M517-V056D
Apr. 2024

Remote-Controlled R/F SYSTEM

FLEXAVISION

F4 Package

Instruction Manual

Read this instruction manual thoroughly before you use the product.
Keep this instruction manual for future reference.

CE 0197

This medical device also complies with RoHS directive.

About the Symbols Appearing in this Operation Manual

Throughout the text in this manual, warnings and other information essential when using this unit, such as cautionary or prohibited items, appear classified as per the following:

⚠ **DANGER**	Indicates an imminently hazardous situation which, if not avoided, will result in serious injury or death.
⚠ **WARNING**	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or possibly death.
⚠ **CAUTION**	Indicates a potentially hazardous situation which, if not avoided, may result in minor to moderate injury or equipment damage.
NOTE	Emphasizes additional information that is provided to ensure the proper use of this product.

Illustrated Symbols

	Indicates an action that must not be performed.
	Indicates an action that must be performed.
	Indicates information for better performance of the product.
	States reference information.

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Operating Precautions

Read the instruction manual thoroughly before you use the product.
Keep this instruction manual for future reference.

Operating Precautions for Safety in the Use of Electric Medical Equipment

1. Only an experienced technician should operate the equipment.
2. When installing the equipment, pay attention to the following items:
   (1) Do Not install system near water faucet or similar equipment.
   (2) Install it away from potential sources of problems such as abnormal pressure, temperature or humidity, drafts, direct sunlight, dust chlorine or sulfur gas.
   (3) Avoid tilting, vibration and any impact during transportation and operation of the equipment.
   (4) Keep the equipment away from the areas where chemicals or gases are stored.
   (5) Use only the correct electrical power source with matching frequency, voltage and current (or wattage).
   (6) Check the condition of the battery power source (power and polarity) before operating the equipment.
   (7) Correctly ground the equipment.
3. Before operating the equipment, pay attention to the following items:
   (1) Check the conditions of switch contacts, polarity, dial settings, and meters, and make sure the equipment performs correctly.
   (2) Confirm that the ground is connected correctly.
   (3) Check the whole wiring is connected correctly and completely.
   (4) Pay attention when using more than one unit at a time, because it may lead to an incorrect diagnosis and cause danger.
   (5) Check the condition of the external electric circuit, which will be directly connected to a patient.
   (6) Check the condition of the battery power source.
4. While operating the equipment, pay attention to the following items:
   (1) Do Not over-exceed time or the amount of equipment use needed for diagnosis or therapy.
   (2) Observe the equipment and patient continuously for early detection of problems.
   (3) When a problem is detected with the equipment, take proper action to stop the equipment without harming the patient.
   (4) Do Not let the patient touch the equipment unless necessary.

5. After operating the equipment, pay attention to the following items:
   (1) Return the operation buttons and the dial to their original states before use in the prescribed order. Then, turn off the main power.
   (2) Do Not pull the power cable forcibly from the outlet.
   (3) When storing the equipment, pay attention to the following factors:
      (i) Keep the equipment away from the water.
      (ii) Store it away from the potential causes of problems such as abnormal pressure, temperature or humidity, draft, direct sunlight, dust chlorine or sulfur gas.
      (iii) Avoid tilting, vibration and any impact when storing.
      (iv) Store the equipment away from areas where chemicals and gases are stored.
   (4) Clean all attachments, cables and contacts, and store them in one place.
   (5) Keep the equipment clean to avoid problems during the next use.
6. If the equipment is found to be out of order, do not try to repair it. Immediately call a certified repair technician for repair.
7. Do Not modify any part of the equipment.
8. Preventive maintenance
   (1) The equipment and its parts should be periodically checked.
   (2) If the equipment has not been in operation for an extended period of time, test it prior to actual operation to make sure it works correctly and safely.
9. Correctly operate the system according to the operation manual.

Precautions in Usage

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

⚠ WARNING

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

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

Never modify the equipment.

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

Perform periodic inspection.

Preventive maintenance is required to maintain long-term safety and performance of the equipment.
The "7 Maintenance" chapter in this manual gives detailed descriptions of daily and periodic maintenance and inspection that a user should perform.
As for the maintenance and inspection that only specially trained experts can perform, utilize the maintenance agreement program offered by Shimadzu.

Repair and maintenance of the inside of the equipment can only be performed by engineers assigned by Shimadzu.

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

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

⚠ CAUTION

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

In order to operate the equipment safely, an explanation of the operation needs to be given. When installing the equipment, Shimadzu service personnel explain the operating procedure using this operation manual. Follow their directions and operate the equipment correctly.

☞"International Standards" P.21

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

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

■ Be sure to Read the Safety Items to Prevent Explosion, Electric Shock, or Injury

⚠ DANGER

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

Use of such gas may cause an explosion.

⚠ WARNING

Check the condition of the patient before conducting a study.

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

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

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

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

Should such liquid drip on equipment surfaces, wipe it off immediately. Any such liquid entering into system electronics may cause failure or malfunction.
Should liquid drip on the operation panel or enter the covers, immediately turn off the power and contact your Shimadzu service representative.

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

Continued use may damage the equipment and cause injury.

Do NOT open the covers of the equipment.

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

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

Otherwise, it may cause injury.

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

This can result in electric shocks.

Patients having difficulty with physical activity must be assisted by a caregiver.

When a caregiver assists a patient, the operator must ensure the safety of the caregiver as the patient to operate the equipment.

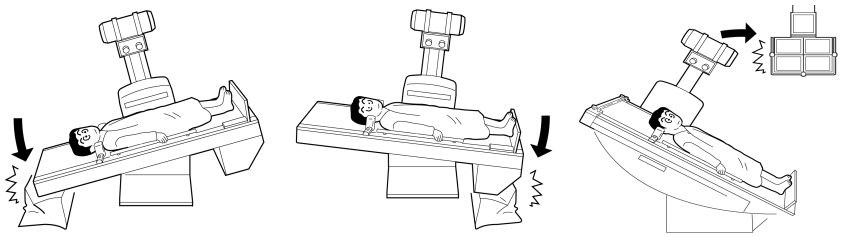
⚠ WARNING

Thoroughly confirm the safety of patient in squeeze compression.

Squeeze compression can fracture the patient's ribs if not performed correctly. After the squeeze compression, press the [Squeeze Compression] button to turn it off.
If the imaging unit or tabletop is moved while the compression cone is operating, the compression cone may collide with the shoulder rests or foot rest and could be damaged.

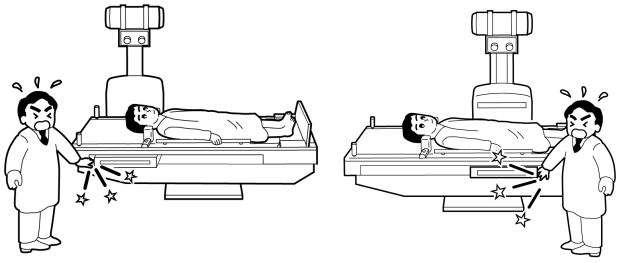
Confirm that there is no apparatus within the operating range when moving the X-ray diagnostic table.

Ensure that no desk, chair, stretcher, foot switch, monitor suspension, etc. is placed within the operating range.
The apparatus may be crushed by or collide with the equipment, causing damage.



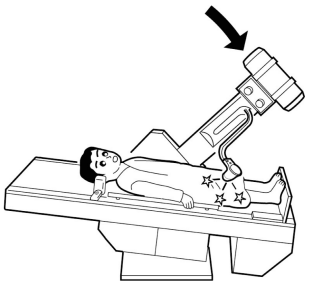
Do NOT put your hand between the tabletop and main frame while moving the imaging unit.

Otherwise, your hand may be caught and injured.



Pay attention to the compression cone in oblique projection.

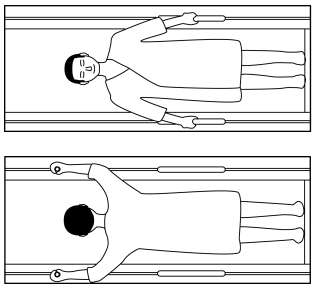
The compression cone, or, when the cone is stored, the projecting portion including the compression unit will be in close proximity to the patient and/or system accessories when inclining the imaging unit in the direction of the patient's feet, or when moving the imaging unit and the tabletop horizontally with the imaging unit inclined to the patient's feet.
Ensure that the compression unit does not hit the patient and/or system accessories. Otherwise, the patient may be injured or the accessories may be damaged.



⚠ WARNING

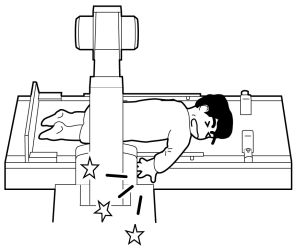
The operator must instruct the patient to hold handgrips firmly on the tabletop.

Otherwise, the patient may fall off the tabletop and be injured.



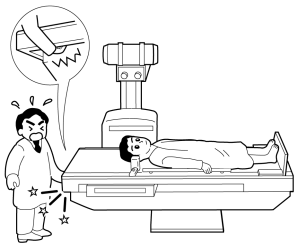
Ensure that the patient does not put his or her hand between the tabletop and imaging unit when moving the imaging unit.

Otherwise, the hand may be caught.



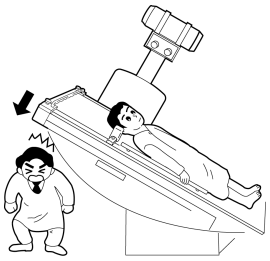
Ensure that the operator does not put his hand between the tabletop and main frame when moving the tabletop.

Otherwise, the hand may become caught.



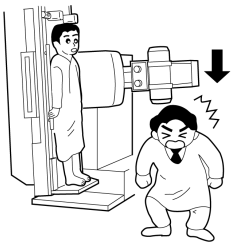
Confirm that no one is under the X-ray diagnostic table.

The person may become caught under the table and injured.



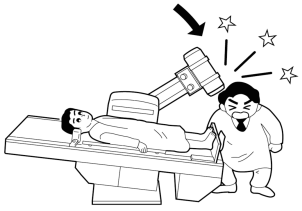
Extra caution is required in using the local console with the tabletop at, or moving to, the vertical position.

When operating the optional local console, be careful that the X-ray tube unit or other unit does not hit the operator's head while the imaging unit is moved longitudinally with the tabletop in a vertical position.



Extra caution is required in using the local console for oblique projection.

When operating the optional local console, be careful that the X-ray tube unit or other unit does not hit the operator's head while the imaging unit is inclined.



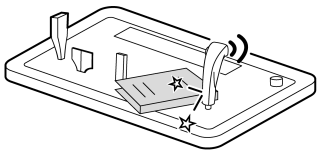
Do NOT perform any maintenance work on any part of the equipment during clinical use.

It may cause injury.

⚠ CAUTION

Do NOT place anything on the console.

The system may be unintentionally activated if anything hits the operation lever.



Do NOT place anything on the control cabinet.

The internal devices may be damaged if anything falls into the control cabinet ventilation openings.

Do NOT hit a stretcher against the front cover of the diagnostic table.

The front cover may be damaged.

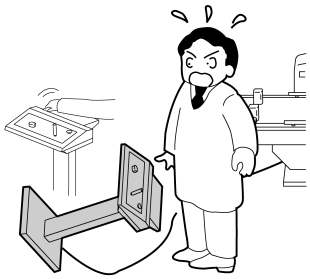
Before using the equipment, confirm that the adjusters are configured to appropriate exposure settings for fluoroscopic or radiographic operation.

After using the equipment, leave the hand switch to which the equipment power cord is connected open for sake of safety.

Move the local console and Monitor Cart by carrying them with both hands; one each side of the console section on the local console and one each side of the tabletop on the Monitor Cart.

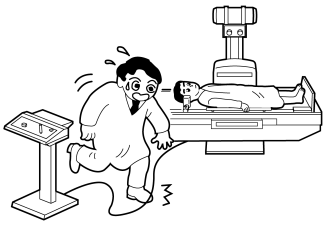
If you attempt to move them with one hand they could fall over.

* Do Not use the Monitor Cart on a floor that is tilted more than 5 degrees.
It could fall over.



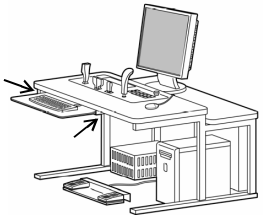
Watch out for the cables of the local console and Monitor Cart.

If you catch the cable with your foot the local console or Monitor Cart could fall over.



Do NOT put your fingers into the rails fitted at each side of the keyboard table.

When pulling out and stowing away the console's keyboard, you could trap your fingers between the rails at the sides and the drawer stops.



⚠ CAUTION

Carefully operate the X-ray diagnostic table to avoid the contact between wheelchair patients and the diagnostic table.

Be extremely careful about the movement of table tilting and Imaging Unit in the vertical position.

NOTE

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

"1.7 Statement of Compliance [For Europe]" P.21

■ Cautions on Environmental Conditions

⚠ WARNING

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

The use in an oxygen-rich environment may cause fatal or serious injuries or damage to the equipment due to easy ignition.

⚠ CAUTION

Be sure to use the equipment under the specified environmental conditions:

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

"1.2 Environmental Conditions" P.8

Note also that there must be no sudden changes in temperature or humidity. This causes condensation, which can lead to trouble.
The calorific power of the power supply is not significant enough to affect the use environment of the equipment.

"X-ray High-voltage Generator" P.92

Confirm the power specifications prescribed for each system configuration.

The rated power of the equipment varies depending on the type of X-ray high voltage generator to be used.

"The images are not only displayed on the monitor but also recorded on the internal memory storage. The user can play back the recorded images and apply various processing on those images. When combined with the X-ray radiography unit for the second X-ray tube (optional), it is also possible to perform radiography using the second tube." P.6

Do NOT disconnect cords, cables and other connections, unless it is required.

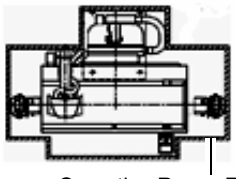
Ground the equipment using ground wires.

To reduce the risk of electric shock, be sure to follow the installation manual to perform the grounding work without fail.

The multibox(MB-01) uses an AC power outlet that accepts three pin plugs for grounding purposes. Do NOT connect the multibox(MB-01) to power strips, extension cords, or overloaded electrical circuits.

Do NOT place any apparatus within the operating range.

- In order to avoid damage to the equipment by interference from another apparatus, do not put any other apparatus inside the operating range marked with a tape pasted onto the floor around the equipment.
- While operating the equipment, the operator and caregiver must not enter the operating range for their safety.



Operating Range Tape

Contact your Shimadzu service representative for installation and relocation of the equipment.

NOTE

- When isolating the equipment from the power supply, open the circuit breaker or knife switch of the switchboard that the equipment is connected to.
- Prepare some locking mechanism to keep an OFF position of the circuit breaker and knife switch.

■ Cautions on Fluoroscopy/Radiography

⚠ WARNING

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

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

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

Be aware of the potential for X-ray irradiation.

If X-ray equipment is not used correctly the operator, the subject, and other persons may receive a greater dose of radiation than is necessary. Nobody other than the subject should remain in the examination room during irradiation. If for some reason another person has to be in the examination room, that person must take adequate measures to protect themselves against radiation (protective apron, screen, etc.).

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

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

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

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

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

⚠ WARNING

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

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

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

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

⚠ CAUTION

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

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

Perform the warm-up if an arc occurs.

Suddenly using the X-ray tube unit near the nominal X-ray tube voltage (above 100 kV) after using the unit at a relatively low tube voltage (80 kV max.) for a prolonged period may result in arc. This arc occurs due to loss of the warm-up effect at high tube voltage after the X-ray tube unit is used at a relatively low tube voltage for a prolonged period. In this case, warm-up the X-ray tube unit by referring to the procedure described in the R/F system operation manual (M506-E051).

Do NOT perform unnecessary standby operations.

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

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

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

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

It may cause a radiation hazard.

Appropriately adjust the collimator to eliminate the range that intense X-rays directly make contact with the FPD as much as possible before use.

A false image may appear if intense X-rays make direct contact with the FPD over a wide area without passing through a subject.

■ Cautions on the FPD

⚠ DANGER

Do NOT touch plugs or connectors with wet hands.

You could be seriously injured or killed by an electric shock.

⚠ WARNING

The surface of the FPD might be hot, such as right after fluoroscopy.

The temperature might reach 45 degrees.
For safety, contact between the patient and FPD should be less than 10 minutes.

⚠ CAUTION

Do NOT connect the FPD to devices other than those specified.

This could cause fire or electric shock.

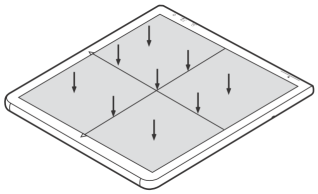
Do NOT turn the system power on while the FPD is wet with condensation.

This could cause fire or electric shock.

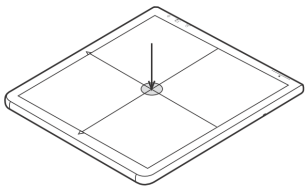
Do NOT rest objects on the FPD, or exceed its load restriction.

Objects could fall off the unit and cause injury.
In addition, using the unit with the load restriction exceeded could cause failure or equipment damage.

Load restriction
Uniform load (entire area): 310 kg



Localized load (ϕ40 mm): 100 kg



Do NOT hit anything against the FPD or connector, drop the unit or subject it to strong impact.

This can result in injury or equipment damage.

⚠ CAUTION

Use FPD on an even floor or a table.

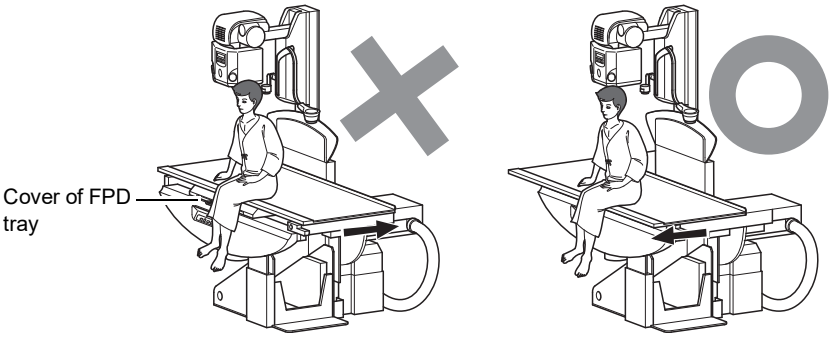
If force is applied to FPD which is put diagonally, it may cause damage or breakage of a sensor inside FPD.

Do NOT apply any force to the top of the FPD tray while it is pulled out.

This could damage the FPD tray.

Extend the tabletop to the most forward position before a patient gets on or off.

If the patient gets on or off the tabletop while it is retracted the cover of the FPD tray may be damaged.



⚠ CAUTION

If radiography is carried out with the FPD in the vertical position, it must be held securely.

It could fall, cause injuries, fail or be damaged.

Do NOT apply any force to the top of the FPD tray while it is pulled out.

This could damage the grid.

Do NOT put your hand on the FPD tray when pushing the FPD tray.

Otherwise, your hand may be caught in it.

Move the tabletop all the way back and lift the hand guard when removing or attaching the grid.

Otherwise, your hand may be caught between the tabletop and the grid, and your fingers may be injured with the hand guard.

Do NOT operate the device by other operators when removing or attaching the grid.

Otherwise, your hand may be caught between the tabletop and the grid.

NOTE

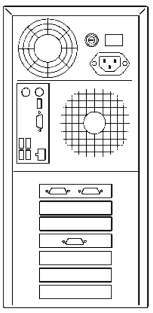
- Push the FPD tray in firmly as far as it will go.
  If it is not in as far as it will go, the X-ray diagnostic table may not operate, and fluoroscopy and radiography may not be possible.
- Check the vertical orientation of the grid when mounting it. It cannot be mounted upside down.
- Push the grid in firmly as far as it will go.
  If it is not in as far as it will go, the X-ray diagnostic table may not operate, and fluoroscopy and radiography may not be possible.

■ Cautions on the LCD Monitor

⚠ WARNING

Do NOT connect devices other than those specified by Shimadzu to the monitor power supply socket or monitor connection terminal.

Such connections may damage the system and cause fire to break out.



⚠ CAUTION

Do NOT scratch or hit the LCD monitor surface with a hard material, such as a ballpoint pen.

Otherwise, the LCD monitor surface may be damaged.

Do NOT push hard on the LCD monitor surface.

It may cause an uneven image, leading to the monitor's failure.

Do NOT leave rubber or vinyl products in contact with the LCD monitor for long periods.

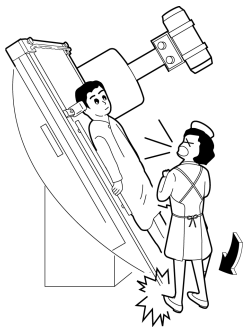
This could cause decomposition, or peeling of the coating.

■ Accessories and Options

⚠ WARNING

Do NOT place the foot switch (optional) under the diagnostic table.

The operator's foot may become caught under the table and injured.

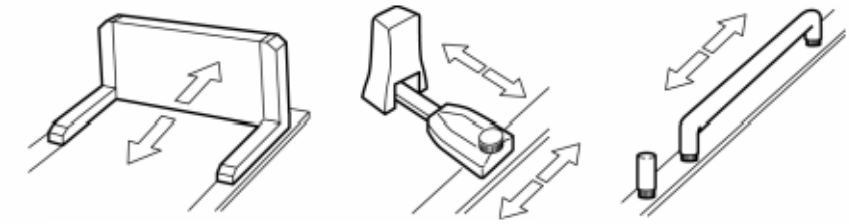


Do NOT place anything on the foot switch. Pay extra attention not to step on the foot switch carelessly.

Unintended X-rays may be radiated.

When starting examination, attach accessories like the foot rest, shoulder rests and handgrips/grip bars according to the patient's physique and body position.

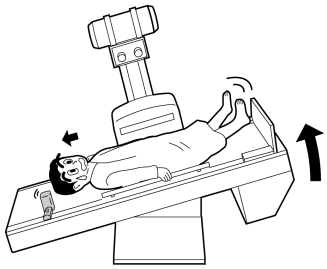
After attaching the accessories or relocating them, vigorously shake them in both directions to confirm that they are secured to the unit completely.



Attaching the foot rest | Attaching a shoulder rest | Attaching a handgrip/grip bar

Completely fasten Shoulder Rests, Grip Bars and Foot Rest to the tabletop.

Otherwise, the patient may fall off and be injured. The accessories may also become detached from the tabletop, fall and injure the patient or damage the equipment. Particularly when tilting the tabletop downward by 20° or more, confirm the patient's safety and proceed carefully.



Completely fasten Compression Band (optional) to the tabletop.

If not fastened firmly, the compression band may come off or the lever may fall over, which could cause injury.

If you do not connect the rotary foot rest to the X-ray diagnostic table using the curl cord, make sure to put the dust cap on.

Do not touch the connecting section to avoid an electric shock.

■ Cautions on the System and Software

⚠ WARNING

Do NOT install any other software on the computer.

Otherwise, the system may not run due to environmental changes of operating system and driver conflicts. Shimadzu is not responsible for the failure and damages caused by neglecting this warning.

⚠ CAUTION

Do NOT turn off the power to the computer while shutdown is in progress.

This could cause hardware to fail or corrupt data.

Do NOT turn the power off within 5 seconds after radiography, except in an emergency.

Wait at least 10 seconds after turning the power off before turning it back on.

Observe the following precautions:

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

⚠ CAUTION

Either transfer important data to the image server for storage (backup), or print it out.

The data stored in the system disk such as images may be deleted due to any system malfunction or unintentional accident.
Make several backups to avoid the loss of data. Shimadzu is not responsible for the deleted data such as images.
When the image data exceeds the predetermined size, records are automatically deleted starting from the oldest and appropriate free space for an examination is secured.
When an examination has ended, output the data to a destination other than the magnetic disc in the equipment, for example by transferring it to the image server for storage (backup) or printing it out.

NOTE

- The program conditions recorded in the X-ray high-voltage generator are linked to the DR unit. Do NOT delete program conditions or change their location.
- If you do not observe the instruction, the system may not work properly.
  Before starting radiography, check the identity of the patient based on the patient information displayed on the equipment.

■ Cautions on Measurement Accuracy

⚠ WARNING

Do NOT attempt to use the measurement function for purposes other than references for evaluation because precise image measurement is not possible.

■ Cautions on Network Connections

This equipment connects to the network for the following purposes.

- Obtains patient information, study information, and previous study images from an external equipment.
- Sends study images, study results information, dose information, and maintenance information of equipment to an external equipment.

Connect with the IPv4 network supporting 1000 Base-T/100 Base-T. Use the UTP LAN cable higher than Enhanced Category 5 (Cat 5e).

Intended Information Flow:

Destination	Typical information
Imager	Study image data
RIS server	Patient information, Study information, Study results information, Dose information
Storage server	Study image data
Remote maintenance server	Maintenance information of equipment

Risks of network failure

Destination	Risks of network failure
Imager	Unable to print study images.
RIS server	Unable to obtain patient information and study information. Unable to send study results information and dose information.
Storage server	Unable to send study images. Unable to obtain previous study images.
Remote maintenance server	Unable to send maintenance information of equipment.

⚠ CAUTION

Shimadzu accepts no responsibility for any of the following items due to infection by malware (i.e. malicious software, including computer viruses and worms, which cause damage to the infected computer):

- Loss, alteration, and leakage of data, including images, recorded on this equipment
- Accidents due to the malfunction of this equipment
- Infection of other equipment via this equipment and any damages incurred due to the infection
- Other issues including all events caused by malware infection

---

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

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

Examples of security management are as follows ;

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

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

The customer should identify, analyze, evaluate and control RISK by Network.

The customer connection of this machine to a NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;

Subsequent changes to the NETWORK could introduce new RISKS and require additional analysis.

Changes to the NETWORK include:

- Changes in NETWORK/DATA COUPLING configuration
- Connection of additional items to the NETWORK
- Disconnecting items from the NETWORK
- Update of equipment connected to the NETWORK
- Upgrade of equipment connected to the NETWORK

■ Cautions on Cleaning and Disinfection

⚠ WARNING

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

Otherwise, a malfunction may occur in the equipment, or the equipment may operate in an unintended way.
Also, thoroughly ventilate the room before turning ON the power after disinfection work is complete.

⚠ CAUTION

Be sure to clean and disinfect the equipment.

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

Be sure to clean the equipment frequently and after each patient use.

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

Use disinfectants at a minimum.

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

☞"Cleaning and Disinfection" in "7.1 Maintenance" P.132

■ Cautions on Emergency Stop

⚠ CAUTION

Press the STOP button or Power button to stop the equipment immediately in times of urgency.

Press the STOP button (red button) to stop the X-ray diagnostic table. The STOP button is provided on the local control panel of the X-ray diagnostic table and the console.

Moreover, press the Power OFF button to stop the X-ray generator. The Power OFF button is provided on the remote console.

☞"6.1 Emergency Stop" P.110

If you notice an abnormal smell or smoke generation during operation, shut off the circuit breaker and contact your Shimadzu service representative.

Continued use could result in injury or damage to the equipment.

■ Cautions Relating to Cellular Telephones

⚠ WARNING

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

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

■ Cautions on Electromagnetic Compatibility (EMC)

⚠ WARNING

This equipment needs special precautions regarding EMC.

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

☞ "5.3 Environmental Conditions of EMC (ElectroMagnetic Compatibility)" P.102

Make sure that electromagnetic compatibility is obtained.

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

☞ "5.3 Environmental Conditions of EMC (ElectroMagnetic Compatibility)" P.102

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

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

☞ "5.3 Environmental Conditions of EMC (ElectroMagnetic Compatibility)" P.102

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

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

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the equipment.

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

■ Cautions When Irradiating Consecutive Pulse X-rays

⚠ WARNING

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

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

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

■ Cautions on Wireless Communication Using AF-B1

For further details, refer to the Canon Wireless FPD manual.

⚠ WARNING

This system operates in the same frequency band as premises radio stations for identifying mobile devices in factory production lines (license required) and specified low-power radio stations (license not required) in addition to industrial devices (ex. microwave ovens), scientific instruments, and medical devices. Other equipment may interfere with the system even if such equipment complies with CISPR EMISSION requirements.
The use of this system may result in RF interference with the above mentioned equipment and radio stations. Make sure you understand and heed the following cautions when operating the system.

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

⚠ CAUTION

Do NOT use the selected frequency channel (2.4 GHz/5 GHz band) for other wireless devices.

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

Do NOT cover the wireless antenna of the imaging unit with your hands.

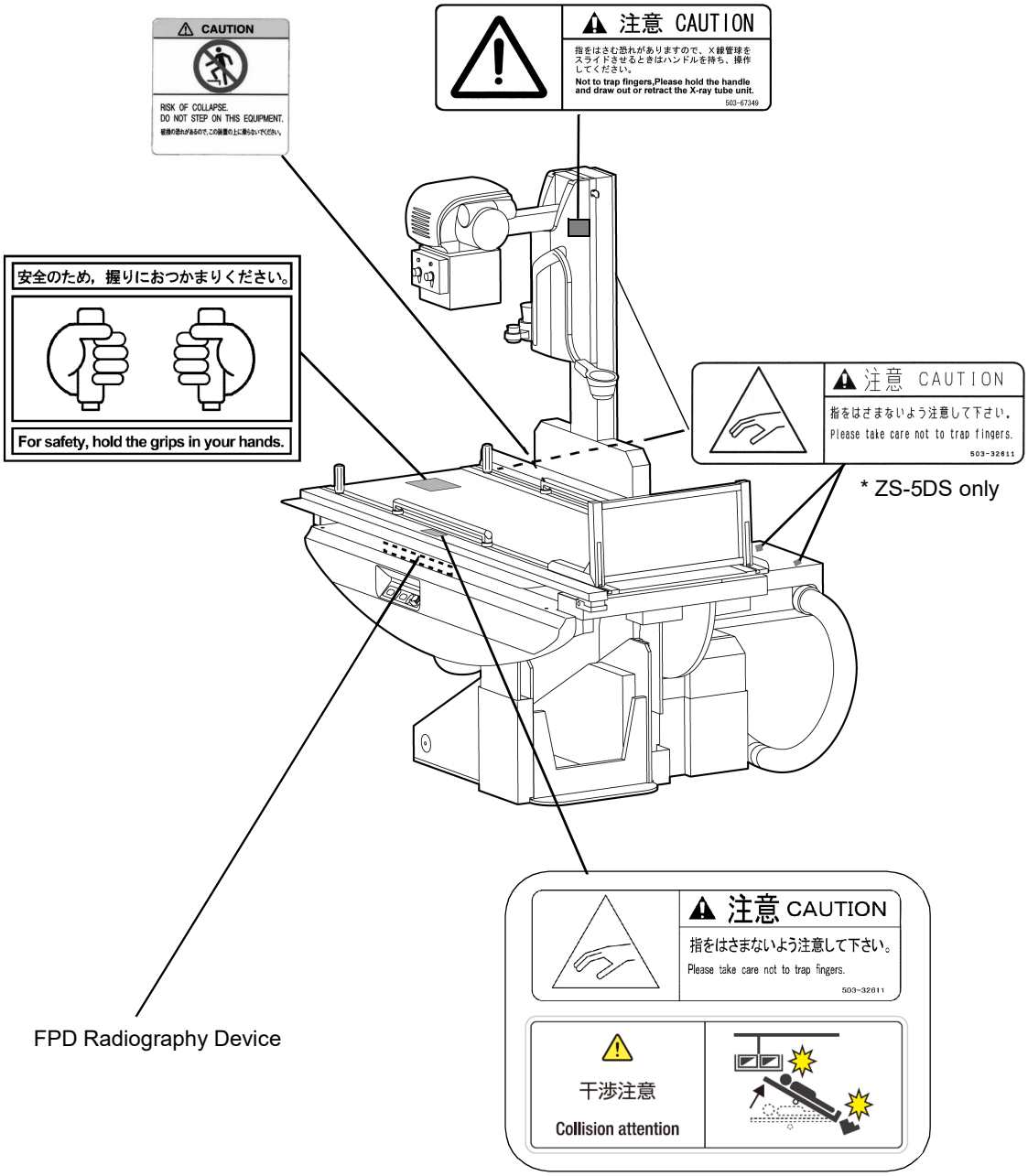
Covering the antenna may hinder the wireless communication properties (throughput and range) of the system.

Warning and Caution Labels

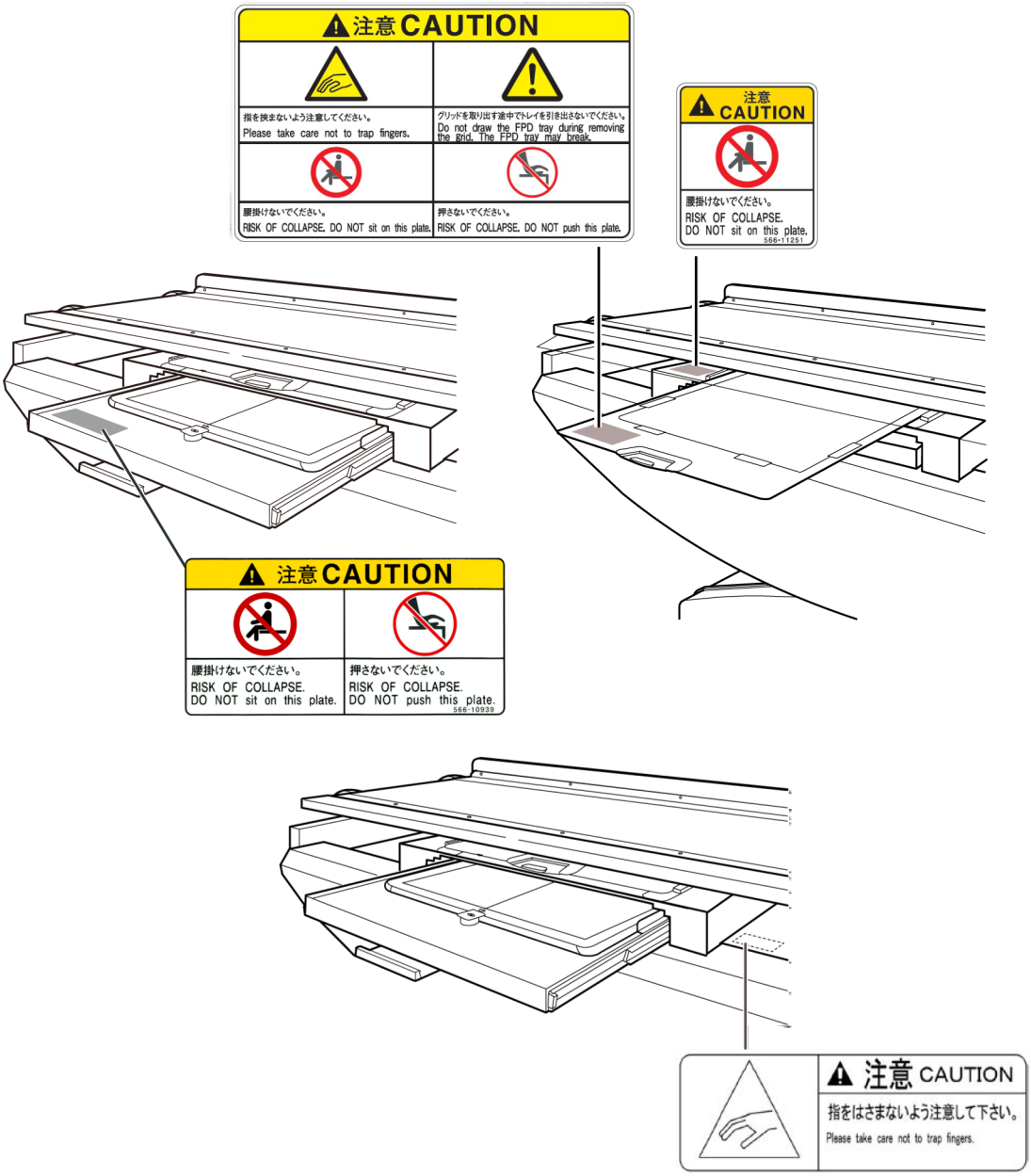
The following safety labels, which describe handling precautions, are attached to the equipment. With adequate understanding of the contents on these labels and the warning/caution items in this manual, operate the equipment safely.
Inspect the safety labels periodically (once a year).
If any label is peeled or unreadable by stain or scratch, replace it with a new one.
For new labels, contact your Shimadzu service representative.

- X-ray Diagnostic Table

  Described 5DS (elevating tabletop) as an example.

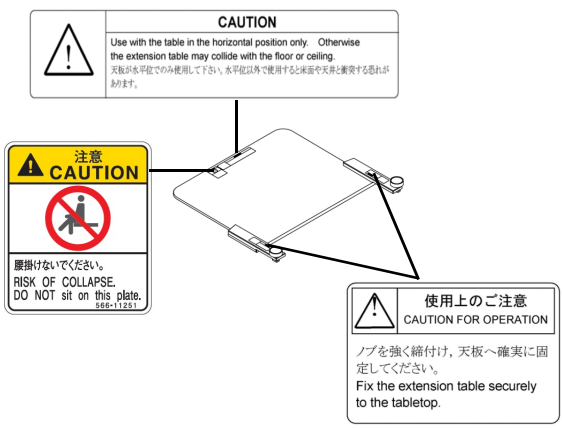


● FPD Radiography Device

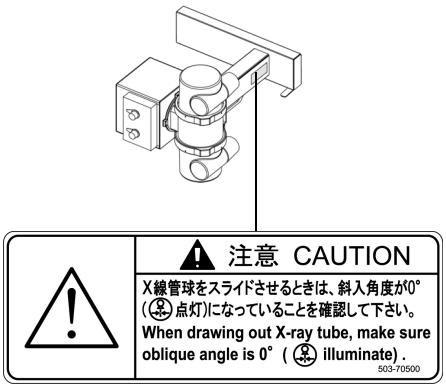


● X-Ray Diagnostic Table (Options)

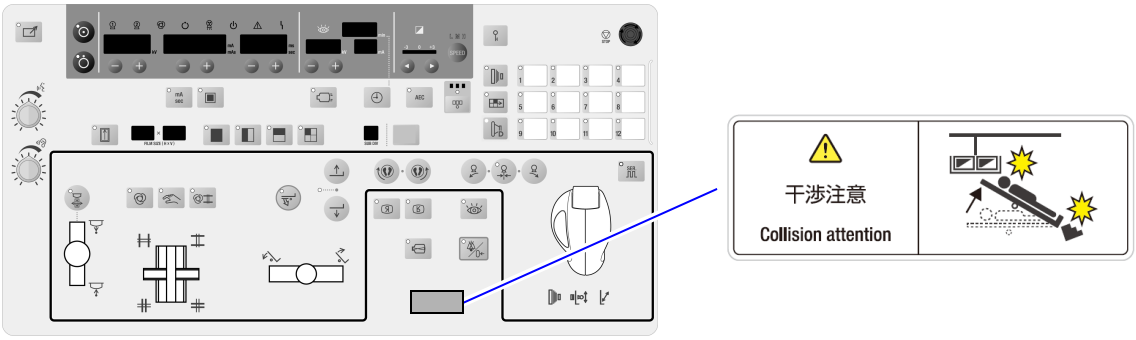
Extension Table (Option)



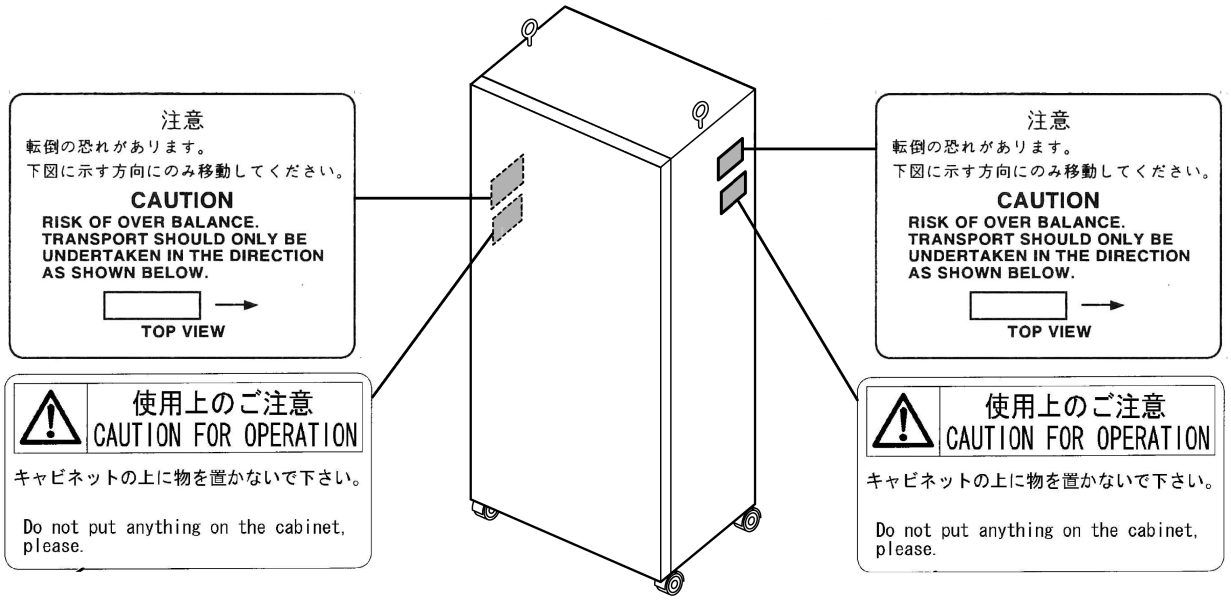
Oblique Radiography Unit (Option)



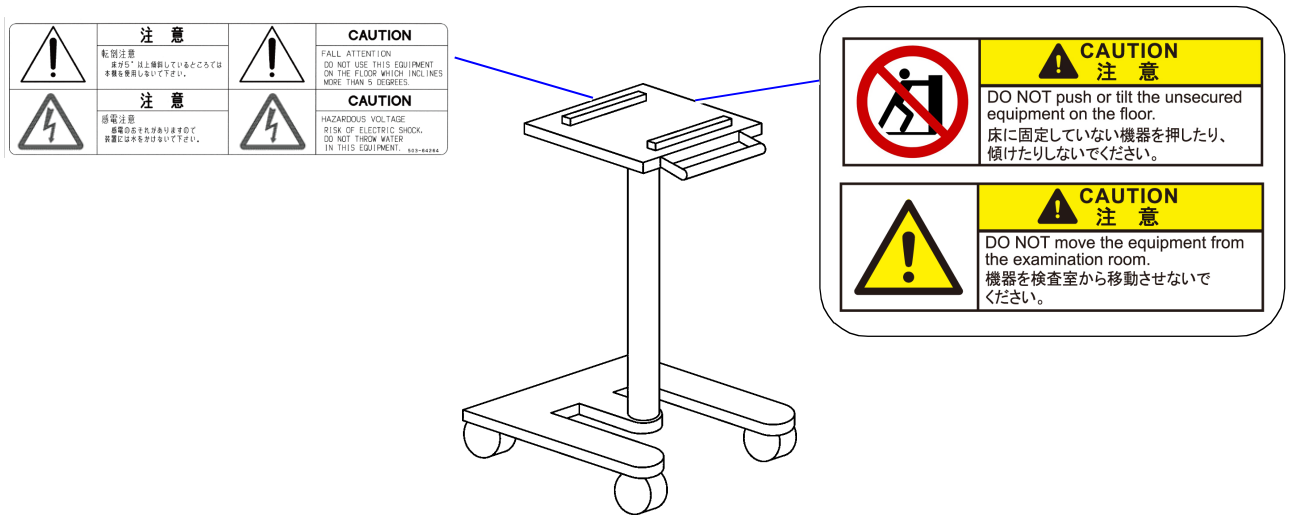
● Remote Console



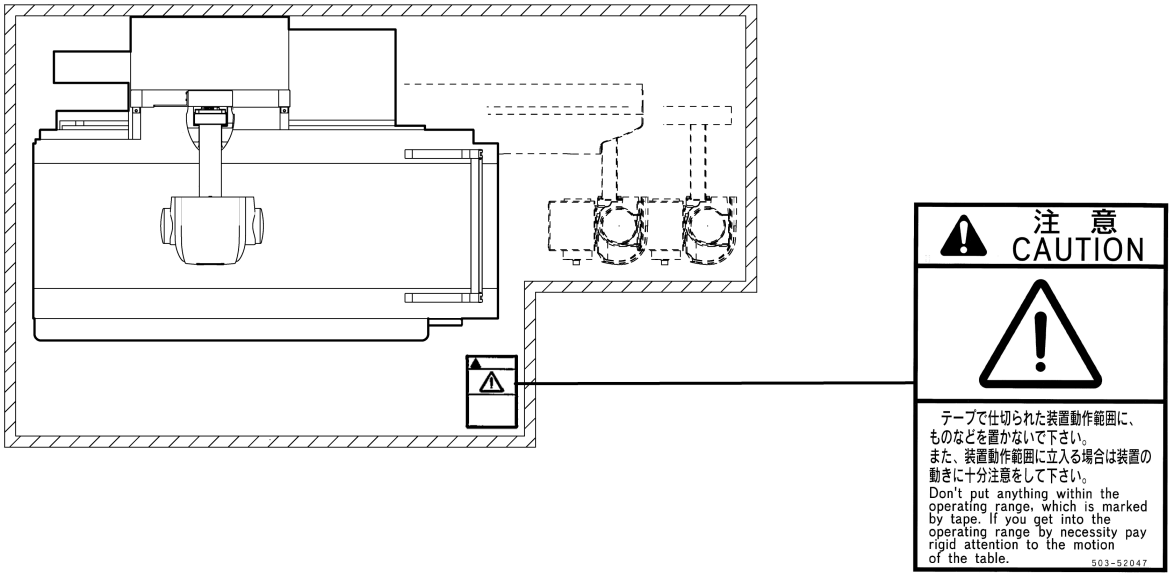
● Control Cabinet



● Monitor Cart



● Equipment Operating Range in Examination Room



● Collimator (R-300)

☞ Refer to COLLIMATOR TYPE R-300 OPERATION MANUAL (M526-E024).

Warranty

The system is warranted to be free from defects in material and workmanship for one year from the date of delivery. If found to be defective, the system must be offered to Shimadzu for inspection and examination. Upon examination, Shimadzu, at its sole option, will repair or replace at no charge, the system or any part found to be defective. Components which wear are not warranted.
This warranty extends to original purchaser or the lessee of the new system only.
If the system is to be resold or delivered to a third party, such third party must be provided with a copy of this manual, the installation manual and the technical manual supplied with the system.

This warranty does not apply to the following:

(1) Failure or damage due to any installation, relocation, or service not provided by your Shimadzu service representative or a SHIMADZU designated contractor.

(2) Failure or damage caused by the product of other companies (except those purchased from SHIMADZU).

(3) Failure or damage due to repairs using non-SHIMADZU certified service parts.

(4) Failure or damage due to non-compliance with the notices and procedures set forth in this manual.

(5) Failure or damage due to any operating environment deviating from the requirements set forth in this manual.

(6) Failure or damage due to natural disasters such as power surge, rain, fire, earthquake, flood, and thunder.

(7) Failure or damage due to installation on non-SHIMADZU approved vehicle, ship, aircraft, or others.

(8) Failure or damage due to use in non-SHIMADZU certified countries.

(9) Failure or damage in case of purchase from entity other than SHIMADZU or Shimadzu service representative.

(10) Failure or damage due to impact, drop, or shock.

(11) Failure of or damage to equipment due to installation of a software product not specified by Shimadzu, or due to connection of external peripheral devices.

(12) Failure of or damage to equipment due to modification or deletion of the environmental setting files (autoexec.bat, config.sys and so on) in the basic software, or of files exclusive to the digital radiography system.

Service after the expiration of the warranty is available at a reasonable cost and should be performed by your SHIMADZU service representative.

IN NO EVENT SHALL SHIMADZU AND ITS AFFILIATED ENTITIES BE LIABLE TO ANY PERSON OR ENTITY FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, ANY DAMAGES RESULTING FROM LOSS OF USE, BUSINESS INTERRUPTION, LOSS OF PROFITS, LOSS OF SAVINGS, THE COST OF PROCUREMENT OF SUBSTITUTED GOODS, SERVICES OR TECHNOLOGIES OR FOR ANY MATTER ARISING OUT OF OR IN CONNECTION WITH THE USE OR INABILITY TO USE THE SYSTEM. In some jurisdictions, some of the foregoing warranty disclaimers or damage limitations may not apply.
Shimadzu will be indemnified for any claim, liability, or damage arising out of the misuse or non-compliance with this manual by the purchaser or lessee of the system.

Shimadzu accepts no responsibility for failure of or damage to the FPD caused by the following factors. Please be forewarned.

(1) Failure or damage caused by hitting the FPD against something or dropping it.
(2) Failure or damage caused by applying a load outside the specified range.
(3) Failure or damage caused by exposure to water, solvents, or a large volume of blood, etc.
(4) Failure or damage caused by usage contrary to instructions in the operation manual.
(5) Failure or damage caused by usage not originally intended for the product.
(6) Failure or damage caused by modification of the product.
(7) Failure or damage caused by natural disasters such as fire, earthquake, flood, or lightning, or that caused by pollution and abnormal power supply conditions.

Software License Agreement

NOTE

(1) Definition of licensed software
The licensed software ("software") refers to all computer programs used by the product, in addition to all related documentation.

(2) Ownership of license
The software used in this product is copyrighted by Shimadzu Corporation ("Shimadzu") who possesses all rights, including sublicenses for those rights (for copyrights, etc.) held by third parties.
The equipment with the installed software is sold on the basis of Shimadzu licensing the software ownership to the customer.
Accordingly, when the customer uses the software, the customer must observe the items outlined below:

(i) The customer shall only use the software for use with a single equipment.

(ii) The intellectual property rights for the software are not transferred to the customer.

(iii) The customer, or any third party, is prohibited from performing any of the following actions:

- Duplicating the software.
- Changing the software, in whole or part.
- Transferring, loaning, or sublicensing the software.
- Transferring the software outside Japan without prior permission of the Japanese or U.S. government.

Service Life

The equipment lifetime is 10 years (based on Shimadzu's criteria) assuming the specified maintenance checks are performed.

Software

This operation manual corresponds to the following software.

- FLEXAVISION F4 S/W Version 3*
- FLEXAVISION F4 SYSTEM S/W Revision 3.0
  *Even if the last digit of the software version is different from that above, the descriptions in the manual are valid.

Disposal Precautions

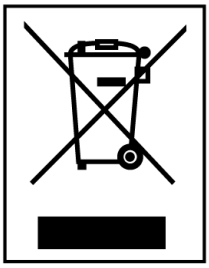
⚠ CAUTION

When disposing of the equipment, contact your Shimadzu service representative.

An improper disposal of this equipment may pollute the environment by substances contained in parts.

Action for Environment (WEEE) To all users of Shimadzu equipment in the European Union:

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



WEEE Mark

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

With your co-operation we are aiming to reduce contamination from waste electronic and electrical equipment and preserve natural resource through re-use and recycling. Do not hesitate to ask your Shimadzu service representative, if you require further information.

System Activation

This equipment needs activation of High-voltage generator during installation. The activation work needs authorization by Shimadzu.

Abbreviations

Abbreviation	Explanation
AEC	Automatic Exposure Control
APR	Anatomical Program
DR	Digital Radiography
IBS	Image Brightness Stabilizer
EMC	Electromagnetic Compatibility
FPD	Flat Panel Detector
SID	Source Image Distance
RIS	Radiology Information System
DM	Deadman function
mA	milliampere
mAs	milliampere second
min	minute
ms (msec)	millisecond
sec	second
kV	kilovolt

List of Related Manuals

This operation manual explains the basic operation of the FLEXAVISION F4 Package.
For details, refer to Operation Manual of each unit.
For details on each package, see "1 Outline".

Component Unit	Manual Name	Manual No.
Fluoroscopy/ Radiography System	Remote-Controlled R/F System ZSU-5D/5DS Operation Manual	M506-E051
Collimator	Collimator Type R-300 Operation Manual	M526-E024
Digital Radiography Unit	Digital Radiography System SDR-150C Control Software Instruction Manual for FLEXAVISION F4 (Operation Guide)	M517-V053
	Digital Radiography System SDR-150C Control Software Instruction Manual for FLEXAVISION F4 (Setting Guide)	M517-E913
X-ray Tube Unit	X-ray Tube Assembly 0.3/0.8P324DK-85 Operation Manual	M535-E263
	X-ray Tube Assembly 0.6/1.2P324DK-85 Operation Manual	M535-E265
	X-ray Tube Assembly 0.6/1.2P326D-150 Operation Manual	M535-E371

This manual should be kept available for future reference. If the user or usage location changes, ensure that this operation manual is always kept together with the equipment. Periodically check to be sure that the operation manual and the warning labels are not missing or damaged. If they are, contact your Shimadzu service representative for replacement.
Original version is approved in English.

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Chapter 1

Outline

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1.1 System Outline

■ Intended Use

FLEXAVISION F4 Package is intended to be used as a diagnostic imaging system for radiographic and fluoroscopic examinations, including general R&F (radiographic and fluoroscopic) and pediatric examinations.

■ Indications for Use

- FLEXAVISION F4 Package is used for radiographic and fluoroscopic examinations of
  - Whole body
  - Skull
  - Spinal column
  - Chest
  - Abdomen
  - Extremities
  - Other body parts
- FLEXAVISION F4 Package is NOT intended to be used for
  - Mammography
  - Interventional procedure
- FLEXAVISION F4 Package must only be operated by qualified personnel, such as radiography technicians or those with equivalent qualifications.

For details of the operator profile, see "1.4 Product Safety" P.14.

- FLEXAVISION F4 Package is used for total patient population including pediatric examinations.

For useful features for the pediatric imaging, see Appendix 8.4.

For wheelchair patients related precautions, see CAUTION on page X.

- Stored images in the equipment can be used for re-monitoring, image processing, storing to optical media (CD/DVD), and sending to DICOM server.

■ Applications

The ability to perform fluoroscopy and radiography with a single FPD increases the efficiency of the recording and management of examinations.
The applications of the system can be broadly divided into "digital radiography" in which the FPD is incorporated into the X-ray diagnostic table, and "FPD portable radiography" in which the FPD is taken out of the X-ray diagnostic table.

When the 2-tube option is added, the equipment can also be used in combination with a Bucky stand or Bucky table.
It is possible to select from among radiography methods for multiple purposes according to the wide ranging requirements of individual clinics. The applications involved can be broadly divided into "X-ray television fluoroscopy" for fluoroscopic diagnosis and "digital radiography" in which the images from the FPD are recorded as digital images.
The figure below shows the X-ray diagnostic table, control cabinet, and remote control console.

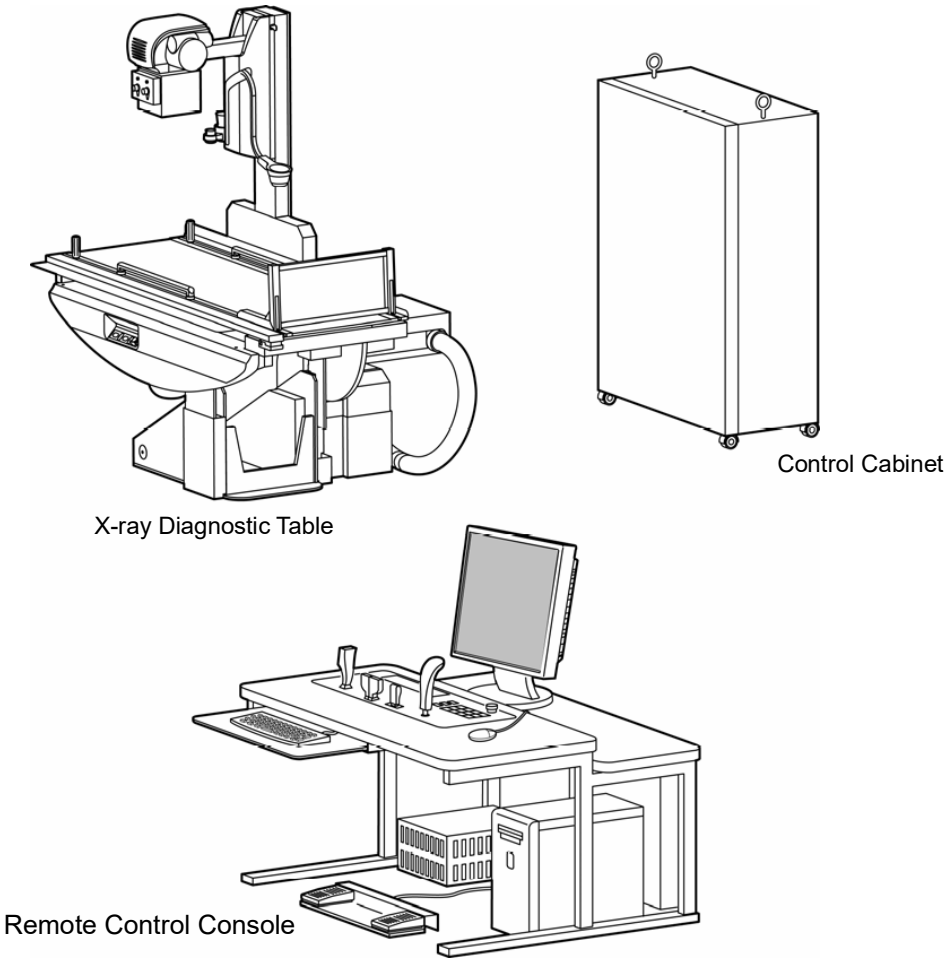


Fig 1.1 FLEXAVISION F4 Package

■ Features

● User-friendly Console

Various operations are available from a single console, i.e. operating diagnostic table and configuring fluoroscopy/radiography settings. Advanced console design can respond flexibly to an immediate radiography setting change.

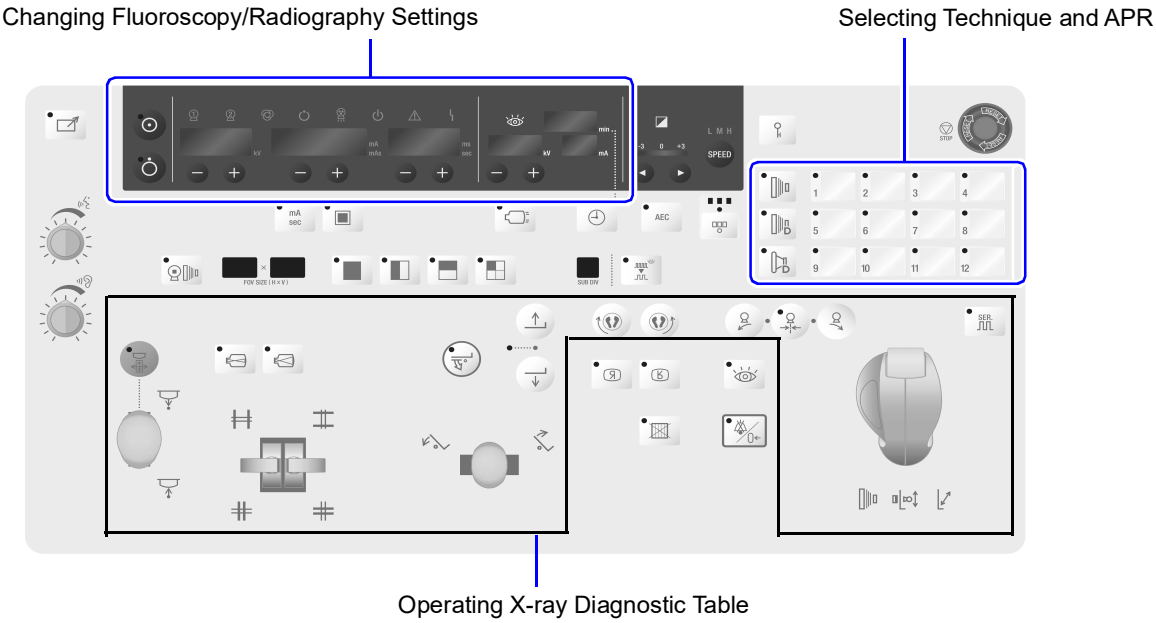


Fig 1.2 Console Features

● Compact Design

Requiring a small installation area, the system facilitates an effective use of your examination room.
*Minimum installation space: approx. 3.5 m × 2.3 m

NOTE The minimum layout does not take the dimensions of other equipment in the facility into account.

● Wide-examination Variety

- Extending the X-ray tube unit by 1.5 m FFD (standard feature) enables a deglutition observation even for patients in wheelchairs.
- Radiography can be performed with the FPD removed from the fluoroscopy table (portable digital radiography), and the system also has a wide range of application to general radiography.
- The X-ray grid can be removed, making it possible to hold exposure in check in gynecological and pediatric examinations.

● User-friendly Tabletop (5DS Elevating Tabletop)

The tabletop can be lowered to a position that reduces patient stress. Adjust the tabletop up/down for the operator to achieve a comfortable posture.

● Supportable to Various Optional Units

◆ Oblique Projection Unit

Oblique projection by tilting the X-ray tube at a maximum 30° allows for effective GI, orthopedics and other examinations.

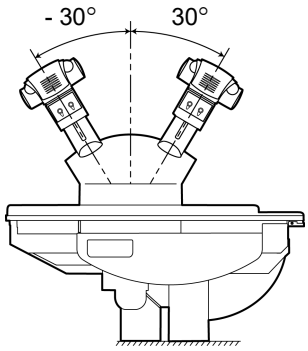


Fig 1.3 Tilting X-ray Tube

◆ X-ray Tube 37°/90° Swing-out Unit

Allows rotating the X-ray tube toward the front side of the diagnostic table to perform chest radiography combined with a lieder stand or bucky stand.

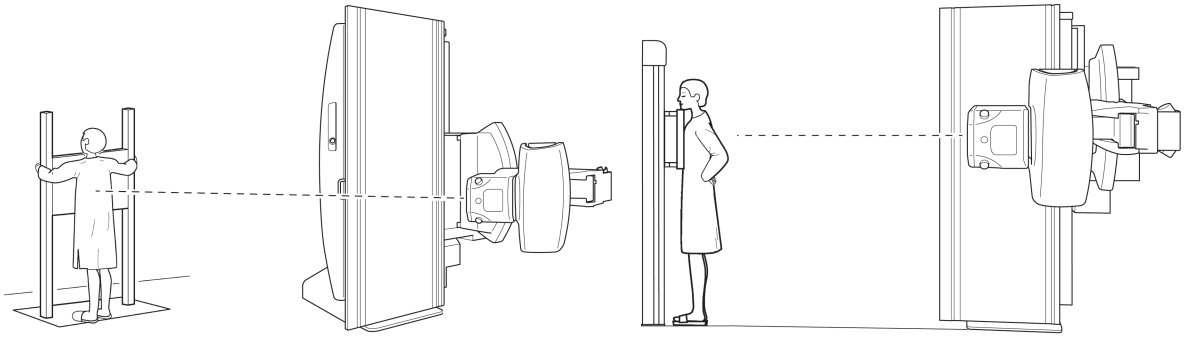


Fig 1.4 Radiography Using Lieder Stand and Bucky Stand

◆ X-ray Tube 180° Swing Unit

Allows rotating the X-ray tube by 90°,180° to perform chest radiography combined with a bucky table, etc. and lieder stand.

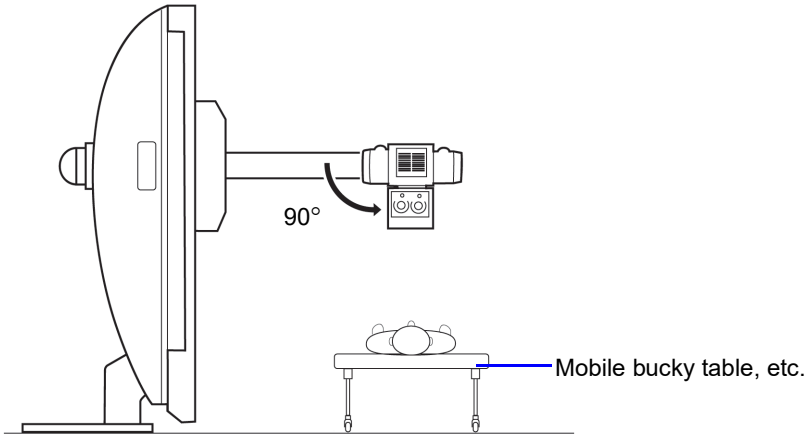


Fig 1.5 In case of bucky table

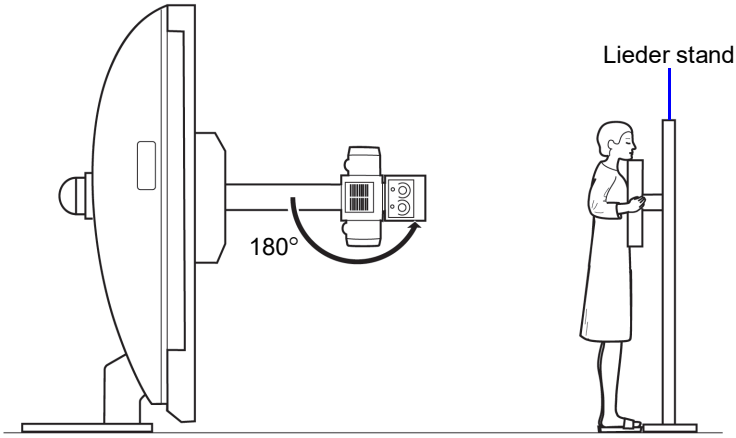


Fig 1.6 In case of Lieder stand

■ Principle

This equipment detects the X-rays, which are radiated from the X-ray tube unit and passed through the patient's body, using an FPD, converts the detected data into image signals, and takes them into the digital image memory device.
The images are not only displayed on the monitor but also recorded on the internal memory storage.
The user can play back the recorded images and apply various processing on those images.
When combined with the X-ray radiography unit for the second X-ray tube (optional), it is also possible to perform radiography using the second tube.

■ Standard Components

Name	Condition
Foot Rest *1,*2	Used to support the patient's body when tilting the tabletop to vertical position.
Grid*1,*2	Used according to the radiography region, SID, etc.
Hand Grips*1,*2	Used to support the patient's body.
Grips*1,*2	Used to support the patient's body.
Shoulder Rests*1,*2	Used to support the patient's body.
Barium Cup Holder*1	Used to hold the barium cup.
Direct Photo Timer (AEC)	Has more photo pickup fields than the standard photo timer. Used for parts such as chest and abdomen, which need wider photo pickup fields.
Add On Console	Used to display dose information etc..

*1: Equipment suitable for use in the patient environment.
*2: An applied part that contacts the patient's body.

■ Optional Components

Name	Condition
Local Console*1	Used to move the diagnostic table and for other operations inside the examination room. Mounted on wheels.
X-ray Tube Swing-out Unit*1	Enables radiography by swinging the X-ray tube unit toward the lieder stand.
Compression Band*1,*2	Fixes patient to compress the region to be examined.
Lateral FPD Holder*1,*2	Mounted on the tabletop side for lateral radiographs. Used for the radiography combined with the second X-ray tube.
Leg Supports*1,*2	Support patient's lower legs for examinations in, e.g. urology and genitalia.
Endoscope Support*1	Supports endoscope-fiber tube. Combined with the optional leg supports.
Drain Bag*1,*2	Holds excretory substances such as urine in urethra or other examinations. Vinyl material.
Elbow Supports*1	Fix operator’s elbows in urology examination. Combined with the drain bag.
Table Extension*1,*2	Supports a tall patient's head as not to come out of the diagnostic table during an examination of the patient’s toes.
Table top Mattress*1,*2	Reduces patient's discomfort on the tabletop.
Foot Switch*1	Used at fluoroscopy or radiography near the diagnostic table.
Monitor Cart*1	Cart that holds the monitor inside the examination room.
GRID*1,*2	Used for anti-scatter.
Rolling Step*1,*2	Rotates with an electric turn table.
Second-tube Option*1	Controls the second X-ray tube. Supplied with a specific operation panel.

*1: Equipment suitable for use in the patient environment.
*2: An applied part that contacts the patient's body.

1.2 Environmental Conditions

■ Operation Environmental

When the equipment is combined with the FPD, use the equipment under the environmental conditions listed below:
The installation of a dedicated air-conditioner is recommended if the building air-conditioner cannot maintain the necessary environmental conditions 24 hours a day.
The calorific power of the power supply is not significant enough to affect the use environment of the equipment.

"X-ray High-voltage Generator" P.92

Item	Condition
Atmosphere	No explosive or corrosive gases
Ambient Temperature	10 °C to 35 °C
Relative Humidity	30 % to 75 % (no dew condensation)
Atmospheric Pressure	800 hPa to 1060 hPa (800 mbar to 1060 mbar)
Environment illuminance	150 lx to 500 lx
Ambient Noise Level	70 dB max.

⚠ WARNING

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

The use of the equipment in an oxygen-rich environment may cause fatal or serious injuries or damage to the equipment due to easy ignition.

⚠ CAUTION

Even under the prescribed conditions, avoid rapid changes of temperature or humidity.

Condensation may occur and cause failure. Also, rust or corrosion may occur inside the equipment.

■ Transportation and Storage Environment

The environmental conditions for transportation and storage are described below.

Item	Condition
Atmosphere	No explosive or corrosive gases
Temperature	- 10 °C to 50 °C
Relative Humidity	10 % to 90 % (no dew condensation)
Atmospheric Pressure	700 hPa to 1060 hPa (700 mbar to 1060 mbar)

⚠ CAUTION

Condensation inside equipment may cause rusting or corrosion.

Freezing due to a low temperature may damage internal circuits.
Be careful if storing the unit where the temperature and humidity can change extremely, such as in a warehouse.

■ Storage Conditions for FPD

Store the FPD under the following conditions.

Item	Specification
Ambient Temperature	-30 °C to 50 °C
Relative Humidity	10 % to 95 %
Atmospheric Pressure	700 hPa to 1060 hPa (700 to 1060 mbar)

⚠ CAUTION

When storing the FPD, keep them in a place where there is no danger that they will fall over or fall from a height.

This could impair image quality, cause the unit to fail or damage it.

■ Operating Range

The unit operating range is shown in Fig 1.7.

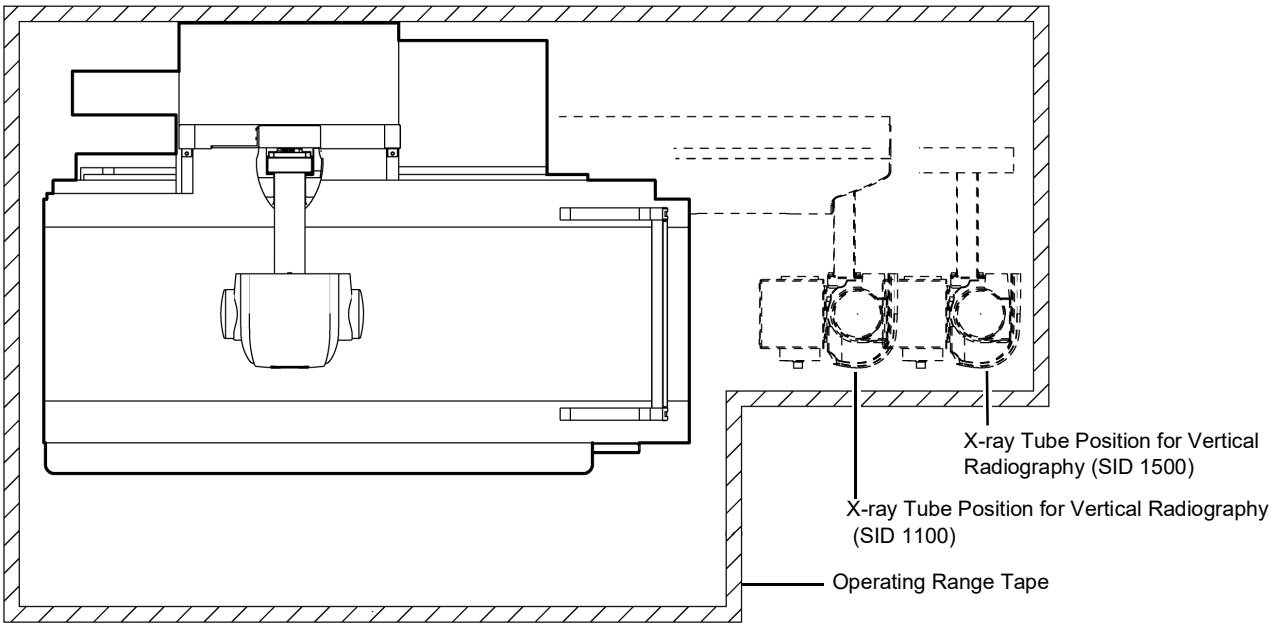


Fig 1.7 Unit Operating Range

NOTE

● Operating Range

- Do NOT place any other equipment inside the operating range tape around this unit to avoid damage by interference from other units.
- The operator and caregiver must not enter the operating range during the system operation for safety.

■ Installation Requirements

- Floor Strength

  The floor structure in the rooms where the system is installed must be strong enough to easily support the weight of the equipment.

  Floor strength must be at least 12.2 kN/m^2 at ZS-5D, and 23.1 kN/m^2 at ZS-5DS.
- Floor Structure

  The floor structure must permit anchor bolts to be installed for anchoring the equipment to the examination room floor. Preferably, the floor should be at least 70 mm thick.

  Make sure the floor at the installation site as follows:
  - Floor levelness: 5/1000 mm max. (measured with a level etc.)
  - Floor flatness: Max. 3 mm difference between high and low points (measured with a feeder gauge etc.)
- Anchoring

  For installation, use the following anchor bolts.
  - HSA M12 × 110/15, 4pcs

■ Power Supply

For power supply, See " Specification" P.89

⚠ DANGER

Be sure to use the power supply specified in the operation manual.

Using a power supply other than the one specified may cause equipment malfunction or serious accidents such as fire, smoke emission, or explosions.

■ Grounding

Class D grounding

⚠ WARNING

Be sure to connect the equipment only to supply mains with protective earth.

If not, electric shock may occur.

■ Wireless Communications

The use of a wireless FPD enables wireless communication between the wireless module built into the imaging unit and the access point.
Wireless communication is performed based on the IEEE 802.11n (2.4 GHz/5 GHz) LAN standard.
During installation, your Shimadzu service representative will change the frequency band from 2.4 GHz/ 5 GHz and select a specific frequency (channel) for use.
In addition, the wireless FPD supports a wired connection by using the optional wired connection kit.

● FPD (AF-B1)

Frequency band	Wireless LAN standard IEEE 802.		Frequency Range (MHz)	Modulation	Date rate (Mbps)
2.4 GHz	11b		2412-2472	DSSS	11
	11g			OFDM	54
	11n	HT20			75
		HT40	2422-2462		150
5 GHz	11a		5180-5320 5500-5700	OFDM	54
	11n	HT20			75
		HT40	5190-5310 5510-5670		150

Frequency band	Wireless LAN standard IEEE 802.		Setting value (dBm)	Deviation (dB)	Antenna factor (dBi)	Maximum effective radiation power (dBm)
2.4 GHz	11b		12	±2	3	17
	11g					
	11n	HT20				
		HT40	11	±2	3	16
5 GHz	11a		11	±2	4.5	17.5
	11n	HT20				
		HT40				

1.3 Classification of Equipment

This equipment is classified as follows, based on safety standards for electrical medical equipment.

- Protection Method Against Electric Shock

  Class I equipment

- Classification of Applied Parts

  Equipment including Type B Applied Parts

- Operation Mode

  Continuous operation with intermittent loading

- Degree of Protection Against Liquid Ingress

  - Ordinary equipment
  - • IPX8* (Temporary immersion in water) for foot switch only
    *The IPX Waterproof Specification, specified by the International Electrotechnical Commission, indicates waterproof/drip-proof performance on instruments and equipment.

- For Use in an Oxygen-rich Environment

⚠ WARNING

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

The use in an oxygen-rich environment may cause fatal or serious injuries or damage to the equipment due to easy ignition.

- For Use in Flammable Atmosphere

⚠ DANGER

Do NOT use the equipment or system in the presence of flammable anesthetics gas.

It may cause an explosion.

- Classification of Installation Type

  Permanently installed equipment

1.4 Product Safety

⚠ CAUTION

If the equipment is seen to be making abnormal movements, stop operation.
Contact your Shimadzu service representative for maintenance and inspection.

Be sure to ground the equipment.
Carry out grounding according to the installation manual to avoid the danger of electric shock.

Keep the patient's absorbed dose as low as reasonably achievable.
Set the source-to-image distance as long as possible.

1.5 Symbols and Product Nameplates

■ Symbols

The symbols used with this system are indicated below.

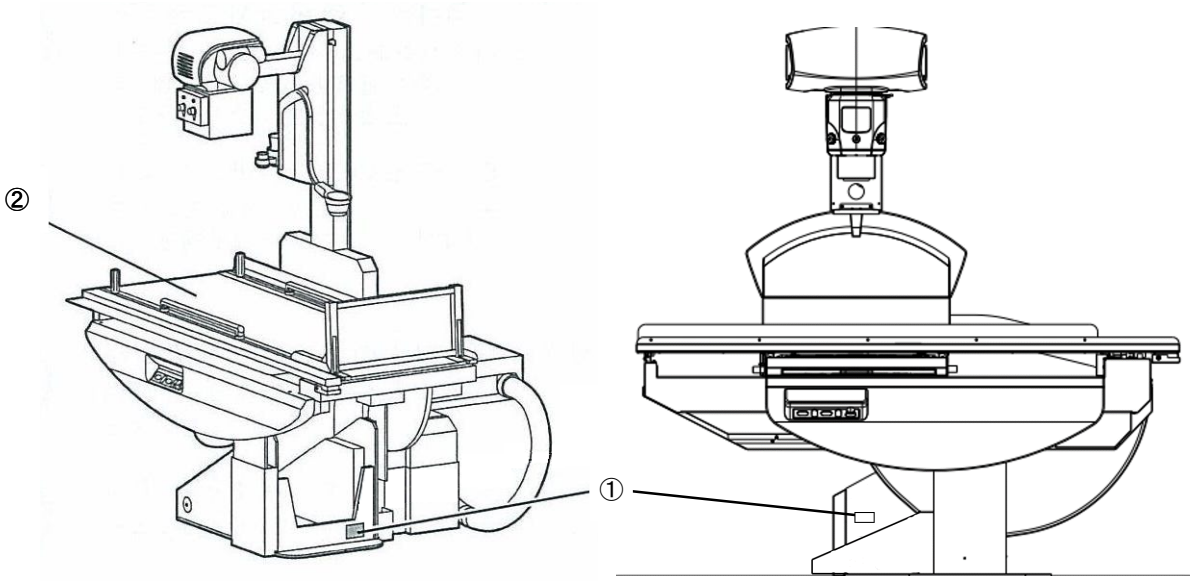
Symbol	Location	Meaning
	On name plate	Alternating current
	On name plate	Direct current
	Inside the equipment, where protective earth conductor in power cord is connected	Protective earth ground
	On applied parts	Safety classification: Type B
	Remote control panel	Power ON (partial circuit ON)
	Remote control panel	Power OFF (partial circuit OFF)
	On warning and caution labels	Observe described items, or refer to operation manual.
	On name plate	Refer to operation manual
	On name plate	Refer to the operation manual
	On name plate	Serial number
	On name plate	Year and month of manufacture
	On name plate	Manufacturer
	Collimator	Danger of X-ray irradiation

Symbol	Location	Meaning
	On warning and caution labels	Refer to operation manual

■ Product Nameplate and Certificate Labels

ZS-5DS (Lifting Type)

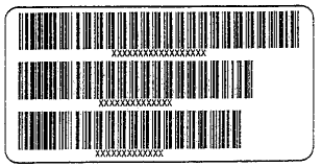
ZS-5D (Non-lifting Type)



(1) Nameplate of FLEXAVISION

(2) CE Label

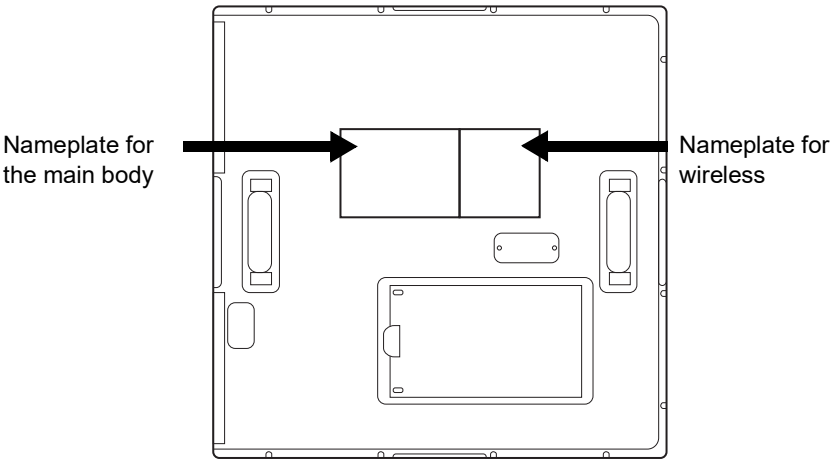
(3) Bar Code Identification Label



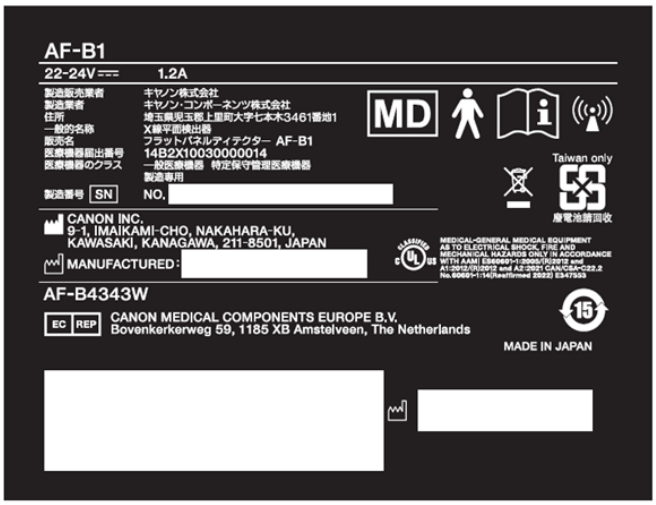
(4) TYPE B Applied Part Label

● FPD

◆ **Position where nameplate affixed**



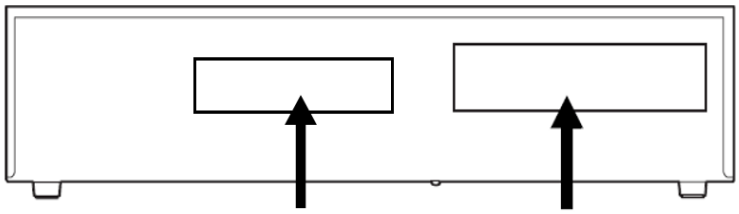
◆ **Nameplate for the main body**



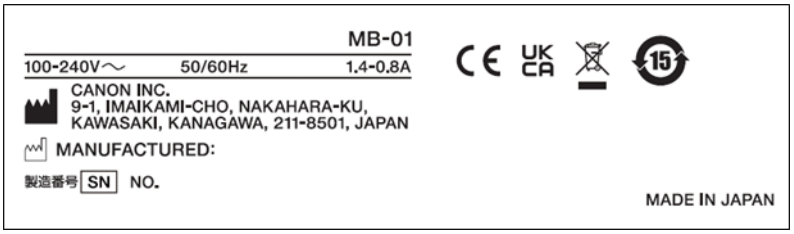
◆ **Nameplate for wireless**

● Multibox(MB-01)

◆ Position where nameplate affixed



◆ Nameplate for ratings



◆ Nameplate for the main body

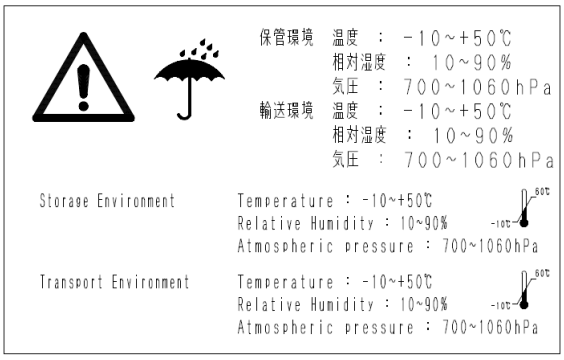
製造販売業者	キヤノン株式会社
製造業者	キヤノン・コンポーネンツ株式会社
住所	埼玉県児玉郡上里町大字七本木3461番地1
一般的名称	X線平面検出器出力読取式デジタルラジオグラフ
販売名	デジタルラジオグラフィ B1
医療機器認証番号	302ABBZX00058A01
医療機器のクラス	管理医療機器 特定保守管理医療機器 製造専用

● Collimator (R-300)

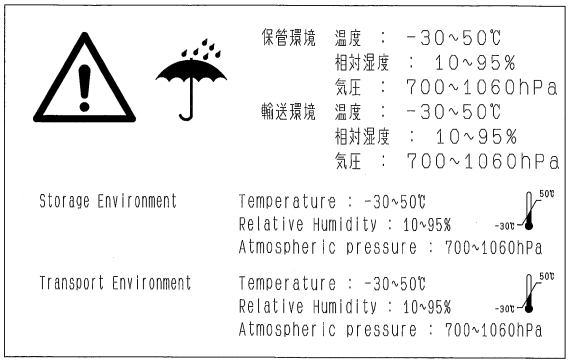
☞ Refer to COLLIMATOR TYPE R-300 OPERATION MANUAL (M526-E024).

● Transportation and Storage Environment Labels

◆ Except the FPD



◆ FPD



1.6 Operator Profile

Item	Details
Age	Old enough to be a radiologic technologist or hold an equivalent qualification
Gender	No restriction
Nationality	No restriction
Education	Must be a radiologic technologist or hold an equivalent qualification.
Knowledge	Must be a radiologic technologist or hold an equivalent qualification.
Language	Must be able to read and understand Japanese or English.
Experience	Mandatory All operators must have received instruction on how to operate the equipment in advance.
Permissible functional impairment	Corrected visual acuity of at least 0.7 Must have at least 60 % of normal hearing in the range 500 Hz to 2 kHz.

1.7 Statement of Compliance [For Europe]

■ Regulatory Information

For Europe:
The product complies with the requirement of the Medical Device Directive 93/42/EEC and RoHS Directive 2011/65/EU

Product Name:	REMOTE-CONTROLLED R/F SYSTEM
Model Name:	REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION
Parts Number:	566-28000
Manufacturer:	SHIMADZU CORPORATION Medical Systems Division
Address:	1, NISHINOKYO-KUWABARACHO, NAKAGYO-KU, KYOTO, 604-8511, JAPAN
Authorized Representative in EU:	SHIMADZU EUROPA GmbH
Address:	Albert-Hahn-Strasse 6-10, 47269 Duisburg Germany

■ Company's Quality System

The company's quality management system complies with the requirements of Annex II, excluding Section 4 of the MDD 93/42/EEC, which is certified by TÜV Rheinland LGA Products GmbH (Notified under No.0197)

■ International Standards

This unit conforms the following international standards.

- EN 60601-1:2006+A1:2013
- EN 606061-1-2:2015
- EN 60601-1-3:2008+A11:2016
- EN 60601-1-6:2010+A1:2015
- EN 60601-2-54:2009+A1:2015
- EN 60627:2001
- EN ISO 10993-1:2009+AC:2010
- EN ISO 14971:2012
- EN 62220-1:2004
- EN 62304:2006+AC:2008
- EN 62366:2008+A1:2015
- EN ISO 15223-1:2016
- EN 1041:2008

■ RE Compliance

Hereby, Canon Inc. declares that this equipment is in compliance with the relevant statutory requirements.
The full text of the EU (including UK) declarations of conformity is available at the following Internet address:
https://global.canon/en/deocouk/medcom/index.html

1.8 Statement of Compliance with Standards

- X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION EN 60601-2-54:2009+A1:2015

1.9 Manufacturer Information

Manufacturer:	SHIMADZU CORPORATION Medical Systems Division
Address:	1, NISHINOKYO-KUWABARACHO, NAKAGYO-KU, KYOTO, 604-8511, JAPAN

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Chapter 2

Contents

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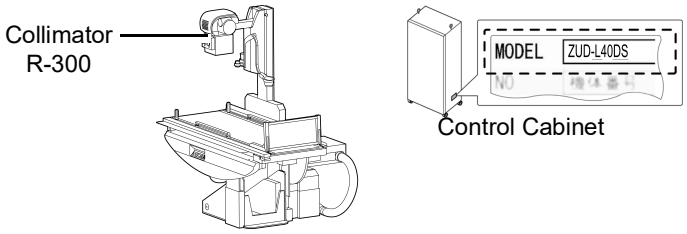
2.3 Remote Control Table 29
2.4 Digital Radiography Unit 31

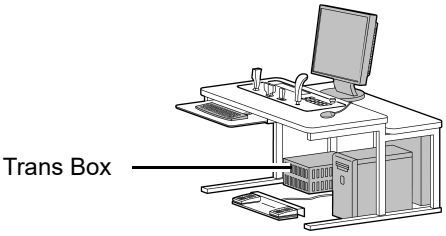
2.1 Package Contents

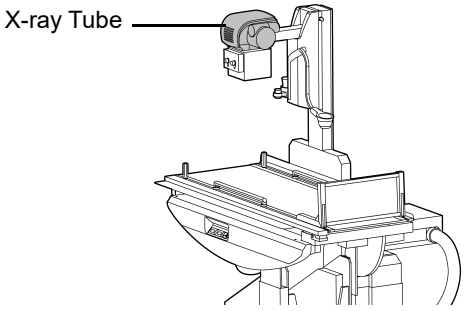
The FLEXAVISION comprises an X-ray diagnostic table, DR unit, control cabinet, remote console, FPD and other units. The required components vary with applications.
The X-ray diagnostic table is available in two types: one with a tabletop that can be raised and lowered and the other without this capability.

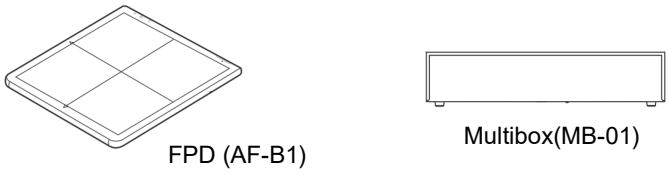
Component Unit	Model No.
REMOTE CONTROLLED R/F SYSTEM (X-ray Diagnostic Table + Control Cabinet)*1,*3	ZUD-*40*
Image Processing Unit	SDR-150C
X-ray Tube*2	0.6/1.2P324DK-85 0.6/1.2P326D-150 0.3/0.8P324DK-85
FPD sensor unit (FPD + Multibox(MB-01))*1,*3	B1



ZUD-*40*
- Type of diagnostic table
  - D: Not elevating tabletop
  - DS: Elevating tabletop
- Output of X-ray high-voltage generator
  - L: 50 kW output, V: 65 kW output,
  - B: 80 kW output







*1: Equipment suitable for use in the patient environment.
*2: The component unit depends on the combined system.
*3: Table surface, compression cone, and FPD are applied parts that contact the patient body.

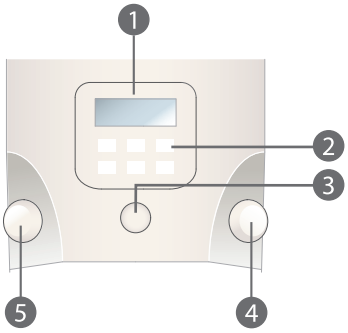
⚠ WARNING

Do NOT connect the equipment other than the designated equipment to the system.

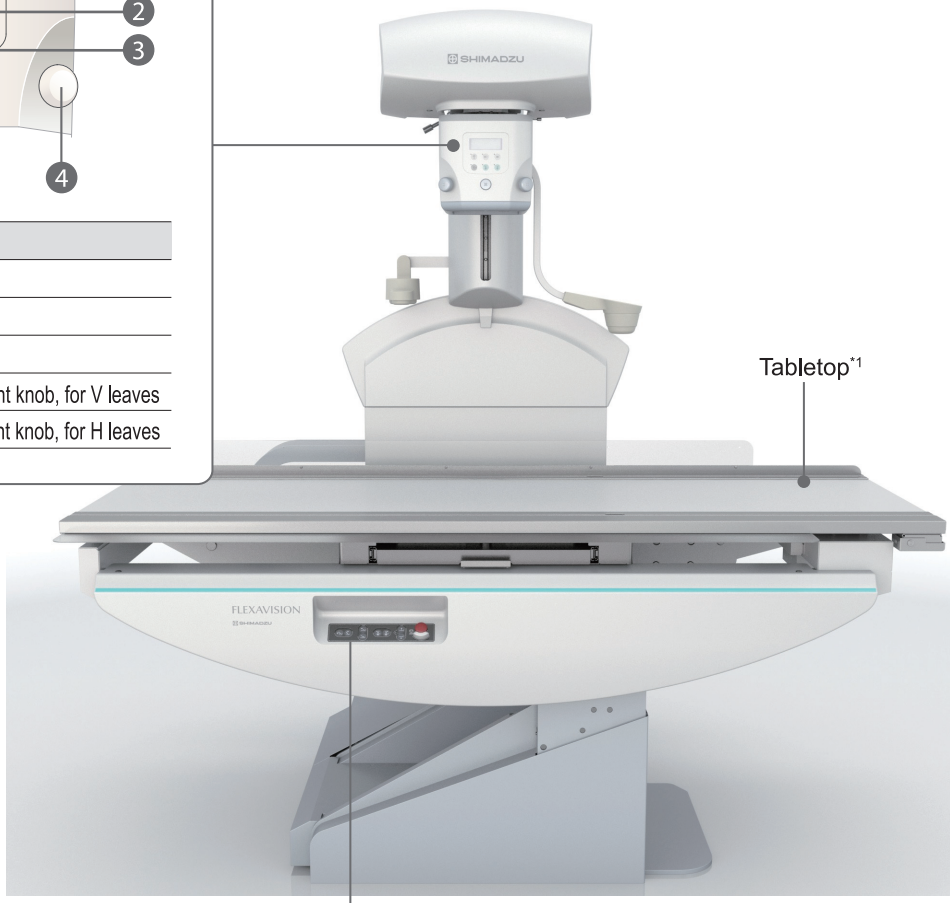
2.2 Diagnostic Table

X-Ray Diagnostic Table

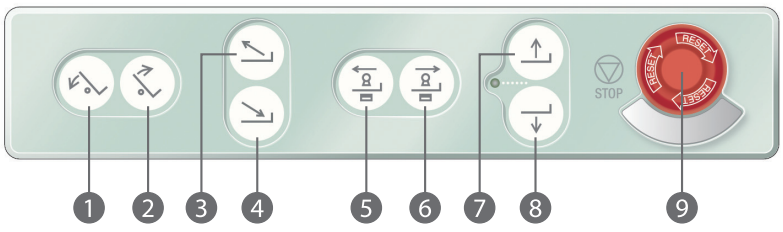
■ Collimator



Name	
1	Display panel
2	Control panel
3	Lamp button
4	Irradiation field adjustment knob, for V leaves
5	Irradiation field adjustment knob, for H leaves



■ Local control panel

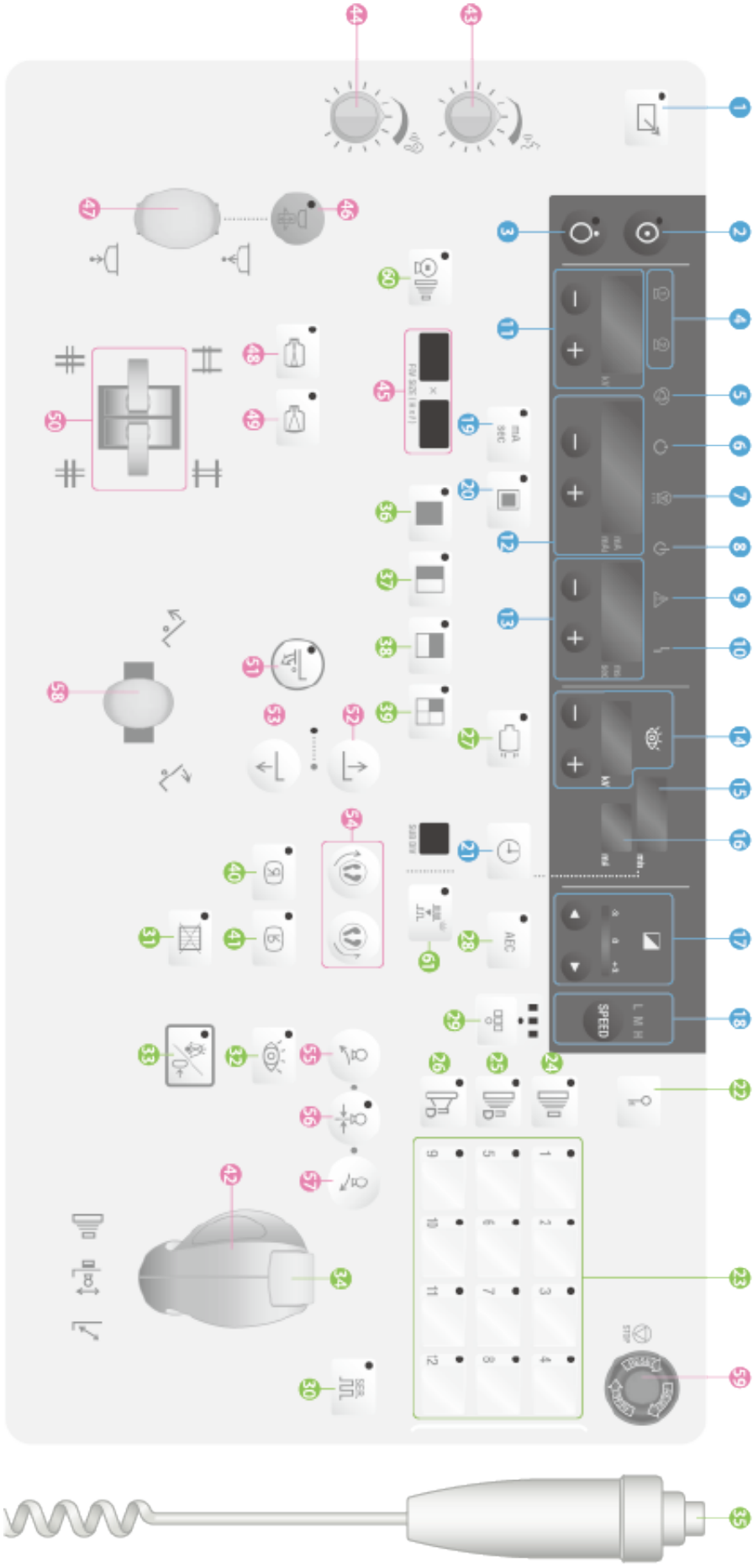


Name	
1	Tabletop Tilt-down button
2	Tabletop Tilt-up button
3	Tabletop **Rear** button
4	Tabletop **Front** button
5	Imaging Unit Head Side button
6	Imaging Unit Feet Side button
7	Tabletop UP button
8	Tabletop DOWN button
9	STOP button

* With tabletop up/down type only

*1: An applied part that contacts the patient's body

2.3 Remote Control Table



Fluoroscopy / Radiography

1. Remote / Local Console Selector
2. Power ON Button
3. Power OFF Button
4. X-ray Tube Indicator
5. Memory Shot Indicator
6. Radiography Ready Up Indicator
7. X-ray Indicator
8. Stand-by Indicator
9. Caution Indicator
10. Fault Indicator
11. Radiography kV Setting
12. Radiography mA/mAs Setting
13. Radiography sec Setting
14. Fluoroscopy kV Setting
15. Fluoroscopy Accumulated Time Indicator
16. Fluoroscopy mA Indicator
17. Density Up / Down Button
18. Speed Button
19. Radiography mA / mAs Switch Button
20. Radiography Focus Switch Button
21. Fluoroscopy Timer Preset Button

Fluoroscopy / Radiography

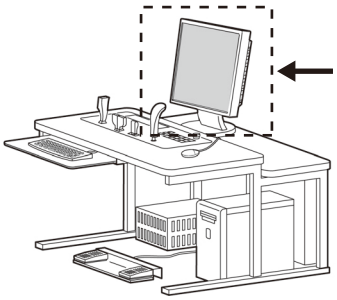
22. APR Setting Button
23. APR Selection Button
24. General Radiography Technique Button
25. FPD Portable Radiography Button
26. Digital Radiography Technique Button
27. IBS Switch Button
28. AEC Switch Button
29. Photo Pickup Field Selection Button
30. SPOT / SERIAL Radiography Selector
31. Grid Status Lamp Button
32. Fluoroscopy Selection Button
33. Fluoroscopy Timer Button
34. Exposure Button
35. Hand Switch
36. 1-ON-1 Format Button
37. 2-ON-1 (vertical) Format Button
38. 2-ON-1 (horizontal) Format Button
39. 4-ON-1 Format Button
40. Image H-reverse Button
41. Image V-reverse Button
60. Anode Rotation Stop Button
61. Pulse Rate Selection Button

X-ray Diagnostic Table

42. Tabletop / Imaging Unit Control Lever
43. MIC Volume
44. Speaker Volume
45. FPD Size Indicator
46. Squeeze Compression Button
47. Compression Control Lever
48. Small Field Size Selection Button
49. Large Field Size Selection Button
50. Collimator Operation Handles
51. Trendelenburg Permission Button
52. Tabletop Ascending Button
53. Tabletop Descending Button
54. Rolling Step Control Button
55. Oblique Projection Head-side Button
56. Oblique Projection Center Button
57. Oblique Projection Foot-side Button
58. Tabletop Tilting Lever
59. Stop Button

2.4 Digital Radiography Unit

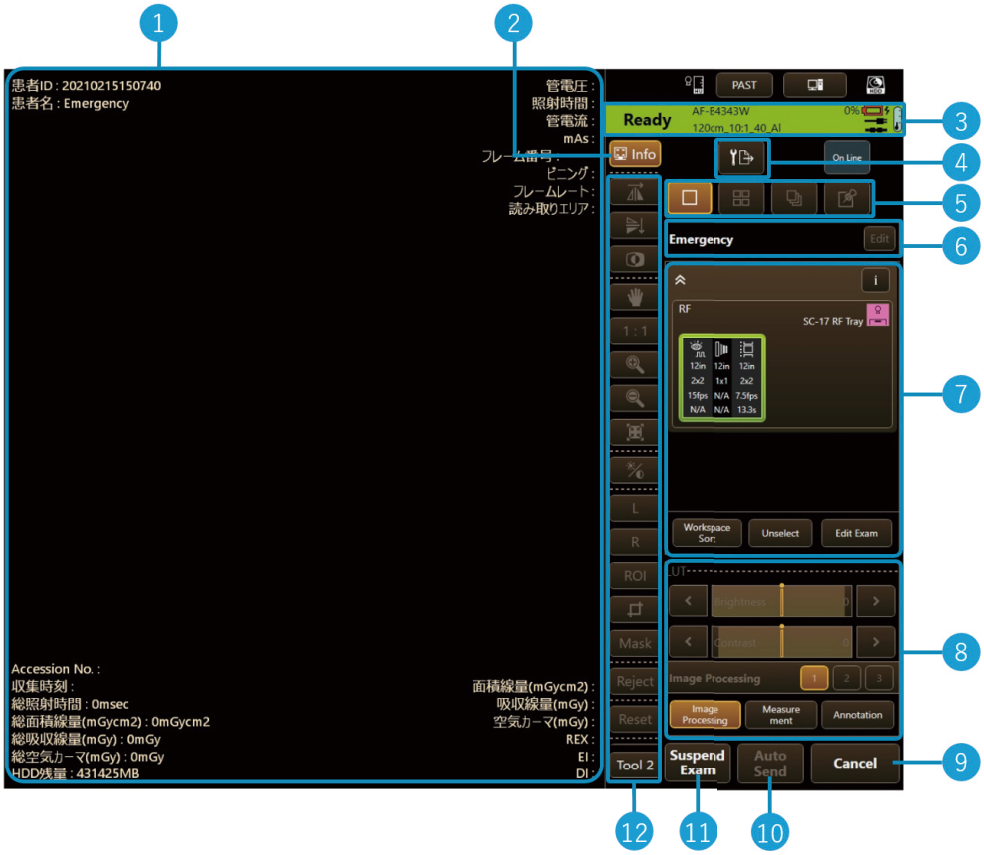
Digital Radiography System Basic Screen



● [EXAM > Worklist] Screen

Screen Names	
1	Study List
2	Search For Study List pane
3	Worklist button
4	EXAM tab
5	Manual button
6	PAST tab
7	System Setup button
8	HDD Free Space icon
9	On Line/Off Line
10	Patient Information pane
11	Study Information pane
12	Edit Exam button
13	Start Exam button
14	Emergency button
15	Refresh button
16	Refresh Option button
17	HU Display pane

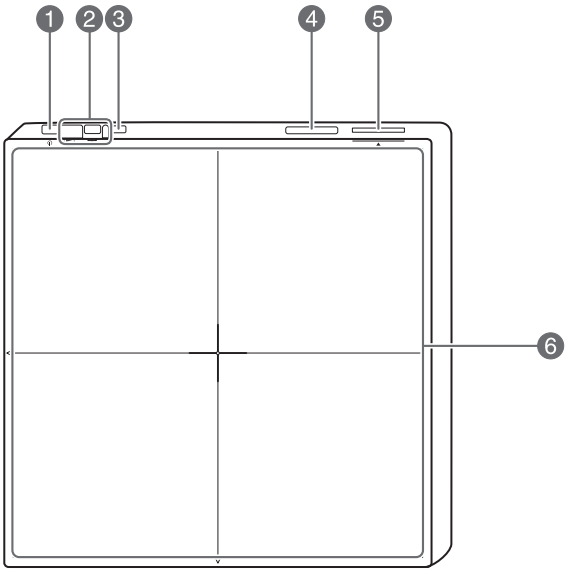
● [EXAM > Examination] Screen



Screen Names	
1	Image View pane
2	Info button
3	System Status bar
4	Output Setting button
5	View Mode buttons
6	Patient Information pane
7	Study Information pane
8	Image Processing buttons
9	Cancel button
10	Send to Storage button
11	Suspend Exam button
12	Toolbar for Reviewing Images

FPD Sensor Unit

● FPD (AF-B1)



Name	Function
1 Power switch	Controls a power supply ON/OFF and infrared communication.
2 Status indicator lamps	Indicate the status of the FPD (see the table below).
3 Infrared transmission part	Detect an infrared data-communication unit and make the system recognize a sensor unit.
4 Wireless aperture	Transmits image data with wireless communication.
5 External cable connector	Connector for a wiring cable connection.
6 Effective imaging area frame	Effective radiography area and center position

FPD status indications

The operation status of the FPD is indicated by the combination of the "POWER" and "READY" lamps.

FPD status	Status indicator lamps	
	Power LED	READY LED
Power ON	Lit	Unlit
Power OFF	Unlit	Unlit
Linkage started	Lit	Flashing (3-sec only)
Switching to exposure ready status	Lit	Flashing
Exposure ready status	Lit	Lit
Error	Flashing	Flashing

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Chapter 3

PREPARATION

3.1 Mounting/Removing the FPD 36
3.2 Mounting/Removing the Grid 39
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3.6 X-ray Tube 180° Swing Unit (Optional) 53
3.7 X-ray Tube 37/90° Swing-out Unit (Optional) 55

3.1 Mounting/Removing the FPD

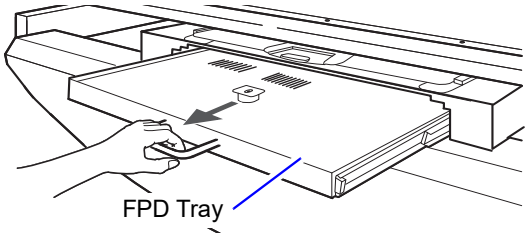
NOTE The FPD can be mounted and removed while the power to it is ON.

■ Mounting the FPD

1 Draw out the FPD tray

1 Press the [Tabletop Rear] button on the local control panel to move the tabletop all the way back.

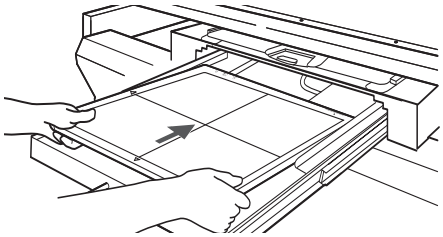
2 Draw the FPD tray toward you by its handle.



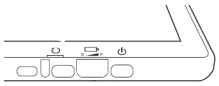
NOTE The following label is attached on the FPD.

2 Mount the FPD.

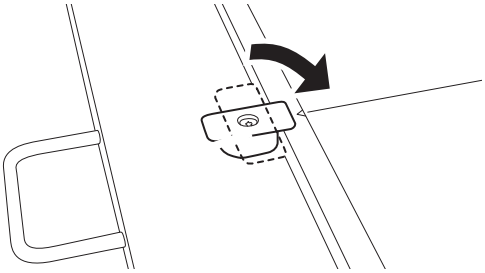
1 Holding both ends, insert the FPD firmly as far as it will go.



At this time, FPD should be inserted so that LED and a connector part may be in the back.

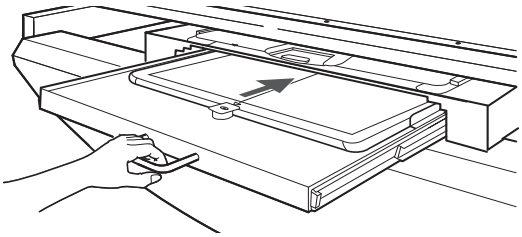


2 Rotate the knob,



3 Stow away the FPD tray.

1 Hold it by the handle and push the FPD tray in firmly as far as it will go.



NOTE Push the FPD tray in firmly as far as it will go.
If it is not in as far as it will go, the X-ray diagnostic table may not operate, and fluoroscopy and radiography may not be possible.

⚠ CAUTION

Do NOT apply any force to the top of the FPD tray while it is pulled out.

This could damage the FPD tray.

Do NOT put your hand on the FPD tray when pushing the FPD tray.

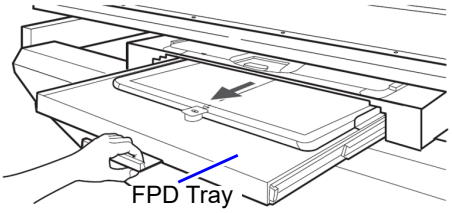
Otherwise, your hand may be caught in it.

■ Removing the FPD

1 Draw out the FPD tray

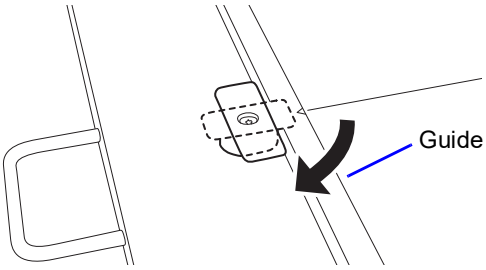
1 Press the [Tabletop Rear] button on the local control panel to move the tabletop all the way back.

2 Draw the FPD tray toward you by its handle.

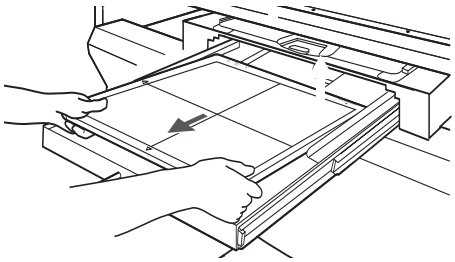


2 Take out the FPD.

1 Rotate the knob.

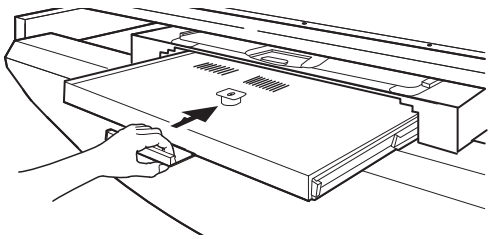


2 Holding both ends, take the FPD out of the FPD tray.



3 Stow away the FPD tray.

1 Hold it by the handle and push the FPD tray in firmly as far as it will go.



3.2 Mounting/Removing the Grid

Using the anti-scatter grid improves image quality by reducing the impact of scattered X-ray.
However, the X-ray grid should be removed when the exposure level must be reduced to perform radiography for pregnant women or infants.

⚠ CAUTION

Move the tabletop all the way back and lift the hand guard when removing or attaching the grid.

Otherwise, your hand may be caught between the tabletop and the grid, and your fingers may be injured with the hand guard.

Do NOT operate the device by other operators when removing or attaching the grid.

Otherwise, your hand may be caught between the tabletop and the grid.

The grid is heavy. Do not hold with one hand or with only the handle.

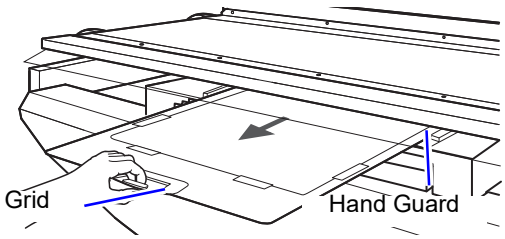
When installing or removing the grid, hold it firmly with both hands.

■ Removing the Grid

1 Remove the grid

1 Press the [Tabletop Rear] button on the local control panel to move the tabletop all the way back.

2 Draw the grid toward you by its handle.



⚠ CAUTION

The grid is heavy. Do NOT hold the grid with one hand. Do NOT hold the grid type indicator.

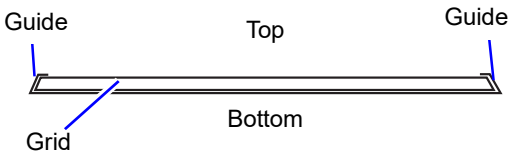
The grid type indicator is not designed to support the entire weight of the grid.
Dropping the grid may cause personal injury or damage the grid.

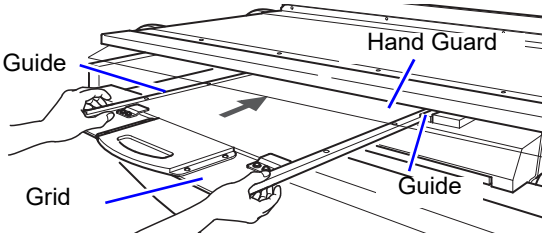
■ Mounting the Grid

1 Mount the grid

1 Press the [Tabletop Rear] button on the local control panel to move the tabletop all the way back.

2 Check the top/bottom orientation of the grid and insert the grid into the groove of the rail, and then put it firmly in as far as it will go.

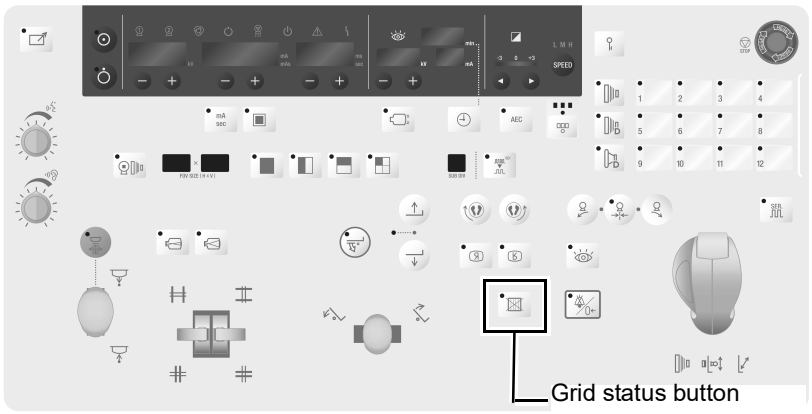




NOTE

- Check the vertical orientation of the grid when mounting it. It cannot be mounted upside down.
- Push the grid in firmly as far as it will go.
  If it is not in as far as it will go, the X-ray diagnostic table may not operate, and fluoroscopy and radiography may not be possible.

The state of the grid can be checked using the grid status button.



Button Display	State
Lit	The grid is not installed.
Blinking	The grid is not inserted all the way in.
Off	The grid is installed.

NOTE

Do NOT apply any force or sit on the grid while it is pulled out halfway.?
The following label is attached on the grid.

3.3 Preparing Wireless AF-B1

■ Charging Battery Pack

When using AF-B1 with Wireless, check the battery status before starting examination.
The remaining battery charge can be confirmed on the monitor of the SDR-150C control software. Recharge the battery pack if needed.

Display of remaining battery charge

Display	Battery level	Countermeasure
	100 to 60 %	Charge sufficient to perform examination.
	59 to 9 %	Charge sufficient to perform examination. A spare battery pack may be required.
	8 to 5 %	Almost discharged (a few examination are possible). Replace the battery pack with a fully charged one.
	4 to 0 %	Discharged. Replace the battery pack with a fully charged one.

1 Fully charge the battery pack in the battery charger.

Battery slowly discharged even if not in use after fully charted.
Charge the battery on the day of examination or on the previous day.

When an electricity is on, the battery charges even if FPD is inserted into the tray.

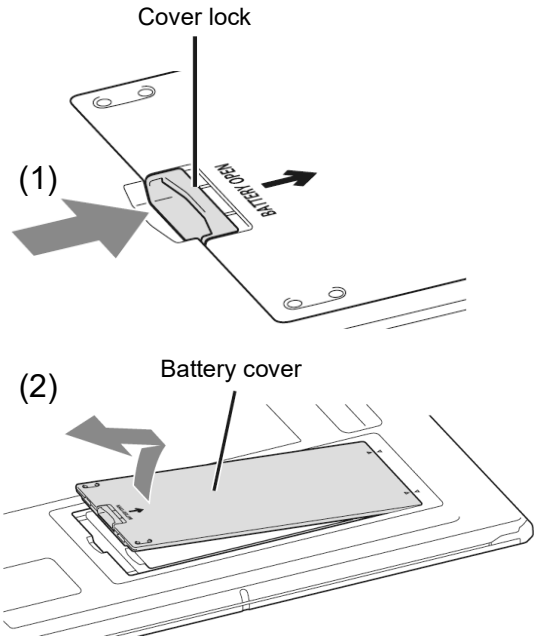
■ Inserting Battery Pack

⚠ CAUTION

Place the AF-B1 on a flat surface before starting work.
Otherwise, the battery pack may fall when it is loaded.

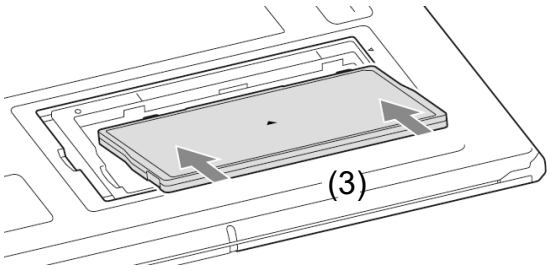
1 Remove the battery cover.

1 Press the cover lock (1) to release the lock, then lift the battery cover up and pull it out (2).



2 Insert the bafttery pack.

1 Insert the battery pack (3).



⚠ CAUTION

Please handle the battery pack carefully. Check the insertion direction of the battery pack before inserting it.

Make sure the battery pack is properly and fully inserted.

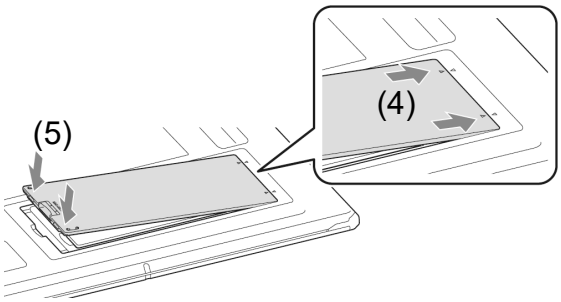
3 Attach the bafttery cover.

1 Check the rubber inside the battery cover for foreign objects and also check that there is no abnormality such as cracks or twists in the rubber.

NOTE

- Wipe off any foreign matter on the rubber.
- If the rubber is twisted, please fix it by hand.

2 Insert the battery cover (4) and press the battery cover from above to lock it (5).



⚠ CAUTION

Make sure that there is no bulge in the center when the battery cover is attached.

If there is bulge, waterproof and dustproof performance will be degraded.

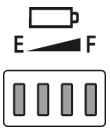
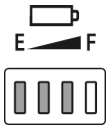
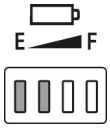
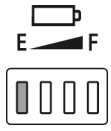
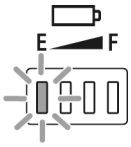
Check the shape of the battery cover. If the inside of the cover is bent into a bowl shape, replace it with a new one.

NOTE

- Make sure that the battery cover is fully inserted.
- Make sure that the lock is securely engaged.

The battery level of the battery pack is displayed on the Power LED lamp of the FPD while the FPD is turned on. *

* When the FPD is connected wirelessly and the battery pack is loaded to the FPD.

Power LED Lamp					
Battery level	100 to 76 %	75 to 51 %	50 to 26 %	25 to 5 %	4 to 0 % *

(▮ : On, ☼ : Blinking (1 second cycle), ▯ : Off)

* You cannot acquire an image when the battery level is 4 to 0% (Blinking).

■ Removing Battery Pack

NOTE If you don't use the FPD for a while, remove the battery pack. If the battery pack is left attached to the FPD for a long period of time, a small amount of current may flow, causing overdischarge and shortening of battery life.

1 Turn off the FPD.

1 Press and hold the POWER switch for approximately 3 seconds to turn off the power.

► The Power LED lamp turns off.

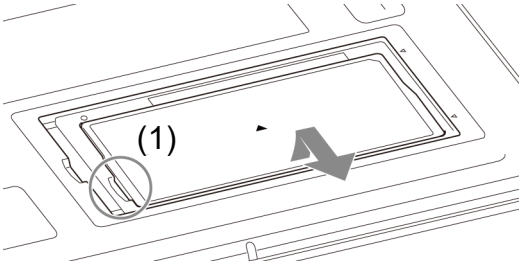
2 Remove the battery pack.

1 Remove the battery cover.

Step 1 onward of "Inserting Battery Pack".

2 Remove the battery pack.

► Place your finger in the mounting groove and pull out the battery pack by grabbing it (1)



3 Attach the battery cover.

Step 3 onward of "Inserting Battery Pack".

3 Place the battery pack in the storage site.

3.4 Operating the X-ray Diagnostic Table

⚠ WARNING

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

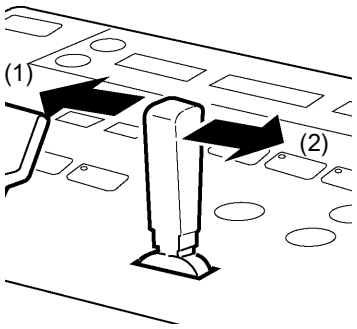
Should such liquid drip on equipment surfaces, wipe it off immediately. Any such liquid entering into system electronics may cause failure or malfunction.
Should liquid drip on the operation panel or enter the covers, immediately turn off the power and contact your Shimadzu service representative.

To operate the diagnostic tabletop or imaging unit, use the buttons and levers with deadman function* (hereinafter represented as [DM]).

*With the deadman function, buttons/levers become activated only while being pressed/tilted.

■ Tilting the Tabletop

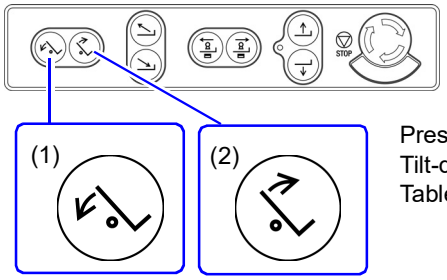
Remote Console



Tilt Tabletop Tilting Lever to Left (1) or Right (2).

[DM]

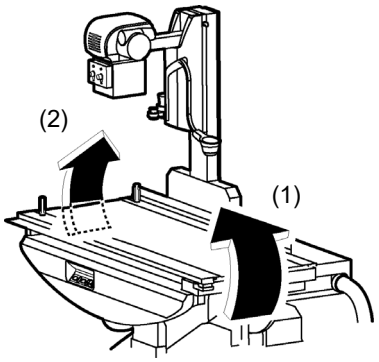
Local Control Panel



[DM]

Press Tabletop Tilt-down Button (1) or Tabletop Tilt-up Button (2)

X-ray Diagnostic Table

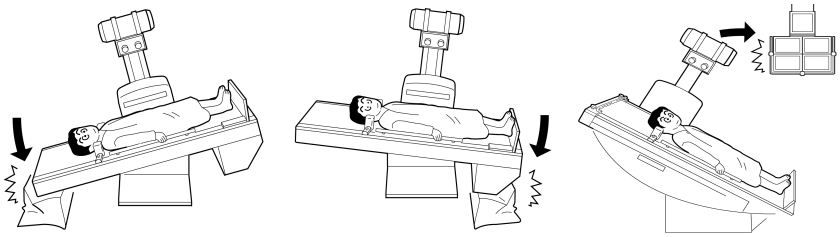


(1) Tilts from vertical or horizontal to Trendelenburg positions.
(2) Tilts from Trendelenburg or horizontal to vertical positions.

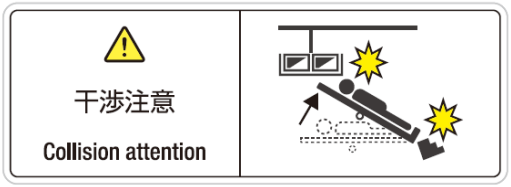
⚠ WARNING

Confirm that there is no apparatus within the operating range when moving the X-ray diagnostic table.

Ensure that no desk, chair, stretcher, foot switch, monitor suspension, etc. is placed within the operating range.
The apparatus may be crushed by or collide with the equipment, causing damage.

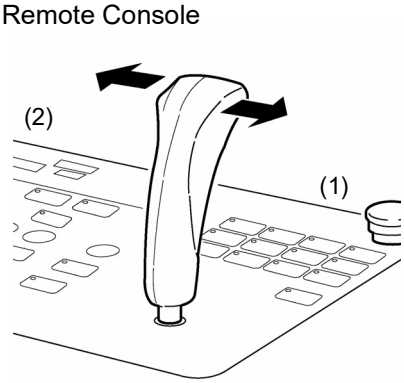


The following label is attached on the front panel and remote console.



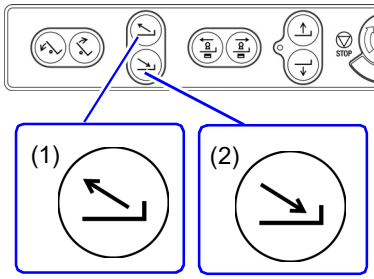
■ Moving the Tabletop Laterally

Remote Console [DM]



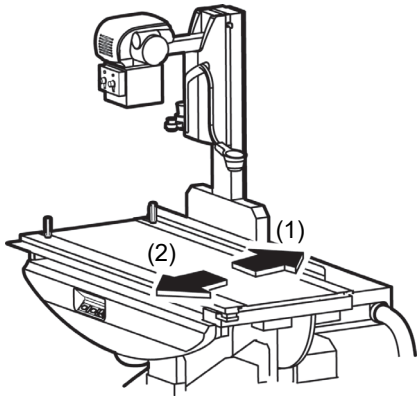
Tilt Tabletop/Imaging Unit Control Lever to Right (1) or Left (2).

Local Control Panel [DM]



Press Tabletop Rear Button (1) or Tabletop Front Button (2).

X-ray Diagnostic Table

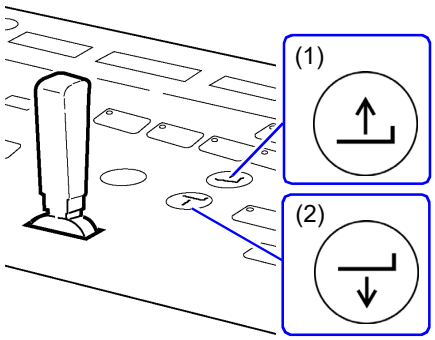


(1) Moves to rear.
(2) Moves to front.

■ Moving the Tabletop to Up/Down

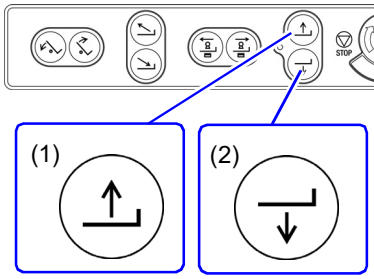
Only the 5DS Tabletop can move up and down.

Remote Console [DM]



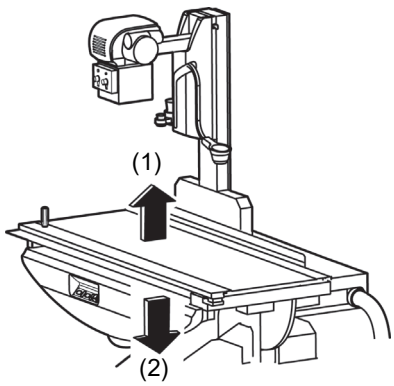
Press Tabletop Ascending Button (1) or Tabletop Descending Button (2).

Local Control Panel [DM]



Press Tabletop Ascending Button (1) or Tabletop Descending Button (2).

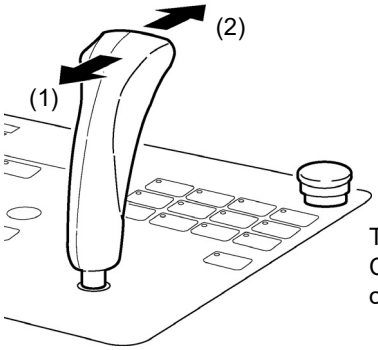
X-ray Diagnostic Table



(1) Moves upwards.
(2) Moves downwards.

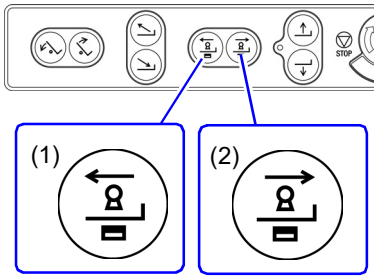
■ Moving the Imaging Unit Longitudinally

Remote Console [DM]



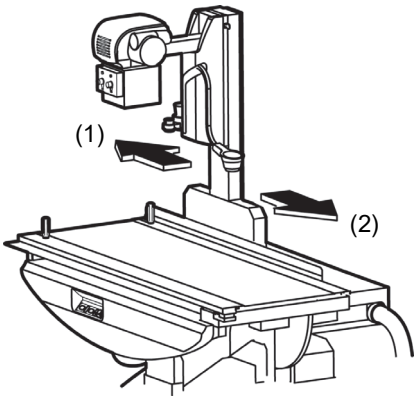
Tilt Tabletop/Imaging Unit Control Lever to Backward (1) or Forward (2).

Local Control Panel [DM]



Press Imaging Unit Head Button (1) or Imaging Unit Foot Button (2).

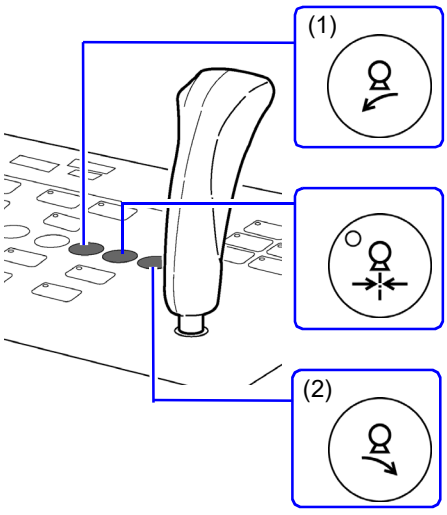
X-ray Diagnostic Table



(1) Moves in the head direction.
(2) Moves in the foot direction.

■ Inclining the Imaging Unit

Remote Console [DM]

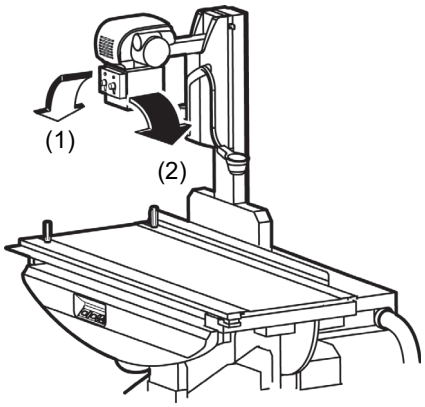


Press Oblique Projection Head-side Button (1).

Press to return from oblique projection position to center.

Press Oblique Projection Foot-side Button (2).

X-ray Diagnostic Table



(1) Moves in the patient's head direction.
(2) Moves in the patient's foot direction.

⚠ CAUTION

Do NOT press the [Exposure Button] accidentally when the tabletop is operated by [Tabletop/Imaging Unit Control Lever].

■ Operating the Compression Cone

⚠ WARNING

The operator must pay attention when using the compression unit.

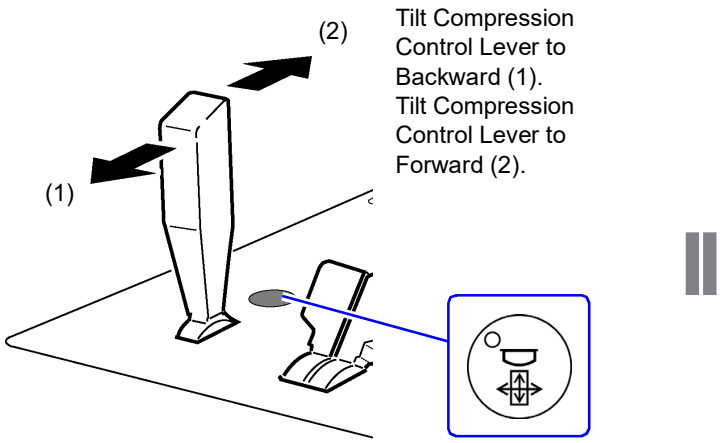
In procedures involving compression of the abdomen, the operator must take great care to avoid hurting the patient (for example ribs) while using the compression unit.
It is suggested to inform the patient in advance about the effects induced by the compression unit and about the movement of the compression cone.

⚠ CAUTION

Measure the compression force of the compression cone periodically to maintain the compression force at the installation.

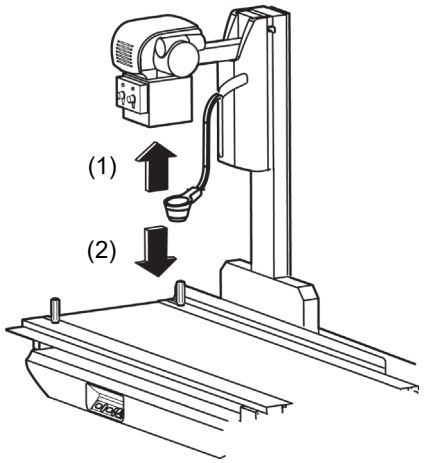
The compression force changes depending on usage. It is dangerous if the compression force exceeds the prescribed value. The measurement and adjustment of the compression force is performed by Shimadzu services during periodic inspections.

Remote Console [DM]



Squeeze Compression Button

X-ray Diagnostic Table



(1) Moves to the stand-by position.
(2) Moves to the compression position.

⚠ CAUTION

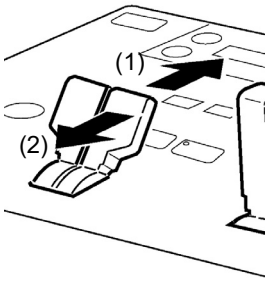
Operate the compression unit while the [Squeeze Compression] button is off, except when conducting Squeeze Compression.

Moving the tabletop or imaging unit while the [Squeeze Compression] button is on could present a risk of fracturing the patient's ribs.

■ Specifying the X-ray Irradiation Field

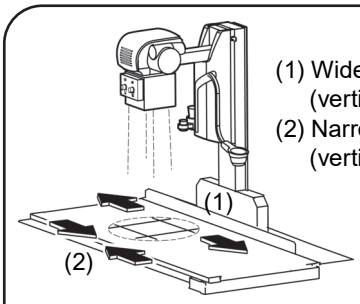
● Adjusting by Collimator Handles (when using the DR technique)

Remote Console

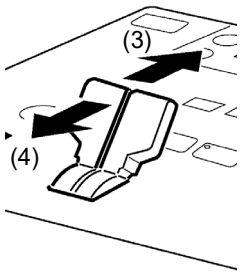


Tilt Right Handle to Forward (1).
Tilt Right Handle to Backward (2).

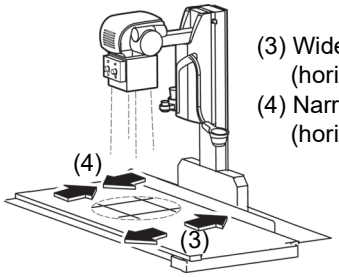
X-ray Diagnostic Table



(1) Widens the shutter (vertical).
(2) Narrows the shutter (vertical).



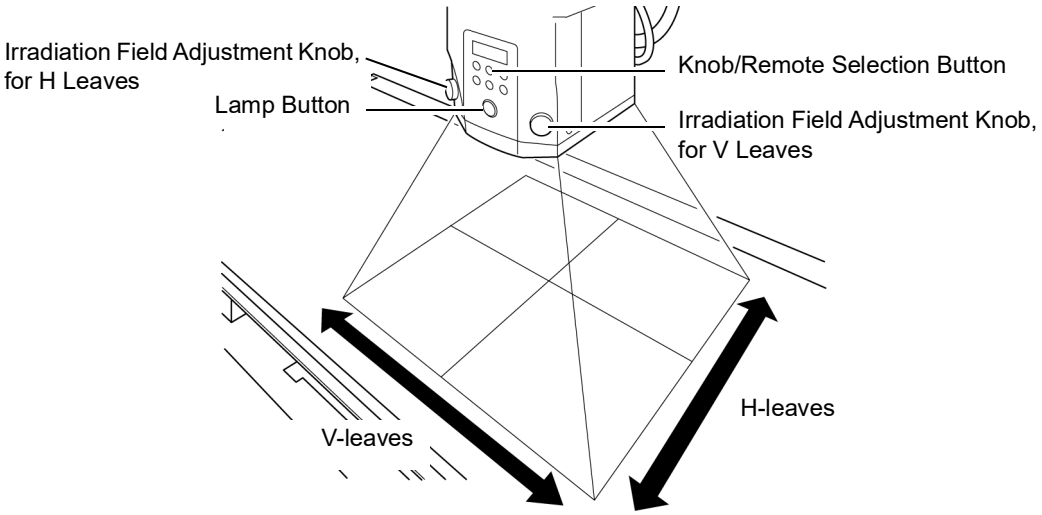
Tilt Left Handle to Forward (3).
Tilt Left Handle to Backward (4).



(3) Widens the shutter (horizontal).
(4) Narrows the shutter (horizontal).

● Adjusting Manually by Collimator Knobs (when using FPD portable radiography/ general radiography)

Press the lamp button on the front face of the collimator, and adjust the irradiation field with the irradiation field adjustment knob.
The size set for the field size is the maximum size for the X-ray irradiation field.



■ Selecting an X-Ray Filter

● Types of X-Ray Filter

Display/Material	Applications
Cu0 mm	No filter
Cu0.1 mm	The limbs, etc.
Cu0.2 mm	Trunk, vertebral body, etc.
Cu0.3 mm	Chest, abdomen, etc.

● Selecting an X-Ray Filter

The X-ray filter is selected automatically in accordance with the set APR, but it is also possible to select the X-ray filter with the collimator's [Filter Selection] button after the APR has been set.

Press the [Filter Selection] button.

Pressing this button takes you to the next filter type in the following selection cycle: "Cu0 mm" → "Cu0.1 mm" → "Cu0.2 mm" → "Cu0.3 mm" → "Cu0 mm".

NOTE In the techniques that permit fluoroscopy (such as the DR technique), the soft x-ray filter to be used is pre-registered in the APR and cannot be switched manually.

The use of X-ray filter of Cu0.1 mm, Cu0.2 mm or Cu0.3 mm can reduce radiation dose in fluoroscopy and radiography for pediatric imaging.

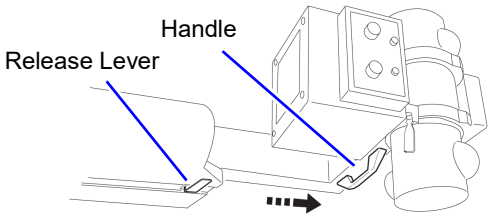
3.5 Extending the X-ray Tube Unit (1.5 m Extension)

The X-ray tube can be extended, for example for video fluorographic/radiographic examination while the patient remains in a wheelchair.

1 Pull out the X-ray tube unit

1 Tilt the X-ray diagnostic table up to the vertical position, as far as the point where it stops.

2 Pull out the X-ray tube unit while operating the releasing lever on the X-ray tube support.



⚠ CAUTION

Pull the unit out by its handle

If you do not use the handle you could trap your hands.

⚠ CAUTION

Do not pull out the X-ray tube unit in the oblique state.

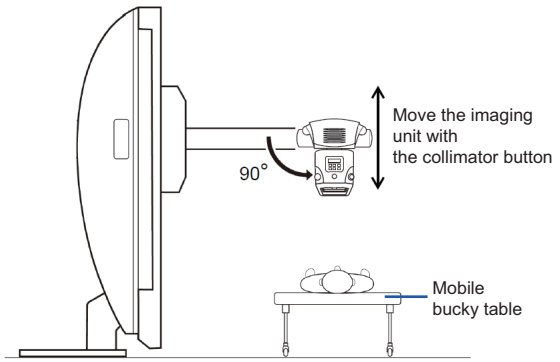
By pulling the release lever, the X-ray tube starts to move vigorously and there is a danger of injury or damage to the equipment.

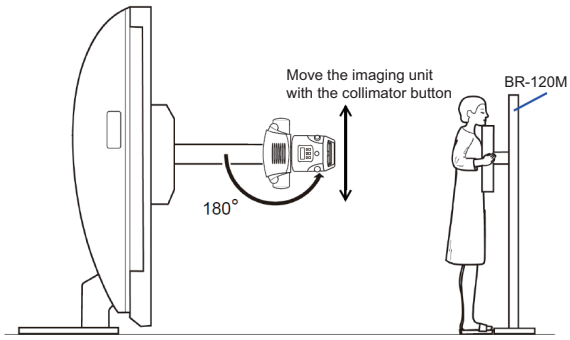
3.6 X-ray Tube 180° Swing Unit (Optional)

Before taking an exposure, set the diagnostic table in the vertical position, and manually rotate the X-ray tube unit in the direction of the optional bucky stand BR-120M. The tube rotation angle is 90° or 180°.

1 Before taking an exposure, set the diagnostic table in the vertical position.

2 Release the rotation lock of the X-ray tube and manually rotate the X ray tube unit at 90° or 180° in the direction of the bucky table, etc. and the lieder stand.



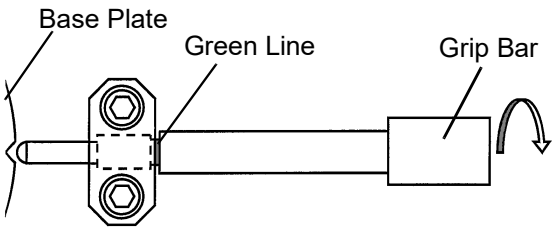


3 Fix the X ray tube with grip bar at 0°, 90° or 180°.

⚠ CAUTION

Certainly release the end of grip bar from base plate when rotating the X-ray tube (make sure that the green line of grip bar is visible).

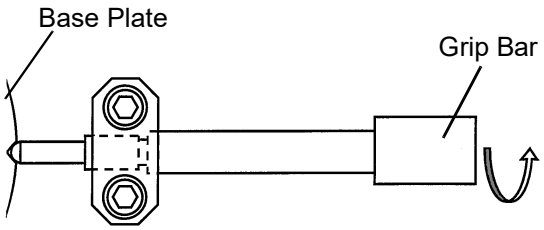
The grip bar and base plate may damage.



⚠ CAUTION

Certainly lock the end of grip bar to the base plate when fixing the X-ray tube.

The X-ray tube may rotate unexpectedly and cause the misalignment of X-ray beam.



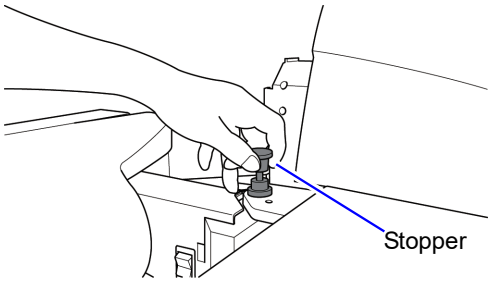
NOTE The X-ray tube unit can only be rotated when the diagnostic table is in the vertical position.
The table cannot be tilted during rotation.

3.7 X-ray Tube 37/90° Swing-out Unit (Optional)

Before taking an exposure, set the diagnostic table in the vertical position, and manually rotate the X-ray tube unit in the direction of the optional bucky stand BR-120M. The tube rotation angle is 37° or 90°.

1 Tilt the diagnostic table up to the vertical position.

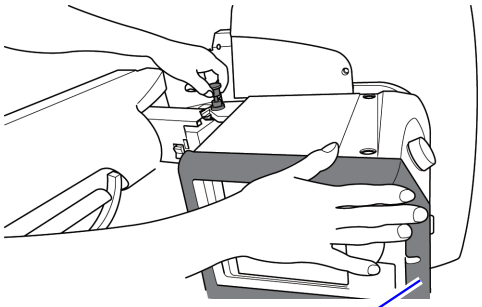
2 Pull up the stopper.



3 Rotate the X-ray tube 37° or 90°.

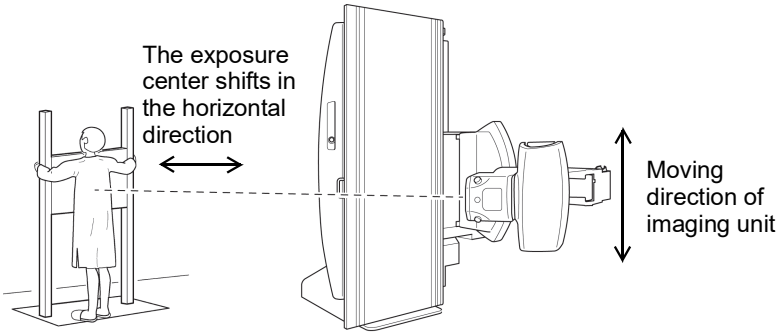
While pulling up the stopper, rotate the tube by pressing the rubber part of the collimator.

Confirm that the X-ray tube clicks to be locked into position. ( )



NOTE

- Tabletop cannot be tilted during operation.
- Be sure to press the rubber part of the collimator when rotating the X-ray tube.
- The vertical position of FLEXAVISION is not completely at 90° but tilted by 2° for safety.
  Therefore, when combined with a BR-120M for general radiography, the exposure center will slightly shift due to the vertical angel 88°, in the horizontal direction of the bucky device according to the longitudinal movement of the imaging unit. (The shift amount is 3.5 mm per 100 mm movement of the imaging unit.)
  For this reason, when using a position-fixed type radiography stand, it is recommended to fix the stand according to the position where the imaging unit is the most frequently used.



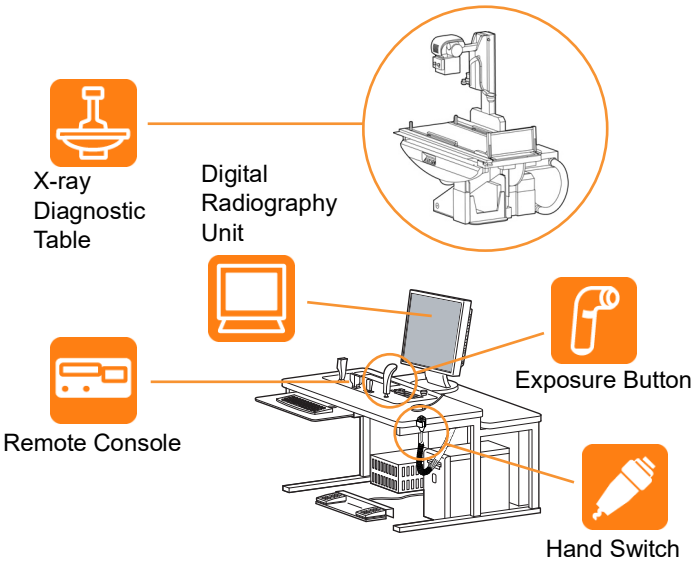
X-ray tube 37° Swing Unit

NOTE Be sure to hold the collimator with your hand when returning the X-ray tube unit to its original position. Collimator may move unintentionally and cause injury.

Chapter 4

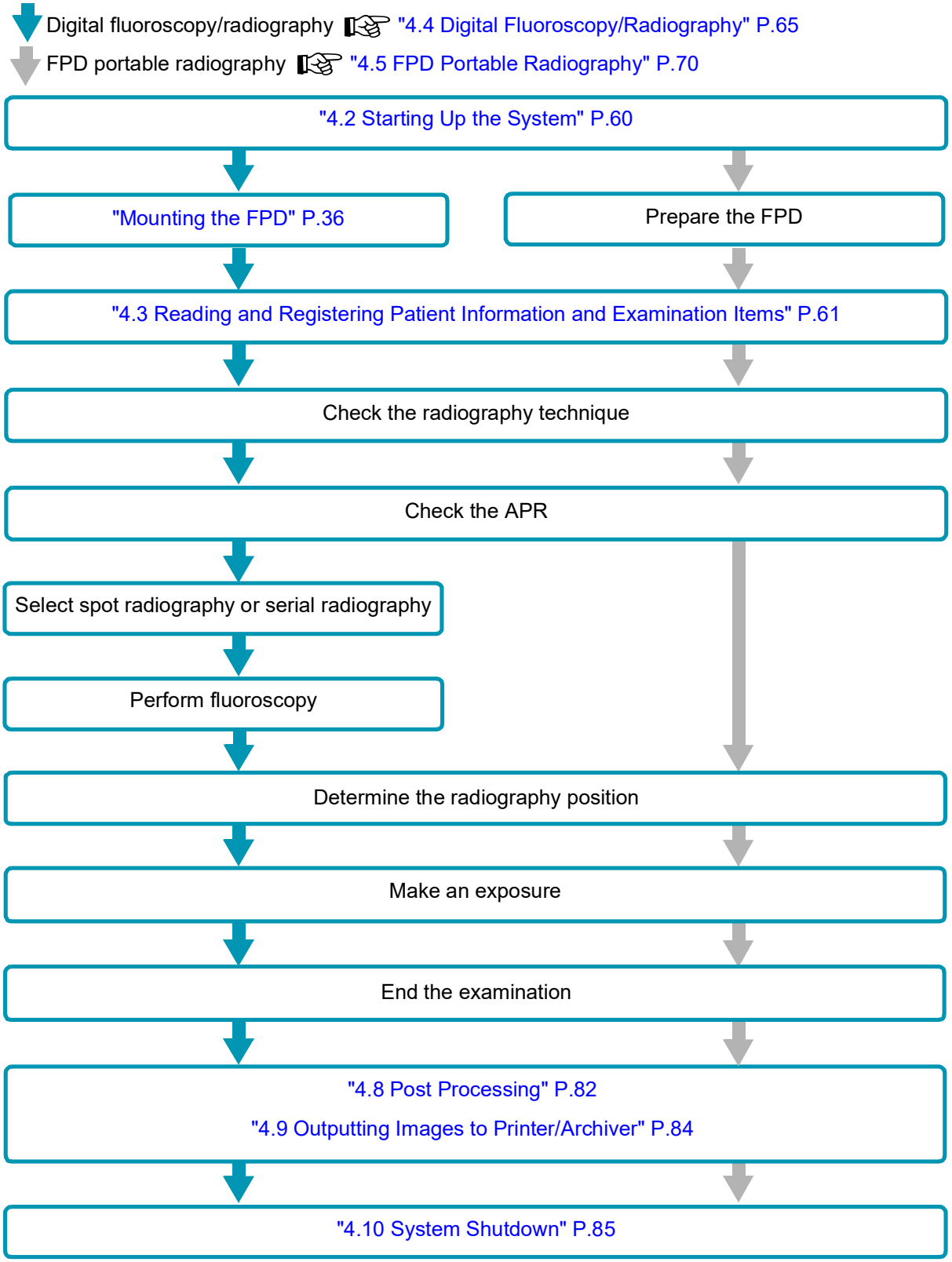
Radiography

4.1 Radiography Flowchart 59
4.2 Starting Up the System 60
4.3 Reading and Registering Patient Information and Examination Items 61
4.4 Digital Fluoroscopy/Radiography 65
4.5 FPD Portable Radiography 70
4.6 Radiography in Vertical Position Using X-ray Tube of Diagnostic Table 74
4.7 DSA Option 77
4.8 Post Processing 82
4.9 Outputting Images to Printer/Archiver 84
4.10 System Shutdown 85


X-ray
Diagnostic
Table
Digital
Radiography
Unit
Remote Console
Exposure Button
Hand Switch

4.1 Radiography Flowchart

A flowchart for radiography with FLEXAVISION F4 Package is given below.



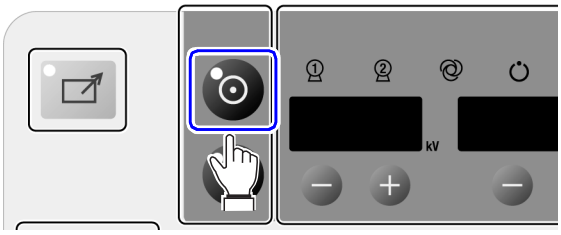
4.2 Starting Up the System

■ Starting Up the System

NOTE Be sure to carry out start-up maintenance before starting the system.

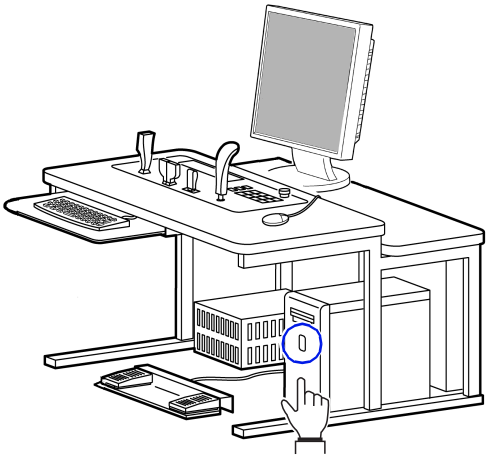
1 Press [ON]

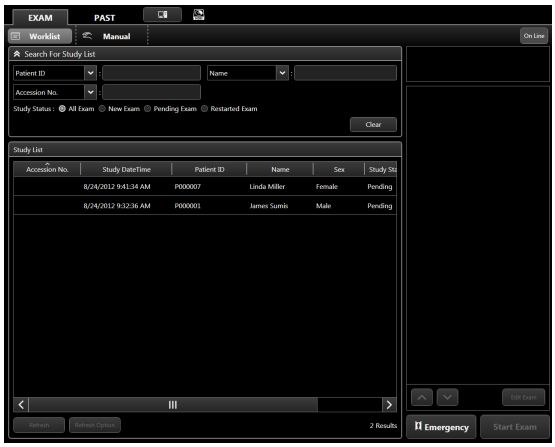
► The system power is turned on.
► Power to the FPD and multibox(MB-01) turns on at the same time.



2 Turn the DR power ON

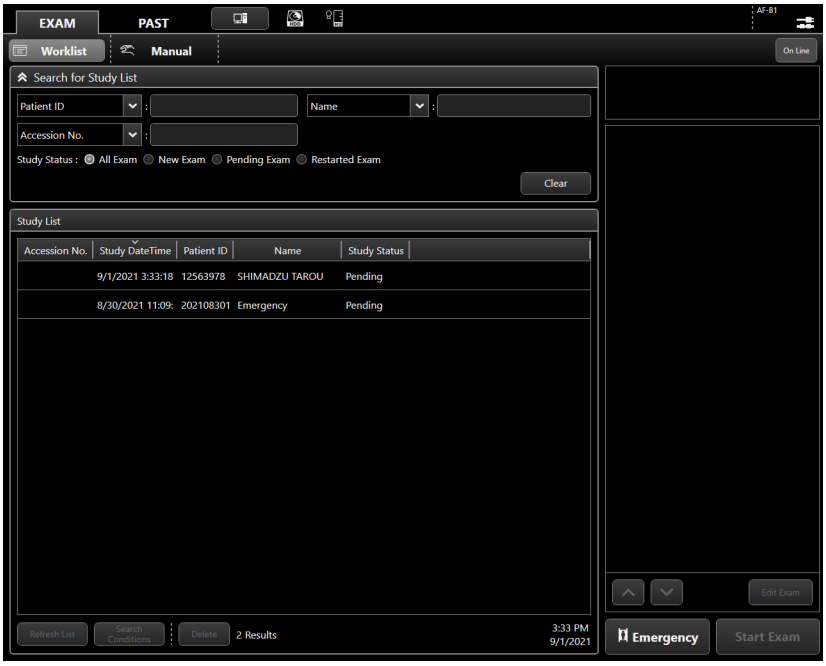
► The Start screen is displayed.
► The Worklist screen is displayed.





NOTE Be sure to boot the system with FPD inserted into the tray.
If FPD is not in the tray at boot time, it may take a long time to start the first study after boot. (The fluoroscopy cannot be performed for about a minute.)

4.3 Reading and Registering Patient Information and Examination Items

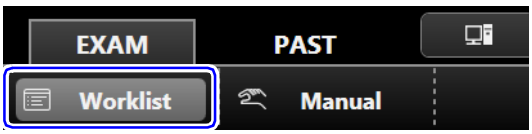


■ Reading from the Worklist

Read information that is already registered in the worklist.

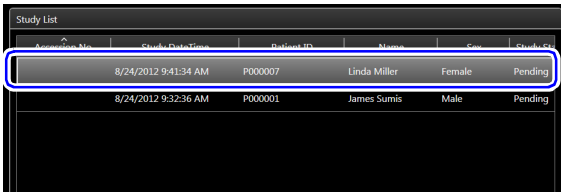
1 Display the Worklist screen

Click [Worklist].



2 Select the patient information

Select a patient from the examination list.



3 Start the examination

Click [Start Exam].

■ Emergency Registration

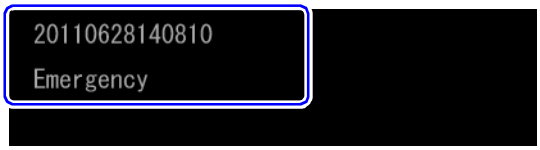
Set provisional information in cases where, for example, there is no time to input the patient information.

1 Set patient information for emergencies

Click [Emergency].

► The Patient's ID will be set automatically, and the Study screen will open.

On completing the examination, register the correct ID and name.



2 Select the radiography protocol among the examination options

See step 3 onward of "Registration in Manual Mode".

■ Registration in Manual Mode

Register the information on the patient to be examined manually.

1 Select the manual mode

Click [Manual].

2 Input the patient information

Set items such as the Patient ID, Patient's name, and Sex.

An examination can be performed by inputting just the Patient ID.

3 Select the radiography protocol among the examination options

1 Select the radiography protocol from the examination options under [Tray List] on the protocol screen.

When selecting the radiography protocol using [Search by Body Part] or [Search by Category], refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.

The radiography protocol can be narrowed down according to purpose.

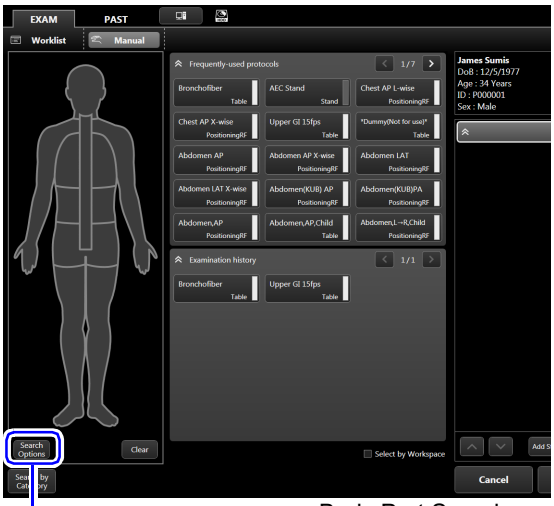
First, press the [Search by Body Part] button and then press the [Search Options] button on the region search screen. Next, select the exposure type to narrow down the radiography protocol according to purpose.

(1) To narrow down the radiography protocol of examinations that use fluoroscopy or radiography ⇒ RF

(2) To narrow down the radiography protocol for only performing radiography that uses the X-ray filter ⇒ Radiography

(3) To narrow down the protocol for general radiography that performs positioning fluoroscopy ⇒ Positioning Fluoro

For details, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.

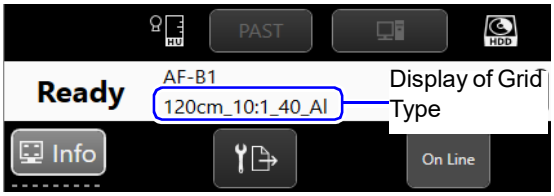


NOTE The factory-registered protocol is an example.
Change it if necessary.

4 Start the examination

Click [Start Exam].

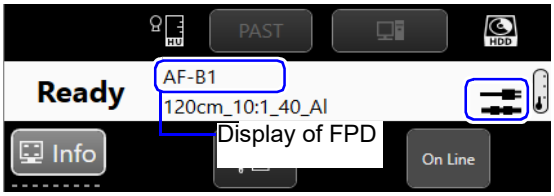
- ► The patient list will be made, and the Start Examination screen will be displayed.
- ► The indication at the top right of the screen will change from "Waiting" to "Ready".
- ► The radiography technique and APR will be selected, and the fluoroscopy/radiography parameters will be set, automatically.
- ► The type of grid set is displayed at the top right of the screen.



Always check the existence of the grid and its type. Note that the system cannot recognize the grid in the case of portable radiography or radiography with the Bucky stand with the FPD removed from the FPD tray on the X-ray diagnostic table.
(In this case, the grid type is displayed as "unknown".)

● FPD (AF-B1)

NOTE Check that the correct FPD for examination is selected. If the radiography is performed with wrong FPD, the image cannot be acquired.



● Wireless FPD Option Kit

NOTE Check that the correct FPD for examination is selected. If the radiography is performed with wrong FPD, the image cannot be acquired.

4.4 Digital Fluoroscopy/Radiography

1 Mount the FPD

Mount the FPD by referring to "Mounting the FPD" P.36.

When performing radiography on pregnant women or infants, the X-ray dose can be reduced by removing the grid.

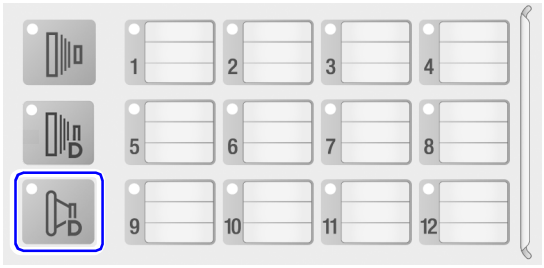
2 Check the patient information

Check the Patient ID and Patient's name.

3 Check the radiography technique

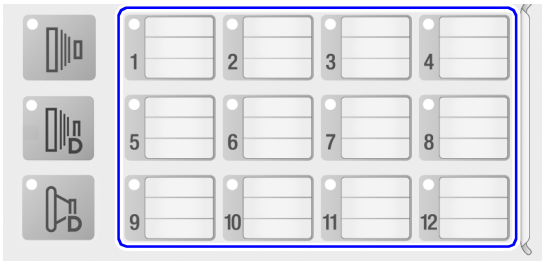
Check that the [Digital Radiography Technique] lamp has lit.

NOTE The X-ray filter setting in the digital radiography technique is fixed to "no filter".



4 Check the APR

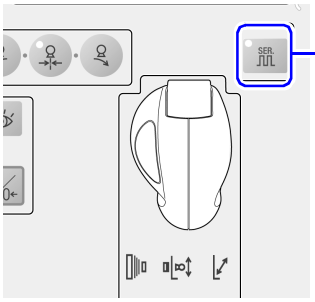
Check that the [APR] lamp corresponding to the relevant examination region has lit.



5 Select spot radiography or serial radiography

Press [Spot/Serial Radiography Selector] to select spot radiography or serial radiography.

Lamp lit: Serial radiography selected
Lamp unlit: Spot radiography selected



Spot/Serial Radiography Selector button

NOTE Digital radiography has limited irradiation duration as follows:

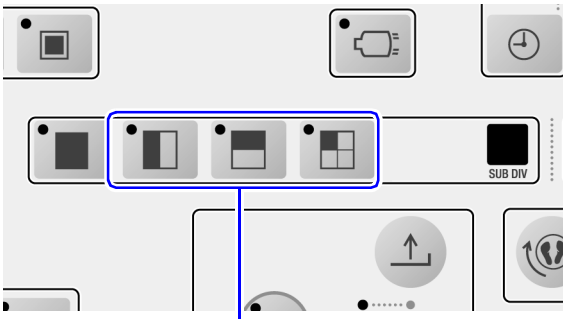
- Serial Radiography
  15 fps (Binning Size 2×2) : 14 msec
  7.5 fps (Binning size 2×2) : 80 msec
  5, 3 fps (Binning size 2×2): 100 msec
  3 fps (Binning size 1×1) : 200 msec
  2, 1 fps (Binning size 2×2): 180 msec
- Spot Radiography: 200 msec

The error (L05) will appear when duration longer than the limitation above is set.

When users switch to serial radiography from spot radiography, radiography conditions may be automatically changed not to exceed the rating. Then when users press [Spot/Serial Radiography Selector] to return the spot radiography, the original radiography conditions will be restored.

For Spot radiography:

Users can perform multi-division (vertical, horizontal, and quarters) exposure by selecting the corresponding division button.



Multi-Division Exposure button

The following operation during multi-division exposure generates a combined image using the frame images already captured (sweep operation).

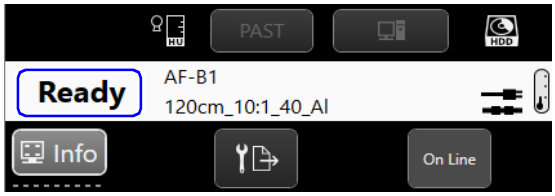
- Pressing the 1-ON-1 format button
- Pressing the 2-ON-1 (vertical) format button
- Pressing the 2-ON-1 (horizontal) format button
- Pressing 4-ON-1 format button
- Clicking a thumbnail to display another image

The auto post-processing begins after the last frame image is captured.

For details, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.

6 Check that the radiography is ready

Check that the top right display of the screen is [Ready].



7 Perform fluoroscopy

1 Press [Fluoroscopy Selection].

► The [Fluoroscopy Selection] lamp will light up.

NOTE Check that [Ready] is displayed by the system state indicator on the DR screen.

2 Step on the fluoroscopy footswitch.

► The [X-ray Indicator] will light up.

► The fluoroscopic image will be displayed on the fluoroscopy/radiography monitor.

3 Check the fluoroscopic image.

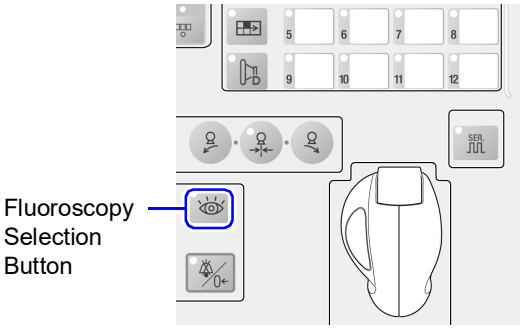
4 Release the foot switch.

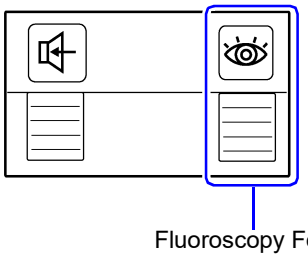
► The X-ray irradiation will stop.

You can set whether to display the acquired fluoroscopy image on the acquisition monitor after the fluoroscopy is completed.
(For settings, refer to “System Options” in the "SETTING GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.)

- •LIH: the fluoroscopy image acquired last appears on the acquisition monitor after the fluoroscopy is completed.
- •LOOP: the fluoroscopy images acquired during fluoroscopy is replayed on the acquisition monitor after the fluoroscopy is completed.
- •OFF: the image display area turns completely black on the acquisition monitor after the fluoroscopy is completed.

NOTE If the patient is a person with an implantable cardiac pacemaker or implantable defibrillator, it is possible to perform fluoroscopy with continuous X-rays instead of pulsed X-rays by the service setting. Please contact your Shimadzu service representative.

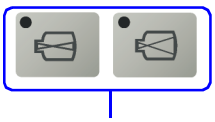




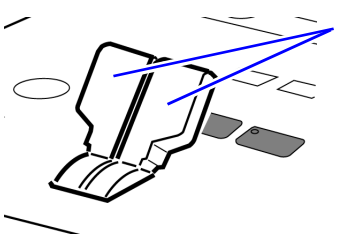
8 Determine the radiography position

1 Move the imaging unit up/down or the tabletop rear/front in accordance with the radiography region.

2 Adjust the size of the irradiation field with (field size selection) and the collimator handles on the remote console.



Field Size Selection Button



Collimator Handles

◆ Virtual Collimation

After performing fluoroscopy, you can adjust the irradiation field on an image of the last image hold.

It can reduce dose, because fluoroscopy is not required during collimator adjustment. To enable the virtual collimation, contact Shimadzu service.

NOTE

- L.I.H. needs to be turned on.
- Virtual collimation cannot be used if the multi-division exposure is selected.

NOTE

Always perform fluoroscopy and check the fluoroscopic image after changing the size and position of the irradiation field.

9 Make an exposure

1 Check that the [Fluoroscopy Selection] lamp is lit.

2 Hold down the Exposure button.

► The [X-ray Indicator] will light up during the irradiation.

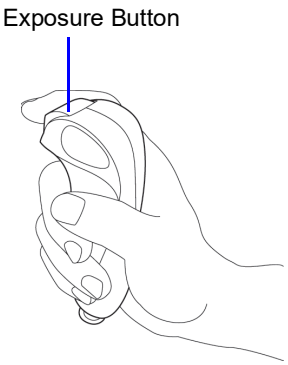
3 Release the Exposure button.

► The exposure will end.

Radiography can also be performed using the hand switch.

For serial radiography:

Press and hold the Exposure button to collect serial images (dynamic images).

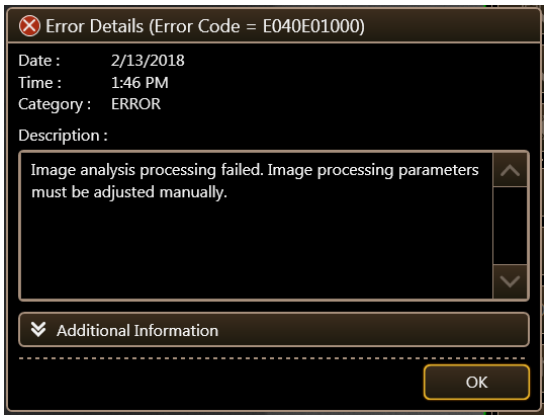


NOTE

If any image not applicable to the pattern recognition of the region is taken in Positioning RF technique, an erroneously processed image significantly off-brightness may be displayed along with the [Error Details] screen.

In such case, click [OK] to display the ROI Settings screen.
To obtain appropriate image brightness, move the cursor to the area in which to adjust brightness and click on it.

For details, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.



10 Click [End Exam]

► The Worklist screen will be displayed.

When examination is ended the captured spot or serial images can be automatically printed at an imager or sent to the server in accordance with the protocol.

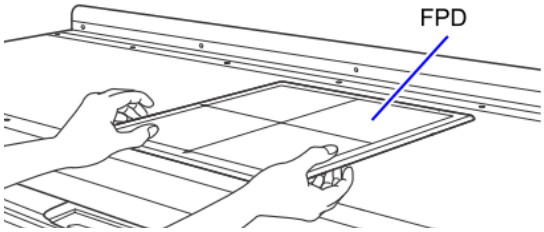
4.5 FPD Portable Radiography

FPD portable radiography is performed for examinations that do not involve fluoroscopy.
Taking the FPD out of the tray and connecting it to the sensor cable (option) or in Wireless, it allows tabletop radiography and stretcher radiography.
The X-ray filter can be used in FPD portable radiography.

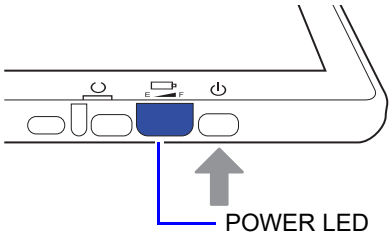
1 Prepare the FPD

- FPD(AF-B1)

1 Place the FPD (AF-B1) on the X-ray diagnostic table.



2 Turn on AF-B1 if the power source is OFF.



3 Move the FPD to where it will be used.

⚠ CAUTION

Do not impact FPD.

Hitting the FPD against anything, dropping it or subjecting it to strong impact could cause its failure or damage it.

To prevent infections, disinfect the applied parts which contact the patient's body, such as the FPD surface, with rubbing alcohol each time a new patient is X-rayed.

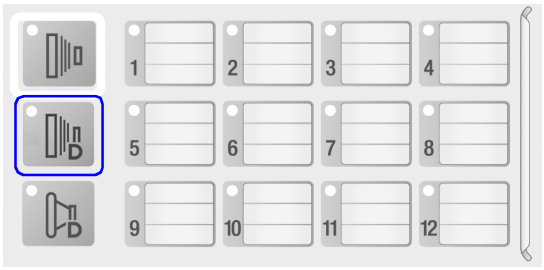
2 Check the patient information

Check the Patient ID, Patient's name and Sex.

3 Check the radiography technique

Check that the [Digital Radiography Technique] lamp has lit.

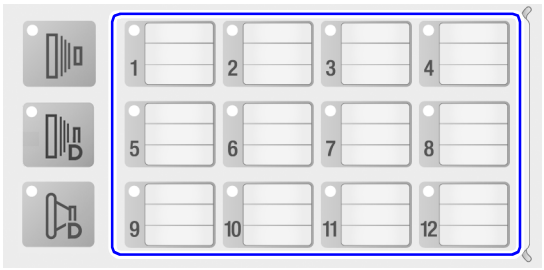
NOTE The digital radiography technique does not support fluoroscopy.



4 Check the APR

Check that the [APR] lamp corresponding to the relevant examination region has lit.

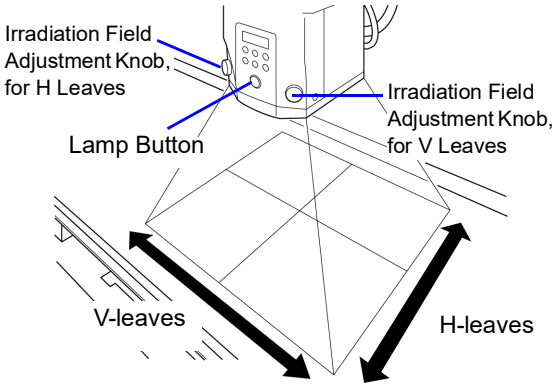
NOTE Digital radiography technique has limited irradiation duration up to 1 sec.
The error (L05) will appear when duration longer than the limitation is set.



5 Determine the radiography position

1. Check that the appropriate X-ray filter is selected.
2. Check the position of the radiography position using collimator lamp switch.
3. Move the tabletop/imaging unit to determine the radiography position.
4. Adjust the size of the irradiation field with the collimator knobs.

"Specifying the X-ray Irradiation Field" P.50



6 Check that the radiography is ready

► For the FPD (AF-B1), check that the top right display of the screen is [Ready].
Check also that the FPD to be used for examination is correctly selected.

"FPD (AF-B1)" P.64 step 4 onward of "Registration in Manual Mode"

► For the wireless FPD option kit, check that the POWER, READY, and LINK lamps light up simultaneously, and that the top right display of the screen is [Ready].
Check also that the FPD to be used for examination is correctly selected.

7 Make an exposure

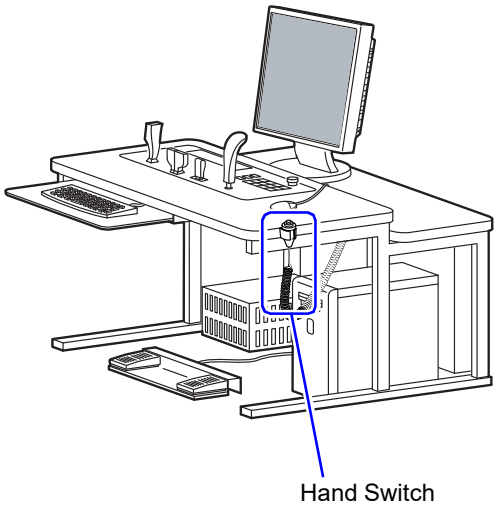
1 Press the button on the hand switch to the first position.

► The [Radiography Ready Up Indicator] will light up.

2 Press the button on the hand switch to the second position.

► The [X-ray Indicator] will light up during the irradiation.

NOTE Keep the hand switch button held down until the exposure is complete. If the button is released during the exposure, the image will not be correctly captured.



3 Release the hand switch.

► The exposure will end.

NOTE

Release the Hand Switch immediately after confirming X-ray irradiation.

When the next protocol automatically selection has been set, keep pressing the Hand Switch will keep the current radiographic conditions such as tube voltage and the tube current for the radiography with the next protocol. Furthermore, the [Grid not used] appears on the screen as the grid state.

When the phenomenon above should occur, the normal operation condition will be restored according to the following procedure.

(1) Click the protocol being selected on the right side of the screen.
The detailed screen of the protocol appears.

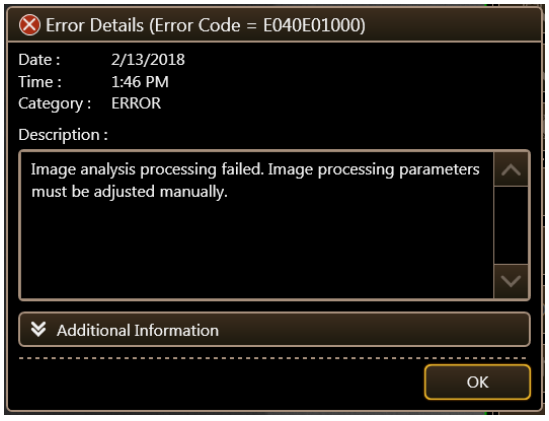
(2) Click [OK].
The correct radiography condition will be set.

NOTE

If any image not applicable to the pattern recognition of the region is taken, an erroneously processed image significantly off-brightness may be displayed along with the [Error Details] screen.

In such case, click [OK] to display the ROI Settings screen.
To obtain appropriate image brightness, move the cursor to the area in which to adjust brightness and click on it.

For details, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.



8 Click [End Exam]

► The Worklist screen will be displayed.

When examination is ended the captured images can be automatically printed at an imager or sent to the server in accordance with the protocol.

4.6 Radiography in Vertical Position Using X-ray Tube of Diagnostic Table

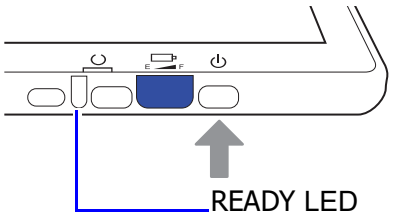
Remove the FPD from diagnostic table and place it on the lieder stand to perform chest radiography. Use wireless or special cable for radiography.

1 Prepare the FPD

1 Remove AF-B1 from diagnostic table.

2 For wireless radiography, turn ON if the power source of AF-B1 OFF.

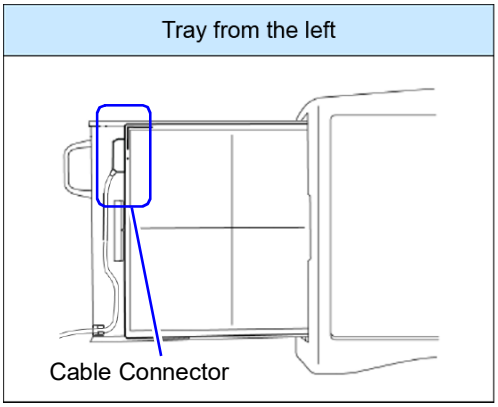
► The power is on if the POWER LED is ON.



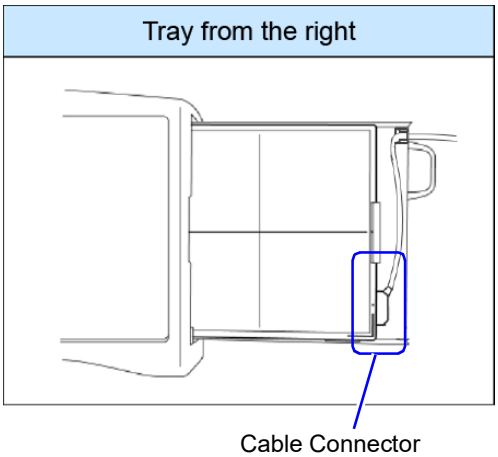
3 Insert FPD into BR-120M tray.
Set the tray insert from the left with the cable connector up and the tray insert from the right with the cable connector down.

4 For wired connection, connect the sensor cable (optional) to FPD.

Tray from the left



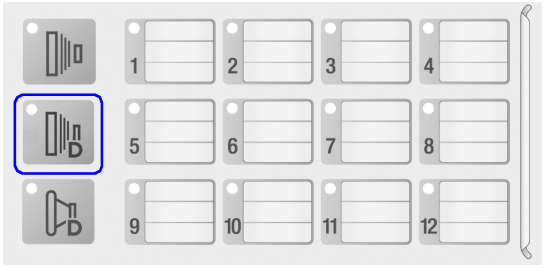
Tray from the right



2 Start the examination

1 Select the general radiography protocol for vertical position and start examination.

2 Check that the technique button B is lit.



► For the radiography without using the photo timer
Check that the technique button B is lit.

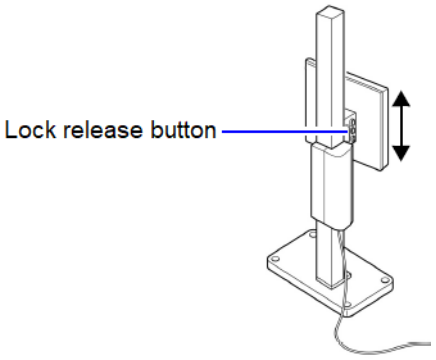
► For the radiography with the photo timer
An optional general radiography console is required.

For details, refer to the "M501-E802A FLEXAVISION 2-Tube Option Instruction Manual" provided with the general radiography console option.

3 Determine the radiography position

1 Position the patient stand position.

2 Manually adjust the height of bucky while pressing the [Lock release] button .



4 Check that the radiography is ready

► For FPD (AF-B1), make sure that the POWER and READY lamps are lit at the same time and check that the top right display of the screen is [Ready].
Also, make sure that you have selected correct FPD to use for the study.

"Registration in Manual Mode" step 4 "FPD (AF-B1)" P.64

5 Make an exposure

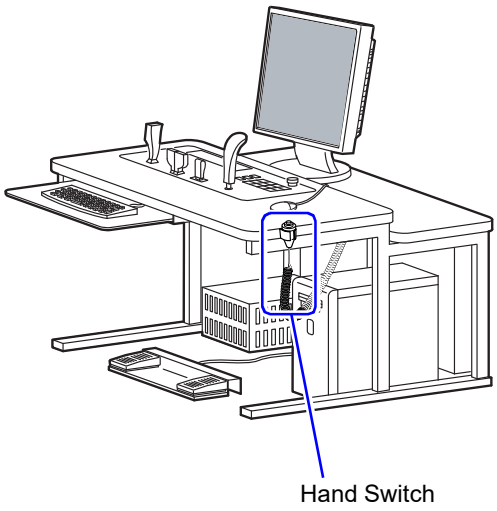
1 Press the button on the hand switch to the first position.

► The [Radiography Ready Up Indicator] will light up.

2 Press the button on the hand switch to the second position.

► The [X-ray Indicator] will light up during the irradiation.

NOTE Keep the hand switch button held down until the exposure is complete. If the button is released during the exposure, the image will not be correctly captured.



When making an exposure combined with the second X-ray tube, use the general radiography console included with the 2-tube option. See “M501-E082 FLEXAVISION 2-Tube Option Instruction Manual” for details.

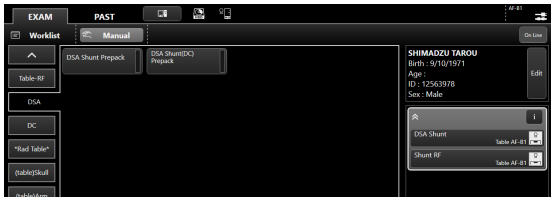
4.7 DSA Option

DSA imaging is a method of radiographic imaging to generate a difference image between a live image and a mask image by intermittently irradiating X-rays. Acquire a mask image first and then a live image.
DSA requires a two-monitor system.
DSA radiography is optional. License registration is required for use.

■ DSA Imaging

NOTE DSA imaging is not available for emergency examinations.
The DSA and RF protocols cannot be selected at the same time for emergency examination.

1 Select DSA and RF protocols, and start the examination



2 Perform fluoroscopy

1 Press [Fluoroscopy Selection].

► The [Fluoroscopy Selection] lamp will light up.

NOTE Check that [Ready] is displayed by the system state indicator on the DR screen.

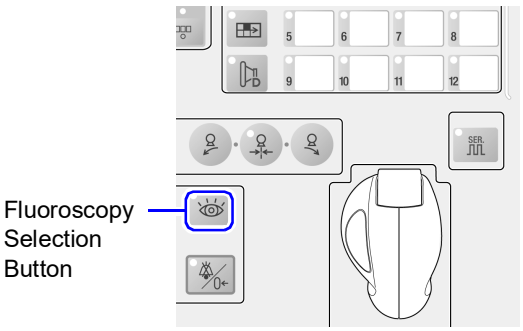
2 Step on the fluoroscopy footswitch.

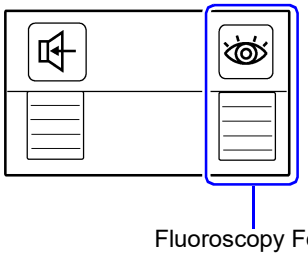
► The [X-ray Indicator] will light up.

► The fluoroscopic image will be displayed on the fluoroscopy/radiography monitor.

3 Check the fluoroscopic image.

4 Release the foot switch.





3 Prepare an injector

4 Set the mask and injection

1 Set the mask and injection start time.

See “9.4.2 Setting of Mask and Injection Start Time” in M517-V053 SDR-150C Control Software Instruction Manual for FLEXAVISION F4 (Operation Guide)” for details.

5 Make an exposure

► Sequence radiography is available.

See “4.2 Serial Radiography” in M517-V053 SDR-150C Control Software Instruction Manual for FLEXAVISION F4 (Operation Guide).

6 Inject the contrast medium to the patient

1 A countdown is displayed on the upper part of the acquisition monitor according to the injection setting set in step 4. And the contrast medium is injected into the patient at the timing when it becomes 0.

► An image subtracted from the mask image is displayed on the acquisition monitor and reference monitor.

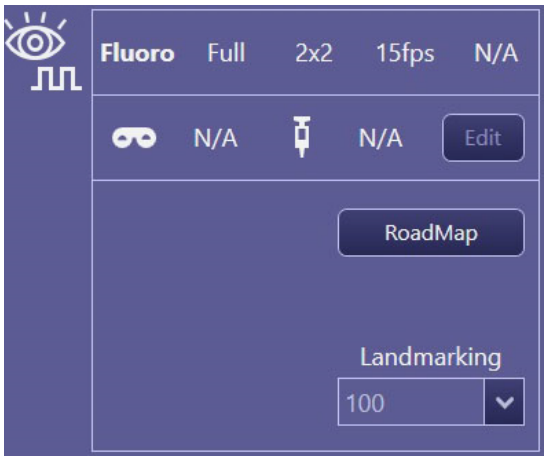
► After acquiring the set number of images, end automatically.

■ Fluoroscopic RoadMap

Fluoroscopic roadmap is a function to observe blood vessels and fluoroscopic images superimposed while operating catheter during fluoroscopy.

1 Select DSA protocol and start the examination

2 Click [RoadMap] on the setting panel displayed on the acquisition monitor



3 Step on a fluoroscopy foot switch

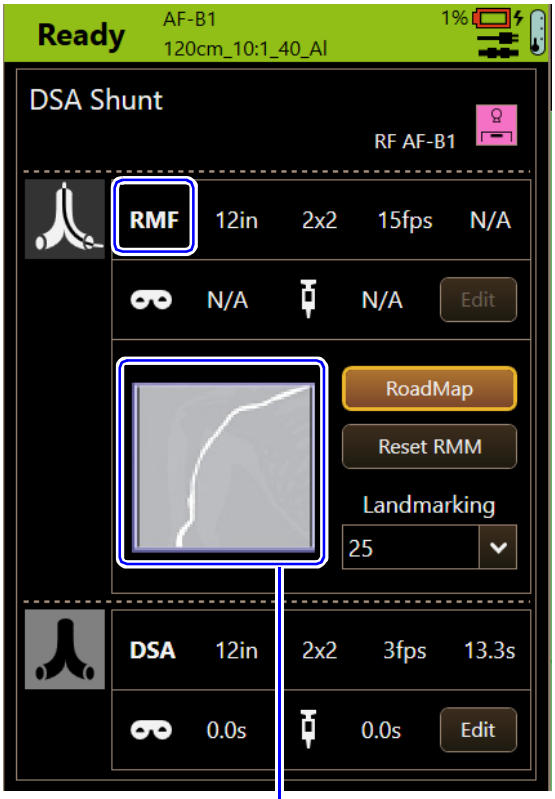
► Fluoroscopy starts and start creating the roadmap mask after the set time has elapsed.

4 Inject the contrast medium to the patient

5 Release the foot switch after acquiring the mask image

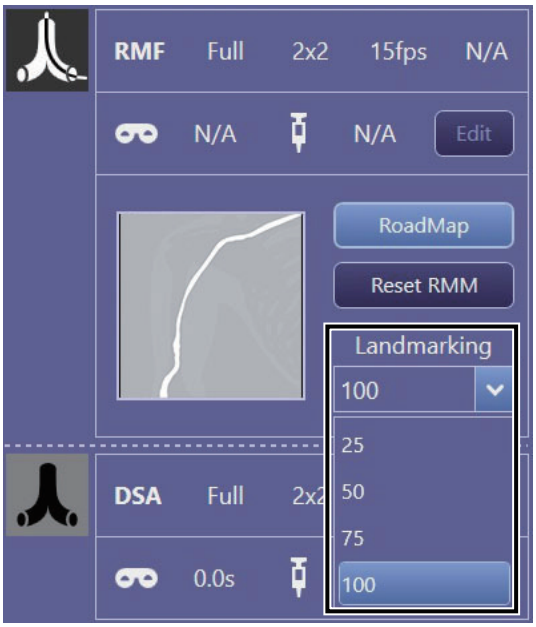
► Roadmap mask is created.

► Thumbnails are displayed on the fluoroscopic switch setting panel and setting information display panel, and radiography mode switches to RMF mode.



6 Select [Landmarking]

► Select the ratio of the roadmap mask and the fluoroscopic image in the drop-down list.



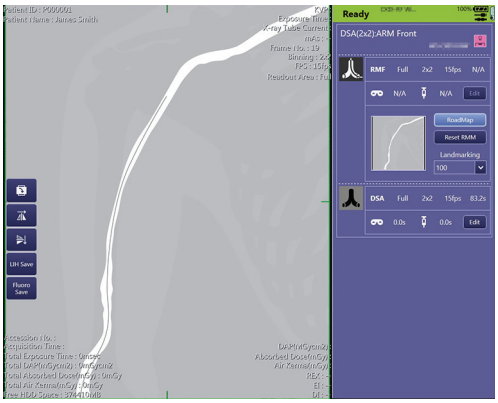
7 Step on a foot switch without injecting the contrast medium to the patient

► A fluoroscopy image is subtracted from a mask image and subtraction image is displayed in real-time.

8 Release the fluoroscopy foot switch

► LIH image is displayed on the acquisition monitor.

ref. monitor



acq. monitor

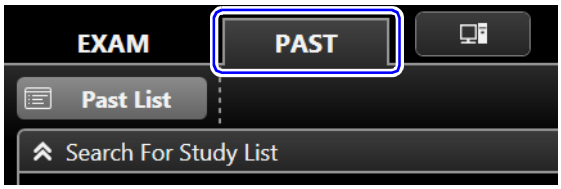
NOTE Changing the FOV size during roadmap, the mask image is discarded, but the roadmap mode continues.
Changing a protocol during roadmap cancels the roadmap mode.

4.8 Post Processing

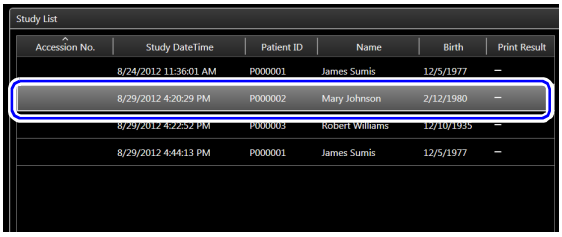
You can use the buttons on the operation panel to change or process the image displayed on the monitor.

1 Select a patient (examination) image

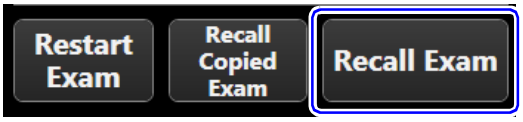
1 Click [PAST].
► The Examination List screen will be displayed.



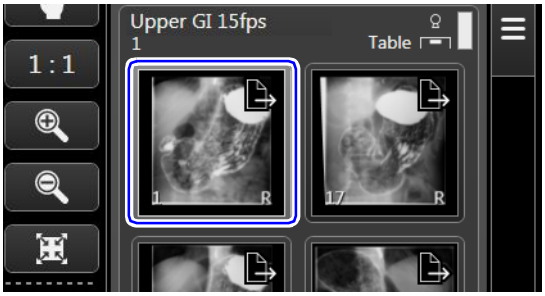
2 Click a Patient's name.
► The patient (examination) images will be displayed as thumbnail images (reduced images).



3 Click [Recall Exam].
► The Image Process screen will open and an image will be displayed.



4 Select the image to be processed from the thumbnail images.



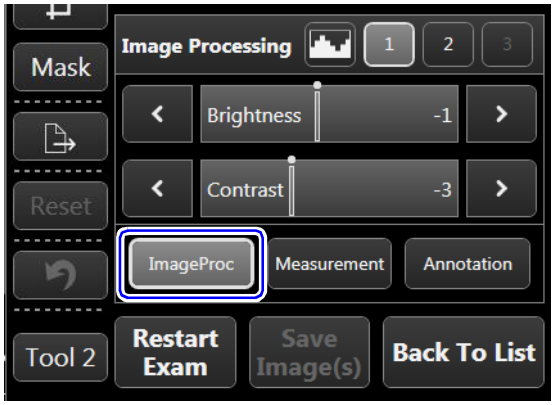
2 Process the image

1 Use the following buttons to process images.

Button	Description
 (Zoom In/Out)	Enlarges/reduces the image.
 (Mask)	Blacks out everything but the specified range.
 (Black and White Inversion)	Inverts the black and white colors of the image.
 (Flip Vertical/ Horizontal)	Flips the image over in the up/ down or rear/front direction.

2 If necessary, make fine settings with [ImageProc].

Item	Description
Brightness/contrast	Displayed on clicking the [ImageProc] button. Adjust the brightness and contrast by dragging the mouse up, down, left, or right on the image.
Gamma	Displayed on clicking the [ImageProc] button and then selecting [3] on the [Image Processing] tab page. Adjust the contrast not of the image as a whole, but that of areas of the image with a median density.

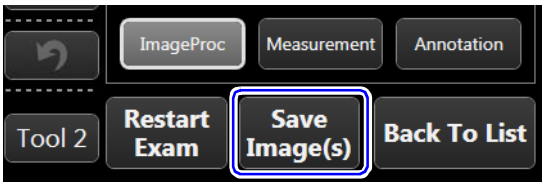


Once editing has been performed using [ImageProc], clicking the [ImageProc] button again displays the original thumbnail image.

3 Save the changes made

Click [Save Image(s)].

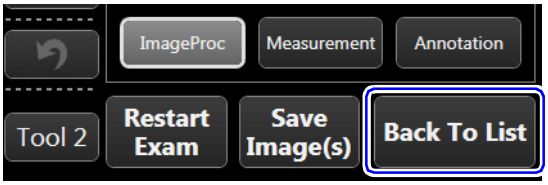
► The changes made when editing the image will be saved.



4 End image processing

Click [Back to List].

► Image processing will end and the Patient List will be displayed.



4.9 Outputting Images to Printer/Archiver

There are the following four modes of image output.

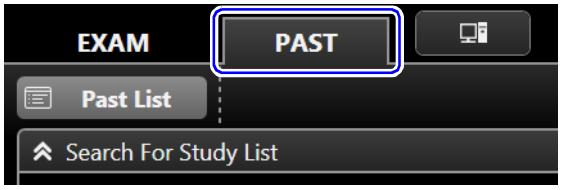
- Auto Print/Send: Prints/Sends automatically when the examination ends.
- Manual Output from Radiography Screen: Outputs manually after the images are checked.
- Manual Output from Image List: Outputs manually from the Image List.
- Manual Output from Image Edit Screen: Outputs manually from the Image Edit screen.

Normally, set the mode to Auto Print.

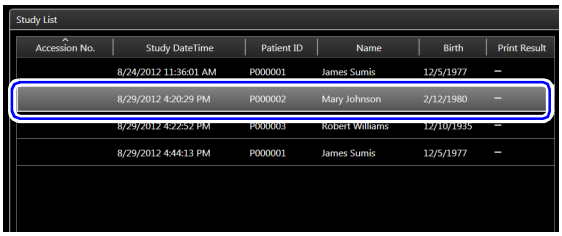
■ Manual Printing from the Image List

1 Select a patient (examination) image

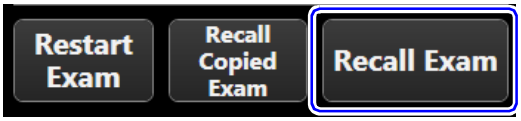
1 Click [PAST].
► The Examination List screen will be displayed.



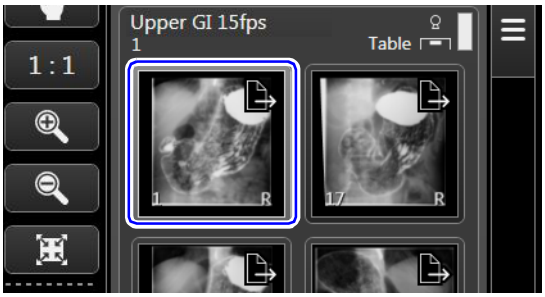
2 Click a Patient's name.
► The patient (examination) images will be displayed as thumbnail images (reduced images).



3 Click [Recall Exam].
► The Image Edit screen will open and an image will be displayed.



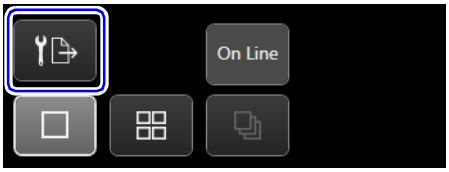
4 Select the image to be outputted from the thumbnail images.



When outputting images from the image list, multiple patient names can be selected by clicking them while holding down the [Ctrl] key.

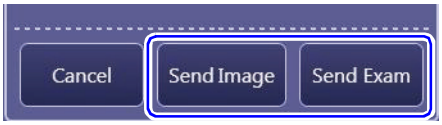
2 Output the images

1 Click (image output).



2 Select the output destination for the images.

3 Click [Send Image] or [Send Exam].



[Send Exam] can also be selected by choosing the image for output in advance using .

4.10 System Shutdown

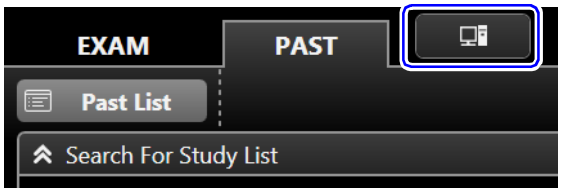
There are two ways to shut down the system: 1) exiting the control software and shutting down the PC, and 2) entering the resume mode without shutting down the PC.

■ Exiting Control Software and Shutting down the PC

1 Click  

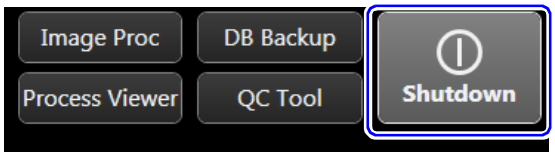
Click  on the EXAM or PAST screen.

► The System Menu screen will be displayed.



2 Click  

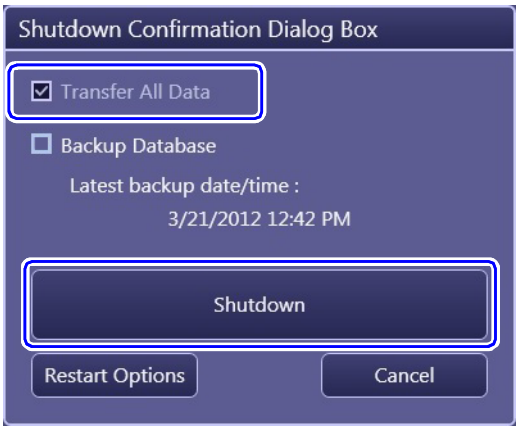
► A confirmation dialog box will be displayed.



3 Shut down 

1. Check the [Transfer All Data] checkbox.
2. Click [Shutdown].

► The digital radiography unit will turn off.



⚠ CAUTION

Do NOT turn off the power to the computer while shutdown is in progress.

This could cause hardware to fail or corrupt data.

NOTE Turn off both the digital radiography unit and the remote console.

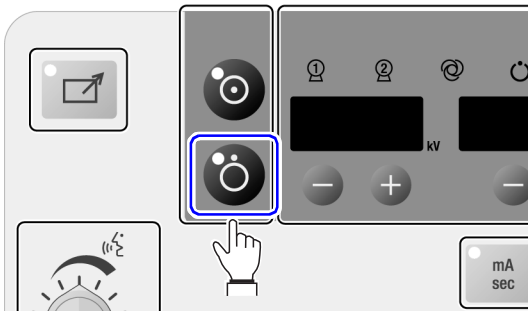
4 Press [OFF]

The system power will turn off.

Even if the power to the remote console is turned off, the digital radiography unit's power remains on. You can continue to view and print images.

How to isolate from SUPPLY MAINS.

- REMOTE CONTROLLED R/F SYSTEM
  Shut off the circuit breaker in the distribution board.
- Image Processing Unit SDR-150C
  Shut off the circuit breaker on the trans box of SDR-150C.



⚠ CAUTION

Do NOT turn the power off within 5 seconds after radiography, except in an emergency.

Wait at least 10 seconds after turning the power off before turning it back on.

5 Remove the battery from FPD.

1 Remove the battery if it is inserted in the FPD. If the FPD is in the tray, remove the FPD from the tray.

See "Removing the FPD" P.38.

2 Press and hold the [POWER] switch for about 3 seconds to turn off the power.

► The POWER LED light turns off.

3 Remove the battery pack.

See "Removing Battery Pack" P.44.

4 Keep the battery charged for the next study.

⚠ CAUTION

Remove the battery from the FPD before the power is turned off.

If the FPD is in the tray of the fluoroscopy table, powering OFF with the battery inserted may cause the battery to discharge and shorten its life.

■ Entering Resume Mode without Shutting down the PC

1 Click  

Click  on the Worklist screen.

► The System Menu screen will be displayed.

2 Click  

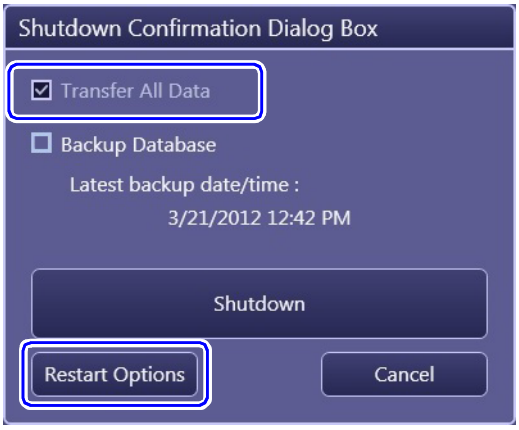
► A confirmation dialog box will be displayed.

3 Enter the resume mode

1 Check the [Transfer All Data] checkbox.

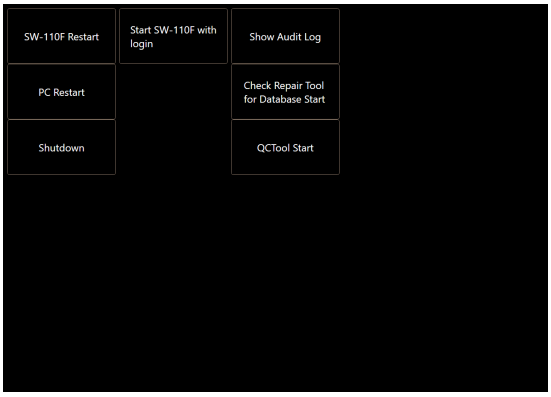
2 Click [Restart Options].

► The resume mode screen will be displayed.



4 Select a mode

► One of the following modes can be selected from the resume mode screen.



Item	Description
[SW-110F Restart]	Restarts the control software.
[Starts SW-110F with login]	The screen changes to the login authentication screen. Start the control software after login authentication.
[PC Restart]	Terminates the control software and reboots the PC.
[Shutdown]	Terminates the control software and shuts down the PC.
Show Audit Log	The function used by the service. Do not use.
Check Repair Tool for Database Start	
QC Tool Start	

When selecting [Shutdown], see step 4 "Exiting Control Software and Shutting down the PC".

⚠ CAUTION

Do NOT turn off the power to the computer while shutdown is in progress.

This could cause hardware to fail or corrupt data.

NOTE Turn off both the digital radiography unit and the remote console.

Chapter 5

Specification

5.1 Specifications of Each Part 90
5.2 Load Condition When Combined with the X-ray Tube Unit 100
5.3 Environmental Conditions of EMC (ElectroMagnetic Compatibility) 102

5.1 Specifications of Each Part

NOTE For details, refer to the instruction manual for the configured equipment.

■ X-ray Diagnostic Table

Item		Description
Configuration of Diagnostic Table		Over-Table tube system Island type
X-ray Irradiation Field		
Method of adjusting irradiation field		Adjusted with automatic collimator.
Irradiation field for fluoroscopy		The square inscribed in the circular FPD input screen is the maximum size. A rectangular field is available with the maximum or given smaller size.
Irradiation field at general radiography		Operate knobs on collimator front panel for setting, checking light irradiation field.
X-ray filters		The X-ray filters can be changed automatically or manually (Cu0.1 mm, Cu0.2 mm, Cu0.3 mm) Only techniques that do not permit fluoroscopy can be manually changed.
Grid		
X-ray grid	Type	48.2 cm × 45.2 cm
	X-ray grid ratio	r 10
	X-ray grid density	N 40 cm^{-1}
	Focusing distance	f0 120 cm
	Intermediate material	Aluminum
Compression Cone		
Compressive strength		80 N max. (approx. 8.2 kgf max.)
Compression position adjustment		Compression position is adjustable by moving imaging unit or tabletop. For the compression cone head, there are Flat and Protrusive types. Choose the type according to the patient's body thickness.
Distance between compression cone head and tabletop		100 mm to 340 mm
Tabletop		
Dimension		792 mm x 2100 mm (W x L) (* Distance between the centers of the accessory rails: 650mm)
Maximum allowable load		135 kg (* 150 kg for some specifications, depending on the options.)
Lateral movement	Travel	220 mm (motor-driven)
	Speed	30 mm/sec 50 Hz 36 mm/sec 60 Hz
Tilting	Angle	- 30° (Trendelenburg) to + 90° (upright)
	Speed	Soft start/stop feature 6°/sec at maximum (* 5 degrees/sec if the option with a maximum allowable load of 150 kg is set.)

Item		Description
Vertical movement	Distance between tabletop and floor	5D (not elevating tabletop): 890 mm 5DS (elevating tabletop): 690 mm to 950 mm (Soft start/stop)
Attenuation equivalent	Wood-made	1.25 mm Al equivalent amount
	Carbon-made	0.59 mm Al equivalent amount
Imaging Unit		
Longitudinal movement	Travel	900 mm (Motor-driven) *May be limited according to tilting angle, tabletop height, oblique angle, and other factors.
	Speed	Soft start/stop feature 50 mm/sec (* 80 mm/sec also can be set if it is not the device with oblique.)
X-ray focus - FPD X-ray conversion face distance		1100 mm With the tabletop at vertical position, SID can be set to 1500 by manually drawing out X-ray tube unit.
Distance between X-ray beam axis and floor (vertical position)		750 mm to 1650 mm
Oblique angle (* factory option)		Patient's head direction: 30° to foot direction: 30°
Component		
Table top mattress*1	Attenuation equivalent	0.33 mm Al equivalent amount*2
Foot rest	Allowable load weight	150 kg
Rolling Step*1		150 kg
Auxiliary tabletop*1		30 kg

*1: Option
*2: If a tabletop mat other than the SHIMADZU certified parts is used, the attenuation equivalent may be affected.

■ Collimator

For collimator specifications, refer to “M526-E024 COLLIMATOR TYPE R-300” OPERATION MANUAL.

■ X-ray Tube Unit

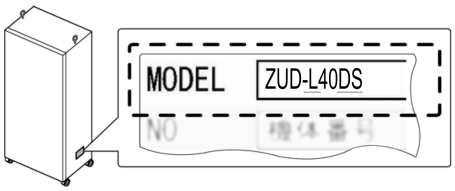
For X-ray tube unit specifications, refer to the operation manual for the combined X-ray tube unit.

*Output of the X-ray high-voltage generator is limited depending on the combined X-ray tube unit ratings.

"5.2 Load Condition When Combined with the X-ray Tube Unit" P.100

■ X-ray High-voltage Generator

* (asterisk) of ZUD-L4*D(S), a model number symbol, represents D (5D: not elevating tabletop), or DS (5DS: elevating tabletop).
The symbol of L represents output of the X-ray high-voltage generator (50 kW/32 kW).
Apart from L, there are V (65 kW) and B (80 kW).
The model number can be identified by a label attached onto the control cabinet.



● ZUD-L4*D(S)

Item	Detail		
System	50 kHz inverter (50 kW/32 kW) max.		
Short-time Rating	150 kV 320 mA (3-phase AC) /150 kV 200 mA (single-phase AC) 125 kV 400 mA (3-phase AC) /125 kV 250 mA (single-phase AC) 100 kV 500 mA (3-phase AC) /100 kV 320 mA (single-phase AC) 80 kV 630 mA (3-phase AC) /80 kV 400 mA (single-phase AC) /60 kV 500 mA (single-phase AC)		
Long-time Rating	125 kV 4 mA		
Number of Connectable X-ray Tubes	2 tubes (Second-tube option is required.)		
Setting Range	Radiography	Tube voltage	40 kV to 150 kV
		Tube current	10 mA to 630 mA
		mAs	0.5 mAs to 800 mAs
		Time	0.001 sec to 10 sec
	Fluoroscopy	Tube voltage	50 kV to 125 kV
		Tube current	0.3 mA to 4.0 mA
	Time	Continuous fluoroscopy time	10 min
Nominal Min. Exposure Time (at AEC radiography)	3 ms		
Nominal Min. Exposure Time (at AEC radiography)	FPD Portable Radiography with AF-B1		7 ms
Nominal Min. Exposure Time (at AEC radiography)	FPD Portable Radiography with AF-B1 (Prolonged Exposure)		17 ms

*1: Output of the X-ray high-voltage generator is limited depending on the combined X-ray tube unit ratings.
*2: Accuracy of each condition is given below (confirm to IEC standards).Tube voltage (within ±8%), tube current (within ±20%)mAs: within ±(10%+0.2mAs), time: within ±(10%+1ms).
*3: When fluoroscopy foot switch is released, X-ray stops within 60ms.

"5.2 Load Condition When Combined with the X-ray Tube Unit" P.100

◆Power Supply Facilities

Item		Detail		
System		Single phase AC	(3-phase AC)	3-phase AC
Frequency		50/60 Hz		
Rated Voltage		200/220/240 V	(200/220/240 V)	380/400/415/440 V
Capacity		30 kVA	(50 kVA min.)	50 kVA
Power-supply Impedance		0.08 Ω max.	(0.087 Ω max.)	0.21 Ω max.
Grounding Resistance		Grounding resistance: less than 100 Ω		Grounding resistance: less than 10 Ω
Knife-switch with Fuse or Molded-case Circuit	Frame Capacity	100 A min.		50 A min.
	Rating Breaking Current	100 A	(100 A max.)	50 A max.

*If using an earth leakage breaker, be sure to use an inverter-type earth leakage breaker in order to prevent malfunctions in the high-frequency circuits.

When using three-phase power voltage of 200 V, Automatic Transformer XAT-2 (Option) is required.

◆Cable Length and Cross-sectional Area to Match the Transformer Capacity

Transformer Capacity	Length	Electric Cable Length and <Nominal Cross-sectional Area> (mm^2)									
		10,	20,	30,	40,	50,	60,	70,	80,	90,	100 m
30 kVA (single-phase)		14,	22,	38,	60,	60,	100,	100,	100,	100,	100
50 kVA (3-phase 200 V)		8,	14,	14,	22,	38,	38,	38,	60,	60,	60
50 kVA (3-phase 400 V)		5.5,	5.5,	5.5,	5.5,	8,	8,	8,	14,	14,	14

● ZUD-V40D(S)

Item	Detail		
System	50 kHz inverter (65 kW) max.		
Short-time Rating	150 kV	400 mA (three-phase)	
	125 kV	500 mA (three-phase)	
	100 kV	650 mA (three-phase)	
	80 kV	800 mA (three-phase)	
Long-time Rating	125 kV	4 mA	
Number of Connectable X-ray Tubes	2 tubes (Second-tube option and tube selector unit are required.)		
Setting Range	Radiography	Tube voltage	40 kV to 150 kV
		Tube current	10 mA to 800 mA
		mAs	0.5 mAs to 800 mAs
		Time	0.001 sec to 10 sec
	Fluoroscopy	Tube voltage	50 kV to 125 kV
		Tube current	0.3 mA to 4.0 mA
	Time	Continuous fluoroscopy time	10 min
Nominal Min. Exposure Time (at AEC radiography)	R/F technique		3 ms
	FPD Portable Radiography with AF-B1		7 ms
	FPD Portable Radiography with AF-B1 (Prolonged Exposure)		17 ms

*1: Output of the X-ray high-voltage generator is limited depending on the combined X-ray tube unit ratings.
*2: Accuracy of each condition is given below (confirm to IEC standards).Tube voltage (within ±8%), tube current (within ±20%)mAs: within ±(10%+0.2mAs), time: within ±(10%+1ms).
*3: When fluoroscopy foot switch is released, X-ray stops within 60ms.

"5.2 Load Condition When Combined with the X-ray Tube Unit" P.100

◆ Power Supply Facilities

Item		Detail	
System		3-phase AC	
Frequency		50/60 Hz	
Rated Voltage		200/220/240 V	380/400/415/440 V
Capacity		75 kVA min.	
Power-supply Impedance		0.054 Ω max.	0.13 Ω max.
Grounding Resistance		Grounding resistance: less than 100 Ω	Grounding resistance: less than 10 Ω
Knife-switch with Fuse or Molded-case Circuit	Frame Capacity	100 A min.	75 A min.
	Rating Breaking Current	100 A max.	75 A max.

*If using an earth leakage breaker, be sure to use an inverter-type earth leakage breaker in order to prevent malfunctions in the high-frequency circuits.
When using three-phase power voltage of 200 V, Automatic Transformer XAT-2 (Option) is required.

◆Cable Length and Cross-sectional Area to Match the Transformer Capacity

Transformer Capacity	Length	Electric Cable Length and <Nominal Cross-sectional Area> (mm^2)									
		10,	20,	30,	40,	50,	60,	70,	80,	90,	100 m
75 kVA (200 V)		14,	22,	38,	38,	60,	60,	60,	100,	100,	100
75 kVA (400 V)		5.5,	8,	14,	22,	22,	22,	38,	38,	38,	38

● ZUD-B40D(S)

Item	Detail		
System	50 kHz inverter (80 kW) max.		
Short-time Rating	150 kV	500 mA (three-phase)	
	125 kV	630 mA (three-phase)	
	100 kV	800 mA (three-phase)	
	80 kV	1000 mA (three-phase)	
Long-time Rating	125 kV	4 mA	
Number of Connectable X-ray Tubes	2 tubes (Second-tube option is required.)		
Setting Range	Radiography	Tube voltage	40 kV to 150 kV
		Tube current	10 mA to 1000 mA
		mAs	0.5 mAs to 800 mAs
		Time	0.001 sec to 10 sec
	Fluoroscopy	Tube voltage	50 kV to 125 kV
		Tube current	0.3 mA to 4.0 mA
	Time	Continuous fluoroscopy time	10 min
Nominal Min. Exposure Time (at AEC radiography)	R/F technique		3 ms
	FPD Portable Radiography with AF-B1		7 ms
	FPD Portable Radiography with AF-B1 (Prolonged Exposure)		17 ms

*1: Output of the X-ray high-voltage generator is limited depending on the combined X-ray tube unit ratings.

*2: Accuracy of each condition is given below (confirm to IEC standards).Tube voltage (within ±8%), tube current (within ±20%)mAs: within ±(10%+0.2mAs), time: within ±(10%+1ms).

*3: When fluoroscopy foot switch is released, X-ray stops within 60ms.

"5.2 Load Condition When Combined with the X-ray Tube Unit" P.100

◆Power Supply Facilities

Item		Detail	
System		Three-phase	
Frequency		50/60 Hz	
Rated Voltage		200/220/240 V	380/400/415/440 V
Capacity		75 kVA or more	
Power-supply Impedance		0.054 Ω max.	0.13 Ω max.
Grounding Resistance		Grounding resistance: less than 100 Ω	Grounding resistance: less than 10 Ω
Knife-switch with Fuse or Molded-case Circuit	Frame Capacity	100 A or more	75 A or more
	Rating Breaking Current	100 A max.	75 A max.

*If using an earth leakage breaker, be sure to use an inverter-type earth leakage breaker in order to prevent malfunctions in the high-frequency circuits.
When using three-phase power voltage of 200 V, Automatic Transformer XAT-2 (Option) is required.

◆Cable Length and Cross-sectional Area to Match the Transformer Capacity

Transformer Capacity	Length	Electric Cable Length and <Nominal Cross-sectional Area> (mm^2)									
		10,	20,	30,	40,	50,	60,	70,	80,	90,	100 m
75 kVA (200 V)		14,	22,	38,	38,	60,	60,	60,	100,	100,	100
75 kVA (400 V)		5.5,	8,	14,	22,	22,	22,	38,	38,	38,	38

◆Power Supply Facilities

⚠ DANGER

Do NOT use a power supply other than those specified.
Otherwise, serious accidents such as fire, smoke emission or explosion may occur.

⚠ CAUTION

Be sure to use an inverter-type earth leakage breaker, which is to prevent malfunctions in the high-frequency circuits, for every power voltage if using an earth leakage breaker.

■ Dimension of Control Cabinet

For 50 kW, 65 kW, and 80 kW System	W × D × H: 700 mm × 400 mm × 1803 mm

■ Digital Radiography Unit

Item	Detail		
Memory Storage Device	CPU	3.1 GHz quad core	
	Memory	16 GB min.	
	OS	Windows10	
	Input	Mouse, keyboard, barcode reader (option)	
	SSD	512 GB	
	No. of saved images	60,000 frames max. (12x12 inch: Radiographic images)	
Image Input	Matrix	Max. 2656 × 2592	
	Density resolution	12 bits/4096 graduation	
Image Output	Display monitor	19-inch LCD monitor	
	Display Matrix	19-inch: 1280 pixels × 1024 pixels	
	Graduation	256 tones	
Fluoroscopy	Pulse rate	15/12.5/7.5/5/3/2 fps	
	Fluoroscopy record	Max. 950 frames	
Radiography	Spot acquisition	Max. acquisition duration	RF protocols: 0.2 second Others: 3.0 second
	Serial acquisition DSA acquisition (Option)	Max. rate	15fps
		Max. acquisition duration	15 fps (Binning size 2×2) : 14 msec 7.5 fps (Binning size 2×2) : 80 msec 5, 3 fps (Binning size 2×2): 100 msec 3 fps (Binning size 1×1) : 200 msec 2, 1 fps (Binning size 2×2): 180 msec Sequence radiography 5, 2.5, 1, 0.5 fps (Binning size 2×2) : 100 msec
Image Processing	Graduation processing	Brightness/contrast	
		Black and white inversion	
		AWC (Auto White balance Control)	
	Gamma	9 types of fluoroscopy, 4 types of radiography	
	H/V Inversion	Vertical inversion, horizontal inversion, 90° rotation to right, 90° rotation to left	
	Noise reduction	Recursive filter, multi-frequency processing	
	Edge reinforcement	20 levels	
	Zoom	Max. 2× magnification	
	Multi display	9 divisions	
	Annotation	"L" and "R" indications, and freely-selectable text	
	DSA (Option)	Re-mask, re-registration, roadmap fluoroscopy	
Measurement Processing	Distance measurement	Distance measurement possible on the image	
	Angle measurement	Angle measurement on the image possible	

Item	Detail	
DICOM	DICOM Print	SCU
	DICOM Storage	SCU
	DICOM MWM	Receives examination information from the server.
	DICOM MPPS	Sends examination information to the server.
	DICOM Media Storage	CD-R, DVD-R, DVD+R, DVD-RAM
	RDSR	Sends dose information to the server in report format.

◆ Power Supply Facilities

Item	Detail
System	Single-phase
Frequency	50/60 Hz
Rated Voltage	200/220/240 V
Capacity	3 kVA min.
Grounding Conditions	Grounding resistance: less than 100 Ω

* A separate power supply from those of the X-ray diagnostic table and X-ray high-voltage generator is required.

■ FPD

● B1

Item	Details		
Sensor Unit (AF-B1)	External dimensions	Width 460 mm × Height 460 mm × Depth 15.5 mm	
	Mass	3.5 kg	
	Pixel spacing	0.16 mm	
	Pixel binning mode	1×1, 2×2	
	Radiography area	17 × 17 inches (415 × 425 mm)	
		14 × 14 inches (353 × 353 mm)	
		12 × 12 inches (307 × 307 mm)	
		9 × 9 inches (230 × 230 mm)	
		6 × 6 inches (154 × 154 mm)	
	Scintillator	CsI	
	Number of bits for A/D conversion	16 bits	
	DQE (0 LP/mm) 0.65		
	MTF(2 LP/mm) 0.3		
Multibox(MB-01)	External dimensions	Width 315 mm × Height 80 mm × Depth 181 mm	
	Mass	2.0 kgf	
	Max. cable length	To sensor unit	10 m
		To digital radiography unit	20 m
		To X-ray high-voltage generator	20 m
	Number of connectable sensor cables	One (standard), with up to three connectable as an option * Only two sensor units can be connected at one time.	

5.2 Load Condition When Combined with the X-ray Tube Unit

● ZUD-L (Single-phase 200 V)

Item	X-ray Tube Unit		
	0.3/0.8P324DK-85	0.6/1.2P324DK-85	0.6/1.2P326D-150
Nominal X-ray tube voltage and max. tube current that can flow at nominal X-ray tube voltage	125 kV, 2.4 mA	125 kV, 2.4 mA	125 kV, 3.0 mA
	150 kV, 200 mA	150 kV, 200 mA	150 kV, 200 mA
Max. tube current and max. tube voltage to achieve max. tube current	75 kV, 4.0 mA	75 kV, 4.0 mA	93 kV, 4.0 mA
	80 kV, 400 mA	80 kV, 400 mA	80 kV, 400 mA
Tube voltage and tube current combination for max. electrical output	125 kV, 2.4 mA 75 kV, 4.0 mA	125 kV, 2.4 mA 75 kV, 4.0 mA	125 kV, 3.0 mA
	80 kV, 400 mA 100 kV, 320 mA	80 kV, 400 mA 100 kV, 320 mA	80 kV, 400 mA 100 kV, 320 mA
Nominal electric power	32 kW (100 kV, 320 mA, 0.1 sec)	32 kW (100 kV, 320 mA, 0.1 sec)	32 kW (100 kV, 320 mA, 0.1 sec)

● ZUD-L (3-phase 200 V) /ZUD-L2

Item	X-ray Tube Unit		
	0.3/0.8P324DK-85	0.6/1.2P324DK-85	0.6/1.2P326D-150
Nominal X-ray tube voltage and max. tube current that can flow at nominal X-ray tube voltage	125 kV, 2.4 mA	125 kV, 2.4 mA	125 kV, 3.0 mA
	150 kV, 320 mA	150 kV, 320 mA	150 kV, 320 mA
Max. tube current and max. tube voltage to achieve max. tube current	75 kV, 4.0 mA	75 kV, 4.0 mA	93 kV, 4.0 mA
	89 kV, 560 mA	80 kV, 630 mA	80 kV, 630 mA
Tube voltage and tube current combination for max. electrical output	125 kV, 2.4 mA 75 kV, 4.0 mA	125 kV, 2.4 mA 75 kV, 4.0 mA	125 kV, 3.0 mA
	100 kV, 500 mA 125 kV, 400 mA	80 kV, 630 mA	80 kV, 630 mA
Nominal electric power	45 kW (100 kV, 450 mA, 0.1 sec)	50 kW (100 kV, 500 mA, 0.1 sec)	50 kW (100 kV, 500 mA, 0.1 sec)

● ZUD-V

Item	X-ray Tube Unit		
	0.3/0.8P324DK-85	0.6/1.2P324DK-85	0.6/1.2P326D-150
Nominal X-ray tube voltage and max. tube current that can flow at nominal X-ray tube voltage	125 kV, 2.4 mA	125 kV, 2.4 mA	125 kV, 3.0 mA
	150 kV, 400 mA	150 kV, 400 mA	150 kV, 400 mA
Max. tube current and max. tube voltage to achieve max. tube current	75 kV, 4.0 mA	75 kV, 4.0 mA	93 kV, 4.0 mA
	116 kV, 560 mA	81 kV, 800 mA	81 kV, 800 mA
Tube voltage and tube current combination for max. electrical output	125 kV, 2.4 mA 75 kV, 4.0 mA	125 kV, 2.4 mA 75 kV, 4.0 mA	125 kV, 3.0 mA
	130 kV, 500 mA	130 kV, 500 mA	130 kV, 500 mA
Nominal electric power	45 kW (100 kV, 450 mA, 0.1 sec)	65 kW (103 kV, 630 mA, 0.1 sec)	65 kW (103 kV, 630 mA, 0.1 sec)

● ZUD-B

Item	X-ray Tube Unit		
	0.3/0.8P324DK-85	0.6/1.2P324DK-85	0.6/1.2P326D-150
Nominal X-ray tube voltage and max. tube current that can flow at nominal X-ray tube voltage	125 kV, 2.4 mA	125 kV, 2.4 mA	125 kV, 3.0 mA
	150 kV, 400 mA	150 kV, 500 mA	150 kV, 500 mA
Max. tube current and max. tube voltage to achieve max. tube current	75 kV, 4.0 mA	75 kV, 4.0 mA	93 kV, 4.0 mA
	84 kV, 800 mA	88 kV, 900 mA	88 kV, 900 mA
Tube voltage and tube current combination for max. electrical output	125 kV, 2.4 mA 75 kV, 4.0 mA	125 kV, 2.4 mA 75 kV, 4.0 mA	125 kV, 3.0 mA
	135 kV, 500 mA	100 kV, 800 mA	100 kV, 800 mA
Nominal electric power	45 kW (100 kV, 450 mA, 0.1 sec)	80 kW (100 kV, 800 mA, 0.1 sec)	80 kW (100 kV, 800 mA, 0.1 sec)

Upper: Long-time rating
Lower: Short-time rating

5.3 Environmental Conditions of EMC (ElectroMagnetic Compatibility)

The equipment satisfies the EMC (Electromagnetic Compatibility) standard below:
IEC 60601-1-2:2014

⚠ CAUTION

Pay attention to the electromagnetic environments at the installation site.

The equipment is suitable for installing at a professional healthcare facility environment except below:

- Medical treatment areas with high-powered medical electrical equipment (High frequency surgical equipment, short-wave therapy equipment)
- Inside the radio frequency shielded room of an MRI.

■ Classification of EMI in Accordance with IEC 60601-1-2:2014

Group 1, Class A
The system uses radio-frequency energy only for its internal function and is not intended to deliver energy to the patient. However, even a small amount of radio frequency energy leakage does harm to high sensitive equipment.
The system main power line in the clinical site should be connected to the domestic power sources which are separated from the public main network.

NOTE

The emissions characteristics of the system 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) the system might not offer adequate protection to radiofrequency communication services.
The user might need to take mitigation measures, such as relocating or reorienting the system.

■ Performance to be EMC Immunity Tested (Essential Performance)

Essential performances of this equipment are as followings;

- Supporting the patient
- Positioning of X-ray field
- Set of X-ray conditions
- X-ray exposure
- Recording patient information
- Radiography
- Displaying images

■ List of Cables

Cable Name	Cable Length (Length between units)	Shield	Note (Manufacturer)
Cable between Control Cabinet and Main Power			
Main Power Cable 3 Phase	12 m	Y	Shimadzu
Grounding Cable	12 m	N	Shimadzu
Door Switch Cable	20 m	N	Shimadzu
Lamp Cable	20 m	N	Shimadzu
Cable between Control Cabinet and Local Console (Option)			
Cable JPNL	10 m	Y	Shimadzu
Grounding Wire	10 m	N	Shimadzu
Cable between Control Cabinet and Remote Console			
Cable JPNL	20 m	Y	Shimadzu
Grounding Wire	20 m	N	Shimadzu
Cable between Control Cabinet and Main Body			
High Voltage Cable-	22 m	Y	Shimadzu
High Voltage Cable+	22 m	Y	Shimadzu
Grounding Wire	8 m	N	Shimadzu
Main Body Power Cable A	9.5 m	Y	Shimadzu
Main Body Power Cable B	9.5 m	Y	Shimadzu
Main Body Power Cable C (Option)	9.5 m	Y	Shimadzu
Main Body Spot Film Device Cable A2 (Option)	9.5 m	Y	Shimadzu
Main Body Collimator Cable	9.5 m	Y	Shimadzu
Main Body Signal Cable A	9.5 m	Y	Shimadzu
Main Body Signal Cable B (Option)	9.5 m	Y	Shimadzu
Oblique Power Cable (Option)	15 m	Y	Shimadzu
Photo-timer Cable	35 m	Y	Shimadzu
R-300 Power Cable	12 m	Y	Shimadzu
R-300 Collimator Cable	12 m	Y	Shimadzu
Fan Cable	9.5 m	Y	Shimadzu
Other			
Foot SW Cable (Option)	10 m	N	Shimadzu
Foot SW Cable	2.0 m	N	Shimadzu
Speaker Cable(control room)	20 m	N	(Accessories of Speaker) Shimadzu
Speaker Cable(exam. room)	20 m	N	
Mic Cable (ZS-5D/5DS Table)	19 m	Y	Shimadzu
Handheld SW Cable	4.5 m	N	Shimadzu
Mic Cable (Monitor Wagon)	17 m	Y	Shimadzu
Cable between GSC-2002S and Control Cabinet			
GSC-2002S Cable	32 m	Y	Shimadzu
Grounding Wire	32 m	N	Shimadzu

Cable Name	Cable Length (Length between units)	Shield	Note (Manufacturer)
Handheld Switch Cable	4.5 m	N	Shimadzu
Cable between Step-up Transformer XAT-2 and Control Cabinet			
XAT-2 Power Cable	3 m	Y	Shimadzu
XAT-2 Grounding Wire	3 m	N	Shimadzu
Cable for Trans Box of SDR-150C (Option)			
Main Power Cable	20 m	N	Shimadzu
Grounding Wire	20 m	N	Shimadzu
Cable SDR-150C (Option)			
PC Power Cable	2.8 m	N	Shimadzu
MBOX PC Cable	20 m	Y	Shimadzu
Barcode Reader Cable	2.0 m	N	Shimadzu
Card Reader Cable	2.0 m	N	Shimadzu
MBOX Xcont Cable	20 m	Y	Shimadzu
External UPS Cable	10 m	Y	Shimadzu
Mouse Cable	1.8 m	N	Shimadzu
Keyboard Cable	1.5 m	Y	Shimadzu
Keyboard Cable	1.5 m	Y	Shimadzu
Electric Shoulder Support Cable (Option)			
Shoulder support Cable1	10 m	Y	Shimadzu
Shoulder support Cable2	10 m	Y	Shimadzu
Cont Cable	20 m	N	Shimadzu
Power Cable	3.5 m	N	Shimadzu
Signal Cable	3.5 m	Y	Shimadzu
Grounding wire	4.0 m	N	Shimadzu
Cable between Add on Display 1			
Cable Dose display	20 m	Y	Shimadzu
Grounding Wire	20 m	N	Shimadzu
Cable between Add on Display 2			
Cable Dose display	20 m	Y	Shimadzu
Grounding Wire	20 m	N	Shimadzu
Rolling step			
Rolling step Cable	1.0 m	N	Shimadzu
Power Divider 1			
Grounding Wire	20 m	N	Shimadzu
Power Cable	20 m	N	Shimadzu
Power Divider 2			
Grounding Wire	20 m	N	Shimadzu
Power Cable	20 m	N	Shimadzu
Scan Converter Cable			
Scan Converter Cable	1.8 m	Y	Shimadzu

Cable Name	Cable Length (Length between units)	Shield	Note (Manufacturer)
Scan Converter TV-Cable	2.5 m	N	Shimadzu
DVI Extendor Cable			
DVI Monitor Cable	1.8 m	Y	Shimadzu
DVI Splitter power Cable A	1.5 m	N	Shimadzu
DVI Splitter power Cable B	1.5 m	N	Shimadzu
Starter SA-42 Cable (Option)			
Low Power Cable for X-ray tube	26 m	N	Shimadzu
Cable between Transformer Box and Multibox(MB-01) (Option)			
MBOX POWER CABLE	20 m	N	Shimadzu
Cable Power Cont GEN	20 m	N	Shimadzu
Remote Maintenance			
Isolater-HUB LAN Cable	3.0 m	N	Shimadzu
Isolator-MPC LAN Cable	2.0 m	N	Shimadzu
Power Cable for HUB	1.8 m	N	Shimadzu
EXT NW-HUB LAN Cable	20 m	Y	Shimadzu
Power Cable for MPC	3.0 m	N	Shimadzu
EXT NW-HUB/MBOX LAN Cable	30 m	N	Shimadzu
FPD Wireless (Optional)			
LAN Cable	20 m	Y	Shimadzu
DC Cable (Access Point)	1.0 m	N	Shimadzu
Power Cable (Access Point)	1.5 m	N	Shimadzu
Monitor Cable for SDR-150C			
DVI Monitor Cable	1.8 m	Y	Shimadzu
DVI Monitor Cable	1.8 m	Y	Shimadzu
DVI Splitter DVI/LAN Cable	1.0 m	Y	Shimadzu
DVI Splitter DVI/LAN Cable	1.0 m	Y	Shimadzu
DVI Monitor Cable	1.8 m	Y	Shimadzu
Monitor Power Cable B	2.5 m	N	Shimadzu
DVI-LAN Cable	30 m	Y	Shimadzu
DVI Monitor Cable	1.8 m	Y	Shimadzu
DVI-LAN Cable	30 m	Y	Shimadzu
Monitor Power Cable A	2.5 m	N	Shimadzu
Monitor Wagon Power Cable	20 m	N	Shimadzu
Grounding wire	20 m	N	Shimadzu
DVI Monitor Cable (RX150)	2.5 m	Y	Shimadzu
DVI Monitor Cable (RX150)	2.5 m	Y	Shimadzu
Monitor Power Cable D	2.5 m	N	Shimadzu
DVI Box Power Cable	30 m	N	Shimadzu
Monitor Power Cable C	2.5 m	N	Shimadzu
Ready Indicator			

Cable Name	Cable Length (Length between units)	Shield	Note (Manufacturer)
Ready Indicator Cable	5.0 m	Y	Shimadzu
DICOM Print Server			
LAN CABLE	20 m	N	Shimadzu
2nd FPD			
FPD Cable	25 m	Y	CANON

NOTE The cables listed above are the parts specified to be compliant with the standards.
These parts are not provided to the equipment.

◆ Accessory List

Accessory Type	Note (Manufacturer)
Rolling Step	Shimadzu

NOTE The accessories listed above are the parts specified to be compliant with the standards.
These parts are not provided to the equipment.

■ Electromagnetic Immunity Test Level

Immunity test	EN/IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) EN 61000-4-2/IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±2, ±4, ±6, ±8 kV contact ±2, ±4, ±8, ±15 kV air
Electrical fast transient / burst EN 61000-4-4/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
Surge EN 61000-4-5/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
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11/IEC 61000-4-11	0 % U_T : 0.5 cycle at 0°, 45°, 95°, 135°, 180°, 225°, 270°, 315° 0 % U_T : 1 cycle at 0° 70 %s U_T : 25 (50 Hz) / 30 (60 Hz) cycles at 0° 0 % U_T : 250 (50 Hz) / 300 (60 Hz)	0 % U_T : 0.5 cycle at 0°, 45°, 95°, 135°, 180°, 225°, 270°, 315° 0 % U_T : 1 cycle at 0° 70 %s U_T : 25 (50 Hz) / 30 (60 Hz) cycles at 0° 0 % U_T : 250 (50 Hz) / 300 (60 Hz)
Power frequency (50/60 Hz) magnetic field EN 61000-4-8/IEC 61000-4-8	30 A/m	30 A/m
Conducted RF EN 61000-4-6/IEC 61000-4-6	150 kHz to 80 MHz 3 Vrms outside ISM bands, 6 Vrms in ISM bands (80 % AM at 1 kHz)	150 kHz to 80 MHz 3 Vrms outside ISM bands, 6 Vrms in ISM bands (80 % AM at 1 kHz)
Radiated RF EN 61000-4-3/IEC 61000-4-3	80 MHz to 2.7 GHz 3 V/m (80 %AM at 1kHz) (Refer to IEC 60601-1-2:2014, table 9.)	80 MHz to 6.0 GHz 3 V/m (80 %AM at 1kHz) ☞ "Test specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment" P.108

NOTE
- U_T is the a.c. mains voltage prior to application of the test level.
- The ISM bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 MHz - 13.567 MHz, 26.957 - 27.283 MHz, and 40.66 - 40.70 MHz.

- Test specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment

Test Frequency [MHz]	Modulation	Test Level
385	Pulse modulation: 18 Hz*1	19 V/m
450	FM ±5 kHz deviation: 1 kHz sine*2	28 V/m
710	Pulse modulation: 217 Hz*1	9 V/m
745		
780		
810	Pulse modulation: 18 Hz*1	28 V/m
870		
930		
1462	Pulse modulation: 217 Hz*1	10 V/m
1720	Pulse modulation: 217 Hz*1	28 V/m
1845		
1970		
2450	Pulse modulation: 217 Hz*1	28 V/m
5240	Pulse modulation: 217 Hz*1	9 V/m
5500		
5785		

*1: The carrier shall be modulated using a 50 % duty cycle square wave signal.
*2: As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Chapter

6

Troubleshooting

6.1 Emergency Stop 110
6.2 Error Display 112

6.1 Emergency Stop

⚠ CAUTION

If you notice an abnormal smell or smoke generation during operation, shut off the circuit breaker and contact your Shimadzu service representative.

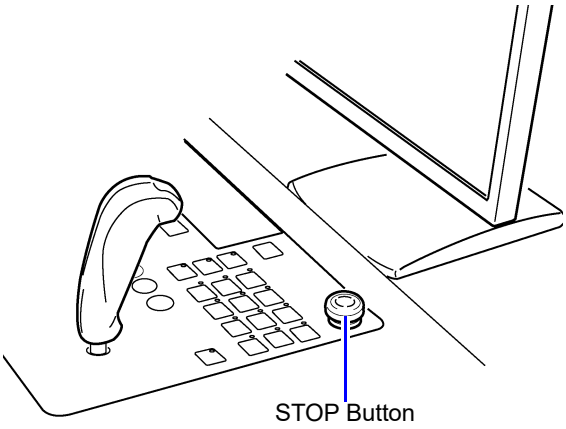
Continued use could result in injury or damage to the equipment.

NOTE If the system software malfunctions and the equipment can no longer be operated, turn off the power to the multibox(MB-01) and the image processing computer and then turn the power back on.

■ Emergency Stop of X-ray Diagnostic Table Operation

- To stop the X-ray diagnostic table operation urgently

  Press the [STOP] button. The diagnostic table operation will stop. The (STOP) button is a red button on the console. This button is also located on the local console and the local control panel of diagnostic table.

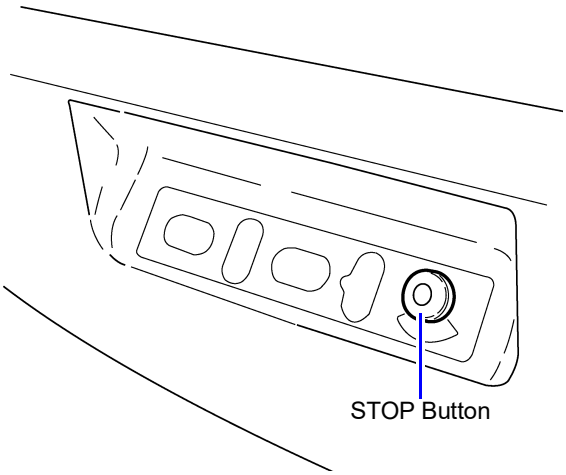


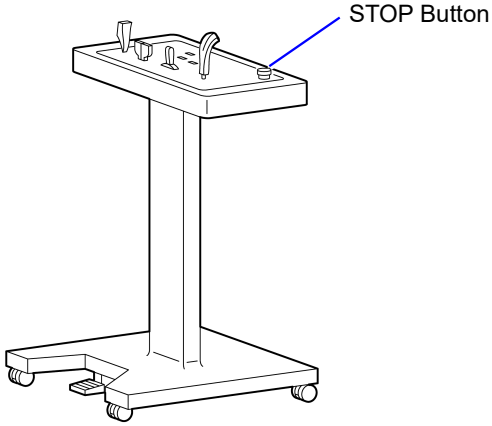
- To reactive the operation

  Rotate the pressed [STOP] button clockwise to release the button.

  NOTE Be sure to rotate the pressed [STOP] button to release.

  NOTE Be sure to wait for more than 10 seconds before releasing the [STOP] button. Otherwise, the system may not operate normally.

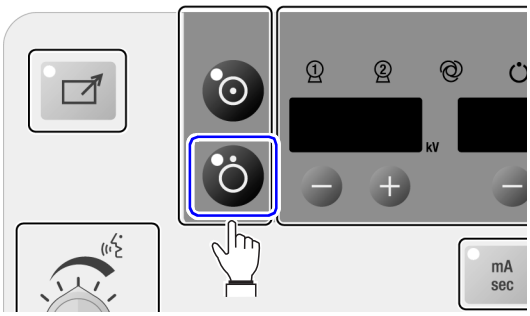




■ Emergency Stop of X-ray Generator

Press the Power OFF button to immediately stop the X-ray generator from operating.

The Power OFF button is located on the remote console.

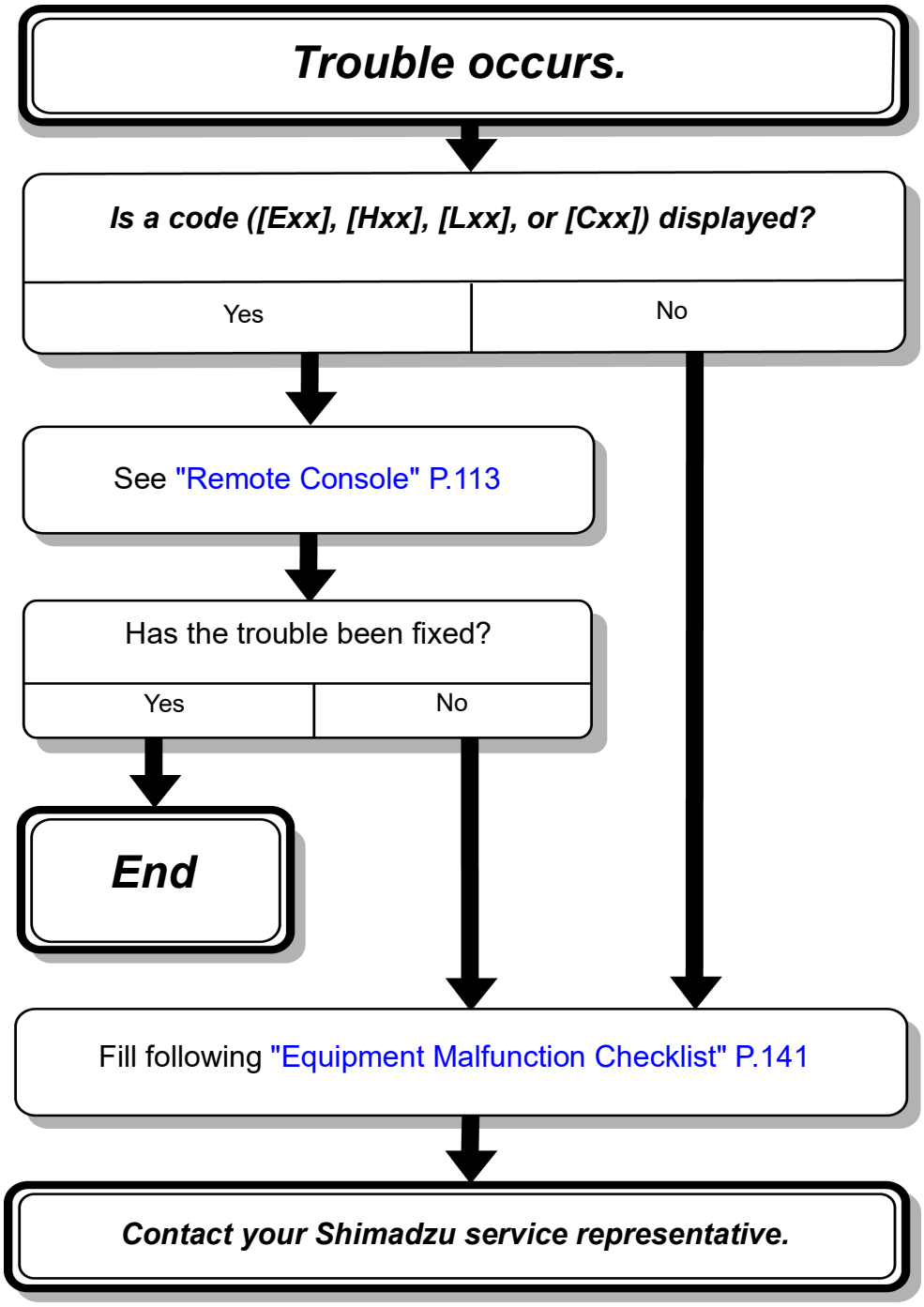


NOTE

- When turning on the power of the system again, pay close attention to the system for any abnormal operations. If you find any abnormality, immediately turn off the power, and then contact your Shimadzu service representative.
- To turn on the power of the system again, wait for more than10 seconds after the power is turned off. Moreover, after the power of the system is turned on again, wait for more than10 seconds before you perform any operation.

6.2 Error Display

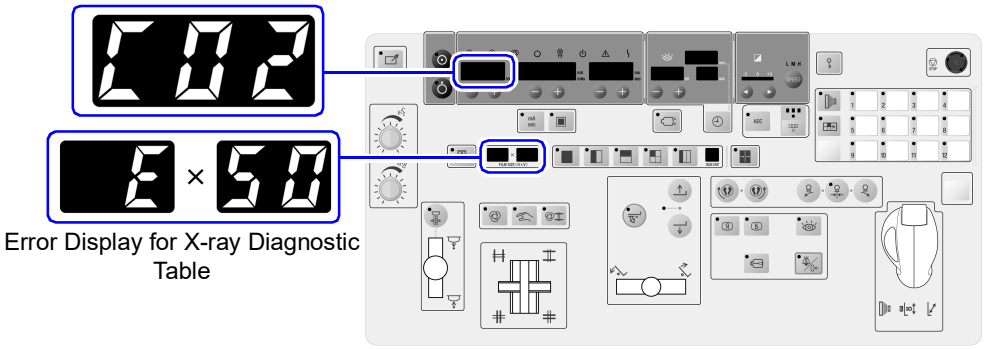
This section describes the codes indicating current system conditions and warnings, as well as countermeasures against errors.
If an error occurs and no code is displayed, contact your Shimadzu service representative.



■ Remote Console

If any failure occurs with the X-ray diagnostic table of X-ray high-voltage generator, a code is displayed on the remote console to indicate the current condition or warning.

Error Display for X-ray High-voltage Generator



Error Display for X-ray Diagnostic Table

■ X-ray High-voltage Generator-related Codes

The codes displayed as [Cxx] automatically disappear by taking the countermeasures in the table below (except C06 to C08).

The codes displayed as [Exx] disappear by pressing the [Power ON] button.

Code	Content	Countermeasure
C01	The examination room door is open.	Close the door.
C02	Timer has operated because fluoroscopy had been performed successively for 10 minutes.	To restart the fluoroscopy, release the fluoroscopy foot switch once and step on it again.
C03	Fluoroscopic mode (Continuous/Pulsed Fluoroscopy) has been switched during fluoroscopy.	To restart the fluoroscopy, release the fluoroscopy foot switch once and step on it again.
C04	AEC did not work but AEC backup was activated during AEC radiography (optional).	Extend the sec.
C05	Unavailable radiography setting has been received from DR.	Send available radiography setting from DR again.
C06	Battery for control panel data memory is empty.	Contact your Shimadzu service representative.
C07	Battery for control panel data memory needs to be replaced soon.	
C08	Clock has been reset.	
C09	Inputting EEPROM was failed.	Input APR again.
L01	Equipment rating has been exceeded.	Decrease the tube voltage or current.
L02	The limit of emission characteristics has been exceeded.	Increase the tube voltage or decrease the tube current.

Code	Content	Countermeasure
	The mAs is below 0.5mAs, or the tube current is below the minimum value in mAs setting formula.	Change the set value.
	The mAs has exceeded equipment rating.	
	The sec exceeds 10seconds because mAs is too large, or the sec has exceeded permitted range.	Reduce the set value.
	The value is beyond available range in mAs setting formula.	
		
		
		
		
		
	The heat unit will exceed permitted limit if the heat expected to go up in the current radiography setting is added.	Change the radiography settings or stop operation until the heat unit decreases.
	The current heat unit has reached permitted limit.	Stop operation until the heat unit decreases.
	X-ray tube unit temperature has exceeded permitted limit.	
	Control board is abnormal.	Contact your Shimadzu service representative.
	24 V power supply/voltage for IGBT is abnormal.	
	- 15 V power supply/voltage is abnormal.	
	+ 15 V power supply/voltage is abnormal.	
	+ 24 V power supply/voltage is abnormal.	
	Connection status to high-voltage transformer is abnormal.	
	Power supply/voltage has exceeded permitted range.	
	Charging voltage of primary smoothing condenser is abnormal.	

Code	Content	Countermeasure
	Filament heating current is abnormal (Large Focus).	If the code appears repeatedly, contact your Shimadzu service representative.
	Filament heating current is abnormal (Small Focus).	
	Filament heating or inverter control was detected to be abnormal.	
	The set tube voltage or current is abnormal.	
	The set filament heating current value is abnormal.	
	Filament heating current is abnormal (Large Focus).	
	Filament heating current is abnormal (Small Focus).	
	Starter is abnormal.	
	Measured tube voltage has exceeded permitted range.	
		
		
		
	The tube current has exceeded the set value.	
	The fluoroscopy tube current has exceeded the set value.	
	Arcing occurred repeatedly.	
		
	Inverter temperature was detected to be abnormal.	
	Any button or lever was operated at the power-on sequence.	
	Hand switch is abnormal.	
		
	Exposure Button is abnormal.	
	Fluoroscopy foot switch is abnormal.	
	Measured mAs has exceeded permitted range.	If the code appears repeatedly, contact your Shimadzu service representative.

Code	Content	Countermeasure
E35	Starter does not operate at the start of fluoroscopy or examination.	If the code appears at the start of an examination, click [Cancel] or [Suspend Exam] on the digital radiography unit. If power to the system has been turned OFF, turn the power back ON and wait about 30 seconds before operating. If the code appears repeatedly, contact your Shimadzu service representative. *Approximately 30 seconds is required after turning the power ON for the starter to be ready for operation. If you attempt to start an examination during the preparation period, this error may occur but does not indicate any abnormality.
E36	The fluoroscopy tube voltage balance is abnormal.	If the code appears repeatedly, contact your Shimadzu service representative.
E37	Radiography timer has trouble.	
E38	Fluoroscopy timer has trouble.	
E39	The power was shut down during the starter operation at high speed.	Do NOT turn OFF the power during  (Anode Rotation Stop Button) blinking. ZSU-5D/5DS Operation Manual "3.5.2 Turning Power Off"
E41	Installation of the equipment has not been completed. If the time displayed in the Radiography mA/mAs Setting has elapsed, the radiography cannot be performed.	Contact your Shimadzu service Radiography timer has trouble. representative.
E42	Installation of the equipment has not been completed. Radiography cannot be performed.	Contact your Shimadzu service Radiography timer has trouble. representative.

■ X-ray Diagnostic Table-related Codes

The codes displayed as [Cxx] appear for 5 seconds and disappear automatically.

The codes displayed as [Exx] are canceled by turning the [STOP] button on/off.

Code	Content	Countermeasure
C × 54	Safety sensor has activated interlock.	Remove the object away to unlock the sensor.
C × 55	Tilting the tabletop or oblique-projecting the X-ray tube was attempted while X-ray tube is extended.	Return the X-ray tube to its original position.
C × 56	Tilting the tabletop or oblique-projecting the X-ray tube was attempted while X-ray tube is rotated.	Return the X-ray tube to its original position.
C × 57	Compression was attempted during oblique projection.	Return the imaging unit to the center of diagnostic table. (Oblique angle is ±10°max.)
C × 59	A button was pressed on the console at start-up or switching. (The code appears for 30 seconds.)	Do not touch any button on the console/front operation panel at startup or switching of the console. If the code is still displayed, contact your Shimadzu service representative.
C × 60	A button was pressed on the front operation panel at start-up. (The code appears for 30 seconds.)	
C × 61	Battery level is low.	Contact your Shimadzu service representative.
C × 62	Stroke end limit switch was detected.	
C × 64	Fluoroscopy and Radiography are not available while the X-ray tube is rotated or extended.	Return the X-ray tube to its original position.
C × 65	Tabletop ascending/descending buttons are valid only at the horizontal position.	Tilt the tabletop to the horizontal position.
C × 66	Operation from remote console is unavailable while the X-ray tube is extended.	Operate from local console or front operation panel.
C × 67	The FPD is not installed correctly.	Install the FPD correctly. If the message is not cleared, contact your Shimadzu service representative.
C × 68	The grid is not installed correctly.	Install the grid correctly. If the message is not cleared, contact your Shimadzu service representative.
C × 69	A button was pressed on the collimator at start-up. (The code appears for 30 seconds.)	Do not touch any button on the collimator at start-up. If the code is still displayed, contact your Shimadzu service representative.
C × 70	Operating the table form remote console is unavailable while the X-ray tube is rotated.	Operate from local console or front operation panel.

Code	Content	Countermeasure
E × 50	Tilting potentiometer value does not change according to the output.	Turn on/off the [Stop] button or the system power. If the system still does not recover, contact your Shimadzu service representative.
E × 51	Imaging unit potentiometer value does not change according to the output.	
E × 52	Table-elevating potentiometer value does not change according to the output.	
E × 53	Tube-oblique potentiometer value does not change according to the output.	
E × 56	The collimator (H leaves) is not operating correctly.	
E × 57	The collimator (V leaves) is not operating correctly.	Turn on/off the [Stop] button or the system power. If the system still does not recover, contact your Shimadzu service representative.
E × 58	Abnormality of the tilting potentiometer has been detected.	
E × 59	Abnormality of the imaging unit potentiometer has been detected.	
E × 60	Abnormality of the tabletop up/down potentiometer has been detected.	
E × 61	Abnormality of the oblique projection potentiometer has been detected.	
E × 64	A sensor or motor may have failed.	
E × 65	A sensor or motor may have failed.	
E × 66	An alert was detected with tilting inverter.	
E × 67	An alert was detected with imaging unit inverter.	
E × 68	An alert was detected with table-elevating inverter.	
E × 69	The positions of drive axes are not registered.	Contact your Shimadzu service representative.
E × 70	An abnormality was detected on the [Stop] button circuit.	
E × 72	The collimator's X-ray filters are not operating correctly.	Press the [Stop] button, or turn the system's power OFF and back ON. If this doesn't recover correct operation, contact your Shimadzu service representative.
E × 73	The motor for the collimator's X-ray filters is not operating correctly.	
E × 76	Cannot communicate with the collimator correctly.	
E × 78	The FPD cooling fan has stopped.	The FPD can reach high temperatures. Do not make continuous exposures. Contact your Shimadzu service representative.
E × 79	Cannot communicate with the dosimeter. Displayed dose value is not reliable.	Contact your Shimadzu service representative.

Code	Content	Countermeasure
E × 80	Software revision of X-ray high-voltage generator is not correct.	Contact your Shimadzu Service Representative.
E × 81	The collimator of the second X-ray tube is abnormal. The potentiometer is disconnected or the position is not registered.	Press the [Stop] button, or turn the system's power OFF and back ON. If this doesn't recover correct operation, contact your Shimadzu service representative.

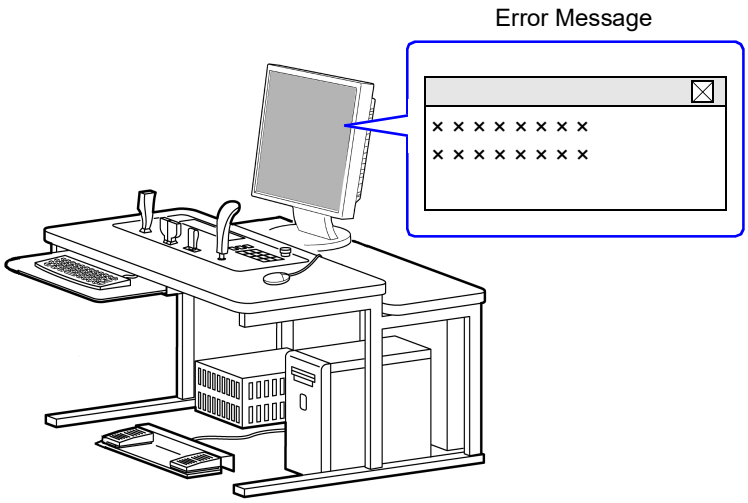
⚠ CAUTION

Do NOT remove the FPD from the tray after fluoroscopy while E × 78 is displayed.

Touching the back surface of the FPD may result in burns.

■ Digital Radiography Unit

A confirmation window is displayed when an error occurs in the digital radiography unit.
Error messages and error codes are displayed on the fluoroscopy/radiography monitor.
For details on error messages, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.



NOTE

If the digital radiography unit does not power on or cannot connect to the sensor, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.

● Fatal error list

Error Code	Error Message	Corrective Action*
F030100005	Required COM+ servers are not installed. Contact a service engineer.	Inform a service engineer of the error code. Click [OK] to close the confirmation window, and then shut down the control software.
F03020200E	Memory allocation failed. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window. Next, shut down the control software and then restart the PC. If the same error occurs after restarting, inform a service engineer of the error code.
F03020201B	Failed to upload calibration data. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	
F03020201C	Failed to transfer the image data. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	
F03020201F	A detector error occurred. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	
F030202022	A suitable jumbo packet is not set or a network card that supports jumbo packets is not being used. Contact a service engineer.	Inform a service engineer of the error code. Click [OK] to close the confirmation window and shut down the control software.
F030202023	The firmware version may have been upgraded after sensor registration. Perform sensor registration again.	
F03020FFFF	An internal error occurred. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window. Next, shut down the control software and then restart the PC. If the same error occurs after restarting, inform a service engineer of the error code.

Error Code	Error Message	Corrective Action*
F040100064	The firmware version may have been upgraded after sensor registration. Perform sensor registration again.	Inform a service engineer of the error code. Click [OK] to close the confirmation window and shut down the control software.
F040100065	A suitable jumbo packet is not set or a network card that supports jumbo packets is not being used. Contact a service engineer.	
F040300049	The firmware version may have been upgraded after sensor registration. Perform sensor registration again.	
F040300050	A suitable jumbo packet is not set or a network card that supports jumbo packets is not being used. Contact a service engineer.	
F040400003	Failed to acquire the system settings. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window, and then shut down and restart the control software. If this error occurs again, inform a service engineer of the error code.
F040700100	The system memory settings are invalid. Check the setting information.	Inform a service engineer of the error code. Click [OK] to close the confirmation window, and then shut down the control software.
F050502009	A detector communication error occurred. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window, and then shut down and restart the control software. If this error occurs again, inform a service engineer of the error code.

* For details, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.

● Error list

Error Code	Error Message	Corrective Action*
E020201004	Unexpected error has occurred. Gamma adjustment is not available. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window, and then shut down the control software. Then restart the PC and perform gamma adjustment. If this error occurs again, inform a service engineer of the error code.
E020201005	Failed to connect to the barcode reader. Check that the barcode reader cable is connected properly and restart the system. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window, and check that the barcode reader is connected properly. Then shut down and restart the control software. If this error occurs again, inform a service engineer of the error code.
E020201006	Cannot start specified examination. Return to the Exam screen and retry the failed examination.	Click [OK] to close the confirmation window and retry the previous operation on the [EXAM > Worklist] screen or the [EXAM > Manual] screen. If this error occurs again, inform a service engineer of the error code.
E020201007	A detector communication error occurred. Please retake this protocol. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window and retry the examination for the same protocol. If this error occurs again, inform a service engineer of the error code.
E020201008	The detector temperature has reached dangerous levels. Images cannot be captured until the temperature has dropped.	Suspend the examination and wait until the temperature decreases. Then restart the suspended study order.
E030100001	No calibration data. Perform calibration in the QC Tool.	Click [QC Tool] on the system setup screen, and perform calibration for the target workspace.
E030201001	A detector communication error occurred. The cable may be disconnected or there may be power discontinuity in the detector. Check that the cable is correctly connected and restart the detector. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window, and then shut down the control software. Check the cable connection to the detector, and the detector's power supply. Then restart the PC. If this error occurs again, inform a service engineer of the error code.
E030201002	Periodic noise detected in acquisition data. The grid must be removed in calibration.	Click [OK] to close the confirmation window. Remove the grid from the detector, and then calibrate the detector.
E030201003	The cooling unit has been attached or detached. Processing was halted.	Click [OK] to close the confirmation window, and then restart the examination.
E030201005	Generator is disconnected. Enable the generator connection with [Connect GEN] on the system setup screen. Restart the system if the generator connection has failed. If the problem is not resolved after restarting, contact a service engineer.	Click [Connect GEN] on the system setup screen. If the connection with the X-ray generator device continues to be disabled, shut down and restart the control software. If this error occurs again, inform a service engineer of the error code.
E030201006		
E030201007	Failed to enter the image capture ready condition. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	Exit the QC Tool mode and click [Connect GEN] on the system setup screen. If the connection with the X-ray generator device continues to be disabled, shut down and restart the control software. If this error occurs again, inform a service engineer of the error code.
E030201009	The detector temperature has reached dangerous levels. Processing was halted.	Suspend the examination and wait until the temperature decreases. Then restart the suspended study order.

Error Code	Error Message	Corrective Action*
E040100001	An invalid workspace has been specified. Check the setting information. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window and retry the previous operation. If this error occurs again, inform a service engineer of the error code.
E040100008	An invalid detector has been specified. Check the setting information. If the problem is not resolved, contact a service engineer.	
E040100023	Generator communication failed. Enable the generator connection with [Connect GEN] on the system setup screen. Restart the system if the generator connection has failed.	Click [OK] to close the confirmation window, and then click [Connect GEN]. If the generator is not connected, shut down and restart the control software. If this error occurs again, inform a service engineer of the error code.
E040100054	The detector issued a fatal error. Restart the system. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window, and then shut down the control software. Then restart the PC and perform the previous operation. (However, users can continue examinations without restarting the PC by switching to another available detector.) If this error occurs again, inform a service engineer of the error code.
E040100056	Generator is disconnected. Enable the generator connection with [Connect GEN] on the system setup screen. Restart the system if the generator connection has failed. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window, and then click [Connect GEN]. If the generator is not connected, shut down and restart the control software. If this error occurs again, inform a service engineer of the error code.
E040500003	Exceeded the maximum number of the study order acquisitions. If you want to change the number of maximum study order acquisitions, contact a service engineer.	Click [OK] to close the confirmation window. When the target study orders have been acquired, start the examination. Otherwise, acquire the target order by narrowing down the study orders using [Refresh Option]. To change the maximum number of orders that can be listed, contact a service engineer.
E040500004	Invalid studies contained in the acquired data are not displayed. Check the data identical to the acquired ones on the RIS database, etc.	Show Additional Information to check the number of the invalid orders and then click [OK] to close the confirmation window. Check the study orders that failed to be shown. The Patient ID and Study Instance UID of the orders may be invalid. In that case, correct the study order information and retry the acquisition. If this error occurs again, inform a service engineer of the error code.
E040500005	Invalid studies contained in the acquired data are not displayed. Check the data identical to the acquired ones on the RIS database, etc.	Show Additional Information to check the study orders that failed to be shown and then click [OK] to close the confirmation window. Correct the study order information and retry the data acquisition. If this error occurs again, inform a service engineer of the error code.
E040500006	Received data includes characters that do not exist in the CXDI system's character set. The characters may not be displayed correctly. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window. Supplementary Chinese characters contained in the acquired study order were replaced with “?.” Do not use the supplementary Chinese characters for study order creation on RIS database for this control software does not support these characters.
E040500008	A date entry before 1753 is included in the acquired Exam. Check the date.	Check the data information and retry a data entry.
E04050000C	Failed to read DICOMDIR file. Check the target disk and retry reading.	Check the external storage devices or media storage, and resend the image to the target storage. If this error occurs again, inform a service engineer of the error code.

Error Code	Error Message	Corrective Action*
E04050000D	A transmission error occurred. Locate the failed study in the [PAST > Past List] and retransmit the study.	Resend the image from the [PAST > View] or [PAST > Past List] screen and delete the data transmission error log from the Process Viewer.
E040501011	Cannot continue the processing because a file already exists at the specified storage destination. Check the setting information.	Click [OK] to close the confirmation window, and then check the storage directory on the Disk Storage tab. Delete all files in the specified folder, or change the directory. Then retry the previous operation.
E040501012	Cannot continue the processing because access to the specified storage destination was denied. Check the setting information.	Click [OK] to close the confirmation window, right-click the destination folder, select [Property > Security] tab, change the access privileges, and then retry the operation from the start. If the destination folder cannot be identified, consult the system administrator. If this error occurs again, inform a service engineer of the error code.
E040501013	Cannot continue the processing because there is not enough space at the specified storage destination. Check the setting information.	Click [OK] to close the confirmation window, delete all files in the destination folder, and then retry the operation from the start. If the destination folder cannot be identified, consult the system administrator. If this error occurs again, inform a service engineer of the error code.
E040501014	DICOM GSPS output was halted because the object image transfer was incomplete. Try again after object image transfer.	Click [OK] to close the confirmation window. Select the halted transmission task, and then click [Retry] on the process viewer to retry the task. If the above remedy does not work, try to reconfigure the Storage tab settings, and manually try to transmit the image starting on the [PAST > View] screen.
E040501016	Data communication between the hospital network was interrupted during file transmission. Check the setting information.	Click [OK] to close the confirmation window, and then check that the destination server and the network are functioning normally.
E040501017	The CXDI system read an unsupported DICOMDIR file. Check the target disk and retry reading.	Check that the DOCOMDIR file in the disk storage was made only with CXDI Control Software RF or NE and retry the previous operation.
E040501018	A transmission error occurred. Try again. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window, and then retry the data transmission from the Process Viewer. Or resend the image from the [PAST > View] or [PAST > Past List] screen. If this error occurs again, inform a service engineer of the error code.
E040502002-040502004	Association negotiation failed. There may be a problem in the settings of the system or that of the other communication party. Check the setting information.	Click [OK] to close the confirmation window and check the properties of Host Name, Port or Called AE title on the [Connection] tab screens. Check that destination server and the network are functioning normally. If the problem cannot be resolved, contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E04050200D-04050200F		
E040502010-040502014		
E04050201B-E04050201F	Association was stopped. There may be a problem in the settings of the system or that of the other communication party. Check the setting information.	
E040502020		
E040502021	Association negotiation failed. There may be a problem in the settings of the system or that of the other communication party. Check the setting information.	
E040502023		
E040502058		

Error Code	Error Message	Corrective Action*
E040505001	An error occurred in DICOM communication. Try again. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window. Click [Refresh] to acquire the study orders. If the problem cannot be resolved, contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E040505002		
E040505004-040505009		
E04050500B-040505014		
E040505015	A response error occurred in DICOM communication. Check the destination modality or server, etc.	Click [OK] to close the confirmation window, and then contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E040505017	An error occurred in DICOM communication. Try again. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window. Click [Refresh] to acquire the study orders. If the problem cannot be resolved, contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E040505018	A response error occurred in DICOM communication. Check the destination modality or server, etc.	Click [OK] to close the confirmation window, and then contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E04050501B	An error occurred in DICOM communication. Try again. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window. Click [Refresh] to acquire the study orders. If the problem cannot be resolved, contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E04050501F	An error occurred in DICOM communication. Contact the system administrator.	Click [OK] to close the confirmation window, and then contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E040505020	A response error occurred in DICOM communication. Check the destination modality or server, etc.	
E040505027	An error occurred in the DICOM printer output. Contact the system administrator.	
E040505029	An error occurred in the DICOM printer output. Contact the system administrator.	Click [OK] to close the confirmation window, and then contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E04050502A		
E04050502E		

Error Code	Error Message	Corrective Action*
E04050502C E04050502F	An error occurred in the DICOM printer output. Try again later.	Click [Retry] to retry the previous operation, or click [OK] to close the confirmation window, and then retry the data transmission from the Process Viewer. If the problem cannot be resolved, contact the system administrator. The problem may be resolved by checking the DICOM conformance statement. If this error occurs again, inform a service engineer of the error code.
E040506001	The transmission was interrupted as the CXDI system received a FAILURE status from the destination DICOM printer. Check the DICOM printer.	Check the DICOM printer. For details of Printer Status, refer to Annex C.13.9.1 in the DICOM standard Part3: Information Object Definitions or the DICOM conformance statement.
E040507001	DICOM Storage Commitment failed. Try again. If the problem is not resolved, contact a service engineer.	Click [Retry] to retry the previous operation, or click [OK] to close the confirmation window, and then retry the data transmission from the Process Viewer. Or resend the image from the [PAST > View] or [PAST > Past List] screen. If this error occurs again, inform a service engineer of the error code.
E040507002- 040507005	DICOM Storage Commitment failed. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window, and then retry sending the image from the [PAST > View] or [PAST > Past List] screen. If this error occurs again, inform a service engineer of the error code.
E040507006	DICOM Storage Commitment failed. Try again. If the problem is not resolved, contact a service engineer.	Click [Retry] to retry the previous operation. Or click [OK] to close the confirmation window, and then retry the data transmission from the Process Viewer. Or resend the image from the [PAST > View] or [PAST > Past List] screen. If this error occurs again, inform a service engineer of the error code.
E040507007	DICOM Storage Commitment failed. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window, and then retry the data transmission from the Process Viewer. Or resend the image from the [PAST > View] or [PAST > Past List] screen. If this error occurs again, inform a service engineer of the error code.
E040600008	Failed to access the target disk. Check the target disk and click [Retry].	Check that the destination storage disk or device is functioning normally. Then, click [Retry] to retry the data transmission.
E040600009	The process was interrupted as there was not enough free disk space. Replace the target disk with a new one and click [Retry].	Exchange the current disk with one containing sufficient free space. Then click [Retry] to retry the data transmission.
E04060000B	Cannot retry the process as an error occurred. Delete the failed process in the process viewer, locate the process in the [PAST > Past List], and then retransmit the process.	Click [OK] to close the confirmation window, and then delete the data transmission error log from the Process Viewer. Then, resend the image from the [PAST > View] or [PAST > Past List] screen. If this error occurs again, inform a service engineer of the error code.
E040700006	Failed to load the image file. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window, and then retry the previous operation.

Error Code	Error Message	Corrective Action*
E040800100	Cannot start the examination as an invalid protocol exists in the study. Delete the invalid protocol and retry the examination.	Click the suspended examination including the target protocol in [EXAM > Worklist] and then [Edit Exam] to delete it. Then delete the data transmission error log from the Process Viewer. Then resend the image from the [PAST > View] or [PAST > Past List] screen. If this error occurs again, inform a service engineer of the error code.
E040D0001F	Failed to free up the hard disk. If the problem is not resolved after restarting, contact a service engineer.	Deselect the Protect Image check box of the study order in the [PAST > Past List]. Then click the examination to delete the data transmission error log or resend the image from the Process Viewer. If this error occurs again, inform a service engineer of the error code.
E040E01000	Image analysis processing failed. Adjust the image processing parameters manually.	If the brightness of selected area is not appropriate, click [ROI] to specify the target area. If the selected area is not cropped appropriately, click crop button to specify the target area. If the selected area is not masked appropriately, click [Mask] to specify the target area.
E040E01001	Failed to load the extra defect correction file. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window, and then perform calibration. If this error occurs again, inform a service engineer of the error code.
E041000004	Failed to start up CxdiInfo. Check the setting information.	Check if the study order is valid. Acquire the study order again from the HIS/RIS database.
E041000005	Entered information has invalid value. Invalid values are replaced with blanks. Check the examination file.	Check if the study order is valid. Acquire the study order again from the HIS/RIS database.
E041000006	Specified ID is not found in the examination file. Check the examination file.	Check if the study order is valid. Acquire the study order again from the HIS/RIS database.
E041000008	An error was discovered while checking the user input by the script. If the problem is not resolved, contact a service engineer.	Inform a service engineer of the error code.
E041000010	An error has occurred in CCRHIS library. Try again. If the problem is not resolved, contact a service engineer.	Show Additional Information to check the error details and click [OK] to close the confirmation window. Then retry the previous operation depending on the error details. If this error occurs again, inform a service engineer of the error code.
E041100004	Failed to start up CxdiInfo. Check the setting information.	Inform a service engineer of the error code.
E050501006	The internal temperature of the detector exceeds the upper limit. Images cannot be captured until the temperature has dropped.	Suspend the examination and wait until the temperature decreases.
E050501008	A drive circuit error occurred. Contact a service engineer.	Inform a service engineer of the error code.
E050501009		
E05050100A	An abnormality was detected in the detector structure. Contact a service engineer.	
E05050100B		
E05050100C	A control line connection error was detected in the detector. Contact a service engineer.	
E05050100D		
E050501010	Failed to transfer the image data. Try again. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window, and then retry the image transmission. If this error occurs again, inform a service engineer of the error code.

Error Code	Error Message	Corrective Action*
E050501012	An abnormality was detected in the analog power supply for the detector. Contact a service engineer.	Inform a service engineer of the error code.
E050501014	A grid error was detected. Contact a service engineer.	
E050501016	The firmware is different. Contact a service engineer.	
E050502026	A detector communication error occurred. The cable may be disconnected or there may be power discontinuity in the detector. Check that the cable is correctly connected and restart the detector. If the problem is not resolved after restarting, contact a service engineer.	Click [OK] to close the confirmation window, check the cable connection to the detector, and restart the detector. If this error occurs again, inform a service engineer of the error code.

* For details, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.

● Warning list

Error Code	Error Message	Corrective Action*
W020202001	The detector temperature has reached warning levels.	Suspend the examination and wait until the temperature decreases. Then restart the suspended study order.
W020202002	The detector temperature has reached dangerous levels.	
W020202003	The detector is not available. Irradiation has finished.	Click [OK] to close the confirmation window and then continue the operation.
W020202005	The specified disk space could not be cleaned up.	Retry the deletable capacity and click [Delete].
W030203003	The internal temperature of the detector exceeds the upper limit.	Suspend the examination and wait until the temperature decreases.
W040100045	Calibration data is invalid. Update the calibration data.	Click [OK] to close the confirmation window and then calibrate the detector.
W040100052	The detector issued a warning.	Click [OK] to close the confirmation window and then continue the operation.
W040500007	Characters which do not match the current character code are used in this data. This character code will be properly changed automatically. Check the setting information.	Click [OK] to close the confirmation window. Characters that do not match the current character code will be replaced with “?.” Continue the operation when the replacement is acceptable. To disable the replacement, inform a service engineer of the error code.
W040500009	Failed to copy a tag to C-STORE. Check the tag information and the C-STORE communication log. If the problem is not resolved, contact a service engineer.	Click [OK] to close the confirmation window, and check the original DICOM tag and the C-STORE communication. Then correct the original tag and retry the previous operation. If this error occurs again, inform a service engineer of the error code.
W04050000A	Failed to copy tag to the DicomFile. Check the original data. If the problem is not resolved, contact a service engineer.	Inform a service engineer of the error code. Click [OK] to close the confirmation window, and then shut down the control software.
W040505003	An error occurred in DICOM communication.	Contact the system administrator. The problem may be resolved by checking the destination server or the DICOM conformance statement. If the problem cannot be resolved, inform a service engineer of the error code.
W04050500A		
W04050501C-04050501E		

Error Code	Error Message	Corrective Action*
W040505030	The transmission was complete normally. However, the CXDI system received WARNING status from the destination DICOM printer. Check the DICOM printer.	Check the DICOM printer. For details on Printer Status, refer to Annex C.13.9.1 in the DICOM standard Part3: Information Object Definitions or the DICOM conformance statement.
W050501002-050501004	A Flash ROM error was detected in the detector. Contact a service engineer.	Click [OK] to close the confirmation window, and then shut down and restart the control software. If this error occurs again, inform a service engineer of the error code.
W050501005	A grid error may have caused an image abnormality.	Click [OK] to close the confirmation window. There may be a problem in the captured image. Check the image and retry the examination.
W050501007	The internal temperature of the detector is close to the upper limit. Do not leave the detector in the Ready condition.	Click [OK] to close the confirmation window, click [Unselect], and wait until the temperature decreases.
W05050100E	An error was detected in the detector.	Inform a service engineer of the error code.
W05050100F		
W050501011	The transfer of the image data was stopped.	Click [OK] to close the confirmation window. There may be a problem in the captured image. Check the image and retry the examination.
W050501013	A grid ID loading error was detected.	Check if the grid is properly attached. If the problem cannot be resolved, inform a service engineer of the error code.
W050501015	A grid error may have caused an image abnormality.	Click [OK] to close the confirmation window, and check the captured image. If there is a problem in the image, inform a service engineer of the error code.

* For details, refer to the "OPERATION GUIDE" section of the control software instruction manual for the SDR-150C digital radiography system.

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Chapter 7

Maintenance

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7.1 Maintenance

The system is shipped in optimum condition through quality management and inspections. Regular maintenance is necessary for maintaining this condition.
Maintenance provides vivid diagnostic images and for the safety of operator/patient.

System maintenance is classified as follows.

Maintenance Item		Performer	Maintenance Cycle
Daily Maintenance	Start-up Maintenance	Operator or equipment manager	Daily (before operation)
	Post-operation Maintenance	Operator or equipment manager	Daily (after operation)
Warning and caution labels		Operator or equipment manager	Once a year
Disinfection		Operator or equipment manager	When needed
Periodic Inspection		Shimadzu service representative	Every 6 months

■ Daily Maintenance

Daily maintenance involves Start-up and Post-operation Maintenance. Perform daily maintenance for longer product life.
Follow the procedures listed on "Checklist for Start-up Maintenance " and "Checklist for Post-operation Maintenance " in "Chapter 8 ".

■ Cleaning and Disinfection

⚠ WARNING

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

Otherwise, a malfunction may occur in the equipment, or the equipment may operate in an unintended way.
Also, thoroughly ventilate the room before turning ON the power after disinfection work is complete.

⚠ CAUTION

Be sure to clean and disinfect the equipment.

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

Be sure to clean the equipment frequently and after each patient use.

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

⚠ CAUTION

Wipe the surface of the equipment with a cloth moistened, not soaked, with the following disinfectants or cleaner.

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

* Using organic solvents other than the above disinfectants causes discoloration. Wipe them off immediately if they adhere to the equipment.
* Some disinfectants shown above require cautious use depending on the site of application.

Do NOT use the following disinfectants:

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

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

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

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

When disinfecting resin parts such as mattress, shoulder rests and reticule of the collimator, dilute a neutral detergent free from any organic solvents with water or lukewarm water and moisten a cloth with it, or moisten a cloth with a designated chlorine disinfectant, and wipe the resin parts with the cloth.

Adhesion of rubbing alcohols, organic solvents, or non-neutral detergents may lead to deformation or crack of resin parts. Wipe them off immediately if they adhere to the resin parts.

Use disinfectants at a minimum.

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

To prevent infections, disinfect the applied parts which contact the patient's body, such as the FPD surface, with rubbing alcohol each time a new patient is X-rayed.

Clean the FPD connector by blowing off dust with an air blow or wiping with a soft, dry cloth.

Do NOT grease tabletop rails.

Be sure to wipe the tabletop rails with a soft dry cloth. Any oil or grease may cause the accessories on the rails to slip off.

■ Inspection for Warning and Caution Labels

Periodically (once a year) inspect the labels attached on the equipment.
If any label is peeled or unreadable by stain or scratch, contact your Shimadzu service representative for replacement of a new one.

"Warning and Caution Labels" P.XXVII

■ Periodic Inspection

Even without any problem in daily inspection, the following items should be inspected periodically.

⚠ WARNING

Be sure to perform periodic inspection (every 6 months).

Failure to do this may cause serious accidents or significantly shorten the lifetime of the equipment.

Periodic inspections mainly check the equipment performance and the internal mechanisms.
The inspections require good knowledge of the internal mechanisms and can also be dangerous. Contact your Shimadzu service representative to request a periodic inspection. It is recommended to conduct periodic inspections every 6 months. A fee is charged for periodic inspections after expiry of the warranty periods.

The maintenance work involves dangerous tasks. Be sure to request your Shimadzu service representative to perform the periodic inspection.

7.2 Periodic Replacement Parts

Replace certain parts periodically to maintain the system performance. These parts are called periodic replacement parts.
Periodic replacement parts must be replaced by a Shimadzu service representative.

■ X-ray Diagnostic Table

● Battery

Part Name	Location	Replacement Cycle
Battery, CR2450	DTC-2 Board	1 year

● Fuse

Part Name	Location	Replacement Cycle
Fuse, FLQ30	Transformer, T1-XV	1 year
Fuse, FLM10	Transformer, T1-XV	1 year
Fuse, FLM12	Transformer, T1-XV	1 year
Fuse, FLM20	Transformer, T1-XV	1 year
Fuse, 313 500	Transformer, T1-XV	1 year
Fuse, 313 001*	Transformer, T1-XV	1 year
Fuse, FLQ1*	Transformer, T1-XV	1 year
Fuse, 313 002	Transformer, T1-XV	1 year
Fuse, 313 003	Transformer, T1-XV	1 year
Fuse, 313 015	Transformer, T1-XV	1 year
Fuse, 326010	Transformer, T1-XV	1 year
Fuse, 600FH-125	IGBT Unit	1 year

* Alternate. Replace to the same kind of fuse as used before replacing.

● Relay

Part Name	Location	Replacement Cycle
Relay, G7J4A-T-KM-DC24V	ZUD Cabinet (Motor Control 50)	2 years

● Switch

Part Name	Location	Replacement Cycle
Table up/down detection ASSY	Base Assy	3 years
Table tilting detection ASSY	Base Assy	3 years
F/R unit detection ASSY	Main Body	3 years
Tube oblique detection ASSY	Column Assy	3 years

■ Digital Radiography Unit

● FPD

Part Name	Location	Replacement Cycle
Fan (FPD)	FPD Tray	5 years

● Digital Radiography PC

Part Name	Replacement Cycle
HDD	3 years
Fan	5 years
Mouse	5 years

● Transformer

Part Name	Quantity	Replacement Interval
Fuse, FLM10	2	1 year
Fuse, FLM20	2	1 year
Fuse, FLM30	1	1 year
Fan, MU-1225S-11	1	2 years

Chapter 8

Checklists

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8.4 Safety Explanation Record 142

8.1 Start-up Maintenance

■ Checklist for Start-up Maintenance

Date:

Name:

(1) Visually inspect the items/areas listed below. Take the recommended corrective action if you find any abnormalities.

Item/Area	Corrective Action
☐ Diagnostic table is free of unnecessary items.	Remove unnecessary items.
☐ System is free of contrast medium or spilled chemicals.	Clean up any spilled liquid.
☐ Floor and movable parts of the diagnostic table are free from rust and metal shavings.	Remove any rust and/or metal shavings.
☐ The connectors are securely connected.	Connect them.
☐ No cables are jammed, twisted, or stripped.	Untangle or replace cables.
☐ No cable stripping.	Contact your Shimadzu service representative.
☐ No dents, cracks, or dew condensation on the exterior of the instrument.	

(2) Manually inspect the following. Take the recommended corrective action if you find any abnormalities.

Item/Area	Corrective Action
☐ Foot rest is locked in place.	Lock completely in place.
☐ Shoulder rests are locked in place.	Lock completely in place.
☐ Grip bars are locked in place.	Lock completely in place.
☐ Handgrips are locked in place.	Lock completely in place.
☐ There are no loose screws or damaged covers in any part of the equipment.	Contact your Shimadzu service representative.

(3) Turn the system on. Check the following points. Take the recommended corrective action if you find any abnormalities.

Item/Area	Corrective Action
☐ System makes abnormal sound after power is turned on.	Contact your Shimadzu service representative.
☐ System emits unusual smell.	
☐ The collimator's lamp is lit brightly.	Contact your Shimadzu service representative.

(4) Confirm that the system has started up normally.

Item/Area	Corrective Action
☐ Fluoroscopy/radiography monitor displays data normally.	Contact your Shimadzu service representative.

(5) Using the remote control, inspect the items/areas listed below. Take the recommended corrective action if you find any abnormalities.

Item/Area	Corrective Action
☐ Tabletop does not make an abnormal sound when tilted.	Contact your Shimadzu service representative.
☐ Tabletop automatically stops at approx. 90° when tilted.	
☐ Tabletop does not make an abnormal sound when adjusted laterally.	
☐ Imaging unit does not make an abnormal sound when adjusted.	
☐ Compression unit does not make an abnormal sound when adjusted.	
☐ Collimator shutters do not make an abnormal sound when opened/closed.	
☐ Voice can be transmitted from the microphone on the remote console to the speaker in the examination room.	

(6) Check the following points before using the equipment.

Point to Check	Corrective Action
☐ Has the X-ray tube been aged? ☞ Refer to the R/F system operation manual (M506-E051).	Perform aging.
☐ When using peripheral equipment such as an AEC (photo timer), ensure that the equipment works correctly including that photographic density is appropriate.	Contact your Shimadzu service representative.
☐ Is there any abnormality in the operation of the IBS (image brightness stabilizer) (option)? Check by following the procedure below. (1) Select the IBS. (2) Fully open the collimator. (3) Perform fluoroscopy. (4) Check that the fluoroscopy tube voltage is close to its lowest (50 kV). (5) Fully close the collimator while performing fluoroscopy. (6) Check that the fluoroscopy tube voltage rises to the maximum.	Contact your Shimadzu service representative.
☐ Is the AKR value displayed on the acquisition monitor appropriate? Check by following the procedure below. (1) Select the IBS OFF. (2) Set the fluoroscopy mode to [PULSE N] with 15 Fps and 70 kV. (3) Perform fluoroscopy with the collimator fully opened. (4) Observe the value of AKR displayed on the Add On Console. Confirm that the difference of the AKR value recorded below and this observation value is less than ±30 %. (5) Restore the normally IBS setting. "AKR value column" Perform fluoroscopy under the same conditions as those described above as soon as possible after installation adjustment and record the AKR value displayed on the acquisition monitor in the column below. mGy/min	Contact your Shimadzu service representative.

8.2 Post-operation Maintenance

■ Checklist for Post-operation Maintenance

Date:

Name:

- X-ray Diagnostic Table Checklist

Item/Area	Corrective Action
☐ Tabletop is returned to the vertical or horizontal position.	Return the tabletop to its proper position.

- Cleaning Checklist

Item/Area	Corrective Action
☐ System is free of contrast medium or spilled chemicals. Wipe off any excess liquid using a cloth moistened with a specified disinfectant or cleaner. Spilled liquid can stain the tabletop.	Wipe the tabletop clean of any spilled liquid.
☐ System has been vacuumed free of dust or dirt. *The keys may be removed from the keyboard if it is vacuumed. Use compressed air to clean dust or dirt from the keyboard.	Vacuum/spray the system free of dust or dirt.
☐ Detached accessories are cleaned and stored.	Clean and store all accessories.

8.3 Equipment Malfunction Record

■ Equipment Malfunction Checklist

Fill following blanks and contact your Shimadzu service representative.

Hospital:

Name:

Phone:

FAX:

E-mail Address:

Unit Name:

System Name:

Serial Number:

Date of Installation:

Question	Answer
☐ Did the malfunction injure anyone?	
☐ When did the malfunction occur?	
☐ Did the system malfunction suddenly? Were there any indications of a problem beforehand?	
☐ Was there a power failure or thunderbolt when the malfunction occurred?	
☐ Has the system come in contact with moisture?	
☐ Has the unit been subjected to a strong impact?	
☐ How many patients per day are diagnosed using the malfunctioning unit?	
☐ When was the last periodic inspection?	

8.4 Safety Explanation Record

Hospital	☐ Hospital Name	
	☐ Phone	
	☐ Extension	
	☐ FAX	
	☐ E-mail Address	
	☐ Address	
	☐ Room Number	
Unit	☐ Unit Name	
	☐ System Name	
	☐ Serial Number	
	☐ Installation Date	
Shimadzu Rep.	☐ Dept./Section	
	☐ Phone	
	☐ FAX	
	☐ E-mail Address	

- Direction Subject

Direction Date	Direction Subject	Administrator/ Operator	Shimadzu Rep.
		Name	Name

A Shimadzu service representative will explain the safety precautions in this operation manual to the system administrator or operator and use this sheet to record what he/she explained when the system is installed or a new operator is hired.
This sheet is important. The system administrator must store it in close proximity to the unit.

Appendix

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1.3 Reference Air Kerma (Rate) 146
1.4 Useful Features for Pediatric Imaging 148
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1.1 Information on Radiation

1.1.1 Radiation Protection

To minimize X-ray exposure on patients and medical staff, the operator must observe the local laws and regulations specified in each region, as well as the following precautions. It is also highly recommended to study and know about the recommendations of the International Commission on Radiological Protection (ICRP).

■ Principle

- Limit X-ray irradiation to the minimum.
- Keep the fluoroscopy duration to the minimum and utilize the LIH feature.
- Use the fluoroscopy mode with low radiation dose.
- To avoid unintended X-ray irradiation, turn OFF the Fluoroscopy Selection Button when unnecessary.

■ For Radiation Protection of Patients

- If there is any possibility that the regions easily affected by radiation (eye balls, gonad, etc.) are irradiated by X-ray, be sure to protect those regions.
- Adjust X-ray irradiation field appropriately to avoid X-ray irradiation to the area other than the region of interest.
- Keep the focus-skin distance as long as possible.
- Always check the cumulative dose area product and the cumulative reference air kerma displayed in the acquisition monitor.

NOTE The measurement uncertainty of the displayed dose value is ±35 %.
Periodical calibration is required for the dose area product meter chamber and the dose calculating function.

■ For Radiation Protection of Medical Staff

- Be sure to execute X-ray irradiation operation at the remote operation desk located outside of the controlled area, as much as possible.
- Limit the time of staying in the controlled area as short as possible. While in the area, be sure to wear the radiation protective gear, such as protective apron, gloves, glasses, etc.
- Keep the distance as far as possible from the X-ray source. The radiation dose is inversely proportional to the square of the distance from the radiation source.
- Be sure to use a badge or pocket dosimeter to check your personal exposure dose.

1.2 Deterministic Effect

In the examination using this equipment, there is a possibility that the cumulative skin dose during the examination may reach the level that could bring a deterministic effect on the patient. According to the ICRP60, the threshold at which a deterministic effect appears on skin or crystalline lens is 1 to 3 Gy. The following shows an example of X-ray conditions which could bring skin dose of 1 Gy during the examination using this equipment.

Example:

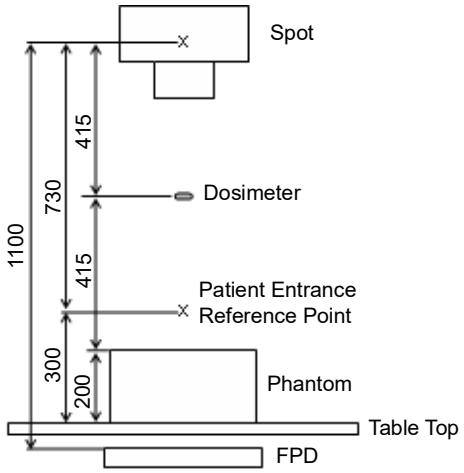
- Performing 20 min of fluoroscopy under the parameters of SID1100, Fluoroscopy mode 15 Fps, Cu0, 115 kV, and 3.1 mA.
- Performing 30 min of fluoroscopy under the parameters of SID1100, Fluoroscopy mode 15 Fps, Cu0.1, 115 kV, and 3.1 mA.

1.3 Reference Air Kerma (Rate)

This section describes representative values of reference air kerma rate of fluoroscopy and reference air kerma of radiography.

■ Measurement Condition (Compliant with IEC 60601-2-54 clause 203.5.2.4.5.102)

SID: 1100 mm
Anti-scatter grid: Used
Phantom: PMMA 400×400×200 mm
Geometry:



Unit: mm

$$\text{Reference Air Kerma} = \text{Measured Dose} \times \left(\frac{415}{730}\right)^2$$

■ Fluoroscopy

● Mode and Application

Mode	Pulse (ms)	Frame Rate (fps)	Application
Pulse 15	9	15	For normal study
Pulse 7.5	9	7.5	For study that needs decreasing dose.
High-definition	9	12.5	For observing fine structure.

● Curves of Tube Voltage-tube Current (mA) (0.3/0.8P324DK-85, 6/1.2P324DK-85)

Mode	50 kV	60 kV	80 kV	90 kV	100 kV	120 kV
Pulse 15	1.2	1.3	2.0	2.3	2.1	1.5
Pulse 7.5	0.6	0.7	1.0	1.2	1.0	0.8
High-definition	1.0	1.0	1.6	1.8	1.6	1.2

● Curves of Tube Voltage-tube Current (mA) (0.6/1.2P326D-150)

Mode	50 kV	60 kV	80 kV	90 kV	100 kV	115 kV
Pulse 15	1.2	1.8	3.0	3.1	2.8	2.3
Pulse 7.5	0.6	0.9	1.5	1.6	1.4	1.2
High-definition	1.0	1.4	2.4	2.5	2.2	1.8

● Reference Air Kerma Rate

X-ray Tube Unit	Mode	15 fps	7.5 fps	High-Definition
0.3/0.8P324DK-85 0.6/1.2P324DK-8	Tube Voltage (kV)	87	87	92
	Tube Current (mA)	2.2	1.1	1.8
	Reference AKR (mGy/min)	9.6	4.8	9.5
0.6/1.2P326D-150	Tube Voltage (kV)	84	84	88
	Tube Current (mA)	3.0	1.5	2.5
	Reference AKR (mGy/min)	10.4	5.2	10.0

*BH Filter: Cu 0.1 mm

● Highest Reference Air Kerma Rate

- 26.4 mGy/min at 115 kV, 2.3 mA, FOV:12×12, Cu0.1

■ Radiography

● Reference Air Kerma

BH Filter	FOV	12×12	9×9
Cu0.1	Tube Voltage (kV)	85	85
	Tube Current (mA)	320	320
	Time (msec)	44	44
	Reference AKR (µGy)	909	909

● Highest Reference Air Kerma

8.7 mGy/Frame at 125 kV, 63 mAs, BH filter: Cu0.1 mm, 12 FOV for DR exposure.

1.4 Useful Features for Pediatric Imaging

There are several useful features for Pediatric Imaging on FLEXAVISION. It is suggested to utilize those features when pediatric examination is performed.

It is also possible to set a protocol suitable for pediatric. Contact your Shimadzu service representative.

■ Removable Anti-scatter Grid

The X-ray grid of the FLEXAVISION is removable. Removing the x-ray grid often contributes to reduce radiation dose especially for infant patient. The way to mount or remove the X-ray grid is explained in the following page.

"3.2 Mounting/Removing the Grid" P.39

■ Irradiation Field Adjustment from Remote Console

Appropriate irradiation field adjustment directly contributes to minimize unnecessary radiation dose.

"3.4 Operating the X-ray Diagnostic Table"-"Specifying the X-ray Irradiation Field"

■ X-ray Filter Selection

X-ray filters of Cu0.1 mm, Cu0.2 mm, Cu0.3 mm or others can be added for pediatric imaging. Details on the X-ray filter selection are explained in the following page.

"3.4 Operating the X-ray Diagnostic Table"-"Selecting an X-Ray Filter"

1.5 NOTATION FOR WIRELESS REGULATIOIN

1.5.1 EU/EFTA *including Northern Ireland

RE compliance (For European Union and EFTA)

English	Hereby, Canon Inc. declares that this equipment is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: https://global.canon/en/deoco/medcom/index.html
Czech	Tímto společnost Canon Inc. prohlašuje, že toto zařízení je v souladu se směrnicí 2014/53/EU. Úplné znění EU prohlášení o shodě je k dispozici na této internetové adrese: https://global.canon/en/deoco/medcom/index.html
Danish	Hermed erklærer Canon Inc., at dette udstyr er i overensstemmelse med direktiv 2014/53/EU. EU-overensstemmelseserklæringens fulde tekst kan findes på følgende internetadresse: https://global.canon/en/deoco/medcom/index.html
German	Hiermit erklärt Canon Inc, dass diese Anlage der Richtlinie 2014/53/EU entspricht. Der vollständige Text der EU-Konformitätserklärung ist unter der folgenden Internetadresse verfügbar: https://global.canon/en/deoco/medcom/index.html
Estonian	Käesolevaga deklareerib Canon Inc., et käesolev seade vastab direktiivi 2014/53/EL nõuetele. ELi vastavusdeklaratsiooni täielik tekst on kättesaadav järgmisel internetiaadressil: https://global.canon/en/deoco/medcom/index.html
Spanish	Por la presente, Canon Inc. declara que este equipo es conforme con la Directiva 2014/53/UE. El texto completo de la declaración UE de conformidad está disponible en la dirección de Internet siguiente: https://global.canon/en/deoco/medcom/index.html
Greek	Με την παρούσα, η Canon Inc. δηλώνει ότι ο παρών εξοπλισμός συμμορφώνεται με την Οδηγία 2014/53/ΕΕ. Το πλήρες κείμενο της δήλωσης συμμόρφωσης της ΕΕ διατίθεται στην ακόλουθη διεύθυνση στο διαδίκτυο: https://global.canon/en/deoco/medcom/index.html
French	Le soussigné, Canon Inc., déclare que le présent équipement est conforme à la Directive 2014/53/UE. Le texte complet de la déclaration UE de conformité est disponible à l'adresse internet suivante : https://global.canon/en/deoco/medcom/index.html
Italian	Con la presente, Canon Inc. dichiara che questa apparecchiatura è conforme alla direttiva 2014/53/UE. Il testo completo della dichiarazione di conformità UE è disponibile al seguente indirizzo Internet: https://global.canon/en/deoco/medcom/index.html

Latvian	Canon Inc. ar šo deklarē, ka šī iekārta atbilst Direktīvai 2014/53/ES. Pilns ES atbilstības deklarācijas teksts ir pieejams šādā interneta vietnē: https://global.canon/en/deoco/medcom/index.html
Lithuanian	Šiuo dokumentu „Canon Inc." patvirtina, kad ši įranga atitinka direktyvą 2014/53/ES. Visas ES atitikties deklaracijos tekstas prieinamas šiuo interneto adresu: https://global.canon/en/deoco/medcom/index.html
Dutch	Hierbij verklaar ik, Canon Inc., dat deze apparatuur conform is met Richtlijn 2014/53/EU. De volledige tekst van de EU-conformiteitsverklaring kan worden geraadpleegd op het volgende internetadres: https://global.canon/en/deoco/medcom/index.html
Maltese	B'dan, Canon, qed tiddikjara li dan it-tip ta' tagħmir huwa konformi mad-Direttiva 2014/53/UE. It-test kollu tad-dikjarazzjoni ta' konformità tal-UE huwa disponibbli f'dan is-sit fuq l-internet: https://global.canon/en/deoco/medcom/index.html
Hungarian	A Canon Inc. igazolja, hogy ez a berendezés megfelel a 2014/53/EU irányelvnek. Az EU-megfelelőségi nyilatkozat teljes szövege elérhető a következő internetes címen: https://global.canon/en/deoco/medcom/index.html
Polish	Canon Inc. niniejszym oświadcza, że niniejsze urządzenie jest zgodne z dyrektywą 2014/53/UE. Pełny tekst deklaracji zgodności UE jest dostępny pod następującym adresem internetowym: https://global.canon/en/deoco/medcom/index.html
Portuguese	Por este meio, a Canon Inc. declara que o presente equipamento está em conformidade com a Diretiva 2014/53/UE. O texto integral da declaração de conformidade da UE está disponível no seguinte endereço de Internet: https://global.canon/en/deoco/medcom/index.html
Slovene	CanonInc.potrjuje,dajetaopremavskladuzDirektivo2014/53/EU. Celotno besedilo izjave EU o skladnosti je na voljo na naslednjem spletnem naslovu: https://global.canon/en/deoco/medcom/index.html
Slovak	Spoločnosť Canon Inc. týmto vyhlasuje, že toto zariadenie je v súlade so smernicou 2014/53/EÚ. Úplné znenie EÚ vyhlásenia o zhode je k dispozícii na tejto internetovej adrese: https://global.canon/en/deoco/medcom/index.html
Finnish	Canon Inc. vakuuttaatäten, että tämä laite on direktiivin 2014/53/EU mukainen. EU-vaatimustenmukaisuusvakuutuksen täysimittainen teksti on saatavilla seuraavassa internetosoitteessa: https://global.canon/en/deoco/medcom/index.html
Swedish	Härmed försäkrar Canon Inc. att denna utrustning överensstämmer med direktiv 2014/53/EU. Den fullständiga texten till EU-försäkran om överensstämmelse finns tillgänglig på följande webbadress: https://global.canon/en/deoco/medcom/index.html
Romanian	Prin prezenta, Canon Inc. declară că acest echipament este în conformitate cu Directiva 2014/53/UE. Textul integral al declarației UE de conformitate este disponibil la următoarea adresă internet: https://global.canon/en/deoco/medcom/index.html

Bulgarian	С настоящото Canon Inc. декларира, че това съоръжение е в съответствие с Директива 2014/53/ЕС. Цялостният текст на ЕС декларацията за съответствие може да се намери на следния интернет адрес: https://global.canon/en/deoco/medcom/index.html
Croatian	Canon Inc. ovime izjavljuje da je oprema u skladu s Direktivom 2014/53/EU. Cjeloviti tekst EU izjave o sukladnosti dostupan je na sljedećoj internetskoj adresi: https://global.canon/en/deoco/medcom/index.html
Irish	Dearbhaíonn Canon Inc., leis seo, go bhfuil an trealamh seo i gcomhlíonadh leis an Treoir 2014/53/AE. Tá an téacs iomlán de Dhearbhú Comhréireachta AE ar fáil ag seoladh an láithreáin ghréasáin mar seo a leanas: https://global.canon/en/deoco/medcom/index.html
Norwegian	Herved erklærer Canon Inc. at dette utstyret er i overensstemmelse med direktiv 2014/53/EU. Den fulle teksten til EUs samsvarserklæring er tilgjengelig på følgende Internett-adresse: https://global.canon/en/deoco/medcom/index.html
Icelandic	Hér með lýsir Canon Inc því yfir að þessi búnaður er í samræmi við tilskipun 2014/53/ESB. Allur texti ESB-samræmisyfirlýsingar er í boði á eftirfarandi veffangi: https://global.canon/en/deoco/medcom/index.html

For information on obtaining the original of the declaration, consult your sales representatives.

1.5.2 United Kingdom *except Northern Ireland

RE compliance (For United Kingdom)

Hereby, Canon Inc. declares that this equipment is in compliance with the relevant statutory requirements. The full text of the UK declaration of conformity is available at the following internet address: https://global.canon/en/deocouk/medcom/index.html

For information on obtaining the original of the declaration, consult your sales representatives.

1.5.3 United States of America

FCC CAUTION:
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

RF exposure compliance

The available scientific evidence does not show that any health problems are associated with using low power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low power Wireless devices emit low levels of radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure of low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research. WM5A16 has been tested and found to comply with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines.

Only a physician or a legally certified operation should use the product. Please do not adhere to your hands and body to an antenna part to restrain exposure of the RF energy when conducting an X-ray examination.

This device complies with below part 15 of the FCC Rules.
Part 15 Subpart C
Part 15 Subpart E

Supplier's Declaration of Conformity

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
The supplier's Declaration of Conformity is available on your request. Please contact at: Distributor

1.5.4 Brazil

Modelo: BM72065

Este produto contém a placa (BM72065) código de homologação Anatel 08505-20-07857

Este equipamento não tem direito à proteção contra interferência prejudicial e não pode causar interferência em sistemas devidamente autorizados.

Para consultas, visite: www.anatel.gov.br

1.5.5 Republic of Korea

이 제품은 제품을 구매한 국가 또는 지역의 현지 무선 주파수 규정을 준거합니다. 본 제품은 구매한 국가 또는 지역 이외의 어떠한 곳에서도 사용할 수 없습니다. 이 제품이 설치된 환경에 다른 기기를 추가하거나, 다른 환경에서 본 제품을 사용하려면 영업 담당자에게 자세한 사항을 문의하십시오.

전파법

AF-B1 는 한국 전파법의 적합성 평가를 받은 무선설비를 탑재하고 있습니다.

모델 번호 : WM5A16

이 기기는 업무용 환경에서 사용할 목적으로 적합성평가를 받은 기기로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다.

1.5.6 Thailand

เครื่องวิทยุคมนาคมนี้มีอัตราการดูดกลืนพลังงานจำเพาะ (Specific Absorption Rate - SAR) อันเนื่องมาจากเครื่องวิทยุคมนาคมเท่ากับ 1.09W/kg and 1.07W/kg ซึ่งสอดคล้องตามมาตรฐานความปลอดภัยต่อสุขภาพของมนุษย์จากการใช้เครื่องวิทยุคมนาคมที่คณะกรรมการกิจการโทรคมนาคมแห่งชาติประกาศกำหนด

The table below shows the revision history of this manual.

Revision	Date	Changes
First edition	Jun. 2021	First edition released.
A	Dec. 2021	Revised for product release.
B	Jan. 2022	Added "System Activation" and relating error codes.
C	Oct. 2023	• Added “WARNING” to “Precautions in Use”. • Added comments on the accuracy of each condition and the responsiveness of fluoroscopy stop for X-ray high voltage generator in Chapter 5.1. • Added High-definition for Fluoroscopy mode in Appendix 1.3. • Added a description of protocol setting for pediatric in Appendix 1.4.
D	Apr. 2024	• Updated a nameplate for the main body of FPD and a nameplate for ratings of Multibox (MB-01) in Chapter 1.5.