Product safety and performance information

Product Name: Digital X-ray Radiography System

Product model: 6600B/9100K/9100K3/9100L2

Product information

Product name: Digital X-ray Radiography System

Model and specification:

6600B/9100K/9100K3/9100L2

Service life: 10 years

Manufactured by

Shenzhen Lanmage Medical Technology Co., Ltd.

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Advisory symbols

The following advisory symbols will be used throughout this manual .Their application and meanings are described below. Users shall be familiar with these symbols and meanings thereof before operation of the equipment.

⚠ **DANGEROUS: It will cause the serious injuries or even death if people do not pay attention to or not avoid this state or condition.**

⚠ **WARNING: It will cause the serious injuries or heavy loss of equipment or data if people do not pay attention to or not avoid this state or condition.**

⚠ **CAUTION: It will cause the injuries or loss of equipment or data if people do not pay attention to or not avoid this state or condition.**

⚠**NOTE: Remind the reader of the relative fact and condition. The notice items show the important information which should be known but has not necessary relationship with possible personal injury or damage of the equipment.**

Revision history

File Number: Muses pro-CE-101

Revision	Date	Reason for change
A/0	2025.7	First edition

CONTENTS

Chapter 1 Product Introduction

1.1 Performance characteristics

Digital X-ray Radiography System is a radiographic x-ray device developed and produced by Shenzhen Lanmage Medical Technology Co., Ltd. It is mainly composed of high-voltage generator, X-ray tube assembly, collimator, flat panel detector, rack and image acquisition workstation. It is used for routine radiography of patients to obtain a single image for clinical diagnosis.

The appearance structure of the system is shown in the figure below:

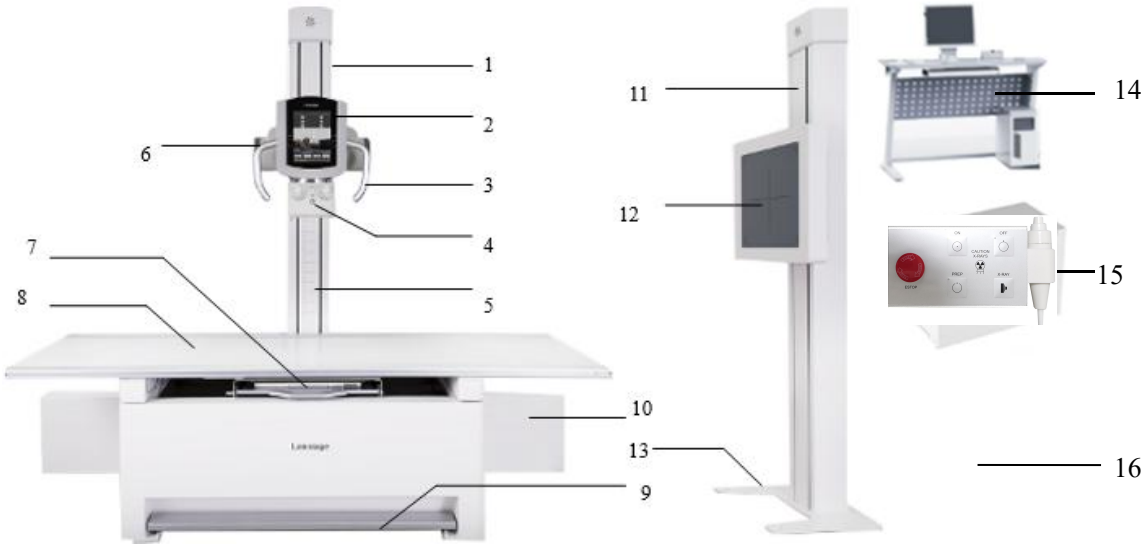


Figure 1-1 System appearance drawing

1-Tube stand	2-Tube head console	3- Tube head handle	4-Collimator
5-SID scale	6-X-ray tube assembly	7-Detector placement box	8-Patient Table
9-Foot switch	10-Tube stand rail	11-Wall Stand	12-Placement box of chest position detector

13-Base of Wall Stand	14-PC workstation	15-Control box	16- Medical X-ray High Frequency High Voltage Generator

1.2 Intended use and contraindications

The digital X-ray radiography system is intended for routine photography of patients to obtain images for clinical diagnosis.

Note:The patient target group of the system is who needs to take X-ray diagnosis examination. The intended users are the clinicians or professional medical staffs who have received adequate training of the product and technical service personnel authorized by Shenzhen Lanmage Medical Technology Co., Ltd..

⚠ **Contraindications: It is strictly prohibited within three months of pregnancy for pregnant women to use the device to be checked.**

For devices incorporating programmable electronic systems, including software or the device itself is software, minimum requirements regarding hardware, IT network characteristics and IT security measures, including protection against unauthorized access, are necessary for the operation of the software.

1.4 Environmental conditions

⚠ **Note:The device cannot be used an oxygen rich environment.**

Operation	Environment temperature : 10ºC ~ 35ºC; Relative humidity : 30% ~ 75%(No condensation); Atmospheric pressure : 700 hPa ~ 1060 hPa
Storage and Transport	Environment temperature :-20ºC ~ 55ºC; Relative humidity :20% ~ 90%(No condensation); Atmospheric pressure : 700 hPa ~ 1060 hPa

Chapter 2 Safety

2.1 General

Keep this operating manual with the equipment at all times and periodically review the operating and safety instructions.

⚠ **CAUTION:For a continuous and safe use of this equipment follow the instructions in this operating manual. Study this manual carefully before using the equipment and keep it at hand for quick reference.**

⚠ **If there is any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority of the Member State in which you are established.**

⚠ **Note: Only connect items that have been specified as part of the device or specified as being compatible with the device.**

⚠ **Note: The assembly of device and modifications during the actual service life require evaluation to the requirements of IEC60601-1.**

⚠ **Note: The surface material of the patient table is High Density Fiberboard.**

⚠ **Note: The surface material of the bucky is acrylic.**

⚠ **Note: The larger the loading factor, the greater the radiation dose.**

⚠ **Note: Before the device is opened and used, contact the manufacturer if the outer packaging occurs in the following situations.**

1) Damaged;

2) Unintentionally opened before use;

3) The packaging is exposed to environmental conditions outside of specified.

⚠ **Note: To avoid touching the equipment directly, the operator should wear gloves before manually operating the rack, the radiography table should be covered with a sterile pad before use, and the service technicians should wear gloves before installing the equipment.**

⚠ **WARNING**

- The equipment described in this manual must only be handled by previously trained and qualified personnel.
- X-ray equipment is dangerous to both patient and operator unless protective measures are strictly observed.

- Everyone associated with this equipment must be familiar with the safety and regulatory instructions contained within this manual and in particular, the statement at the beginning of this manual entitled “important!...X-ray protection”. These instructions should be thoroughly read and understood before attempting to place this equipment in operation.

Although x-ray radiation can be hazardous, x-ray equipment does not pose any danger when it is properly used. Please ensure that all service and operating personnel are properly trained and informed on the hazards of radiation. Those responsible for the system must understand the safety requirements for x-ray operation. Please study this manual and the manuals for each system component to be fully aware of all the safety and operational requirements.

⚠WARNING

- Special attention must be given to diagnostic x--ray equipment specified to be used in combination with accessories or other items. Be aware of possible adverse effect arising from these materials located in the x--ray beam. (see the table below for the maximum equivalent attenuation of materials possibly located in the x-ray beam).

Item	Maximum attenuation equivalent mmAL	
	21 CFR	GB 9706.12(IEC 60601-2-54)
Front panel of wall support or bucky	1.2	1.2
Patient support, movable, without articulated joints	1.7	1.7
Patient support	2.3	2.3

2.2 Responsibilities

⚠ WARNING

- Ensure that all personnel authorized to use the equipment are aware of the dangers of excessive exposure to x-ray radiation.
- The equipment herein described is sold with the understanding that the manufacturer, its agents, and representatives are not liable for injury or damage which may result from overexposure of patients or personnel to x-ray radiation.
- The manufacturer does not accept any responsibility for over exposure of patients or personnel to x-ray radiation generated by this equipment which is a result of poor operating techniques or procedures.
- No responsibility will be assumed for any equipment that has not been serviced and maintained in accordance with the instructions of the manufacturer, or which has been modified or tampered with in

any way.

- It is the responsibility of the operator to ensure the safety of the patient while the x-ray equipment is in operation by visual observation, proper patient positioning, and use of devices that are intended to prevent patient injury.
- Always watch all parts of the system to verify that there is neither interference nor possibility of collision with the patient or with other equipment.
- Make sure that the x-ray tube is set in working position with the reference axis (x-ray beam) pointing to the reception area.
- Should any interference (EMC) be detected with other equipment, please position other equipment away from this one.

2.3 Maximum permissible dose (MPD)

Before operation, persons qualified and authorized to operate this equipment should be familiar with the recommendations of the international commission on radiological protection, contained in annals number 60 of the icrp, with applicable national standards; and should have been trained in use of the equipment.

⚠**WARNING:The operator shall use the largest possible focal spot to skin distance in order to keep the absorbed dose also was reasonably achievable.**

2.4 Radiation protection

Because exposure to x-ray radiation can be damaging to the health, use great care to ensure protection against exposure to the primary beam. Some of the effects of x-ray radiation are cumulative and may extend over a period of months or years. The best safety rule for an x-ray operator is *"avoid exposure to the primary beam at all times"*.

Any object in the path of the primary beam produces secondary (scattered) radiation. The intensity of secondary radiation depends on the energy and intensity of the primary beam and the atomic number of the object material struck by the primary beam. Secondary radiation may be of greater intensity than that of the radiation reaching the film. Take protective measures to safeguard against this.

An effective protective measure is the use of lead shielding. To minimize dangerous exposure, use such items as lead screens, lead impregnated gloves, aprons, thyroid collars, etc. Lead screens should contain a minimum of 2.0 mm of lead or equivalent and personal protective devices (aprons, gloves, etc.) Must contain a minimum of 0.25 mm of lead or equivalent. For confirmation of the local requirements at your site, please refer to your "local radiation protection rules" as provided by your radiation protection advisor.

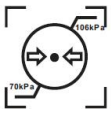
⚠**WARNING: While operating or servicing x-ray equipment, always keep a distance of not less than 2 meters from the focal spot and x-ray beam, protect body and do not expose hands, wrists, arms or other parts of the body to the primary beam.**

Chapter 3 Symbols Instructions

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

CE 0197	CE MARKING.
~	alternating current
V~	alternating current power supply
	Caution
	Ionizing radiation.
	Small focal spot.
	Large focal spot.
	X-ray source assembly, emitting.
	TYPE B APPLIED PART
	Dangerous voltage.
	Emergency stop
	Protective earth (ground)
	Disposal of signs for waste electrical and Electronic equipment (Please comply with local laws and regulations)

	Refer to instruction manual/booklet
	Serial number
	Authorized representative in the European Community (This symbol shall be accompanied by the name and address of the authorized representative in the European Community)
	Date of manufacture
	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.

Chapter 8 System maintenance instruction

In order to ensure that the X-ray machine can continue to operate safely, it should be regularly maintained. Maintenance has two aspects, one is maintenance by the user, and the other is maintained by service technicians trained or authorized by Shenzhen Lanmage Medical Technology Co., Ltd. The maintenance procedures performed by the user or the operator are described below. Manufacturer will provide circuit diagrams,component part lists,descriptions,calibration instructions to assist to service personnel in parts repair.

⚠CAUTION:

- Do not modify the device without unauthorized, unauthorized modification of the device may result in malfunction.
- The professional maintenance and maintenance of this machine must be carried out by service technicians trained or authorized by Shenzhen Lanmage Medical Technology Co., Ltd. The daily maintenance can be carried out by the user.
- User maintenance does not allow the generator cover to be removed. It is not allowed to remove the internal components on the generator cabinet and console. The manufacturer is not responsible for any injury to the personnel caused by the violation of the regulations and damage to the machine.
- Do not clean any part of the generator while the device is working. Turn off the machine and turn off the power before cleaning.
- Do not clean any part of the generator while the device is working. Turn off the machine and turn off the power before cleaning.
- The equipment room should be kept clean, dry and ventilated, and the machine should not be exposed to high temperature and direct sunlight.
- Dehydration of filler in the high-pressure connector. Vaseline should be replaced regularly. In the summer or during periods of heavy workload, it should be NOTE d that regular inspections should be updated in a timely manner.
- The equipment should not be maintained or serviced during use.

⚠CAUTION: In order to ensure that the product is in a good work piece state, during the use of the image workstation, always follow the instructions below for inspection and maintenance, and record each inspection and maintenance in the maintenance record.

- Check the wrong Win XP error log. Clear the log file after the analysis is complete

- Check the error log. Clear the log file after the analysis is complete
- Scan the primary disk drive volume error using the Windows system utility.
- Verify that system fragmentation exceeds 5%. Run Windows Defragmenter when needed.
- Verify that the system has the latest version of the licensed software and that the licensing option is already in use.
- Check the image storage directory of the old image. (Make a list and confirm with the user whether it is still needed and archived before moving out)
- Download the system settings to the database for use as a backup.

8.1 Maintenance tools and consumables

Maintenance tools and consumables

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

8.2 Routing maintenance

- The machine room should be kept clean, dry and ventilated, and the machine should avoid high temperature and direct sunlight. When not in use for a long time, it should be covered with dust proof film.
- During the use of the machine, the surface should be cleaned and protected. When the infectious disease patient is used, the bed surface should be disinfected and sterilized in time (with a clean white gauze stained 70%~ 80% of the ingredients are wiped with alcohol).
- Regularly inspect the bearings and relative moving parts, clean the relevant friction surfaces, and add grease lubrication.
- When in normal use, check the wire rope regularly. If there is any broken wire, immediately notify the company's authorized professional technicians to replace it.
- Always check if the yellow/green two-color protective earthing wire is well connected.
- Pay attention to the power supply situation, check whether the internal resistance of the

power supply (or the power supply voltage drop) changes, and fulfill the requirements of the power supply for the power supply.

Daily routine inspection

1) Check whether there is visible damage in basic system;

2) Visually inspect all displays and indicators on the rack.

3) Ensure that all electric movements are smooth and normal.

4) Check whether the warning and danger labels are intact.

5) Check whether there is abnormal sound at the time of exposure of X-ray generator assembly.

6) Longitudinal and transverse movement of table (focus on stroke, abnormal sound and shaking).

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.

8.4 Cleaning and disinfection

Cleaning:

Attention: the power supply of the equipment must be turned off!

Clean all high-pressure connections with moisture-resistant compound and reapply protective oil.

Clean the shell and surface of the equipment with a wet cloth dipped in neutral soapy water, and then wipe with a clean wet cloth dipped in clean water; The radiography table in contact with patients should be cleaned, disinfected and sterilized regularly, especially when it is polluted in use. Prevent any liquid from flowing into the equipment, and do not use any type of detergent or

solvent.

Sterilization /disinfection process

This product is non-sterile and needn't to be sterilized.

The equipment shall be maintained regularly, and its surface shall be cleaned and disinfected regularly.

The disinfection method must comply with laws and regulations and relevant requirements for disinfection and explosion-proof.

Forbid to use any corrosive, soluble or abrasive cleaners or brighteners.

Regularly disinfect the surface of equipment (including table panel), and recommend to use is opropyl alcohol. Do not recommend disinfectants containing phenol groups and their complexes as they are corrosive to certain extent.

- Before disinfection, turn off the power supply of the equipment.
- If the disinfectant contains explosive mixed gas, the power supply of the equipment shall not be turned on unless the disinfectant is completely volatilized.
- All parts of equipment, including accessories and connecting cables, must be disinfected by wiping.
- Do no recommend spray disinfection as the disinfectant may enter the equipment.
- After turning off the equipment, disinfect the room with a sprayer. After the equipment cools down, cover it carefully with plastic cloth. After the disinfectant mist dissipates, remove the plastic cloth and wipe the equipment for disinfection.
- The table surface shall be often wiped with alcohol or covered with disposable film to keep the table surface clean and disinfected.