FUJIFILM

Whole Body X-ray CT System
SCENARIA View

INSTRUCTION MANUAL
System

Special Notes to Operators and Maintenance Managers

- Before using this system, be sure to thoroughly read this manual and make yourself familiar with this system.
- After reading this manual, keep it in an easily accessible place close to the system.

FUJIFILM Healthcare Corporation

Q1ec-FC0298-01

CE 0197

Introduction

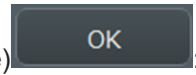
Preface
To our customers
CE Marking
WEEE Marking

Preface

This manual explains how to operate the Whole Body X-ray CT System SCENARIA View. It describes the system configuration, storage, maintenance, and other subjects for using the system safely and correctly.

Conventions used in this manual:

When images of the actual buttons used in screens and dialog boxes are not shown, the names of such buttons are enclosed by square brackets [ ].

(Example) 

: The [OK] button

Symbols used in this manual:

DANGER

Indicates an imminently hazardous situation that, if not avoided, might result in death or serious injury. This symbol also indicates an immediate danger that might result in the total destruction of devices, or in fire.

WARNING

Indicates a potentially hazardous situation that, if not avoided, might result in death or serious injury. This symbol also indicates a potential (latent) danger that might result in the total destruction of devices, or in fire.

CAUTION

Indicates a situation that, if not avoided, might result in light or moderate injury. This symbol also indicates a situation that might result in damage to part of a device or erasure of data stored on the computer.

NOTICE

Indicates a precaution that we strongly urge operators to observe to prevent damage to or deterioration of devices during operation, as well as to ensure that the devices are used efficiently. Alternatively, this symbol indicates a recommended procedure, condition, or action that requires careful attention.

Indicates prohibited conditions or actions. Safety precautions accompanied by this symbol describe conditions or actions that are prohibited.

Indicates required actions that the user must perform.

Indicates supplementary information.

Trademarks and registered trademarks

- CardioConductor, CEV, fatPointer, guideShot, HiMAR, Hyper Q-Net, IntelliEC, Intelli IP, riskPointer, SCENARIA, SCENARIA View are registered trademarks or trademarks authorized by FUJIFILM Healthcare Corporation in Japan and in other countries.
- Other company names and product names used in this manual are the trademarks and registered trademarks of each company.

Cautions on exportation

When exporting this equipment, be sure to check the Foreign Exchange and Foreign Trade Control Law and the regulations related to export control in the United States of America, and perform the necessary procedures.
Contact FUJIFILM Healthcare Corporation or an authorized representative if you have further inquiries.

Revision history

First edition: May 2018 Q1E-HC0298-01
Seventeenth edition: July 2021 Q1ec-FC0298-01

To our customers

Thank you for purchasing the Whole Body X-ray CT System. To use this equipment safely and correctly, and to maintain normal performance for a long period, it is essential to have a full understanding of its functions, operation, and maintenance. Please read this instruction manual thoroughly before using this equipment.

CE Marking

Only for EU countries
The Medical Device as specified below and related options meet the provisions of the EC-Directive 93/42/EEC.

Product Name	Whole Body X-ray CT System
Product Classification	IIb
Model REF	SCENARIA View
Manufacturer 	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan
European Representative EC REP	FUJIFILM Healthcare Deutschland GmbH Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany Phone: +49 6122 7036 0 Fax: +49 6122 7036 10

WEEE Marking

Symbol	Description
	Only for EU countries Do not dispose medical devices together with household waste! In observance of the European Directive on waste electrical and electronic equipment and its implementation in accordance with national law, medical devices that have reached the end of their product life must be collected separately and returned to an environmentally compatible recycling facility. Please contact your local FUJIFILM Healthcare Corporation distributor for information about qualified recycling facility.

Contents

1

Product Overview

1.1 Overview

This equipment is an X-ray CT scanner system that achieves low radiation exposure and high image quality. It uses a scanner gantry with an "Open & Compact" design for patient comfort, and also features functions that are included in high-end equipment, such as the image reconstruction algorithm CORE Plus and the latest noise-reduction technology, Intelli IPV (which is available as an option).

1.2 Features

1. Next-generation iterative approximation processing
   FUJIFILM Healthcare Corporation's "Intelli IPV*" next-generation iterative approximation processing is one of the image reconstruction techniques that reduce the noise in the projection and image space based on a high-precision statistical model by an iterative processing. This is made possible without the need for a dedicated operation room or any additional hardware.
   *: Intelli IPV is available as an option. Intelli IPV is sometimes referred to as IPV. IPV is an acronym for "iterative progressive reconstruction with visual modeling".
2. Substantial reduction of examination times
   The workflow for a CT scan procedure was broken down to more detailed steps to reduce examination times by optimizing the procedure.
   In particular, reduced examination times have been implemented by shortening scenes in which the operator's work load was high.
   The tasks, which required some effort, involved in performing a cardiac CT scan have also been automated. This provides sharp cardiac images through easy-to-perform examinations.
3. Smooth operation and comfortable examinations
   To ease the load on persons who receive examinations periodically and on small children, an examination space was implemented that is both easy on patients and easy to operate.
   A large, spacious (80 cm wide) aperture also affords more flexibility of patient postures during examinations.
   In addition, a patient table lateral slide function allows lateral movement of up to 20 cm, which makes it possible to position the system for use on the cardiac region, but also for use on areas that have undergone surgery, such as the shoulder.

1.3 Purpose

1.3.1 Intended use

This system is intended to use at any part of the whole body to get computed tomography images and those images are used for diagnostic purposes.

1.3.2 Indication for use

The SCENARIA View system is indicated to acquire axial volumes of the whole body including the head. Images can be acquired in axial, helical, or dynamic modes. The SCENARIA View system can also be used for interventional needle guidance.
Volume datasets acquired by a SCENARIA View system can be post-processed in the SCENARIA View system to provide additional information. Post-processing capabilities of the SCENARIA View software include, multi-planar reconstruction (MPR), and volume rendering.
Volume datasets acquired by a SCENARIA View system can be transferred to external devices via a DICOM standard interface.

1.3.3 Indication for use (for USA)

The SCENARIA View system is indicated to acquire axial volumes of the whole body including the head. Images can be acquired in axial, helical, or dynamic modes. The SCENARIA View system can also be used for interventional needle guidance.
Volume datasets acquired by a SCENARIA View system can be post-processed in the SCENARIA View system to provide additional information. Post-processing capabilities of the SCENARIA View software include, multi-planar reconstruction (MPR), and volume rendering.
Volume datasets acquired by a SCENARIA View system can be transferred to external devices via a DICOM standard interface.
The Low Dose CT Lung Cancer Screening Option for the SCENARIA View system is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols that have been approved and published by a governmental body, a professional medical society, and/or FUJIFILM Healthcare Corporation.

1.3.4 Contraindication

None known.

1.4 Environmental conditions

To operate the equipment safely and correctly, observe the following environmental requirements.

Item	CT examination room	Control room
Ambient temperature	Between 20°C and 28°C (When not in use: between -5°C and 33°C)	Between 10°C and 28°C (When not in use: between -5°C and 33°C)
Relative humidity	Between 35% and 80%*1	Between 35% and 80%*1
Average calorific value	4,100 W (3,525 kcal/h)*2	380 W (327 kcal/h)*2

*1:
Rooms must be free of condensation.

*2:

Calorific values are calculated by using the following assumed conditions:
Number of scans: 240 scans/hour
Radiography conditions: 120 kV, 400 mA, 0.5 second × 40 continuous scans

1.5 Power supply and grounding conditions

- Power supply

Item	Value
Main voltage	Three-phase 380/400 V AC
Power frequency	50/60 Hz
Power supply capacity	100 kVA

- Grounding conditions
  Ground the equipment by using a grounding terminal for which grounding work has been performed to achieve a grounding resistance of 10 Ω or less.

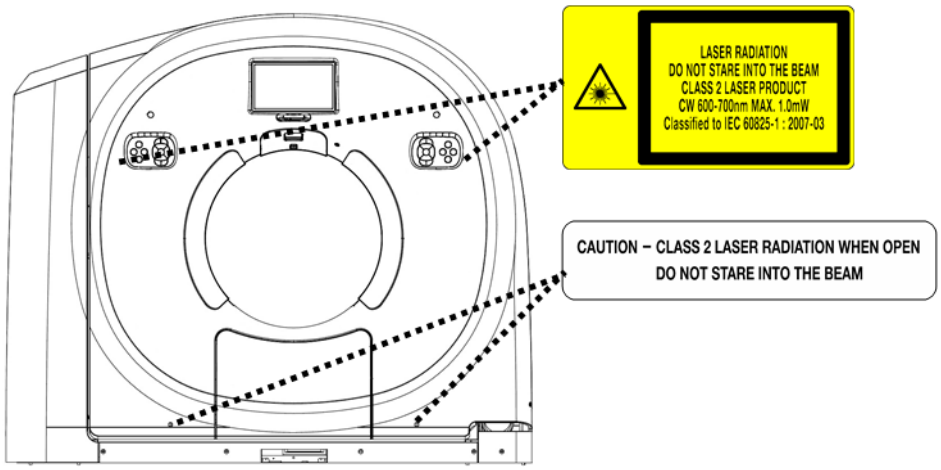
1.6 Service life

The service life of the equipment (as specified by the manufacturer's voluntary standards) is ten years, on the condition that the designated inspections and maintenance have been performed on the equipment. (The life of the equipment varies with conditions of usage, inspection, and maintenance.)

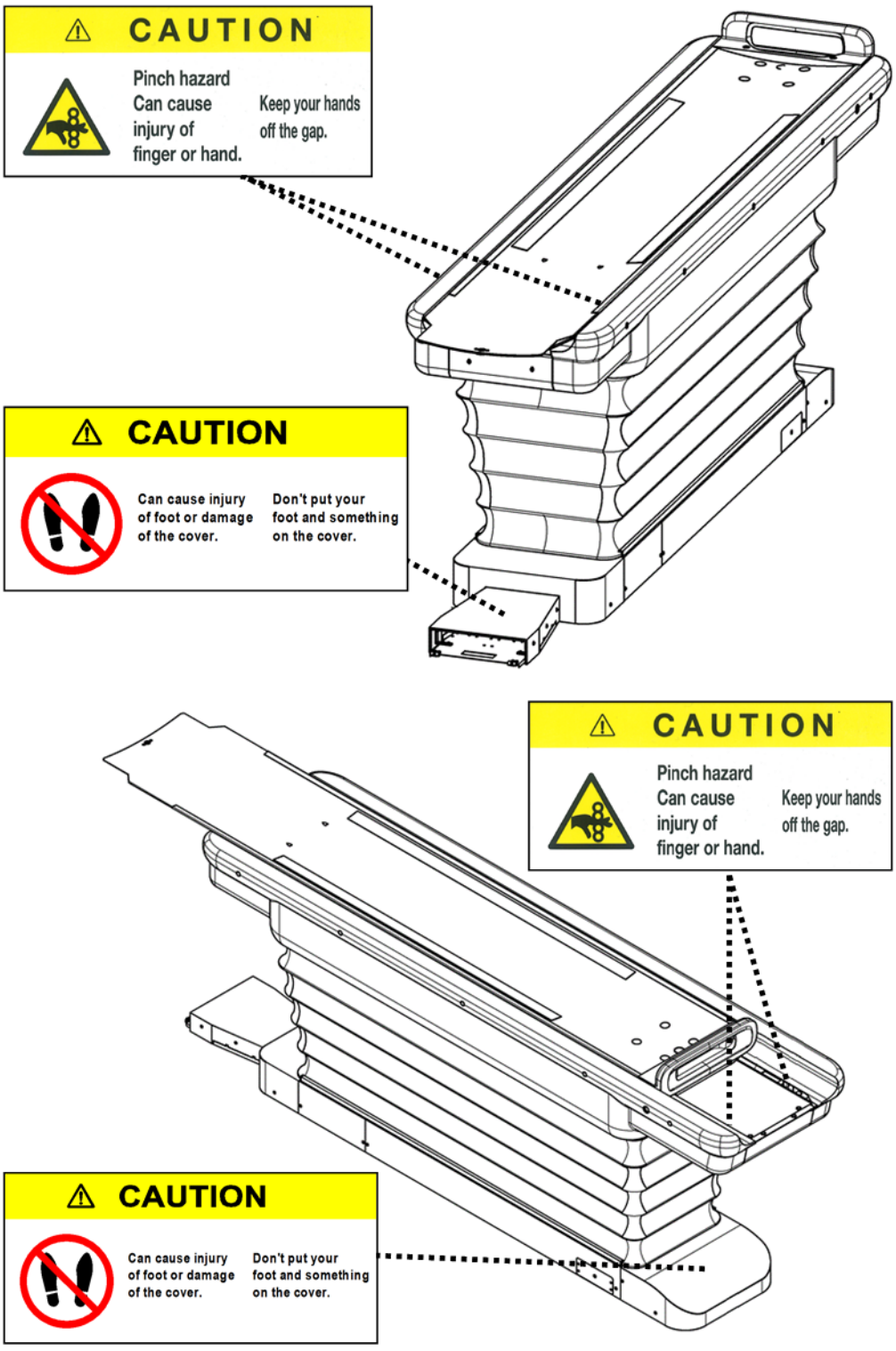
1.7 Label

Labels are attached to the system to ensure it is used correctly. Be sure to read the labels before using the system.

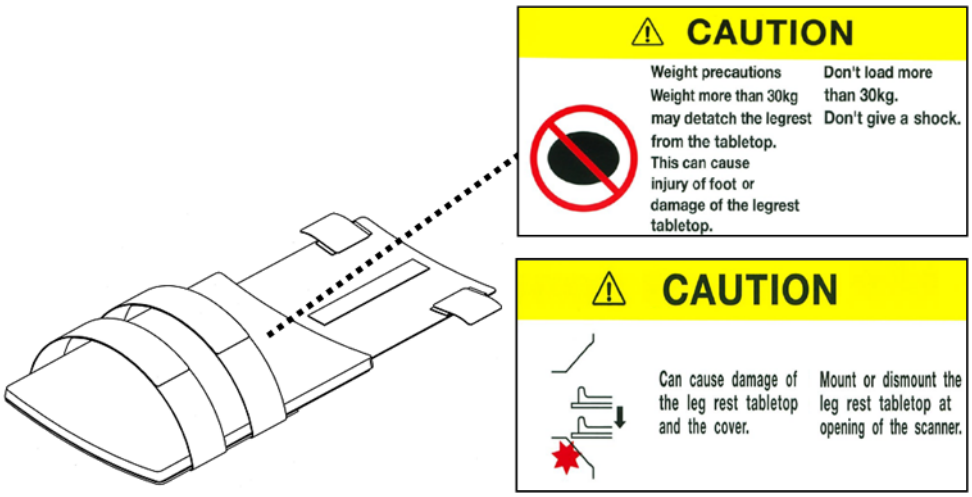
1.7.1 Labels on the scanner gantry



1.7.2 Labels on the patient table and accessories



The following figure shows the legrest tabletop set (optional). The labels are attached to the tabletop and the mat.



1.7.3 Labels on the operator console

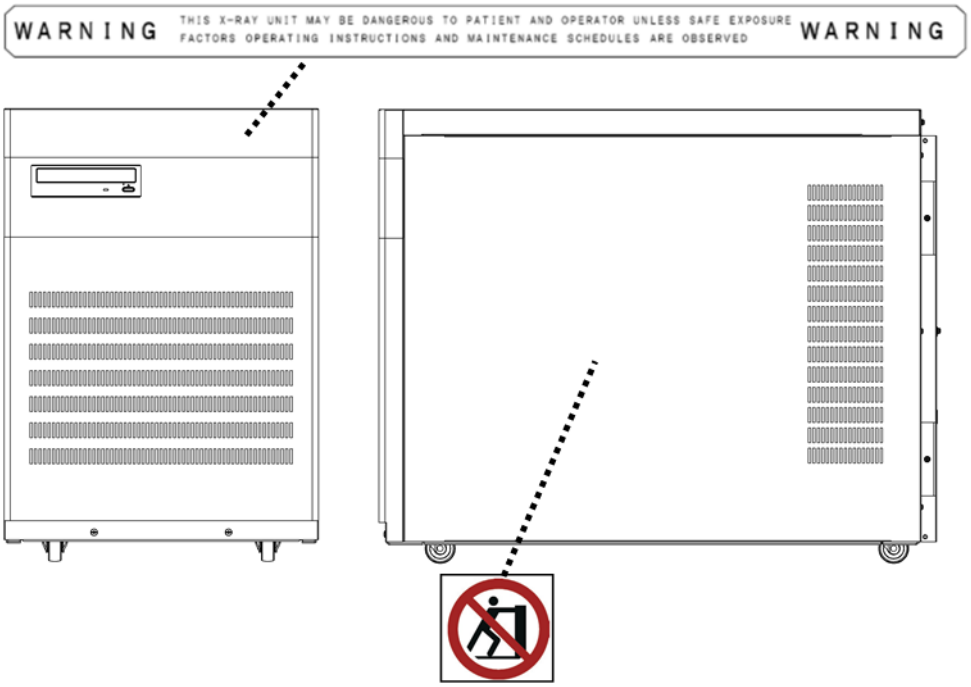


Figure 1-1 Main unit of the operator console


is displayed on both sides of the cover.

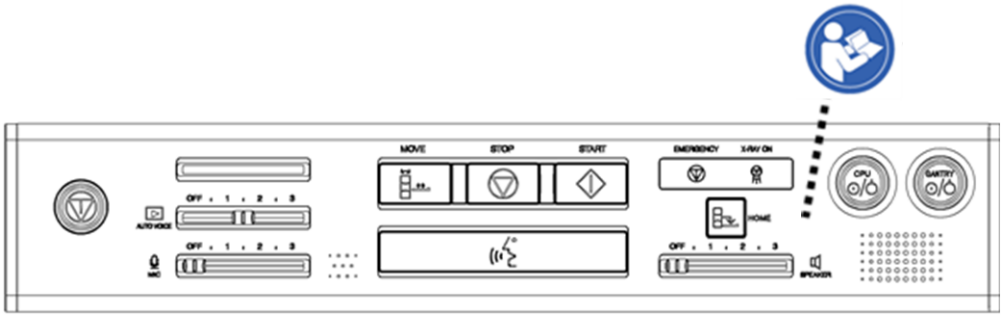
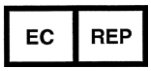


Figure 1-2 Intercom box

1.8 Symbols

The following international symbols are used for the system and Instruction Manual.

Symbol	Definition
	Protective earth; protective ground
	Earth; ground
	ON (Power: Connection to the mains)
	OFF (Power: Disconnection from the mains)
	ON (Power: Partial connection of equipment to power supply)
	OFF (Power: Partial disconnection of equipment from power supply)
~	Alternating current
3 ~	Three-phase alternating current
	Type B applied part
	Caution (or "Attention, consult accompanying documents")
	Refer to instruction manual / booklet
	Hazardous voltage
	X-ray source assembly, emitting
	Ionizing radiation
	Lamp; lighting; illumination
	Warning; Laser beam
	Emergency stop
	Date of manufacture

Symbol	Definition
	Manufacturer
	Authorized representative in the European Community
	Serial number
	Catalogue number
	Pushing prohibited
	Temperature limit (The temperature limits to which the medical device can be safely exposed.)
	Humidity limitation (The range of humidity to which the medical device can be safely exposed.)
	Atmospheric pressure limitation (The range of atmospheric pressure to which the medical device can be safely exposed.)

1.9 Glossary

This section explains the terms used in this instruction manual.
(Definitions marked with an asterisk (*) are excerpts from IEC terminology.)

Type B applied part*

An applied part that complies with the specified requirements of this standard to provide protection against electric shocks, in particular with regard to allowable leakage current

X-ray tube assembly*

An X-ray tube housing that contains an X-ray tube

permanent installation*

A term that refers to a method of establishing an electrical connection to a (commercial) power supply that is permanent and cannot be undone without the use of tools

environmental conditions

Conditions such as atmospheric temperature (room temperature), relative humidity, and atmospheric pressure that are appropriate in order to use the equipment correctly and safely

equipment that operates continuously at intermittent load*

State in which equipment operates continuously via a connection to a (commercial) power supply. The designated allowable load time is short, such that the long-term operating temperature when under load is not reached. However, the interval between

one load and the next is not long enough for the equipment to cool down to the long-term operating temperature when not under load.

patient environment*

A space in which it is possible for contact to occur, either intentionally or unintentionally, between a patient and an ME device or a part of an ME system, or between a patient and an ME device or another person who is in contact with a part of an ME system

X-ray tube voltage*

Potential difference applied between the anode and cathode of the X-ray tube. Normally, X-ray tube voltage is indicated by a peak value expressed in kilovolts (kV).

X-ray tube current*

Current of electron beams that are emitted towards the X-ray tube target. Normally, X-ray tube current is expressed in milliamperes (mA).

Class I*

Electrical equipment that does not rely only on basic insulation to protect against electric shocks, but also for which metal components with which contact is possible or internal metal components are protectively grounded for greater safety

fixed installation*

Equipment to be installed at a specific location, either mechanically or through other means, so that its installation is permanent or cannot be undone without using tools

installation*

Equipment to be installed in a manner in which no change of installation location is intended

electromagnetic compatibility*

In an environment in which devices or systems exist, the act of not generating any kind of electromagnetic interference at an unacceptable level, and the ability for a device or system to function satisfactorily in such an electromagnetic environment. Abbreviated as EMC.

2

Precautions for Operating the Equipment Safely

Although this system was designed and manufactured with careful consideration for reliability and for the safety of the operator and the patient, carefully observe the points described in this chapter to further ensure safety. In addition, read the separate Safety Instruction Manual before reading this manual.

2.1 Classification of the system

Item	Description
Type of protection available against electric shock	Class I equipment
Degrees of protection available against electric shock	Type B applied part (Applied parts are the tabletop and associated patient table accessories.)
Degrees of protection available against entry of water that may damage the system	No protection provided (Protection rating: IPX0)
Degrees of safety when used in an atmosphere containing gas	Equipment unfit for use in environments containing air gas, flammable gas, oxygen, nitrogen monoxide gas, or flammable anesthetic gas.
Operation mode	Equipment for continuous operation with intermittent load
Type of installation	Fixed equipment, Stationary equipment
Connection to power supply	Permanently installed equipment
Type of power supply	External power supply
Protecting patient from influence of discharge from defibrillator	Not provided.
Classification by sterilization method	Sterilization before use is not anticipated for this equipment. This equipment is not sterilized before shipment.

2.2 Cautionary notes on use

2.2.1 Basic precautions

1. The equipment is to be operated only by qualified personnel, such as physicians, dentists, or radiographers.
2. Do not modify the equipment.
3. Ensure that power is supplied continuously to the healthcare facility's distribution board for the CT system.
4. If the power to the CT system distribution board of the hospital facility is turned off, turn it on one hour after the temperature and humidity of the CT examination room and the control room have reached the required levels.
5. If the X-ray tube assembly is used when it is cool, you will not be able to acquire proper images, and the life of the tube will be shortened. Warm up the tube at the start of operations or after X-rays have not been irradiated for a long period of time.
6. Make sure that the equipment is not exposed to water or other fluids.
7. If some parts of the equipment become dirty, such as from being touched by patients or from blood, ensure that the equipment is kept clean and sanitary.

8. Do not use any items other than those included with the equipment or FUJIFILM Healthcare Corporation-specified accessories. FUJIFILM Healthcare Corporation bears no responsibility for any damage that occurs due to the use of other items.
9. The pieces of equipment in the configuration that are used within the patient environment are the patient table and the scanner gantry. To ensure that the patient does not come into contact with any equipment other than the scanner gantry and the patient table, do not allow patients to enter any areas other than the CT examination room.
10. To increase equipment reliability, with the exception of emergencies, turn off the power by using the designated procedure.
11. If you discover an abnormality in the equipment, immediately turn off the power and stop using the equipment, and then contact the service department of FUJIFILM Healthcare Corporation.
12. Before connecting this equipment to equipment from another company, either electrically or mechanically, always contact FUJIFILM Healthcare Corporation or a FUJIFILM Healthcare Corporation-specified agent.
13. Do not use this equipment in a flammable atmosphere.

2.2.2 Handling of patients

1. If there is a chance that any metal objects, such as wristwatches or necklaces, will be included in the scope of radiography, instruct the patient to remove such objects.
2. Pay attention to patients when having them lie on the patient table or get off of the patient table. Assist patients who have difficulty lying down on or getting off of the patient table.
3. When moving the patient table or tilting the scanner gantry, pay attention to ensure that the patient does not come into contact with the equipment and that nothing becomes caught between the patient table and the tabletop.
4. Secure the patient with immobilizing bands to ensure that the patient's arms, legs, and clothing do not protrude from the side of the tabletop or hang off of the tabletop.
5. If the patient is using an IV, pay attention to ensure that the IV line does not catch on anything. In addition, check the length of the IV line before transferring the patient table into the scanner gantry.
6. During radiography, pay attention to the patient, because the condition of the patient might change suddenly or the patient might fall off of the patient table. If you notice anything abnormal, immediately press the emergency button, and ensure that the patient is safe.
7. Do not use this equipment with a patient whose weight exceeds the specified maximum load.

2.2.3 Protection from radiation

1. Take sufficient measures to protect against X-rays.
2. For pediatric radiography, use the radiography conditions (protocol) for pediatrics. Using adult radiography conditions for children results in excessive X-ray radiation.
3. To prevent the need to re-acquire images, sufficiently verify the radiography conditions before pressing the start button.
4. When using this equipment to perform an examination on a patient who is pregnant, might be pregnant, or is nursing, take measures to protect against X-rays in accordance with the physician's instructions to minimize ineffective exposure.
5. During radiography, do not allow anyone other than the patient being examined into the CT examination room (the room in which the scanner gantry is installed). If special circumstances require a caregiver to enter the room with the patient, take sufficient measures to protect the caregiver from X-rays, such as by having the caregiver put on protective clothing.
6. Before warming up the X-ray tube assembly, verify the following:
    - No one is in the CT examination room.
    - Nothing is inside the scanner gantry.
    - The door to the CT examination room is closed.
7. If X-rays are irradiated unintentionally, immediately press the emergency button, and ensure that the patient is safe.
8. The method used to display dose information for this equipment is as described in the following publication:
   ICRP Publication 87 "Managing Patient Dose in Computed Tomography", Annals of the ICRP Vol. 30, No. 4 (2000)
9. Positioning the patient at the center of rotation will ensure a separated distance from the area of the skin being focused on, regardless of the angle of the focal position.

2.2.4 Installation

1. Do not use this equipment in a flammable atmosphere.
2. Install the scanner gantry and the patient table in rooms for which measures have been taken to protect against X-rays.
3. Do not install the equipment in locations
    - with an ambient temperature below -5°C or above 33°C.
    - with a humidity level below 35% or above 80%.
    - with a barometric pressure below 700 hPa or above 1,060 hPa.
    - where the altitude is 3,000 meters or higher.

- where the equipment is exposed to harmful gas.
- where the equipment is exposed to steam.
- where the equipment is exposed to water droplets.
- with excessive dust or sand.
- with excessive oil mist.
- where the equipment is exposed to saline air.
- where there is explosive gas or dust.
- where the equipment is subject to excessive vibration or mechanical shock.
- where the floor is inclined more than 0.1 degrees.
- where the power voltage fluctuates abnormally (with a rate of fluctuation that exceeds 10%).
- where the power voltage suddenly drops when the equipment is under load.
- where the equipment is exposed to direct sunlight.

2.2.5 Electrical safety

1. To prevent accidental electrocution, ground the equipment by performing the specified grounding work.
2. Do not remove covers that are secured with screws. If you remove such covers and come into contact with the inside of the equipment, you might receive an electrical shock.

2.2.6 Mechanical safety

1. Do not remove covers that are secured with screws. If you remove such covers and come into contact with the inside of the equipment, you might be injured by contact with operating parts.
2. Do not place a load on the tabletop of the patient table that exceeds the following maximum load.
   - Maximum load for the patient table: 250 kg
   - Maximum load for the patient table when using the legrest tabletop: 220 kg
3. There is a gap between the patient table cover and the tabletop. When moving the tabletop, there is a risk that someone's hands or fingers might get caught in this gap. Exercise sufficient caution to prevent your own hands or fingers or those of someone else from being caught in the gap.

4. Do not climb onto the cover between the scanner gantry and the patient table, or onto the cover on the back of the patient table. If you do so, you might injure your feet or damage the covers.

5. The maximum load capacity of the legrest tabletop (optional) is 30 kg. Do not apply a load exceeding the maximum load capacity to the legrest tabletop.

6. Before lowering the bed, remove the legrest tabletop (optional).

7. To move a patient off of the scanner gantry in an emergency, press the free float button, and then, while holding the handle on the end of the patient table tabletop or the top or side of the tabletop (mat), move the tabletop towards the back.

During a blackout, when the power is turned off, or when an emergency stop has been performed, you can move the tabletop manually even without pressing the free float button.

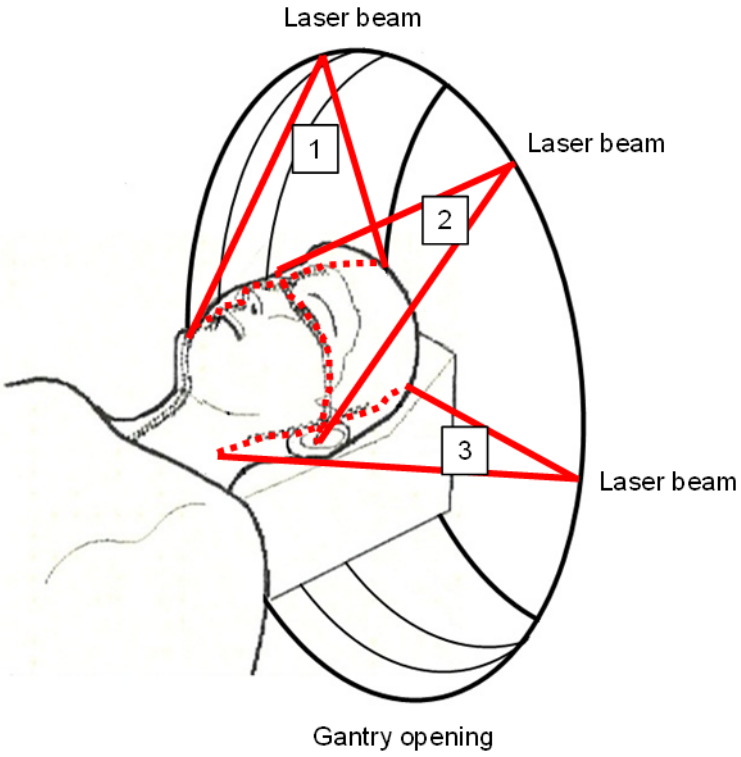
8. If the scanner gantry and patient table move unexpectedly, immediately press the emergency button, and ensure that the patient is safe.

2.2.7 Laser beam safety

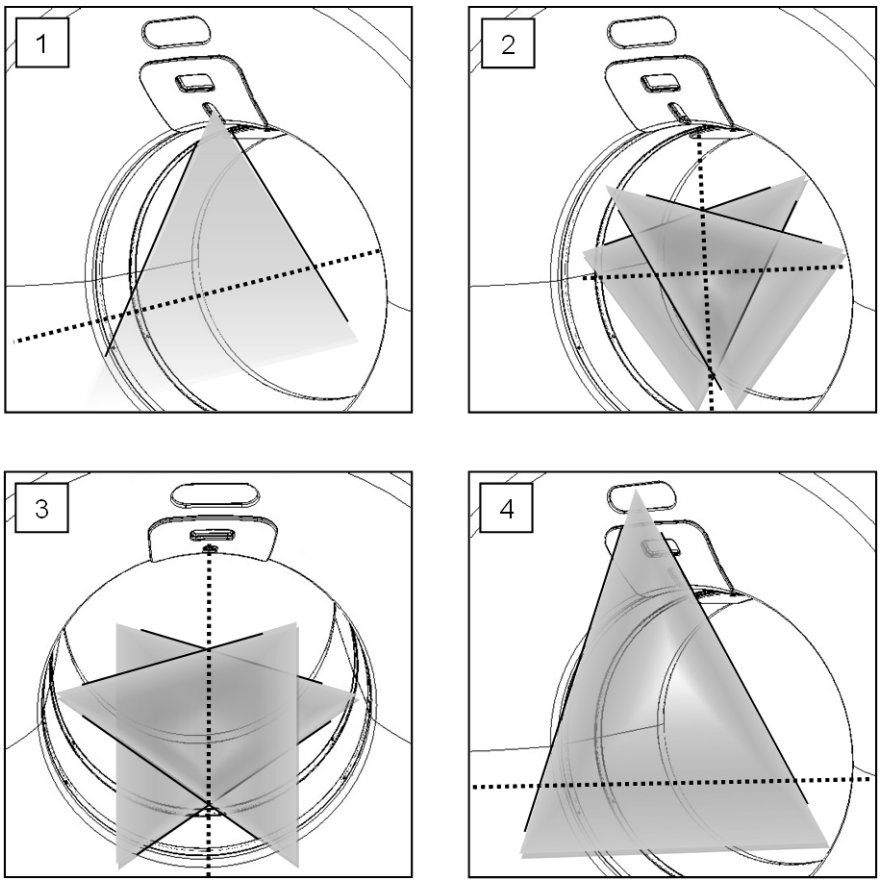
The light localizer uses a laser beam. Avoid looking at the laser light source directly with your eyes. Before lighting the light localizer, instruct patients to close their eyes.
Continuous wave: 600-700 nm
Maximum output: 1 mW
Beam divergence: 1.5 mrad

The light localizer illuminates in three directions, as follows.

1. Sagittal direction
2. Lateral direction
3. Coronal direction



The following illustrates the path of each laser beam.



1. Sagittal direction laser
2. Lateral direction laser (internal)
3. Coronal direction laser
4. External lateral direction laser

2.2.8 Interaction

1. When performing an examination that involves the continuous irradiation of X-rays at the location where an active implantable medical device (such as an implantable cardiac pacemaker or implantable defibrillator) is implanted or at the location where an active attachable medical device is attached, the devices might not operate properly. For examinations in which the irradiation of X-rays at a location where a device is implanted or attached is absolutely necessary, check the instruction manual for the relevant active implantable medical device or active attachable medical device in advance, and take appropriate action according to the information in the safety explanations and the information about interaction with other devices.
2. Do not use devices that generate electromagnetic waves, such as mobile phones, transceivers, mobile wireless devices, or radio-controlled toys, near this equipment. Even if you are only carrying, and not using, such devices, always turn off the power to the devices. The electromagnetic waves generated by such devices might cause this equipment to operate incorrectly or negatively impact images.

2.2.9 Environmental protection

1. The X-ray tube assembly contains lead and oil or coolant. Return any X-ray tube assembly that you remove from the equipment for replacement to FUJIFILM Healthcare Corporation or to a FUJIFILM Healthcare Corporation-specified maintenance agent.
2. Return any parts that you remove from the equipment for repairs or maintenance to FUJIFILM Healthcare Corporation or a FUJIFILM Healthcare Corporation-specified maintenance agent.
3. Infectious pathogens might be present on the equipment due to use. When disposing of this equipment, treat the equipment appropriately to prevent infection, such as by sterilizing and disinfecting the equipment.
4. In Japan, this equipment is subject to the Waste Management and Public Cleansing Act, and customers are responsible for the treatment of industrial waste. If you are unable to perform such treatment, you can entrust such treatment to an industrial waste contractor that has been permitted by the prefectural governor or a similar authority to operate. Outside Japan, dispose of industrial waste in accordance with local laws and regulations.

2.2.10 Precautions regarding electromagnetic compatibility (EMC)

This system is designed to operate in the electromagnetic environment listed in *Table 2-1 Compliance with Electromagnetic Emission Test and Guidance for Electromagnetic Environment* on page 32 to *Table 2-3 Compliance with Electromagnetic Immunity Test and Guidance for Electromagnetic Environment (2)* on page 34 according to the EMC Standard.

1. Special attention needs to be paid to electromagnetic compatibility when using medical equipment. Install and use this system in accordance with the precautions for electromagnetic compatibility (EMC) provided in *2.2.10 Precautions regarding electromagnetic compatibility (EMC)* on page 31. In addition, for the setup and power supply environment, please refer to the description contained in the Site Planning Guide.
2. Prevention of electromagnetic interference
   Do not use this system in a location adjacent to equipment that is a source of electromagnetic inference. If you have to use this system in a location close to such equipment, ensure in advance that the system operates normally in such an environment.
   Sources of electromagnetic interference include medical equipment, communication equipment, and radio and TV antennas. It is not easy to identify the cause of electromagnetic interference. When you attempt to identify the cause of electromagnetic interference, check the following points.
   - Whether the electromagnetic interference is intermittent or continuous.
   - Whether images or system operations are affected by the electromagnetic interference.
   - Whether any types of electronic equipment are being used near this system.

- Whether a communication or broadcasting antenna is located near the facility.

Checking these points will help you to identify whether the system or the operating environment is responsible for the electromagnetic interference. If you cannot identify the cause of electromagnetic interference after checking the points listed above, contact the person in charge at FUJIFILM Healthcare Corporation.

3. Transient noise might intermingle with the images on the LCD of this system due to electromagnetic interference of radio frequency. The doctor in charge must judge whether any noise resulting from electromagnetic interference creates adverse effects on the image quality and the succeeding diagnosis.
4. Use this system in the electromagnetic environment listed in *Table 2-1 Compliance with Electromagnetic Emission Test and Guidance for Electromagnetic Environment* on page 32 to *Table 2-3 Compliance with Electromagnetic Immunity Test and Guidance for Electromagnetic Environment (2)* on page 34.

Table 2-1 Compliance with Electromagnetic Emission Test and Guidance for Electromagnetic Environment

Guidance and manufacturer's declaration - Electromagnetic emission		
This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - Guidance
RF emission CISPR 11	Group 1	This equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	This equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Not applicable	
Voltage fluctuation/flicker emission IEC 61000-3-3	Not applicable	

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 2-2 Compliance with Electromagnetic Immunity Test and Guidance for Electromagnetic Environment (1)

Guidance and manufacturer's declaration - Electromagnetic immunity			
This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Guidance and manufacturer's declaration - Electromagnetic immunity			
This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Electric fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycles	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of this equipment requires continued operation during power mains interruptions, it is recommended that this equipment be powered from an uninterruptible power supply or a battery.
	0% U_T for 1 cycle	Not applicable	
	70% U_T for 25 cycles	Not applicable	
	0% U_T for 250 cycles	0% U_T for 250 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Table 2-3 Compliance with Electromagnetic Immunity Test and Guidance for Electromagnetic Environment (2)

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - Electromagnetic immunity</th></tr>
<tr><td colspan="4">This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V, 6 V in ISM band
150 kHz to 80 MHz
(80% AM at 1 kHz)</td><td>3 V, 6 V in ISM band
150 kHz to 80 MHz
(80% AM at 1 kHz)</td><td rowspan="10">Portable and mobile RF communications equipment should be used no closer to any part of this equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$E = \frac{6}{d}\sqrt{P}$
• 150 kHz to 80 MHz
$d = 2\sqrt{P}$
• 150 kHz to 80 MHz in ISM bands
$d = \sqrt{P}$
• 80 MHz to 2.7 GHz
$d = 2\sqrt{P}$
Where, P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td rowspan="9">Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz
(80% AM at 1 kHz)</td><td>3 V/m
80 MHz to 2.7 GHz
(80% AM at 1 kHz)</td></tr>
<tr><td colspan="2">Proximity fields from RF wireless communications equipment</td></tr>
<tr><td>27 V/m
385 MHz
(Pulse modulation: 18 Hz)</td><td>27 V/m
385 MHz
(Pulse modulation: 18 Hz)</td></tr>
<tr><td>28 V/m
450 MHz
(FM: ±5 kHz, deviation: 1 kHz sine)</td><td>28 V/m
450 MHz
(FM: ±5 kHz, deviation: 1 kHz sine)</td></tr>
<tr><td>9 V/m
710, 745, 780 MHz
(Pulse modulation: 217 Hz)</td><td>9 V/m
710, 745, 780 MHz
(Pulse modulation: 217 Hz)</td></tr>
<tr><td>28 V/m
810, 870, 930 MHz
(Pulse modulation: 18 Hz)</td><td>28 V/m
810, 870, 930 MHz
(Pulse modulation: 18 Hz)</td></tr>
<tr><td>28 V/m
1720, 1845, 1970 MHz
(Pulse modulation: 217 Hz)</td><td>28 V/m
1720, 1845, 1970 MHz
(Pulse modulation: 217 Hz)</td></tr>
<tr><td>28 V/m
2450 MHz
(Pulse modulation: 217 Hz)</td><td>28 V/m
2450 MHz
(Pulse modulation: 217 Hz)</td></tr>
<tr><td>9 V/m
5240, 5500, 5785 MHz
(Pulse modulation: 217 Hz)</td><td>9 V/m
5240, 5500, 5785 MHz
(Pulse modulation: 217 Hz)</td></tr>
</table>

NOTE 1:

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 2:

An exemption has been used and that the equipment has not been tested for radiated RF immunity over the entire frequency range 80 MHz to 6 GHz.

NOTE 3:

WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation.

NOTE a)

Field strengths from fixed transmitters, such as the base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this equipment is used exceeds the applicable RF compliance level above, this equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this equipment.

NOTE b)

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

5. The following table shows the recommended distance between this system and mobile or portable type RF communication equipment.

Table 2-4 Compliance with Electromagnetic Immunity Test and Guidance for Electromagnetic Environment (3)

Recommended separation distances between portable and mobile RF communications equipment and this equipment			
This equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this equipment as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of the transmitter m		
	150 kHz to 80 MHz $d = 2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \sqrt{P}$	80 MHz to 2.7 GHz $d = 2\sqrt{P}$
0.01	0.20	0.10	0.20
0.1	0.63	0.32	0.63
1	2.00	1.00	2.00
10	6.32	3.16	6.32
100	20.00	10.00	20.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

6. Do not use any cables other than those specified by FUJIFILM Healthcare Corporation for the connection cables of this equipment. Using cables other than those specified might result in increased emissions or lower immunity.

Table 2-5 Connection cables

ID	Cable name	Length (m)	Shielding	Number of wire
C1	Gantry Power Cable	20*	Shield	3
C2	Gantry GND Cable	20*	Non shield	1
C6	guideShot Cable	2.3	Non shield	7
C7	Console Power Cable	20	Shield	2
C8	Console GND Cable	20	Non shield	1
C9	Console Signal Cable	20	Shield	26
C10	Console LAN Cable	20	Shield	8
C11	Console Optical Cable	20	--	--
C12	Console LAN Cable	20	Shield	8
C13	DISPLAY Power Cable	1.6	Non shield	3
C14	DISPLAY Signal Cable	1.6	Shield	24
C15	INTERCOM BOX Cable	1.8	Shield	50
C16	Mouse USB Cable	3.3	Shield	4
C17	Keyboard USB Cable	3.0	Shield	4
C18	UPS Power Cable	0.8	Non shield	2
C19	UPS Power Cable	0.8	Non shield	2
C20	UPS Signal Cable	0.8	Shield	2
C21	Stand Microphone Cable	1.8	Non shield	2
C22	Speaker Cable	6.0	Shield	2

*: The standard length of this cable is 15 m. The maximum length of 20 m is available only by special order.

3

Equipment Configuration

3.1 Standard configuration

Component	Quantity
Scanner gantry unit	1
Patient table	1
Operator console	1 set Main unit, monitor, keyboard, intercom box, mouse
Instruction manual	1 set

3.2 Accessories

Accessories	Quantity
External speaker (for the CT examination room)	1
Headrest 1	1
Mat	1
Sliding-type immobilizing bands, head band, chin band	1 set

3.3 Options

3.3.1 Radiography options

1. Items for securing the patient
    - Spacer 1, Spacer 2
    - Armrest HF
    - Headrest 2
    - Chin rest
    - IV pole
    - Head band OP
    - Chin band OP
    - Leg mat
    - Triangular mat
    - Armrest FF
    - Legrest tabletop
    - Wrist band
2. Foot switch
3. Lateral shift patient table

3.3.2 Image processing options

1. ECG Scan
2. Intelli IPV
3. Shuttle Scan
4. Dual Energy Scan
5. MPPS (Modality Performed Procedure Step)
6. MWM (Modality Worklist Management)
7. Remote Service
8. Hyper Q-Net V
9. riskPointer*1
10. fatPointer*1
11. Calcium Scoring*1
12. Cyber Security*2
13. Volume Shuttle Scan*2
14. Exam Split on Hyper Q-Net V*2

NOTICE

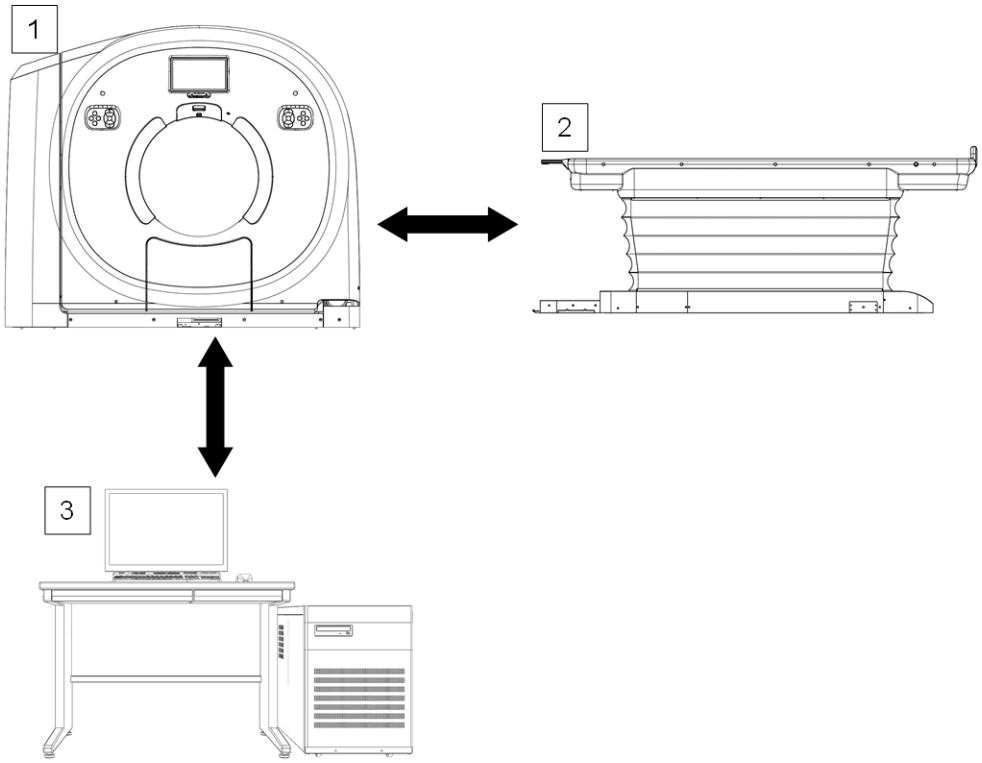
*1: Not released in the USA.
*2: Released only in the USA.

3.3.3 Other options

1. Injector Synchronization
2. QA phantom
3. Water phantom
4. Uninterruptible Power Supply (UPS)
5. Stand microphone
6. guideShot

3.4 System configuration diagram

The following diagram shows the system configuration:



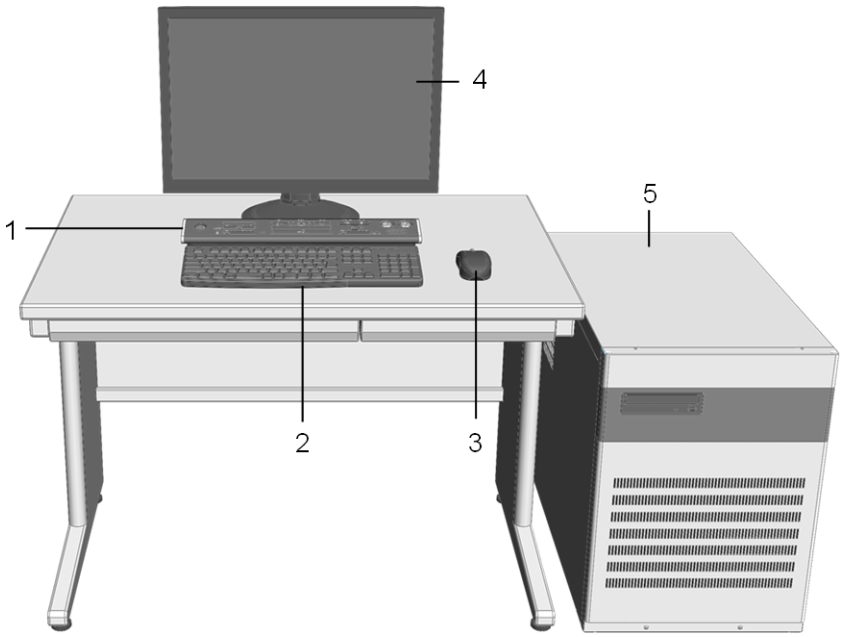
1. Scanner gantry
2. Patient table
3. Operator console (desk not included)

4

Names and Functions of Each Component

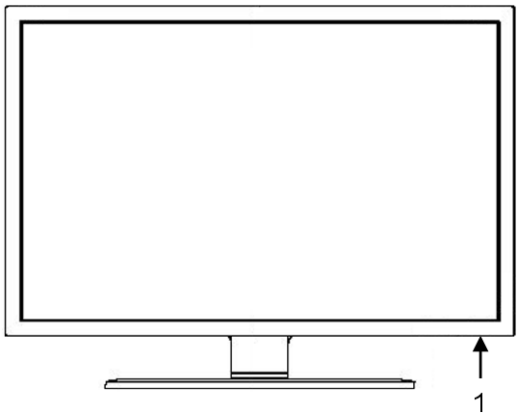
4.1 Operator console

The desk is not included with the operator console.



1. Intercom box
2. Keyboard
3. Mouse
4. Monitor
5. Main unit of the operator console

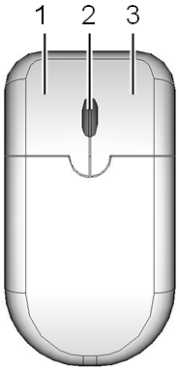
4.1.1 Monitor



1. Monitor power button
   Use this button to turn the power to the monitor on or off.

4.1.2 Keyboard

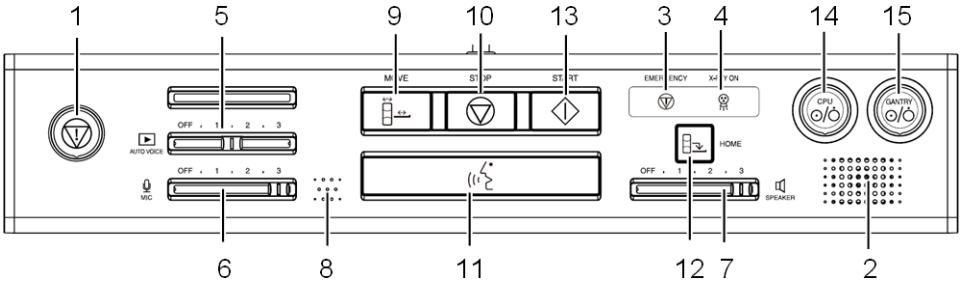
4.1.3 Mouse



1. Left button
2. Wheel
3. Right button

If you use a mouse that has buttons other than above, the other buttons cannot be used.

4.1.4 Intercom box



1. Emergency button
   Press this button to perform an emergency stop. In an emergency situation, the EMERGENCY LED lights up yellow.
2. Speaker
   From this speaker, you can hear someone speaking from the CT examination room.
3. EMERGENCY LED
   In an emergency situation, the EMERGENCY LED lights up yellow.

4. X-RAY LED
   This LED lights up during X-ray irradiation.
5. Voice (AUTO VOICE) volume
   Adjust the AUTO VOICE volume level for the CT examination room.
6. Talk volume
   Adjust the volume of voices picked up by the microphone.
7. SPEAKER volume
   Adjust the volume of sound from the CT examination room.
8. Microphone
   The microphone transmits the voice of someone speaking in the control room to the CT examination room. Sound is transmitted only while the talk button is being held down.
9. MOVE button and MOVE button LED
   Press this button to move the patient table or tilt the scanner gantry.
   When you press the button to move the patient table or tilt the gantry, the MOVE button LED blinks, and during movement, the MOVE button LED lights up.
10. STOP button
    Press this button to stop a scan.
11. TALK button
    Press this button to transmit someone's voice from the control room to the CT examination room. Sound is transmitted from the microphone only while the button is being held down.
12. HOME button
    Press this button to back the patient table into the HOME position. When the tabletop of the patient table reaches the limit for backward movement, press this button again to lower the tabletop. While the HOME button and the START button are pressed, the tabletop of the patient table moves backwards.
    To enable this movement, you must change the settings.
    For details, see the description in "Setting scanning preferences" in the INSTRUCTION MANUAL (Radiography/Image Analysis).
13. START button and START button LED
    Press this button to start a scanogram or a scan. When you press the button to start a scanogram or scan, the START button LED lights up.
14. CPU power button and CPU LED
    Press this button to turn the power of the operator console on. When the power is turned on, the LED lights up.
15. Scanner gantry power button and GANTRY LED
    Press this button to turn the power of the gantry on. When the power is turned on, the LED lights up.

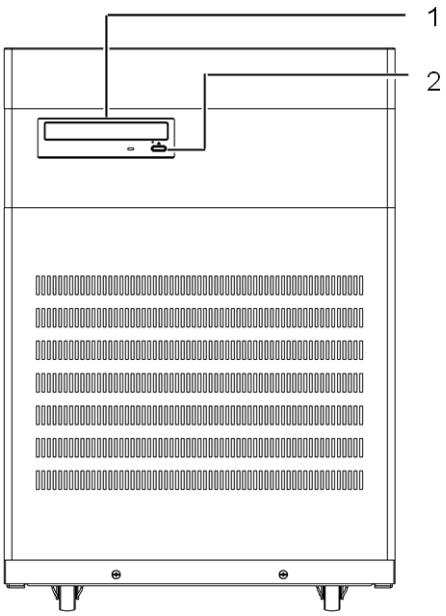
⚠ CAUTION

The monitor, keyboard, and mouse used with the system might differ from those depicted in the figures of these instructions.

NOTICE

Regarding volume levels 5 to 7:
Be careful when sliding to increase the volume at these locations on the console, because doing so might produce feedback.

4.1.5 Main unit of the operator console



1. Media drive unit
   Use this unit to save images, raw data, and user data.
2. Media drive eject button
   Use this button to remove or insert media into the drive.

CAUTION

The drive tray will break if subjected to a physical shock while it is ejected. Do not use the equipment with the drive tray ejected.

CAUTION


Do not push the operator console from a side on which this mark is displayed, because doing so might cause the operator console to tip over.

NOTICE

Compatible media: DVD-R, CD-R
You can record only image data and raw data on these media.
The following table gives reference values for the write speeds for image data and raw data.

Item	Image data			RAW DATA	
Data volume (number of images)	1000	3000	7000	10	28

Item	Image data			RAW DATA	
Write time	About 5 minutes	About 10 minutes	About 20 minutes	About 5 minutes	About 10 minutes

4.2 Scanner gantry

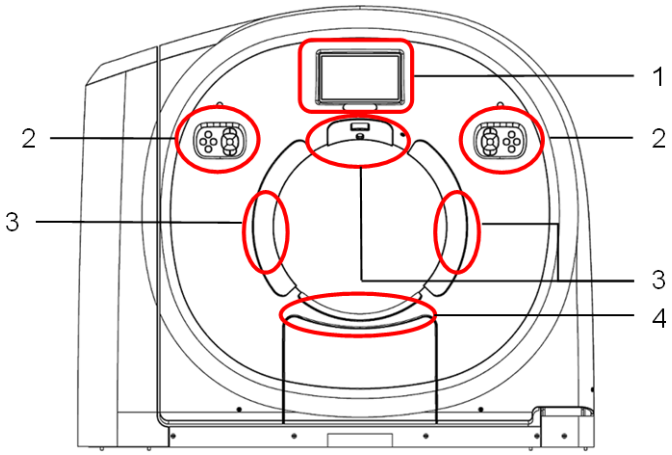


Figure 4-1 Scanner gantry, front

1. Touch Vision
2. Gantry operation panel
3. Touch switch
4. Touch switch for legrest tabletop (optional)

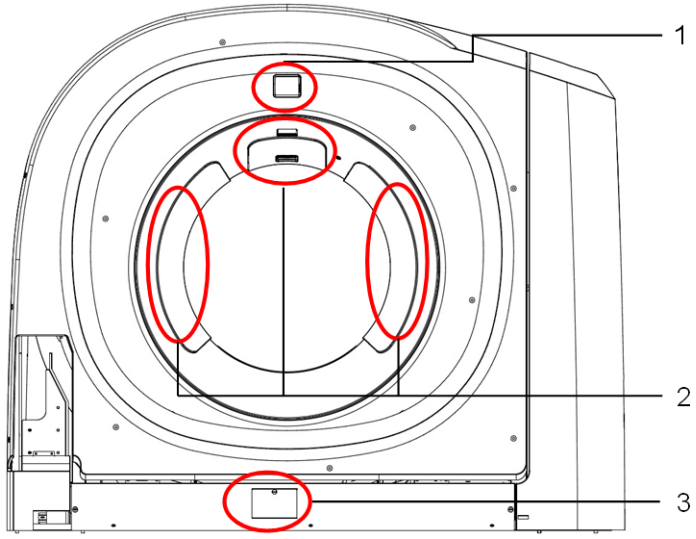
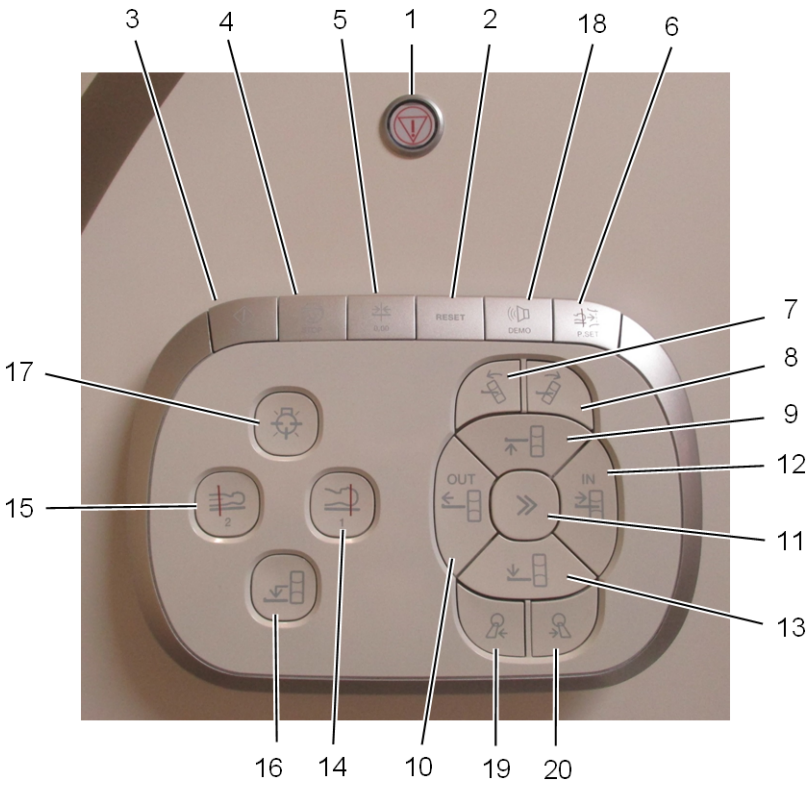


Figure 4-2 Scanner gantry, rear

1. Rear display
2. Touch switch
3. Main breaker operation area

4.2.1 Gantry operation panels

Gantry operation panels are located on both the left and right side of the front of the gantry. The following is an explanation of the switches of the gantry operation panel, using the left side as an example.



1. Emergency button
   Press this button to perform an emergency stop.
2. RESET button
   Press this button to clear the emergency status or touch switch status and allow the patient table and scanner gantry to be inclined.
3. START button
   This button can only be used when it is blinking. In the same way as with the START button on the intercom box, press this button to begin a scan.
4. STOP button
   In the same way as with the STOP button on the intercom box, press this button to stop a scan.
5. 0 clear button
   Press this button to change the position of the tabletop to 0.
6. P.SET button
   Press this button to move the tabletop from the horizontal/up-down light position to the scan position. When moving the tabletop in the forward direction (negative [inward] direction) only, movement will stop automatically when the tabletop reaches -295 mm. To cancel the P.SET function before movement is complete, press the RESET button.
7. Scanner gantry forward tilt button
   Press this button to tilt the scanner gantry in the positive direction.

8. Scanner gantry rear tilt button
   Press this button to tilt the scanner gantry in the negative direction.
9. Patient table up button
   Press this button to raise the patient table.
10. Tabletop backward button
    Press this button to move the tabletop in the positive (outward) direction.
11. If you press this button at the same time that you press the tabletop forward button or tabletop backward button, the tabletop moves quickly. The speed of this movement is 100 mm/s.
    You can change the speed of this setting. The value can be set in the range from 30 to 200 mm/s, selectable at 10 mm/s intervals.
    For details about the settings, contact your service personnel.
    In addition, if you press this button at the same time that you press the patient table up button or the patient table down button, the patient table moves quickly. The speed of this movement is 40 mm/s. After releasing this button, if you immediately press the home button or one of the preset buttons, the patient table might not move. In such cases, release the button, and the patient table will become movable after pressing the button again.
12. Tabletop forward button
    Press this button to move the tabletop in the negative (inward) direction.
13. Patient table down button
    Press this button to lower the patient table.
14. Preset 1 button
    Press this button to move the patient table to the position for scanning the head. Movement will stop when the tabletop is at a height of 100 mm. This height can be set in the range from 5 to 220 mm.
    In addition, if the tabletop is moved forward 630 mm from its most outward position, the light localizer turns on automatically, and at a position of 635 mm, movement will temporarily stop in consideration of safety for the patient's eyes. After movement has stopped, press the button again to restart movement. For this operation, the tabletop moves at a speed of 200 mm/s. Settings, such as the tabletop position, the automatic activation of the light localizer, the temporary stopping of the tabletop, and the tabletop speed, can be changed.
    For details about the settings, contact our service personnel.
15. Preset 2 button
    Press this button to move the patient table to the position for scanning the chest or abdomen. Movement will stop when the tabletop is at a height of 90 mm. This height can be set in the range from 5 to 220 mm.
    In addition, if the tabletop is moved forward 600 mm from its most outward position, the light localizer turns on automatically. For this operation, the tabletop moves at a speed of 200 mm/s. Settings, such as the tabletop position, the tabletop speed, and the automatic activation of the light localizer, can be changed.
    For details about the settings, contact our service personnel.
16. HOME button

Press this button to move the tabletop to the position for raising and lowering the patient. For this operation, the tabletop moves at a speed of 200 mm/s. If the light localizer lights up when you press this button, it will turn off automatically.
The speed of the tabletop can be changed. For details about the settings, contact our service personnel.

17. Light localizer button
    Press this button to set the position of the patient. After you press this button, the light will turn on for about 5 minutes. During this time, the LED on the light localizer button will light up.
    The projection of the light shows the image position for the first image to be displayed. If you press the button while the light is on, the light turns off. At this time, the light localizer button LED will return to a lit state.

    CAUTION

    Do not look directly into the laser beams of the light localizer. Doing so might damage your eyes. To avoid exposing the patient's eyes directly to the laser beams, instruct patients to keep their eyes shut before the beams turn on during OM line setup.

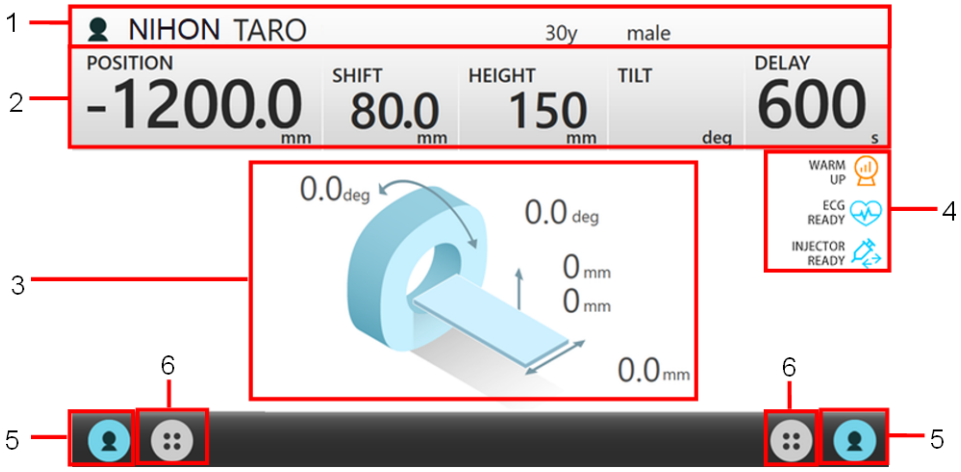
    With the exception of the STOP button, a lit LED on a button indicates that the button is available, and an unlit LED on a button indicates that the button is not available.

18. Breath guide display button
    Press this button before a scan to give a demonstration of the timing at which patients are to breathe in and the timing at which patients are to hold their breath. This demonstration is displayed on the Touch Vision and the breath guide.
    The LED on the Breath guide display button blinks during the demonstration. If you press the button again while the LED is blinking, the display returns to its initial state.
19. Patient table left shift button (only when the optional lateral shift patient table is installed)
    Press this button to shift the patient table to the left relative to the scanner gantry. For this operation, the tabletop moves at a speed of 10 mm/s.
    If you press this button while the patient table is shifting to the right relative to the scanner gantry, the patient table moves in the direction of the center position and stops automatically when it reaches that position.
20. Patient table right shift button (only when the optional lateral shift patient table is installed)
    Press this button to shift the patient table to the right relative to the scanner gantry. For this operation, the tabletop moves at a speed of 10 mm/s.
    If you press this button while the patient table is shifting to the left relative to the scanner gantry, the patient table moves in the direction of the center position and stops automatically when it reaches that position.

4.2.2 Touch Vision

The Touch Vision screen is located on the top of the scanner gantry and is equipped with a touch monitor. If the optional lateral shift patient table is installed, the Touch Vision screen for the lateral shift patient table is also displayed.

(1) Initial window



1. Patient information
   The patient information is displayed.
   When this area is touched, the patient information is hidden.
   When this area is touched again, the patient information is displayed.

2. Scanner gantry information

   - [POSITION]
     The position of the tabletop is displayed.
     In an emergency, this becomes blank.
   - [HEIGHT]
     The height of the tabletop is displayed.
     When the tabletop height is less than 0 mm or in an emergency, this becomes blank.
   - [TILT]
     The angle of inclination of the scanner gantry is displayed.
     When the angle of inclination is 0° or in an emergency, this becomes blank.
   - [DELAY]
     A countdown timer is displayed that counts down the time until the scan starts.
     The time until the scan starts is displayed in seconds.
   - [SHIFT] (only when the optional lateral shift patient table is installed)
     The lateral shift position of the patient table is displayed.
     When the patient table is in the center position or in an emergency, this becomes blank.

3. Scanner gantry operation limit display

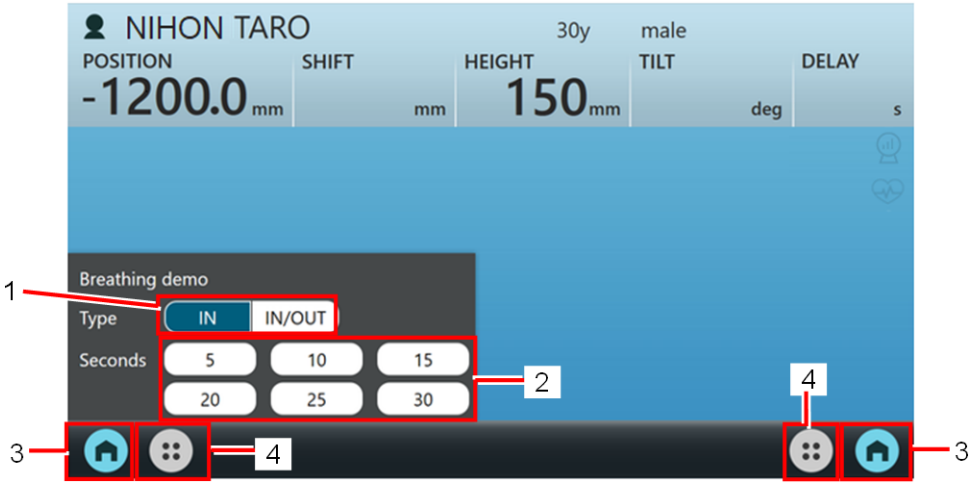
   - [Displayed inclination limit angle of the scanner gantry]
     The inclination limit angle of the scanner gantry is displayed.
     The limit angle changes according to the height of the tabletop.
   - [Displayed limit position of vertical movement of the tabletop]
     The limit position of the vertical movement of the tabletop is displayed.
     The limit position changes according to the inclination angle of the scanner gantry.

- [Displayed shift limit position] (only when the optional lateral shift patient table is installed)
  The limit position of the lateral shift is displayed.
  The limit position changes according to the tabletop position and height, as well as the angle of inclination of the scanner gantry.

4. Displayed icons
   - [Warmup]
     This icon is illuminated when warming up is required.
   - [ECG]
     This icon is illuminated if an electrocardiograph wave form signal is being received.
   - [Injector synchronization] (only when the injector synchronization option is installed)
     Before starting radiography, the READY icon is displayed, and after radiography starts, the START icon is displayed.
     This icon is not displayed on equipment for which the injector option is not installed.
5. Patient information button
   When this button is touched, the patient information window is displayed.
6. Menu button
   The menu dialog box for executing each function is displayed. When the dialog box is displayed, this button becomes a [Close] button. When the button is touched, the menu dialog box closes.
   - [ECG ON/OFF]
     The electrocardiograph waveform display window is displayed.
   - [CardioConductor]
     The breath guide window for the CardioConductor is displayed.
     After the breath guide ends, the CardioConductor window is displayed.
   - [Examination explanation]
     The guidance window is displayed.
   - [For children]
     The window for children is displayed.
   - [Language Settings]
     The language selection window is displayed.

(2) Starting the breath guide window

To start the breath guide window, press the Breathing demo Display button on the gantry operation panel.



1. Selecting the type of instruction for holding the breath

   - [IN]
     The patient practices holding their breath by following the phrases "Take in a breath" and "and hold."
   - [IN/OUT]
     The patient practices holding their breath by following the phrases "Take in a breath," "blow the air out," and "hold."

2. Selecting the length of time for which the patient is to hold their breath
   By touching the buttons for 5, 10, 15, 20, 25, or 30, you can start the breath guide and set a value, in seconds, for how much time passes between the phrases "hold." and "You may breathe."

3. Home button
   This button returns the screen to the initial window.

4. Menu button
   The menu dialog box is displayed. The language settings can be changed.

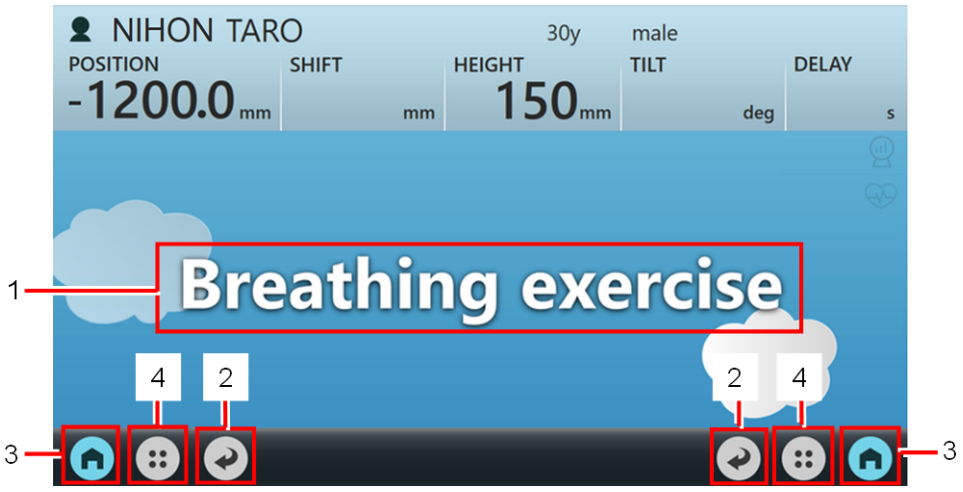


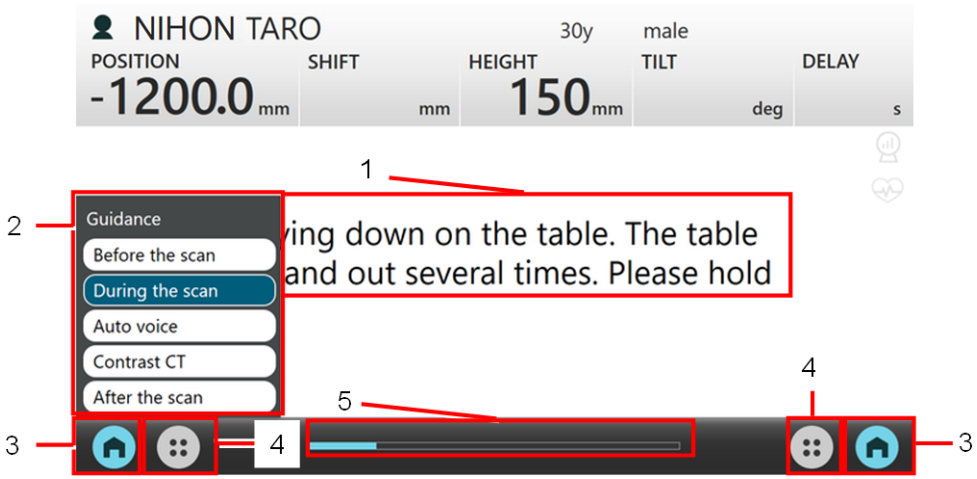
Figure 4-3 Example of the window during execution of the breath guide

1. Phrase display
   The breath guide phrases are displayed.

2. Return button
   This button returns the screen to the previous window.
3. Home button
   This button returns the screen to the initial window.
4. Menu button
   This button is disabled when a phrase is displayed. To change the language settings, touch the Return button to return to the previous window.

(3) Starting the guidance window

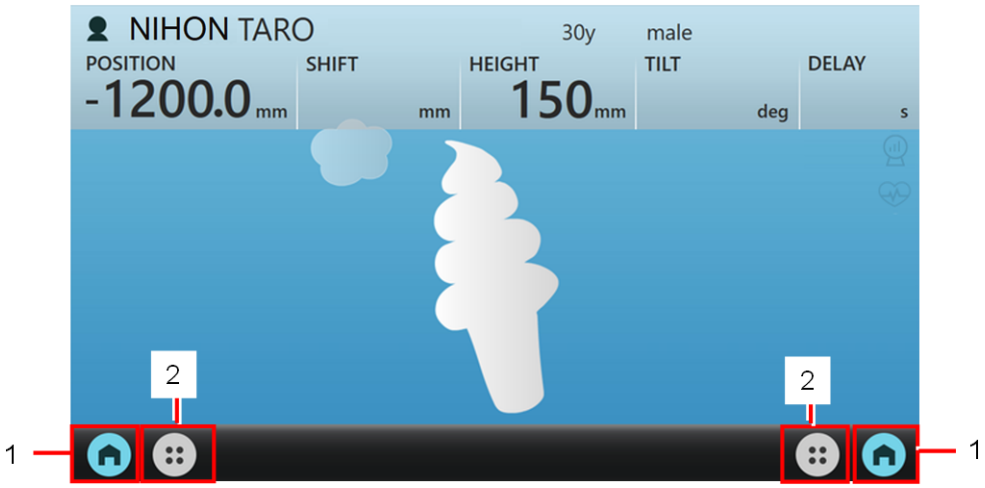
Start the guidance window from the menu dialog box.



1. Guidance display
   The examination instructions are displayed to the patient.
2. Select examination explanation
   If you touch the progress bar, the dialog box is displayed. When the guidance window is started, the guidance explanations from "Before examination" to "After examination ends" are played back automatically. However, you can play back the explanation starting from the content that you select by directly touching the button of the content that you would like explained.
3. Home button
   This button returns the screen to the initial window.
4. Menu button
   The menu dialog box is displayed. The language settings can be changed.
5. Progress bar
   The progress of the process is displayed. If you touch the progress bar, the Select examination explanation dialog box is displayed.

(4) Initializing the window for children

The window for children displays an animation of a cloud shape that changes at a certain interval.



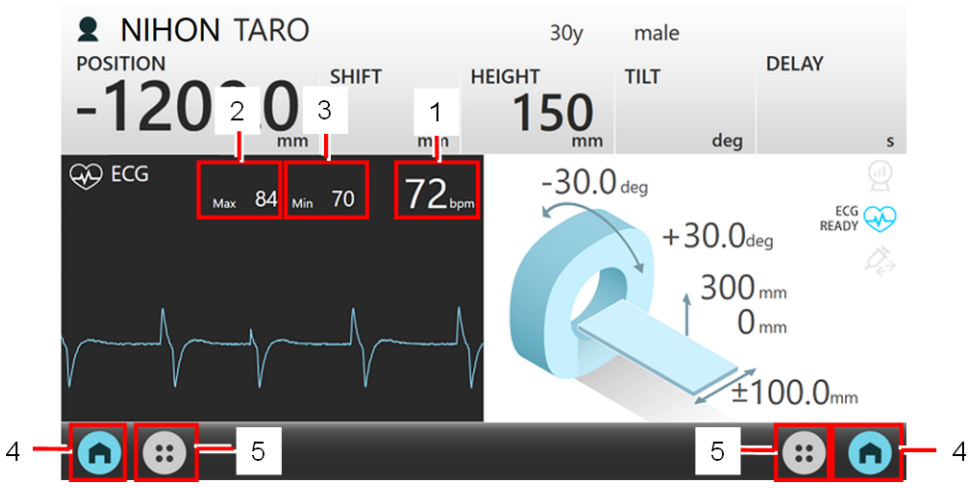
1. Home button
   This button returns the screen to the initial window.
2. Menu button
   The menu dialog box is displayed.

(5) Selecting a language

Start language selection by touching the menu. This allows you to change the language used for the text displayed for the breath guide and the examination explanation. Japanese sign language is also available.

(6) Starting the electrocardiograph display window (only when the ECG scan option is installed)

To start the electrocardiograph waveform display window, touch ECG ON in the menu. An automatic adjustment function for variation is provided on the electrocardiograph waveform display of the Touch Vision screen.

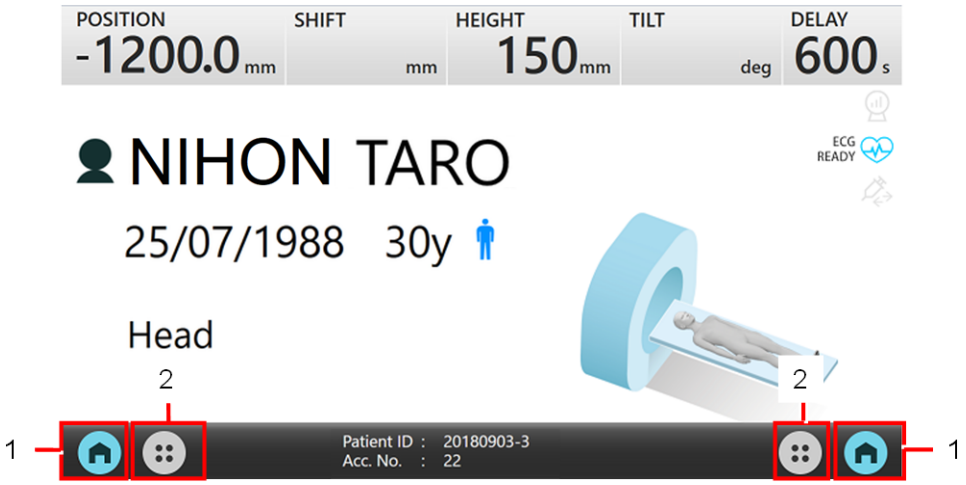


1. Display average pulse rate
   The average pulse rate of the patient is displayed.
2. Display highest pulse rate
   The highest monitored pulse rate of the patient is displayed.

3. Display lowest pulse rate
   The lowest monitored pulse rate of the patient is displayed.
4. Home button
   This button returns the screen to the initial window.
5. Menu button
   The menu dialog box is displayed.

(7) Displaying the patient information window

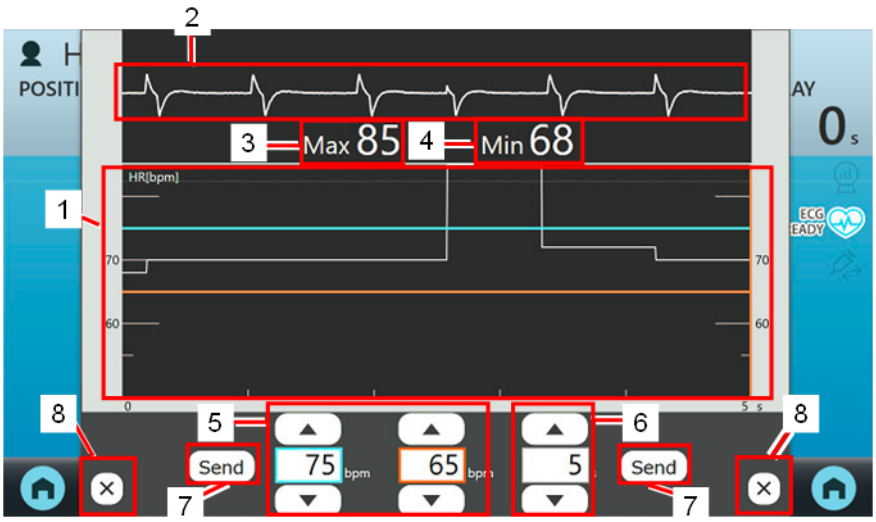
If you register the patient by using the operator console, the patient information is also displayed on the Touch Vision screen.
The patient information can also be erased by using the end radiography button on the operator console.



1. Home button
   This button returns the screen to the initial window.
2. Menu button
   The menu dialog box is displayed.

(8) CardioConductor function (only when the ECG scan option is installed)

To use the CardioConductor function, select the CardioConductor button from the menu. The CardioConductor function will start automatically after the Breath Guide ends.



1. Pulse rate waveform display area
   This displays the pulse rate waveform of the patient measured between the phrases "hold." and "You may breathe." during the operation of the breath guide.

2. Electrocardiograph display area
   This displays the electrocardiograph wave form of the patient measured between the phrases "hold." and "You may breathe." during the operation of the breath guide.

3. Display highest pulse rate
   This displays the highest pulse rate of the patient measured between the phrases "hold." and "You may breathe." during the operation of the breath guide.

4. Display lowest pulse rate
   This displays the lowest pulse rate of the patient measured between the phrases "hold." and "You may breathe." during the operation of the breath guide.

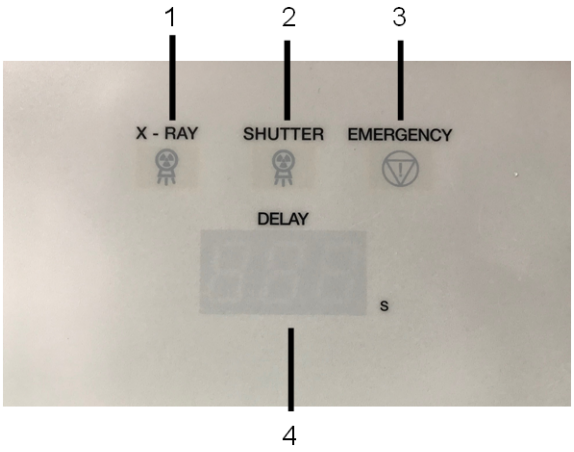
5. Display pulse rate
   This displays the pulse rate (bpm) indicated by a blue line or an orange line in the pulse rate waveform display area.
   You can move lines of the same color by touching inside the frame and then touching the pulse rate waveform display area, or by touching and sliding the lines. In addition, if you touch and slide the line outside of the top or bottom pulse rate waveform display area, you can scroll the area up or down.

6. Elapsed time display
   When the breath guide is in use, this displays the elapsed time (seconds) in 1-second increments starting from when the phrase "hold." is displayed.

7. Send button
   When you touch the Send button, the range of the pulse rate information displayed on the pulse rate display is transmitted to the electrocardiograph information monitor on the operator console.
   To apply this information from the electrocardiograph monitor to the condition settings of prospective scans and retrospective scans, see the "ECG scan option manual".
   Note that the transmittable pulse rate is in the range of 40 to 140 bpm.

8. Close button
   This button returns the screen to the initial window.

4.2.3 Rear display



1. X-RAY LED
   This indicator is illuminated when X-ray irradiation is in progress.
2. Shutter LED
   This indicator is illuminated when a shutter scan is in progress.
3. Emergency LED
   This indicator is illuminated in an emergency.
4. Scan-start countdown timer display
   This displays the time until the start of the scan in seconds.

4.2.4 Touch switches

The touch switches are shown in the circled areas of the following photographs. If a patient or item comes into contact with a touch switch while the tabletop is moving or while the scan gantry is tilting, the movement of the tabletop or tilting of the scan gantry will stop.

(1) Standard touch switches

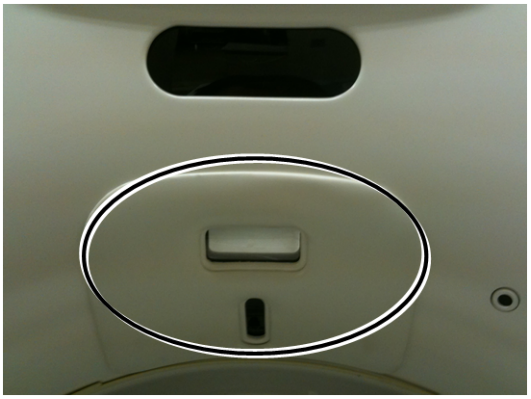


Figure 4-4 Top front of the aperture (standard)

Figure 4-5 Top rear of the aperture (standard)

(2) Touch switches for the lateral shift patient table (optional)

These switches are installed only if the optional lateral shift patient table is installed.

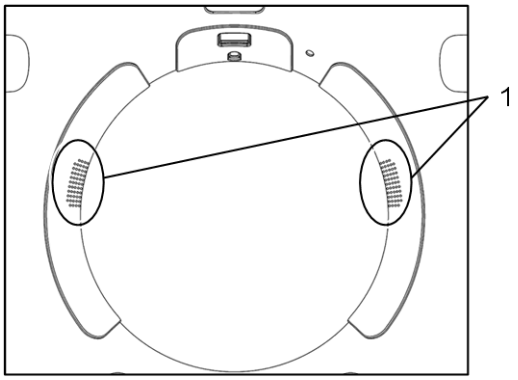


Figure 4-6 Left and right of the front of the aperture

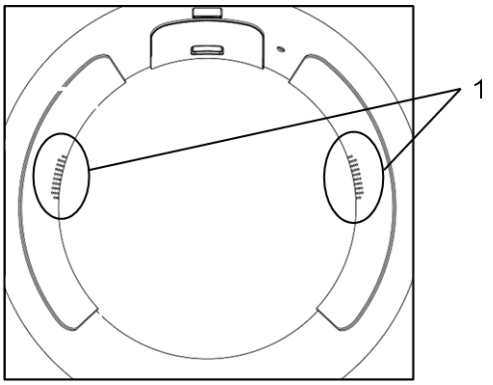


Figure 4-7 Left and right of the rear of the aperture

1. Inactive areas

CAUTION

To facilitate scanning, the marked part of the touch switch is designed not to work while the table is being moved or during a scan.
Secure the patient's arms with the attached arm bands to prevent the patient's arms from coming into contact with a touch switch.

(3) Touch switch for the legrest tabletop (optional)

This touch switch is installed only if you purchase the optional legrest tabletop.
The following figure shows the bottom front part of the aperture.

4.2.5 Breath guide

The breath guide is displayed at the following locations.

1. Top front of the aperture
2. Top rear of the aperture
3. Center of the aperture

The breath guide gives the patient instructions related to their breathing. For example, it tells the patient when to hold their breath and when to breathe.

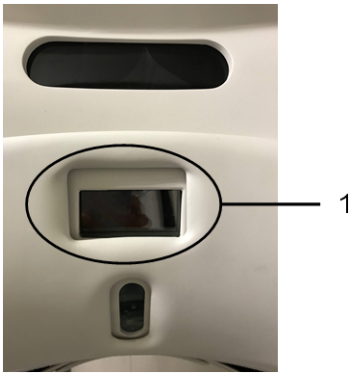


Figure 4-8 Scanner gantry, front

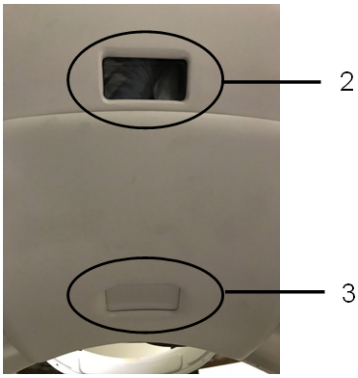


Figure 4-9 Scanner gantry, rear

(1) Auto voice display

The monitor displays screens that are linked to auto voice.
The following figures are some examples of the screens that are displayed:

(2) Radiography preparation screen

This screen indicates that radiography is being prepared.

(3) Screen instructing the patient to breathe (blue)

This screen is displayed to instruct patients to breathe.

(4) Screen instructing the patient to hold their breath (orange)

This screen is displayed to instruct patients to hold their breath.

(5) Auto voice multilingual support

These screens are auto voice displays based on the language selected during patient registration.
The following figures are some examples of the screens that are displayed:

- English

- German

- Korean

(6) Pediatric screen

If [For Child] was displayed on the monitor when the patient was registered, a cloud-shaped animation that changes shape every few seconds is displayed by the pediatric screen feature.

4.3 Explanation of the scanner gantry under various conditions

4.3.1 Explanation of various statuses

(1) When the system is in the emergency status

An emergency status indicator is displayed in Touch Vision and on the rear display, and only the RESET buttons on the gantry operation panels blink. All other buttons are unlit.

(2) When a standard-installation touch switch is activated

The RESET button, the patient table down button, and the scanner gantry rear tilt button (alternatively, the forward tilt button) blink, and the other buttons are unlit. However, if you are unable to lower the patient table, the patient table down button is also unlit, and if you

are unable to tilt the scanner gantry backwards or forwards, the scanner gantry rear tilt button (or forward tilt button) are also unlit. In addition, an indicator that the touch switch has been activated is displayed in Touch Vision.
Pressing the RESET button forcibly clears the touch switch status.
If you touch one of the other blinking buttons while the patient is not in contact with one of the touch switches, the touch switch status is cleared.

(3) When the tabletop is in the overrun status

An overrun status indicator is displayed in Touch Vision. The buttons for moving the tabletop forward or backward blink. When the tabletop returns to a position within the range of allowable movement, the indicator stops blinking.

(4) When the tabletop is in the free float status

A free float status indicator is displayed in Touch Vision. No changes occur on the gantry operation panels.

(5) When the patient table is moved after scan preparation is complete

The tabletop forward button, the tabletop backward button, the patient table left shift button, or the patient table right shift button blinks. You can move the patient table in the same way as when you press the MOVE button on the intercom box.

(6) When the scanner gantry is tilted after scan preparation is complete

The scanner gantry rear tilt button or the scanner gantry forward tilt button blinks. You can move the patient table in the same way as when you press the MOVE button on the intercom box.

(7) When scan preparation is complete

The START button blinks. You can perform operations in the same way as when pressing the START button on the intercom box.

(8) During a scan

All of the LEDs on the gantry operation panels are unlit. During X-ray irradiation, an (orange colored) icon indicating that X-ray irradiation is in progress is displayed in Touch Vision.

(9) During a shutter scan

All of the LEDs on the gantry operation panels are unlit. During a shutter scan, the (orange colored) icon indicating that X-ray irradiation is in progress, and the (green colored) shutter scan icon are displayed in Touch Vision.

4.3.2 Buzzer specifications

The buzzer sounds a set number of times in the following cases.

(1) Buzzer: 1 time

Status	Description
During P.SET operation	When the tabletop of the patient table moves forward 295.0 mm from the P.SET movement start position and stops
During Preset 1 operation	When the tabletop of the patient table moves forward to the set position and stops
When the Scanner Gantry Forward Tilt button or the Scanner Gantry Backward Tilt button on the scanner gantry operation panel is pressed during scanner gantry tilt movement	When the scanner gantry stops at 0 degrees
When the scanner operation panel START button is flashing	When the START button is pressed

CAUTION

The buzzer will not sound when the P.SET operation is terminated. However, the buzzer will sound twice when the deceleration limit switch is detected during operation.

(2) Buzzer: 2 times

Status	Description
When the tabletop of the patient table is moving forward	When the tabletop of the patient table stops at the forward stop limit position
When the tabletop of the patient table is moving backward	When the tabletop of the patient table stops at the backward stop limit position
When the patient table is being raised	When the patient table stops at a height of 220 mm
When the patient table is being lowered	When the patient table stops at the lower stop limit
When the scanner gantry is moving forward	When the scanner gantry stops at the forward stop limit (+30.0 degrees)
When the scanner gantry is moving backward	When the scanner gantry stops at the backward stop limit (-30.0 degrees)
When the scanner operation panel disable button is pressed	When a button that cannot be operated (an LED button, other than the START or STOP buttons, that is not illuminated) is pressed

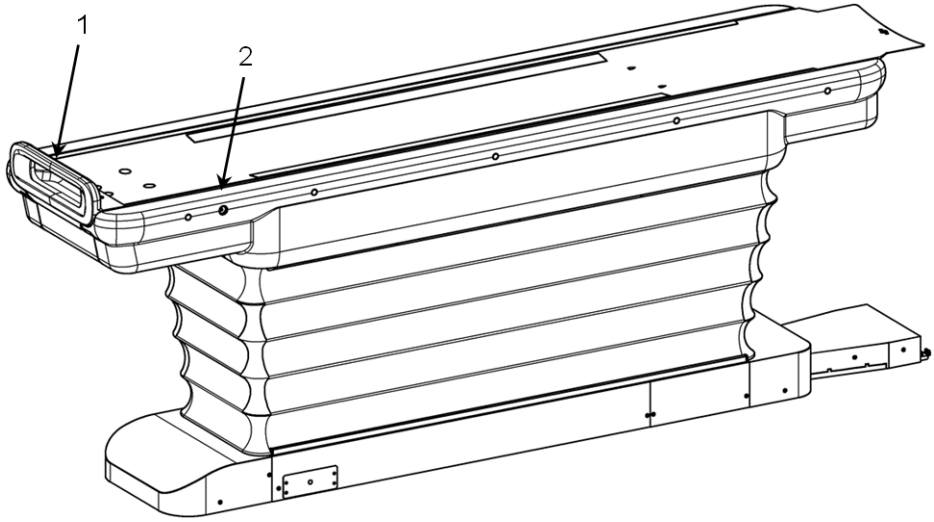
CAUTION

The buzzer does not sound at the tabletop backward limit position during Home operation. The buzzer sounds at the patient table lower limit position.

(3) Buzzer: 3 times

Status	Description
When the patient table is moving vertically or the scanner gantry is being tilted	When the interlock has stopped the patient table vertical movement or the gantry tilt operation
When the patient table is moving vertically, the tabletop is moving forward or backward, or the gantry is being tilted	When an error has caused the patient table vertical movement, tabletop forward or backward movement, or the gantry tilting to stop
When the emergency button has been pressed	When the system enters the emergency state
When a patient table tabletop overrun occurs	When a patient table tabletop overrun is detected

4.4 Patient table



1. Handle
2. Free float button

4.4.1 Free float buttons

The free float buttons are located on the left and right sides of the patient table. If you want to retract the tabletop manually or manually set the tabletop to a particular position, you can press one of the free float buttons to manually move the tabletop. (This is called the free float function.)
To move the tabletop manually, move the table while holding the handle on the outer edge of the tabletop or while holding on to the top of the tabletop (the mat).
After moving the tabletop to the desired position, press the free float button again.

CAUTION

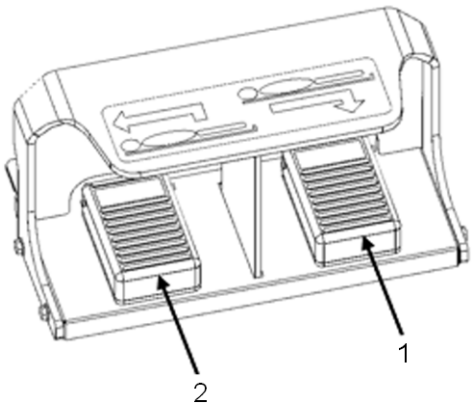
If you (the operator) hold a part of the tabletop other than those mentioned above during the free float operation, you could accidentally pinch your hand between the tabletop and table cover. During the free float operation, take care to ensure that the immobilizing band, the patient's hands and arms, and your hands and arms are not pinched between the tabletop and table cover. Such pinching could result in injury to yourself or to the patient, or damage to the system.

CAUTION

If you do not press the free float button again after moving the patient table by using the free float button, operations to move the tabletop forward and backward cannot be performed via the operation panel or the operator console, and scanning cannot start. The free float status can be checked on the Touch Vision screen.

You can manually move the tabletop without pressing the free float button when there is a power outage, when the power is off, or when the system has been stopped by the emergency stop function.

4.4.2 Foot switches (optional)



1. Home foot switch
   Step on this foot switch to move the table to the patient change position. (This foot switch has the same function as the Home button on the scanner gantry operation panel.)
2. Preset foot switch
   Step on this foot switch to move the tabletop to the set height and send the tabletop to the desired position. (This foot switch has the same function as the Preset 1 and Preset 2 buttons on the scanner gantry operation panel.)

When the Preset foot switch is depressed, the equipment operates as follows.

Operation	Function
The Preset foot switch is depressed after the Preset 1 button on the scanner gantry operation panel is pressed and released.	Preset 1 function

Operation	Function
The Preset foot switch is depressed after the Preset 2 button on the scanner gantry operation panel is pressed and released.	Preset 2 function
The Preset foot switch is depressed when neither the Preset 1 button nor the Preset 2 button on the scanner gantry operation panel has been pressed since the last time the power was turned on.	Preset 1 function*

*: The settings can be changed so that the Preset 2 function is used in this case. For details about the settings, contact our service personnel.

CAUTION

The appearance of foot switch may differ depending on the shipping time or the country.

5

Operation Procedures

5.1 Inspections before and after operation

NOTICE

Always perform inspections when beginning and ending operations to verify that there are no abnormalities in the equipment.
For the items that are included in these inspections, see *8.1.1 Inspection before starting daily work* on page 104 and *8.1.2 Inspection after daily work* on page 104.

5.2 Safety check

This equipment displays indicators to notify the operator of such issues as the usage status of the X-ray tube assembly or abnormal behavior of the control circuitry. If one of these indicators comes on, check the indicator details and then take the appropriate measures.

1. Error display
2. X-ray tube assembly HU display

Cautionary notes regarding the handling of this equipment are displayed on the relevant parts. Make sure you follow such notes when operating this equipment.

5.2.1 Operator precautions

Operators should pay careful attention to the safety and monitoring of patients undergoing scanning as well as the operation of the equipment.

1. Operators should be sufficiently protected against X-rays.
2. Operators should pay careful attention that neither their limbs nor the limbs of patients become caught between moving parts and surrounding items.
3. Operators should offer suitable assistance to patients getting on and off of the patient table. Moreover, in order to prevent the patient from touching the switches of the scanner gantry, operators should make sure that the patient gets on the patient table from a position near the center of the patient table. Furthermore, operators should also take sufficient measures for the safety of patients, such as taking steps to ensure that a patient does not fall from the patient table before, during, or after scanning.
4. Operators should never place more than the following maximum load onto the patient table or the tabletop.
   Patient table maximum load: 250 kg
   When the leg rest tabletop (optional) is used: 220 kg
5. Operators should make sure that there will be no contact between the peripheral equipment and the patient before moving the patient table in a vertical, forward and backward, or horizontal direction, or tilting the scanner gantry.

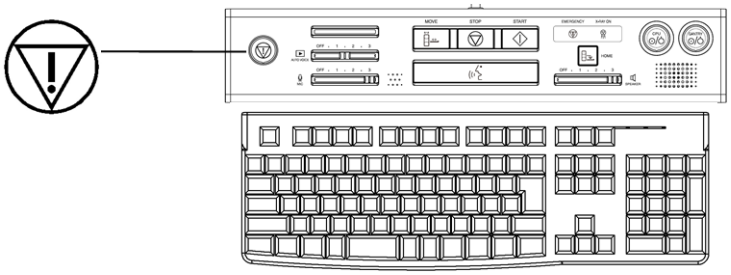
5.2.2 Emergency stop

Press the emergency button to bring the CT system to a complete and immediate stop. Doing so stops the operation of the scanner gantry, patient table, and X-ray emission system.

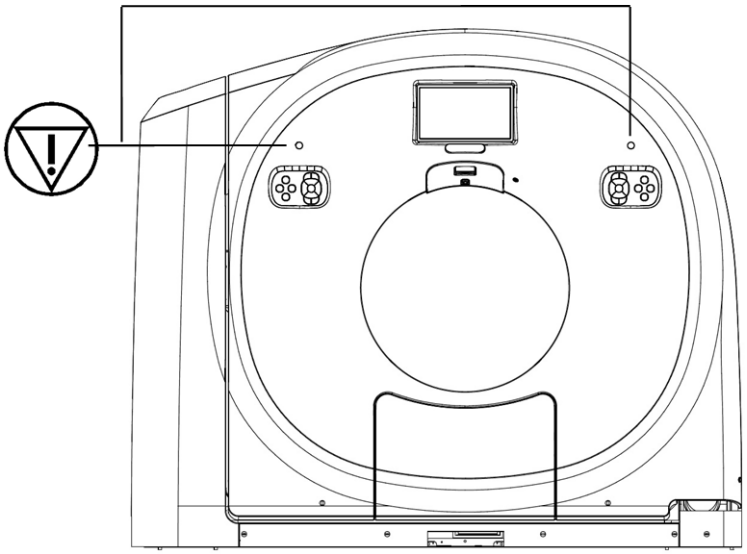
(1) Emergency stop procedure

Press either of the following emergency buttons.

- Emergency button on the intercom box

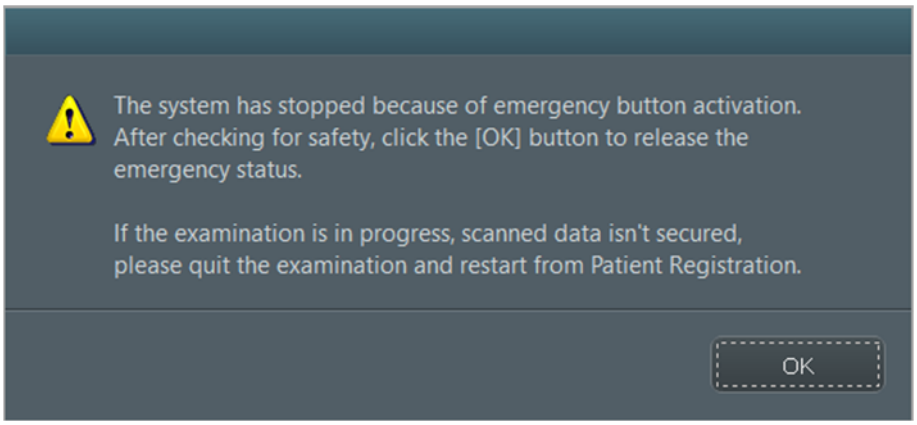


- Emergency button on the gantry operation panel



(2) Reset procedure

The emergency reset screen is displayed.



Click the [OK] button. The emergency stop status is reset after about 20 seconds.
If you press the RESET button on the gantry operation panel, you can move the tabletop even during the emergency stop status.

CAUTION

Confirm that there are no abnormalities before resetting the equipment after an emergency stop.

CAUTION

If the time between an emergency stop and its release is too short, the equipment might not reset correctly and an S28 error might occur. The equipment will reset correctly if you allow the emergency stop to continue for 10 seconds or longer before resetting.

5.2.3 Automatic emergency stopping of X-ray emissions

If X-ray emissions during scanning exceed the specified time (scan time +10%), X-ray emissions are stopped automatically.
The backup timer error release screen is displayed.
Click the [OK] button. The emergency stop is reset approximately 20 seconds later.

5.2.4 Prevention of pressure on the patient

To prevent pressure from being exerted on the patient, touch switches are installed on the front and rear of the scanner gantry aperture. If any of these switches are pressed while the scanner gantry is tilting, while the patient table is being raised, or while the patient table is moving to the left, to the right, forward, or backward, the operation stops and the touch switch release screen appears. If one of the switches is touched when none of these operations is being performed, nothing happens. Once a touch switch is activated, the system enters the emergency stop status. Perform either of the following operations to deactivate the emergency stop status:

- Press the RESET button on the gantry operation panel.
- Click the [OK] button on the touch switch release screen.

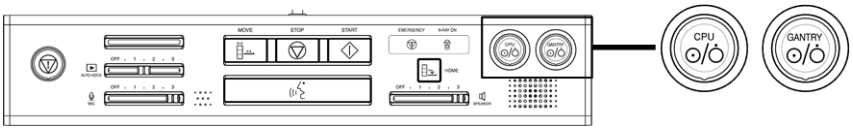
CAUTION

If the time between an operation stop caused by a touch switch and its release is too short, the equipment might not reset correctly and an S28 error might occur. The equipment will reset correctly if you allow the operation stop to continue for 10 seconds or longer before resetting.

5.3 Turning the power on and off

5.3.1 Turning the power on

1. On the intercom box, first press the CPU power button, and then press the scanner gantry power button.
   The power turns on. When this happens, the LEDs on the CPU button and the GANTRY button light up.



5.3.2 Turning the power off

1. Make sure no processes are in progress.

   CAUTION

   If the scanner gantry is being rotated, wait until the scanner gantry stops rotating and then perform the shutdown operation.

2. Click the power button on the home screen, or select [Shut Down] in the menu.
   A message for selecting the shutdown mode is displayed.
3. Click the [Shut Down] button.

   If you click the [Restart Application] button, the application will restart.

4. The power will shut off automatically. When the power shuts off, the LEDs on the CPU and GANTRY buttons for turning on the system also turn off.

   CAUTION

   Do not press the CPU button on the intercom box while the system is shutting down. Doing so could cause the equipment to malfunction.
   In addition, to protect the device, the power cannot be turned on again for 10 seconds after the equipment is shut down. Wait at least 10 seconds before turning the power on again.

5.3.3 Turning the power on or off by using the CT system distribution board of the hospital facility

If you use the distribution board of the CT system to turn the power off and then on again within a short period of time, communication errors or abnormal images might result. When turning the power off and on by using the distribution board, leave an interval of at least 10 seconds from the time that you turn the power off to the time that you turn it on again.
In addition, if power is lost momentarily (the power turns off and then on again momentarily) because of a lightning strike or other reason, the status of the system might become unstable, which might result in communication errors or abnormal images. In such cases, first turn off the power to the equipment, and then turn off the power supplied to the entire CT system from the distribution board of the CT system. After turning off the power to the distribution board off, wait at least 10 seconds, and then turn on the power to the distribution board and to the equipment again.

5.3.4 Turning the power to the scanner gantry and the patient table on or off

You can turn on or off the power to only the scanner gantry and the patient table by pushing the scanner gantry power button on the intercom box for one second or longer.
When power is supplied, the gantry LED lamp lights up.

⚠ CAUTION

If the scanner gantry is being rotated, wait until the scanner gantry stops rotating and then turn off the power to the scanner gantry.

5.4 Components of patient harnesses

5.4.1 Standard items for securing the patient

1. Headrest 1
2. Mat
3. Sliding-type immobilizing bands
4. Head band
5. Chin band

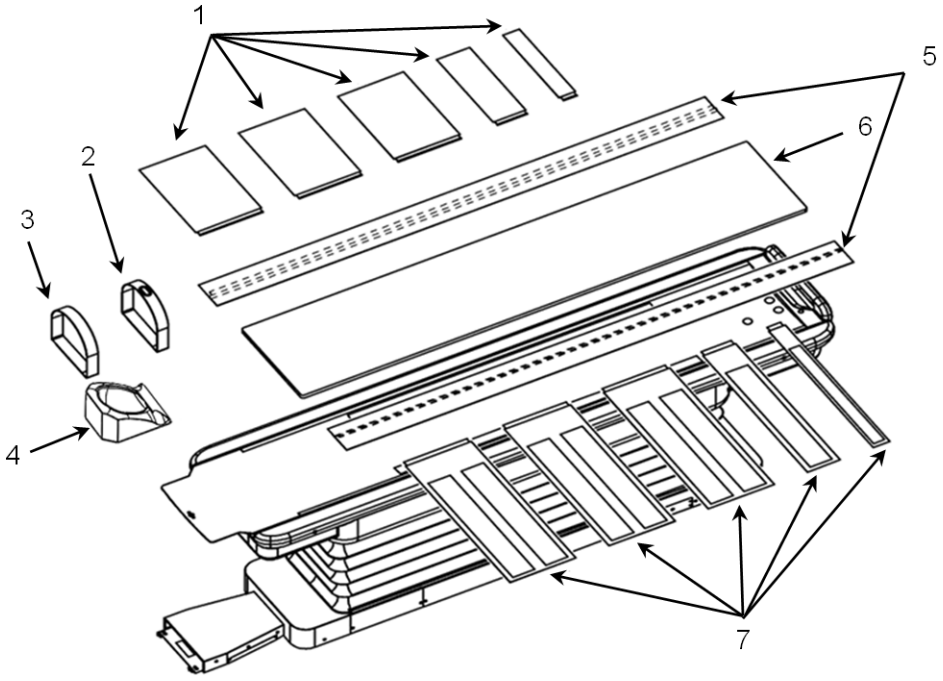
5.4.2 Optional items for securing the patient

1. Spacer 1, Spacer 2
2. Armrest HF
3. Headrest 2
4. Chin rest
5. Head band OP

6. Chin band OP
7. Leg mat
8. Triangular mat
9. Armrest FF
10. Legrest tabletop
11. IV pole
12. Wrist band

5.5 Using patient harnesses

The patient table includes the following accessories for securing the patient in position (patient harnesses). Their usage is described below.



1. Immobilizing bands A (300 [three], 150, 75)
2. Chin band
3. Head band
4. Headrest 1
5. Rails
6. Mat
7. Immobilizing bands B (300 [three], 150, 75)

⚠ CAUTION

- Do NOT use any equipment other than the accessories that are included with the equipment.
- Do NOT use or install the patient harnesses included with the equipment or the optional patient harnesses in any ways other than those described in this manual.
- Do not use the harnesses included with the equipment or the optional patient harnesses for any other purposes.
- Depending on the physical condition of the patient, use Headrest 1, the head band, the chin band, the immobilizing bands (a total of five pairs are included), and the rails to secure the patient's body at each location.

⚠ CAUTION

Clean any accessory that becomes soiled by blood or other bodily fluids.

- Detergent
  Use neutral or weak alkaline detergent and rubbing alcohol. Do not use solvents such as thinner or benzene. (Solvents will damage the surfaces of parts.)
- Cleaning method
  Dampen a soft cloth with detergent, wipe, and then wipe away residual detergent by using a cloth dampened with water.

⚠ CAUTION

Precautions regarding the optional lateral shift patient table

Although scanograms and several types of scans are possible with the table shifted to a horizontal position, touch sensors have been incorporated in the system for safety, in order to prevent a patient from being caught between the scanner gantry and the arm rest.

If a scan is performed while the table is shifted to a horizontal position, the patient might touch the sensors that are designed to prevent the patient's arms and elbows from being caught in the equipment, and the scan might stop. Therefore, please raise the patient's arms as much as possible when securing them, as shown in the figures below.

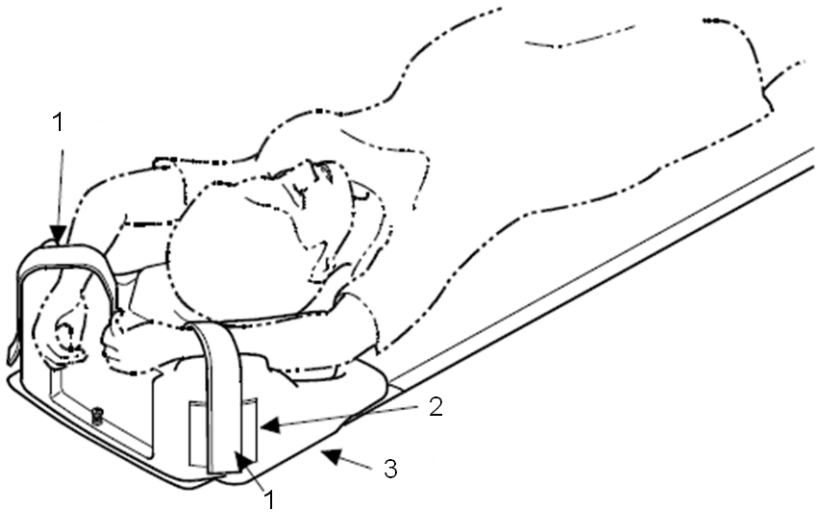


Figure 5-1 When performing head-first (HF) scanning (The armrest is optional.)

1. Arm band
2. Velcro (male)
3. Armrest HF

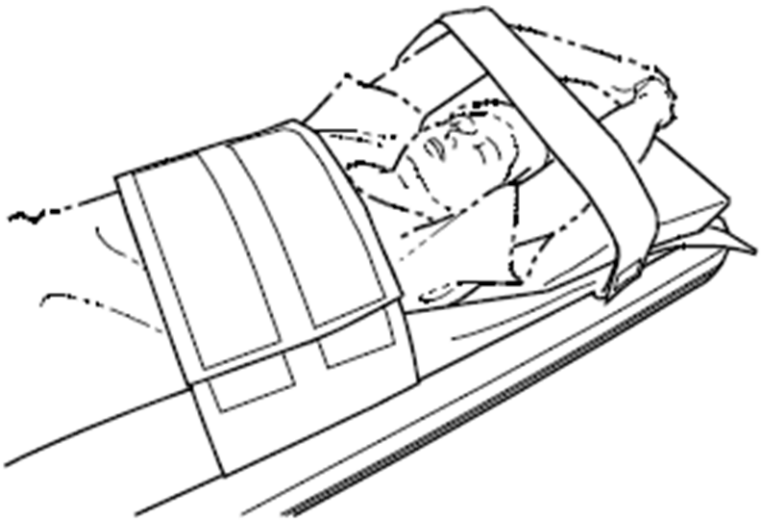
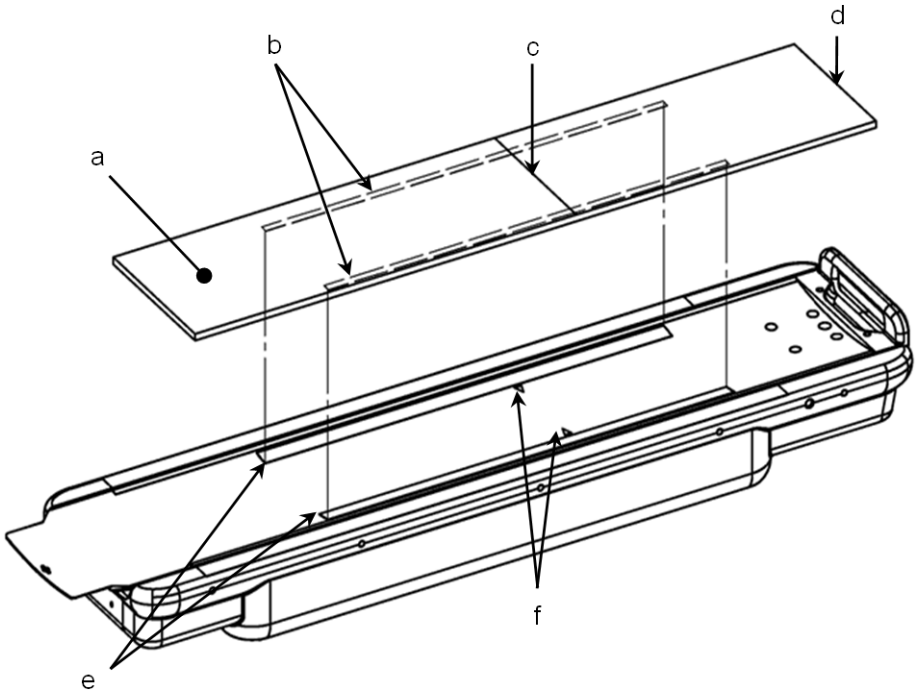


Figure 5-2 When performing feet-first (FF) scanning (The armrest is optional.)

5.5.1 Mat

1. Place the mat on top of the tabletop, and secure the mat by aligning the Velcro on the top of the tabletop with the Velcro on the bottom of the mat.



a. Mat

b. Velcro (bottom surface of the mat)

c. Blue line

d. Blue point

e. Velcro (top surface of the tabletop)

f. Mark

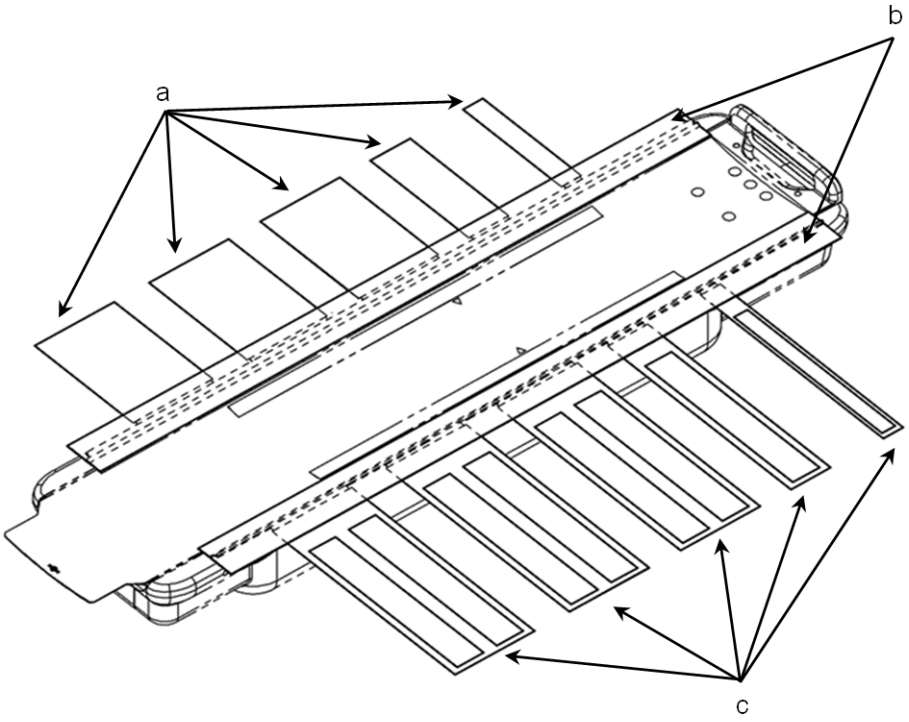
CAUTION

- Set the mat in the center of the tabletop, and then cover the gap between the side covers and the tabletop.
- Align the blue line on the mat with the mark on the top of the tabletop.
- Place the mat so that the blue point on the mat is facing the back of the patient table.

5.5.2 Sliding-type immobilizing bands

Immobilizing bands A and B come in three widths: 300 mm, 150 mm, and 75 mm. Three sets of 300 mm bands and one set each of 150 mm bands and 75 mm bands are included with this equipment.
These bands are used to prevent the patient from falling from the tabletop during an examination.

1. At the ends of the tabletop rails on both the left and right sides, insert the end parts of immobilizing bands A and B onto the rails.
   Set the immobilizing bands so that the Velcro (male) on immobilizing bands A is on the side opposite the patient, and the Velcro (female) on immobilizing bands B is on the patient side.



a. Immobilizing bands A (300 [three], 150, 75)

b. Rails

c. Immobilizing bands B (300 [three], 150, 75)

CAUTION

Note the direction that the immobilizing bands are facing. Set the immobilizing bands so that the Velcro (male) on immobilizing bands A is on the side opposite the patient, and the Velcro (female) on immobilizing bands B is on the patient side.

2. Move the immobilizing bands to the desired positions on the rails.
3. Set the immobilizing bands on the body part of the patient that needs to be immobilized.
4. Together with the rail flaps, wrap the immobilizing band around the patient, and then secure the patient by using the Velcro on immobilizing bands A and B.

CAUTION

- Be sure to firmly secure the patient, making sure that the patient's hands or clothes do not protrude from the sides of the tabletop or hang over the tabletop.
- If you move the tabletop while the surplus portion of the immobilizing band is hanging down, the band might get caught in the gap between the tabletop and the cover, which might cause problems.
- If the patient is using an IV, be sure to secure the line to prevent it from hanging loosely from the tabletop.
  The IV line might become caught in the gaps between the side cover and the tabletop, or between the tabletop and the main unit. Take special care when moving the table outward.
- Make sure that the immobilizing bands do not become caught in the gap between the side covers and the tabletop.
- To move the tabletop forward or backward when no patient is on the tabletop, fold up the immobilizing bands and rails so that they are on top of the tabletop. If the immobilizing bands and rails are not folded up, the immobilizing bands might get caught in the patient table, or the rail might chafe the patient table cover.

CAUTION

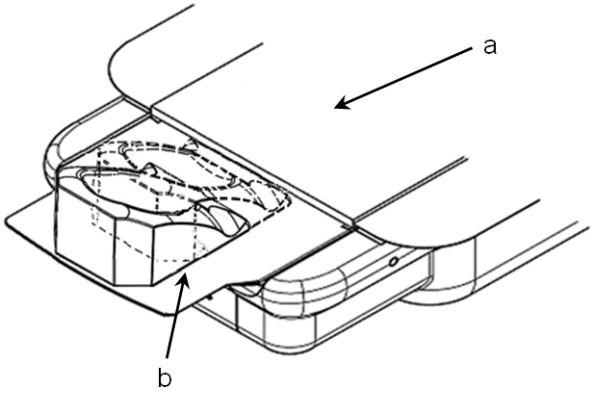
- The flaps prevent the patient from extending their hands, fingers, arms, or legs over the edge of the tabletop. When securing a patient, fold the rail flaps over the patient, and then secure the patient from above the rail flaps by using the immobilizing bands.
- The edge of an immobilizing band that has been folded over might appear on a scanogram image as a linear shape. To prevent this linear shape from causing a shadow on the image, do not fold the immobilizing band when it is in use.
- The shadow of the rail might appear in a scanogram image.
- When performing a scan of the lung area, wrap the immobilizing band around the patient's body so that the band is not within the area to be scanned. If the immobilizing band is within the area subject to the scan, it could cause a streak artifact on the image.

This equipment comes with five sets of immobilizing bands, consisting of three types of bands. Use the bands appropriately to secure the patient's chest, abdomen, and legs. In addition, select the appropriate bands according to the size of the patient to be secured.

5.5.3 Headrest 1, head band, and chin band

Headrest 1 is used by placing it directly on top of the tabletop.

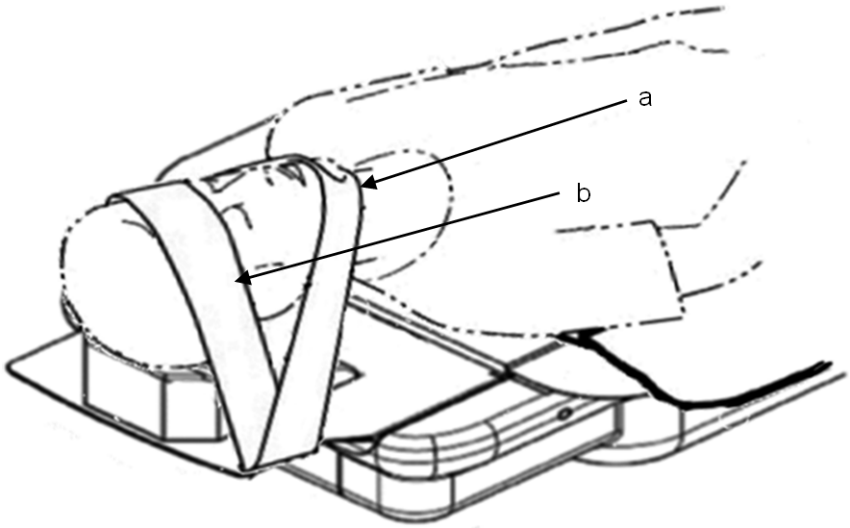
1. Place Headrest 1 on top of the tabletop.



a. Mat

b. Headrest 1

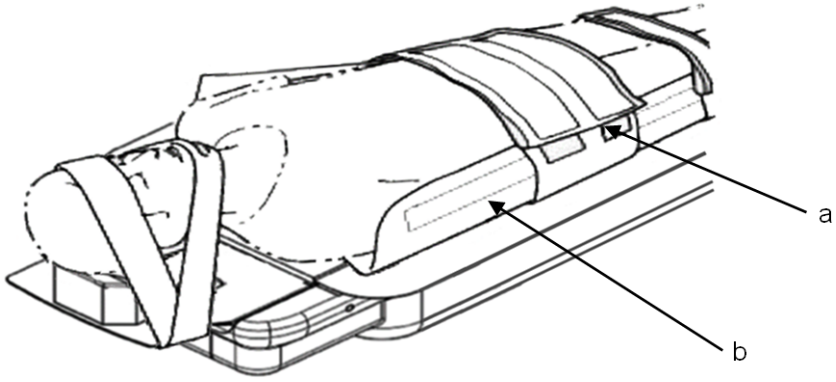
2. Have the patient place their head on Headrest 1, and then secure the patient's head by using the head band and chin band according to the position of Headrest 1.



a. Chin band

b. Head band

3. Cover the patient by using the rail flaps and secure the patient by using the immobilizing bands.



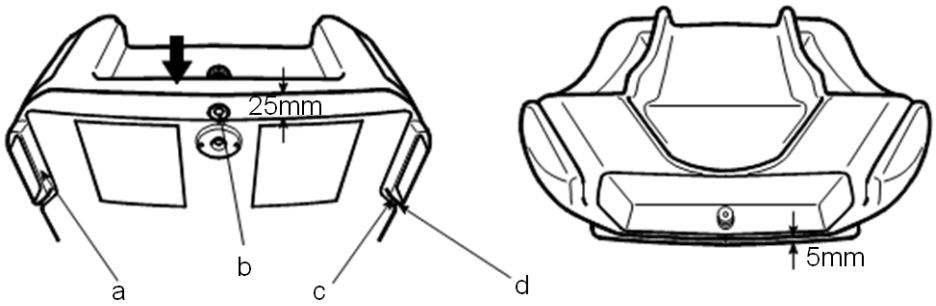
a. Immobilizing bands A and B

b. Rail flap

5.5.4 Headrest 2, Armrest HF, head band, and chin band

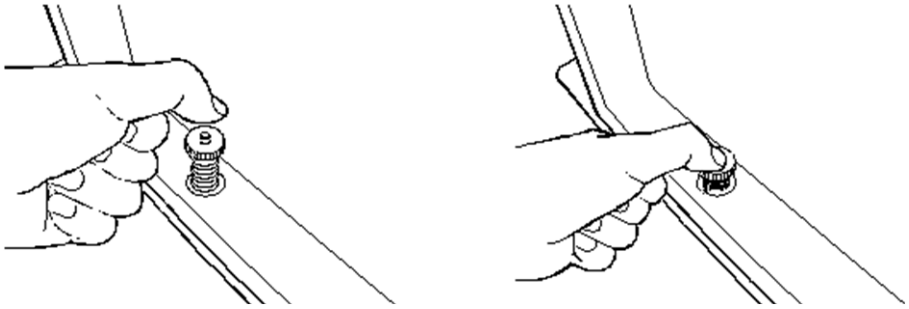
You can prevent Armrest HF from falling from the tabletop by taking the rod that connects to the knob on the back of Headrest 2 and passing it through the hole at the front end of the tabletop.

1. Align the groove on Armrest HF with the edge of the tabletop, and then place Armrest HF on the tabletop so that it extends 25 mm beyond the edge of the tabletop in the direction of the scanner. Then, push Armrest HF up to the shoulder of the tabletop (the part indicated by the arrow in the left figure below). (The shoulder of Armrest HF should be lightly touching the shoulder of the tabletop, and the edge of the tabletop should extend about 5 mm beyond Armrest HF.)

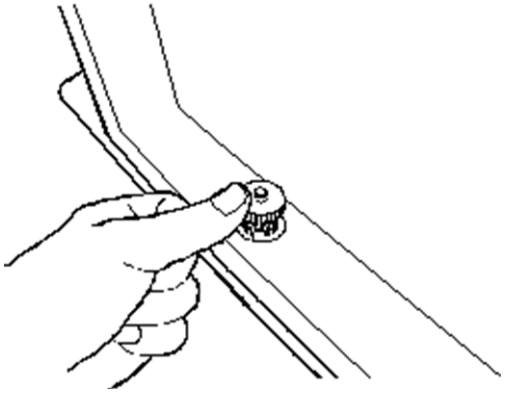


   a. Groove
   b. Rod
   c. Shoulder of the tabletop
   d. Shoulder of Armrest HF

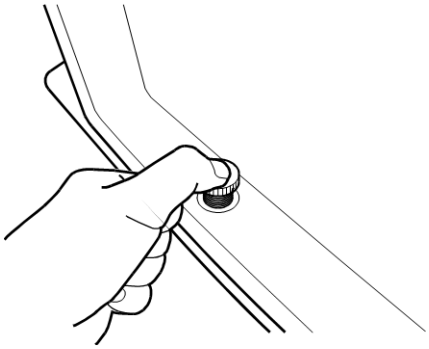
2. Press the center button on the rear of Armrest HF until the spring compresses.

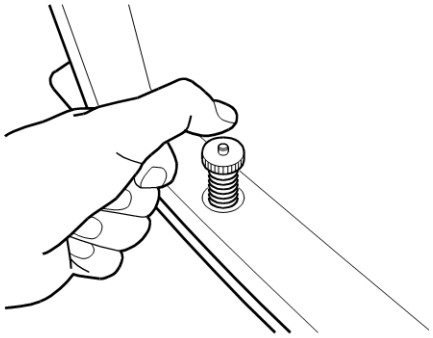


3. As you release your finger from the center button, hold down the knob on the outside of the button with the inside of your finger, and then remove your finger. The latch that extends from the end of the rod catches on the hole in the edge of the tabletop, and the rod is secured in a state where it passes through the hole in the edge of the tabletop. This prevents Armrest HF from falling from the tabletop.

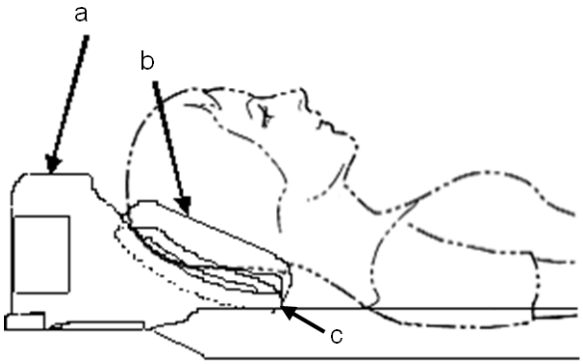


4. To remove Armrest HF from the tabletop, press and release the center button. The rod is pushed out by the energy of the spring, and the rod comes out of the hole in the edge of the tabletop.
   This enables you to remove Armrest HF from the tabletop.

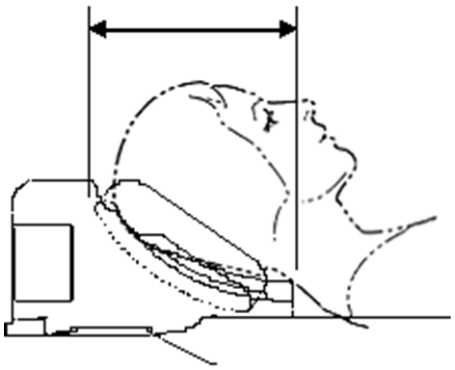




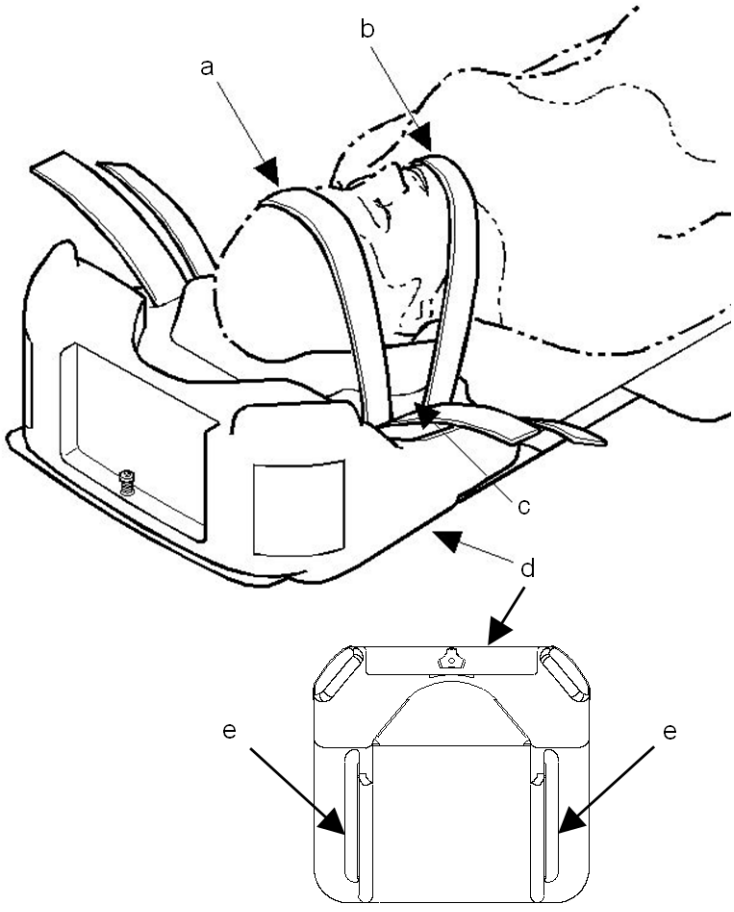
5. Insert Headrest 2 into Armrest HF.
   As shown in the figure for the next step, align the back end of Headrest 2 with the back end of Armrest HF.
6. Have the patient lie face up, on top of the mat on the tabletop.
   Align the back of the patient's head with the depression in Headrest 2.



   a. Armrest HF
   b. Headrest 2
   c. The back end of Headrest 2 and the back end of Armrest HF
7. The position set in steps 5 and 6 is the basic position for Headrest 2. You can change the angle of Headrest 2 to incline the patient's head. The headrest can be adjusted within the range indicated by the arrow in the following figure.



8. Place the head band over the patient's forehead and the chin band over the patient's chin, and secure the bands by using the Velcro (male) on the Armrest HF.
   If there is any slack in the head band or chin band, insert the bands into the grooves on Armrest HF so that the bands do not hang down.



a. Head band
b. Chin band
c. Velcro (male)
d. Armrest HF
e. Groove

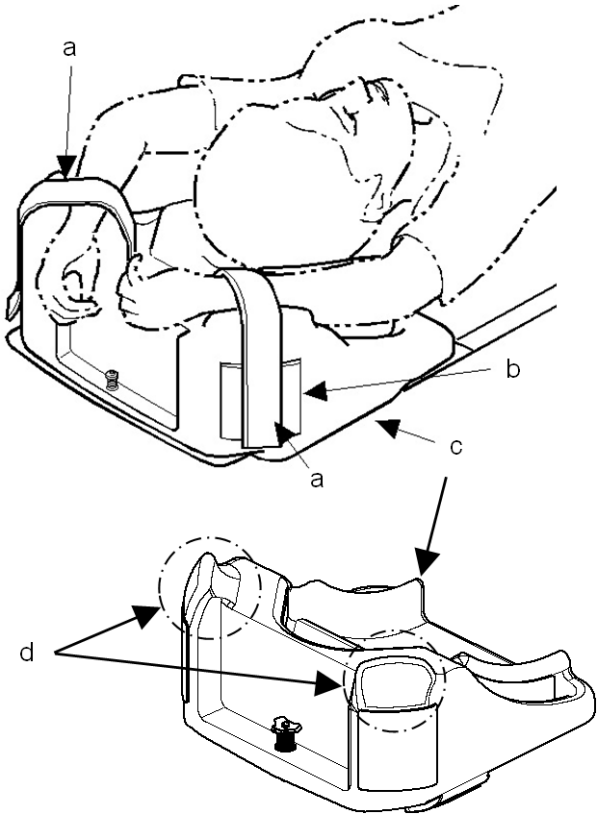
CAUTION

- Be sure to affix Armrest HF to the tabletop.
- Verify that the rod of Armrest HF is secured in the hole in the edge of the tabletop before using the equipment.
- Note that the external appearance of components, such as the knobs, is subject to change without notice.

When changing the angle of Headrest 2, do so in the range of adjustment for the headrest.

5.5.5 Headrest HF and arm band

1. Perform steps 1 through 7 of the procedure in *5.5.4 Headrest 2, Armrest HF, head band, and chin band* on page 80.
2. Have the patient raise their arms over their head to touch the projections on Armrest HF.
3. Place the arm bands around the patient's arms and secure the arm bands by using the Velcro (male) on Armrest HF.



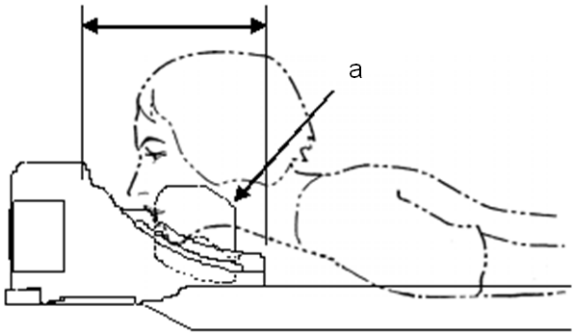
a. Arm band
b. Velcro (male)
c. Armrest HF
d. Projections

CAUTION

- Be sure to affix Armrest HF to the tabletop.
- Verify that the rod of Armrest HF is secured in the hole in the edge of the tabletop before using the equipment.
- When changing the angle of Headrest 2, do so in the range of adjustment for the headrest.
- To remove Headrest HF from the tabletop, see *5.5.4 Headrest 2, Armrest HF, head band, and chin band* on page 80.

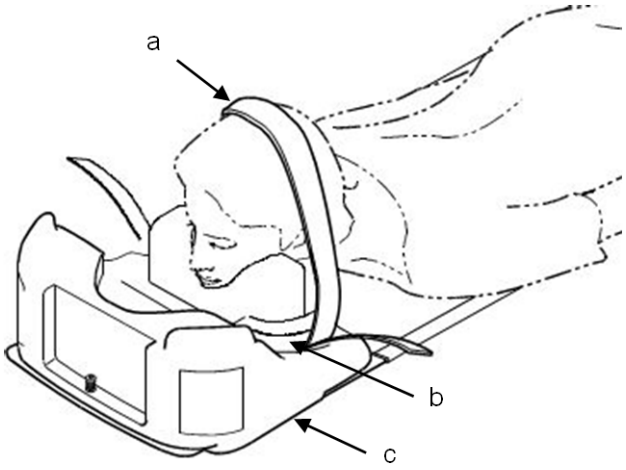
5.5.6 Chin rest and head band

1. Affix the chin rest to Armrest HF.
   As shown in the figure for the next step, insert the chin rest so that it is oriented vertically.
2. Have the patient lie face down on top of the mat on the tabletop.
   Have the patient place their chin on the chin rest. The chin rest can be adjusted within the range indicated by the arrow in the following figure.



   a. Chin rest

3. The position set in step 2 is the basic position for the chin rest.
   You can change the angle of the chin rest to match the patient's body type.
4. Place the head band over the patient's head, and secure the head band by using the Velcro strips (male) on Armrest HF.
   If there is any slack in the head band, insert the band into the groove on Armrest HF so that the band does not hang down.



a. Head band

b. Velcro (male)

c. Armrest HF

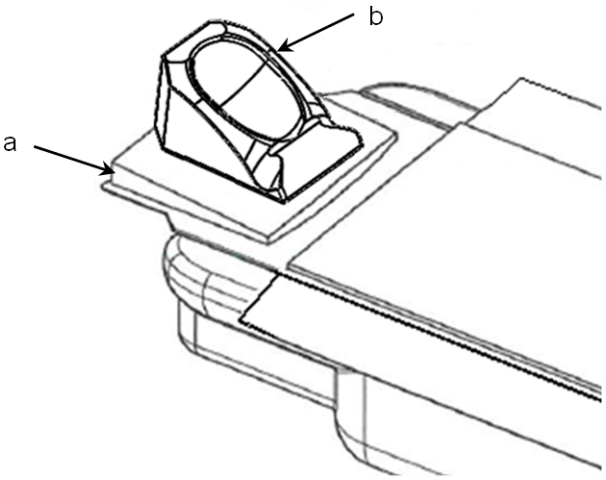
CAUTION

- Be sure to affix Armrest HF to the tabletop.
- Verify that the rod of Armrest HF is secured in the hole in the edge of the tabletop before using the equipment.
- When changing the angle of the chin rest, do so in the range of adjustment for the chin rest.
- To remove Headrest HF from the tabletop, see *5.5.4 Headrest 2, Armrest HF, head band, and chin band* on page 80.

5.5.7 Spacer 1 and Spacer 2

The spacers are used together with Headrest 1 to incline the head when a head-first scan is performed. Spacer 1 is used to incline the head at an angle of 5°, and Spacer 2 is used to incline the head at an angle of 10°.

1. Place Spacer 1 or Spacer 2 on the tabletop, and then place Headrest 1 on top of the spacer.



a. Spacer 1 or Spacer 2

b. Headrest 1

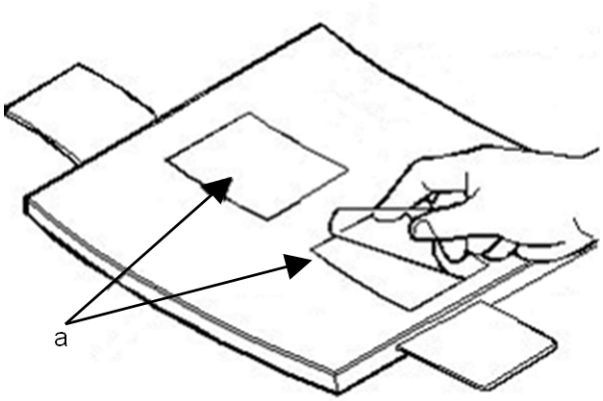
2. Have the patient place their head on Headrest 1.

CAUTION

- Always secure the patient's head by using the head band OP and chin band OP.
- For details about how to use the head band and chin band, see *5.5.3 Headrest 1, head band, and chin band* on page 78.

5.5.8 Leg mat

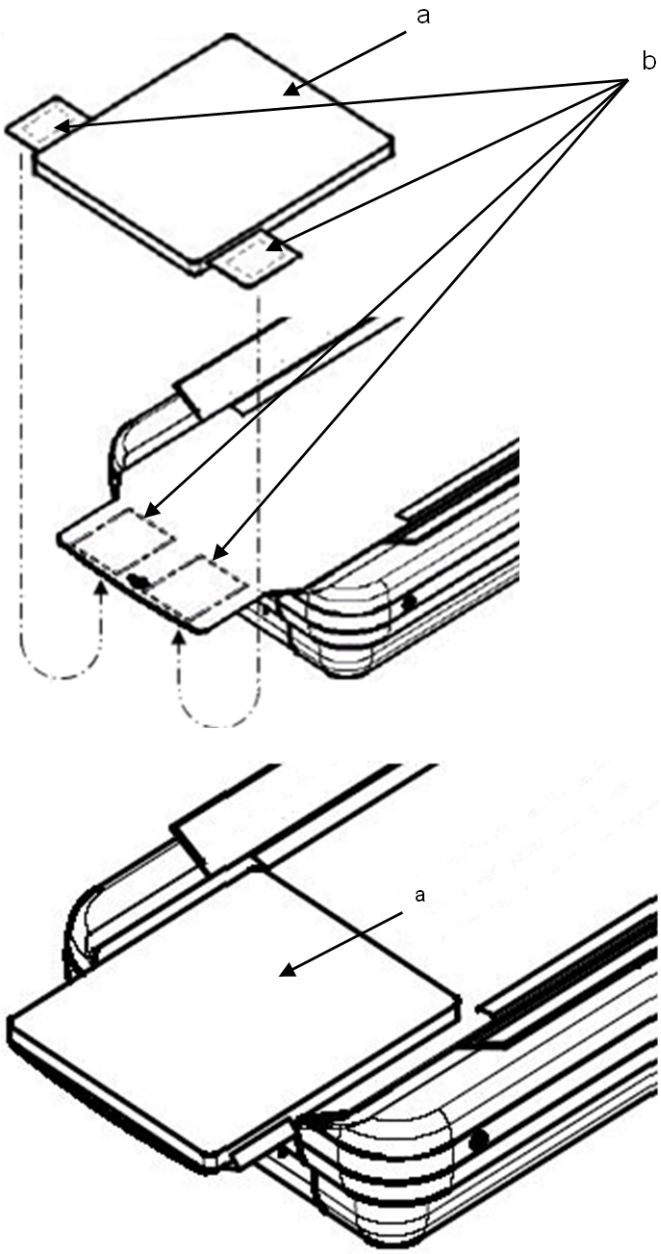
1. Before using the leg mat for the first time, remove the protective sheets from the surfaces of the slip stoppers attached to the back side of the leg mat.



a. Slip stoppers

If there is dust on the surfaces of the slip stoppers, wipe off the dust by using wet gauze.
This restores the slip stopping ability.

2. To perform a feet-first (FF) scan, place the leg mat at the end of the tabletop, and then attach the Velcro on the leg mat to the Velcro on the bottom side of the end of the tabletop.



a. Leg mat

b. Velcro (back side)

5.5.9 Triangular mat

The following describes how to use the triangle mat. Use the triangular mat when necessary.

(1) Using the triangle mat as a knee rest

Set the triangle mat as shown below, and then have the patient rest their legs on the slope of the triangular mat.

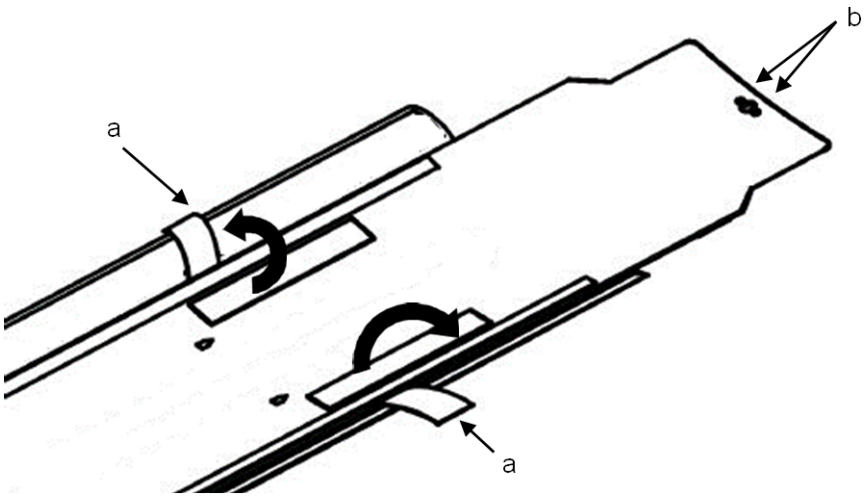
(2) Using the triangle mat as a headrest when performing a feet-first scan

Set the triangle mat as shown below, and then have the patient rest their head on the slope of the triangular mat. The patient's feet should be at the end of the table closest to the scanner gantry.

5.5.10 The legrest tabletop and the mat for the legrest tabletop

When the legrest tabletop is attached to the end of the tabletop, the length of effective radiography area is 2,000 mm.

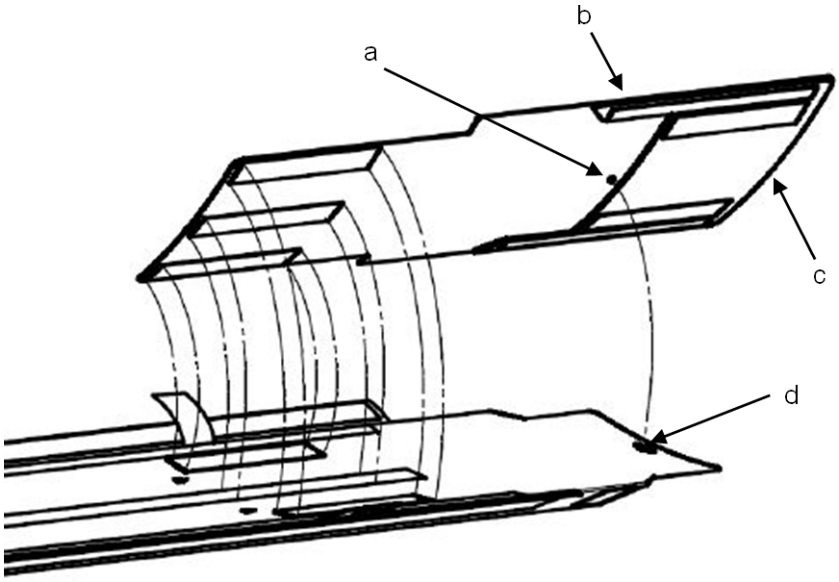
1. Fold the legrest tabletop immobilizing band.



a. Legrest tabletop immobilizing band

b. Screw

2. To attach the legrest tabletop to the end of the tabletop, insert the pin on the back of the legrest tabletop into the hole at the end of the tabletop, and then align the guide on the back of the legrest tabletop with the left and right edges of the tabletop.



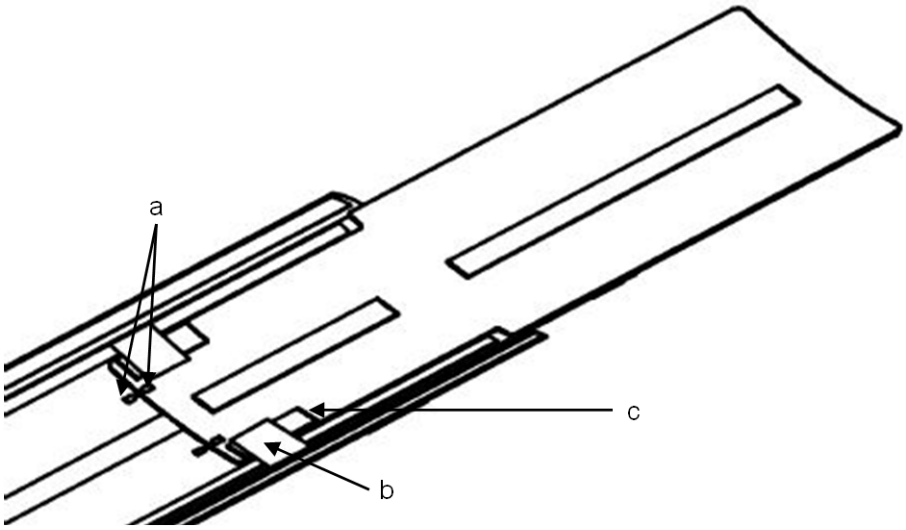
a. Pin

b. Guide

c. Legrest tabletop

d. Hole

3. Place the leg rest tabletop on the tabletop. Make sure that the set mark on the leg rest tabletop is aligned with the set mark on the tabletop.
Next, to secure the legrest tabletop, attach the folded legrest tabletop immobilizing band to the Velcro on the surface of the legrest tabletop.

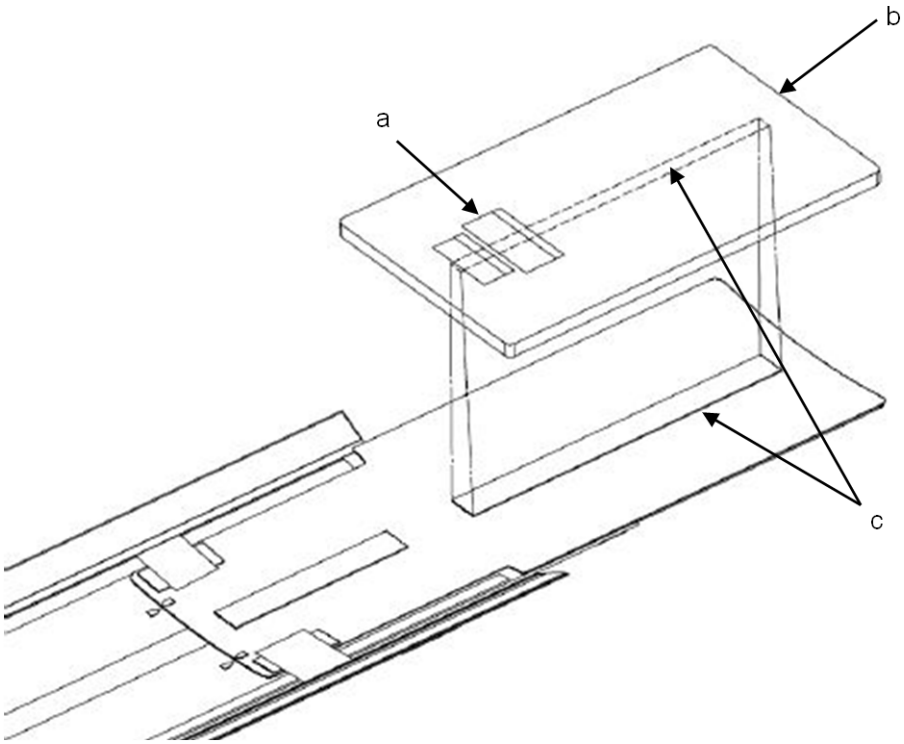


a. Set mark

b. Legrest tabletop immobilizing band

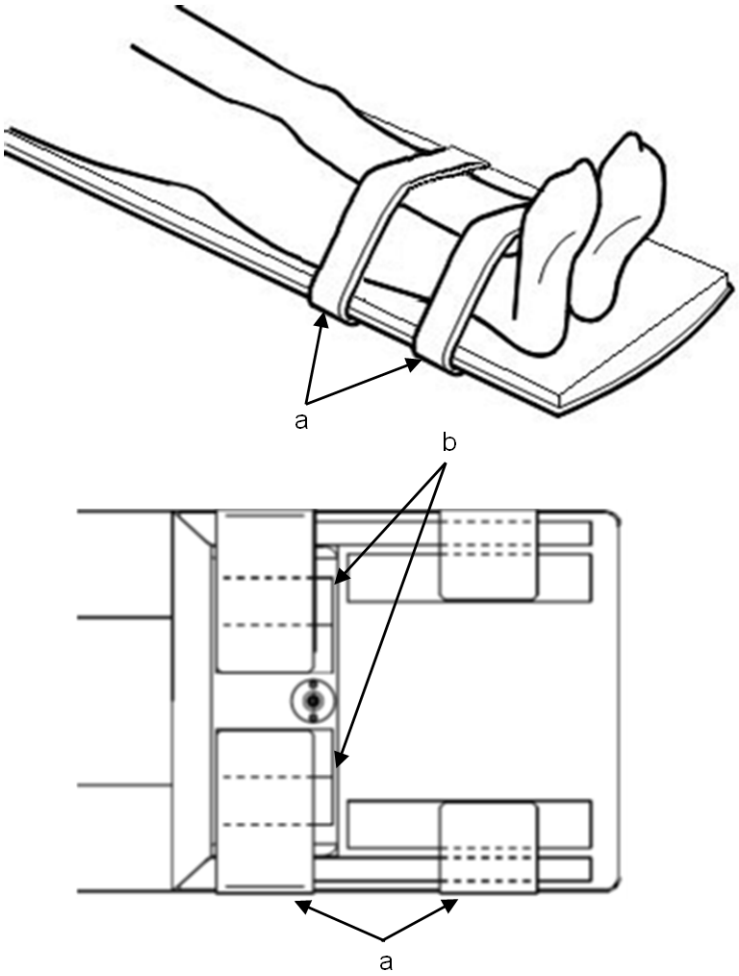
c. Velcro

4. Place the mat for the legrest tabletop on the legrest tabletop. To secure the mat, attach the Velcro on the surface of the tabletop to the Velcro on the back of the mat.



   a. Caution label
   b. Mat for the legrest tabletop
   c. Velcro

5. Have the patient lie down, and then secure the patient's legs to the tabletop and to the leg rest tabletop by using the Velcro band. At this time, secure the Velcro band to the Velcro on the back of the tabletop, as shown in the following figure.



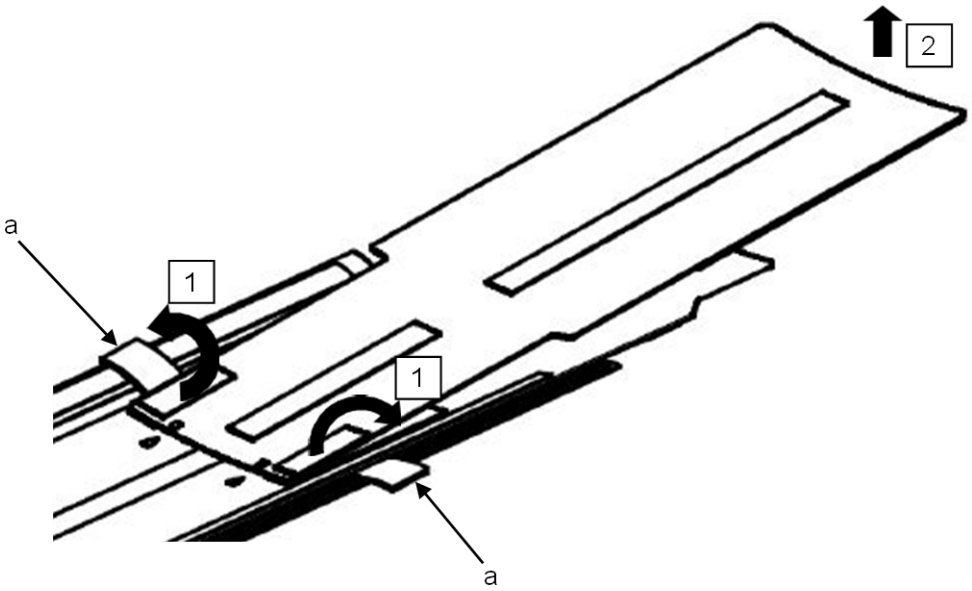
a. Velcro band

b. Velcro

CAUTION

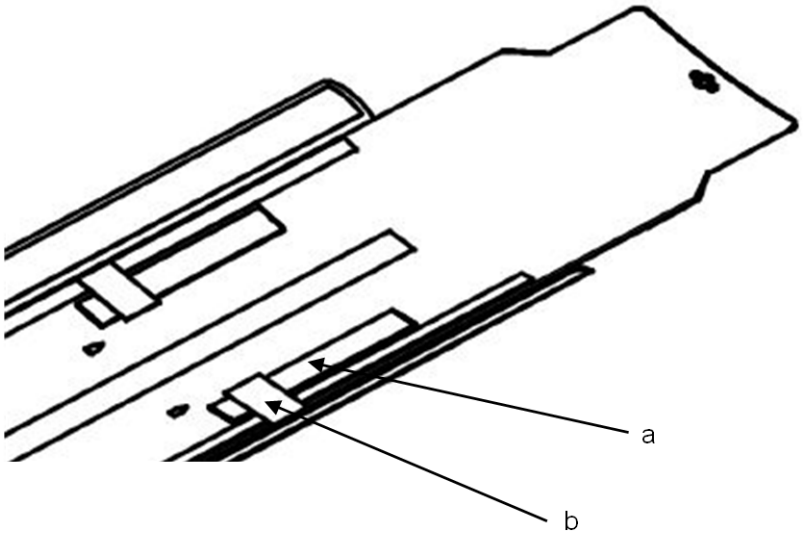
- Use the legrest tabletop as a leg support when performing feet-first scans. Do not use the leg rest tabletop when performing head-first scans. If you use the legrest tabletop for head-first scans, the patient might not be properly secured.
- Do not apply weight to the end of the leg rest tabletop by placing your hands on it. Ignoring this instruction might cause the legrest tabletop to fall from the tabletop and damage the device, or might cause injury if your hands slip.
- Do not sit on the end of the legrest tabletop. Ignoring this instruction might cause injury or might damage the device if the legrest tabletop falls from the tabletop.
- Make sure that the legrest tabletop is firmly secured on the tabletop.

6. To detach the legrest tabletop, remove the legrest tabletop immobilizing bands from the legrest tabletop, and then lift up the end of the legrest tabletop. The legrest tabletop can be easily removed.



a. Legrest tabletop immobilizing band

7. When you are not using the legrest tabletop, attach the legrest tabletop immobilizing bands to the Velcro on the surface of the tabletop.



a. Velcro

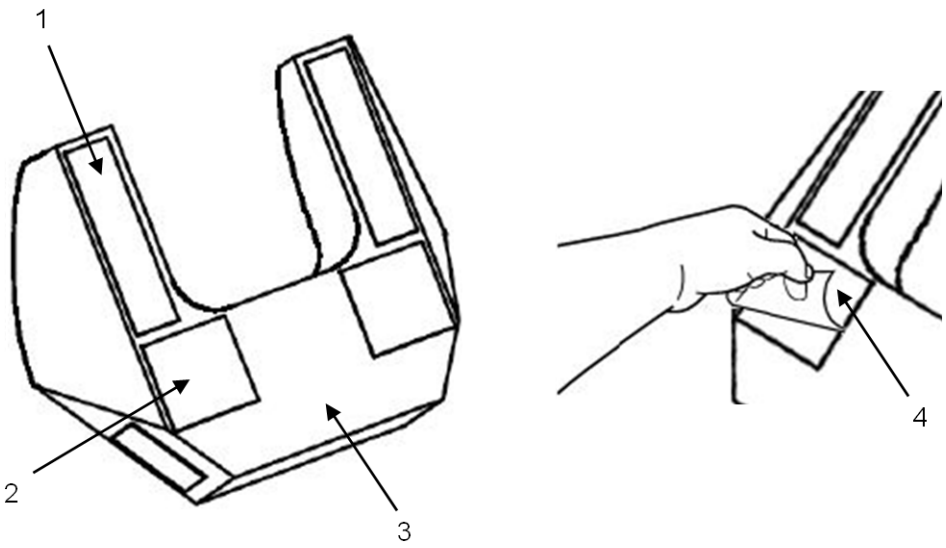
b. Legrest tabletop immobilizing band

CAUTION

You do not need to remove the legrest tabletop immobilizing bands from the left and right edges of the tabletop.

5.5.11 Armrest FF

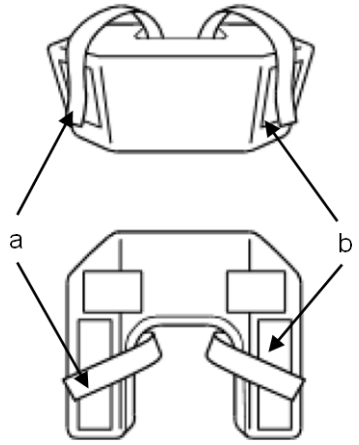
Use this armrest when performing feet-first (FF) scans.
Before using the armrest for the first time, remove the protective sheets from the surfaces of the slip stoppers attached to the bottom of the armrest.



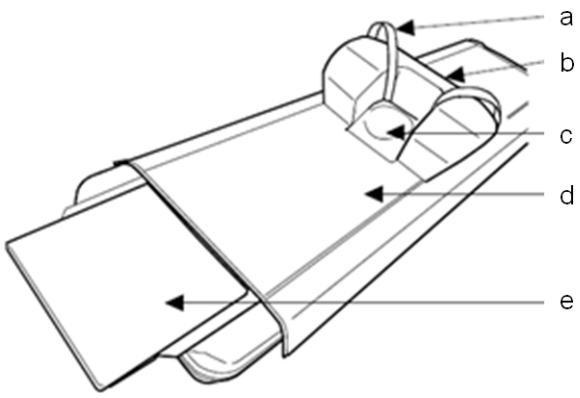
1. Velcro
2. Slip stoppers
3. Armrest FF
4. Protective sheet

If there is dust on the surfaces of the slip stoppers, wipe off the dust by using wet gauze.
This restores the slip stopping ability.

1. Attach the Velcro strips of the arm band to the Velcro strips of Armrest FF.



   a. Arm band
   b. Velcro strips of Armrest FF
2. Place Armrest FF on the mat.
3. Insert Headrest 1 into the space on Armrest FF, and then have the patient rest their head on Headrest 1.



a. Arm band

b. Armrest FF

c. Headrest 1

d. Mat

e. Leg mat (This is an example of using these accessories in combination.)

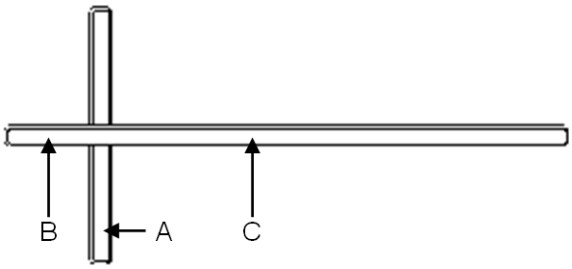
4. Place the patient's upper arms on Armrest FF, and then secure the patient's arms by using the provided arm bands to prevent the patient's arms from falling.

CAUTION

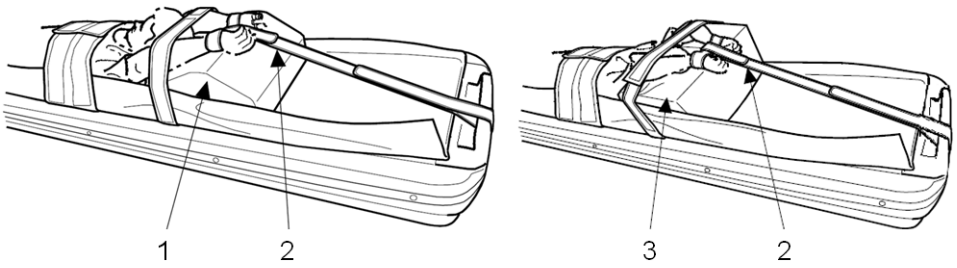
- Secure the patient's arms by using the arm bands provided with Armrest FF.
- Be sure to use the mat, immobilizing bands A300, immobilizing bands B300, immobilizing bands A150, or immobilizing bands B150 to firmly secure the patient.

5.5.12 Wrist band

The wrist band is used for securing the patient's arms when the patient's arms are raised over their head for an FF (feet first) scan. The wristband consists of three parts: bands A to C.



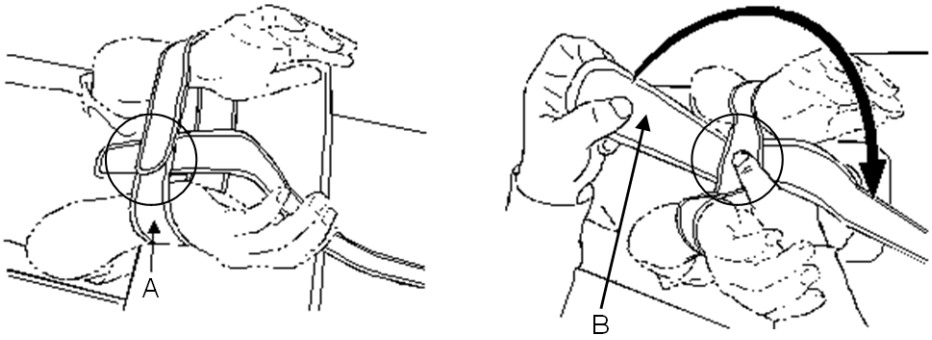
The following figures show examples of using the wrist band.



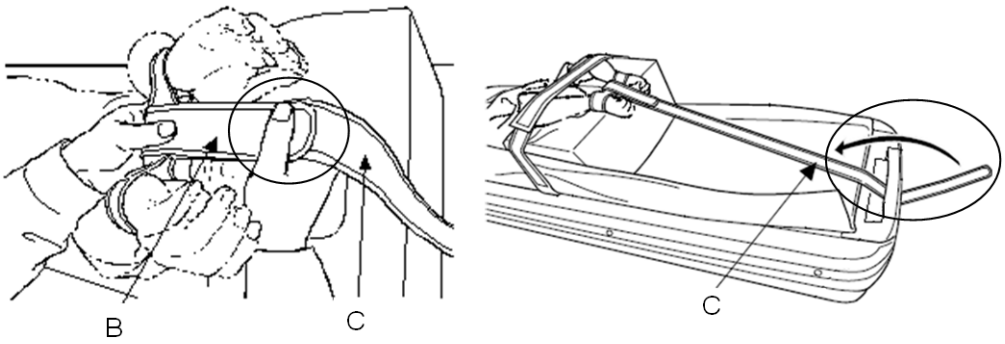
1. Triangular mat
2. Wrist band
3. Armrest FF

The procedure for using the wrist band is as follows:

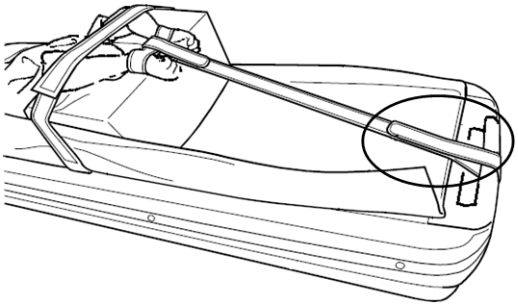
1. Raise the patient's arms over the patient's head.
2. Make a circle with band A around the patient's wrists and fasten the end part of the band.
3. Hold the central part of the circle you made in step 2.



4. Fold back band B and surround the center part (formed in step 3) with it to secure it to band C.
5. Pull band C toward the rear part of the patient table and pass it through the handle.



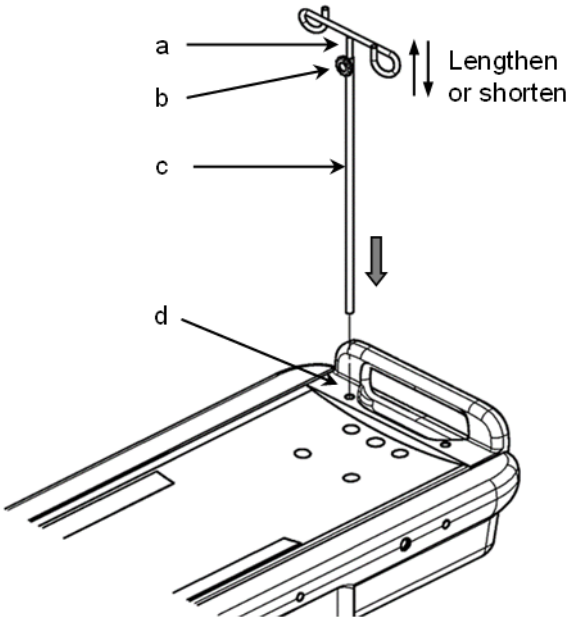
6. Fold back the end of band C and secure it to itself.



5.6 Using the IV pole

5.6.1 IV pole

1. Use the IV pole designed for this system, and insert it into the IV pole holder at the back of the tabletop.
   The height of the IV pole is adjustable in the range from 525 mm to 900 mm. Adjust the IV pole to the appropriate height by using the adjustment knob.



a. Adjustable part of the IV pole

b. Adjustment knob

c. IV pole

d. IV pole holder

CAUTION

- Make sure that the IV bag and the IV line hanging from the IV pole do not come into contact with the peripheral equipment and that they will not be caught in the gap between the tabletop and the cover when the tabletop moves.
- The IV pole holder is designed so that any liquid that spills on the IV pole holder drains into the gap at the bottom of the IV pole holder. The handle holder is designed to retain accumulated liquid. Clean the liquid off appropriately.
- Do not use any IV pole other than the optional part specified for this system.
- When you adjust the length of the IV pole, be sure to fix the length by tightening the adjustment knob. If the knob is not tightly secured, the adjustable part of the IV pole might fall. In addition, when you rotate the IV pole, use the adjustment knob to adjust the rotation and then tightly secure the adjustment knob to fix the IV pole in place.

6

Precautions for Use with Equipment from Other Manufacturers

Do not use this unit with devices other than those indicated in this chapter.

6.1 When using the ECG scan option

6.1.1 Product name: Cardiac Trigger Monitor

1. Model name: Model 3000H
   Manufacturer: Ivy Biomedical Systems, Inc.
2. Model name: Model 7800H
   Manufacturer: Ivy Biomedical Systems, Inc.
3. Model name: BEDSIDE MONITOR Life Scope VS BSM-3000 Series
   Manufacturer: Nihon Kohden co., Ltd.

6.2 When using the Injector Synchronization option

6.2.1 Product name: Contrast Injector

1. Model name: DUAL SHOT alpha7
   Manufacturer: Nemoto Kyorindo co., Ltd
2. Model name: MEDRAD Stellant CT Injection System D with Certegra Workstation (CAN)
   Manufacturer: Bayer Medical Care Inc.
3. Model name: MEDRAD Salient Dual
   Manufacturer: Imaxeon Pty Ltd.
4. Model name: MEDRAD Centargo CT Injection System
   Manufacturer: Bayer Medical Care Inc.
5. Model name: CT motion
   Manufacturer: ulrich GmbH & Co. KG
6. Model name: MEDRAD Stellant FLEX CT Injection System*
   Manufacturer: Bayer Medical Care Inc.

*: Available only in the USA.

7

Storage and Relocation

7.1 Storage

Store the maintenance parts and equipment as follows:

- Maintenance parts
  Maintenance parts might be required when a service engineer visits to maintain or repair the equipment.
  Store these parts in one place, so that you do not lose any of them.
- Environmental conditions
  Pay careful attention to the storage environment to prevent the relay contacts from corroding.
  For details about the conditions, see *1.4 Environmental conditions* on page 15.
- Using equipment that has not been used for a long time
  Before using equipment that has not been used for a long time, the equipment must be inspected. Have FUJIFILM Healthcare Corporation or an authorized service representative carry out the inspection.

7.2 Relocation

This is stationary equipment. Install this equipment in a fixed location for use.

8

Maintenance inspections

8.1 Daily inspections

8.1.1 Inspection before starting daily work

(1) Inspecting the operation panels

Inspect the operation of push buttons and indicators, as well abnormalities in appearance.
If any abnormalities are found, contact FUJIFILM Healthcare Corporation or one of our certified dealers to schedule repairs.

(2) Inspecting the operating space of the equipment

Make sure that no objects, such as chairs or baskets to hold the patient's clothing, impede the operation range of the scanner gantry and table.
Move all objects out of the operating range of the equipment.

(3) Inspecting the wiring

Make sure that there are no disconnections, abnormal twists, or bends in the wiring between devices.
If any abnormalities are found, contact FUJIFILM Healthcare Corporation or one of our certified dealers to schedule repairs.

8.1.2 Inspection after daily work

(1) Inspecting the operation panels

Inspect the operation of push buttons and indicators, and check for soiling and for abnormalities in appearance.
If any abnormalities are found, contact FUJIFILM Healthcare Corporation or one of our certified dealers to schedule repairs.
Clean any equipment that has become soiled. For more details, see *8.1.3 Cleaning the equipment* on page 105.

(2) Inspecting the scanner gantry and table.

Inspect the equipment for abnormalities, such as scratches and dents, as well as for soiling.
If any abnormalities are found, contact FUJIFILM Healthcare Corporation or one of our certified dealers to schedule repairs.
Clean any equipment that has become soiled. For more details, see *8.1.3 Cleaning the equipment* on page 105.

8.1.3 Cleaning the equipment

CAUTION

- When cleaning the equipment, make sure that no liquids get inside the equipment. In particular, give sufficient consideration when cleaning the operation panel and intercom box to prevent cleaning fluid from entering the spaces between keys and operation buttons.
- Do not use thinner, benzene, or other solvents when cleaning. Doing so could damage the paint or coating.

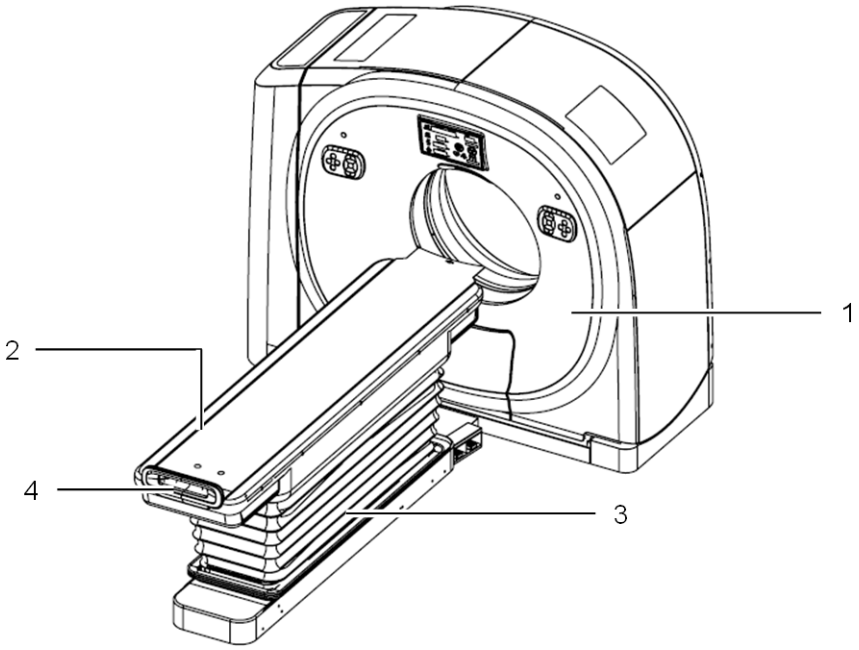
(1) Cleaning the operator console

To clean the operator console, dampen a soft cloth with a neutral detergent (with a pH in the range from 6.0 to 8.0) and gently wipe the areas that have become soiled.

(2) Cleaning the scanner gantry and table

To clean the scanner gantry and table, dampen a soft cloth with a neutral detergent (with a pH in the range from 6.0 to 8.0) and wipe the areas that have become soiled.
When cleaning blood or other bodily fluids or waste from the scanner gantry unit or table, be sure to wear disposable gloves and use ethanol to disinfect the surfaces.
After cleaning the soiled areas, wet and sufficiently wring a soft cloth and use it to immediately wipe the parts that you cleaned, so that neither detergent nor ethanol remains.
Areas 1 through 4 in the following figure indicate locations that are easily soiled. Be sure to inspect these areas and keep them clean.

1. Front cover and aperture of the scanner gantry
2. Surface of the tabletop and mat
3. Table cover
4. Cover for the bottom part of the tabletop (Inspect this cover by moving the tabletop to its farthest point inward.)



8.1.4 Daily inspection records

The form for recording the results of daily inspections is shown below.

Daily Inspection Record SCENARIA View

Enter the following information based on the results of the inspection, and then store this record in a safe place.
Refer to the instruction manual (*8 Maintenance Inspections*) for more information.

Date implemented: _____

Inspected by: _____

Inspection details		Inspection location	Inspection time	Results
At startup	Inspect the operation of push buttons and indicators, and for abnormalities in appearance.	Operation panel	At startup	
	Inspect for objects such as chairs or baskets that impede the operation range of the scanner gantry and table.	Operation space for equipment	At startup	
	Inspect for disconnections, abnormal twisting, and bends in the wiring between devices.	Wiring	At startup	
At shutdown	Inspect the operation of push buttons and indicators, and for abnormalities in appearance.	Operation panel	At shutdown	
	Inspect the equipment for abnormalities, such as scratches and dents, as well as soiling.	Scanner gantry and table	At shutdown	

Remarks:

8.2 Water phantom scanning

You can check system constancy by performing water phantom scanning before starting work. The images acquired during water phantom scanning can be used to check daily changes in the CT numbers, the SD value, and the occurrence of artifacts.
This section describes how to scan the water phantom that is included with the CT system, and provides information about the CT numbers and the SD value of images acquired from a scan performed under typical scan conditions.

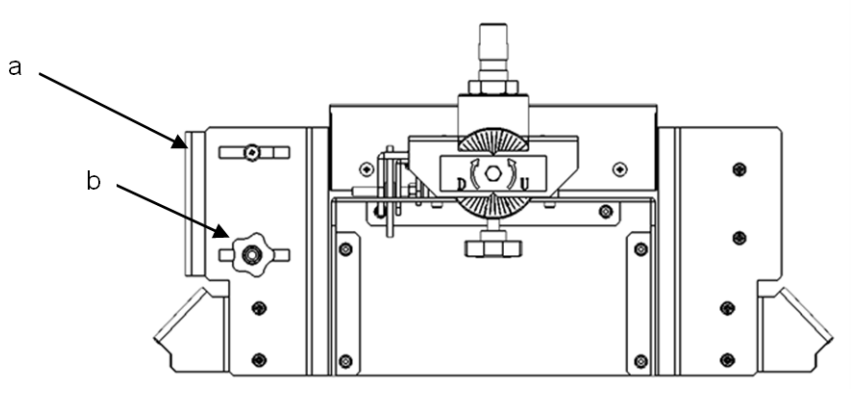
CAUTION

Since the water phantom and the phantom mounting bracket are very heavy objects, dropping them may result in injuries or can cause damage or harm to the system. Note that if the water phantom is damaged, the water inside the phantom may splash or leak out. Pay careful attention when handling the phantom so that it can be installed and removed properly.

8.2.1 Attaching the water phantom mounting bracket

Attach the phantom mounting bracket to the end of the patient table. Make sure that none of the patient harnesses are attached to the end of the patient table at this time.

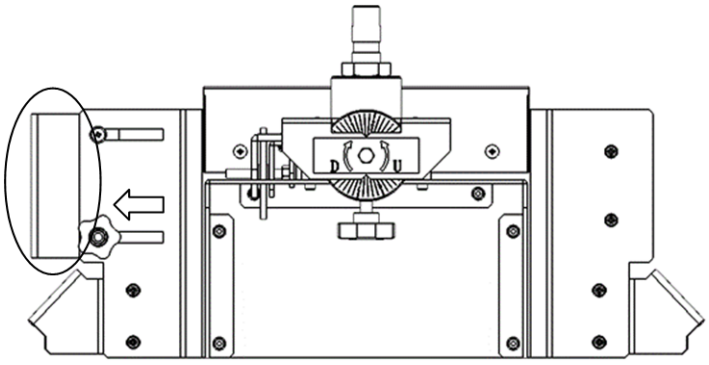
1. Turn the fixing plate adjustment knob of the phantom mounting bracket counterclockwise to loosen the fixing plate.



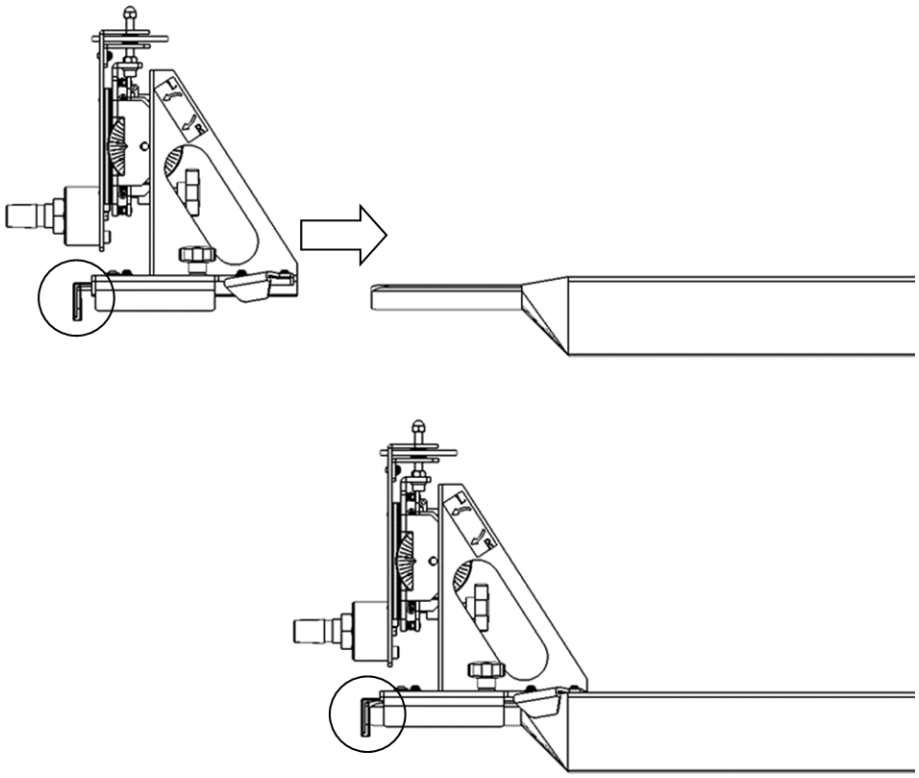
   a. Fixing plate

   b. Fixing plate adjustment knob

2. Move the fixing plate adjustment knob away from the unit to open the fixing plate.



3. Insert the phantom mounting bracket until the end of the bracket touches the end of the tabletop.



4. Slide the fixing plate adjustment knob toward the inside, and close the distance between the fixing plate and the tabletop so that there is no gap. Then turn the fixing plate adjustment knob to secure the phantom mounting bracket.

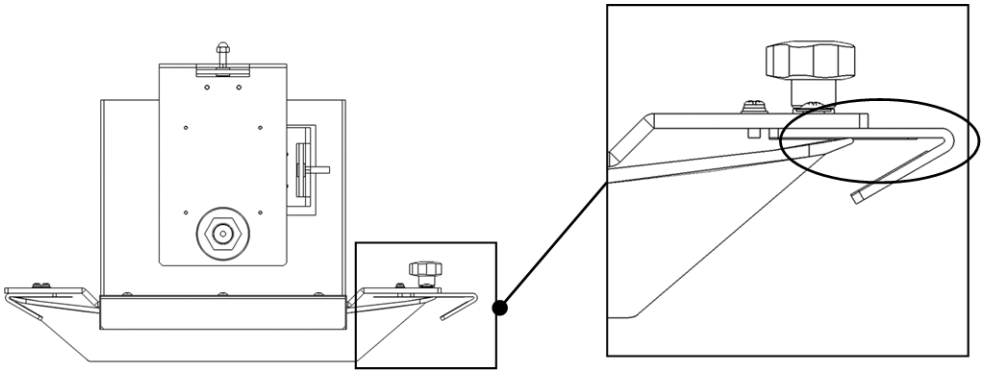


Figure 8-1 Before moving the fixing plate adjustment knob (with a gap)

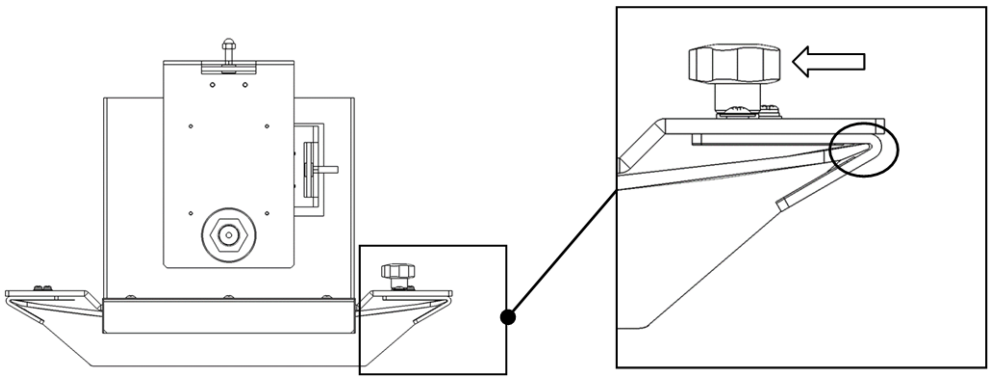


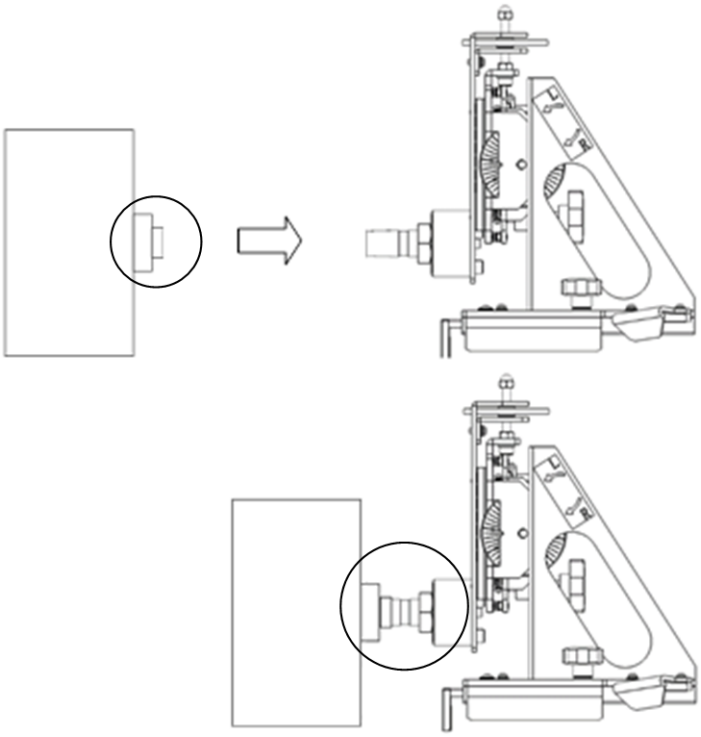
Figure 8-2 After moving the fixing plate adjustment knob (with no gap)

CAUTION

If the mounting bracket is not sufficiently secured, it might fall off and damage the scanner gantry.

8.2.2 Mounting the water phantom

1. Move the tabletop forward to the position where the phantom mounting bracket protrudes from the rear of the scanner gantry.
2. At the rear of the scanner gantry, mount the water phantom onto the phantom mounting bracket so that the shaft of the bracket enters the fixing hole of the water phantom. Press the water phantom so that the shaft reaches the innermost part of the fixing hole.



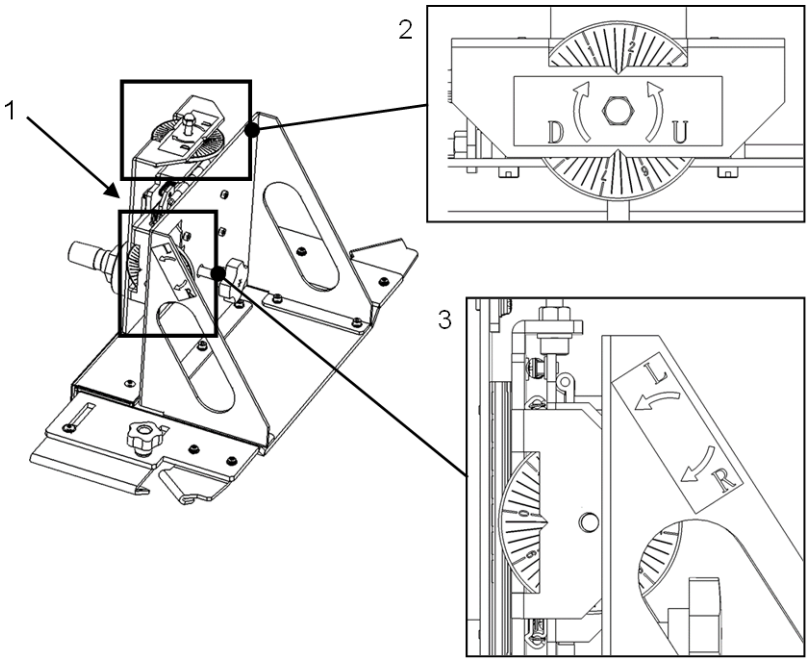
CAUTION

- Check to ensure that the shaft is firmly inserted into the fixing hole. If the water phantom falls, the scanner gantry might be damaged or the water phantom might break, causing water to leak.
- When you remove the water phantom, you will need to bear the weight of the water phantom when the shaft is no longer inserted into the fixing hole. Therefore, handle the water phantom with special care to ensure that it does not hit the surrounding equipment at this time. If the water phantom hits the patient table, the scanner gantry, or the phantom mounting bracket, it might cause damage, and the water phantom itself might fall as a result of the impact.

- To check whether the shaft is fully inserted into the fixing hole, check the depth of the fixing hole and the length of the shaft.
- To remove the water phantom efficiently, hold the water phantom firmly and pull it, while slightly rotating it around the shaft.

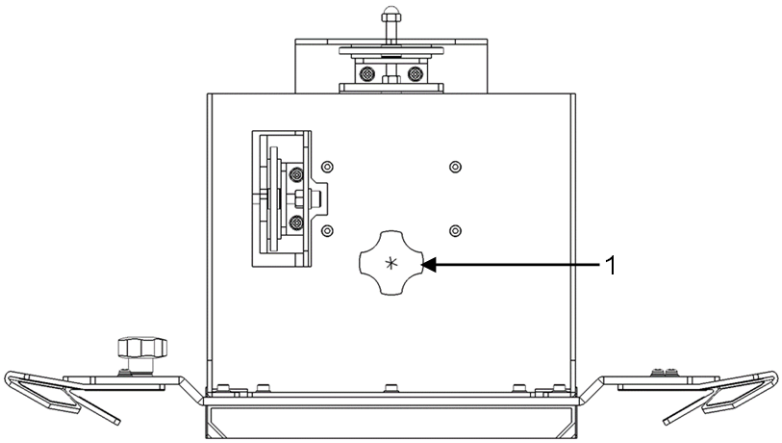
8.2.3 Adjusting the position of the water phantom

You can adjust the position of the water phantom by moving the tabletop up and down or forward and backward, or by using the fine movement mounting base attached to the phantom mounting base.
The fine movement mounting base (1 in the figure) can be moved by rotating the DU (Down/Up) adjustment dial (2 in the figure) and the LR (Left /Right) adjustment dial (3 in the figure).



Dial display	Shift (mm)
Between thick lines (numbers)	0.1
Between thin lines (the smallest graduations)	0.02

The angle of the water phantom can be adjusted by using the angle adjustment knob of the phantom mounting bracket.

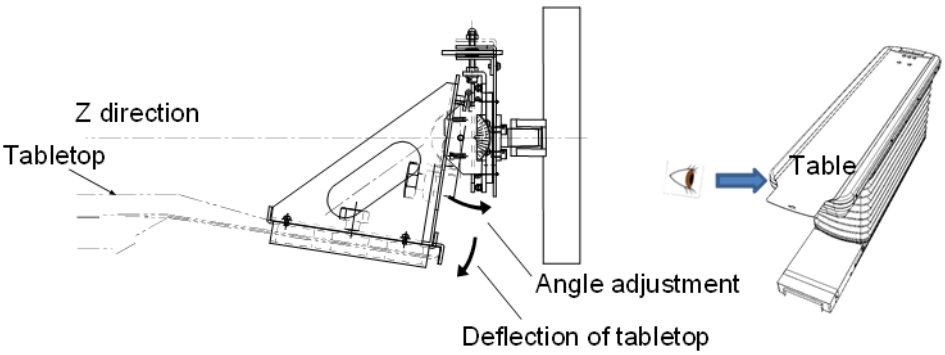


1. Angle adjustment knob

CAUTION

When adjusting the angle, take sufficient care so that the water phantom does not fall.

If you lift the water phantom slightly by hand, the angle adjustment knob becomes easier to rotate.



8.2.4 Scanning the water phantom

You can check system constancy by scanning the same phantom under the same conditions every day to check the CT numbers and SD value, even if you do not follow the water phantom scanning procedure described in this section. However, please note that the CT value linearity, CT value uniformity and image noise values shown in *Table 8-3 CT values (linearity and uniformity) and SD value (image noise)* on page 114 are obtained by following the water phantom mounting method, scan conditions, and ROI settings specified in this section. If the water phantom is scanned by using a procedure different from that provided in this manual (for example, if you do not use the phantom mounting bracket, but instead perform scans while the water phantom is placed on the tabletop), the values obtained may be different from those shown in *Table 8-3 CT values (linearity and uniformity) and SD value (image noise)* on page 114.

1. Use the phantom mounting bracket to position the water phantom in the center of the gantry aperture (deviation from the FOV center: less than 1 mm).

You can confirm the position of the water phantom by using the grid functions detailed in the Instruction Manual (Radiography / Image Analysis).

2. Perform a scan according to the conditions shown in the following table.

Table 8-1 Scan conditions

Radiography conditions	165 mm diameter water phantom	305 mm diameter water phantom
Scan type	Normal scan	Normal scan
Bow tie	Standard	Standard
Tube voltage (kV)	120	120
Tube current (mA)	300	400
Scan time (s)	1.0	0.5
FOV (mm) The values shown in parentheses ( ) are the center coordinates.	210 (0,0)	350 (0,0)
Collimation (mm) Thickness (mm), Image mode	0.625 × 32 10.0 [mm], 2 [i]	0.625 × 32 10.0 [mm], 2 [i]
Reconstructed filter	F12	F32
B.H.C./B.G.C.	OFF/OFF	OFF/OFF

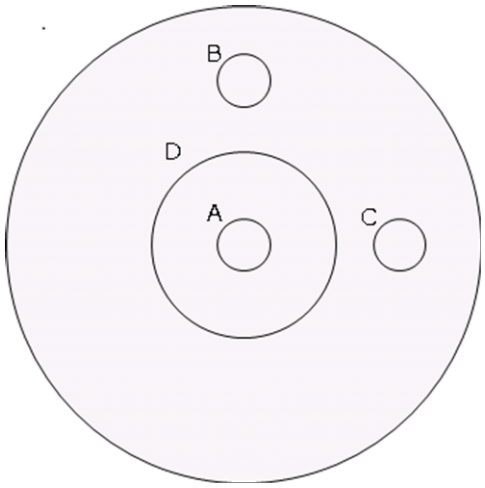
3. For the acquired images, specify ROI settings by entering the specified settings shown in *Table 8-2 ROI settings* on page 113 in the ROI information area.

For details on the ROI operation, refer to the Instruction Manual (Radiography / Image Analysis).

Table 8-2 ROI settings

Item	165 mm diameter water phantom				305 mm diameter water phantom			
	ROI A	ROI B	ROI C	ROI D	ROI A	ROI B	ROI C	ROI D
Center (X,Y): [pix]	0,0	0,135	135,0	0,0	0,0	0,155	155,0	0,0
Radius (X,Y): [pix]	21,21	21,21	21,21	89,89	21,21	21,21	21,21	89,89
Angle: [°]	0	0	0	0	0	0	0	0

The following figure shows the image that is displayed after ROI settings are specified.



The CT numbers (CT value linearity and uniformity) and SD value (image noise) that are listed in the following table are obtained.

Table 8-3 CT values (linearity and uniformity) and SD value (image noise)

Item	165 mm diameter water phantom	305 mm diameter water phantom
CT value linearity: MN value of ROI A	0.0 HU ± 4.0 HU	0.0 HU ± 8.0 HU
CT value uniformity: Calculate the MN value of each ROI as follows |ROI A - ROI B| and |ROI C - ROI B|	≤ 4.0 HU	≤ 8.0 HU
Image noise: SD value of ROI D	1.72 HU-2.32 HU	7.39 HU-9.99 HU

8.3 Periodic inspections

We recommend periodic inspections of this equipment, generally every 3 months.
These inspections must be performed by a trained service engineer to ensure safety and to protect the equipment. Contact either FUJIFILM Healthcare Corporation or one of our certified dealers for assistance or to schedule an inspection.

8.4 Parts list

If any of the accessories for the patient table become soiled or damaged or need to be replaced, contact FUJIFILM Healthcare Corporation for assistance.

9

Repair

9.1 Responsibility for repair

Should any problems occur or readjustment be required, be sure to contact FUJIFILM Healthcare Corporation or an authorized service representative. Do not repair or readjust the equipment on your own. If anyone other than FUJIFILM Healthcare Corporation or an authorized representative repairs or readjusts the equipment, responsibility for such repair or readjustment shall lie with the executer, and FUJIFILM Healthcare Corporation shall in no event be liable for failure, damage, or accidents that might be caused by such repair or readjustment.

9.2 Service calls

Should any abnormalities occur in the equipment, immediately turn off the power. Check the abnormal condition, and contact FUJIFILM Healthcare Corporation or an authorized service representative with as much information about the problem as you can provide. A service representative will perform the necessary service as soon as possible.

10

Specifications

10.1 Specifications

10.1.1 Scanner gantry

Item	Specifications
Scan scope	Full body
Scan method	Continuous rotation
Rotational speed	0.35, 0.4, 0.5, 0.75, 1.0, and 2.0 seconds/rotation
Collimation width	1.25, 5, 10, 20, and 40 mm (measured from the center of rotation)
Number of slices	64 slices/scan*
Effective field of view	500 mm
Scanner gantry tilt angle	-30° to +30° (The tilt angle might be limited by the size and position of the patient's body and the height of the patient table.)
Light localizer	Laser beam

*: This number indicates the number of measured slices and differs from the number of reconstruction image slices.

10.1.2 Patient table

Table 10-1 For CT-WT-22

Item	Specifications
Type	Cantilever supporting mass
Tabletop material	Carbon fiber
Patient table height	From 490 mm (at the lowest position) to 970 mm
Tabletop width	475 mm
Tabletop range of motion	2,110 mm
Maximum effective radiography range	1,750 mm When the optional leg rest tabletop is attached: 2,000 mm
Maximum load	250 kg When the optional leg rest tabletop is attached: 220 kg

Table 10-2 For CT-WT-23

Item	Specifications
Type	Cantilever supporting mass
Tabletop material	Carbon fiber
Patient table height	From 490 mm (at the lowest position) to 970 mm
Tabletop width	475 mm
Tabletop range of motion	2,110 mm
Upper frame lateral range of motion	100 mm to the left and right

Item	Specifications
Maximum effective radiography range	1,750 mm When the optional leg rest tabletop is attached: 2,000 mm
Maximum load	250 kg When the optional leg rest tabletop is attached: 220 kg

10.1.3 X-ray emission system

Item		Standard	Option*
X-ray emission type		Continuous X-rays (high-frequency inverter control)	
X-ray tube assembly heat capacity		7.5 MHU	
Maximum output		72 kW (120 kV, 600 mA)	84 kW (120 kV, 700 mA) (140 kV, 600 mA)
Tube voltage and tube current (Tube current steps up at 5 mA intervals.)	80 kV	10 mA-600 mA	10 mA-670 mA
	100 kV	10 mA-600 mA	10 mA-700 mA
	120 kV	10 mA-600 mA	10 mA-700 mA
	140 kV	10 mA-510 mA	10 mA-600 mA
Tube voltage precision		Within ±5%	
Tube current precision		If the tube current exceeds 30 mA: within ±6% If the tube current is less than or equal to 30 mA: within ±2 mA	

*: Not available for systems distributed in China.

10.1.4 X-ray detectors

Item	Specifications
Element composition	912 ch × 64 columns
Element output	888 ch × 64 columns
Detector width (slice direction)	40 mm (measured from the center of rotation)

10.1.5 Operator console/image processing

Item	Specifications
CPU	Multiple processors
Display monitor	24 inch liquid crystal display
Magnetic disk units	1 TB or greater × 5 for 600,000 or more saved images
DVD drive unit	4.7 GB for 7,000 or more saved images (dependent on file type)
Image reconstruction resolution	512 × 512
Image display resolution	1,920 × 1,200

Item	Specifications
Window width adjustment	1 to 6,000 (1 to 32,767 when using extended CT values)
Window level adjustment	-2,000 to +4,000 (-32,768 to +32,767 when using extended CT values)

10.1.6 Radiography system

1. Scanogram

Item	Specifications
Scan length	150, 250, 350, 500, 750, 1,000, 1,250, 1,500, 1,750 mm
Slice thickness	0.625 mm × 8

2. Normal scan

Item	Specifications
Scan time	0.35, 0.4, 0.5, 0.75, 1.0, and 2.0 seconds/rotation
Reconstruction slice thickness	0.625, 1.25, 2.5, 5.0, or 10 mm

3. Volume scan

Item	Specifications	
Scan time	0.35, 0.4, 0.5, 0.75, or 1.0 seconds rotation	
Reconstruction slice thickness	0.625, 1.0 1.25, 2.5, 3.75, 5.0, 7.5, or 10 mm	
Table feed rate	For 20 mm (0.625 × 32) collimation	11.875 to 31.875 mm/rotation
	For 40 mm (0.625 × 64) collimation	23.125 to 63.125 mm/rotation
Table pitch	For 20 mm (0.625 × 32) collimation	0.594, 0.844, 1.094, 1.344, 1.594
	For 40 mm (0.625 × 64) collimation	0.578, 0.828, 1.078, 1.328, 1.578

4. Dynamic scan

Item	Specifications
Scan time	0.35, 0.4, 0.5, 0.75, 1.0, and 2.0 seconds/rotation
Continuous scan time	Maximum of 100 seconds

5. Predict scan
6. Preview scan
7. Orbital synchronization

10.1.7 Image reconstruction calculations

1. CORE Plus
2. Intelli IP Advanced
3. HiMAR

10.1.8 Radiography conditions settings

1. IntelliEC
2. IntelliEC Plus
3. Dose Check
4. AutoPose

10.1.9 Data management and information management

1. Patient information registration
2. Examination information display
3. Dose management
4. Film output
5. DICOM transmissions
6. Writing to media
7. Saving images
8. User settings
9. Storage commitment
10. Data security

10.1.10 Image display and image processing

1. Image information display
2. Slice image display
3. Film image display
4. Density gradation
5. Annotations
6. Image filtering
7. Test injections
8. Quality Exam

10.1.11 3D image processing

1. Orthogonal Three Sections display
2. MPR image display
3. 3D image display
4. Mask extraction and editing
5. CEV-CPR image display

10.2 Rated output

Item		Standard (72 kW)	Option (84 kW)*
Power supply voltage		Three-phase 380/400 V AC	
Nominal power (4 seconds at 120 kV)		72 kW	84 kW
Nominal tube voltage and the maximum tube current possible at the nominal tube voltage		140 kV, 510 mA	140 kV, 600 mA
Maximum tube current and the maximum tube voltage possible at the maximum tube current		600 mA, 120 kV	700 mA, 120 kV
Combinations of the tube voltage and tube current at maximum output		120 kV, 600 mA	120 kV, 700 mA/ 140 kV, 600 mA
Power input	Intermittent	100 kVA	
	Continuous (standby state)	8 kVA	

*: Not available for systems distributed in China.

10.3 Safety circuits and functions

The following protective circuits and functions are available to prevent dangers to patients and operators.

1. Emergency buttons
2. Touch switches
3. Door interlock function
4. Lamp display output during CT system operation, display function during X-ray irradiation
5. Functions to prevent accidental X-ray irradiation
   The following protective circuits have been prepared to prevent irregular X-ray irradiation:
   a. X-ray filament circuit breakage detection circuit
   b. Anode drive circuit breakage detection circuit
   c. X-ray tube assembly overheating prevention circuit
   d. High-voltage circuit ground fault (due to reasons such as poor insulation) detection circuit
   e. Overload prevention function
   f. Overvoltage prevention function
   g. Function for protecting X-ray tube assembly via residual HU management
   h. Backup timer function for protecting against X-ray irradiation that exceeds the specified time
   i. Simultaneous irradiation prevention function (I/O interface)

A

Technical Descriptions

This appendix provides users with technical descriptions of measures to be taken when a problem occurs.
Technical descriptions for installation and maintenance technicians are provided in the following documents.
Technical Guide: Principles of Operation, Technical Guide: Installation and Adjustment, and Technical Guide: Maintenance and Inspection

A.1 Allowable environmental conditions

This system was not designed to be transported or stored by users. However, the conditions for transportation before installation and for storage of this equipment are as follows:

Item	Conditions
Ambient temperature	-10°C to 55°C
Relative humidity	10% to 90%
Atmospheric pressure	700 hPa to 1,060 hPa
Handling conditions	Must be protected from water

Note that if the relative humidity is in the range from 10% to 55%, the ambient temperature must be at or below 55°C; from 56% to 75%, at or below 50°C; from 76% to 85%, at or below 45°C; and from 86% to 90%, at or below 40°C. All of these combinations of relative humidity and ambient temperature also require that there is no condensation.
The operating conditions of this system are as described below.

Item	CT examination room	Control room
Ambient temperature	20°C to 28°C (When not in use: -5°C to 33°C)	10°C to 28°C (When not in use: -5°C to 33°C)
Relative humidity	35% to 80%	35% to 80% (There must be no condensation.)

If the power to the CT system distribution board of the hospital facility is turned off, turn it on one hour after the temperature and humidity of the CT examination room and the control room have reached the required levels.

A.2 Power supply facility and grounding conditions

A.2.1 Power supply facility conditions

Item	Conditions	
Power supply voltage	Three-phase 380 V AC	Three-phase 400 V AC
Power supply frequency and capacity range	50/60 Hz ±1 Hz	
Rate of voltage fluctuation due to load changes	5% or less	
Power supply voltage fluctuation rate	±10%	
Power supply capacity	100 kVA	
Resistance of apparent power supply	0.09 Ω or less	0.10 Ω or less
Circuit breaker capacity	150 A (150 A*1)	125 A (150 A*1)
Line current value	150 A (180 A*1)	135 A (160 A*1)

*1: When the optional 84 kW system configuration is used.
When installing an earth leakage breaker, note the following points.

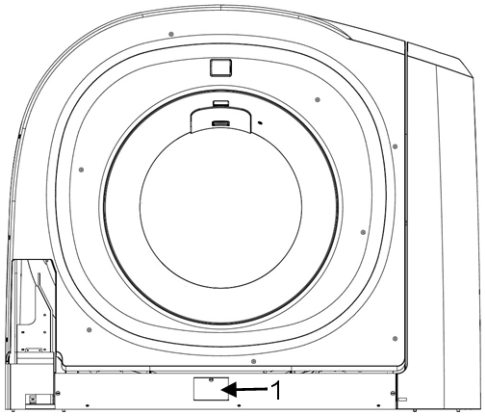
- The CT system uses an inverter for the main X-ray circuit and the motor drive circuit. Therefore, it generates high-frequency leakage current.
- In order to prevent the CT system from malfunctioning, set a minimum of 100 mA for the current to be detected. Use of an earth leakage breaker designed to suppress earth leakage trips due to harmonics is also recommended. (Recommended earth leakage breakers designed for harmonics include the NV series from Mitsubishi Electric and the EG/SG series from Fuji Electric.)

A.2.2 Grounding conditions

Connect the power supply to an earthing terminal for which the earthing resistance has been adjusted to 10 Ω or less (when using a 380/400 V power voltage input).
Collectively connect the protective earth conductors of the scanner gantry and operator console to the protective earth terminal on the hospital's distribution board.

A.3 Disconnecting the equipment from the power supply

The circuit breaker used to electrically disconnect the equipment from a (commercial) power supply is inside the power supply cover located at the bottom of the back of the scanner gantry, as shown in the following figure. To turn off the power, open the power supply cover by turning the screw that holds the cover in place, and then pull the circuit breaker handle down to the left.



1. Power supply cover

A.4 Modification of the equipment

DO NOT MODIFY THE EQUIPMENT.
In order to maintain its effective quality and safety, medical equipment is strictly regulated by law. If you modify medical equipment, the act of modification itself might be in violation of the law. Furthermore, such acts might compromise the quality, effectiveness, or safety of the equipment, and could make you liable for any injuries or deaths that result. For these

reasons, we are unable to respond to requests to modify equipment that qualifies as medical equipment under the law after the delivery of such equipment.

CAUTION

Do not attempt to modify this equipment without approval from FUJIFILM Healthcare Corporation.

CAUTION

Any modifications made to this equipment require inspections and examinations. For this reason, we cannot guarantee continuous safe operation if the equipment is modified without our authorization.

A.5 Operating principles

When X-ray CT scanners were first developed, they were considered to be critical in clinical diagnoses involving the patient's head. Thereafter, CT systems for the entire body with faster scanning times were developed, resulting in a widening of their clinical application fields.
Early X-ray CT scanners used a scanning system called the "Pencil beam" system, which involved a single thin beam of X-rays that scanned the area around the patient's head by using repeated translation and rotation movements. (*Figure A-1 Principles of different scan systems* on page 127 (a))
Later, a new scanning system was developed to reduce scanning time. This system used a greater number of detectors and an X-ray beam shaped like a fan with a 3° to 10° angle as shown in (b) of the same figure, thereby reducing the number of transverse operations and reducing the scanning time to 20 to 30 seconds. This scanning system is called the "Second Generation" system, while the pencil beam system is called the "First Generation" system.
For anatomical regions such as the head, in which internal movement is not an issue during examinations, reasonably satisfactory images can be obtained at relatively low cost even with this second generation system. Therefore, this scanning technique, called the translate/rotate system, has become the mainstream CT scanner system for the head and neck area.
To further speed up scanning time, as shown in (c) of the same figure, a newer system was developed in which the fan angle of the X-ray beam was widened and the number of detectors increased to fully cover a slice section of the patient. This eliminated the translation scan system and enabled a scan to be completed only by rotating the X-ray tube assembly and a group of detectors. This system uses 300 to 1,000 detector elements and completes a 360° rotation in 0.3 to 4 seconds. In comparison with the former two systems, this new system is called the "Third Generation" CT system.
In addition to the above systems, another system was developed in which approximately 800 detector elements are arrayed around the patient, as shown in (d) of the same figure, and only the X-ray tube assembly is rotated to make a scan. This system is called the "Stationary/Rotate" system or the "Fourth Generation" system.
This Fourth Generation system is superior in terms of image quality to the early Third Generation system. However, since image quality for the Third Generation system has been improved through the adoption of a multi-channel detector system, the "Rotate/Rotate" system (the Third Generation system) has now become the mainstream X-ray CT scanner system for the entire body. The FUJIFILM Healthcare Corporation Whole Body X-ray CT System is a "Rotate/Rotate" system.

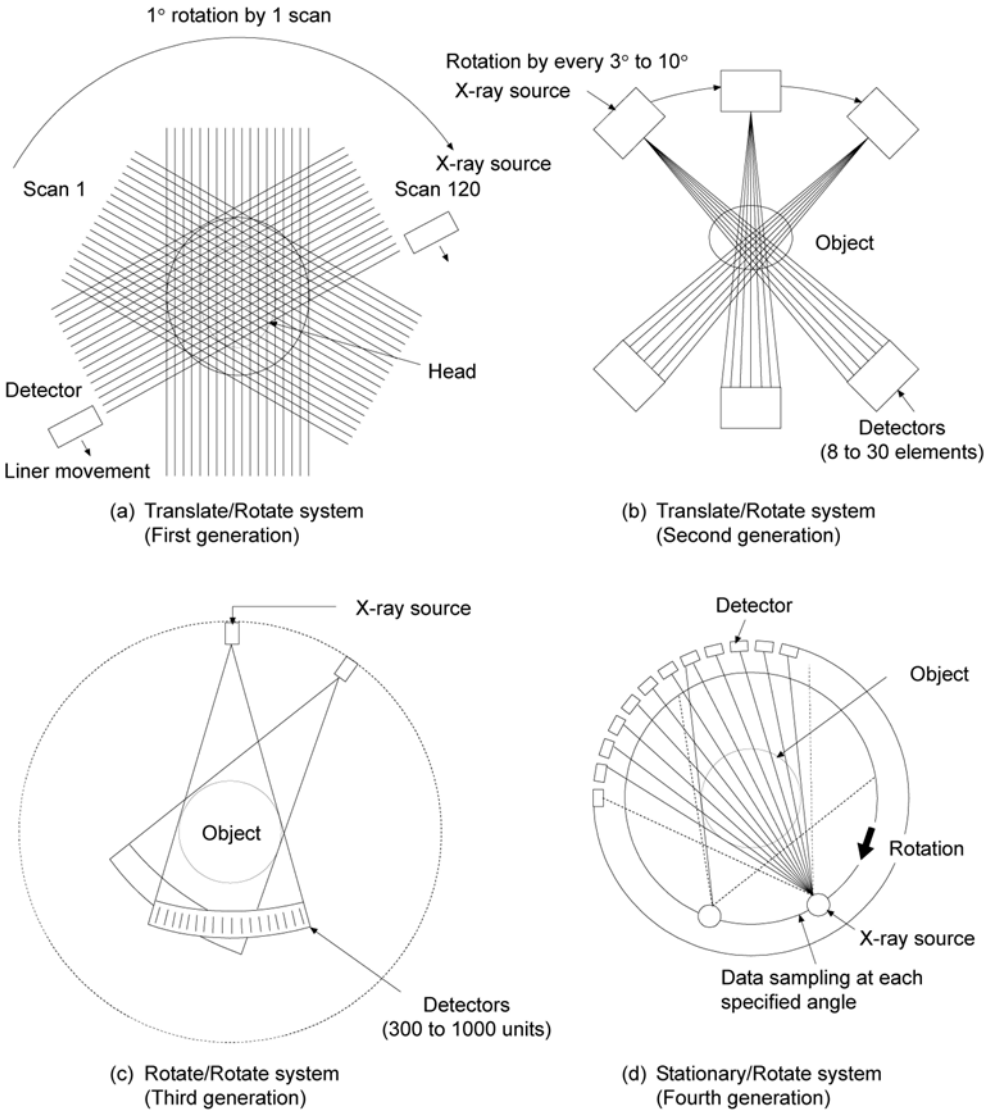


Figure A-1 Principles of different scan systems

Differences between conventional X-ray radiography, X-ray tomography and computed tomography:

If conventional X-ray radiography is used, as shown in the above figure, the object is placed in the X-ray beams radiated from the X-ray source that is considered the point source, and the image is recorded on the 2-dimensional recording medium set at the back of the object. Accordingly, in a system that uses an intensifying screen and film as a recording medium, the density at each point on the film is determined depending upon the total absorption of the X-ray beam transmitted through the object. That is, the image thus obtained is a 2-dimensional projection image of a 3-dimensional object, and all information of the object in the thickness direction is overlapped and recorded.

On the other hand, conventional tomography provides an image of only a single sectional layer perpendicular to the X-ray beam by making the X-ray source and recording system move synchronously. In rotational axial tomography, a tomographic image perpendicular to the longitudinal axis of the patient can be obtained.

When conventional tomography is used:

1. Images might be blurred depending on the distance from the focal plane.

2. Since the image on film includes not only the image on the focal plane but also a blurry image on the planes in front of and behind the focal plane, it is difficult to reproduce the information at low contrast even on the focal plane.

3. The images on the planes other than the focal plane are produced with artificial image blur inherent to the direction of movement and distance between the X-ray source and the film.
   The CT system projects a fan-shaped X-ray beam from many different directions, collimated thinly in the direction perpendicular to the longitudinal axis of the patient, and the intensity of the X-ray beam that penetrates through the patient's body is detected by the high sensitivity X-ray detector at each X-ray projection. Based on each of the acquired data, a distribution image of X-ray absorption coefficients in the sectional plane is reconstructed and displayed. As a result, a CT image is produced without any overlaps of images other than the desired slice image, resulting in the provision of an accurate tomographic image. This is the greatest feature of the CT scanner system. Image contrast is improved because no images are overlapped other than the specified slice. Furthermore, because a thinly (or narrowly) collimated X-ray beam is used, the influence of scattered X-rays is so small that image sharpness is improved.

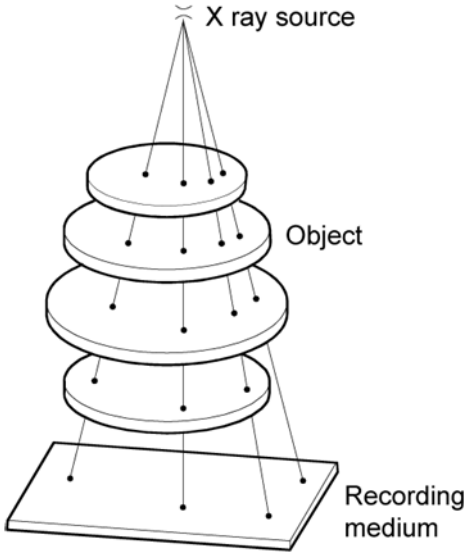


Figure A-2 Conventional X-ray radiography

A.6 Dimensions and weight

A.6.1 Scanner gantry and patient table (combination of CT-WT-22 and CT-WT-23)

(1) Dimensions (unit: mm)

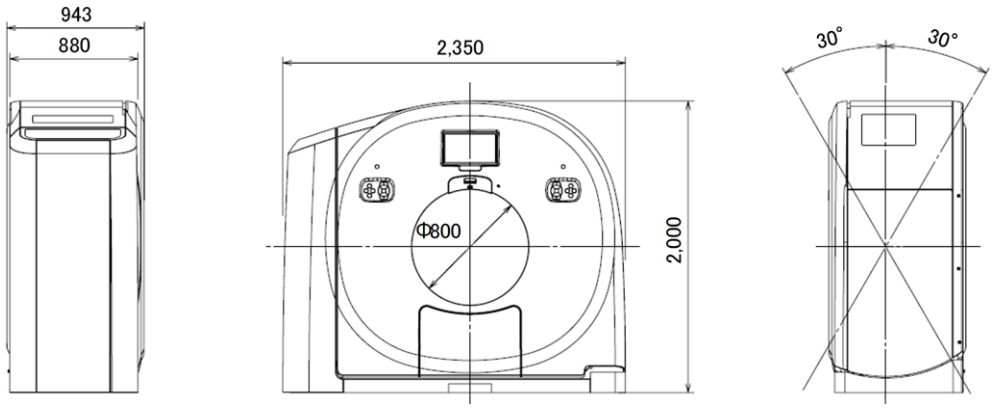


Figure A-3 Front view and side view

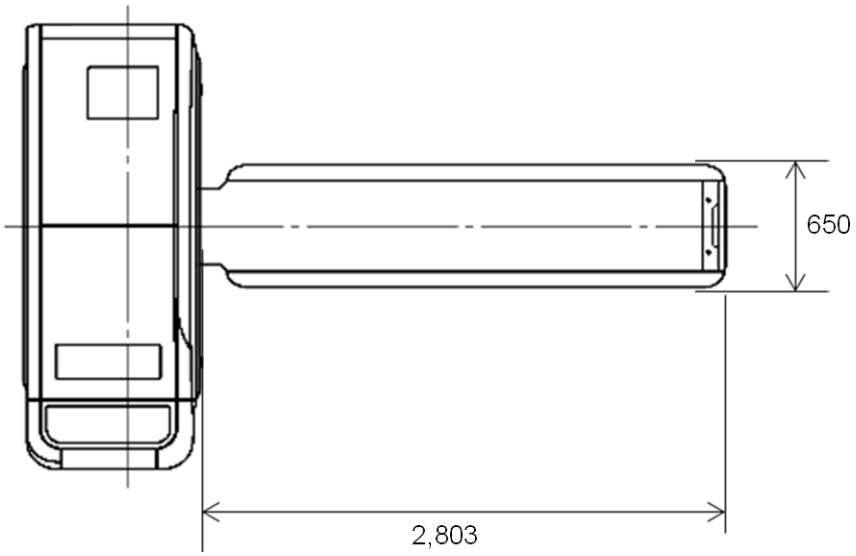


Figure A-4 Top view

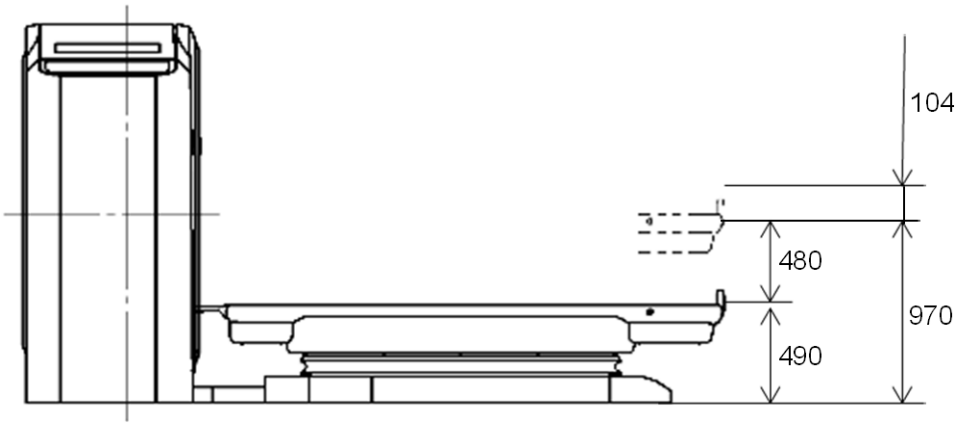


Figure A-5 Side view

(2) Weight

- Scanner gantry
  2,200 kg
- Patient table
  500 kg

A.6.2 Operator console

The dimensions and weight of the monitor, keyboard, and mouse might vary, because any compatible product can be used for these components.

(1) Dimensions (unit: mm)

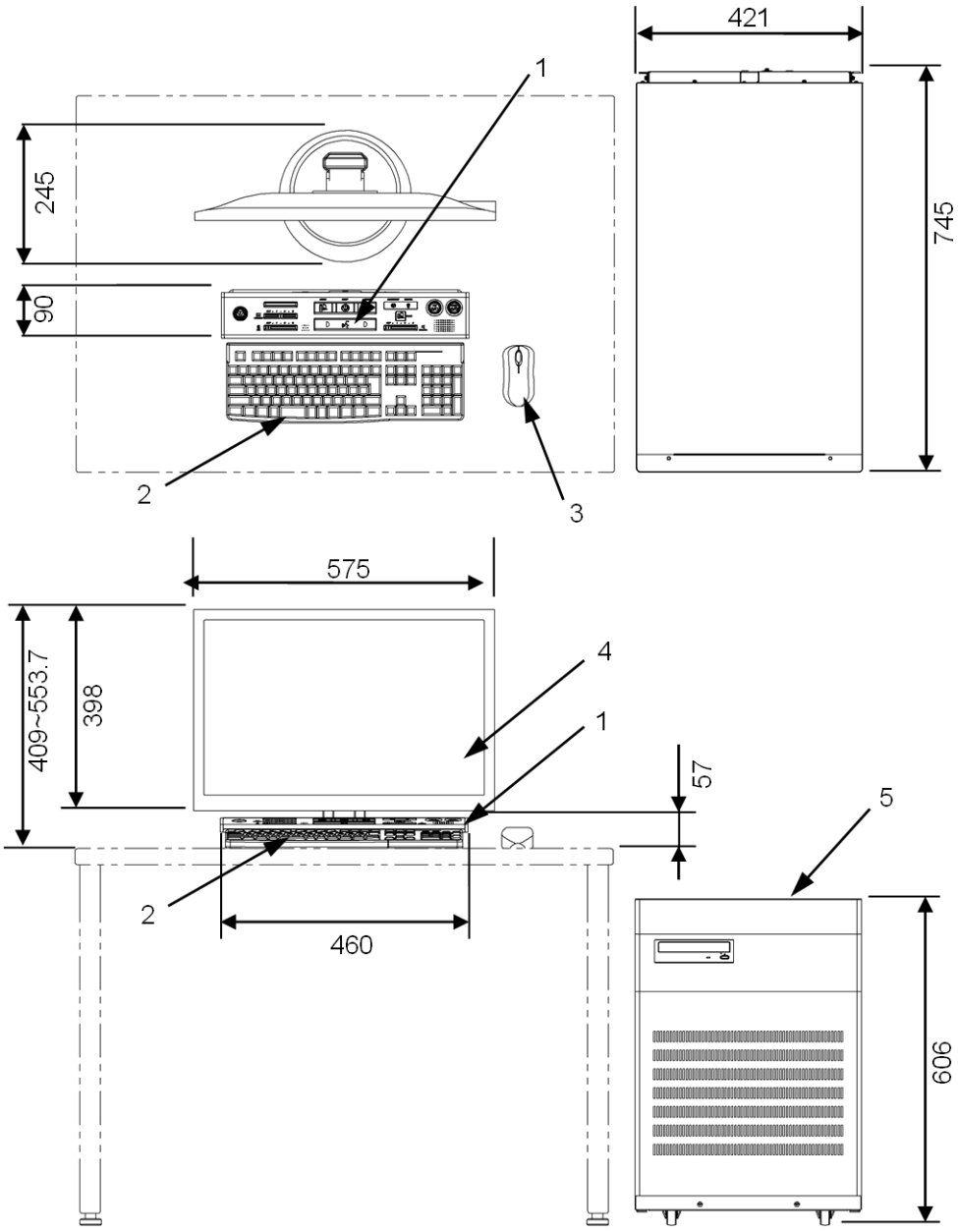


Figure A-6 Operator console, intercom box, and monitor

1. Intercom box
2. Keyboard
3. Mouse
4. Monitor
5. Main unit of operator console

(2) Weight

84 kg (main unit of the operator console, intercom box, and monitor)

A.7 Guidelines on network connection

1. Introduction
   The performance of the DICOM application (for tasks such as image transfer, filming and MWM) greatly depends on the network environment of the facility. Building and maintaining a network environment, therefore, is very important. The following describes guidelines and points to be checked when building and maintaining a network environment.
2. Guidelines
   The following provides guidelines for building a network environment.
   - We recommend contracting the building and maintenance of the facility network to a professional service provider.
   - Ask the service provider to evaluate the capability of your network design, including the installed equipment and the connection topology.
   - In addition, have the service provider verify the capability of your network performance.
   - When building the network, introduce security measures such as a VPN or a firewall, according to the security policy of the facility.
3. Points to be checked when building a network environment
   The following lists points to be checked when building a network environment.
   - Do the cables that are used comply with the applicable standards?
   - Does the total length of cables meet the applicable standards?
   - Are the laid cables adequately protected without being left exposed?
   - Is any heat-generating equipment or any noise sources, such as a power supply, located near the patient table?
   - Does the cascade arrangement of the repeater hub meet the applicable standards?
   - Does the arrangement of the routers, switches, and hubs take traffic considerations into account?
   - Is network equipment installed in positions that make maintenance easy?
   - Is network equipment fixed in place by using clasps, brackets or other suitable devices?

   The following table shows the restrictions imposed by the major standards.

Standard	10BASE-T	100BASE-TX	1000BASE-T
Between a repeater hub and a terminal	100 m	100 m	100 m
Between repeater hubs	100 m	5 m	5 m
Maximum number of repeater hubs	4	2	2
Between a switching hub and a terminal	100 m	100 m	100 m

Standard	10BASE-T	100BASE-TX	1000BASE-T
Between switching hubs	100 m	100 m	100 m
Maximum number of switching hubs	7 (in ideal circumstances)	7 (in ideal circumstances)	7 (in ideal circumstances)

A.8 Connection to a network

When connecting this system to a network*, pay attention to the following points.

- Connecting this system to a network that also contains other types of equipment can might cause unforeseen problems for the patient, the operator, or a third party.
- The user must identify, analyze, assess, and control such problems.
- Continuous changes made to the network connection can induce new risks that require additional analysis.

* "Connecting this system to a network" refers not only to the act of connecting the system to a network that was already in place when the system was installed, but also to modifications made to the network connection. These modifications include the following:

- Changing the network connection settings
- Adding new equipment to be connected to the network
- Removing equipment currently connected to the network
- Updating equipment connected to the network
  (Example: Updating the software used on equipment connected to the network)
- Upgrading equipment connected to the network
  (Example: Adding functions to equipment connected to the network by replacing the software used on such equipment.)

A.9 Interlock

This system provides an interlock mechanism that is necessary to prevent contact between the scanner gantry and the tabletop of the patient table.
The interlock generates a buzzer sound three times if vertical or lateral-shift movement of the patient table or tilting of the gantry is stopped. Also note that pressing a gantry operation panel button that is not lit will not start any operation.
The operating range of the interlock varies depending on the height of the patient table, the vertical shift position, and the gantry tilt angle. Each possible operating range is displayed on the Touch Vision initial screen.

- If the tilting movement of the scanner gantry or the vertical shift movement of the patient table is stopped by the interlock, you can cancel the interlock by changing the height of the patient table.

- If vertical movement is stopped by the interlock, you can cancel the interlock by changing the tilt angle of the scanner gantry or the vertical shift position of the patient table.

A.10 Application Specification

This system is intended for use as follows.

1. Medical purpose
   CT examination (Diagnostic imaging)
2. Patient population
   This system can be used on any body part of a patient of any age, race, or nationality.
   The patient table can withstand a maximum load of 250 kg, and equipment operation is guaranteed when the patient's body weight is equal to or less than this maximum load.
   This system can be used to examine both healthy patients and patients suffering from an illness. However, the patient's physical condition must allow them to lie on the patient table.
   An examination is to be conducted only when deemed necessary by a medical doctor.
3. Intended region of body or type of tissue
   This system can be used to perform examinations of the entire body, including the head.
   Movement of the target region must be minimized.
4. Intended profile of operators
   This system is intended to be operated only by medical doctors and radiography technicians (qualified personnel).
   This system does not require special training as long as the operator has the necessary qualifications.
   After installation, our service representatives will provide training on equipment usage methods, based on the instruction manual.
   An applicationist dispatch program is also available for a separate fee.
5. Intended operating conditions
   This system is intended for use in a radiation-controlled area at the specified temperature and humidity.
   It is assumed that this system will be used every day except holidays, and that it will also be used on holidays at emergency hospitals.
6. Operating principle
   The basic principle of X-ray CT systems is based on the following theorem proved by Austrian mathematician J. Radon.
   "A 2-dimensional or 3-dimensional object can be uniquely reproduced from the infinite set of its projection data."
   Here, an X-ray CT system displays a cross section of the object by reconstructing the distribution image of X-ray absorption coefficient through use of the X-ray attenuation data as the projection data.
7. Usability in terms of transportation, storage, operation, repair and disposal
   Environmental conditions for transportation and storage are as described below.
   (a) Ambient temperature: -10°C to +55°C

(b) Relative humidity: 10% to 90%
Note that if the relative humidity is in the range from 10% to 55%, the ambient temperature must be at or below 55°C; from 56% to 75%, at or below 50°C; from 76% to 85%, at or below 45°C; and from 86% to 90%, at or below 40°C. All of these combinations of relative humidity and ambient temperature also require that there is no condensation.
(c) Atmospheric pressure: 700 hPa to 1,060 hPa
The system is to be transported by a professional carrier.
Operation training will be provided when the system is installed, based on the instruction manual.
An applicationist dispatch program is also available for a separate fee.
Repairs are carried out by FUJIFILM Healthcare Corporation or a provider authorized by FUJIFILM Healthcare Corporation.
Repair personnel must have undertaken preliminary training at FUJIFILM Healthcare Corporation.
System disposal must be carried out by a disposal company in compliance with the laws that are applicable at the time.

A.11 Combination of equipment

This system can only be used in the following combinations. Models are described on the component nameplate.

Component	Type
Scanner gantry	CT-WS-21
Patient table (either of the models listed on the right)	CT-WT-22
	CT-WT-23
Operator console	CT-OC-22

A.12 Compliance with standards

This system complies to the following standards.

- IEC 60601-1:2005+A1:2012 and JIS T 0601-1:2017
- IEC 60601-1-2:2014 and JIS T 0601-1-2:2018
- IEC 60601-1-3:2008+A1:2013 and JIS T 0601-1-3:2015
- IEC 60601-2-44:2009+A1:2012+A2:2016 and JIS Z 4751-2-44:2018
- IEC 60601-2-28:2017, IEC 60522:1999, IEC 60336:2005, IEC 60613:2010, JIS Z 4751-2-28:2018, JIS Z 4121:2009, JIS Z 4120:2008 and JIS T 60613:2013
- IEC 60825-1:2007 and JIS C 6802:2011

A.13 IntelliEC

A.13.1 Overview

IntelliEC automatically controls the tube current so that the image quality target value specified by the operator before scanning is achieved. IntelliEC has two modes (SD mode and CNR mode) with different control methods. Operators can select the more suitable of the two modes according to the examination to be performed.

A.13.2 Image quality target value

Image quality is closely related to image noise (image SD: standard deviation). If the image SD is small, signals can be correctly detected instead of being covered up by noise. However, if the image SD is large, signals are covered up by noise and are difficult to detect. In the SD mode, when the operator directly enters the target image SD, the dose is controlled based on the entered image SD. Therefore, you can perform a scan by using a dose that is appropriate for the size of the patient.
The contrast-to-noise ratio (CNR) is defined as contrast (the difference in the CT value between signals and surrounding tissues) that is eliminated by the image SD. CNR is a parameter that greatly affects signal detection. For signal detection, not only the image SD but also the contrast is very important. In contrast scanning, the contrast varies depending on the scan tube voltage and the patient size.
In the CNR mode, the dose is controlled, taking the contrast changes of patients in contrast scanning into consideration, so that images have an appropriate signal detection function regardless of the patient size and scan conditions.

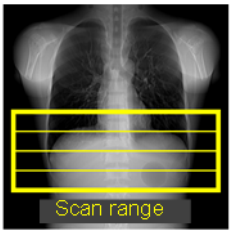
A.13.3 Control methods

IntelliEC uses scanogram data to calculate, in advance, the scan tube current at which the image quality target value can be achieved. The tube current is controlled so that the actual current matches the calculated planned tube current. In addition, to moderate the changes in the x-ray transmission intensity within the same cross-section, the planned tube current is calculated to be sinusoidal so that the tube current becomes lower in the direction where the water approximation equivalent length is shorter, and higher in the direction where the water approximation equivalent length is long. In other words, IntelliEC controls the tube current three-dimensionally, taking both the body axis direction (the z axis) and the inside cross-section (within the x-y plane) into consideration.

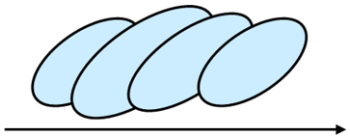
- Image quality target value
  Target image SD (SD mode) set by the operator
  Reference SD (CNR mode) set by the operator
- Applied scanogram
  AP, PA, LAT
- Applied scan
  Normal scan, volume scan, continuous dynamic scan, intermittent dynamic scan

A.13.4 Operation overview

1. Take a scanogram of the patient.
2. Set the scan range.

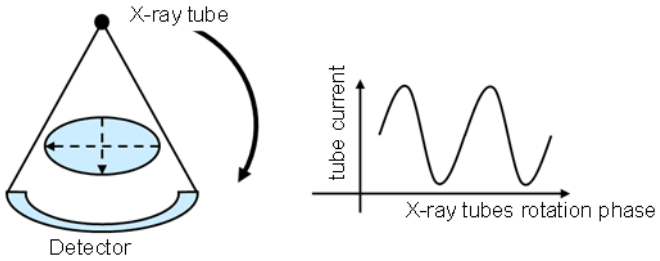


3. By using the scanogram raw data, an oval cross-section model, equivalent to water, is built along the body axis of the patient. Thereafter, the tube current that achieves the image quality target value for this model is calculated.



The arrow indicates the body axis direction.

4. Enter the target image SD or reference SD as the image quality target value. Note that the CNR mode can be used by setting the contrast button in the Scan Condition Settings window, which indicates contrast scanning, to ON. If you set the contrast button to OFF, the CNR mode functions in the same way as the SD mode.
5. Change the lower and upper limits of the tube current for scanning, as needed.
6. The planned tube current for scanning is calculated.



The tube current decreases in the direction in which the equivalent length is short.

7. Perform the scan.

A.13.5 IntelliEC Plus

IntelliEC Plus is a function that links with IntelliEC and Intelli IP Advanced or Intelli IPV (optional). A suitable tube current is automatically calculated by taking the image noise reduction effects of Intelli IP Advanced or Intelli IPV (optional) into consideration. Compared to when such linkage is not used, a scan can be performed by using a lower dose. For this reason, a reduction of radiation exposure can be expected. However, if the Intelli IP Advanced or Intelli IPV (optional) level is set too high, the dose to be irradiated becomes low, and the expected image quality might not be obtained. Examine the IntelliEC Plus settings carefully.

B

Frequently Asked Questions

B.1 Problems and corrective actions

B.1 Problems and corrective actions

What do I do if the system freezes up?

Try shutting down or restarting the system by using one of the following procedures.

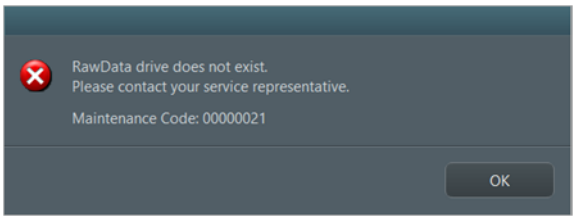
- If you can use the mouse and click the menu:
  From the menu in the lower left corner of the window, select [Shut Down] to display the window for selecting the shutdown mode. Select [Restart Application], and then click the [OK] button. The software restarts.
  If the problem is not resolved after the software restarts, from the window for selecting the shutdown mode, select [Shut Down], and then turn the power on again.
- If you cannot select the menu:
  Press Ctrl+Shift+Spacebar to display the window for selecting the shutdown mode. Press the Tab key to move the cursor to [Shut Down], and then press the Enter key. The system shuts down automatically.
- If you are unable to use the mouse or the keyboard:
  Press and hold the CPU power button on the operator console to shut down the system.
  Performing this operation might corrupt internal files. Always contact the FUJIFILM Healthcare Corporation call center before performing this operation.

C

Messages Displayed by the Equipment

C.1 Message dialog boxes

The message dialog boxes displayed by the equipment consist of the following.
For message details, see *C.2 Message list* on page 142 because the message details vary depending on the situation.



Item	Description
Message type	: Error : Warning : Information : Check
Message details	Messages based on the message type and messages that indicate measures are displayed.
Maintenance code	Some messages show maintenance codes. These codes are used by our service personnel.

C.2 Message list

If a message is displayed, perform the operations indicated in the instructions or continue the processing.

Type	Message details
Error	Could not acquire the RawData information. Perform the Rebuild RawData Database.
Error	Failed to acquire the ECG data. Please shut the system down, and then restart.
Error	RawData could not be written. There is a problem with the RawData disk. Please contact your service representative.
Error	RawData disk could not be initialized. Please contact your service representative.
Error	Could not acquire the RawData information. Please contact your service representative.
Error	Detected abnormality when the application starts. Please restart the application or shut the system down. When this message appears repeatedly, please contact your service representative.

Type	Message details
Error	HU will exceed the limit for scan with current parameters. Correct the scan parameters.
Error	Generator overload. Correct the scan parameters.
Error	The Auto Voice Settings cannot be started. Please contact your service representative.
Error	Failed to acquire the number of RawData. Please shut the system down, and then restart. And try the Rebuild RawData Database again.
Error	Could not acquire the ECG information. Perform the breath hold practice from the ECG monitor and set the ECG information.
Error	The recon. queue could not be processed due to an internal parameter error. Delete the queue suspended due to the error, and then re-register and process the queue.
Error	Cannot establish communication with the scanner gantry. Please shut the system down, and then restart.
Error	Table does not move to the specified position. Please shut the system down, and then restart.
Error	Cannot complete the scanner gantry preparation within predetermined time. Please retry. If it occurs continuously, please contact your service representative.
Error	Could not start the IRS process. Please shut the system down, and then restart. If it occurs continuously, please contact your service representative.
Error	The table height is low. Please raise the table height.
Error	The scanner gantry is in an abnormal condition. Please contact your service representative.
Error	An abnormality has occurred in the scanner gantry. Leave the system power on and allow to cool.
Error	An abnormality has occurred in the scanner gantry. Leave the system power on and allow to cool.
Error	The front cover of the scanner gantry is open. Please contact your service representative.
Error	An error has occurred in the scanner gantry. Please shut the system down, and then restart.
Error	An abnormality in the X-ray Generator was detected. Please contact your service representative.
Error	X-ray is being emitted by other system. Wait until the other system completes X-ray emission.
Error	An error has occurred in DMS. Please shut the system down and turn off the FFB on the hospital power distribution board, and then restart.
Error	The number of arcing recoveries has been exceeded. Please retry.

Type	Message details
Error	An error has occurred in the patient table. Please retry. When an error occurs even if you operate it again, please restart the scanner gantry by turning its power supply OFF and ON.
Error	An error has occurred in the scanner control. Please retry.
Error	An error has occurred in images and RawData acquisition system. Please retry.
Warning	Could not establish communication with the scanner application. Please shut the system down, and then restart.
Warning	There is a possibility that you cannot get usual image quality because detector is getting ready. Because during the detector preparation the state of the detector will change gradually, please perform a scan just after performing Warm-up and Air Calibration as soon as possible.
Warning	The system has stopped because of emergency button activation. After checking for safety, click the OK button to release the emergency status. If the examination is in progress, scanned data isn't secured, please quit the examination and restart from Patient Registration.
Warning	AutoPose could not be executed because scanogram was performed with not covered posture.
Warning	The system has stopped because of the occurrence of a backup timer error. Click the OK button to release the stop status.
Warning	The touch switch has activated. Please confirm safety, and then click OK button to release the stop status.
Warning	The scanner gantry check is operating. Please wait for a while and then retry.
Warning	A rotation encoder alarm has occurred. Please contact your service representative to cleaning rotation encoder.
Warning	The slip ring needs to be cleaned. Please contact your service representative.
Warning	Collimator movement retry has occurred. If it occurs continuously, an investigation by a log analysis is needed.
Information	It is necessary to clean up the system because of working continuously. Please shut the system down after the current patient examination, and then restart.
Information	Table limit. (Outward) Press and hold Home and Start button again to move table down.
Information	Air Calibration data is old. There is a possibility that it influence image quality. Please perform Air Calibration.
Information	The setting process will exit. Please shut the system down, and then restart.
Information	The process was stopped because ECG was disconnected. Please retry after checking that ECG is connected.
Information	Arrhythmia was determined during scanning. After determination of arrhythmia, X-ray was irradiated with high tube current.

Type	Message details
Information	Setting of Dose Modulation starting value was failed. After detection of abnormal heartbeat, X-ray was irradiated with high tube current.
Check	Data with different information already exists for the same patient ID. Do you want to proceed to scanning with this input patient information?
Check	There is a sequence with less than 70% of geometric efficiency. Do you want to continue to scan?
Check	Multiple scans will be run at the same position. Are you sure you want to continue?

D

Cybersecurity Related Matters

D.1 Overview

The cybersecurity of our medical devices complies with regulations and international standards at the development and shipping stage. It is commonly said that there is no perfect security response. To maintain and ensure security, care must also be taken during the installation, operation and use phases. For this reason, we ask that you understand the security information pertaining to this medical device, and properly manage and use it with care.

D.2 Basic precautions

- Do not connect the medical device to a network whose security cannot be trusted.
- When connecting medical devices to the network, use a firewall or other means to limit the amount of unnecessary or unauthorized traffic to the network to which the medical devices are connected.
- Ensure that all other devices connected to the network to which the medical device is connected are secured with respect to security, and are properly managed.

  Example:

  The office PC used in the medical facility is connected to a network segment different from the network segment of the medical device.

Note: Do not connect the medical device if the security of the network cannot be ensured (e.g., in the event of a security incident).

D.3 System configuration

An outline of the system configuration of the medical device is shown below.

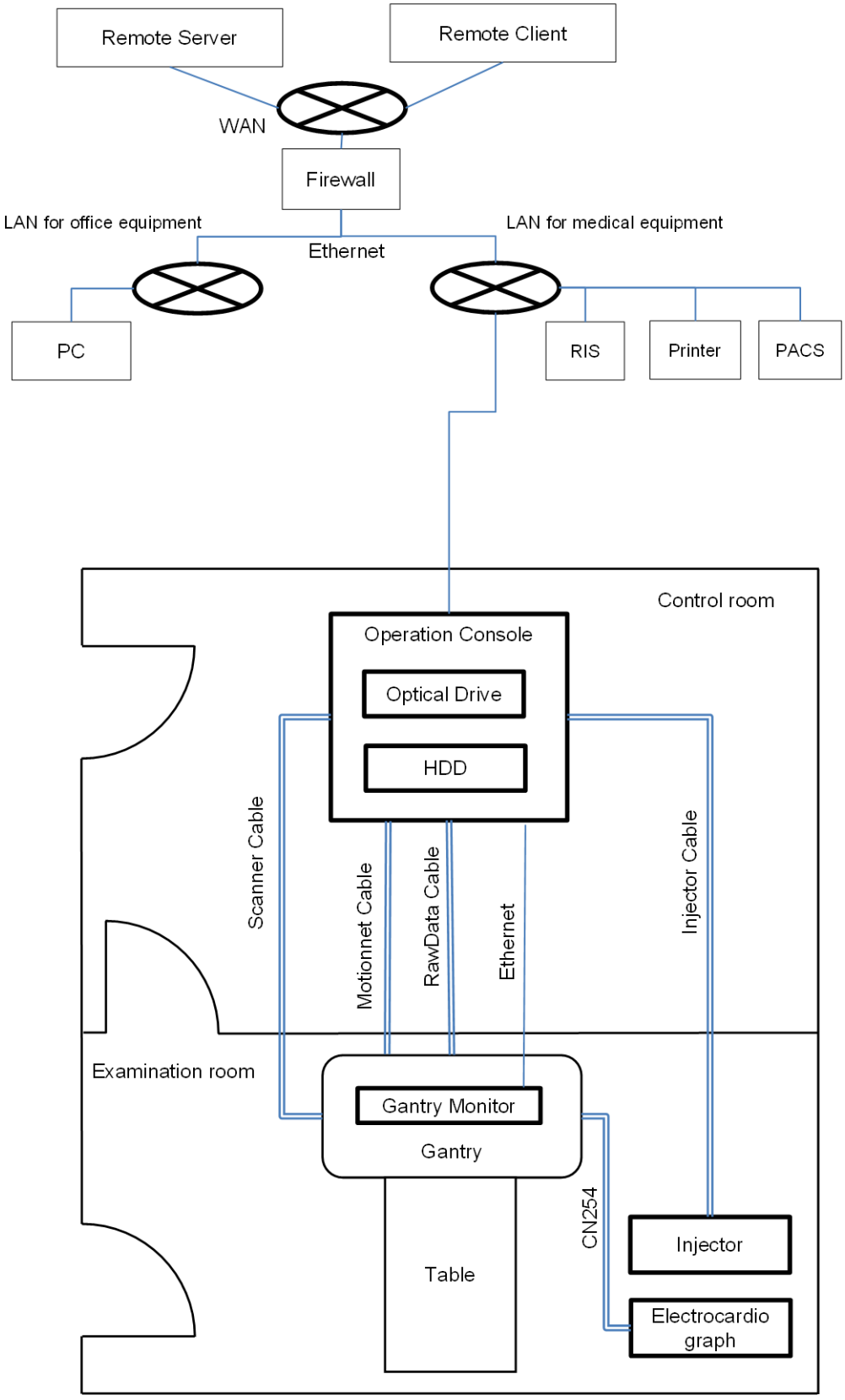


Figure D-1 Example of the medical device system configuration

D.4 Data to be transferred externally

The network, and contents of the data transfer in the medium are shown in the table below.

Table D-1 Data and equipment interfaces

Category (diagnostics/ systems)	Features	Uses	Exchange method	Transfer direction
Diagnostic data	Electronic data exchange (bi-directional data communication)	Clinical image transfer Patient Information Reception	DICOM: Ethernet	Receive/ Send
System data	Long distance control (real-time)	Remote maintenance	https/IP-VPN	Send
Diagnostic data	Electronic data exchange (bi-directional data communication)	Backup and restore of clinical imaging data	DICOM: DVD-R/CD-R	Import/ Export
System data	Electronic data exchange (unidirectional data communication)	Software version update	DVD-R/CD-R	Import

D.5 User authentication function

Only authorized users can operate the device.
The medical device authenticates the user by a user ID and password.
Only the administrator of the system can register, modify, and delete user authentication settings.
In addition, the password can be set and changed by each user.

D.5.1 User authentication (user account)

- The user ID and password limit are shown below.
  - User ID
    You can use from 4 to 16 half-width alphanumeric characters.
    No distinction is made between uppercase and lowercase.
  - Password
    Sets the minimum number of characters from 0 to 16 characters. The initial value is 8 characters.
    The following conditions are required to set the password.
    - You cannot set a password that includes the user ID.
    - Password cannot be set to less than the minimum number of characters.
    - Letters and numbers must be combined.

    * If the setting does not meet the conditions, registration is not possible.
- Passwords have an expiration date, so it is necessary to change the password regularly.

You can change the password expiration time range from 0 days to 999 days.
* Since this is not set initially, be sure to set an expiration date.

D.5.2 User types and permissions

User accounts have the following types and permissions.

- System administrator
  Manages general user accounts and operation logs.
- Protocol administrator
  Manages the scanning protocol.
- General user (scan user)
  Can operate the device.
- Service maintenance user
  Used by our service personnel for maintenance.

D.5.3 User account management features

The system administrator is responsible for registering, modifying, and deleting user accounts.
You can set the password expiration date and password length.

D.5.4 Screensavers

If there is no action for a certain amount of time, the screen saver will be automatically activated.
To unlock the screen saver, you will need to authenticate the user again.

- Protection function by ID and password input at release
  To unlock the screen saver, enter your ID and password, and re-authenticate the operator.
- You can set the time to activate a screensaver after no operation.

D.5.5 Operation logging/management functions

Log on/log off, account operations, date and time of scanning operations, and the contents of operations are recorded in the log.
If you suspect abuse, check the log on your medical device on a regular basis.
You can back up (export) the contents of the account management function and the data in the operation log.
Note: Make sure that the time is synchronized with other devices connected to the network to which the medical device is connected.

D.5.6 Emergency access features

This is a function that can operate even if a user account is not registered so that scanning can be performed in an emergency.

- The user authority is a general user (scan).
- Scanning can be performed up to five times during emergency access.

D.6 Data backup

- You can store information that the user has set up and registered on the system, on the media.
  You can also select data that the user wants to read, and restore it by reading.
- You can restore the contents set by the account function, and the data in the operation log back up.
  Only system administrators can view the log of past operations.

Note: The media on which data is exported from medical devices should be strictly managed by the customer to prevent information leakage, and prevent loss.

D.7 Data security features

D.7.1 DICOM Transfer

- The data transferred by the medical device can be sent and received using IPv6 encryption (IPsec).: (Option)
  Note: Your communication partner must also be configured to use IPv6.
- Verify the DICOM server before transferring data.
  Note: If the DICOM server is not configured correctly or the server does not exist, it will result in a transfer error, so check the destination settings.

D.7.2 Encrypting saved data: (Option)

You can encrypt data in the image data folder and patient Information folder.

D.7.3 Encrypting DICOM stored data: (Option)

It is possible to encrypt the DICOM image data stored in the media.

D.8 Software updates

- The medical equipment does not require upgrading by the customer because our service personnel will upgrade it as required.
- We will confirm the need for security patches, and provide them after checking operation.
  Therefore, the customer does not need to do this.

Note:
We continuously monitor the vulnerability of software installed in our products.

If security is likely to be compromised, we will respond promptly.

Note:

For updates to the medical device, authorized maintenance personnel will bring software that has been thoroughly tested, and instal it at the place where the target device is located.
This minimizes the possibility of software mix-ups, downgrade and malware. In addition, the maintenance employee will confirm the current configuration of the target device, and check its operation after installation on-site to make sure the update is completed. It is not possible to update the device on your own.

D.9 Detection of cybersecurity incidents

- Configuring Windows Firewall
  Control communication of the device by setting up Windows Firewall.
  If there is an unauthorized communication, block and log the communication.
- If you have detected a security incident, please contact our service department.

Note: If there is no problem with the medical device, but a security incident occurs in the hospital information system or a network-wide failure occurs, it is necessary to disconnect the equipment from the network. The device can then continue to be used for scanning. After recovery from the incident, you will be able to connect to the network again so that the device can be used automatically, including for communication.

D.10 Support information for third party software

We have confirmed the support information for the device, so we will let you know if there are any problems with end of support.
Even if support ends, please connect to a secure network in the facility in order to use the device without any problems.

D.11 Ensuring security

Please understand the following information in order to maintain security and use the device safely.

- After you have completed transmission or export, delete any images that you no longer need to store in the equipment, subject data, etc., promptly.
- Do not allow people who do not need medical care to view the contents of the screen.
  If you have taken a photograph with a camera or smartphone, please take measures to prevent information leakage, tampering or loss.
- Please keep all passwords strictly confidential so that they are not known to those who do not need them.

- Do not allow unauthorized persons to enter the location where the medical device is installed. Please ensure that equipment rooms (rooms that are normally locked without human access other than maintenance) are locked at all times if possible.
- Any backup media read or written on a non-medical device must be thoroughly malware checked before connection.
- To prevent information leakage, if you discard media, or if you dispose of medical equipment, such as by destruction, please erase the recorded data completely.

D.12 Other security features

Data transmission and reception ports and servicess

- Services that are not required for diagnostic functions have been removed.
- The external connection function that connects externally and communicates data is as follows'
    - LAN: Can be connected by wire.
      This is used for DICOM communication and remote maintenance of diagnostic images and examinee information.
    - USB: Cannot be connected.
- The opening and closing of the port used in the device is appropriately controlled by the medical device software.

Index

Manufacturer
FUJIFILM Healthcare Corporation
2-1, Shintoyofuta, Kashiwa-shi,
Chiba, 277-0804 Japan