Digital Color Doppler Palm Ultrasound System

Model
SonoEye P1/ SonoEye V1/ SonoEye G1/ SonoEye P1-G/SonoEye V1-G/SonoEye G1-G

USER MANUAL

CHGA-SonoEye-043-P1

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Rev. 2.1

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 P1/ SonoEye V1/ SonoEye G1/ SonoEye P1-G/SonoEye V1-G/ SonoEye G1-G. Please verify that you are using the latest revision of this document. If you need to know the latest revision, contact your distributor.

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Chapter 1 Introduction

This manual contains necessary information for safe system operation.

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

1.1 System Overview

Indications for Use

The Digital Color Doppler Palm Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), B/M, Color Doppler, Combined(B+Color), Pulsed Wave and Fusion Harmonic Imaging modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Pediatrics, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Nerve, Lung.

The 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.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: 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 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 disconnect system when the system is in active operation. Always go to EXAM screen when you need to disconnect 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 the protective covers on the system. These covers protect users from hazardous voltages. A qualified electronic technician must make all internal replacements.
- Do not operate this system in the presence of flammable gases or anesthetics.

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. 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.

 ***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

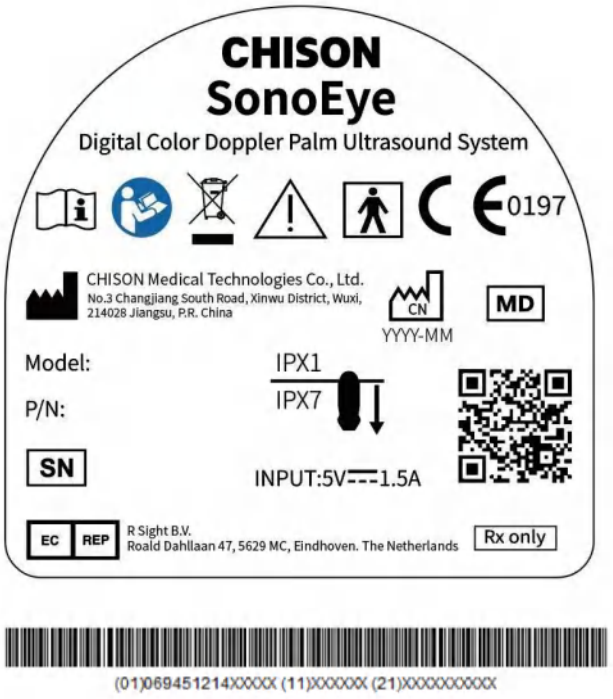
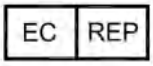


Fig. 2: SonoEye Label

2.3.1 Symbols on Label

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.
	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.
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.
	Scan the QR code to open CHISON website.
	Unique Device Identifier.

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:

CAUTION

- *DO NOT connect any 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 the requirement 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 printing 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. Two 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 Flow Map mode 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:*

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

TI	Maximum exposure time (minutes)
0.7	60
1.0	30
1.5	15

2.0	4
2.5	1

- 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 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, 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 CFM 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 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.

Display and Report in Different Mode

Located on the upper middle section of the displayer, 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 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 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.

2.7 Device instructions of cybersecurity controls

2.7.1 Software Integrity Control

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

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

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

- Installing OS Updates Immediately

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

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

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

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

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

2.7.2 Device instructions of cybersecurity controls

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

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

2.8 Insturctions to the intruded device

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

- Back up the patient data.

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

Chapter 3 Preparing the System for Use

3.1 Site Requirement

3.1.1 Operation 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 as above, otherwise the system may be damaged or can't work.

3.1.3 Hardware Requirements

The digital color doppler palm ultrasound system includes the transducer, software and a COTS device. The minimum requirements for COTS equipment are as follows:

- *IEC 60950-1 compliant*

- *IEC 55032 compliant*
- *Octa-core processor (CPU)*
- *1 GB of memory*
- *1 GB of storage (on-board)*
- *Touch interface*
- *Internally mounted speakers*
- *Operating System: Android 9 or newer*
- *Display Resolution (in pixels): 1920×1200 or more*
- *Interface: Type C, USB 2.0*

WARNING

Using the SonoEye app on a COTS device that does not meet the minimum specification may result in poor image quality, unexpected results, possible misdiagnosis or not working.

WARNING

The COTS cannot be charged while the transducer is in use for safety.

3.1.4 Programming Language Requirements

Operation System: Android

Programming Environment: Android Studio

3.1.5 The requirement of commercial off-the-shelf (COTS) devices

All models need to comply with IEC55032, IEC60950-1, among which we have selected typical models to do verification testing with SonoEye on ANSI/AAMI ES60601-1 and IEC60601-1-2, such as Samsung Galaxy A70s or Huawei MatePad Pro.

- Electrical Safety

  The transducer and software, along with a representative device, have been verified as compliant with IEC 60601-1. The transducers meet Type BF isolated applied part requirements. When the transducer and software are used in conjunction with a device (COTS devices) compliant with IEC 60950-1, the system meets IEC 60601-1 requirements for Class II equipment.

- Electromagnetic Compatibility

  The transducer and representative Android device are classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. When the transducer and software are used in conjunction with a device (COTS devices) compliant with IEC 55032, the system meets IEC 60601-1-2 requirements for Group1, Class A equipment.

- Android devices' output current and voltage

The representative Android devices' output current is 1.5A and voltage is 5V. A COTS device connected to our transducer and system should meet the current and voltage range, the output current is greater than or equal to 1.5A, and the output voltage is 5V±5%.

- Full compliance with USB 2.0 standard

  The representative Android devices are full compliance with USB 2.0 standard. A COTS device connected to our transducer and system should meet the standard.

- Representative Android devices

  Representative Android devices are Samsung Galaxy A70s and Huawei MatePad Pro. The configuration is as follows.

  Samsung Galaxy A70s：

  - CPU frequency 2.0GHz (big quad core), 1.7GHz (small quad core), Octa-core
  - RAM capacity 8GB
  - ROM capacity 128GB
  - Main screen resolution 2400x1080 pixels
  - WLAN function Dual-band WIFI, IEEE 802.11 a/b/g/n/ac (support 2.4G and 5GHz)
  - Operating System: Android 9
  - Support Bluetooth 5.0

  Huawei MatePad Pro：

  - CPU frequency 2 x Cortex-A76 Based 2.86 GHz+ 2 x Cortex-A76 Based 2.09 GHz+ 4 x Cortex-A55
  - 1.86 GHz, Octa-core
  - RAM capacity 8GB
  - ROM capacity 128GB
  - Main screen resolution 2560x1600 pixels
  - WiFi function supports dual frequency (2.4GHz+5GHz)
  - Bluetooth function supports Bluetooth 5.1 module
  - Operating System: Android 9

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 terminal

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 terminal. Select the update package to install APP.

Turning the System On and Off

1. Power on:

Connect the SonoEye to your device, the SonoEye will be on automatically. And after a few seconds,

the device will be automatically connected.

If you turn off the SonoEye, you can press  for 3 seconds to turn on the system.

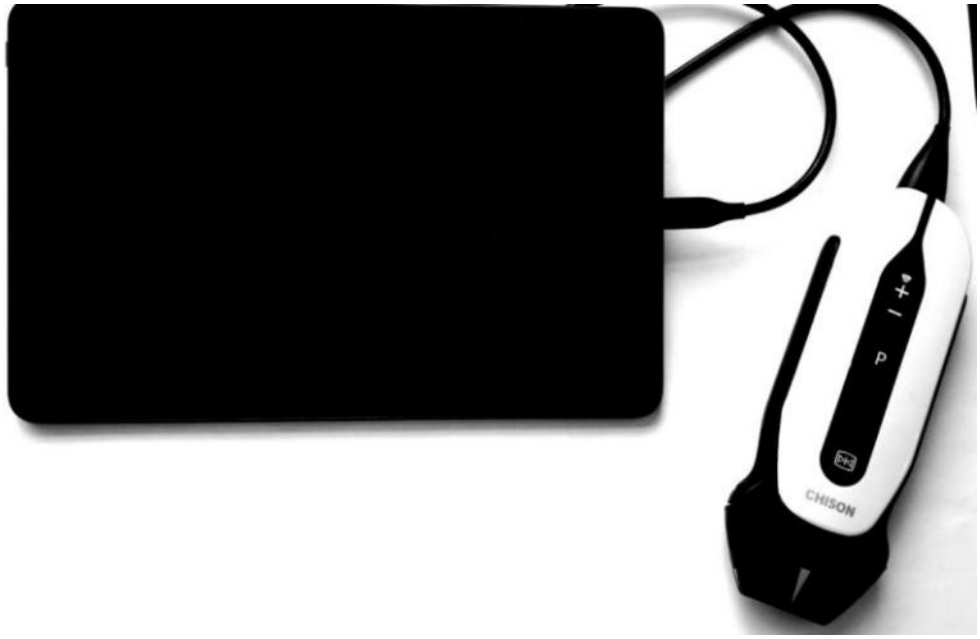
2. Power off:

Press  for 3 seconds to shut down the system

3.3 System Specifications

3.3.1 Console Overview

SonoEye P1/ SonoEye V1/SonoEye G1 system:



SonoEye P1-G/ SonoEye V1-G/ SonoEye G1-G system:

Fig. 3-1 a: Console Overview

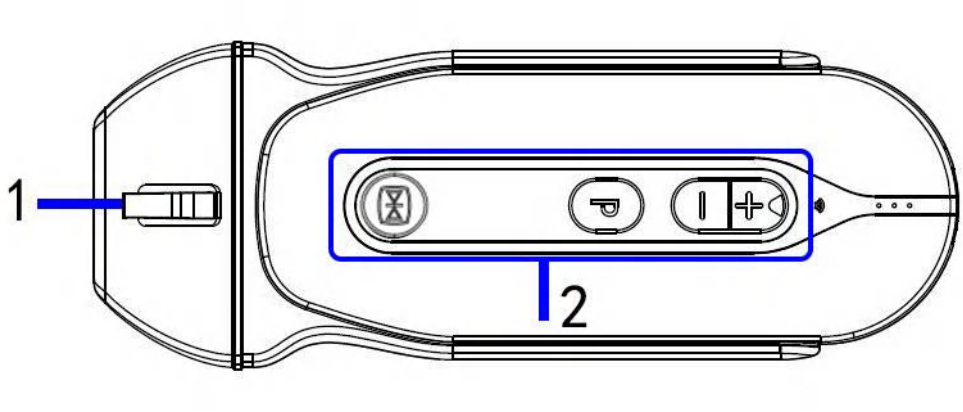


Fig. 3-2: Firmware Front View for SonoEye P1-G/ SonoEye V1-G/ SonoEye G1-G

1. Acuductor Hook 2. From left to right: Freeze Button, P, - & + (They can be set as None, Freeze/Unfreeze, Gain+, Gain-, Depth+, Depth- and Save Image)

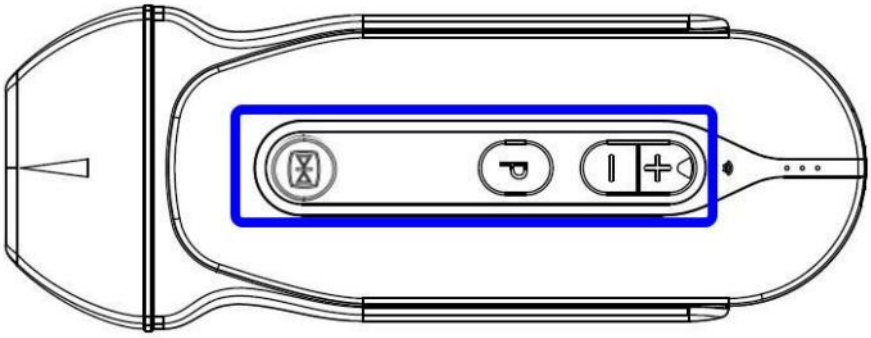


Fig. 3-3: Firmware Front View SonoEye P1/ SonoEye V1/ SonoEye G1

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）*171mm（Height）*24mm（Depth）

Net weight of main unit (approx): 195g

3.3.3 Image Modes

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

3.3.4 Type

 Linear Array: P1 6.0MHz-11.0MHz	 Linear Array: P1-G 6.0MHz-11.0MHz
 Linear Array: V1 6.0MHz-11.0MHz	 Linear Array: V1-G 6.0MHz-11.0MHz
 Linear Array: G1 6.0MHz-11.0MHz	 Linear Array: G1-G 6.0MHz-11.0MHz

3.3.5 System Configuration

Function	SonoEye P1	SonoEye V1	SonoEye G1	SonoEye P1-G	SonoEye V1-G	SonoEye G1-G
B mode	Standard	Standard	Standard	Standard	Standard	Standard
B/M mode	Option	Option	Option	Option	Option	Option
PW mode	Option	Standard	Option	Option	Standard	Option
CFM mode	Option	Option	Option	Option	Option	Option
FHI	Option	Option	Standard	Option	Option	Standard
Type-C cable	Standard	Standard	Standard	Standard	Standard	Standard
Identify probe	Standard	Standard	Standard	Standard	Standard	Standard
Switch exam mode	Standard	Standard	Standard	Standard	Standard	Standard
Gain	Standard	Standard	Standard	Standard	Standard	Standard

Function	SonoEye P1	SonoEye V1	SonoEye G1	SonoEye P1-G	SonoEye V1-G	SonoEye G1-G
Depth	Standard	Standard	Standard	Standard	Standard	Standard
STC	Standard	Standard	Standard	Standard	Standard	Standard
Focus	Standard	Standard	Standard	Standard	Standard	Standard
Zoom	Standard	Standard	Standard	Standard	Standard	Standard
Adjust sample Gate location	Option	Option	Option	Option	Option	Option
Adjust size of sample Gate horizontal	Option	Option	Option	Option	Option	Option
Adjust size of sample Gate vertical	Option	Option	Option	Option	Option	Option
Adjust PW sample gate	Option	Option	Option	Option	Option	Option
Compound	Standard	Standard	Standard	Standard	Standard	Standard
Frequency Scaling	Standard	Standard	Standard	Standard	Standard	Standard
Freeze/Unfreeze	Standard	Standard	Standard	Standard	Standard	Standard
B-distance	Standard	Standard	Standard	Standard	Standard	Standard
B-Circumference	Standard	Standard	Standard	Standard	Standard	Standard
B-Area	Standard	Standard	Standard	Standard	Standard	Standard
B-Volume	Standard	Standard	Standard	Standard	Standard	Standard
B/M-Distance	Option	Option	Option	Option	Option	Option
B/M-Time	Option	Option	Option	Option	Option	Option
B/M-HR	Option	Option	Option	Option	Option	Option
PW-Velocity	Option	Option	Option	Option	Option	Option
PW-Time	Option	Option	Option	Option	Option	Option
Vessel measure package	Option	Option	Option	Option	Option	Option
Small organ measure package	Option	Option	Option	Option	Option	Option
Lung measurement	Option	Option	Option	Option	Option	Option
General report	Option	Option	Option	Option	Option	Option
Vessel report	Option	Option	Option	Option	Option	Option
Small Organ report	Option	Option	Option	Option	Option	Option
Lung report	Option	Option	Option	Option	Option	Option
English Interface	Standard	Standard	Standard	Standard	Standard	Standard
Multi-language	Option	Option	Option	Option	Option	Option

Function	SonoEye P1	SonoEye V1	SonoEye G1	SonoEye P1-G	SonoEye V1-G	SonoEye G1-G
Interface						
Auto vascular tracking	Option	Option	Option	Option	Option	Option
Instant AIO	Standard	Option	Option	Standard	Option	Option
Biopsy Guide	Option	Option	Option	Standard	Standard	Standard
SonoNeedle	Standard	Standard	Standard	Option	Option	Option
SuperNeedle	Standard	Standard	Standard	Option	Option	Option
SonoRemote	Option	Option	Option	Option	Option	Option
Save Cine	Option	Option	Option	Option	Option	Option
Save Image	Option	Option	Option	Option	Option	Option
Cine Loop	Option	Option	Option	Option	Option	Option
Annotation	Option	Option	Option	Option	Option	Option
Bodymark	Option	Option	Option	Option	Option	Option
Mark	Standard	Standard	Standard	Standard	Standard	Standard
Patient management	Standard	Standard	Standard	Standard	Standard	Standard
Voice/Angle/Baseline on PW	Standard	Standard	Standard	Standard	Standard	Standard
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)	Standard	Standard	Standard	Standard	Standard	Standard
Physical key	Standard	Standard	Standard	Standard	Standard	Standard
Setting	Standard	Standard	Standard	Standard	Standard	Standard
Archives	Standard	Standard	Standard	Standard	Standard	Standard
Tutorials	Standard	Standard	Standard	Standard	Standard	Standard
EasyView	Standard	Standard	Standard	Standard	Standard	Standard
Demo	Standard	Standard	Standard	Standard	Standard	Standard
About	Option	Option	Option	Option	Option	Option

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 power cord, DO NOT pull excessively on the cord or sharply bend the cord while wrapping it.

- Store the systems in their original case 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 and on inclines. Ask for help if necessary.
- 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 case.
- 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 with displayer, 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 displayer; otherwise there is possibility of electricity shock.

- *Connect the connector from the* SonoEye P1/ SonoEye V1/ SonoEye G1/ SonoEye P1-G/ SonoEye V1-G/ SonoEye G1-G *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
4. Center Line
5. Full Screen
6. B/M mode
7. PW mode
8. CFM mode
9. Freeze
10. Logo
11. Patient information
12. End Exam
13. Connection status
14. Image parameter area
15. 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 patient ID.

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

3. Click the [Save] button.

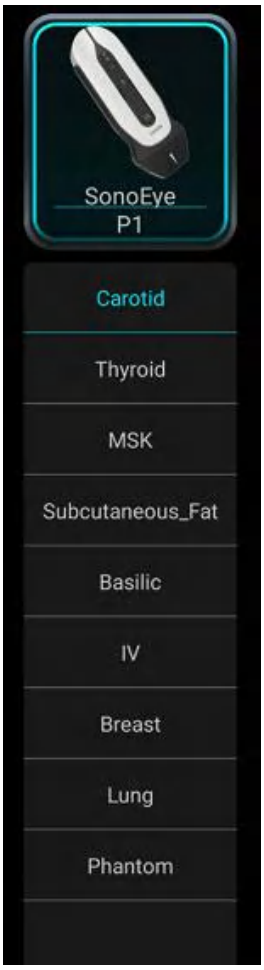
Patient Information:

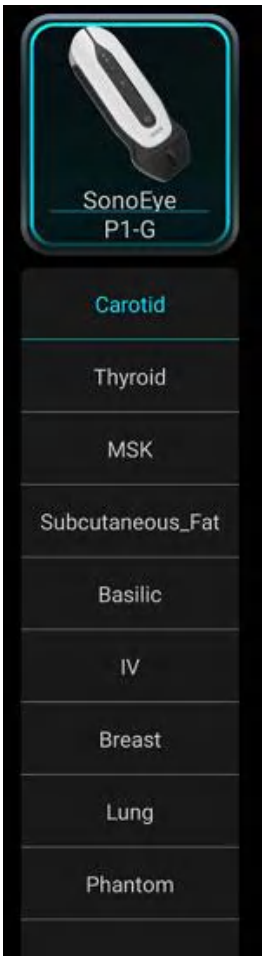
MRN	Medical Record Number
ID	Patient ID
Date	Date of the study

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
Birthday	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
BSA	

Application

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





4.3 Switching Function

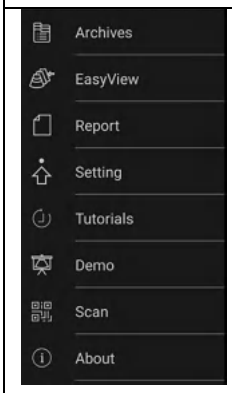
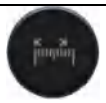
Follow the blue arrow to slide the menu list to show Freq.

4.4 Switching Mode

The system will start B mode while the user first enters App, press M, PW and CFM to enter corresponding exam mode.

4.5 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.

4.6 Image Parameter Area

Display information about application, frequency, mode, depth, gain and etc.

4.7 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.

5.1.2 Select Application

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

Start App to enter Compound Image automatically.

There are five image display modes: B mode, B/M mode, CFM mode, FHI 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 mode 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.

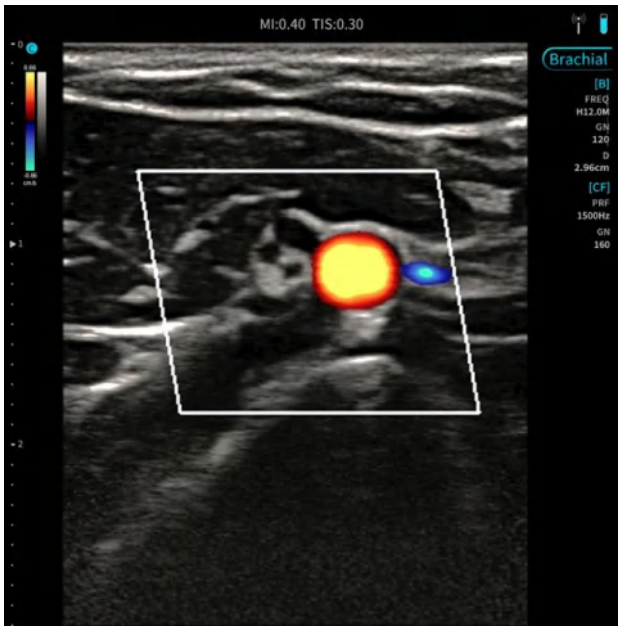


Fig. 5-1 CFM Mode

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  to help locate the vessel you wish to examine.
- Press  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  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 and hold the existed B-Lines to active current B-Lines, then touch the Delete icon on the left of image area to delete current B-Lines.

- **Lung Report:**

After finishing all operations on lung, press the **Report** button 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 into 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

At real-time state, touch the screen with two fingers and slide it outward to enlarge the image.

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 to 255, the minimum unit of adjustment is 1.

2. Voice

At real-time state, press the voice button on displayer 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. The user can add annotations to: zoomed image, cine review image and frozen image.

WARNING: *The user shall guarantee that the entered annotations are correct. Incorrect annotations may cause misdiagnosis!*

Operation:

1. Freeze image and slide the menu list to select 

2. Press  in submenu. “ | ”is displayed in image area and the soft icon board appeared in the bottom of screen.

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

4. Press and hold the added annotation, the soft icon board appears, the user can re-input annotation.

5.4.2 Adding BodyMark

Operation:

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

2. The submenu appears, press  . The body mark list displays, select desired body mark and 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 “+” icons. 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 the result and hold it,  appears, touch it to 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 “+” icons, 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 the result and hold it,  appears, touch it to 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

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

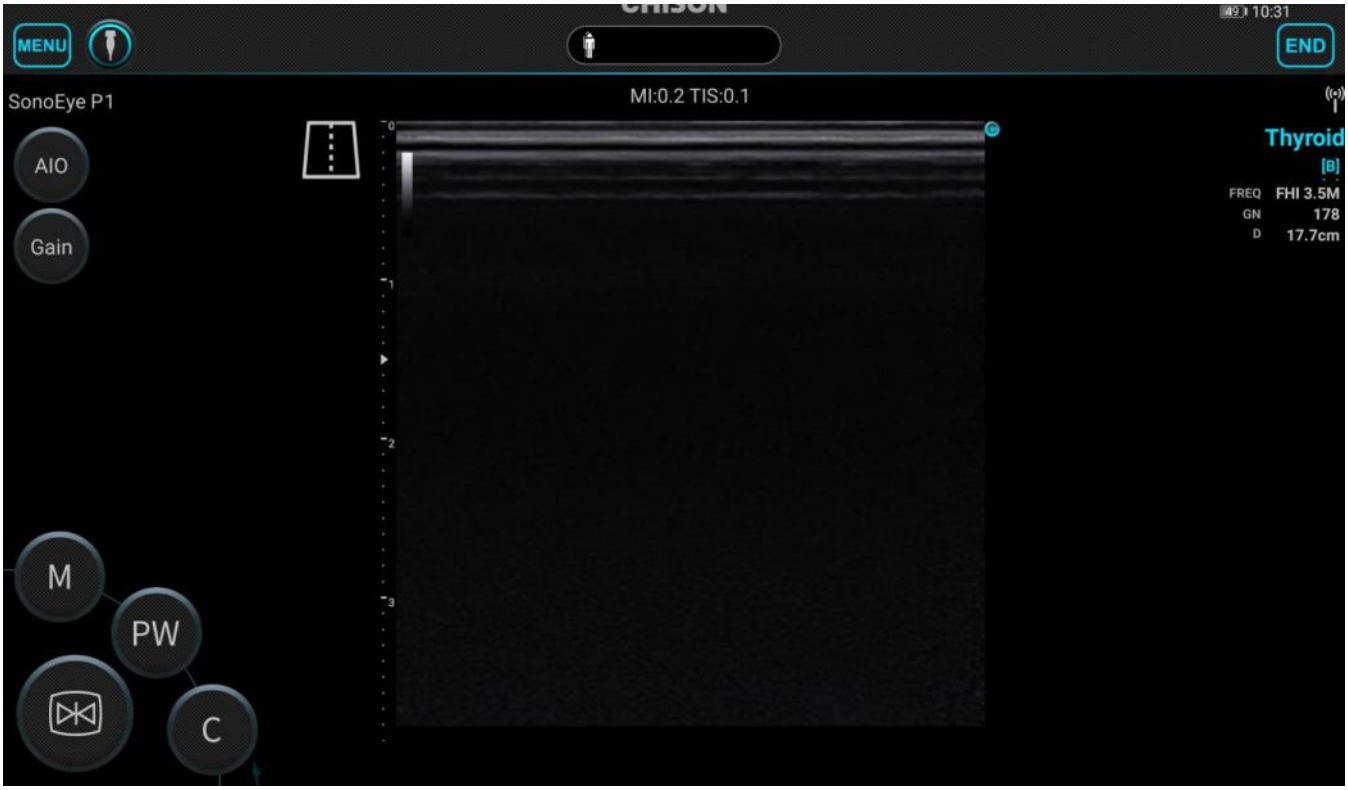
Press Freeze and click  to start automatic playback.

7.4 Cine Save

Press Freeze and click  to save current cine.

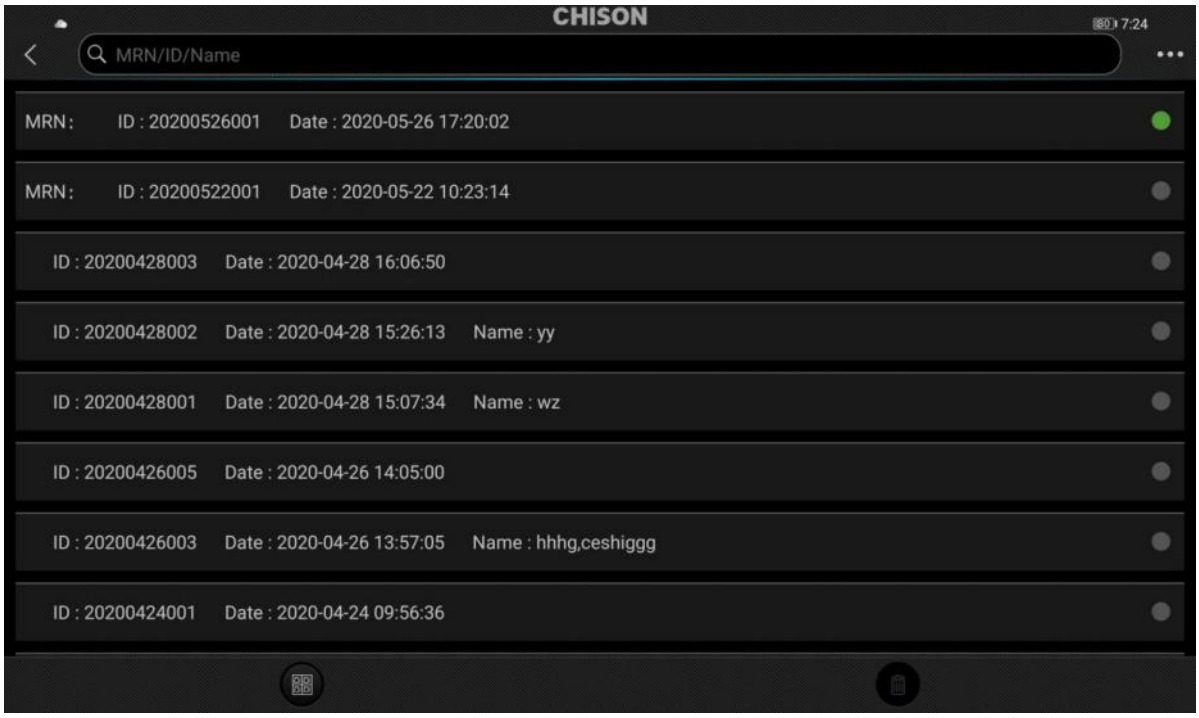
Chapter 8 Side Menu

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.

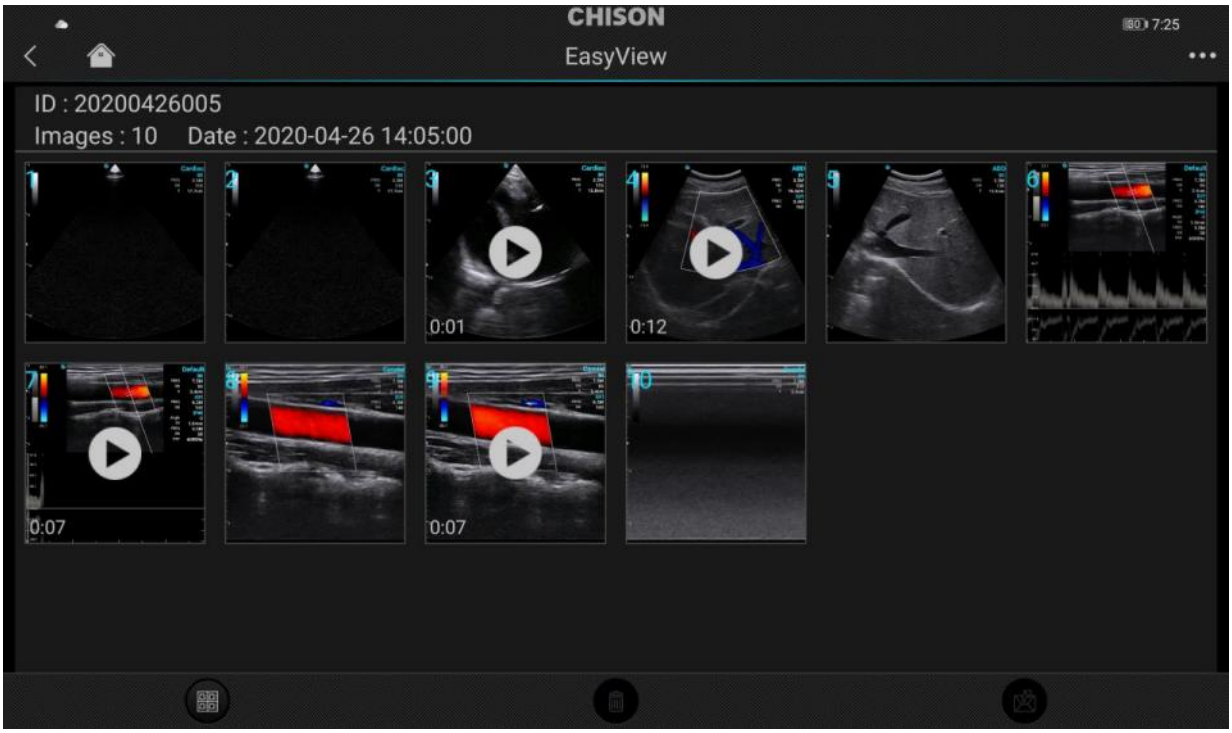
 : Press it to select all archives.

 : Press it to delete selected archive.

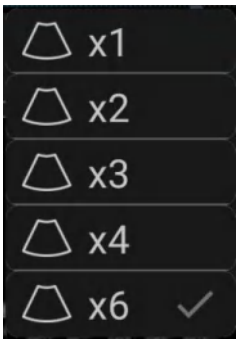
Press selected archive to enter EasyView.

8.2 EasyView

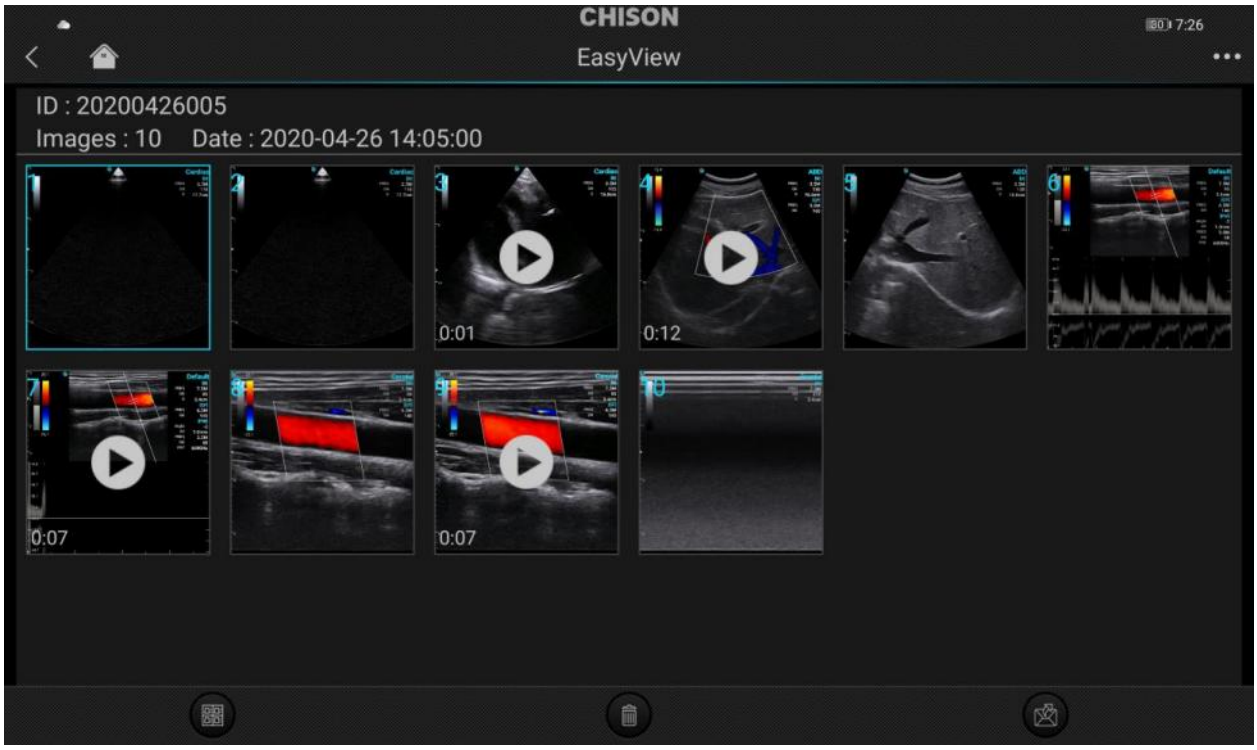
Press EasyView to check the patient information, saved images and cines.



Press  on the top right corner of screen, 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 selected image.

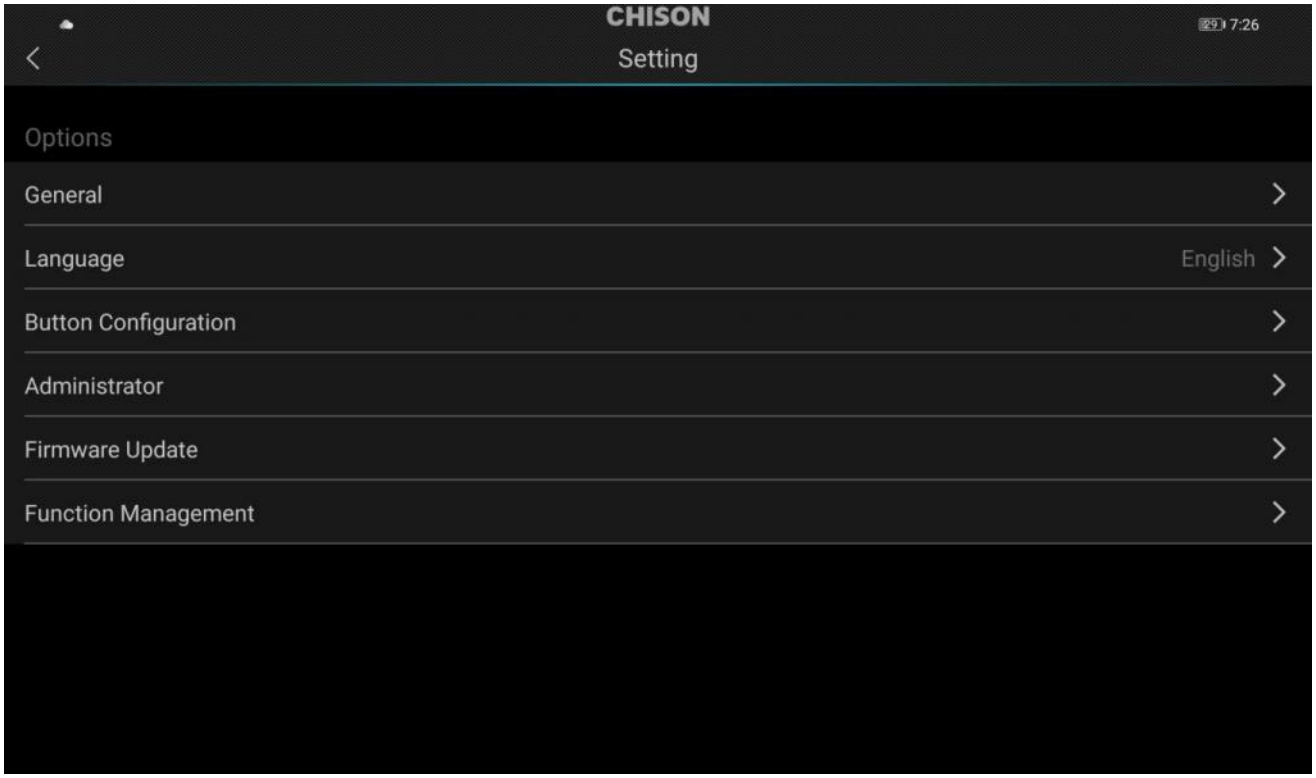
8.3 Report

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.

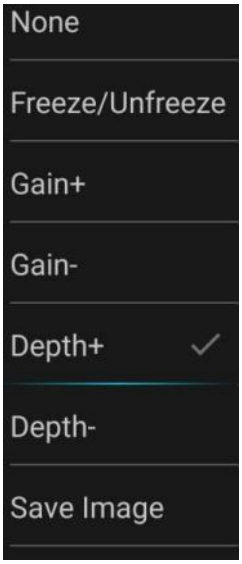
8.4.2 Language

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

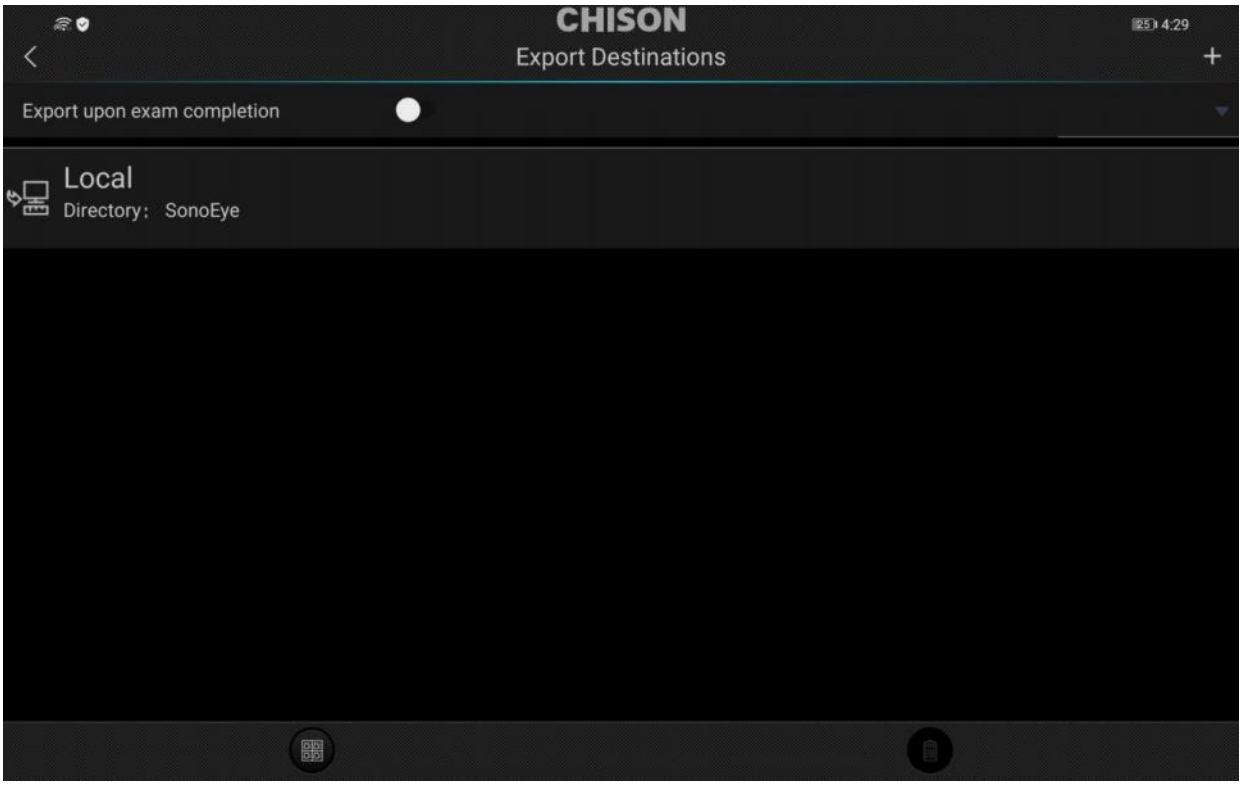
Select firmware update to upgrade system software version.

8.4.6 Function Management

Select function management to manage system functions.

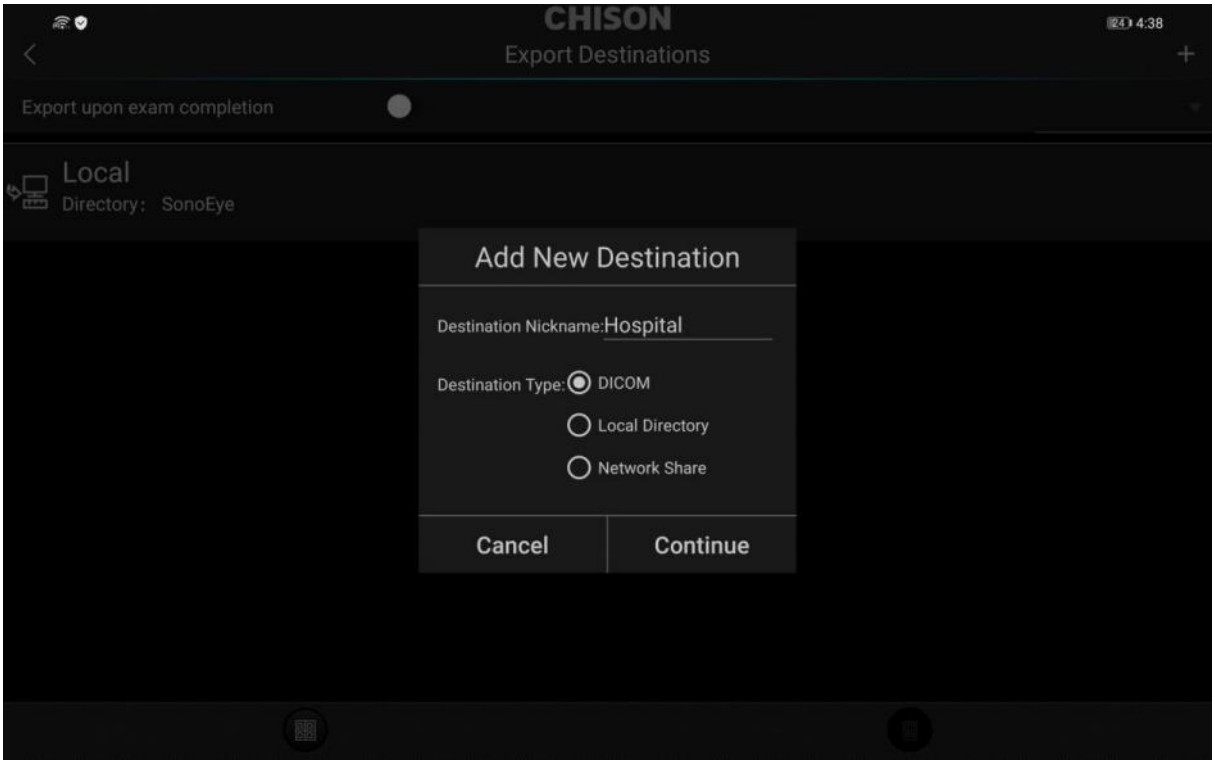
8.1 Export Destinations

Press MENU and select Export Destinations.

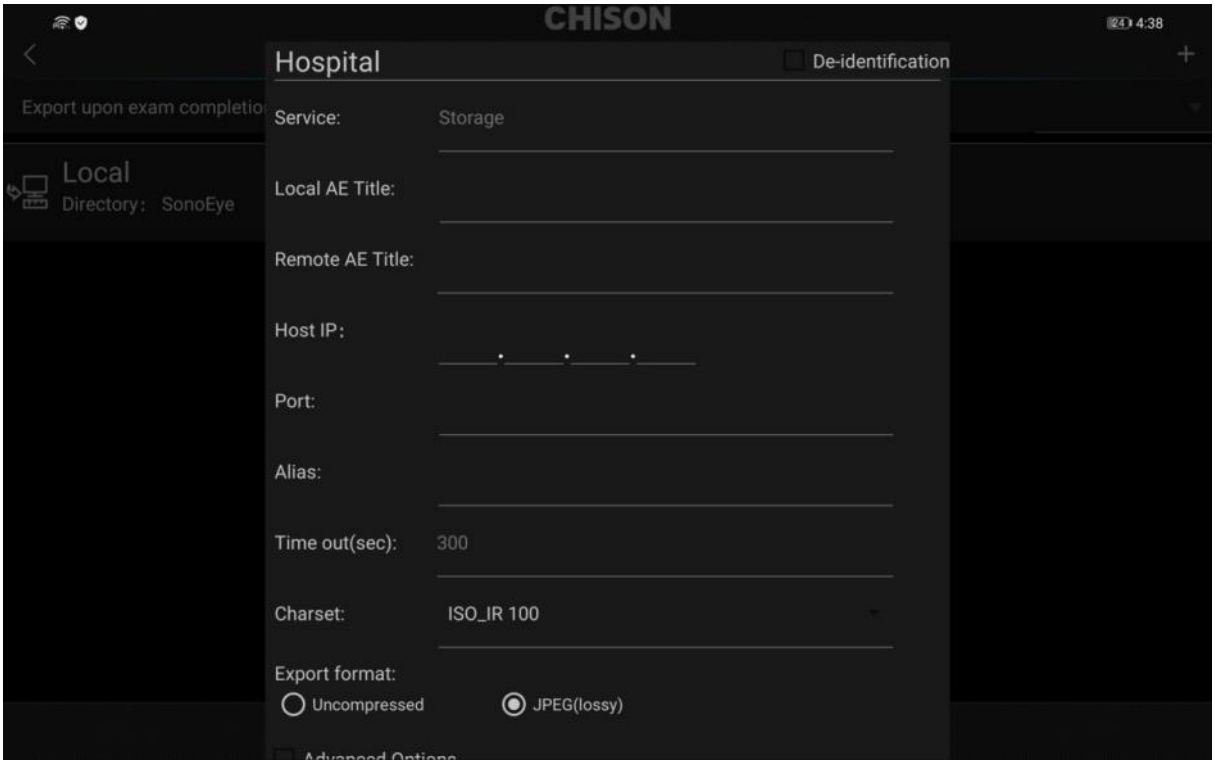


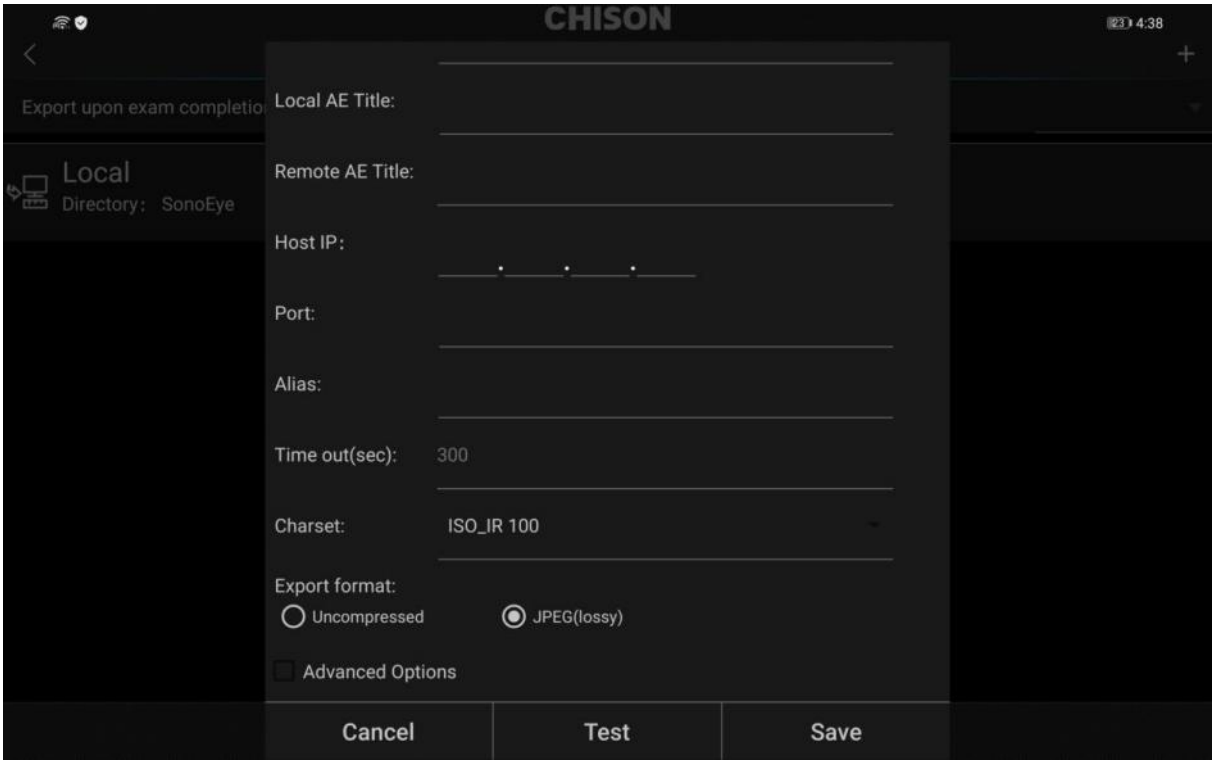
From this interface, you can add or remove export destinations.

You can enter the new interface by press +. There are three Destination types to choose from:DICOM, Local Directory, Network Share



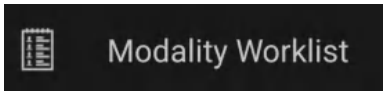
Fill in the information and select the corresponding type to enter the next level interface





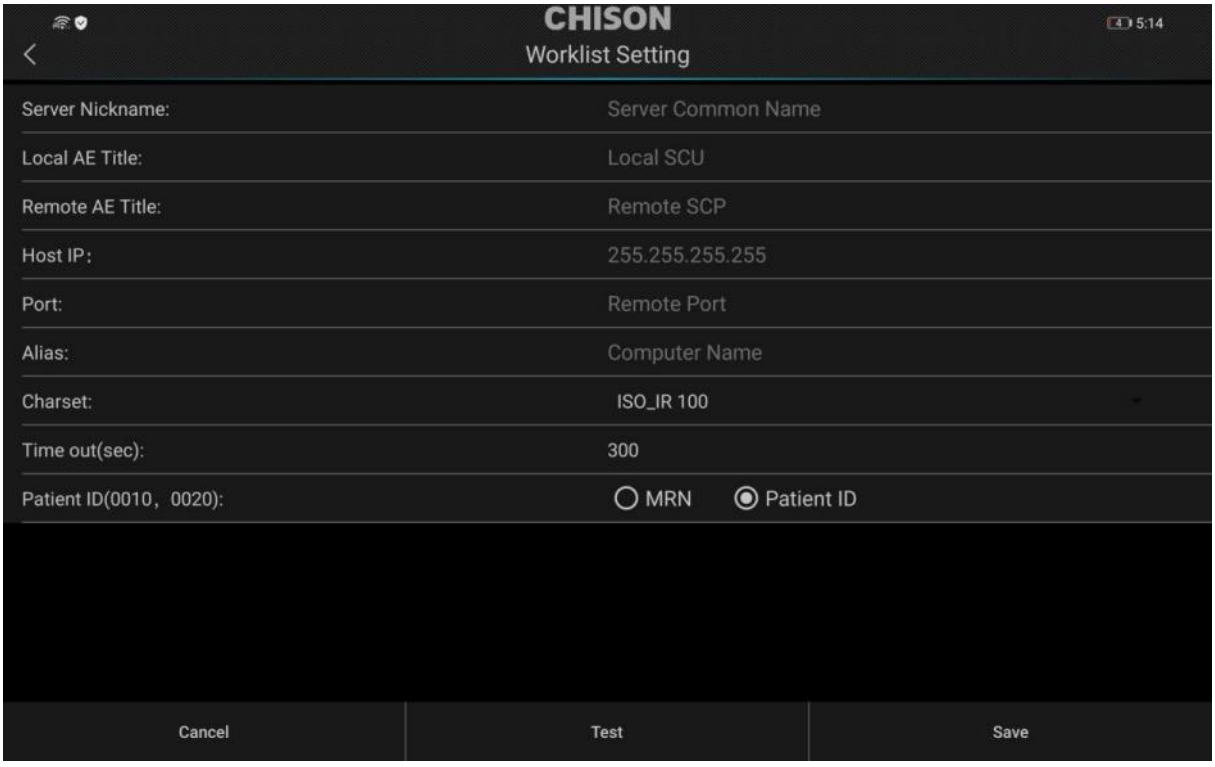
Fill in the information and click Save to complete the new Export Destination.

8.2 Modality Worklist

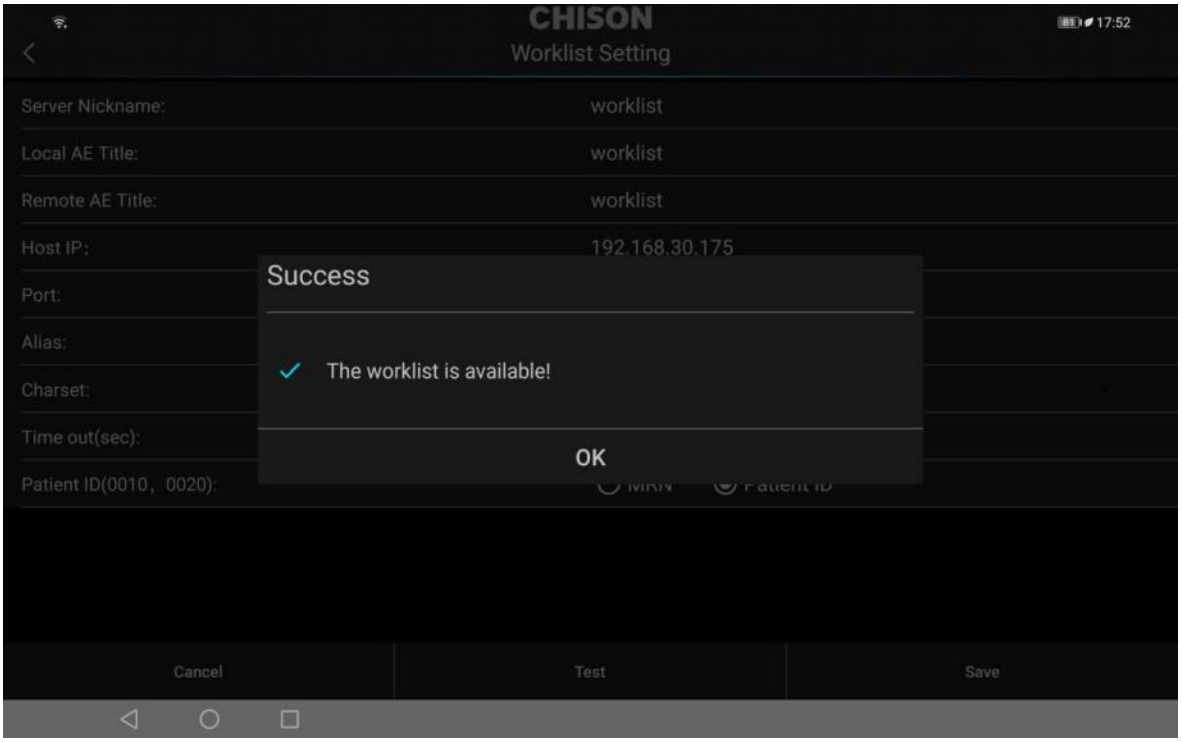
Click 

to enter it, the user can Import the worklist from the server.

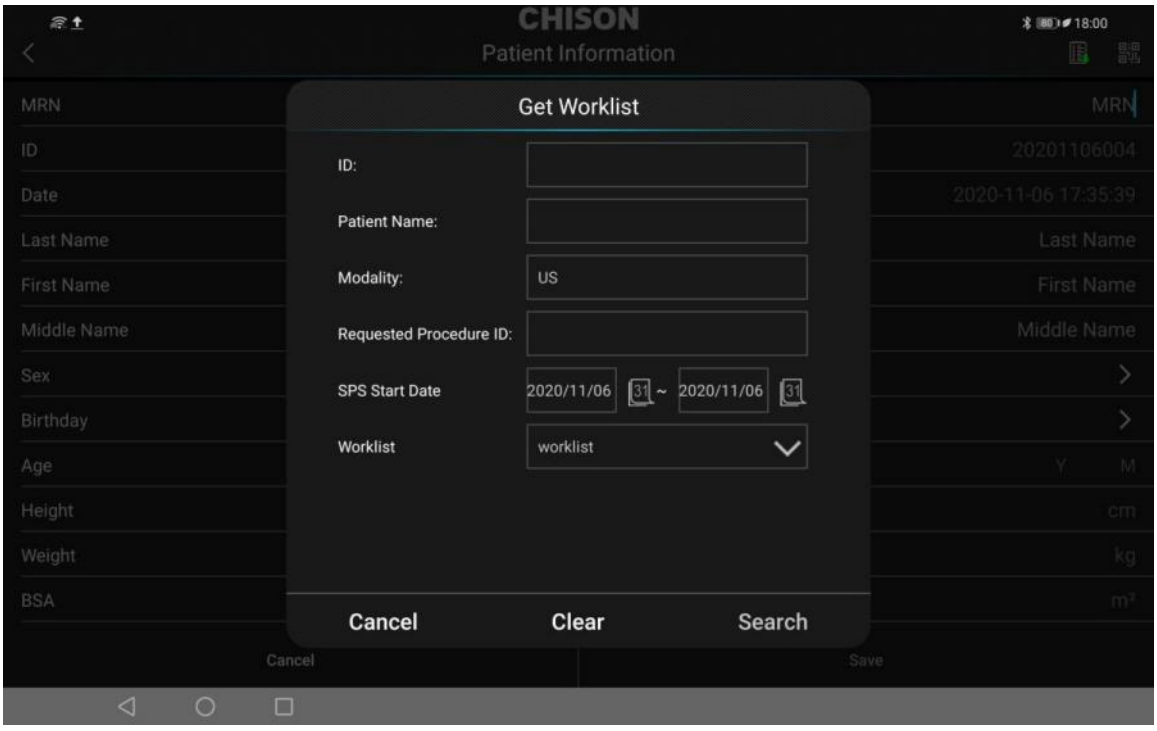
Click + to add server information



Click Test to make sure the server is connected. Then click Save to save server information.



Click on enter the Patient interface and click  to enter Get worklist to import worklist from the server



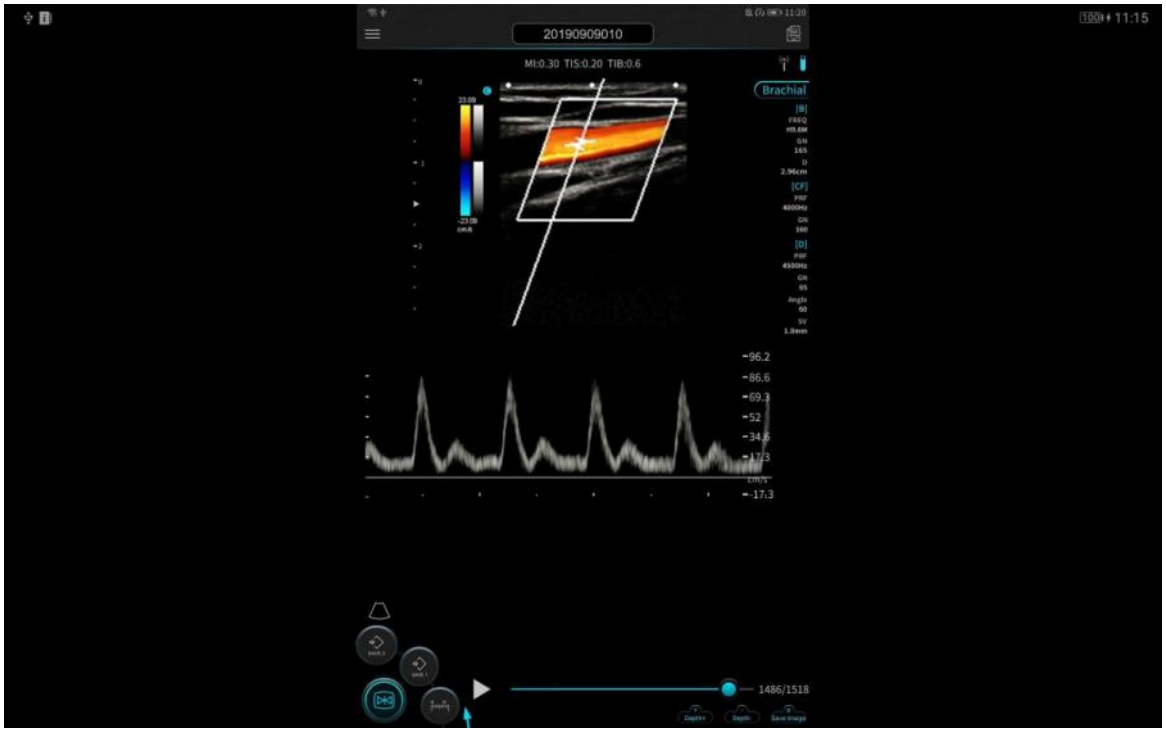
8.5 Tutorials

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 

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 if there is any broken phenomenon on the electricity cable. Otherwise there will be a danger of the electric 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 use and maintain the system fully according to CHISON's installation manual, operation manual and service manual, then SonoEye P1/ SonoEye V1/ SonoEye G1/ SonoEye P1-G/ SonoEye V1-G/ SonoEye G1-G 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.

Chapter 10 System

10.1 General Description

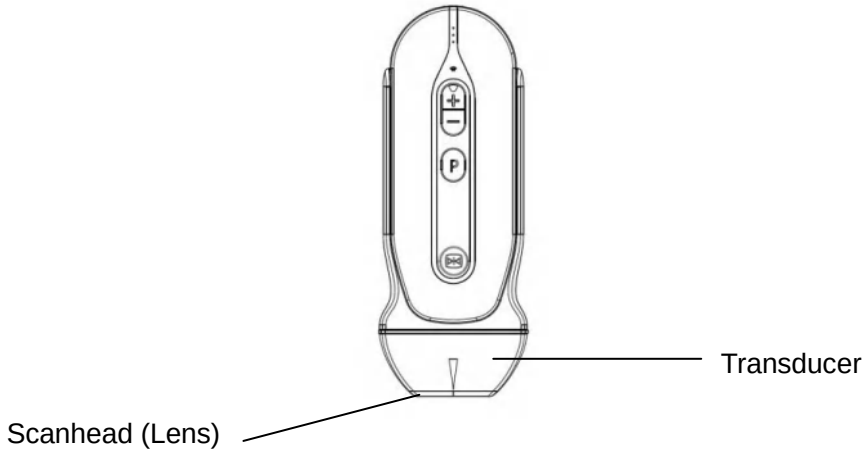


Fig.10-1: Linear Probe Overview

The system provides high spatial and contrast ultrasound imaging of frequencies from 6.0MHz to 11.0MHz. The system operates 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 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 system or a non-qualified system may cause electrical shock or damage on the system/transducer.

10.2.2 Cleaning and Disinfecting

Definitions

Cleaning removes visible soil (for example, organic and inorganic material) from the probe surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection because inorganic and organic materials that remain on the surfaces of probes interfere with the effectiveness of these processes.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.

Low-Level Disinfection (LLD) destroys most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium tuberculosis or bacterial spores.

Intermediate-Level Disinfection (ILD) inactivates Mycobacterium tuberculosis, bacteria, most viruses, most fungi, and some bacterial spores.

High-Level Disinfection (HLD) destroys or removes all microorganisms except bacterial spores.

Transducer Components

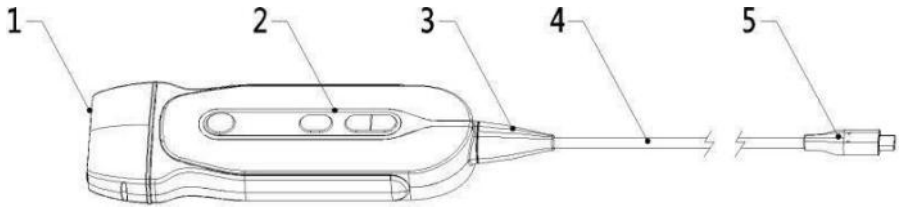


Fig.10-2: Transducer Components

1. Lens 2. Cover 3.Sheath 4.Cable 5. TYPE-C connector

To choose a suitable probe disinfection method, you must first determine its category according to the purpose of the probe. For more information about compatible cleaning and disinfecting agents, please refer to the section "Cleaning or disinfecting ". When using detergents and disinfectants, be sure to follow the manufacturer's instructions.

WARNING

After each use of the probe, it must be cleaned. Cleaning the probe is an important step before effective disinfection. When using detergents and disinfectants, be sure to follow the manufacturer's label instructions.

WARNING

When cleaning and disinfecting any instrument, be sure to wear protective glasses and gloves.

CAUTION

Using non-recommended disinfectants, inappropriate disinfectant concentration, or the immersion depth or immersion time of the probe exceeding the recommended value will cause damage or discoloration of the probe, and invalidate the probe warranty.

CAUTION

Do not use a brush when cleaning transducers. Even the use of soft brushes can damage transducers.

CAUTION

Do not leave the probe in contact with cleaning agents and disinfectants for a long time. Limit the time the probe is exposed to cleaners and disinfectants to the shortest time recommended by the manufacturer.

When you use OPA (ortho-phthalaldehyde)-based disinfectants, if you do not follow the manufacturer's instructions carefully, residual solution may remain on the probe. In order to minimize the impact of residual OPA or any other disinfectant, it is recommended as below:

- Follow the instructions of the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends as below immersing the probe in drinking water three times to rinse the probe.
- Limit the time the probe is exposed to the disinfectant to the shortest time recommended by the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends a minimum time of 12 minutes.
- Prevent any fluid from splashing on your mobile device’s touchscreen during cleaning and during disinfecting. Damage may result due to fluid.

Point-of-use processing

Before cleaning, check the probe first. If any particles or body fluids adhere to the probe or cable, you can wipe it off with a soft cloth dipped with 80% ethanol.

10.2.2.1 Cleaning

Recommended supplies:

Dust-free cloth or soft cloth;

Compatible cleaner or wipes for probe cleaning;

1. Disconnect the probe from the system.

2. Wear sterile gloves and use protective eyewear to prevent infection.

3. Remove Ultrasound transmission gel from the transducer by using a soft cloth dipped with potable water (not to exceed 43°C (110°F)) or an approved cleaning or disinfectant agent or by using an approved disinfectant wipe.

Gently wipe the lens to remove the gel, then wipe the probe，cable for 1 minute and until visibly clean(There is no gel, hair, debris or other residue on the probe.).

Do not wipe the connector to prevent liquid from entering the inside. Please refer to Table 10-1 below for approved compatible cleaning and disinfection products.

4. Dry the transducer using a sterile cloth or gauze after cleaning. Blot the lens dry. Do not wipe the lens. Do not dry the transducer by heating it.

10.2.2.2 Disinfecting

After cleaning the probe, you must disinfect the probe.

To reduce the risk of contamination and infection, it is important to choose the appropriate level of disinfection, based on prior exam usage and whether the use is classified as non-critical or semi-critical. Use Table, “Probe Disinfection Class, Use, and Method” to determine the appropriate class and then follow the appropriate intermediate-level or high-level disinfection procedure.

Probe Disinfection Class, Use, and Method

Class	Use	Method
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate- level disinfection (ILD)
Semi-Critical Class	Touches mucous membranes and non-intact skin	Cleaning followed by high-level disinfection (HLD)

Intermediate-Level Disinfection (ILD)

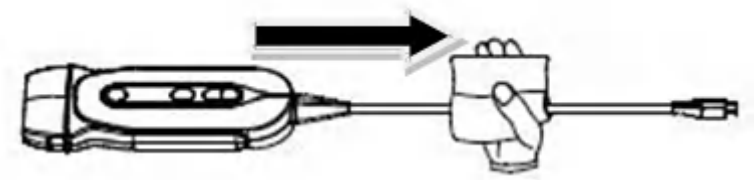


Fig.10-2: Wipe direction

1. Wear sterile gloves to prevent infection.
2. Wipe the probe, with approved compatible disinfectant wipes or soft cloth dipped in disinfectant agent. As shown in the figure above, wiping from lens toward cable. Do not wipe the type-c linker to prevent poor contact.
3. Ensure that the disinfected surface remains visibly moist for at least two (2) minutes, use additional

   fresh wipes as needed.
4. Allow to air dry.
5. After cleaning and disinfection, check the appearance of the probe to see whether the transducer and cable are worn or damaged

High Level Disinfection

It is recommended that you use Cide®OPA by Ethicon US, LLC.

1. After cleaning the probe, you must disinfect the probe. It is recommended that you use Cidex® OPA high- level disinfection solution.

2. Prepare Cidex® OPA high-level disinfection solution for use per the manufacturer's instructions. Fill a tray or basin with the disinfectant solution at room temperature (minimum temperature of 20°C) to a level allowing immersion of the probe up to the immersion line (As shown below),

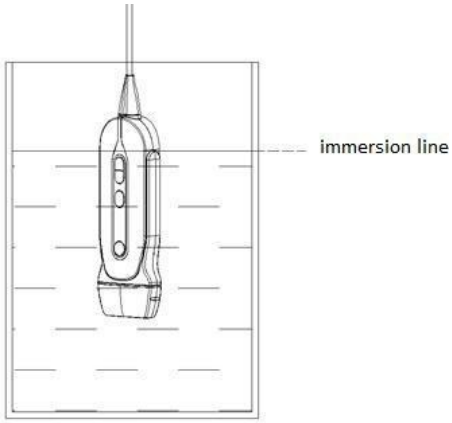


Fig.10-3: Soaking depth

3. Immerse the probe in Cidex® OPA solution up to the immersion line and ensure no air or bubbles are trapped. Allow soaking according to the manufacturer's instructions.

4. Thoroughly rinse the probe (up to the immersion line) by immersing it in a large volume of room temperature purified water for a minimum of one (1) minute. Remove the probe and discard the rinse water.

Do not reuse the water. Always use fresh volumes of water for each rinse. Repeat this stage two (2) additional times for a total of three (3) rinses.

5. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the device is completely dry. Inspect the device to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is visible.

6. Once clean and disinfected, inspect the probe, strain relief, cable, and connector for signs of damage or wear.

7. Daily and Long-Term Storage follow these guidelines to protect the probe.

8. Always store transducers in the probe case when you are not using them.

 ***CAUTION***

Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use. Do not soak the transducer connector or the cable near it into water or any solution.

 ***CAUTION***

Follow local regulations when selecting and using the disinfectant.

10.2.2.3 **Approved and compatible cleaning and disinfectant**

Table 10-1：Cleaning and disinfection list

Wipes type	Brand	Place of origin	Chemical ingredient	solution
80% Ethanol (Soak with a soft cloth)	Any manufacturer	Any	Ethanol	Clean/LLD/ILD
70% Isopropyl alcohol (Soak with a soft cloth)	Any manufacturer	Any	Isopropyl alcohol	Clean/LLD/ILD
Universal wipes	Clinell	United Kingdom	Compound double chain quaternary ammonium salt	Clean/LLD/ILD
perform classic wipes EP	Schulke&Mayr GmbH	Germany	Compound alcohol	Clean/LLD/ILD
WIP'ANIOS	Laboratoires ANIOS	France	Isopropyl alcohol/Didecyl dimethyl ammonium chlorides	Clean/LLD/ILD
Sani-cloth AF3,Sani- Cloth AF	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopropyl alcohol	Clean/LLD/ILD
Super Sani-Cloth	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopropyl alcohol	Clean/LLD/ILD

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 signsof 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

- Before cleaning, turn off the system
- To clean the touch screen.

  a. Remove dust with a soft, lint-free cloth.

  b. Please wipe the screen with cleaner specially designed for LCD. Spray the liquid onto the cleaning cloth and gently wipe the screen clean. You can also use pre-moistened screen wipes.

  c. Dry the screen with a soft, lint-free cloth
- Wipe the remaining external surfaces of the system with soft cloth dipped few 70% isopropyl, 80%

  Ethanol solution or recommended wipes.
- Gently remove any residue with a cloth lightly moistened with purified water.
- Dry the equipment to prevent potential corrosion.

  If the equipment has come in contact with blood or infectious material, see “Infection Control”.

Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection control procedures established in your facility for the protection of both the staff and the patient.

WARNING

If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your CHISON service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

CAUTION

Remove blood on the system and the transducer connectors and cables with a soft cloth dipped few soap and potable water. Then dry the equipment with a soft, dry, lint-free cloth to prevent corrosion.

⚠*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

R Sight B.V.

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Appendix B: ACOUSTIC OUTPUT REPORT TABLE

Transducer Model: SonoEye P1/ SonoEye V1/ SonoEye G1/ SonoEye P1-G/ SonoEye V1-G/ SonoEye G1-G

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.10	0.04		0.04		0.04
Index component Value				0.04	0.04	0.04	0.04	
Acoustic Parameters	**$p_{r.\alpha}$ at Z_{MI}**	**(MPa)**	3.09					
	P	**(mW)**		0.92		0.92		0.67
	P_{1*1}	**(mW)**		0.92		0.92		
	Z_s	**(cm)**			0.90			
	Z_b	**(cm)**					0.90	
	Z_{MI}	**(cm)**	1.15					
	$Z_{pii.\alpha}$	**(cm)**	1.15					
	f_{awf}	**(MHz)**	7.93	8.20		8.20		10.65
Other Information	**prr**	**(Hz)**	-					
	srr	**(Hz)**	9.00					
	n_{pss}	**NA**	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	**(W/cm^2)**	437.39					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	**(mW/cm^2)**	0.09					
	I_{spta} at Z_{pii} or Z_{sii}	**(mW/cm^2)**	0.09					
	p_r at Z_{pii}	**(MPa)**	4.15					
Operating control conditions	**Focus**	**(cm)**	1.50	5.50		5.50		1.00
	Depth	**(cm)**	4.90	8.90		8.90		4.90
	Freq	**MHz**	9.00	9.00		9.00		11.00
	PRF	**HZ**	-	-		-		-

Transducer Model: SonoEye P1/ SonoEye V1/ SonoEye G1/ SonoEye P1-G/ SonoEye V1-G/ SonoEye G1-G

Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.22	0.05		0.08		0.07
Index component Value				0.05	0.04	0.05	0.08	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	3.50					
	P	(mW)		2.68		2.68		2.68
	P_{1*1}	(mW)		2.68		2.68		
	Z_s	(cm)			0.95			
	Z_b	(cm)					0.95	
	Z_{MI}	(cm)	1.05					
	$Z_{pii.\alpha}$	(cm)	1.05					
	f_{awf}	(MHz)	8.24	8.20		8.20		8.20
Other Information	prr	(Hz)	245					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	450.24					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	10.26					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	15.22					
	p_r at Z_{pii}	(MPa)	4.55					
Operating control conditions	Focus	(cm)	1.50	5.50		5.50		5.50
	Depth	(cm)	4.90	8.90		8.90		8.90
	Freq	MHz	9.00	9.00		9.00		9.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P1/ SonoEye V1/ SonoEye G1/ SonoEye P1-G/ SonoEye V1-G/ SonoEye G1-G

Operation Mode: B+CFM

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.30	0.08		0.08		0.18
Index component Value				0.08	0.08	0.08	0.08	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	3.17					
	P	(mW)		2.81		2.81		2.81
	P_{1*1}	(mW)		2.81		2.81		
	Z_s	(cm)			0.75			
	Z_b	(cm)					0.75	
	Z_{MI}	(cm)	0.75					
	$Z_{pii.\alpha}$	(cm)	0.75					
	f_{awf}	(MHz)	5.93	5.93		5.93		5.93
Other Information	prr	(Hz)	-					
	srr	(Hz)	3.54					
	n_{pss}	NA	9.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	499.13					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	2.74					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	2.74					
	p_r at Z_{pii}	(MPa)	3.61					
Operating control conditions	Focus	(cm)	1.00	1.00		1.00		1.00
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	6.00	6.00		6.00		6.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P1/ SonoEye V1/ SonoEye G1/ SonoEye P1-G/ SonoEye V1-G/ SonoEye G1-G

Operation Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.19	0.23		0.83		0.33
Index component Value				0.23	0.18	0.23	0.83	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	3.08					
	P	(mW)		7.11		7.11		7.11
	P_{1*1}	(mW)		7.11		7.11		
	Z_s	(cm)			0.50			
	Z_b	(cm)					0.85	
	Z_{MI}	(cm)	1.05					
	$Z_{pii.\alpha}$	(cm)	1.05					
	f_{awf}	(MHz)	6.67	6.66		6.66		6.66
Other Information	prr	(Hz)	4500					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	513.21					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	432.56					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	710.03					
	p_r at Z_{pii}	(MPa)	3.82					
Operating control conditions	Focus	(cm)	1.50	7.00		7.00		7.00
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	6.00	6.00		6.00		6.00
	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
SonoEye P1	<39.9	<36.5
SonoEye P1-G	<39.9	<36.5
SonoEye V1	<39.9	<36.5
SonoEye V1-G	<39.9	<36.5
SonoEye G1	<39.9	<36.5
SonoEye G1-G	<39.9	<36.5

Overall uncertainties

Center Frequency: The accuracy of the center frequency measurement is primarily dependent on the digitizer, and is therefore given as ± 2%.

Pressue: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 13.37%.

Intensity and Power: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 26.75%.

It can be summarized in below table:

Item	Measurement Uncertainty (95% Confidence Level)
Center frequency	±2.00%
Pressure	±13.37%
Intensity	±26.75%
Power	±26.75%

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 environment.
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.

Appendix F: PULSED WAVE DOPPLER VELOCITY MEASUREMENT RESULTS SUMMARY

Probe type: SonoEye P1, Scan mode: PW, fc: 9.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.26	104.62	148.24
Measurement Error (%)	2.60%	4.62%	-1.17%

Probe type: SonoEye P1, Scan mode: CFM, fc: 9.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.82	52.69	102.84
Measurement Error (%)	-1.80%	5.38%	2.84%

Probe type: SonoEye V1, Scan mode: PW, fc: 9.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.28	103.65	148.20
Measurement Error (%)	2.80%	3.65%	-1.20%

Probe type: SonoEye V1, Scan mode: CFM, fc: 9.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.80	52.50	102.60
Measurement Error (%)	-2.00%	5.00%	2.60%

Probe type: SonoEye G1, Scan mode: PW, fc: 9.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.35	97.24	153.81
Measurement Error (%)	3.50%	-2.76%	2.54%

Probe type: SonoEye G1, Scan mode: CFM, fc: 9.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.22	47.15	106.73
Measurement Error (%)	2.2%	5.7%	6.73%

Probe type: SonoEye P1-G, Scan mode: PW, fc: 9.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.36	105.54	143.63
Measurement Error (%)	3.60%	5.54%	-4.25%

Probe type: SonoEye P1-G, Scan mode: CFM, fc: 9.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.64	49.10	97.64
Measurement Error (%)	-3.60%	1.80%	2.36%

Probe type: SonoEye V1-G, Scan mode: PW, fc: 9.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.45	104.81	139.72
Measurement Error (%)	4.50%	4.81%	-6.85%

Probe type: SonoEye V1-G, Scan mode: CFM, fc: 9.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.54	52.91	96.47
Measurement Error (%)	5.40%	5.82%	-4.53%

Probe type: SonoEye G1-G, Scan mode: PW, fc: 9.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.73	107.56	145.55
Measurement Error (%)	7.30%	7.56%	-2.97%

Probe type: SonoEye G1-G, Scan mode: CFM, fc: 9.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.43	47.12	106.97
Measurement Error (%)	-5.70%	5.76%	6.97%

Digital Color Doppler Palm Ultrasound System

Model
SonoEye P2/ SonoEye V2/ SonoEye G2

USER MANUAL

CHGA-SonoEye-043-

P2 Feb.25th, 2024

Rev. 2.1

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/SonoEye V2/SonoEye G2. 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

The Digital Color Doppler Palm Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), B/M, Color Doppler, Combined(B+Color), Pulsed Wave and Fusion Harmonic Imaging modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Pediatrics, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid.

The 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.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: 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: SonoEye 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.
Rx only	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.
	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.
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.
	Scan the QR code to open CHISON website.
UDI	Unique Device Identifier.

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:

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 printing 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:

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

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

2.5	1

- 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.

Models	Thermal	Composition	Mode	Specification	Application
1	TIS	Soft tissue	Unscanned	Large aperture (>1cm2)	Liver PW
2	TIS	Soft tissue	Unscanned	Small aperture (<1cm2)	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.

2.7 Device instructions of cybersecurity controls

2.7.1 Software Integrity Control

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

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

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

- Installing OS Updates Immediately

  Whenever an update appears on the screen, consider installing an operating system update immediately to avoid virus and malware attacks.
- The device software doesn't provide any entrance for executing third party application
- Never trust an unknown computer

  The device connect computer with USB port. Do not plug the device into an unknown computer. Install anti-virus software and use firewall and scan device regularly with antivirus software.
- Keep network safe

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

2.7.2 Device instructions of cybersecurity controls

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

- Install anti-virus software and use firewall before connecting the device with wifi.
- Install anti-virus software and use firewall before connecting the device with DICOM server.
- Limit access to device software through the authentication of users by user name and

password. Ownership of a device is assigned to one user at a time.

- To protect the patient information, the system should hide the critical patient information when exporting the image and cine. And the hidden function is configurable.
- Image and cine data contains no patient or user-identifying information. If want to encrypt this data, please connect to a network that uses an encryption protocol.
- The software uses private custom format to store patient data and cannot be recognized by general tools.
- Connect the network only to run the DICOM functions or transmission functions. Otherwise disconnect the network.
- When connecting the device with wifi, use a network that supports Wi-Fi 802.11n. We recommend that secure this network using WPA (Wi-Fi Protected Access) or WPA2 (Wi-Fi Protected Access II) as security protocol.

2.8 Insturctions to the intruded device

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

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

Chapter 3 Preparing the System for Use

3.1 Site Requirement

3.1.1 Operation 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 as above, otherwise the system may be damaged or can't work.

3.1.3 Hardware Requirements

The digital color doppler palm ultrasound system includes the transducer, software and a COTS device. The minimum requirements for COTS equipment are as follows:

- IEC 60950-1 compliant
- IEC 55032 compliant
- Octa-core processor (CPU)
- 1 GB of memory
- 1 GB of storage (on-board)
- Touch interface

- Internally mounted speakers
- Operating System: Android 9 or newer
- Display Resolution (in pixels): 1920×1200 or more
- Interface: Type C, USB 2.0

WARNING

Using the SonoEye app on a COTS device that does not meet the minimum specification may result in poor image quality, unexpected results, possible misdiagnosis or not working.

WARNING

The COTS cannot be charged while the transducer is in use for safety.

3.1.4 Programming Language Requirements

Operation System: Android

Programming Environment: Android Studio

3.1.5 The requirement of commercial off-the-shelf (COTS) devices

All models need to comply with IEC55032, IEC60950-1, among which we have selected typical models to do verification testing with SonoEye on ANSI/AAMI ES60601-1 and IEC60601-1-2, such as Samsung Galaxy A70s or Huawei MatePad Pro.

- Electrical Safety

  The transducer and software, along with a representative device, have been verified as compliant with IEC 60601-1. The transducers meet Type BF isolated applied part requirements. When the transducer and software are used in conjunction with a device(COTS devices) compliant with IEC 60950-1, the system meets IEC 60601-1 requirements for Class II equipment.

- Electromagnetic Compatibility

  The transducer and representative Android device are classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. When the transducer and software are used in conjunction with a device(COTS devices) compliant with IEC 55032, the system meets IEC 60601-1-2 requirements for Group1,Class A equipment.

- Android devices' output current and voltage

  The representative Android devices' output current is 1.5A and voltage is 5V. A COTS device connected to our transducer and system should meet the current and voltage range, the output current is greater than or equal to 1.5A, and the output voltage is 5V±5%.

- Full compliance with USB 2.0 standard

  The representative Android devices are full compliance with USB 2.0 standard. A COTS device connected to our transducer and system should meet the standard.

- Representative Android devices

Representative Android devices are Samsung Galaxy A70s and Huawei MatePad Pro. The configuration is as follows.

Samsung Galaxy A70s：

•CPU frequency 2.0GHz (big quad core), 1.7GHz (small quad core), Octa-core

•RAM capacity 8GB

•ROM capacity 128GB

•Main screen resolution 2400x1080 pixels

•WLAN function Dual-band WIFI, IEEE 802.11 a/b/g/n/ac (support 2.4G and 5GHz)

•Operating System: Android 9

•Support Bluetooth 5.0

Huawei MatePad Pro：

•CPU frequency 2 x Cortex-A76 Based 2.86 GHz+ 2 x Cortex-A76 Based 2.09 GHz+ 4 x Cortex-A55

•1.86 GHz, Octa-core

•RAM capacity 8GB

•ROM capacity 128GB

•Main screen resolution 2560x1600 pixels

•WiFi function supports dual frequency (2.4GHz+5GHz)

•Bluetooth function supports Bluetooth 5.1 module

•Operating System: Android 9

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:

Connect the SonoEye to your device,the SonoEye will be on automatically. And after a few seconds, the device will be automatically connected.

If you turn off the SonoEye,you can press  for 3 seconds to turn on the system.

2.Power off:

Press  for 3 seconds to shut down the system.

3.3 System Specifications

3.3.1 Console Overview

SonoEye P2/SonoEye V2/SonoEye G2 system:

Fig. 3-1: Console Overview

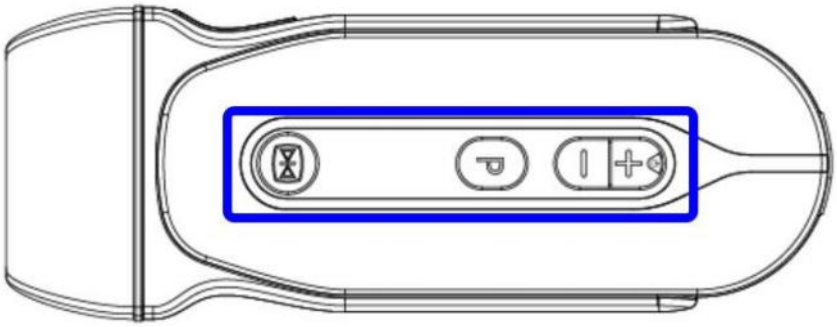


Fig. 3-2: Firmware Front View

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

3.3.4 Type

		
Linear Array: P2 4.5MHz-10.0MHz	Linear Array: V2 4.5MHz-10.0MHz	Linear Array: G2 4.5MHz-10.0MHz

3.3.5 System Configuration

Function	SonoEye P2	SonoEye V2	SonoEye G2
B mode	Standard	Standard	Standard
B/M mode	Option	Option	Option
PW mode	Option	Standard	Option

Function	SonoEye P2	SonoEye V2	SonoEye G2
CFM mode	Option	Option	Option
FHI	Option	Option	Standard
Type-C cable	Standard	Standard	Standard
Identify probe	Standard	Standard	Standard
Switch exam mode	Standard	Standard	Standard
Gain	Standard	Standard	Standard
Depth	Standard	Standard	Standard
STC	Standard	Standard	Standard
Focus	Standard	Standard	Standard
Zoom	Standard	Standard	Standard
Adjust sample Gate location	Option	Option	Option
Adjust size of sample Gate horizontal	Option	Option	Option
Adjust size of sample Gate vertical	Option	Option	Option
Adjust PW sample gate	Option	Option	Option
Compound	Standard	Standard	Standard
Frequency Scaling	Standard	Standard	Standard
Freeze/Unfreeze	Standard	Standard	Standard
B-distance	Standard	Standard	Standard
B-Circumference	Standard	Standard	Standard
B-Area	Standard	Standard	Standard
B-Volume	Standard	Standard	Standard
B/M-Distance	Option	Option	Option
B/M-Time	Option	Option	Option
B/M-HR	Option	Option	Option
PW-Velocity	Option	Option	Option
PW-Time	Option	Option	Option
Vessel measure package	Option	Option	Option
Small organ measure package	Option	Option	Option
General report	Option	Option	Option
Vessel report	Option	Option	Option
Small Organ report	Option	Option	Option
English Interface	Standard	Standard	Standard
Multi-language Interface	Option	Option	Option
Instant AIO	Standard	Option	Option
Biopsy Guide	Option	Option	Option
Save Cine	Standard	Standard	Standard
Save Image	Standard	Standard	Standard
Cine Loop	Option	Option	Option
Annotation	Option	Option	Option

Function	SonoEye P2	SonoEye V2	SonoEye G2
Bodymark	Option	Option	Option
Mark	Option	Option	Option
Patient management	Option	Option	Option
Voice/Angle/Baseline on PW	Option	Option	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)**	Standard	Standard	Standard
Physicial key	Standard	Standard	Standard
Setting	Standard	Standard	Standard
Archives	Standard	Standard	Standard
Tutorials	Standard	Standard	Standard
Easyview	Standard	Standard	Standard
Demo	Standard	Standard	Standard
About	Standard	Standard	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/SonoEye V2/SonoEye G2 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

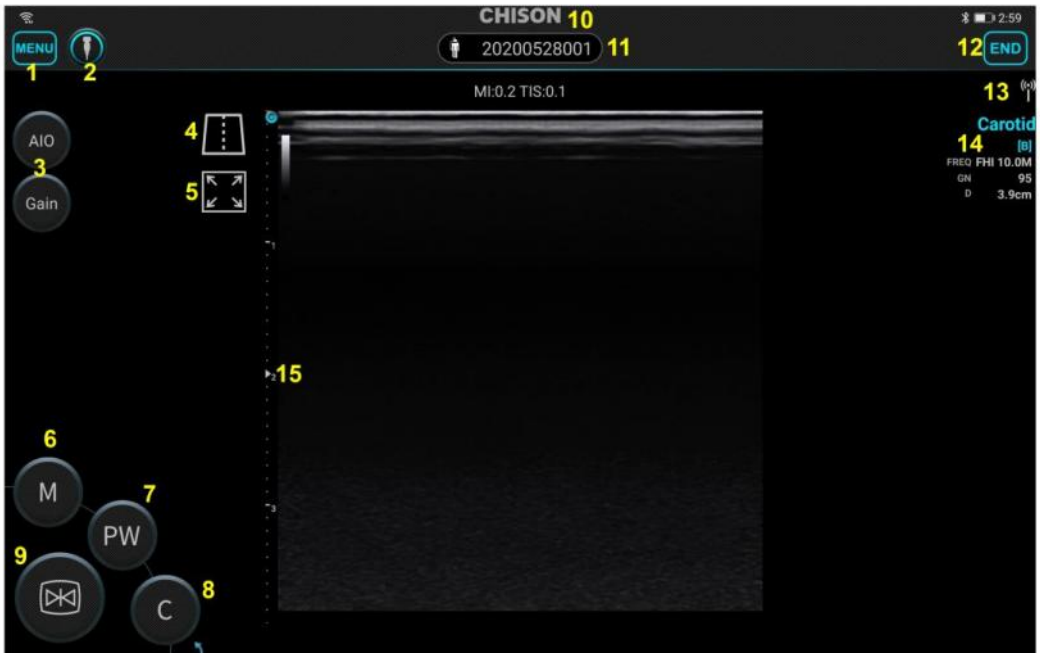


Fig 4.1a Display Interface

1. Side Menu
2. Application
3. Parameters control
4. Center Line
5. Full Screen
6. M mode
7. PW mode
8. CFM mode
9. Freeze
10. Logo
11. Patient information
12. End Exam
13. Connection status
14. Image parameter area
15. 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.

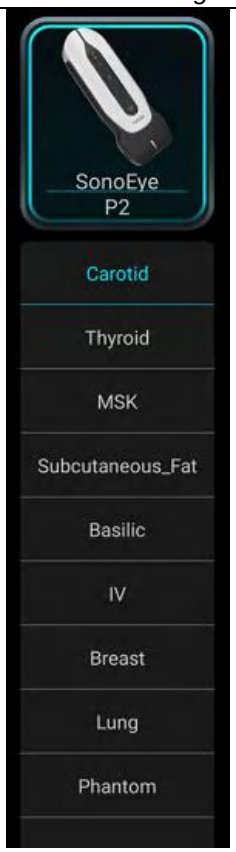
Patient Information:

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

4.3 Application

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

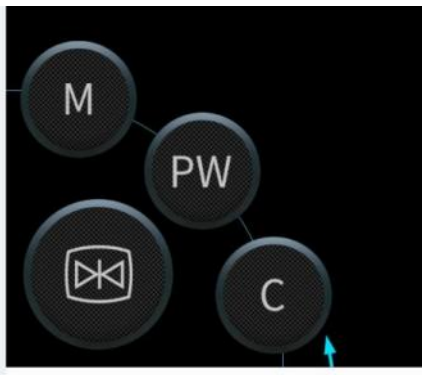


4.4 Switching Function

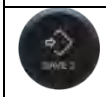
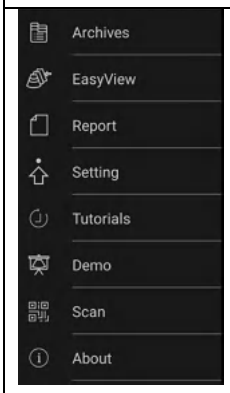
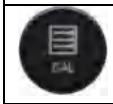
Slide the top left along the buttons to show Freq.

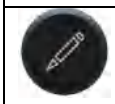
4.5 Switching Mode

Available imaging modes are B, CFM, PW, 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.
	M Mode	Press this key to enter 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 application, frequency, mode, depth, gain 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, 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 M Mode

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

Click [M] icon to enter M ready mode, then move the M-line to enter M mode. 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.

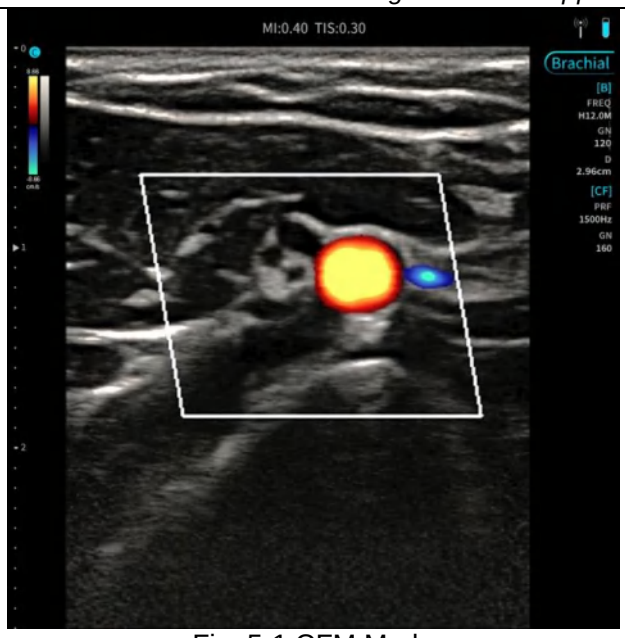


Fig. 5-1 CFM Mode

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  to help locate the vessel you wish to examine.
- Press  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  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

At real-time state, touch the screen with two fingers and slide it outward to enlarge the image.

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 Parts 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 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

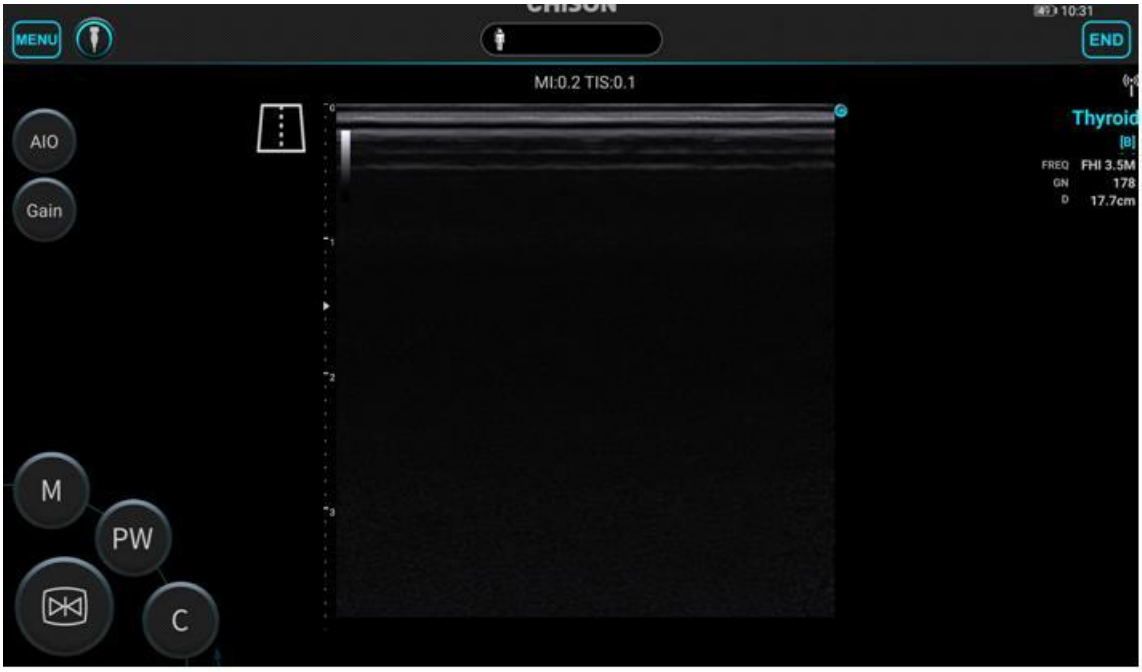
Press Freeze and click  to start automatic playback.

7.4 Cine Save

Press Freeze and click  to save current cine.

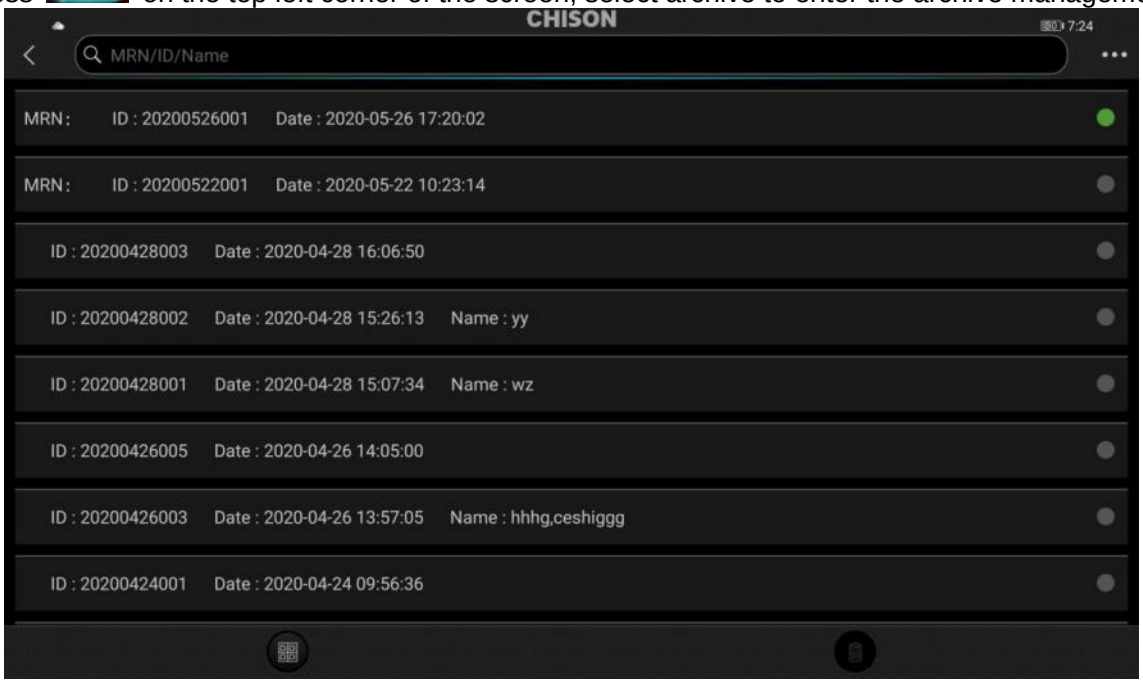
Chapter 8 Side Menu

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.

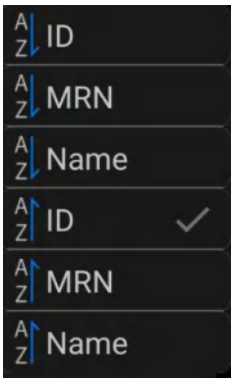


8.1 Archive

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.

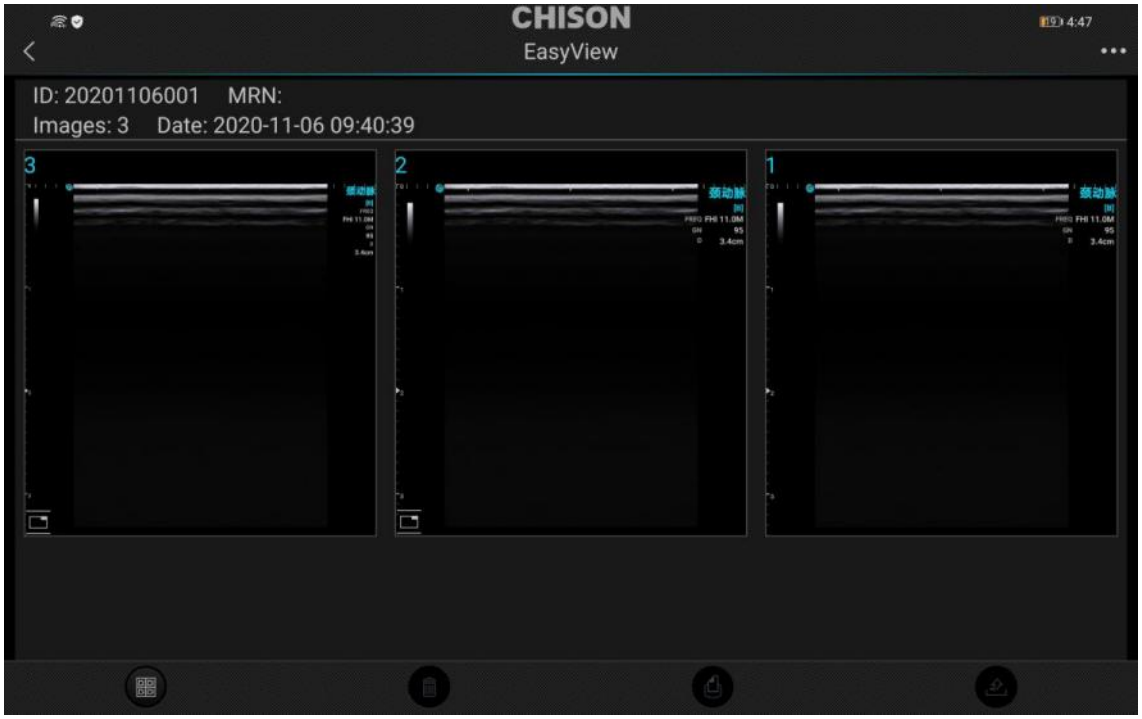
 : Select all archives.

 : Press it to delete selected archive.

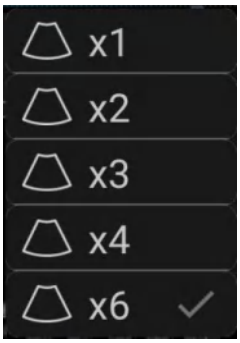
Press selected archive to enter EasyView.

8.2 EasyView

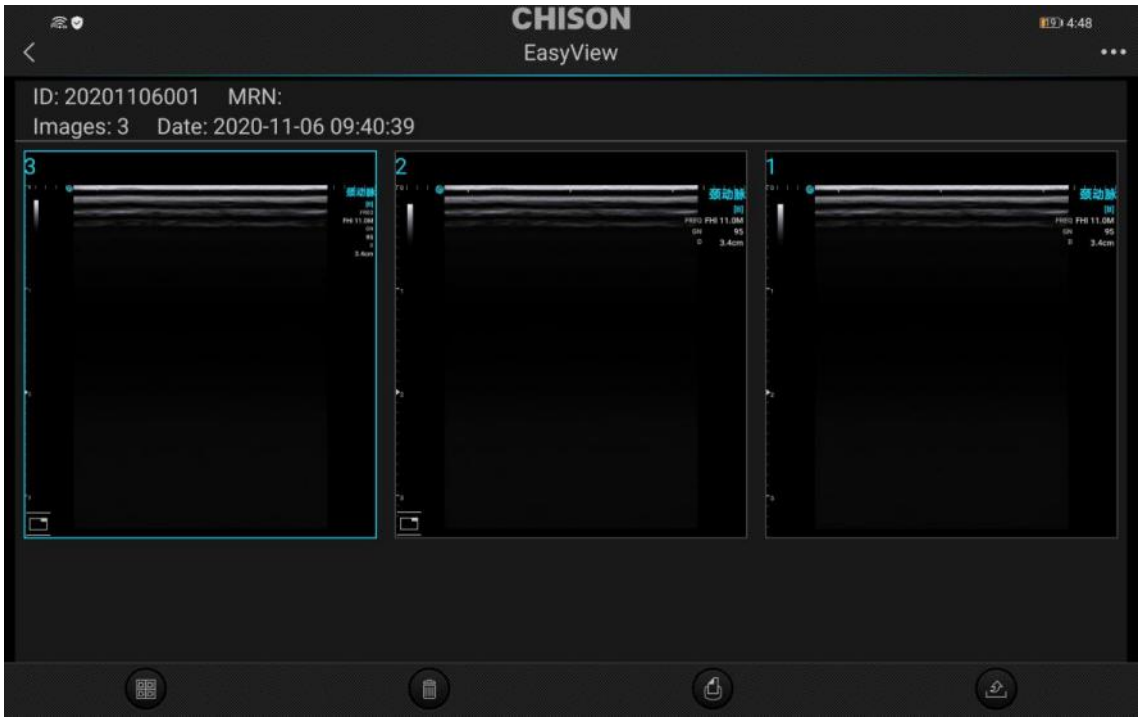
Press EasyView to check the patient information, saved images and cines.



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.

 : Press this button to print selected image

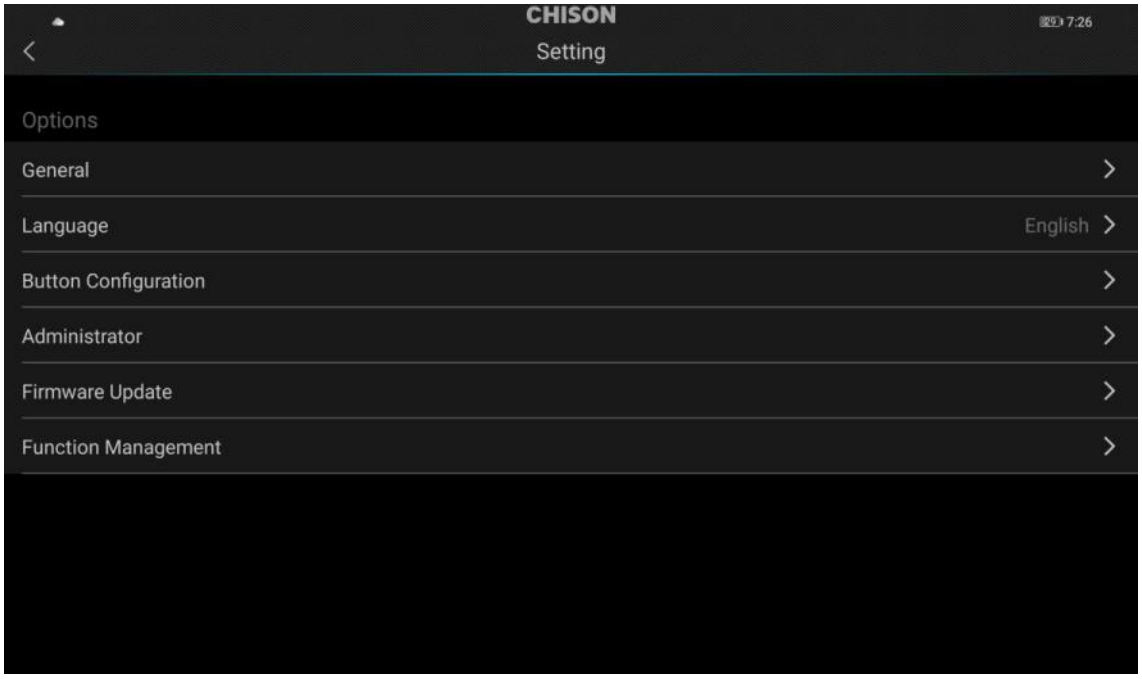
8.3 Report

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.

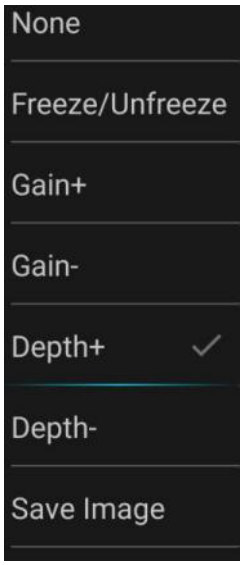
8.4.2 Language

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

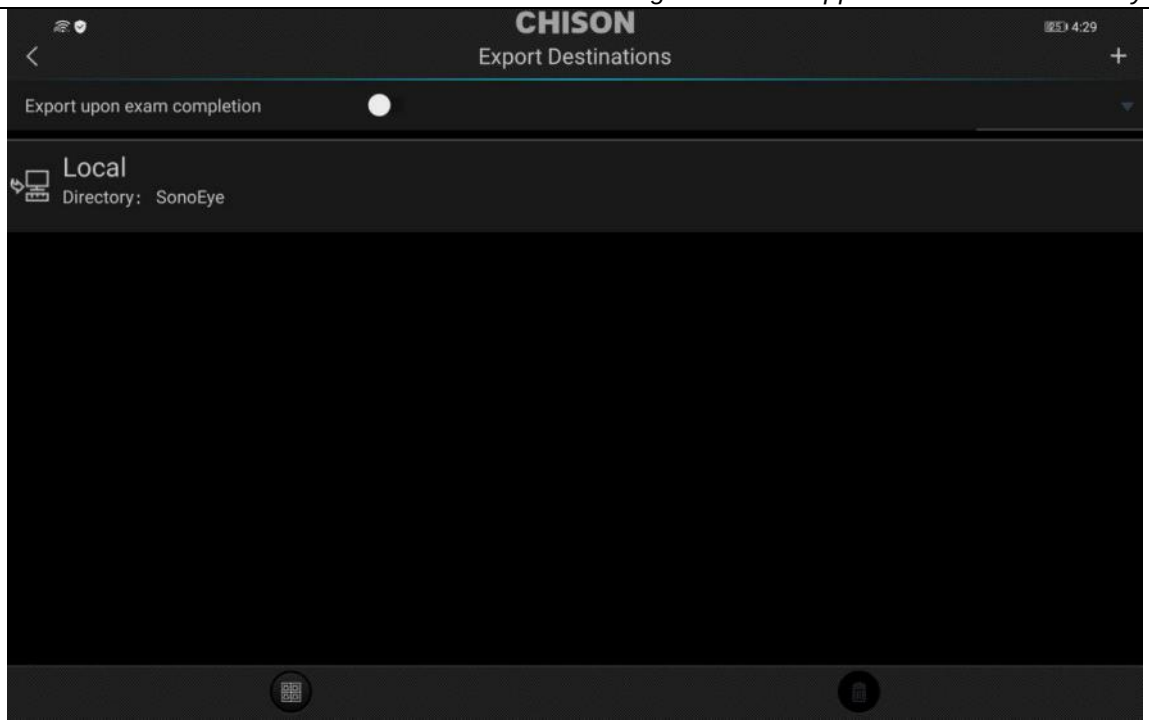
Select firmware update to upgrade system software version.

8.4.6 Function Management

Select function management to manage system functions.

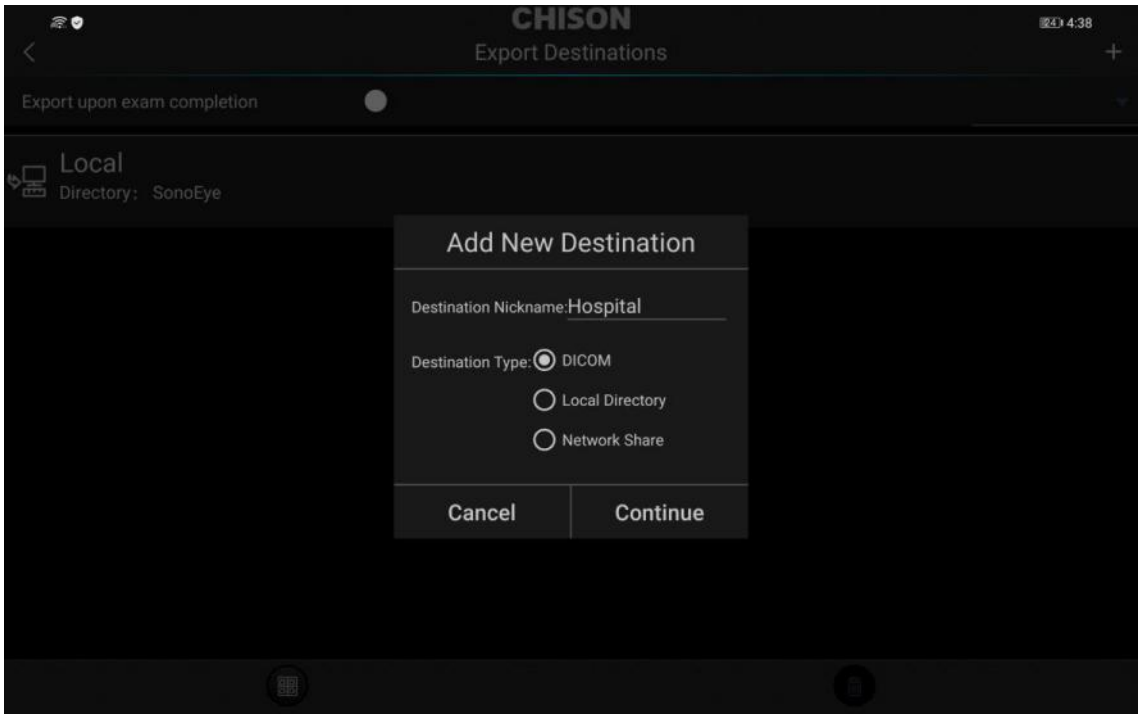
8.5 Export Destinations

Press MENU and select Export Destinations.

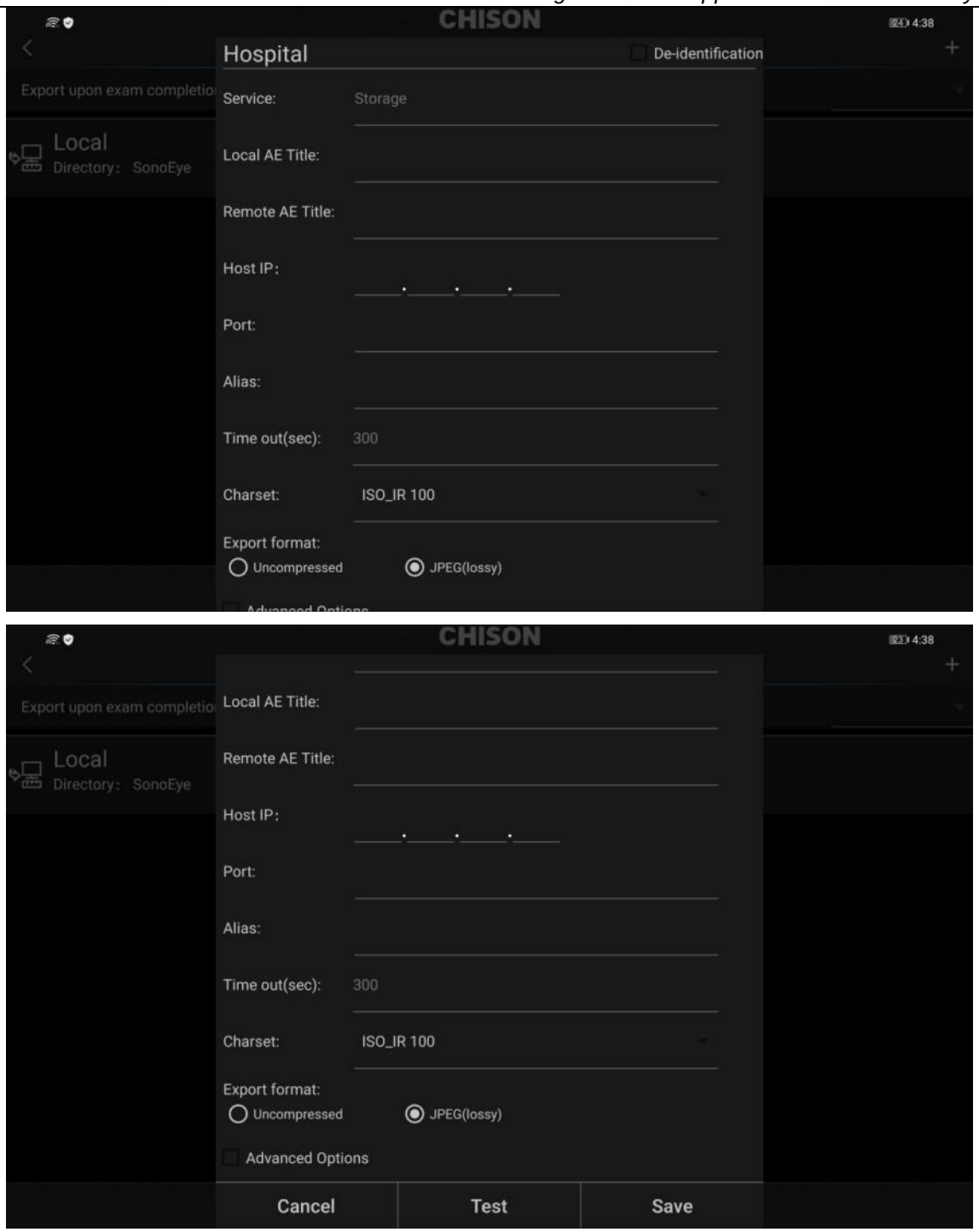


From this interface, you can add or remove export destinations.

You can enter the new interface by press +. There are three Destination types to choose from: DICOM, Local Directory, Network Share

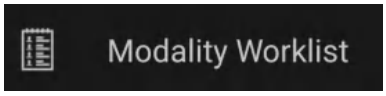


Fill in the information and select the corresponding type to enter the next level interface



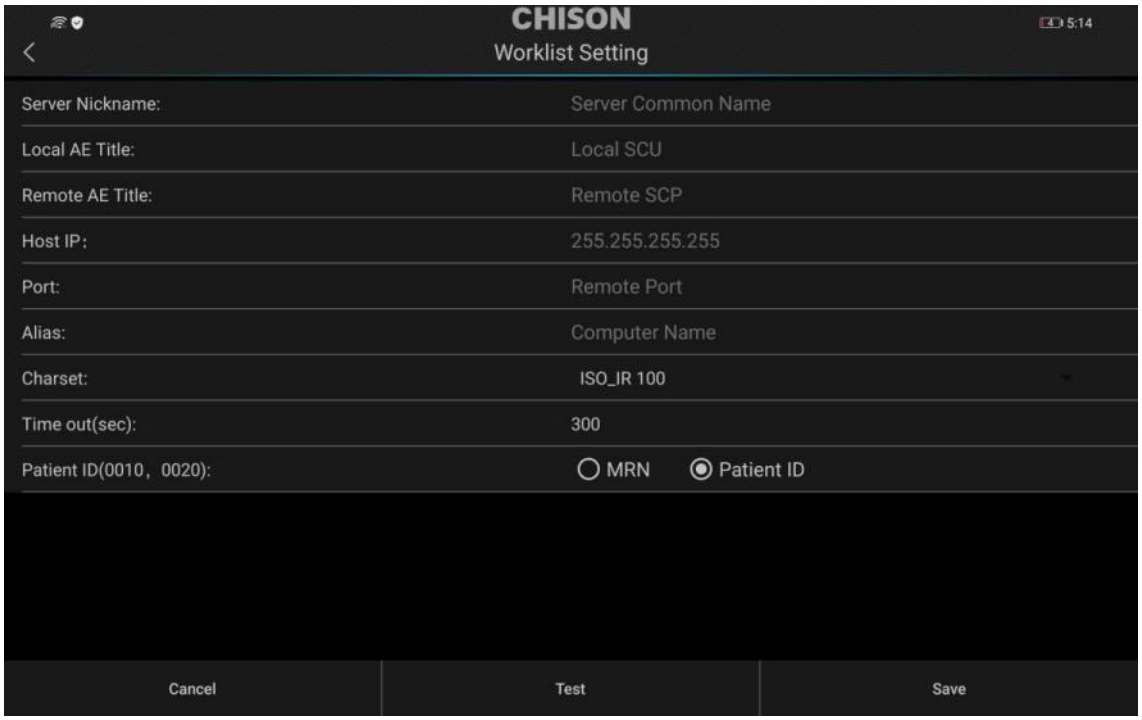
Fill in the information and click Save to complete the new Export Destination.

8.6 Modality Worklist

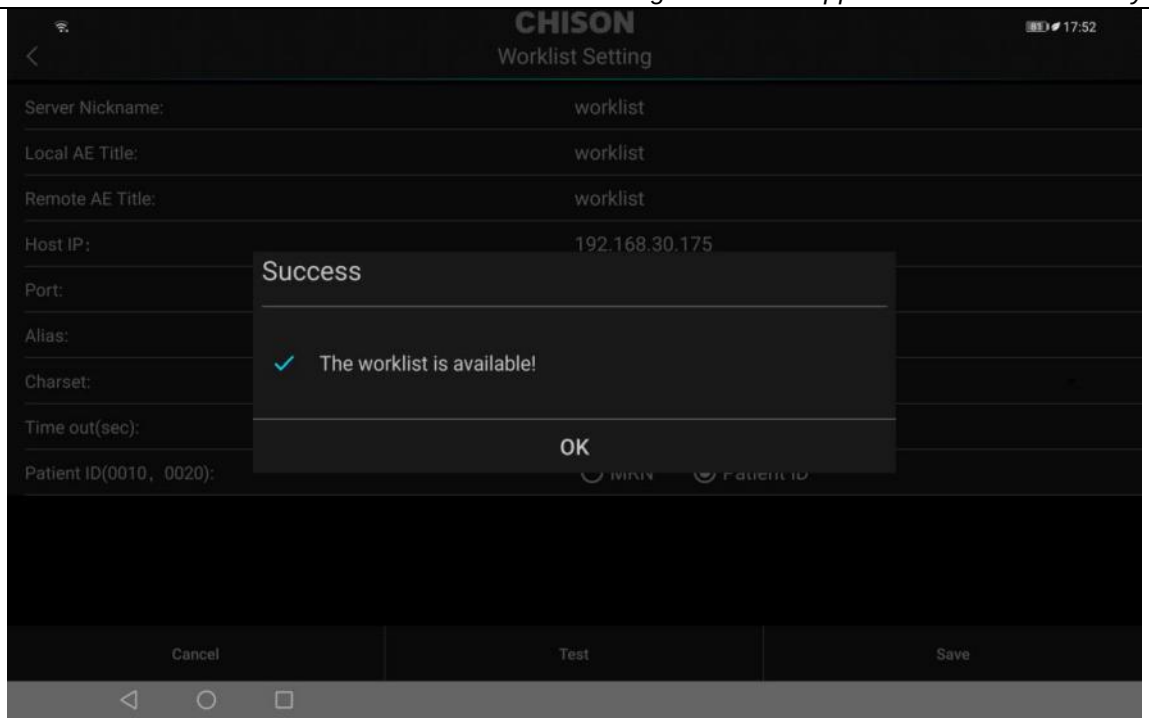
Click 

to enter it, the user can Import the worklist from the server.

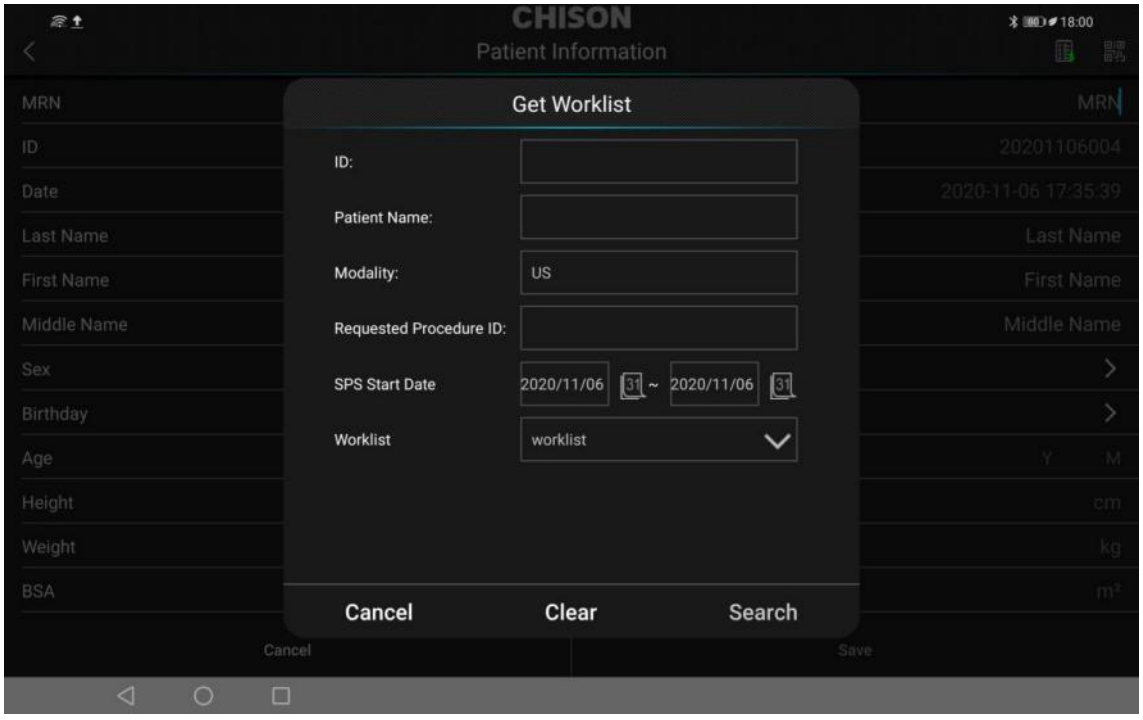
Click + to add server information



Click Test to make sure the server is connected. Then click Save to save server information.



Click on enter the Patient interface and click  to enter Get worklist to import worklist from the server



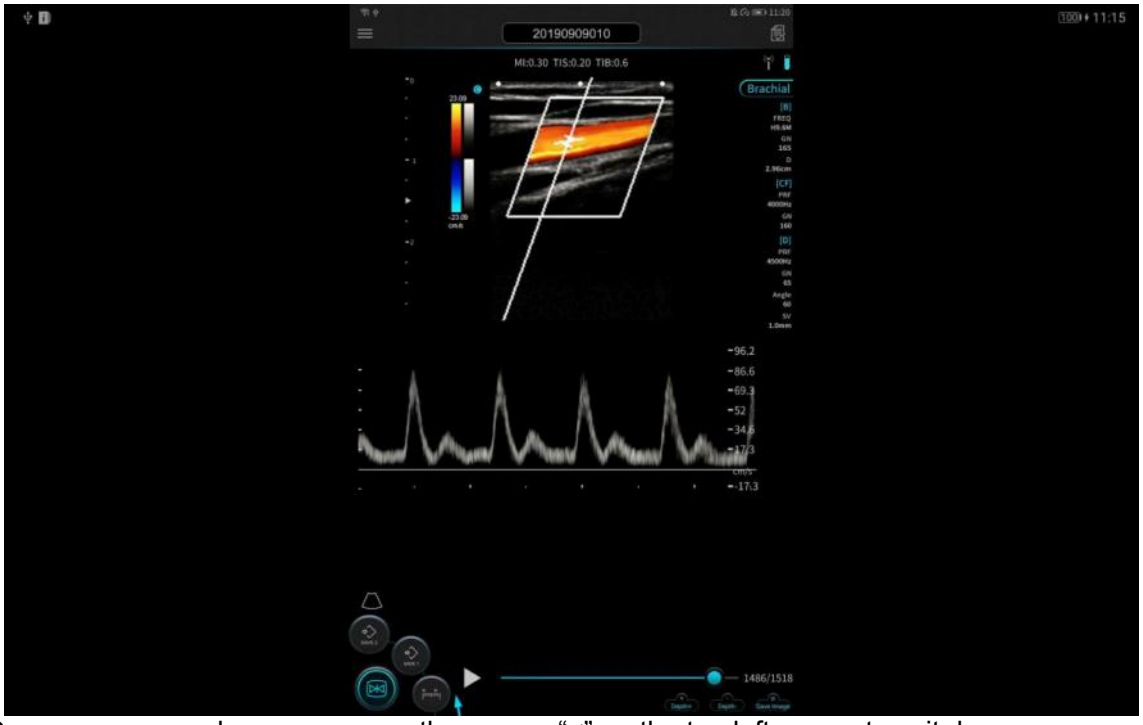
8.7 Tutorials

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  and select tutorials to enter it, there is a short video to help you learn the system.

8.8 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.

8.9 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.*

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/SonoEye V2/SonoEye G2 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 with 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

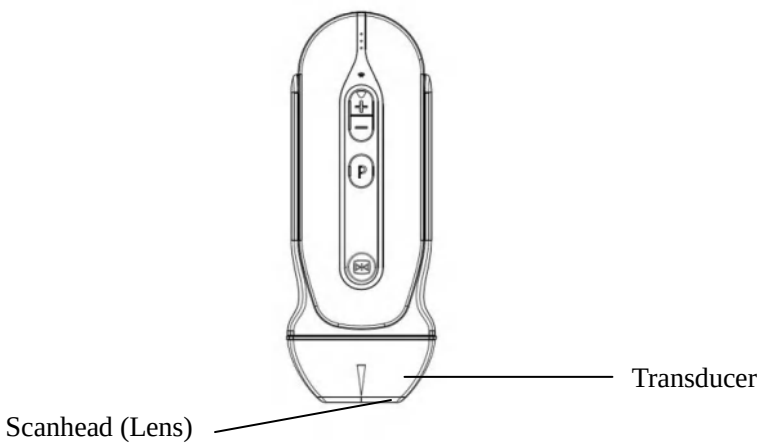


Fig.6-1: Linear Probe Overview

The system provides 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

Definitions

Cleaning removes visible soil (for example, organic and inorganic material) from the probe surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection because inorganic and organic materials that remain on the surfaces of probes interfere with the effectiveness of these processes.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.

Low-Level Disinfection (LLD) destroys most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium tuberculosis or bacterial spores.

Intermediate-Level Disinfection (ILD) inactivates Mycobacterium tuberculosis, bacteria, most viruses, most fungi, and some bacterial spores.

High-Level Disinfection (HLD) destroys or removes all microorganisms except bacterial spores.

Transducer Components

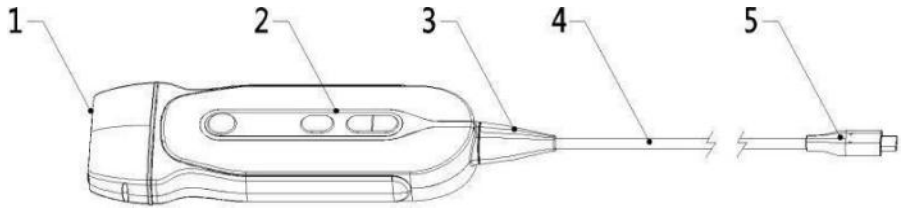


Fig.10-1: Transducer Components

1. lens 2. cover 3.Sheath 4.Cable 5. TYPE-C connector

To choose a suitable probe disinfection method, you must first determine its category according to the purpose of the probe. For more information about compatible cleaning and disinfecting agents, please refer to the section "Cleaning or disinfecting ". When using detergents and disinfectants, be sure to follow the manufacturer's instructions.

WARNING

After each use of the probe, it must be cleaned. Cleaning the probe is an important step before effective disinfection. When using detergents and disinfectants, be sure to follow the manufacturer's label instructions.

WARNING

When cleaning and disinfecting any instrument, be sure to wear protective glasses and gloves.

CAUTION

Using non-recommended disinfectants, inappropriate disinfectant concentration, or the immersion depth or immersion time of the probe exceeding the recommended value will cause damage or discoloration of the probe, and invalidate the probe warranty.

CAUTION

Do not use a brush when cleaning transducers. Even the use of soft brushes can damage transducers.

CAUTION

Do not leave the probe in contact with cleaning agents and disinfectants for a long time. Limit the time the probe is exposed to cleaners and disinfectants to the shortest time recommended by the manufacturer.

When you use OPA (ortho-phthalaldehyde)-based disinfectants, if you do not follow the manufacturer's instructions carefully, residual solution may remain on the probe. In order to minimize the impact of residual OPA or any other disinfectant, it is recommended as below:

- follow the instructions of the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends as below immersing the probe in drinking water three times to rinse the probe.
- Limit the time the probe is exposed to the disinfectant to the shortest time recommended by the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends a minimum time of 12 minutes.
- Prevent any fluid from splashing on your mobile device’s touchscreen during cleaning and during disinfecting. Damage may result due to fluid.

Point-of-use processing

*Before cleaning, check the probe first. If any particles or body fluids adhere to the probe or cable, you can wipe it off with a soft cloth dipped with 80% e*thanol*.*

10.2.2.1 **Cleaning**

Recommended supplies:

Dust-free cloth or soft cloth;

Compatible cleaner or wipes for probe cleaning;

1. Disconnect the probe from the system.
2. Wear sterile gloves and use protective eyewear to prevent infection.
3. Remove Ultrasound transmission gel from the transducer by using a soft cloth dipped with potable water (not to exceed 43°C (110°F)) or an approved cleaning or disinfectant agent or by using an approved disinfectant wipe.

Gently wipe the lens to remove the gel, then wipe the probe，cable for 1 minute and until visibly clean(There is no gel, hair, debris or other residue on the probe.).

Do not wipe the connector to prevent liquid from entering the inside. Please refer to Table 10-1 below for approved compatible cleaning and disinfection products.

4. Dry the transducer using a sterile cloth or gauze after cleaning. Blot the lens dry. Do not wipe the lens. Do not dry the transducer by heating it.

10.2.2.2 **Disinfecting**

After cleaning the probe, you must disinfect the probe.

To reduce the risk of contamination and infection, it is important to choose the appropriate level of disinfection, based on prior exam usage and whether the use is classified as non-critical or semi-critical. Use Table, “Probe Disinfection Class, Use, and Method” to determine the appropriate class and then follow the appropriate intermediate-level or high-level disinfection procedure

Probe Disinfection Class, Use, and Method

Class	**Use**	**Method**
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate- level disinfection (ILD)
Semi-Critical Class	Touches mucous membranes and non-intact skin.	Cleaning followed disinfection (HLD) by high-level

Intermediate-Level Disinfection (ILD)

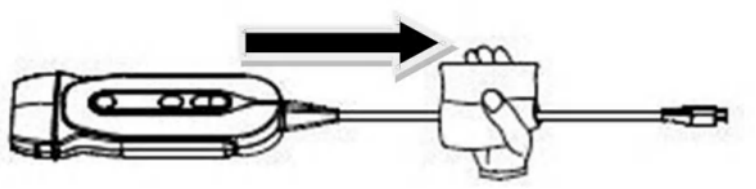


Fig.10-2: Wipe direction

1. Wear sterile gloves to prevent infection.
2. Wipe the probe, with approved compatible disinfectant wipes or soft cloth dipped in disinfectant agent. As shown in the figure above, wiping from lens toward cable. Do not wipe the type-c linker to prevent poor contact.
3. Ensure that the disinfected surface remains visibly moist for at least two (2) minutes, use additional

   fresh wipes as needed.
4. Allow to air dry.
5. After cleaning and disinfection, check the appearance of the probe to see whether the transducer and cable are worn or damaged

High Level Disinfection

1. It is recommended that you use Cide®OPA by Ethicon US, LLC.
2. After cleaning the probe, you must disinfect the probe. It is recommended that you use Cidex® OPA high- level disinfection solution.
3. Prepare Cidex® OPA high-level disinfection solution for use per the manufacturer’s instructions. Fill a tray or basin with the disinfectant solution at room temperature (minimum temperature of 20°C) to a level allowing immersion of the probe up to the immersion line (As shown below),

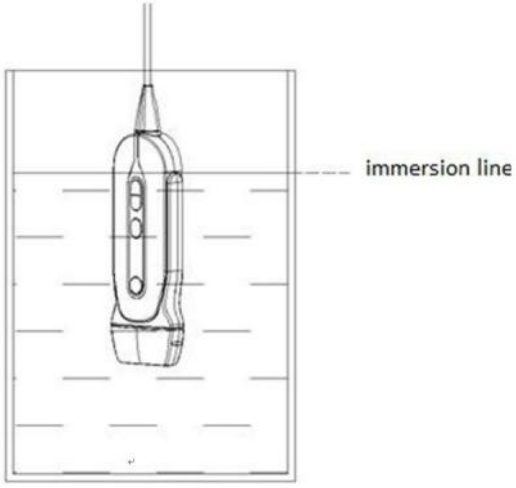


Fig.10-3: Soaking depth

4. Immerse the probe in Cidex® OPA solution up to the immersion line and ensure no air or bubbles are trapped. Allow soaking according to the manufacturer's instructions.
5. Thoroughly rinse the probe (up to the immersion line) by immersing it in a large volume of room temperature purified water for a minimum of one (1) minute. Remove the probe and discard the rinse water.

Do not reuse the water. Always use fresh volumes of water for each rinse. Repeat this stage two (2) additional times for a total of three (3) rinses.

6. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the device is completely dry. Inspect the device to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is visible.
7. Once clean and disinfected, inspect the probe, strain relief, cable, and connector for signs of damage or wear.
8. Daily and Long-Term Storage follow these guidelines to protect the probe.
9. Always store transducers in the probe case when you are not using them.

⚠*CAUTION*

Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use. Do not soak the transducer connector or the cable near it into water or any solution.

⚠*CAUTION*

Follow local regulations when selecting and using the disinfectant.

10.2.2.3 **Approved and compatible cleaning and disinfectant**

Table 10-1：Cleaning and disinfection list

Wipes type	Brand	Place of origin	Chemical ingredient	solution
80% Ethanol (Soak with a soft cloth)	Any manufacturer	Any	Ethanol	Clean/LLD/ILD
70% Isopropyl alcohol (Soak with a soft cloth)	Any manufacturer	Any	Isopropyl alcohol	Clean/LLD/ILD
Universal wipes	Clinell	United Kingdom	Compound double chain quaternary ammonium salt	Clean/LLD/ILD
perform classic wipes EP	Schulke&Mayr GmbH	Germany	Compound alcohol	Clean/LLD/ILD
WIP'ANIOS	Laboratoires ANIOS	France	Isopropyl alcohol/Didecyl dimethyl ammonium chlorides	Clean/LLD/ILD
Sani-cloth AF3,Sani- Cloth AF	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopropyl alcohol	Clean/LLD/ILD
Super Sani-Cloth	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopropyl alcohol	Clean/LLD/ILD

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

- Before cleaning, turn off the system
- To clean the touch screen.

  a. Remove dust with a soft, lint-free cloth.

  b. Please wipe the screen with cleaner specially designed for LCD. Spray the liquid onto the cleaning cloth and gently wipe the screen clean. You can also use pre-moistened screen wipes.

  c. Dry the screen with a soft, lint-free cloth
- Wipe the remaining external surfaces of the system with soft cloth dipped few 70% isopropyl, 80%

  Ethanol solution or recommended wipes.
- Gently remove any residue with a cloth lightly moistened with purified water.
- Dry the equipment to prevent potential corrosion.

If the equipment has come in contact with blood or infectious material, see “Infection Control”.

Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection control procedures established in your facility for the protection of both the staff and the patient.

WARNING

If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your CHISON service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

⚠***CAUTION***

Remove blood on the system and the transducer connectors and cables with a soft cloth dipped few soap and potable water. Then dry the equipment with a soft, dry, lint-free cloth to prevent corrosion.

⚠***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

R Sight B.V.

Add R Sight B.V.

Add: Roald Dahllaan 47, 5629 MC, Eindhoven. The Netherlands

SRN: NL-AR-000010445

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Appendix B: ACOUSTIC OUTPUT REPORT TABLE

Transducer Model: SonoEye P2/SonoEye V2/SonoEye G2

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/SonoEye V2/SonoEye G2
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/SonoEye V2/SonoEye G2
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 $Z_{sii.\alpha}$	**(mW/cm^2)**	0.39					
	I_{spta} at Z_{pii} or Z_{sii}	**(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/SonoEye V2/SonoEye G2
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**
SonoEyeV2	**<37.4**	**<32.0**
SonoEyeG2	**<37.4**	**<32.0**

Overall uncertainties
Center Frequency: The accuracy of the center frequency measurement is primarily dependent on the digitizer, and is therefore given as ± 2%.

Pressue: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 13.37%.

Intensity and Power: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 26.75%.

It can be summarized in below table:

Item	Measurement Uncertainty (95% Confidence Level)
Center frequency	±2.00%
Pressure	±13.37%
Intensity	±26.75%
Power	±26.75%

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 environment.
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.

Appendix F: Pulsed Wave Doppler Velocity Measurement Results Summary

Probe type: SonoEye P2, Scan mode: PW, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.76	106.82	161.34
Measurement Error (%)	7.60%	6.82%	7.56%

Probe type: SonoEye P2, Scan mode: CFM,fc: 6.5MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.12	54.95	108.64
Measurement Error (%)	-8.80%	9.90%	8.64%

Probe type: SonoEye V2, Scan mode: PW, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	9.12	109.13	161.34
Measurement Error (%)	-8.80%	9.13%	7.56%

Probe type: SonoEye V2, Scan mode: CFM, fc: 6.5MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.65	46.73	107.83
Measurement Error (%)	6.5%	6.54%	7.83%

Probe type: SonoEye G2, Scan mode: PW, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.86	97.87	157.32
Measurement Error (%)	8.60%	-2.13%	4.88%

Probe type: SonoEye G2, Scan mode: CFM, fc: 6.5MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.85	53.25	109.43
Measurement Error (%)	8.5%	6.50%	9.43%

Digital Color Doppler Palm Ultrasound System

Model
SonoEye P3/SonoEye V3/SonoEye G3

USER MANUAL

CHGA-SonoEye-043-P3

Feb.25th, 2024

Rev. 2.1

CHISON Medical Technologies Co., Ltd.

We reserve the right to make changes to this manual without prior notice.

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 P3/SonoEye V3/SonoEye G3. Please verify that you are using the latest revision of this document. If you need to know the latest revision, contact your distributor.

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Chapter 1 Introduction

This manual contains necessary information for safe system operation.

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

1.1 System Overview

Indications for Use

The 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 Abdominal, Neonatal Cephalic, Adult Cephalic, Cardiac Adult, Cardiac Pediatric.

The 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.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: 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 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.

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).

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

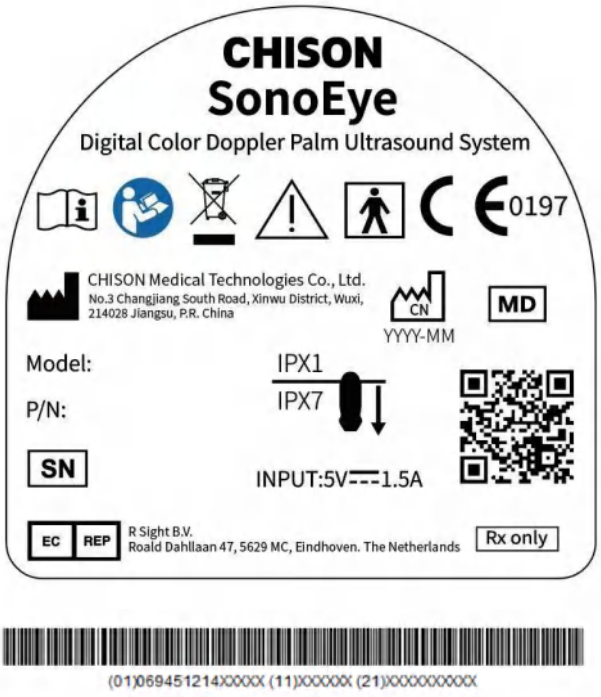


Fig. 2-1: SonoEye Label

2.3.1 Symbols on Label

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.
Rx only	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.
	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.
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.
	Scan the QR code to open CHISON website.
UDI	Unique Device Identifier.

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:

CAUTION:

- *DO NOT connect any systems 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.*

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 printing 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 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 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.

2.7 Device instructions of cybersecurity controls

2.7.1 Software Integrity Control

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

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

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

- Installing OS Updates Immediately

  Whenever an update appears on the screen, consider installing an operating system update immediately to avoid virus and malware attacks.
- The device software doesn't provide any entrance for executing third party application.

- Never trust an unknown computer

  The device connect computer with USB port. Do not plug the device into an unknown computer.
- Install anti-virus software and use firewall and scan device regularly with antivirus software.
- Keep network safe

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

2.7.2 Device instructions of cybersecurity controls

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

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

2.8 Insturctions to the intruded device

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

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

Chapter 3 Preparing the System for Use

3.1 Site Requirement

3.1.1 Operation 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 C, 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 as above, otherwise the system may be damaged or can't work.

3.1.3 Hardware Requirements

The digital color doppler palm ultrasound system includes the transducer, software and a COTS device. The minimum requirements for COTS equipment are as follows:

- IEC 60950-1 compliant
- IEC 55032 compliant
- Octa-core processor (CPU)
- 1 GB of memory
- 1 GB of storage (on-board)
- Touch interface
- Internally mounted speakers
- Operating System: Android 9 or newer
- Display Resolution (in pixels): 1920×1200 or more

- Interface: Type C, USB 2.0

WARNING

Using the SonoEye app on a COTS device that does not meet the minimum specification may result in poor image quality, unexpected results, possible misdiagnosis or not working.

WARNING

The COTS cannot be charged while the transducer is in use for safety.

3.1.4 Programming Language Requirements

Operation System: Android
Programming Environment: Android Studio

3.1.5 The requirement of commercial off-the-shelf (COTS) devices

All models need to comply with IEC55032, IEC60950-1, among which we have selected typical models to do verification testing with SonoEye on ANSI/AAMI ES60601-1 and IEC60601-1-2, such as Samsung Galaxy A70s or Huawei MatePad Pro.

- Electrical Safety

  The transducer and software, along with a representative device, have been verified as compliant with IEC 60601-1. The transducers meet Type BF isolated applied part requirements. When the transducer and software are used in conjunction with a device(COTS devices) compliant with IEC 60950-1, the system meets IEC 60601-1 requirements for Class II equipment.

- Electromagnetic Compatibility

  The transducer and representative Android device are classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. When the transducer and software are used in conjunction with a device(COTS devices) compliant with IEC 55032, the system meets IEC 60601-1-2 requirements for Group1,Class A equipment.

- Android devices' output current and voltage

  The representative Android devices' output current is 1.5A and voltage is 5V. A COTS device connected to our transducer and system should meet the current and voltage

range, the output current is greater than or equal to 1.5A, and the output voltage is 5V±5%.

- Full compliance with USB 2.0 standard

  The representative Android devices are full compliance with USB 2.0 standard. A COTS device connected to our transducer and system should meet the standard.

- Representative Android devices

  Representative Android devices are Samsung Galaxy A70s and Huawei MatePad Pro. The configuration is as follows.

  Samsung Galaxy A70s：

  - •CPU frequency 2.0GHz (big quad core), 1.7GHz (small quad core), Octa-core
  - •RAM capacity 8GB
  - •ROM capacity 128GB
  - •Main screen resolution 2400x1080 pixels
  - •WLAN function Dual-band WIFI, IEEE 802.11 a/b/g/n/ac (support 2.4G and 5GHz)
  - •Operating System: Android 9
  - •Support Bluetooth 5.0

  Huawei MatePad Pro：

  - •CPU frequency 2 x Cortex-A76 Based 2.86 GHz+ 2 x Cortex-A76 Based 2.09 GHz+ 4 x Cortex-A55
  - •1.86 GHz, Octa-core
  - •RAM capacity 8GB
  - •ROM capacity 128GB
  - •Main screen resolution 2560x1600 pixels
  - •WiFi function supports dual frequency (2.4GHz+5GHz)
  - •Bluetooth function supports Bluetooth 5.1 module
  - •Operating System: Android 9

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 terminal.

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 terminal. Select the update package to install APP.

Turning the System On and Off

1. Power on:

Connect the SonoEye to your device,the SonoEye will be on automatically. And after a few seconds, the device will be automatically connected.

If you turn off the SonoEye,you can press  for 3 seconds to turn on the system.

2.Power off:

Press  for 3 seconds to shut down the system

3.3 System Specifications

3.3.1 Console Overview

SonoEye P3/SonoEye V3/SonoEye G3 system:

Fig. 3-1: Console Overview

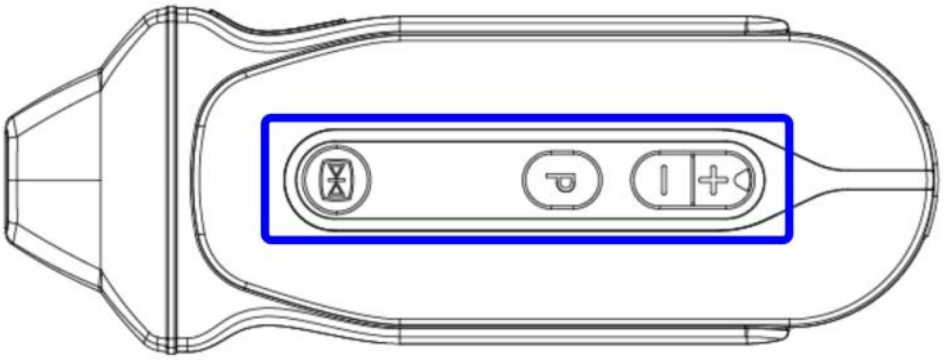


Fig. 3-2: Firmware Front View SonoEye P3/SonoEye V3/SonoEye G3

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）*173mm（Height）*24mm（Depth）
Net weight of main unit (approx):194g

3.3.3 Image Modes

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

3.3.4 Type

 Phased Array: P3 1.5MHz-4.0MHz	 Phased Array: V3 1.5MHz-4.0MHz	 Phased Array: G3 1.5MHz-4.0MHz

3.3.5 System Configuration

Function	SonoEye P3	SonoEye V3	SonoEye G3
B mode	Standard	Standard	Standard
B/M mode	Option	Option	Option
PW mode	Option	Standard	Option
CFM mode	Option	Option	Option
FHI	Option	Option	Standard
Type-C cable	Standard	Standard	Standard
Identify probe	Standard	Standard	Standard
Switch exam mode	Standard	Standard	Standard
Gain	Standard	Standard	Standard
Depth	Standard	Standard	Standard
STC	Standard	Standard	Standard
Focus	Standard	Standard	Standard
Zoom	Standard	Standard	Standard
Adjust sample Gate location	Option	Option	Option
Adjust size of sample Gate horizontal	Option	Option	Option
Adjust size of sample Gate vertical	Option	Option	Option
Adjust PW sample gate	Option	Option	Option
Compound	Standard	Standard	Standard
Frequency Scaling	Standard	Standard	Standard
Freeze/Unfreeze	Standard	Standard	Standard
B-distance	Standard	Standard	Standard
B-Circumference	Standard	Standard	Standard
B-Area	Standard	Standard	Standard
B-Volume	Standard	Standard	Standard
B/M-Distance	Option	Option	Option
B/M-Time	Option	Option	Option
B/M-HR	Option	Option	Option
PW-Velocity	Option	Option	Option
PW-Time	Option	Option	Option
Vessel measure package	Option	Option	Option
Abdomen measure package	Option	Option	Option
Cardiac measure package	Option	Option	Option
General report	Option	Option	Option
Vessel report	Option	Option	Option
Abdomen report	Option	Option	Option

Function	SonoEye P3	SonoEye V3	SonoEye G3
Cardiac report	Option	Option	Option
English Interface	Standard	Standard	Standard
Multi-language Interface	Option	Option	Option
Instant AIO	Standard	Option	Option
Biopsy Guide	Option	Option	Option
SonoNeedle	Option	Option	Option
SuperNeedle	Option	Option	Option
SonoRemote	Option	Option	Option
Save Cine	Standard	Standard	Standard
Save Image	Standard	Standard	Standard
Cine Loop	Option	Option	Option
Annotation	Option	Option	Option
Bodymark	Option	Option	Option
Mark	Option	Option	Option
Patient management	Option	Option	Option
Voice/Angle/Baseline on PW	Option	Option	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)	Standard	Standard	Standard
Physical key	Standard	Standard	Standard
Setting	Standard	Standard	Standard
Archives	Standard	Standard	Standard
Tutorials	Standard	Standard	Standard
EasyView	Standard	Standard	Standard
Demo	Standard	Standard	Standard
About	Standard	Standard	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 P3 /SonoEye V3/SonoEye G3 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 4-1 Display Interface

1. Side Menu
2. Application
3. Parameters control
4. Center Line
5. Full Screen
6. B/M mode
7. PW mode
8. CFM mode
9. Freeze
10. Logo
11. Patient information
12. End Exam
13. Connection status
14. Image parameter area
15. 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.

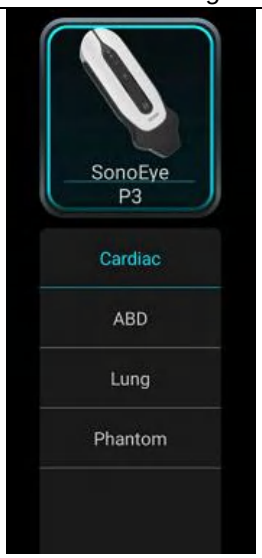
Patient Information:

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

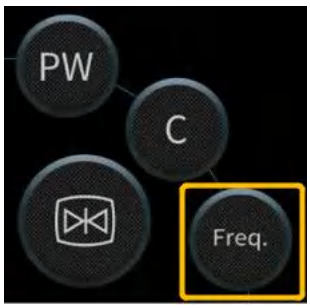
4.3 Application

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



4.4 Switching Function

Slide the top left along the buttons to show Freq.

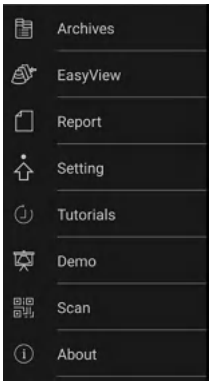


4.5 Switching Mode

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.
	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 application, frequency, mode, depth, gain 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 and patient's gender 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.

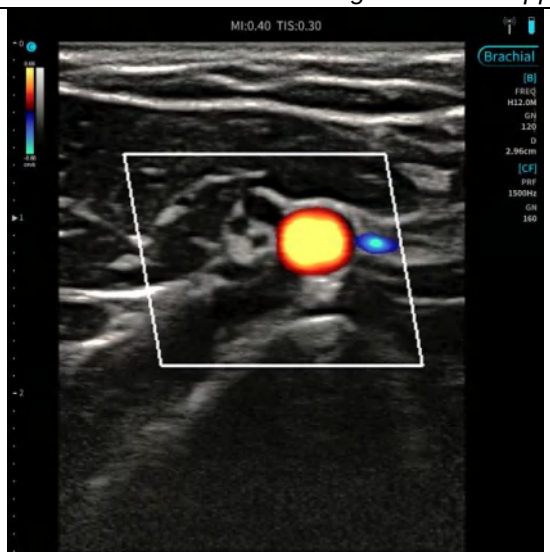


Fig. 5-1 CFM Mode

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 to help locate the vessel you wish to examine.
- Press 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 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 account 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 account 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

At real-time state, touch the screen with two fingers and slide it outward to enlarge the image.

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

Area 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 Abdomen Measurement in B mode

Meas. item name	mark	unit	Meas. Method and calc. formula
CBD	CBD	cm	Refer to “Distance” measurement in 6.1
GB Wall	GB Wall	cm	Refer to “Distance” measurement in 6.1
Liver Length	Liver Length	cm	Refer to “Distance” measurement in 6.1
Spleen	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
Renal 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
GB Volume	Length	cm	Refer to “Distance” measurement in 6.1
	Width	cm	Refer to “Distance” measurement in 6.1
	Height	cm	(3.14159265/6) * Length * Height * Width
IVC	IVC Ins	cm	Refer to “Distance” measurement in 6.1
	IVC Exp	cm	Refer to “Distance” measurement in 6.1

6.2.3 Cardiac Measurement in B mode

Meas. item name	mark	unit	Meas. Method and calc. formula
IVSd	IVSd	cm	Refer to “Distance” measurement in 6.1
LVIDd	LVIDd	cm	Refer to “Distance” measurement in 6.1
LVPWd	LVPWd	cm	Refer to “Distance” measurement in 6.1
IVSs	IVSs	cm	Refer to “Distance” measurement in 6.1
LVIDs	LVIDs	cm	Refer to “Distance” measurement in 6.1
LVPWs	LVPWs	cm	Refer to “Distance” measurement in 6.1
EDV	EDV	ml	$(7*LVIDd^3/1000)/(2.4+(LVIDd/10))$
ESV	ESV	ml	$(7*LVIDd^3/1000)/(2.4+(LVIDd/10))$
SV	SV	ml	EDV-ESV
CO	CO	L/min	HR*SV/1000
EF	EF	%	100*SV/EDV

FS	FS	%	100*（LVIDd-LVIDs）/LVIDd
SI	SI		SV/BSA
CI	CI		CO/BSA
EDV(A2C/A4C)		ml	$EDV(ml)=\pi\times\frac{LVLd\ apical(cm)}{20}\times\sum_{i=1}^{20}r_i^2(cm)$
ESV(A2C/A4C)		ml	$ESV(ml)=\pi\times\frac{LVLs\ apical(cm)}{20}\times\sum_{i=1}^{20}r_i^2(cm)$
SV	SV	ml	EDV-ESV
CO	CO	L/min	HR*SV/1000
EF	EF	%	100*SV/EDV
SI	SI		SV/BSA
CI	CI		CO/BSA
IVC Ins	IVC Ins	cm	Refer to “Distance” measurement in 6.1
IVC Exp	IVC Exp	cm	Refer to “Distance” measurement in 6.1
LVOT Diam	LVOT Diam	cm	Refer to “Distance” measurement in 6.1
LVOT Area	LVOT Area	cm^2	Refer to “Ellipse” measurement in 6.1
AV Diam	AV Diam	cm	Refer to “Distance” measurement in 6.1
AV Area	AV Area	cm^2	Refer to “Ellipse” measurement in 6.1

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

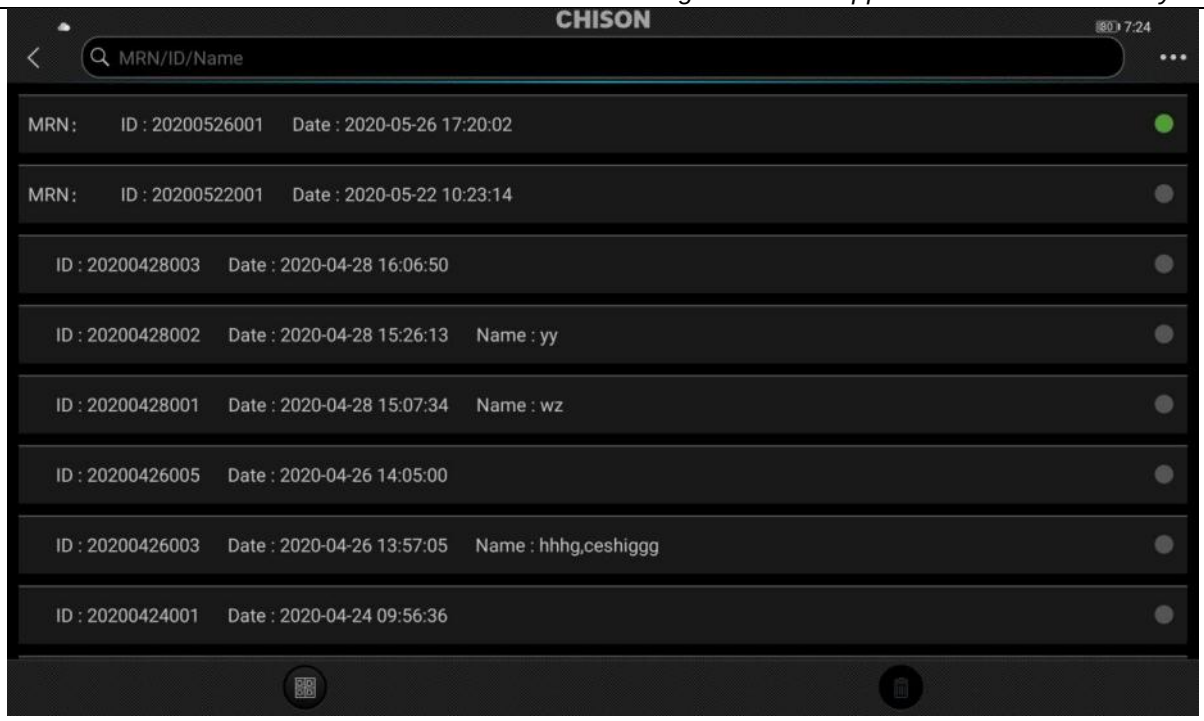
Press Freeze and click  to save current cine.

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.

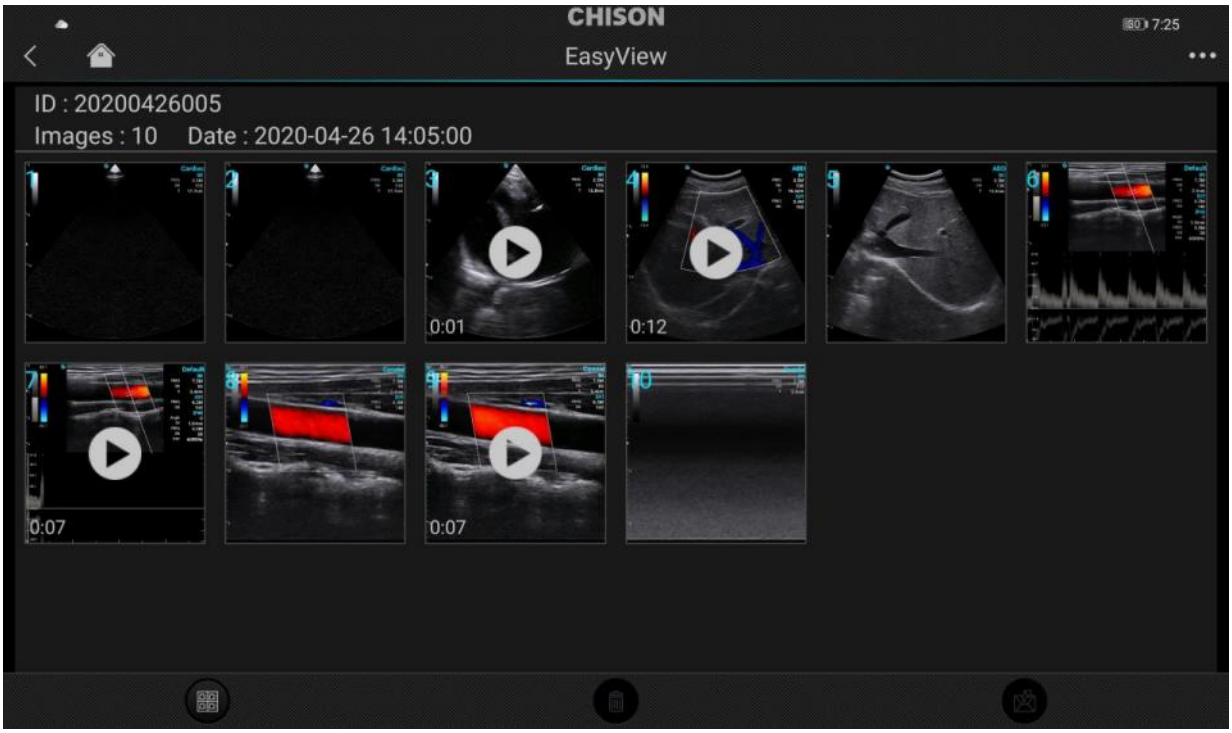
 : Select all archives.

 : Press it to delete selected archive.

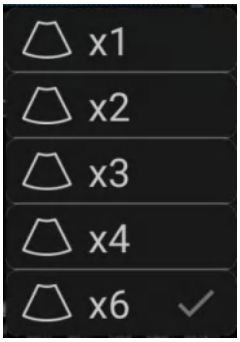
Press selected archive to enter EasyView.

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.

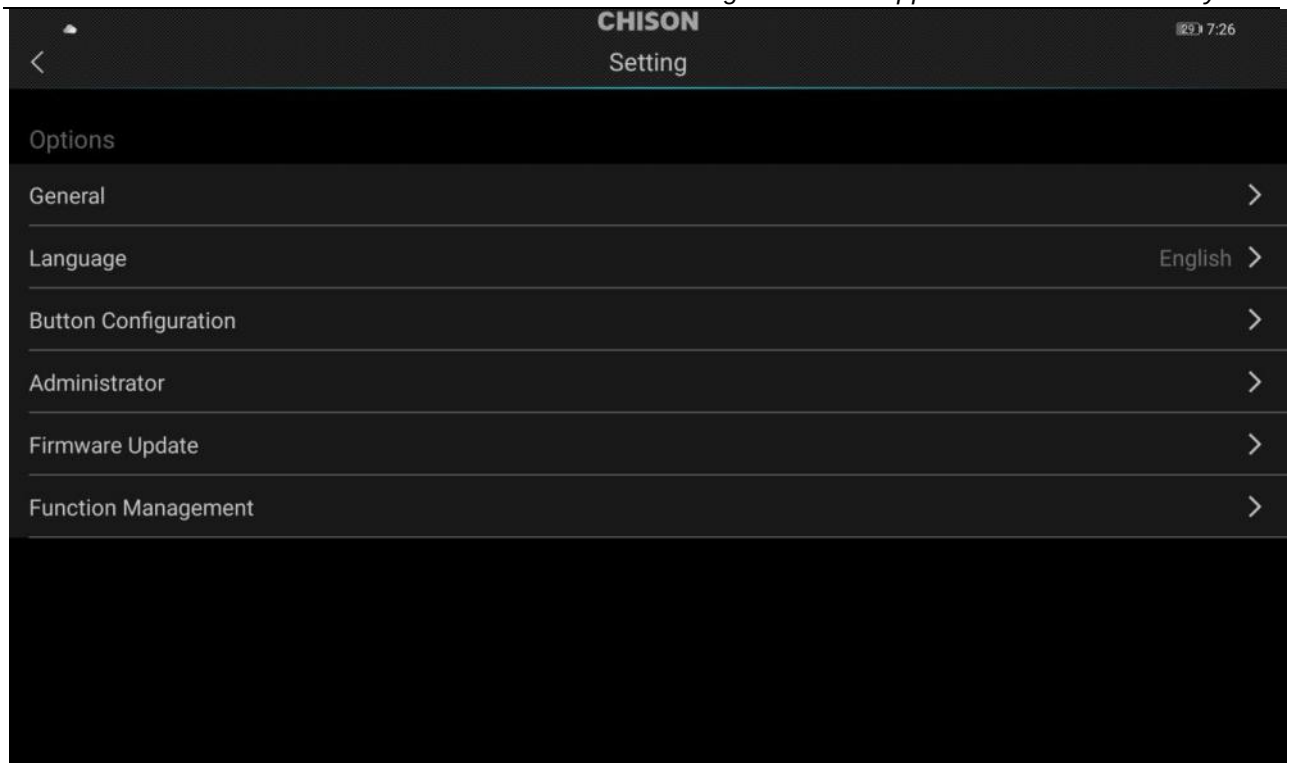
8.3 Report

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, Abdomen, Cardiac 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.

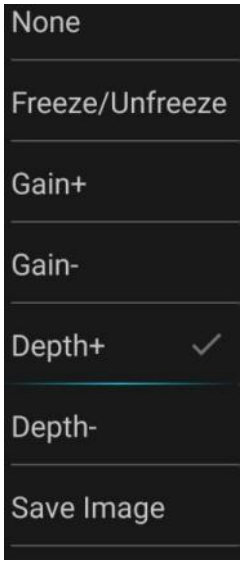
8.4.2 Language

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.

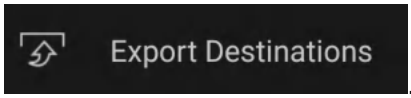
8.4.5 Firmware Update

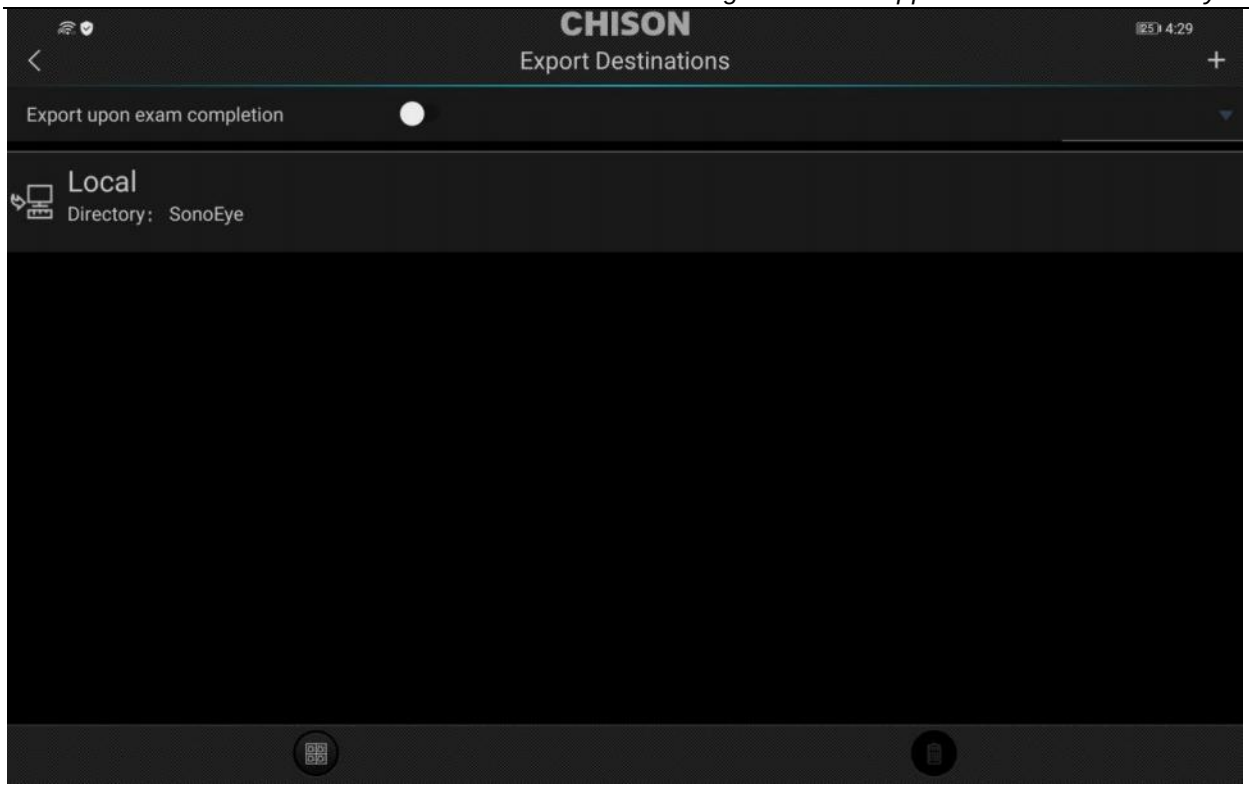
Select firmware update to upgrade system software version.

8.4.6 Function Management

Select function management to manage system functions.

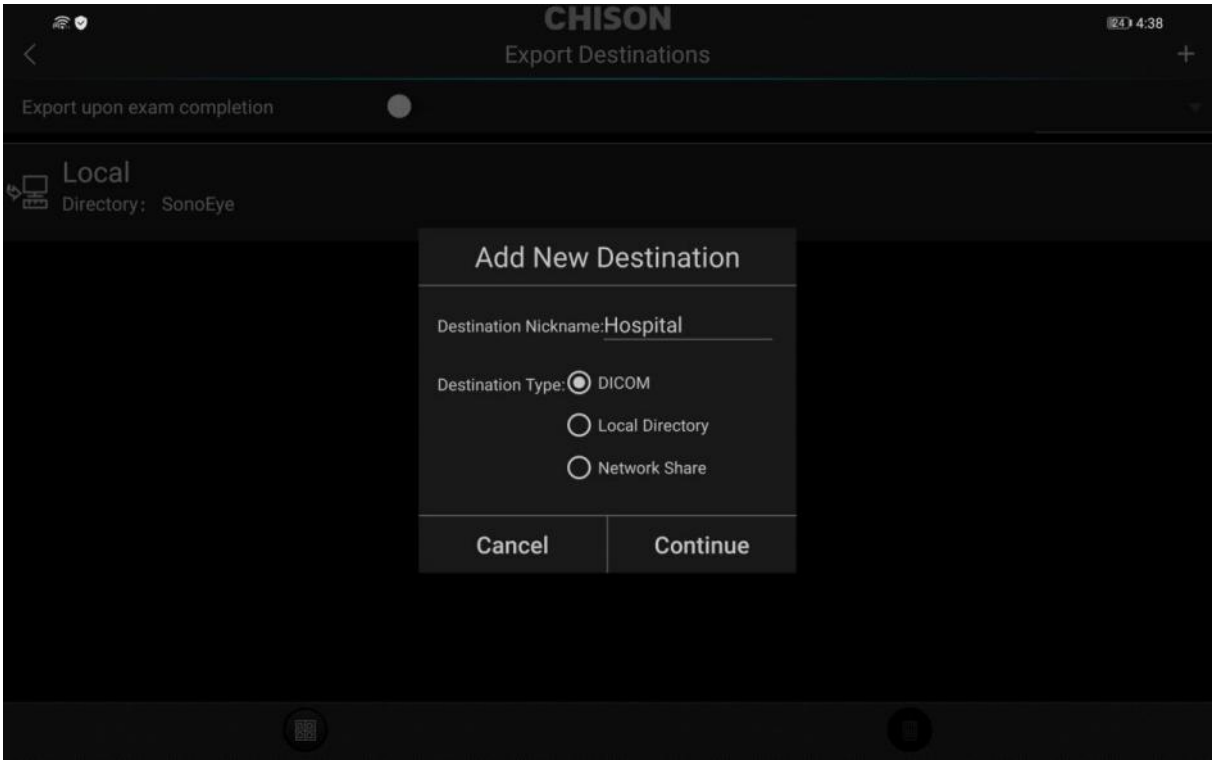
8.5 Export Destinations

Press  and select  .

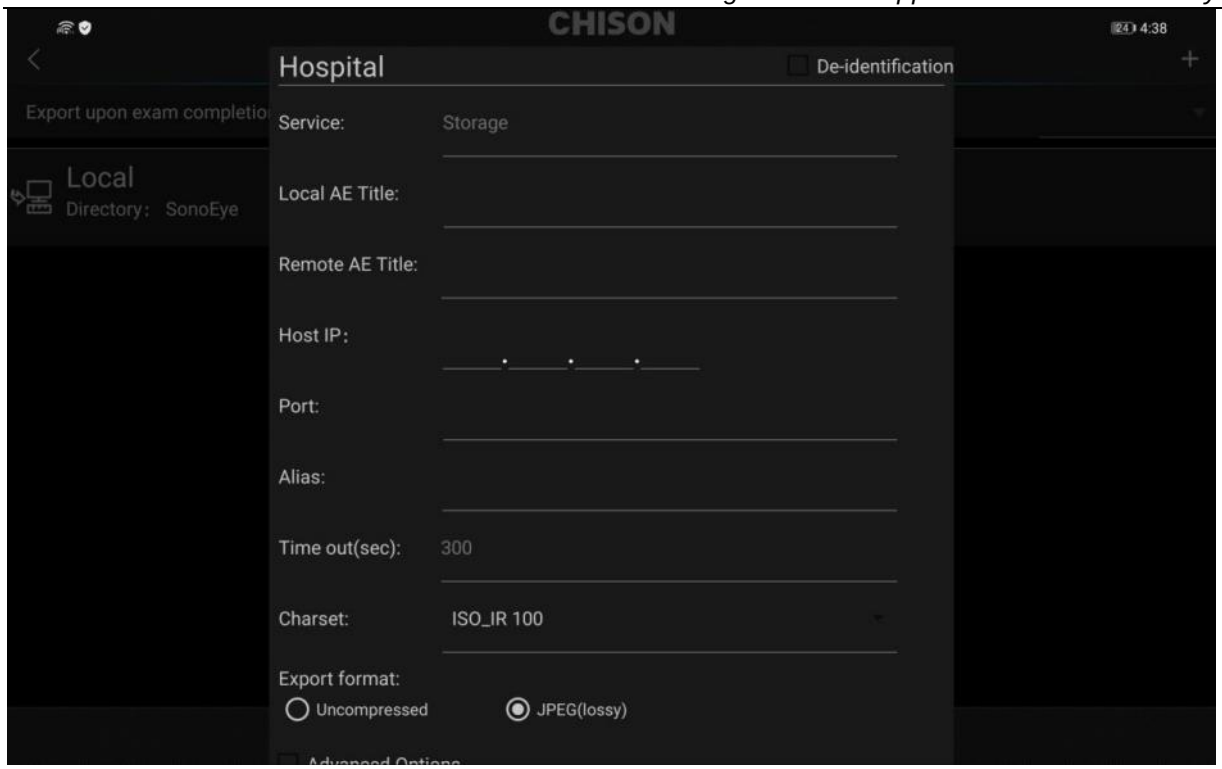


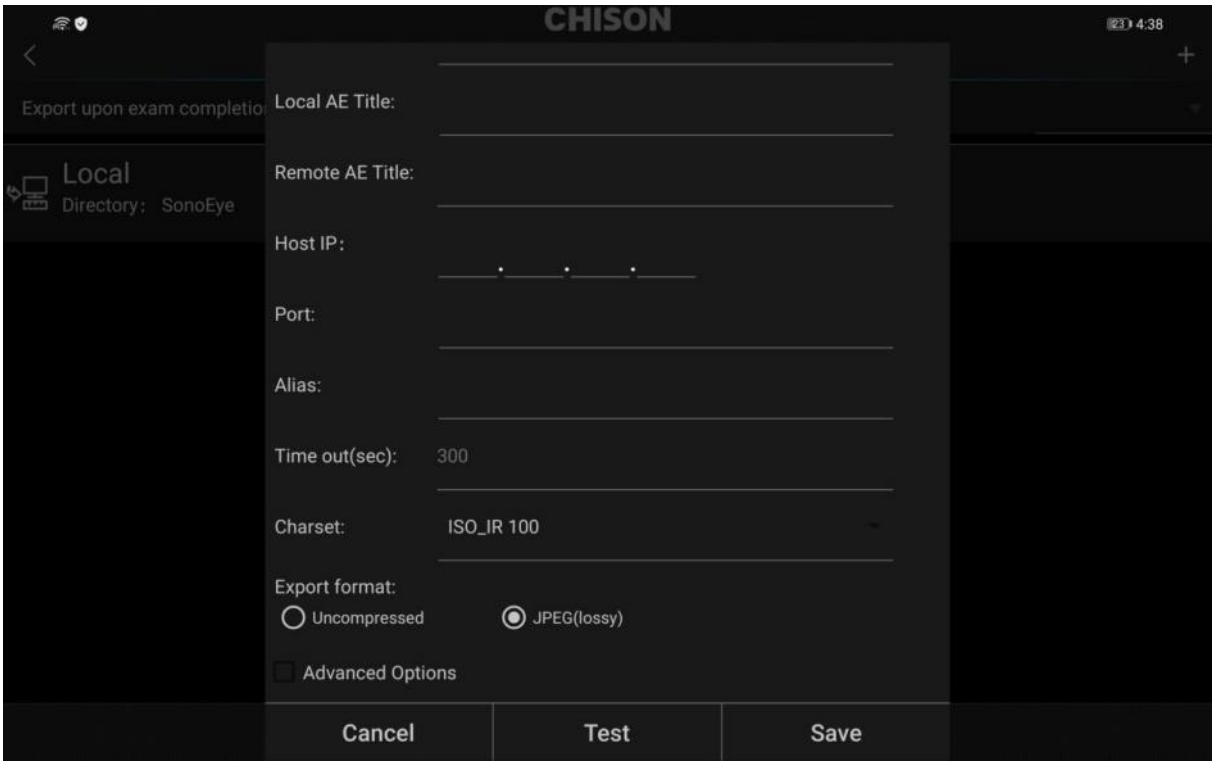
From this interface, you can add or remove export destinations.

You can enter the new interface by press +. There are three Destination types to choose from: DICOM, Local Directory, Network Share



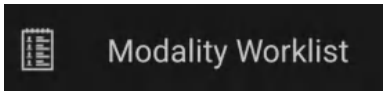
Fill in the information and select the corresponding type to enter the next level interface





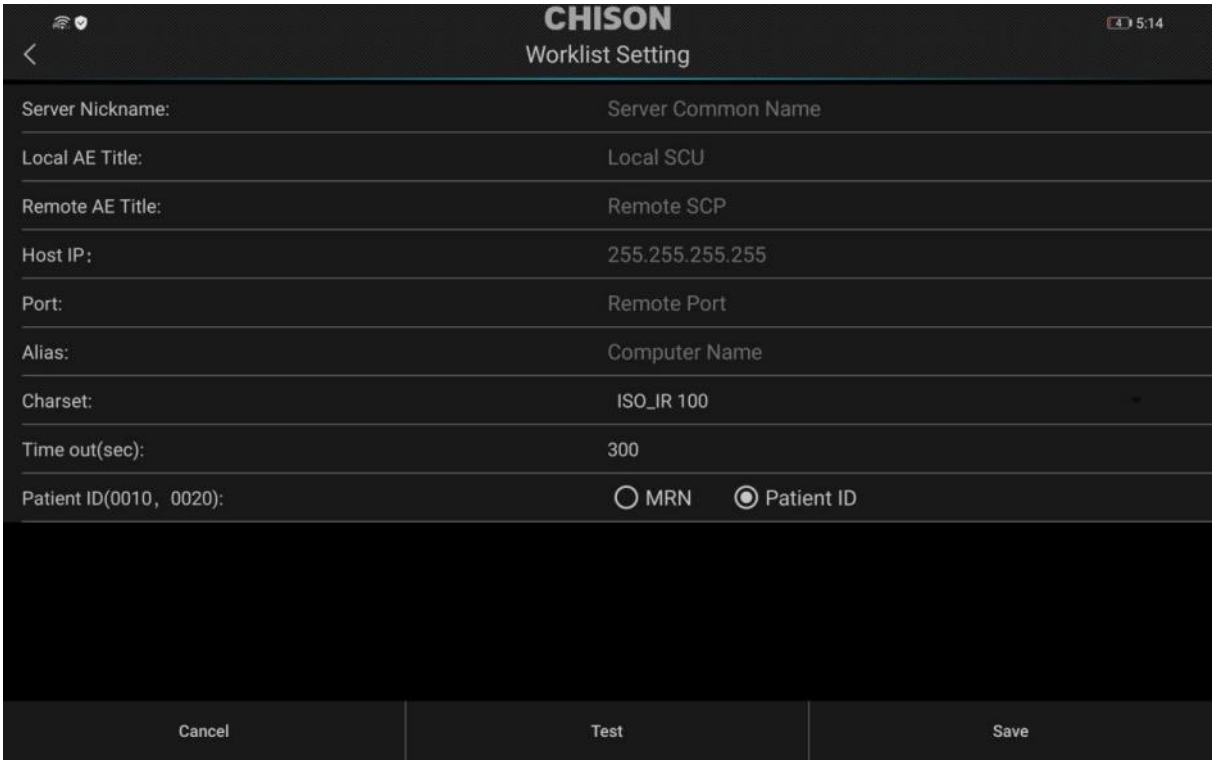
Fill in the information and click Save to complete the new Export Destination.

8.6 Modality Worklist

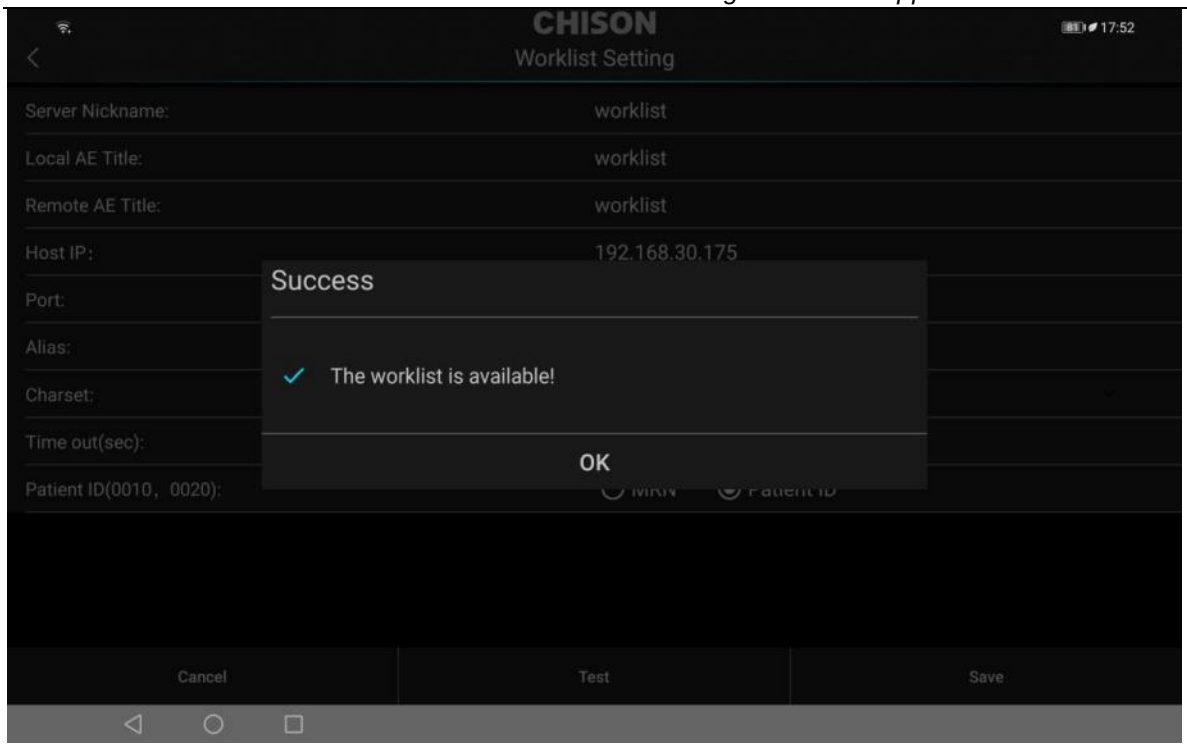
Click 

to enter it, the user can Import the worklist from the server.

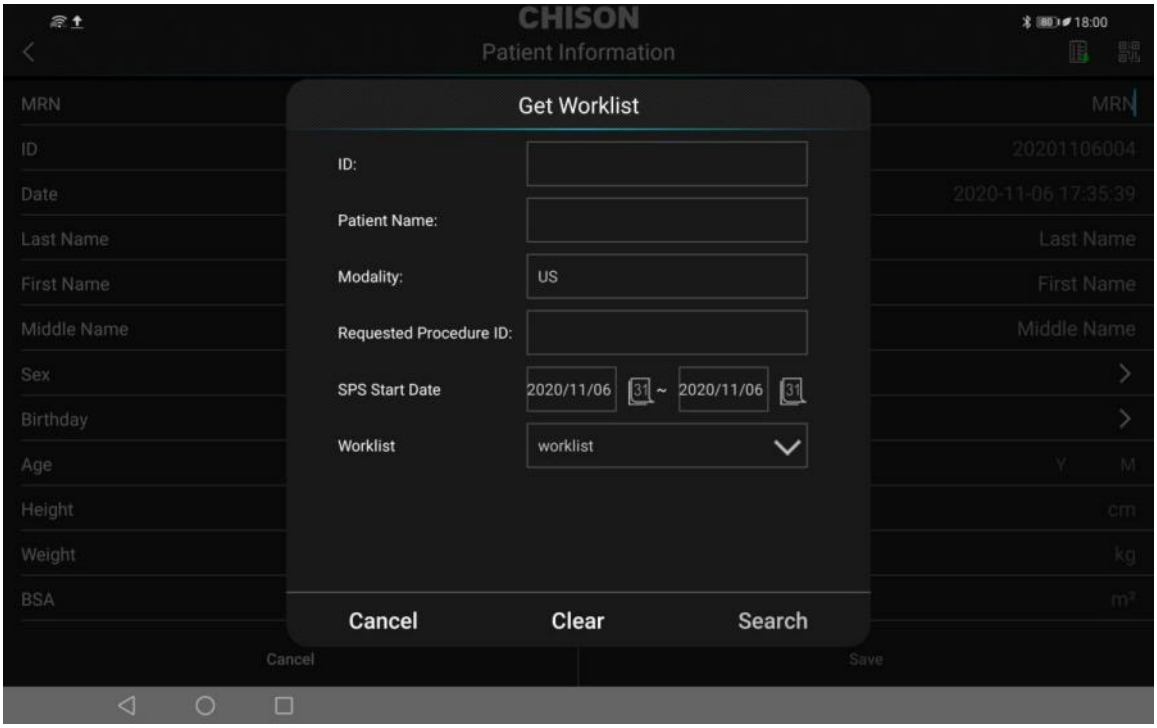
Click + to add server information



Click Test to make sure the server is connected. Then click Save to save server information.



Click on enter the Patient interface and click  to enter Get worklist to import worklist from the server



8.7 Tutorials

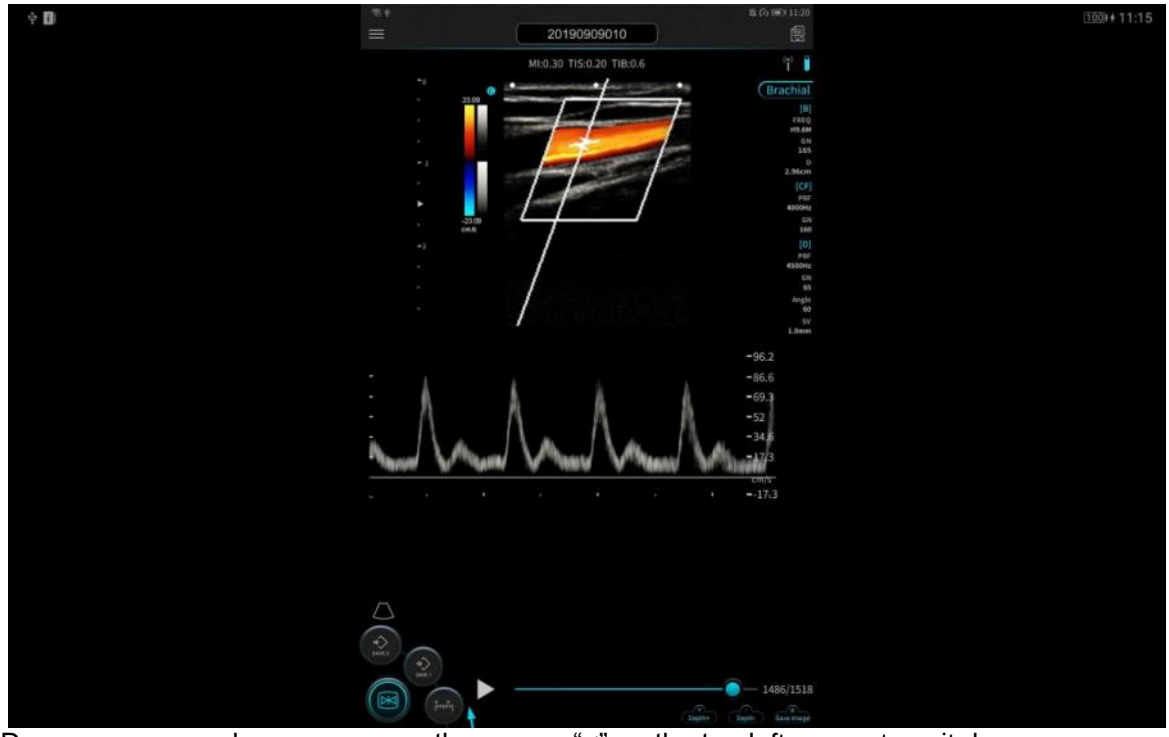
The first time you enter the app, it displays tutorials to familiarize you with the features of the system.

You can view the Tutorials at any time. Press 

and select tutorials to enter it, there is a short video to help you learn the system.

8.8 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.

8.9 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.

Cleaning the system:

1) System tip

Rinsing: 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 P3/ SonoEye V3/SonoEye G3 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

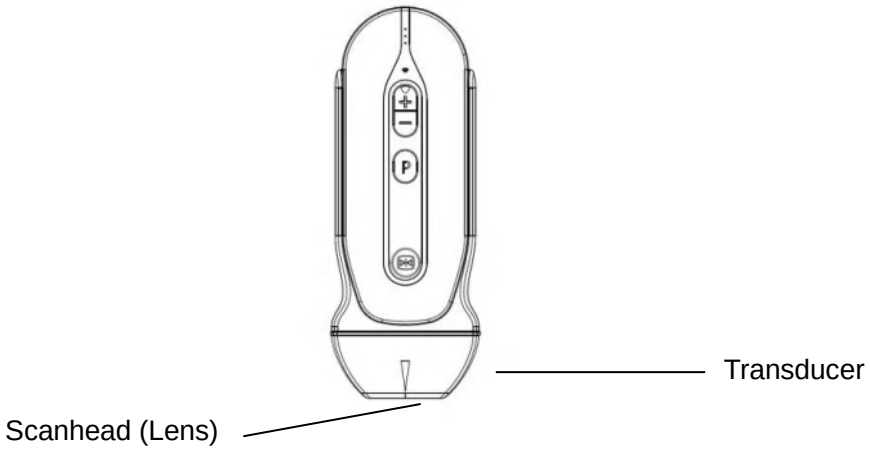


Fig.10-1: Linear Probe Overview

The probes provide high spatial and contrast ultrasound imaging of frequencies from 1.5MHz to 4.0MHz. 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

Definitions

Cleaning removes visible soil (for example, organic and inorganic material) from the probe surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection because inorganic and organic materials that remain on the surfaces of probes interfere with the effectiveness of these processes.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.

Low-Level Disinfection (LLD) destroys most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium tuberculosis or bacterial spores.

Intermediate-Level Disinfection (ILD) inactivates Mycobacterium tuberculosis, bacteria, most viruses, most fungi, and some bacterial spores.

High-Level Disinfection (HLD) destroys or removes all microorganisms except bacterial spores.

Transducer Components

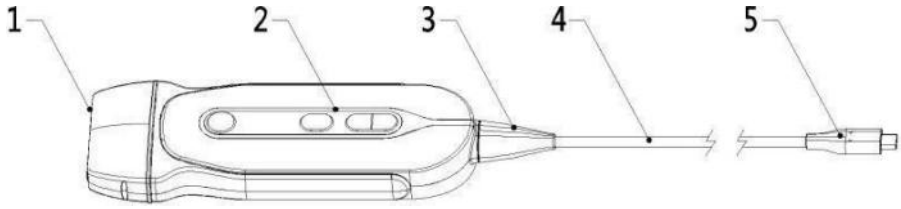


Fig.10-2: Transducer Components

1. Lens 2. Cover 3.Sheath 4.Cable 5. TYPE-C connector

To choose a suitable probe disinfection method, you must first determine its category according to the purpose of the probe. For more information about compatible cleaning and disinfecting agents, please refer to the section "Cleaning or disinfecting ". When using detergents and disinfectants, be sure to follow the manufacturer's instructions.

WARNING

After each use of the probe, it must be cleaned. Cleaning the probe is an important step before effective disinfection. When using detergents and disinfectants, be sure to follow the manufacturer's label instructions.

⚠*WARNING*

When cleaning and disinfecting any instrument, be sure to wear protective glasses and gloves.

⚠*CAUTION*

Using non-recommended disinfectants, inappropriate disinfectant concentration, or the immersion depth or immersion time of the probe exceeding the recommended value will cause damage or discoloration of the probe, and invalidate the probe warranty.

⚠*CAUTION*

Do not use a brush when cleaning transducers. Even the use of soft brushes can damage transducers.

⚠*CAUTION*

Do not leave the probe in contact with cleaning agents and disinfectants for a long time. Limit the time the probe is exposed to cleaners and disinfectants to the shortest time recommended by the manufacturer。

When you use OPA (ortho-phthalaldehyde)-based disinfectants, if you do not follow the manufacturer's instructions carefully, residual solution may remain on the probe. In order to minimize the impact of residual OPA or any other disinfectant, it is recommended as below:

- Follow the instructions of the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends as below immersing the probe in drinking water three times to rinse the probe.
- Limit the time the probe is exposed to the disinfectant to the shortest time recommended by the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends a minimum time of 12 minutes.
- Prevent any fluid from splashing on your mobile device’s touchscreen during cleaning and during disinfecting. Damage may result due to fluid.

Point-of-use processing

Before cleaning, check the probe first. If any particles or body fluids adhere to the probe or cable, you can wipe it off with a soft cloth dipped with 80% ethanol.

10.2.2.1 Cleaning

Recommended supplies:

Dust-free cloth or soft cloth;

Compatible cleaner or wipes for probe cleaning;

1. Disconnect the probe from the system.
2. Wear sterile gloves and use protective eyewear to prevent infection.
3. Remove Ultrasound transmission gel from the transducer by using a soft cloth dipped with potable water (not to exceed 43°C (110°F)) or an approved cleaning or disinfectant agent or by using an approved disinfectant wipe.

Gently wipe the lens to remove the gel, then wipe the probe，cable for 1 minute and until visibly clean(There is no gel, hair, debris or other residue on the probe.).

Do not wipe the connector to prevent liquid from entering the inside. Please refer to Table 10-1 below for approved compatible cleaning and disinfection products.

4. Dry the transducer using a sterile cloth or gauze after cleaning. Blot the lens dry. Do not wipe the lens. Do not dry the transducer by heating it.

10.2.2.2 Disinfecting

After cleaning the probe, you must disinfect the probe.

To reduce the risk of contamination and infection, it is important to choose the appropriate level of disinfection, based on prior exam usage and whether the use is classified as non-critical or semi-critical. Use Table, “Probe Disinfection Class, Use, and Method” to determine the appropriate class and then follow the appropriate intermediate-level or high-level disinfection procedure

Probe Disinfection Class, Use, and Method

Class	**Use**	**Method**
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate- level disinfection (ILD)
Semi-Critical Class	Touches mucous membranes and non-intact skin.	Cleaning followed disinfection (HLD) by high-level

Intermediate-Level Disinfection (ILD)

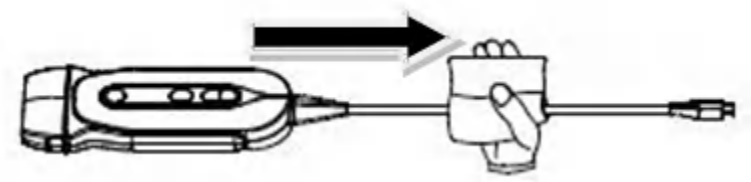


Fig.10-3: Wipe direction

1. Wear sterile gloves to prevent infection.
2. Wipe the probe, with approved compatible disinfectant wipes or soft cloth dipped in disinfectant agent. As shown in the figure above, wiping from lens toward cable. Do not wipe the type-c linker to prevent poor contact.
3. Ensure that the disinfected surface remains visibly moist for at least two (2) minutes, use additional

   fresh wipes as needed.
4. Allow to air dry.
5. After cleaning and disinfection, check the appearance of the probe to see whether the transducer and cable are worn or damaged

High Level Disinfection

It is recommended that you use Cide®OPA by Ethicon US, LLC.

1. After cleaning the probe, you must disinfect the probe. It is recommended that you use Cidex® OPA high- level disinfection solution.
2. Prepare Cidex® OPA high-level disinfection solution for use per the manufacturer's instructions. Fill a tray or basin with the disinfectant solution at room temperature (minimum temperature of 20°C) to a level allowing immersion of the probe up to the immersion line (As shown below),

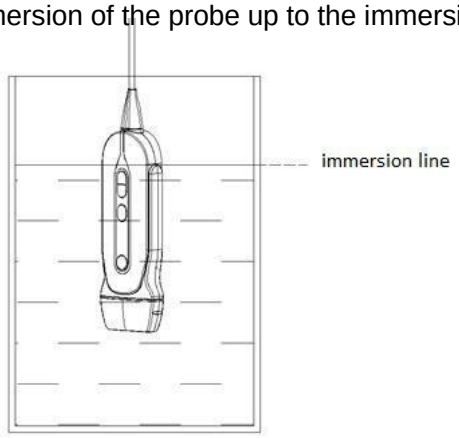


Fig.10-4: Soaking depth

3. Immerse the probe in Cidex® OPA solution up to the immersion line and ensure no air or bubbles are trapped. Allow soaking according to the manufacturer's instructions.

4. Thoroughly rinse the probe (up to the immersion line) by immersing it in a large volume of room temperature purified water for a minimum of one (1) minute. Remove the probe and discard the rinse water.
5. Do not reuse the water. Always use fresh volumes of water for each rinse. Repeat this stage two (2) additional times for a total of three (3) rinses.
6. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the device is completely dry. Inspect the device to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is visible.
7. Once clean and disinfected, inspect the probe, strain relief, cable, and connector for signs of damage or wear.
8. Daily and Long-Term Storage follow these guidelines to protect the probe.
9. Always store transducers in the probe case when you are not using them.

 ***CAUTION***

Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use. Do not soak the transducer connector or the cable near it into water or any solution.

 ***CAUTION***

Follow local regulations when selecting and using the disinfectant.

10.2.2.3 **Approved and compatible cleaning and disinfectant**

Wipes type	Brand	Place of origin	Chemical ingredient	solution
80% Ethanol (Soak with a soft cloth)	Any manufacturer	Any	Ethanol	Clean/LLD/ILD
70% Isopropyl alcohol (Soak with a soft cloth)	Any manufacturer	Any	Isopropyl alcohol	Clean/LLD/ILD
Universal wipes	Clinell	United Kingdom	Compound double chain quaternary ammonium salt	Clean/LLD/ILD
perform classic wipes EP	Schulke&Mayr GmbH	Germany	Compound alcohol	Clean/LLD/ILD
WIP'ANIOS	Laboratoires ANIOS	France	Isopropyl alcohol/Didecyl dimethyl ammonium chlorides	Clean/LLD/ILD
Sani-cloth AF3,Sani- Cloth AF	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopropyl alcohol	Clean/LLD/ILD
Super Sani-Cloth	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopropyl alcohol	Clean/LLD/ILD

Table 10-1：Cleaning and disinfection list

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

- Before cleaning, turn off the system
- To clean the touch screen.

  a. Remove dust with a soft, lint-free cloth.

  b. Please wipe the screen with cleaner specially designed for LCD. Spray the liquid onto the cleaning cloth and gently wipe the screen clean. You can also use pre-moistened screen wipes.

  c. Dry the screen with a soft, lint-free cloth
- Wipe the remaining external surfaces of the system with soft cloth dipped few 70% isopropyl, 80%

  Ethanol solution or recommended wipes.
- Gently remove any residue with a cloth lightly moistened with purified water.
- Dry the equipment to prevent potential corrosion.

  If the equipment has come in contact with blood or infectious material, see “Infection Control”.

Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection control procedures established in your facility for the protection of both the staff and the patient.

WARNING

If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your CHISON service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

CAUTION

Remove blood on the system and the transducer connectors and cables with a soft cloth dipped few soap and potable water. Then dry the equipment with a soft, dry, lint-free cloth to prevent corrosion.

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

R Sight B.V.
Add: Roald Dahllaan 47, 5629 MC, Eindhoven. The Netherlands
SRN: NL-AR-000010445
Tel: 0031640845545
CCI No.: 76704726
E-mail: info@rsight.nl

Appendix B: ACOUSTIC OUTPUT REPORT TABLE

Transducer Model: SonoEye P3/SonoEye V3/SonoEye G3

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.10	0.04		0.04		0.04
Index component Value				0.04	0.04	0.04	0.04	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	3.09					
	P	(mW)		0.92		0.92		0.67
	P_{1*1}	(mW)		0.92		0.92		
	Z_s	(cm)			0.90			
	Z_b	(cm)					0.90	
	Z_{MI}	(cm)	1.15					
	$Z_{pii.\alpha}$	(cm)	1.15					
	f_{awf}	(MHz)	7.93	8.20		8.20		10.65
Other Information	prr	(Hz)	-					
	srr	(Hz)	9.00					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	437.39					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Zsii.\alpha$	(mW/cm^2)	0.09					
	I_{spta} at Z_{pii} or $Zsii$	(mW/cm^2)	0.09					
	p_r at Z_{pii}	(MPa)	4.15					
Operating control conditions	Focus	(cm)	1.50	5.50		5.50		1.00
	Depth	(cm)	4.90	8.90		8.90		4.90
	Freq	MHz	9.00	9.00		9.00		11.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P3/SonoEye V3/SonoEye G3
Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.22	0.05		0.08		0.07
Index component Value				0.05	0.04	0.05	0.08	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	3.50					
	P	(mW)		2.68		2.68		2.68
	P_{1*1}	(mW)		2.68		2.68		
	Z_s	(cm)			0.95			
	Z_b	(cm)					0.95	
	Z_{MI}	(cm)	1.05					
	$Z_{pii.\alpha}$	(cm)	1.05					
	f_{awf}	(MHz)	8.24	8.20		8.20		8.20
Other Information	prr	(Hz)	245					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	450.24					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	10.26					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	15.22					
	p_r at Z_{pii}	(MPa)	4.55					
Operating control conditions	Focus	(cm)	1.50	5.50		5.50		5.50
	Depth	(cm)	4.90	8.90		8.90		8.90
	Freq	MHz	9.00	9.00		9.00		9.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P3/SonoEye V3/SonoEye G3
Operation Mode: B+CFM

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.30	0.08		0.08		0.18
Index component Value				0.08	0.08	0.08	0.08	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	3.17					
	P	(mW)		2.81		2.81		2.81
	P_{1*1}	(mW)		2.81		2.81		
	Z_s	(cm)			0.75			
	Z_b	(cm)					0.75	
	Z_{MI}	(cm)	0.75					
	$Z_{pii.\alpha}$	(cm)	0.75					
	f_{awf}	(MHz)	5.93	5.93		5.93		5.93
Other Information	prr	(Hz)	-					
	srr	(Hz)	3.54					
	n_{pss}	NA	9.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	499.13					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	2.74					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	2.74					
	p_r at Z_{pii}	(MPa)	3.61					
Operating control conditions	Focus	(cm)	1.00	1.00		1.00		1.00
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	6.00	6.00		6.00		6.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P3/SonoEye V3/SonoEye G3
Operation Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.19	0.23		0.83		0.33
Index component Value				0.23	0.18	0.23	0.83	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	3.08					
	P	(mW)		7.11		7.11		7.11
	P_{1*1}	(mW)		7.11		7.11		
	Z_s	(cm)			0.50			
	Z_b	(cm)					0.85	
	Z_{MI}	(cm)	1.05					
	$Z_{pii.\alpha}$	(cm)	1.05					
	f_{awf}	(MHz)	6.67	6.66		6.66		6.66
Other Information	prr	(Hz)	4500					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	513.21					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Zsii.\alpha$	(mW/cm^2)	432.56					
	I_{spta} at Z_{pii} or Zsii	(mW/cm^2)	710.03					
	p_r at Z_{pii}	(MPa)	3.82					
Operating control conditions	Focus	(cm)	1.50	7.00		7.00		7.00
	Depth	(cm)	8.90	8.90		8.90		8.90
	Freq	MHz	6.00	6.00		6.00		6.00
	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
SonoEye P3	**<39.9**	**<36.5**
SonoEye V3	**<39.9**	**<36.5**
SonoEye G3	**<39.9**	**<36.5**

Overall uncertainties
Center Frequency: The accuracy of the center frequency measurement is primarily dependent on the digitizer, and is therefore given as ± 2%.

Pressue: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 13.37%.

Intensity and Power: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 26.75%.

It can be summarized in below table:

Item	Measurement Uncertainty (95% Confidence Level)
Center frequency	±2.00%
Pressure	±13.37%
Intensity	±26.75%
Power	±26.75%

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 environment.
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.

Appendix F: Pulsed Wave Doppler Velocity Measurement Results Summary

Probe type: SonoEye P3, Scan mode: PW, fc: 2.5MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.21	97.42	148.14
Measurement Error (%)	2.10%	-2.58%	-1.24%

Probe type: SonoEye P3, Scan mode: CFM, fc:2.5MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.56	53.69	106.84
Measurement Error (%)	5.60%	7.38%	6.84%

Probe type: SonoEye V3, Scan mode: PW, fc: 2.5MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.51	97.45	147.25
Measurement Error (%)	5.10%	-3.55%	-1.84%

Probe type: SonoEye V3, Scan mode: CFM, fc:2.5MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.85	54.45	106.78
Measurement Error (%)	-1.50%	8.90%	6.78%

Probe type: SonoEye G3, Scan mode: PW, fc 2.5MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	9.34	91.96	139.86
Measurement Error (%)	-6.60%	-8.04%	-6.76%

Probe type: SonoEye G3, Scan mode: CFM, fc:2.5MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.85	53.74	91.24
Measurement Error (%)	8.50%	7.48%	-8.76%

Digital Color Doppler Palm Ultrasound System

Model
SonoEye P5/SonoEye V5/SonoEye G5

USER MANUAL

CHGA-SonoEye-043-P5

Feb.25th, 2024

Rev. 2.1

CHISON Medical Technologies Co., Ltd.

Regulatory Requirement

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 P5/SonoEye V5/SonoEye G5. 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

Indicationsfor Use

The 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 Fetal,Abdominal,OB/GYN,Urology,Cardiac.

The Digital Color Doppler Palm Ultrasound System isintended 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.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: 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 ortherapist.

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 the protective covers on the system. These covers protect users from hazardous voltages. A qualified electronic technician must make all internal replacements.
- Do not operate this system in the presence of flammable gases or anesthetics.

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. 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.

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 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.
Rx only	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.
	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.
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.
	Scan the QR code to open CHISON website.
UDI	Unique Device Identifier.

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:

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

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

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

- 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 bythe 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 CFMmode.

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 to4, wherefc is the center frequency in MHz.

W_{deg}= 40 K D for model 5 and 6, whereK (beamshape 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.

DisplayGuideline:

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.

2.7 Device instructions of cybersecurity controls

2.7.1 Software Integrity Control

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

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

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

- Installing OS Updates Immediately

  Whenever an update appears on the screen, consider installing an operating system update immediately to avoid virus and malware attacks.
- The device software doesn't provide any entrance for executing third party application.
- Never trust an unknown computer

  The device connect computer with USB port. Do not plug the device into an unknown computer.
- Install anti-virus software and use firewall and scan device regularly with antivirus software.
- Keep network safe

  Set a strong network access password, and do not open public Wi-Fi connections, use WPA, WPA2 encryption or the latest WPA3 encryption. Don't open email attachments from unknown

people or companies, don't click links in unsolicited emails, do not download suspicious apps, etc.

2.7.2 Device instructions of cybersecurity controls

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

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

2.8 Insturctions to the intruded device

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

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

Chapter 3 Preparing the System for Use

3.1 Site Requirement

3.1.1 Operation 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: WARNING: Maintain a fluctuation range as above, otherwise the system may be damaged or can't work.

3.1.3 Hardware Requirements

The digital color doppler palm ultrasound system includes the transducer, software and a COTS device. The minimum requirements for COTS equipment are as follows:

- IEC 60950-1 compliant
- IEC 55032 compliant
- Octa-core processor (CPU)
- 1 GB of memory
- 1 GB of storage (on-board)
- Touch interface

- Internally mounted speakers
- Operating System: Android 9 or newer
- Display Resolution (in pixels): 1920×1200 or more
- Interface: Type C, USB 2.0

WARNING

Using the SonoEye app on a COTS device that does not meet the minimum specification may result in poor image quality, unexpected results, possible misdiagnosis or not working.

WARNING

The COTS cannot be charged while the transducer is in use for safety.

3.1.4 Programming Language Requirements

Operation System: Android

Programming Environment: Android Studio

3.1.5 The requirement of commercial off-the-shelf (COTS) devices

All models need to comply with IEC55032, IEC60950-1, among which we have selected typical models to do verification testing with SonoEye on ANSI/AAMI ES60601-1 and IEC60601-1-2, such as Samsung Galaxy A70s or Huawei MatePad Pro.

- Electrical Safety

  The transducer and software, along with a representative device, have been verified as compliant with IEC 60601-1. The transducers meet Type BF isolated applied part requirements. When the transducer and software are used in conjunction with a device (COTS devices) compliant with IEC 60950-1, the system meets IEC 60601-1 requirements for Class II equipment.

- Electromagnetic Compatibility

  The transducer and representative Android device are classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. When the transducer and software are used in conjunction

with a device(COTS devices) compliant with IEC 55032, the system meets IEC 60601-1-2 requirements for Group1,Class A equipment.

- Android devices' output current and voltage

  The representative Android devices' output current is 1.5A and voltage is 5V. A COTS device connected to our transducer and system should meet the current and voltage range, the output current is greater than or equal to 1.5A, and the output voltage is 5V±5%.

- Full compliance with USB 2.0 standard

  The representative Android devices are full compliance with USB 2.0 standard. A COTS device connected to our transducer and system should meet the standard.

- Representative Android devices

  Representative Android devices are Samsung Galaxy A70s and Huawei MatePad Pro. The configuration is as follows.

  Samsung Galaxy A70s：

  - •CPU frequency 2.0GHz (big quad core), 1.7GHz (small quad core), Octa-core
  - •RAM capacity 8GB
  - •ROM capacity 128GB
  - •Main screen resolution 2400x1080 pixels
  - •WLAN function Dual-band WIFI, IEEE 802.11 a/b/g/n/ac (support 2.4G and 5GHz)
  - •Operating System: Android 9
  - •Support Bluetooth 5.0

  Huawei MatePad Pro：

  - •CPU frequency 2 x Cortex-A76 Based 2.86 GHz+ 2 x Cortex-A76 Based 2.09 GHz+ 4 x Cortex-A55
  - •1.86 GHz, Octa-core
  - •RAM capacity 8GB
  - •ROM capacity 128GB
  - •Main screen resolution 2560x1600 pixels
  - •WiFi function supports dual frequency (2.4GHz+5GHz)
  - •Bluetooth function supports Bluetooth 5.1 module
  - •Operating System: Android 9

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:

Connect the SonoEye to your device, the SonoEye will be on automatically. And after a few seconds, the device will be automatically connected.

If you turn off the SonoEye, you can press  for 3 seconds to turn on the system.

2. Power off:

Press  for 3 seconds to shut down the system

3.3 System Specifications

3.3.1 Console Overview

SonoEye P5/SonoEye V5/SonoEye G5 system:

Fig. 3-1: Console Overview

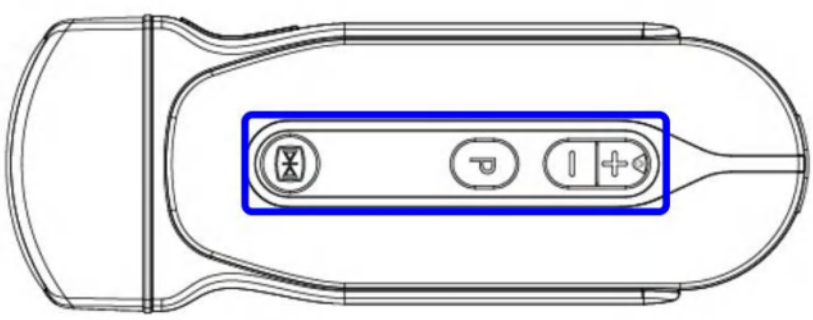


Fig. 3-2: Firmware Front View for SonoEye P5/SonoEye V5/SonoEye G5 system

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）*172mm（Height）*24mm（Depth）

Net weight of main unit (approx): 213g

3.3.3 Image Modes

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

3.3.4 Type

		
Convex Array: P5 2.0MHz- 4.5MHz	Convex Array: V5 2.0MHz- 4.5MHz	Convex Array: G5 2.0MHz- 4.5MHz

3.3.5 System Configuration

Function	SonoEye P5	SonoEye V5	SonoEye G5
B mode	Standard	Standard	Standard
B/M mode	Option	Option	Option
PW mode	Option	Standard	Option
CFM mode	Option	Option	Option
FHI	Option	Option	Standard
Type-C cable	Standard	Standard	Standard
Identify probe	Standard	Standard	Standard
Switch exam mode	Standard	Standard	Standard
Gain	Standard	Standard	Standard
Depth	Standard	Standard	Standard
STC	Standard	Standard	Standard
Focus	Standard	Standard	Standard
Zoom	Standard	Standard	Standard
Adjust sample Gate location	Option	Option	Option
Adjust size of sample Gate horizontal	Option	Option	Option
Adjust size of sample Gate vertical	Option	Option	Option
Adjust PW sample gate	Option	Option	Option
Compound	Standard	Standard	Standard
Frequency Scaling	Standard	Standard	Standard

Freeze/Unfreeze	Standard	Standard	Standard
B-distance	Standard	Standard	Standard
B-Circumference	Standard	Standard	Standard
B-Area	Standard	Standard	Standard
B-Volume	Standard	Standard	Standard
B/M-Distance	Option	Option	Option
B/M-Time	Option	Option	Option
B/M-HR	Option	Option	Option
PW-Velocity	Option	Option	Option
PW-Time	Option	Option	Option
Vessel measure package	Option	Option	Option
Abdomen measure package	Option	Option	Option
Obstetrics measure package	Option	Option	Option
Cardiac measure package	Option	Option	Option
General report	Option	Option	Option
Vessel report	Option	Option	Option
Abdomen report	Option	Option	Option
Obstetrics report	Option	Option	Option
Cardiac report	Option	Option	Option
English Interface	Standard	Standard	Standard
Multi-language Interface	Option	Option	Option
Auto vascular tracking	Option	Option	Option
Instant AIO	√	Option	Option
Biopsy Guide	Option	Option	Option
SonoNeedle	Option	Option	Option
SuperNeedle	Option	Option	Option
SonoRemote	Option	Option	Option
Save Cine	Standard	Standard	Standard
Save Image	Standard	Standard	Standard
Cine Loop	Option	Option	Option
Annotation	Option	Option	Option
Bodymark	Option	Option	Option
Mark	Option	Option	Option
Patient management	Option	Option	Option
Voice/Angle/Baseline on PW	Option	Option	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)**	Standard	Standard	Standard
Physical key	Standard	Standard	Standard
Setting	Standard	Standard	Standard
Archives	Standard	Standard	Standard
Tutorials	Standard	Standard	Standard
EasyView	Standard	Standard	Standard
Demo	Standard	Standard	Standard
About	Standard	Standard	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 cable 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 P5/SonoEye G5/SonoEye V5 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 4-1 Display Interface

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

4.2 Start a New Exam

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

To add patient information:

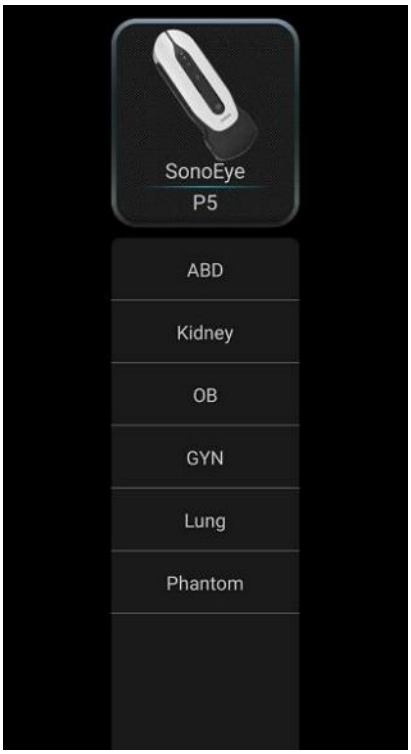
1. On the imaging display, touch the ID number.
2. On the patient Info display, type the patient information.
3. Click the [Save] button.

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

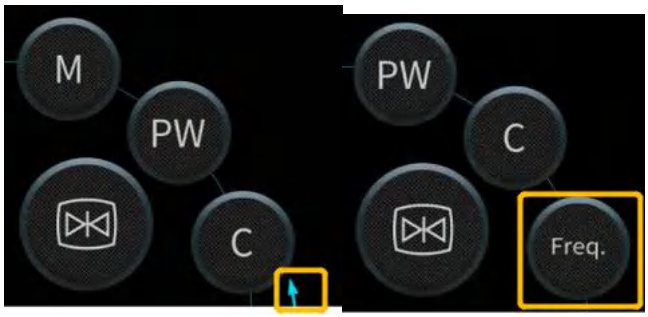
4.3 Application

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



4.4 Switching Function

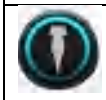
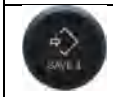
Slide the top left along the buttons to show Freq.

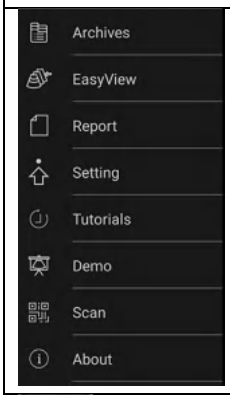


4.5 Switching Mode

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.
	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 application, frequency, mode, depth, gain 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.

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, FHI 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.

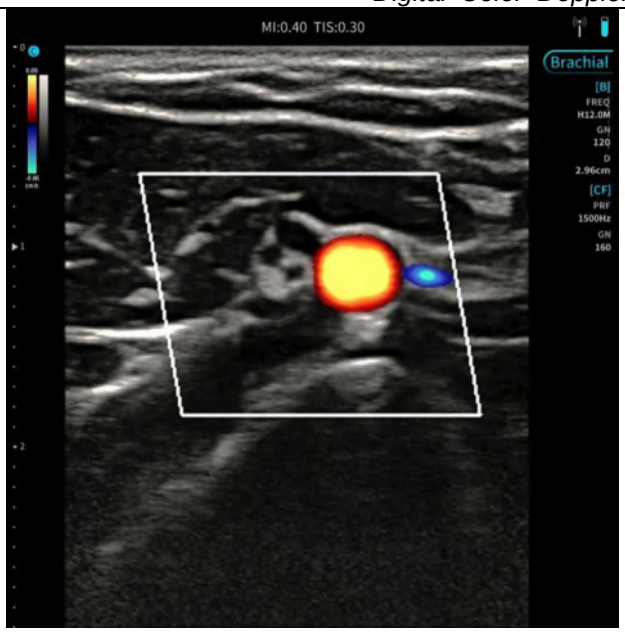


Fig. 5-1 CFM Mode

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 onside 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 account automatically when you first log into 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 account automatically when you first log into 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

At real-time state, touch the screen with two fingers and slide it outward to enlarge the image.

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 annotationsare correct. Incorrect annotations may cause misdiagnosis!

Operation:

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

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

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

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

5.4.2 Adding BodyMark

Operation:

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

2. The submenu 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 Obstetrics Measurement in B mode

Meas. item name	mark	unit	Meas. Method and calc. formula
BPD	BPD	cm	Refer to “Distance” measurement in 6.1
	GA	w	Hadlock
	EDD		EDD=System Data-GA×7 days+280 days
	EFW	g	Hadlock
FL	FL	cm	Refer to “Distance” measurement in 6.1
	GA	w	Hadlock

	EDD		EDD=System Data-GA×7 days+280 days
AC(Ellipse)	AC(Ellipse)	cm	Refer to “Ellipse” measurement in 6.1
	GA	w	Hadlock
	EDD		EDD=System Data-GA×7 days+280 days
HC	HC	cm	Refer to “Ellipse” measurement in 6.1
	GA	w	Hadlock
	EDD		EDD=System Data-GA×7 days+280 days
CRL	CRL	cm	Refer to “Distance” measurement in 6.1
	GA	w	Hadlock
	EDD		EDD=System Data-GA×7 days+280 days
GS	GS	cm	Refer to “Distance” measurement in 6.1
	GA	w	Tokyo
	EDD		EDD=System Data-GA×7 days+280 days
AFI	AFI_1	cm	Refer to “Distance” measurement in 6.1
	AFI_2	cm	Refer to “Distance” measurement in 6.1
	AFI_3	cm	Refer to “Distance” measurement in 6.1
	AFI_4 AFI	cm	Refer to “Distance” measurement in 6.1 AFI= AFI_1+ AFI_2+ AFI_3+ AFI_4

6.2.3 Abdomen Measurement in B mode

Meas. item name	**mark**	**unit**	**Meas. Method and calc. formula**
CBD	CBD	cm	Refer to “Distance” measurement in 6.1
GB Wall	GB Wall	cm	Refer to “Distance” measurement in 6.1
Liver Length	Liver Length	cm	Refer to “Distance” measurement in 6.1
Spleen	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
Renal 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
GB Volume	Length	cm	Refer to “Distance” measurement in 6.1
	Width	cm	Refer to “Distance” measurement in 6.1
	Height	cm	(3.14159265/6) * Length * Height * Width

IVC	IVC Ins	cm	Refer to “Distance” measurement in 6.1
	IVCExp	cm	Refer to “Distance” measurement in 6.1

6.2.4 Cardiac Measurement in B mode

Meas. item name	mark	unit	Meas. Method and calc. formula
IVSd	IVSd	cm	Refer to “Distance” measurement in 6.1
LVIDd	LVIDd	cm	Refer to “Distance” measurement in 6.1
LVPWd	LVPWd	cm	Refer to “Distance” measurement in 6.1
IVSs	IVSs	cm	Refer to “Distance” measurement in 6.1
LVIDs	LVIDs	cm	Refer to “Distance” measurement in 6.1
LVPWs	LVPWs	cm	Refer to “Distance” measurement in 6.1
EDV	EDV	ml	$(7*LVIDd^3/1000)/(2.4+(LVIDd/10))$
ESV	ESV	ml	$(7*LVIDd^3/1000)/(2.4+(LVIDd/10))$
SV	SV	ml	EDV-ESV
CO	CO	L/min	HR*SV/1000
EF	EF	%	100*SV/EDV
FS	FS	%	100*（LVIDd-LVIDs）/LVIDd
SI	SI		SV/BSA
CI	CI		CO/BSA
EDV(A2C/A4C)		ml	$EDV(ml)=\pi\times\frac{LVLd\ apical(cm)}{20}\times\sum_{i=1}^{20}r_i^2(cm)$
ESV(A2C/A4C)		ml	$ESV(ml)=\pi\times\frac{LVLs\ apical(cm)}{20}\times\sum_{i=1}^{20}r_i^2(cm)$
SV	SV	ml	EDV-ESV
CO	CO	L/min	HR*SV/1000
EF	EF	%	100*SV/EDV
SI	SI		SV/BSA
CI	CI		CO/BSA
IVC Ins	IVC Ins	cm	Refer to “Distance” measurement in 6.1
IVC Exp	IVC Exp	cm	Refer to “Distance” measurement in 6.1
LVOT Diam	LVOT Diam	cm	Refer to “Distance” measurement in 6.1
LVOT Area	LVOT Area	cm^2	Refer to “Ellipse” measurement in 6.1
AV Diam	AV Diam	cm	Refer to “Distance” measurement in 6.1
AV Area	AV Area	cm^2	Refer to “Ellipse” measurement in 6.1

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.

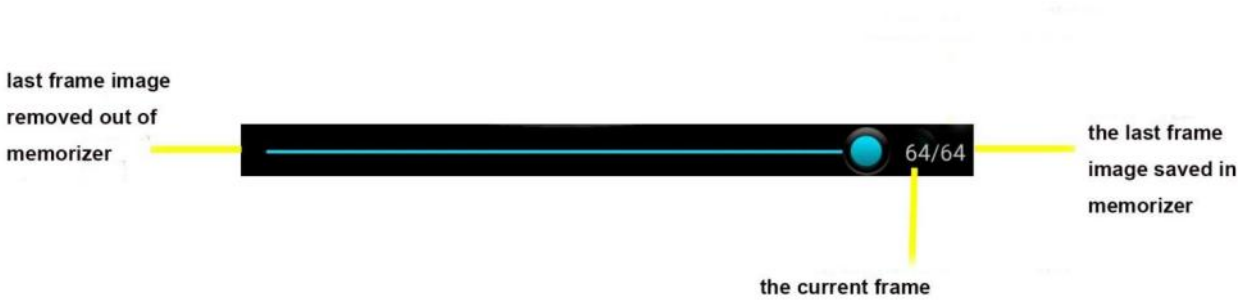


Fig. 7-1 Movie playback bar diagram

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

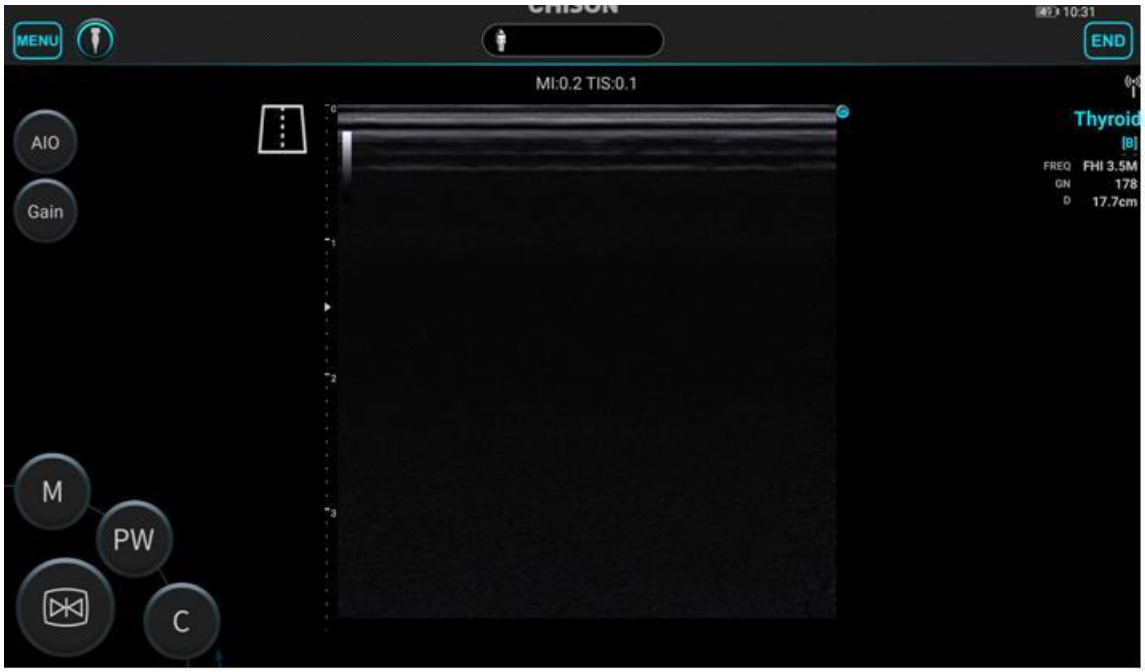
Press Freeze and click  to start automatic playback.

7.4 Cine Save

Press Freeze and click  to save current cine.

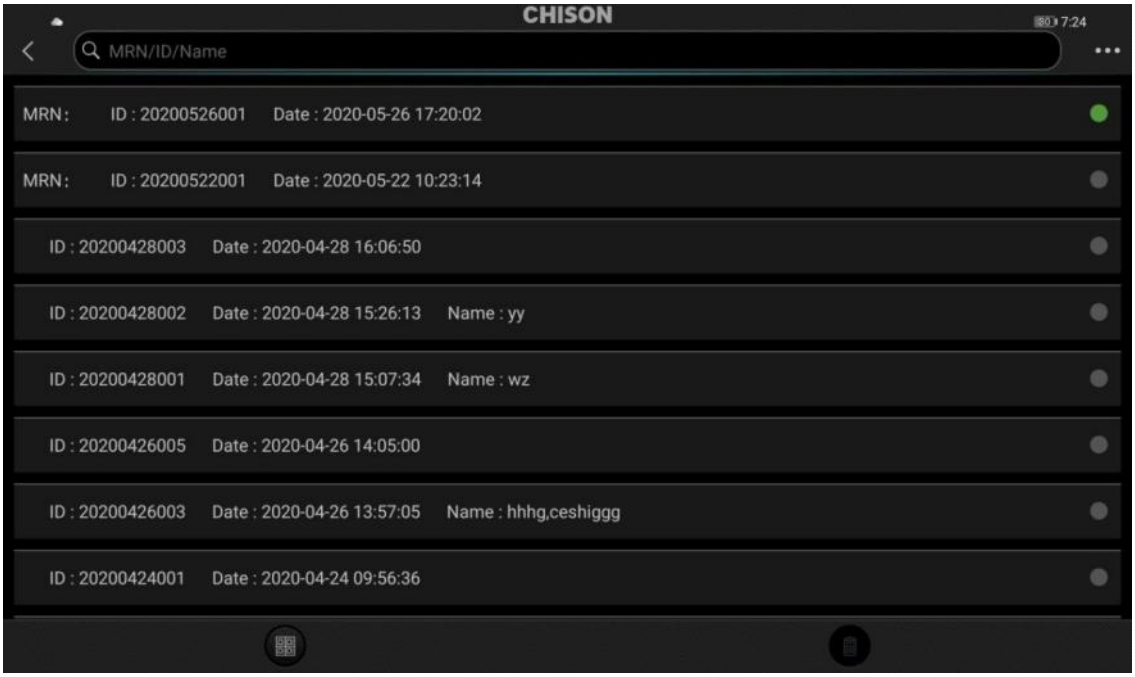
Chapter 8 Side Menu

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.

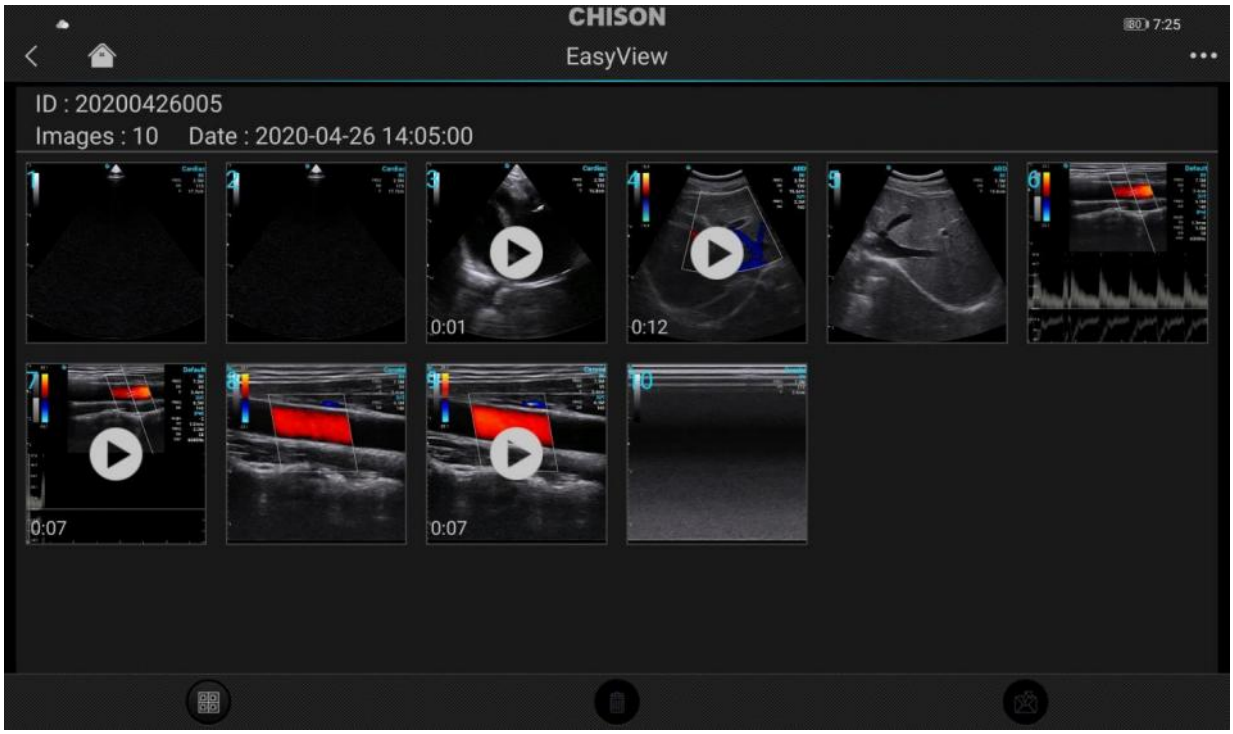
 : Select all archives.

 : Press it to delete selected archive.

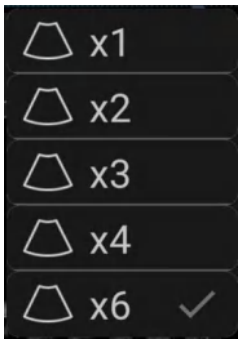
Press selected archive to enter EasyView.

8.2 EasyView

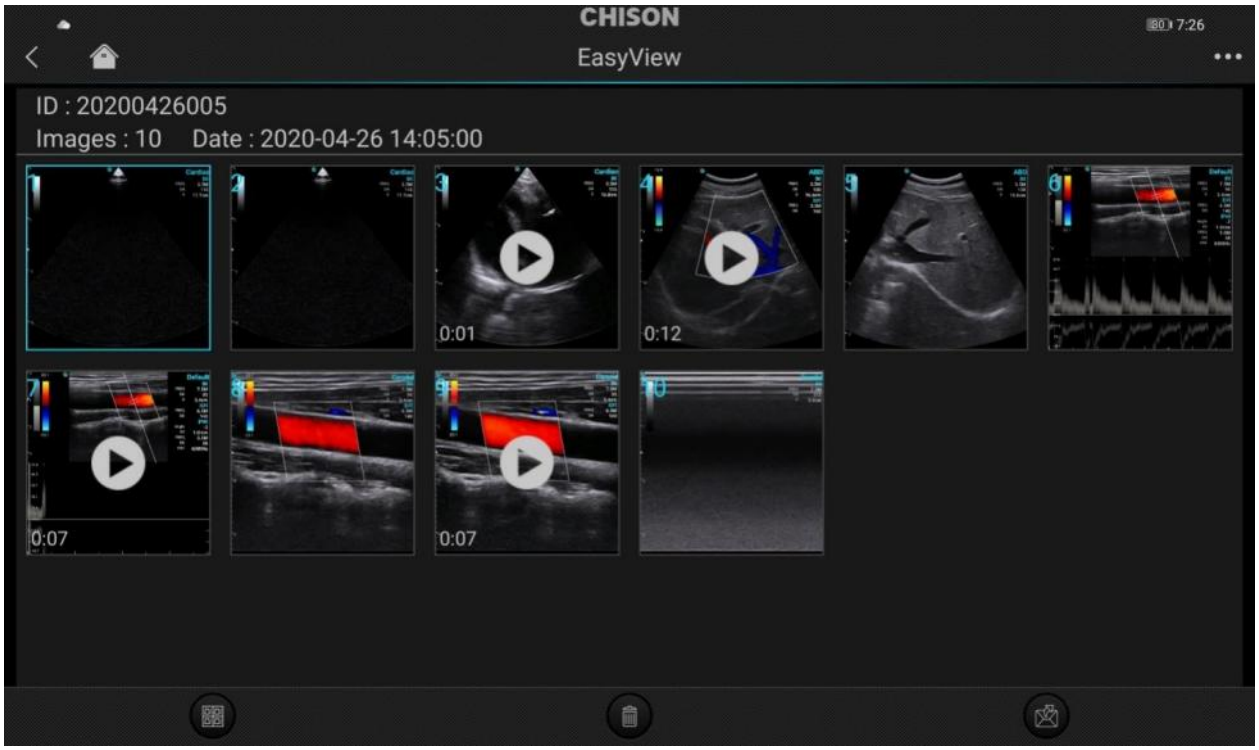
Press EasyView to check the patient information, saved images and cines.



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 selected image.

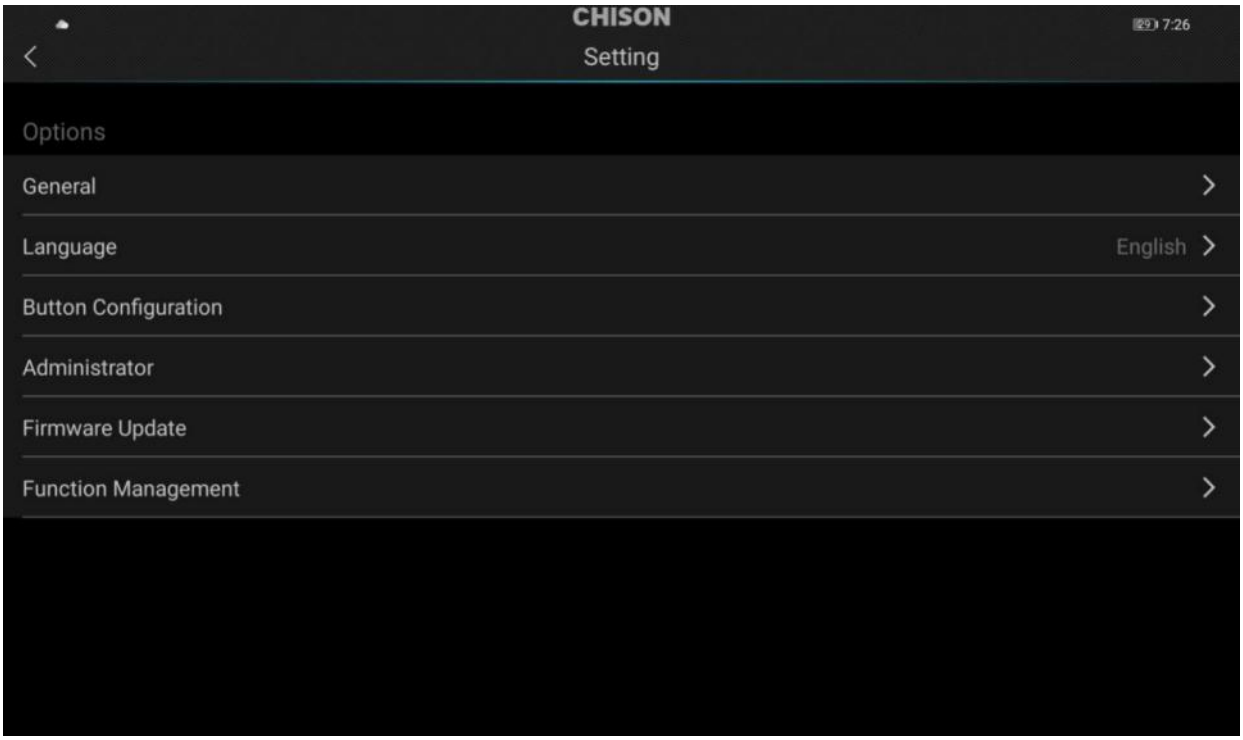
8.3 Report

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, Abdomen, Obstetrics, Cardiac 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.

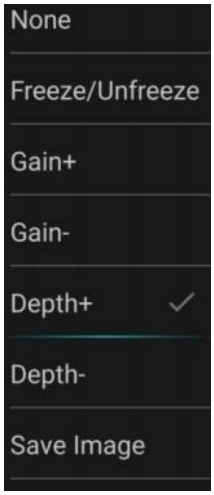
8.4.2 Language

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”	

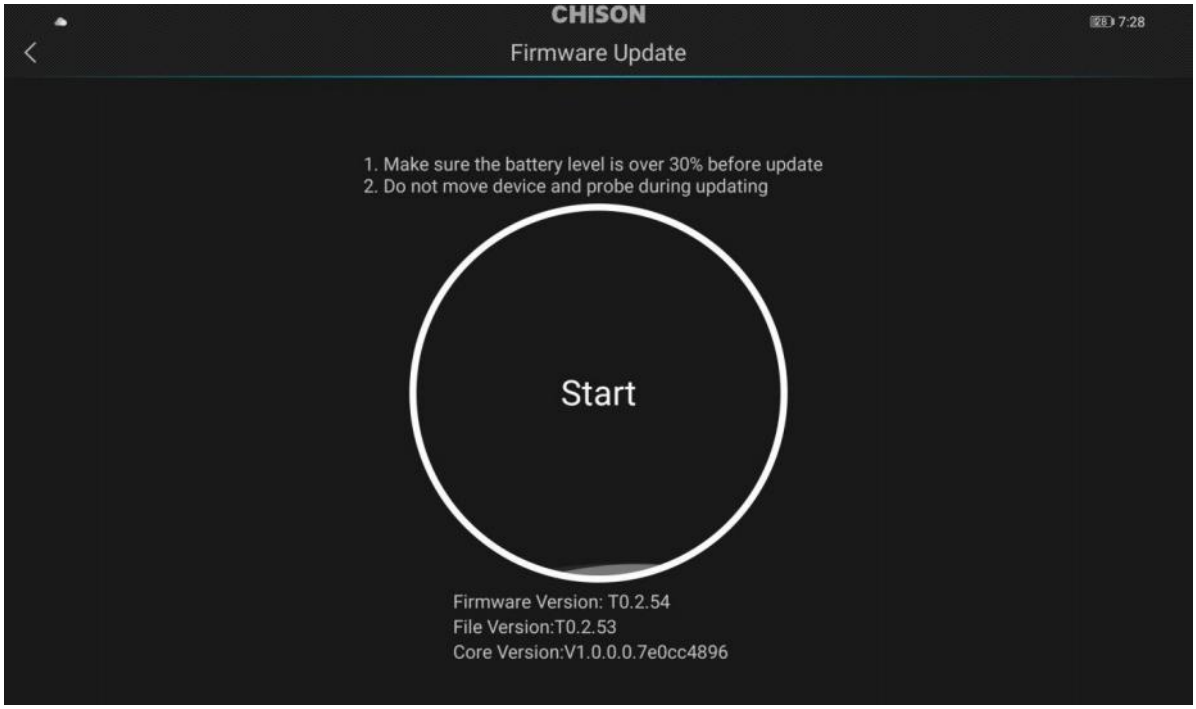


8.4.4 Administrator

Click the Administrator to manage accounts.

8.4.5 Firmware Update

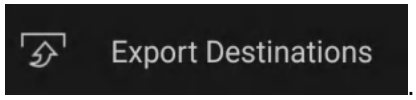
Select firmware update to upgrade system software version.



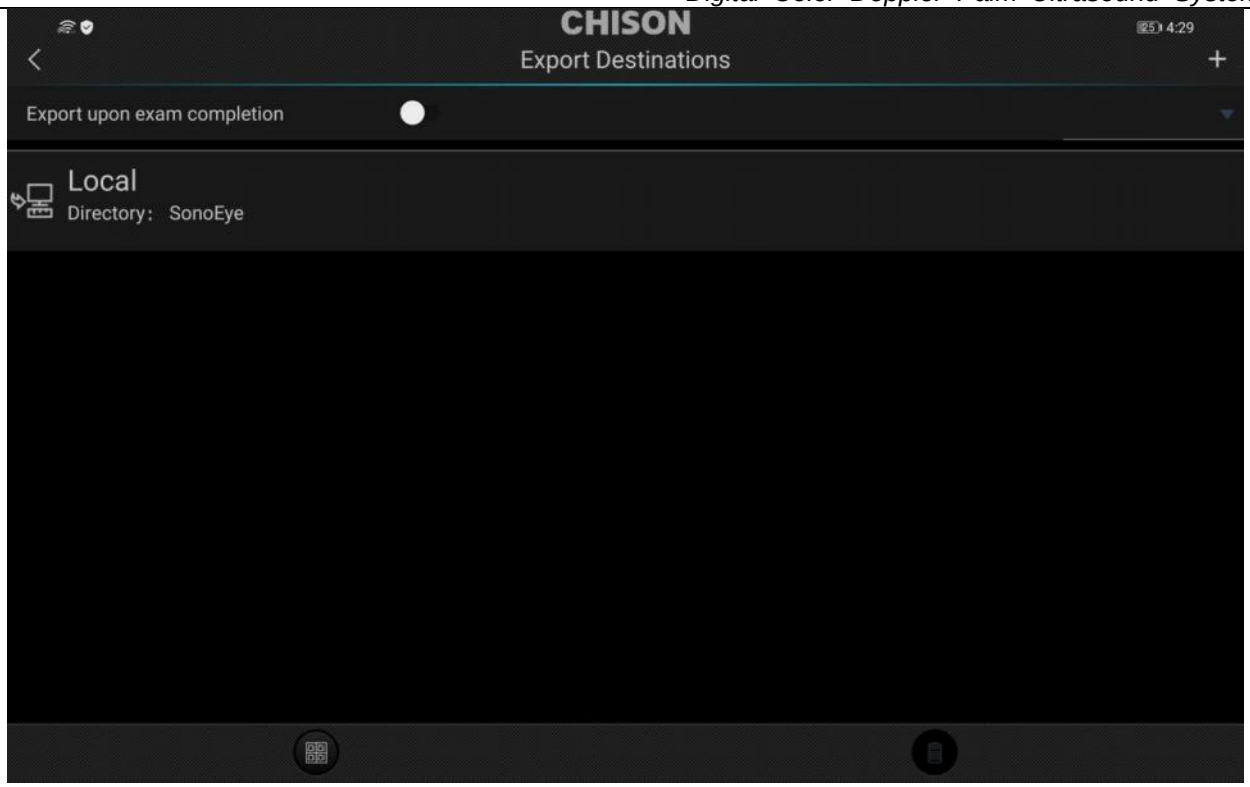
8.4.6 Function Management

Select function management to manage system functions.

8.5 Export Destinations

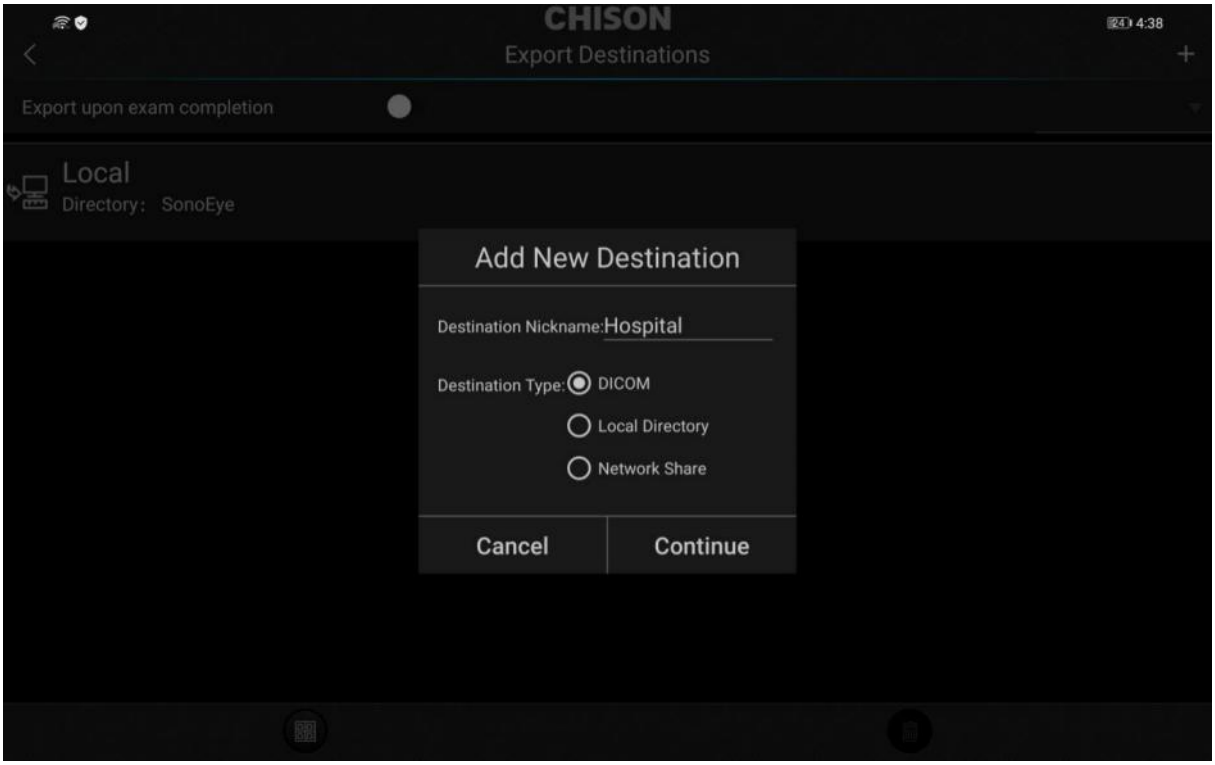
Press  and select 

.

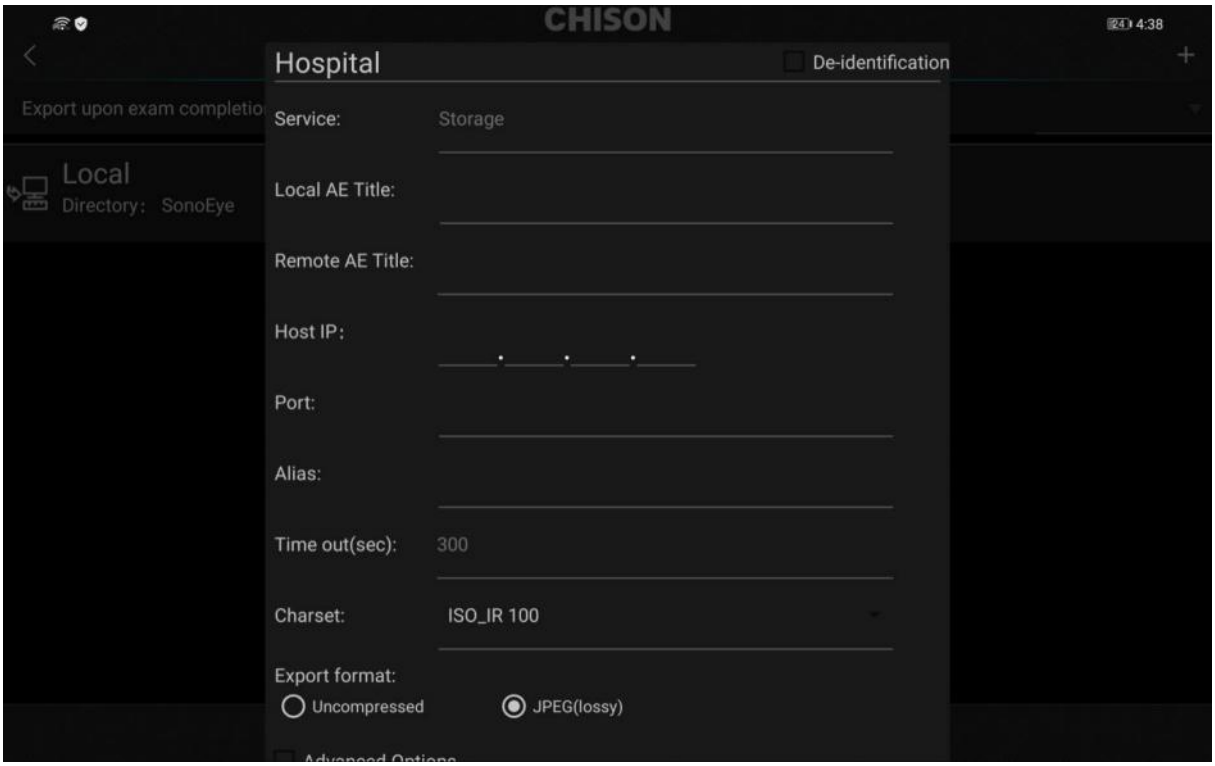


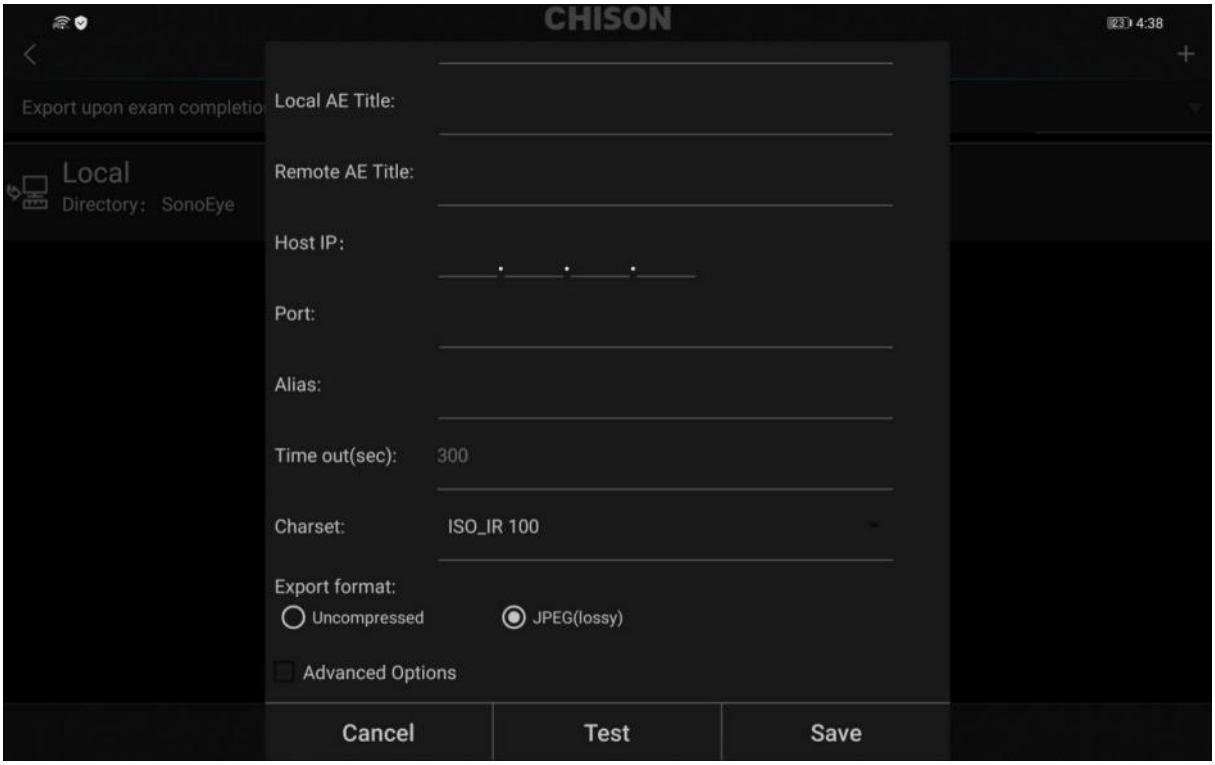
From this interface, you can add or remove export destinations.

You can enter the new interface by press +. There are three Destination types to choose from: DICOM, Local Directory, Network Share



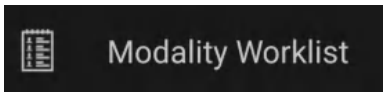
Fill in the information and select the corresponding type to enter the next level interface





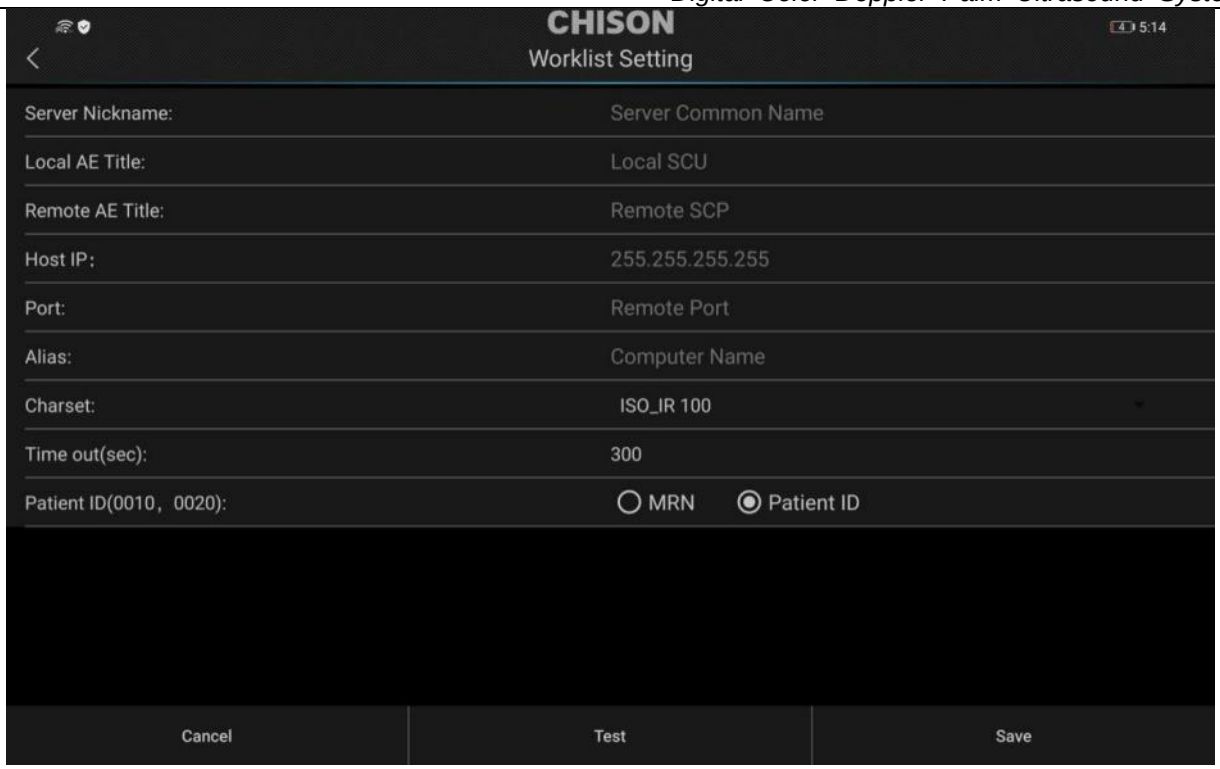
Fill in the information and click Save to complete the new Export Destination.

8.6 Modality Worklist

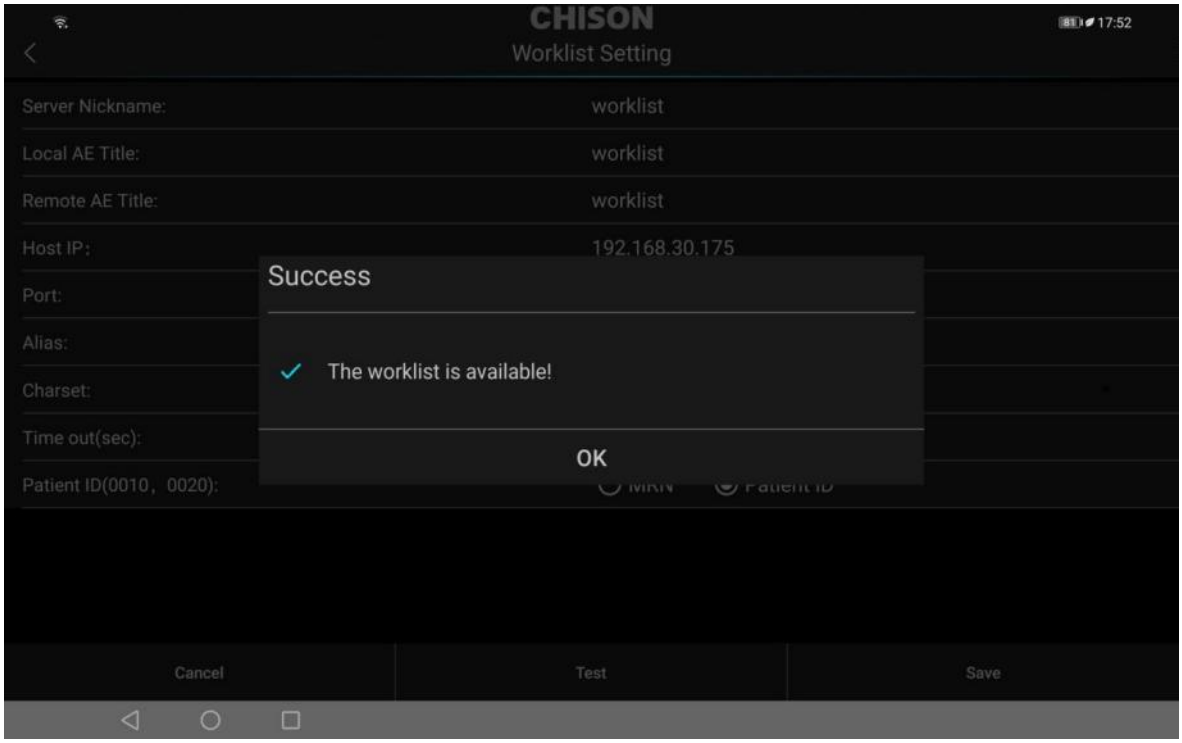
Click 

to enter it, the user can Import the worklist from the server.

Click  to add server information

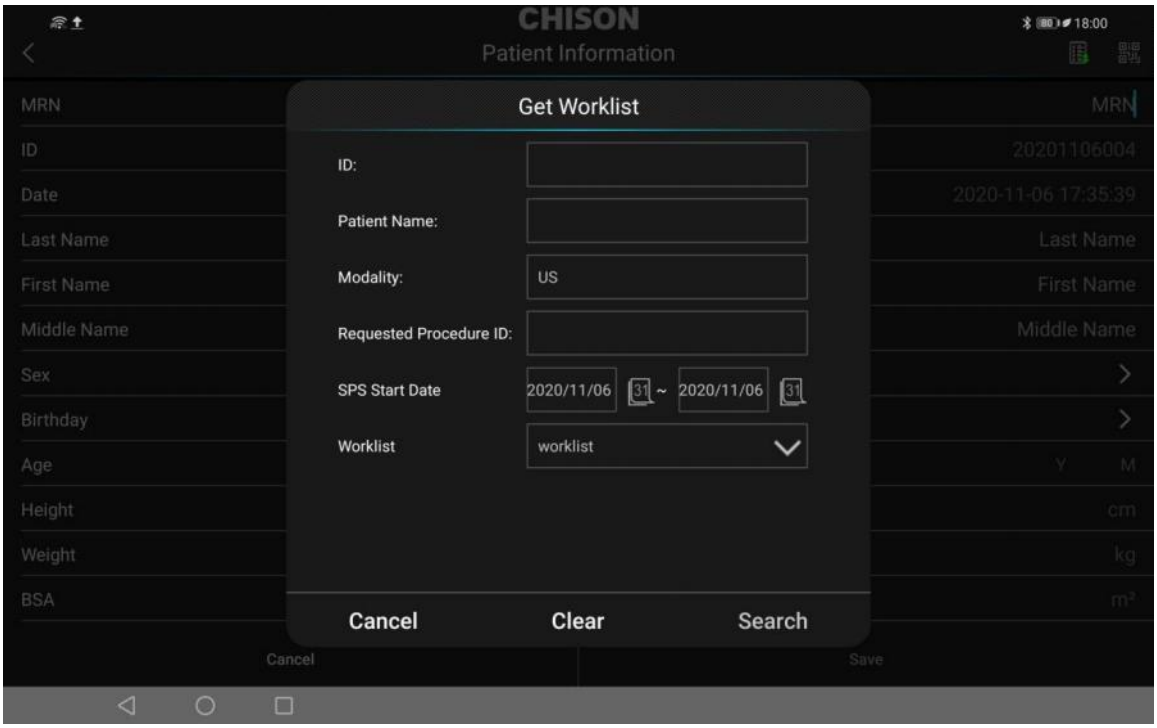


Click Test to make sure the server is connected. Then click  to save server information.



Click on enter the Patient interface and click  to enter Get worklist to import worklist from the

server

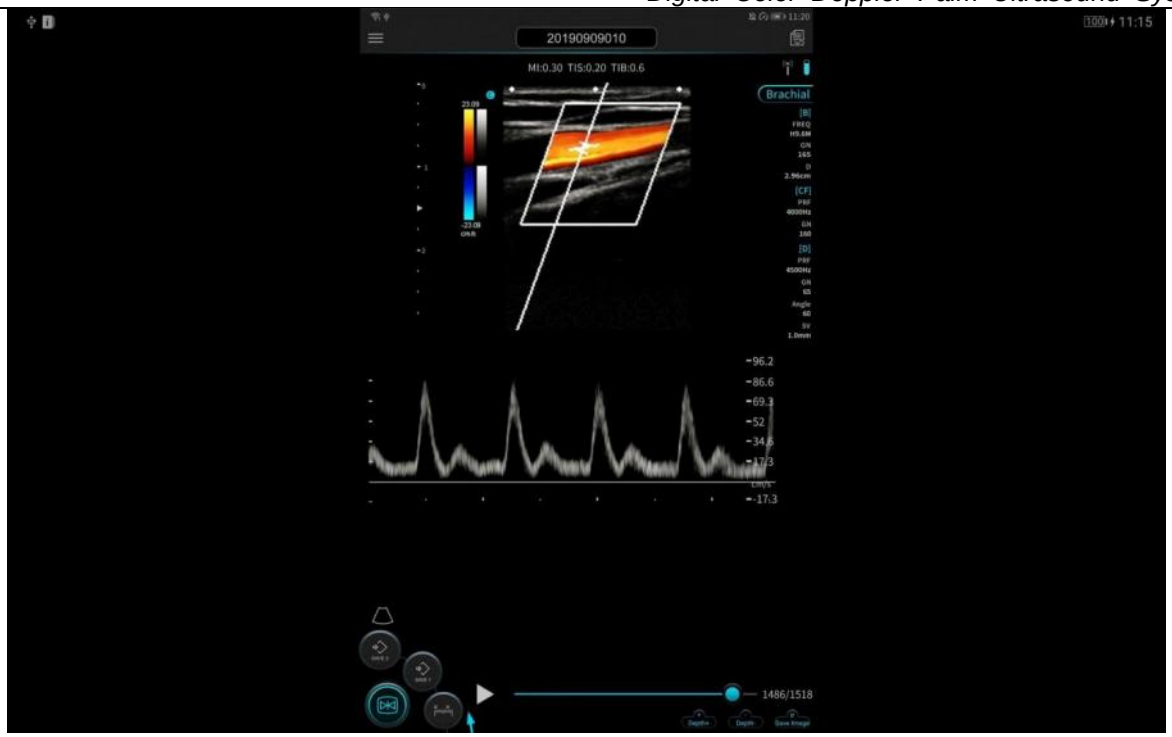


8.7 Tutorials

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  and select tutorials to enter it, there is a short video to help you learn the system.

8.8 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.

8.9 About

Press About to check the current software version.

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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 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 P5/SonoEye G5/SonoEye V5 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

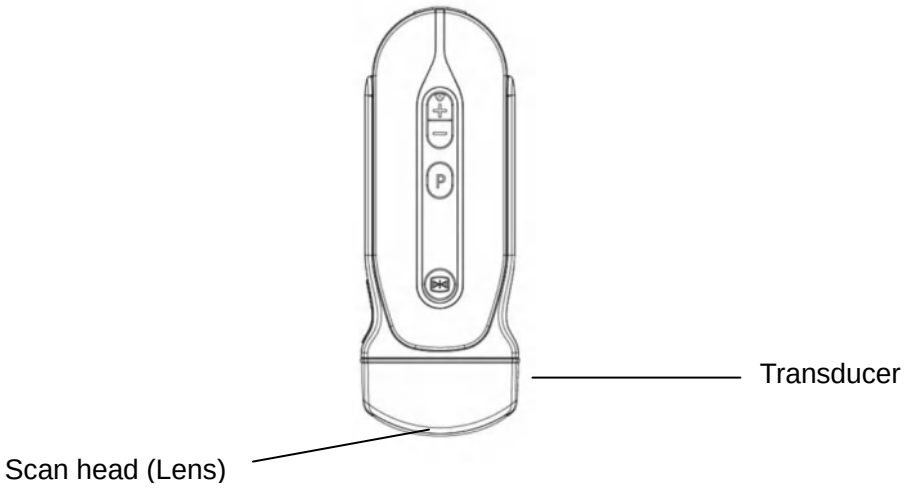

Fig.10-1: Convex Probe Overview

The system provides high spatial and contrast ultrasound imaging of frequencies from 2.0MHzto4.5MHz. 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

Definitions

Cleaning removes visible soil (for example, organic and inorganic material) from the probe surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection because inorganic and organic materials that remain on the surfaces of probes interfere with the effectiveness of these processes.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.

Low-Level Disinfection (LLD) destroys most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium tuberculosis or bacterial spores.

Intermediate-Level Disinfection (ILD) inactivates Mycobacterium tuberculosis, bacteria, most viruses, most fungi, and some bacterial spores.

High-Level Disinfection (HLD) destroys or removes all microorganisms except bacterial spores.

Transducer Components

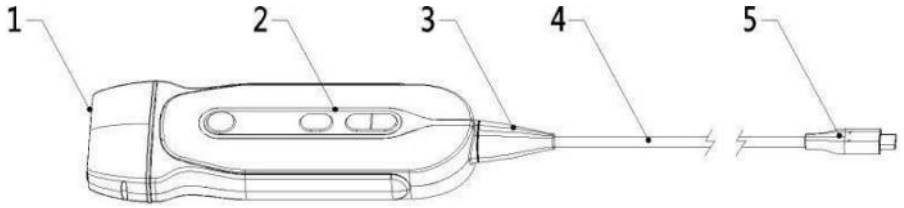

Fig.10-2: Transducer Components

1. Lens 2. Cover 3.Sheath 4.Cable 5. TYPE-C connector

To choose a suitable probe disinfection method, you must first determine its category according to the purpose of the probe. For more information about compatible cleaning and disinfecting agents, please refer to the section "Cleaning or disinfecting ". When using detergents and disinfectants, be sure to follow the manufacturer's instructions.

WARNING

After each use of the probe, it must be cleaned. Cleaning the probe is an important step before effective disinfection. When using detergents and disinfectants, be sure to follow the manufacturer's label instructions.

WARNING

When cleaning and disinfecting any instrument, be sure to wear protective glasses and gloves.

CAUTION

Using non-recommended disinfectants, inappropriate disinfectant concentration, or the immersion depth or immersion time of the probe exceeding the recommended value will cause damage or discoloration of the probe, and invalidate the probe warranty.

CAUTION

Do not use a brush when cleaning transducers. Even the use of soft brushes can damage transducers.

CAUTION

Do not leave the probe in contact with cleaning agents and disinfectants for a long time. Limit the time the probe is exposed to cleaners and disinfectants to the shortest time recommended by the manufacturer.

When you use OPA (ortho-phthalaldehyde)-based disinfectants, if you do not follow the manufacturer's instructions carefully, residual solution may remain on the probe. In order to minimize the impact of residual OPA or any other disinfectant, it is recommended as below:

- Follow the instructions of the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends as below immersing the probe in drinking water three times to rinse the probe.
- Limit the time the probe is exposed to the disinfectant to the shortest time recommended by the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends a minimum time of 12 minutes.
- Prevent any fluid from splashing on your mobile device’s touchscreen during cleaning and during disinfecting. Damage may result due to fluid.

Point-of-use processing

Before cleaning, check the probe first. If any particles or body fluids adhere to the probe or cable, you can wipe it off with a soft cloth dipped with 80% ethanol.

10.2.2.1 **Cleaning**

Recommended supplies:

Dust-free cloth or soft cloth;

Compatible cleaner or wipes for probe cleaning;

1. Disconnect the probe from the system.
2. Wear sterile gloves and use protective eyewear to prevent infection.
3. Remove Ultrasound transmission gel from the transducer by using a soft cloth dipped with potable water (not to exceed 43°C (110°F)) or an approved cleaning or disinfectant agent or by using an approved disinfectant wipe.

Gently wipe the lens to remove the gel, then wipe the probe，cable for 1 minute and until visibly clean(There is no gel, hair, debris or other residue on the probe.).

Do not wipe the connector to prevent liquid from entering the inside. Please refer to Table 10-1 below for approved compatible cleaning and disinfection products.

4.Dry the transducer using a sterile cloth or gauze after cleaning. Blot the lens dry. Do not wipe the lens. Do not dry the transducer by heating it.

10.2.2.2 **Disinfecting**

After cleaning the probe, you must disinfect the probe.

To reduce the risk of contamination and infection, it is important to choose the appropriate level of disinfection, based on prior exam usage and whether the use is classified as non-critical or semi-critical. Use Table, “Probe Disinfection Class, Use, and Method” to determine the appropriate class and then follow the appropriate intermediate-level or high-level disinfection procedure.

Probe Disinfection Class, Use, and Method

Class	**Use**	**Method**
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate- level disinfection (ILD)
Semi-Critical Class	Touches mucous membranes and non-intact skin.	Cleaning followed disinfection (HLD) by high-level

Intermediate-Level Disinfection (ILD)

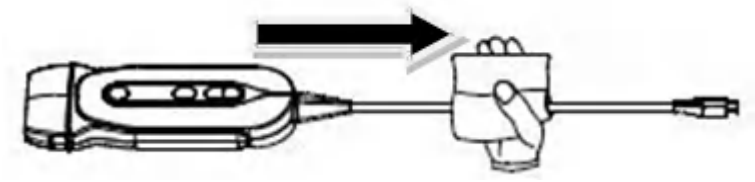

Fig.10-3: Wipe direction

1. Wear sterile gloves to prevent infection.
2. Wipe the probe, with approved compatible disinfectant wipes or soft cloth dipped in disinfectant agent. As shown in the figure above, wiping from lens toward cable. Do not wipe the type-c linker to prevent poor contact.
3. Ensure that the disinfected surface remains visibly moist for at least two (2) minutes, use additional
   fresh wipes as needed.
4. Allow to air dry.
5. After cleaning and disinfection, check the appearance of the probe to see whether the transducer and cable are worn or damaged

High Level Disinfection

It is recommended that you use Cide®OPA by Ethicon US, LLC.

1. After cleaning the probe, you must disinfect the probe. It is recommended that you use Cidex® OPA high- level disinfection solution.
2. Prepare Cidex® OPA high-level disinfection solution for use per the manufacturer's instructions. Fill a tray or basin with the disinfectant solution at room temperature (minimum temperature of 20°C) to a level allowing immersion of the probe up to the immersion line (As shown below),

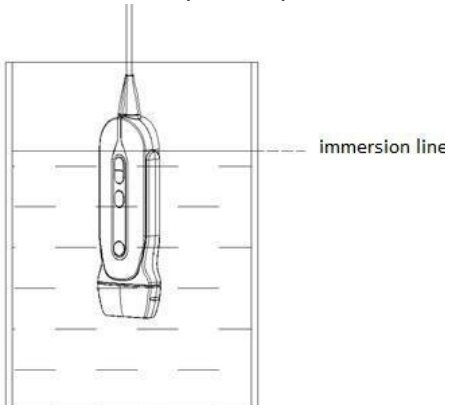

Fig.10-4: Soaking depth

3. Immerse the probe in Cidex® OPA solution up to the immersion line and ensure no air or bubbles are trapped. Allow soaking according to the manufacturer's instructions.
4. Thoroughly rinse the probe (up to the immersion line) by immersing it in a large volume of room temperature purified water for a minimum of one (1) minute. Remove the probe and discard the rinse water. Do not reuse the water. Always use fresh volumes of water for each rinse. Repeat this stage two (2) additional times for a total of three (3) rinses.
5. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the device is completely dry. Inspect the device to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is visible.
6. Once clean and disinfected, inspect the probe, strain relief, cable, and connector for signs of damage or wear.
7. Daily and Long-Term Storage follow these guidelines to protect the probe.
8. Always store transducers in the probe case when you are not using them.

CAUTION

Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use. Do not soak the transducer connector or the cable near it into water or any solution.

CAUTION

Follow local regulations when selecting and using the disinfectant.

10.2.2.3 **Approved and compatible cleaning and disinfectant**

Table 10-1：Cleaning and disinfection list

Wipes type	Brand	Place of origin	Chemical ingredient	solution
80% Ethanol (Soak with a soft cloth)	Any manufacturer	Any	Ethanol	Clean/LLD/ILD
70% Isopropyl alcohol(Soak with a soft cloth)	Any manufacturer	Any	Isopropyl alcohol	Clean/LLD/ILD
Universal wipes	Clinell	United Kingdom	Compound double chain quaternary ammonium salt	Clean/LLD/ILD
perform classic	Schulke&Mayr	Germany	Compound	Clean/LLD/ILD

wipes EP	GmbH		alcohol	
WIP'ANIOS	Laboratoires ANIOS	France	Isopropyl alcohol/Didecyl dimethyl ammonium chlorides	Clean/LLD/ILD
Sani-cloth AF3,Sani- Cloth AF	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopropyl alcohol	Clean/LLD/ILD
Super Sani-Cloth	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopropyl alcohol	Clean/LLD/ILD

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 signsof 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

- Before cleaning, turn off the system
- To clean the touch screen.

  a. Remove dust with a soft, lint-free cloth.

  b. Please wipe the screen with cleaner specially designed for LCD. Spray the liquid onto the cleaning cloth and gently wipe the screen clean. You can also use pre-moistened screen wipes.

  c. Dry the screen with a soft, lint-free cloth
- Wipe the remaining external surfaces of the system with soft cloth dipped few 70% isopropyl, 80% Ethanol solution or recommended wipes.
- Gently remove any residue with a cloth lightly moistened with purified water.
- Dry the equipment to prevent potential corrosion.

If the equipment has come in contact with blood or infectious material, see “Infection Control”.

Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection control procedures established in your facility for the protection of both the staff and the patient.

WARNING

If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your CHISON service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

CAUTION

Remove blood on the system and the transducer connectors and cables with a soft cloth dipped few soap and potable water. Then dry the equipment with a soft, dry, lint-free cloth to prevent corrosion.

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 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

R Sight B.V.

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Appendix B: ACOUSTIC OUTPUT REPORT TABLE

Transducer Model: SonoEye P5/SonoEye G5/SonoEye V5

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.05	0.11		0.11		0.25
Index component Value				0.11	0.11	0.11	0.11	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.58					
	P	(mW)		10.02		10.02		12.62
	P_{1*1}	(mW)		10.02		10.02		
	Z_s	(cm)			2.15			
	Z_b	(cm)					2.15	
	Z_{MI}	(cm)	2.15					
	$Z_{pii.\alpha}$	(cm)	2.15					
	f_{awf}	(MHz)	2.25	2.25		2.25		2.22
Other Information	prr	(Hz)	-					
	srr	(Hz)	18.94					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	79.17					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.79					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.82					
	p_r at Z_{pii}	(MPa)	1.79					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		3.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	2.00	2.00		2.00		2.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P5/SonoEye G5/SonoEye V5

Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.12	0.26		0.58		0.36
Index component Value				0.26	0.18	0.26	0.58	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.65					
	P	(mW)		20.12		20.12		20.12
	P_{1*1}	(mW)		14.58		14.58		
	Z_s	(cm)			1.52			
	Z_b	(cm)					2.22	
	Z_{MI}	(cm)	2.05					
	$Z_{pii.\alpha}$	(cm)	2.05					
	f_{awf}	(MHz)	2.16	2.16		2.16		2.16
Other Information	prr	(Hz)	346					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	80.46					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	8.77					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	8.89					
	p_r at Z_{pii}	(MPa)	1.75					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		3.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	2.00	2.00		2.00		2.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P5/SonoEye G5/SonoEye V5

Operation Mode:B+CFM

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.88	0.22		0.22		0.50
Index component Value				0.22	0.22	0.22	0.22	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.39					
	P	(mW)		24.21		24.21		28.90
	P_{1*1}	(mW)		18.68		18.68		
	Z_s	(cm)			3.20			
	Z_b	(cm)					3.20	
	Z_{MI}	(cm)	2.60					
	$Z_{pii.\alpha}$	(cm)	2.60					
	f_{awf}	(MHz)	2.51	2.48		2.48		2.38
Other Information	prr	(Hz)	-					
	srr	(Hz)	6.49					
	n_{pss}	NA	8.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	94.79					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.50					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.51					
	p_r at Z_{pii}	(MPa)	1.73					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		5.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	3.00	3.00		3.00		3.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEye P5/SonoEye G5/SonoEye V5

Operation Mode:PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.63	0.20		0.74		0.38
Index component Value				0.15	0.20	0.16	0.74	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.00					
	P	(mW)		21.79		18.92		22.59
	P_{1*1}	(mW)		12.61		14.60		
	Z_s	(cm)			1.40			
	Z_b	(cm)					3.20	
	Z_{MI}	(cm)	3.05					
	$Z_{pii.\alpha}$	(cm)	3.05					
	f_{awf}	(MHz)	2.48	2.47		2.50		2.45
Other Information	prr	(Hz)	2000					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	40.29					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	109.67					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	213.87					
	p_r at Z_{pii}	(MPa)	1.22					
Operating control conditions	Focus	(cm)	4.00	11.00		4.00		7.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	3.00	3.00		3.00		3.00
	PRF	HZ	2000	2000		2000		2000

Appendix C: TRANSDUCER MAXIMUM SURFACE TEMPERATURE

Transducer model	Maximum surface temperature(℃) Contacting human-tissue mimicking material	Maximum surface temperature(℃) Suspending in air
SonoEye P5	**<37.6**	**<31.4**
SonoEye V5	**<37.6**	**<31.4**
SonoEye G5	**<37.6**	**<31.4**

Overall uncertainties

Center Frequency: The accuracy of the center frequency measurement is primarily dependent on the digitizer, and is therefore given as ± 2%.

Pressue: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 13.37%.

Intensity and Power: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 26.75%.

It can be summarized in below table:

Item	Measurement Uncertainty (95% Confidence Level)
Center frequency	±2.00%
Pressure	±13.37%
Intensity	±26.75%
Power	±26.75%

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 ofSonoEye 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 electronicequipment.
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 environment.
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 table 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.

Appendix F: PULSED WAVE DOPPLER VELOCITY MEASUREMENT RESULTS SUMMARY

Probe type: SonoEye P5, Scan mode: PW, fc: 3.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.26	107.64	138.74
Measurement Error (%)	2.60%	7.64%	-7.50%

Probe type: SonoEye P5, Scan mode: CFM, fc: 3.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.62	51.69	102.64
Measurement Error (%)	-3.80%	3.38%	2.64%

Probe type: SonoEyeV5, Scan mode: PW, fc: 3.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.34	103.87	141.24
Measurement Error (%)	3.40%	3.87%	-5.84%

Probe type: SonoEye V5, Scan mode: CFM, fc: 3.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.86	52.97	107.32
Measurement Error (%)	8.60%	5.94%	7.32%

Probe type: SonoEye G5, Scan mode: PW, fc: 3.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	9.14	108.36	161.85
Measurement Error (%)	-8.60%	8.36%	7.9%

Probe type: SonoEye G5, Scan mode: CFM, fc: 3.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	9.12	46.56	108.12
Measurement Error (%)	-8.80%	-6.88%	8.12%

Digital Color Doppler Palm Ultrasound System

Model
SonoEye P6/SonoEye V6/SonoEye G6

USER MANUAL

CHGA-SonoEye-043-P6

Feb.25th, 2024

Rev. 2.1

CHISON Medical Technologies Co., Ltd.

We reserve the right to make changes to this manual without prior notice.

Regulatory Requirement

CE 0197 This product conforms to the essential requirements of the Medical Device Directive93/42/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 SonoEyeP6/SonoEyeV6/SonoEyeG6. 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

The 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 Cardiac, Abdomen.

The Digital Color Doppler Palm Ultrasound System isintended 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.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: 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 the protective covers on the system. These covers protect users from hazardous voltages. A qualified electronic technician must make all internal replacements.
- Do not operate this system in the presence of flammable gases or anesthetics.

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

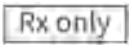
User modifications may cause degradation in EMC performance. Modification of the product includes changes in:

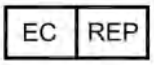
- Cables (length, material, wiring, etc.)
- System installation/layout
- System configuration/components

2.3 Labels

Fig. 2-1: SonoEye 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.

	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.
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY: This symbol is accompanied by the name and the address of the authorized representative in the European Community.
	Scan the QR code to open CHISON website.
	Unique Device Identifier.

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:

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

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

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

- 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 bythe 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 CFM 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 to4, wherefc is the center frequency in MHz.

W_{deg}= 40 K D for model 5 and 6, whereK (beamshape 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.

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.

2.7 Device instructions of cybersecurity controls

2.7.1 Software Integrity Control

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

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

  The following controls are in place to assure that the device software will be protected from malware from the point of origin to the point at which that device leaves the manufacturer’s control point.
- Installing OS Updates Immediately

  Whenever an update appears on the screen, consider installing an operating system update immediately to avoid virus and malware attacks.
- The device software doesn't provide any entrance for executing third party application.
- Never trust an unknown computer

  The device connect computer with USB port. Do not plug the device into an unknown computer.
- Install anti-virus software and use firewall and scan device regularly with antivirus software.
- Keep network safe

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

2.7.2 Device instructions of cybersecurity controls

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

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

2.8 Insturctions to the intruded device

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

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

Chapter 3 Preparing the System for Use

3.1 Site Requirement

3.1.1 Operation 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 as above, otherwise the system may be damaged or can't work.***

3.1.3 Hardware Requirements

The digital color doppler palm ultrasound system includes the transducer, software and a COTS device. The minimum requirements for COTS equipment are as follows:

- IEC 60950-1 compliant
- IEC 55032 compliant
- Octa-core processor (CPU)
- 1 GB of memory
- 1 GB of storage (on-board)
- Touch interface
- Internally mounted speakers
- Operating System: Android 9 or newer

- Display Resolution (in pixels): 1920×1200 or more
- Interface: Type C, USB 2.0

WARNING

Using the SonoEye app on a COTS device that does not meet the minimum specification may result in poor image quality, unexpected results, possible misdiagnosis or not working.

WARNING

The COTS cannot be charged while the transducer is in use for safety.

3.1.4 Programming Language Requirements

Operation System: Android
Programming Environment: Android Studio

3.1.5 The requirement of commercial off-the-shelf (COTS) devices

All models need to comply with IEC55032, IEC60950-1, among which we have selected typical models to do verification testing with SonoEye on ANSI/AAMI ES60601-1 and IEC60601-1-2, such as Samsung Galaxy A70s or Huawei MatePad Pro.

- Electrical Safety

  The transducer and software, along with a representative device, have been verified as compliant with IEC 60601-1. The transducers meet Type BF isolated applied part requirements. When the transducer and software are used in conjunction with a device (COTS devices) compliant with IEC 60950-1, the system meets IEC 60601-1 requirements for Class II equipment.

- Electromagnetic Compatibility

  The transducer and representative Android device are classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. When the transducer and software are used in conjunction with a device (COTS devices) compliant with IEC 55032, the system meets IEC 60601-1-2 requirements for Group1, Class A equipment.

- Android devices' output current and voltage

The representative Android devices' output current is 1.5A and voltage is 5V. A COTS device connected to our transducer and system should meet the current and voltage range, the output current is greater than or equal to 1.5A, and the output voltage is 5V±5%.

- Full compliance with USB 2.0 standard

  The representative Android devices are full compliance with USB 2.0 standard. A COTS device connected to our transducer and system should meet the standard.

- Representative Android devices

  Representative Android devices are Samsung Galaxy A70s and Huawei MatePad Pro. The configuration is as follows.

  Samsung Galaxy A70s：

  - •CPU frequency 2.0GHz (big quad core), 1.7GHz (small quad core), Octa-core
  - •RAM capacity 8GB
  - •ROM capacity 128GB
  - •Main screen resolution 2400x1080 pixels
  - •WLAN function Dual-band WIFI, IEEE 802.11 a/b/g/n/ac (support 2.4G and 5GHz)
  - •Operating System: Android 9
  - •Support Bluetooth 5.0

  Huawei MatePad Pro：

  - •CPU frequency 2 x Cortex-A76 Based 2.86 GHz+ 2 x Cortex-A76 Based 2.09 GHz+ 4 x Cortex-A55
  - •1.86 GHz, Octa-core
  - •RAM capacity 8GB
  - •ROM capacity 128GB
  - •Main screen resolution 2560x1600 pixels
  - •WiFi function supports dual frequency (2.4GHz+5GHz)
  - •Bluetooth function supports Bluetooth 5.1 module
  - •Operating System: Android 9

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:

Connect the SonoEye to your device, the SonoEye will be on automatically. And after a few seconds, the device will be automatically connected.

If you turn off the SonoEye, you can press  for 3 seconds to turn on the system.

2. Power off:

Press  for 3 seconds to shut down the system

3.3 System Specifications

3.3.1 Console Overview

SonoEye P6/SonoEye V6/SonoEye G6 system:

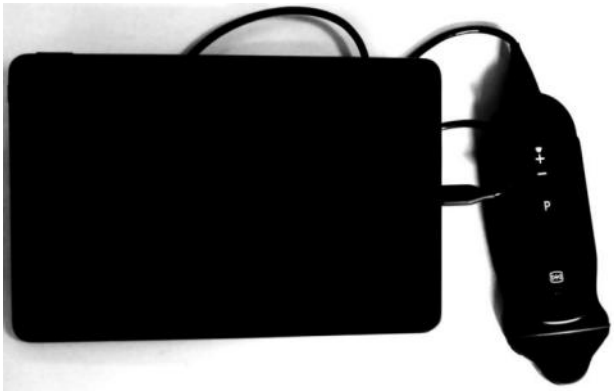


Fig. 3-1: Console Overview

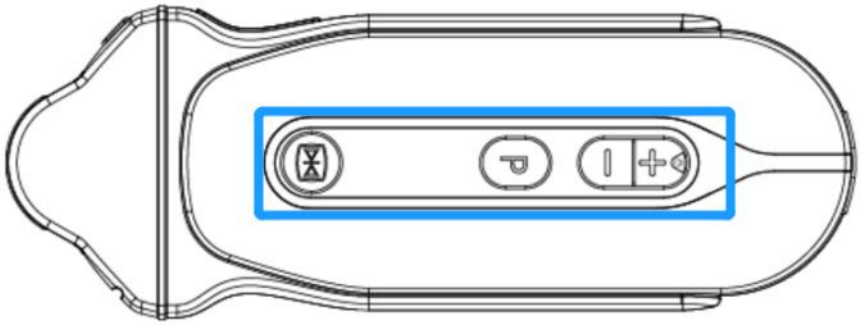


Fig. 3-2: Firmware Front View for SonoEyeP6/SonoEyeV6/SonoEyeG6 system

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）*174mm（Height）*24mm（Depth）

Net weight of main unit (approx): 195g

3.3.3 Image Modes

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

3.3.4 Type

		
Micro-convex Array: P6 4.0MHz-8.0MHz	Micro-convex Array: V6 4.0MHz-8.0MHz	Micro-convex Array: G6 4.0MHz-8.0MHz

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 cable 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.

3.3.5 System Configuration

Function	SonoEye P6	SonoEye V6	SonoEye G6
B mode	Standard	Standard	Standard
B/M mode	Option	Option	Option
PW mode	Option	Standard	Option
CFM mode	Option	Option	Option
FHI	Option	Option	Standard
Type-C cable	Standard	Standard	Standard
Identify probe	Standard	Standard	Standard
Switch exam mode	Standard	Standard	Standard
Gain	Standard	Standard	Standard
Depth	Standard	Standard	Standard
STC	Standard	Standard	Standard
Focus	Standard	Standard	Standard
Zoom	Standard	Standard	Standard

Adjust sample Gate location	Option	Option	Option
Adjust size of sample Gate horizontal	Option	Option	Option
Adjust size of sample Gate vertical	Option	Option	Option
Adjust PW sample gate	Option	Option	Option
Compound	Standard	Standard	Standard
Frequency Scaling	Standard	Standard	Standard
Freeze/Unfreeze	Standard	Standard	Standard
B-distance	Standard	Standard	Standard
B-Circumference	Standard	Standard	Standard
B-Area	Standard	Standard	Standard
B-Volume	Standard	Standard	Standard
B/M-Distance	Option	Option	Option
B/M-Time	Option	Option	Option
B/M-HR	Option	Option	Option
PW-Velocity	Option	Option	Option
PW-Time	Option	Option	Option
Vessel measure package	Option	Option	Option
Abdomen measure package	Option	Option	Option
Cardiac measure package	Option	Option	Option
General report	Option	Option	Option
Vessel report	Option	Option	Option
Abdomen report	Option	Option	Option
Cardiac report	Option	Option	Option
English Interface	Standard	Standard	Standard
Multi-language Interface	Option	Option	Option
Instant AIO	√	Option	Option
Biopsy Guide	Option	Option	Option
SonoNeedle	Option	Option	Option
SuperNeedle	Option	Option	Option
SonoRemote	Option	Option	Option
Save Cine	Standard	Standard	Standard
Save Image	Standard	Standard	Standard
Cine Loop	Option	Option	Option
Annotation	Option	Option	Option
Bodymark	Option	Option	Option
Mark	Option	Option	Option
Patient management	Option	Option	Option
Voice/Angle/Baseline on PW	Option	Option	Option
Content in interference:	Standard	Standard	Standard

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)**			
Physical key	Standard	Standard	Standard
Setting	Standard	Standard	Standard
Archive	Standard	Standard	Standard
Tutorials	Standard	Standard	Standard
EasyView	Standard	Standard	Standard
Demo	Standard	Standard	Standard
About	Standard	Standard	Standard

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 SonoEyeP6/SonoEyeG6/SonoEyeV6 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 4-1 Display Interface

1. Side Menu
2. Application
3. Parameters control
4. Center Line
5. Full Screen
6. B/M mode
7. PW mode
8. CFM mode
9. Freeze
10. Logo
11. Patient information
12. End Exam
13. Connection status
14. Image parameter area
15. 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.

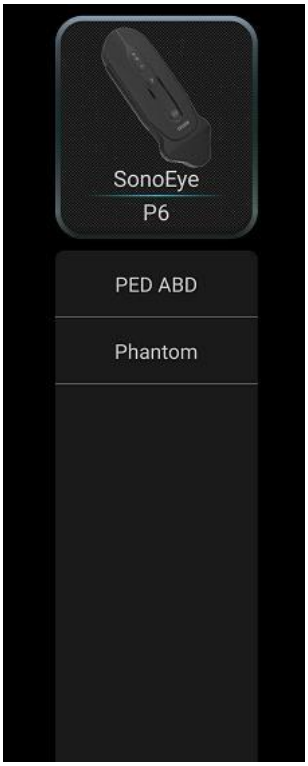
2. On the patient Info display, type the patient information.

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

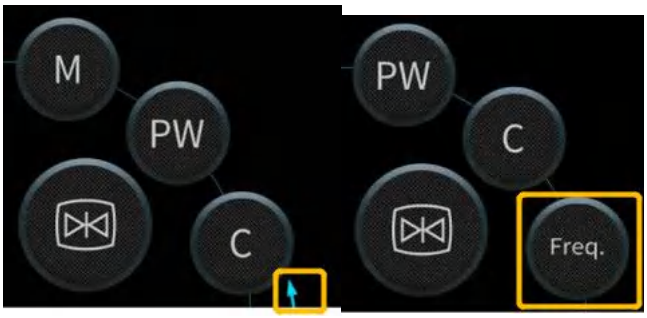
4.3 Application

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



Switching Function

Slide the top left along the buttons to show Freq.

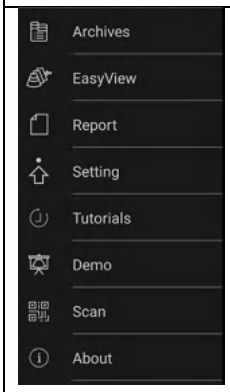
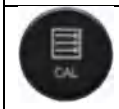
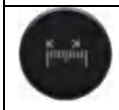


4.4 Switching Mode

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

4.5 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.
	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.

4.6 Image Parameter Area

Display information about application, frequency, mode, depth, gain and etc.

4.7 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.

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, FHI 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 pseudomorphism 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.

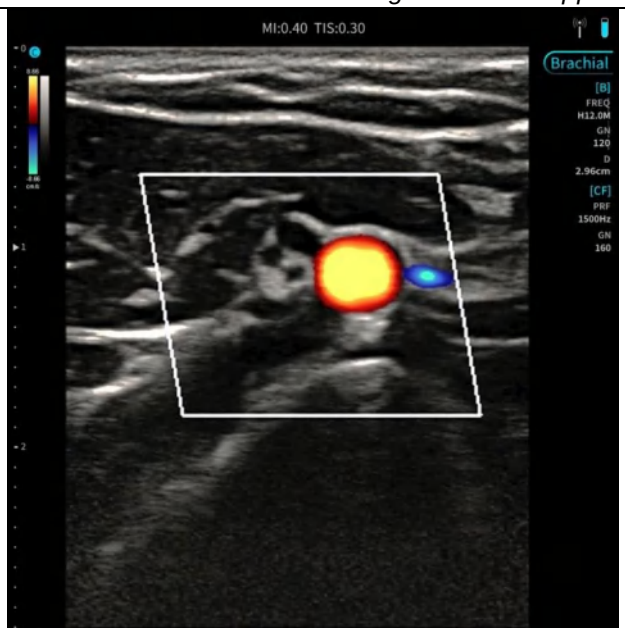


Fig. 5-1 CFM Mode

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 onside menu, select images on current exam and compare exam to start lung analysis, and result will display below the image.

5.1.9Biopsy 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.

5.1.10SonoNeedle

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

5.1.11SuperNeedle

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

5.1.12SonoRemote

SonoRemote enables remote real-time ultrasound diagnosis.

Install SonoRemote on PC and open it, check the network connection. The SonoRemote will register an account automatically when you first log into 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 account automatically when you first log into 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

At real-time state, touch the screen with two fingers and slide it outward to enlarge the image.

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 submenu appears, press  . “ | ”is displayed in image area and the soft icon board appeared

in the bottom of screen.

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

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

5.4.2 Adding BodyMark

Operation:

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

2. The submenu 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.

5.4.3Adding 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 Abdomen Measurement in B mode

Meas. item name	mark	unit	Meas. Method and calc. formula
CBD	CBD	cm	Refer to “Distance” measurement in 6.1
GB Wall	GB Wall	cm	Refer to “Distance” measurement in 6.1
Liver Length	Liver Length	cm	Refer to “Distance” measurement in 6.1
Spleen	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
Renal 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
GB Volume	Length	cm	Refer to “Distance” measurement in 6.1
	Width	cm	Refer to “Distance” measurement in 6.1
	Height	cm	(3.14159265/6) * Length * Height * Width
IVC	IVC Ins	cm	Refer to “Distance” measurement in 6.1
	IVCExp	cm	Refer to “Distance” measurement in 6.1

6.2.3 Cardiac Measurement in B mode

Meas. item name	mark	unit	Meas. Method and calc. formula
IVSd	IVSd	cm	Refer to “Distance” measurement in 6.1
LVIDd	LVIDd	cm	Refer to “Distance” measurement in 6.1
LVPWd	LVPWd	cm	Refer to “Distance” measurement in 6.1
IVSs	IVSs	cm	Refer to “Distance” measurement in 6.1
LVIDs	LVIDs	cm	Refer to “Distance” measurement in 6.1
LVPWs	LVPWs	cm	Refer to “Distance” measurement in 6.1

EDV	EDV	ml	(7*LVIDd^3/1000)/(2.4+(LVIDd/10))
ESV	ESV	ml	(7*LVIDd^3/1000)/(2.4+(LVIDd/10))
SV	SV	ml	EDV-ESV
CO	CO	L/min	HR*SV/1000
EF	EF	%	100*SV/EDV
FS	FS	%	100*（LVIDd-LVIDs）/LVIDd
SI	SI		SV/BSA
CI	CI		CO/BSA
EDV(A2C/A4C)		ml	$EDV(ml)=\pi\times\frac{LVLd\ apical(cm)}{20}\times\sum_{i=1}^{20}r_i^2(cm)$
ESV(A2C/A4C)		ml	$ESV(ml)=\pi\times\frac{LVLs\ apical(cm)}{20}\times\sum_{i=1}^{20}r_i^2(cm)$
SV	SV	ml	EDV-ESV
CO	CO	L/min	HR*SV/1000
EF	EF	%	100*SV/EDV
SI	SI		SV/BSA
CI	CI		CO/BSA
IVC Ins	IVC Ins	cm	Refer to “Distance” measurement in 6.1
IVC Exp	IVC Exp	cm	Refer to “Distance” measurement in 6.1
LVOT Diam	LVOT Diam	cm	Refer to “Distance” measurement in 6.1
LVOT Area	LVOT Area	cm^2	Refer to “Ellipse” measurement in 6.1
AV Diam	AV Diam	cm	Refer to “Distance” measurement in 6.1
AV Area	AVArea	cm^2	Refer to “Ellipse” measurement in 6.1

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

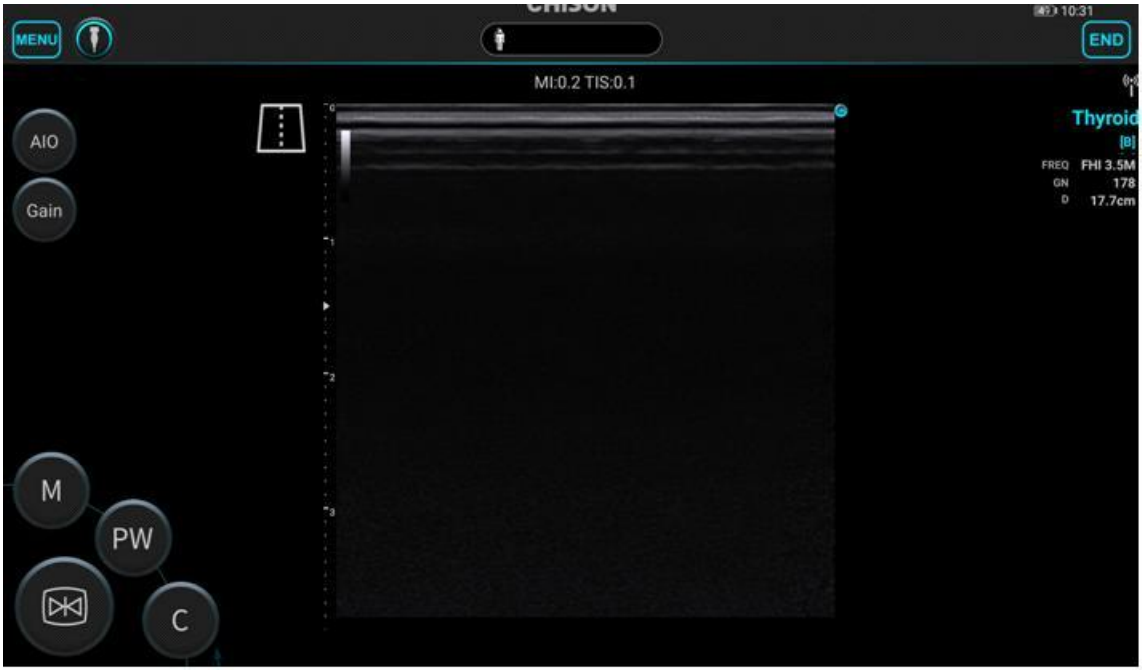
Press Freeze and click  to start automatic playback.

7.4 Cine Save

Press Freeze and click  to save current cine.

Chapter 8 Side Menu

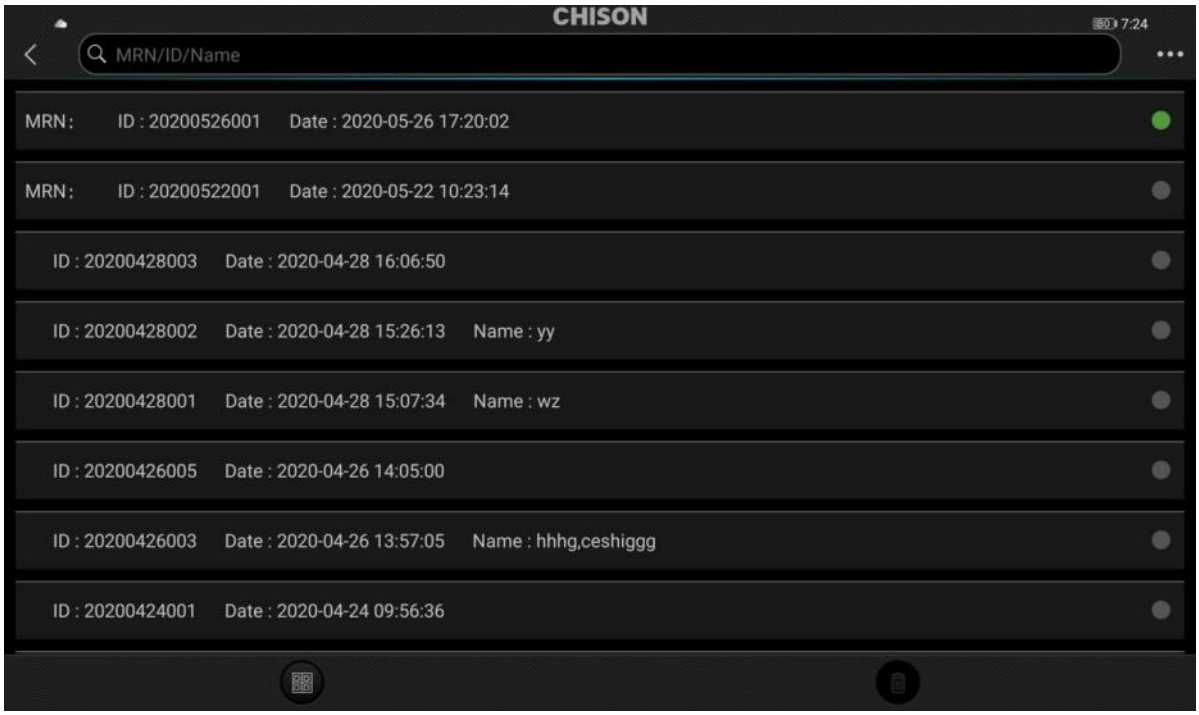
The setting function is used to set the system's startup operating environment, state and configuration parameters of each exam mode. The settings are stored in system's memory and are not lost when the power is turned off.



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.

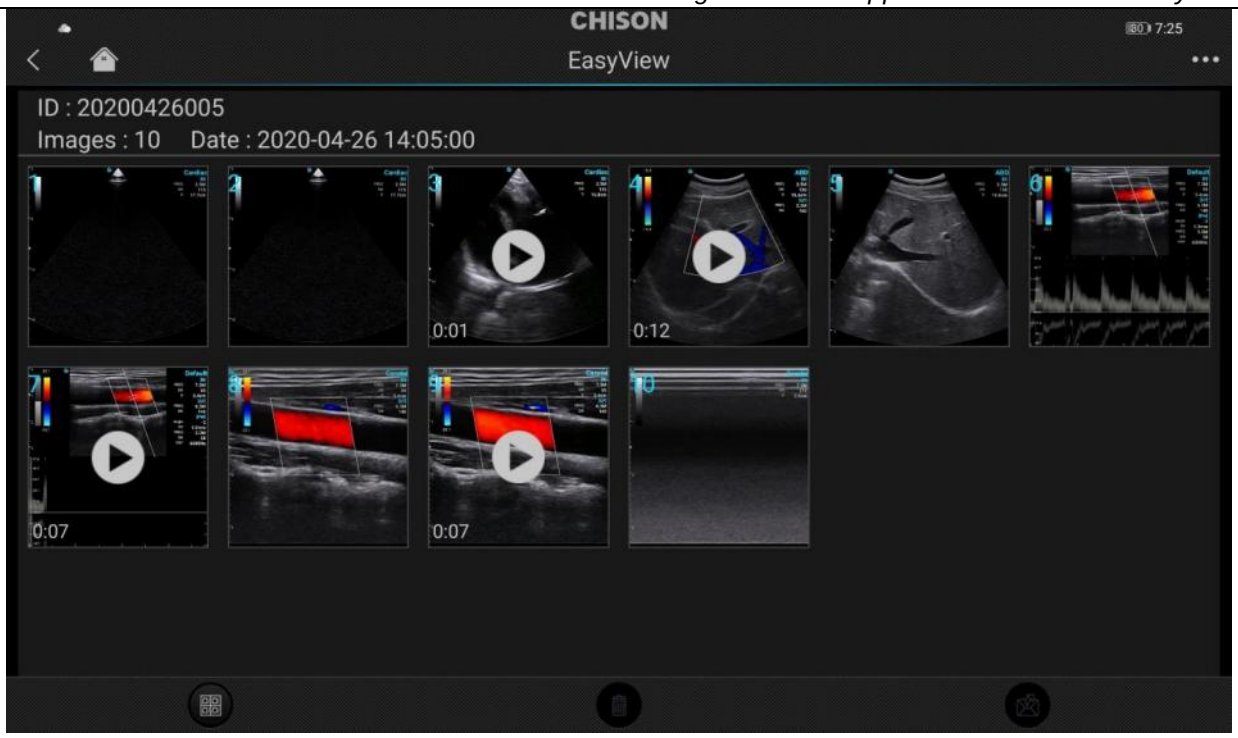
 : Select all archives.

 : Press it to delete selected archive.

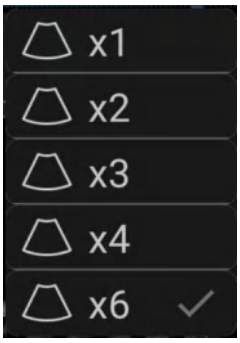
Press selected archive to enter EasyView.

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 selected image.

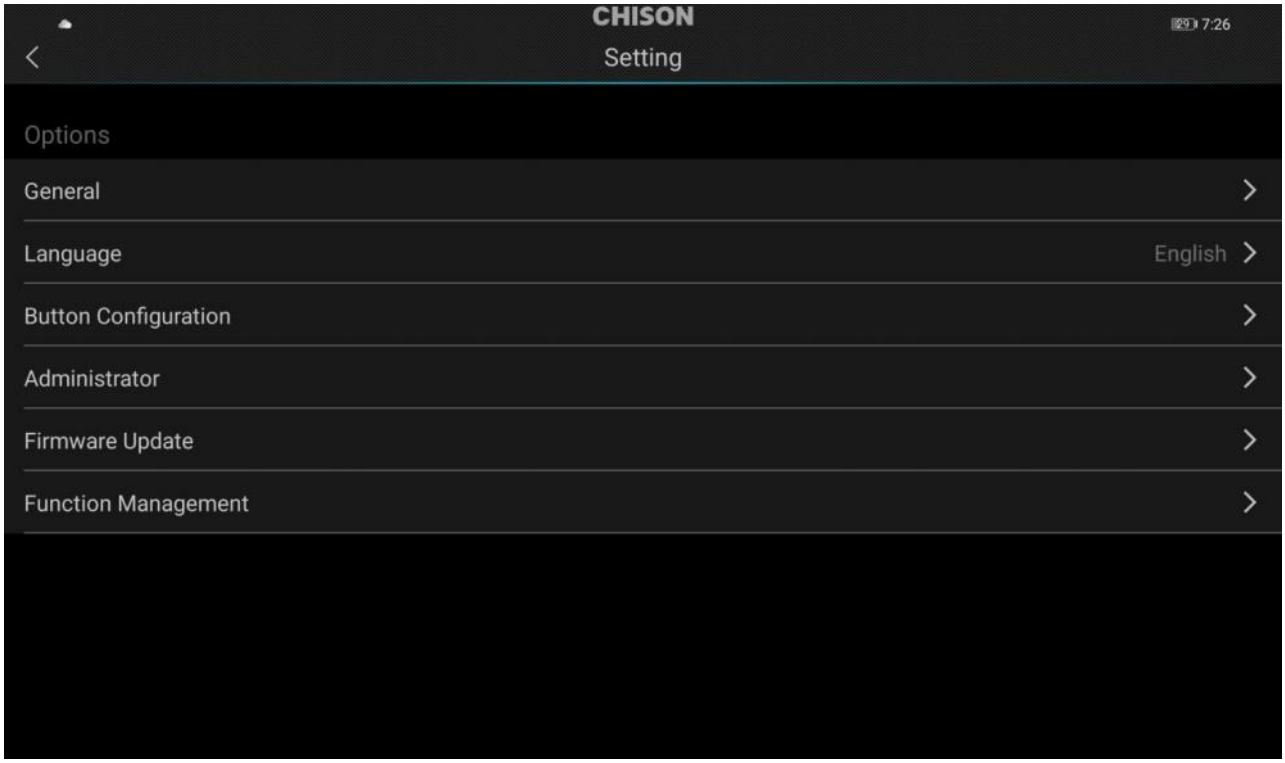
8.3 Report

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, Abdomen, Cardiac 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.

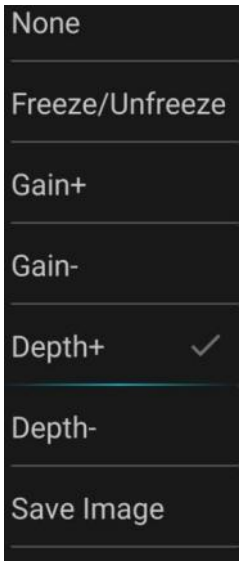
8.4.2 Language

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”	

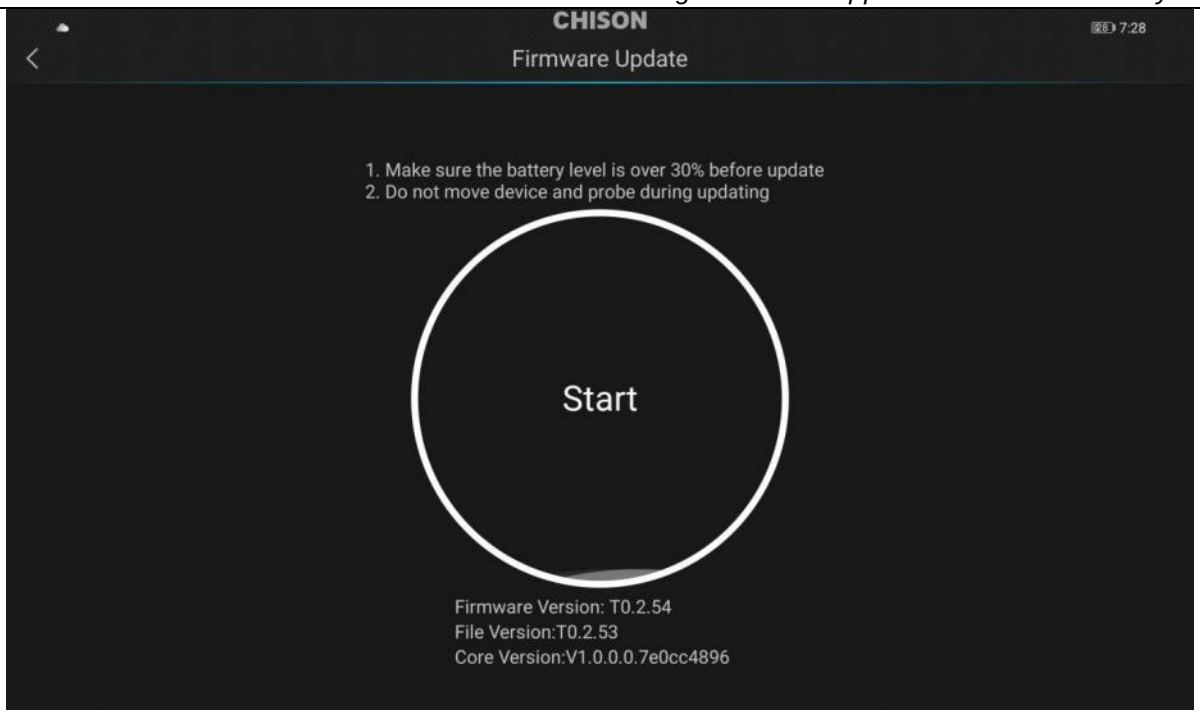


8.4.4 Administrator

Click the Administrator to manage accounts.

8.4.5 Firmware Update

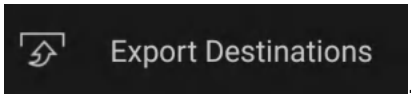
Select firmware update to upgrade system software version.



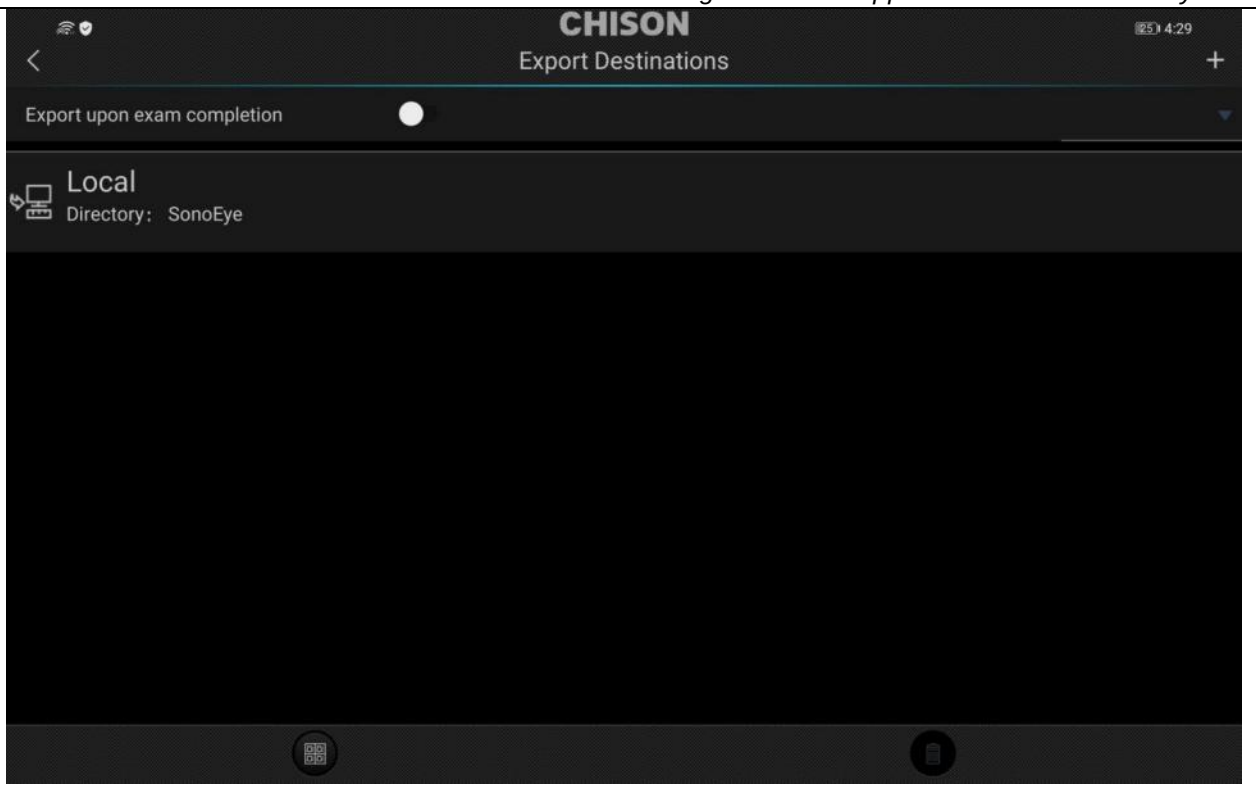
8.4.6 Function Management

Select function management to manage system functions.

8.5 Export Destinations

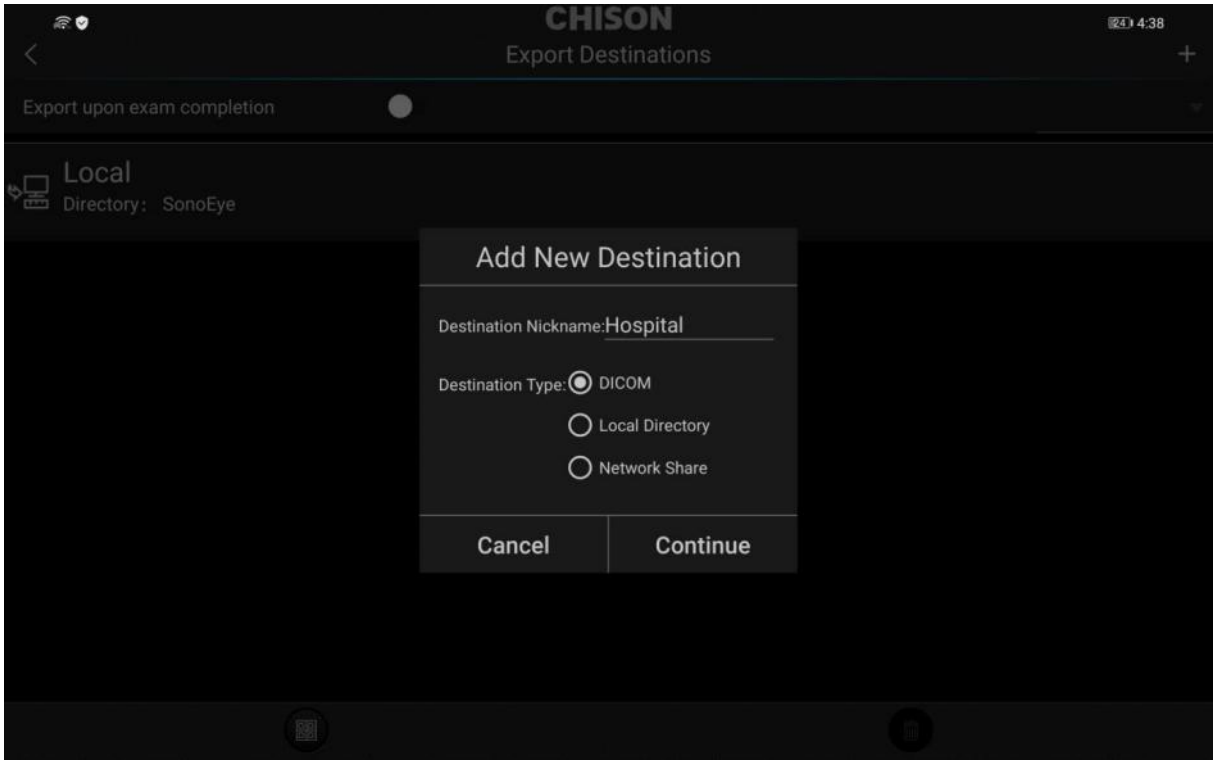
Press and select 

.

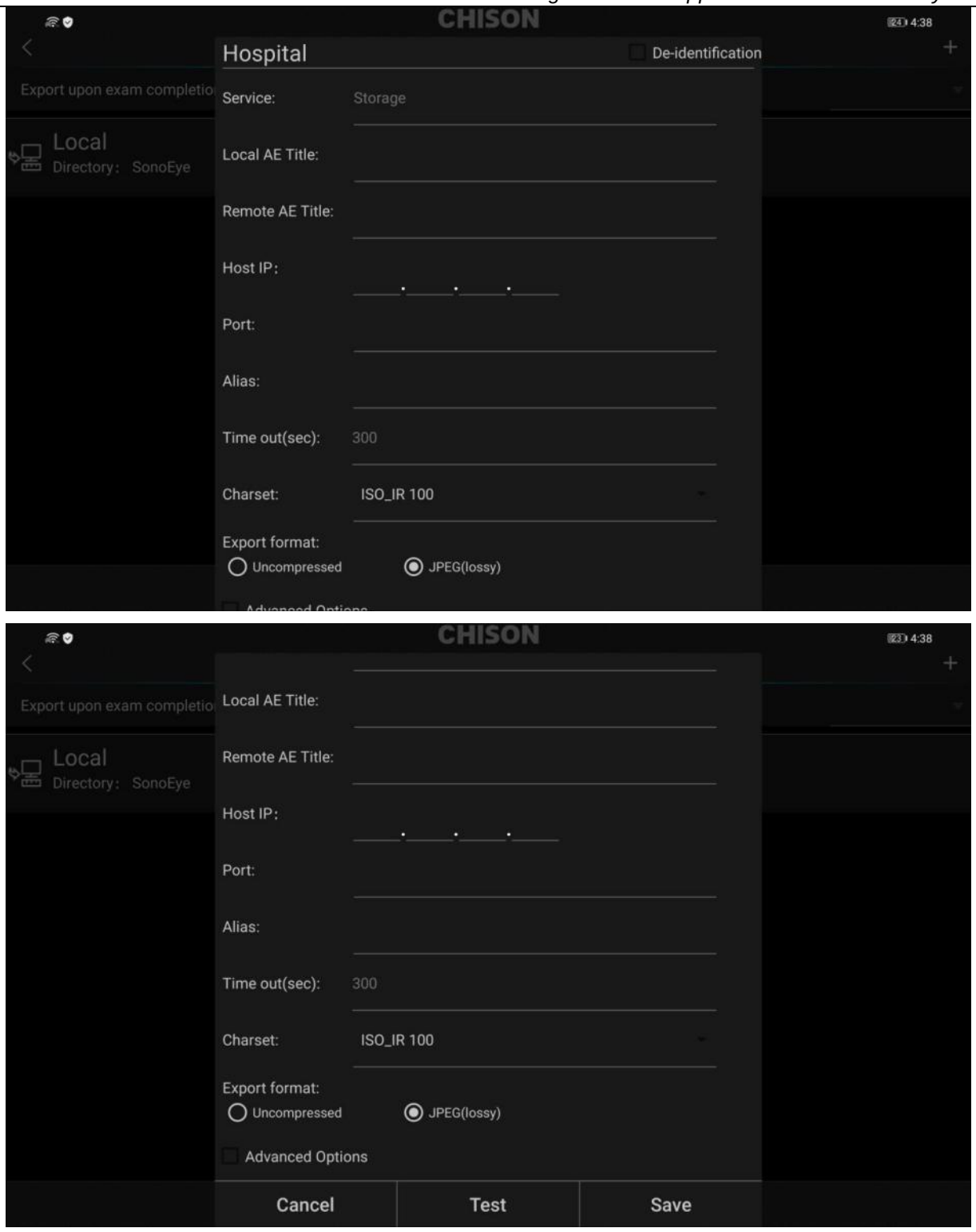


From this interface, you can add or remove export destinations.

You can enter the new interface by press +. There are three Destination types to choose from: DICOM, Local Directory, Network Share

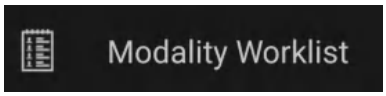


Fill in the information and select the corresponding type to enter the next level interface



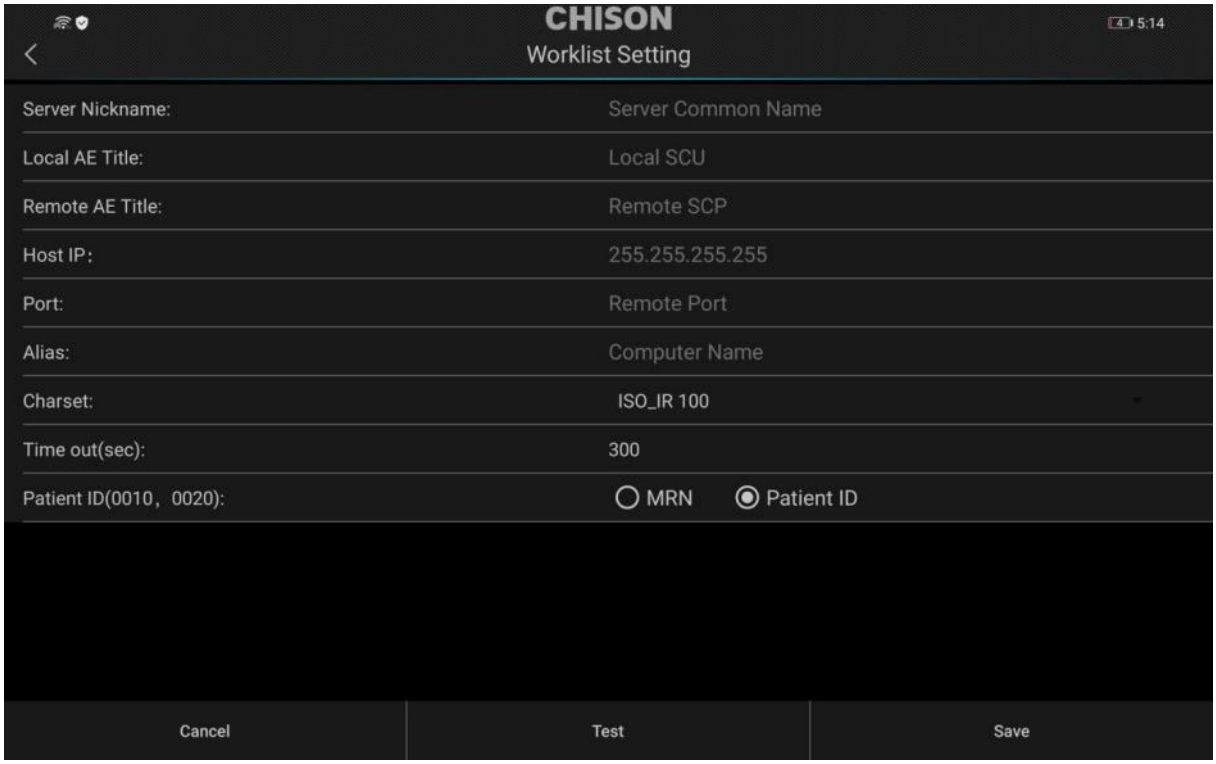
Fill in the information and click Save to complete the new Export Destination.

8.6 Modality Worklist

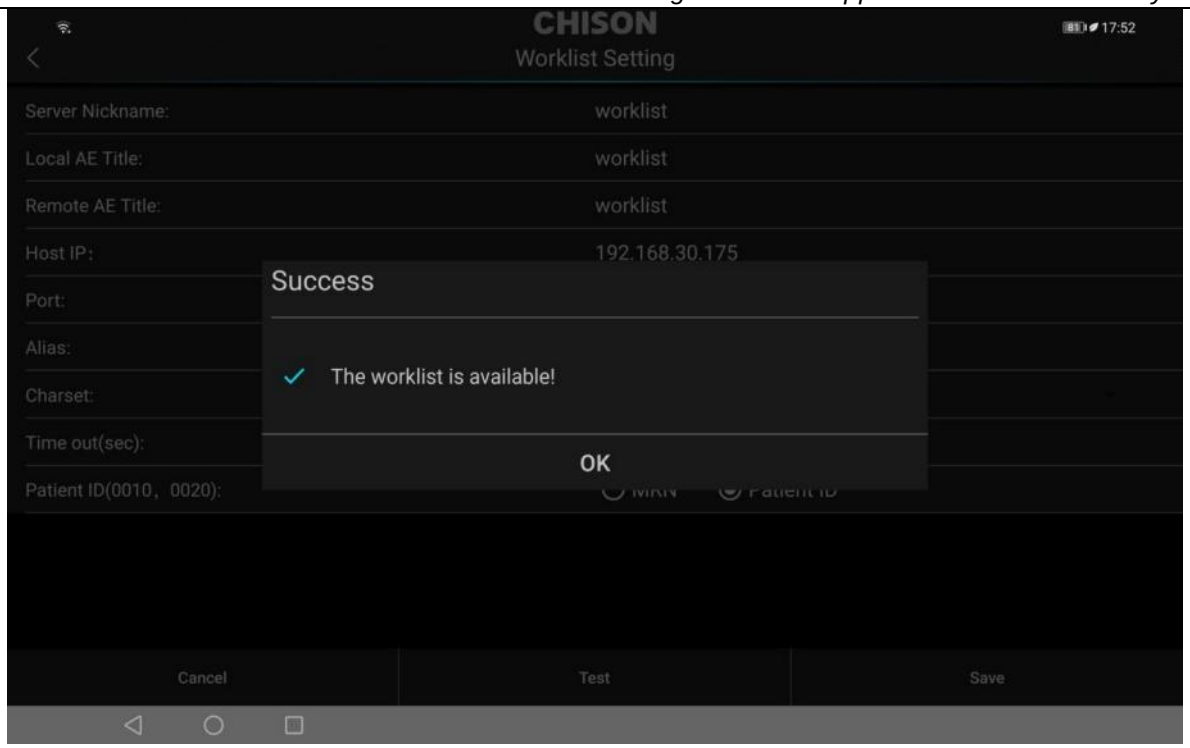
Click 

to enter it, the user can Import the worklist from the server.

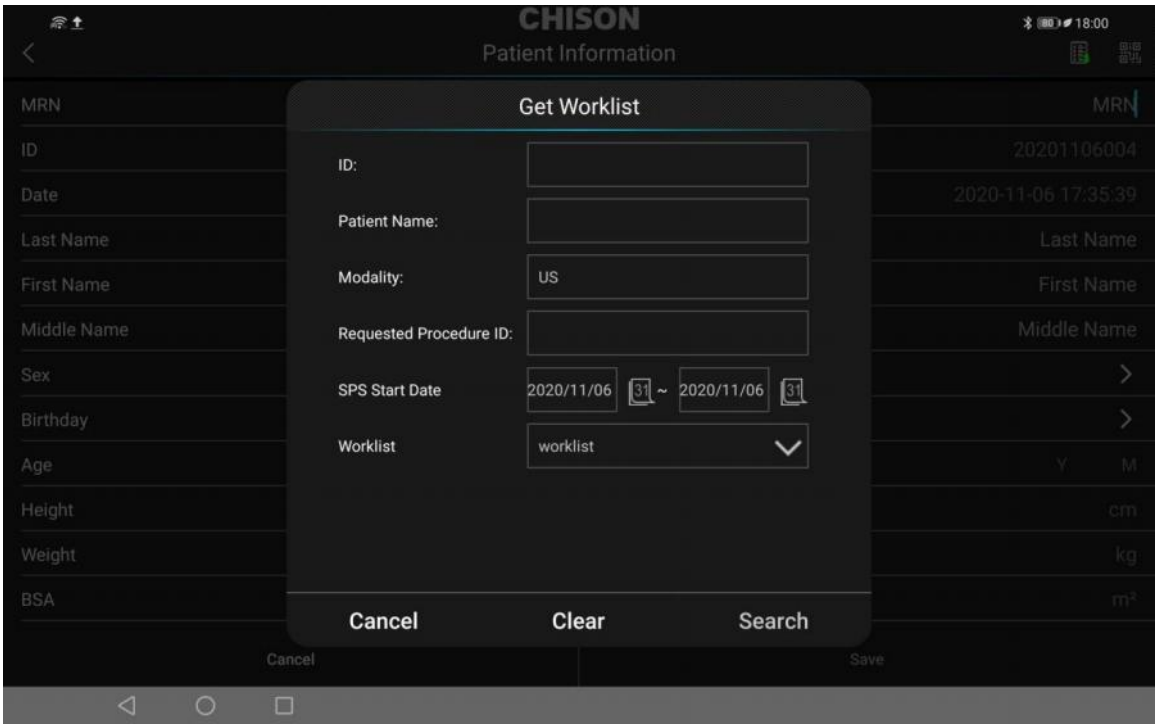
Click + to add server information



Click Test to make sure the server is connected. Then click Save to save server information.



Click on enter the Patient interface and click  to enter Get worklist to import worklist from the server



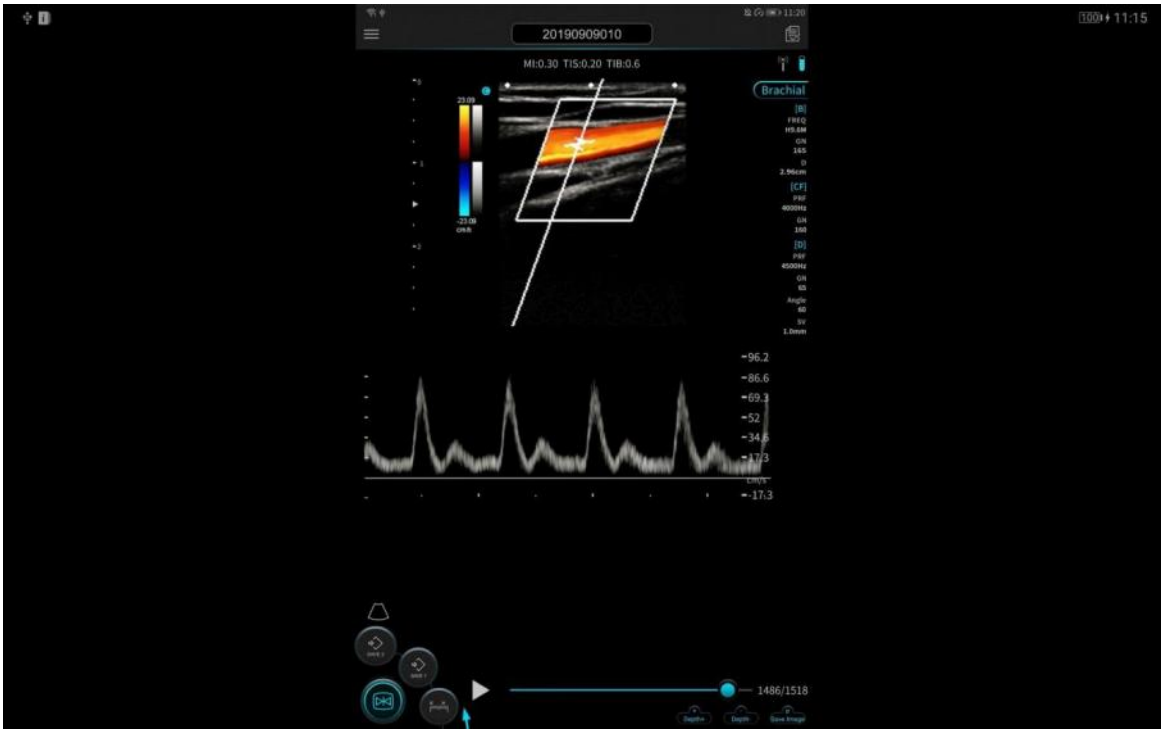
8.5 Tutorials

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  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.

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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 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 SonoEyeP6/SonoEyeG6/SonoEyeV6 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**

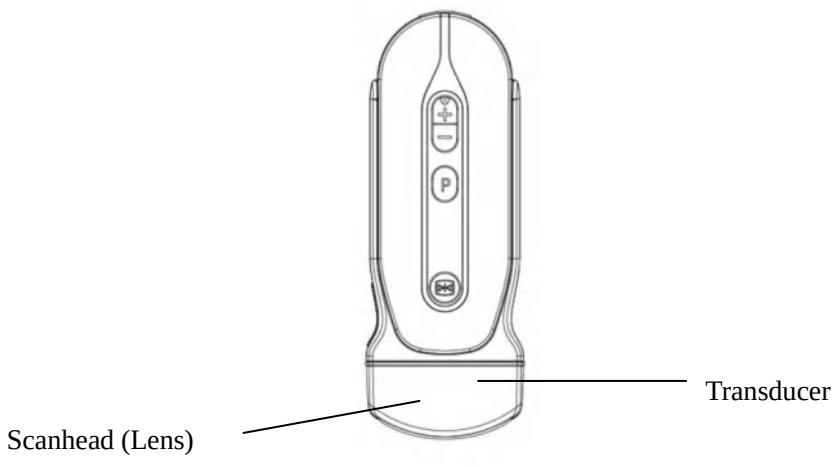

Fig.10-1: Convex Probe Overview

The system provides high spatial and contrast ultrasound imaging of frequencies from 4.0MHz to 8.0MHz. 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

Definitions

Cleaning removes visible soil (for example, organic and inorganic material) from the probe surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection because inorganic and organic materials that remain on the surfaces of probes interfere with the effectiveness of these processes.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.

Low-Level Disinfection (LLD) destroys most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium tuberculosis or bacterial spores.

Intermediate-Level Disinfection (ILD) inactivates Mycobacterium tuberculosis, bacteria, most viruses, most fungi, and some bacterial spores.

High-Level Disinfection (HLD) destroys or removes all microorganisms except bacterial spores.

Transducer Components

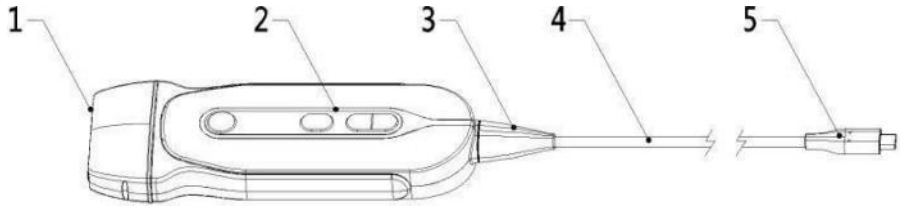

Fig.10-2: Transducer Components

1. Lens 2. Cover 3.Sheath 4.Cable 5. TYPE-C connector

To choose a suitable probe disinfection method, you must first determine its category according to the purpose of the probe. For more information about compatible cleaning and disinfecting agents, please refer to the section "Cleaning or disinfecting ". When using detergents and disinfectants, be sure to follow the manufacturer's instructions.

WARNING

After each use of the probe, it must be cleaned. Cleaning the probe is an important step before effective disinfection. When using detergents and disinfectants, be sure to follow the manufacturer's label instructions.

WARNING

When cleaning and disinfecting any instrument, be sure to wear protective glasses and gloves.

CAUTION

Using non-recommended disinfectants, inappropriate disinfectant concentration, or the immersion depth or immersion time of the probe exceeding the recommended value will cause damage or discoloration of the probe, and invalidate the probe warranty.

CAUTION

Do not use a brush when cleaning transducers. Even the use of soft brushes can damage transducers.

CAUTION

Do not leave the probe in contact with cleaning agents and disinfectants for a long time. Limit the time the probe is exposed to cleaners and disinfectants to the shortest time recommended by the manufacturer。

When you use OPA (ortho-phthalaldehyde)-based disinfectants, if you do not follow the manufacturer's instructions carefully, residual solution may remain on the probe. In order to minimize the impact of residual OPA or any other disinfectant, it is recommended as below:

- Follow the instructions of the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends as below immersing the probe in drinking water three times to rinse the probe.
- Limit the time the probe is exposed to the disinfectant to the shortest time recommended by the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends a minimum time of 12 minutes.
- Prevent any fluid from splashing on your mobile device’s touchscreen during cleaning and during disinfecting. Damage may result due to fluid.

Point-of-use processing

Before cleaning, check the probe first. If any particles or body fluids adhere to the probe or cable, you can wipe it off with a soft cloth dipped with 80% ethanol.

10.2.2.1 Cleaning

Recommended supplies:

Dust-free cloth or soft cloth;

Compatible cleaner or wipes for probe cleaning;

1. Disconnect the probe from the system.
2. Wear sterile gloves and use protective eyewear to prevent infection.
3. Remove Ultrasound transmission gel from the transducer by using a soft cloth dipped with potable water (not to exceed 43°C (110°F)) or an approved cleaning or disinfectant agent or by using an approved disinfectant wipe.

Gently wipe the lens to remove the gel, then wipe the probe，cable for 1 minute and until visibly clean(There is no gel, hair, debris or other residue on the probe.).

Do not wipe the connector to prevent liquid from entering the inside. Please refer to Table 10-1 below for approved compatible cleaning and disinfection products.

4. Dry the transducer using a sterile cloth or gauze after cleaning. Blot the lens dry. Do not wipe the lens. Do not dry the transducer by heating it.

10.2.2.2 Disinfecting

After cleaning the probe, you must disinfect the probe.

To reduce the risk of contamination and infection, it is important to choose the appropriate level of disinfection, based on prior exam usage and whether the use is classified as non-critical or semi-critical. Use Table, “Probe Disinfection Class, Use, and Method” to determine the appropriate class and then follow the appropriate intermediate-level or high-level disinfection procedure

Probe Disinfection Class, Use, and Method

Class	Use	Method
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate- level disinfection (ILD)
Semi-Critical Class	Touches mucous membranes and non-intact skin.	Cleaning followed disinfection (HLD) by high-level

Intermediate-Level Disinfection (ILD)

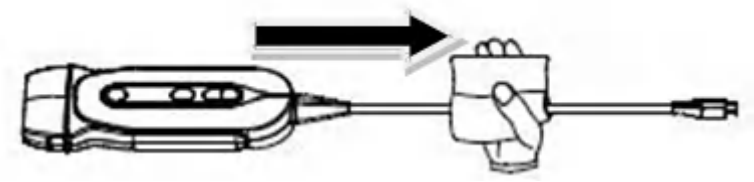

Fig.10-3: Wipe direction

1. Wear sterile gloves to prevent infection.
2. Wipe the probe, with approved compatible disinfectant wipes or soft cloth dipped in disinfectant agent. As shown in the figure above, wiping from lens toward cable. Do not wipe the type-c linker to prevent poor contact.
3. Ensure that the disinfected surface remains visibly moist for at least two (2) minutes, use additional

   fresh wipes as needed.
4. Allow to air dry.
5. After cleaning and disinfection, check the appearance of the probe to see whether the transducer and cable are worn or damaged

High Level Disinfection

It is recommended that you use Cide®OPA by Ethicon US, LLC.

1. After cleaning the probe, you must disinfect the probe. It is recommended that you use Cidex® OPA high- level disinfection solution.
2. Prepare Cidex® OPA high-level disinfection solution for use per the manufacturer's instructions. Fill a tray or basin with the disinfectant solution at room temperature (minimum temperature of 20°C) to a level allowing immersion of the probe up to the immersion line (As shown below),

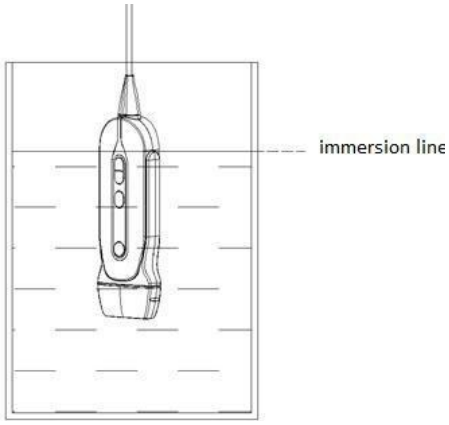

Fig.10-4: Soaking depth

3. Immerse the probe in Cidex® OPA solution up to the immersion line and ensure no air or bubbles are trapped. Allow soaking according to the manufacturer's instructions.
4. Thoroughly rinse the probe (up to the immersion line) by immersing it in a large volume of room temperature purified water for a minimum of one (1) minute. Remove the probe and discard the rinse water.

Do not reuse the water. Always use fresh volumes of water for each rinse. Repeat this stage two (2) additional times for a total of three (3) rinses.

5. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the device is completely dry. Inspect the device to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is visible.
6. Once clean and disinfected, inspect the probe, strain relief, cable, and connector for signs of damage or wear.
7. Daily and Long-Term Storage follow these guidelines to protect the probe.
8. Always store transducers in the probe case when you are not using them.

 ***CAUTION***

Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use. Do not soak the transducer connector or the cable near it into water or any solution.

 ***CAUTION***

Follow local regulations when selecting and using the disinfectant.

10.2.2.3 **Approved and compatible cleaning and disinfectant**

Table 10-1：Cleaning and disinfection list

Wipes type	Brand	Place of origin	Chemical ingredient	solution
80% Ethanol (Soak with a soft cloth)	Any manufacturer	Any	Ethanol	Clean/LLD/ILD
70% Isopropyl alcohol (Soak with a soft cloth)	Any manufacturer	Any	Isopropyl alcohol	Clean/LLD/ILD
Universal wipes	Clinell	United Kingdom	Compound double chain quaternary ammonium salt	Clean/LLD/ILD
perform classic wipes EP	Schulke&Mayr GmbH	Germany	Compound alcohol	Clean/LLD/ILD
WIP'ANIOS	Laboratoires ANIOS	France	Isopropyl alcohol/Didecyl dimethyl ammonium chlorides	Clean/LLD/ILD
Sani-cloth AF3,Sani- Cloth AF	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopro pyl alcohol	Clean/LLD/ILD
Super Sani-Cloth	Professional Disposables International Inc.	USA	Quaternary ammonium chlorides/Isopro pyl alcohol	Clean/LLD/ILD

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

- Before cleaning, turn off the system
- To clean the touch screen.

  a. Remove dust with a soft, lint-free cloth.

  b. Please wipe the screen with cleaner specially designed for LCD. Spray the liquid onto thecleaning cloth and gently wipe the screen clean. You can also use pre-moistened screen wipes.

  c. Dry the screen with a soft, lint-free cloth
- Wipe the remaining external surfaces of the system with soft cloth dipped few 70% isopropyl, 80%

  Ethanol solution or recommended wipes.
- Gently remove any residue with a cloth lightly moistened with purified water.
- Dry the equipment to prevent potential corrosion.

  If the equipment has come in contact with blood or infectious material, see “Infection Control”.

Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection control procedures established in your facility for the protection of both the staff and the patient.

WARNING

If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your CHISON service representative. Components inside the system cannot be

disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

CAUTION

Remove blood on the system and the transducer connectors and cables with a soft cloth dipped few soap and potable water. Then dry the equipment with a soft, dry, lint-free cloth to prevent corrosion.

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 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

R Sight B.V.

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Appendix B: ACOUSTIC OUTPUT REPORT TABLE

Transducer Model: SonoEyeP6/SonoEyeG6/SonoEyeV6

Operation Mode: B

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.05	0.11		0.11		0.25
Index component Value				0.11	0.11	0.11	0.11	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.58					
	P	(mW)		10.02		10.02		12.62
	P_{1*1}	(mW)		10.02		10.02		
	Z_s	(cm)			2.15			
	Z_b	(cm)					2.15	
	Z_{MI}	(cm)	2.15					
	$Z_{pii.\alpha}$	(cm)	2.15					
	f_{awf}	(MHz)	2.25	2.25		2.25		2.22
Other Information	prr	(Hz)	-					
	srr	(Hz)	18.94					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	79.17					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.79					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.82					
	p_r at Z_{pii}	(MPa)	1.79					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		3.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	2.00	2.00		2.00		2.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEyeP6/SonoEyeG6/SonoEyeV6
Operation Mode: B+M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.12	0.26		0.58		0.36
Index component Value				0.26	0.18	0.26	0.58	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.65					
	P	(mW)		20.12		20.12		20.12
	P_{1*1}	(mW)		14.58		14.58		
	Z_s	(cm)			1.52			
	Z_b	(cm)					2.22	
	Z_{MI}	(cm)	2.05					
	$Z_{pii.\alpha}$	(cm)	2.05					
	f_{awf}	(MHz)	2.16	2.16		2.16		2.16
Other Information	prr	(Hz)	346					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	80.46					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	8.77					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	8.89					
	p_r at Z_{pii}	(MPa)	1.75					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		3.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	2.00	2.00		2.00		2.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEyeP6/SonoEyeG6/SonoEyeV6
Operation Mode:B+CFM

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.88	0.22		0.22		0.50
Index component Value				0.22	0.22	0.22	0.22	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.39					
	P	(mW)		24.21		24.21		28.90
	P_{1*1}	(mW)		18.68		18.68		
	Z_s	(cm)			3.20			
	Z_b	(cm)					3.20	
	Z_{MI}	(cm)	2.60					
	$Z_{pii.\alpha}$	(cm)	2.60					
	f_{awf}	(MHz)	2.51	2.48		2.48		2.38
Other Information	prr	(Hz)	-					
	srr	(Hz)	6.49					
	n_{pss}	NA	8.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	94.79					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	0.50					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	0.51					
	p_r at Z_{pii}	(MPa)	1.73					
Operating control conditions	Focus	(cm)	3.00	3.00		3.00		5.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	3.00	3.00		3.00		3.00
	PRF	HZ	-	-		-		-

Transducer Model: SonoEyeP6/SonoEyeG6/SonoEyeV6
Operation Mode:PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.63	0.20		0.74		0.38
Index component Value				0.15	0.20	0.16	0.74	
Acoustic Parameters	$p_{r.\alpha}$ at Z_{MI}	(MPa)	1.00					
	P	(mW)		21.79		18.92		22.59
	P_{1*1}	(mW)		12.61		14.60		
	Z_s	(cm)			1.40			
	Z_b	(cm)					3.20	
	Z_{MI}	(cm)	3.05					
	$Z_{pii.\alpha}$	(cm)	3.05					
	f_{awf}	(MHz)	2.48	2.47		2.50		2.45
Other Information	prr	(Hz)	2000					
	srr	(Hz)	-					
	n_{pss}	NA	1.00					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm^2)	40.29					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm^2)	109.67					
	I_{spta} at Z_{pii} or Z_{sii}	(mW/cm^2)	213.87					
	p_r at Z_{pii}	(MPa)	1.22					
Operating control conditions	Focus	(cm)	4.00	11.00		4.00		7.00
	Depth	(cm)	16.00	16.00		16.00		16.00
	Freq	MHz	3.00	3.00		3.00		3.00
	PRF	HZ	2000	2000		2000		2000

Appendix C: TRANSDUCER MAXIMUM SURFACE TEMPERATURE

Transducer model	Maximum surface temperature(℃) Contacting human-tissue mimicking material	Maximum surface temperature(℃) Suspending in air
SonoEyeP6	<37.6	<31.4
SonoEyeV6	<37.6	<31.4
SonoEyeG6	<37.6	<31.4

Overall uncertainties
Center Frequency: The accuracy of the center frequency measurement is primarily dependent on the digitizer, and is therefore given as ± 2%.

Pressue: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 13.37%.

Intensity and Power: Depends on the hydrophone measurement, digitizer, non-linear distortion, and water temperature. The contributions from each of the sources in Section I may therefore be added on an RMS basis to yield an uncertainty of ± 26.75%.

It can be summarized in below table:

Item	Measurement Uncertainty (95% Confidence Level)
Center frequency	±2.00%
Pressure	±13.37%
Intensity	±26.75%
Power	±26.75%

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 electronicequipment.
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 SonoEyeshould 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 environment.
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.

Appendix F: PULSED WAVE DOPPLER VELOCITY MEASUREMENT RESULTS SUMMARY

Probe type: SonoEye P6, Scan mode: PW, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.54	105.22	141.25
Measurement Error (%)	5.40%	5.22%	-5.83%

Probe type: SonoEye P6, Scan mode: CFM, fc: 5.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.52	52.15	97.75
Measurement Error (%)	5.20%	4.30%	-2.25%

Probe type: SonoEye V6, Scan mode: PW, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	9.55	104.45	145.74
Measurement Error (%)	-4.5%	4.45%	-2.84%

Probe type: SonoEye V6, Scan mode: CFM, fc: 5.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.34	52.74	98.24
Measurement Error (%)	3.40%	5.48%	-1.76%

Probe type: SonoEye G6, Scan mode: PW, fc: 5.0MHz, Power: 100%			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 100 cm/sec	V3: 150 cm/sec
Measured Target Velocity (cm/sec)	10.37	104.85	153.45
Measurement Error (%)	3.70%	4.85%	2.30%

Probe type: SonoEye G6, Scan mode: CFM, fc: 5.0MHz, Power: 100%,			
Phantom Target Velocity (cm/sec)	V1: 10 cm/sec	V2: 50 cm/sec	V3: 100 cm/sec
Measured Target Velocity (cm/sec)	10.35	52.12	98.75
Measurement Error (%)	3.50%	4.24%	-1.25%