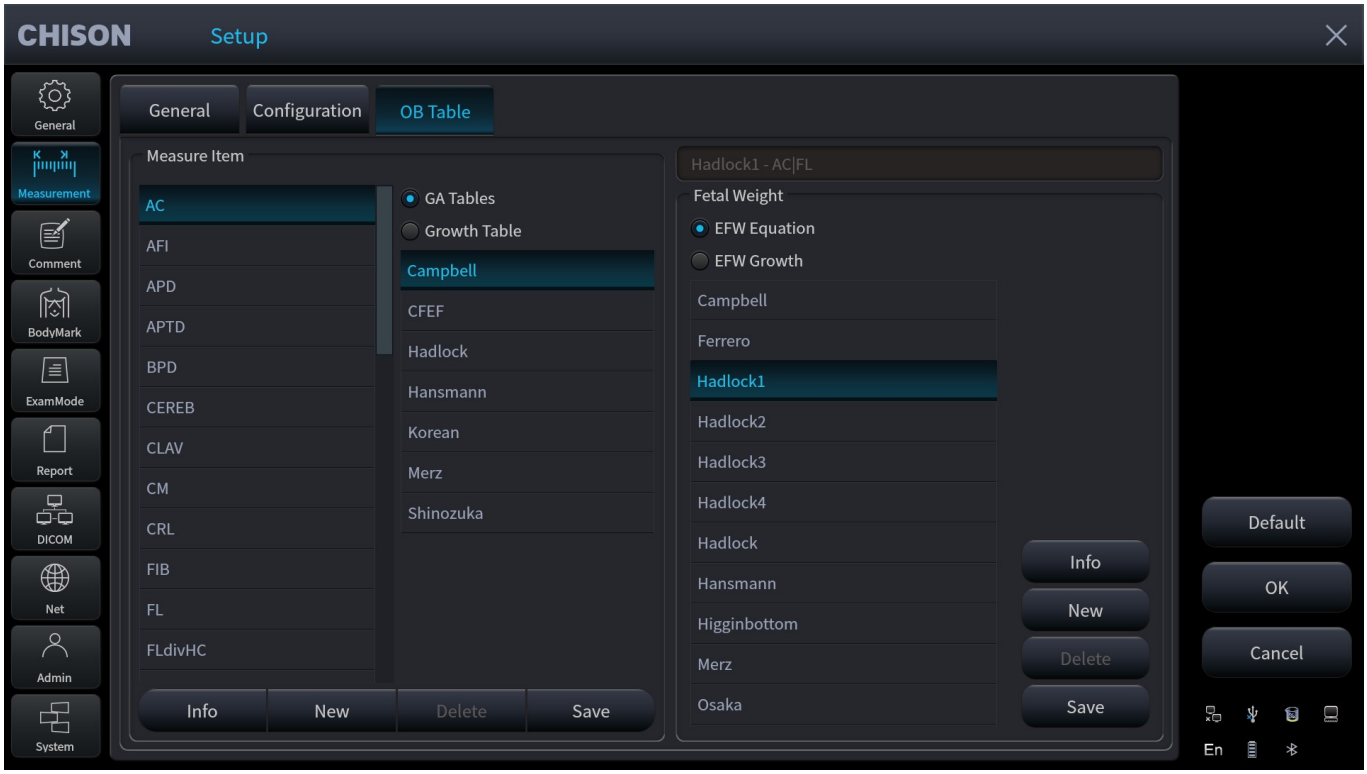


Fig. 8-10

- **Measure Item:** Display OB measurement Item.
- **GA Tables:** Gestational list for the current measuring project.
- **Growth Table:** Growth table for the current measuring.
- **Fetal Weight:** Fetal weight calculation formula.
- **EFW Equation:** Fetal weight calculation for the current measuring.
- **EFW Growth:** Fetal weight growth curve for the current measuring.
- **Info:** Display the gestational age and fetal weight for the current measuring.
- **New:** Create new formula.
- **Save:** Save the users' choice of formulas.

8.3 Comment Setup

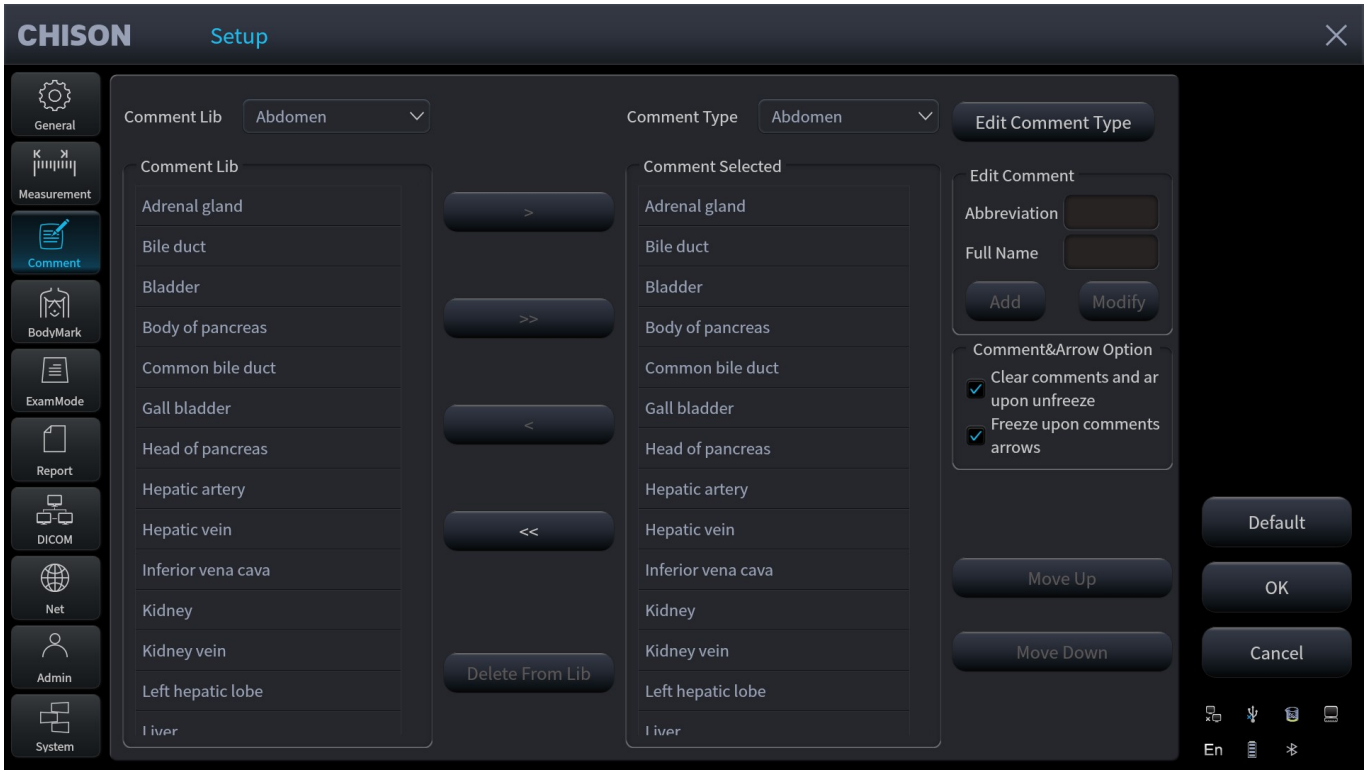


Fig. 8-11

- **Comment Lib**：The annotation database of the system is classified as: Abdomen, Cardiac, Gynecology, Obstetrics, Pathological Changes, Small Parts, Vessel. Annotation can be made by inputting characters from the soft keyboard or recalling the terms saved in annotation database.
- **Comment Type**：Choose desired annotation type.
- **Edit Comment Type**：Enter a new type name and click Rename to change the name of the current annotation type.
- **Edit Comment**：Enter the abbreviation and full name of the desired comment.
- **Comment & Arrow Option**：User can set to clear comments and arrows when unfreezing, and freeze images when adding comments or arrows.
- **Move Up/Down**：After selected “Comment Selected”, you can move comments up or down as required
- **>**：Select the type of comment you want to add from the comment library and click to add it to the comment type.
- **>>**：Imports all annotations in the comment library into the selected comment type.
- **<**：Select the annotation you want to move from the comment type and click to move into the source comment library.
- **<<**：Moves all comments in the selected comment bar to the source comment library.
- **Delete From Lib**：Delete the selected comment from the comment library.

◆Edit Comment Type

Operation:

1. Press **[Edit Comment Type]** item, edit type box pops up.
2. Input new type name into the new created comment box. Press **[Create]** button, the new comment will be created and appear in selected comment list.
3. Press **[Delete]** button to delete current type name in the selected list.
4. To alter current type name, input new name and press **[Rename]** button.

8.4 BodyMark Setup

Fig. 8-12

- **BodyMark Lib**：The bodymark database of the system is classified as: Abdomen, Obstetrics, Gynecology, Cardiology, Small Organs, Urology, Vessel, Nerve, Fast.
- **Bodymark Type**：Select the bodymark type.
- **Edit BodyMark Type**：Create, delete, rename the bodymark.
- **BodyMark Option**：User can set to clear bodymark upon unfreeze; freeze upon bodymark.

◆Edit BodyMark Type

Operation:

1. Press **[Edit BodyMark Type]** item, edit box pops up.
2. Input new type name into the new created bodymark box. Press **[Create]** button, the new bodymark will be created and appear in selected bodymark list.
3. Press **[Delete]** button to delete current type name in the selected list.
4. To alter current type name, input new name and press **[Rename]** button.

8.5 Exam Mode Setup

8.5.1 Exam Mode Selection Interface

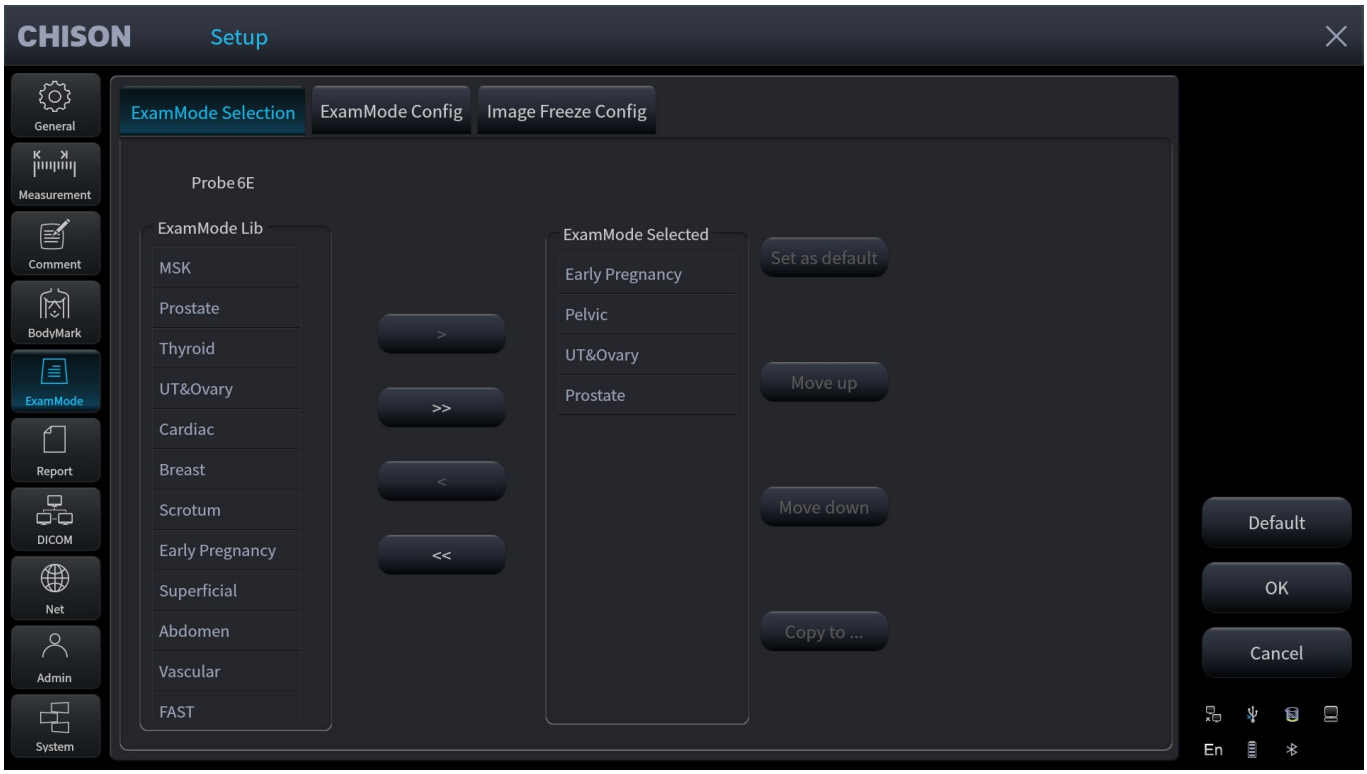


Fig. 8-13

- **Probe 6E:** Show the current probe in use (The name varies with the probe type).
- **ExamModeLib:** Show all existing exam modes for the current probe.
- **ExamMode Selected:** Show the selected exam modes for the probe.
- **>:** Import selected exam modes from ExamModeLib column to ExamMode Selected column.
- **>>:** Import all exam modes from ExamModeLib column into ExamMode Selected column.
- **<:** Delete selected exam modes in ExamMode Selected column.
- **<<:** Delete all exam modes in ExamMode Selected column.
- **Set as default:** Set selected exam modes in ExamMode Selected column as default.
- **Move up:** Move selected exam modes in ExamMode Selected column up.
- **Move down:** Move selected exam modes ExamMode Selected column down.
- **Copy to:** Copy the exam mode selected in ExamMode to a specified preset.

8.5.2 Exam Mode Config Interface

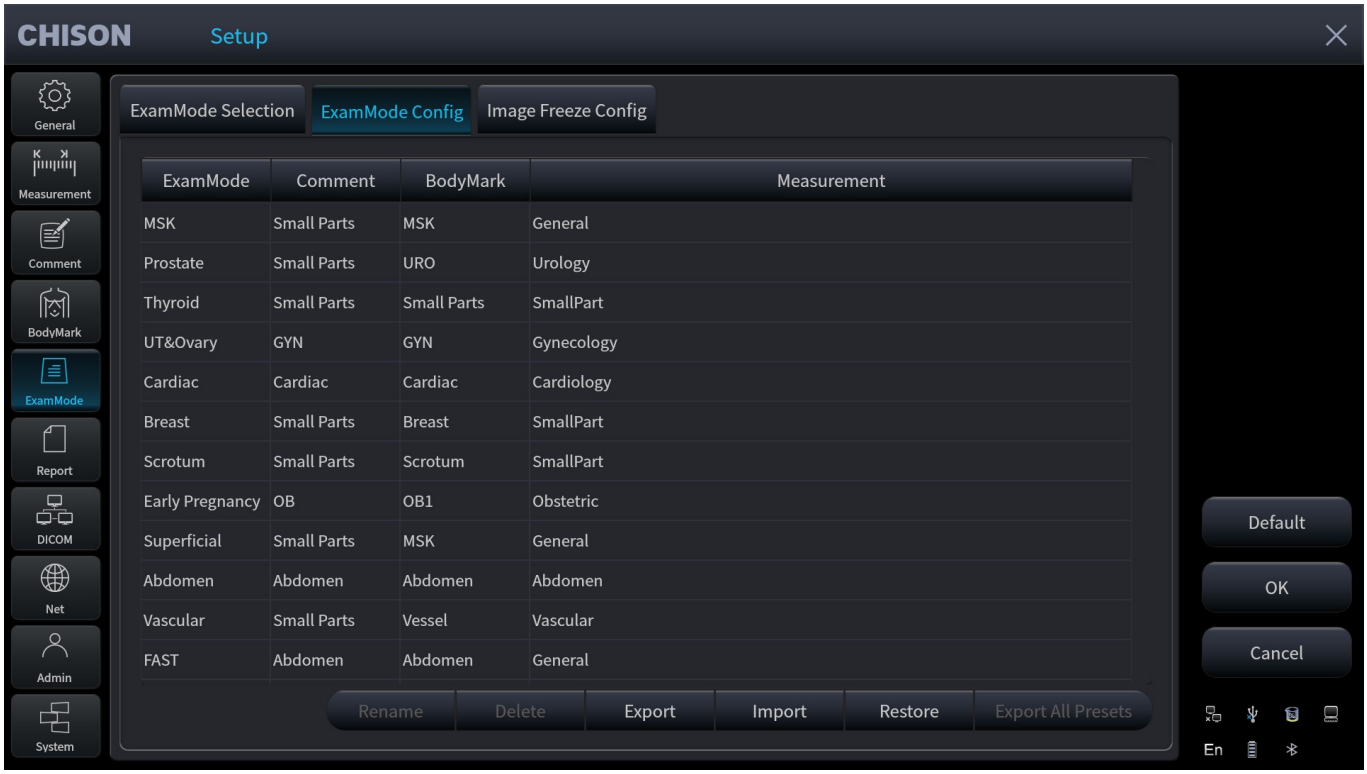


Fig. 8-14

- **ExamMode:** Show all existed exam modes in system.
- **Comment:** Press on the widget box and choose existed annotation name form the dropdown list. After setting, the default of the exam mode is user-selected.
- **BodyMark:** Same as Comment, select user-needed default body marks.
- **Measurement:** Same as Comment, select user-needed default measurement menu.
- **Rename:** Rename selected exam mode.
- **Delete:** Delete selected exam mode.
- **Export:** Export all built-in exam modes into USB flash disk.
- **Import:** Import all built-in exam modes into USB flash disk.
- **Restore:** Restore all exam mode as factory setting.

8.5.3 Image Freeze Config Interface

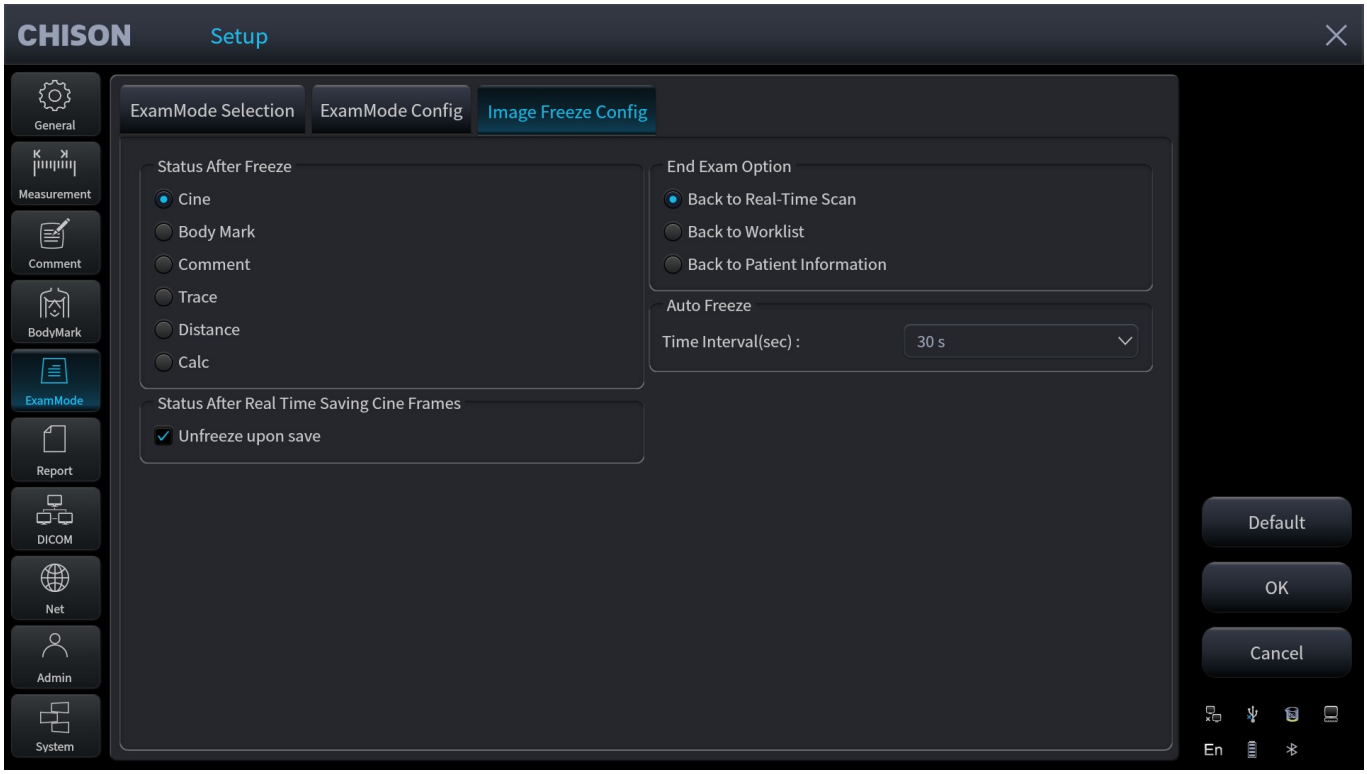


Fig. 8-15

- **Status After Freeze:** Set the status after freezing. After freezing, the system automatically goes into Cine/ Body Mark/ Comment/ Trace/ Distance/ Cal status.
- **Status After Real Time saving Cine Frames:** Whether unfreezing upon save or not.
- **End Exam Option:** Select the working status after finish the exam.
- **Auto Freeze:** Activate auto freeze function and set the time interval for auto freeze.

8.5.4 Scanning Mode Preset Edit

After freezeing, **[Utility]** menu displays. Click it to activate the preset edit function. The parameter control area will appear as the picture shows. Enable related functions by using SK keys or just clicking on the touchscreen.

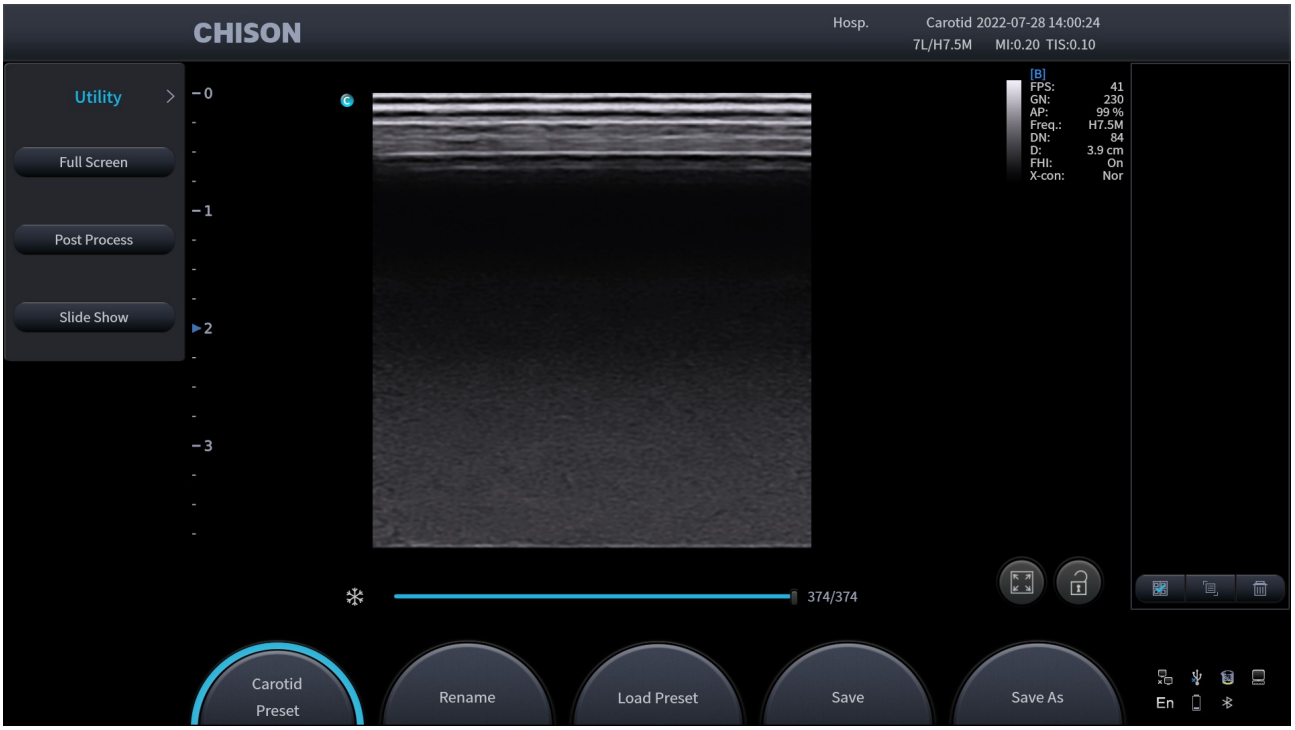


Fig. 8-16

- **Preset:** Display the current preset. Press SK1 or directly click it on the touchscreen to switch to available preset.
- **Rename:** Rename the current preset.
- **Load Preset:** Load the preset displayed.
- **Save:** Save the current preset.
- **Save As:** Save the current preset as others.

8.6 Report Setup

Users can set the layout and diagnostic template for report as required.

8.6.1 General Interface

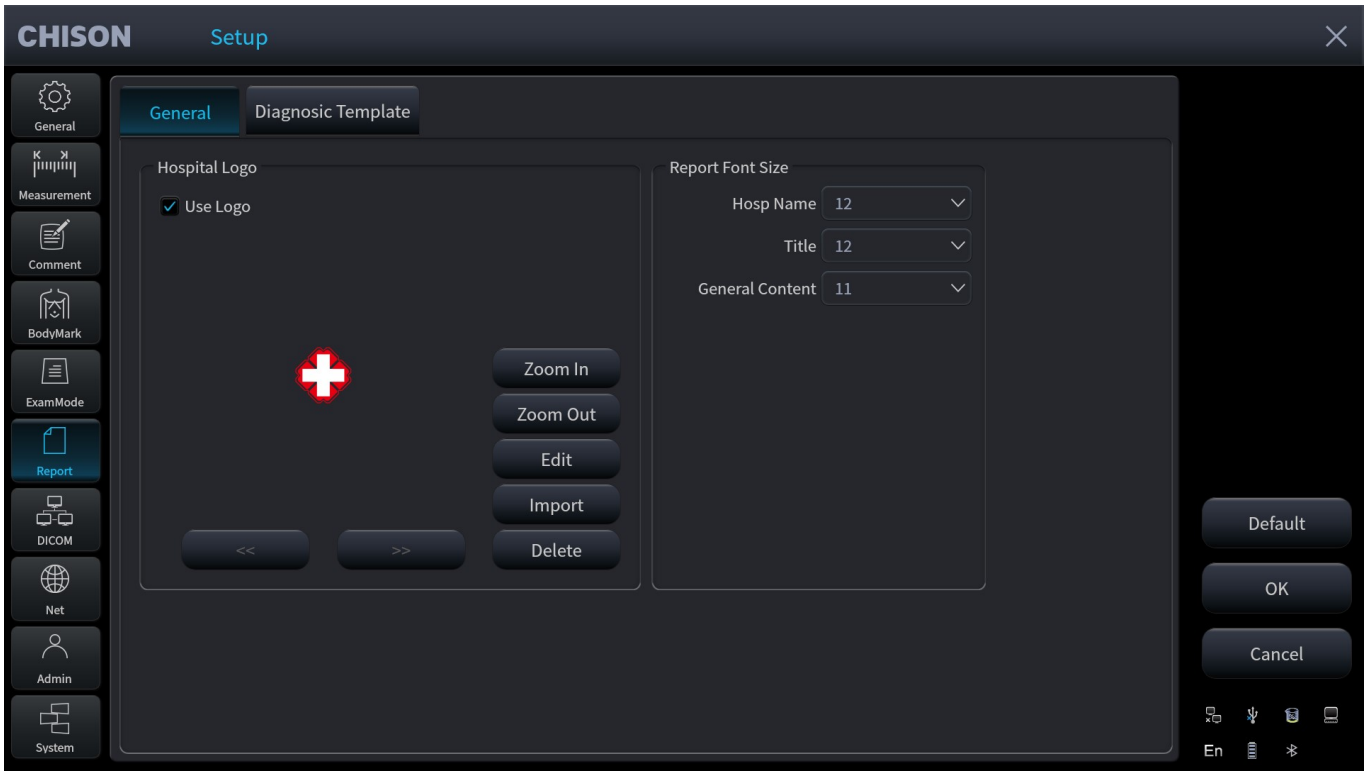


Fig. 8-17

- **Hospital Logo:** Set to use logo in report.
- **Report Font Size:** set up the font size of the hospital name, title, general content.
- **Zoom In：** Zoom in the logo.
- **Zoom Out：** Zoom out the logo.
- **Edit：** Edit the logo.
- **Import：** Import a new logo image from the USB disk.
- **Delete：** Delete the current logo image.
- **>>：** Import all the content from sections to the selected sections.
- **<<：** Delete all the content in the selected sections.

8.6.2 Diagnostic Template Interface

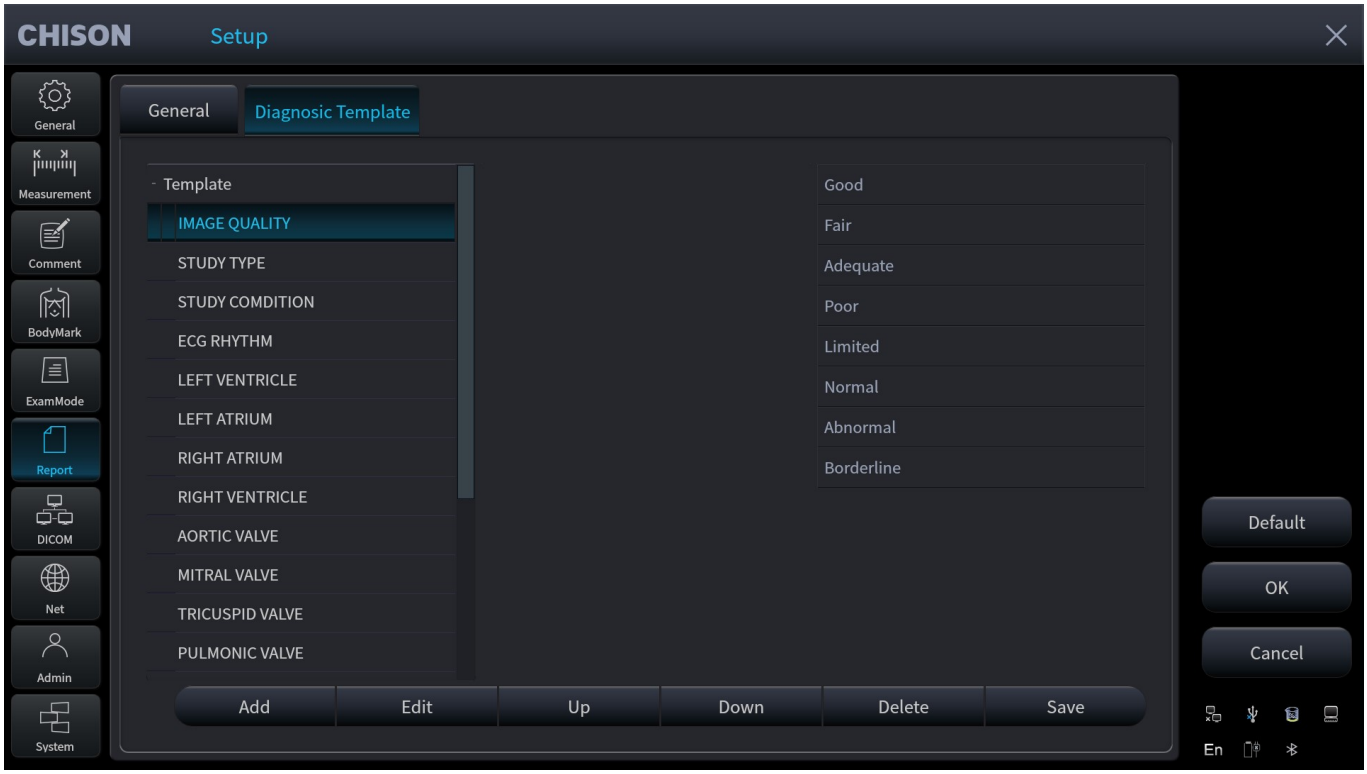


Fig. 8-18

- **Template:** Show the content of all the templates. Click the “+” icon to expand the submenu of the template. Select a specific template and the description list for this template displays in the right column.
- **Add:** Add a new report template.
- **Edit:** Edit the current selected report template.
- **Up/Down:** Adjust the display order for the content in the template or in the description you have selected.
- **Delete:** Delete the content in the template or in the description you have selected.
- **Save:** After you complete the setting, select this option to save all the modification.

8.7 DICOM Setup

The system supports DICOM storage, DICOM print, DICOM MPPS, DICOM worklist, DICOM SR, DICOM query/retrieve.

1. Connect the machine into LAN before setting the DICOM.
2. Press DICOM page in the system setting.

⚠NOTE

If the DICOM function is not open, the system setting interface will not display DICOM page. Please make sure the DICOM function is open before you use DICOM function.

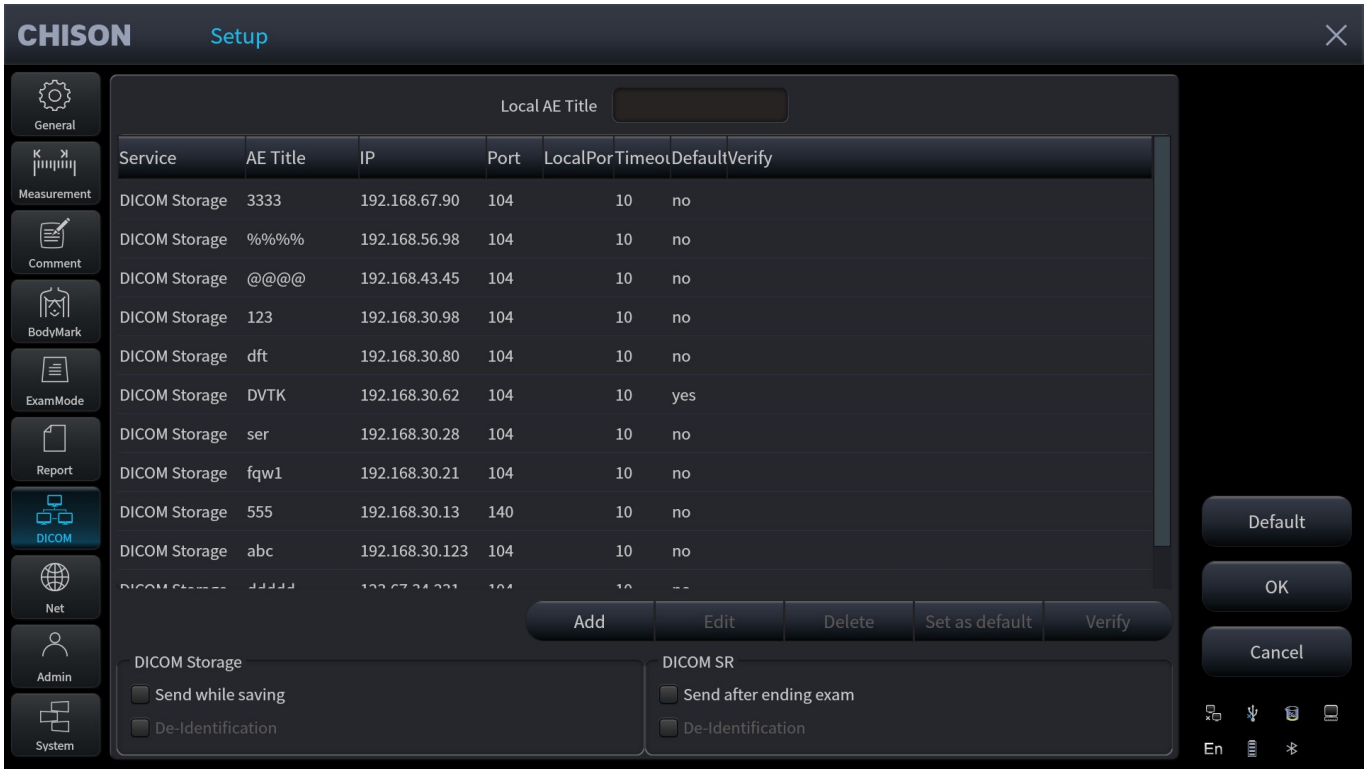


Fig. 8-19

- **Local AE Title:** Input local DICOM Title to separate the DICOM equipment in local network.
- **Service:** Display the local DICOM function worklist.
- **AE Title:** Display the name of local DICOM AE title.
- **IP:** Display the IP of DICOM server.
- **Port:** Display the port of DICOM server.
- **Local Port:** Display the local Port.
- **Timeout(s):** Display the delay time.
- **Default:** Display whether DICOM is default or not.
- **Verify:** Press verify button and display whether DICOM setting is correct or not.
- **Add:** Add DICOM function and pop up setting dialog.
- **Edit:** Edit information of DIOM function.

- **Delete:** Delete the existed DICOM function.
- **Set as default:** Set one DICOM service as default.
- **DICOM Storage:** Check this item and enable DICOM storage while saving image or cine, send clip or image according to activated function. You can also check De-Indentification when save or send image or cine.
- **DICOM SR:** Select this option, the system will send DICOM structured report after the operator ends the exam. You can also check De-Indentification.

8.7.1 Add/Edit DICOM Function

Press **[Add]** button in the above displayed figure, the system pops up the DICOM Setting interface.

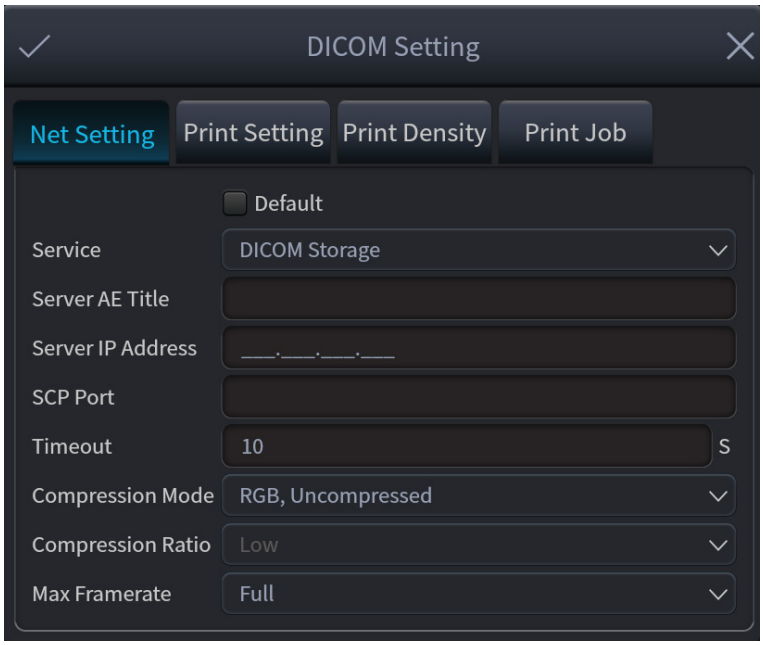


Fig. 8-20

- **Default:** check this option, set DICOM function as default.
- **Service:** choose DICOM Storage, DICOM Worklist, DICOM Print, DICOM SR, DICOM Query/Retrieve, DICOM MPPS.
- **Server AE Title:** input DICOM server AE name.
- **Server IP Address:** input DICOM IP address.
- **SCP Port:** input DICOM server SCP port.
- **Timeout:** set the delay time of DICOM.
- **Compression Mode:** check this option, set Uncompressed or JPEG according to the corresponding requirements.
- **Compression Ratio:** after selecting the JPEG as the compression mode, choose the appropriate compression ratio.
- **Max Framerate:** check this option, select proper feamerate according to the requirement.

⚠***NOTE***

Relative printing setting can be set only after choosing the DICOM print type.

8.8 Net Setup

Set the unit's and target unit's IP and do the connection testing. And network storage settings, details see the appendix H: Procedures of setting network sharing.

8.9 Admin Setup

NOTE

If the HIPPA function is not open, the system setting interface will not display Admin page. Please make sure the HIPPA function is open before you use this function.

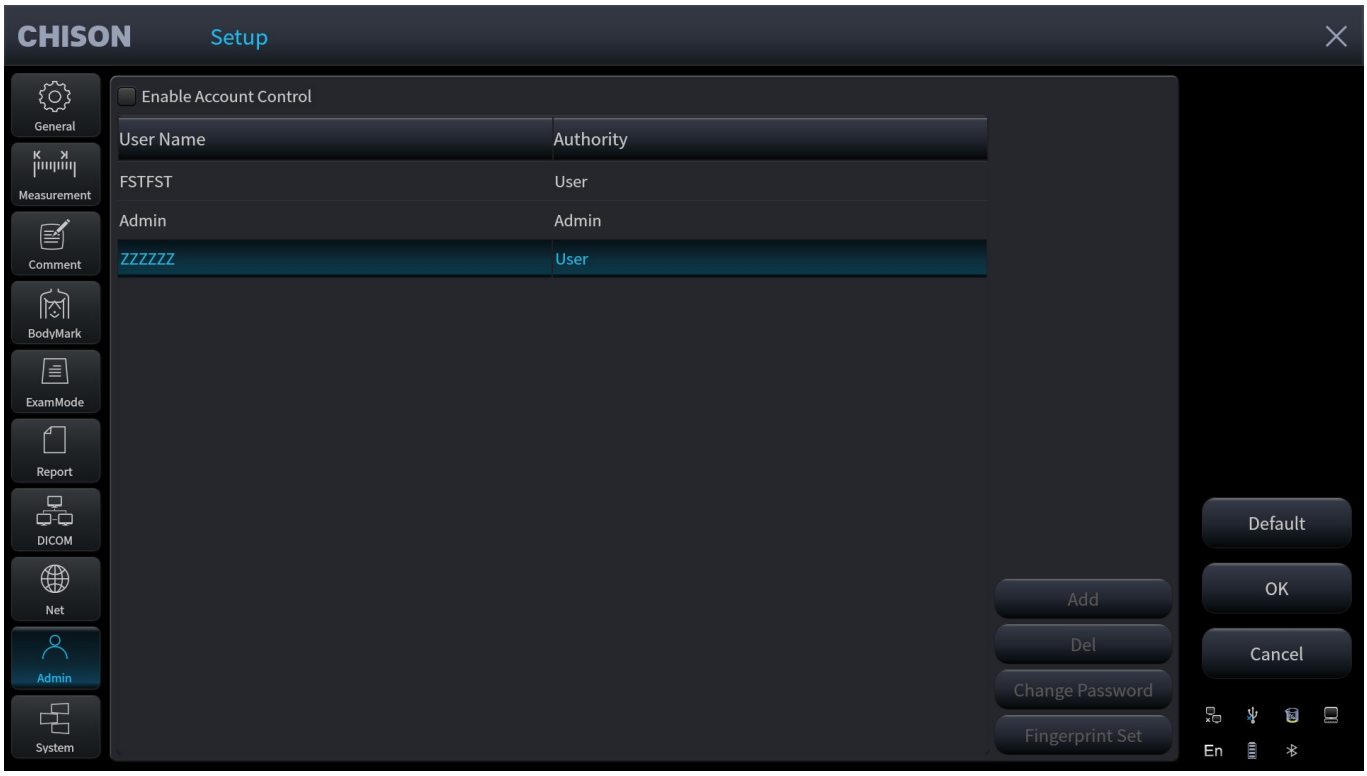


Fig. 8-21

There are two kinds of users: the system administrator and operator customer.

The authority of login account decides the operation authority of the patient information.

The Admin can view all patient data, such as patient information, image and report, ect. The Admin can also manager the user account such as add or delete the accounts and change password for user accounts.

The user can only review and manage the patient that was created by himself or herself. The user cannot view the exam data operated by others.

Emergency operators are general ones; they can enter system without entering password.

Setting Account Control

The Admin can set the access control.

Tick the "Enable Account Control" for the first time to enable Account Control function. After enable

Account Control, users must use user name and password to login the system every time the system turns on. If the “Enable Account Control” is not selected, users can access all the data without the authority.

System Login

If control has been set by the Admin, you can access the data in the system only after you log into the system.

The items in login interface are listed as follows:

User Name: Select the user name which want to login.

Password: Input the password for user name.

Login: Click the icon to login the system.

Emergency: Login as “Emergency User”, no password required.The Emergency user only can review and manage the patient information that was created by Emergency User.

⚠NOTE

User can select the “Admin” to login for the first time and the default password for Admin is ADM123456.

Add/Delete a User

The Admin can add and delete a user, change password, while the users cannot.

Add a user:

Click “Add” to enter the operation page.

Enter the user name (you are not allowed to enter the same name or modify the name already exist), Enter the password and confirm password.

Set the user authority in the drop-down list: Administrator or User.

Click “OK” to confirm the setting and exit the dialogue box, then the new user will appear on the User List.

Change Password

Adimin/ Administrator/ User authority can change password.

Click “Change Password” to change the current password.

8.10 System Setup

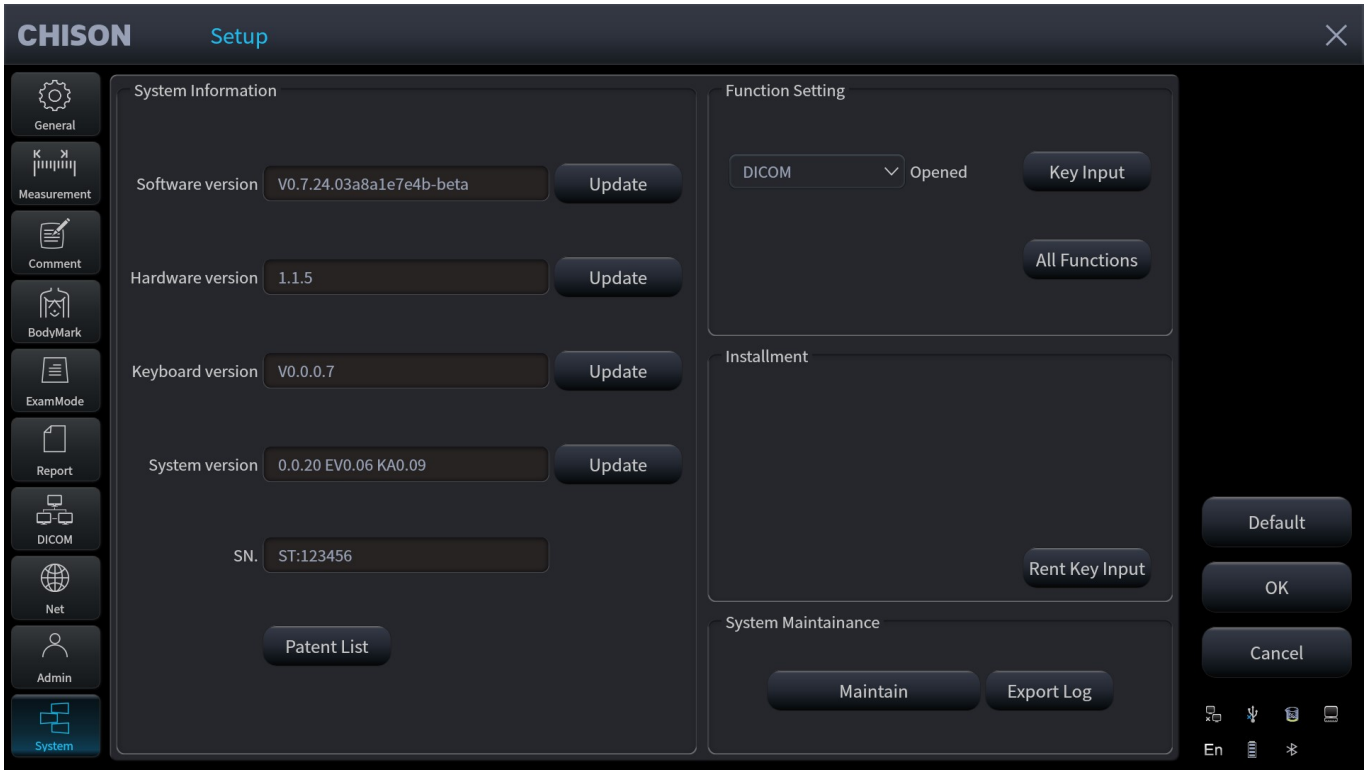


Fig. 8-22

- **System information**

Display the software version, hardware version, keyboard version, system version and SN..

- **Update**

Software and Hardware can be updated by USB disk.

Software upgrades File Path**:** X**:**\update_machine code\AAA.

Hardware upgrades File Path**:** X**:**\fpga_machine code\AAA.

Keyboard upgrades File Path**:** X**:**\keyboard_update_machine code\AAA.

X means USB disk. AAA means upgrade content. It should restart manually after hardware update, and after software update, machine can be restarted automatically.

- **Patent List**

Display the current patent used in this system.

- **Function Setting**

Show the status of current functions, and click the related button to turn on/off this function (need the key provided by CHISON).

- **Installment**

Input relevant key to open trial function and the detail please contact CHISON Company.

- **System Maintenance**

Only an authorized service engineer may perform maintenance.

Chapter 9 System Maintenance

9.1 Cleaning

9.1.1 Main unit

⚠CAUTION

Do turn off the power before cleaning and pull out the cable from socket. There is possibility of electric shock if the device is on.

◆ **Cleaning frequency and methods**

Clean the main unit once a week.

Use the soft dry cloth to wrap the machine. If the device is quite dirty, use wet soft cloth. After wiping the blot, use soft dry cloth to wipe.

⚠CAUTION

- *Don't use organic solvent such as alcohol, otherwise surface may be ruined.*
- *When cleaning the machine, don't let the liquid inflow the machine, otherwise it may malfunction and there is a danger of electric shock.*
- *When it is necessary to clean the probe connector and peripheral instrument, please contact Sales office contact customer service or agent of CHISON. Any self-cleaning may result in malfunction or degrading the function of device.*

9.1.2 LCD screen

Gently wipe the surface of the LCD display with a soft folding cloth. Take care not to scratch the LCD display. Do not use glass cleaners with hydrocarbons (such as benzene, methanol, or methyl ethyl ketone) on displays containing filters. Excessive wiping will cause damage to the filter.

9.1.3 Control panel

- Moisten a soft, unworn folded cloth, never use soapy water.
- Wipe the control panel.
- Clean around the buttons and control panel with cotton swabs, and remove hard objects between the buttons and control panel with toothpicks.

⚠CAUTION

- *When cleaning the control panel, be sure not to splash or spray liquid onto the control panel, inside the control panel and the probe connection port.*
- *Do not use spray or sanitary wipes on the control panel.*

9.2 Maintenance

Planned maintenance for the main unit

The following maintenance plan is suggested for the main unit to ensure optimum operation and safety.
Daily check: inspect the main unit for any broken phenomenon both on the main unit and the electricity cable.

⚠CAUTION

Please immediately stop using the system if there is any broken phenomenon on the electricity cable or the system transducer. Otherwise there will be a danger of the electricity shock.

9.3 Safety Check

CHISON has verified ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency and test reports are available from our factory.
To ensure the system work normally, please make a maintenance plan, check the safety of the system periodically. If there is any abnormal phenomenon with the machine, please contact our authorized agent in your country as soon as possible.
If there is no image or menu on the screen or other phenomenon appears after switching on the machine, please do troubleshooting first according to the following check list. If the trouble is still not solved, please contact our authorized agent in your country as soon as possible.

⚠WARNING

When using battery power, please do periodically check whether the battery works properly.

9.4 Troubleshooting

According to the most frequently occurred errors and system messages, the list of possible causes and relevant solutions is attached as below:

Malfunction	Reason	Measures
Switch button lights but power LCD not	1. Battery lose efficacy 2. Adapter works irregular	Check the connector between cable and power
Power LCD lights but LCD no image	The interval time is too short to restart	Restart after 1 minute
LCD display character menu but no scan image	1. Launch power, gain or STC control errors 2. Not connect to probe or the probe connection is not correct 3. Device is in freezing condition	1. Control launch power, gain or STC control 2. Make sure of right connection 3. Exit from freezing condition
Abnormal image	1. Exam mode errors 2. Image processing setting errors	1. Whether Exam mode is proper or not 2. Adjust image processing setting or set it as default
Probe works improperly	1. The plug plugs loosely 2. Internal circuit protects	1. Extract the probe and reinsert 2. Restart
PRINT-button doesn’t work	1. The connected printer isn’t approved 2. Printer power is not on 3. Printer is not connect well	1. Change the approved printer 2. Turn on the printer 3. Connect the printer again

9.5 Service Responsibility

If users install, use and maintain the system fully according to CHISON's installation manual, operation manual and service manual, then the main unit has a life time of 5 years and probes have life time of 5 years after ex-work.

The warranty of the system and probes after ex-work is as the time in the warranty card.

The system is a precise electronic system. Only the CHISON's authorized service engineer could replace the defective parts. Any assembly, disassembly, handling, repair, or replacement by any other people may have adverse impact on the safety and effectiveness of the systems and probes, and thus will reduce the life time of the system and probes, and such systems and probes will not be covered by CHISON warranty after the above improper handling. Standard maintenance must be performed by CHISON's authorized service engineer during the life time of the product.

CAUTION

When the above life time is expired, the effectiveness and safety of system and probes maybe greatly affected, so it's NOT suggested to continue using the system and probes even the system and probes seem work properly. But if user still wants to continue using the system and probes, user should first contact CHISON service center at CHISON headquarter to arrange the necessary safety check and calibration by CHISON's authorized service engineer. If CHISON headquarter service center provides the calibration certificate for the related system or probe, then user could continue use the system or probes according to the calibration certificate. However, if CHISON headquarter service center concludes that the system or probe is no longer complied to the safety and effectiveness standard, then user should immediately stop using the system or probe. User understands that such check and calibration cost will be born by the user.

Systems and probes keep on using after the life time may also be difficult to repair and maintain, so it's suggested to renew the product after the life time.

Chapter 10 Probes

10.1 General Description

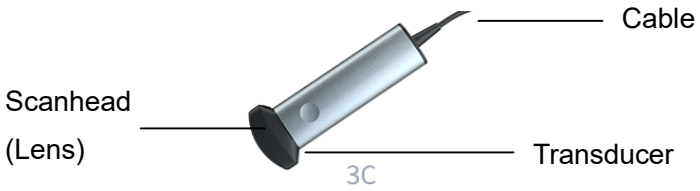


Fig.10-1 Convex Probe Overview

⚠NOTE

The photograph above is 3C probe for reference. It is used only to identify component names. The appearance of different probes varies. Please be subject to the actual product you have purchased.

The probes provide high spatial and contrast ultrasound imaging. These probes operate by pulsing sound waves into the body and listening to the returning echoes to produce high-resolution brightness mode, and a real time display.

10.2 Care and Maintenance

The probes that come with the system are designed to be durable and dependable. These precision instruments should be inspected daily and handled with care. Please observe the following precautions:

1. Do not drop the transducer on hard surface. This can damage the transducer elements and compromise the electrical safety of the transducer.
2. Avoid kinking or pinching the transducer cable.
3. Use only approved ultrasonic coupling gels.
4. Follow the instructions for cleaning and disinfecting that come with each probe.

⚠CAUTION

- *Only person received professional training can use the probes.*
- *Probes can't receive pressure sterilizer, when operation in sterile area, disposable sterile probe hood should be applied.*
- *Make sure not to drop the transducer on hard surface. This can damage the transducer elements and compromise the electrical safety of the transducer.*
- *Be careful when doing operation. Make sure not to scratch the probe surface.*
- *Avoid kinking or pinching the transducer cable.*
- *Make sure not to connect the probe to plug or put adjacent cable into any kind of liquid.*
- *Keep the probe clean and dry. Power off or freeze when fixing or dismantling the probe.*

- *Make sure not to use or deposit the probe in the environment above 50 degree.*
- *If any abnormal phenomena of probe is found, immediately stop operation and contact with Sale Office, Customer Service department or Agents of manufacturer.*
- *No matter which type of examination is performed, please always try to reduce the unnecessary radiation of ultrasound wave to the patient during the ultrasound examination.*

10.2.1 Inspecting Probes

Before and after each use, inspect carefully the probe's lens, cable, casing, and connector. Look for any damage that would allow liquid to enter the probe. If any damage is suspected, do not use the probe until it has been inspected and repaired/replaced by an authorized Service Representative.

⚠NOTE

Keep a log of all probe maintenance, along with a picture of any probe malfunction.

⚠WARNING

The probes are designed to be used only with this ultrasound system. Use of these probes on any other system or a non-qualified probe may cause electrical shock or damage on the system/transducer.

10.2.2 Cleaning and Disinfecting

Definitions

Cleaning removes visible soil (for example, organic and inorganic material) from the probe surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection because inorganic and organic materials that remain on the surfaces of probes interfere with the effectiveness of these processes.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.

Low-Level Disinfection (LLD) destroys most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium tuberculosis or bacterial spores.

Intermediate-Level Disinfection (ILD) inactivates Mycobacterium tuberculosis, bacteria, most viruses, most fungi, and some bacterial spores.

High-Level Disinfection (HLD) destroys or removes all microorganisms except bacterial spores.

Transducer Components

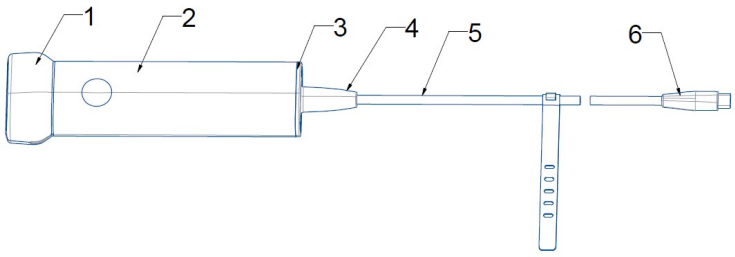


Fig.10-2: Transducer Components

1. Lens 2. Shell 3. Cover 4. Sheath 5. Cable 6. TYPE-C connector

To choose a suitable probe disinfection method, you must first determine its category according to the purpose of the probe. For more information about compatible cleaning and disinfecting agents, please refer to the section "Cleaning or disinfecting ". While using detergents and disinfectants, be sure to follow the manufacturer's instructions.

⚠*WARNING*

After each use of the probe, it must be cleaned. Cleaning the probe is an important step before effective disinfection. While using detergents and disinfectants, be sure to follow the manufacturer's label instructions.

⚠*WARNING*

When cleaning and disinfecting any instrument, be sure to wear protective glasses and gloves.

⚠*CAUTION*

Using non-recommended disinfectants, inappropriate disinfectant concentration, or the immersion depth or immersion time of the probe exceeding the recommended value will cause damage or discoloration of the probe, and invalidate the probe warranty.

⚠*CAUTION*

Do not use a brush when cleaning transducers. Even the use of soft brushes can damage transducers.

⚠*CAUTION*

Do not leave the probe in contact with cleaning agents and disinfectants for a long time. Limit the time the probe is exposed to cleaners and disinfectants to the shortest time recommended by the manufacturer.

When you use OPA (ortho-phthalaldehyde)-based disinfectants, if you do not follow the manufacturer's instructions carefully, residual solution may remain on the probe. In order to minimize the impact of residual OPA or any other disinfectant, it is recommended as below:

- Follow the instructions of the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends as below immersing the probe in drinking water three times to rinse the probe.

- Limit the time the probe is exposed to the disinfectant to the shortest time recommended by the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends a minimum time of 12 minutes.

- Prevent any fluid from splashing on your mobile device's touchscreen during cleaning and during disinfecting. Damage may result due to fluid.

⚠CAUTION

Before cleaning, check the probe first. If any particles or body fluids adhere to the probe or cable, you can wipe it off with a compatible disinfectant wipe.

10.2.2.1 Cleaning

Recommended supplies:

Dust-free cloth or soft cloth;
Compatible cleaner or wipes for probe cleaning;
1. Disconnect the probe from the system.
2. Wear sterile gloves and use protective eyewear to prevent infection.
3. Remove Ultrasound transmission gel from the transducer by using a soft cloth dampened with potable water (not to exceed 43° C (110° F)) or an approved cleaning or disinfectant agent or by using an approved disinfectant wipe.
4. Gently wipe the lens to remove the gel, then wipe the probe, cable for 1 minute and until visibly clean (There is no gel, hair, debris or other residue on the probe.). Do not wipe the connector to prevent liquid from entering the inside. Please refer to Table 10-1 below for approved compatible cleaning and disinfection products.
5. Dry the transducer using a sterile cloth or gauze after rinsing. Blot the lens dry. Do not wipe the lens. Do not dry the transducer by heating it.

10.2.2.2 Disinfecting

After cleaning the probe, you must disinfect the probe.
To reduce the risk of contamination and infection, it is important to choose the appropriate level of disinfection, based on prior exam usage and whether the use is classified as non-critical or semi-critical. Use table below named "Probe Disinfection Class, Use, and Method" to determine the appropriate class

and then follow the appropriate intermediate-level or high-level disinfection procedure.

Probe Disinfection Class, Use, and Method

Class	Use	Method
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate-level disinfection (ILD)
Semi-Critical Class	Touches mucous membranes and non-intact skin	Cleaning followed by high-level disinfection (HLD)

Intermediate-Level Disinfection (ILD)

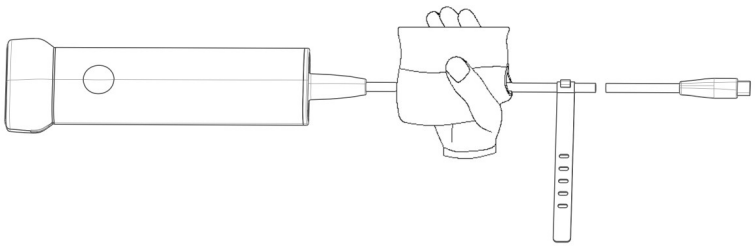


Fig.10-3: Wipe Direction

1. Wear sterile gloves to prevent infection.
2. Wipe the probe, with approved compatible disinfectant wipes or soft cloth dipped in detoxifier. As shown in the figure above, wiping from lens toward cable. Do not wipe the type-c linker to prevent poor contact.
3. Ensure that the disinfected surface remains visibly moist for at least two (2) minutes，use additional fresh wipes as needed.
4. Allow to air dry.
5. After cleaning and disinfection, check the appearance of the probe to see whether the transducer and cable are worn or damaged

High Level Disinfection (HLD)

It is recommended that you use Cide®OPA by Ethicon US, LLC.

1. After cleaning the probe, you must disinfect the probe. It is recommended that you use Cidex® OPA high-level disinfection solution.
2. Prepare Cidex® OPA high-level disinfection solution for use per the manufacturer's instructions. Fill a tray or basin with the disinfectant solution at room temperature (minimum temperature of 20°C) to a level allowing immersion of the probe up to the immersion line (As shown below).

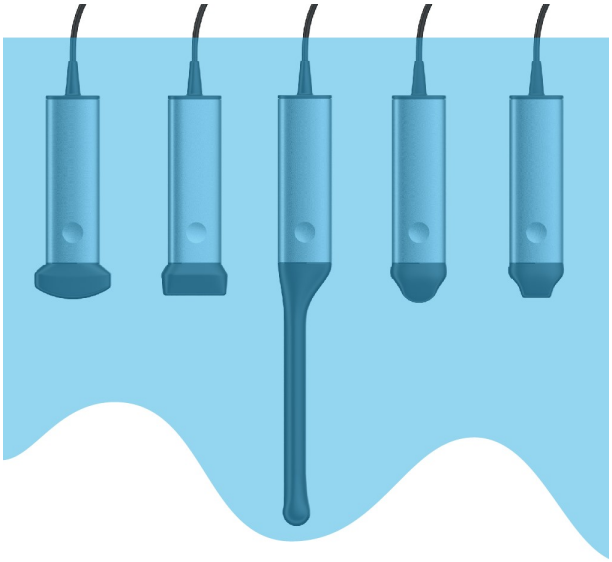


Fig.10-4: Probe Immersion Levels

3. Immerse the probe in Cidex® OPA solution up to the immersion line and ensure no air or bubbles are trapped. Allow soaking according to the manufacturer's instructions.

4. Thoroughly rinse the probe (up to the immersion line) by immersing it in a large volume of room temperature purified water for a minimum of one (1) minute. Remove the probe and discard the rinse water. Do not reuse the water. Always use fresh volumes of water for each rinse. Repeat this stage two (2) additional times for a total of three (3) rinses.

5. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the device is completely dry. Inspect the device to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is visible.

6. Once clean and disinfected, inspect the probe, sheath, cable, and connector for signs of damage or wear.

7. Daily and Long-Term Storage follow these guidelines to protect the probe. Always store probes in the probe case when you are not using them.

⚠*CAUTION*

Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use. Do not soak the transducer connector or the cable near it into water or any solution.

⚠*CAUTION*

Follow local regulations when selecting and using the disinfectant.

10.2.2.3 Approved and compatible cleaning and disinfectant

Trade name	Manufacturer	Origin	Qualified Use	Remarks
80% Ethanol	/	Any	Wipe	
70% Isopropyl alcohol	/	Any	Wipe	
Universal wipes	clinell	United Kingdom	Wipe	
Perform classic wipes EP	Schulke&Mayr GmbH	Germany	Wipe	
WIP'ANIOS	Laboratoires ANIOS	France	Wipe	
Sani-Cloth AF3,Sani-Cloth AF	Professional Disposables International Inc.	United States	Wipe	Recommended for American customers
Super Sani-Cloth	Professional Disposables International Inc.	United States	Wipe	Recommended for American customers
Cide®OPA	Ethicon US, LLC	United States	Soak	Recommended for American customers

Table 10-1：Cleaning and Disinfection List

⚠CAUTION

These transducers are not designed to withstand heat sterilization methods. Exposure to temperatures in excess of 60 ºC will cause permanent damage. The transducers are not designed to be totally submerged in fluid, as permanent damage will result if the entire transducer is submerged.

10.2.3 Probe Safety

10.2.3.1 Handling Precaution

Ultrasound probes are highly sensitive medical instruments that can easily be damaged by improper handling. Use care when handling and protect from damage when not in use. DO NOT use a damaged or defective probe. Failure to follow these precautions can result in serious injury and equipment damage.

◆ **Electrical shock hazard:**

The probe is driven with electrical energy that can injure the patient or user if live internal parts are contacted by conductive solution**:**

- DO NOT immerse the probe into any liquid beyond the level indicated by the immersion level diagram.

Never immerse the probe connector into any liquid.

- Prior to each use, visually inspect the probe lens and case area for cracks, cuts, tears, and other signs of physical damage. DO NOT use a probe that appears to be damaged until you verify functional and safe performance. You need to perform a more thorough inspection, including the cable, strain relief, and connector, each time you clean the probe.
- Before inserting the connector into the probe port, inspect the probe connector pins. If a pin is bent, DO NOT use the probe until it has been inspected and repaired/replaced by a CHISON Service Representative.
- Electrical leakage checks should be performed on a routine basis by CHISON Service or qualified hospital personnel.

◆ Mechanical hazard:

A defective probe or excess force can cause patient injury or probe damage**:**

- Observe depth markings and do not apply excessive force when inserting or manipulating endo-cavitary probe.
- Inspect probes for sharp edges or rough surfaces that may injure sensitive tissue.
- DO NOT apply excessive force to the probe connector when inserting into the probe port. The pin of a probe connector may bend.

◆ Special handling instructions

Using protective sheaths

The use of market cleared probe sheaths is recommended for clinical applications. Reference FDA March 29, 1991 "Medical Alert on Latex Products".

Protective sheaths may be required to minimize disease transmission. Probe sheaths are available for use with all clinical situations where infection is a concern. Use of legally marketed, sterile probe sheaths is strongly recommended for endo-cavitary procedures.

DO NOT use pre-lubricated condoms as a sheath. In some cases, they can damage the probe. Lubricants in these condoms may not be compatible with probe construction.

Devices containing latex may cause severe allergic reaction in latex sensitive individuals. Refer to FDA's March 29, 1991 Medical Alert on latex products.

DO NOT use an expired probe sheath. Before using a sheath, verify if it has expired.

Endo-cavitary Probe Handling Precautions

If the sterilization solution comes out of the endo-cavitary probe, please follow the cautions below**:**

Sterilant Exposure to Patient (e.g., Cidex): Contact with a sterilant to the patient's skin for mucous membrane may cause an inflammation. If this happens, refer to instruction manual of the sterilant.

Sterilant Exposure from Probe handle to Patient (e.g. Cidex): DO NOT allow the sterilant to contact the patient. Only immerse the probe to its specified level. Ensure that no solution has entered the probe's handle before scanning the patient. If sterilant comes into contact with the patient, refer to the sterilant's instruction manual.

Sterilant Exposure from Probe connector to Patient (e.g. Cidex): DO NOT allow the sterilant to contact the patient. Only immerse the probe to its specified level. Ensure that no solution has entered the probe's connector before scanning the patient. If sterilant comes into contact with the patient, refer to the sterilant's instruction manual.

Endo-cavitary Probe Point of Contact: Refer to the sterilant's instruction manual.

10.2.3.2 Probe Handling and Infection Control

This information is intended to increase user awareness of the risks of disease transmission associated with using this equipment and provide guidance in making decisions directly affecting the safety of the patient as well as the equipment user.

Diagnostic ultrasound systems utilize ultrasound energy that must be coupled to the patient by direct physical contact.

Depending on the type of examination, this contact occurs with a variety of tissues ranging from intact skin in a routine exam to recirculating blood in a surgical procedure. The level of risk of infection varies greatly with the type of contact.

One of the most effective ways to prevent transmission between patients is with single use or disposable devices. However, ultrasound transducers are complex and expensive devices that must be reused between patients. It is very important, therefore, to minimize the risk of disease transmission by using barriers and through proper processing between patients.

◆ Risk of infection

ALWAYS clean and disinfect the probe between patients to the level appropriate for the type of examination and use FDA-cleared probe sheaths where appropriate.

Adequate cleaning and disinfection are necessary to prevent disease transmission. It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures in use. Always use sterile, legally marketed probe sheaths for intra-cavitary procedures.

◆ Perform cleaning probe after each use

1 . Disconnect the probe from the ultrasound console and remove all coupling gel from the probe by wiping with a soft cloth and rinsing with flowing water.

2 . Wash the probe with mild soap in lukewarm water. Scrub the probe as needed using a soft sponge, gauze, or cloth to remove all visible residue from the probe surface. Prolonged soaking or scrubbing with a soft bristle brush (such as a toothbrush) may be necessary if material has dried onto the probe surface.

⚠WARNING

To avoid electrical shock, always turn off the system and disconnect the probe before cleaning the probe.

⚠CAUTION

- *Take extra care when handling the lens face of the Ultrasound transducer. The lens face is especially sensitive and can easily be damaged by rough handling. NEVER use excessive force when cleaning the lens face.*
- *Rinse the probe with enough clean potable water to remove all visible soap residue.*
- *Air dry or dry with a soft cloth.*

⚠*CAUTION*

To minimize the risk of infection from blood-borne pathogens, you must handle the probe and all disposables that have contacted blood, other potentially infectious materials, mucous membranes, and non-intact skin in accordance with infection control procedures. You must wear protective gloves when handling potentially infectious material. Use a face shield and gown if there is a risk of splashing or splatter.

◆ Coupling gels

DO NOT use unrecommended gels (lubricants). They may damage the probe and void the warranty. *AQUASONIC Gel made by R. P. Kincheloe Company in USA is recommended.*

In order to assure optimal transmission of energy between the patient and probe, a conductive gel must be applied liberally to the patient where scanning will be performed.

⚠*CAUTION*

- *Please do not use any gel or other materials which are not provided by CHISON. Un-authorized gel, lubricants and other materials may corrode probes and other parts of the device, for example the keyboard. This may reduce the safety and effectiveness of the system and probes, and may also reduce the life time of the systems and probes. Damages caused by such reason will not be covered by the warranty.*
- *DO NOT apply gel to the eyes. If there is gel contact to the eyes, flush eyes thoroughly with water.*
- *Coupling gels should not contain the following ingredients as they are known to cause probe damage:*

× *Methanol, ethanol, isopropanol, or any other alcohol-based product*
× *Mineral oil*
× *Iodine*
× *Lotions*
× *Lanolin*
× *Aloe Vera*
× *Olive Oil*
× *Methyl or Ethyl Parabens (para hydroxybenzoic acid)*
× *Dimethyl silicone*

10.2.3.3 Planned and Special Maintenance

◆ Planned maintenance for the probes

The following maintenance plan is suggested for the probes to ensure optimum operation and safety.

Daily check: inspect the probes.

After each use: clean the probes and disinfect the probes.

As necessary: inspect the probes, clean the probes, and disinfect the probes.

◆ Returning/Shipping probes and repair parts

Transportation dept. and our policy require that equipment returned for service MUST be clean and free of blood and other infectious substances.

When you return a probe or part for service, you need to clean and disinfect the probe or part prior to packing and shipping the equipment.

Ensure that you follow probe cleaning and disinfection instructions provided in this Manual.

This ensures that employees in the transportation industry as well as the people who receive the package are protected from any risk.

◆Probe covers

The transducer should be covered with a barrier. If the barriers used are condoms, these should be nonlubricated and nonmedicated. Practitioners should be aware that condoms have been shown to be less prone to leakage than commercial probe covers, and have a six-fold enhanced AQL (acceptable quality level) when compared to standard examination gloves. They have an AQL equal to that of surgical gloves. Users should be aware of latex-sensitivity issues and have available nonlatex-containing barriers.

10.2.3.4 AIUM Outlines Cleaning the Endocavotary Transducer

Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducers between Patients from AIUM

Approved June 4, 2003

The purpose of this document is to provide guidance regarding the cleaning and disinfection of transvaginal and transrectal ultrasound probes.

All sterilization/disinfection represents a statistical reduction in the number of microbes present on a surface. Meticulous cleaning of the instrument is the essential icon to an initial reduction of the microbial/organic load by at least 99%. This cleaning is followed by a disinfecting procedure to ensure a high degree of protection from infectious disease transmission, even if a disposable barrier covers the instrument during use.

Medical instruments fall into different categories with respect to potential for infection transmission. The most critical level of instruments are those that are intended to penetrate skin or mucous membranes. These require sterilization. Less critical instruments (often called "semi-critical" instruments) that simply come into contact with mucous membranes such as fiber optic endoscopes require high-level disinfection rather than sterilization.

Although endocavitary ultrasound probes might be considered even less critical instruments because they

are routinely protected by single use disposable probe covers, leakage rates of 0.9% - 2% for condoms and 8%-81% for commercial probe covers have been observed in recent studies. For maximum safety, one should therefore perform high-level disinfection of the probe between each use and use a probe cover or condom as an aid in keeping the probe clean.

There are four generally recognized categories of disinfection and sterilization. Sterilization is the complete elimination of all forms or microbial life including spores and viruses.

Disinfection, the selective removal of microbial life, is divided into three classes**:**

High-Level Disinfection - Destruction/removal of all microorganisms except bacterial spores.

Mid-Level Disinfection - Inactivation of Mycobacterium Tuberculosis, bacteria, most viruses, fungi, and some bacterial spores.

Low-Level Disinfection - Destruction of most bacteria, some viruses and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium Tuberculosis or bacterial spores.

The following specific recommendations are made for the use of Endocavitary ultrasound transducers. Users should also review the Centers for Disease Control and Prevention document on sterilization and disinfection of medical devices to be certain that their procedures conform to the CDC principles for disinfection of patient care equipment.

10.2.3.5 Aspetic Technique

For the protection of the patient and the health care worker, all endocavitary examinations should be performed with the operator properly gloved throughout the procedure. Gloves should be used to remove the condom or other barrier from the transducer and to wash the transducer as outlined above. As the barrier (condom) is removed, care should be taken not to contaminate the probe with secretions from the patient. At the completion of the procedure, hands should be thoroughly washed with soap and water.

⚠NOTE

Obvious disruption in condom integrity does NOT require modification of this protocol. These guidelines take into account possible probe contamination due to a disruption in the barrier sheath.

In summary, routine high-level disinfection of the endocavitary probe between patients, plus the use of a probe cover or condom during each examination is required to properly protect patients from infection during endocavitary examinations. For all chemical disinfectants, precautions must be taken to protect workers and patients from the toxicity of the disinfectant.

10.3 Probe Operation Instructions

This section introduces instruction for details on connecting, activating, deactivating, disconnecting, transporting and storing the probes, see Chapter 3.

10.3.1 Scanning the Patient

In order to assure optimal transmission of energy between the patient and probe, a conductive gel must be applied liberally to the patient where scanning will be performed.
After the examination is complete, follow the cleaning and disinfecting, or sterilizing procedures as appropriate.

10.3.2 Operating Transvaginal probe

The transvaginal probe is an endo-cavity probe, for the operation safety, please refer to “Care and Maintenance” for cleaning and disinfection.

The temperature at the tip of the probe displays on the screen for monitoring. No temperature above 43ºC is allowed. It also depends on the patient’s body temperature. When the temperature of probe tip exceeds 43ºC, the probe will stop working immediately to protect the patient.

Transvaginal probe should be used with FDA approved condom or probe cover. See the following instructions to put the probe into the condom:

⚠CAUTION

- *Some patients may be allergic to natural rubber or medical device with rubber contains. FDA suggests that the user to identify these patients and be prepared to treat allergic reactions promptly before scanning.*
- *Only water-solvable solutions or gel can be used. Petroleum or mineral oil-based materials may harm the cover.*
- *When the transvaginal probe is activated outside patient’s body, its acoustic output level should be decreased to avoid any harmful interference with other equipment.*

Operation Procedure:

1 . Put on medical sterile glove.
2 . Get the condom for the package.
3 . Unfold the condom.
4 . Load some ultrasound gel into condom.
5 . Take the condom with one hand, and put the probe head into the condom.
6 . Fasten the condom on the end of the probe handle.
7 . Confirm the integrity of the condom, and repeat the above steps to the condom if any damage to the condom is found.

10.3.3 Cleaning and Disinfecting Transvaginal Probe

We strongly recommend wearing gloves when cleaning and disinfecting any endocavitary probe.

- Every time before and after each exam, please clean the probe handle and disinfect the transvaginal probe using liquid chemical germicides.
- If the probe is contaminated with body fluids, you should disinfect the probe after cleaning.
- Regard any exam waste as potentially infectious and dispose of it accordingly.

⚠*CAUTION*

Since the main unit is not waterproof, you should disconnect the probe from the system before cleaning or disinfecting.

◆ Cleaning

You can clean the transvaginal probe to remove all coupling gel by wiping with a soft cloth and rinsing with flowing water. Then wash the probe with mild soap in lukewarm water. Scrub the probe as needed and use a soft cloth to remove all visible residues from the probe surface. Rinse the probe with enough clean potable water to remove all visible soap residues, and let the probe air dry.

⚠*CAUTION*

- *Please remove the cover (if any) before cleaning the probe. (The cover like condom is one time usable).*
- *When cleaning the transvaginal probe, it is important to be sure that all surfaces are thoroughly cleaned.*

◆ Disinfecting

Cidex is the only germicide that has been evaluated for compatibility with the material used to construct the probes.

To keep the effectiveness of the disinfection solutions, a thoroughly cleaning must be done to the probe before the disinfecting, make sure no residues remain on the probe.

Disinfecting Procedure:

1 . Following all precautions for storage, use and disposal, prepare the germicide solution according to the manufacturer’s instructions.
2 . Place the cleaned and dried probe to contact with the germicide, being careful not to let the probe drop to the bottom of the container and thus damage the probe.
3 . After placing/immersing, rotate and shake the probe while it is below the surface of the germicide to eliminate air pockets. Allow the germicide to remain in contact with the fully immersed probe. For high level disinfection, follow the manufacturer’s recommended time.
4 . Following all precautions for storage, use and disposal, prepare the germicide solution according to the manufacturer’s instructions.
5 . After removing from the germicide, rinse the probe according to the germicide manufacturer’s rinsing

instructions.

6 . Flush all visible germicide residues from the probe and allow to air dry.

REFERENCE:

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5) Sterilization and Disinfection of Medical Devices: General Principles. Centers for Disease Control, Division of Healthcare Quality Promotion. http://www.cdc.gov/ncidod/hip/sterile/sterilgp.htm (5-2003).

6) ODE Device Evaluation Information--FDA Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices, March 2003. http://www.fda.gov/cdrh/ode/germlab.html (5-2003).

Appendix A: The Information of EC Representative

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Appendix B: Acoustic Output Report Table

Transducer Model: 7L

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.88	0.24		0.24		0.24
Index component Value				0.24	0.24	0.24	0.24	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	**(MPa)**	1.93					
	P	**(mW)**		6.06		6.06		6.33
	P_{1*1}	**(mW)**		6.06		6.06		
	Z_s	**(cm)**			2.00			
	Z_b	**(cm)**					2.00	
	Z_{MI}	**(cm)**	1.55					
	$Z_{pii.\alpha}$	**(cm)**	1.55					
	f_{awf}	**(MHz)**	4.80	8.22		8.22		7.62
Other Information	**prr**	**(Hz)**	-					
	srr	**(Hz)**	27.63					
	n_{pss}	**NA**	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	**(W/cm^2)**	88.02					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	**(mW/cm^2)**	0.36					
	I_{spta} at Z_{pii} or Z_{sii}	**(mW/cm^2)**	0.36					
	p_r at Z_{pii}	**(MPa)**	2.53					
Operating control conditions	**Focus**	**(cm)**	2.00	3.00		3.00		2.00
	Depth	**(cm)**	8.90	8.90		8.90		8.90
	Freq	**MHz**	4.50	7.50		7.50		7.50
	PRF	**HZ**	-	-		-		-

Transducer Model: 7L

Operation Mode: M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.02	0.22		0.32		0.28
Index component Value				0.18	0.22	0.18	0.32	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	2.25					
	P	(mW)		6.85		6.85		6.85
	P_{1*1}	(mW)		6.85		6.85		
	Z_s	(cm)			1.25			
	Z_b	(cm)					1.65	
	Z_{MI}	(cm)	1.65					
	$Z_{pii.\alpha}$	(cm)	1.65					
	f_{awf}	(MHz)	4.85	4.88		4.88		4.88
Other Information	prr	(Hz)	513					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	100.05					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	16.44					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	18.95					
	p_r at Z_{pii}	(MPa)	2.55					
Operating control conditions	Focus	(cm)	2.00	3.00		3.00		3.00
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	4.50	4.50		4.50		4.50
	PRF	HZ	-	-		-		-

Transducer Model: 7L

Operation Mode: B+C

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.92	0.38		0.38		0.62
Index component Value				0.38	0.38	0.38	0.38	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	2.14					
	P	(mW)		10.74		10.74		7.73
	P_{1*1}	(mW)		10.74		10.74		
	Z_s	(cm)			2.05			
	Z_b	(cm)					2.05	
	Z_{MI}	(cm)	0.90					
	$Z_{pii.\alpha}$	(cm)	0.90					
	f_{awf}	(MHz)	5.37	7.60		7.60		8.74
Other Information	prr	(Hz)	-					
	srr	(Hz)	4.50					
	n_{pss}	NA	8.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	209.60					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.39					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.40					
	p_r at Z_{pii}	(MPa)	2.24					
Operating control conditions	Focus	(cm)	1.00	1.50		1.50		0.50
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	6.50	7.50		7.50		7.50
	PRF	HZ	-	-		-		-

Transducer Model: 7L

Operation Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.34	0.15		0.54		0.30
Index component Value				0.15	0.10	0.15	0.54	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	0.77					
	P	(mW)		5.91		5.91		5.91
	P_{1*1}	(mW)		5.91		5.91		
	Z_s	(cm)			1.00			
	Z_b	(cm)					1.50	
	Z_{MI}	(cm)	1.55					
	$Z_{pii.\alpha}$	(cm)	1.55					
	f_{awf}	(MHz)	5.19	5.18		5.18		5.18
Other Information	prr	(Hz)	4500					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	25.72					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	209.29					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	366.44					
	p_r at Z_{pii}	(MPa)	0.99					
Operating control conditions	Focus	(cm)	2.00	1.50		1.50		1.50
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	5.00	5.00		5.00		5.00
	PRF	HZ	4500	4500		4500		4500

Transducer Model: 3S

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.50	0.05		0.05		0.12
Index component Value				0.05	0.05	0.05	0.05	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	2.16					
	P	(mW)		8.32		8.32		8.32
	P_{1*1}	(mW)		4.78		4.78		
	Z_s	(cm)			4.65			
	Z_b	(cm)					4.65	
	Z_{MI}	(cm)	4.15					
	$Z_{pii.\alpha}$	(cm)	4.15					
	f_{awf}	(MHz)	2.88	3.08		3.08		3.08
Other Information	prr	(Hz)	-					
	srr	(Hz)	24.15					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	266.51					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	1.49					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	1.49					
	p_r at Z_{pii}	(MPa)	3.07					
Operating control conditions	Focus	(cm)	5.00	5.00		5.00		5.00
	Depth	(cm)	16.76	16.76		16.76		16.76
	Freq	MHz	2.50	2.50		2.50		2.50
	PRF	HZ	-	-		-		-

Transducer Model: 3S

Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.46	0.24		0.33		0.28
Index component Value				0.24	0.08	0.24	0.33	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	2.38					
	P	(mW)		18.46		18.46		18.46
	P_{1*1}	(mW)		10.25		10.25		
	Z_s	(cm)			2.05			
	Z_b	(cm)					4.85	
	Z_{MI}	(cm)	4.22					
	$Z_{pii.\alpha}$	(cm)	4.22					
	f_{awf}	(MHz)	2.66	2.66		2.66		2.66
Other Information	prr	(Hz)	296					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	250.12					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	15.43					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	18.22					
	p_r at Z_{pii}	(MPa)	2.89					
Operating control conditions	Focus	(cm)	5.00	5.00		5.00		5.00
	Depth	(cm)	16.76	16.76		16.76		16.76
	Freq	MHz	2.50	2.50		2.50		2.50
	PRF	HZ	-	-		-		-

Transducer Model: 3S

Operation Mode: B+C

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.23	0.09		0.09		0.27
Index component Value				0.09	0.09	0.09	0.09	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.51					
	P	(mW)		18.64		18.64		18.94
	P_{1*1}	(mW)		9.21		9.21		
	Z_s	(cm)			4.80			
	Z_b	(cm)					4.80	
	Z_{MI}	(cm)	4.95					
	$Z_{pii.\alpha}$	(cm)	4.95					
	f_{awf}	(MHz)	2.45	2.45		2.45		2.45
Other Information	prr	(Hz)	-					
	srr	(Hz)	18.07					
	n_{pss}	NA	8.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	267.10					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.59					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.59					
	p_r at Z_{pii}	(MPa)	2.91					
Operating control conditions	Focus	(cm)	5.00	5.00		5.00		5.00
	Depth	(cm)	16.76	16.76		16.76		16.76
	Freq	MHz	2.50	2.50		2.50		2.50
	PRF	HZ	-	-		-		-

Transducer Model: 3S

Operation Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.96	0.10		0.42		0.25
Index component Value				0.06	0.10	0.06	0.42	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	**(MPa)**	0.77					
	P	**(mW)**		13.45		14.25		17.22
	P_{1*1}	**(mW)**		7.95		8.89		
	Z_s	**(cm)**			1.05			
	Z_b	**(cm)**					5.00	
	Z_{MI}	**(cm)**	4.83					
	$Z_{pii.\alpha}$	**(cm)**	4.83					
	f_{awf}	**(MHz)**	2.17	2.22		2.36		2.28
Other Information	**prr**	**(Hz)**	2000					
	srr	**(Hz)**	-					
	n_{pss}	**NA**	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	**(W/cm^2)**	112.08					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	**(mW/cm^2)**	462.94					
	I_{spta} at Z_{pii} or Z_{sii}	**(mW/cm^2)**	973.71					
	p_r at Z_{pii}	**(MPa)**	2.01					
Operating control conditions	**Focus**	**(cm)**	5.00	4.00		5.00		7.00
	Depth	**(cm)**	16.76	16.76		16.76		16.76
	Freq	**MHz**	2.50	2.50		2.50		2.50
	PRF	**HZ**	2000	2000		2000		2000

Transducer Model: 3C

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.05	0.11		0.11		0.25
Index component Value				0.11	0.11	0.11	0.11	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.58					
	P	(mW)		10.02		10.02		12.62
	P_{1*1}	(mW)		10.02		10.02		
	Z_s	(cm)			2.15			
	Z_b	(cm)					2.15	
	Z_{MI}	(cm)	2.15					
	$Z_{pii.\alpha}$	(cm)	2.15					
	f_{awf}	(MHz)	2.25	2.25		2.25		2.22
Other Information	prr	(Hz)	-					
	srr	(Hz)	18.94					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	79.17					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.79					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.82					
	p_r at Z_{pii}	(MPa)	1.79					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		3.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	2.00	2.00		2.00		2.00
	PRF	HZ	-	-		-		-

Transducer Model: 3C

Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.12	0.26		0.58		0.36
Index component Value				0.26	0.18	0.26	0.58	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.65					
	P	(mW)		20.12		20.12		20.12
	P_{1*1}	(mW)		14.58		14.58		
	Z_s	(cm)			1.52			
	Z_b	(cm)					2.22	
	Z_{MI}	(cm)	2.05					
	$Z_{pii.\alpha}$	(cm)	2.05					
	f_{awf}	(MHz)	2.16	2.16		2.16		2.16
Other Information	prr	(Hz)	346					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	80.46					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	8.77					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	8.89					
	p_r at Z_{pii}	(MPa)	1.75					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		3.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	2.00	2.00		2.00		2.00
	PRF	HZ	-	-		-		-

Transducer Model: 3C

Operation Mode: B+C

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.88	0.22		0.22		0.50
Index component Value				0.22	0.22	0.22	0.22	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.39					
	P	(mW)		24.21		24.21		28.90
	P_{1*1}	(mW)		18.68		18.68		
	Z_s	(cm)			3.20			
	Z_b	(cm)					3.20	
	Z_{MI}	(cm)	2.60					
	$Z_{pii.\alpha}$	(cm)	2.60					
	f_{awf}	(MHz)	2.51	2.48		2.48		2.38
Other Information	prr	(Hz)	-					
	srr	(Hz)	6.49					
	n_{pss}	NA	8.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	94.79					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.50					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.51					
	p_r at Z_{pii}	(MPa)	1.73					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		5.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	3.00	3.00		3.00		3.00
	PRF	HZ	-	-		-		-

Transducer Model: 3C

Operation Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.63	0.20		0.74		0.38
Index component Value				0.15	0.20	0.16	0.74	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.00					
	P	(mW)		21.79		18.92		22.59
	P_{1*1}	(mW)		12.61		14.60		
	Z_s	(cm)			1.40			
	Z_b	(cm)					3.20	
	Z_{MI}	(cm)	3.05					
	$Z_{pii.\alpha}$	(cm)	3.05					
	f_{awf}	(MHz)	2.48	2.47		2.50		2.45
Other Information	prr	(Hz)	2000					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	40.29					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	109.67					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	213.87					
	p_r at Z_{pii}	(MPa)	1.22					
Operating control conditions	Focus	(cm)	4.00	11.00		4.00		7.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	3.00	3.00		3.00		3.00
	PRF	HZ	2000	2000		2000		2000

Transducer Model: 6MC

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.05	0.11		0.11		0.25
Index component Value				0.11	0.11	0.11	0.11	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	**(MPa)**	1.58					
	P	**(mW)**		10.02		10.02		12.62
	P_{1*1}	**(mW)**		10.02		10.02		
	Z_s	**(cm)**			2.15			
	Z_b	**(cm)**					2.15	
	Z_{MI}	**(cm)**	2.15					
	$Z_{pii.\alpha}$	**(cm)**	2.15					
	f_{awf}	**(MHz)**	2.25	2.25		2.25		2.22
Other Information	**prr**	**(Hz)**	-					
	srr	**(Hz)**	18.94					
	n_{pss}	**NA**	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	**(W/cm^2)**	79.17					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	**(mW/cm^2)**	0.79					
	I_{spta} at Z_{pii} or Z_{sii}	**(mW/cm^2)**	0.82					
	p_r at Z_{pii}	**(MPa)**	1.79					
Operating control conditions	**Focus**	**(cm)**	3.00	3.00		3.00		3.00
	Depth	**(cm)**	16.00	16.00		16.00		16.00
	Freq	**MHz**	2.00	2.00		2.00		2.00
	PRF	**HZ**	-	-		-		-

Transducer Model: 6MC

Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.12	0.26		0.58		0.36
Index component Value				0.26	0.18	0.26	0.58	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	**(MPa)**	1.65					
	P	**(mW)**		20.12		20.12		20.12
	P_{1*1}	**(mW)**		14.58		14.58		
	Z_s	**(cm)**			1.52			
	Z_b	**(cm)**					2.22	
	Z_{MI}	**(cm)**	2.05					
	$Z_{pii.\alpha}$	**(cm)**	2.05					
	f_{awf}	**(MHz)**	2.16	2.16		2.16		2.16
Other Information	**prr**	**(Hz)**	346					
	srr	**(Hz)**	-					
	n_{pss}	**NA**	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	**(W/cm^2)**	80.46					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	**(mW/cm^2)**	8.77					
	I_{spta} at Z_{pii} or Z_{sii}	**(mW/cm^2)**	8.89					
	p_r at Z_{pii}	**(MPa)**	1.75					
Operating control conditions	**Focus**	**(cm)**	3.00	3.00		3.00		3.00
	Depth	**(cm)**	16.00	16.00		16.00		16.00
	Freq	**MHz**	2.00	2.00		2.00		2.00
	PRF	**HZ**	-	-		-		-

Transducer Model: 6MC

Operation Mode: B+CFM

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.88	0.22		0.22		0.50
Index component Value				0.22	0.22	0.22	0.22	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	**(MPa)**	1.39					
	P	**(mW)**		24.21		24.21		28.90
	P_{1*1}	**(mW)**		18.68		18.68		
	Z_s	**(cm)**			3.20			
	Z_b	**(cm)**					3.20	
	Z_{MI}	**(cm)**	2.60					
	$Z_{pii.\alpha}$	**(cm)**	2.60					
	f_{awf}	**(MHz)**	2.51	2.48		2.48		2.38
Other Information	**prr**	**(Hz)**	-					
	srr	**(Hz)**	6.49					
	n_{pss}	**NA**	8.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	**(W/cm^2)**	94.79					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	**(mW/cm^2)**	0.50					
	I_{spta} at Z_{pii} or Z_{sii}	**(mW/cm^2)**	0.51					
	p_r at Z_{pii}	**(MPa)**	1.73					
Operating control conditions	**Focus**	**(cm)**	3.00	3.00		3.00		5.00
	Depth	**(cm)**	16.00	16.00		16.00		16.00
	Freq	**MHz**	3.00	3.00		3.00		3.00
	PRF	**HZ**	-	-		-		-

Transducer Model: 6MC

Operation Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.63	0.20		0.74		0.38
Index component Value				0.15	0.20	0.16	0.74	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	**(MPa)**	1.00					
	P	**(mW)**		21.79		18.92		22.59
	P_{1*1}	**(mW)**		12.61		14.60		
	Z_s	**(cm)**			1.40			
	Z_b	**(cm)**					3.20	
	Z_{MI}	**(cm)**	3.05					
	$Z_{pii.\alpha}$	**(cm)**	3.05					
	f_{awf}	**(MHz)**	2.48	2.47		2.50		2.45
Other Information	**prr**	**(Hz)**	2000					
	srr	**(Hz)**	-					
	n_{pss}	**NA**	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	**(W/cm^2)**	40.29					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Zsii.\alpha$	**(mW/cm^2)**	109.67					
	I_{spta} at Z_{pii} or $Zsii$	**(mW/cm^2)**	213.87					
	p_r at Z_{pii}	**(MPa)**	1.22					
Operating control conditions	**Focus**	**(cm)**	4.00	11.00		4.00		7.00
	Depth	**(cm)**	16.00	16.00		16.00		16.00
	Freq	**MHz**	3.00	3.00		3.00		3.00
	PRF	**HZ**	2000	2000		2000		2000

Transducer Model: 6E

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.36	0.12		0.12		0.16
Index component Value				0.12	0.12	0.12	0.12	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	0.78					
	P	(mW)		4.14		4.14		4.14
	P_{1*1}	(mW)		4.14		4.14		
	Z_s	(cm)			2.65			
	Z_b	(cm)					2.65	
	Z_{MI}	(cm)	2.30					
	$Z_{pii.\alpha}$	(cm)	2.30					
	f_{awf}	(MHz)	4.70	5.84		5.84		5.84
Other Information	prr	(Hz)	-					
	srr	(Hz)	51.75					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	20.92					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.04					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.08					
	p_r at Z_{pii}	(MPa)	1.04					
Operating control conditions	Focus	(cm)	1.50	1.50		1.50		1.50
	Depth	(cm)	8.20	8.20		8.20		8.20
	Scanning width	%	-	-		-		-
	PRF	Hz	-	-		-		-
	Freq	MHz	5.30	6.00		6.00		6.00
	Power	(%)	100.00	100.00		100.00		100.00

Transducer Model: 6E

Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.36	0.06		0.06		0.09
Index component Value				0.06	0.06	0.06	0.06	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	0.78					
	P	(mW)		2.14		2.14		2.14
	P_{1*1}	(mW)		2.14		2.14		
	Z_s	(cm)			2.30			
	Z_b	(cm)					2.30	
	Z_{MI}	(cm)	2.30					
	$Z_{pii.\alpha}$	(cm)	2.30					
	f_{awf}	(MHz)	4.70	4.70		4.70		4.70
Other Information	prr	(Hz)	-					
	srr	(Hz)	42.35					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	20.92					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.03					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.07					
	p_r at Z_{pii}	(MPa)	1.04					
Operating control conditions	Focus	(cm)	1.50	1.50		1.50		1.50
	Depth	(cm)	8.20	8.20		8.20		8.20
	Scanning width	%	-	-		-		-
	PRF	Hz	-	-		-		-
	Freq	MHz	5.30	5.30		5.30		5.30
	Power	(%)	100.00	100.00		100.00		100.00

Transducer Model: 6E

Operation Mode: B+CFM

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.37	0.04		0.04		0.08
Index component Value				0.04	0.04	0.04	0.04	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	0.73					
	P	(mW)		2.06		2.06		2.06
	P_{1*1}	(mW)		2.06		2.06		
	Z_s	(cm)			2.20			
	Z_b	(cm)					2.20	
	Z_{MI}	(cm)	2.10					
	$Z_{pii.\alpha}$	(cm)	2.10					
	f_{awf}	(MHz)	4.00	3.98		3.98		3.98
Other Information	prr	(Hz)	-					
	srr	(Hz)	150.18					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	21.72					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.09					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.17					
	p_r at Z_{pii}	(MPa)	0.95					
Operating control conditions	Focus	(cm)	1.50	2.50		2.50		2.50
	Depth	(cm)	8.20	8.20		8.20		8.20
	Scanning width	%	-	-		-		-
	PRF	Hz	3500.00	3500.00		3500.00		3500.00
	Freq	MHz	5.00	5.00		5.00		5.00
	Power	(%)	100.00	100.00		100.00		100.00

Transducer Model: 6E

Operation Mode: B+PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.32	0.11		0.27		0.22
Index component Value				0.11	0.08	0.10	0.27	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	0.64					
	P	(mW)		5.82		5.34		5.82
	P_{1*1}	(mW)		5.82		5.34		
	Z_s	(cm)			1.00			
	Z_b	(cm)					2.00	
	Z_{MI}	(cm)	1.65					
	$Z_{pii.\alpha}$	(cm)	1.65					
	f_{awf}	(MHz)	3.97	3.95		3.95		3.95
Other Information	prr	(Hz)	1750.00					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	13.53					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	21.83					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	35.22					
	p_r at Z_{pii}	(MPa)	0.79					
Operating control conditions	Focus	(cm)	4.00	3.50		2.50		3.50
	Depth	(cm)	8.20	8.20		8.20		8.20
	Scanning width	%	-	-		-		-
	PRF	Hz	1750.00	6000.00		6000.00		6000.00
	Freq	MHz	5.00	5.00		5.00		5.00
	Power	(%)	100.00	100.00		100.00		100.00

Appendix C: Guidance and Manufacturer's Declaration

1. Guidance and manufacturer's declaration – electromagnetic emissions		
The SonoAir series is intended for use in the electromagnetic environment specified below. The customer or the user of the SonoAir series should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SonoAir series uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SonoAir series is suitable for use in medical establishments including domestic establishments and those directly connected to the public high-voltage power supply network that used for non-domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

2. Guidance and manufacturer's declaration – electromagnetic immunity		
The SonoAir series is intended for use in the electromagnetic environment the SonoAir series should assure that it is used in such an environment.		
Immunity test	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ±2 kV,±4 kV, ±8 kV, ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Electrical fast transient/burst IEC 61000-4-4	± 2 kV , 100 kHz, for AC power port	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0 % UT, 1 cycle and 70 % UT, 25/30 cycles Single phase: at 0° 0 % UT, 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SonoAir series requires continued operation during power mains interruptions, it is recommended that the SonoAir series be powered from an uninterruptible power supply or a battery.
Power frequency frequency (50-60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

<table>
<tr><td colspan="3">3. Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="3">The SonoAir series is intended for use in the electromagnetic environment specified below. The customer or the user of the SonoAir series should assure that it is used in such an environment.</td></tr>
<tr><td>3.1. Immunity test</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Radiated RF EM fields
IEC 61000-4-3</td><td>3V/m, 80MHz-2.7GHz
80%AM at 1kHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the SonoAir series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1,2 \sqrt{P}$
$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz
$d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz
where P is the maximum output power rating o the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,. should be less than the compliance level in ea frequency range.b
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>150 kHz to 80 MHz, 3Vrms
ISM band, 6Vrms</td></tr>
</table>

NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SonoAir series is used exceeds the applicable RF compliance level above, the SonoAir series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SonoAir series. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communication equipment and the powered endoscopic linear cutting staplers and components for single use

Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The Digital Color Doppler Ultrasound System has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the Digital Color Doppler Ultrasound System recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation	2	0.3	28

			1 kHz sine			
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Except for cables sold as spare parts for internal components, the use of accessories and cables outside the regulations may result in increased emission or a decreased immunity of the powered stapler for single use. This device contains the following cables:

Cable or transducer	**Manufacturer**	**Model and specification**
Power cable	KING-CORD	2m long, 60227IEC 53 (RVV) 3×0.75mm^2 300/500V unshielded wire
Cable of powered supply	MEGMEET	1.2m long, 2464 18AWG VW-1 80℃ 300V unshielded wire,1core
Cable of probe	CHISON	2m,shielded wire

Appendix D: Measurement Results Summary

Measurement	**Useful Range**	**Accuracy**
Distance	Image Area	<±5%
Circumference: trace method, ellipse method	Image Area	<±5%
Area: trace method, ellipse method	Image Area	<±10%
Volume	Image Area	<±5%
Angle	Image Area	<±5%

Appendix E: Display Accuracy and Acoustic Measurement Uncertainties

Overall uncertainties

Center Frequency: The accuracy of the center frequency measurement is primarily dependent on the digitizer, and is therefore given as ± 15%.

Pressure: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 15%.

Intensity and Power: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 30%.

It can be summarized in below table:

Item	**Measurement Uncertainty (95% Confidence Level)**
Center Frequency	±15%
Pressure	±15%
Power	±30%
Intensity	±30%

Appendix F: Transducer Maximum Surface Temperature

According to the requirements of the section 201.11 in the standard IEC60601-2-37:2007/AMD1:2015, the transducer surface temperature has been tested in two kinds of conditions**:** the transducer suspended in still air or transducer contacting human-tissue mimicking material. The calculation of the expanded uncertainty is based on the ISO Guide tout ye Expression of uncertainty in measurement. Three transducer samples have been tested and the confidence coefficient is at 95%, the value of t.975 is 4.30.

The measurement data were obtained under the test conditions employed at CHISON.

Transducer model	**Maximum surface temperature(℃)** **Contacting human-tissue mimicking material**	**Maximum surface temperature(℃)** **Suspending in air**
7L	≤37.4	≤32
3S	≤38.8	≤34.1
3C	≤37.6	≤31.4
6MC	≤37.6	≤31.4
6E	≤39.7	≤30.7

⚠NOTE

Values following the "±"mark indicate the expanded uncertainty with a confidence lever of 95%, t.975=4.30.

Appendix G: Pulsed Wave Doppler Velocity Measurement Results Summary

Probe type: 7L, Scan mode: PW, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.76	106.82	161.34
Measurement Error (%)	7.60%	6.82%	7.56%

Probe type: 7L, Scan mode: CFM,fc: 6.5MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.12	54.95	108.64
Measurement Error (%)	-8.80%	9.90%	8.64%

Probe type: 3S, Scan mode: PW, fc: 2.5MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.21	97.42	148.14
Measurement Error (%)	2.10%	-2.58%	-1.24%

Probe type: 3S, Scan mode: CFM, fc:2.5MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.56	53.69	106.84
Measurement Error (%)	5.60%	7.38%	6.84%

Probe type: 3C, Scan mode: PW, fc: 3.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.26	107.64	138.74
Measurement Error (%)	2.60%	7.64%	-7.50%

Probe type: 3C, Scan mode: CFM, fc: 3.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.62	51.69	102.64
Measurement Error (%)	-3.80%	3.38%	2.64%

Probe type: 6MC, Scan mode: PW, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.54	105.22	141.25
Measurement Error (%)	5.40%	5.22%	-5.83%

Probe type: 6MC, Scan mode: CFM, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.52	52.15	97.75
Measurement Error (%)	5.20%	4.30%	-2.25%

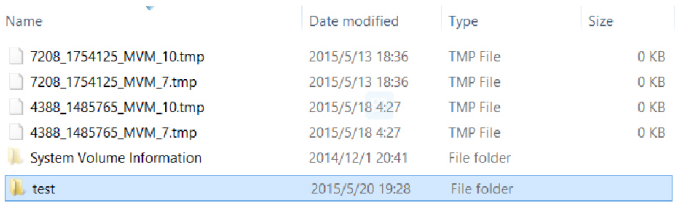
Probe type: 6E, Scan mode: PW, fc: 9.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.26	104.62	148.24
Measurement Error (%)	2.60%	4.62%	-1.17%

Probe type: 6E, Scan mode: CFM, fc: 9.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.82	52.69	102.84
Measurement Error (%)	-1.80%	5.38%	2.84%

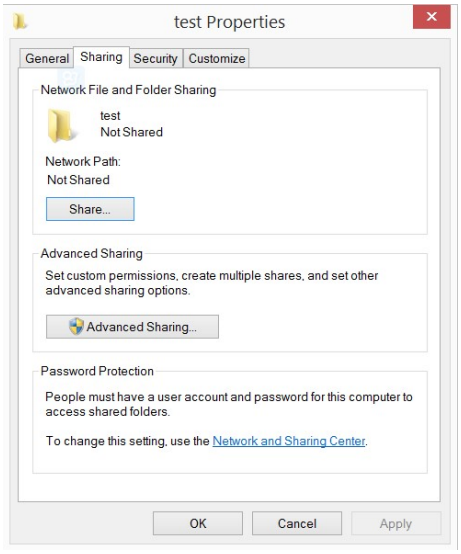
Appendix H: Procedures of setting network sharing

For Windows set up, set up a shared document

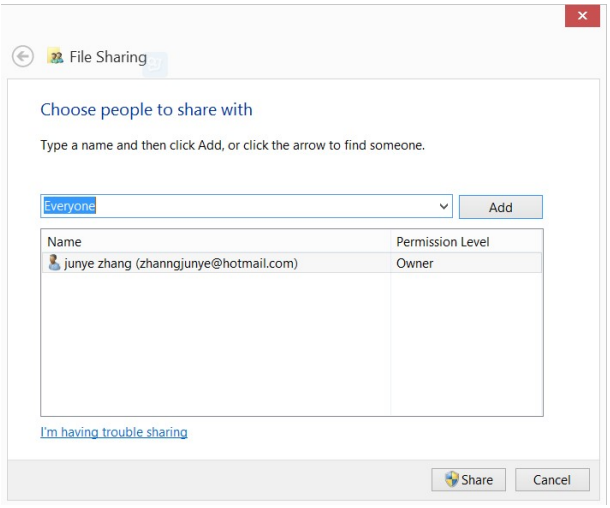
1. Choose the file you want to share, as the “test” file.



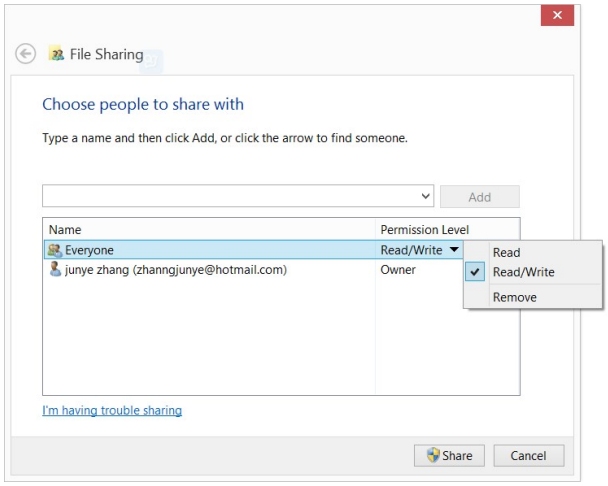
2. Right click this file, choose “properties”, and click “share”.



3. Then you can see the sharing setting interface, as you can see in the picture, choose “everyone”, and click “add”.

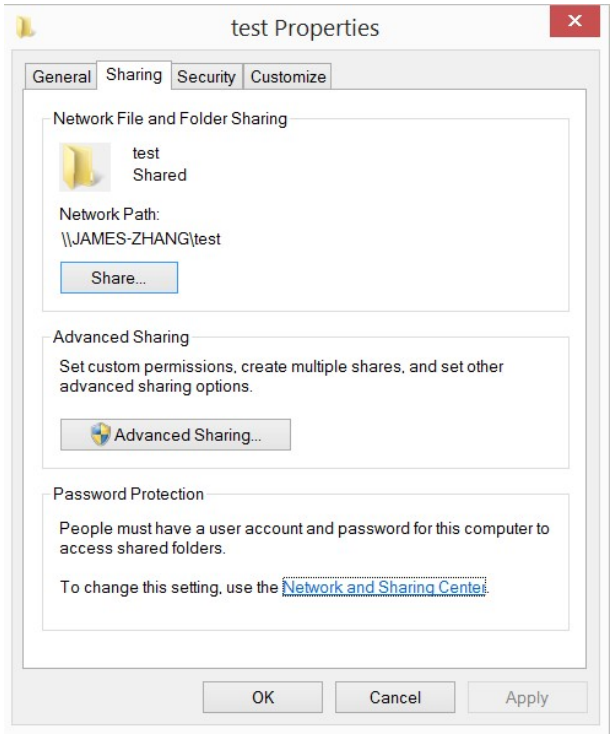


4. Choose “read/write” in the permission level in everyone, then click “share”, after that, confirm.

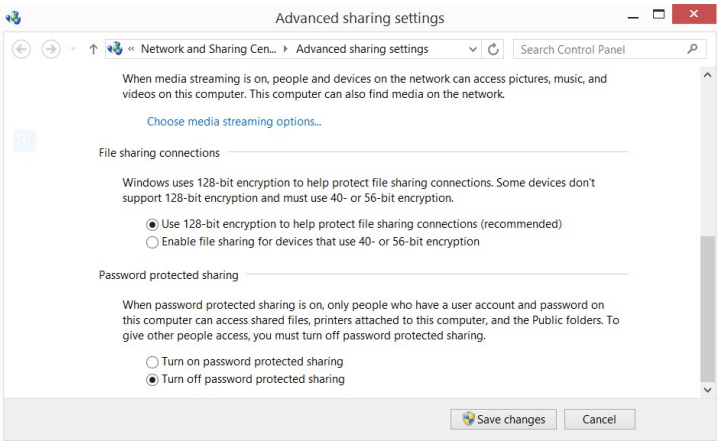


5. If the windows have not set the code, then turn off the password protected sharing is necessary. Instructions as the image shows.

a) Click “network and sharing center” in the sharing properties.



b) In the network and sharing center interface, choose “public”, in the password protected sharing; choose turn off password protected sharing.

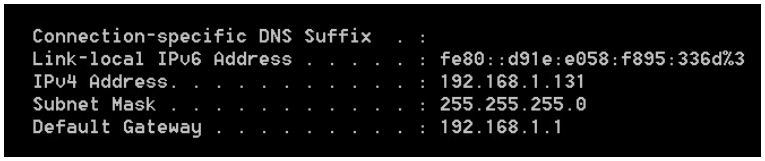


Set up in system

IP set up

1. First confirm the service address of shared files, you can get the IP address in windows interface.

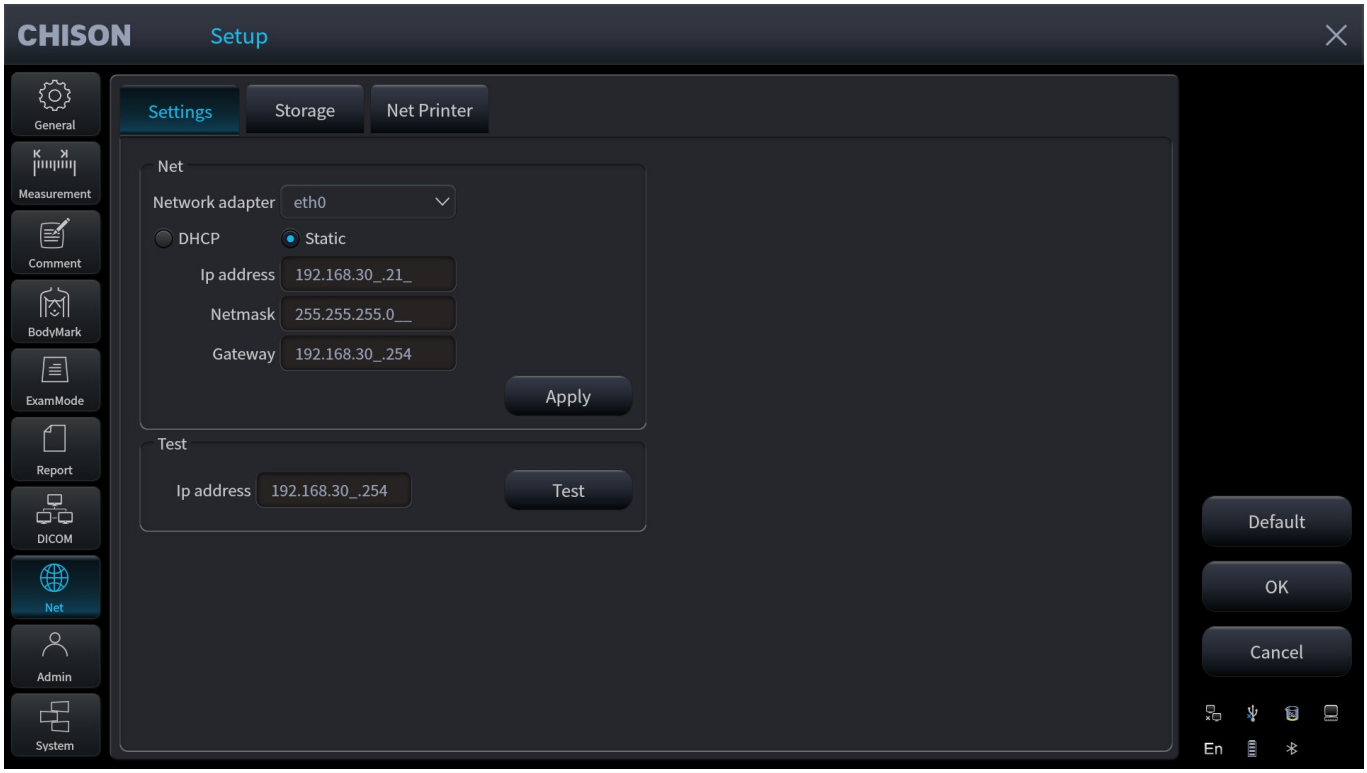
In windows “start”-“run” type in “cmd” and enter, then type in “ ipconfig” and enter, you can see the IP address of local service.



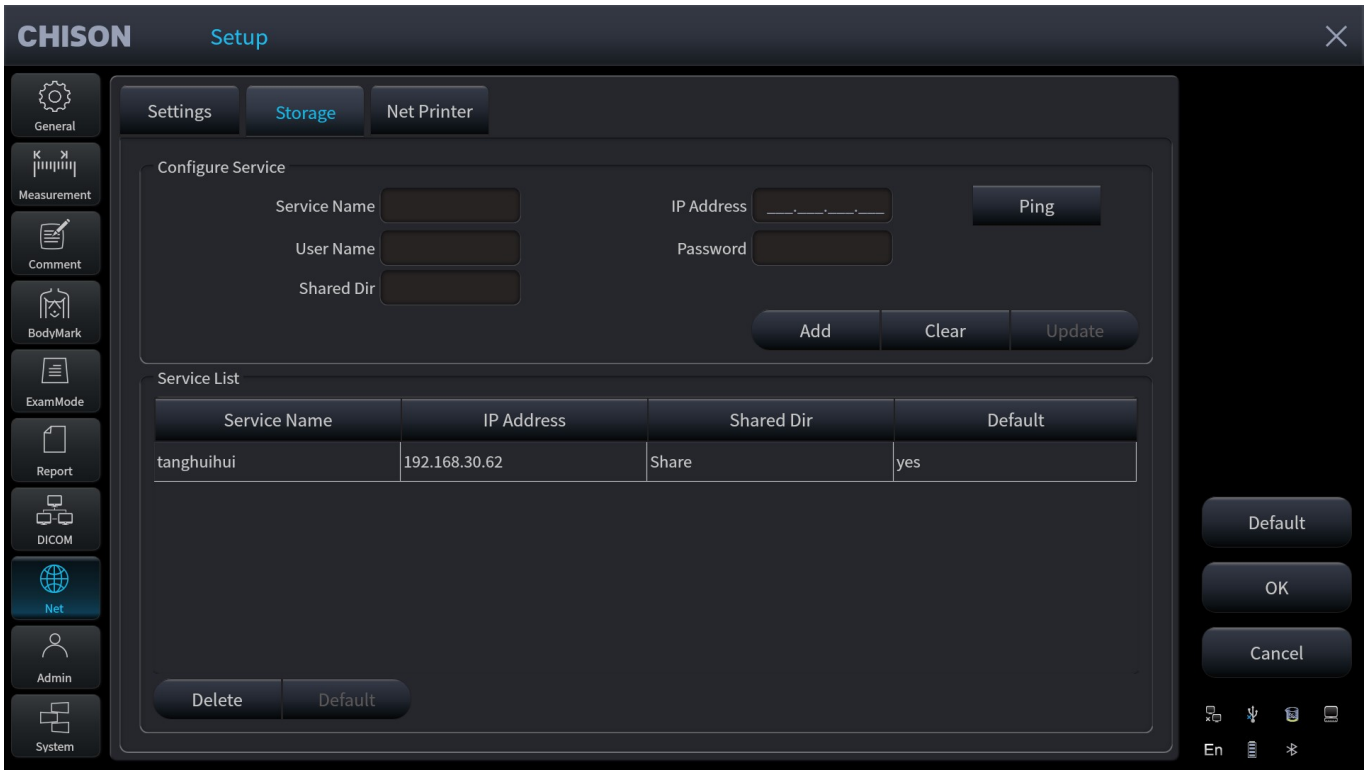
2. Press【SETUP】key to enter into set up interface. Choose Net setting. Then choose Net Address interface. Choose “DHCP” (automatically get the IP address) or “static” (type in IP address manually).

TIP

If you want to type in IP address manually, make sure the IP address is in the same internet section with the service, and won’t confused with other IP in the LAN.



3. Choose “Storage” interface, type in service name, IP address, user name, password and the name of shared files, click “Add” to add a network storage, you can choose the export route. As shown in the picture.



Ping: test if the IP is connected or not.

Clear: clear all the IP address, user name, password and names of shared file

Update: update the content to the chosen item.

Delete: delete the chosen service item.

Default: set the chosen item as the default net route.

⚠*NOTE*

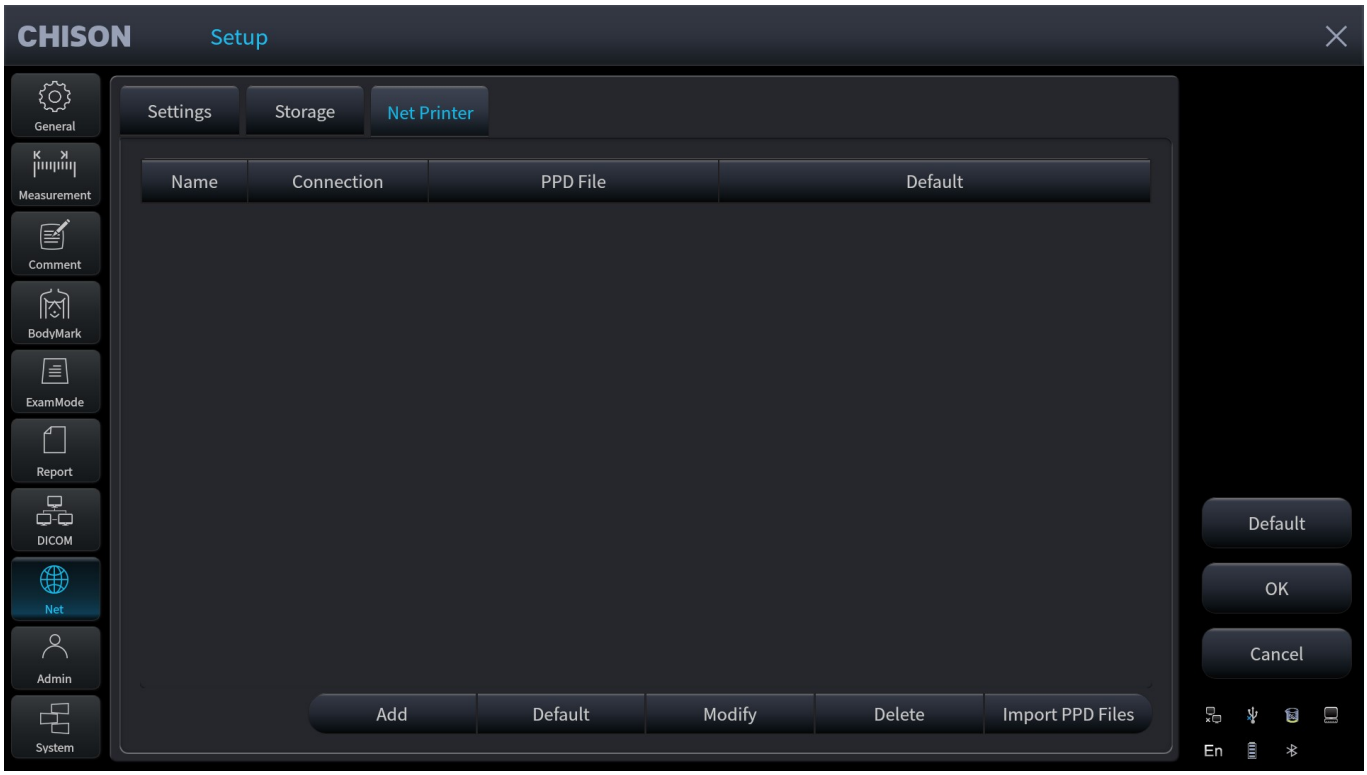
You can add multi-numbers of network storage service to realize the transmission among multi systems.

⚠*NOTE*

If windows turn off password protected sharing, then in SonoAir set up, you can type in user name and password arbitrarily.

Net Printer Setup

1. Press【SETUP】key to enter into the setup interface, then click Net setting. Choose Net Printer. See picture as follows:



2. Configure Net Printer

Operation:

a) Input name and IP Address which has installed printer equipment.

b) Click **[Ping]** to confirm whether the net connect normally.

c) Select PPD File and click **[Add]**, the net connecting information can be saved on the Printer List.

3. Choose the information on the Printer List to finish the printing according to the requirement.

CHISON
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