CHISON

Value Beyond Imaging

Digital Color Doppler Ultrasound System

SonoAir 10/ SonoAir 20/ SonoAir 30/ SonoAir 40/ SonoAir 50/ SonoAir 60/ SonoAir 70/ SonoAir 80/ SonoAir 90

Operation Manual

V1.0

Dec.6th 2021

CHUM SonoAir -001

CHISON Medical Technologies Co., Ltd.

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

TOP MEDICAL – 2, rue Agdal-Rabat
SARL au capital de 10 000 000 MAD – RC 27587 – ICE 001576661000058

Regulatory Requirement

CE 0197 This product conforms to the essential requirements of the Medical Device Regulation (EU) 2017/745. Accessories without the CE mark are not guaranteed to meet the Essential Requirements of the Medical Device Regulation.

This manual is a reference for the SonoAir 10/ SonoAir 20/ SonoAir 30/ SonoAir 40/ SonoAir 50/ SonoAir 60/ SonoAir 70/ SonoAir 80/ SonoAir 90. Please verify that you are using the latest revision of this document. If you need the latest revision, cont act your distributor.

Statement

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

Meaning of the signal words

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

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

Important information

⚠**CAUTION**

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

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

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

⚠NOTE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Content

Chapter 1 Introduction

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

1.1 System Overview

Indications for Use

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

Contraindication

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

1.2 Contact Information

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

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

US Agent	Mr. Marco Mu, 2219 Rimland Drive, Suite 301, Bellingham, Barkley Villiage Bellingham, Washington, 98226, UNITED STATES Phone: (702)209-5185, Fax: 360-9253199 Email: us.agent@mid-link.net MID-LINK INTERNATIONAL CO., LTD

⚠*CAUTION*

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

Chapter 2 System Safety

2.1 Safety Overview

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

Users should observe the following precautions:

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

⚠*NOTE*

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

2.2 Electrical Safety

Type of protection against electric shock

- **Class II Equipment**

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

⚠*NOTE*

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

Degree of protection against electric shock

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

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

Level of protection against harmful ingress of water

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

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

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

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

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

Conduction Interference

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

⚠***WARNING***

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

Mode of operation

Continuous Operation

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

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

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

Notice upon Installation of Product

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

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

Notice against User Modification

The user should never modify this product.

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

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

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

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

Essential performance

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

2.3 Labels

Labels on main unit

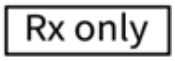
Fig. 2-1 SonoAir Label

Labels on transducers

Fig. 2-2 Probe Label

2.3.1 Symbols on Label

 This mark indicates that this product contains a limited amount of hazardous substances in the Chinese Standard GB/T 26572-2011 "Limited Requirements for Restricted Substances in Electrical and Electronic Products". The numbers in the logo are the environmental protection use period of the product, indicating that under the normal use conditions, the harmful substances will not leak or be abrupt. The use of the product will not cause serious pollution to the environment or cause personal or property serious damage, the term unit is year.	 WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE): This symbol is used for Environment Protection, it indicates that the waste of electrical and electronic equipment must not be disposed as unsorted waste and must be collected separately. Please contact your local Authority or distributor of the manufacturer for information concerning the decommissioning of your equipment.

 Do not use the following devices near this equipment**:** cellular phone, radio receiver, and mobile radio transmitter, radio controlled toy, etc. Use of these devices near this equipment could cause this equipment to perform outside the published specifications. Keep power to these devices turned off when near this equipment.	 Caution, consult accompanying documents. This symbol advises the reader to consult the accompanying documents for important safety related information such as warnings and pre-cautions that cannot be presented on the device itself.
 Refer to instruction manual.	 The CE mark of Conformity indicates this equipment conforms with the Medical Device Regulation 2017/745 [MDR].
 AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.	 This symbol is followed by the serial number of the device.
 YYYY-MM This symbol indicates the country of manufacture of products is china, and this symbol is followed by the manufacturing date of the device in the form YYYY-MM.	 MANUFACTURER: This symbol is accompanied by the name and the address of the manufacturer.
 Scan the QR code for model info and serial number.	 This symbol indicates that in the united states of America, Federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.

 Direct current To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	IPX7 Protection against the effects of immersion
 Refer to instruction manual/booklet.	 This symbol indicates the item is a medical device
 This symbol is accompanied by the name and the address of the importing entity.	
 This symbol indicates the UDI of the device, (01) is followed by the UDI-DI code of the device, (11) is followed by the manufacturing date of the device, (21) is followed by the serial number of the device.	

2.3.2 Other Device Labels

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

Table 2-1: Symbol Icons

Icon	Meaning
	Type-BF applied part

2.4 Patient Environmental Devices

Left side:

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

Right side:

- 4 Probe connection ports

Acceptable Devices

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

⚠*CAUTION*

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

Unapproved Devices

⚠*CAUTION*

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

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

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

⚠*CAUTION*

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

Peripheral used in the patient environment

The system may be used safely while connected to devices other than those recommended if the devices and their specifications, installation, and interconnection with the system conform to the requirements of IEC/EN 60601-1.

Adapter is considered as a part of ME equipment.

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

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

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

Peripheral used in the non-patient environment

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

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

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

⚠CAUTION

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

⚠CAUTION

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

2.5 Biological Safety

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

Clinical Safety Quoted from AIUM

Approved March 26, 1997

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

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

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

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

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

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

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

2.6 Scanning Patients and Education

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

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

2.6.1 Safe Scanning Guidelines

- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.
- Diagnostic ultrasound procedures should be done only by personnel fully trained in the use of the equipment, in the interpretation of the results and images, and in the safe use of ultrasound (including education as to potential hazards).

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

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

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

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

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

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

- Non-diagnostic use of ultrasound equipment is not generally recommended. Examples of non-diagnostic uses of ultrasound equipment include repeated scans for operator training, equipment

demonstration using normal subjects, and the production of souvenir pictures or videos of a fetus. For equipment of which the safety indices are displayed over their full range of values, the TI should always be less than 0.5 and the MI should always be less than 0.3. Avoid frequent repeated exposure of any subject. Scans in the first trimester of pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs, nor should their production involve increasing the exposure levels or extending the scan times beyond those needed for clinical purposes.

- Diagnostic ultrasound has the potential for both false positive and false negative results. Misdiagnosis is far more dangerous than any effect that might result from the ultrasound exposure. Therefore, diagnostic ultrasound system should be performed only by those with sufficient training and education.

2.6.2 Understanding the MI/TI Display

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

For any diagnostic ultrasonic systems, Track-3 provides an Output Indices Display Standard. The diagnostic ultrasound systems and its operation manual contain the information regarding an ALARA (As Low As Reasonably Achievable) education program for the clinical end-user and the acoustic output indices, MI and TI. The MI describes the likelihood of cavitations, and the TI offers the predicted maximum temperature rise in tissue as a result of the diagnostic examination. In general, a temperature increase of 2.5°C must be present consistently at one spot for 2 hours to cause fetal abnormalities. Avoiding a local temperature rise above 1°C should ensure that no thermally induced biologic effect occurs. When referring to the TI for potential thermal effect, a TI equal to 1 does not mean the temperature will rise 1 degree C. It only means an increased potential for thermal effects can be expected as the TI increases. A high index does not mean that bio effects are occurring, but only that the potential exists and there is no consideration in the TI for the scan duration, so minimizing the overall scan time will reduce the potential for effects. These operator control and display features shift the safety responsibility from the manufacturer to the user. So it is very important to have the Ultrasound systems display the acoustic output indices correctly and the education of the user to interpret the value appropriately.

RF: (De-rating factor)

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

RF=10 (-0.1 a f z)

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

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

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

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

Tissue Model:

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

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

Soft tissue:

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

Scanned: (auto-scan)

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

Unscanned:

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

TI:

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

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

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

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

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

MI:

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

MI=Pr'/sqrt(fc)

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

Display Guideline:

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

Display and Report

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

For Scan

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

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

Operator Control Features:

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

Controls Affecting Acoustic Output:

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

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

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

Always observe the Acoustic Output display for possible effects.

Best practices while scanning

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

⚠*WARNING*

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

Acoustic Output Default Levels

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

2.7 Device Instructions of Cybersecurity Controls

2.7.1 Software Integrity Control

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

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

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

- Installing OS Updates Immediately

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

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

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

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

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

2.7.2 Device Instructions of Cybersecurity Controls

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

- Install anti-virus software and use firewall before connecting the device with wifi.
- Install anti-virus software and use firewall before connecting the device with DICOM server.
- Limit access to device software through the authentication of users by user name and password. Ownership of a device is assigned to one user at a time.
- To protect the patient information, the system should hide the critical patient information when exporting the image and cine. And the hidden function is configurable.
- Image and cine data contains no patient or user-identifying information. If want to encrypt this data, please connect to a network that uses an encryption protocol.
- The software uses private custom format to store patient data and can not be recognized by general tools.
- Connect the network only to run the DICOM functions or transmission function, otherwise disconnect the network.
- When connecting the device with wifi, use a network that supports Wi-Fi 802.11n. We recommend that secure this network using WPA (Wi-Fi Protected Access) or WPA2 (Wi-Fi Protected Access II) as security protocol.

2.8 Insturctions to the Intruded Device

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

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

Chapter 3 Preparing the System for Use

3.1 Site Requirement

3.1.1 Operation Environment Requirement

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

Environment / Parameter	Operation	Transportation & Storage
Temperature	10℃ ~ 38℃	-10℃ ~ 50℃
Relative Humidity	30% ~ 75%	≤80%, non-condensing
Atmosphere Pressure	700hPa ~ 1060hPa	700hPa ~ 1060hPa

⚠NOTE

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

3.1.2 Electrical Requirements

Adapter power supply voltage: 100-240V～ 50-60Hz
Main system power input: 19V⎓7.9A
Battery type: U726467PHVG-4S1P: 70Wh
Power consumption: 150VA

⚠WARNING

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

⚠NOTE

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

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

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

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

Build in Battery specification:

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

3.1.3 Battery Handling Instructions

⚠*CAUTION*

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

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

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

3.1.4 Hardware requirements

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

3.1.5 Programming Language Requirements

Operation System: Ubuntu 20.04
Programming Environment: QtCreator

CHISON

Value Beyond Imaging

CHISON Medical Technologies Co., Ltd.

No.3 Changjiang South Road, Xinwu District, Wuxi, 214028 Jiangsu, P.R. China