# **FUJIFILM**

**DIGITAL RADIOGRAPHY** 

**FUJIFILM DR** 



**Operation Manual** 

18th Edition : January 2014

**For Safe Operation** 

System
Configuration
(Product Overview)

**Basic Operation** 

**Troubleshooting** 

Daily Inspection and Maintenance

**Appendix** 

Maintenance and Inspection

This Operation Manual describes details on how to operate the FDR D-EVO and cautions to be observed when operating it. Please read the Operation Manual thoroughly before actually operating the FDR D-EVO along with "DR-ID 300CL Operation Manual" and other manuals for the related products.

After reading this manual, store it nearby the FDR D-EVO so that you can see it whenever necessary.

**FUJIFILM Corporation** 

# Introduction

This Operation Manual includes descriptions of matters necessary when using the FDR D-EVO, such as the equipment overview, operation procedures and precautions to observe, as well as daily inspections and maintenance.

Accompanying documents were originally drafted in the English language.

Installation may only be conducted by authorized service personal.

#### Indications for use (for U.S.)

The Wired/Wireless FDR D-EVO flat panel sensor system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.

#### Intended use (for European Union and other countries.)

The FDR D-EVO flat panel detector system 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.

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

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

#### Open-Source Software Contained in This Product

This product contains third party's software that is made available as open source software or free software. This software is provided "as is" with no warranty of any kind as to its merchantability or fitness for any particular purpose.

For the information on open source software contained in this product, please see the attached DVD. Source codes for certain type of open source software used in this product are available at delivery cost. If you would like to receive such source codes, please contact FUJIFILM 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.)

Note: FUJIFILM has successfully performed verification and validation testing on all third party software and has confirmed its suitability to be used in this system.

#### **Trademarks**

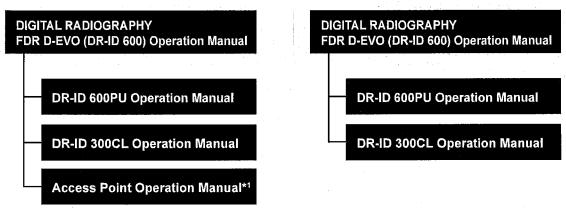
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# **FDR D-EVO System Operation Manuals**

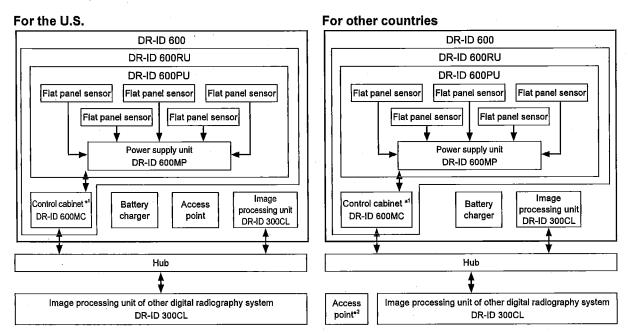
For the U.S.

#### For other countries



- \*1 See the operation manual for the designated access point.
- See "DR-ID 300CL Operation Manual" along with the manuals for the related products.
- ◆ The DR-ID 600MC runs on a commercially available personal computer. However, operations are not required to use the FDR D-EVO. For operations of a commercially available personal computer, see the operation manual provided by the manufacturer.

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



The configuration of the system varies depending on the country.

There are six types of flat panel sensors: DR-ID 601SE, DR-ID 602SE, DR-ID 611SE, DR-ID 612SE and DR-ID 613SE (wireless/wired communication mode) and DR-ID 600SE (wired communication mode). Although the contents of this manual are described by taking the example of DR-ID 601SE, the same can also be applied to other flat panel sensors. With regard to the description specific to a certain type of flat panel sensor, the product name is given in the description.

\*1 Depending on the configuration, the control cabinet (DR-ID 600MC) may not be included in the system. If not included, the software for the control cabinet can be installed on the image processing unit (DR-ID 300CL).

For detail specification of image processing unit, please refer to "DR-ID 300CL Operation Manual".

\*2 With regard to the access point, consult our official dealer or FUJIFILM Representative.

# **Contents at a Glance**



#### For Safe Operation

This chapter presents Warnings and Cautions we wish you to observe for safe operation of the FDR D-EVO.



## System Configuration (Product Overview)

This chapter gives the various unit names and describes their functions and features of the FDR D-EVO.



#### **Basic Operation**

This chapter describes start-up, shut-down and other basic operations of the FDR D-EVO.



#### **Troubleshooting**

This chapter describes how to troubleshoot in the event of an error on the FDR D-EVO, and provides explanations about a list of error messages each of which appears when an error occurs.



#### Daily Inspection and Maintenance

This chapter describes daily care and maintenance we wish you to perform so that you can use the FDR D-EVO optimally.



Appendix A Specifications

Appendix Z Precautions for Exposure

Appendix O Use of Optional Items



Maintenance and Inspection

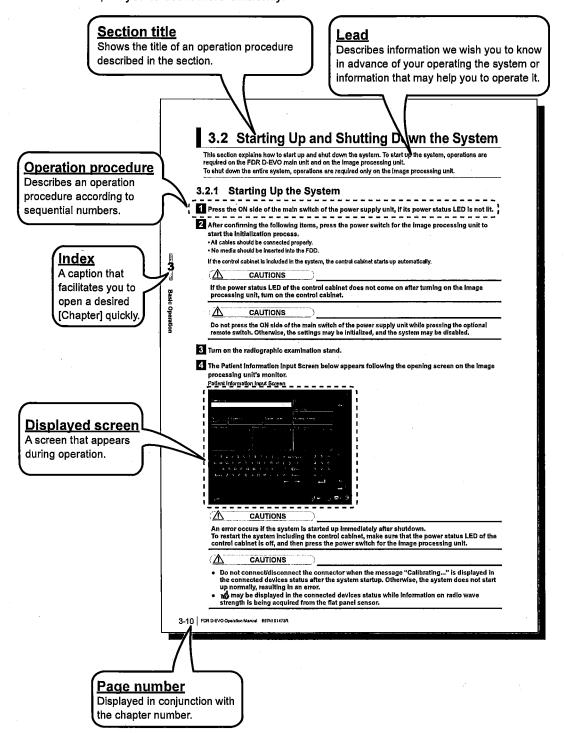


Radio frequency (RF) compliance information

# **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.



## 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.



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



Shows an item helpful for further effective system operation.



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

## **Expressions**

Messages appear on the display panel and the buttons are shown as below.

• Buttons (example)



The button to operate is shown.

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# **Maintenance and Inspection**

# Chapter 1 For Safe Operation

# 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.

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 doctors or suitably trained staff.

This system is classified as a medical device under EC Directive 93/42/EEC. This equipment has been designed on the assumption that the patient would not come into direct contact with it or for operation by appropriately trained operator.

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. For details on product disposal, contact a FUJIFILM dealer.

# 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 installing the equipment.
  - 2-1. Install the equipment where water will not splash it.
  - 2-2. Install 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.
  - 2-3. Make sure the equipment will remain in stable condition on a level surface and not be subjected to vibration or shock.
  - 2-4. Do not install the equipment in places where chemicals are stored or gases emitted.
  - 2-5. Make sure that the power frequency, voltage and power consumption are appropriate.
  - 2-6. Connect the ground wire correctly.
- 3. Observe the following precautions before beginning to use the device.
  - 3-1. Confirm that the ground wire has been completely connected.
  - 3-2. Make sure that all cords have been connected properly and safely.
  - 3-3. Be aware that correct diagnosis can be hindered and danger can result from using different pieces of equipment together.
  - 3-4. Make sure that the battery and power supply are installed properly.
- 4. Observe the following precautions when using the equipment.
  - 4-1. Make sure not to exceed the time and dose required for diagnosis.
  - 4-2. Always monitor the patient and the equipment for abnormalities.
  - 4-3. 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.
- 5. Observe the following precautions after using the equipment.
  - 5-1. Using the established procedure, then turn the power off.
  - 5-2. When unplugging cords, do not pull on the body of the cord itself or apply unnecessary force.
  - 5-3. Observe the following precautions when storing the equipment.
    - 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.
  - 5-4. After using the accessories, recollect them and put them back in order.
  - 5-5. Make sure to clean the equipment for the next use.
- 6. If there is trouble with the equipment, do not attempt to fix it randomly. Instead, do what is indicated and entrust repairs to a professional.
- 7. Do not remodel the equipment.
- 8. Maintenance and Inspection
  - 8-1. Make inspect the equipment and parts periodically.
  - 8-2. 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
  - 9-1. When subjecting patients (particularly infants and pregnant women) to radiation, make sure not to exceed the necessary time and dose. Also, ensure that radiation is contained within the exposure plane of the flat panel sensor.
  - 9-2. Follow the Operation Manual and operate the equipment correctly.

# 1.3 Safety

Before using the FDR D-EVO, read this section thoroughly to ensure that you use the product properly.

## Electric Shock Warnings and Cautions

- 1	Δ
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#### WARNING

The power supply to the FDR D-EVO is AC100 to 240V.

To avoid electric shocks, users should always take the following precautions:

- Never open any covers of the equipment.
- Install the equipment in a location where it will not be exposed to water.
- · Check that the equipment is securely earthed.
- Check that all of the cords and cables are completely and securely connected.
- Keep the image processing unit and the control cabinet out of reach of patients.



#### WARNING

Do not touch the patient's body while touching the control cabinet. Otherwise, the patient may receive an electric shock.



#### **WARNING**

Do not use a multiple tap connector or extension cable for powering the devices constituting the system. Otherwise, fire or electric shock may occur due to the electrical load exceeding the allowable limit.

#### WARNING

Observe the following precautions when using the cables.

- Turn off each unit before connecting/disconnecting the cable. Do not touch the plug and connector with wet hands. Otherwise, electric shock may result, causing death or severe injury.
- Hold the plug or connector when removing the cable. 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 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.
- 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.



#### **WARNING**

Do not turn on the system with dew condensation on the flat panel sensor. Otherwise, fire or electric shock may result.



#### WARNING

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

<u> </u>
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.
<u></u> WARNING
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.
<u></u> WARNING
Before using the flat panel sensor (DR-ID 601SE, DR-ID 602SE, DR-ID 611SE, DR-ID 612SE and DR-ID 613SE), make sure that the battery cover or battery pack is attached. If not attached, an electric shock may result.
.↑\ WARNING
Make sure to use the optional parts and accessories recommended by us. Failure to use the optional parts and accessories recommended by us may result in damage to the equipment and/or electric shock and injury.
(A CAUTIONS
As the cables of the equipment are long, be careful not to entangle the cables during use.  Also, be careful not to trip over the cables. Falls could result in injury.
(A CAUTIONS
Follow the specified procedure when turning off the equipment. Otherwise, the flat panel sensor could be damaged by thermal shock.
(A CAUTIONS )
Do not store magnetic media near the DR system and control cabinet. Otherwise, magnetism generated by the equipment may cause the data to be lost.
(A CAUTIONS
Keep the equipment away from patient's body fluids, chemicals, water, etc. Otherwise, it may become damaged, causing fire or electric shock. If necessary, protect the flat panel sensor by covering it with a disposable bag.
Explosion Warnings
<u> </u>

Because this equipment is not explosion-proof, do not use combustible and explosive gases

near the equipment.

Flammable gasses may stay in th powering on the system following	ne room after disinfection. Ventilate the room well before
Jowering on the system following	, distinction.
arnings for Abnormalitie	es
<b>. </b>	
and the same of th	mediately turn off the newer of each unit unplug the newer
it any of the following occurs, impossible from the outlet, and then co	mediately turn off the power of each unit, unplug the power ontact a FUJIFILM dealer.
<ul> <li>When smoke, strange odor, or</li> </ul>	abnormal sound is present.
<ul><li>When a foreign object (such as</li><li>When the equipment is droppe</li></ul>	s a metal object) or liquid enters the product.
- I I I I I I I I I I I I I I I I I I I	and to warring-at
stallation Precautions	
A CAUTIONS	
	ation with the following conditions.
<ul> <li>Where the temperature change</li> <li>Close to heat sources such as</li> </ul>	
	osed to water due to water leakage or ingress.
Where corrosive gas may be go	
<ul> <li>Where there is excessive dust.</li> <li>Where the system is subject to</li> </ul>	o frequent or excessive vibration/shock.
• Where the system is exposed to	•
• Where there is no ventilator.	
For veterinary or mobile applicati	ions, contact a FUJIFILM dealer.
<b>A</b> CAUTIONS	
Use the system indoor in wireless	s communication mode. For details, contact a FUJIFiLM deale
A CAUTIONS	

**WARNING** 

Make sure that the devices to be connected to the equipment are authorized for connection.

**WARNING** 

Connect the DR-ID 600PU only to the designated control cabinet (DR-ID 600MC). When the DR-ID 600PU is connected to X-ray equipment, make sure that the equipment complies with IEC 60601-1.

## **Precautions on External Network Connection**



#### **CAUTIONS**

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:

- Change of connection destination
- Addition of devices
- Removal of devices
- Update of devices
- Upgrade of devices

## Cautions on Network



#### **CAUTIONS**

Connect to the Ethernet Network of 1000BASE-T, 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.



#### **CAUTIONS**

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.

# 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 a FUJIFILM dealer.



#### WARNING

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



#### **WARNING**

Do not move the image processing unit from where it is installed.



#### **WARNING**

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.

## **Software Precautions**



#### **CAUTIONS**

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.

#### Disinfection 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.



#### WARNING

Do not use the following disinfectants or sterilizers at the time of disinfection. Quality, performance and safety of the equipment cannot be assured.

- Chloric disinfectant which is strongly corrosive to metals and rubber parts.
- Disinfectant whose uses on metals, plastics, and coating are forbidden according to the instructions supplied with the disinfectant.
- Formalin gas and disinfectant sprays that may get inside the equipment.
- 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 a FUJIFILM dealer or the service representatives at the agency from which you purchased the disinfectant.



#### **CAUTIONS**

Clean the sensor unit of the flat panel sensor with ethanol for disinfection, etc. for each patient to prevent infection.

# Precautions for Charging the Battery



#### **CAUTIONS**

Observe the following precautions when charging the battery pack (optional) using the battery charger (optional).

- Do not use the battery pack (125N100050) or battery charger in combination with any battery pack or battery charger (including the AC adapter) other than those recommended by FUJIFILM Corporation.
- Do not disassemble or convert the battery pack or battery charger.
- If the battery pack or battery charger becomes faulty, consult our official dealer.
- Do not cover the holes in the battery charger with foreign matter.
- Avoid the accumulation of dust on the battery charger.
- Insert the battery pack into the battery charger securely.
- . If the insertion direction or position of the battery pack is incorrect, the battery is not
- When inserting the battery pack, prevent foreign matter from getting into the battery charger.

- While charging the battery, do not allow the battery pack or battery charger get wet or dusty.
- Do not step on the AC adapter of the battery charger. Also, be careful not to trip over the power cable.
- Do not subject the battery and battery charger to severe shock (by dropping them, etc.).
- Do not place the battery charger within the reach of patients.
- 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 FUJIFILM Corporation. 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 AC adapter.
- Do not use the broken battery charger.

## Battery Pack (Optional) Instructions



WARNING

If this equipment is not in use for while, store it with the battery pack removed. Not removing the battery pack may cause malfunction.



#### **CAUTIONS**

Observe the following precautions when using the battery pack (optional).

- The battery pack (125N100050) is exclusively for the flat panel sensor (DR-ID 601SE, DR-ID 602SE, DR-ID 611SE, DR-ID 612SE and DR-ID 613SE). 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 FUJIFILM Corporation, the battery pack may emit smoke, ignite, explode or leak fluid.
- When storing the battery pack for a long period, charge the battery fully, remove it from the flat
  panel sensor and then store it in a cool and dark place. Recharge the stored battery 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 FUJIFILM Corporation. 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.
- 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.
- 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 (80°C 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 quaranteed 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.
- Keep the equipment or battery pack out of the reach of small children to prevent them from accidentally swallowing the battery pack. If swallowed, consult a doctor immediately.
- 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.

## Warnings for Pediatric Use

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#### WARNING

- If the exposure conditions for average-size adults are applied to children, it may cause excessive radiation exposure.
- Studies show that children are more radiosensitive than adults (i.e. children are at higher risk of developing cancer compared to adults exposed to the same dose of ionizing radiation). Accordingly, in pediatric use, special attention needs to be paid to avoid unnecessary exposure.
- Based on the clinical application, pathological conditions of the patient, patient size, and anatomical imaging region, adjust the exposure conditions to use the minimum amount of radiation necessary to obtain appropriate medical images.
- An additional filter can also be used for children to reduce unnecessary exposure further.
- If children cannot be exposed at an appropriate dose with the AEC, do not use the AEC.
- Adjust the exposure conditions to minimize the X-ray exposure time to avoid repeated exposure due to body movement.

## Other Warnings and Cautions

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WARNING

No modification of this equipment is allowed.



**CAUTIONS** 

Install the system in accordance with what is provided by IEC 60601-1-1:2000 and IEC 60601-1:2005 Chapter 16. Contact a FUJIFILM dealer for installation and relocation (except the flat panel sensor) of the system.



**CAUTIONS** 

Do not hit or drop the equipment. Otherwise, injury or damage to images, etc. may result.



**CAUTIONS** 

Be sure to inspect the system periodically.

To assure optimum performance of the equipment, it is necessary to systematically perform maintenance and inspection. For information on maintenance and inspection, contact a FUJIFILM dealer.

# **Contraindications and Prohibitions**

No contraindications present.

# 1.4 Electromagnetic Compatibility (EMC)

#### Essential performance

- (1) DR-ID 600SE/DR-ID 601SE/DR-ID 602SE/DR-ID 611SE/DR-ID 612SE/DR-ID 613SE obtains images.
- (2) DR-ID 600MC stores images.
- (3) DR-ID 600MC corrects images.
- (4) Image transfer in order from DR-ID 600SE/DR-ID 601SE/DR-ID 602SE/DR-ID 611SE/DR-ID 612SE/ DR-ID 613SE, DR-ID 600MP, DR-ID 600MC, to DR-ID 300CL
- (5) DR-ID 300CL stores and displays images after correction.
- (6) It shall fulfill and maintain the safety requirement of the standards.

DR-ID 600 is consists of following components and conforms to IEC 60601-1-2 as a result of each component conforms to following standards.

- DR-ID 600PU ----- IEC60601-1-2
- DR-ID 600MC ----- CISPR 22 /CISPR 24
- DR-ID 300CL ----- CISPR 22 /CISPR 24
- · Access point (DAP-2553) ----- EMI: CE, FCC, IC (It is equivalent to CISPR 22.)

#### 1.4.1 **DR-ID 600PU**

DR-ID 600PU consists of DR-ID 600MP and DR-ID 600SE/DR-ID 601SE/DR-ID 602SE/DR-ID 611SE/ DR-ID 612SE/DR-ID 613SE.

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2 (EN60601-1-2), Medical Device Directive 93/42/EEC.

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)

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

# Further information for IEC 60601-1-2 (EN60601-1-2)

- 1. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information 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	Connected Device	Maximum Length	General Specification
Network Cable	Between the DR-ID 600PU and the DR-ID 600MC	30m (98.4 ft)	Cat5e or more, UTP type and straight cable
	Between the DR-ID 600MC and the DR-ID 300CL	100m (328.1 ft)	
Power Cable	DR-ID 600PU	3m (9.8 ft)	Use a hospital grade power cable. (for North America)
			A non-hospital grade power cable can be used. (for other countries)

- 4. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by FUJIFILM Corporation as replacement parts for internal components, may result in increased emissions or decreased immunity of the DR-ID 600PU.
- 5. The DR-ID 600PU should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the DR-ID 600PU should be observed to verify normal operation in the configuration in which it will be used.
- 6. Basic performance of the equipment and the system After image data are acquired from the DR-ID 600PU, data correction is performed by the control cabinet (DR-ID 600MC), and the image is saved in and displayed on the image processing unit (DR-ID 300CL).
- 7. Test items (Tables 1 to 4)

#### Table 1

Guidance and manufacturer's declaration - electromagnetic emissions					
			c environment specified below. e that it is used in such an environment.		
Emissions test		Compliance	Electromagnetic environment - guidance		
RF emissions CISPR 11	Group 1		The DR-ID 600PU 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.		
RF emissions CISPR 11 Class A		The DD ID COORD is suitable for use in all catablishments			
Harmonic emissions IEC61000-3-2	Complies	DR-ID 600PU: Class A	The DR-ID 600PU is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies		
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies		buildings used for domestic purposes.		

Table 2

#### Guidance and manufacturer's declaration - electromagnetic immunity

The DR-ID 600PU is intended for use in the electromagnetic environment specified below. The customer or the user of the DR-ID 600PU should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV 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 differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	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	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ (>95% dip in $U_T$ ) for 5 s	$<5\%\ U_T$ $(>95\%\ dip\ in\ U_T)$ for 0.5 cycle $40\%\ U_T$ $(60\%\ dip\ in\ U_T)$ for 5 cycles $70\%\ U_T$ $(30\%\ dip\ in\ U_T)$ for 25 cycles $<5\%\ U_T$ $(>95\%\ dip\ in\ U_T)$ for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DR-ID 600PU requires continued operation during power mains interruptions, it is recommended that the DR-ID 600PU be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3

#### Guidance and manufacturer's declaration - electromagnetic immunity

The DR-ID 600PU is intended for use in the electromagnetic environment specified below. The customer or the user of the DR-ID 600PU should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DR-ID 600PU, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Radiated RF	3 V/m	3 V/m	d = 1.2√P
IEC61000-4-3	80 MHz to 2.5 GHz		$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (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. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, 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.

- 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 DR-ID 600PU is used exceeds the applicable RF compliance, the DR-ID 600PU should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DR-ID
- 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 and the DR-ID 600PU

The DR-ID 600PU is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the DR-ID 600PU can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DR-ID 600PU as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 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.

## 1.4.2 DR-ID 600MC and DR-ID 300CL

This equipment has been tested and found to comply with the international standard for medical devices below, according to the requirement of the IEC 60601-1-2/EN 60601-1-2.

EMC Standard: CISPR 22/EN 55022

**CISPR 24/EN 55024** 

IEC61000-3-2/EN61000-3-2 IEC61000-3-3/EN61000-3-3

This does not guarantee that there is no harmful electromagnetic interference under any installation environment.

This equipment can generate, use and radiate radio frequency energy. If the equipment is not installed and used in accordance with the instructions, or if peripheral devices that are not complied with the EMC standard, harmful interference may be generated under a particular environment causing malfunction of the equipment and other devices.

If this equipment causes harmful interference to other devices, or if this equipment is affected by interference from other devices, 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 or our official dealer for help.



WARNING

Do not place devices generating electromagnetic wave near this equipment.

## Further information for CISPR 22 / EN55022 and CISPR 24 / EN55024

- 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	Connected Device	Maximum Length	General Specification	
Network Cable	Between the DR-ID 600PU and the DR-ID 600MC	30m (98.4 ft)	Cat5e or more, UTP type and straight cable	
	Between the DR-ID 600MC and the DR-ID 300CL	100m (328.1 ft)		
Power Cable	DR-ID 600MC and DR-ID 300CL	Depends on the cabl	e length of a personal computer.	

- 4. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by FUJIFILM Corporation as replacement parts for internal components, may result in increased emissions or decreased immunity of the DR-ID 600MC and the DR-ID 300CL.
- 5. The DR-ID 600MC and the DR-ID 300CL should not be used adjacent to or stacked with other equipment.
  - If adjacent or stacked use is necessary, the DR-ID 600MC and the DR-ID 300CL should be observed to verify normal operation in the configuration in which it will be used.
- Basic performance of the equipment and the system
   After image data are acquired from the DR-ID 600PU, data correction is performed by the control cabinet (DR-ID 600MC), and the image is saved in and displayed on the image processing unit (DR-ID 300CL).
- 7. Test items (Tables 1 to 3)

#### Table 1

#### Guidance and manufacturer's declaration - electromagnetic emissions

The DR-ID 600MC and the DR-ID 300CL are intended for use in the electromagnetic environment specified below. The customer or the user of the DR-ID 600MC and the DR-ID 300CL should assure that they are used in such an environment.

Emissions test	Compliance	
Noise terminal voltage		
CISPR 22 EN55022	Class A	
Electric field noise strength	,	
CISPR 22 EN55022	Class A	
Harmonic emissions		
EN61000-3-2 IEC61000-3-2	Class D	
Voltage fluctuations/flicker emissions		
EN61000-3-3 IEC61000-3-3	Complies	

#### Table 2

#### Guidance and manufacturer's declaration - electromagnetic immunity

The DR-ID 600MC and the DR-ID 300CL are intended for use in the electromagnetic environment specified below. The customer or the user of the DR-ID 600MC and the DR-ID 300CL should assure that they are used in such an environment.

Immunity test	EN/IEC test	Compliance leve
Electrostatic discharge (ESD)		
<b>5</b> \ ,	±4kV contact	±4kV contact
EN61000-4-2	±8kV air	±8kV air
IEC61000-4-2		<u> </u>
Electrical fast transient/burst		
	±1kV for power supply lines	±1kV for power supply lines
EN61000-4-4	±0.5kV for input/output lines	±0.5kV for input/output lines
IEC61000-4-4		
Surge		
	±1.0kV differential mode	±1.0kV differential mode
EN61000-4-5	±2.0kV common mode	±2.0kV common mode
IEC61000-4-5	<u> </u>	
Voltage dips, short interruptions and	<5% <i>U<sub>T</sub></i>	<5% <i>U<sub>T</sub></i>
voltage variations on power supply	$(>95\%$ dip in $U_T)$	(>95% dip in $U_T$ )
input lines	for 0.5 cycle	for 0.5 cycle
	70% <i>U<sub>T</sub></i>	70% <i>U<sub>T</sub></i>
EN61000-4-11	(30% dip in $U_T$ )	(30% dip in $U_T$ )
IEC61000-4-11	for 25 cycles	for 25 cycles
	<5% <i>U</i> <sub>T</sub>	<5% <i>U<sub>T</sub></i>
	(>95% dip in $U_T$ )	$(>95\% \text{ dip in } U_T)$
	for 250 cycles	for 250 cycles
Power frequency (50/60Hz)		
magnetic field	·	
	1 A/m	1 A/m
EN61000-4-8		
IEC61000-4-8		

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

Table 3

#### Guidance and manufacturer's declaration - electromagnetic immunity

The DR-ID 600MC and the DR-ID 300CL are intended for use in the electromagnetic environment specified below. The customer or the user of the DR-ID 600MC and the DR-ID 300CL should assure that they are used in such an environment.

Immunity test	EN/IEC test	Compliance level
Conducted RF EN61000-4-6 IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms
Radiated RF EN61000-4-3 IEC61000-4-3	3 V/m 80 MHz to 1 GHz	3 V/m

# 1.5 Precautions in Using the FDR D-EVO

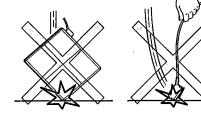
This section describes the precautions in using the FDR D-EVO.

#### 1.5.1 Handling

Handle the flat panel sensor carefully since it is manufactured with precision.

If the flat panel sensor or the SE cable connector is hit or dropped or is subject to severe shock, it may be damaged. If the front and rear of the flat panel sensor are subject to impact by a projection, it may be damaged.

DR-ID 600SE is equipped with a shock sensor that detects a severe impact. For details, see "■ DR-ID 600PU" (page 2-3).





#### **CAUTIONS**

If the shock sensor lights red, contact a FUJIFILM dealer.

Do not pull the cable of the flat panel sensor (wired communication mode).

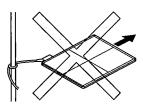
Also, do not pull the flat panel sensor with something caught by the cable.

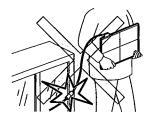
Make sure that the cable is not trapped under the wheels of a stretcher or wheelchair.

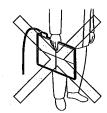
Otherwise, the cable will be damaged, causing electric shock

When carrying the flat panel sensor (wired communication mode), do not drag the sensor cable relay connector on the floor or ground. Make also sure that no one or object comes into contact with the flat panel sensor. It is recommended to hold the connector when carrying the flat panel sensor. Unless these cautions are observed, the flat panel sensor may be caught by an object, personal injury may result, or properties or the connector may be damaged.

Do not hold the flat panel sensor in one hand when carrying it. Hold it in both the hands or under the arm.





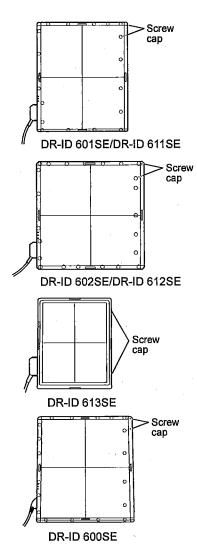


If any of the screw caps on the flat panel sensor comes off, attach a spare cap. Otherwise, artifacts may appear in the image due to static electricity.

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.

To ensure optimal image quality, it is recommended that you do not place the cables (power cable, communication cable, etc.) of the equipment near devices (motor, transformer, switching supply, etc.) that generate electromagnetic noise and their cables.

Make sure that no liquid enters the flat panel sensor from around the battery section. Otherwise, the flat panel sensor may be damaged.



Do not use a multiple tap connector or extension cable for powering the devices constituting the system.

Up to five flat panel sensors can be connected. If you intend to use six or more flat panel sensors, only the first five that were connected to the image processing unit can be used. For this reason, when six or more flat panel sensors are registered, be careful not to use a wrong one, as you may confuse which flat panel sensor is connected.

Make also sure, before making an exposure, that the color label on the flat panel sensor to be used matches the color of the panel icon selected on the image processing unit.

Be sure to disconnect the wired connection of the panel in the first room prior to connecting and imaging the patient with the same panel in the second room to avoid mis-identification of the patient.

Do not place the cable terminal on the floor, as doing so may cause infection.

Also, clean the cable and the terminal periodically.

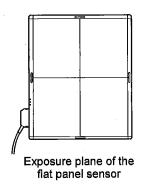
Do not insert the flat panel sensor into a CR reader unit.

# 1.5.2 Before Exposure

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

If an exposure is made with the front and rear of the flat panel sensor facing the other way round, re-exposure and electric parts may be damaged.

Do not use the flat panel sensor, which is communicating with the power supply unit in wired communication mode, for the radiographic examination stand equipped with an automatic loading function.



#### 1.5.3 **During Exposure**

Before making an exposure, make sure that exposure conditions most appropriate for this system are set.

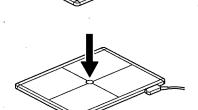
Do not apply an excessive force to the exposure plane. The sensor inside the flat panel sensor may be damaged, and it may not be possible to make an exposure properly. <Load restriction>

Entire surface load: DR-ID 600SE: 125kg (275.6 lb)

DR-ID 601SE, DR-ID 602SE, DR-ID 611SE and DR-ID 612SE : 150kg (330.8 lb) DR-ID 613SE : 310kg (683.6 lb)

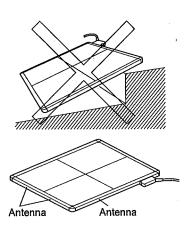
Local load: DR-ID 600SE: 40kg (88.2 lb) / ø40mm (1.6in.)

DR-ID 601SE, DR-ID 602SE, DR-ID 611SE and DR-ID 612SE: 100kg (220.5 lb) / ø40mm (1.6in.) DR-ID 613SE: 160kg (352.8 lb) / ø40mm (1.6in.)



Use the flat panel sensor on a flat floor or platform. When an excessive force is applied to the unit when it is tilted, the sensor inside the flat panel sensor may be damaged.

Do not place a metal plate, etc., which blocks radio waves, before the antenna. Otherwise, data may not be sent correctly from the flat panel sensor.



#### 1.5.4 **During Cleaning**

To clean the outer surfaces, use commercially available ethanol papers for disinfection or a cleaning cloth tightly wrung out of ethanol (or diluted neutral detergent).



#### **CAUTIONS**

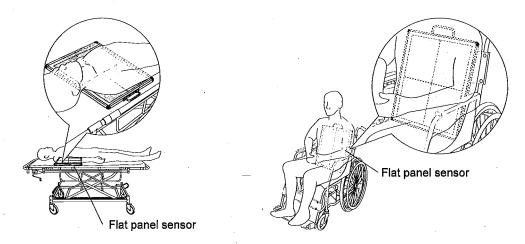
- Do not use an excessive amount of ethanol (or neutral detergent), as doing so may allow the liquid to enter from the gap on the outer surfaces, resulting in the damage to the flat panel sensor, or cause the labels to come off.
- Do not use a solvent such as thinner or benzine, as it corrodes the outer surfaces.
- For other available disinfectants, consult our official dealer.

#### 1.5.5 **Storage**

When the flat panel sensor is not in use, store the device in a place where it does not fall or drop.

# **Precautions Related to the Load Applied to the Flat Panel Sensor**

If excessive load is applied to the flat panel sensor, use it on a flat floor or platform. When making an exposure for the patient in a wheelchair or adjustable bed or on a stretcher, the flat panel sensor may be deformed (deflection by some millimeters).



If DR-ID 600SE is used in such an exposure, insert the flat panel sensor into the cassette holder (optional).

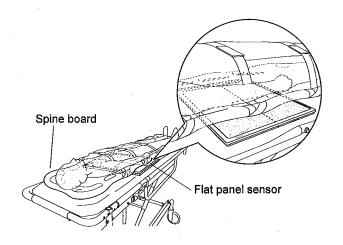
Even when the cassette holder is used, however, avoid using the flat panel sensor if the applied load is expected to exceed the limit (local load: 100kg (220.5 lb) / ø40mm (1.6in.), entire surface load: 150kg (330.8 lb)).

In case that the flat panel sensor is deformed, make sure that X-ray images are not adversely affected before continuing the use of the flat panel sensor.

The precautions below must also be observed when making an exposure.

- Do not have the patient stand on the flat panel sensor.
- Do not place the hard devices such as spine board on the flat panel sensor.

Excessive load is applied locally and the flat panel sensor may be damaged.



Even when the flat panel sensor is used on a flat floor or platform, it may be damaged if the applied load exceeds the limit.