Product Safety and Performance Information

1 Product Description

1.1 Product name and model

Product name: Direct Digital Radiology System

Product model: New Oriental 1000FC, New Oriental 1000LB, New Oriental 1000N5s, New Oriental 1000N2s, New Oriental 1000N1a, New Oriental 1000U1, Starview

1.2 Basic UDI-DI

693896431200N7

1.3 Intended Purpose

The system is general purpose digital radiographic imaging system, intended to be used for performing radiological diagnosis for the human body in medical or research organizations.

1.4 Indications for use

The System is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and the system is intended for use in all routine radiographic exams.

This product is intended to be used for X-ray radiography and fluoroscopic diagnosis in medical institutions. It is not intended for use in X-ray diagnostic imaging for angiocardiography, nor for mammography or dental X-ray diagnostic imaging.

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 system is the medical institutions, and the operator should have the following skills, knowledge and training:

1) Professional nurses and other technical personnel shall be trained and qualified in relevant professional systems of radiodiagnosis and treatment.
2) Have the certificate of Radiation Safety and Protection Training.
3) After the operation training of the company's authorized professional and technical personnel, and passed the examination.

1.7 Intended Patient Population

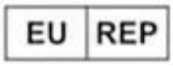
The intended patient population of this system: patients who need DR examination. Patient weight should not exceed 250kg.

2 Product Safety Information

2.1 Product label Safety Information

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

Name	Symbol / Label	Description
Company Logo		It represents Beijing Wandong Medical Technology Co.,Ltd.
CE Mark		It refers to CE conformity marking, and compliance with the EU Medical Device Regulation (MDR).
Manufacturer		It indicates the manufacturer of the

		product.
Date of Manufacturing		It indicates manufacturing date of the product.
European Authorized Representative		It indicates European Authorized Representative.
Serial Number		It indicates product serial number.
Disposal Warning		Do not dispose of this equipment or its parts with domestic waste.
Safety Label - Refer to Instructions for Use		It indicates a potential safety risk.Refer to the Instructions for Use before proceeding with the operation.
General Warning		It alters you to safety information about Caution, Warning or Caution.
X-ray Source Assembly: Emitting		It indicates that x-ray are being emitted or about to emit.
Small Focal Spot		It indicates the small focal spot of the X-ray tube.
Large Focal Spot		It indicates the large focal spot of X-ray tube.
Emergency Stop		It indicates the location of the emergency stop switch.
Warning Injure Hand		Be careful with your hand.

Warning Ionizing Radiation		Dangerous levels of ionizing radiation are present.
Warning High Voltage		Hazardous voltage may be present.
People's Republic of China - Ministry of Information Industry Order #39		It Indicates the equipment contains substances controlled under No. 39. The central number denotes the environmental protection use period (in years).
(Power) On		It indicates the circuit is connected or the power is on.
(Power) Off		It indicates the circuit is disconnected or the power is off.
Waiting		It indicates a process is ongoing, the user must wait for its completion.
Protective Earth (Ground)		It identifies the protective grounding.
Neutral	N	It indicates neutral line in the circuit.
Live	L	It indicates a live line in the circuit which is used to transmit electrical energy.

2.2 Electrical Safety

Obey the following before the operations:

- Ensure the connections between the equipment and the power supply is correct, and verify proper operations.
- Ensure the device is well grounded.
- Ensure the voltage of power supply is correct, and pay attention to the frequency and voltage of the AC supply and the allowable current.

Obey the following during the operations:

- Power on and off the equipment according to the instructions.
- Perform all operations according to the instructions.
- Maintain and clean according to the instructions.
- Observe the equipment during operation, and power it off immediately if any abnormality occurs.

The equipment must be connected to a protective grounding power supply to prevent electric shock risks.

2.3 Mechanical Safety

Ensure that your and patient's hands and clothes are out of the equipment movement area during operation. Ignoring this warning can result in equipment damage or personal injury.

Ensure that there are no obstacles in the equipment movement area. Ignoring this warning can result in collisions and equipment damage.

Ensure that both the patient and the operator stay more than 300 mm away from the suspended gantry and the X-ray tube assembly of the equipment during its vertical movement. Ignoring this warning can result in a collision and may cause personal injury or equipment damage.

2.4 Remote Control Safety

In the case of the product configured with a remote controller, please follow the following warnings.

The wireless remote controller must be charged using the manufacturer-provided dedicated charging dock. Using any third-party charging dock is strictly prohibited to prevent damage or other adverse effects on the device.

Always operate the wireless remote controller near the workbench. Do not use it beyond a safe distance. Ignoring this warning can result in safety risks such as product damage or personal injury.

2.5 Fire Safety

Before using fire-fighting facilities, disconnect the power supply to prevent electric shock. Additionally, the use of fire-extinguishing

sprays that are flammable or explosive is prohibited. The spray and dust from fire-fighting facilities may damage the equipment, and

appropriate protective measures must be taken.

2.6 Precaution for Data Backup

It is recommended to promptly back up patient or image data stored on the hard disk of the imaging workspace. The manufacturer is not responsible for the loss of information resulting from inadequate backup procedures. Ignoring this note can result in data loss.

2.7 Recommendations for Failure and Emergency

Ensure that the equipment always connects to mains power supply with protective earth to avoid risk of electric shock. Ignoring this warning could result in fatal injury.

Do not dismount or remove the equipment parts in the event of any failure. Service must be performed by personnel approved by Wandong. Ignoring this warning can result in personal injury or product damage.

The manufacturer is not responsible for interference caused by use of

unspecified parts, unauthorized changes or modifications to the equipment.

In case of a **Failure**, please following these steps:

1. Power off the equipment immediately and disconnect it with the mains power supply.
2. Attach a notice “Malfunction!” to the device.
3. Contact the after-sales service or local service agency authorized by the manufacturer for assistance.

In case of an **Emergency**, please following these steps:

1. Press emergency stop switch to disconnect the equipment with the mains power supply immediately.
2. Take the necessary steps to address the emergency (e.g. instruct the patient to leave the diagnostic room).
3. If necessary, contact the after-sales service or local service agency authorized by the manufacturer for assistance.

2.8 Precautions for Cleaning and Disinfection

Please disconnect the power supply to the equipment before cleaning or using disinfectant spray. Ignoring this warning may result in personal injury from electrical contact.

Never use flammable or explosive sprays. The spray may cause fire or explosion. Ignoring this warning may result in serious personal injury due to fire or explosion.

Do not allow water or other liquids to enter the device. Ignoring this warning may result in electrical short circuits, metal corrosion, and other forms of equipment damage.

Do not use spray cleaners in medical equipment rooms, as the spray may

enter the devices. If this warning is ignored, the spray could cause electrical short circuits, metal corrosion, or other equipment damage.

2.9 Precautions for Lifting Heavy Parts

During installation, debugging, or maintenance, please comply with local health and safety regulations and procedures. Otherwise, do not lift or move heavy components. Ignoring this warning may result in personal injury.

Heavier components must be moved and installed by qualified personnel using appropriate lifting equipment. Ignoring this warning may result in personal injury.

2.10 Precautions for Long.term Inactive Equipment

If the equipment has not been used for a long time, commission it according to the instructions provided in this document before resuming clinical use. Ignoring this warning can result in equipment damage or personal injury.

2.11 Disposal of the Equipment

This product is designed in accordance with the latest environmental protection standards. When users operate properly and does not dismantle, it does not harm humans or the environment.

Due to its functional requirements, this product have to utilize materials that can be harmful to the environment. Consequently, the waste from this X-ray product must not be disposed of as common industrial or domestic waste. All removed components should be recycled.

For instance, when replacing high-voltage transformer oil, the removed waste oil must be disposed of and recycled in compliance with local environmental protection regulations.

Please always ensure that the product waste is disposed of in compliance with the local environmental protection regulations.
Ignoring this caution can result in personal injury or environmental damage.

2.12 Individual Dose Measurement

Although X-rays can be harmful to human health, X-ray equipment poses no danger when operated properly.

Therefore, all personnel servicing or operating equipment must receive adequate training, and must be aware of the associated radiation risks and the specific operational requirements.

Do not modify the radiation protection electrical circuit without authorization from the manufacturer. Ignoring the warning can result in personal injury and equipment damage.

It is recommended to take measures to prevent or avoid direct exposure to X-rays all the time. Additionally, the equipment owner must ensure that the X-ray room complies with the local environment requirements and physicians or operators should follow requirements below:

- Use the DAP to assess radiation risk and dose to patient.
- Position patient correctly and use protective devices to minimize radiation.
- Select appropriate parameters, dose, and SID to prevent excessive exposure and minimize radiation for individual safety and image quality.
- Wear a personal dosimeter to monitor personal exposure and ensure it remain safe limits, and undergo periodic body examinations.

The equipment is equipped with a shielding door interlock as a safety measure against radiation exposure. The interlock prevents the shielding door from being opened during exposure, and prevents exposure if the door is open.

2.12.1 Maximum Permissible Dose (MPD)

According to the recommendations of International Committee of Radiation Protection (ICRP), maximum permissible dose (MPD) for operator must not exceed the following annual limits:

Stochastic Effect

Annual Dose Equivalent	20mSv (2rem)
Non-Stochastic Effect	
Annual dose equivalent to eye lens	20mSv (2rem)
Annual dose equivalent to other sections	500mSv (50rem)

2.12.2 Stray Radiation Protection

Any object in the path of X-ray may produce secondary or scattered radiation. Its intensity depends on the energy and intensity of primary radiation as well as and the atomic number of the irradiated object.

Ensure that protective devices (e.g. lead screens, gloves, aprons, and thyroid collars) are used during radiation diagnostics. Ignoring this warning can result in personal injury.

Lead screens must have a minimum thickness or lead equivalent of 0.5mm. Personnel safety wears (lead gloves or apron) must have a minimum lead thickness or lead equivalent of 0.25mm.

2.12.3 Pediatric Ionizing Radiation Protection

Children, especially infants, are more sensitive to radiation, and the associated risk is much higher than adults.

For pediatric patients, in addition to standard radiation protection measure, it is strongly recommended to shield non-target body parts to minimize radiation expose. For uncooperative newborn or infant patient, proper immobilization (e.g.,sandbags to secure limbs) may be necessary to avoid unnecessary repeat exposures.

When highly radiation-sensitive organs such as the lens, thyroid, and gonads are not the radiation target, they should be protected with appropriate shielding devices.

When using a mobile X-ray equipment in the ward, lead screen must be used to isolate the pediatric patients. All non-essential personnel must stay away from the radiation area.

2.12.4 Dose and Effect

(A) Acute effect

Symptom might take months or years to appears due to cumulative effect of X-ray exposure. The relationship between the acute effect and dose is as follows:

Dose Range	Acute Effect
≤0.5Gy	No clinical symptoms
0.5 Gy-1Gy	Possible symptoms including dizziness, fatigue, insomnia, loss of appetite and nausea
1Gy-10Gy	Damage to the Hematopoietic system, with severity increasing with dose: • Mild:1Gy～2Gy • Moderate: 2Gy～3.5Gy • Severe:3.5Gy～5.5Gy • Extreme: 5.5Gy～10Gy
≥10Gy	Radiation gastrointestinal sickness
≥50Gy	Brain damage

(B) Chronic effect

Prolonged exposure to low-dose-rate radiation at levels exceeding permissible limit can induce chronic systemic radiation damage. When the cumulative dose reaches a certain threshold, it may lead to systemic diseases, primarily characterized by injury to hematopoietic tissue and accompanied by changes in other systems.

3 Product Performance Metrics

performance	**parameters**
spatial resolution	**New Oriental 1000N5s:** 1) WDF 4343RFi fluoroscopy spatial resolution：in maximum field of view (430mm × 430mm) : Should not be less than 1.2lp/mm,High resolution mode: Should not be less than 2.0lp/mm 2) WDF 4343RWi and WDF 4343RFi radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 3.7lp/mm；

	3) WDF 4343Rs and WDF 4343RFs radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 5lp/mm； 4) WDF 4343RFs fluoroscopy spatial resolution：in maximum field of view (430mm × 430mm) : Should not be less than 1.6lp/mm,High resolution mode: Should not be less than 2.5lp/mm **New Oriental 1000FC:** 1) WDF 4343RFi fluoroscopy spatial resolution：in maximum field of view (430mm × 430mm) : Should not be less than 1.2lp/mm； 2) WDF 4343RWi and WDF 4343RFi radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 3.7lp/mm； 3) WDF 4343Rs and WDF 2530Rsi radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than or 5lp/mm； 4) High resolution mode: Should not be less than 2.0lp/mm； **New Oriental 1000LB：** 1) WDF 4343RWi and WDF 1748RL radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 3.7lp/mm； 2) WDF 4343Rs radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 5lp/mm()； **New Oriental 1000N1a：** 1) WDF 4343RWi radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 3.7lp/mm 2) WDF 4343Rs radiography spatial resolution: in maximum field of view (430mm×430mm): Should not be less than 5lp/mm； **New Oriental 1000N2s：**

	1) WDF 4343RFi fluoroscopy spatial resolution()：in maximum field of view (430mm × 430mm) : Should not be less than 1.2lp/mm； 2) High resolution mode: Should not be less than 2.0lp/mm； 3) WDF 4343RWi and WDF 4343RFi radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 3.7lp/mm； 4) WDF 4343Rs radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 5lp/mm **New Oriental 1000U1**: 1) WDF 4343RFi fluoroscopy spatial resolution：in maximum field of view (430mm × 430mm) : Should not be less than 1.2lp/mm； 2) High resolution mode: Should not be less than 2.0lp/mm； 3) WDF 4343RWi and WDF 4343RFi radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 3.7lp/mm； 4) WDF 4343Rs radiography spatial resolution:in maximum field of view (430mm×430mm): Should not be less than 5lp/mm **Starview**: radiography spatial resolution: in maximum field of view (430mm×430mm): Should not be less than 3.7lp/mm
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%.
Imaging area	WDF 4343RWi：430mm(h)×430mm(v) WDF 4343Rs：430mm(h)×430mm(v) WDF 4343RFi：430mm(h)×430mm(v) WDF 4343RFs：430mm(h)×430mm(v)

Nominal incident field size	>95%
Artifact	No visible artifacts exist in the image.
Erasure thoughness	No visible blur on the obtained image.
Dynamic range	The number of dynamic wedges that can be identified by fluoroscopy mode shall not be less than 15; The number of dynamic wedges recognizable by radiog mode shall not be less than 17
Image distance measurement function	The distance measurement deviation is not more than 5%

STATEMENT TO USERS

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