

Mirror 2 Touch\Mirror 5 Touch

(Ultrasound Color Doppler Diagnostic Scanner)User's Manual

Information

Code: CC18-H-002

Revision: A2

ISSUE DATE: 2019-12

CE Declaration

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Shenzhen Lanmage Medical Technology Co., Ltd. is a sub-company of Shenzhen Landwind Industry Co., Ltd. dedicated to R&D, manufacturing and marketing of ultrasound imaging, radiology solutions etc.

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Production date: see the machine.

Usage period: 5 years.

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Instructions before Use

Users must read and understand the instructions carefully before use. The following warning symbols are used in this manual. The user must know the meanings of these symbols before operating the instrument.



Warning: Indicates a danger. Warnings are intended to alert you to the importance of following the correct operating procedures where risk of injury to the patient or system user exists. Do not proceed to any further operation until the specified conditions are fully understood and satisfied.



Caution: Indicates a danger. Cautions are intended to alert you to the importance of following correct operating procedures to prevent the risk of damage to the system. Do not proceed to any further operation until the specified conditions are fully understood and satisfied.



Note: Notes contain special information concerning the proper use of the system

and/or additional instructions.

Safety Classification

1. Type of protection against electrical shock: Class I equipment
2. Degree of protection against electrical shock: Type BF equipment
3. Degree of protection against harmful ingress of water: Ordinary equipment
4. Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Do not use this equipment in an environment in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
5. Operation mode: Continuous operation

Requirements for the Installation Site

- Install this instrument in an environment with a sound earthing system.
- Never install this instrument in a place beside water and chemicals.
- Never install this instrument in a place vulnerable to harmful conditions, such as direct sunshine, high temperature, excessive humidity and dust, and it shall be operated and stored in a place with good air environment, free from corrosive substances including the salt, alkali and sulfur.
- Avoid the excess inclination, swinging, impact and other unstable elements during installation.
- Make sure that there are no other instruments producing strong magnetic field near the Scanner.

Warranty

Please do not disassemble this instrument on your own. The warranty does not include the following items, even during the warranty period:

1. Disassemble the instrument on your own.
2. Damage or loss resulting from disoperation or improper use (any application beyond the application scope of this instrument).
3. Damage or loss due to the failure to follow regulations on power supply, installation and operating conditions.
4. Damage or loss caused by the installation, modification and checkup or repair by an unauthorized service engineer.
5. Damage or loss caused by natural disasters, such as fires, earthquakes, lightning, and So on.

Environmental

Lanmage designs the ultrasound diagnostic system according to the requirements of safety and environmental protection. If user does not disassemble the instrument or perform an improper use, the system will not cause any harm to anyone and environment. In accordance with the requirement of regulations, if materials that may be hazardous to the environment must be used, they should be disposed properly.

 **Warning:**

- Do not dispose the waste of ultrasound diagnostic system together with industrial waste and household garbage.
- According to the local and national environment protection law, the waste generated by ultrasound diagnostic system must be dispose properly, and the equipment should be properly processed when it reaches its service life.
- Recycling the recyclable materials by qualified Waste Management, thereby reducing environment pollution.

For relevant information, please contact the Lanmage service department, or dispose the waste properly according to local refuse collection method.

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Chapter 1 Safety Precautions

1.1 Safety Information

1.1.1 Safety Classification

The system complies with EN 60601-1 (GB 9706.1) and is classified as follows:

It is classified as class I equipment according to type of protection against electrical shock;

It is classified as type BF applied parts according to degree of protection against electrical shock;

It is classified as ordinary equipment according to protection against harmful ingress of liquids or particulate matter;

It is classified as equipment unsuitable for use according to suitability degree for use in a flammable anesthetic mixture with air, oxygen or nitrous oxide;

It is classified as continuous operation according to mode of operation.

1.1.2 Electrical Safety

The system is provided with a cable which has a removable power plug with a grounding contact connecting to the grounding part of the cable. Accordingly, the wall outlet should be connected to the protective earthing systems of the room where the system is to be operated.



Note: To avoid electrical shock, never modify the ultrasound system's AC power connector plug as doing so may overload your equipment's power circuits. To ensure grounding reliability, connect the system only to an equivalent outlet.



Note: Using an extension cord or multi-socket outlet setup to provide power to the imaging system or to the system's peripheral devices, may compromise the system grounding and cause your system to exceed leakage current limits.



Note: Operators of the instrument shall be qualified service-trained professionals or shall use the instrument under the supervision of qualified professionals.



Warning: Maintenance is prohibited during equipment use.



Warning: Connect the system only to a sound wall outlet provided with a protective ground lead and therefore use only a proper power cable. You are not allowed to remove or disconnect the ground lead, no matter when.

The system is equipped with an equipotential terminal  to connect a potential equalizing wire (a copper wire of at least 4mm²cross-sectional area) to the protective earthing system of the room where the system is to be operated.

The operating room should be provided with a wall outlet having a grounding contact. The state

of both wall outlet and wiring in the operating room should be inspected by qualified personnel.



Note: Install the system only in rooms intended for medical use. The system complies with the EN 60601-1 Electrical Safety Requirements (EN 60601-1).



Warning: if the system keeps making alarming sound, please

- Turn off the system, and
- Contact Lanmage client service center

The alarming sound is a warning of non-functioning of the cooling fan. Operation of the system must be ceased under such condition to avoid malfunction.

Observe the following guidelines to ensure safety:

- Do not remove the cover of the system.
- Operate the system in the room complying with the Sanitary Norms and Rules when Operating Equipment Producing Ultrasound Transmitted to Operators' Hands through Contact, No. 2282 – 80.
- The operating room should at least occupy an area of 20 m² and each system should be installed in a separate room.
- Ensure the following environment is maintained in the operating room: Temperature: 22°C, relative humidity: 40% - 60%, air flow velocity: ≥0.15m/sec
- Check the state of wall outlets in a regular manner;
- Do not remove the plug out of the outlet by pulling the wire;
- Replace mains fuses, and pull the power cable plug out of the wall outlet. Do not install fuses that do not correspond to the current value specified;
- Do not place any foreign objects into the system components;
- To ensure normal thermal conditions when operating the system, and not to install the system near space heaters, ovens, etc.;
- When the system is applied on patients, it should not be connected to any peripherals such as PC and printer, which fail to comply with EN 60601-1 in terms of electrical safety features, unless special isolating devices are used complying with the requirements of EN 60601-1



Caution: The power characteristics should comply with those of industrial enterprises and/or health care institutions.



Caution: The system should be provided with an uninterrupted power supply (UPS) in places where the main power supply is likely to suspend temporarily. Otherwise, the service warranty

clause will become invalid automatically.

 **Caution:** Do not operate the system near the sources of heat, strong electrical and magnetic fields such as transformers as well as close to equipment generating high- frequency signals, for example, electrosurgical units (ESUS)). Failure to comply with this requirement will have a negative impact on ultrasound image quality and the subsequent diagnosis.

 **Caution:** Do not remove the system hood due to the presence of dangerous voltage. When the system is being used, the control panel shall be in place. All internal adjustments and replacements should only be conducted by qualified service-trained Lanmage customer service professionals.

 **Caution:** Equipment connected to the ultrasound system and located in the patient zone must be powered from a medically-isolated power source or must be a medically- isolated device. Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the ultrasound system.

 **Caution:** To make electrical or mechanical connection between this instrument and the equipment of other manufactures, confirm that it complied with the EN 60601-1 standard, and recheck the leakage current and other safety indices of the entire set of system, to avoid possible hazard arising from leakage current overlapping.

 **Caution:** To avoid electrical shock and damage to the ultrasound system, shut down and disconnect the equipment from the AC power source before cleaning and disinfection.

 **Caution:** Do not use the system in an environment with combustible gases or anesthetic, to avoid explosions.

 **Caution:** Do not use the system in damp or wet environments. Keep it away from inflammables and explosives.

 **Caution:** Do not pour any fluid onto the system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.

 **Caution:** To avoid the possibility of static shock and damage to the system, avoid using aerosol spray cleaners on the monitor screens.

 **Caution:** Use the probe with care. Do not use damaged probes. Do not use probes with cracks or surface crimps, since such probes might have their insulation damaged, which easily

causes electric shock to patients.

 **Caution:** When the system is displaced to a room with a higher temperature from one with a lower temperature, it is highly recommended to turn on the system several hours later when the temperature inside the system has been stabilized.

 **Caution:** Do not attempt to modify the instrument. If it is really necessary to do so, please notify us or our agent.

 **Caution:** Operators of the instrument shall be qualified service-trained professionals or shall use the instrument under the supervision of qualified professionals.

 **Caution:** To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 12 months. Electric safety test must be performed at periodic intervals at regular intervals as specified by local safety regulations, or as needed.

 **Caution:** Upon the expiration of the service life of the system, please notify your dealer or Lanmage to handle properly.

 **Caution:** Although the instrument is produced according to the existing EMI/EMC requirement, its use in electromagnetic environments may still cause instantaneous attenuation of the ultrasound images. If such a phenomenon often occurs, Lanmage recommends you to check the system operating environment to locate the possible radiation sources. Such radiation may arise from other electric devices in the same or neighboring room. Such communication devices as phones and pagers may generate such radiation, and such devices as radio receivers, TVs or microwave transmitting devices in proximity may also produce such radiation. If electromagnetic interferences exist, please move the instrument to another place.

 **EMC Note:** Operating the ultrasound imaging system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

1.1.3 Ultrasound Safety Information General

 **Caution:** For neonatal head imaging, Lanmage recommends that you exercise special care during neonatal cephalic scanning to avoid possible damage to the posterior region of the eye. The ultrasound energy emitted by the probe easily penetrates the fontanelles of the infant.

 **Caution:** To avoid possible damage, without doctor's guidance, it prohibits from using the working probe scan the eye directly.

 **Caution:** Lanmage makes every effort to manufacture safe and effective probes. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, and during end cavity scanning; during biopsy or Biopsy procedures; or scanning patients with open wounds.

 **Caution:** To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, handle dangerous or infectious materials all along according to the medical specifications for handling biohazard castoffs.

 **Caution:** The assessment of biological effects of diagnostic ultrasound on humans is a subject of ongoing scientific research. This system and all diagnostic ultrasound procedures should be used for valid reasons, for the shortest period of time, and at the lowest mechanical and thermal indices necessary to produce clinically acceptable images.

 **Caution:** Do not use the system if irregular and unusual repeated video refreshes occur. Discontinuous scanning frequency is a hardware fault, please remove it before use.

 **Caution:** Use the diagnostic ultrasound only when there is a good medical reason, minimize exposure times, and select the lowest scanning power value required to create images that are suitable for clinical exam.

 **Caution:** When making ultrasonic scanning, the instrument shall be used with ultrasound coupling agent, and no biologic compatibility problem is found. However, to ensure safety, only qualified ultrasound coupling agent in compliance with related standard shall be used.

 **Caution:** If error information occurs to the video display, it indicates that a danger happens to the system; please suspend the use of the system immediately. Record the error information, turn off the system, and notify your supplier.

 **Warning:** The system is not intended for Trans orbital or other ophthalmologic exams!

 **Warning:** To ensure the safety of examined patients, do not scan the same part of an examined patient consecutively for a long period of time.

 **Warning:** The values of the mechanical index (MI) and technical index (TI) are not applicable for ophthalmologic ultrasound. Take special cautions when scanning the head of a fetus to avoid damage to the posterior region of the eye.

 **Warning:** To avoid any patient health hazard, use probes to examine only those exam zones,

where a given probe is intended for.



Warning: Take Caution when contrast substances are used to scan heart, abdominal. Cavity and other organs. Be careful that the lower the MI value is, the less possible ultrasonic cavitation is.



Warning: Lanmage recommends adhering to the principles of ALARA (as low as reasonably achievable). In accordance with these principles, a physician shall select the lowest ultrasound exposure (the lowest ultrasound intensity and exposure time) that produces diagnostically acceptable information and, in doing so, minimize harmful effect risk.



Warning: Ultrasound power is better transmitted through water than tissues. The actual MI and TI values may be higher than those displayed on the imaging screen when buffer materials such as gel pad are used.

Mechanical Index (MI)

Mechanical Index which indicates the potential for mechanical bio effect is calculated as the peak rare fractional pressure (unit: Map) at a tissue damping coefficient of 0.3 dB/cm/MHz Map divided by the square root of the center frequency of the transmitted field in MHz. By using MI, the risk for mechanical bio effects when acquiring diagnostically acceptable images will be reduced as much as possible. The higher the MI value is, the higher this risk is. However, the actual occurrence of bio effects cannot be judged in terms of MI. In all imaging modes, the system will display MI in real-time.

Please change ultrasound transmission power, mode set, probe type and/or focus position depth to change MI value.

Thermal Index (TI)

Thermal index (TI) indicates a temperature rise in about 1°C.

The purpose of displaying TI is to warn the user about conditions which may cause temperature to rise. TI is the ratio of the acoustic signal power to the power causing a temperature rise in 1°C (value based on the temperature model). There are three thermal indices which are based on specific temperature model respectively to evaluate the temperature rise near the surface of and inside soft tissue when the ultrasound beam passes through soft tissue and focuses on the immediate vicinity of bone:

- Soft tissue thermal index (TIS): indicates the potential temperature rise of soft tissue when ultrasound beam passes through and focuses on them.
- Cranial thermal index (TIC): indicates the potential temperature rise of bones near the beam's entrance into the body when ultrasound beam passes through the body.

- Bone tissue thermal index (TIB): indicates the potential temperature rise where the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
- Both MI and TI are relative indicators which reflect potential temperature rise. The higher the MI or TI value is, the higher the temperature rise is. They provide a relative value for applying the concept of ALARA.

Please change the ultrasound transmission power, mode set, probe type, focus number, Focus position depth, scanning depth and/or other parameters to change TI value.

Mechanical Index and Thermal Index Errors

MI and TI errors are dependent on probe type used and the laboratory measurement errors of ultrasound intensity.

Mechanical Index and Thermal Index Interpretation

The principal obligation of the user is to ensure the safety of the patient. To organize his work properly, the user should be well aware of the equipment can be the source of hazard. It is impossible to evaluate the level of hazard without the correct interpretation of MI and TI.

Ultrasound exposure parameters: thermal index (TI) and mechanical index (MI).

At present, the dependence of the immediate ultrasound bio effects on ultrasound output parameters such as sound intensity and sound pressure is still under research. Two principal mechanisms of such dependence have been found, namely, the thermal mechanism and the mechanical mechanism.

It is known that the likelihood of temperature rise and cavitation is determined by total output, operation mode, ultrasound beam shape, focus position, frame frequency and time factor. TI and MI must take all these factors into account and provide the user with information about possible thermal and mechanical effects in tissues. Since MI and TI which indicate current output conditions and do not take into account of accumulation effects (especially, heating) throughout the exam period, it has been found that the likelihood of cavitation tend to rise with increase in the negative peak pressure in tissues. TI makes it possible to evaluate approximately the potential temperature rise in a certain location of tissue in the ultrasound beam path. The approximation of such evaluation is conditioned by a great number of factors affecting the temperature rise. Under such circumstances, there are no index value which can provide an exhaustively full evaluation of the actual temperature rise for all possible conditions and tissue types. It only means that, for a given particular ultrasound beam shape, $TI = 2$ (the value that corresponds to a temperature rise in a model specimen of 2°C) reflects a greater temperature rise in tissue than $TI = 1$. The temperature rise in the actual tissue, however, is not 2°C . Refer to the following for a detail description of the limitation regarding the use of MI and TI.

It should also be kept in mind that the margin of safety for MI and TI has not been established. Researches on margin of safety based on bio effects, up to now, are rather fragmentary and still at the development stage. However, it has been found that the temperature rise in embryonic or fetal tissue of not below 41°C (i.e., 5°C above the normal temperature) within 5 minutes must be considered potentially hazardous. Potential hazards are also considered present in cases where ultrasound exams with a sound pressure amplitude near the pulmonary tissue of a neonate not below 1MPa at MI=0.7 (Pinter mode) or MI=0.5 (Resold mode) as well as any ultrasound exams at a frequency of above 4 MHz with MI=0.5. Moreover, in the obstetric practice, ultrasound scanning modes in which TI value is higher than 1.0 should be preferably avoided to comply with the reasonable margin of safety recommended by WFUMB. If an acceptable diagnostic result is unable to be achieved under such conditions, a short-time output increase is permitted. But, any additional thermal load on the fetus is impermissible if the body temperature of the mother has gone up.

The models created to forecast TI take into account of the cooling effect of tissue with blood flowing through it. Therefore, TI value should be maintained at a lower level if the hem perfusion of the tissue under exam is poor. However, if the organs scanned are known to be well washed with blood, for example, liver and heart, TI value can be maintained at a higher level.

In some cases, when the soft tissues to be examined as well as bones behind them are present in the scanning region, TIB (the thermal index for bone) other than TIS (the soft tissue thermal index) should be used for a better gauge of temperature rise. Such a situation occurs in examining the female breast, as well as in vascular exams if a vessel lies on a bone surface. MI becomes of special importance in examining heart when lungs (the 'gas-soft tissue' boundary) may be in the scanning region. The likelihood of cavitations is especially high in ultrasound exams with the application of bubble materials. In such exams, the limitation of the MI should be paid special attention. In summing up, the following should be emphasized once more:



Note: Monitoring MI is of special importance in the examinations with the application of a contrast (bubble) material, scanning heart (the possible presence of lungs in the scanning region) as well as abdominal exams (the possible presence of intestinal gases in the scanning region). It is less important to trace MI in the absence of gas-containing cavities in the scanning region, i.e., in examining most parenchymatous organs, muscles, etc.



Note: Monitoring TI is of special importance in the examinations of pregnant women (especially during the first trimester); embryo's skull and vertebral column; a patient having body temperature rising; any tissue with poor hem perfusion; as well as any ophthalmologic exams. Where ribs or other bones are present in the scanning region, TIB should be preferably used instead of TIS. It is of less important to trace TI in examining tissues with good hem

perfusion such as liver and spleen, in scanning heart as well as in vascular exams.

 **Note:** In a scanning mode, a temperature rise in the surface of soft tissue is always higher than that in bone deep. But this is not the case sometimes, and Caution should be therefore taken in interpreting TI values in both B mode and Doppler mode for second and third trimesters of pregnancy.

 **Note:** In cavities filled with liquid, ultrasound power could not be absorbed to such substantial extent as expected from model calculations. So the values of MI and TI can often be underestimated when ultrasonic scans through a full urinary bladder or amniotic fluid.

 **Note:** TI is not intended for use in ophthalmologic practice and cannot be used in assessing thermal effects in ophthalmologic exams.

 **Note:** In a scanning mode, TI values give an idea about tissue heating near the probe surface which is only based on an absorbed ultrasound beam power but take no account of a temperature rise in tissue due to contact with the surface heated up by the probe, though this temperature rise can be rather significant.

 **Note:** The displayed TI values are averaged values and should not, therefore, be interpreted as the actual temperature rise (unit: °C). TI and MI calculation models are based on many simplifications of an actual situation. Therefore, it should be born in mind, in some especially unfavorable situations; the actual temperature rise can be three times as much as the displayed TI value.

 **Note:** Unlike X-Ray beams, an unfavorable bioeffect of ultrasound on tissues only manifests in situations where it exceeds certain threshold value. For instance, temperature of a scanned tissue portion that goes up within a range of 37°C to 41°C is acceptable for a rather prolonged period while a temperature elevation of up to 45°C is impermissible: no cavitations effect and therefore, no bioeffect would occur below the threshold level.

 **Note:** A preferable exam approach, in terms of safety, would appear as follows: first, set the lowest index and then increase it until a satisfactory image or a Doppler signal is produced. Exposure time is another important parameter. Lanmage recommends that you select the lowest possible exposure time that produces diagnostically acceptable information.

Maximal values of each index and corresponding control parameters

Refer to Appendix B for the maximal values of each index and corresponding control parameters. The index values are given for each of the probes used in accordance with EN 60601-2-37 (GB 9706.9) standard.

Maximal acoustic parameters and corresponding control parameters

Refer to Appendix B for nominal values of each index and corresponding control parameters for each of the probes used in accordance with EN 61157 (GB 16846) standard.

1.1.4 Mechanical Safety

 **Warning:** Be aware of wheels and control panel, especially when you moved the machine. Depending on its configuration and accessories, the weight of the system could be over 88 kilograms, it might cause bodily injury when the machine roll over a foot or press against tibia. The control panel can be turned right or left, Land wind recommends pushing but not pulling when moving the machine. Beware especially when moving on a slope.

 **Warning:** Use only the probe cable holder provided by Lanmage.

 **Caution:** Ensure all probe cables are safe. Avail of the cable management system for ensuring the probe cables are free from damage. When moving the diagnostic equipment or attempting to go over obstacles, don't use the probe cable hook to lift up or pull the system.

 **Note:** The wheels of the system are installed with brakes. The wheels can be locked with stepping down on brakes, and freed when the brakes are lifted. The brakes should be released when moving the system.

 **Note:** If the system does not function properly after moving, please contact your supplier immediately. The installation of each component within the system can be relied upon and can suffer relative great force, but excessive force could cause malfunction to the system.

 **Note:** In the process of machine use, pay attention to the load bearing of each part. Being overweight may damage the machine parts. The main load-bearing components: keyboard panel 5kg, probe hook 1kg, probe placed rack 2kg, 2kg storage basket.

1.1.5 Acoustic Output Limits

Transmission Power

The system is provided with the function of displaying ultrasound power. The mechanical and thermal indices enabling ultrasound power transmitted to the patient to be monitored and limited.

The range of power transmission (scanning signal amplitude) is -18dB ~ 0dB. The selection Of 0dB (or 100%), in conjunction with other controls or functions of the system, sets the maximum sound intensity and the mechanical index of each probe where:

$$I_{SPTA3} \leq 720 \text{mW} / \text{cm}^2 \cdot MI \leq 1.9$$

Use the power transmission presets of the system.

Please refer to Table 1.1 for the possible transmission power values.

Table 1.1 Possible Transmission Power Values

0	-6dB	-12dB	-18dB(-15dB)
100%	50%	25%	12% (18%)

The system ensures the real-time displaying of scanning parameters on the field of the active probe in all imaging modes.

The real-time display of output power provides the user with the relevant information related to ultrasound intensity.



Warning: The user is responsible for selecting the signal level used. To adjust transmission power applied to the patient through the probe, use the respective keys on the system control panel. Please refer to the introduction to keys in Chapter 2 System Controls for the application of available keys. Rotate [Select] and move the cursor to select [A. Power], and click to adjust the transmission power. As the fundamental function of the system, it determines the transmission power of all probes and modes in the period of real-time scanning. However, it is not the only factor to influence MI and TI.

The range and, in particular, the maximum value of MI and TI vary with probes. In addition, MI and TI preset values are provided for each type of diagnostic exam.

Imaging Functions That Change Acoustic Output



Warning: Monitor the real-time display of MI and TI all times.



Note: In addition to rotate [Select] and move the cursor to select [A. Power], and click to adjust the transmission power, the acoustic output may be affected by such functions or system controls as follows:

- Power ON/OFF;
- Pulse repetition frequency (PRF) of transmitter emission in PW-mode;
- PRF in Color-mode;
- Exam zone (Zone);
- Focusing, the number of focuses and focus position depth;
- Freeze Mode;
- Imaging depth;
- Color beam density;
- Color sensitivity;
- Color window size in color mapping modes;
- System presets (See Chapter 8 Preset);
- Probe type;
- using a gel pad;
- Operating mode.

1.1.6 Probe Surface Temperature

The maximum surface temperature of the probe applied to the patient's body and operating at the same time of emitting shall not exceed 41°C.



Caution: Be extremely careful! Never to operate a probe whilst emitting without contacting the patient's body.

The surface temperature of a probe which is being operated but makes no contact with the patient's body may rise until the emission function is cut off automatically (the Freeze Mode will be automatically activated in 5 minutes).

1.1.7 Electromagnetic Compatibility

EMC is defined as the ability of the product, equipment or diagnostic system to function with the requirements in an electromagnetic environment and yet without producing any unbearable electromagnetic interference to any equipment in such environment.

EMI is defined as the ability of the product, equipment or diagnostic system to function satisfactorily despite the existence of EMI.

Electromagnetic radiation is the ability of the product, equipment or diagnostic system to channel the unbearable EMI into the usage environment.

The digital colored ultrasound diagnosis system is made with the existing EMC requirements. The use of this diagnostic system in a place where magnetic field exists may cause momentary degradation of ultrasound image. If this phenomenon occurs in high frequency, the user is recommended to run a check on the environment where the system is in use, in order to ascertain the possible radiation source. The radiation may come from the same room or adjoining room where other electrical equipment are in use, or it may also come from portable and radio-frequency-generated telecommunication equipment such as cell phones or pagers, or wireless equipment, televisions or microwave transmission equipment in the vicinity. In case EMI may cause interference to this diagnostic system, it may become necessary to move the system to another location. The digital colored ultrasound diagnostic system has complied with international CISPR 11 standards in radiation and transmission of EMI. Due to achieving such standards, this diagnostic system can be used in all facilities (except civil use or the public low voltage supply network that directly connects to buildings intended for civil use).

EMC Tests includes all n that pertains to the relevant electromagnetic radiation and interference resistance of the diagnostic equipment. They ensure the operating environment of the diagnostic equipment can fulfill all the prescribed conditions set out in the reference information. The system functions may be lowered if operating the equipment in an environment that fails to fulfill these conditions.

Preferable operation conditions and electromagnetic compatibility levels of digital colored Doppler diagnostic scanner is given in Table 1.2 and 1.3. The system is designed to be

operated in the designed electromagnetic environment.

Table 1.2 —Electromagnetic emissions

Guidance and manufacturer's declaration — electromagnetic emissions		
The Touch series scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Touch series scanner should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment —guidance
RF emissions CISPR 11	Group 1	The Touch series scanner 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	Touch series scanners are suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is needed. Warning: Touch series scanners are intended for use by healthcare professionals only. Touch series scanner may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Touch series scanners or shielding the location.
Harmonic Emissions EN 61000-3-2	Class A	
Voltage Fluctuations/flicker emissions EN 61000-3-3	Complies	

Table 1.3 —Electromagnetic immunity

Guidance and manufacturer's declaration — electromagnetic immunity			
The Touch series scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Touch series scanner should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) EN 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±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%.
Electrical fast transient/burst EN 61000-4-4	±2kV for power supply lines ±1kV for signal input/output lines	±2kV for power supply lines ±1kV for signal output lines	Mains power quality Should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV line to line ±2kV line to earth	±1 k V d i f f e r e n t l a l mode ±2 k V common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% UT (>95% dip in UT) For 0.5 cycle <5% UT (>95% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95% dip in UT) for 5/6 sec	<5% UT (>95% dip in UT) For 0.5 cycle <5% UT (>95% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95% dip in UT) for 5/6 sec	Mains power quality Should be that of a typical commercial or hospital environment. If the user of the Touch series scanner requires continued operation during power mains interruptions, it is recommended that the Touch series scanner Be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field EN 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.

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3Vrms 0.15MHz to 80MHz 6 Vrms in ISM bands 3V/m 80MHz to 2.7GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment	3Vrms 0.15MHz to 80MHz 6 Vrms in ISM bands 3V/m 80MHz to 2.7GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment	Portable and mobile RF communications equipment should be used no closer to any part of the Touch series scanner, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation Distance $d=[3.5/\sqrt{P}] \times P^{1/2}$ $d=1.2 \times \sqrt{P}$ 80MHz to 800 MHz $d=2.3 \times \sqrt{P}$ 800MHz to 2.7GHz Where P is the maximum output power rating of The transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following Symbol: 

Table 1.4 Recommended separation distance between portable and mobile RF communications equipment and (Touch series scanner)

Transmitter rated maximum output power /W	Corresponding transmitter isolation frequency of different distances /m		
	150 kHz ~ 80 MHz $d = 1.2 \times P^{1/2}$	80 MHz ~ 800 MHz $d = 1.2 \times P^{1/2}$	800 MHz ~ 2.5 GHz $d = 1.2 \times P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23



Note: The production and usage of this equipment may emit some radio frequency energy. Equipment may cause radio frequency interference for other medical and non- medical equipment and radio communication. To prevent to produce such interference, this product has passed the tests that confirmed its compliance with electromagnetic compatibility (EMC) requirements of EN 60601-1-2, which is from European standard (EN60601-1-2). The EN

standard used for European norms in Europe. But the company does not guarantee would never have interference in individual installation environment.



Note: If found the equipment emerge interference which can be determined through open and close the equipment. Users (or qualified maintenance personnel) should take the following one or more measures to solve interference problems:

- Adjusting the affected equipment direction or location.
- Add the distance between this equipment and the affected equipment.
- Using other power supply (not affected equipment used) for this equipment.
- Contact the after-sales maintenance personnel of the Lanmage Company in time.



Note: For the following caused circumstances of EMC interference, the manufacturer shall not be responsible for: Using the other Internet cables which not recommended. Apart or refit the equipment without permission.



Note: All of the enclosure should be closed when operate system, ensure the intactness of the machine before system operating, it may affect the system EMC performance in the enclosure open operating system.

Chapter 2 Introduction

2.1 User's Manual

User's Manual including this manual and online help, introduces the system basic performance, safety precautions, imaging mode, measurements and calculations, and maintenance of probe and system.

This manual contains all the necessary and sufficient information for securely operating the system and the after-sales service personnel of Lanmage will provide advanced training for operators within the valid period of agreement. Before you try to use this system, please make sure you have read and understood all of the information contained in this manual.



Note: Please always keep this manual being placed next to the device, and periodically review relevant operation procedures and security considerations.

2.2 Working Theories

Under the system control signal, the transmitting circuit will generate transmitting actuating signal that will be formed into transmitting high-voltage pulse via the high voltage driver, this group of high-voltage pulse is sent to the array element of the corresponding probe via the multiplexer T/R switch, resulting in the ultrasound of specific frequency, delay and intensity.

The ultrasonic echo signals that are reflected back by the human tissues are received by the same set of array elements and converted into the echo electrical signals, which will directly enter the high-speed analog-to-digital converter (ADC) via pre-amplification and pretreatment of gain compensation, and ADC will carry out the signal sampling and generate the digital signal in quantization.

The sophisticated dynamic delay of digital echo signal can be realized by using the programmable logic devices, and then carry out beam synthesis. The beam synthesis is composed of dynamic focusing, dynamic aperture and dynamic iodization as well as other processing procedures.

The signals of beam synthesis adopt dynamic filtering, amplitude detection, second sampling, dynamic range conversion, time and space filtering, frame processing as well as other signal and image processing technologies so as to improve the image resolution; the processed image data will be sent to the host control system via digital scan conversion to achieve real-time image display and interaction.

2.3 Intended Use

Ultrasound Color Doppler Diagnostic Scanner is intended to be used in the ultrasound diagnostic of the human body. It is applicable for adults, pregnant women, pediatric patients and neonates.

It is used for ultrasound diagnosis on tissue organs, which is applicable to Abdomen, gynecology and obstetrics, urology, blood vessels, small organs, such as heart, emergency treatment and pediatric diagnosis.

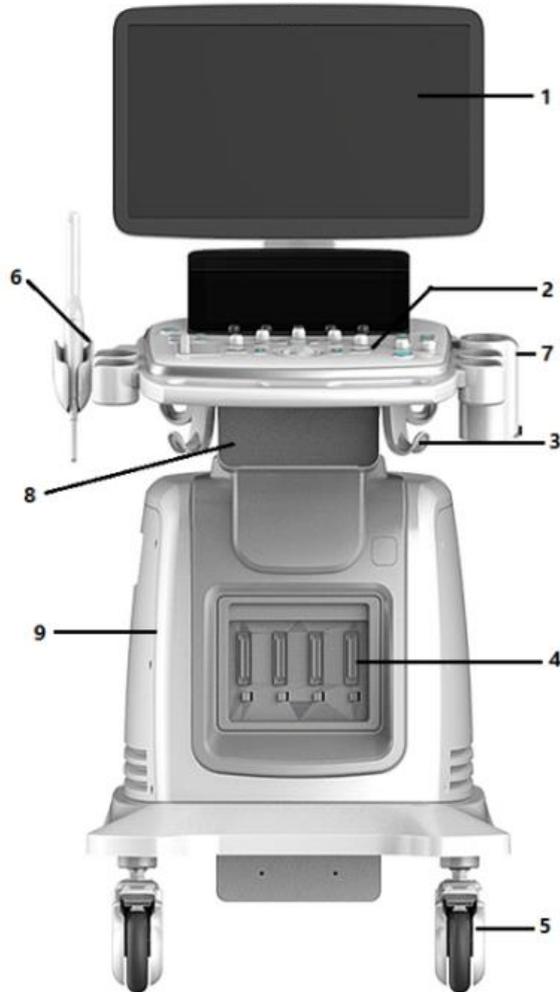
2.4 Imaging Modes

This system is able to support the measurements in B Mode, M Mode, Color Mode, PDI Mode, PW Mode and THI Mode, etc.

2.5 General View

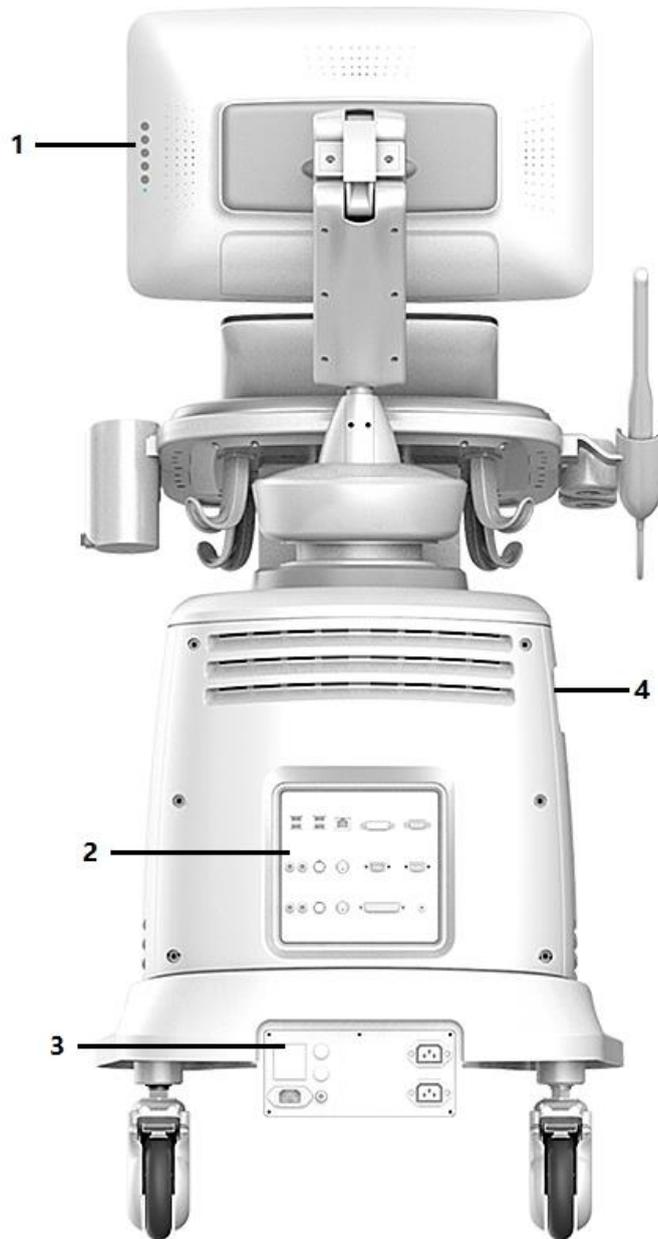
This system is configured in standard version. Its front view and left view are shown in the figures below.

Front view of the system



- | | | |
|--------------------------|-------------------|---------------------|
| 1. Monitor (LCD) | 2. Control panel | 3. Probe cable hook |
| 4. Probe connection port | 5. Wheel | 6. Probe Holder |
| 7. Gel Bottle Holder | 8. Storage basket | 9. Host |

Back view of the system

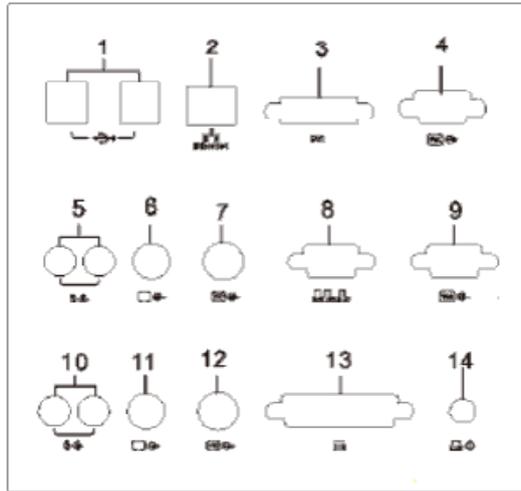


1. Monitor brightness adjustment button 2. Input/output Port

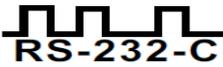
3. Power Supply Panel 4. DVD R/W drive

2.6 Connectors

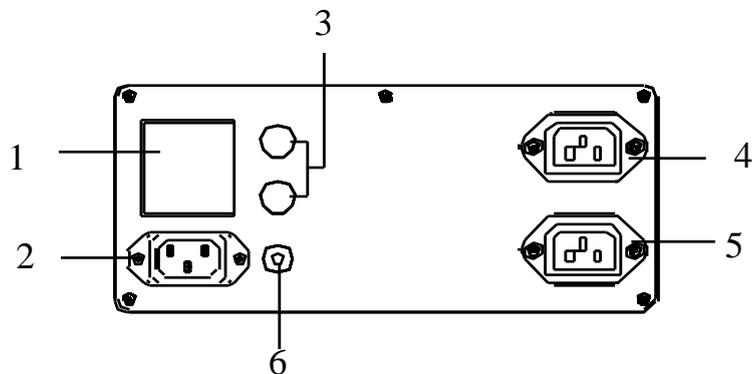
I/O Panel:



Serial number	Icon	Name
1		USB Port
2		Ethernet Connection Port
3		DVI Output
4		VGA Output
5		Audio Input
6		Composite video input
7		S-video Input

Serial number	Icon	Name
8		RS-232-C Serial Port
9		VGA Input
10		Audio Output
11		Composite video Output
12		S-video Output
13		Printer Port
14		Printer Remote Port

Power supply panel:



1. Power switch 2. Power input jack 3. Fuse
 4. Auxiliary output 150VA 5. Auxiliary output 20VA 6. Grounding terminal

Monitor Keys:

Keys in the rear of the monitor can directly adjust the settings of monitor brightness and contrast. You can use the menu options to adjust the other settings of the monitor.

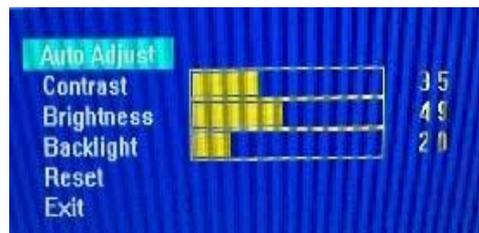
 **Note:** Language settings of the monitor menu are separate from language settings of the ultrasonic system.

 **Note:** The manufacturer defaults the settings of monitor brightness, contrast and backlight control as imaging presets defined by the manufacturer. Adjusting monitor brightness, contrast

and backlight control may have an impact on the image optimization effects arising from preset values defined by the manufacturer.

In order to guarantee consistency in the process of image reproduction, you should adjust brightness and contrast of the image monitor before adjusting print quality of the installed recording equipment.

The monitor has the functions of automatic adjustment, contrast adjustment, brightness adjustment, backlight control, reset and exit, as shown in the figure below, through which you can adjust these controls to match your preferences, and make it in line with the lighting conditions of the room.



The back wall of the system is respectively attached with a nameplate (top) for full-digital color ultrasonic diagnosis system and a label for system warning (bottom), on which relevant information about the system is noted.

Ultrasound Color Doppler Diagnostic Scanner

Model: Mirror 5 Touch
Security Type: Class I

Power: 100-240V~ 50/60Hz 5.5-2.5A

Shenzhen Lanmage Medical Technology Co., Ltd.
 1st Floor, Building B Jingchengda Industrial Park, No.4 keji road,
 Langxin Community, Shiyuan Street, 518000 Bao'an District, Shenzhen China

Lotus NL B.V.
 Koningin Julianaplein 10, 1e Verd, 2595AA,
 The Hague, Netherlands.

Service : 400-888-6452

Origin: Shenzhen, P.R. China

CE 0197

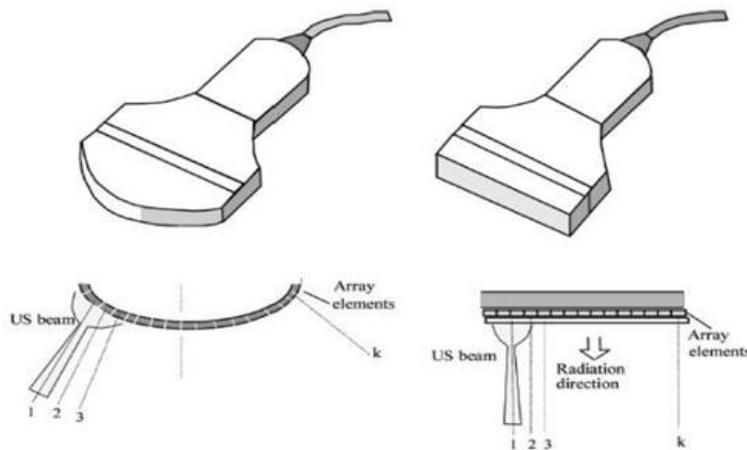
	Warning: Risk of electric shock. Do not open the device.
	Warning: Risk of explosion, Do not use in the presence of flammable anesthetics.
	Warning: Please refer to instruction manual.
	Warning: Max. 5kg for printer shelf Max. 2kg for accessories shelf.
	Warning: Pushing prohibited when the wheels are locked.

2.7 Probe

2.7.1 Probe Types and Scanning Principles

This system mainly uses the following electronic scanning ultrasonic probes: convex array probe (e.g.C2-5) and linear array probe (e.g.L5-10).

The following figure shows the overall view of the ultrasonic probe configured in the system and its scanning principles.



Overall view of electronic scanning probe and its scanning principles

A) Convex array probe; B) Linear array probe

All probes have more than one frequency spot. Probe is an applied part of the system, and users can connect four probes on the ultrasonic imaging system, but there is only one probe to be activated at the same moment. Probe configurations are based on your contract of purchase, as shown in the following table.

Model	Type	Center Frequency
C1-5	Convex Probe	3.5 MHz
C2-5	Convex Probe	3.5 MHz
L5-10	Linear Probe	7.5 MHz
L4-13	Linear Probe	7.5 MHz
EC4-9	Convex Probe	6.5MHz
C4-9MC	Micro Convex Probe	6.5 MHz
C4-9ER	Convex Probe	6.5 MHz
P2-3	Phased array Probe	2.5 MHz
P1-4	Phased array Probe	2.5 MHz
4C2-5n	Convex Probe	4 MHz

2.7.2 Probe Connection



Note: Before connecting or disconnecting the probe, make sure that "Freeze" mode is enabled!

Plug the probe connector into a free socket. Turn the probe lock-lever to lock position. Ensure that the probe sits tight. Four probes can be simultaneously connected to the system: one is connected to Port A, one to Port B and other to Port C and D. There is a label attached on the probe connector, listing the probe name, serial number, center frequency, and etc.

2.7.3 Selecting Active Probe

Press [Probe] on the control panel to enter probe selection menu. The system will list the probe connected to the system. If the probe port is not connected with a probe, the probe area will display a blank; if there is only one probe connected to the system, the system will default this probe as the active probe.

2.7.4 Probe Applications



Note: Please make sure that the ultrasonic probe is always applied in accordance with the intended uses that are prescribed for the related exam items in the following table.

Exam Subjects	Probe						
	C1-5 C2-5	L5-10	L4-13	4C2-5n	P2-3 P1-4	EC4-9 C4-9ER	C4-9MC
Abdomen	+				+	+	+
Gynecology	+			+		+	+
Obstetrics	+				+		+
Urology	+						
Carotid artery		+	+				
Peripheral arterial		+	+				
Intravenous		+					
small organs		+	+				
Heart					+		
pediatric							
musculoskeletal		+	+				

* Including probes in the Item of the basic system.

** Not including probes in the Item of the basic system. They can be available if required by customers.

2.8 Peripherals

2.8.1 List of Peripherals

The system is configured with the following peripherals:

- Foot switch (optional);
- Printer (optional).



Note: Please choose the printers recommended by the personnel working in the Lanmage Customer Service Center, and connect the printer with the system.

2.8.2 Connections of Peripheral Devices

The signal cables of peripheral device shall be connected to the port on the I/O panel of the system.



Note: when you connect additional peripherals, please observe the following requirements: when you need to connect this system to the equipment produced by any other manufacturers for electrical connection or mechanical connection, make sure they conform to EN 60601-1 standards, and re-examine leakage current and other safety performance indicators of the whole system, so as to avoid potential dangers caused by leakage current overlay.

You can connect this system with LAN of the medical institutions with a category-5 twisted pair wire (not included in the kit of the system).

Caution: If the system is connected with LAN, the warranty and after-warranty services shall be implemented in accordance with the independent service agreement signed between the operating organization and Lanmage.



Caution: Please be careful when you connect this system with LAN (i.e. Ethernet). To do this kind of connection, consult Lanmage Customer Service Center. Any person who connects this medical unit with other devices shall take responsibilities for such connection safety.



Caution: To connect this system with LAN, the network administrator shall be responsible for the correct settings and antivirus security for the network connection. If necessary, consult Lanmage Customer Service Center.

2.9 Control Panel

The ultrasound diagnostic system is equipped with keys, trackball, knobs, TGC (time gain compensation) slider controls and toggles. You can access system settings, exam area and patients' exam results by using these buttons on the control panel. The logically arranged buttons and knobs will surely facilitate your work.

2.9.1 Control Panel Brightness

The system provides two levels of brightness on the control panel: when the ultrasonic imaging system is in use, the control panel shows white backlight; when a knob or button is active, the active knob or button becomes blue Backlight. Buttons without active functions have no backlight.

2.9.2 Introduction of Control Panel Buttons



2.9.2.1 Function keys

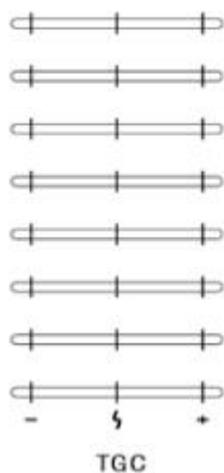
1. Power button and TGC Slider Control

Power button



To switch on/off the system.

TGC Slider Control



Located at the bottom left side of the system control panel, TGC slide controls to selectively adjust the gain (brightness) in depth. Slide a slide control to the left to decrease the gain in the corresponding specific 2D depth. Slide a slide control to the right to increase the gain in the corresponding specific 2D depth. The system displays a graph representing the TGC curve on the image.

2. Patient Exam Process

Patient



Enter the new patient interface, that you can input a new patient information; also you can view or edit the current and previous patient's information.

Probe



Enter the probe and exam selection interface which displays a list of probes and exams, including available system-defined exam types and user-defined settings.

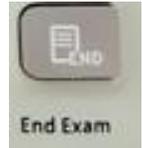
Review



Enter the interface to review, select and save the patient's basic information and image information.

Report

Enter the Patient Report interface to display the reports about corresponding exam items of the patient, and execute the functions of print preview, print, export, and page turning.

End Exam

End the current patient exam, and start a new patient exam.

3. Parameter adjustment knob:**Parameter adjustment knob**

Using the Parameter adjustment knob to activate, adjust the key options displayed at the bottom of the screen. There are 5 parameters of the Parameter adjustment knob, corresponding to the 5 column parameters below the screen.

Press the parameter adjusting key to switch between the first and the second line of the corresponding parameters. Rotate the parameter adjustment knob can adjust the corresponding parameters.

4. Image Operation Controls**B**

Press [B] knob to enter B mode for grayscale imaging. If a combination mode or other imaging mode is activated, pressing [B] knob will allow the system to exit the current mode or function and return to B mode.

Rotating [B] knob can change the total gain of B mode. Clockwise rotating can increase gain; and counter-clockwise rotating can decrease gain.

Gain value will be displayed in the imaging parameter area on the top left corner of the screen.



Press [C] to enter the color flow imaging mode. Clockwise rotating [C] knob to increase total gain of Color mode while counter-clockwise rotating to decrease it.



Note: in the PDI mode, rotating [C] knob can change the total gain of power mode. Gain value will be displayed in the imaging parameter area on the top left corner of the screen.



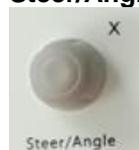
Pressing [D] knob can display a Doppler Sampling line and a Sampling gate in the B-mode image. According to the system presets, pressing [D] knob for the first time can also enable the display of Doppler spectrum. For pulsed Doppler, pressing PW knob again can enable the system to display B/PW modes and give out Doppler sound signals. Rotating [D] knob can change the total gain of PW mode. Clockwise rotating [D] knob can increase gain; and counter-clockwise rotating [D] knob can decrease gain. In 3D/4D mode, rotate the knob to rotate the image around the Z axis.



Pressing [M] knob can display M-mode cursor in the image of B mode. Roll the trackball to place the cursor on the desired area. Press [M] knob again to display B/M mode.

Rotating [M] knob to change the total gain of M mode. Clockwise rotating [M] knob can increase gain; and counter-clockwise rotating [M] knob can decrease gain. Gain value will be displayed in the imaging parameter area on the top left corner of the screen. In 3D/4D mode, rotate the knob to rotate the image around the Y axis.

Steer/Angle



Angle value is displayed in the imaging parameter area on the top left corner of the screen. The system can also display the angle values greater than 1° on the image screen. When the

angle is greater than or equal to 60°, the system will highlight angle values in red.

In the PW mode (when the Angle function is activated), rotating [Steer/Angle] can adjust the Doppler angle.

When using a linear array probe, you can press [Steer/Angle] to switch functions of angle and steering in the process of Doppler imaging. The system will highlight cine and image in green under the control of the trackball, so as to tell users which function is activated.

In 3D/4D mode, rotate the knob to rotate the image around the x axis.

4D



It is only used for 4D probe, press [4D] key to enter the pre-acquisition interface of 3/4d mode, and activate this control to observe 3d image, as well as to conduct various kinds of rendering, cutting, rotation and other processing of 3d image.

CW



Press the activation of continuous wave Doppler imaging. Is suitable for the purpose of heart ultrasound (the CW mode is only available under the phased array probe).

Depth/Zoom



Rotate the knob to change imaging depth; Press the knob to activate a zoom window, and start amplification; We can Zoom the image no matter in real-time state or freeze state ,Press again to exit zoom mode.

Depth value is displayed on the left lower corner of the image.

Focus



Press this button to change the number of focuses in the image, and rotate this button to position the focus.

5. Controls around the trackball:

Trackball



The trackball can position the image body mark, measuring mark and text. You can also use trackball in combination with the Set key on the control panel.

The System will tell users which functions are controlled by the trackball, for which the method is: the system highlights the selected image body mark, measuring mark and text in green, and/or lists their active functions on the bottom left of the screen.

You can use the system presets to adjust the moving speed of the trackball.

Update



In a mixed-mode imaging process, you can switch between frozen display and real-time display.

For example, if a B-mode image is in a frozen state, while Doppler spectrum is in a real-time state, after you press [Update], the system will display real-time 2D images, and freeze the Doppler spectrum.

When performing a measurement, pressing [Update] can circularly view the measuring mark for editing

Caliper



Press [Caliper] to activate General Measurement function. The system will display the measurement options for selected imaging mode and exam. Press the [Cancel] on the touchscreen to exit the measurement function.

Measure



Press [Measure] to activate the specialized measurement function;

When the measurement function is activated, the system will display the specialized

measurement options for the selected imaging mode and exam.

Press [Freeze] on the control panel or the [Cancel] on the touchscreen to exit the measurement function. The measurement results can be exported to the patient report.

Cursor



Activate the cursor, the cursor can move in the entire screen.

Clear



Clear the contents of the screen

Set



Used to confirm selection of a specific function or command. For example, you can use it to lock the caliper, select a menu or body mark, including measuring values in the patient report or delete a measurement from the worksheet.

When it is used along with the trackball, the Confirm function is similar to the mouse click based on Windows technology.

Freeze



Freeze the image, scan or spectrum on the screen. If images or scans is frozen, press [Freeze] to restore to real-time Imaging.

System presets can change the response of the Freeze key. When you press [Freeze], other functions will be activated.

User-defined keys

F1, F2, F3, F4 keys are user-defined function keys. The default function of each key can be preset in the system settings. See chapter 8 preset for more information.

6. Storage Controls:**Save**

Press to save images, the images displayed in the thumbnail area. You can use system presets to set the area for image storage.

2.9.2.2 Touchscreen common buttons

You can use the touch screen keyboard to Input patient data, Select exam, Annotate clinical images and Configure system preset. Some of the common use buttons are:

Keyboard

Press to dial out the soft keyboard for inputting content. The touch screen keyboard layout is similar to standard computer keyboard. Some special function key are listed as below:

Help	Press to display online help to view the user's manual.
Capture	Press to access the screen for saving, deleting, and overwriting quick settings (used for imaging settings of certain types of probes and exams)
work queue	Press to display the screen of DICOM work queue to view the sending status of DICOM images.
Full Screen	Press to display the image in full screen size, press again to exit.
Clear	Press to clear all annotations, arrows, body marks and measurements on the screen.

Mark

Press the [Mark] key to display a list of the available body marks of the selected exam type. Click on the body icon on the touch screen to select the appropriate body mark.

Text

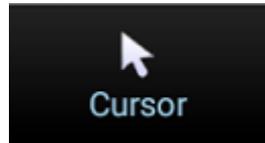
Press to activate the annotation function and place the text cursor on the image screen. Enter the texts through the keyboard or by selecting the terms in the annotation list.

Arrow

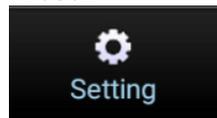
Press to Place an arrow on the image area of the screen.

Backspace key

Press to Exit the current display mode, function or page, and reactivate the previous mode, function or page.

Cursor

Press to show/hide cursor.

Preset

Press to enter system setting interface. Use the system presets to modify and customize the system

2.10 System Symbols

Symbol	Description
	Alternating current
	Type BF Applied Part
	Caution.
	Equipotential Connection
	ON (power)

	OFF (power)
	Footswitch Connector
	Contrast control
	Monitor brightness Control
	Probe port
IPX7	Probe anti-flooding (host not applicable)
	USB port
	Refer to instruction manual
	General warning sign
	Bar code
	Grounding mark
	Manufacturer (This symbol shall be accompanied by the name and address of the manufacturer.)
	Authorized representative in the European Community (This symbol shall be accompanied by the name and address of the authorized representative in the European Community.)
	Date of manufacture
	Serial number
	CE marking
	Dangerous voltage
	Pushing prohibited when the wheels are locked.
	Danger: An explosive danger may occur if it is used in the presence of flammable anesthetics
	No heavy load

Chapter 3 Starting Examinations

3.1 System Start-up and Running Sequence Inspection

The system should be used in a medical room with an ambient temperature of 5°C–40°C.

Lanmage recommends not installing this system in the vicinity of X-ray equipment, ultrasonic and microwave frequency therapy equipment.



Warning: This system will generate, receive and radiate RF electromagnetic waves. If it is not installed or used strictly in accordance with the system installation and operating instructions, it may have a detrimental impact on other devices, and may also interfere with itself.

We encourage users to take the following measures to exclude interferences (by switching

"ON/OFF" the system to identify interferences):

- To changes the direction or position of the device;
- To improve the isolation between the system and the equipment;
- The socket connected to this system is different from those to other devices;
- If you need help, please contact Lanmage' Customer Service Center.

Install the system monitor and avoid its screen being exposed to local lighting and direct sunlight as well as other light sources.

This system shall be installed, assembled, customized an adjusted by the personnel from Lanmage Customer Service Center. Lanmage Customer Service Center can also provide services upon the expiry of warranty in accordance with the independent service agreements signed between the operation institutions and Lanmage. After transport or storage, please contact Lanmage Customer Service Center for any questions about the system's basic information about re-storage, installation and assembly.

Before being installed at the scheduled location, the system shall be unpacked, and stored in the environment at the temperatures below 5°C. After being placed for at least two hours at the room temperature, turn on/off the system and ultrasonic probe.



Caution: Before moving the system from one place to another place, first open the lock on the caster brake, and lock the caster near the step or ramp.



Caution: This system shall be always installed on a level surface; therefore, the casters must

be locked. Any failure in following these requirements may cause overturning or rolling of the system.



Caution: In the process of using the machine, rotate the monitor slowly, not too large. When the rotation Angle reaches the limit, stop rotating in the same direction.

3.1.1 System Start-up



Caution: Before starting this system with mains power supply for the first time, please make sure that voltage and frequency are in line with the technical specifications described on the nameplate on the back panel of the system.

Start the system, and perform the following steps:

- Make sure that the system has been connected with the feeder line of the monitor, and has been properly connected to the three-hole socket with protective grounding in 100-240V 50Hz;
- After being connected to the mains power supply, adjust the electric switch "POWER"
- On the back panel to "I" for starting, and press  on the top left corner of the control panel;
- Turn on the printer and load paper into it.

3.1.2 System Operation

When you start the system, the logo of Lanmage will appear, and after several seconds of program loading, the system will automatically enter the main interface, and the image is defaulted as B Mode.



Note: If the system loading fails, an error message will prompt. In this case, please contact the personnel in Lanmage Customer Service Center.



Warning: Users are not allowed to install other software without authorization.

3.1.3 System Continuous Operation

This system can continuously run for 12 hours. If you need to shut down the system in the running process, turn on the system after 20 seconds.

! **Note:** Due to the compatibility issues arising out of the English operating system, the system will come to occasionally stop responding, which can be resolved by restarting the system, and the system needs to put on a patch so as to completely solve the problem.

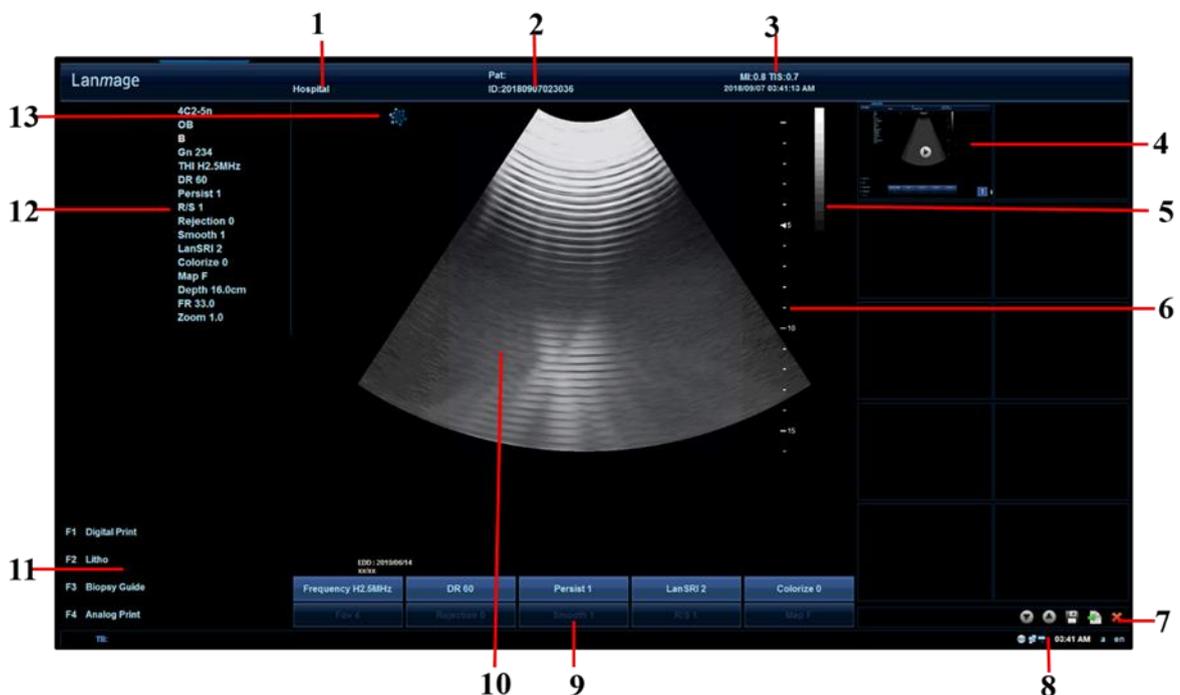
3.1.4 System Shutdown

After ensuring the system data has been completely saved, return the menu to main interface, and press  on the left corner of the control panel. The prompt information of "Do you want to shut down?" pops up and the system will be automatically off in several seconds after confirmation.

! **Caution:** When the machine is downloading, you cannot shut down the system; otherwise, this could cause the failure of software downloading. If you need to shut down the system, please wait until the operating system has finished the downloading.

3.2 Information on the Imaging Screen

Information that is displayed on the imaging screen consists of two categories: symbol information and image information. The locations for various display areas of these two types of information are shown in the following diagrams.



1. Hospital name;
2. Current patient name and ID number;
3. Mechanical index (MI), thermal index for soft-tissue (TIS), System time and date (the time does not go when being frozen);
4. Thumbnails area;

5. Gray scale (right); color scale will occur on the left of gray scale in Color Doppler Blood Flow Imaging (color mode) or Power Doppler Blood Flow Imaging (PDI mode).
6. Scale and focus marking;
7. Option buttons from left to right: Page-down, Page-down, save to a USB Disk or CD, Sent to the report and Delete images;
8. From left to right are network connection, CD, USB flash drive icon, System time, change case display, and System language;
9. Soft menu ;
10. Image display area;
11. Display the current custom key preset;
12. active Probe Type, exam section, Scanning and Processing Parameters;
13. Probe direction signs. Freeze indication

3.3 Patient Information

Press [Patient] on the control panel, and the patient information interface pops up, which includes patient general information and exam information about the current patient and search menu.

The screenshot shows the 'Patient' information window. It is divided into several sections:

- General Information:** Includes fields for Patient ID (20180907023036), Last Name, Ref.M.D, First Name, Operator, DOB (20180907), Age (xxxx), MI, and Gender (Female, Male, Unknown). A 'Clear Data' button is present.
- Exam Information:** Includes fields for Height (0 cm), Weight (0 kg), BSA (0 m²), and a text area for 'Additional Info.' Below this is a search section with 'Search Key' set to 'Patient ID' and a 'String' input field.
- Table:** A table with columns: Patient ID, Last Name, First Name, DOB, Gender, Exam Date, Exam. It contains one row of data: 20180907023036, (empty), (empty), 2018/09/07, Unknown, 2018/09/07 02:30:52, ABD.
- Buttons:** At the bottom are buttons for 'New Patient', 'New Exam', 'Delete Exam', 'Find Patient', 'OK', 'Apply', and 'Cancel'.

3.3.1 New Patient information

1. Press the [Patient] button on the control panel;
2. Roll the trackball to [New Patient] and select the information box, press [Set], and input patient information by using the keyboard;

3. Select the information edit boxes of the remaining patients in the same operation, and the operator shall enter patient information as detailed as possible.
4. Click [Apply] to save the settings, and click [OK] to return to main interface.

3.3.2 Previous patients

- If you have saved this patient's information, you do not need to re-enter the information, and just click ▼ in the [Search], and select one of the information to input in the [Search Key] for searching, press [New Patient] after exporting the information, then you can re-establish the patient's information exam.
- If you have saved the patient information, and would like to continue the last exam, you can search the patient according to the method above, then double-click the patient list information, and press [Set] to resume the last exam.
- If the patient's information is incorrect and has to be re-established, you can move the arrow to the appropriate setting area for modification; to clear all the information,
- Click the [Delete Exam] button below, then re-enter the information.

3.4 Probe and Exam Items

Four probe icons and corresponding probe measurement item menus will occur after pressing the [Probe / Exam] on the control panel, and the models and appearances of these probes connected with the system are respectively in line with the interface, of which the probe model in blue background is the default active probe, and the exam items followed with [*] are the default exam items of this probe. When the port is not connected with a probe, the corresponding probe area will be displayed in blank.

Probe/Exam			
4C2-5n	L5-10	P2-3	C1-5
			
Exam Name	Exam Name	Exam Name	Exam Name
ABD	Vascular	Cardiac *	ABD *
Renal	Carotid *	Dif-Cardiac	Renal
ABD-Vascular	P-Arterial	Ped-Cardiac	ABD-Vascular
Dif-ABD	VA	TCD	Ped-ABD
Ped-ABD	Venous	ABD	GYN
GYN	SMP	Dif-ABD	OB
OB *	Thyroid	OB	OB-1
OB-1	Breast	Vascular	OB-2/3
OB-2/3	Testicle	EM	Fetal Heart
Fetal Heart	SmEye		Urology
Urology	OB		Prostate
Prostate	OB-1		Vascular
Vascular	MSK		EM
EM	Orthopedics		Ultrasonic Contrast
Volume	ABD		Physical Exam
Volume1	EM		
Volume2			
Volume3			

Click the probe icon, select the desired probe and return to the main interface; the user can also click the [Exam Item] of the corresponding probe, and the main interface will carry out the measurement to the exam item of the current probe.

User can also select desire probe and exam item on the touch screen.



Note: If the port is connected with the probe, and the corresponding area is still displayed in blank, please contact the appropriate service personnel for inspection.

3.5 End Exam

Before examining a new patient, press <End Exam> to end the exam of the previous patient, update the patient ID and information, to avoid mixing data of the next new patient.

Click the [End/Exam] to see whether the current patient check menu is finished and the current patient will be checked. You can use the system preset, select whether the "end check" prompt message will pop up and the state after the check.

To end an exam, you can do one of the following:

- Press [End Exam] on the control panel.
- Click [New Patient] on the Patient screen to end the last patient exam and clear the patient information.
- Click [New Exam] on the Patient screen to end the last exam and clear the exam data.

Chapter 4 Optimizing the Image

4.1 Imaging Mode

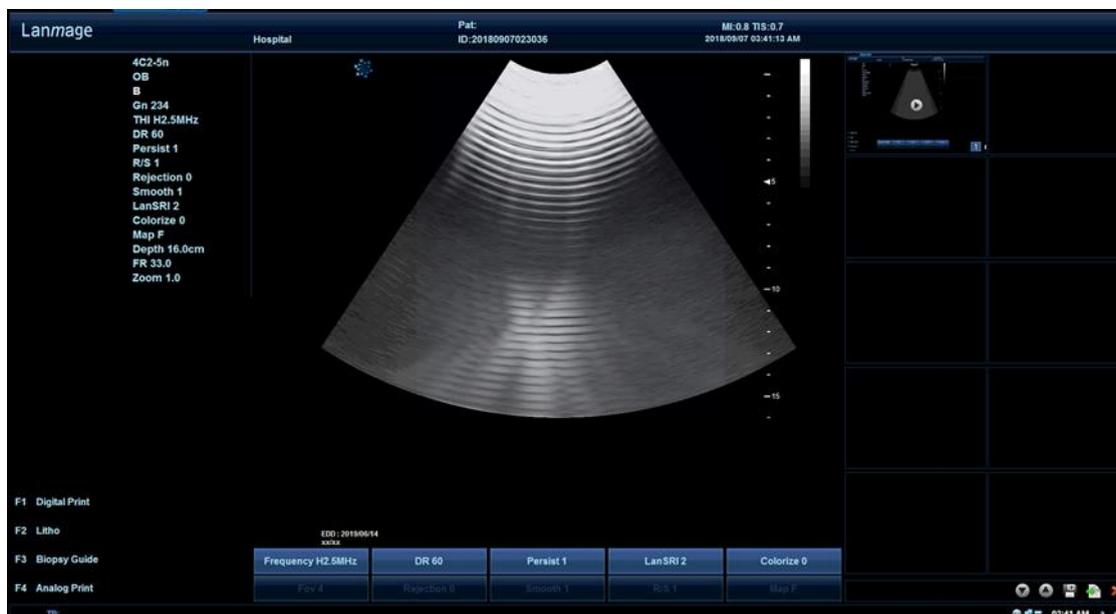
- 2D Mode B THI 2B (Dual-mode) 4 B Split mode
- C Mode Color PDI Directional PDI
- M Mode M
- Doppler Mode PW CW



Note: When operating in M mode, Color mode, PDI mode or PW mode, you can exit from these mode interfaces by pressing the B button, B mode will be displayed.

4.2 B Mode

To enter B mode, press [B] on the control panel. B mode is the default mode when the system is on.



4.2.1 B mode Exam Steps

General exam steps in B mode are as follows:

- Record the related information of the patient, and verify the system settings (probe settings and B-mode preset)
- Place the patient in the appropriate position and put the machine in place for the patient to receive a comfortable exam and for the operator to control the machine more easily and carry out the exam to the patient.
- Collect all of the data.

4.2.2 B mode Parameter Settings

The B-mode parameters can be set in the soft menu of main interface:

Frequency H4.5MHz	DR 65	Persist 1	LanSRI 3	Colorize 0
Fov 4	Rejection 0	Smooth 1	R/S 2	Map C

There are 5 parameters of the Parameter adjustment knob, corresponding to the 5 column parameters below the screen. Press the parameter adjusting key to switch between the first and the second line of the corresponding parameters. Rotate the parameter adjustment knob can adjust the corresponding parameters.

In the image above, when you change the parameters of the B mode menu bar, the parameter area on the top left of main menu will display the corresponding indicator changes (as shown below):

```

4C2-5n
OB
B
Gn 234
THI H2.5MHz
DR 60
Persist 1
R/S 1
Rejection 0
Smooth 1
LanSRI 2
Colorize 0
Map F
Depth 16.0cm
FR 33.0
Zoom 1.0

```

In B mode, to optimize the specific image scanning parameters above, you can make the

following adjustments:

Gn (Gain)

Operation: rotate [B] knob on the control panel to adjust.

Function: to set the brightness of a two-dimensional image. This knob decides the coefficients of the increasing amplitudes of echo signals. All incoming echo signals make use of the sample gain for amplification non-relevant with the depth.

You can also use TGC slider knobs to make compensations for gain through depth (Sensitivity time control), so as to select gain for different images in different depths by means of separate methods. In this way, you can determine the accurate attenuation compensation of echo signal according to the entering time (depth of emission non-uniformity). The standard position of the slider knob is located in the central position. This position corresponds to the propagation time compensation of echo signal.

F (Frequency)

Operation: Rotate [frequency] corresponding knob to change frequency range.

Function: For special types of patients, you can change the frequency parameters so as to achieve the best possible optimization effects.

DR (Dynamic Range)

View the soft menu [DR], rotate the corresponding adjustment knob to adjust the contrast of grayscale images.

Persist

Operation: View the soft menu [Persist], and rotate the corresponding adjustment knobs to adjust.

Function: This function is used to superimpose average adjacent B images, so as to optimize the image and remove noise. Persistence increasing may lead to signal missing.

R/S (Line Density)

Operation: View the soft key menu [R / S], then rotate the corresponding adjustment knob to change the size of the line density.

Function: Adjust the balance between the image line density (resolution) and the frame rate. Increasing the line density increases resolution and decreases frame rate.

Colorize

Operation: View the soft menu [Colorize] and rotate the corresponding knob to adjust.

Function: Change the color of the image.

Rejection

Operation: rotate the corresponding adjustment knob to change the rejection range.

Function: Select a level below which echoes will not be amplified (an echo must have certain minimum amplitude before it will be processed)

Smooth

Operation: View the soft menu [Smooth], rotate the corresponding adjustment knob to change the smoothness.

Function: This function is to reject image noise and to make images smooth.

LanSRI

Operation: activate the soft menu [LanSRI], rotate the corresponding adjustment knob to change the image edge.

Function: Optimize the clarity of image edge.

Map (Grayscale Map)

Operation: View the soft menu [Map], rotate the corresponding adjustment knob to adjust.

Function: This function applies the gray correction to obtain the optimum images, but it would be easy to affect the information in B mode.



Note: Before making other adjustments, please choose the grayscale map, because there is mutual dependence among grayscale map, gain and dynamic range. If you change the grayscale map, you have to reset gain and dynamic range.

Focus

Operation: Press [Focus] key on the control panel.

Function: Selection of focal area has determined the depth range for the purpose of having the best shape in this ultrasonic beam. The position of focal area can be represented with the arrow on the right side of the image.

Scanning Depth

Operation: Press [Depth / Zoom] on the control panel;

Function: rotate this key, and you can set the depth range of the echo image in a certain desired area. Only real-time depth adjustments are allowable. Changing echo image depth will cause the changes of depth proportion, MI/TIS/TIB/TIC and other indexes as well as frame rate.

FR (frame rate)

Operation: View the soft menu [FR]; rotate the [Depth/Zoom] button to change the FR

parameter

Function: This parameter will change the image frame rate

You can rotate the menu button to change B-mode image display, Functions of specific parameters and methods of operation are as follows:



Functions of specific parameters and methods of operation are as follows:

Acoustical Power

Operation: Click on the left and right button on the touch screen [A Power] icon, click the right button to increase the acoustical power, and click the left button to reduce the acoustical power.

Up/Down Flip and Left/Right Flip

Operation: Click on the touch screen [U/D flip], [L/R flip] button to flip the image upside down, or left to right.

Trapezoidal Imaging

Operation: Click on the touch screen [Trapezoidal], to open trapezoidal imaging, and click again to close the trapezoidal imaging.

Function: Activate sector sensor format for linear sensor.

Split mode

Operation: Click on the touch screen double real time button, open the 2B real time Button Blue highlight, the two images on the left and right of the screen will be displayed in real time; press the button again, real time 2B is closed in.

LanTissue

Operation: Click on the left and right button on the touch screen [LanTissue] and there will be four options to adjust, namely General, Liquid, Fat and muscle.

4B Mode

Operation: Click the touch screen [4B] button to open the 4B mode, and the continuous click screen image display area will appear four images in turn. One of the four images is in real time, and the rest are in a frozen state.

THI (Tissue Harmonic Imaging)

Operation: Press the [THI] user custom key (preset needed) on the control panel or click the touch screen [THI] button.

Function: Enhance near-field and mid-field resolution to improve the imaging contrast, and at the same time enhance far-field of Biopsy. To enter/exit the secondary (tissue) harmonic mode.

Com-Frequency

Click the "Com-Frequency" menu of the touch screen to turn on or off the frequency composition function.

4.3 Dual-B Mode

To enter the non-real time 2B mode, press the B button on the system panel, click on the [Dual] button on the touch screen, and appear on the left of the image a B MODE image, and click on the touch screen again on the [Dual] button screen to show a B mode image on the right. At this point, the image on the left is frozen and the right is real time. The image parameters can be adjusted the same as the B mode.



4.4 M Mode

M mode is a movement mode used to identify the motion pattern of objects under the ultrasonic beam. It is most commonly used to view the motion mode of the heart.

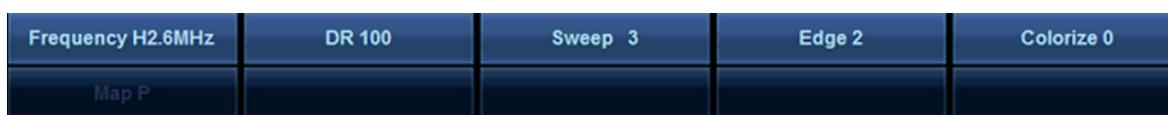


4.4.1 M mode Operating Methods

1. Press [M] on the control panel to enter B/M mode; a green sampling line will occur, and rotate the trackball to change the direction of sampling line, and locate the sampling line on the non-display B-mode area;
2. Press [M] again on the control panel to enter M mode. The position of the sampling line can also be changed by moving the trackball.
3. If necessary, you can preset the M mode, such as adjustment of scanning speed, gain, focal position and others M-mode imaging settings.
4. Press [Freeze]; then press [measure] to image measurements.
5. Press [M] again to exit M mode.

4.4.2 M mode Parameter Settings

In M mode, the parameters (as shown below) displayed in the soft menu are different from B mode, which can be adjusted just similar to B mode:



Sweep

Operation: rotate the corresponding adjustment knob to increase or decrease the scanning speed.

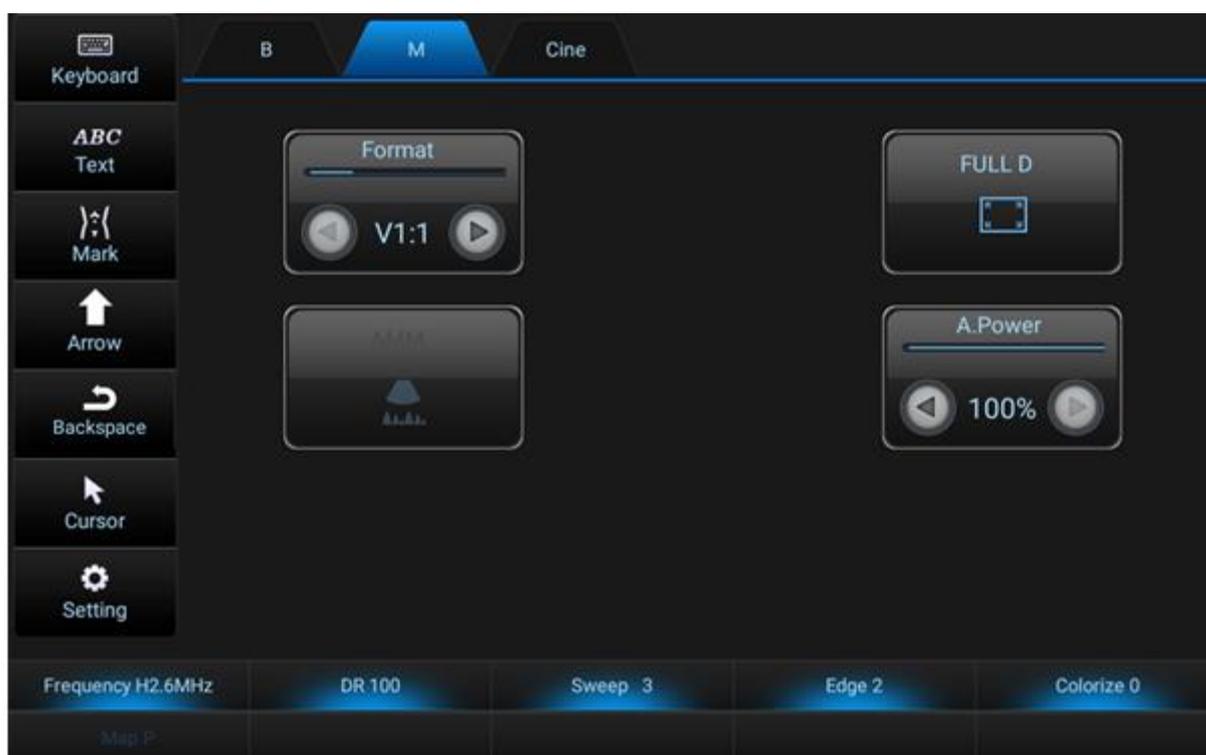
Function: Scan Speed is used to change the speed of the time line in M mode.

Edge

Operation: View the soft menu [Edge], and rotates the corresponding function knob to adjust.

Function: Optimizes the clarity of image edge.

In the main menu of M mode (as shown below), you can also set acoustical power, screen layout and others.



4.5 Color Mode

Color mode is a Doppler mode for inputting the color-coded qualitative information associated with the relative speed and direction of the fluid movement.



4.5.1 Color mode Operating Methods

1. Press [C] on the control panel, and a green sampling box will pop up, and change the position of the sampling box by rotating the trackball.
2. Press [Set], and the green box will be displayed in a dotted line; rotate the trackball to adjust the size of the box. Press [Set] again to confirm the size of the box.
3. Set the color blood flow parameters through the system preset or directly set up on the touch screen.
4. Record color blood flow images.
5. Press [C] or [B] to exit color mode.

4.5.2 Color mode Parameter Settings

The parameters of color mode can be adjusted by the soft menu, as shown below:

Frequency 4.1MHz	Scale 19.53	LanFlow M	R/S 0	Map A
Persist 3	Filter 1	Priority 4	Smooth 3	Baseline 0

Set the parameters in the following figure to optimize images through the menu above.



In color mode, the methods for setting the images shown in the figure above:

Gn (Gain)

Operation: You can change the gain by rotating [C] on the control panel, in which left/right adjustment is to decrease/increase gain.

Function: Gain can amplify the overall echo intensity processed in the color-mode window or spectrum Doppler timeline, and its value will vary depending on the probes and applications. Gain has no effects on power output. But increasing gain will lower the power output level to so as to produce images in equal quality.

Scale

Operation: rotate the corresponding adjustment knob to reduce/increase scale.

Function: Scale will affect the output energy, frame rate and wall filter.

LanFlow

Operation: rotate the corresponding adjustment knob to change the color blood flow.

Function: This function is used for image optimization by providing adjustment on parameters, including scales and filters.

R/S (Line Density)

Operation: rotate the corresponding adjustment knob to adjust the linear density.

Function: Line density helps to optimize color blood flow or spatial resolution in order to get the best color images, which will be greatly helpful for high-frame-rate fetal heartbeats, adult heart applications and clinical radiology applications. Changes of line density will also change the volume density and frame rate, and at the same time, it will Change thermal index and/or mechanical index, or may also affect the output display.

Baseline

Operation: rotate the corresponding function key to move the baseline.

Function: In the Color Mode, you can move the baseline so as to avoid aliasing in the direction of blood flow (similar to the baseline displacement in pulse Doppler mode). By moving the baseline, you can expand the speed range in one of the directions. The zero line of color scale will also make corresponding displacement. The maximum and minimum blood speed will be respectively displayed on the top and bottom of the color scale.

Persist (Frame Correlation)

Operation: Press and rotate the corresponding adjustment knob to adjust.

Function: Frame correlation can determine the persistent time of color data in the sampling box, and the persistent color data will remain on the screen until the persistent time has expired or the system has detected a higher rate of blood flow.

Filter (Wall Filter)

Operation: Press and rotate the corresponding adjustment knob to adjust the size of the filter (Hz in unit).

Function: filter the speed signal of lower-speed blood flow so as to remove the fake images resulting from breathing and other activities of patients.

Priority

Operation: Press and rotate the corresponding adjustment knob can change its size.

Function: Color priority can be used to choose whether to display arbitrary pixel color or threshold value of B mode data, and color priority increase will lead to displaying more color pixel information on the B mode image.

Smooth

Operation: Press and rotate the corresponding adjustment knob to adjust.

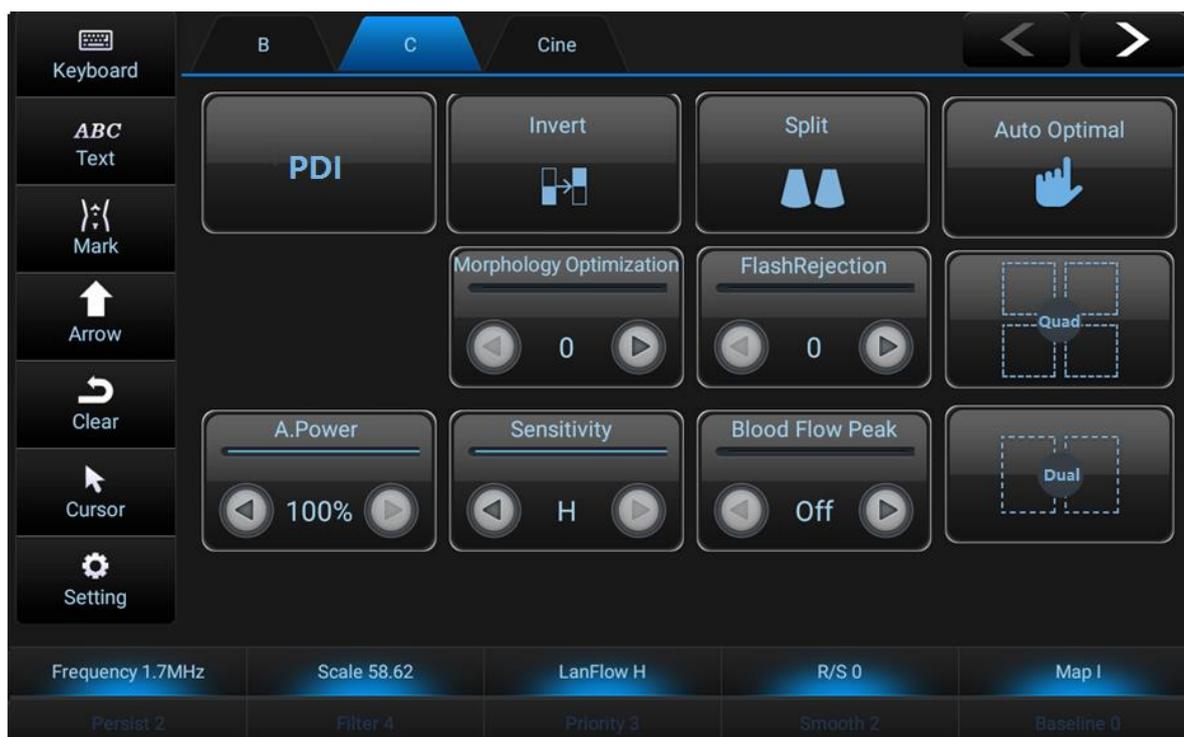
Function: This function is to reject image noise and to make images smooth.

Map

Operation: rotate the corresponding adjustment knob of map to change the color of the maps.

Function: Color-scale map refers to the color range that is allocated to the desired color or power area, and the color-scale map is based on the flow rate of color flow imaging and the flow intensity of power mode.

For color imaging, color changes mean the changes of flow rate. A dark color means a lower rate while a light color means a higher flow rate, and these maps have the red and blue colors to indicate the flow direction, while the color flow rate and deviated maps use green shadows to indicate the flow disorders



A. Power

Please see the methods of B mode.

Color Flip

Operation: Click on the touchscreen [Invert], turn the color invert function, the color on the right side of the image will turn upside down, and the color in the collection box will also turn over. Then click the [Invert] key to turn off the color invert.

Split Mode

Operation: The image area will be displayed in real time with two same images, in which the image sampling box is displayed in the right area, and the left is the B pattern image without color flow. The image can be compared conveniently.

Sensitivity

Operation: Click on the left and right direction buttons on the [Sensitivity] icon of the touch screen. The [Sensitivity] option will display L, M, and H letters, where H has the highest resolution and L has the lowest.

Function: By using this function, you can change the scanning operation frequency of color Doppler imaging to adjust the sensitivity. Sensitivity increase will lead to decrease of frame rate, while sensitivity reduction will lead to increase of frame rates (See frame display area on the bottom right of the image for more details).

Peak

Operation: Click on the left and right arrow keys on the touch screen [peak] icon, and the 1sec, 2sec, 3sec, off characters will appear on the peak capture icon.

Function: When the ultrasonic system continues accumulation, and displays the peak color

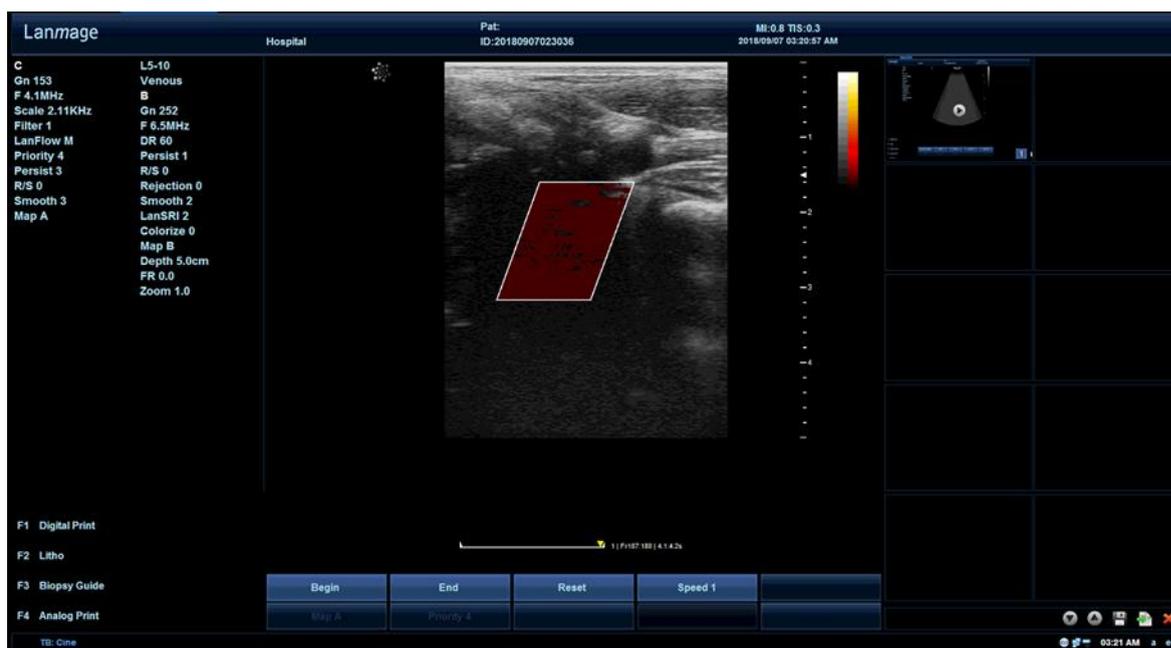
rate associated with flow rate in the selected time, there will be a phenomenon of persistent peak in order to designate the time period for collecting the color rate of flow peak; when you select 1sec, the system will maintain the peak for 1 second.

4B

Operation: Click the touch screen [4B] button to open the 4B mode, and the continuous click screen image display area will appear four images in turn. One of the four images is in real time, and the rest are in a frozen state.

4.6 PDI Mode (Power Doppler Imaging Mode)

PDI mode is a color blood flow imaging technology, which is used to reflect the Doppler signal intensity resulting from flow, rather than the frequency shift of signals. By using this technology, the ultrasonic system can map the color flow based on the amount of the moving reflectors, rather than take into account their speeds. As PDI does not affect the speed, thus there will be no aliasing.



4.6.1 PDI mode Operating Steps

1. Preset one of the custom key as PDI function fast key, press to activate PDI; or Press[C] to activate color mode and then click the touch screen menu [PDI] to enter PDI mode.
2. The method of setting PDI mode sampling box is the same as that of Color mode;
3. Optimize images through parameter preset or interface settings;
4. Record the data.

4.6.2 PDI mode Parameter Settings

You can also set the parameters of the following image directly on the main interface:

Frequency 1.6MHz	Scale 21.78cm/s	LanFlow L	R/S 2	Map C
Persist 2	Filter 1	Priority 4	Smooth 3	

These parameters will be displayed on the left side of the screen, as shown below:

```

C
Gn 153
F 4.1MHz
Scale 2.11KHz
Filter 1
LanFlow M
Priority 4
Persist 3
R/S 0
Smooth 3
Map A

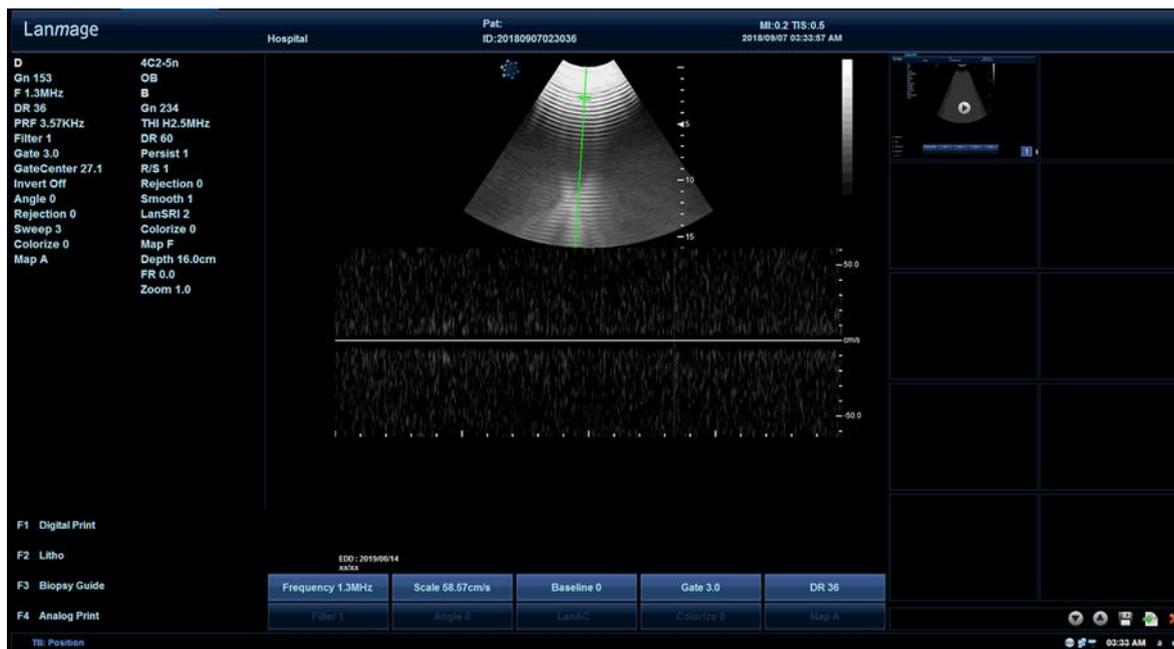
```

For the relevant adjustment functions in PDI mode, the user can refer to the operating methods of Color mode, which will not be repeated here.

4.7 Pulse-wave Doppler (PW)

Doppler can provide the measurement data on the rates of the moving tissues and fluids, and PW mode can receive the echo signals that are given out from the flow in the preset direction and depth; carry out the spectral analysis on the echo signal, and work out values of flow parameters according to the analysis.

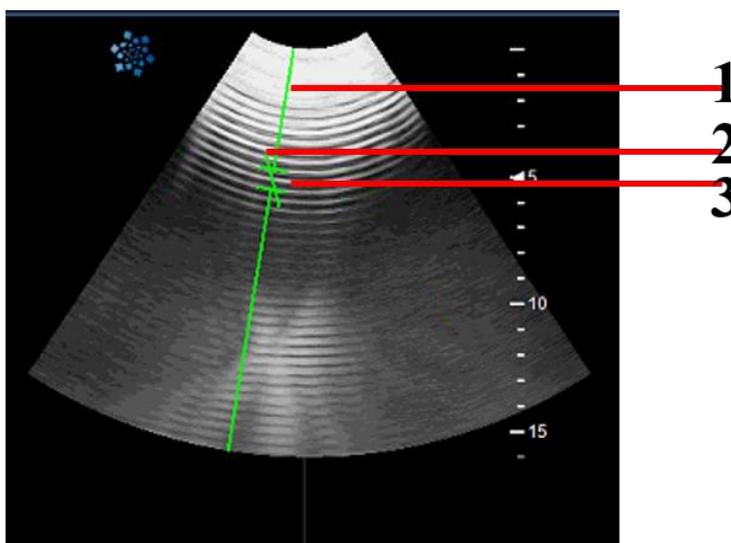
Under normal circumstances, flow is not uniform, but consists of mixed blood cells in different rates and directions. Therefore, the contents are displayed with a combination of spectrum in different grayscale values. Strong signals will be displayed relatively brighter, but weaker signals are shown in the different levels of gray.



4.7.1 PW mode Operating Steps

1. Press [D] for the first time, then a green sampling line and deviation angle appear (Click on [Setting]→ click [Exam Preset] on the left of the screen, and this step will be omitted if "No cursor M/D display" is checked);
2. Press [D] for the second time, and two images will occur respectively on the top and bottom, in which on the top is the B-mode image, and on the bottom is the transverse section of the sampling line;
3. Set the image parameters through [Setting] or the toggle so as to optimize images;
4. Record the data.
5. Press [D] for the third time to exit the PW mode.

Instructions for PW-mode images:



1. Sampling line
2. Blood flow angle Indicator

3. Sampling gate

Sampling Line

Function: When activating Doppler in the B mode, [Sampling line] will be displayed in the B-mode image and this cursor is the graphical indication of the acoustical line.

Blood-flow Angle Indicator

Function: The indicator is represented as the angle between Doppler-mode sampling line and the calibration indicator, which will be displayed when there is a Doppler sampling line, and the indicator means the blood-flow direction, and the specific angle deflection is displayed on the top left corner of the image.

Sampling Gate

Function: For the B-mode images, Doppler-mode sampling line moves the sampling gate, and the gate is located on a specific position. Press the function keys to change the size of the gate. Changing sampling gate will change heat index and/or mechanical index.

Please note that it may affect output display.

Steps for angle of deflection;

1. Press [D], and the sampling line, sampling gate and blood-flow angle indication will appear as shown in the figure above;
2. Press [D] again, and two images will appear on the top and bottom; rotate the trackball to adjust the sampling depth and sampling line position of the image above;
3. Rotate [Sampling gate] corresponding adjustment knob to change the size of the gate frame;
4. Rotate [Angle] corresponding adjustment knob, and there will be three angle settings including 0, 60 and -60, and you can use [Steer/Angle] if you would like to slightly adjust the angle, which can be steered to the left with the maximum of 89° and to the right with the minimum of -89°.

After determining the sampling position, size and direction, you can carry out the PW- mode measurements to the following images.

4.7.2 PW mode Parameter Settings

You can use the soft menu to set a specific parameter, and its value will be displayed on the left of the screen, as shown below:

Frequency 1.3MHz	Scale 62.37cm/s	Baseline 0	Gate 8.0	DR 36
Filter 1	Angle 23	LanAC	Colorize 0	Map A



D
 Gn 153
 F 1.3MHz
 DR 36
 HPRF 3.66KHz
 Filter 1
 Gate 8.0
 GateCenter 236.0
 Invert Off
 Angle 23
 Rejection 0
 Sweep 3
 Colorize 0
 Map A

Functions of specific parameters and setting methods are as follows:

Gn (Gain)

Operation: Use the rotary knob [D] to change the amplitude of Doppler signal and their display brightness on the imaging screen.

Function: The selected gain shall be matched with the signal amplitude and the used grayscale. In this case, make sure that spectrum diagram does not appear on a lot of noise. When rotating the control in a clockwise direction, the entire spectrum diagram becomes brighter. When rotating the control in a counter-clockwise direction, the entire spectrum diagram becomes darker.

DR (Dynamic Range)

Operation: rotate the corresponding adjustment knob to adjust.

Function: Affect the amount of the displayed Doppler amplitude data.

Filter

Operation: Press and rotate the corresponding adjustment knob to adjust the size of the filter.

Function: Remove the noises that are caused by cardiovascular or heart wall movements. It will be at the price of lowering the sensitivity of flow.

PRF (Pulse Repetition Frequency)

Operation: Press the corresponding function keys on the soft menu [PRF].you shall Press the corresponding function key to switch the settings between [Filter] and [PRF], and the system will automatically update the speed scale.

Function: Regulate the speed scale so as to accommodate faster/slower rates of blood flow. The PRF is based on the speed scale.

Baseline

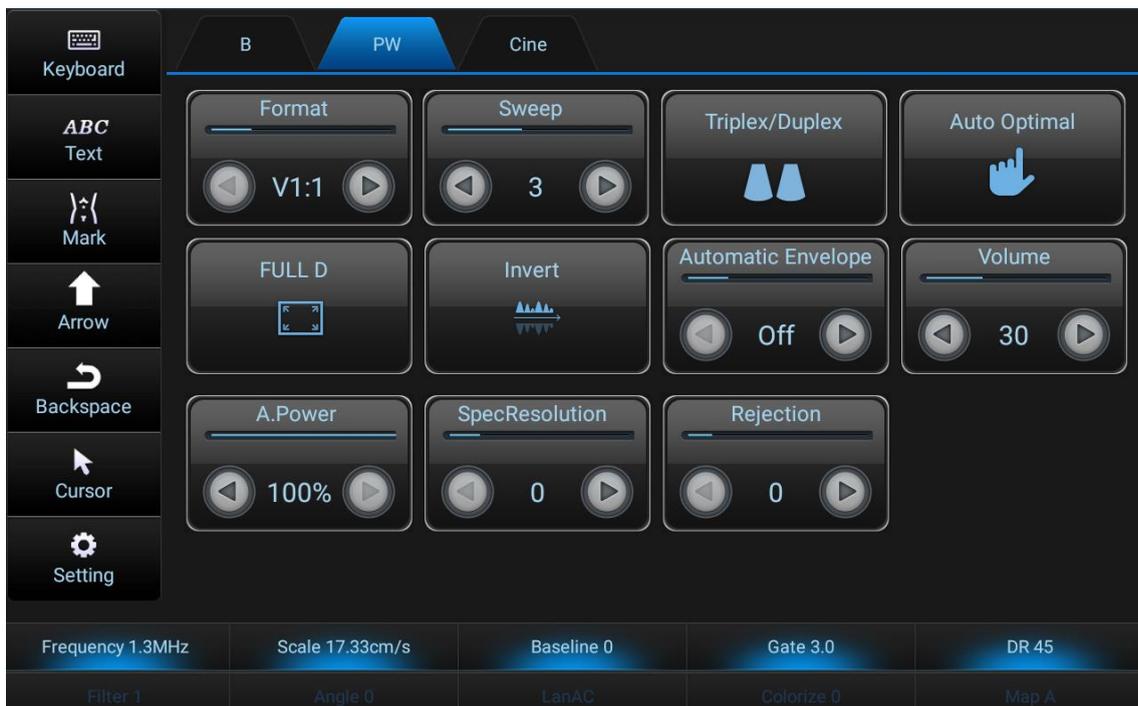
Operation: you shall use the toggle [Baseline]. Moving the baseline on the spectrogram can extend the speed range in one direction, while the speed range displayed in another direction is reduced.

Function: As the leveling line corresponding to the zero velocity and zero Doppler frequency on the spectrum diagram.

Spectrum Invert

Operation: Invert the spectrum curve in the vertical direction without affecting the baseline position, press the touch screen [Invert].

Function: The function key [Invert] will be displayed on the top left of the screen, and [+] and [-] on the speed scale will be accordingly inverted. By doing this, you can also change the speed (frequency) calibration. In the initial state, the area above the baseline means the blood-flow movement towards the direction of the probe, while the area below the baseline means the blood-flow movement away from the probe. If the inverting function is enabled, the area above baseline means the blood-flow movement away from the probe, while the area below baseline means the blood-flow movement towards the probe.



Functions of specific parameters and setting methods are as follows:

Rejection

Function: The noise and interference caused by the spectrum of Doppler signal can be properly controlled by pressing the left and right buttons on the touch screen.

Sweep

Operation: Click on the touch screen [sweep] icon on the left and right button to adjust.

Function: The scan speed can control the updating frequency of the spectrum, and the scale will be displayed on the bottom of the screen.

Full Screen

Operation: Click on the touch screen [Full D] icon, open the full screen display of PW mode, and facilitate the careful and clear observation of images.

Duplex

Operation: Duplex and Triplex sync are in the same menu. Click on the touch screen [Triplex/Duplex] icon to open the dual sync function, and there are B mode and PW mode in real time. When the double sync closes, the B mode is frozen, and the PW time line is activated. Dual synchronous active mode: B+PW.

Triplex

Operation: After the Color (PDI) mode is opened, press [D] button and click the icon of the touch screen [Triplex/Duplex] to activate the three synchronous mode of real-time B, Color and PW. In this mode, the adjustment of image optimization is roughly the same as that in B, Color (PDI) and PW mode.

Three synchronous and active modes: B+ Color+ PW, B+PDI+PW.

Automatic Spectrum Envelope

Operation: Click the left and right buttons on the icon of [Automatic Envelope] on the touch screen, and Off, Up, Down and Both appear successively. The red-green line appears above the baseline when Up, and the red-green line appears below the baseline when Down. Both red and green lines appear above and below the baseline. The largest is green and the average is red

Format

Operation: Clicking on the left and right knobs on the touch screen [Format] icon, V1:1, V1:2, V2:1, and H2:3 appear in turn, and the proportion of the two images is different. You can use it according to your own habits.

Adjust Doppler Volume

Operation: PW mode click on the touch screen [volume] icon on the left and right button to increase or decrease the volume.

Function: The loudspeakers in the monitor can make sounds in Doppler mode. The system

uses different acoustical signals to indicate the flow direction that flows towards or away from the sensor; in general, the flow towards the sensor is displayed above the Doppler baseline, and gives out sounds from the loudspeaker on the right side, while the flow away from the sensor is displayed below the baseline, and make sounds from the loudspeaker on the left side.



Note: In inverting the Doppler, the acoustical signals will also be inverted.

4.8 4D Mode

The 4D imaging mode includes both static 3D and real-time 4D imaging

4.8.1 3D Mode



4.8.1.1 3D Mode Operating Steps

1. Click [4D] on the control panel to enter the pre-collection interface, and click [3D] on the touch screen to enter the 3D pre-collection interface.
2. Click [set] key and the green box is shown as dotted line. Rotate the track ball to adjust the size of the box.
3. Move the track ball, and the sampling box moves within the image sector. The location of the sample box is determined by the user as required.
4. Select one of the [resolution priority], [speed priority] and [penetration priority] as the 3D image preset in the [imaging preset] of the touch screen. Selecting different presets will affect the parameter values.

5. Select one of [Render], [Multi Slice], [Niche] and [Free Line] as the default 3D image in [imaging mode], and select different imaging mode parameter types.
6. According to the prompt, press [Update] to enter the 3D view interface.
7. Press [Update] again to return to the 3D pre-collection status.
8. Press the button of [B] and [4D] to exit 3D mode and enter the state of B real-time imaging.

3D pre acquisition interface mode parameters are shown below:

Frequency 2.5MHz	DR 80		Sweep 70	Quality Hi2

Scanning angle

Operation: Rotate the corresponding knob of [scanning Angle].

Function : Set the Angle of probe scan.

Quality

Operation: Rotate the corresponding knob of [Quality].

Function: The image quality under the state of 4D image can be adjusted. Currently, adjustable gears include Hi2, Hi1, Mid and Low. The quality ranges from high to Low.

Frequency

Operation: Check the knob corresponding to the soft menu [frequency] and rotate the parameter adjustment knob to change.

Function: For special patient type, change the frequency parameters to achieve the best optimization effect.

Dynamic

Operation: Check the corresponding knob of soft menu [dynamic range] and rotate the corresponding parameter adjustment key to change.

Function: Can increase or decrease the contrast of gray image.

If the pre-collection parameters are changed, corresponding indicators will be displayed in the parameter area on the left of the main screen

Resolution priority

Operation: Click the [resolution priority] button on the pre-set of the subject check on the touch screen, and the button is highlighted. The subject check is changed to resolution priority at the parameter on the left.

Function: Optimum volume imaging effect. The system will automatically adjust the image parameters according to the selected style. This option is recommended for regular 3D features.

Speed priority

Operation: Click the preset [speed priority] on the touch screen to check the subject. The button is highlighted. The parameter on the left will change the subject to speed priority.

Function: Optimum volume imaging effect. The system will automatically adjust the image

parameters according to the selected style. This option is recommended for general 4D functionality.

Through the priority

Operation: Click the [penetration priority] preset at the subject check on the touch screen, the button is highlighted, and the subject check at the parameter on the left is changed to penetration priority. Function: optimum volume imaging effect. The system will automatically adjust the image parameters according to the selected style. This option is recommended for patients who have a larger body, a deeper site to be examined, and difficult ultrasound penetration.

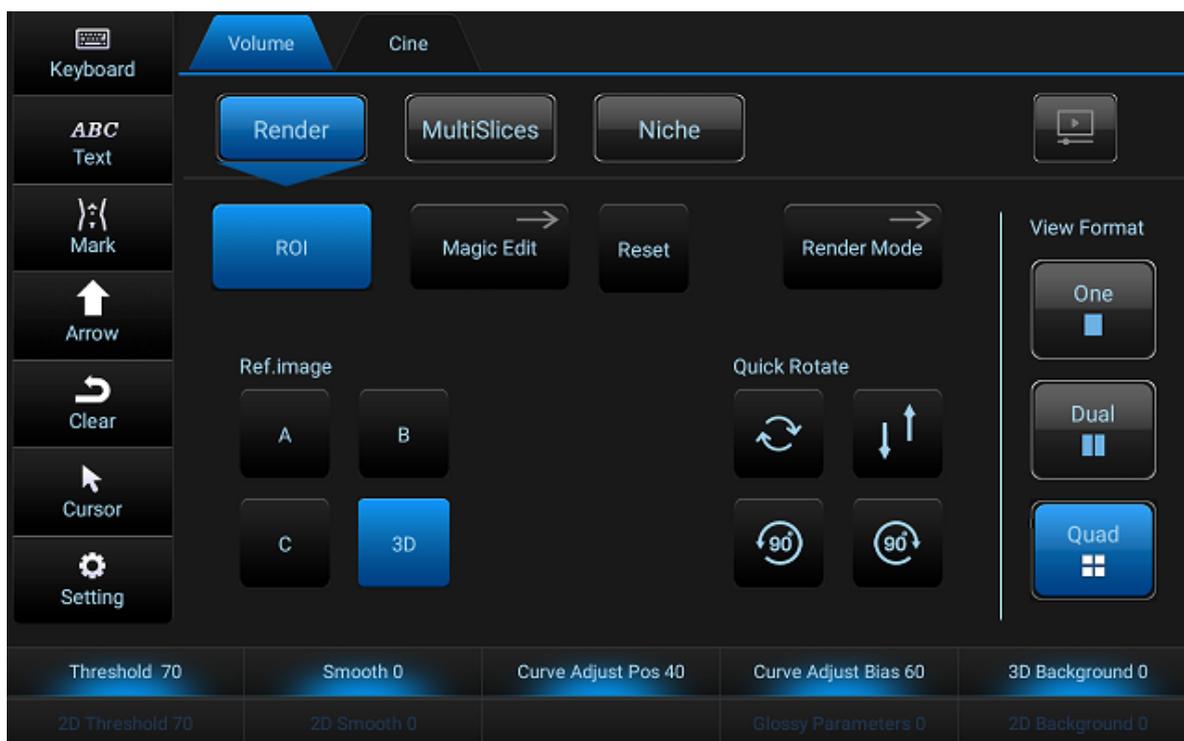
4.8.1.2 3D Mode Parameter Settings

The parameter value can be displayed on the left side of the screen. The specific parameter setting method is as follows:

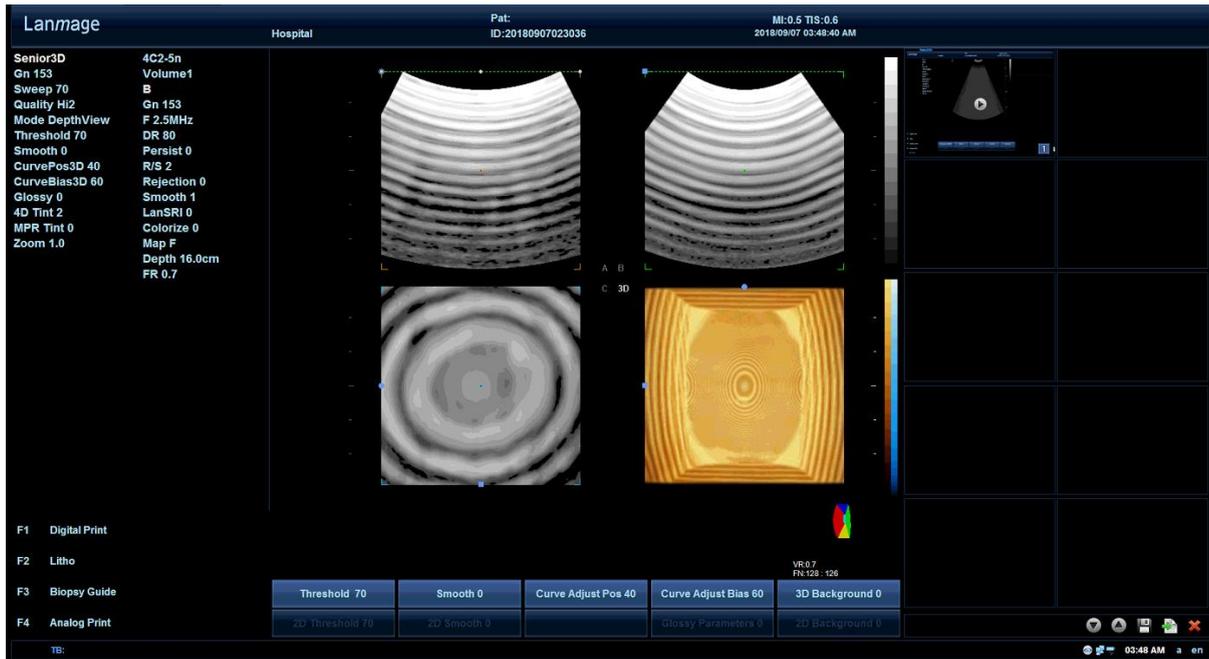
Render

Operation: In the touch screen, press [Render] to enter the Render page.

Function: Will render mode to various types of image rendering, the diagram below:



The Render main page is shown below:

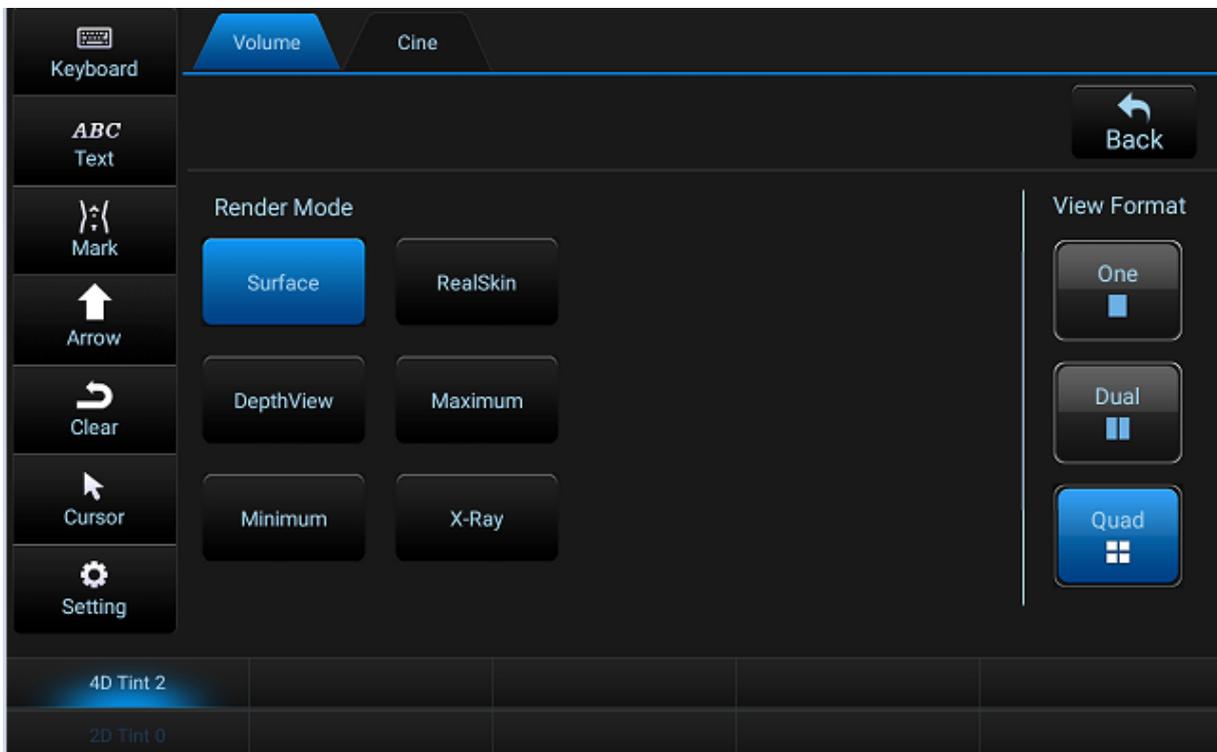


Parameter :

Render

Operation: Click [Render mode] on the touch screen to select different image processing modes.

Function: Define rendering mode, including surface, depth, the simulation model, the maximum, minimum, perspective the six kinds of patterns.



One

Operation: Click the [One] in the view on the touch screen.

Function: Select the one view. After entering the 3D view interface, only 3D images will be

displayed on the screen.

Dual

Operation: Click [Dual] in the view on the touch screen and highlight the button.

Function : Select [Dual] view and enter the 3D view interface. The screen displays cut surface +3D image.

Quad

Operation: Click the [Quad] in the view on the touch screen and highlight the button.

Function : Select "Quad" view, and after entering the 3D view interface, the screen will display all the cut and 3D images.

ROI

Operation: Click the [ROI] button, which is highlighted. Press [Set] to move the track ball and change the ROI size of the selected window. Press [Set] again to move the track ball and change the position of the upper edge of the ROI box.

Function: Enable the volume adjustment for the reconstruction of the box. Volume rendering.

Reset

Operation: Click the [Reset] button to reset the image.

Function: After the image has gone through the [ROI] operation, click the [Reset] button to restore the image to its original shape.

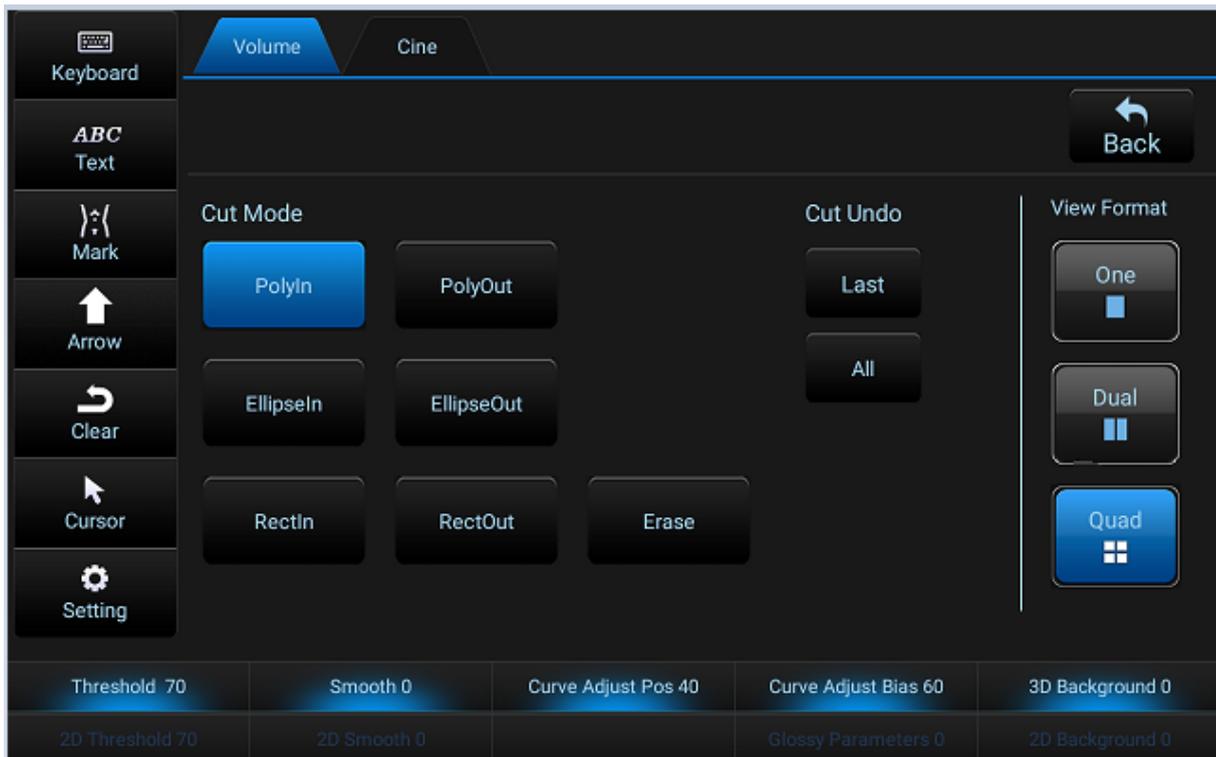
4DTint 2

Operation: Rotate the soft menu [4DTint 2] to adjust.

Function: Adjust the false colorize effect of the image.

Magic editor

Operation: Click [magic edit] and the touch screen enters the magic edit page, as shown in the figure below.



1. Move the trackball, move the cursor to the desired position, and press [Set]. Move the trackball again and mark the part that needs cutting. Press [Set] and the demarcation is cut out.
2. If not satisfied with cutting, in cancellation, click on the [Last] / [All] button, can be cancelled for cutting action.
3. If the cutting is complete, click on the [Back] menu, exit the magic edit page. Function: To cut image of each spare part of the image.

Ref. image

Operation: click the button [A] / [B] / [C] / [3D]. The button is highlighted and the number in the window turns green on the display screen.

Function: Select the reference image A, B, C or 3D.

Quick Rotate

Operation: Click [clockwise 90 °] / [90 ° anticlockwise] / [180 °] / [reset] menu, menu highlighting, restore the original state.

Function: Rotate the 3D image; if the 3D image is rotated (including X/Y/Z axis rotation), [reset] returns the 3D image to its original state.

Threshold

Operation: Click the left and right direction button on the [threshold] button on the touch screen for adjustment.

Function: Gray value threshold definition for the reconstruction of gray value and regarded as noise. Opacity define a threshold for distinguishing the stringency Degrees, low opacity value

makes the surface look stiff, high opacity value makes the image reconstruction with a transparent appearance.

Smoothness

Operation: Rotate the soft menu [smooth] to adjust.

Function: adjust the 3 d data smoothing effect.

CurvePos

Operation: Rotate the parameter adjustment key corresponding to [Curve Pos], rotate left/right, and reduce/increase the curve Pos value.

Function: Grey value of the input signal calibration and compensation, get the ideal output.

Curve Bias

Operation: Rotate the parameter adjustment knob corresponding to [Curve Bias], rotate left/right, and reduce/increase the curve Bias value.

Function: Change the visibility of the input signal with "Curve Pos" desired output.

3D background

Operation: Rotate the parameter adjustment knob corresponding to [3D background], rotate left/right, reduce /increase the 3D background value.

Function: For 3D rendering imaging window with a certain gray value of background color.

Glossy Parameters

Operation: Press the parameter adjustment button corresponding to the [Polishing parameter], the soft menu is highlighted, turn left/right, and reduce/increase the lighting parameter.

Function: Make the rendering reconstruction object can be unable to move ahead on the light to illuminate. This parameter is used to adjust the effect of the light source.

2D smoothness

Operation: Press the [2D smooth], the soft menu is highlighted, turn left/right, and reduce/increase 2D smooth.

Function: Surface shows through the smooth treatment improved; at the same time keep the details in the image.

2D threshold

Operation: Press the parameter adjustment knob corresponding to [2D threshold] soft menu highlights, turn left/right, reduce/increase 2D threshold. Function: If you choose to render mode, generally need to adjust the minimum threshold to identify surface boundary. All color values below this level are ignored in the render calculation.

2D background

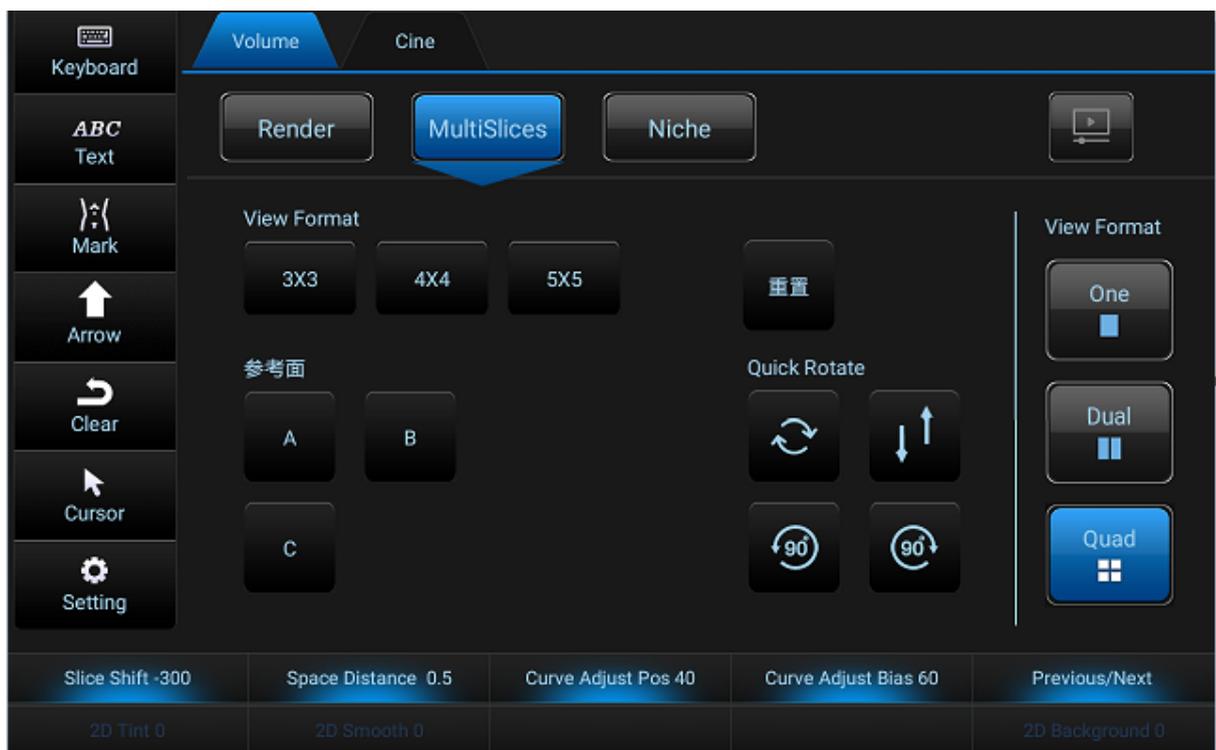
Operation: Press the parameter adjustment knob corresponding to [2D background][2D background]soft menu highlights , turn left/right, reduce/increase 2D background.

Function: For 2D plane imaging window combined with the background color of the grey value.

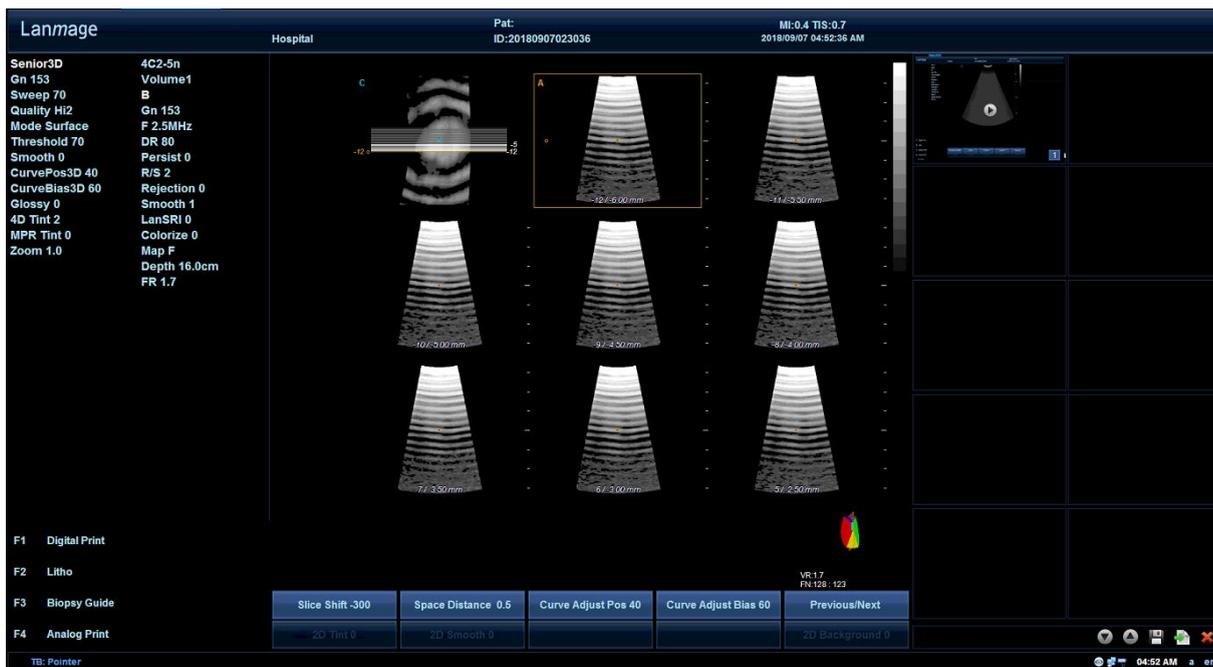
Multi Slices

Operation: Click [Multi Slices] in imaging mode and highlight the button.

Function: An intuitive display 3D data set patterns. The data in the data set is displayed in layers parallel to each other. The overview image is orthogonal to the parallel plane, showing the parts of the volume that are shown in the parallel plane. This visualization approach is consistent with the approach used by other medical systems, such as CT or MRI, in presenting data to users. The distance between parallel planes can be adjusted to suit the requirements of a given data set. In addition, you can set the number of planes.



The MultiSlice main page is shown below :



Parameter :

Format

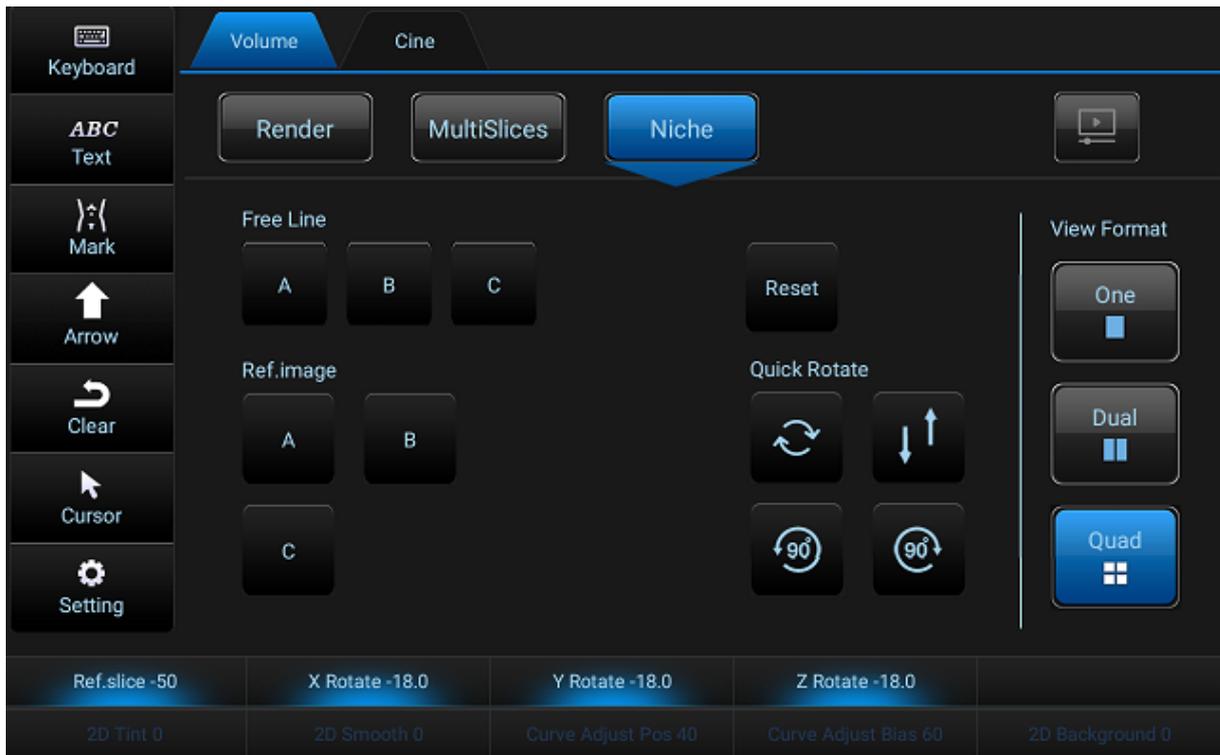
Operation: Click the [View Format] button on the touch screen for adjustment.

Function: Switch interface display format.

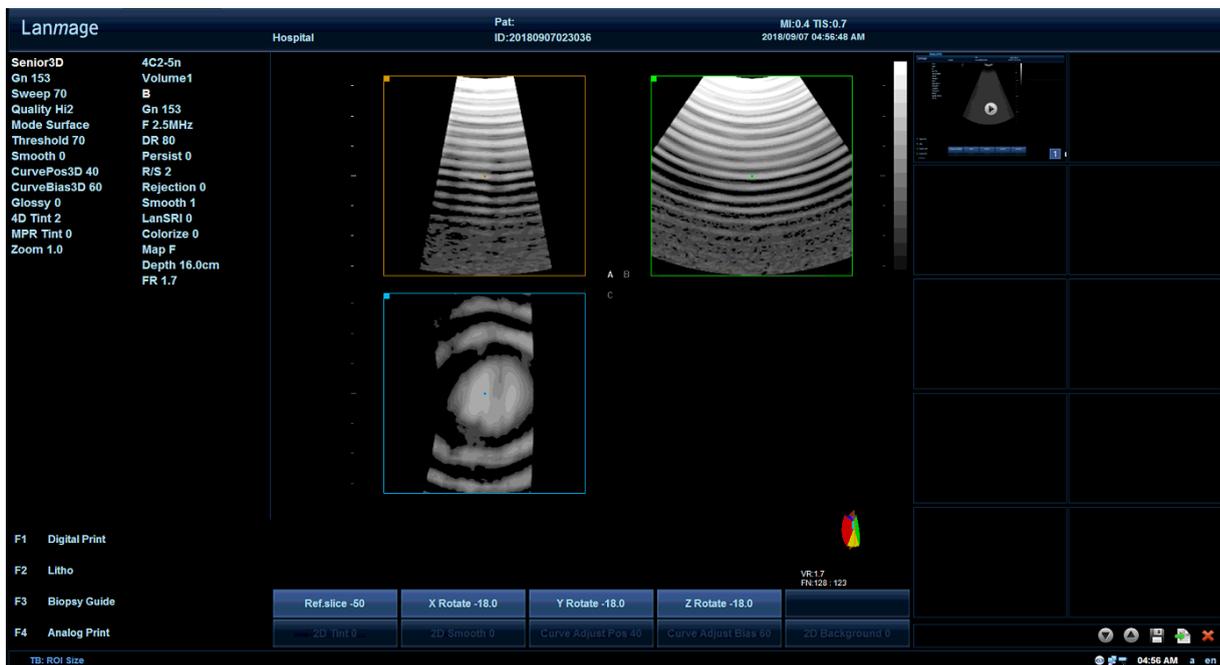
Niche

Operation: Click the [Niche] in the rendering of the touch screen and highlight the button.

Function: The perpendicular part of section A, B, C editing to 3D section view. The niche shadow is named because this view shows something like inserting a spatial figure into the volume. Niche model will have special parameters are as follows:



The Niche main page is shown below:



Parameter :

Niche restoration

Operation: Rotate the soft menu [Niche restoration].

Function: all Niche regulation operation is reset to its original state

4.8.2 4D Mode

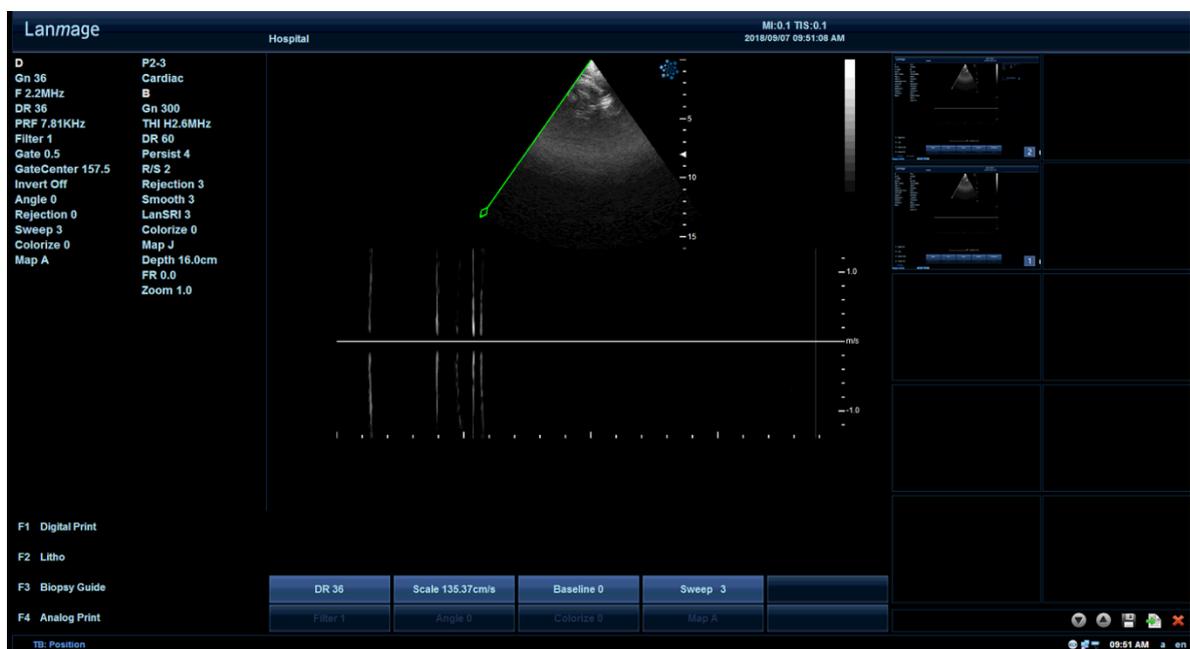
4.8.2.1 4D Mode Operating Steps

The basic operation steps of 4D mode are the same as that of 3D mode. Only the selection of [3D] and [4D] on the touch screen should be replaced by the selection of [4D]. Details can be seen in 4.9.1.1 "3D Mode Operating Steps".

4.8.2.2 4D Mode Parameter Settings

4D mode is to add time parameters on 3D mode to reflect the changes of 3D image in real time. For detailed parameter Settings, see the section "3D Mode Parameter Settings".

4.9 CW imaging model (optional)



CW Mode Operating Steps

Allow the examination of blood flow data along the sampling line of the Doppler model, rather than the blood flow data at any given depth. Collect samples along the entire Doppler beam to quickly scan the heart..

1. Press [CW] for the first time, show a green sampling line
2. Press [CW] for the second time, and two images will occur respectively on the top and bottom, in which on the top is the B-mode image, and on the bottom is the CW spectrum ;
3. Press [freeze] to image;
4. Press [Measure] to perform imaging measurements;
5. Press [CW] for the third time to exit the CW mode, enter B real-time imaging status

For more information about controls, refer to the "PW Doppler" optimization control specification

Chapter 5 Scan/Display Function

5.1 Image Zoom

[Dept/Zoom] is used to zoom the desired area, and the system will accordingly adjust the imaging parameters to help us view the small parts of the image. There are two types of imaging zoom, namely real-time imaging zoom (front-end zoom) and freeze imaging zoom (back-end zoom).

Real-time imaging zoom

1. Press [Dept/Zoom] to activate the green zoom window;
2. Move the trackball and change the position of the zoom window; Press [Set] to determine the size of the desired area;
3. Then press [Dept/Zoom] again to zoom the window; rotate [Depth/Zoom] to adjust the magnification, clockwise for magnification, and counter-clockwise for magnification;
4. Press [Dept/Zoom] again to exit the partial zoom.

Freeze imaging zoom

1. Press the [Freeze] button and rotate the [Dept/Zoom] knob to enable the overall magnification;
2. Rotate [Dept/Zoom] knob to adjust the magnification;
3. Move the trackball to adjust the position of the desired magnified area;
4. Press [Dept/Zoom] again to exit the overall magnification

Zoom the image to change its frame frequency, which will frequently change heat index and position of focal area may also be changed, and it could lead to peak intensity in different positions in the acoustic area, and MI may also be changed.



Note: It may affect output display. Setup

5.2 Image Freeze

Freezing real-time images would stop all the movements, and be allowed to measure, remark, save and print images.

When you turn on the system, the system will be defaulted as the real-time state, and press [Freeze] to switch between real-time image state and freeze image state.

In the frozen state, the system can respond to different functions according to preset. The method of viewing the preset is:

Click on the [Setting] on the touch screen → Click [Exam Preset] on the left of the screen,

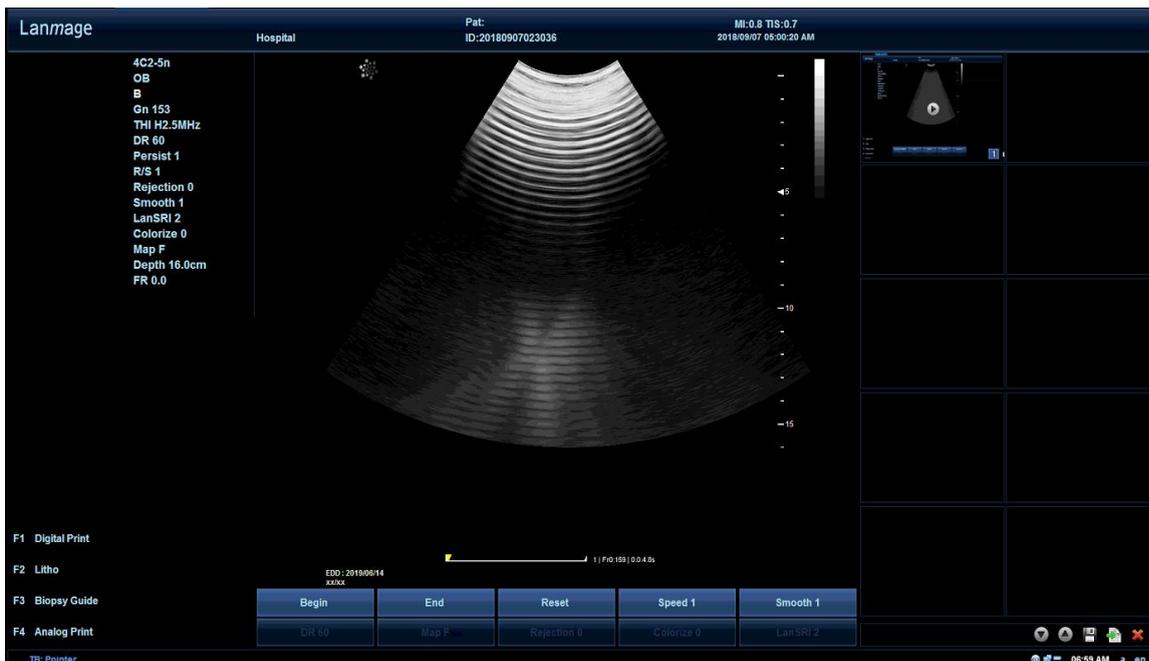
and then you can select [Freeze Response].

When you use a pedal switch, you can also use the pedal switch to freeze the image, and the specific settings are:

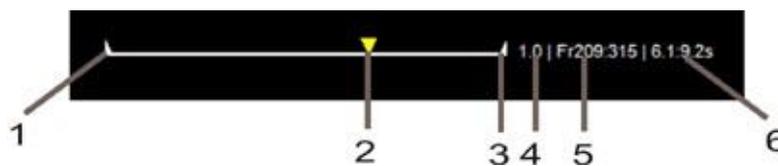
Click on the [Setting] on the touch screen → Click [Peripheral Preset] on the left of the screen → Click [Pedal Switch] of the sub-menu above the screen to carry out relevant settings for left-foot pedal switch and right-foot pedal switch.

5.3 CINE Mode

Cineloop and images will be continuously stored in the system so that users can automatically and manually play cine and images. The data in the cine can be available until new data has been captured; the cine can either be stored in the system memory or be filed. Cine mode is very helpful for great concerns about the images in the special period of Cardiac cycle and viewing short cine fragments.



You can enter the cine mode by selecting the [Freeze Response] of the [Exam Preset] module to Cine. In Cine mode, "ring Indicator" will be displayed on the bottom right of the screen (as shown below):



No.	Name	Explanation
1	Left CINE marking	indicating the start of CINE data;
2	Frame indicator	Indicating the position of the current frame on the CINE data cycle;
3	Right CINE marking	Indicating the end of CINE data;
4	Speed indicator	Indicating the speed of CINE data playback, which can be set to 1, 2, 4, 1/8, 1/4, 1/3, 1/2 and 2/3, of which 1 means equal to the scan speed; you can adjust the speed in the Soft menu.
5	Frame counter	Indicating the frame number of the current frame and the total frames stored in the cine buffer zone;
6	CINE Time	Current data time and time of the total storage data.

5.3.1 Cine loop

There are two ways to review Cine loops, one is frame-by-frame review, and the other is automatic cine loop:

Frame-by-frame review:

1. Press [Freeze] to move the trackball for viewing the cine loop frame by frame.
2. Press [Freeze] again to exit the CINE mode, remove memory area and start the real-time imaging.

Automatic cine loop:

1. Press [Freeze] and click the touch screen [Cine] for automatic cine loop.
2. Click [Cine] again to stop playing;
3. Press [Freeze] to exit the cine mode, clear memory area and start the real-time imaging.

5.3.2 Cine Editing

In the CINE mode, we can not only use the method above to carry out the CINE review, but also view the cineloop in a certain time period, and edit the cine by using the function keys in the soft menu.

Begin	End	Reset	Speed 1	Smooth 1
DR 60	Map F	Rejection 0	Colorize 0	LanSRI 2

Cine editing can also be made through the touch screen. The editing method is:

1. Press [Freeze] to start cine mode;
2. Roll the trackball to locate the starting point of the frame indicator, and Click on the touch screen [Begin].
3. Roll the trackball again to locate the end point of the frame indicator, and Click on the touch screen [End].

4. If you are still not satisfied, you can click [Reset] to restart the cine editing.
5. Click [Cine] or manually rotate the trackball to view the Cine data of the new area; Click on menu [Speed] to adjust the speed of the automatic cine loop, and the speed will be displayed on the indicator of the cine icon.

5.3.3 Cine Storage

Cine storage can be divided into static memory and dynamic memory. Static memory involves the frame-by-frame image while dynamic memory is the video clips. These two types of memory are workable in both real-time and frozen states.

The method is: Click on [Image Save] or [Cine Save] on the touch screen to display the images or cine on the right thumbnail of the screen.

5.3.4 Thumbnails

In order to distinguish between images and cine in the thumbnail, there will be  displayed between cine and images. By using the icon below the thumbnail, we can flip up and down, store, transmit and delete the images.

	Flip the thumbnail display area to the next page;
	Flip the thumbnail display area to the previous page;
	Store the selected images and cine in the thumbnail to U Disk;
	Transmit the selected images in the thumbnail to the report;
	Delete the selected images and cine in the thumbnail.

Specific operations:

1. Click on [Image Save] or [Cine Save] on the touch screen, and the image or cine can be seen in the thumbnail area in order.
2. Press the [Pointer] on the touch screen, and use the trackball to move the cursor. Place the cursor on the selected thumbnail, press [Set], and the selected image will occur in a yellow box.
3. Use the trackball and [Set] to select multiple images, and click the icon to store, transmit and delete images.
4. Select the thumbnail and double-press [Set] to view the big image, and Click [Freeze] to exit the larger image;
5. Press [Set] again in the selected thumbnail to cancel the selection.



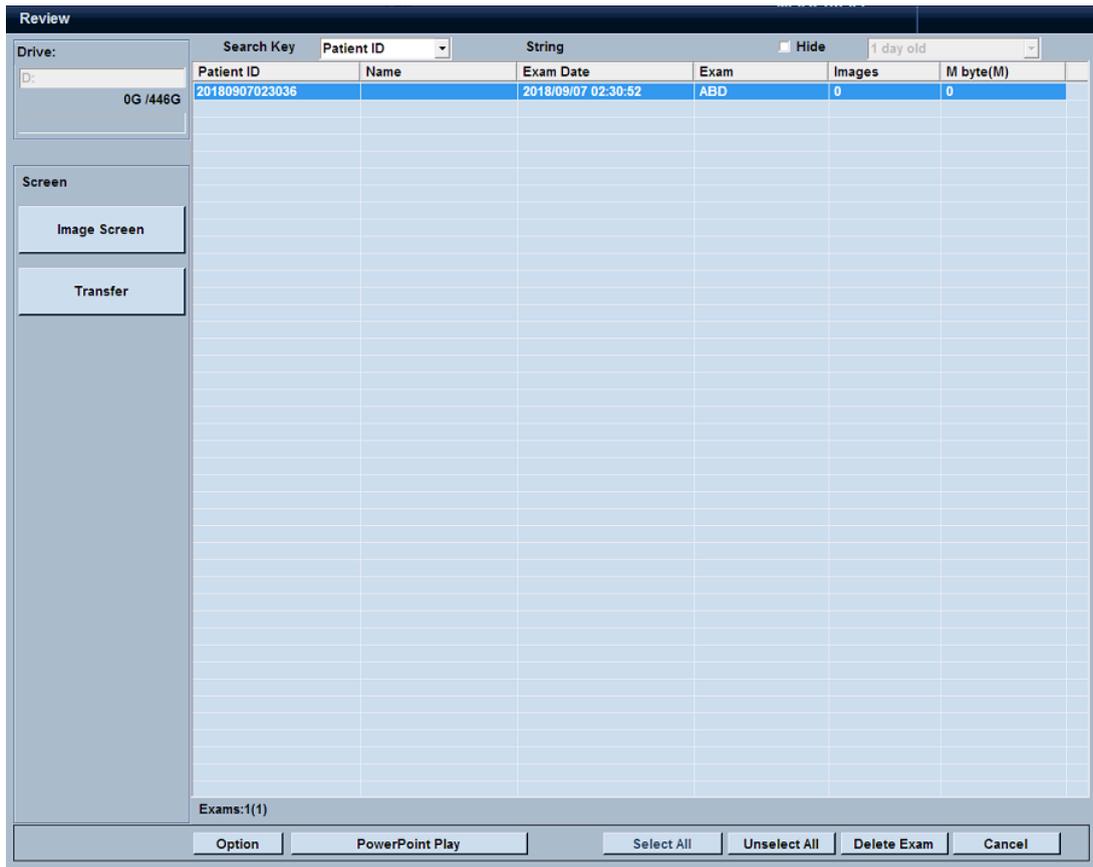
Note: Cineloop will occupy a great portion of the system memory. Therefore, in order to avoid system memory overflows, it is recommended to output the recorded cine into CD or U Disk,

and then delete the recorded contents from the database in accordance with the sequences.

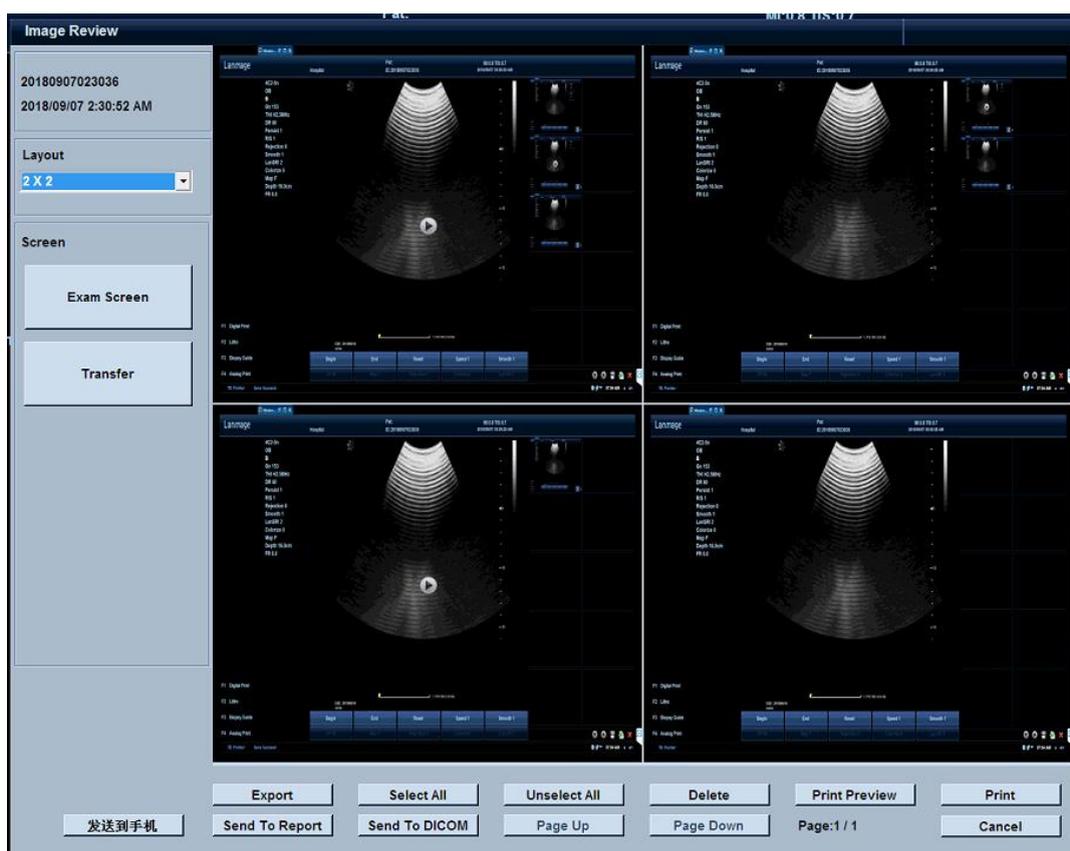
Note: In order to store images in the thumbnail into the preview area, you must establish a new patient; otherwise, the images cannot be viewed in the Review.

5.3.5 Cine Review

Press [Review] on the control panel to enter the review menu, as shown below:



- The images that are saved in the thumbnail will be stored in the D disk of the system by default. The green area below is the currently used capacity and prompt of D disk so as to avoid image(s) from failing to be saved due to memory overflow.
 - When there are a larger number of patients, we can find a patient through [Search Key];
 - Click the menu below the screen to carry out the following actions such as, "select all", [Unselect all] [send], [cancel], [delete Exam], [Hide] and so on.
 - Click the menu [Image Screen] on the right to enter the interface [Image Review];
- When clicking [Image Screen], you will enter the interface [Image Review], as shown below:



- On the upper left is the system's image default saving path, folder and storage time.
- You can view the image size in line with the operator's habits and page layout, and double-press [Set] to view the single-frame image, click on the "Freeze" key to exit display;
- Click the button below the image to transmit the selected image(s) to a U disk and/or CD, and carry out other actions such as "select all", "delete", "send to report", "send to DICOM", Page up and Page down, etc...
- Click the exam screen to return to the [Review] interface;

5.4 Image Annotation

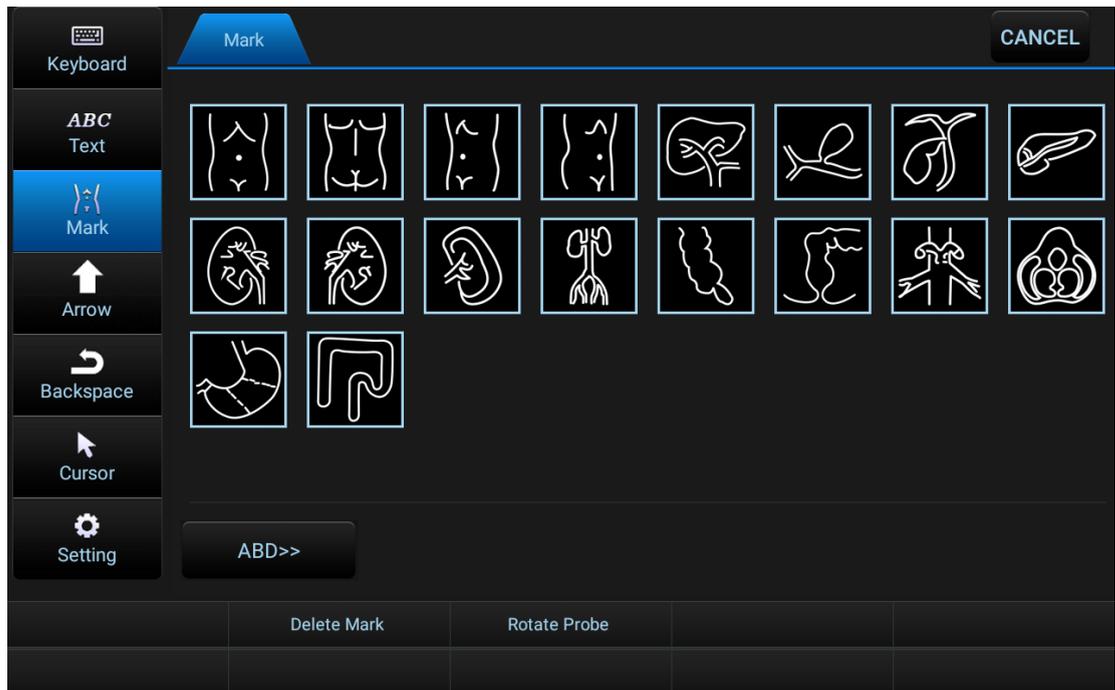
The Annotation function can allow us to enter free text notes and insert pre-defined annotation into the imaging display information. It can also provide marks, arrows and texts, thus you can respectively enable [Mark], [Arrow] and [Text] on the touch screen to make annotations for image(s).

Images with an annotation can be:

1. Saved in the system database (Please press [Save] on the control panel);
2. Printed (See "Print" in Chapter 7).

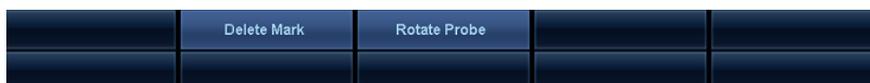
5.4.1 Mark Annotation

Press [Mark] on the touch screen, for which the icon is displayed on the lower right corner of the image, and a human icon is displayed in the area on the right of the icon; to change a mark, you can do this through the touch screen (as shown below), of which the settings of human icon are based on the current exam item.



The operating method of Mark is as follows:

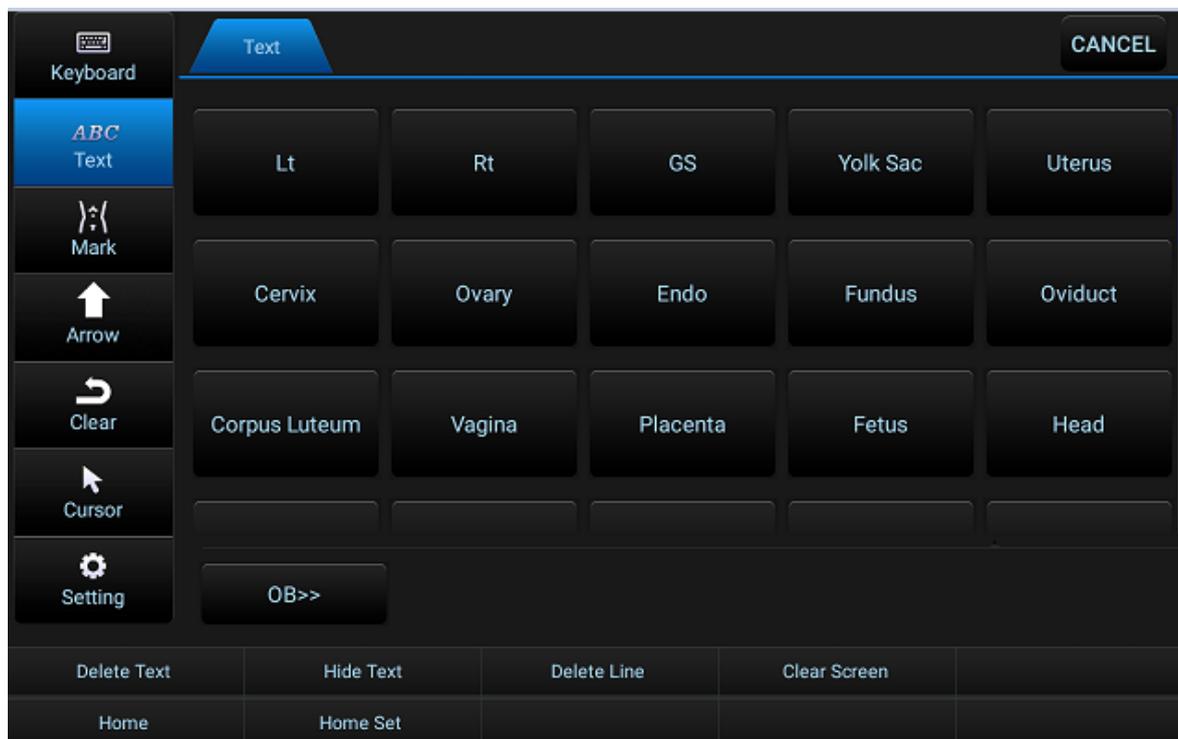
1. Click on the touch screen [mark] button to activate the marks annotation function. Click on the body mark in the marks display area to select the target mark. The selected target is displayed in the lower right corner of the image.
2. To change the marks of the examination title, click the current examination account button to enter the examination account selection interface.
3. Operate the following soft menu to rotate Probe and delete the marks.



4. The first individual marks and the volume library can be set using a preset system.

5.4.2 Text Annotation

Press [Text] on the touch screen to enable the text annotation. You can select the body mark characters displayed on the [Text] page of the touch screen, or use the touch screen keyboard to freely input text. Detailed operation can be carried out by rotating the corresponding knob.



Methods of text annotation:

1. Click [Text] on the touch screen to enable the text annotation;
2. Click on the text, select the desired text;
3. Move the trackball again and move the cursor to the desired image, then press [Set].
4. Use the text to carry out the functions of deleting (move the cursor to the front of the text), hiding/showing, screen clearing, text word library on/off, cursor reset, starting point setting and so on; you can also use Preset for character color and size settings.

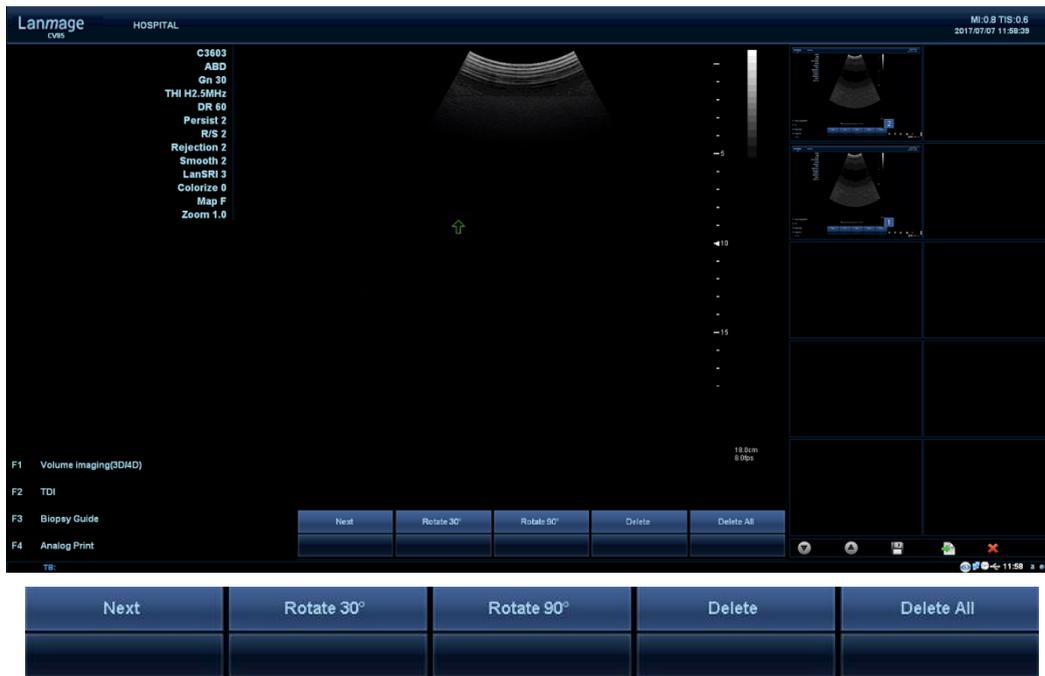
If you use the keyboard to freely input text, you need to click the touch screen [keyboard] button to open the touch screen keyboard. After the cursor stays at the ideal image position, tap the keyboard to enter characters, and then press the [Set] key to confirm.

Operating methods for annotation preset:

Press [Setting] → Click [Text Preset] on the left of the screen → [Text Properties] on the sub-Menu of the screen to preset relevant information for annotation.

5.4.3 Arrow Annotation

Press [Arrow] on the touch screen, and a green arrow icon will occur on the screen, and you can see corresponding parameter settings on the screen.



Operating methods for arrow annotation:

1. Press [Arrow] to enter the arrow annotation;
2. Move the trackball to place the arrow on the desired target;
3. Rotate the [Select] key to rotate the direction of the arrow; or press the toggle for 30° or 90° rotation, and press [Set].
4. Click [Next] to enable the next arrow and repeat the steps above; click [Delete] and
5. [Delete All] to remove individual or all arrows.

5.5 Biopsy

5.5.1 Introduction

The function of Biopsy can help the doctors to accurately locate the transducer and the ancillary Biopsy needle in the process of Biopsy; this is because the Biopsy guideline displayed on the imaging screen is just pointed to the preset path of the Biopsy needle.



Note: Biopsy is of high risk to the patients and the doctors, thus the user must comply with the correct needling sequences when using the Biopsy stand and its accessories so as to avoid unnecessary risks to the patients.



Note: The Biopsy guideline displayed on the screen is used for reference only. The user must verify the exact puncturing position in the operations of biopsy, tapping and aspiration, etc.

5.5.2 Adjustment of Biopsy Guideline

Each Biopsy function shall be properly adjusted before use. You can set the puncturing probe, angle, Biopsy line size and other relevant functions according to the following steps:

Press [Setting] on the keyboard → Click [System Preset] on the left of the screen → Click [Biopsy] on the sub-menu of the screen, then you can carry out the default settings to the relevant Biopsy functions.



Note: The Biopsy line shall be demonstrated by the representative or user from Customer Service Center, and if the probe or biopsy bracket is replaced, the Biopsy program must be repeated.



Note: Before Biopsy, make sure the track that the Biopsy needle enters is in line with the guide line displayed on the imaging screen, which can be pre-tested in a water tank filled with 47°C water. For an individual user, each type of probe needs to make only one debugging.

5.5.3 Biopsy-supporting Modes

Modes that support Biopsy include:

- B mode
- Color mode
- PDI mode
- THI mode

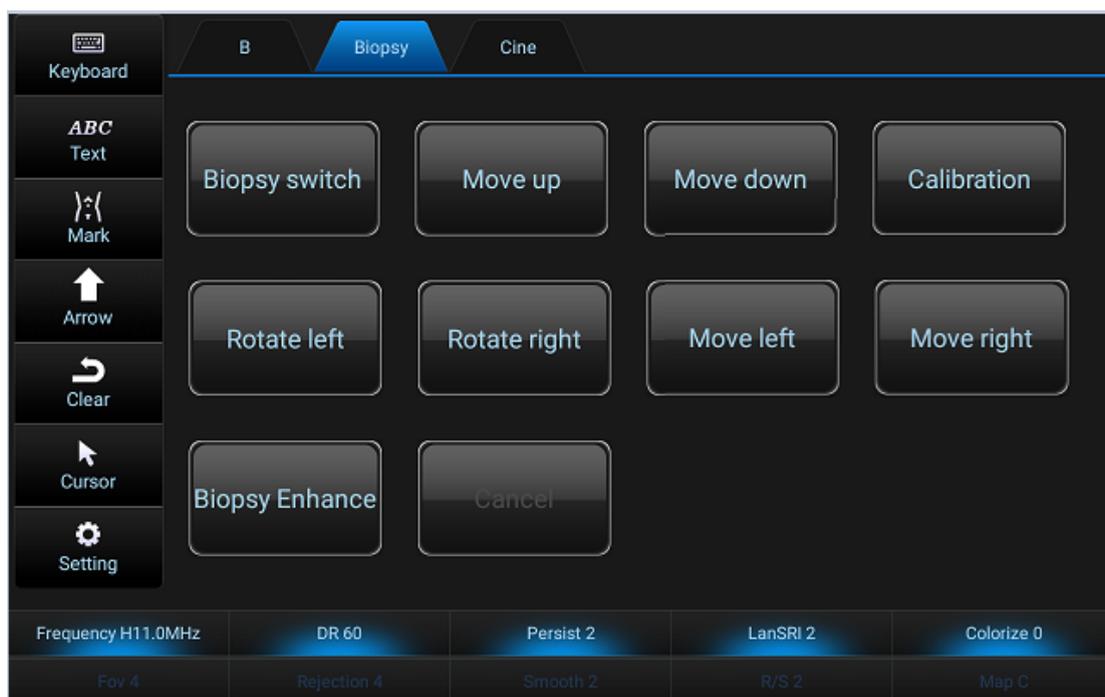
The Biopsy function can only be used in the real-time state. Enable the Biopsy function by taking B mode as an example:

1. Press [B] to enter the B mode;
2. Press the [Biology] button on the keyboard, and a dotted Biopsy guideline in a certain angle will occur in the image, and the angle mark [Biology] will occur on the top right of the screen;
3. To adjust the angle, press [Biopsy] again, and the Biopsy line angle will be changed and the angle mark [Biology2] will occur;
4. Then press [Biopsy], followed by Biopsy 3, Biopsy 4, Biopsy 5 and Exit Biopsy.



Note: Before Biopsy, make sure that the track of pointer is consistent with the guideline on the screen.

Fine tuning function of moving the biopsy guide line steps:



1. When enter the biopsy, Click [Calibration] to active the Fine tuning function;
2. Press [Move left] on the touch screen can left move the biopsy guide line; [Move right] can right move the guide line; [Move up] can up move the guide line; and [Move down] down move the guide line.
3. Roll the [Steer/Angle] knob to change the biopsy guide line angle.
4. Press [Calibration] again to exit the fine tuning function.

5.5.4 Disposable Protective Case

The probe needs to use a disposable case in the process of Biopsy.

⚠️ Note: All medical institutions must provide a disposable case for the probe so as to prevent infection. Currently, it is recommended to use formal and standard disposable cases without containing any pyrogen or other pathogenic agents.

⚠️ Note: Each of the probes is provided with an independent case, which shall be consisted of protective shell and cable as well as fixed ring. The sterile probes shall be placed in the biopsy-dedicated probe device; in addition to the above, the case shall be equipped with relevant biopsy-dedicated accessories.

⚠️ Note: The latex contained in the product is likely to cause a latex-allergic patient to suffer from a strong allergic reaction.



Note: Do not use condoms containing lubricants to protect the case, as this may damage the probe. Condom lubricants are not compatible with the probe materials.



Note: Do not use any expired probe case; before use, please be sure of the service life of the case.

5.5.5 Patient Preparations

Preparations for patients shall be followed in accordance with the routine operation steps of Biopsy. Any exam or Biopsy under the ultrasonic diagnostic system shall be carried out by the personnel with corresponding qualifications or professional training or under their guidance.

Needle track testing:

1. Connect the biopsy bracket with the sensor;
2. Connect the sensor to the system, and activate the sensor;
3. set the system to the proper depth required by a centesis;
4. Click [Biopsy] on the keyboard to start the Biopsy function;
5. To adjust the angle, click [Biopsy] again;
6. Submerge the sensor head into the de-aerated water, and insert the needle into the guider;
7. Based on the needle track testing with a guide line displayed on the image screen, the guider can be put into use after verification.



Note: Only the doctors experiencing with full testing are qualified to carry out a centesis. Appropriate preventive measures must be taken and a sterile environment must be provided.



Note: The Biopsy function cannot be used for IVF and chorionic tissue test and umbilical cord blood sampling and so on.

5.5.6 Puncture



Note: Before centesis, make sure that the puncturing path of the needle-holder is consistent with the guideline on the screen. It can be tested by putting it into a water tank filled with 47°C water.



Note: Do not use the guide needle that has been tested whether the puncturing path is consistent with the guide line on the screen, or use the guide needle that is used for positioning the puncturing path. Make sure that a new guide needle is used for every Biopsy.



Note: There are several guide lines that are commonly used for Biopsy and do not make any Biopsy before the guide line is completely determined.



Note: When setting the guide line, we do not take into account the bending or deformation of the Biopsy needle.



Note: The intersection of Biopsy guide line on the screen and the offset of the probe scanning central axis (depth) are able to be calculated, which can be tested in the water tank filled with 47°C water.

5.6 Viewing the User's Manual

Press [Help] on the touchscreen to enter the user's manual;

- Slide the scroll bar by sliding the trackball to carry out page up and page down.
- Press [Help] on the touchscreen again to exit the user's manual.



Chapter 6 Measurements and Calculations

6.1 Measurement Overview

When the system is carrying out the measurement, you can press the trackball button on the control panel (Please refer to Control Panel in Chapter 2); there are two types of measurements and calculations: general measurement and special measurement.

 **Note:** In order to guarantee the desired area from any miscalculation due to the measurement value in the measuring process, and therefore we should adjust the parameters so as get the best image quality for measurement.

 **Note:** In order to obtain accurate Doppler blood flow measurements, we should keep the sampling angle at 60 degrees, as Doppler angle lower or higher than 60 degrees is prone to misdiagnosis arising from reading errors.

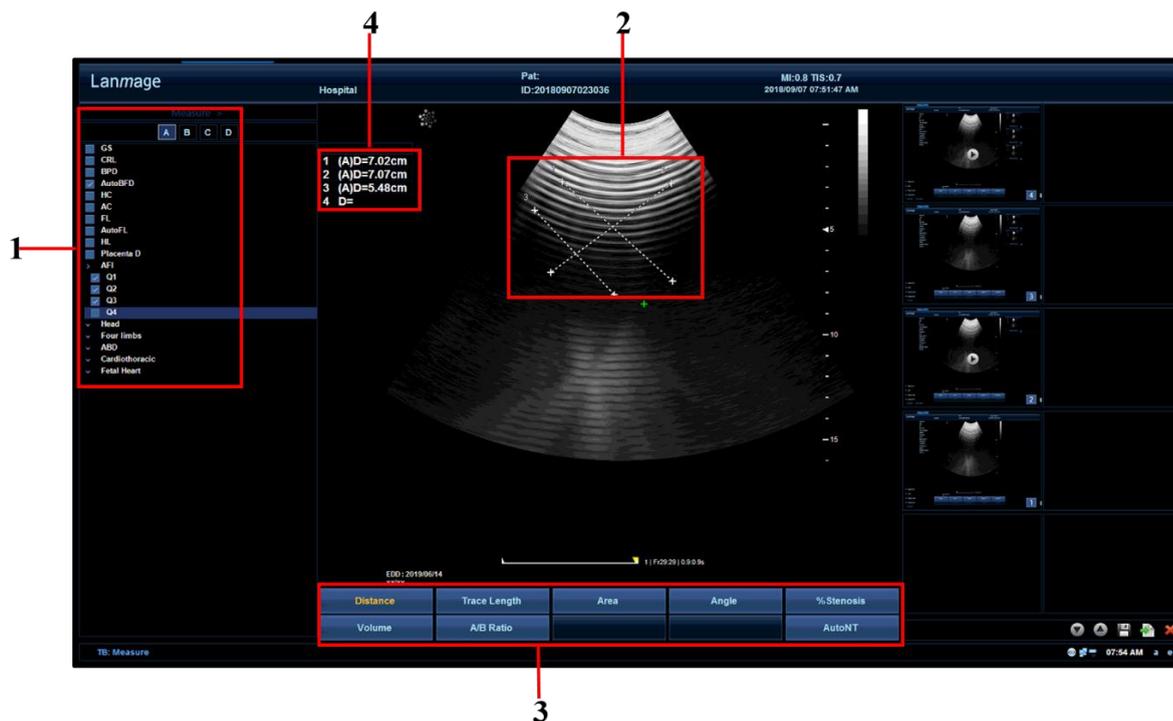
 **Note:** If the image is not frozen or the measurement mode is changed in the measuring mode, the measurements and calculations data will disappear from the screen, and the General measurement data will not be saved (Special measurement data will be saved in the worksheet and the report)

 **Note:** If the system is suddenly shut down in the measuring process, the measurement data will not be saved.

In general, the user can carry out the functions of measurements and calculations in the real-time, zoomed or frozen image, but in M mode and PW mode, the measurement function cannot be implemented in the real-time image, for which the image shall be frozen first.

6.1.1 Measurement Interface

As shown in the following figure, we need to have a detailed understanding of the following four areas/menus in the measurement process:



1. Special Measurement main menu: from top to bottom: measurement item, page turning display of measurement item (this option will occur in the case there is a single page), special measuring item, worksheet, report and cursor shows state.
2. Image measuring area: Use the trackball and [Set] to activate the measurement display of the caliper.
3. General measurement menu: Click the soft menu to select the measurements of the corresponding general items.
4. Measurement result display area: Move the cursor to the top column and press [Set], and rotate the trackball to press [Set] to move the measurement results to your preferential area. This area can support 8 groups of data display, and the data after the eighth group will automatically overwrite the previous measurement data.

6.1.2 Caliper Type

The caliper is a measuring mark used to indicate the starting point and the end point. Some caliper groups need multiple measurements to calculate a value, and a group of measured data will use the same caliper number for marking, and an image can display eight calipers at most. The mark will also be displayed in the result box; different measuring methods will have different calipers displayed on the image, which can be distinguished by referring to the list table.

Caliper Type	Description	Mode
++ xx	To indicate the starting point and end point of each pair of marks	B mode: distance, tracing length, area, angle, volume, stenosis rate, A/B ratio
⋮	To draw the starting position for a vertical dotted line, capable of marking the horizontal position or spacing	M mode: time, HR PW mode: time, HR, PI (automatic), PI (manual), flow
⋮ + ⋮	To indicate the vertical and horizontal positions.	PW mode: velocity, resistance index, acceleration, velocity ratio M mode: distance, slope, A/B ratio

6.1.3 Default Measurement Methods and Units

- In different imaging modes, there are different default measuring methods. Please refer to relevant chapters of "Measure Preset" for the system default imaging measurement methods.
- Some General measurements have more than one measuring method, for example, the area method includes elliptical method and tracing method; please see relevant chapters of "Measure Preset" for its default settings.
- When the system is measuring different General measurement items, the measurement units are also different; please see Chapter 8 of "Measure Preset" for their default units; you can change the unit settings, if necessary.

The users can set the default measuring method and unit in the Preset according to their preferences:

Press [Setting] on the touch screen → Click [Measure Preset] on the left of the screen → Click [General] and [Caliper] on the sub-menu above the screen, and the user can make the default settings to the general measurement methods above.

6.1.4 Basic Measurement Procedures

In general, the basic measurement procedures are as follows:

1. Enter the required measurement mode, and press [Measure] or [Caliper] to activate specialized measurement or general measurement. ;
2. press the parameter knob to select a general measurement item or use [trackball] to select a Special Measurement;
3. Use the trackball and [Set] to measure the desired area of the image; and press [Save] to save the image;
4. Results of the measurements will be displayed on the measurement result box;
5. If you want to modify results, you can re-measure this item when the data is presented with a color highlight in the measurement result area; and then press [Caliper] return measurement state.
6. If you want to remove the measuring scale and measurement result in the image, press [Clear] on the keyboard to clear the screen (but the measurement data will be saved to

- the report and worksheet);
7. Click [Cancel] on the touchscreen or press [Freeze] to exit the measurement.
 8. After the measurement is completed, the Special Measurement results will be saved to the report and the worksheet for viewing and editing.

6.2 General Measurement

General measurements and calculations refer to all the measurements and calculations that are able to be carried out in the exam items, under which there are different general measurement items in each type of imaging modes. The specific methods of general measurements are displayed in the soft menu, and general measurements and calculations include the measurements and calculations of general 2D mode (including modes of B, Color, THI and PDI), general M mode and Doppler mode (including PW mode).

6.2.1 General 2D-mode Measurements and Calculations

In 2D mode, you can set its measurement method in the Preset or select:

Distance	Trace Length	Area	Angle	% Stenosis
Volume	A/B Ratio			AutoNT

6.2.1.1 Distance Measurement

Function: measuring the distance between two respective points on the ultrasonic image.

Measurement methods:

1. Enter B mode and press [Caliper].
2. Rotating menu [Distance] to select distance measurement.
3. Roll the trackball to place the caliper on the image, and position the first measurement mark and press [Set].
4. Roll the trackball to move the caliper and position the second measurement mark, then press [Set] to measure the distance between two points of the image, meanwhile, the measurement result will be displayed in the result box of the imaging screen.
5. Click [Cancel] on the touchscreen or press [Freeze] to exit the measurement.

6.2.1.2 Tracing Length Measurement

Function: To use the manual tracing to calculate the distance. In general, B mode tracing length measurement is used for measuring non-linear distance.

Measurement methods:

1. Press [Caliper] to enable the measurement function;
2. Rotating menu [Trace Length];
3. Roll the trackball to position the first measurement mark, and press [Set], then the

system will fix this position.

4. Roll the trackball again to position the second measurement mark, and press [Set] to complete the measurement, then the system will record the measuring results to the result box on the screen.

6.2.1.3 Area Measurement

There are two type of area measurements, namely elliptical method and tracing method, and users can use the system preset to select the default measurement method, or Press the menu [Area], then elliptical and tracing options will occur for selecting.

Making an ellipse measurement

Function: To measure the circumference and area of a closed area through the elliptical method. When two diameters D1 and D2 used in the measurement are almost equal, the formula for calculating circumference is very accurate. When the image needs to measure the circumference, and the ratio between two diameters exceeds 2:1, it is recommended to use the tracing method so as to ensure the accuracy of the measurements.

Measurement methods:

1. Activating general measurement function;
2. Press menu [Area] and select [Ellipse];
3. Roll the trackball to position the first measurement mark, and press [Set]; roll the trackball again, and the system will display an ellipse, press [Set] to position an axis of the ellipse.
4. Roll the trackball again, the system will adjust the shape of the ellipse along its second axis; press [Set], the system will display the measuring data to the result box.
5. Roll the trackball again, and press [Set] to position the ellipse on the image. If you are not satisfied in the process of measurement, you can return to the previous step and press [Set] to revise the measurements.

Making a Trace Area Measurement

Function: calculating the area/circumference by manual tracings.

1. Activating measurement function;
2. Press menu [Area] and click [Trace];
3. Roll the trackball and press [Set] to position the first measurement mark, Roll the trackball again , the system will display the second measurement mark;
4. Roll the trackball and the mark line will establish a tracing by following the trackball; press [Set] to position the second mark, and the system will display the circumference and area of the tracing in the measurement result.

6.2.1.4 Angle Measurement

Function: To measure the angle between two intersecting planes on the ultrasonic plane, of which the larger angle is α , and the smaller angle is β , and these two angles will be displayed in the result box.

1. Press menu [Angle] to select the angle measurement.
2. Roll the trackball to place the caliper on the image, and position the first measurement mark and press [Set];
3. Roll the trackball to move the caliper to position the second measurement mark, then press [Set] and a line segment will occur;
4. Roll the trackball to position the third measurement mark and press [Set];
5. Roll the trackball to move the caliper to position the fourth measurement mark, then press [Set] and another line segment will occur;
6. The measurement angle between these two line segments will be displayed in the result box.

6.2.1.5 Stenosis Rate Measurement

Stenosis rate measurement consists of diameter stenosis rate and area stenosis rate, which can be set in the Preset or through the soft menu; refer to distance measurement and ellipse area measurement for its measuring method, which will not be repeated here.

6.2.1.6 Volume Measurement

Press the menu [volume] and five volume measurement methods will occur, as shown below:

Ellipse+Distance	1-Distance	2-Distance	3-Distance	1-Ellipse
Disc Method				

Ellipse + Distance method

Measurement methods:

1. Activating general measurement function;
2. Press menu [Volume], and press the toggle to select [Ellipse+ Distance].
3. Roll the trackball to position the first measurement mark, and press [Set], then the system will fix the mark; roll the trackball again, and the system will display an ellipse, press [Set] to position an axis of the ellipse.
4. Roll the trackball again, and the system will adjust the shape of the ellipse along its second axis; press [Set].
5. Roll the trackball again to position the ellipse on the image and press [Set] to fix the position. If you are not satisfied in the process of measurement, you can return to the previous step and press [Set] to revise the measurements.
6. Roll the trackball again and move the caliper to position the starting point of the line

segment, then press [Set];

- Roll the trackball again. Move the caliper to position the end point of the line segment, then press [Set] to complete the measurement; the measuring results will be displayed in the result box.

Formula:

$$V = \frac{\pi(D1 \times D2 \times D3)}{6}$$

Elliptic long axis D1, Elliptic short axis D2, Segment line D3. Formula unit: mm.

1-Distance Method

Function: The system uses a single distance measurement to calculate the volume.

- Activating measurement function;
- Press menu [Volume] and then press [1-Distance];
- Roll the trackball to position the first measurement mark, and press [Set], then the system will fix this position, and display the second mark;
- Roll the trackball to position the second measurement mark, and press [Set]. The system will fix this mark, and the measuring results will be displayed in the measuring result box.

Formula:

$$V = \frac{(\pi \times D^3)}{6}$$

D=length of the Segment, Formula unit: mm

2-Distance Method

Function: The system uses two distance measurements to calculate the volume. Use the caliper to respectively measure the length and the depth. The measuring results are successively displayed in the result box of the imaging screen. After the measurement is completed, the measuring results will be displayed in the result box.

Formula:

$$V = \frac{(\pi \times D1 \times D2^2)}{6}$$

Segment length D1, D2, Formula unit: mm

3-Distance Method

Function: Use the caliper to measure the three distances of D1 length, D2 width and D3 thickness of elliptical-similar object. The results of these linear measurements will be accordingly displayed in the result box of the imaging screen. After the thickness is measured, the volume will be displayed in the result box.

Formula:

$$V = \frac{\pi \times (D1 \times D2 \times D3)}{6}$$

Segment length D1, D2, D3, Formula unit: mm

1-Ellipse Method

Function: Use the ellipse method to calculate the volume, and please refer to the Ellipse Area Method for specific measurement methods. After the measurement is completed, the volume will be displayed in the result box.

Formula:

$$V = \frac{(8 \times A^2)}{3\pi \times D}$$

Segment length D, ellipse area A, Formula unit: mm.

6.2.1.7 A/B Ratio Measurement

A/B ratio measurement consists of distance ratio, area ratio and volume ratio, which is a measurement to calculate the ratio between two measurements; users can set this method in the Preset, or select this method in the soft menu; refer to the measurement methods of distance, area and volume for its measuring methods, which will not be repeated here.

6.2.2 General M Mode Measurements and Calculations

In the measurement of M mode, if you want to conduct a system preset, please refer to the method of B mode Measure Preset;

Distance	HR	Slope	Time	A/B Ratio

6.2.2.1 Distance Measurement

Function: To measure the distance between two vertical points on the M mode. Measurement methods:

1. Enter M mode, and press [Freeze] to freeze the image;
2. Press [Measure] on the touch screen, and rotate the menu [Distance] to measure the distance;
3. A dotted line will occur; rotate the trackball to adjust the position of the starting point, then press [Set];
4. Rotate the trackball again to fix the vertical dotted lines, and align the end points on the dotted line, press [Set] to locate the vertical line segment; the measuring results will be displayed in the result box;
5. If you want to re-position the points, press [Update] to revise the results.

6.2.2.2 HR Measurement

Function: To measure the HR between two vertical dotted lines on the M image.

1. Click menu [HR] and a dotted line will occur; rotate the trackball to position the dotted line and press [Set];
2. Move the trackball and another dotted line will occur, press [Set] to position the dotted
3. Line. The HR measurements between two points will be displayed in the result box.

Formula:

$$HR = \frac{60 \times n}{T}$$

T is the length of time represented by the line segment length, n is the number of cardiac cycles, Formula unit: s.

6.2.2.3 Slope Measurement

Function: To calculate the slope via measuring the distance between the two points of M mode ultrasound image.

Measurement methods:

Rotate menu [Slope], and refer to Distance Measurement for the methods of slope measurement, which will not be introduced in details here.

6.2.2.4 Time Measurement

Function: To measure the time interval between two respective points of the M mode image.

1. Select [Time] to switch to the measurement for time interval;
2. A dotted line occurs; roll the trackball and press [Set] to position the dotted line as the starting point of the time interval;
3. Move the trackball and another dotted line will occur, press [Set] to position the end point of the time interval. The time interval between two respective points will be displayed in the result box.

6.2.2.5 A/B Ratio

A/B ratio measurement consists of distance ratio and time ratio measurements; please refer to distance measurement and time measurement above for specific operating methods, and the results will be displayed in the result box.

6.2.3 General Doppler mode Measurements and Calculations

You can carry out the following general measurements in Doppler mode:

Velocity	PI Auto	Acceleration	Velocity Ratio	HR
RI	PI Manual	Flow Volume	Time	

6.2.3.1 Velocity

Function: This measurement is used to calculate speed.

1. Enter PW mode , and press [Freeze] , then press [Measure] to enter the PW measurement mode;
2. Rotate menu [Velocity] to switch to the flow velocity measurements;
3. A measuring cursor arising from the intersection of vertical line and horizontal line occurs, and roll the trackball to adjust the position of focus, press [Set] to position the focus, and the velocity measurement will be displayed in the result box.

6.2.3.2 PI (Auto)

1. After entering PW measurement mode, Rotate menu [PI Auto] to select automatic tracing measurement;
2. A tracing caliper occurs on the screen, press [Set] to position the caliper and fix the starting point;
3. Move the trackball to position the end point, and press [Set] for positioning;
4. The system will automatically fix these two calipers and find out the maximum value between the two points. In addition, a caliper will automatically occur, and rotate the trackball and press [Set] to confirm the second caliper; after the measurement is completed, the measuring results will be displayed in the result box.

6.2.3.3 PI (Manual)

1. After entering PW measurement mode, Rotate menu [PI Manual] to select the manual tracing measurement;
2. A tracing caliper occurs on the screen, press [Set] to position the caliper and fix the starting point;
3. Move the trackball for the maximum spectrum value required by manual tracing, and press [Set] to position the end point.
4. A caliper will occur, and rotate the trackball to set the second caliper; after the

measurement is completed, the measuring results will be displayed in the result box.

6.2.3.4 Acceleration Measurement

Function: To measure the ratio between acceleration or deceleration time; it is composed of two measurement marks: distance mark and velocity mark, so as to calculate the peak velocity (V_{max}), Time (T) and acceleration.

Measurement method:

1. Rotate menu [Acceleration] and switch to the corresponding measurement.
2. Roll the trackball to place the caliper on the starting point, and press [Set];
3. Roll the trackball to place the caliper on the end point, and press [Set];
4. The measuring results will be displayed in the result box.

6.2.3.5 Velocity Ratio Measurement

Function: To measure the velocities of two respective points (V_1 , V_2) and calculate the velocity ratio (V_1/V_2 , V_2/V_1 , $(V_1-V_2)/V_1$).

Refer to Acceleration Measurement for measuring methods.

6.2.3.6 HR Measurement

Function: To depict a cardiac cycle through the measurement mark displayed in the form of vertical line, based on which the HR can be determined.

1. Measurement methods:
2. Rotate menu [HR].
3. Roll the trackball to place the caliper on the starting point of the cardiac cycle on the spectrum, and press [Set];
4. Roll the trackball to place the caliper on the end point of the cardiac cycle, and press [Set];
5. The measuring results will be displayed in the result box.

6.2.3.7 RI (Resistance Index) Measurement

Function: This measurement is used to calculate the resistance index, measuring the peak systole (PS) and the velocity of end diastole (ED) as well as their velocity rate.

Refer to Velocity Measurement for its measuring methods.

6.2.3.8 Flow Volume Measurement

Flow Volume measurement consists of D-Flow and A-Flow, of which D-Flow is diameter flow measurement and A-Flow is area flow measurement; you can select the default measurement method in the Preset or in the soft menu.

The preset method is: Click the menu [Setting] on the touch screen → Click [Measure Preset] on the left of the screen → Click [General Measurement] on the sub-menu above the screen, and the user can make the default settings to the flow measurement method.

Making a Diameter Flow Volume Measurement

Function: Diameter flow is an estimated value of the flow that is calculated based on the vascular diameter. Diameter flow needs to carry out the measurement of vascular diameter in B mode with Doppler velocity tracing.

Measurement methods:

1. Rotate menu [Flow Volume], in which there are [D-Flow] and [A-Flow], then select [D-Flow];
2. Place the cursor in the starting point of PW mode image, and press [Set];
3. Roll the trackball to place the cursor on the end point, and press [Set];
4. Roll the trackball and move the caliper to the B mode image, then select the starting point and press [Set];
5. Roll the trackball to place the caliper on the end point, and press [Set];
6. The measuring results will be displayed in the result box.

Making an Area Flow Volume Measurement

Function: Area flow is an estimated value of the blood flow that is calculated based on the area. Area flow also needs to carry out the area measurement in B mode with Doppler velocity tracing.

Measurement methods:

- Rotate menu [Flow], in which there are [D-Flow] and [A-Flow], then select [A-Flow];
- Place the cursor in the starting point of PW mode image, and press [Set];
- Roll the trackball to place the cursor on the end point, and press [Set];
- Roll the trackball and move the caliper to the B mode image for area measurement (Refer to Area Measurement in 2D-mode General measurement for details).
- The measuring results will be displayed in the result box.

6.2.3.9 Time Measurement

Function: To be used to measure the time interval between two vertical measurement marks. Refer to Velocity Measurement for its measuring methods.

6.2.4 Measurement Errors

Although the system has a very high accuracy of scan and measurement, users should also be aware of the errors arising from ultrasonic signal characteristics and scanning structure, organization and physiological characteristics of liquids.

In order to ensure the best possible measurement accuracy, the image zoom proportion shall be used for measurement.

In order to improve lateral resolution, select the proper probe according to the depth range of

the measurement structure.

During the measuring process, the following measurement errors shall be taken into account:

- Distance measuring error: $\pm 3\%$ or less;
- Circumference measuring error: $\pm 3\%$ or less;
- Area measuring error: $\pm 6\%$ or less;
- Volume measuring error: $\pm 9\%$ or less;
- When the ultrasonic beam axis is aligned with the blood flow, the measuring error of flow velocity shall be within $\pm 5\%$.

The measuring errors are acquired from assessment to the testing targets in the laboratory environment.

In the process of diagnosis, the measurement data of the ultrasonic systems must be used in combination with other clinical data, and no diagnosis shall be made only in terms of measurement data. When the data are acquired by using the ultrasonic system, other factors shall also be taken into account. Analysis of these factors has shown that the accuracy of measurement and further calculation depend on the quality image to a large extent. In turn, the image quality depends on system design and skills of operators as well as their understandings of system features.

The ultrasound imaging algorithms are based on the sound velocity in the 1540 m/s tissues. However, in different tissues, sound velocity may be different. In soft tissue, the error is usually by 2%, and sometimes even reaches 5%, particularly when a fat tissue occurs in the measured area.

In order to ensure the best measurement precision, please align the probe carefully and keep the sound beam aligned with the direction of flow.



Note: The calculation precision of blood flow parameters depends on:

- System design and signal processing algorithms used in the system;
- Quality of reflection signals, including signal-to-noise ratio and Doppler change;
- Skills of the users, whether they can correctly adjust the probe in line with the direction of the exam item and select the system parameters;
- All of these above will affect the quality of reflection signals and the suitability of processing algorithms.

Due to the above and other factors, the aggregate error of such an absolute measurement like flow velocity sometimes even reaches $\pm 50\%$ or higher. Even in ideal laboratory environment, it is very difficult to achieve an error within $\pm (5-10)\%$.

Therefore, we should try our best to avoid absolute measurement, but give priority to the relative measurements such as resistance index and plasticity index, etc., of which the errors are around 10%.

In the absolute measurement, angle between beam axis and flow direction is very important.

If the angle exceeds 60° , the measurement error will increase dramatically. Even if the angle is less than 60° , the error also depends on the parallel positioning accuracy between flow

direction line and actual flow direction performed by an operator. The calculation precision of the average velocity will be greatly affected by the relative position of sampling volume and blood vessel. The sampling volume must be large enough so as to be able to "ensonify" the entire sample volume. The sampling volume must be aligned with the blood vessel axis. Users must receive trainings from skilled experts so as to ensure proper use of the Doppler ultrasonic diagnostic system.

6.3 Special Measurement

Special Measurements and calculations refer to the measurements and calculations of various specific exam items, including abdomen Renal, abdominal blood vessel, pediatric abdomen, gynecology, obstetrics, early pregnancy, middle and late pregnancy, fetal heart, urinary tract, prostate, blood vessel, Carotid, peripheral arteries, vein, Small Parts, thyroid, mammary glands, testes, orthopedics, cardiology, pediatric cardiology, Transcranial, emergency and other measuring items. The system will store the measuring and calculating results into the worksheet and report.

Special Measurement shares a similar operating method with general measurement, but the specific measurement items can be selected from the main menu, for which the specific operating steps are as follows:

1. Press [Patient] to input relevant patient information;
2. Press [Probe] to select the measuring items under the corresponding probe;
3. Enter the desired measurement mode, and press [Measure] (press [Freeze] first and then [Measure] in M mode and PW mode);
4. Move the trackball to the measurement items on the left, and click on the touch screen to select the measurement items; the corresponding measurement methods will be displayed in the soft menu of the screen.
5. Rotate the trackball to the desired area of the image and press [Measure] for measurement; the system will be defaulted to measure the next item after completing the current item, in front of which the icon $\sqrt{\quad}$ will be displayed; if all the items are measured, the system will continue to carry out the measurements again;
6. The latest eight data of the measuring results will be displayed in the measurement result display area;
7. Click the worksheet and report on the left, and view the measuring results; all of the measurements will be saved into the worksheet, while the latest measurement data will be saved in the report.

We will introduce the measuring Items, measurement methods, measurement steps, formula and export reports of the items above respectively in 2D mode, M mode and PW mode.

6.3.1 Abdominal Measurement

Preparations before measurement:

1. Check whether the current probe is suitable for abdominal measurement;

2. Check whether the system date is the current date;
3. Press [Patient] to input the information of the patient;
4. Press [Probe] to select the items of abdominal measurement.

6.3.1.1 Abdominal Measurement in 2D Mode

In 2D mode, abdominal measurement is divided into general measurement and Renal, abdominal blood vessel and Pediatric abdominal measuring Items, all of which are measured through the distance method, and the specific measurement items include:

- Liver: R Live Max, R Live W, R Live D, L Live L, L Live D, CBD, CHD,
- Gall bladder: GB L, GB W, GB Wall- D,
- Pancreas: Pancr. Head, Pancr. Corus, Pancr. Tail, Pancr. Duct,
- Spleen: SP-L, SP-D, SP-W;
- Right kidney: RK-L, RK-D, RK-W;
- Left kidney: LK-L, LK-D, LK-W;
- ABD-Vascular: Ao, CHA, Celiac Axis, SMA, Splenic A, Rt Renal A, Lt Renal A, IVC, Portal V, Hepatic V, SMV, Splenic V, Rt Renal V, Lt Renal V.
- Ped-ABD: R Live Max, R Live W, R Live D, L Live L, L Live D, CBD, CHD, GB L, GB W, GB Wall- D, Pancr. Head, Pancr. Corus, Pancr. Tail, Pancr. Duct, SP-L, SP-D, SP-W; Right kidney: RK- L, RK-D, RK-W; Left kidney: LK-L, LK-D, LK-W;

Measurement methods:

1. Press [B] to enter the B mode measurement;
2. Press [Measure] and the abdominal measuring items will be displayed in the main menu on the left; rotate the trackball to select the corresponding item and press [Set], then move the trackball to the image for distance measurement (the measurement method is displayed in the soft menu);
3. The measurement result is displayed in the result box; click the main menu or the
4. [Report] to view the report or worksheet.

Formula for Renal:

Calculation Item	Input Parameter	Formula
Renal volume	3-Distance (length, width and height)	$V = \frac{\pi(D1 \times D2 \times D3)}{6}$

6.3.1.2 Abdomen Measurement in Doppler Mode

In Doppler mode, you can carry out the measurements to each part of abdominal entire sample volume, and the concrete measurement items and methods are:

- RI , PS and ED of Ao, CHA, Celiac Axis, SMA, Splenic A, Rt Renal A, Lt Renal A;

- PV of IVC, Portal V, Hepatic V, SMV, Splenic V, Rt Renal V, Lt Renal V;

Among them, the measurement methods of the arteries above are PI (automatic); RI measurement methods are: RI;

PS measurement methods are: V (velocity); ED measurement methods are: V (velocity); PV measurement methods are: V (velocity).

Measurement methods of PI (Auto), RI, PS, ED and PV:

1. Press [D] to enter the PW mode, press [Freeze] and press [Measure] to enter the PW measurement interface;
2. On the left occurs the abdominal menu items; click on the touch screen or trackball to select the measurement item; (refer to general Measurement for specific measurement methods that are displayed in the soft menu)
3. A vertical line will be displayed on the system screen; move the trackball to position the starting point of the vertical line and press [Set], then move the trackball to position the vertical line and press [Set] (taking RI as an example);
4. The measurement values will be displayed in the result box.

6.3.1.3 Abdominal Measurement Report

The report includes patient information, measurements, images, description and conclusion of the measurement result made by doctors.

Hospital

Patient Information

Name:	Patient ID:20180907023036	Gender:Unknown
Ref.M.D:	Exam Date:2018/09/07 02:30:52	Age:

Measurements

OB

LMP:2018/09/07	EDD:2019/06/14	GA:wxwd
EDD(CUA):2019/06/14	CUA:wxwd	CUA Based on:Hadlock11(BPD,HC,AC,FL)

Fetus A

B Mode:

Q1	4.7 cm
Q2	6.32 cm
BPD	0 cm
Q3	6.1 cm

ABD

B Mode:

R Liver W	3.99 cm
LK L	2.82 cm
LK D	5.23 cm
LK W	0.11 cm
LK-V	0.89 cm ³
Ao	2.49 cm
CHA	17.12 cm
R Liver Max	4.11 cm
R Liver D	3.99 cm

Cardiac

M Mode:

Images



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6.3.2 Gynecological Measurement

Preparations before measurement:

1. Check whether the probe is suitable for the current measurement item;
2. Check whether the system date is the current date;
3. Press [Patient] to input the information of the patient;
4. Press [Probe] to select gynecological measurement.

6.3.2.1 Gynecological Measurement in 2D Mode

In B mode, users can carry out the gynecological measurements that are listed in the menu:

- Uterus: UT-L, UT-D, UT-W ,Endo, Cervix,
- Rt Ovary: OV-L, OV-D, OV-W;
- Lt Ovary: OV-L, OV-D, OV-W;

- Rt Follicle:#1~#15;
- Lt Follicle:#1~#15;
- CRL, Yolk Sac, GS

Among them, Uterus, Rt Ovary, Lt Ovary, CRL, Yolk Sac, GS use the distance method for measurement:

1. Place the caliper on the starting point, and press [Set];
2. Roll the trackball to place the caliper on the end point, and press [Set];
3. The measuring results will be displayed in the result box.
4. Measurement steps for Follicle:
5. Place the caliper on the starting point, and press [Set];
6. Roll the trackball to place the caliper on the end point, and press [Set], then a line segment occurs;
7. Place the caliper on the starting point, and press [Set];
8. Roll the trackball to place the caliper on the end point, and press [Set], then a line segment occurs;
9. The measuring results will be displayed in the result box.

Gynecological 2D mode calculation

When you measure the long diameter, thick diameter and wide diameter of the uterus and ovaries in the measurement results, the system will carry out the volume measurement according to the formula in the following table.

Calculation Item	Input Parameter	Formula
Uterine Volume	3-Distance (long diameter D1, thick diameter D2 and wide diameter D3)	$UT - Vol = 0.5236 \times D_1 \times D_2 \times D_3$
Ovarian Volume	3-Distance (D1, D2, D3)	$OV - Vol = 0.5236 \times D_1 \times D_2 \times D_3$

6.3.2.2 Gynecological Measurement in Doppler Mode

In Doppler mode, users can conduct the measurements of UT A, Rt OV A, Lt OV A; the measurement method is PI (automatic), and the operating steps are:

1. Press [Probe], and select [GYN] to return to the main interface;
2. Press the PW mode, and press [Freeze], then press [Measure] to enter the measurement interface;
3. The gynecological measurement option will pop up in the main interface, and select the measurements;
4. A vertical line occurs, and rotate the trackball and [Set] to position the vertical line; then a second vertical line occurs, rotate the trackball and press [Set] to position the vertical line;
5. The system will automatically fix these two vertical lines and work out the maximum value between the two points. A caliper will automatically occur, and rotate the trackball and press [Set] to position the second caliper, then the measurement is completed.
6. The measurements will be displayed in the result box, and saved to the worksheet and

report.

6.3.2.3 Gynecological Report

The report includes patient information, measurements, images, description and conclusion of the measurement results made by doctors, allowing users to view the conditions of the patient; the report is as follows:

Hospital

Patient Information

Name:	Patient ID:20180907023036	Gender:Unknown
Ref.M.D:	Exam Date:2018/09/07 02:30:52	Age:

Measurements

OB

LMP:2018/09/07	EDD:2019/06/14	GA:0w0d
EDD(CUA):2019/06/14	CUA:xwxd	CUA Based on:Hadlock11(BPD,HC,AC,FL)

Fetus A

B Mode:

Q1	4.7 cm
Q2	6.32 cm
BPD	0 cm
Q3	6.1 cm

ABD

B Mode:

R Liver W	3.99 cm
LK L	2.82 cm
LK D	5.23 cm
LK W	0.11 cm
LK-V	0.89 cm ²
Ao	2.49 cm
CHA	17.12 cm
R Liver Max	4.11 cm
R Liver D	3.99 cm

Cardiac

M Mode:

GYN

LMP:2018/09/07	EDD:2019/06/14	GA:0w0d
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B Mode:

Endo	5.21 cm
Rt OV-L	4.03 cm
Rt OV-D	5.19 cm

Images



6.3.3 Obstetric Measurement

Preparations before measurement:

1. Check whether the current probe is suitable for obstetric measurement;
2. Check whether the system date is the current date;
3. Press [Patient] to input the patient information, and confirm last menstrual period,

selection of single birth or multiple births as well as other cases;

4. Press [Probe] to select OB-1 or OB-2/3, OB in the obstetric measurement.
5. Press [Setting] on the key → Click [Measure Preset] on the left of the screen → Press [Measure] on the sub-menu above the screen to preset the related obstetric measurements and reference author as well as other information.

6.3.3.1 Obstetric Classification

There are two exam types of obstetric application, including early obstetric exam and standard obstetric exam, both of which have formula to calculate the menstrual age and fetal weight and to speculate the growth ratio of fetus. Each type of exam can support measurements of multiple births.

- Early obstetric exam is mainly targeted at the measurements of pregnant women in the first trimester.
- Standard obstetric exam is mainly targeted at the measurements of intermediate 3 months and last 3 months.

6.3.3.2 Estimation of Fetal Weight and Gestational Age

Estimation of fetal weight:

When the system carries out related obstetric measurements, it will automatically calculate the fetal weight and gestational age, of which EFW1 and EFW2 are the estimated fetal weights (g).

The fetal weight can be calculated through the following methods:

- Shepard
- Hansmann
- Merz
- Hadlock1
- Hadlock 2
- Hadlock 3
- Hadlock 4

By default, the system will use Hadlock 2 to estimate the fetal weight, and if the user wants to select other methods, click [Worksheet] to select the calculation method of fetal weight in the drop-down list in EFW1 or EFW2, or can make settings in the Preset; the operating methods are:

Press [Setting] on the keyboard → Click [Measure Preset] on the left of the screen → Click [EFW/CUA] under the sub-menu [Measure] above the screen to select the calculation method of fetal weight and gestational age.

Gestational age calculation:

Enter the last menstrual period in the obstetric report or patient information menu in accordance with the following steps:

1. Move the cursor to the last menstrual period ▼ and a date list occurs (as shown below);
2. Click ◀ or ▶ to change the menstrual period, and press [Set] to select the appropriate date;
3. After entering the last menstrual period, the system will automatically calculate the clinical expected date of confinement through corresponding methods.
4. Click [Worksheet] to select the reference author of gestational age from the drop-down menu of [CUA Based on].



The reference author and corresponding estimating formula can be seen from the following table:

Reference Author	Estimating Formula and Measuring Item
Hadlock1	$CUA(BPD, HC) = 10.32 + 0.009 * HC^2 + 1.3200 * BPD + 0.00012 * HC^3$
Hadlock2	$CUA(BPD, AC) = 9.57 + 0.524 * AC + 0.1220 * BPD^2$
Hadlock3	$CUA(BPD, FL) = 10.50 + 0.197 * BPD * FL + 0.9500 * FL + 0.7300 * BPD$
Hadlock4	$CUA(HC, AC) = 10.31 + 0.012 * HC^2 + 0.3850 * AC$
Hadlock5	$CUA(HC, FL) = 11.19 + 0.070 * HC * FL + 0.2630 * HC$
Hadlock6	$CUA(AC, FL) = 10.47 + 0.442 * AC + 0.3140 * FL^2 - 0.0121 * FL^3$
Hadlock7	$CUA(BPD, HC, AC) = 10.58 + 0.005 * HC^2 + 0.3635 * AC + 0.02864 * BPD * AC$
Hadlock8	$CUA(BPD, HC, FL) = 11.38 + 0.070 * HC * FL + 0.9800 * BPD$
Hadlock9	$CUA(BPD, AC, FL) = 10.61 + 0.175 * BPD * FL + 0.2970 * AC + 0.7100 * FL$
Hadlock10	$CUA(HC, AC, FL) = 10.33 + 0.031 * HC * FL + 0.3610 * HC + 0.0298 * AC * FL$
Hadlock11	$CUA(BPD, HC, AC, FL) = 10.85 + 0.060 * HC * FL + 0.6700 * BPD + 0.1680 * AC$

6.3.3.3 Measurement of Single Birth and Multiple Births

1. Press [Patient] to enter the basic information of patients, and enter the number of fetus in the patient information, in which the user can enter 4 at most, meaning a maximum of four fetuses can be measured at the same time;
2. Press [Measure] and four letters A, B, C and D will appear on the top of main menu, of

which the system will highlight the letter of the designated fetus under measurement, and A is the default letter.

3. To carry out measurements of multiple births (take twins for example), the user can define the fetuses as A and B; to measure A, roll the trackball to select A and press [Set] to measure the following items; to measure B, select B and press [Set] to measure the following items.

6.3.3.4 Obstetric Measurement in 2D Mode

In B mode, in accordance with the classification of obstetrics, the obstetric measurements consist of three measuring items, namely early pregnancy, middle/late pregnancy and fetal heart:

- General: GS, CRL, BPD, HC, AC, FL.AFI:Q1, Q2, Q3, Q4, NT, OFD, ASD, ATD, FTA, APTD, TTD, HL, C Lav, Ulna, Tibia, Radial, FIB, FT, Ear, BN, Placenta D, TC, HeartC, CTAR, THD, Rt Renal L, Lt Renal L, Rt RAP, Lt RAP, Cervix Len, TCD, Cist Magna, HW, OOD(Outer Orbital Diameter), IOD(Outer Orbital Diameter), Umb VD;

For the measurements above, except that HC, AC, FTA, TC, CTAR and Heart C the area measurements and heart chest area ratio is the area ratio measurement, all of the others are distance method measurements, for which the measurement steps are as follows:

1. Roll the trackball to place the first caliper on the starting point to be measured;
2. Press [Set];
3. Roll the trackball to place the second caliper on the end point to be measured;
4. Press [Set];
5. The measuring results will be displayed in the result box of the imaging screen.

The operating methods to use the elliptical area method to measure HC, AC, FTA, TC and heart C are:

1. Press [Patient] to enter and save the patient information, and press [Probe] to select the obstetric measurement item and return to main interface;
2. Press B mode and press [Measure] to enter the measurement interface;
3. The obstetric items pop up in the main menu, and select the measurement of Head Circumference (taking HC measurement for example);
4. The area method measurement will occur in the menu: rotate the trackball and press [Set] to position the starting point of the ellipse; and rotate the trackball and press [Set] again to position an axis of the ellipse; then rotate the trackball and press [Set] to position the other axis of the ellipse; and finally rotate the trackball to select the position of ellipse and press [Set] for positioning;
5. The measurements will be displayed in the result box, and saved to the worksheet and report.
6. The measurement of CTAR can refer to the ellipse area method above, and another an ellipse needs to be drawn for calculating the area ratio in the process of the measurement.

6.3.3.5 Measurement Item and Calculation of Fetal Heart

There is a measurement kit for fetal heart in the obstetric submenu, and measurement items, descriptions and measurement methods are listed in the following table.

Measurement Item	Description	Measurement methods
AoD Arch	Diameter of aortic arch	Distance
Asc AoD	Diameter of ascending aorta	Distance
Desc AoD	Diameter of descending aorta	Distance
IVSd	Interventricular septum dimension at end systole	Distance
LVIDd	Left ventricular internal dimension at end systole	Distance
LVPWd	Left ventricular posterior wall dimension at end systole	Distance
IVSs	Interventricular septum dimension at end systole	Distance
LVIDs	Left ventricular internal dimension at end systole	Distance
LVPWs	Left ventricular posterior wall dimension at end systole	Distance
LVOT Diam	Left ventricular outflow tract diameter	Distance
PA	Pulmonary artery	Distance
RVDd	Right ventricular dimension at end systole	Distance
RVOT Diam	Right ventricular outflow tract diameter	Distance
CTAR	Heart-chest area ratio	Area ratio
Cardiac Axis	Cardiac axis	Angle

Measurement method from fetal heart aortic arch diameter to right ventricle outflow tract diameter:

1. Press [Exam/Item] to select the fetal heart measurement Item in the obstetric menu or directly click [OB]; and click [Measure] to select [AoD Arch] in the main menu (taking AoD Arch for example);
2. Place the third caliper on the starting point of D1 segment;
3. Press [Set];
4. Roll the trackball to place the second caliper on the end point of D1 segment;
5. Press [Set];
6. The measurements will be displayed in the result box of the screen, and saved to the worksheet and report. If you want to continue with the following measurements, please repeat steps 2-5.
7. Measurements of CTAR can refer to the measurement of ellipse area method of head circumference, while another an ellipse shall be also measured, and the measurements will be displayed in the result box.

Fetal heart formula

The table below shows the formula of fetal heart measurement in 2D mode and M mode, and the calculation results will be saved to the report and worksheet.

Measurement Item	Description	Desired Measurement	Unit
EDV &ESV	left ventricular end-systole volume and Left ventricular end-diastole volume are estimated by measuring the distance from left ventricular internal diameter (LVID). Teichholz Volume method: $EDV = 7(LVIDd^3/1000)/(2.4 + LVIDd/10)$ $ESV = 7(LVIDs^3/1000)/(2.4 + LVIDs/10)$ Cube: $EDV = LVIDd^3/1000$ $ESV = LVIDs^3/1000$ Gibson: $EDV = 0.52(0.98*LVIDd/10 + 5.90)*LVIDd^2/100$ $ESV = 0.52(1.14*LVIDs/10 + 4.18)*LVIDs^2/100$	LVIDd LVIDs	mL
EF	Ejection fraction refers to the ratio between stroke volume and end-diastolic volume: $EF=SV/EDV*100$	EDV ESV	%
FS	Systolic percentage refers to the systolic percentage of LV size: $FS=[(LVIDd-LVIDs)÷LVIDd]*100$	LVIDd LVIDs	%
SV	Stroke volume refers to the ventricular ejection volume in a cardiac cycle or ventricular systolic phase: $SV=EDV-ESV$	EDV ESV	mL

6.3.3.6 Obstetric Measurement in M Mode

In M mode, you can view the routine fetal heart rate and fetal heart measurement Item, which has been listed in the table above (excluding FHR and fetal heart measurement items), and will not be repeated here.

6.3.3.7 Obstetric Measurement in Doppler Mode

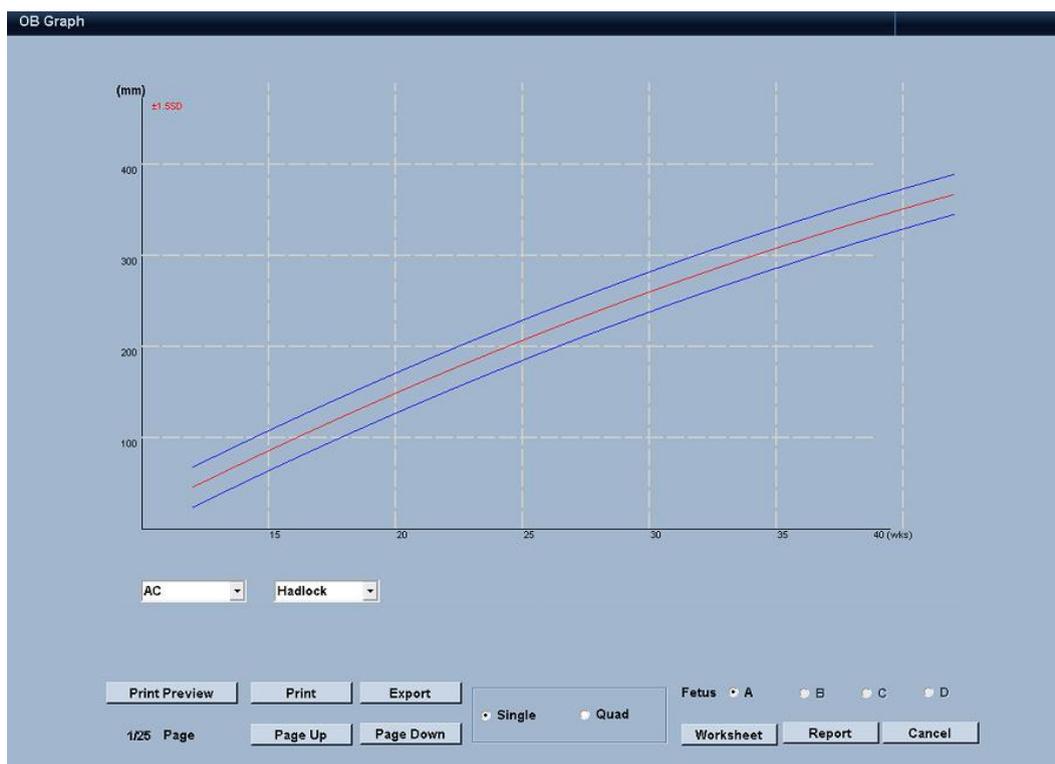
In Doppler mode, you can carry out the measurements of Umb A, MCA, FHR and fetal heart measuring Items. The measuring Item will be listed in the table below along with the description of measurement items and measurement methods. Please refer to corresponding general measurement items in Doppler mode for its operating methods.

Measurement Item	Description	Measurement methods
Preload Index		RI
Tel Index a	Time interval between beginning and end of mitral valve filling	Time
Tel Index b	Time interval between beginning and end of aortic flow	Time
LVOT Max	Left ventricular outflow tract maximum velocity	Velocity

LVET	Left ventricular ejection time	Time
Asc Ao Vmax	Ascending aorta maximum velocity	Velocity
Ao Arch Vmax	Aortic arch maximum velocity	Velocity
Desc Ao Vmax	Descending aorta maximum velocity	Velocity
DA Vmax	Arterial duct maximum velocity	Velocity
RVOT Vmax	Right ventricle maximum velocity	Velocity
RVET	Right ventricle ejection time	Velocity
PA	Pulmonary artery	Velocity
FHR	Fetal heart rate	Time

6.3.3.8 Obstetric Graph and Report

In the main menu of obstetric measurements, there are worksheets and reports as well as obstetric graphs; click graphs to view the growth curve of the fetus.



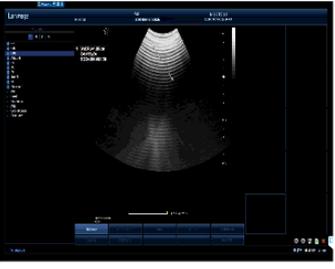
- From the graph, you can view the corresponding obstetric measurement items and the selected growth curve of the reference authors, and these reference authors can be set in the Preset; Preset of reference author: press [Setting] on the touch screen → Click [Measure Preset] on the left of the screen → Click the sub-menu [Measure] on the screen, and then click [Graph] for setting.
- There are three curves in the obstetric graph, respectively showing the maximum value, normal value and minimum value of the measurement item of the fetus. Red point

represents the position of the current measurement value. The fetal growth can be judged by viewing the growth curve.

- Click the [single]or [Quad] below the graph to carry out image switching and selection of multiple births, as well as other functions such as graph print previewing, printing, page up and page down, switching to worksheet or report, etc.

6.3.3.9 Obstetric Report

On the basis of routine report, obstetric report is included with LMP, EDD (LMP), EDD (CUA), GA (LMP), CUA, selection of single birth/multiple births and CUA Based on, so as to allow us to calculate the subsequently input data.

Hospital		Images
Patient Information Name: Patient ID:20180907023036 Gender:Unknown Ref.M.D: Exam Date:2018/09/07 02:30:52 Age:		
Measurements OB LMP:2018/09/07 EDD:2019/06/14 GA:0w0d EDD(CUA):2019/06/14 CUA:xxxx CUA Based on:Hadlock11(BPD,HC,AC,FL)		
Fetus A B Mode: Q1 4.7 cm Q2 6.32 cm BPD 0 cm Q3 6.1 cm GS 3.63 cm 8w3d4d 2019/04/16 FL 0.14 cm CRL 4.69 cm 11w3d4z7d 2019/03/26 BPD 6.43 cm 26w0d2z1f1d 2018/12/14 HC 1.98 cm OOR EDD=OOR FL 5.57 cm 29w2d2z1w1d 2018/11/21 FL/BPD Holter 0.87		Description Conclusion
ABD B Mode: R Liver W 3.99 cm LK L 2.82 cm LK D 5.23 cm LK W 0.11 cm LK-V 0.89 cm² Ao 2.49 cm CHA 17.12 cm R Liver Max 4.11 cm R Liver D 3.99 cm		
Cardiac M Mode: GYN LMP:2018/09/07 EDD:2019/06/14 GA:0w0d B Mode: Endo 5.21 cm RT OV-L 4.03 cm RT OV-D 5.19 cm		
Page 1/2	Print Date:2018/09/07	Page 2/2
		Print Date:2018/09/07
		Operator:

6.3.4 Urological Measurement

Preparations before measurement:

1. Check whether the probe is suitable for the current measurement item;
2. Check whether the system date is the current date;
3. Press [Patient] to input the information of the patient;
4. Press [Probe] to select urological measurement.

6.3.4.1 Urological Measurement in 2D Mode

In B mode, users can carry out any of the following urological measurements:

- Right kidney: RK L,RK D,RK W;

- Left kidney: RK L,RK D,RK W;
- Right Adrenal: Adrenal L, Adrenal D, Adrenal W;
- Left Adrenal: Adrenal L, Adrenal D, Adrenal W;
- Bladder: Bladder-V, Residual;
- Prostate: Prostate-L, Prostate-D, Prostate-W;

In the measurements above, the measurement methods of long diameter, thick diameter and wide diameter are distance measurements, and refer to Distance Measurement in the chapter of “General Measurement” for specific methods; we will make measurements on bladder size and residual urine volume in volume measurement method, which has been introduced to include five methods in the chapter of “Volume Measurement”, and users can set specific methods through Preset:

Press [Setting] on the touch screen → Click [Measure Preset] on the left of the screen → Click the sub-menu [General Measurement] on the screen, and the user can select the volume measurement method for preset in [Default Measurement Method].

Measurement methods of Bladder-V and Residual:

1. Press [Measure];
2. A measurement items will occur on the left, menu [Bladder-V]
3. and then press [Set], or click on the touch screen for selection;
4. Relevant volume measurements will be displayed in the soft menu (for example, 1-Ellipse), which can be selected here or preset as above;
5. Rotate the trackball and press [Set] to position the starting point of the ellipse; and rotate the trackball and press[Set] again to position an axis of the ellipse; then rotate the trackball and press [Set] to position the other axis of the ellipse; and finally rotate the trackball to select the position of ellipse and press [Set] for positioning;
6. The system will display the measuring values of bladder size in the result box; in case of pressing [Measure], the system will measure the next residual urine by following the measurement items; repeat steps 3 -4.

Urological calculation in 2D mode

Calculation Item	Input Parameter	Formula
Bladder-V	3-Distance	$Vol = 0.7 \times D1 \times D2 \times D3$ or $Vol = (\pi \times D1 \times D2 \times D3) / 6$
Prostate-V	3-Distance (long diameter, wide diameter and thick diameter)	$Vol = (\pi \times D1 \times D2 \times D3) / 6$

6.3.4.2 Urological Measurement in Doppler Mode

In Doppler mode, users can carry out the following urological measurements: Rt Renal A: RI (Resistance Index), PS (Peak Systole), ED (End Diastole);

Lt Renal A: RI (Resistance Index), PS (Peak Systole), ED (End Diastole);
 Specific measurement methods may refer to the chapter of “Abdominal Measurement in Doppler Mode”.

6.3.4.3 Urological report

In the urological measurements, the final data of each measurement item will be saved to the report, and the report format is as follows:

Hospital		Images	
Patient Information Name: Patient ID:20180907023036 Gender:Unknown Ref.M.D: Exam Date:2018/09/07 02:30:52 Age:			
Measurements OB LMP:2018/09/07 EDD:2019/06/14 GA:0w0d EDD(CUA):2019/06/14 CUA:xwxd CUA Based on:Hadlock11(BPD,HC,AC,FL)			
Fetus A B Mode: O1 4.7 cm O2 6.32 cm BPD 0 cm O3 6.1 cm GS 3.63 cm 8w3d40d 2019/04/16 FL 0.14 cm CRL 4.69 cm 11w3d47d 2019/03/26 BPD 6.43 cm 26w0d12w1d 2018/12/14 HC 1.98 cm OOR EDD=OOR FL 5.57 cm 29w2d12w1d 2018/11/21 FL/BPD Hohtler 0.87		Description Conclusion	
ABD B Mode: R Liver W 3.99 cm LK L 2.82 cm LK D 5.23 cm LK W 0.11 cm LK V 0.89 cm Ao 2.49 cm CHA 17.12 cm R Liver Max 4.11 cm R Liver D 3.99 cm			
Cardiac M Mode: CYN LMP:2018/09/07 EDD:2019/06/14 GA:0w0d		Page 2/2 Print Date:2018/09/07 Operator:	
B Mode: Endo 5.21 cm Rt OV-L 4.03 cm Rt OV-D 5.19 cm			
Urology B Mode: RK D 4.92 cm RK L 5.83 cm		Page 1/2 Print Date:2018/09/07	

6.3.5 Vascular Measurement

Preparations before measurement:

1. Check whether the probe is suitable for the current measurement item;
2. Check whether the system date is the current date;
3. Press [Patient] to input the information of the patient;
4. Press [Probe] to Select Vascular, Carotid, P-Arterial or Venous Exam.

6.3.5.1 Vascular Measurement in 2D Mode

In B mode, users can carry out the vascular measurements in the main menu, including measurement Items of Carotid, P-Arterial and Venous, and divide them into right side and left side in the measuring process according to the vascular parts of human bodies. Users can conduct the following Carotid measurements:

Aortic artery Measurement Item	Description	Measurement methods
CCA-Prox	Common Carotid - Prox	D-%stenosis/A-%stenosis
CCA-Mid	Common Carotid -Mid	D-%stenosis/A-%stenosis
CCA-Dist	Common Carotid -Dist	D-%stenosis/A-%stenosis
ICA	Internal Carotid	D-%stenosis/A-%stenosis
ECA	External Carotid	D-%stenosis/A-%stenosis
VA	Vertebra artery	D-%stenosis/A-%stenosis

- P-Arterial: CIA, EIA, CFA, PFA, PFA-Prox, PFA-Mid, PFA-Dist, POPA, TRUNK, ATA, PTA, PERA, DP- A, Subc A, Axil A, Brachial A, Radial A, Ulnar A;
- Venous: CIV, EIV, CFV, GSV, FV, SFV, DFV, Pop V, LSV, Subc V, Axill V, Brachial V, CephV, Basilar V;

P-Arteries and Carotid arteries are under fractional shortening measurements; veins are under distance method measurements. Fractional shortening is divided into diameter fractional shortening and area fractional shortening, and users can select them through the toggle or in the Preset.

Determining a Diameter Percent Stenosis

A Diameter Percent Stenosis shall compare the diameters in the same blood vessel, and after acquiring two diameters in the same blood vessel, the system will automatically carry out the calculations in terms of the following formula:

$$\%Steno = \frac{D1-D2}{D1} \times 100$$

D1, larger diameter; D2, smaller diameter

Operating steps of diameter fractional shortening to measure arteries:

1. Press [Probe] to view the Carotid measuring Item or directly click the vascular item; after pressing [Measure], select "Carotid" in the main menu (taking Carotid for example); to measure the left Carotid, click [Left] on the top of the menu;
2. Place the third caliper on the starting point of D1 segment;
3. Press [Set];
4. Roll the trackball to place the second caliper on the end point of D1 segment;
5. Press [Set];
6. Roll the trackball to place the third caliper on the starting point of D2 segment;
7. Press [Set];
8. Roll the trackball to place the fourth caliper on the end point of D2 segment
9. Press [Set].
10. The measurements will be displayed in the result box of the screen, and saved to the

worksheet and report. If you want to continue with the following measurements, please repeat steps 2-9.

Determining an Area Percent Stenosis

An Area Percent Stenosis shall compare the cross-sectional areas in the same blood vessel, and after carrying out two tracings in the same blood vessel, the system will automatically carry out the calculations in terms of the following formula:

$$\%Steno = \frac{A1-A2}{A1} \times 100$$

A1, larger area; A2, smaller area.

Operating steps of area fractional shortening to measure arteries:

1. Press [Measure] to enter the measurement interface;
2. Measurement items will pop up in the main menu, and select the measurement item of Carotid (taking Carotid measurement for example);
3. Click [A-%stenosis] in the soft menu;
4. Rotate the trackball and press [Set] to position the starting point of the ellipse;
5. Rotate the trackball and press [Set] again to position an axis of the ellipse;
6. Then rotate the trackball and press [Set] to position the other axis of the ellipse;
7. And finally rotate the trackball to select the position of ellipse and press [Set] for positioning;
8. After the measurement of an ellipse is completed, repeat steps 4-7 to complete the measurement of another ellipse;
9. The measurements will be displayed in the result box of the screen, and saved to the worksheet and report. If you want to continue with the following measurements,
10. Please repeat steps 3-8.

Vein measurement through Distance Method

Operating steps of measuring veins through Distance Method:

1. Press [Probe] to view the vein measuring item or directly click the vascular item; after pressing [Measure], select "vein" in the main menu (taking common iliac vein for example); to measure the common iliac vein, click [Left] on the top of the menu;
2. Place the first caliper on the starting point of line segment;
3. Press [Set];
4. Roll the trackball to place the second caliper on the end point of line segment;
5. Press [Set];
6. The measurements will be displayed in the result box of the screen, and saved to the worksheet and report. If you want to continue with the following measurements, please repeat steps 2-5.

6.3.5.2 Vascular Measurement in Doppler Mode

In Doppler mode, users can carry out the vascular measurements including RI (resistance

index), PS (peak systole) and ED (end diastole) of Carotid measuring Item and peripheral artery measuring Item(refer to Vascular Measurement in 2D Mode in Chapter 6). The system will divide the blood vessel measurement into the left side and right side according to the vascular parts of human bodies; See the left menu interface for measurement.

Abbreviations for veins:

CIV	Common Iliac Vein
EIV	External Iliac Vein
CFV	Common Femoral Vein
GSV	Great Saphenous Vein
FV	Femoral Vein
SFV	Superficial Femoral Vein
DFV	Deep Femoral Vein
Pop V	Popliteal Vein
LSV	Little Saphenous Vein
Subc V	Subclavian Vein
AxillV	Axillary Vein
Brachial V	Brachial Vein
CephV	Cephalic Vein
Basilar V	Basilar Vein

RI measurement method is: RI;

PS measurement methods are: velocity

ED measurement methods are: velocity

PV measurement methods are: velocity

Measurement methods of RI, PS, ED and PV:

1. Press [D] to enter the PW mode, press [Freeze] and press [Measure] to enter the PW measurement interface;
2. On the left occurs the vascular menu; rotate [Select] or trackball to select the measurement item;
3. A vertical line will be displayed on the system screen; move the trackball to position the starting point of the vertical line and press [Set], then move the trackball to position the vertical line and press [Set];
4. The measurements will be displayed in the result box, and saved to the worksheet and report. If you want to continue with the following measurements, please repeat Step 3.

6.3.5.3 Vascular Report

Hospital		
Patient Information		
Name:	Patient ID:20180907023036	Gender:Unknown
Ref.M.D.:	Exam Date:2018/09/07 02:30:52	Age:
Measurements		
OB		
LMP:2018/09/07	EDD:2019/06/14	GA:0w0d
EDD(CUA):2019/06/14	CUA:xwxd	CUA Based on:Hadlock11(BPD,HC,AC,FL)
Fetus A		
B Mode:		
Q1	4.7 cm	
Q2	6.32 cm	
BPD	0 cm	
Q3	6.1 cm	
GS	3.63 cm	8w3ds0d 2019/04/16
FL	0.14 cm	
CRL	4.69 cm	11w3ds7d 2019/03/26
BPD	6.43 cm	26w0ds2w1d 2018/12/14
HC	1.96 cm	OOR EDD=OOR
FL	5.57 cm	29w0ds2w1d 2018/11/21
FL/BPD	Hohter 0.87	
ABD		
B Mode:		
R Liver W	3.99 cm	
LK L	2.82 cm	
LK D	5.23 cm	
LK W	0.11 cm	
LK-V	0.89 cm ³	
Ao	2.49 cm	
CHA	17.12 cm	
R Liver Max	4.11 cm	
R Liver D	3.99 cm	
Cardiac		
M Mode:		
GYN		
LMP:2018/09/07	EDD:2019/06/14	GA:0w0d
B Mode:		
Endo	5.21 cm	
Ri OV-L	4.03 cm	
Ri OV-D	5.19 cm	
Urology		
B Mode:		
RK D	4.92 cm	
RK L	5.83 cm	
Vascular		
B Mode:		
Ri CCA-Prox	0.88 cm	
Ri CCA-Mid	1.11 cm	

Images	
	
Description	
Conclusion	

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6.3.6 Small Parts Measurement

Preparations before measurement:

1. Check whether the probe is suitable for the current measurement item;
2. Check whether the system date is the current date;
3. Press [Patient] to input the information of the patient;
4. Check whether the measurement mode is correct.

6.3.6.1 Small Parts Measurement in 2D Mode

In 2D mode, users can carry out the measurements of Small Parts including thyroids, breasts and testicles, and the system will divide the measurements into left thyroid and right thyroid, left breast and right breast, and left testicle and right testicle according to the position of Small Parts.

Users can conduct the following measurements:

- Thyroid: Thyroid-L, Thyroid-D, Thyroid-W, Isthmus H;
- Breast: Breast-D, Mass1, Mass2, Mass3;
- Testicle: Testicle-L, Testicle-D, Testicle-W;

Thyroid Measurement:

Users can conduct the following measurements on thyroid volume:

1. To measure thyroid right lobe size, click [Right] in the measurement items of the main menu, and use the distance method to measure the length, thickness and width of the right lobe, then the system will automatically calculate the right lobe volume in

accordance with the formula listed in the table below.

2. In order to measure thyroid left lobe size, please refer to the measurement method of thyroid right lobe size.
3. After measuring the sizes of two lobes of the thyroid, the total sum is the size of the whole thyroid. The results will be saved to the worksheet and report.

Specific operating procedures:

1. Click the thyroid measuring Item in the Small Organ menu of [Probe] or directly click the Small Organ item; after clicking [Measure], select “Thyroid“ in the main menu; to measure the left thyroid, click [Left] on the top of the menu;
2. Place the first caliper on the starting point of line segment;
3. Press [Set];
4. Roll the trackball to place the second caliper on the end point of line segment;
5. Press [Set];
6. Roll the trackball to place the third caliper on the starting point of line segment;
7. Press [Set];
8. Roll the trackball to place the fourth caliper on the end point of line segment;
9. Press [Set];
10. Roll the trackball to place the fifth caliper on the starting point of line segment;
11. Press [Set];
12. Roll the trackball to place the sixth caliper on the end point of line segment;
13. Press [Set];
14. The measurements will be displayed in the result box of the screen, and saved to the worksheet and report.

Breast Measurements:

Click the Breast Measuring Item under the Small Part menu of [Probe] or directly click the Small Organ item, and select “Breast” to measure breast thickness, Mass 1, Mass 2 and Mass 3 through the distance method; refer to “Thyroid Measurements” for its operating methods, which will not be repeated here.

Testicular Measurements:

Click the Testicle Measuring Item under the Small Part menu of [Probe] or directly click the Small Organ item, and select “Testicle” to measure long diameter, thick diameter and wide diameter through the distance method, then the system will automatically calculate the testicular size; refer to “Thyroid Measurements” for its operating methods, which will not be repeated here.

Calculation Item	Input Parameter	Formula
Thyroid - volume	3-Distance (length , thickness , width)	$Vol = 0.479 \times D1 \times D2 \times D3$
Testical - volume	3-Distance (length , thickness , width)	$Vol = 0.523598775 \times D1 \times D2 \times D3$

6.3.6.2 Small Parts measurement report

Small Parts measurement report is shown in the figure below.

Hospital

Patient Information
Name: Patient ID:20180907023036 Gender:Unknown
Ref.M.D: Exam Date:2018/09/07 02:30:52 Age:

Measurements
OB
LMP:2018/09/07 EDD:2019/06/14 GA:0w0d
EDD(CUA):2019/06/14 CUA:xwxd CUA Based on:Hadlock11(BPD,HC,AC,FL)

Fetus A
B Mode:
Q1 4.7 cm
Q2 8.32 cm
BPD 0 cm
Q3 6.1 cm
QS 3.63 cm 8w3d10d 2019/04/16
FL 0.14 cm
CRL 4.69 cm 11w3d17d 2019/03/26
BPD 6.43 cm 26w0d12w1d 2018/12/14
HC 1.98 cm OOR EDD=OOR
FL 5.57 cm 29w2d12w1d 2018/11/21
FL/BPD Hohler 0.87

ABD
B Mode:
R Liver W 3.99 cm
LK L 2.52 cm
LK D 5.29 cm
LK W 0.11 cm
LK-V 0.89 cm²
Ad 2.49 cm
CHA 17.12 cm
R Liver Max 4.11 cm
R Liver D 3.99 cm

Cardiac
M Mode:
GYN
LMP:2018/09/07 EDD:2019/06/14 GA:0w0d
B Mode:
Endo 5.21 cm
Ri OV-L 4.03 cm
Ri OV-D 5.19 cm

Urology
B Mode:
Rk D 4.92 cm
Rk L 5.83 cm

Vascular
B Mode:
Ri CCA-Prox 0.88 cm
Ri CCA-Mid 1.11 cm

SMP
B Mode:
Ri Thyroid-D 0.97 cm
Ri Thyroid-W 1.61 cm

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Conclusion

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6.3.7 Orthopedic Measurement

Preparations before measurement:

1. Check whether the probe is suitable for the current measurement item;
2. Check whether the system date is the current date;
3. Press [Patient] to input the information of the patient;
4. Press [Probe] to select Orthopedics exam.

6.3.7.1 Orthopedic Measurement in 2D Mode

In B mode, users can carry out the measurements on R Hip Angle and L Hip Angle. The measurement method is angle method.

Orthopedic steps through angle measurement method:

1. Press [Measure] in the corresponding mode;
2. On the left occurs the orthopedic menu; click on the touch screen or trackball to select the measurement item;
3. Place the caliper on the starting point of line segment, and press [Set];
4. Roll the trackball to place the second caliper on the end point of line segment, and press [Set].
5. Place the third caliper on the starting point of line segment, and press [Set];
6. Roll the trackball to place the fourth caliper on the end point of line segment, and press [Set];
7. The measurements will be displayed in the result box of the screen, and saved to the worksheet and report. If you want to continue with the following measurements, please repeat steps 3-6.

6.3.7.2 Orthopedic Report

Hospital			
Patient Information			
Name:	Patient ID:20180907023036	Gender:Unknown	
Ref.M.D.:	Exam Date:2018/09/07 02:30:52	Age:	
Measurements			
OB	EDD:2019/06/14	GA:0w0d	
LMP:2018/09/07	CUA:xwxd	CUA Based on:Hadlock11(BPD,HC,AC,FL)	
EDD(CUA):2019/06/14			
Fetus A			
B Mode:			
Q1	4.7 cm		
Q2	6.32 cm		
BPD	0 cm		
Q3	6.1 cm		
CS	3.63 cm	8w3d10d	2019/04/16
FL	0.14 cm		
CRL	4.69 cm	11w3d17d	2019/03/26
BPD	6.43 cm	26w0d12w1d	2018/12/14
HC	1.98 cm	OKR	EDD=OKR
FL	5.57 cm	29w2d12w1d	2018/11/21
FL/BPD	Hohler 0.87		
ABD			
B Mode:			
R Liver W	3.99 cm		
LK L	2.82 cm		
LK D	5.23 cm		
LK W	0.11 cm		
LK-V	0.89 cm ³		
Ap	2.49 cm		
CHA	17.12 cm		
R Liver Max	4.11 cm		
R Liver D	3.99 cm		
Cardiac			
M Mode:			
GYN			
LMP:2018/09/07	EDD:2019/06/14	GA:0w0d	
B Mode:			
Endo	5.21 cm		
Rt OV-L	4.03 cm		
Rt OV-D	5.19 cm		
Urology			
B Mode:			
RK D	4.92 cm		
RK L	5.83 cm		
Vascular			
B Mode:			
Rt CCA-Prox	0.88 cm		
Rt CCA-Mid	1.11 cm		
SMP			
B Mode:			
Rt Thyroid-D	0.97 cm		
Rt Thyroid-W	1.61 cm		
Orthopedics			
B Mode:			
R Hip Angle α	56 °		
β	56 °		
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L Hip Angle α 56 °	
β 56 °	
Images	
	
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Conclusion	
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6.3.8 Cardiology Measurement

Cardiology measurements include general cardiology measurement and ped-cardiology measurement, and ped-cardiology measurement is the same with general cardiology measurement, thus you can refer to relevant measurements of general cardiology. Preparations before measurement:

1. Check whether the probe is suitable for the current measurement item;
2. Check whether the system date is the current date;

3. Press [Patient] to input the information of the patient;
4. Press [Probe] to select cardiac Exam.

6.3.8.1 Cardiology Measurement in 2D Mode

In 2D mode, users can carry out the measurements of cardiac area listed in the main menu, and the following table has listed the measurement items, descriptions and measurement methods of cardiac measurements defined in the system, and the measuring results will be displayed in the corresponding measurement worksheet and patient report.

Measurement Item	Description	Measurement methods
MV	Mitral Valve	
EPSS	Distance from E point to septal separation, that is, distance from mitral valve anterior lobe in diastole to ventricular septum.	Distance
MVA(Trace)	Mitral Valve Area	Trace/Ellipse
MV Diam	Mitral Valve Diameter	Distance
AV/LA	Aortic Valve / Left Atrium	
RV Diam	Right Ventricle Diameter	Distance
AO	Aorta	Distance
ACS	Acute Coronary Syndrome	Distance
LA Diam	Left Atrium Diameter	Distance
AV	Aortic Valve	
LVOT Diam	Left ventricular outflow tract diameter	Distance
AV Area	Aortic Valve Area	Trace/Ellipse
Mod.Simpson		
LVAd sax PM	Left ventricular short axis area at papillary muscle level at end diastole	Trace/Ellipse
LVAd sax MV	Left ventricular short axis area at mitral valve level at end diastole	Trace/Ellipse
LVLd apical	Left ventricular length at end diastole, apical	Distance
LVAs sax PM	Left ventricular short axis area at papillary muscle level at end systole	Trace/Ellipse
LVAs sax MV	Left ventricular short axis area at mitral valve level at end systole	Trace/Ellipse
LVLs apical	Left ventricular length at end diastole, apical	Distance
Single plane Method		
LVAd apical	Left ventricular area at end diastole, apical	Trace/Ellipse
LVLd apical	Left ventricular length at end diastole, apical	Distance
LVAs apical	Left ventricular area at end diastole, apical	Trace/Ellipse
LVLs apical	Left ventricular length at end diastole, apical	Distance
Bi plane Method		
LVAd apical	Left ventricular area at end diastole, apical	Trace/Ellipse

Measurement Item	Description	Measurement methods
LVAAd sax MV	Left ventricular short axis area at mitral valve level at end diastole	Trace/Ellipse
LVIDd	Left ventricular internal dimension at end diastole	Distance
LVAAs apical	Left ventricular long-axis area at end systole, apical	Trace/Ellipse
LVAAs sax MV	Left ventricular short axis area at mitral valve level at end systole	Trace/Ellipse
LVIDs	Left ventricular internal dimension at end systole	Trace/Ellipse
Teichholz		
Diastole	Diastole	
RVAWd	Right ventricular anterior wall thickness at end systole	Distance
RVDd	Right ventricular dimension at end systole	Distance
IVSd	Interventricular septum dimension at end systole	Distance
LVIDd	Left ventricular internal dimension at end systole	Distance
LVPWd	Left ventricular posterior wall dimension at end systole	Distance
Systole	Cardiac systole	
IVSs	Interventricular septum dimension at end systole	Distance
LVIDs	Left ventricular internal dimension at end systole	Distance
LVPWs	Left ventricular posterior wall dimension at end systole	Distance



Note: The black font refers to the measuring Items of the following measurement items.

As shown in the table above, the measurement Item mainly includes Distance Method and Trace/Ellipse Method, and operations of Distance Method are:

1. Press [Probe] to select [Cardiac], and enter B mode;
2. Press [Measure] and select MV measurement Item in the main menu (taking mitral valve for example), and then click [MV] to display the measurement items of mitral valve;
3. Place the first caliper on the starting point of line segment;
4. Press [Set];
5. Roll the trackball to place the second caliper on the end point of line segment;
6. Press [Set];
7. Roll the trackball to place the third caliper on the starting point of line segment;
8. The measurements will be displayed in the result box, and saved to the worksheet and report.

Operations in elliptical area measurement are:

1. Click B mode and press [Measure] to enter the measurement interface;
2. The cardiac measurement items pop up in the left menu, select the MV measurement

- Item (taking mitral valve for example); then click [MV] to display the measurement items of mitral valve, and click [MVA];
3. The area method measurement occurs in the soft menu: press the toggle to select [Ellipse] measurement;
 4. Rotate the trackball and press [Set] to position the starting point of the ellipse; and rotate the trackball and press [Set] again to position an axis of the ellipse; then rotate the trackball and press [Set] to position the other axis of the ellipse; and finally rotate the trackball to select the position of ellipse and press [Set] for positioning;
 5. The measurements will be displayed in the result box, and saved to the worksheet and report.

Operations of tracing area method measurements are:

1. The cardiac measurement items pop up in the left menu, select the MV measurement Item (taking mitral valve for example); then click [MV] to display the measurement items of mitral valve, and click [MVA];
2. The area method measurement occurs in the soft menu: press the toggle to select [Trace] measurement;
3. Place the first caliper on the starting point of line segment;
4. Press [Set];
5. Roll the trackball to display the tracing line, and press [Set] after locating the position of end point;
6. The measurements will be displayed in the result box of the screen, and saved to the worksheet and report.

Cardiology calculations in 2D mode

When the measurements are completed, the system will perform the 2D mode calculation, and the calculation results will be displayed on the screen and saved to the cardiac worksheet and report, of which the calculation and description of the measurement items will be listed in the table below for reference.

Calculati on Item	Description	Desired Measurement	Calculating Result
AO/LA	Aorta / Left Atrium	AO	
CI (cardiac index)	Cardiac index refers to the cardiac output per square meter of body surface area (BSA): $CI = CO \div BSA$. If the height is expressed in cm, the weight will be expressed in kg: $BSA = 0.007184 \times (\text{weight}^{0.425}) \times (\text{height}^{0.725})$ If the height in expressed in feet/ inches, the weight will be expressed in pounds: $BSA = 0.007184 \times (\text{weight} \times 0.454)^{0.425} \times (\text{height} \times 2.54)^{0.725}$	HR, BSA EDV ESV	L/min/m ²
CO (Cardiac Output)	Cardiac output refers to the effective left ventricular ejection volume per unit time:	EDV ESV HR	L/min

	$CO = [(EDV - ESV) \div 1000] (HR).$		
EDV, ESV	End-diastolic volume, End-systolic volume		
EF (ejection fraction)	Ejection fraction refers to the ratio between stroke volume and end-diastolic volume: $EF = 100 [(EDV - ESV) \div EDV].$	EDV ESV	%
FS (fractional shortening)	Systolic percentage refers to the systolic percentage of LV size: $FS = 100[(LVIDd - LVIDs) \div LVIDd].$	LVIDd LVIDs	%
SV (stroke volume)	Stroke volume refers to the ventricular ejection volume in a cardiac cycle or ventricular systolic phase: $SV = EDV - ESV.$	LVIDd LVIDs	ml
SI (stroke index)	Cardiac index is used to measure the standardized stroke volume in terms of BSA (body surface area): $SI = SV \div BSA.$	SV BSA	ml/m ²

Left ventricular function assessment in 2D mode

The following table lists the cardiac measurement calculation formulas in Simpson Bi-Plane, single-plane, dual-plane, Teichholz (2D), Mod Simpson for your reference.

Calculation Item	Description	Desired Measureme	Calculating Result
Simpson BP (Simpson Bi-Plan)	Use the end-diastolic and end-systolic disk in the apical four-chamber view to measure and estimate volumes. $EDV(mL) = \pi * (LVLd(mm)/20)^2 * \Sigma(r2i(mm)*r4i(mm))/1000$ $ESV(mL) = \pi * (LVLs(mm)/20)^2 * \Sigma(r2i(mm)*r4i(mm))/1000$	LVLd LVLs 4chEDV, ESV 2chEDV, ESV	SV ml CO L/min EF % SI mL/m2 CI n/a
Single-plane	Use the end-diastolic and end-systolic single-plane tracing in the two-chamber or four-chamber view to measure and estimate volumes. In addition, you also need to carry out the distance measurement on the long-axis dimension in the apical view in end-diastole and end-systole: $EDV = (8 \div (3 \pi)) * (LVAd \text{ long-axis apical (cm}^2) / LVLd \text{ apical (mm)} * 10)$ $EDV = (8 \div (3 \pi)) * (LVAs \text{ long-axis apical (cm}^2) / LVLs \text{ apical (mm)} * 10)$	LVAd apical LVAs apical LVLd LVLs	EDV ml ESV ml SV ml CO L/min EF % SI mL/m2 CI n/a
Dual-plane	Use the apical and sax MV end-diastolic and end-systolic dual-plane tracing to measure and estimate volumes. In addition, you also need to perform the distance measurements on LVIDd and LVIDs: $EDV = (8 \div (3 \pi)) * (LVAd \text{ long-axis apical (cm}^2) * (LVAd \text{ short-axis MV (cm}^2) / LVIDd (mm)} * 10)$ $ESV = (8 \div (3 \pi)) * (LVAs \text{ long-axis apical (cm}^2) * (LVAs \text{ short-axis MV (cm}^2) / LVIDs (mm)} * 10)$	LVAd apical LVAs apical LVAd sax MV LVAs sax MV LVLd LVLs	EDV ml ESV ml SV ml CO L/min EF % SI mL/m2 CI n/a

Teichholz (2D)	Use the distance measurement to estimate volumes from left ventricular internal diameter (LVID): $EDV(mL) = 7 * (LVIDd(mm) * LVIDd(mm) * LVIDd(mm) / 1000) / (2.4 + LVIDd(mm) / 10)$ $ESV(mL) = (7 * LVIDs(mm) * LVIDs(mm) * LVIDs(mm) / 1000) / (2.4 + LVIDs(mm) / 10)$	LVIDd LVIDs	EDV ml ESV ml SV ml CO L/min EF % SI mL/m2 CI n/a
Mod Simpson	$EDV (mL) = LVLd \text{ apical}(mm)/9 * (4 * LVA \text{d sax } MV(cm^2) + 2 * LVA \text{d sax } PM(cm^2) + SQRT (LVA \text{d sax } MV(cm^2) * LVA \text{d sax } PM(cm^2)) / 10)$ $ESV (mL) = LVLs \text{ apical}(mm)/9 * (4 * LVA \text{s sax } MV(cm^2) + 2 * LVA \text{s sax } PM(cm^2) + SQRT (LVA \text{s sax } MV(cm^2) * LVA \text{s sax } PM(cm^2)) / 10)$	LVLd apical LVLs apical LVA d sax MV LVA s sax MV LVA d sax PM LVA s sax PM	EDV ml ESV ml SV ml CO L/min EF % SI mL/m2 CI n/a

6.3.8.2 Cardiac Measurement in M Mode

In M mode, users can carry out the measurements of MV, AV/LA and LV, and the following table has listed the measurement items, descriptions and measurement methods of cardiac measurements defined in the system, and the measuring results will be displayed in the corresponding measurement worksheet and patient report.

Measurement Item	Description	Measurement methods
MV	Mitral valve	
CE amp	E-wave amplitude	Distance
CA amp	A-wave amplitude	Distance
DE Excursion	Mitral valve leaflet excursion in anterior diastole	Slope
DE amp	DE-wave amplitude	Distance
EPSS	Distance from E point to septal separation, that is, distance from mitral valve anterior lobe in diastole to ventricular septum	Distance
EF Slope	Mitral valve early diastolic closing velocity	Slope
AV/LA		
RV Diam	Right Ventricle Diameter	Distance
AO	Aorta	Distance
ACS	Acute Coronary Syndrome	Distance
LA Diam	Left Atrium Diameter	Distance
LVET	Left Ventricular Ejection Time	Time
LVPEP	Left Ventricular Pre-ejection Period	Time
Teichholz		
Diastole		

RVAWd	Right Ventricular Anterior Wall Thickness at end diastole	Distance
RVDd	Right Ventricular Dimension at end diastole	Distance
IVSd	Interventricular Septal Size at end diastole	Distance
LVIDd	Left Ventricular Internal Dimension at end diastole	Distance
LVPWd	Left Ventricular Posterior Wall Dimension at end diastole	Distance
Systole		
IVSs	Interventricular Septum Dimension at end systole	Distance
LVIDs	Left Ventricular Internal Dimension at end systole	Distance
LVPWs	Left Ventricular Posterior Wall Dimension at end systole	Distance
HR	Heart Rate	HR

- The table above includes the methods of Distance, Slope, Time and HR in the process of cardiac measurement, and the operating methods are:
 1. Press [M] to enter the M mode, and press [Measure] to enter the M mode measurement interface;
 2. On the left occurs the cardiac menu options; click on the touch screen or trackball to select the measurement item; the appropriate measurement methods are displayed in the soft menu;
 3. A vertical line will be displayed on the system screen; move the trackball to position the starting point of the vertical line and press [Set], then move the trackball to position the vertical line and press [Set];
 4. The measurements will be displayed in the result box of the screen, and saved to the worksheet and report. If you want to continue with the following measurements, please repeat Step 3.

Cardiac calculation in M Mode

When the measurements are completed, the system will perform the M mode calculation, and the calculation results will be displayed on the screen and saved to the cardiac worksheet and report, of which the calculation and description of the measurement items will be listed in the table below for reference.

Calculation Item	Description	Desired Measurement	Unit
CI (cardiac index)	Cardiac index refers to the cardiac output per square meter of body surface area (BSA): $CI = CO \div BSA$. If the height is expressed in cm, the weight will be expressed in kg: $BSA = 0.007184 \times (\text{weight}^{0.425}) \times (\text{height}^{0.725})$	HR, BSA EDV ESV	L/min/m ²

	If the height is expressed in feet/inches, the weight will be expressed in pounds: $BSA = 0.007184 \times (\text{weight} \times 0.454) \times (\text{height} \times 2.54) \times 0.725$		
CO (Cardiac Output)	Cardiac output refers to the effective left ventricular ejection volume per unit time: $CO = [(EDV - ESV) \div 1000] \times (HR)$.	EDV ESV HR	L/min
EDV, ESV	Cubed Volume Method: $EDV = LVIDd^3$ $ESV = LVIDs^3$ Teichholz Volume Method: $EDV = 7(LVIDd^3 / 1000) / (2.4 + LVIDd/10)$ $ESV = 7(LVIDs^3 / 1000) / (2.4 + LVIDs/10)$ Gibson Volume Method: $EDV = \pi / 6 * (0.98 * LVIDd/10 + 5.90) * LVIDd / 10 * LVIDd / 10$ $ESV = \pi / 6 * (1.14 * LVIDs/10 + 4.18) * LVIDs / 10 * LVIDs / 10$	LVIDd LVIDs	ml
CA/CE	$CA/CE = CA \text{ amp (mm)} / CE \text{ amp (mm)}$	CA amp CE amp	
EF (ejection fraction)	Ejection fraction refers to the ratio between stroke volume and end-diastolic volume: $EF = 100[(EDV - ESV) \div EDV]$	EDV ESV	%
AO/LA	Aorta / Left Atrium	LA AO	Ratio
SV (stroke volume)	Stroke volume refers to the ventricular ejection volume in a cardiac cycle or ventricular systolic phase: $SV = EDV - ESV$.	EDV ESV	ml
SI (stroke index)	Cardiac index is used to measure the standardized stroke volume in terms of BSA (body surface area): $SI = SV \div BSA$.	SV BSA	ml/m ²
HR (heart rate)	$HR = 60 \div (R-R \text{ interval})$	HR cycle	bpm

6.3.8.3 Cardiac Measurement in Doppler Mode

In Doppler mode, users can carry out the measurements of MV, AV, TV and PV, and the following table has listed the measurement items, descriptions and measurement methods of cardiac measurements defined in the system, and the measuring results will be displayed in the corresponding measurement worksheet and patient report.

Measurement Item	Description	Measurement method
MV (Mitral Valve)		
EPSS	Distance from E point to septal separation, that is, distance from mitral valve anterior lobe in diastole to ventricular septum.	Distance
E Dur	E-wave duration	Time
A Dur	A-wave duration	Time
IVRT	Isovolumic relaxation time	Time

Measurement Item	Description	Measurement method
MV E pt	Mitral valve E point	Velocity
MV A pt	Mitral valve A point	Velocity
MVA		
PHT	Pressure half-time	Pressure half-time
MVA(Trace)	Mitral valve area	Trace
CO	Cardiac output	
MV VTI	Mitral valve velocity time integral	PI (Manual)
MC diam	Mitral valve diameter	Distance
HR	Heart rate	HR
LVIMP	Left ventricular intramvocardial pressure	
LVET	Left Ventricular Ejection Time	Time
MV C.O dur	Mitral valve close/open duration	Time
Tel index		
Tel Index a	Time interval between beginning and end of mitral valve filling	Time
Tel Index b	Time interval between beginning and end of aortic flow	Time
AV	Aortic Valve	
AV Vmax	Aortic valve maximum velocity	Velocity
LVOT Vmax	Left ventricular outflow tract maximum velocity	Velocity
IVRT	Isovolumic relaxation time	Time
AVA(VTI)		
AV VTI	Aortic valve velocity time integral	PI (Manual)
LVOT VTI	Left ventricular outflow tract velocity time integral	PI (Manual)
LVOT diam	Left ventricular outflow tract diameter	Distance
AVA(trace)	Aortic valve area	
AV area	Aortic valve area	Trace
VSD	Ventricular septal defect	
VSD Vmax	Ventricular septal defect maximum velocity	Velocity
LVSTI	Left ventricular systolic time intervals	

Measurement Item	Description	Measurement method
LVET	Left Ventricular Ejection Time	Time
LVPEP	Left Ventricular Pre-ejection Period	Time
HR	Heart rate	HR
TV	Tricuspid valve	
TV VTI	Tricuspid valve velocity time integral	
TV E pt	Tricuspid valve E point	Velocity
TV A pt	Tricuspid valve A point	Velocity
RVIMP	Right ventricular intramyocardial pressure	
RVET	Right ventricle ejection time	Time
TV C.O dur	Tricuspid valve close/open duration	Time
PV	Pulmonary valve	
PV Vmax	Pulmonary valve maximum velocity	Velocity
RVET	Right ventricle ejection time	Time
RV Act	Right ventricular acceleration time	Time
RV PEP	Right ventricular pre-Ejection period	Time
CO	Cardiac output	
PV VTI	Pulmonary valve velocity time integral	PI (Manual)
PV diam	Pulmonary valve diameter	Distance
HR	Heart rate	HR

Users can refer to the operations described in general measurement chapters.

Cardiac special calculation in Doppler mode

When the measurements are completed, the system will perform the PW mode calculation, and the calculation results will be displayed on the screen and saved to the cardiac worksheet and report, of which the calculation and description of the measurement items will be listed in the table below for reference.

Calculation Item	Description	Desired Measurement	Unit
Mitral valve A point and E point ratio (A/E)	A/E= mitral valve A point (m/s)/mitral valve E point (m/s)	Mitral valve A point (Distance)	N/A
Mitral valve E point and A	E/A=MV E pt(m/s) / MV A	Mitral valve E	N/A

Calculation Item	Description	Desired Measurement	Unit
point ratio (E/A)	pt (m/s)	point (Distance)	
Mitral valve maximum pressure gradient (MV PG max)	$MV\ PG_{max}(mmHg)=(MV\ V_{max}(m/s))^2 \times 4$	Mitral valve maximum velocity	mmHg
Mitral valve mean pressure gradient (MV PG mean)	$MV\ PG_{mean}(mmHg)=(MV\ V_{mean}(m/s))^2 \times 4$	Mitral valve mean velocity	mmHg
Aortic valve maximum pressure gradient (AV PG max)	$AV\ PG_{max}(mmHg)=(AV\ V_{max}(m/s))^2 \times 4$	Aortic valve maximum velocity	mmHg
Aortic valve mean pressure gradient (AV PG mean)	$AV\ PG_{mean}(mmHg)=(AV\ V_{mean}(m/s))^2 \times 4$	Aortic valve mean velocity	mmHg
Pulmonary valve maximum pressure gradient (PV PG max)	$PV\ PG_{max}(mmHg)=(PV\ V_{max}(m/s))^2 \times 4$	Pulmonary valve maximum velocity	mmHg
Pulmonary valve mean pressure gradient (PV PG mean)	$PV\ PG_{mean}(mmHg)=(PV\ V_{mean}(m/s))^2 \times 4$	Pulmonary valve mean velocity	mmHg
Left ventricular outflow tract maximum pressure gradient (LVOT PG max)	$LVOT\ PG_{max}(mmHg)=(LVOT\ V_{max}(m/s))^2 \times 4$	Left ventricular outflow tract maximum velocity	mmHg
Left ventricular outflow tract mean pressure gradient (LVOT PG mean)	$LVOT\ PG_{mean}(mmHg)=(LVOT\ V_{mean}(m/s))^2 \times 4$	Left ventricular outflow tract mean velocity	mmHg
Ventricular septal defect maximum pressure gradient (VSD PG max)	$VSD\ PG_{max}(mmHg)=(VSD\ V_{max}(m/s))^2 \times 4$	Ventricular septal defect maximum velocity	mmHg
Tricuspid valve maximum pressure gradient (TV PG max)	$TV\ PG_{max}(mmHg)=(TV\ V_{max}(m/s))^2 \times 4$	Tricuspid valve maximum velocity	mmHg
Tricuspid valve mean pressure gradient (TV PG mean)	$TV\ PG_{mean}(mmHg)=(TV\ V_{mean}(m/s))^2 \times 4$	Tricuspid valve mean velocity	mmHg
Left ventricular intramyocardial pressure (LVIMP)	$LVIMP=(MV\ C-O\ dur(ms) - LVET(ms)) / LVET(ms)$	MV C.O duration LV ejection time (ET)	--
Right ventricular intramyocardial pressure (RVIMP)	$RVIMP=(TV\ C-O\ dur(ms) - RVET(ms)) / RVET(ms)$	TV C.O duration LV ejection time (ET)	--
Heart rate (HR)	HR = 60/R-R interval.	The measurement covers a cardiac cycle	bpm
Mitral valve area (Velocity time integral) [MVA (VTI)]	$MVA(VTI)(cm^2) = \pi \times (LVOT\ diam(mm)/2/10)^2 \times (LVOT\ VTI(cm) / MV\ VTI(cm))$	Left ventricular outflow tract diameter Left ventricular outflow tract velocity time integral Mitral valve velocity time integral	cm ²
Aortic valve area (velocity time integral) [AVA (VTI)]	$AVA(VTI)(cm^2) = \pi \times (LVOT\ diam(mm)/2/10)^2 \times (LVOT\ VTI(cm) / AV\ VTI(cm))$	Left ventricular outflow tract diameter Left ventricular outflow tract velocity time integral Aortic valve velocity time integral	cm ²
Left ventricular	((LVOT	LVOT Diam	

Calculation Item	Description	Desired Measurement	Unit
outflow tract cardiac index (LVOT CI)	$Diam)^2 * 0.785 * (LVOT VTI) * (HR) / 1000 / BSA$	LVOT VTI HR	
Ratio between left ventricular pre- ejection period and left ventricular ejection time	$LVSTI = LVPEP / ET$	LVPEP LVET	LVPEP / ET
Mitral valve area (velocity time integral)[MVA (VTI)]	$3.14 / 4 * (LVOT Diam)^2 * (LVOT VTI) / (MV VTI)$	LVOT Diam LVOT VTI MV VTI	
Mitral valve area (Pressure half-time) [MVA (PHT)]	$220 / (MV PHT (ms))$	MV PHT	MVA (PHT)
Ratio between right ventricular pre- ejection period and right ventricular ejection time	$RVSTI = RVPEP / ET$	RVPEP ET	RVPEP / ET

Please refer to Appendix D for professional contents of cardiac measurement.

6.3.8.4 Cardiac Measurement Report

The following figure is the worksheet and report of cardiac measurement, in which you can view the measurement results. If you are not satisfied with the result, you can enter the worksheet to revise and save the data, which will be saved into the report.

Hospital

Patient Information

Name: Patient ID:20180907023036 Gender:Unknown
 Ref.M.D: Exam Date:2018/09/07 02:30:52 Age:

Measurements

OB
 LMP:2018/09/07 EDD:2019/06/14 GA:0w0d
 EDD(CUA):2019/06/14 CUA:xawd CUA Based on:Hadlock11(BPD,HC,AC,FL)

Fetus A
B Mode:
 C1 4.7 cm
 Q2 6.32 cm
 BPD 0 cm
 Q3 6.1 cm
 SS 3.63 cm 8w3d40d 2019/04/16
 FL 0.14 cm
 CRL 4.69 cm 11w3d47d 2019/03/26
 BPD 6.43 cm 26w0d12w1d 2018/12/14
 HC 1.98 cm OOR EDD=OOR
 FL 5.57 cm 29w2d12w1d 2018/11/21
 FL/BPD Hohler 0.87

ABD
B Mode:
 R Liver W 3.99 cm
 LK L 2.82 cm
 LK D 5.23 cm
 LK W 0.11 cm
 LK-V 0.69 cm²
 Ao 2.49 cm
 CHA 17.12 cm
 R Liver Max 4.11 cm
 R Liver D 3.99 cm

Cardiac
M Mode:
GVN
 LMP:2018/09/07 EDD:2019/06/14 GA:0w0d
B Mode:
 Endo 5.21 cm
 Rt OV-L 4.03 cm
 Rt OV-D 5.19 cm

Urology
B Mode:
 Rk D 4.92 cm
 Rk L 5.83 cm

Vascular
B Mode:
 Rt CCA-Prox 0.88 cm
 Rt CCA-Mid 1.11 cm

SMP
B Mode:
 Rt Thyroid-D 0.97 cm
 Rt Thyroid-W 1.61 cm

Orthopedics
B Mode:
 R Hip Angle α 56 °
 β 56 °
 Page 1/2 Print Date:2018/09/07

L Hip Angle α 56 °
 β 56 °
Ped_Cardiac
B Mode:
 MVA 0.19 cm²
 MV Diam 5.56 cm

Images



Description

Conclusion

Page 2/2 Print Date:2018/09/07 Operator:

6.3.9 Transcranial Measurement

Preparations before measurement:

1. Check whether the probe is suitable for the current measurement item;
2. Check whether the system date is the current date;
3. Press [Patient] to input the information of the patient;
4. Press [Probe] to select transcranial measurement.

6.3.9.1 Transcranial Measurement in 2D Mode

In 2D mode, users can carry out the transcranial measurements, the following table has listed the measurement items, descriptions and measurement methods of transcranial measurements.

Measurement Item	Description	Measurement method
MCA	middle cerebral artery	Distance
ICA.Siphon	carotid siphon	Distance
ACA.A1	anterior meningeal artery A1	Distance
ACA.A2	anterior meningeal artery A2	Distance
ACoA	anterior communicating artery	Distance
PCA.P1	posterior cerebral artery P1	Distance
PCA.P2	posterior cerebral artery P2	Distance
PCoA	posterior communicating artery	Distance
PCA	posterior cerebral artery	Distance
Basilar A	basilar artery	Distance
Vert A	vertebral artery	Distance

Transcranial measurement through Distance Method;

1. Press [Measurement], and roll the trackball to the transcranial measurement items and select [MCA] (taking MCA for example);
2. Place the first caliper on the starting point of line segment, and press [Set];
3. Roll the trackball to place the second caliper on the end point of line segment, and press [Set].
4. The measurements will be displayed in the result box of the screen, and saved to the worksheet and report. If you want to continue with the following measurements, please repeat steps 2-3.

6.3.9.2 Transcranial Measurement in Doppler Mode

In Doppler mode, users can carry out the transcranial measurements, and the measurement items and methods can refer to the chapter of Transcranial Measurement in 2D Mode.

Steps for transcranial measurements:

1. In PW mode, press [Freeze] and then press [Measure];
2. roll the trackball to the transcranial measurement items and select [MCA] (taking MCA for example);
3. Place the first caliper on the starting point of line segment, and press [Set];
4. Roll the trackball to place the second caliper on the end point of line segment, and press [Set].
5. The measurements will be displayed in the result box, and saved to the worksheet and report. If you want to continue with the following measurements, please repeat steps 2-3.

6.3.9.3 Transcranial Report

Hospital		
Patient Information		
Name:	Patient ID:20180907023036	Gender:Unknown
Ref.M.D.:	Exam Date:2018/09/07 02:30:52	Age:
Measurements		
OB		
LMP:2018/09/07	EDD:2019/06/14	GA:0w0d
EDD(CUA):2019/06/14	CUA:xwxd	CUA Based on:Hadlock11(BPD,HC,AC,FL)
Fetus A		
B Mode:		
Q1	4.7 cm	
Q2	6.32 cm	
BPD	0 cm	
Q3	6.1 cm	
GS	3.63 cm	8w3d40d 2019/04/16
FL	0.14 cm	
ORL	4.69 cm	11w3d27d 2019/03/26
BPD	6.43 cm	28w0d52w1d 2018/12/14
HC	1.98 cm	ORR EDD=OOR
FL	5.57 cm	29w2d12w1d 2018/11/21
FL/BPD	Holtzer 0.87	
ABD		
B Mode:		
R Liver W	3.99 cm	
LK L	2.82 cm	
LK D	5.23 cm	
LK W	0.11 cm	
LK-V	0.89 cm ²	
Ao	2.49 cm	
CHA	17.12 cm	
R Liver Max	4.11 cm	
R Liver D	3.99 cm	
Cardiac		
M Mode:		
GYN		
LMP:2018/09/07	EDD:2019/06/14	GA:0w0d
B Mode:		
Endo	5.21 cm	
Ri OV-L	4.93 cm	
Ri OV-D	5.19 cm	
Urology		
B Modes:		
RK D	4.92 cm	
RK L	5.83 cm	
Vascular		
B Modes:		
Ri CCA-Prox	0.88 cm	
Ri CCA-Mid	1.11 cm	
SMP		
B Mode:		
Ri Thyroid-D	0.97 cm	
Ri Thyroid-W	1.61 cm	
Orthopedics		
B Mode:		
R Hip Angle α	56 °	
β	56 °	
Page 1/2 Print Date:2018/09/07		
		<p>L Hip Angle α 56 °</p> <p>β 56 °</p> <p>Ped_Cardiac</p> <p>B Mode:</p> <p>MVA 0.19 cm²</p> <p>MV Diam 5.56 cm</p> <p>EM</p> <p>B Mode:</p> <p>CBD 4.18 cm</p> <p>Ac 5.71 cm</p> <p>TCD</p> <p>B Mode:</p> <p>Ri ICA Siphon 3.52 cm</p> <p>Ri ACA-A2 2.78 cm</p>
		<p>Images</p> 
		<p>Description</p> <p>Conclusion</p>
		<p>Page 2/2 Print Date:2018/09/07 Operator:</p>

6.3.10 Emergency Medicine Measurement

Preparations before measurement:

- Check whether the probe is suitable for the current measurement item;
- Check whether the system date is the current date;
- Press [Patient] to input the information of the patient;
- Press [Probe] to select EM measurement.

6.3.10.1 EM Measurement in 2D Mode

In 2D mode, users can carry out the EM measurement in the main menu, and the measurement method is the Distance Method.

EM measurements include: GB Wall-D, CBD, Ao, EDV, ESV, GS, CRL, BPD, BI Trans D, BI Trans W, BI Sag D, and BI Sag L;

Steps of EM measurement through Distance Method:

1. Press [Measurement], and roll the trackball to the EM measurement items and select [GB Wall-D](taking gallbladder wall thickness for example);
2. Place the first caliper on the starting point of line segment, and press [Set];
3. Roll the trackball to place the second caliper on the end point of line segment, and press [Set].
4. The measurements will be displayed in the result box, and saved to the worksheet and report. If you want to continue with the following measurements, please repeat steps 2-3

6.3.10.2 EM Measurement in M Mode

In M mode, users can carry out the fetal heart rate of EM measurement in the main menu, and the measurement method is the Time Method; refer to Fetal Heart Rate in Obstetric Measurement.

6.3.10.3 EM Report

Hospital

Patient Information
 Name: Patient ID:20180907023036 Gender:Unknown
 Ref.M.D: Exam Date:2018/09/07 02:30:52 Age:

Measurements
OB
 LMP:2018/09/07 EDD:2019/06/14 GA:0w0d
 EDD(CUA):2019/06/14 CUA:xwxd CUA Based on:Hadlock11(BPD,HC,AC,FL)

Fetus A
B Mode:
 Q1 4.7 cm
 Q2 6.32 cm
 BPD 0 cm
 Q3 6.1 cm
 SS 3.63 cm 8w3ds0d 2019/04/16
 FL 0.14 cm
 CRL 4.69 cm 11w3ds7d 2019/03/26
 BPD 6.43 cm 26w0ds2w1d 2018/12/14
 HC 1.98 cm OOR EDD=OOR
 FL 5.57 cm 29w2ds2w1d 2018/11/21
 FL/BPD Hohler 0.87

ABD
B Mode:
 R Liver W 3.99 cm
 LK L 2.82 cm
 LK D 5.23 cm
 LK W 0.11 cm
 LK-V 0.89 cm³
 Ao 2.49 cm
 CHA 17.12 cm
 R Liver Max 4.11 cm
 R Liver D 3.99 cm

Cardiac
M Mode:
GYN
 LMP:2018/09/07 EDD:2019/06/14 GA:0w0d
B Mode:
 Endo 5.21 cm
 Rt OV-L 4.03 cm
 Rt OV-D 5.19 cm

Urology
B Mode:
 RK D 4.92 cm
 RK L 5.83 cm

Vascular
B Mode:
 Rt CCA-Prox 0.88 cm
 Rt CCA-Mid 1.11 cm

SMP
B Mode:
 Rt Thyroid-D 0.97 cm
 Rt Thyroid-W 1.61 cm

Orthopedics
B Mode:
 R Hip Angle α 56 °
 β 56 °
 Page 1/2 Print Date:2018/09/07

Ped_Cardiac
B Mode:
 MVA 0.19 cm²
 MV Diam 5.56 cm
EM
B Mode:
 CBD 4.18 cm
 Ao 5.71 cm

Images



Description
Conclusion

Page 2/2 Print Date:2018/09/07 Operator:

Chapter 7 Record of Images and Reports

7.1 Worksheet and Report

Different from general measurements (distance, circumference, volume, time, slope, HR, velocity and angle), data of Special measurements will be saved into the worksheet and report, and distributed to various report database according to different exam items; different reports of exam items are divided into general report and branch report, and gynecological, obstetric, early pregnancy, middle/late pregnancy and cardiac exam items are categorized into the branch report, which are added with some other menus on the basis of general report; here by taking general report as an example, we will make an introduction to the branch reports in terms of the specific measurement items in Chapter

7.1.1 Report Viewing

Users can access to report and worksheet through two ways:

1. Press [Report] on the control panel to enter the report, and then click [Worksheet] on the screen to enter the worksheet; Then press [Report] on the control panel to exit the worksheet and report.
2. Press [Measure] on the control panel to enter the measurement menu, and the buttons of [Worksheet] and [Report] will occur below the measurement items, then click the button to enter the interface;

Then press [Report] on the control panel to exit the worksheet and report. Report is divided into five parts, namely Patient Information, Measurements, Images, Description and Conclusion, which is displayed in three sections; click [Page up] or [Page down] to view the complete report; here we will come to understand the contents of these three sections.

The interface in Section One is shown below:

The screenshot displays a software interface for medical reports. At the top, there is a 'Report' header with a list of medical specialties: ABD, OB, Cardiac, GYN, Urology, Vascular, SMP, Orthopedics, Ped_Cardiac, EM, and TCD. Below this is a 'Patient Information' section containing fields for Name, Patient ID (20180907023036), Ref.M.D., DOB (2018/09/07), Gender (Unknown), Exam Date (2018/09/07 02:30:52), Operator, and Age.

The main content area is divided into two sections: 'ABD' and 'OB'. The 'ABD' section contains a table of measurements:

R Liver W	3.99	cm
LK L	2.82	cm
LK D	5.23	cm
LK W	0.11	cm
LK-V	0.89	cm ³
Ao	2.49	cm
CHA	17.12	cm
R Liver Max	4.11	cm
R Liver D	3.99	cm

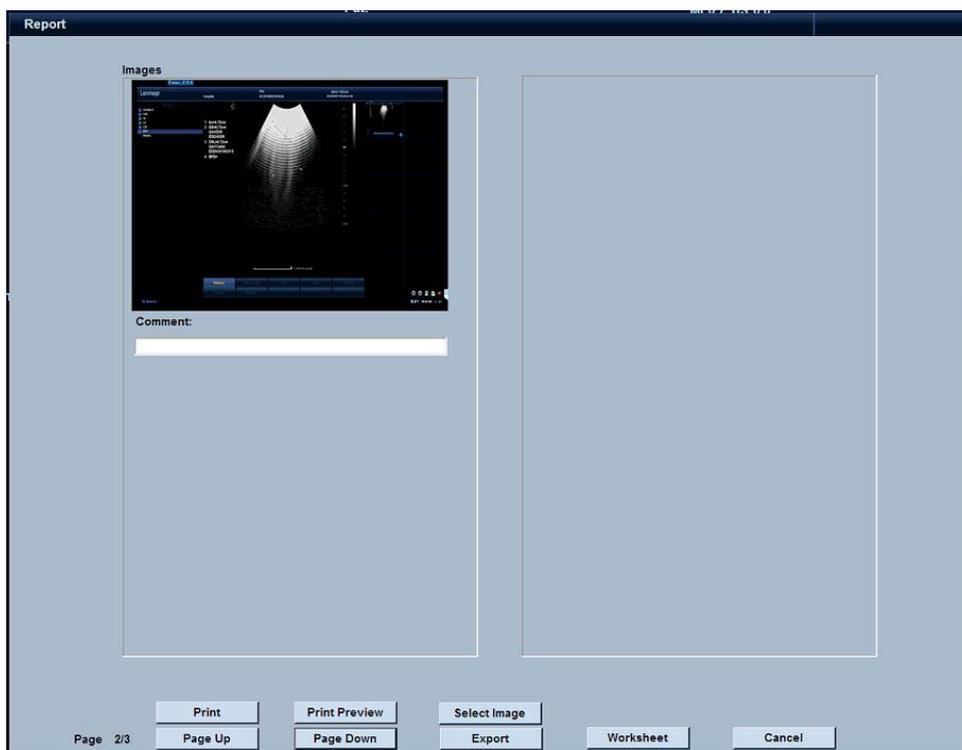
The 'OB' section contains a form for obstetric data. It includes dropdown menus for LMP (20180907), EDD (20190614), and EDD(CUA) (2019/06/14). There are also input fields for GA (x w x d) and CUA (x w x d). Below this is a 'Fetus' section with radio buttons for A, B, C, and D, and a 'CUA Based on' dropdown set to 'Hadlock11'. The 'B Mode' section contains a table of measurements:

Q1	4.7	cm		
Q2	6.32	cm		
BPD	0	cm		
Q3	6.1	cm		
GS	3.63	cm	8w3d±0d	2019/04/16
FL	0.14	cm		
CRL	4.69	cm	11w3d±7d	2019/03/26
BPD	6.43	cm	28w0d±2w1d	2018/12/14
HC	1.98	cm	OOR	EDD=OOR
FL	5.57	cm	29w2d±2w1d	2018/11/21

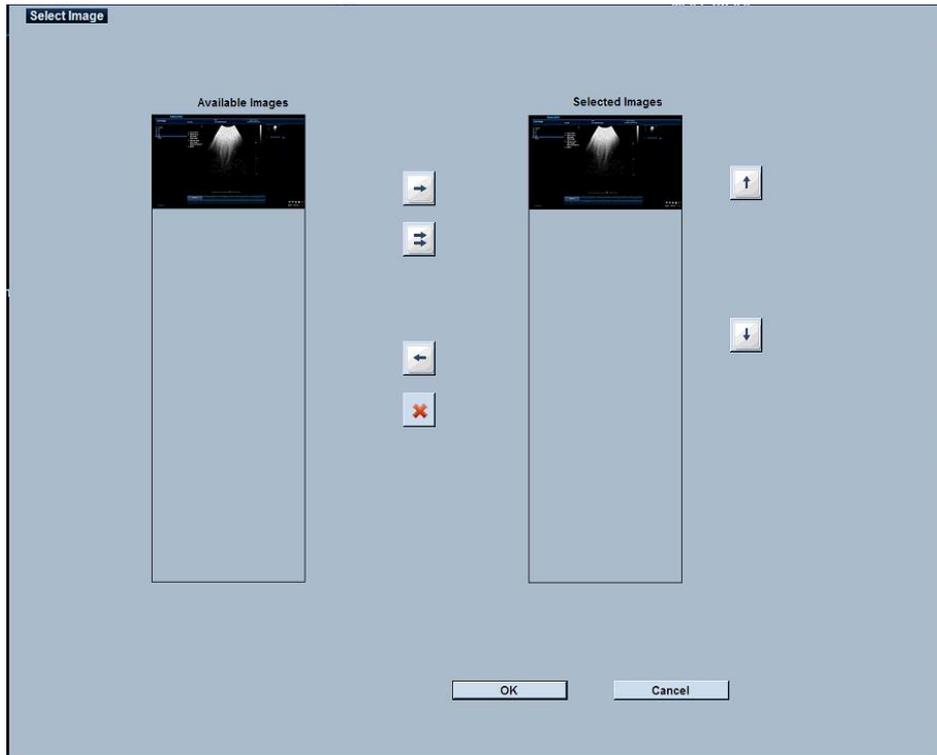
At the bottom of the interface, there is a 'Ratio:' field and a set of navigation buttons: Print, Print Preview, Select Image, Export, Worksheet, Page Up, Page Down, and Cancel. The page number 'Page 1/3' is also visible.

- The system will set the Report Database as the database of the current measurement item by default;
- The basic information filled by users in the patient-Information interface will be displayed in [Patient Information];
- For measurement data, you can click [Worksheet] to enter the worksheet for editing; in case there are a large number of data, you can move the roll bar on the right of the screen for viewing.
- Users can perform the functions such as image print, print preview, select images, export, access to worksheet and page turning.

Section Two is shown in the figure below:



- You can click [Select Images] and in the thumbnail of main interface to select images in the report. However, a maximum of four images can be simultaneously displayed in the report.
- Users can enter relevant comments below each image.
- Click [Select Image] to pop up the interface below, and the left image is the one saved in the current measurement item by clicking [Save], while the cine images in Cine Save cannot be displayed in this interface:



Parameter	Description
Available Images	The left column shows the images saved in the hard disk;
Selected Images	The right column shows the images that are selected into the report;
	Select all images in the left column to add to the report, which are displayed in the [Selected Images]; if there are more than four images uploaded to the left column, the report will only show the first four images;
	Select an image in the left column to the report;
	Delete a selected image from the right column;
	Move the selected image up to a location;
	Move the selected image down to a location.

Section Three is shown in the following figure, in which users can enter the Patient's case description and conclusions:

The screenshot shows a window titled "Report" with two large text input areas. The top area is labeled "Description:" and the bottom area is labeled "Conclusion:". Below these areas is a control bar containing several buttons: "Print", "Print Preview", "Select Image", "Export", "Worksheet", and "Cancel". On the left side of the control bar, it says "Page 3/3".

If you want to check out the complete report, please click [Print Preview].

7.1.2 Worksheet Viewing

The worksheet can be entered in the same way as report, and you can change or delete data in the worksheet and repeat measurements and save the final measurement result to the report; as shown below, press [Report] to enter the report interface:

The screenshot shows a window titled "Worksheet" with a table of data. The table has columns for "Label", "Value", "1", "2", "3", and "Method". The "Value" column contains "0.84 cm" and "1.07 cm". The "1" column contains input fields with "0.84" and "1.07". The "Method" column contains dropdown menus with "Direct" selected. Below the table are sections for "M Mode:" and "PW Mode:". At the bottom of the window are buttons for "Clear All", "Delete value", "Report", and "Cancel".

Label	Value	1	2	3	Method
CBD	0.84 cm	0.84			Direct
Ao	1.07 cm	1.07			Direct

7.2 Storage of Image and Report

In the measurement process, Press [Save] on the control panel or click [Image Save] or [Cine save] to display images or cine in the thumbnail, which will be automatically saved to the system's Hard disk. We can also save the images (including images and cine to an optical disk (CD/DVD) or USB disk.

When the measurement is completed, patient reports and graphs can also be exported to an optical disk or USB disk;

7.2.1 Reviewing Image and Report

If you want to view the patient's images and reports, you can perform the following operations:

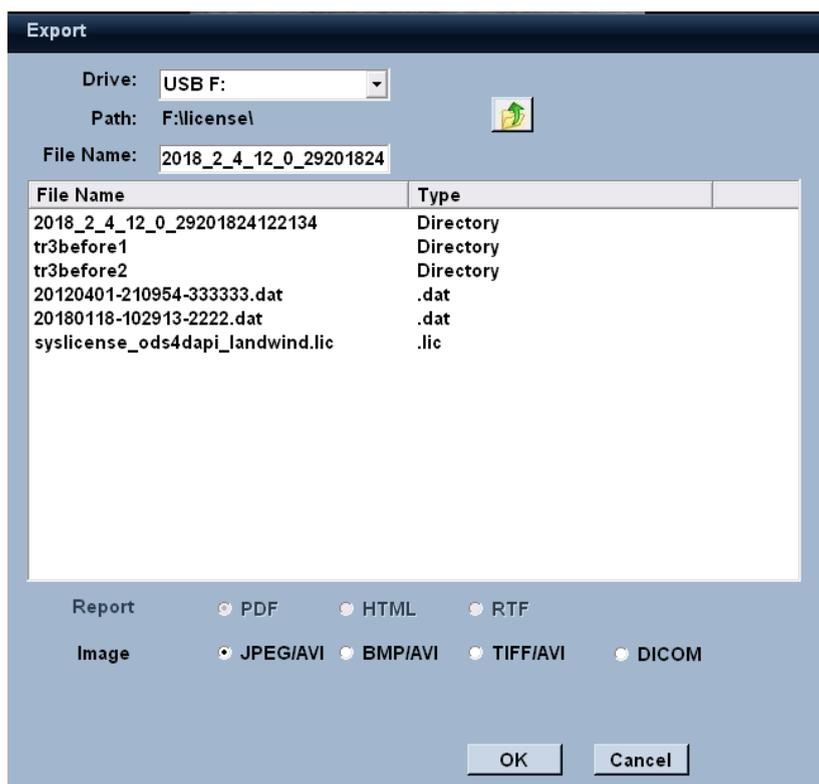
1. First press [Patient] to enter the interface Patient Information, and search the desired patient in the patient information list, and press [Set] to exit;
2. This patient's images will be displayed in the thumbnail of the main interface, or press the [Review] button to enter the Reviewing interface; search the patient in the patient information list, and click [Image Screen] on the interface to view the images.
3. Press [Report] and then click [Worksheet] to view patient report and worksheet.

7.2.2 Export Image and Report

7.2.2.1 Export to USB

When you insert a U disk, the  icon will appear on the bottom right of the screen, then you can store images into the U disk, and export the reports and images; click [Export] or

the  thumbnail to pop up the export dialog box (as shown below):



- The default display of U disk is the letter following the name of the last disk of hard drive, for example, if the system is named to D disk, the default optical drive is E disk and displayed as CD/DVD E, then the first inserted U disk will be automatically identified as USB F disk, and the second will be USB G disk, likewise; click [▼] on the right of hard drive to select the location of data storage.
- When a data is stored, the system will automatically name the file and displayed in the [File Name], and users can change the name by clicking.
- The list below the file name is the files in the U disk; double-click the folder to enter and view the files. Click  to return to operation.
- Users can save images and reports by selecting different formats, for reports, there are PDF, HTML and RTF; for images, there are JPEG, BMP and TIFF.
- Press [Set], and the data will be uploaded to the U disk and a prompt for successfully sending data to the removable storage device will be displayed.

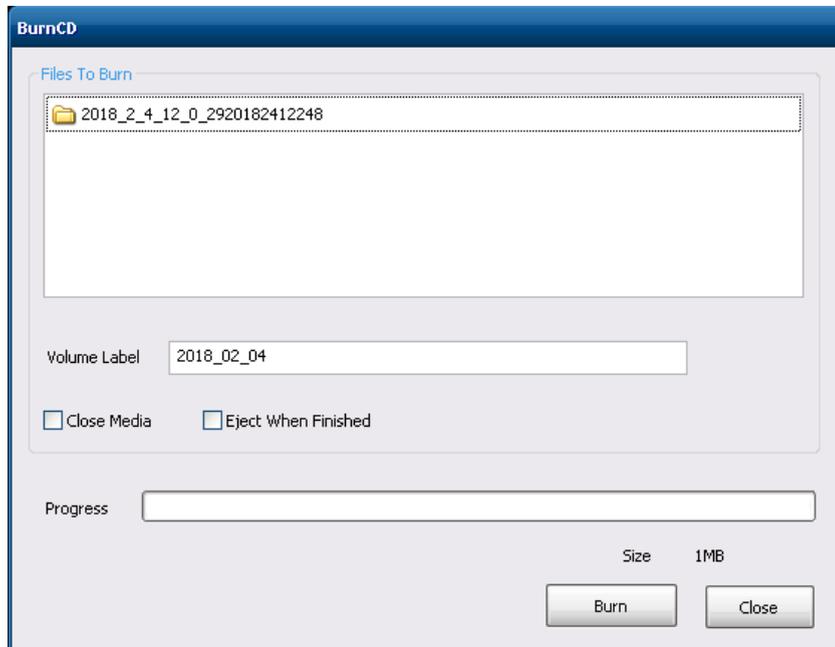


Note: It is recommended to use the 512M Netac U265 or 1G Netac U208 matched by Lanmage; The system supports FAT32 file format, and before the U disk is used, it shall be formatted into FAT32 on the computer. The system update can only be used by the customer service staff of the company. All the consequences caused by the user's unauthorized operation shall be undertaken by the user.

7.2.2.2 Export to CD/DVD

When you insert a CD/DVD, the  icon will appear on the bottom right of the screen,

through which you can burn the reports and images; click [Export] in the menu or the thumbnail  to pop up the export dialog box, then you can select CD/DVD E from the drop-down drive list, and modify the file names and data formats; after the changes are finished, press [Set] to pop up the following dialog box:



- The system will automatically create a folder, click [Burn] to save the desired files into this folder.
- You can view the burning progress through [Progress], and click [Close] when the burning is completed.
- Close Media: When clicking [Close Media], the system will not perform a second burning after the optical disk finishes its burning.
- Eject When Finished: When clicking [Eject When Finished], the CD/DVD burning is finished and will be automatically ejected.

7.3 Data Transmission

Press [Review] to enter the Reviewing interface, and then click [Data Transfer] to enter the interface of data transmission, as shown below:

Transfer

Search Key **Patient ID** String

PC Import
 PC Export
 DICOM Export
 DICOM Import
 Q/R

From:

Patient ID	Last Name	First Name	Exam Date	DOB	M byte(M)
2018_2_4_12_0_29	zhang	san	2018/02/04 12:00:47	2018/02/04	14.97
2018_2_4_6_41_33	zhang	san	2018/02/04 06:41:45	2018/02/04	188.5

Select All Transfer

Search Key **Patient ID** String

To:

Patient ID	Last Name	First Name	DOB	Gen...	Exam Date	M byte(...)
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Image Screen

Cancel

Export: to export the patient information on the Local HD to an optical disk (CD/DVD) or USB disk.

1. Click [Export], and the patient information list on the first row will pop up the patient data stored in the system;
2. On the bottom left corner occurs from [Local HD] to [], and click the drop-down list of [] to select the export device;
3. Click [Select All] or select single patient information as required;
4. Then click [Data Transfer] to transmit the patient data from the system to the removable device.

Import: to import patient information from an optical disk (CD/DVD) or USB device to the Local HD.

1. Click [Import], and the patient information list on the second row will pop up the patient data stored in the system;
2. On the bottom left corner occurs from [] to [Local HD], and click the drop-down list of [] to select the import device;
3. Patient data in the import device will be displayed in the patient information list in the first row;
4. Click [Select All] or select single patient information as required;
5. Then click [Data Transfer] to transmit the patient data from the removable device to the system.

7.4 Add a Printer

- This system can be directly connected to a printer for analog signal printing (the system supports the analog printer models SONY UP-897MD/Mitsubishi P93).
- It can also be connected with a printer for digital signal printing (this system supports the digital printer models HP LaserJet 5200LX PCL 6).

7.4.1 Connected to an Analog Signal Printer

If the system is configured with an analog signal printer, please observe the following steps: Before settings, please read carefully and have a profound understanding of the user's manual of the provided printer models.

Connect a cable of the printer with Video Output on the back panel of the ultrasonic system, and connect the other cable to Remote Port of the printer; press [Print] on the printer or press [Print] on the ultrasonic system to print images and data.

7.4.2 Connected to a Digital Signal Printer

The system can be connected to a digital signal printer directly through USB or LAN.

Connected to a local printer

1. The system will automatically install the driver programs required for the optional printer, and users can add the printer according to their needs.
2. Press [Setting] on the touch screen, and click [Peripheral Preset], then click [Printer] above the sub-menu to pop up the printer menu.
3. Click [Add printer] to pop up the Add Printer Wizard menu, and when you are prompted to do so, you can select the local printer connected to your computer in the menu [Local or Network Printer], and click [Next].
4. The menu [Printer Port] will pop up for selection, and select the USB port in the drop-down list, then click [Next];
5. The menu [Install Printer Software] will pop up, and select the printer manufacturer in the list of [Manufacturer] on the left, then select the printer model on the right, and click [Next];
6. The menu [Use the Current Driver Program] will pop up, and select the driver program, then click [Next];
7. If you have been prompted to complete the printer adding, the added printer model will appear in the list.

Connected to a network printer

1. Click [Setting] on the touch screen, and click [Peripheral Preset] on the left, then click [Printer] above the sub-menu to pop up the printer menu.
2. Click [Add printer] to pop up the Add Printer Wizard menu, and when you are prompted to do so, you can select the network printer connected to your computer in the menu [Local or Network Printer], and click [Next];

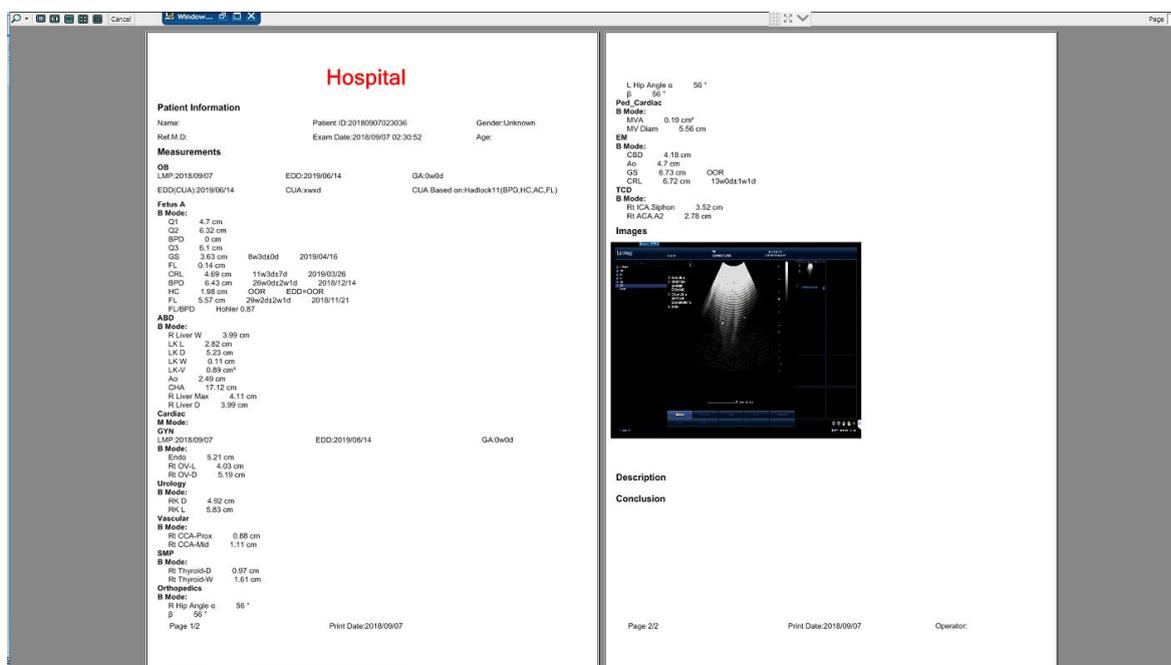
- The menu [Designate a Printer] will pop up, and you will be prompted to determine the printer connected to Internet, Home or Office Network and to enter the printer model, then click [Next].
- If you have been prompted to complete the printer adding, the added printer model will appear in the list.

7.5 Report Printing

7.5.1 Print Preview

In the Report interface, click [Print Preview] to preview the report (as shown below), and users can zoom the report and carry out paging layout and display according to the content size.

After confirming there are no errors in the report, click [Cancel] to exit the preview interface.



7.5.2 Report Printing

- Click [printer] in the preset interface, we can choose the Print type from the down list of [Print Key Destination] (Please see the detail in Chapter 8).
- Press [Report] on the control panel or enter the Report interface, then click [Print].

7.6 DICOM Connection

Connect the ultrasonic system with the hospital network with a network cable, and connect the system to the DICOM server for testing; the images (DICOM server storage non supporting videos) in the ultrasonic system can be stored into the DICOM server after it is successfully tested; refer to Network Preset in Chapter 8 for specific methods.

Chapter 8 Preset

8.1 Preset

Press [Setting] on the touch screen to enter the preset interface, through which users can preset the system parameters according to their own needs for faster and accurate data measurement. The preset menu includes System Preset, Exam Preset, Measure Preset, Text Preset, Body Mark Preset, Peripheral Preset and Service. We can change the settings according to our needs.

8.1.1 Operation methods of preset

1. Press [Setting] on the touch screen to enter the preset interface;
2. Each function module menu is listed on the left of the menu, and use the trackball in combination with the [Set] key to enter the corresponding module menu for parameter selecting, editing (you can use the keyboard for input) and revising; click [Reload Factory] to restore to the default settings;
3. Click [Apply] to save settings, and [OK] to save settings and exit the interface and [Cancel] to exit the interface.

Save changes in each module; if the changes are not saved, and when it is switched to another module, a prompt will pop up.

8.1.2 System Preset

System Preset includes the four sub-menus, namely Region Setting, General Setting, Biopsy Setting, and User defined.

8.1.2.1 Region Setting

Click [System Preset] on the left, and click [Region] on the top of sub-menu, then the following menu below pops up, including Hospital Information, Language, Time and Weight Format Settings;

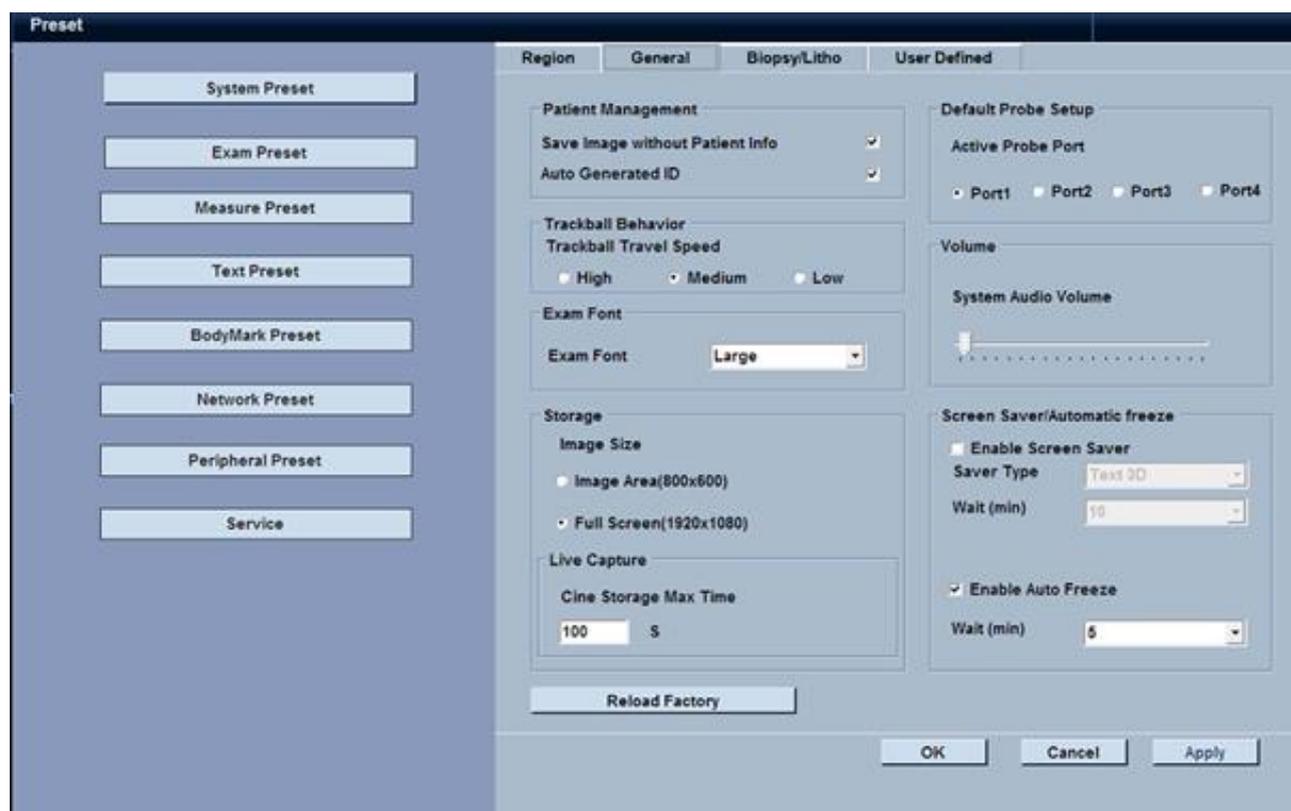
Parameter	Description
Hospital Name	Enter the hospital name in the keyboard, and press Ctrl + space key to switch language input.
Language	Select the appropriate language from the drop-down list: Chinese, English;
Time Format	Time format selection: 12 h, 24 h
Date Format	Date format selection: YY/MM/DD, MM/DD/YY, DD/MM/YY;
System Date	Input system date and select calendar;
System Time	Input system time for and select time;
Weight & Height Unit Format	Select measurement units: Metric System, American System (Metric system available only)
Surface Area Formula	Set the surface area formula: East, West (East available only)



Note: After the language is switched, the system will restart to enable the new language; Please save the data before switching the language.

8.1.2.2 General Setting

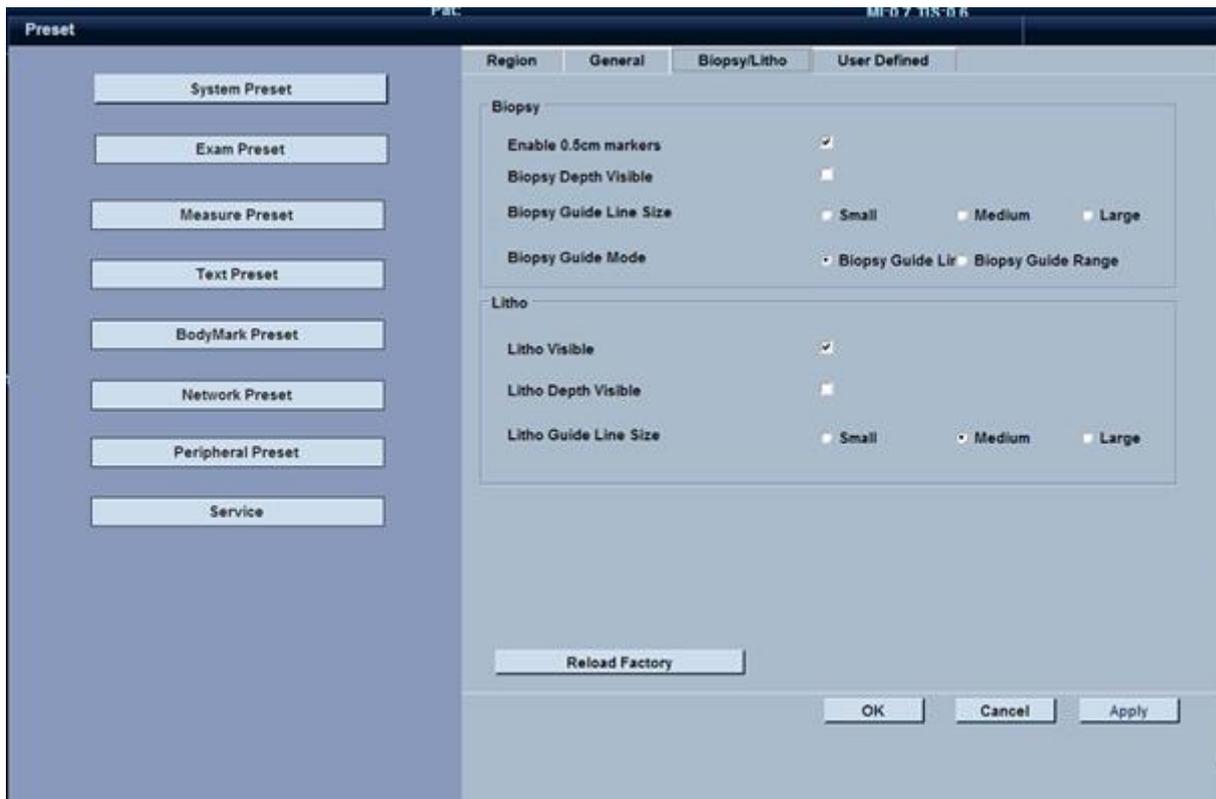
Click the [General Settings] above the sub-menu, through which we can set Patient Management, Trackball Movement, Storage, Probe Default Setting, Doppler Volume and Screen Saver, etc.



Parameter	Description
Save the images when without patient info	Select: when saving images, and if there is no patient information, the system will automatically create a patient ID, which will be displayed in the report and on the main screen; Unselect: When saving images, and if there is no patient information, it will prompt to create a new patient.
Auto generated ID	Select: When a new patient is created, it will automatically generate a patient ID (date + current patient number, for example, 20101122), which can also be edited; Unselect: To create a new patient, you can manually enter the patient ID.
Active probe port	Available ports when starting the system: Port1, Port 2 and Port 3; If the preset port is not installed with the probe, the system will automatically identify the next port in sequence;
Trackball travel speed	Select trackball movement speed: high, medium and low.
Doppler Audio Volume	Regulate Doppler audio volume: 1% to 100 %.
Image Size	Select the image area to be stored: image area 800x600 Full screen 1920x 1080
Cine Store Time	Edit the stored cine time, and support backward storage. Storage Time: 0 ~ 120 s, Default Value: 60 s.
Enable Screen save	Select: When there is no system operation exceeding the setting time, the system will enter the screensaver status. Unselect: The screen saver function is not enabled;
Screen saver Type	Select the screen-saver type: black screen, text3D ;
Screen saver Waiting	Select the screensaver waiting time from the drop-down menu (min): 5, 10, 15, 15, 20 and 25.

8.1.2.3 Biopsy Setting

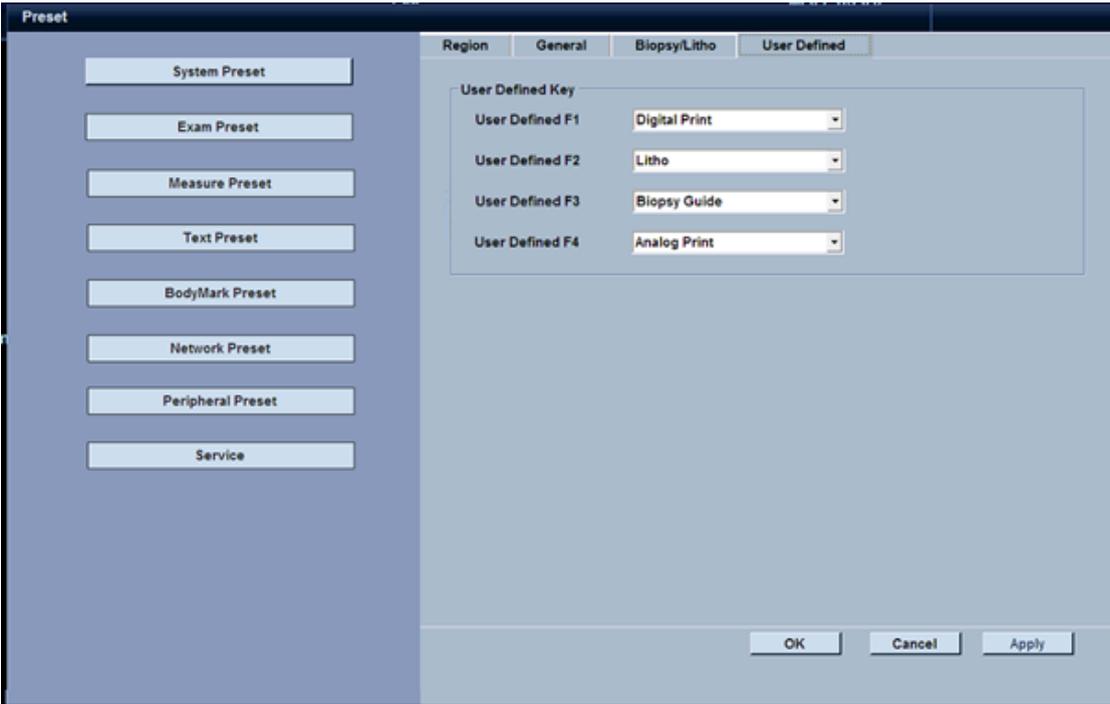
Click [Biopsy/Litho] above the sub-menu to pop up the menu for relevant Biopsy Settings;



Parameter	Description
Probe Type	N/A
Bracket Type	N/A
Default Angle	N/A
Angle 1, Angle 2 and Angle 3	N/A
Initial Position	N/A
Enable 0.5cm Markers	Select: activate Biopsy depth marking every 0.5 cm. Unselect: no depth marking.
Biopsy Guide Line size	Select the size of Biopsy guide wire: small, medium and large

8.1.2.4 User Defined

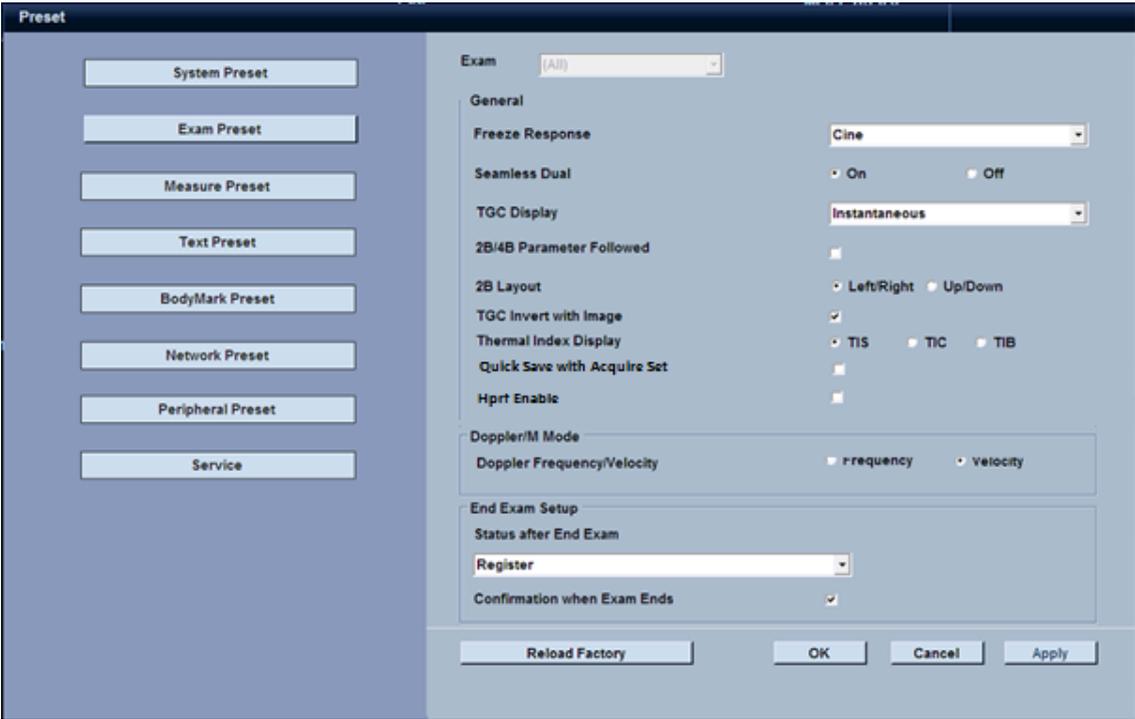
Click [User Defined] above the sub-menu for the user-defined settings. You can carry out the following shortcut settings through the customized key functions on the control panel.



There are four customized function keys on the right of the control panel, and you can carry out the following shortcut settings in this interface: None, Biopsy Guide, Acquire Set, Litho, Digital Printing, Analog Printer, image save, cine save, 2B, 4B, PDI, LanScape, TDI, A mode, LVivoEF, ECG, Print.

8.1.3 Exam Preset

Click [Exam Preset] to pop up the Exam Preset menu, through which you can carry out settings of general measurements on exam items, Doppler/M Mode and End exam settings, etc.



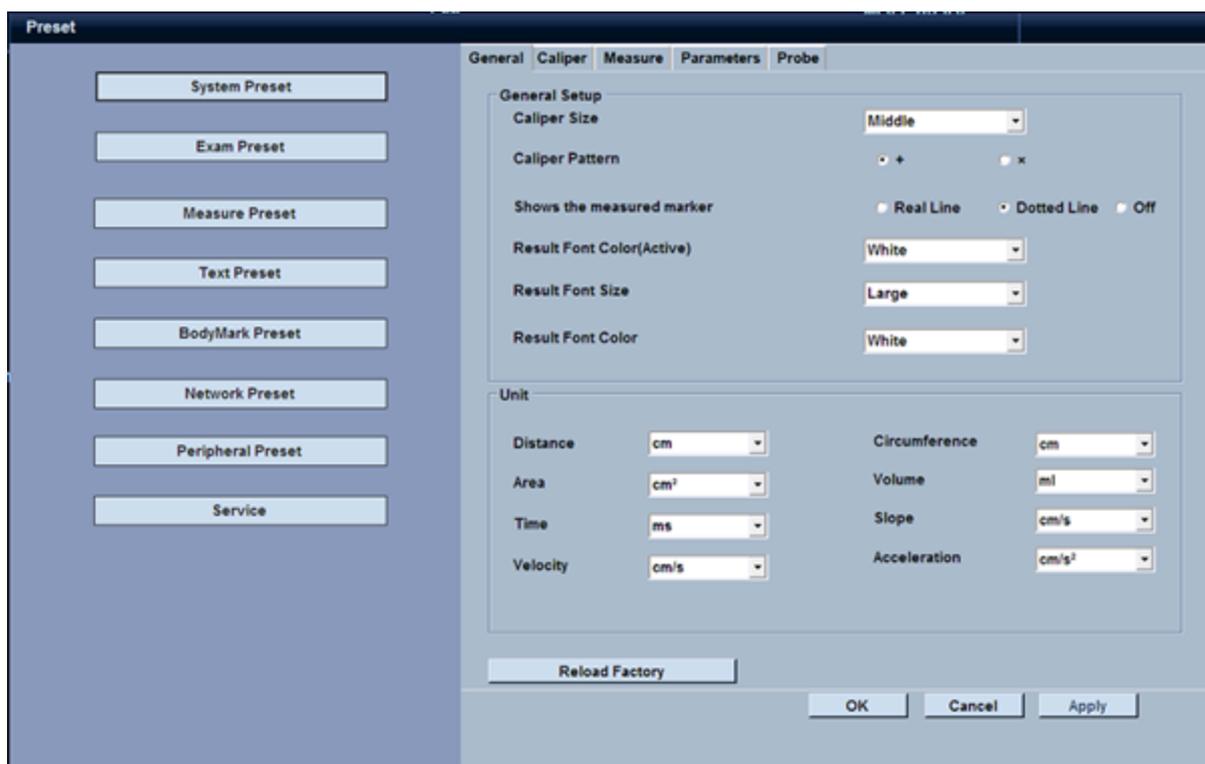
Exam Item	Description
Exam Item	N/A
Freeze Response	Select [Freeze Response] and the system will enter: Cine, Text, Mark and Measure;
Seamless Dual	ON: In 2B imaging mode (real-time/non-real-time), there is no gap between two images; OFF: there is a gap between two images;
TGC Display	TGC curve options on the right of image in the main interface: Always , Instantaneous, Close
TGC invert with Images	Select: flip; Unselect: no flip
Thermal index Display	Select thermal index: TIS, TIC, or TIB. When TIS/TIC/TIB is ≥ 0.4 , thermal index will be displayed
Quick save with acquire Set	Select : Press [Capture] or [acquire set] shortcut key to save current parameters as default. Unselect: press [Capture] or [acquire set] to enter acquire setting interface.
HPRF Enable	Select: add HPRF menu in PW mode. And vice versa.
Bypass M/D cursor	Select: immediately display M mode/PW mode imaging, no displaying sampling line; Unselect: display the sampling line and the corresponding imaging mode can be displayed by pressing the M/PW button.
Doppler Frequency/ Velocity	Frequency: the frequency spectrum scale shows the frequency value; Velocity: the frequency spectrum scale shows the velocity value.
Status after End Exam	Region: to create a new patient; Live Scanning: to clear the patient information, and reserve the probe and exam settings of the previous exam, then enter B mode imaging.
Confirmation when exam ends	Select: when the exam is completed, the system will pop up a dialog box to confirm whether to end the patient exam, and the Patient Information menu will pop up after the selection of the user; Unselect: directly access to the Patient Information menu.

8.1.4 Measure Preset

Click [Measure Preset] and then click the menu above the interface to pop up the general measurement settings, Special measurement setting and parameter setting. The items in bold font are the system default settings.

8.1.4.1 General Setting

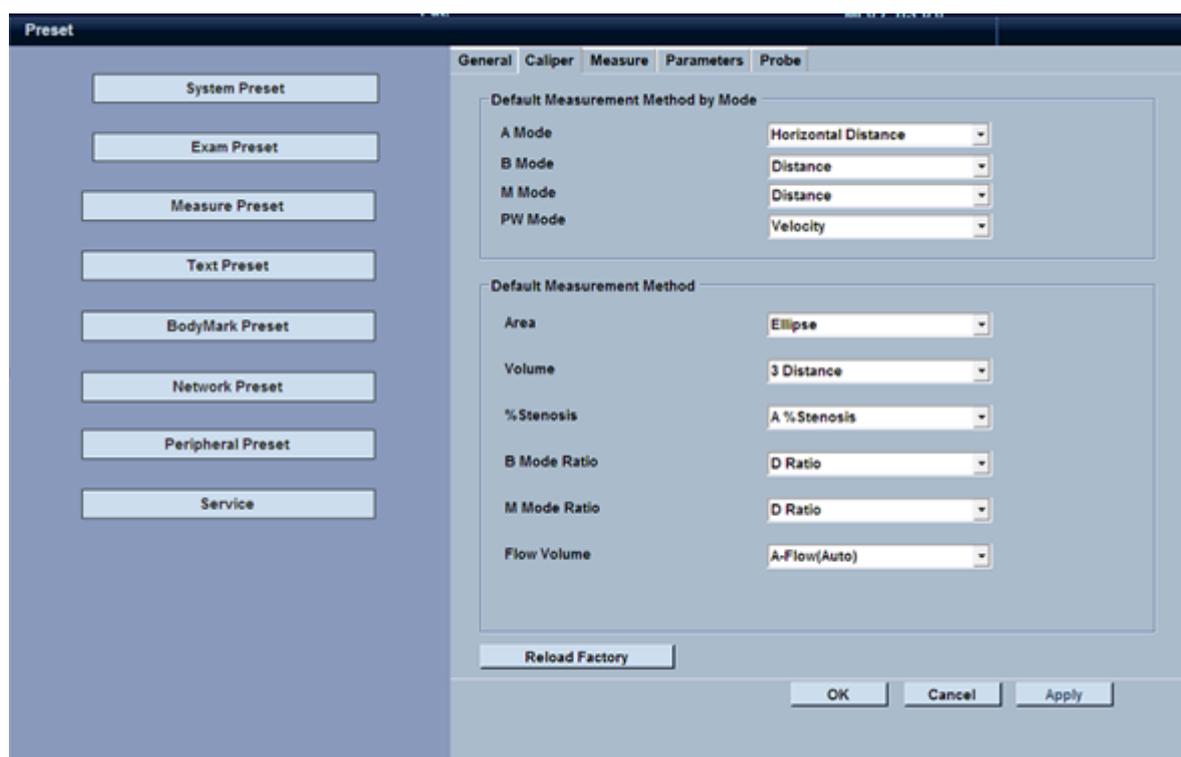
Click [General Settings] to pop up the General Setting menu, through which you can carry out settings for caliper and measuring results, and select the units on general measurement.



Parameter	Description
Caliper Size	Caliper size setting: large, medium, small;
Caliper Pattern	"+" and "X " display option;
Measurement Result Background	Measurement result background display: Display: transparent; Non-display: non-transparent
Result Font Size	Measurement result font size: small, medium, large
Result Font Color	Final measurement result font color: white, yellow, blue
Distance	Units of general distance measurements and distance-type measurement results: mm, cm
Circumference	Units of general circumference measurements and circumference-type measurement results: mm, cm
Area	Units of general area measurements and area-type measurement results: mm ² , cm ² , m ²
Volume	Units of general volume measurements and volume-type measurement results: mm ³ , cm ³ , L
Velocity	Units of general velocity measurements and velocity-type measurement results: mm/s, cm/s, m/s
Time	Units of general time measurements and time-type measurement results: ms, s
Slope	Units of general slope measurements and slope-type measurement results: mm/s, cm/s, m/s
Acceleration	Units of general acceleration measurements and acceleration-type measurement results: mm/s, cm/s ² , m/s ²

8.1.4.2 General Measurement Settings

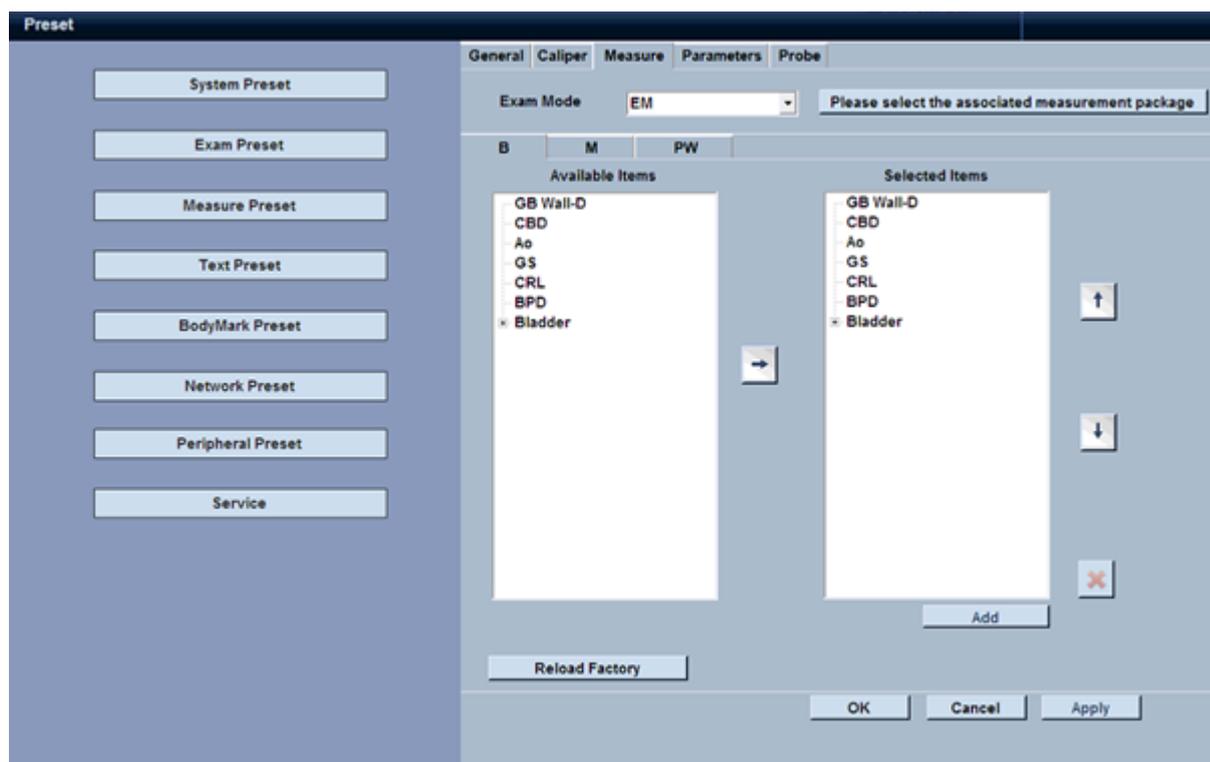
Click [Caliper] to display the measurement method options in various modes.



Parameter	Description
B mode	Default B mode measurements Value: distance, Trace length, area, angle, volume, stenosis rate, A/B ratio
M mode	Default M mode measurements Value: distance, HR, slope, time, A/B ratio;
PW mode	Default PW mode measurements Value: velocity, PI (Auto), acceleration, velocity rate, HR, RI, PI (Manual), flow, time;
Area	Methods of setting default area measurement: ellipse, trace;
Volume	Methods of setting default volume measurement: 1-distance, 1-ellipse, 2-distance, 3-distance, ellipse + distance;
%stenosis	Methods of setting default stenosis rate measurement: D-%stenosis, A- %stenosis;
B mode Ratio	Methods of setting default B-mode ratio measurement: D ratio, area ratio and volume ratio;
M mode Ratio	Methods of setting default M-mode ratio measurement: D ratio, time ratio;
Flow volume	Methods of setting default flow measurement: A-flow, D-flow.

8.1.4.3 Measurement Settings

Click [Specialist Measure] to pop up the Special Measurement interface, through which we can edit the measurement items in B mode, M mode and PW mode, and save the settings to the measurement menu and report.



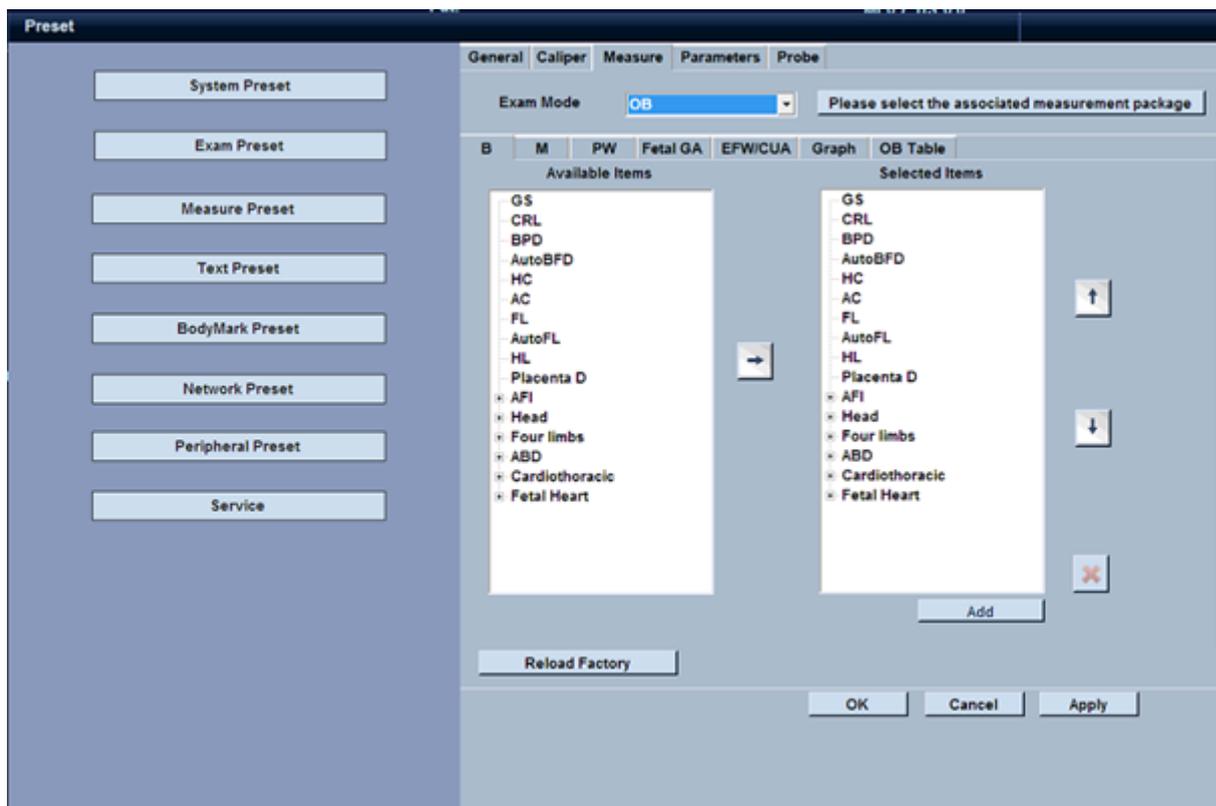
Selection methods of measurement items in the imaging mode:

1. Click ▼ on the right of [Exam mode] to select the desired measurement item;
2. Then click B, M and PW to enter the measurement items in the imaging mode, on the left of which are the optional items, and on the right are the selected items; the system will set all of the measurement Items in [Exam Item] as the selected items by default;
3. If you want to cancel a measurement, you can use the trackball and [Set] to select
4. [Select item], then press  on the right to delete it; to add a new measurement item, you can click  , and the item will be selected to [Select item];
5. Click  to move the selected item to the upper location; click  to move the selected item to the lower location;
6. Click [OK] to save the measurement item settings and return to main interface; click [Apply] to save settings; click [Cancel] to return to the main interface without saving settings.

8.1.4.4 Obstetric Measurement Settings

When the three measurement Items, namely obstetrics, early pregnancy and late pregnancy are selected in the measurement item, the system will add four more parameter settings, including Ratio, EFW/CUA (fetal weight/ultrasonic compound gestational age), Graph (growth curve graph) and OB table (gestational age/fetal growth curve), you can select a reference author behind the obstetric measurement item; please refer to Appendix E for

more details.



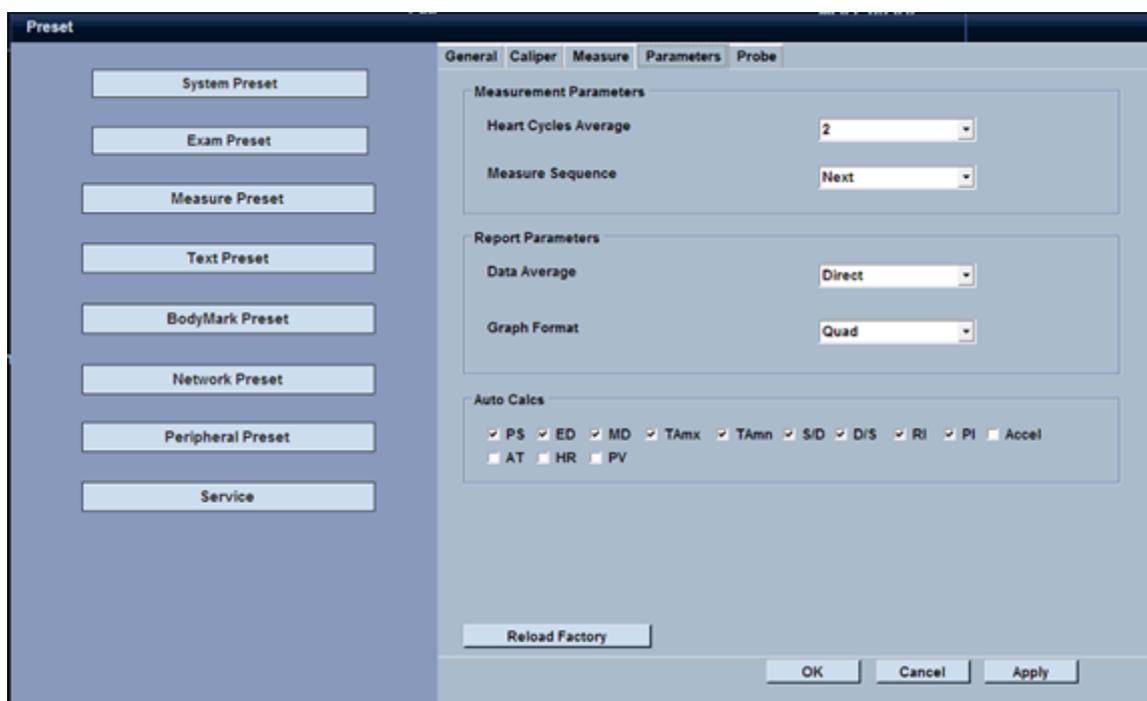
Gestational Age (GA) Table

Measurement items	Author
B mode	Default B mode measurements Value: distance, Trace length, area, angle, volume, stenosis rate, A/B ratio
GS	Tokyo, Osaka
CRL	Hadlock, Robinson, Hansmann, Lasser, Tokyo, Osaka, JSUM, ASUM
BPD	Hadlock, Merz, Lasser, Rempen, Tokyo, Osaka, JSUM, ASUM
OFD	ASUM
ASD	Merz
ATD	Merz
HC	Hadlock, Lasser
AC	Hadlock, Merz, Lasser, JSUM
FTA	Osaka
FL	Hadlock, Merz, Jeanty, Tokyo, Osaka, JSUM
HL	Jeanty, Osaka
Ulna	Jeanty
Tibia	Jeanty
BN	Jeanty, Tongsong
FT	Mercer
HC/AC	Campbell
FL/AC	Hadlock
FL/BPD	HadLock
GS	Tokyo, Rempen

Measurement items	Author
CRL	Hadlock, Rempen, Robinson, Hansmann, Tokyo, Osaka, JSUM, ASUM
BPD	Hadlock, Merz, Lasser, Rempen., Hansmann, Tokyo, Osaka, JSUM, ASUM, Chitty
OFD	ASUM, Chitty, Hansmann
HC	Hadlock, Merz, Hansmann, Chitty, ASUM
AC	AUSM, Hadlock, Merz, Jeanty, JSUM, Chitty.
AxT	Tokyo, JSUM
FTA	Osaka
FL	Hadlock, Merz, Jeanty, Hansmann, Tokyo, Osaka, JSUM, ASUM
HL	Jeanty, Merz, Hansmann, Osaka, ASUM
Ulna	Jeanty, Merz, Hansmann
Tibia	Jeanty, Merz, Hansmann
FT	Mercer
Renal L	Bertagnoli, Hansmann
RAP	Bertagnoli, Hansmann
Clav	Yarkoni
TC	Chitkara

8.1.4.5 Parameter Settings

Click [Other Parameters] to pop up the measurement and report settings, as shown below:



Parameter	Description
Heart Cycles Average	Select the default measurement item of mean cardiac cycle, values: 1, 2, 3, 4 and 5;
Measure Sequence	Select the action upon completion of a measured value: None , Repeat, Next;
Data Average	Data value after selecting the measurement data: Average, Direct;

Parameter	Description
Graph Format	Set the default method of growth curve display: single, Quad;

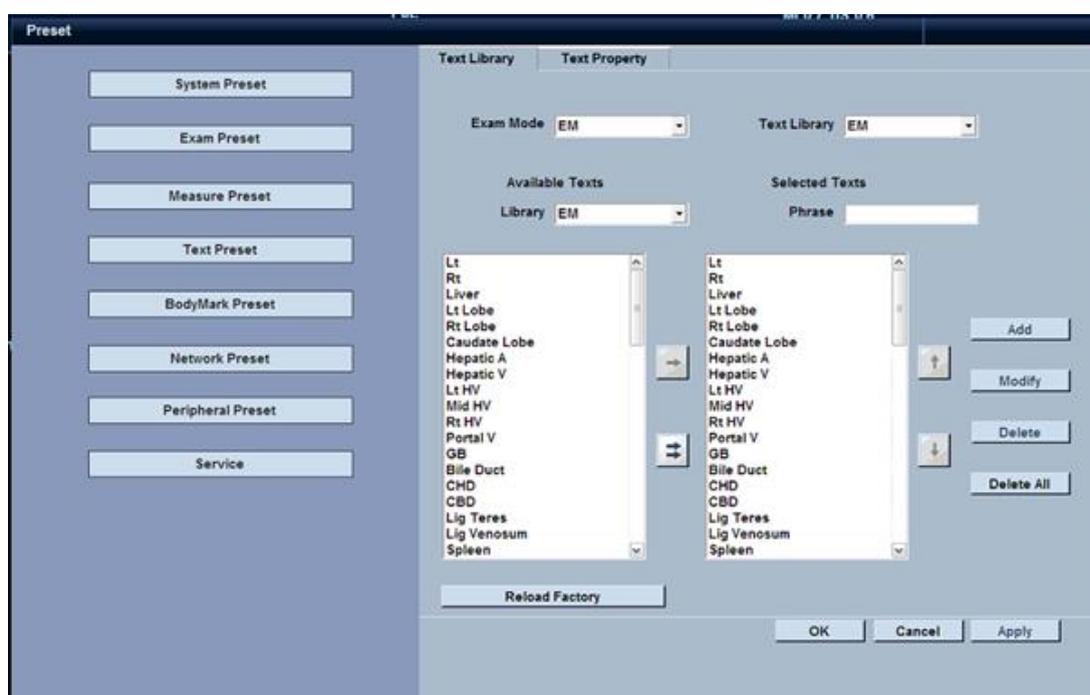
8.1.4.6 Probe

To customize the order of exam sections for each probe.

8.1.5 Text Preset

8.1.5.1 Text Library Settings

Click [Text Preset] and then click [Text Library] to enter the Text library setting.



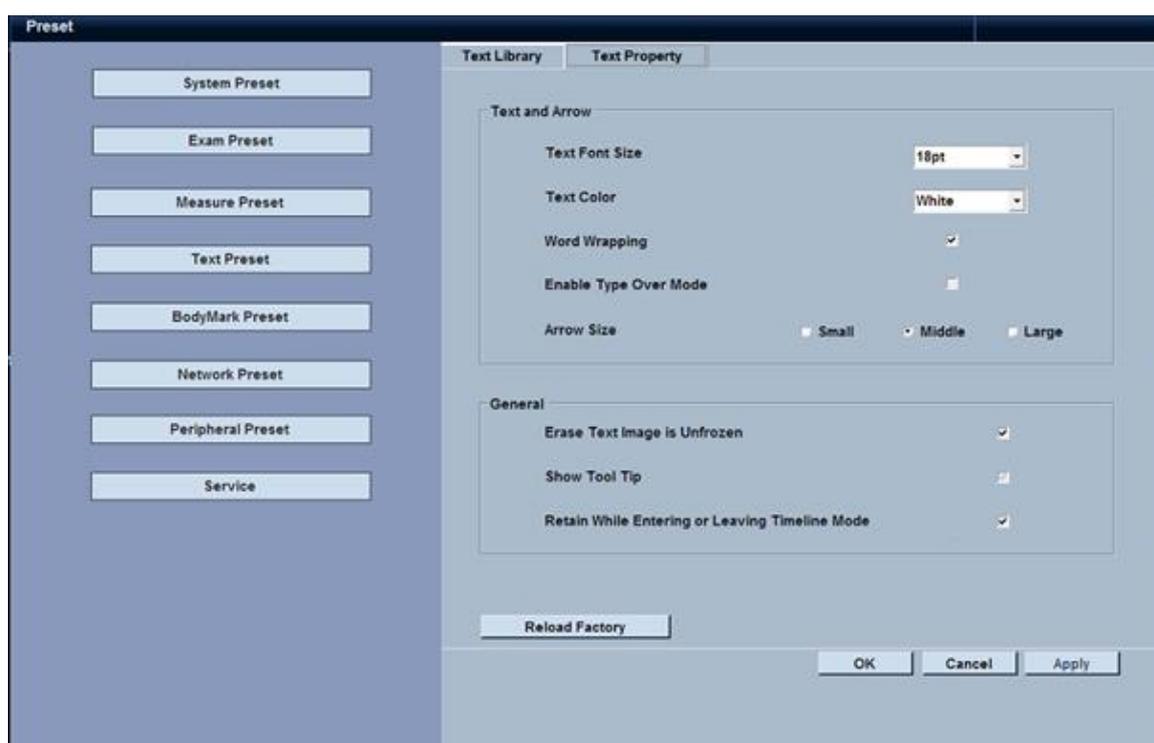
Operation methods for annotation library setting:

1. Click ▼ on the right of [Exam Mode] to select the item; The exam items are set in the default exam mode on the right of annotation library, and users can select the annotation library on their own, in which the measurement items will appear on the right of annotation box.
2. If you want to cancel the annotation of an item, you can use the trackball and [Set] to select the annotation item, then click [Delete] on the right or click [Delete All] to delete the whole annotation library of the current item; if you want to add an item annotation, click  to select the annotation library on the left; when clicking , all the items in the annotation library of the current item will be added.
3. You can manually enter the annotation on the upper-right corner, and click [Add] to add the annotation into the annotation library; select the annotation and click [Modify] to revise the annotation in the annotation library;

4. Click  to move the selected item to the upper location; click  to move the
5. selected item to the lower location;
6. Click [OK] to save the measurement item settings and return to main interface; click [Apply] to save settings; click [Cancel] to return to the main interface without saving settings.

8.1.5.2 Text Property Settings

Click [Text Property] to carry out settings of annotation attribute.



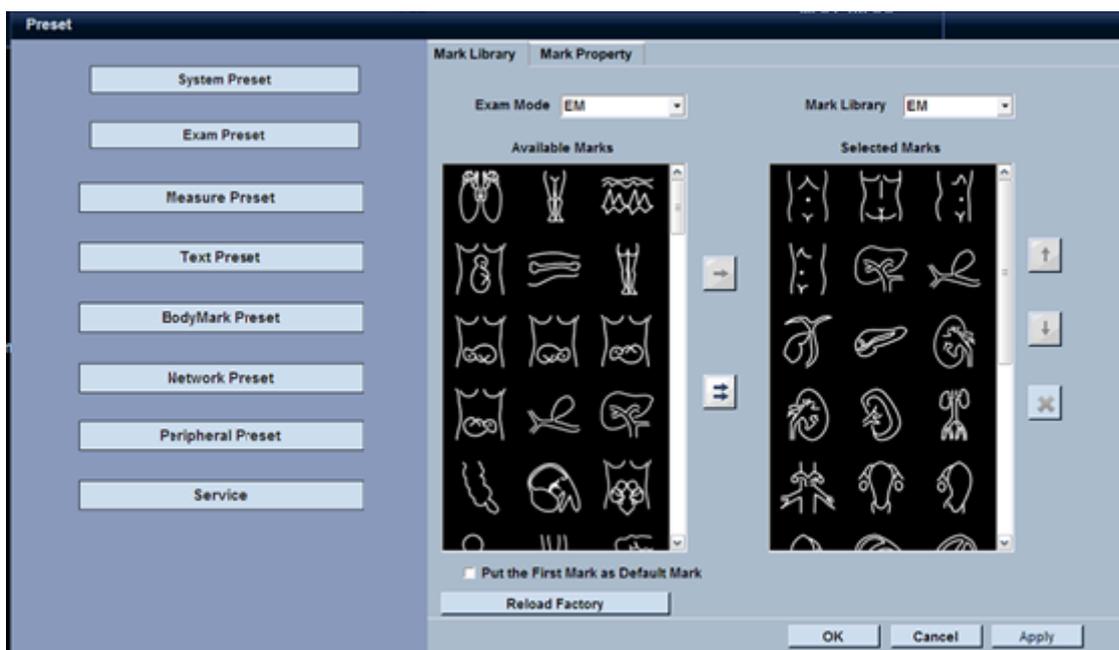
Parameter	Description
Text Font Size	Annotation text font size: 10, 12, 14, 18, 20; unit: Pound(s)
Text Color	Set annotation text font and arrow color, and values are: yellow, red, blue, orange, white and purple;
Word Wrapping	When selected, it will automatically wrap when the text length exceeds the image boundary; otherwise it needs to wrap manually;
Arrow Size	Set the arrow size: small, medium, large
erase Text Image is Unfrozen	Select the text, and the annotation will be erased when the image is frozen; otherwise the erasing function will not be performed.
Retain while Entering or Leaving Time Line Mode	When selected, upon entering and exiting the timeline mode, the system will reserve the annotation on the monitor display; otherwise it will not reserve the annotation;

8.1.6 Body Mark Preset

8.1.6.1 Mark Library Settings

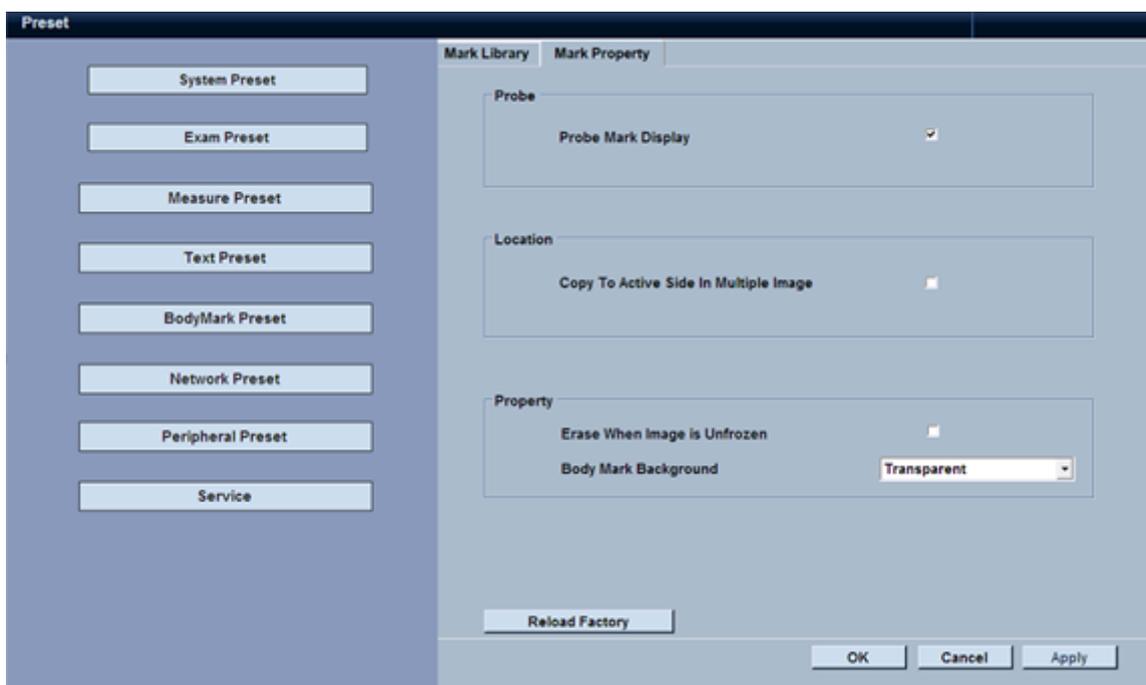
Click [Body Mark Preset] on the right and click [Mark Library] to pop up the body mark library;

please refer to the setting methods of annotation library described in the previous section.



8.1.6.2 Mark property Settings

Click [Mark property] to conduct settings of body mark attribute, including: displaying or non-displaying the probe marking, erasing the annotation when the image is unfrozen, copied to the sliding side with multiple images and displaying or non-displaying body mark background, etc.



Parameter	Description
Probe Mark Display	When selected, the probe mark will be displayed in the body mark; otherwise it will not be displayed.

Parameter	Description
Copy to active side in multiple image	When selected, the body mark will be erased when the image is unfrozen; otherwise it will not be erased.
Erase When Image is unfrozen	When selected, the system will copy the body mark to the active images in the multiple images; otherwise it will only appear on the current image.
Body Mark Background	Select the body mark background display: transparent and non-Transparent.

8.1.7 Network Preset

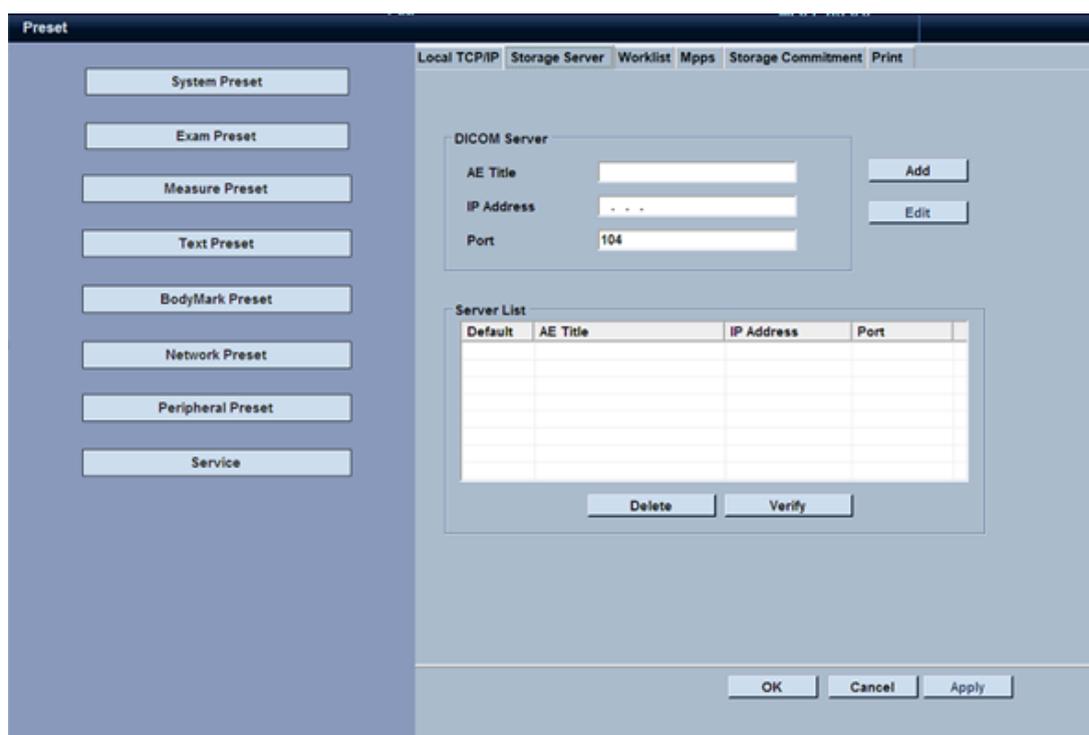
8.1.7.1 TCP/IP Settings

Click [Network Preset] on the left menu and then click [Local TCP/IP]; the system can input IP connection network, and can also enter the host name of the ultrasonic system, IP address, and set DICOM, including the following parameters in the table below:

Parameter	Description
Host Name	Host name of the ultrasonic system
IP Address	IP address of the ultrasonic system host
Subnet Mask	Subnet mask of the ultrasonic system host
Gateway	Default gateway of the ultrasonic system host
AE Title	Application entity title of local DICOM service
Port	Store service port number (local port number). 104 by default
PDU	Largest PDU packet size and range: 16k to 64k. If the settings are beyond this range, the system will set 32k by default.

8.1.7.2 Storage Server Settings

Click [Storage Server] above the menu to pop up the DICOM server settings.



Operation methods of connecting storage server:

1. Connect the system to the hospital network with a network cable;
2. Click [Local TCP/IP], and we can automatically obtain or manually input IP address for the ultrasonic system according to various network connection and based on our needs;
3. Enter AE Title, Port and PDU of DICOM of the ultrasonic system;
4. Then click [Storage Server] to input AE Title, IP Address and Port of DICOM of the storage server. The IP address is the IP address of the server, and the port is generally 104 by default;
5. Click [Add], and the server will be displayed in the server list;
6. Select the added server in [Server List], and then click [Verify] to test the connection between ultrasonic host and storage server, and pop up relevant prompts.

Re-add, modify and delete the server:

- Re-add: the ultrasonic system can be connected with multiple servers, and when you want to connect the system to other servers, you can modify AE title, IP address and port of DICOM, then click [Edit];
- Modify: If you want to modify the servers in the list, select the desired storage server entries in the list; after modification, click [Edit] for modifying and saving;
- Delete: Select a storage server entry in the list, and click [delete] to remove the server.

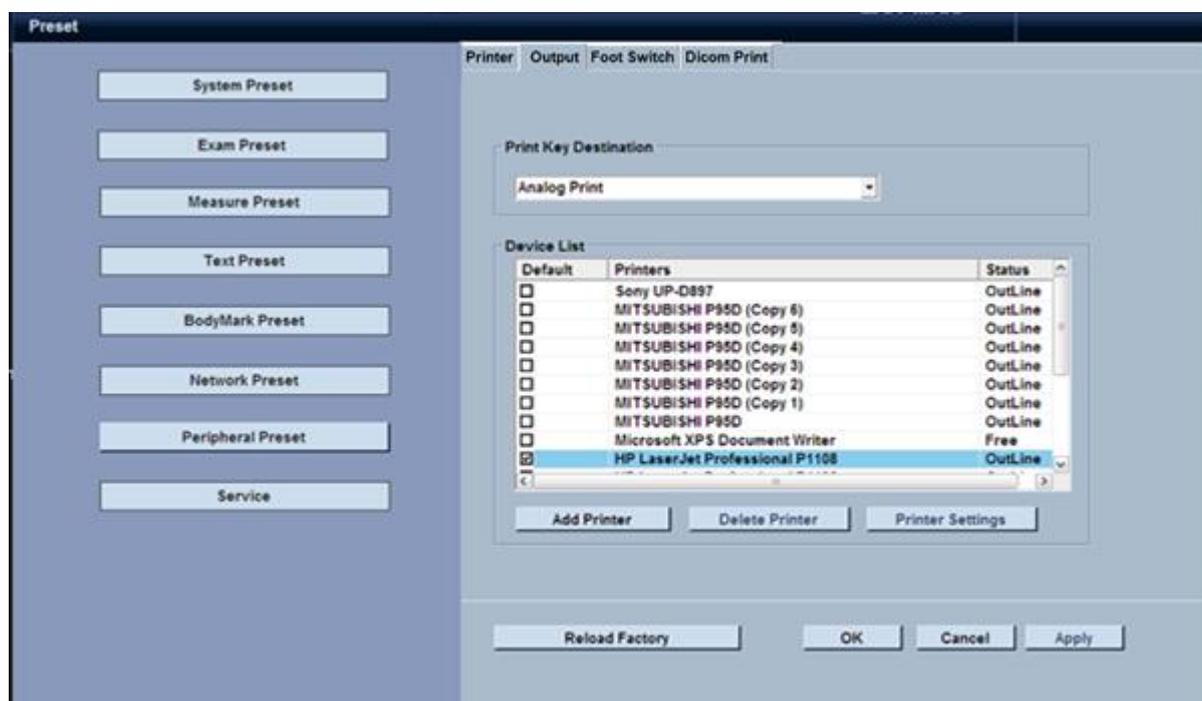


Note: The server Settings of Worklist, MPPS, storage commitment, and printing interface are the same as above.

8.1.8 Peripheral Preset

8.1.8.1 Printer Setting

Click [Peripheral Preset] on the right and click [Printer] on the top of the screen.



Printing device selection: In accordance with differences of peripheral signal ports, the printers can support:

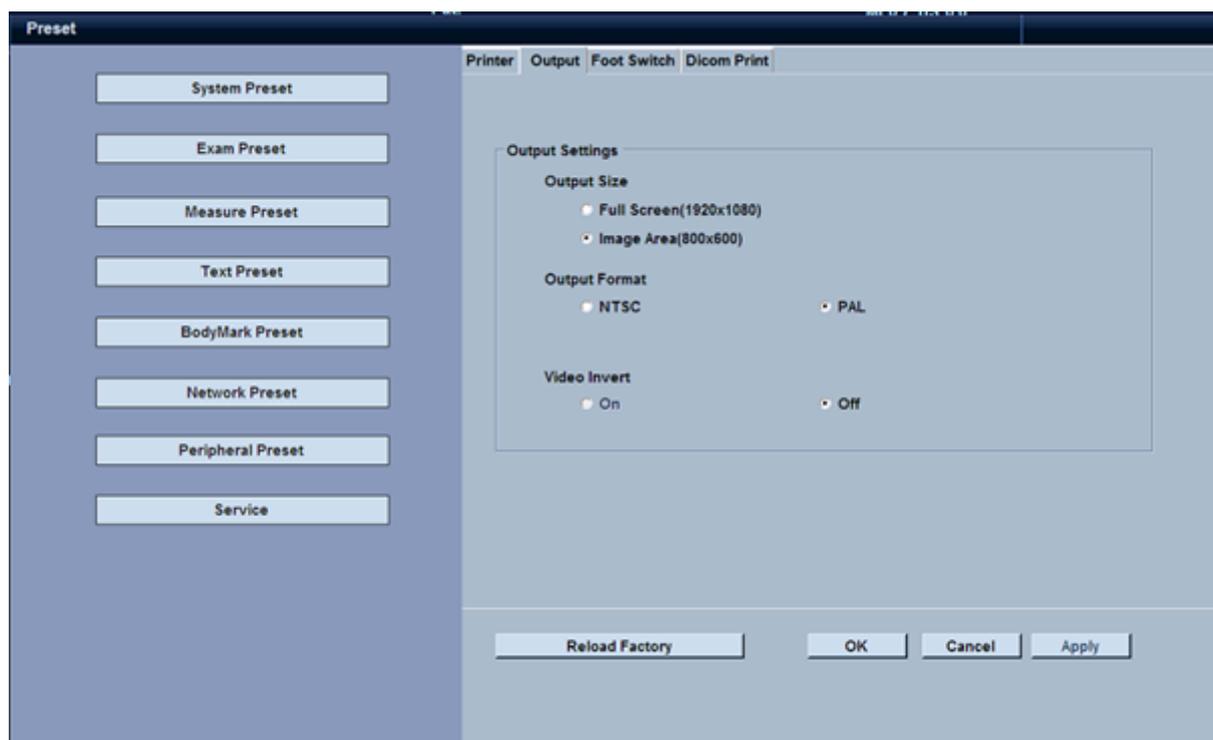
- Numeric Print: to print numerically (including picture and text print and digital video print):
- Analog Print: to print analog videos.
- Disk Storage and DICOM Storage: When choose this and return the interface, press [print], the Image will be stored in Disk and send to DICOM.

Add Printer: click the button to enable "Add Printer Wizard". You can add the printer driver from the system or optical disk according to your needs; after the completion of adding, the list will show the added printer model and status information (see Chapter 6 Add Printer).

Remove Printer: select a printer from the printer list, and click [Delete] to remove the printer.

8.1.8.2 Output Setting

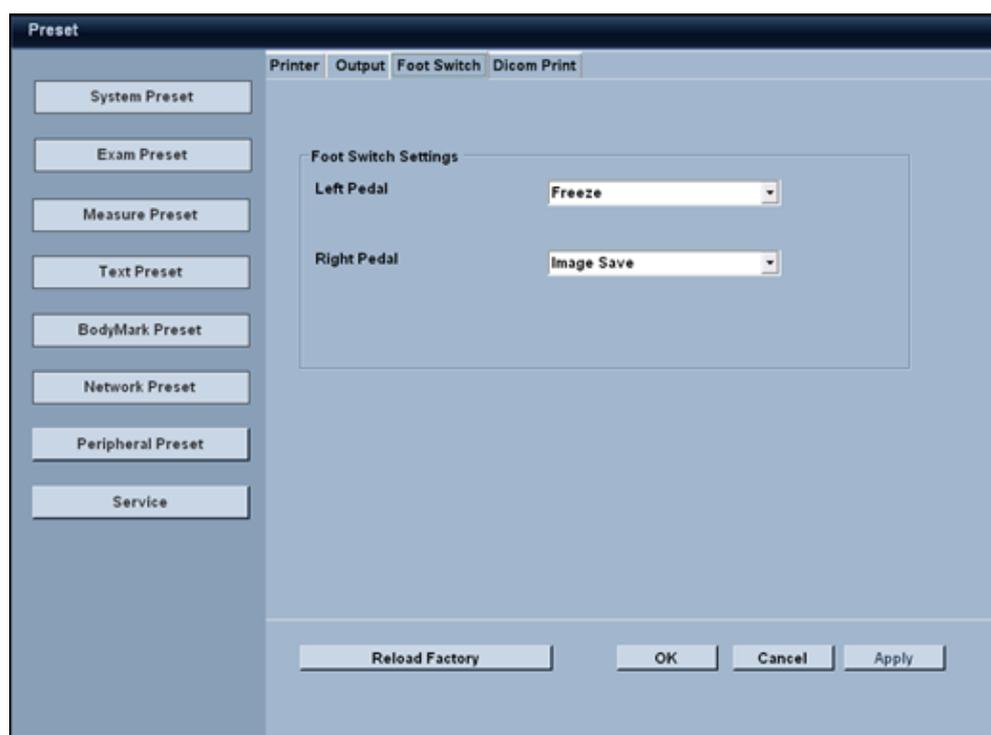
Click [Output] on the top the screen to carry out relevant output settings.



Parameter	Description
Output size	You can set two types of video signal output sizes: Full-screen (1920* 1080); image area (800 * 600).
Output Format	Select the standard for video printer output. PAL, NTSC
Video Invert	After video reserve is started, and if the video output is full-screen, the image area remains unchanged, and non-image video signal will be reverse; if [image area] is selected, the video inverse will be automatically restricted to close, that is, the video reserve would only be enabled in full- screen output.

8.1.8.3 Foot Switch Settings

Click [Foot Switch] on the screen menu to carry out settings of None, Freeze, Image Save, Cine Save, Print and so on to left pedal and right pedal.



This system can connect a USB footswitch to replace some control panel keys. Before connect you need to setup the footswitch as below:

Connect the footswitch to a computer, and insert the footswitch driver to define the key. Define CTRL+ SHIFT+ Left key as left pedal, CTRL+ SHIFT+ right key as right pedal.

- Connect the footswitch
 1. Connect the footswitch to the USB port of the system.
 2. Preset the footswitch function as shown above the figure.
 3. Step on the footswitch in the main surface to perform the function.

8.1.8.4 DICOM Print

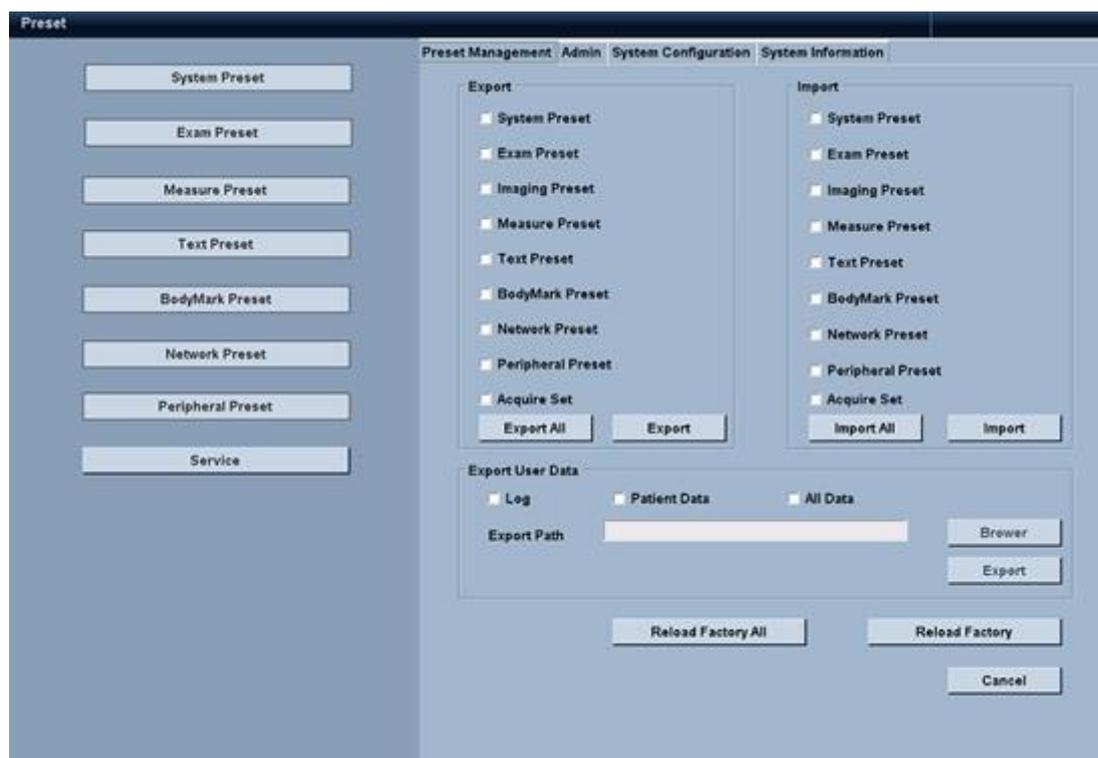
To set DICOM print detailed Settings, such as orientation, layout, copies, magnification, etc.

8.1.9 Service Preset

Click [Service Preset] on the left menu to preset the system setting management, user management and system information.

8.1.9.1 Preset Management

Click [Preset Management] on the top of the screen to carry out import and export management of the preset data.



Export Preset Data

1. You can select one or more of the preset data to export to the system;
2. Select one or more of the preset data to be exported in the export list;
3. Click [Export] to pop up the dialog box [Export Setting];
4. Choose the location and the file naming rule is: YYMMDD-HHMMSS.dat, and users can click [File Name] in the export preset menu to revise the file name, which cannot be opened for revising.
5. Click [OK] to complete export and return to preset interface.

Import Preset Data

Preset data import and export are the two opposite processes, therefore identify the location of the files for data import, and click [Set] after data import, then the system will restart to carry out preset data settings according to the imported data.

Export user data

1. select Log / patient Data / All Data
2. select the location to be stored
3. click the [Export] button to pop up the export completed prompt box
4. click [OK] to complete the export, return to the preset interface



Note: Before importing preset, please save the measurement data; otherwise the system restart will lose data.

8.1.9.2 Admin

If Enable user access control is checked, user access control is activated, user name and password will be needed to enter system operation.

8.1.9.3 System configuration

To view the current device identifier, import product key and system configuration information.

8.1.9.4 System Information

Click [System Information] on the top of the screen to view software and hardware version information of the current system.

8.1.10 Acquire Settings

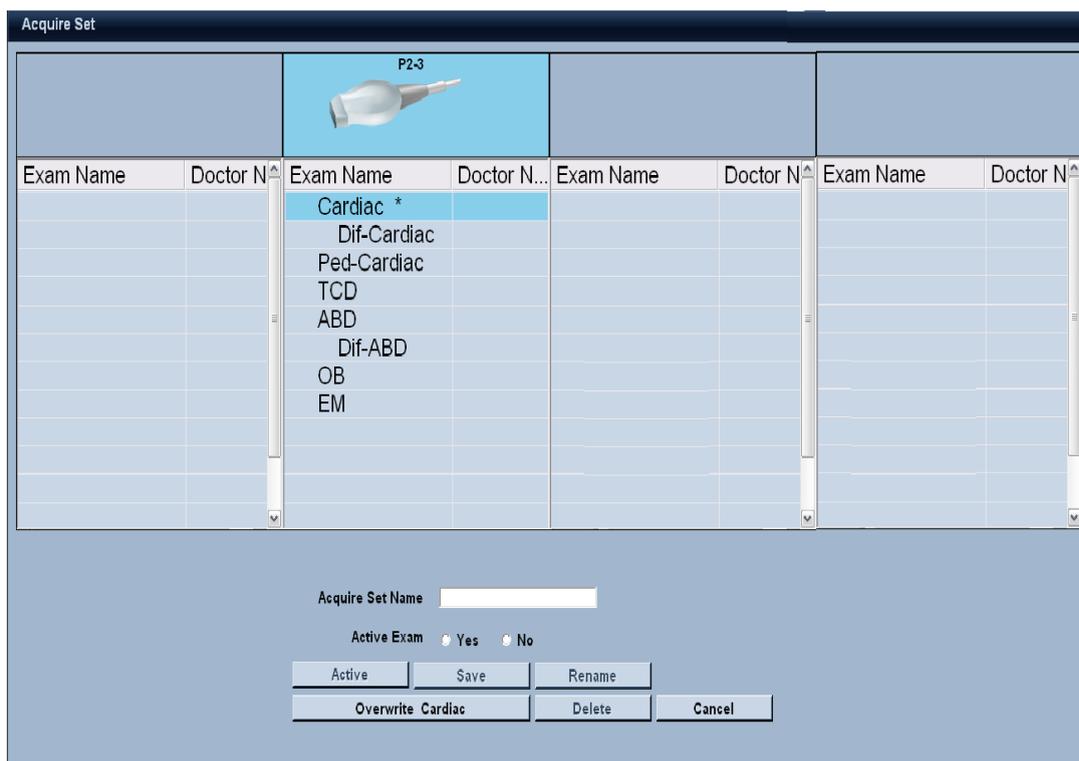
The acquire setting can be accessed through touchscreen keyboard [Capture] or user define key on the control panel.

- Click [keyboard] on the touchscreen, then press [Capture] on the touchscreen keyboard.
- Click [Setting] on the touchscreen, then <User Defined> to set one of the user defined key function as acquire set.

Click [Capture] on the touchscreen keyboard, or press the preset user define key on the keyboard to pop up the [Acquire Set] interface, which is similar to [Probe], which is the exam of system configuration while the Acquire setting is the custom exam created by users.



Note: In system preset, note whether 'quick save acquire set' is selected, see <8.1.3 Exam Preset>. If selected, Click [Capture] or the user define key can only save the current parameters as the default setting of current exam mode.



Customize Exam Method:

1. Users can press [Probe] to carry out selection of items.
2. In the course of exam, you can regulate imaging parameters through the software so as to achieve a satisfactory image quality;
3. Click [Capture], or press the user define key to enable the capture of imaging condition and input the corresponding name of acquire setting, then press [Save] to save the imaging conditions; which can be displayed in the interface of [Probe], and can be used as the imaging condition by users. Likewise, measurement library, annotation library and mark body library related to exam can be accordingly copied to the new exam item.
4. When clicking [Active], the system will pop up a message to prompt whether to set it as the default setting; when clicking [Delete], you can only delete the User Defined, but cannot delete system exam; click [Cancel] to return to the main interface without saving settings.

Chapter 9 Maintenance

9.1 Caring for the System

It is the responsibility of the user to verify that the ultrasound system is safe for diagnostic operation on a daily basis. Each day, prior to using the system, performs the steps of the Daily Checklist.

All exterior parts of the system, including the control panel, keyboard and probe, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect the components to kill vegetative organisms and viruses.

9.1.1 Daily Checklist

Complete the following each day before using the system:

- Visually inspect all probes. Do not use a probe which has a cracked, punctured, or discolored casing, or a frayed cable.
- Visually inspect all power cables. Do not turn on the power if a cable is frayed or split, or shows signs of wear. Contact your dealer for replacement of the power cable if a cable is frayed or split, or shows signs of wear.
- Verify that the trackball, TGC sliding controls, and other controls on the control panel are clean and free from gel or other contaminants.

Once the system is powered on:

- Visually check the on-screen displays and lighting.
- Make sure the monitor displays the current date and time.
- Verify that the probe identification and indicated frequency are correct for the active probe.

9.1.2 Maintenance



Note: To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 12 months. Electric safety test must be performed at periodic intervals according to the local safety regulations or as needed.

Repair:

For the repair or replacement of system equipment parts, please contact Lanmage or your dealer.

Lanmage Authorized Care:

Installers and operators must observe any statutory regulations that govern the installation, operation, inspection and maintenance of this equipment.

To ensure the safety of patients, operators, and third parties, you must check this equipment every 12 months, and replace any component if necessary. This maintenance must be performed by a qualified Lanmage authorized representative. It is important to inspect the equipment more frequently if it is operated under extraordinary conditions. Check and maintenance must be performed at specified intervals to avoid any part becoming hazardous due to wear. Contact the Lanmage service department for information regarding the required maintenance. As manufacturers and installers of ultrasound equipment, Lanmage cannot assume responsibility for the safety properties, reliability, and/or performance of the equipment if:

- Installations, extensions, readjustments, modifications, additions, or repairs are carried out by persons not specifically authorized by Lanmage.
- Components that affect the safe operation of the system are replaced by parts not authorized by Lanmage.
- The electrical installation of the room where the equipment is located does not meet the power and environment requirements specified in this manual.
- The equipment is not used in accordance with the operation instructions.
- The probe is non-factory configuration.
- The system is operated by persons who do not receive good education or training.

Lanmage suggests that you request any person that performs maintenance, or repairs, to provide you with a certificate showing:

- The nature and extent of the work performed
- Changes in rated performance
- Changes in working ranges
- Date of service
- Name of the person or firm performing the service
- Signature of the person performing the service

Lanmage refuses any responsibility whatsoever for repairs performed without the express written consent of the Lanmage.

9.2 Cleaning and Disinfecting System Parts

If the system is in operation, you should regularly (daily) clean the system.

Before cleaning and disinfecting the system, check to make sure that the system is turned off and unplugged. Regularly clean the external surfaces of the system parts with a soft cloth. Wipe the system body with a water-moistened cloth or cotton swab. Where required, you can wash system components with soapy water.

When cleaning, avoid any excessive watering of the system parts cleaned and the entry of liquid solutions inside the system via vents. If this is the case, allow the system to dry for the

appropriate time before you turn the system on.

Clean the external filters located on the fans of the back panel of the system once a month.

Replace them if required with those from the spare parts kit.

Perform the maintenance of the components of the system by such methods and in such time as directed in their service documentation.

If a printer is included in the system, check the cartridge state and replace it if required.

Inspect periodically the paper bin and the paper feed roll.

Cleaning and Disinfecting the System:



Note: To avoid electrical shock and damage to the ultrasound system, always power off and disconnect the equipment from the AC power source before cleaning and disinfection.



Note: Do not pour any fluid onto the system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.



Note: remove gel residuals out of the probe after each use!



Note: To avoid the possibility of static shock and damage to the system, avoid the use of aerosol spray cleaners on the monitor screens.

To clean the system surfaces:

1. Power off the ultrasound system and disconnect it from the power source.
2. Use a clean gauze pad or lint-free cloth, lightly moistened with a mild detergent, to widen the surface of the ultrasound system. Take particular care to clean the areas near the trackball and the slide controls. Ensure these areas are free of gel and any other visible residue.
3. After cleaning, use a clean, lint-free cloth to dry the surface.
4. After cleaning, reconnect the ultrasound system to the power supply.

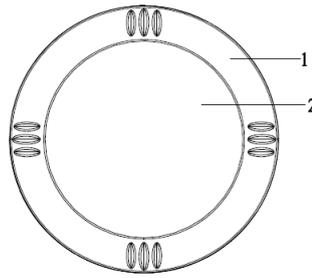
To remove and clean the holders for probes and coupling agent (gel):

Use neutral cleaning agent to clean the surfaces of the holders for probes and coupling agent, and then use a piece of lint-free cloth to dry them.

To clean the trackball



Note: Do not drop or place foreign objects inside the trackball assembly. This may affect the trackball's operation and damage the system.



1. Trackball bezel
2. Trackball

Disassemble the trackball

1. Rotate the trackball bezel clockwise and lift up to remove the trackball bezel from the trackball assembly.
2. Remove the trackball out of the trackball assembly.

Cleaning

- Clean the bezel and trackball with a cotton swab or lint-free pad moistened with mild detergent solution.
- Clean the inside of the trackball assembly, using a cotton swab moistened with mild detergent solution.
- Allow the trackball components to completely dry before reassembly.

Reinstall the trackball and replace the trackball bezel

1. Place the trackball inside the trackball assembly.
2. Place the trackball bezel over the trackball.
3. Use the bezel fastener to aim at the trackball slot, Press down and counterclockwise the bezel until it snaps into position.

9.3 Caring for and Using` Probes

9.3.1 Using Probes

Before you begin using the system, inspect all the probes on a daily basis. Do not use the probe with cracks in the probe or connector shell, or cuts, gouges or swelling of lens material or in the event of signs of damage to the cable.

Immediately clean and disinfect the probe after each use to avoid the infection of patient and operator during exam.

Cuts in the probe cable or cracks in the probe or connector shell can destroy the electrical safety features of the probes.



Caution: Ensure surfaces of the probe are always disinfected during procedures requiring

disinfection.

 **Caution:** To minimize the risk of cross contamination and infectious diseases, Endocavity and intraoperative probes must be cleaned and high-level disinfected after each use.

 **Caution:** The outer surfaces of an Endocavity or intraoperative probe should be checked to ensure there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard.

 **Caution:** Probes are sensitive devices—irreparable damage may occur if they are dropped, knocked against other objects, cut, or punctured. Do not attempt to repair or replace any part of a probe.

 **Caution:** To avoid cable damage, do not roll the system over probe cables.

 **Caution:** Do not use probe sheaths containing oil-based coatings or petroleum- or mineral oil-based ultrasonic coupling agents. Use only water-based ultrasonic coupling agent.

 **Caution:** Take extreme care when handling or storing probes. They must not be dropped, jarred, or knocked against other objects. Do not allow probes to come into contact with any sharp-edged or pointed object.

 **Caution:** Do not attempt repairing or modifying probe Parts!

 **Caution:** Maintenance and repair should only be carried out by the duly authorized personnel. Do not attempt opening the probe or connector. This could void your warranty!

 **Caution:** All probes, no matter what their design is, are sensitive to strikes. And therefore, handle them with care. Pay attention to any cracks, through which a current-conducting liquid can enter the probes!

 **Caution:** Prevent twisting, kinking, and looping of the probe cables, as well as protect them from exposure to mechanical factors, in particular, from getting to under equipment wheels or feet!



Caution: Damage to the probe due the above causes could void your warranty!



Caution: The system and probes should be inspected regularly for damages by the duly authorized personnel!



Warning: Damages to the probe or probe cable can affect safe operation of the system and therefore, repair them immediately!

You should inspect periodically the probes on the following signs of damage (pins shouldn't be bent or damaged). When you are not using the probe, place it in the probe holder located on the side on your system to assure safe, convenient storage.

To improve acoustic contact, use only a special ultrasound transmission gel. Never use the following substances to improve acoustic contact:

1. Mineral oils;
2. Mineral oil based gels;
3. Gels containing lotions or any softeners;

9.3.2 Cleaning and Disinfection

Cleaning

Remove gel residuals out of the probe after each use. Where required, wipe the probe and cable with a water-moistened gauze pad. Wipe the probe by any of the recommended disinfectant. Remove disinfectant solutions residuals out of the probe with a water-moistened gauze pad. Do not allow the disinfectant solution drying up on the probe. Do not wipe the working surface of the probe with hard material, do not use a stiff brush to clean the probe, and do not scrape gel residuals with sharp tools.

Disinfection

You should disinfect the probe after the probe lens contacts affected tissues, mucous membranes and blood. The essential disinfection level of the ultrasound probe is defined by tissue type, probe contacted with.

- Unplug the probe.
- Sterilize the probe with isopropanol in terms of requirements.

To prevent probe damage, follow the immersion depth guidelines for each probe type.



Caution: To avoid electrical shock and damage to the system, disconnect the probe prior to cleaning or disinfecting.

 **Caution:** Do not immerse the probe cable or the connector housing in liquid and prevent them from soaking!

 **Caution:** Do not immerse the probe in a disinfectant for more than 1 hour! Wipe the residual of disinfectant solution, if any, from the probe with a clean cloth which dips in water. Then cool the probe to room temperature. Do not air dry the disinfectant solution on the probe. After disinfection, wipe the probe with a dry clean cloth. When cleaning, avoid any the

 **Caution:** Never sterilize the probe with sterilization techniques such as gas or heat sterilization techniques. It can cause the serious probe damages!

 **Caution:** Do not use abrasive cleaning agents, organic solvents such as benzene, isopropyl alcohol, or phenol-based substances, or cleaning agents containing organic solvents to clean or disinfect probes. These substances can damage the probes.

 **Caution:** Do not use a spray cleaner on a probe, as this may force cleaning fluid inside the housing and damage the probe.

 **Caution:** All probes should be cleaned and disinfected prior to their use on each patient. Endocavity and intraoperative probes require high-level disinfection prior to use.

9.3.3 Storage

Store the probes in a clean and dry environment. Extreme temperature or humidity may damage the probes.

9.3.4 Protective Case

Due to the mechanical sensitivity of probes, Lanmage recommends that you always use the probe case when you ship a probe or transport it from one place of exam to another. The case is specially designed to protect the sensitive parts of the probe. Be sure that all parts of the probe are properly placed inside the case before you close the lid.

9.3.5 Helpful Hints for Endocavity Probes

Before use, place an adequate amount of ultrasound transmission gel at the tip of the probe. Place the disposable sheath (contraceptive) over the probe.

After each use, remove the sheath (contraceptive) and place it to a special container for further disposal.



Caution: You must follow the disinfectant manufacturer's instructions carefully.



Caution: Do not immerse the probe in a disinfectant for more than 1 hour!



Caution: Do not use abrasive cleaners, substances based on acetone, phenol, ethyl alcohol, de-chlorinating agents and organic solvents to clean and sterilize the probe!

9.3.6 Protect shell

Because of the mechanical sensitivity of the probe, it is recommended that you use the probe box when you transport the probe or move from one inspection site to another. The box is specially designed to protect sensitive parts of the probe. Before you cover the top of the probe box, make sure all parts of the probe are correctly placed in the box

9.3.7 Caring Coupling Agent



Caution: Before use, examine the coupling agent for any material flaws. Thinning, bulging, or brittleness of the material indicates damage. Any product showing flaws should not be used.

Do not store coupling agent below 5°C nor above 57°C. Coupling agent has a limited shelf life. Before use, examine these products for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.

Appendix A Specifications

A.1 Working, Storage and Transport Environment and Packaging

Storage Environment Requirements:

- Temperature: -20°C ~ + 55°C
- Relative Humidity: 10% to 90% (non-condensing)
- Atmospheric Pressure: 500hPa ~ 1060hPa

Working Environment Requirements:

- Temperature: 5 °C ~ 40 °C
- Relative Humidity: 30% to 85% (non-condensing)
- Atmospheric Pressure: 700hPa ~ 1060hPa

Transport Environment Requirements

- Temperature: -20°C ~ + 55°C
- Relative Humidity: 10% to 90% (non-condensing)
- Atmospheric Pressure: 500hPa ~ 1060hPa

Protective Measures:

- Liquid Protection: This system does not have the function of liquid protection;
- Heat Protection: There are two fans installed on the back of the system host for heat protection.

Packaging and Size:

- Size: 995x590x1380 mm³ (machine);
1050x700x1580 mm³ (including packaging).
- Weight: 95 kg (N.W.); 139kg (G.W.)



Note :

1. Far away from equipment with strong electric and magnetic field and high voltage;
2. Avoiding the exposure of the screen in direct sunlight; light shielding indoors for easy observation; good ventilation and anti-dust measures;
3. Operate system in the environment GB/T14710-93 specifying for.

A.2 Probe Surface Temperature

Probe Type	Surface Temperature (°C)
Output size	You can set two types of video signal output sizes: Full-screen (1920* 1080); image area (800 * 600).
C1-5 Convex Probe C2-5 Convex Probe	≤ 41;
4C2-5n Convex Probe	< 41;
P1-4 Phased-array probe P2-3 Phased-array probe	< 41;
EC4-9 Convex Probe C4-9ER Convex Probe	< 41.
C4-9MCCConvex Array	< 41.
L5-10 Linear Probe L4-13 Linear Probe	< 41.

A.3 Monitor

Monitor:	High-resolution 21.5" TFT LCD, no interlaced scan.
Resolution:	1920 x 1080 pixels.
Synchronization:	Horizontal:30 Hz to 70 Hz; Vertical:50 Hz to 85 Hz.
Controlled tilt/rotation:	Tilt angle: Up/down 90; Rotation angle: Left/right 90°.
Safety classification:	Class 1 in accordance with EN60601-1.

A.4 DVD-Drives

CD/DVD-R and CD/DVD-RW drive :	Reading speed: 48x (7.2 Mb/s); Caching: 2M; Writing speed: CD-R: 48x (7.2 Mb/s); CD-RW: 32x (4,8 Mb/s); DVD+/-R 20X DVD+RW 8X Access time:100 ms
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A.5 Power Supply

Mains voltage:	100-240V~ , 50/60HZ , 5.5-2.5A
Power supply requirements:	Standard power supply
Power requirement:	Max. rated power requirements: 500 VA including regular and additional equipment connected to outlets on a circuit, and consuming in the aggregate not more than 220VA
Outlets:	Monitor, Printer, AUX voltage: 100-120V~ , 50/60HZ , 5.5-4.5A 200-240V~ , 50/60HZ , 3.0-2.5A. Output power: Monitor 100 VA; Printer :100VA; Acoustic system :20 VA Acoustic system 20 VA AUX 20 VA.

A.6 Imaging Modes

A.6.1 B Mode

Imaging Mode	B, real-time 2B, non-real-time 2B,4B
Frequency	2.5MHz~5 MHz
DR	30~120
Persist	0~4
Maximum Scan Depth	31cm
R/S	0~3
Colorize	0~15
Fov	19.2~36.1fps
Rejection	0~5
Smooth	0~3
LanSRI	0~4
Map	A~P
Flip	U/D,L/R
LanTissue	Normal, Liquid, Fat, Muscle
Frame counter	1055

A.6.2 M Mode

Imaging Mode	B/M, Full-M
Frequency	2.5MHz~5 MHz
DR	30~120
Sweep	1~7
LanSRI	0~3
Colorize	0~15
Map	A~P
Rejection	0~5

A.6.3 Color Mode

Imaging Mode	Color, 4B, Real-time 2B
Frequency	2.2MHz~2.6 MHz
PRF	3.97KHz~175.07Hz
LanFlow	L,M,H
R/S	0~3
Map	A~H
Persist	0~4
Filter	0~4
Smooth	0~3
Invert	Available
Sensitivity	L,M,H
Peak	off,1,2,3

A.6.4 PDI Mode

Imaging Mode	PDI, 4B, Real-time 2B
Frequency	2.2MHz~2.6 MHz
PRF	5.44KHz~239.90Hz
LanFlow	L,M,H
R/S	0~3
Map	A~H
Persist	0~4
Filter	0~4
Priority	0~4
Smooth	0~3
Sensitivity	L,M,H

A.6.5 PW Mode

Imaging Mode	B/PW, Full-PW
Frequency	2.2MHz~2.6 MHz
PRF	15.87KHz~732.49Hz
Gate	0.5~20
Colorize	0~11
DR	30~60
Filter	0~4
Angle	-60~60
Invert	Available
Map	A~H
Rejection	0~5
Sweep	1~7
Auto Trace	Off, Up, Down
Tri Plex/Duplex	On, Off
Format	V1:1,V1:2,V2:1,H2:3

A.7 Regulatory Compliance

Item	Scope	Number of standard	Name of standard
1	General, Safety	EN 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
2	General, EMC	EN 60601-1-2	Medical electrical equipment --Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic disturbances - Requirements and tests
3	General, Usability	EN 60601-1-6	Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance –Collateral standard: Usability.
4	General, Usability	EN 62366-1	Medical device –Part 1: Application of usability engineering to medical devices

Item	Scope	Number of standard	Name of standard
5	Safety	EN 60601-2-37	Medical Electrical Equipment Part 2-37: Particular Requirements for the basic safety and essential performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
6	General, Software	EN 62304	Medical device software – Software life-cycle processes.
7	Acoustic output	EN 61157	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
8	Risk management	EN ISO 14971	Medical devices- Application of risk management to medical devices.
9	Labeling	EN ISO 15223-1	Medical devices - symbols to be used with medical device labels, labeling and information to be supplied.
10	Information	EN 1041	Information Supplied by the Manufacturer for Medical Devices
11	Biological evaluation	EN ISO 10993-1	Biological evaluation of medical devices—Part 1 : Evaluation and testing within a risk management process.
12	Biological evaluation	EN ISO 10993-5	Biological evaluation of medical devices-- Part 5:Tests for in vitro cytotoxicity
13	Biological evaluation	EN ISO 10993-10	Biological evaluation of medical devices-- Part 10:Tests for irritation and skin sensitization