Fluoroscope X-ray system

OSCAR 15FD

User Manual

UM-A02 FDA

2024.06.07 Document Rev. 0.4

Preface

This User Manual contains general explanation of how the system works and other useful information.

Please read and comprehend this manual thoroughly for safe and effective use of the system.

This manual uses the following signs for instructions and warnings.

Information including these signs should be carefully read and fully understood.

	Failure to follow instructions marked with this sign may cause an accident or severe injury. Make sure that the user follows the instructions marked with a "Warning" sign.
	Failure to follow instructions marked with this sign may damage the equipment or embedded software or cause data loss. Make sure that the user follows the instructions marked with a "Caution" sign.
	This sign indicates instructions that must be checked by the user. Make sure that the user checks and follows the instructions marked with a "Note" sign.
	This sign indicates instructions that must be noted by the user.
The manufacturer and importer of this product shall ensure its safety, reliability, and installation/calibration/repair to be done by a qualified person.	
Federal law restricts this device to sale by or on the order of a physician, radiogical technologist, and surgeon. (Only U.S.A)	

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1. System Introduction and safety

1.1) System Introduction

Features of OSCAR 15FD

- Easy to operate with the LCD touch panel and user-friendly UI.
- ABC feature and various exposure modes are available.
- High-resolution and high-quality image obtained through a detector.
- High-quality image created with a small amount of radiant exposure using the pulsed fluoroscopy mode and DNR feature.
- A minimum exposure area set via the LCD touch panel using the virtual collimator even without exposing X-ray.

Indications for use

OSCAR 15FD is a mobile fluoroscopy system designed to provide fluoroscopic and spot film images of the patient during diagnostic, surgical and interventional procedures. Examples

of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac and critical care. The system may be used for other imaging applications at the physician's discretion.

OSCAR 15FD is indicated only for adult patients.

Contraindications

None.

Intended User

Experts such as radiologist and medics.

1.2) Before Starting Up the System

Any medical device using X-ray and electricity can be a source of potential danger.

Please read and fully comprehend how to use the system and to deal with emergencies provided in the manual.

- Users of this system are required to fully understand how to protect themselves from potential danger- and the conditions of the system that may cause such danger.
- Failure to follow these instructions on how to use the system safely can endanger both the user and patient.
- Only a qualified person should use the system.
- Please read and comprehend this manual thoroughly.
- Never attempt to modify this equipment.

  No modification of this equipment is allowed
- Do not install to the equipment any other parts than those provided.
- Do not use the power strip or extension wire to supply power to the system. This may lead to failure or malfunction of the unit.
- Do not use the system if any failure or malfunction occurs. Contact Customer Service immediately and wait for a technician to contact you.
- Do not use the PC for any other purposes than producing an x-ray image.
- Please do not look into the laser while the laser is running.
- If the device has caused to user and/or patient that any serious incident, you should report to the manufacturer and the competent authority of the Member state in which the user and/or patient is established.

If a malfunction occurs in the equipment during use, stop using the equipment and request repair

through the manufacturer or an agency designated by the manufacturer.

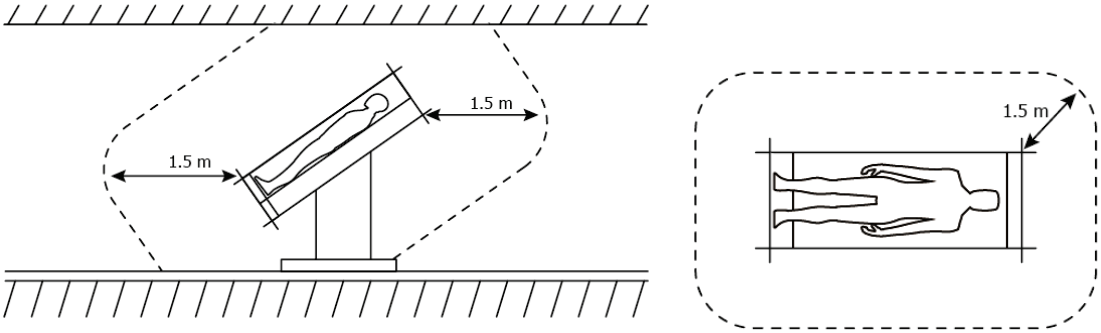
- Do not install any parts on the equipment other than those of the equipment provided.
- All users must be trained on how to use the equipment before using it. Users should contact the manufacturer or dealer for instruction on how to use it.
- This equipment must be operated only by qualified persons.
- Before using the equipment, check the specifications of the equipment and the major components that make up the equipment.
- Do not share the power of the equipment with peripheral devices.

Exposing X-ray in the form of pulses continuously at the site where a cardiac pacemaker or defibrillator is implanted may cause an error or malfunction of such device.

Avoid exposing directly at those devices and minimize the duration and output of an x-ray.

1.2.1) Patient environment

- The patient environment for OSCAR 15FD equipment is defined by IEC 60601-1.
- Typically in the realm of patient care, the patient environment is any space that has surfaces likely to come into contact with the patient or a caregiver who may touch the patient.
- It encloses a space 1.5 m beyond the perimeter of the bed (examination table, operating table, treatment booth, etc.) in its intended location.



1.3) Fitness

- The user of this system shall be responsible for maintaining accuracy of x-ray exposure amount, leakage radiation dose, effective center of the beam, kV, and mAs.
- Only a qualified physician and radiographer can use this system.
- Power Requirements

  Before plugging in the system, please check adequate power is being supplied to the site for installation.

NOTE

Use of exclusive AC power is recommended in order to prevent any conflict with power requirements of other devices.

1.4) Electrical and Fire Safety

Please check the following before using this system.

- Make sure that the power supply for the system is adequate before using it.
- Connect the power cable of the system to a power socket.
- Please take the same step for other peripherals (including signal input/output) before supplying power.
- Do not apply power to the equipment via a power strip and extension cord.
- OSCAR 15FD should be installed independently in the distribution panel.
- X-ray unit connected to the signal input, signal output or other connectors must comply with the relevant IEC standards (e.g., IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment). In addition, all such combination systems must comply with IEC60601-1 and/or IEC60601-1-1 harmonized national standards or relevant combination standards. If in doubt, contact a qualified technician.
- Place this product away from other X-ray products, power generating equipment and broadcasting stations. If the product is sharing the power with other electric devices, abnormal image might occur.
- For reducing the risk of electrical shock, and when connecting to power, there needs protecting ground connection.

- Users should not remove the cover of the equipment arbitrarily.
- Do not unplug the instrument's power cable while the power is on.
- Before supplying power to the equipment, check the power cable connection and voltage of the equipment.
- To avoid the risk of electric shock, it should only be connected to a power supply and outlet with a protective earth ground. If the equipment is used without protective grounding, an operation error may occur or equipment may be damaged due to leakage current and noise.

Keep the system away from any power generator, other x-ray equipment, or base station in order to avoid electrical interference during exposing. Sharing power with other electrical or electronic devices may affect the quality of an image.

In respect of the protection level and protection type for rating, OSCAR 15FD is classified as Class I, Type B ME equipment.

This system is not protected from liquid invasion.

Check ground connection in order to avoid electric shock.

The electric circuit of this equipment uses voltage that can cause serious damage or even death by electric shock. Never remove any cover of this equipment so as to avoid such danger.

Please observe the following safety instructions so as to avoid failure of the system and significant danger that may cause serious injury or electric shock to a user or patient.

- Always turn off the system and disconnect it from the power source before wiping it with a wet cloth or sponge.
- Never remove any cover of the equipment.

The electrical circuitry of this equipment uses voltages that could cause death by electric shock. To eliminate this risk, users should not remove any covers from the body.

- Turn off the system and pull out the plug when it is not in use.
- Never place food on any part of the equipment. It may come in contact with a conductive material in the electric circuit.

This system is not protected from liquids such as water or soapy water.

Any liquid coming in contact with the system can cause fire or electrical shock. If you spill liquid over the equipment, do not touch the cable connected to the power supply and wait until the liquid is dried up completely.

Please take the following measures in order to deal with emergencies.

- Turn off the system and disconnect the cable from the power socket.
- Keep away from the place where the system is installed.
- Seek help from people around you.
- Use a fire extinguisher especially approved for electrical fire.

Use a wrong type of a fire extinguisher can cause electric shock and burn.

To avoid this risk, check whether the system is allowed to use in the area and only use an allowed system.

1.5) Electromagnetic Compatibility

This equipment generates electromagnetic waves. Turn off the system and take the following measures if the equipment is affected by electromagnetic waves or causes such interference.

- Change the location of the system, taking into account other devices in the space.
- Connect the cable of the system to another power socket.
- Please contact Customer Service if you need to take other measures to meet specific requirements.

Do not place electromagnetic wave generators (cell phones, walkie-talkies, radio control devices, etc.) in the space where the equipment is installed, as electromagnetic waves may cause equipment malfunction.

1.6) Radiation safety

- Radiation-related laws and regulations in the country where the equipment is used should be applied.
- A user of this unit shall wear radiation protection equipment.
- Objects such as operating tables and patient supports can cause the imaging system to increase the radiation dose to obtain an optimal image of the patient. Minimize additional exposure by removing unwanted objects from the path of the X-ray beam. List of accessories recommended protective equipment
- List of accessories recommended protective equipment
  - Lead gloves
  - Lead glasses
  - Lead apron
  - Lead Thyroid protectors
  - Lead Barrier
  - Suspended shield

- Wear the radiation protection provided to minimize exposure to X-rays.
- This equipment must be used in a shielded room.

Failure to set safe exposure values for the x-ray unit and follow correct operating order can cause a danger to both a user and patient.

Consult a doctor if the system is used for a pregnant woman.

1.7) Over heating

The following warnings will be displayed if a high-voltage generator is overheating.

Temperature	OP display	Description
Temp 10℃~41℃	 (Blue)	X-ray exposure is possible
Temp 42℃~51℃	 (Green)	X-ray exposure is possible (Overheating warning)
Temp 52℃ or above	 (Red)	X-ray exposure is impossible (Overheating)

- If the warning is displayed, turn off the system and do not use it for 2~3 hr.
- Once the overheated unit cools off, power on the system, check if the warning is turned off, and then continue to use the equipment.

Please cool off the system for the set amount of time after exposing x-ray because failure to do so can damage the X-ray tube.

Be careful of contact as the generator surface may become hot while the equipment is in use, limit the contact time to less than one minute if it is necessary to contact the generator surface while the equipment is in use.

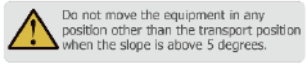
1.8) Operating Environment

Please avoid the following conditions when you use the system or put it in storage.

- Exposure to direct sunlight
- Exposure to excessive dust
- Exposure to high humidity
- Any environment that can cause a ventilation problem
- Exposure to air containing a lot of salt
- Exposure to chemicals or hazardous gases

- Be sure to operate the equipment only within the suggested operating environment.
- The suggested environment must be observed when storing and transporting the equipment.

1.9) Signs Used for the System

Symbol	Description	Location
	AC (Current)	Label, Manual
	Protective earth (Ground)	Boards
	"ON" (Power)	Equipment (Circuit breaker)
	"OFF" (Power)	Equipment (Circuit breaker)
	"ON" For parts of equipment	Equipment (Cart)
	"OFF" For parts of equipment	Equipment (Cart)
	X-Ray generator, X-Ray inspection	Label, Manual
	Warning, electricity	Generator
	Laser	Equipment
	WEEE Mark	Label, Manual
	Name of Manufacturer and Address	Label, Manual
	Manufactured Date	Label, Manual
SN	Equipment Serial Number	Label, Manual
	Refer to instruction manual	Label, Manual
MD	Medical Device	Label, Manual
UDI	Unique Device Identifier	Label, Manual
CC	Country Of Manufacture	Label, Manual
STOP	Emergency stop	Equipment (Emergency Button)
	5 degree tilt shift warning	Equipment

1.10) Waste Management

The equipment and parts whose life has ended should be disposed of as follows.

Item	Recycling	Industrial waste treatment service provider	Dangerous substances
X-ray tube		●	
Metal Frame	●		
Plastic	●		
PCB & harness		●	

1.11) Main Power outage

1.11.1) Preparation for power recovery

If the power is cut off by a power failure, etc., the equipment can't operation, you can install emergency power supply for the following cases.

- For the preservation of stored images only.
- For emergency Radioscopy and fluoroscopy.
- For all functions for performing Radiography and fluoroscopy.

Thus, the power assist system as described below must be installed in the surgery room, and please be well-informed of how to use.

- UPS
- Emergency power supply

In the space where the equipment is used, an emergency supply such as a UPS should be installed and the user should be familiar with how to use it.

1.11.2) Time to recover equipment power and functionality

- The time to recover a minimum set of function: within 40 seconds
- Disconnect the power and reconnect: within 20 seconds
- Re-starting the equipment and Preparation of the X-ray irradiation: within 20 seconds

1.11.3) Procedure for recovering power and function of equipment

1. Check the problem of main power supply.
2. The main power switches OFF. (The lower rear of the monitor cart)
3. Disconnect the Power Plug of Monitor cart.
4. Connect the Power Plug to the UPS equipment.
5. Main Power Switch ON. (The lower rear of the monitor cart)
6. Equipment ON. (Refer to User manual **3 Turning the Device On/Off**)
7. X-ray irradiation, after check completion of equipment booting.

1.12) Information security

This equipment contains a storage device (hard disk drive) which can store personal and medical information about patients. Access to or distribution of patient information for purposes other than diagnostic purposes is prohibited. Users may be subject to regulations relating to privacy security and data loss, depending on the country and region.

All the other networks should be restrained for the equipment except for the DICOM service. If you need another network other than DICOM, contact the equipment manager or the engineer. Also, contact the customer help desk immediately upon any cyber-security accident. The company will contact you for a security patch when a terrible threat to the system operation is detected.

NOTICE

- Customer Help Desk
  - Trained engineers are on standby for the emergency call.
  - Operating hours: Monday - Saturday, 09:00 am-06:00 pm (KST)
  - Contact number: +82-31-5178-5500
  - Contact web page: http://www.genoray.com/cs/contact_us

NOTICE

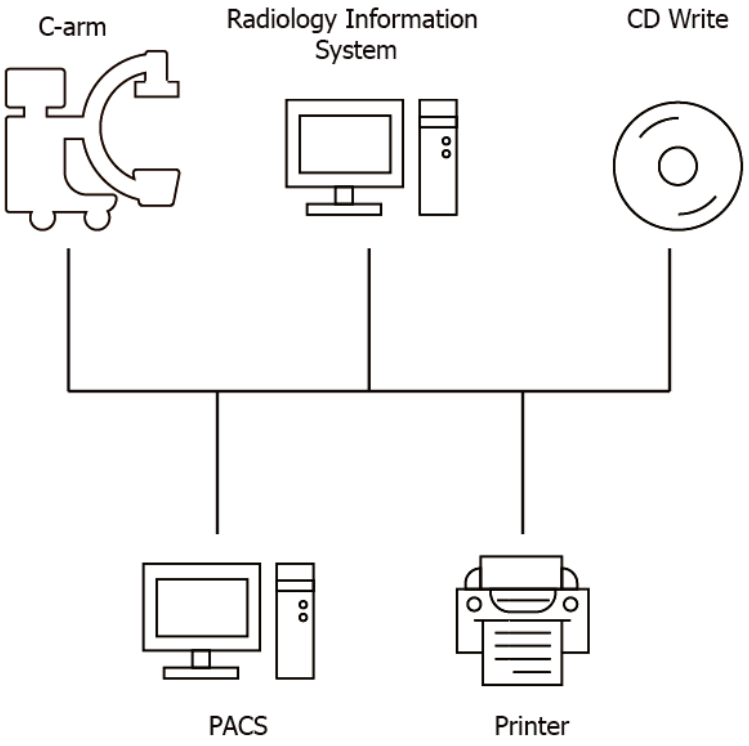
It is recommended to use only within a closed network of the medical institution where the physical and/or virtual firewall is established.

NOTICE

The software update should be performed by the customer service engineer from the manufacturer in the presence of the manager of the medical institution all the time.

Digital Imaging and Communications in Medicine

- Digital Imaging and Communications in Medicine(DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. The communication protocol is an application protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format.
- The National Electrical Manufacturers Association holds the copyright to this standard. It was developed by the DICOM Standards Committee, whose members are also partly members of NEMA.
- DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS). The different devices come with DICOM conformance statements which clearly state the DICOM classes they support. DICOM has been widely adopted by hospitals and is making inroads in smaller applications like dentists' and doctors' offices.
- DICOM is known as NEMA standard PS3, and as ISO standard 12052.



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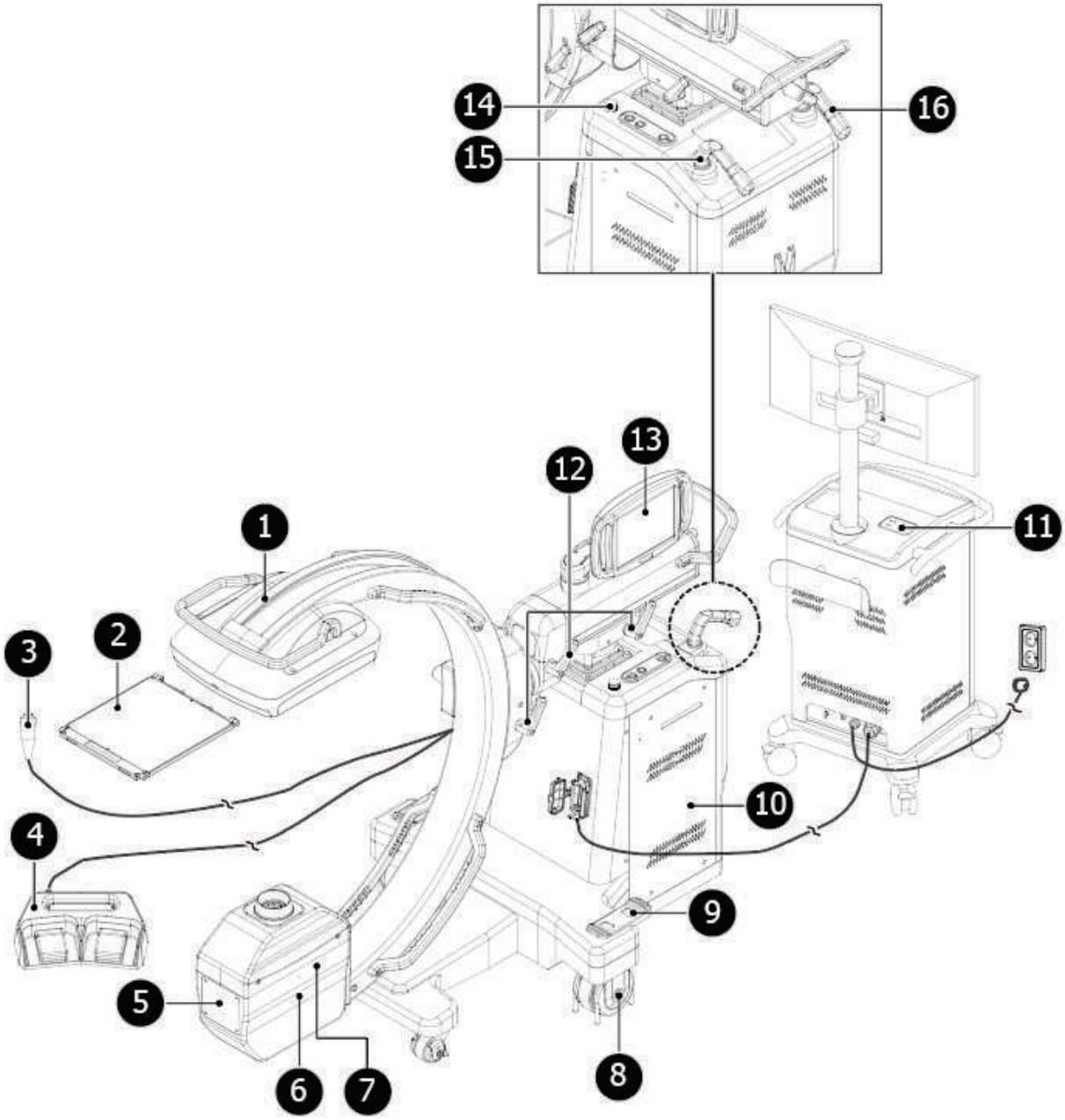
2. Construction of OSCAR 15FD

2.1) Structure and name



No.	Description	No.	Description
1	Detector	9	Fixing brake
2	Grid(Option)	10	X-ray support
3	Hand switch (x-ray exposure switch)	11	Power control panel
4	Foot switch (x-ray exposure switch)	12	Fixing lever
5	X-ray generator	13	X-ray control unit
6	X-ray tube	14	Emergency switch
7	X-ray exposure field controller	15	Fixing handle
8	Wheel	16	Steering handle

2.2) Exposure Switches

Use the switches to expose X-ray for fluoroscopy or radiography.

Exposure switches include the hand switch, foot switch, and shot switch.

CAUTION

Press and hold the corresponding switch to maintain X-ray irradiation.

NOTE

Before exposing the X-ray, please check the X-ray key ON/OFF switch which is located on the cart is on the right side.

2.2.1) Hand Switch

This switch can be used for both fluoroscopy and radiography modes.

- Fluoroscopy mode

  Pressing the hand switch in Step II will expose x-ray.

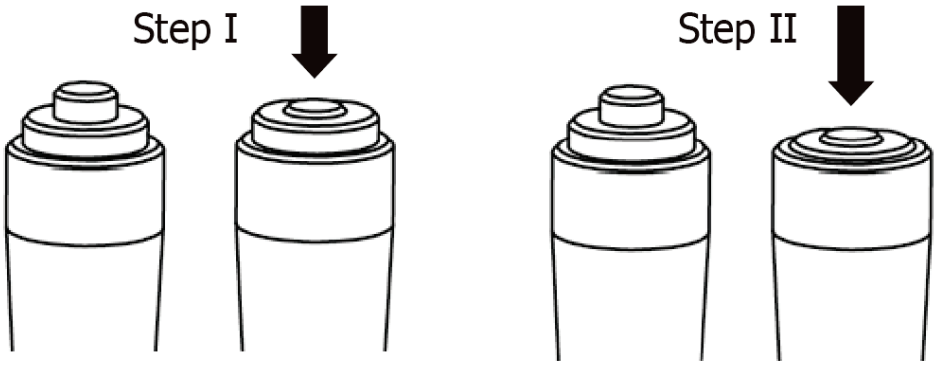
- Radiography mode

  X-ray exposure for radiography will be ready if you press the hand switch in Step I

  for 2 secs.

  Here, the preparation icon () in the operation panel will flash the green and white lights and after about 2 secs. only green light when x-ray exposure is ready.

  When ready, press the hand switch in Step II to expose x-ray.



2.2.2) Foot Switch

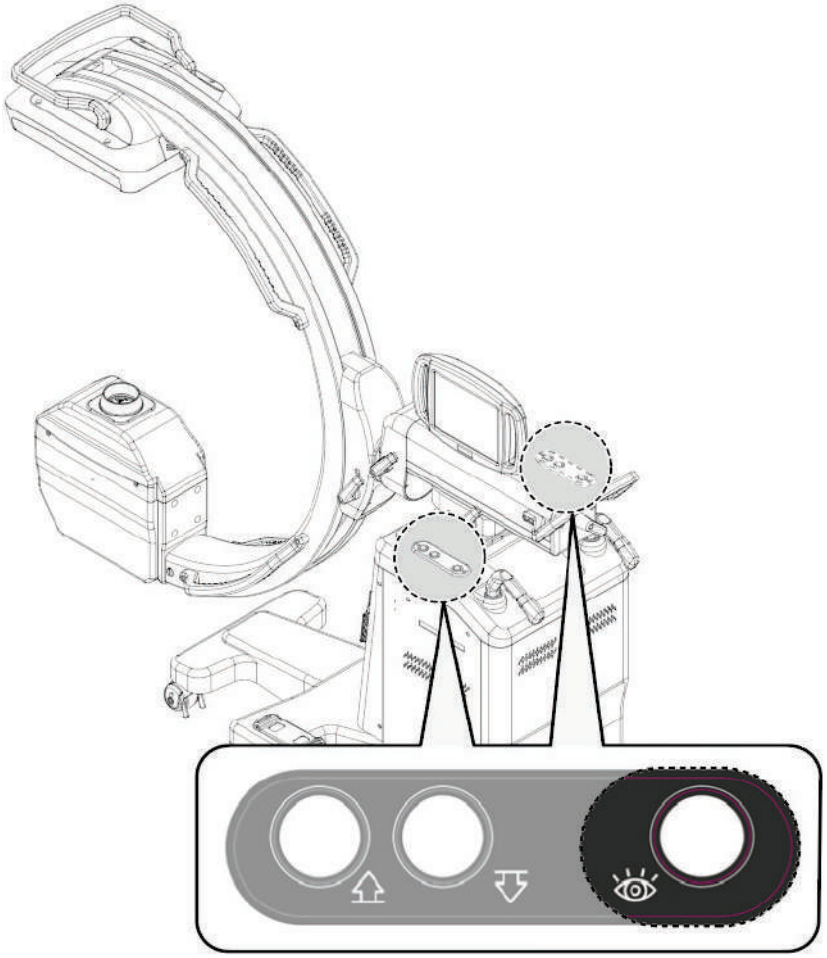
There are two types of foot switches, and you can select options as shown below.

Foot Switch	Step II Foot Switch		Step III Foot Switch		
	Left	**Right**	**Left**	**Middle**	**Right**
Option 1	X-ray exposure	Save image	X-ray exposure	Save image	Fluoroscopy
Option 2	-	-	X-ray exposure	Save image	Dose Level (Low/Normal/High)

If liquid flows or gets on the Foot Switch, it can be used immediately after washing.

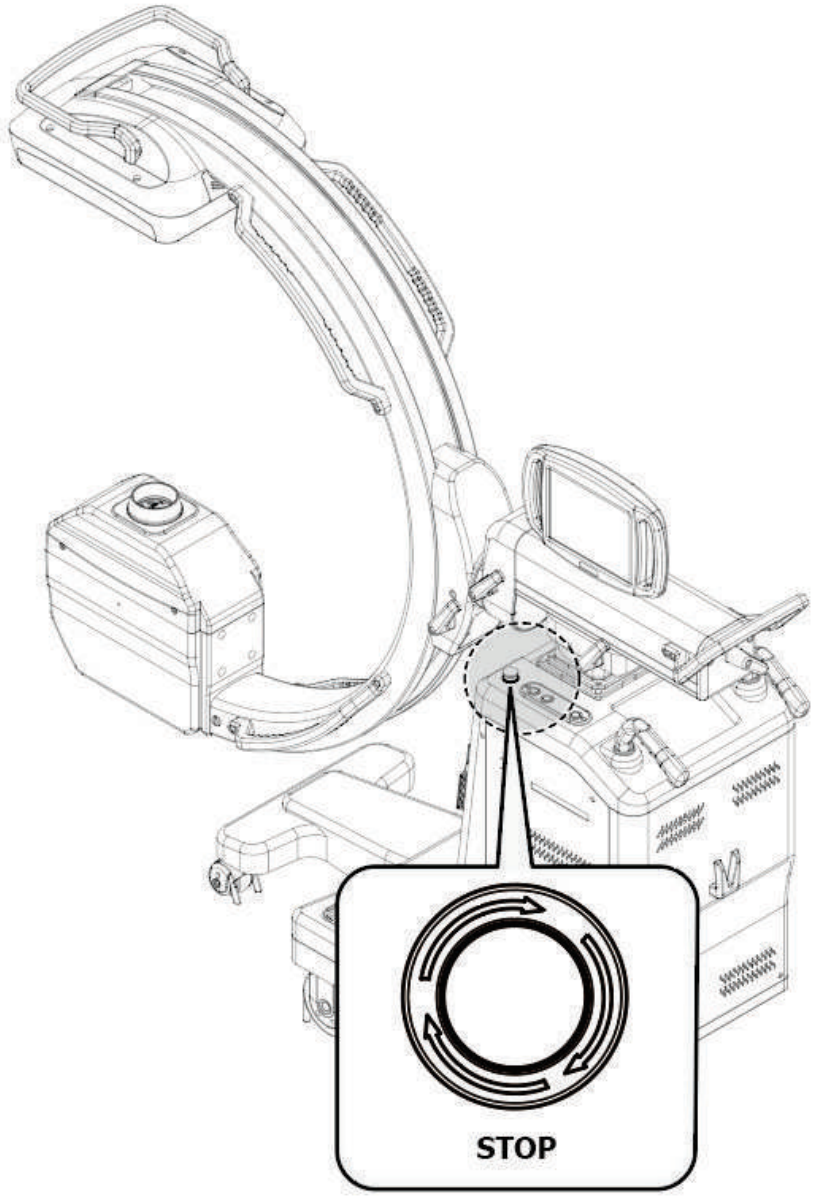
2.2.3) Shot switch

This switch is used for the fluoroscopy mode, and x-ray will be shot right away if you press the exposure switch.



2.3) Emergency Switch

- In an emergency, you can stop the system by pressing the emergency switch on the left side of the body.
- If you press the switch, the message of "EMERGENCY" will appear on the x-ray controller and the system will stop operating.
- The system will start again if you turn the switch in the direction of the arrow.

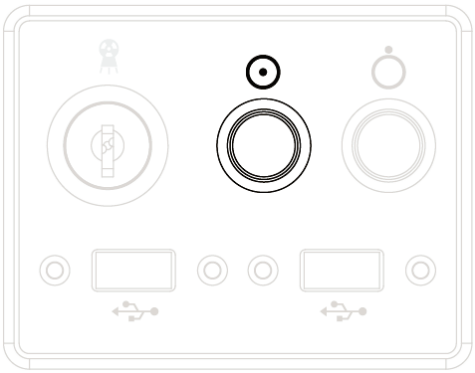


CAUTION

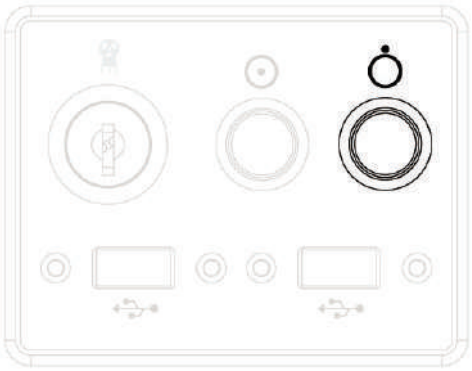
Please use the emergency switch only when an emergency situation occurs in the operation of the equipment including the drive unit.

2.4) Power control panel

2.4.1) Power ON/OFF



ON



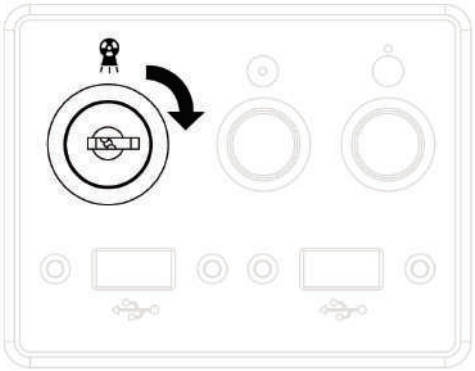
OFF

- When the ON switch is pressed, all power is supplied for system operation.
- When the OFF switch is pressed, all power supplies for system operation are cut off.

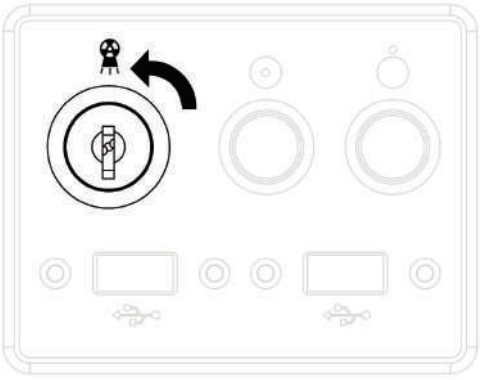
NOTE For details on powering on/off the equipment, refer to **3.2)Power ON/OFF**

2.4.2) X-ray ON/OFF

To exposure the X-ray from this equipment, use the X-ray ON/OFF key switch.



ON



OFF

- When turning the key to the right, it is able to exposure X-ray.
- When turning the key to the left, it is "NOT" able to exposure X-ray.

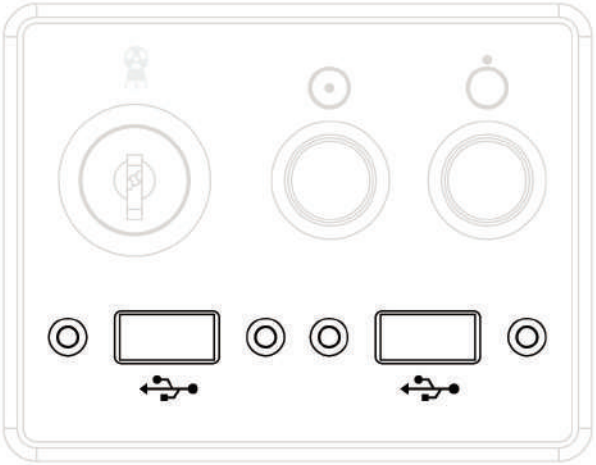
NOTE

This system requires several seconds for warm-up.

NOTICE

Contact Customer Service immediately if there is an error in indicator light or the main screen, which may cause a danger to both a user and patient.

2.4.3) USB Dongle



- USB Dongle is used to connect the mouse used for ZENIS operation.
- USB Dongle is used to connect an external device to back up the archived video.

NOTE

The USB Dongle cannot be used for any purpose other than the above.

NOTE

This system requires several seconds for warm-up.

NOTICE

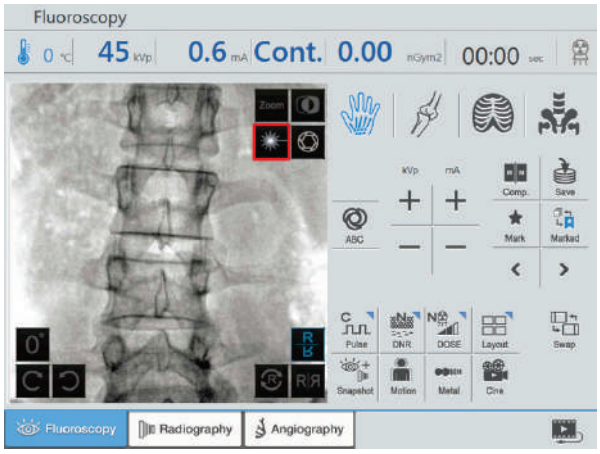
Contact Customer Service immediately if there is an error in indicator light or the main screen, which may cause a danger to both a user and patient.

2.5) Laser

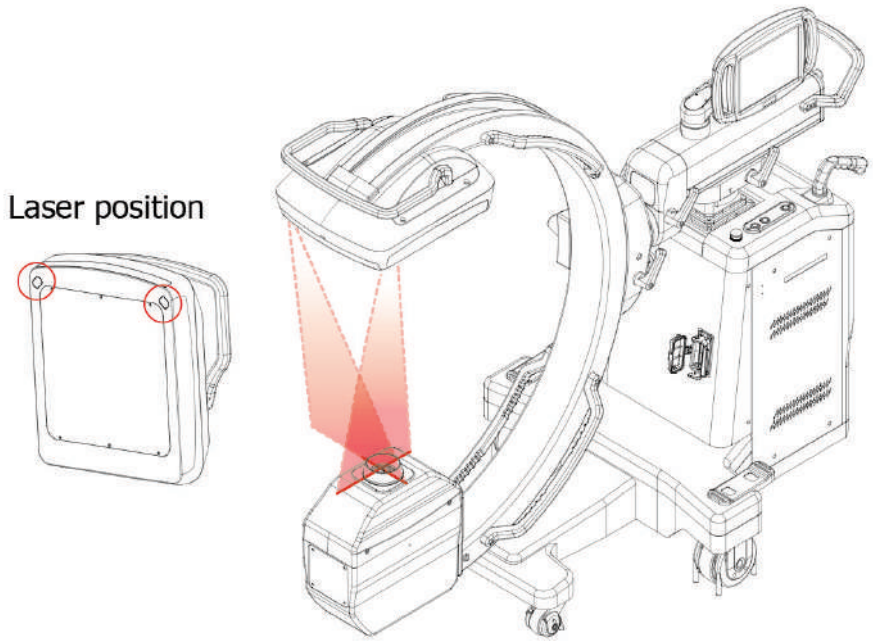
This equipment takes X-rays of the desired area by using the laser function.

2.5.1) How to Use laser

1. Click the Laser button on the OP.



2. When you click the laser button, it is activated in the shape of an X on the upper surface of the tank cover as shown in the figure.
   - Laser is maintained for 10 seconds.
   - When the laser is activated, click it again to exit.



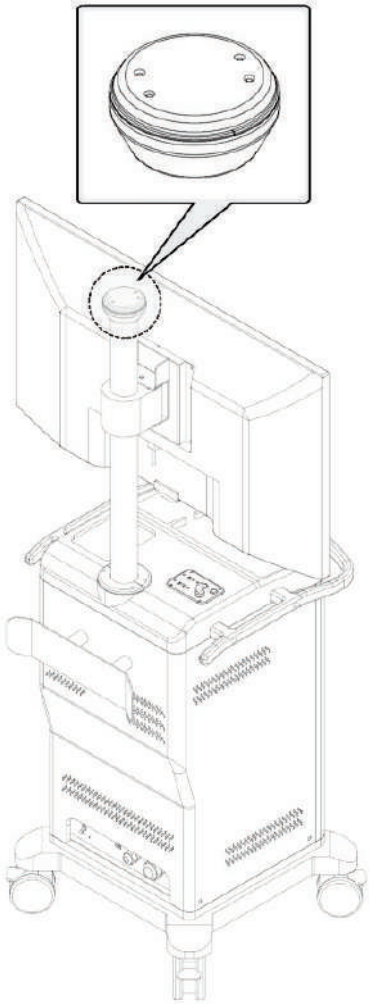
3. After aligning the body part to the center of the X-shape of the laser, take a picture.

CAUTION

If the patient or user's eyes are exposed to the laser, it may cause eye damage.

2.6) Warning lamp and Alarm

This equipment is guided by dividing it into the color of the warning light of the monitor cart according to the current state of the equipment.



State	Description
Lamp off	Standby state
Green	X-ray ready
Yellow	X-ray on
Blue	X-ray waiting (Cool time)
Red	Equipment Error / Emergency switch on

Refer to the color of the warning lamp during operation of the equipment

During X-ray exposure, the Warning Lamp changes color to yellow, and a sound alarm is generated.

CAUTION

Check the current equipment condition according to the color of the warning lamp.

2.7) Grid (Option)

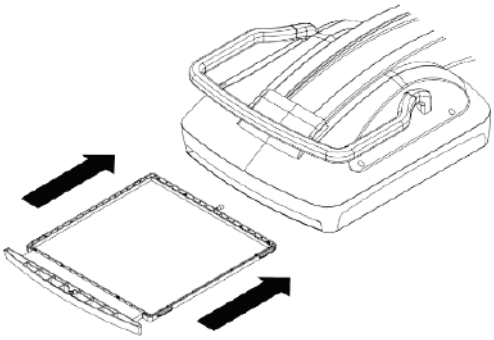
OSCAR 15FD provides a Grid to minimize the scattered X-ray.

2.7.1) How to Attach/Detach the Grid

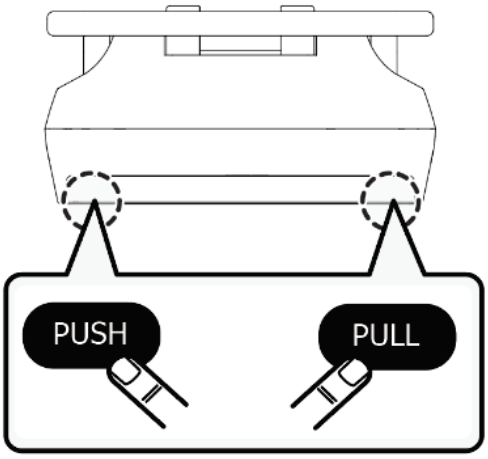
NOTE

It is recommended to detach the Grid when you scan using Low dose.

1. Lower the front of the Detector cover and fit the Grid into the rail.



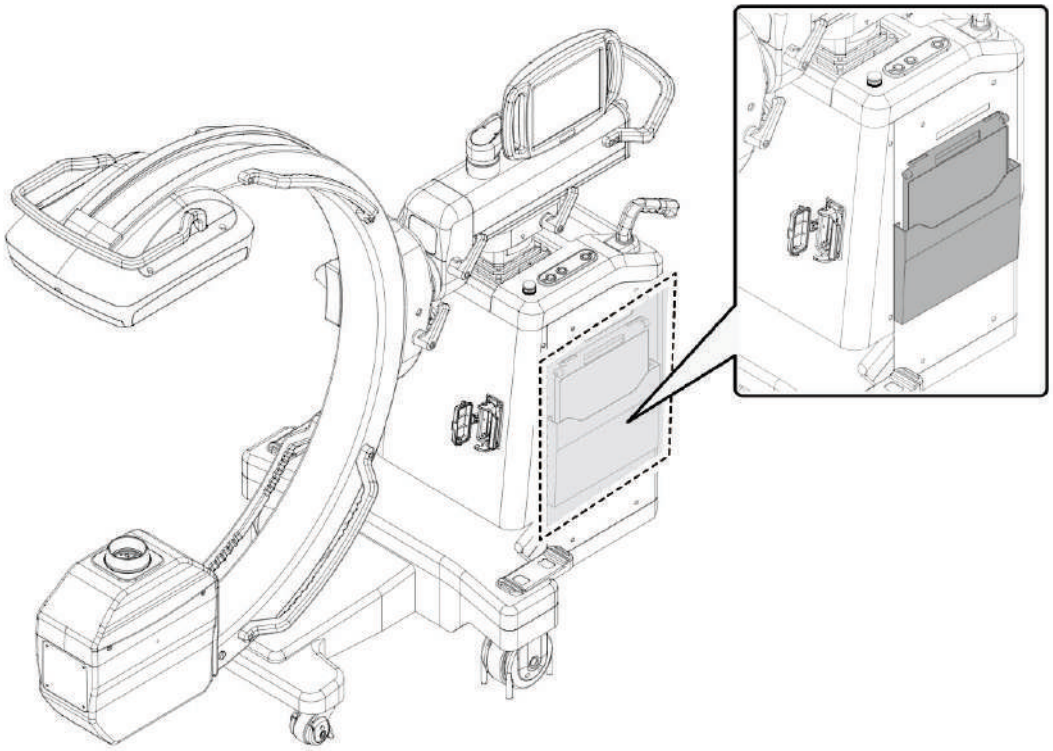
2. Push the marked area to fix it.



3. To detach the Grid, push the same area one more time.

2.7.2) How to Grid storage

Once the Grid has been detached, it can be stored in the side of the body of the equipment. Be careful not to inflict any damage to the surface of the Grid while storing it.



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3. Turning the Device On/Off

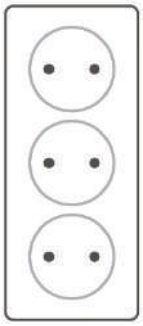
3.1) Connecting the Device

CAUTION

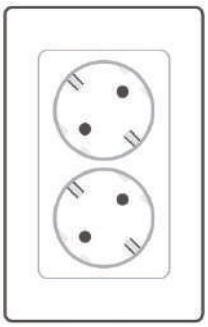
- This equipment is intended primarily for use in non-domestic environments and should not be directly connected to the public mains power supply network.
- This equipment is used in environments with power supply systems and in X-ray shield rooms.

Checklist before connecting the device

1. Check if there is a grounding pin for the outlet before connection.



No pin is installed



A pin is installed

NOTE

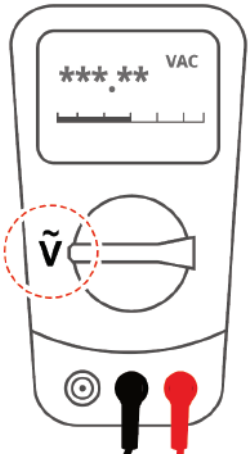
Although there is a grounding pin, there is still a chance that it is not connected to the power supply. So be sure to check the power supply was grounded.

NOTE

When using a power strip inevitably, make sure to use one that is equipped with a grounding pin and whose rated current exceeds 16 A, with no other device connected to the power strip.

2. Using a multi tester, check if there is any problem with the voltage.

a. Set the multi tester as the measurement mode for AC voltage.

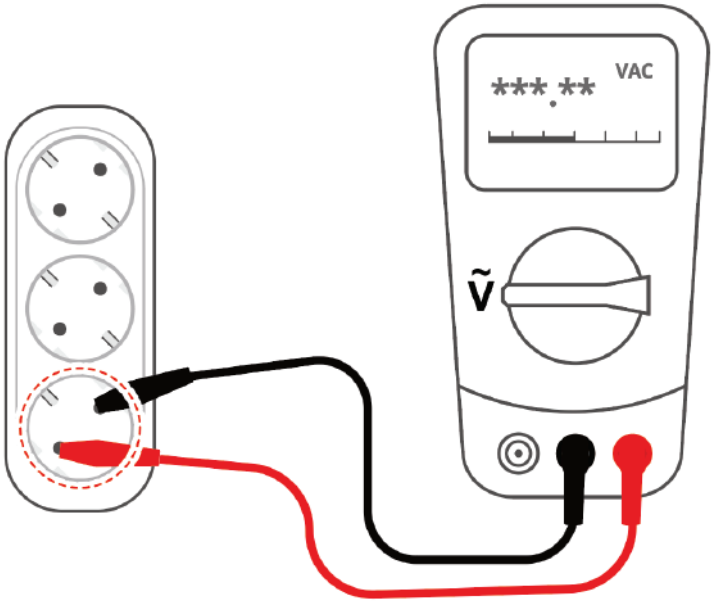


NOTE

The multi tester is not a basic component for the device.

Depending on the multi tester, the shape and mode selection UI can vary.

b. Put the two probe pins into the holes of the outlet, one into each hole, and check the voltage.

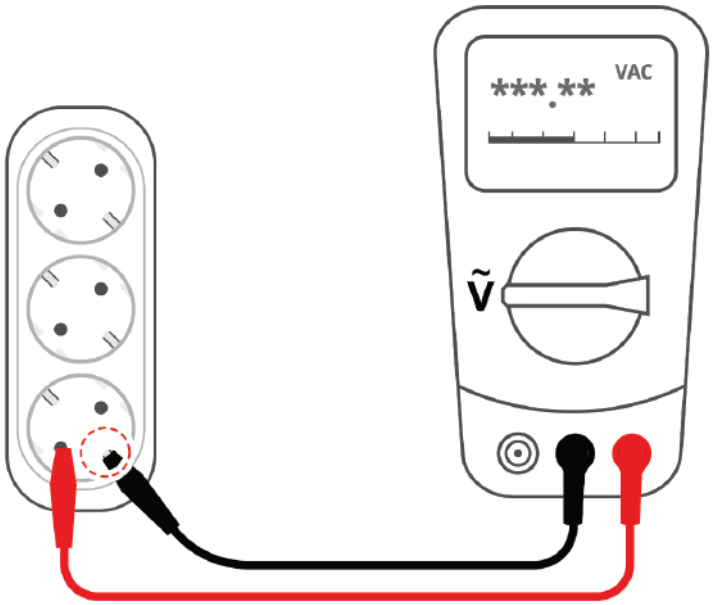


NOTE

The voltage value can vary depending on the voltage at the installed place.

- For example: 100 V+, 110-120 V+, 200-230 V, etc.

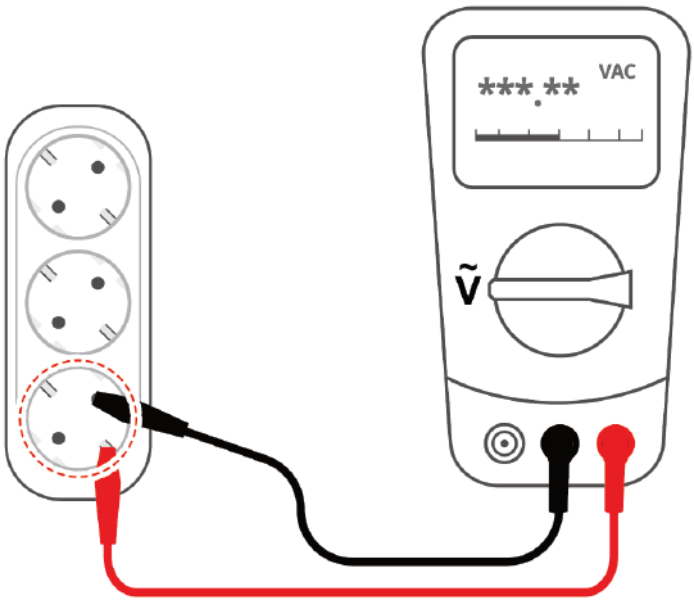
c. Retrieve a probe pin and connect it to the grounding pin of the power outlet.



NOTE

If the measured voltage value here is not very different from that of the previous step (step 2), the hole of the outlet for the red probe pin is "Line" and the other hole is "Neutral".

d. Check the voltage of the "Neutral" hole and the grounding pin of the outlet.



NOTE

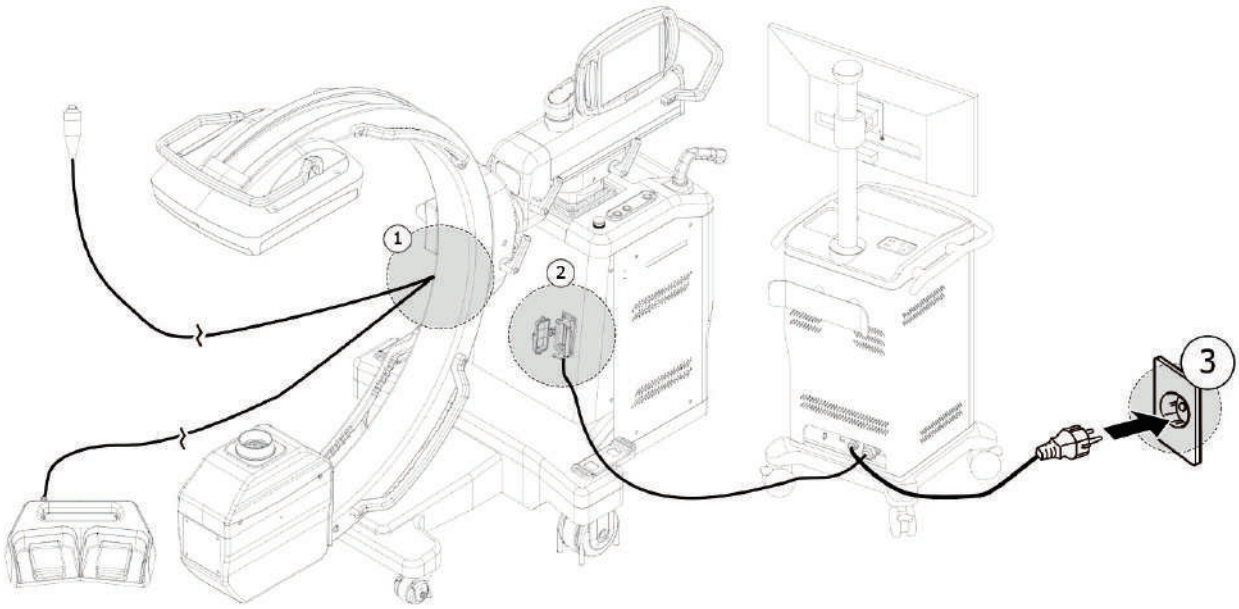
If the voltage value reads 0-5 V, the grounding is properly connected.

NOTE

If the voltage reads 60-80 V, 110V, or higher at the "Neutral" hole and the grounding pin, it means there is a problem with the grounding. In this case, you should ask an expert for help to check the power supply, then check the voltage at the same spot one more time.

How to connect the device

1. Connect the hand switch to left port and connect foot switch to right port.
2. Insert a cable into image port in equipment body.
3. Insert a plug of power cable from monitor cart in a wall outlet.



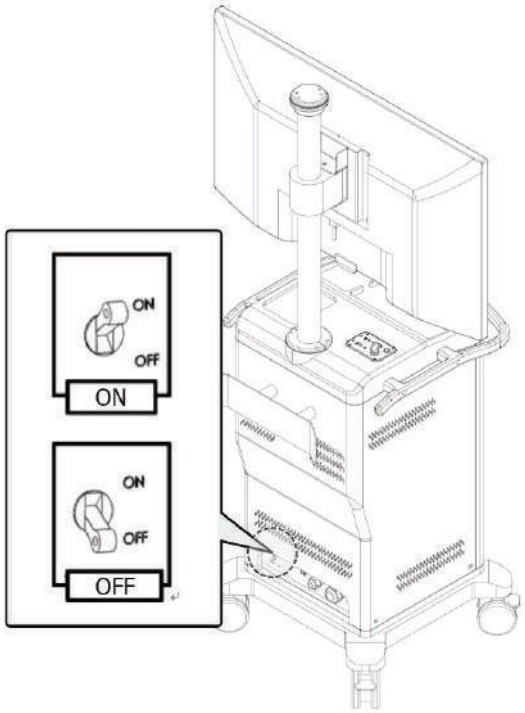
NOTICE

- Do not change anything with the other cables or accessories other than the components provided with the device. This can negatively affect the electromagnetic compatibility of the device.
- The operator should not touch the connection port with the patient when the hand switch and foot switch are not connected.

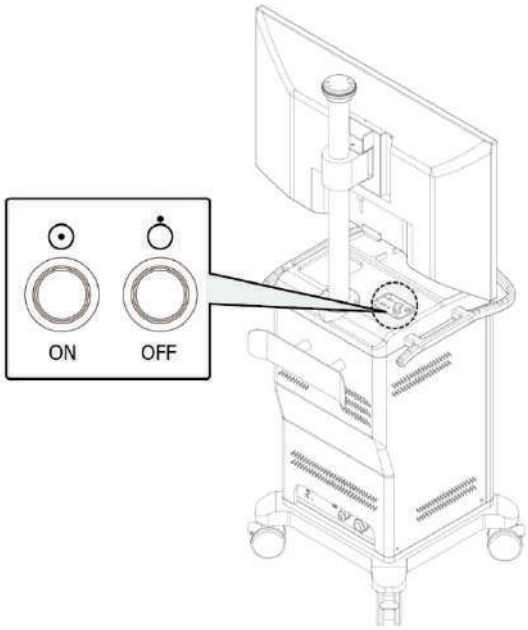
3.2) Power ON/OFF

Power ON/OFF switches is on the middle of cart.

Once the users turn on power, the product proceeds self-test for few seconds.



Main circuit brake



ON/OFF Switch

Equipment ON/OFF

1. Connect the cable of the equipment to a power socket.
2. Turn on the main circuit brake switch located at the bottom of the back.
3. Press the Power ON switch, located on the top left corner, for 1 sec. or more.

Cart alone ON/OFF

1. Turn on the main circuit brake switch at the bottom of the rear of the cart.
2. Press the power switch ON button on the top left of the cart for at least 1 second.
3. When the Cart and the equipment main body are not connected, ON/OFF is executed by the Cart alone.

- Do not press the power switch for more than 3 seconds.

  If you press the power switch for more than 3 seconds, the equipment will be forced to shut down, which may cause equipment failure.
- If the main body of the equipment and the cart are connected after the Cart is ON alone, the main body of the equipment does not operate.

  Reapply the power to use with the equipment body.

4. Operation of OSCAR 15FD

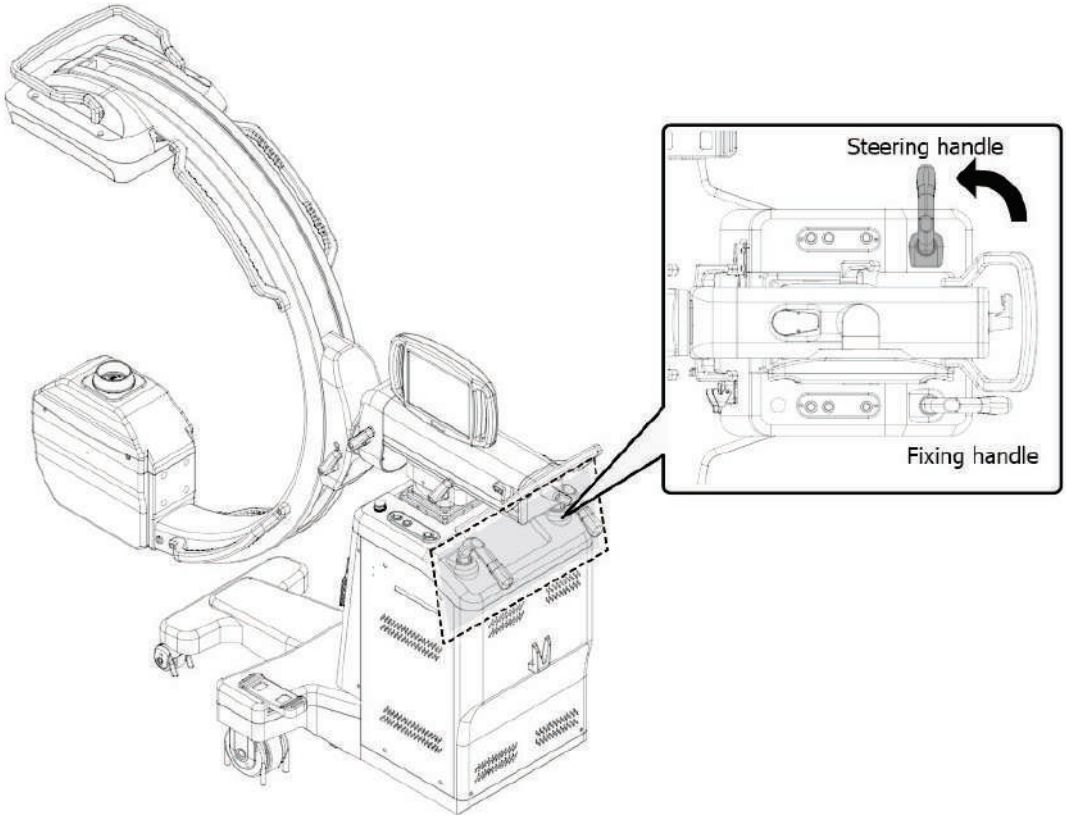
4.1) Moving and Fixing of the Equipment

- Move the system with the steering and fixing handles.
- Two people should maintain control of the equipment when moving up or down an incline.
- Excessive shock or vibrations caused to the system while moving can lead to electrical or mechanical problems inside the unit.
- If the system fails to operate properly after moving, immediately contact Customer Service to seek help.
- Exercise extreme caution when moving the equipment over rough surfaces such as tile flooring, concrete pavement, or carpet. Take care that the cable guards do not drag and the wheels do not catch or tilt causing damage to the equipment.

Do not move the equipment in any position other than the transport position when the slope is above 5 degrees.

4.1.1) Moving to the Left/Right

- Move the unit to the left or right with the steering handle as depicted in the picture.
- Turning the steering handle will move the wheels of the unit.

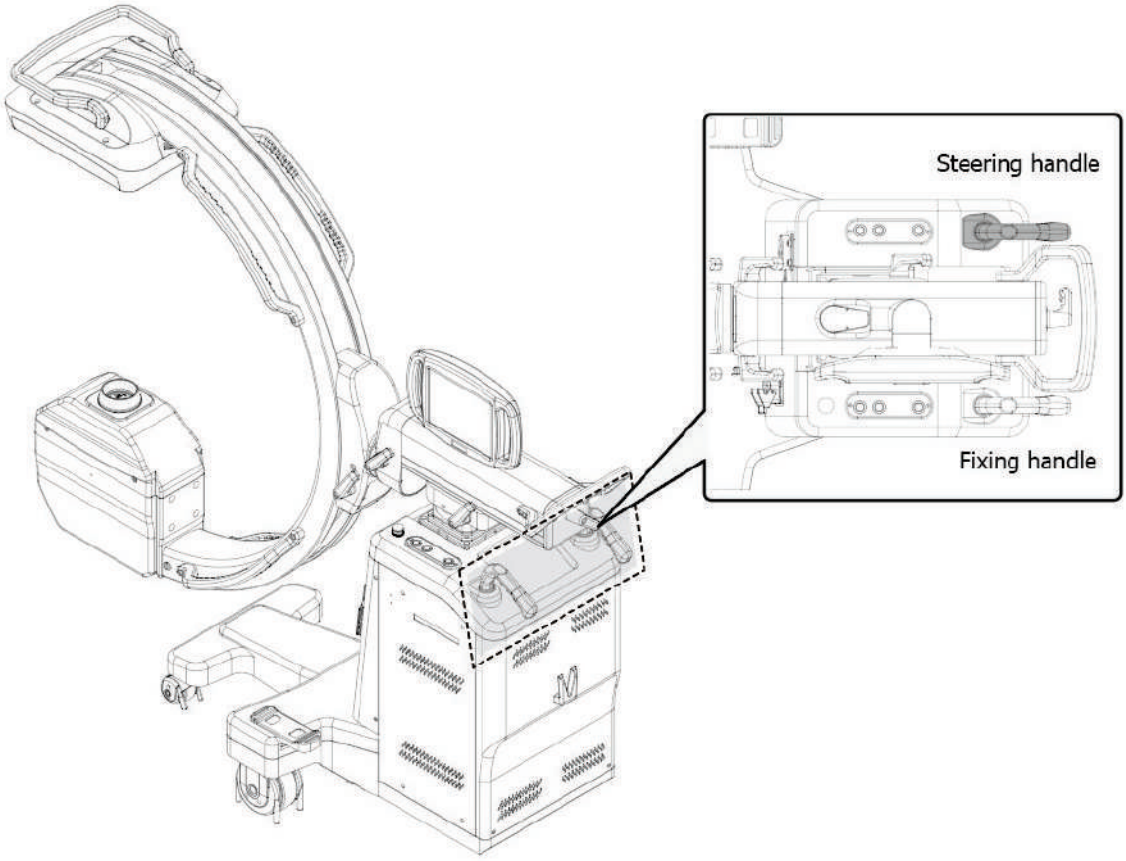


NOTICE

When moving the equipment, consider the weight and size of the equipment.

4.1.2) Moving Forward/Backward

Move the unit forward or backward with the steering handle as depicted in the picture.

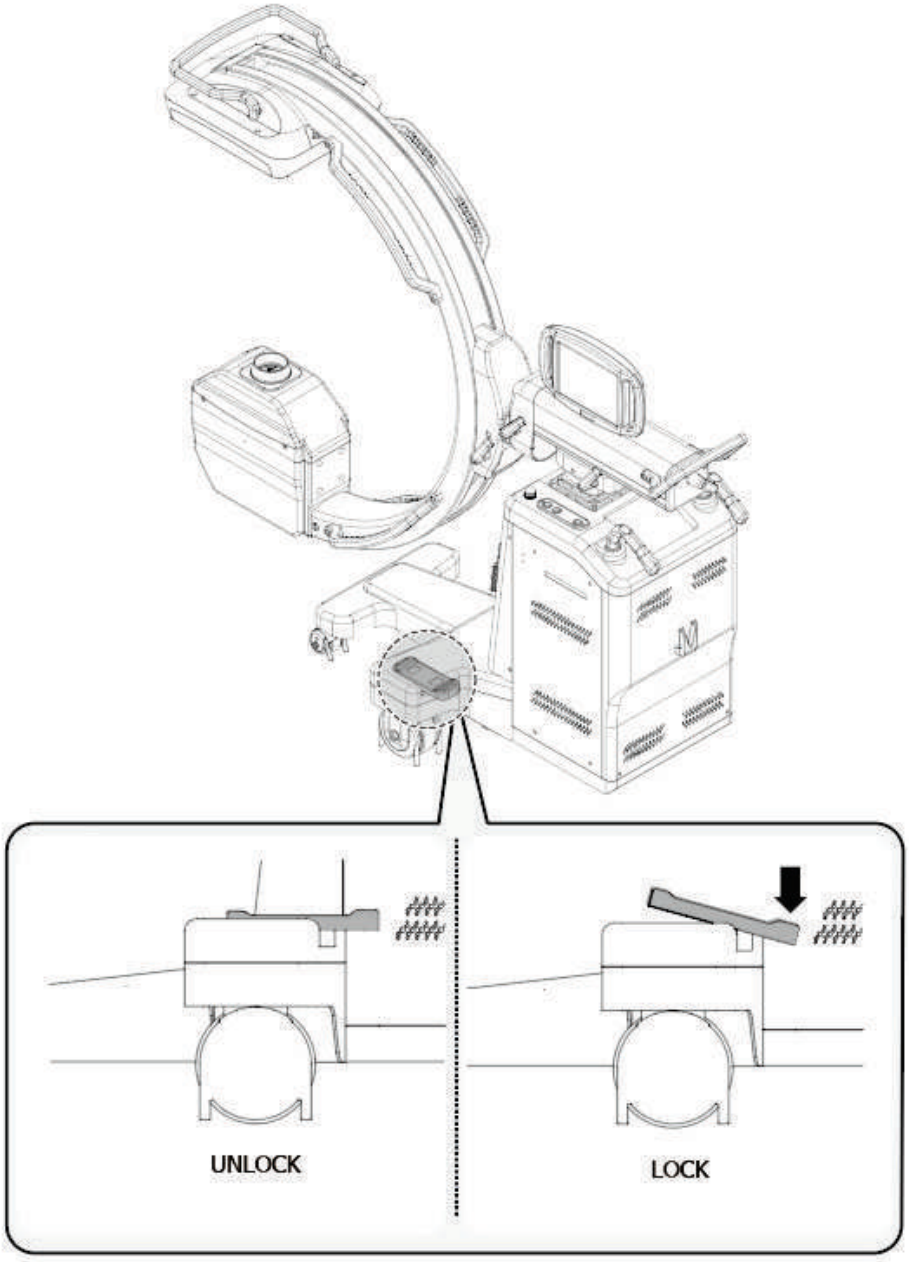


4.1.3) Fixing the System

Step on the pedal to fix the brake as depicted in the picture.

WARNING Do not apply unnecessary shock or hang on the equipment.

CAUTION Be sure to use the brake to fix the position before using the machine.



4.2) C-arc operation

CAUTION

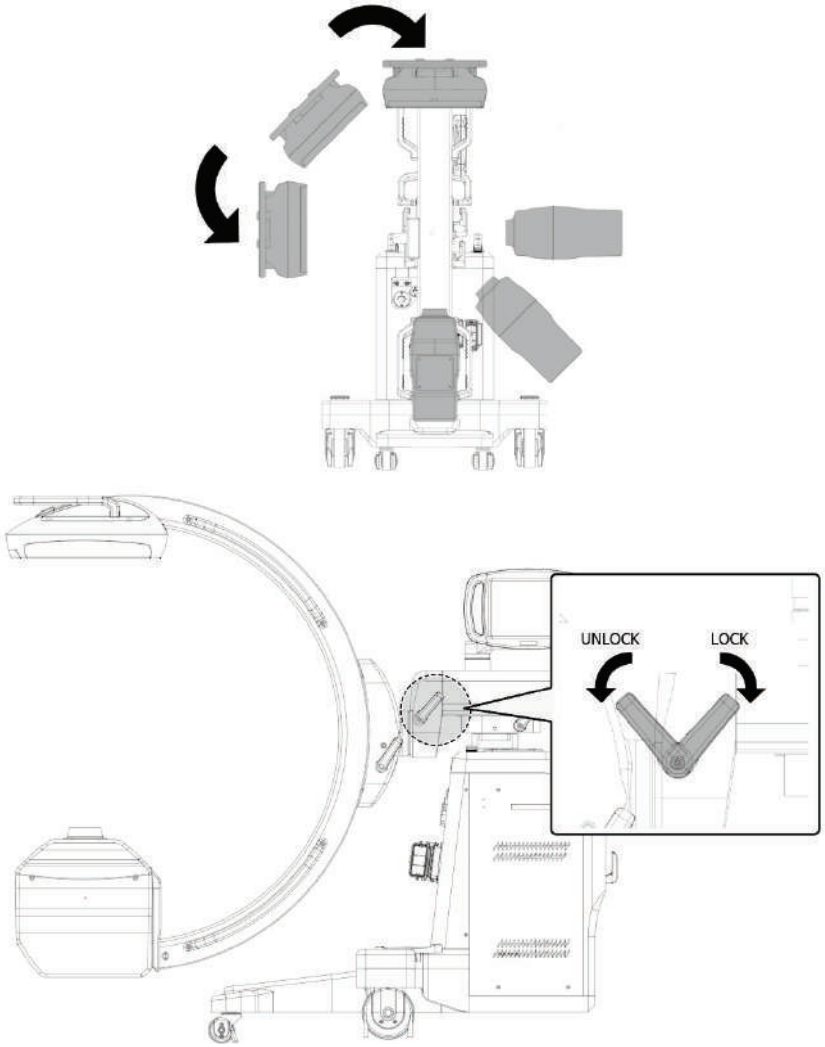
The release of the fixing lever of the C-arm must be carried out while holding the C-arm by hand.

4.2.1) C-arc Left/Right Rotation

1. Unlock the lever and adjust the C-arc.
2. After adjusting the C-arc that user wants, lock the lever to fix it.

CAUTION

Be careful not to bump into the C-arc when moving it.



NOTICE

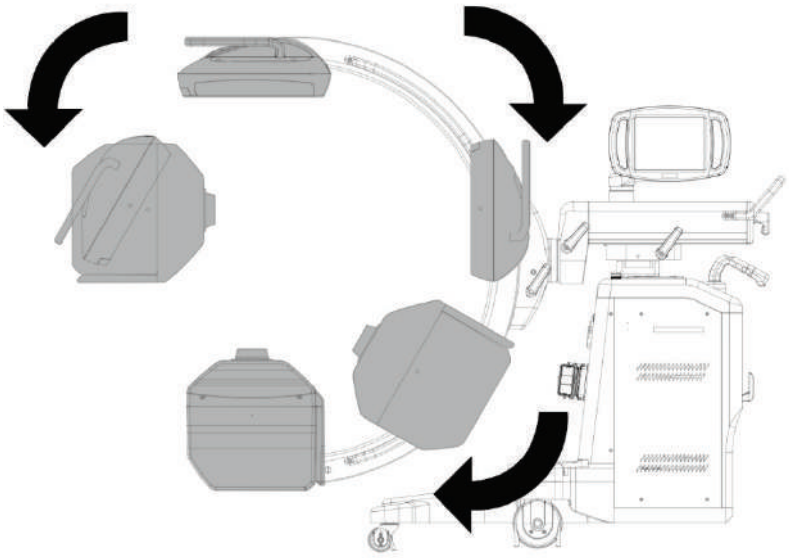
Please make sure that there is no person or object within the rotation radius of C-arm in order to prevent an injury or damage to the equipment.

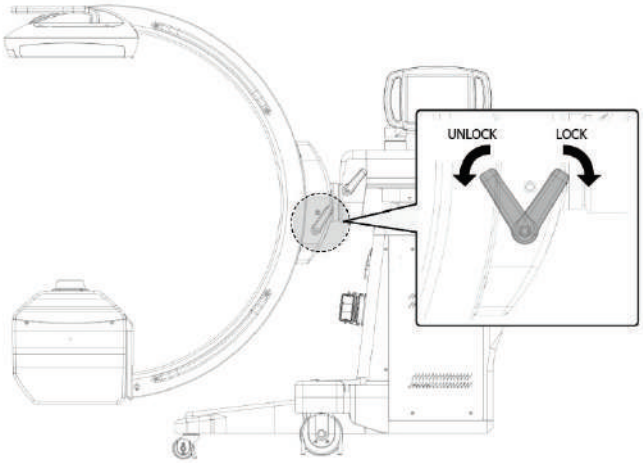
4.2.2) C-arc Orbital Rotation

1. Unlock the lever and adjust the C-arc.
2. After adjusting the C-arc that user wants, lock the lever to fix the C-arc.

CAUTION

Be careful not to bump into the C-arc when moving it.





NOTICE

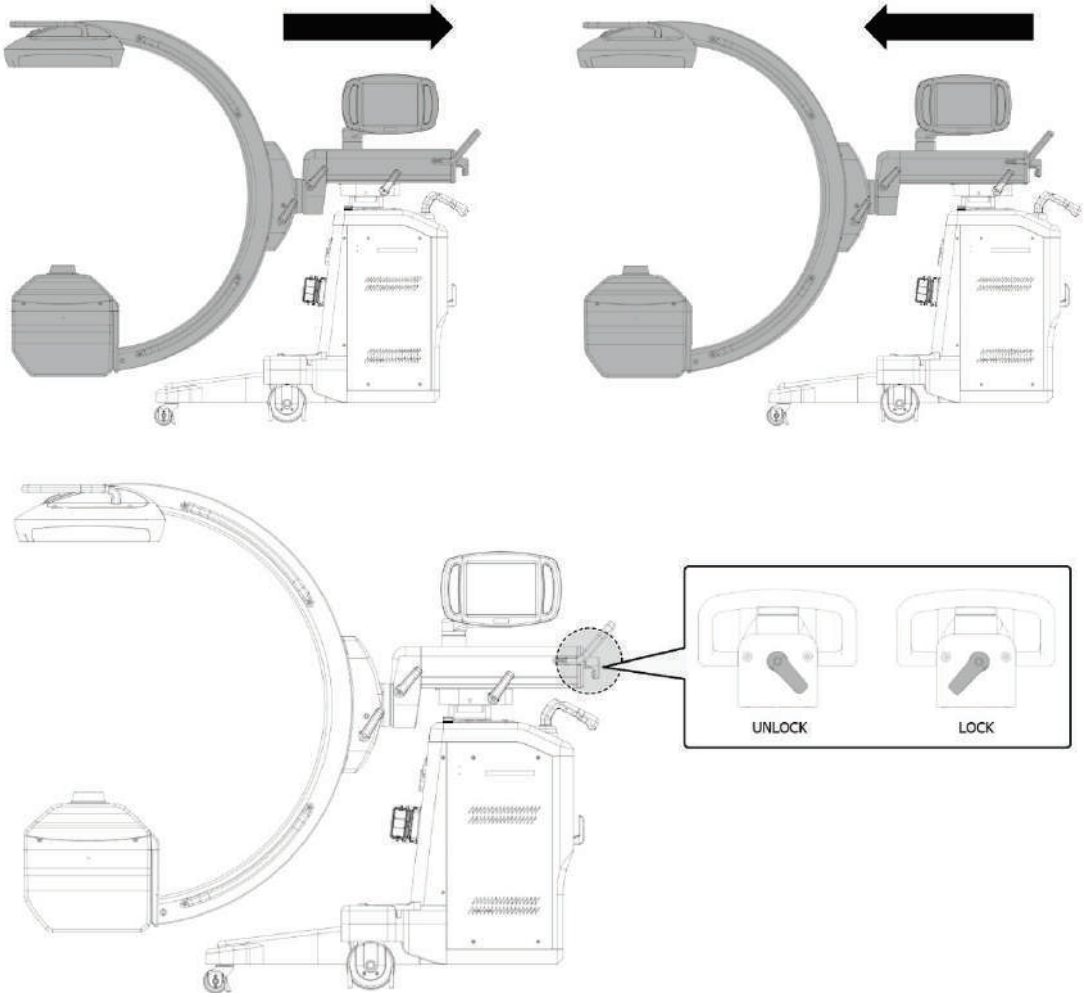
- Do not put your foot on the base cover during the orbital rotation of C-arc. This may lead to an injury.
- Do not put your hand on the C-arc support during the orbital rotation of C-arc. This may lead to an injury.

4.2.3) C-arc Horizontal Moving

1. Unlock the lever and adjust the C-arc.
2. After adjusting the C-arc that user wants, lock the lever to fix the C-arc.

CAUTION

Be careful not to bump into the C-arc when moving it.



NOTICE

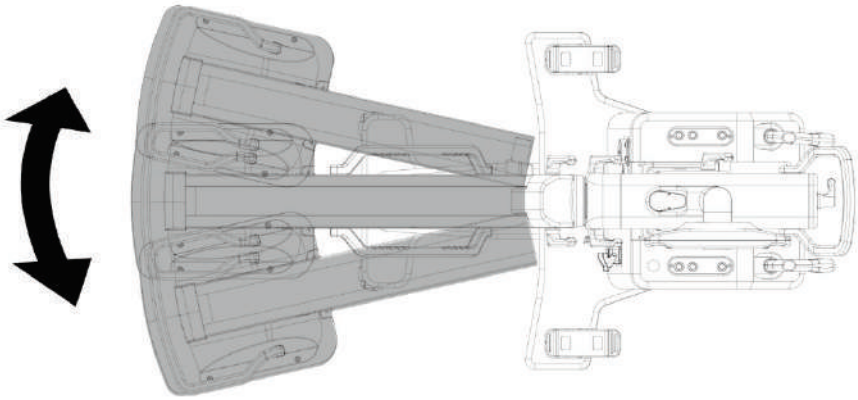
Be careful not to bump against C-arc while moving it. This may lead to an injury.

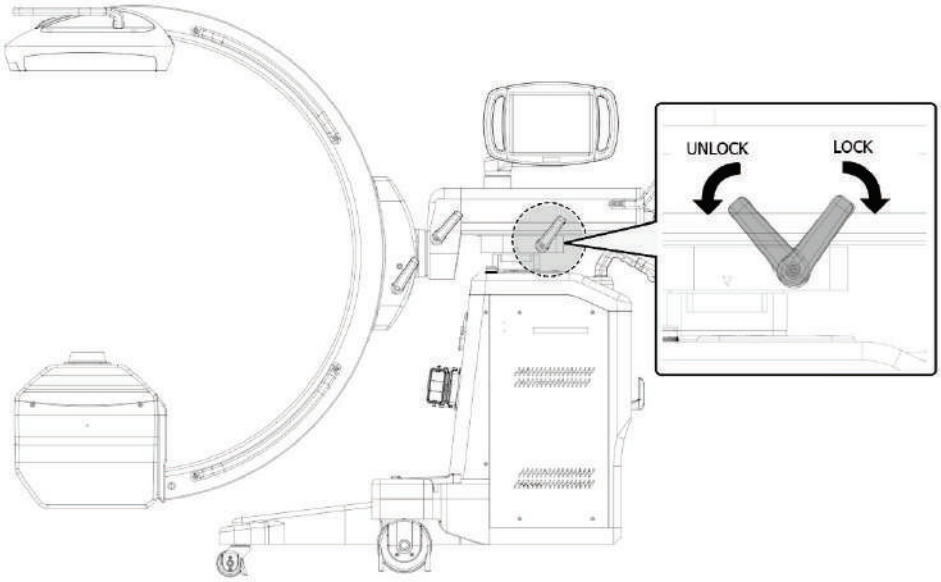
4.2.4) C-arc Panning

1. Unlock the lever and adjust the C-arc.
2. After adjusting the C-arc that user wants, lock the lever to fix the C-arc.

CAUTION

Be careful not to bump into the C-arc when moving it.



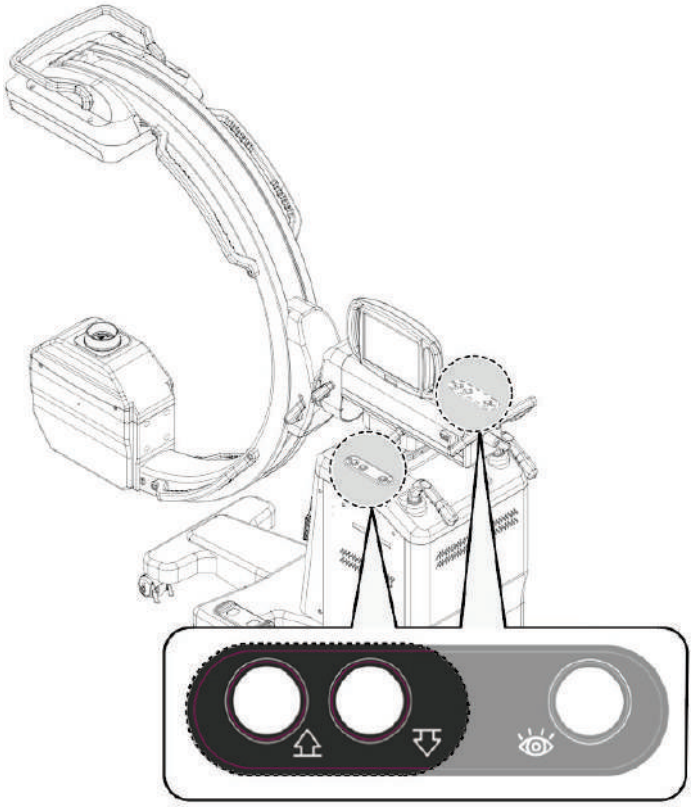


NOTICE

Please make sure that there is no person or object within the rotation radius of C-arc during panning in order to prevent an injury or damage to the equipment.

4.2.5) Up/Down Movement

Press the UP/DOWN button to adjust height of the device.

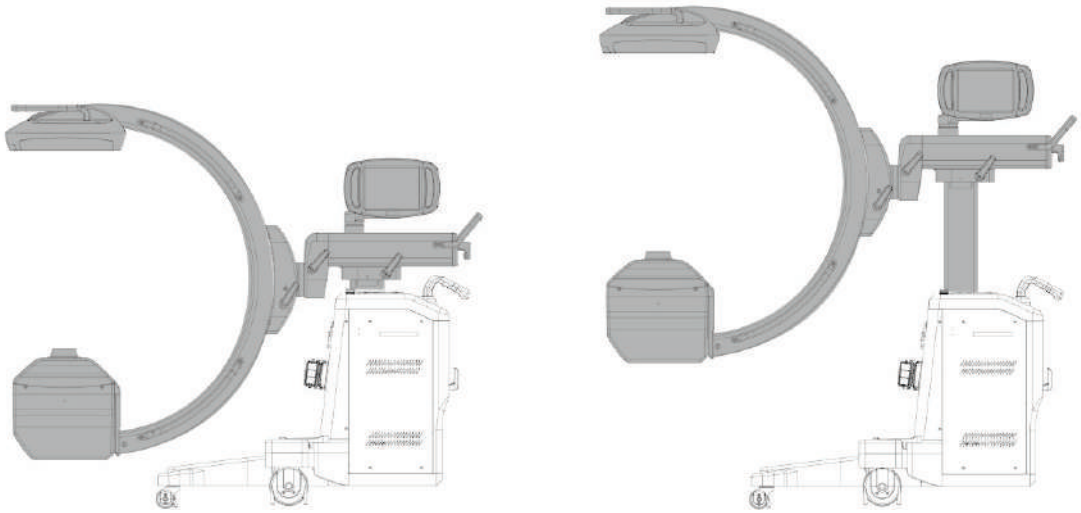


NOTICE

It may be damaged if excessive force is arbitrarily applied when ascending or descending.

CAUTION

- Be careful not to bump into the C-arc when moving it
- Be careful not to bump against C-arc while moving it. This may lead to an injury.



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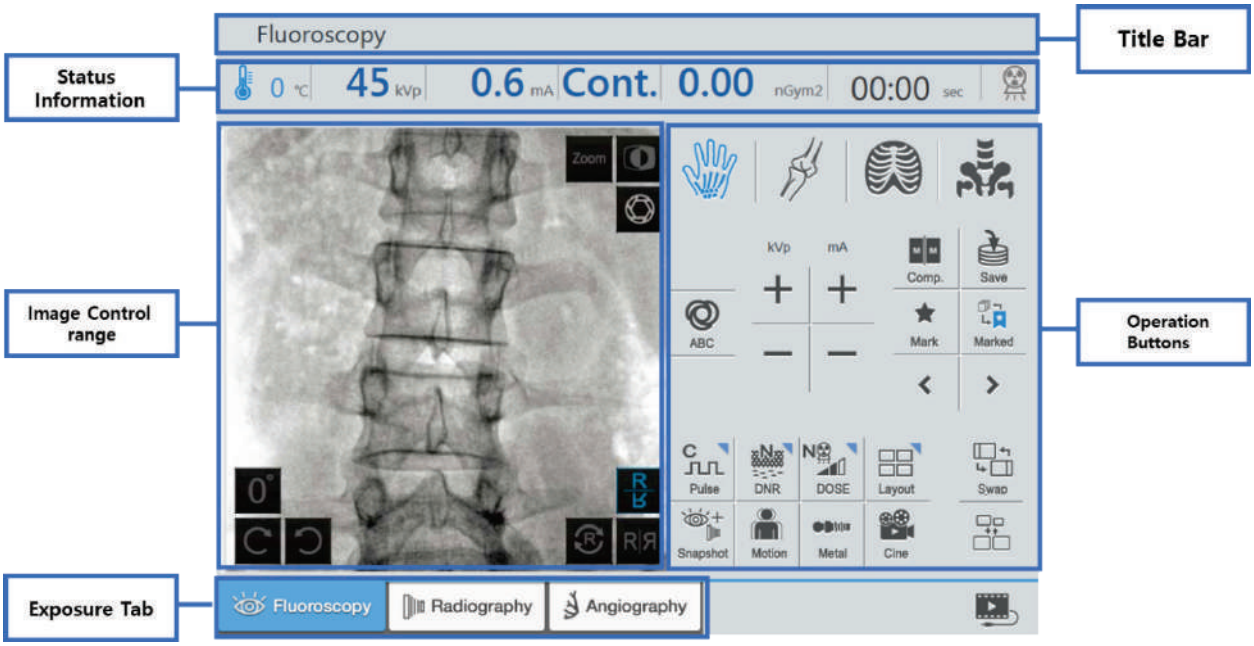
5. X-ray Control and Additional Features

OSCAR 15FD can set X-ray exposure methods, tube voltage and tube current through the operation panel (or OP). Various other features are available as well for a user to obtain a desired image. The following table shows X-ray exposure methods available per mode.

X-Ray exposure mode	X-Ray exposure method
Fluoroscopy	Continuous
	30 Pulses
	15 Pulses
	8 Pulses
	4 Pulses
	2 Pulses
	1 Pulse
	Snap Shot
Radiography	Film mode

5.1) How to Use OP

The OP of OSCAR 15FD is a controller of the system for X-ray tube input and X-ray exposure conditions, and is composed of the title bar, status information, image display/control area, control buttons, and control area with two modes available for fluoroscopy and radiography.



5.1.1) Title Bar

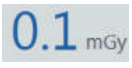
The title bar displays the mode currently selected and information of the foot switch.

5.1.2) Status Information

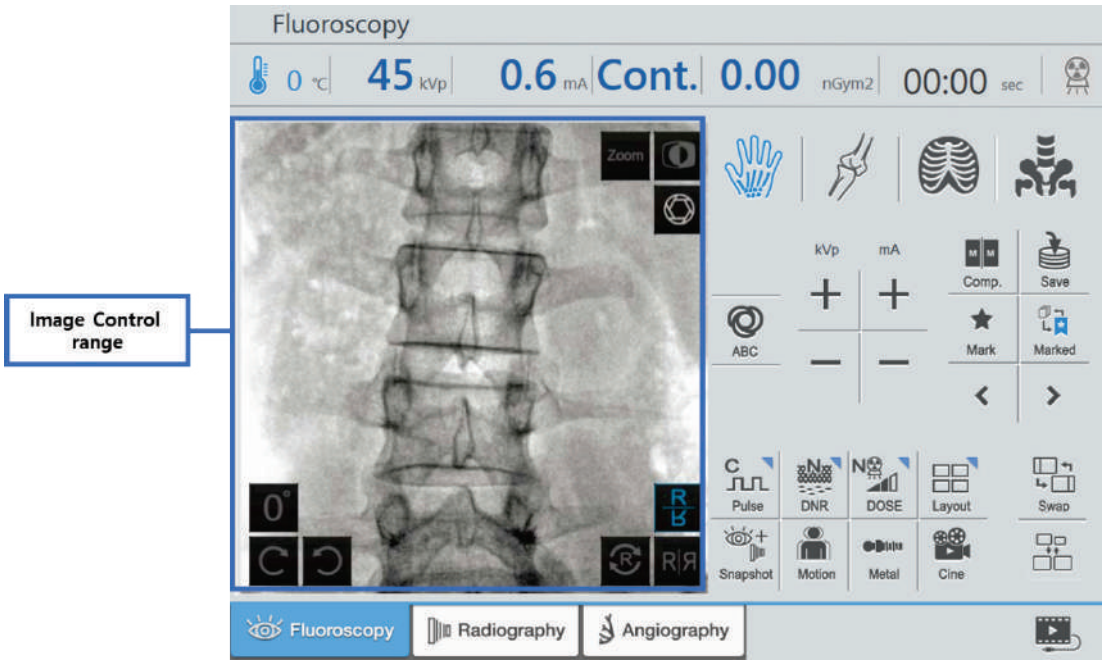
The current status of the system and exposure conditions are displayed.

NOTICE	▪ Users should pay attention to the display color of the status LED below. • Blue - Room Temp 10°C - 41°C → X-ray exposing is possible • Green - Room Temp 42°C to 51°C → X-ray exposing is possible (overheating warning) • Red - Room Temp 52°C or above → X-ray exposing is impossible

CAUTION	▪ During the diagnosis process, the manual guides the patient so that he or she can know about the time and amount of exposure to X-rays. ▪ If 4 minutes have elapsed since the time of X-ray irradiation, an alarm is generated and X-ray irradiation stops when 5 minutes have elapsed. ▪ If the X-ray irradiation is restricted, you can release the X-ray irradiation limit by briefly pressing the time display.

Symbol	Description
	**X-ray Tube Temperature** ▪ Blue-Room Temp 10°C - 41°C → X-ray exposing is possible ▪ Green-Room Temp 42°C to 51°C → X-ray exposing is possible (Overheating Warning) ▪ Red-Room Temp 52°C or above → X-ray exposing is impossible
	**Tube Voltage (kV)** Shows the current tube voltage value.
	**Tube Current (mA)** Shows the current tube current value.
	**Pulse** The value currently set for pulses rate is displayed.
	**Radiation Dose** The value currently set for radiation dose is displayed.
	**Exposure Time** ▪ Displays the elapsed time for currently exposed X-ray. ▪ When the exposure time exceeds 4 minutes, an alarm occurs. When the time gets 5 minutes, the X-ray exposure is aborted. ▪ When the exposure is restricted, a quick click on the time display resets the timer, releasing the exposure restriction of the X-ray. However, the elapsed time is not reset, adding every new time for acquisition to the accumulated time for all the previous exposures.
	**X-ray exposure condition** Current status of X-ray exposure is displayed.

5.1.3) Image Control range



Buttons that can control images and obtained images are displayed.

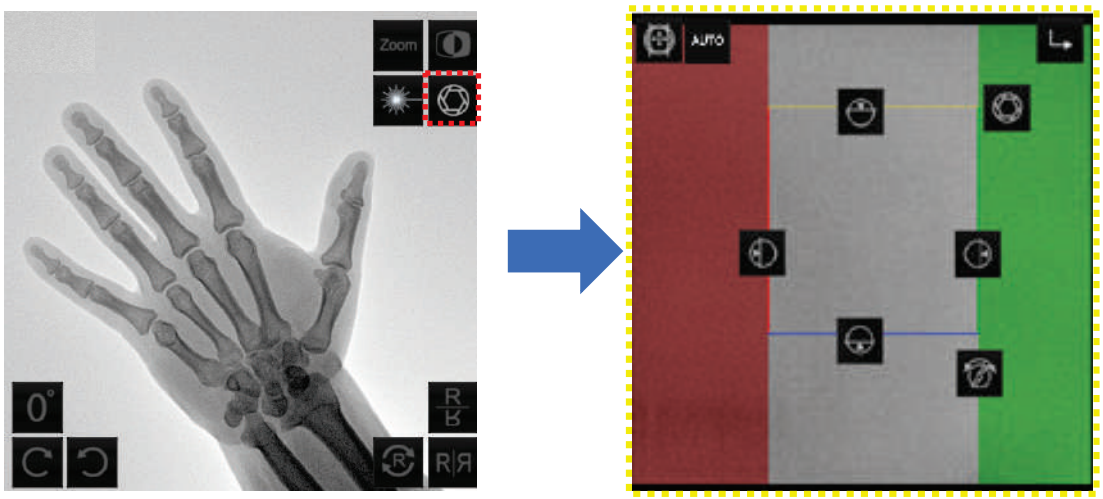
Symbol	Description
	**Magnification Ratio** Pressing the button changes the magnification ratio in the order of 1 → 1.5 → 2 → 1.
	**Reverse Image** You can create a reverse image with this button. ▪ Left: OFF ▪ Right: ON
	**Laser** Mark the position of image acquisition.
	**Collimator Control** The collimator control mode is selected.
	**Initializing Rotation** You can initialize the change back after rotating the image.

Symbol	Description
	**CW (Clockwise Rotation)** ▪ Rotate an image clockwise. ▪ The angle for rotation can be set among 1, 3, 5, 15, 30,45, and 90 degrees under [Configuration > System >Image Rotation].
	**CCW (Counterclockwise Rotation)** ▪ Rotate an image counterclockwise. ▪ The angle for rotation can be set among 1, 3, 5, 15, 30,45, and 90 degrees under [Configuration > System >Image Rotation].
	**Initializing flipped image** You can initialize the image which was adapted flip function.
 **ON**  **OFF**	**Reverse the left and right** ▪ Reverses the image horizontally. ▪ Clicking the button, while no image has been currently acquired, makes the image acquired with the left and right sides reversed.
 **ON**  **OFF**	**Reverse up and down** ▪ Reverses the image vertically. ▪ Clicking the button, while no image has been currently acquired, makes the image acquired with the up and down sides reversed.

5.1.4) Collimator Control Area

CAUTION

Before X-ray exposure, the area of the collimator must be adjusted to minimize the X-ray exposure area.



Buttons that can control the collimator and obtained images are displayed.

Symbol	Description
	**Initialization** The position of the collimator is initialized.
	**Iris** Drag the button to open or close the iris collimator.
	**Left Shutter** Drag the button to open or close the left shutter.
	**Right Shutter** Drag the button to open or close the right shutter.
	**Front Shutter** Drag the button to open or close the front shutter.
	**Back Shutter** Drag the button to open or close the back shutter.

Symbol	Description
	**Shutter Rotation** Drag the button to rotate the shutter.
	**Shutter Rotation** The system reverts to the image control mode.
 	**Auto** Set up auto collimation function

5.1.5) Operation Buttons

CAUTION

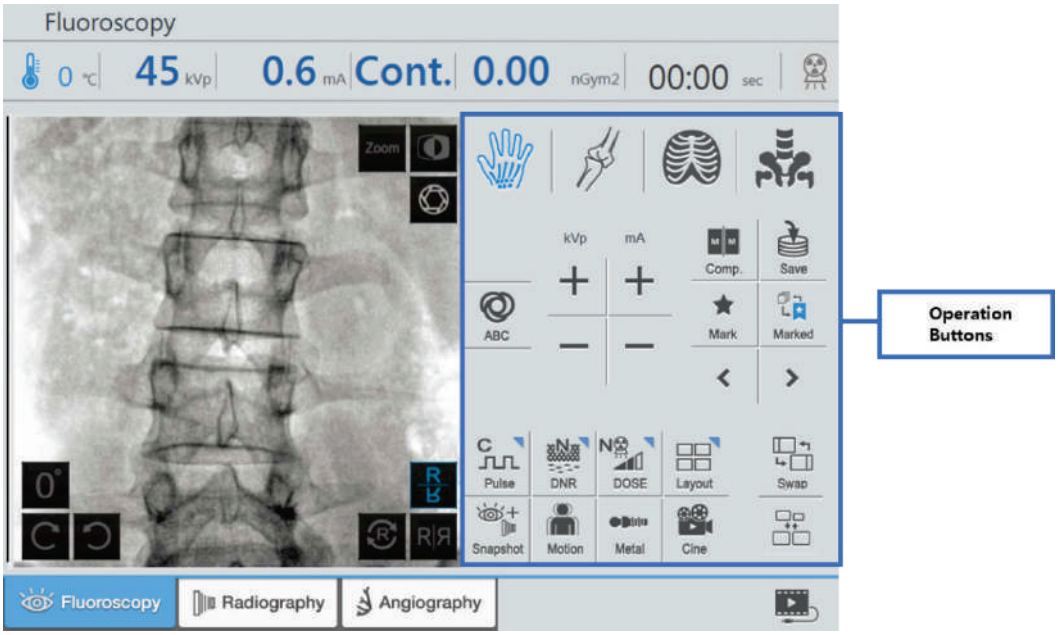
It is necessary to set the appropriate X-ray output condition for the subject requiring X-ray diagnosis.

WARNING

Inappropriate images can be obtained when X-rays are taken without using the ABC function.

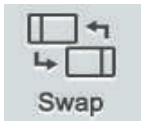
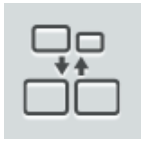
You can control the system, images, and image processing unit of the cart.

A button with a triangle activates the Control Area.



Symbol	Description
	**Anatomical program** Optimized exposure and image processing conditions are applied according to target sites (hand, spine, thoracic, and knee).
 **ON**  **OFF**	**ABC, Auto Brightness Control** ABC automatically searches optimized kV, mA according to the irradiation position of the patient. It's applied for the machine. Then the user can get the optimized real-time image. This function can be used on Continue Mode, Pulse Mode and is used for either if there is frequent change or if it's hard to adjust kV and mA. (It's impossible to adjust kV and mA by manual during using ABC)

Symbol	Description
 **ON**  **OFF**	**Compare** ▪ Shows the selected image from the Reference screen on the Live screen. ▪ The screen does not change until scanning and image control occur.
 **ON**  **OFF**	**Mark** ▪ Marks the favorite images. ▪ Images with marks are displayed like the following on ZENIS and the system OP: ▪ System OP: Images with marks are displayed with the mark activated ( ). ▪ On ZENIS: Images with marks are displayed with an icon ( ).
	**Save** Function to save the obtained LIH image.
	**Image Scroll Type** Scroll all images.
	**Image Scroll Type** Scrolls only the images with markers. ( )
	**Image Scroll** LIH image of the cart can be scrolled.
	**Pulse** X-ray purses are controlled. (Refer to 5.1.5.3)
	**DNR (Dynamic Noise Reduction)** DNR mode is selected. (Refer to 5.1.5.4)
	**Dose Level** Set up the level of dose. (Refer to 5.1.5.5)

Symbol		Description
 **ON**	 **OFF**	**Swap** Change the image location of Live and Reference.
		**Snap Shot** Snap shot mode is selected.
 **ON**	 **OFF**	**Motion detection** Afterimage created by motion of a subject is removed.
 **ON**	 **OFF**	**Metal detection** Provide high quality images by optimizing the brightness and contrast of the image.
 **ON**	 **OFF**	**Cine** Images obtained are saved in Cine.
 **ON**	 **OFF**	**Reference Layout** Change the arrangement of images in cart.
 **ON**	 **OFF**	**Monitor Layout** Change the Cart monitor layout. This function is only available on 43” monitors.
 **ON**	 **OFF**	**External Camera** ▪ Shows the images from the external cameras on the Reference screen. ▪ The screen does not change until saving and marking the images, and scrolling through the images. ▪ During the display of the images from the external cameras, the functions of ZENIS are not available from the cart.

5.1.5.1 Anatomical program

According to anatomical program, default exposure condition and parameters for image processing is automatically changed. By changing anatomical program, the system is adjusted to optimal system for performance.

- Hand

  The hand is optimized for bone contrast and detailed visibility. This program provides improved sharpness.

- Knee

  The knee is optimized for joints and cervical spine. This program provides increased contrast and sharpness. Systems become more robust to motion blur by patients' movement on this program.

- Thoracic

  The thoracic is optimized for increased visibility for vertebral spine overlapped by rib cage.

  This program provides increased contrast and noise reduction

- Spine

  The spine is optimized for improved visibility of lumbar and spine imaging. This program provides increased contrast and noise reduction.

- Low Dose

Mode	Program			
	 Hand	 Knee	 Thoracic	 Spine
Continue	45 kVp 0.2 mA	60kVp 0.8 mA	70kVp 1.2 mA	80kVp 1.6 mA
30 pulses	45 kVp 3.0 mA	60 kVp 3.0 mA	70 kVp 3.0 mA	80 kVp 3.8 mA
15 pulses	45 kVp 3.0 mA	60kVp 3.0 mA	70kVp 3.5 mA	80kVp 4.7 mA
8 pulses	45 kVp 3.0 mA	60kVp 3.0 mA	70kVp 3.5 mA	80kVp 4.7 mA
4 pulses	45 kVp 3.0 mA	60kVp 3.0 mA	70kVp 3.5 mA	80kVp 4.7 mA
2 pulses	45 kVp 3.0 mA	60kVp 3.0 mA	70kVp 4.2 mA	80kVp 5.7 mA
1 pulse	45 kVp 3.0 mA	60kVp 3.0 mA	70kVp 4.2 mA	80kVp 5.7 mA

- Middle Dose

Mode	Program			
	 Hand	 Knee	 Thoracic	 Spine
Continue	45 kVp 0.4 mA	60 kVp 1.4 mA	70 kVp 2.1 mA	80kVp2.9 mA
30 pulses	45 kVp 3.0 mA	60 kVp 3.2 mA	70 kVp 5.0 mA	80 kVp 6.8 mA
15 pulses	45 kVp 3.0 mA	60 kVp 4.1 mA	70 kVp 6.3 mA	80 kVp 8.5 mA
8 pulses	45 kVp 3.0 mA	60 kVp 4.1 mA	70 kVp 6.3 mA	80 kVp 8.5 mA
4 pulses	45 kVp 3.0 mA	60 kVp 4.1 mA	70 kVp 6.3 mA	80 kVp 8.5 mA
2 pulses	45 kVp 3.0 mA	60 kVp 4.5 mA	70 kVp 7.9 mA	80 kVp 10.2 mA
1 pulse	45 kVp3.0 mA	60 kVp 4.5 mA	70 kVp 7.9 mA	80 kVp 10.2 mA

- High Dose

Mode	Program			
	 Hand	 Knee	 Thoracic	 Spine
Continue	45 kVp 1.0 mA	60 kVp 2.2 mA	70 kVp 3.4 mA	80kVp 4.6 mA
30 pulses	45 kVp 3.0 mA	60 kVp 5.2 mA	70 kVp 8.0 mA	80 kVp 10.8 mA
15 pulses	45 kVp 3.0 mA	60 kVp 6.5 mA	70 kVp 10.0 mA	80 kVp 13.6 mA
8 pulses	45 kVp 3.0 mA	60 kVp 6.5 mA	70 kVp 10.0 mA	80 kVp 13.6 mA
4 pulses	45 kVp 3.0 mA	60 kVp 6.5 mA	70 kVp 10.0 mA	80 kVp 13.6 mA
2 pulses	45 kVp 3.0 mA	60 kVp 7.8 mA	70 kVp 12.0 mA	80 kVp 16.8 mA
1 pulse	45 kVp 3.0 mA	60 kVp 7.8 mA	70 kVp 12.0 mA	80 kVp 16.8 mA

- The X-ray exposure condition can be changed depending on the device specification.
- Though exposure condition is automatically changed by changing the anatomical program, it is recommended to control exposure condition using ABC.

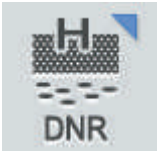
5.1.5.2 kVp/mA setting

Symbol	Description
	**kVp** Function to increase or decrease by 1 of kVp.
	**mA** Function to increase or decrease by 0.1 of mA

5.1.5.3 Pulses mode

Symbol	Description
	**Continue** Function to set up Continuous fluoroscopy mode.
	**30 Pulse** Function to set up pulse rate to 30.
	**15 Pulse** Function to set up pulse rate to 15.
	**8 Pulse** Function to set up pulse rate to 8.
	**4 Pulse** Function to set up pulse rate to 4.
	**2 Pulse** Function to set up pulse rate to 2.
	**1 Pulse** Function to set up pulse rate to 1.

5.1.5.4 DNR

Symbol	Description
	**Low** Function to set up DNR to low mode.
	**Normal** Function to set up DNR to middle mode.
	**High** Function to set up DNR to high mode.

5.1.5.5 Dose Level

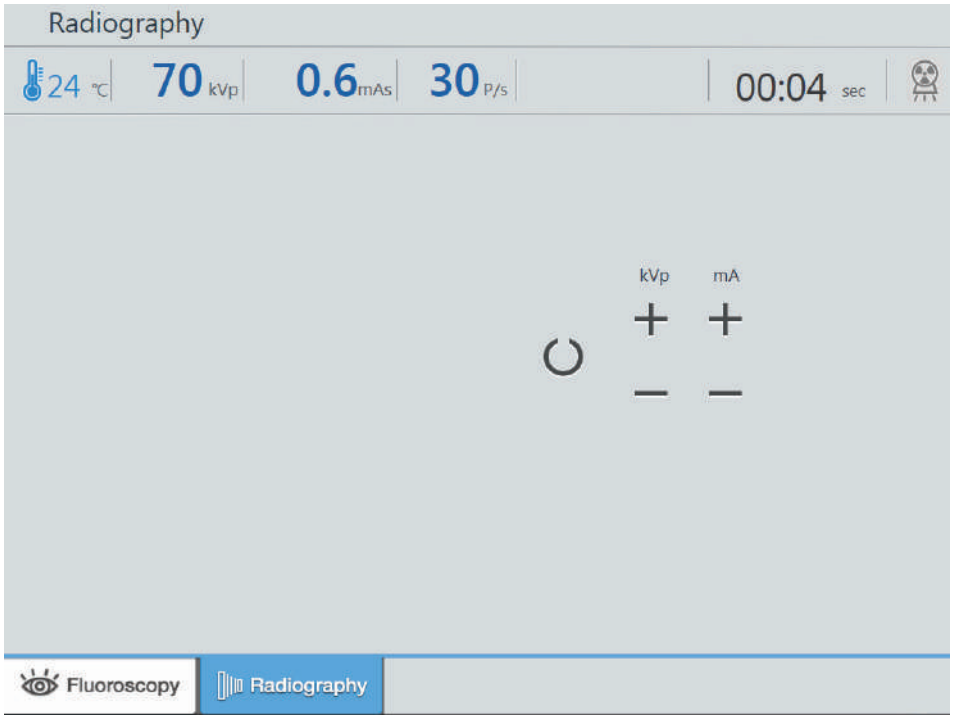
CAUTION	▪ Provides a low dose mode during the X-ray output conditions so that low radiation exposure can be diagnosed. ▪ If you are using the system for pregnant women you should consult your doctor before using it.

NOTICE	According to 203.6.101, 50% or more dose rates in low dose is decreased compared to normal dose.)

Symbol	Description
	**Low** Exposure the X-Ray in minimum dose.
	**Normal** Exposure the X-Ray in normal dose.
	**High** Exposure the X-Ray in maximum dose.

5.1.6) Radiography

When radiography mode is activated, mA value will change in to mAs and create buttons that can control kVp and mAs.



5.1.6.1 kVp/mAs setting

Symbol	Description
	**kVp** Function to increase or decrease by 0.1 of kVp.
	**mAs** mAs increase or decrease according to the specified mAs table

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6. Creation of Images with OSCAR 15FD

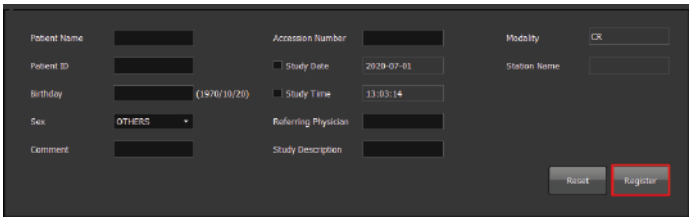
6.1) Patient Registration

Please follow the process below after running ZENIS software to operate OP for the equipment image acquisition.

NOTE

For more information related to Software program, please refer to the ZENIS Software User manual.

Patient registration

1. Patient registration	 Click the patient registration button on ZENIS. or when press the hand switch and foot switch of the equipment, Patient registration displayed.
2. Register new patient	 Enter the "patient information" on the left side of patient registration When you have finished entering data, click patient [Register] button.
3. Open existing patient record	On the "Patient list", searching for a patient in a condition the patient's name, chart number, date of registration and etc. is entered by double click.
4. Image acquisition	When you have finished "Patient registration, and press the hand switch or Foot switch of the equipment, OP screen for exposure is displayed.

6.2) Image acquisition

CAUTION	If foreign substances are found in the recorded video, contact the manufacturer first.

Basically, you can obtain images with OSCAR 15FD four ways as follows.

Exposure Mode	Exposure Method	OP Setting	Tube Voltage and Current Setting	
Fluoroscopy Mode	Continuous Fluoroscopy		Manual Control	(Manual)
			Automatic Control	(ABC)
	Pulsed Fluoroscopy		Manual Control	(Manual)
			Automatic Control	(ABC)
	Snap Shot		Manual Control (Large focus)	(Manual)
Radiography Mode	Radiography		Manual Control	(Manual)

Characteristics of Exposure Modes

Symbol	Description
	**Continuous fluoroscopy mode** Continuous fluoroscopy mode allows a user to expose X-ray at a patient continuously and to view the obtained live images through the live monitor.
	**30/15/8/4/2/1 Pulsed fluoroscopy mode** 30/15/8/4/2/1 pulsed fluoroscopy mode allows a user to expose x-ray at a patient at regular intervals and to view the obtained live images through the live monitor.  In the pulse mode X-Ray irradiates divided 30/15/8/4/2/1 times in 1 second. By using this function patient and user dosage can be lower and the device usage time can be longer.
	**Snap shot mode** Snapshot mode is used when the user needs to acquire high-quality images during the procedure using fluoroscopic mode. It is a function that enables high-quality images to be obtained by instantaneously exposure X-rays at a high level for a short period of time. However, ABC (or automatic brightness control) feature is not available in this mode, and a user sets the tube current manually.
	**Radiography mode** Radiography is a technology of implementing a radiographic method with the C-arm, allowing a user to set tube voltage (kVp) and tube current (mAs) manually and view images with cassette film. However, ABC (or automatic brightness control) feature is not available in this mode. Referring to Appendix 3. users should adjust exposure condition.

6.2.1) Patient Positioning

Before using the equipment, the Equipment must be oriented towards the patient.

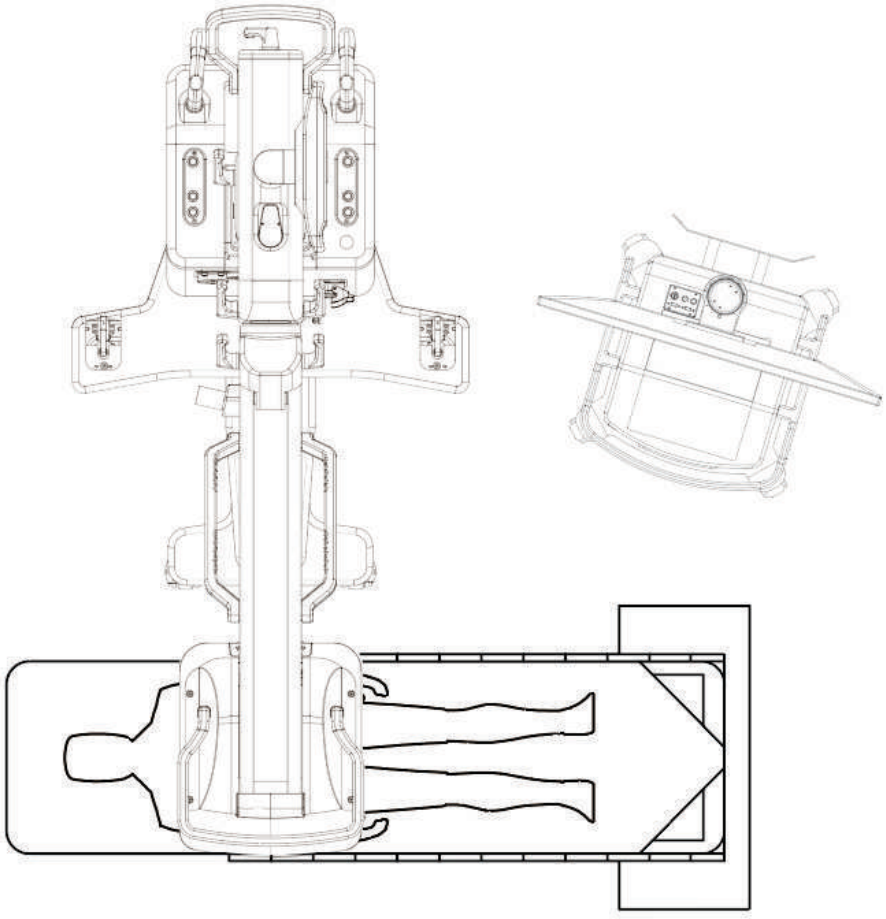
Use the following steps to orient the C-Arm.

Patient positioning will depend on the actual clinical procedure.

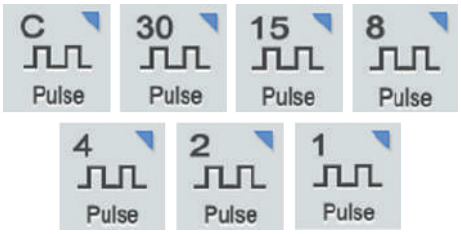
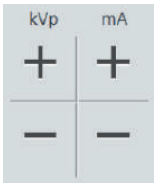
1. Assume the patient is lying face up on a table with the C-Arm positioned perpendicular to the table.
2. Position the C-Arm gantry to the left of the patient with the image detector over the patient's chest.
3. Imagine the patient lying face up to on the table with the C-arm

NOTE

Do not place the patient's body directly on the detector or use the detector as a work surface. Avoid direct contact between sensor and patient.

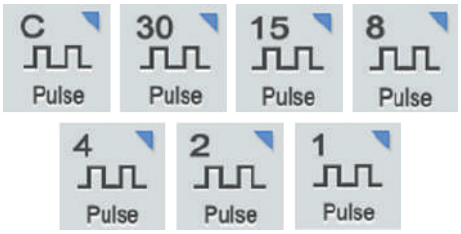


6.2.2) Instruction Use the Fluoroscopy Mode with Manual Control

<table>
<tr><th>Procedure</th><th>Symbol</th></tr>
<tr><td>1. Set the exposure mode to Continuous or Pulsed Fluoroscopy (30,15,8,4,2,1).</td><td> 
</td></tr>
<tr><td>2. Adjust tube voltage and tube current manually using the control buttons.</td><td> 
</td></tr>
<tr><td>3. Set up DNR setting, that user prefer.
<table>
<tr><th>Mode</th><th>Noise</th><th>Motion detection</th><th>Remarks</th></tr>
<tr><td>High</td><td>↓</td><td>↑</td><td>Obtain a clear image</td></tr>
<tr><td>Middle (Normal)</td><td>○</td><td>○</td><td></td></tr>
<tr><td>Low</td><td>↑</td><td>↓</td><td>A lot of movement in the treatment area</td></tr>
</table></td><td> 
</td></tr>
<tr><td>4. Once the settings are selected, exposures the x-ray by using the Shot switch, or Hand switch or Foot switch of the device.</td><td> 

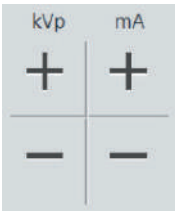
Hand Switch or Foot Switch</td></tr>
</table>

6.2.3) Instruction Use the Fluoroscopy Mode with Automatic Control

Procedure	Symbol
1. Set the exposure mode to Continuous or Pulsed Fluoroscopy (30,15,8,4,2,1).	
2. Select the exposure area. If the exposure area changes frequently, select the ABC button.	
NOTE If you find it difficult to set proper tube voltage and tube current or the target site keeps changing, activate ABC (Automatic Brightness Control) feature for automatic settings.	or 
3. Set up DNR setting, that user prefer.	
4. Once the settings are selected, exposures the x-ray by using the Shot switch, or Hand switch or Foot switch of the device.	 Hand Switch or Foot Switch

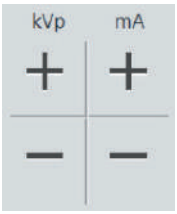
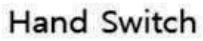
Mode	Noise	Motion detection	Remarks
High	↓	↑	Obtain a clear image
Middle (Normal)	○	○	
Low	↑	↓	A lot of movement in the treatment area

6.2.4) Instruction to Use the Snap Shot Mode

Procedure	Symbol
1. Set the Snap Shot mode.	
2. Adjust tube voltage and tube current manually using the control buttons.	
3. Check the icon for atmospheric status.	
4. Once the settings are selected, exposures the x-ray by using the Hand switch.	Hand Switch
5. Check if the icon for exposure status is yellow.	

If snap shot is misused, the image display delay may be longer than the delay seen in fluoroscopy.

6.2.5) Instruction to Use the Radiography Mode

Procedure	Symbol
1. Set the exposure mode to Radiography.	
2. Adjust tube voltage and tube current manually using the control buttons.	
3. Check the icon for atmospheric status.	
4. Check the icon (white) for exposure.	
5. Press the Hand switch to expose x-ray.	
6. Check if the icon for exposure status is yellow.	

NOTE

- ABC is not available on Radiography mode because ABC is operated with acquired image data from image sensor.
- Users should adjust exposure condition according **to Appendix3 X-ray Exposure Reference chart for Radiography**

7. Cautions, Storage, and Maintenance After Use

7.1) Cautions

- Disconnect the power plug by pulling the plug, not the cable.
- Organize the equipment, parts, and cord before keeping them in storage.
- Contact Customer Service immediately and wait for a technician to contact you in case of system malfunction or failure.
- Never attempt to disassemble or modify the system.

7.2) Storage

- The place for installment should be free from moisture.
- The place should be also free of negative impact from atmospheric pressure, temperatures, humidity, ventilation problems, dust, salt, air containing sulfur content, and so forth.
- Keep the system safe from a slope, vibrations and shocks (Also during transportation).

7.3) Maintenance

- The performance of the system and parts should be inspected on a regular basis. (Refer to **Appendix1 Maintenance**)
- Please make sure if the system operates properly before use after a long period of storage. Contact Customer Service if you need help.

7.4) Cleaning

- Turn off the system before cleaning.
- During the procedure, coverings of the Image Receiver and Tank that may be located close to the patient's body area must be visually checked prior to the procedure and cleaned immediately if any foreign substances are present.
- If cleaning of the equipment surface is deemed necessary, clean according to the following conditions
- Use a neutral detergent to clean the equipment on a regular basis and make sure that no liquid comes in contact with the inside.
- Please wipe gently with a sponge or damp cloth
- Do not use a detergent or antiseptic solution that may cause corrosion.

Recommended disinfectants

For proper cleaning and disinfection, use the following recommended disinfectants:

Recommended cleaning fluid	▪ Water or Water with ethyl alcohol (up to 96%)
Recommended disinfectants	▪ 70% isopropyl alcohol by volume, not diluted.

8. Specification

8.1) Classification and Applicable Standard

Medical equipment classification

Item	Specifications
Protection level and type for rating	Class I, Type B ME equipment

Standards and regulations

Item	Item
IEC/EN 60601-1	IEC/EN 60601-2-28
IEC/EN 60601-1-2	IEC/EN 60601-2-43
IEC/EN 60601-1-3	IEC/EN 60601-2-54
IEC/EN 60601-1-6	

8.2) Power and Other Specifications

System

- Technical Data

No.	Item	Specifications
1	Rated power	▪ 110-120 V~ ±10 %
2	Power consumption	▪ For 110-120 V~ • 5 kVA(Momentary), 2.5 kVA(Long time)
3	Frequency	50/60 Hz
4	Maximum impedance of supply mains	▪ For 110-120 V~ • ≤ 0.3 Ω

- Environment

No.	Item		Specifications
1	In Use	Temperatures	+15 ˚C to +35 ˚C
		Humidity	30 % to 75 %RH (no dew condensation)
		Atmospheric pressure	800 to 1060 hPa
2	In storage	Temperatures	-15 ˚C to 45 ˚C
		Humidity	10 % to 90 % RH (no dew condensation)
		Atmospheric pressure	700 to 1060 hPa

8.3) Major Parts Specification

NOTICE

Users refer to the maximum X-ray exposure conditions.

X-ray Generator

No.	Item		Specifications
1	Type		HF Inverter 57.2 KHz
2	Phase		Single
3	Nominal Peak Output Power		15.0 kW
4	Output power range	Radiography	▪ 40-120 kV ▪ 0.4 mAs-100 mAs
		Fluoroscopy (Normal) ▪ Cont. ▪ 30,15,8,4,2,1 Pulsed	▪ 40-120 kV ▪ 0.2 mA-6.0 mA ▪ 2.0 mA-10.0 mA
		Fluoroscopy (High) ▪ Cont. ▪ 30,15 Pulsed ▪ 8,4,2,1 Pulsed ▪ Snap shot	▪ 40-120 kV ▪ 1.0 mA-20.0 mA ▪ 3.0 mA-30.0 mA ▪ 3.0 mA-50.0 mA ▪ 1.0 mA- 50.0 mA
5	Max. Operating data	Radiography	▪ 150mA@100kV (at 8mAs) ▪ 120kV@100mA (at 8mAs)
		Fluoroscopy (Normal) ▪ Cont. ▪ 30,15,8,4,2,1 Pulsed	▪ 6mA@80kV, 120kV@4mA ▪ 10mA@96kV, 120kV@8mA
		Fluoroscopy (High) ▪ Cont. ▪ 30 Pulsed ▪ 15 Pulsed ▪ 8, 4,2,1 Pulsed ▪ Snap shot	▪ 20mA@48kV, 120kV@8mA ▪ 30mA@96kV, 120kV@24mA ▪ 30mA@120kV, 120kV@30mA ▪ 50mA@120kV, 120kV@50mA ▪ 120kV@40mA, 50mA@96kV
6	Duty cycle		▪ Radiography 1:60 ▪ Fluoroscopy 1:30 ▪ Snap shot 1:500
7	Total filtration		▪ 3.6 mm Al ▪ 7.5 mm Al
8	Housing heat unit		1,209,600 HU
9	Time Control		0-5 min.

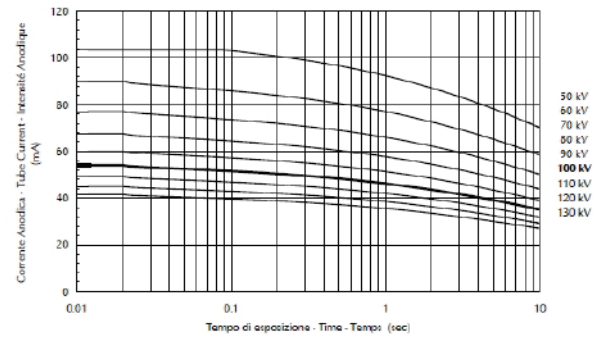
X-ray Tube

- RTM 70H

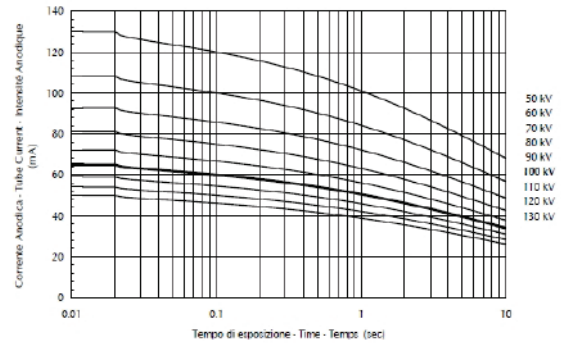
No.	Item		Specifications
1	Electrical Data	Circuit	DC (Center Grounded)
		Focal Spot	0.3/0.6 mm
2	Mechanical Data	Tube type	Rotating
		Target angle	10˚
		Inherent filtration	0.7 mm Al
3	Max. Assessment	Max. Tube voltage	130 kV
		Anode Heat Capacity	300 kHU(225kJ)

If the HVL measurement value is lower than the value provided during the equipment safety inspection, request repair through the manufacturer or an agency designated by the manufacturer.

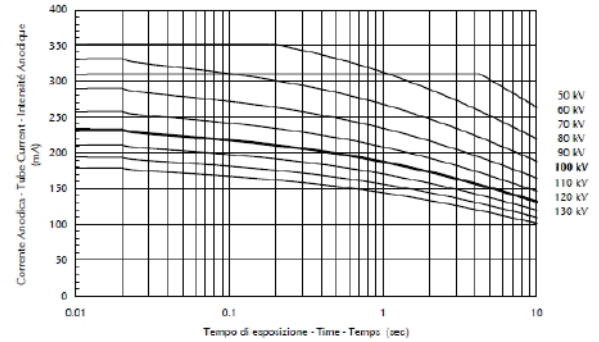
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE
0.3 - 1 ~ - 3000 min⁻¹



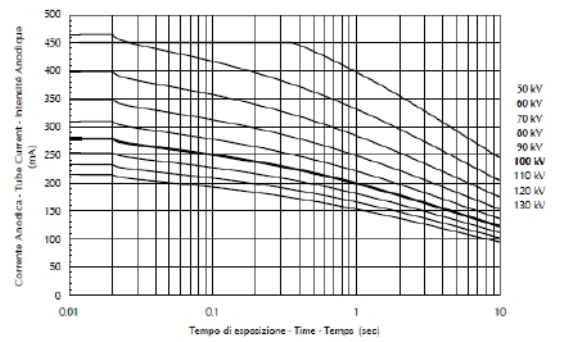
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE
0.3 - 3 ~ - 3000 min⁻¹



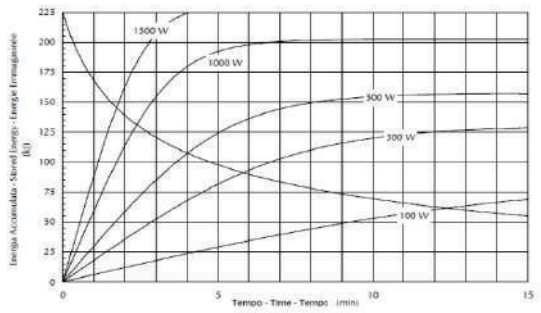
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE
0.6 - 1 ~ - 3000 min⁻¹

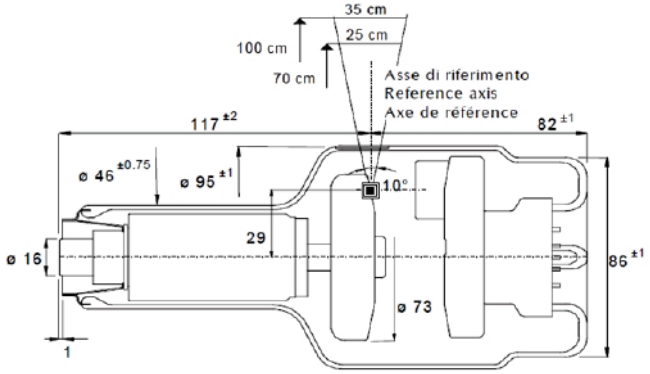


CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE
0.6 - 3 ~ - 3000 min⁻¹



Curve di riscaldamento e raffreddamento dell'anodo
Anode heating and cooling curves
Courbes d'échauffement et de refroidissement de l'anode



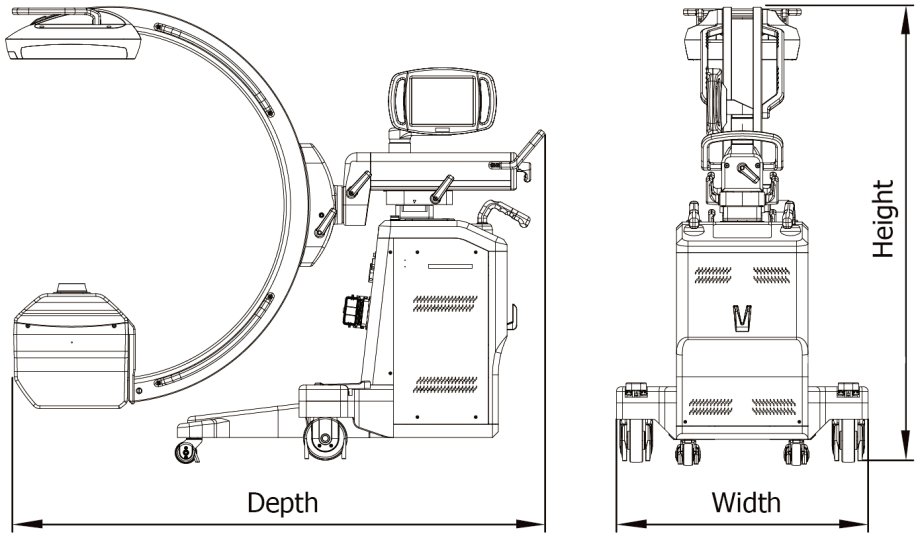


X-Ray Detector

- 30 X 30 Detector

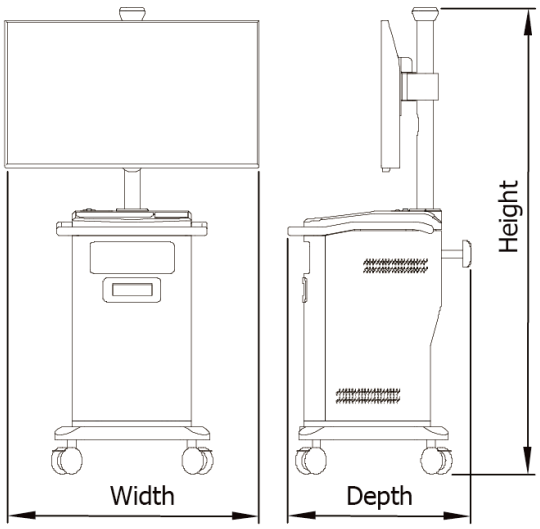
No.	Item	Specifications
1	Model	FXDD-1212GA
2	Type	TFT
3	Active image area	296.96 X 296.96 mm
4	Minimum Resolution(lp/mm)	3.4
5	Frame rate	30 frames/s
6	Number of Pixel	2,024 x 2,024 pixel
7	Pixel sampling resolution	16 bits
8	Pixel pitch	145 μm
9	Detective Quantum Efficiency	60 % (0.5 lp/mm)
10	Modulation Transfer Function	78 % (0.5 lp/mm)

Geometry and Mechanical Data



- Main body Dimension and weight

No.	Item		Specifications
1	Dimension (Unit: mm) ±10mm	Width	860
		Height	1555(Standard)-2055(Max.)
		Depth	1820(Standard)-2020(Max.)
2	Weight (Unit: kg) ± 5%		340

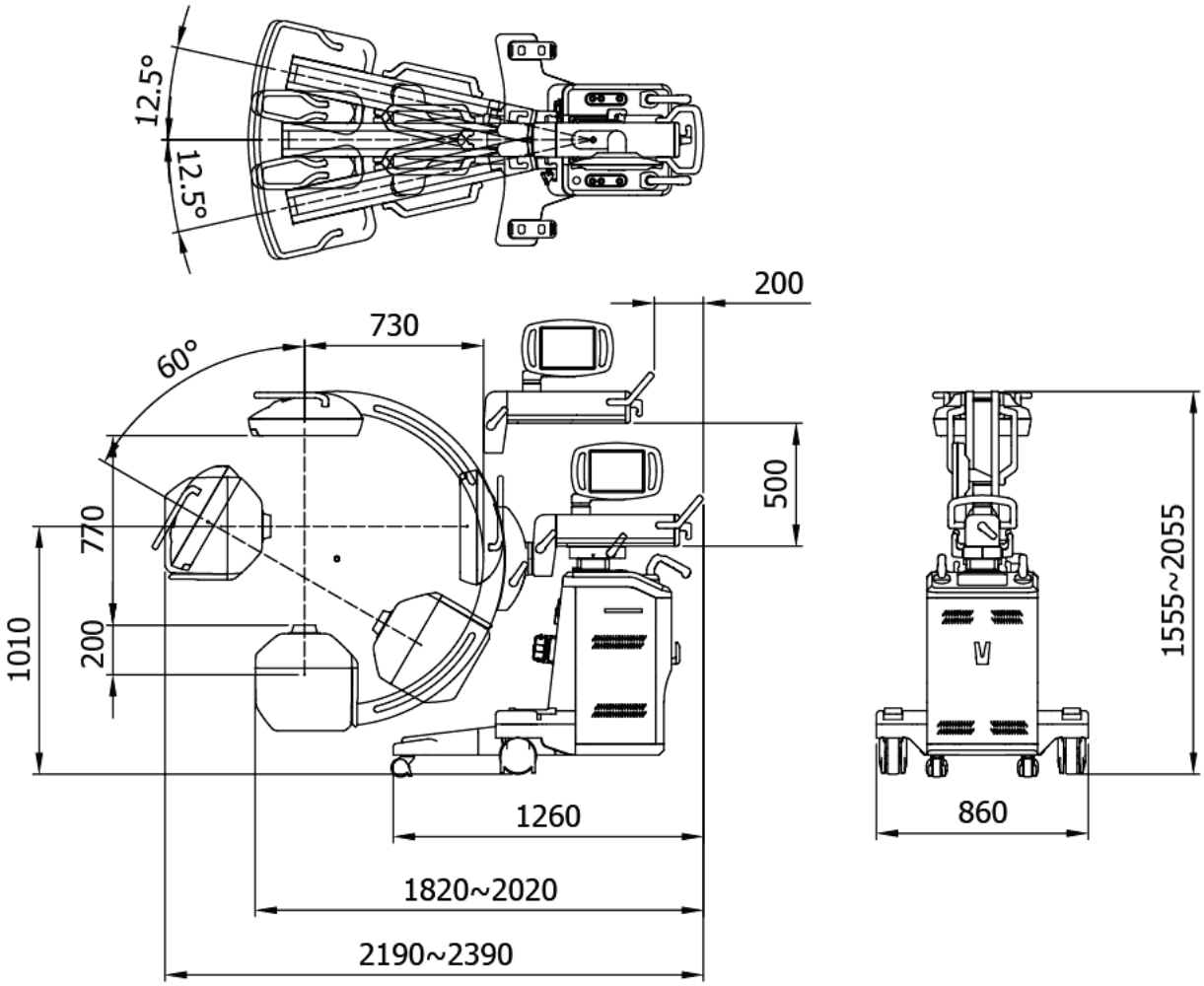


- Monitor Cart Weight

No.	Item		Specifications
1	Dimension (Unit: mm) ±10mm	Width ▪ 43" monitor	▪ 970
		Height ▪ 43" monitor	▪ 1810
		Depth	695
2	Weight (Unit: kg) ± 5%		100

Geometry and Mechanical Data

- C-arm



No.	Item	Specifications
1	SID (Source to Image-receptor Distance)	1000 mm
2	Free Space	770 mm
3	C-arc Depth	730 mm
4	C-arc up/down range	500 mm
5	C-arc back/forward range	200 mm
6	C-arc orbital angle	150 ˚
7	C-arc Lateral angle	460˚
8	C-arc Panning	± 12.5˚
9	Lowest Lateral High	1010 mm

Geometry and Mechanical Data

- Collimator

No.	Item		Specifications
1	Operation		Manual, Remote motor drive
2	Structure		Lead shutter
3	Speed	▪ Rotation ▪ Long & Cross	▪ 180˚ ▪ 15 sec. (Open-close)
4	Aperture		Round 14.8 mm for 8" x 10 cassette
5	Precision		2 % OF SID in use
6	Add filter		▪ 1.6 mm Al ▪ 3.0 mm Al + 0.1 mm Cu

- Grid

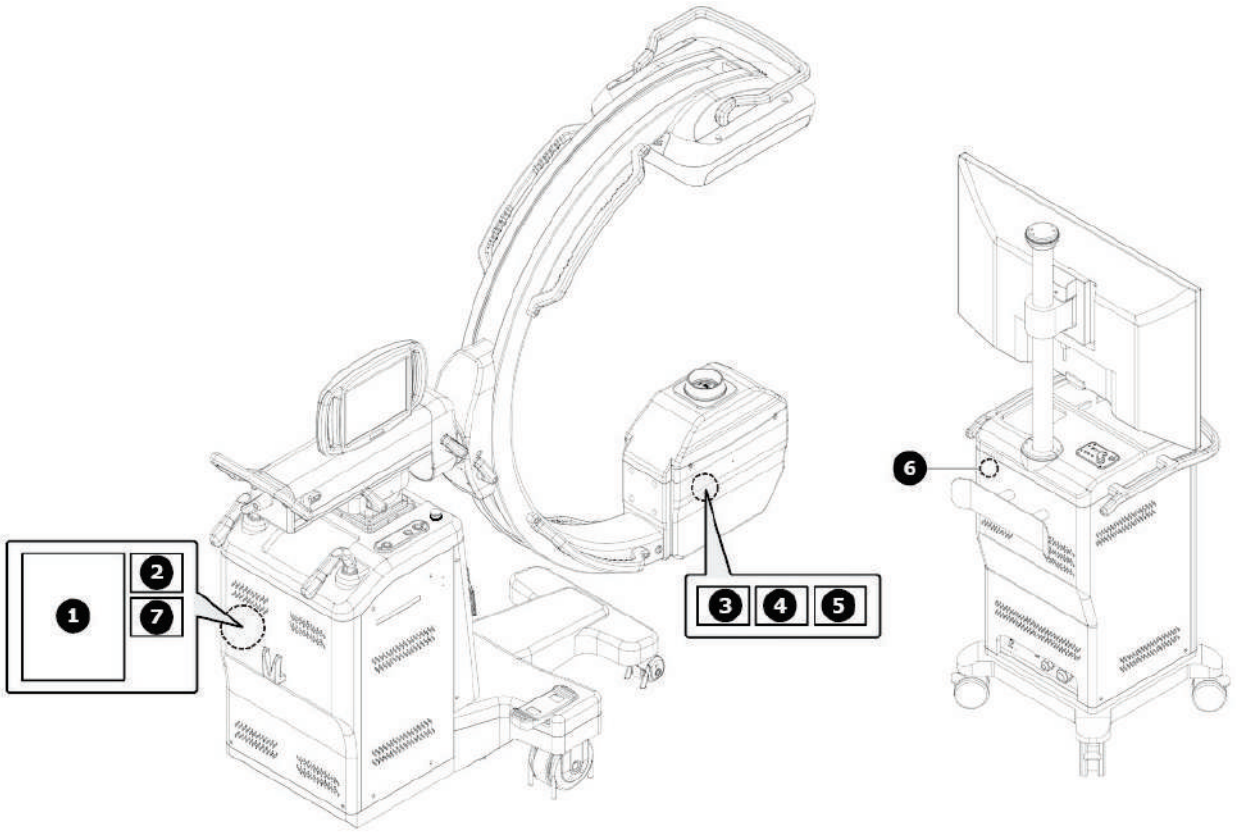
No.	Item	Specifications
1	SID	1,000 mm
2	Ratio	10:1
3	Line/inch	230

- Laser

No.	Item	Specifications
1	Type	Line Beam Laser Diodes
2	Level	Class II
3	Wave length	655±5 mm
4	Power	DC 5 V±5 %
5	Fan Angle	58 ˚

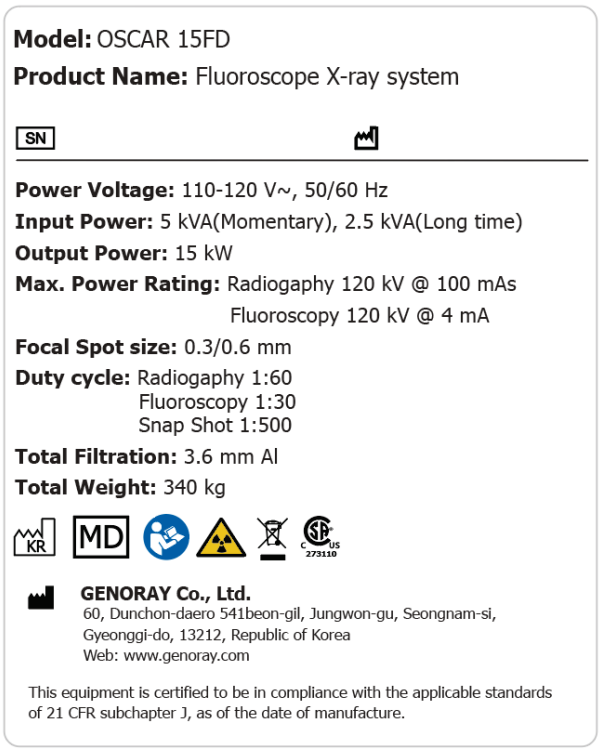
8.4) Labeling

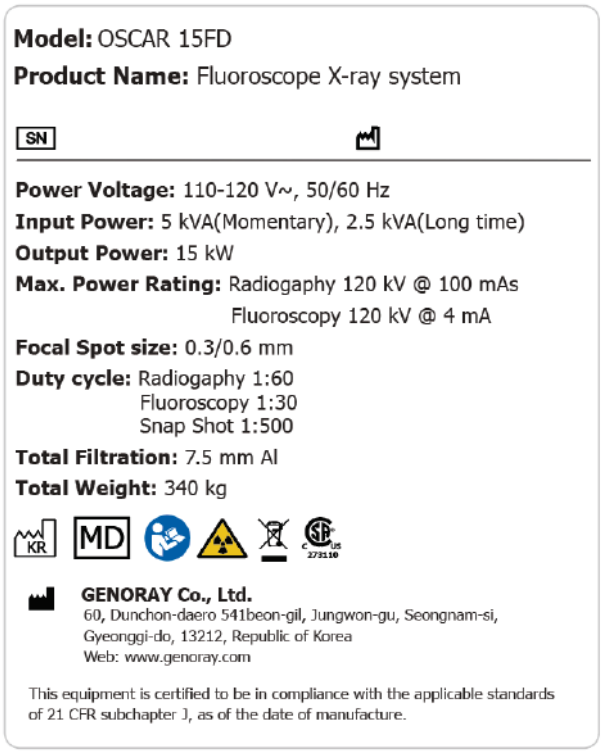
Please check the labels and manual before you connect the system to power.



No.	Label
1	Detector Label
2	Main Label
3	X-ray controller Label
4	X-ray Tube Support Label
5	X-ray Tube Label
6	X-ray Collimator Label
7	X-ray Generator Label
8	Monitor Support Label

8.4.1) Main Label





8.4.2) Part label

X-ray Generator

- Model: XHEART
- Manufacturer: GENORAY Co., Ltd.
- Max. Power Rating:
  Radiography 120 kV, 100 mAs
  Fluoroscopy 120 kV, 4 mA
- Serial No.:

X-ray Tube

- Model: RTM 70H
- Manufacturer: I.A.E(Italy)
- Maximum Tube Voltage: 130 kV
- Inherent Filtration: 0.7 mm Al
- Focal Size: 0.3/0.6 mm
- Serial No.:

X-ray Tube Support

- Model: SP01F003
- Manufacturer: GENORAY Co., Ltd.
- Serial No.:

X-ray Collimator

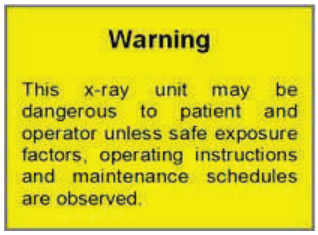
- Model: ZIC-800
- Manufacturer: GENORAY Co., Ltd.
- Add filtration: 1.6 mm Al
- Serial No.:

X-ray Collimator

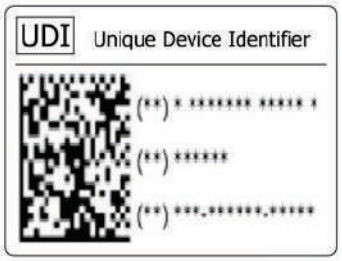
- Model: ZIC-800
- Manufacturer: GENORAY Co., Ltd.
- Add filtration:
  2.0 mm Al + 0.1 mm Cu
- Serial No.:

Monitor Support

- Model: SP01D003
- Manufacturer: GENORAY Co., Ltd.
- Weight : 100 kg ± 5%
- Serial No.:



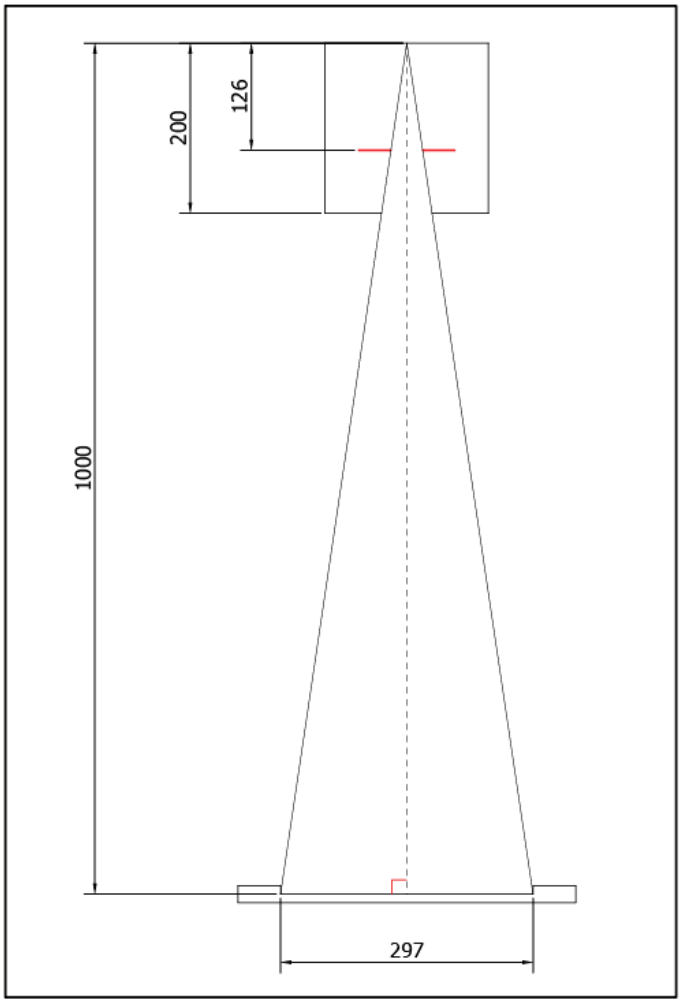
UDI (Unique Device Identifier) label



8.5) Dose information

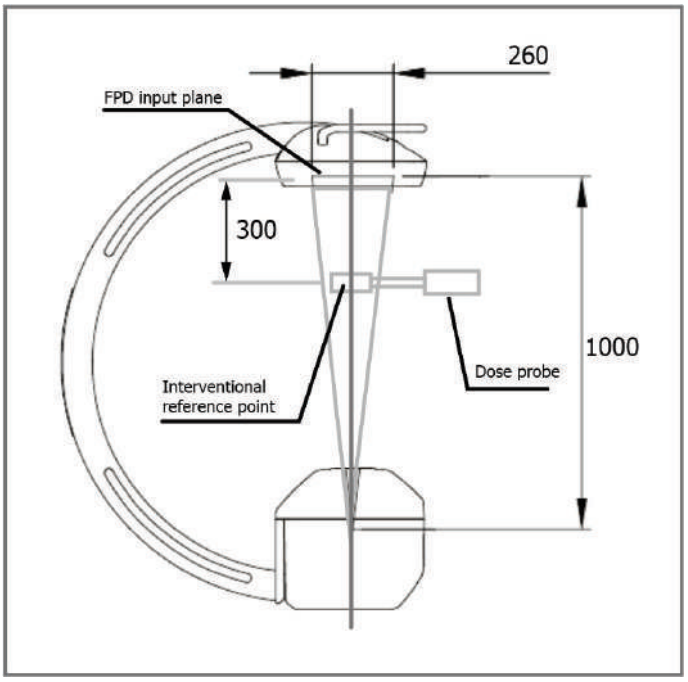
X-ray beam information

- Focal spot to collimator: 126 mm
- SSD: 200 mm
- SID: 1000 mm



8.5.1) Dose limit

- OSCAR 15FD equipment is complied with the requirements of international standards.
- Air Kerma of OSCAR 15FD was measured through dose probe from the interventional reference point.



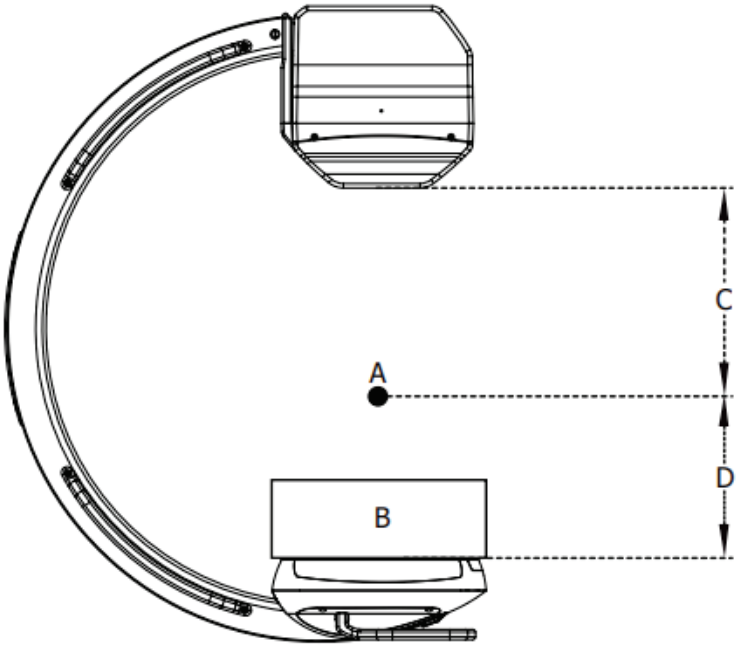
- As international standards requires (IEC 60601-2-43), OSCAR 15FD is not operated on any combination of tube voltage and tube current which can be exposed with exposure rate in excess of 88 mGy/min for normal dose mode and 176mGy/min for high dose mode.

8.5.2) Air kerma rate

Geometry for measuring the air kerma rate

The air kerma rates represents the measured air kerma rates at the reference point as shown below. The AKR is measured with ABC enabled.

- A: Air kerma reference point
- B: PMMA Phantom (30cm x 30cm x 20cm)
- C: 70cm
- D: 30cm



The air kerma on snap shot is measured cumulative air kerma, whereas the others are measured air kerma rates represented as mGy/min

PMMA represents the abdomen of normal patients.

Default Filter (Added filter with Al 1.6mm)

- Low Dose

Exposure Modes			Low Dose		
			Standard	Zoom 1.5	Zoom 2.0
Fluoroscopy & Roadmap	Continuous	kV	80	82	85
		mA	2.2	2.5	2.4
		ESD	14.69	17.45	17.79
	30 pulse	kV	83	85	88
		mA	5.5	5.7	6.2
		ESD	17.97	19.38	21.85
	15 pulse	kV	82	85	89
		mA	6.6	7.1	7.8
		ESD	10.50	11.96	13.94
	8 pulse	kV	82	85	88
		mA	6.7	7.2	7.7
		ESD	5.783	6.596	7.328
	4 pulse	kV	82	85	88
		mA	6.7	7.1	7.7
		ESD	2.908	3.295	3.654
	2 pulse	kV	81	84	87
		mA	7.8	8.4	9.1
		ESD	1.650	1.908	2.160
	1 pulse	kV	79	82	85
		mA	7.2	8.1	8.7
		ESD	0.789	0.859	0.948
Snap Shot		kV	N/A		
		mA			
		ESD			

- Normal Dose

Exposure Modes			Normal Dose		
			Standard	Zoom 1.5	Zoom 2.0
Fluoroscopy & Roadmap	Continuous	kV	81	82	85
		mA	5.0	5.2	5.6
		ESD	36.60	38.07	42.94
	30 pulse	kV	85	85	87
		mA	10.0	10.0	10.0
		ESD	33.53	33.21	33.76
	15 pulse	kV	87	87	93
		mA	10.0	10.0	10.0
		ESD	17.47	17.31	19.13
	8 pulse	kV	89	89	98
		mA	10.0	10.0	9.7
		ESD	9.827	9.760	11.15
	4 pulse	kV	93	93	95
		mA	10.0	10.0	10.0
		ESD	5.295	5.256	5.342
	2 pulse	kV	91	91	95
		mA	10.0	10.0	10.0
		ESD	2.638	2.619	2.77
	1 pulse	kV	95	95	94
		mA	10.0	10.0	10.0
		ESD	1.410	1.393	1.335
Snap Shot		kV	N/A		
		mA			
		ESD			

- High Dose

Exposure Modes			High Dose		
			Standard	Zoom 1.5	Zoom 2.0
Fluoroscopy & Roadmap	Continuous	kV	81	82	85
		mA	7.8	8.2	8.8
		ESD	62.22	62.57	69.89
	30 pulse	kV	84	85	88
		mA	20.3	20.7	22.2
		ESD	60.40	62.28	69.48
	15 pulse	kV	82	85	88
		mA	24.2	25.9	27.7
		ESD	34.03	38.67	43.01
	8 pulse	kV	83	86	90
		mA	25.1	26.5	28.3
		ESD	18.41	20.58	23.45
	4 pulse	kV	83	86	90
		mA	25.1	26.5	28.3
		ESD	8.920	10.01	11.33
	2 pulse	kV	83	86	90
		mA	30.2	31.8	33.9
		ESD	5.188	5.870	6.343
	1 pulse	kV	83	86	90
		mA	30.2	31.8	33.9
		ESD	2.558	2.748	3.118
Snap Shot		kV	82	82	85
		mA	8.2	8.2	8.8
		ESD	0.164	0.164	0.186

Option Filter (Added filter with Al 3.0 mm + Cu 0.1 mm)

- Low Dose

Exposure Modes			Low Dose		
			Standard	Zoom 1.5	Zoom 2.0
Fluoroscopy & Roadmap	Continuous	kV	77	78	79
		mA	1.5	2.0	1.9
		ESD	3.146	4.522	4.162
	30 pulse	kV	80	82	84
		mA	4.5	5.0	5.3
		ESD	4.824	5.686	6.279
	15 pulse	kV	79	80	82
		mA	5.3	5.7	6.2
		ESD	2.756	3.045	3.443
	8 pulse	kV	80	82	85
		mA	5.7	6.1	6.6
		ESD	1.697	1.895	2.217
	4 pulse	kV	78	79	81
		mA	5.0	5.4	6.0
		ESD	0.733	0.791	0.879
	2 pulse	kV	79	81	83
		mA	6.5	7.3	7.7
		ESD	0.444	0.473	0.556
	1 pulse	kV	76	80	80
		mA	5.7	6.8	6.7
		ESD	0.201	0.236	0.232
Snap Shot		kV	N/A		
		mA			
		ESD			

- Normal Dose

Exposure Modes			Normal Dose		
			Standard	Zoom 1.5	Zoom 2.0
Fluoroscopy & Roadmap	Continuous	kV	78	78	78
		mA	3.9	3.9	4.1
		ESD	9.143	9.212	9.467
	30 pulse	kV	78	81	81
		mA	9.3	10.0	10.0
		ESD	9.186	10.90	10.50
	15 pulse	kV	81	81	81
		mA	10.0	10.0	10.0
		ESD	5.445	5.390	5.240
	8 pulse	kV	81	81	81
		mA	10.0	10.0	10.0
		ESD	2.934	2.898	2.828
	4 pulse	kV	79	79	79
		mA	10.0	10.0	10.0
		ESD	1.366	1.349	1.313
	2 pulse	kV	75	77	77
		mA	10.0	10.0	10.0
		ESD	0.626	0.631	0.633
	1 pulse	kV	73	73	75
		mA	10.0	10.0	10.0
		ESD	0.274	0.279	0.313
Snap Shot		kV	N/A		
		mA			
		ESD			

- High Dose

Exposure Modes			High Dose		
			Standard	Zoom 1.5	Zoom 2.0
Fluoroscopy & Roadmap	Continuous	kV	75	77	79
		mA	6.2	6.8	7.2
		ESD	13.33	16.15	18.11
	30 pulse	kV	79	81	83
		mA	17.0	18.9	20.3
		ESD	15.51	18.35	20.58
	15 pulse	kV	81	81	83
		mA	23.6	23.6	25.3
		ESD	11.61	11.48	12.83
	8 pulse	kV	82	82	84
		mA	23.8	24.2	25.3
		ESD	6.210	6.224	6.776
	4 pulse	kV	79	80	83
		mA	21.0	22.4	25.5
		ESD	2.557	2.695	3.211
	2 pulse	kV	78	81	82
		mA	25.2	28.3	29.0
		ESD	1.617	1.656	1.756
	1 pulse	kV	80	80	84
		mA	26.7	26.9	30.4
		ESD	0.821	0.827	1.245
Snap Shot		kV	77	77	77
		mA	6.8	6.8	6.8
		ESD	0.047	0.047	0.047

During repetitive or prolonged interventional procedures skin dose levels can be high enough under intended use to cause a risk of deterministic effects. The severity of the deterministic injury is directly proportional to the skin dose, and appropriate management. The best X-ray mode for the procedure should be used.

NOTICE

- If Operator can, stand at least about 1.8m (6 feet) from the x-ray tube and behind leaded shielding. Otherwise, stand out of the direct line of the primary projection beam and wear:
  - Leaded aprons;
  - Thyroid shields when close to the patient;
  - Eye protection when next to the patient during frequent or long periods of fluoroscopy;
  - Radioprotective gloves if hands are exposed to the direct beam
- Face the unit when wearing leaded aprons.
- Do not hold the patient in position during fluoroscopy unless absolutely necessary.
- Do not fold leaded aprons and shields. Hang them or lay them flat to decrease cracking.
- Test leaded devices regularly for effectiveness.

8.5.3) Maximum radiation

The maximum air kerma rates and per frame are delivered with following loading factors

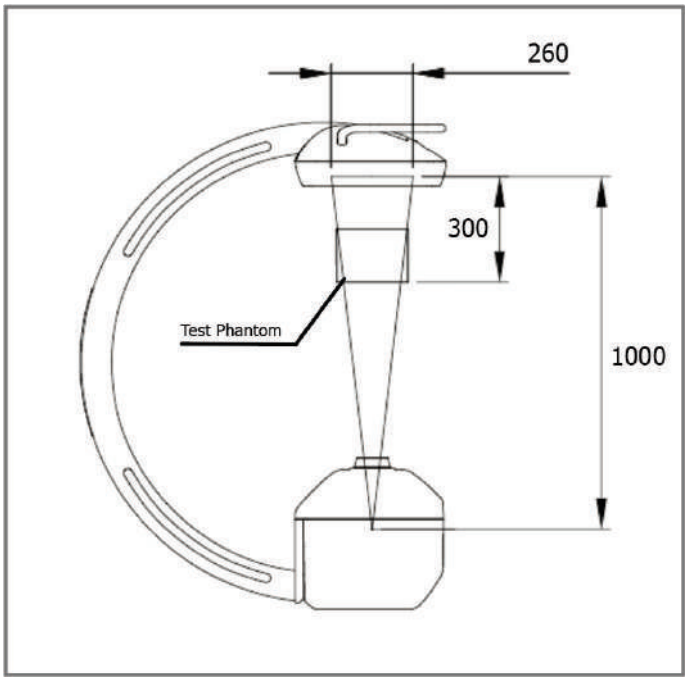
- Continuous / RoadMap : 120kV / 8mA
- Pulsed(30 pulse) : 120kV / 24mA
- Pulsed(15 pulse) : 120kV / 30mA
- Pulsed(8 pulse) : 120kV / 50mA
- Pulsed(4 pulse) : 120kV / 50mA
- Pulsed(2 pulse) : 120kV / 50mA
- Pulsed(1 pulse) : 120kV / 50mA
- Snap Shot : 120kV / 40mA
- DSA : 120kV / 50mA
- Radiography : 120kV / 100mAs

8.5.4) Deterministic effects of X-ray

- Higher exposure conditions(kV, mA) and prolonged exposure may increase the risk of deterministic effects on patients.
- In order to predict the deterministic effect from radiation, cumulative air kerma is usefully used. While 1 Gy is suggested as threshold dose level according to FDA, threshold of 2Gy is suggested by ICRP which may cause deterministic effects.
- In fluoroscopy modes, it is possible for radiation to reach deterministic threshold, if exposure time is long enough. However, OSCAR 15FD limits exposure time by 5 minutes. If exposure time reaches 5 minutes, X-ray exposure is limited.
- In addition, the maximum air kerma rates from OSCAR 15FD is limited up to 176mGy / min in high dose mode as explained in **8.5.1) Dose limit**.
- Though OSCAR 15FD is limited to avoid reaching the threshold, users is also required to reduce dose as reasonably possible.

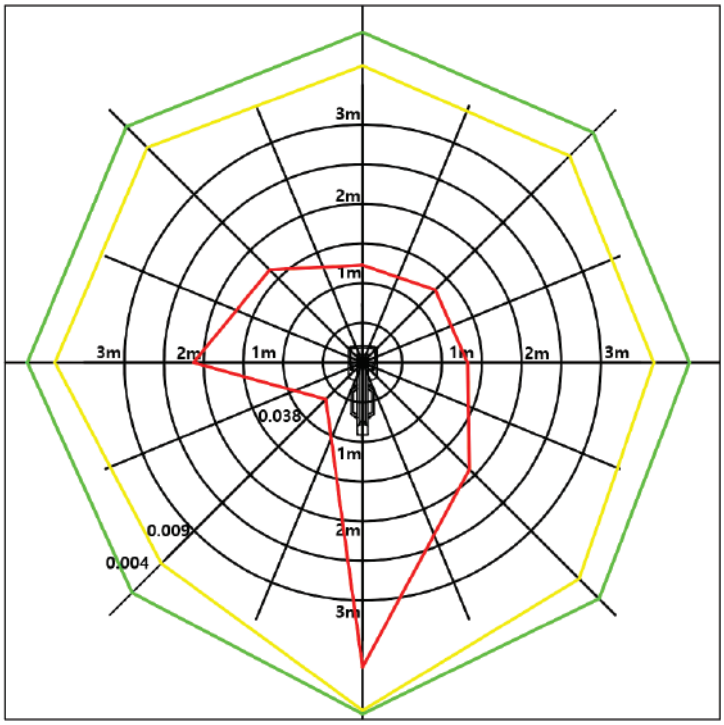
8.5.5) ISO kerma

Geometry for measuring ISO kerma

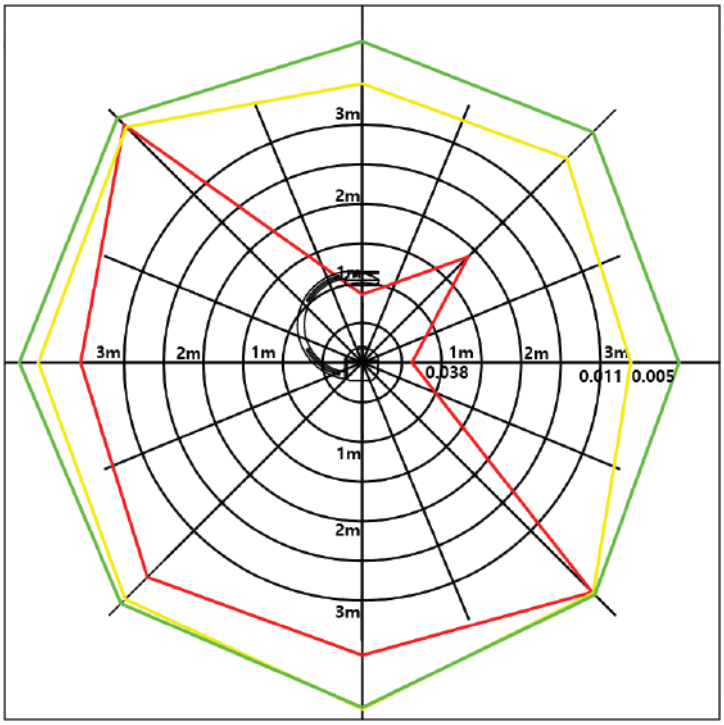


Scatter Map

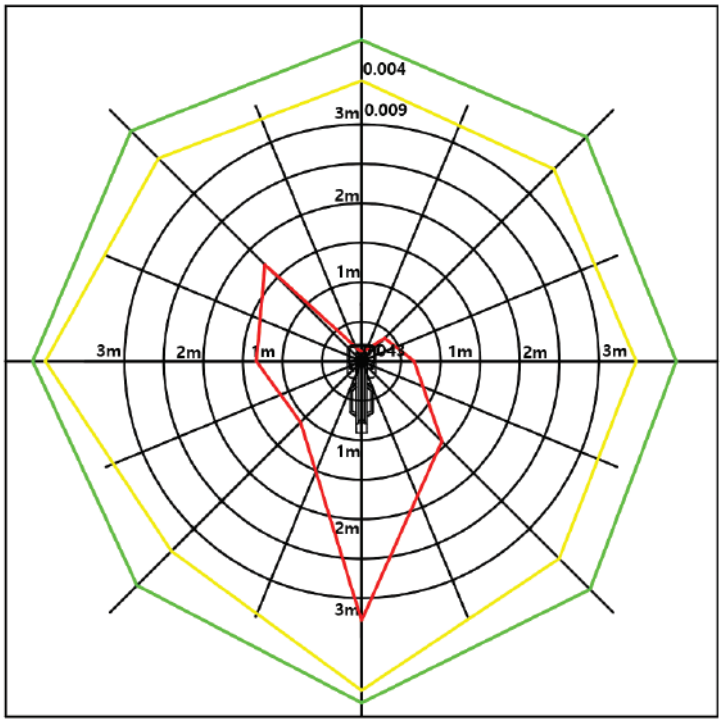
- ISO kerma map for horizontal beam Small Focus 1m 120kV 4mA Continue



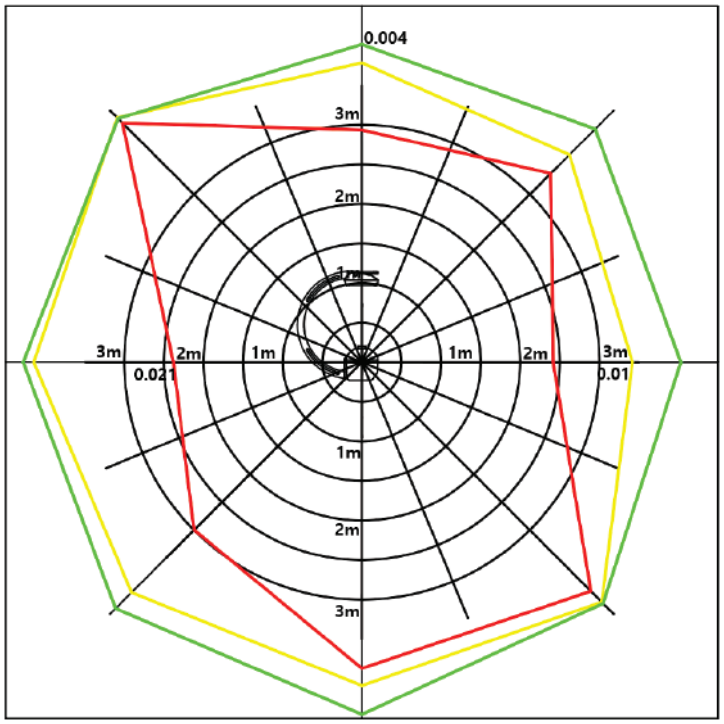
- ISO kerma map for vertical beam Small Focus 1m 120kV 4mA Continue



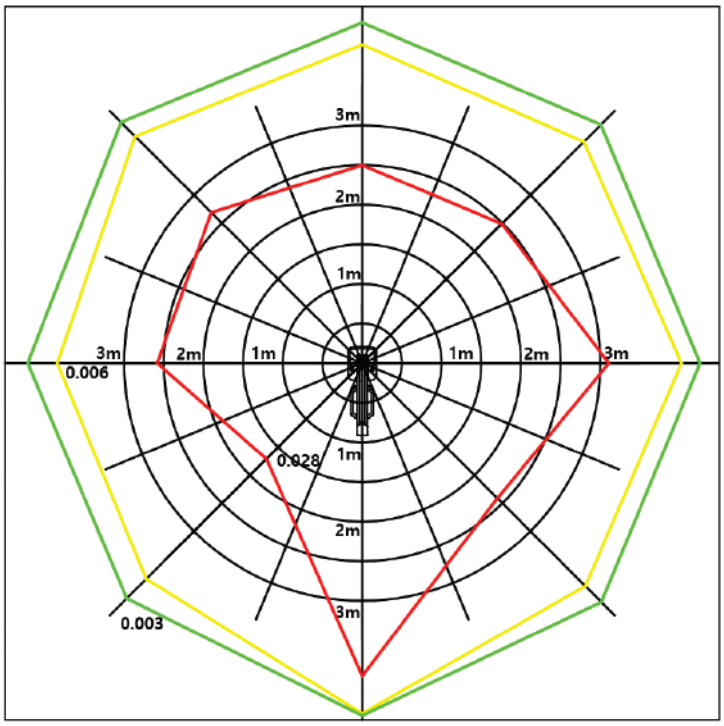
- ISO kerma map for horizontal beam Small Focus 1.5m 120kV 4mA Continue



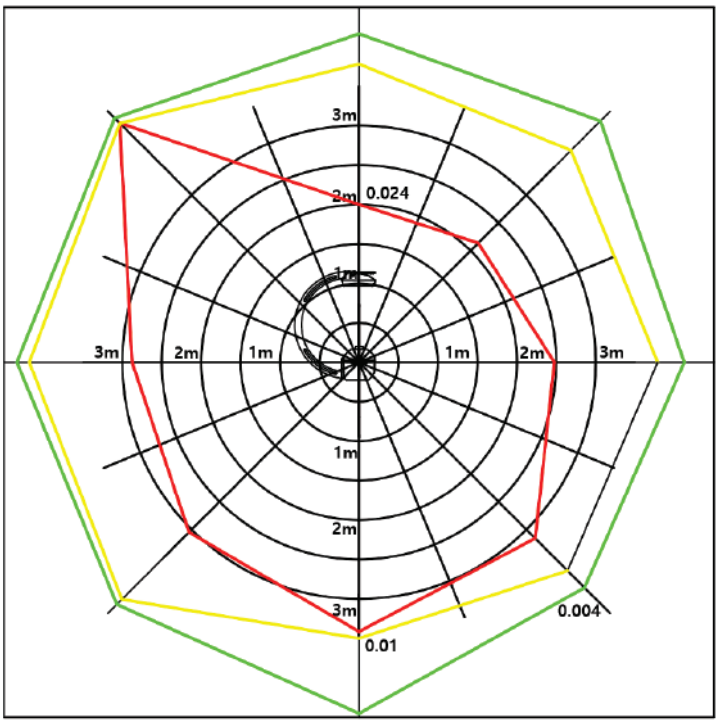
- ISO kerma map for vertical beam Small Focus 1.5m 120kV 4mA Continue



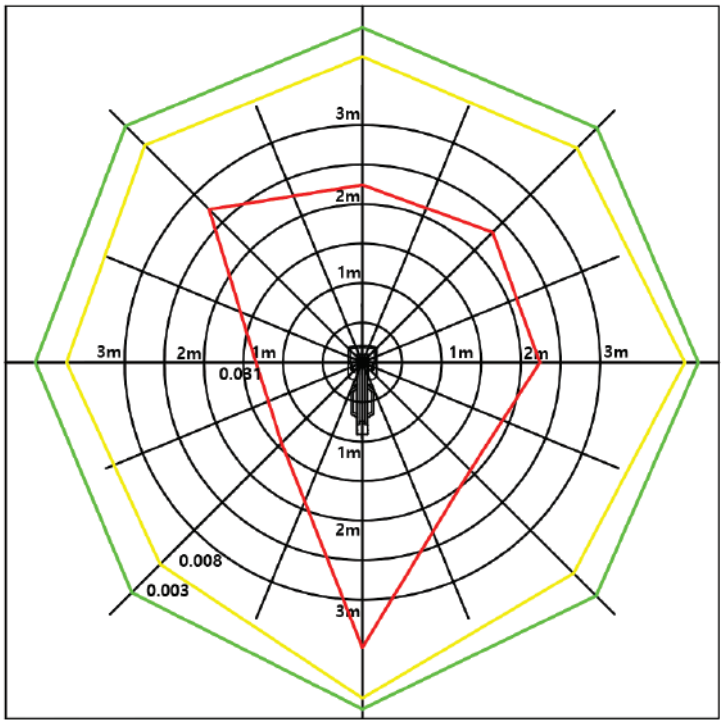
- ISO kerma map for horizontal beam Large Focus 1.0m 120kV 5mA Continue



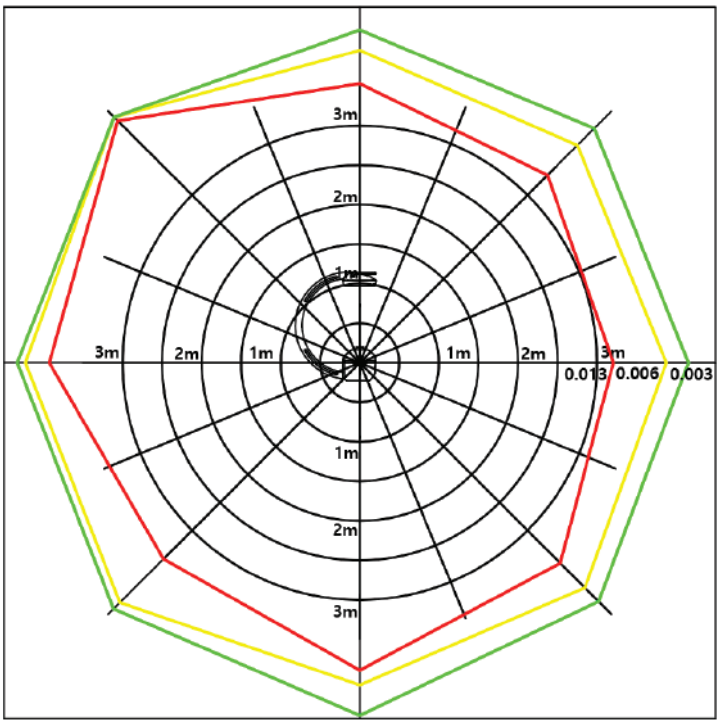
- ISO kerma map for vertical beam Large Focus 1.0m 120kV 5mA Continue



- ISO kerma map for horizontal beam Large Focus 1.5m 120kV 5mA Continue

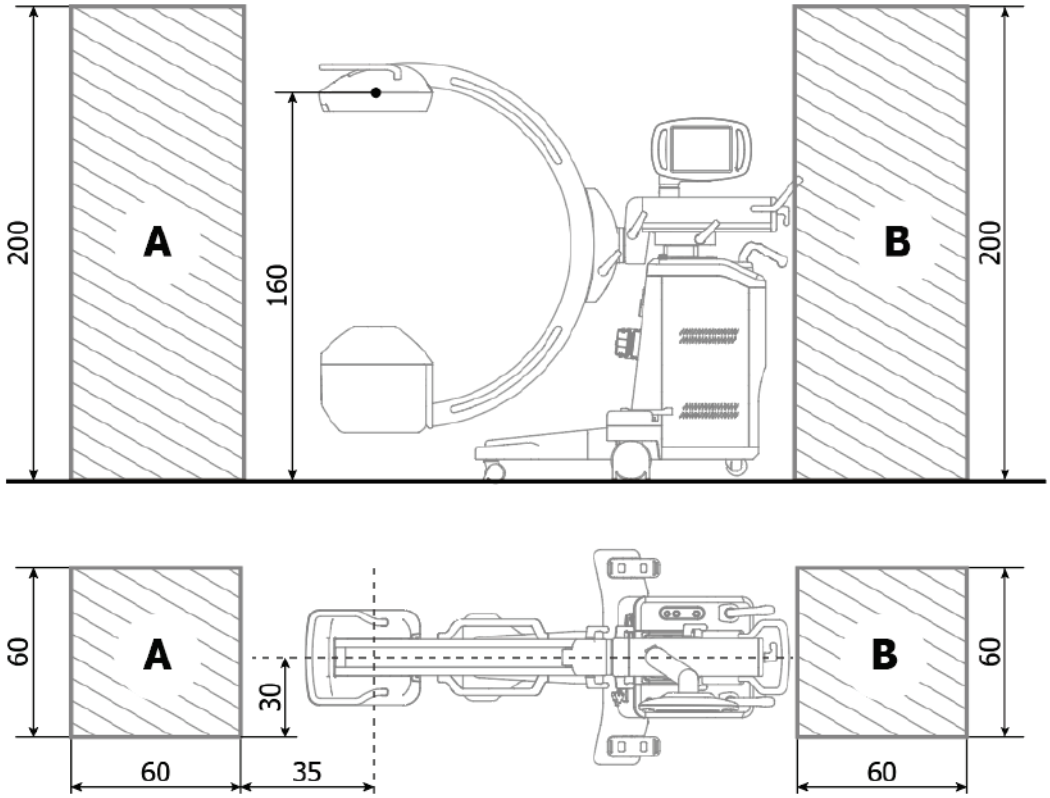


- ISO kerma map for vertical beam Large Focus 1.5m 120kV 5mA Continue



Scatter Radiation

- Measurement position



- Measurement value
  - 110kV, 4mA Continuous Mode
  - Scatter Absorber (Water Phantom): W25 * H25 * D20 (CM)

Height above the floor [cm]	Measurement A [mGy/h]	Measurement B [mGy/h]
200	2.27	0.26
190	2.73	0.24
180	3.26	0.25
170	3.81	0.25
160	4.42	0.17
150	5.11	0.11
140	6.05	0.09
130	6.89	0.08
120	8.01	0.08
110	8.41	0.06
100	8.29	0.06
90	7.09	0.07
80	6.07	0.06
70	5.58	0.04
60	4.58	0.03
50	4.23	0.03
40	3.54	0.02
30	3.04	0.02
20	2.78	0.02
10	2.49	0.02
0	2.56	0.02

8.5.6) Dose Indication

Dose Area Product(DAP)

- DAP is a quantity used to assess the radiation risk from X-ray. DAP is defined as the air kerma multiplied by the area. DAP is not related to the position of the patient(distance).
- OSCAR 15FD Supports adjustable collimator to adjust x-ray field . On OSCAR 15FD, the adjusted x-ray field is automatically reflected to calculate appropriate DAP.
- Unit: mGym2, uGym2, uGycm2, mGym2/s, uGym2, mGycm2/s, uGycm2/s

Air kerma/Air kerma Rates

- The air kerma is a measure of energy transferred from radiation to matter. It is not same with absorbed dose but related to. The air kerma is measured on patients' skin(Reference point), which is located 30cm away from the detector surface.
- The air kerma rates is an instant unit of rate of radiation.
- The air kerma is suitable for predicting deterministic effect by X-ray. According to the international commission on Radiological protection, more than 2Gy of x-ray is suggested as threshold dose.
- The accuracy of DAP and air kerma is controlled based on the IEC 60601-2-43
- UNIT: mGy/min, mGy/s, uGy/min, uGy/s
- The method of measuring air kerma complies IEC 60601-2-43

Dose Accuracy

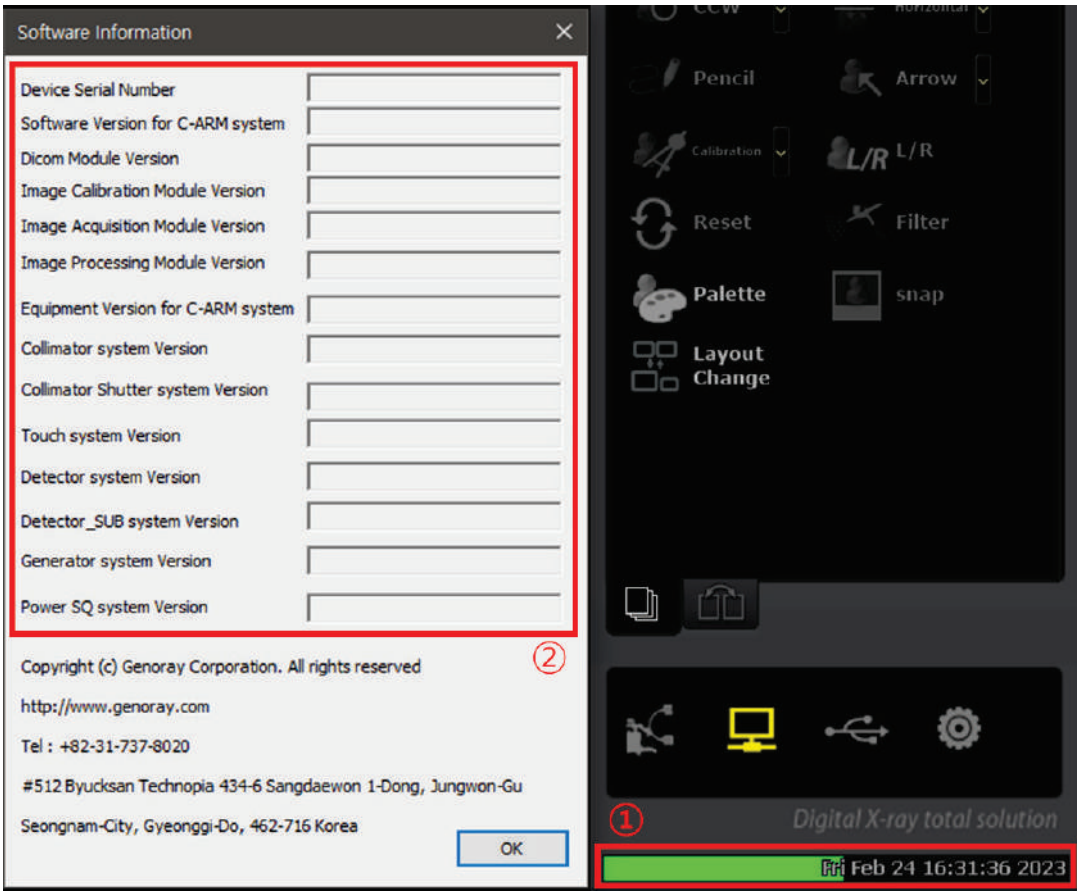
- OSCAR 15FD
- provides DAP meter optionally. It is equipped to the generator side.
- The installed DAP meter shall be periodically calibrated to provide accurate dose information.
- The device with DAP meter provides not only DAP but also air kerma.
- The air kerma is calculated by dividing exposure area from measured DAP.
- Even if DAP meter is not installed, OSCAR 15FD provides dose information by using pre-measured air kerma and field of radiation. The pre-measured air kerma shall be regularly updated referring to 5.9 Dose in OSCAR 15FD technical manual.
- The accuracy is calculated as below.

$$Error = 100\,x\,\frac{Measured\ dose - displayed\ dose}{measured\ dose}$$

- The tolerance of error is ±25 %
- If the test fails, make sure that dosimeter is calibrated and centered on the detector.

8.6) System Version information

1. Click status condition (storage & date time) tab on the right below.
2. Check the current F/W & S/W version.



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Appendix1. Maintenance

The user is responsible for proper operation and maintenance of the system.

Please perform a regular inspection for your and a patient's safety according to the following.

Check term	Check point	Checker	Result					
			1	2	3	4	5	Remarks
Everyday	Power plug connect state	User						
	Ground connect state							
	Power off after use							
	Cleanliness of product, image receiver and tank cover							
	On / off switch							
	Up/down, right/left buttons							
	Hand switch							
	Patient registration							
	Image save and import							
Once a week	Temperature and humidity							
	Emergency switch							
Unused more than 6 months	Tube voltage accuracy test	Manufacturer						
	Tube current accuracy test							
	Exposure dose to the patient							
	Detector calibration							

Carry out periodic inspections and tests in accordance with suggested maintenance practices to maintain equipment and image quality.

This system should receive an inspection per every 3 years for proper use from the date upon which it is purchased.

Appendix2. Error message

An error message is displayed on an x-ray control device if a problem occurs and the system cannot be operated properly. Check the message and take corrective measures.

When a problem occurs with the equipment, the user should be able to recognize it.

1	**Code No.**	Error1
	Error message	Exposure lower than setting data of kV
	Reason	It is taken lower than the set kV value.
	Temporarily	Reboot the device and check the problems.
2	**Code No.**	Overheat
	Error message	Overheat tank
	Reason	High voltage generator is overheating.
	Temporarily	Reboot the device and check after 2 hours
3	**Code No.**	Emergency
	Error message	Emergency switch was pressed
	Reason	Emergency Switch is pressed.
	Temporarily	Return the emergency switch to original state.
4	**Code No.**	Foot Switch
	Error message	Foot Switch was pressed
	Reason	Foot Switch is pressed.
	Temporarily	Reboot the device and check the problems.
5	**Code No.**	Shot Switch
	Error message	Shot Switch was pressed
	Reason	Shot Switch is pressed when the power is turned on.
	Temporarily	Reboot the device and check the problems.
6	**Code No.**	Ready Switch
	Error message	Ready Switch was pressed
	Reason	Ready Switch is pressed when the power is turned on.
	Temporarily	Reboot the device and check the problems.

7	**Code No.**	Error13
	Error message	when CCU VD signal is absent
	Reason	Detector or camera output signal is wrong.
	Temporarily	Reboot the device and check the problems.
8	**Code No.**	Error14
	Error message	Exposure abort
	Reason	Hand switch released earlier than mAs time set for the shooting mode or snap shot mode.
	Temporarily	Shoot again by not releasing the hand switch until the Waiting Message is displayed.
9	**Code No.**	Error15
	Error message	Inverter Fail
	Reason	An error occurred on Inverter A'ssy.
	Temporarily	Reboot the device and check the problems.
10	**Code No.**	Error16
	Error message	Rotor Fail
	Reason	The START_OK signal of Driver Rotor B/D is not input.
	Temporarily	Reboot the device and check the problems.
11	**Code No.**	Error17
	Error message	Filament Fail
	Reason	Generator Tube Heating has failed.
	Temporarily	Reboot the device and check the problems.
12	**Code No.**	Error19
	Error message	Capbank Fail
	Reason	An error occurred on Cap Charger A'ssy.
	Temporarily	Reboot the device and check the problems.
13	**Code No.**	UP/DOWN Switch
	Error message	UP/DOWN switch was pressed
	Reason	UP/DOWN button is pushed while power ON.
	Temporarily	Reboot the device and check the problems.
14	**Code No.**	Error25
	Error message	EEPROM Write Fail
	Reason	When EEPROM of MAIN B/D error happens
	Temporarily	Reboot the device and check the problems.

15	**Code No.**	Error26
	Error message	CAN1_ERR
	Reason	CAN communication inside the device does not work.
	Temporarily	Reboot the device and check the problems.
16	**Code No.**	Error28
	Error message	CAN_ERR
	Reason	CAN communication between the device and cart is not available.
	Temporarily	Reboot the device and check the problems.
17	**Code No.**	Error31
	Error message	MAIN_FAULT_ERR
	Reason	Communication with Main B/D is not available.
	Temporarily	Reboot the device and check the problems.
18	**Code No.**	Error100
	Error message	I-100 INVERTER_ERR
	Reason	An error has occurred in Inverter Assy.
	Temporarily	Power OFF and reboot after 10 min.
19	**Code No.**	Error101
	Error message	I-101 INVERTER_CURRENT_OVER_ERR
	Reason	Inverter Ass'y output current is higher than the set value.
	Temporarily	Power OFF and reboot after 10 min.
20	**Code No.**	Error102
	Error message	I-102 INVERTER_DELTA_EPFB_ERR
	Reason	Tank (Generator) output +, - kV Feedback value is wrong.
	Temporarily	Power OFF and reboot after 10 min.
21	**Code No.**	Error103
	Error message	I-103 INVERTER_P_EPFB_110_ERR
	Reason	Tank (Generator) output + kV Feedback value is 110%.
	Temporarily	Power OFF and reboot after 10 min.
22	**Code No.**	Error104
	Error message	I-104 INVERTER_N_EPFB_110_ERR
	Reason	When tank (Generator) output + kV Feedback feature is 110%.
	Temporarily	Power OFF and reboot after 10 min.

23	**Code No.**	Error105
	Error message	I-105 INVERTER_EPFB_LOW_ERR
	Reason	Tank (Generator) output kV Feedback value is low.
	Temporarily	Power OFF and reboot after 10 min.
24	**Code No.**	Error106
	Error message	I-106 INVERTER_DRV_OVERHEAT_ERR
	Reason	Inverter Ass'y is overheating.
	Temporarily	Power OFF and reboot after 20 min.
25	**Code No.**	Error110
	Error message	F-110 FILAMENT_ERR
	Reason	The X-ray Tube Filament current is different from the set value.
	Temporarily	Power OFF and reboot after 10 min.
26	**Code No.**	Error111
	Error message	F-111 FILAMENT_FIL_LOW_ERR.
	Reason	X-ray Tube Filament current is low.
	Temporarily	Power OFF and reboot after 10 min.
27	**Code No.**	Error112
	Error message	F-112 FILAMENT_FIL_OCP_ERR
	Reason	X-ray Tube Filament current is high.
	Temporarily	Power OFF and reboot after 10 min.
28	**Code No.**	Error113
	Error message	F-113 FILAMENT_NO_SETI_FIL_OCP_ERR
	Reason	There is no Filament Current value. (SET_I_FIL)
	Temporarily	Power OFF and reboot after 10 min.
29	**Code No.**	Error114
	Error message	F-114 FILAMENT_SET_I_FIL_OCP_ERR
	Reason	The set filament current value (SET_I_FIL) is normal but OCP has occurred.
	Temporarily	Power OFF and reboot after 10 min.
30	**Code No.**	Error115
	Error message	F-115 FILAMENT_SEI_I_FIL_LOW_ERR
	Reason	The set filament current is low (SET_I_FIL DATA).
	Temporarily	Power OFF and reboot after 10 min.

31	**Code No.**	Error120
	Error message	R-120 ROTOR_ERR
	Reason	When output of driver rotor B/D error is detected error code D/A output feature is detected.
	Temporarily	Power OFF and reboot after 10 min.
32	**Code No.**	Error121
	Error message	R-121 ROTOR_CURRENT_OCP_ERR
	Reason	When tank (generator) or driver rotor B/D setting current is high.
	Temporarily	Power OFF and reboot after 10 min.
33	**Code No.**	Error122
	Error message	R-122 ROTOR_CURRENT_LOW_ERR
	Reason	When tank(generator) or driver rotor B/D setting voltage is low.
	Temporarily	Power OFF and reboot after 10 min.
34	**Code No.**	Error123
	Error message	R-123 ROTOR_HZ_NOT_INPUT_ERR
	Reason	When driver rotor B/D AC power input is not authorized
	Temporarily	Power OFF and reboot after 10 min.
35	**Code No.**	Error124
	Error message	R-124 ROTOR_HZ_FAIL_ERR
	Reason	When frequency of AC input power in driver rotor B/Dis unstable.
	Temporarily	Power OFF and reboot after 10 min without any other medical device.
36	**Code No.**	Error130
	Error message	C-130 CAPBANK_ERR
	Reason	Capbank error has occurred and D/A output is not stable.
	Temporarily	Power OFF and reboot after 5 min.
37	**Code No.**	Error131
	Error message	C-131 Capbank is charging.
	Reason	Capbank Ass'y is charging.
	Temporarily	Power OFF and reboot after 5 min.
38	**Code No.**	Error132
	Error message	C-132 CAPBANK_NOT_CHARGING_ERR
	Reason	There is no change in Capbank Ass'y Charging voltage. (Check the charging status within 17 secs. when the power is on)
	Temporarily	Power OFF and reboot after 5 min.

39	**Code No.**	Error133
	Error message	C-133 CAPBANK_OVER_CHARGING_ERR
	Reason	Charging voltage is higher than set value for Capbank Ass'y.
	Temporarily	Power OFF and reboot after 5 min.
40	**Code No.**	Error134
	Error message	C-134 CAPBANK_LOW_CHARGING_ERR
	Reason	Charging voltage is lower than set value for Capbank Ass'y. (Check the charging status after 17 secs. when the power is on)
	Temporarily	Power OFF and reboot after 5 min.
41	**Code No.**	Error135
	Error message	C-135 CAPBANK_PFC_OCP_ERR
	Reason	Capbank Ass'y Charging voltage is higher than the set charging current.
	Temporarily	Power OFF and reboot after 5 min.
42	**Code No.**	Error136
	Error message	C-136 CAPBANK_OVER_TEMP_ERR
	Reason	Capbank Ass'y is overheating
	Temporarily	Power OFF and reboot after 20 min.
43	**Code No.**	Error138
	Error message	C-138 CAPBANK_FULL_CHARING_FAIL_ERR
	Reason	Charging is done at the level lower than the set voltage when the PFC actual signal is given within Capbank Ass'y.
	Temporarily	Power OFF and reboot after 5 min.

Appendix3. X-ray Exposure Reference chart for Radiography

Part	Direction	Thickness(Cm)	Distance(Cm)	kVp	mAs
Skull	A.P.	18	80	70	25
	A.P.	20	80	75	25
	Lat.	15	80	70	20
	Lat.	17	80	70	25
Thoracic spine	A.P.	19	80	65	20
	A.P.	12	80	70	16
	Lat.	26	80	80	25
	Lat.	11	80	70	12
Lumbar spine	A.P.	19	80	80	25
	A.P.	21	80	80	32
	Lat.	25	80	100	40
	Lat.	28	80	100	50
Pelvis	A.P.	19	80	80	25
	A.P.	21	80	80	32
Shoulder joint		9	80	60	8
Humerus		6	80	55	6
Hand		2	80	45	3
Femur		15	80	65	8
Knee joint		12	80	65	10
Ankle		7	80	65	6
Toes		3	80	50	6
Bladder		20	80	80	20

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