

PORTABLE X-RAY UNIT

FIR Xair II

(XD4000)

Operation Manual

1st Edition : 2025-03-01

Precautions

System configuration (Product Overview)

Basic Operation

Various Setting

Trouble exposure

Daily Inspection and Maintenance

FUJIFILM Corporation

This Operation Manual describes details on how to operate the XD4000 and cautions to be observed when operating it. Please read the Operation Manual thoroughly before actually operating the XD4000 and other manuals for the related products.

After reading this manual, store it nearby the XD4000 so that you can see it whenever necessary.

Introduction

The XD4000 PX is a "battery-type portable X-ray system" which provides image data of the human body for diagnosis by utilizing the scintillation effect, photographic effect and ionization effect of X-rays permeated through the human body.

The XD4000 PX needs to be used in combination with the holding device XD2000 ST-M or XD2000 ST-S. Other devices cannot be used in combination with the XD4000 PX.

The X-ray generator, XD4000 PX is provided with a scale, AC adapter and shoulder strap.

This Operation Manual includes descriptions matters necessary when using the battery-type portable X-ray system XD4000 (hereafter referred to as the "XD4000"), such as the equipment overview, operation procedures and precautions to observe, as well as daily inspections and maintenance.

The XD4000 PX can be used for irradiating X-ray onto the human body at the time of X-ray radiography. This device is intended to be reused on multiple patients.

The XD4000 can also be carried into a long-term care health facility for radiography at the patient's bedside or in the imaging room.

Intended purpose

The XD4000 PX is a battery-type portable X-ray device intended for use by qualified physicians and technologists in generating radiographic images of human anatomy. The XD4000 PX is intended to be used in home health care and similar conditions. It is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Patient population

The use of the XD4000 PX is limited to exposure of patient's body parts with a thickness suitable for radiographic output. (In the case of the chest radiography of a patient with a body thickness of 28 cm or more, front abdominal or lumbar spine radiography of a patient with a body thickness of 31 cm or more, or lateral lumbar spine radiography, sufficient image quality may not be sufficient. or more, or lateral lumbar spine radiography, sufficient image quality may not be obtained.)

There is no restriction on age / height / sex / nationality.

Indications

Generating radiographic images of human anatomy.

Do not use the XD4000 PX for any purposes other than diagnosis.

Accompanying documents were originally drafted in the English language.

Installation ***may only be conducted by authorized service personnel.***

Note : The above statements were determined by applicable medical device regulations which vary throughout the world. These statements are subject to revision when additional clearance or approval is obtained.



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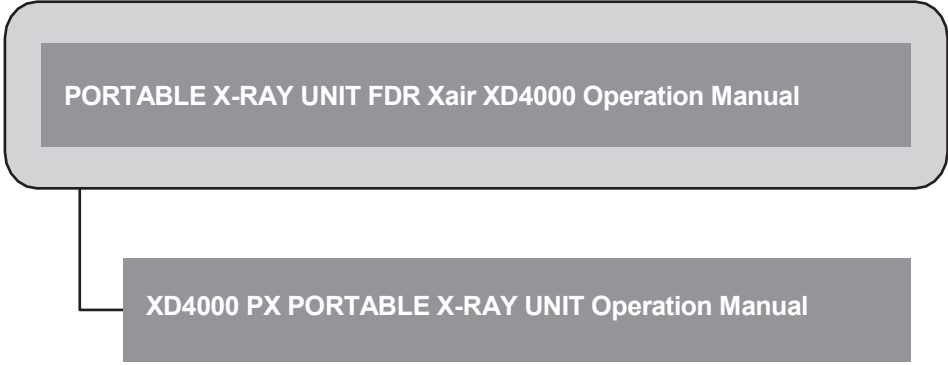
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XD4000 System Operation Manuals



PORTABLE X-RAY UNIT FDR Xair XD4000 Operation Manual

XD4000 PX PORTABLE X-RAY UNIT Operation Manual

Manage and store all the Operation Manuals of the devices constituting the XD4000 together as a set.

Contents at a Glance

Chapter 1	Precautions This chapter presents Warnings and Cautions we wish you to observe for the safe operation of the XD4000 PX.
Chapter 2	System Configuration (Product Overview) This chapter gives the various unit names and describes their functions and features of the XD4000 PX.
Chapter 3	Basic Operation This chapter describes start-up, shut-down and other basic operations of the XD4000 PX.
Chapter 4	Various Setting This chapter describes start-up, shut-down and other basic operations of the XD4000 PX.
Chapter 5	Trouble exposure This chapter describes how to troubleshoot in the event of an error on the XD4000 PX, and provides explanations about a list of error messages each of which appears when an error occurs.
Chapter 6	Daily Inspection and Maintenance This chapter describes daily care and maintenance we wish you to perform so that you can use the XD4000 PX optimally.
Appendix	Appendix A Specifications Appendix Z Precautions for Exposure Appendix O Use of Optional Items

How to Read This Manual

Basic page layout

Please have a good grasp of the basic page configuration of this Operation Manual, as illustrated below, for you to use it more efficiently.

Section title

Shows the title of an operation procedure described in the section.

Lead

Describes information we wish you to know in advance of your operating the system or information that may help you to operate it.

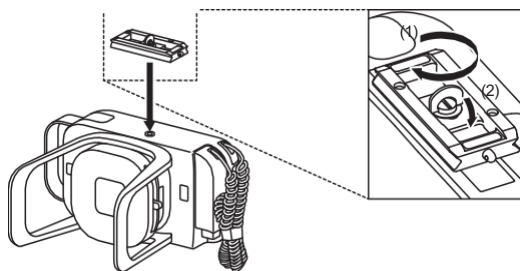
Operation procedure

Describes an operation procedure according to sequential numbers.

3.7 Attaching the X-Ray Generator

This section explains how to attach the X-ray generator.

- 1 Ensure that each part of the holding device is locked.
- 2 Wear the shoulder strap of the X-ray generator across your body, and move the X-ray generator close to the holding device.
- 3 Attach the quick shoe to the X-ray generator.
 - (1) Attach the quick shoe to the X-ray generator and secure it by rotating the tab.
 - (2) Tilt the tab by 90 degrees.



CAUTIONS

- Do not hang or attach items other than X-ray generator specified by FUJIFILM such as a protective apron onto the holding devices.
- When the quick shoe is attached to the platform, detach the quick shoe from the platform by referring to "Step 4(3)-(5) of 3.10.1 XD2000 ST-M [3.10 Removal and Clearance]".
- Do not turn the quick shoe after attaching it to this equipment. may be scraped or the indications may disappear.

- 4 Attach the X-ray generator to the supporting device.

CAUTIONS

- When attaching the X-ray generator to the supporting device, take care not to drop the X-ray generator onto the patient or operator.
- The X-ray generator may drop, causing injury to the patient.

3-13

Page number

Marks

Information items to be observed when you are operating this system and the supplementary remarks are described in this manual with the respective marks.

For the safe system operation, be sure to observe Warning/Caution.



Warning

Indicates hazardous situations that may lead to serious injuries or even death if the precaution is not or cannot be followed.



CAUTIONS

Indicates hazardous situations that may lead to mild or moderate injury or physical damages if the caution is not or cannot be followed.



Notice

Failure to follow these instructions or to avoid them may result in minor or moderate injury.

Indicates a hazardous situation which may result in injury or property damage.



Indicates procedures requiring special attention, instructions that must be followed, supplementary explanations, etc.



HINT

Shows an item helpful for further effective system operation.



Shows a more detailed operation method or an item that describes additional information.

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Chapter 1 Precautions

1.1 Precautions Before Operating This Equipment

Before using this equipment, please read "Precautions Before Operating This Equipment" carefully so that you can operate it correctly. Before using this equipment, please read "Precautions
Whenever you operate this equipment, be sure to observe those precautions. Failure to do so may cause you to subject to injuries or property damage to occur. .

The institution where the equipment is installed is responsible for its use and maintenance.
In addition, this equipment should not be used by persons other than healthcare professionals engaged in radiography.

This equipment has been designed on the assumption that the patient would not come into direct contact with it or for operation by healthcare professionals engaged in radiography.

Process waste correctly, as stipulated by local law or any regulations that apply.

Part of the components contains harmful substances which may pollute the ambient environment if disposed carelessly. In particular, lead is contained in concentrations > 0.1 wt% in X-ray tube and collimator. For details on product disposal, contact our official dealer or FUJIFILM representative.

The XD4000 PX must only be used by a qualified radiation professional.
Store it in a locked location to prevent it from being used by unauthorized users.

1.2 Precautions to be Observed When Using the Electric Medical Equipment

We ask that you observe these usage precautions and use the equipment correctly.

1. This equipment should be used only by people who have the proper skills.
2. Observe the following precautions when using the equipment.
 - Use the equipment where water will not splash it.
 - Use the equipment where it will not be adversely affected by air pressure, temperature, humidity, ventilation, sunlight, dust or the presence of salt, sulfur or like substances in the atmosphere.
 - Make sure the equipment will remain in stable condition on a level surface and not be Subjected to vibration or shock.
 - Do not use the equipment in places where chemicals are stored or gases emitted.
 - When using an AC adapter, make sure that the power frequency, voltage and power consumption are appropriate.
 - Check the conditions of the battery power source (power and polarity) before operating the system.
3. Observe the following precautions before beginning to use the device.
 - Inspect the contact condition of the switch, etc. to make sure that the equipment operates correctly.
 - Confirm that the wire has been completely connected.
 - Check the remaining capacity of the battery.
 - Do not hold the skin guard when carrying the X-ray generator.
4. Observe the following precautions when using the equipment.
 - At the time of X-ray irradiation, make sure not to exceed the time and dose necessary for diagnosis.
 - Always monitor the patient and the equipment for abnormalities.
 - Take an appropriate action, such as stopping the equipment after ensuring the patient's safety, if any abnormalities are found in his/ her health or in the equipment. Take an appropriate action, such as stopping the equipment after ensuring the patient's safety, if any abnormalities are found in his/her/the equipment.
 - Do not touch the X-ray generator with wet hands.
 - Be sure to touch an antistatic means such as a metallic object before touching the equipment. Otherwise, the equipment may be broken due to static electricity.
 - During X-ray irradiation, make sure that no one, including the operator or patient, touches this equipment body.
 - Make sure that liquids such as water do not splash over the wireless hand switch.
 - Always wear a lead apron during x-ray exposures.
 - Make sure to leave at least 2 meters between the operator and the unit.
5. Observe the following precautions after using the equipment.
 - Restore the switch, etc. to the state before use by following the established procedure, then turn the power off.
 - When unplugging cords, do not pull on the body of the cord itself or apply unnecessary force.
 - I Store the equipment where water will not splash it.
 - II Store the equipment where it will not be adversely affected by air pressure, temperature, humidity, ventilation, sunlight, dust or the presence of salt, sulfur or like substances in the atmosphere.

III Make sure the equipment will remain in stable condition on a level surface and not be Subjected to vibration or shock.

IV Do not store the equipment in places where chemicals are stored or gases emitted.

Make sure to clean the equipment for the next use.

6. If there is trouble with the equipment, turn the power off immediately, affix a proper indication showing that the equipment is faulty, and contact our official dealer or FUJIFILM Representative.

7. Do not remodel the equipment.

8. Maintenance and Inspection

Make inspect the equipment and parts periodically.

If the equipment has not been used for a long time, make sure that it operates normally and safely prior to using it again.

9. Other Items

Follow the Operation Manual and operate the equipment correctly.

1.3 Safety

Before using the XD4000, read this section thoroughly to ensure that you use the product properly.

Electric Shock Warnings and Cautions



warning

- Keep each device away from patient's body fluids, chemicals, water, etc. Otherwise, it may become damaged, causing fire or electric shock. If necessary, protect the X-ray detector by covering it with a disposable bag.
- The power supply to this equipment is AC100 to 240V.
To avoid electric shocks, users should always take the following precautions:
 - Do not open any covers of the equipment.
 - Place the equipment in a location where it will not be exposed to water.
- Do not disassemble or remodel each device. Otherwise, fire or electric shock may result. If you touch them accidentally, death or severe injury may result.
- Do not use the equipment in a location where metal particles could come into the equipment. This may cause an electric shock.
- Do not use a power strip or extension cable for charging the battery. Otherwise, fire or electric shock may occur due to the electrical load exceeding the allowable limit. Otherwise, fire or electric shock may occur due to the electrical load exceeding the allowable limit.
- Observe the following precautions when using the cables.
 - Do not touch the plug with wet hands. Otherwise, electric shock may result, causing death or severe injury.
 - Pulling the cable or carrying by holding it may damage the cable, causing fire or electric shock.
 - Do not damage or remodel the cable. Do not place a heavy object on the cable. Do not step on, pull, forcibly bend, or bundle the cable. Otherwise, fire or electric shock may result.
- Do not turn on the system or charge the battery with dew condensation on each device. Otherwise, fire or electric shock may result.
- Do not hit or drop each device or subject it to severe shock. Otherwise, the device may be damaged. If the damaged device is used, fire or electric shock may result.
- Failure to use the optional parts recommended by us may result in damage to the equipment and/or Failure to use the optional parts recommended by us may result in damage to the equipment and/or electric shock and injury.
- Do not touch the patient's body while touching this product to avoid electric shock.
- Do not touch signal input, signal output or other connectors, and the patient simultaneously



CAUTIONS

- If any fluid splashes onto the surface of the equipment, wipe it off immediately. If any fluid soaks into the internal electronic components, it may cause equipment failure or malfunction.
- Avoid rapid changes in temperature and humidity even within the specified range. Otherwise, dew condensation may occur, causing equipment failure or otherwise, dew condensation may occur, causing equipment failure or rust and corrosion inside the equipment.

Explosion Warnings



warning

- Because each device is not explosion-proof, do not use combustible and explosive gases near each device.
- Flammable gasses may stay in the room after disinfection. If you turn the system on just after disinfection, ensure that the room is well ventilated before powering on the system.

Warnings for Abnormalities



warning

- If any of the following occurs, immediately turn off the power of each unit, unplug the power cable from the outlet, and then contact our official dealer or FUJIFILM Representative.
 - When smoke, strange odor, or abnormal sound is present.
 - When a foreign object (such as a metal object) or liquid enters the product.
 - When the equipment is dropped or hit and is damaged.

Radiation safety instructions



warning

- Only qualified technologists are allowed to make X-ray exposures.
- Exposure should be made in an environment where the technologist can visually and aurally determine the patient's condition.
- Technologists must wear an individual radiation exposure dosimeter to monitor exposure doses they receive.
- Wrong operations of the X-ray generator could expose a technologist, patient or person in the vicinity of the X-ray generator to unnecessary X-ray exposure. Technologists must keep a distance of at least 2m from the focal spot and X-ray beam when making an exposure. In addition, before making an exposure, ensure that persons other than the patient keep a distance of at least 2m from the focal spot and the X-ray beam.
- Confirm the radiation field size by using the light field lamp of the collimator. If the radiation field size is unnecessarily large, the patient may be subject to unnecessary X-ray exposure.
- Reduce the radiation field size to the minimum necessary size for the exposure. If X-rays are unavoidably radiated to areas outside of the subject region, take protective measures such as wearing a protective apron with a lead equivalence of at least 0.25mm.
- When the patient needs assistance during an exposure, the assistant should take protective measures such as wearing a protective apron with a lead equivalence of at least 0.25mm.
- Use the longest possible focal spot to skin distance to minimize the exposure dose.
- When making X-ray exposures, if the patient needs to be supported frequently, the patient must be supported by a person registered as a radiation worker.
- Take extreme care when making a long exposure or repeated exposures may be compromised.

Warnings on Carrying This Product



warning

- Collision or dropping of the X-ray generator may cause not only damage to the X-ray generator, but also serious accidents.
 - Before carrying this product, attach the shoulder strap to the X-ray generator, ensure that the strap is securely attached, and then wear the shoulder strap across your body.
 - When carrying this product while the wired hand switch is connected, be sure to bundle the cable of the hand switch with the supplied band so that the cable does not hang low from this product. If the cable is hanging low, it may get caught by a door knob, etc. and cause this product to fall and sustain damage.
 - Before carrying this product, confirm that the wireless hand switch is securely attached to the XD4000 PX.
 - Carry this product while paying attention to the difference in level on the floor.
 - When carrying the holding device, follow the instructions provided in the operation manual of the holding device.
 - Turn off the power before carrying the X-ray generator.
 - Before carrying, place each lock mechanism in a lock state and put the parts in cases.
- Do not carry this product while an AC adapter is connected to it.
- Do not carry this product while charging it.

X-Ray Generator Battery Instructions



CAUTIONS

If the following precautions are not observed properly, it may cause injury or unrecoverable damage to the battery or X-ray generator.

- Battery capacity begins to wane after a period of time.
- Use the X-ray generator under the conditions of use specified by FUJIFILM Corporation. is used in a place where it is exposed to high temperature, the battery may emit smoke, ignite, explode or leak fluid.
- It is recommended to replace the battery once every 1 year.
- Store the battery pack in a cool and dark place. Recharge the stored battery pack every six months or every year. Otherwise a decrease in battery capacity or other problems may result.
- Do not leave the removed battery pack in the car or other places exposed to high temperature. If the battery pack is used or stored in a place where it is exposed to high temperature, the battery pack may emit smoke, ignite, explode or leak fluid.
- The battery pack is equipped with built-in safety and protection mechanisms. If they are damaged, the battery pack may overheat, emit smoke, explode or ignite.
- Do not use or leave the battery pack in a place where it is exposed to high temperature (80°C or higher), such as fire or a heater. Damaged due to heat, the battery pack may short-circuit, causing it to overheat, emit smoke, explode or ignite.
- Do not immerse the battery pack in water or seawater, and do not allow it to become wet. If the built-in protection mechanisms are damaged, the battery pack If the built-in protection mechanisms are damaged, the battery pack may overheat, emit smoke, explode or ignite.
- Do not pierce the battery pack with a nail, hit it with a hammer, or step on it. Otherwise, the battery pack may be damaged or deformed and short-circuit, causing it to overheat, emit smoke, explode or ignite.
- Do not subject the battery pack to strong impact or throw it. If the built-in protection mechanisms are damaged, the battery pack may be charged with extremely high current and voltage, and abnormal chemical reactions may occur inside the battery pack, causing it to

overheat, emit smoke, explode or If the built-in protection mechanisms are damaged, the battery pack may be charged with extremely high current and voltage, and abnormal chemical reactions may occur inside the battery pack, causing it to overheat, emit smoke, explode or If the built-in protection mechanisms are damaged, the battery pack may be charged with extremely high current and voltage, and abnormal chemical reactions may occur inside the battery pack, causing it to overheat, emit smoke, explode or ignite.

- Do not use an apparently damaged or deformed battery pack. Otherwise, the battery pack may overheat, emit smoke, explode or ignite.
- Do not solder the battery pack directly. Otherwise, its insulator may melt, or its gas release vent or safety mechanisms may be damaged, causing the battery pack to overheat, emit smoke, explode or ignite. Otherwise, its insulator may melt, or its gas release vent or safety mechanisms may be damaged, causing the battery pack to overheat, emit smoke, explode or ignite.
- Do not reverse the positive (+) and negative (-) terminals. Otherwise, the battery pack may be reverse-charged during charging. As a result, abnormal chemical reactions may occur inside the battery pack, or extremely high current may flow during discharging, causing it to overheat, emit smoke, explode or ignite.
- If you cannot connect the battery pack to the battery charger or other equipment, do not connect the battery pack forcefully. Make sure that the terminals are correctly oriented. If the battery pack is connected in reverse, it will be reverse-charged, and If the battery pack is connected in reverse, it will be reverse-charged, and abnormal chemical reactions may occur inside the battery pack, causing it to overheat, emit smoke, explode or ignite.
- Do not connect the battery pack to an electrical outlet or cigarette lighter socket in a car. Overcurrent may flow to the battery pack due to high voltage applied, causing the battery pack to overheat, emit smoke, explode or ignite.
- Do not use the battery pack for equipment other than those specified. Otherwise, the guaranteed performance will be reduced and/or the service life will be shortened. Depending on the equipment to which the battery pack is connected, extremely high current may flow, causing the battery pack to be damaged, overheat, emit smoke, explode or ignite. Depending on the equipment to which the battery pack is connected, extremely high current may flow, causing the battery pack to be damaged, overheat, emit smoke, explode or ignite.
- If the electrolyte leaked from the battery pack enters the eyes, do not rub them. Wash the eyes immediately with clean water such as tap water, and consult a doctor. Otherwise, eye injury may result.
- Be careful not to drop the battery pack. The patient may be injured.
- Do not touch the terminal of the battery pack directly. There is a risk of electric shock.
- Do not connect the positive (+) and negative (-) terminals with a wire or any metal object. Otherwise, the battery pack may short-circuit and overcurrent may flow, causing Metal objects such as necklaces or hairpins may also become hot.
- Do not throw the battery pack into fire or expose it to excessive heat. Otherwise, its insulator may melt, its gas release vent or safety mechanisms may be damaged, and/or its electrolyte may catch fire, causing the battery pack to overheat, emit smoke, explode or ignite.
- Do not use the battery pack in combination with a primary battery such as a dry battery or other battery of a different capacity, type and/or brand. Otherwise, the battery pack may be overcharged during charging, and abnormal chemical reactions may occur inside the battery pack, causing it to overheat, emit smoke, explode or ignite. Otherwise, the battery pack may be overcharged during charging, and abnormal chemical reactions may occur inside the battery pack, causing it to overheat, emit smoke, explode or ignite.
- Do not put the battery pack in a microwave oven or high-pressure container. Otherwise, the battery pack may be rapidly heated or damaged, causing it to overheat, emit smoke, explode or ignite.
- If the battery pack leaks or emits an unusual odor, remove it from fire immediately. Otherwise, the leaked electrolyte may catch fire, causing the battery pack to overheat, emit smoke, explode or ignite.
- If you notice an unusual odor, heat, discoloration, deformation or any other abnormality

during use, charging or storage, remove the battery pack from the equipment or battery charger, and stop using it. Otherwise, the battery pack may overheat, emit smoke, explode or ignite.

- Do not use the battery pack exposed to a strong magnetic field of an MRI system, etc.
- Do not use the battery pack immersed in liquid.
- Do not use the battery not recommended by FUJIFILM Corporation since it may cause Damage to the equipment.
- Otherwise, it may result in failure at an early stage, explosion or ignition. Do not leave this equipment in any place exposed to high temperature such as in a closed vehicle exposed to direct sunlight.
- If the equipment has not been used for about 10 minutes, the equipment automatically turns off to save battery power consumption. Check the remaining capacity of the battery before using the equipment.
- Before using or carrying the X-ray generator, be sure to check that the remaining battery capacity is sufficient. If no charging status is displayed even after connecting the AC adapter, consult our If no charging status is displayed even after connecting the AC adapter, consult our official dealer or FUJIFILM Representative.
- When all five battery indicators are lit, do not charge the battery.



-
- To maximize the service life and performance of the battery, use or store the battery under the conditions specified in "A.1.3 Environmental Conditions". Otherwise, a decrease in battery capacity or other problems may result.
-

Precautions for Charging the Battery Pack



CAUTIONS

- Do not use Li-ion Battery or this product in combination with any battery pack or this product (including the power cable) other than those recommended by FUJIFILM Corporation.
- Do not disassemble or modify Li-ion Battery or this product.
- If Li-ion Battery or this product becomes faulty, consult our official dealer.
- Avoid the accumulation of dust on this product.
- Insert Li-ion Battery into this product securely.
- If the insertion direction or position of Li-ion Battery is incorrect, the battery is not charged properly.
- When inserting Li-ion Battery, prevent foreign matter from getting into this product.
- While charging the battery, do not allow Li-ion Battery or this product get wet or dusty.
- Do not step on the AC adapter of this product. Also, be careful not to trip over the power cable.
- Do not subject the battery and this product to severe shock (by dropping them, etc.).
- Do not charge Li-ion Battery near fire or under strong sunshine. If the built-in protection mechanisms are activated by a high temperature, Li-ion Battery may be charged with extremely high current and voltage, and abnormal chemical reactions may occur inside Li-ion Battery, causing it to overheat, emit smoke, explode or ignite.
- To charge Li-ion Battery, be sure to use the designated this product and to observe the charging conditions specified by FUJIFILM Corporation. Battery is charged in other conditions (temperature or voltage/current higher than specified, remodeled this product, etc.), Li-ion Battery may be If Li-ion Battery is charged in other conditions (temperature or voltage/current higher than specified, remodeled this product, etc.), Li-ion Battery may be overcharged or charged with extremely high current, and abnormal chemical reactions may occur inside Li-ion Battery, causing it to overheat, emit smoke, explode or ignite.
- Immediately stop charging Li-ion Battery, if charging is not completed within the specified time. Otherwise, Li-ion Battery may overheat, emit smoke, explode or ignite.
- Do not use a faulty or broken this product or AC adapter.

Disinfection and Cleaning Instructions



warning

- Confirm that the respiratory density of disinfectant including solvent is under legal regulation. Certain disinfectants may damage health. When using a disinfectant, follow instructions supplied by the manufacturers.
- Do not use the following disinfectants or sterilizers at the time of disinfection. Performance and safety of each device cannot be assured.
 - Chloric disinfectant which is strongly corrosive to metals and rubber parts.
 - Disinfectant whose uses on metals, plastics, rubber parts and coatings are forbidden according to the instructions supplied with the disinfectant.
 - Formalin gas and disinfectant sprays that may get inside the equipment.Carefully read the instructions and cautions supplied with the disinfectant before use. For details on the disinfectant, contact a FUJIFILM dealer or the service representatives at the agency from which you purchased the disinfectant.

Connection Instructions



warning

Make sure that the devices to be connected to each device are specified by FUJIFILM Corporation.

System Isolation Instructions



warning

To ensure complete system isolation, never install any unauthorized items. When it is necessary to install authorized optional items, contact our official dealer or FUJIFILM Representative.

Software Precautions



CAUTIONS

- Do not install additional software to the system. Do not uninstall any of the software preinstalled in the system.
- If other software is installed or if the existing software is uninstalled, various operational errors may result.

Warnings and Cautions on Network



warning

- Make sure to use the optional parts and networks recommended by FUJIFILM Corporation. Failure to do so may result in damage to the equipment and/or Failure to do so may result in damage to the equipment and/or electric shock and injury.

Wireless Communication

- Make sure that there are no shielding materials between this product and the communication device
- Do not use this product near the following devices.
 - Industrial, scientific and medical equipment such as a microwave oven, pacemaker, etc.
 - Local private radio stations for mobile object identification used in factory production lines, etc. (radio stations requiring a license)
 - Specified low power radio stations (radio stations requiring no license)
- When using this product, place it at least 20cm (7.9in.) away from the body.

Other Cautions



warning

- Use the holding device by placing it on a flat place or a slope with an angle of inclination of up to 5 degrees. Otherwise, the holding device may tip over, causing damage to the holding device or personal injury.
- Do not lean against or hang from the holding device. Otherwise, the holding device may tip over, causing damage to the holding device or personal injury.
- When assembling or disassembling the holding device, ensure that your head does not hit against the parts and that your fingers do not get caught between the parts.
- When assembling or disassembling the parts, secure an enough space and ensure the

Safety of the surroundings so as not to hit the parts against the patient or other persons.

- When assembling or disassembling the parts, keep a sufficient distance from the patient.
- Do not pull the hand switch excessively at the time of X-ray exposure. Otherwise, the holding device may fall onto the patient or other persons, causing personal injury.
- Do not use this product outdoors to avoid possible damage.



CAUTIONS

Be sure to use the X-ray generator in combination with the holding device.

- Do not use or store the system in a location with the following conditions.
 - Where the temperature changes sharply.
 - Close to heat sources such as a heater.
 - Where the system may be exposed to water due to water leakage or ingress.
 - Where corrosive gas may be generated.
 - Where there is excessive dust.
 - Where the system is subject to frequent or excessive vibration/shock.
 - Where the system is exposed to direct sunlight.
 - Where there is no ventilator.
- To assure optimum performance of each device, it is necessary to systematically perform maintenance and inspection. For information on maintenance and inspection, contact our official dealer or FUJIFILM Representative.
- Do not perform maintenance and inspection while the equipment is used for a patient.
- If any water splashes onto the equipment, wipe it off, and make sure that the equipment is Completely dry before use.
- Do not hold the skin guard of the X-ray generator or place the X-ray generator with the skin guard facing downward.
- Do not attach the X-ray generator other than the one specified by FUJIFILM Corporation to the holding device.
- In the case of the chest radiography of a patient with a body thickness of 28cm or more, front abdominal or lumbar spine radiography of a patient with a body In the case of the chest radiography of a patient with a body thickness of 28 cm or more, front abdominal or lumbar spine radiography of a patient with a body thickness of 31 cm or more, sufficient image quality may not be obtained.

Contraindications and Prohibitions

No contraindications present.

Classification

- According to the type of protection against electrical shock
 - Class II device (while charged)
 - Internally powered equipment (when operated with the battery)
- According to the degree of protection against harmful ingress of water IP00
- According to the suitability for use in an oxygen-rich environment
 - Equipment not suitable for use in an oxygen-rich environment
- According to the degree of safety of application in the presence of a flammable anesthetics mixture with air or with oxygen or nitrous oxide
 - Equipment not suitable for use in the presence of a flammable anesthetics mixture with air or with oxygen or nitrous oxide.
- According to the mode of operation
 - Continuous operation with intermittent load

Declaration of Conformity

X-RAY EQUIPMENT for RADIOGRAPHY XD4000 PX IEC 60601-2-54

The XD4000 PX conforms to the following standards.

IEC 60601-1:2005/A1:2012 Chapter 16

1.4 Electromagnetic Compatibility (EMC)

In order to prevent the occurrence of problems caused by electromagnetic waves in the operating environment, read carefully this section and operate the equipment and other devices in the vicinity properly.

1.4.1 XD4000 PX

Electromagnetic Compatibility (EMC) Standards

This unit conforms to IEC 60601-1-2 (EN60601-1-2) Collateral standard: Electromagnetic Compatibility - Requirements and Tests, and EN 55011 Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics Limits and methods of measurement Group 1, Class B. Electromagnetic compatibility (EMC) and its special preventive measures apply to medical Electromagnetic compatibility (EMC) and its special preventive measures apply to medical electrical equipment.

This device generates and radiate radio frequency energy and, if not installed and used in accordance However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to other devices, which can be determined by tuning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: However, there is no guarantee that interference will not occur. If this device does cause harmful interference to other devices, which can be determined by tuning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: However, there is no guarantee that interference will not occur in a particular installation. However, there is no guarantee that interference will not occur in a particular installation.

If each device does cause harmful interference to other devices, which can be determined by tuning the equipment off and on, the user is encouraged to try to If each device does cause harmful interference to other devices, which can be determined by tuning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Ask the manufacturer or local service engineer for support.

If the problem cannot be solved with the above measures, stop using this equipment and consult the manufacturer, our official dealer or FUJIFILM Representative for help.



warning

- Do not place devices generating electromagnetic waves near this equipment.
- If a device(s) other than those specified is connected, predetermined EMC performance cannot be guaranteed.
- Do not use mobile RF communications equipment within 30 cm (11.8 in.) of this equipment.
- The product may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.
- Do not use this equipment near devices that generate strong electromagnetic waves, such as thermotherapy devices or HF surgical equipment.
- If this equipment is used near commercially available electronic devices, such as mobile phones, laptop computers or home appliances, which generate electromagnetic waves, this equipment may malfunction due to electromagnetic interference.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and residential environments and hospitals (CISPR 11 class B). If it is used in a residential

environment, this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

- Do not use this equipment outside of the specified environment near large medical devices such as MRI scanners or X-ray CT scanners.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Further Information for IEC 60601-1-2 (EN 60601-1-2)

1. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Tables 1 to 4.
2. Portable and mobile RF communications equipment can affect medical electrical equipment.
3. The use of optional items, transducers and cables other than those specified, with the exception of transducers and cables sold by FUJIFILM Corporation The use of optional items transducers and cables other than those specified, with the exception of transducers and cables sold by FUJIFILM Corporation, may result in increased emissions or decreased immunity of the equipment.
4. The equipment should not be used adjacent to other equipment.
If adjacent use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
5. Basic performance of the equipment and the system.
 - The X-ray tube loading factors are accurate.
 - The equipment has the reproducibility of the X-ray output.
 - X-rays are radiated by using the prescribed power source (battery).
6. Test items (Tables 1 to 4)

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The XD4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the XD4000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The XD4000 uses RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The XD4000 is suitable for use in all establishments, including residential environments and those directly connected to the commercial low-voltage power supply network that supplies buildings used for residential purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Note : Harmonic emission IEC 61000-3-2 and voltage fluctuation/flicker emission IEC 61000-3-3 are
Applicable only to the devices with a rated voltage of 220V AC or higher.

Table 2

Guidance and manufacturer's declaration - Electromagnetic susceptibility (EMS)			
The XD4000 PX is intended for use in the electromagnetic environment specified below. The customer or the user of the XD4000 PX should assure that it is used in such an environment.			
EMS test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV line(s) to line(s) ±2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% U_T for 0.5 cycle and 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 0% U_T for 5 s	0% U_T for 0.5 cycle and 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 0% U_T for 5 s	Mains power quality should be that If the user of the XD4000 PX requires continued operation during power mains interruptions, it is If the user of the XD4000 PX requires continued operation during power mains interruptions, it is recommended that the XD4000 PX be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated fields in close proximity IEC 61000-4-39	65 A/m Max 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2	65 A/m Max 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2	XD4000 PX is suitable to use in home healthcare environment. Portable radio frequency (RF, RFID) communication devices can interfere with the medical electrical device.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration - Electromagnetic susceptibility (EMS)			
The XD4000 PX is intended for use in the electromagnetic environment specified below. The customer or the user of the XD4000 PX should assure that it is used in such an environment.			
EMS test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 V 150 kHz to 80 MHz ISM Frequency band Amateur radio band	3 V *See Table 5.	It is recommended that portable and mobile RF communications devices, such as mobile phones, not be used closer to any part of the XD4000 PX, including cables, than the recommended separation distance of 1.2 [m] calculated using the equation applicable to the transmitter frequency. Recommended separation distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC61000-4-3	10 V/m 80 MHz to 2.7 GHz Proximity fields from RF	10 V/m *See Table 5.	
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines do not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the XD4000 PX is used exceeds the applicable RF compliance, the XD4000 PX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the XD4000 PX.			
b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.			

Table 4

Recommended separation distances between Portable and mobile RF communications equipment such as cellular phones and the XD4000 PX			
The XD4000 PX is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the XD4000 PX can help to reduce electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) such as mobile phones and the XD4000 PX as recommended below, based on the maximum output power of the transmitting equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 5

Test compliance levels between Portable and mobile RF communications equipment and the XD4000 PX			
ISM (Industrial, Scientific and Medical) Frequency Band Compliance level			
Frequency MHz	Test Level V	Frequency MHz	Test Level V
6.765	6	13.553	6
26.957	6	40.66	6
Amateur radio band compliance level			
Frequency MHz	Test Level V/m	Frequency MHz	Test Level V/m
1.8	6	3.5	6
5.3	6	7	6
10.1	6	14	6
18.7	6	21	6
24.89	6	28	6
50	6		
Proximity fields from RF Compliance level			
Frequency MHz	Test Level V/m	Frequency MHz	Test Level V/m
385	27	450	28
710	9	745	9
780	9	810	28
870	28	930	28
1720	28	1845	28
1970	28	2450	28
5240	9	5500	9
5785	9		

1.5 Precautions in Using the XD4000 PX

This section describes the precautions in using the XD4000 PX.

1.5.1 Handling

- Do not use this product in the vicinity of the devices that generate magnetic field noise and cellular phones.
- Do not use this product in a moving body such as an aircraft or watercraft.
- Use this product indoors only.
- If this product is to be used in a motor vehicle, be sure that the motor vehicle is not moving.
- Use this product in a temperature- and humidity-controlled environment, including storage.



CAUTIONS

When moving the equipment, ensure that the wired/wireless hand switch cable is not broken by being caught on surrounding objects.

1.5.2 Charging

- Check the charging state before use and charge the battery if necessary.

1.5.3 Transportation

- In addition, make sure that the equipment does not hit against any obstacles. If the equipment is subjected to strong impact, the equipment may be damaged, or it may cause personal injury due to dropping of the equipment.
- When transporting the equipment in a vehicle, secure the handle with a seatbelt, etc. In addition, do not place any object on the equipment.
- When transporting the equipment, be sure to attach the wireless hand switch to the main unit.
- When transporting the equipment, be sure to take it out of the holding device to prevent possible damage.

1.5.4 Before Exposure

- The use of an air-conditioner may dramatically change the temperature of the room where the system is installed. When an air-conditioner is used, change the temperature gradually to avoid temperature variation in order not to cause dew condensation. This may cause dew condensation on the system where the room where the system is installed, resulting in quality problems.

1.5.5 During Exposure

- Before performing exposure, confirm that everybody except the patient is at least 2m away from the X-ray generator. Also confirm that nobody is in the direction of X-ray irradiation except the patient.
- Explain to the patient about the necessity of X-ray radiography and radiation protection, and use this equipment only for the necessary regions of the patient.
- Fix the X-ray generator with an optional holding device before making exposures.
- Before making an exposure, be sure to stand away from the X-ray generator by 2m or more.

- Before making an exposure, ensure that persons around the patient are kept away from the X-ray generator or more. In addition, ensure that nobody except the patient exists in the irradiation direction.
- All personnel present during an x-ray examination must comply with safety regulations concerning protection against radiation. For their own safety, the operator must always keep a distance of more than 2 meters and out of the path of the x-ray beam, in order to avoid the exposition to the stray radiation.
- Inverse Square Law- The intensity of radiation at any distance from a point source varies inversely as the square of that distance. For example: if the radiation exposure is 100 R/hr at 1 inch from a source, the exposure will be 0.01 R/hr at 100 inches



CAUTIONS

- The user must wear radiation protective clothing and personal protective equipment.
 - The user must secure a minimum safety distance from the radiation source and collateral radiation area.
 - The user must remove unnecessary objects in and around the irradiation area.
 - Be sure to secure a distance between the patient and the X-ray generator by 20 cm or more.
 - When the user uses this equipment experimentally, use the minimum kV and mAs values.
 - The user must take care not to exceed proper X-ray dose within the irradiation area.
-

1.5.6 Removal

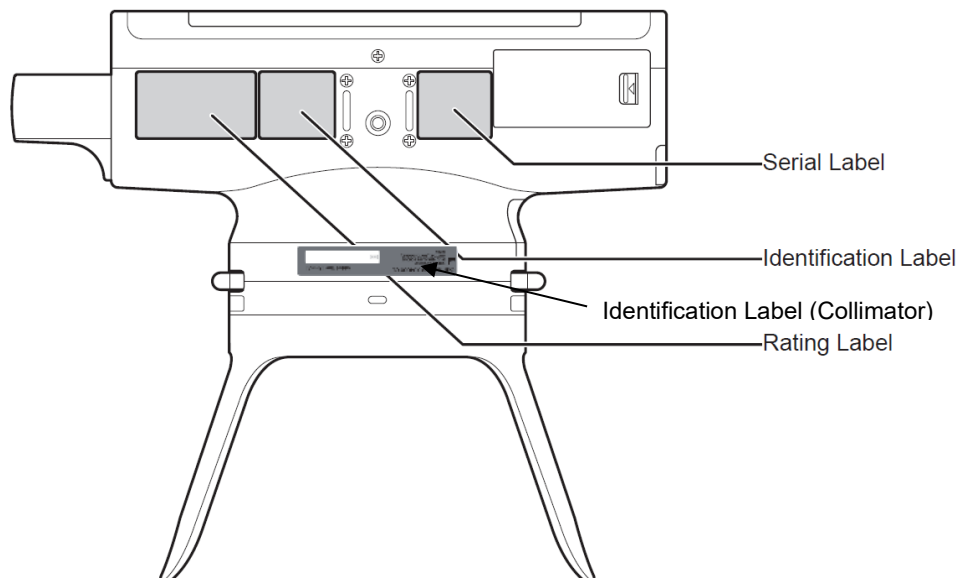
- To prevent the X-ray generator from falling, remove the X-ray generator with the shoulder strap worn.

1.6 Locations of Labels and Signs

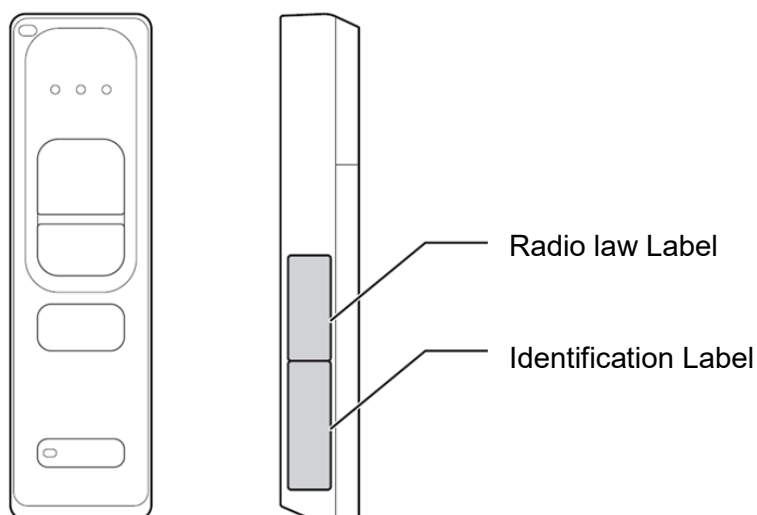
Locations of labels and signs affixed to the XD4000 PX, and the relevant safety signs are shown below.

1.6.1 Locations of Labels

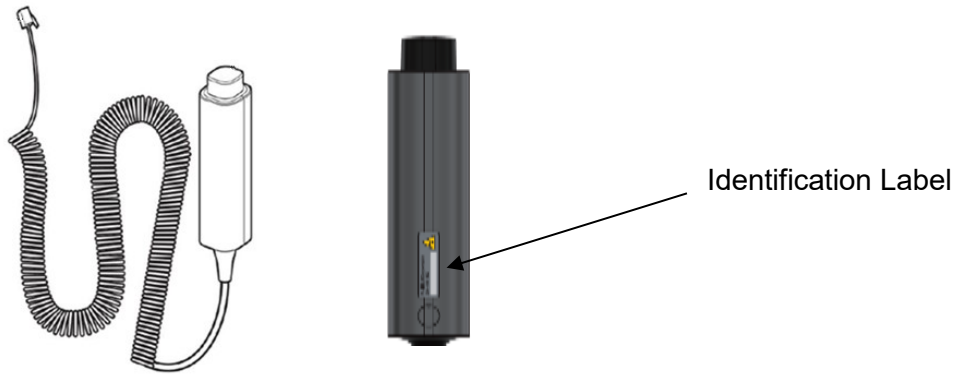
(1) XD4000 PX



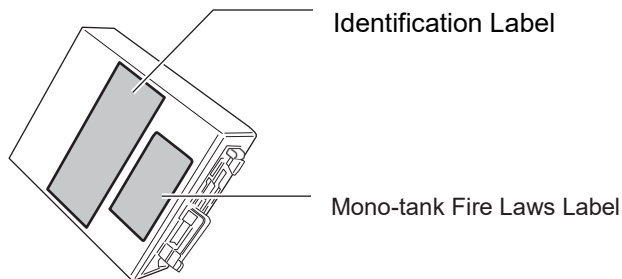
(2) Wireless handswitch



(3) handswitch

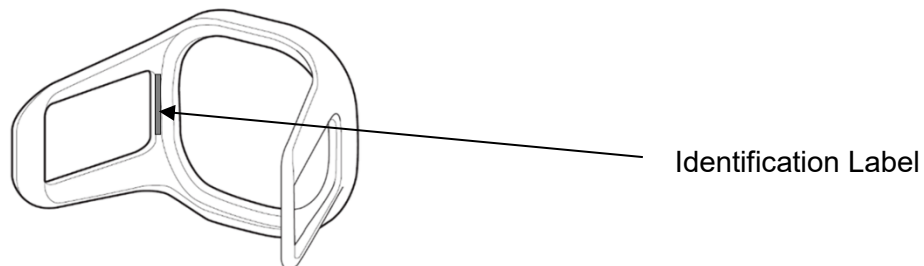


(4) Mono-tank in XD4000 PX

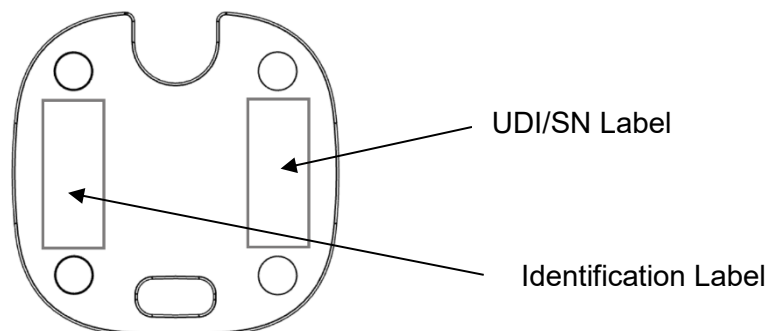


The mono-tank is built in the equipment.

(5) Skin guard



(6) Added filter

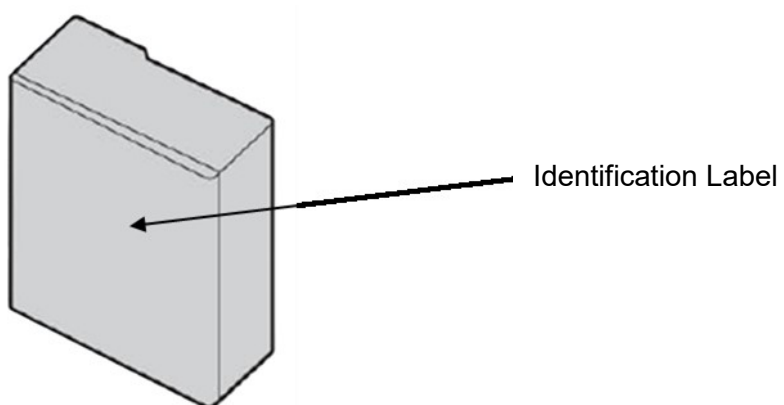


Notice

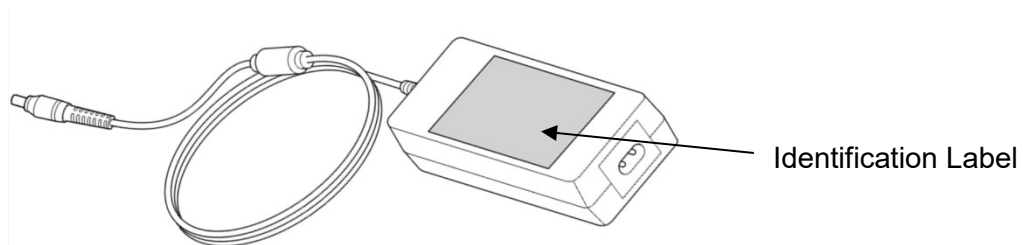
This added filter should be attached in front of the collimator when used for pediatric patients.

The age of the "pediatric patients" group is under the age of 19 based on the Ministry of Food and Drug Safety in Korea, and the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines pediatric patients as persons aged 21 or younger.

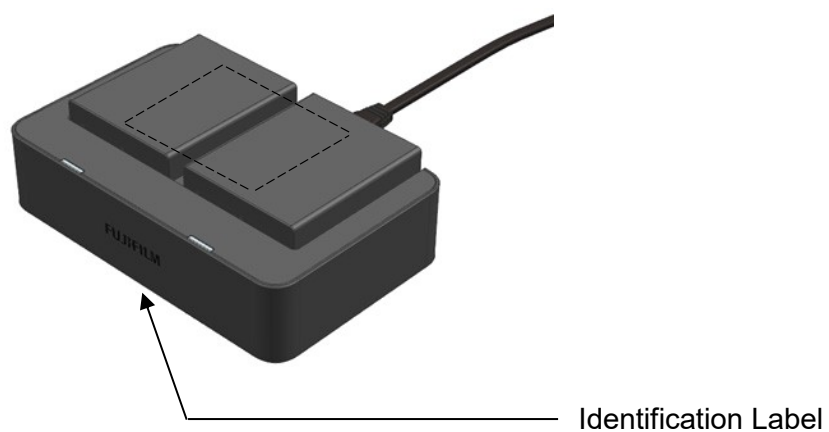
(7) Battery (Model number: PFF-031P)



(8) AC adapter (Model number: MEA-065Z15BA)



(9) Battery charger (optional)



1.6.2 Safety and Other Symbols

The following safety symbols are used in the XD4000 PX

Symbol	Description
	CE marking
	Indicates the Authorized representative in the European Community.
	Consult accompanying documents (IEC60601-1 Ed3.1) Refer to instruction manual/booklet. Note: On ME EQUIPMENT "Follow instructions for use".
	X-ray source assembly, Emitting
	Warning: Dangerous voltage
	Caution
	Direct current
	Alternating current
	Disposal instruction
	Battery status
	Radiation field indicator
	Date of manufacture
	This symbol indicates that the country of manufacturer is Korea.
	Manufacturer
	Serial Number
	Model number
	Power ON / OFF
	Ready for exposure
	Not in operation
	Lithium ion battery



Medical Device



<https://med-lib.fujifilm.com/>

Consult an electronic instructions for use (e-IFU)



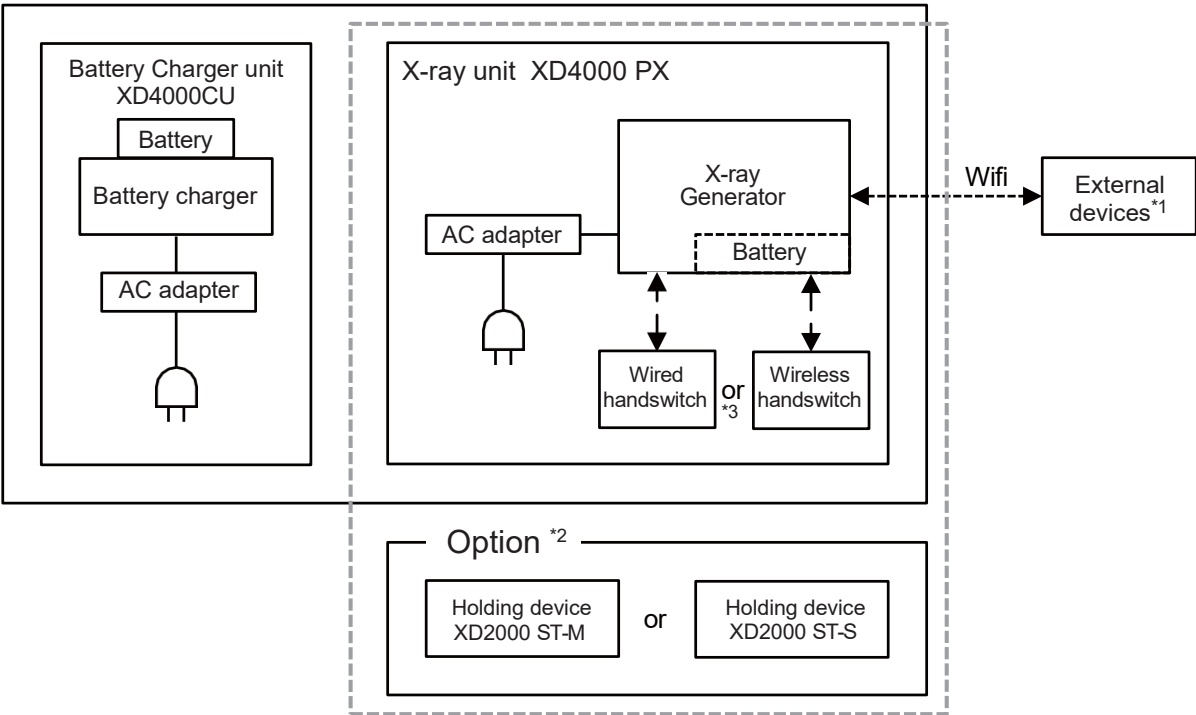
Importer

Chapter2 System Configuration (Product Overview)

2.1 XD4000

2.1.1 System Configuration

Portable X-ray unit XD4000



The sales unit of the system components is as follows. These components are selectively used depending on the system configuration.

Name
Portable X-ray unit FDR Xair XD4000 (XD4000 PX, Wired hand switch, Wireless hand switch, Handle, Shoulder strap, Skin guard, Added filter, AC adapter, Velcro band (S) X 2, Velcro band (L) X 2, Measurement tape, USB memory, Lens Cap)
Battery Charger unit XD4000CU (Battery charger, AC adapter) (optional)
Spare battery (optional)

*1 Up to three external devices can be registered to the system, but only one external device can be connected.

*2 When using this device, be sure to use the separately sold XD2000 ST-M or XD2000 ST-S for safety reasons.

*3 If both are connected, the wired hand switch will take priority.

· The products in  can be installed in a patient environment.

2.1.2 Features of XD4000 PX

This section describes the main features of the system.

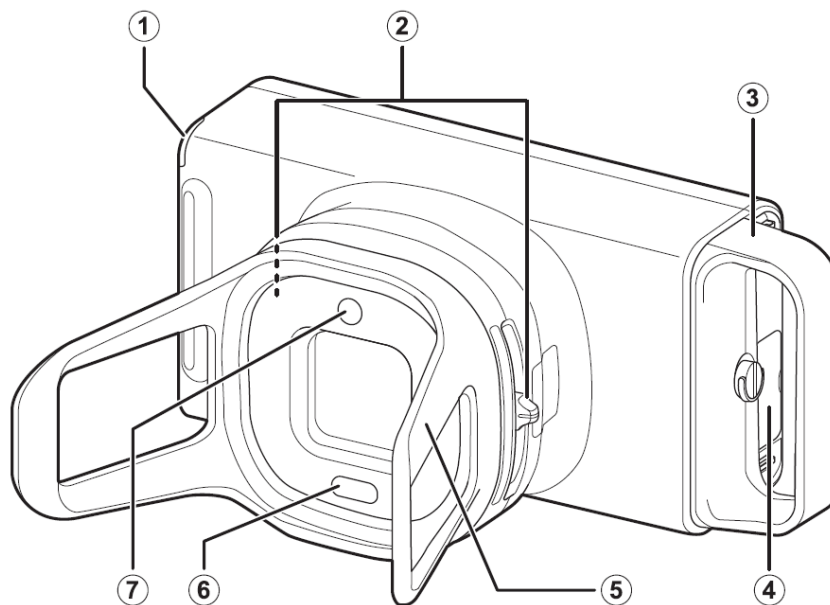
- Maximum output: 90kV/5mA
- Built-in LED collimator
- A wireless hand switch is provided for exposure without cabling restrictions
- The wireless hand switch is provided with a light field lamp switch for remotely checking the exposure field
- Exposure can be performed while charging the battery through an AC adapter
- Easy operation using the rear touch panel and three types of memory settings
- The angle of the rear touch panel is adjustable for operation using the operation panel during exposure in the supine or recumbent position
- A built-in camera is provided for operation while checking the state of the patient
- Information obtained by the built-in camera can be sent to external devices through wireless connection. Or, information sent from external devices can be displayed on the rear monitor. Or, information sent from external devices can be displayed on the rear monitor
- A skin guard can be attached. It can be removed when carrying this product for less cumbersome transportation
- Product life of XD4000 PX is designed for a service life of 6 years

2.2 Unit Names and the Functions

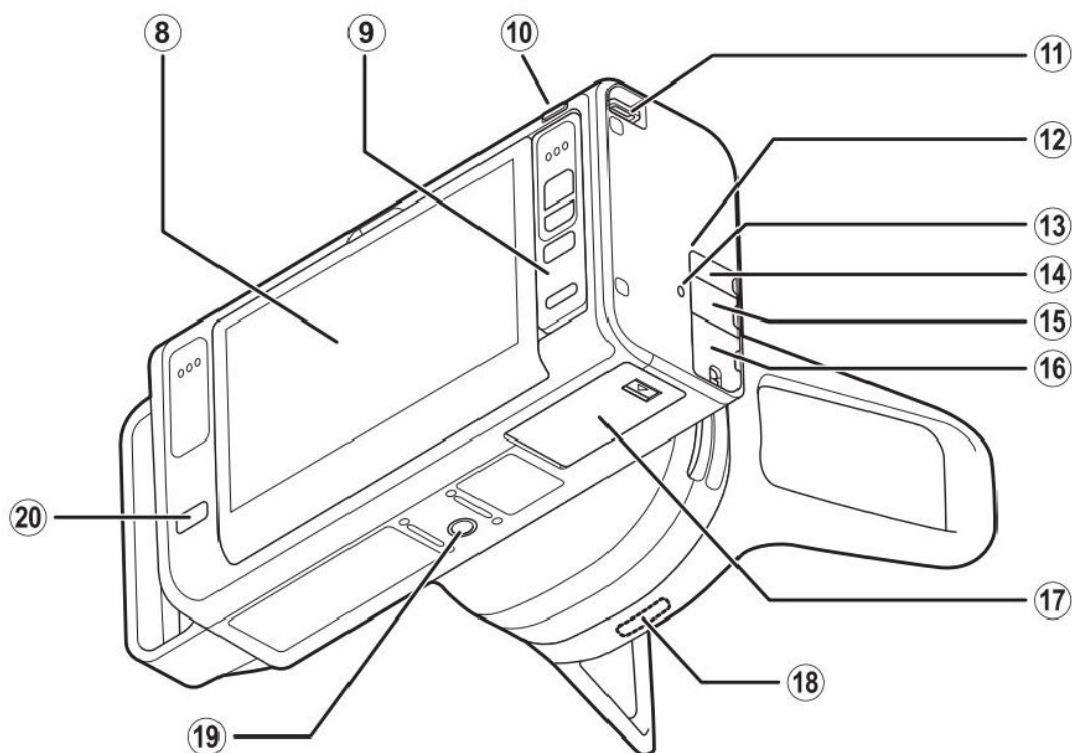
Unit names and the functions of the XD4000 PX are described below.

2.2.1 Part Names

(1) Main unit(XD4000 PX)

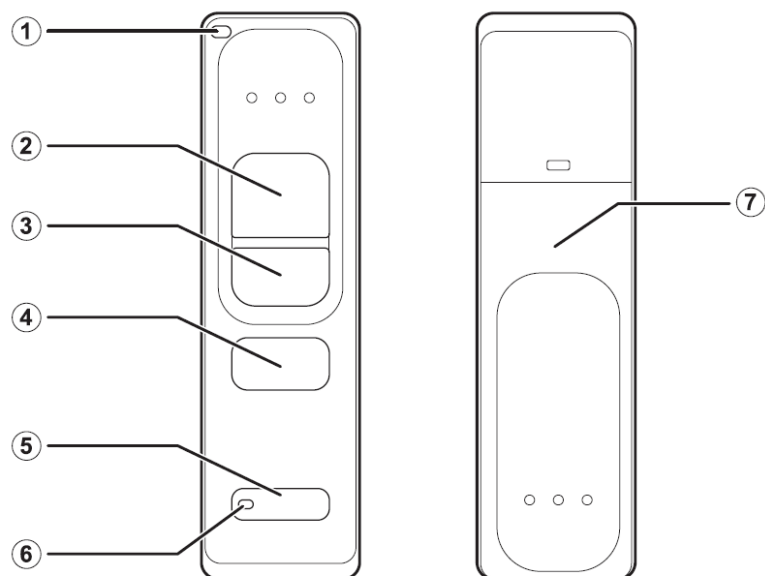


Name	Description
(1) Status LED	X-ray device status indicator LED. White: power on. Green: ready for exposure. Orange: exposure in progress.
(2) Irradiation field adjustment knobs	When these knobs are rotated, the light field lamp is adjusted.
(3) Handle	It can be detached by unscrewing the screw at the middle. The same screw is used to secure it in place.
(4) USB connector cover	This is a protective cover for the USB-A and USB-B connectors. Connect a USB memory to the USB-A connector. This allows you to output the operation log to a USB memory stick. This cannot be used due to maintenance
(5) Skin guard	Secures the minimum focal spot to skin distance (20cm) Do not hold the skin guard
(6) SSD Status LED	Indicates the skin guard attachment status. Light up: Wearing. Light off: Not wearing.
(7) Camera	Camera to monitor the conditions in front of the device.



Name	Description
(8) Operation panel	Tilting LCD touch panel for operating the X-ray device.
(9) Wireless hand switch	Wireless hand switch for exposure. Communicates through Bluetooth. provided with a light field lamp switch.
(10) Wireless hand switch lock release lever	Wireless hand switch body lock release lever.
(11) Shoulder strap holder	Holder for attaching a shoulder strap.
(12) Focus position	Displays the focus position.
(13) Charging LED	Charging status indicator LED. Lit: Charging. Off: Not charging.
(14) Door switch connector cover	This is the cover for the interlock connector. Under the cover is the connector for kV and mA signals as well.
(15) Charging connector cover	This is a protective cover for the AC adapter connector that is connected when charging.
(16) Wired hand switch connector cover	Cover for protecting the connector of the wired hand switch.
(17) Battery cover	This is the battery cover. There is a tab inside to prevent it from falling off. When removing the battery, slide the tab to remove it.
(18) Skin guard interlock	X-ray will not be possible unless the skin guard is properly installed.
(19) Mounting screw hole	Screw holes for mounting the X-ray device.
(20) Power switch	This is the power ON/OFF switch.

(2) Wireless handswitch(XD4000 RS)

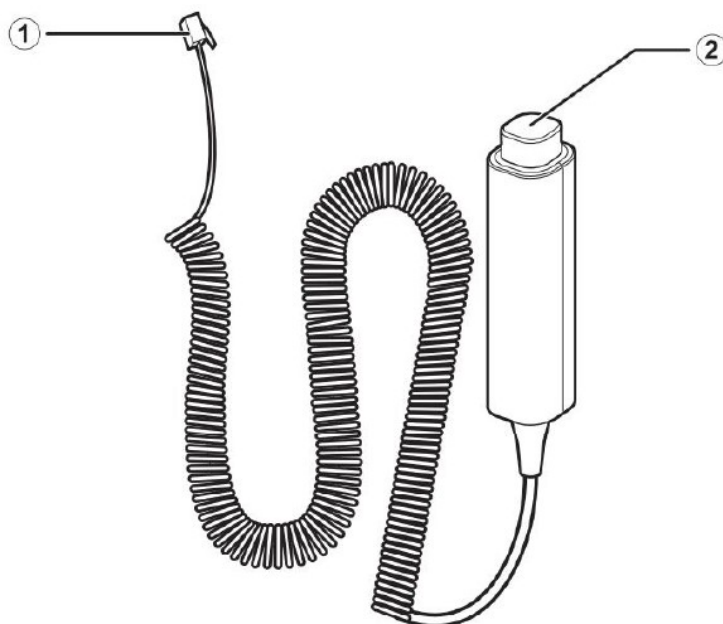


Name	Description
(1) Status LED	Indicates the operation status of the wireless hand switch. Green: ready for exposure. Orange: exposure in progress.
(2) Radiography preparation button	Push this switch down to the first level to heat the filament of the X-ray tube.
(3) X-Ray exposure button	Push this switch down to the second level to radiate X-rays.
(4) Light field lamp switch	This switch turns the collimator lamp on and off.
(5) Power status LED	Indicate the power status. Blue: power on. Orange: battery level is low. Off: Power OFF. Paring: Blinking
(6) Power button	Turns on/off the wireless hand switch
(7) Battery cover	Cover for the battery.

Notice

ME equipment must be positioned so as not to make it difficult to operate the isolation device.

(3) Wired handswitch(XD4000 HS)



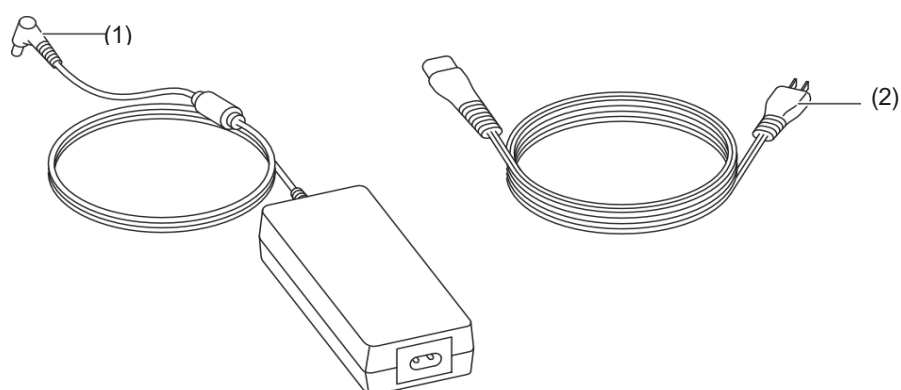
Name	Description
Wired Hand Switch Connector	When using a wired hand switch, connect this connector to 2.2.1 (1) (16)
Wireless hand switch	This is a two-stage switch for X-ray irradiation. The first stage is the exposure preparation switch, which heats the filament of the X-ray tube. The second stage is the X-ray shooting switch, and X-rays are emitted while the second stage is pressed or until the set time has elapsed.



Notice

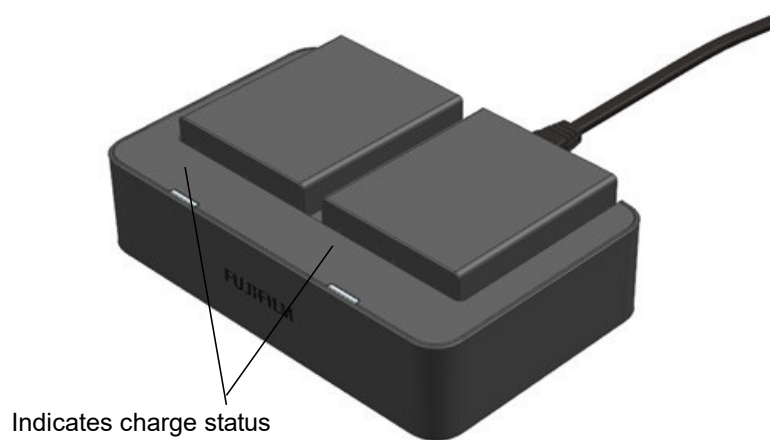
ME equipment must be positioned so as not to make it difficult to operate the isolation device.

(4) AC Charging adapter (MEA-065Z15BA)



Name	
(1)	DC jack
(2)	AC plug
 The shape of the AC plug varies depending on the country.	

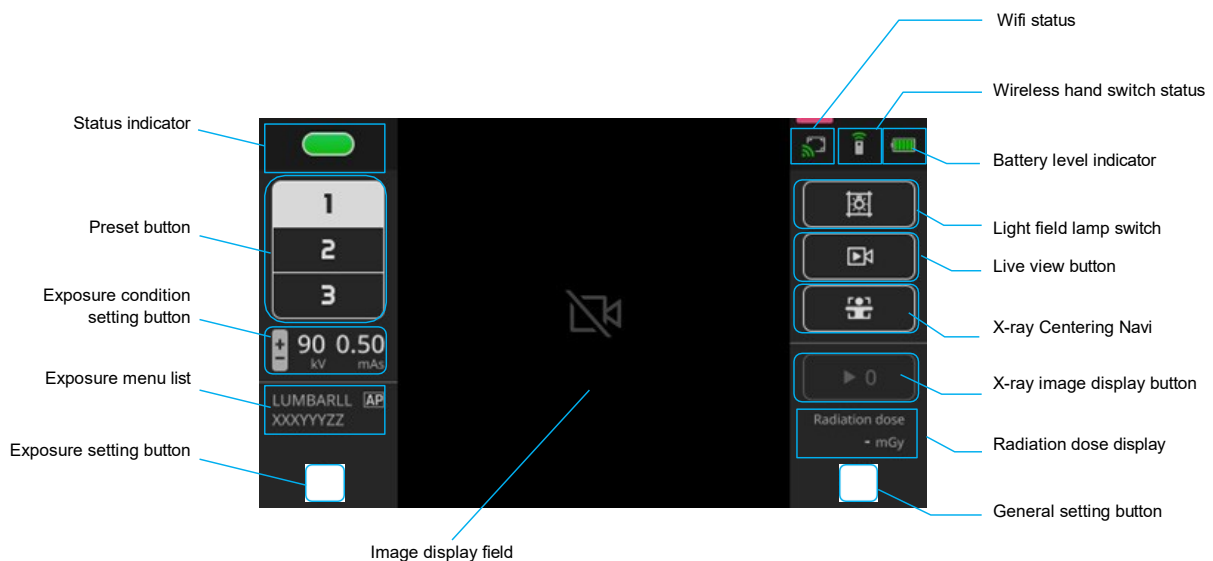
(5) Battery charger (XD4000 CU) (Option)



2.2.2 Operation Panel

There are the Exposure mode and the X-ray image display mode on the operation panel.

(1) Exposure Mode



Name	Description
Status indicator	Indicates the exposure status of this device. The status indicator changes as below according to the status. - Stand by - DR-ID 300CL has completed exposure preparation * - This device has completed exposure preparation - Exposure in progress - X-ray preparation in progress after exposure
Preset button	Calls three preset exposure conditions. The conditions registered to the presets can be changed to any value.
Exposure condition setting button	Used for setting exposure conditions. See “3.8 Setting of irradiation conditions” for how to set them.
Exposure menu list	Displays the exposure menu sent from DR-ID 300CL.*
Exposure setting button	Used for changing preset settings or setting the body thickness. See “4.1 Exposure Settings” for how to change preset settings.
Image display field	Displays an image. If live view is selected, image taken by the camera of this device will be displayed. It can also show X-ray image after exposure.* The icon below will be shown while no image is displayed.
Wifi status	Indicates the status of the wireless connection. : Connecting. Wireless signal strength is indicated in 3 levels. : Not connected : Offline mode

Name	Description
Wireless hand switch statue	Displays the connection status of the hand switch.  : Wirelessly connected  : Not connected  : Wired hand switch is connected
Battery level indicator	Indicates the battery level.  : 100~80%  : 80~60%  : 60~40%  : 40~20%  : 20~0%  : AC adapter for charging is connected. The indicators inside the battery are as shown
 Notice When the device is connected AC adapter it is displayed for charging” . When the battery is low it is displayed with battery warning”  or .	
Light field lamp switch	This switch turns the collimator lamp on and off. The collimator lamp automatically goes off after 30 seconds (default). How long The collimator lamp stays on can be changed through the settings. See “4.2 General Settings” for how to change it.
Live view button	Switches between displaying and hiding the camera image. The camera image will be hidden after X-ray irradiation even if you do not operate this button. Images taken with this function will not be saved, but be sure to inform the patient that the camera will be used as an auxiliary for X-ray photography.
X-ray Centering Navi	Used for displaying the center of the estimated exposure position calculated by DR-ID 300CL, superimposed on the live view image. This button will be enabled only while live view image is being displayed.
X-ray image display button	Used for displaying X-ray images taken by this device during the period from turning the power on to ending the exposure menu.
Radiation dose display	Displays the radiation dose of the exposure. The displayed value is calculated after each exposure based on the exposure conditions used for the exposure. You can calculate the area dose product by multiplying the displayed radiation dose by the irradiation area. Area dose product [uGy/cm2] = Displayed radiation dose [uGy] × Opening X [cm] × x Opening Y [cm].
General setting button	Used for changing the settings of this device.

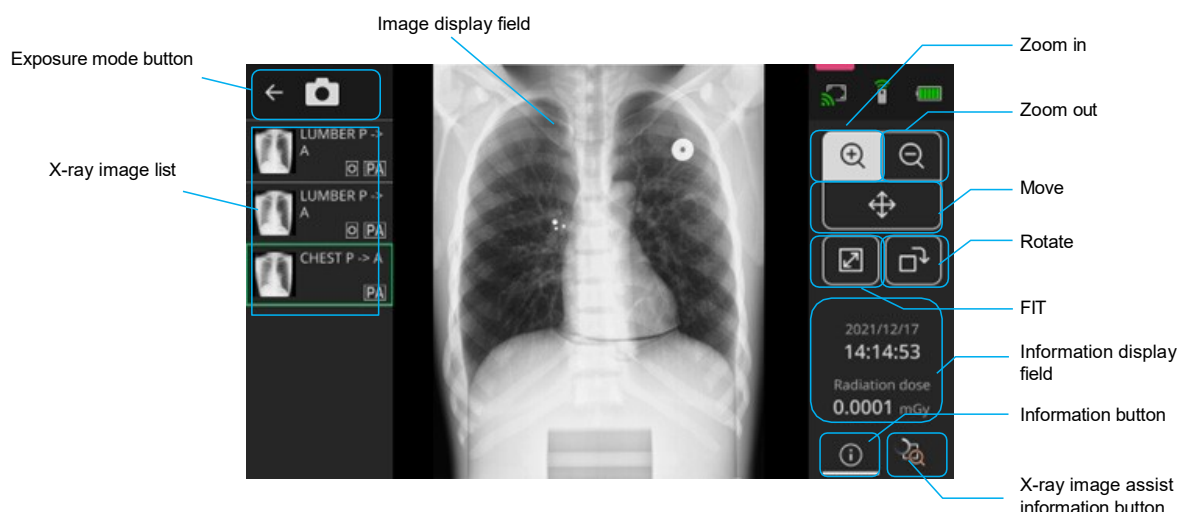
*1 Needs to be connected to DR-ID 300CL through wireless connection. See “3.16 Wireless Connection with CALNEO FLOW” for how to connect to CALNEO FLOW.

*1 Requires wireless connection to CALNEO Flow or Console Advance (DR-ID 300CL V16.3 or later). For details on the shooting menus in which this function is available, refer to the "Console Advance CALNEO Xair PLUS Link Software Reference Guide."

Calculations may not be performed correctly under the following environmental conditions.

- When SID is other than 100cm
- When the subject's head, knees, shoulders, or buttocks are not visible in the camera video
 - *When shoulders etc. are hidden by hair
- When the colour of the subject's clothes blends in with the background
- When obliquely lit
- When an assistant (such as the technician's hand) is visible in the camera video

(2) X-ray image display mode *



Name	Description
Exposure mode button	When pressed, the system transitions into the exposure mode.
X-ray image list	Click on the thumbnail to show the image in the image display field.
Image display field	Displays the X-ray image of the current exposure, or any of the X-ray images taken during the period from turning the power on to ending the exposure menu of DR-ID 300CL.
Zoom in	By selecting an arbitrary position in the image display field, the image is zoomed in with the selected position to be its center.
Zoom out	By selecting an arbitrary position in the image display field, the image is zoomed out with the selected position to be its center.
Move	By selecting any position on the image and then moving the position from side to side and up and down, the image can be moved freely.
Rotate	The displayed X-ray image rotates 90° clockwise on each tapping.
FIT	The displayed image will be enlarged to fit the entire window.
Information display field	Displays information about the X-ray and X-ray image.
X-ray image assist information button / Information button	Used for changing the information displayed in the information display field between X-ray image assist information and X-ray information from DR-ID 300CL.

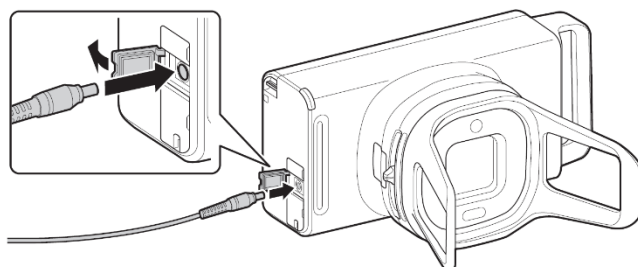
* Needs to be connected to DR-ID 300CL through wireless connection.

Chapter 3 Basic Operation

3.1 Preparation of X-ray generator

3.1.1 How to charge the battery with the X-ray generator

- 1** Open the charging connector cover and connect the DC jack.



- 2** Connect the AC plug of the AC adapter to the power outlet.

- 3** Verify that the charge LED is lit.

If the charge LED does not illuminate, check that **1** and **2** is properly connected and a fully charged battery is not installed.

- 4** When charging is complete, the charging LED will turn off. Disconnect the AC plug of the AC adapter from the power outlet, remove the DC jack, and then close the charging connector cover.



Notice

Do not work with wet hands. Failure to do so may result in electric shock.



Warning

Warning that there is a risk if you use a different AC adapter than the specified one.

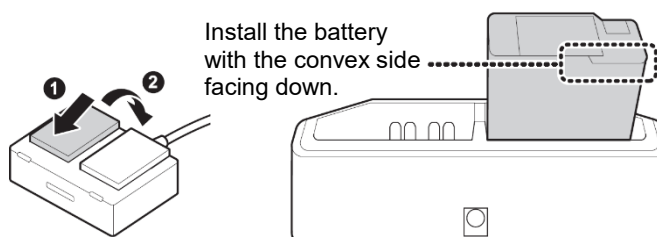


Warning

Do not place any object in a place where removal of the power cable is prevented.

3.1.2 How to charge the battery with the battery charger (optional)

- 1** Place the battery in the battery charger.



Notice

Make sure that the battery is oriented correctly before placing it in the battery charger. Failure to do so may damage the battery and the battery charger.

- 2** Confirm that the charge status indicator LED is lit orange or yellow.

If the charge status indicator LED does not light, check that the AC plug of the battery charger is properly connected to the outlet and that the battery is properly loaded in the battery charger.



Hint

Up to two batteries can be charged simultaneously.

- 3** When the charge LED turns green, the battery is charged. Remove the battery from the battery charger by following the reverse procedure at **1**.

3.1.3 How to replace the battery

This section explains how to replace the battery in the XD4000 PX. Please understand the precautions and other instructions carefully before replacing the battery.



attention

When replacing the battery, do so with the power to the equipment turned off and the AC adapter for charging disconnected, to avoid the risk of electric shock.

Battery replacement should not be performed with wet hands due to the possibility of electric shock.

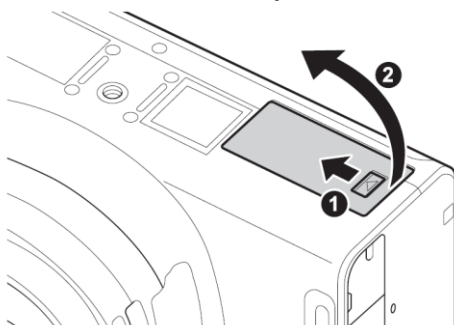
When replacing the battery, be careful not to drop anything inside the device as it may be damaged.



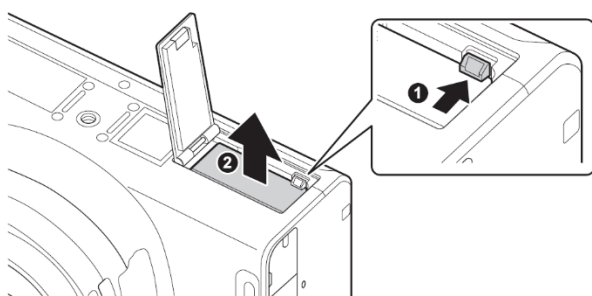
Warning

Please remove the battery if you are not going to use the device for a long time.

- 1** Slide the battery cover knob as shown by the arrow to open the cover.



- 2** Slide the internal lever and then remove the battery.



Notice

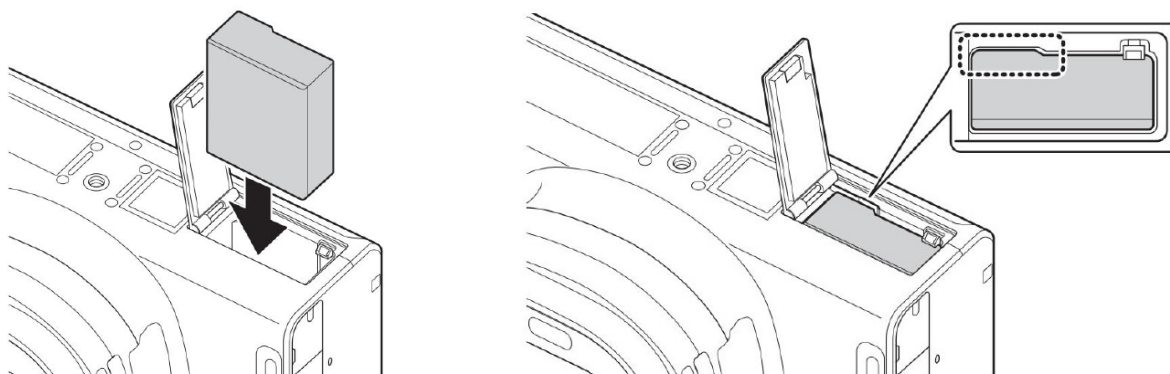
Do not touch the terminals inside the main unit. There is a possibility of electric shock or damage. Do not drop the battery as it may be damaged or smoke.



Warning

Warning that there is a risk if you use a different battery than the specified one.

- 3** Insert the battery in the direction of the arrow and push it in until it clicks.



! Notice

When inserting the battery, make sure it is in the correct orientation before inserting it. Insert the battery so that the convex side of the battery shown below is aligned with the concave side of the main unit.
Hold the battery by hand while installing it. Dropping the battery onto the mounting area may damage the terminals.

- 4** Close the battery cover and then slide the knob to lock it. Make sure the battery cover is securely closed.

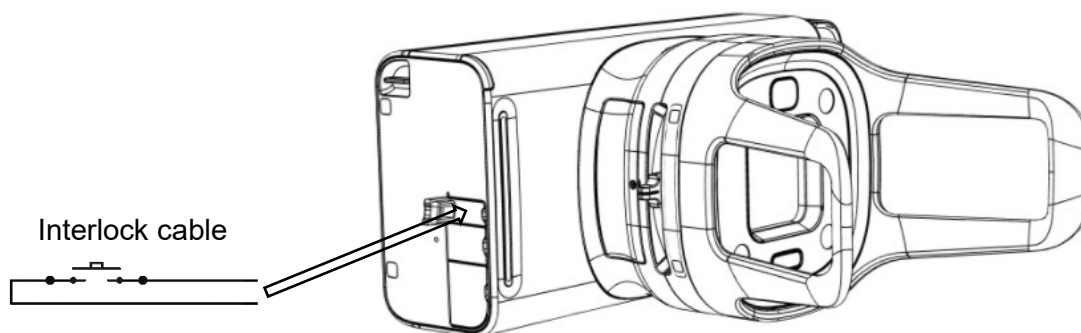
3.1.4 How to connect interlock cable

In case of using the door interlock for external electrical devices, this section explains how to connector an interlock cable in the in the XD4000 PX..

If there is no interlock connection, an error (E.24 or E.27) occurs when emitting X-ray radiation and the X-ray radiation stops.

It is recommended to indicate the interlock status by visual means.

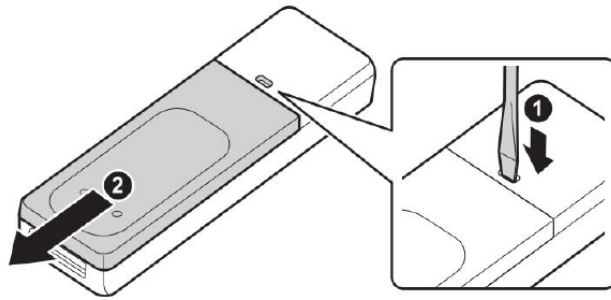
- 1** Open the interlock connector cover and connect the interlock cable as shown by the arrow to open the cover.



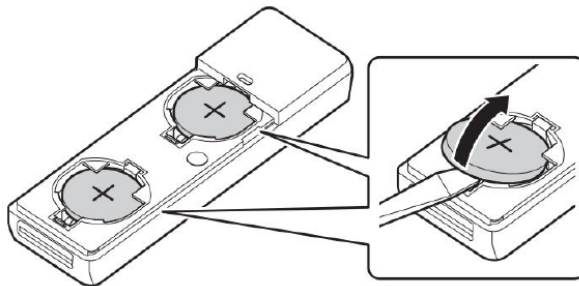
- 2** When operating is complete, disconnect the interlock cable from the unit, and then close the interlock connector cover.

3.1.5 How to replace the batteries in a wireless hand switch

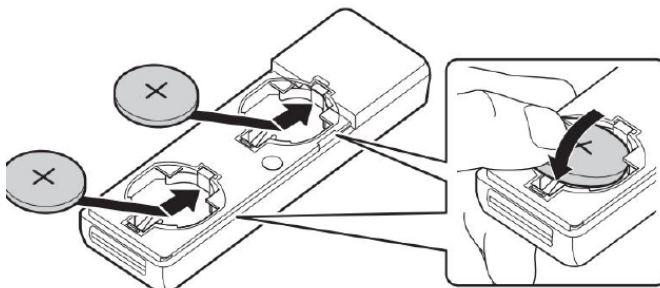
- 1** Slide the battery cover while pressing down with a fine tip.



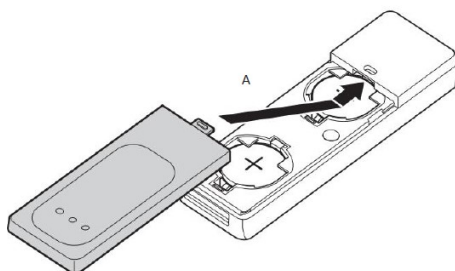
- 2** Remove the two batteries and replace with new batteries (CR2032).
Used a flat-haed screwdriver to push up on the front of the battery and remove it.



- 3** Install a new battery. With the positive pole facing out, hook it onto the back of the battery, then push the front of battery in.



- 4** Slide and install the battery cover.



3.2 Routine operation

This section describes the routine (basic) operation of the XD4000 PX.

Advance preparation

- | | | |
|---|------------------------------|---|
| Step 1 | Checking the state of charge | ➤ For details, see "3.3 Checking Status Check". |
|  | | |
| Step 2 | Transportation | ➤ For details, see "3.4 Transportation". |

X-ray irradiation implementation method

- | | | |
|---|---|--|
| Step 3 | Setup | ➤ For details, see "3.5 Installation". |
|  | | |
| Step 4 | X-ray generator startup | ➤ For details, see "3.6 Startup of X-Ray Equipment" |
|  | | |
| Step 5 | Installation of the X-ray generator | ➤ For details, see "3.7 Installation of X-ray Generator" |
|  | | |
| Step 6 | Setting of X-ray irradiation conditions | ➤ For details, see "3.8 Setting Irradiation Conditions" |
|  | | |
| Step 7 | Preparation of Wireless Hand Switch | ➤ For details, see "3.9 Hand Switch Preparation" |
|  | | |
| Step 8 | Positioning | ➤ For details, see "3.10 Positioning". |
|  | | |
| Step 9 | x-ray radiography | ➤ For details, see "3.11 Radiography". |
|  | | |
| Step 10 | Image Confirmation | ➤ For details, see "3.13 Image Confirmation". |

End of irradiation

- | | | |
|---|------------------------|--|
| Step 11 | End of X-ray generator | ➤ For details, see "3.14 Termination of the X-ray Generator" |
|  | | |
| Step 12 | Transportation | ➤ For details, see "3.4 Transportation" |
|  | | |
| Step 13. | Cleaning | ➤ For details, see "3.15 Cleaning and Charging" |

3.3 Charging Status Check

This section describes how to check the charging status of the device.

1 Press the power button for at least 2 seconds to start up the device.

2 Check the battery status display to see how much charge is available.



Hint



100~80%



80~60%



60~40%



40~20%



20~0%

If the charge is low, connect a recharging AC adapter to recharge the battery or replace it with another charged battery.

For instructions on how to connect the AC adapter to charge the battery, refer to see "3.1.1 How to charge the battery with the X-ray generator"

For instructions on how to replace the battery, refer to see "3.1.3 How to replace the battery".

3 After confirming the charge status, press the power button again for at least 2 seconds to exit the device.

3.4 Transport

This section explains how to transport the XD4000. Please understand the precautions before transporting the XD4000.

1 Make sure that the wireless hand switch is properly attached to the main unit.

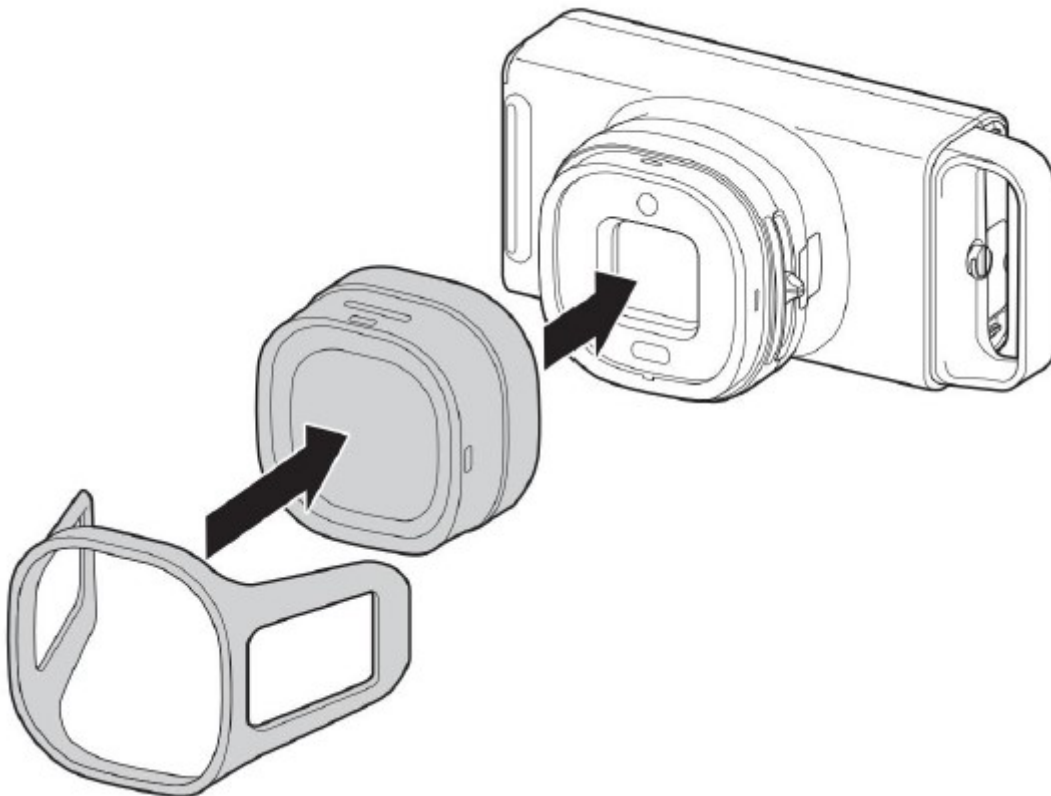
2 Make sure that the device and shoulder strap are properly attached.

attention

- When carrying the X-ray generator, remove the skin guard, handle, etc. as necessary.
- When carrying the device, carry it with the shoulder strap slung over your shoulder. Failure to do so may cause the device to fall, resulting in injury or damage.
- Be careful not to let the shoulder straps wrap around your neck or shoulders. This may lead to injury.
- When carrying this equipment, do not swing it around. Doing so may result in injury or damage.
- Carrying the unit with the wired hand switch cable hanging down may cause the cable to catch on a doorknob or other protruding object, causing the unit to fall, resulting in injury or damage. Do not use the unit for any other purpose.
- When carrying the device, be very careful not to let it fall over.
- Do not carry the device with the AC adapter for charging connected to it. The cable may get caught and cause the device to fall, break, or cause injury.

Hint

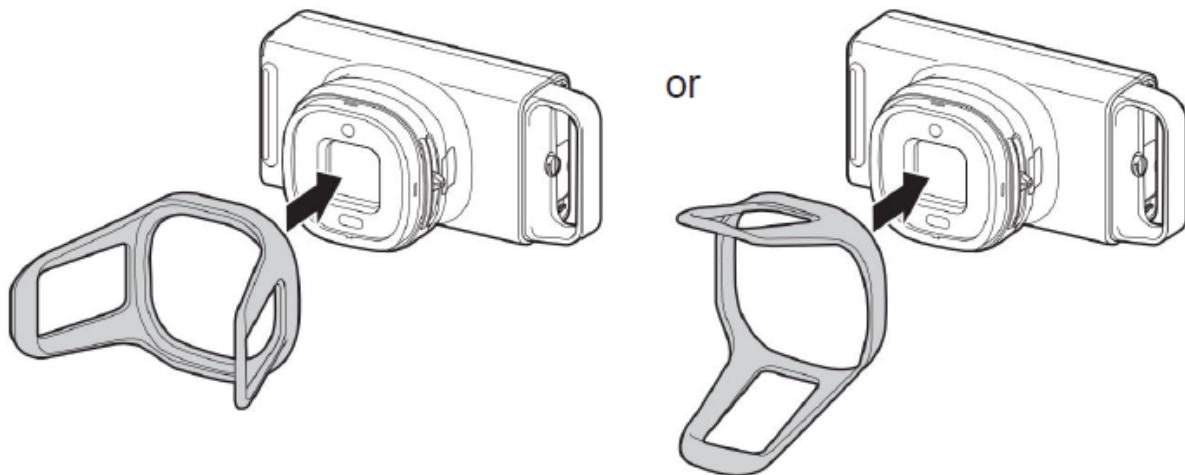
As shown in the figure below, after attaching the lens cap to the camera body, attach the skin guard to the lens cap with the skin guard facing towards the camera body to make the camera compact and easy to carry.



3.5 Installation

This section describes the installation of the X-ray system.

1 Install the skin guard.

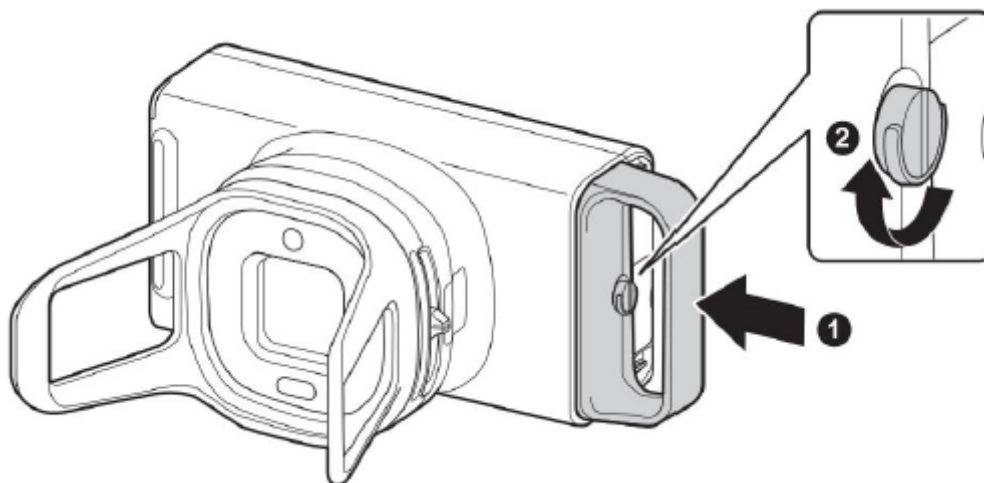


Hint

Depending on the function of the external device connected wirelessly, there may be restrictions on the direction in which the skin guard can be installed.

The skin guard can also be mounted in a 90° rotated position.

2 If necessary, install the handle and turn the screw to secure it.



Notice

Make sure the handle is properly secured before holding the handle. Failure to do so may cause the handle to fall off and result in injury.

3 Install the retention device in accordance with the instruction manual for the retention device.



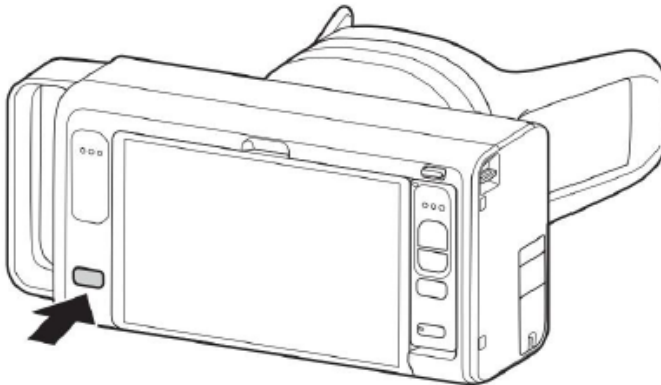
Notice

When installing or moving the holding device, be careful not to hit it against surrounding objects and damage the equipment or device.

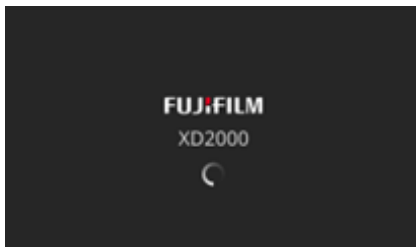
3.6 Startup of the X-ray system

This section describes the startup procedure for the X-ray system.

- 1 Press and hold the power button for at least 2 seconds.

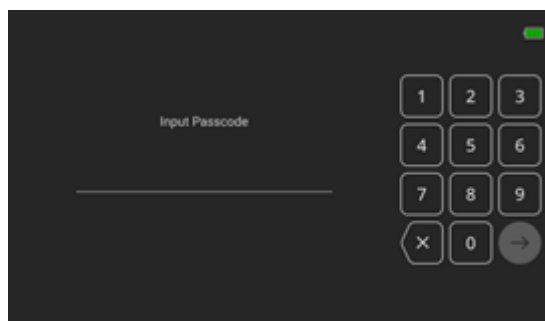


- 2 When the power is turned on, the following screen appears.



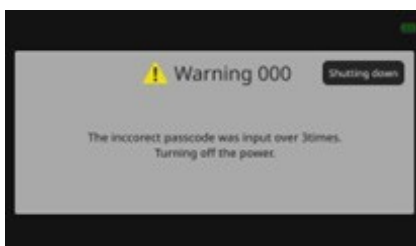
- 3 If a passcode has been set, the passcode entry screen will appear. Enter the passcode, and then tap .

If you have not set up a passcode, please go to "4.2 General Settings". For instructions on how to set the passcode, please refer to "4.2 General Settings" for details on how to set the passcode.

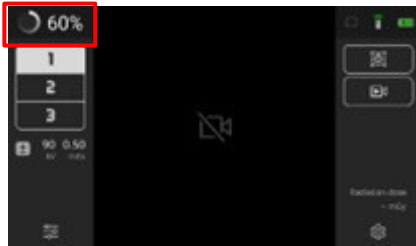


Notice

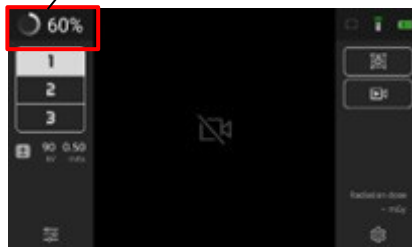
Please note that if you make a passcode mistake three times, you will be taken to the shutdown screen.



- 4** Wait until the device is ready. Preparation takes approximately 2 minutes after pressing the power switch. During preparation, a loading animation is shown on the status display (except for the passcode input operation)



- 5** When the status display on the operation panel reads  or,  the system is ready.



- 6** The battery indicator in the upper right corner shows the remaining battery charge. Also, when connecting to CALNEO FLOW wirelessly, check the Wifi status indicator in the upper right corner to confirm that a wireless connection is established.

3.7 Installation of the X-ray generator

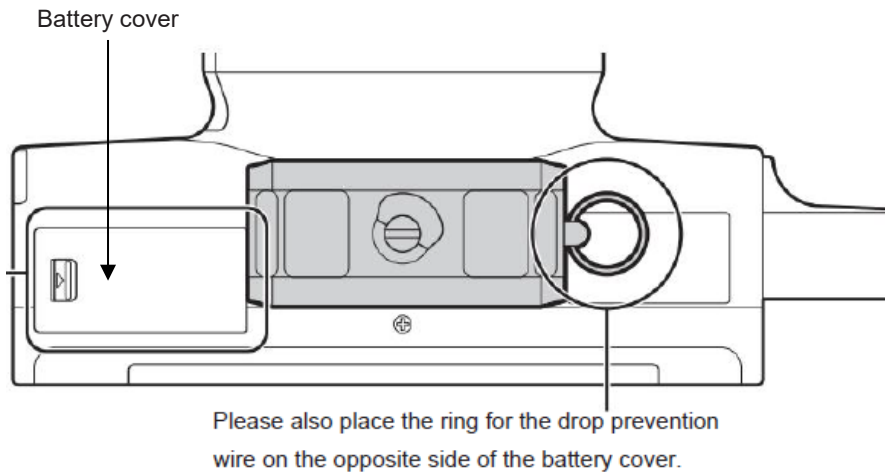
Install the holding device according to the instruction manual for the holding device and attach the X-ray generator to the holding device.

Notice

- When carrying the X-ray generator to the holding device, attach a shoulder strap to prevent it from falling. Be careful that the shoulder strap does not wrap around your neck or other parts of your body.
- To prevent damage, please do so with the control panel closed.

Hint

As shown in the figure below, by attaching the holder bracket in a position that does not overlap with the battery cover, it is possible to replace the battery even when the battery is attached to the holding device.



3.8 Setting of irradiation conditions

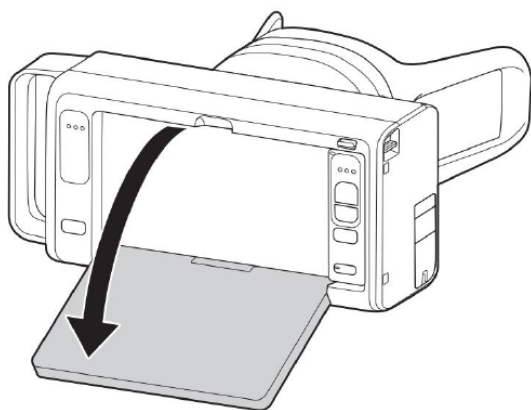
This section describes how to set the X-ray irradiation conditions.

- 1 Set the exposure conditions by selecting one of the preset buttons 1~3 or by pressing the exposure condition setting button.



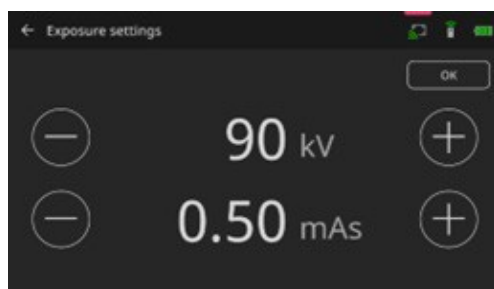
Hint

- When connected wirelessly to CALNEO Flow, it is possible to set this device to automatically select a preset according to the imaging menu selected in Console Advance (DR-ID 300CL V16.3 or later). Please contact our designated vendor when using this function.
Up to 20 exposure menus can be associated with each preset of the device.
- The kV can be changed according to the patient's body thickness. See "4.1 Exposure Settings".
- If the control panel is difficult to see, the angle can be adjusted by opening the control panel.
- You can also change the passcode by entering the administrator passcode on this screen. For instructions on how to change the passcode, see "3.6 Startup of the X-ray system" for instructions on how to change the passcode.



(1) How to use the Exposure Condition Setting button

1. Tap the Exposure Condition Setting button.
2. Tap the + and - buttons to adjust kV and mAs.



See "A.1 Specifications" for values that can be adjusted.

- 3 Tap the OK button.



Hint

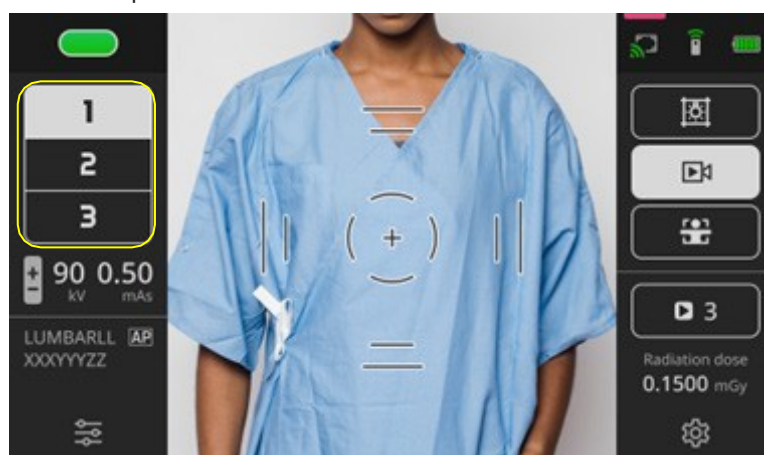
Without tapping OK, tap the back arrow to return to exposure mode without changing the exposure conditions.

- 4 Verify that the exposure condition setting values displayed on the exposure condition setting buttons are correct.



(2) How to set by preset buttons

Select and tap 1~3 below.



The preset exposure conditions are as follows (Medium size is the average adult patient)

APR	kV	mAs	Reference Air Kerma
1(Small)	90	0.50	35.9
2(Large)	90	2.5	179.7
3(Medium)	70	2.0	91.3

If you want to change the values of these presets, you can use the "4.1 Exposure Settings".

** Reference Air Kerma

mAs \ kV	50	60	70	80	90
0.5	9.7	16.3	22.8	29.4	35.9
1	19.5	32.6	45.7	58.8	71.9
2.5	48.7	81.4	114.2	146.9	179.7

* Calculate DAP

Memo the "uGy" value after exposure and the collimator scale values(X axis and Y axis).

Calculate the Dose Area Product value("uGy · cm²")

DAP[uGy · m²] = "uGy" * X[m] * Y[m] (Accuracy : under 35%)

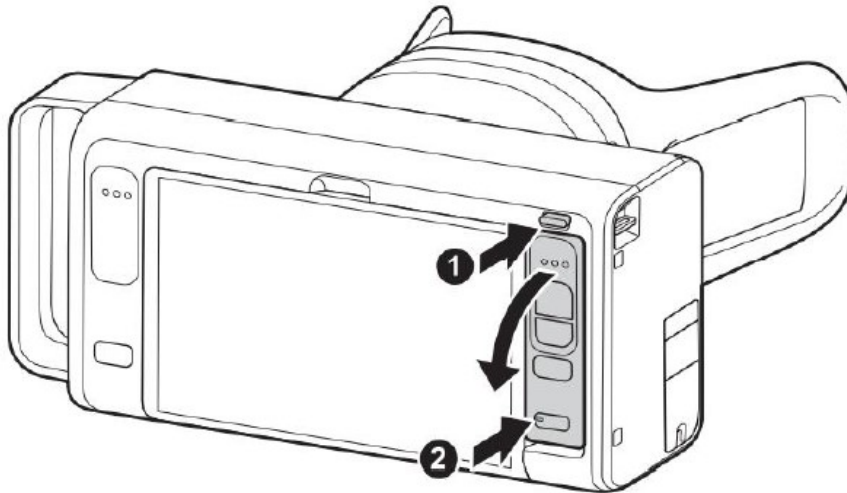
** The DAP value, for example is 179.7uGy under the usage conditions of 90kV, 2.5mAs, SID 1m, 30*30cm, so 179.7*0.3*0.3 is 16.2uGy · m².

3.9 Hand Switch Preparation

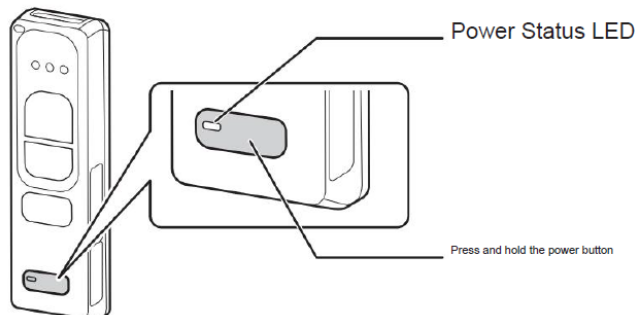
This section describes the preparation of wireless/wired hand switches.

3.9.1 For wireless hand switches

- 1 Remove the wireless hand switch from the main unit.



- 2 Turn on the power by pressing and holding the power button on the wireless hand switch (about 2 seconds) and confirm that the power status LED on the wireless hand switch is solid blue.



Hint

If the power status LED is orange, the battery is low and should be replaced. For battery replacement instructions, refer to "3.1.5" for battery replacement instructions.

- 3 Confirm that communication with the wireless hand switch is possible () by using the wireless hand switch status indicator on the operation panel.



If communication is not working, please check Troubleshoot [Chapter 5]

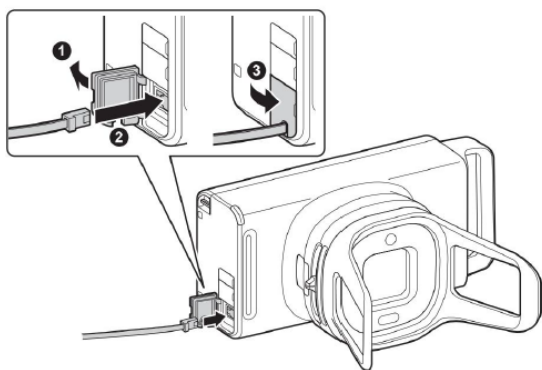


Hint

The standard communication distance for wireless hand switches is 2.5 m.

3.9.2 For wired hand switches

- 1** Connect the wired hand switch to the main unit.



Open the wired hand switch connector cover.

Connect the connector of the wired hand switch.

Close the wired hand switch connector cover.



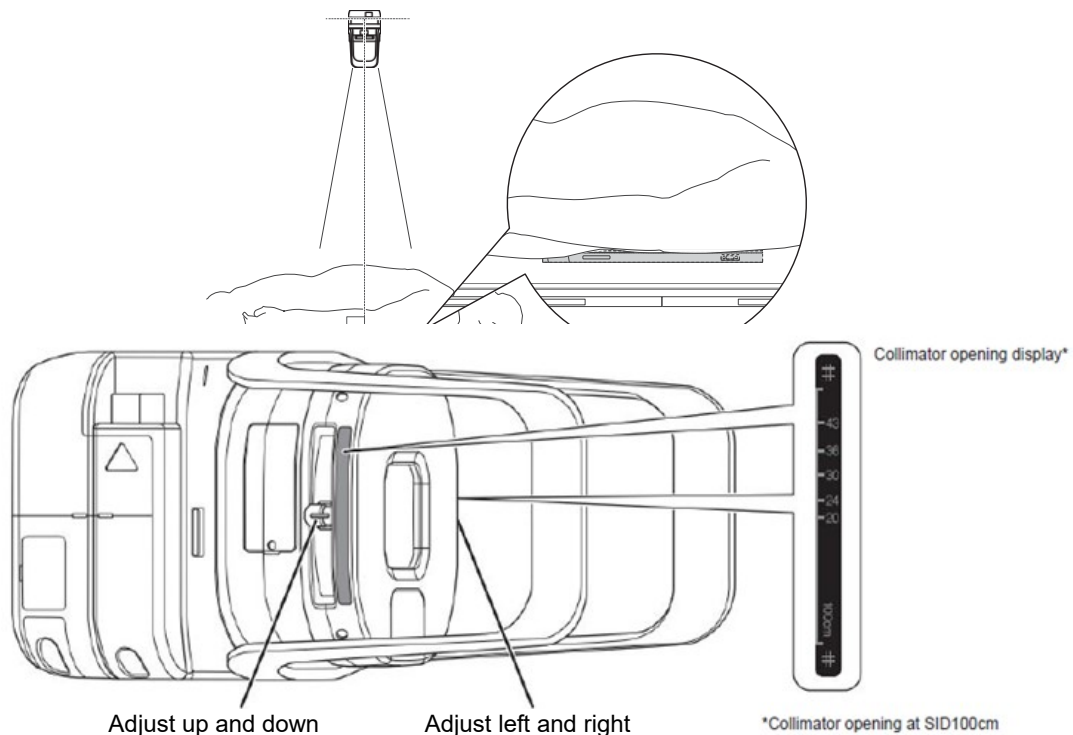
Notice

- Install the connector in the correct orientation. Failure to do so may result in damage.
- Be careful not to press the switch unintentionally to prevent unnecessary X-ray exposure.
- Be careful not to pull the hand switch too far when using the wired hand switch so that the device does not fall on the patient.

3.10 Positioning

This section describes positioning.

- 1 Tap the light irradiation field button on the operation panel or press the light irradiation field switch on the wireless hand switch to turn on the light irradiation field.
- 2 Position the X-ray system while confirming the irradiation area and the area to be photographed.
Follow the instruction manual of the holding device for each adjustment method.



- 3 Adjust the X-ray beam size using the collimator knob on the X-ray generator.
Place the loaded cassette or DR plate on the patient's back. At this time, the size of the cassette and DR plate is 14" *17" or 17"17" or less, and the material between the patient and the image plate should take into account the maximum attenuation equivalent.
Arrange the SID(Focal Spot to Image Receptor Distance) 1m using a scale along with the unit.
Arrange the X-ray beam size in accordance with the cassette or DR plat size using the X-ray collimator handle. X-RAY FIELD make the measurements with the REFERENCE AXIS normal to the IMAGE RECEPTOR PLANE within three degrees. The collimator will turned off automatically after 30 seconds.



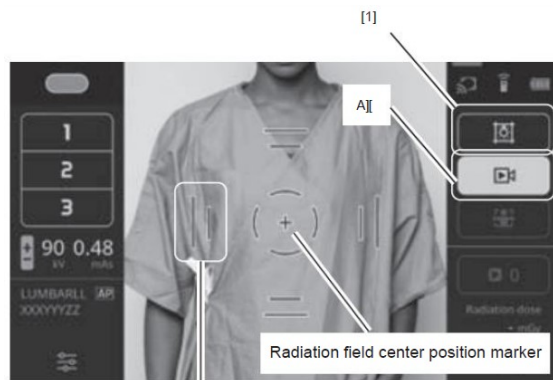
Warning

When adjusting the beam field of the collimator, it should be adjusted to be smaller than or equal to the maximum detector size(17"*17").



Hint

The Live View button (A) allows the camera image and center mark to be displayed on the control panel. Positioning can also be performed using this as a reference. However, final confirmation of positioning should be made in the light-illuminated field.

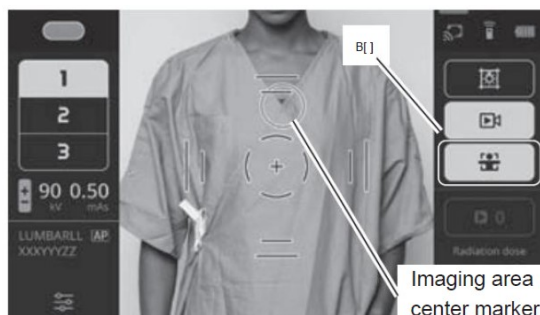


Calculated camera image from 14 and 17 inch positions at SID 100cm



Hint

When connected wirelessly to CALNEO Flow or Console Advance (DR-ID 300CL V16.3 or later), X-ray Centering Navi(B) can display on the operation panel the estimated center position of the imaging site calculated by Console Advance. The results can be displayed on the operation panel.



Notice

- Final confirmation of positioning should be made with the light irradiated field.
- Always ensure that the distance between the patient and the device is at least 20 cm.
- If there is a possibility of exposure to X-rays in radiation-sensitive areas (e.g., eyes, gonads, etc.), protect these areas.
- Adjust the X-ray irradiation field appropriately to prevent X-ray irradiation to areas outside the region of interest.
- Place the loaded cassette or DR plate on the patient's back. At this time, the size of the cassette and DR plate is 17" or less, and the material between the patient and the image plate should take into account the maximum attenuation equivalent.

3.11 Radiography

1 Check that the status display looks like the following

When connected wirelessly to Console Advance 

When not connected wirelessly to Console : Advance 



Hint

If there is no problem with the Wifi status display and the above status is not displayed when connected wirelessly to Console Advance, there may be a problem with the wireless status between Console Advance and CALNEO Flow. Please check and improve the wireless communication status according to the instruction manual of CALNEO Flow before use.

2 Keep at least 2 m away from the X-ray generator.



Notice

When using a wireless hand switch, check the wireless hand switch status indicator and make sure the wireless hand switch is connected.

3 Press the ready-to-shoot switch on the wired/wireless hand switch to confirm that the camera is ready to shoot.



Hint

In the case of the wireless hand switch, the camera is ready to shoot when pressed for 1 second.

For wired hand switches, hold down the ready to shoot switch until the camera is ready to shoot.

When the camera is ready to shoot, a sound is made, the ready-to-shoot symbol is displayed on the operation panel, and the frame of the image display area and the status LED turn green.

4 Press and hold the radiography switch on the wired/wireless hand switch until radiography is complete.



Hint

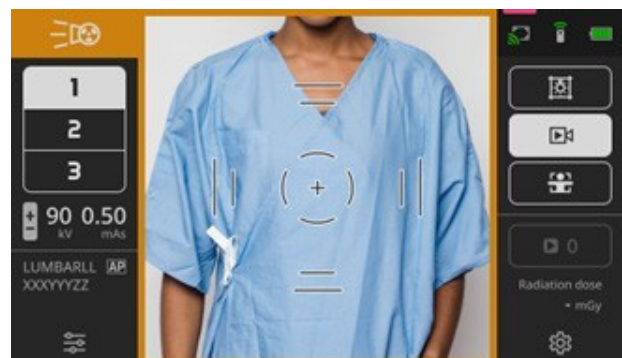
While an x-ray is being taken, a sound is made, the x-ray symbol is displayed on the operation panel, and the frame of the image display area and the status LED turn orange.

If the x-ray generator does not operate properly and x-ray irradiation does not stop, disconnect the battery or unplug the AC adapter to stop x-ray irradiation.

Ready for radiography state



X-ray irradiation state

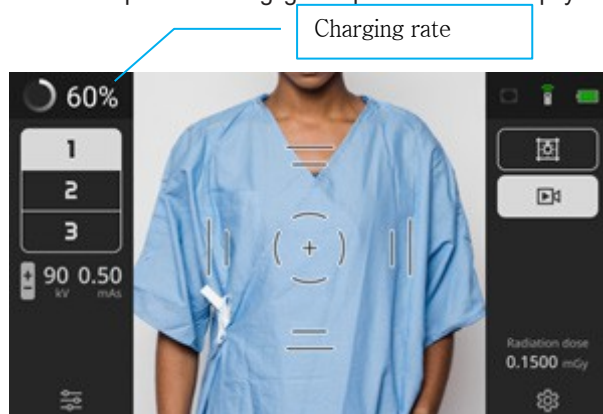


Hint

Be sure to confirm that X-ray irradiation is complete before releasing the radiography switch; if the radiography switch is released during X-ray irradiation, X-ray irradiation will be aborted.

5 When exposure is finished, the capacitor inside the device is charged and the charge rate is displayed on the status display on the operation panel.

Take the next picture after charging is complete and the status display changes to standby.



Warning)

Slight scattering of X-rays may occur during radiography. Operators and patients must always use the legally required
The worker must wear a lead apron and all other protective equipment that has been

Notice)

- Before irradiating X-rays, make sure that the device is stationary.
- The minimum interval for X-irradiation in this system is 8 seconds. Continuous irradiation at an interval of 8 seconds can be used up to 10 times under the condition of 90 kV 0.5 mAs.
- Note that if the unit is left unattended for more than 10 minutes without operating it, the power will automatically turn off. This time can be changed by setting. For details, see "4.2 General Settings5. Auto Power OFF" for details.

X-ray irradiation is possible even when the AC adapter is connected. "3.12 AC adapter connection exposure" See



section

Warning)

- To avoid injury from bumping into the AC adapter, fix and use the AC adapter as shown below.
- Fix and use the AC adapter as shown below to prevent injury from tripping over the AC adapter cable.
- Make sure that the patient does not touch the AC adapter or the cable.
- Fix the AC adapter and cable so that they do not enter the X-ray irradiation area.
- Be careful not to get liquids on the AC adapter and cables.
- When positioning, please remove the AC adapter for positioning.

3.12 AC adapter connection exposure

The following procedure should be followed when performing X-ray exposure with the AC adapter connected.

- 1** Attach this device to the holding device.
- 2** Secure the AC adapter to the holding device with the supplied Velcro band.



Notice)

When positioning, be sure to secure the AC adapter in a position where the AC adapter cable will not be pulled .

If you are unable to position the device due to the AC adapter cable, or

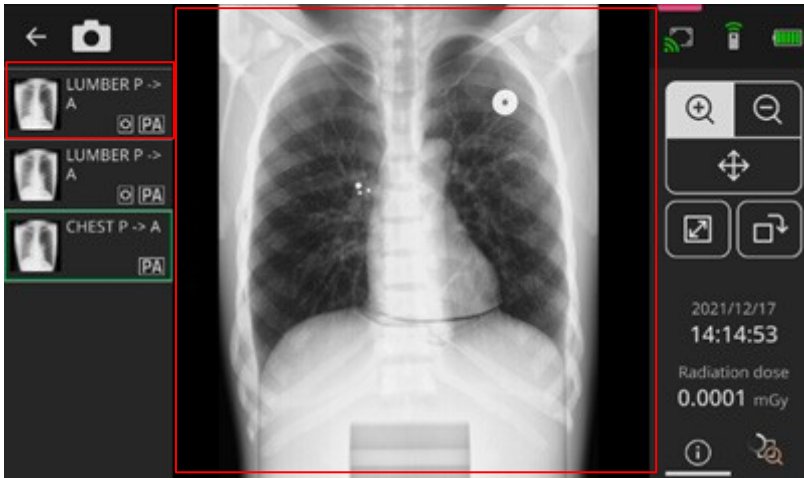
The AC adapter may be damaged or fall.

- 3** Connect the plug of the AC adapter to the device.
- 4** Connect the AC plug of the AC adapter to the power outlet.
- 5** Turn on the power of the device.

3.13 Image Confirmation

The X-ray images taken can be viewed on this device only when it is wirelessly connected to CALNEO Flow or Console Advance (DR-ID 300CL V16.3 or later). This section describes the procedure.

- 1 When the data sent from Console Advance is received after an x-ray is taken, the x-ray image is automatically displayed in the image display area and the captured image menu.



Hint

In this state, pressing the ready switch on the wired/wireless hand switch returns the camera to exposure mode. To continue exposure, press the ready switch again.



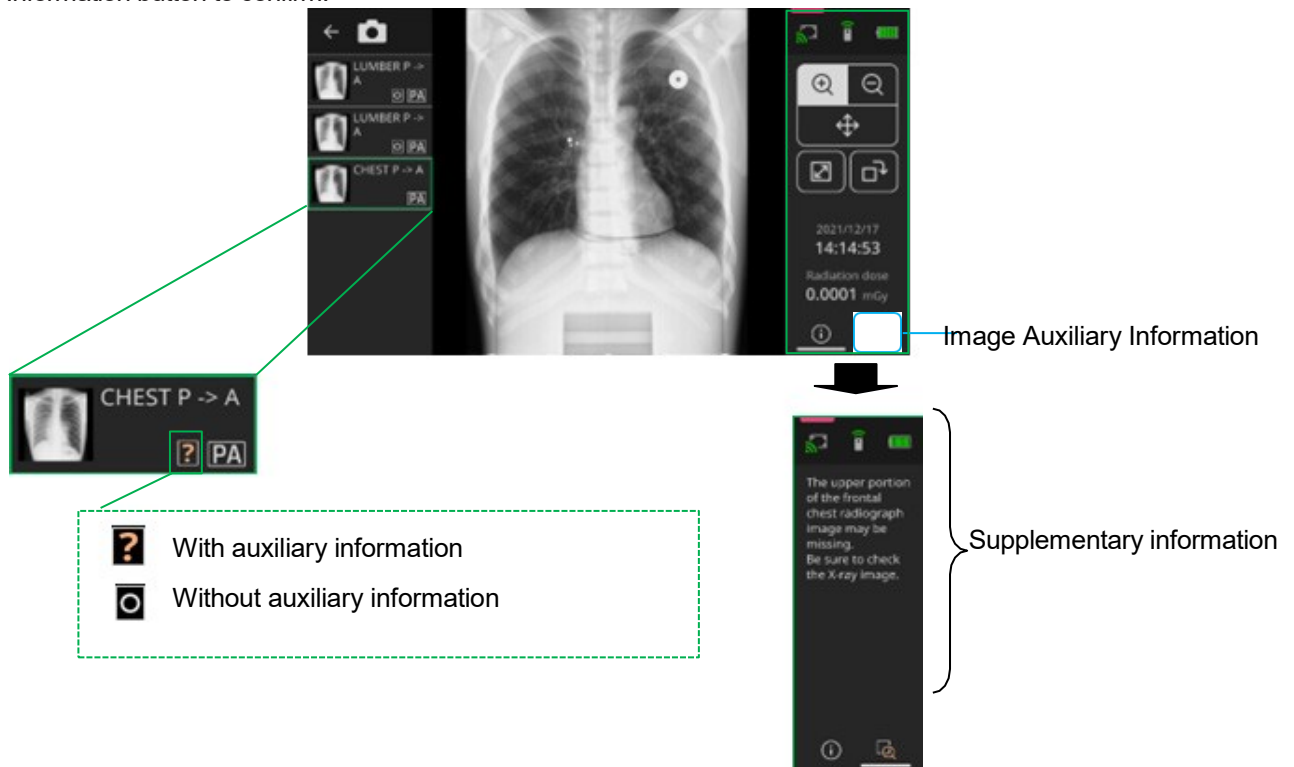
Notice)

- The image display on this device is intended for checking radiological images. Do not use the displayed images for diagnosis.

Be sure to check the display image on Console Advance.

- The menu after X-ray shooting and editing operations on the X-ray image using Console Advance are not reflected in this display.

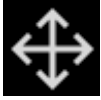
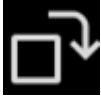
- 2 If  appears in the Exposure Image Menu there is additional information press the Image Supplementary Information button to confirm.



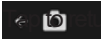
 Notice)

- Auxiliary information is an auxiliary function for image confirmation, so be sure to check the diagnostic X-ray image before making a diagnosis.
- Auxiliary information is a function that can be used under specific shooting conditions and target ranges. The shooting conditions and target ranges can be set on the Console. Please refer to the advance instruction manual.

3 If you want to change the display state of the image, you can zoom in/out, rotate, move, and fit the image using the icons below.

Icon	Description
	When any position in the image display area is selected with this button selected, the image will be displayed with the selected position as the center and the image is zoomed in.
	When any position in the image display area is selected with this button selected, the image will be displayed with the selected position as the center and the image is zoomed out.
	With this button selected, select an appropriate position on the image and move it up, down, left, or right can be moved.
	Images are displayed according to the size of the image
	The image can be rotated 90 degrees

4 Returns to exposure mode.

Tap the exposure mode button  to return to the exposure mode and take the next x-ray image.

3.14 Termination of the X-ray generator

- 1 Press and hold the power button on the wireless hand switch to turn off the power.
Verify that the power status LED on the wireless hand switch is off.

- 2 Attach the wireless hand switch to the main unit.

- 3 Press and hold the power button on the main unit to turn off the power.



Hint

If the power is turned off with the wireless hand switch not installed, a warning message will appear, but the unit will automatically shut down after a certain period of time.

- 4 Remove the retention device according to the instruction manual for the retention device.



Notice

If the LCD is open, close it before removal.

- 5 If necessary, remove the handle and skin guard.



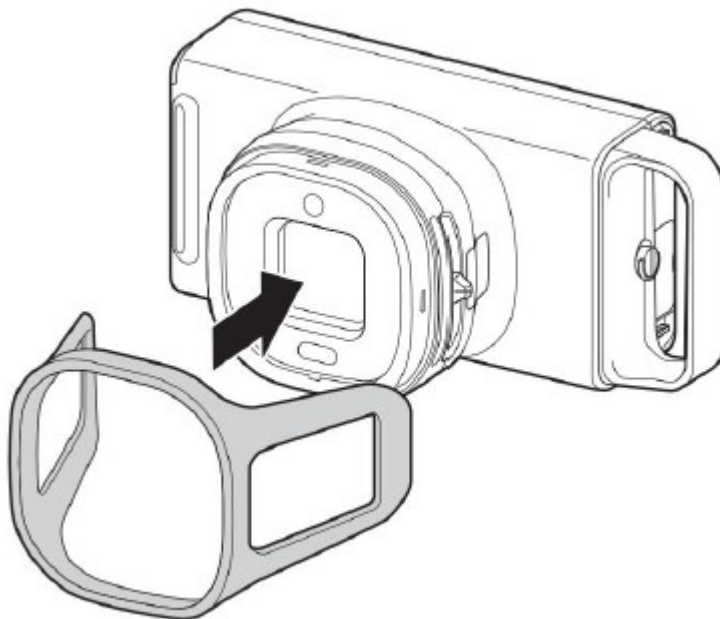
Notice

The skin guard must be worn for X-ray irradiation, so be careful not to lose it.



ヒント

The skin guard can be compactly when stored as shown below.



3.15 Cleaning-Charging

Make sure the main unit power is turned off and the AC adapter for charging is removed before cleaning.

3.16 Wireless Connection with CALNEO FLOW

This section explains how to make a wireless connection with CALNEO Flow and Console Advance (DR-ID 300CL)

- 1 Turn on the power of the panel to be connected wirelessly.



Hint

Set the panel to be connected wirelessly to Panel AP mode in advance. For details, refer to "How to use Panel AP mode" in the "Digital Radiography FUJIFILM DR CALNEO Flow System User's Manual".

- 2 Select the DR-ID 1800 panel* to which you want to connect wirelessly by following the steps in [1] of the General Settings in 4.2.



Notice

To register additional DR-ID 1800 panels, please contact our service. The panels that can be connected wirelessly are below.

DR-ID 1811SE / DR-ID 1812SE / DR-ID 1814SE / DR-ID 1831 SE / DR-ID 1832SE

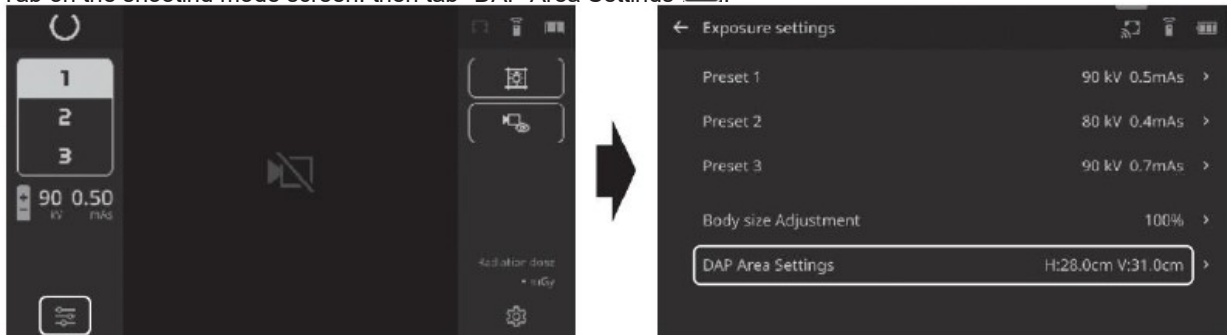
- 3 When the Wifi status display on the operation panel reads , the wireless connection is complete.

3.17 Dose

This device can calculate the X-ray irradiation area from the input collimator opening and calculate the area dose based on the shooting conditions..

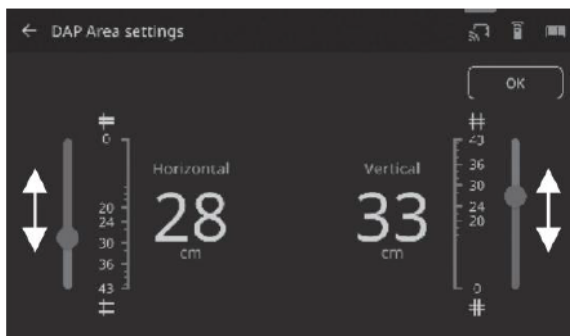
1 Preparation for input of collimator opening.

Tap on the shooting mode screen, then tap "DAP Area Settings" .



2 Input of collimator opening

After positioning, measure the collimator opening and adjust it using the slider below. When you're done adjusting, tap "OK".



Notice

The collimator opening input using the slider is for inputting the currently opened collimator opening, and is not for controlling the collimator opening with this slider.

3 X-ray irradiation

4 Dose check

Tap on the shooting mode screen, then tap "Operation log."



5 The calculated value is displayed.

← Operation log

Time	Ex. num	kV	mAs	mGy	mGy/Inch
2022/2/22 12:34:56	1234567	90	0.00	123	123.4567
2022/2/22 12:34:55	1234566	90	0.00	123	123.4567
2022/2/22 12:34:54	1234565	90	0.00	123	123.4567
2022/2/22 12:34:53	1234564	90	0.00	123	123.4567
2022/2/22 12:34:52	1234563	90	0.00	123	123.4567
2022/2/22 12:34:51	1234562	90	0.00	123	123.4567
2022/2/22 12:34:50	1234561	90	0.00	123	123.4567
2022/2/22 12:34:49	1234560	90	0.00	123	123.4567

Number of exposures
1234567

Cumulative dose
12345678
mGy

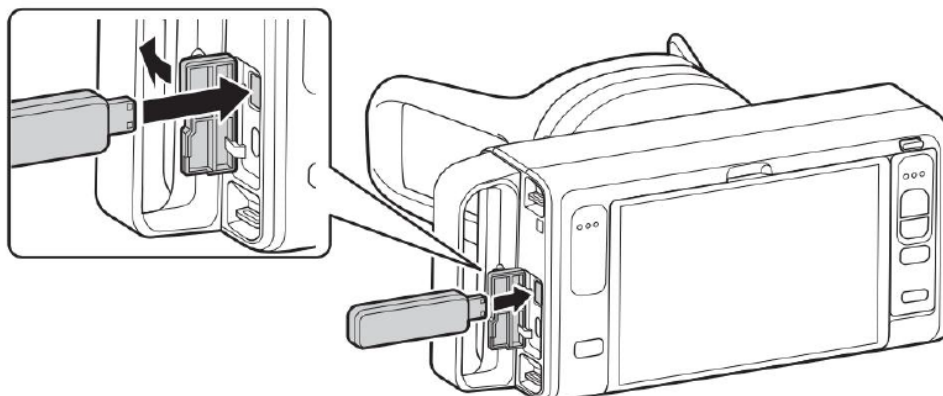
! Notice

The collimator opening set in this section will be cleared every time an X-ray is taken. If you need to calculate the collimator opening and dose, set the collimator opening each time.

Hint

You can save the operation log to a USB memory stick by clicking "Export operation log".

1. Open the USB connector cover and insert the USB memory stick.



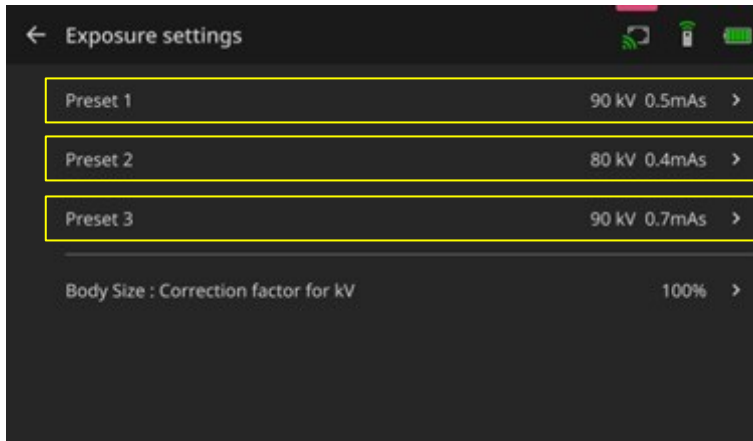
2. Tap "Export operation log" and follow the on-screen instructions.

Chapter 4 Various Setting

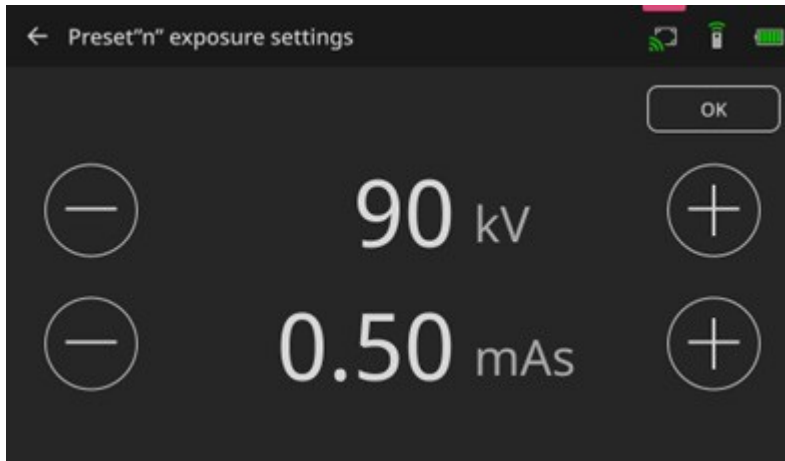
4.1 Exposure Settings

This section explains how to change the preset exposure settings.

- 1 Enter the exposure setting menu by pressing the exposure setting button.
- 2 Tap the preset you want to change.



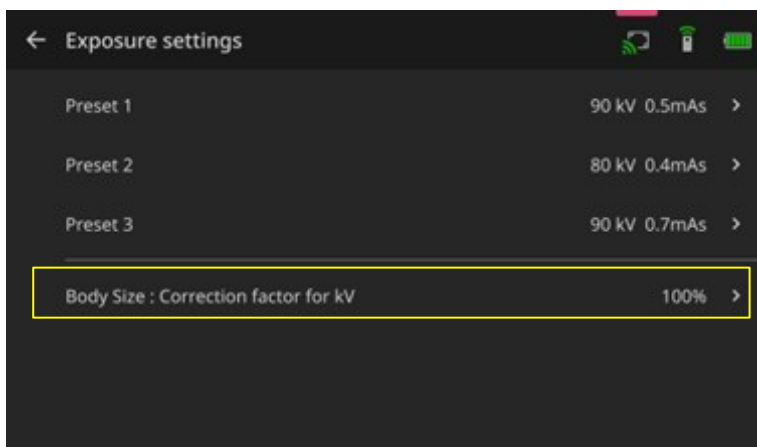
- 3 The following menu is displayed. Use the + and - buttons to change the kV and mAs values, and tap OK.



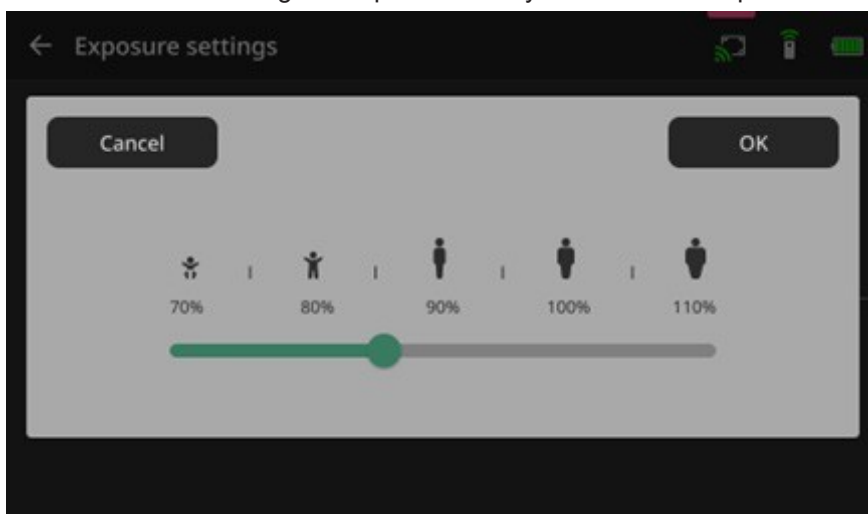
Hint

Tap the Back button without tapping OK to return without changing the preset.

4 To change the patient's body thickness condition, tap



5 Move the slide according to the patient's body thickness and tap the OK button.

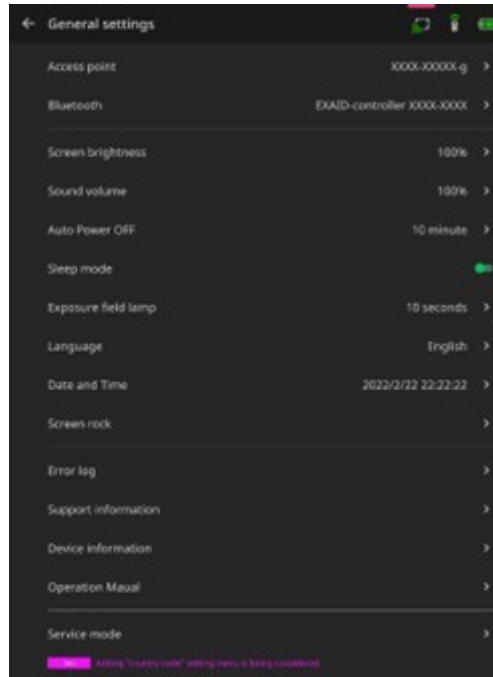


! attention

- The kV will be multiplied according to the selected body thickness. When taking an X-ray, be sure to check the X-ray conditions before exposing the X-ray.
 - Depending on the selected kV value, it may not be changed.
 - If the device is restarted or wireless communication is interrupted, the body thickness setting value will return to the default (100%).
- Please be careful.
- Please check the body thickness setting every time you take a picture.

4.2 General Settings

The following items can be set in the general settings



Setting items	Description
Access Point	Access points can be selected and deactivated.
Bluetooth	Pairing with wireless hand switch.
Screen brightness	The brightness of the operation panel can be adjusted.
Sound Volume	The volume can be adjusted.
Auto Power OFF	Time can be selected from no operation to automatic shutdown.
Sleep mode	Time from no operation to sleep can be selected.
Exposure field lamp	The lighting time of the light irradiation field can be selected.
Language	The display language can be changed.
Screen lock	You can select whether to use passcode authentication at startup or not.
Error Log	You can check the error log.
Support information	Displays support contact information.
Device Information	Displays information specific to the device.
Operating Manual	Displays the instruction manual for the device.
Service Mode	This menu is for maintenance and cannot be used.

1 Access Point

1. Tap "Access Point" to move to the access point selection screen.

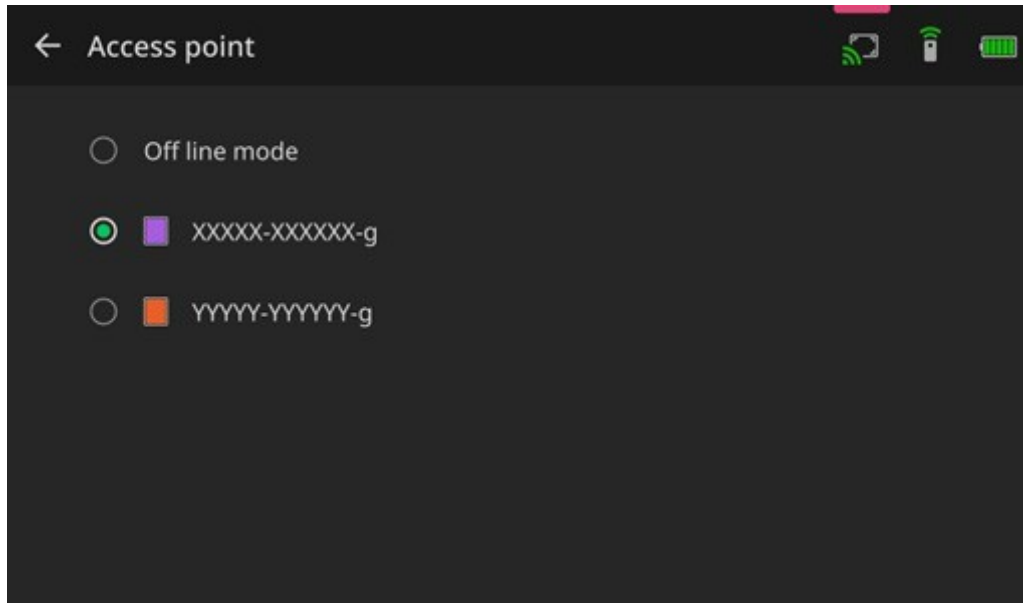


2. Select the access point (flat panel sensor) to be connected and you are done.



Hint

If your flat panel sensor is not DR-ID 1811SE / DR-ID 1812SE / DR-ID 1814SE / DR-ID 1831 SE / DR-ID 1832SE, select "Off" line mode.



Hint

The LED display color of the flat panel sensor is shown next to the radio button for reference.

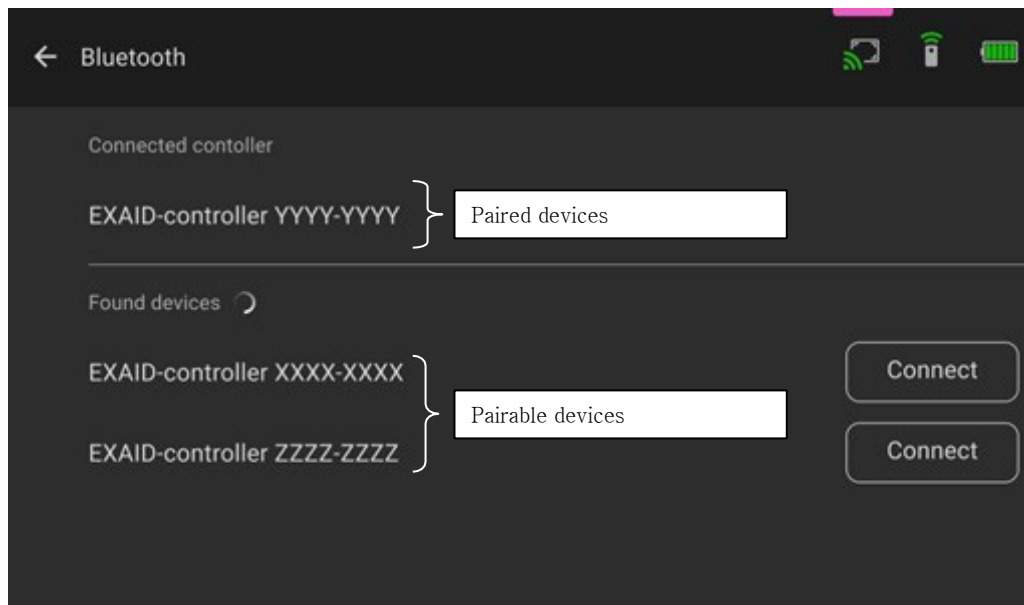
2 Bluetooth

1. Tap "Bluetooth" to go to the Bluetooth screen.



2. Tap the "Connect" button next to the device you wish to connect.

3. When the wireless hand switch to be connected appears in the paired device column, you are done.

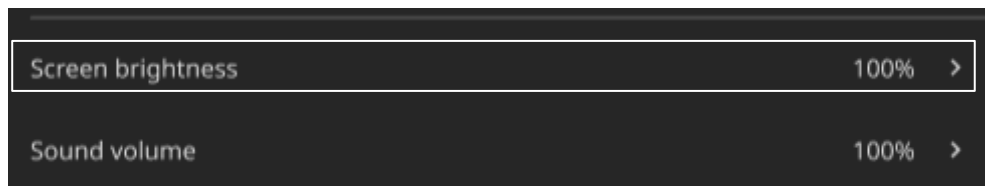


ヒント

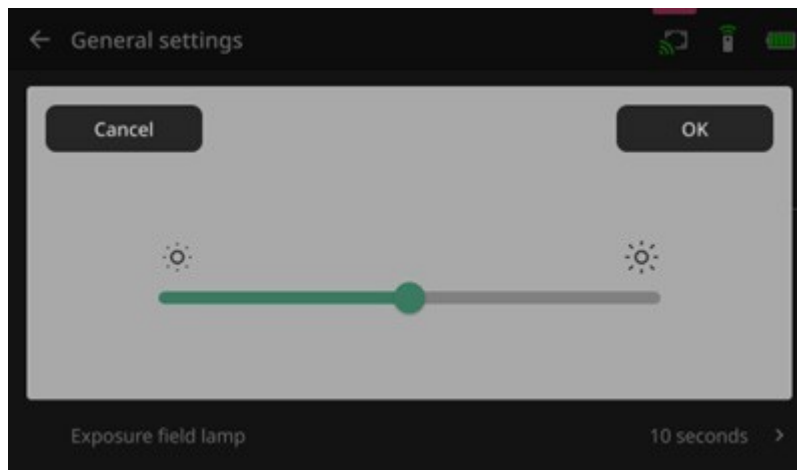
If you do not know which Bluetooth device to select, turn on/off the wireless hand switch you wish to pair with and look for one that is displayed/hidden accordingly.

3 Screen brightness

1. Tap "Screen brightness" to go to the Screen brightness screen.

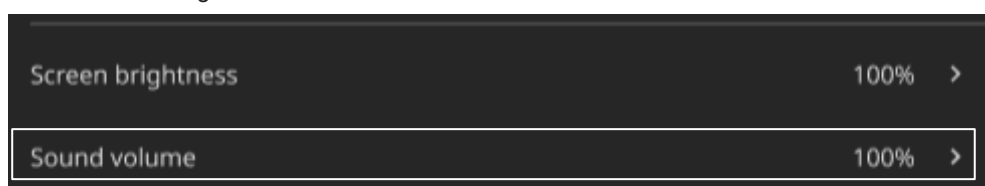


2. slide the brightness knob and tap "OK" to reflect the change. If you do not wish to make any changes, tap "Cancel".

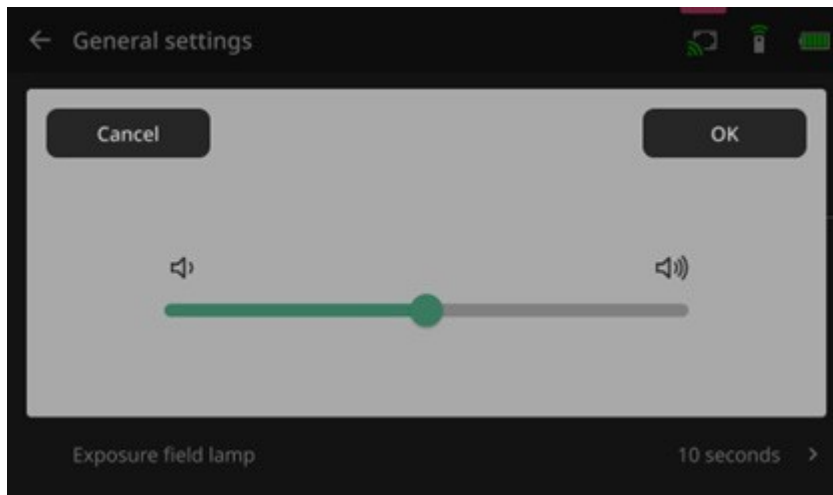


4 Sound Volume control

1. Tap "Sound volume" to go to the Sound volume screen.



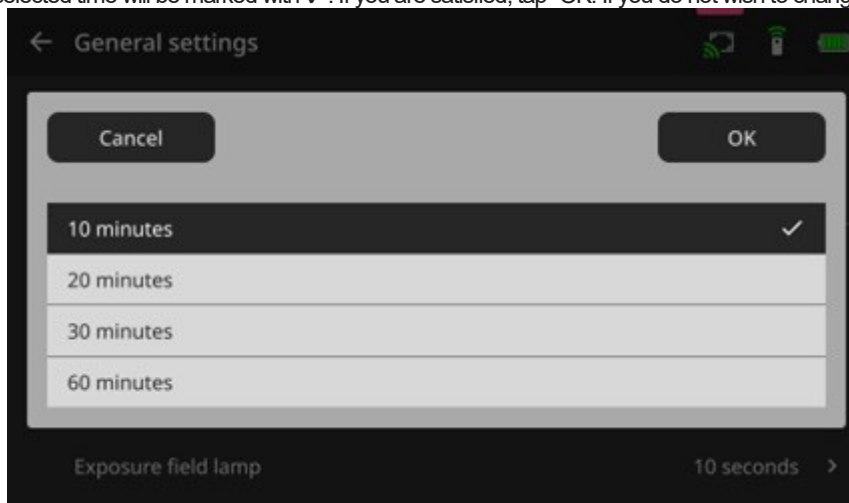
2. Slide the volume control knob and tap "OK" to reflect the change. If you do not wish to make any changes, tap "Cancel".



5 Auto Power OFF

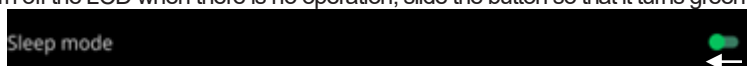
1 Tap "Auto Power OFF" to move to the Auto Power OFF screen. 2. Select the amount of time to wait before shutting down if there is no operation.

The selected time will be marked with ✓. If you are satisfied, tap "OK". If you do not wish to change the time, tap "Cancel".



6 Sleep Mode

To turn off the LCD when there is no operation, slide the button so that it turns green



7 Exposure field lamp

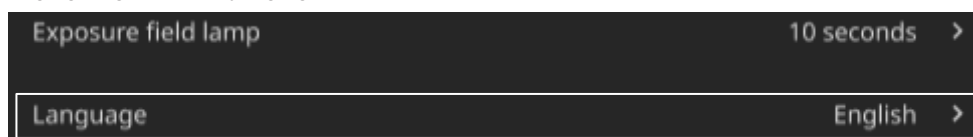
Tap "Exposure field lamp" to go to the Exposure field lamp screen. 2. 2. set the exposure time when you press the Exposure button.

Tap "OK" if you are satisfied with the selected time. If you do not wish to change the time, tap "Cancel" or tap ← (Back).



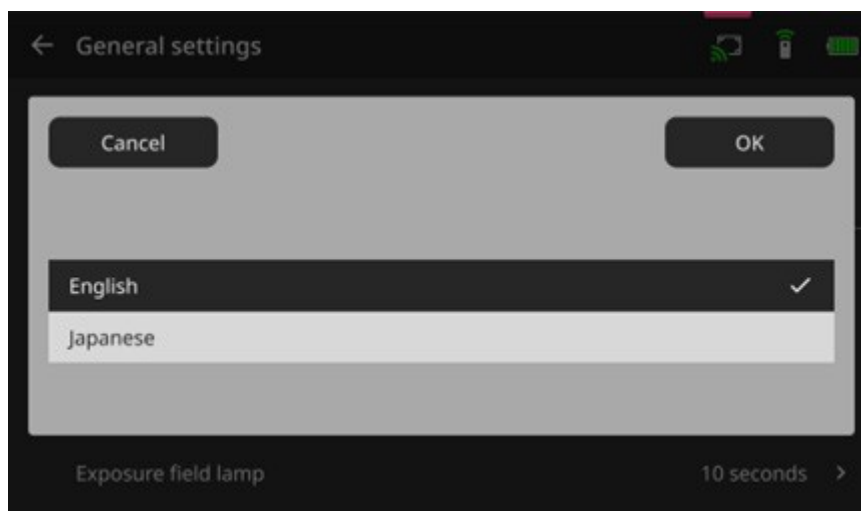
8 Languages

1. tap "Language" to go to the display language screen.

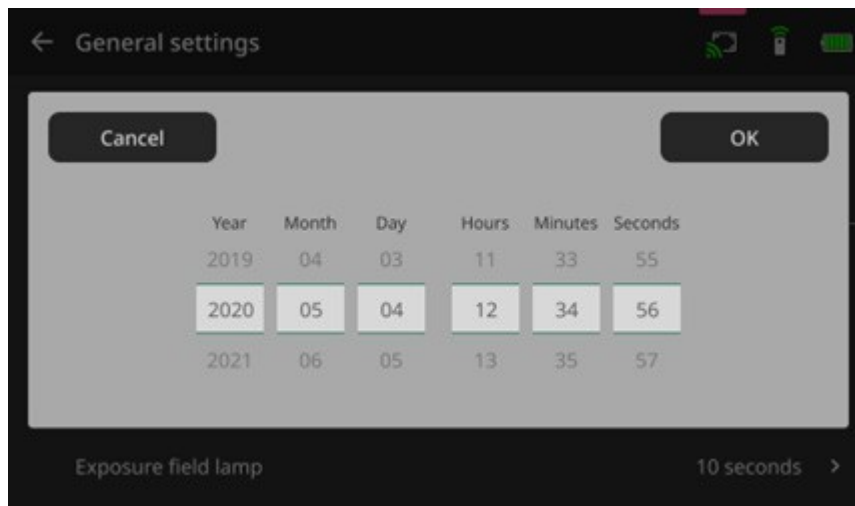


2. Select the display language.

A ✓ will appear for the language you selected. Tap "OK" if you are satisfied. If you do not wish to change the language, tap "Cancel".

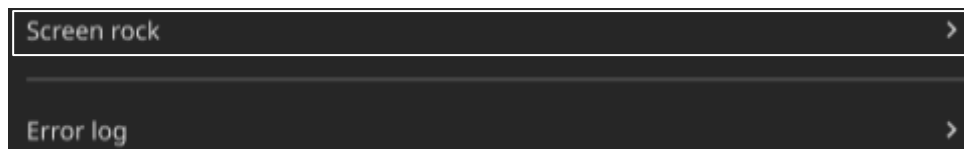


9 Date and Time



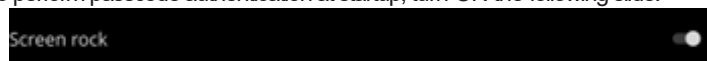
10 Screen Lock

1. Tap "Screen Lock" to go to the passcode authentication setting screen.

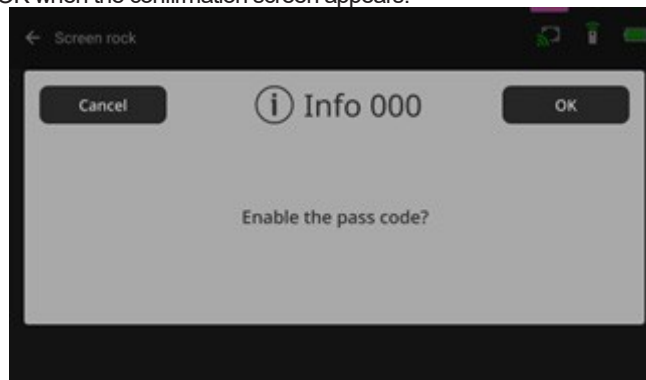


2. passcode authentication setting

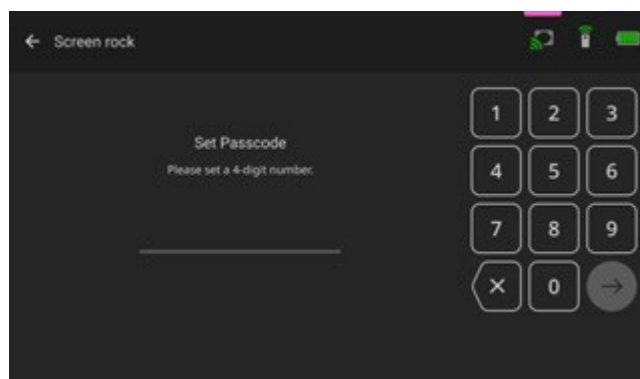
(1) To perform passcode authentication at startup, turn ON the following slide.



Tap OK when the confirmation screen appears.



Enter the passcode (4 digits) and tap . Tap OK when the passcode setting completion message is displayed.





Hint

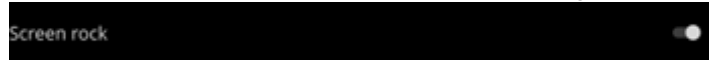


Tap to return to the screen in (1).

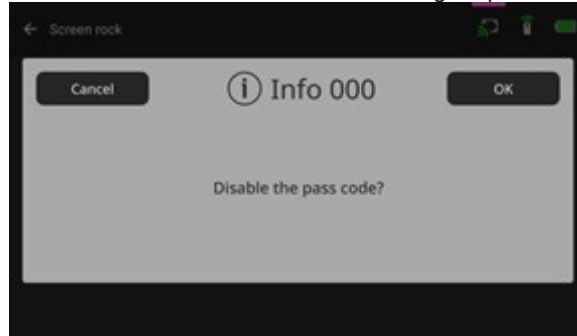
To correct an entry, tap  to delete one character.

3. unlock passcode

(1) To cancel passcode authentication at startup, turn off the following slide.



Tap OK when the confirmation screen for canceling the passcode is displayed.



Tap Cancel to return to the screen in (1).

Enter the passcode and tap .



Hint



Tap to return to the screen in (1).

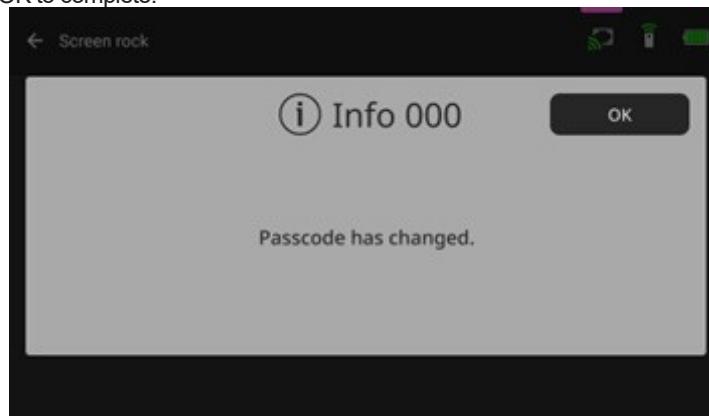
To correct an entry, tap  to delete one character.



Notice

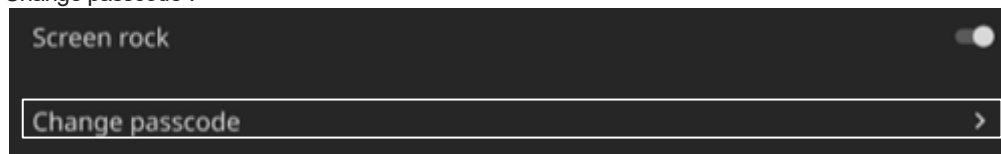
If the passcode is wrong three times in a row, the system will automatically shut down.

Tap OK to complete.

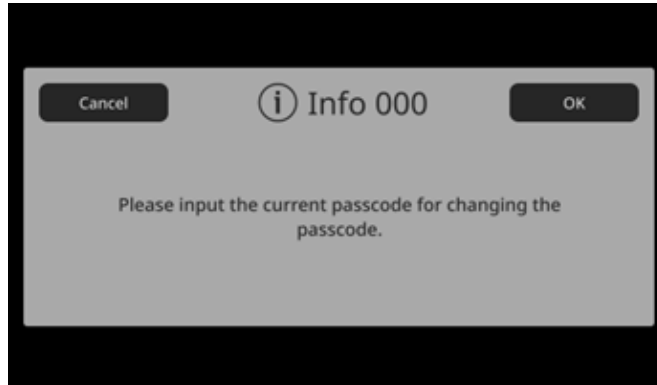


4. passcode change

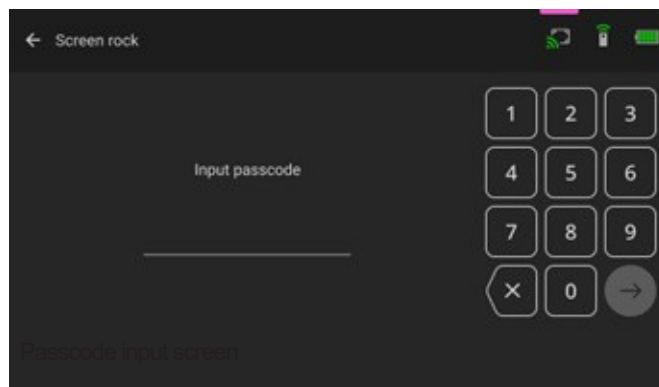
Tap "Change passcode".



Tap OK when prompted to enter the current passcode, then tap  after entering the passcode.

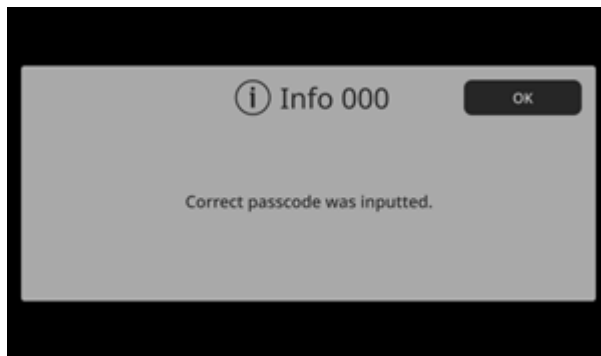


passcode entry message

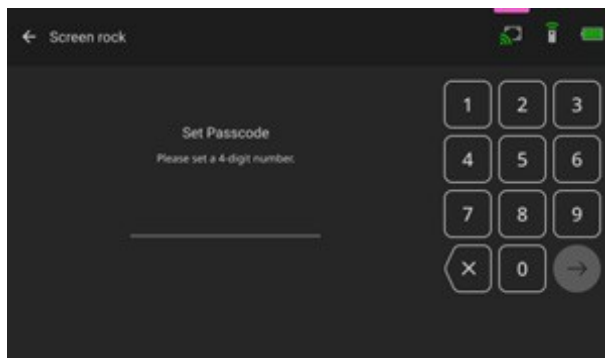


If the passcode is wrong three times in a row, the system will automatically shut down.

Tap OK, then enter the new 4-digit passcode and tap .

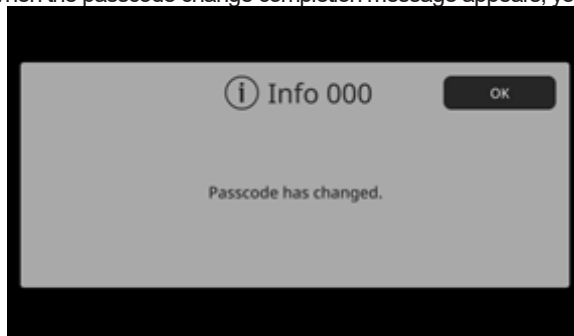


passcode entry success indication



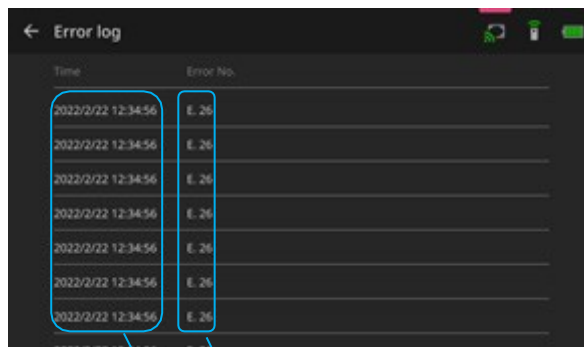
New passcode entry screen

When the passcode change completion message appears, you are done.



11 Error Log

Displays error logs.

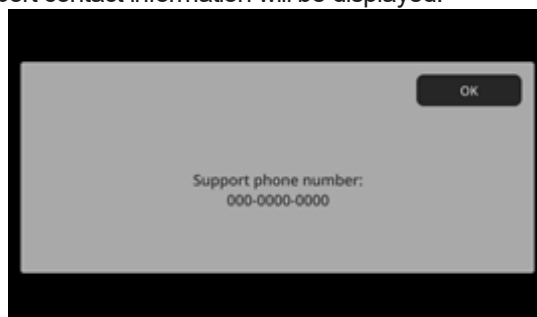


Error Code. See Chapter 5 Troubleshoot for more information.

Time of error.

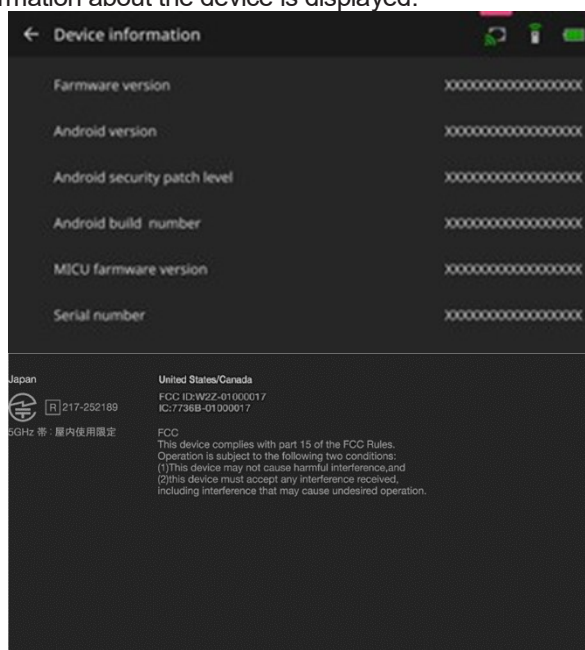
12 Support Information

Support contact information will be displayed.



13 Device Information

Information about the device is displayed.



14 Operating Manual

Displays the instruction manual.

15 Service mode

This menu is for maintenance and inspection and cannot be used.

Chapter 5 Trouble shooting

5.1 If an Error is displayed on the X-ray Generator

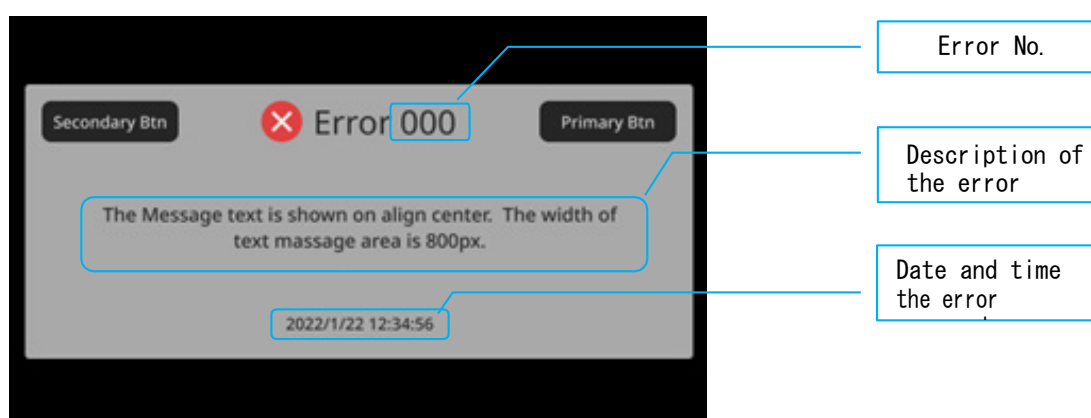
This subsection provides explanations about warnings and error messages.

If an unresolvable error has occurred or the same error frequently occurs, contact our official dealer.

If an error of unknown cause has occurred, immediately turn the power off and contact our official dealer.

5.1.1 Warnings and Error Messages

Warnings and error messages will be displayed like shown in the figure below.



5.1.2 Warning description

Warning/ error No.	Description	Countermeasure
005	The power of the device was turned on with the X-ray exposure button on the wireless hand switch pressed.	Check whether or not the X-ray exposure button on the wireless hand switch is pressed. If this error occurs repeatedly, contact our official dealer or FUJIFILM Representative.
006	The power of the device was turned on with the radiography preparation button on the wireless hand switch pressed.	Check whether or not the radiography preparation button on the wireless hand switch is pressed. If this error occurs repeatedly, contact our official dealer or FUJIFILM Representative.
007	The power of the device was turned on with the radiography preparation button on the wired hand switch pressed.	Check whether or not the X-ray exposure button on the wired hand switch is pressed. If this error occurs repeatedly, contact our official dealer or FUJIFILM Representative.
008	The power of the device was turned on with the X-ray exposure button on the wired hand switch pressed.	Check whether or not the radiography preparation button on the wired hand switch is pressed. If this error occurs repeatedly, contact our official dealer. If this error occurs repeatedly, contact our official dealer or FUJIFILM Representative.
009	Exposure was interrupted since the X-ray exposure button was released before the exposure was completed.	If this error occurs repeatedly, contact our official dealer or FUJIFILM Representative.

Warning/ error No.	Description	Countermeasure
011	Abnormality was detected in the tube voltage feedback signals while X-ray was not irradiated.	Contact our official dealer or FUJIFILM Representative.
012	Abnormality was detected in the tube current feedback signals while X-ray was not irradiated.	
013	Abnormality was detected in the filament current feedback signals while X-ray was not irradiated.	
014	Abnormality was detected in the filament current feedback signals while exposure preparation was completed.	
015	The actual tube voltage is 40kV or less.	
016	The actual tube current is 2mA or less.	
017	The actual tube voltage is 100kV or more.	
018	The actual tube current is 7.5mA or more.	
019	The actual tube voltage is 10% or less of the set value.	
020	The actual tube voltage is 10% or more of the set value.	
021	The X-ray tube is hot.	Turn off the device, wait for 1.5 hours or more, turn on the device, and then check whether exposure can be performed under the conditions of 50kV and 0.2mAs. If the error persists or exposure cannot be performed, contact our official dealer or FUJIFILM Representative with the following information.
022	The actual tube current is 10% or less.	Contact our official dealer or FUJIFILM Representative.
023	The actual tube current is 10% or more.	
024 Warning	The radiography preparation button was pressed while the door interlock was open.	When the door interlock is in use, check the connection.
025	Abnormality was detected in the internal circuit of the device.	Contact our official dealer or FUJIFILM Representative.
027 Warning	The X-ray exposure button was pressed while the door interlock was open.	When the door interlock is in use, check the connection.
028	Abnormality was detected in the duration of X-ray irradiation.	Contact our official dealer or FUJIFILM Representative.
100 Warning	The battery is depleted. Charge it or replace it with a new charged battery.	
101 Warning	Failed to load instruction manual did	Please go back to "General Settings" and try again.
102 Warning	Failed to output log.	
103 Warning	Instruction manual installation failed	

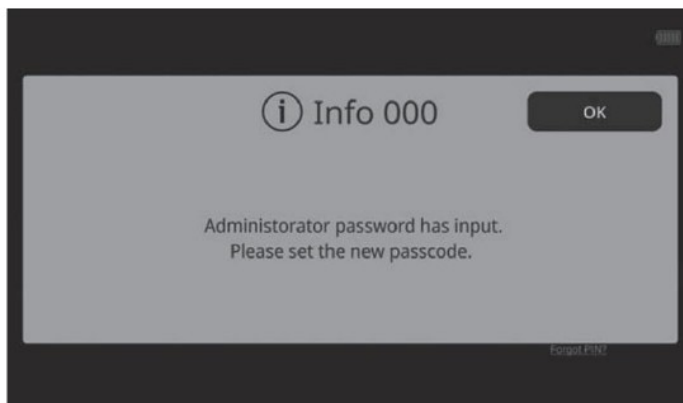
If an error other than those above has occurred, contact our official dealer or FUJIFILM Representative.

* When contacting our official dealer or FUJIFILM Representative, please inform the error number, use frequency of the device, and occurrence frequency of the error.

5.2 When Something Went Wrong

5.2.1 Forgotten your passcode?

If you forget your passcode, you can change it by entering the administrator passcode. Enter [874284] on the passcode entry screen, press OK on the following screen, and enter a new passcode.



5.2.2 If the System Does Not Become Ready for Exposure When the Radiography Preparation Button Is Pressed

When the wireless hand switch is in use: The wireless hand switch is in use.

1. Check the wireless hand switch status and confirm that the wireless hand switch is able to communicate with the XD4000 PX through wireless connection.

If the wireless hand switch is able to wirelessly communicate with the XD4000 PX, go to 2.

Otherwise, follow 5.2.2 and see if the system transitions into a radiography preparation completed state.

2. If radiography preparation does not complete even if the wireless hand switch is able to wirelessly communicate with the XD4000 PX, connect the wired hand switch supplied and hold down the radiography preparation button to see if radiography preparation completes.

3. Turn off the power to the camera once, then press the camera's hand switch's shooting preparation button again to complete the shooting preparation. Please check if this is the case.

When the wired hand switch is in use: The wired hand switch is in use.

1. Reconnect the wired hand switch and hold down the radiography preparation button to see if radiography preparation completes.

2. If radiography preparation does not complete, pull out the wired hand switch connector and press down the radiography preparation button on the wireless hand switch to see if radiography preparation completes.

3. If the problem still persists, contact our official dealer.

5.2.3 If the XD4000 PX Is Unable to Communicate with the Wireless Hand Switch through Wireless Connection

1. Check the power status LED on the wireless hand switch. If the power is off, hold down the power button on the wireless hand switch to turn the power on. If the battery level is low, replace the batteries (see 3.1.5).

2. Check if something is obstructing wireless communication between the wireless hand switch and

the XD4000 PX. If wireless communication is obstructed, remove the obstruction and check the wireless hand switch status again.

3. Check if any other product near this device is using Bluetooth. If any products are found to be using Bluetooth, move them away from the device and check the If any products are found to be using Bluetooth, move them away from the device and check the wireless communication status.
4. Pair the wireless hand switch to the XD4000 PX. See[4.2 General Settings].
5. If the problem still persists, contact our official dealer or FUJIFILM Representative.

5.2.4 X-ray Images Are Not Displayed after Exposure

1. Confirm that a wireless connection is established between this device and Console Advance.
2. If a wireless connection is not established, check the Wi-Fi status of this device and the wireless communication status of Console Advance, and follow the table below to address the issue.

Console Advance X-ray image display	Wireless Status		CANLEO Flow Status LED	Action to take
	Console Advance	This device		
None	O	O	green	Check that the collimator is not closed. The subject's body thickness may not be appropriate.
	O	O	white	Check if the Console Advance menu is registered. Make sure there are no metal objects near this device, Console Advance, or CALNEO Flow.
	O	O	red	This is a malfunction of the CALNELO Flow Please check the instruction manual.
	O	X		The AP selection for this device may not be appropriate. Please check The radio waves of this device may be blocked. Check that it is not blocked by metal objects.
	X	O		The Console Advance selector is not appropriate. It's possible. Please check. The Console Advance radio waves may be blocked. It may be possible that the equipment is not shielded by metal objects. Check whether the wireless is turned off.Console Advance Please check the status.
	X	X		The operation mode of CALNEO Flow may not be appropriate. It is possible that the device is in AP mode. •The CALNEO Flow signal may be blocked. Yes. It may not be shielded by the patient. Is it blocked by a waterbed or other object? Please confirm.
Can be	O	O		

○: Able to communicate through wireless connection

×: Unable to communicate through wireless connection

5.2.5 If the touch panel is not responding

Clean with a dry cloth. A dirty LCD may reduce its sensitivity.

5.2.6 If kV and mAs conditions different from the set kV and mAs conditions are displayed

Please check if the body thickness condition is set to 100%. If it is not, set it to 100%.

If the display conditions are different when the value is 100%, the kV and mAs settings may not be correct.

So please set it again.

Also, if you have associated a preset with a Console Advance shooting menu, the setting will change according to the shooting menu. The associated preset is automatically selected.

Chapter6 Daily Inspection and Maintenance

6.1 Daily User Inspection and Maintenance

During maintenance and inspection, strictly observe precautions contained in "Chapter 1 For Safe Operation" in this manual During maintenance and inspection, strictly observe precautions contained in "Chapter 1 For Safe Operation" in this manual.

6.1.1 Daily Inspection

Be sure to inspect the following items before use and ensure that the equipment is not faulty. If any abnormality is found in the equipment, do not use the equipment.

Inspection Before Use

Item	Inspection Work
Exterior	Check that the cover is free from breakage including cracks. Check that each cord, especially the cord for the hand switch, is free from damages such as twists or breakage of sheath.
Shoulder strap	Check that the shoulder strap is free from damages such as rips, frays, tears and deformation.
Skin guard	Press the radiography preparation button with skin guard removed, and confirm That radiography preparation does not complete. Check that the SSD status LED turns on and off when a skin guard is attached and detached.
Collimator	Press the light field button to make sure that the light field is lit. Check that the X-ray radiation window of the collimator is free from adhesion of dirt or foreign matter.
Battery	Make sure that at least three battery indicators are lit. If it's below that, please charge it.

Cleaning Before Use

To clean the outer surfaces, use a cleaning cloth tightly wrung out of commercially available ethanol.



CAUTIONS

- Be sure to turn off the power before performing cleaning and disinfection of the X-ray generator. If the power is left on, it may result in unintended operations.
- Do not use an excessive amount of ethanol, as doing so may allow the liquid to enter from the gap on the outer surfaces, resulting in the damage to the equipment, or cause the labels to come off. Make sure not to let ethanol get inside the equipment.
- Do not use a solvent such as thinner or benzine, as it corrodes the outer surfaces.
- Use dehydrated ethanol or ethanol diluted with purified water.
- When cleaning or disinfecting the operation panel, observe the following precautions.
 - Do not rub or hit the operation panel with something hard since it can easily be scratched.
 - If any dust adheres to the operation panel, wipe it off with a soft cloth moistened with water.
- When cleaning the AC adapter, unplug the cable from the outlet. If cleaning is performed while the power is on, it may cause an electric shock.

6.1.2 Term of Validity/Period for Use (Durability) of XD4000 PX

The term of validity (durability) is 6 years from first use of the X-ray generator, provided that the precautions for use are followed and that the X-ray generator undergoes regular maintenance and inspection. "Based on our company's criteria".

6.1.3 Aging

All portable x-ray units require aging to protect the x-ray tube from an instant surge of current that may damage your device and to insure the longevity and continued safe operation of your system. Aging of the x-ray tube is required before use.

The following aging procedure is recommended.

Wear appropriate protective equipment and install the equipment where safety against radiation is secured.

To perform aging of the filament of the X-ray tube, make X-ray exposures at intervals of 15 seconds.

- (1) 1st time: 3 consecutive exposures at 50kV/1.0mAs
- (2) 2nd time: 3 consecutive exposures at 60kV/1.2mAs
- (3) 3rd time: 3 consecutive radiations at 90kV/2.0mAs



CAUTIONS

- If aging has not been done, the X-ray tube unit may cause electric discharge when exposure is performed.
- The overcurrent protection circuit may activate and cause an error during aging. If that happens, turn the power off and on to recover from the error, and perform aging. If the error occurs frequently, contact our official dealer.
- Pay attention not to cause exposure to any nearby persons during aging.
- Pay attention not to irradiate radiography devices during aging.

6.2 Maintenance and Inspection Items Assigned to Specified Dealer

For safety of patients, users and third parties, please carry out regular maintenance inspections.

This will be carried out by our official dealer.

6.2.1 Periodical Maintenance

Maintenance and Inspection Items Assigned to Specified Dealer

Periodical Maintenance and Inspection Items	Period
Check of exterior and operation panel	Every year
Check of all display devices	Every year
Check of all functions	Every year
Check of exposure dose	Every year
Check of error logs	Every year
Check of the number of exposures	Every year
Battery performance	Every year

Appendix A Specifications

A.1 Specifications

Specifications of the XD4000 PX are shown below.

A.1.1 X-ray Generator

Item		Specification
Input power	Equipment power supply	DC11.1V $\pm$ 0.1V / 2000mA
	Charger power supply	AC100 - 240V, 50/60Hz, 1.5A
Output power		450W (90kV/5mA)
Tube voltage range [kV]		50 to 90kV (in 2kV steps)
Tube current time product setting range [mAs]		0.20 to 2.50 mAs (12 steps) (0.20, 0.25, 0.32, 0.40, 0.50, 0.63, 0.80, 1.00, 1.25, 1.60, 2.00, 2.50)
Tube voltage [mA]		5mA (fixed)
APR (Anatomical Programmed Radiography)		3 memories
Maximum deviation	kV	$\pm$ 4%
	mAs	$\pm$ 10%
Display		LCD panel
X-ray tube	Model name	OX80-0.8
	Focal spot size	0.8 $\times$ 0.8mm
	Target angle	16° (target angle)
	Inherent filtration	0.5mm Al at 75kV
	Anode heat storage	8.0kJ (10.0kHU)
Collimator	Type	Double slit type, manual operation
	Minimum X-ray field size	$\leq$ 5 $\times$ 5cm @ 100cm SID
	Maximum X-ray field size	$\geq$ 43 $\times$ 43cm @ 100cm SID
	Illumination period	30 sec. (This setting can be changed to 10 sec. or 20 sec. in the general setting), automatic off timer
	Lamp	3.3V LED lamp
Added filter		Permanent filtration : 1.0 mm Al eq. Added filter : 1.5 mm Al Added filter : 0.1mm Cu
Total filtration		2.5mmAl/70kV (minimum) (without the added filter)
Dimensions		301 x 257 x 144mm
Weight		3.8kg $\pm$ 5
Battery		Lithium polymer, 11.1V, 2000mAh(Model : PFF-031P)
Total mAs value acceptable in 1 hour		100mAs/h
The nominal highest tube voltage and the highest tube current obtainable at the nominal highest tube voltage		90kV, 5mA
The highest tube current and the highest tube voltage at which the highest tube current is obtainable		90kV, 5mA
The combination of the tube voltage and the tube current which results in the highest electric output power		90kV, 5mA
Wired hand switch connector Number of insertions/pullouts		200 times



The specification, dimensions and weight are subject to change for improvement without prior notice.

A.1.2 Information of receive RF electromagnetic energy

• Reception frequency band and bandwidth

Device	Frequency band	Frequency range	bandwidth
XD4000 PX, XD4000 RS	BLE	2.4GHz	1M
XD4000 PX	2.4GHz	2.4GHz	20 MHz
XD4000 PX	5.2GHz	5150 ~ 5250 MHz	20, 40, 80 MHz
XD4000 PX	5.8GHz	5725 ~ 5825MHz	20, 40, 80 MHz

• Transmit frequency band

Device	Frequency band	Frequency range
XD4000 PX, XD4000 RS	BLE	2.4GHz
XD4000 PX	2.4GHz	2.4GHz
XD4000 PX	5.2GHz	5150 ~ 5250 MHz
XD4000 PX	5.8GHz	5725 ~ 5825MHz

• Frequency characteristics of the modulation : IEEE 802.11a/b/g/n/ac

• EFFECTIVE RADIATED POWER

Device	Frequency band	EFFECTIVE RADIATED POWER
XD4000 PX, XD4000 RS	BLE	$\leq 10 \text{ dBm}$
XD4000 PX	2.4GHz	$\leq 20 \text{ dBm}$
XD4000 PX	5.2GHz	$\leq 23 \text{ dBm}$
XD4000 PX	5.8GHz	$\leq 30 \text{ dBm}$



CAUTIONS

FCC:

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.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

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

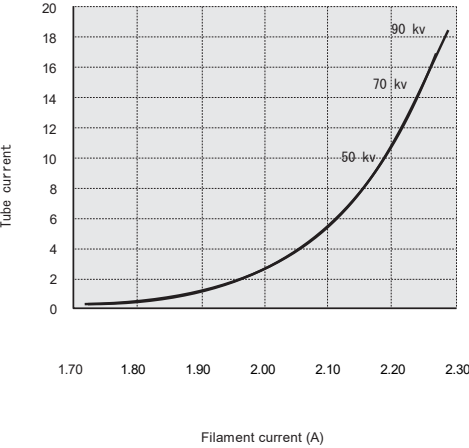
A.1.3 X-ray Tube Assembly Support Section

■ General specification

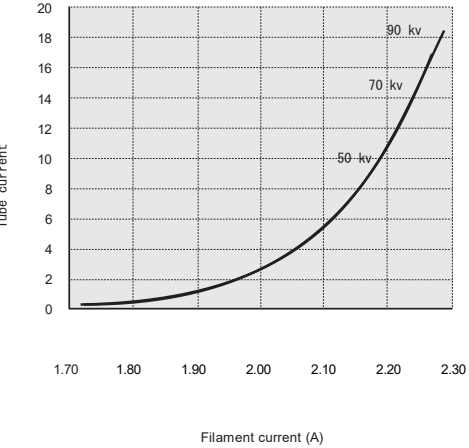
Model name (manufacturer)	OX80-0.8(Skan-X Radiology Devices S.p.A.)
Tube voltage range	50 to 90kV
Focal spot size	0.8 × 0.8mm
Input power (0.1 sec.)	1280W
Anode heat index	8 kJ (10 kHU)

■ Filament characteristic curve

EMISSION CHARACTERISTICS DC

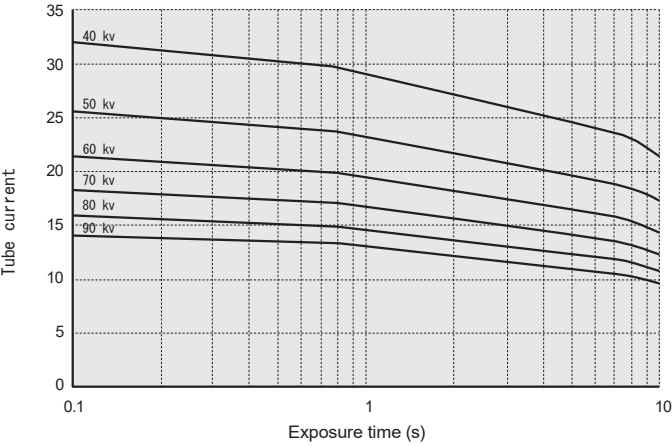


EMISSION CHARACTERISTICS DC

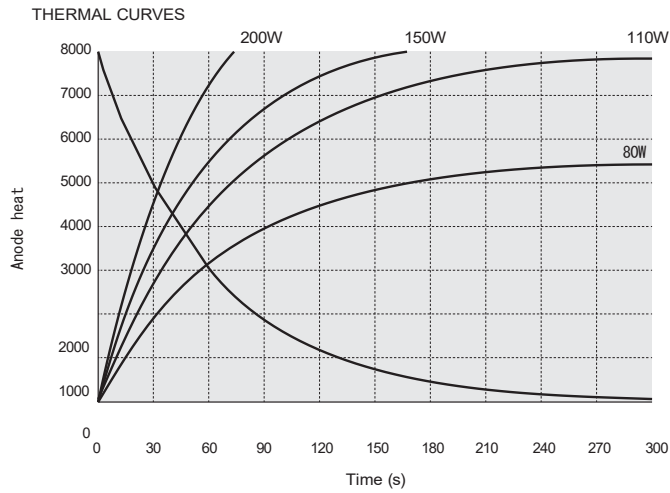


■ Maximum output graph

RATING CHARTS DC

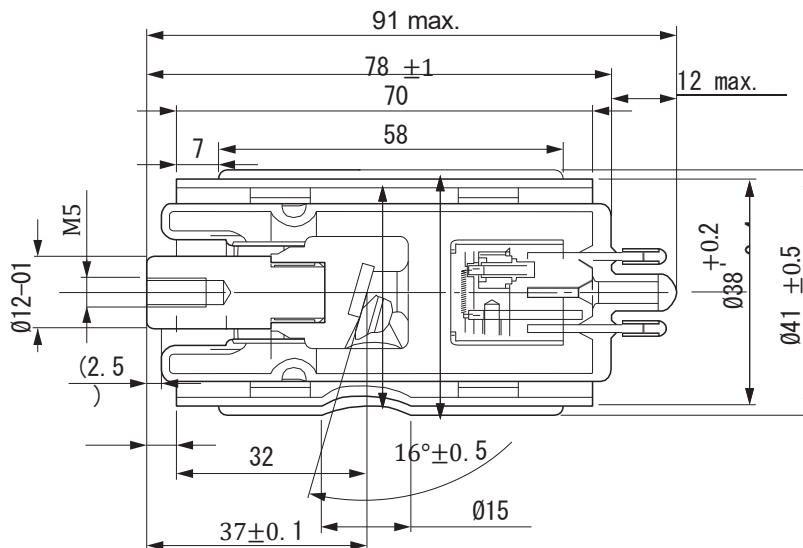


■ Anode heat characteristic curve



200 shots/h (90kV, 0.5 mAs, at intervals of 18 seconds)

■ Dimensions



A.1.4 Environmental Conditions

(1) Operating Environment

Temperature range : 15°C - 30°C

Humidity range : 15%RH - 80%RH

Atmospheric pressure range : 700hPa - 1060hPa

(2) Transport and Storage Environment

Temperature range (with battery) : -10°C - 50°C

Humidity range : 10%RH - 90%RH

Atmospheric pressure range : 700hPa - 1060hPa

A.1.5 Entrance Surface Dose Reference Values

The reference values of the entrance surface dose under typical exposure conditions are listed below.
(Accuracy : under 35%)

Exposure menu name	Specification	kV	mAs	Entrance surface dose[mGy]
Chest-Front	Normal	90	0.50	0.076
Abdomen-Front	Normal	90	2.5	0.391
Hand	Normal	50	2.0	0.082

The reference values of the entrance surface dose under typical exposure conditions are listed below.

• Distance between the focal spot and the image receptor	100 cm
• Acrylic phantom (Length x Width x Thickness)	25 cm x 25 cm x 20 cm
• Collimator radiation field (Length x Width)	43 cm x 43 cm
• Dosimeter	Ionization chamber type, RAMTEC 1000plus(RAMTEC)
• Environmental conditions	Temperature 19°C, Atmospheric pressure 1013 hPa, Humidity 33%



Notice

Periodic verification is required for the above reference values to be maintained/used.

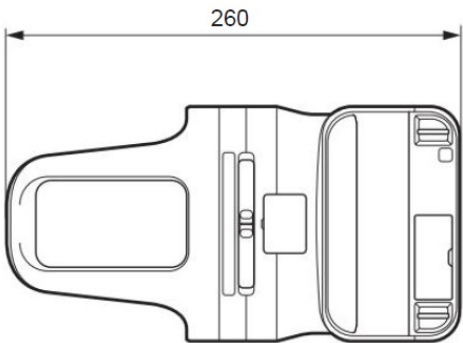
A.2 External View and Weight



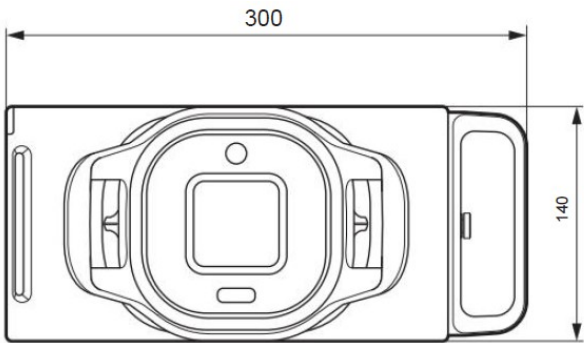
Specifications, dimensions and weight are subject to change for improvement without prior notice.

A.2.1 X-ray Generator

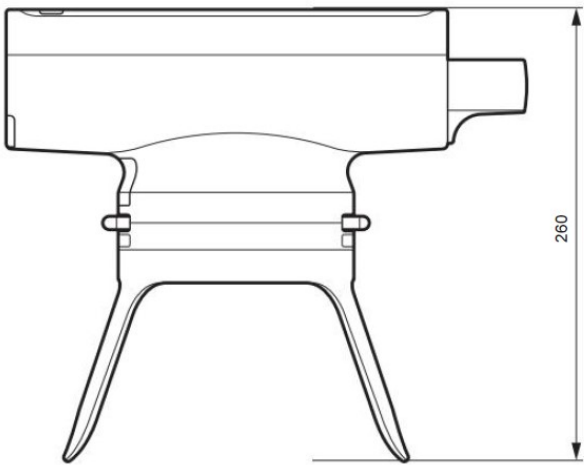
	Width (mm (in.))	Depth (mm (in.))	Height (mm (in.))	Weight (kg (lb))
XD4000 PX	300(11.8)	260(10.2)	140(5.5)	3.8(8.4)



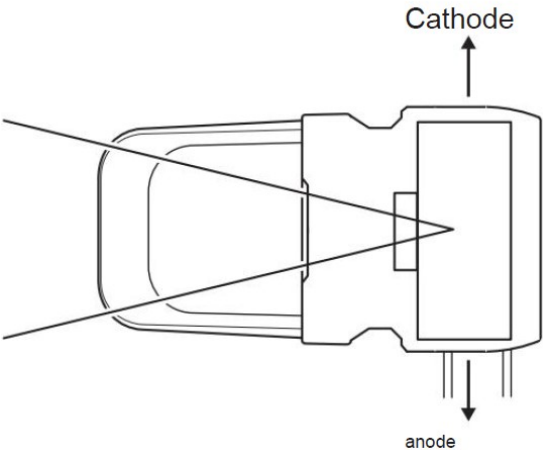
Side View



Front View

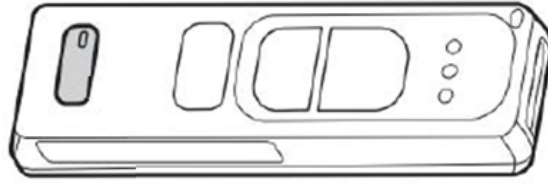


Bottom View



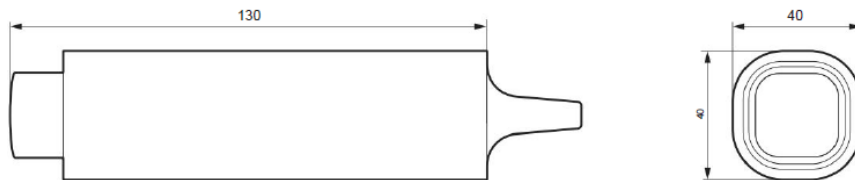
A.2.2 Wireless handswitch

	Width (mm (in.))	Depth (mm (in.))	Height (mm (in.))
Wireless handswitch	27(1.06)	97.5(3.38)	15(0.59)



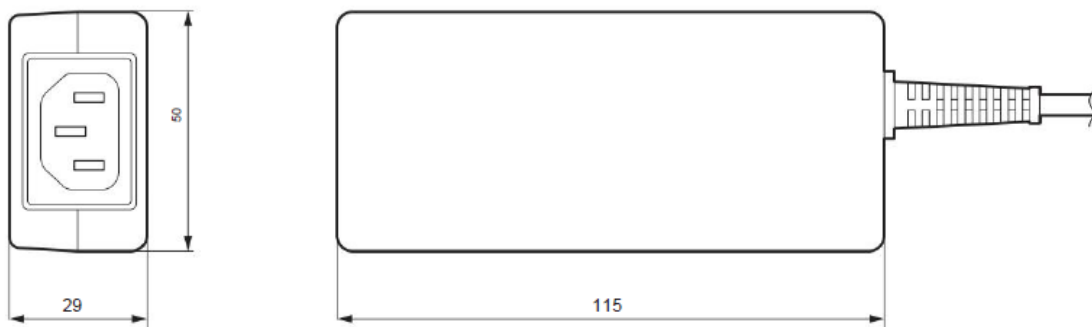
A.2.3 Wire handswitch

	Width (mm (in.))	Depth (mm (in.))	Height (mm (in.))
Wire handswitch	130(5.11)	40(1.75)	40(1.75)



A.2.4 AC adapter

	Width (mm (in.))	Depth (mm (in.))	Height (mm (in.))
AC adapter	115(2.92)	50(1.96)	29(1.14)



MEA-065Z15BA

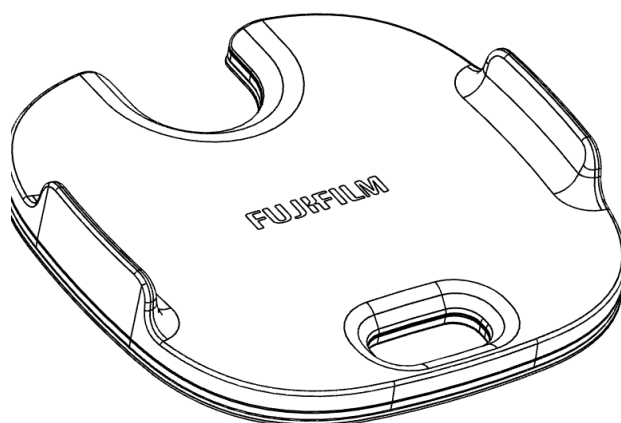
A.2.5 Battery Charger

	Width (mm (in.))	Depth (mm (in.))	Height (mm (in.))
Battery Charger	102.4(4.0)	142.6(5.6)	48(1.88)



A.2.6 Added Filter

		Width (mm (in.))	Depth (mm (in.))	Height (mm (in.))
Added	(0.1mm Cu)	106.4(4.18)	107.1(4.2)	17(0.67)



Appendix Z Precautions for Exposure

Z.1 Information on Radiation

Z.1.1 Radiation Protection

The operator has an obligation to follow the local laws and regulations to minimize radiation exposure to the patients and medical professionals. For persons other than patients, a minimum distance from the equipment is specified in each area.

Z.1.2 Deterministic Effects

Among the tissues which are considered important from the perspective of radiation protection, skin, crystalline lens and gonads are especially vulnerable to deterministic effects of radiation exposure even at low dose levels. The threshold dose for skin injuries is 3 Gy or more, that for crystalline lens opacities is 1 Gy or more, and that for gonadal disorders is 0.15 Gy or more.

When an exposure is made under the conditions which maximize the entrance surface dose (90kV, 2.5mAs, SID = 100cm), the reference value of the entrance When an exposure is made under the conditions which maximize the entrance surface dose (90kV, 2 5mAs, SID = 100cm), the reference value of the entrance is 300uGy.

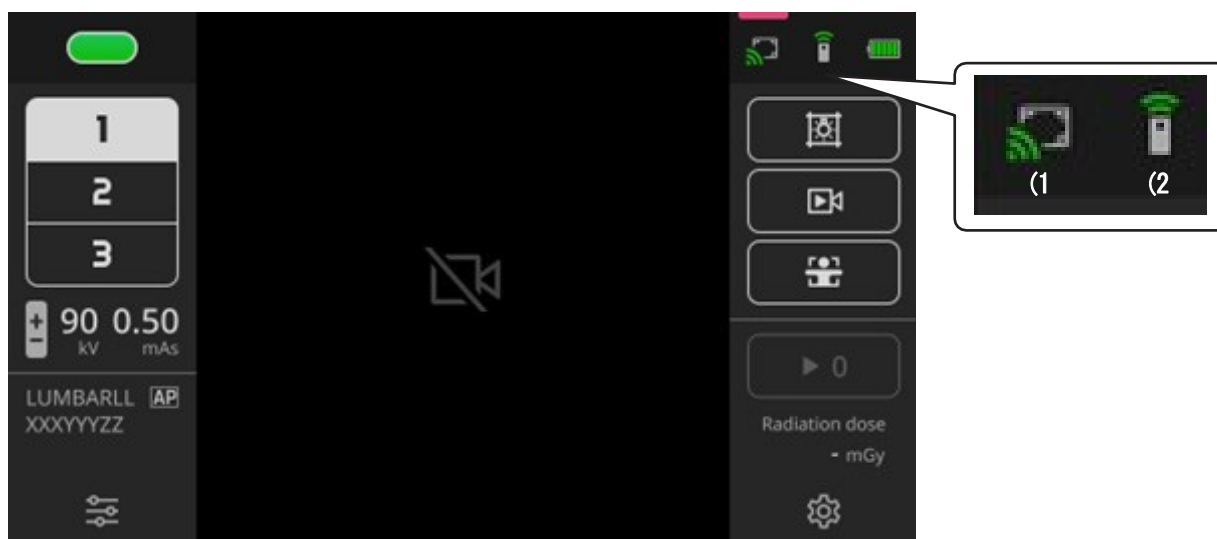
During an examination, if 500 or more consecutive exposures are made under the conditions which maximize When using the equipment, the operator should control the exposure dose appropriately, considering deterministic effects.

Z.1.3 Precautions for Assuring the Radiation Field

Especially when the high tube voltage is set, the radiation field size should not be larger than the subject unless necessary. Especially when the high tube voltage is set, the radiation field size should be larger than the subject unless necessary.

Z.2 Precautions for When Using Devices in Wireless Communication Mode

Care should be taken when the devices are used in wireless communication mode. Thoroughly read the following precautions in order to use the devices properly.



An icon indicating the status of wireless communication is displayed in the connected devices status at the top right of the operation panel. Before an exposure is made, check the displayed icon to make sure that proper wireless communication is established.

(1) Wifi communication indicator

Displayed icon	Description
	Wirelessly connected (wireless signal strength is indicated in 3 levels. means the communication is unstable although the wireless connection is working.)
	Offline mode
	Unable to perform exposure (unable to communicate through wireless connection)

(2) Wireless hand switch communication indicator

Displayed icon	Description
	Wirelessly connected
	Not connected
	Wired hand switch is connected

Appendix O Use of Optional Items

O.1 Optional Item

Shown below are optional products that can be used in combination with this device.

Name	Description
Battery Charger	Charger for batteries used in this device.
Battery	Batteries for this device.
AC adapter	AC adapter for the battery charger.
Holding device (XD2000 ST-M)	This holding device has casters and can be moved on flat floors. Retainer with casters for easy movement
Holding device (XD2000 ST-S)	This is a simple holding device that is easy to carry. It can hold the device.

O.2 Battery charger

When using the battery charger to charge, be sure to observe the following precautions.

- Do not charge any batteries other than the battery pack (PFF-031P) specified by our company.
- Do not disassemble or modify the battery charger under any circumstances.
- If the battery charger malfunctions, contact a dealer specified by our company.
- Do not allow dust to accumulate on the battery charger.
- Attach the battery pack to the battery charger in the correct orientation.
- Charging will not be performed correctly if the battery pack is inserted in the wrong direction or position.
- Do not allow any foreign objects to get inside when inserting.
- Do not allow the battery pack or battery charger to get wet or have dust or other particles attached to it while charging.
- Be careful not to step on the AC adapter of the battery charger or trip over the power cord.
- Do not subject the battery pack or battery charger to strong shocks (such as dropping them).
- Do not charge the battery pack near a fire or in direct sunlight.

If the battery becomes too hot, the protective device will activate to prevent danger and charging will no longer be possible.

If the protective device is damaged, the battery pack will be charged with an abnormal current or voltage, causing an abnormal chemical reaction inside the battery pack, which may result in heat generation, smoke, explosion, or fire.

- When charging the battery pack, please observe the charging conditions specified by our company. Charging under other charging conditions (unspecified high temperatures, voltages, large currents, or modified battery chargers, etc.) may cause the battery pack to be overcharged or charged with an abnormal current, resulting in an abnormal chemical reaction inside the battery pack, which may cause heat generation, smoke, explosion, or fire.

When charging, if charging is not completed within the specified charging time, stop charging. This may cause smoke, explosion or fire.

- Do not place the AC adapter near the flat panel sensor. This may cause artifacts.

There may be cases where this is the case.

- Do not use a faulty or damaged battery charger or AC adapter.
- Do not allow metal to come into contact with the electrodes. This may cause damage.
- Do not use the battery charger outdoors.

O.3 Radiation Personal Protective Equipment

Use of the following radiation personal protective equipment is recommended.

- Radiation protection apron
- Radiation protection glasses
- Thyroid protector
- Radiation protection gloves

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