

## Safety, Environmental, and Regulatory Information For Medical Device

### 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.

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### Indications Used in This Booklet

#### 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.

### Precautions in Usage

When using this equipment, please observe the following precautions for safety of the operator and patient:

#### 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.
- Perform periodic inspection.
- Repair and maintenance of the inside of the equipment can only be performed by engineers assigned by Shimadzu.

#### 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 Shimadzu service personnel or someone who has adequate experience in using the equipment.
- Secure the means for the operator and the patient to communicate with each other.

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

#### WARNING

- Check the condition of the patient before conducting a study.
- Do NOT use the equipment at places where the liquid may enter. Do NOT spill liquids onto the surface or the inside of the equipment.
- When there is any abnormality in operation, or unusual smell or smoke emission during operation, stop operation immediately and contact your Shimadzu service representative.
- Do NOT open the covers of the equipment.
- 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.

**Cautions on Environmental Conditions**

**⚠ WARNING**

Do NOT use the equipment in an oxygen-rich environment.

**⚠ CAUTION**

Be sure to use the equipment under the designated environmental conditions (temperature, humidity, etc.).

**Note also that there must be no sudden change in temperature or humidity.**

**Confirm the power specifications prescribed for each system configuration.**

**Cautions on Radiography**

**⚠ WARNING**

- Restrict all persons other than the patient from accessing the equipment in accordance with local regulations.
- The equipment can be operated only by qualified personnel, such as radiology technicians or those with equivalent qualifications.
- During X-ray irradiation, ensure that the X-rays irradiate the necessary region only.

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

**Cautions on Cleaning and Disinfection**

**⚠ WARNING**

- Be sure to clean and disinfect the equipment.
- Be sure to turn the equipment power OFF before cleaning and disinfecting the equipment.

- Do not perform a cleaning method and the disinfectants use prohibited in an instruction manual.

**Cautions on Emergency Stops**

**⚠ CAUTION**

Press the stop switch to perform an emergency stop.





**Cautions on Electromagnetic Compatibility (EMC)**

**⚠ WARNING**

- Make sure that setting environment and peripheral devices satisfy electromagnetic compatibility (EMC).

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

**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.

## Regulatory Information

For Europe:

The product complies with the following requirements.

Medical Device Directive, RoHS Directive



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## Revision History

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