

# Product safety and performance information

## Product information

Product name: Digital Color Doppler Diagnostic Scanner

Model: Galaxy 7、 Galaxy 7S、 Galaxy 7 Exp、 Galaxy 8、 Galaxy 8S、 Galaxy 8 Exp、 Galaxy 9、 Galaxy 9S、 Galaxy 9 Exp、 Lux 8、 Lux 8S、 Lux 8 Exp、 Lux 9、 Lux 9S、 Lux 9 Exp、 Sonus 5、 Sonus 5S、 Sonus 5 Exp、 Sonus 5 Max、 Sonus 5 Pro、 Sonus 5 Super、 Sonus 6、 Sonus 6S、 Sonus 6 Exp、 Sonus 6 Max、 Sonus 6 Pro、 Sonus 6 Super、 CV95、 CV95 Exp、 CV95 Max、 CV95 Pro、 CV95 Super、 CV90、 CV90 Exp、 CV90 Max、 CV90 Pro、 CV90 Super、 CV85、 CV85 Exp、 CV85 Max、 CV85 Pro、 CV85 Super、 CV80、 CV80 Exp、 CV80 Max、 CV80 Pro、 CV80 Super、 CV76、 CV75、 CV75 Exp、 CV75 Max、 CV75 Pro、 CV75 Super、 CV72、 CV70、 CV70 Exp、 CV70 Max、 CV70 Pro、 CV70 Super、 CV69、 CV68、 CV63、 CV65、 CV65 Exp、 CV65 Max、 CV65 Pro、 CV65 Super、 CV60、 CV60 Exp、 CV60 Max、 CV60 Pro、 CV60 Super、 CV55、 CV55 Exp、 CV55 Max、 CV55 Pro、 CV55 Super、 CV50、 CV45、 CV40、 CV39、 CV38、 CV36、 CV35、 CV33、 CV31、 CV30.

Usage period: 10 years.

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## Safety signs

In this manual, the safety signs “ **DANGER**”, “ **WARNING**”, “ **CAUTION**” and “ **NOTE**” are used regarding safety and other important instructions. The safety signs and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

 **DANGER**: Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury. Do not proceed to any further operation until the specified conditions are fully understood and satisfied.

 **WARNING**: Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury. Do not proceed to any further operation until the specified conditions are fully understood and satisfied.

 **CAUTION**: Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. Do not proceed to any further operation until the specified conditions are fully understood and satisfied.

 **NOTE**: Indicates a potentially hazardous situation that, if not avoided, may result in property damage. Do not proceed to any further operation until the specified conditions are fully understood and satisfied.

#### **Check the provided accessories**

After opening the package box, please check if the accessories are complete and undamaged.

- **If there are incomplete or damaged accessories, please contact your supplier immediately.**
- **Unintentionally opened before use , please contact your supplier immediately.**
- **If the packaging is exposed to environmental conditions outside of those specified, please contact the Lanmage staff immediately for handling.**
- **The list of accessories depends on your purchase contract.**

 **NOTE**: The hard drive is a vulnerable item. To facilitate the retrieval of historical data, it is recommended to backup important data in time.

 **NOTE**: To ensure the normal operation of the system, it is necessary to clean the dust from the dustproof mesh and ventilation grille once per month.

When the machine malfunctions, please contact your supplier or manufacturer promptly for repair.

 **WARNING**: This equipment must be operated by skilled/trained clinical professionals.

 **NOTE**: Under no circumstances shall Lanmage be responsible for any problems, damage, or loss caused by reinstallation, modification, or repair of this system by personnel other than personnel designated by Lanmage.

 **NOTE:** This system aims to provide doctors with the data needed for clinical diagnosis. Doctors are responsible for the diagnostic process. Lanmage assumes no responsibility for the diagnostic process.

 **NOTE:** This user manual contains warnings about foreseeable potential hazards. Be alert at all times to dangers that are not stated. Lanmage shall not be responsible for any damage or loss caused by negligence or disregard of the preventive measures specified in this user manual.

 **WARNING:** It is forbidden to modify the software or hardware of this product without authorization

System packaging material handling

- **Please keep all the internal and external packaging for transportation and handling.**
- **Please store the inner and outer packaging together.**

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### **Environmental protection**

Lanmage designs the ultrasound diagnostic system according to the requirements of safety and environmental protection. If user does not disassemble the equipment or perform an improper use, the system will not cause any harm to anyone and environment.

 **NOTE:** 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 environmental regulations, the waste generated by ultrasound diagnostic system must be disposed properly, and the obsolete 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 method of local garbage collection facilities.**

### **Requirements for installation site**

- **Install this equipment in an environment with a sound earthing system.**

- **Do not install this system in a place where it is easily exposed to water and chemicals.**
- **Do not install this equipment 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 systems generating strong magnetic field near this system..**

#### **Loss declaration**

- **There are no replaceable parts of this system.**
- **If there is a malfunction, please contact the supplier and do not dismantle the machine without authorization**
- **If the system power fuse is blown, please do not replace it by yourself, which may cause electric shock, and contact the supplier.**

#### **Description of electromagnetic interference**

This system is used in hospitals, physical examination and other places that can provide protection against strong electromagnetic interference and power supply protection. If the ability to resist electromagnetic interference is not good enough, the system will be interfered by radio signals, television signals, or other signals, affecting normal use.

#### **Revision history**

| <b>File Number</b> | <b>Revision</b> | <b>Date</b> | <b>Reason for Change</b> | <b>Comment</b> |
|--------------------|-----------------|-------------|--------------------------|----------------|
| 1818-CE-101        | A/0             | 2026.9      | Initial release          | /              |
|                    |                 |             |                          |                |
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# Chapter 1 Safety Precautions

## 1.1 Safety Information

### 1.1.1 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.



**WARNING:** It is prohibited for the operator of this device to come into contact with the patient and the live parts of this device or other devices connected to it at the same time (such as various signal input and output ports), otherwise it may pose a risk of electric shock to the patient.



**WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a supply AC Mains with protective earth.



**WARNING:** Within a range of 1.5 meters from the operator and patient, the peripheral equipment of the ultrasound diagnosis system is finally powered by an isolation transformer that meets the requirements of IEC 60601-1:2020 or a power supply that proves to have equivalent safety.



**WARNING:** Do not maintain any parts of the equipment when used by patients, as this may pose a risk of electric shock to the operator, patient, and maintenance personnel.



**WARNING:** 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.



**WARNING:** This machine can replace fuses inside the machine and can only be replaced by Lanmage maintenance engineers or Lanmage designated technicians.



**WARNING:** If the circuit breaker and fuse of the socket are the Same as those used in this system and are used to control the current of devices such as life support systems, do not connect this system to this socket. Because once the system operates abnormally or generates over current, or generates instantaneous current during startup, the circuit breakers and fuses of the power supply system are in a protective working state.



**WARNING:** 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:** If there is any doubt about the integrity and reliability of the protective grounding of external power supply, please use the built-in rechargeable battery for power supply, do not use AC power supply.

 **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 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:** This system can only be installed in a medical computer room. This system complies with the "Electrical Safety Requirements" IEC 60601-1:2020.

 **CAUTION:** If the system keeps making alarming sound, please

- **Turn off the system**
- **Contact Lanmage customer service center**
- **If 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.

The operating room should at least occupy an area of 20 m<sup>2</sup>, 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:  $\geq 0.15\text{m/sec}$

Check the state of wall outlets in a regular manner.

Do not remove the plug out of the outlet by pulling the wire.

Do not place any foreign objects on 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 to patients, avoid connecting any peripheral devices with electrical safety performance that does not comply with IEC 60601-1:2020 specifications, such as computers, printers, and other devices. To connect such non compliant peripheral devices, special isolation devices that meet the requirements of IEC 60601-1:2020 should be used.

 **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:** 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:** When it is necessary to electrically or mechanically connect this instrument to any other manufacturer's equipment, please confirm that it complies with the IEC 60601-1:2020 standard and recheck the leakage current and other safety performance indicators of the entire system to avoid potential hazards caused by leakage current superposition.

 **CAUTION:** To make electrical or mechanical connection between this instrument and the equipment of other manufactures, confirm that it complied with the IEC 60601-1-1:1995 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 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 equipment. If it is really necessary to do so, please notify us or our agent.

 **CAUTION:** Operators of the equipment 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 per 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.

### 1.1.2 Ultrasound Safety

General information: the following is a list of some precautions related to ultrasonic safety that Lanmage reminds you to follow when using the diagnostic device.

 **NOTE:** The application part of the device is the probe.

 **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 suitable images for clinical exam.

 **WARNING:** Do not use this device with electronic devices such as high frequency electrotome, high frequency therapy devices or defibrillators. Otherwise, there may be an electric shock to the patient.

 **CAUTION:** Without a doctor's guidance, it is forbidden to use the working ultrasonic probe to directly scan the eyes, otherwise the energy emitted by the probe will cause the injury to eyes.

 **WARNING:** This system is not intended for use in eyebrow, orbit, or other ophthalmic examinations

 **WARNING:** The probe is not allowed to scan the eyes.

 **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 injury to the posterior region of the eye.

 **WARNING:** 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.

 **WARNING:** To avoid any patient health hazard, use probes to examine only those exam zones, where a given probe is intended for.

 **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:** Take caution when contrast substances are used to scan heart, abdominal cavity and other organs. The lower the MI value, the less possible ultrasonic cavitation is.

 **WARNING:** Within a reasonable range, the lowest possible output power should be used. The time of physical examination should not be too long, and only the time necessary to make a diagnosis is limited. Prolonging the use of time will damage the health of the human body.

 **WARNING:** When clinically indicated, the user of the instrument must have adequate knowledge of the acoustic output or be able to obtain the associated thermal index value. The ultrasound probe that can detect its self-heating in the air should not be used for transvaginal exploration; Special **NOTE** should be taken to reduce the radiated acoustic output power and irradiation time to the embryo or fetus.

 **NOTE:** The device can be directly applied to routine examination of the heart.

 **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.

 **NOTE:** 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 in a prudent manner for valid reasons, for the shortest period of time, and at the lowest mechanical and thermal indices necessary to produce clinically acceptable images.

 **NOTE:** 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.

 **NOTE:** In accordance with the principles of ALARA (as low as reasonably achievable), Lanmage recommends that a physician shall select the lowest ultrasound exposure (the lowest ultrasound intensity and exposure time) to produce clinically acceptable images in order to minimize the risk of adverse effects.

 **NOTE:** 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.

 **NOTE:** When making ultrasonic scanning, the equipment 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. In addition, it is important to properly manage and use ultrasound coupling agent to ensure that they do not become a source of infection.

 **NOTE:** When using ultrasound probes, sterile gloves must be worn to prevent infection.

Mechanical Index (MI):

Mechanical Index which indicates the potential for mechanical bio effect is calculated as the peak rare factional 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  $2^{\circ}\text{C}$ ) reflects a greater temperature rise in tissue than  $TI = 1$ . The temperature rise in the actual tissue, however, is not  $2^{\circ}\text{C}$ . 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  $41^{\circ}\text{C}$  (i.e.,  $5^{\circ}\text{C}$

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 cavitation 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 Manual 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 Manual 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 bio effect 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 cavitation effect and therefore, no bio effect 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.

### 1.1.3 Mechanical Safety

 **WARNING:** Pay attention to the casters and control panel, especially when moving the machine. According to different configurations, the estimated weight of the entire machine is 118KG, which may cause harm to people when it rolls over the foot or compresses the tibia. The control panel can be moved left and right. Our company recommends using push instead of pull when moving the machine, and be particularly careful when climbing up and down slopes.

 **WARNING:** Only the probe cable hooks provided by Lanmage can be used.

 **CAUTION:** Ensure all probe cables are safe. 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 casters of the system are equipped with brakes. Pressing the brake with your foot can lock the wheel, while lifting it will open it. Release the brakes 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.

 **CAUTION:** Pay extra attention when moving the system on a sloping ground, do not move it on a more than 10°-sloped plane to avoid system toppling. The slope is shown below:

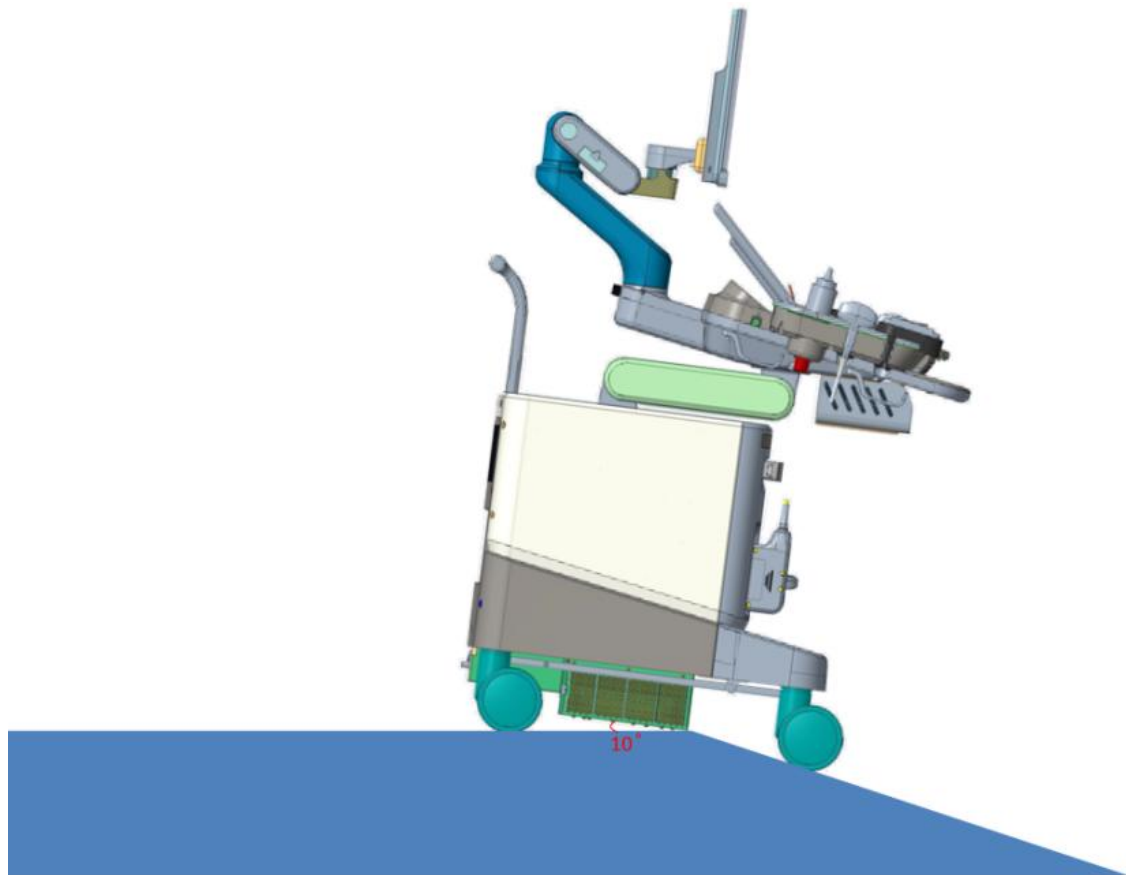


**Fig. 1-1-4-1 Transport Angle**

### **1.1.4 Requirements for installation site**

Please install the instrument in a stable place, away from electric fields, strong magnetic field equipment, and high-voltage equipment. Avoid direct sunlight on the display screen, avoid light indoors to facilitate image observation, and maintain ventilation and dust prevention.

Before placing the system, please carefully read and understand the safety notes to ensure the safety of personnel and equipment.

- 1) Turn off the system power and unplug the power plug;

- 2) Disconnect all non onboard peripheral devices and organize all cables to prevent tripping;
- 3) Loosen the four casters and hold the handle to move the machine;
- 4) After pushing the system to the predetermined position, lock the four casters.



**Note:** Sufficient space must be left behind and on both sides of the machine; otherwise, it will be difficult to operate the disconnection device.



**Note:** Sufficient space must be left behind and on both sides of the machine; otherwise, malfunctions may occur due to the rise in internal temperature.

## 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:

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

Use the power transmission presets of the system.

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

**Table 1-1-6-1 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.

The system has a set of calculation formula that can calculate the surface temperature according to the emission parameters (emission waveform, emission PRF, and voltage), etc. When the acoustic output calculation results exceed the limit value, the emission voltage within the system will be automatically reduced. Users should avoid accidental control Settings and unnecessary acoustic output adjustments.

 **WARNING:** 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 control panel for the application of available keys.

To adjust the transmitting power, turn the corresponding knob of the soft menu [Power] to reduce or increase the transmitting acoustic 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 at all times.

 **NOTE:** In addition to adjust the acoustic 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 C-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;**
- **Probe type;**
- **Using a gel pad;**
- **Operating mode.**

User should keep in mind to avoid unintended adjustment.

### 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 43°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 system supports preset that if the machine is not operated for a certain time, it will automatically cut off the transmission and freeze automatically; The minimum time can be set to 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 Color Doppler Diagnostic 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 is 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 Color Doppler 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 Color Doppler Diagnostic System is given in Table 1.2 to 1.5. The system is designed to be operated in the designed electromagnetic environment.

The essential performance is as follows:

The images are displayed without artifacts or image distortion;

Ultrasound output is within the standard range ( $ISPTA3 \leq 720 \text{mW} / \text{cm}^2$ ,  $MI \leq 1.9$ );

TRANSDUCER ASSEMBLY surface temperature does not exceed  $43^\circ\text{C}$ .

TRANSDUCER ASSEMBLIES intended for intra-corporeal use operate with controlled and intended motion. When the performance of the ultrasound equipment degrades due to electromagnetic interference (EMI), cut off the power supply of the surrounding equipment one by one and observe the recovery of the ultrasound performance; Ensure that the resistance of the grounding wire is  $< 0.1 \Omega$  (wire diameter  $\geq 6 \text{ mm}^2$ ), and the grounding bar is directly connected to the building ground pile; The equipment shall be powered by a dedicated power line and kept away from high - power motors; Lay an anti - static mat on the operation table, and regularly detect the grounding point of the equipment (impedance  $< 4 \Omega$ ).

**Table 1-1-8-1 Electromagnetic emissions**

| <b>Guidance and manufacturer's declaration — electromagnetic emissions</b>                                                                                                                                                                        |                   |                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Digital Color Doppler Diagnostic System is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Color Doppler Diagnostic System should assure that it is used in such an environment. |                   |                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Emission test</b>                                                                                                                                                                                                                              | <b>Compliance</b> | <b>Electromagnetic environment —guidance</b>                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>RF emissions</b><br><b>CISPR 11</b>                                                                                                                                                                                                            | Group 1           | The Digital Color Doppler Diagnostic System uses RF energy only for its internal function. Therefore, its RF emissions is very low and is not likely to cause any interference in nearby electronic equipment.                                                                                                                                                                                                               |
| <b>RF emissions</b><br><b>CISPR 11</b>                                                                                                                                                                                                            | Class A           | The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. |
| <b>Harmonic Emissions</b><br><b>IEC 61000-3-2</b>                                                                                                                                                                                                 | N/A               |                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Voltage Fluctuations/flicker emissions</b><br><b>IEC 61000-3-3</b>                                                                                                                                                                             | N/A               |                                                                                                                                                                                                                                                                                                                                                                                                                              |

**Table 1-1-8-2 Electromagnetic immunity**

| <b>Guidance and manufacturer's declaration — electromagnetic immunity.</b>                                                                                                                                                                         |                                                                                                                                              |                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Digital Color Doppler Diagnostic System, is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Color Doppler Diagnostic System should assure that it is used in such an environment. |                                                                                                                                              |                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                 |
| <b>Immunity test</b>                                                                                                                                                                                                                               | <b>IEC 60601 test level</b>                                                                                                                  | <b>Compliance level</b>                                                                                                                      | <b>Electromagnetic environment — guidance</b>                                                                                                                                                                                                                                                                                                   |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                                                                                                                                                                                                     | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV,<br>±15 kV air                                                                                          | ±8 kV contact<br>±2 kV, ±4 kV, ±8<br>kV, ±15 kV 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<br>IEC 61000-4-4                                                                                                                                                                                                   | ±2kV for power supply lines<br>±1kV for SIP/SOP                                                                                              | ±2kV for power supply lines<br>±1kV for SIP/SOP                                                                                              | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                                                                                             |
| Surge<br>IEC 61000-4-5                                                                                                                                                                                                                             | ±0.5 kV, ±1 kV line to line<br>±0.5 kV, ±1 kV, ±2 kV line to ground                                                                          | ±0.5 kV, ±1 kV line to line<br>±0.5 kV, ±1 kV, ±2 kV line to ground                                                                          | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                                                                                             |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11                                                                                                                                             | 0 % UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % UT, 1 cycle and 70% UT, 25/30 cycles at 0°<br>0% UT, 250/300 cycle | 0 % UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % UT, 1 cycle and 70% UT, 25/30 cycles at 0°<br>0% UT, 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Digital Color Doppler Diagnostic Scanner require continued operation during power mains interruptions, it is recommended that the Digital Color Doppler Diagnostic Scanner be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) Magnetic field<br>IEC 61000-4-8                                                                                                                                                                                         | 30 A/m                                                                                                                                       | 30 A/m                                                                                                                                       | Power frequency magnetic fields/ Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital Proximity magnetic environment.                                                                                                                                                         |
| Proximity magnetic environment. fields<br>IEC 61000-4-39                                                                                                                                                                                           | CW 8A/m for 30kHz<br>Pluse modulation 2.1kHz, 65A/m for 134.2KHz<br>Pluse modulation 50kHz, 7.5A/m for 13.56MHZ                              | CW 8A/m for 30kHz<br>Pluse modulation 2.1kHz, 65A/m for 134.2KHz<br>Pluse modulation 50kHz, 7.5A/m for 13.56MHZ                              |                                                                                                                                                                                                                                                                                                                                                 |

| Guidance and manufacturer's declaration — electromagnetic immunity.                                                                                                                                                                                |                      |                  |                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|----------------------------------------|
| The Digital Color Doppler Diagnostic System, is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Color Doppler Diagnostic System should assure that it is used in such an environment. |                      |                  |                                        |
| Immunity test                                                                                                                                                                                                                                      | IEC 60601 test level | Compliance level | Electromagnetic environment — guidance |
| NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.                                                                                                                                                                      |                      |                  |                                        |

**Table 1-1-8-3 Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF**

| Guidance and manufacturer's declaration — electromagnetic immunity.                                                                                                                                                                                |                                                                                                                                                                                         |                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Digital Color Doppler Diagnostic System, is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Color Doppler Diagnostic System should assure that it is used in such an environment. |                                                                                                                                                                                         |                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                  |
| Immunity test                                                                                                                                                                                                                                      | IEC 60601 test level                                                                                                                                                                    | Compliance level                                                                                                                                                                        | Electromagnetic environment — guidance                                                                                                                                                                                                                                                                                                           |
| Conducted RF<br>IEC 61000-4-6                                                                                                                                                                                                                      | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM bands                                                                                                                                      | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM bands                                                                                                                                      | Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Digital Color Doppler Diagnostic Scanner, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. |
| Radiated RF<br>IEC 61000-4-3                                                                                                                                                                                                                       | 3 V/m<br>80 MHz to 2.7 GHz<br>385MHz-5785MHz<br>Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020) | 3 V/m<br>80 MHz to 2.7 GHz<br>385MHz-5785MHz<br>Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020) |                                                                                                                                                                                                                                                                                                                                                  |

**Table 1-1-8-5 The sample cable information**

| No. | Name             | Cable Length (m) | Whether to block | Magnet ring or not | Type    |
|-----|------------------|------------------|------------------|--------------------|---------|
| 1   | Power Cord       | 3                | No               | No                 | AC Port |
| 2   | Probe Cable      | 2                | Yes              | No                 | SIP/SOP |
| 3   | Footswitch Cable | 3                | Yes              | No                 | SIP/SOP |

| No. | Name                   | Cable Length (m) | Whether to block | Magnet ring or not | Type    |
|-----|------------------------|------------------|------------------|--------------------|---------|
| 4   | Data Acquisition Cable | 2.8              | Yes              | No                 | SIP/SOP |

 **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 IEC 60601-1-2, which is from European standard (IEC60601-1-2). The IEC standard used for European norms in Europe. But the company does not guarantee would never have interference in individual installation environment.

 **Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

 **Warning:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 **Warning:** The ultrasound system cannot be used together with HF surgical equipment.

 **Warning:** The equipment cannot be operated in environments where strong electromagnetic interference exists and is not applicable (such as CT, MRI, operating rooms with HF surgical equipment, etc.).

 **NOTE:** For the following caused circumstances of EMC interference, the manufacturer shall not be responsible for: using the other cables which not recommended. Disassemble or modify the equipment without permission.

 **NOTE:** When operating the system, all of the enclosure should be closed to ensure the integrity of the machine before operating. Operating the system without intact enclosure may affect the system EMC performance.

## 1.2 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 unit for heat protection.



**NOTE:**

Keep away from equipment with strong electric and magnetic field and high voltage;

Avoiding the exposure of the screen in direct sunlight; the room should be shaded to facilitate image observation, and to maintain ventilation and dustproof ;

This system can operate under the environmental conditions specified in IEC 60601-1:2020.



**WARNING:** Do not use, store or transport this system outside the specified environmental conditions.

# Chapter 2 System Overview

## 2.1 User Manual

The user manual introduces the system basic performance, safety precautions, imaging mode, measurement/calculations, probe and the instruction for maintenance of probe and system. And it contains all the necessary and sufficient information for securely operating the system. Within the valid period of agreement, the after-sales service personnel of Lanmage will provide advanced training for operators. Before attempting to use this system, please be sure to read and understand all of the information contained in this manual.



**NOTE:** Please always keep this manual being placed next to the equipment, and periodically review relevant operation procedures and Safety precautions.

## 2.2 Intended Use

### 2.2.1 Intended purpose

The Digital Color Doppler Diagnostic Scanner is applicable for abdomen, GYN, OB, urology, artery, vein and other clinical exams.

### 2.2.2 Indications

The Digital Color Doppler Diagnostic Scanner is applicable for abdomen, GYN, OB, urology, artery, vein and other clinical exams. The Digital Color Doppler Diagnostic Scanner is not intended for ophthalmic use.

### 2.2.3 Target patient populations

The Digital Color Doppler Diagnostic Scanner is intended to be used for adults and children.

Age: not limited;

Gender: not relevant;

Weight: no restrictions for weight of the patients;

Health: Patients who need observation and diagnosis;

Nationality: multiple.

Patient state: Patient is not the Operator.

Clinical benefits

- 1) No ionizing radiation exposure associated with ultrasound imaging.
- 2) Provide non-invasive imaging to support evaluating, diagnosing or treating patients.

### 2.2.4 Intended user

The clinicians, professional medical staffs who have received adequate training of the product and technical service personnel authorized by Shenzhen LANMAGE Medical Technology Co., Ltd.

## 2.3 Contraindication

The Digital Color Doppler Diagnostic Scanner is not intended for ophthalmic use.

## 2.4 Imaging Modes

This system supports the imaging mode of B Mode, C, PDI Mode, PW Mode, CW Mode, M Mode, 3D, 4D Mode, and TDI.

## 2.5 Introduction of Each Unit

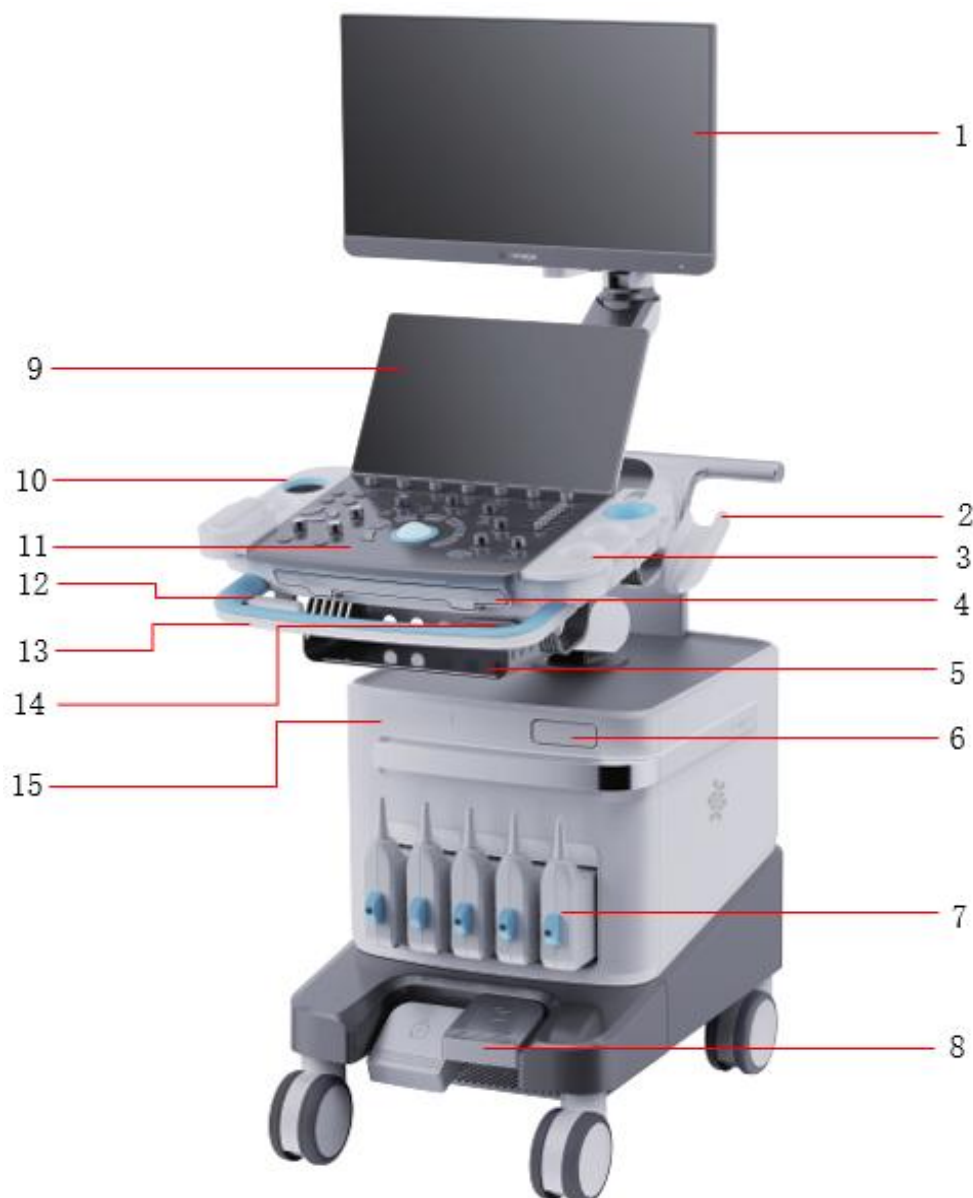


**Fig. 2-5-1 Main view**

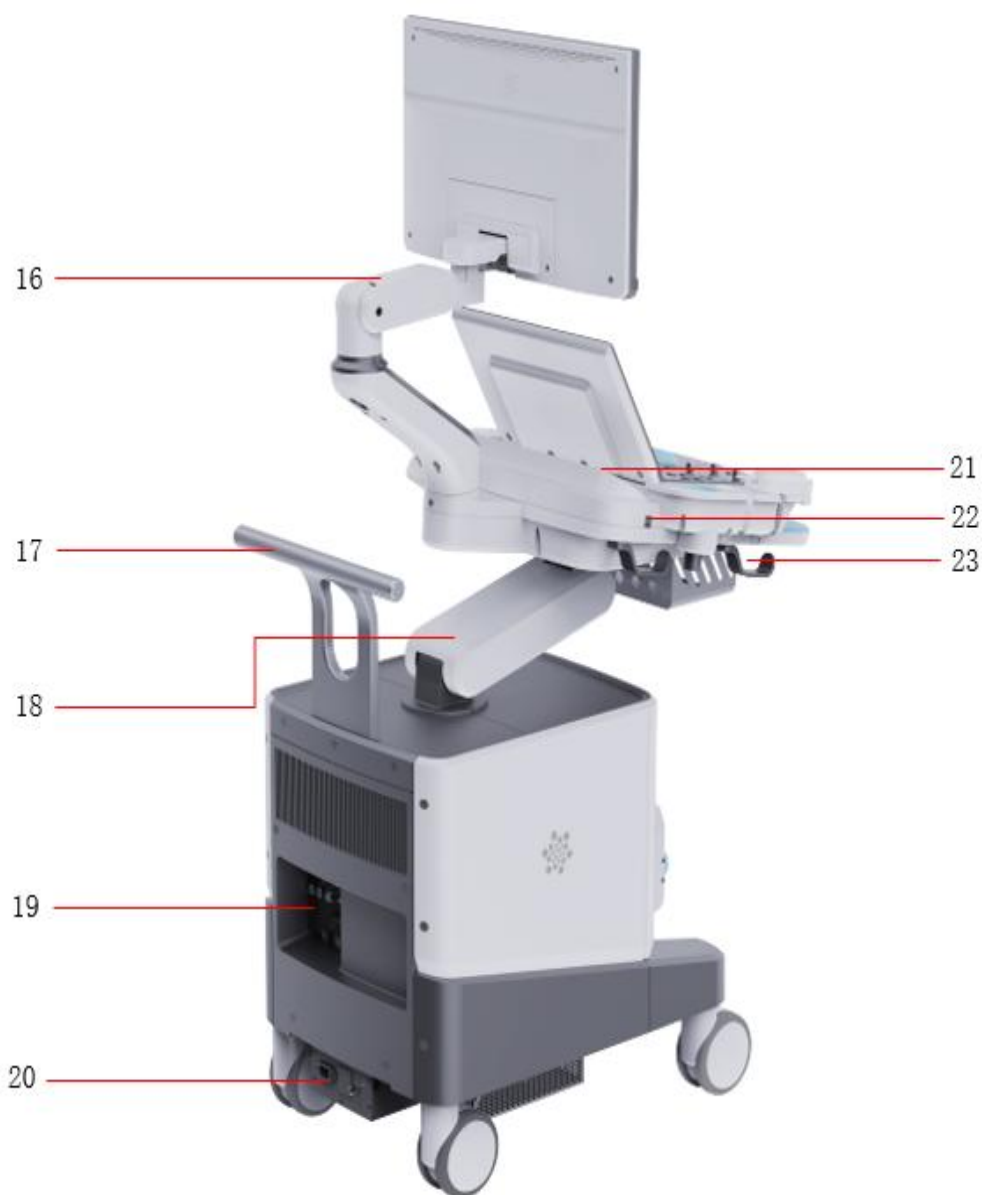


**Fig. 2-5-2 Side view**

**Table 2-5-1 Introduction of Each Unit**

| No. | Name                         | Function                                                |
|-----|------------------------------|---------------------------------------------------------|
| 1   | Monitor                      | Displays the images and parameters.                     |
| 2   | Probe holder (intracavitary) | To place the probe (intracavitary).                     |
| 3   | Probe holder(general)        | To place the general probe, such as convex, linear,etc. |

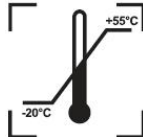
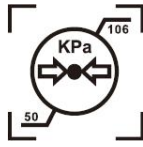
| No. | Name                     | Function                                                                                                                            |
|-----|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 4   | Keyboard                 | Used for input.                                                                                                                     |
| 5   | Storage compartment      | To place small objects.                                                                                                             |
| 6   | ECG and USB ports        | Connects USB devices and ECG module.                                                                                                |
| 7   | Probe sockets            | Connects a probe to the main unit.                                                                                                  |
| 8   | Foot switch              | The left used for braking lock, the right used for unlocking the casters.                                                           |
| 9   | Touch panel              | Used for selection and input.                                                                                                       |
| 10  | Gel Warmer               | Used for placing coupling gel and heating.                                                                                          |
| 11  | Control panel            | Controls operations, such as switching image modes, creating new patients, commenting, reporting, and other operations.             |
| 12  | Switch lever(left/right) | Presses only this lever to adjust console in left or right direction, the range of rotation angle is $-90^{\circ}\sim 90^{\circ}$ . |
| 13  | Front handle             | Used for moving the system.                                                                                                         |
| 14  | Switch lever(up/down)    | Presses two levers simultaneously to adjust console in up or down direction, the height adjustable range is 0~200mm.                |
| 15  | DVD+RW                   | DVD+RW drive.                                                                                                                       |
| 16  | Monitor support arm      | Supports the monitor, for adjusting the height and position of the monitor.                                                         |
| 17  | Rear handle              | Used for pushing and moving the system.                                                                                             |
| 18  | Console support arm      | Supports the console, for adjust the height above the control panel (for adjustment method, please refer to No.14) .                |

| No. | Name               | Function                                                                                                                     |
|-----|--------------------|------------------------------------------------------------------------------------------------------------------------------|
| 19  | I/O panel          | Interface panel used for inputting and outputting singals(for more details about ports, please refer to the section of`2.6`. |
| 20  | Power supply panel | Connects to have power supply and other power unit.                                                                          |
| 21  | Speaker            | Used for sound output.                                                                                                       |
| 22  | USB3.0 port        | Connects USB devices.                                                                                                        |
| 23  | Cable hook         | Probe cable hanger.                                                                                                          |

## 2.6 System Symbols

| Symbol                                                                              | Description                                                                                         |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
|  | AC(Alternating current)                                                                             |
|  | Type-BF applied part                                                                                |
|  | Caution                                                                                             |
|  | Degree of protection against harmful ingress of water for Probe.                                    |
|  | USB Port                                                                                            |
|  | Consult accompanying documents. This symbol advises the user to consult the accompanying documents. |
|  | Serial number                                                                                       |
|  | Date of manufacture                                                                                 |
|  | Manufacturer (This symbol shall be accompanied by the name and address of the manufacturer.)        |
|  | General symbol for recovery/recyclable                                                              |

| Symbol                                                                              | Description                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | CE MARKING                                                                                                                                                                                                                                                                                         |
|    | General warning sign.                                                                                                                                                                                                                                                                              |
|    | Bar code                                                                                                                                                                                                                                                                                           |
|    | Standby status indicator                                                                                                                                                                                                                                                                           |
|    | Battery Status Indicator                                                                                                                                                                                                                                                                           |
|    | This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment according to local regulations. |
|  | No sitting                                                                                                                                                                                                                                                                                         |
|  | No stepping                                                                                                                                                                                                                                                                                        |
|  | No stepping on surface                                                                                                                                                                                                                                                                             |
|  | Probe interface identification                                                                                                                                                                                                                                                                     |
|  | Watch out for the rocker arm                                                                                                                                                                                                                                                                       |
|  | EU Authorised Representative                                                                                                                                                                                                                                                                       |
|  | The correct upright position of the distribution packages for transport and/or storage.                                                                                                                                                                                                            |
|  | Fragile, handle with care.                                                                                                                                                                                                                                                                         |
|  | Do not roll.                                                                                                                                                                                                                                                                                       |

| Symbol                                                                              | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Do not stack.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|    | Keep away from rain.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|    | Keep away from sunlight.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|    | Temperature limits. Indicates the temperature limits to which the device can be safely exposed.                                                                                                                                                                                                                                                                                                                                                                                                           |
|    | Humidity limitation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|  | Atmospheric pressure limitation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|  | Shockwatch monitored shipment. A device or system used to monitor the impact and vibration of goods during transportation. This identification indicates that the transportation process of the goods is under its monitoring, ensuring that any damage to the goods caused by impact or other factors during transportation can be recorded and traced. If shock watch indicator is red, please contact Lanmage staff for handling immediately                                                           |
|  | Tiltwatch XTR. It is used to monitor whether goods are tilted, placed horizontally or inverted during transportation and storage. The principle is that when the goods are tilted by more than 80° (±5°), the gravity device rolls and causes the display window to change color (such as from silver/green to red). It can provide evidence of misoperation of the goods and assist in quality and process control. If the window color turns red, please contact Lanmage staff immediately for handling |

## Chapter 3 System Maintenance

### 3.1 General

The following are recommended maintenance and care operations.

#### 3.1.1 List of Tools and Consumables

**Table 13-1-1-1 List of tools and consumables**

| Tools/Consumable           | Quantities   | Note                           |
|----------------------------|--------------|--------------------------------|
| <b>Plastic Basin</b>       | 1pc          | To hold soapy water            |
| <b>Soft Brush</b>          | 1pc          | About the size of a toothbrush |
| <b>Soapy Water</b>         | About 400 ml | To clean the host              |
| <b>Dry Cloth</b>           | 10pcs        | To clean the host              |
| <b>24# Open End Wrench</b> | 1pc          | To fasten the casters          |
| <b>Adhesive Paper</b>      | 1 volume     | To take out the trackball      |
| <b>Cotton swab</b>         | 1 box        | To clean the trackball         |

#### 3.1.2 List of Maintenance and servicing

**Table 13-1-2-1 List of maintenance and servicing**

| NO.      | Maintenance and Servicing details       | Frequency      | Methods              |
|----------|-----------------------------------------|----------------|----------------------|
| <b>1</b> | Clean dustproof net                     | 1 time/month   | Refer to section 3.2 |
| <b>2</b> | Clean the monitor and touch screen      | 1 time/month   | Refer to section 3.2 |
| <b>3</b> | Clean the trackball                     | 1 time/month   | Refer to section 3.2 |
| <b>4</b> | Clean control panel and pull-out keypad | 1 time/month   | Refer to section 3.2 |
| <b>5</b> | Clean the probe sound head              | After each use | Refer to section 3.2 |
| <b>6</b> | Clean probe cable and connector         | 1 time/month   | Refer to section 3.2 |
| <b>7</b> | Clean probe cup holder                  | 1 time/month   | Refer to section 3.2 |

| <b>NO.</b> | <b>Maintenance and Servicing details</b> | <b>Frequency</b> | <b>Methods</b>       |
|------------|------------------------------------------|------------------|----------------------|
| <b>8</b>   | Clean the coupler heating cup            | 1 time/month     | Refer to section 3.2 |
| <b>9</b>   | Clean plastic case                       | 1 time/month     | Refer to section 3.2 |
| <b>10</b>  | Clean peripherals                        | 1 time/month     | Refer to section 3.2 |
| <b>11</b>  | Check the Probe                          | 1 time/day       | Refer to section 3.2 |
| <b>12</b>  | Check power cable and switch             | 1 time/year      | Refer to section 3.2 |
| <b>13</b>  | Check peripheral functions               | 1 time/year      | Refer to section 3.2 |
| <b>14</b>  | Mechanical safety inspection             | 1 time/year      | Refer to section 3.2 |
| <b>15</b>  | Electrical safety inspection             | 1 time/year      | Refer to section 3.2 |

## **3.2 Cleaning**

### **3.2.1 Cleaning the Host**

#### **3.2.1.1 Cleaning Process**

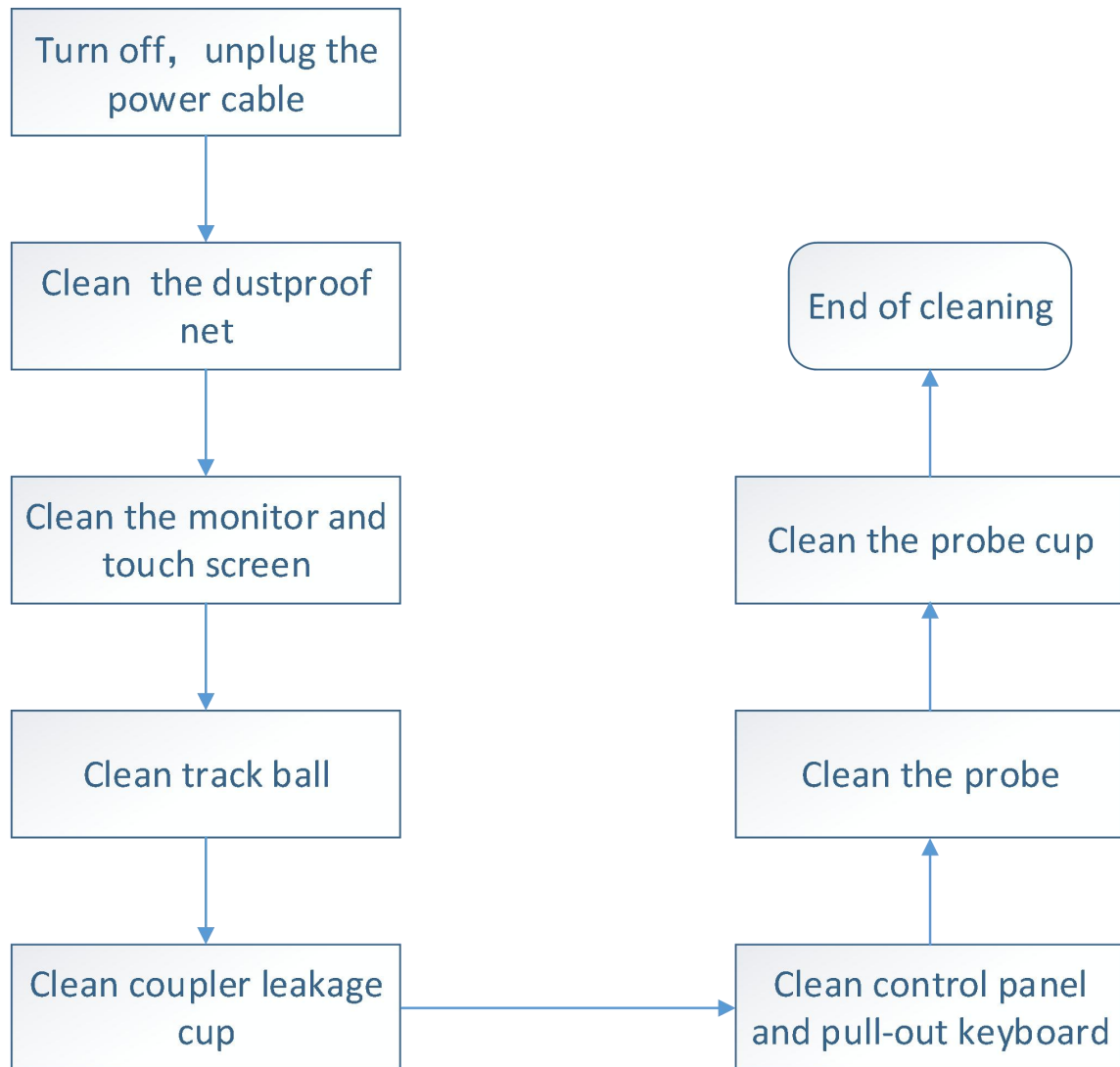


**Fig. 13-2-1-1 Flowchart**

**NOTE:** Before cleaning the Host, always make sure that it is power off, the power cable is unplugged and the power switch is set to OFF.

### 3.2.1.2 Cleaning contents

Cleaning the dustproof nets

Tool: soft brush

Removing the dustproof nets: Pull out the captive screw, press the buckle bit with the finger and pull out the 2pcs dustproof nets indicated by the arrow;

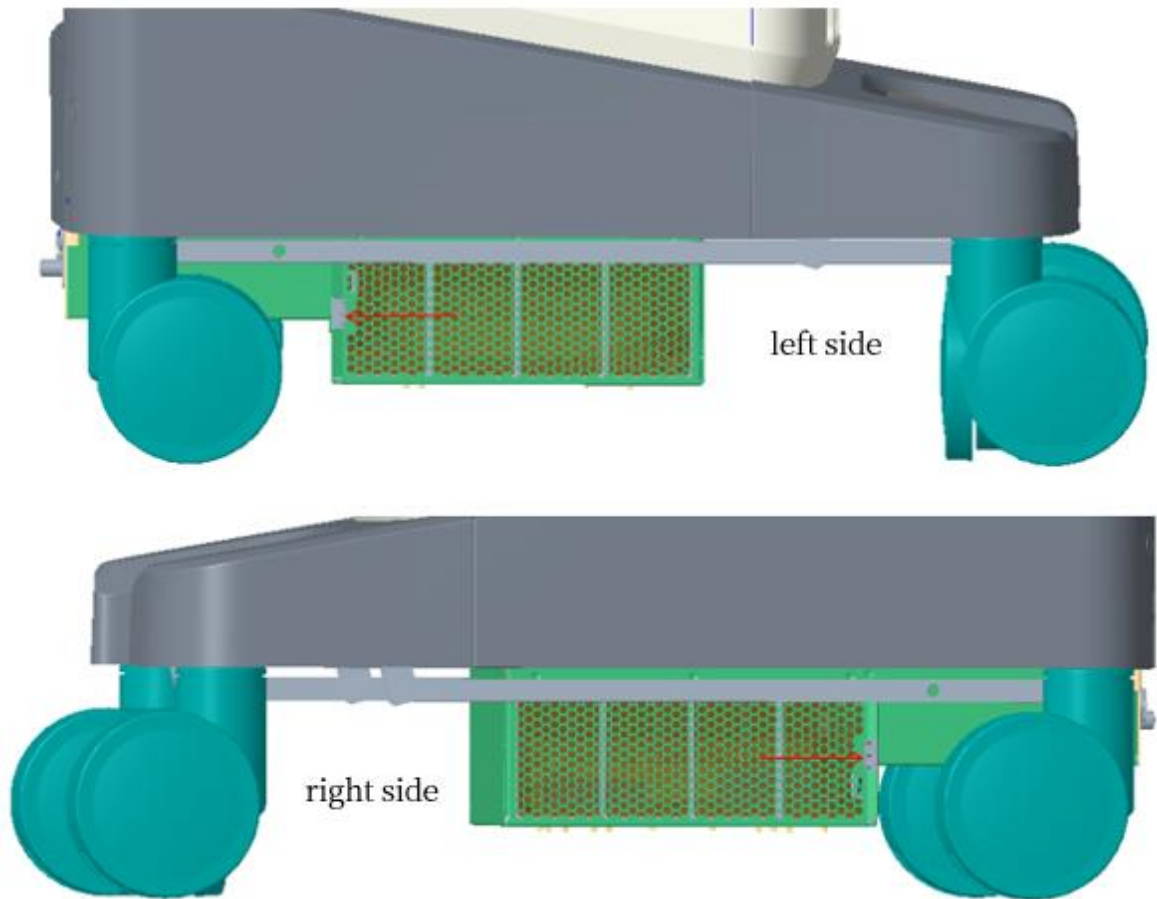


**Fig.13-2-1-2 Cleaning dustproof nets**

Cleaning: Remove the dust of the dustproof nets with soft brush;

Installing: Reinstall the dustproof nets to its original position.

Cleaning the monitor and touch screen

Tools: dry soft cloth, soapy water

Cleaning: Pull out the captive screw, align the dust-proof nets with the gap in the AC bottom box, and loosen the captive screw.

Note: Clean the dustproof nets every month. Otherwise, the system may be damaged. When the system is used in the open air or in dusty places, cleaning times can be appropriately increased.

Cleaning the trackball

Note: When cleaning make sure that the water droplets doesn't drip onto the mainframe, the following cleaning steps are the same.

Tools: dry soft cloth, soapy water, adhesive paper;

Removing the trackball:

Clasp the convex of the trackball top cover with your fingers, rotate counterclockwise along the arrow, and then remove the top cover and dust ring of the trackball;

Stick the trackball with adhesive paper and pull it out;

Note: Keep your hand next to the trackball at all times, grab the trackball while pulling it out to avoid it come off and fall to the bottom of the groove.

Cleaning: Use a soft cloth to remove dust from the trackball ball, cover of the trackball, dust ring, and base of the trackball. Use a soft cloth dipped in soapy water to wipe away any remaining dirt that cannot be removed.

Cleaning couplant leakage cup and heating cups

Tools: soft cloth or cotton cloth, soapy water;

Disassembly: two fingers pinch the coupling leakage cup clip, slowly pull down to remove the coupling leakage cup;

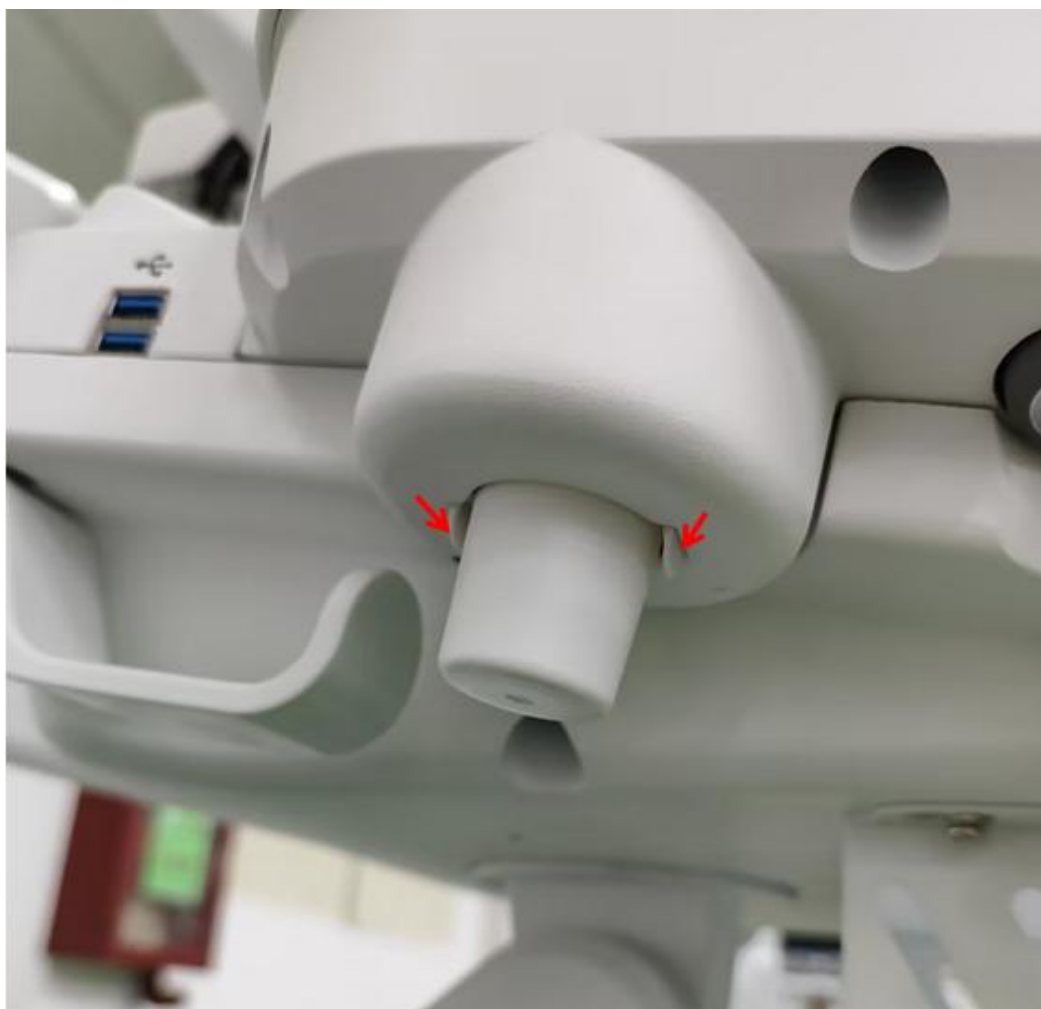


**Fig. 13-2-1-6 Cleaning the couplant leakage cup**

#### Cleaning:

Wipe off the dirt on the couplant leakage cup with soft cloth, if there is residual dirt can not be cleaned, please use a soft cloth dipped in a little soapy water to wipe it off;

Wipe off the dirt on the couplant heating cup with soft cloth, if there is residual dirt can not be cleaned, please use a soft cloth dipped in a little soapy water to wipe it off.

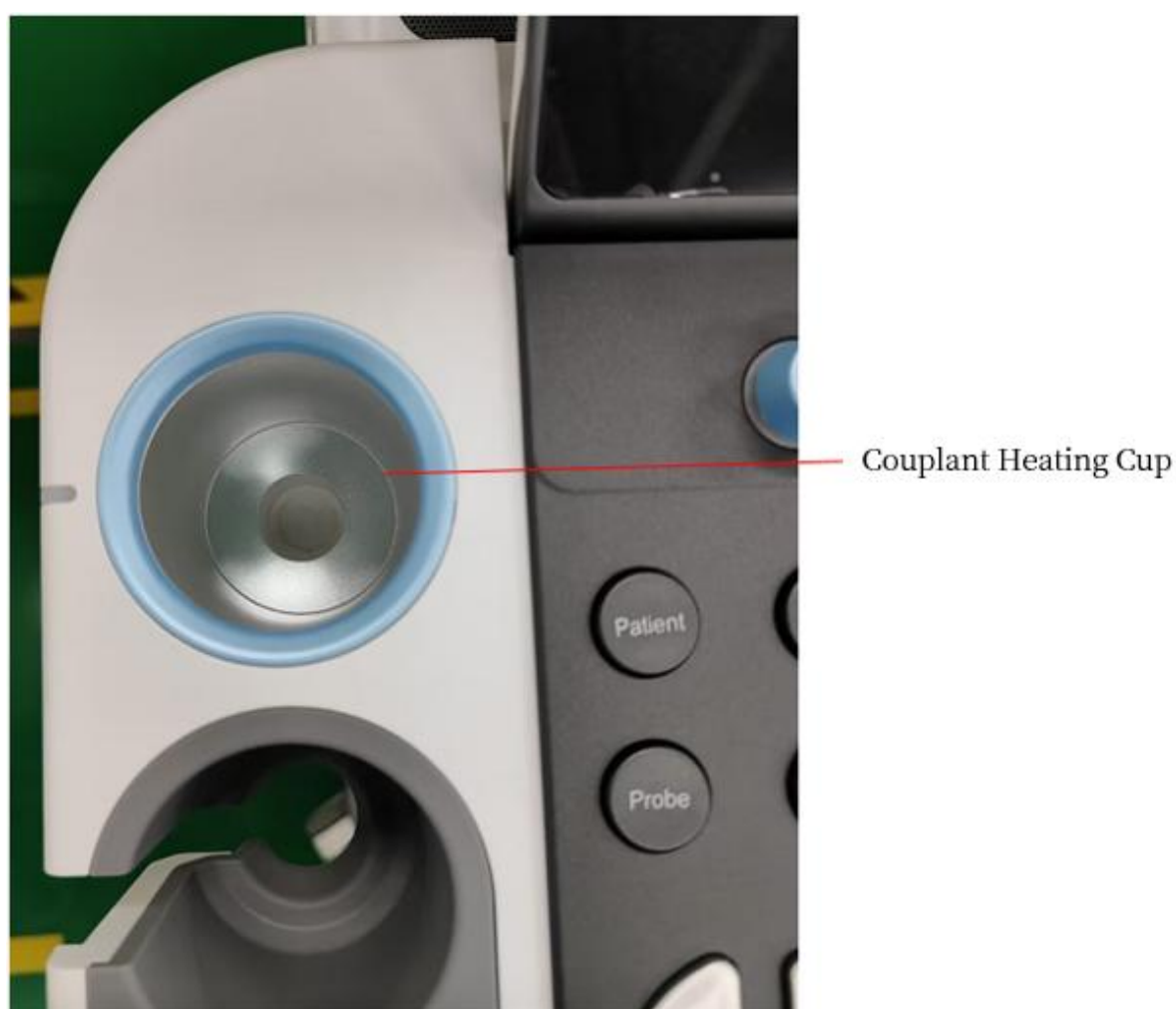


**Fig. 13-2-1-7 Cleaning couplant heating cup**

#### Cleaning the control panel and pull-out keypad

Tools: dry soft cloth, soapy water;

#### Cleaning:

Wipe off the dirt on the control panel with dry soft cloth, if there is residual dirt can not be cleaned, please use a soft cloth dipped in a little soapy water to wipe if off.

Wipe off the dirt on the pull-out keypad with dry soft cloth, if there is residual dirt can not be cleaned, please use a soft cloth dipped in a little soapy water to wipe it off.

NOTE: The control panel and pull-out keypad should be cleaned regularly to prevent dust from causing the keys to jam.

#### Cleaning Probes

Tools: dry soft cloth, soapy water, soft brush

Cleaning:

Wipe off the dirt on the surface of the sound head, cables, and connectors with a dry soft cloth;

Use a soft brush to gently sweep dust from the inside of the connector;

Use a soft cloth dipped in a little soapy water to wipe off the residual dirt on the surface of the sound head, cables, and connectors.

Note: The inside of the connector cannot be cleaned with wet tools.

#### Cleaning probe cup holder

Tools: dry soft cloth, soapy water

Cleaning: Wipe off the dirt on the probe cup with dry soft cloth, if there is residual dirt can not be cleaned, please use a soft cloth dipped in a little soapy water to wipe it off.

#### Cleaning plastic cases

Tools: dry soft cloth, soapy water, soft brush

Cleaning:

Wipe off the dirt on the plastic cases with dry soft cloth, if there is residual dirt can not be cleaned, please use a soft cloth dipped in a little soapy water to wipe it off;

Use a soft brush to sweep the dirt on the connector (e.g. probe connector, USB port, power connector, etc.).

### 3.2.2 Cleaning Peripherals

Note: Depending on the actual peripherals to be cleaned, if not, ignore them.

**Table 13-2-2-1 Cleaning methods**

| NO. | Peripherals | Cleaning methods                                                                                                                                                                                                                                                                                                                                     |
|-----|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | Workstation | Wipe off the dirt on the surface of the workstation with dry soft cloth, if there is residual dirt can not be cleaned, please use a soft cloth dipped in a little soapy water to wipe it off; use a soft brush to sweep the dust on the keys aperture; to do the cleaning according to the manual guidelines which bring along with the workstation. |
| 2   | Harvester   | Wipe off the dirt on the surface of the collector with a dry soft cloth, use a soft brush to sweep the dust on the keys aperture.                                                                                                                                                                                                                    |

| NO. | Peripherals | Cleaning methods                                                                                                                                                                                                                                                                                                                             |
|-----|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3   | Printer     | Wipe off the dirt on the surface of the printer with dry soft cloth, if there is residual dirt can not be cleaned, please use a soft cloth dipped in a little soapy water to wipe it off; use a soft brush to sweep the dust on the keys aperture; to do the cleaning according to the manual guidelines which bring along with the printer. |
| 4   | Foot Switch | Wipe off the dirt on the surface of the foot switch with dry soft cloth; to do the cleaning according to the manual guidelines which bring along with the foot switch.                                                                                                                                                                       |

### 3.3 Functional checks

#### 3.3.1 Routine inspections

**Table 13-3-1-1 Checklist of routine inspection**

| No. | Items                      | Inspection methods                                                                                                                                                                          |
|-----|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | Probe                      | 1. Visual inspection of the sound head without cracking or swelling;<br>2. Visual inspection of cables without aging or peeling;<br>3. Visual inspection of connector pins without skewing. |
| 2   | Power cable and Connectors | 1. Visual power cord is not aging or peeling;<br>2. All of the connectors do not become loose or split.                                                                                     |
| 3   | Power Switch               | The host is in normal condition when the power is turned on or off.                                                                                                                         |

#### 3.3.2 Inspection of System Function

**Table 13-3-2-1 Checklist of system function inspection**

| NO. | Items      | Inspection methods                                                                                        |
|-----|------------|-----------------------------------------------------------------------------------------------------------|
| 1   | B Mode     | Verify basic operation of B-mode and confirm that the software and hardware functions are normal          |
| 2   | C Mode     | Verify basic operation of C-mode and confirm that the software and hardware functions are normal          |
| 3   | PW/CW mode | Verify basic operation of PW and CW modes and confirm that the software and hardware functions are normal |

| NO. | Items                 | Inspection methods                                                                        |
|-----|-----------------------|-------------------------------------------------------------------------------------------|
| 4   | Pull-out keypad test  | Press all the key to confirm that the keypad functions are normal                         |
| 5   | Software Button Check | Verify the display of the software menu and confirm that every button function are normal |

### 3.3.3 Inspection of Peripheral Function

**Table 13-3-3-1 Checklist of peripheral function inspection**

| No. | Peripherals      | Cleaning methods                                                                                                             |
|-----|------------------|------------------------------------------------------------------------------------------------------------------------------|
| 1   | Workstation      | Check the basic operation and confirm that the function is normal                                                            |
| 2   | Harvester        | Check the basic operation and confirm that the image can be acquired normally                                                |
| 3   | Printer          | Check the basic operation and confirm that the printer can work properly                                                     |
| 4   | Foot Switch      | Check the basic operation and confirm that the function is normal                                                            |
| 5   | DICOM            | Check that DICOM is working properly and send pictures or other data to the DICOM server                                     |
| 6   | DVD              | Check that the DVD can read and write normally, and eject normally                                                           |
| 7   | ECG module       | Check the basic operation and confirm that the ECG function is normal                                                        |
| 8   | Couplant heating | Check the basic operation and confirm that the couplant heating function is normal                                           |
| 9   | Check the horn   | Enter the PW mode, press the Update button, adjust gain, the horn sound output is normal and the horn has no cracking voice. |

### 3.3.4 Inspection of Mechanical Function

#### 3.3.4.1 Inspection Process

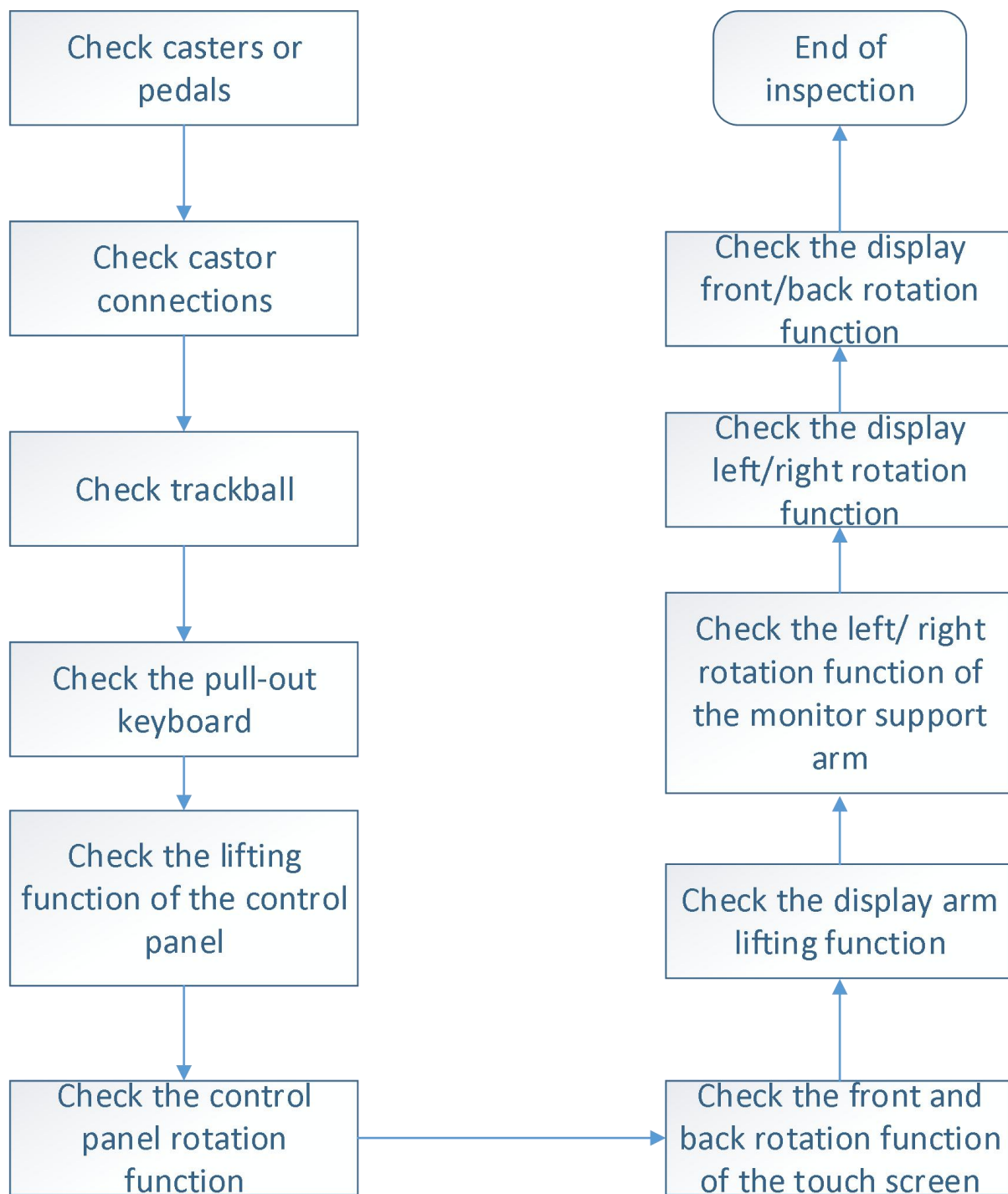


**Fig.13-3-4-1 Mechanical function check flowchart**

### 3.3.4.2 The Contents of Inspection

Check the casters or pedals

Tools: none

Inspection:

Visual caster without aging and cracking;

Castor with lock: press 4 castor pedals ON, the host is locked; Press 4 castor pedals OFF to unlock the host .



**Fig.13-3-4-2 Checking the casters**

Configure the pedal: press the locking pedal, the host is locked; Press the release pedal to unlock the host.

Checking the connection of casters

Tools: 24# open-end spanner

Inspection:

Castor with lock: Visually, the screw is not loose;

Use 24# open wrench to confirm that the 4 casters are fixed firmly;

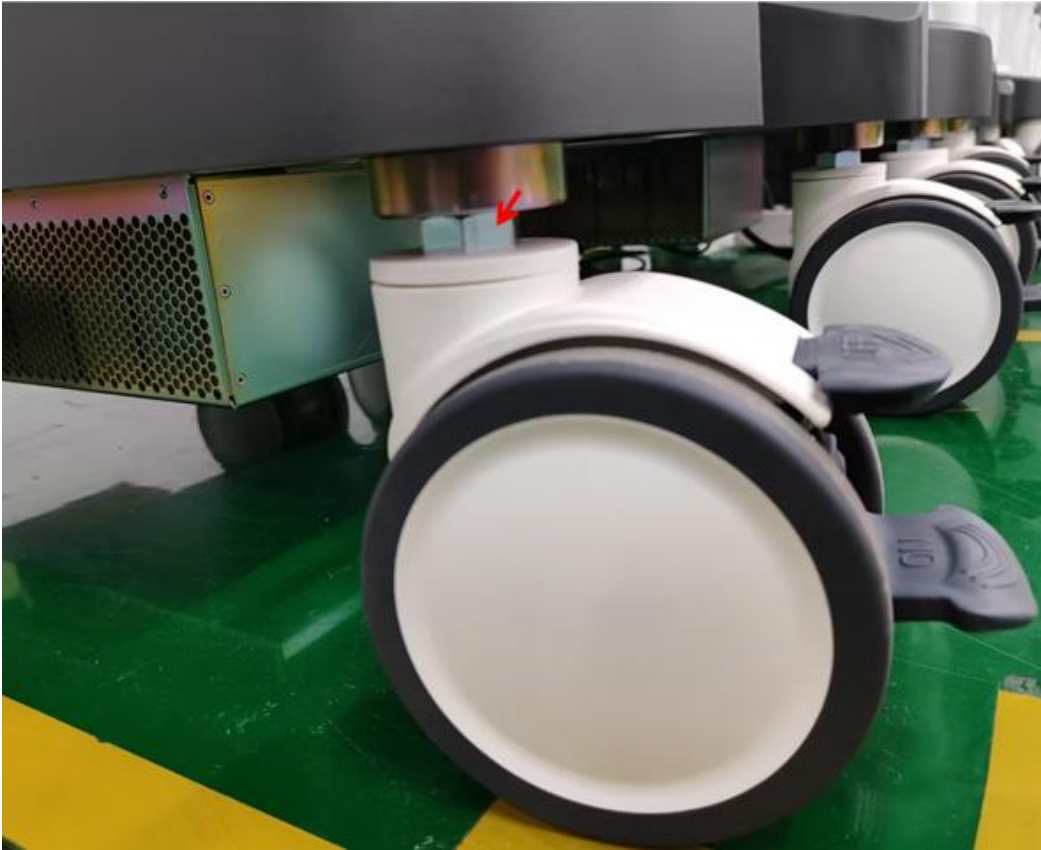


**Fig.13-3-4-4 Checking the connection of casters**

Configure the pedal: No need to check.

Check trackball

Tools: none

Inspection: Rotate the trackball in the forward, backward, left and right, the trackball is not stuck.

Checking pull-out keypad

Tools: none

Inspection: When pressing the pull-out keypad it can be popped out a section; Confirm that it slides smoothly when pulling it back and forth; Push the pull-out keypad to the end, and it can be locked.

Checking lifting Function of the Control Panel

Tools: none

Inspection:

Hold the "Lifting Handle" with one hand, press the control panel to the lowest point, release the "Lifting Handle" and stop the control panel;

Hold the "lifting handle" with one hand, the control panel can be lifted upwards freely for a certain distance, and lift the front armrest with force, the control panel can be lifted to the top;

The control panel can be stopped at any position by releasing the "lifting handle" during the lifting and lowering of the control panel.

Checking the rotation function of control panel

Tools: none

Inspection:

The control panel is able to rotate from side to side by holding the rotating handle firmly in your hand;

The control panel is able to stop in any position by releasing the rotating handle.

Checking the touch screen front/back rotation function

Tools: none

Inspection:

Rotate the touch screen back and forth and it can stop at any position;

No wobbling of the touch screen during rotation.

Checking lifting function of the monitor arm

Tools: none

Inspection:

Hold the monitor in your hand and lift it upwards, with the monitor support arm spread upwards;

Hold the monitor with your hand and press down, the monitor support arm closes downward;

The monitor can be stopped at any position by releasing the monitor during the opening and closing of the monitor arm.



**Fig.13-3-4-8 Checking lifting function of the monitor arm**

Check the monitor arm left/right rotation function

Tools: none

Inspection:

Push the A and B positions separately by hand and both are damped;

The B position is more damped than the A position.



**Fig.13-3-4-9 Checking the left and right rotation function of the monitor arm**

Check the monitor left/right rotation function

Tools: none

Check: Hold the left middle position of the monitor with your hand and rotate it left and right, should feel smooth and damped.

Checking the monitor front/back rotation function

Tools: none

Check: Hold the top middle of the monitor with your hand and rotate it back and forth, smoothly, should feel smooth and damped, and no noise.



Fig.13-3-4-11 Checking the display front and rear rotation function

## 3.4 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.

### 3.4.1 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., please immediately contact your dealer for replacement of the power cable.
- 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 probe was activated.**

Functional test:

Functional tests are carried out according to the manual to check the operability of the functional modules and the system as a whole and accessories.

### **3.4.2 Maintenance**



**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.**

#### **Repairing:**

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 is not responsible for the effects on safety, reliability and performance of this product, 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:

- 1) The nature and extent of the work performed;
- 2) Changes in rated performance;
- 3) Changes in working ranges;
- 4) Date of service;
- 5) Name of the person or firm performing the service;
- 6) Signature of the person performing the service;

Lanmage refuses any responsibility whatsoever for repairs performed without the express written consent of the Lanmage.

### 3.4.3 Data Backup

We recommended that you regularly back up the data (such as patient information and configuration data etc.) on the system hard disc to prevent these data damage or loss. Please refer to the "Export" instructions in each section for more information on how to do this.

### 3.4.4 Failure checking

General system faults and troubleshooting table (for reference only):

| No. | Failure                                                                                       | Causes                                                                                                                                           | Measure                                                                                                                                                                           |
|-----|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | After the AC Power input is connected. Pressing the power button can not start up the system. | Abnormal power system or incorrect connection of the power cord.                                                                                 | Check that the system is plugged in. Make sure that the plug and wire has not become loose and dislodged.                                                                         |
| 2   | The power indicator of the monitor is lit up, but the image is blank.                         | <p>The interval between turning off and restarting the system is too short;</p> <p>The monitor brightness or contrast may be improperly set.</p> | <p>Turn off the system and wait at least 1 minute, then restart the system;</p> <p>Adjust the monitor brightness and contrast;</p> <p>Use [Fn]+ key to adjust the brightness.</p> |

| No. | Failure                                      | Causes                                                                                                                                       | Measure                                                                                                                                                                             |
|-----|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                              |                                                                                                                                              |                                                                                                                                                                                     |
| 3   | Characters can be displayed, but not images. | Abnormalities in transmit power, gain or TGC control;<br>Probe disconnected or not connected correctly;<br>The system is in freeze mode.     | Adujusts the transmit power,gain or TGC control;<br>Ensure that the probe is connected properly;<br>Exiting the Freeze Mode.                                                        |
| 4   | The image quality is degraded                | The image presets are inappropriate;<br>The image post-processing settings are incorrect;<br>The image parameter settings are inappropriate. | Select an appropriate default presets;<br>Adjust the image post-processing settings or reset post-processing to the default values;<br>Reset the factory default presets and retry. |
| 5   | The button does not respond                  | There is dirt blocking the button.                                                                                                           | Check the control panel for the blocked button and press it several times to release it;<br>Clean the button.                                                                       |

### 3.5 Cleaning and Disinfecting System Parts

You must take every precaution to prevent patients, operators or third parties from being exposed to hazardous or infectious materials. Take general precautions when cleaning and disinfecting. If known to be infected, you should treat all probes that come into contact with human blood or other body fluids.

All external parts of the system, including control panel, keypad and probes, should be cleaned or disinfected when necessary or between uses. Cleaning can remove particles on the surface of the parts, and disinfection can kill organisms and viruses growing on the 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.

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 dustproof nets on the AC-DC power module at the bottom of the system once a month. Replace them if required with those from the spare parts kit.

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

 **Note:** remove gel residuals out of the probe after each use!

#### To clean the system surfaces:

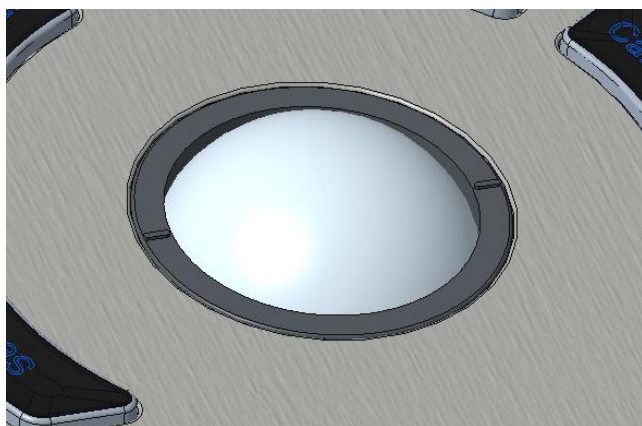
1. Power off the ultrasound system and disconnect it from the power source.
2. Use a clean gauze pad or lint-free cloth, lightly moistened with a mild detergent, to widen the surface of the ultrasound system. Take particular care to clean the areas near the trackball and the slide controls. Ensure these 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.



Trackball

Clean the trackball, upper cover and inside of the trackball slot with cotton paper and ethanol.

## 3.6 Caring for and Using Probes

### 3.6.1 Using Probes

Before you begin using the system, inspect all the probes on a daily basis. Do not use the probe if the sound head is cracked or expanded, the cable is aged or peeled, and the connector pin is crooked or has foreign objects.

Immediately clean and disinfect the probe after each use to avoid the infection of patient and operator during exam.

Damage or aging of the probe can destroy the electrical safety features.



**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: Probes are sensitive devices——irreparable damage may occur if they are dropped, knocked against other objects, cut, or punctured.**



**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. To avoid damaging the cable, do not roll the instrument over the probe cable.**



**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.**



**Warning: 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;

## 3.6.2 Cleaning and Disinfection

Before cleaning and disinfecting, check for damage at the probe head, housing and cables, and if damage is found, do not put it into any liquid (e.g. disinfectant).

### ● Cleaning

Remove gel residuals out of the probe after each use. Where required, wipe the probe and cable with a water-moistened gauze pad. When cleaning, do not allow water to drip on the probe connector housing. 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.

Cleaning procedure for probes:

1. Unplug the probe from the system (Intracavitary probe require removal of the probe sheath).
2. Wipe off all couplant and other visible residue with a soft cotton ball or dry soft cloth. If necessary, wipe the probe with a gauze moistened with water to remove any gel or particles left on the probe.
3. Dry the probe with a clean soft cloth.

### ● Disinfection

Disinfect the probe after each use, please follow below steps to disinfect the probe after the lens has come into contact with mucous membranes:

1. Unplug the probe from the system;
2. Prepare 2% glutaraldehyde disinfectant after cleaning the probe;
3. Immerse the probe in the disinfectant solution for a certain period of time (refer to the time specified by the manufacturer); the level of the liquid during immersion should not exceed the probe cable connector.
4. Rinse the probe well with enough clean water to remove any residual disinfectant from the probe in accordance with the manufacturer's instructions after removing the probe from the disinfectant.
5. Do not allow water to drip on the probe connector housing when cleaning.



**Note:** Ensure that the probe surface is always cleaned during the steps requiring disinfection.



**CAUTION:** To prevent probe damage, follow the immersion depth guidelines for each probe.



**CAUTION:** It is strictly forbidden to immerse or soak the probe cable or connector housing in liquids.



**Caution:** Do not immerse the probe in a disinfectant for more than 1 hour! The disinfectant solution air-dried on the probe is not allowed.



**Caution:** Never sterilize the probe with sterilization techniques such as gas or heat sterilization techniques.

 **Caution:** Do not use hot steam, cold air, or vinyl oxide (ETO) to disinfect the probe. Please contact your supplier before using any other method recommended by the manufacturer of the disinfection equipment.

 **Caution:** The probes that preform for intra-cavity examinations must be cleaned and disinfected after each use to minimise the risk of cross-contamination and infectious disease.

 **Caution:** All probes should be cleaned and disinfected prior to their use on each patient. endocavity probes require high-level disinfection prior to use.

 **CAUTION:** Take care to handle or store the probes. They must not be dropped, vibrated, or shocked against other objects. Do not allow the probes to come in contact with any object with sharp edges or corners.

 **Caution:** To avoid electrical shock and damage to the system, disconnect the probe prior to cleaning or disinfecting.

 **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:** Must be strictly adhered to the instructions provided by disinfection manufacturers for use.

### **3.6.5 Maintenance**

It is forbidden to repair or replace any parts of the probe by yourself. In the event of any kind of damage or malfunction of the probe, contact your supplier immediately.

### **3.6.6 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.

## **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.

### 3.8 Battery care

 **Warning:** Do not disassemble the battery. The battery has protection mechanism and protection circuit to avoid danger. Improper disassembly will damage the protection function and will cause the battery to overheat, smoke, deform or burn.

 **Warning:** Do not short-circuit the battery. Do not connect the positive and negative terminals of the battery with metal. Do not store and move the battery with metal. If the battery is short-circuited, a very large current will flow through the battery, which will damage the battery, causing it to heat, smoke, deform or burn.

 **Warning:** Do not heat or burn batteries. Heating and burning batteries will cause melting of battery isolators, loss of safety functions or electrolyte combustion.

 **Warning:** Avoid using batteries near heat sources. Do not use batteries near fires, ovens, or over 800°C. Overheating can cause a short circuit inside the battery, causing it to overheat, smoke, deform or burn.

 **Warning:** Do not wet the battery or throw it into water. Otherwise, the function of the battery's internal protection circuit will be lost and abnormal chemical reactions will occur. The battery may get hot, smoke, deform or burn.

#### 3.8.1 Notes on battery use

 **NOTE:** During the first use of the battery, if the battery is found to be untidy or abnormal such as peculiar smell, do not continue to use the battery, and return it to the dealer.

 **NOTE:** Please do not use the battery in the strong sunlight to avoid heat, deformation and smoke. It will at least avoid battery performance degradation, usage period decrease.

 **NOTE:** Batteries should be placed where children cannot reach. Prevent children from taking the battery out of the charger or play with it.

 **NOTE:** The battery shall be inspected at least every three months. If the battery is found to have peculiar smell, deformation, discoloration or distortion, the battery shall be removed from the device or charger and discarded. Using an abnormal battery can cause overheat, smoke, distortion, or

combustion.

 **WARNING:** Attempting to open or incinerate the battery may result in serious injury. Do not hit, puncture, drop or throw the battery.

 **WARNING:** Do not short-circuit the battery by immersing it in liquid or allowing it to come into contact with liquid or metal objects.

 **WARNING:** Keep batteries neat and dry.

 **WARNING:** If the battery leaks or emits a strong odour, remove it from the system and store it away from any source of ignition. Avoid contact with liquids, If liquid comes in contact with your skin, wash the area with plenty of water and seek medical attention.

 **NOTE:** Do not operate the system at ambient temperatures below 5°C or above 40°C.

 **NOTE:** Only batteries supplied by Lanmage can be used in the system.

 **NOTE:** Charge the battery in the main unit for one hour before using it for the first time.

 **NOTE:** Charge batteries immediately after use. Storing discharged batteries will impair their capacity. When stored, batteries should be charged to at least 40 per cent of capacity

 **NOTE:** The batteries are sealed and can be used safely and normally, provided that the operating instructions are followed and the case is not damaged.

 **NOTE:** If storing batteries for longer than 6 months, charge batteries to between 40% and 60%.

 **NOTE:** Batteries can only be charged when they are in the system.

 **NOTE:** Batteries can be safely cleaned with dry soft cloth.

### 3.8.2 Battery Replacement and Disposal

When the system is frequently powered by batteries alone, the batteries should be replaced every 12 to 18 months.

When the battery life is exhausted or damaged, please contact Lanmage customer service staff or the service provider designated by Lanmage immediately for replacement.

 **WARNING:** The battery replacement was incorrect, posing an explosion risk. Only the same or similar batteries recommended by the device manufacturer can be used for replacement. Used

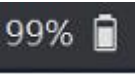
batteries must be disposed of in accordance with the manufacturer's instructions and local regulations. The battery needs to be replaced by contacting Lanmage customer service staff, the service provider designated by Lanmage, or personnel who have received professional training.

### 3.8.3 Battery Charging and Discharging

When the machine is connected to the AC power supply, the batteries status icon  in the lower right corner of the main screen indicates that it is charging, After the batteries are fully charged, the batteries

status indication icon is



When the machine is not connected to the AC power supply and is powered by the batteries alone, please check the batteries status indicator icon on the main screen. As the power goes down, the icon  changes accordingly.