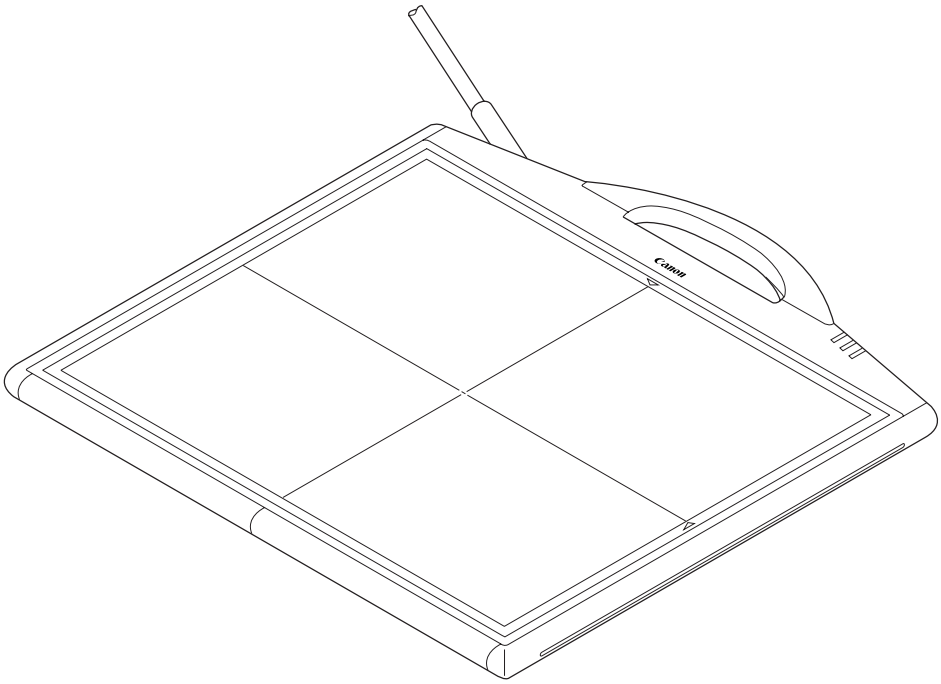
Canon

DIGITAL RADIOGRAPHY

CXDI-50G

User's Manual



Before using the instrument, be sure to read this manual thoroughly.
Also, read the manuals of other instruments in the system.
Keep the manual where it is easily accessible.

PLEASE NOTE

1. The user is responsible for the use and maintenance of the product.
   We suggest that a member of the user's staff be designated as being in charge of maintenance so as to ensure that the product is kept in a safe and good condition.
   Also, medical products must be used only by a qualified person.

2. Roentgenography, image processing, reading of image, and storage of data must be performed in accordance with the law of the country where the product is being used.
   Also, the user is responsible for maintaining the privacy of image data.

3. In no event will Canon be liable for direct or indirect consequential damage arising out of the use of this product. Canon will not be liable for loss of image data due to any reason.

4. This product may malfunction due to electromagnetic waves caused by portable personal telephones, transceivers, radio-controlled toys, etc. Be sure to avoid having objects such as these, which affect this product, brought near the product.

5. Canon reserves the right to change the specifications, configuration and appearance of the product without prior notice.

European Union (and EEA*) only.
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, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). 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 where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or your household waste disposal service.
For more information regarding return and recycling of WEEE products, please visit www.canon-europe.com.
* EEA : Norway, Iceland and Liechtenstein

- System and product names in this manual are the trademarks of each manufacturer that developed them.

Safety Information

Regulations

This instrument conforms to IEC 60601-1-2:2001.

For U.S.A. and Canada

This instrument is a CLASS I EQUIPMENT according to UL60601-1.

WITH RESPECT TO ELETRIC SHOCK, FIRE MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2 NO. 601.1, MEDICAL EQUIPMENT CERTIFIED FOR CANADA

MEDICAL EQUIPMENT WITH RESPECT TO ELETRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1 <CONTROL NUMBER 41C4>

Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked “Hospital Only” or “Hospital Grade”.

For EU Countries

The following mark shows compliance of the instrument with Directive 93/42/EEC.

CE 0197

This instrument has been classified into EN55011 Group 1/Class A.

This instrument is a CLASS I EQUIPMENT according to EN 60601-1.

Guidance and Manufacturer's Declaration for EMC Directive

Electromagnetic Emissions

The CXDI-50G is intended for use in the electromagnetic environment specified below.
The user of the CXDI-50G should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	GROUP 1	The CXDI-50G uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electromagnetic equipment.
RF emissions CISPR 11	Class A	The CXDI-50G is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	100-120VAC: Not Applicable 200-240VAC: Complies	

Electromagnetic Immunity

The CXDI-50G is intended for use in the electromagnetic environment specified below. The user of the CXDI-50G should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±(2, 4, 6) kV contact ±(2, 4, 8) kV air	±(2, 4, 6) kV contact ±(2, 4, 8) kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV 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 IEC 61000-4-11	<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 sec.	<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 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CXDI-50G requires continued operation during power mains interruptions, it is recommended that the CXDI-50G be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	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.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the CXDI-50G, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separations distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in 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[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 reflections from structures, object and people.

[a] Field strengths 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 CXDI-50G is used exceeds the applicable RF compliance level above, the CXDI-50G should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CXDI-50G.

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

Recommended Separation Distances

The CXDI-50G is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the CXDI-50G can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CXDI-50G as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separtion distance according to frequency of transmitter m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 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 reange applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

General Safety Information

Follow the safety instructions in this manual and all warnings and cautions printed on the warning labels. Ignoring such cautions or warnings while handling the product may result in injury or accident.
Be sure to read and fully understand the manual before use.
Keep this manual for future reference.

Meaning of Caution Signs

⚠ WARNING	This indicates a potentially hazardous situation which, if not heeded, could result in death or serious injury to you or others.
⚠ CAUTION	This indicates hazardous situation which, if not heeded, may result in minor or moderate injury to you or others, or may result in machine damage.
NOTE	This is used to emphasize essential information. Be sure to read this information to avoid incorrect operation.

Installation and Environment of Use

⚠ WARNING	Do not use or store the instrument near any flammable chemicals such as alcohol, thinner, benzine, etc. Also, this instrument is not a category AP or APG equipment. If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the instruments. Also, some disinfectants are flammable. Be sure to take care when using them.
⚠ CAUTION	Do not install the instrument in a location with the conditions listed below. Otherwise, it may result in failure or malfunction, fall or cause fire or injury. • Close to facilities where water is used. • Where it will be exposed to direct sunlight. • Close to air-conditioner or ventilation equipment. • Close to heat source such as a heater. • Prone to vibration. • Insecure place. • Dusty environment. • Saline or sulfurous environment. • High temperature or humidity. • Freezing or condensation.

Installation Operation

⚠ WARNING	Do not connect the instrument with anything other than specified. Otherwise, it may result in fire or electric shock.

Power Supply

⚠ WARNING	Be sure to turn OFF the power of each instrument before connecting or disconnecting the cables. Also, do not handle them with wet hands. Otherwise, you may get an electric shock that may result in death or serious injury.
⚠ WARNING	Be sure to hold the plug or connector to disconnect the cable. If you pull the cable, the core wire may be damaged, resulting in fire or electric shock.
⚠ WARNING	Do not cut or process the cables. Also, do not place anything heavy, including the instrument on it, step on it, pull it, bend it, or bundle it. Otherwise, the cable may be damaged, which may result in fire or electric shock.
⚠ WARNING	Do not turn ON the system power when condensation is formed on the instrument. Otherwise, it may result in fire or electric shock.
⚠ CAUTION	Because the instrument's cable is long, take care so cables do not get tangled during use. Also, be careful not to get your feet caught in the cable.

Handling

⚠ WARNING	Always be sure to keep checking the condition of the system and the patient to ensure they are normal during the use of the instrument. If any problem is found, take appropriate measures, such as stopping the operation of the instrument, as required.
⚠ WARNING	Never disassemble or modify the product as it may result in fire or electric shock. Also, since the instrument incorporates parts that may cause electric shocks and other hazardous parts, touching them may cause death or serious injury.
⚠ WARNING	Do not hit or drop the instrument. The instrument may be damaged if it receives a strong jolt, which may result in fire or electric shock if the instrument is used without it being repaired.
⚠ CAUTION	Do not spill liquid or chemicals onto the instrument or, in cases where the patient is injured, allow it to become wet with blood or other body fluids, as doing so may result in fire or electric shock. In such situation, protect the instrument with disposable covering as necessary.
⚠ CAUTION	Wipe the CFRP plate of the sensor unit with ethanol or glutaraldehyde solution to disinfect it each time a different patient uses the instrument, in order to prevent infection. If the optional grid unit is being used, disinfect its surface. Please consult a specialist for the procedure for disinfection.
⚠ CAUTION	Turn off the power of each instrument for safety when they are not going to be used.

When Problem Occurs

⚠ WARNING	Should any of the following occur, immediately turn OFF the power of each instrument, unplug the power cable from the AC outlet, and contact Canon representative or distributor. • When there is smoke, odd smell or abnormal sound. • When liquid has been spilled into the instrument or a metal object has entered through an opening. • When the instrument has been dropped and it is damaged.

Maintenance and Inspection

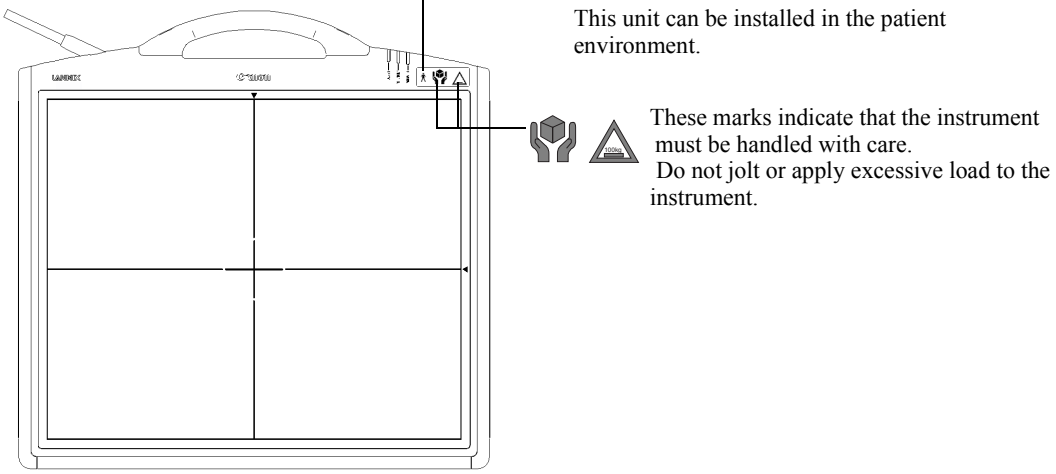
⚠ WARNING	For safety reasons, be sure to turn OFF the power of each instrument when the inspections indicated in this manual are going to be performed. Otherwise, it may result in electric shock.
⚠ WARNING	When the instrument is going to be cleaned, be sure to turn OFF the power of each instrument, and unplug the power cable from the AC outlet. Never use alcohol, benzine, thinner or any other flammable cleaning agents. Otherwise, fire or electric shock may result.
⚠ WARNING	The instrument must be repaired by a qualified engineer only. If it is not repaired properly, it may cause fire, electric shock, or accident.
⚠ CAUTION	For safety reasons, be sure to inspect the instrument before using it. In addition, carry out a regular inspection at least once a year.

Labels and Markings on the Instrument

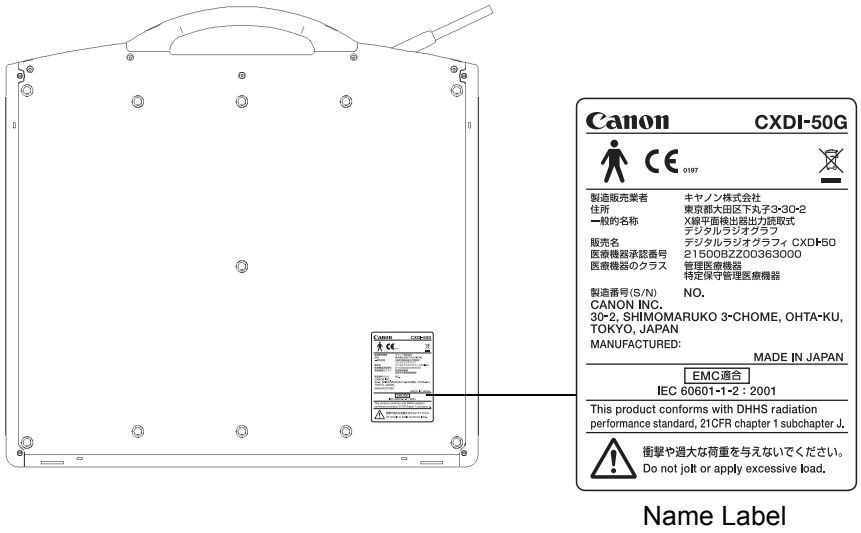
The CXDI-50G has a few labels and markings on it.
Contents of those and positions where they are attached are indicated below.

Sensor Unit

Front



Rear



Name Label

Contents

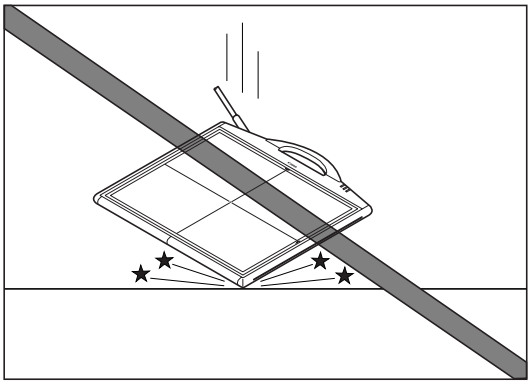
1. Overview

The *Canon Digital Radiography CXDI-50G* is a portable X-ray digital camera that can take images of any part of the body.
It directly converts the X-ray images captured by the LANMIT (Large Area New MIS Sensor and TFT) sensor into a high-resolution digital images.

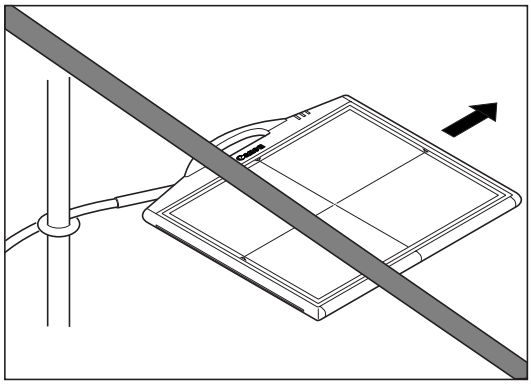
2. Notes for Using the Instrument

(1) Handling

Handle the instrument carefully, as it may be damaged if something is hit against it, dropped, or receives a strong jolt.
Also, handle the optional grid unit with care too.



Do not pull the cable. Also, do not pull the sensor unit when the cable is tangled with something. Otherwise, the cable may be damaged, which may result in fire or electric shock.



(2) Before Exposure

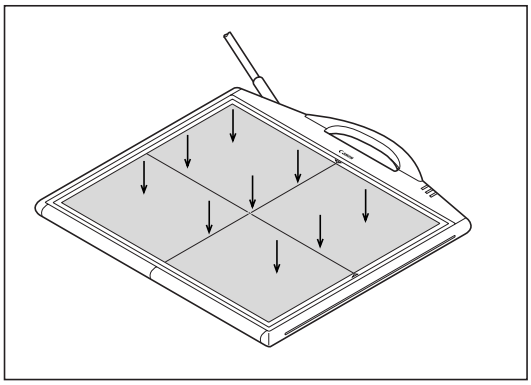
Sudden heating of the room in cold areas will cause condensation to form on the instrument. In this case, wait until condensation disappears before performing exposure.
If the instrument is used with condensation formed on it, problems may occur in the quality of the instrument.
When an air-conditioner is going to be used, be sure to raise/lower the temperature gradually so that a difference in temperature in the room and in the instrument does not occur, to prevent forming of condensation.

(3) During Exposure

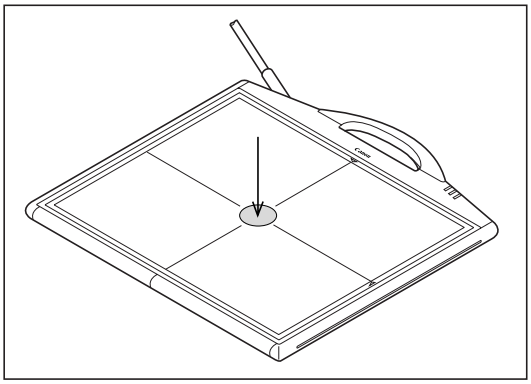
Do not apply excessive weight to the sensor unit. Otherwise, the sensor may be damaged.

Limit of Load

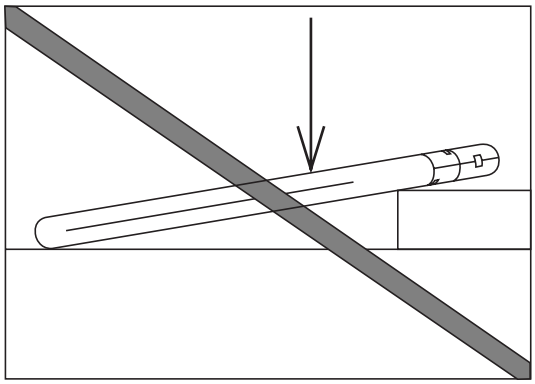
Uniform load: 150 kg over the whole area of sensor unit surface.



Local load: 100 kg on an area 40 mm in diameter.



Be sure to use the sensor unit on a flat place so it will not bend. Otherwise, the sensor may be damaged.



Perform exposure after checking that the exposure conditions are optimally suited to this product. The sensitivity of this product's sensor differs from that of the series product CDXI-50C.

(4) During Cleaning

Do not use anything other than neutral detergent for cleaning the cover of the instrument. Otherwise, the coating will be corroded.

(5) Storage

Be sure to store the sensor unit and the optional grid unit in a safe place where it will not fall or drop.

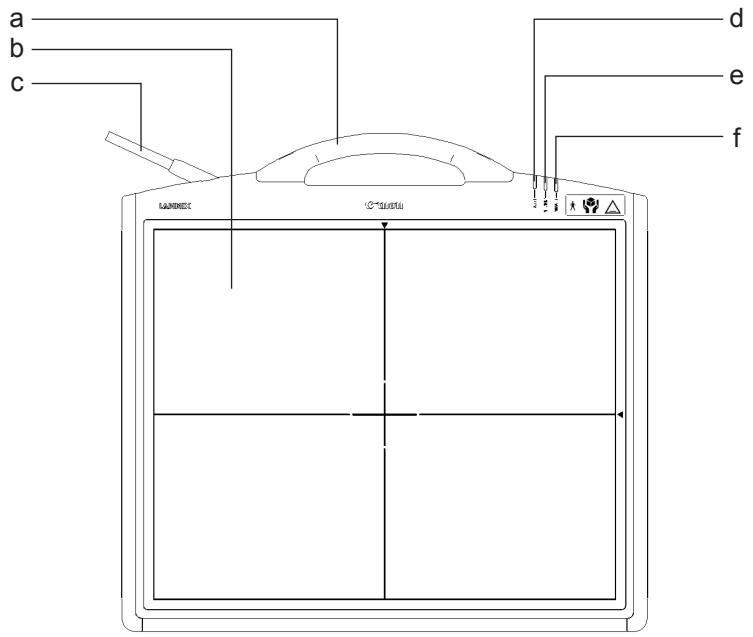
(6) Others

Be sure to reconnect the cables to the proper connectors. Otherwise, the instrument may malfunction or may be damaged.

3. Description

Sensor Unit

This unit converts the X-rays into digital signals.



	Name	Description
a	Grip	Hold this grip when carrying the sensor unit.
b	CFRP (Carbon Fiber Reinforced Plastic) plate	The part of the patient's body to which an image is to be taken should be placed against this plate. This plate should be disinfected each time a different patient uses the instrument in order to prevent infection.
c	Sensor cable	Connect this cable to the power box.
d	BUSY lamp	Blinks when the sensor unit is busy communicating.
e	SENSOR lamp	Blinks when the sensor unit is ready for exposure or when error has occurred.
f	POWER lamp	Turns ON when the power of sensor unit is ON.

4. Operation

4.1 Turning ON/OFF the Power of the System

When turning ON/OFF the power of the sensor unit, refer to the Power Box (option) Operation Manual.

4.2 Calibration

Calibration is important to ensure that a good image is achieved with the CXDI-50G by obtaining the calibration data of the sensor unit. Perform calibration when exposure conditions have changed significantly.

NOTE: For procedure for calibrating, refer to “Calibrating the Instrument” in the CXDI Series Operation Manual.

5. Inspection and Maintenance

⚠ WARNING	The instrument must be repaired by a qualified engineer only. If it is not repaired properly, it may cause fire, electric shock, or accident.
⚠ CAUTION	For safety reasons, be sure to inspect the instrument before using it. In addition, carry out a regular inspection at least once a year.

5.1 Inspection

In order to ensure that the instrument is used safely and normally, please be sure to inspect the instrument before use.
If any problem is found during the inspection, please take measures indicated in this chapter.
If problem still cannot be corrected, please contact Canon representative or distributor.

It is recommended that a record of the inspection be kept by making copies of the check lists in this section, or making a separate check list.

5.1.1 Daily Inspection

5.1.1.1 Before Turning ON the Power

⚠ WARNING	For safety reasons, be sure to turn OFF the power of each instrument when the following inspections are going to be performed. Otherwise, it may result in electric shock.

	Inspection	Result			Remedy
		Date /	Date /	Date /	
Cable	Check that cables are not damaged or cover of cables is not torn.	Good/Bad	Good/Bad	Good/Bad	Contact Canon or distributor if there is any problem.
	Check that the plugs and locks of connectors are not loose.	Good/Bad	Good/Bad	Good/Bad	Fully insert the cables and lock them.
Sensor unit	Check that the cover or parts are not damaged and not loose.	Good/Bad	Good/Bad	Good/Bad	Contact Canon or distributor if there is any problem.

5.1.1.2 After Turning ON the Power

	Inspection	Result			Remedy
		Date /	Date /	Date /	
General	Check that power lamp is lit.	Good/Bad	Good/Bad	Good/Bad	Connect the power cable and sensor cable properly.
	Perform test exposure.	Good/Bad	Good/Bad	Good/Bad	Take measures if error message is displayed by referring to the CXDI Series Operation Manual. Contact Canon or distributor if the problem cannot be solved.

5.1.2 Monthly Inspection

Perform the following inspection periodically more than once a month. Contact Canon representative or distributor if there is any problem or if you cannot do it.

	Inspection	Result			Remedy
		Date /	Date /	Date /	
General	Check the performance of the instrument by performing exposures using a phantom or a resolution chart, or perform self-test.	Good/Bad	Good/Bad	Good/Bad	Refer to the CXDI Series Operation Manual for the procedure for self-test. Contact Canon or distributor if there is any problem.

5.1.3 Yearly Inspection

Perform the following inspection periodically more than once a year. Contact Canon representative or distributor if there is any problem or if you cannot do it.

	Inspection	Result			Remedy
		Date /	Date /	Date /	
General	Check the performance of the instrument by performing exposures using a phantom or a resolution chart.	Good/Bad	Good/Bad	Good/Bad	Contact Canon or distributor if there is any problem.

5.1.4 Calibration

Perform calibration when exposure conditions have changed significantly.
See the CXDI Series Operation Manual for the procedure for calibration.

5.2 Cleaning

5.2.1 CFRP (Carbon Fiber Reinforced Plastic) Plate of the Sensor Unit

⚠ WARNING	Wipe the CFRP plate of the sensor unit with ethanol or glutaraldehyde solution to disinfect it each time a different patient uses the instrument, in order to prevent infection. If the optional grid unit is being used, disinfect its surface. Please consult a specialist for the procedure for disinfection. If you are using disinfectant other than those specified above, or you are mixing another disinfectant with ethanol, please also consult a specialist, because they may harm the CFRP plate and grid unit.

Disinfect the CFRP plate of the sensor unit each time a different patient uses the instrument. If the optional grid unit is being used, disinfect its surface.

5.2.2 Cover

⚠ WARNING	When the instrument is going to be cleaned, be sure to turn OFF the power of each instrument, and unplug the power cable from the AC outlet. Never use alcohol, benzine, thinner or any other flammable cleaning agents. Otherwise, fire or electric shock may result.

Clean the cover by the following procedure if it is dirty.

(1) Turn OFF the power of the power box.
Shut down the control computer, and press side “0” of the power switch.

(2) Turn OFF the power of each instrument.
Turn OFF the power of each instrument if connected.

(3) Unplug the power cables.
Unplug the power cables of each instrument from the AC outlet.

(4) Wipe the cover using neutral detergent.
Wipe the cover with a piece of cloth soaked in neutral detergent diluted in water and wrung dry.

(5) Wipe out neutral detergent.
Wipe the cover with a piece of cloth soaked in water and wrung dry whenever neutral detergent has been used.

6. Service Information

(1) Repair

If problem cannot be solved even after taking the measures indicated in chapter 5, contact Canon representative or distributor for repair.
Please refer to the name label and let us have the following information:

Name of the unit: It is indicated on the name label.
Serial number: 6-digit number indicated on the name label.
Phenomenon: In detail.

(2) Limit for Supplying Performance Parts for Repair

Performance parts* of this product will be stocked for eight years after discontinuance of production, to allow for repair.

* Parts required to maintain the functioning of the product

7. Specifications

7.1 Main Specifications

Sensor Unit

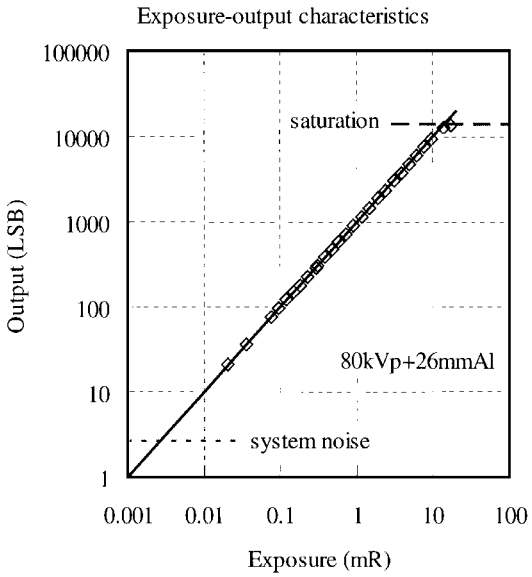
Purpose	General radiography
Pixel size	160 μm × 160 μm
Image matrix size	2208 × 2688 pixels
Number of pixels	Approx. 5.9 million pixels
Dynamic range	Approx. 80 dB
Resolution	3.1 lp/mm
Gray scale	12-bit, 4,096 gray scale
Environmental requirements	Operation: Temperature: +5 to +35 °C Humidity: 30 to 75 %RH (no condensation) Storage and transportation: Temperature: -30 to +50 °C Humidity: 10 to 60 %RH (no condensation) Atmospheric pressure: 700 to 1060 hPa
Power	Supplied from the power box.
Dimensions and mass	491 (W) × 477 (H) × 23 (D) mm, 4.8 kg (without sensor cable)

7.2 Characteristics

(1) Required patient doses

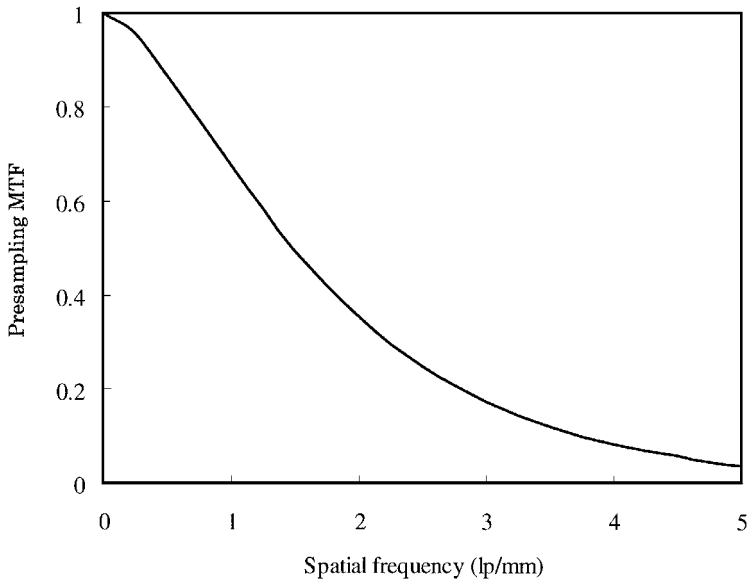
Equivalent to exposure dose of 200 or 400 speed film/screen system.

(2) Sensitometric characteristics and dynamic range



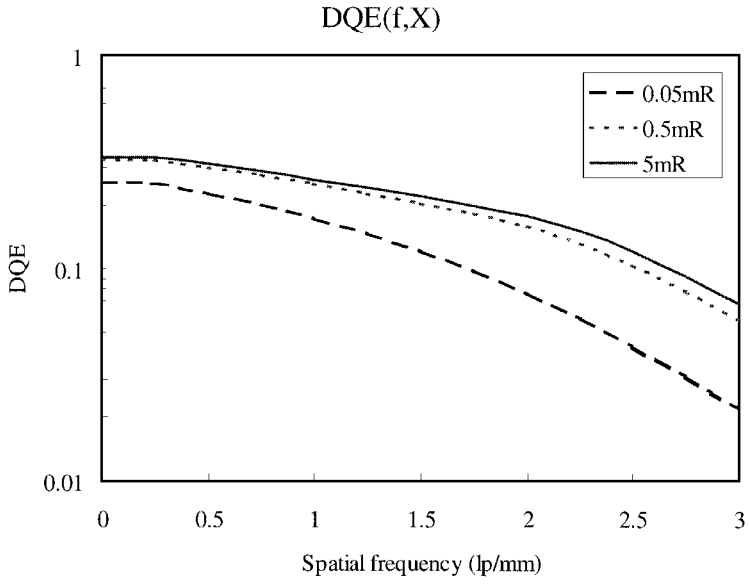
Dynamic range is determined by the levels of system noise and saturation.
The level of uncertainty is estimated to be less than ±10%.

(3) Presampling MTF



The level of uncertainty is estimated to be less than ±2% or ±0.015, whichever is greater.

(4) DQE



The level of uncertainty is estimated to be less than ±10% or 0.02, whichever is greater.

8. Components

Sensor unit.....1

Installation parts .....1 set

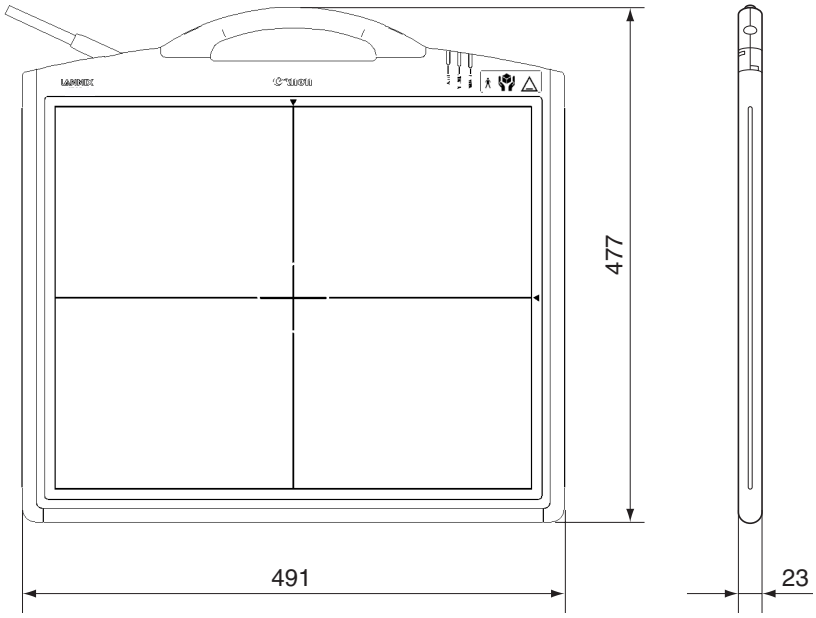
Options

Digital Radiography CXDI-50 Power Box (with Remote switch)

Grid unit for CXDI-50
Grid: 40 line/cm 110 cm (4:1)
40 line/cm 110 cm (8:1)
40 line/cm 150 cm (6:1)
40 line/cm 180 cm (10:1)

9. Dimensions

Sensor Unit



Unit: mm

Appendix: Attaching the Optional Grid Unit

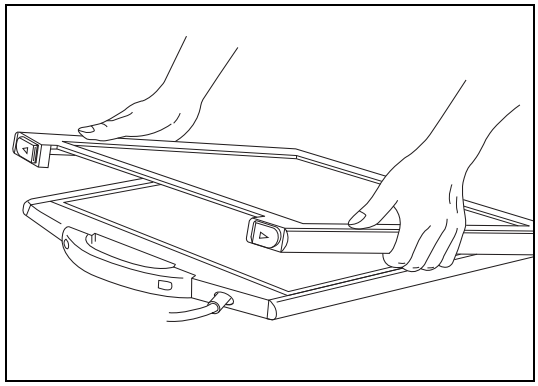
Attach the optional grid unit to the sensor unit by the procedure indicated below.

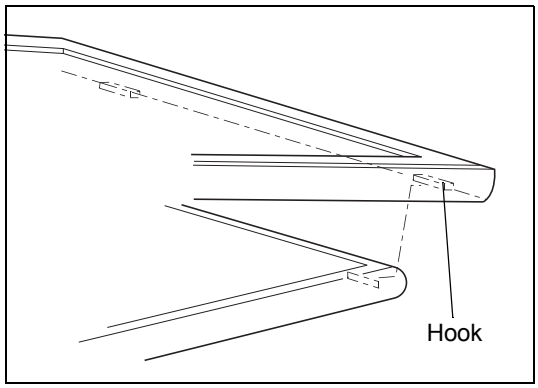
NOTE: Structure of grid unit is delicate. Do not drop, knock over, bend, or apply force or jolt to it. Otherwise, the unit may be damaged.
When the grid unit is not in use, remove it from the sensor unit and store it in a safe place where it will not fall.
Even if it is not extremely damaged, its characteristics may be changed, which may cause a problem in image quality.

(1) Blow off the dust on the front and back of the grid unit.

(2) Place the sensor unit horizontally on a table.

(3) Hold the grid unit with both hands and engage the hooks on the bottom of the grid unit to the holes on the bottom of the sensor unit.



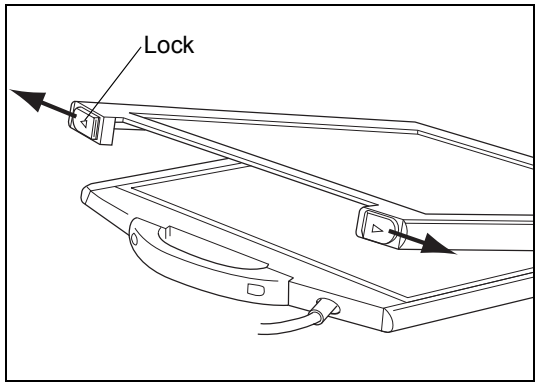


(4) Gently set the grid unit over the sensor unit. A click sound is heard when the grid unit is locked properly.

NOTE: Ensure that the grid unit is locked before lifting the sensor unit. Otherwise, the grid unit will fall and be damaged.

To remove the grid unit

While sliding the locks on top of the grid unit outward, lift and remove the grid unit.



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PUB. L-IE-4134A 0406P0.001 Printed in Japan