

Digital Color Doppler Ultrasound System

CBit 9

Instruction Manual

57-00907-00

Mar. 1st, 2022

V1.1

CHISON Medical Technologies Co., Ltd.

We reserve the right to make changes to this manual without prior notice.

Regulatory Requirement



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 CBit 9. Please verify that you are using the latest revision of this document. If you need the latest revision, contact your distributor.

NOTE:

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.
4. CHISON's Warranty only cover material and parts costs for repair, but do not cover any labor cost or onsite service cost at end user's side.

NOTE:

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 operating 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 solving 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 to use the device for fetal sex examination, except for necessary medical needs. The device can only be sold to qualified medical institutions or

doctors. The users shall fully understand and master the devices before operating. The users shall have got the qualification, and shall comply with the local laws and regulations, the 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 9.5.

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 to use the device for fetal sex examination, except for necessary medical needs. The device can only be sold to qualified medical institutions or doctors. The users shall fully understand and master the devices before operating. The users shall have got the qualification, and shall comply with the local laws and regulations, the local religion and customs, etc.*



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

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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, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, Cardiac (adult, pediatric), Musculo-skeletal (Conventional, Superficial), Peripheral Vascular, Transesophageal, Transrectal, Transvaginal, Urology.

Contraindication

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

1.2 Contact Information

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

CHISON website www.chison.com

Service Support CHISON Medical Technologies Co., Ltd.

Tel: 0086-400-8878-020; 0086-0510-85311707

Fax: 0086-0510-85310726

E-mail: service@chison.com.cn

Placing an Order CHISON Medical Technologies Co., Ltd.

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Manufacturer	CHISON Medical Technologies Co., Ltd. No.3 Changjiang South Road, Xinwu District, Wuxi, 214028 Jiangsu, P.R. China
US Agent	Mr. Marco Mu, 2219 Rimland Drive,Suite 301,Bellingham, Barkley Villiage Bellingham,Washington,98226, UNITED STATES Phone: 360-3257028, Fax: 360-9253199, Email: us.agent@mid-link.net MID-LINK INTERNATIONAL CO., LTD



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

Chapter 2 System Safety

2.1 Safety Overview

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

Users should observe the following precautions:

- This system complies with Type BF general equipment, and the IEC standard. Please follow Chapter 2 “System Safety” in the operation manual to use this system properly.
- Please do not modify this system in any way. If modifications are necessary, please contact the manufacturer first to get more information and permission.
- 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 cord of the system should 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 IEC/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 a CHISON's authorized service engineer can perform maintenance.
- Only a qualified operator, or someone under qualified supervision, can 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, only use qualified ultrasound gel that complies with system standards.
- Do not unplug probe when the system is in active operation. Always go to transducer Selection 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.



To dispose of this product properly, please contact the local CHISON's Authorized Service Representative.

2.2 Electrical Safety

Type of protection against electric s hock

Class I Equipment

CLASS I EQUIPMENT in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that accessible conductive parts are connected to the protective earthing conductor in the electrical installation in such a way that accessible parts cannot become live in the event of a failure of the basic insulation.

Degree of protection against electric shock

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

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

Level of protection against harmful ingress of water

- Parts of **probe** likely to come into contact with **operator** or **patient** meet the requirements of **drip-proof equipment (IPX1)**

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)

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

Mode of operation

- Continuous Operation

For maximum safety, always follow these guidelines:

- Proper grounding of the system is critical to avoid electric shock. For protection, ground the chassis with a three-wire cable, and plug the system into three-hole outlet.
- Do not remove or circumvent the grounding wire.
- Do not remove the protective covers on the system. These covers protect users against 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 with an optional isolation transformer.
- Suggest to power off the system in 30 minutes if the system continuously works in 8 hours.

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 only use the cables provided by or designated by CHISON. Connect these cables following the installation procedures (e.g. wire power cord 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 Labels

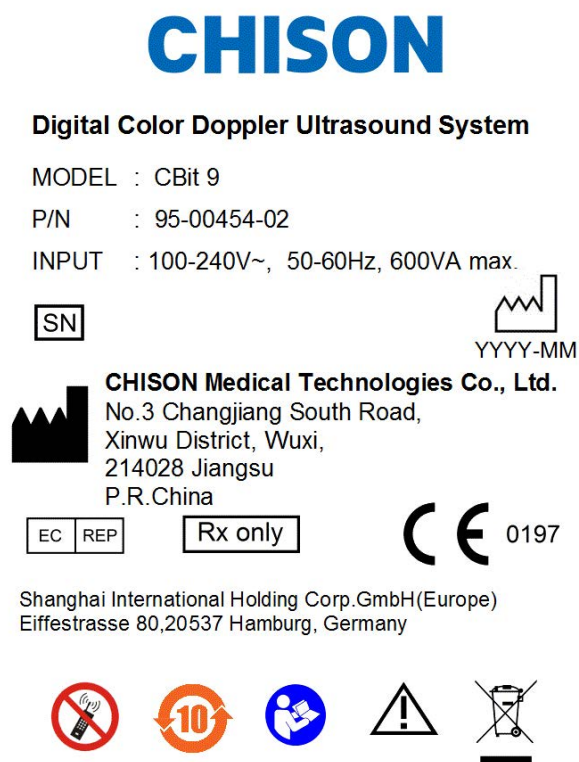


Fig.2-1Rear panel label

2.3.1 Symbols on label

 WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE): This symbol is used for Environment Protection, it indicates that the waste of electrical and electronic equipment must not be disposed as unsorted waste and must be collected separately. Please contact your local Authority or distributor of the manufacturer for information concerning the decommissioning of your equipment.	 This mark indicates that this product contains a limited amount of hazardous substances in the Chinese Standard GB/T 26572-2011 "Limited Requirements for Restricted Substances in Electrical and Electronic Products". The numbers in the logo are the environmental protection use period of the product, indicating that under the normal use conditions, the harmful substances will not leak or be abrupt. The use of the product will not cause serious pollution to the environment or cause personal or property serious damage, the term unit is
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	year.
 Do not use the following devices near this equipment: cellular phone, radio receiver, and mobile radio transmitter, radio controlled toy, etc. Use of these devices near this equipment could cause this equipment to perform outside the published specifications. Keep these devices power off when near this equipment.	 Caution, consult accompanying documents. This symbol advises the reader to consult the accompanying documents for important safety related information such as warnings and pre-cautions that Cannot be presented on the device itself.
 This symbol is followed by the manufacturing date of the device in the form YYYY-MM.	 The CE mark of Conformity indicates this 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.
 Potential equilibrium connection	 Main power switch ON
 Main power switch OFF	 Power On/off.

	Power On: the main unit connects to the adapter with power supply, the battery start charge. Power off: the main unit disconnects to the adapter with power supply, the battery end charge. CAUTION: This Power Switch DOES NOT ISOLATE Mains Supply.
 The “Alternating current” symbol indicates that the equipment is suitable for alternating current only.	 Refer to instruction manual.
IPX7 Protection against the effects of immersion (probes)	IPX0 No protection against ingress of water (system)
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.	 Sleep Indicator: When the system is sleep, the indicator lights, otherwise extinguishes.
 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 flashes once every three seconds, when the battery is lower capacity, the indicator flashes once every second.
 Show the State of charging and remaining electricquantity	 Show the State of discharge and remaining electricquantity and available time.

 Be careful, arrow area may Clamp hand !	  Please read the user handbook Before operation.
 In the process of push down the monitor, it is forbidden to place items to this region, otherwise there is oppression may flip monitor.	 Forbidden to push the monitor to move the machine.
 Forbidden to place heavy objects on the monitor after push down the monitor.	 Forbidden to press the monitor after push down the monitor.
 Forbidden to put the hand at the bottom of the monitor when turning the monitor.	 This part it is forbidden to impose extra upward or downward force (especially when transporting need to up and down movement machine)
 Authorised person open only! Warning: Authorised person open only!	

2.4 Patient Environmental Devices

Front side (refer to Fig. 3-1 b in Chapter 3):

- DVD RW

Right side (refer to Fig. 3-1 c in Chapter 3):

- 4 Probe ports
- 2 USB ports on control panel

Rear panel (refer to Fig.3-1d in Chapter3) :

- 4 USB ports
- 1 LAN port
- 1 Remote port
- 1 S-VIDEO port
- L/R AUDIO port
- 1 DVI port
- 1 VGA port
- 1 VIDEO port
- 2 Foot-switch ports

Acceptable Devices

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



- ***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



- ***DO NOT use unapproved devices.***
- ***If devices are connected without the approval of CHISON, the warranty will be INVALID.***

- ***The system can't be used with HF surgical equipment; otherwise the burns to patient may occur.***
- ***Any device connected to this system must conform to one or more of the requirements listed below:***
 - IEC standard or equivalent standards appropriate to devices.***
 - The devices shall be connected to PROTECTIVE EARTH (GROUND).***



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

Peripheral used in the patient environment

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

B/W video printer: Mitsubishi P93W, Sony UP-711MD, Sony UP-X898MD

Color video printer: Mitsubishi CP31W

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/EN 60601-1.

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

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

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

Peripheral used in the non-patient environment

The system has been verified for compatibility, and compliance for connection to a local area network (LAN) via a wire LAN. The provided 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.



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



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

2.5 Biological Safety

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

Clinical Safety Quoted from AIUM

Approved March 26, 1997

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits

and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:

There are no confirmed biological effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any that may be present.

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

Soft Tissue Thermal Index (TIS). Used when imaging soft tissue only, it provides an estimate of potential temperature increase in soft tissue.

Bone Thermal Index (TIB). Used when bone is near the focus of the image as in the third trimester OB examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.

Cranial Bone Thermal Index (TIC). Used when bone is near the skin surface as in transcranial examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.

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

MI recognizes the importance of non-thermal processes, cavitations in particular, and the Index is an attempt to indicate the probability that they might occur within the tissue.

2.6 Scanning Patients and Education

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

- In order to maintain proper cleanliness of the probes, always clean them between patients.
- Always use a disinfected sheath on all EV/ER probes during every exam.
- Continuously move the probe, rather than staying in a single spot, to avoid elevated temperatures in one part of the patient's body.
- Move probe away from the patient when not actively scanning.
- Understand the meaning of the TI, TIS, TIB, TIC and MI output display, as well as the relationship between these parameters and the thermal/cavitation 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 to the patient and the operator).
- Operators should understand the likely influence of the machine controls, the operating mode (e.g. B-mode, color Doppler imaging or spectral Doppler) and probe frequency on thermal and cavitations 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 adjusted 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. It should be removed from the patient whenever there is no need for real-time imaging or spectral Doppler acquisition. 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 I_{spta} must be $\leq 720 \text{ mW/cm}^2$ and either the global maximum MI must be ≤ 1.9 or the global maximum de-rated I_{sppa} must be $\leq 190 \text{ W/cm}^2$. An exception is for ophthalmic use, in which case the $TI = \max(TIS_{as}, TIC)$ is not to exceed 1.0; $I_{spta.3} \leq 50 \text{ mW/cm}^2$, and $MI \leq 0.23$. 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 $I_{spta} \leq 720 \text{ mW/cm}^2$ 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 $\text{dB cm}^{-1} \text{ MHz}^{-1}$, 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 $0.3 \text{ dB cm}^{-1} \text{ MHz}^{-1}$ 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 $0.3 \times 7.5 \times 5 = -11.25 \text{ dB}$. The De-rated Intensity is also referred to as '.3' at the end (e.g. $I_{\text{sp}} \text{ta}.3$).

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

$I' = I \cdot R_F$ 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
1	TIS	Soft tissue	Unscanned	Large aperture ($>1\text{cm}^2$)	Liver PW
2	TIS	Soft tissue	Unscanned	Small aperture ($<1\text{cm}^2$)	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}), $TI = W_3/W_{\text{deg}}$.

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:

$$W_{\text{deg}} = 210/f_c, \quad \text{for model 1 to 4, where } f_c \text{ is the center frequency in MHz.}$$

$$W_{\text{deg}} = 40 K D^2 \quad \text{for model 5 and 6, where } K \text{ (beam shape factor) is } 1.0, D \text{ is the aperture diameter in cm at the depth of interest.}$$

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 ratio of the peak pressure to the square root of the frequency.

$$MI = P_r' / \sqrt{f_c}$$

P_r' is the de-rated (0.3) peak rare-fractional pressure in Mpa at the point where PII is the maximum, and f_c 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 in Different Mode

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 B-Scan Mode

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

For Color Mode

Only display and report TIS or TIB and start from 0.4 if maximum TI > 1.0, display in increments of 0.2 for values of indices of 2.0 or less, and 0.5 for values of indices greater than 2.0.

For Doppler Mode

Only display and report TIS or TIB and start from 0.4 if maximum TI > 1.0, display in increments of 0.2 for values of indices of 2.0 or less, and 0.5 for values of indices greater than 2.0.

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 affect Acoustic Output.

Use the minimum necessary acoustic output to get the best diagnostic image or measurement during an examination. Begin the exam with the probe that provides an optimum focal depth and penetration.

Acoustic Output Default Levels

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

Chapter 3 Preparing the System for Use

3.1 Site Requirements

3.1.1 Operation Environmental Requirements

The following environmental conditions are within system tolerances for operation:

Temperature:	10° C ~ 40° C
Relative Humidity:	30%~75%, non-condensing
Atmosphere Pressure:	700hPa ~ 1060hPa

Strong radiation sources or powerful electromagnetic waves (e.g. electro-magnetic waves from radio broadcasting) may result in image ghosting or noise. The system should be isolated from such radiation sources or electromagnetic waves.

To prevent damage to the system, do not use in the following locations:

- Exposed to direct sunlight
- Subject to sudden changes in temperature
- Dusty
- Subject to vibration
- Near heat generators
- High humidity



- ***This equipment generates, uses and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, this product complies with emissions limits for a Group 1, Class A Medical Devices Directive as stated in IEC/EN 60601-1-2. However, there is no guarantee that interference will not occur in a particular installation.***
- ***If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measure(s):***

- ***reorient or relocate the affected device(s).***
- ***increase the separation between the equipment and the affected device.***
- ***power the equipment from a source different from that of the affected device.***
- ***consult the point of purchase or service representative for further suggestions.***

3.1.2 Transport and Storage Environmental Requirements

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

Temperature: -5° C ~ 40° C

Relative Humidity: ≤80% non-condensing

Atmosphere Pressure: 700hPa ~ 1060hPa

3.1.3 Electrical Requirements

Power Requirements

AC 100-240V, 50-60Hz

Fuse Requirements

Fuse specification is 250V, 5.0 A (time-lag), the model is 50T T5AL 250V



CAUTION: Please use the fuse provided by manufactory if the fuse need replace. User can't buy and exchange the fuse by themselves.

Power Consumption: 600VA max.

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



- ***Please follow the outlined power requirements. Only use power cords that meet the system guidelines—failure to follow these procedures may result in 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.*** Built in battery specifications

Battery model	BT-2000	
Capacity	9000mAh	
Rated voltage	14.4V	
Standard charge voltage	16.8V	
Discharge closing voltage	11V	
Discharge time	About 90 minutes	
Standard charge current	1800mA	
Maximum continuous discharge current	9000mA	
Battery structure	4S3P	
Cycle life	300 times	
Charging time	About 150 minutes	
Operating temperature	Charge	0℃～55℃
	Discharge	-20℃～65℃
	Storage	-20℃～60℃ for less than 1 months; -20℃～30℃ for less than 6 months
Battery status indicator	1%-100%	Power balance display
	Charge tips	Charge indicator

Adapter specifications

Adapter model	MINT1150
Input	100-240V~2A, 47-63Hz
Output	18.5V= 8.33A



To avoid the battery bursting, igniting, or fumes from the battery to cause the equipment damage.

Do observe the following precautions:

- 1) Do not immerse the battery in water or allow it to get wet.**
- 2) Do not put the battery into a microwave oven or pressurized container.**
- 3) If the battery leaks or emits an odor, remove it from all possible flammable sources.**
- 4) 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.**
- 5) The battery shall be storied within -10 ℃~ 45 ℃ range environmental condition .If stored for a long time (exceed three months), the cell should be stored in dry and cooling place. The cell's storage voltage should be14.0~14.8V and the cell is to be stored in a condition as Temperature: 23±5 ℃, Humidity: 65±20 %RH.**
- 6) Upon receipt of the CBit 9 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 over 2 months, the customer is recommended to perform one full discharge/charge cycle. One Full Discharge/Charge Cycle Process: 1. Full discharge of battery to let the CBit 9 automatically shut down.2. Charge the CBit 9 to 100% FCC (full current capacity). When storing packs for more than 3 months, charge the pack at least once during the 3 month time frame to prevent leakage and deterioration in performance.**
- 7) Do not dismantle the battery. If need to change the battery, please contact CHISON's authorized service engineer.**
- 8) To avoid the battery bursting, igniting, or fumes from the battery to cause the equipment damage.**



- 1. Do not immerse the battery in water or allow it to get wet.**
- 2. Do not use or store the battery near sources of heat such as a fire or heater.**
- 3. Do not use any chargers other than those recommended.**
- 4. Do not put the battery into a fire or apply direct heat to it.**
- 5. Do not short-circuit the battery by connecting wires or other metal objects to the positive (+) and negative (-) terminals.**
- 6. Do not pierce the battery casing with a nail or other sharp object, break it open with a hammer, or step on it.**
- 7. Do not strike, throw or subject the battery to sever physical shock.**
- 8. Do not attempt to disassemble or modify the battery in any way.**
- 9. Do not place the battery in a microwave oven or pressurized container.**
- 10. Do not use the battery if it gives off an odor, generates heat, becomes discolored or deformed, or appears abnormal in any way. If the battery is in use or being recharged, remove it from the device or charger immediately and discontinue use.**
- 11. Do not use or store the battery where is exposed to extremely hot, such as under window of a car in direct sunlight in a hot day. Otherwise, the battery may be overheated. This can also reduce battery performance and/or shorten service life.**
- 12. If the battery leaks and electrolyte gets in your eyes, do not rub them. Instead, rinse them with clean running water and immediately seek medical attention. If left as is, electrolyte can cause eye injury.**

3.2 System Specifications

3.2.1 Console Overview



Fig. 3-1 a: Console Overview

The following pictures show the system in different views.

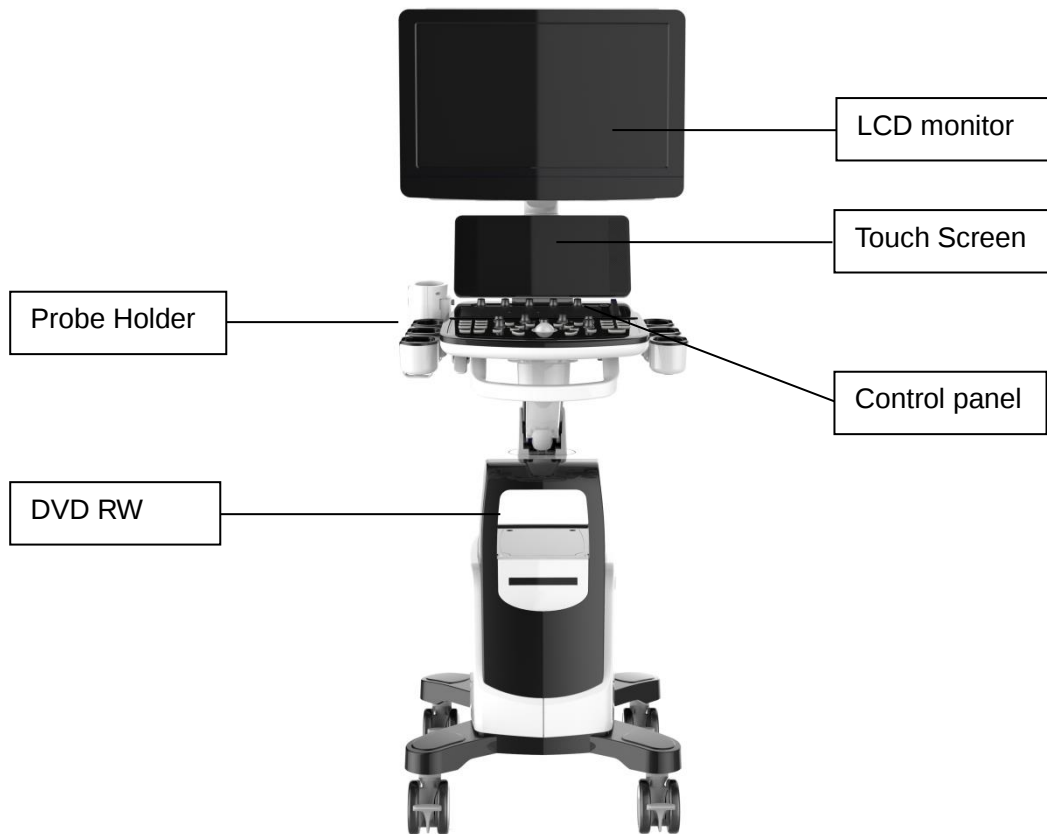


Fig. 3-1 b: Front Side View

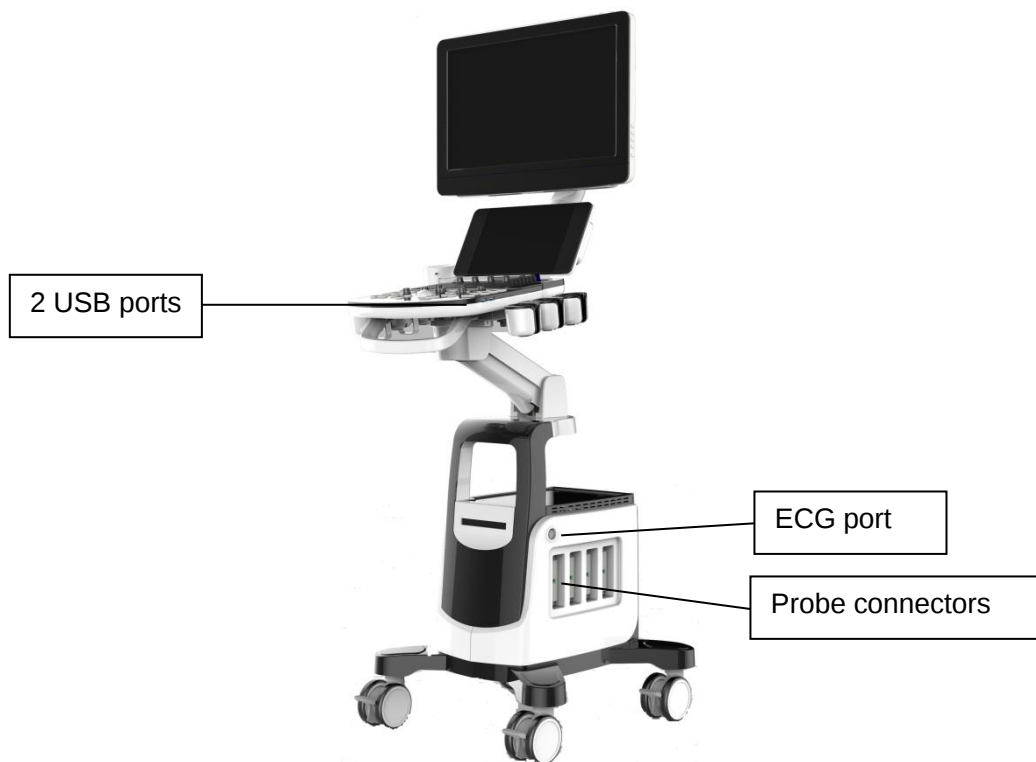


Fig. 3-1 c: Right Side View

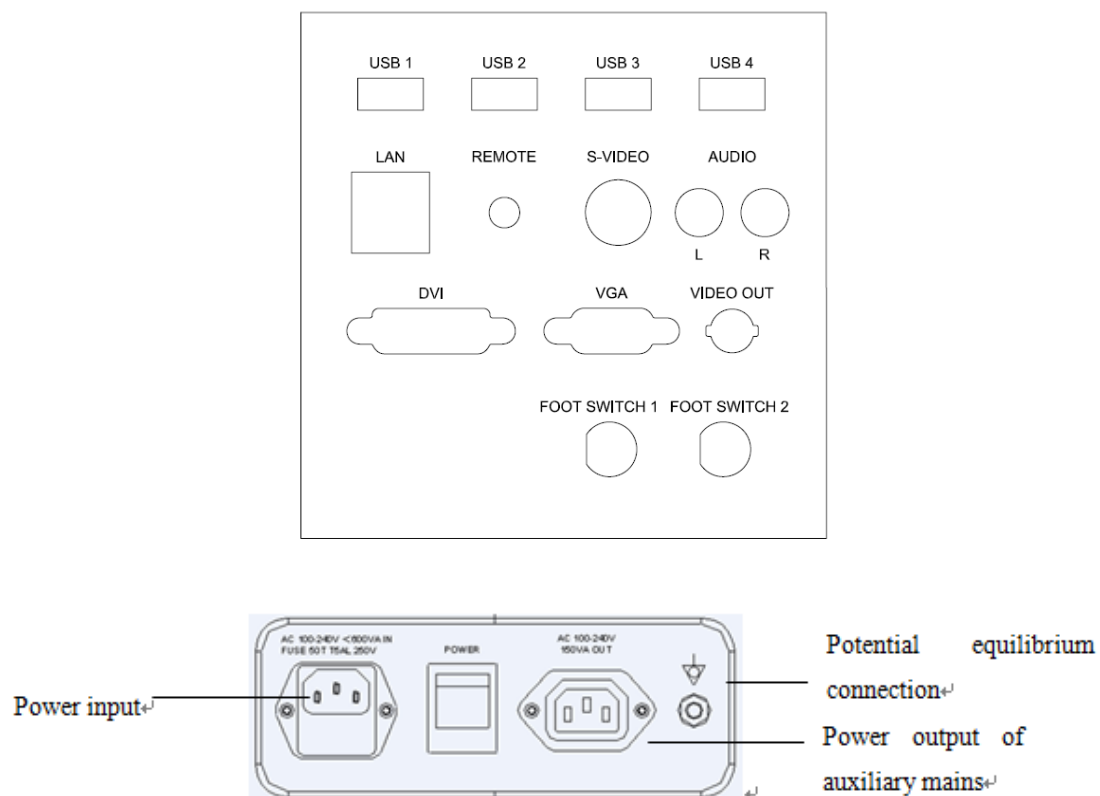


Fig. 3-1 d: Back Side View

3.2.2 Physical Specification

Dimensions of main unit (approx.): 806mm (Depth) *543mm (Width) *1423mm (Height)

Net weight of main unit (approx): 52kg (no probe included)

3.2.3 Key System Features

- Display B, B/M, M, B/B, 4B, 2D Steer, CFM, PD, DPD, PW, B/BC, Triplex, Quadplex, CW, Free Steering M, TDI, Color M, Curved Panoramic, Trapezoid Image, Compound, SRA, Elastography, Stress Echo, Super Needle, 4D, Virtual HD, Sono Crystal, FHI, AIO.
- ECG
- Zoom and depth adjustment.
- Set the total gain, contrast, frequency band, 8 segments of TGC, dynamic range, persistence.
- Image post-processing of raw data: measurement and zoom after freezing the image.
- 256 gray-scale image display technology, Q-image technology, stable performance, high resolution.
- Image freezing and storage function; the stored images can be recalled for analysis.
- Storage file format: single and movie file formats
- Scanning direction can be changed and the image can be reversed in left/right, up/down direction.
- Distance, area, circumference, volume, fetal weight, heart rate etc. measurements are available and automatic calculation of OB, cardiology are available. direct display of gestation age and expected date of child delivery.
- Elliptical method and tracing method are provided for area/circumference measurement
- Many kinds of body marks can be displayed together with corresponding probe position indication.
- Comment function in image area of the screen, special comment terms for different exam mode can be added according to user's requirement.
- Display of Patient ID, Time and Date display according to real-time clock.
- Trackball available for operation and measurement. Characters can be input directly by keyboard.
- When one function is under operation, the corresponding key on the control panel will be brightly lit. When exiting from the function, the corresponding key on the control panel will be slightly lit.
- Measure the percentage of stenosis, blood flow velocity, velocity ratio, blood flow volume and pressure gradient. Automatically measure the values of maximum velocity, minimum velocity,

time interval, pulsatility index and resistance index.

- Built in battery. Turn on /off the green power switch to charge /incharge the battery.

Configuration of the System

Mode	CBit 9
B mode	Standard
B/M Mode	Standard
M Mode	Standard
Dual Mode	Standard
Quad Mode	Standard
2D Steer	Option
CFM Mode	Standard
CPA Mode	Standard
DPD Mode	Option
PW Mode	Option
B/BC Mode	Option
Triplex	Option
Quadplex	Option
HD 3D	Option
CW Mode	Option
Free Steering M Mode	Option
HPRF	Option
TDI	Option
Color M Mode	Option
Curved Panoramic	Option
Trapezoidal Image	Option

Compound	Standard
SRA	Standard
Elastography	Option
Stress Echo	Option
LV Tracking	Option
Strain	Option
S-flow	Option
LGC	Standard
Auto LGC	Option
ECG	Option
Intergrated hard disk	Option
Human Body Mark	Standard
Auto IMT	Option
Free NT	Option
Super Needle	Option
General measurement package	Option
OB measurement package	Option
GYN measurement package	Option
URO measurement package	Option
Cardiac measurement package	Option
Vascular measurement package	Option
Small parts measurement package	Option
Pediatric measurement package	Option

TCD measurement package	Option
Breast measurement package	Option
Standby	Option
DICOM 3.0	Option
4D Software package	Option
Virtual HD	Option
X-Contrast	Option
FHI	Option
Q-image	Option
Q-flow	Option
Q-beam	Option
AIO	Option
D3C60L	Option
D7L40L	Option
D12L40L	Option
D7L40L-REC	Option
D6C12L	Option
D7C10L	Option
D3P64L	Option
D5P64L	Option
V4C40L	Option
D6C15L	Option
D3C20L	Option

D5C20L	Option
M8L40L	Option
D10L30L	Option
D8L50L	Option
Biopsy	Option
Probe connector	4

3.2.4 Accessories

 Convex probe: D3C60L 2.0-6.8MHz	 Linear probe: D7L40L 4.0-15.0MHz
 Linear probe: D12L40L 7.0-15.0MHz	 Linear probe: D7L40L-REC 4.0-15.0MHz
 Trans-vaginal transducer: D6C12L 4.0-12.0MHz	 Trans-vaginal transducer: D7C10L 4.0-15.0MHz
 Phased array probe: D3P64L 1.5-5.3MHz	 Phased array probe: D5P64L 2.0-8.0MHz

 Volume transducer: V4C40L 2.0-6.8MHz	 Micro convex probe: D6C15L 4.0-12.0MHz
 Micro convex probe: D3C20L 2.0-6.8MHz	 Micro convex probe: D5C20L 4.0-10.7MHz
 Signal crystal linear reansducer: M8L40L 4.0-15.0MHz	 Intra-operative transducer: D10L30L 4.0-10.7MHz
 Liner probe: D8L50L 5.0-16.0MHz	

3.2.5 I/O ports

- VGA ,DVI output for external monitor
- S-VIDEO,TV output for B&W video printer or Color video printer
- Remote port for video printer
- LAN port output for PC printer, DICOM and image review station
- 6 USB 2.0 ports for flash drive
- Foot switch ports

3.2.6 DVD/CD-RW

The supported DVD/CD disk information and compatibility of DVD/CD-RW see the following table:

DS-8ACSH				
Compatibility	DOS 6.xx, XP / 2003 / Vista / Win7 / Win8 / Win8.1 / Linux OS			
DVD	Write Speed	DVD+R	PCAV	8X maximum
		DVD-R	PCAV	8X maximum
		DVD+R9	PCAV	6X maximum
		DVD-R9	PCAV	6X maximum
	Read Speed	DVD-ROM	CAV	8X maximum
	ReWrite Speed	DVD+RW	ZCLV	8X maximum
		DVD-RW	ZCLV	6X maximum
CD	Write Speed	CD-R	PCAV	24X maximum
	Read Speed	CD-ROM	CAV	24X maximum
	ReWrite Speed	CD-RW	ZCLV	24X maximum

3.3 System Positioning & Transporting

Moving the System

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

Before Moving the System

- Completely switch off the system. See Section 3.4.4 “Power Off” for more information.

- Unplug the power cord (if the system is plugged into wall outlet).
- 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.

- Disconnect all probes from main unit. See Section 3.5 “Probes” for more information.
- 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 main unit.

When Moving the System

Carry the system with handle, or put the system on the cart to move it. Use extra care when crossing door or elevator thresholds.



NOTE:

***Always use the handle to move the system. The system weighs approx. 53 kg.
In order to avoid possible injury or equipment damage:***

- ***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:

- Before transporting, place the system in its original storage case.
- Ensure that the system is firmly secured while inside the vehicle.
- Load the unit aboard the vehicle carefully and over its center of gravity.
- Keep the storage case still and upright. Secure that 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.

3.4 Powering the System

3.4.1 Acclimation Time

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



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.

3.4.2 Connecting and Using the System

To connect the system to the electrical supply:

- Check the power voltage input labeling at rear panel of the system.
- Ensure that the wall outlet is the appropriate type and well grounded.
- Ensure that the system powers off.
- Unwrap the power cord, and allow sufficient slack in the cable so that the plug will not be pulled out of the wall outlet if the system is moved slightly.
- Attach the power plug to the system and secure it in place by using the retaining clamp.
- Push the power plug securely into the wall outlet.



NOTE:

- ***Only use the power cord provided by Manufacturer.***
- ***Use caution to ensure that the power cord does not disconnect during system use.***
- ***If the system is accidentally unplugged, data may be lost.***



- ***To avoid risk of fire, the system power must be supplied from a separate, properly rated outlet.***
- ***Under no circumstances should the AC power plug be altered, changed, or adapted to a configuration rated less than specified. Never use an extension cord or adapter plug.***
- ***To help assure grounding reliability, connect to a “hospital grade” or “hospital only” grounded power outlet.***

3.4.3 Power On



Turn on the green power switch (main power circuit breaker switch, see Fig. 3-1 d in Section 3.2.1 Console Overview) at the back of the system, and then press the Power button on the right of control panel to turn on the system.

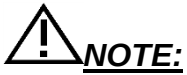
Power up Sequence:

The system is initialized and start-up status is reflected on the monitor:

- control panel flashing and then getting dark.
- system checking BIOS data.
- booting the operation system.
- loading software.
- entering examination status.

HINTS

The power up procedure takes about approx. 100 seconds. If a problem occurs, take a picture and record the error information for service reference.



- ***After powering off the system, please wait for more than 3 minutes to power on again.***
- ***When the system is powered on, for safety reason, please avoid moving the system***

3.4.4 Power Off

To power off the system:

- Press the Power button on the right of control panel.
- When the screen shows “Turn Off”, “Standby”, and “Cancel”, press “Turn off” to shut down the system.



If the system is down or has not fully shut down, press and hold the Power button located on the right of control panel for more than 4 seconds and release it, this will force the system to shut down completely.

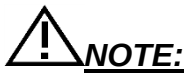
- ***Disconnect the probes. Clean or disinfect all probes as necessary. Store them in their original cases to avoid any damage.***
- ***To ensure the system is disconnected from the power source, disconnect power plug from the wall outlet.***

3.4.5 Standby

To enter standby:

- Press the power button on the right of control panel.
- Select “Standby” to enter into the standby status.

To exit standby: press the power button.



- ***Power off the system if you will not use the system for a long period of time (including storage/transportation condition), and you should not allow the system in standby status, otherwise the batteries will be out of power and permanently damaged.***
- ***If you will not use the system for a long period of time, DO NOT leave the system in the standby status, you should shut down the system, disconnect power adapter, mains power, and turn off powers of all connected peripherals.***

3.5 Probes



Selecting probes

- Choose the probe according to the different examination.
- Begin the scanning session by choosing the correct application and preset for the examination.

Connecting the Probe

When you connect the probes, please ensure that the probe ports are not active. Place the system in “Transducer Selection” interface by pressing PROBE-key to deactivate the probe ports.

To connect a probe:

- Place the probe’s carrying case on a stable surface and open the case.
- Carefully remove the probe and unwrap the probe cord.
- DO NOT allow head of the probe hang freely. Impact to head of the probe could result in irreparable damage.



NOTE: *Inspect the probe before and after each use for damage or degradation to the housing, strain relief, lens, seal and connector. DO NOT use a probe that appears damaged until its functional and safe performance is verified. A thorough inspection should be performed during the cleaning process.*

- Align the connector with the probe port and carefully push into place with the cable facing the back of the system.
- Turn the probe connector locking lever to “lock” status.
- Carefully position the probe cord so it is free to move and is not resting on the floor.
- When the probe is connected, the system will be automatically recognized.



CAUTION:

- *Fault conditions can result in electric shock hazard. DO NOT touch the surface of probe connector that is exposed when the probe is removed. DO NOT touch the patient when connecting or disconnecting a probe.*
- *Take precautions with probe cables. DO NOT bend the cable acutely.*

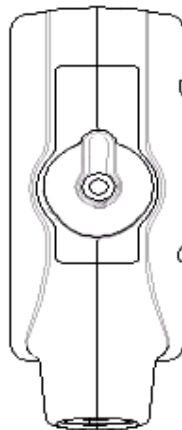


Fig.3-2 a Probe connector “Unlock” status

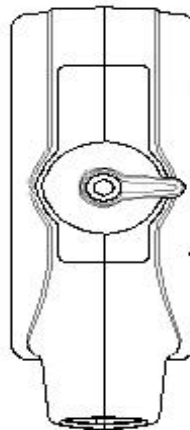


Fig.3-2 b Probe connector “Lock” status

Deactivating the Probe

When deactivating the probe, the probe is automatically placed in a standby mode.

To deactivate a probe:

- Ensure the system is in “Transducer Selection” interface. If necessary, press the PROBE-key to return.
- Gently wipe off the excess gel from the probe surface.
- Carefully slide the probe toward the probe holder, and place the probe gently in the probe holder.

Disconnecting the Probe

Probes can be disconnected when the system is “Transducer Selection” interface.

To disconnect a probe:

- Turn the connector locking lever to an “Unlock” position.
- Pull the probe and connector straight out of the probe port.
- Carefully slide the probe and connector away from the probe port.
- Ensure that the head of the probe is clean before placing the probe in its storage box.

Transporting the Probe

When transporting a probe a long distance, store it in its original carrying case.

Storing the Probe

It is recommended that all probes should be stored in the original carrying case.

- Place the probe connector into the carrying case.
- Carefully wind the cable into the carrying case.
- Carefully place the probe head into the carrying case. DO NOT use excessive force or impact on the probe head.

3.6 Optional installation

3.6.1 Connect the printer

- 1) It needs three cables: Remote cable, Video signal cable, Power cord. See picture in Fig.3-3.
- 2) Connect the remote cable to remote port on the back panel of ultrasound system. See picture in Fig.3-3.
- 3) Connect the video signal cable to the Video Out port on the back panel of the ultrasound system. See picture in Fig.3-3.
- 4) Connect the Power cord to the Power output of auxiliary mains on the back panel of the ultrasound system. See picture in Fig.3-3.

⚠ NOTE: *If you don't connect remote cable, you still can do the printing by pressing the key on printer.*

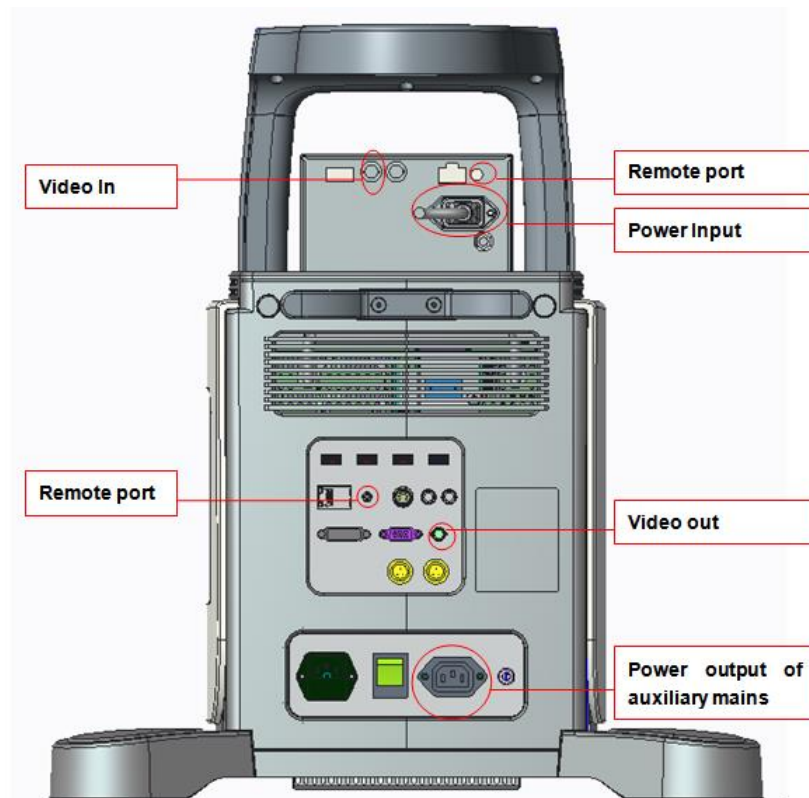


Fig.3-3

3.6.2 Set the system for Video Printer

 **CAUTION:** Please confirm the video printer is turned on and connected well with the main unit, then you can do below setting.

- 1) Press the  key to enter "System Settings" interface, select "General", click "Keyboard".
See picture in Fig.3-4.

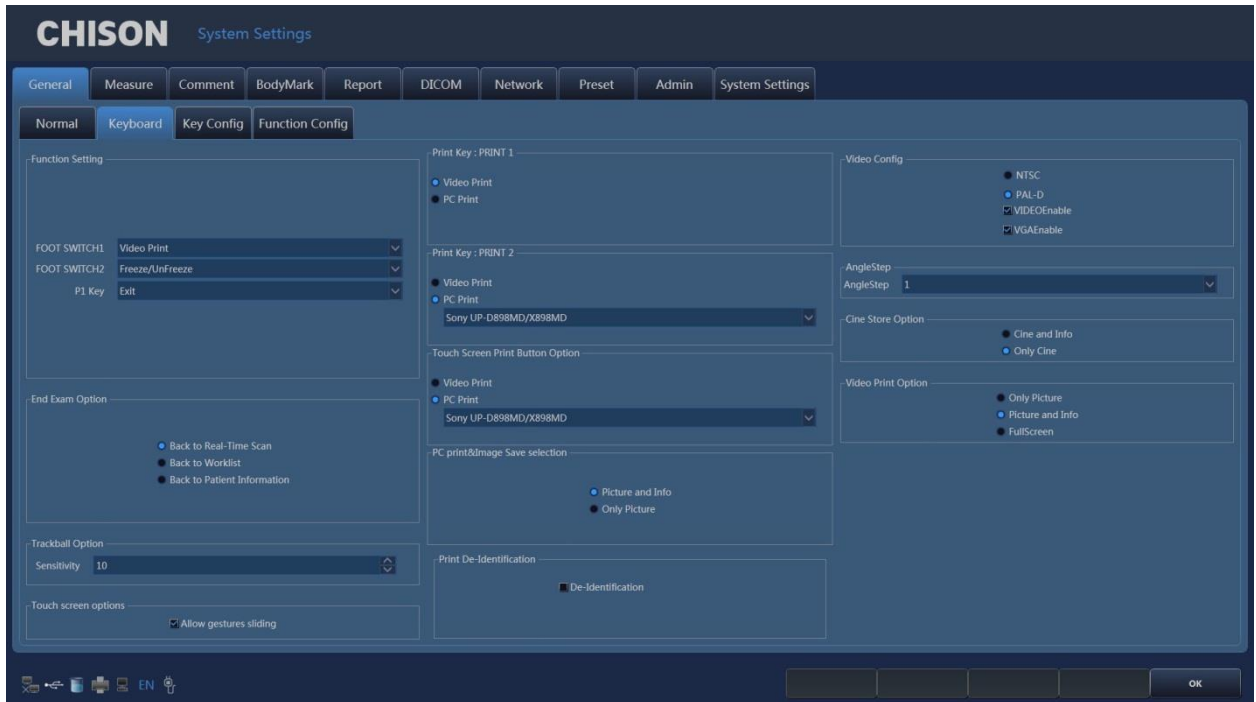


Fig.3-4

- 2) Select Video Enable, Choose "Video Print" under Print key menu or Touch Screen Print, and set the "Video Print Option".

"Only Picture" means only print the ultrasound image.

"Picture and Info" means print the ultrasound image with patient information.

"Full Screen" means print the full screen image.

- 3) Press the print key on keyboard or use touch screen for printing.

 **NOTE:**

- You need to restart the system after connecting the cables between Video printer and the System.

- ***You can't print the system information.***

3.6.3 Connect the PC printer

1. Place the printer smoothly.
2. Connect the printer to the system.
3. Set the print manager. Please see more information in 7.8.
4. Choose "PC print selection" in system setting, chooses "Picture and Info", or "Only Picture".
5. Choose "PC Print" under Print key menu or Foot SW menu.
6. Press the print key on keyboard or use foot switch for printing.

3.6.4 Connect the Footswitch

1. Connect the footswitch to the footswitch port of the system, see Fig. 3-1 d: Back Side View.
2. Enter into the system settings, set the function for the foot switch.

3.7 User Interface Control

- B gain, Color gain and Doppler gain
- TGC
- Brightness
- Acoustic power
- Gamma
- Smooth
- Edge enhance
- Persistence
- Depth control
- Focal position/number
- Dynamic range selection
- Audio volume control
- U/D inversion
- Biopsy guide
- PRF
- Wall filter
- Blood Effecton
- Steering
- Color ROI panning
- Doppler sample volume adjustment
- Doppler angle correction
- Baseline movement
- Time base scrolling speed

- Annotation
- Measurement and calculation package
- File management and image archiving
- DICOM setting
- User defined preset
- Clip image saving
- Patient data entry
- Q-image
- Space compound imaging
- Freeze/Unfreeze
- Image storage
- Scanning width
- Zoom
- Dual display: Dual B or color
- Quad display
- L/R inversion

3.7.1 Control Panel and Alphanumeric Keyboard



Fig. 3-5: Overview of Control Panel and Alphanumeric Keyboard

See layout of the Control Panel and Alphanumeric Keyboard in the above figure.

The main function of each key is introduced in the following table.

 POWER	✧ Press system power key momentary on the right top of Alphanumeric Keyboard to turn on the system. Press this key and choose “turn off” to turn off the system. Press this key longer than 4 seconds to force the system to shut down in case the system is down.
 SK1-SK5	✧ Press or rotate the keys to change the parameters of the corresponding menu at the bottom of the touch screen.
	✧ Manipulate the TGC (Time Gain Compensation) with 8 pairs of sliders.

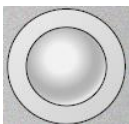
TGC Sliders	
 Alphanumeric Keyboard	✧ Input comment by alphanumeric keyboard. ✧ : Finish the exam of current patient; delete the information of current patient. ✧  (Body mark): Enter to the Bodymark function. ✧ : Enter to the ARROW mark function. ✧  (Comment): Enter to the Comment function. ✧ : Delete all comments, arrows, bodymarks and measure tracks on the screen. ✧  (Biopsy): Enter to the biopsy function. ✧  (Single): Enter to the Single B display. ✧  (Dual): Enter to the Dual B display. ✧  (Quad): Enter to the Quad B display. ✧ : Turn down the volume. ✧ : Turn up the volume. ✧ : Enter to the system recovery mode. ✧  (Archive): Enter to the Archive function. ✧  (Setup): Enter to the system setting. ✧ P1: Function config key. ✧ Q-beam: Turn on/off Q-beam. ✧ Q-flow: Turn on/off Q-flow.

	✧ One key to full screen, press the key to enlarge the image to full screen.
 X -CONTRAST	✧ Press the key to adjust X –CONTRAST.
 INVERT	✧ In B mode, reverse the 2D image orientation 180 degrees. ✧ In Color mode, the flow direction (blue and red) can be inverted by pressing the INVERT key. ✧ In PW mode, the spectrum will be reversed according to the baseline when INVERT key is pressed.
 L/R	✧ Reverse the 2D(B or Color) image between the left/right orientations.
 SAVE	✧ Store still images.
 SAVE CLIP	✧ Store selected clips.
 FREEZE	✧ Freeze/Un-freeze the ultrasound image and enter/quit the Cine mode automatically.
	✧ Turn on/off FHI. FHI can be activated in 2D mode.
 B	✧ Press the B-knob to turn on B-mode imaging. The system will stay in B mode if the current state is B, or return to B-mode if the current state is not B (e.g. M, color, Duplex Doppler). ✧ Rotate this knob to change the overall B gain throughout the image.

 CPA	Activate/turn off CPA Mode (also named as Color Power Angio mode). ✧ Press the CPA-key to turn on the CPA mode if the system is in B mode; ✧ Press the CPA-key for second time to turn off CPA and return to the previous mode (either B-mode or duplex Doppler)
 DEPTH/FOCUS	✧ Press this key to select DEPTH, change the image depth of view. ✧ Press this key to select FOCUS, change the focus Position.
 C	✧ Press the C-knob to turn on the Color Flow Map (CFM) mode if the system's current state is B; ✧ Press this knob can turn on Color if the system's current state is duplex Doppler; Press the C-knob for second time to turn off color and return to the previous mode (either B-mode or Duplex Doppler). ✧ Rotate C-knob to change the overall Color gain for CFM (PD) mode. ✧ In 4D mode, rotate C-knob to rotate image by X-axis.
 TDI	✧ Press the TDI key to turn on the TDI mode if the current mode is B;
 D	✧ Press the PW-knob to turn on the duplex Doppler duplex mode if the current mode is B; ✧ Rotate the knob to change the overall Doppler gain for PW mode, when activate the spectral Doppler mode. ✧ In 4D mode, rotate D-knob to rotate image by Y-axis.
	✧ In the Spectral Doppler mode, the default angle correction feature remains active. In the real time or cine modes, rotate this knob to adjust the Doppler Angle Correction by lining up the cursor with the vessel wall for an accurate reading. The Doppler Angle Correction setting can be adjusted 5 degrees at a time.

	✧ Rotate it to adjust the probe direction on the body mark status. ✧ In B and CFM mode, rotate it to zoom the image. Press twice to enter multipleen largements.
 CW	✧ If the probe supports CW mode, e.g. a phased array probe, press CW-key starts CW mode. The CW control operates in the same manner as the PW.
 M	✧ Press the M-knob to enter B/M mode if the current mode is B; ✧ Press the M-knob for second time to enter M-mode without B- mode ✧ Press the M-knob for third time to go back to B-mode ✧ Rotate the knob to change the overall M gain throughout the image. ✧ In 4D mode, rotate M-knob to rotate image by Z-axis.
 AIO	✧ AIO means Automatic Imaging Optimization. During image scanning, press this key will optimize the image for a better quality in resolution automatically.
 PATIENT	✧ Use the PATIENT-key to start a new patient record, edit a current patient's data, or select a patient's exam data from worklist.
 PROBE	✧ Press PROBE-key to enter the "Transducer Selection" interface showing all available applications supported for the probes connected to the system.
 4D	✧ Press this key to enter into 4D(2D setting) mode.
 LIVE	✧ Press this key to enter into 4D mode.
 	✧ Press this key to enter system setting.

SYSTEM SETTING	
 REPORT	✧ Press this key to enter REPORT function.
 PRINT2	✧ Print the images when the printer is working.
 PRINT1	✧ Print the images when the printer is working.
 ENTER	✧ Confirm the command entry; ✧ Confirm EXAM mode and menu setting; ✧ Confirm caliper and measurement setting; ✧ Toggle Trackball function between Re-sizing and Re-positioning for the CROI, and Doppler Sample Volume Gate.
 CALC	✧ Use this key to activate calculation packages under different applications. This feature supports the optional OB, GYN, Vessel, Urology, Cardiac, Small parts, Pediatrics, Carotid Abdomen and General calculation packages. Refer to Measurement & Calculation section for details.
 TRACE	✧ Enter to Trace fast-measurement
 DIST	✧ Enter to DIST fast-measurement
	This key provides multiple functions according to the active mode on the screen. ✧ In real-time mode, it accesses the Soft- Menu that corresponds to each mode. Press MENU-knob for second

Menu	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.
 Change	✧ Press to change Calc package. ✧ Press to change menus of different modes.
 Cursor	✧ Press to display cursor.
 Exit	✧ Exit from current operation status.
 UPDATE	✧ Press the UPDATE-key after the sample volume gate is defined to activate the Spectral Doppler mode. Press the UPDATE-key for second time to toggle back to 2D (B or Color) update and deactivate the Spectral Doppler. ✧ In Measurement mode, it can be used to switch between start point and end point (distance), long-axis and short-axis (ellipse), and return back to last position in trace measurement before the measurement is finished.
 Trackball	✧ Position calipers in measurement; ✧ Position 'mouse' cursor for exam mode selection; ✧ Position the M-mode, PW cursor; ✧ Select entry in soft-menu; Select EXAM mode; ✧ Position and re-size the Color Region of Interest (CROI); ✧ Position and re-size the Doppler Sample Volume Gate; ✧ Control digital cine review frames.

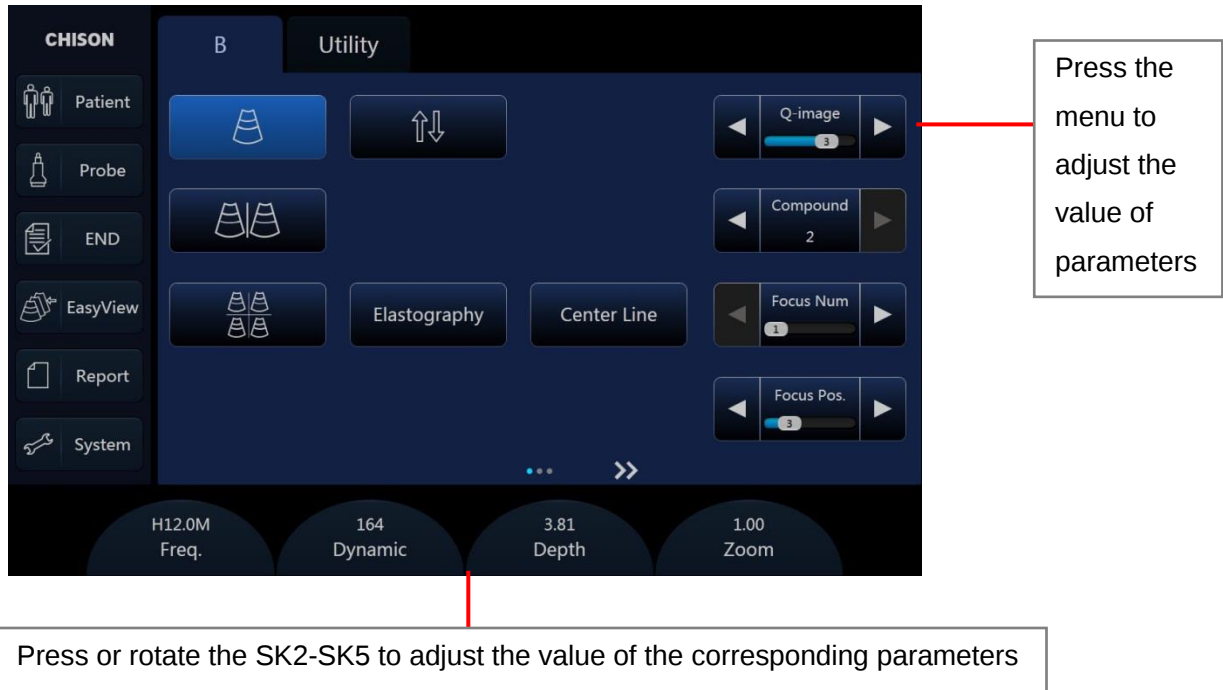
3.7.2 Soft-Menu Controls

The Soft-Menu is activated depending on the current active mode. The Soft-Menu will provide a second level control to set the parameters in the system. The default setting depends on different applications.

Soft-Menu provides the user with an easy and flexible approach to access additional system

controls. The system will display the appropriate menus for the selected Mode and functions.

There two soft-Menu controls, user can press Menu-knob on the control panel or touch the parameters on the touch screen to set the value.



Chapter 4 Imaging

4.1 General Description

- How to begin an exam
- How to select a probe and an application.
- How to optimize the image
- The operations after getting the image: adding annotation and body mark, storing and recalling the image

4.2 Beginning an Exam

Begin an exam by entering new patient information. You should enter as much information as possible, such as patient ID, patient name.

The patient name and ID number are retained with each patient's image and transferred with each image during archiving or hard copy printing.



To avoid patient identification errors, always verifying the identification with the patient. Make sure the correct patient identification appears on all screens and hard copy prints.

4.2.1 Selecting a Probe and an Application

The system has four built-in probe connectors, so it can connect four probes at the same time.

Press PROBE-key to back to "Transducer Selection" interface.

1. Select the proper probe.
2. Select the proper Application.
3. Click the preset to enter into the default preset.

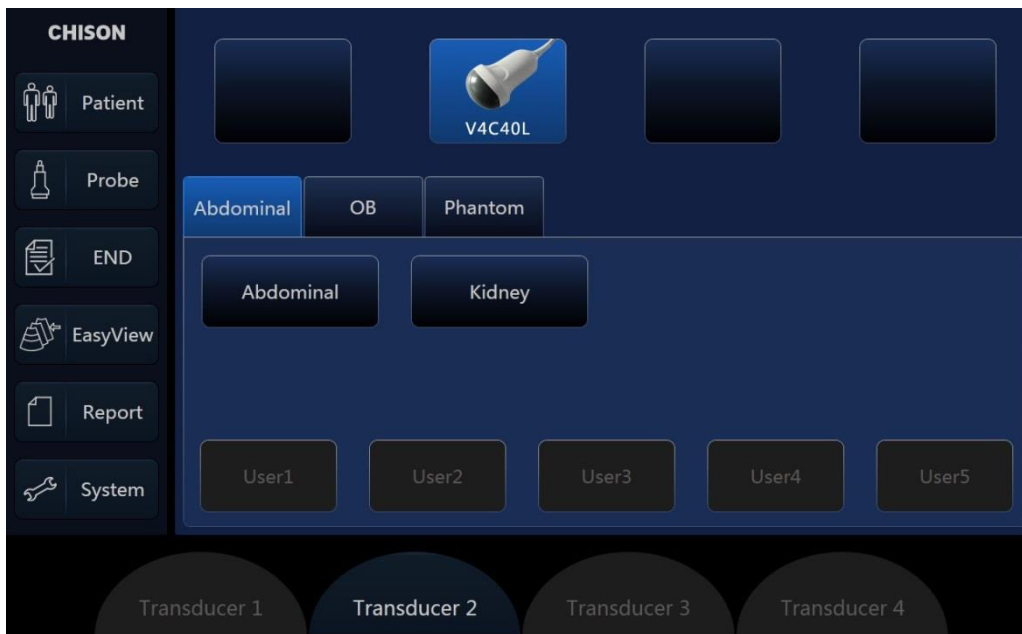


Fig.4-1

4.2.2 Patient Data Entry

Press the PATIENT-key to display the Patient interface.

The image displays the 'Patient Information' form in the CHISON system. It is divided into two main sections: 'Basic Information' on the left and 'Detail Information' on the right. The 'Basic Information' section includes fields for Patient ID (2019-11-16-051805), First Name, Middle Name, Last Name, Birthday (with a dropdown), Age (0 Y 0 M), and Gender (with a dropdown). Below these are 'Search In' buttons for 'Archive' and 'WorkList'. The 'Detail Information' section includes a 'Study Type' dropdown (set to 'Normal') with a 'Clear' button, and input fields for Height (0 cm), Weight (0 kg), and BSA (0 m²). It also has fields for Study Description, Accession #, Primary Indications, CPT4 Code, Secondary Indications, CPT4 Description, Diag. Physician, Ref. Physician, and Sonographer (all with dropdowns). A large 'Comment' text area is at the bottom of the detail section. At the very bottom of the screen are buttons for 'New Patient', 'New Study', 'OK', and 'Cancel'.

Fig.4-2

Method of entering the patient information:

- 1) Move the cursor to input area and input the patient information through the keyboard. Move

trackball to exchange between each option. E.g., patient name, birthday (birthday result will be automatic calculated after entering the age), age (age result will be automatic calculated after entering the birthday), sex, weight, height.etc.

- 2) Click “OK” key to save the data after entering the appropriate information, then the system will go back to B mode.

4.2.3 Display Interface

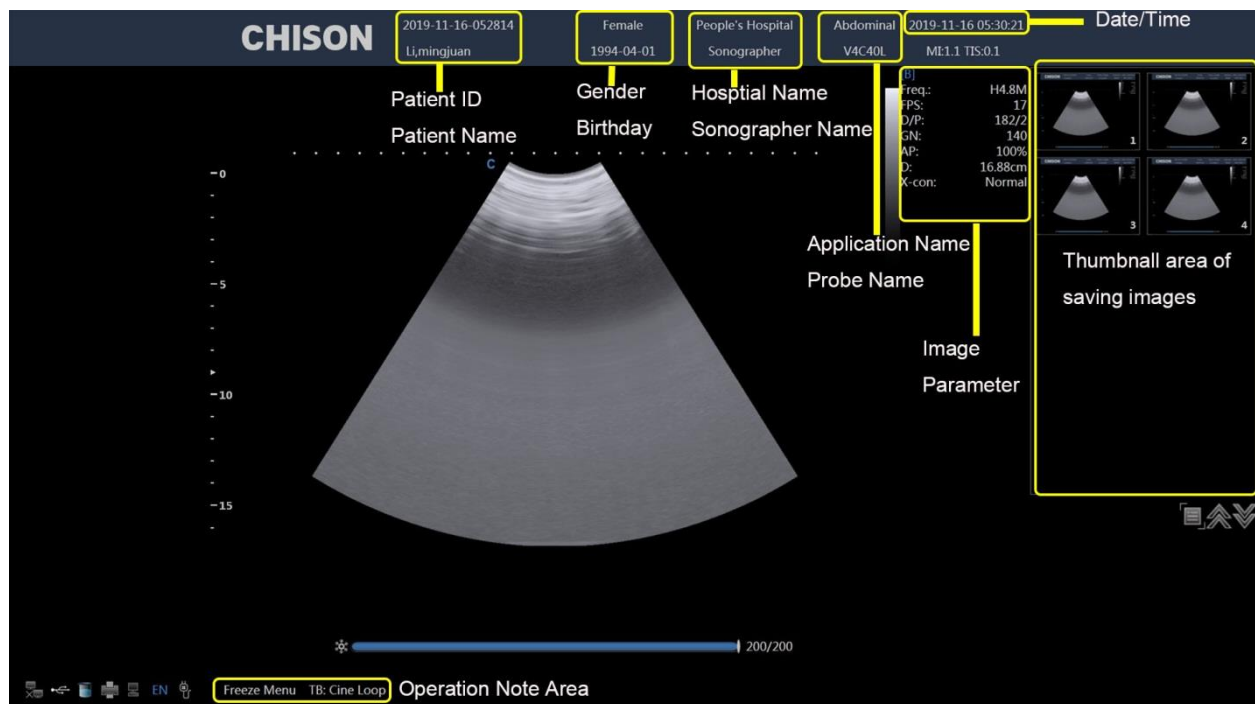


Fig.4-3

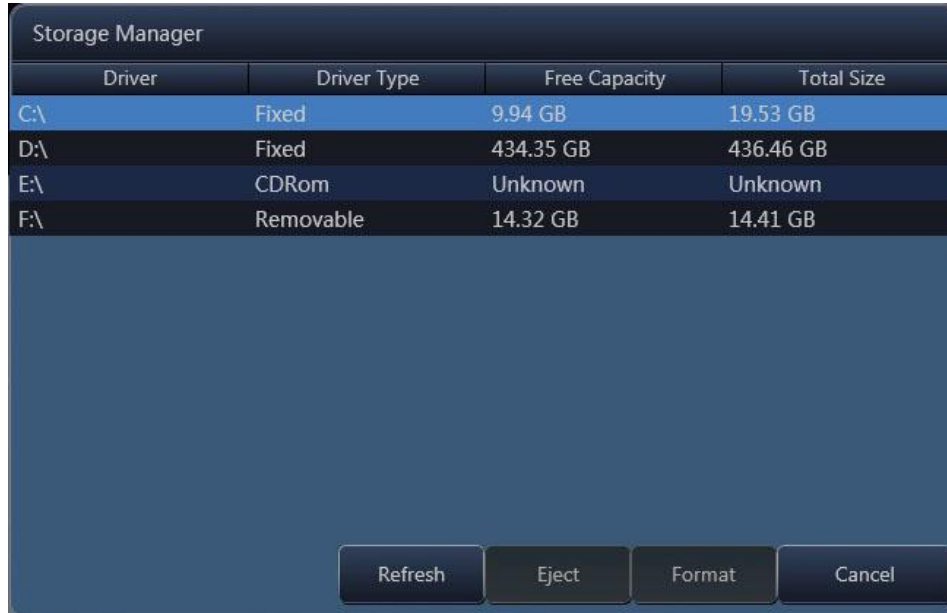
- image parameter area: Display the parameters under current mode. The different modes have different parameters.
- thumbnail area of saving images: This area displays the thumbnail images of current patient. Selecting thumbnail images can recall this image immediately.
- operation note area: The first line shows the status of the current system. The second line indicates the current function of the trackball. In the picture Fig. 4-3, the first line display “freeze menu”. It means the system is in frozen status. The second line display “recall image”. It means moving the trackball can recall the images in current status.
- system information area: Display the current system information. Moving the mouse to different icon will display detailed information accordingly.



Display current network situation. It will display the IP address after connecting to the network.



Display the status of current removable disks. If exist removable disks, click this icon can quickly enter into the storage manager interface and do the operation for disks.



The image shows a 'Storage Manager' window with a table of disk information. The table has four columns: Driver, Driver Type, Free Capacity, and Total Size. It lists four drives: C:\ (Fixed, 9.94 GB free, 19.53 GB total), D:\ (Fixed, 434.35 GB free, 436.46 GB total), E:\ (CDRom, Unknown free, Unknown total), and F:\ (Removable, 14.32 GB free, 14.41 GB total). Below the table are four buttons: Refresh, Eject, Format, and Cancel.

Driver	Driver Type	Free Capacity	Total Size
C:\	Fixed	9.94 GB	19.53 GB
D:\	Fixed	434.35 GB	436.46 GB
E:\	CDRom	Unknown	Unknown
F:\	Removable	14.32 GB	14.41 GB

Fig.4-4



Display space size of all the drivers.



Printer management, refer to section 7.8.



Task manager: display the state of current task.

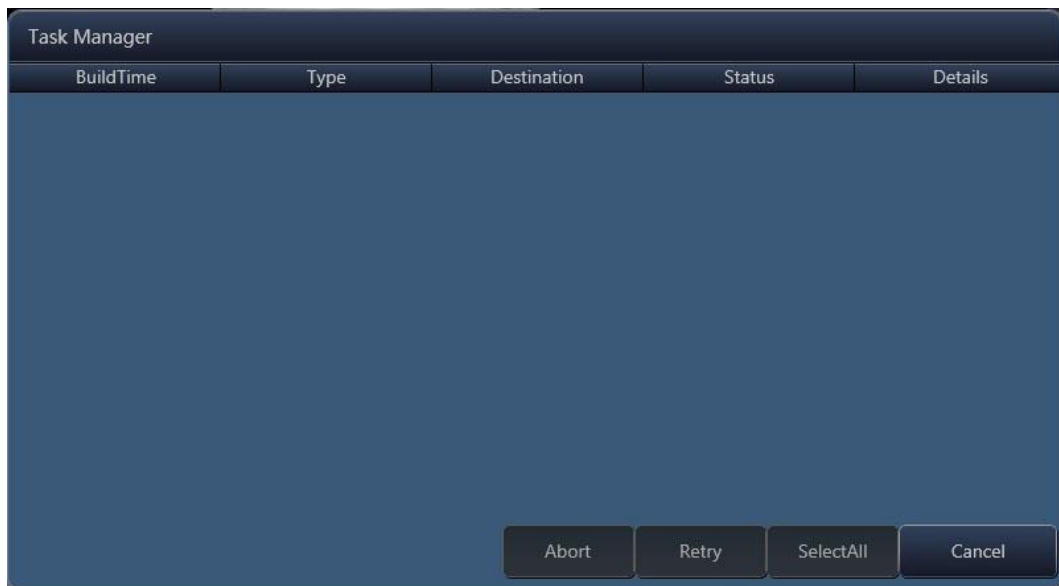


Fig.4-5



Show the present state of charge and connection of adapter.

4.3 Optimizing the Image

4.3.1 Image Parameters Display

B	Meaning	CFM /PD	Meaning	PW	Meaning	M	Meaning
Freq.	Frequency	Freq.	Frequency	Freq.	Frequency	SR	Sweep Speed
FPS	Frame rate	PRF	PRF	PRF	PRF	D/G	Dynamic range G:Gain
D/P	D:Dynamic range P: Persistence	WF	Wall Filter	WF	Wall Filter		
GN	B Gain	GN	Color Gain	GN	Doppler Gain		

AP	Acoustic power	C/P	C: Color map /direction power P:Persistence	Angle	Doppler angle		
D	Display depth			SV	Sample volume gate		

4.3.2 Scanning Modes

The system can support the following modes:

- B Mode
- B/M Mode
- M Mode
- Dual mode
- Quad mode
- 2D Steer
- CFM mode
- CPA mode
- DPD mode
- PW mode
- B/BC mode
- Triplex Mode
- Quadplex Mode
- CW mode
- Free Steering M mode (option)
- HPRF(option)
- TDI
- Color M Mode (option)
- Curved Panoramic (option)
- Trapezoidal image
- Elastography(option)

4.3.3 B Mode

Intended Use:

B-mode is intended to provide two-dimensional images and measurement capabilities concerning the anatomical structure of soft tissue. Press B-knob to enter into B mode. Rotate B-knob to adjust B gain.



Fig.4-6 B Mode

4.3.4 Dual Mode

In B mode, press  key. System will display the current image at the left side of the screen, Press  key second time, system will freeze the image displayed at the left side and activate the image displayed at the right side at the same time. Press  key continuously to achieve exchange of the freeze/real status between left side image and right side image. Use the  key to invert image which is activated in left and right direction. Use the  key to invert image which is activated in up and down direction. Press  key to go back to B mode.

 **NOTE:** *There is only one image could be activated. Dual display is also available for the Color Mode and PD Mode.*

4.3.5 Quad Mode

In B Mode, press  key, the image which is activated will be displayed at the upper left side of the screen, press  key continuously will freeze and activate the upper right image, lower left image, and lower right image in order. Use  key do the Left/Right invert for current archiving image, use the  key which on the control panel can do the up/down invert for current achieving image. It will go back to B Mode if press  key again.



NOTE: *There is only one image could be activated at one time. Quad display is also available for the Color Mode and PD Mode.*

4.3.6 B/BC Mode

In active color mode, turn the [B/BC] item on to display a real B mode image at the right side of the screen and active Color mode image at the left side of the screen.

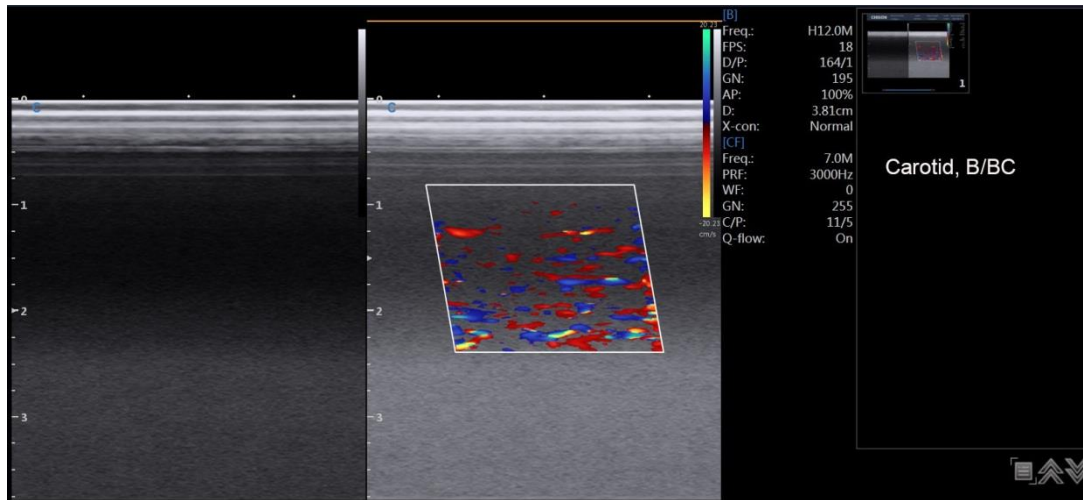


Fig.4-7 B/BC Mode

4.3.7 B/M and M Mode

Intended Use:

M-mode is used to determine patterns of motion for objects within the ultrasound beam. The most common use is for viewing motion patterns of the heart.

This system provides B mode image and M mode image at the same time. Press M knob to enter into B/M mode. Press M knob again to enter into M mode. M mode is fit for heart scanning and measurement.

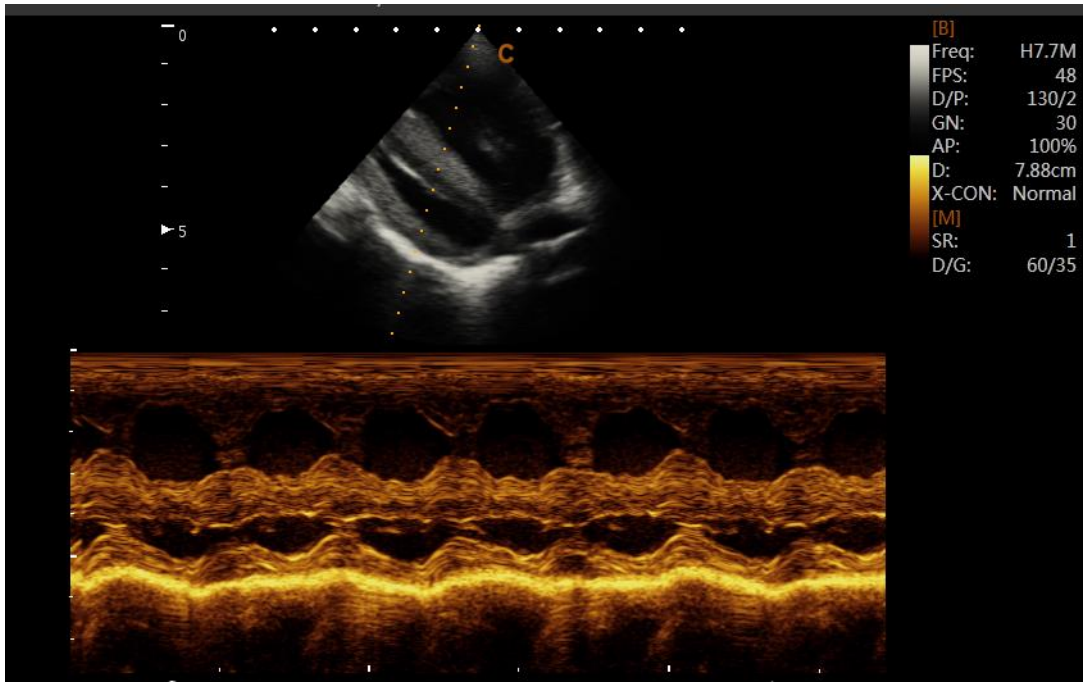


Fig.4-8 B/M Mode

M-mode Exam Procedure:

- Get a good B-mode image. Survey the anatomy and place the area of interest near the center of the B-mode image.
- Press the M-knob, move the Trackball to position the M cursor over the area that you want to display in M-mode.
- Adjust the Sweep Speed, TGC, Gain etc, as needed.
- Press the FREEZE-key to stop the M scanning.
- Record the image to hard disk or to the printer (hard copy device).
- Press FREEZE-key to continue imaging.
- Press M-knob to enter into M-mode.
- Press M –knob again to exit M-mode.

M-mode Scanning Hints:

Sweep speed: control speed of M-mode update.

4.3.8 CFM mode

Intended Use:

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

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

In CFM mode, move the trackball to change the position of sampling box. [STEER] menu is used to adjust the angle of color sampling box (if current probe is linear probe). Press ENTER-key to fix the position of color sampling box. At this time adjust the size of color sampling box through moving trackball. Press ENTER-key again and move trackball to change the color sampling position again.

Press C knob to enter into CFM mode; after C knob light is on, rotate the knob for adjusting the gain of CFM.

CFM mode Exam Procedure:

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

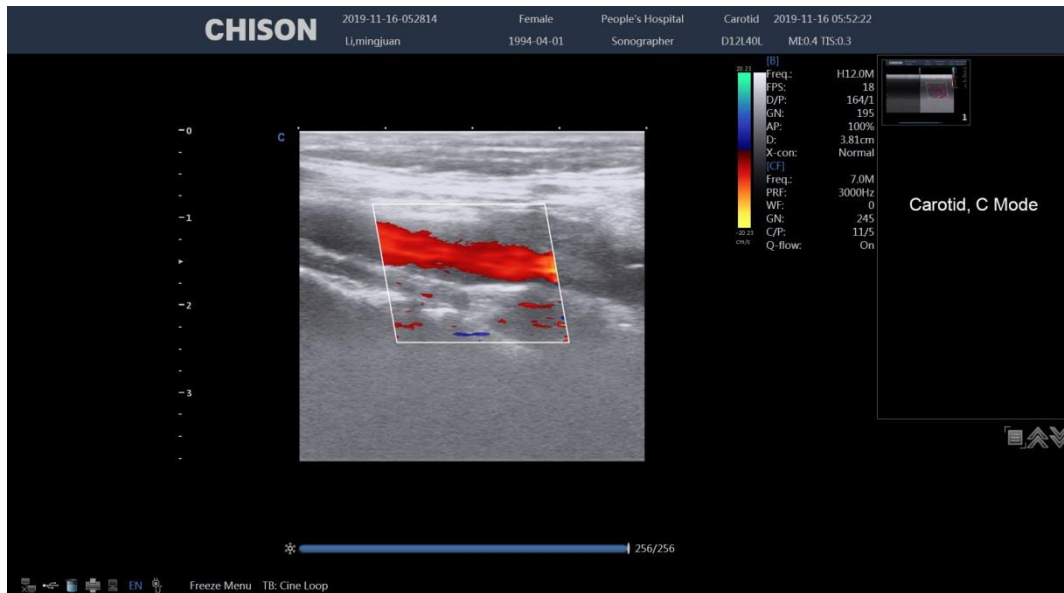


Fig.4-9 CFM Mode

CFM Scanning Hints:

PRF: increase/decrease the PRF on the color bar. Imaging of higher velocity flow requires increased velocity scale values to avoid aliasing

Wall Filter: affect low flow sensitivity versus motion artifact

Color Map: allow you to select a specific color map. It shows the direction of the flow and highlights the higher velocity flows.

Color Gain: amplify the overall strength of echoes processed in the CROI

Persistence: affect temporal smoothing and color Doppler 'robustness'.

Line Density: trade frame rate for sensitivity and spatial resolution. If the frame rate is too slow, decrease the CROI size and the line density.

4.3.9 CPA Mode

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

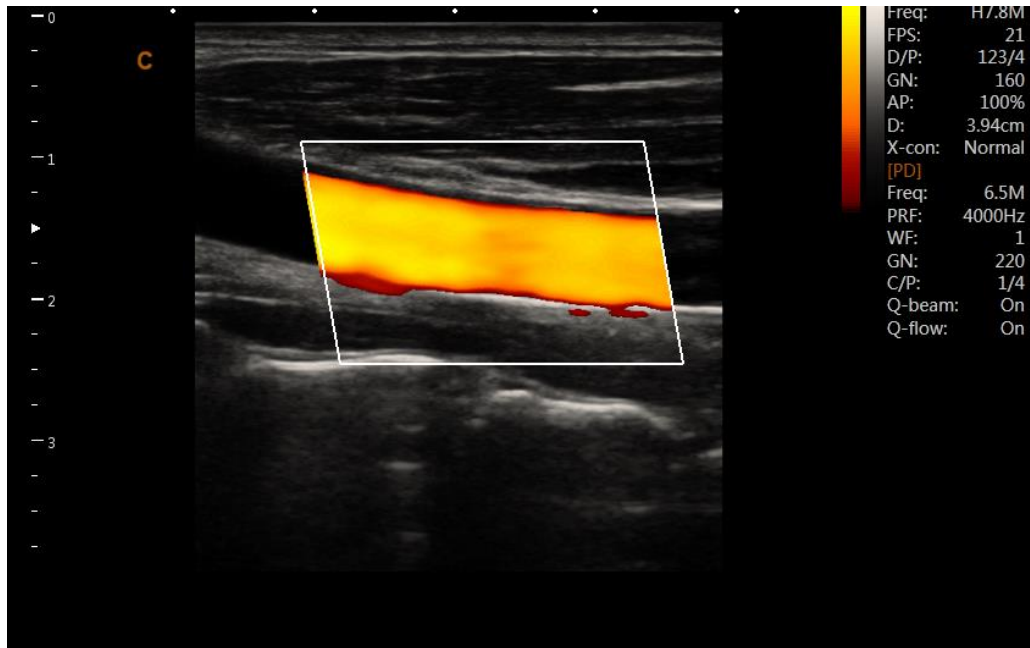


Fig.4-10 CPA Mode

Press CPA -key to enter into the CPA mode and then CPA light is on.

Direction PD mode

In CPA mode, press MENU-knob to pop up the CPA Menu. Rotate MENU-knob to select the DPD Mode and press MENU-knob to enter into DPD mode.

If you need go back to PD mode from DPD mode, you could press CPA key.

4.3.10 PW mode

Intended Use:

Doppler is intended to provide measurement data concerning the velocity of moving tissues and fluids. PW Doppler lets you examine blood flow data selectively from a small region called the Sample Volume.

The X axis represents time while the Y axis represents velocity in either a forward or reverse direction.

PW Doppler is typically used for displaying the speed, direction, and spectral content of blood flow at selected anatomical sites.

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

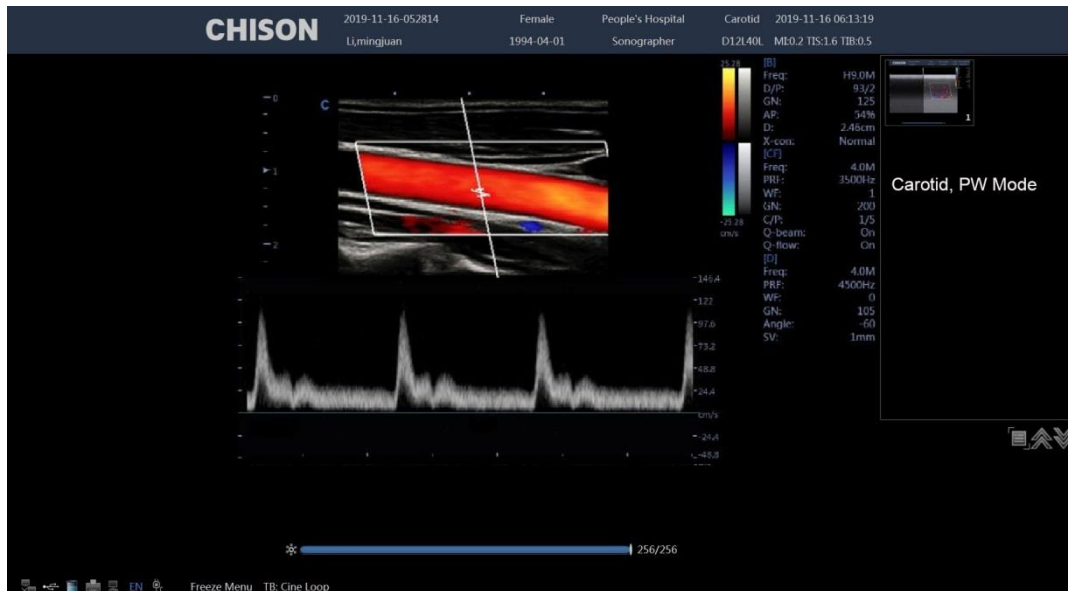


Fig.4-11 PW Mode

PW mode Exam Procedure:

- Get a good B-mode image. Press C-knob to help locate the vessel you wish to examine.
- Press PW-knob to display the sample volume cursor and gate.
- Position the sample volume cursor by moving the Trackball left and right. Position or re-size the sample volume gate by moving the Trackball up and down, then press Enter-key.
- Press UPDATE-key to display PW Doppler spectrum and the system will run in combined B+Doppler mode. The Doppler signal can be heard through the speakers.
- Optimize the PW Doppler spectrum, as necessary.
- Ensure that the sample line is parallel to the blood flow.
- Press FREEZE-key to hold the trace in cine memory and stop imaging.
- Perform measurements and calculations, as necessary.
- Record results with your recording devices.
- Press FREEZE-key to resume imaging.
- Repeat the above procedure until all relevant flow sites have been examined.
- Replace the probe in its respective holder.

When pressing D-knob for the first time, the Doppler spectrum is not activated. The Doppler Sample Volume appears in the default position, and the B mode image or 2D (either B or Color) mode are active. Moving the Trackball will change the Sample Volume position. Press the Enter-

key to toggle the Trackball function between Sample Volume Gate position and size. Press the UPDATE-key after the Sample Volume Gate is defined to activate the Spectral Doppler mode. Press the UPDATE-key for second time to toggle back to 2D (B or Color) update and deactivate the Spectral Doppler.

Doppler mode Scanning Hints:

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

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

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

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

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

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

Sweep Speed: control speed of spectral update.

Doppler Sample Volume Gate Position and Size (Trackball and Enter)

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

- To move Doppler cursor position, turn the trackball left or right until positioned over the vessel.
- To move sample volume gate position, move the trackball up or down until positioned inside the vessel.
- To size sample volume gate, press Enter-key to toggle trackball function from sample volume gate positioning to sizing, then move the trackball to change sample volume gate size.

Activating Triplex mode

- While in **B** mode, press **C**-knob and **D**-knob to access the **B+Doppler+Color** mode, turn

Triplex menu on to enter the **Triplex** active mode.

- While in **B** mode, press **CPA-key** and **D-knob** access the **B+Doppler+CPA** mode, turn Triplex menu on to enter the **Triplex** active mode.

Activating Quadplex mode

- While in **B** mode, press **C-knob** and **D-knob** to access the **B+Doppler+Color** mode, turn Quadplex menu on to enter the Quadplex active mode.
- While in **B** mode, press **CPA-key** and **D-knob** access the **B+Doppler+CPA** mode, turn Quadplex menu on to enter the Quadplex active mode.

4.3.11 Curved Panoramic

In B real time mode, turn on the Panoramic on the touch screen, then move the probe linearly to get a series of B mode images, and the system piecing together multiple B images into a single, extended B image. Curved Panoramic is available for linear probes.

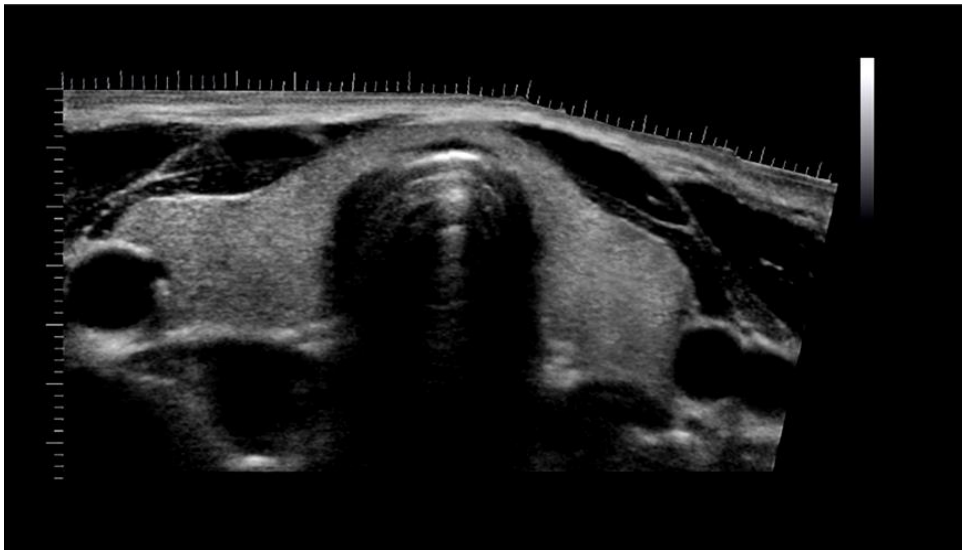


Fig.4-12 Curved Panoramic Mode

4.3.12 2D Steer

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

In B mode, press menu knob to pop up B Menu, adjust 2D Steer item to change 2D steer angle.

4.3.13 Trapezoidal Mode

Trapezoidal image is available for linear probes. In B mode, press menu knob to pop up B Menu, turn Trapezoidal Mode menu on to enter to Trapezoidal Mode.

4.3.14 Free Steering M mode (option)

Free steering M mode is only available for phased array probe. This mode can give you the ability to manipulate the cursor at different angle and position. The M-mode display changes as per the M cursor position.

User can activate the Steering M mode using Soft-Menu. Turn the item Free M Mode on, and turn Angle to rotate free steering M line. The system provides maximum 3 free steering M line and you can select either of them with ENTER-key.

Trackball: used to move the free steering M line.

Angle: used to rotate the free steering M line.

4.3.15 Color M mode (option)

Color M mode is used for fetal cardiac applications. Color flow overlays color on the M-mode image using velocity and variance color maps. The color flow wedge overlays the B-mode image and M-mode timeline. The color flow maps available in M-mode are the same as in CFM mode.

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

If the system is in color mode and the probe supports Color M mode (e.g. phased array probe), press M-knob to enter Color M mode.

4.3.16 CW Mode

Continuous Wave Doppler allows examination of blood flow data all along the Doppler cursor rather than from any specific depth. Gather samples along the entire Doppler beam for rapid scanning of the heart. Range gated CW allows information to be gathered at higher velocities.

It works with a phased array or pediatric probe.

If the velocity of the blood flow is even too high for the HPRF mode to detect, you have to try CW mode. Press CW-key to enter CW mode when the probe supports CW mode.

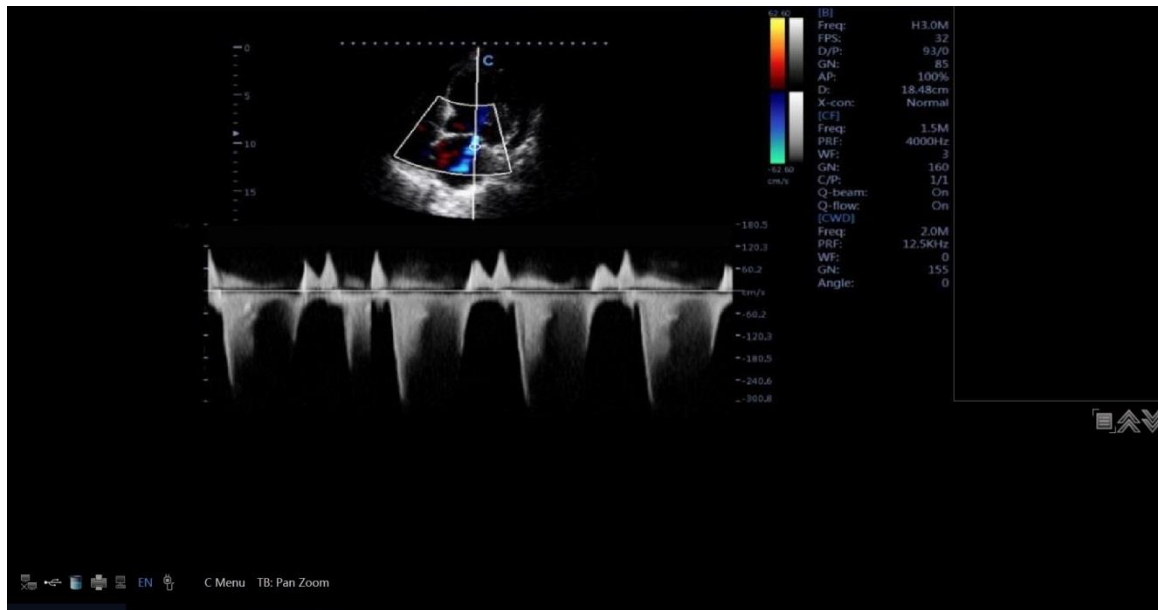


Fig.4-13 CW Mode

4.3.17 TDI Mode

TDI mode is tissue Doppler mode, which is intended to provide information of low-velocity tissue motion, specifically for cardiac movement. Only phased array probe is available for TDI function.

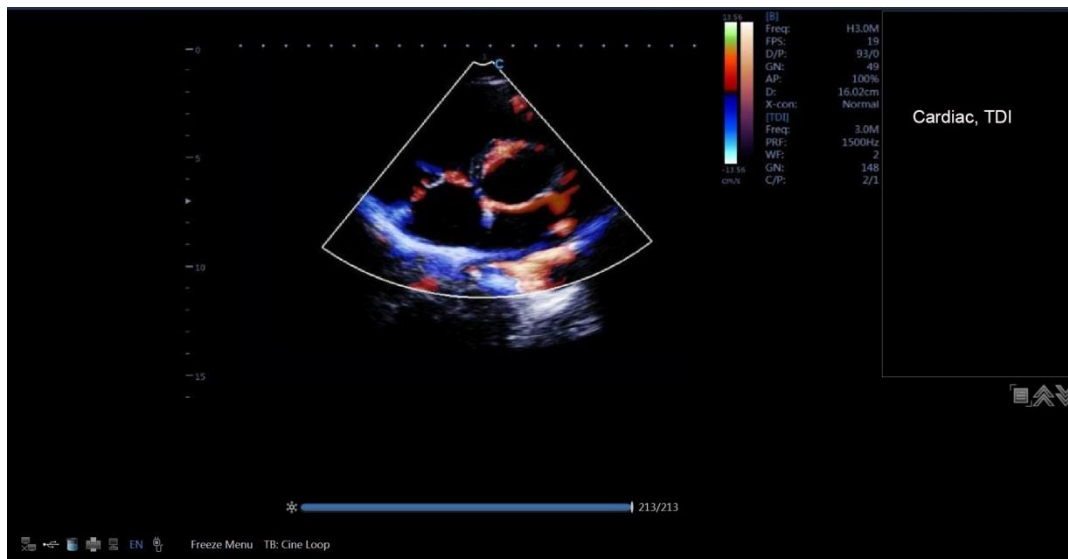


Fig.4-14 TDI Mode

Press TDI-key to enter into TDI mode.

4.3.18 Elastography mode (option)

Elastography shows the biological tissue elasticity properties with the ultrasound imaging system. It records the ultrasound signals before and after tissue distortion caused by applying external or

internal forces. Based on the recorded signals, it analyzes, estimates and displays the strain of biological tissue.

In B mode, turn elastography menu on can enter into elastography mode.

The Elastography screen:

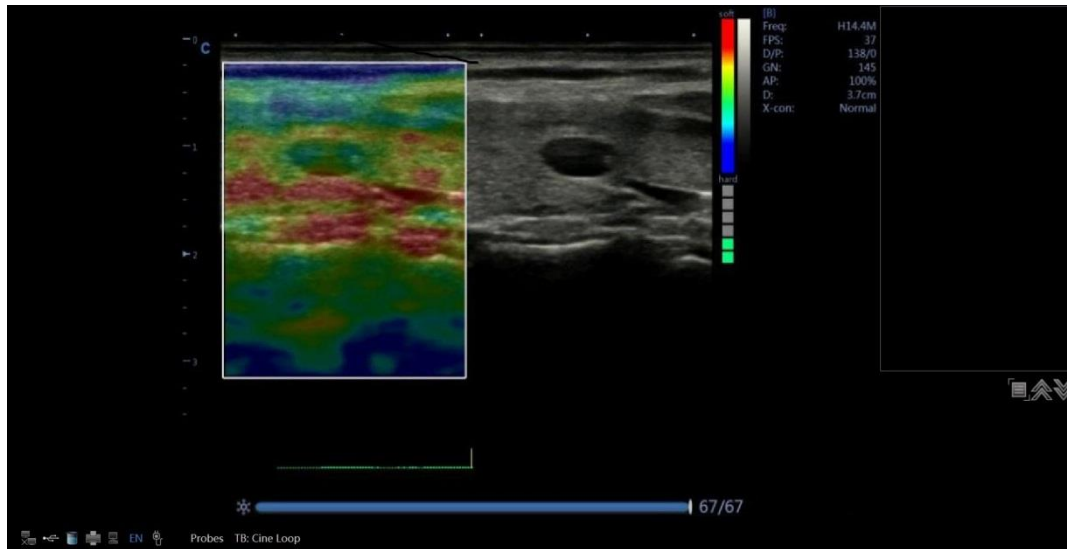


Fig.4-15 Elastography Mode

Change the size and the position of the Elastography box by using the trackball.

Change between size and position by using the ENTER key.

4.3.19 Optimize Image

Methods for optimizing:

1. Use soft menu

Press MENU-knob under the display mode and tune out the soft menu. Press Change-key now can do the exchange of the menu to different exam mode. Rotate MENU-knob to select the menu items. Press MENU- knob to enter. Now rotate MENU-knob can change the parameter of selected item. After adjustment, press Menu-knob to exit from selected item, at this time rotate the Menu-knob can select the item again. Press the EXIT-key or press Menu-knob to exit from the menu.

User can also use the menu on the touch screen.

2. Use shortcut menu

SK2—SK5 shortcut key respectively corresponding NO.1—NO.4 menu. Press and rotate shortcut key will choose the menu function corresponded.

3. Use other keys

4.3.20 Image Optimization of B ModeSoft menu adjustment:

Menu	Function
Q-Image	Adjust the parameter of the Q-Image.
SRA	Turn on the SRA function.
Compound	Turn on the compound function. SRA and Compound can't work at the same time.
Focus Num	Adjust focus number.
Focus Pos.	Adjust focus position.
Full Screen	Turn on the full screen function.
X-contrast	Adjust X-contrast function.
Persistence	Adjust the persistence function.
Density	Choose from low, mid and high.
2D map	Choose the format of 2D map.
Noise Reject	Adjust noise reject.
Scan width	Adjust scan width of B image; frame rate will be fast if scan width is small.
Image Rotate	Change the direction of B image. The angle will be increased at 90° interval in clockwise direction.
Gamma	Adjust gamma value.
Smooth	Adjust the image smooth.
Edge enhance	Adjust edge enhance.
A. power	Adjust acoustic power.
Trapezoidal Mode	Turn on Trapezoidal Mode
Biopsy	Turn on the biopsy guide line function

2D Steer	Adjust the steer angle of B image
Elastography	Turn on Elastography
Center Line	Turn on the center line
Utility	Post Processing, Slide Show, Demo Image, Protocol

Shortcut adjustment:

Shortcut (Action)	Menu	Menu function
SK2 (rotate)	Frequency	Adjust frequency of the probe.
SK3 (rotate)	Dynamic	Adjust the image dynamic range, increase or decrease, System dynamic range and contrast resolution.
SK4 (rotate)	Depth	Adjust the image depth.
SK5 (rotate)	Zoom	Adjust the size of the image.

Other adjustments:

1. Depth (DEPTH Knob)

DEPTH toggle key is used for the adjustment of image depth. Depth will increase if adjust downward; Depth will decrease if adjust upward. For the best resolution of focusing and edge enhancement, it needs to adjust TGC after the depth has been adjusted.

2. Scanning direction

Under the single display mode, the scanning direction will be left/right inverted if press the



key; images scanning direction will be up/down inverted if press



key.

3. Gain (B knob)

Adjust gain of B mode could enhance or reduce quantities of echo information in images. Adjust the main gain can adjust sensitivity of overall images (brightness). Rotate the knob of B mode could adjust B gain after the B light is on. The gain will be increased if rotate clockwise; the gain will be decreased if rotate contra. Adjust range is from 0 to 255. TGC will influence on each other between gain adjustment and TGC adjustment.

4. TGC

TGC with 8 adjustable slides: Slide the set of slider bars can change the depth gain of 2D images.

TGC returns signal amplifier to correct for the attenuation caused when adding depth. TGC balance the image and make the density of echo uniformly distributed in images. Similarly the enlargement of every sliding channel area is also different.

The range of TGC will redistribute according to the new depth while depth is changing.

Move the slide bar Left/Right can reduce/increase TGC.

5. Image magnification (ZOOM-knob)

Press ZOOM-knob, press UPDATE-key to choose the size of ROI box, and then press UPDATE-key again to choose the position. Press ENTER-key can realize multiple enlargements. Press EXIT-key or ZOOM knob to exit operation.

4.3.21 Image Optimization of M mode

Soft menu adjustment:

Menu	Function
Layout	Choose from LR and UD
Display Format	Choose from 1:2,1:1,2:1
Chroma	Adjust chroma of M image
Free M Mode	Turn on the function of Free M Mode
Color Map	Adjust color map of M image

Shortcut menu adjustment:

Shortcut (action)	Menu	Menu Function
SK3 (rotate)	Dynamic	Adjust the image dynamic range
SK5(rotate)	Speed	Adjust scanning speed

4.3.22 Color Flow Map(CFM) Mode image optimization

Soft menu adjustment:

Menu	Function
Color Map	Adjust the color map
Color Invert	Realize invert of blood flow
Q-beam	Turn on Q-beam function
Q-flow	Turn on Q-flow function
Persistence	Adjust the value of persistence
Color Mode	The way of selecting color
Wall Filter	Adjust the wall filter
Density	Change the density
Wall Thre	Adjust wall threshold
Blood Efection	Choose different blood effection
B/BC	turn on B/BC Mode

Shortcut Adjustment:

Shortcut (action)	Menu	Menu Function
SK2 (rotate)	Frequency	Adjust the frequency of probe
SK3 (rotate)	Baseline	Change the baseline of color-map
SK4 (rotate)	PRF	Change the value of PRF
SK5 (rotate)	Steer	Adjust angle of sampling box of blood flow under the linear probe

Other adjustments:

1. CFM gain control.

Rotate C- knob after C lights is on .Adjust the color gain and adjust range is from 0 to 255.

2. Sampling box.

Moves sampling box through trackball to the area which you are interested and press the ENTER-key to confirm the position of sampling box then adjust the size of box trough trackball and press ENTER-key to confirm.

Rotate SK5 to change the steer angel of sampling box under the linear probe.

4.3.23 CPA Mode imaging optimization

Soft menu adjustment:

Menu	Function
Wall Thre.	Adjust wall threshold
Q-beam	Turn on Q-beam function
Q-flow	Turn on Q-flow function
Wall Filter	Adjust the wall filter
Persistence	Adjust the value of persistence
Blood Efection	Choose blood effectiotn
DPD Mode	Exchange between CPA Mode and DPD Mode

Shortcut Adjustment:

Shortcut (action)	Menu	Menu Function
SK2 (rotate)	Frequency	Adjust the probe launch frequency
SK3 (rotate)	PRF	Adjust PRF value
SK4 (rotate)	Steer	Adjust angle of sampling box of blood flow under the linear probe

Other adjustments:

1. CPA gain control

Rotate C knob after CPA light is on then adjust the gain and the range is from 0 to 255.

2. Sampling box.

Moves sampling box through trackball to the area which you are interested and press the ENTER- key to confirm the position of sampling box then adjust the size of box through trackball and press ENTER- key to confirm.

Rotate SK1 to change the steer angle of sampling box under the linear probe.



NOTE: this function can only support linear probe.

4.3.24 Pulse Wave Doppler Imaging Optimization(PWD)

Soft menu adjustment:

Menu	Function
2D Map	Adjust the color of spectrum
Wall Filter	Change Wall Filter
Spectrum Enhance	Adjust the brightness of the spectrum
Dynamic Range	Adjust the dynamic range of the spectrum
Auto Cal Parameter	Set the auto Calc parameters
DTrace Smooth	Adjust the smooth of the trace of the spectrum
Threshold	Adjust the threshold of the spectrum
DVmean	Turn on to display the trace of the Vmean
DVmax	Turn on to display the trace of the Vmax
Trace Area	Set the auto cal range
Layout	1:1,1:2,2:1 can be chosen
Audio	Adjust the audio

Color Map	Change the color map
QuickAngle	Turn on the Quick Angle function
Auto Cal	Turn on Auto Cal function

Shortcut adjustment:

Shortcut (action)	Menu	Menu Function
SK2 (rotate)	Freq.	Adjust the probe launch frequency
SK3 (rotate)	Baseline	Adjust the baseline position
SK4 (rotate)	PRF	Adjust PRF value
SK5 (rotate)	Speed	Adjust scanning speed

Other adjustments:

1. Sampling line

In PW mode, move the trackball left and right to adjust the position of sampling line

2. Sampling gate (Sampling volume)

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

To move Doppler line position, move the Trackball left or right until positioned over the vessel.

To move sample volume gate position, move the Trackball up or down until positioned inside the vessel.

To size sample volume gate, press [Enter] key to toggle Trackball function from sample volume gate positioning to sizing, then move the Trackball to change sample volume gate size.

3. Gain

Rotate PW knob and adjust gain of PWD mode when PW light is on. Gain will be increased if rotate clockwise; Gain will be decreased if rotate anti-clockwise. Adjustable range is from 0 to 255.

4.3.25 Continuous Wave Doppler Imaging Optimization(CW)

Soft menu adjustment:

Menu	Function
2D Map	Adjust the color of spectrum
Spectrum Enhance	Adjust the brightness of the spectrum
Dynamic	Adjust the dynamic range of the CW spectrum
Audio	Adjust from 1% to 100%
Wall Filter	Adjust wall filter
Color Map	Change the color map
QuickAngle	Turn on the Quick Angle function
Layout	Choose from 1:2, 1:1, 2:1

Shortcut adjustment:

Shortcut (action)	Menu	Menu Function
SK2 (rotate)	Baseline	Adjust the baseline position
SK3 (rotate)	PRF	Adjust PRF value
SK4 (rotate)	Speed	Adjust scanning speed

Other adjustments:

1. Sampling line

In PW mode, move the trackball left and right to adjust the position of sampling line

2. Gain

Rotate PW knob and adjust gain of CWD mode when CW light is on. Gain will be increased if rotate clockwise; Gain will be decreased if rotating anti-clockwise. Adjustable range is from 0 to 255.

4.3.26 ECG (option)

The ECG module is a device that provides the 3 lead ECG signal acquisition for cardiac application. It is not intent for the ECG diagnostic purpose as in the 12-lead module. In the cardiac application, the ECG trace is displayed on the bottom of the screen. For echo-stress, the R-wave triggering is used to gate or synchronize the image acquisition. The ECG has 3 leads: LL (left leg, RED), LA (left arm, BLACK), RA (right arm, WHITE). LA is for reference, which usually provides a bias voltage from the ECG module, and the LL, LA are the two signals from the body and going to the differential input of the ECG isolation amplifier.

The ECG control is in the soft-menu available for the cardiac probe, it allows the user to set up the following control:

ECG ON/OFF: turn on/off the ECG trace.

ECG GAIN: increase or decrease the ECG gain.

ECG POS: set the ECG trace position.

ECG Velocity: set the ECG Velocity.

Dynamic Range: adjust dynamic range.

4.3.27 Biopsy and Super needle (option)

1. How to enter into Biopsy

Press the MENU in B mode and choose biopsy to turn on to display biopsy line and verify the biopsy line before biopsy. Press the Biopsy again to turn off the biopsy.

2. How to adjust the biopsy

Press Enter to edit the biopsy line and move the trackball to change the biopsy line position. Press Enter again to fix the biopsy line.

3. Super needle

Super needle is used for enhance the needle image in the B mode image. After turn on the super needle ,super needle and needle angle function will be active and user can adjust the needle angle to optimize the image for needle only (The angle is 5 degree per step.).

4.3.28 Stress Echo (option)

It works with a phased array probe.

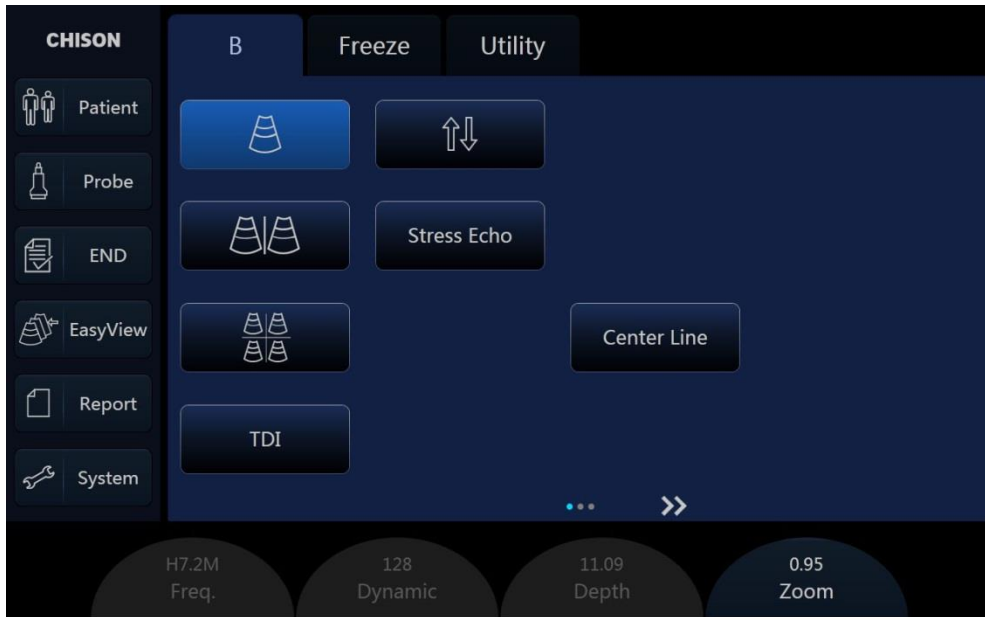


Fig.4-16

Press the Stress Echo button on the touch panel to enter the Stress Echo.

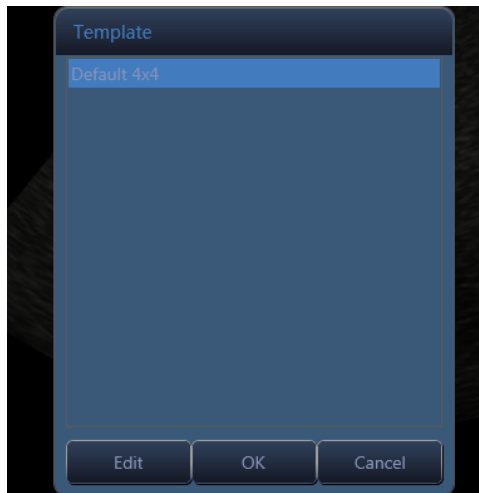


Fig.4-17

When the Stress Echo turns on, select the Default 4x4 template to start the study. User can also open the Timer1 for the study if needed. Save the cine for the study. After finishing the study, press the Analyze on touch panel to enter the Protocol Analyze interface. User can edit the Score for the study.

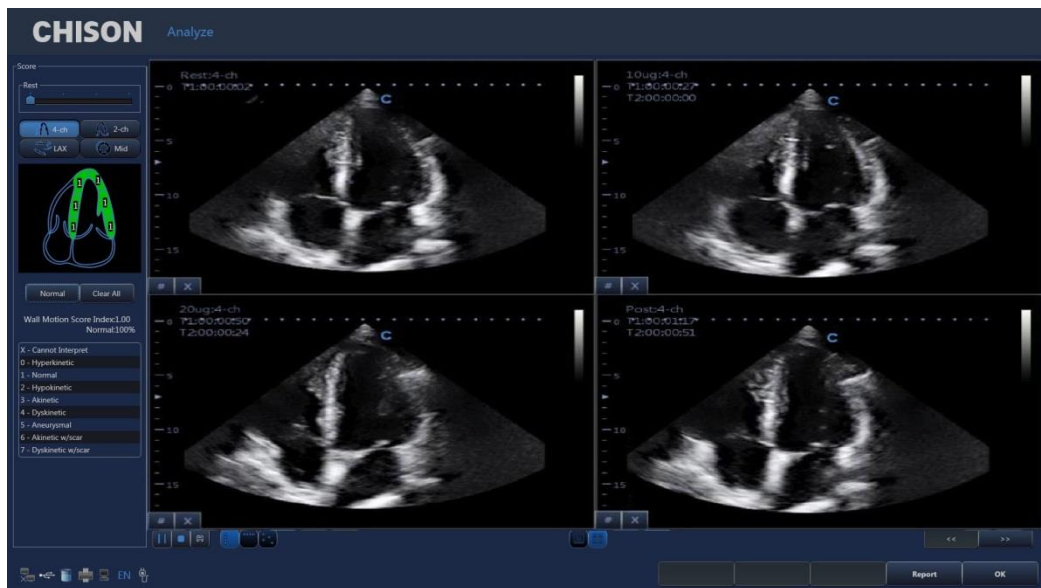


Fig.4-18

Press OK to exit the Protocol Analyze.

User also can edit the Template, define the Number levels and Number projection views.

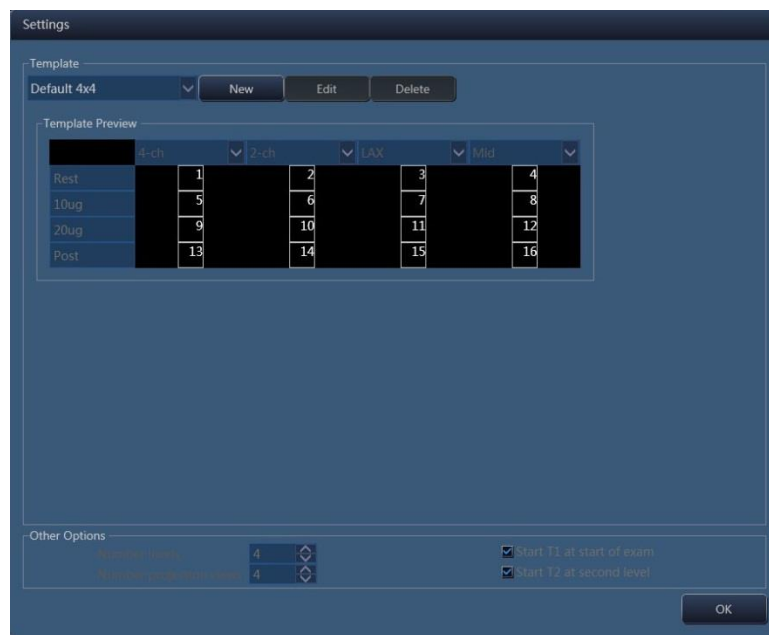


Fig.4-19

4.4 After Capturing the Image

4.4.1 Adding Comments

Comments means input the words or symbols on an ultrasound image to bring attention, notate or communicate information observed during the examination. You can add comments to: zoomed

image, cine review image, real-time image, frozen image. You can input characters as comments; add custom comment bar; insert the pre-defined comments from the comment library.

Input characters

1. Press  key will display “ | ” on the screen, and then system will enter into the comment status.
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  key or EXIT-key to exit.

Add comment form comment library

1. Press  key will display “ | ” on the screen, and then system will enter into the comment status.
2. The comments from the comment library will display on the touch screen.
3. Press the comment that want to be added.
4. Press  key to exit the comment status.

Adjust font size of comments

1. Rotate SK3 in comment status.
2. Move the cursor to the comment note. Press [ENTER] key and adjust the font size of comment note. Press [ENTER] key again to confirm revision.

Adjust position of comments

1. In comments status, moves the cursor to the comment which need to be changed and then press [ENTER] key to select it.
2. Moves the comment to the position wanted to be and press [ENTER] key to confirm.

4.4.2 Adding Body Mark

Operation:

1. Press  key to enter into the body mark status. The body marks will display on the touch

screen.

2. Press the bodymark that want to be added, move trackball after adding the bodymark image and then adjust the position of probe. Rotate SK5 knob to adjust the probe direction. Press ENTER-key to confirm after finishing the adjustment.
3. Press UPDATE-key and move the Trackball to change the position of the body mark.
4. Press Enter- key to confirm when adjustment is finished.
5. If you want to exit the body mark function, press  key or EXIT-key.

Delete comments, body marks and measure tracks

Press  key to delete all comments, arrows, body marks and measure tracks.

4.4.3 Saving Still Images

Save single image: Press  key to save the single image in the real time and frozen statue. The saved thumbnail images will be displayed under the image area for users to playback or post-process quickly.

Re-call single image: Press cursor key in re-call status, then the mouse will appear on the screen. Move the mouse to thumbnail images then click.

4.4.4 Saving Clips

Save forward cine files: Press  key in the real time to save forward cine files.

Save backward cine files: Press  key in frozen statue to save backward cine files.

The saved cine images will be displayed under the image area for users to playback or post-process quickly.

Playback cine files: Press cursor key in recall status, then the mouse will appear on the screen. Move the mouse to the cine thumbnail image then click.



Fig.4-20

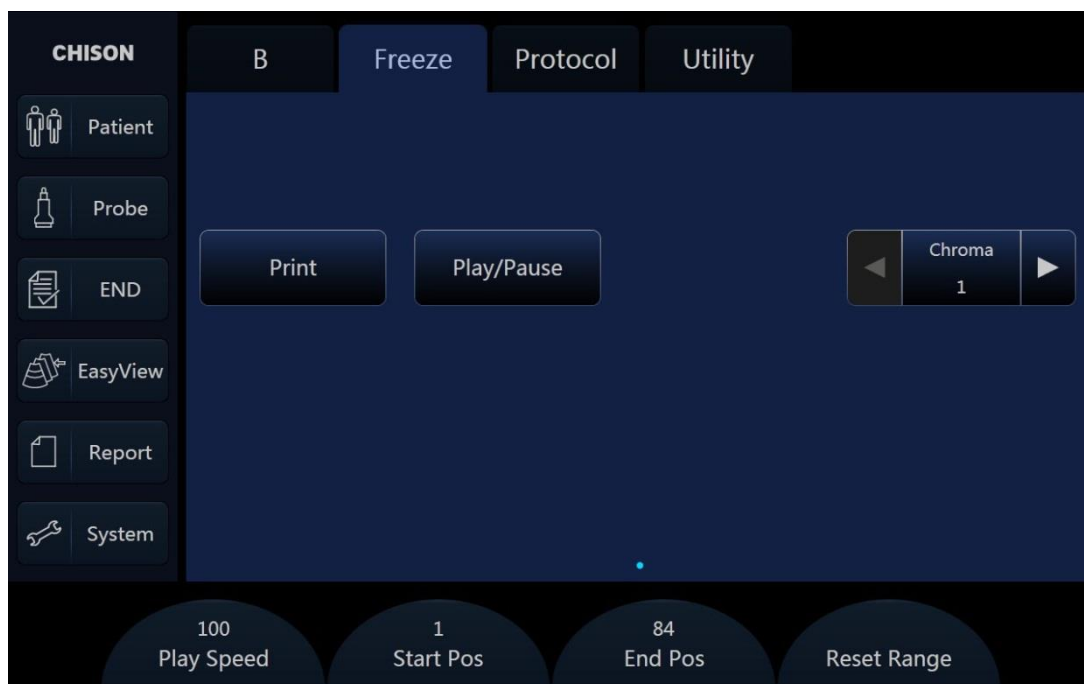


Fig.4-21

Play/Pause: Press this key to Play or Pause cine playback.

Play Speed: Rotate the SK2 knob to adjust the playback speed of cine.

Start Pos: Rotate the SK3 knob to set the frame of start position.

End Pos: Rotate the SK4 knob to set the frame of final position.

Reset Range: Reset the range of cine playback, the default range of playback is 1-maximum frame of current cine.

Manual playback cine: Press cursor key and back to recall status then manual playback through trackball.



NOTE: When you save the still images or cine images, if you do not establish a new patient, the system will establish a new ID according to the current date of the system automatically and save the data and operation under the folder of this ID.

Quick transmission of image:

Image transmission: Press CURSOR key. Choose the image which you want to transfer or delete, and press Update-key. Three icons will display in the thumbnail area.

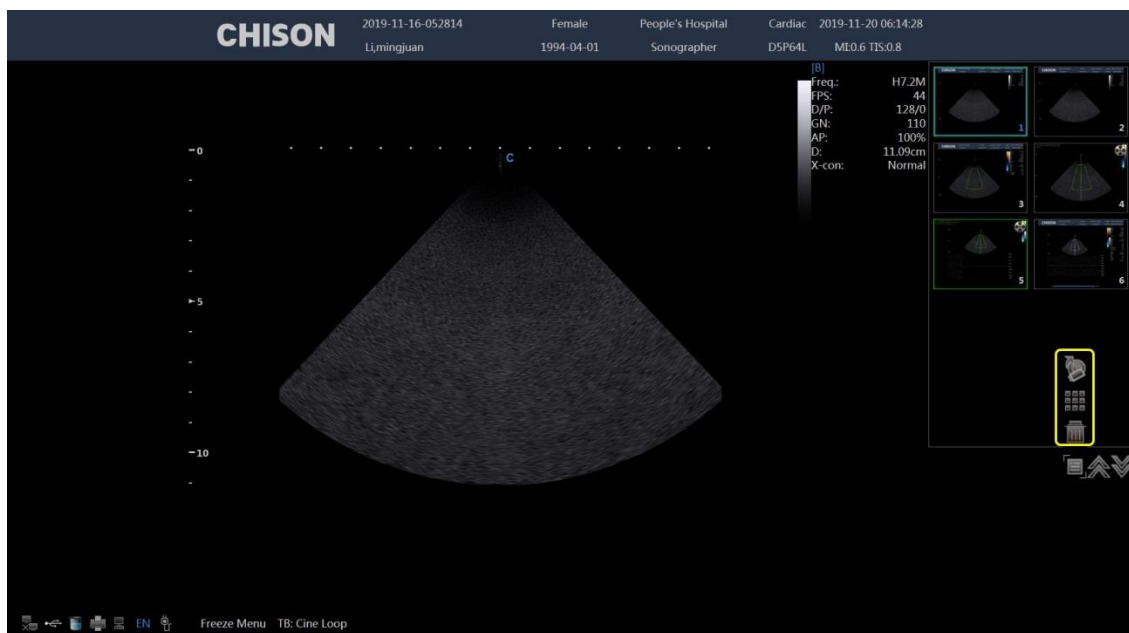


Fig.4-22



Enter into the export interface.



Enter into the EasyView interface.



Delete the file.



4.4.5 Browse Images



Press key to enter into the EasyView interface.

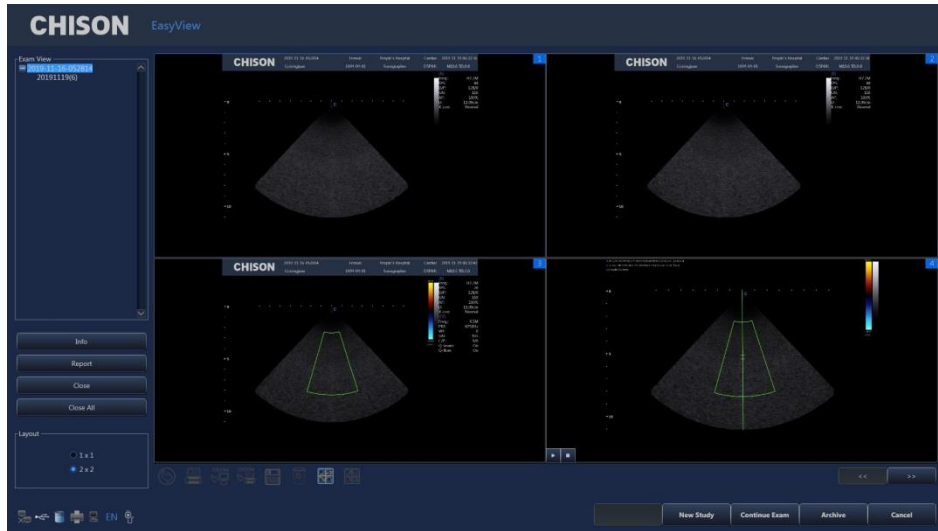


Fig.4-23

Info: press this key can check the information of current patient.

Report: press this key to enter into the report interface.

Close: click this key and choose to close information of patient.

Close all: close all current patients.

New Study: create a new patient, then the system will automatically go to this new page.

Continue/Edit Exam: continue to check the current patient and back to B mode if press this key. If current exam is 48 hours later than last exam, the system will not allow you to continue the exam. The function will be changed to "Edit".

Archive: Pop up Files Management interface. Multiple patients can be compared and browsed.

Cancel: Exit.

4.4.6 Fast Storage

Setting: Enter into System Settings. Press General Menu and choose Normal Sub Menu to do fast storage setting.

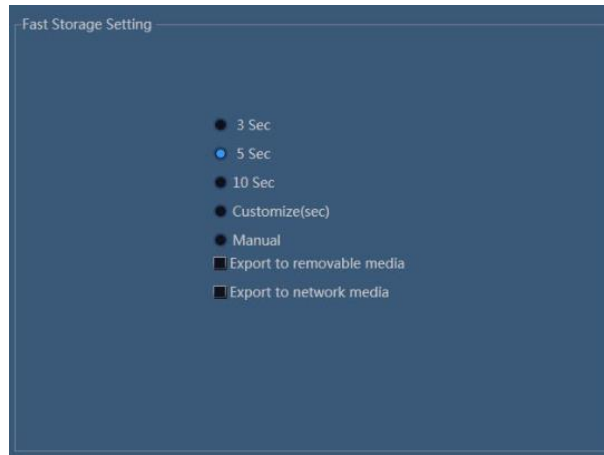


Fig.4-24

After confirming time, back to examination.

For example, choose 5 seconds in the fast storage setting. The system begins to save cine in the

5 seconds after press  .

If you choose Manual in the fast storage setting, you should press  for two times. First time is to start saving and the second time is to finish.

If you choose Export to removable media, it will save the images to the removable media.

4.4.7 Files Management

In this interface you can manage patient's files. Press  key to enter into the EasyView interface. Then click "Archive" to enter into file management interface.

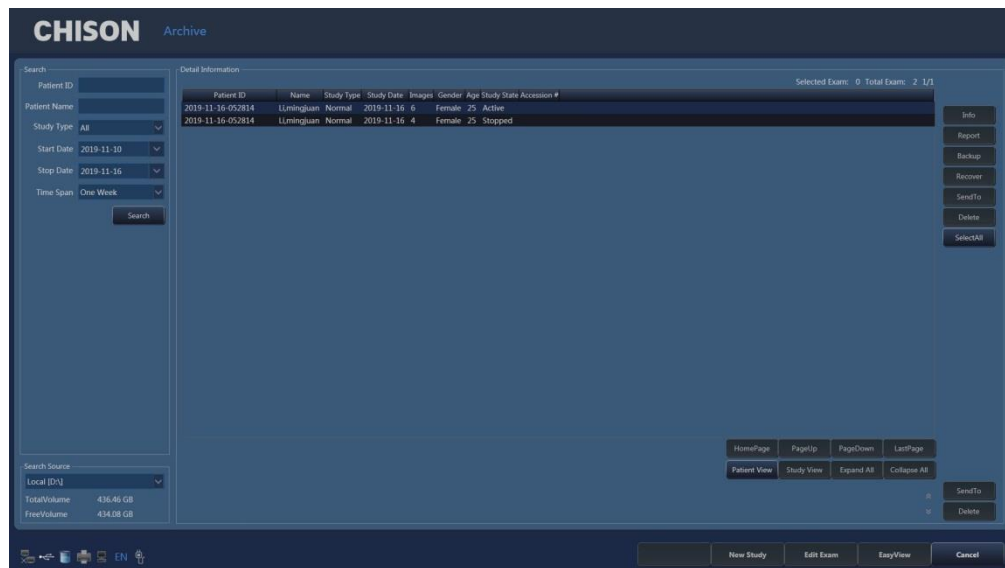


Fig.4-25

Search: Can search the patient files after enter a search term. Search will be more accurate when input more conditions.

Information: View the selected patient information.

Report: select a patient and click this item, patient report information will appear.

Backup: Click this item will store the database of this patient to the portable storage medium

Recover: Click this item can recover the images or video from USB to the system

Send to: Select the content and click, can send files to other medium.

Delete: delete patient's files, images etc.

Select all: Select all patients.

Patient view: Under this view, one patient with multiple inspection data will be listed in column and also you can check each exam file in details.

Study view: This view can list exam types one by one. Different exam type of one patient will not be listed in one column.

New study: Create a new patient and recall into the patient information interface.

Continue Exam: Continue to check the current patient and back to B mode if press this key. If current exam is 24 hours later than last exam, the system will not allow you to continue the exam. The function will be changed to "Edit".

Easy View: Select patient and click it to enter into easy view.

Cancel: Click "Cancel" to exit.

4.4.8 Network Storage Function

Before you use this function, please refer to Section 7.5 to set network storage parameters.

Click  button to enter into the Easy Review interface, select the picture you want to send, click



to enter into the export interface, select the network drive and click "OK" to send.

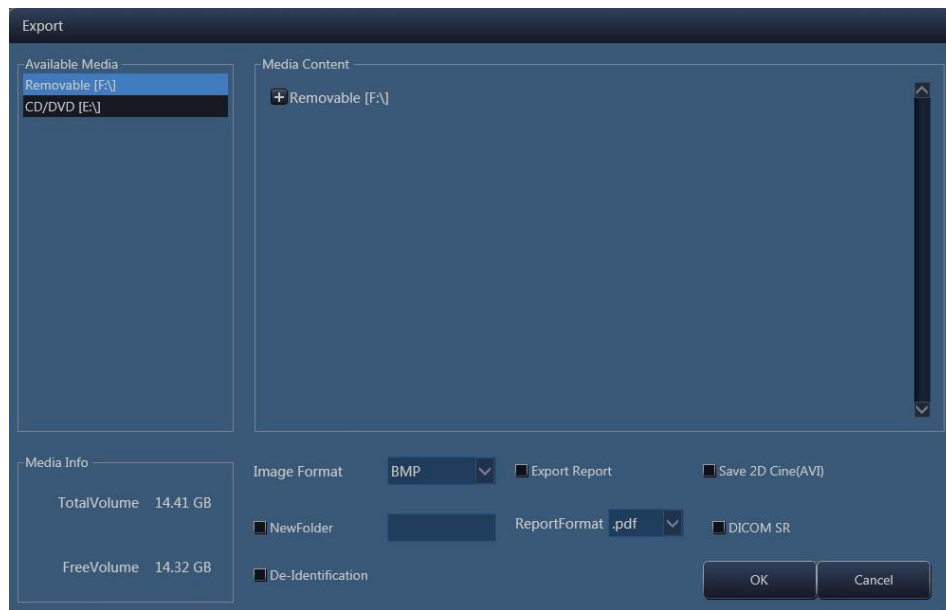


Fig.4-26

After transmitting into the target computer, open the shared folder, you can see the pictures you sent.

4.4.9 DICOM Function (Option)

The system support DICOM storage, DICOM print, MPPS, WORKLIST, DICOM SR storage.

1. Connect the machine into LAN before setting the DICOM
2. Enter into DICOM Setting interface.
3. Press Utility key to enter into system setting interface. Press DICOM page to enter into DICOM interface.



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

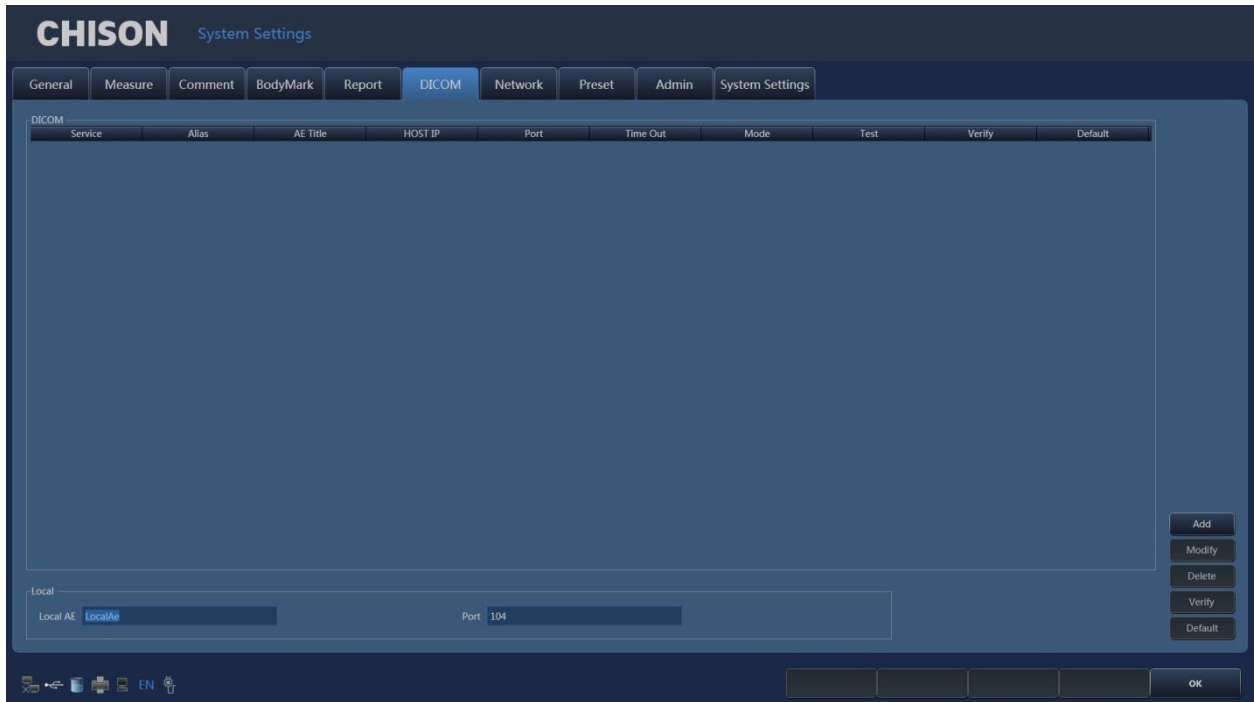


Fig.4- 27

Add: Press this icon to add a DICOM service link

Modify: Select the DICOM link which need to be modified. Press this icon to modify the parameters inside.

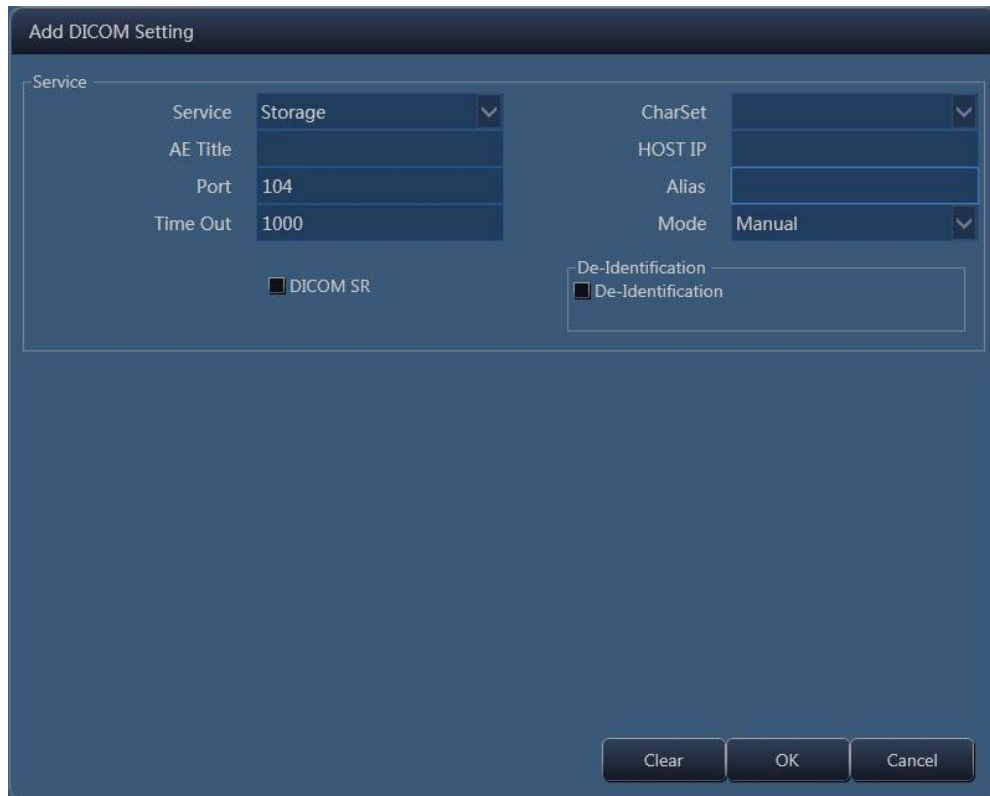
Delete: Select the DICOM link which needs to be deleted. Press this icon to delete the DICOM link.

Verify: Select the DICOM link which need to be verified. Press this icon to verify the current DICOM link status.

Default: If there are several service links of same type, you can select one of them as the default one.

DICOM storage

- DICOM storage parameters setting



The image shows a software dialog box titled "Add DICOM Setting". It contains two columns of settings. The left column includes "Service" (a dropdown menu showing "Storage"), "AE Title" (an empty text field), "Port" (a text field with "104"), and "Time Out" (a text field with "1000"). Below these is a checkbox labeled "DICOM SR". The right column includes "CharSet" (a dropdown menu), "HOST IP" (an empty text field), "Alias" (an empty text field), and "Mode" (a dropdown menu showing "Manual"). Below these is a checkbox labeled "De-Identification". At the bottom right of the dialog are three buttons: "Clear", "OK", and "Cancel".

Fig.4-28

Service: Click the drop list to select storage function.

AE title: Name the server at will.

Host IP: Set the IP of the service host.

Port: Make the port of the work station the same as the port of the server.

Alias: The name of current link.

Time out: time delay.

Mode: batch, follow, manual selectable

Batch: all the saved images in current exam will be sent to the server in one time..

Follow: When one image is saved, the system will send this image to the server.

Manual: The user has to select the image by manual.

After all the settings are completed, please click OK to save current setting. Click clear to clear all the setting. Clicking cancel will not save the current setting.

- DICOM storage

Batch mode: In batch mode, when the patient finishes his exam, press End key to end the current exam. All the saved images will be saved as DCM format and sent to the server automatically.

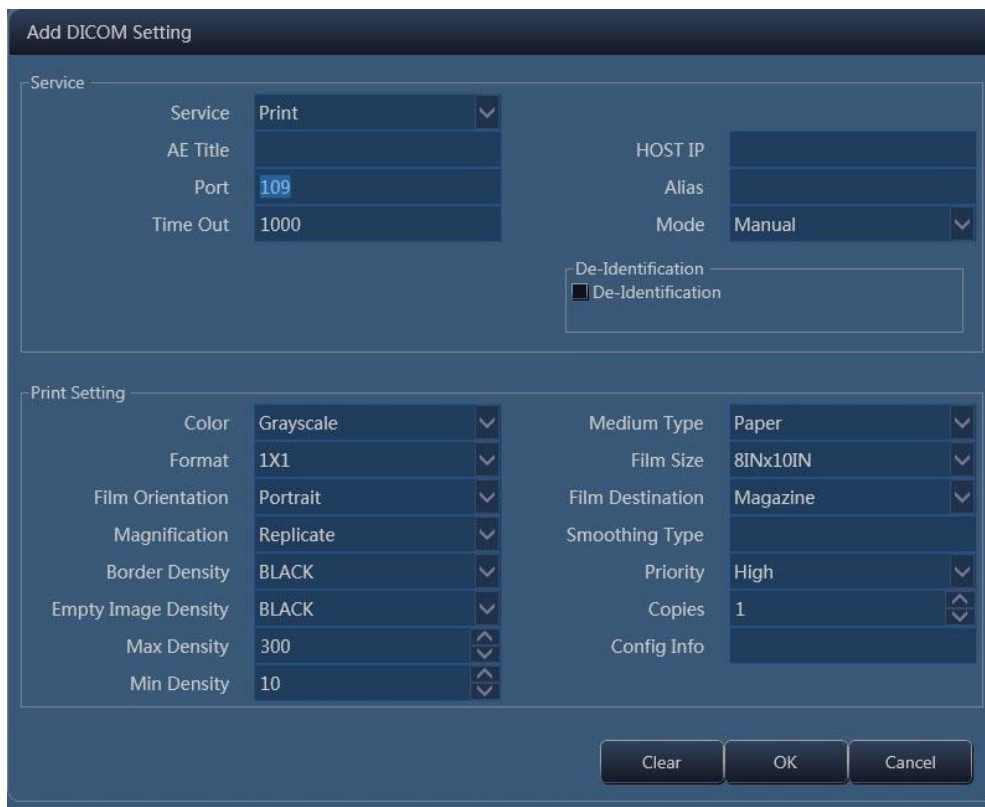
Follow: In follow mode, during the exam, press  key to save the image. The current image will be saved as DCM format and sent to the server.

Manual: In manual mode, the user has to select the image by manual and do DICOM transfer.

Press  key to enter into review interface. Select the images need to be sent, press  key to send.

DICOM print

- DICOM print parameters setting.



Add DICOM Setting	
Service	
Service	Print
AE Title	
Port	109
Time Out	1000
HOST IP	
Alias	
Mode	Manual
De-Identification	
☐ De-Identification	
Print Setting	
Color	Grayscale
Format	1X1
Film Orientation	Portrait
Magnification	Replicate
Border Density	BLACK
Empty Image Density	BLACK
Max Density	300
Min Density	10
Medium Type	Paper
Film Size	8INx10IN
Film Destination	Magazine
Smoothing Type	
Priority	High
Copies	1
Config Info	
Clear OK Cancel	

Fig.4-29

Service: Click the drop list to select print function.

AE title: Name the server at will.

Host IP: Set the IP of the server.

Port: Make the port of the work station the same as the port of the server.

Alias: The name of current link.

Time out: time delay.

Mode: batch, follow, manual selectable.

Batch: all the saved images in current exam will be sent to the server and printed automatically in one time.

Follow: When one image is saved, the system will send this image to the server and print it.

Manual: The user has to select the image by manual and print it.

After all the settings are completed, please click OK to save current setting. Click clear to clear all the setting. Clicking cancel will not save the current setting.

- DICOM print

Batch mode: In batch mode, when the patient finishes his exam, press End key to end the current exam. All the saved images will be saved as DCM format and sent to the server automatically to be printed.

Follow: In follow mode, during the exam, press save key to save the image. The current image will be saved as DCM format and sent to the server to be printed.

Manual: In manual mode, the user has to select the image by manual and do DICOM transfer.

Press browse key to enter into review interface. Select the images need to be sent, click icon to print.



DICOM Worklist

- DICOM Worklist parameters setting.

Add DICOM Setting

Service

Service: Worklist

CharSet:

AE Title:

HOST IP:

Port: 107

Alias:

Time Out: 1000

Update Method

☒ Only on user request

☐ On Startup and Every 5 Min

Scheduled Station AE Title

☒ Any

☐ This System

☐ Another

Start Date

Today

Clear OK Cancel

Fig.4-30

Service: Click the drop list to select worklist function.

AE title: Name the server at will.

Host IP: Set the IP of the server.

Port: Make the port of the work station the same as the port of the server.

Alias: The name of current link.

Time out: time delay.

For “Update Method” parameter group, the worklist update can only started by user request for “Only on user request”, or user can set N(1~60) minutes to update worklist automatically for “On Startup and Every X minutes”.

For “Scheduled Station AE Title” parameter group, the schedule station AE title, which is one of a matching key, will be set to blank for “Any”, “LocalAE” for “This System” or user customized string for “Another”. And only the matched items will be queried for each worklist update.

For “Start Date” parameter group, it is the matching key for “Scheduled Procedure Step Start Date”, and there are five “Start Date” types to select.

- DICOM Worklist

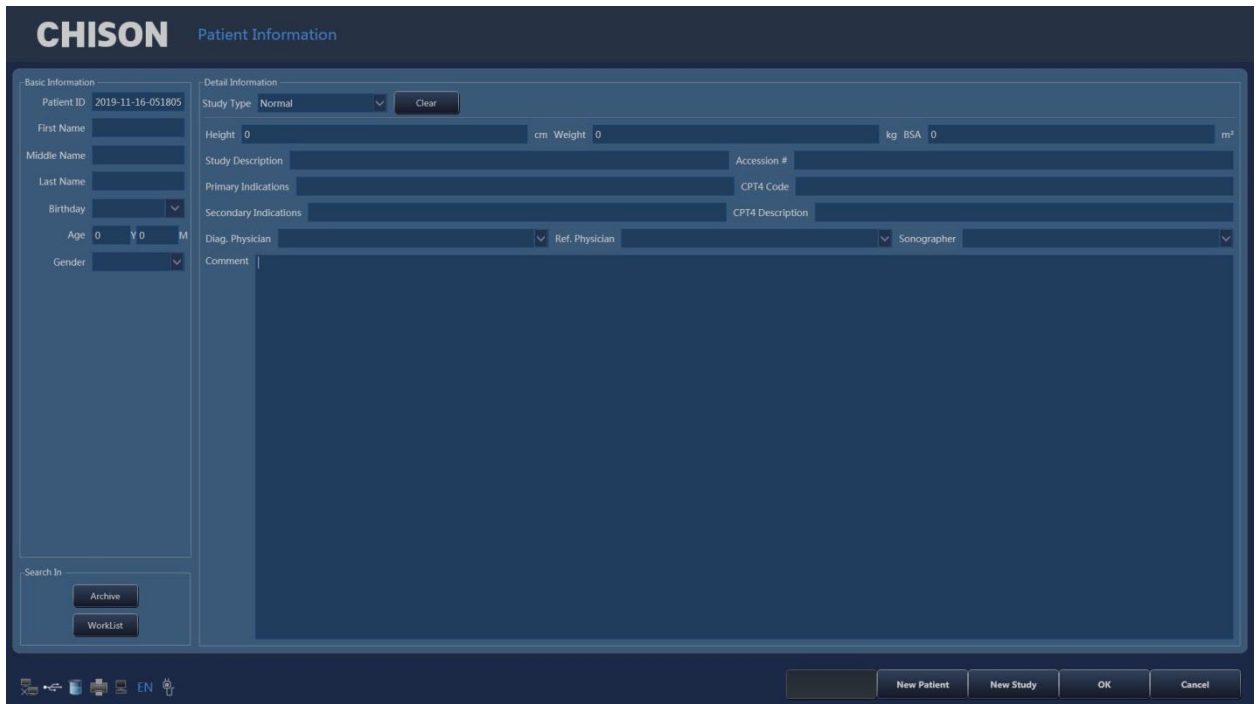
The image shows a software interface for patient information entry. The title bar at the top left says "CHISON" in large white letters, followed by "Patient Information" in smaller white text. The interface is divided into two main sections: "Basic Information" on the left and "Detail Information" on the right. The "Basic Information" section includes fields for Patient ID (2019-11-16-051805), First Name, Middle Name, Last Name, Birthdate (with a dropdown arrow), Age (0, Y 0, M), and Gender (with a dropdown arrow). Below these is a "Search In" section with "Archive" and "WorkList" buttons. The "Detail Information" section includes a "Study Type" dropdown (Normal) and a "Clear" button. It also has fields for Height (0 cm), Weight (0 kg), BSA (0 m²), Study Description, Accession #, Primary Indications, CPT4 Code, Secondary Indications, CPT4 Description, Diag. Physician, Ref. Physician, and Sonographer (all with dropdown arrows). A large "Comment" text area is at the bottom of the detail section. At the very bottom of the interface, there are icons for various functions and a row of buttons: "New Patient", "New Study", "OK", and "Cancel".

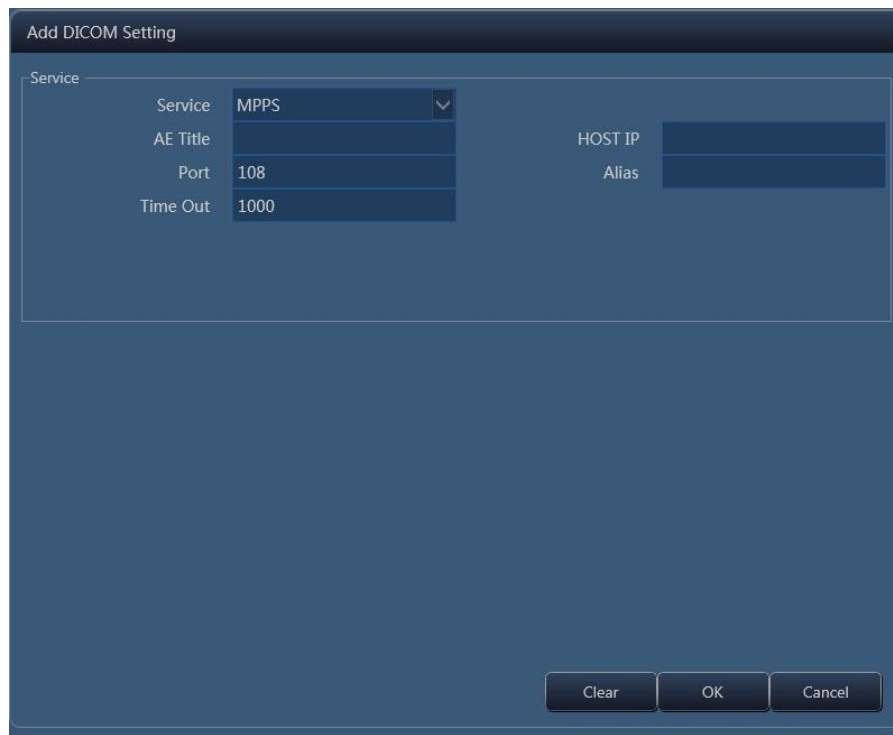
Fig.4-31

Press the keyboard button shaped as “”, and press “Worklist”.

Press “Search” to start a worklist update by the matching key specified in Worklist Configuration, all the matched items will be queried in worklist table. User also can add additional for matching keys, which are “PatientID”, “PatientName”, “Accession#” and “ProcedureId”, for a more precise query.

Select one matched item and press “Apply” for the current exam application. At this moment, a MPPS service will be started which will be introduced in MPPS section.

DICOM MPPS



The image shows a software dialog box titled "Add DICOM Setting". It contains several input fields for configuring a DICOM service. On the left, under the "Service" label, there is a dropdown menu currently showing "MPPS", and below it are text boxes for "AE Title", "Port" (containing "108"), and "Time Out" (containing "1000"). On the right, there are text boxes for "HOST IP" and "Alias". At the bottom right of the dialog are three buttons: "Clear", "OK", and "Cancel".

Field	Value
Service	MPPS
AE Title	
Port	108
Time Out	1000
HOST IP	
Alias	

Fig.4-32

Service: Click the drop list to select MPPS function.

AE title: Name the server at will

Host IP: Set the IP of the server

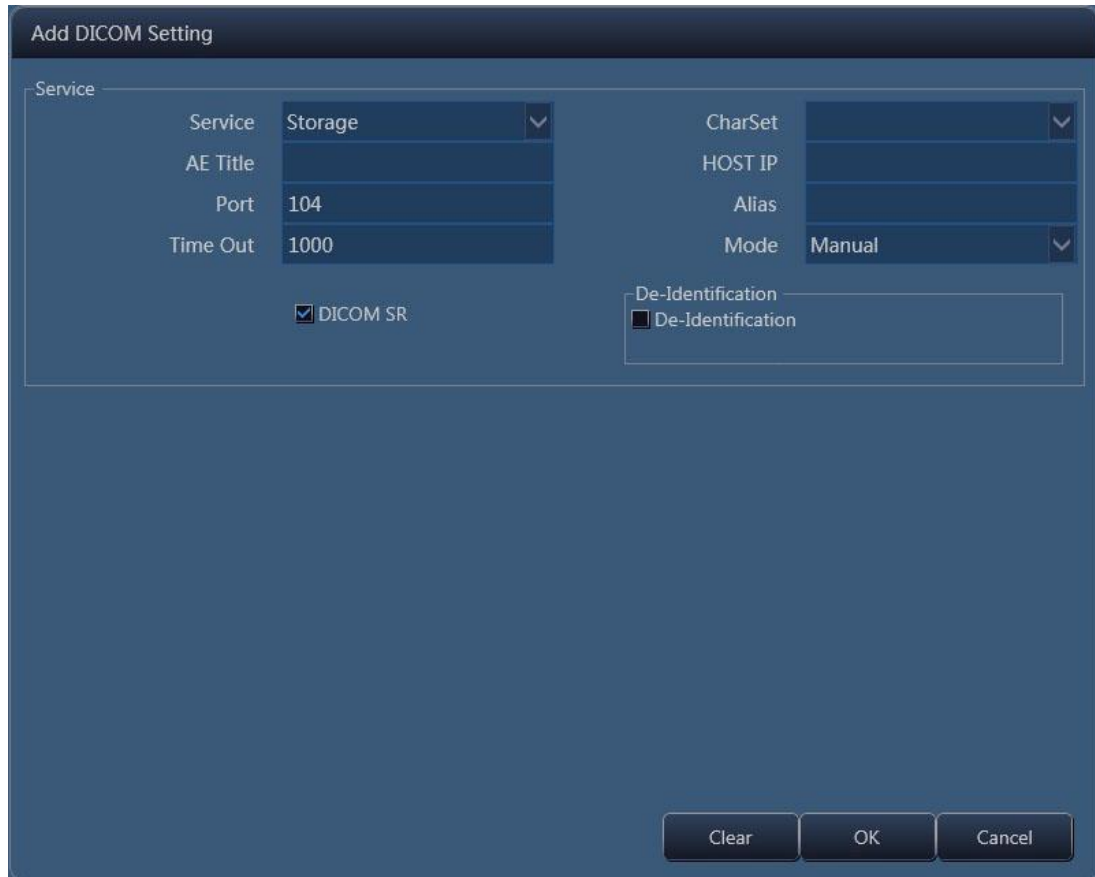
Port: Make the port of the work station the same as the port of the server.

Alias: The name of current link

Time out: time delay

Applying the selected worklist item will result in automated creation of an MPPS instance.

DICOM SR Storage



The image shows a software dialog box titled "Add DICOM Setting". It contains two columns of settings. The left column includes "Service" (a dropdown menu set to "Storage"), "AE Title" (an empty text field), "Port" (a text field with "104"), and "Time Out" (a text field with "1000"). Below these is a checked checkbox labeled "DICOM SR". The right column includes "CharSet" (a dropdown menu), "HOST IP" (an empty text field), "Alias" (an empty text field), and "Mode" (a dropdown menu set to "Manual"). Below these is a "De-Identification" section with an unchecked checkbox labeled "De-Identification". At the bottom right of the dialog are three buttons: "Clear", "OK", and "Cancel".

Fig.4-33

Service: Click the drop list to select Storage function. Select the DICOM SR which below the Time Out item.

AE title: Name the server at will.

Host: Set the IP of the server.

Port: Make the port of the work station the same as the port of the server.

Alias: The name of current link.

Time out: time delay.

Only OB/GYN and Cardiac report support this server.

After finishing OB/GYN or Cardiac measurements, press report key to create report for current exam. When the patient finishes his exam, press End key to end the current exam, the SR report will be sent to the server automatically.

Chapter 5 General Measurements

Introduction

Measurements and calculations derived from ultrasound images are intended to supplement other clinical procedures available to the physician. The accuracy of measurements is not only determined by system accuracy, but also by the use of proper medical protocols by the operator. When appropriate, make sure to note any protocol associated with a particular measurement or calculation.



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

Overview

This section provides information about taking measurements and describing calculations available in each mode. It includes the following topics:

- List of generic measurements.
- Mode Measurements: Step-by-step instructions for taking specific measurements, organized by mode.
- Measurement results display and erasing.

5.1 Key for Measurement

◆ Trackball

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

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

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

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

◆ 【ENTER】

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

When cursor is on the menu, press the key to choose the options and start the measurement.

During the measurement, press the key to anchor the start point and end point.

◆ 【CLEAR】

Main functions are as follows:

In frozen status, press the  key, delete all the measurement results, comments and traces.

◆ 【UPDATE】

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.

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.

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.

5.2 Fast measurement

The system use Dist, Trace, SK2~SK4 to make fast measurement. Users can choose the measurement items on the touch screen.

5.2.1 Enter fast measurement

Press Dist or Trace to enter fast measurement.

Dist: distance measurement.

Trace: Area measurement.

5.2.2 Exit fast measurement

During measurement, press the Dist key for second time, or press Trace-key or Exit-key.

5.2.3 Fast measurement in B mode

Distance

1. In B Cine mode, press the DIST-key to bring up the first white plus sign (“+”) cursor.
2. Use the Trackball and the ENTER-key to anchor the start point of the desired distance to be measured.
3. Move the Trackball and a second white plus sign cursor will automatically appear. Move the second cursor to the specified position. With the movement of cursor the system will update the measurement distance in real time in Result Window on the right side of the screen.
4. Press the ENTER-key to fix the second cursor, the first measurement result will appear on the screen.
5. When two points have been defined, a white plus sign cursor of next distance pair will pop out. Repeat the same steps to create other distance pairs.
6. Press the DIST-key or EXIT-key to exit.

Area - trace

1. In B mode, press the TRACE-key to bring up the trace start cursor plus sign (“+”).
2. Use the trackball to move the cursor, press ENTER-key to set the start point.
3. Use the Trackball to trace the perimeter of the object to be measured, and press the Enter-key to set the end point. The end point and the starting point of the trace will be automatically connected with a straight line. The area and the Circumference of the shape will be calculated. With the movement of the cursor, the result will appear on the right side of the screen, and will change along with the moving of the trace.
4. To get the multiple data, repeat the same steps to create other distance pairs.
5. Press the Trace-key or EXIT-key to exit.

Area - ellipse

1. In B mode, press the TRACE-key to bring up the trace start cursor plus sign (“+”).
2. Press Area Auto on the touch screen.

3. Move the Trackball and press ENTER-key to set start point
4. The second point marker is displayed by a line connecting the first and second points. Use the Trackball to lengthen the line in order to change the diameter and press the ENTER-key to fix the length.
5. Use the Trackball to change the length of another axis. Press the ENTER-key to fix the length. The total area and circumference will be displayed in the result window.
6. To get the multiple data, repeat the same steps to create other distance pairs.
7. Press the Trace-key or EXIT-key to exit.

Volume - 1Dis1Ellip

1. In B mode, press the DIST-key or trace-key to enter the measurement mode.
2. Press Volume on the touch screen and choose 1Dis1Ellip.

Volume - 3 Dis

1. In B Cine mode, press the DIST-key or trace-key to enter the measurement mode.
2. Press Volume on the touch screen and choose 3Dis.

5.2.4 Fast measurement in PW mode

Peak

1. In PW Cine mode, press the Dist-key to bring up the sample marker.
2. Press Peak on the touch screen.
3. Move the marker to the measurement start point with the Trackball, press Enter key, velocity and pressure of the current point will appear on the screen automatically.
4. Go on to measure Vd, after getting the result, the system will calculate S/D, RI, heart rate automatically.

Automatic envelope measurement

1. In PW mode, press the Trace-key to enter automatic envelope measurement. The system will

- finish the envelope of spectrum automatically. The cursor“+”will appear on the screen.
2. Move the trackball to choose a start point of one cycle, press the Enter-key to confirm.
 3. The second cursor“+”will appear on the screen automatically, move the trackball to the end point of current cycle, and press the ENTER-key to set.
 4. The measurement result and the other calculated parameters will appear on the screen automatically.
 5. If the spectrum automatic envelop is not accurate, rotate SK4 and reselect cycle to correct.

Manual envelope

1. In PW Cine mode, press the Trace-key to enter automatic envelope measurement.
2. Press Manual on the touch screen.
3. Move the trackball to choose a start point of one cycle, press the Enter-key to confirm.
4. Move the trackball to trace the spectrum, press the ENTER-key to finish the envelope.
5. The measurement results and the other calculated results will appear on the screen automatically.
6. If the spectrum manual envelop is not accurate, rotate SK5 and restart to manual envelop.

5.2.5 Fast measurement in M mode

M Distance

1. In M mode, press the DIST-key to enter M distance measurement. The cursor“+” on a line will appear on the screen.
2. Move the trackball to move the cursor and the line, press ENTER-key to fix it.
3. One dotted line and second cursor will appear on the screen..
4. Move the cursor by moving the trackball to the end point in the dotted line vertically, press the Enter-key to confirm.
5. The measurement result will appear on the screen automatically.

M Time

1. In M Cine mode, press the DIST-key or TRACE-key to enter M fast measurement. The cursor“+” on a line will appear on the screen.
2. Press MTime on the touch screen.
3. Move the trackball to move the cursor, press Enter-key to fix it.
4. One dotted line and second cursor on a line will appear.
5. Move the trackball and press the Enter-key to fix the cursor.
6. The measurement result will appear on the screen automatically.

M Speed

1. In M Cine mode, press the DIST-key or TRACE-key to enter M fast measurement. The cursor“+” on a line will appear on the screen.
2. Press M Speed on the touch screen.
3. Move the trackball to move the cursor, press Enter-key to fix it.
4. One dotted line and second cursor on a line will appear.
5. Move the trackball and press the Enter-key to fix the cursor.
6. The measurement result will appear on the screen automatically.

5.3 Measurement and Calculation

There are Corresponding measurement menu in different modes. Press Calc-key to recall the measurement menu.

Press Change-key to do exchange during the measurements menus of different modes. Press Exit key to close the measurement menu.

Move the trackball to select the measurement item on the measurement menu and do the measurement in the image.

After finishing the measurement, press Report-key to generate the report template to view the measurement results or print the report.

5.3.1 Measurement in B mode

Press Calc-Key to enter into measurement package menu. Press Change-Key to change measurement package.

5.3.1.1 General Measurement in B mode



Fig.5- 1

1. Distance

- 1) Move the trackball to move the cursor to the “distance” item. Press Enter-key to select it and a mark “+” will appear on the screen
- 2) Move the trackball to anchor the first mark and press Enter-key to set it.
- 3) The second mark will appear on the screen. Move the trackball to place the mark to the aimed place. The value of the measurement will be displayed on the right side of the screen and will be changed along with the trace of the measurement.
- 4) Press Enter-key to fix the second mark and the measurement results will be fixed and displayed on the screen.
- 5) To get the multiple data, repeat the same steps to create other distance pairs.
- 6) Press Calc-key or Exit-key to exit.

2. Length_Area(Ellipse)

- 1) Rotate the trackball to move the cursor to the “Area (ellipse)” item. Press Enter-key to select it. At this time, a mark “+” will appear on the screen.

- 2) Rotate the trackball to anchor the first mark and press Enter-key to fix it.
- 3) The second mark will appear on the screen. Rotate the trackball to change the length of the long axis of the ellipse. Press Enter-key to confirm the length.
- 4) Rotate the trackball to change the length of another axis of the ellipse and press Enter-key to fix it. The value of the area and perimeter will be displayed on the right side of the screen.
- 5) To get the multiple data, repeat the same steps to create other distance pairs.
- 6) Press Calc-key or Exit key to exit.

3. Length_Area(Trace)

- 1) Rotate the trackball to move the cursor to the "Area (trace)" item. Press Enter-key to select it. At this time, a mark "+" will appear on the screen.
- 2) Move the trackball to move the mark to the start point of the measurement. Press Enter-key to confirm.
- 3) Rotate the trackball to trace the edge of the aimed object and press Enter-key to fix the end point. The second mark will appear on the screen. Rotate the trackball to place the mark to the aimed place. The value of the measurement will be displayed on the right side of the screen and will be changed along with the moving of the measurement.
- 4) To get the multiple data, repeat the same steps to create other distance pairs.
- 5) Press Calc-key or Exit key to exit.

4. Volume(1distance)

Calculate the volume of the object by one line.

$$\text{Volume} = \text{distance} \times \text{distance} \times \text{distance} \times 3.1415926 / 6$$

5. Volume (1ellipse)

Through 1 ellipse measurement, calculate the volume of the object.

$$\text{Volume} = \text{axis A} \times \text{Axis B} \times \text{axis B} \times 3.1415926 / 6$$

6. Volume(2distance)

Through 2 distance measurement, calculate the volume object.

$$\text{Volume} = \text{distance1} \times \text{distance2} \times \text{distance2} \times 3.1415926 / 6 \quad (\text{distance1} > \text{distance2})$$

$$\text{Volume} = \text{distance2} \times \text{distance1} \times \text{distance1} \times 3.1415926 / 6 \quad (\text{distance2} > \text{distance1})$$

7. Volume(3 distance)

Through 3 distance measurement, calculate the volume of object

$$\text{Volume} = \text{distance1} \times \text{distance2} \times \text{distance3} \times 3.1415926/6$$

8. Volume(1distance1ellipse)

Through 1distance measurement and 1 ellipse measurement, calculate the volume of object.

$$\text{Volume} = \text{distance} \times \text{axis A} \times \text{axis B} \times 3.1415926/6$$

9. Volume(2 ellipse)

Through 2 ellipse measurement, calculate the volume of the object.

$$\text{Volume} = d1 \times d2 \times d4 \times 3.1415926/6$$

d1 and d2 are axis of ellipse1; d3 and d4 are axis of ellipse 2: $|d2 - d3| \leq |d1 - d4|$, $d2 > d3$

10. Ratio

Through 2 distance measurement, calculate the ratio of the 2 distance

$$\text{Ratio} = \text{distance1} / \text{distance2}$$

11. Angle

1) Rotate the trackball to move the cursor to the "Angle" item. Press Enter-key to select it and d1 line will appear on the screen.

2) Rotate the trackball to move d1 and rotate the Angle button to adjust the direction of the line ,then press Enter-key to fix it.

3) Fix other 2 lines of d2 and d3 as step2).

4) After finishing the measurement, the result of the angles named α and β will be displayed on the left side of the screen. α is the angle between line d1 and line d2. β is the angle between line D1 and D3.

5) Press Calc-key or Exit key to exit.

12. Strain Ratio

Calculate the ratio between Strain A and Strain B.

13. HR Manual

Select this item to input Heart rate manually.

5.3.1.2 Cardiology Measurement in B mode

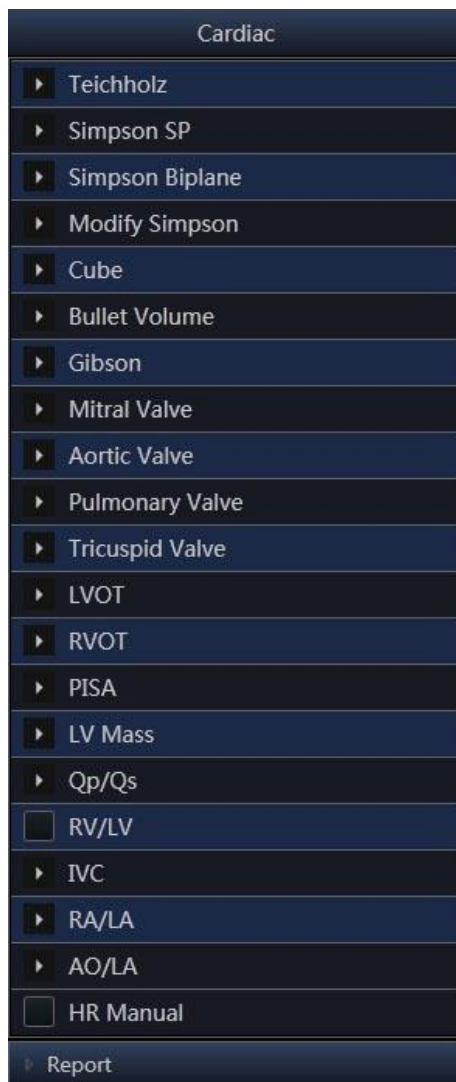


Fig.5-2

1. Teichholz

Calculation formula for volume

$$EDV = \frac{7 \times LVIDd^3}{2.4 + LVIDd}$$

$$ESV = \frac{7 \times LVIDs^3}{2.4 + LVIDs}$$

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVIDd [cm]	Left ventricular internal diameter at end diastole	Line
LVIDs [cm]	Left ventricular internal diameter at end systole	Line

<< Items to be calculated >>

Calc. item	Description	Calc. formula
EDV [ml]	End-diastolic left ventricular Volume	Please refer to <<Calculation formula for volume>>
ESV [ml]	End-systolic left ventricular Volume	Please refer to <<Calculation formula for volume>>
SV [ml]	Stroke Volume	SV=EDV – ESV
CO [l/min]	Cardiac Output	CO=SV*HR/1000
EF [%]	Ejection Fraction	EF=SV/EDV
FS [%]	Fractional Shortening	FS=(LVIDd-LVIDs)/LVIDd
SI	Stroke Volume Index	SI=SV/BSA
CI	Cardiac Output Index	CI=CO/BSA

2. Simpson SP

This method calculates the left ventricular volumes by using the 2D mode long-axis image. When the left ventricle is traced and its long axis is specified on a 2D mode cross-sectional image, this method allows the system to automatically divide the long axis into 20 segments to calculate the volume of the left ventricle as the 2D mode cross-sectional image is rotated.

Calculation formula for volume

$$EDV = \pi \times \frac{LVLd}{20} \times \sum_{i=1}^{20} r_i^2$$

$$ESV = \pi \times \frac{LVLs}{20} \times \sum_{i=1}^{20} r_i^2$$

ri: Radius of the i-th circle

LVLd: Left ventricular long-axis diameter at end diastole

LVLs: Left ventricular long-axis diameter at end systole

<<Items to be measured>>

Meas. item	Description	Meas. Tool
EDV(A4C) [ml]	End-diastolic volume (A4C)	Measurement (trace)
ESV(A4C) [ml]	End-systolic volume (A4C)	Measurement (trace)

<< Items to be calculated >>

Calc. item	Description	Calc. formula
EDV [ml]	End-diastolic left ventricular Volume	Please refer to <<Calculation formula for volume>>
ESV [ml]	End-systolic left ventricular Volume	Please refer to <<Calculation formula for volume>>
SV [ml]	Stroke Volume	$SV = EDV - ESV$
CO [l/min]	Cardiac Output	$CO = SV \times HR / 1000$
EF [%]	Ejection Fraction	$EF = SV / EDV$
SI	Stroke Volume Index	$SI = SV / BSA$
CI	Cardiac Output Index	$CI = CO / BSA$

3. Simpson Biplane

This method allows the volume of the left ventricle to be calculated by repeating “Simpson SP method” on two 2D mode cross-sectional images (two-chamber and four-chamber cross-sectional images).

Calculation is also possible for only two-chamber cross-sectional images or only four-chamber cross-sectional images.

Calculation formula for volume

$$EDV (A2C) = \pi \times \frac{LVLd_2}{20} \times \sum_{i=1}^{20} r_{2i}^2$$

$$ESV (A2C) = \pi \times \frac{LVLs_2}{20} \times \sum_{i=1}^{20} r_{2i}^2$$

r_{2i}:Radius of i-th ellipse for 2CH

LVLd₂: Length of the left-ventricular long axis at end diastole for 2CH.

LVLs₂: Length of the left-ventricular long axis at end systole for 2CH .

$$EDV (A4C) = \pi \times \frac{LVLd_4}{20} \times \sum_{i=1}^{20} r_{4i}^2$$

$$ESV (A4C) = \pi \times \frac{LVLs_4}{20} \times \sum_{i=1}^{20} r_{4i}^2$$

r_{4i}:Radius of i-th ellipse for 4CH

LVLd₄: Length of the left-ventricular long axis at end diastole for 4CH.

LVLs₄: Length of the left-ventricular long axis at end systole for 4CH .

$$EDV = \pi \times \frac{MAX \{LVLd_2, LVLd_4\}}{20} \times \sum_{i=1}^{20} (r_{2i} \times r_{4i})$$

$$ESV = \pi \times \frac{MAX \{LVLs_2, LVLs_4\}}{20} \times \sum_{i=1}^{20} (r_{2i} \times r_{4i})$$

<<Items to be measured>>

Meas. item	Description	Meas. Tool
EDV(A2C) [ml]	End-diastolic volume (A2C)	Measurement (trace)
ESV(A2C) [ml]	End-systolic volume (A2C)	Measurement (trace)
EDV(A4C) [ml]	End-diastolic volume (A4C)	Measurement (trace)

ESV(A4C) [ml]	End-systolic volume (A4C)	Measurement (trace)
---------------	---------------------------	---------------------

<< Items to be calculated >>

Calc. item	Description	Calc. formula
EDV[ml]	End-diastolic left ventricular volume	Please refer to <<Calculation formula for volume>>
ESV[ml]	End-systolic left ventricular volume	Please refer to <<Calculation formula for volume>>
SV [ml]	Stroke Volume	SV=EDV – ESV
CO [l/min]	Cardiac Output	CO=SV*HR/1000
EF [%]	Ejection Fraction	EF=SV/EDV
SI	Stroke Volume Index	SI=SV/BSA
CI	Cardiac Output Index	CI=CO/BSA

4. Modify Simpson

This method calculates the left ventricular using the 2-D mode long-axis image, the short-axis image at the level of the mitral valve, and the short-axis image at the level of the papillary muscle.

Calculation formula for volume:

$$EDV = \frac{LVLd}{9} \times (4 \times LVAMd + 2 \times LVAPd + \sqrt{LVAMd \times LVAPd})$$

$$ESV = \frac{LVLs}{9} \times (4 \times LVAMs + 2 \times LVAPs + \sqrt{LVAMs \times LVAPs})$$

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVLd[cm]	Left ventricular long-axis length at end diastole	Refer to "Distance Measurement (Distance)"
LVLs[cm]	Left ventricular long-axis length at end	Refer to "Distance

	systole	Measurement (Distance)"
LVAMd[cm ²]	Left ventricular short-axis area at the level of the mitral valve at end diastole	Refer to "Area/Circumference Measurement (Area)"
LVAMs [cm ²]	Left ventricular short-axis area at the level of the mitral valve at end systole	Refer to "Area/Circumference Measurement (Area)"
LVAPd [cm ²]	Left ventricular long-axis area at the level of the papillary muscle at end diastole	Refer to "Area/Circumference Measurement (Area)".
LVAPs[cm ²]	Left ventricular long-axis area at the level of the papillary muscle at end systole	Refer to "Area/Circumference Measurement (Area)".

<<Items to be calculated>>

Calc. item	Description	Calc. formula
EDV [ml]	End-diastolic left ventricular volume	Refer to << Calculation formula for volume>>
ESV[ml]	End-systolic left ventricular volume	Refer to << Calculation formula for volume>>
SV [ml]	Stroke volume	SV=EDV – ESV
CO [L/min]	Cardiac output	CO=SV x HR /1000
EF	Ejection fraction	EF=SV/ EDV
SI	Stroke Volume Index	SI=SV/BSA
CI	Cardiac Output Index	CI=CO/BSA

5. Cube

This method calculates the left ventricular volume by approximating the given region to a cube.

Calculation formula for volume:

$$EDV = LVIDd^3$$

$$ESV = LVIDs^3$$

<< Items to be measured>>

Meas. item	Description	Meas. Tool
IVSd[cm]	Interventricular septal thickness at end diastole	Line
LVIDd[cm]	Left ventricular short-axis diameter at end diastole	Line
LVPWd[cm]	Left ventricular posterior wall thickness at end diastole	Line
IVSs[cm]	Interventricular septal thickness at end systole	Line
LVIDs[cm]	Left ventricular short-axis diameter at end systole	Line
LVPWs[cm]	Left ventricular posterior wall thickness at end systole	Line

<<Items to be calculated>>

Calc. item	Description	Calc. formula
EDV[ml]	End-diastolic left ventricular volume	Refer to << Calculation formula for volume>>
ESV[ml]	End-systolic left ventricular volume	Refer to << Calculation formula for volume>>
SV [ml]	Stroke volume	SV=EDV – ESV
CO	Cardiac output [L/min]	CO=SV x HR /1000
EF	Ejection fraction	EF=SV/ EDV
FS	Fractional shortening	FS=(LVIDd-LVIDs)/LVIDd
SI	Stroke Volume Index	SI=SV/BSA
CI	Cardiac Output Index	CI=CO/BSA

6. Bullet Volume

This method calculates the left ventricular volume using the 2D mode long-axis image and the short-axis image at the level of the mitral valve.

Calculation formula for volume:

$$EDV = \frac{5}{6} \times LVLd \times LVAMd$$

$$ESV = \frac{5}{6} \times LVLs \times LVAMs$$

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVLd[cm]	Left ventricular long-axis length at end diastole.	Line
LVLs[cm]	Left ventricular long-axis length at end systole.	Line
LVAMd[cm]	Left ventricular short-axis area at the level of the mitral valve at end diastole.	Area
LVAMs[cm]	Left ventricular short-axis area at the level of the mitral valve at end systole.	Area

<<Items to be calculated>>

Calc. item	Description	Calc. formula
EDV[ml]	End-diastolic volume	Refer to << Calculation formula for volume>>
ESV[ml]	End-systolic volume	Refer to << Calculation formula for volume>>
SV[ml]	Stroke Volume	SV=EDV – ESV
CO[L/min]	Cardiac output	CO=SV * HR /1000
EF	Ejection Fraction	EF=SV/EDV
SI	Stroke Volume Index	SI=SV/BSA
CI	Cardiac Output Index	CI=CO/BSA

7. Gibson

Calculation formula for volume:

$$EDV = \frac{\pi}{6} \times (0.98 \times LVIDd + 0.59) \times LVIDd^2$$

$$ESV = \frac{\pi}{6} \times (0.98 \times LVIDs + 0.59) \times LVIDs^2$$

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVLd[cm]	Left ventricular long-axis length at end diastole.	Line
LVLs[cm]	Left ventricular long-axis length at end systole.	Line
LVAMd[cm]	Left ventricular short-axis area at the level of the mitral valve at end diastole.	Area
LVAMs[cm]	Left ventricular short-axis area at the level of the mitral valve at end systole.	Area

<<Items to be calculated>>

Calc. item	Description	Calc. formula
EDV[ml]	End-diastolic volume	Refer to << Calculation formula for volume>>
ESV [ml]	End-systolic volume	Refer to << Calculation formula for volume>>
SV[ml]	Stroke Volume	$SV = EDV - ESV$
CO[L/min]	Cardiac output	$CO = SV * HR / 1000$
EF	Ejection Fraction	$EF = SV / EDV$
SI	Stroke Volume Index	$SI = SV / BSA$
CI	Cardiac Output Index	$CI = CO / BSA$

8. Mitral Valve

<<Items to be measured>>

Meas. item	Description	Meas. Tool
MV Diam[cm]	Mitral valve diameter	Line
MV Area[cm ²]	Mitral valve area	Ellipse
LAD[cm]	Left ventricular diameter	Line
AOD[cm]	Aortic dimension	Line

<<Items to be calculate>>

Calc. item	Description	Calc. formula
LAD/AOD	LAD/AOD	AOD/AOD

9. Aortic Valve

<<Items to be measured>>

Meas. item	Description	Meas. Tool
AV Diam[cm]	Aortic valve diameter	Line
AV Area[cm ²]	Aortic valve area	Ellipse

10. Pulmonary Valve

<<Items to be measured>>

Meas. item	Description	Meas. Tool
PV Diam[cm]	Pulmonary valve diameter	Line
PV Area[cm ²]	Pulmonary valve area	Ellipse

11. Tricuspid Valve

<<Items to be measured>>

Meas. item	Description	Meas. Tool
TV Diam[cm]	Tricuspid valve diameter	Line
TV Area[cm ²]	Tricuspid valve area	Ellipse

12. LVOT

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVOT Diam[cm]	Left ventricular outflow tract diameter	Line

LVOT Area[cm ²]	Left ventricular outflow tract area	Ellipse
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13. RVOT

<<Items to be measured>>

Meas. item	Description	Meas. Tool
RVOT Diam[cm]	Right ventricular outflow tract diameter	Line
RVOT Area[cm ²]	Right ventricular outflow tract area	Ellipse

14. PISA

PISA MR

Calculation formula

MR Flow Rate(ml/s)=2πR Flow²* MR Als.Vel

<<Items to be measured>>

Meas. item	Description	Meas. Tool
MR Rad[cm]	Radius of mitral stenosis	Line
MR Als Vel [cm/s]	Input manually	

15. LV Mass

Cube

<<Items to be measured>>

Meas. item	Description	Meas. Tool
IVSd[cm]	Interventricular septal thickness at end diastole	Line
LVIDd[cm]	Left ventricular short-axis diameter at end diastole	Line
LVPWd[cm]	Left ventricular posterior wall thickness at end diastole	Line

<<Items to be calculated>>

Calc. item	Description	Calc. formula
LV Mass(g)	Left ventricular mass	$1.04 \times [(LVPWd + IVSd + LVIDd)^3 - LVIDd^3] - 13.6$
LV Mass index	Left ventricular mass index	LV Mass/BSA

A-L (Area-Length)

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVAd sax Epi[cm ²]	Left ventricular epicardial short axis area at the level of the papillary muscle tips at end diastole	Area
LVAd sax Endo[cm ²]	Left ventricular endocardial short axis area at the level of the papillary muscle tips at end diastole	Area
LVLd apical	Left ventricular long axis length at end diastole	Line

<<Items to be calculated>>

Calc. item	Description	Calc. formula
LV Mass(g)	Left ventricular mass	$LV\ Mass = 1.05 \times \frac{5}{6} \left\{ LVAd\ sax\ Epi \times \left(LVLd\ apical + \sqrt{\frac{LVAd\ sax\ Epi}{\pi}} - \sqrt{\frac{LVAd\ sax\ Endo}{\pi}} \right) - (LVAd\ sax\ Endo \times LVLd\ apical) \right\}$
LV Mass index	Left ventricular mass index	LV Mass/BSA

T-E (Area-Length)

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVAd sax Epi[cm ²]	Left ventricular epicardial short axis area at the level of the papillary muscle tips at end diastole	Area
LVAd sax Endo[cm ²]	Left ventricular endocardial short axis area at the level of the papillary muscle tips at end diastole	Area

a[cm]	From the widest long axis radius to the semi-major axis tips	Line
d[cm]	From the widest long axis radius to the semi-major axis tips of mitral valve	Line

<<Items to be calculated>>

Calc. item	Description	Calc. formula
LV Mass(g)	Left ventricular mass	$LV\ Mass = 1.05\pi \times \left\{ (b+t)^2 \left[\frac{2(a+t)}{3} + d - \frac{d^3}{3(a+t)^2} \right] - b^2 \left(\frac{2a}{3} + d - \frac{d^3}{3a^2} \right) \right\}$
LV Mass index	Left ventricular mass index	LV Mass/BSA

$$t(\text{cm}) = \sqrt{\frac{LVAd\ \text{sax}\ Epi}{\pi}} - \sqrt{\frac{LVAd\ \text{sax}\ Endo}{\pi}}$$

$$b(\text{cm}) = \sqrt{\frac{LVAd\ \text{sax}\ Endo}{\pi}}$$

16. Qp/Qs

Qp: Pulmonary flow

Qs: Systemic flow

<<Items to be measured>>

Meas. item	Description	Meas. Tool
AV Diam	Aortic valve diameter	Area
PV Diam	Pulmonary valve diameter	Area
AV VTI	Aortic valve Velocity Time Integral	Trace- PW Mode
PV VTI	Pulmonary valve Velocity Time Integral	Trace- PW Mode

<<Items to be calculated>>

Meas. item	Description	Calc. formula
AV HR	Aortic valve Heart Rate	HR=VTI/Mean

AV SV(ml)	Aortic valve Stroke Volume	$SV=0.785 \times AV \text{ Diam} \times AV \text{ Diam} \times \text{abs} \text{ (VTI)}$
PV HR	Pulmonary valve Heart Rate	$HR=VTI/\text{Mean}$
PV SV	Pulmonary valve Stroke Volume	$SV=0.785 \times AV \text{ Diam} \times AV \text{ Diam} \times \text{abs} \text{ (VTI)}$
PV CO	Pulmonary valve Cardiac output	$CO=SV \times HR/1000$
Qp/Qs	The ratio of Pulmonary flow volume and Systemic flow volume	$PV \text{ CO} / AV \text{ CO}$
Qp-Qs	The balance of Pulmonary flow volume and Systemic flow volume	$PV \text{ CO} - AV \text{ CO}$

17. RV/LV

<<Items to be measured>>

Meas. item	Description	Meas. Tool
RVIDd	Right ventricular short-axis diameter at end diastole	Line
LVIDd	Left ventricular short-axis diameter at end diastole	Line

<<Items to be calculated>>

Meas. item	Description	Calc. formula
RV/LV	The ratio of RV and LV	$RVIDd/LVIDd$

18. 18. IVC

<<Item to be measured>>

Meas. item name	Description	Meas. method
IVC Ins[mm]	Inferior Vena Cava inspiration	Measurement (Distance)
IVC Exp[mm]	Inferior Vena Cava expiration	Measurement (Distance)

<<Items to be calculated>>

Meas. item	Description	Calc. formula
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IVC Ins / IVC Exp	The ratio of IVC Ins and IVC Exp	IVC Ins/IVC Exp
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19. RA/LA

<<Item to be measured>>

Meas. item name	Description	Meas. method
RA[cm ²]	Right Atrium	Measurement (Area)
LA[cm ²]	Left Atrium	Measurement (Area)

<<Items to be calculated>>

Meas. item	Description	Calc. formula
RA / LA	The ratio of RA and LA	RA/LA

20. AO/LA

<<Item to be measured>>

Meas. item name	Description	Meas. method
AO[mm]	Aorta Diameter	Measurement (Distance)
LA[mm]	Left Atrium Diameter	Measurement (Distance)

<<Items to be calculated>>

Meas. item	Description	Calc. formula
AO / LA	The ratio of AO and LA	AO/LA

5.3.1.3 Urology Measurement in B mode



Fig.5-3

Meas. item name	mark	unit	Meas. method
Residual Vol.	Pre Length	cm	Refer to "Distance Measurement (Distance)".
	Pre Width	cm	Refer to "Distance Measurement (Distance)".
	Pre Height	cm	Refer to "Distance Measurement (Distance)".
	Pre Vol.	ml	$\text{Pre Vol.} = (\pi/6) * \text{Pre Length} * \text{Pre Width} * \text{Pre Height}$
	Post Length	cm	Refer to "Distance Measurement (Distance)".
	Post Width	cm	Refer to "Distance Measurement (Distance)".
	Post Height	cm	Refer to "Distance Measurement (Distance)".
	Post Vol.	ml	$\text{Post Vol.} = (\pi/6) * \text{Post Length} * \text{Post Width} * \text{Post Height}$
	Void Vol.	ml	$\text{Void Vol.} = \text{Pre Vol.} - \text{Post Vol.}$
Prostate Vol.	Length	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"

	Height	cm	Refer to "Distance Measurement (Distance)"
	Volume	ml	$V = (\pi/6) * PV \text{ Length} * PV \text{ Width} * PV \text{ Height}$
	PPSA	ml	$PPSA = 0.12 * PV$
	PSAD	ng/ ml	$PSAD = SPSA[ng]/PV[ml]$
			Note: SPSA must be input by manual in patient interface when you select the urology exam type
Kid Volume	Length	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"
	Height	cm	Refer to "Distance Measurement (Distance)"
	Renal Pelvis	cm	Refer to "Distance Measurement (Distance)"
T-Zone Vol.	Length	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"
	Height	cm	Refer to "Distance Measurement (Distance)"
	Volume	ml	$V = (\pi/6) * \text{length} * \text{Width} * \text{Height}$
Bladder Vol.	Length	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"
	Height	cm	Refer to "Distance Measurement (Distance)"
	Volume	ml	$V = (\pi/6) * \text{length} * \text{Width} * \text{Height}$
StA%	A Out	cm ²	Refer to "Area Measurement (Area)"
	A In	cm ²	
	StA%	%	
StD%	D Out	cm ²	Refer to "Area Measurement (Area)"
	D In	cm ²	
	StD%	%	
Vessel Area	Vessel Area	cm ²	Refer to "Area Measurement (Area)"

Vessel Dis	Vessel Dis	cm	Refer to "Distance Measurement (Distance)"
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5.3.1.4 Pediatric Measurement in B mode

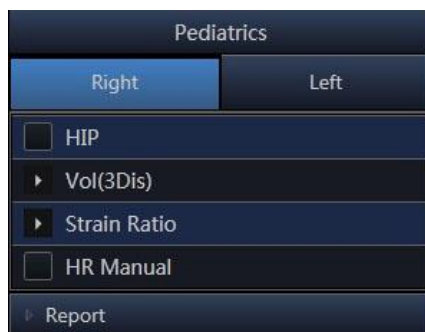


Fig.5-4

Hip

Hip is used for evaluating the abnormality of the cotyle. In order to make measurement, user has to draw three lines on the image responding to the anatomy. The system will calculate the angles automatically.

Operation Method:

1. Select HIP from Pediatric submenu on CALC menu. Press Enter key to select it.
2. The first line D1 will be displayed on the screen and use the Trackball to move the line.
3. The second line D2 will be displayed on the screen, repeat the above procedure to fix the second line and third line D3. The angles between these three lines will be displayed on the screen.

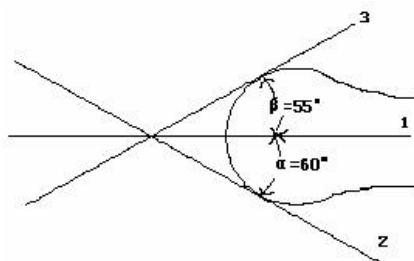


Fig.5-5



NOTE: α is the angle between the D1 and D2 (acute angle). β is the angle

between D1 and D3(acute angle).

5.3.1.5 Vascular Measurement in B mode

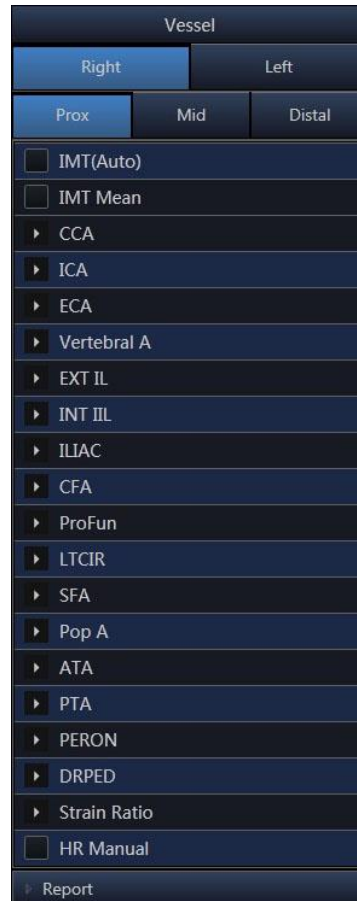


Fig.5-6

For CCA and ICA, user also can measure the thickness of intima.

IMT: measure the thickness of intima manual.

IMT Auto: get a good B image for intima, and then click this measurement. Set start position and end position, be sure to contain the intima in the box, the system will calculate the thickness of intima.

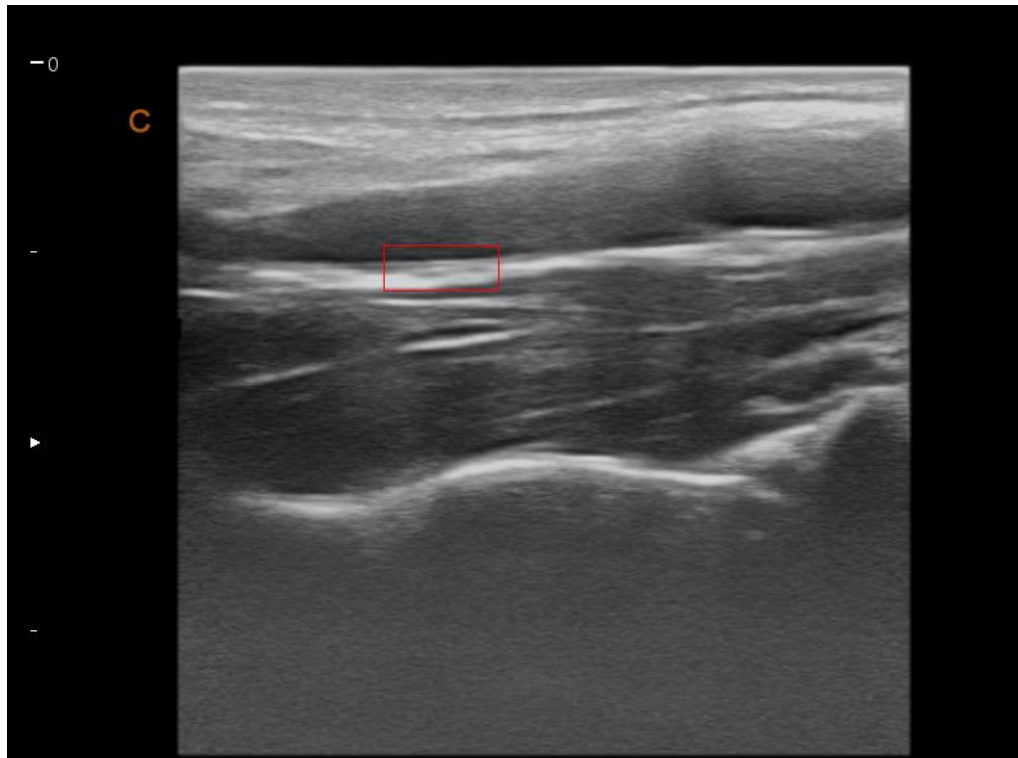


Fig.5-7

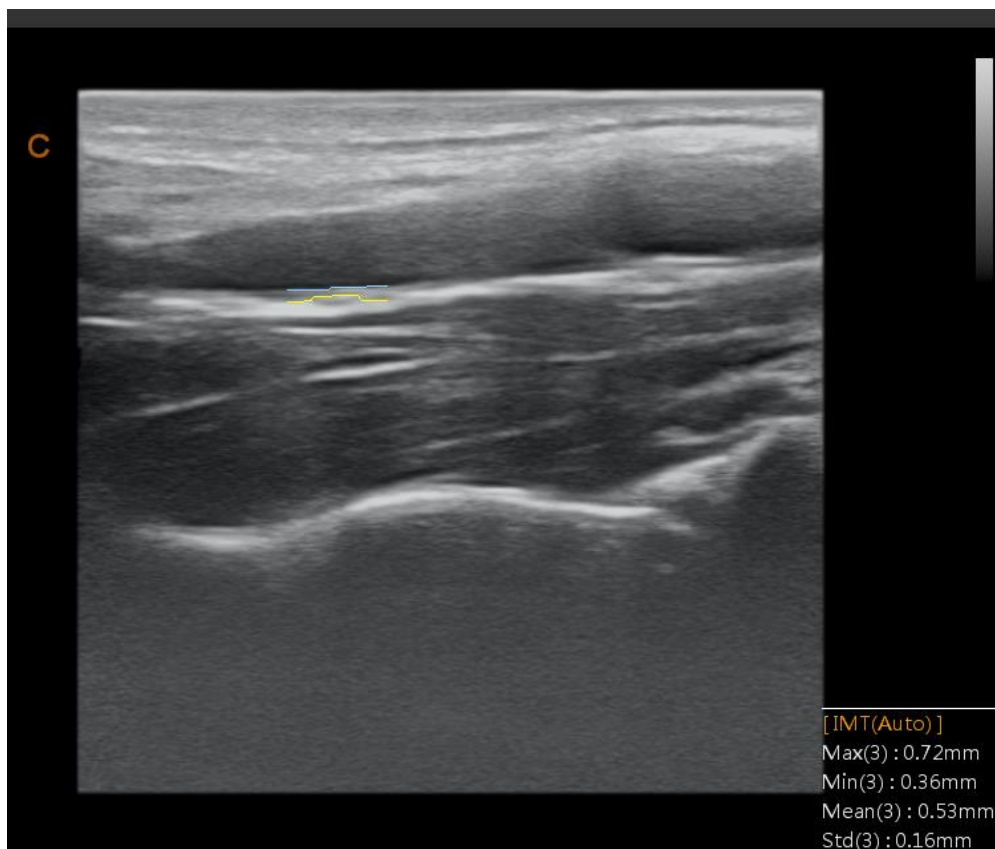


Fig.5-8

Meas. item name	mark	unit	Meas. Method and calc. formula
CCA (Rt) / (Lt)	A Out	cm ²	Refer to "Area/Circumference Measurement (Area)"
	A In	cm ²	Refer to "Area/Circumference Measurement (Area)"
	StA%	%	$StA\% = (A\ Out - A\ In) / A\ Out * 100\%$
	D Out	cm	Refer to "Distance Measurement (Distance)"
	D In	cm	Refer to "Distance Measurement (Distance)"
	StD%	%	$StD\% = (D\ Out - D\ In) / D\ Out * 100\%$
	Vessel Area	cm ²	Refer to Area(Ellipse)
	Vessel Dis	cm	Refer to "Distance Measurement (Distance)"
ICA	The same as above	The same as above	The same as above

(Rt) / (Lt)			
ECA (Rt) / (Lt)	The same as above	The same as above	The same as above
Vertebral A (Rt) / (Lt)	The same as above	The same as above	The same as above
INT IIL (Rt) / (Lt)	The same as above	The same as above	The same as above
EXT IL (Rt) / (Lt)	The same as above	The same as above	The same as above
ILIAC (Rt) / (Lt)	The same as above	The same as above	The same as above
CFA (Rt) / (Lt)	The same as above	The same as above	The same as above
ProFun (Rt) / (Lt)	The same as above	The same as above	The same as above
LTCIR (Rt) / (Lt)	The same as above	The same as above	The same as above
SFA (Rt) / (Lt)	The same as above	The same as above	The same as above
Pop A (Rt) / (Lt)	The same as above	The same as above	The same as above
ATA (Rt) / (Lt)	The same as above	The same as above	The same as above
PTA	The same as above	The same as above	The same as above

(Rt) / (Lt)			
PERON (Rt) / (Lt)	The same as above	The same as above	The same as above
DRPED (Rt) / (Lt)	The same as above	The same as above	The same as above

5.3.1.6 GYN Measurement in B mode



Fig.5- 9

Meas. item name	Mark	Unit	Meas. Method and calc. formular
UT	UT_L	cm	Refer to "Distance Measurement (Distance) "
	UT_W	cm	Refer to "Distance Measurement (Distance) "
	UT_H	cm	"Refer to "Distance Measurement (Distance) "
	UT_D	cm	UT_D= UT_L +UT_H + UT_W
	CX_L	cm	Refer to "Distance Measurement (Distance) "
Cervix Vol.	Length	cm	Refer to "Distance Measurement (Distance) "
	Height	cm	Refer to "Distance Measurement (Distance) "

	Width	cm	Refer to "Distance Measurement (Distance) "
	Volume	cm	$PV = (\pi/6) * L * W * H$
ENDO	endometrium	cm	Refer to "Distance Measurement (Distance) "
OV_Volume	LengthWidthHeightVolume	cm	Refer to "Distance Measurement (Distance) "
		cm	Refer to "Distance Measurement (Distance) "
		cm	Refer to "Distance Measurement (Distance) "
		ml	$Volume = (\pi/6) * L * W * H$
FO_D	Length	cm	Refer to "Distance Measurement (Distance) "
	Width	cm	Refer to "Distance Measurement (Distance) "
	Height	cm	Refer to "Distance Measurement (Distance) "
FO Auto			Auto calculate Area and Length
Uterine Artery	A Out	cm ²	Refer to "Refer to Area(Ellipse)"
	A In	cm ²	Refer to "Refer to Area(Ellipse)"
	STA%	%	$StA\% = (A\ Out - A\ In) / A\ Out * 100\%$
	D Out	cm	Refer to "Distance Measurement (Distance)"
	D In	cm	Refer to "Distance Measurement (Distance)"
	STD%	%	$StD\% = (D\ Out - D\ In) / D\ Out * 100\%$
	Vessel Area	cm ²	Refer to "Refer to Area(Ellipse)"
	Vessel Dis	cm	Refer to "Distance Measurement (Distance)"

5.3.1.7 OB Measurement in B mode



Fig.5- 10

Meas. item name	Mark	Unit	Meas. Method and calc. formula
GS	GS	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	EDD = current date + (280days – average UGA)
CRL	CRL	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	EDD = current date + (280days – average UGA)
BPD	BPD	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	

	EFW	g	
AC (ellipse)	AC	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	
	EFW	g	
HC	HC	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	
FL	FL	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	
Humerus	Humerus	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	
OFD	OFD	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	
YS	YS	cm	Refer to "Distance Measurement (Distance)"
APD	APD	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	
TAD	TAD	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	
FTA	FTA	cm	Refer to "Distance Measurement (Distance)"

	GA EDD	week/day mm/dd/yyyy	
SL	SL	cm	Refer to "Distance Measurement (Distance)"
APTD	APTD GA EDD	cm week/day mm/dd/yyyy	Refer to "Distance Measurement (Distance)"
TTD	TTD GA EDD	cm week/day mm/dd/yyyy	Refer to "Distance Measurement (Distance)"
ThC	ThC	cm	Refer to "Distance Measurement (Distance)"
ULNA	ULNA GA EDD	cm week/day mm/dd/yyyy	Refer to "Distance Measurement (Distance)"
Tibia	Tibia GA EDD	cm week/day mm/dd/yyyy	Refer to "Distance Measurement (Distance)"
RAD	RAD	cm	Refer to "Distance Measurement (Distance)"
FIB	FIB	cm	Refer to "Distance Measurement (Distance)"
CLAV	CLAV GA EDD	cm week/day mm/dd/yyyy	Refer to "Distance Measurement (Distance)"
CER	CER GA EDD	cm week/day mm/dd/yyyy	Refer to "Distance Measurement (Distance)"
CM	CM	cm	Refer to "Distance Measurement (Distance)"

NF	NF	cm	Refer to "Distance Measurement (Distance)"
NT	NT	cm	Refer to "Distance Measurement (Distance)"
OOD	OOD	cm	Refer to "Distance Measurement (Distance)"
	GA	week/day	
	EDD	mm/dd/yyyy	
IOD	IOD	cm	Refer to "Distance Measurement (Distance)"
NB	NB	cm	Refer to "Distance Measurement (Distance)"
LVent	LVent	cm	Refer to "Distance Measurement (Distance)"
	GA		
	EDD		
HW	HW	cm	Refer to "Distance Measurement (Distance)"
Kid	Kid	cm	Refer to "Distance Measurement (Distance)"
RenalAP	RenalAP	cm	Refer to "Distance Measurement (Distance)"
LVWrHEM	LVWrHEM	cm	Refer to "Distance Measurement (Distance)"
MAD	MAD	cm	Refer to "Distance Measurement (Distance)"
AFI	AF1	cm	Refer to "Distance Measurement (Distance)"
	AF2	cm	Refer to "Distance Measurement (Distance)"
	AF3	cm	Refer to "Distance Measurement (Distance)"
	AF4	cm	Refer to "Distance Measurement (Distance)"
	AFI	cm	AFI=AF1+AF2+AF3+AF4
FBP	AF	cm	Refer to "Distance Measurement (Distance)"
	Result	Scores	Give result according to AF
Ductus Venosus	A Out	cm ²	Refer to "Area/Circumference Measurement (Area)"
	A In	cm ²	Refer to "Area/Circumference Measurement (Area)"
	StA%	%	StA%= (A Out- A In) / A Out *100%

	D Out	cm	Refer to "Distance Measurement (Distance)"
	D In	cm	Refer to "Distance Measurement (Distance)"
	StD%	%	$StD\% = (D\ Out - D\ In) / D\ Out * 100\%$
	Vessel Area	cm ²	Refer to Area(Ellipse)
	Vessel Dis	cm	Refer to "Distance Measurement (Distance)"
CX_L	CX_L	cm	Refer to "Distance Measurement (Distance)"
Aorta	A Out	cm ²	Refer to "Area/Circumference Measurement (Area)"
	A In	cm ²	Refer to "Area/Circumference Measurement (Area)"
	StA%	%	$StA\% = (A\ Out - A\ In) / A\ Out * 100\%$
	D Out	cm	Refer to "Distance Measurement (Distance)"
	D In	cm	Refer to "Distance Measurement (Distance)"
	StD%	%	$StD\% = (D\ Out - D\ In) / D\ Out * 100\%$
	Veslumen_D	cm	Refer to "Distance Measurement (Distance)"
	VesIntimal_D	cm	Refer to "Distance Measurement (Distance)"
	VesOutside_D	cm	Refer to "Distance Measurement (Distance)"
	VesIntimal_A	cm ²	Refer to "Area/Circumference Measurement (Area)"
	Veslumen_A	cm ²	Refer to "Area/Circumference Measurement (Area)"
Descending Aorta	The same as above	The same as above	The same as above
MCA	The same as above	The same as above	The same as above
Umb A	The same as above	The same as above	The same as above
Uterine Artery	The same as above	The same as above	The same as above
Pulmonary Artery	The same as	The same	The same as above

	above	as above	
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5.3.1.8 Carotid Measurement in B mode



Fig.5-11

Meas. item name	Mark	Unit	Meas. Method and calc. formular
Subclavian A (Lt/Rt)	A Out	cm ²	Refer to "Area Measurement (Ellipse)"
	A In	cm ²	Refer to "Area Measurement (Ellipse)"
	StA%	%	StA % = (A Out - A In) / A Out * 100%
	D Out	cm	Refer to "Distance Measurement (Distance)"
	D In	cm	Refer to "Distance Measurement (Distance)"
	StD%	%	StD % = (D Out - D In) / D Out * 100%
	Vessel Area	cm ²	Refer to "Area Measurement (Ellipse)"
	Vessel Dis	cm	Refer to "Distance Measurement (Distance)"
CCA (Lt/Rt)	The same as above	The same as above	The same as above
Bulb	The same as	The same as	The same as above

(Lt/Rt)	above	above	
ICA (Lt/Rt)	The same as above	The same as above	The same as above
ECA (Lt/Rt)	The same as above	The same as above	The same as above
Vertebral A (Lt/Rt)	The same as above	The same as above	The same as above
General Measurement	The same as above	The same as above	The same as above
Strain Ratio	Strain A Strain B		

5.3.1.9 Abdomen Measurement in B mode



Fig.5-12

Meas. item name	Mark	Unit	Meas. Method and calc. Formula
CBD	CBD	cm	Refer to "Distance Measurement (Distance)"
GB Wall	GB Wall	cm	Refer to "Distance Measurement (Distance)"
Liver Length	Liver Length	cm	Refer to "Distance Measurement (Distance)"

Artery	Height	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"
	A Out	cm	Refer to "Area Measurement (Trace)"
	A In	cm ²	Refer to "Area Measurement (Trace)"
	StA%	%	$StA\% = (A\ Out - A\ In) / A\ Out * 100\%$
	D Out	cm	Refer to "Distance Measurement (Distance)"
	D In	cm	Refer to "Distance Measurement (Distance)"
	StD%	%	$StD\ \% = (D\ Out - D\ In) / D\ Out * 100\%$
	Vessel Area	cm ²	Refer to "Area Measurement (Trace)"
	Vessel Dis	cm	Refer to "Distance Measurement (Distance)"
Splee	Length	cm	Refer to "Distance Measurement (Distance)"
	Height	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"
	Volume	ml	$Volume = (\pi/6) * Length * Width * Height$
Renal Vol.	Length	cm	Refer to "Distance Measurement (Distance)"
	Height	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"
GB Volume	Length	cm	Refer to "Distance Measurement (Distance)"
	Height	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"
Iliac	Height	cm	Refer to "Distance Measurement (Distance)"
	Width	cm	Refer to "Distance Measurement (Distance)"
	A Out	cm ²	Refer to "Area Measurement (Trace)"
	A In	cm ²	Refer to "Area Measurement (Trace)"
	StA%	%	$StA\% = (A\ Out - A\ In) / A\ Out * 100\%$

	D Out	cm	Refer to "Distance Measurement (Distance)"
	D In	cm	Refer to "Distance Measurement (Distance)"
	StD%	%	$StD\% = (D\ Out - D\ In) / D\ Out * 100\%$
	Vessel Area	cm ²	Refer to "Area Measurement (Trace)"
	Vessel Dis	cm	Refer to "Distance Measurement (Distance)"

5.3.1.10 Small Parts Measurement in B mode

Refer to general measurement in B mode.



Breast /Thyroid measurement: measure length, height and width, and calculate volume. Length, height and width measurement method refer to Distance measurement.

5.3.1.11 TCD Measurement in B mode



Meas. item name	mark	unit	Meas. Method and calc. Formula
ICA (Rt) / (Lt)	A Out	cm ²	Refer to "Area/Circumference Measurement (Area)"
	A In	cm ²	Refer to "Area/Circumference Measurement (Area)"
	StA%	%	StA%= (A Out- A In) / A Out *100%
	D Out	cm	Refer to "Distance Measurement (Distance)"
	D In	cm	Refer to "Distance Measurement (Distance)"
	StD%	%	StD%= (D Out- D In) / D Out *100%
	Vessel Area	cm ²	Refer to Area(Ellipse)
	Vessel Dis	cm	Refer to Distance Measurement (Distance)
CS (Rt) / (Lt)	The same as above	The same as above	The same as above
MCA (Rt) / (Lt)	The same as above	The same as above	The same as above
ACA (Rt) / (Lt)	The same as above	The same as above	The same as above
PCA (Rt) / (Lt)	The same as above	The same as above	The same as above
ACOA	The same	The same	The same as above

(Rt) / (Lt)	as above	as above	
PCOA (Rt) / (Lt)	The same as above	The same as above	The same as above
OA (Rt) / (Lt)	The same as above	The same as above	The same as above
Vertebral A (Rt) / (Lt)	The same as above	The same as above	The same as above
BA (Rt) / (Lt)	The same as above	The same as above	The same as above
PICA (Rt) / (Lt)	The same as above	The same as above	The same as above

5.3.2 Measurement in M mode

5.3.2.1 General Measurement in M mode



Fig.5-13

1. M distance

This feature allows the measurement of the distance between two points. It is a measurement between the two horizontal lines that lean on the two cursors. The position of the vertical time line does not affect the distance measurement.

Operation:

Rotate the trackball to select the “M distance” item in the menu. A start cursor“+” will appear on the screen. Move the cursor through rotating the trackball and press Enter-key to fix the first point. The second cursor will appear. Move the second cursor to the end point and press Enter-key to fix it. The measurement result will appear on the right side of the screen.

2. M time

Time is the measurement between the two vertical time lines created by two cursors. The position of the horizontal distance line does not affect time measurements.

3. Velocity

Velocity is the measurement between the intersections of the two cursors. Velocity can be positive or negative, and is measured as the rate of change between the two points defined by the intersections of the cursors in cm/sec.

4. HR

HR is the measurement between the two vertical lines that are created by two cursors in beat per minute (BPM). The position of the horizontal distance line does not affect HR.

5.3.2.2 Cardiac Measurement in M mode



Fig.5-14

1. Distance

Refer to distance measurement in general measurement in M mode.

2. Time

Refer to time measurement in general measurement in M mode.

3. Slope

Refer to slope measurement in general measurement in M mode.

4. HR

Refer to HR measurement in general measurement in M mode.

5. Left Ventricle

Cube

Calculation formula for volume:

$$EDV = LVIDd^3$$

$$ESV = LVIDs^3$$

<< Items to be measured>>

Meas. item	Description	Meas. Tool
IVSd[cm]	Interventricular septal thickness at end diastole	M Line
LVIDd[cm]	Left ventricular short-axis diameter at end diastole	M Line
LVPWd[cm]	Left ventricular posterior wall thickness at end diastole	M Line
IVSs[cm]	Interventricular septal thickness at end systole	M Line
LVIDs[cm]	Left ventricular short-axis diameter at end systole	M Line
LVPWs[cm]	Left ventricular posterior wall thickness at end systole	M Line

<<Items to be calculated>>

Calc. item	Description	Calc. formula
EDV[ml]	End-diastolic left ventricular volume	Refer to << Calculation formula for volume>>
ESV[ml]	End-systolic left ventricular volume	Refer to << Calculation formula for volume>>
SV [ml]	Stroke volume	SV=EDV – ESV

CO	Cardiac output [L/min]	CO=SV x HR /1000
EF	Ejection fraction	EF=SV/ EDV
FS	Fractional shortening	FS=(LVIDd-LVIDs)/LVIDd
SI	Stroke Volume Index	SI=SV/BSA
CI	Cardiac Output Index	CI=CO/BSA

Teichholz

<<Calculation formula for volume>>

$$EDV = \frac{7 \times LVIDd^3}{2.4 + LVIDd}$$

$$ESV = \frac{7 \times LVIDs^3}{2.4 + LVIDs}$$

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVIDd [cm]	Left ventricular internal diameter at end diastole	M Line
LVIDs [cm]	Left ventricular internal diameter at end systole	M Line

<< Items to be calculated >>

Calc. item	Description	Calc. formula
EDV [ml]	End-diastolic left ventricular Volume	Please refer to <<Calculation formula for volume>>
ESV [ml]	End-systolic left ventricular Volume	Please refer to <<Calculation formula for volume>>
SV [ml]	Stroke Volume	SV=EDV – ESV
CO [l/min]	Cardiac Output	CO=SV*HR/1000
EF [%]	Ejection Fraction	EF=SV/EDV

FS [%]	Fractional Shortening	$FS = (LVIDd - LVIDs) / LVIDd$
SI	Stroke Volume Index	$SI = SV / BSA$
CI	Cardiac Output Index	$CI = CO / BSA$

Gibson

Calculation formula for volume:

$$EDV = \frac{\pi}{6} \times (0.98 \times LVIDd + 0.59) \times LVIDd^2$$

$$ESV = \frac{\pi}{6} \times (0.98 \times LVIDs + 0.59) \times LVIDs^2$$

<<Items to be measured>>

Meas. item	Description	Meas. Tool
LVLd[cm]	Left ventricular long-axis length at end diastole.	M Line
LVLs[cm]	Left ventricular long-axis length at end systole.	M Line

<<Items to be calculated>>

Calc. item	Description	Calc. formula
EDV[ml]	End-diastolic volume	Please refer to <<Calculation formula for volume>>
ESV [ml]	End-systolic volume	Please refer to <<Calculation formula for volume>>
SV[ml]	Stroke Volume	$SV = EDV - ESV$
CO[L/min]	Cardiac output	$CO = SV * HR / 1000$
EF	Ejection Fraction	$EF = SV / EDV$
SI	Stroke Volume Index	$SI = SV / BSA$
CI	Cardiac Output Index	$CI = CO / BSA$

IVSd/LVPWd

<<Items to be measured>>

Meas. item	Description	Meas. Tool
IVSd[cm]	Interventricular septal thickness at end diastole	M Line
LVPWd[cm]	Left ventricular posterior wall thickness at end diastole	M Line

6. Mitral Valve

<<Items to be measured>>

Meas. item name	Description [Unit]
EPSS[cm]	Distance between the mitral valve and interventricular septum[cm]
MV E Amp[cm]	Mitral Valve E wave amplitude
MV F Amp[cm]	Mitral Valve E wave amplitude
MV D-E Exc Dist	D-E Slope (cm/s)
	D-E Exc Time(s)
	D-E Exc Distance(cm)
MV E-F slope	E-F Slope (cm/s)
	E-F Time(s)
	E-F Distance(cm)
MV D-E slope	D-E Slope (cm/s)
	E-F Time(s)
	E-F Distance(cm)
MV A-C Int time	A-C Int slope (cm/s)
	A-C Int Time(s)
	A-C Int Distance(cm)
E Duration	E Duration
A Duration	A Duration

7. Aortic Valve

<Items to be measured>>

Meas. item name	Description	Meas. Method
AOD[cm]	Aorta diameter at diastole	Refer to distance measurement in M mode
Ao Sinus Diam[cm]	Aortic sinus diameter	Refer to distance measurement in M mode
Ao Asc Diam[cm]	Aorta ascendens diameter	Refer to distance measurement in M mode
Ao Arch Diam[cm]	Aortic arch diameter	Refer to distance measurement in M mode
Ao Desc Diam[cm]	Descending artery diameter	Refer to distance measurement in M mode
LVOT Diam[cm]	Left ventricular outflow tract diameter	Refer to distance measurement in M mode
LAD[cm]	Left atrium diameter	Refer to distance measurement in M mode
AA[cm]	Aorta amplitude	Refer to distance measurement in M mode
LVEP	Left ventricular pre-ejection phase	Refer to time measurement in M mode
LVET	Left ventricular ejection time	Refer to time measurement in M mode

8. Tricuspid Valve

<<Items to be measured>>

Meas. item name	Description [Unit]
RVOT Diam[cm]	Right ventricular outflow tract diameter
RA Diam[cm]	Right atrium diameter
D-E Exc Dist	D-E Slope (cm/s)
	D-E Exc Time(s)
	D-E Exc Distance(cm)
E-F slope	E-F Slope (cm/s)

	E-F Time(s)
	E-F Distance(cm)
MV A-C Int time	A-C Int slope (cm/s)
	A-C Int Time(s)
	A-C Int Distance(cm)

9. Pulmonary Valve

<<Items to be measured>>

Meas. item name	Description [Unit]
RVPEP[s]	Right ventricular pre-ejection phase
RVET[s]	Right ventricular ejection time
A wave Amp (cm)	Atrium wave amplitude
B-C slope	B-C Slope (cm/s)
	B-C Time(s)
	B-C Distance(cm)

10. RV/LV

<<Items to be measured>>

Meas. item	Description	Meas. Tool
RVIDd	Right ventricular short-axis diameter at end diastole	M Line
LVIDd	Left ventricular short-axis diameter at end diastole	M Line

<<Items to be calculated>>

Meas. item	Description	Calc. formula
RV/LV	The ratio of RV and LV	RVIDd/LVIDd

11.LV Mass

<<Items to be measured>>

Meas. item name	Description
IVSd	Interventricular septal thickness at end diastole
LVIDd	Left ventricular short-axis diameter at end diastole
LVPWd	Left ventricular posterior wall thickness at end diastole

12.TAPSE

<<Items to be measured>>

Meas. item name	Description
TAPSE	Tricuspid annular plane systolic excursion

5.3.3 Measurement in PW mode

5.3.3 1 General Measurement in PW mode

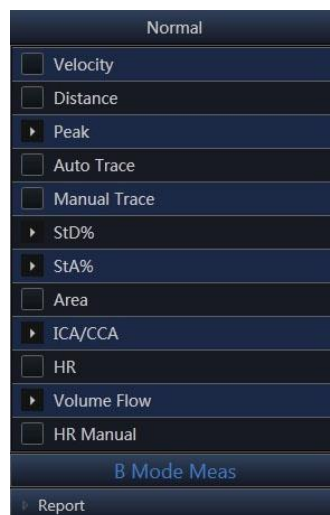


Fig.5- 15

1. Velocity

- 1) Rotate the trackball to move the cursor to the velocity item in the menu and press Enter-key to select it. A cursor" + " will appear on the screen.

- 2) Move the cursor "+" to the place where need to be measured and press Enter-key to fix it.
- 3) The value of velocity and pressure will appear on the screen.
- 4) Repeat step 1) to 3) to measure the next point.

2. Distance

The measurement method is the same as distance in general measurement in B mode.

3. Peak

Calculate the velocity over one cardiac cycle. The velocity, slope, RI and SD ratio are calculated.

- 1) Scan the object area in PW mode and freeze the image.
- 2) Rotate the trackball to move the cursor to the Peak item in the menu and press Enter-key to select.
- 3) A cursor "+" will appear on the screen. Move the cursor "+" to the peak point where the cardiac systole and press Enter-key to fix it.
- 4) A second cursor "+" will appear on the screen again. Fix the second cursor to the end point where the cardiac diastole
- 5) When the two points are all fixed, the value of Vs,Vd,RI,SD(Vs/Vd) will appear on the right side of the screen.

4. Auto Trace

- 1) Rotate the trackball to move the cursor to the auto trace item in the menu.
- 2) Press Enter-key to select it. A cursor "I" will appear on the screen.
- 3) Move the cursor by rotating the trackball to the start point of the one cycle and press Enter-key to fix it. A second cursor "I" will appear.
- 4) Rotate the trackball the end point of the cycle and press Enter-key to fix it.
- 5) After the measurement, the value of Vs,Vd,RI,SD ratio,PI will appear on the screen.

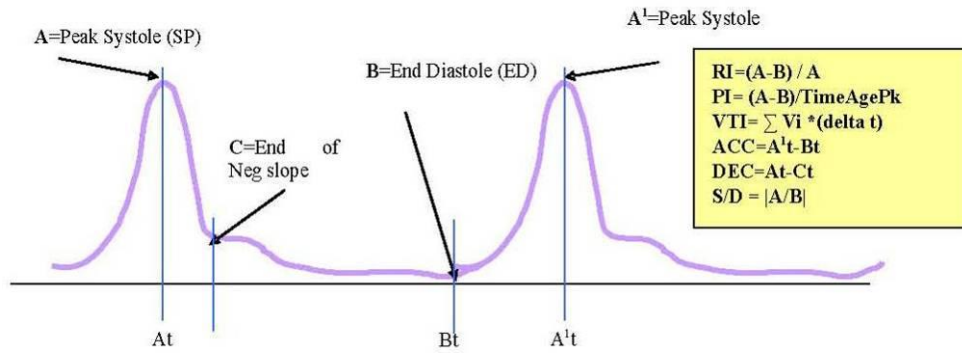


Fig.5- 16

- Peak Velocity or Doppler frequency

Peak velocity over one cardiac cycle (Vpk)

- Doppler Time Distance

Time distance between two cursors in ms. The invert is the heart beat rate if the two cursors are at one cardiac cycle period. (T)

- Spectral Velocity Time Integral (VTI)

$VTI = \sum V_{pk} * (\Delta t)$. Where Δt is T/N , N is the data point over one cardiac cycle.

- Pulsatility Index (PI)

It can be used to represent the degree of pulse-wave damping at different arterial sites; the smaller the PI, the greater the degree of damping. Typical value for CCA is 1.90 ± 0.5 .

$PI = | (A-B) / \text{TimeAvgPk} |$, $\text{TimeAvgPk} = \sum V_{pk} / N$

- Resistive Index (RI)

Vary from 0 to 1. It is an indicator of the circulatory resistance. Typical value for CCA is 0.75 ± 0.05 .

$RI = | (A-B) / A |$

NOTE:

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

5. Manual trace

Automatically measure the Peak Systolic Velocity, VTI, end diastolic velocity, HR, Time, minimum velocity, PI, and RI after manually tracing of the curve is finished.



NOTE: Manual trace requires the user to trace two peak point of two cycles.

6. STD%

Measure the diameter reduction ratio of vessel in B mode

- 1) Move the cursor to the “STD” item and press Enter-key to select it .A cursor “+” will appear on the screen.
- 2) Move the cursor to the point of outside wall of the vessel and press Enter key to fix it. The method to measure the diameter of the outside wall of the vessel is the same as “distance” in genera measurement in B mode.
- 3) When the diameter of outside wall of the vessel is finished, the cursor “+”will appear on the screen again. Measure the diameter of the stenosis area.
- 4) The value of diameter and STD will be displayed in the result window.

7. STA%

Measure the area reduction ratio of vessel in B mode

- 1) Move the cursor to the “STA” item and press Enter-key to select it .A cursor “+”will appear on the screen.
- 2) Move the cursor to the point of outside wall of the vessel and press Enter-key to fix it. The method to measure the area of the outside of the vessel is the same as “area-ellipse” in genera measurement in B mode.
- 3) When the area of outside of the vessel is finished , the cursor “+”will appear on the screen again. Measure the area of the stenosis area.
- 4) The value of area and STD will be displayed in the result window.

8. Area

The same as “area-trace” in general measurement in B mode.

9. ICA/CCA

Measure ICA and CCA separately and get the ratio value of ICA/CCA

10. Volume Flow

<<Items to be measured>>

Meas. item name	Description [Unit]	Meas. Method
Diam	Diameter of vessel [mm]	Refer to “distance” measurement
VTI	Velocity time integral	Refer to “area-trace” measurement
Time	Time	Refer to “time” measurement in M mode

<<Items to be calculated>>

Calc. item name	Description [Unit]	Calc. formula
SV	Stroke volume[ml]	$SV = 0.785 * \text{diameter} * \text{diameter} * VTI $
CO	Cardiac output[L/min]	$CO = SV * \text{heart rate} / 1000$
HR	Heart rate	$\text{Heart rate} = 60 / \text{time}$

11. HR

The measurement is the same as “heart rate” in general measurement in M mode.

5.3.3.2 Cardiology Measurement in PW mode

1. MV

Measurement of Mitral valve function is performed in frozen Doppler spectral trace.

<<Measurement and calculation items>>

Meas. item	Description [Unit]	Meas. procedure / Calc. formula
------------	--------------------	---------------------------------

name		
E Vel	E-wave flow velocity [cm/s]	Refer to "Velocity Measurement".
A Vel	A-wave flow velocity [cm/s]	Refer to "Velocity Measurement".
PHT	Pressure half time [ms]	Refer to "Velocity Measurement".
E Dur	E-wave duration [ms]	Refer to "Time Measurement (Time)".
A Dur	A-wave duration [ms]	Refer to "Time Measurement (Time)".
IRT	Isovelocity relaxation time [ms]	Refer to "Time Measurement (Time)".
MV VTI	Mitral valve VTI [m]	Refer to "Full trace".
MV VM	Mitral valve mean velocity [cm/s]	Refer to "Full trace"
MV VP	Mitral valve maximum velocity [cm/s]	Refer to "Full trace"
MV MPG	Mitral valve mean pressure gradient [mmHg]	Refer to "Full trace"
MV PPG	Mitral valve maximum pressure gradient [mmHg]	Refer to "Full trace"
MV Diam	Mitral valve diameter [mm]	Refer to "Distance Measurement in B mode"
HR	Heart rate [bpm]	Refer to "Heart Rate Measurement (HR)"
E/A	[no unit]	E Vel / A Vel
A/E	[no unit]	A Vel / E Vel
SV	Stroke volume [mL]	$0.785 \times (\text{MVDiam})^2 \times \text{abs VTI }$
CO	Cardiac output [L/min]	$\text{SV} \times \text{HR} / 1000$
MV Area	Mitral valve area [mm ²]	220/ PHT

Note: [MV Diam] can only be performed in 2-D mode.

<<Measurement points>>

1) Measure [E Vel] and [A Vel]. Measure [PHT]. Measure [E-Dur], [A-Dur], and [IR] Measure [HR].

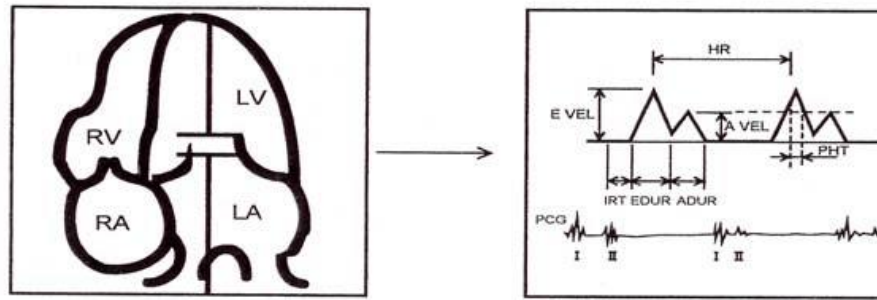


Fig.5-17

2) Measure [MV V Trace].

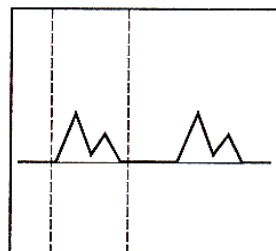


Fig.5-18

3) Measure [MV Diameter

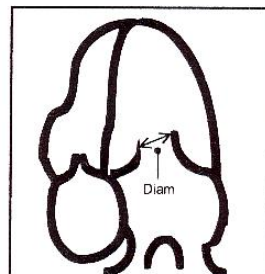


Fig.5-19

2. AV

Measurement of aortic valve function is performed by using 2-D-mode and Doppler images.

<<Measurement items>>

Meas. Item name	Description [Unit]	Meas. method
LVOT Vel	PW-mode LV out tract flow velocity [cm/s]	Refer to "Velocity Measurement".

LVOT PG	PW-mode LV out tract pressure gradient [mmHg]	Refer to "Velocity Measurement".
---------	---	----------------------------------

LVOT V General

Meas. Item name	Description [Unit]	Meas. method
LVOT VTI	Aortic valve VTI [m]	Refer to "Full trace"
LVOT VM	Aortic valve mean velocity [cm/s]	Refer to "Full trace"
LVOT VP	Aortic valve maximum velocity [cm/s]	Refer to "Full trace"
LVOT MPG	Aortic valve mean pressure gradient [mmHg]	Refer to "Full trace"
LVOT PPG	Aortic valve maximum pressure gradient [mmHg]	Refer to "Full trace"

AoV VM

Meas. Item name	Description [Unit]	Meas. method
AoV MPG	Aortic valve mean pressure gradient [mmHg]	Refer to "Full trace"
AoV PPG	Aortic valve maximum pressure gradient [mmHg]	Refer to "Full trace"
LVOT Diam	Left ventricular outflow tract diameter [mm]	Refer to "Distance Measurement in B mode".
HR	Heart rate [bpm]	Refer to "Heart Rate Measurement (HR)".
SV	Stroke volume [mL]	$0.785 \times (\text{LVOT Diam})^2 \times \text{abs VTI }$
CO	Cardiac output [L/min]	$\text{SV} \times \text{HR} / 1000$
AV Area	AoV area [cm ²]	$\text{SV} / \text{AoV VTI} / 100$

Note: [LVOT Diam] can only be performed in 2D mode

<<Measurement points>>

1) Measure [LVOT Vel]. Measure [HR].

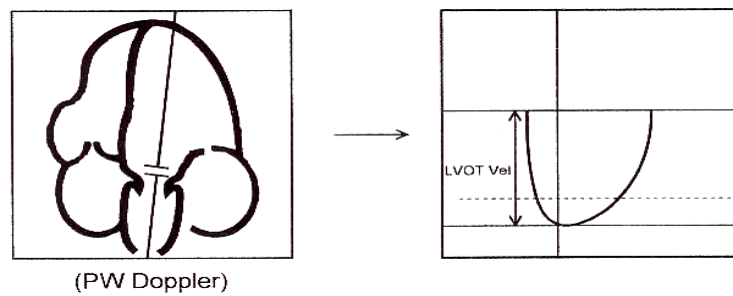


Fig.5- 20

2) Measure [LVOT Diam]

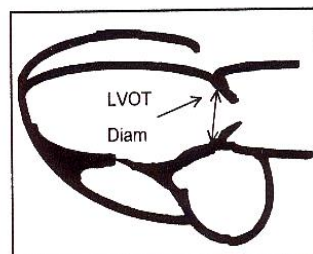


Fig.5- 21

3. TV

Measurement of tricuspid valve function is performed by using Doppler images.

<<Measurement items>>

Meas. Item name	Contents	Meas. Method
TV VTI	Tricuspid valve VTI [m]	Refer to "Manual Trace Measurement "
TV VM	Tricuspid valve mean velocity [cm/s]	Refer to " Manual Trace Measurement "
TV VP	Tricuspid valve maximum velocity [cm/s]	Refer to " Manual Trace Measurement "
TV MPG	Tricuspid valve mean pressure gradient [mmHg]	Refer to " Manual Trace Measurement "
TV PPG	Tricuspid valve maximum pressure gradient [mmHg]	Refer to "Manual Trace Measurement "

TV Vel	Tricuspid valve velocity [cm/s]	Refer to "Velocity Measurement"
TV PG	Tricuspid valve pressure gradient [mmHg]	Refer to " Velocity Measurement"

<<Measurement points>>

- 1) Measure [TV VEL Trace]

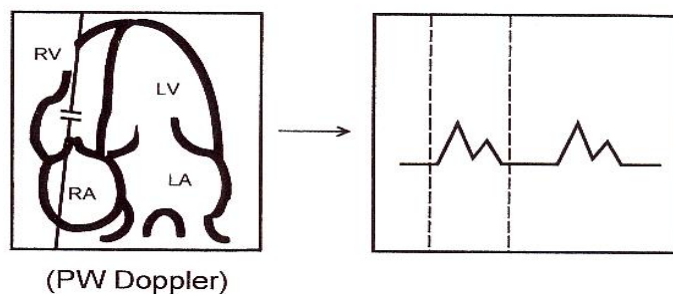


Fig.5-22

- 2) Measure [TV VEL]

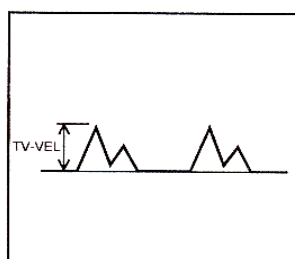


Fig.5-23

4. PV

Measurement of pulmonary valve function is performed by using a Doppler image.

<<Measurement items>

Meas. item name	Description [Unit]	Meas. method
PV VTI	Pulmonary valve VTI [m]	Refer to "Full Trace Measurement ".
PV VM	Pulmonary valve mean velocity [cm/s]	Refer to "Full Trace Measurement ".

PV VP	Pulmonary valve maximum velocity [cm/s]	Refer to "Full Trace Measurement ".
PV MPG	Pulmonary valve mean pressure gradient [mmHg]	Refer to "Full Trace Measurement ".
PV PPG	Pulmonary valve maximum pressure gradient [mmHg]	Refer to " Velocity Measurement"
PV Max Vel	Maximum velocity [cm/s]	Refer to " Velocity Measurement"
PV Max PG	Maximum pressure gradient [mmHg]	Refer to "Velocity Measurement"
PV Diam	Pulmonary artery diameter [mm]	Refer to "Distance Measurement in B mode"
HR	Heart rate [bpm]	Refer to "Heart Rate Measurement (HR)"
RV ET	Ejection time [ms]	Refer to "Time Measurement (Time)"
RV AcT	Acceleration time [ms]	Refer to "Time Measurement (Time)"
RV PEP	Pre-ejection period [ms]	Refer to "Time Measurement (Time)"



NOTE: [PV Diam] can only be performed in 2D mode.

<<Calculation items>>

Calc. item name	Description [Unit]	Calc. formula
SV	Stroke volume [mL]	$0.785 \times (\text{PV Diam})^2 \times \text{abs VTI }$
CO	Cardiac output [L/min]	$\text{SV} \times \text{HR} / 1000$
RV AcT/ET	Ratio of AcT to ET	$\text{RV ACT} / \text{RV ET}$
RV STI	Systolic time interval	$\text{RV REP} / \text{RV ET}$

<<Measurement points>>

1) Measure [PV Vel]

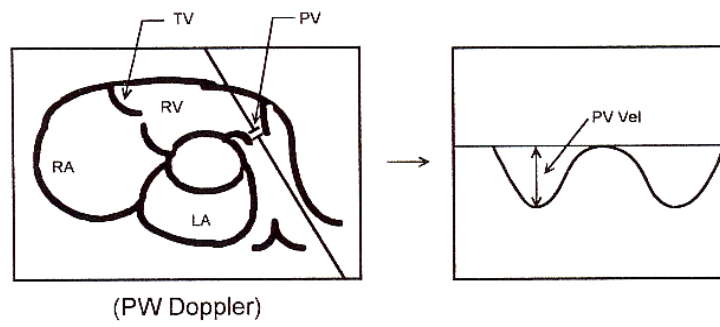


Fig.5-24

2) Measure [PVV Trace]

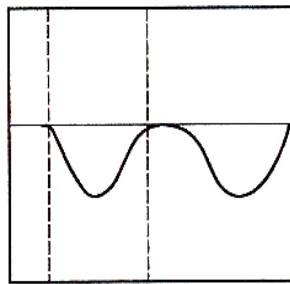


Fig.5-25

3) Measure [ET],[ACT], and [PEP]

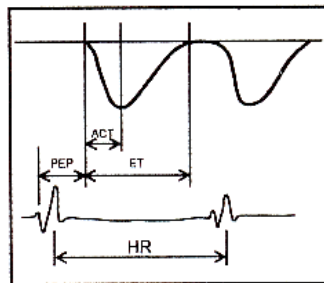


Fig.5-26

4) Measure [PV Diam]

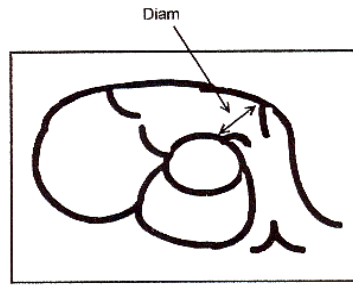


Fig.5-27

5.3.3.3 Urology Measurement in PW mode

The measurement method and calculation items are the same as general measurement in PW mode.

5.3.3.4 Pediatric Measurement in PW mode

The measurement method and calculation items are the same as general measurement in PW mode.

5.3.3.5 Small parts Measurement in PW mode

The measurement method and calculation items are the same as general measurement in PW mode.

5.3.3.6 Vascular Measurement in PW mode

Refer to general measurement in PW mode.

5.3.3.7 GYN Measurement in PW mode

The measurement method and calculation items are the same as “manual trace”.

5.3.3.8 OB Measurement in PW mode

The measurement method and calculation items are the same as “manual trace”.

5.3.3.9 TCD Measurement in PW mode

Refer to general measurement in PW mode.

5.4 Edit measurement results

After the user finishes the measurements, this system allows users to move the position of measurement results, or change the font size of measurement results.

To move result position, operations are as follows:

1. In the measurement status, rotate SK2-key to choose “Move result position”.
2. Press SK2-key, and use trackball to move the position of measurement results.
3. Press Enter-key to confirm it.

To reset result position, operations are as follows:

1. In the measurement status, rotate SK3-key to choose “Reset result position”
2. Press SK3-key, the position of current measurement result will be reset back to default.

To change the font size of measurement results, operations are as follows:

In the measurement status, rotate SK1-key to adjust the font size of measurement results.

To reset the font size of measurement results, operations are as follows:

In the measurement status, press SK1-key, the font size of measurement results will be reset back to default. The system default font size can be set in system setting, refer to 7.2.

5.5 Report

After finishing the exam, press the Report-key to pop up report interface, edit and print the report.

Report Interface:

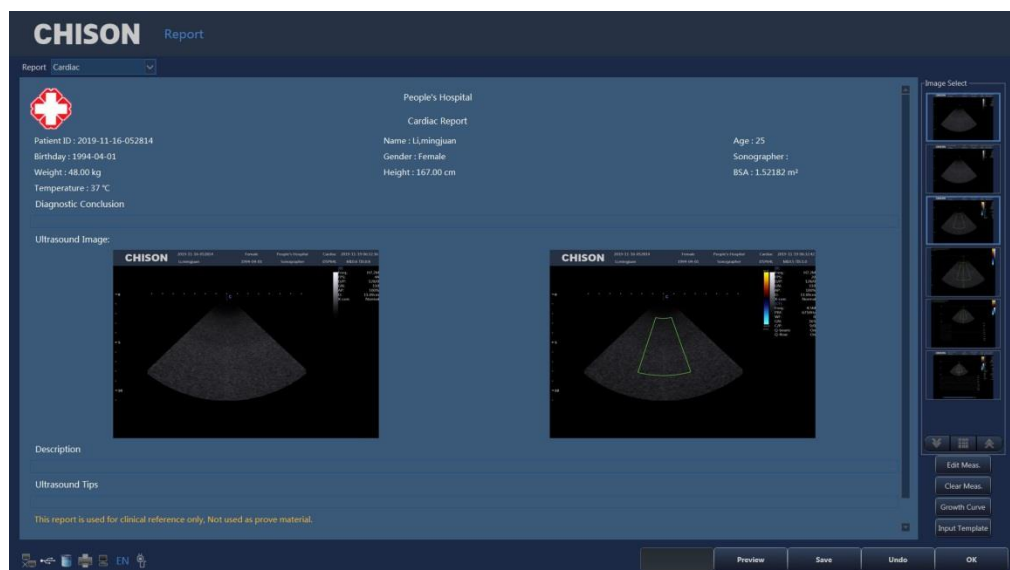


Fig.5- 28

Choose the image: Click the image can add the image to the image area in the report, and click the image in the report to remove it.

Preview: preview the whole report and its format before printing

Print: print the current report, please make sure that the printer is normal working.

Save: store the report on the disk.

Undo: cancel the operation and exit the interface

OK: confirm the operation and exit the interface

Edit Meas: Press this icon to enter into Measurement Edit Item. Choose the measurement result, which you want to display in the report. Customer also can edit the result.

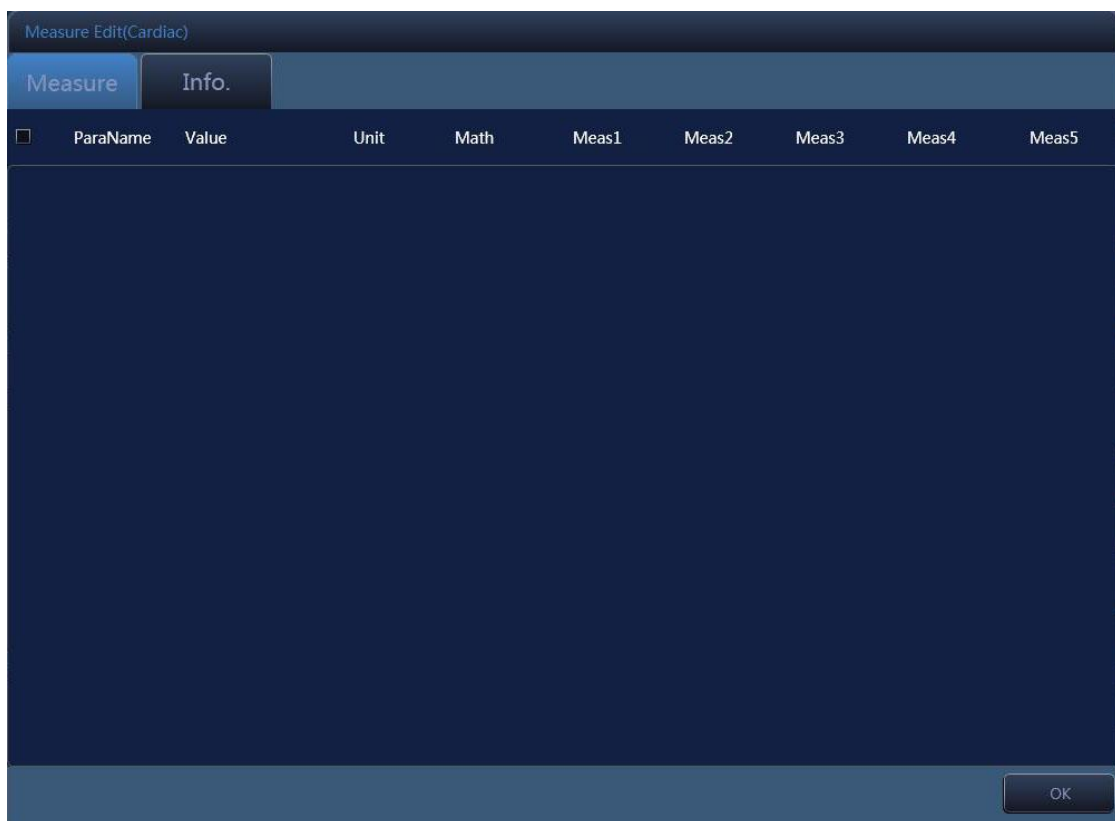


Fig.5-29

Graph: Under OB report you can press this icon to enter in to see the fetal production graph.

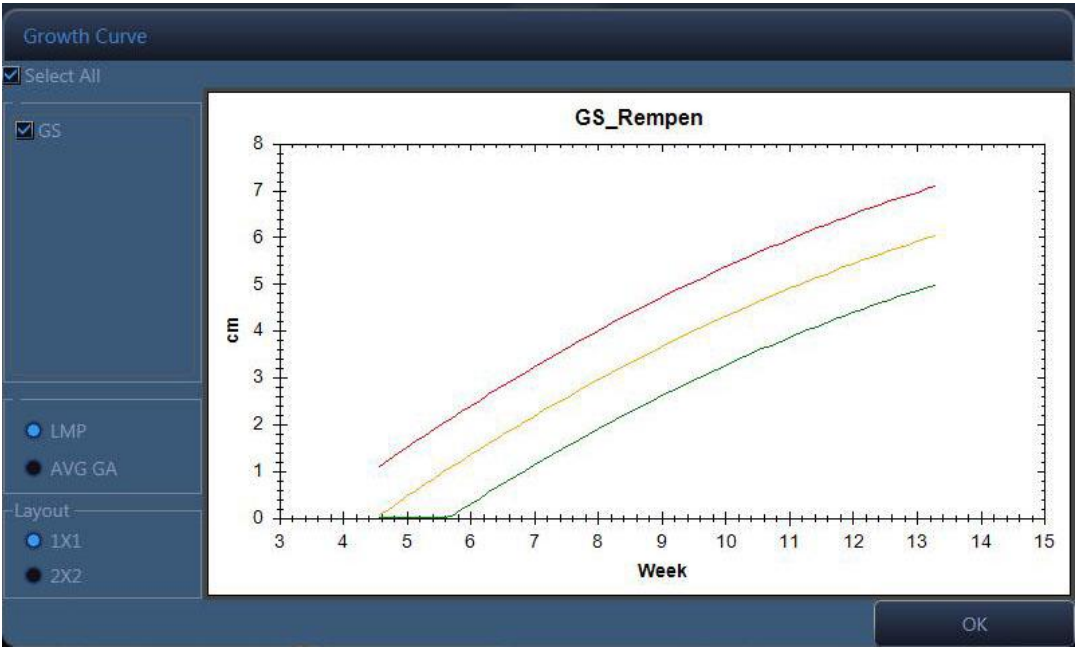


Fig.5-30

Input Template: Input annotation from templates.

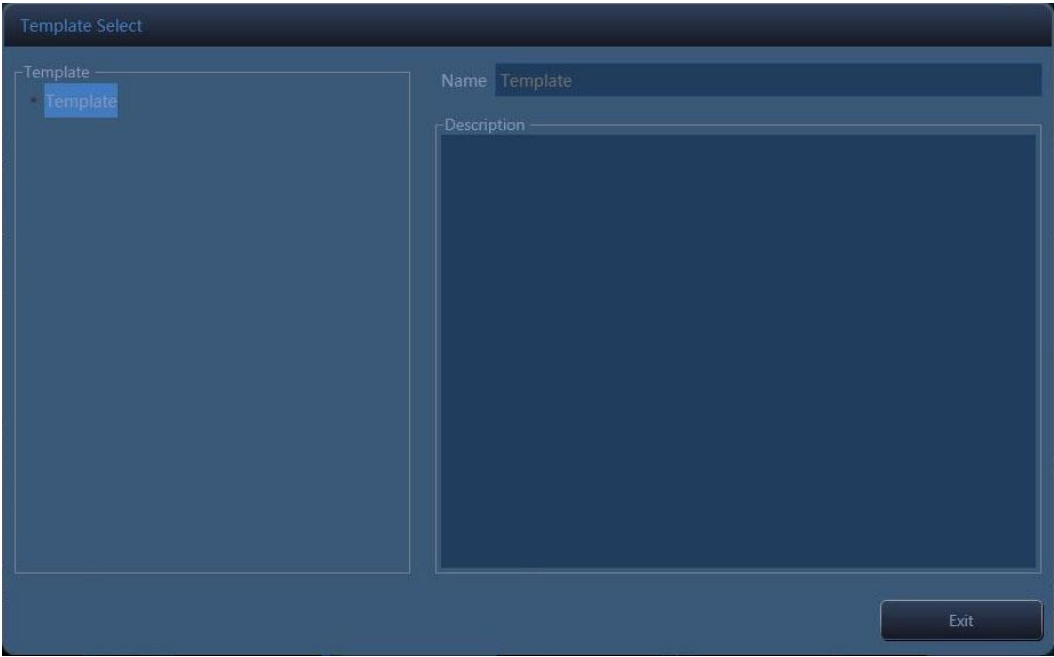


Fig.5-31

Chapter 6 Preset

6.1 Recall Preset



- a) Press button to choose the probe type.
- b) Choose a clinical application.
- c) Choose a preset.

The default choice of the system is DEFAULT preset.

After entering into the system, if you want to change preset and do not want to quit the current interface, operate as follows:

1. Press MENU- knob.
2. Rotate MENU- knob and select [Utility] item.
3. Press MENU-knob to enter into the item.
4. Now SK2—SK5 Shortcut keys and touch screen are corresponding with following operation:

SK2—rotate SK3 to choose the clinical application.

SK3—rotate SK3 to choose the preset.

SK4—press SK4 edit user name (just user 1 to user 5 can be edited).

SK5—press SK5 to save preset. (Just can save into user 1 to user 5,which can be edited)

Load Preset on touch screen—press to load preset.

6.2 Save user defined preset

- 1) Choose and recall a preset first.
- 2) Adjust parameters to current preset.
- 3) Press MENU-knob when adjustment is finished. Rotate MENU-knob and select [utility] item.
Press MENU-knob to enter.
- 4) Rotate SK2 to choose clinical application name (skip this step if do not need adjustment).
- 5) Rotate SK3 to choose the name of preset (skip this step if do not need adjustment).

- 6) Rotate SK4 to choose user defined. Press SK4 for editing user name. (Just user 1 to user 5 can be edited).
- 7) Press SK5 to save preset.

6.3 Manage Preset



Press key to enter into system setting interface. Select preset page. Add or delete the current preset.

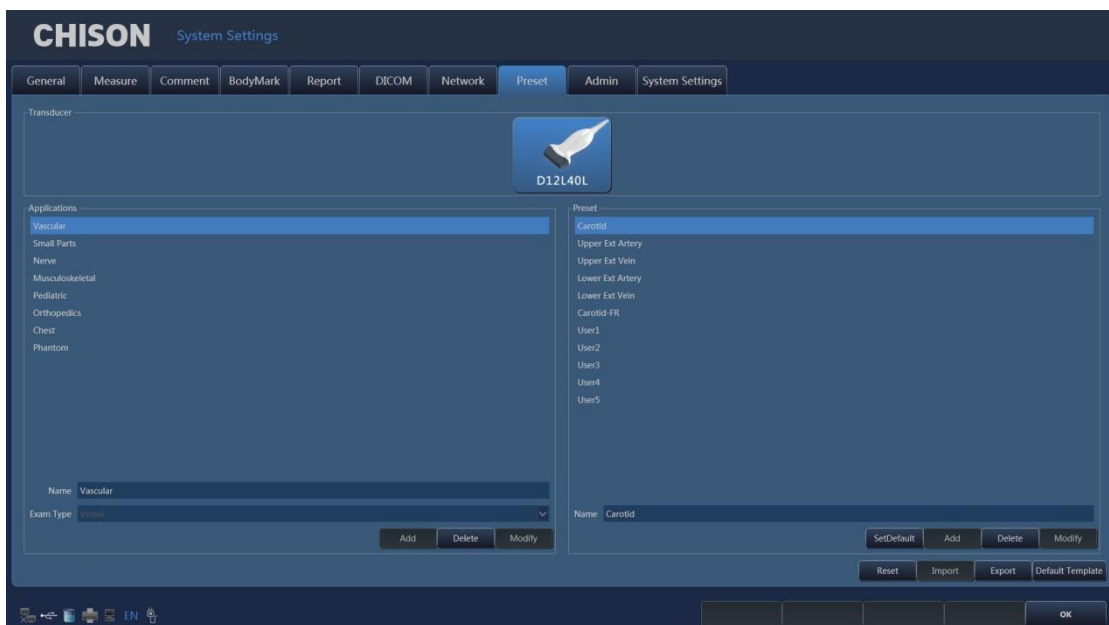


Fig.6-1

Name: input Application/Preset/User Defined name.

Exam Type: select clinical application.

Add: add Application/Preset.

Delete: delete a Application/Preset.

Modify: revise Application/Preset/User Defined name

SetDefault: user can set the default preset of the probe on the first connector

Reset: restore the preset to factory setting.

Import: import preset to system. Plug in U disk which has preset. Press Import key ,preset can be imported into the system .

Export: export system preset. Plug in USB, press the Export key, system automatically derive the preset to U disk.

OK: exit system setting interface

Chapter 7 System Setting



Press the key to enter system setting interface. User can do user-defined setting.

7.1 General settings

Normal Settings:

Set the hospital information, date-time, language etc.

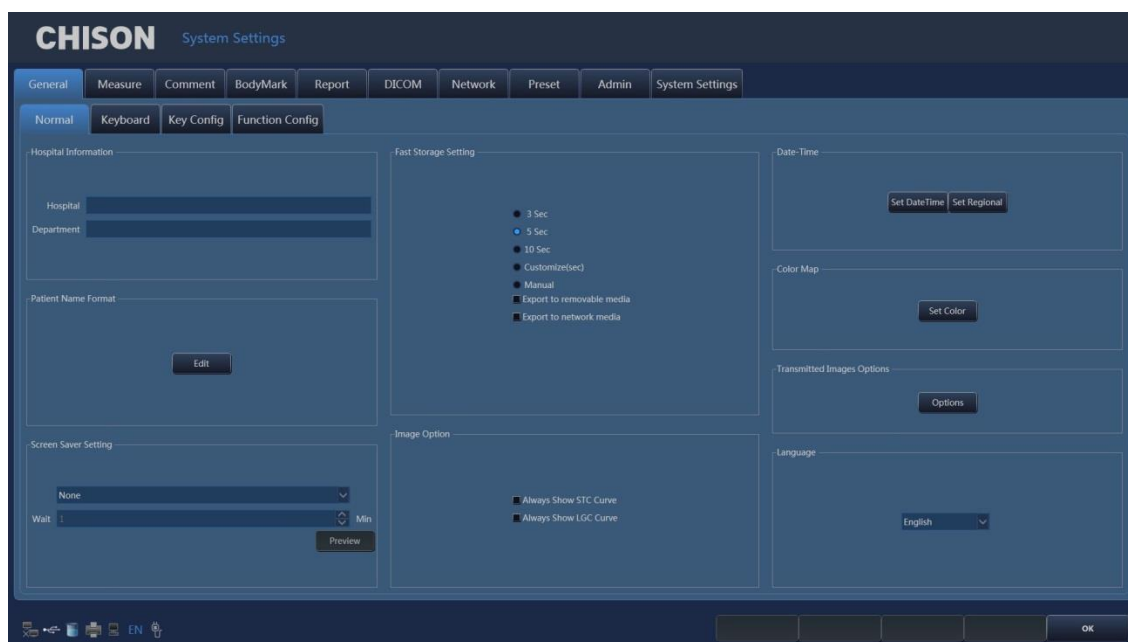


Fig.7-1

Hospital Information	Hospital; Department	Input hospital name, department name
Screen Saver Setting	To set Screen Saver ON or OFF and Screen Saver wait time.	
Fast storage setting	3 seconds/5 seconds/10 seconds fast storage Customize storage seconds Manual storage Export to removable media	Please refer 4.4.6

	Export to network media	
Image Option	Always show STC Curve Always show LGC Curve	Select according to the requirement.
Date-Time	Set Date Time Set Regional	Set Date and time (need password) Set Time Zone, Data Format, Time Format
Color Map	Set Color	Click the Configure key to set the color map
Transmitted Images Options	Set transmitted images	Set according to the requirement
Language	Chinese;English; French; Spanish; Russian; Polish; Portuguese; Danish; German; Italian; Turkish; Romanian	Switch language interface

Keyboard Settings

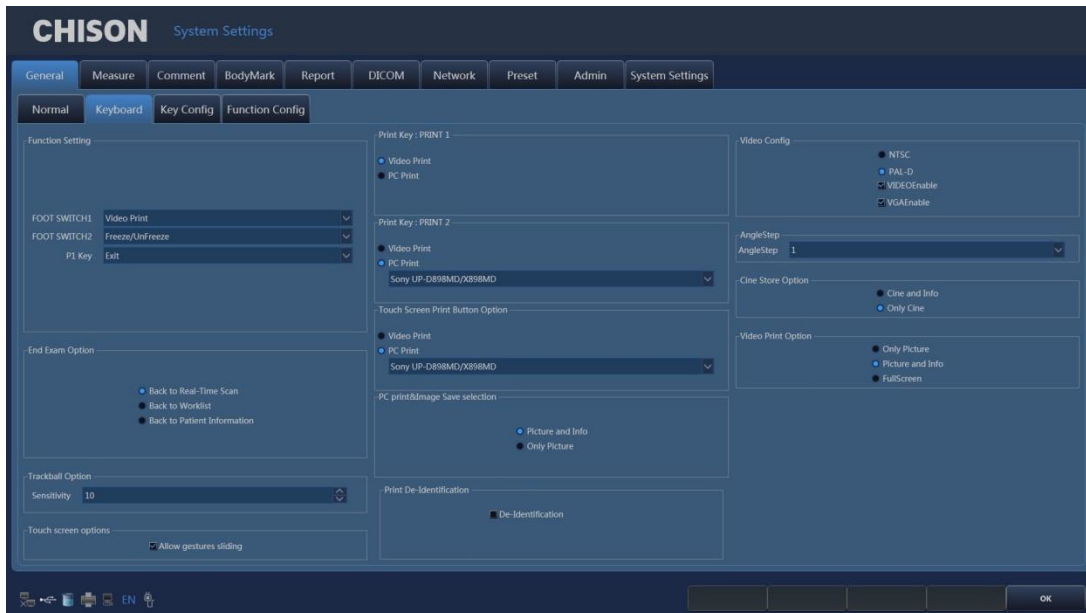


Fig.7-2

Function Setting	FOOT SWITCH1	Choose the function for User1
	FOOT SWITCH2	Choose the function for User2
	P1 Key	Choose the function for P1-key
End Exam Option	Back to Real-Time Scan	Select according to the requirement.
	Back to Worklist	
	Back to Patient Information	
Trackball Option	Sensitivity(1~20)	Set the sensitivity of the trackball option.
Touch screen options	Allow gestures sliding	
Print key: Print 1, Print 2, Touch Screen Print Button	Video Print; PC Print	Set the print-key function
PC print & Image Save selection	Picture and info or Only Picture	Please refer to 3.6.3
Video Config	NTSC, PALD	Set the video standard
	VIDEOEnable	Select "Video Enable" to enable video port
	VGA Enable	Select "VGA Enable" to enable VGA port
Cine Store Option	Cine and Info	Select according to the requirement.
	Only Cine	

Key Config:

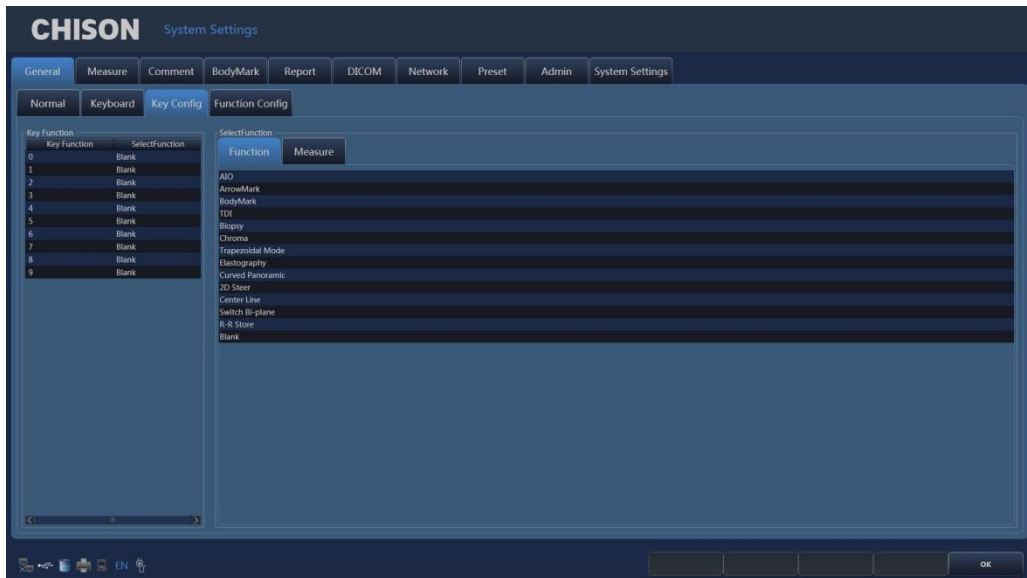


Fig.7-3

Set the function for the 0~9 keys of Alphanumeric Keyboard. Select the Key Function that want to set, then select the Function for the selected key.

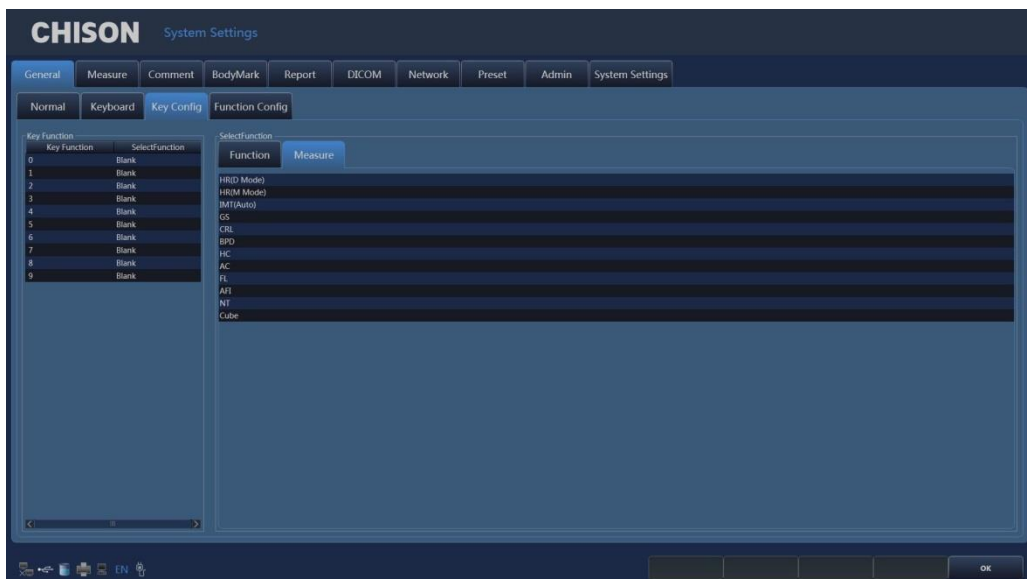


Fig.7-4

Set the function for the 0~9 keys of Alphanumeric Keyboard. Select the Key Function that want to set, then select the Measure for the selected key.

Function Config:

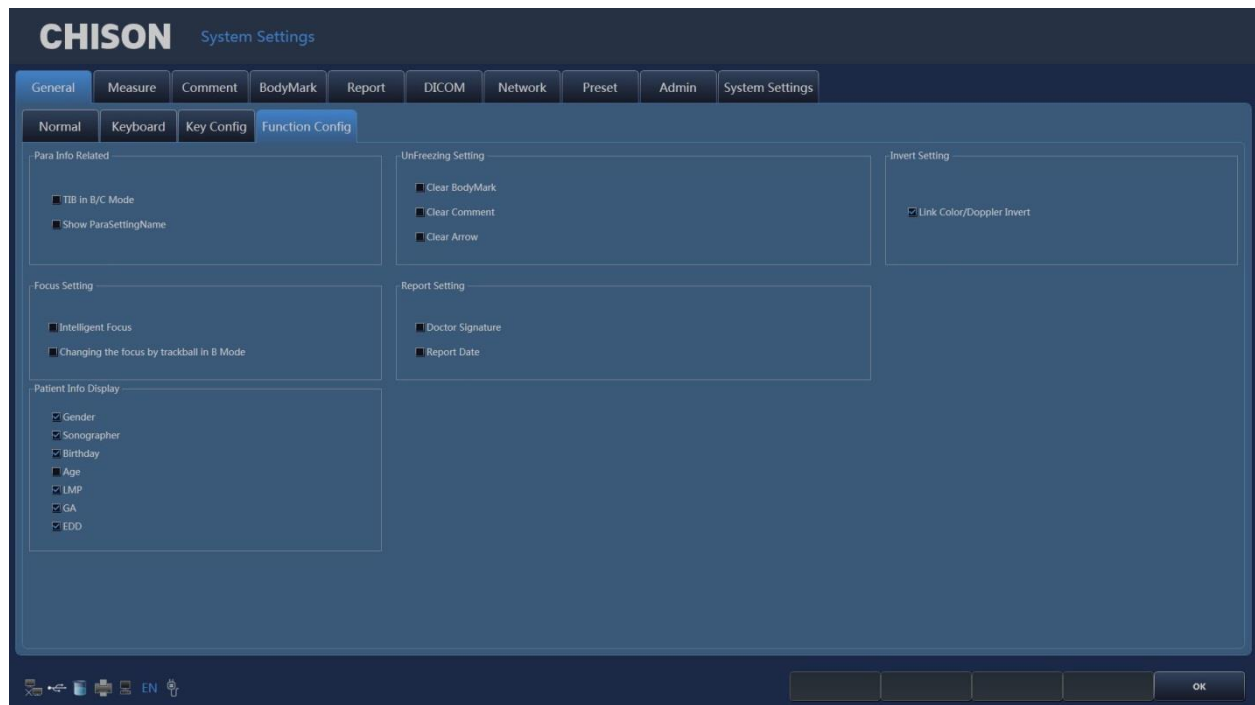


Fig.7-5

Items	Description
Para Info Related	Select to display TIB in B/C mode and show para setting name
Focus Setting	Select it to change the focus by trackball in B Mode or focus position changed by depth
Patient Info Display	Select to display Gender and Age
UnFreezing Setting	Set the Unfreezing setting: Select to Clear BodyMark, Clear Comment, and Clear Arrow when Unfreezing the image.
Report Setting	Select to display Doctor Signature and Report Date in the report.
Invert Setting	Select it to set color/Doppler Invert

7.2 Measurement

Set the measurement formula of measurement.

Edit Settings:

Click the measurement page, and click on the Edit page, then users can edit custom configuration measurement.

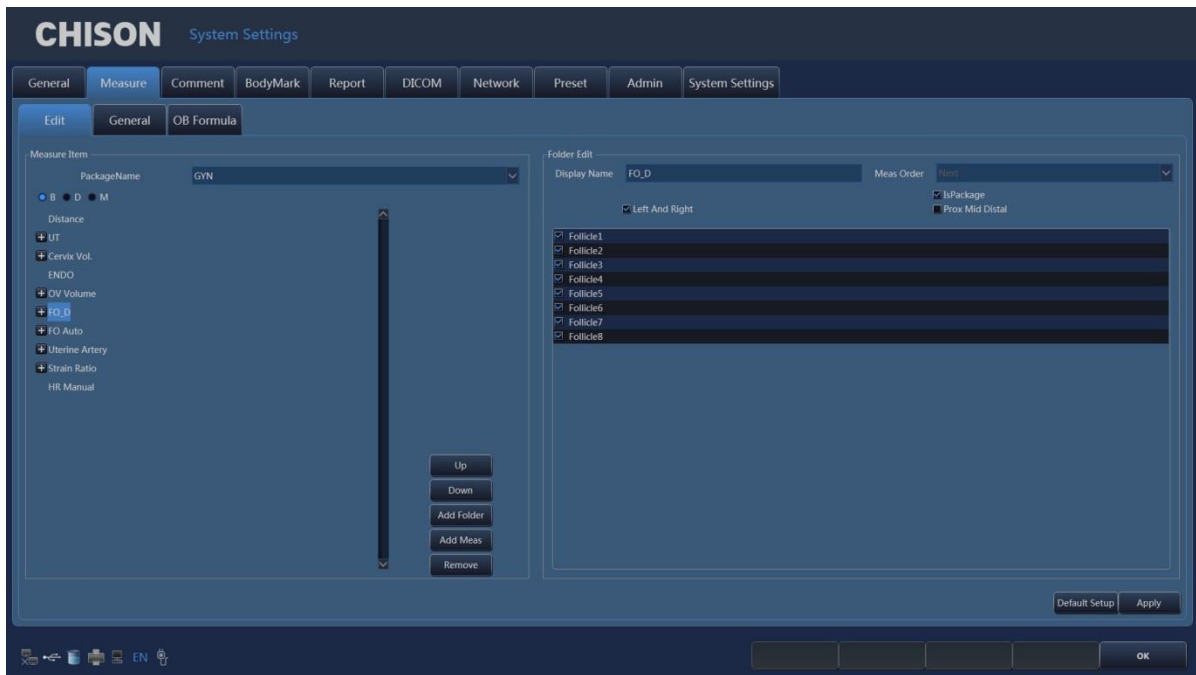


Fig.7-6

1. Package Name: Choose the different examinations.
2. Choose the different exam modes.
3. Choose the measurement item and click "UP" or "Down" button to move it's position.
4. Add Folder: Click this button to add a new item.
5. Clicking "Add Meas." can add a new measurement.
6. Remove: Click this button to remove the selected item.

General Settings:

Click the General page, and you can do some general settings of measurement items

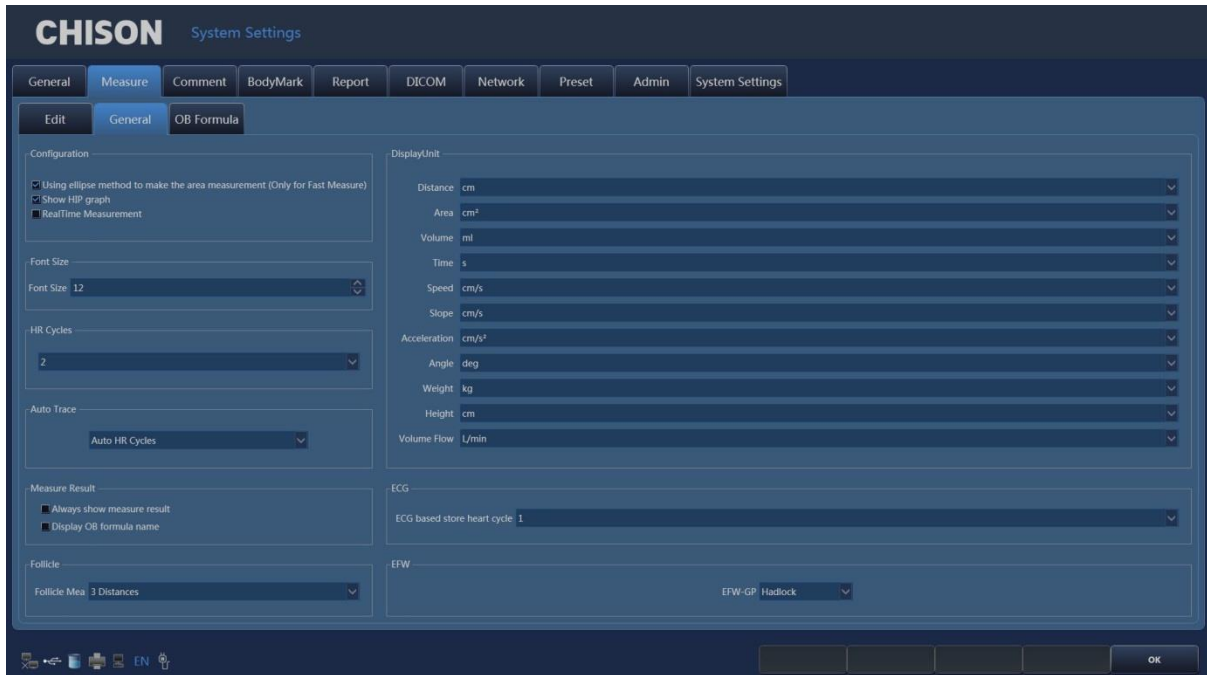


Fig.7-7

Items	Description
Configuration	Select according to the requirement
Font size	Set to default font size of the measurement results
HR cycle	One: one cycle to measure heart rate in the Doppler envelope calculation Two: two cycles to measure heart rate in the Doppler envelope calculated, the result will be more accurate. 1~6 can be chosen.
Auto Trace	Select Auto HR Cycles or Manual HR Cycles
Measure Result	Select according to the requirement
Follicle	Select Follicle measurement (2 distances or 3 distances)
Display Unit	Set the unit of measurement results
ECG	Select ECG based store heart cycle
EFW	Select measurement of EFW, Hadlock, Brenner, Williams

OB Table Setting:

Click OB Table page, you can set the formula of the OB measurement items for measuring fetal weight formula.

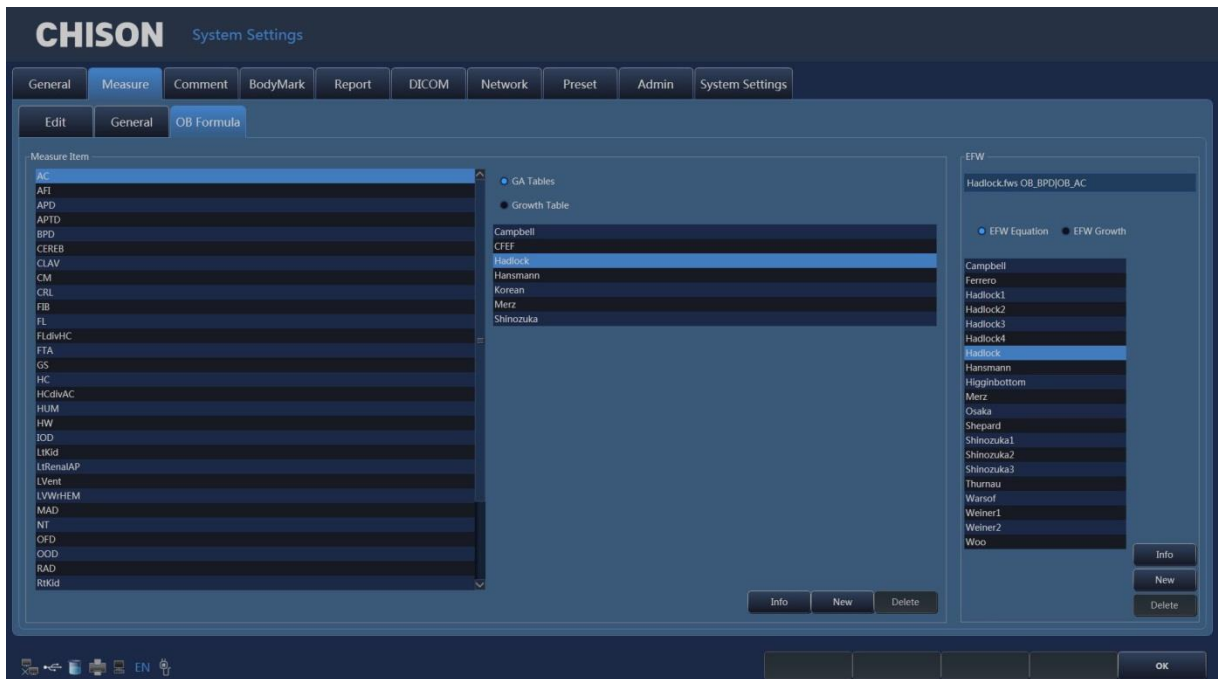


Fig.7-8

Set measurement Item: choose a measurement project, gestational age table or developmental table, and then choose a formula, click the information button, you can view the current formula. Click New, you can create a new formula in the current directory.

Fetal Weight: Select the EFW equation, or EFW development table, and then choose a formula, click on the information button, you can view the information of current fetal weight formula. Click New, you can create a new fetal weight formula in the current directory.

7.3 Comment

Set the comment function, manage the comment Library.

Options Page:

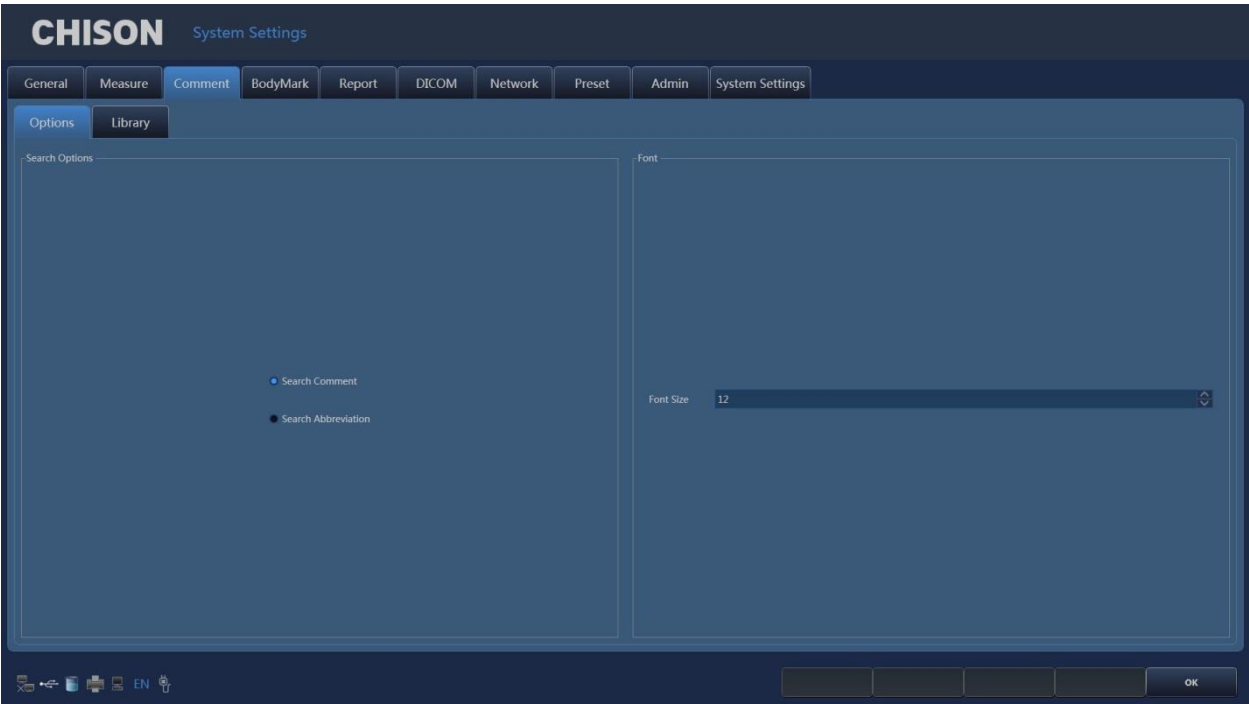


Fig.7-9

Search option	Search comment or Abbreviations	Input search function Select the comment item, it will search notes when searching Select abbreviations, it will search abbreviations when searching
Font size	Font size	Set the font size of notes

Library Page:

Edit and delete the annotation in the comment library.

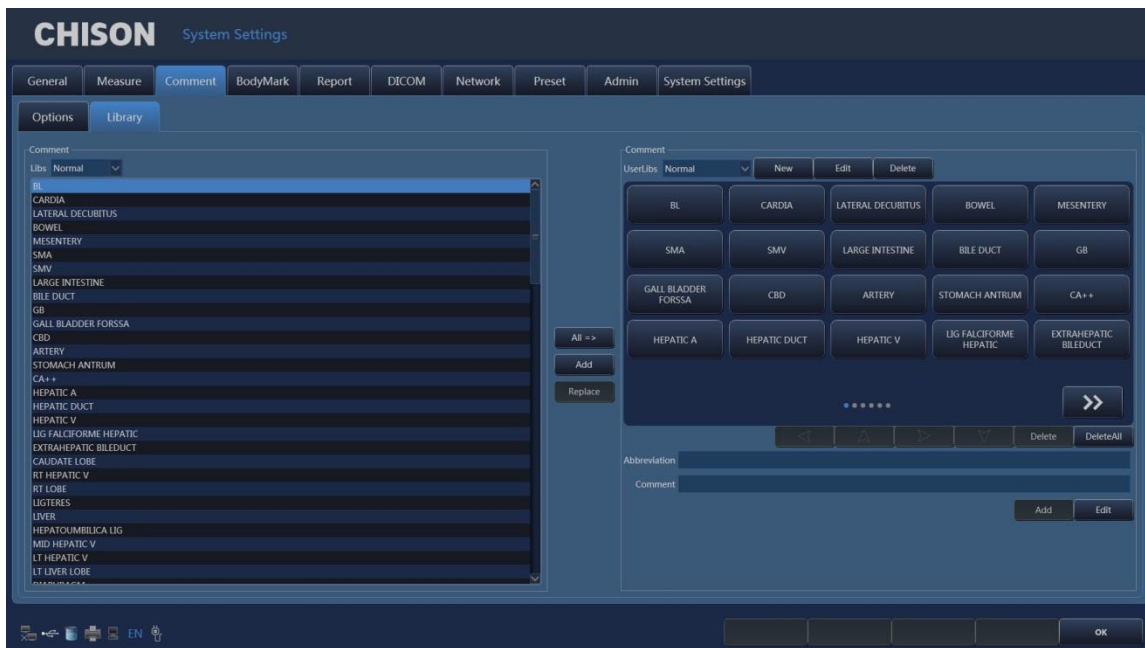


Fig.7-10

Comment Libs	Provide the comment notes in different exam types.
Comment UserLibs	List the comment notes have been chosen from Libs and added by user.
Exam type in UserLibs	Establish the new exam type: click New near the drop-down list on the right to establish the new exam type.
	Edit the name of the exam type: click Edit near the drop-down list on the right to edit the name of current exam type displayed in the drop-down list box.
	Delete the exam type: click Delete near the drop-down list on the right to delete the current exam type displayed in the drop-down list box.
Comment notes	Add comment notes from Libs: select the comment note on the left, click “->” to add it on the right; click “=>” to add all comment notes on the left to the UserLibs.
	Add comment notes by user-defined: input the comment note in boxes after Abbreviation and Comment, and click Add to create the new comment note.
	Click delete, delete all to delete the selected note or all the notes on the right.
	Edit the comment note: select the comment note on the right, and input comment notes in boxes after Abbreviation and Comment, then click Edit to

	edit the selected comment note.
	Click Up, Down, Top, Bottom to adjust the sequence of the comment note selected.
OK	Click OK to save the edit and exit the system settings interface.

7.4 BodyMark

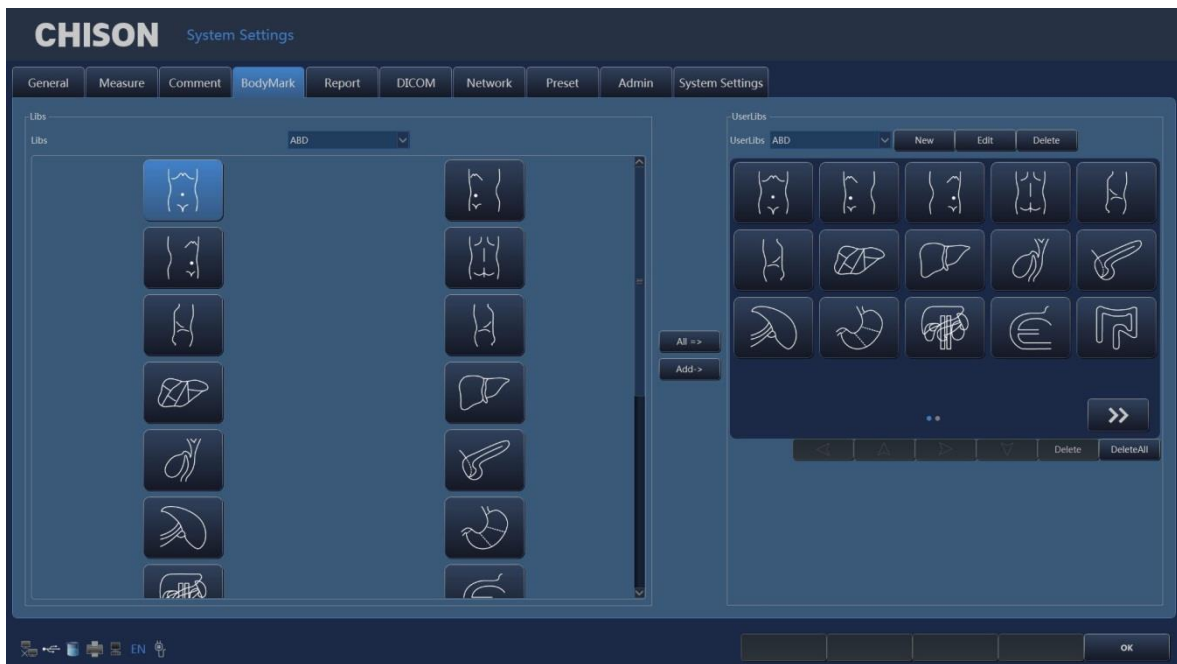


Fig.7-11

This function is to preset body marks in each preset or application of probes.

Libs: provide different body marks of different presets or applications of probes

UserLibs: list the body mark chosen from the Libs.

Establish the new category in the UserLibs:

Click the New icon near the drop-down list in the right to create a new category of body marks.

Click the Edit icon near the drop-down list in the right to change the name of current category displayed in the drop-down list box.

Click the Delete icon near the drop-down list in the right to delete the current category displayed in the drop-down list box.

Add or delete body mark:

Click  to add the selected item in the body mark library into User Body Mark.

Click  to add all items in the body mark library into User Body Mark.

Click Delete icon to delete the selected item on the right.

Click Delete All icon to delete all items on the right.

Click  to adjust the sequence of the selected items.

7.5 Report

Including the report design and report template

Customize settings:

Set the design of the report

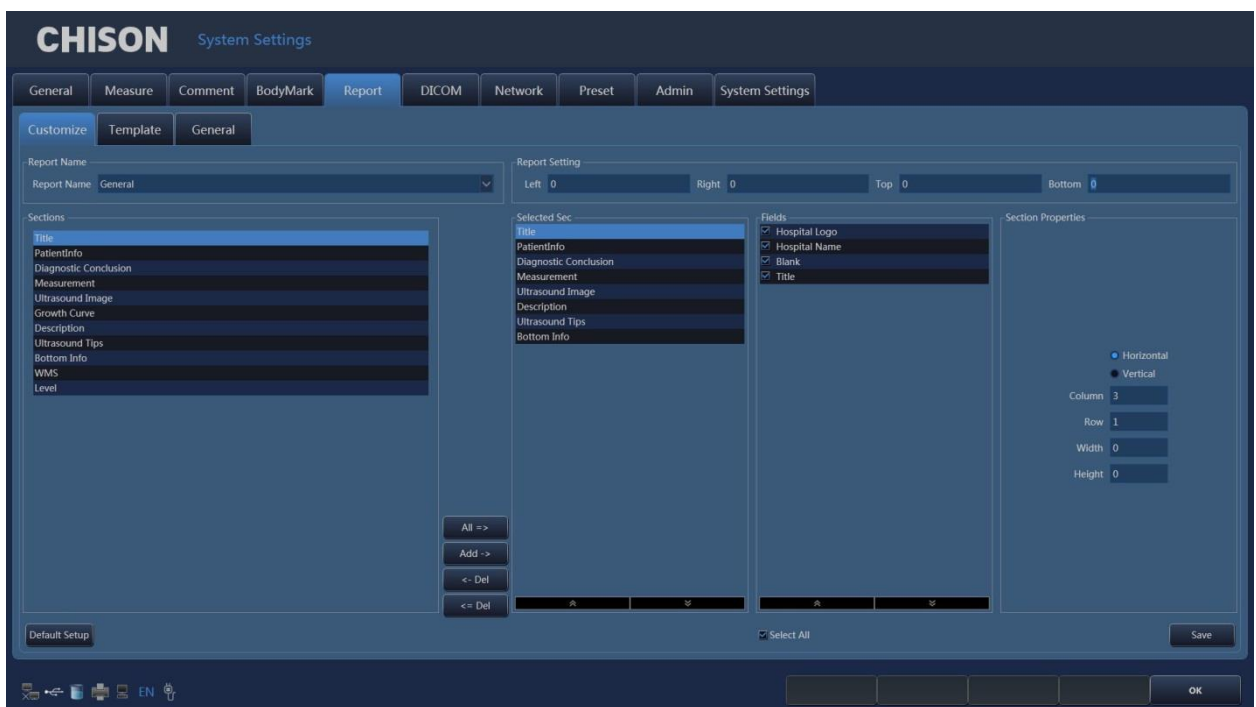


Fig.7-12

Report Name: select report type.

Report Setting: Set left, right, top and bottom margins.

Sections: list all the sections which can be added.

Selected sections: Section used in current report.

Fields: Display the content of the selected section.

All: Click this button to add "available section "to " selected section.

Add: Select the section that need to be added, then click this button, add selected section "selected section".

Delete: Select the section that need to be deleted, then click this button, delete the selected section from the "selected section".

Delete all: Click this button to empty the content of "selected section".

Section Properties: Set the display of section, you can select arrange horizontally or vertically.

Set rows and columns of the arrangement.

Select the "Ultrasound image", set the width and height of the image.

Save: After setting the current report, click the button, save the settings.

OK: Save and exit the page.

Template Page:

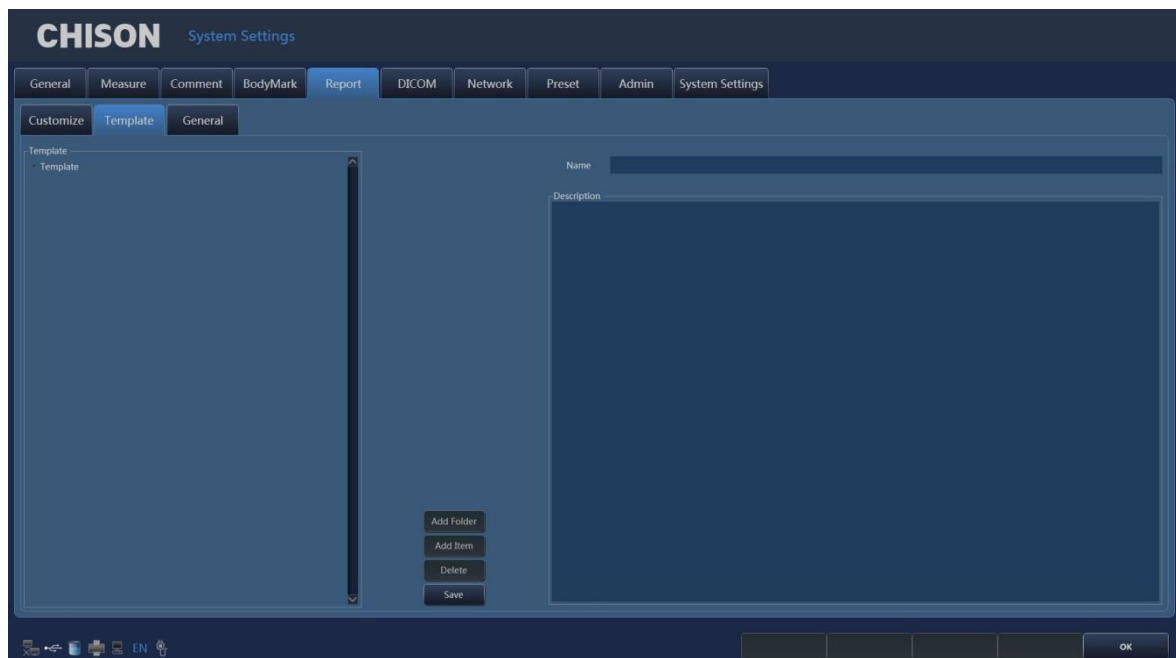


Fig.7-13

Modify template note: Select the template note which you want to change, input modification content in the right box

Add Folder: Press this icon to add a new Folder and name it.

Add Item: Press this icon to a new Item under current folder, and name it.

Delete: Press this icon to delete the template, which you selected.

Save: Save the changes.

General Page:

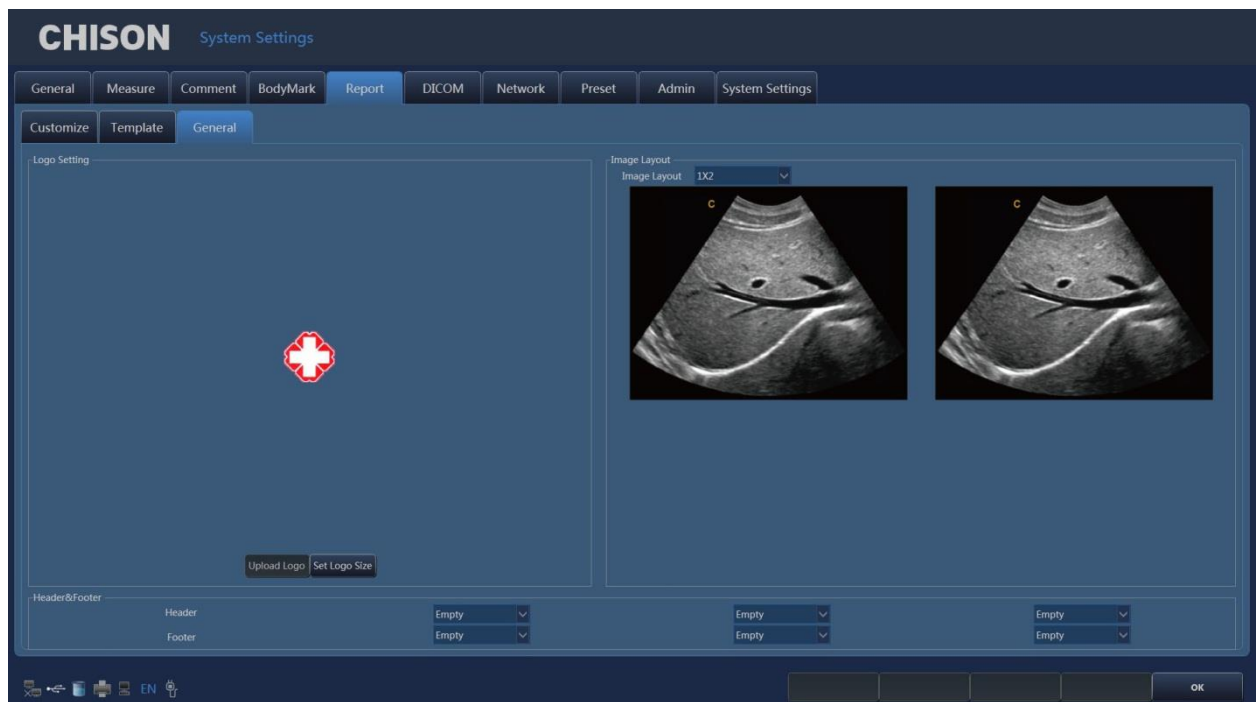


Fig.7-14

Logo Setting: Upload Logo and set logo size.

Image Layout: Choose different styles of image layout.

Header&Footer: Set the format of the header and footer.

OK: Save the changes and exit the system setting interface.



NOTE: the LOGO should be named with 'hLogo' in PNG format, which resolution is 168x169. And put LOGO file into the folder named 'hLogo'.

7.6 Admin

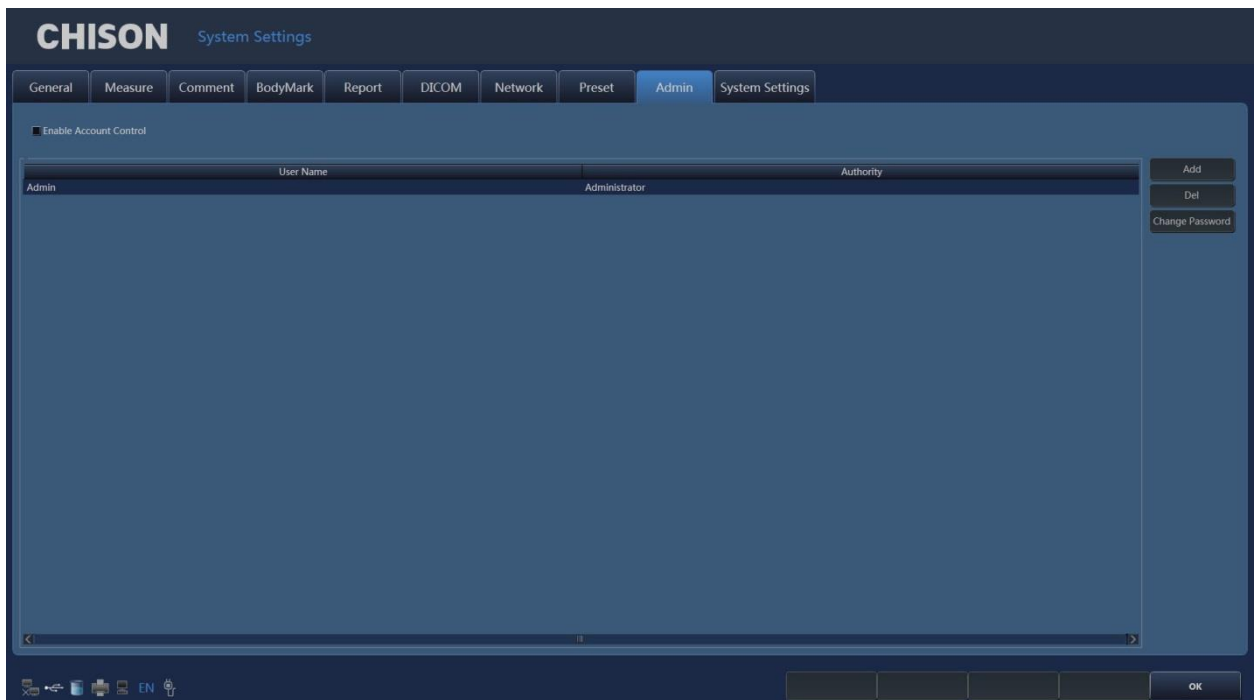


Fig.7-15

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

Enable Account Control: Select the “Enable Account Control” to enable Account Control. Unselect the “Enable Account Control” if the user doesn’t want to use the Account Control.

After enable Account Control, the user must use user name and password to login the system every time the system turns on. The login interface see as below.

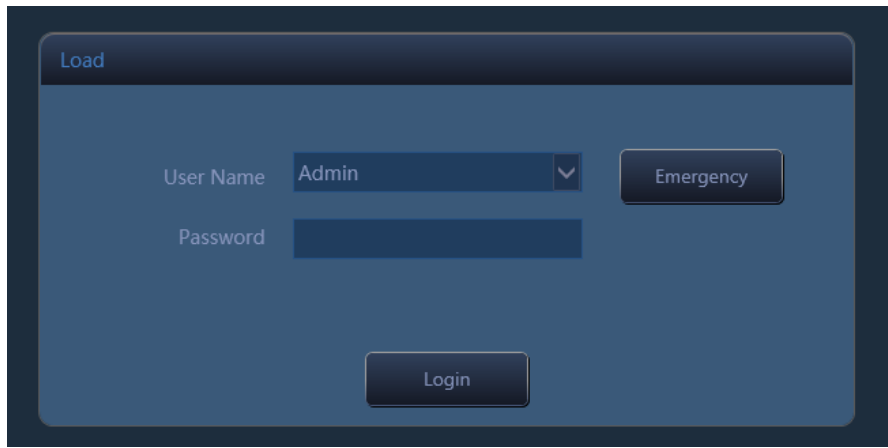


Fig.7-16

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

Password: Input the password for user name.

Login: Click the icon to login the system.

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

User can select the “Admin” to login first time, the default password for Admin is 123456.

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

Administrator user can review and manager all the patient information. Administrator user also cans manager the user account such as add or delete the accounts and change password for user accounts.

Customer user only can review and manager the patient that was created by user himself.

7.7 Network



Press  key to enter into the system setting unit. Click the page of Network Settings to enter into the network settings interface.

Before setting up the network settings, plug the cable into the LAN port of the system.

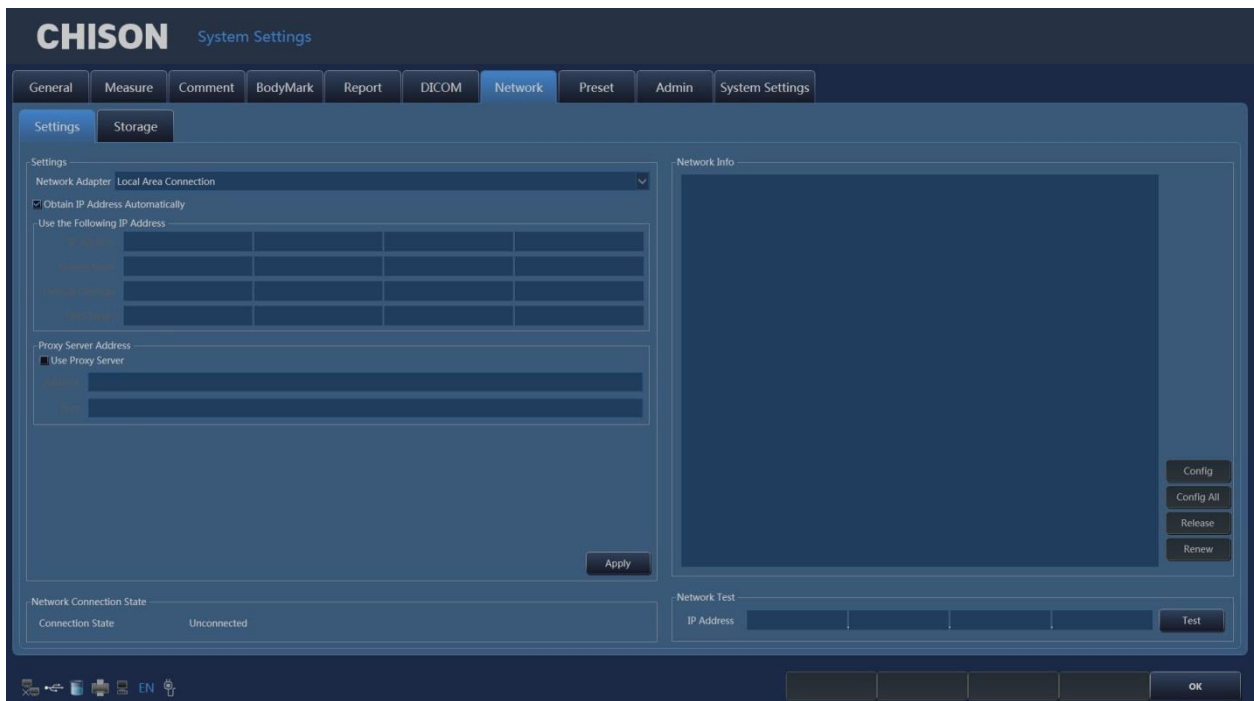


Fig.7-17

Network Settings:

Network Adapter	Display the existing network cards on this system. The user can select the network card for current use.
Obtain an IP address automatically	When this option is selected, the system will obtain an IP address automatically
Use the following IP address (recommended)	Set the IP address of the system manually. After setting, click Apply to confirm the application.
IP address	Input the IP address of the system manually, and make sure the IP address of the network printer is in the same network segment.
Subnet Mask	Input the subnet mask manually.
Default Gateway	Input the gateway manually.
DNS server	Input DNS server manually.
Network server Address	
Use Proxy Server	Select to use Proxy Server
Address	Input the address information

Port	Input the port information
Network Connection Status	Check the network connection status.
Connected	The system is connected to the network successfully.
Unconnected	The system is not connected to the network.
Network Information	Display the current network information
Config	Configuration information: Click this button to display the network configuration information
Config All	Click this button to display network details
Release	Release of the connection: Click this button to disconnect the current connection
Release	Release of the connection: Click this button to update the current connection status
Network test	In the case of network connection status is connected, enter the IP address of the test, click the test, you can test the network the connection status between the IP of current system and the IP that needs to be tested.

Network Storage:

With this feature, you can save the image to PC by network.

To use the network storage function, the user should connect the target computer to the network first, and build a new folder on the computer, right-click it to open the attribute, select shared page, set to share this folder on the network and allow network users to change the file (as shown below).



NOTE: the folder built on the computer is not allowed to sit on the desktop, otherwise create an error 67.

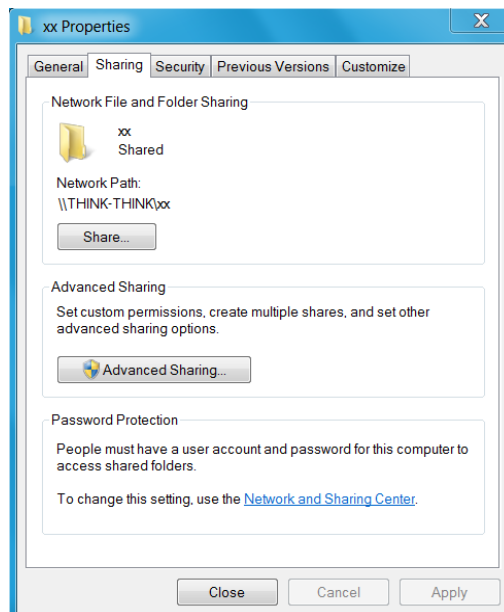


Fig.7-18

Click "Advanced Sharing"

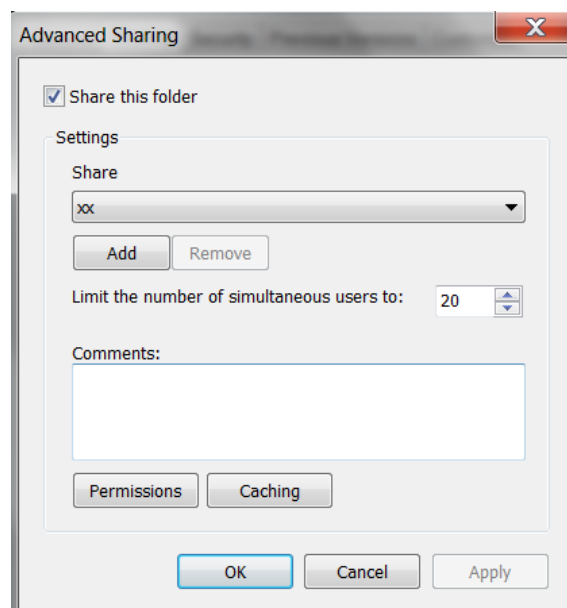


Fig.7-19

Select "Share this folder", and click "Permissions" to modify user permissions.

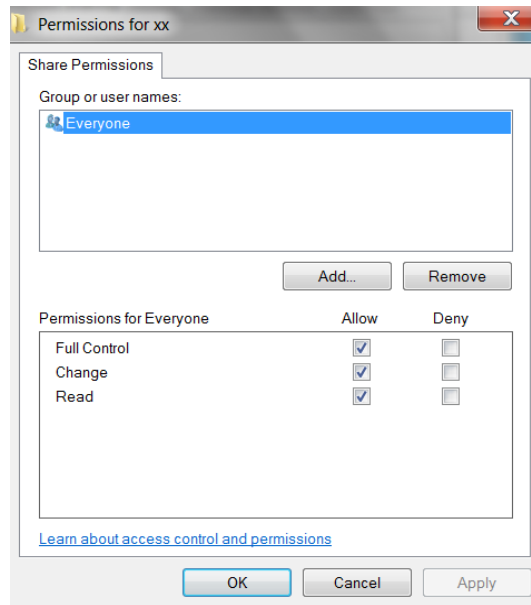


Fig.7-20

Select “Full Control”, “Change”, “Read” for “Allow”, click “OK” to complete modification.

Click Network Storage page, enter the network storage settings page. Then input shared directory name and IP address, and click Add.

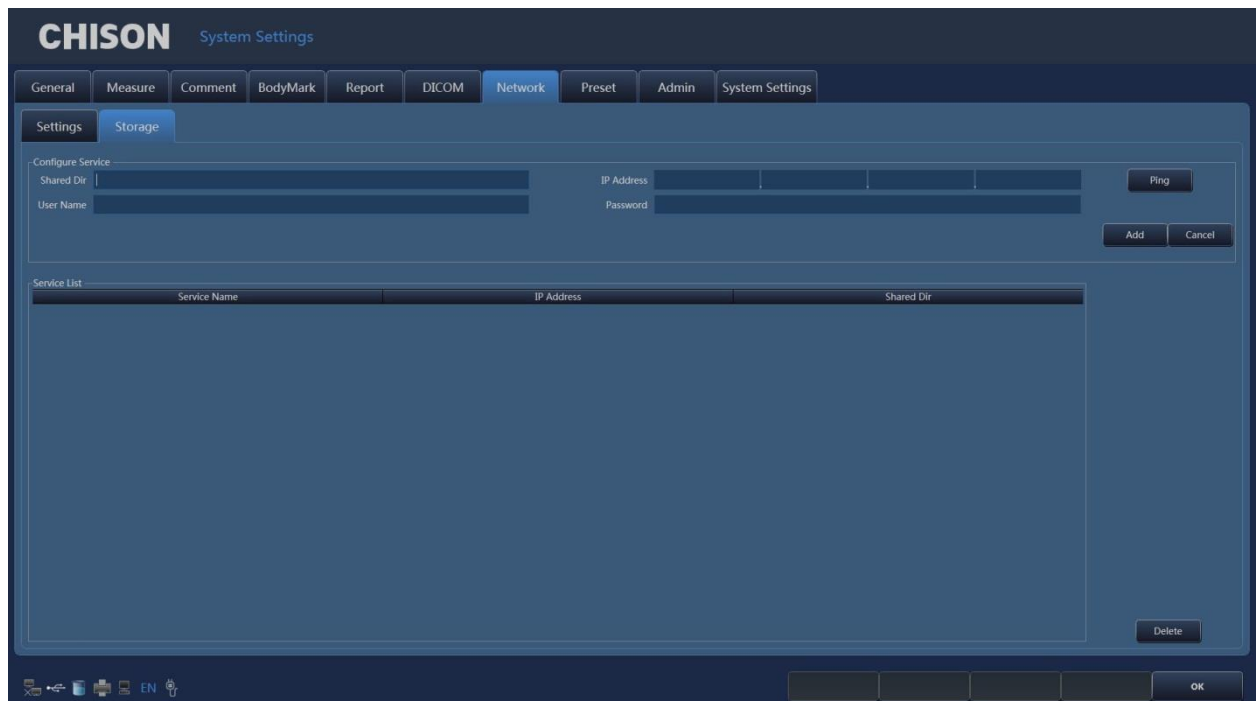


Fig.7-21

Shared Dir: The shared directory name should be same as the shared folder name in target computer.

IP address: the IP address of the computer with the shared directory.

User name: input the name of computer account.

Password: input the password of computer account.

Ping: Click it test the communication between the shared PC and the system.

Add: add a network storage service.

Cancle: press Cancle to clear the contents on Shared Dir, IP Address, User Name and password.

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

7.8 System

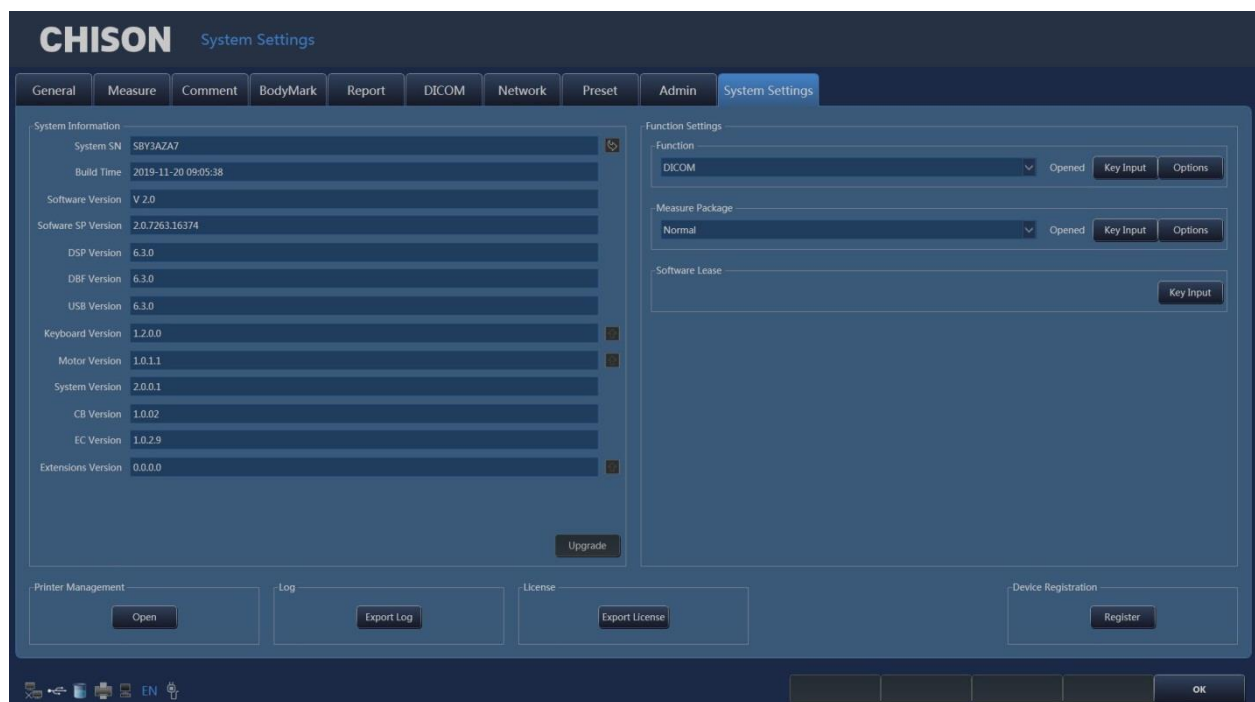


Fig.7-22

Display the settings of system configuration information and functions

System information:

System SN: display the unit SN

Build time: The build time of software

Version: display the current software version and hardware version.

SW Upgrade: When the U-disk with the upgrade software is inserted to the system, click this button to upgrade software.

FW Upgrade: When the U-disk with the upgrade FPGA is inserted to the system, click

this button to upgrade FPGA.

Function settings: Display the status of current function, click the “open” or “close” and input password to turn on or turn down the function.

Measure package: Display the status of current measurement package, click the “open” or “close” and input password to turn on or turn down the function.

Printer Management: Click open to set and manage the printer information.

Log: Select to export log.

License: Select to export license.

Device Registration: Select this item to activate the device if the user does not activate after powering on the system.

 **NOTE: DICOM is option. If need to turn on this function, the user need to input the password. Please contact the CHISON's authorized service engineer to get the corresponding password.**

Software Lease: Key Input

It is time to the data time, the system cannot be entered for use. User can decode by pressing Key Input key and input the code which gets from CHISON's authorized service engineer.

Log: Export Log

Plug in U disk to export log files which saved on system automatically for engineers to analyze.

License: Export License

Plug in U disk to export license to U Disk.

Printer management: Users can manage the printers. Click “Open” to into the printer management screen.

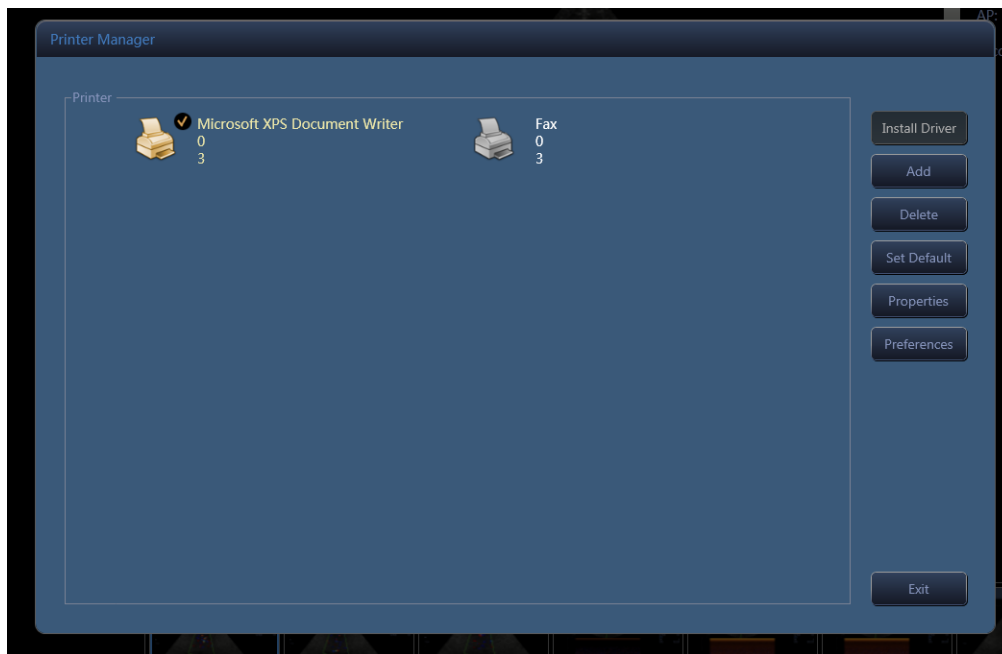


Fig.7-23

Operating methods: insert U disk with installation driver to the system, click “Install Driver”.

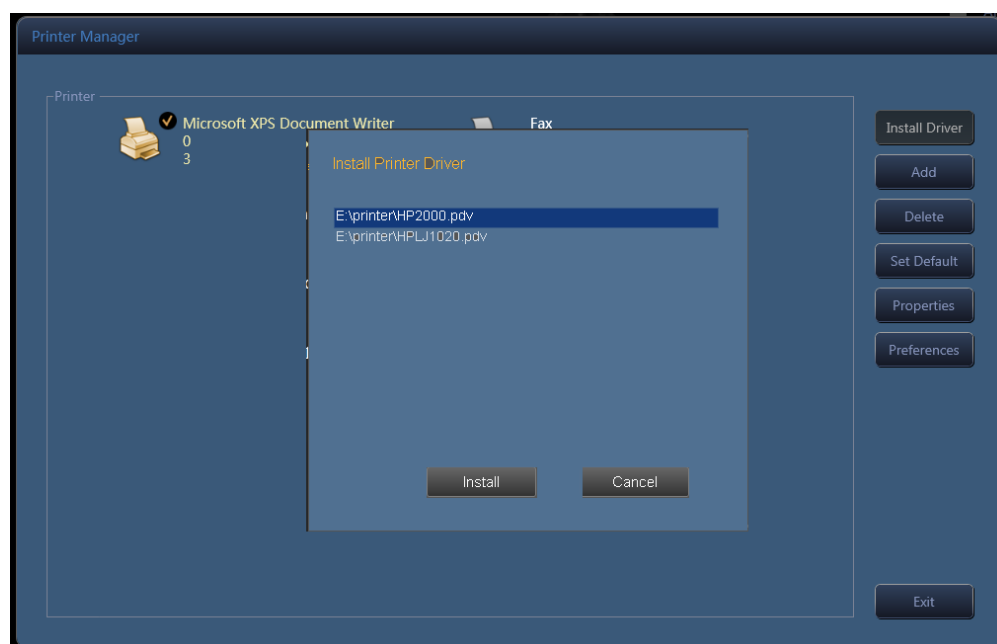


Fig.7-24

Select the driver, click “Install”, the system will jump out installation guide. Complete the installation by following up the guide.

The steps are as below:

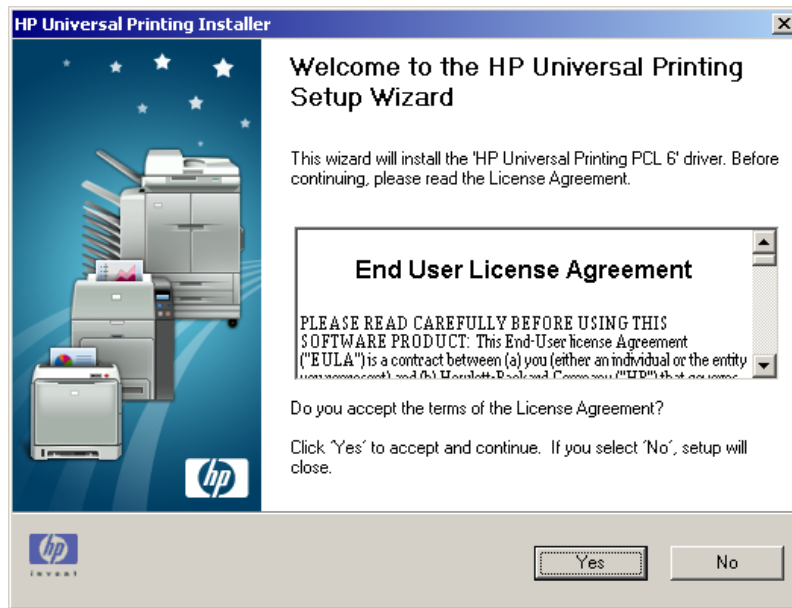


Fig.7-25

Click "Yes".

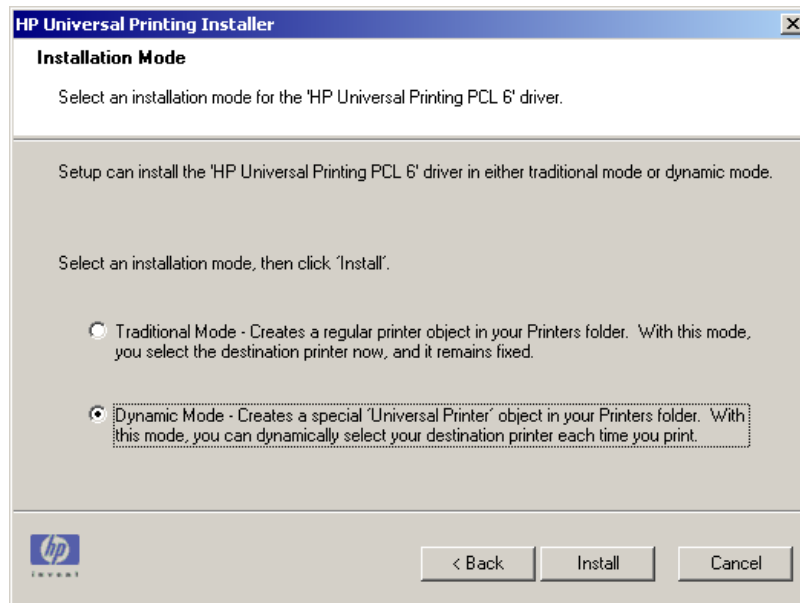


Fig.7-26

Select "Dynamic Mode", click "Install".

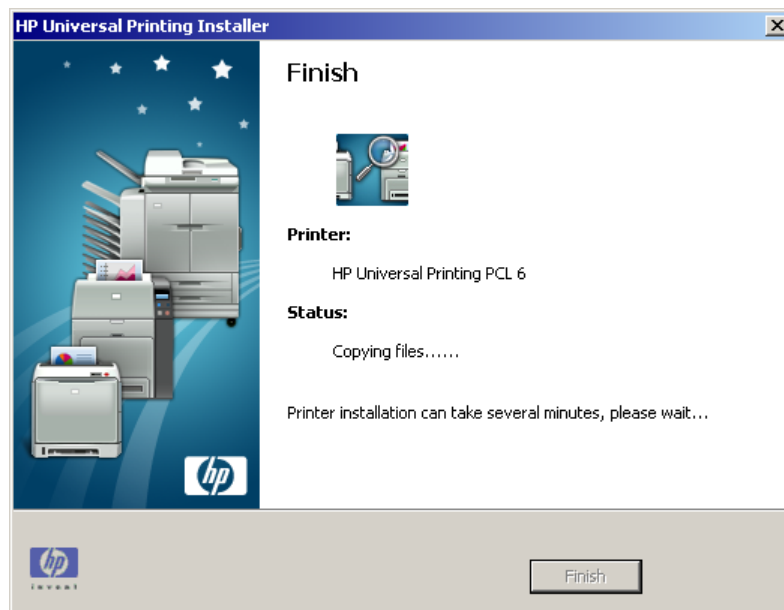


Fig.7-27

Being installed automatically.

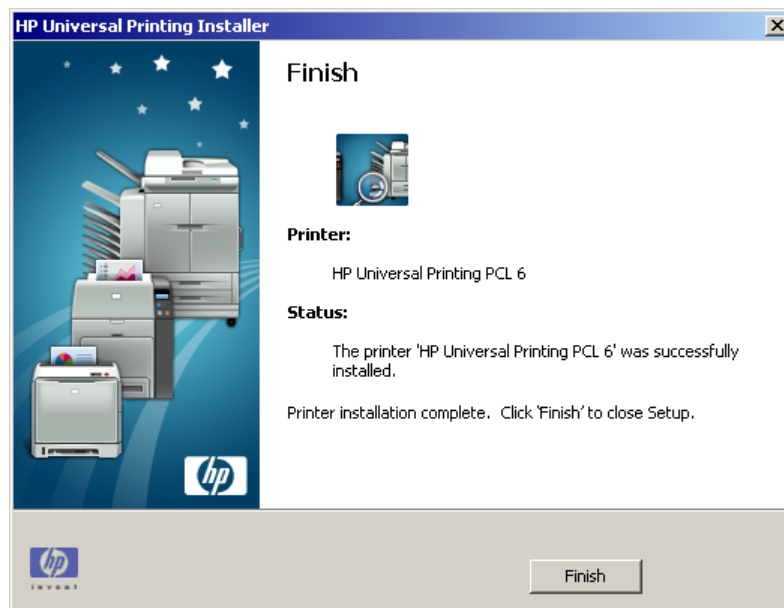


Fig.7-28

Click "Finish" to finish the printer installation.

Add: Click "Add", complete adding printer according to operation guide.



Fig.7-29

Click "NEXT".

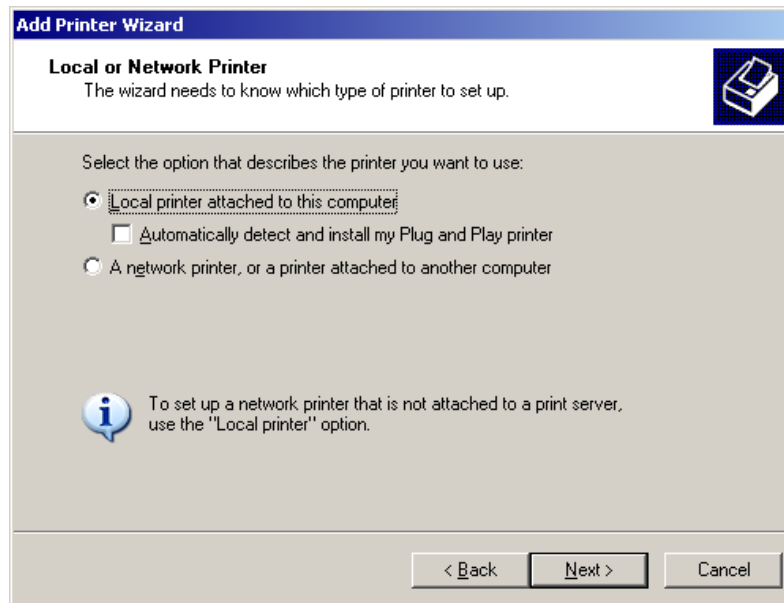


Fig.7-30

Select "Local printer attached to this computer", and Click "Next".

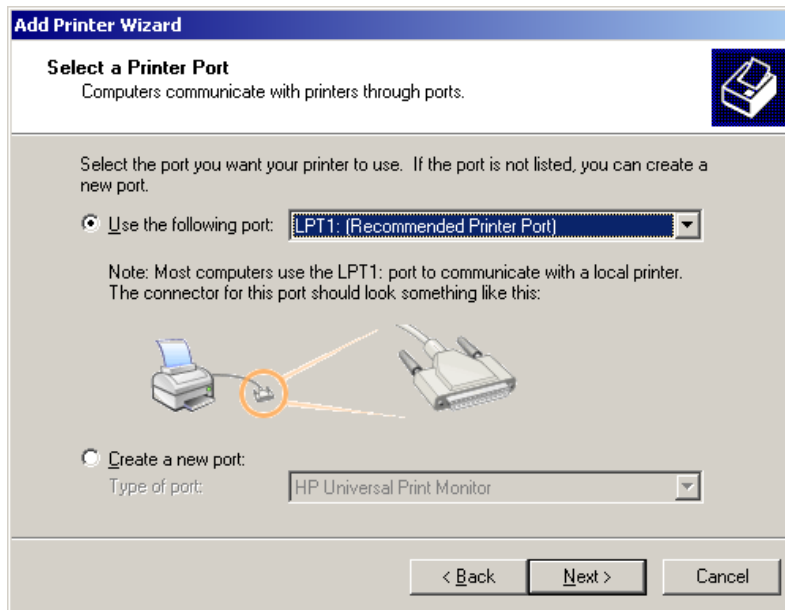


Fig.7-31

Select "Use the following port", and click "Next".

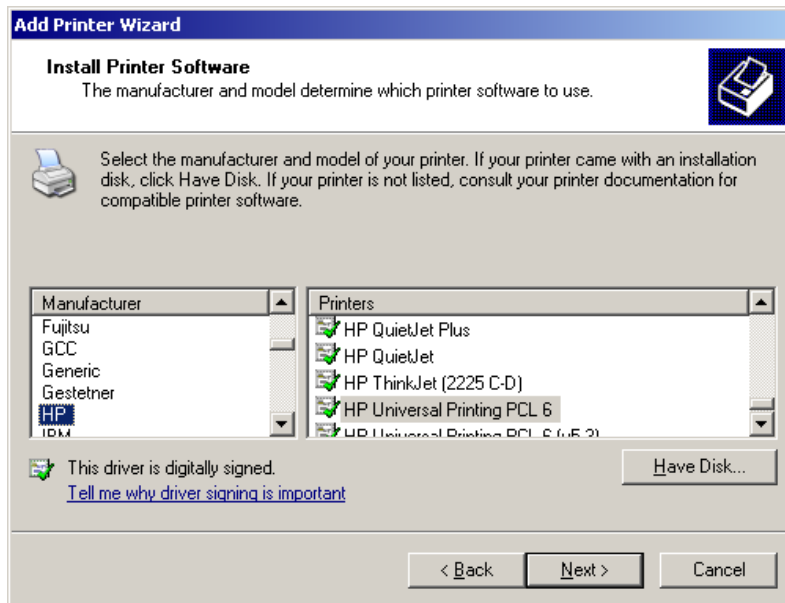


Fig.7-32

Select the printer, and click "Next".

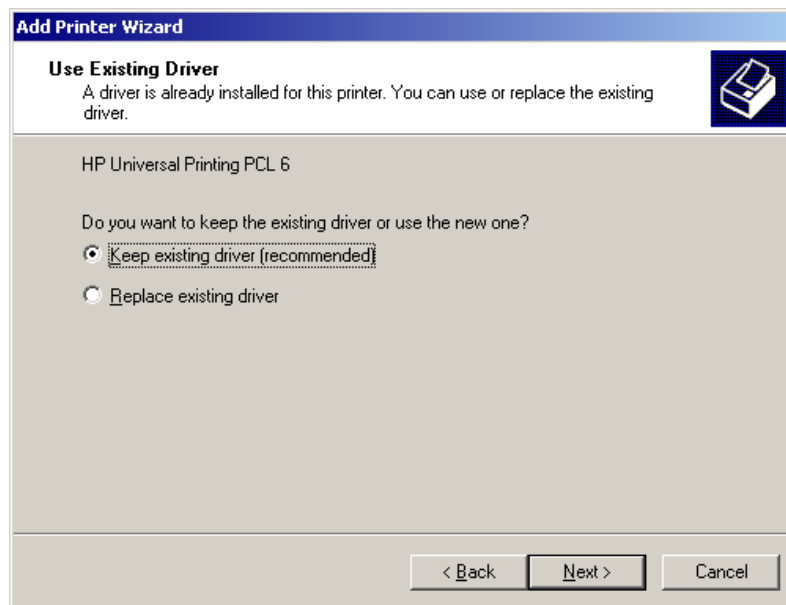


Fig.7-33

Select "Keep existing driver (recommended)", and Click "Next".

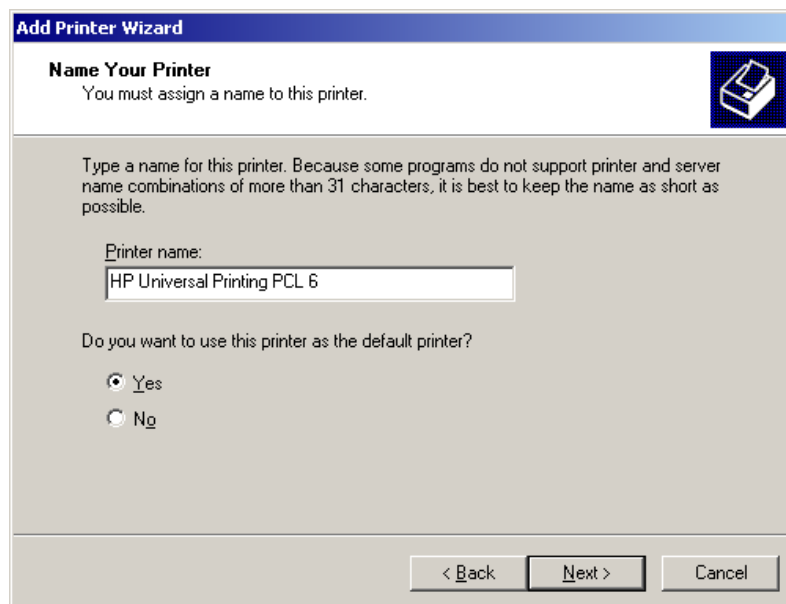


Fig.7-34

Select "Yes", and Click "Next".

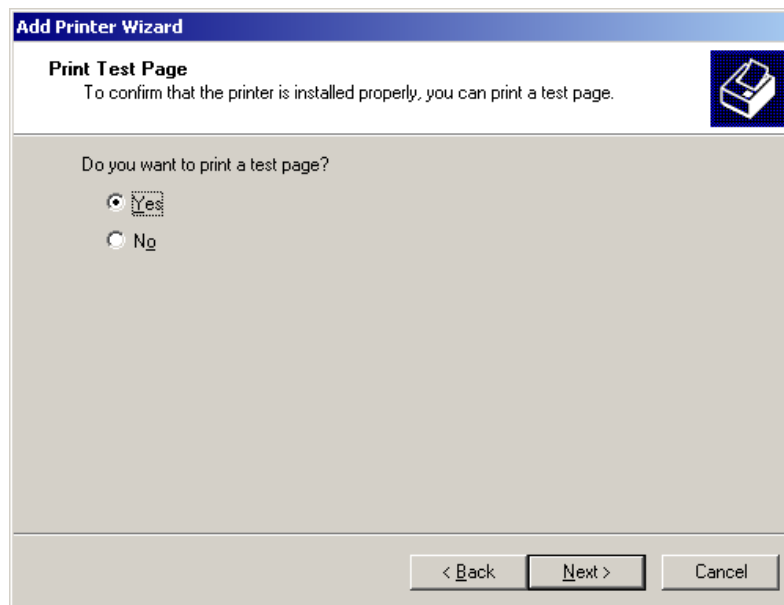


Fig.7-35

Select "Yes" to print a test page, and click "Next" to continue.

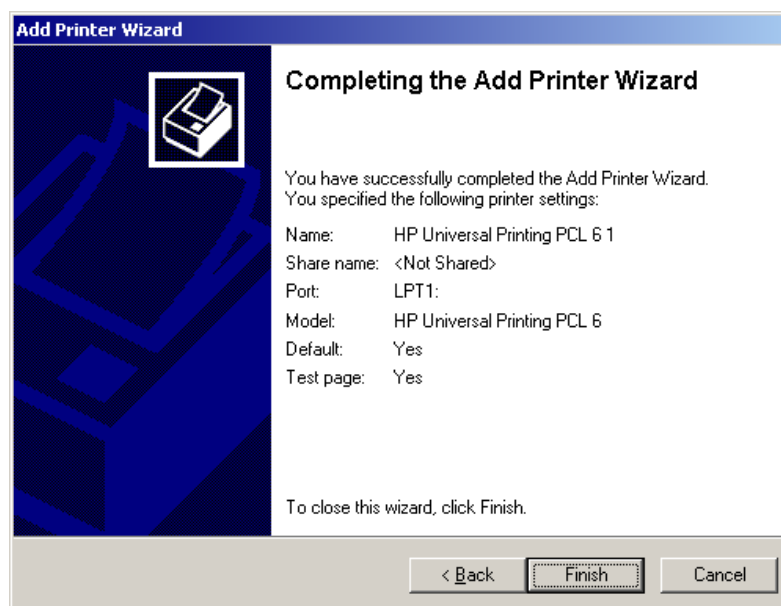


Fig.7-36

Click "Finish".

Chapter 8 Probes

8.1 General Description

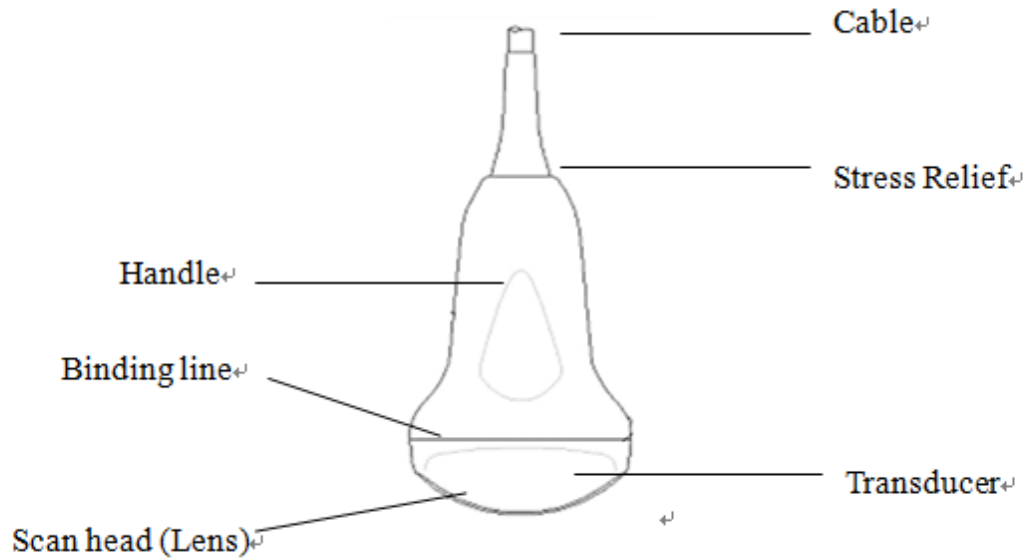


Fig.8-1: Convex Probe Overview

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

8.2 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.

8.2.1 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 a CHISON's authorized service engineer.



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 electric shock or damage on the system/ transducer.*

8.2.2 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

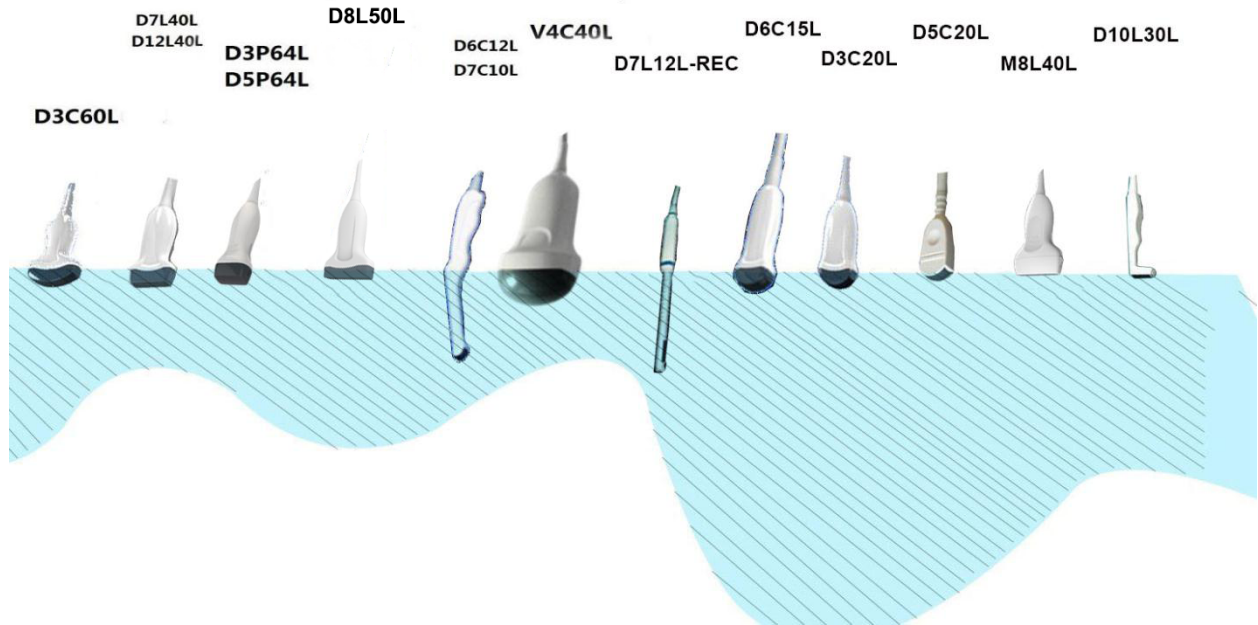


Fig.8-1

Recommended materials for cleaning and disinfecting probe

Solution	Origin	Qualified Use	Active Ingredients	Purpose
CIDEZYME	Any	Soak	enzyme	Clean
Epizyme Rapid(Rapid Multi-Enzyme cleaner	Any	Soak	enzyme	Clean
ANIOSYME DD1	FRA	Soak	enzyme	Clean
neodisher mediclean	DEU	Soak	enzyme	Clean
MetriZyme	USA	Soak	enzyme	Clean
Endozyme Xtreme Power	USA	Soak	enzyme	Clean
AVAGARD Environmental Surface Wipe	Any	Wipe	Quat.Ammonia	disinfection
WIP'ANIO	FRA	Wipe	Quat.Ammonia	disinfection
Sani-Cloth AF3	USA	Wipe	Quat.Ammonia	disinfection
MetriCide OPA Plus	USA	Soak	Ortho-phthalaldehyde	disinfection

CIDEX OPA	Any	Soak	Ortho-phthalaldehyde	disinfection
Sani-Cloth Bleach Germicidal Wipes	USA	Wipe	Sodium hypochlorite	disinfection

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.

Electric 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's authorized service engineer.
- Electrical leakage checks should be performed on a routine basis by CHISON's authorized service engineer.

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: 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: 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: 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.



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



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.



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 60° 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

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.



Please do not use any gel or other materials which are not provided by CHISON. Un-authorized gel, lubricants and other materials may corrode probes and other parts of the device, for example the keyboard. This may reduce the safety and effectiveness of the system and probes, and may also reduce the life time of the systems and probes. Damages caused by such reason will not be covered by the warranty.

DO NOT apply gel to the eyes. If in eyes, flush 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, and disinfect the probes.

Returning/Shipping Probes and Repair Parts

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

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

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

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

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 key 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 of 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:

- 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 no lubricated and no medicated. 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 no latex-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).

8.3 Probe Operation Instructions

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

8.3.1 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.

8.3.2 Operating TV,TR probe

The TV,TR probes are endo-cavity probes, for the operation safety, please refer to “Care and Maintenance” for cleaning and disinfection.

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



- ***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.

8.3.3 Cleaning and Disinfecting TV,TR probe

We strongly recommend wearing gloves when cleaning and disinfecting any endo-cavitary probe.

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



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 endo-cavitary probe using liquid chemical germicides.

Cleaning

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



- ***Please remove the cover (if any) before cleaning the probe.(The cover like***

condom is one time usable).

- ***When cleaning the endo-cavitary probe, it is important to be sure that all surfaces are thoroughly cleaned.***

Disinfecting

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.

Chapter 9 System Maintenance and Troubleshooting

9.1 Back up information

CAUTION:

- *All patient data created is NOT backed-up! It is highly recommended to create a full system backup of patient data regularly and empty the hard disk (HDD), to ensure the hard disk (HDD) has never reached its maximum capacity.*

NOTE:

- *To Backup exams to USB DVD/CD+(R)W disk, please confirm that the USB DVD/CD+(R)W storage medium used is clean and not scratched!*

WARNING:

- *Do not disconnect an external USB pen drive without stopping it. Disconnecting without stopping can lead to data loss on the external device.*

9.2 System Care and Maintenance

The system is a precise electrical device. To ensure the best performance and operation of the system, observe proper maintenance procedures. Contact the local CHISON's Authorized Service Representative for parts or periodic maintenance inspections. CHISON will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Inspecting the System

Examine the following on a monthly basis:

- Connectors on cables for any mechanical defects.
- Entire length of electrical and power cords for cuts or abrasions.
- Equipment for loose or missing hardware.

- Control panel and keyboard for defects.

To avoid electric shock hazard, do not remove panels or covers from console. This servicing must be performed by CHISON's authorized service engineer. Failure to do so could serious injury.

If any defect is observed or malfunctions occur, do not operate the equipment but inform CHISON's authorized service engineer for information.

Weekly Maintenance

The system requires weekly care and maintenance to function safely and properly. Clean the following:

- LCD monitor
- Operator control panel
- Footswitch
- Printer

Cleaning the System

Prior to cleaning any part of the system, turn off the system power and disconnect the power cord. See Section 3.4.4 "Power Off" in Chapter 3 for more information.

Cleaning Method

- Moisten a soft, non-abrasive folded cloth.
- Wipe down the top, front, back, and both sides of the system.



- ***Do not spray any liquid directly into the unit.***
- ***Do not use acetone/alcohol or abrasives on painted or plastic surfaces.***

Cleaning LCD Monitor

To clean the monitor face:

- Use a soft, folded cloth. Gently wipe the monitor face.

- Do NOT use a glass cleaner that has a hydrocarbon base (such as Benzene, Methyl Alcohol or Methyl Ethyl Ketone) on monitors with the filter (anti-glare shield). Hard rubbing will also damage the filter.



NOTE: When cleaning the screen, make sure not to scratch the LCD.

Cleaning Control Panel

- Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.
- Wipe down operator control panel.
- Use a cotton swab to clean around keys or controls. Use a toothpick to remove solids from between keys and controls.



NOTE:

- ***When cleaning the operator control panel, make sure not to spill or spray any liquid on the controls, into the system cabinet, or in the probe connection receptacle.***
- ***DO NOT use Tspray or Sani Wipes on the control panel.***

Cleaning Footswitch

- Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.
- Wipe the external surfaces of the unit then dry with a soft, clean cloth.

Cleaning Printer

- Turn off the power. If possible, disconnect the power cord.
- Wipe the external surfaces of the unit with a soft, clean, dry cloth.
- Remove stubborn stains with a cloth lightly dampened with a mild detergent solution.



NOTE:

- ***Never use strong solvents, such as thinner or benzene, or abrasive***

cleansers because they will damage the cabinet.

- ***No further maintenance, such as lubrication, is required.***
- ***For more information, see the Printer's Operation Manual.***

9.3 Safety Check

To ensure the system work normally, please make a maintenance plan, check the safety of the system periodically. If there is any abnormal phenomenon with the machine, please contact our authorized agent in your country as soon as possible.

If there is no image or menu on the screen or other phenomenon appears after switching on the machine, please do troubleshooting first according to the following check list. If the trouble is still not solved, please contact our authorized agent in your country as soon as possible.

9.4 Troubleshooting

It is necessary to maintain the system regularly, as it can ensure the system being operated under safe state by eliminating possible trouble, and it can shorten the checking and repair period, lower the service costs and reduce the operation danger.

If you have any difficulty with the system, use the following information for your reference to help correct the problem. For a problem not covered here, contact your local distributor or Manufacturer.

Symptom	Solution
The system can't power on	1) Check power connections, e.g. power cord connection on the rear panel; 2) Check the fuse: if it is burnt due to mains fluctuation, use spare fuse for replacement.
When starting the system, the monitor has signal but no ultrasound image	Switch off the system, and check probe connection.
System image quality is not good	1) Adjust the LED monitor position for a better viewing angle; 2) Adjust the brightness and contrast of LED monitor;

	3) Adjust the image parameters, e.g. Gain, Dynamic range.
No OB calculation package menu	Select the OB application before scanning.
PRINT-key doesn't work	1) Check if the approved printer is connected; 2) Check if the printer power is on; 3) Check printer connection; 4) Check printer setting in system setup.
External monitor doesn't work	1) Check the monitor connections; 2) Check if the monitor power is on and is set up correctly.
CFM or PW Doppler image has noise	1) Adjust CFM or PW gain value properly; 2) Check if there is appliance or equipment resulting in strong electromagnetic interference
Image has interference	1) Move or avoid interference source; 2) Use separate power outlet; 3) Perform good ground protection
The gray scale is S-twisted in the image area	Adjust the power supply to normal voltage or use a voltage stabilizer
The date and time on the screen is not correct	Press Setup-key to display General Setting screen, and correct time and date.
The Video printer is not work	1) Please confirm the signal cable, Remote cable are connected well. 2) Please make sure you have finished the setting for Video printer at system interface. 3) If you can't change the setting at system interface, please check whether the video printer is turned on and connected well with the main unit. 4) Please make sure the switch on the rear panel of printer is "on" status.

9.5 Service Responsibility

If users install, use and maintain the system fully according to CHISON exchange the momanual, operation manual and service manual, then main unit has a life time of 5 years and probes have life time of 5 years after ex-work (except that the 4D probe life time is 18 months).

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 transducers, 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

REFERENCE:

1. AIUM: Medical Ultrasound Safety, American Institute of Ultrasound in Medicine, Laurel, MD, 1994. NOTE: As of this writing an update of this publication is being finalized by the AIUM. AIUM: Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data, Revision 1, American Institute of Ultrasound in Medicine, Laurel, MD, 2008.
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3. AIUM/NEMA: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3. NEMA Standards Publication UD 2-2004; American Institute of Ultrasound in Medicine, Laurel, MD; National Electrical Manufacturers Association, Rosslyn, VA; 2004b.
4. 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
5. FDA Center for Devices and radiological Health (CDRH), 510(K) Guidance for Diagnostic Ultrasound and Fetal Doppler Ultrasound Medical Devices, September 8 1989 draft
6. FDA/CDRH,510(K) Diagnostic Ultrasound Guidance Update of 1991, April 26, 1991 draft
7. Biological Effects of Ultrasound: Mechanisms and Clinical Implications, NCRP Report No. 74, December 30,1983
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9. Bioeffects Considerations for the safety of Diagnostic Ultrasound, Journal of Ultrasound in Medicine, AIUM, September1988
10. Geneva Report on Safety and Standardization in Medical Ultrasound, WFUMB, May 1990 Medical Ultrasound Safety, AIUM, 1994

11. Medical Electrical Equipment standard IEC 60601-1, IEC60601-1-2, IEC 60601-2-37
12. Diagnostic Ultrasound Physics and Equipment, edit by P. R. Hoskins, in 2003

APPENDIX A The Information of EC Representative

Shanghai International Holding Corp. GmbH (Europe)

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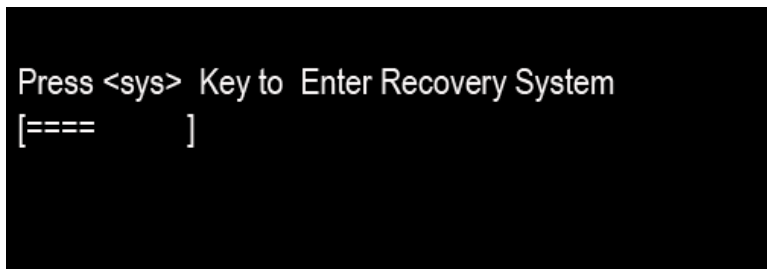
E-mail: antonsissi@hotmail.com shholding@hotmail.com

APPENDIX B System one-key-recovery Function

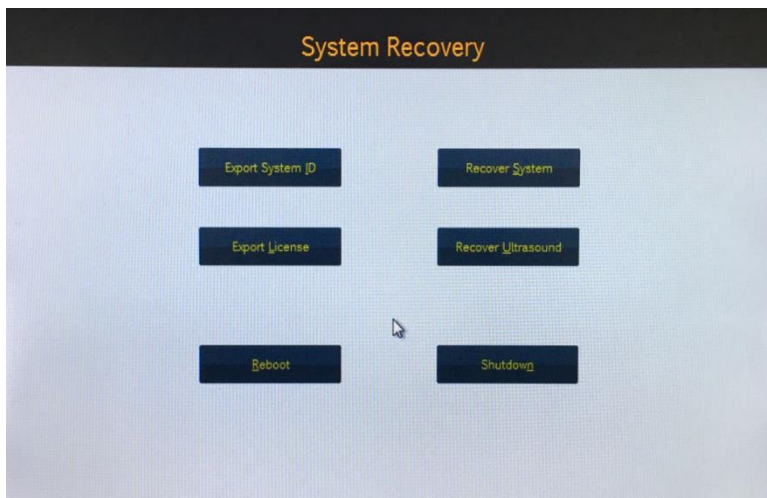
This system has one-key-recovery function. Users can use this function to recovery system when the system has problems.

Detailed operations are as follows:

1. Press  button to boot the system.
2. Press <sys> button when the system enter into the following boot screen.



3. When the recovery system starts, the following interface will pop up.



Export System ID: export system ID to the removeable storage device.

Recovery system: restore machine to the factory version.

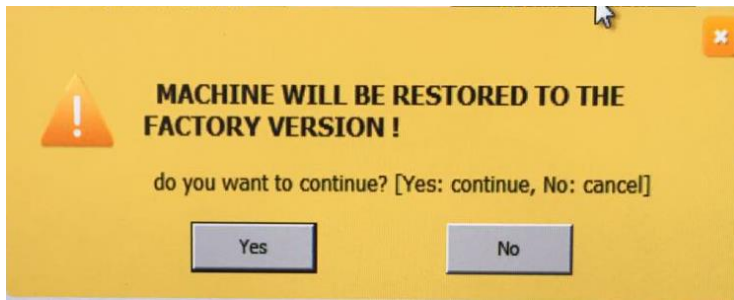
Export License: export license to the removeable storage device.

Recover Ultrasound: restore ultrasound software to the factory version.

Reboot: click to boot the system again.

Shutdown: click to close the system.

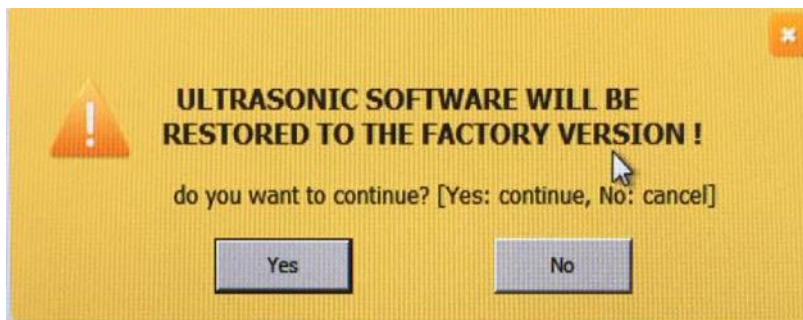
4. After click the "Recover System", the following interface will pop up:



Click "Yes" to confirm and start system recovery. The system will start to backup ultrasound system data, after finishing the backup, the system will transfer to the recovery procedure automatically.

Click "No" to cancel system recovery.

5. After click the "Recover Ultrasound", the following interface wil pop up.



Click "OK" to confirm and start ultrasound software recovery.

Click "Cancel" to cancel ultrasound software recovery.

6. After finishing the recover, the system will pop the CMD interface. Input EXIT in the command line to reboot the system will reboot.

APPENDIX C MAXIMUM ACOUSTIC OUTPUT REPORT

Transducer Model: **D3C60L**Operating Mode: **B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.0		1.5		—
Index component value				1.0	1.0	1.5	1.0	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.34					
	P	mW		149.33		149.33		—
	$P_{1 \times 1}$	mW		77.21		77.21		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	6.55					
	$z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	2.68	2.72		2.72		—
Other Information	p_{rr}	Hz	9678					
	s_{rr}	Hz	75.67					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	11.26					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	37.85					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	7.0	7.0		7.0		—
	Depth	cm	20.45	20.45		20.45		—
	Scanning width	%	100	100		100		—
	Freq	MHz	3.0	3.0		3.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: **D3C60L**

Operating Mode: **B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.7		1.4		–
Index component value				0.7	0.7	1.4	0.7	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.93					
	P	mW		144.78		144.78		–
	$P_{1 \times 1}$	mW		50.69		50.69		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	6.15					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	2.89	2.90		2.90		–
Other Information	p_{rr}	Hz	12000					
	s_{rr}	Hz	93.75					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	13.22					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	45.13					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	6.0	8.0		8.0		–
	Depth	cm	11.82	9.36		9.36		–
	Scanning width	%	100	100		100		–
	Freq	MHz	3.0/3.0	3.0/3.0		3.0/3.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3C60L

Operating Mode: PW

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	1.0		2.0		–
Index component value				1.0	0.8	2.0	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.81					
	P	mW		210.22		198.89		–
	$P_{1 \times 1}$	mW		73.17		70.12		
	Z_s	cm			4.08			
	Z_b	cm					6.35	
	Z_{MI}	cm	4.40					
	$Z_{pii,\alpha}$	cm	4.40					
	f_{awf}	MHz	2.85	2.87		2.88		–
Other Information	p_{rr}	Hz	12000					
	s_{rr}	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	129.25					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	122.33					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	290.89					
	p_r at Z_{pii}	Mpa	1.45					
Operating control conditions	Focus	cm	6.0	7.0		10.0		–
	Depth	cm	9.36	8.13		11.82		–
	Scanning width	%	100	100		100		–
	Freq	MHz	3.0/3.0	3.0/3.0		3.0/3.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: **D3C60L**

Operating Mode: **B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	1.5		0.9		—
Index component value				0.8	1.5	0.8	0.9	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.51					
	P	mW		246.23		246.23		—
	$P_{1 \times 1}$	mW		60.87		60.87		
	Z_s	cm			4.16			
	Z_b	cm					5.08	
	Z_{MI}	cm	5.60					
	$Z_{pii,\alpha}$	cm	5.60					
	f_{awf}	MHz	2.72	2.76		2.78		—
Other Information	p_{rr}	Hz	4756					
	s_{rr}	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	115.56					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	112.22					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	321.39					
	p_r at Z_{pii}	Mpa	2.62					
Operating control conditions	Focus	cm	7.0	6.0		6.0		—
	Depth	cm	8.13	6.89		6.89		—
	Scanning width	%	100	100		100		—
	Freq	MHz	3.0	3.0		3.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: **D3C60L**

Operating Mode: **Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	1.1		1.6		—
Index component value				1.1	1.1	1.6	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.47					
	P	mW		160.12		160.12		—
	$P_{1 \times 1}$	mW		84.93		84.93		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	6.55					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	2.68	2.72		2.72		—
Other Information	p_{rr}	Hz	9678					
	s_{rr}	Hz	75.67					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	11.26					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	37.85					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	7.0	7.0		7.0		—
	Depth	cm	20.45	20.45		20.45		—
	Scanning width	%	100	100		100		—
	Freq	MHz	3.0	3.0		3.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7L40L

Operating Mode: B

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.0	0.5		0.7		–
Index component value				0.5	0.5	0.7	0.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.39					
	P	mW		30.34		30.34		–
	$P_{1 \times 1}$	mW		16.94		16.94		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	2.00					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	6.20	6.22		6.22		–
Other Information	p_{rr}	Hz	2870					
	s_{rr}	Hz	22.42					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$	mW/cm ²	12.34					
	I_{spta} at Z_{pii} OR Z_{sii}	mW/cm ²	29.06					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.0	2.0		2.0		–
	Depth	cm	4.93	4.93		4.93		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.0	5.0		5.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7L40L

Operating Mode: B+C

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.8		1.1		–
Index component value				0.8	0.8	1.1	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.39					
	P	mW		46.25		46.25		–
	P_{1x1}	mW		26.37		26.37		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	1.65					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	6.36	6.37		6.37		–
Other Information	p_{rr}	Hz	20000					
	s_{rr}	Hz	156.25					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	18.55					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	38.30					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.5	1.0		1.0		–
	Depth	cm	4.93	3.70		3.70		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.0/6.5	5.0/6.5		5.0/6.5		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7L40L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.8		1.1		—
Index component value				0.8	0.7	1.1	0.9	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.59					
	P	mW		40.13		46.59		—
	$P_{1 \times 1}$	mW		27.16		31.28		
	Z_s	cm			1.75			
	Z_b	cm					1.83	
	Z_{MI}	cm	1.70					
	$Z_{pii,\alpha}$	cm	1.70					
	f_{awf}	MHz	6.30	6.28		6.36		—
Other Information	pr	Hz	20000					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	178.81					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	201.15					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	421.52					
	p_r at Z_{pii}	Mpa	2.14					
Operating control conditions	Focus	cm	4.0	2.5		2.5		—
	Depth	cm	7.39	3.70		7.39		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0/6.5	5.0/6.5		5.0/6.5		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7L40L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.4		1.1		—
Index component value				1.0	1.4	1.0	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.91					
	P	mW		65.49		66.13		—
	$P_{1 \times 1}$	mW		33.87		35.41		
	Z_s	cm			1.78			
	Z_b	cm					1.82	
	Z_{MI}	cm	1.65					
	$Z_{pii,\alpha}$	cm	1.65					
	f_{awf}	MHz	6.18	6.20		6.19		—
Other Information	pr	Hz	2870					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	202.26					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	243.21					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	491.92					
	p_r at Z_{pii}	Mpa	2.58					
Operating control conditions	Focus	cm	2.0	1.5		2.0		—
	Depth	cm	3.70	3.70		3.70		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7L40L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	0.6		0.8		—
Index component value				0.6	0.6	0.8	0.6	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.24					
	P	mW		36.48		36.48		—
	$P_{1 \times 1}$	mW		20.11		20.11		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.00					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	6.20	6.22		6.22		—
Other Information	pr	Hz	2870					
	srr	Hz	22.42					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	12.34					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	29.06					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	2.0	2.0		2.0		—
	Depth	cm	4.93	4.93		4.93		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D10L30L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.5		0.7		—
Index component value				0.5	0.5	0.7	0.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.42					
	P	mW		28.59		28.59		—
	P_{1x1}	mW		11.13		11.13		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.00					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	9.14	9.13		9.13		—
Other Information	pr	Hz	2977					
	srr	Hz	23.26					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	22.31					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	78.75					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	3.0	2.0		2.0		—
	Depth	cm	4.93	6.16		6.16		—
	Scanning width	%	100	100		100		—
	Freq	MHz	9.0	9.0		9.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: **D10L30L**Operating Mode: **B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.8		0.9		–
Index component value				0.8	0.8	0.9	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.53					
	P	mW		35.21		35.21		–
	P_{1x1}	mW		17.42		17.42		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	1.80					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	9.34	9.36		9.36		–
Other Information	pr	Hz	20000					
	srr	Hz	156.25					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	20.33					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	64.72					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	3.0	2.0		2.0		–
	Depth	cm	4.93	4.93		4.93		–
	Scanning width	%	100	100		100		–
	Freq	MHz	9.0/9.0	9.0/9.0		9.0/9.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D10L30L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.8		1.0		–
Index component value				0.6	0.8	1.0	0.9	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.73					
	P	mW		39.69		43.81		–
	$P_{1 \times 1}$	mW		15.15		18.56		
	Z_s	cm			1.89			
	Z_b	cm					1.94	
	Z_{MI}	cm	1.80					
	$Z_{pii,\alpha}$	cm	1.80					
	f_{awf}	MHz	8.30	8.35		6.36		–
Other Information	pr	Hz	20000					
	srr	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	134.23					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	186.59					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	523.71					
	p_r at Z_{pii}	Mpa	2.27					
Operating control conditions	Focus	cm	3.0	2.0		3.5		–
	Depth	cm	7.39	3.70		7.39		–
	Scanning width	%	100	100		100		–
	Freq	MHz	9.0/9.0	9.0/9.0		9.0/9.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D10L30L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.4		1.1		—
Index component value				1.0	1.4	1.0	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.11					
	P	mW		55.46		54.94		—
	$P_{1 \times 1}$	mW		23.98		25.26		
	Z_s	cm			1.88			
	Z_b	cm					2.00	
	Z_{MI}	cm	2.00					
	$Z_{pii,\alpha}$	cm	2.00					
	f_{awf}	MHz	9.11	9.18		9.07		—
Other Information	pr	Hz	2905					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	156.89					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	231.08					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	813.50					
	p_r at Z_{pii}	Mpa	2.66					
Operating control conditions	Focus	cm	2.0	2.0		2.0		—
	Depth	cm	9.86	3.70		8.62		—
	Scanning width	%	100	100		100		—
	Freq	MHz	9.0	9.0		9.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D10L30L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	0.4		0.7		—
Index component value				0.4	0.4	0.7	0.4	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.12					
	P	mW		28.61		28.61		—
	$P_{1 \times 1}$	mW		10.70		10.70		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.00					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	9.14	9.13		9.13		—
Other Information	pr	Hz	2977					
	srr	Hz	23.26					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	22.31					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	78.87					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	3.0	2.0		2.0		—
	Depth	cm	4.93	6.16		6.16		—
	Scanning width	%	100	100		100		—
	Freq	MHz	9.0	9.0		9.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D12L40L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.1		0.3		–
Index component value				0.1	0.1	0.3	0.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.39					
	P	mW		12.33		12.33		–
	$P_{1 \times 1}$	mW		3.55		3.55		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	1.80					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	5.91	5.91		5.91		–
Other Information	pr	Hz	5319					
	srr	Hz	41.55					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	20.46					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	42.66					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.5	2.5		2.5		–
	Depth	cm	4.93	4.93		4.93		–
	Scanning width	%	100	100		100		–
	Freq	MHz	7.0	7.0		7.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D12L40L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.4		0.8		—
Index component value				0.4	0.4	0.8	0.4	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.18					
	P	mW		32.45		32.45		—
	$P_{1 \times 1}$	mW		15.56		15.56		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	1.80					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	5.12	5.40		5.40		—
Other Information	pr	Hz	20000					
	srr	Hz	156.25					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	26.12					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	50.50					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	2.5	2.5		2.5		—
	Depth	cm	9.86	8.62		8.62		—
	Scanning width	%	100	100		100		—
	Freq	MHz	7.0/7.0	7.0/7.0		7.0/7.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D12L40L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.2	0.9		1.4		—
Index component value				0.7	0.9	1.4	0.9	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.54					
	P	mW		54.14		54.14		—
	$P_{1 \times 1}$	mW		28.41		28.41		
	Z_s	cm			1.80			
	Z_b	cm					1.80	
	Z_{MI}	cm	3.00					
	$Z_{pii,\alpha}$	cm	3.00					
	f_{awf}	MHz	5.43	5.43		5.43		—
Other Information	pr	Hz	20000					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	113.77					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	120.32					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	370.71					
	p_r at Z_{pii}	Mpa	0.75					
Operating control conditions	Focus	cm	2.5	2.5		2.5		—
	Depth	cm	6.16	6.16		6.16		—
	Scanning width	%	100	100		100		—
	Freq	MHz	7.0/7.0	7.0/7.0		7.0/7.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D12L40L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	1.0		1.4		–
Index component value				0.9	1.0	0.9	1.4	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	<i>Mpa</i>	1.21					
	P	mW		45.61		44.56		–
	$P_{1 \times 1}$	mW		32.20		31.23		
	Z_s	cm			1.80			
	Z_b	cm					1.80	
	Z_{MI}	cm	1.80					
	$Z_{pii,\alpha}$	cm	1.80					
	f_{awf}	MHz	5.85	5.87		5.82		–
Other Information	pr	Hz	5319					
	srr	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	170.00					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	125.43					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	259.60					
	p_r at Z_{pii}	<i>Mpa</i>	1.74					
Operating control conditions	Focus	cm	2.5	2.5		2.0		–
	Depth	cm	4.93	4.93		6.16		–
	Scanning width	%	100	100		100		–
	Freq	MHz	7.0	7.0		7.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D12L40L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.2		0.4		–
Index component value				0.2	0.2	0.4	0.2	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	<i>Mpa</i>	1.22					
	P	mW		15.24		15.24		–
	$P_{1 \times 1}$	mW		7.11		7.11		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	1.80					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	5.91	5.91		5.91		–
Other Information	pr	Hz	5319					
	srr	Hz	41.55					
	Π_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	20.46					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	42.66					
	p_r at Z_{pii}	<i>Mpa</i>	–					
Operating control conditions	Focus	cm	2.5	2.5		2.5		–
	Depth	cm	4.93	4.93		4.93		–
	Scanning width	%	100	100		100		–
	Freq	MHz	7.0	7.0		7.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C12L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	0.4		0.7		—
Index component value				0.4	0.4	0.7	0.4	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.46					
	P	mW		30.33		30.33		—
	$P_{1 \times 1}$	mW		16.37		16.37		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.50					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	4.90	5.13		5.13		—
Other Information	pr	Hz	7286					
	srr	Hz	56.92					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	20.61					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	48.04					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	3.0	2.0		2.0		—
	Depth	cm	4.29	3.06		3.06		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.3	5.3		5.3		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C12L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.8		1.5		–
Index component value				0.8	0.8	1.5	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.91					
	P	mW		61.25		61.25		–
	$P_{1 \times 1}$	mW		32.06		32.06		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	3.35					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	4.09	5.24		5.24		–
Other Information	pr	Hz	6000					
	srr	Hz	46.88					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	18.94					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	48.80					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	4.0	2.5		2.5		–
	Depth	cm	6.75	3.06		3.06		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.3/4.0	5.3/4.0		5.3/4.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C12L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.7		1.0		—
Index component value				0.5	0.7	1.0	0.9	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.11					
	P	mW		36.28		39.56		—
	$P_{1 \times 1}$	mW		21.16		24.41		
	Z_s	cm			1.77			
	Z_b	cm					1.93	
	Z_{MI}	cm	2.40					
	$Z_{pii,\alpha}$	cm	2.40					
	f_{awf}	MHz	5.16	5.21		5.18		—
Other Information	pr	Hz	6000					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	142.87					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	120.25					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	282.88					
	p_r at Z_{pii}	Mpa	1.56					
Operating control conditions	Focus	cm	3.0	3.5		3.5		—
	Depth	cm	3.06	9.22		5.52		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.3/4.0	5.3/4.0		5.3/4.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C12L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.6		1.3		—
Index component value				0.5	0.6	0.5	1.3	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.72					
	P	mW		34.26		38.33		—
	$P_{1 \times 1}$	mW		21.60		22.42		
	Z_s	cm			1.78			
	Z_b	cm					2.07	
	Z_{MI}	cm	2.30					
	$Z_{pii,\alpha}$	cm	2.30					
	f_{awf}	MHz	4.83	4.86		4.83		—
Other Information	pr	Hz	7287					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	120.53					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	124.36					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	267.89					
	p_r at Z_{pii}	Mpa	2.27					
Operating control conditions	Focus	cm	3.0	3.0		3.0		—
	Depth	cm	4.29	10.45		5.22		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.3	5.3		5.3		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C12L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.3		0.6		—
Index component value				0.3	0.3	0.6	0.3	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.77					
	P	mW		25.42		25.42		—
	$P_{1 \times 1}$	mW		12.28		12.28		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.50					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	4.90	5.13		5.13		—
Other Information	pr	Hz	7286					
	srr	Hz	56.92					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	20.61					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	48.04					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	3.0	2.0		2.0		—
	Depth	cm	4.29	3.06		3.06		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.3	5.3		5.3		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7C10L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.2		0.4		–
Index component value				0.2	0.2	0.4	0.2	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.99					
	P	mW		16.65		16.65		–
	$P_{1 \times 1}$	mW		10.17		10.17		
	Z_s	cm			–			
	Z_b	cm						–
	Z_{MI}	cm	2.25					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	4.13	4.16		4.16		–
Other Information	pr	Hz	4345					
	srr	Hz	33.95					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	22.12					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	42.03					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.5	1.5		1.5		–
	Depth	cm	3.93	2.70		2.70		–
	Scanning width	%	100	100		100		–
	Freq	MHz	4.0	4.0		4.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7C10L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.4	0.7		1.3		–
Index component value				0.7	0.7	1.3	0.7	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.96					
	P	mW		50.24		50.24		–
	$P_{1 \times 1}$	mW		27.95		27.95		
	Z_s	cm			–			
	Z_b	cm						
	Z_{MI}	cm	2.46					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	5.26	5.26		5.26		–
Other Information	pr	Hz	6000					
	srr	Hz	46.88					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	30.12					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	73.63					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.5	2.0		2.0		–
	Depth	cm	10.09	3.93		3.93		–
	Scanning width	%	100	100		100		–
	Freq	MHz	4.0/5.3	4.0/5.3		4.0/5.3		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7C10L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	1.0		1.5		–
Index component value				0.9	1.0	1.5	0.2	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.07					
	P	mW		55.58		58.44		–
	$P_{1 \times 1}$	mW		38.25		40.55		
	Z_s	cm			1.73			
	Z_b	cm					1.99	
	Z_{MI}	cm	2.60					
	$Z_{pii,\alpha}$	cm	2.60					
	f_{awf}	MHz	5.28	5.29		5.27		–
Other Information	p_{rr}	Hz	6000					
	s_{rr}	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	142.89					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$	mW/cm ²	150.24					
	I_{spta} at Z_{pii} OR Z_{sii}	mW/cm ²	387.82					
	p_r at Z_{pii}	Mpa	1.49					
Operating control conditions	Focus	cm	3.0	2.5		2.0		–
	Depth	cm	8.86	6.39		2.70		–
	Scanning width	%	100	100		100		–
	Freq	MHz	4.0/5.3	4.0/5.3		4.0/5.3		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7C10L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.8		0.6		–
Index component value				0.6	0.8	0.6	0.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.98					
	P	mW		50.22		51.53		–
	$P_{1 \times 1}$	mW		30.14		30.58		
	Z_s	cm			1.75			
	Z_b	cm					2.29	
	Z_{MI}	cm	2.40					
	$Z_{pii,\alpha}$	cm	2.40					
	f_{awf}	MHz	4.11	4.18		4.13		–
Other Information	p_{rr}	Hz	5554					
	s_{rr}	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	140.33					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	154.23					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	304.85					
	p_r at Z_{pii}	Mpa	1.29					
Operating control conditions	Focus	cm	3.0	2.0		3.0		–
	Depth	cm	10.09	5.16		10.09		–
	Scanning width	%	100	100		100		–
	Freq	MHz	4.0	4.0		4.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7C10L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.4	0.4		0.8		—
Index component value				0.4	0.4	0.8	0.4	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.81					
	P	mW		31.23		31.23		—
	$P_{1 \times 1}$	mW		20.19		20.19		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.25					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	4.13	4.16		4.16		—
Other Information	pr	Hz	4345					
	srr	Hz	33.95					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	22.12					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	42.03					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	2.5	1.5		1.5		—
	Depth	cm	3.93	2.70		2.70		—
	Scanning width	%	100	100		100		—
	Freq	MHz	4.0	4.0		4.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3P64L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.1	1.2		2.0		2.0
Index component value				1.2	1.2	2.0	1.2	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.63					
	P	mW		142.23		142.23		142.23
	$P_{1 \times 1}$	mW		101.61		101.61		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	4.50					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	2.28	2.48		2.48		2.48
Other Information	pr	Hz	3333					
	srr	Hz	26.04					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	14.56					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	29.58					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	4.0	1.0		1.0		1.0
	Depth	cm	25.87	29.57		29.57		29.57
	Scanning width	%	100	100		100		100
	Freq	MHz	2.5	2.5		2.5		2.5
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3P64L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	0.5		0.9		0.9
Index component value				0.5	0.5	0.9	0.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.35					
	P	mW		65.22		65.22		65.22
	$P_{1 \times 1}$	mW		45.26		45.26		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	3.37					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	2.25	2.32		2.32		2.32
Other Information	pr	Hz	9000					
	srr	Hz	70.31					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	21.22					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	35.83					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	4.0	1.0		1.0		1.0
	Depth	cm	20.94	7.39		7.39		7.39
	Scanning width	%	100	100		100		100
	Freq	MHz	2.5/2.5	2.5/2.5		2.5/2.5		2.5/2.5
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3P64L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	0.8		1.3		1.3
Index component value				0.6	0.8	1.3	0.4	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.25					
	P	mW		90.02		90.02		90.02
	$P_{1 \times 1}$	mW		63.32		63.32		
	Z_s	cm			3.05			
	Z_b	cm					5.35	
	Z_{MI}	cm	5.92					
	$Z_{pii,\alpha}$	cm	5.92					
	f_{awf}	MHz	1.99	1.99		1.99		1.99
Other Information	pr	Hz	9000					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	150.40					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	164.25					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	370.62					
	p_r at Z_{pii}	Mpa	1.12					
Operating control conditions	Focus	cm	1.0	1.0		1.0		1.0
	Depth	cm	7.39	7.39		7.39		7.39
	Scanning width	%	100	100		100		100
	Freq	MHz	2.5/2.5	2.5/2.5		2.5/2.5		2.5/2.5
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3P64L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.2	1.2		1.0		0.9
Index component value				0.7	1.2	0.7	1.0	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	<i>Mpa</i>	1.64					
	P	mW		125.42		129.20		129.20
	$P_{1 \times 1}$	mW		77.78		81.48		
	Z_s	cm			2.85			
	Z_b	cm					2.92	
	Z_{MI}	cm	2.55					
	$Z_{pii,\alpha}$	cm	2.55					
	f_{awf}	MHz	1.89	1.89		1.88		1.88
Other Information	pr	Hz	5532					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	129.20					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	155.28					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	216.62					
	p_r at Z_{pii}	<i>Mpa</i>	1.59					
Operating control conditions	Focus	cm	5.0	5.0		6.0		6.0
	Depth	cm	8.62	8.62		7.39		7.39
	Scanning width	%	100	100		100		100
	Freq	MHz	2.5	2.5		2.5		2.5
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3P64L**Operating Mode: CW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.1	0.8		2.0		1.0
Index component value				0.6	0.8	1.0	2.0	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.20					
	P	mW		66.58		70.00		70.00
	$P_{1 \times 1}$	mW		48.87		50.21		
	Z_s	cm			5.40			
	Z_b	cm					6.75	
	Z_{MI}	cm	6.80					
	$Z_{pii,\alpha}$	cm	6.80					
	f_{awf}	MHz	2.80	2.75		2.80		2.76
Other Information	pr	Hz	0					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	43.21					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	123.25					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	459.18					
	p_r at Z_{pii}	Mpa	0.12					
Operating control conditions	Focus	cm	5.0	4.0		6.0		6.0
	Depth	cm	6.16	8.62		7.39		7.39
	Scanning width	%	100	100		100		100
	Freq	MHz	2.5/2.5	2.5/2.5		2.5/2.5		2.5/2.5
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3P64L**Operating Mode: CFM-M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.0	0.3		0.7		0.7
Index component value				0.3	0.1	0.7	0.6	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.57					
	P	mW		44.28		48.55		48.55
	$P_{1 \times 1}$	mW		26.47		28.51		
	Z_s	cm			6.15			
	Z_b	cm					6.14	
	Z_{MI}	cm	6.15					
	$Z_{pii,\alpha}$	cm	6.15					
	f_{awf}	MHz	2.36	2.38		2.36		2.36
Other Information	pr	Hz	252					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	79.50					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	110.25					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	300.47					
	p_r at Z_{pii}	Mpa	2.63					
Operating control conditions	Focus	cm	5.0	3.0		6.0		6.0
	Depth	cm	6.16	8.62		8.62		8.62
	Scanning width	%	100	100		100		100
	Freq	MHz	2.5	2.5		2.5		2.5
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3P64L

Operating Mode: TDI

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.6		1.0		1.0
Index component value				0.6	0.6	1.0	0.6	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.35					
	P	mW		71.23		71.23		71.23
	$P_{1 \times 1}$	mW		55.51		55.51		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	3.35					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	2.27	2.35		2.35		2.35
Other Information	pr	Hz	9000					
	srr	Hz	70.31					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	22.43					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	37.93					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	4.0	1.0		1.0		1.0
	Depth	cm	20.94	7.39		7.39		7.39
	Scanning width	%	100	100		100		100
	Freq	MHz	2.5/2.5	2.5/2.5		2.5/2.5		2.5/2.5
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5P64L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	1.4		2.2		2.2
Index component value				1.4	1.4	2.2	1.4	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.75					
	P	mW		75.12		75.12		75.12
	$P_{1 \times 1}$	mW		74.43		74.43		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	2.20					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	3.78	3.95		3.95		3.95
Other Information	pr	Hz	4199					
	srr	Hz	32.80					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	15.24					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	27.07					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	5.0	8.0		8.0		8.0
	Depth	cm	23.32	9.86		9.86		9.86
	Scanning width	%	100	100		100		100
	Freq	MHz	6.4	6.4		6.4		6.4
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5P64L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	0.9		1.4		1.4
Index component value				0.9	0.9	1.4	0.9	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.31					
	P	mW		47.13		47.13		47.13
	$P_{1 \times 1}$	mW		46.21		46.21		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	2.30					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	4.07	4.09		4.09		4.09
Other Information	pr	Hz	10000					
	srr	Hz	78.13					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	21.12					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	40.32					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	6.0	7.0		7.0		7.0
	Depth	cm	19.71	11.09		11.09		11.09
	Scanning width	%	100	100		100		100
	Freq	MHz	6.4/4.0	6.4/4.0		6.4/4.0		6.4/4.0
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5P64L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.4	0.4		1.1		0.9
Index component value				0.2	0.4	0.9	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.00					
	P	mW		25.71		29.45		29.45
	$P_{1 \times 1}$	mW		25.55		28.88		
	Z_s	cm			1.68			
	Z_b	cm					1.79	
	Z_{MI}	cm	1.95					
	$Z_{pii,\alpha}$	cm	1.95					
	f_{awf}	MHz	7.32	7.35		7.34		7.34
Other Information	pr	Hz	10000					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	109.15					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	122.13					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	327.37					
	p_r at Z_{pii}	Mpa	1.42					
Operating control conditions	Focus	cm	7.0	5.0		5.0		5.0
	Depth	cm	7.39	11.09		7.39		7.39
	Scanning width	%	100	100		100		100
	Freq	MHz	6.4/6.4	6.4/6.4		6.4/6.4		6.4/6.4
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5P64L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	1.6		1.1		0.9
Index component value				0.9	1.6	0.9	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.87					
	P	mW		50.24		52.11		52.11
	$P_{1 \times 1}$	mW		49.48		50.55		
	Z_s	cm			1.78			
	Z_b	cm					1.98	
	Z_{MI}	cm	2.10					
	$Z_{pii,\alpha}$	cm	2.10					
	f_{awf}	MHz	3.82	3.82		3.81		3.81
Other Information	pr	Hz	5816					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	147.19					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	155.16					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	270.05					
	p_r at Z_{pii}	Mpa	2.31					
Operating control conditions	Focus	cm	5.0	5.0		6.0		6.0
	Depth	cm	11.09	11.09		8.62		8.62
	Scanning width	%	100	100		100		100
	Freq	MHz	6.4	6.4		6.4		6.4
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5P64L**Operating Mode: CW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.3	0.9		1.0		0.9
Index component value				0.9	0.8	0.9	1.0	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.47					
	P	mW		54.00		55.58		55.58
	$P_{1 \times 1}$	mW		53.31		54.21		
	Z_s	cm			3.88			
	Z_b	cm					4.08	
	Z_{MI}	cm	4.00					
	$Z_{pii,\alpha}$	cm	4.00					
	f_{awf}	MHz	3.25	3.50		3.61		3.54
Other Information	pr	Hz	0					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	26.80					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	105.64					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	259.32					
	p_r at Z_{pii}	Mpa	0.09					
Operating control conditions	Focus	cm	5.0	5.0		6.0		6.0
	Depth	cm	6.16	8.62		7.39		7.39
	Scanning width	%	100	100		100		100
	Freq	MHz	6.4/6.4	6.4/6.4		6.4/6.4		6.4/6.4
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5P64L

Operating Mode: CFM-M

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	0.3		0.5		0.5
Index component value				0.2	0.3	0.5	0.3	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.22					
	P	mW		11.90		16.00		16.00
	$P_{1 \times 1}$	mW		11.78		15.78		
	Z_s	cm			2.88			
	Z_b	cm					3.00	
	Z_{MI}	cm	3.18					
	$Z_{pii,\alpha}$	cm	3.18					
	f_{awf}	MHz	3.48	3.53		3.63		3.53
Other Information	pr	Hz	200					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	55.88					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	103.25					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	221.76					
	p_r at Z_{pii}	Mpa	2.39					
Operating control conditions	Focus	cm	5.0	5.0		6.0		6.0
	Depth	cm	6.16	8.62		8.62		8.62
	Scanning width	%	100	100		100		100
	Freq	MHz	6.4	6.4		6.4		6.4
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5P64L**Operating Mode: TDI**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.8		1.2		1.2
Index component value				0.8	0.8	1.2	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.61					
	P	mW		42.22		42.22		42.22
	$P_{1 \times 1}$	mW		41.28		41.28		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	2.32					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	4.05	4.07		4.07		4.07
Other Information	pr	Hz	10000					
	srr	Hz	78.13					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	20.22					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	38.70					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	6.0	7.0		7.0		7.0
	Depth	cm	19.71	11.09		11.09		11.09
	Scanning width	%	100	100		100		100
	Freq	MHz	6.4/4.0	6.4/4.0		6.4/4.0		6.4/4.0
	Power	%	100	100		100		100

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: M8L40L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.5		0.8		—
Index component value				0.5	0.5	0.8	0.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.86					
	P	mW		35.14		35.14		—
	$P_{1 \times 1}$	mW		17.24		17.24		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.05					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	6.02	6.09		6.09		—
Other Information	pr	Hz	2764					
	srr	Hz	21.59					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	14.28					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	33.49					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	2.5	3.0		3.0		—
	Depth	cm	4.93	4.93		4.93		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: M8L40L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.8		1.2		—
Index component value				0.8	0.8	1.2	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.25					
	P	mW		52.49		52.49		—
	$P_{1 \times 1}$	mW		26.42		26.42		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	1.65					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	6.34	6.36		6.36		—
Other Information	pr	Hz	20000					
	srr	Hz	156.25					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	16.26					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	33.49					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	2.0	1.5		1.5		—
	Depth	cm	4.93	3.70		3.70		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0/6.5	5.0/6.5		5.0/6.5		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: M8L40L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.6		0.9		–
Index component value				0.6	0.5	0.9	0.9	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.44					
	P	mW		38.89		38.89		–
	$P_{1 \times 1}$	mW		20.25		20.25		
	Z_s	cm			1.66			
	Z_b	cm					1.74	
	Z_{MI}	cm	1.65					
	$Z_{pii,\alpha}$	cm	1.65					
	f_{awf}	MHz	6.23	6.48		6.35		–
Other Information	pr	Hz	20000					
	srr	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	220.50					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	180.29					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	366.74					
	p_r at Z_{pii}	Mpa	2.14					
Operating control conditions	Focus	cm	3.5	3.5		3.5		–
	Depth	cm	7.39	7.39		7.39		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.0/6.5	5.0/6.5		5.0/6.5		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: M8L40L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.2		0.8		—
Index component value				0.7	1.2	0.7	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.73					
	P	mW		47.00		47.00		—
	$P_{1 \times 1}$	mW		24.14		24.14		
	Z_s	cm			1.76			
	Z_b	cm					1.80	
	Z_{MI}	cm	1.90					
	$Z_{pii,\alpha}$	cm	1.90					
	f_{awf}	MHz	6.11	6.09		6.13		—
Other Information	pr	Hz	2796					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	241.60					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	175.64					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	391.65					
	p_r at Z_{pii}	Mpa	2.70					
Operating control conditions	Focus	cm	2.0	2.0		2.0		—
	Depth	cm	11.09	4.93		4.93		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: M8L40L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	0.4		0.7		—
Index component value				0.4	0.4	0.7	0.4	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.21					
	P	mW		28.54		28.54		—
	$P_{1 \times 1}$	mW		13.79		13.79		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.05					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	6.02	6.09		6.09		—
Other Information	pr	Hz	2764					
	srr	Hz	21.59					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	14.28					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	33.49					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	2.5	3.0		3.0		—
	Depth	cm	4.93	4.93		4.93		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.**Transducer Model: D7L40L-REC**

Operating Mode: B

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.5		0.8		–
Index component value				0.5	0.5	0.8	0.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.08					
	P	mW		32.56		32.56		–
	$P_{1 \times 1}$	mW		17.10		17.10		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	1.95					
	$Z_{pii,\alpha}$	cm	–					
	f_{avf}	MHz	6.14	6.14		6.14		–
Other Information	pr	Hz	2865					
	srr	Hz	22.38					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	13.46					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	30.78					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	3.0	3.0		3.0		–
	Depth	cm	4.93	4.93		4.93		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.0	5.0		5.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.**Transducer Model: D7L40L-REC**

Operating Mode: B+C

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.8		1.2		—
Index component value				0.8	0.8	1.2	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	<i>Mpa</i>	1.25					
	P	mW		50.21		50.21		—
	$P_{1 \times 1}$	mW		26.46		26.46		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	1.65					
	$Z_{pii,\alpha}$	cm	—					
	f_{avf}	MHz	6.36	6.35		6.35		—
Other Information	pr	Hz	20000					
	srr	Hz	156.25					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	14.62					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	30.18					
	p_r at Z_{pii}	<i>Mpa</i>	—					
Operating control conditions	Focus	cm	2.0	2.5		2.5		—
	Depth	cm	4.93	3.70		3.70		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0/6.5	5.0/6.5		5.0/6.5		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D7L40L-REC

Operating Mode: PW

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.8		0.9		—
Index component value				0.6	0.8	0.9	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.39					
	P	mW		33.23		38.44		—
	$P_{1 \times 1}$	mW		18.99		21.26		
	Z_s	cm			1.45			
	Z_b	cm					1.65	
	Z_{MI}	cm	1.65					
	$Z_{pii,\alpha}$	cm	1.65					
	f_{awf}	MHz	6.32	6.32		6.30		—
Other Information	pr	Hz	20000					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	120.41					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	118.99					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	244.54					
	p_r at Z_{pii}	Mpa	1.90					
Operating control conditions	Focus	cm	2.0	2.0		3.0		—
	Depth	cm	7.39	7.39		7.39		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0/6.5	5.0/6.5		5.0/6.5		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.**Transducer Model: D7L40L-REC**

Operating Mode: B+M

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.4		0.9		—
Index component value				0.9	1.4	0.9	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.71					
	P	mW		46.36		46.69		—
	$P_{1 \times 1}$	mW		30.58		30.77		
	Z_s	cm			1.77			
	Z_b	cm					1.86	
	Z_{MI}	cm	2.45					
	$Z_{pii,\alpha}$	cm	2.45					
	f_{avf}	MHz	6.05	6.18		6.05		—
Other Information	pr	Hz	2655					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	134.51					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	122.56					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	341.21					
	p_r at Z_{pii}	Mpa	2.52					
Operating control conditions	Focus	cm	2.0	2.0		2.0		—
	Depth	cm	7.39	3.70		7.39		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.**Transducer Model: D7L40L-REC**

Operating Mode: Elasticity imaging

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.6		1.0		—
Index component value				0.6	0.6	1.0	0.6	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	<i>Mpa</i>	1.49					
	P	mW		45.21		45.21		—
	$P_{1 \times 1}$	mW		20.52		20.52		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	1.95					
	$Z_{pii,\alpha}$	cm	—					
	f_{avf}	MHz	6.14	6.14		6.14		—
Other Information	pr	Hz	2865					
	srr	Hz	22.38					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	15.68					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	35.85					
	p_r at Z_{pii}	<i>Mpa</i>	—					
Operating control conditions	Focus	cm	3.0	3.0		3.0		—
	Depth	cm	4.93	4.93		4.93		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: V4C40L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.3		1.6		–
Index component value				1.3	1.3	1.6	1.3	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.40					
	P	mW		123.40		123.40		–
	$P_{1 \times 1}$	mW		63.05		63.05		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	3.20					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	4.25	4.33		4.33		–
Other Information	pr	Hz	9260					
	srr	Hz	72.34					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	15.36					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	39.30					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	4.0	2.0		2.0		–
	Depth	cm	6.61	5.40		5.40		–
	Scanning width	%	100	100		100		–
	Freq	MHz	4.0	4.0		4.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: V4C40L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.5	0.5		0.6		—
Index component value				0.5	0.5	0.6	0.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.94					
	P	mW		46.52		46.52		—
	$P_{1 \times 1}$	mW		27.93		27.93		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	5.27					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	3.85	3.76		3.76		—
Other Information	pr	Hz	6000					
	srr	Hz	46.88					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	15.84					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	64.33					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	6.0	6.0		6.0		—
	Depth	cm	10.59	11.82		11.82		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0/5.0	5.0/5.0		5.0/5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: V4C40L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.4	1.0		1.1		–
Index component value				0.9	1.0	1.1	1.0	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.78					
	P	mW		85.28		86.92		–
	$P_{1 \times 1}$	mW		47.73		48.55		
	Z_s	cm			4.02			
	Z_b	cm					3.98	
	Z_{MI}	cm	3.20					
	$Z_{pii,\alpha}$	cm	3.20					
	f_{awf}	MHz	3.85	3.96		4.02		–
Other Information	pr	Hz	6000					
	srr	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	121.20					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	126.34					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	295.90					
	p_r at Z_{pii}	Mpa	1.20					
Operating control conditions	Focus	cm	6.0	7.0		6.0		–
	Depth	cm	8.13	8.13		8.13		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.0/5.0	5.0/5.0		5.0/5.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: V4C40L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.5		1.6		–
Index component value				1.3	1.5	1.3	1.6	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	<i>Mpa</i>	1.29					
	P	mW		124.55		126.91		–
	$P_{1 \times 1}$	mW		69.12		69.46		
	Z_s	cm			3.78			
	Z_b	cm					5.03	
	Z_{MI}	cm	4.10					
	$Z_{pii,\alpha}$	cm	4.10					
	f_{awf}	MHz	3.93	3.95		4.02		–
Other Information	pr	Hz	4642					
	srr	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	198.00					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	132.42					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	403.04					
	p_r at Z_{pii}	<i>Mpa</i>	2.36					
Operating control conditions	Focus	cm	7.0	4.0		5.0		–
	Depth	cm	8.13	5.40		6.61		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.0	5.0		5.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: **V4C40L**Operating Mode: **Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.2		1.2		—
Index component value				1.2	1.2	1.1	1.2	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.65					
	P	mW		89.25		89.25		—
	$P_{1 \times 1}$	mW		58.20		58.20		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	3.20					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	4.25	4.33		4.33		—
Other Information	pr	Hz	9260					
	srr	Hz	72.34					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	15.33					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	39.22					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	4.0	2.0		2.0		—
	Depth	cm	6.61	5.40		5.40		—
	Scanning width	%	100	100		100		—
	Freq	MHz	4.0	4.0		4.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C15L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.2		1.4		–
Index component value				1.2	1.2	1.4	1.2	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.93					
	P	mW		58.79		58.79		–
	$P_{1 \times 1}$	mW		42.86		42.86		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	2.70					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	5.66	5.88		5.88		–
Other Information	pr	Hz	5924					
	srr	Hz	46.28					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	15.20					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	43.68					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.5	2.0		2.0		–
	Depth	cm	5.69	6.92		6.92		–
	Scanning width	%	100	100		100		–
	Freq	MHz	4.0	4.0		4.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C15L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.1		1.3		–
Index component value				1.1	1.1	1.3	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.72					
	P	mW		55.60		55.60		–
	P_{1x1}	mW		43.10		43.10		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	1.80					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	5.26	5.36		5.36		–
Other Information	pr	Hz	10000					
	srr	Hz	78.13					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	14.57					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	28.02					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.5	1.0		1.0		–
	Depth	cm	11.85	3.22		3.22		–
	Scanning width	%	100	100		100		–
	Freq	MHz	4.0/5.3	4.0/5.3		4.0/5.3		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C15L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.4		1.6		—
Index component value				1.4	1.1	1.6	0.7	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.58					
	P	mW		66.36		66.36		—
	$P_{1 \times 1}$	mW		55.13		55.13		
	Z_s	cm			1.80			
	Z_b	cm					1.80	
	Z_{MI}	cm	2.85					
	$Z_{pii,\alpha}$	cm	2.85					
	f_{awf}	MHz	5.21	5.38		5.38		—
Other Information	pr	Hz	10000					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	138.48					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	147.55					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	411.52					
	p_r at Z_{pii}	Mpa	2.40					
Operating control conditions	Focus	cm	2.5	3.5		3.5		—
	Depth	cm	3.22	4.46		4.46		—
	Scanning width	%	100	100		100		—
	Freq	MHz	4.0/5.3	4.0/5.3		4.0/5.3		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C15L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.9		1.5		—
Index component value				1.3	1.9	1.3	1.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.79					
	P	mW		60.22		63.54		—
	$P_{1 \times 1}$	mW		50.18		52.28		
	Z_s	cm			2.00			
	Z_b	cm					2.00	
	Z_{MI}	cm	3.55					
	$Z_{pii,\alpha}$	cm	3.55					
	f_{awf}	MHz	4.92	5.44		4.99		—
Other Information	pr	Hz	11236					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	180.80					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	152.39					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	509.26					
	p_r at Z_{pii}	Mpa	2.44					
Operating control conditions	Focus	cm	4.0	2.0		3.5		—
	Depth	cm	10.62	4.46		8.15		—
	Scanning width	%	100	100		100		—
	Freq	MHz	4.0	4.0		4.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D6C15L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.0		1.1		–
Index component value				1.0	1.0	1.1	1.0	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.67					
	P	mW		44.68		44.68		–
	$P_{1 \times 1}$	mW		35.71		35.71		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	2.70					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	5.66	5.88		5.88		–
Other Information	pr	Hz	5924					
	srr	Hz	46.28					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	16.23					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	46.64					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.5	2.0		2.0		–
	Depth	cm	5.69	6.92		6.92		–
	Scanning width	%	100	100		100		–
	Freq	MHz	4.0	4.0		4.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3C20L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.3		1.5		–
Index component value				1.3	1.3	1.5	1.3	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.26					
	P	mW		105.23		105.23		–
	$P_{1 \times 1}$	mW		79.82		79.82		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	4.95					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	3.25	3.42		3.42		–
Other Information	pr	Hz	3844					
	srr	Hz	30.03					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	14.52					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	44.12					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	5.0	7.0		7.0		–
	Depth	cm	8.84	10.70		10.70		–
	Scanning width	%	100	100		100		–
	Freq	MHz	3.5	3.5		3.5		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3C20L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.3	0.5		0.8		—
Index component value				0.5	0.5	0.8	0.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.47					
	P	mW		56.52		56.52		—
	$P_{1 \times 1}$	mW		37.10		37.10		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	3.90					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	2.82	2.83		2.83		—
Other Information	pr	Hz	6000					
	srr	Hz	46.88					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	13.68					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	29.24					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	5.0	5.0		5.0		—
	Depth	cm	7.61	7.61		7.61		—
	Scanning width	%	100	100		100		—
	Freq	MHz	3.5/3.5	3.5/3.5		3.5/3.5		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3C20L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.4	0.6		1.2		—
Index component value				0.6	0.5	1.2	0.8	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	0.59					
	P	mW		75.44		78.68		—
	P_{1x1}	mW		40.13		42.25		
	Z_s	cm			3.88			
	Z_b	cm					3.48	
	Z_{MI}	cm	5.60					
	$Z_{pii,\alpha}$	cm	5.60					
	f_{awf}	MHz	2.88	2.91		2.90		—
Other Information	pr	Hz	6000					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	101.35					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	156.43					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	476.61					
	p_r at Z_{pii}	Mpa	0.77					
Operating control conditions	Focus	cm	5.0	5.0		5.0		—
	Depth	cm	8.84	8.84		17.46		—
	Scanning width	%	100	100		100		—
	Freq	MHz	3.5/3.5	3.5/3.5		3.5/3.5		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3C20L**Operating Mode: B+M**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.5		0.8		—
Index component value				0.8	1.5	0.8	0.3	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.22					
	P	mW		98.55		98.55		—
	$P_{1 \times 1}$	mW		51.69		51.69		
	Z_s	cm			3.48			
	Z_b	cm					4.25	
	Z_{MI}	cm	4.65					
	$Z_{pii,\alpha}$	cm	4.65					
	f_{awf}	MHz	3.22	3.25		3.25		—
Other Information	pr	Hz	7568					
	srr	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	102.39					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	161.34					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	453.87					
	p_r at Z_{pii}	Mpa	1.90					
Operating control conditions	Focus	cm	5.0	5.0		5.0		—
	Depth	cm	6.37	6.37		6.37		—
	Scanning width	%	100	100		100		—
	Freq	MHz	3.5	3.5		3.5		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D3C20L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	1.1		1.6		–
Index component value				1.1	1.1	1.6	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.08					
	P	mW		108.94		108.94		–
	P_{1x1}	mW		67.54		67.54		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	4.95					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	3.25	3.42		3.42		–
Other Information	p_{rr}	Hz	3844					
	s_{rr}	Hz	30.03					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	13.55					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	41.17					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	5.0	7.0		7.0		–
	Depth	cm	8.84	10.70		10.70		–
	Scanning width	%	100	100		100		–
	Freq	MHz	3.5	3.5		3.5		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5C20L**Operating Mode: B**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	0.9		1.3		—
Index component value				0.9	0.9	1.3	0.9	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.88					
	P	mW		58.40		58.40		—
	$P_{1 \times 1}$	mW		38.97		38.97		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.45					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	4.78	4.85		4.85		—
Other Information	pr	Hz	14703					
	srr	Hz	114.90					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	13.25					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	29.75					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	4.0	1.5		1.5		—
	Depth	cm	11.77	5.61		5.61		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5C20L**Operating Mode: B+C**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.7	1.1		1.6		–
Index component value				1.1	1.1	1.6	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.36					
	P	mW		72.30		72.30		–
	$P_{1 \times 1}$	mW		57.46		57.46		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	2.85					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	4.03	4.02		4.02		–
Other Information	pr	Hz	10000					
	srr	Hz	78.13					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	12.50					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	27.64					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	3.5	3.5		3.5		–
	Depth	cm	9.30	9.30		9.30		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.0/4.0	5.0/4.0		5.0/4.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5C20L**Operating Mode: PW**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.0		1.7		—
Index component value				1.0	0.8	1.7	1.1	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.55					
	P	mW		78.88		78.88		—
	P_{1x1}	mW		53.44		53.44		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.35					
	$Z_{pii,\alpha}$	cm	2.35					
	f_{awf}	MHz	3.95	3.93		3.96		—
Other Information	p_{rr}	Hz	10000					
	s_{rr}	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	100.58					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	111.88					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	212.44					
	p_r at Z_{pii}	Mpa	2.09					
Operating control conditions	Focus	cm	2.0	3.0		3.0		—
	Depth	cm	4.37	4.37		4.37		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0/4.0	5.0/4.0		5.0/4.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5C20L

Operating Mode: B+M

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	1.2		1.5		–
Index component value				1.1	1.2	1.1	1.5	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.95					
	P	mW		65.45		69.24		–
	$P_{1 \times 1}$	mW		48.53		51.43		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	2.05					
	$Z_{pii,\alpha}$	cm	2.05					
	f_{awf}	MHz	4.71	4.76		4.79		–
Other Information	pr	Hz	14698					
	srr	Hz	–					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	110.36					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	124.32					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	242.22					
	p_r at Z_{pii}	Mpa	2.80					
Operating control conditions	Focus	cm	3.5	2.5		2.0		–
	Depth	cm	4.37	3.14		5.61		–
	Scanning width	%	100	100		100		–
	Freq	MHz	5.0	5.0		5.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D5C20L**Operating Mode: Elasticity imaging**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.7		1.0		—
Index component value				0.7	0.7	1.0	0.7	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.75					
	P	mW		46.58		46.58		—
	$P_{1 \times 1}$	mW		30.31		30.31		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	2.45					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	4.78	4.85		4.85		—
Other Information	pr	Hz	14703					
	srr	Hz	114.87					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	mW/cm ²	13.26					
	I_{spta} at Z_{pii} or Z_{sii}	mW/cm ²	29.78					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	4.0	1.5		1.5		—
	Depth	cm	11.77	5.61		5.61		—
	Scanning width	%	100	100		100		—
	Freq	MHz	5.0	5.0		5.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D8L50L

Operation Mode: B

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.9	0.6		0.6		—
Index component value				0.6	0.6	0.5	0.6	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.43					
	P	mW		32.16		32.16		—
	$P_{1 \times 1}$	mW		17.31		17.31		
	Z_s	cm			—			
	Z_b	cm					—	
	Z_{MI}	cm	1.88					
	$Z_{pii,\alpha}$	cm	—					
	f_{awf}	MHz	7.28	7.28		7.28		—
Other Information	p_{rr}	Hz	2891					
	s_{rr}	Hz	22.59					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	—					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$	mW/cm ²	15.46					
	I_{spta} at Z_{pii} OR Z_{sii}	mW/cm ²	39.79					
	p_r at Z_{pii}	Mpa	—					
Operating control conditions	Focus	cm	2.0	2.0		2.0		—
	Depth	cm	4.93	4.93		4.93		—
	Scanning width	%	100	100		100		—
	Freq	MHz	8.0	8.0		8.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D8L50L

Operation Mode: B+C

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.6	0.7		0.8		–
Index component value				0.7	0.7	0.8	0.7	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	1.54					
	P	mW		45.32		45.32		–
	$P_{1 \times 1}$	mW		22.17		22.17		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	1.68					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	6.61	6.63		6.63		–
Other Information	p_{rr}	Hz	20000					
	s_{rr}	Hz	156.25					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$	mW/cm ²	20.11					
	I_{spta} at Z_{pii} OR Z_{sii}	mW/cm ²	43.31					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.5	1.0		1.0		–
	Depth	cm	4.93	3.70		3.70		–
	Scanning width	%	100	100		100		–
	Freq	MHz	8.0/6.5	8.0/6.5		8.0/6.5		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D8L50L

Operation Mode: PW

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.1		1.0		—
Index component value				1.1	0.9	0.9	1.0	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.06					
	P	mW		51.28		54.59		—
	$P_{1 \times 1}$	mW		35.11		37.28		
	Z_s	cm			1.75			
	Z_b	cm					1.83	
	Z_{MI}	cm	1.73					
	$Z_{pii,\alpha}$	cm	1.73					
	f_{awf}	MHz	6.63	6.58		6.58		—
Other Information	p_{rr}	Hz	12000					
	s_{rr}	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	181.23					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$	mW/cm ²	221.44					
	I_{spta} at Z_{pii} OR Z_{sii}	mW/cm ²	489.05					
	p_r at Z_{pii}	Mpa	2.18					
Operating control conditions	Focus	cm	4.0	2.5		2.5		—
	Depth	cm	7.39	3.70		7.39		—
	Scanning width	%	100	100		100		—
	Freq	MHz	8.0/6.5	8.0/6.5		8.0/6.5		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D8L50L

Operation Mode: B+M

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	1.2		1.0		—
Index component value				0.8	1.2	0.8	1.0	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.02					
	P	mW		61.22		65.12		—
	$P_{1 \times 1}$	mW		29.58		31.26		
	Z_s	cm			1.84			
	Z_b	cm					1.88	
	Z_{MI}	cm	1.68					
	$Z_{pii,\alpha}$	cm	1.68					
	f_{awf}	MHz	6.35	6.39		6.38		—
Other Information	p_{rr}	Hz	2877					
	s_{rr}	Hz	—					
	n_{pps}		—					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	205.36					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$	mW/cm ²	251.02					
	I_{spta} at Z_{pii} OR Z_{sii}	mW/cm ²	524.50					
	p_r at Z_{pii}	Mpa	2.62					
Operating control conditions	Focus	cm	2.0	1.5		2.0		—
	Depth	cm	3.70	3.70		3.70		—
	Scanning width	%	100	100		100		—
	Freq	MHz	8.0	8.0		8.0		—
	Power	%	100	100		100		—

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Transducer Model: D8L50L

Operation Mode: Elasticity imaging

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.8	0.7		0.7		–
Index component value				0.7	0.7	0.6	0.7	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	Mpa	2.16					
	P	mW		38.44		38.44		–
	$P_{1 \times 1}$	mW		20.19		20.19		
	Z_s	cm			–			
	Z_b	cm					–	
	Z_{MI}	cm	1.88					
	$Z_{pii,\alpha}$	cm	–					
	f_{awf}	MHz	7.28	7.28		7.28		–
Other Information	p_{rr}	Hz	2891					
	s_{rr}	Hz	22.59					
	n_{pps}		–					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	W/cm ²	–					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$	mW/cm ²	15.46					
	I_{spta} at Z_{pii} OR Z_{sii}	mW/cm ²	39.79					
	p_r at Z_{pii}	Mpa	–					
Operating control conditions	Focus	cm	2.0	2.0		2.0		–
	Depth	cm	4.93	4.93		4.93		–
	Scanning width	%	100	100		100		–
	Freq	MHz	8.0	8.0		8.0		–
	Power	%	100	100		100		–

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 The depths Z_{pii} and $Z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths Z_{sii} and $Z_{sii,\alpha}$ apply to SCANNING MODES.

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 $\pm 20\%$, and TI is $\pm 40\%$ or < 0.2 , if MI, TI below 0.5.

Item	Measurement Uncertainty (Percentage, 95% Confidence Value)
Center Frequency	$\pm 15\%$
Acoustic Power	$\pm 30\%$
Acoustic Intensity	$\pm 30\%$
Peak Rarefactional Pressure	$\pm 15\%$

APPENDIX D Transducer Maximum Surface Temperature

According to the requirements of the section 201.11 in the standard IEC60601-2-37:2007/AMD1:2015, the transducer surface temperature has been tested in two kinds of conditions: the transducer suspended in still air or transducer contacting human-tissue mimicking material. The calculation of the expanded uncertainty is based on the ISO Guide to the 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(°C)	Maximum surface temperature (°C)	Transducer model	Maximum surface temperature(°C)	Maximum surface temperature (°C)
	Contacting human-tissue mimicking material	Suspending in air		Contacting human-tissue mimicking material	Suspending in air
D3C60L	41±1	44±1	D7L40L	40±1	43±1
D12L40L	39±2	43±1	D3P64L	39±2	42±1
D6C12L	41±1	43±1	D5P64L	40±1	40±1
D7C10L	41±1	43±1	D6C15L	41±1	42±1
D3C20L	38±2	42±2	V4C40L	40±2	38±1
D7L40L-REC	40±2	42±1	D5C20L	41±1	44±1
M8L40L	39±2	43±1	D10L30L	39±2	43±2
D8L50L	40±2	42±1			



NOTE: Values following the “±” mark indicate the expanded uncertainty with a confidence level of 95%, $t_{.975}=4.30$.

APPENDIX E GUIDANCE AND MANUFACTURER'S DECLARATION

1. Guidance and manufacturer's declaration – electromagnetic emissions		
The CBit 9 is intended for use in the electromagnetic environment specified below. The customer or the user of the CBit 9 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CBit 9 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 CBit 9 is suitable for use in medical establishments including domestic establishments and those directly connected to the public high-voltage power supply network that used for non-domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

2. Guidance and manufacturer's declaration – electromagnetic immunity
The CBit 9 is intended for use in the electromagnetic environment specified below. The customer or the user of the CBit 9 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	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i>	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i>	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CBit9 requires continued operation during power mains interruptions, it is recommended that the CBit 9 be powered from an uninterruptible power

IEC 61000-4-11	(30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	(30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	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 <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

3 Guidance and manufacturer's declaration – electromagnetic immunity			
The CBit Series is intended for use in the electromagnetic environment specified below. The customer or the user of the CBit Series should assure that it is used in such an environment.			
3.1. Immunity	IEC 60601	IEC 60601	Electromagnetic environment –
Test	test level	test level	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 CBit Series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

			$d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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 CBit 9 is used exceeds the applicable RF compliance level above, the CBit 9 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CBit 9. 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 CBit Series
The CBit 9 is intended for use in an electromagnetic environment in which radiated RF

disturbances are controlled. The customer or the user of the CBit 9 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CBit 9 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 meters (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 F Measurement Results Summary

Measurement	Useful Range	Accuracy
Distance	Full Screen	<±5%
Circumference: trace method, ellipse method	Full Screen	<±5%
Area: trace method, ellipse method	Full Screen	<±10%
Volume	Full screen	<±10%
Angle	Full screen	<±5%
Time	Full Screen	<±5%
Heart rate	Full Screen	<±5%
Velocity	Full Screen	<±10%



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