Product safety and performance information

Product information

Product name: Digital Mammography System

Model and specification: 8100A、8100A0、8100A1、8100A2、8100A3、8100A4

8100C、8100C0、8100C1、8100D、8100D0、8100D1

Service life: 12 years

Information of Manufacturer

Manufacturer: Shenzhen Lanmage Medical Technology Co., Ltd.

Address of Manufacturer: No.103, Baguang Service Center, No. 2 Baisha Bay Road, Baguang Community, Kuiyong Sub-district, Dapeng New District, Shenzhen,518119,Guangdong,P.R.China

Production address:1st Floor, Building B, Jingchengda Industrial Park, No. 4 keji road, Tangtou Community, Shiyan Street, Bao'an District, Shenzhen, 518000, Guangdong, P.R. China

Customer service center of manufacturer:400-888-6452

After-sale service provider: Shenzhen Lanmage Medical Technology Co., Ltd.

Postal code: 518000.

Official account of customer service center of Lanmage

EU Authorized Representative

Company: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

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Warning Symbol

The following symbols are used in this manual. Users should understand the implication of these

symbols before operating this instrument.

⚠ **Danger: Personnel will be seriously injured or even die if failing to be aware of or avoid this state or situation. Do not neglect the symbol until the specified conditions are fully understood and met.**

⚠ **Warning: Personnel will be seriously injured or even die, and equipment or data will be seriously damaged if failing to be aware of or avoid this state or situation. Do not neglect the symbol until the specified conditions are fully understood and met.**

⚠ **Caution: Personnel will be injured, and equipment or data will be damaged if failing to be aware of or avoid this state or situation. Do not neglect the symbol until the specified conditions are fully understood and met.**

⚠ **Note: Remind the reader of relevant facts and situations. It implies operating information or additional guidance that users should follow, but it is not necessarily related to possible personal injury or equipment damage.**

Requirements for Installation Site

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

Revision history

File No	Revision	Date	Reason for revision
Luna mini -CE-101	A/0	2026.07	First edition

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Chapter1 Overview

1.1 Structure

Digital Mammography System is an breast X-ray radiography device developed and produced by Shenzhen Lanmage Medical Technology Co., Ltd., which mainly consists of high-voltage generator, high-voltage cable, X-ray tube assembly, collimator, flat-panel detector, stand with C-arm, and image processing system. They have been designed to perform Screening examinations as well as Diagnostic Views (including Spot compression, Magnified and/or Coned views). These systems eliminate the need for film cassettes, and take advantage of digital technology, including on-screen image display, Networking, Filming, and Archiving.

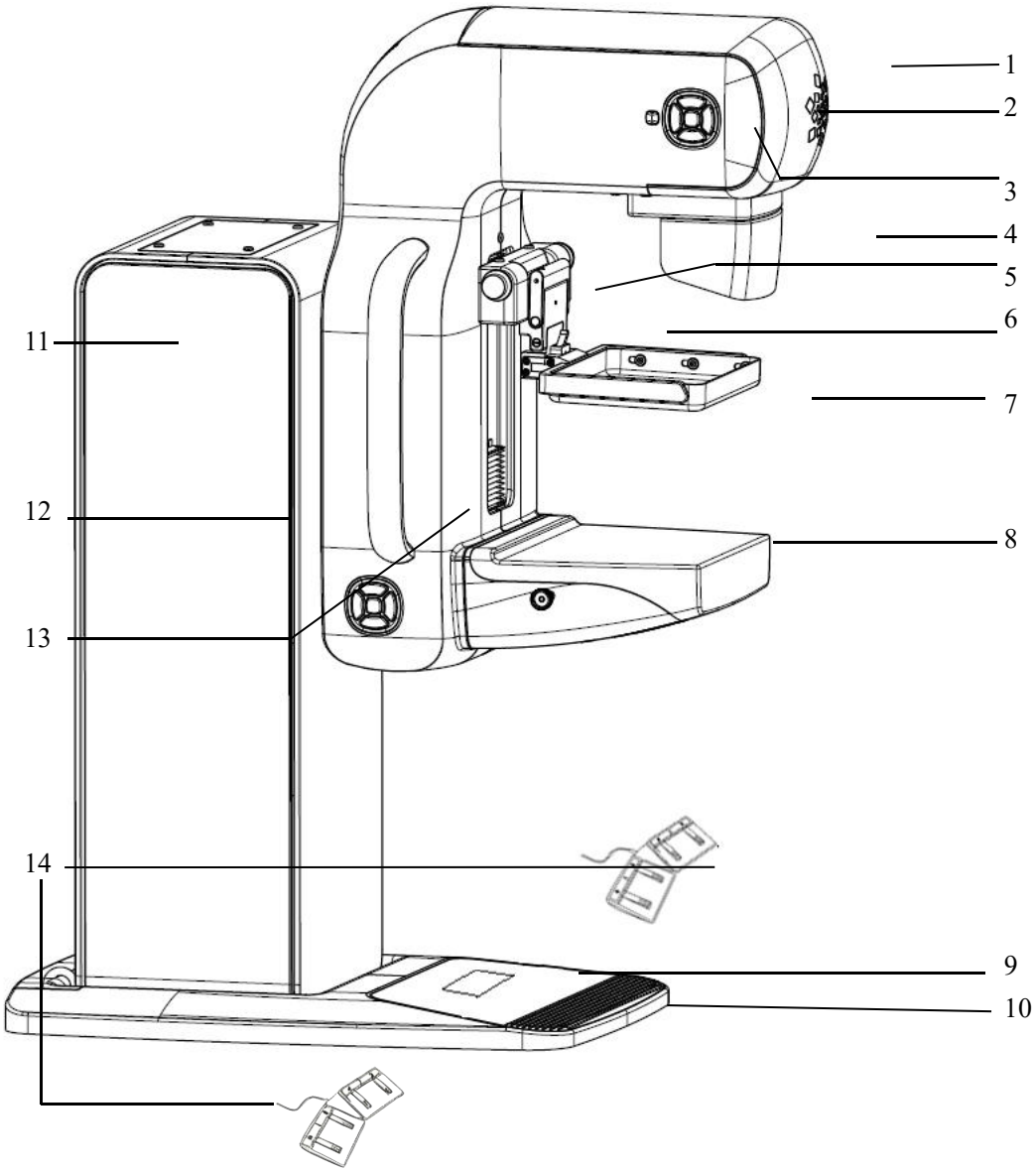


Figure 1-1

1-X-ray tube assembly	2-C-arm height adjustment and rotary button	3- Projector light button
4- Protective face shield	5- Manual pressurization / decompression knob	6- Compressor installation button
7- Compressor	8- Radiography Platform	9-Column LED Display
10-Column base	11-Emergency stop switch (on the rear shell)	12-Column
13- Patient handle	14- Foot brake	

1.2 Intended use and contraindications

1.2.1 Intended purpose

The system is intended to be used in the same clinical applications as traditional mammographic film/screen systems. It generates digital mammographic images which can be used for screening and diagnosis of breast cancer. The digital mammography system is mainly used for screening and diagnostics in medical units.

1.2.2 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.

1.2.3 Patient populations

The patients who need to take diagnostic mammography.

Age groups: Adult;

Gender: Women.

Health: Be able to receive mammography and who needs to take general radiographic diagnosis. Pregnant woman is forbidden.

Application: Breast.

1.2.4 Indication

The device is applicable for medical imaging of the human breast.

⚠ Contraindications: It is strictly prohibited the pregnant women to use the device to be checked.

1.2.5 Clinical benefits

The intended clinical benefits of Digital Mammography System are used for routine radiography of patients to obtain a single image for clinical diagnosis and screening, provide efficient digital imaging solution.

1.3 Environmental Condition

Table1-8

Operation	Temperature range	10℃～40℃
	Relative humidity	30%~75%（non-condensing）
	Atmospheric pressure	700hPa～1060 hPa
Transport and Storage	Temperature range	-20℃～55℃
	Relative humidity	20%~93%（non-condensing）
	Atmospheric pressure	700hPa～1060 hPa

1.4 Operating environment

Table 1-9

Items	**Description**
Hardware configuration (minimum)	Computer: Processor (CPU) ≥ i3 and above Memory ≥16G Hard disk capacity ≥1T hard disk Monitor: Screen resolution≥1920×1080 The mainboard should have 2 or more LAN network ports, RS232 serial ports, and an interface that can expand PCI.
Soft dog	Super dongle
Software environment	Windows 10 64-bit or higher
Network environment	100M/1000M Ethernet LAN
Complies with standards	IEC 60950 or IEC 62368-1 or IEC60601-1

Chapter2 Safety

X-ray equipment operators must have experience or knowledge of X-ray protection, and received X-ray equipment operation training.

In the installation and operation, the user always has the responsibility to comply with the relevant provisions of the laws and regulations. All the assembly operations, expansions, re-adjustment, modifying or repair work should be authorized by the manufacturer's maintenance personnel. Equipment must be used according to instructions. Failure to comply with the guidance may lead operators, maintenance staff or patients to extreme risk will result in personal injury.

The basic safety and essential performance of the Digital Mammography System comply with the requirements of the standards IEC 60601-1, IEC 60601-1-3, and IEC 60601-2-45.

WARNING:

- Do not use the system to perform repeated exposures on the same patient at a high frequency, especially for children.
- During X-ray irradiation, non-examined individuals are prohibited from entering the operating site (except when the examined patient requires assistance to complete the examination); if other personnel need to accompany the patient due to their medical condition, corresponding protective measures must be taken for the accompanying person.
- Protective measures shall be adopted for the non-examined parts of the patient's body to prevent these parts from being exposed to X-rays.
- In accordance with the national standard IEC60601-1-2, this system is equipped with an EMC filter. Improper grounding will pose an electric shock hazard to users.
- Do not charge or plug/unplug any connected components when the system is turned on; otherwise, damage may occur and the system may fail to work normally.
- To avoid the risk of electric shock, this equipment shall only be connected to a power supply network with protective earthing.
- Except for the signal input/output ports that can be connected as part of this equipment/system, any other connections to external devices or network/data coupling are restricted.
- 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.

- 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– Optimized Compression Technology

The automatic optimized compression function automatically adjusts the optimal compression speed based on individual patient differences to improve comfort and ensure high-quality diagnostic images.

- Patients with breast implants or those who have recently undergone breast surgery should not use the optimized compression technology (flexible compression function).

2.1 Operation safety

⚠ Warning：The device cannot be used in an oxygen-rich environment.

⚠ WARNING: Modification of this equipment is not permitted.

⚠ WARNING: The maximum surface temperature measured for the applied parts of this device reached 42.1℃, Avoid prolonged contact with the applied parts to prevent skin discomfort or burns caused by high temperatures.

⚠WARNING: This equipment shall only use original factory-supplied accessories. The use of any non-original accessories is strictly prohibited. Using non-original accessories may result in abnormal equipment performance, increased safety risks, or failure to operate normally. The manufacturer shall not be liable for any consequences arising therefrom.

⚠WARNING: This equipment shall only use original factory-supplied accessories. The use of any non-original accessories is strictly prohibited. Using non-original accessories may result in abnormal equipment performance, increased safety risks, or failure to operate normally. The manufacturer shall not be liable for any consequences arising therefrom.

⚠ WARNING: Any modification to medical electrical equipment (ME equipment), including circuit modification, software tampering, structural disassembly, parameter adjustment, and accessory replacement, must be authorized by the manufacturer and performed by professional personnel! Unauthorized modification will not only cause equipment data distortion and functional failure, trigger safety accidents such as electric shock and radiation leakage, and lead to medical risks including misdiagnosis and missed diagnosis, but also directly result in the loss of equipment compliance. The manufacturer shall not assume any responsibility for any equipment damage, personal injury, property loss, or related legal disputes arising from unauthorized modification; all responsibilities shall be borne by the party that performed the unauthorized

modification and the user.

Warning：To connect only items designated as part of the SYSTEM or that have been specified as being compatible with the SYSTEM.

WARNING:In order to continue to use the equipment safety, please send this manual and equipment store together,and regularly review the manual.

WARNING: Beware of electric shock hazards! Do not move the case or faceplate of the equipment. For generating and controlling the X-ray, there are circuits with high voltage in the console and generator. The high voltage is fatal so that only trained or qualified personnel can handle the internal components of the equipment.

CAUTION: Do not place any object onto the system.

CAUTION: During operation of the equipment, operators should always remain vigilant. You must be sufficiently familiar with the equipment to identify any fault that could be dangerous. If there is any malfunction or safe problem, do not use this device before the problem is solved.

NOTE: The user should provide the communication tools for operators and patients.

WARNING: The equipment described in this manual must only be handled by previously trained or qualified personnel.

CAUTION: Inspect carefully before operation, making sure that the patient and other equipment will not be interfered or collided.

WARNING: The operator should be responsible for the safety of patient all the time. During the operations, the operator should protect the patient by locating the patient accurately and using the protective devices.

NOTE: Press down the red emergency stop button to stop the mechanical movements when meeting any emergency in working of the equipment.

CAUTION: Using the equipment must meet the environmental conditions required by normal operations. Turn off the main power switch when operations finished.

NOTE: Conduct periodic maintenance to ensure the safety of operation.

NOTE: There must be some fixture in transportation of the equipment to prevent it from shaking. The equipment must be covered with felt cloth in the truck transportation. Contact manufacturer when you find damages, malfunctions or other problems with the product.

WARNING: Cut off power when you change the fuse of the device.

WARNING: All other equipment which need connect with this device should meet the GB / IEC requirements. Manufacture has no responsibility for data loss or equipment damages which was caused by using the external devices not meet the GB / IEC requirements.

2.2 Serious Incident Reporting

For any serious incident caused by the device, the user should report it to the manufacturer and the local Competent Authorities (CA).

2.3 Classification

The system of unit has the following classification:

- Protection against Electric Shock: Class I - Type B Applied Part
- Protection against Harmful Liquid: Ordinary Device
- Degree of Safety in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide: Not suitable for use in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide.
- Work Mode: Continuous running with intermittent loading.

2.4 Electromagnetic Compatibility

Designed to use, this device complies with EMC regulations, including the electromagnetic interference level and the necessary performance electromagnetic shield.

It is almost impossible to eliminate electromagnetic interference completely, unless exclude all the equipments possible to generate high-frequency signals. Although some high-frequency device in line with the requirements of EMC regulations itself, but can not determine whether the high-frequency radio transmitter signals will affect the normal operation of the device. Therefore, to eliminate the interference, avoid using the radio equipment such as mobile phones, wireless microphones, etc. in the vicinity of the X-ray system.

2.5 Radiation Safety

2.5.1 Equipment of effective area

For security reasons, the Image workstation must be installed on the outside of the patient effective area.

2.5.2 Radiation safety

⚠ **NOTE: Take all necessary protective measures before every exposure.**

The actual design of any device is not able to provide complete protection. As the same, nor is there a device to enable operators to make adequate preventive measures in advance. Therefore, we believe that all personnel who are authorized to use, install, inspect and maintain the equipment are able to recognize the hazards of excessive exposure to X-ray radiation. At the same time, we assume that all qualified personnel shave received adequate training and mastered the necessary knowledge. In this manual, this product is sold with a statement: manufacturers, distributors and sales representatives are not responsible for any possible injury or loss caused by exposure to X-ray radiation.

When using the X-ray equipment, who want to check the room must comply with the correct radiation protection. Specific rules see as follows:

- Distance is the most effective way of radiation protection. If possible, please maintain the longest between patient and X-ray tube.
- Wear protective clothing. The protective aprons which equal to 0.35mm thick lead can reduce 99.95% of the 50 kV X-rays, or 94.5% of the 100 kV X-ray.
- Avoid working in the straight-ray beam direction, and if it is inevitable, please wear protective gloves and protect yourself.
- Select the shortest radioscopy time as possible to reduce the amount of radiation.
- Wear personal dosimeter.
- In order to protect patients from radiation damage, in addition to use the protective facilities fixed X-ray device, but also should use of protective accessories (Such as the diaphragm, filter, etc.).
- Select the focus which has the largest relative distance from skin as possible, and make dose absorbed by patient as small as possible in the case of reasonableness.
- Before use the equipment, you should be clear that any material in radiation pathway between patient and the image receiver (such as film) will affect the image quality and patient dose.

During the examination, ensure the vocal and visual communication be available between operators and patients.

⚠ **NOTE: Keep the hand, arm or other parts of body out of the X-ray field during operating and maintaining the equipment.**

2.5.3 Patients Safety

Before exposure operation, ensure that the exposure parameter is conform to the patient, otherwise may cause the patient excessive exposure.

Mask type shield can protect the head into the X-ray beam patch inside.

Absorbed dose=Incident dose-Dose reaching the detector.

Incident dose: It is calculated according to the exposure KV value and mAs value.

Do all KV dose lookup tables in advance, and then according to the actual.

The exposure parameters can calculate the incident dose.

Dose reaching the detector: Calculated according to the gray value of the image.

Dose reaching the detector = a * Gray + b ; where a and b are coefficients.

These two values are different for different types of detectors. Gray is the gray value of the image organization area.

Through monitoring, the radiation dose can be determined, which can not only determine whether the safety measures taken are appropriate, but also reflect the problems in radiation protection.

- The most effective way to identify whether the existing safety measures are appropriate is to regularly use the instrument measurement to ensure that the measured value of the instrument is consistent with the value provided by the equipment. If there is a certain error between the two, it can follow the steps below to check the accuracy step:

  Place the detector of the X-ray dosimeter in an appropriate position in the X-ray beam, if the surface of the image receiver or bed, and adjust the size of the X-ray field to 15cm× 15cm or other appropriate size. The dose area displayed by the photographic device is greater than 5 $pGy \cdot m^2$, and the measured dose value is multiplied by the radiation field area at the air-specific kinetic dosimeter detector. Direct measurements can also be made using a dose area meter. Calculate the error between the displayed value and the measured value.

⚠ **NOTE: Anti-radiation measures should be taken whenever any part of the operator 's body may be exposed to radiation. Radiation dose must not exceed the allowable dose range.**

- A common but not accurate method of measuring radiation dose is to wash the film after placing it in a critical position for a certain period of time to determine the radiation dose.
- The general method for determining whether there is excessive radiation exposure is to wear a radiation dose plate. Its dose plate contains X-ray sensing film active thermoluminescent material.
- Although the re-dosing plate can only measure the radiation received on the body parts, but

to some extent reflects the amount of radiation received.

2.6 Fire Safety

WARNING:

- **Use only electrical or chemical fire extinguisher. Water or other liquid fire extinguishers may cause serious injury or even be fatal to personnel.**
- **When the equipment running, the vent of equipment does not allow to be overwritten.**
- **Make sure cooling of the collimator.**

2.7 Electrostatic Safety

WARNING: There exist dangerous of electric shock if the equipment without correct earthing. Before handling, must ensure the equipment have been connected all safe earthing.

WARNING: Confirm the legitimacy first, when you need electrical connection or mechanical connection between this equipment and any other manufacturer's equipment. Manufacturer does not bear any responsibility for damages to equipment or injuries to people brought by connection without permission. In order to avoid system harm caused by leakage current overlay, make sure the connection meets GB9706.15 standards and re-examine the entire system for the leakage current and other safety indicators.

DANGER: Complete system can produce lethal voltages; pay enough attention to prevent contacting with these voltages.

WARNING: To avoid electric shock, cut off the power and unplug it before the maintenance of the equipment.

WARNING: Do not use the equipment in environment with combustible gas or anesthetic to avoid explosion.

WARNING: Do not open the equipment enclosure of the device to avoid risk of electric shock.

WARNING: Do not use the equipment when there is any electrical or mechanical failure. Do not remove protection circuit of the equipment.

WARNING: Electrical safety tests must be made according to local safety regulations or relevant regulations to ensure the safety of this device.

WARNING: Do not use the equipment when there is any electrical or mechanical

failure. Do not remove protection circuit of the equipment.

⚠ WARNING: Electrical safety tests must be made according to local safety regulations or relevant regulations to ensure the safety of this device.

⚠ WARNING: The electrical control cabinet is equipped with a power status indicator light, whose status is defined as follows — When the electrical control cabinet is connected to a valid power supply and the power supply circuit is normal, the indicator light remains steadily green; if the indicator light is not illuminated, it indicates that the power supply is not connected or there is a power supply abnormality. Disconnect the main power supply before troubleshooting the circuit.

2.8 Machinery Safety

⚠ WARNING:

- **Make sure the head and limbs of patient or operator do not move within the range of device movement, and any part of clothes is not stuck.**
- **Remove any object equipment within the scope of equipment moving.**
- **Make sure the safety to stand or lie down of patients during the examination.**
- **Emergency stop switch button: Press the button in case of emergency, all movement will be stopped immediately. This button locates on the system console and right corner of control panel beside table.**

Possible risk area as below:

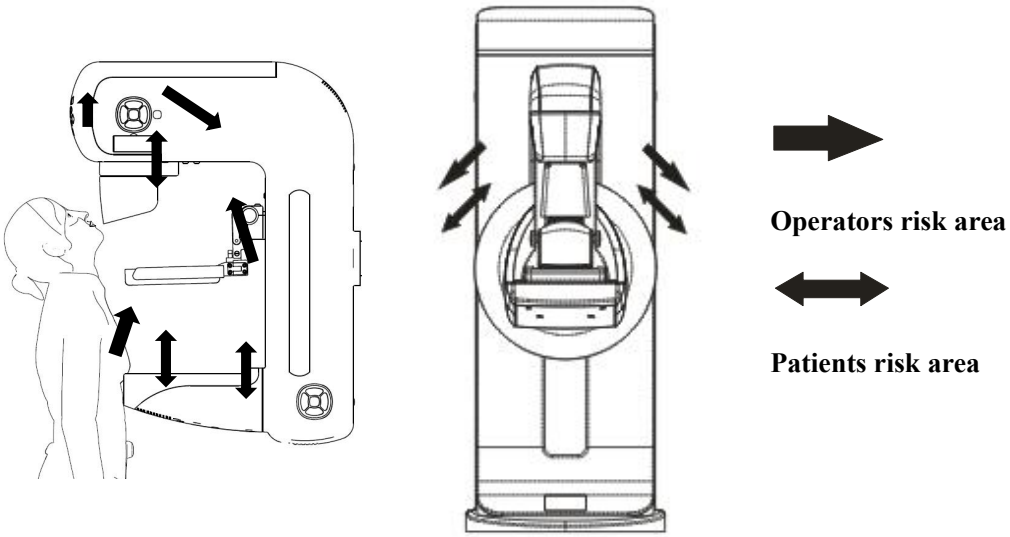


Figure 2-1

Patient safety

While preparing for tests, the operator shall be responsible for ensure the exposure parameters set on the workstation meets the requirements and have no change. If you do not do this check, the patient may be overexposed. Mask-type shield can prevent the patient's head into the beam range.(EN 60601-2-45—29.207.1)

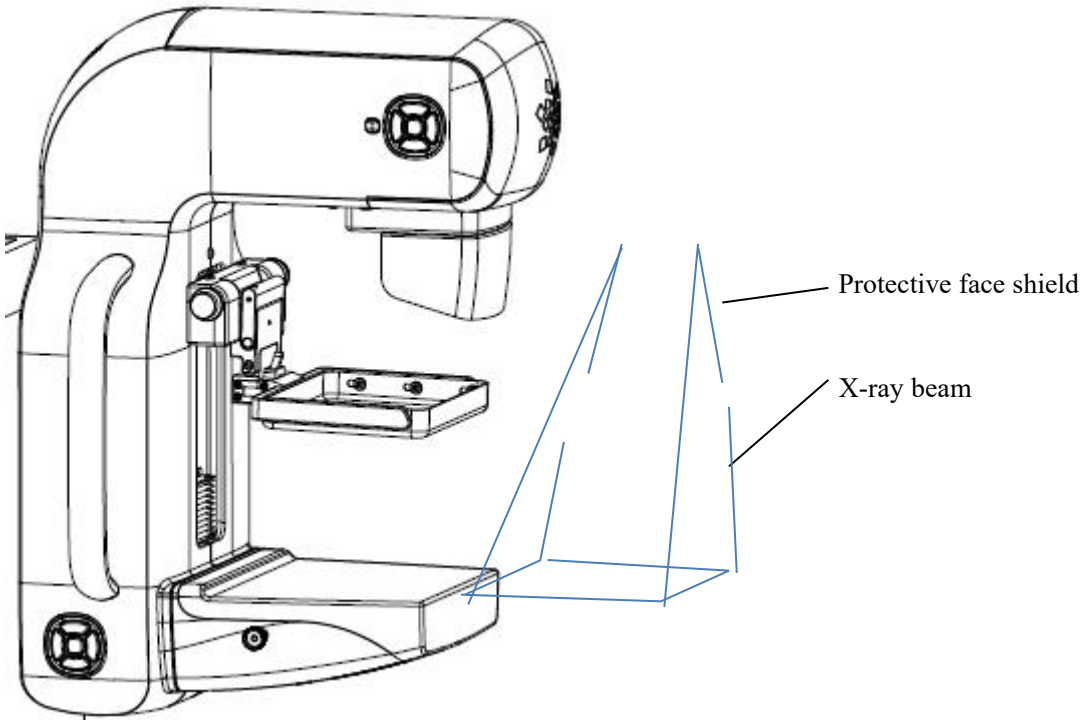


Figure 2-2

2.9 Environment Protection

The Lanmage Company designs and manufactures X-ray equipments under the requirements of safety and environment protection. If the cover of this equipment is not dismantled, the device will not cause any harm to people or environment when it is operated correctly.

Under the conditions allowed by regulations, if you must use any material may cause harm to the environment, this situation must be handled in proper way.

WARNING:

- **The waste produced by the X-ray equipment cannot be disposed as industrial or household waste.**
- **Deal with the waste generated by the X-ray equipment in the correct way according to local environmental regulations.**
- **To reduce environmental pollution, reusable materials can be recycled through the qualified disposal.**

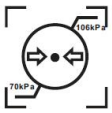
2.10 Symbols Instructions

Following table can help users identify the symbols used in on this equipment.

Table2-1

Symbols	Description
CE 0197	CE MARKING.
~	Alternating current
	Type B Applied Part
	Emergency stop switch
	Caution
	Ionizing radiation.
	Small focal spot.
	Large focal spot.
	X-ray source assembly, emitting.
	Dangerous voltage.
	General warning sign

	*Dangerous Voltage*
	Pinch Hazard
	Radiation Warning
	Measurement circuit symbol Protective Earth
	WEEE Instruction recovery icon
	Refer to instruction manual/booklet
	Serial number
	Authorized representative in the European Community
	Date of manufacturer
	Manufacturer (This symbol shall be accompanied by the name and address of the manufacturer.)
	Medical device: Indicates the item is a medical device
	Unique device identifier: Indicates a carrier that contains unique device identifier information
Outer packaging marking	
	The correct upright position of the distribution packages for transport and/or storage.
	Fragile, handle with care.

	Do not roll.
	Do not stack.
	Keep away from rain.
	Keep away from sunlight.
	Temperature limits. Indicates the temperature limits to which the device can be safety exposed.
	Humidity limitation.
	Atmospheric pressure limitation.

Chapter3 Regular Maintenance

To ensure the continuous safety performance of the equipment, regular maintenance shall be performed. Maintenance includes two aspects: one is maintenance by users or operators, and the other is maintenance by qualified X-ray maintenance personnel. The following introduces the maintenance procedures performed by users or operators.

⚠ **Notes:**

- Professional maintenance and servicing of this machine must be carried out by professional maintenance personnel, while daily maintenance can be performed by users themselves.
- User maintenance does not allow removal of the generator cover, nor disassembly of internal components in the generator cabinet and console. The manufacturer shall not be held liable for personal injury or machine damage caused by non-compliance with these regulations.
- Do not clean any part of the generator when the equipment is powered on and in operation. Before cleaning, please turn off the machine and disconnect the power supply.
- Clean the machine regularly. Use a cloth with inorganic cleanser to remove dirt from the cabinet enclosure. Do not use a vacuum cleaner or other organic solvents.
- The equipment room shall be kept clean, dry and well-ventilated; the machine shall be protected from high temperatures and direct sunlight.
- The filler (dehydrated petroleum jelly) in the high-voltage plug socket shall be replaced regularly. Special attention shall be paid to frequent inspection and timely replacement during summer or periods of heavy workload.

⚠ **Note: To ensure that this product is in good working condition, during the use of the image workstation, inspections and maintenance shall be carried out in accordance with the following instructions, and each inspection and maintenance shall be recorded in the maintenance records.**

- Check the Windows error logs. Clear the log files after analysis.
- Check the DR software error logs. Clear the log files after analysis.
- Use Windows system utilities to scan for volume errors of main disk drives.
- Verify if system fragmentation exceeds 5%. Run Windows Disk Defragmenter if necessary.
- Verify that the system has the latest version of authorized software and that authorized options are in use.

- Check the image storage directory for old images (make a list and confirm with the user whether they are still needed and whether they have been archived before removal).
- Download system settings to the database as a backup.

⚠ Warning: **Do not perform maintenance or service on any part of the equipment while in use.**

If any faults are identified during function and safety checks, the digital mammography system must not be used until the faults have been resolved on-site by Lanmage maintenance engineers or technicians trained by Lanmage.

⚠ **Note: Only maintenance personnel who have received professional training in the maintenance of medical X-ray equipment can perform system maintenance work.**

⚠ **Note: When the equipment is in use by a patient, no parts of the equipment shall be maintained or serviced.**

3.1 Maintenance tools and consumables

Maintenance tools and consumables

Table 7-1

Consumables	Number
soap-suds	some
anhydrous alcohol	some
cleaning cloth	some

3.2 Routine maintenance

The equipment room shall be kept clean, dry and well-ventilated; the machine shall be protected from high temperatures and direct sunlight. When not in use for a long time, the machine shall be covered with a dust-proof film to prevent dust accumulation.

During the use of this machine, the surface of the machine shall be properly cleaned and protected; when used by patients with infectious diseases, the radiography platform surface shall be promptly disinfected.

Regularly inspect bearings and relative moving parts at all positions, clean the relevant friction surfaces, and apply grease for lubrication.

During normal use, inspect the steel wire ropes regularly. If broken wires are found, immediately notify the professional technicians authorized by the company for replacement.

Frequently check whether the connection of the yellow/green dual-color protective grounding wire is in good condition.

Pay attention to the power supply status, check whether the power supply internal resistance (or power supply voltage drop) has changed, and strictly comply with the machine's requirements for the power supply.

For environmental requirements, please refer to《1.3 Environmental Conditions》

Table 7-2

Regular maintenance tasks shall include the following items:： Daily Routine Inspection	
Basic System	Check the basic system for visible damage (to the naked eye).
Displays and Indicator Lights	Visually inspect all displays and indicator lights on the stand.
Compressor	The compressor can only be used if there is no visible damage. Only in this way can the system be ensured to perform optimally and minimize risks to patients.
Electric Movement	Ensure all electric movements are smooth and normal.
Height Adjustment and Rotation:	When the displayed compression force is ≥ 30N, confirm that the C-arm cannot rotate or move up and down.
C-arm Movement	During the rotating arm movement using the one-touch function, ensure the safety of patients or other personnel and

	that no components are within the rotating movement range.
Monthly Inspection	
Emergency Stop Button	Check whether the emergency stop button works well ——After pressing the emergency stop button, all motor-driven movements must stop. In case of failure, cut off the main power supply of the system and notify the the after-sales service department of Shenzhen Lanmage Medical Technology Co., Ltd.
Annual Routine Maintenance	
The equipment must be maintained every 12 months to ensure the equipment safety and reliability. Any wearing of system components may cause danger. Be sure to designate professional personnel to check regularly and replace these components if necessary.	

3.3 Cleaning and disinfection

3.3.1 Cleaning

Before cleaning, the equipment must be turned off and disconnected from the power supply. It is not necessary to shut down the system when cleaning and inspecting the components that come into contact with patients.

All system components that come into contact with patients must be cleaned before inspection. The compressor on the stand can be removed to facilitate cleaning.

This product is a non-sterile product and does not require sterilization.

The equipment shall undergo regular maintenance, and its surface shall be cleaned and disinfected regularly.

⚠ **Note: The compressor and mammography platform must be cleaned in accordance with the guidelines.**

When selecting a cleaner, please note: Use a neutral, mild soapy water solution to clean the surface. Using other cleaners (such as those with a high alcohol content) may cause the surface to become dull or cracked. Under no circumstances should any corrosive, solvent-based, or abrasive cleaners or polishes be used.

⚠ **Warning: The use of corrosive cleaners will accelerate the aging of plastics and even cause equipment damage. Cleaners must never seep into the equipment.**

⚠ **Caution: Incorrect cleaning may cause damage to the equipment. The following are two daily cleaning methods:**

- Wipe the system with a damp, non-abrasive non-woven cloth or (100%) cotton cloth.
- Moisten a cleaning cloth with a neutral, mild soapy water solution to clean the surface of components.

3.3.2 Disinfection

⚠ **Warning: Use non-alcohol-based disinfectants for surface disinfection. Under no circumstances should any alcohol-based, corrosive, solvent-based, or abrasive cleaners or polishes be used for disinfection.**

Disinfection with solutions containing phenol and parachlorinated compounds may have a slight corrosive effect and is generally not recommended.

In general, disinfection sprays must not be used, as the mist from sprays may seep into the interior of the equipment. This means the safety of the system cannot be guaranteed (e.g., damage to electronic components, formation of a flammable air-vapor mixture).

⚠ **Note: Ensure that the concentration of the disinfectant in the air does not exceed the statutory limit, as disinfectants are hazardous to health.**

3.4 Regular Maintenance Procedures

1) Check whether the indicator and signal displaying is normal.
2) Check the labels indicating danger or warning.
3) Check whether there is any abnormal noise with exposure.
4) Confirm the grounding wires all work in good status.
5) Clean the cover with warm soapy water. Check all the covers, buttons and handles are no

damage or missing.

6) Check and make sure that all the electric lines are connected firmly.

7) Check and make sure all the moving parts can be run smoothly in their movement range.

8) Measure and adjust the power supply equipment.

9) Scanning for Volume Errors.

10) Run the Windows Disk Defragmenter.

11) Clean keyboard and mouse.

12) Check the brightness of monitor.

13) Create a backup.