Product Safety and Performance Information

1 Product Description

1.1 Product name and model

Product name: Digital Radiography and Fluoroscopy System

Product model: DRF-6A、DRF-6A、DRF-6A、DRF-6A

1.2 Basic UDI-DI

Basic UDI-DI	UDI-DI	Product Model
693896431300NC	06938964313178	DRF-6A
693896431300NC	06938964313208	DRF-7B
693896431300NC	06938964313222	DRF-8B
693896431300NC	06938964313260	DRF-8PRO

1.3 Intended Purpose

This system can be used by medical institutions for gastrointestinal examinations, as well as medical X-ray examination and diagnosis of cranial, skeletal, thoracic, lung, urogenital tract and other parts. This system may also be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography and other parts radiography. This system is not for mammography and dental X-ray examination.

This system is to provide digital X-ray fluoroscopy and radiography images during diagnostic procedure.

1.4 Indications for use

This system can be used by medical institutions for gastrointestinal examinations, as well as

medical X-ray examination and diagnosis of cranial, skeletal, thoracic, lung, urogenital tract and other parts.This system may also be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography and other parts radiography. This system is not for mammography and dental X-ray examination.

This system is applicable to patients with body weight less than 200kg.

1.5 Contraindications:

Contra-indications: 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.

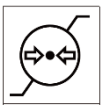
1.7 Intended Patient Population

The intended patient population of this product: patients with weight less than 200kg.

2 Product Safety Information

2.1 Product label Safety Information

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

Marks	Position	Description
	Packaging box	Fragile
	Packaging box	Keep dry
	Packaging box	Up
	Packaging box	Package recycling
	Packaging box	Stacking layer limit
	Packaging box	Lift here
	Packaging box	Center of gravity
	Packaging box	Temperature limit
	Packaging box	Humidity limit
	Packaging box	Limit of atmospheric pressure

Marks	Position	Description
	Nameplate of system	It indicates that the electrical security type of X - ray machine is B.
	High frequency and high voltage generator Diagnostic table	Protection grounding (earth) sign
	Outer cover of X-ray tube assembly	Warning sign of ionizing radiation
	High frequency and high voltage generator	Pay attention to the high voltage hazard sign.
	High frequency and high voltage generator	Pay attention to the ray radiation hazard sign.
	Diagnostic table	Emergency stop switch
	Diagnostic table	Beware of hand injury.
	Diagnostic table	Beware of mechanical injury.
	Diagnostic table	No sitting
	Diagnostic table	Follow instructions for use

2.2 Electrical Safety

Meanings of the electrical safety symbols used in this product are as follows:

Symbols of type B device

Symbol of neutral line

Dangerous voltage

Symbol of protective earthing

2.3 Mechanical Safety

Warning Please ensure that the patient or your hands are placed in a safe position in the moving range of this product. Please ensure that the patient's or your clothing does not intertwine with the device.

Notes Do not place any unnecessary object within the range of moving parts of this product.

Meanings of mechanical safety symbols used in this product are as follows:

	Be careful with your hand
	Be careful with the machine injury

2.4 Radiation Protection

X-ray is harmful to health. Wrong understanding and operation may cause radiation damage to

patients, operators, etc.

Access to and use of equipment needs to be restricted in accordance with local radiation protection regulations.

Operators shall be trained in radiation protection, familiar with the appropriate protection knowledge, and pay attention to the following matters:

Notes Precautions for radiation protection:

- ☆ Over exposure not only affects image quality, but also may cause radiation damage. So the selection of reasonable exposure parameters and doses is very important.
- ☆ Unnecessary exposure or wrong operation will cause radiation damage to patients, operators, etc.
- ☆ The operator shall reasonably position the patient,and use the facilities designed to prevent or minimize radiation exposure to the patient in order to ensure the safety of patient.
- ☆ The focal point shall be as far away from the skin as possible in order to keep the dose absorbed by the patient as low as possible and reasonable.
- ☆ In any case, it is necessary to avoid direct exposure of operators, health care workers and other personnel to X-ray, and take adequate measures to prevent direct X-ray exposure.
- ☆ Prevent the secondary radiation such as stray radiation.
- ☆ Operators shall focus on personal dose monitoring and regular physical examination.
- ☆ The equipment room must meet the requirements of the national and local environmental protection departments and health and epidemic prevention departments to avoid radiation damage to operators and other personnel.
- ☆ Do not change the radiation protection circuit of this product without the Company’s permission.

3 Product Performance Metrics

3.1 Power

Performance	Parameters
Last frame hold	It shall have the function of keeping the last frame of fluoroscopy
Automatic fluoroscopy	There shall be automatic fluoroscopy function.
Nominal incident field size	Nominal incident field size of detector in x and y directions: 430mm × 430mm, the actual imaging size should be greater than 95% of the nominal value.
spatial resolution	DRF-6A/7B: fluoroscopy spatial resolution： in maximum field of view (430mm × 430mm) : Should not be less than 1.4lp/mm； High resolution mode (200mm×200mm): Should not be less than 2.2lp/mm； radiography spatial resolution: in maximum field of view (430mm×430mm): Should not be less than 3.7lp/mm DRF-8B,DRF-8PRO： fluoroscopy spatial resolution: Maximum field of view (430mm × 430mm，1364 × 1364 pixel matrix), should not be less than 1.8lp/mm; High resolution mode (2046 × 2046 pixel matrix), which should not be less than 2.5lp/mm; Radiography spatial resolution:

	in maximum field of view (430mm × 430mm) : DRF-8B, DRF-8PRO: not less than 5.0lp/mm.
FPD image uniformity	The ratio of the standard deviation R of the pixel gray value at the specified sampling point of the X-ray image to the mean value V_m of the pixel gray value at the specified sampling point shall not be greater than 2.5%.
Image acquisition rate	DRF-6A/7B:Continuous fluoroscopy: At 430 × 430mm field of view, not less than 25 frames/s under 1024 ×1024 pixel matrix; At 430 × 430mm field of view, not less than 15 frames/s under 1536 ×1536 pixel matrix; Pulse fluoroscopy: At 430 × 430mm field of view, not less than 25 frames/s under 1024 ×1024 pixel matrix; At 430 × 430mm field of view, not less than 15 frames/s under 1536 ×1536 pixel matrix; Radiography: At 430 × 430mm field of view, not less than 3 frames/s under 3072 ×3072 pixel matrix; Radiography grading: single frame, 1 frame/s, 2 frames/s, 4 frames/s, 7.5 frames/s, 15 frames/s. DRF-8B/8PRO: The maximum fluoroscopy image acquisition rate for fluoroscopy should not be less than 30 frames/s. Radiography grading: single frame, 1 frame/s, 2 frames/s, 4 frames/s, 7.5 frames/s, 15 frames/s.

Artifact	X-ray fluoroscopy and X-ray radiography should not have artifacts that affect the diagnosis.

STATEMENT TO USERS

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