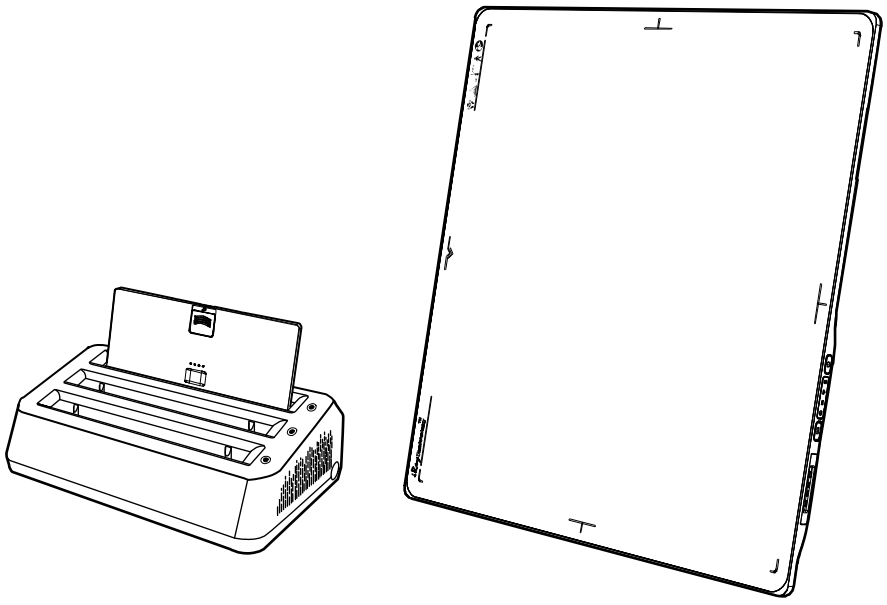
CE 0197

Mars1717XF

Wireless Digital Flat Panel Detector



User Manual

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To Customers

Thanks you for purchasing the Mars1717XF Wireless Digital Flat Panel Detector (hereinafter referred to as Mars1717XF) from iRay Technology Co., Ltd. (hereinafter referred to as iRay).

This manual contains all the general information about the Mars1717XF, which is intended to provide users with instructions on installation, use and maintenance.

All information in this manual, including illustrations, is based on the equipment prototype. If your equipment does not match with these contents, they will not apply to your equipment.

Information regarding the specifications, compositions, appearance, etc. of this product is subject to change without prior notice.

Store this manual safely so that you can access it in the future.

Copyright

Trademarks

The name and logo of iRay are registered trademarks of iRay Technology Co., Ltd.

Environmental Protection

This symbol indicates that this product cannot be disposed as domestic or commercial waste. Improper handling of this type of waste may result in a negative impact on health and environment.

Some countries or regions, such as the European Union, have set up systems to collect and recycle electrical or electronic waste items. Please contact your local authorities for information about practices established in your region. If collection systems are not available, call iRay Customer Service for assistance.

For Your Safety

- To avoid personal injury or product damage, be sure to read the user manual and all accompanying information carefully and pay attention to all safety information before installing and using the detector.
- The installation, debugging, addition, modification and maintenance of this product can only be carried out by operators who has accepted the professional training offered by the iRay's customer service staff.
- The equipment should be maintained in a safe and operable condition by maintenance personnel.
- Only a physician or a legally certified operator is allowed to use this product.
- Use only computers and image display monitors complying with IEC 60601-1 or IEC 60950-1. For details, consult our sales representative or local iRay dealer. For details, consult our sales representative or local iRay dealer.

Disclaimer

- iRay will not bear any responsibilities for any abnormality, equipment damage and personal injury caused due to your failure to follow the warnings and operating instructions in this manual.
- iRay shall not be liable to the purchaser of this product or third parties for any damage, loss, or injury incurred by purchaser or third parties as a result of fire, earthquake, any accident, misuse or abuse of this product.
- iRay shall not be liable to any damage, loss, or injury arising from unauthorized modifications, repairs, or alterations to this product or failure to strictly comply with iRay’s operating and maintenance instructions.
- iRay shall not be liable for any damage or loss arising from the use of any options or consumable products other than those dedicated as original iRay products.
- During X-ray imaging, collecting, processing, reading and storing of image data, the user should comply with the law of the countries where the product is used.
- The users and operators of the product shall protect the privacy of image data.
- The clinician is responsible for providing medical service and erroneous treatment due to misdiagnosis.

Warning Symbols

The warning symbols that appear in this user manual are classfied as follows for better comprehension of their meanings. Make sure that you fully understand them and obey the instructions they contain.

 **WARNING**	This indicates a potentially hazardous situation which, if ignored, may result in severe personal injury, death, or substantial product damage.
 **CAUTION**	This indicates a potentially hazardous situation which, if ignored, may result in minor personal injury, or product damage.
 **PROHIBITED**	This symbol is used to indicate a prohibited operation.

 NOTE	This emphasizes or supplements important information about the main text.
 REFERENCE	This symbol is used to indicate “please refer to accompanying documents attached to the CD disk or sections in this manual”.

Abbreviations

Abbreviations	Explanation
AC	Alternating Current
AED	Automatic Exposure Detection
AP	Access Point
DC	Direct Current
DR	Digital Radiography
EMC	Electro Magnetic Compatibility
FPD	Flat Panel Detector
FTP	File Transfer Protocol
HVG	High Voltage Generator
IP	Internet Protocol
IT	Information Technology
LAN	Local Area Network
LED	Light Emitting Diode
PC	Personal Computer
ROI	Range of Interest
RF	Radio Frequency
SAR	Specific Absorption Rate
SDK	Software Development Kit
SN	Serial Number
SSID	Service Set Identifier
TFT	Thin Film Transistor
UI	User Interface
WL	Window Level
WW	Window Width

Contents

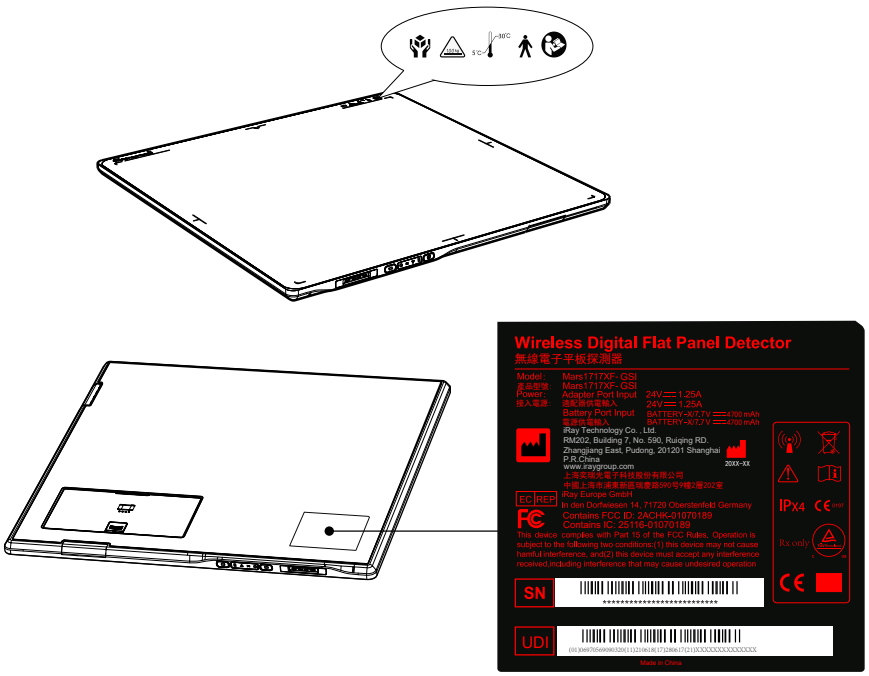
1 Safety Information

1.1 Label Description

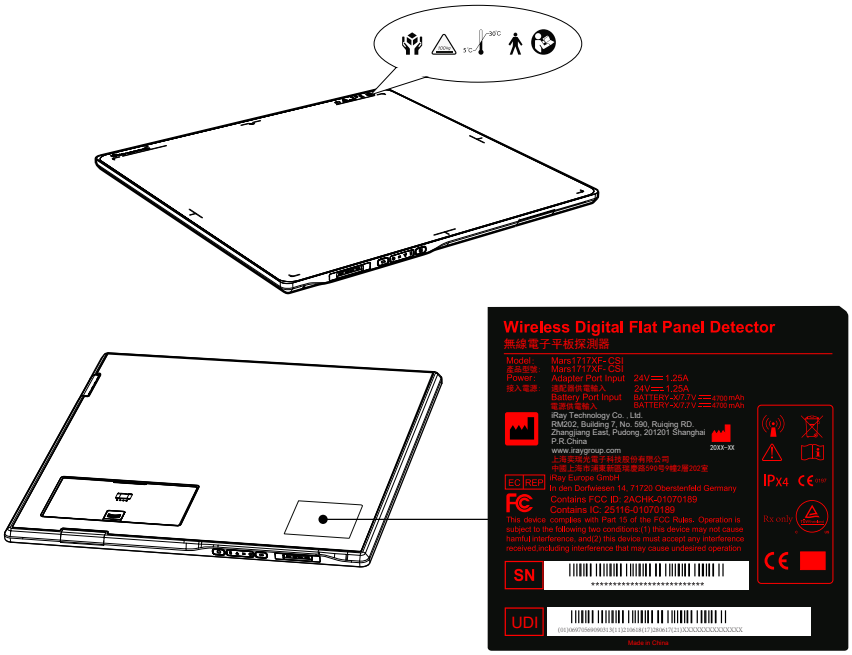
All labels shown below are for description and explanation only. The actual labels may vary due to product enhancement.

■ **Packaging Box**

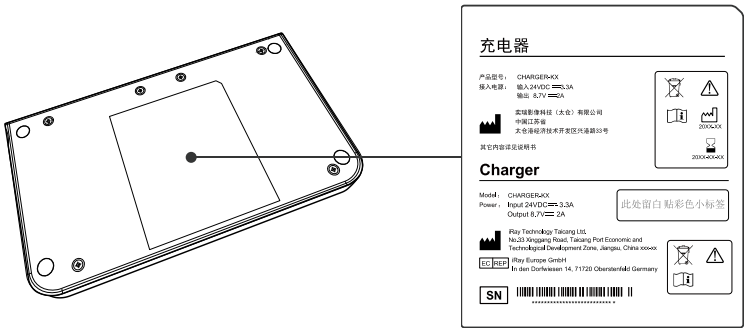
■ **Mars1717XF-GSI**



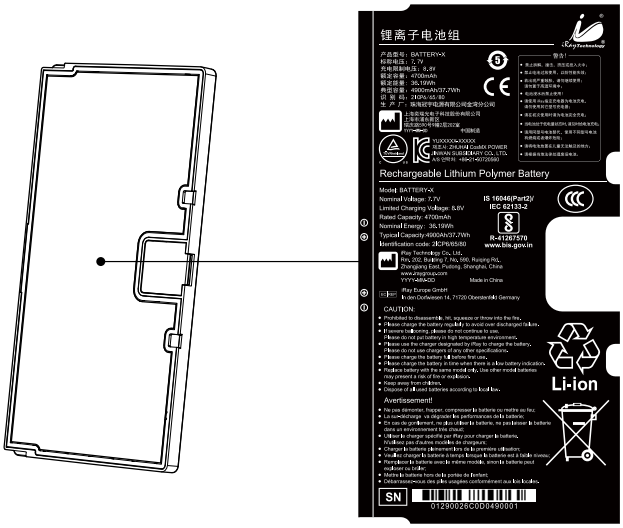
■ Mars1717XF-CSI



■ Battery Charger



■ Battery Pack



Symbol	Explanation
	This side up
	Fragile, handle with care
	Keep dry
	Stacking limit by number
	Temperature limits
	Humidity limits
	Keep away from direct sunlight
SN	Indicates the manufacturer's 19-digit serial number: $A_1A_2A_3A_4$ B_1B_2 C_1C_2 L $M_1M_2D_1D_2Y_1Y_2$ $X_1X_2X_3X_4$ Production Series No. Production Date Production Site Production Version No. Derivative Type Production Type
EC REP	iRay Technology's authorized representative in the European community
	Indicates the information of the manufacturer, including the name and address of the manufacturer
	Caution! Consult accompanying documents
	Consult instructions for use
	When the end user intends to discard the product, it must be sent to separate collection facilities for recovery and recycling
IP56	Indicates the degrees of protection provided by enclosure (IP Code) against solid objects or liquids is equivalent to IP56
	Indicates the country (CN refers to China) where the product is manufactured
	Use-by date
	Non-ionized electromagnetic radiation

Symbol	Explanation
Rx only	For prescription use only
CE 0197	European conformance mark, followed by a CE number
FC	Federal Communications Commission certificate
MD	Indicates this product is a medical device
UDI	Unique Device Identification
TÜVRheinland c US	Represents the NRTL certification mark, proving the product has passed the cTUVus certification, only limited to NRTL certification
IPX4	Indicates the degrees of protection provided by enclosure (IP Code) against solid objects or liquids is equivalent to IPX4
	Type B applied part, marked on the detector
	Handle with care, marked on the detector
100 kg	Indicates the maximum allowed weight over a 4cm diameter circular area, marked on the detector
30°C 5°C	Indicates the operating temperature limits, marked on the detector
	A safety sign indicating “Refer to the user manual”, marked on the detector
	Power off (disconnect from the main switch)
	Power on (connect to the main switch)
	Direct current

1.2 Safety Precautions

1.2.1 Operation and Storage Environment

WARNING	• **Do not operate or store the equipment in or around flammable or corrosive gases, gas mixtures, liquids, chemicals, or other substances.** Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.


CAUTION

- **Do not operate the detector in a location with the following conditions. Ignoring this warning may result in equipment failure, fire, or personal injury.**
  - Close to fluid or places where fluid is used
  - Where is will be exposed to direct sunlight
  - Close to the air outlet of an air-conditioner or ventilation equipment
  - Close to a heat source such as a heater
  - Where the power supply is unstable
  - In a dusty environment
  - In a saline or sulfurous environment
  - Where temperature or humidity is high
  - Where there is freezing or condensation
  - In an area prone to vibration
  - On an incline or in an unstable area
- **Non-medical equipment, such as battery chargers, wireless routers, and infrared devices, should not be used near patients.**
- **All patients using active implantable medical devices should stay away from this product.**
- **Do not turn on the power switch when there is condensation on the detector or any of its components or accessories.**

  Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.

1.2.2 Equipment, Interface, Power Source, and Cables


WARNING

- **Do not connect the detector to any component or accessory other than the manufacturer's specified ones. Do not use any power source other than the one provided with the equipment.**

  Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.
- **Be sure to turn OFF the power of the detector, including turning off the power supply or removing the battery (if applicable) before connecting or disconnecting the cables or accessories.**
- **Do not touch the power supply, battery pack, detector, cable, connector, or any other components with wet hands.**

  Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.
- **To avoid the risk of electric shock, this equipment must be connected to a power supply with protective earth.**
- **When connected to patient, it is only allowed be powered by battery and shall disconnect adapter cord.**
- **Use only dedicated cables for the device. Do not use any other cables.**

 CAUTION	• **Observe and follow all safety information in this manual and on the warning labels on the battery (if applicable).** Ignoring warnings could result in personal injury or product damage. • **Do not modify the cables or subject the cable to external stress or damage. Avoid placing anything heavy, including the detector, on the cable, stepping on the cable, pulling the cable, or subjecting the cable to excessive bending or bundling.** Ignoring this warning may result in cable failure, which may result in personal injury, death, or product damage. • **Do not place excessive heavy objects on the equipment.** Otherwise, the internal sensor may be damaged and the equipment may not work normally to acquire images. • **Do not exceed the maximum uniform load weight of 150 kg distributed across the surface of the X-ray detector.** • **Do not exceed the maximum load weight of 100 kg distributed on an area of 40 mm in a diameter of the X-ray detector surface.** • **Do not hit or drop the equipment.** The equipment may be damaged if it receives a strong jolt, which may result in fire or electric shock if the equipment is used without being repaired. • **Do not use any power source other than the one provided with this equipment.** Otherwise, improper power connection may lead to fire or electric shock. • **Only dedicated cables can be used on this equipment. Do not use any cable other than those supplied with this product.** • **The power cord plug must be firmly inserted into the power socket.** If contact failure occurs, or if metal objects come into contact with the exposed metal prongs of the plug, fire or electric shock may result. • **Do not supply power to more than one piece of equipment using the same AC outlet.** Doing so may result in fire or electric shock. • **Do not connect a multiple portable socket-outlet or extension cord to the equipment.** Otherwise, it may result in fire or electric shock. • **To make it easy to disconnect the plug at any time, avoid putting any obstacles near the outlet.** Otherwise, it may not be possible to disconnect the plug immediately in case of an emergency. • **Be sure to disconnect the power cable by holding the plug or connector, not by pulling the cable.** If you pull the cable too hard, the core wire may be damaged, resulting in fire or electric shock.

1.2.3 Handling

 WARNING	• **Personnel not authorized by iRay are prohibited to open the equipment enclosure.** Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage. • **Do not touch the interface and power unit or cable and the patient at the same time. Do not let the patient touch the interface and power unit or cable. Have the patient take a fixed posture and do not let the patient touch parts unnecessarily.**

	Ignoring this warning may cause electrical shock and/or unknown hazards, which may result in severe personal injury, death, or substantial product damage.
 PROHIBITED	• **Do not handle the equipment with wet hands.** Otherwise, it may result in electric shock that could result in death or serious injury. • **Make sure the equipment is used on a flat and stable surface to prevent bending and deformation of the equipment.** Otherwise, the internal image sensor may get damaged. • **If the detector is placed vertically or in any tilted position, the X-ray detector must be securely placed in the Bucky tray or securely fastened to the X-ray detector enclosure or support structure.** Otherwise, the detector may tip over, causing injury to the patient, or damage to internal equipment. • **Keep the detector under even load (same pressure) during image acquisition.** Otherwise, the quality of acquired images is not guaranteed. • **Do not spill liquids or chemicals onto the equipment. Do not let the equipment come into contact with the patient's blood or other body fluids.** Otherwise, it may result in fire or electric shock. For avoiding such contact, the disposable protective covers should be used to protect the equipment. • **Do not place any superfluous objects within the moving range of the parts of this product.** • **Disconnect the power supply when the equipment is not used for the sake of safety.**

1.2.4 Failure Handling

 CAUTION	• **Turn off the detector, unplug the adapter or battery power cord immediately and contact your sales representative or local iRay distributor if any of the following occurs:** ◆ When there is smoke, an odd smell or abnormal sound ◆ When liquid has been spilled into the equipment or a metal object has entered the equipment through an opening ◆ When the equipment has been dropped and is damaged • **When liquid has been spilled into or on any part of the X-ray detector or power supply (if applicable), or when the X-ray detector, its component, or accessory is dropped, unplug the power supply from the AC outlet, and immediately contact your sales representative or local iRay distributor.** Further use under abnormal conditions may result in severe personal injury, death, or substantial product damage.

1.2.5 Battery Pack

 CAUTION	• **If the enclosure is broken or overheating, or emits unusual odors, smoke, or leaks anything. Avoid contact with any material leaking from the battery pack.** If any liquid comes into contact with your skin or eyes, wash the affected area with clean running water and seek immediate medical attention. • **If this device is not in use for a long period of time (more than 5 days), store it with the battery pack moved. Make sure to recharge it to 30%~50% every 3 months, and 50%~70% every 6 months to maintain its best performance.** • **Do not hit or squeeze the battery. Do not insert any object into the battery or use any device to pry open the battery pack case.** Attempting to doing so will damage the battery case, which may cause the battery to release toxic and hazardous substances, resulting in injuries such as electric shock, burns, or fire, and render the battery unusable.
 PROHIBITED	• **Keep the battery away from fire, do not use it at high temperature, and do not charge the battery near flammable materials.** • **Do not invert positive and negative poles.** • **Do not touch the battery with metal to prevent short circuit.** • **Do not use non-standard batteries.** • **Do not change the internal structure of the battery.** • **Do not immerse the battery in water or other liquids, keep it dry when using the battery.** • **Do not use batteries not provided by iRay.** • **Do not charge damaged batteries or charge batteries with damaged chargers.** • **Do not use the battery charger around the patient.** • **Please remove the battery when the detector is not used for a long time.**

1.2.6 Maintenance and Inspection

 WARNING	• **Be sure to turn off the power of detector when the inspections indicated in this manual are going to be performed. If the detector is powered by AC power supply, turn off the power switch and/or unplug the AC power cord. If the detector is powered by a battery, remove the battery.** Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage. • **NEVER use alcohol, ether and other flammable cleaning agent to clean the equipment for the sake of safety. NEVER use methanol, benzene, acid, alkali or other corrosive liquids to clean the equipment.** • **The X-ray detector must be repaired by X-ray detector manufacturer authorized personnel only.** Ignoring this warning may result in explosion, fire, electric shock, or unknown hazards, which may result in severe personal injury, death, or substantial product damage.

CAUTION	• **Clean the plug of power cord periodically by unplugging it from the AC outlet and remove dust and dirt from the plug, its periphery and AC outlet with a dry cloth.** If the power cord is left plugged in for an extended period of time in a dusty, dark and humid environment, the dust around the outlet will absorb moisture, possibly causing insulation failure and a fire. • **Make sure that the equipment's surface & plugs are dry before turning ON the power.** Otherwise, it may result in fire or electric shock.

1.3 Notes for Using the Equipment

Pay attention to the following precautions when using the equipment. Otherwise, the equipment may not function correctly.

■ Before Exposure

- Be sure to check the connection of all the parts are set properly & check the detector is kept in insulated cover that operator or patient can't touch the detector directly before powered up.
- Be sure to check the equipment daily and confirm that it works properly.
- When room is heated up suddenly in cold areas, it will cause condensation on the equipment. In this case, wait until the condensation evaporates before performing an exposure. If condensation occurs during the use of the equipment, the images captured may suffer from quality problems. When an air-conditioner is used, be sure to raise/decrease temperature gradually to ensure that the temperature difference between room and equipment will not cause condensation.
- The detector should be warmed up for 20 minutes before exposure or creation of calibration template.

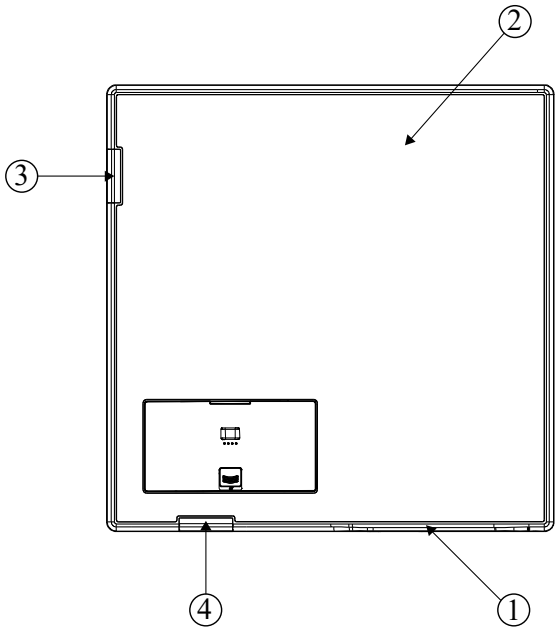
■ During Exposure

- Do not move the powecable or Ethernet cable during exposure. Otherwise, it may cause image noise, artifacts or incorrect images.
- Do not use the equipment in areas with strong magnetic field. Otherwise, it may cause image noise, artifacts or incorrect images.
- Do not make an exposure within 60 seconds after 4 full range exposures. Otherwise, the image will be incorrect. Do not make an exposure within 30 seconds after a full-range exposure. The larger the dose used, the longer the wait should be before the next exposure.
- During image acquisition, detector should not be influenced in a physical or electrical way.

■ After Exposure

If the detector will not be used for 5 days, it is required to take out the battery. If the battery will not be used for a long time, it must be charged to 30%~50% every 3 months or 50%~70% every 6 months.

■ Disinfection and Cleaning



	①	②	③
Dehydrated ethanol	Yes	Yes	Yes
Isopropyl alcohol (Concentration of 99.0% or more)	Yes	Yes	Yes

After every examination, wipe the patient contact surfaces or any other surfaces of FPD with dehydrated ethanol or isopropyl alcohol to prevent the risk of infection. The accessories include battery, charger, adaptor and DC adaptor can also be cleaned by dehydrated ethanol or isopropyl alcohol. However, the cleaning must be operated under the condition that the FPD and accessories are not electrified. The FPD and accessories cannot be electrified until the cleanser is fully evaporated. For details on how to sterilize the device, consult a specialist.

① Do not spray the detector directly with disinfectants or detergents.

② Wipe it with a cloth slightly damped with a neutral detergent. Do not use solvents such as alcohol, thinner, benzene, acid and base. Doing so may damage the surface of the equipment.

③ It's recommended to use a waterproof non-woven cover as the isolated layer between detector and the blooding patient.

2 Regulatory Information

2.1 Medical Equipment Classification

Mars1717XF has two power supply modes (power adaptor and battery pack) and a single way for signal transmission (wireless).	
Protection type against electrical shock	Class I equipment, using medically approved adaptor supply Internally powered equipment, using battery power supply
Degree of protection against electrical shock	B Type
Protection degree against water penetration	IPX4 (Detector) IPX0 (Charger-KX)
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in situation with flammable anesthetic mixture with air, oxygen or nitrous oxide Not suitable for use in oxygen-rich situation

2.2 Safety Standard Reference

The applicable safety standards for this product covers the product host, battery charger, rechargeable battery (if applicable) and other accessories.

No.	Standard
1	IEC 60601-1:2005 +CORR.1 (2006) + CORR. 2 (2007) + AM1 (2012)
2	EN 60601-1:2006+A11:2011+ A1:2013+A12:2014
3	BS EN 60601-1:2006+A11:2011
4	ANSI/AAMI ES60601-1:2005/(R)2012+A1:2012+ C1:2009/(R)2012+A2:2010/ (R)2012
5	CAN/CSA-C22.2 No.60601-1:14
6	KS C IEC 60601-1
7	SS-EN 60601-1:2006+A11:2011+A1: 2013+AC1: 2014+A12:2014
8	IEC 60601-2-54:2009+A1:2015
9	CAN/CSA-C22.2 NO. 60601-2-54:11
10	KS C IEC 60601-2-54:2012
11	SS-EN 60601-2-54:2010+A1:2015
12	IEC 60601-1-6:2010+A1:2013

No.	Standard
13	CAN/CSA-C22.2 NO. 60601-1-6:11+A1:2015
14	KS C IEC 60601-1-6:2011
15	EN 60601-1-6:2010+A1:2015
16	EN 60601-1-2:2015/IEC 60601-1-2:2014
17	IEC 62133:2012
18	IEC 62366:2007, AMD1:2014

2.3 Guidance and Manufacturer's Declaration For EMC

2.3.1 EMI Compliance Table

- **Emissions**

Phenomenon	Compliance	Electromagnetic Environment
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	

2.3.2 EMS Compliance Table

- **Enclosure Port**

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Professional Healthcare Facility Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Near fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table "Near Fields from RF Wireless Communications Equipment"
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

■ Near Fields from RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)	Immunity Test Levels
		Professional Healthcare Facility Environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

■ Input AC Power Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Professional Healthcare Facility Environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% UT; 1 cycle 70% UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 cycles

■ Recommended Separation Distances

Portable RF communications equipment, including antennas, can effect medical electrical equipment. The warning should include a use distance such as “be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer”.

■ Cable Provided for EMC

Cable	Recommended Length	Shield/Unshielded	Number (piece)	Cable Classification
AC power cable	1.8m	Unshielded	1 piece	AC power
DC power cable	3m	Unshielded	1 piece	DC power

■ Electromagnetic Compatibility (EMC)

The Mars1717XF series wireless flat panel detector needs special precautions regarding EMC, and should be installed by local supplier or authorized personnel and follow EMC guidance in the user manual. The Mars1717XF series product when in use may interfere with portable and mobile RF communication devices such as mobile (cellular) telephones. Electromagnetic interference may result in incorrect operation of the system and a potentially dangerous situation.

The Mars1717XF series wireless flat panel detector should not be stacked with or adjacent to other devices. If inevitable, verify the detector.

The Mars1717XF series wireless flat panel detector conforms to this EN 60601-1-2:2015/IEC 60601-1-2:2014 standard on both immunity and emissions.

Accessories, transmitters and cables other than those specified by the user manual or sold by local supplier may result in increased emissions or decreased immunity of the detector.

2.4 Radio Frequency Compliance Information

Country	Item
U.S.A	KDB 865664 D01 47 CFR part 15, subpart B 47 CFR part 15, subpart C 15.247 47 CFR part 15, subpart E 15.407 KDB447498 D01 v06 General Exposure Guidance

Country	Item
European Union	EN 62209-2:2010 EN 50566:2017 EN 62479:2010 EN 55032:2015 EN 61000-3-2:2014 EN 61000-3-3:2013 EN 301 489-1 V2.1.1 EN 301 489-17 V3.1.1 ETSI EN 300 328 V2.1.1 EN 300 328 V2.1.1 ETSI EN 300 440 V2.1.1 ETSI EN 301 489-1 V2.1.1 ETSI EN 301 489-17 V3.1.1 ETSI EN 301 893 V2.1.1

2.5 Battery Safety Standards

Standards	Description
IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
UN38.3	United Nations Recommendations on the Transport of dangerous goods Manual of tests and Criteria ST/SG/AC.10/11/Rev.6

2.6 Environmental Directive

Europe WEEE directive

ROHS(2011/65/EU)

PFOS legislation(No.757/2010)

REACH legislation(No.1907/2006)

Cadmium legislation (Controlled substance: Annex XVII)

REACH legislation (No.1907/2006) (SVHC: Annex XVII)

New batteries directive(2006/66/EC)

EU Packaging Directive(94/62/EC)

2.7 Radio Frequency (RF) Energy

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the United States.

The exposure standard for wireless devices employing a unit of measurement is known as the Specific Absorption Rate, or SAR. The SAR limit recommended by the general public is 1.6W/kg Averaged over one gram of tissue by IEEE Std 1528.

The FCC has granted an Equipment Authorization for this product with all reported SAR Levels evaluated as in compliance with the FCC RF exposure guidelines. While there may be differences between the SAR levels of various product and at various positions, they all meet the government requirements.

SAR compliance for body-worn operation is based on a separation distance of 0 mm between the unit and the human body. Carry this device at least 0 mm away from your body to ensure RF exposure level compliant or lower to the reported level.

2.8 FCC

Contains FCC ID：2ACHK-01070189

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

  (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

  — Reorient or relocate the receiving antenna.

  — Increase the separation between the equipment and receiver.

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

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

- Changes or modifications not expressly approved by the manufacturer could void the user’s authority to operate the equipment.

2.9 IC Notice

This device complies with Industry Canada license-exempt RSS standard(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.

This Class B digital apparatus complies with Canadian ICES-003.

Contains IC:25116-01070189

5150-5250MHz is in door use only.

IC Radiation Exposure Statement

This EUT is in compliance with SAR for general population/uncontrolled exposure limits in IC RSS-102 and had been tested in accordance with the measurement methods and procedures specified in IEC/IEEE 62209-1528: 2020. The SAR limit is 1.6 W/kg by Industry Canada. This equipment should be installed and operated with minimum distance of 0 mm between the radiator and your body. This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.

2.10 Remarque IC

Cet appareil est conforme aux Normes RSS d'Industy Canada. Son utilisation est soumise à deux conditions:

(1) Ce dispositif ne peut pas provoquer d'interférences, et

(2) Ce dispositif doit accepter toutes les interférences reçues, y compris les interférences susceptibles de provoquer un fonctionnement non souhaité.

Cet appareil de classe B est conforme à la norme canadienne ICES-003.

Contient IC:25116-01070189

5150-5250MHz est dans l’usage de porte seulement.

Déclaration d'exposition IC

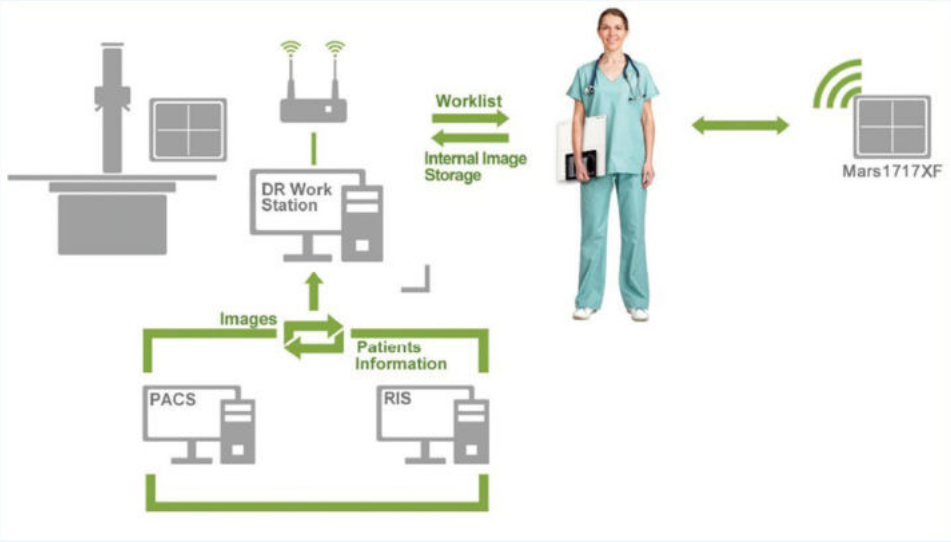
Cet EUT est conforme aux valeurs SAR à la norme SAR pour le grand public ainsi qu'aux limites d'exposition non règlementée IC RSS-102 et a été testé selon les méthodes et procédures spécifiées par les Normes IEC/IEEE 62209-1528: 2020.La limite DAS est de 1,6W/kg par Industrie Canada. Cet appareil devrait être installé et utilisé en respectant une distance minimale de 0 mm avec votre corps. Cet appareil et son (ses) antenne (s) ne doivent pas être situés à proximité l'un de l'autre et ne doivent pas fonctionner en même temps qu'une autre antenne ou qu'un autre émetteur.

3 Product Introduction

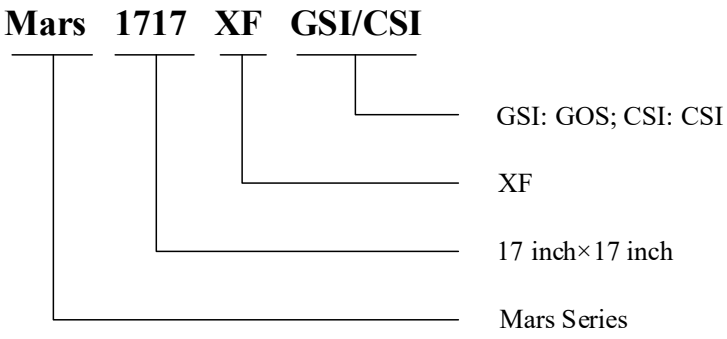
3.1 Overview

Mars1717XF is a cassette-size wireless digital X-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It is developed to provide the highest quality of radiographic images, and contains an active matrix of 2832×2836 with 150um pixel pitch.

The detector's scintillator has two options: GOS (Gadolinium Sulfoxylate) and CsI (Caesium Iodide). However, the greatest improvement is wireless communication between the detectors and PC. In addition, it can be powered with a battery for portable panel use.



3.2 Lineup



3.3 Intended Use

Wireless Digital Flat Panel Detector is intended for digital imaging solutions and designed to provide general radiographic diagnosis of the human anatomy. It is intended to replace radiographic CR and DR systems in all general-purpose diagnostic procedures. This device is not intended for mammography or dental applications.

The detector can be used for general X-ray diagnosis of certain body parts. It is not intended for mammography, dental applications, neonatal and fluoroscopy. More care should be taken when making a diagnosis of people with allergies. In addition, it is also prohibited for use on pregnant women. Shielding of none-inspection body areas is necessary during X-ray exposure. There is no contraindication.

According to intended use and results of risk management, essential performance is identified and described as the following:

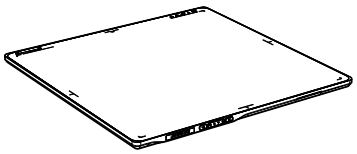
- To acquire dark images, detector shall be not influenced by imaging acquisition.
- To maintain data transmission, detector shall be not influenced by data and signal transmission.

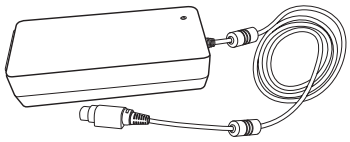
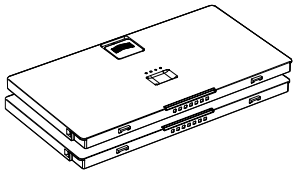
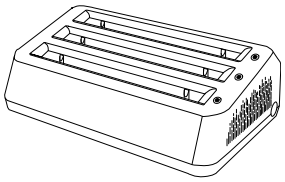
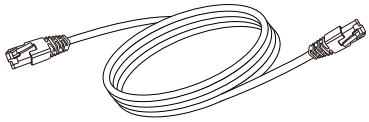
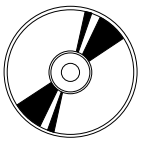
3.4 Characteristics

- Wireless static Flat Panel Detector used for general radiography.
- 17×17 inch
- AED trigger
- Easy-to-change cable and charge in tray
- Battery rechargeable
- IPX4

3.5 Packing List

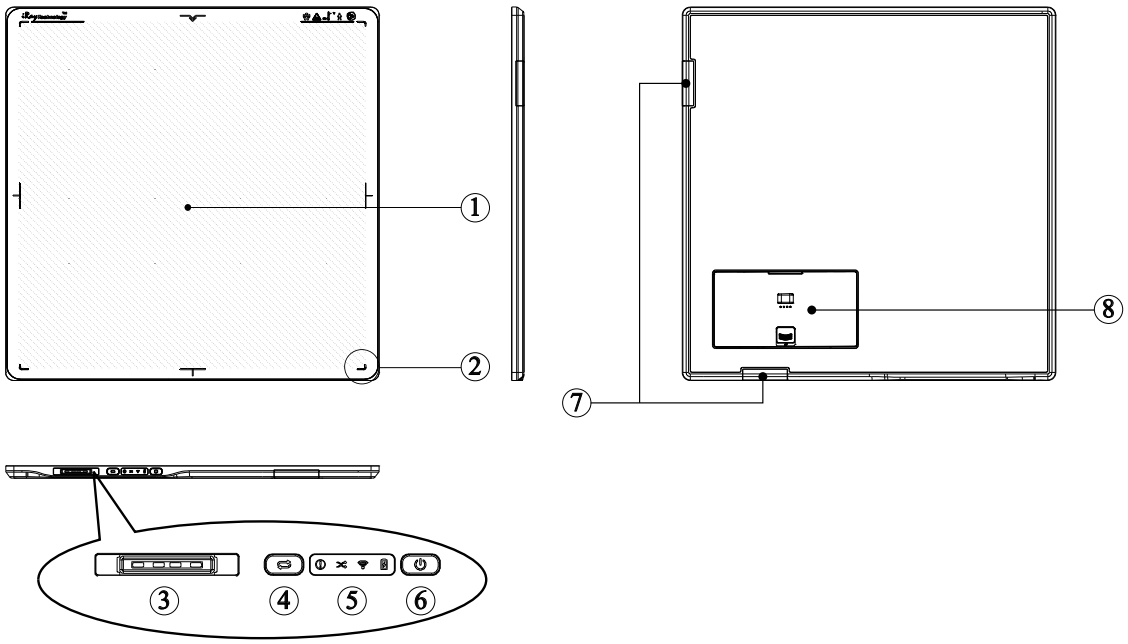
Check the list below to verify that all the items have been included. Contact your iRay dealer if anything is missing or damaged.

Item	Figure	Qty. (unit: piece)
Mars1717XF GSI/CSI Detector		1

Item	Figure	Qty. (unit: piece)
Power adapter (24V)		1
Battery pack (7.6V)		2
Battery charger		1
Gigabit Ethernet cable		1
User Manual (Paper Print)		1
CD		1

3.6 Component Description

3.6.1 Detector



No.	Name	Description
①	Active area	Indicates the active imaging area (shaded area)
②	Origin position	Indicates the position of the first pixel (0,0)
③	Power interface	Supplies power to the detector
④	Reserved	Not used
⑤	LED indicators	Indicates the status of the detector
⑥	Power switch	Used to power on/off the detector
⑦	Antenna	Transmits image data with wireless communications (IEEE802.11a/b/g/n/ac)
⑧	Battery	Battery inserted to supply electrical power when connecting wirelessly

■ **Status Indicator**

Status Indicator	Color	Description
OFF		• Detector is turned off • Exposure prohibited
Green ON		Ready for exposure

Status Indicator	Color	Description
Orange blinking		Safety Mode
Orange ON		Fatal Error
Green blinking		Wireless configuration reset

■ Mode Indicator

Mode Indicator	Color	Description
Blue ON		Default
OFF		Detector is turned off

■ Link Indicator

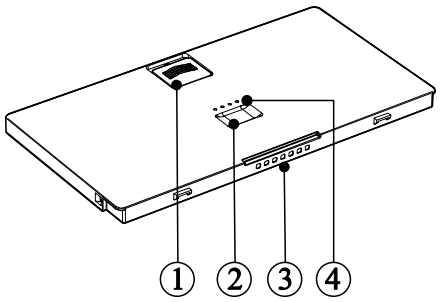
Link Indicator	Color	Description
OFF		• Detector is turned off • Wired connection broken and wireless connection not ready
Blue ON		Wireless connection is enabled
Green ON		Wired connection is enabled (Service Mode)
Blue blinking		• Detector Initialization • Wireless configuration reset
Green blinking		Wireless configuration reset

■ Power Indicator

Power Indicator	Color	Status		
		Battery Capacity	DC Input	Description
OFF		NO	NO	Detector is turned off
Orange ON		≥7% & ≤15%	NO	Detector is turned on
Green ON		>15%	NO	Detector is turned on
		NO	YES	

Power Indicator	Color	Status		
		Battery Capacity	DC Input	Description
Orange Blinking		≥7% & < 15%	YES	Detector is turned on
Green Blinking		≥15% & < 95%	YES	Detector is turned on or detector is in sleep mode

3.6.2 Battery Pack



No.	Name	Description
①	Lock	Locks the battery in place
②	Touch button	Touches to display the remaining battery level
③	Battery connector port	Connects to the detector or the battery charger
④	Battery LEDs	● ○ ○ ○ Battery remaining ≤10%
		● ● ○ ○ Battery remaining 10%~25%
		● ● ● ○ Battery remaining 25%~50%
		● ● ● ● Battery remaining ≥75%

■ **Battery Activation**

The battery is set to ship mode when shipped. Prior to its initial use, three methods are available to activate your battery pack:

Method	Operation
Battery charger activation	1) Insert the locked battery pack into the battery charger 2) Power up the charger and the battery will be activated in about 13~15 seconds

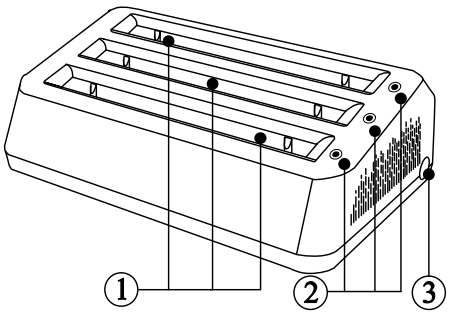
Method	Operation
Power adapter activation	1) Insert the battery pack into the battery compartment of the detector 2) Plug the power adapter into your detector and into the AC outlet 3) The activation will take approximately 18~20 seconds
Web activation	1) Establish a wired/wireless connection between the computer and the detector 2) Insert the battery pack into the battery compartment of the detector 3) Type *http://192.168.8.8/cgi-bin/shipmode.cgi?action=off* in the Web to exit the ship mode

■ Battery Lock

To ensure the safety of the battery pack during transportation or storage, the battery pack can be set to the ship mode.

Method	Operation
Factory lock	/
Web lock	1) Establish a wired/wireless connection between the computer and the detector 2) Insert the battery pack into the battery compartment of the detector 3) Type *http://192.168.8.8/cgi-bin/shipmode.cgi?action=on* in the Web to enter the ship mode

3.6.3 Battery Charger



No.	Name	Description
①	Battery slot	Charges the battery when properly placed
②	Charging indicator	Indicates the charging status
③	24V DC Jack	Supplies power to the battery charger

■ **LED Indicators**

Indicator	Status	Operating Status
OFF		No battery inserted
Green blinking		Battery inserted with capacity ≤95%, charging
Green ON		Battery inserted with capacity >95%
Orange blinking		Battery slot malfunction

3.6.4 Power Adapter

Detector supports an external adapter powered, It gets CB certificate No. SG PSB-MD-00005 and NRTL certificate No. U8V 093768 0016.The ports defined as bellow:

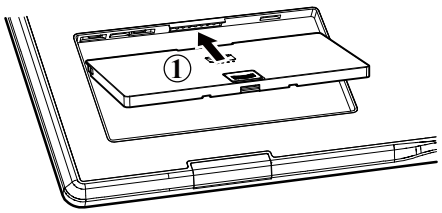
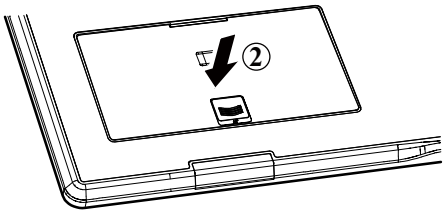
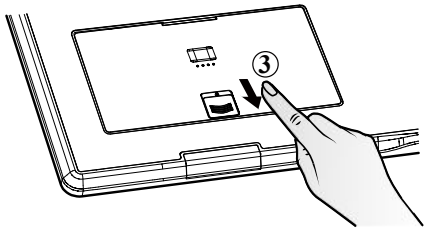
No.	Definition	Voltage Range	Rated Current
P1	DC Power Negative	0~0.5V	0~0.42A
P2	DC Power Positive	23~25V	0~0.42A
P3	DC Power Positive	23~25V	0~0.42A
P4	DC Power Negative	0~0.5V	0~0.42A

4 Basic Operation

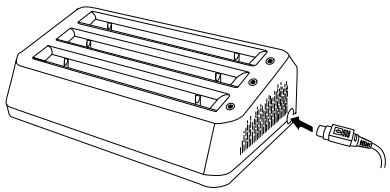
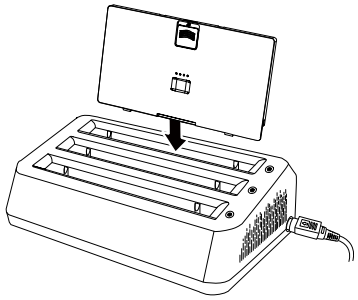
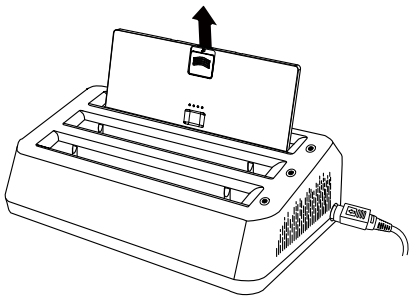
4.1 Preparation

4.1.1 Attaching Battery Pack to Detector

Mars1717XF can be powered by both a battery pack and DC power. Once the battery pack is inserted or DC power is connected, detectors will be turned on immediately. If neither battery nor DC power is connected, detector will power off. Please see below for battery installation.

① Holding the battery pack with the terminals facing as shown, and align the battery connector port on the battery with the Mars1717XF battery connector port	
② Slide the battery pack into battery compartment until fully inserted	
③ Slide the battery lock to lock the battery pack	

4.1.2 Installing the Battery into the Charger

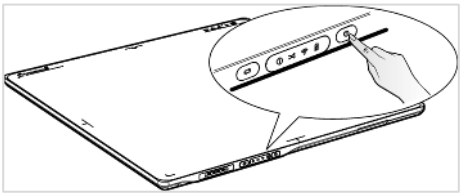
① Connect one end of the power adapter to the AC jack of the battery charger, the other to an AC outlet	
② Insert a low battery pack into an available slot, and press down it until you hear a “click” sound. The indicator of the slot and the battery pack LED will start to flash	
③ Remove the battery pack when charging is complete	

4.2 Routine Operation

■ Startup/Shutdown

Press the power button to turn on or off the detector.

Startup: when the detector battery is installed and the power is not less than 15% or the detector is connected with the DC power supply, you can press the button for 4 seconds to turn on the detector.



Shutdown: when the detector is turned on, you can press the button and hold for 4 seconds to turn off the detector.

Reboot: if the panel is disconnected, you may press and hold the power button for 8 seconds to restart the connect.

5 IT Network

5.1 Purpose for IT Network

Transmission between the detector and the workstation (FDR SE Console or iDetector) is image data and command /status communication.

5.2 Required Characteristics

Wireless communication follows IEEE 802.11a/b/g/n protocol. It works on 2.4GHz and 5GHz.

It supports at least 2 routers.

5.3 Required Configuration

The wireless card and the detector must work on the same IP segment such as 192.168.100.XXX

They must support IEEE 802.11.a/b/g/n.

5.4 Technical Specifications (Only for CE)

Image Transfer	Wireless: IEEE802.11a/b/g/n/ac
Wireless Frequency Range	2.412~2.472GHz, 5.18~5.22GHz;5.745~5.85GHz
Modulation Type	802.11b DSSS (CCK, DQPSK, DBPSK) 802.11 a/g/n/ac: (OFDM, 256QAAM, 64QAM, 16QAM, QPSK, BPSK)
Wireless Band	2.4GHz≤40MHz 5.19GHz≤80MHz 5.8GHz≤80MHz

5.5 Intended Information Flow

The detector sends image data acquired to the workstation (FDR SE Console or iDetector). The workstation (FDR SE Console or iDetector) sends users' commands to the detector. Please refer to the operation manual of the console for detail.

5.6 Hazardous Situations Resulting from Failure of the IT Network

- Failure of completing essential performance
- Failure of finishing configuration of product
- Operating system is not compatible
- Change or update software failed
- Compatibility of interface
- Data transfer protocol error
- Inconsistency of interface or format leads to data distortion;
- Data output failed

5.7 Warning

Connection of the main unit to an IT-network that includes other equipment can result in previously unidentified risks.

The manufacturer of the X-ray machine should identify, analyze, evaluate and control these risks.

Subsequent changes to the IT-network can introduce new risks and require additional analysis.

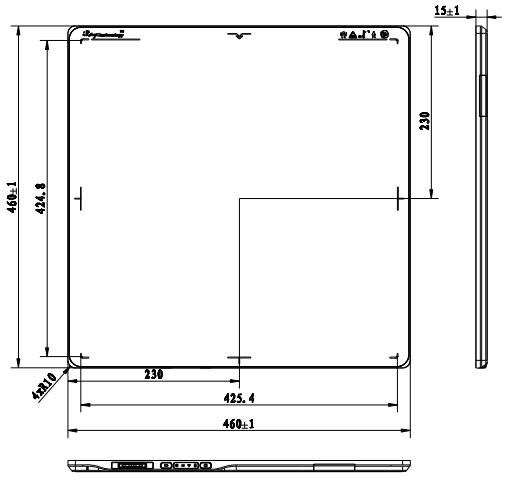
5.8 Changes to IT Network

Changes to IT Network include:

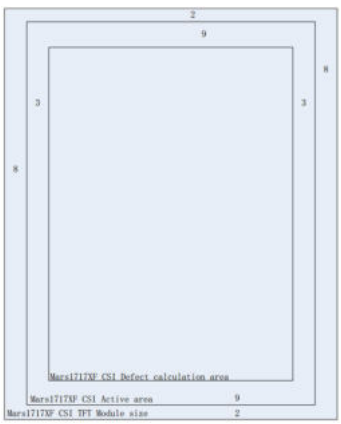
- Changes in IT network configuration
- Connection of additional items to IT network
- Disconnecting items from IT network
- Update of equipment connected to IT network

6 Technical Specifications

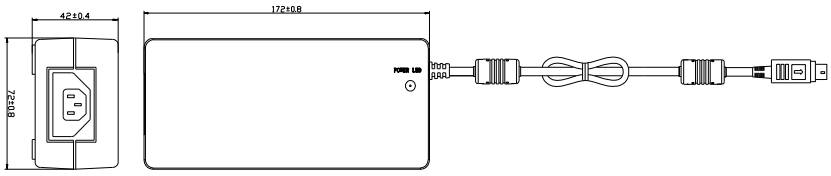
6.1 Detector



Item	Specification
Model	Mars1717XF-GSI (GOS) Mars1717XF-CSI (CsI)
Pixel size	150μm
Effective array	2832×2836
Effective area (H x V)	424.8mm×425.4mm
Greyscales	16 bits

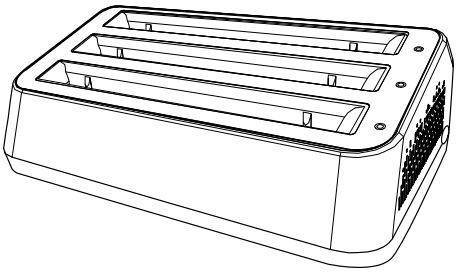
NOTE	Mars1717XF-GSI's active area and defect calculation area is 2832×2836 and TFT module size is 2848×2840.	Mars1717XF-CSI defect calculation area is 2826×2818, the active area is 2336×2836, TFT module size is 2848×2840. 

6.2 Power Adapter



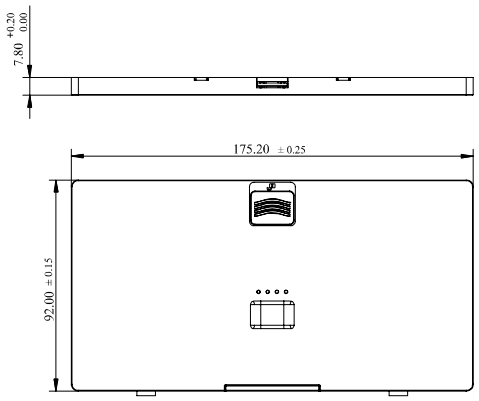
Item	Specification
Model	LXCP120-0240500(C005)
Input	100~240V 50Hz/60Hz AC input
Output	24V single output, 120W
Dimensions (W×H×D)	172mm×72mm×42mm

6.3 Battery Charger



Item	Specification
Model	Charger-KX
Simultaneous Charging	3 battery packs
Full Charging Time	2.5 hours
Full Charging Time	≤4hours

6.4 Battery Pack



Item	Specification
Model	BATTERY-X
Rated Capacity	Min. 4700mAh, Typ.4900mAh @ Discharge 0.2C
Nominal voltage	7.7V
Charge Voltage	8.8V
Discharged end voltage	6.0 V
Storage environment conditions	-20℃~45℃ (0~3months) -20℃~35℃ (3~6months) -20℃~30℃ (6~12months) 5%~95%RH
Operating environment conditions	Charge 0℃~60℃ Discharge -20℃~60℃ 5%~90%RH
Dimensions (W×H×D)	175.20mm×92.00mm×15.39mm

6.5 Environment Requirements

The device must be transported, stored, and operated in permissible environmental conditions, as stated below:

Item	Operation	Storage & Transportation
Ambient temperature	5~30℃	-20℃~50℃
Relative humidity	10%~80% RH (non-condensing)	10%~90% RH (non-condensing)
Atmospheric pressure	700~1060mbar	700~1060mbar
Altitude	Max. altitude 3000m	/

7 Service Information

7.1 Product Life

The estimated product lifetime is up to 7 years under appropriate regular inspection and maintenance.

NOTE	• The product life cycle is decided by the life cycle of the detector. • For other replaceable parts, their service life will not affect the life cycle of the whole product. • Main parts (parts required to maintain the function of the product) of this product will be stocked for 5 years after discontinuance of production for repairing.

7.2 Sterilization and Shelf Life

This does not apply.

7.3 Regular Inspection and Maintenance

In order to ensure the safety of patients, operating person and third parties, and to maintain the performance and reliability of the equipment, be sure to perform regular inspection at least once a year. If necessary, clean up the equipment, make adjustments, or replace consumables such as fuses, detector cable, etc.

There is a lithium battery in the detector whose lifetime is more than 5 years; the battery needs to be replaced when it finishes. Contact iRay service office or local iRay dealer for regular inspection or maintenance.

7.3.1 Daily Inspection

The following checks should be performed before and after use of this product.

Item	Operation
Detector	Make sure there are no loose screws or cracks in the detector Make sure there is no dust and impurities attached to the battery connection pins Make sure there are no cracks or short circuits at the battery connection pins
Cables	Ensure that the cable is not damaged and the cable shell is not torn Verify that the power cord is reliably connected to the power socket of the detector
Battery	Make sure there is no short circuit at the battery connection pins Make sure the battery is not expanding

7.3.2 Monthly and Yearly Inspection

Item	Frequency	Operation
Resolution	Monthly/yearly	Check detector resolution by resolution graphic or using phanton
Linear	Monthly/yearly	Evaluate by examining the gray value of images
Calibra-tion	Monthly/yearly	When the X-ray generator, tube, collimator or exposure environment changes

WARNING	For the maintenance and overhaul involving the disassembly of the equipment shell, contact qualified service engineers. Please contact iRay's Customer Service Department or your product distributors.

7.4 Troubleshooting

If any fault occurs but cannot be solved, turn off the detector and contact iRay's Customer Service Department (service@iraygroup.com) for professional technical support and provide the following information as per the product label: ① Name and model of product; ②Product SN; ③ Description of product failure as detailed as possible.

7.5 Customer Service

CS Dept.:	Service Office of iRay Technology Co. Ltd.
Address:	Building 45, No. 1000, Jinhai RD., Pudong New Area, 201206 Shanghai China
Telephone:	+86-21-50720560
Fax:	+86-4008266163-60610
Email:	service@iraygroup.com
Website:	www.iraygroup.com

7.6 Manufacturer Information

Manufacturer：	iRay Technology Co., Ltd
Address：	RM202, Building 7, No. 590, Ruiqing RD., Zhangjiang East, Pudong, 201201 Shanghai P. R. China
Telephone：	+86 0512-53690872
Fax：	+86 0512-53690872
Website：	www.iraygroup.com

■ Medical Device Directive European Representative

EC REP

Name：	iRay Europe GmbH
Address:	In den Dorfwiesen 14, 71720 Oberstenfeld Germany
Telephone:	+49-7062-977 88 00
Fax:	+49-7062-976 0571
Email:	S.feng@iraygroup.com
Website：	www.iraygroup.com

■ European Importer

Company:	FUJIFILM Europe B.V.
Address:	Oudenstaart 1, 5047 TK Tilburg, the Netherlands
Website:	https://www.fujifilm.eu/eu/manufacturing-europe