

# Product Safety and Performance Information

## 1 Product Description

### 1.1 Product name and model

Product name: Mobile Radiographic Unit

Product model: M50-1A、M800-1E、M880、M40-1、M40-1A

### 1.2 Basic UDI-DI

Basic UDI-DI	UDI-DI	Product Model
693896431500NN	06938964315066	M50-1A
693896431500NN	06938964315219	M800-1E
693896431500NN	06938964315417	M880
693896431500NN	06938964315011	M40-1
693896431500NN	06938964315028	M40-1A

### 1.3 Intended Purpose

This product is suitable for medical units to conduct radiography examination, not for mammography and dental X-ray diagnosis.

The medical conditions for each model are digital X-ray radiography.

### 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.


This system can be reused. Please refer to the product manual for requirements on product cleaning and disinfection.

This system is not intended to be used in combination with other devices.

## 1.5 Contraindications:

No contraindications are known.

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.

 Warning	Do not use this product for any purpose other than its intended use.
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## 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.





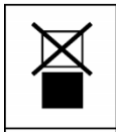



## 1.8 Intended Patient Population

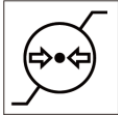





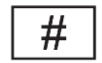






The intended patient population of this product: patients who need digital X-ray radiography.













## 2 Product Safety Information


### 2.1 Product label Safety Information

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


Marking	Location	Description
	Packaging Box	Fragile, handle with care.
	Packaging Box	Avoid rain
	Packaging Box	Up
	Packaging Box	Recyclable
	Packaging Box	No stacking
	Packaging Box	Center of gravity
	Packaging Box	Temperature limit
	Packaging Box	Humidity limit


Marking	Location	Description
	Packaging Box	Limit of atmospheric pressure
	System nameplate	Manufacture date
	System nameplate and Packing Box	Use-by date
	System nameplate and Packing Box	Batch code
	Packing Box	Imporer
	Packing Box	Distributor
	System nameplate and Packing Box	Model Number
	Packing Box	Country and Date of manufacture
	System nameplate and Packing Box	Medical device
	System nameplate and Packing Box	Unique device identifier
	System nameplate	Authorized representative in the European Community
	System nameplate	CE Certification mark
	System Plate	Type B Application Part


Marking	Location	Description
	Power Connection Cable	Protective Ground (Earth) Symbol
	X-ray tube assembly	Ionizing Radiation Symbol
	Mobile DR trolley	Dangerous voltage
	Mobile DR trolley	X-ray Radiation Hazard Symbol
	Mobile DR trolley	Standby
	Mobile DR trolley	Emergency Stop Switch
	Mobile DR trolley	Caution: Pinch Point
	Mobile DR trolley	Non-ionizing Electromagnetic Radiation Symbol
	System nameplate	Waste Electrical and Electronic Equipment
	System nameplate	Serial number
	Next to the System Plate, Collimator Plate	Follow the Operation Manual
	Mobile DR trolley	No Treading


Marking	Location	Description
	Mobile DR trolley	No Sitting

## 2.2 Product Maintenance and Inspection

 Warning	Any wear on components of the product can result in hazards. It is imperative to perform maintenance every 12 months, and replace the corresponding parts if necessary.
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 Warning	Please perform maintenance and care according to the requirements of this user manual; product maintenance should include testing of image quality.
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 Warning	Before using this product, the operator must ensure that all safety-related functions are operating properly and that the system is ready.
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 Warning	Installation, commissioning, addition, modification, and repair of this product shall be carried out by approved by the manufacturer, unauthorized modifications to this equipment are not allowed, and this product should not be connected to components not specified, as this may cause damage to the product or injury to personnel, in which case this company shall not bear any responsibility.
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## 2.3 Radiation Protection

X-ray radiation is harmful to human health, especially the cumulative effects and excessive exposure to X-rays. X-ray operators should avoid direct exposure to the X-ray beam as much as possible, and should take protective measures to prevent exposure to stray radiation. Any object obstructing the direct X-ray beam can cause scattering, the intensity of which may be equal to or

less than the intensity of the radiation incident on the screen.

For operators or maintenance personnel who do not adopt adequate safety protection measures, no practical design can fully protect their safety. Only authorized and professionally trained operators and maintenance personnel should operate this equipment. Operators should be trained in radiation protection and possess the corresponding protective knowledge. Avoid allowing unauthorized or unqualified personnel to operate the equipment. Qualified and authorized personnel should understand radiation protection measures before each operation and pay attention to the following matters:

 <p>Note</p>	<p>Radiation protection precautions:</p> <ul style="list-style-type: none"> <li>☆ Excessive exposure not only affects image quality but can also cause damage from radiation. Therefore, it is crucial to select appropriate exposure parameters and dose.</li> <li>☆ Unnecessary exposure or incorrect operation can cause radiation damage to patients, operators, and other personnel.</li> <li>☆ Operators should properly position the patient and use facilities designed to prevent or minimize radiation damage to the patient to ensure patient safety.</li> <li>☆ To keep the patient's absorbed dose as low as reasonably achievable, the focal-skin distance should be maximized.</li> </ul>
 <p>Note</p>	<ul style="list-style-type: none"> <li>☆ Under no circumstances should the operator, healthcare workers, and other personnel be directly exposed to X-rays, except for the patient, the operator, healthcare workers, and other personnel should stay away from the exposure area. Sufficient measures should be taken to prevent direct X-ray exposure.</li> <li>☆ Pay attention to the protection against stray radiation and secondary radiation.</li> <li>☆ Operators should pay attention to personal dose monitoring and regular health check-ups.</li> <li>☆ The machine room should comply with relevant requirements of national and local environmental protection and health departments to ensure that operators and other personnel are not harmed by radiation.</li> <li>☆ Do not modify the radiation protection circuits of this product without permission from this company.</li> </ul>

## 3 Product Performance Metrics

### 3.1 Power

#### 3.1.1 Maximum Output

Intermittent Mode: 5kW (40kV×125mA).

### 3.1.2 Nominal Output

When the X-ray tube loading time is 0.1s, and the X-ray tube voltage is 30kV:

The nominal output is 4.8kW (30kV × 160mA).

## 3.2 Loading Factors Control and Indication

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

1) X-ray tube voltage:

M40-1/M40-1A/M50-1A: The adjustment range of the radiography tube voltage is (40-125) kV, adjustable in stages;

M800-1E/M880: The adjustment range of the radiography tube voltage is (40-150) kV, adjustable in stages.

2) X-ray tube current:

M40-1/M40-1A/M50-1A: The adjustment range of the radiography tube current: (10-500) mA, adjustable in stages;

M800-1E/M880: The adjustment range of the radiography tube current: (10-630) mA, adjustable in stages.

3) X-ray tube loading time:

M40-1/M40-1A/M50-1A: The adjustment range of the radiography tube current: (10-500) mA, adjustable in stages;

M800-1E/M880: The adjustment range of the radiography tube current: (10-630) mA, adjustable in stages.

4) The adjustment range of Tube current-time product:

M40-1/M40-1A/M50-1A: (0.1-400) mAs, adjustable in stages;

M800-1E/M880: (0.1-630) mAs, adjustable in stages.

5) Maximum output power(intermittent mode):

M40-1/M40-1A : 40kW;

M50-1A: 50 kW;

M800-1E/M880: 54kW.

6) Image no visible artifacts.

7) Image no visible afterimage.

8) Low contrast resolution  $\leq 0.5\%$

9) Dynamic Range: In nominal FOV mode, the number of resolvable dynamic steps  $\geq 17$

10) Pediatric Radiography

Actual measurement:

a) Clinical protocols for pediatric radiography is available.

b) selecting a clinical protocol for pediatric radiography must prompt the operator whether to remove the physical grid.

c) the physical grid must be removable without tools, and its inserted or removed status shall be clearly visible or explicitly indicated.

d) additional filtration: 3.5 mm aluminum.

11) Spatial resolution:

M40-1/M40-1A : In the nominal effective imaging area, when there is an attenuated phantom, its spatial resolution is not less than 3.7lp/mm;

M800-1E/M880: In the nominal effective imaging area, when there is an attenuated phantom, its spatial resolution is not less than 5lp/mm.

12) Effective field of view: 43x43cm, 35x43cm, 25x30cm.

## STATEMENT TO USERS

For detailed usage information, please refer to the paper version of the instruction manual.