Safety, Environmental, and Regulatory Information For Medical Device

and

Performance information

Product name

- **X-RAY TV SYSTEM SONIALVISION G4**
- **X-ray radiography table BK-12HK**
- **Digital Angiography System Trinias**
- **X-ray radiography table BK-120MK**
- **RADspeed Pro**
- **X-Ray Radiography Table BK-200**
- **X-ray tube assembly 0.2/0.8P38C-85**
- **X-RAY RADIOGRAPHY STAND BR-120**
- **X-ray tube assembly 0.3/0.8P18DK-85**
- **X-ray Radiography Stand BR-120T**
- **X-ray tube assembly 0.6/1.2P13DK-85**
- **X-RAY RADIOGRAPHY STAND BR-120M**
- **X-ray tube assembly 0.6/1.2P33DK-85**
- **X-RAY TUBE STAND FH-20HR**
- **X-ray tube assembly 0.6/1.2P18DE-85**
- **X-RAY TUBE STAND FH-21HR**
- **X-ray tube assembly 0.6/1.2P38DE-85**
- **Ceiling Type X-ray Tube Support CH-200M**
- **X-ray tube assembly 1/2P13DK-85**
- **CEILING TYPE X-RAY TUBE SUPPORT CH-200**
- **X-ray tube assembly 1/2P33D-85**
- **COLLIMATOR TYPE R-300**
- **X-ray tube assembly 1/2P18DK-85**
- **Collimator Type R-20J**
- **X-ray tube assembly 1/2P38D-85**
- **Radiography System RADspeed fit**
- **X-ray tube assembly 0.3/0.8P323DK-85**
- **GENERAL RADIOGRAPHIC SYSTEM EZy-Rad Pro**
- **X-ray tube assembly 0.6/1.2P123DK-85**
- **Mobile X-ray System MUX-10**
- **X-ray tube assembly 0.6/1.2P323DK-85**
- **Mobile X-ray System MobileDaRt Evolution**
- **X-ray tube assembly 0.8P323DK-85**
- **Mobile X-ray System MobileArt Evolution**
- **X-ray tube assembly 0.2/0.8P39CK-85**
- **FDR Visionary Suite**
- **X-ray tube assembly 0.3/0.8P324DK-85**
- **Mobile X-ray System FDR Go**
- **X-ray tube assembly 0.6/1.2P324DK-85**
- **Mobile X-ray System Mobirex i9**
- **X-ray tube assembly 0.6/1.2P164DK-85**
- **SURGICAL MOBILE C-ARM IMAGING SYSTEM OPESCOPE ACTENO**
- **X-ray tube assembly 0.6/1.2P364DK-85**
- **REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION**
- **X-ray tube assembly 0.6/1.2P324DK-125**
- **X-RAY R/F SYSTEM FLUOROspeed**
- **X-ray tube assembly 0.6/1.2P364DK-125**
- **X-ray tube assembly 1.2U161CS-31**
- **X-ray tube assembly 0.8P324DK-85**
- **X-ray tube assembly 0.7U161CS-36**
- **X-ray tube assembly 0.4/0.7JG326D-265**
- **X-ray tube assembly 0.7U163CS-36**
- **X-ray tube assembly 0.7/1.2JG326D-265**
- **X-ray tube assembly 0.7/1.3U163C-36**
- **X-RAY HIGH VOLTAGE GENERATOR UD150B-40**
- **X-ray tube assembly 0.6/1J327C-280**
- **X-RAY HIGH VOLTAGE GENERATOR UD150V-40**
- **X-ray tube assembly 0.6/1J317C-282**
- **X-RAY HIGH VOLTAGE GENERATOR UD150L-40**
- **X-ray tube assembly 0.6/1.2P326D-150**
- **X-RAY HIGH VOLTAGE GENERATOR UD150L-40F**
- **X-ray tube assembly 0.6/1.2P366D-150**
- **X-RAY HIGH VOLTAGE GENERATOR UD150L-40E**

- English -

Safety, Environmental, and Regulatory Information For Medical Device

General

Introduction

This booklet contains the essential information about the safety instructions and precautions to ensure safe operation of the instrument. For details, please refer to the instruction manuals for the product.

Read this booklet thoroughly before using the product and operate the product in accordance with the instructions in the manuals.

IMPORTANT

- If the user or usage location changes, ensure that this booklet is always kept together with the product.
- If this booklet, manual or a product warning label is lost or damaged, immediately contact your Shimadzu representative to request a replacement.
- To ensure safe operation, read all safety instructions before using the product.
- To ensure safe operation, contact your Shimadzu representative if product installation, adjustment, re-installation (after the product is moved), or repair is required.

Notice

- Information in this booklet is subject to change without notice and does not represent a commitment on the part of the vendor.
- Any errors or omissions which may have occurred in this booklet despite the utmost care taken in its production will be corrected as soon as possible.
- All rights are reserved, including those to reproduce this booklet or parts thereof in any form without permission in writing from Shimadzu Corporation.
- The original version is approved in English.

IMPORTANT

"Operating Precautions for Safety in the Use of Electric Medical Equipment"

1. Only a technician who takes training for operating the equipment should operate the equipment,
2. When installing the equipment, pay attention to the following items:
   (1) Do not install system near water faucet or similar equipment.
   (2) Install it away from potential sources of problems such as abnormal pressure, temperature or humidity, drafts, direct sunlight, dust chlorine or sulfur gas.
   (3) During transportation and operation of the equipment, avoid tilting, vibration and any impact.
   (4) Keep the equipment away from the areas where chemicals or gases are stored.
   (5) Use only the correct electrical power source with matching frequency, voltage and current (or wattage).
   (6) Check the condition of the battery power source (power and polarity) before operating the equipment.
   (7) Properly ground the equipment
3. Before operating the equipment, pay attention to the following items:
   (1) Check the conditions of switch contacts, polarity, dial settings, and meters, and make sure the equipment performs correctly.
   (2) Conform that the ground is connected properly.
   (3) Check all wiring for proper and correct connections.
   (4) Pay attention when using more than one unit at a time, because it may lead to an incorrect diagnosis and cause complications.
   (5) Check the condition of the external electric circuit, which will be directly connected to a patient.
   (6) Check the condition of the battery power source.
4. While operating the equipment, pay attention to the following items:
   (1) Do not over-exceed time or the amount of equipment use needed for diagnosis or therapy.
   (2) Observe the equipment and patient continuously for early detection of problems.
   (3) When a problem is detected with the equipment, take proper action to stop the equipment without harming the patient.
   (4) Do not let the equipment touch the patient.
5. After operating the equipment, pay attention to the following items:
   (1) Turn off the switches and return the dial to their original before use in the prescribed order. Then, turn off the main power switch.
   (2) Do not pull the power cable forcibly from the outlet.

(3) When storing the equipment, pay attention to the following factors:
  (i) Keep it away from the water.
  (ii) Store it away from the potential causes of problems such as abnormal pressure, temperature or humidity, draft, direct sunlight, dust chlorine or sulfur gas.
  (iii) Avoid tilting, vibration and any impact when storing.
  (iv) Store the equipment away from areas where chemicals and gases are stored.
(4) Clean all attachments, cables and contacts, and store them in one place.
(5) Keep the equipment clean to avoid problems during the next use.

6. When the equipment is found to be out of order, do not try to repair it. Immediately call a certified repair technician for repair.
7. Do not modify and part of the equipment.
8. Preventive maintenance
   (1) The equipment and its parts should be periodically checked.
   (2) If the equipment has not been in operation for an extended period of time, test it prior to actual operation to make sure it works correctly and safety.
9. Operate properly according to the operating manual.

Indications Used in This Booklet

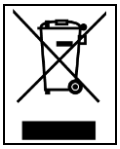
Mark	Description
DANGER	States a direct danger that may cause death or serious injury if it is not avoided.
WARNING	States an indirect or potential danger that may cause death or serious injury if it is not avoided.
CAUTION	States a danger that may cause slight or medium injury or may cause damage in equipment or fire if it is not avoided.
NOTE	States information which helps to use the system correctly.

Warning Labels

Symbol	Application	Symbol	Application
	Refer to the Instruction Manual when handling or operating any section marked with this symbol.		Indicates that some parts will reach high temperatures.
	Indicates that lethal voltage is present.		Indicates that the equipment emits ionizing radiation (X-rays).

Action for Environment (WEEE)

To all users of Shimadzu equipment in the European Union:



WEEE Mark

Equipment marked with this symbol indicates that it was sold on or after 13th August 2005, which means it should not be disposed of with general household waste. Note that our equipment is for industrial/professional use only.

Contact Shimadzu service representative when the equipment has reached the end of its life. They will advise you regarding the equipment take-back.

With your co-operation we are aiming to reduce contamination from waste electronic and electrical equipment and preserve natural resource through re-use and recycling.

Do not hesitate to ask Shimadzu service representative, if you require further information.

- English -

Regulatory Information

For Europe:
The product complies with the following requirements.
Medical Device Regulation, RoHS Directive

CE 0197
This medical device also complies with RoHS directive.

Manufacturer	Shimadzu Corporation
Address	1, Nishinokyo Kuwabara-cho, Nakagyo-ku, Kyoto 604-8511, Japan
Authorized Representative in EU	SHIMADZU EUROPA GmbH
Address	Albert-Hahn-Strasse 6-10, 47269 Duisburg, Germany

Digital Angiography System Trinias

Precautions in Usage

WARNING

The responsibility for management of use and maintenance of medical equipment lies in a user.

Use of this device is restricted to use by a diagnostic radiology technician or a person with a certificate indicating equal proficiency.

Do not remodel the equipment.

Repair and inspection of the inside of the equipment is dangerous. Make sure to contact our service agency for repair and inspection.

Perform periodical maintenance.

Maintenance is required in order to uphold the safety and performance of this equipment. For details on the maintenance inspection to be periodically carried out by the operator, please refer to the description contained in this operation manual.

Repair and maintenance of equipment can only be performed by engineers to whom Shimadzu assigns.

Maintenance must be assigned to specially trained experts. Contact the Shimadzu Service Representative for repair and maintenance.

Do not connect the equipment other than the designed equipment to the system.

Considerations against exposure to X-rays

Improper use of the X-ray equipment might cause the operator or patient to be accidentally exposed to X-ray radiation. During X-ray radiation, any person other than the subject patient should not stay in the irradiation room. If circumstances compel any non-subject person to stay in the room, enough protection should be provided for that person.

Considerations for mechanical safety

The operator should be very careful when moving the catheterization table and the C-arm support so that his (or her) or the patient's hand, limb, etc. does not get caught between the table and the C-arm support.

Never splash water to the equipment because you could get an electric shock. When cleaning the equipment, use cloth moistened with an antiseptic solution (Medical Alcohol) to wipe its surface.

Emergency procedures

To stop the equipment in an emergency, press the stop switch. This will turn off the power supply.

There is a stop switch (round red switch) which is located on the control console.

The operator should set the focal spot to skin distance as large as practicable to ensure the absorbed dose to the patient is as low as possible.

While performing rotational radiographing, C-arm rotates at high speed around the patient. Should C-arm collide with the patient or the tabletop, the patient may be injured or the equipment may be damaged.

Prior to radiographing, safety check must be performed. While performing rotational radiographing, always keep watching the patient and be ready to press stop switch ▽ .

Pay rigid attention so that any object is not placed upon the foot switch or the foot switch is not pressed by mistake. Otherwise, the X-ray may be generated or the table may be moved unexpectedly.

When operating the C-arm, confirm the safety in the operating range of the C-arm. Otherwise, the operator's foot may be caught between C-arm and the floor, or C-arm may collide with other equipment or the patient. It may cause a serious personnel injury.

Accuracy of displayed values is not guaranteed.

Displayed values measured by the measurement functions of this equipment are not absolute values but relative values based on the capability of the instruments used.

Measuring a vessel diameter from angiography causes several errors. Therefore, do not diagnose or treat based solely upon this analysis result.

Use the analysis result as a reference value.

Do not use the Injector which is not conformed to the standard of IEC60601-1.

Do not open the covers. This can result in electric shocks.

- English -

WARNING

Do not use in a location where flammable or explosive gases may be generated. The equipment does not have a flameproof construction. Do not use the equipment in a location where flammable or explosive gases may be generated.

Do not use in a location where metal fragments may enter the equipment. This can result in electric shocks.

During X-ray irradiation, ensure that the X-rays irradiate the necessary region only. To avoid X-ray irradiation, narrow down the collimator and take protection measures, such as following items.

- Lower body protector for tabletop rail
- Lead acrylic protective shield
- Protective apron
- Protective glasses
- Protective gloves

Turn off the power before starting work.

Always turn off the equipment power before starting cleaning or disinfecting work. Failure to turn off the power can result in electric shock injuries or current leakage.

Do not directly pour or spray disinfectant onto the equipment. Take due care when using a disinfectant spray.

Disinfectant entering the equipment can result in electric shock injuries or short circuits. To disinfect the equipment, wipe the surface with a cloth dampened with disinfectant. Do not use disinfectant sprays that may be flammable or explosive. Vapor from these sprays may result in fire or breakdown.

Thoroughly ventilate the room before turning on the power after disinfection work is complete.

Flammable gases accumulated in the room may ignite, smoke, explode or cause electric shocks when the power is turned on.

Do not bring cellular telephones or related devices into the examination room

Do not bring mobile devices that emit electromagnetic waves (e.g. cellular telephones) into the examination room. Such devices can exceed the EMC electromagnetic wave standards, and under some conditions this can impair the proper functioning of the system. In the worst case, this can cause serious injuries or clinical errors.

Check that the electromagnetic fields are compatible.

All peripheral devices must satisfy the EMC standards regarding emission of electromagnetic waves and sensitivity to emitted electromagnetic waves. Devices that do not satisfy these standards may disturb the correct functioning of the system. In the worst case, this can cause serious injuries or clinical errors.

Prepare alternative system with fluoroscopy function, in case any trouble happens and fluoroscopy/radiography cannot be operated normally.

To prevent from generating the unintended X-ray, move the C-arm to the park position and push the X-ray off button of System Display except operating the equipment.

Do not allow operation of this apparatus by any person other than qualified personnel (physicians, radiotherapy engineers and clinical X-ray engineers) or under observation by them.

Do not place unnecessary objects in the area of X-ray exposure. Doing so might subject the patient to unnecessary exposure.

Pay attention to the risk of local skin dose levels that cause tissue reactions under the intended use in the case of repetitive or prolonged exposure.

Do NOT perform any maintenance work on any part of the equipment during clinical use.

It may cause injury to patient.

This system operates in the same frequency band as premises radio stations for identifying mobile devices in factory production lines (license required) and specified low-power radio stations (license not required) in addition to industrial devices (ex. microwave ovens), scientific instruments, and medical devices. Other equipment may interfere with the system even if such equipment complies with CISPR EMISSION requirements.

The use of this system may result in RF interference with the above

mentioned equipment and radio stations. Make sure you understand and heed the following cautions when operating the system.

- Before using this system, make sure that no RFID premises radio stations and specified low-power radio stations or similar equipment are used in the immediate area.
- If this system causes damaging RF interference to affect an RFID premises radio station, stop using the system immediately and contact your Shimadzu service representative.
- If this system causes damaging RF interference to affect an RFID specified low-power radio station or amateur radio station, contact your Shimadzu service representative.
- This system may suffer interference from other equipment that emits radio waves (such as microwave ovens, Bluetooth devices, and digital cordless telephones). Use the system after moving such devices as far away as possible to prevent interference.

WARNING

When using the networks described below, the customer must implement security measures to prevent infection by malware

(i.e. malicious software, including computer viruses and worms, which causes damage to the infected computer).

- Networks that lack security management
- Networks that may be subject to malware intrusion
- Networks that are connected to or have the ability to connect to the following devices
  Devices that lack security management by the customer
  Devices that can be used by persons unauthorized by the customer
  Wireless communication devices

Examples of security management are as follows:

- NOT connecting to networks that lack security management
- NOT connecting to the internet
- Checking whether media (external storage media such as FDs, CDs and DVDs) are infected with malware before use.
- Avoiding actions that may result in malware infection
- NOT connecting to the network of another PC connectable to the internet.

Any viral infection or leakage of hospital information or patient information via internet connections is not covered under warranty.

It is strongly recommended that the user identify, analyze, evaluate, and control unacceptable risks resulting from a network connection.

A connection of the equipment to a network might cause unacceptable risks that were not specified in advance for patients, operators or third parties.

Also, changing the network connection will invite new risks, which will also require additional analysis.

Changing the network connection includes the following:

- Changing the network configuration
- Adding on equipment to the network
- Removing equipment from the network
- Updating equipment connected to the network
- Upgrading equipment connected to the network

CAUTION

Be sure to age the X-ray tube!

It is important to run-in (age) the X-ray tube before commencing actual X-ray irradiation. Follow the aging procedure described in the section X-ray Tube Aging.

Suddenly reverting to the nominal maximum tube voltage range (above 100 kV) after using the X-ray equipment at a relatively low tube voltage (80 kV max.) for a prolonged period may result in arc. This arc occurs due to loss of the high-tube-voltage aging effect if the X-ray equipment is used at a relatively low tube voltage. Follow the X-ray Tube Aging procedure described in the operation manual before using the X-ray equipment at a high tube voltage after a prolonged period of use at a relatively low voltage.

Avoid unnecessary Ready-up. Failure to conduct radiographic operation in the Ready-up status (lit) may result in a discontinuity or defective withstand voltage due to filament evaporation.

For operating in the control room, provide means for audio and visual communication between the operator and the patient.

If the operator has no experience in operating the equipment, be sure that he or she receives instruction on how to operate it from our engineers or someone who has enough experience to use the equipment.

In order to operate the equipment safely, an explanation of the operation needs to be lectured. When installing the equipment, our engineers explain the operating procedure. Follow their directions and operate the equipment correctly.

- English -

CAUTION

Consider the following cautions when using a network/data coupling.
- Connection to a network/data coupling that includes other equipment may result in previously unidentified risks to patients, operator or third parties. The administrator of this equipment should identify, analyze, evaluate and control these risks.
- Subsequent changes to the network/data coupling may introduce new risks and require additional analysis. Changes to the network/data coupling include the followings.
  - Changes in network/data coupling configuration
  - Connection of additional items to the network/data coupling
  - Disconnecting items from the network/data coupling
  - Update of equipment connected to the network/data coupling
  - Upgrade of equipment connected to the network/data coupling

Check regularly the available storage capacity on image processing equipment. Be sure to secure and archive important records.

Do not confuse the fluoroscopy and radiography. If the radiography mode is misused on purpose by the operator for real-time imaging, the image display delay may be longer than in the fluoroscopy.

Do NOT directly apply or spray subbing alcohol or water onto the equipment.

Wipe the surface of the equipment with a cloth moistened with rubbing alcohol.(intermediate level disinfectant) If rubbing alcohol gets inside the equipment, it can cause failure or accidents.

Do NOT use the selected frequency channel (2.4 GHz band) for other wireless devices.

Mutual interference between the system and other devices may result in decreased image data transfer speeds.

Do NOT cover the wireless receiver of the Wireless Foot Switch with your hands.

Covering the antenna may hinder the wireless communication properties (throughput and range) of the system.

If wireless foot switch cannot be used due to run out of battery, or does not work stably due to radio wave interference and so on, immediately stop using the wireless foot switch and use the wired foot switch.

In case that two foot-switch units are linked to one output unit, put both foot switch units in the examination room and turn on both during operation even if one of them is not used. If one foot-switch unit is turned off while the other is in use, the active foot switch may not work stably depending on the wireless communication conditions.

For California, USA Only

This product contains a battery that contains perchlorate material.

Perchlorate Material-special handling may apply.

See www.dtsc.ca.gov/hazardouswaste/perchlorate

1. This equipment is connected to the network in order to achieve the following purpose.
   - Acquire patient information, study information and past study image from the external equipment.
   - Send study image, study record, dose information and system maintenance information to the external equipment.
2. Connect to the IPv4 network that supports 1000 Base-T/100 Base-T.
3. Use UTP cable with enhanced category 5 (Cat 5e) or higher for LAN cable.
4. Intended information flow

Destination	Typical Information
DICOM Printer	Study image data
MWM server PPS manager	Patient information, Study information Study record, Dose information
DICOM image server	Study image data
Remote maintenance server	System maintenance information

5. Hazardous conditions in case of network failure

Destination	Hazardous Situation
DICOM Printer	Cannot print study image.
MWM server PPS manager	Cannot acquire patient information and study information. Cannot send study record and dose information.
DICOM image server	Cannot send study image. Cannot acquire past study image.
Remote maintenance server	Cannot send system maintenance information.

NOTE

When any serious incident occurred in relation to the system, report that to your Shimadzu service representative and to the competent authority of the Member State in you are established.

"Serious incident" means any incident that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat.

- English -

RADspeed Pro

Precautions in Usage

WARNING

The responsibility for management of use and maintenance of medical equipment lies with the user.

This equipment is restricted to use by, or under supervision of, a diagnostic radiology technician or a person with a certificate indicating equal proficiency. Repair and inspection of the inside of the equipment is dangerous. Be sure to contact your Shimadzu service representative for repair and inspection.

Never modify the equipment.

In general, modifications are strictly prohibited by the Regulatory requirements of the law of the country where the device is installed. Please contact your Shimadzu service representative if it is necessary to modify the equipment.

Perform periodic inspection.

Preventive maintenance is required to maintain long-term safety and performance of the equipment.

The "7 Inspection and Maintenance" chapter in this manual gives detailed descriptions of daily and periodic maintenance and inspection that a user should perform.

As for the maintenance and inspection that only specially trained experts can perform, utilize the maintenance agreement program offered by your Shimadzu service representative.

Repair and maintenance of the inside of the equipment can only be performed by your Shimadzu service representative.

Maintenance must be assigned to specially trained experts. Contact your Shimadzu service representative for repair and maintenance.

Connect this equipment only to Shimadzu certificated devices or devices that are proven to be safe and show no performance degradation in any combination including connecting system.

In order to ensure safety when using the system, read the operation manual provided with each system component for details on usage and relevant precautions.

CAUTION

If the operator has no experience in operating the equipment, be sure that he or she receives instruction on how to operate it from your Shimadzu service representative or someone who has adequate experience in using the equipment.

In order to operate the equipment safely, an explanation of the operation needs to be given. When installing the equipment, your Shimadzu service representative explains the operating procedure using this operation manual.

Follow their directions and operate the equipment correctly.

Secure the means for the operator and the patient to communicate with each other.

If equipment usage is deemed to put the patient at risk due to his or her condition, refrain from conducting the study or treatment.

Always identify the patient based on the patient information displayed by the equipment before performing exposure.

(This applies to cases where the system is upgraded to a digital radiography system.)

Be Sure to Read the Following to Prevent Explosion, Electric Shock, or Injury

DANGER

Do NOT use any potentially flammable or explosive gas, such as disinfectant sprays, near the equipment.

Use of such gas may cause an explosion.

WARNING

Check the condition of the patient before conducting a study.

If equipment usage is deemed to put the patient at risk due to the his or her condition, refrain from conducting the study or treatment.

Do NOT use the equipment in places where liquid may enter.

The equipment is not designed to be waterproof. Invasion of any liquid should cause electric shock, system failure or malfunction.

Do NOT spill any liquid, such as contrast medium, saline, or disinfectant, onto the equipment.

Should such liquid drip on equipment surfaces, wipe it off immediately. Any such liquid entering into system electronics may cause failure or malfunction.

Should liquid drip on the equipment or enter the covers, immediately turn off the power and contact your Shimadzu service representative.

When there is any abnormality in operation, or unusual smell or smoke emission during operation, stop operation immediately and contact your Shimadzu service representative.

Continued use may damage the equipment and cause injury.

Do NOT open the covers of the equipment.

Otherwise, electric shock may result. When opening the covers for maintenance, contact your Shimadzu service representative.

Always be very careful when moving the equipment to avoid contact with the patient or operator and to ensure that the patient or operator does not become caught between the equipment and any neighboring devices.

Otherwise, it may cause injury.

Do NOT use in a location where metal fragments may enter the equipment.

This can result in electric shocks.

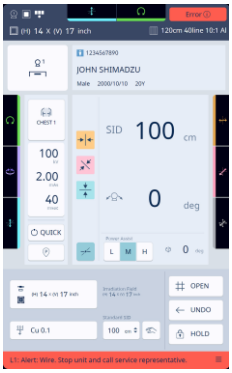
Do NOT perform any maintenance work of the equipment during study.

The patient may be injured.

(When combined with CH-200)

If the message "Alert: Wire. Stop unit and call service representative" is displayed on the operation touch panel, stop using the equipment and contact your Shimadzu service representative.

- The equipment is suspended by two wire ropes. If either of these ropes break, radiography is disabled.
- A buzzer sounds continuously when the warning message is displayed on the operation touch panel. Any continued use of the equipment while this message is displayed may result in serious injury to the patient or operator.



- When combined with the X-ray high-voltage generator D150B-40/V-40/L-40, press the hand switch to display the warning message on the touch panel of the X-ray high-voltage generator D150B-40/V-40/L-40.

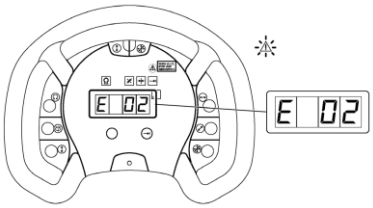
- English -

WARNING

(When combined with CH-200M)

If a warning display and error code [E02] are displayed on the operation panel, stop using the device and immediately contact your Shimadzu service representative.

- The equipment is suspended by two wire ropes. If either of these ropes break, radiography is disabled.
- A buzzer sounds continuously when the warning message is displayed as an error code on the operation panel. Any continued use of the equipment in this state may result in serious injury to the patient or operator.



CAUTION

Wait at least 10 seconds before turning the power on again after shutting it off.
If you do not, devices may not function correctly.

When using the system for long periods, take breaks of 10 to 15 minutes every hour to rest your eyes and hands for the sake of your health.

Always use the monitor that is a component of the system to read images.
Other monitors may not be suited to X-ray image diagnosis.

Perform equipment calibration by appropriately setting the exposure field, grid configuration, and the position of the equipment according to the directions described in the Operation Guide and DR-ID 900 Operation Manual.

NOTE

The values displayed by this equipment contain the prescribed margin of error appropriate for the relevant standard.

Cautions on Environmental Conditions

WARNING

Check the condition of the patient before conducting a study.
If equipment usage is deemed to put the patient at risk due to the his or her condition, refrain from conducting the study or treatment.

Do NOT use the equipment in places where liquid may enter.
The equipment is not designed to be waterproof. Invasion of any liquid should cause electric shock, system failure or malfunction.

Do NOT spill any liquid, such as contrast medium, saline, or disinfectant, onto the equipment.
Should such liquid drip on equipment surfaces, wipe it off immediately. Any such liquid entering into system electronics may cause failure or malfunction.
Should liquid drip on the equipment or enter the covers, immediately turn off the power and contact your Shimadzu service representative.

When there is any abnormality in operation, or unusual smell or smoke emission during operation, stop operation immediately and contact your Shimadzu service representative.
Continued use may damage the equipment and cause injury.

Do NOT use the equipment in an oxygen-rich environment.
The use in an oxygen-rich environment may cause fatal or serious injuries or damage to the equipment due to easy ignition.

CAUTION

Abide by the conditions for correct usage.

Install a dedicated air conditioner to the examination room and run the air conditioner 24 hours to satisfy the specified environmental conditions.

Note also that there must be no sudden changes in temperature or humidity. This causes condensation, which can lead to trouble.

The calorific power of the power supply is not significant enough to affect the use environment of the equipment.

The power box uses an AC power outlet that accepts three pin plugs for grounding purposes. Do NOT connect the power box to power strips, extension cords, or overloaded electrical circuits.

Please confirm input power specifications prescribed for each system configuration.

This equipment is different in input power rating from X-ray high voltage generators.

Do NOT let rubber or vinyl contacted with LCD monitor.

It may cause the deterioration or the paint may come off.

Cautions on Radiography

WARNING

Restrict all persons other than the patient from accessing the equipment in accordance with local regulations.

To avoid unnecessary exposure, acceptable distances (maximum access values) to the equipment by any person other than the patient are defined for each region.

The equipment can be operated only by qualified personnel, such as radiology technicians or those with equivalent qualifications.

No person but the patient is allowed to stay in the examination room during X-ray irradiation.

If the equipment is not used correctly, the operator, the patient, and other persons may receive a greater dose of radiation than necessary. If for some reason another person has to be in the examination room, that person must take adequate measures to protect themselves against radiation (protective apron, screen, etc.).

* During radiography, the radiography indicator illuminates and the buzzer sounds an audible warning.

Perform X-ray irradiation carefully and according to the doctor's directions when using the equipment with expectant mothers, women who suspect they are pregnant, lactating women, or children.

Particular ways of using the equipment may increase the scatter dose absorbed into the patient, which may cause a radiation hazard.

Always check the X-ray exposure region using the collimator lamp.

Irradiating a patient with X-rays outside the required region risks exposure of the patient to unnecessary radiation.

During X-ray irradiation, ensure that the X-rays irradiate the necessary region only.

To avoid unnecessary exposure, narrow down the collimator and take protection measures, such as wearing a protective apron.

Before starting radiography, confirm the following points:

- The appropriate radiography protocol has been selected. If you select a wrong radiography protocol for the region of interest or radiography method, the X-ray parameters will not be automatically selected correctly. Apart from that, images will not be processed properly which will prevent the system to deliver its intended performance.
- The appropriate technique, irradiation field and positioning direction have been selected or set.
- The appropriate X-ray parameters have been set. Do NOT expose X-rays if you cannot confirm the X-ray parameters on the operation panel. There is a danger that the patient will be exposed to a greater X-ray dosage than necessary. Apart from that, suitable images will not be obtained.

Do NOT place any unnecessary object in the location within the X-ray exposure region.

Doing so may result in unnecessary radiation exposure to the patient.

- English -

CAUTION

Be sure to carry out a warm-up (running-in operation of the X-ray tube unit) before taking an X-ray radiograph.

Follow the warm-up procedure described in the X-ray high voltage generator operation manual.

Perform the warm-up if an arc occurs.

Suddenly using the X-ray tube unit near the nominal X-ray tube voltage (above 100 kV) after using the unit at a relatively low tube voltage (80 kV max.) for a prolonged period may result in arc. This arc occurs due to loss of the warm-up effect at high tube voltage after the X-ray tube unit is used at a relatively low tube voltage for a prolonged period.

In this case, warm-up the X-ray tube unit by referring to the procedure described in the X-ray high voltage generator operation manual.

Do NOT perform unnecessary standby operations.

If standby status continues after the radiography preparation button is pressed, wire disconnection or withstand voltage failure may result owing to the evaporation of the X-ray tube filament.

In order to minimize the radiation dose on the patient, make the distance between the focus and the patient's body surface as long as possible (Minimum 45 cm).

The shorter the distance becomes, the greater the amount of scatter dose absorbed into the patient, which may cause a radiation hazard.

Pay extra attention when irradiating X-rays for a long time or repeatedly.

It may cause a radiation hazard.

In exposure, press and hold down the "READY" switch and "X-RAY" switch until the set exposure time has elapsed.

Releasing these switches during exposure will prematurely end X-ray irradiation. This may result in failure to acquire a satisfactory exposure image and risks exposing the patient to unnecessary radiation.

NOTE

(When combined with DR-ID 900)

If the Virtual Grid software (option) is incorporated, observe the following precautions when performing radiography with Virtual Grid enabled.

- Set appropriate radiography conditions instead of using the AEC function. Use of the AEC function may result in insufficient exposures.
- Image contrast may become high if the additional filter is used. Refer to the DR-ID 900 operation manual and adjust the grid ratio of the Virtual Grid software.
- Image contrast may become high if an FPD is set in the tray of the X-ray radiography stand or the X-ray radiography table. Refer to the DR-ID 900 operation manual and adjust the grid ratio of the Virtual Grid software.

(When combined with digital radiography system)

AEC function should be OFF with grid-less acquisition that be intended to scatter correction* .

Use of the AEC function may result in insufficient exposures.

* Scatter correction: This function improves contrast decreased by scattered radiation.

Cautions on Long View Radiography

WARNING

Always set the collimator to "Auto".

When the collimator is set to "Manual", the equipment is unable to narrow down the exposure field to the region determined from the results of calculation. This risks exposing the patient to unnecessary radiation.

When using the RC-300, switch the manual operation key on the CH-200 LCD screen to the OFF state and set the collimator to automatic operation.

CAUTION

Observe the following precautions when using the X-ray radiography stand.
Failure to do so may result in injury.

- Do NOT allow the patient to become caught between the X-ray radiography stand and the floor when lowering the stand.
- Do NOT allow fingers to become caught in the gap between the Bucky and the X-ray radiography stand for long view radiography.

Observe the following precautions when using the patient stand for long view radiography.
Failure to do so may result in damage or accidents.

- Only use the patient stand for long view radiography. Do NOT use the patient stand in other types of radiography.
- Do NOT move the patient stand from the examination room.
- Do NOT push or tilt the patient stand on the floor.
- Do NOT use the patient stand on the floor having an inclination of more than 5°.
- Be sure to keep the patient stand on a flat floor. When keeping it in storage, lock the stoppers at the wheels.
- When moving the patient stand, be careful not to get your foot or an object caught between the floor and the patient stand.
- Do NOT move the patient stand while a patient is resting on it.
- Check that the wheel stoppers on the patient stand are locked.
- Before placing a patient, lock the patient stand to the X-ray radiographystand with the pin and lock its wheels. Do NOT allow the patient to get on while the patient stand is not locked.
- Do NOT allow the patient to come into contact with the backplate when the patient is positioned on the stand.
- Do NOT allow the patient to lean on the stand.
- The patient or operator must exercise caution when moving around the stand to avoid tripping over the setting base.
- Pull the step out completely when using it.
- Before moving the patient stand, push the step inward and keep it completely retracted in position.
- Do NOT hang on the hand grip for patient stand or apply a force greater than 30 kgf.
- Tighten the fastening screw at the hand grip for patient stand firmly.

Cautions on the FPD

WARNING

Do NOT touch plugs or connectors with wet hands.
You could be seriously injured or killed by an electric shock.

CAUTION

When using the portable FPD, read the operation manual provided with digital radiography system for details on relevant precautions.

Disinfect the applied parts on the surface of the FPD, which the patient comes into contact with, with alcohol every time the patient changes.
Using the FPD without disinfection could spread infectious diseases.

Cautions on the Cabinet

CAUTION

Do NOT place anything on the control cabinet.
The internal devices may be damaged if anything falls into the control cabinet ventilation openings.

- English -

Cautions on the Monitor

CAUTION

Do NOT irradiate X-ray when DR-ID 900 monitor shows nothing.

There is a danger that the patient will be exposed to a greater X-ray dosage than necessary.

Do NOT touch or swallow the liquid crystal that may leak from the damaged panel.

It could cause skin irritation. If it gets into the eye, flush the eye with water and call your doctor. If it adheres to skin or clothes, wash it off immediately with water. It contains a stimulating substance.

Observe the following cautions when using the monitor.

Failure to observe these cautions can result in fire, electric shock, equipment failure, and shortening of equipment life.

- Do NOT place any object on the monitor or its cables, or cover the monitor or cables with anything.
- Do NOT handle the monitor with wet hands.
- If smoke is emerging or there is a strange smell or noise, turn off the monitor's power switch immediately and pull the power plug out of the outlet.
- If the monitor is dropped or subjected to a strong impact, switch off the monitor's power switch immediately and pull the power plug out of the outlet.
- If any liquid or foreign matter gets inside the monitor, turn off the monitor's power switch immediately and pull the power plug out of the outlet.
- To prevent accidents due to lightning strikes, do NOT touch the power plug or cable after hearing thunder nearby.
- Do NOT use the monitor while it has dew condensation on it.
- Do NOT use the monitor while it is facing upward, or use it built into a site that cannot be ventilated, since this will adversely affect the cabinet and parts.
- Do NOT press against or catch anything against the LCD panel, or rub anything hard against it, such as a ballpoint pen.

Make sure to use the supplied power cable.

The use of a cable other than supplied could cause the display to fail.

The display must be grounded.

Failure to do so could cause electric shock.

When using a 2P plug, ground the display before plugging into a wall outlet. To remove the grounding cable, unplug the display first.

Follow the instructions below in handling the power plug.

It could cause fire or electric shock.

- Hold the plug when unplugging.
- Do NOT plug/unplug with wet hands.
- Do NOT overload wall outlets.
- Dust the plug periodically and keep it dust-free to avoid fire or electric shock.
- Keep the area around the power plug clear so that the plug can be pulled out immediately in an emergency.

Before moving, fitting or removing the monitor, turn off the power to the devices connected to the monitor and to the monitor itself, and take the power plug out of the power outlet. Handle the monitor by gripping it firmly with both hands.

Do NOT install the monitor at locations subject to the following conditions.

Failure to observe these cautions can result in fire, electric shock, equipment failure, heat generation, ignition or injuries.

- Poor ventilation, dust, high humidity, exposure to oil smoke or steam
- Instability
- Exposure to direct sunlight, proximity to heat-generating equipment
- Outdoors, in a ship, in a vehicle, etc.
- Strong magnetic fields, or vibration
- Exposure to corrosive gases
- Static electricity

Do NOT display a static image for too long.

It could cause "ghosting," a phenomenon where the previous image displayed on the screen is seen for moments after the image has changed.

CAUTION

Turn on a screensaver or enable the standby mode to avoid "burning in," the burning of an image onto the LCD panel after hours of the same image being displayed.

Do NOT set maximum luminance or closer to it when using the display in a dim room below 100 lx.
It could cause eyestrain. We recommend the factory default. Setting it too low could make it hard to see the image.

Do NOT leave rubber or vinyl products in contact with the LCD monitor for long periods.
This could cause decomposition, or peeling of the coating.

When cleaning the monitor, do NOT use solvents such as thinners, benzene, wax, alcohol or abrasive cleaners.
Never use them on the surface of the LCD panel since they will damage it.

NOTE

- Even when the monitor is handled correctly, it may be affected by the reception of radio and television signals depending on the prevailing radio wave conditions.
  If this happens, observe the following points.
  - Use the monitor at a sufficient distance from radios and televisions.
  - Connect the monitor at a different power outlet than radios and televisions.
- With LCD panels, observe the following points.
  When the panel is used in cold locations the images may leave a trail or may appear dark, but this is not a fault. When the temperature rises it will return to normal. Also, depending on the display conditions, tiny blotches or irregularities may become apparent, but this is not a fault either.
  LCD panels utilize extremely high-definition technology and are manufactured with an effective pixel ratio of 99.999466 % or higher, but pixels that display incorrectly (missing, permanently on, etc.) can occur.
- If you plan to leave the unit unused for an extended period, disconnect the power cord from the wall socket after turning off the power switch for the safety and the power conservation.

Cautions on Cleaning and Disinfection

WARNING

Be sure to turn the equipment power OFF before cleaning and disinfecting the equipment.
Otherwise, a malfunction may occur in the equipment, or the equipment may operate in an unintended way.
Also, thoroughly ventilate the room before turning ON the power after disinfection work is complete.

CAUTION

Be sure to clean and disinfect the equipment periodically.
Cleaning and disinfection is very important to ensure that the equipment can be used hygienically and safely. Strictly follow the methods prescribed.

Be sure to clean the equipment frequently and after each patient use.
While doing so, do NOT directly apply or spray any disinfectant, cleaner, or water onto the equipment. Wipe down all contact surfaces using a cloth moistened, not soaked, with an appropriate disinfectant or cleaner. Make sure the cloth is NOT too wet. If it is, liquid may enter into system electronics, causing failure or malfunction.

Observe the following precautions when cleaning and disinfecting the touch panel:

- Do NOT rub or hit the panel surface because it tends to scar easily.
- Wipe gently with moistened, not soaked, soft cloth to remove the dust from the panel surface.

- English -

CAUTION

Wipe the surface of the equipment with a cloth moistened with rubbing alcohol. (intermediate level disinfectant) If rubbing alcohol gets inside the equipment, it can cause failure or accidents. with the following disinfectants or cleaner.

- Chlorine disinfectants
  Sodium dichloroisocyanurate solution (1 % maximum)
  Sodium hypochlorite solution (1 % maximum)
- Alcohol disinfectants
  Commercially available isopropyl alcohol solution (Up to 99 wt% can be used)
- Rubbing alcohol
  (76.9 - 81.4 vol% Ethanol, Isopropyl alcohol as an additive)
- Glass cleaner (Only onto the touch panel)

Do NOT use the following disinfectants:

If any of the following disinfectants are applied, the equipment performance and safety cannot be guaranteed.

- Disinfectants that corrode metals, plastics, rubber, or paint
- Disinfectants unsuitable for metals, plastics, rubber, or paint
- Spray-gas type disinfectants
- Volatile disinfectants
- Disinfectants that may enter the equipment

Use disinfectants at a minimum.

Repeated disinfection over a long time may lead to discoloring and cracking on the equipment surface, and deterioration of rubber and plastic. If any abnormality is found on the equipment after disinfection, stop using the equipment immediately. Contact your Shimadzu service representative for repair.

Do NOT use an organic solvent.

Organic solvents may change the surface color. If an organic solvent adheres to the surface, wipe it out immediately.

When disinfecting unpainted metals, do NOT use chlorine-based disinfectants.

Chlorine-based disinfectants may corrode the surface of the equipment. If chlorine-based disinfectants adhere to the surface, wipe them off immediately.

When disinfecting resin parts such as acrylic tabletop and reticule of the collimator, do NOT use rubbing alcohol.

Rubbing alcohol may lead to deformation or crack of resin parts such as acrylic tabletop and reticule of the collimator. Wipe it off immediately if it adheres to the resin parts.

When cleaning resin parts such as acrylic tabletop and reticule of the collimator, use cloth lightly moistened, not soaked, with cold or warm water mixed with neutral detergent that does not include organic solvent.

Rubbing alcohol, organic solvents or non-neutral detergents may lead to deformation or crack of resin parts such as acrylic tabletop and reticule of the collimator. Wipe them off immediately if they adhere to the resin parts.

On completing the work, check the following points before switching the power ON again.

- There must be no water or disinfectant adhering to the equipment.
- The tools used in cleaning and disinfecting work must be tidied away.

WARNING

When turning the power ON after cleaning, make sure the examination room is properly ventilated.

Turning the power ON while any flammable gas remains in the examination room could lead to fire, smoke, explosion or electrocution.

Cautions on the System and Software

CAUTION

Observe the following precautions about the system software.

- Do NOT attempt to alter any system software.
  Doing so could disrupt the functioning of the system and result in loss of images.
- Do NOT attempt to alter any system hardware components.
  Doing so could disrupt the functioning of the system and result in loss of images. Use of any hardware components not provided by Shimadzu is strictly prohibited. This includes peripherals (mouse, keyboard, monitor, etc.).
- Pay careful attention to other high frequency-generating equipment in the room.
  The DR-ID 900 console PC cabinet should be as far as possible from any such device to prevent noise from affecting the image video signal.
- Do NOT disconnect the cables connected to this system.
  Otherwise the image may not be displayed, the data may be damaged and the system may not be started up.
- Do NOT move any system component.
  If necessary, move it carefully to avoid damaging.
- Do NOT apply any shocks to the system components.
- Do NOT place anything which may generate magnetic fields near the system components.
- Do NOT alter the system setting.
  Do NOT install any software to the system other than that provided by Shimadzu for this system.
  Otherwise, the system may not be started up.

NOTE

- Before performing an examination, check that the patient information - the patient name and patient ID that are displayed by the system – are correct.
- When a correct definite diagnosis is required, make the diagnosis based not on the images output from this system alone but on the results of multiple examinations.

Open Source Software Used in This Product This product uses software whose copyright is owned and distributed by a third party. These software are provided "AS IS" and without warranty of any kind, including warranties of merchantability or fitness for a particular purpose. Refer to the following URL for licenses of the open source software used in this product.
(Please do not inquire about the contents of the software source code.)

Cautions on Data Loss

CAUTION

The important image data or original data should be archived (backup) in an external file system such as an optical magnet disc or printed on film.

Trouble with, or misoperation of, the system hardware, or unexpected accidents, may cause loss of or damage to the image data or the original data stored on the equipment's magnetic disc.

- Shimadzu accepts no responsibility for loss or damaged image data or original data.
- Shimadzu accepts no responsibility whatsoever for incidental, consequential, or indirect damages (destruction to property, loss of opportunities, tangible and intangible damages such as lost profits, etc.)
  resulting from or arising out of using, not using, or inability to use the equipment.
- External file systems, such as media, could also be damaged. Create multiple backups to avoid data loss.

Cautions on Network Connections

1. This system is connected to a network in order to acquire information (specifically, patient information and information related to examinations) from external devices, and to provide data (specifically, examination images and other data) to external devices.
2. Connect the system to a 1000 Base-T, 100 Base-T, or 10 Base-T network compliant with the IEEE standards.
3. Use a UTP type LAN cable compliant with category 5 (CAT 5e) or higher.
4. If any of the following networks are used, the customer is responsible for implementing security measures in order to prevent malware infection (computer viruses, worms, or other malicious software that damages infected computers).
   (1) Networks without security controls

- English -

(2) Networks accessible to malware
(3) Networks to which the following devices are or could be connected
  (i) Devices for which security is not controlled by the customer
  (ii) Devices that can be used by persons not authorized by the customer
  (iii) Devices capable of wireless communication

5. The following are examples of security measures.
  (1) Do NOT connect to networks without security controls.
  (2) Do NOT connect to the Internet.
  (3) Confirm that external storage media (such as CD and DVD media) is not infected with malware before using any media.
  (4) Do NOT perform any actions that could infect equipment with malware.
  (5) Do NOT connect to networks that include a separate computer that is able to connect to the Internet.

> NOTE
>
> Shimadzu in no way warrants against malware infections or leakage of hospital or patient information due to an Internet connection.

6. Flow of Intended Information
  (1) RIS server
    (i) Flow of patient information and information related to examinations
  (2) Storage server
    (i) Flow of examination images and other data
  (3) Print server
    (i) Flow of examination images and other data, and information for printing
7. Risks When the IT Network Is Down
  (1) RIS server
    (i) Examinations cannot be performed.
    (ii) Examinations cannot be completed.
  (2) Storage server
    (i) Examinations (interpretation of images) cannot be performed.
  (3) Print server
    (i) Hardcopies of examination images cannot be created.
8. Be aware of the following points when connecting to a network.
  (1) The network connection for the system may cause unacceptable, unanticipated risks to patients, operators, or third parties.
  (2) The system administrator must specify, analyse, and evaluate these risks, and specify countermeasures for these risks.
9. If the network connection is changed, new risks may be incurred and additional analysis will also be required. The following matters are included in changes to the network connection.
  (1) Changes to the network structure
  (2) Addition of equipment to the network
  (3) Removal of equipment from the network
  (4) Updates to equipment connected to the network
  (5) Upgrades to equipment connected to the network

> CAUTION
>
> **Shimadzu accepts no responsibility for any of the following items due to infection by malware (i.e. malicious software, including computer viruses and worms, which cause damage to the infected computer):**
>
> - Loss, alteration, and leakage of data, including images, recorded on this equipment
> - Accidents due to the malfunction of this equipment
> - Infection of other equipment via this equipment and any damages incurred due to the infection
> - Other issues including all events caused by malware infection

CAUTION

When using the networks described below, the customer must implement security measures to prevent infection by malware (i.e. malicious software, including computer viruses and worms, which causes damage to the infected computer).

- Networks that lack security management
- Networks that may be subject to malware intrusion
- Networks that are connected to or have the ability to connect to the following devices

  Devices that lack security management by the customer
  Devices that can be used by persons unauthorized by the customer
  Wireless communication devices

Examples of security management are as follows ;

- NOT connecting to networks that lack security management
- NOT connecting to the internet
- Checking whether media (such as CDs, DVDs, and external storage devices) are infected with malware before use.
- Avoiding actions that may result in malware infection
- NOT connecting to the network of another PC connectable to the internet.

Any viral infection or leakage of hospital information or patient information via internet connections is not covered under warranty.

It is strongly recommended that the user identify, analyze, evaluate, and control unacceptable risks resulting from a network connection.

A connection of the equipment to a network might cause unacceptable risks that were not specified in advance for patients, operators or third parties.

Also, changing the network connection will invite new risks, which will also require additional analysis.

Changing the network connection includes the following:

- Changing the network configuration
- Adding on equipment to the network
- Removing equipment from the network
- Updating equipment connected to the network
- Upgrading equipment connected to the network

Cautions Relating to Cellular Telephones

WARNING

Do NOT bring any cellular telephones or related devices into the examination room with their power ON.

Such devices can exceed the EMC standard limitations, and under some conditions this can impair the proper functioning of the equipment. In the worst case, this can cause serious injuries or clinical errors.

Cautions on Electromagnetic Compatibility (EMC)

WARNING

This equipment needs special precautions regarding EMC.

Install and use the equipment according to the EMC information provided in this operation manual.

Make sure that electromagnetic compatibility is obtained.

All peripheral devices must satisfy EMC standards regarding emission of electromagnetic energy and susceptibility to electromagnetic environment.

Devices that do not satisfy these standards may disturb the correct functioning of the equipment. In the worst case, this can cause serious injuries or clinical errors.

Do NOT use this equipment adjacent to, or stacked with, other equipment.

If adjacent or stacked use is necessary, check to be sure that this equipment works properly in the environment.

- English -

WARNING

Do not use accessories, transducers and cables other than those specified or provided by Shimadzu.

The use of accessories, transducers and cables other than those specified or provided by Shimadzu could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RADspeed Pro, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) using TETRA (TErrestrial Trunked RAdio) should not be used no closer than 50 cm to any part of the RADspeed Pro, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) using Bluetooth, Wireless LAN (2.4 GHz), RFID, LTE (Band7) should not be used no closer than 45 cm to any part of the RADspeed Pro, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) using GSM 180, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS should not be used no closer than 45 cm to any part of the RADspeed Pro, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

Cautions on Wireless Communication

WARNING

This system operates in the same frequency band as premises radio stations for identifying mobile devices in factory production lines (license required) and specified low-power radio stations (license not required) in addition to industrial devices (ex. microwave ovens), scientific instruments, and medical devices. Other equipment may interfere with the system even if such equipment complies with CISPR EMISSION requirements.

The use of this system may result in RF interference with the above mentioned equipment and radio stations. Make sure you understand and heed the following cautions when operating the system.

- Before using this system, make sure that no RFID premises radio stations and specified low-power radio stations or similar equipment are used in the immediate area.
- If this system causes damaging RF interference to affect an RFID premises radio station, stop using the system immediately and contact your Shimadzu service representative.
- If this system causes damaging RF interference to affect an RFID specified lowpower radio station or amateur radio station, contact your Shimadzu service representative.
- This system may suffer interference from other equipment that emits radio waves (such as microwave ovens, Bluetooth devices, and digital cordless telephones). Use the system after moving such devices as far away as possible to prevent interference.

Cautions When Irradiating Consecutive Pulse X-Rays

WARNING

Observe the following precautions when irradiating consecutive pulse X-rays:

- Conducting studies involving irradiating consecutive pulse X-rays onto the region where an implantable pacemaker or defibrillator is implanted may cause these devices to malfunction.
- Refer to the "Important General Cautions," "Interactions," or other relevant sections in the accompanying documentation of the implantable pacemaker or defibrillator and take the prescribed measures before irradiating the implanted region of these devices with consecutive pulse X-rays.

Fluoroscopy or radiography performed by irradiating consecutive pulse X-rays (such as serial radiography with a few second intervals, pulsed fluoroscopy, digital angiography, DSA, or cineradiography) can adversely affect the CMOS circuit in implantable pacemakers and defibrillators. Such affects may cause oversensing in these devices that can temporarily inhibit pacing pulse output and result in an inappropriate heart rate.

Performance Information For Medical Device

Refer to https://www.shimadzu.com/med/ other than below.

Product name	Performance indicator	Rated value
X-ray tube assembly 0.2/0.8P38C-85	Nominal X-ray tube Voltage	Max. 125 kV
	Nominal focal spot value	0.2 / 0.8 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.3/0.8P18DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.3 / 0.8 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P13DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 /1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P33DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6/ 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P18DE-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6/ 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P38DE-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6/ 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 1/2P13DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	1 / 2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 1/2P33D-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	1 / 2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 1/2P18DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	1 / 2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 1/2P38D-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	1 / 2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.3/0.8P323DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.3 / 0.8 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P123DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P323DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.8P323DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.8 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.2/0.8P39CK-85	Nominal X-ray tube Voltage	Max. 125 kV
	Nominal focal spot value	0.2 / 0.8 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.3/0.8P324DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.3 / 0.8 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P324DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV

- English -

Product name	Performance indicator	Rated value
X-ray tube assembly 0.6/1.2P164DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P364DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P324DK-125	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.6/1.2P364DK-125	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.8P324DK-85	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.8 mm
	Permanent filtration	1.0 mm Al/75 kV
X-ray tube assembly 0.4/0.7JG326D-265	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.4 / 0.7 mm
	Permanent filtration	1.1 mm Al/75kV
X-ray tube assembly 0.7/1.2JG326D-265	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.7 / 1.2 mm
	Permanent filtration	1.1 mm Al/75kV
X-ray tube assembly 1.2U161CS-31	Nominal X-ray tube Voltage	Max. 125 kV
	Nominal focal spot value	1.2 mm
	Permanent filtration	1.9 mm Al/75kV
X-ray tube assembly 0.7U161CS-36	Nominal X-ray tube Voltage	Max. 125 kV
	Nominal focal spot value	0.7 mm
	Permanent filtration	2.0 mm Al/75kV
X-ray tube assembly 0.7U163CS-36	Nominal X-ray tube Voltage	Max. 125 kV
	Nominal focal spot value	0.7 mm
	Permanent filtration	2.0 mm Al/75kV
X-ray tube assembly 0.7/1.3U163C-36	Nominal X-ray tube Voltage	Max. 133 kV
	Nominal focal spot value	0.7 / 1.3 mm
	Permanent filtration	2.0 mm Al/75kV
X-ray tube assembly 0.6/1J327C-280	Nominal X-ray tube Voltage	Max. 125 kV
	Nominal focal spot value	0.6 / 1 mm
	Permanent filtration	1.5 mm Al/75kV
X-ray tube assembly 0.6/1J317C-282	Nominal X-ray tube Voltage	Max. 125 kV
	Nominal focal spot value	0.6 / 1 mm
	Permanent filtration	1.5 mm Al/75kV
X-ray tube assembly 0.6/1.2P326D-150	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2mm
	Permanent filtration	1.0 mm Al/75kV
X-ray tube assembly 0.6/1.2P366D-150	Nominal X-ray tube Voltage	Max. 150 kV
	Nominal focal spot value	0.6 / 1.2mm
	Permanent filtration	1.0 mm Al/75kV

Revision History

Revision	Date	Descripiton
-	2019-12-11	Newly published
A	2023-04	Product identifications and product performance were added.
B	2025-03-19	Added products to product identifications and product performance. Modifying Regulatory Information.
C	2025-05-26	Modified “Safety, Environmental, and Regulatory Information For Medical Device” - Modified “General” - Added “Digital Angiography System Trinias” - Added “RADspeed Pro”