

Product Safety and Performance Information

1 Product Description

1.1 Product name and model

Product name: Mobile C-arm X-ray System

Product model: Hypernova-Y Plus, Flexion

1.2 Basic UDI-DI

Basic UDI-DI	UDI-DI	Product Model
693896431401NK	06938964324013	Hypernova-Y Plus
693896431401NK	06938964315219	Flexion

1.3 Intended Purpose

This product is used for digital radiography, fluoroscopy and pulsed Fluoroscopy to obtain images for clinical diagnosis.

1.4 Indications for use

This product is used for routine radiography of patients, obtaining a single image for clinical diagnosis.

It is suitable for ward, radiology department, orthopedics department, emergency room and other places of medical units to meet the work requirements of digital radiography of the whole body parts such as head, chest, limbs, spine, lumbar spine, abdomen and so on.

The target user of this system is a medical institution. The operator should have certain qualifications and comply with the relevant national regulations. Before operating this system, the operator should also receive equipment operation training.

1.5 Contraindications:

Not found yet.

Warning: Because medical X-ray diagnosis itself brings X-ray radiation hazards, pregnant women or other patients who are not suitable for X-ray radiation exposure should be prohibited or carefully used.

1.6 Intended user

The intended user of this product is the medical institutions, and the operator should have the following skills, knowledge and training:

- 1) Obtained the Medical Practicing Certificate, and the scope of practice is medical imaging and radiotherapy or clinical specialty applicable to the interventional therapy. It is better to have more than 3 years of experience in interventional clinical diagnosis and treatment.
- 2) It has been systematically trained and passed the examination by the intervention diagnosis and treatment training base recognized by the health administrative department at or above the provincial level.
- 3) Professional nurses and other technical personnel shall be trained and qualified in relevant professional systems of interventional diagnosis and treatment.
- 4) Have the certificate of Radiation Safety and Protection Training.
- 5) After the operation training of the company's authorized professional and technical personnel, and passed the examination.











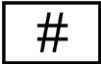


1.8 Intended Patient Population

The intended patient population of this product: patients who need surgical fluoroscopy and radiography examination.



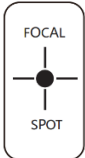
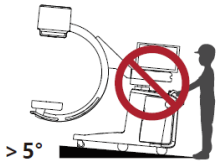




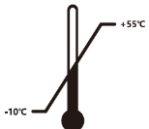
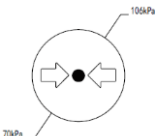
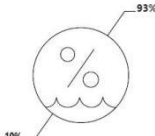
2 Product Safety Information


2.1 Product label Safety Information

This product has the following external markings, as shown in the table below.

	Medical device
	Authorized representative in the European Community
	Name and address of manufacturer.
	Date of manufacture.
	Use- by date
	Importer
	CE Certification mark
	Unique device identifier
	This symbol is used to indicate consultation of the user guide for general information
	Serial number
	Model number
	AC voltage
	This symbol is used to indicate protective earthing






	<p>Warning: ionizing radiation.</p>
	<p>Hand crushing hazard. This symbol indicates that serious injury to the hand may occur.</p>
	<p>dangerous voltage</p>
	<p>Safety warning label</p>
	<p>This symbol is used to indicate "beware of lasers".</p>
	<p>This symbol is used to indicate "no pedaling".</p>
	<p>This symbol is used to indicate "Safety sign: Do not look directly at the laser for a long time".</p>
	<p>This symbol is used to indicate "follow the operating instructions".</p>
	<p>This symbol is used to indicate "ON".</p>
	<p>This symbol is used to indicate "Disconnect".</p>
	<p>This symbol is used to indicate "UP".</p>












	<p>This symbol indicates "Down".</p>
	<p>This symbol is used to indicate "Emergency Deactivation".</p>
	<p>X-ray tube focus symbol</p>
	<p>This symbol is used to indicate that the product is not to be used on slopes of more than 5° .</p>
	<p>Packaging graphic mark used to indicate fragility.</p>
	<p>The packaging graphic symbol is used to indicate holding the device upward.</p>
	<p>This symbol is used to indicate rain and damp.</p>
	<p>This symbol is used to indicate the limit of stack layers.</p>
	<p>This symbol is used to indicate the temperature range in which the transportation package should be maintained.</p>
	<p>This symbol is used to indicate Atmospheric pressure limitation.</p>
	<p>This symbol is used to indicate Humidity limitation.</p>











	<p>This symbol is used to indicate that the transportation package must not be rolled over during handling.</p>
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2.2 Warning

Observe the following safety precautions and use the equipment properly to avoid personal injury and equipment damage.

	<p>Do not use or store near flammable chemicals such as alcohol, diluents, benzene, etc.</p> <p>If chemicals are sprayed or vaporized on the equipment, they may cause fire or electric shock through contact with live parts of the equipment. In addition, some disinfectants are also flammable, so be sure to be careful when using them.</p>
	<p>Do not connect with other equipment specified.</p> <p>Otherwise, a fire or electric shock may occur.</p>
	<p>Do not use power sources other than those indicated on the nameplate to supply power to the equipment.</p> <p>Otherwise, a fire or electric shock may occur.</p>
	<p>Do not use wet hands to carry the equipment.</p> <p>Otherwise, an electric shock may occur, which can result in death or serious injury.</p>
	<p>Do not place heavy objects such as medical devices on the cables.</p> <p>Do not pull, bend, bind, or step on the cable to prevent damage to the sheath.</p> <p>Otherwise, the cables may be damaged, resulting in fire or electric shock.</p>

	<p>To avoid electric shock, the equipment can only be powered by a power supply device with protective grounding.</p> <p>Otherwise, a fire or electric shock may occur.</p>
	<p>Do not disassemble or modify the equipment. Any changes to the equipment are not allowed.</p> <p>Otherwise, it may result in a fire or electric shock. In addition, touching an integrated component may cause electric shock, which can result in death or serious injury.</p>
	<p>Do not hit or knock the equipment and parts.</p> <p>The equipment may be damaged if it is subjected to strong turbulence.</p> <p>If the equipment is not repaired in time, it will result in fire or electric shock.</p>
	<p>Do not spray liquids or chemicals on the equipment. Do not allow the device to come into contact with the patient's blood or other body fluids.</p> <p>Otherwise, it could cause a fire or get an electric shock.</p>
	<p>Do not modify this equipment without the manufacturer's authorization.</p>
	<p>If this equipment is modified, it must be properly inspected and tested to ensure continued safe use.</p>
	<p>This equipment should not be used in environments with flammable gases, corrosive gases, or explosive atmospheres.</p>
	<p>Care should be taken to prevent the intrusion of liquids or conductive substances into the instrument to avoid short circuits.</p>
	<p>It is prohibited to disassemble the device by non-authorized personnel.</p>
	<p>It is prohibited to sell the device to non-medical institutions or non-licensed physicians.</p>
	<p>Before operating the equipment, you should ensure that there are no other people or obstacles within the range of mechanical movement of the equipment, to avoid collision damage to the equipment, or cause injury to personnel.</p>

	The equipment should not be used if there is any electrical or mechanical failure that has not been eliminated.
	Do not use excessive force when using the knobs, and do not mistake the direction of rotation between locking and loosening.
	The equipment may be affected by electromagnetic interference during special diagnosis or treatment.
	Do not place the medical device equipment in a place where it is difficult to disconnect the power supply unit.
	Ensure that the power is off before connecting or disconnecting cables between devices. Otherwise, it can result in electric shock, which can result in death or serious injury.
	Immediately turn off the power box and disconnect the power cord and contact our sales representative or local dealers if any of the following occurs: When there is smoke, accompanied by odor or abnormal sound.
	Before cleaning, power off the equipment and unplug the power cable. Before powering on the equipment, ensure that the equipment surface and plug are dry. Otherwise, a fire or electric shock may occur.
	Remove the plug from the ac socket and clean it regularly. Use a dry cloth to remove dust and dirt from the socket and surrounding area. If the power cord is plugged in for too long in a dusty, dark, damp environment, the dust around the socket will absorb moisture, which may cause insulation failure and cause a fire.
	For safety purposes, ensure that all power supplies are turned off before performing routine checks according to the product instruction. Otherwise, an electric shock may occur.
	Means of monitoring, evaluation and control Please refer to the "Product installation and connection" section of this manual for the status indication of the product. Do not use the product if the status is not correctly indicated.

3 Product Performance Metrics

3.1 Power

3.1.1 Maximum Output

The combination of loading factors leading to a maximum output electrical power of 5 kW in photographic mode is 100 kV, 50 mA;

The combination of loading factors leading to a maximum electrical output power of 0.693 kW in continuous fluoroscopy mode is 110 kV, 6.3 mA;

The combination of loading factors leading to a maximum output power of 2.5 kW in pulsed perspective mode is 100 kV, 25 mA.

3.1.2 Nominal electric power

The nominal electrical power is 5 kW, corresponding to a loading factor combination of 100 kV, 5 mAs (50 mA, 0.1 s)

3.2 Loading Factors Control and Indication

The main performance parameters of this system mainly include the following:

1) X-ray tube voltage:

Photography mode: 40 kV~125 kV, continuously adjustable, step length of 1 kV;

Continuous perspective: 40 kV~110 kV, continuously adjustable, step length of 1 kV;

Pulse perspective: 40 kV~125 kV, continuously adjustable, step length of 1 kV.

The voltage deviation of the X-ray tube should not be greater than 8%.

2) X-ray tube current:

Photography mode: 2 mA~100 mA; R'10 number system;

Continuous fluoroscopy: 0.5 mA~6.3mA; Continuously adjustable, step size is 0.1 mA;

Pulse perspective: 0.5 mA~32mA; Continuously adjustable, 0.5mA ~ 8mA the step size is 0.1mA, and 8mA ~ 50mA the step size is 1 mA.

Photography mode: 2 mA ~ 100mA, staging adjustment of the current, using the R'10

number system.

3) Loading time:

Photography time 10ms~1600ms; Using R'10 number system;

The deviation of X-ray design should not be greater than $\pm(10\%+1 \text{ ms})$;

4) Current time product:

The current time product shall meet the following requirements:

Adjustment range and adjustment mode: 0.2 mAs ~ 100 mAs; current time integral gear adjustment, using R'10 number system;

The deviation of the current time product should be no more than $\pm(10\%+0.2 \text{ mAs})$.

5) Maximum output electric power:

The combination of loading factors leading to a maximum output electrical power of 5 kW in photographic mode is 100 kV, 50 mA;

The combination of loading factors leading to a maximum electrical output power of 0.693 kW in continuous fluoroscopy mode is 110 kV, 6.3 mA;

The combination of loading factors leading to a maximum output power of 2.5 kW in pulsed perspective mode is 100 kV, 25 mA.

6) Image no visible artifacts.

7) Image no visible afterimage.

8) Low contrast resolution:

The low contrast resolution of fluoroscopy mode is not greater than 5.6%;

The low contrast resolution of radiography mode is not greater than 4%.

9) Dynamic Range:

The discernible dynamic order wedge number of fluoroscopy mode is not less than 14;

The number of discernible dynamic order wedges of photography mode is not less than 16.

10) Pediatric Radiography

- a) The instructions for use shall take measures to reduce the dose in the pediatric examination;

- b) The anti-scatter filter grid should be removable without tools.

11) Spatial resolution:

The nominal incident field size and spatial resolution meet the following requirements:

Flat panel detector	Mercu0909X	Mercu1212X	Pluto0909X	Pluto1212X
Nominal incident field size (mm)	213.5×213.5	307.2×307.2	213.2×213.2	294×313.6
Spatial resolution in photographic mode (lp/mm) \geq	≥ 3.6	≥ 3.1	≥ 4.0	≥ 4.0
Spatial resolution in perspective mode (lp/mm) \geq	≥ 3.4	≥ 2.5	≥ 3.7	≥ 3.7

12) Effective field of view:

When the distance of the X-ray tube to the image receiving surface is 65cm, the maximum size of X-ray field available for the beam limiter shall not be greater than 35cm × 35cm.