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X-Ray Flat Panel Sensor

Operation Manual

FDR ES II G35 (DR-ID 1281SE)
FDR ES II G43 (DR-ID 1282SE)
FDR ES II C35 (DR-ID 1283SE)
FDR ES II C43 (DR-ID 1284SE)
FDR ES II C25 (DR-ID 1285SE)

Radiologist or any other practitioners licensed should ensure that they have adequate knowledge of the operation prior using the FDR ES II X-Ray Flat Panel Sensor.

This Operation Manual should be studied and understood before proceeding to operate the equipment on patients; it describes details on how to operate the FDR ES II X-Ray Flat Panel Sensor and cautions to be observed when operating it.

After reading this manual, store it nearby the FDR ES II X-Ray Flat Panel Sensor so that you can see it whenever necessary.

"Caution: Federal Law restricts this device to sale by or on the order of a radiologist or any other practitioners licensed by the law of the state in which that person practices to use or order the use of the device."

 **Caution**

This Operation Manual contains confidential and proprietary information of the Manufacturer.

Before using the device, please check local regulations. If any local legislation is violated, use cannot be authorized.

If additional training or material for training is needed, please directly contact our official dealer or company representative.

This system is classified as a medical device under EC Directive 93/42/EEC.

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

Caution : Rx Only in the United States (Federal law restricts this device to sale by or on the order of a physician.)

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Chapter 1 Introduction

This manual is intended to provide the operator with an overview of the operation and safety requirements for the FDR ES II X-Ray Flat Panel Sensor. This manual is not intended to provide instructions on actual treatment procedures and it is expected that users should have official radiologist or any other practitioners license prior to using the device. The Manufacturer and Distribution organization assume no liability through the use of the device.

All care has been taken in the preparation and checking of this manual however there is no guarantee provided that all information is correct. The information provided in this manual is subject to change without notice.

Only authorized accessories may be used in this device. The Manufacturer and Distribution organization shall not be held liable or responsible for damages or injury caused as a result of using non-approved accessories. Installation may only be conducted by authorized service personal. Some maintenance and service work also must be carried out by authorized service agents and only those procedures outlined in the operator and service manual are allowed. Any service work carried out by unauthorized person will void all warranties. No circuit diagrams or component part lists are to be provided for this device. If you require technical documentation that is not provided in this manual then please contact the manufacturer or your local distributor in writing with your reasons for wanting them and then a copy of the service manual may be provided. Before using the FDR ES II X-Ray Flat Panel Sensor, the operator should read this manual carefully and pay particular attention to the sections of Safety, Operation and Maintenance.

Caution

- Manufacturer shall not be liable for malfunctions and damages resulting from use under environment conditions outside the range of using conditions for this product such as power

supply, installation environment, etc. contained in this manual.

- Manufacturer shall not be liable for malfunctions and damages resulting from natural disasters such as fires, earthquakes, floods, lightning, etc.

1.1 Product Introduction

FDR ES II X-Ray Flat Panel Sensor is an X-ray image acquisition device that is based on flat-panel. This device should be integrated with an operating PC and an X-ray generator. It can do to utilize as digitalizing X-ray images and transfer for radiography diagnostic. Each X ray photon will be converted to electronic signal by scintillator and the sensor array. Electronic signal in the pixel will be readout by driver IC and then become an image before send to PC.

1.2 Product Series

Model	Description
FDR ES II DR-ID 1281SE	14”x 17” FPD with GOS
FDR ES II DR-ID 1282SE	17”x 17” FPD with GOS
FDR ES II DR-ID 1283SE	14”x 17” FPD with CsI
FDR ES II DR-ID 1284SE	17”x 17” FPD with CsI
FDR ES II DR-ID 1285SE	10”x 12” FPD with CsI

1.3 Product Intended Use

The DR-ID 1281SE, DR-ID 1282SE, DR-ID 1283SE, DR-ID 1284SE, DR-ID 1285SE FDR ES II X-Ray Flat Panel Sensor is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications wherever conventional film/screen or CR systems may be used. The FDR ES II X-Ray Flat Panel Sensor is not intended for mammography, fluoroscopy, tomography, and angiography applications. The use of this product is not recommended for pregnant women and the risk of radioactivity must be evaluated by a physician.

1.4 Product Significant Performance Characteristics

Items		Characteristics	
Image Grayscale resolution (Vertical*Horizontal)		DR-ID 1281SE	2836pix *2336pix
		DR-ID 1282SE	2836pix *2832pix
		DR-ID 1283SE	2836pix *2336pix
		DR-ID 1284SE	2836pix *2832pix
		DR-ID 1285SE	1980pix *1648pix
Grayscale resolution/Reading grayscale		16 bit data	
MTF (Modulation transfer function) (Typical)	DR-ID 1283SE DR-ID 1284SE DR-ID 1285SE	61±10% (54.9～67.1) @1cyc/mm	
	DR-ID 1281SE DR-ID 1282SE	58±10% (52.2～63.8) @1cyc/mm	
DQE (Sensor quantum efficiency) (Typical)	DR-ID 1283SE DR-ID 1284SE DR-ID 1285SE	54%±10% (48.6～59.4) @8.73uGy, 1lp/mm	
	DR-ID 1281SE DR-ID 1282SE	31%±10% (27.9～34.1) @8.73uGy, 1lp/mm	
Dynamic range (upper)		87.3uGy (RQA5)	
Sensitivity (after correction, @80kV)	DR-ID 1283SE DR-ID 1284SE DR-ID 1285SE	343.6 (LSB/uGy) ±10%	
	DR-ID 1281SE	343.6 (LSB/uGy) ±10%	

	DR-ID 1282SE	

1.5 Product Intended Part of the body or type of tissue applied to or interacted with

- Measurement site: body
- Condition: Intact or wound skin

1.6 Product Intended conditions of use

Considerations	Condition
Environment including hygienic requirements	- Non-sterile - Multiple patient use - Less than ten minute contact Indoors and outdoors (If used in outdoors, luminance could go over 1500lx. Viewing angle has nothing to do with these products. Ambient luminance range: 100 to 1500 lx. Viewing angle: normal to the display ±20°)
Frequency of use	- Reusable
Mobility	- Portable ME equipment to be used on a patient

1.7 Product Features

- 150 micron pixel pitch
- 16-bit dynamic range output
- Wireless communication mode or wired communication mode is available. When used in wireless communication mode, an access point and battery pack (optional) are required.

1.8 Clinical Guide

Users may require to attend the training courses held by manufacturer before using.

A complete training should consist of the following elements:

1. All safety precautions for practitioners and patients when using the device.

2. A review of published clinical literature should be conducted to understand the indications and effects of the X-Ray Flat Panel Sensor.

Chapter 2 Safety and Regulatory

This FDR ES II X-Ray Flat Panel Sensor has been designed and tested to function in a safe and correct when used as indicated in this manual. Do not use this device before reading and completely understand this Operation Manual. Always observe precautions for safety and only operates the device in a qualified room that provides protection.

2.1 Compliance Standards and Classification

2.1.1 Compliance Standards

- Risk management:
  EN ISO 14971：2019+A11:2021

- Safety:
  IEC 60601-1:2005+A1:2012+A2:2020 (Ed.3.2) For Europe and the United States, comply with Ed.3.2 as soon as the EN and ANSI/AAMI standards are issued.

- EMC (System):
  IEC 60601-1-2:2014+A1:2020 (Ed.4.2)
  EN 60601-1-2:2015+A1:2021 (Ed.4.2)

- EMC (Charger):
  EN55032:2015+A1:2020+A11:2020
  EN55035:2017+A11:2020

- Usability:
  EN 62366-1:2015

- Software:
  EN 62304：2006+A1:2015

2.1.2 Classification

- Type of protection against electrical shock: Class I Equipment

- Degree of protection against electrical shock: Type B Equipment
- 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.

2.2 Contraindications

No contraindications present.

2.3 Power Supply Hazard

 **Warning**

- The power supply to the FDR ES II is AC 100 to 240V. Do not use insufficient current or voltage of power supply, which will result in line defect in the image, and patient need to retake.
- To avoid electric shocks, users should always take the following precautions:
    1. Do not open any covers when it is not necessary.
    2. Install the equipment in a location where it will not be exposed to water.
    3. Check that the equipment is securely earthed.
    4. Check that all of the cables are completely and securely connected.
    5. Keep the control cabinet out of reach of patients.

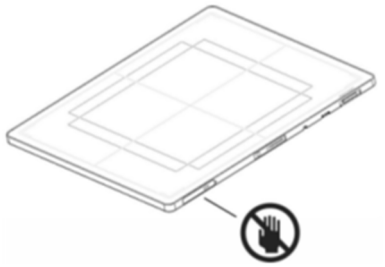
 **Cautions**

Do not reverse connecting positive and negative power terminal, it might cause short circuit and patient/user will be harmed.

2.4 Electric Shock Hazard

Warning

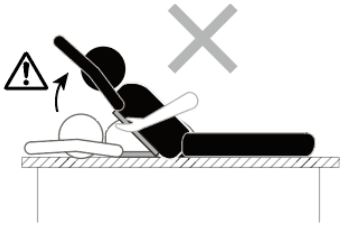
- Observe the following precautions when using the cables:
  1. Do not touch the plug and connector with wet hands. Otherwise, electric shock may result causing death or severe injury.
  2. Hold the plug or connector when removing the cable.
  3. Pulling the cable or carrying by holding it may damage the cable, causing fire or electric shock.
  4. Do not damage or remodel the cable.
  5. Do not place a heavy object on the cable or lay it under the flat panel sensor. Do not step on, pull, forcibly bend, or bundle the cable. Otherwise, fire or electric shock may result.
  6. Do not use the flat panel sensor for the radiographic examination stand if its cable becomes overloaded. Otherwise, the cable may be damaged, causing fire or electric shock.
  7. Do not touch the SE cable connector of FDR ES II, otherwise it may result in electric shock or malfunction of the equipment.



  8. Do not attract any metal conductive objects to avoid short circuit, make sure the SE cable is clean

- Do not use the equipment in a location where metal particles could come into the equipment. This may cause an electric shock.

- Do not disassemble or remodel the equipment. Otherwise, fire or electric shock may result. Keep away from the parts inside the product, which may cause electric shock. If you touch them accidentally, death or severe injury may result.
- Do not hit or drop the equipment or subject it to severe shock. Otherwise, the equipment may be damaged. If the damaged equipment is used, fire or electric shock may result.
- Do not use the flat panel sensor to lift up patient.



- In addition, do not apply strong pressure onto the flat panel sensor. If applied, the flat panel sensor deforms and the waterproof function may be invalid.
- Have the patient take a fixed posture and do not let the patient touch parts unnecessarily. If the patient touches connectors or switches, it may result in electric shock or malfunction of the equipment.
- Do not use the flat panel sensor without the battery packs. If the battery packs are not attached, an electric shock may result.
- Make sure to use the optional parts and accessories provided by manufacturer. Failure to use the optional parts and accessories recommended by us may result in damage to the equipment and/or electric shock and injury.
- Keep the equipment away from patient's body fluids, chemicals, water, etc. Otherwise, it may be damaged, causing fire or electric shock. If necessary, protect the flat panel sensor by covering it with a disposable bag.

2.5 Abnormalities Hazard

 **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 manufacturer office.
    1. When smoke, strange odor, or abnormal sound is present.
    2. When a foreign object (such as a metal object) or liquid enters the product.
    3. When the equipment is dropped or hit and is damaged. sensor

2.7 Connection Instructions

 **Warning**

- Make sure that the devices to be connected to the equipment are authorized for connection.
- Connect the panel unit FDR ES II only to the access point or DR system.

2.8 External Network Connection

 **Caution**

- When a setting of the network to which the equipment is connected has been changed, check that the change does not affect the system operation and take measures if necessary.
- The setting change may include the following:
    1. Change of connection destination
    2. Addition of devices
    3. Removal of devices

4. Update of devices
5. Upgrade of devices

- After connecting this system to the network with other systems, confirm that the other systems are not affected. If they are affected, take countermeasures such as network separation.

 **Warning**

- Make sure to use the optional parts, accessories and networks recommended by manufacturer. Failure to use the optional parts, accessories and networks recommended by us may result in damage to the equipment and/or electric shock and injury.

- Connect to the Ethernet Network of 100BASE-TX or 10BASE-T prescribed in the IEEE standard 802.3. Do not connect telephone lines to LAN connector. Only UTP-type straight LAN cables of 4-pair Category 5 cable (CAT 5E) or higher are appropriate for connection to this connector. Compliant with FCC part15.

2.9 System Isolation Instructions

 **Warning**

- To ensure complete system isolation, never install any unauthorized accessories or other such items.

- When it is necessary to install authorized accessories or optional items, contact our official dealer or company representative.

- Keep equipment other than those used for patients out of their reach to ensure appropriate system isolation.

- In normal use, have a patient take a proper positioning for exposure. The operator should operate the system in a place where safety from radiation is ensured. The operator should also make sure before exposure that no one but the patient is in the exposure area and the operating area of the system.

2.10 Software Precautions

 **Caution**

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

- Open-Source Software Contained in This Product
  1. This product contains third party's software that is made available as open source software or free software.
  2. This software is provided "as is" with no warranty of any kind as to its merchantability or fitness for any particular purpose.
  3. If you would like to receive such source codes, please contact official dealer or the service representatives at the agency from which you purchased this product. (Please be noted that any inquiries concerning the contents of source codes should be directed to original licensors of open source software.)

2.11 Disinfection Instructions

Warning

- Do not use the following disinfectants at the time of disinfection, which the quality, performance and safety of the equipment cannot be assured.
    1. Chloric disinfectant which is strongly corrosive to metals and rubber parts.
    2. Disinfectant whose uses on metals, plastics, and coating are forbidden according to the instructions supplied with the disinfectant.
    3. Formalin gas and disinfectant sprays that may get inside the equipment.
    4. Ultraviolet sterilizers.
- Disinfectant ethanol is recommended for disinfection. Carefully read the instructions and cautions supplied with the disinfectant before use.
- For details on the disinfectant, contact an official dealer or the service representatives at the agency from which you purchased the disinfectant.

Caution

- If flat panel sensor is not disinfected, it may lead secondary infection.
- Be sure to disinfect with ethanol after use.
- Clean the flat panel sensor with ethanol for disinfection, etc. for each patient to prevent infection.

2.12 Charging the Battery Pack

Caution

- Charging battery only by the SE cable provided by manufacturer when battery is installed on FDR ES II flat panel sensor or use the battery charger provided by manufacturer. For details on operations, refer to the instruction manual for the battery charger.
- Do not charge the battery pack near fire or under strong sunshine. If the built-in protection mechanisms are activated by a high temperature, the battery pack cannot be charged. Also, 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.
- To charge the battery pack, be sure to use the designated battery charger and to observe the charging conditions specified by manufacturer. If the battery pack is charged in other conditions (temperature or voltage/current higher than specified, remodeled battery charger, etc.), the battery pack may be overcharged or charged with extremely high current, and abnormal chemical reactions may occur inside the battery pack, causing it to overheat, emit smoke, explode or ignite.
- Immediately stop charging the battery pack, if charging is not completed within the specified time. Otherwise, the battery pack may overheat, emit smoke, explode or ignite.
- Do not use the flat panel sensor near the power cable.
- Do not use a faulty or broken battery charger or AC adapter.
- Do not over-charge battery (temperature higher than 60℃), it may burned patient.

2.13 Battery Pack Instructions

Warning

- Battery pack requires regular checkup and replacement. Battery capacity begins to warm after a period of time.
- If this equipment is not in use for a period of time, store it with the battery pack removed. Not removing the battery pack may cause malfunction.

Caution

- The battery pack is used with the flat panel sensor. Do not use them in other combinations.
- Charge the battery pack only with the designated battery charger. If the battery pack is charged under the charging conditions (voltage, current and charging method) different from those specified by manufacturer, the battery pack may emit smoke, ignite, explode or leak fluid.
- 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.
- Use or store the battery pack only in the environmental conditions specified by manufacturer. 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.
- When disposing of the battery pack, consult our official dealer or company representative.
- Do not disassemble or remodel the battery pack. 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.

- 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.
- Do not carry or store the battery pack together with metal objects such as necklaces or hairpins. Otherwise, the battery pack may short-circuit and overcurrent may flow, causing the battery pack to overheat, emit smoke, explode or ignite. 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 or leave the battery pack in a place where it is exposed to high temperature (60C or higher), such as fire or a heater. If the resin separator is 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 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 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.
- 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.
- The battery pack has a predetermined polarity. 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 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.
- 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.

- 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.
- 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, exploder 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.
- Keep the battery away from fire. Avoid the action of short circuit. Never attempt to disassemble the battery pack.
- Use the designated chargers to charge the battery pack. Risk of explosion if battery replaced by an incorrect type.
- Dispose of used batteries according to the instructions.
- When using the FPD for the first time, because the internal battery may be empty, do not install the main battery, but use the wire to charge the FPD internal battery, and charge it for at least 15 minutes before it can be used normally.

- Regarding the storage of the battery, first of all, the best storage capacity of the battery is about 40~50%.
- The main battery needs to be charged to 50%, two bars of the charging stand, and it takes about 2 hours to charge from 0%. ; The internal battery is also charged to 50%, you can use the UI to check the level of the internal battery, and it takes about 1 hour to charge from 0%.
- After charging, make sure that the hotswap function operates normally, please unplug the main battery and press the power button to test the internal battery power at least 3 lights, and the internal battery power should be more than 50%

2.14 Warnings for Pediatric Use

 **Warning**

- If the exposure conditions for average-size adults are applied to children, it may cause excessive radiation exposure.
- Study indicates that children are more radiosensitive than adults (i.e. children are at higher risk of developing cancer compared to adults exposed under same dose of ionizing radiation). Accordingly, please pay attention to avoid unnecessary exposure in pediatric use.
- Adjust the exposure conditions to obtain appropriate medical images with the minimum amount of radiation necessary based on the clinical application, pathological conditions of the patient, patient size, and anatomical imaging region.
- For system operation, do not use the AEC when children cannot be exposed at an appropriate dose with the AEC.
- Adjust the exposure conditions to minimize the X-ray exposure time for avoiding repeated

exposure due to body movement.

2.15 Other Precautions

Warning

- No modification of this equipment is allowed.
- Because this equipment is not explosion-proof, do not use combustible and explosive gases near the equipment.

Caution

- Implement a regular inspection and check the condition of equipment.
- Do not frequently expose flat panel sensor to X-ray without any tested subject.
- Beware the LED indicator and make sure the exposure is executed under proper condition.
- Do not take image while FPD is in busy state, the image may not be acquired.
- When multiple FPD are set in the same environment, make sure the right FPD is connected to system before exposure.
- To avoid compatibility issue, do not install software except this product on the computer, including software of hospital system.
- Be careful when holding the FPD, drop or impact may cause damage to the circuits or water-proof material and lead to malfunction.
- Place charger cable properly. Getting tripped by the devices may cause injury.
- Please follow the proper procedure to turn off the equipment. Otherwise, the flat panel sensor could be damaged due to thermal shock.
- High temperature may not be detected if temperature sensor is damaged.
- Operating FPD exceeds temperature specification may cause ADC shut down. Image acquisition

should be executed after system return normal.

- Operating FPD exceeds temperature specification may cause system shut down or image loss.
- Operating FPD exceeds temperature specification may cause burn Injury to patient.
- Beware not to hit or drop the FPD. Any damage on FPD may result in personal injury or cause damage to images.
- The water-proof property may be damaged by impact on the sensor which will lead to moisture.
- The sensor has been designed to stand certain level of impact, and drop test has been performed to our product. However, high G-value causing by impact on FPD may still cause image ripple.
- To assure optimum performance of the equipment, it is necessary to systematically perform maintenance and inspection. For information on maintenance and inspection, contact our official dealer or company representative.
- Maintenance or inspection should not be performed when the equipment is being used for a patient.
- The institution where the equipment is installed is responsible for its operation and maintenance. In addition, this equipment should be operated only by radiologist, doctor or trained staff.
- External equipment intended for connecting signal inputs, signal outputs or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 or IEC 62368-1 for IT-equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations, medical electrical systems, shall comply the safety requirements stated in the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents.
- Any person who connects external equipment for signal inputs, signal outputs or other connectors has formed a medical electrical system and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.
- If there is a strong EMI source near FPD, it may introduce noise or line defect on FPD and lead to image retake.
- Bucky tray design may be different with customers. System integrator should beware the shielding of WIFI signal situation.

- Welding or changes on panel circuit may lead to short circuit.
- Please follow the manual instruction when operation. Using power adapter which provides insufficient current or voltage may lead to horizontal line defect randomly appear in the image.

2.16 Disposal of Waste

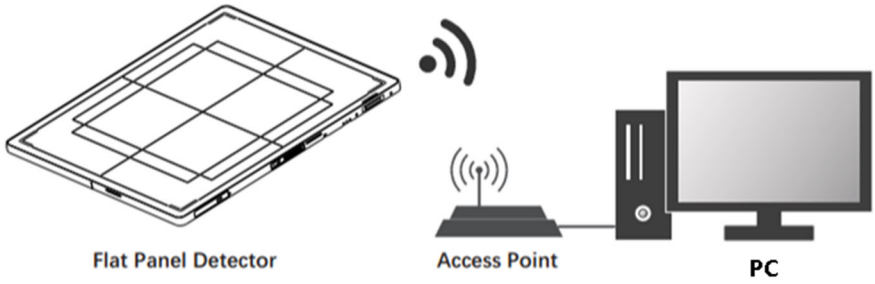
- The disposal procedure should comply with local law. Please contact the qualified local recycling provides before disposing the device.

Chapter 3 System Configuration

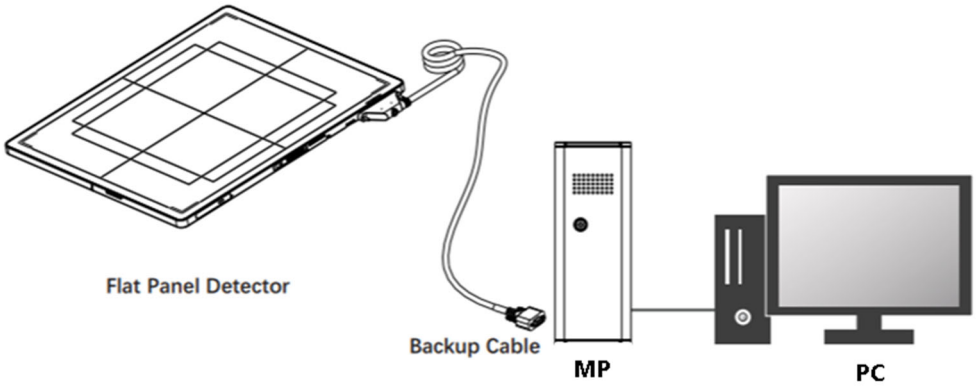
3.1 How to Connect FPD

FDR ES II FPD can be operated either in wireless connection mode or wired connection mode. When using wired mode, SE cable is necessary to provide the link from FPD to network switch hub or to PC. User can also connect SE cable to the adapter provided by manufacturer to give the power to operate or charging its battery. If the adapter is not connected, FPD will be powered by its own battery.

Wireless mode



Wired Connection mode



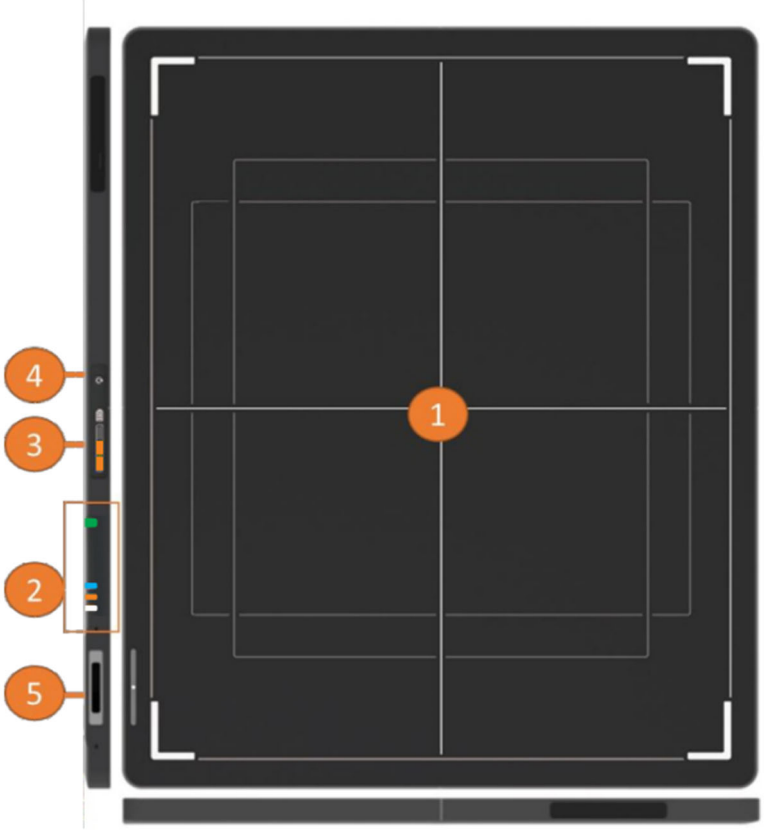
Caution

- Do not touch the SE cable connector of FDR ES II when in wired mode, otherwise it may result in electric shock or malfunction of the equipment.

3.2 Unit Names and the Functions

3.2.1 Flat Panel Sensor

Unit names and the functions of the FDR ES II FPD are described below.



1. Applied part

2. Status LED
3. Battery LED
4. Power switch
5. SE cable connector

3.3 LED indicators

There are 2 sets of LED indicating panel status and battery information on the side of FDR ES II series FPD.

3.3.1 Status LED

The behavior and the relations to the FPD status are described in the table below.

ITEM	Describe	
Power LED	ON	FPD is started
	Blink	Start up
	OFF	FPD is not started
Link LED	ON	Link with the PC is established
	OFF	Link with the PC is not established
Ready LED	ON	Ready for exposure
	Blink	Busy(reading an image , acquiring calibration data)
	OFF	Others*
Error LED	ON	Error occurs
	OFF	No Error occurs

*Note: If the Error LED is on, the Ready LED will not be displayed.

3.3.1 Battery LED

The behavior and the relations to the battery status are described in the table below.

	Main Battery	LED1	LED2	LED3
With DC	<31%	Blink	OFF	OFF
	>=31% ~ < 61%	ON	Blink	OFF
	> 61%	ON	ON	Blink
	100%	ON	ON	ON
Without DC	<31%	ON	OFF	OFF
	>=31% ~ < 61%	ON	ON	OFF
	> 61%	ON	ON	ON
	100%	ON	ON	ON

3.3.2 Switch

With DC and battery power input, long press switch for 5 seconds, the LED will turn off and panel will be power off.

Chapter 4 Basic Operation

4.1 Preparing the Flat Panel Sensor

This section describes how to prepare the flat panel sensor.

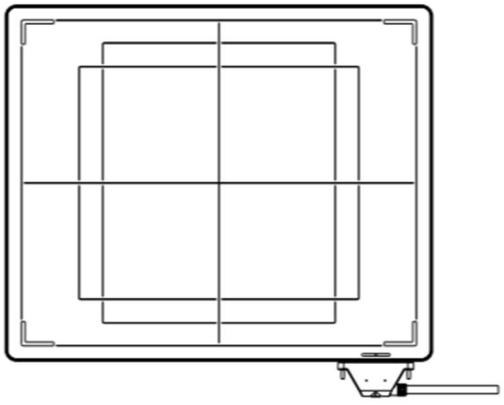
4.1.1 Type of Flat Panel Sensor

FDR ES II DR-ID 1281SE, DR-ID 1282SE, DR-ID 1283SE, DR-ID 1284SE, DR-ID 1285SE

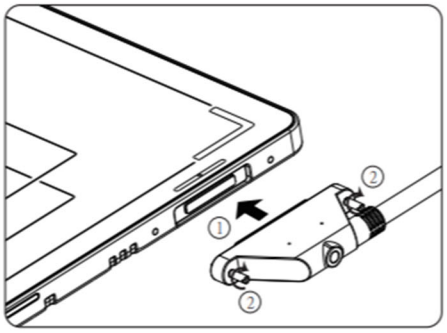
4.1.2 Number of the Connectable Flat Panel Sensor

Up to 5 panels can connect to system at the same time.

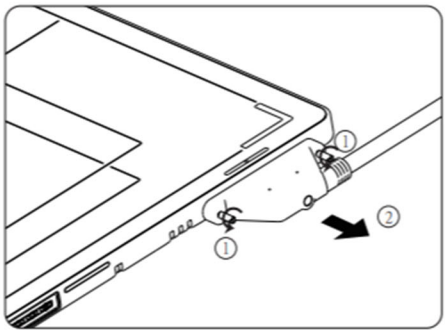
4.1.3 Connecting/Disconnecting the Flat Panel Sensor



▼ Connecting the FPD



▼ Disconnecting the FPD

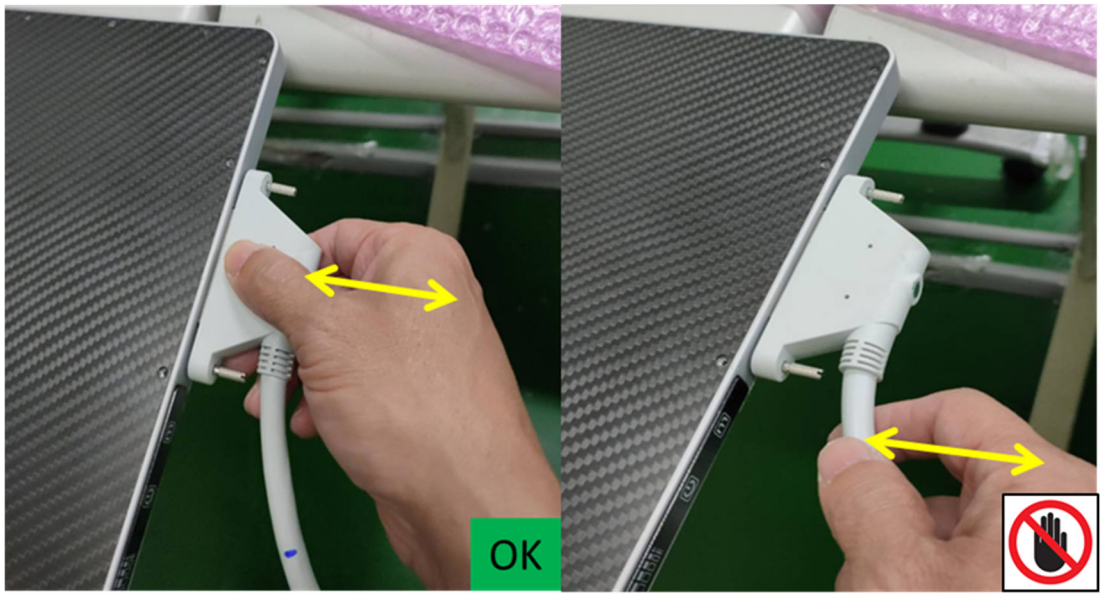


⚠ Do not place the connector on floor.

Make sure that the latches on both sides are properly engaged when connecting the connector. If the connector is inserted incompletely, the power may turn off.

Caution

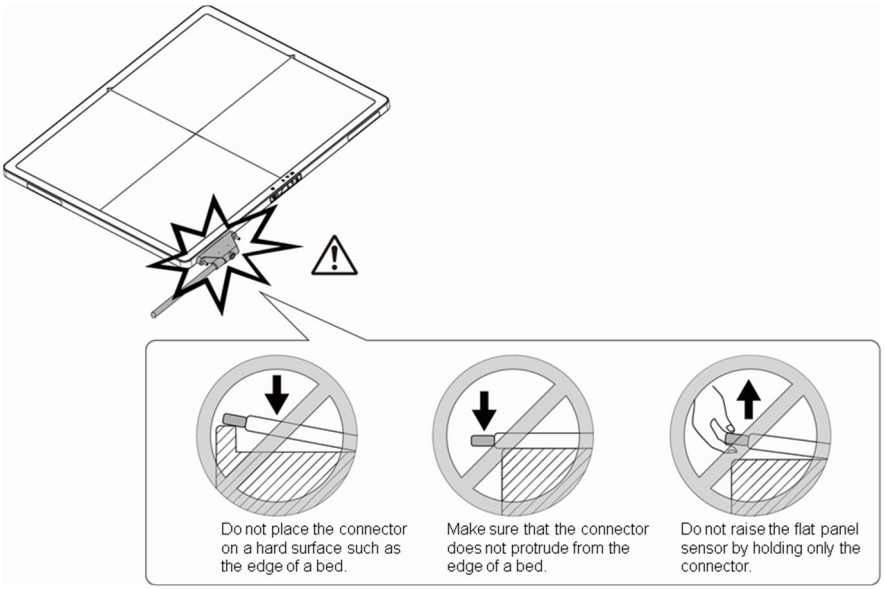
When removing the cable, hold the plug and never yank on the cable wire.



Caution

Make sure to install the connector carefully otherwise it could cause image loss while the power is not supplied to FPD.

Caution



4.1.4 Charging the Battery Pack for the Flat Panel Sensor

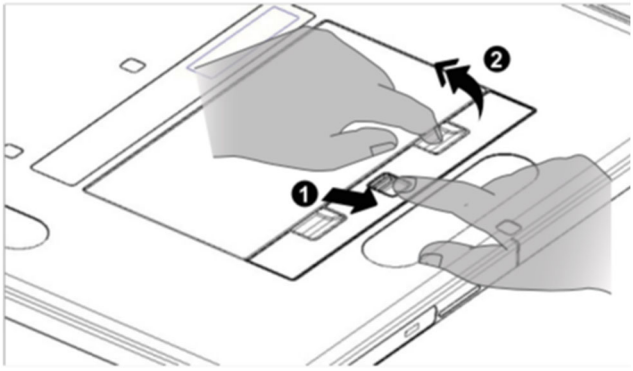
Use the battery charger recommended by manufacturer. For details on operations, refer to the instruction manual for the battery charger.

4.1.5 Installing/Removing the Battery Pack for the Flat Panel Sensor

Follow the procedure below to install/remove the battery pack for the flat panel sensor. When installing/removing the battery pack, place the flat panel sensor on a flat place.

Do not remove the battery pack until a processed image appears in the window of the image processing unit after the exposure.

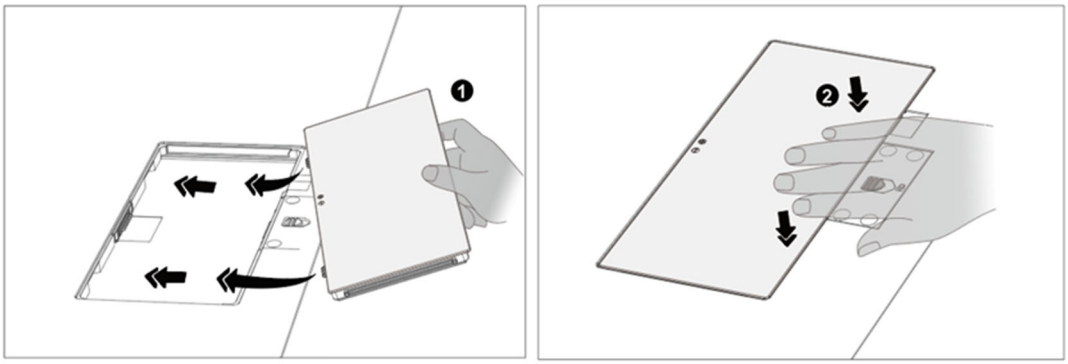
Remove the battery pack



Step ❶ Slide the arrow switch toward right side and hold it.

Step ❷ Pick up the edge of battery by finger, then lift it.

Install the battery pack



Step ❶ Following the picture and install the battery.

Step ❷ Push the battery pack and make sure the battery is tightly installed.

4.2 Sensor Connection

FDR ES II sensor can be connected to system either by wireless or by wire cable. ES IIPlease refer to

3.1 How to Connect FPD

4.3 Turning ON/OFF the FDR ES II FPD

This section explains how to start up and shut down the FDR ES II.

4.3.1 Starting Up the FDR ES II

FDR ES II FPD was designed to auto power-on with battery or DC input.

4.3.3 Standby off the FDR ES II

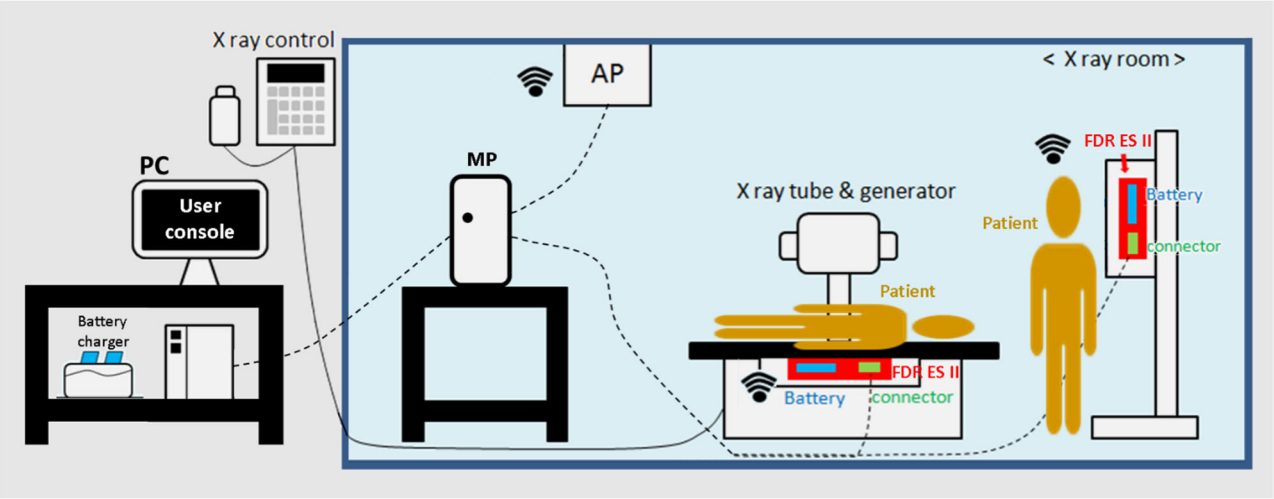
Press the power button for more than 2 second to put SE into standby off.

4.4 Standard Configuration

A. Other Essential System Components necessary to perform Digital Radiography

- FDR ES II (Supporting SDK Interface) can be used in combination with DR-ID 300CL the image processing unit provided by System Integrator.
- The X-ray equipment is composed of X-ray high voltage generator and X-ray console, etc. The hand switch is connected with the console for the exposure.
- The Access Point is required system, when FDR ES II is used in wireless communication mode. Access point is not provided by manufacturer.
- MP: DR-ID-1280MP
- PB: DR-ID-1280PB

B. A standard configuration of this device is as below.



- FDR ES II (Supporting SDK Interface):

Flat panel sensor: FDR ES II DR-ID 1281SE, DR-ID 1282SE, DR-ID 1283SE, DR-ID 1284SE, DR-ID 1285SE .

The control software is installed and used in a Windows PC (the image processing unit) prepared by the System Integrator.

This variation provides images, which diagnostic image process is not implemented, to the image processing unit.

An X-ray automatic detection function is used for FDR ES II DR-ID 1281SE, DR-ID 1282SE, DR-ID 1283SE, DR-ID 1284SE, DR-ID 1285SE . This function could detect a start timing of an X-ray exposure using readout signals in the sensor. After detecting the start timing of the X-ray exposure, the sensor starts collecting of X-ray signals and image readout.

ES IIES IIsensor

Chapter 5 Daily Inspection and Maintenance

5.1 Daily User Inspection and Maintenance

During maintenance and inspection, strictly observe precautions contained in “Chapter 2 Safety and Regulatory” in this manual for you to use the device under best conditions.

5.1.1 Periodical Inspection

End User	
Remove any dirt or dust accumulated in each part of the equipment using a vacuum cleaner or air duster, clean each part with a slightly moistened soft cloth and then wipe off any moisture with a dry cloth. See “3.2 Unit Names and the Functions”.	Every Three Months
Authorized Personnel	
There are no parts/components that needed to be replaced by manufacturer or any authorized personnel.	

Caution

- Be sure to turn off the power before cleaning each part of the device.
- Ensure sufficient space when cleaning the equipment on a table, etc.

Chapter 6 Troubleshooting

- In case of smoke, fire, abnormal high temperature, remove battery and power supply and turn off sensor immediately.
- In case of abnormal image, calibrate sensor by standard method. Contact service engineer or local representative if error is not removed by calibration.
- Other technical issue, contact service engineer or local representative.
- When FDR ES II cannot be turned on, please check if the battery has power or if the DC power supply is connected.
- When the software shows that the network can't connect, please confirm the signal of FDR ES II first. If it is wireless network, the third light needs to be solid green to indicate that it has been connected. If the green light flashes, it means that FDR ES II is not connected. At this time, please check the network settings of the environment and the computer, and have successfully connected.

Appendix A Specifications of FDR ES II

A.1 Specifications

Specifications of the FDR ES II are shown below.

A.1.1Power Consumption by Battery

Item	Specification (typical)	Unit
Battery operating time in stand-by mode	6	hours
Battery operating time in Operating mode	3	hours
Battery operating time in AED mode	1.5	hours

A.1.2 Environmental Conditions

A.1.2.1 Storage and Transport

Item	Min	Max
Temperature	-30**℃**	50**℃**
Humidity[1]	10%	90%
Pressure[2]	700mBar	1060mBar

- note1: Non-condensing
- note2: 700mBar is equivalent to 3000m in altitude

A.1.2.2 Operational environment

sensorsensorThis session states the operating condition for FDR ES II.

Item	Min	Max
Temperature	15**℃**	37**℃**

Humidity	15%	90%
Pressure	700mBar	1060mBar
Weight (uniform load)		300 kg
Weight (local load on 4 cm diameter)		120 kg
Drop height (the reversibility to full performance is not guaranteed for this item)		100 cm

---

Caution

When the flat panel sensor is used in high temperature condition for long period of time, it may cause image artifacts and/or failure of the device.

A.1.3 Image Performance

The testing measurement procedure of MTF and DQE is complies with IEC 62220-1 (MEDICAL ELECTRICAL EQUIPMENT - CHARACTERISTICS OF DIGITAL X-RAY IMAGING DEVICES) as a general X-ray radiography equipment.

To ensure optimal image quality, it is recommended that you do not use the flat panel sensor near devices (motor, transformer, switching supply, etc.) that generate electromagnetic noise.

DR-ID 1285SE, DR-ID 1283SE, DR-ID 1284SE (CsI Version) Performance

Item	Min	Typ.	Max	unit
MTF @ 1 lp / mm (RQA5)	54.9%	61%	67.1%	
DQE @ 0 lp / mm (RQA5)	64.8%	72%	79.2%	

DQE @ 1 lp / mm (RQA5)	48.6%	54%	59.4%	
Dynamic range (RQA5)			87.3	uGy
Sensitivity	309	343.6	378	LSB/uGy

DR-ID 1285SE, DR-ID 1283SE, DR-ID 1284SE (CsI Version) Life Time Performance

Item	Min	Typ.	Max	unit
DQE @ 1 lp / mm (RQA5)	43.7%	48.6%		

DR-ID 1281SE, DR-ID 1282SE (GOS Version) Performance at

Item	Min	Typ.	Max	unit
MTF @ 1 lp / mm (RQA5)	52.2%	58%	63.8%	
DQE @ 0 lp / mm (RQA5)	40.5%	45%	49.5%	
DQE @ 1 lp / mm (RQA5)	27.9%	31%	34.1%	
Dynamic range (RQA5)			87.3	uGy
Sensitivity	309	343.6	378	LSB/uGy

DR-ID 1281SE, DR-ID 1282SE (GOS Version) Life Time Performance

Item	Min	Typ.	Max	unit
DQE @ 1 lp / mm (RQA5)	25.1%	48.6%		

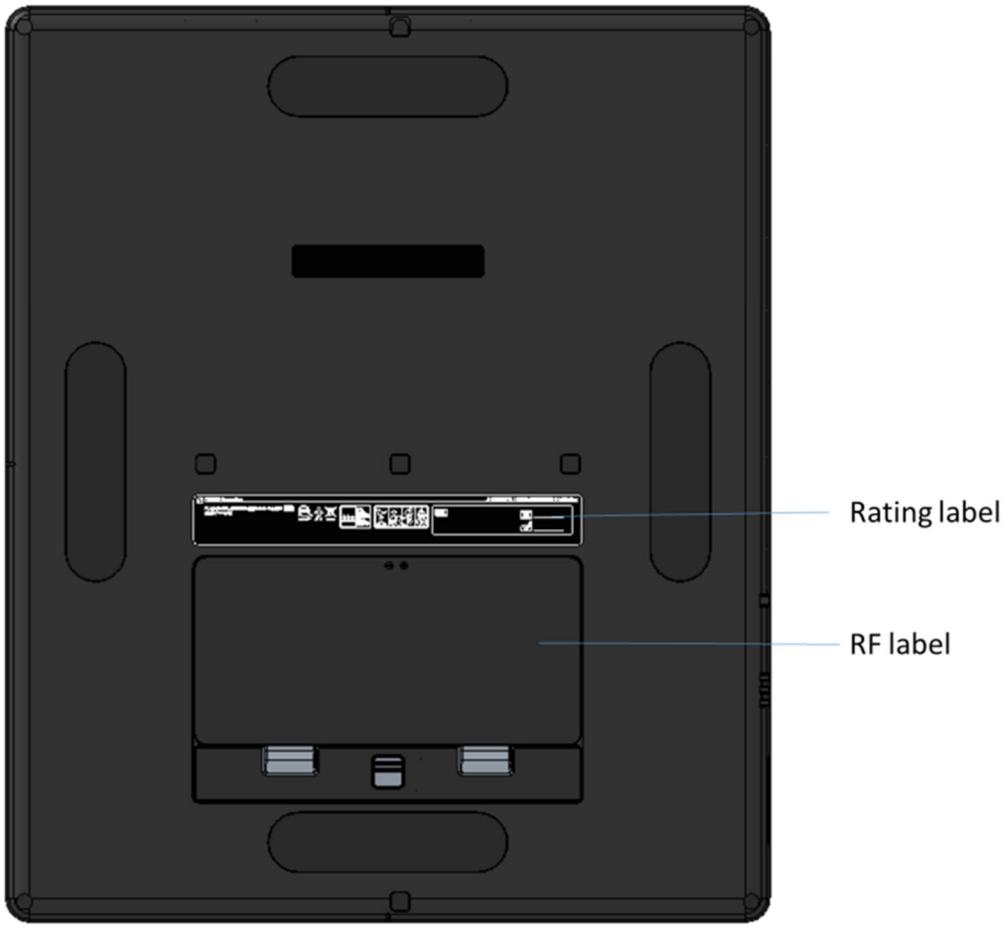
***The above specifications have been verified by manufacturer; The physical characterization of the systems was obtained with the standard beam conditions RQA5 (in accordance with IEC 61267:1994).**

A. 1.4 External View and Weight

Item	Width	Length (mm)	Height (mm)	Weight (Kg)

DR-ID 1281SE	459.5±1	383.5±1	15 +1/-2	2.95
DR-ID 1282SE	459.5±1	459.5±1	15 +1/-2	3.75
DR-ID 1283SE	459.5±1	383.5±1	15 +1/-2	2.95
DR-ID 1284SE	459.5±1	459.5±1	15 +1/-2	3.75
DR-ID 1285SE	332.5±1	281.5±1	15 +1/-2	1.75

A.1.5 Label



A.1.5.1 SE II label

FDR ES II C25

FDR ES II C35

FDR ES II G35

FDR ES II C43

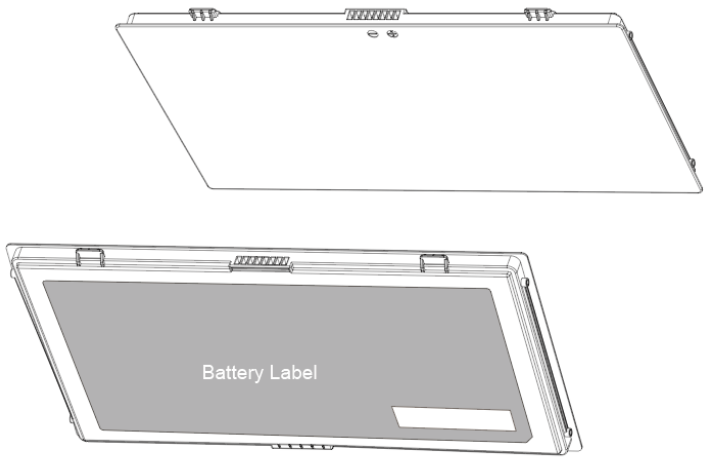
FDR ES II G43

A.1. 5.2 Safety Symbols

Symbol	Description
	Caution
	This symbol indicates compliance of the equipment with Directive 93/42/EEC.
	Federal Communications Commission FCC Marking.
	This symbol indicates that this product is not to be disposed of with your household waste, according to the WEEE Directive (2002/96/EC) and your national law. This product should be handed over to a designated collection point. Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information about waste, please contact our official dealer or InnoCare Representative.
	This symbol indicates that the batteries with more than 0.004% (40 ppm) lead.
	This symbol indicates that the equipment is a Type B Applied Part. IEC 60417/Graphical symbols for use on equipment.
	Refer to instruction manual/booklet
	Serial number
	Manufacturer
	Date of manufacture
	Direct current, DC
	Protective earth (ground)
	Authorized representative in the European Community.
	Prescription use only. Federal Law restricts this device to sale by or on the order of a radiologist or any other practitioners licensed by the law of the state in which that person practices to use or order the use of the device.
	Non-sterile
	Caution for local load
	Do not drop the flat panel detector to the user/patient.
	Entire surface load
	Single point load
	Handle with care
	**Power**
	**Battery**
	**Link**
	**Error**

A.1.6 Accessory

Battery (Optional)



Description: Rechargeable Li-Ion battery designed for Ridge FPD.

- Capacity: 4212 mAh
- Rating voltage: 11.4V, TYP:4212mAh/48Wh
- Weight: ~260g
- UL certified Safety (must in accordance with IEC 62133:2012)

A.1.7 Radio Waves

Wireless specifications for the flat panel sensor and the access point are as follows.

Item	Specification
Wireless specification	IEEE 802.11ax/ac/a/b/g/n (2T2R)
Data rate	802.11b: 11Mbps 802.11a/g: 54Mbps 802.11n: MCS0~15 802.11ac: MCS0~9

	802.11ax: HE0~11
Modulation	802.11b: DSSS (DBPSK, DQPSK, CCK) 802.11g: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11n: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11a: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11ac: OFDM (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM) 802.11ax: OFDMA (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM, 1024-QAM)
Security	64/128-bits WEP, WPA, WPA2, WPA3, 802.1x
Antenna	2

- Note: Use of 2.4GHz: ch11 for America, ch13 for Europe (ETSI)
- Transmit frequencies available vary, depending on the country.
- Radio waves available outdoors vary, depending on the country where the system is used.
- When the FDR ES II and any other wireless equipment are operating on the same frequency channel in a hospital, it may take time to show an image on the image processing unit monitor.
- This equipment uses wireless LAN (WLAN) radios for transferring images. The WLAN power levels and antenna configurations have been tested and certified compliant through specific absorption rate (SAR) limit set by FCC testing with separations as small as 0 cm between the panel antennas and human tissue.
- 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 device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada’s licence-exempt RSS(s). Operation is subject to the

following two conditions: (1) This device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

-

Appendix B Electromagnetic Compatibility (EMC)

B.1 FDR ES II FPD

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2014+AMD1:2020; EN 60601-1-2:2015+AMD1:2021.

These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 other devices in the vicinity.

However, there is no guarantee that interference will not occur in a particular installation.

If this equipment 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 equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

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

Warning

Do not place devices generating electromagnetic wave near this equipment.

If a device(s) other than those specified is connected, predetermined EMC performance can not be guaranteed.

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

Caution

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

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1. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
2. Portable and mobile RF communications equipment can affect medical electrical equipment.
3. Information regarding the cable affecting EMC is as follows.

Name	Connection	Maximum length	General specification
Network cable	Extend SE cable to PC or network switch.	20m	Cat 5e or more UTP type and straight cable

Power cord	From adaptor to AC outlet	Use a hospital grade power cord

4. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the FDR ES II.
5. The FDR ES II should not be used adjacent to or stacked with other equipment.
6. If adjacent or stacked use is necessary, the FDR ES II FPD should be observed to verify normal operation in the configuration in which it will be used.
7. Basic performance of the equipment and the system

After image data are acquired from the flat panel sensor, offset data correction is performed by flat pane sensor and then the image is send to DR system via wireless connection or wired connection.

Appendix C Trouble shooting

- In case of smoke, fire, abnormal high temperature, remove battery and power supply and turn off sensor immediately.

- In case of yellow error LED on, it may trigger the impact. Please read the manual to release the status and restart the power; if the yellow light cannot be removed, contact InnoCare service engineer or local representative

- In case of abnormal image, calibrate sensor by standard method. Contact InnoCare service engineer or local representative if error is not removed by calibration.

- Other technical issue, contact InnoCare service engineer or local representative.

- When SE II cannot be turned on, please check if the battery has power or if the DC power supply is connected.

- When the software shows that the network can't connect, please confirm the signal of SE II first. If it is wireless network, the third light needs to be solid green to indicate that it has been connected. If the green light flashes, it means that SE II is not connected. At this time, please check the network settings of the environment and the computer, and have successfully connected.