CHISON

Value Beyond Imaging

Ultrasound Diagnostic System

Model

ECO 1

ECO 3

March 5, 2014

OPERATION MANUAL

Direction: CHUM ECO-001

V1.4b

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 ECO3/ECO1. Please verify that you are using the latest revision of this document. If you need the latest revision, contact your distributor.

Important

1.No part of this manual may be reduced, 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.

Important information

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 the software or hardware of this system and probes.

4.During operate the system, if user has any doubt, difficulty or any unclear, please contact CHISON's authorized service engineer immediately. Please describe the situation clearly to solve the question in time. Before solve the question, please don’t operate the system.

5.This system shall not be used by persons other than fully qualified and certified medical personnel.

6.It is prohibited the device is used for checking fetus gender, except the necessary medical requirement. The device can only be sold to qualified medical institutions and doctors. The users should fully understand and grasp the products strictly in according to the local laws and regulations to carry out. At the same time, the users should comply with local religion and customs, etc.

7.The System modified or repaired by people other than CHISON’s qualified service engineers, CHISON shall not be liable for the system.

8.The purpose of this 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 of diagnostic procedures

9.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.

10. Due to negligence not following operation manual, CHISON shall not be liable for the results.

11. Each time before and after ultrasound examination, please check the probe surface, probe cable and sheath whether they are abnormal, such as cracking, peeling and deformation. Also check whether the lens is strongly fixed. Abnormal probes may cause electric shock and injure the patient. Once any abnormal, user must stop using and contact CHISON's authorized service engineer.

12. If the probe is dropped or scratched by hard part, please stop using the probe immediately. And contact CHISON's authorized service engineer to make sure the safety and effectiveness is in good condition before use.

13. If there is any liquid or metal to enter to the system, please power off the system and stop using it immediately. Please first contact CHISON’s authorized service engineer to make sure it’s safe before restart using it.

14. Please don't use solvents (such as paint thinner, benzine, or alcohol) or abrasive cleansers for cleaning the system (including monitor and probes, etc). It may corrode the system and probes.

15. While the system or probe is over life time, please refer to operation manual section 9.4

16. 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.

17. Please put this operation manual with the system to ensure operator and manager can reach it at any time.

Caution： It is prohibited the device is used for checking fetus gender, except the necessary medical requirement. The device can only be sold to qualified medical institutions and doctors. The users should fully understand and grasp the products strictly in according to the local laws and regulations to carry out. At the same time, the users should comply with local religion and customs, etc.

Caution： The users should read the operation manual before operate the device. Turn on the device means the users have read the operation manual and accept the items of the caution. If the users disagree and don’t accept, the user can request to return the goods.

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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 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ(breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal.

Contraindication

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

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 Imaging Co., Ltd.
Tel:0086-0510-85311707
Fax: 0086-0510-85310726
E-mail: service@chison.com.cn

Placing an Order CHISON Medical Imaging Co., Ltd.
Tel: 0086-0510-8531-0593/0937
Fax: 0086-0510-85310726
Email: export@chison.com.cn

Manufacturer CHISON Medical Imaging Co., Ltd.
No. 8, Xiang Nan Road, Shuo Fang,
New District, Wuxi, China 214142

US Agent: MR. NANPING WU, 3040 Edenberry Street, Madison, WI 53711 USA
Phone: 608-277-9432, Fax: 920-648-1584
Email: nanpingwu@yahoo.com

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 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 or even loss of life for operator or patient.**

Users should observe the following precautions:

- This system complies with Type BF general equipment, and the IEC standard.
- Do not modify this system in any way. Necessary modifications must be made only by the manufacturer or its designated agents.
- This system has been fully adjusted at the factory. Do not adjust any fixed adjustable parts.
- In the event of a malfunction, turn off the system immediately and inform the manufacturer or its designated agents.
- The power cable of the system should only be connected to a grounded power socket. Do not remove the ground cable for any reason.
- 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.
- 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.
- The system should be installed only by personnel authorized by the manufacturer. Do not attempt to install the system by yourself.
- Only an authorized service engineer may perform maintenance.
- Only a qualified operator, or someone under qualified supervision, should use the system.
- Do not use this system in the presence of flammable substances, otherwise an explosion may occur.
- Do not continuously scan the same part of a patient or expose the patient to prolonged scanning, otherwise it may harm the patient.
- When using the system for ultrasound testing, use only qualified ultrasound gel that complies with system standards.
- Do not unplug probe when the system is in active operation. Always go to EXAM screen when need to remove the probe.
- 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.
- 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 I Equipment**

CLASS I EQUIPMENT in which protection against electric shock does not rely on BASIC INSULATION only, but includes a protective earth ground. This additional safety precaution prevents exposed metal parts from becoming LIVE in the event of an insulation failure.

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

BF: Isolation from ground; max. Patient leakage current: normal mode ≤100 μA, single fault condition ≤ 500 μA

Level of protection against harmful ingress of water

- Parts of **probe** likely to come into contact with **operator** or **patient** meet the requirements of **drip-proof equipment (**IP**X1)**

  Parts of **probe** intended to be immersed in **normal use** meet the requirements of **watertight equipment** (IPX7)
- The IP Classification of System is Ordinary Equipment (IPX0)

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)

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 by 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.

Notice against User Modification

The user should never modify this product.

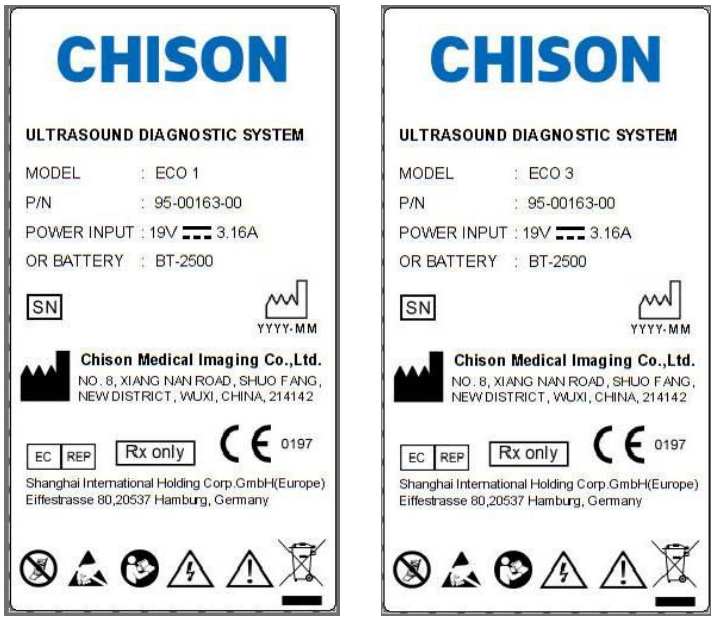
User modifications may cause degradation in Electrical Safety . Modification of the product includes changes in:

- ●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)

2.3 Lables



Real panel label

2.3.1 Warning Symbols

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 can not be presented on the device itself.	Dangerous electric voltage. Unplug the main plug before opening the system!
Do not use the following devices near this equipment: cellular phone, radio receiver, 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.	Be careful of static.
WASTE OF ELECTRICAL AND	The CE mark of Conformity indicates this

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.	equipment conforms with the Council Directive 93/42/EEC
AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.	Insulated patient application part (Type BF)
This symbol is followed by the serial number of the device.	MANUFACTURER: This symbol is accompanied by the name and the address of the manufacturer.
Power On/off. **CAUTION:** This Power Switch **can isolate** Mains Supply.	This symbol signifies that the user manual must be read.
The "Alternating current" symbol indicates that the equipment is suitable for alternating current only.	**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.
 This symbol is followed by the manufacturing date of the device in the form YYYY-MM.	

2.4 Patient Environmental Devices

Left side:

- 1 LAN port
- 1 VGA port: External monitor
- 2 USB ports
- 1 Footswitch port

- 1 Power in port

Rear panel:

- 2 Probe ports
- 1 USB port
- 1 BNC port
- 1 Video out port
- Battery holder
- Probe holder

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 result. Use only the accessories, options and supplies approved or recommended in these instructions for use.

Peripheral used in the patient environment

The system has been verified for overall safety, compatibility and compliance with the following on-board image recording devices:

B/W video printer: Sony SONY UP-711MD

The system may also be used safely while connected to devices other than those recommended above if the devices and their specifications, installation, and interconnection with the system conform to the requirements of IEC/EN60601-1-1.

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 60601-1-1 by the installer. Equipment modifications and possible resulting malfunctions and electromagnetic interference are the responsibility 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 60950 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.

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 bioeffect 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 bioeffects 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),

$$R_F = 10^{(-0.1\ a\ f\ z)}$$

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 R_F 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

$I'=I*R_F$ 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
			Large aperture (>1cm^2)	
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:

Describes 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 (W_{deg}), TI = $W.3/W_{deg}$.

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:

W_{deg} = 210/fc, for model 1 to 4, where fc is the center frequency in MHz.

W_{deg} = 40 K D for 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, 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 bioeffects (MI) or thermal bioeffects (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 bioeffect 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 TGC.

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 effect 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.

Chapter 3 System Introduction

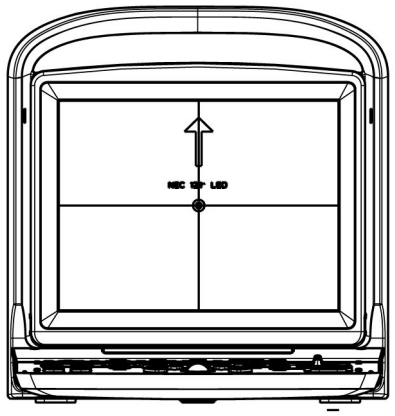
3.1 Consol Overview

Console Overview

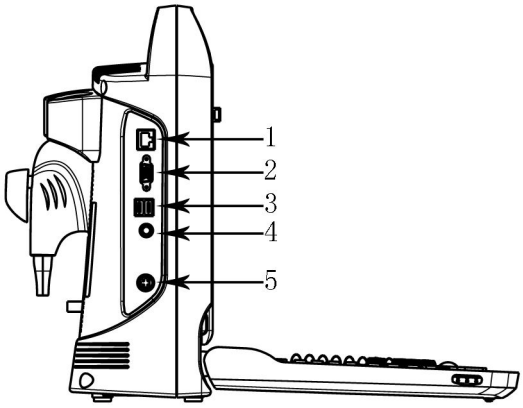
3.2 Physical Specification

335mm（Length）×155mm（Width）×350mm（Height）

3.3 System View in Different Views

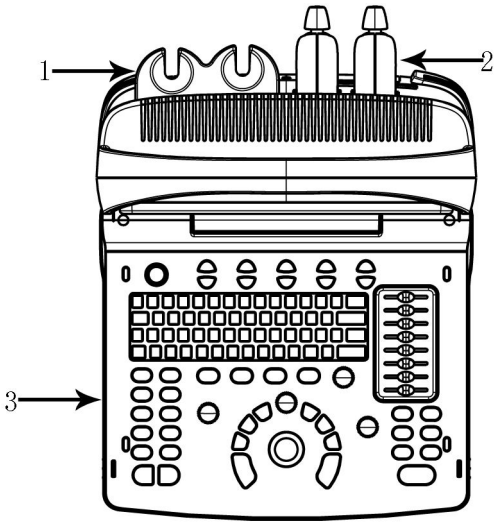


System Front View



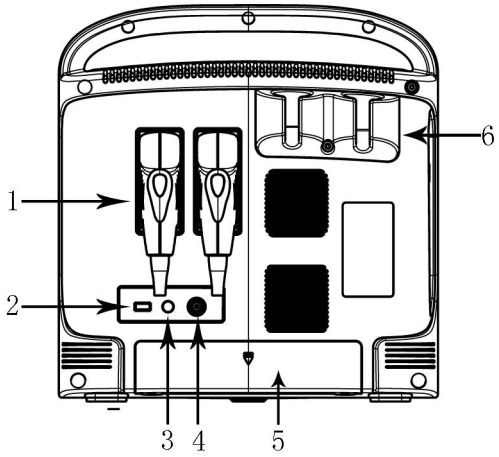
System Side View

1.Ethernet 2.VGA 3.USB 4.Footswicth 5.Power in



Console Overview

1.Probe Holder 2.Probe 3.Keyboard



System Rear View

1. Probe 2.USB 3.BNC 4. Video 5.Battery Holder 6. Probe Holder

3.4 Function Introduction

1.Possess B, B/B, 4B, B/M, M display mode M, B/M mode possess 4 kinds of scan velocity;
2.Possess many combination of focus, total gain control 8 segments STC;
3.Possess depth scan and image left-right up-down rolling-over function;
4.Possess a lot of imaging technology for example multiple compound imaging (space frequency compound), multiple frequency, multiple zoom ratio, pan zoom, screen scroll, chroma, harmonic imaging etc;
5.Possess image processing, total gain, dynamic range, frequency, focus number, focus position, zoom, compound, scan width, line density, smooth, edge enhancement, frame, persistence, gray scale, restrain boost multi-beam, acoustic power, M velocity;
6.Possess distance proportion circumference volume rate angle histogram in B mode distance time velocity heart rate measurement function in M mode ;GYN measurement software package, small parts measurement software package, ventricle function measurement software package and user defined formula;
7.Possess body mark arrow case number display, real time clock display annotation in image user-defined annotation;
8.Possess multi-language interface display User interface change, shear plate, printing ,DICOM3.0 biopsy guided functions;
9.It has permanent storage for image and cine and optional 320GB HDD. It can also be connected to removable storage via USB port. To realize mass storage ,can recall saved image for analysis;
10. Cine loop storage 256frames real time image;
11. Screen rotation function make you adjust screen angle according to users' requirement 0~30°;
12. Output standard PAL or NTSC video signal and VGA signal;
13. Print or export graphic report.

3.4.1 Image Modes

- B mode
- B/M mode
- M mode

- 2B mode
- 4B mode

3.4.2 Accessories

Transducers:

 C3-A, 2.5-5.0MHz Convex Array Indications for Use: Fetal/OB; Abdominal (GYN & Urology); Pediatric;	 L7M-A, 5.3-10.0MHz Linear Array Indications for Use: Pediatric; Small Organ(breast, testes, thyroid); Peripheral Vascular, Musculo-skeletal Conventional & Superficial;
 L7S-A, 5.3-11.0MHz Linear Array Indications for Use: Pediatric; Small Organ(breast, testes, thyroid); Peripheral Vascular, Musculo-skeletal Conventional & Superficial;	 V6-A, 4.5-8.0MHz Micro-convex Array Indications for Use: OB; GYN & Urology; Transvaginal;
 R7-A, 5.0-10.0MHz Linear Array Indications for Use: Urology; Transrectal;	 MC6-A, 4.5-8.0MHz Convex Array Indications for Use: AAbdominal (GYN & Urology); Pediatric; Small Organ(breast, testes, thyroid); Cardiac (pediatric);
 MC3-A ,2.5-5.0MHz Convex Array Indications for Use: Abdominal (GYN & Urology); ; Cardiac (adult & pediatric);	 P3-A, 2.5-4.5MHz Phased Array Indications for Use: Cardiac (adult & pediatric);

Peripherals

VGA output for external monitor

VIDEO output for B&W video printer

LAN port output

LAN for DICOM and image review station

USB 2.0 for flash drive

Foot switch

AC/DC adapter:GTMB1057-6019,

Input: 100-240V~, 50-60Hz, 1.5A max.

Output: 19V ⎓ 3.16A.

GLOBTEK INC, adapter is a part of ME equipment.

Battery Pack :BT-2500, 4400mAh,DONGGUAN POWER INC

3.4.3 Configuration of the System

Configuration	ECO1	ECO3
Color	Grey/White	Black/White
Probe	1(standard), 2(option)	2(standard)
Maximum memory	256MB	8GB
320G HDD	No	Option
Built in battery	Option	Standard
Compound, THI, i-Image	No	Standard
Trapezoidal	No	Standard
Chroma	No	Standard
DICOM 3.0	Option	Option
Graphic Printer	Option	Option: HP LaserJet P2055d
Probe configuration	Six: C3-A, V6-A, MC3-A, L7M-A, L7S-A, MC6-A	Eight: C3-A, V6-A, MC3-A, L7M-A, L7S-A, MC6-A, P3-A, R7-A

3.5 Installation Procedures

Note: Please do not turn on the power switch until finishing all the installation and necessary preparation.

3.5.1 Environment Condition

The system should be operated under the following environment.

3.5.1.1 Operation Environment Requirement

Ambient Temperature: 10 ℃～40 ℃
Relative Humidity: 30%～75%RH
Atmospheric Pressure: 700hPa～1060hPa

3.5.1.2 Transport and Storage Environmental Requirement

The following environmental transport and storage conditions are within system tolerances:

Temperature: -5º C ~ 40º C

Relative Humidity:≤ 80% non-condensing

Atmosphere Pressure:700hPa ~ 1060hPa

3.5.1.3 Electrical Requirements

Power Consumption: less than 60 VA

Voltage Fluctuation

WARNING

Maintain a fluctuation range of less than ±10% of voltage labeling on rear panel of the system, otherwise the system may be damaged.

Grounding

Before connecting the power cable, connect the attached ground protection cable from Equipotentiality terminal on system rear panel to a specialized grounding device.

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.*
- *Line power may vary in different geographic locations. Refer to the detailed ratings on the rear panel of the system for detailed information.*
- **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. If you have any questions about the battery, Short term (less than one month) storage of battery pack: Store the battery in a temperature range between 0 degrees C (32 degrees F) and 50 degrees C(122 degrees F).

  Long term (3 months or more) storage of battery pack: Store the battery in a temperature range between-20 degrees C (-4 degrees F) and 45 degrees C(113 degrees F); Upon receipt of the ECO and before first time usage, it is highly recommended that the customer performs one full discharge/charge cycle. If the battery has not been used for >2 months, the customer is recommended to perform one full discharge/charge cycle. It is also recommended to store the battery in a shady and cool area with FCC (full current capacity).• One Full Discharge/Charge Cycle Process:1. Full discharge of battery to let the ECO automatically shut down.2. Charge the ECO to 100% FCC (full current capacity).3. Discharge of Venue 40 for complete shut down(takes one hour for discharge).• When storing packs for more than 6 months, charge the pack at least once during the 6 month timeframe to prevent leakage and deterioration in performance.

3.5.1.4 Operation Space

Please leave enough free space from the back of the system to ensure well ventilation.
Caution: Leave enough free space from the back of the system, Otherwise, with the increasing of the temperature inside the unit, malfunction may occur.

3.5.1.5 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 equipments.

Before Moving the System

- Press 3 s, system will forced shut down and completely switch off the system.
- 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 handle, 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 and over its center of gravity. Keep the unit still and upright.
- Ensure that the transporting vehicle can bear the weight of system plus the passengers.
- Secure the system firmly with straps or as directed within the vehicle to prevent movement during transport. Any movement, coupled with the weight of the system, could cause it to break loose.

- Drive carefully to prevent damage from vibration. Avoid unpaved roads, excessive speeds, and erratic stops or starts.

3.5.2 Powering the System

3.5.2.1 Acclimation Time

After being transported, the unit requires one hour for each 2.5 º increment if its temperature is below 10 ºC or above 40 ºC.

NOTE

Please keep at least 20 to 30 cm spare space away from the back of the system to ensure well ventilation. Otherwise, with the increasing of the temperature inside the unit, malfunction may occur.

3.5.2.2 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 POWER IN socket at the rear panel of the system， 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.

Press 1 s, system boot,

press and pop up dialog for shut down. Click the enter key then power off.

or press 3 s, system will forced shut down

CAUTION

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

3.5.3 Probe Installment

Caution：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 the damage to the system and the probe.

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 system; otherwise there is possibility of electricity shock.

- Hold the probe connector lock switch, and insert the connector socket vertically.
- Release the probe lock switch.

- Check the locked probe with one hand to make sure that it's not loose, and it's securely connected

CAUTION

- Only power supply at "turn off" state, can install / take-down the probe, otherwise it will damage the machine or the probe.
- When installing and disassembling probe, please put the probe head inside the probe holder, it can prevent the probe falling down to the ground.

3.5.3.1 Probe Disassembly

Turn the dead lock switch 90degree in counterclockwise direction, extract probe connector plug vertically.

3.5.4 Accessories Installment

Caution： Please only use the optional parts provided or suggested by manufacturer! Using other types of optional devices may cause the damage to the system and the connected optional devices.

3.5.4.1 Video printer installment

1.Put video printer stably.
2.Connect cable of video printer to video port in the back of the device. And connect the other side to video signal output port in the rear side.
3.Connect the printer line to print control port in the printer rear side, And connect the other side to the print control port in the unit rear side.
4.Connect power cable of video printer to power system..
5.Adjust printer parameter preset according to the type of printing paper

Caution: Do not use any other power cable to replace 3-wire power cable manufacturer provides, otherwise there is danger of electric shock.

Video printer sign introduction

: Video signal input port

： Video signal output port

： Print control port

： Video printer switch

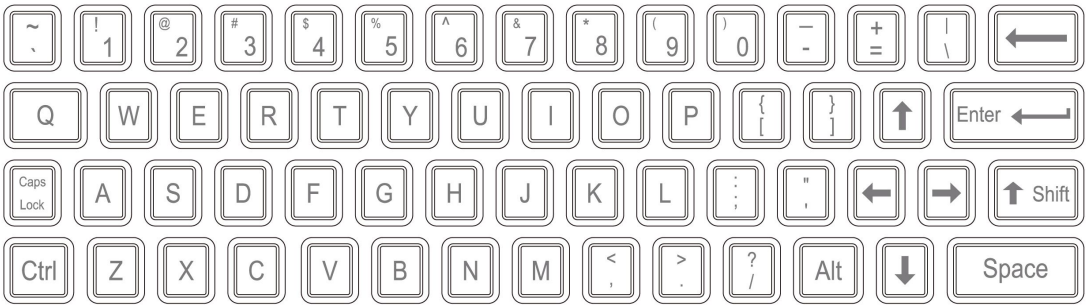
3.5.4.2 Graphic printer installment

Put graphic printer stably, connect printer cable to USB port in the left side of the unit.
Connect the power cable of graphic printer to power system.

Caution： Please see packing list for fundamental configuration!

Chapter 4 Control Panel

4.1 Alphanumeric Keyboard



Alphanumeric Keyboard

The alphanumeric keys are used for inputting patient number, name, character and figure etc.

4.2 Function Keys/Knob

4.2.1 SWITCH

Turn on or off the device

4.2.2 PATIENT

Set up a new patient data, input name and other information.

4.2.3 PROBE

Press this button for selecting probe. It can only select the connected probe.

4.2.4 SETUP

Press this button to get in or out the system setting page.

4.2.5 END

Press END key to finish the exam.

4.2.6 BODYMARK

Press this key to enter into body mark working status, select the body mark and confirm the probe scanning position on the screen. It is only available in frozen status.

4.2.7 COMMENT

Press this key to enter into comment status, and add comments in the image area on the screen.

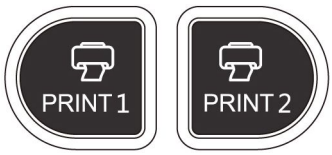
4.2.8 ARROWS

Add arrows key to the image area.

4.2.9 DEL

Press this key to clear the measurement lines, body mark, and comments.

4.2.10 Print



Print the screen image and report by video printer connected to the system.

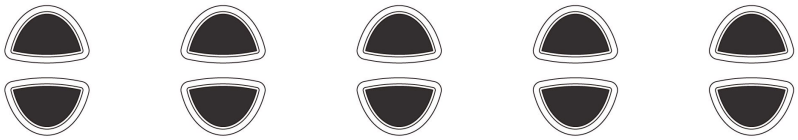
4.2.11 Archive

File management of system, you can view and edit the patient data.

4.2.12 Report

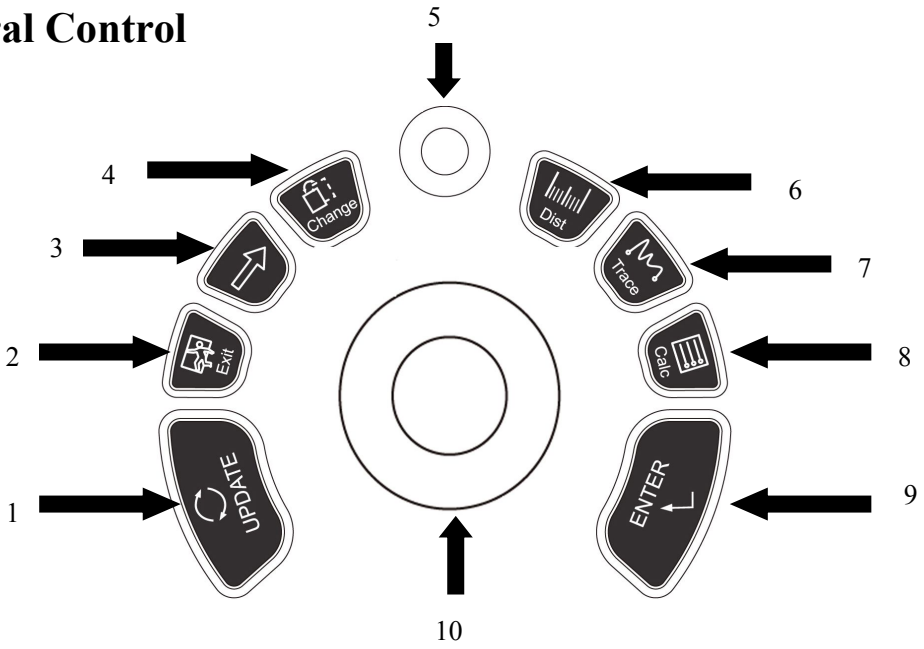
Produce/ Save/ Recall an examination report.

4.2.13 Parameter Control Button



Increase/decrease the corresponding parameters of the screen, Or open/close the function.

4.3 Central Control



1. UPDATE 2.EXIT 3.Cursor 4.Change 5.MENU
6. Dist 7.Trace 8.Calc 9.ENTER 10.Trackball

4.3.1 ENTER

This multifunction key is work with trackball. The function switches with the unit status. Such as, set the cursor position, body mark position, comment position, toggle trackball function, selected the menu, and confirm the input.

4.3.2 UPDATE

This multifunction key is work with trackball. The function switches with the unit status. Such as, call the annotation and back in measuring.

4.3.3 Exit

Press this key can exit measurement, dialog, and menu.

4.3.4 Cursor

Press this key to show or hide the cursor.

4.3.5 Change

Press this key to change the menu.

4.3.6 Dist

Press this key to enter into distance measurement.

4.3.7 Trace

Press this key to enter into trace measurement, and press **UPDATE** to change between trace and ellipse.

4.3.8 Calc

Press this key to enter into measurement software package.

4.3.9 MENU

Press MENU-knob for second time to select the item and adjust the parameters. Press MENU-knob for third time to exit from current item. Rotate the MENU- knob to select the item

4.3.10 Trackball

Trackball is the main operation tool on screen. Position calipers in measurement, the function of the trackball is different under diverse working status.

4.4 The key of Image Mode

4.4.1 B

Display B mode

4.4.2 B/B

Press this key to enter into 2B mode.

4.2.3 4B

Press this key to enter into 4B mode.

4.2.4 M

Press this key to change the mode between B/M and M.

4.5 Control of Image

4.5.1 THI

Press this key to open or close the THI function.

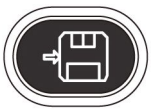
4.5.2 AIO

Only press this key for automatic optimization image.

4.5.3 CINE

Only press this key to save the current cine loop.

4.5.4 SAVE

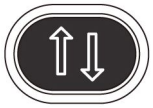


Only press this key to save the current image.

4.5.5 Left and Right Invert

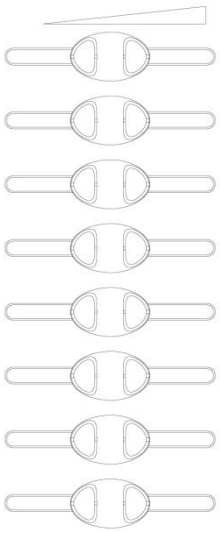
Press this key to invert the image from left and right.

4.5.6 Up and Down Invert



Press this key to invert the image from up and down.

4.5.7 STC



STC can be used for adjusting gain compensation in different image depth.

4.5.8 GAIN

Rotate the knob to adjust the gain of B mode and M mode.

4.5.9 ANGLE/ZOOM Knob

Rotate the knob to adjust the angle or zoom. Press this knob to change the function between angle and zoom.

4.5.10 DEPTH/FOCUS Knob

Press the knob to adjust the depth and function position. Press the knob to change the function between depth and focus position.

4.5.11 Information Area Indicating Machine Status

Left-to-Right of the up row: hard disk, cable network, USB

●Hard disk: press this icon to show the capacity of disc to used save data or USB flash disk in current system

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

●USB: show whether this system connects USB flash disk or not, press this icon to show USB safely remove interface.

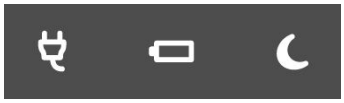
Left-to-Right of the down row: input method,DICOM Task Sequence, battery gauge

●Input method: press this icon to switch Chinese and English input method.

●DICOM Task Sequence: press this icon to show DICOM task and its situation ,To terminate the DICOM task, delete, and so on（Need to activate DICOM）

●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.

4.5.12 Indicator Light



From left to right: Adapter Indicator, Charge Indicator, Sleep Indicator.

●Adapter Indicator: when the main unit connects to the adapter with power supply, the indicator lights, otherwise extinguishes.

●Charge Indicator: When the battery is charging, the indicator lights, Once the battery is charged, the indicator goes out.

●Sleep Indicator: When the main unit is in sleep mode, the indicator lights, otherwise extinguished.

Chapter 5 Operation and Exam Mode

This chapter mainly describes the process of the normal operation of the device, including the preparation before examination, how to get the image, optimize the image, add comments, body mark and so on.

5.1 Preparing the System for Use

5.1.1 The Device Inspection

(1)The device is placed stability;
(2) The grid voltage AC 100-240V, 50Hz-60Hz;
(3)Cable is properly connected, firm and ground, the adapter is properly connected to the device;
(4)Probe is connected and fixed.

5.1.2Power On

Long press 1 second to start the machine, wait for the system to enter the user interface, activate the probe slot into the B-mode.

5.2 Choose Exam Mode

5.2.1 The Probe Identification

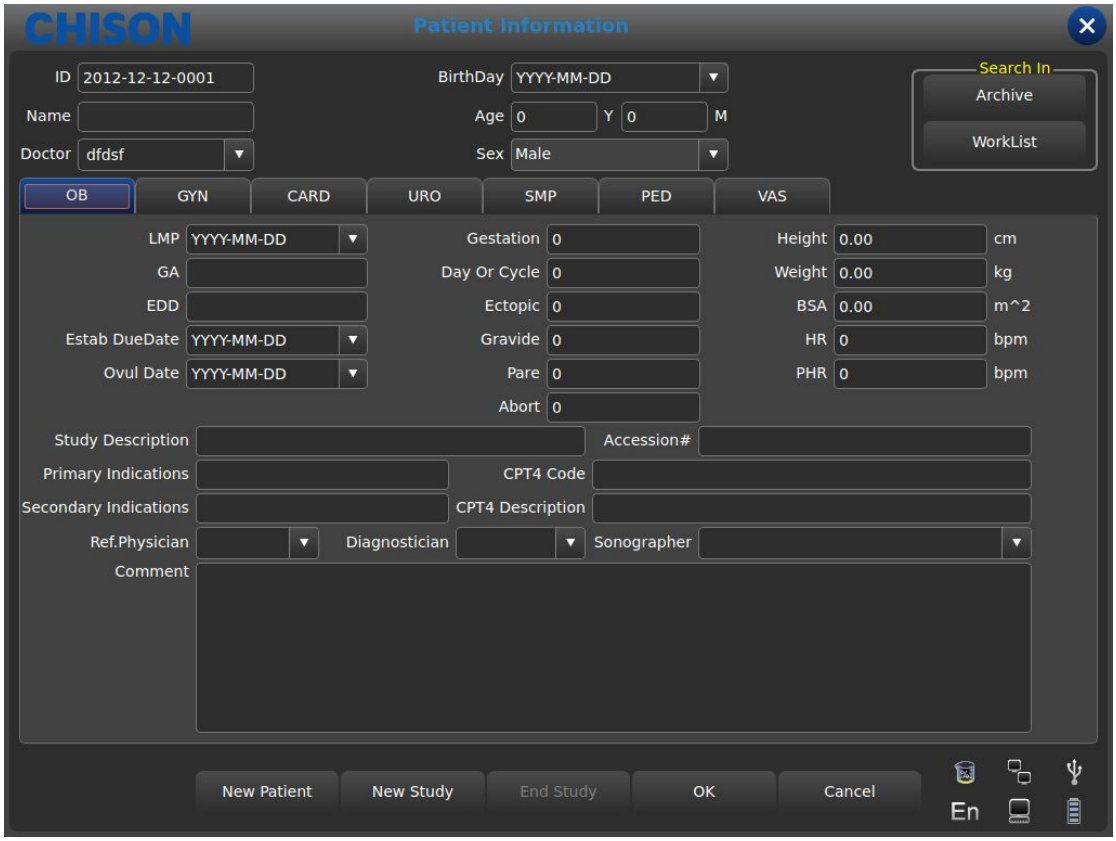
The system default automatically identify the current probe type, When the probe is inserted, Press to switch the probe.
CAUTION: Please connect or disconnect the probe only after the system is freezing, in order to ensure stability and extend the service life of the probe.

5.2.2 Mode Selection

In probe selection interface, probe and clinical application selection page is displayed, you can choose needed probe and inspection part, and press the default into the B-mode, start scan detection.
NOTE: The system has been set clinical application pre-set before leaving factory, each probe has its own pre-set.
The detailed operation steps of the clinical application pre-set of the probe, please refer to the pre-set section.

5.3 Patient Data Entry

Press the to display the Patient screen



Patient's Information Screen

Function Buttons on Patient screen:

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

[Wordlist]： Recall patient information in worklist. And need to open the DICOM function;

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

[New Study]： Choose exam applications(OB、GYN、CARD and so on) for the new patient;

[End Study]： Edit patient's exam item;

[OK]： Save patient information;

[Cancel]： Cancel the operation of new patient information;

Operation Methods:

(1) Move the Trackball to the position of inputting character, then input patient information by character keyboard.

(2)Use the Trackball and the **[ENTER]** key to switch between different input options: ID, patient name, doctor's name, birthday (It can be automatically calculated when input age), age (It can be automatically calculated when input birthday), gender.

(3)Select the exam items, and input the regular inspection information.

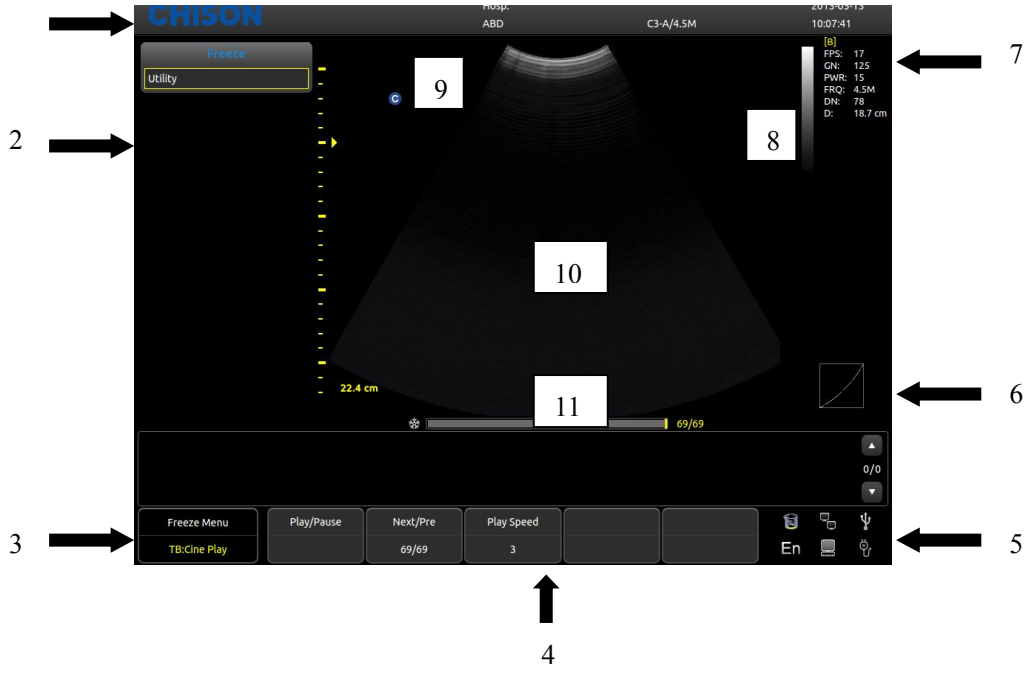
(4)After inputting the required information, click on the **OK** button to save the patient information, the system will return to the B-mode.

(5)Recall information of the previous patient, you can use the **Archive** or **Worklist** to recall patient information to exam.

CAUTION: Creating a diagnostic record, you should check the accuracy of the patient information

before saving measurement or image; otherwise, it will be stored in the wrong patient records. After checking the patient, press the **[END]** key to save the patient information in the system.

5.4 Image Interface Display



1, Logo 2, Control menu 3, Image status prompt 4, Image parameter area
5, System state prompt 6, Gray curve 7, Image parameter area 8, Gray-scale strip
9, Start point of scanning 10, Image Region 11, Cine loop

5.5 Display Mode

Display Mode: B,2B,4B,M,B/M, they can be shifted by the mode key.

5.5.1 B Mode

Press [B] Mode key, and display the single B Mode image, B Mode is the basic mode for two-dimensional scanning and diagnosis.

5.5.2 B/B Mode

Press [2B] 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 2B button in [B/B] mode, the original active image is frozen while the original frozen image is activated.

5.5.3 4B Mode

Press [4B] button to enter into 4B mode, the screen will display four B mode images side by side, but only one image is in real-time status. Pressing it again can switch the real-time status among four images.

5.5.4 B/M Mode

Press [B/M] button, a real time B-mode image and a real-time M-mode image will be displayed at the same time. And a sample line will appear in the B-mode image area, which indicates the active sample position for M image on the B image area. Click the position on the B image area to fix the position of sampling line.

5.5.5 M Mode

Press [M] button again, B mode image will disappear; M mode image is still active on the whole screen. M mode image stands for the tissue movement status at the sampling line. The M mode image varies with time, so it is mainly used for cardiac applications.

5.6 Image Adjustment

5.6.1 Frequency

In real status, press the first line button of **[frequency]** to increase the frequency, and press the second line button of **[frequency]** to decrease the frequency.

5.6.2 Persistent range

In real status, adjust the contrast and resolution.
In real status, press the first line button of **[Persistent]** to adjust. The range is 0~7.

5.6.3 i-Image

In real status, press the corresponding button of **[i-Image]** to adjust, the range is 0~3.

5.6.4 Compound

In real status, press the corresponding button of **[compound]** to adjust, and the range is 0~3.
The SRA can't be edited after opening the compound.

5.6.5 SRA

In real status, press the corresponding button of **[SRA]** to turn on or off.

5.6.6 M Speed Adjustment

In real M status, press the corresponding button of **[Speed]** to adjust M speed, and the range is 1~4.

5.6.7 Gain

In real status, rotate **[Gain]** button to adjust the Gain, and the range is 0~255, the step is 5.

5.6.8 STC

STC curves can be used for adjusting gain compensation in different image depth.

There are two methods for adjustment, as follows:

1: Drag the slide of STCto adjust the value.

2: You can also drag the image area left and right in different depth on the screen to adjust the depth, when the 『Lock』 is not opened.

During adjustment, the STC curve will appear automatically on the left of the screen.

STC curve will disappear automatically 1 second later after stopping adjustment.

5.6.9 Depth

Press **[DEPTH/ZOOM/IP]** selection knob until the indicator of **[DEPTH]** is lit, then rotate the knob to change the depth of image.

5.6.10 Focus Pos

Press the **[FOCUS NUM/FOCUS POS/FREQ]** selection knob until the indicator of **[**FOCUS POS**]** is lit. Then turn the knob to change Focus Position.

5.6.11 ANGLE/ZOOM

Press [ANGLE/ZOOM]button until the indicator of [ANGLE] is lit, and the angle of sample gate will rotate with the rotation direction.

Press [ANGLE/ZOOM]button to confirm the ZOOM button is lit, and it will appear the zoom box, rotate the button to select the zoom steps.

5.6.12 INVERT

B mode image and B/M mode image can be reversed horizontally and vertically.

Press the key, the displayed image is reversed in the right-left horizontal direction.

Press the key, the displayed image is reversed in the up-down direction.

The horizontal flip status indicators of the upper-left corner of the image window have the following meanings:

The meaning of the symbol "⎔" indicating the probe initiative scanning position "⎔" situated in the left indicates that the first scanning line in the left of the screen is corresponding to the initiative scanning position of the probe,

"⎔" situated in the right indicates that the first scanning line in the right of the screen is corresponding to the initiative scanning position of the probe.

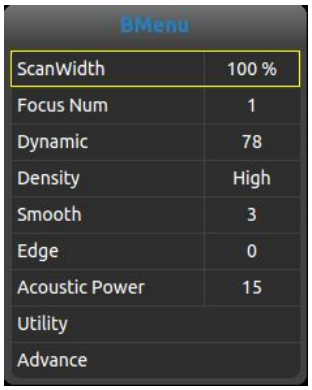
5.6.13 THI(ECO1 Without THI)

Turn ON/OFF THI

5.6.14 AIO

Only press this key to optimize image.

5.7 B Image Menu Adjustment



Click **[Change]** button or **[MENU]** button to display the menu.

Rotate**[MENU]**button or press**[Cursor]**button to display the cursor ,and move the sample box to the corresponding function, press **[MENU]**button to update the function, then rotate**[MENU]**button to adjust the function, press **[MENU]**again to exit the function.

5.7.1 Scan Width

Select **[Scan Width]**, and adjust the scan width to the corresponding size.

5.7.2 Focus Num

In B mode, 4 focus points can be selected simultaneously,and the number controlled by the depth, SRA and Compond.
Move the cursor to **[Focus Num]** selection to adjust, and the range is 1~4.

5.7.3 Dynamic

Dynamic range is used for adjusting the contrast resolution of B mode image and mode image, compressing or enlarging the display range of gray scale.
At the real-time status, drug the slide of dynamic to adjust the gain value from 30 to 90.

5.7.4 Line Density

Scan Line Density function is only valid for the image in B mode, B/B mode, B/M mode or 4B mode image. The line density has two types: high density and low density. High density means better image quality while low density image has higher frame rate.
To do the adjustment, please select the submenu item [**LINE DENSITY**] and press [MENU] to adjust the line density.

5.7.5 Smooth

Smoothness function is used for restraining the image noise and performing axial smooth processing to make the image smoother.
Move the cursor to [Smoothness] selection to adjust, and the range is 0~7.

5.7.6 Edge Enhance

Edge enhancement is used for enhancing the image outline. In this way the user can view the tissue structure more clearly.
Move the cursor to **[Smoothness]** selection to adjust, and the range is 0~7.

5.7.7 Acoustic Power

Acoustic power means the acoustic power transmitting from the probe.

At the real-time status, Move the cursor to [Acoustic power] selection to adjust, and the range is 0~15,and the least adjustable level is 1 dB/level.

5.7.8 Utility

This function includes post processing, slide show and other items. Press **[MENU]** button, then choose Utility selection, it will appear Utility options.

5.7.8.1 Post Processing

5.7.8.1.1Chroma

Adjust the type of the chroma.

Update **[Chroma]**, and rotate **[MENU]** button to select the Chroma type, the range is 0~31.

5.7.8.1.2 2D Map

Select the type of the scale curve.

Update **[2D Map]**, and rotate **[MENU]** button to select the scale curve type, the range is 0~4.

5.7.8.1.3 B Gamma

Adjust image gray value parameters.

Update **[B Gamma]**, and rotate **[MENU]** button to select the B Gamma parameters, the range is 0~8.

5.7.8.1.4 B Rejection

Adjust image gray scale inhibition parameters

Update **[B Rejection]**, and rotate **[MENU]** button to adjust B Rejection parameters, the range is 0~256.

5.7.9 Advance

In B Mode, select **Advance**, after pressing **[MENU]** button, it will appear Advance options.

5.7.9.1 Zoom Coef

Adjust the size of the ruler.

Update **[Zoom Coef]**, and rotate **[MENU]** button to adjust, the range is 60%~100%.

5.7.9.2 MB

Through opening MB to improve image quality

Update **[MB]**, and rotate **[MENU]** button to adjust, the range is 0~3.

Note: The ECO1 only has the function to turn on or off.

5.7.9.3 Trapezoidal Mode

Press [MENU]to turn on or turn off the trapezoidal function.

5.7.9.4 Biopsy

Show or hide biopsy.
Press the [MENU]to show or hide biopsy line.

5.7.9.5 Center Line

Show or hide Center Line.
Press the [MENU]to show or hide Center line.

5.7.10 Gray Scale Curve

Move the cursor to the gray-scale curve, and press the **[ENTER]** button to show gray-scale curve dialog box, click the sliding contacts on the curve to adjust, image, article gray-scale changed. Or through the drop-down box choose pre-settings parameters to show, including standard, High, Low, Equal, Negative.

5.8 Edit Comment

5.8.1 Overview

The comment is to enter text or symbols on the image, the device is Chinese and English annotation system.

ENTER COMMENT: Press enter into comments status;

Exit COMMENT: Press again or[FREEZE]key to exit;

Comment means input the words or symbols on images for making explanation. Add comments can through keyboard input directly 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
Heart	Anatomy term of Heart
Small Parts	Anatomy term of Small Parts
Lesion	Lesion term：Abdomen、Obstetrics、Gynecology、Heart、Small Parts

NOTE: If you need to custom the default comments, refer to the pre-set section.

5.8.2 Input Characters

Operation：

1. Press button, then system will go into the comment process.
2. Move the cursor to the position where need to comments.
3. Input characters at cursor position by keyboard then press [ENTER] key to confirm.
4. Press COMMENT-key again to exit. The COMMENT-key will light off and the comments process is finished.

5.8.3 Input Comment Library Characters

1、In comment status, move trackball to image area to edit;
2、Press[Font size]to adjust front size of comments, the range is 10~20;
3、Rotate[MENU]to select needed comments, then press[MENU] to exit ;

5.8.4 Edit Quick Comments

1、Press[Edit]to pop quick comment edit box;
2、Input customized comments;
3、Press[Done]to finish edit, press[X]to cancel edit;

5.8.5 Input Quick Comments

1、Press[Text]to select needed quick comments;
2、Adjust front size of comments;
3、Press[Input]to place comments in the image area;

5.8.6 Move Comments

1、In comment status, move trackball to the comment, press **ENTER** key to activate it;
2、Move trackball to place the comment to target area;
3、Press **ENTER** again to confirm the comment;

5.8.7 Edit Comments

1、In comment status, move trackball to the comment, press **ENTER** key to activate it
2、Press[BACKSPACE]to delete unnecessary characters;

3、Press[ENTER]to confirm;

5.8.8 Delete Comments

5.8.8.1 Delete Characters

In comment status, activate the comment that need to be deleted, then press the **ENTER** key, it will display "|" on the screen, press[BACKSPACE]key to delete the character.

5.8.8.2 Delete Single Comment

Activate the comment that need to be deleted, press[DEL]to delete comment;

5.8.8.3 Delete All Contents of the Comment

Don't activate the single comment, press[DEL]to delete all characters that has input;
Caution: Press[DEL]key, but it will delete the measurement and body mark at the same time;

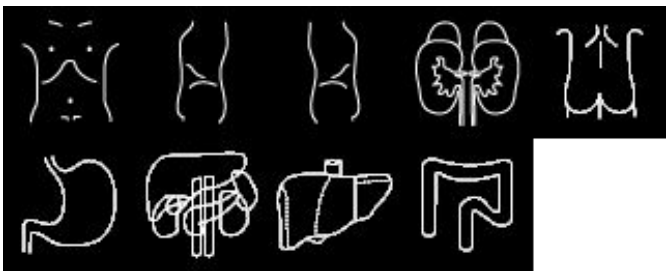
5.8.9 Set the Position of Default Comment

Operation:
1、Press[Save Home Pos.]to move cursor to the initial position;
2、Press[Load Home Pos.]to set the initial position ;

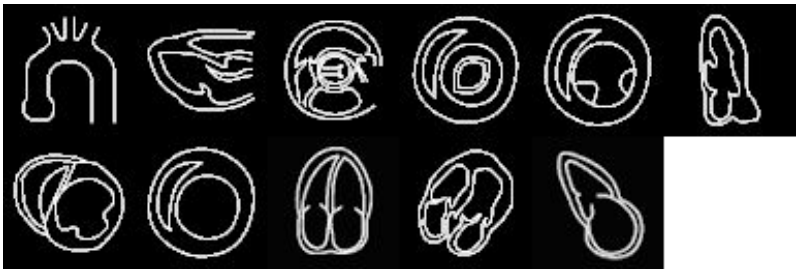
5.9 Set Body Mark

5.9.1General Description

The body mark indicates patient's examination position and the direction of probe scan on the image.
Body marks are divided into: obstetric, abdomen, gynecology, heart and small parts, each has different body mark. Each type of body mark automatically is corresponding to current examination mode.
Icon:

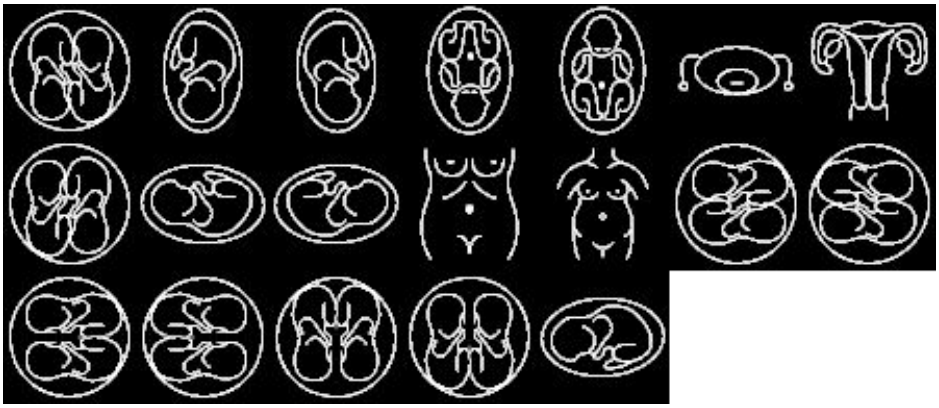


Abdomen Mark

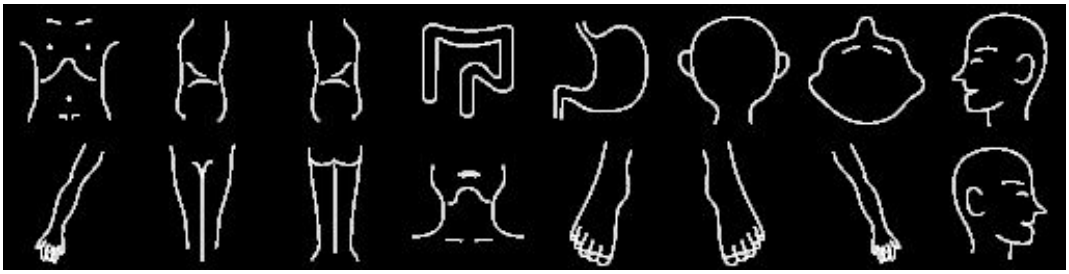


Cardiac Mark

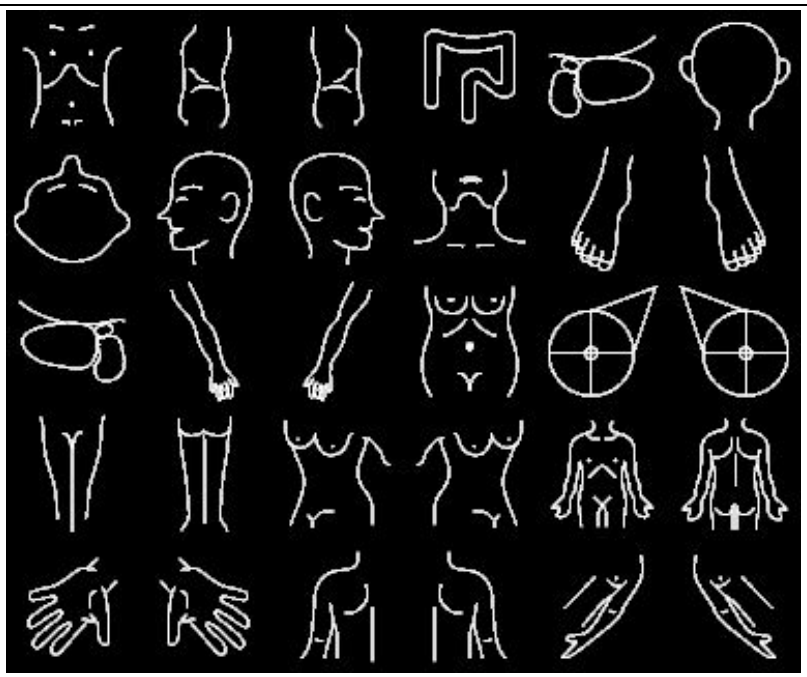
Obstetric Mark



Gynecology Mark

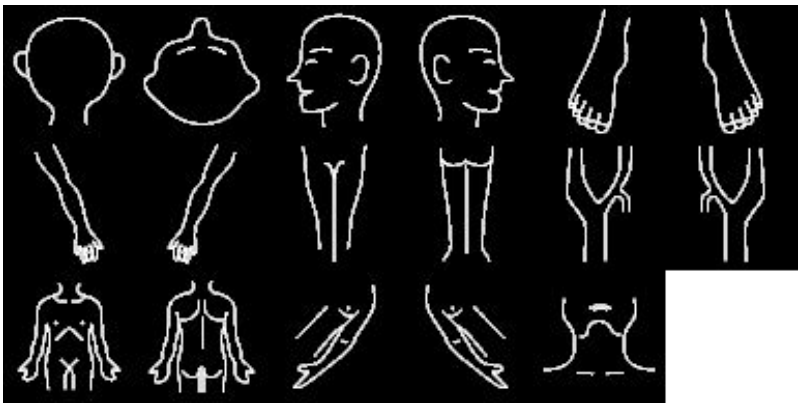


Pediatric Mark



Small Part Mark

Urology Mark



Vascular Mark

5.9.2 Body Mark Operation

Operation：

1、 Press to enter into the body status.

2、 Select the body mark that you need.

3、 Move trackball after adding the body mark image and then adjust the position of probe. Rotate [MENU] key can adjust the probe direction. Press Enter- key to confirm when adjustment was

finished.

4、 Move the Trackball to change the position of the body mark;

5、 If you want to exit from the body mark function, press again;

6、 Press [EXIT]to exit body status and the body mark is fastened to the screen.

7、 Press [DEL] to delete body marks.

5.10 Set the Direction of Arrow

Operation：

1、Press

to display arrow;

2、Adjust the position of probe. Rotate [MENU] key can adjust the probe direction.

3、Press [ENTER] to confirm when adjustment was finished.

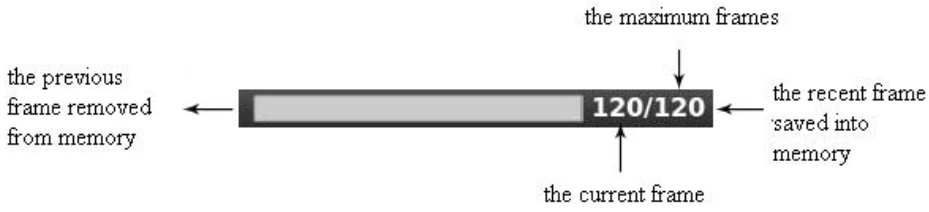
4、Press[EXIT]to exit the arrow settings.

5、Press[DEL]to clear the arrows has inputed,

5.11 Image and Cine Disposition

5.11.1 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 pre-set chapter.
If the movie memory is full, the recent frame saved into memory, the previous frame removed from memory.



Cine loop indicate diagram

5.11.2 Manual Loop

Press[FREEZE]to freeze image, pop cine playback bar, at this time, move cursor to play by hand; Track ball rolling to the right, the loop play with ascending order side by side.
Or press[Next/Pre]to play.

5.11.3 Automatic Loop

After freezing image, press[Play/Pause]to play, press it again to stop.
Press [ENTER]to choose the are of automatic playback area needed.

5.11.4 Save and Recall Image

1.Press to save current image, the image will be displayed below the screen;
2.If you need to recall images that has been stored, move cursor to needed image, press [ENTER]to recall it; Or you can recall archived patient's information to recall image, please refer to archive chapter.

5.11.5 Save and Recall Cine

In freeze status, press to save cine, then it will be displayed below the screen, move cursor to needed cine ,press [ENTER]to recall cine.

5.12.6 Delete images

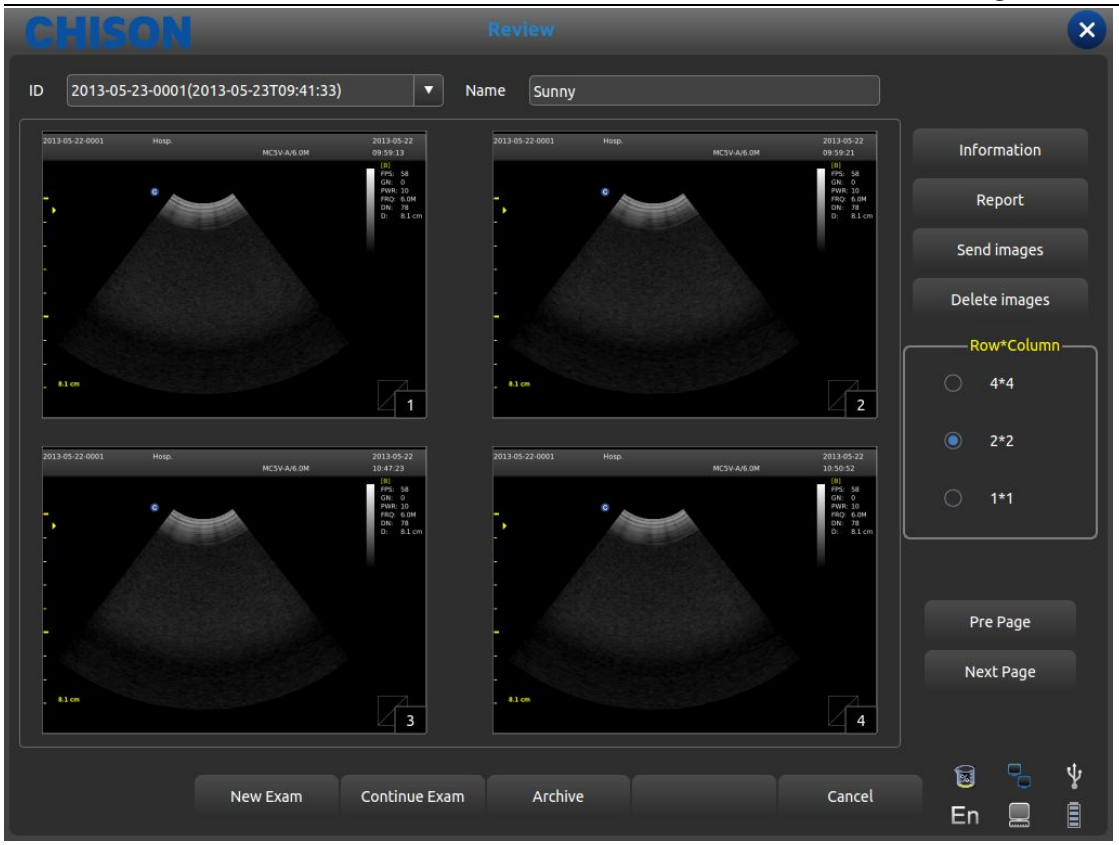
After recalling the images , press the [Delete images] to delete the files.

5.12.7 Send images

After recalling the images , press the [Send images] to send images to USB flash disk , DICOM storage and print.
Hint:Activate the DICOM before DICOM storage and print.

5.12 Image Browse

Press to enter image information browsing interface. Press[ENTER]to any function in the image.

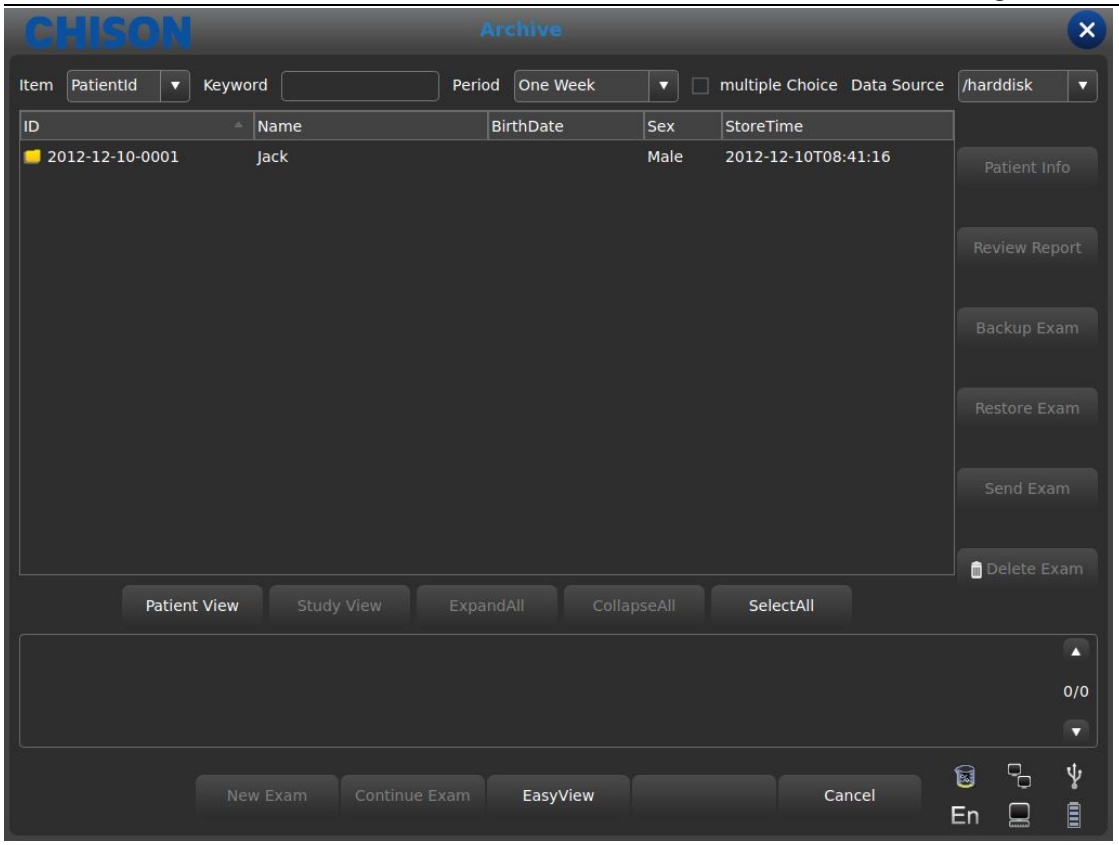


Review interface

- ID: ID of Current patient.
- Name: Current patient's name.
- Information: 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;
- Delete images: Delete selected image;
- Row*Column: Select image's format;
- Pre page: Page up;
- Next page: Page back;
- New Exam: Exit current examination and open a new dialog box.
- Continue Exam: Exit image browsing interface and go on checking current patient;
- Archive: Open up archive management interface;
- Cancel: Turn off image browsing interface;

5.13 Archive Management

Archive management can search for patient's information which has been stored in system. Press[Archive]to archive management interface, all process can be opened up by moving cursor.



Archive interface

- 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;
- Dada 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;
- 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;
- Cancel: Exit archive management interface and go on checking current patient;

5.14 Report

Press[ENTER]on the image to add the image into the report page. The report can be saved and printed. It is convenient for the doctor to view and edit the patients' information.

Reports contain normal report, abdominal report, cardiac report, small part report etc. Move the cursor to the required report page and press[ENTER] to choose.

Click the "Report" button and the page pop up the report page of the current exam mode. Change the other exam mode report by the drop-down box.

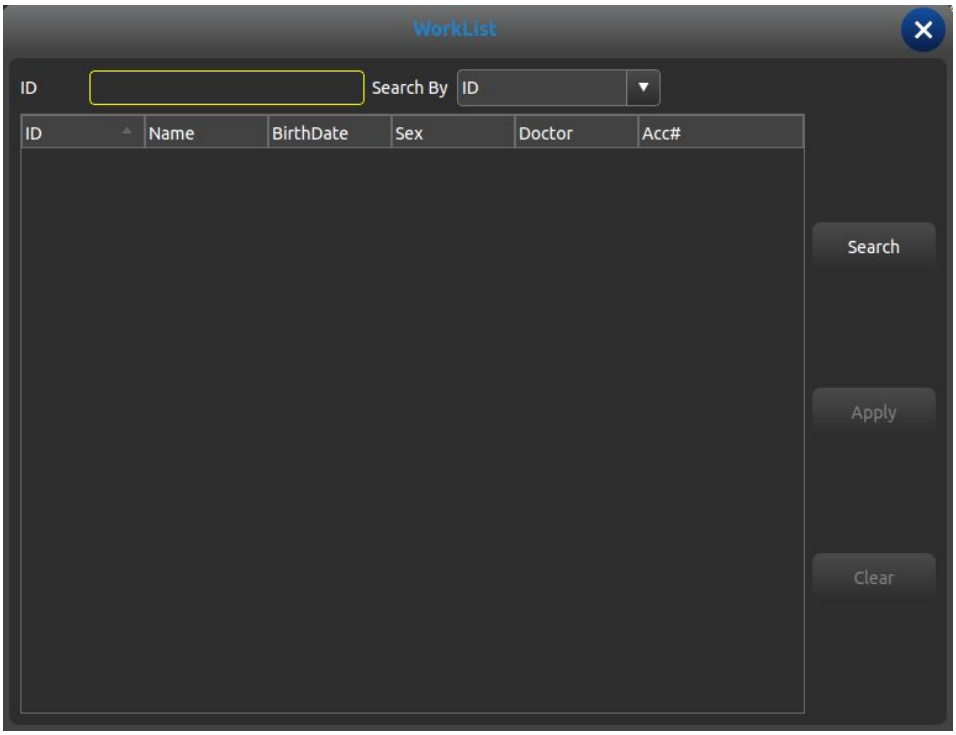
Report Interface

- ReportTitle: Report options, different kinds of report can choose, such as Normal, OB/GYN etc.
- Hosp: Display the hospital name.
- Abdomen Report: Display the kind of report.
- Patient Name: Display the patient name.
- Age: Display the patient age.
- Gender: Display the patient sex.
- Patient ID: Display the patient ID.
- Diagnostic: Input the diagnostic instructions.
- Description: Input the description of symptom.
- Tips: Input note information.
- Send DICOM SR: After activating DICOM , send DICOM structural report to server
- Print: Print the report with image.
- Export: Export the PDF report to the U disk.
- Save: Save the report in system.
- The image on the right side: Press[ENTER]on the image to add the image into the report.

5.15 DICOM

5.15.1 DICOM Worklist

Press [Worklist] 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 pstients

BirthDate:display the birthdate of patients

Sex:display sex of patients

Doctor:display names of doctors

Acc#:dispaly the NO. of patients

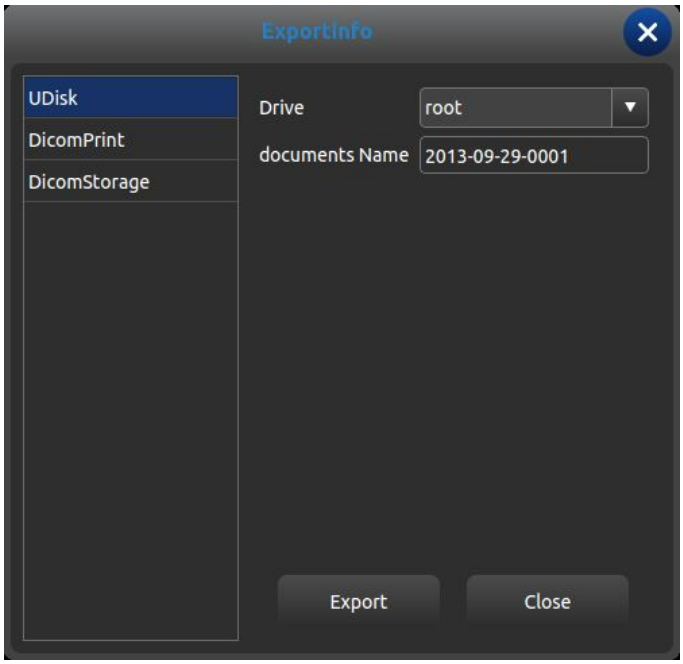
Search:press this button to do search operation

Apply:selete the searched patient and press this button , input all patient information into the new patient interface

Clear:clear all searched content.

5.15.2 DICOM Storage

Check the “save and send” in setting , then DICOM stroage when saving cine and images . Press send button in archive or freeze interface. DICOM Send interface as follows:



DICOM Send Interface

Select DICOMStroage in left , choose DICOM server and press Export button to DICOM storage.

Enter DIOCM Task Sequece and watch or edit DICOM process.

5.15.3 DICOM Print

DICOM Print operation is the same as DICOM storage

5,15.4 DICOM SR

Press Send DICOM SR button in report interface , this task is added into DICOM Tash Sequence.

Chapter 6 Measurement and Calculation

Main content of this chapter:
Normal calculation and measurement on B mode image and M mode image, OB calculation and Urology measurement etc,system can enter into corresponding measurement mode depend on current exam mode, and enter into the corresponding report depend on the measurement mode.
System has built-in the default measurement according to the exam mode, the change of measurement please refer to the chapter of preset settings.

6.1 Keyboard for Measurement

6.1.1 Trackball

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

1、Before starting a measurement, use the trackball to choose the menu options;

2、After starting a measurement, move the trackball to move the cursor, during the measurement, the cursor should not be moved out image area;

3、During the Ellipse method measurement, use trackball to change the length of short axis.

4、Update the moving of the measurement result, move the traceball to change the position of the measurement result.

6.1.2 [ENTER]

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.

6.1.3 [UPDATE]

1、Before the measurement, press[UPDATE]to change the measurement method, such as ellipse, trace. The changeable measurement item has "< >".

2、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.

3、During the distance measurement, press the[ENTER]to fix the start point, when the end point is not fixed, press the UPDATE-KEY to switch the start point and end point.

4、During the Ellipse measurement, when fix the long axis, but the short axis is not fixed, press the UPDATE-KEY to switch the long axis and short one.

6.1.4 [DEL]

Main functions are as follows:

In frozen status, press the[DEL], delete all the measurement results, comments and traces.

6.1.5 [Change]

Press[Change]to switch other menu;
Press[Exit]to exit;

6.1.6 [Exit]

Press[Exit]to exit the measurement menu.

6.1.7 Parameters control button

Press the corresponding button to update the function and use the function.

6.2 B Mode general Measurement methods

The system B mode contains Distance, Ellipse, and Trace.

6.2.1 Meas. Distance

Measurement steps:
1: Press the [Calc] button to enter into measurement. Update the [distance] item in the menu or press the quick measure button [Dist], it will display a segment “+”icon.
2: Move the “+”icon by cursor to fit the one point of the line. Press [RNTER] key to fix the start point and the cursor can be moved to the next position.
3: Press [UPDATE] key can change the activated point, and fit the other point of the line.
4: Move the cursor to the end-point, press [ENTER] again to complete the measurement.
5: After the measurement, the result will display in the measurement results area.
6: Repeat the steps from 1 to 4 to start next “distance” measurement. Press [DEL] key to delete all the

measurements.

Note:

Each group of measurement is limited, if the measurement results beyond, it will begin a new group of measurement automatically.

6.2.2 Ellipse

Measurement steps:

1: Press the [Calc] button to enter into measurement. Update the [Ellipse] item in the menu or press the quick measure button [Ellipse], it will display a segment "+"icon.

2: Move the "+"icon by cursor, Press [RNTER] key to fix the point and the cursor can be moved to form a round.

3: Press [UPDATE] key can exchange the activated point and the fixed point.

4: Move the cursor to the end-point of the ellipse, press [ENTER] to fix the axis, at the same time, the next axis be updated, and can change the size of the axis by the cursor.

5: Now press [UPDATE] key can exit to the step 4.

6: After fixing the next axis, can press [ENTER] key to complete the measurement.

7: After the measurement, the result will display in the measurement results area.

8: Repeat the steps from 1 to 6 to start next "ellipse" measurement. Press [DEL] key to delete all the measurements.

Note:

Each group of measurement is limited, if the measurement results beyond, it will begin a new group of measurement automatically.

6.2.3 Trace

Measurement steps:

1: Press the [Calc] button to enter into measurement. Update the [Trace] item in the menu or press the quick measure button [Trace], it will display a segment "+"icon.

2: Move the "+"icon by cursor, Press [RNTER] key to fix the point and the cursor can be moved to the next position.

3: Make the cursor tracing along the edge of required area, the traced line can be not closed..

4: Now press [UPDATE] key to cancel the tracing.

5: Press [ENTER] key again in the endpoint, the start point and end point of trace line will be closed by a straight line.

6: After the measurement, the result will display in the measurement results area.

7: Repeat the steps from 1 to 5 to start next "trace" measurement. Press [DEL] key to delete all the measurements.

Note:

Each group of measurement is limited, if the measurement results beyond, it will begin a new group of measurement automatically.

6.2.4 Histogram

Histogram is used to calculate the gray distribution of the ultrasound echo signals within a specified area. Use the rectangle, ellipse or trace method to draw along the desired measurement area. The result is shown in the form of histogram.

Histogram can be measured only on the frozen image.

◆ Measurement steps by rectangular method:

① Click[FREEZE]key to freeze the image.

② Press [ENTER] in [Histogram] menu to enter into measurement status.

③ Click [ENTER] to fix one apex of the rectangle.

④ Move the trace ball to change the cursor positon and fix the diagonal point of the rectangle

⑤Move the trace ball to change the cursor positon, fix the diagonal point of the rectangle, and press [ENTER]again to confirm the measurement area. The result will display on the measurement result area..

◆ Measure the histogram by ellipse or trace method: The method is the same as that to measure y ellipse or trace method, press [UPDATE] to change the measurement between ellipse and trace.

The horizontal axis represents the gray scale of the image ranging from 0 to 255.

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.

6.2.5 Cross-section Diagram

Cross-section Diagram 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:

①Click[FREEZE]key to freeze the image.

②Click[Meas.]key , and choose [B NORMAL MEAS].

③Draw a straight line at the measuring position. The method is the same as that to measure distance.

④, Click [Done] .The calculated result of the profile will be displayed at the centre of the screen.

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

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

The range is 0 to 255.

6.3 Normal measurement and calculation in B mode

Click display [B], [B/B] or 4B to enter into B, B/B or 4B mode, then click[Calc]key to enter into measurement status. Or press [Change] to choose the normal measurement.

Meas. Menu	**Submenu**	**Unit**	**Meas. Method/ Meas. Formula**	**Comment**
	Distance	cm	Refer to distance Meas.	
	area/circle	Area cm^2 Circle cm	Refer to Ellipse and trace meas.	Ellipse and trace. Press[UPDATE]to change.
	Volume （1straight line）	ml	Refer to distance Meas. Formula: V ＝（π/6）×D^3	D means: Depth
	Volume （1ellipse）	ml	Refer to ellipse meas. Formula:V ＝（π/6）×A×B^2	A: Long Axis B: Short Axis
	Volume （2 straight line）	ml	Refer to distance Meas. Formula: V ＝（π/6）×D1×$D2^2$	D1: the longer distance D2: the shorter distance
	Volume （3 straight line）	ml	Refer to distance Meas. Formula: V ＝（ π/6 ）×D1×D2×D3	D1, D2, D3: Distance
	Volume （ 1 straight line 1 ellipse）	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（area）		Refer to ellipse Meas. Formula: R=A1/A2	A1: First Drea A2: Second Area
Angle		deg	Refer to distance Meas.	Angle Range: 0°~ 180°
Histogram			Refer to histogram	
Cross-section diagram			Refer to Cross-section	

6.4 ABD measurement and calculation

Choose ABD exam mode. Freeze the required image, then Press [Calc] to enter into ABD measurement status. Or press[Change]to choose the ABD measurement.

Meas. Menu	**Submenu**	**Unit**	**Meas. Method/ Meas. Formula**	**Comment**
Distance		cm	Refer to distance Meas.	
CBD		cm	Refer to distance Meas.	
GB wall		cm	Refer to distance Meas.	
Liver Length		cm	Refer to distance Meas.	
Pro 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	cm^2	Refer to ellipse and trace Meas.	Ellipse and trace. Press[UPDATE]to change.
	Vessel Dis	cm	Refer to distance Meas.	
Mid Aorta	The same as above	The same as above	The same as above	The same as above
Distal Aorta	The same as above	The same as above	The same as above	The same as above
Spleen	Length Height	cm cm	Refer to distance Meas. Formula: V = （π/6）	L: Length H: Height W: Width

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
	Width Volume	cm ml	×L×H×W	
Renal Vol. (Rt/Lt)	Length Height Width	cm	Refer to distance Meas.	
Lliac(Rt/Lt)	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	cm^2	Refer to ellipse and trace Meas.	Ellipse and trace. Press[UPDATE]to change.
	Vessel Dis	cm	Refer to distance Meas.	

6.5 OB measurement and calculation

Choose OB exam mode. Freeze the required image, then Press [Calc] to enter into OB measurement status. Or press[Change]to choose the OB measurement.

Meas. Menu	Submenu	Unit	Meas. Method	Comment
Distance		cm	Refer to distance Meas.	
Fetal Biological	GS	cm	Refer to distance Meas.	Formula to choose: CFEF, Campbell, Hadlock, Hansmann, Korean, Merz, Shinozuka
	CRL	cm	Refer to distance	Formula to choose:

Meas. Menu	Submenu	Unit	Meas. Method	Comment
			Meas.	Hadlock, Hansmann, Korean, Nelson, Osaka, Rempen, Robinson, Shinozuka
	YS	cm	Refer to distance Meas.	
	BPD	cm	Refer to distance Meas.	Formula to choose: Bessis, CFEF, Campbell, Chitty, Hadlock, Hansmann, Jeanty, Johnsen, Korean, Kurtz, Merz, Osaka, Rempen, Sabbagha, Shinozuka
	OFD	cm	Refer to distance Meas.	Formula to choose: Hansmann, Korean
	HC	cm	Refer to ellipse and trace Meas.	Formula to choose: CFEF, Campbell, Chitty, Hadlock, Hansmann, Johnsen, Korean, Merz
	APPD	cm	Refer to distance Meas.	Formula: Bessis
	TAD	cm	Refer to distance Meas.	Formula: CFEF
	AC	cm	Refer to ellipse and trace Meas.	Formula to choose: CFEF, Campbell, Hadlock, Hansmann, Korean, Merz, Shinozuka
	TCA	cm	Refer to distance Meas.	Formula: Osaka
	FL	cm	Refer to distance Meas.	Formula to choose: Bessis, CFEF, Campbell, Chitty, Doubilet, Hadlock, Hansmann, Hohler, Jeanty, Johnsen, Korean, Merz, Osaka, Shinozuka
	Spine Long	cm	Refer to distance Meas.	
	APD	cm	Refer to distance Meas.	Formula: Hansmann
	TTD	cm	Refer to distance Meas.	Formula: Hansmann
	TC	cm	Refer to distance	

Meas. Menu	Submenu	Unit	Meas. Method	Comment
			Meas.	
Fetal Long Bones	HL	cm	Refer to distance Meas.	Formula to choose: Jeanty, Korean, Merz, Osaka
	Ulna Long	cm	Refer to distance Meas.	Formula: Jeanty
	Tibia Long	cm	Refer to distance Meas.	Formula to choose: Jeanty, Merz
	Radius Long	cm	Refer to distance Meas.	
	Fibula Long	cm	Refer to distance Meas.	
	Clavicle Long	cm	Refer to distance Meas.	Formula: Yarkoni
Fetal Cranium	Cerebellum	cm	Refer to distance Meas.	Formula to choose: Chitty, Hill
	Posterior Cistern	cm	Refer to distance Meas.	
	NF	cm	Refer to distance Meas.	
	NB	cm	Refer to distance Meas.	
	OOD	cm	Refer to distance Meas.	Formula: OOD
	IOD	cm	Refer to distance Meas.	
	NB	cm	Refer to distance Meas.	
	Paracele	cm	Refer to distance Meas.	Formula: Tokyo
	HC Width	cm	Refer to distance Meas.	
OB Others	LtRenal	cm	Refer to distance Meas.	
	RtRenal	cm	Refer to distance Meas.	
	LtRenalAP	cm	Refer to distance Meas.	
	RtRenalAP	cm	Refer to distance Meas.	
	LVWrHEM	cm	Refer to distance Meas.	
	TAD	cm	Refer to distance Meas.	

Meas. Menu	Submenu	Unit	Meas. Method	Comment
EFBW		g	Refer to distance and ellipse Meas.	Modify the fomula automatically acorrding to EFBW formula in setting
AFI		cm	Refer to distance Meas.	AFI=AFI1+AFI2+AFI3 +AFI4
FBP		cm	Refer to distance Meas.	
Cervical Length		cm	Refer to distance Meas.	

6.5.1 EDD (estimated date of delivery) Estimation

6.5.1.1 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 directely.
3. The calculated EDD value will appear in the result measurement area of OB page.

6.5.1.2 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 with the LMP method.

6.5.2 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:

- Finish the measurement of the OB item and get into the report page.
- Choose the growth curve at the right list and press [ENTER] to display the growth curve.
- Choose the growth curve need to display, and check it to show the growth curve on report..
- Click [×] icon on the dialog box to exit.

Tips: The abscissa of Groth curves is the gestational weeks calcuated according to the LMP in patient information.

6.6 Pediatric measurement

Select OB mode, press[Calc]to enter OB mode, then enter into pediatrics mode. Or press[Change]to Switch to pediatrics measurement menu

6.6.1 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:

➢Choose [HIP Angle] menu item, and click it to enter into measurement.

➢Add three distances consistent with fetal anatomy.

➢After the above operations are finished, the result of measured ANGLE will be displayed in the measurement result area.

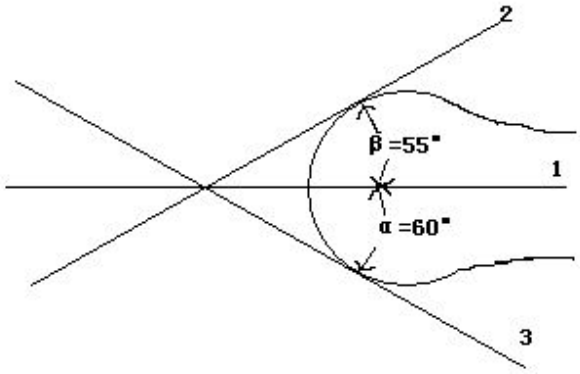
Caution

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）.



HIP angel

6.7 GYN Measurement and Caculatoin

GYN measurement includes measurement of UT-D (uterus diameter), ENDO (endometrium), CX-L (Uterine cervix length), LEFT OV and RIGHT OV (volume of left and right ovary) and LEFT FO and RIGHT FO (left and right follicle). The result will be calculated and displayed automatically on the screen by measuring relevant parameters.

Freeze the required image under GYN examination, then click [Calc] key to enter into GYN measurement status.

Meas. Menu	Submenu	Unit	Meas. Method	Comment
Distance		cm	Refer to distance Meas.	

Meas. Menu	Submenu	Unit	Meas. Method	Comment
UT	UT_L	cm	Refer to distance Meas.	
	CUT_L	cm	Refer to distance Meas.	
	UT_W	cm	Refer to distance Meas.	
	UT_H	cm	Refer to distance Meas.	
	UT_V	ml	Refer to distance Meas. 公式：V＝（π/6）×L×H×W	L: UT_L H: UT_H W: UT_W
	UT_D	cm	Refer to distance Meas. Formula: UT_D =L+W+H	L: UT_L H: UT_H W: UT_W
Cervix Vol.		ml	Refer to distance Meas. 公式：V＝（π/6）×L×H×W	L: Cervix _L H: Cervix _H W: Cervix _W
ENDO		cm	Refer to distance Meas.	
OV Vol.（L/R）		ml	Refer to distance Meas. 公式：V＝（π/6）×L×H×W	L: OV _L H: OV _H W: OV _W
FO（L/R）	FO_L	cm	Refer to distance Meas.	
	FO_W	cm	Refer to distance Meas.	

6.8 Small Parts Measurement and Calculation

Freeze the required image under Small parts examination, then click [Calc] key to enter into small parts measurement status.

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
Distance		cm	Refer to distance Meas.	
Thyroid（L/R）	Volume	ml	Refer to distance Meas. Formula: V ＝（ π/6 ）×L×H×W	L: Thyroid_L H: Thyroid_H W: Thyroid_W

Meas. Menu	**Submenu**	**Unit**	**Meas. Method/ Meas. Formula**	**Comment**
Angle		deg	Refer to distance Meas.	Angle Range: 0°～180°
Ratio			Refer to distance Meas. Formula: R=D1/D2	D1: First Distance D2: Second Distance

6.9 B Mode Vessel Measurement and Calculation

The same as normal measurement in B mode.

6.10 Urology Measurement and Calculation

Normally urology measurements are performed in B and B/B mode.

Freeze the required image under Urology examination, then click [Calc]key to enter into Urology measurement status.

Meas. Menu	**Submenu**	**Unit**	**Meas. Method/ Meas. Formula**	**Comment**
Kidney Vol.（L/R）		ml	Refer to distance Meas. Formula: V＝（π/6）×L×H×W	L: Kidney_L H: Kidney_H W: Kidney_w
Bladder Vil.	V（L*W*H）	ml	Refer to distance Meas. Formula: V＝（π/6）×L×H×W	L: Bladder _L H: Bladder _H W: Bladder _w
Prostate	Volume	ml	Refer to distance Meas. Formula: V＝（π/6）×L×H×W	L: Prostate _L H: Prostate _H W: Prostate _w
	PPSA	ng/ml	Formula: PPSA ＝ 0.12×V	
	PSAD	ng/ml	Formula: PSAD=SPSA/V	SPSA: input the SPSA When create a new Patient
RVU	Volume	ml	Refer to distance Meas. Formula: V＝（π/6）×L×H×W	L: RVU _L H: RVU _H W: RVU _w

6.11 Cardiac Measurement and Calculation

Normally urology measurements are performed in B and B/B mode.

Freeze the required image under Cardiac examination, then click [Calc]key to enter into Cardiac status.

Meas. Menu	**Submenu**	**Unit**	**Meas. Method/ Meas. Formula**	**Comment**
Distance		cm	Refer to distance Meas.	
Single Plane		ml	Refer to distance Meas. Formula: V＝（π/6）×L×D^2	Left ventricular parameter at end diastole: LV long-axis SL; LV short-axis SD; Left ventricular parameter at end systole: LV long-axis DL; LV short-axis DD
Bi-Plane		ml	Refer to distance Meas., ellipse Meas. Formula: V＝（8/3）×Am×Ai÷（π×D）	D: LV short-axis Am: LV area on mitral valve level figure Ai: LV area on apex level figure
Bullet Volume		ml	Refer to distance Meas., ellipse Meas. Formula: V＝（5/6）×Am×L	Am: LV area on mitral valve short-axis figure L: LV long-axis
Modi_Simpson		ml	Refer to distance Meas., ellipse Meas. Formula: V＝（Am＋5×Ap/18）×L	Am: LV area on mitral valve short-axis figure Ap: LV cross sectional on papillary muscle level figure. L: LV long-axis

6.12 Normal Measurement and Calculation in M, B/M mode

At real-time status, click [B/M] key twice to enter M mode, press [Calc]key to enter into M mode measurement status.

OR

At real-time status, click [B/M] key to enter B/M mode, press [Calc]key to enter into M mode measurement status.

6.12.1 Distance

Measurement steps:

①Select menu item-“Distance” to enter into measurement.

②Click on the M image area, it will display a blue dotted line with two horizontal short line. The blue dotted line represents the position need to be measured. The distance between the two short lines is the distance you

want to measure. The yellow short line represents it's in active status. Click it and drag the short line to anywhere you want to put. .

③Click Switch key to active the two short line in turns and dragon them to change the distance between them.

④After the measurement, press done key to finish this operation. The measurement result will be displayed on the result area.

6.12.2 Time

Measurement steps:

①Select menu item『Time』 to enter into measurement.

②Click on the M image area, it will display two blue straight dotted line. The blue dotted line with one yellow short line on it represents it is in active status. 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.

③Click Switch key to active the two straight line in turns and dragon them to change the distance between them.

④After the measurement, press [Done] key to finish this operation. The measurement result will be displayed on the result area .

6.12.3 Heart rate

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

Measurement steps::

①Choose『Heart rate』menu item to enter into measurement.

②The method is same as Time .

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

④Repeat the steps form1 to 3 to start next measurement.

6.12.4 Velocity

Measurement step:

①Choose『Velocity』menu item to enter into measurement.

②Select the start point of the measurement and click on the screen. The yellow "+" cursor is active. Drag the cursor to the peak systolic wave.

③Click on the Switch key to active another point. Drag the active point to the end diastolic wave.

④Repeat 1-3 to do another measurement.

Note: The maximum number of the measurement result on the image area is one. The second measurement result will cover the first one. The measurement result area will list all the measurement values.

6.13 General Measurement in M mode

At real-time status, click [B/M] key twice to enter M mode, click [Calc]key to enter into M mode cardiology measurement status.

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.	
HR	One Cycle	bpm	Refer to M HR Meas.	
	Double Cycles	bpm	Refer to M HR Meas.	

6.14 M Abdomen Measurement

The same with M mode general measurement.

6.15 M OB Measurement

The same with M mode general measurement.

6.16 M GYN Measurement

The same with M mode general measurement.

6.17 M Mode Cardiac Measurement

Normally urology measurements are performed in M and B/M mode.

Freeze the required image under Urology examination, then click [Calc] key to enter into Urology measurement status. Or press [Change]to choose the cardiac measurement.

Meas. Menu	**Submenu**	**Unit**	**Meas. Method/ Meas. Formula**	**Comment**
Distance		cm	Refer to M distance Meas.	
ET		s	Refer to M time Meas.	
HR	One Cycle	bpm	Refer to M velocity Meas.	

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
	Double Cycles	bpm	Refer to M velocity Meas.	
LVMM	IVSd	cm	Refer to M distance Meas.	Interventricular Septum
	LVIDd	cm	Refer to M distance Meas.	Left Ventricular Diameter at diastole
	LVIDs	cm	Refer to M distance Meas.	Left Ventricular Diameter at systole
	LVPWd	cm	Refer to M distance Meas.	Left Ventricular Posterior Wall at diastole
	IVSs	cm	Refer to M distance Meas.	Interventricular Septal Thickness at Systole
	LVPWs	cm	Refer to M distance Meas.	Left Ventricular Posterior Wall at Systole
	EDV	ml	EDV = 7.0/（2.4+LVIDd）×$LVIDd^3$	Left Ventricular Volume at end diastole
	ESV	ml	ESV = 7.0/（2.4+LVIDs）×$LVIDs^3$	Left Ventricular Volume at end Systole
	SV	ml	SV＝|EDV-ESV|	Stroke Volume
	SI		SI＝SV/BSA	Stroke Volume, BSA: Body Surface Area, it calculated by input the height and weight.
	EF	%	EF＝SV/EDV×100	Ejection Fraction
	SF	%	SF＝（LVIDd-LVIDs）/LVIDd×100	Contraction Fraction
	CO	L/min	CO＝SV×HR/1000	Cardiac Output
	CI		CI＝CO/BSA	ECG Index, BSA: Body Surface Area, it calculated by input the height and weight.
	LVMW		LVMW = 1.04×[(IVSd+LVIDd +LVPWd)^3-$LVIDd^3$]-13.6	
	LVMWI		LVMWI = LVMW/BSA	BSA: Body Surface Area, it calculated by

Meas. Menu	Submenu	Unit	Meas. Method/ Meas. Formula	Comment
				input the height and weight.
	MVCF		MVCF =（LVIDd-LVIDs）/（LVIDd×LVET）	Average Reduction of Length
Mitral Valve	EF Velocity	cm/s	Refer to M HR Meas.	
	AC Velocity	cm/s	Refer to M HR Meas.	
	A peak/E peak		Refer to M distance Meas.	
	Mitral Orifoce Flow		Refer to M HR and time Meas. QMV = 4 × DEV × DCT	DEV: Mitral Valve Opening Velocity DCT: Mitral Valve Opening Time
Arota	LAD/AOD		Refer to M distance Meas.	LV and aorta diametrical ratio
	Aortic Valvular Orifice Flow		AVSV = (MAVO1+MAVO2)× LVET×50+AA	MAVO1: Aorta opening distance at the beginning. MAVO2: Aorta opening distance at the end. AA: Range of Aorta Wall Motion

6.18 M Urology Measurement

The same as general measurement in M mode.

6.19 M Small Parts Measurement

The same as general measurement in M mode.

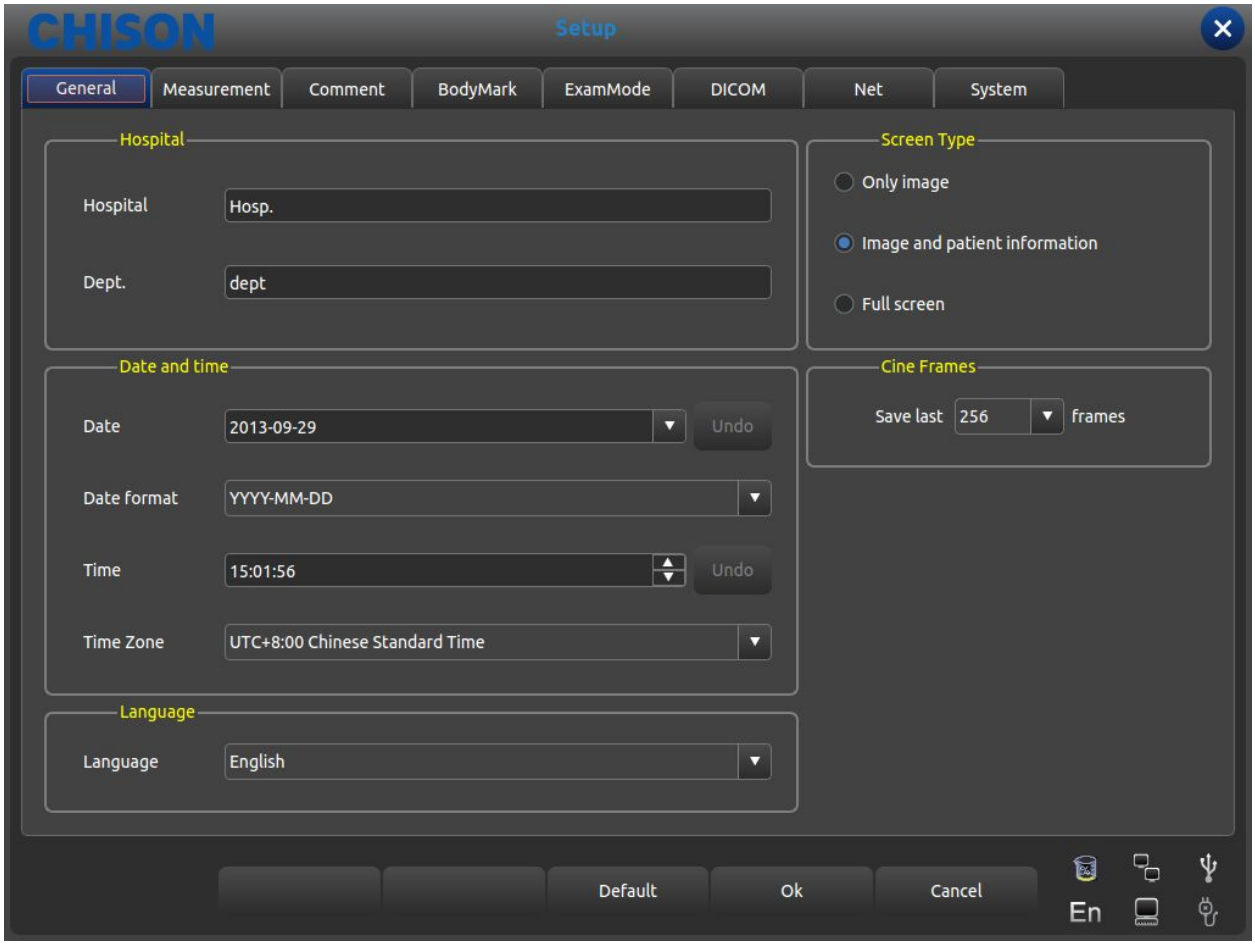
6.20 M Pediatric Measurement

The same as general measurement in M mode.

Chapter 7 Preset

This chapter introduces the operation to make settings of the system through preset menu at preset mode.
Preset function is used to set up working environment and status, parameters of each examination mode. The setting will be stored in the memory of system and not be 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.
In preset interface, all operation relies on moving trackball to required Function button position. Press [ENTER]button to start operation.

7.1 General setting



General Setting Interface

Press the [SETUP] key to enter system setting interface. User can do user-defined setting.
Click [X] in the title bar or the exit key on the button can exit the system setting interface.

Form 1 General setting

Function name	Setting method	Function description
Hospital、Department	Input freely	Set up the hospital name which is shown at top left corner of “General Setting” dialog box, 20 characters

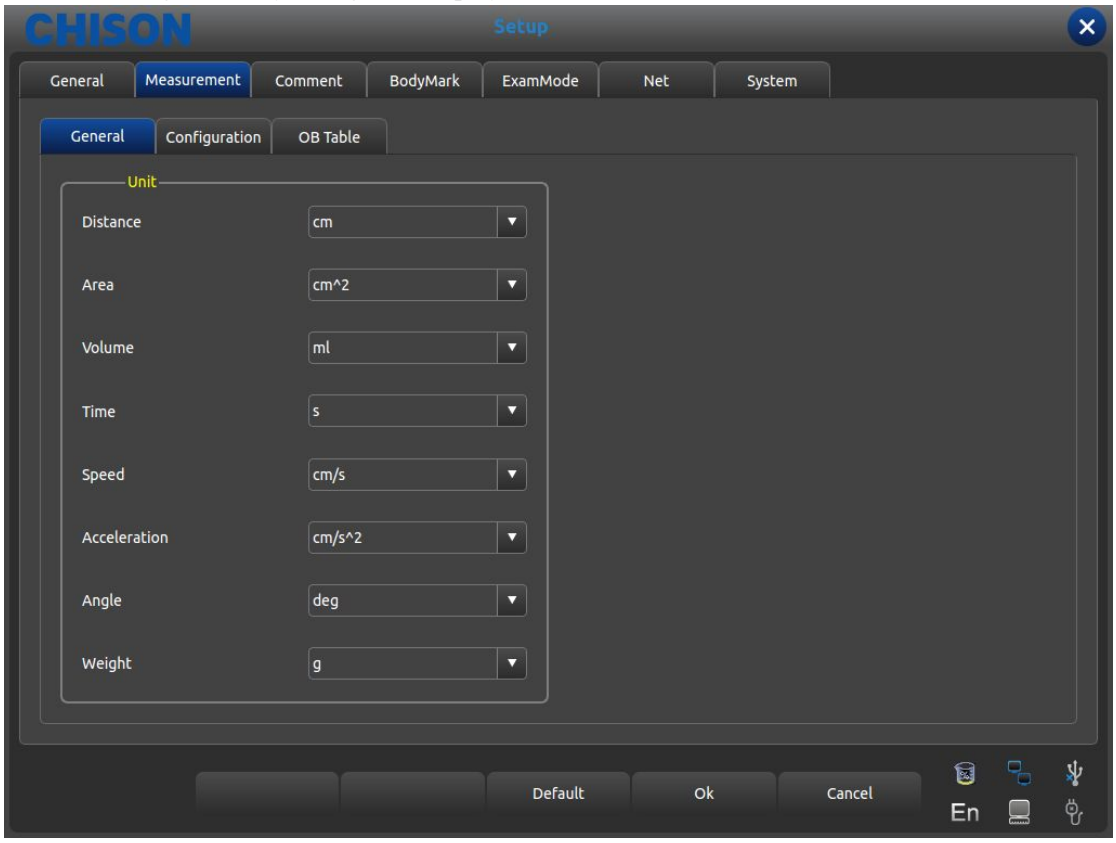
		Max. can be input
Date and Time	Input freely	Set up the system date (calendar format), select current date directly. Date format can be changed by format setting.
Date Format	Set up freely	Set up date format: Year/Month/Date, Month/Date/Year, Date/Month/Year
Time zone	Set up freely	Set up the working clock of the system.
Language	Select language	Select the language of operation interface(Simplified Chinese English and so)
Screen shot Type	Select the need type	Set the content which screen picture contain: only picture, image area and patient information, full screen
Frame number choice	Set up freely	Set the default frame when save the film
default	Press button	Recover all preset to factory setting

7.2 Measurement

Measurement includes general measurement setting and measurement formula setting

7.2.1 General measurement setting

General settings can only change the display of measurement unit.



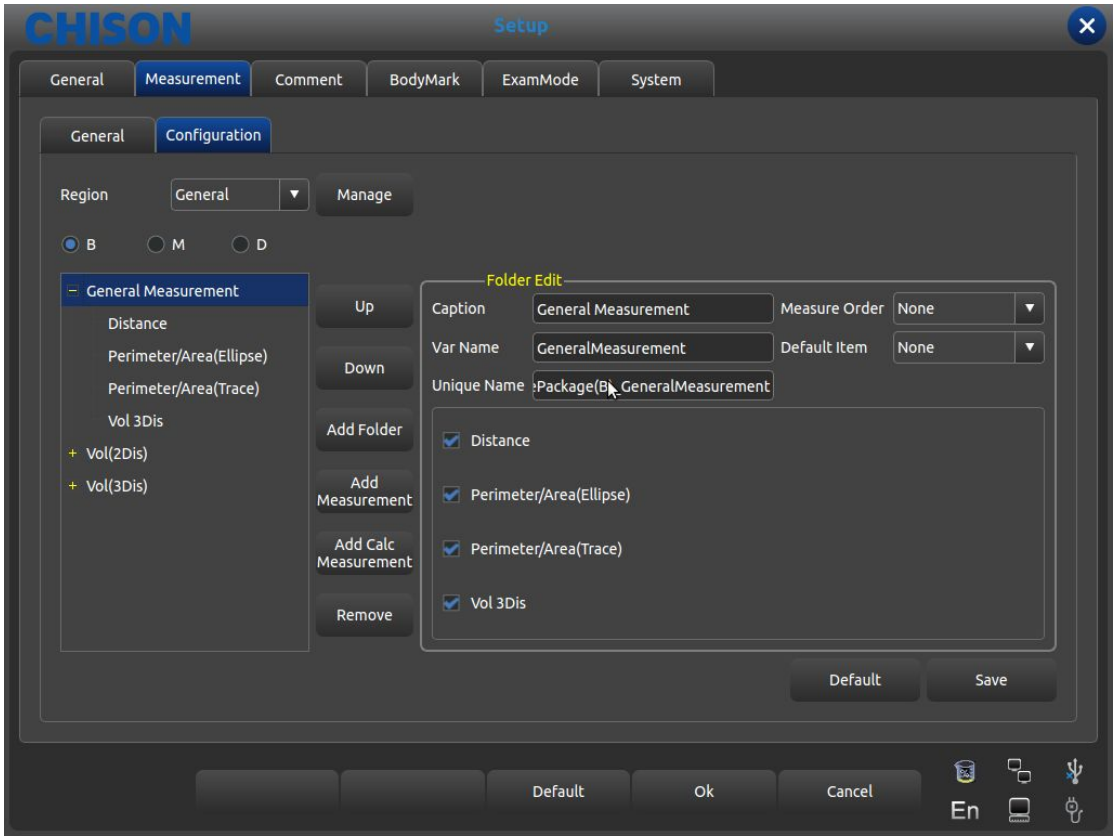
General Measurement settings interface

●Distance: cm, mm

●Area: cm^2, mm^2
●Volume: ml, l
●Time: s, ms
●Speed: cm/s, mm/s
●Acceleration: cm/s^2, mm/s^2
●Angle: deg, rad
●Weight: g, kg

7.2.2 Measurement formula setting

7.2.2.1 Interface Description-Measurement Menu



Interface for Edition of measurement Formula

●Region: pull down and select needed measurement menu
●Manage: pop up measurement software edition interface ,add modify delete change marshalling sequence in measurement menu.
●B、M: 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 cal item for a measurement term
●Remove: remove selected measurement term or item.

●Default: restore all measurement term as factory setting.

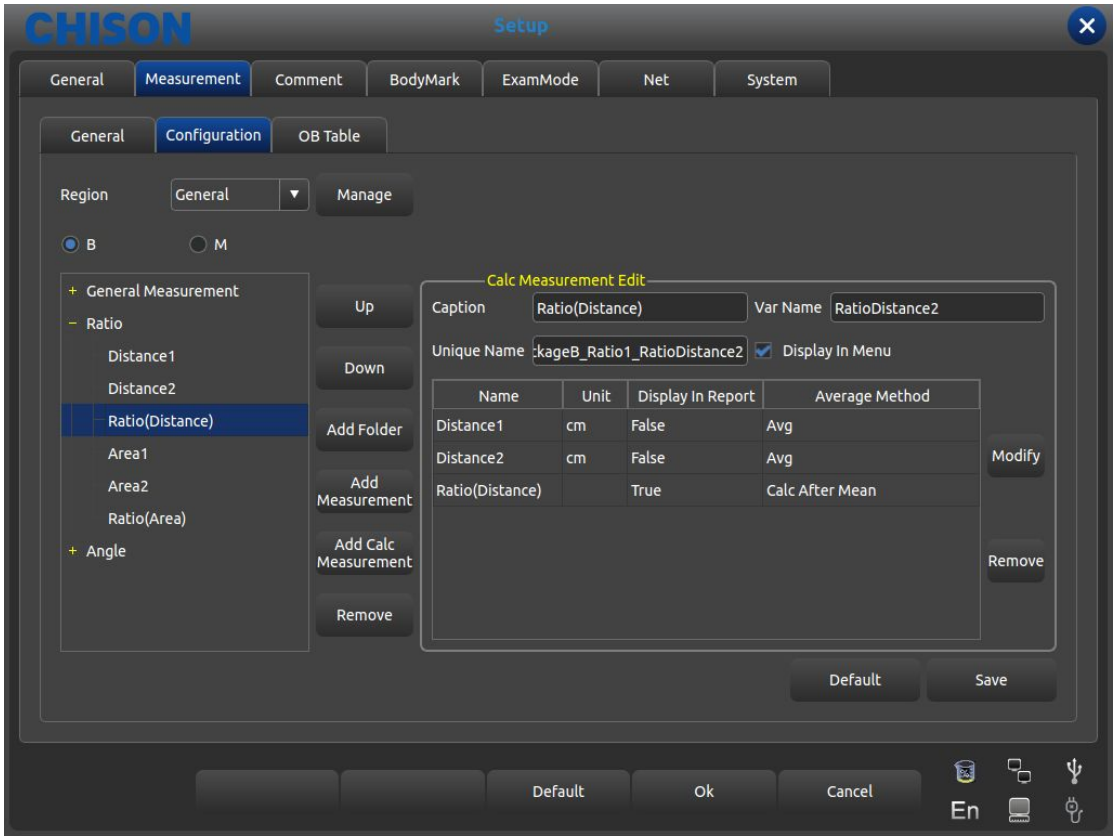
●Save: save measurement item modification users did

●Check : display needed items on measurement menu, otherwise not displayed

Sheet 2 Folder Edit content description

Caption	Display names of all items that is displayed name in 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 don't need modify
Measurement rule	None: Disable rule , Repeat: Repeat this item , Sequential: measure by sequence
Default item	After choosing the Repeat and Sequential , choose one measurement or calculation to activate the measurement rule

7.2.2.2 Interface Description-Measurement Manipulation



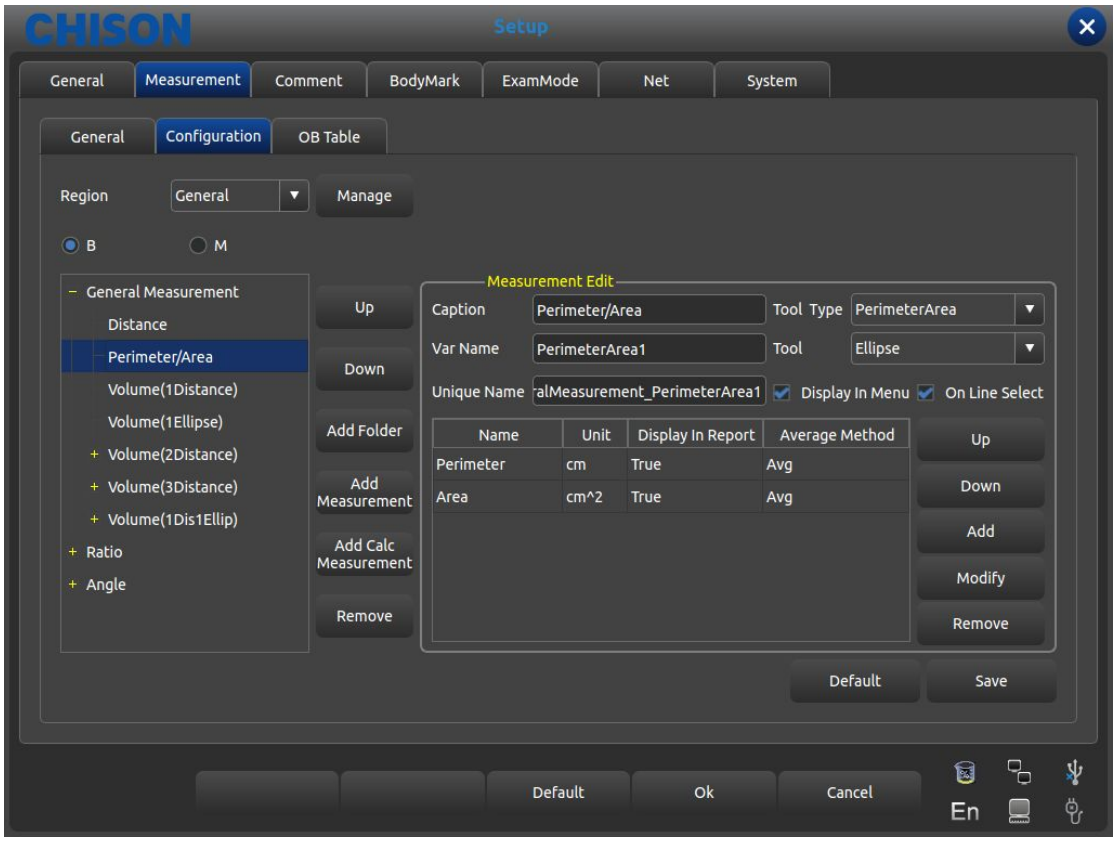
Interface for Edition of Measurement Formula

Sheet 3 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
Unique Name	Built-in code, user don't need modify
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.
Choose measurement methods	Check the methods in measurement menu , press [update] to switch the method, Otherwise , the measurement is not available
Display in Report	Check and display the item in measurement menu , otherwise ,the item is not displayed
Name	Measurement operation of specific measurement display in results
Unit	Data unit which measurement operation produces
Display In Report	Whether display in the report or not.
Average Method	The average rule of data
Modify	Press this button to pop up interface to modify measurement operation
Remove	Press this button to delete selected measurement operation

7.2.2.3 Interface Description-Measurement Calculation



Interface for Edition of Measurement Formal

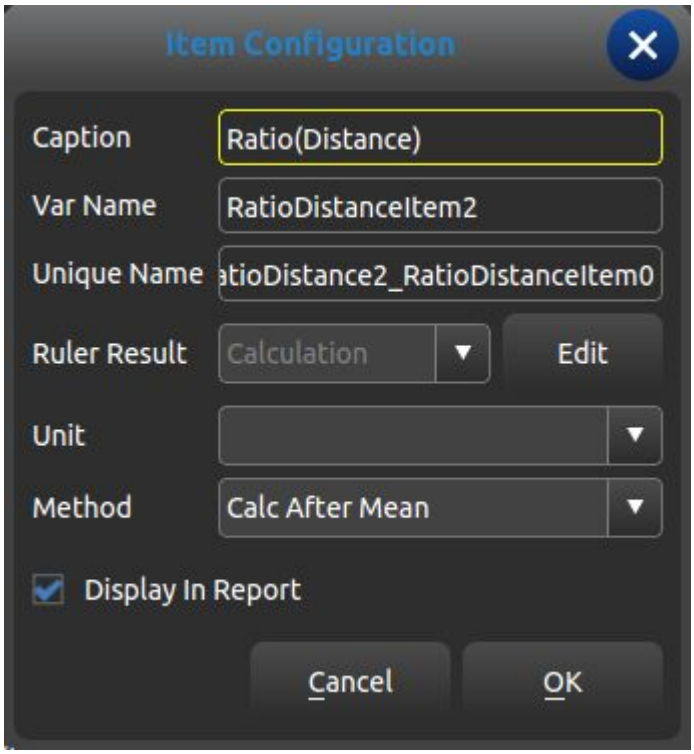
Sheet 4 Calc Measurement Edit content description

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

Unique Name	Built-in code, user don't need modify
Tool Type/Tool	Select available measurement tool type B distance (B line),area/circumference(ellipse, trace),M distance(M vertical line),time(M horizontal line),M slope(M slant)
Name	Needed measurement operation of specific measurement and calculation
Unit	Data unit which measurement operation produces
Display In Report	Whether display in the report or not.
Up	Press this button to move measurement operation up
Down	Press this button to move measurement operation down
Average Method	The average rule of data
Add	Press this button to pop up interface to add add measurement operation
Modify	Press this button to pop up interface to modify measurement operation
Remove	Press this button to delete selected measurement operation

7.2.2.4 Create Measurement Operation

Press [Add] in measurement operation interface, pop up the following dialog box



Interface for Edition of Measurement Formula

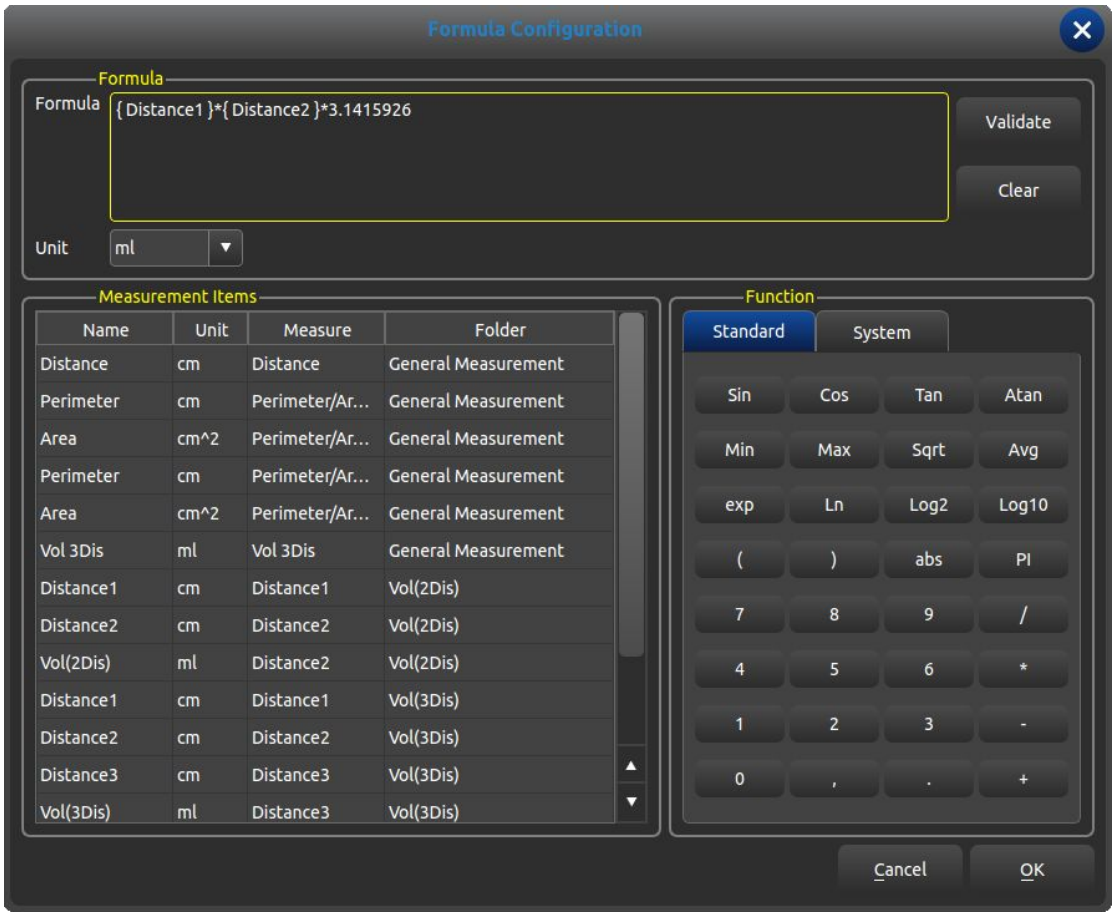
Sheet 5 Operation content description of creating new measurement

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
Unique Name	Built-in code, user don't need modify
Ruler Result	Needed measurement operation of specific measurement and calculation
Edit	Enter into interface to edit formula when selecting calculation item
Maximum	The maximum value displays in result zone and report
Minimun	The minimum value displays in result zone and report
Unit	Data unit which measurement operation produces
Display In Report	Whether display in the report or not.
Method	The average rule of data

7.2.2.5 Formula Edit-Normal

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



Interface for Edition of Measurement Formula

●Formula: edit formula in input box via 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

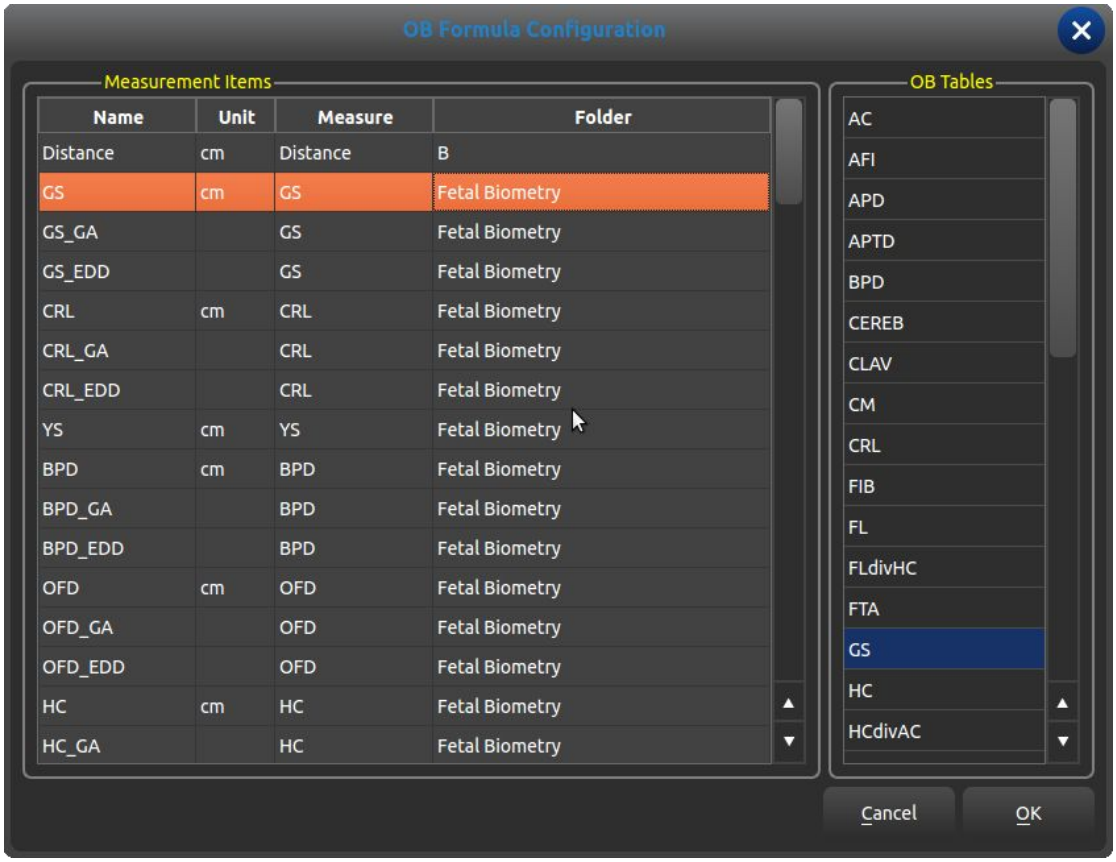
●Cancel: cancel editing formula and close the interface

●OK: save edited operation and close the interface

7.2.2.6 Formula Edit-OB

It is necessary to call built-in OB formula sheet when creating OB measurement operation the following function interface is required.

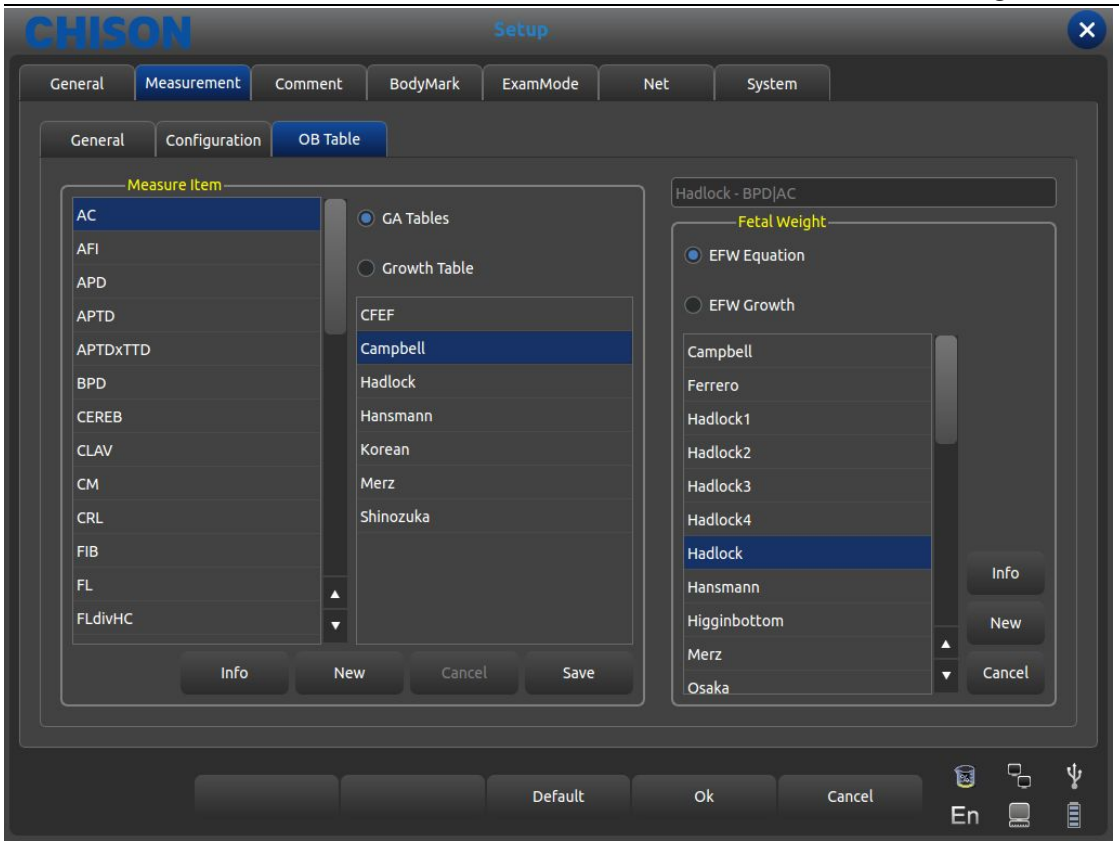
Caution: the results of GA and EDD don't require unit, the unit of this class has been built-in.



Measurement Items: display created measurement term by now

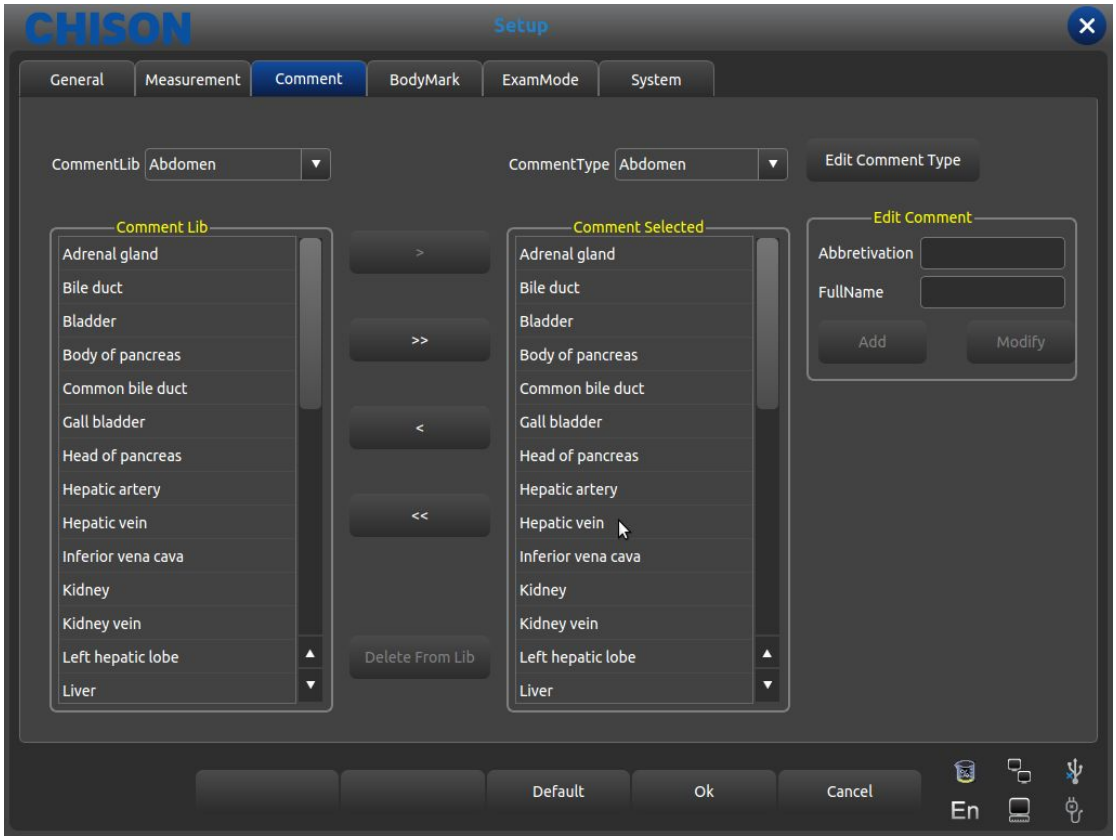
OB Tables: built-in OB formula table

OB List



- Measure Item: 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.
- Cancel:Cancel the operation of choosing the formula
- Save:Save the users' choice of formulas

7.3 Annotation



Annotation Setting Interface

7.3.1 Annotation Library

The annotation database of the system is classified as : abdomen、OB、GYN、Cardiac、small part、Pathological change Annotation can be made by inputting characters from the soft keyboard or recalling the terms saved in annotation database.

Press[CommentLib]pull down button, pop up annotation name within system

, through trackball and [ENTER] to show required annotation status.

7.3.1.1 Edit Annotation Library

Operation:

1.At the annotation status, Move the cursor to the [Edit Comment Type]button then press [ENTER] key, the annotation will be updated, and can be edited.

2.Input name into the new created annotation status box, Move the cursor to the [Create]button then press [ENTER] key, then create new annotation status and appear in selected annotation status list

3.Move the cursor to the [Delete]button ,press [ENTER] key, then delete current annotation status in the selected annotation list.

4.Alter name of current annotation status list in[Current Type Name]input box, press[ENTER] on

the[Rename]button, then rename the selected annotation status name.

7.3.2 Edit Annotation

Operator uses only current annotation instead of all content annotation status provides, inlay common annotation If necessary, user can import annotation or self-compiled annotation into common annotation.

7.3.2.1 Add annotation from annotation library

Operation:

1.Select needed source annotation status via Trackball and [ENTER]

2.Select needed annotation at [CommentLib]column then press the[ENTER]button to activate this annotation.

3.press[ENTER] on[>]button to import selected annotation into user-selected annotation status;press[ENTER] on[>]button to move selected annotation in[Comment Selected]column into source annotation.

4.press[ENTER]on[>>]button to import all annotation in source into user-selected annotation status;press[ENTER]on[>>] button to move all annotation in[Comment Selected]column into source annotation.

7.3.2.2 Add annotation manually

Operation:

1.Activate[Edit Comment]input box via Trackball and[ENTER] button, then input needed abbreviation and full name of annotation.

2.press[ENTER]on[Add]button, meanwhile this handout will be added into source and user-selected annotation status.

7.3.2.3 Alter annotation

Operation:

1.Alter annotation in user-selected status, the abbreviation and full name of annotation will be displayed in[Edit Comment] box.

2.Activate needed abbreviation and full name via [ENTER]and alter via keyboard.

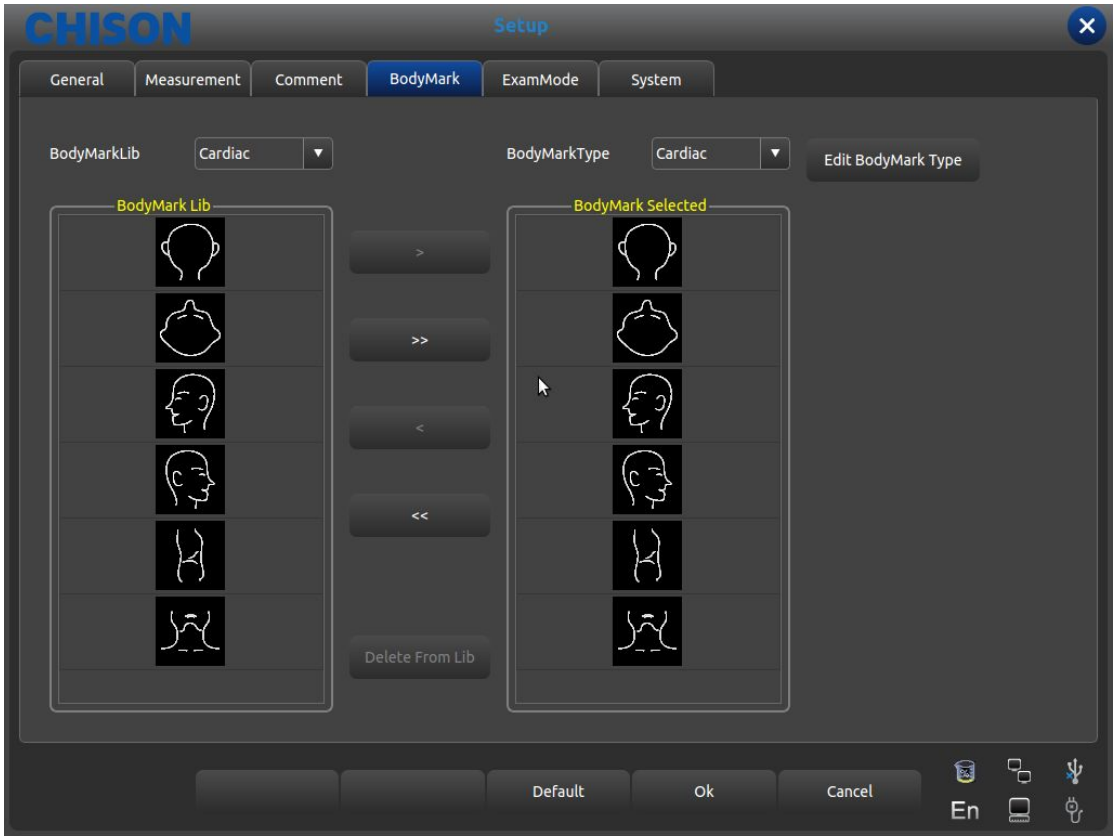
3.press[ENTER]on[Modify]button, modify the annotation in both source and user-selected status.

7.3.2.4 Delete annotation in library

Operation:

Select needed annotation in source status, press [ENTER]on [Delete From Lib]button then the annotation deleted.

7.4 Body marks



Interface for Body Mark Setting

7.4.1 Body Marks Library

Built-in body marks: abdomen OB, GYN, Cardiac, small part, urology, vessel.

Press [BodyMarkLib]pull down button, pop up name of built-in body marks, show needed body marks via Trackball and[ENTER]button.

7.4.1.1Edit body marks library

Operation:

1.press[ENTER]on [Edit BodyMark Type], pop edit box.

2.Input name into the new created body marks box, Move the cursor to the [Create]button then press [ENTER] key, then the new body marks will be created and appear in selected body marks list

3.Move the cursor to the [Delete]button then press [ENTER] key, then delete current body marks in the selected list.

4.alter current annotation status list name in[Current Type Name]input box, press[ENTER] on the[Rename]button, then rename the selected body marks.

7.4.2 Body mark edition

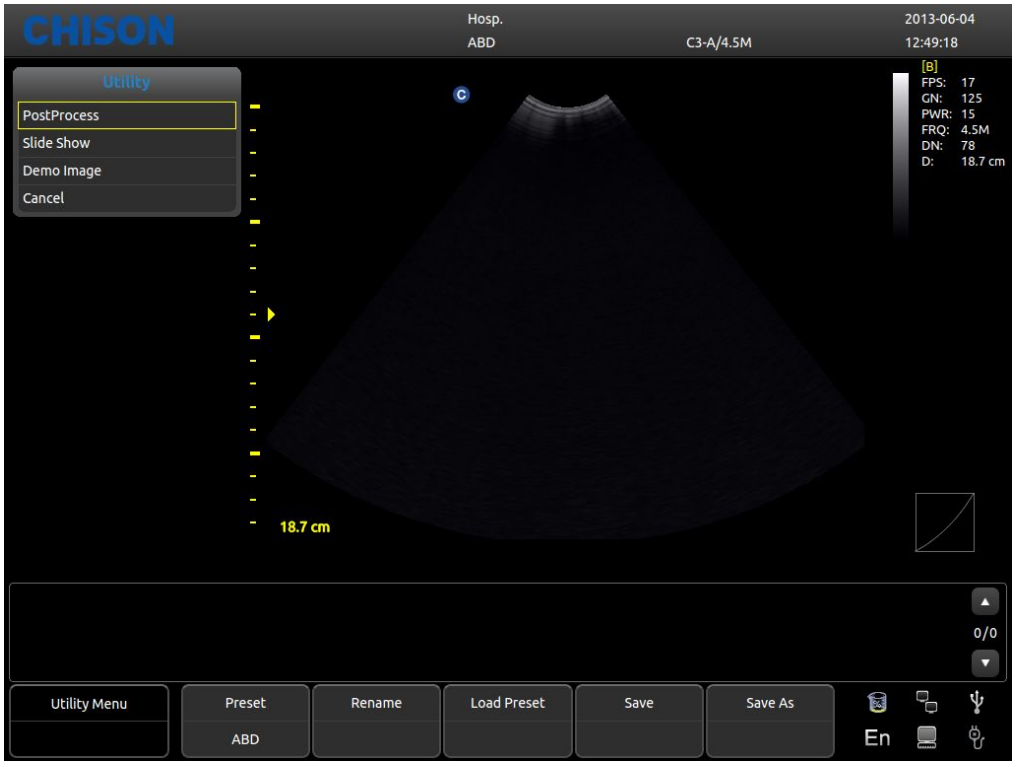
Operation:

1.Select needed source body marks via Trackball and [ENTER]
2.Select needed body marks at [BodyMarkLib]column then press the[ENTER]button to activate it.
3.press[ENTER] on[>]button to import selected body marks into user-selected status; press[ENTER] on[>]button to move selected body marks in[BodyMark Selected]column into source body marks.
4.press[ENTER]on[>>]button to import all body marks in source into user-selected status; press[ENTER]on[>>] button to move all body marks in[BodyMarks Selected]column into source .

7.5 Exam Mode

7.5.1 Exam Mode Edit

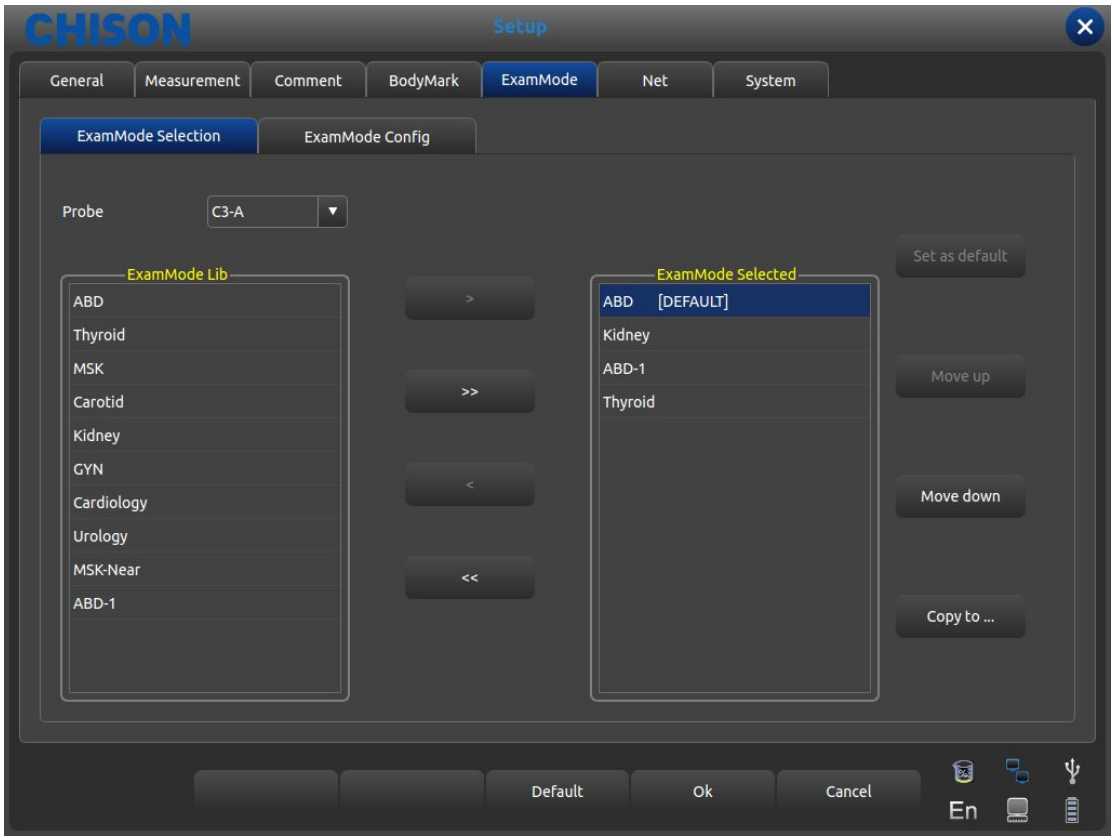
Press Utility in the submenu of [MENU], the parameters control area shows as following. According to the corresponding control button to turn on or off the function.



- Preset: Display the current 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.

7.5.2 Exam Mode Selection

Choose Utility and press [MENU],the following interface pop up. Open the relate function by corresponding control area.

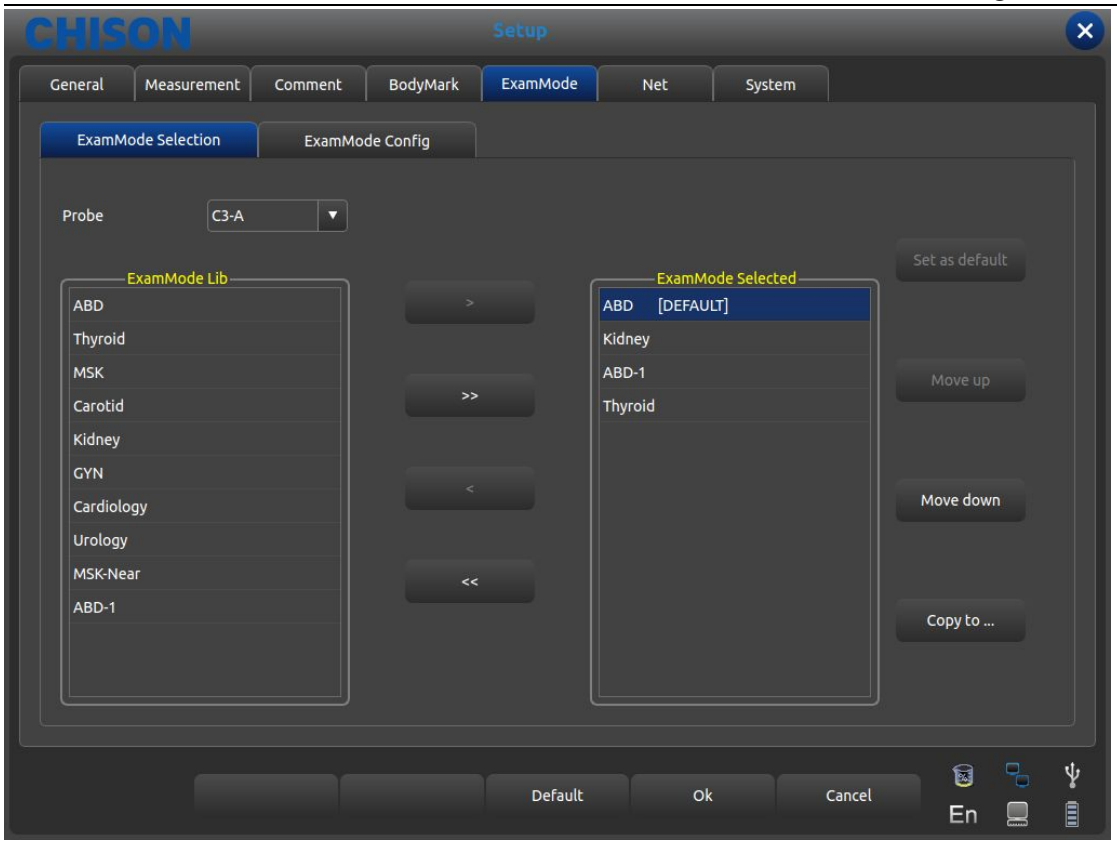


Interface for ExamMode Setting

- Probe: select needed probe and ExamMode fit for it.
- ExamModeLib: show all existed Exam modes.
- ExamMode Selected: show Exam modes in probe column.
- >: 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.

7.5.3 Exam mode selection

Operator can define needed Exam mode in detail including annotation, body marks, measurement menu import and export etc.



Interface for Exam Mode Setting

●ExamMode: show all existed Exam modes in system

●Comment: double click[ENTER]to activate widget box, can choose existed annotation status name. 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.

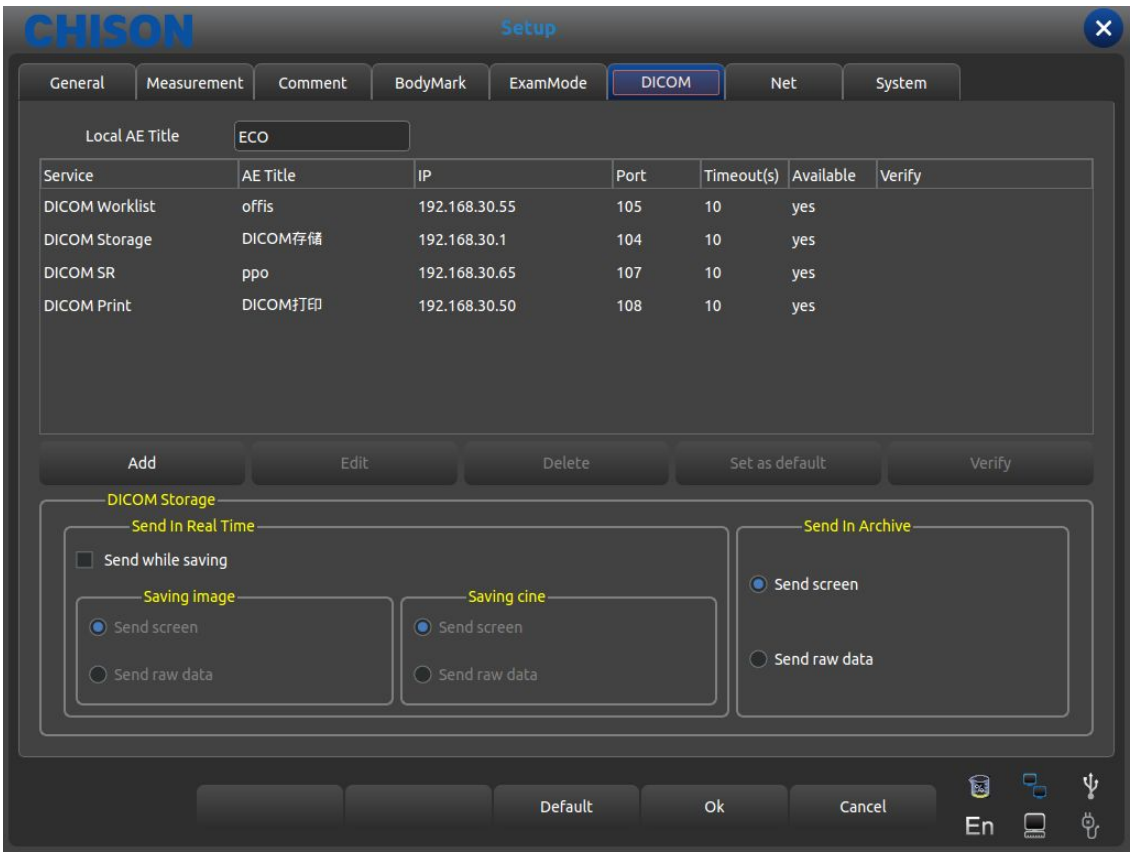
●Import: import all built-in Exam modes into USB flash disk.

●Restore: restore all Exam mode as factory setting.

7.6 DICOM

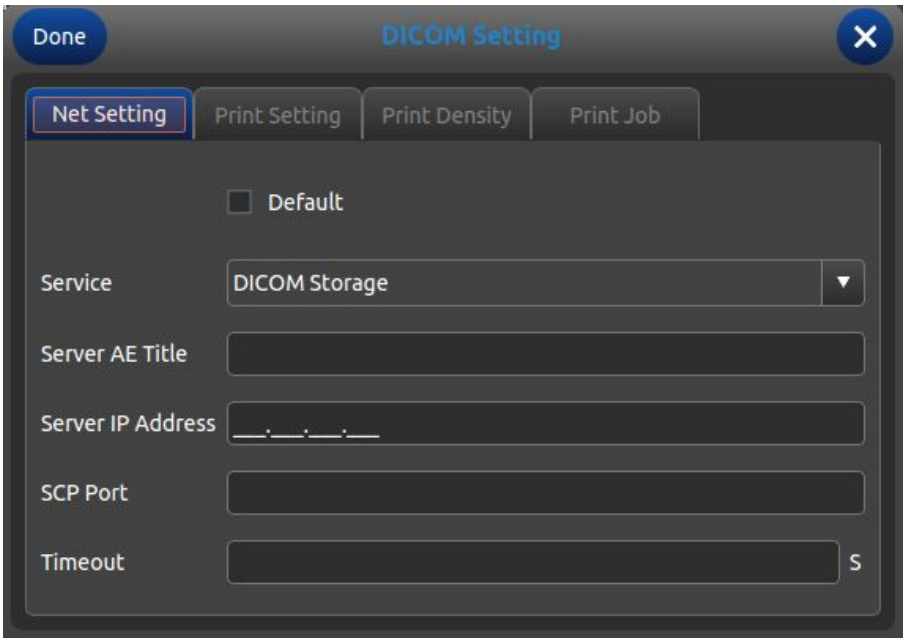
DICOM includes DICOM Storage , DICOM Worklist , DICOM Print and DICOM SR . If DICOM is to be applied , please make sure DICOM has been activated . In the system page of setting interface , you can check whether DICOM is open or not . If you want to activate DICOM , please contact with Chison.

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



Local AE Title:input local DICOM Title to sepearte the DICOM equippments 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
Timeout(s): display the delay tim
Available: 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,
Delete: delete the existed DICOM function
Set as default: set one DICOM service as default ,
Send while saving: check this item and enable DICOM storage while saving image or cine , send clip or image according to activated function.
Send in archive: send DICOM storage in archive or review , send clip or image according to activated function.

7.6.1 Add/Edit DICOM Function



Default: check this option , set DICOM function as default;
Service: choose DICOM Storage , DICOM Worklist , DICOM Print or DICOM SR;
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;
Tip: choosing the DICOM Print type must be before relative print setting.

7.7 NET Work

Set the unit's and target unit's IP and do the connection testing.

7.8 System

7.8.1 System information

Display the software version, Hardware version, System version

7.8.2 Upgrade

Software and Hardware can be updated by USB flash drives.
Software upgrade File Path: X:\update\XXX or X:\update_SN\XXX.Hardware update File Path: "X:\fpga_update\XXX", Keyboard upgrade File Parth: "X:\ keyboard_update \XXX". X means USB flash drives.XXX means upgrade content .It should restart manually after hardware update, and after software update, machine can be restarted automatically.

7.8.3 Function Setting

DICOM: Click 『Open』 key, it will bring up the DICOM Key Input dialog box. Input the DICOM SN, and click『OK』key to save and exit.

7.8.4 Installment setting

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

7.8.5 Video VGA

Choose the video data: NTSC or PAL.

Video opened: Choose the item to open this function.
VGA opened: Choose the item to open this function.

7.8.6 Image function

Export hardware SN and import hardware secret key, it only for engineer use.

7.8.7 System Maintenance

Only an authorized service engineer may perform maintenance.

7.8.8 USB Video Printer Option

Adjust the parameters of Video Printer Option：Dark, Light, Sharpness, Gamma.
Select the parameters needed to adjust, press [Comfirm] button on the slider of the parameter, and move the traceball to change the parameter.

Chapter 8 System Maintenance

8.1 Machine Clean

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

Clean methods:

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 dry

Caution:

1. Don't use organic solvent such s alcohol ,otherwise surface may be ruined
2. When cleaning the machine, don't let the liquid inflow the machine, otherwise it may malfunction and there is danger of electric shock.
3. 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.

8.2 Probe Maintenance

The probes used by this machine can be divided into two series: body surface and intracavity

During all ultrasound scan , ultrasonic radiation on the human body should be as less as possible.

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 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.

Cleaning

The cleaning procedure is fit for all probes. After operation every probe should do cleaning according to stated procedure of this passage. Inspection should be done for intracavity probe depends on condition of use

Cleaning procedure:

1. Wipe the remaining coupling gel and blot with flowing clear water. Avoid the joint part between cable and

probe touching the water or others

2. Use wet gauze or other soft cloth with a little liquid soap to clean the probe totally. Don't use cleaning agent and cleaner with abrasiveness

3. Use flowing water to rinse fully. Use soft cloth which has been soaked by the concentration of 70% isopropyl alcohol to scrub. Then check the probe to make sure there is no blot.

4. Use clean cloth to dry the probe

caution: Don't put the body surface probe into liquid below acoustical lens. Intracavity probe can't exceed insertion region. Prohibit putting connector of probe into any liquid.

Infection

Infection procedure id fit for intracavity probe

If it is necessary to use in surgery, please abide with instruction of professional infection person

infection procedure:

1. Obey the cleaning procedure to clean the probe totally

2. Prepare and retreat The concentration of 2% glutaraldehyde solution as the infection solution according to the instruction of manufacturer

3. Put the insertion region of probe into infection solution, the inserting depth can't exceed insertion region. Don't let the probe connector touch any liquid.

4. Soak the probe for 3 h

5. Pull out the probe, immediately rinse totally with sterile water and saline. To make sure of no any solution remaining. Please obey the rule to do right rinsing procedure including enough rinsing water and times

6. When probe is used in sterile area ,make sure to use disposable sterile probe hood

caution:

- Don't soak probe connector into any liquid
- Don't let the soaking depth of intracavity probe exceed insertion region
- Prohibit soaking the probe in the liquid for more than 12 h
- Only use qualified inspection resolution

Deposit:

Please replace the probe in clean and dry environment, avoid direct sunshine

Keep the environment to deposit the probe during -10 — 50℃, Do not put it in high pressure and vacuum environment.

When accessing probe be careful and avoid ruin.

During transportation or leisure, the probe should be deposited in probe box.

8.3 Safety Check

To make sure this device works normally, a piece of maintenance plan is suggested to make to check the device regularly If any abnormal phenomena, immediately stop operation and contact with Sale Office, Customer Service department or Agents of manufacturer.

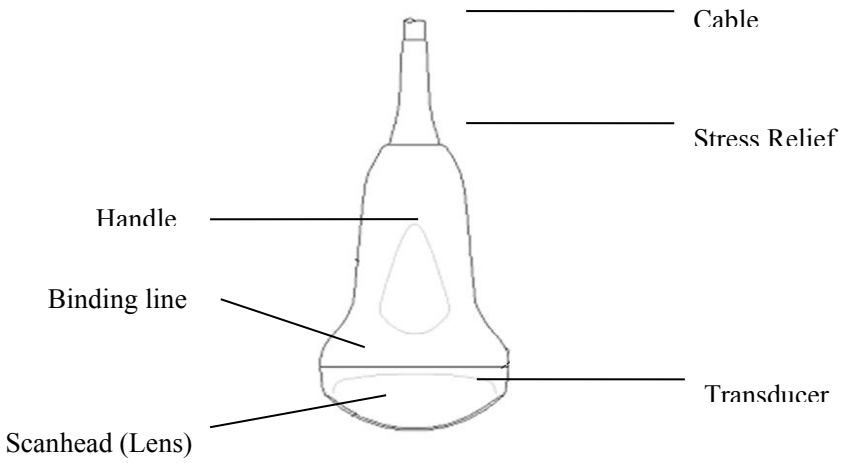
If no image or menu but image, please check following malfunction table. If the malfunction can't be solved, please contact with Sale Office, Customer Service department or Agents of manufacturer.

8.4 Malfunction Check

serial number	malfunction	reason	Measures
1	Switch button lights but power LED not	Battery lose efficacy, Adapter works irregular	Check the connector between cable and power
2	Power Led lights but LED no image	The interval time is too short to restart	Restart after 1 minute
3	LED 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
4	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
5	Probe works improperly	1.The plug plugs loosely 2.Internal circuit protects	1.Extract the probe and reinsert 2.Restart
6	No OB calculation package menu	Do not select the OB application before scanning.	Select the OB application
7	PRINT-key doesn't work	1.The connected printer is 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

Chapter 9 Probes

9.1 General Description



Convex Probe Overview

The probes provide high spatial and contrast ultrasound imaging of frequencies from 2.0MHz to 11.0MHz. 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.

9.2 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:

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

9.2.1 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.

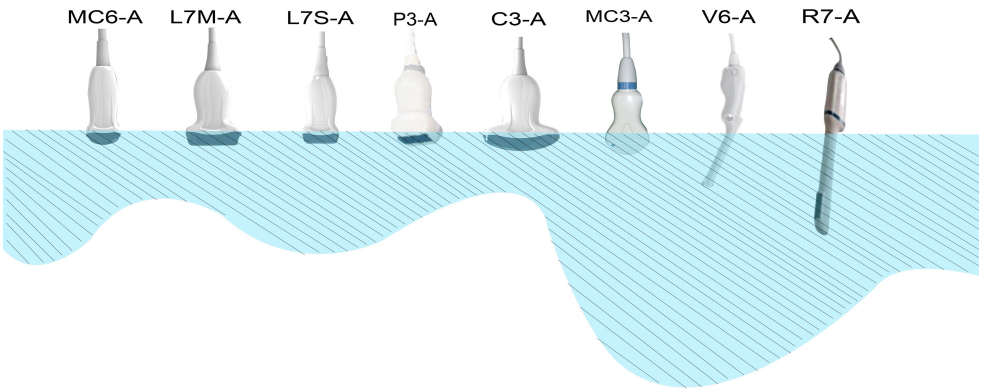
WARNING

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.

9.2.2 Cleaning and Disinfecting

- Place the probe into the solution of cleaning-disinfectant. Make sure not to immerse the probe into the liquid beyond the immersion level given in the pictures below. Make sure that the probe is covered with the cleaning-disinfectant up to the immersion level during the complete disinfection time.
- For the recommended cleaning and disinfection time, please see your Operating Manual .
- Scrub the probe as needed using a soft sponge, gauze, or cloth to remove all visible residue from the probe surface.
- Rinse the probe with enough clean, potable water to remove all disinfectant residues.
- Use a soft cloth to clean the cable and the user section of the probe with the cleaning disinfectant liquid. Make sure that the surface of the probe and cable is wetted thoroughly with the cleaning-disinfectant.
- Allow probe to air dry completely.
- Reconnect the probe to the ultrasound console and place the probe into it's holder.

Probe Immersion Levels



CAUTION

These transducers are not designed to withstand heat sterilization methods. Exposure to temperatures in excess of 60 ° C 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.

Probe Safety

Handling precautions

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 endocavitary 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.

Endocavitary Probe Handling Precautions

If the sterilization solution comes out of the endocavitary 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.

Endocavitary Probe Point of Contact: Refer to the sterilant's instruction manual.

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.

Probe Cleaning process:

DO disconnect the probe from the system prior to cleaning/disinfecting the probe. Failure to do so could damage the system.

Perform Cleaning probe after each use

- 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.
- 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.

Disinfecting the probes:

After each use, please disinfect the probes. Ultrasound probes can be disinfected using liquid chemical germicides. The level of disinfection is directly related to the duration of contact with the germicide. Increased contact time produces a higher level of disinfection.

In order for liquid chemical germicides to be effective, all visible residue must be removed during the cleaning process. Thoroughly clean the probe, as described earlier before attempting disinfection.

You MUST disconnect the probe from the system prior to cleaning/disinfecting the probe. Failure to do so could damage the system.

DO NOT soak probes in liquid chemical germicide for longer than is stated by the germicide instructions for use. Extended soaking may cause probe damage and early failure of the enclosure, resulting in possible electric shock hazard.

- Prepare the germicide solution according to the manufacturer's instructions. Be sure to follow all precautions for storage, use and disposal. The transducer is not designed to be totally submerged in fluid. Permanent damage will result if the entire transducer is submerged. The immersed part shall not exceed the transducer binding line.
- Place the cleaned and dried probe in contact with the germicide for the time specified by the germicide manufacturer. High-level disinfection is recommended for surface probes and is required for endocavitary probes (follow the germicide manufacturer's recommended time).
- After removing from the germicide, rinse the probe following the germicide manufacturer's rinsing instructions. Flush all visible germicide residue from the probe and allow to air dry.

Ultrasound transducers can easily be damaged by improper handling and by contact with certain

chemicals. Failure to follow these precautions can result in serious injury and equipment damage

- Do not immerse the probe into any liquid beyond the level specified for that probe. Never immerse the transducer connector or probe adapters into any liquid.
- Avoid mechanical shock or impact to the transducer and do not apply excessive bending or pulling force to the cable.
- Transducer damage can result from contact with inappropriate coupling or cleaning agents:
    - Do not soak or saturate transducers with solutions containing alcohol, bleach, ammonium chloride compounds or hydrogen peroxide
    - Avoid contact with solutions or coupling gels containing mineral oil or lanolin
    - Avoid temperatures above 60°C. Under no circumstances should the transducer be subjected to heat sterilization method. Exposure to temperatures above 60º C will cause permanent damage to the transducer.
- Inspect the probe prior to use for damage or degeneration to the housing, strain relief, lens and seal. Do not use a damaged or defective probe.

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.

DO NOT apply gel to the eyes. If there is gel contact to the eye, flush eye 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)
- Dimethylsilicone

Planned maintenance

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

Daily: inspect the probes

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

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

AIUM outlines cleaning the endocavitary 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.

1. CLEANING

After removal of the probe cover, use running water to remove any residual gel or debris from the probe. Use a damp gauze pad or other soft cloth and a small amount of mild non-abrasive liquid soap (household dishwashing liquid is ideal) to thoroughly cleanse the transducer. Consider the use of a small brush especially for crevices and areas of angulation depending on the design of your particular transducer. Rinse the transducer thoroughly with running water, and then dry the transducer with a soft cloth or paper towel.

2. DISINFECTION

Cleaning with a detergent/water solution as described above is important as the first step in proper disinfection since chemical disinfectants act more rapidly on clean surfaces. However, the additional use of a high level liquid disinfectant will ensure further statistical reduction in microbial load. Because of the potential disruption of the barrier sheath, additional high level disinfection with chemical agents is necessary. Examples of such high level disinfectants include but are not limited to:

- 2.4-3.2% glutaraldehyde products (a variety of available proprietary products including "Cidex," "Metricide," or "Procide").
- Non-glutaraldehyde agents including Cidex OPA (o-phthalaldehyde), Cidex PA (hydrogen peroxide & peroxyacetic acid).
- 7.5% Hydrogen Peroxide solution.
- Common household bleach (5.25% sodium hypochlorite) diluted to yield 500 parts per million chlorine (10 cc in one liter of tap water). This agent is effective, but generally not recommended by probe manufacturers because it can damage metal and plastic parts.

Other agents such as quaternary ammonium compounds are not considered high level disinfectants and

should not be used. Isopropanol is not a high level disinfectant when used as a wipe and probe manufacturers generally do not recommend soaking probes in the liquid.

The FDA has published a list of approved sterilants and high level disinfectants for use in processing reusable medical and dental devices. That list can be consulted to find agents that may be useful for probe disinfection.

Practitioners should consult the labels of proprietary products for specific instructions. They should also consult instrument manufacturers regarding compatibility of these agents with probes. Many of the chemical disinfectants are potentially toxic and many require adequate precautions such as proper ventilation, personal protective devices (gloves, face/eye protection, etc.) and thorough rinsing before reuse of the probe.

3. 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.

4. ASEPTIC 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.

Amis S, Ruddy M, Kibbler CC, Economides DL, MacLean AB. Assessment of condoms as probe covers for
transvaginal sonography. J Clin Ultrasound 2000;28:295-8.

Rooks VJ, Yancey MK, Elg SA, Brueske L. Comparison of probe sheaths for endovaginal sonography. Obstet. Gynecol 1996;87:27-9.

Milki AA, Fisch JD. Vaginal ultrasound probe cover leakage: implications for patient care. Fertil Steril 1998;69:409-11.

Hignett M, Claman P. High rates of perforation are found in endovaginal ultrasound probe covers before and after oocyte retrieval for in vitro fertilization-embryo transfer. J Assist Reprod Genet 1995;12:606-9.

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).

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).

9.3 Probe Operation Instructions

For details on connecting, activating, deactivating, disconnecting, transporting and storing the probes, see Section **3.7 "Probes"** in Chapter 3.

9.3.1 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.

9.3.2 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 43º C is allowed. It also depends on the patient's body temperature. When the temperature of probe tip exceeds 43º C, 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:

➢Put on medical sterile glove

➢Get the condom for the package.

➢Unfold the condom.

➢Load some ultrasound gel into condom.

➢Take the condom with one hand, and put the probe head into the condom.

➢Fasten the condom on the end of the probe handle.

➢ Confirm the integrity of the condom, and repeat the above steps to the condom if any damage to the condom is found.

9.3.3 Cleaning and Disinfecting TV and TR Probes

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 and transrectal probes 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 probe is not waterproof, you should disconnect it from the system before cleaning or disinfecting.

Before and after each exam, please clean the probe handle and disinfect the transvaginal and transrectal probes using liquid chemical germicides.

Cleaning

You can clean the transvaginal and transrectal probes 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 transvaginal 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 TV and TR probes, it is important to be sure that all surfaces are thoroughly cleaned.*

Disinfecting

2 Glutaraldehyde-based solutions have been shown to be very effective for this purpose. 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:

- Following all precautions for storage, use and disposal, prepare the germicide solution according to the manufacturer's instructions.
- 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.

- 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.
- Following all precautions for storage, use and disposal, prepare the germicide solution according to the manufacturer's instructions.
- After removing from the germicide, rinse the probe according to the germicide manufacturer's rinsing instructions.
- Flush all visible germicide residues from the probe and allow to air dry.

9.3.4 Thermal and Tip Angle Monitoring

The Transvaginal and Transrectal probes are equipped with a thermal sensor providing continuous feed-back to the system on the temperature of the probe tip. The tip temperature is displayed in Celsius(^{o} C). Whenever the probe is activated , the temperature and tip angle are displayed on the screen. An optional patient body temperature is entered in the system menu, and the default is 37 degree C.

For maximum safety, the temperature will flash when the tip temperature reach 41^{o} C, and the system has a thermal limit of 43^{o} C; when the probe tip reaches this limit, the system will automatically deactivates the probe and back to the EXAM screen.

You should remove the probe from the patient and wait the probe cool down. As soon as the probe has cooled, the exam can be restored. At the thermal limit, all system controls are inhibited under normal operating conditions, the probe will not reach the thermal limit except scanning febrile patients or the thermal sensor of the probe fails.

See following suggestions that may help to keep the probe tip temperature in safe range:
In 2D, scan with the maximum available angle and deeper depth available.
CFM and Doppler are the modes with the possibility of temperature increasing; in febrile patients, use these modes as little and as short time possible.

9.4 Service Responsibility

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

REFERENCE:

1)AIUM/NEMA: Standard For Real-Time Display of Thermal and Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment, Revision 2. NEMA Standards Publication UD 3-2004; American Institute of Ultrasound in Medicine, Laurel MD; National Electrical Manufacturers Association, Rosslyn, VA; 2004a.

2)Implementation of the Principle of As Reasonably Achievable (ALARA) for Medical and Dental Personnel, National Council on Radiation Protection and Measurements (NCRP), report NO.107, December 31,1990

3)FDA Center for Devices and radiological Health (CDRH), 510(K) Guidance for Diagnostic

Ultrasound and Fetal Doppler Ultrasound Medical Devices, September 8 1989 draft

4)FDA/CDRH,510(K) Diagnostic Ultrasound Guidance Update of 1991, April 26, 1991 draft

5)Biological Effects of Ultrasound: Mechanisms and Clinical Implications, NCRP Report No. 74, December 30,1983

6)Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms, NCRP Report No.113, June 1,1992

7)Bioeffects Considerations for the safety of Diagnostic Ultrasound, Journal of Ultrasound in Medicine, AIUM, September1988

8)Geneva Report on Safety and Standardization in Medical Ultrasound, WFUMB, May 1990 Medical Ultrasound Safety, AIUM, 1994

9)Medical Electrical Equipment standard IEC 60601-1, IEC60601-1-1, IEC60601-1-2, IEC 60601-2-37, IEC 60601-2-4

10) Diagnostic Ultrasound Physics and Equipment, edit by P. R. Hoskins, in 2003

Appendix A: The Information of CE Representative

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Appendix B: Acoustic Output Report Table

Transducer Model: C3-A **Operating Mode: B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			0.459	0.09				#
Assocoiated Acoustic Parameter	$P_{r.3}$	(MPa)	0.889					
	W_o	(mW)		2				#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	z@$PII_{.3max}$	(cm)	3.05					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	3.76	3.848				#
	Dim of A_{aprt}	X (cm)		2.088				#
		Y (cm)		1.1				#
Other Information	PD	(μsec)	0.546					
	PRF	(Hz)	2293.6					
	p_r@PII_{max}	(MPa)	1.31					
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)		0.781				#
		FL_y (cm)		0.259				#
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	32.433					
Operating Control Conditions	Mode		B	B				#
	Focus	(cm)	4	2				#
	Power	(%)	100	100				#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: C3-A **Operating Mode: THI-B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.317	0.094				#
Assocoiated Acoustic Parameter	$P_{r.3}$	(MPa)	0.626					
	W_o	(mW)		20				#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$z@PII_{.3max}$	(cm)	3.5					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	3.894	4.031				#
	Dim of A_{aprt}	X (cm)		2.088				#
		Y (cm)		1.1				#
Other Information	PD	(μsec)	1.227					
	PRF	(Hz)	1802.8					
	$p_r@PII_{max}$	(MPa)	0.996					
	$d_{eq}@PII_{max}$	(cm)						
	Focal Length	FL_x (cm)		0.781				#
		FL_y (cm)		0.259				#
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	39.47					
Operating Control Conditions	Mode		THI-B	THI-B				#
	Focus	(cm)	4	2				#
	Power	(%)	100	100				#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: C3-A **Operating Mode: M**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					A_{aprt}≤1	A_{aprt}>1		
Global Maximum Index Value			0.353			0.181	0.247	#
Assocoiated Acoustic Parameter	$P_{r.3}$	(MPa)	0.666					
	W_o	(mW)					20	#
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				10.627		
	z_1	(cm)				3.05		
	z_{bp}	(cm)				2.56		
	z_{sp}	(cm)					3.55	
	z@$PII_{.3max}$	(cm)	2.85					
	$d_{eq}(z_{sp})$	(cm)					0.802	
	f_c	(MHz)	3.562			3.581	3.569	#
	Dim of A_{aprt}	X (cm)				6.96	6.96	#
		Y (cm)				1.1	1.1	#
Other Information	PD	(μsec)	0.54					
	PRF	(Hz)	2293.6					
	p_r@PII_{max}	(MPa)	0.946					
	d_{eq}@PII_{max}	(cm)					0.775	
	Focal Length	FL_x (cm)				0.781		#
		FL_y (cm)				0.259		#
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	14.419					
Operating Control Conditions	Mode		M			M	M	#
	Focus	(cm)	5			11	6	#
	Power	(%)	100			100	100	#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: MC6-A **Operating Mode: B**

Index Label			MI	TIS			TIB	TIC
				Scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.444	0.133				
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	0.95					
	W_o	(mW)		2				
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$z@PII_{.3max}$	(cm)	3.25					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	4.572	5.716				
	Dim of A_{aprt}	X (cm)		0.72				
		Y (cm)		1.7				
Other Information	PD	(μsec)	0.212					
	PRF	(Hz)	3246.8					
	$p_r@PII_{max}$	(MPa)	1.588					
	$d_{eq}@PII_{max}$	(cm)						
	Focal Length	FL_x (cm)		0.781				
		FL_y (cm)		0.259				
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	50.017					
Operating Control Conditions	Mode		B	B				
	Focus	(cm)	4	0.5				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: MC6-A **Operating Mode: THI-B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			0.444	0.149				
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.116					
	W_o	(mW)		2				
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	z@$PII_{.3max}$	(cm)	2.8					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	6.316	6.399				
	Dim of A_{aprt}	X (cm)		0.72				
		Y (cm)		1.7				
Other Information	PD	(μsec)	0.772					
	PRF	(Hz)	3424.7					
	p_r@PII_{max}	(MPa)	2.055					
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)		0.781				
		FL_y (cm)		0.259				
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	37.004					
Operating Control Conditions	Mode		THI-B	THI-B				
	Focus	(cm)	4	0.5				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: MC6-A **Operating Mode: M**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.425			0.122	0.108	
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	0.903					
	W_o	(mW)					2	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				0.973		
	z_1	(cm)				2		
	z_{bp}	(cm)				1.87		
	z_{sp}	(cm)					2.8	
	$z@PII_{.3max}$	(cm)	2.8					
	$d_{eq}(z_{sp})$	(cm)					0.182	
	f_c	(MHz)	4.527			5.215	4.527	
	Dim of A_{aprt}	X (cm)				2.4	2.4	
		Y (cm)				1.7	1.7	
Other Information	PD	(μsec)	0.209					
	PRF	(Hz)	3246.8					
	$p_r@PII_{max}$	(MPa)	1.4					
	$d_{eq}@PII_{max}$	(cm)					0.182	
	Focal Length	FL_x (cm)				0.781		
		FL_y (cm)				0.259		
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	44.014					
Operating Control Conditions	Mode		M			M	M	
	Focus	(cm)	4			8	4	
	Power	(%)	100			100	100	

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: L7S-A **Operating Mode: B**

Index Label			MI	TIS			TIB	TIC
				Scan	non-scan		non-scan	
					A_{aprt}≤1	A_{aprt}>1		
Global Maximum Index Value			0.694	0.035				
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.929					
	W_o	(mW)		2				
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$_Z$@PII$_{.3max}$	(cm)	1.5					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	7.717	9.424				
	Dim of A_{aprt}	X (cm)		0.768				
		Y (cm)		0.5				
Other Information	PD	(μsec)	0.18					
	PRF	(Hz)	4717					
	p_r@PII$_{max}$	(MPa)	2.877					
	d_{eq}@PII$_{max}$	(cm)						
	Focal Length	FL_x (cm)		2.059				
		FL_y (cm)		0.486				
	$I_{PA.3}$@ MI$_{max}$	(W/cm^2)	237.09					
Operating Control Conditions	Mode		B	B				
	Focus	(cm)	5.5	1.5				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: L7S-A **Operating Mode: THI-B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.731	0.031				
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	2.063					
	W_o	(mW)		30				
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	z@$PII_{.3max}$	(cm)	1.5					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	7.976	8.218				
	Dim of A_{aprt}	X (cm)		0.768				
		Y (cm)		0.5				
Other Information	PD	(μsec)	0.618					
	PRF	(Hz)	3424.7					
	p_r@PII_{max}	(MPa)	3.119					
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)		2.059				
		FL_y (cm)		0.486				
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	184.797					
Operating Control Conditions	Mode		THI-B	THI-B				
	Focus	(cm)	5.5	2.5				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: L7S-A **Operating Mode: M**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					A_{aprt}≤1	A_{aprt}>1		
Global Maximum Index Value			0.745		0.077		0.229	
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.913					
	W_o	(mW)			2		2	
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)					1.55	
	z@$PII_{.3max}$	(cm)	1.5					
	$d_{eq}(z_{sp})$	(cm)					0.082	
	f_c	(MHz)	6.599		8.035		6.599	
	Dim of A_{aprt}	X (cm)			2.56		2.56	
		Y (cm)			0.5		0.5	
Other Information	PD	(μsec)	0.179					
	PRF	(Hz)	4717					
	p_r@PII_{max}	(MPa)	2.723					
	d_{eq}@PII_{max}	(cm)					0.081	
	Focal Length	FL_x (cm)			2.059			
		FL_y (cm)			0.5			
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	221.385					
Operating Control Conditions	Mode		M		M		M	
	Focus	(cm)	6.5		0.5		6.5	
	Power	(%)	100		100		100	

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: R7-A **Operating Mode: B**

Index Label			MI	TIS			TIB	TIC
				Scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.663	0.151				
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.566					
	W_o	(mW)		2				
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$_Z$@PII$_{.3max}$	(cm)	2.5					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	5.572	6.485				
	Dim of A_{aprt}	X (cm)		1.224				
		Y (cm)		1.6				
Other Information	PD	(μsec)	0.199					
	PRF	(Hz)	3246.5					
	p_r@PII$_{max}$	(MPa)	2.533					
	d_{eq}@PII$_{max}$	(cm)						
	Focal Length	FL_x (cm)		0.781				
		FL_y (cm)		0.259				
	$I_{PA.3}$@ MI$_{max}$	(W/cm^2)	105.474					
Operating Control Conditions	Mode		B	B				
	Focus	(cm)	2.5	0.5				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: R7-A **Operating Mode: THI-B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.295	0.185				
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	0.822					
	W_o	(mW)		6				
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	z@$PII_{.3max}$	(cm)	2.6					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	7.761	7.913				
	Dim of A_{aprt}	X (cm)		1.224				
		Y (cm)		1.6				
Other Information	PD	(μsec)	0.652					
	PRF	(Hz)	3242.7					
	p_r@PII_{max}	(MPa)	1.629					
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)		0.781				
		FL_y (cm)		0.259				
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	15.076					
Operating Control Conditions	Mode		THI-B	THI-B				
	Focus	(cm)	5	0.5				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model:__R7-A_____ Operating Mode:__M___

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					A_{aprt}≤1	A_{aprt}>1		
Global Maximum Index Value			0.705			0.02	0.139	
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.644					
	W_o	(mW)					2	
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				0.797		
	z_1	(cm)				2.5		
	z_{bp}	(cm)				2.37		
	z_{sp}	(cm)					2.5	
	z@$PII_{.3max}$	(cm)	2.8					
	$d_{eq}(z_{sp})$	(cm)					0.127	
	f_c	(MHz)	5.44			5.33	5.415	
	Dim of A_{aprt}	X (cm)				4.08	4.08	
		Y (cm)				1.6	1.5	
Other Information	PD	(μsec)	0.217					
	PRF	(Hz)	3246.8					
	p_r@PII_{max}	(MPa)	2.783					
	d_{eq}@PII_{max}	(cm)					0.127	
	Focal Length	FL_x (cm)				0.781		
		FL_y (cm)				0.259		
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	85.121					
Operating Control Conditions	Mode		M			M	M	
	Focus	(cm)	3			8	2.5	
	Power	(%)	100			100	100	

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: V6-A **Operating Mode: B**

Index Label			MI	TIS			TIB	TIC
				Scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.412	0.018				#
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	0.932					
	W_o	(mW)		2				#
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$_Z$@PII$_{.3max}$	(cm)	3.29					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	5.138	5.508				#
	Dim of A_{aprt}	X (cm)		0.864				#
		Y (cm)		0.7				#
Other Information	PD	(μsec)	0.168					
	PRF	(Hz)	3846.2					
	p_r@PII$_{max}$	(MPa)	1.643					
	d_{eq}@PII$_{max}$	(cm)						
	Focal Length	FL_x (cm)		0.781				#
		FL_y (cm)		0.259				#
	$I_{PA.3}$@ MI$_{max}$	(W/cm^2)	20.432					
Operating Control Conditions	Mode		B	B				#
	Focus	(cm)	1	0.5				#
	Power	(%)	100	100				#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: V6-A **Operating Mode: THI-B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.365	0.023				#
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	0.676					
	W_o	(mW)		2				#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$z@PII_{.3max}$	(cm)	2.2					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	6.223	6.243				#
	Dim of A_{aprt}	X (cm)		0.864				#
		Y (cm)		0.7				#
Other Information	PD	(μsec)	0.767					
	PRF	(Hz)	3424.7					
	$p_r@PII_{max}$	(MPa)	1.054					
	$d_{eq}@PII_{max}$	(cm)						
	Focal Length	FL_x (cm)		0.781				#
		FL_y (cm)		0.259				#
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	13.436					
Operating Control Conditions	Mode		THI-B	THI-B				#
	Focus	(cm)	6.5	4.5				#
	Power	(%)	100	100				#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: V6-A **Operating Mode: M**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.843		0.053		0.123	#
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.865					
	W_o	(mW)			2		2	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)					3.95	
	$z@PII_{.3max}$	(cm)	3.95					
	$d_{eq}(z_{sp})$	(cm)					0.075	
	f_c	(MHz)	5.065		5.654		5.065	#
	Dim of A_{aprt}	X (cm)			2.88		2.88	#
		Y (cm)			0.7		0.7	#
Other Information	PD	(μsec)	0.211					
	PRF	(Hz)	3846.2					
	$p_r@PII_{max}$	(MPa)	3.753					
	$d_{eq}@PII_{max}$	(cm)					0.075	
	Focal Length	FL_x (cm)			0.781			#
		FL_y (cm)			0.259			#
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	156.436					
Operating Control Conditions	Mode		M		M		M	#
	Focus	(cm)	1.5		0.5		1.5	#
	Power	(%)	100		100		100	#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: MC3-A **Operating Mode: B**

Index Label			MI	TIS			TIB	TIC
				Scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.555	0.08				#
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.053					
	W_o	(mW)		2				#
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$_Z$@$PII_{.3max}$	(cm)	5					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	3.363	3.437				#
	Dim of A_{aprt}	X (cm)		0.96				#
		Y (cm)		1.1				#
Other Information	PD	(μsec)	0.665					
	PRF	(Hz)	2293.6					
	p_r@PII_{max}	(MPa)	1.884					
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)		0.781				#
		FL_y (cm)		0.259				#
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	50.235					
Operating Control Conditions	Mode		B	B				#
	Focus	(cm)	6	2				#
	Power	(%)	100	100				#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: MC3-A **Operating Mode: THI-B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.534	0.084				#
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.059					
	W_o	(mW)		12				#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$z@PII_{.3max}$	(cm)	2.5					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	3.546	3.539				#
	Dim of A_{aprt}	X (cm)		0.96				#
		Y (cm)		1.1				#
Other Information	PD	(μsec)	1.392					
	PRF	(Hz)	3413					
	$p_r@PII_{max}$	(MPa)	1.423					
	$d_{eq}@PII_{max}$	(cm)						
	Focal Length	FL_x (cm)		0.781				#
		FL_y (cm)		0.257				#
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	45.923					
Operating Control Conditions	Mode		THI-B	THI-B				#
	Focus	(cm)	4	2				#
	Power	(%)	100	100				#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: MC3-A **Operating Mode: M**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					A_{aprt}≤1	A_{aprt}>1		
Global Maximum Index Value			0.532			0.02	0.164	#
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	0.934					
	W_o	(mW)					2	#
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				1.416		
	z_1	(cm)				1.8		
	z_{bp}	(cm)				1.737		
	z_{sp}	(cm)					4.95	
	z@$PII_{.3max}$	(cm)	5.23					
	$d_{eq}(z_{sp})$	(cm)					0.113	
	f_c	(MHz)	3.349			3.342	3.342	#
	Dim of A_{aprt}	X (cm)				3.84	3.84	#
		Y (cm)				1.1	1.1	#
Other Information	PD	(μsec)	0.613					
	PRF	(Hz)	2293.6					
	p_r@PII_{max}	(MPa)	1.716					
	d_{eq}@PII_{max}	(cm)					0.113	
	Focal Length	FL_x (cm)				0.781		#
		FL_y (cm)				0.259		#
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	46.235					
Operating Control Conditions	Mode		M			M	M	#
	Focus	(cm)	6			4	4	#
	Power	(%)	100			100	100	#

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: L7M-A **Operating Mode: B**

Index Label			MI	TIS			TIB	TIC
				Scan	non-scan		non-scan	
					A_{aprt}≤1	A_{aprt}>1		
Global Maximum Index Value			0.787	0.017				
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.923					
	W_o	(mW)		2				
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	z@$PII_{.3max}$	(cm)	1.9					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	5.834	7.234				
	Dim of A_{aprt}	X (cm)		1.224				
		Y (cm)		0.45				
Other Information	PD	(μsec)	0.196					
	PRF	(Hz)	4717					
	p_r@PII_{max}	(MPa)	2.826					
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)		0.781				
		FL_y (cm)		0.295				
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	223.653					
Operating Control Conditions	Mode		B	B				
	Focus	(cm)	2.5	0.5				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: L7M-A **Operating Mode: THI-B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.54	0.03				
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.554					
	W_o	(mW)		2				
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$z@PII_{.3max}$	(cm)	1.5					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	7.876	8.002				
	Dim of A_{aprt}	X (cm)		0.768				
		Y (cm)		0.5				
Other Information	PD	(μsec)	0.613					
	PRF	(Hz)	3424.7					
	$p_r@PII_{max}$	(MPa)	2.323					
	$d_{eq}@PII_{max}$	(cm)						
	Focal Length	FL_x (cm)		2.059				
		FL_y (cm)		0.486				
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	75.234					
Operating Control Conditions	Mode		THI-B	THI-B				
	Focus	(cm)	2.5	0.5				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: L7M-A **Operating Mode: M**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					A_{aprt}≤1	A_{aprt}>1		
Global Maximum Index Value			0.623		0.066		0.036	
Assoc Acoustic Parameter	$P_{r.3}$	(MPa)	1.534					
	W_o	(mW)			2		2	
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)					1.5	
	z@$PII_{.3max}$	(cm)	1.8					
	$d_{eq}(z_{sp})$	(cm)					0.545	
	f_c	(MHz)	5.654		7.123		7.123	
	Dim of A_{aprt}	X (cm)			2.56		2.56	
		Y (cm)			0.5		0.5	
Other Information	PD	(μsec)	0.168					
	PRF	(Hz)	4717					
	p_r@PII_{max}	(MPa)	2.254					
	d_{eq}@PII_{max}	(cm)					0.545	
	Focal Length	FL_x (cm)			2.059			
		FL_y (cm)			0.486			
	$I_{PA.3}$@ MI_{max}	(W/cm^2)	134.678					
Operating Control Conditions	Mode		M		M		M	
	Focus	(cm)	2.5		0.5		0.5	
	Power	(%)	100		100		100	

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: P3-A **Operating Mode: B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					A_{aprt}≤1	A_{aprt}>1		
Global Maximum Index Value			0.559	0.014				
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	0.923					
	W_o	(mW)		2				
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$z@PII_{.3max}$	(cm)	3.35					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	2.816	2.846				
	Dim of A_{aprt}	X (cm)		0.96				
		Y (cm)		1.4				
Other Information	PD	(μsec)	0.654					
	PRF	(Hz)	2293.6					
	$p_r@PII_{max}$	(MPa)	1.26					
	$d_{eq}@PII_{max}$	(cm)						
	Focal Length	FL_x (cm)		0.781				
		FL_y (cm)		0.259				
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	30.59					
Operating Control Conditions	Mode		B	B				
	Focus	(cm)	6	10				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: P3-A **Operating Mode: THI-B**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			0.349	0.017				
Assocoiated Acoustic Parameter	$P_{r.3}$	(MPa)	0.659					
	W_o	(mW)		22				
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	z@PII$_{.3max}$	(cm)	3.7					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	3.425	3.417				
	Dim of A_{aprt}	X (cm)		0.96				
		Y (cm)		1.4				
Other Information	PD	(μsec)	1.38					
	PRF	(Hz)	3424.7					
	p_r@PII$_{max}$	(MPa)	0.979					
	d_{eq}@PII$_{max}$	(cm)						
	Focal Length	FL_x (cm)		0.781				
		FL_y (cm)		0.259				
	$I_{PA.3}$@ MI$_{max}$	(W/cm^2)	16.157					
Operating Control Conditions	Mode		THI-B	THI-B				
	Focus	(cm)	6	14				
	Power	(%)	100	100				

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: P3-A **Operating Mode: M**

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			0.549			0.018	0.138	
Assocoiated Acoustic Parameter	$P_{r.3}$	(MPa)	0.883					
	W_o	(mW)					2	
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				1.348		
	z_1	(cm)				2		
	z_{bp}	(cm)				1.96		
	z_{sp}	(cm)					3.3	
	$z@PII_{.3max}$	(cm)	3.3					
	$d_{eq}(z_{sp})$	(cm)					0.173	
	f_c	(MHz)	2.879			2.857	2.879	
	Dim of A_{aprt}	X (cm)				1.92	1.92	
		Y (cm)				1.4	1.4	
Other Information	PD	(µsec)	0.66					
	PRF	(Hz)	2293.6					
	$p_r@PII_{max}$	(MPa)	1.221					
	$d_{eq}@PII_{max}$	(cm)					0.163	
	Focal Length	FL_x (cm)				0.781		
		FL_y (cm)				0.259		
	$I_{PA.3}@ MI_{max}$	(W/cm^2)	26.325					
Operating Control Conditions	Mode		M			M	M	
	Focus	(cm)	6			4	6	
	Power	(%)	100			100	100	

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Appendix C: Guidance and Manufacturer's Declaration

1. Guidance and manufacturer's declaration – electromagnetic emissions		
The ECO 1/3 is intended for use in the electromagnetic environment specified below. The customer or the user of the ECO 1/3 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ECO 1/3 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 ECO 1/3 is suitable for use in all establishments, including domestic stablishments and those directly connected to the public low-voltage power supply network that supplies buildings used for 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 ECO 1/3 is intended for use in the electromagnetic environment the ECO 1/3 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	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 for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	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	±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	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ECO 1/3 requires continued operation during power mains interruptions, it is recommended that the ECO 1/3 be powered from an uninterruptible power supply or a battery.
Power frequency frequency (50-60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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.			

3 Guidance and manufacturer's declaration – electromagnetic immunity			
The ECO 1/3 is intended for use in the electromagnetic environment specified below. The customer or the user of the ECO 1/3 should assure that it is used in such an environment.			
3.1. Immunity test	**IEC 60601 test level**	**IEC 60601 test level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ECO 1/3, 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,a 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:

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 ECO 1/3 is used exceeds the applicable RF compliance level above, the ECO 1/3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ECO 1/3.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ECO 1/3

The ECO 1/3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ECO 1/3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ECO 1/3 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1,2\ \sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\ \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3\ \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73

1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and

reflection from structures, objects and people.

Appendix D:Measurement Results Summary

C3-A, 3.5MHz Convex Array

Measurement	Unit	Useful Range	Accuracy
Axial Distance	mm	Full Screen (0~230mm)	<±5%
Lateral Distance	mm	Full Screen (0~230mm)	<±5%
Circumference: trace method,ellipse method	mm	Full Screen (0~230mm)	<±5%
Area: trace method,ellipse method	mm^2	Full Screen (0~230mm)	<±10%

V6-A, 6.0MHz Micro-convex Array (Transvaginal)

Measurement	Unit	Useful Range	Accuracy
Axial Distance	mm	Full Screen (0~100mm)	<±5%
Lateral Distance	mm	Full Screen (0~100mm)	<±5%
Circumference: trace method,ellipse method	mm	Full Screen (0~100mm)	<±5%
Area: trace method,ellipse method	mm^2	Full Screen (0~100mm)	<±10%

L7S-A, 9.0MHz Linear Array

Axial Distance	mm	Full Screen (0~100mm)	<±5%
Lateral Distance	mm	Full Screen (0~100mm)	<±5%
Circumference: trace method,ellipse method	mm	Full Screen (0~100mm)	<±5%
Area: trace method,ellipse method	mm^2	Full Screen (0~100mm)	<±10%

MC3-A, 3.0MHz Micro Convex Array

Measurement	Unit	Useful Range	Accuracy
Axial Distance	mm	Full Screen (0~230mm)	<±5%
Lateral Distance	mm	Full Screen (0~230mm)	<±5%
Circumference: trace method,ellipse method	mm	Full Screen (0~230mm)	<±5%
Area: trace method,ellipse method	mm^2	Full Screen (0~230mm)	<±10%

R7-A, 7.5MHz Linear Array

Measurement	Unit	Useful Range	Accuracy
Axial Distance	mm	Full Screen (0~100mm)	<±5%
Lateral Distance	mm	Full Screen (0~100mm)	<±5%
Circumference: trace method,ellipse method	mm	Full Screen (0~100mm)	<±5%
Area: trace method,ellipse method	mm^2	Full Screen (0~100mm)	<±10%

P3-A, 3.0MHz Phased Array

Measurement	Unit	Useful Range	Accuracy
Axial Distance	mm	Full Screen (0~200mm)	<±5%
Lateral Distance	mm	Full Screen (0~200mm)	<±5%
Circumference: trace method,ellipse method	mm	Full Screen (0~200mm)	<±5%
Area: trace method,ellipse method	mm^2	Full Screen (0~200mm)	<±10%

MC6-A, 6.0MHz Convex Array

Measurement	Unit	Useful Range	Accuracy
Axial Distance	mm	Full Screen (0~100mm)	<±5%
Lateral Distance	mm	Full Screen (0~100mm)	<±5%
Circumference: trace method,ellipse method	mm	Full Screen (0~100mm)	<±5%
Area: trace method,ellipse method	mm^2	Full Screen (0~100mm)	<±10%

L7M-A, 7.5MHz Linear Array

Axial Distance	mm	Full Screen (0~100mm)	<±5%
Lateral Distance	mm	Full Screen (0~100mm)	<±5%
Circumference: trace method,ellipse method	mm	Full Screen (0~100mm)	<±5%
Area: trace method,ellipse method	mm^2	Full Screen (0~100mm)	<±10%

Appendix E: Display Accuracy and Acoustic Measurement Uncertainties

According to IEC60601-2-37 and NEMA UD-3 2004, the display accuracy and acoustic measurement uncertainties are summarized in the table below.

Display accuracy of MI is ±20%, and TI is ±40% or <0.1, if MI,TI below 0.5.

Item	Measurement Uncertainty (Percentage, 95% Confidence Value
Center Frequency	±5%
Acoustic Power	±30%
Acoustic Intensity	±30%
Peak Rarefactional Pressure	±15%

Appendix F: Transducer Maximum Surface Temperature

According to the requirements of the section 42.3 in the standard IEC 60601-2-37:2007,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(℃)
C3-A	<41.0
V6-A	<41.0
L7M-A	<41.0
P3-A	<41.0
R7-A	<41.0
L7V-A	<41.0
MC6-A	<41.0
L7S-A	<41.0