



Digital Color Doppler Ultrasound System

QBit 3/QBit 5

Operation Manual

V1.1

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CHISON Medical Technologies Co., Ltd.

We reserve the right 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

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




This manual is a reference for the QBit 3/QBit 5. Please verify that you are using the latest revision of this document. If you need the latest revision, please contact 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.

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. *Federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.*
2. *It is prohibited to use the device for fetal sex examination, except for necessary medical needs.*
3. *The device can only be sold to qualified medical institutions or doctors.*
4. *The users shall have got the qualification, and shall comply with the local laws and regulations, the local religion and customs, etc.*
5. *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. *LED display screen may have some dark or light dots, it is normal for the LED. It does not mean that LED screen is defective.*

Service Responsibility

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

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

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

CAUTION:

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

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

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

Contraindication

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

1.2 Contact Information

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

CHISON website	www.chison.com
Service Support	CHISON Medical Technologies Co., Ltd. Tel:0086-0510-85311707 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

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Fax: 0049-40-255726
E-mail: antonsissi@hotmail.com shholding@hotmail.com

Chapter 2 System Safety

2.1 Safety Overview

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

Users should observe the following precautions:

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

occur.

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

 **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 contact the local CHISON's Authorized Service Representative.*

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 which includes an additional safety precaution in that accessible conductive parts are connected to the protective earthing conductor in the electrical installation in such a way that accessible parts cannot become live in the event of a failure of the basic insulation.

Degree of protection against electric shock

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

TYPE BF APPLIED PART providing a specified degree of protection against electric shock, with

particular regard to allowable LEAKAGE CURRENT.

Level of protection against harmful ingress of water

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

Parts of probe intended to be immersed in normal use meet the requirements of watertight equipment (IPX7).

- The IP Classification of System is Ordinary Equipment (IPX0)

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

Mode of operation

- Continuous Operation

For maximum safety, always follow these guidelines:

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

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 only use the cables provided by or designated by CHISON. Connect these cables following the installation procedures (e.g. wire power cord separately from signal cables).
- Lay out the main equipment and other peripherals following the installation procedures described in this manual.

Notice against User Modification

The user should never modify this product.

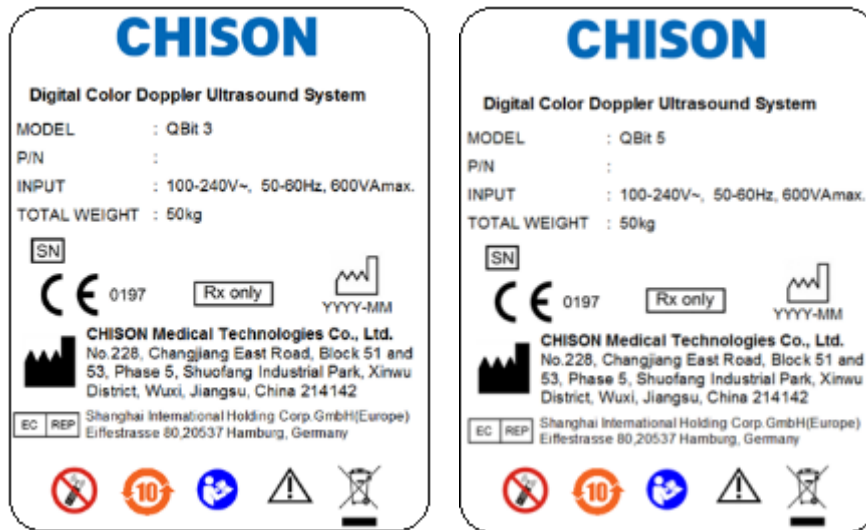
User modifications may cause degradation in Electrical Safety. Modification of the product includes changes in:

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

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






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








2.3 Label








Rear panel label

2.3.1 Warning Symbols on Label

Icon	Meaning
	<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>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>Refer to instruction manual/booklet.</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>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</p>

	collected separately. Please contact your local Authority or distributor of the manufacturer for information concerning the decommissioning of your equipment.
	The CE mark of Conformity indicates this equipment conforms to the Council Directive 93/42/EEC.
	This symbol indicates that federal law restricts the device to sale by or on the order of a licensed practitioner or therapist in the united states.
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.
	MANUFACTURER: This symbol is accompanied by the name and the address of the manufacturer.
	Manufacturing date of the device in the form YYYY-MM.
	Serial number of the device.
	The “Alternating current” symbol indicates that the equipment is suitable for alternating current only.

2.3.2 Symbols used in the system

Icon	Meaning
	Power On/off CAUTION: This Power Switch cannot isolate Mains Supply completely.
	Type-BF applied part
	Main power switch ON
	Main power switch OFF
	Potential equilibrium connection
IPX0	No protection against ingress of water (system)
IPX7	Protection against the effects of immersion (probes)

2.4 Patient Environmental Devices

Right side:

- 2 Probe ports (standard)
- 2 USB ports on control panel

Rear panel:

- 4 USB ports
- 1 VIDEO OUT port
- 1 DVI port
- 1 VGA port
- 1 Remote port
- 1 ECG port
- 2 Footswitch ports
- 1 LAN port
- 1 S-VIDEO port
- 1 Power in port
- 1 Power out 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 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 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 IEC/EN 60601-1.

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

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

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


60601-1-2.


Peripheral used in the non-patient environment

The system has been verified for compatibility, and compliance for connection to a local area network (LAN) via a wire LAN. The provided LAN components are IEC/EN 60950 compliant.

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

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

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

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

2.5 Biological Safety

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

Clinical Safety Quoted from AIUM

Approved March 26, 1997

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

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

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

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

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

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

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

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

2.6 Scanning Patients and Education

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

- In order to maintain proper cleanliness of the probes, always clean them between patients.
- Always use a disinfected sheath on all EV/ER probes during every exam.
- Continuously move the probe, rather than staying in a single spot, to avoid elevated temperatures in one part of the patient's body.
- Move probe away from the patient when not actively scanning.
- Understand the meaning of the TI, TIS, TIB, TIC and MI output display, as well as the relationship between these parameters and the thermal/cavitation 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 to the patient and the operator).
- Operators should understand the likely influence of the machine controls, the operating mode (e.g. B-mode, color Doppler imaging or spectral Doppler) and probe frequency on thermal and cavitations hazards.
- Select a low setting for each new patient. Output should only be increased during the examination if penetration is still required to achieve a satisfactory result, and after the Gain control has been adjusted to its maximum value.
- Maintain the shortest examination time necessary to produce a useful diagnostic result.

- Do not hold the probe in a fixed position for any longer than is necessary. It should be removed from the patient whenever there is no need for real-time imaging or spectral Doppler acquisition. The frozen frame and Cine loop capabilities allow images to be reviewed and discussed without exposing the patient to continuous scanning.

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

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

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

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

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

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

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

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

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 $\text{dB cm}^{-1} \text{MHz}^{-1}$, f is the transducer center frequency, and z is the distance along the beam axis between the source and the point of interest.

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

Unscanned:

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

TI:

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

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

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

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

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

MI:

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

$$MI=Pr'/\text{sqrt}(f_c)$$

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 in Different Mode

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

For B-Scan Mode

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

For Color Mode

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

For Doppler Mode

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

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

Operator Control Features:

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

Controls Affecting Acoustic Output

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


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

Indirect: Indirect effects may occur when adjusting controls. Controls that can influence MI and TI are detailed under the 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.

Chapter 3 System Introduction

3.1 Console View



Fig. 3-1 Console View

NOTE: *The photograph above is adapted for 15 inch monitor. For device of 19 inch monitor please be subject to the actual product.*

3.2 Physical Specification

Dimensions of main unit (approx.):

1 . 15 inch monitor: 747mm (Length)*517mm (Width)*1283mm (Height)

2 . 19 inch monitor (option): 747mm (Length) ×517mm (Width) ×1358.23mm (Height)

Net weight of main unit (approx.): 50 kg (no probe included)

3.3 External Interface View

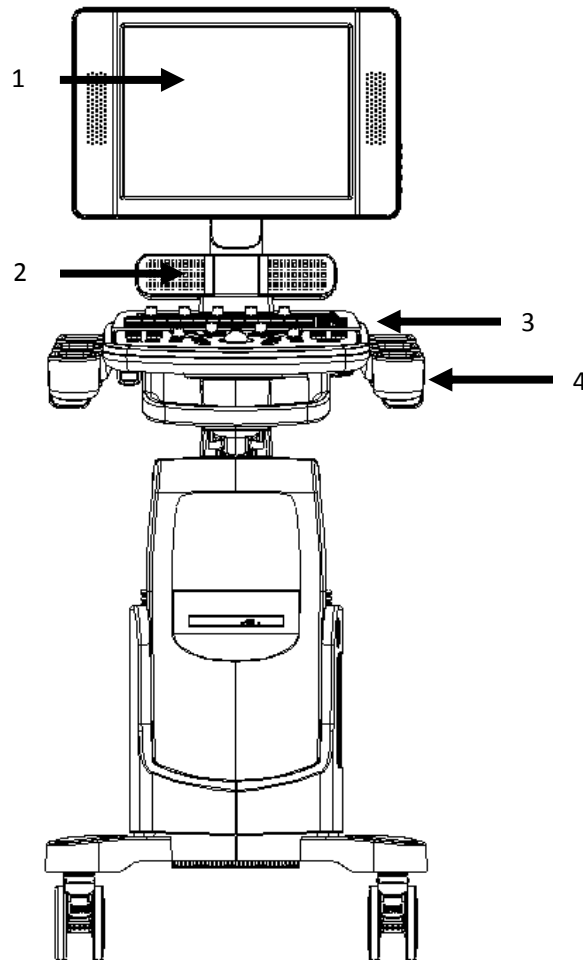


Fig. 3-2 Front Side View

1. Monitor 2. Speaker 3. Keyboard 4. Probe holder

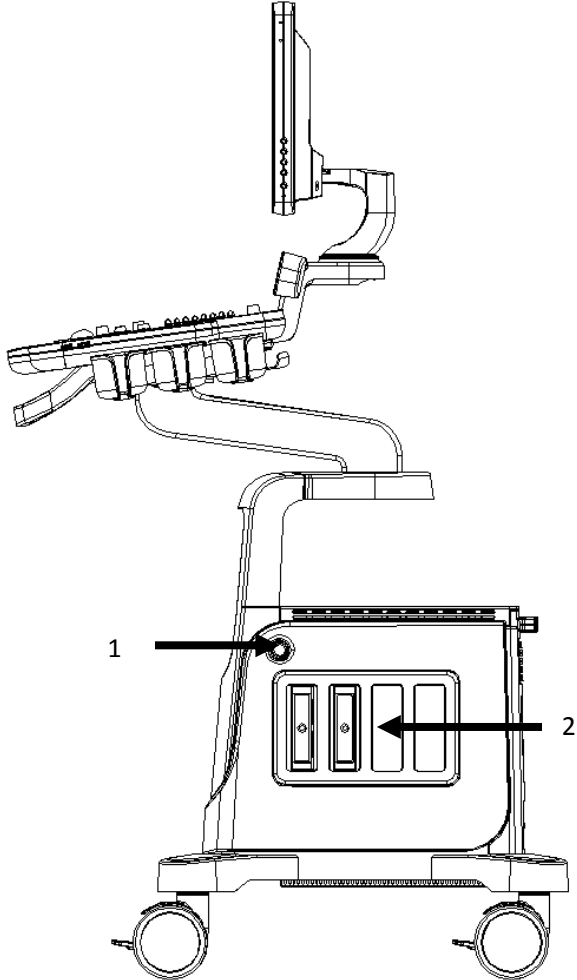


Fig. 3-3 Right Side View
1.ECG port 2. Probe ports

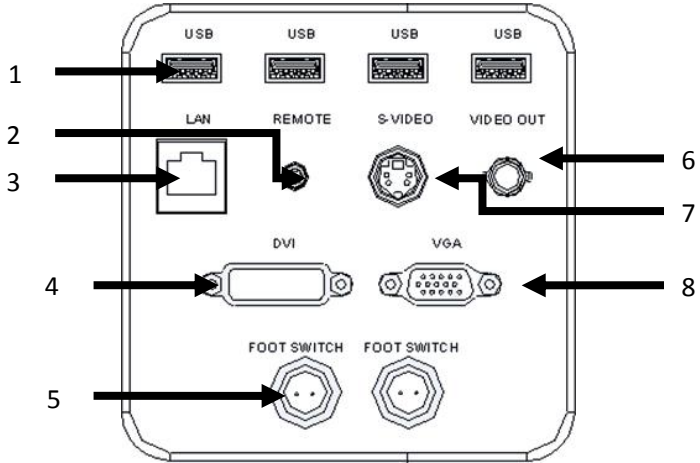


Fig. 3-4 Rear panel
1.USB 2.0 ports 2.Remote port 3.LAN port 4.DVI port
5.Foot Switch ports 6.Video Out port 7.S-Video port 8.VGA port







14. Possess multi-language interface display User interface change, shear plate, printing, DICOM 3.0, biopsy guided functions.
15. It has permanent storage for image and cine on HDD. It can also be connected to removable storage via USB 2.0 port. To realize mass storage ,can recall saved image for analysis.
16. Cine loop storage 256 frames real time image.
17. Output standard PAL or NTSC video signal and VGA/DVI signal.
18. Print or export graphic report.





3.4.1 Image Modes

Mode	QBit 3	QBit 5
B Mode	Standard	Standard
2 B Mode	Standard	Standard
B/M Mode	Standard	Standard
M Mode	Standard	Standard
4B Mode	Standard	Standard
2D Steer	Standard	Standard
CFM Mode	Standard	Standard
CPA(PD) Mode	Standard	Standard
DPD Mode	Standard	Standard
PW Mode	Standard	Standard
Triplex Mode	Standard	Standard
CW Mode	N/A	Option
TDI	N/A	Option
Color M Mode	N/A	Option
Trapezoidal Mode	Standard	Standard
ECG	N/A	Option
B/BC Mode	Standard	Standard
Super Needle	Option	Option
HD 3D	Option	Option

3.4.2 Accessories

Probes:

Probe	Frequency	QBit 3	QBit 5
 <p>D3C60L Convex probe</p>	3.5MHz, 2.0-6.8MHz	Option	Option
 <p>D7L40L Linear probe</p>	7.5MHz, 4.0-15.0MHz	Option	Option
 <p>Micro convex probe D6C12L</p>	6.0MHz, 4.0-12.0MHz	Option	Option
 <p>Micro convex probe D7C10L</p>	7.5MHz, 4.0-15.0MHz	Option	Option
 <p>Linear probe D7L40L-REC</p>	7.5MHz, 4.0-15.0MHz	Option	Option
 <p>Micro convex probe D3C20L</p>	3.0MHz, 2.0-6.8MHz	Option	Option

 <p>Micro convex probe D6C15L</p>	<p>6.0MHz, 4.0-12.0MHz</p>	<p>Option</p>	<p>Option</p>
 <p>Micro convex probe D5C20L</p>	<p>5.0MHz, 4.0-10.7MHz</p>	<p>Option</p>	<p>Option</p>
 <p>Phased array probe D3P64L</p>	<p>2.5MHz, 1.5-5.3MHz</p>	<p>N/A</p>	<p>Option</p>
 <p>Linear probe D12L40L</p>	<p>12.0MHz, 7.0-15.0MHz</p>	<p>Option</p>	<p>Option</p>

Peripherals

S-VIDEO, VGA, DVI 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

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 IEC/EN 60601-1-2. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measure(s):

- Reorient or relocate the affected device(s).
- Increase the separation between the equipment and the affected device.
- Power the equipment from a source different from that of the affected device.
- Consult the point of purchase or service representative for further suggestions.

3.5.1.2 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 Requirements: AC 100-240V, 50-60Hz.

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

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

Power Consumption: 600 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.

3.5.1.4 Operation Space

Please leave enough free space for the system to ensure well ventilation.

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

3.5.2 System Positioning & Transporting

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

- Power off the system, refer to power off section.
- Switch off the power and unplug the power cord (if the system is plugged into wall outlet).
- Disconnect all cables from off-board peripheral devices (external printer, etc.) from the console.

NOTE:

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

When Moving the System

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

NOTE:

Always use the handle to move the system. The system weighs approx. 50 kg. For avoid possible injury or equipment damage.

- *Walk slowly and carefully when moving the system.*
- *Do not let the system strike walls or doorframe.*

Transporting the System

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

Powering the System

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

- Keep the storage case still and upright. Secure that the system firmly with straps or as directed within the vehicle to prevent movement during transport.
- Any movement, coupled with the weight of the system, could cause it to break loose. Drive carefully to prevent damage from vibration.
- Avoid unpaved roads, excessive speeds, and erratic stops or starts.

3.5.3 Powering the System

3.5.3.1 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.

3.5.3.2 Connecting the electric power

To connect the system to the electrical supply:

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

NOTE:


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

WARNING:

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

3.5.3.3 Power on

NOTE:

Turn on the green power switch (main power circuit breaker switch) at the back of the main unit, and then press the Power button  on the control panel to turn on the system.

Starting Sequence

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

- Control panel initiate
- Boot up the operation system
- Load the software
- Entering into examination status

HINTS


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


NOTE:

- **After powering off the system, please wait for 1 minute to power on again.**
- **When the system is powered on, for safety reason, please avoid moving the main unit.**

3.5.3.4 Power off

To power off the system:

Press  on control panel. When the screen shows shut down dialog box, press “shutdown” to shut down the system.

Or press  for 4 seconds to shut down the system directly.

 **NOTE:**

After powering off the system

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

3.5.4 Probes

 **NOTE:**

Only use the probes approved by Manufacturer.

Selecting probes

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

Connecting the Probe

When you connect the probes, please ensure that the probe ports are not active. Freeze the image by pressing [**Freeze**] key to deactivate the probe ports.

To connect a probe:

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

 **NOTE:**

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

- Align the connector with the probe port and carefully push into place with the cable facing the back of the system.
- Turn the probe connector locking lever to "lock" status.

- Carefully position the probe cord so it is free to move and is not resting on the floor.
- When the probe is connected, the system will be automatically recognized.

⚠ CAUTION:

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

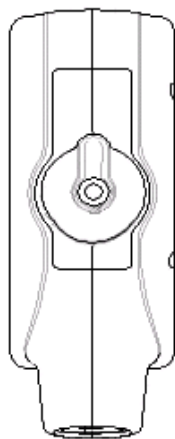


Fig. 3-6 Probe connector “Unlock” status

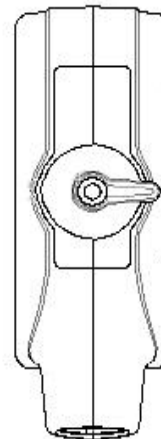


Fig. 3-7 Probe connector “Lock” status

Deactivating the Probe

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

To deactivate a probe:

- Ensure the system is in freezing mode.
- Gently wipe off the excess gel from the probe surface.
- Carefully slide the probe toward the probe holder, and place the probe gently in the probe holder.

Disconnecting the Probe

Probes can be disconnected when the system is in freezing mode.

To disconnect a probe:

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

Transporting the Probe

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

Storing the Probe

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

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

3.5.5 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.*


3.5.5.1 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

3.5.5.2 Graphic & PC printer installation

Put the printer stably; connect printer cable to USB port of the system (right side of control panel or back of the main unit).

Connect the power cable of the printer to power system.

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