



Ultrasound Diagnostic System

ECO 2 Instruction Manual

V2.3

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CHISON Medical Technologies Co., Ltd.

We reserve the rights to make changes to this manual without prior notice

Notice d'information

Documentation utilisateur complète disponible sur demande

Vous consultez actuellement une version synthétique de la documentation relative à ce dispositif médical.

Seule une version allégée du manuel d'utilisation est mise à disposition sur notre site internet. Le manuel utilisateur complet peut être obtenu gratuitement sur simple demande.

Pour recevoir la version intégrale du manuel, nous vous invitons à compléter le formulaire de contact disponible sur notre site internet en précisant la référence du produit concerné.


Notre équipe vous transmettra la documentation complète dans les meilleurs délais, sous format électronique.

Pour toute question complémentaire, notre service client reste à votre disposition.

Important : Avant toute utilisation du dispositif, assurez-vous d'avoir pris connaissance des informations et consignes adaptées à votre usage.

La direction

Regulatory Requirement

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

This manual is a reference for the ECO 2. 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 9.4


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

17. Please put this operation manual with the system to ensure operator and

manager can reach it at any time.

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

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

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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 keeping this manual with the equipment, and periodically review the procedures for operation and safety precautions.

1.1 System Overview

Indications for Use

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

Contraindication

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

1.2 Contact Information

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

CHISON website www.chison.com

Service Support CHISON Medical Technologies Co., Ltd.
Tel:0086-0510-85311707
Fax: 0086-0510-85310726
E-mail: service@chison.com.cn

Placing an Order CHISON Medical Technologies Co., Ltd.
Tel: 0086-0510-8531-0593/0937
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Chapter 2 System Safety

2.1 Safety Overview

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

Users should observe the following precautions:

- This system complies with Type BF general equipment, and the IEC standard.
- Do not modify this system in any way. Necessary modifications must be made only by the manufacturer or its designated agents.
- This system has been fully adjusted at the factory. Do not adjust any fixed adjustable parts.
- In the event of a malfunction, turn off the system immediately and inform the manufacturer or its designated agents.
- The power cable of the system should only be connected to a grounded power socket. Do not remove the ground cable for any reason.
- Only connect this system, either electronically or mechanically, with devices that comply with the EN60601-1 standard. Recheck the leakage current and other safety performance indices of the entire system to avoid potential system damage caused by leakage from a current superposition.
- The system does not incorporate any specialized protective measures in the event it is configured with high-frequency operation devices. The operator should use caution in these types of applications.
- The system should be installed only by personnel authorized by the manufacturer. Do not attempt to install the system by yourself.
- Only an authorized service engineer may perform maintenance.
- Only a qualified operator, or someone under qualified supervision, should use the system.
- Do not use this system in the presence of flammable substances, otherwise an explosion may occur.

- Do not continuously scan the same part of a patient or expose the patient to prolonged scanning; otherwise it may harm the patient.
- When using the system for ultrasound testing, use only qualified ultrasound gel that complies with system standards.
- Do not unplug probe when the system is in active operation. Always go to EXAM screen when need to remove the probe.
- To prevent from arm or neck injury, the operator should not stay at the same position for too long during patient scanning without taking break.
- Do not put liquid on top of the main unit.

 **NOTE:**

**The system has built-in screen saver to avoid the tic mark on the display. It is not recommended to constantly turn on and off the unit.*


**To dispose of this product properly, please call your local service department.*

2.2 Electrical Safety

Type of protection against electric shock

- **Class I Equipment**

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

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

Degree of protection against electric shock

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

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

Level of protection against harmful ingress of water

- Parts of probe 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).

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

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

Mode of operation

- Continuous Operation

For maximum safety, always follow these guidelines:

- Proper grounding of the system is critical to avoid electrical shock. For protection, ground the chassis with a three-wire cable and plug, and plug the system into a hospital-grade, three-hole outlet.
- Do not remove or circumvent the grounding wire.
- Do not remove the protective covers on the system. These covers protect users from hazardous voltages. Cabinet panels must remain in place while the system is in use. A qualified electronic technician must make all internal replacements.
- Do not operate this system in the presence of flammable gases or anesthetics.
- All peripheral devices (unless certified as medical grade) that are connected to the system must be powered through the electrical outlet through an optional isolation transformer.

Notice upon Installation of Product

Separation distance and effect from fixed radio communications equipment: field strengths from

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

- Use either power supply cords provided or designated by CHISON. Products equipped with a power source plug should be plugged into the fixed power socket which has the protective grounding conductor. Never use any adaptor or converter to connect with a power source plug (e.g. three-prong-to-two-prong converter).
- Locate the equipment as far away as possible from other electronic equipment.
- Be sure to use only the cables provided by or designated by CHISON. Connect these cables following the installation procedures (e.g. wire power cables separately from signal cables).
- Lay out the main equipment and other peripherals following the installation procedures described in this manual.

Notice against User Modification

The user should never modify this product.

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

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

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

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

- Securing system parts (cover open/close, cover screwing)

2.3 Label

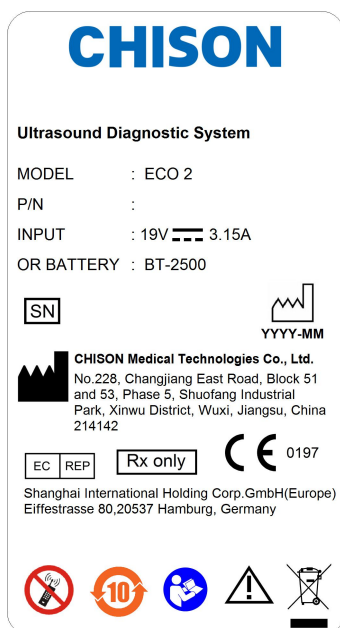












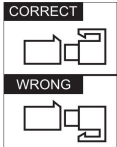


Fig. 2-1 Real panel label

2.3.1 Warning Symbols

 <p>This mark indicates that this product contains a limited amount of hazardous substances in the Chinese Standard GB/T 26572-2011 "Limited Requirements for Restricted Substances in Electrical and Electronic Products". The numbers in the logo are the environmental protection use period of the product, indicating that under the normal use conditions, the harmful substances will not leak or be abrupt. The use of the product will not cause serious pollution to the environment or cause personal or property serious damage, the term unit is year.</p>	 <p>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.</p>
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 <p>Do not use the following devices near this equipment: cellular phone, radio receiver, and mobile radio transmitter, radio controlled toy, etc. Use of these devices near this equipment could cause this equipment to perform outside the published specifications. Keep power to these devices turned off when near this equipment.</p>	 <p>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.</p>
 <p>This symbol signifies that the user manual must be read.</p>	 <p>The CE mark of Conformity indicates this equipment conforms with the Council Directive 93/42/EEC.</p>
 <p>AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.</p>	 <p>Type-BF applied part.</p>
 <p>This symbol is followed by the serial number of the device.</p>	 <p>MANUFACTURER: This symbol is accompanied by the name and the address of the manufacturer.</p>
 <p>Direct current To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.</p>	<p>Rx only</p> <p>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.</p>
 <p>This symbol is followed by the manufacturing date of the device in the form YYYY-MM.</p>	 <p>CORRECT: The correct connection of the battery connector. WRONG: The wrong connection of the battery connector.</p>

2.4 Patient Environmental Devices

Left side:

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

Rear panel:

- 1 Probe port (option 2 probe ports)
- 1 USB port
- 1 Video out port
- 1 Remote port

Acceptable Devices

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

CAUTION:

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

Unapproved Devices

CAUTION:

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

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

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

 **CAUTION:**

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

Peripheral used in the patient environment

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

B/W video printer: SONY UP-X898MD

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 EN60601-1.

Adapter is considered as a part of ME equipment

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

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

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

Peripheral used in the non-patient environment

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

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

include:

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

 CAUTION:

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

 CAUTION:

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

2.5 Biological Safety

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

Clinical Safety Quoted from AIUM

Approved March 26, 1997

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:

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

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

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

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

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

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

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

2.6 Scanning Patients and Education

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

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

2.6.1 Safe Scanning Guidelines

- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.
- Diagnostic ultrasound procedures should be done only by personnel fully trained in the use of the equipment, in the interpretation of the results and images, and in the safe use of ultrasound (including education as to potential hazards).
- Operators should understand the likely influence of the machine controls, the operating mode (e.g. B-mode) and probe frequency on thermal and cavitation hazards.
- Select a low setting for each new patient. Output should only be increased during the examination if penetration is still required to achieve a satisfactory result, and after the Gain control has been moved to its maximum value.
- Maintain the shortest examination time necessary to produce a useful diagnostic result.
- Do not hold the probe in a fixed position for any longer than is necessary. The frozen frame and Cine loop capabilities allow images to be reviewed and discussed without exposing the patient to continuous scanning.

- Do not use endo-cavitary probes if there is noticeable self heating of the probe when operating in the air. Although applicable to any probe, take particular care during trans- vaginal exams during the first eight weeks of gestation.

- Take particular care to reduce output and minimize exposure time of an embryo or fetus when the temperature of the mother is already elevated.

- Take particular care to reduce the risk of thermal hazard during diagnostic ultrasound when exposing: an embryo less than eight weeks after gestation; or the head, brain or spine of any fetus or neonate.

- Operators should continually monitor the on-screen thermal index (TI) and mechanical index (MI) values and use control settings that keep these settings as low as possible while still achieving diagnostically useful results. In obstetric examinations, TIS (soft tissue thermal index) should be monitored during scans carried out in the first eight weeks after gestation, and TIB (bone thermal index) thereafter. In applications where the probe is very close to bone (e.g. trans-cranial applications), TIC (cranial bone thermal index) should be monitored.

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

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

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

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

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),

$$RF = 10^{-0.1 a f z}$$

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

De-rating factor RF for the various distances and frequencies with attenuation coefficient 0.3dB cm⁻¹ MHz⁻¹ in homogeneous soft tissue is listed in the following table. An example is if the user uses 7.5MHz frequency, the power will be attenuated by .0750 at 5cm, or $0.3 \times 7.5 \times 5 = -11.25\text{dB}$. The De- rated Intensity is also referred to as 'I₃' at the end (e.g. I_{spta.3}).

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

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

Tissue Model:

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

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

Soft tissue:

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 mode.

Unscanned:

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

TI:

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

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

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

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

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

MI:

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

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

Pr' 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, and 3).

Display and Report

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

For Scan

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

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

Operator Control Features:

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

Controls Affecting Acoustic Output

The potential for producing mechanical 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 STC.

 **WARNING:** *Be sure to have read and understood control explanations for each mode used before attempting to adjust the Acoustic Output control or any control that can affect Acoustic Output.*

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

Acoustic Output Default Levels

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

2.7 Battery Handling Instructions

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

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

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

Chapter 3 System Introduction

3.1 Console View



Fig. 3-1 Console View

3.2 Physical Specification

Dimensions of main unit (approx.): 335mm (Length) ×155mm (Width) ×350mm (Height)

Net weight of main unit (approx.): 6.5kg

3.3 System View in Different Views

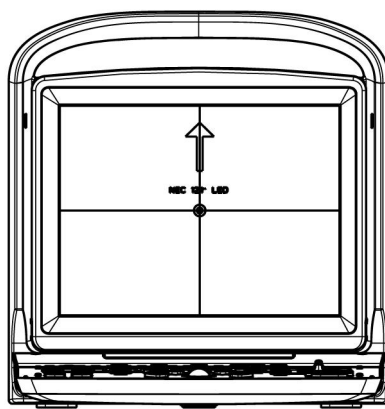


Fig. 3-2 System Front View

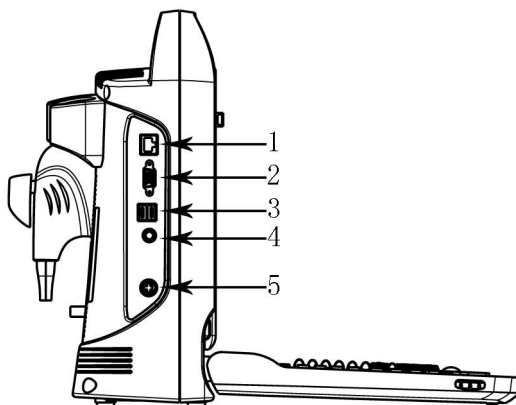


Fig. 3-3 System Side View

1. Ethernet 2. VGA 3.USB 4.FOOT SWITCH 5.DC IN

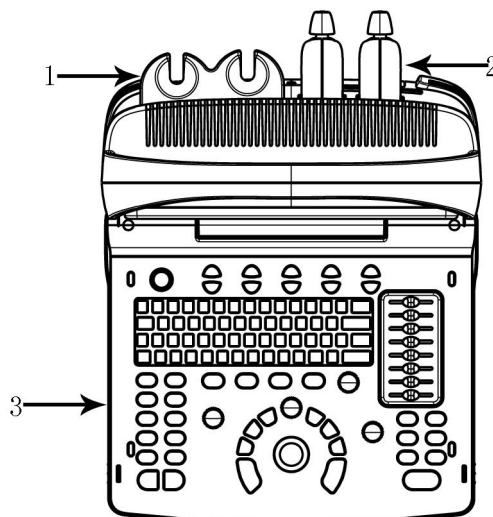


Fig. 3-4 Console Overview

1.Probe Holder 2.Probe 3.Keyboard

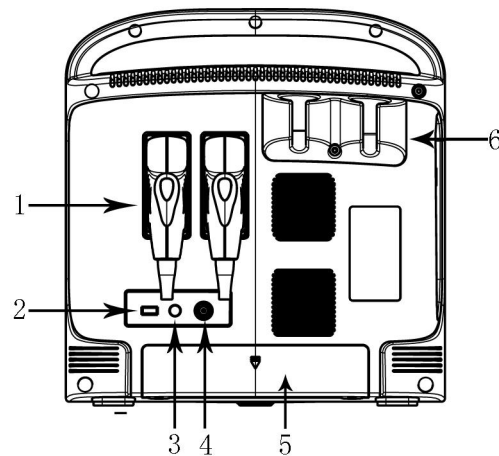


Fig. 3-5 System Rear View

1. Probe 2.USB 3. REMOTE 4. VIDEO OUT 5.Battery Holder 6. Probe Holder

3.4 Function Introduction

1. Possess B, 2B, 4B, B/M, M, PW display mode M, B/M mode possess 4 kinds of scan velocity;
2. Possess many combination of focus, total gain control 8 segments STC;
3. Possess depth scan and image left-right up-down rolling-over function;
4. Possess a lot of imaging technology for example multiple compound imaging (space frequency compound), multiple frequency, multiple zoom ratio, pan zoom, screen scroll, chroma, harmonic imaging etc.;
5. Possess image processing, total gain, dynamic range, frequency, focus number, focus position, zoom, compound, scan width, line density, smooth, edge enhancement, frame, persistence, gray scale, restrain boost multi-beam, acoustic power, M velocity;
6. Possess distance proportion circumference volume rate angle histogram in B mode distance time velocity heart rate measurement function in M mode ;GYN measurement software package, small parts measurement software package, ventricle function measurement software package and user defined formula;
7. Possess body mark arrow case number display, real time clock display annotation in image user-defined annotation;
8. Possess multi-language interface display User interface change, shear plate, printing, DICOM 3.0, biopsy guided functions;
9. It has permanent storage for image and cine and optional 320GB HDD minimum. It can also be connected to removable storage via USB port. To realize mass storage ,can recall saved image for

analysis;

10. Cine loop storage 256 frames real time image;
11. Screen rotation function make you adjust screen angle according to users' requirement 0~30°;
12. Output standard PAL or NTSC video signal and VGA signal;
13. Print or export graphic report.

3.4.1 Image Modes

- B mode
- B/M mode
- M mode
- 2B mode
- 4B mode
- PW mode

3.4.2 Accessories

Transducers:

	C3-A, 2.5-5.0MHz Convex Array
	L7M-A, 5.3-10.0MHz Linear Array
	L7S-A, 5.3-11.0MHz Linear Array
	V6-A, 4.5-8.0MHz Micro-convex Array
	MC3-A, 2.5-5.0MHz Micro-convex Array
	MC6-A, 4.5-8.0MHz Micro-convex Array
	R7-A, 5.0-10.0MHz Linear Array

Peripherals

VGA output for external monitor

VIDEO output for B&W video printer

LAN port output

LAN for DICOM and image review station

USB 2.0 for flash drive

Foot switch

AC/DC adapter: MDS-060AAS19 B


Input: 100-250V~1.5-0.75A, 50-60Hz

Output: 19V=3.15A

DELTA ELECTRONICS, INC.

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

3.5 Installation Procedures

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

3.5.1 Environment Condition

The system should be operated under the following environment.

3.5.1.1 Operation Environment Requirement

Ambient Temperature: 10 °C~40 °C.

Relative Humidity: 30%~75%RH.

Atmospheric 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

NOTE:

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 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.

3.5.1.2 Transport and Storage Environmental Requirement

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

3.5.1.3 Electrical Requirements

Power Consumption: less than 60 VA

Voltage Fluctuation

WARNING:

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

Grounding

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

 **NOTE:**

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

- Line power may vary in different geographic locations. Refer to the detailed ratings on the rear panel of the system for detailed information.


- **Battery**

To avoid the battery bursting, igniting, or fumes from the battery; causing equipment damage, observe the following precautions: Do not immerse the battery in water or allow it to get wet. Do not put the battery into a microwave oven or pressurized container. If the battery leaks or emits an odor, remove it from all possible flammable sources. If the battery emits an odor or heat, is deformed or discolored, or in a way appears abnormal during use, recharging or storage, immediately remove it and stop using it. If you have any questions about the battery, short term (less than one month) storage of battery pack: Store the battery in a temperature range between 0 degrees C (32 degrees F) and 50 degrees C (122 degrees F).

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

3.5.1.4 Operation Space

Please leave enough free space from the back of the system to ensure well ventilation.


 **CAUTION:** Leave enough free space from the back of the system; otherwise, with the increasing of the temperature inside the unit, malfunction may occur.

3.5.1.5 System Positioning & Transporting

Moving the System

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

Before Moving the System

- Press  3 s, system will be forced to shut down and completely switch off the system.
- Disconnect all cables from off-board peripheral devices (external printer, etc.) from the console.

NOTE:

- *To prevent damage to the power cord, DO NOT pull excessively on the cord or sharply bend the cord while wrapping it.*
- *Store all probes in their original cases or wrap them in soft cloth or foam to prevent damage.*
- *Replace gel and other essential accessories in the appropriate storage case.*
- *Ensure that no loose items are left on the console.*

When Moving the System

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

NOTE:

Walk slowly and carefully when moving the system.

Do not let the system strike walls or doorframe.

Transporting the System

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

- Only use vehicles that are suitable for transport of the system.
- Before transporting, place the system in its original storage carton.
- Load and unload the system to a vehicle parked on a level surface.
- Load the unit aboard the vehicle carefully and over its center of gravity. Keep the unit still and upright.
- Ensure that the transporting vehicle can bear the weight of system plus the passengers.
- Secure the system firmly with straps or as directed within the vehicle to prevent movement

during transport. Any movement, coupled with the weight of the system, could cause it to break loose.

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

3.5.2 Powering the System

3.5.2.1 Acclimation Time

After being transported, the unit requires one hour for each 2.5 ° 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.

3.5.2.2 Connecting the electric power

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


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

Press  1 s, system boot, Press  and pop up dialog for shutting down. Click the enter key then power off. Or press  3 s, system will be forced to shut down.

CAUTION:

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

3.5.3 Probe Installation

 **CAUTION:** *Please only use the probes provided by manufacturer for this model, other types of probes are not allowed to use with this system! Otherwise it may cause the damage to the*

system and the probe.

CAUTION:

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

- Hold the probe connector lock switch, and insert the connector socket vertically.
- Release the probe lock switch.
- Check the locked probe with one hand to make sure that it's not loose, and it's securely connected


CAUTION:

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

3.5.3.1 Probe Disassembly

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

3.5.4 Accessories Installation

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


3.5.4.1 Video printer installation


1. Put video printer stably.
2. Connect cable of video printer to video port in the back of the device. And connect the other side to video signal output port in the rear side.
3. Connect the printer line to print control port in the printer rear side, and connect the other side to the print control port in the unit rear side.
4. Connect power cable of video printer to power system.


5. Adjust printer parameter preset according to the type of printing paper


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

Video printer sign introduction

 : Video signal input port

 : Video signal output port

 : Print control port

 : Video printer switch

3.5.4.2 Graphic printer installation

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

Connect the power cable of graphic printer to power system.

⚠ CAUTION: *Please see packing list for fundamental configuration!*

CHISON



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