CHISON
Value Beyond Imaging

Digital Color Doppler Palm Ultrasound System

Model
SonoEye P2

USER MANUAL

Direction: CHUM SonoEye-P2-001a

June.5th ,2020

Rev. 1.01

CHISON Medical Technologies Co., Ltd.

Regulatory Requirement

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

This manual is a reference for the SonoEye P2. Please verify that you are using the latest revision of this document. If you need to know the latest revision, contact your distributor.

TABLE OF CONTENTS

Chapter 1 Introduction

This manual contains necessary information for safe system operation.

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

1.1 System Overview

Indications for Use

SonoEye P2 Digital Color Doppler Palm Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), B/M, CFM, Combined (B+CFM), Pulsed Wave and Fusion Harmonic Imaging modes. It is indicated for Pediatrics, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Nerve, Lung.

SonoEye P2 Digital Color Doppler Palm Ultrasound System is intended for use in environments where healthcare is provided by healthcare professionals.

Contraindication

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

1.2 Contact Information

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

CHISON website	www.chison.com
Service Support	CHISON Medical Technologies Co., Ltd.. Tel: 0086-400-8878-020; 0086-0510-85311707 Fax: 0086-0510-85310726 E-mail: service@chison.com.cn
Placing an Order	CHISON Medical Technologies Co., Ltd. Tel: 0086-0510-8531-0593/0937 Fax: 0086-0510-85310726 Email: export@chison.com.cn
Manufacturer	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 No.9, Xinhuihuan Road, Xinwu District, Wuxi, Jiangsu, China 214028
US Agent	Mr. Marco Mu, 2219 Rimland Drive,Suite 301,Bellingham, Barkley Villiage Bellingham,Washington,98226, UNITED STATES Phone: 360-3257028, Fax: 360-9253199, Email: us.agent@mid-link.net MID-LINK INTERNATIONAL CO., LTD

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

Chapter 2 System Safety

2.1 Safety Overview

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

Users should observe the following precautions:

- This system complies with Type BF general equipment, and the IEC standard. Please follow Chapter 1 “System Safety” in the user’s manual to use this system properly.
- Do not modify this system in any way. The system is prohibited to dismount. Necessary modifications must be made only by the manufacturer or its designated agents.
- This system has been fully adjusted at the factory. Do not adjust any fixed adjustable parts.
- In the event of a malfunction, turn off the system immediately and inform the manufacturer or its designated agents.
- Only connect this system, either electronically or mechanically, with devices that comply with the EN60601-1 standard. Recheck the leakage current and other safety performance indices of the entire system to avoid potential system damage caused by leakage from a current superposition.
- The system does not incorporate any specialized protective measures in the event it is configured with high-frequency operation devices. The operator should use caution in these types of applications.
- The system should be installed only by personnel authorized by the manufacturer. Do not attempt to install the system by yourself.
- Only an authorized service engineer may perform maintenance.
- Only a qualified operator, or someone under qualified supervision, should use the system.
- Do not use this system in the presence of flammable substances, otherwise an explosion may occur.
- Do not continuously scan the same part of a patient or expose the patient to prolonged scanning, otherwise it may harm the patient.
- When using the system for ultrasound testing, use only qualified ultrasound gel that complies with system standards.

- Do not unplug system when the system is in active operation. Always go to EXAM screen when you need to remove the system.
- To prevent from arm or neck injury, the operator should not stay at the same position for too long during patient scanning without taking break.
- Do not put the system near the liquid.

NOTE

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

2.2 Electrical Safety

Type of protection against electric shock

- **Class I Equipment**

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

NOTE

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

Degree of protection against electric shock

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

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

BF: Isolation from ground; max. Patient leakage current: normal mode ≤100 μA, single fault condition≤ 500 μA

Level of protection against harmful ingress of water

- The IP Classification of System is Ordinary Equipment, immersed part is IPX7, the other part is IPX1.

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

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

Conduction Interference

NOTE

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

Mode of operation

- Continuous Operation

For maximum safety, always follow these guidelines:

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

Notice upon Installation of Product

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

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

WARNING:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this medical system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Notice against User Modification

The user should never modify this product.

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

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

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

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

2.3 Labels

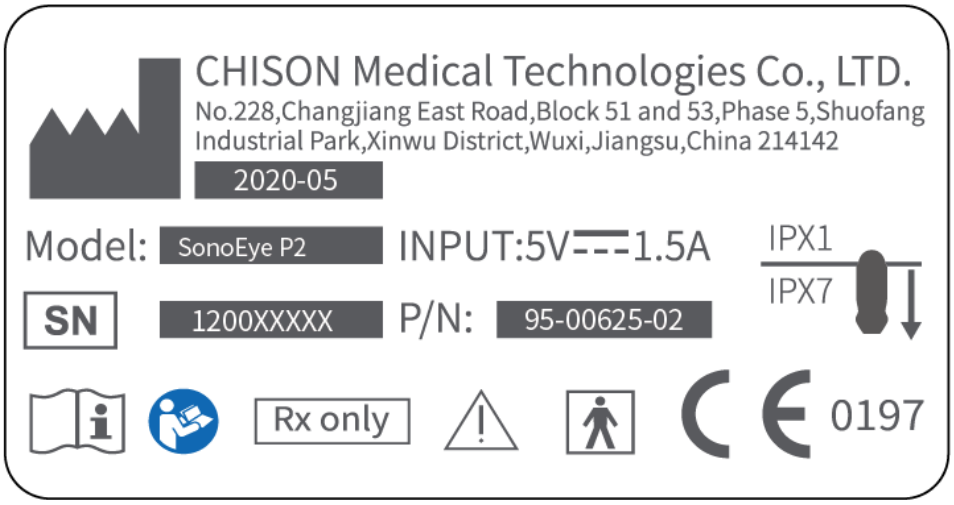
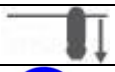
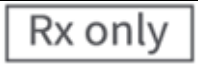


Fig. 2-1: SonoEye P2 Label

2.3.1 Warning Symbols

Icon	Meaning
	Refer to instruction manual/booklet.
	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.
	The CE mark of Conformity indicates this equipment conforms to the Council Directive 93/42/EEC.
	Serial number of the device.
	This symbol is accompanied by the name and the address of the manufacturer and the manufacturing date of the device in the form YYYY-MM.
IPX7,IPX1	Protection against the effects of immersion
	This label indicates immersed part.
	Refer to instruction manual.
	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.

2.3.2 Other Device Labels

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

Table 2-1: Symbol Icons

Icon	Meaning
Identification and Rating Plate	• Manufacture's name • Serial number
	Type-BF applied part

2.4 Patient Environmental Devices

Front side :

- Power switch
- Freeze button, P button, + button, - button

Acceptable Devices

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

Anyone using the equipment must be able to recognize the ESD symbol and understand how to take the necessary precautionary procedures, as described in the caution below:

ESD CAUTION

Sensitive part in system has been labeled with anti-static label, please pay attention on electrostatic protection.

ESD CAUTION

Sensitive part in system has been labeled with anti-static label, please pay attention on electrostatic protection.

CAUTION:

- *DO NOT connect any device 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.*

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.

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

Peripheral used in the patient environment

The system has been verified for overall safety, compatibility and compliance with the printer which is Mopria certified.

CAUTION: *Printing quality may vary depending on the printer. If there is any quality problem, Chison will not be responsible.*

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 60601-1-1.

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 60601-1-1 by the installer.

Equipment modifications and possible resulting malfunctions and electromagnetic interference are the responsibility of the owner.

WARNING:

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of

this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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**).

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.

Cavitation: Cavitation 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 cavitation, 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 cavitation and the related adverse effects.

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

2.6.1 Safe Scanning Guidelines

- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.
- Diagnostic ultrasound procedures should be done only by personnel fully trained in the use of the equipment, in the interpretation of the results and images, and in the safe use of ultrasound (including education as to potential hazards).
- Operators should understand the likely influence of the machine controls, the operating mode (e.g. B-mode, color Doppler imaging or spectral Doppler) and system frequency on thermal and cavitation hazards.
- Select a low setting for each new patient. Output should only be increased during the examination if penetration is still required to achieve a satisfactory result, and after the Gain control has been moved to its maximum value.
- Maintain the shortest examination time necessary to produce a useful diagnostic result.
- Do not hold the system 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.

- 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.

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 cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation 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 Ispta** must be ≤ 190 W/cm^2. An exception is for ophthalmic use, in which case the TI = max (**TIS_as**) 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 operator's 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 cavitation, 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 RF for the various distances and frequencies with attenuation coefficient 0.3dB cm-1 MHz-1 in homogeneous soft tissue is listed in the following table. An example is if the user uses 7.5MHz frequency, the power will be attenuated by .0750 at 5cm, or 0.3x7.5x5=-11.25dB. The De- rated Intensity is also referred to as '.3' at the end (e.g. Ispta.3).

Distance	**Frequency (MHz)**			
(cm)	1	3	5	7.5
1	0.9332	0.8128	0.7080	0.5957

2	0.8710	0.6607	0.5012	0.3548
3	0.8128	0.5370	0.3548	0.2113
4	0.7586	0.4365	0.2512	0.1259
5	0.7080	0.3548	0.1778	0.0750
6	0.6607	0.2884	0.1259	0.0447
7	0.6166	0.2344	0.0891	0.0266
8	0.5754	0.1903	0.0631	0.0158

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

Tissue Model:

Tissue temperature elevation depends on power, tissue type, beam width, and scanning mode. Six models 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 System
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

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 mode.

TI:

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

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

An estimate of the acoustic power in milliwatts 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 contais 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.

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.

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 influnced 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 Bioeffects portion of each control in the Optimizing the Image chapter.

Always observe the Acoustic Output display for possible effects.

Best practices while scanning

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

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

Use the minimum necessary acoustic output to get the best diagnostic image or measurement during an examination. Begin the exam with the system 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 system selected. It takes effect when the system is powered on or New Patient is selected. To modify acoustic output, adjust the Power Output level on the Soft Menu.

Chapter 3 Preparing the System for Use

3.1 Site Requirement

3.1.1 Operation Environmental Requirement

The following environmental conditions are within system tolerances for operation:

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

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

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

3.1.2 Electrical Requirements

Power Requirements：DC 5V

Power Consumption：≤10VA

Voltage Fluctuation：±5%

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

3.2 Downloading and Installing the App

Downloading the App

Use a computer to obtain the.apk installation package from Chison and move it to a mobile device.

Installing the App

1. Select the file which ended by .apk to install APP.
2. After installation, press the icon to enter the interface.

Giving App Access to Shared Device Storage

App uses shared device storage for the patient database and to access your device's camera for QR code

scanning.

Some versions of the Android operating system require that you specify that an app is allowed access to shared device storage. If your device prompts you to allow App to access photos, media, or files on your device, touch Allow. If you touch Deny, you cannot use App until you give access to shared device storage in the Android App Permissions settings.

Updating the App

Use a computer to obtain the.apk update package from Chison and move it to the mobile device. Select the update package to install APP.

Turning the System On and Off

1. Power on:

Press  for 3 seconds to turn on the system. The blue light is on while the system is on.

2.Power off:

Press  for 3 seconds to shut down the system.

3.3 System Specifications

3.3.1 Console Overview

SonoEye P2 system:

Fig. 3-1: Console Overview

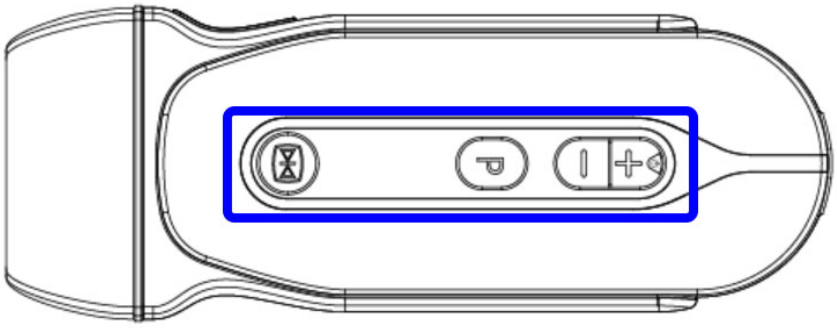


Fig. 3-2: Firmware Front View

From left to right: Freeze Button，P，- & + (They can be set as None, Freeze/Unfreeze, Gain+, Gain-, Depth+, Depth- and Save Image)

3.3.2 Physical Specifications

Dimensions of main unit (approx.): 64mm（Width）*170mm（Height）*24mm（Depth）

Net Weight: 200g

3.3.3 Image Modes

- B mode

- B/M mode
- Color Flow Map mode
- Pulsed Wave Doppler mode

3.3.4 Type

- SonoEye P2 4.5MHz-10.0MHz/7MHz-12.0MHz Linear Array

3.3.5 System Configuration

Function	SonoEye P2
B mode	√
B/M mode	Option
PW mode	Option
CFM mode	Option
FHI	Option
Type-C cable	√
Identify probe	√
Switch exam mode	√
Gain	√
Depth	√
STC	√
Focus	√
Zoom	√
Adjust sample Gate location	Option
Adjust size of sample Gate horizontal	Option
Adjust size of sample Gate vertical	Option
Adjust PW sample gate	Option
Compound	√
Frequency Scaling	√
Freeze/Unfreeze	√
B-distance	√
B-Circumference	√
B-Area	√
B-Volume	√
B/M-Distance	Option
B/M-Time	Option
B/M-HR	Option
PW-Velocity	Option
PW-Time	Option
Vessel measure package	Option
Small organ measure package	Option
Lung measurement	Option

General report	Option
Vessel report	Option
Small Organ report	Option
Lung report	Option
English Interface	√
Multi-language Interface	Option
Auto vascular tracking	Option
Instant AIO	√
Biopsy Guide	Option
Save Cine	√
Save Image	√
Cine Loop	Option
Annotation	Option
Bodymark	Option
Mark	Option
Patient management	Option
Voice/Angle/Baseline on PW	Option
Content in interference: **Image area(Probe type, frequency, probe direction, Image depth and depth ruler, gray scale ruler, color power ruler, cine loop ruler, focus position, AIO, A.P., battery condition)** **Title area:(menu, switch probe, product logo, patient ID, End exam)**	√
Physicial key	√
Setting	√
Archives	√
Tutorials	√
Easyview	√
Demo	√
About	√

" √ " : Standard

3.4 System Positioning & Transporting

Moving the System

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

Before Moving the System

Completely switch off the system.

NOTE

To prevent damage to the cable, DO NOT pull excessively on the cord or sharply bend the

cable while wrapping it.

- Store all systems 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.

When Moving the System

- Take extra care when you move the system long distances.
- Use extra care when crossing door or elevator thresholds.

Caution

- *Walk slowly and carefully when moving the system.*
- *Be sure the pathway is clear.*
- *Do not let the system strike walls or doorframe.*

Transporting the System

After preparing the system as described above, take the following additional precautions:

- Before transporting, place the system in its original storage carton.
- Drive carefully to prevent damage from vibration. Avoid unpaved roads, excessive speeds, and erratic stops or starts.

3.5 Powering the System

3.5.1 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 38 ºC.

3.5.2 Connecting the Electric Power

After making sure the power supply on displayer is normal status, and the voltage type is matched to the power requirement indicated on the label of system, then connect the connector with displayer.

3.6 The System

Caution

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

- *Connect the connector from the* SonoEye P2 system to displayer.

Caution

- *The system can only be disconnected with displayer while the power supply is off to prevent damage to*

the system.

- *If system is not correctly or completely connected with displayer, this may cause mis-operation, e.g. the system cannot be recognized, mis-recognized, or the system may drop off from the main unit and be damaged.*

Deactivating the System

Disconnect the connector from displayer to deactivate the system.

Chapter 4 Control Panel

4.1 Overview of Display Area

Fig 4.1a Display Interface

1. Side Menu	2. Application	3. Parameters control
3. Center Line	4. Full Screen	5. B/M mode
6. PW mode	7. CFM mode	8. Freeze
9. Logo	10. Patient information	11. End Exam
12. Connection status	13. Image parameter area	14. Focal indicator

4.2 Start a New Exam

Press 

to end the current exam, and start a new patient.

To add patient information:

1. On the imaging display, touch the ID number.

2. On the patient Info display, type the patient information.

3. Click the [Save] button.

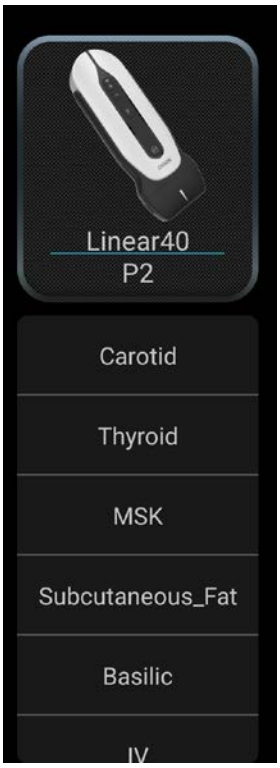
Patient Information:

MRN	Medical Record Number
ID	Patient ID
Date	Date of the study
First Name	Input patient's First Name
Middle Name	Input patient's Middle Name
Last Name	Input patient's Last Name
Sex	Select the patient's sex
Age	Set the patient's age, the system will automatically calculate the patient's birthday
Birth	Set the patient's birthday, the system will automatically calculate the patient's age
Height	Input the patient's height
Weight	Input the patient's weight


CHISON
8:53
Patient Information
MRN
20200001
ID
20200526002
Date
2020-05-26 17:00:00
First Name
123
Middle Name
456
Last Name
789
Sex
Male
Birth
2002-02-26
Age
18 Y 3 M
Height
158.0 cm
Weight
40.0 kg
Cancel
Save

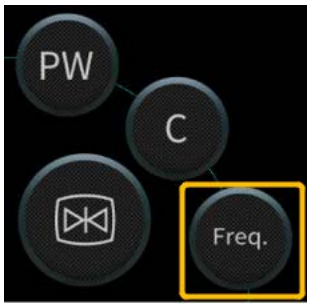
4.3 Probe

Press  to display current probe preset. Choose the desired preset to start an exam.



4.4 Switching Function

Slide the top left along the buttons to show Freq.

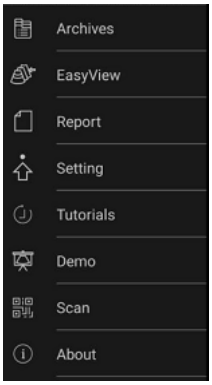


4.5 Switching Mode

Available imaging modes are B, CFM, PW, B/M Mode.

4.6 Function Key Introduction

Button	Name	Function
	Freeze	Touch this icon to freeze the current image
	Preset	Press this button to select preset.
	AIO	Press this button to optimize current image.
	Auto vascular tracking	Press this key to help user identify artery and vein in current image automatically.
	Freq.	Press this button in phantom preset to adjust the Freq.
	Image save	Press this key to save image

	Cine save	Press this key to save cine
	B Mode	Press this key to enter B mode.
	B/M Mode	Press this key to enter B/M mode.
	CFM Mode	Press C to enter CFM Mode.
	PW Mode	Press PW to enter PW Mode.
	Side Menu	Press  to enter the side menu list.
	Full Screen	Press the key to turn on the full screen function.
	Measure	Press this key to enter measurement.
	Ellipse	Press this key to start ellipse measurement.
	Distance	Press this key to start distance measurement.
	Mark	Press this button and the user can select the content to add in current exam interface.
	Annotation	Press this button to add annotation in current exam interface.

	Arrow	Press this button to add arrow in current exam interface.
	BodyMark	Press this button to add body mark in current exam interface.
	Clear	Press this button to clear all the content that user have added in current exam interface.

4.7 Image Parameter Area

Display information about Patient ID, Frequency, time, current exam and etc.

4.8 Cine Control

No.	Item	Description
<1>		Starts Cine playback.
		Stops Cine playback.
<2>		Press and slide on the processing bar to view frames.
<3>	Current/Total	The number corresponds to the current frame and total frame.

Chapter 5 Imaging

This chapter will introduce image display modes and the operation of image control and adjustment.

5.1 Select Scan Mode

5.1.1 System Identify

The App will identify the system automatically while system is connected.

Caution

When inserting the system, please make sure the surface which has CHISON logo is always upside.

5.1.2 Select Application

Click  icon, the examination interface will pop-up, according to the type of probe to select corresponding application. Press it to enter into expected exam.

Start App to enter Compound Image automatically.

There are five image display modes: B mode, B/M mode, CFM mode and PW mode, they can be shifted by the mode icon.

5.1.3 B mode

Click [B] icon to display single B mode image. B mode is the basic operating mode for two-dimensional scanning and diagnosis.

5.1.4 FHI

Press [Freq.] button to open its sub-menu, select the expected frequency to optimize current image. Press [Freq.] again to exit FHI selection menu. FHI is used for improving SNR (Signal to Noise Ratio) and remitting pseudo morphism on current image. Thus, the image quality is improved by this function.

5.1.5 B/M Mode

B/M-mode is used to determine patterns of motion for objects within the ultrasound beam.

Click [M] icon to enter B/M ready mode, then move the M-line to enter B/M mode. B/M mode is fit for heart scanning and measurement.

5.1.6 CFM Mode

Color Flow Map is a technique for imaging blood flow by displaying flow data such as velocity and direction on B mode image. Based on Doppler Effect, normally the blood flow moving toward the probe scan direction is marked in red, while blood flow moving away from probe scan direction is marked in blue. Touch [C] icon,

screen only displays color mode operation interface.

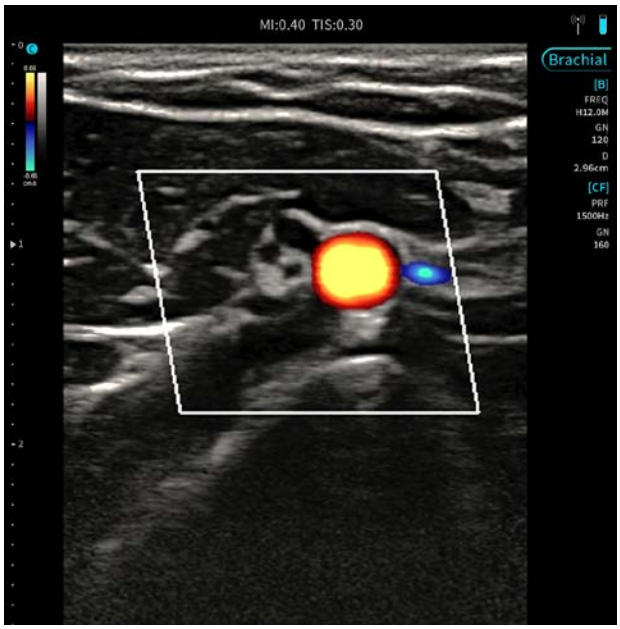


Fig. 5-1 CFM Mode

5.1.7 PW mode

Intended Use:

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

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

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

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

PW mode Exam Procedure:

- Connect the appropriate system, leaving the systems in their respective holders.
- Position the patient for the examination.
- Press ID number and enter the appropriate patient data.
- Select the application and system to be used.
- Locate the anatomy to be examined. Get a good B-mode image. Press **C**- icon to help locate the vessel you wish to examine.
- Press **PW**- icon to display the sample volume cursor and gate.
- Position or re-size the sample volume gate by moving the slide left, right, up and down.
- Press **PW**- icon to display PW Doppler spectrum and the system operates in combined B+Doppler mode. The Doppler signal is heard through the speakers.
- Optimize the PW Doppler spectrum, as necessary.

- Press the corresponding button to transfer the exam mode between real time B-mode with Doppler mode (with audio).
- Sample along the whole length of the vessel. Ensure that the system is parallel to flow. Listen, then look, when positioning the sample volume cursor.
- Perform measurements and calculations, as necessary.
- Record results with your recording devices.
- Press  to resume imaging.
- Repeat the above procedure until all relevant flow sites have been examined.
- Replace the system in its respective holder.

5.1.8 B-Lines

Select the Lung preset to start an exam, press the lung icon on the left side while freeze image. The analysis data of lung will display on the right bottom corner which include B-Lines, mean pleural thickness, maximum pleural thickness, minimum pleural thickness, standard deviation on pleural and diffuse.

- **Edit pleural line:**

Press the Edit icon on the left of image, press the image with single finger and blue line display, move the blue line with finger to edit pleural line.

- **Add B-Lines:**

Press Add icon on the left of image, a yellow line displayed, press it and move it to the target position and release finger to add B-lines.

- **Delete B-Lines:**

Press the existed B-Lines with single push to active current B-Lines, press the Delete icon on the left of image area to delete current B-Lines.

- **Lung Report:**

After finishing all operation on lung, press the Report key on side menu, select images on current exam and compare exam to start lung analysis, and result will display below the image.

5.1.9 Biopsy Guide

Press Biopsy Guide icon and the guide line displays. Press the icon again to exit Biopsy Guide.

- **Adjust Biopsy Guide Line:**

  Press the Biopsy Guide line and slide it to adjust the guide line.

- **Adjust Biopsy Guide Angle:**

Press the Biopsy Guide line, the angle icon displayed, press to slide it to adjust the Biopsy Guide angle.

5.1.10 SonoNeedle

Select SonoNeedle in B mode, the system will recognize and mark the needle position and needle trajectory automatically.

5.1.11 SuperNeedle

SuperNeedle is to balance the B mode image. Select SuperNeedle, the user can optimize image by adjusting angles.

5.1.12 SonoRemote

SonoRemote enables remote real-time ultrasound diagnosis.

Install SonoRemote on PC and open it, check the network connection. The SonoRemote will register an ID automatically when you first log in to it. After registration, each time you open it, SonoRemote will log in your account automatically.

Check the network connection on system, click SonoRemote icon to open it. The SonoRemote will register an ID automatically when you first log in to it. After registration, each time you open it, SonoRemote will log in your account automatically.

Input the ID of answer terminal on originate and start a call. System will receive the signal and connect with originate terminal. If the connection is successful, the camera on the original terminal will automatically turn on. The ultrasound screen and camera screen will be displayed on the PC. Before connecting, users can set up video, microphone and speakers on the original terminal. The video data on the originate terminal will be displayed on the answering terminal. Before connecting, the user can set the video, microphone and speaker on the answering terminal.

Note: *When the network connection of either originate or answer is disconnected automatically, it will be automatically reconnected.*

5.2 Functional Description of Parameter Adjustment

1. Gain

To adjust the Gain:

Swipe left, right in arbitrary place of screen.

Press the Gain button and slide the block to adjust the Gain.

2. Depth

To adjust the Depth:

Swipe up and down in the image area to adjust the depth.

3. Frequency

Click 

to choose Frequency. The range of the frequency depends on different probes.

4. Focus position

Press and hold the target position of the ruler, the focus will automatically jump to the position.

5. Zoom

Touch the screen with two fingers and slide it outward to adjust the zoom position.

6. Sample Gate

In the real-time state of CFM mode, press the blood flow sampling gate and move it to adjust the position.

In the real-time state of CFM mode, press and hold the lower left corner of the blood flow sampling gate. After the adjustment mark appears, slide left and right to adjust the horizontal size of the blood flow sampling gate, and slide up and down to adjust the vertical size of the blood flow sampling gate.

5.3 Parameter Adjustment in PW mode

1. PW Gain

At real-time state, slide left or right in spectrum area to adjust the size of doppler gain, adjustment range from 0~255, the smallest value of adjustment is 1.

2. Voice

At real-time state, press the display device sound keys to adjust the voice.

3. Angle

At real-time state, press the angle icon to adjust the angle.

4. PW Sample Gate

At real-time state, use two fingers to slide it outward to adjust the size of sample gate.

At real-time state, press the sample gate and move it to adjust the location.

5. Baseline

At real-time state, press the baseline and move it to up and down to adjust the location.

5.4 After Capturing the Image

5.4.1 Adding Annotation

Annotation can be added to an ultrasound image to bring attention, notate or communicate information observed during the examination. You can add annotations to: zoomed image, cine review image and frozen image.

WARNING

You must ensure that the entered annotations are correct. Incorrect annotations may cause misdiagnosis!

Operation:

1. Freeze image and slide the menu list to select  .

2. The secondary menu appears, press  . “ | ”is displayed in image area and the soft icon board appeared in the bottom of screen.

3. After the user inputs the comment, press it with a single finger to move it to target position.

4. To edit existed comment, press and hold it, the soft icon board appears, the user can re-input comment.

5.4.2 Adding BodyMark

Operation:

1. Freeze image and slide the menu list to select  .

2. The secondary menu appears, press  . The body mark list displays, select the body mark in desired application. The body mark displays in image area.

3. Slide the blue dot to adjust the probe direction.

4. To move the body mark, press it and move it to target position.

5.4.3 Adding Mark

Operation:

1. Freeze image and slide the menu list to select  .

2. The submenu appears, press  . The mark displays in image area.

3. Slide the blue dot to adjust the mark direction.

4. To move the mark, press it and move it to target position.

Chapter 6 Measurement and Calculation

6.1 Measurement Methods:

The system contains Distance, Ellipse.

1. Distance

Measurement steps:

- Click the『Distance』icon under the measurement menu to enter into measurement.
- Click the B image area; it will display a segment with two "+" icon. One of the "+" is active, you can move it by dragging your finger to fit the one point of the line.
- After measurement, the result will appear on the exam interface.
- Repeat the above step to start a new measurement, press  can delete the current measurement result.
- Press  can delete all the measurements.

2. Ellipse

Measurement steps:

- Click the [Ellipse] icon under the measure menu to enter into measurement.
- Click in the B image area，it will display an ellipse with four "+" icon, you can move the "+" by dragging your finger on B image area to fit it's position.
- After measurement, the result will appear on the exam interface.
- Repeat the above step to start a new measurement, press  can delete the current measurement result.
- Press  can delete all the measurements.

6.2 B Mode Measurement

Press B to enter the B mode and press measure to start measurement.

1. Distance

Distance measurement is the same as section 6.1.

2. Area

Area measurement is the same as section 6.1.

3. Circumference

Circumference measurement is the same as section 6.1.

4. Volume

Volume measurement is the same as section 6.1.

6.2.1 Vessel Measurement in B mode

IMT(Auto): Press CALC icon to enter Vascular measurement, click IMT(Auto) icon, the sampling frame

appears in image area. Use a finger to slide on the top right or left corner to adjust location, press image area to finish measurement. The measurement results display on result area.

Meas. item name	mark	unit	Meas. Method and calc. formula
IMT(Auto)	Max Min Mean Std	cm	Refer to Auto IMT in 6.2.1
StA%	A Out	cm^2	Refer to “Ellipse” measurement in 6.1
	A In	cm^2	Refer to “Ellipse” measurement in 6.1
	StA%	%	StA%=（A Out-A In）/ A Out*100%
StD%	D Out	cm	Refer to “Distance” measurement in 6.1
	D In	cm	Refer to “Distance” measurement in 6.1
	StD%	%	StD%=（D Out-D In）/ D Out*100%

6.2.2 Small Organ Measurement in B mode

Meas. item name	mark	unit	Meas. Method and calc. formula
Thyroid Vol.	Length	cm	Refer to “Distance” measurement in 6.1
	Width	cm	Refer to “Distance” measurement in 6.1
	Height	cm	Refer to “Distance” measurement in 6.1
	Volume	ml	Volume=Length*Width*Height*3.14159265/6

6.3 B/M Mode Measurement

1. Distance

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

Distance measurement is the same as distance measurement in B mode.

2. Time

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

3. HR

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

6.4 PW Mode Measurement

1. Velocity

Press Freeze after finish the scan, select the velocity in menu, the blue “+” displayed on the screen, move it to desired position to start measurement. The result will display on image area and result area. Repeat the above steps to start new measurement.

2. Time

Press Freeze after finish the scan, select the time in menu, there are two blue “+” displayed on the screen, move it to desired position to start measurement. The result will display on image area and result area. Repeat the above steps to start a new measurement.

Chapter 7 Cine-Memory

This chapter introduces the theory of saving images in Cine-Memory and the operation of image playback in Cine-Memory.

7.1 Image Storage

Images in B-mode can be stored in Cine-Memory at the unit of frame in time sequence. If the storage is full of images, when storing a latest new frame image, the first saved frame image will be removed out of Cine-Memory. Therefore, there are always the latest images in the storage. All the images in Cine-Memory can be played back manually or automatically.

Fig 7-1 Movie playback bar diagram

7.2 Manual playback

After clicking the  button to freeze the image, the movie playback bar pops up. At this time, slide to right in image area to display the images in ascending order of frames, that is, the same order as the images are stored, otherwise frames are displayed in descending order.

7.3 Automatic playback

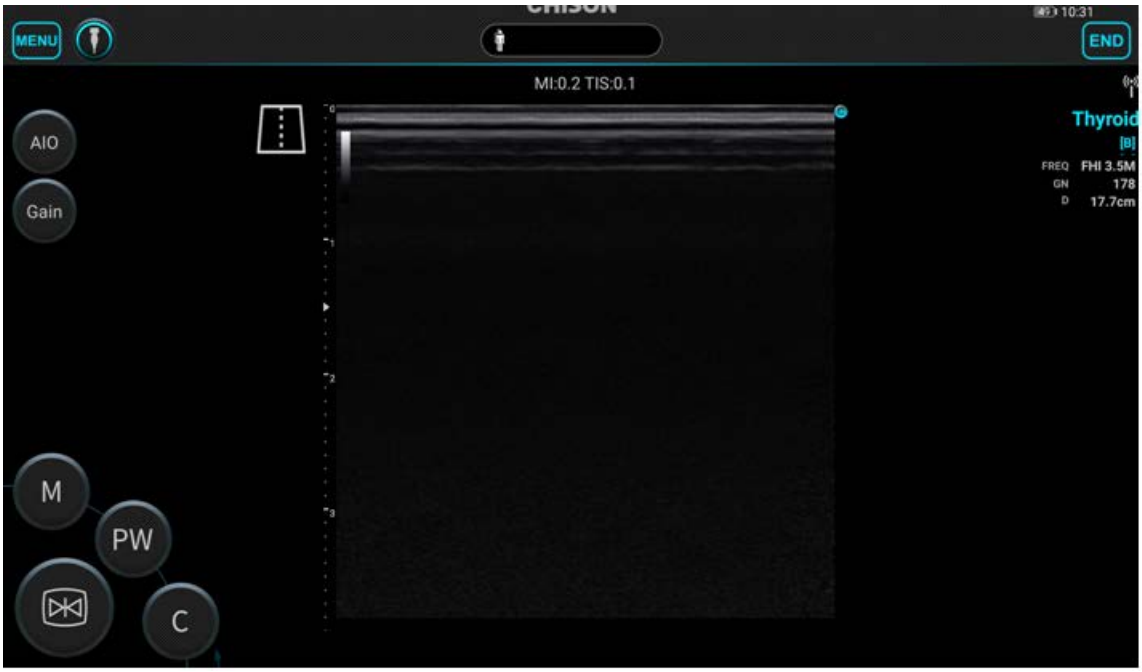
Press Freeze and click  to start automatic playback.

7.4 Cine Save

Press Freeze and click  to save current cine.

Chapter 8 Side Menu

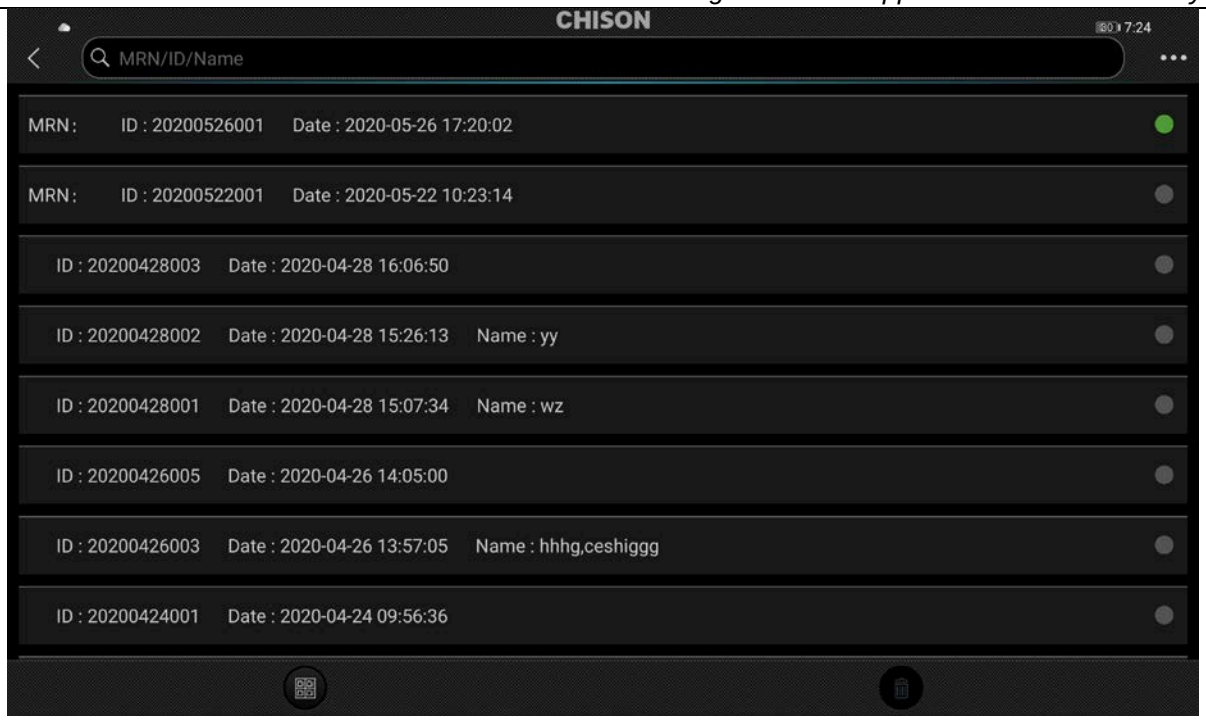
The setting function is used to set the system's startup operating environment, state and configuration parameters of each exam mode. The settings are stored in system's memory and are not lost when the power is turned off.



8.1 Archive

Press 

on the top left corner of the screen, select archive to enter the archive management.



Press  on the top right corner of the screen, user can manage archive according to ID, MRN and Name.

Select archive: Press archive and hold it, the current archive is selected.

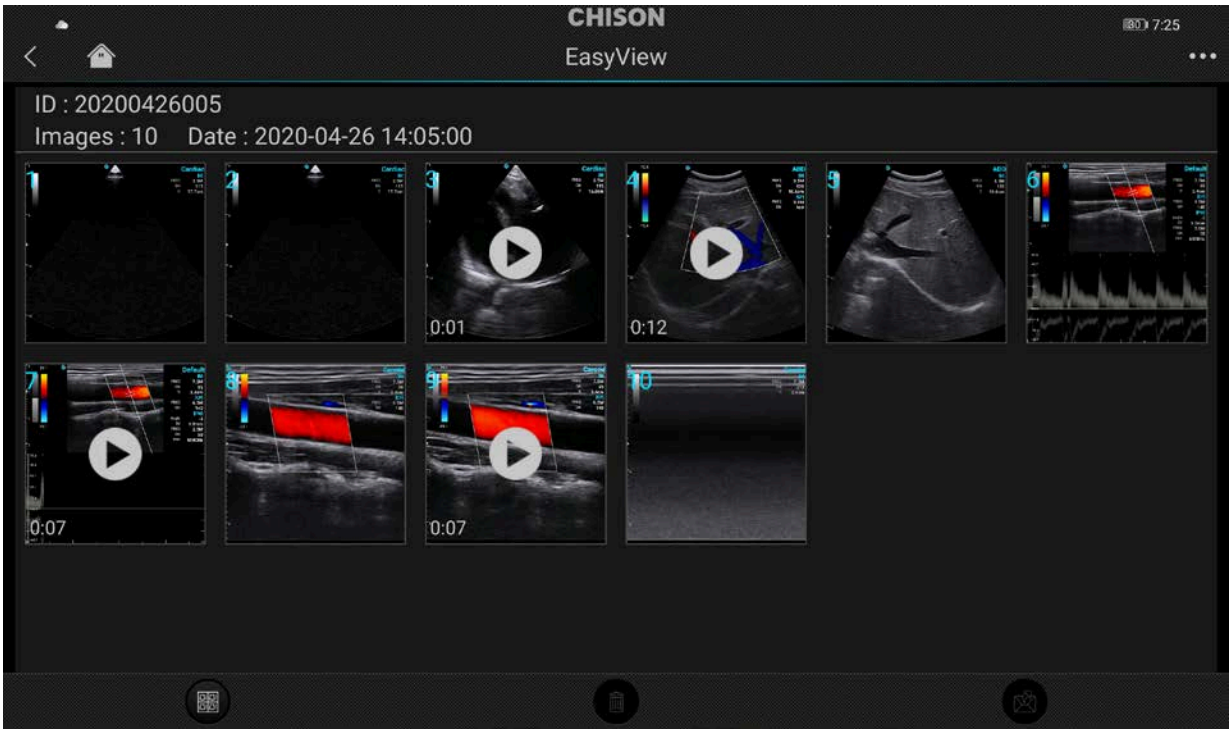
 : Select all archives.

 : Press it to delete selected archive.

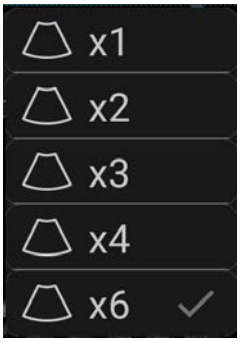
Press selected archive to enter EasyView.

8.2 EasyView

Press EasyView to check the patient information, saved images and cines.



Press  on the top right corner of the displayer, the user can set the image preview mode.



Press an image and hold it to select the current image, the frame of image will turn to blue.

 : Press this button to send selected image to external media device.

 : Press this button to select all images.

 : Press this button to delete current image.

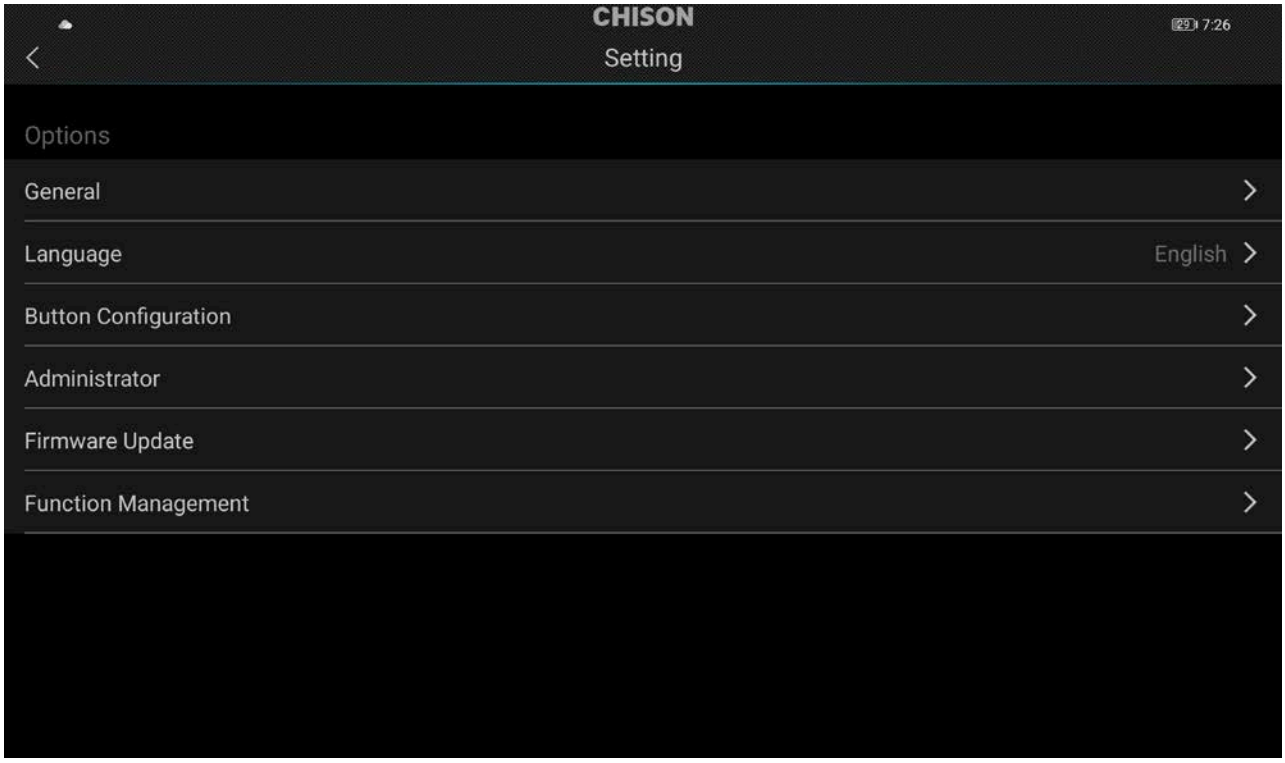
8.3 Report

Select the report from side menu, press “<” on the top left corner to return to the exam interference.

Press  on the top right corner to select the report type, the General, Vessel, Small Organ and Lung can be selected.

8.4 Setting

Press the setting button to enter the setting interface.



8.4.1 General

Set STC display and ID display on system.

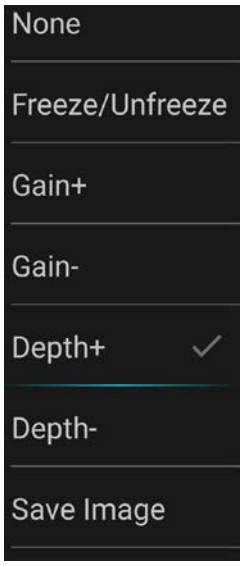
8.4.2 Language

Press language to select the needed language. The system supports English, Chinese and Deutsch.

8.4.3 Button Configuration

Select the button configuration to set the key function.

Button	Function
“+”	None/Freeze, Unfreeze/Gain+/ Gain-/Depth+/Depth-/Save Image
“-”	
“P”	

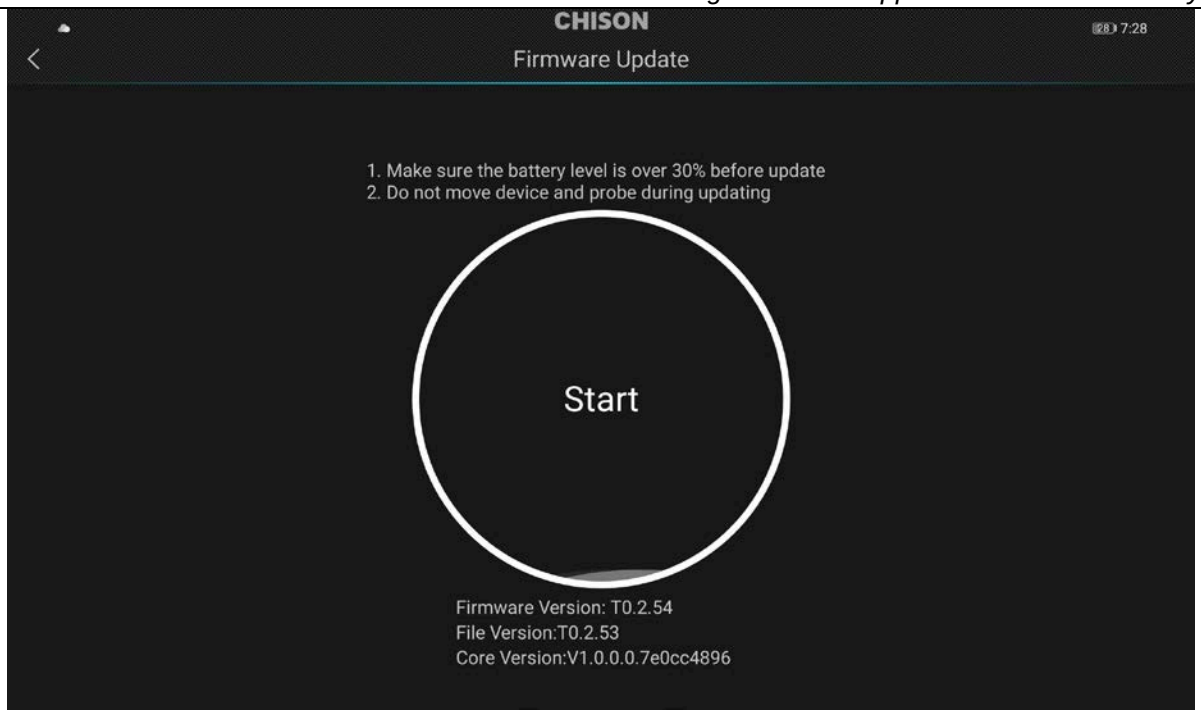


8.4.4 Administrator

Click the Administrator to manage accounts.

8.4.5 Firmware Update

Select firmware update to upgrade system software version.



8.4.6 Function Management

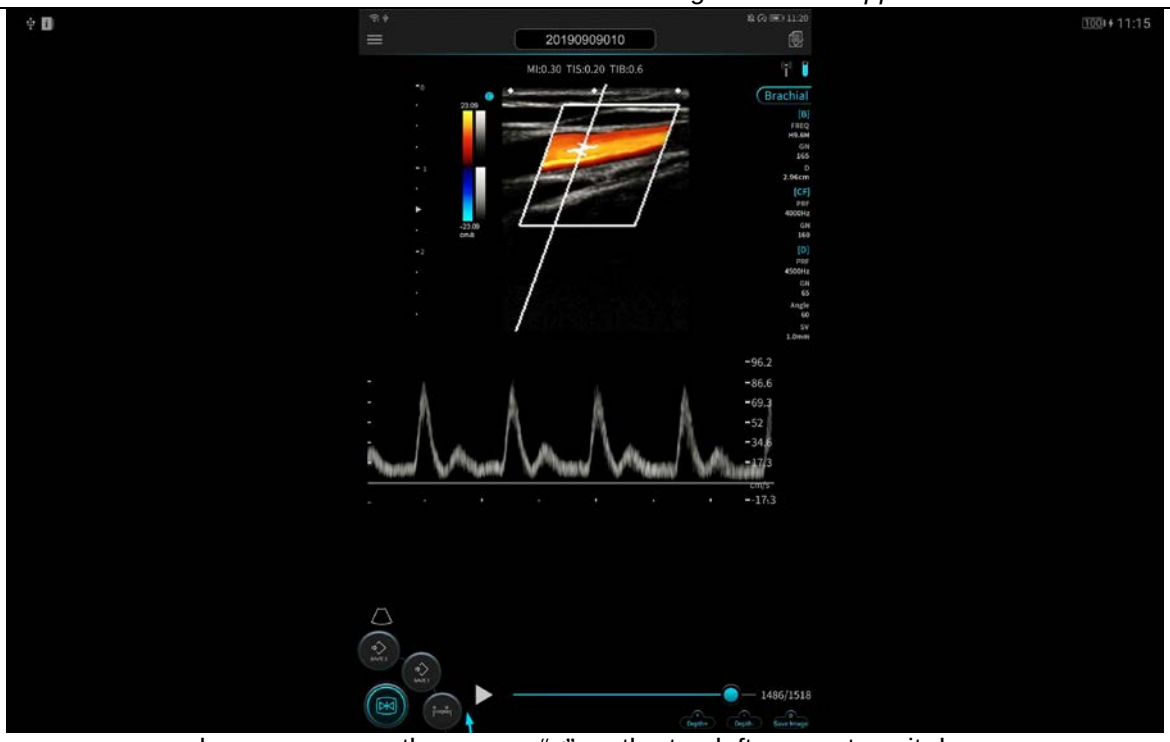
Select function management to manage system functions.

8.5 Tutorials

The first time you enter the app, it displays tutorials to familiarize you with the features of the system. You can view the Tutorials at any time. Press MENU and select tutorials to enter it, there is a short video to help you learn the system.

8.6 Demo

Click Demo to enter it, the user can view the exam images and cines.



Exit Demo: press anywhere on screen, then press “<” on the top left corner to exit demo.

8.7 About

Press About to check the current software version.

.

Chapter 9 System Maintenance

9.1 Cleaning

Caution

Before cleaning any part of the system, please make sure that the system is turned off and the power cord is disconnected from the power supply socket. Otherwise there will be danger of electricity shock.

Cleaning method:

Please use a piece of soft and dry cloth to clean the system. If there's some dirty difficult to be cleaned, please use wet cloth to clean system, and then use dry cloth to wipe off the water on the system.

Caution

Please don't use organic solvent to clean the system; otherwise it will damage the system surface.

Please never allow any liquid get inside the system or system, otherwise it will damage the system and cause electronic short.

If the system connector is required to be cleaned, please contact our authorized agent in your country in advance. Any cleaning by unauthorized person may result in system malfunction or affect its features.

9.2 System Maintenance

According to the purposes, the system is used on the surface of patient body.

Caution

No matter which type of examination is performed, please always try to reduce the unnecessary radiation of ultrasound wave to the patient during the ultrasound examination.

Caution

1. *System can only be used by professional doctor who has received professional training of ultrasound.*
2. *It is forbidden to sterilize and disinfect system by high pressure. If it needs to be used in sterilized occasion, please use a sterilized disposable system cover on the system.*
3. *Please avoid drop off or hitting the system by anything.*
4. *Don't scratch the system surface while using it.*
5. *Please use the authorized ultrasound gel during scanning. Using un-authorized gel may cause scratch or damage to system surface.*
6. *Please keep the system clean and dry.*

7. *Please don't use or preserve the system where it is over 50℃.*
8. *Please carefully check the system surface before using. If there is any abnormal phenomenon (eg. there's a leakage on the system surface), please stop using the system immediately and contact our authorized agent in your country as soon as possible. If you don't know the contact number of your authorized agent, please contact us by detail contact information at the end of this chapter.*

System maintenance

Please take good care of the system. Collision and dropping is strongly prohibited.

Please use the ultrasound gel which is acknowledged by the manufacture of the unit. We recommend AQUASONIC Gel made by R. P. Kincheloe Company in USA.

Plug and unplug of system in real-time is strongly prohibited.

Clean the system:

1) System tip

Cleaning: Use a sponge or soft cloth to remove gently the dirt and gel on system tip.

2) Connector, Cable, other part of the system tip must not be soaked in a solution. Simply clean it using a soft cloth moistened with alcohol and then dry it.

Aeration and let the system become dry in normal temperature.

Please strictly keep the system away from the paint thinner, ethylene oxide, other organic solvent, etc

Please keep the system inside the system case when it is not in use.

Dipping the system into any liquid is strongly prohibited.

Caution

Please immediately stop using the system and system if there is any broken phenomenon on the electricity cable or the system transducer. Otherwise there will be a danger of the electricity shock.

9.3 Safety Check

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

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

9.4 Troubleshooting

According to the most frequently occurred errors and system messages, the list of possible causes and relevant solutions is attached as below:

Errors & Messages	Possible Cause	Solution
Power-indicating lamp is not lit When user turn on the system.	Type C cord may not be connected, or may not be well connected with the displayer.	Please contact with Sales office, service department and distributor.
Power indicating lamp is lit When turn on the system, but no images on displayer.	The restart time interval after shutdown is too short	Wait 1 minute after power off and then power on.
Menu bar displays on the screen but no scanning image.	Transmission frequency, gain or STC control is not set properly. System is connected improperly. The system is in frozen status	Adjust the transmission frequency, gain or STC control. Ensure the system is connecting correctly Defreeze the system by pressing the FREEZE icon.
Image quality is abnormal	Examination mode is not correct. The image post-processing setting is abnormal.	Adjust image post-processing settings or set it to default.
The system is not working properly	Internal circuit protection	Restart the system

9.5 Service Responsibility

If users install, use and maintain the system fully according to CHISON's installation manual, operation manual and service manual, then SonoEye P2 main unit has a life time of 5 years,

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

The system is a precise electronic system. Standard maintenance must be performed by CHISON's authorized service engineer during the life time of the product.

CAUTION:

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

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

Chapter 10 System

10.1 General Description

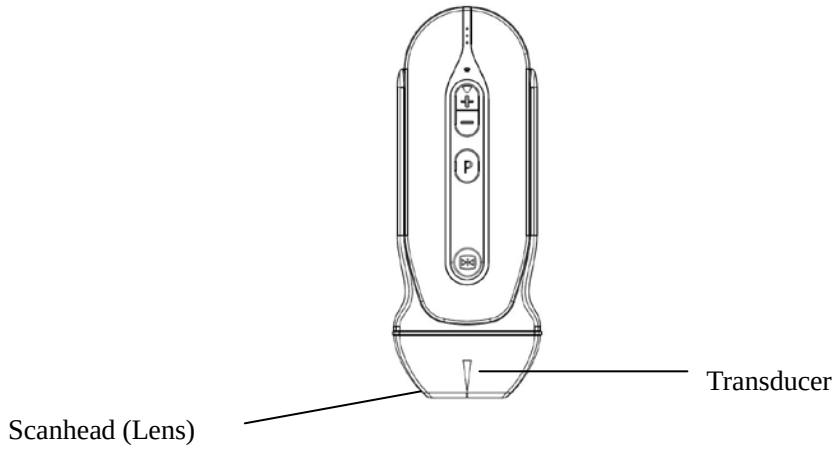


Fig.6-1: Linear Probe Overview

The system provide high spatial and contrast ultrasound imaging of frequencies from 4.5MHz to 10.0MHz. These systems operate by pulsing sound waves into the body and listening to the returning echoes to produce high-resolution brightness mode, and a real time display.

10.2 Care and Maintenance

The system is designed to be durable and dependable. These precision instruments should be inspected daily and handled with care. Please observe the following precautions:

- Do not drop the transducer on hard surface. This can damage the transducer elements and compromise the electrical safety of the transducer.
- Avoid kinking or pinching the transducer cable.
- Use only approved ultrasonic coupling gels.
- Follow the instructions for cleaning and disinfecting that come with each system.

10.2.1 Inspecting Systems

Before and after each use, inspect carefully the system's lens, cable, casing, and connector. Look for any damage that would allow liquid to enter the system. If any damage is suspected, do not use the system until it has been inspected and repaired/replaced by an authorized Service Representative.

NOTE

Keep a log of all system maintenance, along with a picture of any system malfunction.

WARNING

The systems are designed to be used only with this ultrasound system. Use of these systems on any other device or a non-qualified device may cause electrical shock or damage on the system/transducer.

10.2.2 Cleaning and Disinfecting

This section provides information and instructions for properly cleaning and disinfecting the system. Following these instructions will also help to avoid damaging the system during cleaning and disinfection. After each exam, clean and disinfect the system.

CAUTION: *Prevent any fluid from entering electrical or metal portions of the cable's connector during the cleaning and disinfecting process. Damage due to fluid in these areas may result.*

- Scrub the system as needed using a soft sponge, gauze, or cloth to remove all visible residue from the system surface.
- Use a soft cloth to clean the cable and the user section of the system with the cleaning disinfectant liquid. Make sure that the surface of the system and cable is wetted thoroughly with the cleaning-disinfectant.
- Allow system to air dry completely.

Recommended materials for cleaning and disinfecting transducer

Solution	Origin	Qualified Use	Active Ingredients	Purpose	Time
WIP'ANIOS	FRA	Wipe	Isopropyl alcohol/Didecyl dimethyl ammonium chlorides	Disinfection	NA
80% Ethanol（Using clean cloth soak the liquid）	Any	Wipe	Ethanol	Clean or Disinfection	NA
70% Isopropyl alcohol （Using clean cloth soak the liquid）	Any	Wipe	Isopropyl alcohol	Clean or Disinfection	NA
Clinell Sporicidal Wipes	GBR	Wipe	Sodium Percarbonate Citric Acid	Disinfection	NA
mikrozid PAA wipes	DEU	Wipe	peracetic acid,Hydrogen peroxid,Acetic acid	Disinfection	NA
Universal wipes	GBR	Wipe	Quaternary ammonium	Disinfection	NA
perform classic wipes EP	DEU	Wipe	EP	Disinfection	NA

CAUTION

These transducers are not designed to withstand heat sterilization methods. Exposure to temperatures in excess of 60 º C will cause permanent damage. The transducers are not designed to be totally submerged in fluid, as permanent damage will result if the entire transducer is submerged.

System Safety

Handling precautions

Ultrasound systems are highly sensitive medical instruments that can easily be damaged by improper handling. Use care when handling and protect from damage when not in use. DO NOT use a damaged or defective system. Failure to follow these precautions can result in serious injury and equipment damage.

Electrical shock hazard:

The system is driven with electrical energy that can injure the patient or user if live internal parts are contacted by conductive solution:

- DO NOT immerse the system and the system connector into any liquid.
- Prior to each use, visually inspect the system lens for cracks, cuts, tears, and other signs of physical damage. DO NOT use a system that appears to be damaged until you verify functional and safe performance. You need to perform a more thorough inspection, including the cable, strain relief, and connector, each time you clean the system.

Electrical leakage checks should be performed on a routine basis by CHISON Service or qualified hospital personnel.

Mechanical hazard:

A defective system or excess force can cause patient injury or system damage:

- Inspect systems for sharp edges or rough surfaces that may injure sensitive tissue.
- DO NOT apply excessive force to the system connector when inserting into the system port.

Special handling instructions

Using protective sheaths

The use of market cleared system sheaths is recommended for clinical applications. Reference FDA March 29, 1991 "Medical Alert on Latex Products".

Protective sheaths may be required to minimize disease transmission. System sheaths are available for use with all clinical situations where infection is a concern.

DO NOT use pre-lubricated condoms as a sheath. In some cases, they can damage the system. Lubricants in these condoms may not be compatible with system construction.

Devices containing latex may cause severe allergic reaction in latex sensitive individuals. Refer to FDA's March 29, 1991 Medical Alert on latex products.

DO NOT use an expired system sheath. Before using a sheath, verify if it has expired.

System handling and infection control:

This information is intended to increase user awareness of the risks of disease transmission associated with using this equipment and provide guidance in making decisions directly affecting the safety of the patient as well as the equipment user.

Diagnostic ultrasound systems utilize ultrasound energy that must be coupled to the patient by direct physical contact.
Depending on the type of examination, this contact occurs with a variety of tissues ranging from intact skin in a routine exam to recirculating blood in a surgical procedure. The level of risk of infection varies greatly with the type of contact.

One of the most effective ways to prevent transmission between patients is with single use or disposable devices. However, ultrasound transducers are complex and expensive devices that must be reused between patients. It is very important, therefore, to minimize the risk of disease transmission by using barriers and through proper processing between patients.

Risk of Infection

ALWAYS clean and disinfect the system between patients to the level appropriate for the type of examination and use FDA-cleared system sheaths where appropriate.

Adequate cleaning and disinfection are necessary to prevent disease transmission. It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures in use.

System Cleaning process:

DO disconnect the system from the displayer prior to cleaning/disinfecting the system. Failure to do so could damage the system.

Perform Cleaning system after each use

- Disconnect the system and remove all coupling gel from the system by wiping with a soft cloth and rinsing with flowing water.
- Wash the system with mild soap in lukewarm water. Scrub the system as needed using a soft sponge, gauze, or cloth to remove all visible residue from the system surface. Prolonged soaking or scrubbing with a soft bristle brush (such as a toothbrush) may be necessary if material has dried onto the system surface.

WARNING

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

CAUTION

Take extra care when handling the lens face of the system. The lens face is especially sensitive and can easily be damaged by rough handling. NEVER use excessive force when cleaning the lens face.

- *Rinse the system with enough clean potable water to remove all visible soap residue.*
- *Air dry or dry with a soft cloth.*

CAUTION

To minimize the risk of infection from blood-borne pathogens, you must handle the system and all disposables that have contacted blood, other potentially infectious materials, mucous membranes, and non-intact skin in accordance with infection control procedures. You must wear protective gloves when handling potentially infectious material. Use a face shield and gown if there is a risk of splashing or splatter.

Disinfecting the systems:

After each use, please disinfect the systems. Ultrasound systems can be disinfected using liquid chemical germicides. The level of disinfection is directly related to the duration of contact with the germicide. Increased contact time produces a higher level of disinfection.

In order for liquid chemical germicides to be effective, all visible residue must be removed during the cleaning process. Thoroughly clean the system, as described earlier before attempting disinfection.

You MUST disconnect the system from the displayer prior to cleaning/disinfecting the system. Failure to do so could damage the system.

DO NOT soak systems in liquid chemical germicide. Soaking may cause system damage and early failure of the enclosure, resulting in possible electric shock hazard.

- Prepare the germicide solution according to the manufacturer's instructions. Be sure to follow all precautions for storage, use and disposal. The transducer is not designed to be totally submerged in fluid. Permanent damage will result if the entire transducer is submerged.
- Place the cleaned and dried system in contact with the germicide for the time specified by the germicide manufacturer.

Ultrasound transducers can easily be damaged by improper handling and by contact with certain chemicals. Failure to follow these precautions can result in serious injury and equipment damage.

- Avoid mechanical shock or impact to the transducer and do not apply excessive bending or pulling force

to the cable.

- Transducer damage can result from contact with inappropriate coupling or cleaning agents:
    - Do not soak or saturate transducers with solutions containing alcohol, bleach, ammonium chloride compounds or hydrogen peroxide.
    - Avoid contact with solutions or coupling gels containing mineral oil or lanolin.
    - Avoid temperatures above 60°C. Under no circumstances should the transducer be subjected to heat sterilization method. Exposure to temperatures above 60º C will cause permanent damage to the transducer.
- Inspect the system prior to use for damage or degeneration to the housing, strain relief, lens and seal. Do not use a damaged or defective system.

Coupling gels

DO NOT use gels (lubricants) that are not recommended. They may damage the system and void the warranty. *AQUASONIC Gel made by R. P. Kincheloe Company in USA is recommended.*

In order to assure optimal transmission of energy between the patient and system, a conductive gel must be applied liberally to the patient where scanning will be performed.

DO NOT apply gel to the eyes. If there is gel contact to the eye, flush eye thoroughly with water.

Coupling gels should not contain the following ingredients as they are known to cause system damage:

- Methanol, ethanol, isopropanol, or any other alcohol-based product.
- Mineral oil
- Iodine
- Lotions
- Lanolin
- Aloe Vera
- Olive Oil
- Methyl or Ethyl Parabens (para hydroxybenzoic acid)
- Dimethylsilicone

Planned maintenance

The following maintenance plan is suggested for the system and systems to ensure optimum operation and safety.

Daily: inspect the systems

After each use: clean the system, disinfect the system.

As necessary: inspect the system, clean the system, disinfect the system.

Returning/Shipping Systems and Repair Parts

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

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

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

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

10.3 System Operation Instructions

For details on connecting, activating, deactivating, disconnecting, transporting and storing the systems, see Chapter 3.

Scanning the Patient

In order to assure optimal transmission of energy between the patient and system, a conductive gel must be applied liberally to the patient where scanning will be performed.

After the examination is complete, follow the cleaning and disinfecting, or sterilizing procedures as appropriate.

10.4 Service Responsibility

The system is a precise electronic system. Only an authorized service contractor should replace defective parts. Failures caused by unauthorized service are not the responsibility of the manufacturer.

REFERENCE:

1) AIUM/NEMA: Standard For Real-Time Display of Thermal and Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment, Revision 2. NEMA Standards Publication UD 3-2004; American Institute of Ultrasound in Medicine, Laurel MD; National Electrical Manufacturers Association, Rosslyn, VA; 2004a.
2) Implementation of the Principle of As Reasonably Achievable (ALARA) for Medical and Dental Personnel, National Council on Radiation Protection and Measurements (NCRP), report NO.107, December 31,1990
3) FDA Center for Devices and radiological Health (CDRH), 510(K) Guidance for Diagnostic Ultrasound and Fetal Doppler Ultrasound Medical Devices, September 8 1989 draft
4) FDA/CDRH,510(K) Diagnostic Ultrasound Guidance Update of 1991, April 26, 1991 draft
5) Biological Effects of Ultrasound: Mechanisms and Clinical Implications, NCRP Report No. 74, December 30,1983
6) Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms, NCRP Report No.113, June 1,1992
7) Bioeffects Considerations for the safety of Diagnostic Ultrasound, Journal of Ultrasound in Medicine,

AIUM, September1988

8) Geneva Report on Safety and Standardization in Medical Ultrasound, WFUMB, May 1990 Medical Ultrasound Safety, AIUM, 1994

9) Medical Electrical Equipment standard IEC 60601-1, IEC60601-1-2, IEC 60601-2-37

10) Diagnostic Ultrasound Physics and Equipment, edit by P. R. Hoskins, in 2003

Appendix A: THE INFORMATION OF EC REPRESENTATIVE

Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175
Fax:+49-40-255726
Dimdi No.:DE/0000040627
E-mail: shholding@hotmail.com

Appendix B: ACOUSTIC OUTPUT REPORT TABLE

Transducer Model: SonoEye P2

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.88	0.24		0.24		0.24
Index component Value				0.24	0.24	0.24	0.24	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.93					
	P	(mW)		6.06		6.06		6.33
	P_{1*1}	(mW)		6.06		6.06		
	Z_s	(cm)			2.00			
	Z_b	(cm)					2.00	
	Z_{MI}	(cm)	1.55					
	$Z_{pii.\alpha}$	(cm)	1.55					
	f_{awf}	(MHz)	4.80	8.22		8.22		7.62
Other Information	prr	(Hz)	-					
	srr	(Hz)	27.63					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	88.02					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Zsii.\alpha$	(mW/cm^2)	0.36					
	I_{spta} at Z_{pii} or $Zsii$	(mW/cm^2)	0.36					
	p_r at Z_{pii}	(MPa)	2.53					
Operating control conditions	Focus	(cm)	2.00	3.00		3.00		2.00
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	4.50	7.50		7.50		7.50
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P2
Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.02	0.22		0.32		0.28
Index component Value				0.18	0.22	0.18	0.32	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	2.25					
	P	(mW)		6.85		6.85		6.85
	P_{1*1}	(mW)		6.85		6.85		
	Z_s	(cm)			1.25			
	Z_b	(cm)					1.65	
	Z_{MI}	(cm)	1.65					
	$Z_{pii.\alpha}$	(cm)	1.65					
	f_{awf}	(MHz)	4.85	4.88		4.88		4.88
Other Information	prr	(Hz)	513					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	100.05					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	16.44					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	18.95					
	p_r at Z_{pii}	(MPa)	2.55					
Operating control conditions	Focus	(cm)	2.00	3.00		3.00		3.00
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	4.50	4.50		4.50		4.50
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P2
Operation Mode: B+CFM

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.92	0.38		0.38		0.62
Index component Value				0.38	0.38	0.38	0.38	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	2.14					
	P	(mW)		10.74		10.74		7.73
	P_{1*1}	(mW)		10.74		10.74		
	Z_s	(cm)			2.05			
	Z_b	(cm)					2.05	
	Z_{MI}	(cm)	0.90					
	$Z_{pii.\alpha}$	(cm)	0.90					
	f_{awf}	(MHz)	5.37	7.60		7.60		8.74
Other Information	prr	(Hz)	-					
	srr	(Hz)	4.50					
	n_{pss}	NA	8.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	209.60					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Zsii.\alpha$	(mW/cm^2)	0.39					
	I_{spta} at Z_{pii} or $Zsii$	(mW/cm^2)	0.40					
	p_r at Z_{pii}	(MPa)	2.24					
Operating control conditions	Focus	(cm)	1.00	1.50		1.50		0.50
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	6.50	7.50		7.50		7.50
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P2
Operation Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.34	0.15		0.54		0.30
Index component Value				0.15	0.10	0.15	0.54	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	0.77					
	P	(mW)		5.91		5.91		5.91
	P_{1*1}	(mW)		5.91		5.91		
	Z_s	(cm)			1.00			
	Z_b	(cm)					1.50	
	Z_{MI}	(cm)	1.55					
	$Z_{pii.\alpha}$	(cm)	1.55					
	f_{awf}	(MHz)	5.19	5.18		5.18		5.18
Other Information	prr	(Hz)	4500					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	25.72					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $z_{sii.\alpha}$	(mW/cm^2)	209.29					
	I_{spta} at Z_{pii} or z_{sii}	(mW/cm^2)	366.44					
	p_r at Z_{pii}	(MPa)	0.99					
Operating control conditions	Focus	(cm)	2.00	1.50		1.50		1.50
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	5.00	5.00		5.00		5.00
	PRF	HZ	4500	4500		4500		4500

Appendix C: TRANSDUCER MAXIMUM SURFACE TEMPERATURE

Transducer model	Maximum surface temperature(℃) Contacting human-tissue mimicking material	Maximum surface temperature(℃) Suspending in air
SonoEyeP2	**<37.4**	**<32.0**

Appendix D: MEASUREMENT RESULTS SUMMARY

Measurement	Useful Range	Accuracy
Distance	Image area	<±5%
Circumference: trace method,ellipse method	Image area	<±5%
Area: trace method,ellipse method	Image area	<±10%
Volume	Image area	<±5%
Angle	Image area	<±5%

Appendix E: GUIDANCE AND MANUFACTURER'S DECLARATION

1. Guidance and manufacturer's declaration – electromagnetic emissions		
SonoEye is intended for use in the electromagnetic environment specified below. The customer or the user of SonoEye Series should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	SonoEye uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	SonoEye is suitable for use in all professional healthcare environments, like physicians, offices, dental offices and those not directly connected to the public low-voltage power supply net work that supplies buildings used for professional medical purposes.

2. Guidance and manufacturer's declaration – electromagnetic immunity			
The SonoEye is intended for use in the electromagnetic environment the SonoEye should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital
Radiated RF EM fields IEC61000-4-3	3V/M 80MHz-2.7GHz 80%AM at 1KHz	3V/M 80MHz-2.7GHz 80%AM at 1KHz	Radiated RF EM fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See teble 9	See table 9	Proximity fields from RF wireless communications equipment should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.