

Product Safety and Performance Information

1 Product Description

1.1 Product name and model

Product name: Digital angiography system

Product model: CGO-2100 Plus、CGO-5200 Pro

1.2 Basic UDI-DI

Basic UDI-DI	UDI-DI	Product Model
693896431400NH	06938964314076	CGO-2100 Plus
693896431400NH	06938964314113	CGO-5200 Pro

1.3 Intended Purpose

This product is used for clinical angiography, and provides X-ray fluoroscopy, radiography, digital subtraction angiography, and digital sectional images during interventional surgery for patients from newborn to geriatric.

The medical conditions for each model of CGO-2100 Plus/CGO-5200 Pro are X-ray fluoroscopy, radiography, cine, digital subtraction angiography, and cone beam computed tomography.

1.4 Indications for use

This system can be used by medical institutions for clinical angiography, and provides X-ray fluoroscopy, radiography, digital subtraction angiography, and digital sectional images during interventional surgery for patients from newborn to geriatric. This system is applicable to organs, cardiovascular, peripheral, and nervous systems; and is applicable to the examination and treatment

of systemic vascular diseases, emergency bleeding, visceral and venous embolism, and tumors.

This system is not for mammography and dental X-ray examination.

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 who need angiography and interventional treatment. Patient weight should not exceed 235kg+50kg CPR.




2 Product Safety Information

2.1 Product label Safety Information


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


Tags	position	description
	Packing case	Fragile
	Packing case	Keep dry
	Packing case	Upright
	Packing case	Packaging recycling
	Packing case	Stacking layer limit
	Packing case	Lift here
	Packing case	Center of gravity
	Packing case	Temperature limit
	Packing case	Humidity limit
	Packing case	Atmospheric pressure limit
	System nameplate	It indicates that the electrical security type of X-ray machine is B type.
	High voltage generator	Protection grounding (earth) sign


Tags	position	description
	Cardiovascular table	Warning sign of ionizing radiation
	X-ray tube assembly housing	Pay attention to the high voltage hazard sign
	High voltage generator	Pay attention to the ray radiation hazard sign
	High voltage generator	Emergency stop switch
	Cardiovascular table	Power on
	High voltage generator Mini control box	Power off
	High voltage generator Mini console	Non-ionizing electromagnetic radiation
	Control box	Follow the operating instructions
	High voltage generator	Environmental protection mark: This product conforms to the provisions of "Electronic Information Pollution Control Management Measures".
	C-arm	Beware of mechanical injury


Tags	position	description
	C-arm and table	Dangerous to hands
	Table	<p>CPR position: Retract the tabletop to the end when first aid needed.</p> <p>Do not defibrillate the bed while it is out which will cause serious injury to the equipment.</p>
	Table	The forbidden position of CPR
<p>Max load</p> <p>235KG</p> <p>Normal service load not exceeding 135kg</p> <hr/> <p>Beijing Wandong Medical Technology Co.,Ltd.</p>	Table	<p>Load label: When the load weight is not greater than 135kg, the service performance of the equipment will not be affected; When the weight of normal patients is less than 235kg, the load safety performance of the equipment will not be affected.</p>

2.2 Electrical Safety


 <p>WARNING</p>	<p>To avoid the risk of electric shock, the device must be connected to a main power supply that meets the standard and has a protective grounding.</p>
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 <p>NOTICE</p>	<p>Notes for pressure test:</p> <ul style="list-style-type: none"> ✧ The mains power inlet of this product is equipped with varistor to prevent electromagnetic compatibility lightning surge. If a voltage resistance test is required, the varistor at the power inlet of the network should be disconnected. <p>Electromagnetic compatibility notes:</p> <ul style="list-style-type: none"> ✧ The electromagnetic compatibility of this system is designed at the same time of function design. The system works normally in the expected electromagnetic environment without performance degradation or failure. ✧ The electromagnetic environment of the system is not a source of pollution. <p>These EMC effects may be more pronounced with other devices having relatively high levels of transmitting power and being close to the system. It is therefore recommended to restrict the use of mobile phones, wireless mics and other similar mobile radio devices around the system.</p>
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 <p>WARNING</p>	<p>Unless specifically instructed in this manual, do not remove the device panel or cover to prevent possible electric shock hazards. Removal of the cover may result in fatal or other serious injury.</p> <p>There are no parts in the equipment for the operator to repair or adjust. Only trained and qualified maintenance service personnel are allowed to handle the parts inside the equipment.</p>
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 <p>NOTICE</p>	<p>Do not place any liquid (such as water or disinfectant) on the device. Otherwise, the liquid may flow into the device and cause damage to the device.</p>
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2.3 Mechanical Safety

 <p>NOTICE</p>	<ul style="list-style-type: none"> ✧ Please do not place any excess objects within the range of moving parts of this product. ✧ Please ensure that the patient and operators hands are placed in the permitted safe position within the range of moving parts of this product. And ensure that the patient and operators clothing is not entangled with the equipment. Otherwise, serious or fatal injury may result.
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 <p>NOTICE</p>	<p>Except for normal operation, do not use additional large external forces on the equipment to prevent damage or imbalance.</p>
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 <p>WARNING</p>	<p>This product cannot be put into clinical use until it has been properly installed and adjusted by trained professionals approved by our company. Otherwise, it may affect the conformity of product safety, function and performance, or even cause product damage or personal injury and other safety risks.</p>
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 <p>NOTICE</p>	<p>When handling products, pay attention to the following:</p> <ul style="list-style-type: none"> ✧ Please try to avoid unnecessary tilt, vibration and impact. ✧ Carry the equipment according to the requirements in the relevant chapters of this operation manual to avoid damage to the equipment .
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2.4 Radiation Protection


The X-ray radiation is harmful to human health, especially with the cumulative effect and excessive exposure of X-rays. **X-ray operators should avoid direct exposure to the X-ray beam as much as possible and take protective measures to prevent scattered radiation.** Anything that obstructs the direct exposure of the X-ray beam may cause scatter, and the intensity of the scattered radiation may be equal to or less than that of the incident radiation on the input screen.


For operators or maintenance personnel who do not take sufficient safety measures, no practical design can fully protect their safety. **Only authorized and professionally trained operators and maintenance personnel can operate this equipment.** Operators should receive training in radiation protection and have relevant protection knowledge. Avoid unauthorized or untrained personnel from operating the equipment. Qualified and licensed personnel should be aware of radiation protection measures before each operation and pay attention to the following issues:


 <p style="text-align: center;">NOTICE</p>	<p>Radiation protection precautions:</p> <ul style="list-style-type: none"> ✧ Overexposure not only affects image quality, but also may cause radiation damage. Therefore, it is very important to select reasonable exposure parameters and dose. ✧ Unnecessary exposure or incorrect operation can cause radiation damage to patients, operators and other personnel. ✧ Operators should properly position patients and use facilities designed to prevent or minimize radiation damage to patients to ensure patient safety. ✧ To keep the absorbable dose as low and reasonable as possible for the patient, the focal distance to the skin should be as large as possible.
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 <p style="text-align: center;">NOTICE</p>	<ul style="list-style-type: none"> ✧ Under no circumstances should operators, medical personnel and other personnel be directly exposed to X-rays, and adequate measures should be taken to prevent direct X-ray exposure. ✧ Pay attention to the protection of secondary radiation such as stray radiation.
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	<ul style="list-style-type: none"> ✧ The operator should pay attention to individual dose monitoring and regular physical examination. ✧ The equipment room should comply with the relevant requirements of the national and local environmental protection authorities, health and epidemic prevention authorities to ensure that no radiation damage is caused to operators and other personnel. ✧ The radiation protection circuit of the product shall not be altered without the permission of the Company.
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 <p>WARNING</p>	<p>When operating or servicing the X-ray equipment, keep at least 2 meters away from the focal point and beam. Do not expose your hands, wrists, arms, or other body parts to direct radiation.</p>
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 <p>NOTICE</p>	<p>When adjusting the space position of the collimator, it must be operated in the non-loading state. Otherwise, the radiation will cause harm to the operator!</p>
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 <p>NOTICE</p>	<p>Although the collimator system reduces X-ray exposure to patients, the following recommendations should be followed:</p> <ul style="list-style-type: none"> ✧ X-ray radiation field is set to small as far as possible. ✧ To provide the best protection for patients, such as the use of special protective screen, with lead rubber apron when exposure to cover the patient's other organs, etc. ✧ Exposure, the staff should wear protective clothing, beside patients suggested that wear contain the equivalent of at least 1/64 "(0.35 mm) thick lead protective skirt.
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	<ul style="list-style-type: none"> ✧ Operators should be worn if possible dose table, etc. ✧ Operator as far as possible away from is light objects, and X ray tube component, and keep proper distance with the X-ray beam. ✧ Don't with explosion danger area in the equipment operation. Cleaners and disinfectants, including those used on patients, can produce explosive gas mixtures. Please comply with relevant regulations. ✧ Use other mobile protective equipment to minimize radiation exposure to patients and operators.
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 NOTICE	<p>During exposure, the operator must be as far away from the source as possible. When the operator must operate near the patient, take appropriate protective measures, such as using a suspended lead screen, a lead curtain by the table, wearing protective clothing (lead rubber apron), and, if necessary, wearing a film ray meter or pen dosimeter.</p>
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 NOTICE	<p>Exposure to and use of equipment should be restricted according to local radiation protection laws!</p>
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3 Product Performance Metrics

performance	Parameters
spatial resolution	Radiography: not be less than 3.1lp/mm(WDF 4030CV) or 5.0lp/mm(4131Z);
Image acquisition rate	a) During cardiac imaging, the maximum fluoroscopy image acquisition rate should be no less than 60 frames/second (WDF

	<p>4030CV) or no less than 100 frames/second (4131Z).</p> <p>b) The DSA imaging rate should be adjustable, and the minimum image acquisition rate should not exceed 0.5 frames/second;</p> <p>c) During peripheral angiography, the highest fluoroscopy image acquisition rate should be no less than 45 frames/second (WDF 4030CV) or no less than 60 frames/second (4131Z);</p>
Fluoroscopy performance during network transmission	When using fluoroscopy, if network transmission is selected, it should not affect the Fluoroscopy.
Fluoroscopy recovery time	The recovery time of fluoroscopy should not exceed 1 minute.
Artifact	The image has no artifacts that affect clinical application.
image measurement function	With distance, angle, and ratio measurements
DQE (detective quantum efficiency)	<p>WDF 4030CV: DQE(0)(RQA5, 1×1, $2\mu\text{Gy}$): 77% (Typical)</p> <p>4131Z: DQE(0)(RQA5, 1×1): 77% (Typical)</p>
Effective imaging area	<p>WDF 4030CV:400mmx300mm</p> <p>4131Z:408mmx306mm</p>
Last frame hold and fluoroscopy loop storage	It should have the function of maintaining the last frame of the fluoroscopy and storing the fluoroscopy loop
3D image acquisition	Can acquire three-dimensional images of various parts of the body (including nerves, chest, abdomen, limbs)

STATEMENT TO USERS

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