Wireless Digital Flat Panel Detector

Mars1717XU-VSI

User Manual



Before operating, please read this user manual and pay attention to all safety precautions.

Please ensure that this user's manual is properly maintained so that it can be accessed at any time (reserve).

Please use it correctly on the basis of full understanding of the content.

Congratulations on your purchase of the Mars1717XU-VSI Wireless Digital Flat Panel detector (hereinafter referred to as Mars1717XU) which is manufactured by iRay Technology Co.Ltd. (Hereinafter referred to as iRay).



Please take time to read through this user guide in order to utilize the product effectively. We hope you enjoy the experience with iRay Mars1717XU.

If you have any questions or suggestions, please feel free to contact us.

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Location: 2F, Building 9, No.590, Ruiging Rd, Pudong, Shanghai,

Notes on usage and management of the equipment

- Read all of the instructions in the user guide before your operation. Give particular attention to all safety precautions.
- 2. Only a physician or a legally certified operator should use this product.
- The equipment should be maintained in a safe and operable condition by maintenance personnel.
- 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.
- Use only the dedicated cables. Do not use any cables other than those supplied with this product.
- The equipment should not be used in inflammable gas or corrosive gas environment.
- Give particular attention to avoiding liquid or conductive materials invading into inside of the equipment in order to prevent the equipment from short circuit.
- 8. House of the equipment forbids opening by unauthorized personnel.
- Request your sales representative or local iRay dealer to install this product,

Caring for your environment



This symbol indicates that this product is not to be disposed of with your residential or commercial waste.

Recycling iRay Equipment

Please do not dispose of this product with your residential or commercial waste. Improper handling of this type of waste could have a negative impact on health and on the environment. Some countries or regions, such as the European Union, have set up systems to collect and recycle electrical or electronic waste items. Contact your local authorities for information about practices established in your region. If collection systems are not available, call iRay Customer Service for assistance.

Disclaimer

- iRay shall not be liable to the purchaser of this product or third parties for any damage, losse, 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 by iRay Technology.
- 4. It is the responsibilities of the user/attending physicians for maintaining the privacy of image data and providing medical care services. iRay shall not be responsible for the legality of image processing, reading and storage nor it shall be responsible for loss of image data for any reason.
- Information regarding specification, compositions, and appearance of this product is subject to change without prior notice.

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Symbols and Conventions

The following symbols and conventions are used throughout the user guide.

॒ WARNING	This symbol is used to identify conditions under which improper use of the product may cause death or serious personal injury.
<u> </u>	This notice is used to identify conditions under which improper use of the product may cause minor personal injury.
CAUTION	This notice is used to identify conditions under which improper use of the product may cause property damage.
Prohibited	This is used to indicate a prohibited operation.
0	This is used to indicate an action that must be performed.
♠ Important	This is used to indicate important operations and restrictions.
(i) Information	This is used to indicate operations for reference and complementary information.

Labels and markings on the equipment

The contents of the labels and markings on iRay Mars1717XU product are indicated below:

Symbol	Indication
SN	This symbol is used to identify the manufactuer's series number which is after, below or adjacent to the symbol. The series number of iRay products is usually made of thirteen digits as shown below: A1A2A3A4 C1C2 M DD Y XXX Numerical Order Year Date Product Code
***	This symbol is used to indicate the name and address of the manufacturerthe date of manufacture can be combined in this symbol.
[]i	This symbol is used to indicate consultation of the user guide for general information.
	Safety Signs: please refer to the user guide for safety instructions.
100.	This symbol is used to indicate detector is allowed to withstand 100 kg on the surface.
<u> </u>	Caution: please refer to the instructions in the user manual.
5 °C 35°C	This symbol is used to indicate the operational temperature limits.
((<u>@</u>))	This symbol is used to indicate non-ionizing radiation.

Ø	This symbol is used to indicate when end-user plans to discard this product, this product should be sent to the appropriate facilities for recovery and recycling.
IPX4	This symbol is used to indicate the degrees of protection provided by enclosures.
†	This symbol is used to indicate B type applied part.
	Handled with care.
Ţ	Caution: refer to appending files for important information about safety, such as warnings and matters needing attention which is not suitable to be shown on the instrument for various reasons.
Ī	Package symbol, fragile, handle with care.
类	Package symbol, keep away from sunlight.
*	Package symbol, keep dry.
See See	Package symbol on the the detector packing-case: storage temperature limits
	Package symbol, this symbol is used to indicate the humidity limits.
<u>11</u>	Package symbol, keep the equipment up right.

Package symbol, do not roll the transportation package.
Package symbol, this symbol is used to indicate stacking limit number.

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1. Safety Information

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1.1 Safety precautions

Follow these safeguards and properly use the equipment to prevent injury and damage to any equipment/data.

damage to any equ	лрпп	
		WARNING
Installation and environment of	•	Do not use or store the equipment near flammable chemicals such as alcohol, thinner, benzene, etc.
use		If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the equipment. Also, some disinfectants are flammable. Be sure to take care when using them.
Prohibited	•	Do not connect the equipment with anything other than specified.
		Doing so may result in fire or electric shock.
Prohibited	•	All the patients with active implantable medical devices should be kept away from the equipment.
Power supply	•	Do not operate the equipment using any type of power supply other than the one indicated on the rating label.
\Diamond		Otherwise, it may result in fire or electric shock.
Prohibited	•	Do not handle the equipment with wet hands.
		You may experience electric shock that could result in death or serious injury.
	•	Do not place heavy object such as medical equipment on cables and cords. Do not pull, bend, bundle, or step on them to prevent their sheath from being damaged, and do not alter them neither.
		Doing so may damage the cords which could result in fire or electric shock.
	•	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 turn ON the system power when condensation has formed on the equipment.
		Doing so may result in fire or electric shock.
	•	Do not connect a multiple portable socket-outlet or extension cord to the system.
		Doing so may result in fire or electric shock.
	•	To avoid the risk of electric shock, this equipment must only be connected to power supply with protective earth.
		Not doing so may result in fire or electric shock.
•	•	Securely plug the power cord into the AC outlet.
U		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.
	•	Be sure to turn OFF the power to each piece of equipment before connecting or disconnecting the cords.
		Otherwise, you may get an electric shock that could result in death or serious injury.
	•	Be sure to hold the plug or connector to disconnect the cord.
		If you pull the cord, the core wire may be damaged, resulting in fire or electric shock.

	_	WARNING.
		WARNING
Handling	•	Never disassemble or modify the equipment. No modification of this equipment is allowed. Parts of the Mars1717XU that are not serviced or maintained while in use with the patient.
riomoleu		Doing so may result in fire or electric shock. Also, since the equipment incorporates parts that may cause electric shock as well as other hazardous parts, touching them may cause death or serious injury.
	•	Do not place anything on top of the equipment.
		The object may fall and cause an injury. Also, if metal objects such as needles or clips fall into the equipment, or if liquid is spilled, it may result in fire or electric shock.
	•	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 put the equipment and pointed objects together.
		The equipment may be damaged. If so, the equipment should be used in bucky.
	•	Have the patient take a fixed posture and do not let the patient touch parts unnecessarily.
		If the patient touches connectors or switches, it may result in electric shock or malfunction of the equipment.
When a problem occurs	•	Should any of the following occurs, immediately unplug the power cord of Control Box, and contact your sales representative or local iRay dealer:
		When there is smoke, an odd smell or abnormal sound.
		When liquid has been spilled into the equipment or a metal object has entered through an opening.
		When the equipment has been dropped and damaged.
Maintenance and inspection	•	Please turn OFF the power of the equipment and unplug the power cord of adaptor before cleaning.
Prohibited	•	NEVER use alcohol, ether and other flammable cleaning agent for safety. NEVER use methanol, benzene, acid and base because they will erode the equipment.
	•	DON'T dip the equipment into the liquid.
	•	Please make sure that the equipment's surface & plugs are dry before turning ON.
		Otherwise, it may result in fire or electric shock.
0	•	Clean the plug of the power cord periodically by unplugging it from the AC outlet and removing dust or dirt from the plug, its periphery and AC outlet with a dry cloth.
		If the cord is kept plugged in for a long time in a dusty, humid or sooty place, dust around the plug will attract moisture; this could cause insulation failure that may result in a fire.
	•	For safety reasons, be sure to turn OFF the power to each piece of equipment when performing inspections indicated in this manual.
		Otherwise, electric shocks may occur.

CAUTION Do not install the equipment in any of the locations Installation and listed below. Doing so may result in failure, environment of malfunction, equipment falling, fire or injury. use Close to facilities where water is used Where it will be exposed to direct sunlight Close to the air outlet of an air-conditioner or ventilation equipment Close to 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 areas prone to vibration On an incline or in an unstable area Take care that cables do not become tangled during use. Also, be careful not to get your feet caught by cable. Otherwise, it may cause a malfunction of the equipment or injury of the user due to tripping over the cable. 1.5 m 2.5 m 1.5 m Always connect the three-core power cord plug to a **Power supply** grounded AC power outlet. 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 in an emergency. Be sure to ground the equipment to an indoor grounded connector. Also, be sure to connect all the grounds for the system to a common ground. Do not use any power source other than the one provided with this equipment. Otherwise, fire or electric shock may be caused due to leakage. Do not spill liquid or chemicals onto the equipment. In Handling case the patient is injured, it is not allowed to contact with blood or other body fluids. Doing so may result in fire or electric shock. In such a situation, protect the equipment with a disposable cover as necessary.

Turn OFF the power and pull out the plug to each piece

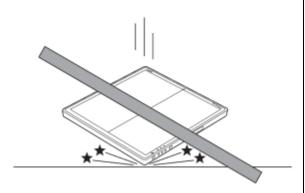
of equipment for safety when not used.

CAUTION

Handling



- · Handle the equipment carefully.
- · Do not submerge the equipment in water.
- The internal image sensor may be damaged if something hits against it or it is dropped.

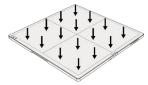


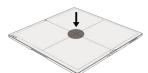
• Do not place excessive weight on the equipment.

Otherwise, the internal image sensor may be damaged and image collection may be malfunction.

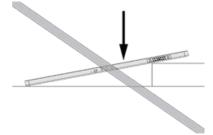
<Load Limit> Uniform load: 135 kg over the whole area of the detector surface.

Local load: 100 kg on an area 4 cm diameter.





 Be sure to use the equipment on a flat surface so it will not bend. Otherwise, the internal image sensor may be damaged. Be sure to securely hold the detector while using it in upright positions. Otherwise, the detector may flip over, resulting in injury to the user or patient as well as damage of the inner device.



Keep the same load (same pressure) on the detector when acquiring the image. Or the image will be incorrect.

CAUTION

⚠ CAUTION	•	Do not close to fire, do not use in high temperature
ZIV CAUTION	•	Do not invert positive and negative pole
	•	Do not contact with metal in case of short circuit
	•	Do not insert sharp objects into the Lithium-ion capacitor
	•	Do not beat the Lithium-ion capacitor
	•	Do not squeeze the Lithium-ion capacitor
	•	Do not use the Lithium-ion capacitor out of rules
	•	Do not change internal structure of the Lithium-ion capacitor
	•	Do not submerge the Lithium-ion capacitor in water, please keep dry in storage and do not contact with water in use
	•	Please charge the Lithium-ion capacitor with charger following IEC60601-1 Standards provide by us
	•	Do not mix the Lithium-ion capacitor with ones not provided by iRay
	•	Do not charge the Lithium-ion capacitor already damaged
	•	Adverse events may be caused by the product
V		Due to operation or corresponding device malfunction, no valuable clinical image is acquired after exposure accomplished.
		Due to disturbance from a device which does not complied with IEC60601-1-2 standard, functions of the product are abnormal, which results in no valuable clinical image is acquired after exposure accomplished
0	•	The product is intended to be used with registered X-ray instruments. Please refer to this manual for installment and software operation part of the product.
	•	For the rest part of operation, please refer to the operation manual of the applied X-ray instrument.
	•	Means for monitoring, evaluation, and control
•	•	The product status indication is referred in "Product installation, connection" part of this manual. If the indication is not correct, please do not use.
•	•	The measuring function must be re-calibrated after exchanging or re-installation of FPD.
•	•	The measuring function should be calibrated every half year if the product structure is not disassembled.
	•	

1.2 Notes for Using

When using the equipment, take the following precautions. Otherwise, problems may occur and the equipment may not function correctly.

Before exposure

Be sure to check the equipment daily and confirm that it works properly.

- Sudden heating of the room in cold areas will cause condensation to form on the equipment. In this case, wait until the condensation evaporates before performing an exposure. If the equipment is used while condensation is formed on it, problems may occur in the quality of captured images. When an air-conditioner is used, be sure to raise/lower the temperature gradually so that a difference of temperature in the room and equipment does not occur, to prevent condensation.
- The detector should warm up for 30 minutes before exposure or updating the gain map or defect map.

During exposure

- Do not move the power or Ethernet Cables during exposure, or it may cause image noise or artifacts, even incorrect images.
- Do not use the devices near the equipment generating a strong magnetic field. Otherwise, it may cause image noise, artifacts or even incorrect images.

After exposure

Recommend to shut down the detector's power for storage when no use.

Disinfection and Cleaning

- After every examination, wipe the patient contact surfaces of the detector using disinfectants such as ethanol, to prevent the risk of infection. For details on how to sterilize, consult a specialist.
- Do not spray the detector directly with disinfectants or detergents.
- 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.
- It's recommended to use a waterproof non-woven cover as the isolated layer between detector and the blooding patient.

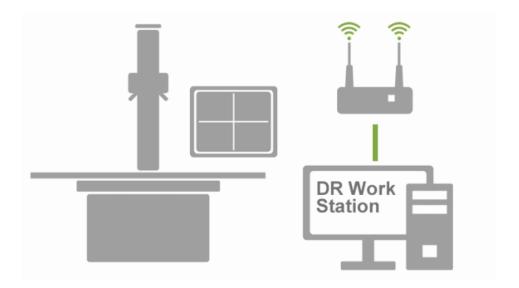
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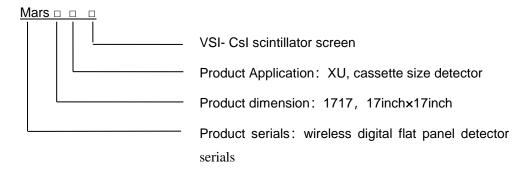
Mars1717XU is a cassette-size wireless X-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It is developed to provide the highest quality of radiographic image, which contains an active matrix of 3072×3072 with 139um pixel pitch. Detectors' scintillator is CsI(Caesium lodide). The greatest improvement is Mars1717XU supports wireless communication between detectors and PC, and employs Lithium-ion capacitor, which makes Mars1717XU a real portable panel.

2.1 Scope

This manual contains information about the iRay Mars1717XU. All operators must read and understand this manual before using equipment. All information in this manual, including the illustrations, is based on equipment prototype. If configuration of your equipment does not have any of these items, information about these items in the manual does not apply to your equipment.



2.2 Characteristic



- Wireless static Flat Panel Detector used for general radiography.
- 17 x 17 inch
- Built-in non-detachable Lithium-ion capacitor

2.3 Intended use

The Mars1717XU Wireless Digital Flat Panel detector (hereinafter referred to as Mars1717XU) is compatible with digital medical X-ray radiography system for a medical institute to acquire digital X-ray imaging of patient body.

The Flat Panel Detector (FPD) of Mars1717XU is one of the flat panel detector series based on amorphous silicon technology, which are used in DR system to provide clinical X-ray images. The host computer of Mars1717XU-VSI flat panel detector employs Caesium Iodide (CsI) scintillation screen, and provides WIFI data port and DC power supply.

This panel is not intended for mammography or dental applications, and **prohibited for pregnant women.**

According to the Mars1717XU intended use and the result of risk management, identifying and describing the essential performance as the following:

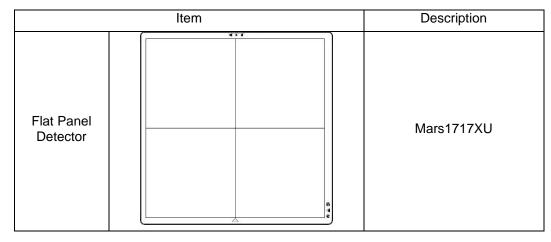
- a) To perform communication and instruction transmission between the flat plane detector and computer system through wireless router
- b) To perform imaging acquisition by the flat panel detector

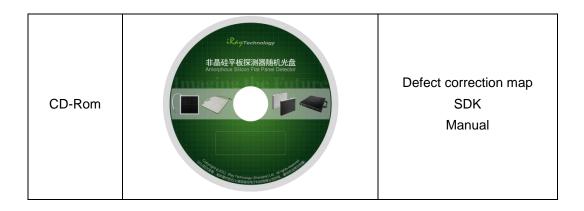
This equipment provides digital X-ray imaging for diagnosis of disease, injury, or any applicable health problem. The image is obtained as the result of X-ray passing through the human body and detected by the equipment. iRay will provide equipment and software support for integration of system. The length of DC Power Cable cannot exceed 3.5 m. Or the impedance of protective earth connections may exceed the safety threshold.

2.4 Standard Product Components

Mars1717XU comes with power supply by both 12V DC and bulit-in Lithium-ion capacitor.

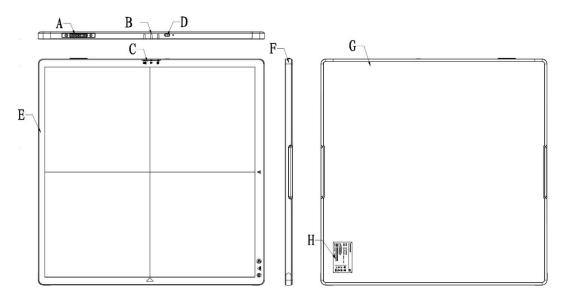
Once powered on, it would build a connection with PC through Wireless connection.





2.5 Components Description

2.5.1 DETECTOR



Item	Name	Description	
Α	DC Input Interface	DC input	
В	Detector Indicator	Power/Internet Connection/Status	
С		Detector indicator of detector	
D	Button	Power button / Reset Switch hole	
E	Front surface film	In line with biological compatibility	
F	Middle frame	Supporting and fixation	
G	Back surface film	In line with biological compatibility	
Н	Detector Label	Product information.	

2.5.2 POWER SUPPLY

Mars1717XU supports both DC and bulit-in Lithiu-ion capacitor power supply.

The DC power supply is not in the product package, and the external power adapter is only used for customer service maintenance and production.

2.6 Product Specification

2.6.1 DETECTOR

2.6.1.1 BASIC

Item	Specification	
Model	Mars1717XU-VSI	
Image Sensor	a-Si (Amorphous Silicon) TFT	
Pixel Size	139 μm	
Pixel Matrix	3072 x 3072	
Effective Area (H x V)	427 x 427 mm	
Greyscales	16bit	
Spatial Resolution	3.6 Lp/mm	
Preview Acquisition Time@Client (5GHz)	2.5 sec (since exposure ends)	
Processed Acquisition Time@Client (5GHz)	5 sec. (since exposure ends)	
Cycle Time	Min. 8.5s	
Power Consumption	Max. 30W (including charging)	
Stand-by Power Consumption	Max.5W	
Charging Time	Max. 50minutes	
Discharging Time	Cycle time=30s, 30min, 60images	
	Cycle time=90s, 45min, 30images	
Exposure Preparation Time	1s	
Sleeping Awakening Time	2s	
Sleeping Endurance Time	1h	
Dimension (L × W × H)	460 x 460 x 15.4 mm	
Weight	3.9kg	

WIFI	IEEE802.11a/b/g/n/ac (2.4G/5G)
X-ray Energy	40kV to 150kV

2.6.1.2 MTF

Spatial Frequency (lp/mm)	MTF(CsI)	
1.0	0.65	
2.0	0.43	
3.0	0.17	

2.6.1.3 DQE

Spatial Frequency (lp/mm)@RQA5	DQE (CsI)@2.5uGy	
0	0.65	
1.0	0.45	
2.0	0.30	
3.0	0.20	

2.6.2 POWER SUPPLY

Mars1717XU supports both DC and built-in Lithium-ion capacitor power supply..

ltem	Specifications
DC Power	12V(DC),2.5A
Lithium-ion Capacitor	7.6V(DC),0.93A

2.6.3 AP ROUTER (OPTIONAL)

Mars1717XU does not include a wireless AP Router. Users can choose according to their requirement, but the following specification must be matched.

Item	Specifications
Wireless Standard	IEEE 802.11 a/b/g/n/ac
Frequency Range	2.400 ~ 2.4835 GHz and 5.15~5.25 GHz 5.725~5.85 GHz
Wireless Data Rate	802.11b : Max. 11Mbps 802.11a/g : Max. 54Mbps 802.11n : Max. 300Mbps (MIMO 2x2)

2.6.4 WIRELESS COMMUNICATION

Item	Description	
Wireless Standard	IEEE802.11a/b/g/n/ac	
	2.4G: 2.400 ~ 2.4835 GHz	
	@CH1-CH13 HT20 Section	
Fraguenov Bongo	@CH3-CH11 HT40 Section	
Frequency Range	5G: 5.15~5.25 GHz and 5.725~5.85 GHz	
	@CH36-CH165 HT20 Section	
	@CH38-CH163 HT40 Section	
	802.11b:	
	CCK, DQPSK, DBPSK	
Madulatian	802.11a/g:	
Modulation	64 QAM, 16 QAM, QPSK, BPSK	
	802.11n:	
	64 QAM, 16 QAM, QPSK, BPSK	
Antenna 2 Dual Band internal antenna		

2.6.5 RECOMMENDED APPLIANCE CONDITION

Item	Description
Operating System	Windows 8 64bit
CPU	Intel Core i7 3.6G
Memory	8G DDR3
Hard Disk	640 G
LAN Card	Intel Pro EXP9301CT PRO

2.6.6 USE ENVIRONMENT

	Operating	Storage	
Temperature	5~35℃	-30~55℃	
Temperature change	<1k/min <1k/min		
Humidity	30%~80% RH	10%~90% RH	
Atmospheric Pressure	700~1060hPa	700~1060hPa	
Pressure Change	<10kp/min	<10kp/min	
	(1kp=1.0197E-5Pa)	(1kp=1.0197E-5Pa)	

The Mars1717XU serial detectors shall operate at an altitude specified NO more than 3000m.

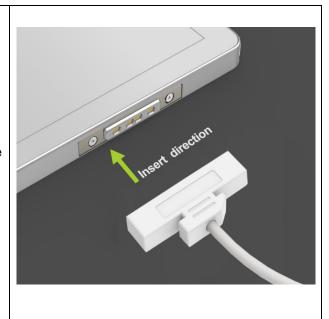
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3.1 Detector Installation

3.1.1 ATTACH DC POWER

Insert the DC power cable into the DC input port of the detector



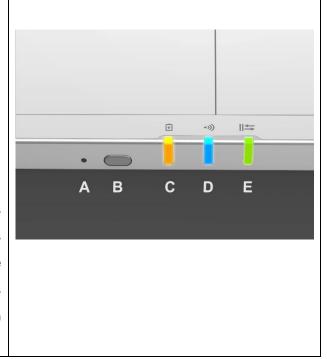
3.1.1 BOOTING UP

On the control panel, user can press power button to power on/off the detector.

If detector is powered off, users can press the button for 3 seconds to power on the detector when a Lithium-ion capacity is inserted and the Lithium-ion capacitor is no less than 20%, or direct current power is connected.

If detector is powered on, users can press the button for 5 seconds to shut down the detector. On the other hand, it can also be used as internal control IC reset button when button is active for 8s.

25



After booting up the detector, user can check the status LED indicator of detector.

The power indicator C shows as following:

Power Indicator	Lighting Status	Operating	Battery Capacity	DC Input
OFF	1	Power OFF/Sleep	/	/
Orange On	F	Power ON/Wake up	≤30%	NO
Green On	7	Power ON/Wake up	≧30%	NO
Orange Slow Blinking	9 (3	Power ON	≤30%	YES
Green Slow Blinking	3 3	Power ON	≧30%	YES
OFF after Orange ON with 1sec	7	Power OFF	≤20%	NO
OFF after Green ON with 1sec	9	Power OFF	≧20%	NO

Link indicator D shows as following:

LINK Indicator	Lighting Status	Description
OFF	?	Shut down/Wired&Wireless connection not ready
Blue ON	•1)	Client mode, Wireless connection is ready
Blue Blinking	?	AP mode, Wireless AP is ready
Green ON	(i-	Wired Connection is ready
Green Blinking	?	Or RST key(AP/Client switch) active

Status indicator E shows as following:

Status indicator	Lighting Status	Description
OFF	4	Shut down/Idle
Green ON	<u>II</u>	Data Transmission/RST Key(Recovery) active
Orange ON	<u>II</u>	ERROR

KEY button as following table: PWB key-B; RST key-A

Key	Push Time	Description
	≤1.5s	None action
PWB key	≧ 1.5s - <3s	Power ON or Wake up
I WD Key	≧3s - <7.5s	Power OFF
	≧7.5s	Power Reset
Key	Push Time	Description
	<3s	None action
RST key	≧3s - <7.5s	AP/Client mode switch
	≧7.5s	Recovery Factory Parameters(include AP address)

3.2 Software Installation

In the case of IDetector doesn't work, please install following VC redistribute package .NET Framework. (IDetector should not be used for terminal hospital)

- 1. Install Microsoft .NET Framework 4.5 before first use, which needs to be downloaded from the Microsoft website.
- Need to install VC redistribution package vcredist_x86_2013 (or vcredist_x64_vs2013).

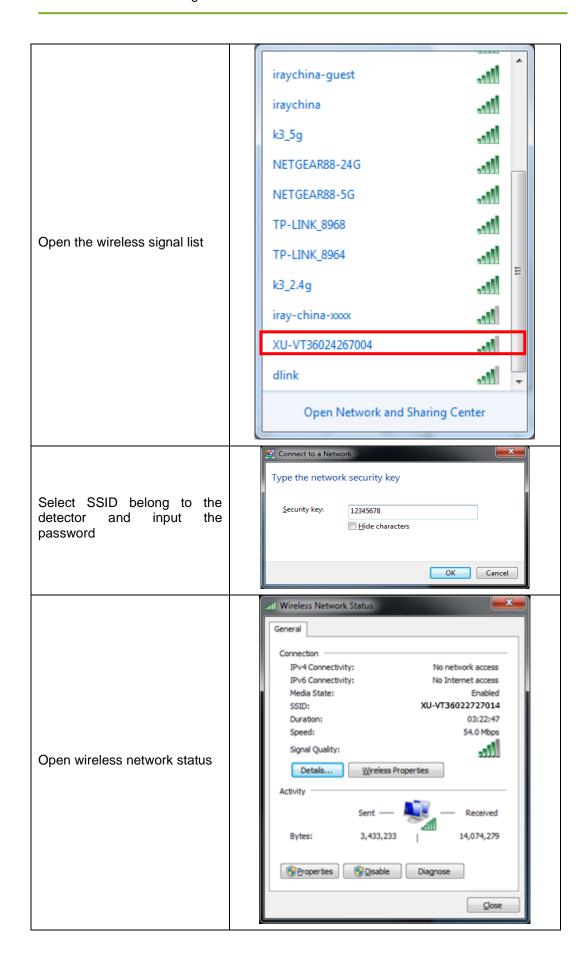
3.3 Detector Configuration

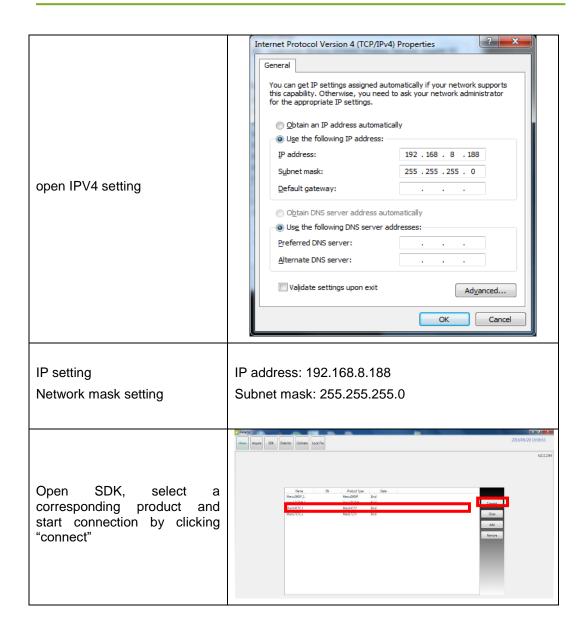
3.3.1 AP MODE

AP Mode is the default set mode of the product during purchasing. The default SSID is XU-SN, password is 12345678, and IP address is 192.168.8.8. The detector will directly connect to wireless LAN when power on.

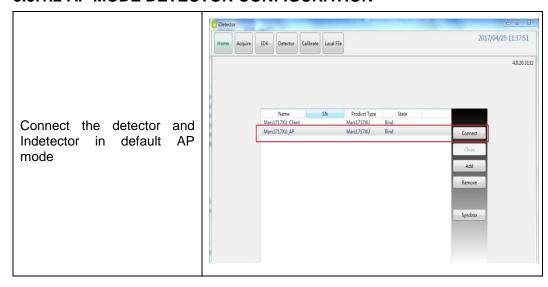
A user should accomplish wireless client configuration of AP mode as following steps:

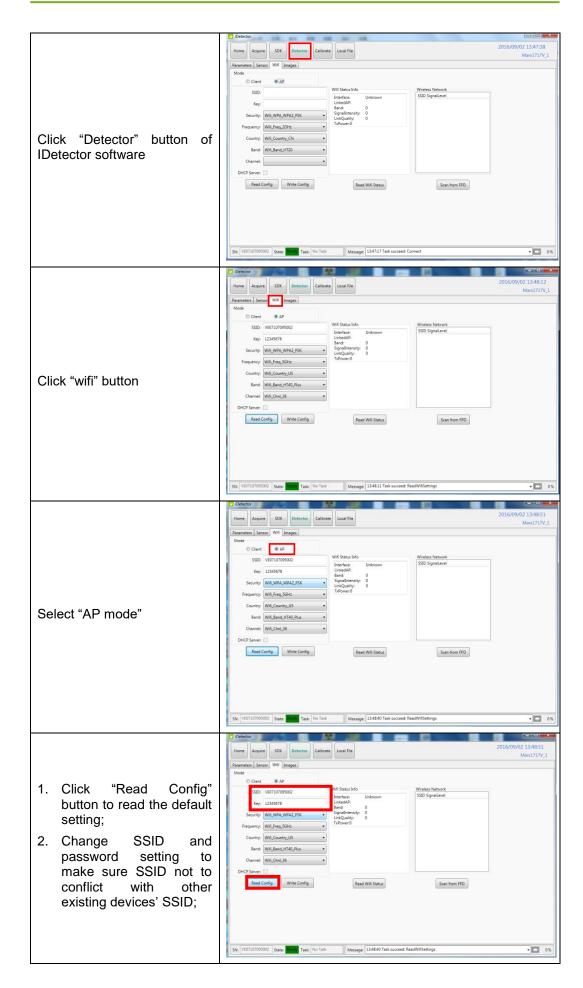
3.3.1.1 EXTERNAL WIRELESS LAN SETTING

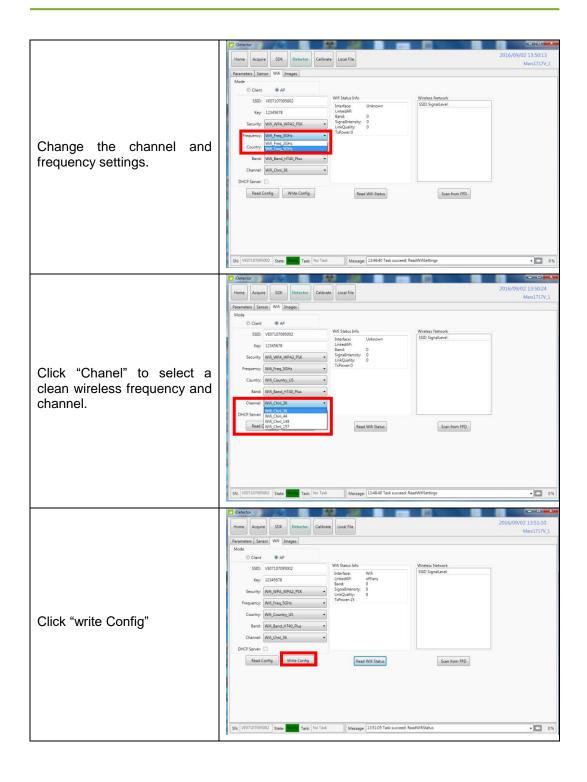


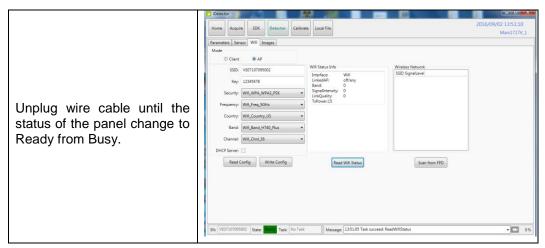


3.3.1.2 AP MODE DETECTOR CONFIGURATION







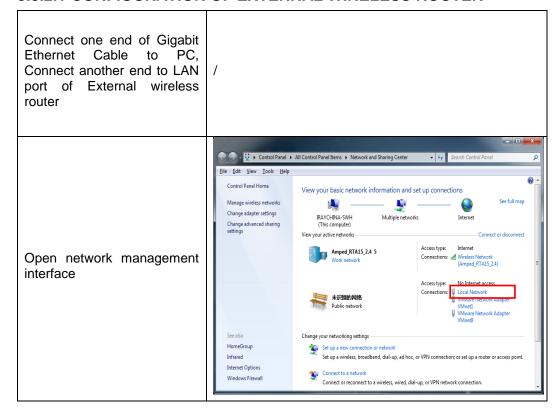


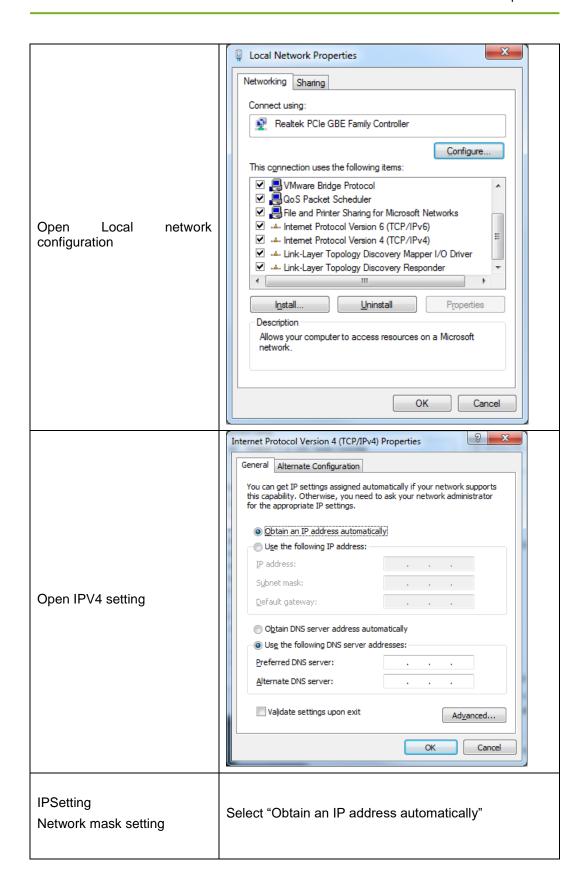
Since the default SSID and password have been changed, a revised AP SSID will be shown when the detector is power on next time.

3.3.2 CLIENT MODE

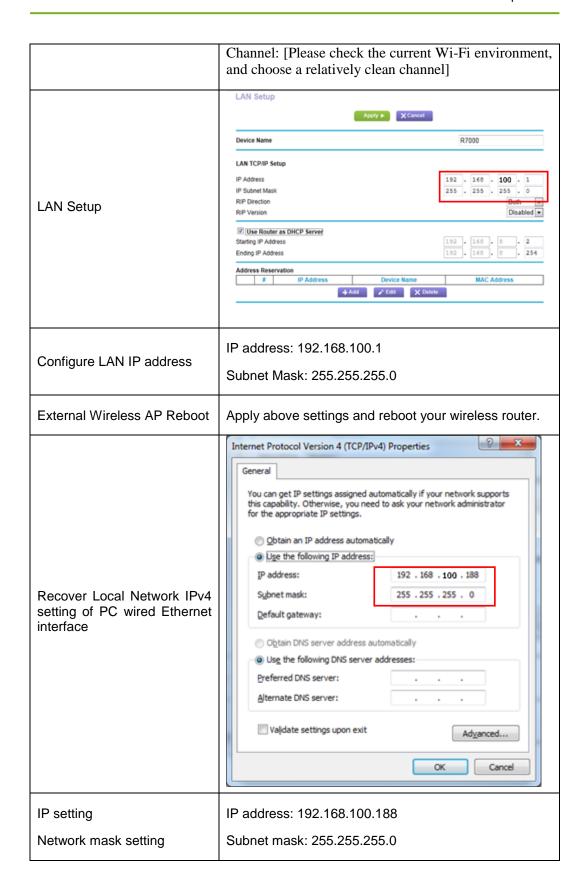
The user needs to complete the wireless client mode configuration according to the following operation. When different detectors are used, it is strictly forbidden to use the same SSID name for connection.

3.3.2.1 CONFIGURATION OF EXTERNAL WIRELESS ROUTER

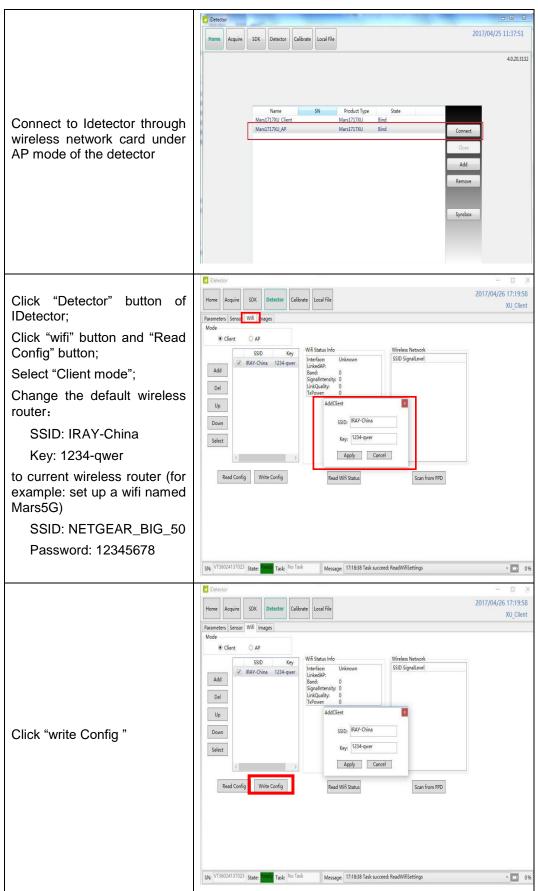


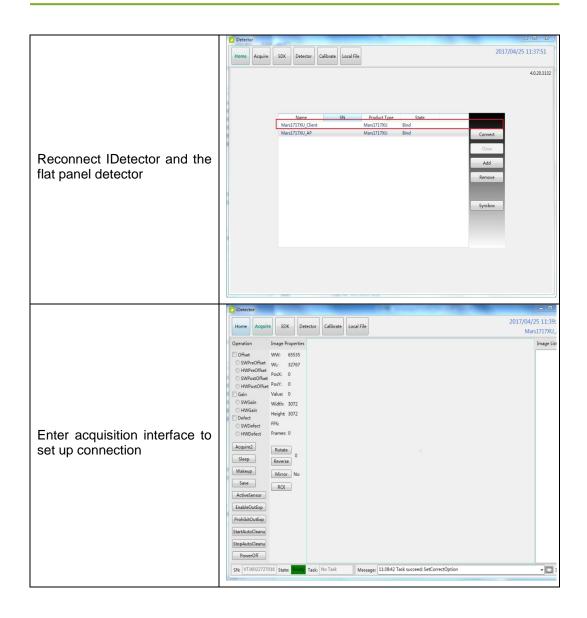


Open browser and type 192.168.1.1 Log into external wireless router to set configuration through the interface. OK Cancel Wireless Setup Apply ► XCancel Region Selection Region: Asia • Vireless Network (2.4GHz b/g/n) Enable SSID Broadcast NETGEAR_BIG_24 Name (SSID): Channel: 13 🔻 Up to 600 Mbps ▼ /lode: Security Options O None O WPA-PSK [TKIP] WPA2-PSK [AES] WPA-PSK [TKIP] + WPA2-PSK [AES] WPA/WPA2 Enterprise Wireless setup 12345678 63 characters or 64 hex digits) Passphrase: Wireless Network (5GHz a/n/ac) Enable SSID Broadcast NETGEAR_BIG_50 Name (SSID): 153 Up to 1300 Mbps Channel: Mode: ecurity Options O None WPA2-PSK [AES] WPA-PSK [TKIP] + WPA2-PSK [AES] WPA/WPA2 Enterprise 12345678 -63 characters or 64 hex digits) Passphrase: SSID: NETGEAR_BIG_24 (For example, set up a wifi named Mars2.4G) Security: WPA2-PSK Configure 2.4GHz wireless network Password: 12345678 Channel: [Please check the current Wi-Fi environment, and choose a relatively clean channel] SSID: NETGEAR_BIG_50 (For example, set up a wifi named Mars5G) Configure 5GHz wireless network Security: WPA2-PSK Password: 12345678



3.3.2.2 CLIENT MODE CONFIGURATION OF DETECTOR





4. Operation

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4.2 Block diagram	39
4.3 Work Flow	40
4.4 Description of workflow	40

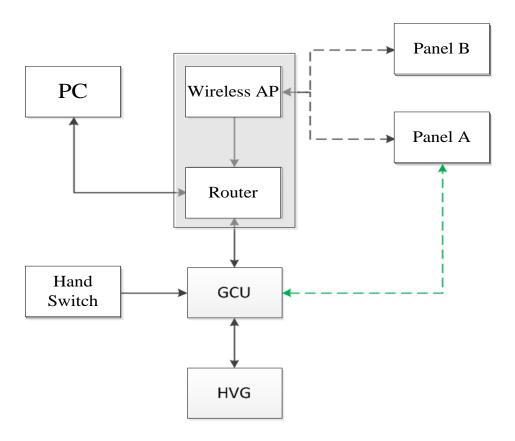
Mars1717XU provides SDK for users to integrate detector into their DR system. Additionally, it also provides applications for demonstration, iDetector. User can use iDetector to control detector without DR system.

4.1 Main Operation

To Acquire X-ray image is the main operation of Mars1717XU. Most importantly, detector should build synchronization with X-ray generator.Mars1717XU is born with PREP_ACQ2 Mode to acquire X-ray image.

4.2 Block diagram

Software mode is the basic way to acquire X-ray image. Please see figure below for general feature



Workstation is a host PC device installed with IDetector or SDK. In RREP_ACQ2 Mode, the workstation communicates with GCU through SDK (double panel mode) or the flat panel detector to control X-ray imaging time of X-ray generator.

4.3 Work Flow

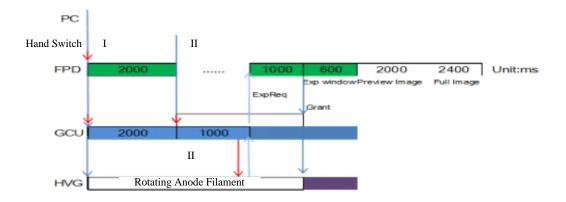
Push down "hand switch I" button GCU informs high voltage exposure preparation, meanwhile informs the Panel to prepare for exposure through AP The panel starts an action of "exposure preparation"; after the action finishes, the panel informs GCU to make exposure enable through AP Enable exposure, open the window, start "hand switch II" to expose End the exposure window, upload the acquired image SDK uploads pre-viewed image SDK uploads full image The system go to sleep

4.4 Description of workflow

- Workstation PC receives "Awaken hand switch I prep " request, sends command
 "Awaken" to the detector; the detector starts internal clear after receiving "Awaken"
 command sent from the workstation;
- 2. Meanwhile the workstation informs GCU (I/O Box) to control high voltage generator to start anode rotation;

- Workstation PC receives "Hand switch II exposure" request, confirms whether GCU
 anode rotation has ended and whether the detector has completed awaken
 preparation;
- If the preparation is completed, the workstation PC asks GCU to send "Hand switch
 II exposure" request to high voltage generator;
- 5. Send "Exposure" request to the flat panel detector if preparation of the high voltage generator is confirmed to be completed;
- The detector sends "Exposure" information to GCU, and then corresponding
 information will be shown in IDetector information bar, and the user is noticed that
 the detector is ready to receive X-ray;
- 7. GCU receives "Exposure" to start generating X-ray, and the X-ray generator starts to release X-ray;
- 8. After the X-ray generator finishes X-ray shooting, GCU send "End exposure" request to the detector;
- The detector receives "End exposure" request from GCU and then perform "Acquire" action;
- 10. The detector completes image acquisition and begins to send data to the workstation;
- Workstation receives all image data from the detector (including preview image and full image).

Typical Cycle Analysis



5. Regulatory Information

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5.1 Registrant Information

Registrant: iRay Technology Co., Ltd.

Address: Room 202, Building 9, No.590, Ruiqing Rd, East area of Zhangjiang

Hi-tech industrial district, Pudong, Shanghai, PRC, 201201

Contact: +86-21-50720560

After-sales Service Office: iRay Technology Co., Ltd .

Address of After-sales Service Office: Building 45, No.1000, Jinhai Rd, Pudong

New Area, Shanghai, PRC, 201206

Contact of After-sales Service Office: +86-21-50720560

5.2 Manufacturer Information

Manufacturer: iRay Technology Co., Ltd .

Address: Room 202, Building 9, No.590, Ruiqing Rd, East area of Zhangjiang

Hi-tech industrial district, Pudong, Shanghai, PRC, 201201

Production Address: Room 202, Building 9, No.590, Ruiging Rd, East area of

Zhangjiang Hi-tech industrial district, Pudong, Shanghai, PRC, 201201

Contact: +86-21-50720560

Production Licence Number: Shanghai Food and Drug Machinery Safety

Production Permission No. 20121946

5.3 Medical equipment safety standards

Medical equipment classification

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Type of protection against electrical shock	Class I Equipment (using Mars1717XU medical approved adaptor supply)
	Internally powered Equipment (using Mars1717XU Lithium-ion capacitor power supply)
Degree of protection against electrical shock	B-type Applied Parts
Degree of protection against ingress of water	IPX4 (Mars1717XU)
Mode of operation	Continuous operation

There are two modes for power supply and signal transmission of the product: internal

Lithium-ion capacitor power supply and adaptor supply, wireless transmission. Any one of power supply modes may combine with wireless transmission.

Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

5.4 References harmonized standards under Directive 93/42/EEC

Applicable safety standards of Mars1717XU series digital wireless X-ray imaging device cover the product host and other accessories.

MDD (93/42/EEC)	Medical Device Directive
EN ISO 13485:2012/EN ISO 13485:2012/AC:2012	Medical devices Quality management systems Requirements for regulatory purposes
EN ISO14971: 2012	Medical device – Application of risk management to medical devices
IEC 60601-1:2005+ Amendment 1:2012/EN 60601-1:2006+ Amendment 1:2013	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014/EN60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-2-54:2015/EN 60601-2-54:2015	Medical electrical equipment Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
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
EN 62220-1:2004	Medical electrical equipment - Characteristics of

digital X-ray imaging devices - Part 1: Determination

of the detective quantum efficiency

EN 62304:2006/AC:2008

Medical device software - Software life-cycle

processes

EN 62366:2008 Medical devices - Application of usability engineering

to medical devices

5.5 The compliance for each EMISSIONS and IMMUNITY standard or test specified by IEC60601-1-2 standard

EMI Compliance Table

Emission

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

EMS Compliance Table

Enclosure Port

	Basic EMC	Immunity test levels
Phenomenon	standard	Professional healthcare facility environment
		environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact
Licetrostatic Discharge	120 01000 4 2	±2kV, ±4kV, ±8kV, ±15kV air
		3V/m
Radiated RF EM field	IEC 61000-4-3	80MHz-2.7GHz
		80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table "Proximity fields from RF wireless communications equipment"
Rated power frequency magnetic	IEC 61000-4-8	30A/m

fields	50Hz or 60Hz

Proximity fields from RF wireless communications equipment

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

Input d.c. power Port

Phenomenon	Basic EMC	Immunity test levels
	standard	Professional healthcare facility environment
		12.137
Electrical fast transients/burst	IEC 61000-4-4	±2 kV
		100kHz repetition frequency
Conducted disturbances induced by RF fields		3V, 0.15MHz-80MHz
	IEC 61000-4-6	6V in ISM bands between 0.15MHz and
		80MHz
		80%AM at 1kHz

◆ Cables information below is provided for EMC reference.

Cable	Recommended cable length	Shielded or Unshielded	Number	Cable classification
AC Power Cable	3m	Unshielded	1 Set	AC Power
DC Power Cable	3.5m	Unshielded	1 pcs	Signal

Important information regarding Electro Magnetic Compatibility (EMC)

Mars1717XU require special precautions regarding EMC and needs to be installed only by iRay or authorized personnel and put into service according to EMC information provided in the user manual. Mars1717XU in use may be susceptible to electromagnetic interference from portable and mobile RF communications such as mobile (cellular) telephones. Electromagnetic interference may result in incorrect operation of the system and create a potentially unsafe situation.

Mars1717XU conforms to this EN60601-1-2:2015 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

The use of accessories, transmitters and cables other than those specified by this User Manual, with the exception of accessories and cables sold by iRay of Mars1717XU as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of Mars1717XU.

5.6 Lithium-ion Capacitor Reference Standards

Standards	Description
IEC 62813, Ed. 1	Lithium ion capacitors for use in electric and electronic equipment - Test methods for electrical characteristics
QC-T 741-2014	Ultra-capacitor for Electric Vehicles
UN38.3	United Nations Recommendations on the Transport of dangerous goods Manual of tests and Criteria ST/SG/AC.10/11/Rev.5/Amend.1&Amend.2
GB31241-2014	Lithium ion cells and batteries used in portable electronic equipments - Safety requirements

5.7 Product Label

5.7.1 DETECTOR HOST LABEL









Wireless Digital Flat Panel Detector

Model: Mars1717XU-VSI Power: 12V==-2.5A







iRay Technology Co.,Ltd.
Rm.202,Building 7,No.590,Ruiqing Rd.,
Zhangjiang East,Pudong,Shanghai,China
www.iraychina.com 2018-XX-XX





IPX4







5.7.2 HOST HOUSING LABEL







HANDLE WITH CARE

5.8 Radio Frequency Compliance Information 5.8.1 SRRC COMPLIANCE

- This equipment has been tested and found to comply with CMIIT ID:2017AP3876 of SRRC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- Operation is subject to the following tow conditions.

This device may not cause harmful interference.

This device must accept any interference received, including interference that may cause undesired operation.

• This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, 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 measure.

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 distributor or an experienced X-ray technician for help.

5.9 INFORMATION TO USER.

- The users manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. In cases where the manual is provided only in a form other than paper, such as on a computer disk or over the Internet, the information required by this section may be included in the manual in that alternative form, provided the user can reasonably be expected to have the capability to access information in that form.
- (A) ALL OTHER DEVICES SHALL BEAR THE FOLLOWING STATEMENT IN A CONSPICUOUS LOCATION ON THE DEVICE:
- 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.

(B) FOR A CLASS B DIGITAL DEVICE OR PERIPHERAL, THE INSTRUCTIONS FURNISHED THE USER SHALL INCLUDE THE FOLLOWING OR SIMILAR STATEMENT, PLACED IN A PROMINENT LOCATION IN THE TEXT OF THE MANUAL:

NOTE: 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.
- This device has been tested and meets the FCC RF exposure guidelines. The maximum SAR value reported is 0.28 w/kg.

6. Software Operation Information

6.1	Default Settings52	2
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Please refer to Chapter 3 of this manual "IDetector use method" and description of iRayDR user manual for operation of the software.

6.1 Default Settings

Default setting parameters of part of detector software are as following:

[Battery]

Battery_Level_1_H=100

Battery_Level_1_L=60 ; normal operation, allow exposure

Battery_Level_2_H=59

Battery_Level_2_L=40 ; normal operation, low power warning, allow exposure

Battery_Level_3_H=39

Battery_Level_3_L=30 ; normal operation, low power warning, forbid exposure

Battery_Level_4_H=29 ; forbid use, the system needs shut down (<20% auto shut down)

Battery_Level_4_L=0

[Wireless]

Signal_Split_1=70 ; normal operation, allow exposure

Signal_Split_2=40 ; normal operation, forbid exposure

[Temperature]

Temp_NormalRange_H=50 ; normal operation, allow exposure

Temp_NormalRange_L=10 ; normal operation, allow exposure

Temp_FatalLimit_H=60 ; not recommend use, forbid exposure

Temp_FatalLimit_L=5 ; not recommend use, forbid exposure

[SDK]

Cfg_FpsCheck_Enable=0

Cfg_FpsCheck_Tolerance=0

Cfg_FWUpdTimeOut=1800

Cfg_OfflineInspectTimeout=10

Cfg_AllowReconnectByOnlineNotice=1

Cfg_ResetTimeout=120

Cfg_PreviewImage_Enable=1

 $Cfg_PushImageAtExpTimeout_Enable=1$

Cfg_RetransferCount=3

Cfg_ClearAcqParam_DelayTime=600

Cfg_ConnRecoverTimeout=60

Cfg_TemperatureHighThreshold=40

Cfg_AllowMismatchSN=1

Cfg_ImagePacketGapTimeout=1000

Cfg_FwAllowedDefectPoints=8000

Cfg_PostOffsetStart_DelayTime=300

Cfg_TotalAcqTimeout=30000

Cfg_PreExpImageAcqTimeout=1000

Cfg_CleanupProcessTime=2000

[FactoryParameters]

Product No=45

Product No=45

Sub Product No=SubProductNo_Csl550

Serial No=VT36xxxxxxxxx

Main Version=1.6.x.x

Read Version=0.0.0.0

Master Build Time=17-03-02:1

Slave Build Time=00-00-00:0

MCU Build Time=00-00-00:0

CBX Build Time=00-00-00:0

Src IP=192.168.100.8

Src MAC=000FEAEF6FBE

Dest Port=28000

Dest IP=192.168.100.188

Dest MAC=5CF9DD5FE30E

Sync-Box IP=192.168.100.96

Auto Sleep Idle Time (minute)=0

Trigger Mode=TriggerMode_Prep

Prep CapMode=PrepCapMode_Acq2

Self CapEnable=On

Integrate Time (ms)=776

Self Clear Span Time (us)=100

Sequence Interval Time (ms)=8000

Tube Ready Time=500

Set Delay Time (ms)=600

Exp Window Time (ms)=10000

Sync Exp Time (ms)=65535

VT (v)=0.87

Dyna Offset Gap Time (ms)=100

Image Channel Protocol=Ethernet_TCP

7. Trouble Shooting

This section is detailed in the Mars1717XU service manual.

8. Service Information

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	8.2.2 Monthly and annual inspection	57
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8.4	Replacement parts support	58

8.1 Product lifetime

The estimated product lifetime is up to 7 years under appropriate regular inspection and maintenance. (The Lithium-ion capacitor could last for 7 years)

8.2 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 may be cases where overhaul is recommended depending on conditions. Contact iRay service office or local iRay dealer for regular inspection or maintenance.

Cause the Lithium-ion capacitor products have its own power consumption, Please make sure that Mars1717XU is fully charged before it is stored and shipment, alse it needs take a full charge each two months during storage.

8.2.1 DAILY INSPECTION

Before and after using this product, following inspections should be taken:

Item	Operation
	Ensure the detector has no screw loosening or cracks.
Detector	Ensure there is no dust or dirt attached on connection pins of Lithium-ion capacitor
	Ensure there is no crack or short circuit in the Lithium-ion capacitor connection pin.
	Ensure the cables have no damage and no torn shell
Cables	Ensure connection between power cable and AC I/O socket reliable

8.2.2 MONTHLY AND ANNUAL INSPECTION

Item	Frequency	Operation
Resolution	Every month/ Every year	Use resolution image or body model to inspect
Linearity	Every month/ Every year	Evaluate through checking the grey value of images
Correction	Every month/ Every year	When X-ray generator, bulb, collimator or exposure environment changes

If there is any repair, maintenance and inspection involved with opening the housing of the instrument, please make sure to contact after-sale service engineering with corresponding qualification, or please contact Shanghai iRay after-sales service department or authorized product distributors.

There is a Lithium-ion capacitor in the FPD, its lifetime is 7 years, when arrived in the lifetime of the capacitor it needs to be placed. And the placement needs contact Shanghai iRay after-sales service departments or authorized product distributors.

8.3 Repair

The product faults may be decreased to the minimum if the user follow this manual to do maintenance on time. However, if a problem cannot be solved even taking the measures indicated in troubleshooting, contact your sales representative or local iRay dealer for repairs. Please refer to the name label and provide the following information:

Product Name:

Series Number:

Description of Problem: as clearly as possible

8.4 Replacement parts support

Performance parts (parts required to maintain the function of the product) of this product will be stocked for 8 years after discontinuance of production, to allow for repair.

Appendix

Appendix A Information of	Manufactures	60
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Appendix A Information of Manufactures



COMPANY: iRay Technology Co.LTD.

ADDRESS: Rm202, Building 7, No. 590, Ruiqing Rd, Zhangjiang

East, Pudong New Area, Shanghai, China

ZIP CODE: 201201

TELEPHONE: +86-21-50720560 **FAX:** +86-21-50720561

HOMEPAGE: WWW.IRAYCHINA.COM

SERVICE: SERVICE DEPARTMENT OF IRAY

SERVICE TEL +86-21-50720560 **MARKET TEL** +86-21-50720560