CHISON
Value Beyond Imaging

Digital Color Doppler Ultrasound System

SonoMax 1/ SonoMax 2/ SonoMax 3/ SonoMax 5/ SonoMax 6
SonoMax 7/ SonoMax 7 Super/ SonoMax 7 EXP
SonoMax 8/ SonoMax 8 Super/ SonoMax 8 EXP
SonoMax 9/ SonoMax 9 Super/ SonoMax 9 EXP
SonoMax 10/ SonoMax 11/ SonoMax 22

Instruction Manual

CHGA-SonoMax-058
Jan. 29th, 2023
V1.0

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 SonoMax 1/ SonoMax 2/ SonoMax 3/ SonoMax 5/ SonoMax 6/ SonoMax 7/ SonoMax 7 Super/ SonoMax 7 EXP/ SonoMax 8/ SonoMax 8 Super/ SonoMax 8 EXP/ SonoMax 9/ SonoMax 9 Super/ SonoMax 9 EXP/ SonoMax 10/ SonoMax 11/ SonoMax 22. Please verify that you are using the latest revision of this document. If you need the latest revision, contact your distributor.

⚠*NOTE:*

Important

1. No part of this manual may be reduced, modified, copied or reprinted, in whole or in part, without written permission from CHISON.
2. The contents of this manual are subject to change without prior notice and without our legal obligation.
3. Before operating the system, please read and understand this manual. After reading, keep this manual in an easily accessible place. If you have any question or doubt, please contact CHISON's authorized service engineer.
4. CHISON’s Warranty only cover material and parts costs for repair, but do not cover any labor cost or onsite service cost at end user's side.
5. 5.A notice to the user and/or patient that 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 establishe.

⚠*NOTE:*

Important information

1. It is the customer's responsibility to maintain and manage the system after delivery.
2. The warranty does not cover the following items, even during the warranty period:
   a) Damage or loss due to misuse or abuse with system and probes, for example, drop the probe, the liquid or the metal part fall into the system.
   b) Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
   c) Damage or loss caused by failure to meet the specified conditions for this system, such as inadequate power supply, improper installation or environmental conditions.
   d) Damage or loss caused by non-approved transportation by CHISON.
   e) Damage or loss due to use the system outside the region where the system was originally sold.
   f) Damage or loss involving the system purchased from a source other than CHISON or its authorized agents.
3. Do not make changes or modifications to the software or hardware of this system and probes.
4. During operate the system, if user has any doubt, difficulty or any unclear, please contact CHISON's authorized service engineer immediately. Please describe the situation clearly to solve the question in time. Before solve the question, please don't operate the system.
5. This system shall not be used by persons other than fully qualified and certified medical personnel.
6. It is prohibited to use the device for fetal sex examination, except for necessary medical needs. The device can only be sold to qualified medical institutions or doctors. The users shall fully understand and master the devices before operating. The users shall have got the qualification, and shall comply with the local laws and regulations, the local religion and customs, etc.
7. The System modified or repaired by people other than CHISON's qualified service engineers, CHISON shall not be liable for the system.

8. The purpose of this system is to provide physicians with data for clinical diagnosis. It is the physician's responsibility for diagnostic procedures. CHISON shall not be liable for the results of diagnostic procedures
9. This manual contains warnings regarding foreseeable potential dangers, but user shall always be alert to dangers other than those indicated as well. CHISON shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions described in this operation manual.
10. Due to negligence not following operation manual, CHISON shall not be liable for the results.
11. Each time before and after ultrasound examination, please check the probe surface, probe cable and sheath whether they are abnormal, such as cracking, peeling and deformation. Also check whether the lens is strongly fixed. Abnormal probes may cause electric shock and injure the patient. Once any abnormal, user must stop using and contact CHISON's authorized service engineer.
12. If the probe is dropped or scratched by hard part, please stop using the probe immediately. And contact CHISON's authorized service engineer to make sure the safety and effectiveness is in good condition before use.
13. If there is any liquid or metal to enter to the system, please power off the system and stop using it immediately. Please first contact CHISON's authorized service engineer to make sure it's safe before restart using it.
14. Please don't use solvents (such as paint thinner, benzine, or alcohol) or abrasive cleansers for cleaning the system (including monitor and probes, etc.). It may corrode the system and probes.
15. While the system or probe is over life time, please refer to operation manual section 9.5.
16. Important data must be backed up on external memory media. CHISON shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
17. Please put this operation manual with the system to ensure operator and manager can reach it at any time.

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

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

TABLE OF CONTENTS

Chapter 1 Introduction 10

1.1 System Overview 10

1.2 Contact Information 10

1.3 Clinical Benefits 11

Chapter 2 System Safety 12

2.1 Safety Overview 12

2.2 Electrical Safety 13

2.3 Label 15

2.4 Patient Environmental Devices 17

2.5 Biological Safety 20

2.6 Scanning Patients and Education 21

2.6.1 Safe Scanning Guidelines 21

2.6.2 Understanding the MI/TI Display 23

Chapter 3 Preparing the System for Use 28

3.1 Site Requirements 28

3.1.1 Operation Environmental Requirements 28

3.1.2 Transport and Storage Environmental Requirements 29

3.1.3 Electrical Requirements 29

3.2 System Specifications 32

3.2.1 Console Overview 32

3.2.2 Physical Specification 35

3.2.3 Differences between models 36

3.2.4 Key System Features 43

3.2.5 Accessories 43

3.2.6 I/O ports 44

3.3 System Positioning & Transporting 44

3.4 Powering the System 45

3.4.1 Acclimation Time 45

3.4.2 Connecting and Using the System 45

3.4.3 Power On 46

3.4.4 Power Off 47

3.4.5 Standby 47

3.5 Probes 48

3.6 Optional installation 50

3.6.1 Connect the printer 50

3.6.2 Set the system for Video Printer 50

3.6.3 Connect the PC printer 51

3.6.4 Use the Gel Warmer 52

3.7 User Interface Control 53

3.7.1 Control Panel and Alphanumeric Keyboard 54
3.7.2 Soft-Menu Controls 61
Chapter 4 Imaging 62
4.1 General Description 62
4.2 Beginning an Exam 62
4.2.1 Selecting a Probe and an Application 62
4.2.2 Patient Data Entry 63
4.2.3 Display Interface 64
4.3 Optimizing the Image 66
4.3.1 Image Parameters Display 66
4.3.2 Scanning Modes 66
4.3.3 B Mode 67
4.3.4 FHI 68
4.3.5 Dual Mode 68
4.3.6 Quad Mode 69
4.3.7 B/M and M Mode 69
4.3.8 CFM Mode 70
4.3.9 B/BC Mode 73
4.3.10 CPA Mode 73
4.3.11 DPD Mode 74
4.3.12 PW Mode 74
4.3.13 Triplex 78
4.3.14 Quadplex 78
4.3.15 Curved Panoramic 78
4.3.16 2D Steer 79
4.3.17 Trapezoidal Imaging 79
4.3.18 Free Steer M Mode 79
4.3.19 Color M Mode 79
4.3.20 CW Mode 80
4.3.21 TDI 80
4.3.22 4D software package and Virtual HD 80
4.3.23 Elastography 81
4.3.24 ECG 90
4.3.25 Biopsy and Super Needle (Linear probe only) 90
4.3.26 Stress Echo 91
4.3.27 HPRF 93
4.3.28 TSS 93
4.3.29 Auto TGC 93
4.3.30 LGC 93
4.3.31 HD 3D 93
4.3.32 Compound 94
4.3.33 SRA 94
4.3.34 AIO 94
4.3.35 Q-image 94

4.3.36 Q-beam 94
4.3.37 Q-flow 94
4.3.38 X-con 94
4.3.39 Zoom 95
4.3.40 Auto IMT 95
4.3.41 Sono IMT+ 95
4.3.42 Free NT 95
4.3.43 Human Measurement Package 95
4.3.44 Human Bodymark 95
4.3.45 SonoContrast 95
4.3.46 SoundFlow 96
4.3.47 SonoVector 97
4.3.48 Zoom 97
4.3.49 SonoFollicle 97
4.3.50 SonoOB 97
4.3.51 SonoFusion 97
4.3.52 SonoHelp 98
4.3.53 SonoColor 98
4.3.54 SonoBeam 98
4.3.55 Virtual Apex 98
4.3.56 SonoWifi 99
4.3.57 SonoBlue Tooth 99
4.3.58 Hard Disk 99
4.3.59 Strain and Strain Rate 99
4.3.60 Remote Control 99
4.3.61 DICOM 99
4.3.62 Optimize Image 100
4.3.63 B Mode Image Optimization 100
4.3.64 M Mode Image Optimization 102
4.3.65 Color Flow Map (CFM) Mode Image Optimization 102
4.3.66 CPA Mode Imaging Optimization 103
4.3.67 DPD Mode Imaging Optimization 104
4.3.68 Pulse Wave Doppler (PWD) Imaging Optimization 105
4.3.69 Continuous Wave Doppler (CWD) Imaging Optimization 106
4.4 After Capturing the Image 107
4.4.1 Adding Comments 107
4.4.2 Adding Body Mark 108
4.4.3 Saving Still Images 108
4.4.4 Saving Clips 108
4.4.5 Browse Images 111
4.4.6 Fast Storage 111
4.4.7 Files Management 112
4.4.8 Network Storage Function 113
4.4.9 DICOM Function 113

Chapter 5 General Measurements 120
5.1 Key for Measurement 121
5.2 Fast measurement 121
5.2.1 Enter fast measurement 121
5.2.2 Exit fast measurement 121
5.2.3 Fast measurement in B mode 121
5.2.4 Fast measurement in PW mode 123
5.2.5 Fast measurement in M mode 124
5.3 Measurement and Calculation 126
5.3.1 Measurement in B mode 126
5.3.2 Measurement in M mode 150
5.3.3 Measurement in PW mode 156
5.4 Edit measurement results 165
5.5 Report 165
Chapter 6 Preset 169
6.1 Recall Preset 169
6.2 Save User Defined Preset 169
6.3 Manage Preset 169
Chapter 7 System Setting 171
7.1 General 171
7.2 Measurement 176
7.3 Comment 178
7.4 BodyMark 181
7.5 Report 181
7.6 Admin 184
7.7 Remote Service 186
7.8 Scan Code 186
7.9 Network 187
7.10 System Settings 191
Chapter 8 Probes 200
8.1 General Description 200
8.2 Care and Maintenance 200
8.2.1 Inspecting Probes 201
8.2.2 Preparation at the Point of Use 201
8.3 Cleaning and Disinfecting 201
8.3.1 Surface probe as Non-critical 203
8.3.2 TV, TR probe as Semi-Critical 203
8.3.3 TEE probe as Semi-Critical 204
8.4 Using protective sheaths 206
Chapter 9 System Maintenance and Troubleshooting 207
9.1 Back up information 207

9.2 System Care and Maintenance 207
9.3 Safety Check 209
9.4 Troubleshooting 209
9.5 Service Responsibility 211
APPENDIX A The Information of EC Representative 213
APPENDIX B System one-key-recovery Function 214
APPENDIX C Maximun Acoustic Output Report 216
APPENDIX D Display Accuracy and Acoustic Measurement Uncertainties 402
APPENDIX E Transducer Maximum Surface Temperature 403
APPENDIX F Guidance and Manufacture's Declaration 404
APPENDIX G Measurement Results Summary 409
APPENDIX H Pulsed Wave Doppler Velocity Measurement Results Summary 410

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

Intended use

The SonoMax Series Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications,which is intended for use in multiple areas within a professional healthcare facility on one patient at a time.

Indications

The SonoMax Series Digital Color Doppler Ultrasound System is intended for diagnostic ultrasound imaging in B(2D/3D/4D), B/M, M, B+CFM, B+CPA(PD), B+DPD, B+PW, B+CW, B+CFM+D(PW)/CW, 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), Neonatal Cephalic, Adult Cephalic, Cardiac (adult, pediatric), Musculo-skeletal (Conventional, Superficial), Peripheral Vascular, Trans-esophageal, Trans-rectal, Trans-vaginal, OB/GYN and Urology, which is intended to be used in a hospital or medical clinic.

Contraindication

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

Patient target group

Adults and Children

Intended users

Qualified sonographers

1.2 Contact Information

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

CHISON website	www.chison.com
Service Support	CHISON Medical Technologies Co., Ltd. Tel: 0086-400-8878-020; 0086-0510-85311707 Fax: 0086-0510-85310726

	E-mail: service@chison.com.cn
Placing an Order	CHISON Medical Technologies Co., Ltd. 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

1.3 Clinical Benefits

The expected clinical benefits of the SonoMax series diagnostic ultrasound systems are related to the device's intended purpose to provide diagnostic ultrasound imaging and fluid flow analysis of the human body. These clinical benefits can be broadly classified as providing real-time noninvasive or minimally invasive visualization of the internal organs and anatomy to assist in providing a medical evaluation and diagnosis to direct patients' medical care. Because the SonoMax series diagnostic ultrasound systems provide images of human anatomy without the use of ionizing radiation, the systems can provide information about a patient's health status, without the risks of some other medical imaging modalities

Chapter 2 System Safety

2.1 Safety Overview

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

Users should observe the following precautions:

- This system complies with Type BF general equipment, and the IEC standard. Please follow Chapter 2 “System Safety” in the operation manual to use this system properly.
- Please do not modify this system in any way. If modifications are necessary, please contact the manufacturer first to get more information and permission.
- This system has been fully adjusted at the factory. Do not adjust any fixed adjustable parts.
- In the event of a malfunction, turn off the system immediately and inform the manufacturer or its designated agents.
- The power cord of the system should be connected to a grounded power socket. Do not remove the ground cable for any reason.
- Only connect this system, either electronically or mechanically, with devices that comply with the IEC/EN60601-1 standard. Recheck the leakage current and other safety performance indices of the entire system to avoid potential system damage caused by leakage from a current superposition.
- The system does not incorporate any specialized protective measures in the event it is configured with high-frequency operation devices. The operator should use caution in these types of applications.
- The system should be installed only by personnel authorized by the manufacturer. Do not attempt to install the system by yourself.
- Only a CHISON's authorized service engineer can perform maintenance.
- Only a qualified operator, or someone under qualified supervision, can use the system.
- Do not use this system in the presence of flammable substances, otherwise an explosion may occur.
- Do not continuously scan the same part of a patient or expose the patient to prolonged scanning. Otherwise, it may harm the patient.
- When using the system for ultrasound testing, only use qualified ultrasound gel that complies with system standards.
- Do not unplug probe when the system is in active operation. Always go to transducer Selection screen when need to remove the probe.
- To prevent from arm or neck injury, the operator should not stay at the same position for too long during patient scanning without taking break.

- Remove the transesophageal probe from the patient prior to application of a defibrillator.
- Do not put liquid on top of the main unit.

⚠***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.*

⚠***NOTE:*** *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 and ECG marked with BF symbol)

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

Level of protection against harmful ingress of water

- Parts of **probe** likely to come into contact with **operator** or **patient** meet the requirements of **drip-proof equipment (**IPX1**)**
-
- Parts of **probe** intended to be immersed in **normal use** meet the requirements of **watertight equipment** (IPX7)
- The IP Classification of System is Ordinary Equipment (IPX0)
  The equipment is not suitable for use in the presence of a flammable anesthetic mixed with air (with oxygen or with oxide)

Mode of operation

- Continuous Operation

For maximum safety, always follow these guidelines:

- Proper grounding of the system is critical to avoid electric shock. For protection, ground the chassis with a three-wire cable, and plug the system into three-hole outlet.
- Do not remove or circumvent the grounding wire.
- Do not remove the protective covers on the system. These covers protect users against hazardous voltages. Cabinet panels must remain in place while the system is in use. A qualified electronic technician must make all internal replacements.
- Do not operate this system in the presence of flammable gases or anesthetics.
- All peripheral devices (unless certified as medical grade) that are connected to the system must be powered through the electrical outlet with an optional isolation transformer.
- Suggest power off the system in 30 minutes if the system continuously works in 8 hours.

Notice upon Installation of Product

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

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

Notice against User Modification

The user should never modify this product.

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

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

- User modifications may cause degradation in EMC performance. Modification of the product includes changes in:
  - Cables (length, material, wiring, etc.)
  - System installation/layout
  - System configuration/components
  - Securing system parts (cover open/close, cover screwing)

2.3 Label

Label of Main Unit

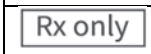
Fig.2-1 Rear panel label

Label of Probes

Fig.2-2 Probe label

2.3.1 Symbols on label

Caution, consult accompanying documents. This symbol advises the reader to consult the accompanying documents for important safety related information such as warnings and pre-cautions that cannot be presented on the device itself.	This 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.
 Do not use the following devices near this equipment: cellular phone, radio receiver, and mobile radio transmitter, radio controlled toy, etc. Use of these devices near this equipment could cause this equipment to perform outside the published specifications. Keep these devices power off when near this equipment.	 WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE): This symbol is used for Environment Protection, it indicates that the waste of electrical and electronic equipment must not be disposed as unsorted waste and must be collected separately. Please contact your local Authority or distributor of the manufacturer for information concerning the decommissioning of your equipment.
 This symbol is followed by the serial number of the device.	 The CE mark of Conformity indicates this equipment conforms with the Medical Device Regulation 2017/745 [MDR]
 This symbol is accompanied by the name and the address of the importing entity	 **MANUFACTURER:** This symbol is accompanied by the name and the address of the manufacturer.
 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.	 YYYY-MM This symbol indicatesthe country of manufacture of products is china, and this symbol is followed by the manufacturing date of the device in the form YYYY-MM.
 Refer to instruction manual.	 This symbol indicates the item is a medical device.
 This symbol indicates the item is a medical device	 Insulated patient application part (Type BF)
 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 numberof the device.	 AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.

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
IPX7	Protection against the effects of immersion (probes)

IPX0	No protection against ingress of water (system)
	In the process of push down the monitor, it is forbidden to place items to this region, otherwise there is oppression may flip monitor.
	Forbidden to push the monitor to move the machine.
	Forbidden to place heavy objects on the monitor after push down the monitor.
	Forbidden to press the monitor after push down the monitor.
	Forbidden to put the hand at the bottom of the monitor when turning the monitor.
	This part it is forbidden to impose extra upward or downward force (especially when transporting need to up and down movement machine).
	Be careful, arrow area may Clamp hand!
	No heavy load To prohibit the placing of heavy objects on a surface.

2.4 Patient Environmental Devices

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

- 1 ECG port
- 4/5 Probe ports (Number of ports varies with system types)
- 1 Pencil Probe port

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

- 1 DVD RW
- 2 USB ports on touchscreen

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

- 2 USB ports on touchscreen

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

- 2 USB ports
- 1 LAN port
- 1 S-VIDEO port
- 1 VIDEO OUTport
- L/R AUDIO port
- 1 VGA port
- 1 REMOTE port
- 1 HDMI 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, compatibilityand compliance with the following on-

board image recording devices:

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

Color video printer: Mitsubishi CP31W

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

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

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

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

Peripheral used in the non-patient environment

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

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

- The added device(s) must have appropriate safety standard conformance and CE Marking.

The added device(s) must be used for their intended purpose having a compatible interface.

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

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

2.5 Biological Safety

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

Clinical Safety Quoted from AIUM

Approved March 26, 1997

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

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

Soft Tissue Thermal Index (TIS). Used when imaging soft tissue only, it provides an estimate of potential temperature increase in soft tissue.
Bone Thermal Index (TIB). Used when bone is near the focus of the image as in the third trimester OB examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.
Cranial Bone Thermal Index (TIC). Used when bone is near the skin surface as in transcranial examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.

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

2.6 Scanning Patients and Education

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

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

2.6.1 Safe Scanning Guidelines

- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.

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

- Operators should understand the likely influence of the machine controls, the operating mode (e.g. B-mode, color Doppler imaging or spectral Doppler) and probe frequency on thermal and cavitations hazards.

- Select a low setting for each new patient. Output should only be increased during the examination if penetration is still required to achieve a satisfactory result, and after the Gain control has been adjusted to its maximum value.

- Maintain the shortest examination time necessary to produce a useful diagnostic result.

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

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

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

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

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

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

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

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

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

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

- Non-diagnostic use of ultrasound equipment is not generally recommended. Examples of non-diagnostic uses of ultrasound equipment include repeated scans for operator training, equipment demonstration using normal subjects, and the production of souvenir pictures or videos of a fetus. For equipment of which the safety indices are displayed over their full range of values, the TI should always be less than 0.5 and the MI should always be less than 0.3. Avoid frequent repeated exposure of any subject. Scans in the first trimester of pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs, nor

should their production involve increasing the exposure levels or extending the scan times beyond those needed for clinical purposes.

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

2.6.2 Understanding the MI/TI Display

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

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

RF: (De-rating factor)

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

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

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

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

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

$I'=I*R_F$Where I' is the intensity in soft tissue, Iis 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/fc, for model 1 to 4, where fc is the center frequency in MHz.

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

MI:

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

MI = Pr' / sqrt(fc)

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

Display Guideline:

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

Display and Report in Different Mode

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

For B-Scan Mode

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

For Color Mode

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

For Doppler Mode

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

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

Operator Control Features:

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

Controls Affecting Acoustic Output

The potential for producing mechanical bioeffects (MI) or thermal bioeffects (TI) can be influenced by certain controls.
Direct: The Acoustic Output control has the most significant effect on Acoustic Output.
Indirect: Indirect effects may occur when adjusting controls. Controls that can influence MI and TI are detailed under the bioeffect portion of each control in the Optimizing the Image chapter.
Always observe the Acoustic Output display for possible effects.

Best practices while scanning

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

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

Acoustic Output Default Levels

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

Cable Information

Except for cables sold as spare parts for internal components, the use of accessories and cables outside the regulations may result in increased emission or a decreased immunity of the powered stapler for single use. This device contains the following cables:

Cable or transducer	Manufacturer	Model and specification
Power cable	KING-CORD	2m long, 60227IEC 53 (RVV) 3×0.75mm^2 300/500V unshielded wire
Cable of probe	CHISON	2m, shielded wire
Foot Switch	ZHEJIANG KACON ELECERIC CO.	2m, unshielded wire
ECG three-lead wire	Shenzhen Med-link Electronics Tech Co.	3.6m, unshielded wire

WIFI

Model: XPC240200B

RF Protocols: 5GHz Wi-Fi 20M 802.11n

Antenna Type and Antenna Gain: On-Board antenna 4dBi

Modulation: OFDM with BPSK, QPSK, 16-QAM, 64-QAM

Effective Transmitted Power (ERP): 13dBm

Basic performance

υ Display images

υ Doppler audio and spectrum display

υ The measurement function is normal

υ The ultrasonic output is normal

υ The ECG function is triggered normally

υ The system interface functions normally

Chapter 3 Preparing the System for Use

3.1 Site Requirements

3.1.1 Operation Environmental Requirements

The following environmental conditions are within system tolerances for operation:

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

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

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

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

⚠***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.

3.1.2 Transport and Storage Environmental Requirements

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

Temperature: -5º C ~ 40º C

Relative Humidity: ≤80% non-condensing

Atmosphere Pressure: 700hPa ~ 1060hPa

3.1.3 Electrical Requirements

Power Requirements

AC 100-240V, 50-60Hz

Fuse Requirements

Fuse specification is 250V, 6.3 A (time-lag), the model is 50CT-063H

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

Power Consumption: 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 cord, 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 cords that meet the system guidelines—failure to follow these procedures may result in system damage.***
- ***Line power may vary in different geographic locations. Refer to the detailed ratings on the rear panel of the system for detailed information.***

Built in battery specifications

Battery model	BT-3000	
Capacity	6450mAh	
Rated voltage	14.4V	
Standard charge voltage	16.8V	
Discharge closing voltage	11V	
Discharge time	Less than 20 minutes	
Standard charge current	1800mA	
Maximum continuous discharge current	9000mA	
Battery structure	4S3P	
Cycle life	300 times	
Charging time	About 150 minutes	
Operating temperature	Charge	0℃～55℃
	Discharge	-20℃～65℃
	Storage	-20℃～60℃for less than 1 month; -20℃～30℃for less than 6 months
Battery status indicator	1%-100%	Power balance display
	Charge tips	Charge indicator

Adapter specifications

Adapter model	MKP150-19A
Input	100-240V~,50-60Hz
Output	19V ⎓ 11.84A

NOTE:

- ***To avoid the battery bursting, igniting, or fumes from the battery to cause the equipment damage.***
- ***Do observe the following precautions:***

  1) Do not immerse the battery in water or allow it to get wet.

  2) Do not put the battery into a microwave oven or pressurized container.

  3) If the battery leaks or emits an odor, remove it from all possible flammable sources.

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

  5) The battery shall be storied within -10℃~ 45℃ range environmental condition .If stored for a long time (exceed three months), the cell should be stored in dry and

cooling place. The cell's storage voltage should be14.0~14.8V and the cell is to be stored in a condition as Temperature: 23±5℃, Humidity: 65±20％RH.

6) Upon receipt of the SonoMax series and before first time usage, it is highly recommended that the customer performs one full discharge/charge cycle. If the battery has not been used for over 2 months, the customer is recommended to perform one full discharge/charge cycle. One Full Discharge/Charge Cycle Process: 1. Full discharge of battery to let the SonoMax series automatically shut down. 2. Charge the SonoMax series to 100% FCC (full current capacity). When storing packs for more than 3 months, charge the pack at least once during the 3 month timeframe to prevent leakage and deterioration in performance.

7) Do not dismantle the battery. If need to change the battery, please contact CHISON's authorized service engineer.

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

CAUTION:

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

3.2 System Specifications

3.2.1 Console Overview

Fig. 3-1 a: Console Overview

NOTE:

The appearance may vary slightly with types. Please refer to the actual machine you have purchased.

The following pictures show the system in different views.

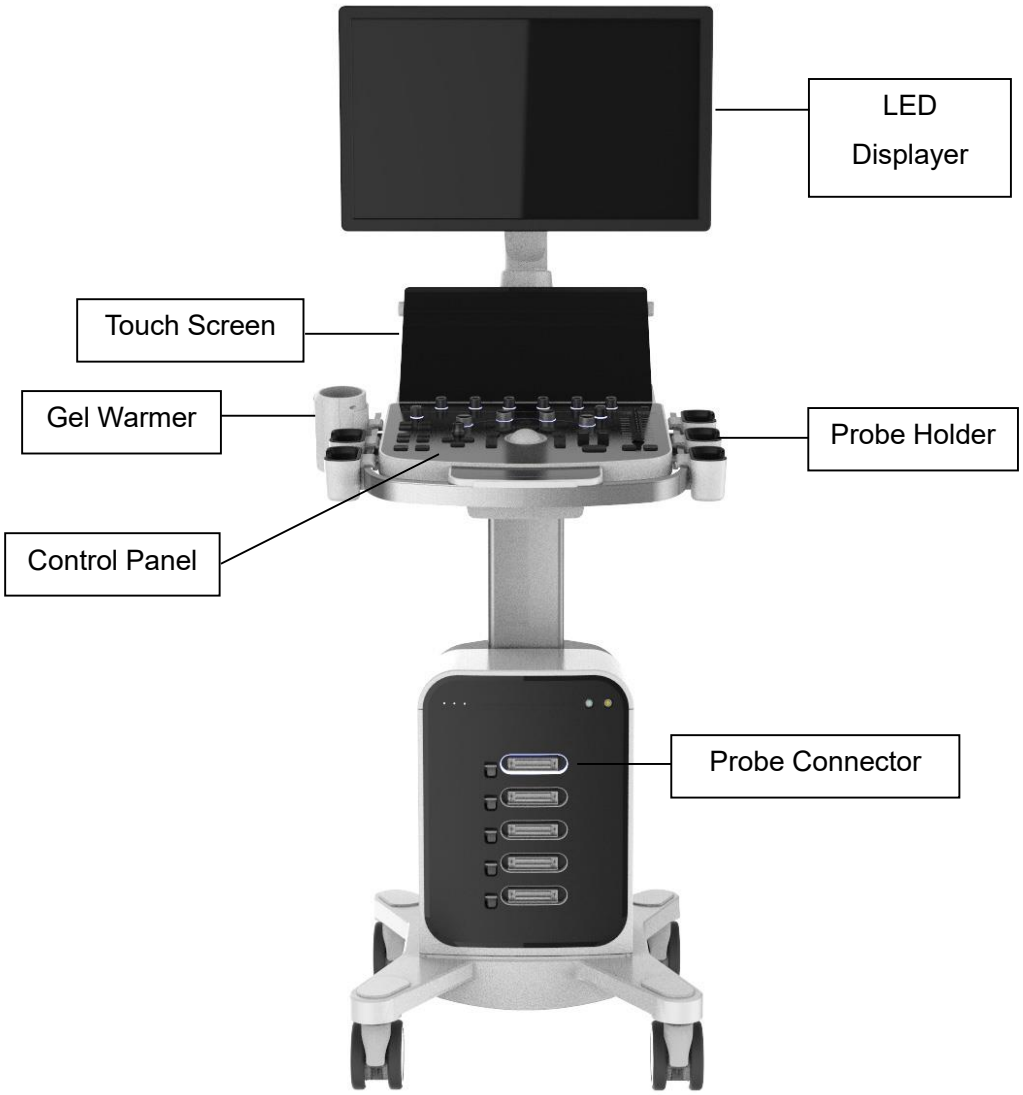


Fig. 3-1 b: Front Side View

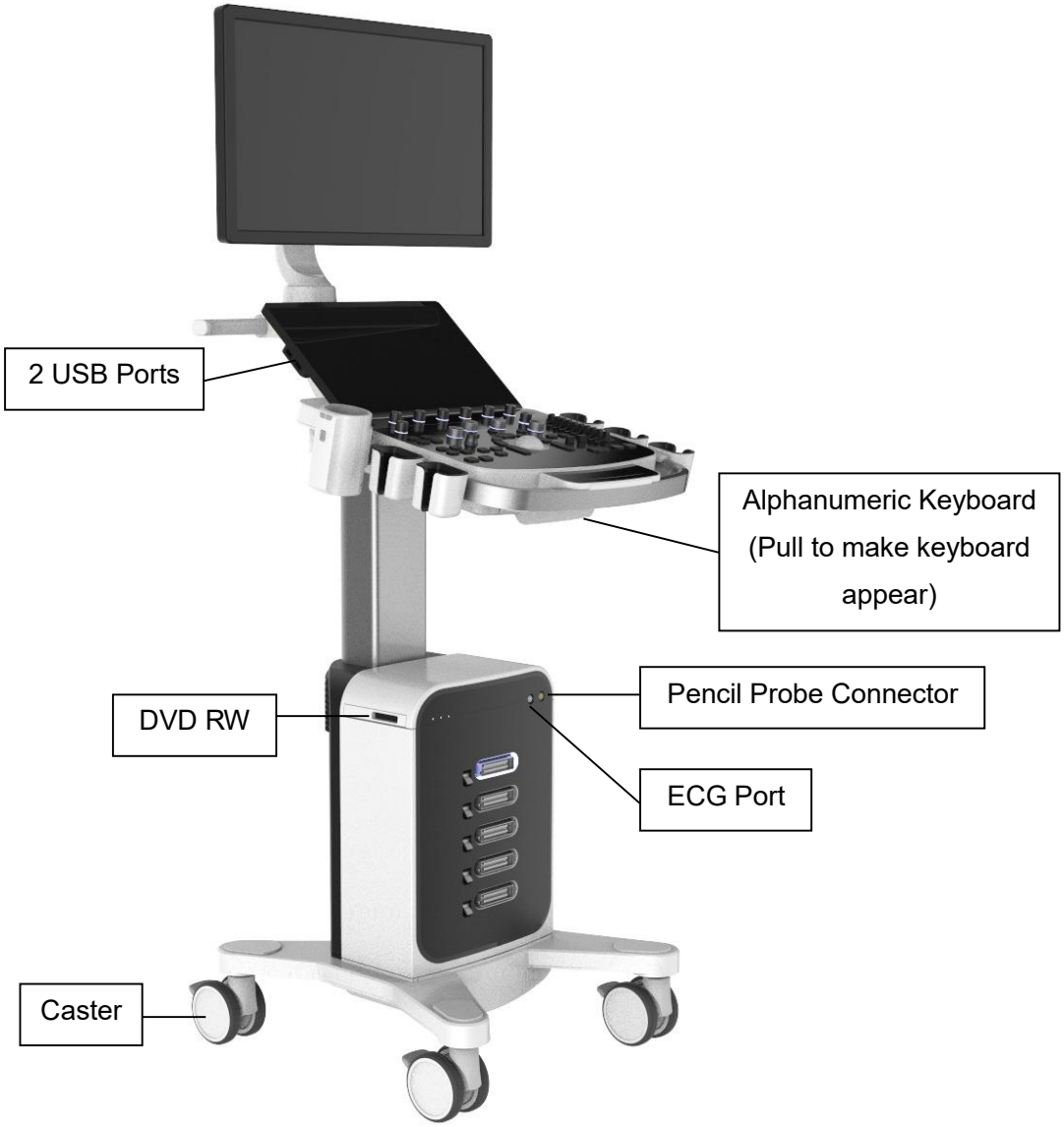
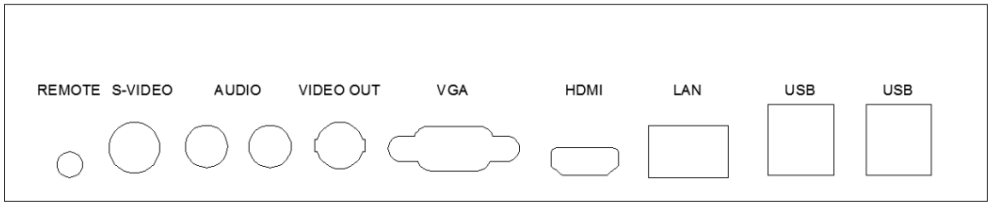


Fig. 3-1 c: Right Side View



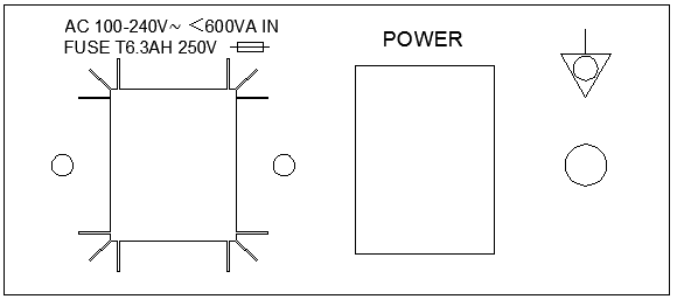


Fig. 3-1 d: Back Side View

3.2.2 Physical Specification

Dimensions of main unit (approx.): 685mm (Length) *604mm (Width) *1728.5mm (Height)

Net weight of main unit (approx): 58kg (no probe included)

3.2.3 Differences between models

Model	**SonoMax 1**	**SonoMax 2**	**SonoMax 3**	**SonoMax 5**	**SonoMax 6**	**SonoMax 7**	**SonoMax 7 Super**	**SonoMax 7 EXP**	**SonoMax 8**	**SonoMax 8 Super**	**SonoMax 8 EXP**	**SonoMax 9**	**SonoMax 9 Super**	**SonoMax 9 EXP**	**SonoMax 10**	**SonoMax 11**	**SonoMax 22**
5th Probe connector	option	option	option	option	option	option	option	option	option	option	option	√	√	√	√	√	√
LED	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
LED Size	21.5	21.5	21.5	21.5	21.5	23.8	23.8	23.8	23.8	23.8	23.8	23.8	23.8	23.8	23.8	23.8	23.8
Touch Screen	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
CD/DVD	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Gel Warmer	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Integrated Battery	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Footswitch	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
B mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
FHI	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
B/M mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
M mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
Dual mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
Quad mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
CFM mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
CPA mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
DPD mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
PW mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
CW mode	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
B/BC mode	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
2D Steer	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Triplex	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Quadplex	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Free Steer M	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option

Model	**SonoMax 1**	**SonoMax 2**	**SonoMax 3**	**SonoMax 5**	**SonoMax 6**	**SonoMax 7**	**SonoMax 7 Super**	**SonoMax 7 EXP**	**SonoMax 8**	**SonoMax 8 Super**	**SonoMax 8 EXP**	**SonoMax 9**	**SonoMax 9 Super**	**SonoMax 9 EXP**	**SonoMax 10**	**SonoMax 11**	**SonoMax 22**
mode																	
Free Curved M	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
HPRF	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
TDI	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Color M mode	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
TSS	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Curved Panoramic	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoContrast	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SoundFlow	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoVector	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Auto TGC	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
LGC	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
HD 3D	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Stress Echo	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Strain and Strain Rate	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Zoom	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
DICOM	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Trapezoidal Imaging	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Compound	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SRA	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
ECG	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Hard disk	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
Human Bodymark	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Auto IMT	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option

Model	**SonoMax 1**	**SonoMax 2**	**SonoMax 3**	**SonoMax 5**	**SonoMax 6**	**SonoMax 7**	**SonoMax 7 Super**	**SonoMax 7 EXP**	**SonoMax 8**	**SonoMax 8 Super**	**SonoMax 8 EXP**	**SonoMax 9**	**SonoMax 9 Super**	**SonoMax 9 EXP**	**SonoMax 10**	**SonoMax 11**	**SonoMax 22**
Sono IMT+	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Free NT	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Biopsy	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Super Needle	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Human measurement package	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
4D software package	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Virtual HD	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoFollicle	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoOB	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoFusion	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoHelp	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
X-con	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Q-image	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Q-flow	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Q-beam	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoColor	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoNeedle	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoPW	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Extended Imaging	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Intelligent doppler	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Volume Flow	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Elastography	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoCNS	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoBreast	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option

Model	**SonoMax 1**	**SonoMax 2**	**SonoMax 3**	**SonoMax 5**	**SonoMax 6**	**SonoMax 7**	**SonoMax 7 Super**	**SonoMax 7 EXP**	**SonoMax 8**	**SonoMax 8 Super**	**SonoMax 8 EXP**	**SonoMax 9**	**SonoMax 9 Super**	**SonoMax 9 EXP**	**SonoMax 10**	**SonoMax 11**	**SonoMax 22**
SonoThyroid	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoBladder	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Lung Assistant	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Auto B-Line	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoPleural	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoWork	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Auto EF	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Photo Tool	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoCoach	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Echo Compare	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Screen Saver	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
Report	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
Measurement	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
Comment	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
Bodymark	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
Hot Key	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard	standard
HL7	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoFIS	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoVocal	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Remote Control	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Image Sharing	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Printer Manager	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Remote Update	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Barcode	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option

Model	**SonoMax 1**	**SonoMax 2**	**SonoMax 3**	**SonoMax 5**	**SonoMax 6**	**SonoMax 7**	**SonoMax 7 Super**	**SonoMax 7 EXP**	**SonoMax 8**	**SonoMax 8 Super**	**SonoMax 8 EXP**	**SonoMax 9**	**SonoMax 9 Super**	**SonoMax 9 EXP**	**SonoMax 10**	**SonoMax 11**	**SonoMax 22**
Reader																	
Electronic Signature	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SWE	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Raw Data	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
NanoFlow	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Microflow MVI	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
ATI	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
PWV	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Auto Face	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoBeam	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Virtual Apex	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
AIO	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoWifi	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
SonoBlue tooth	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
Standby	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L4-10	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L4-10R	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L6-18	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L3-8	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L4-15B	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L3-10	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L5-14	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L4-15	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L5-15P	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L11-20	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L6-15i	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option

Model	**SonoMax 1**	**SonoMax 2**	**SonoMax 3**	**SonoMax 5**	**SonoMax 6**	**SonoMax 7**	**SonoMax 7 Super**	**SonoMax 7 EXP**	**SonoMax 8**	**SonoMax 8 Super**	**SonoMax 8 EXP**	**SonoMax 9**	**SonoMax 9 Super**	**SonoMax 9 EXP**	**SonoMax 10**	**SonoMax 11**	**SonoMax 22**
C1-5	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
C1-6	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
C1-7	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
C1-7P	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
C2-6	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
C4-11	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
E4-10	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
E3-14	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
E4-13	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
BL3-12	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
VE4-10	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
V2-6	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
CW2	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
T4-6	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
MT4-6	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
S1-5P	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
S1-5	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
S2-8	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
S4-12	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
L5-10W	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
S1-5W	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
ML4-6	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
MC1-5	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
MS1-5	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option
LA1-15	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option	option

Components of L5-10W and S1-5W

1. Transducer part: Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS.
2. Cover part: Allowable maximum temperatures for ACCESSIBLE PARTS that are likely to be touched by operators.

L5-10W

S1-5W

3.2.4 Key System Features

- Display B, B/M, M, Dual, Quad, CFM, CPA, DPD, PW, B/BC, 2D Steer, Triplex, Quadplex, CW, Free Steer M, HPRF, TDI, Color M, TSS, Curved Panoramic, SonoContrast, SoundFlow, SonoVector, HD 3D, Stress Echo, Trapezoidal Imaging, ECG, Biopsy, Super Needle, FHI, Elastography, 4D, VirtualHD, SonoOB, SonoFusion, SonoColor, SonoBeam, Virtual Apex
- X-con, Q-image, Q-flow, Q-beam, AIO, Zoom, Compound, SRA
- LGC, Auto TGC
- Human measurement package
- Remote Control
- Touch Screen, CD/DVD, Gel Warmer, Integrated Battery, Footswitch, Hard Disk
- SonoWifi, SonoBlue Tooth, Standby, Screen Saver
- DICOM
- Auto IMT, Sono IMT, Free NT, SonoFollicle, Strain and Strain Rate
- SonoHelp

3.2.5 Accessories

Transducers

No.	Probe Type	Probe Name
1	Linear probe	L4-10
2	Linear probe	L4-10R
3	Linear probe	L6-18
4	Linear probe	L3-8
5	Linear probe	L4-15B
6	Linear probe	L3-10
7	Linear probe	L5-14
8	Linear probe	L4-15
9	Linear probe	L5-15P
10	Linear probe	L11-20
11	Linear probe	L6-15i
12	Convex probe	C1-5
13	Convex probe	C1-6
14	Convex probe	C1-7
15	Convex probe	C1-7P
16	Micro convex probe	C2-6
17	Micro convex probe	C4-11
18	Micro convex probe	E4-10
19	Micro convex probe	E3-14
20	Micro convex probe	E4-13
21	Micro convex probe	BL3-12
22	Volume probe	VE4-10
23	Volume probe	V2-6
24	Pencil probe	CW2
25	Tee probe	T4-6

No.	Probe Type	Probe Name
26	Tee probe	MT4-6
27	Phased array probe	S1-5P
28	Phased array probe	S1-5
29	Phased array probe	S2-8
30	Phased array probe	S4-12
31	Linear probe	L5-10W
32	Phased array probe	S1-5W
33	Linear probe	ML4-6
34	Convex probe	MC1-5
35	Phased array probe	MS1-5
36	Phased array probe	LA1-15

3.2.6 I/O ports

- VGA output for external monitor
- S-VIDEO,VIDEO output for B&W video printer or Color video printer
- Remote port for video printer
- LAN port output for PC printer, DICOM and image review station
- 6 USB 3.0 ports for flash drive
- 2 AUDIO ports for audio R/L transport
- HDMI port for video transport

3.3 System Positioning & Transporting

Moving the System

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

Before Moving the System

- Completely switch off the system. See Section 3.4.4 “Power Off” for more information.
- Unplug the power cord (if the system is plugged into wall outlet).
- Disconnect all cables from off-board peripheral devices (external printer, etc.) from the console.

⚠***NOTE**: To prevent damage to the power cord, DO NOT pull excessively on the cord or sharply bend the cord while wrapping it.*

- Disconnect all probes from main unit. See Section 3.5 “Probes” for more information.
- Store all probes in their original cases or wrap them in soft cloth or foam to prevent damage.
- Replace gel and other essential accessories in the appropriate storage case.
- Ensure that no loose items are left on the main unit.

When Moving the System

Move the system by pushing or pulling the handle. Use extra care when crossing door or elevator thresholds.

NOTE: *Always use the handle to move the system. In order to avoid possible injury or equipment damage：*

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

Transporting the System

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

- Before transporting, place the system in its original storage case.
- Ensure that the system is firmly secured while inside the vehicle.
- Load the unit abroad the vehicle carefully and over its center of gravity.
- Keep the storage case still and upright. Secure that the system firmly with straps or as directed within the vehicle to prevent movement during transport.
- Any movement, coupled with the weight of the system, could cause it to break loose. Drive carefully to prevent damage from vibration.
- Avoid unpaved roads, excessive speeds, and erratic stops or starts.

3.4 Powering the System

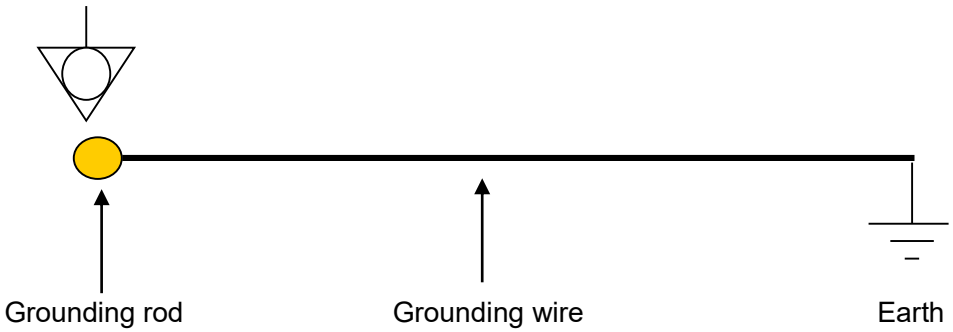
3.4.1 Acclimation Time

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

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

3.4.2 Connecting and Using the System

***NOTE*:** Before using the ultrasound system with a mains power supply connection, it is necessary to connect one end of the grounding wire from the accessories to the grounding rod of the ultrasound system, and the other end should be connected to a well-grounded metal object in contact with the earth. The diagram below illustrates the equipotential connection:



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.

3.4.3 Power On

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

Power up Sequence:

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

- control panel flashing and then getting dark
- system checking BIOS data

- booting the operation system
- loading software
- entering examination status

HINTS

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

NOTE:

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

3.4.4 Power Off

To power off the system:

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

NOTE:

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

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

3.4.5 Standby

To enter standby:

- Press the power botton on the top left of control panel.
- Select “Standby” to enter into the standby status.

To exit standby: press the power button.

⚠***NOTE:***

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

3.5 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. Place the system in “Transducer Selection” interface by pressing PROBE-key to deactivate the probe ports.

To connect a probe:

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

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

- Align the connector with the probe port and carefully push into place with the cable facing the back of the system.

- Turn the probe connector locking lever to “lock” status.
- Carefully position the probe cord so it is free to move and is not resting on the floor.
- When the probe is connected, the system will be automatically recognized.

CAUTION:

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

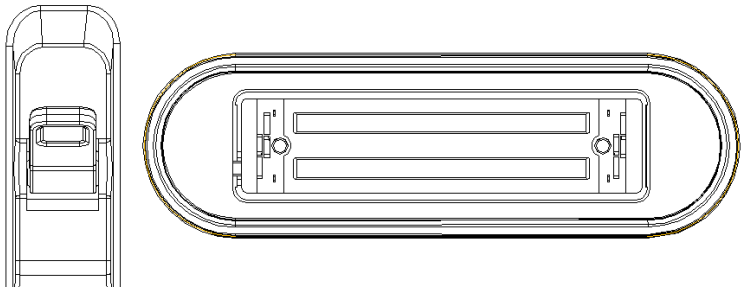


Fig.3-2 a Probe connector “Unlock” status

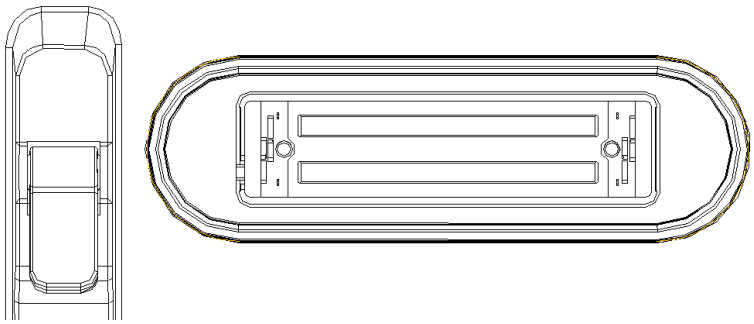


Fig.3-2 b Probe connector “Lock” status

Deactivating the Probe

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

To deactivate a probe:

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

Disconnecting the Probe

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

To disconnect a probe:

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

Transporting the Probe

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

Storing the Probe

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

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

3.6 Optional installation

3.6.1 Connect the printer

1) It needs three cables: Remote cable, Video signal cable, Power cord.

2) Connect the remote cable to remote port on the back panel of ultrasound system.

3) Connect the video signal cable to the Video Out port on the back panel of the ultrasound system.

4) Connect the Power cord to the Power output of auxiliary mains on the back panel of the ultrasound system.

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

3.6.2 Set the system for Video Printer

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

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

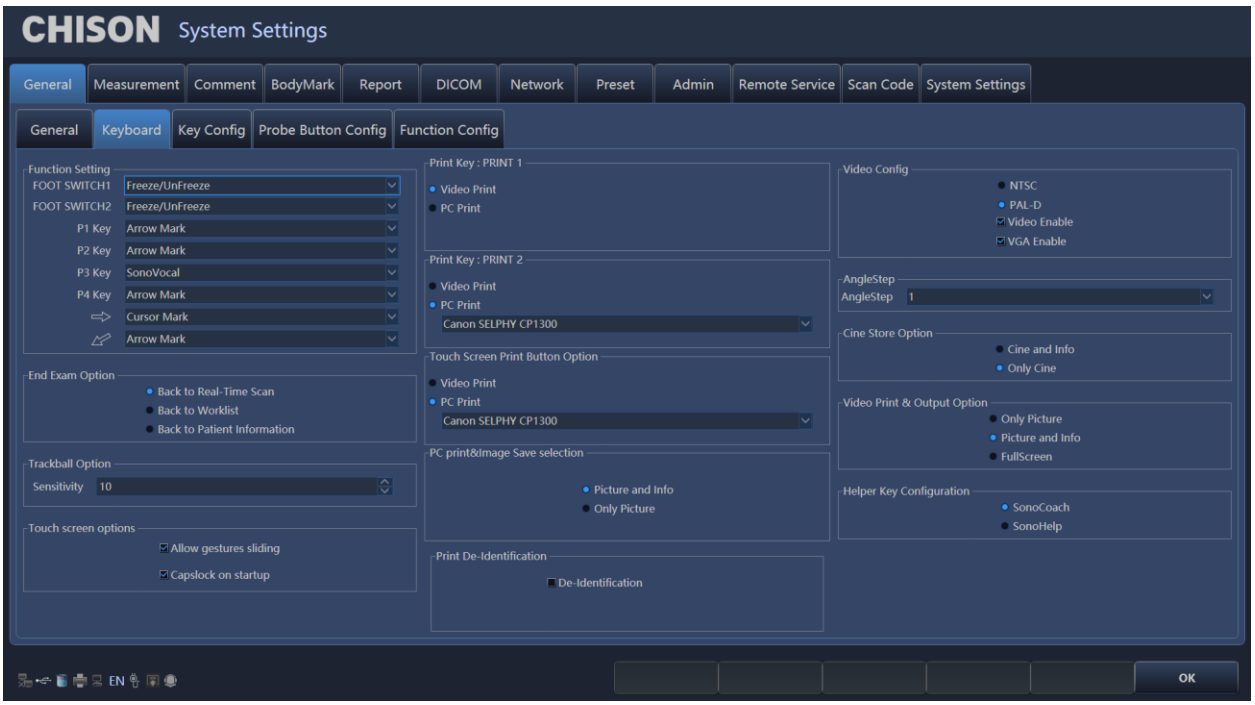


Fig.3-3

2) Choose “Video Print” under Print Key or Touch Screen Print Button Option, and set the “Video Print & Output Option”.

“Only Picture” means only print the ultrasound image.

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

“Full Screen” means print the full screen image.

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

NOTE:

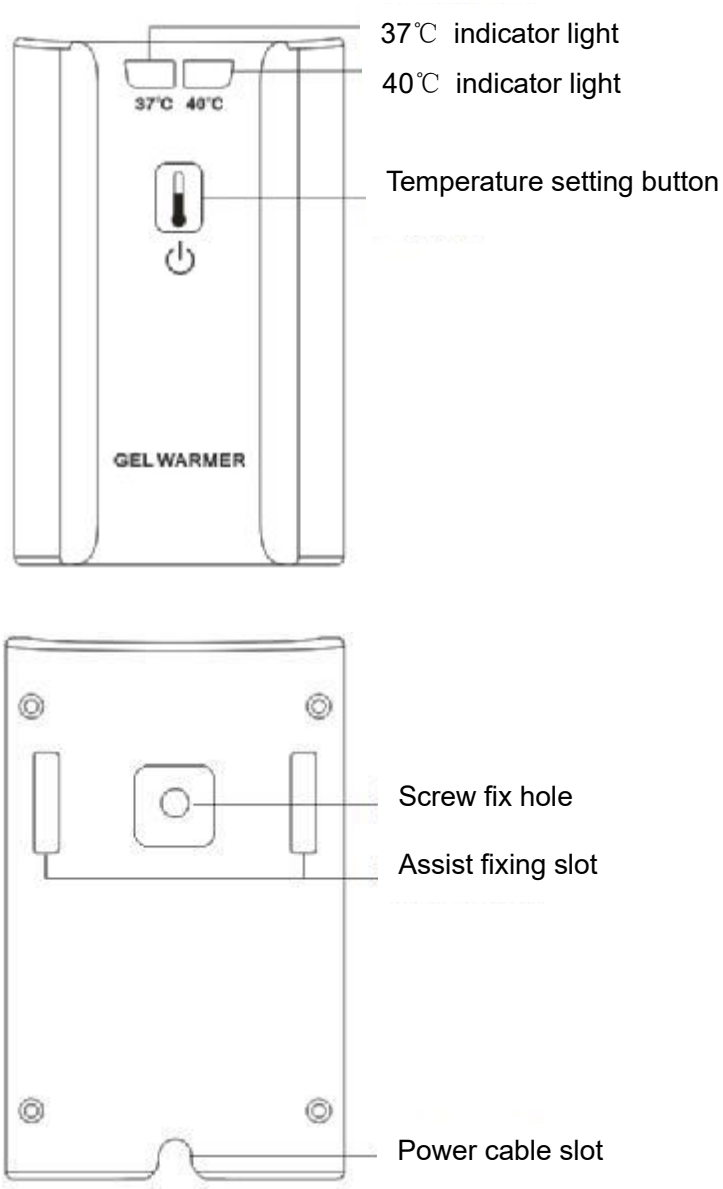
- ***You need to restart the system after connect the cables between Video printer and the System.***
- ***You can't print the system information.***

3.6.3 Connect the PC printer

1. Place the printer smoothly.
2. Connect the printer to the system.
3. Set the print manager. Please see more information in 7.10.
4. Choose “PC Print & Image Save Selection” in system setting, chooses “Picture and Info”, or “Only Picture”.
5. Choose “PC Print” under Print Key.
6. Press the print key on keyboard for printing.

3.6.4 Use the Gel Warmer

Insert the interface of the gel warmer into the circular concave hole in the lower left corner at the back of the keyboard. It can be fixed through the fixing screw hole and the auxiliary fixing slot.



1. Button Description

Button Name	Operation	Function Description
Temperature setting button	Press (less than 1 second)	Setting temperature：It can be set to 37℃ and 40℃. (Save the settings automatically and call the settings automatically every time you start up)
	Long Press (more than 1 second)	Power On/Off

2. Indicator Light Description

Indicator Light Status	Description
Indicator light turns green for 37℃	Temperature reaches to 37℃
Indicator light turns green for 40℃	Temperature reaches to 40℃
Two green indicators blink slowly at the same time (Blinking at 2Hz)	Overtemperature alarm (over 42.5℃) 【Indicators turn normal after malfunction is resolved】
Two green indicators blink quickly at the same time (Blinking at 0.5Hz)	Temperature sensor malfunction 【Indicators turn normal after malfunction is resolved】
	Voltage input is too low (Lower than 7V) 【Indicators turn normal after malfunction is resolved】
	Voltage input is too high (Higher than 24V) 【Indicators turn normal after malfunction is resolved】
Off	Power off

3. Overtemperature Protection

In the case of single fault, the warmer has overtemperature protection function, which can automatically cut off the heating power when the temperature of the aluminum drum rises to 50±10℃. The reset temperature of the overtemperature protection device is ≥ 33℃.

3.7 User Interface Control

- B gain, Color gain and Doppler gain
- TGC
- Brightness
- Acoustic power
- Gamma
- Smooth
- Edge enhance
- Persistence
- Depth control
- Focal position/number
- Dynamic range selection
- Audio volume control
- Q-image
- Space compound imaging
- Freeze/Unfreeze
- Image storage
- Scanning width
- Zoom

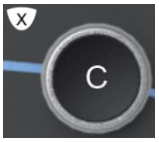
- Dual display: Dual B or color
- Quad display
- L/R inversion
- U/D inversion
- Biopsy guide
- PRF
- Wall filter
- Blood Effection
- Steering
- Color ROI panning
- Doppler sample volume adjustment
- Doppler angle correction
- Baseline movement
- Time base scrolling speed
- Annotation
- Patient data entry
- Measurement and calculation package
- File management and image archiving
- Clip image saving
- DICOM setting
- User defined preset

3.7.1 Control Panel and Alphanumeric Keyboard

Fig. 3-4: Overview of Control Panel

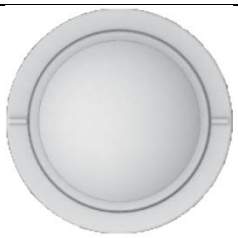
The main function of each key is introduced as below.

 POWER	✧ Press system power key momentary on the left top of control panel to turn on the system. Press this key and choose “turn off” to turn off the system. Press this key longer than 4 seconds to force the system to shut down in case the system is down. Press this key and choose “standby” to enter stand by status.
 SK1-SK6	✧ Press or rotate the keys to change the parameters of the corresponding menu at the bottom of the touch screen.
 TGC Sliders	✧ Manipulate the TGC (Time Gain Compensation) with 10 pairs of sliders.
 STILL SAVE	✧ Store still images.
 CINE SAVE	✧ Store selected clips.
 FREEZE	✧ Freeze/Un-Freeze the ultrasound image and enter/quit the Cine mode automatically.
	✧ Push it left for 3D function; push it right for 4D function. ✧ Angle: Rotate it for angle correction. In the Spectral Doppler mode, the default angle correction feature remains active. In the real time or cine modes, rotate this knob to adjust the Doppler Angle Correction by lining up the cursor with the vessel wall for an accurate reading. The Doppler Angle Correction setting can be adjusted 1 degree at a time. Rotate it to adjust the probe direction on the body mark status.
 B	✧ Press the B-knob to turn on B mode imaging. The system will stay in B mode if the current state is B, or return to B-mode if the current state is not B (e.g. M, color, Duplex Doppler). ✧ Rotate this knob to change the overall B gain throughout the image.

 CPA	Activate/turn off CPA Mode (also named as Color Power Angio mode). ✧ Press the CPA-key to turn on the CPA mode if the system is in B mode; ✧ Press the CPA-key for second time to turn off CPA and return to the previous mode (either B-mode or duplex Doppler).
 DEPTH	✧ Change the image depth of view.
 FOCUS	✧ Change the focus position.
 C	✧ Press the C-knob to turn on the Color Flow Map (CFM) mode if the system's current state is B; ✧ Press this knob can turn on Color if the system's current state is duplex Doppler; Press the C-knob for second time to turn off color and return to the previous mode (either B-mode or Duplex Doppler). ✧ Rotate C-knob to change the overall Color gain for CFM (PD) mode. ✧ In 4D mode, rotate C-knob to rotate image by X-axis.
 PW	✧ Press the PW-knob to turn on the duplex Doppler duplex mode if the current mode is B; ✧ Rotate the knob to change the overall Doppler gain for PW mode, when activate the spectral Doppler mode; ✧ In 4D mode, rotate PW-knob to rotate image by Y-axis.
	✧ Fingerprint recognization
 ZOOM	✧ In B and CFM mode, rotate it to zoom the image. Press twice to enter multiple enlargement.
	✧ Rotate it to adjust the volume of the Doppler spectrum.
 CW	✧ If the probe supports CW mode, e.g. a phased array probe, press CW-key starts CW mode. The CW control operates in the same manner as the PW.

 M	✧ Press the M-knob to enter B/M mode if the current mode is B; ✧ Press the M-knob for second time to enter M-mode without B- mode ✧ Press the M-knob for third time to go back to B-mode ✧ Rotate the knob to change the overall M gain throughout the image. ✧ In 4D mode, rotate M-knob to rotate image by Z-axis.
 AIO	✧ AIO means Automatic Imaging Optimization. During image scanning, press this key will optimize the image for a better quality in resolution automatically.
 PRINT1	✧ Print the images when the printer is working.
 PRINT2	✧ Print the images when the printer is working.
 UPDATE	✧ Press the UPDATE key after the sample volume gate is defined to activate the Spectral Doppler mode. ✧ In Measurement mode, it can be used to switch between start point and end point (distance), long-axis and short-axis (ellipse), and return back to last position in trace measurement before the measurement is finished.
 CALC	✧ Use this key to activate calculation packages under different applications. This feature supports the optional OB, GYN, Vascular, Urology, Cardiac, Small parts, Pediatrics, Carotid Abdomen, TCD and General calculation packages. Refer to Measurement & Calculation section for details.
 MEASURE	✧ Enter into fast measurement.
 CURSOR	✧ Press to display cursor.

 P1	✧ Function config key. Set the function on the system settings interface.
 P2	✧ Function config key. Set the function on the system settings interface.
 P3	✧ Function config key. Set the function on the system settings interface.
 P4	✧ Function config key. Set the function on the system settings interface.
 Clear	✧ Delete all comments, arrows, bodymarks and measure tracks on the screen.
 Comment	✧ Enter to the Comment function.
 Bodymark	✧ Enter to the Bodymark function.
 Single	✧ Enter to the Single display.
 Dual	✧ Enter to the Dual display.
 Arrow	✧ Enter to the ARROW mark function.
 Elastic	✧ Enter to Elastography mode.
 SonoContrast	✧ Enter to SonoContrast mode.

 SonoOB	✧ Activate SonoOB function.
 Remote Service	✧ Activate Remote Service function.
 Enter	✧ Confirm the command entry; ✧ Confirm EXAM mode and menu setting; ✧ Confirm caliper and measurement setting; ✧ Toggle Trackball function between Re-sizing and Re-positioning for the CROI, and Doppler Sample Volume Gate.
	✧ It works as UPDATE button.
 Trackball	✧ Position calipers in measurement; ✧ Position 'mouse' cursor for exam mode selection; ✧ Position the M-mode, PW cursor; ✧ Select entry in soft-menu; Select EXAM mode; ✧ Position and re-size the Color Region of Interest (CROI); ✧ Position and re-size the Doppler Sample Volume Gate; ✧ Control digital cine review frames.
 Alphanumeric Keyboard	The Aplhanumenric Keyboard hides below the control panel. ✧ Input comment by alphanumeric keyboard. ✧  : Enter to the system recovery mode. ✧  : Turn down the volume. ✧  : Turn up the volume. ✧  : Delete all comments, arrows, bodymarks and measure tracks on the screen. ✧  : (Function key) user can set the function on the system setting.

	✧ P5: (Function key) user can set the function on the system setting.

3.7.2 Soft-Menu Controls

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

Soft-Menu provides the user with an easy and flexible approach to access additional system controls. The system will display the appropriate menus for the selected mode and functions.

There are two soft-Menu controls, user can press or rotate the SK1-SK6 keys on the control panel or touch the parameters on the touch screen to set the value.

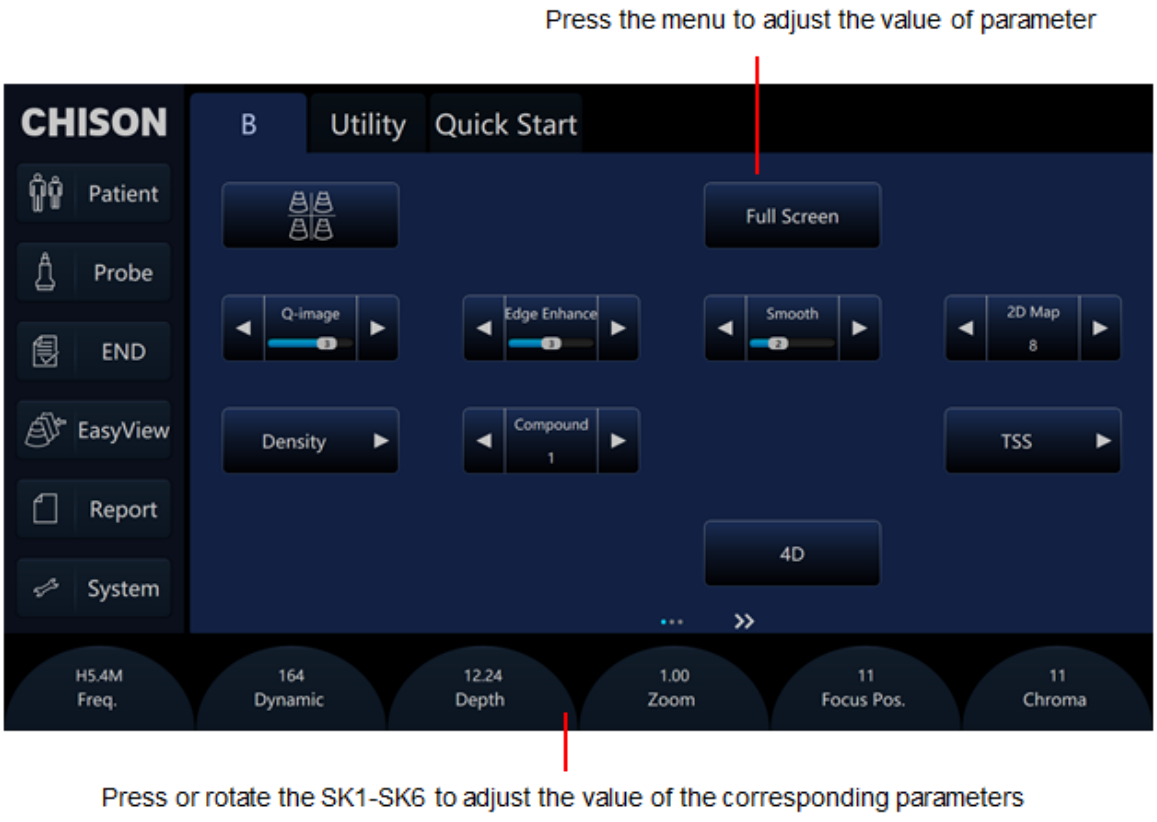


Fig. 3-5: Overview of touch screen

CHISON

CHISON Medical Technologies Co., Ltd.

No.228, Changjiang East Road, Block 51 and 53, Phase 5, Shuofang Industrial Park, Xinwu District, Wuxi, Jiangsu, China 214142