

Wireless Digital Flat Panel Detector

Mars1417X

User Manual



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

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

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

About FCC

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

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

Attention must be paid to the fact that changes or modifications not expressly approved by the party responsible for compliance can void the user's authority to operate the equipment.

Note: This product 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 product 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 product 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 to 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

Congratulations on your purchase of the Flat Panel Detector (hereinafter referred to as Mars1417X) which is manufactured by iRay Technology Company 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 Mars1417X.

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

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Please take time to read through this user guide in order to utilize the product effectively. We hope you enjoy the experience with iRay Mars1417X.

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

Notes on usage and management of the equipment

1. 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.
3. The equipment should be maintained in a safe and operable condition by maintenance personnel.
4. 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.
5. Use only the dedicated cables. Do not use any cables other than those supplied with this product.
6. 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

1. 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.
2. 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.
3. 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.
5. Information regarding specification, compositions, and appearance of this product is subject to change without prior notice.

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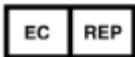
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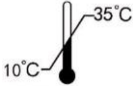
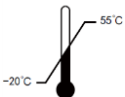
Symbols and Conventions

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

	Identify the conditions under which improper use of the product may cause death or serious personal injury.
	Identify conditions under which improper use of the product may cause minor personal injury.
	Identify conditions under which improper use of the product may cause property damage.
	Indicate a prohibited operation.
	Indicate an action that must be performed
	Indicate important operations and restrictions.
	Indicate operations for reference and complementary information.

Labels and markings on the equipment

Symbol	Description
	Caution: please refer to the instructions in the user manual.
	Indicates that the equipment has passed CE testing and the CE Notified Body number follows it.
	Serial number of the product.
	Name and address of the manufacturer.
 20XX-XX-XX	Expiring date of this product.
	This symbol is used to indicate non-ionized electromagnetic radiation.
	Name and address of iRay authorized representative in the European region.
	Consultation of the user guide for general information.
	This product is not to be disposed of with your residential or commercial waste.
	Safety Signs: Please refer to the user guide for safety instructions.
	B Type.

	Load limit. (Central area)
	Handled with care.
	Operational temperature limits.
	Storage temperature limits.
	Fragile
	Keep away from sunlight
	Keep dry
	Humidity limits.
	Keep the equipment up right.
	Do not roll the transportation package.
	Stacking limit number.
IP56	IP56 for Detector
Rx only	Detector symbol : device is for prescription use only

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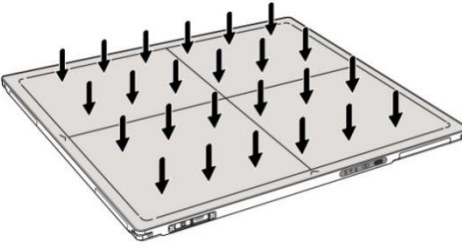
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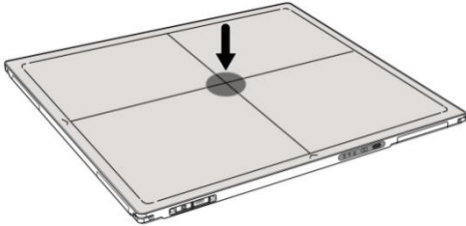
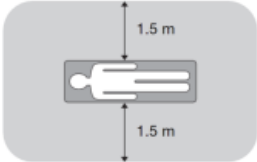
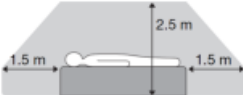
1.1. Safety Precautions

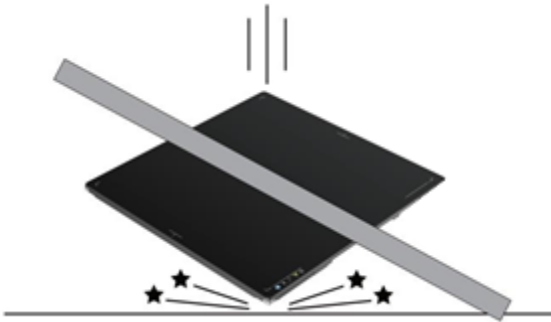
Follow these safeguards and properly use the equipment to prevent injury and damage to any equipment/data

WARNING	
Installation and environment of use  Prohibited	Do not use or store the equipment near flammable chemicals such as alcohol, thinner, benzene, etc. 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. Do not connect the equipment with anything other than specified. Doing so may result in fire or electric shock. All the patients with active implantable medical devices should be kept away from the equipment.
Power supply  Prohibited	Do not operate the equipment using any type of power supply other than the one indicated on the rating label. Otherwise, it may result in fire or electric shock. 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.

Power supply  Prohibited	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. 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	
Handling  Prohibited	Never disassemble or modify the equipment. No modification of this equipment is allowed. Parts of the Mars1417X that are not serviced or maintained while in use with the patient. 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  Prohibited	Please turn OFF the power of the equipment and unplug the power cord of adaptor before cleaning. 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.
	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. <Load Limit> Uniform load: 300kg over the whole area of the surface  Local load: 150kg on an area 4cm diameter

	
CAUTION	
Installation and environment of use 	Do not install the equipment in any of the locations listed below. Doing so may result in failure, malfunction, equipment falling, fire or injury. - 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.  

Power supply 	Always connect the three-core power cord plug to a 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.
Handling 	Do not spill liquid or chemicals onto the equipment. In 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. Be sure to use the equipment on a protected foam. 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 fall over, resulting in injury to the user or patient, or may flip over, resulting in damage to 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 operate close to fire, do not use in high temperatures Do not invert positive and negative poles Do not contact with metal in case of a short circuit Do not insert sharp objects into the battery Do not hit the battery Do not stand on the battery Do not use the battery for purposes other than those stipulated in the rules Do not dispose of the battery or change its internal structure Do not submerge the battery in water; please keep it dry in storage and do not contact with water while in use Please charge the battery with the charger provided by Manufacturer Do not mix the battery with ones not provided by Manufacturer Do not charge the battery with a broken charger. Charge the battery regularly to avoid over-discharge failure. Do not use the battery when it is severe ballooning.
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1.2. Notes for Using

When using the product, take the following precautions. Otherwise, problems may occur and the product 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 product daily and confirm it work properly.
- Sudden heating of the room in cold areas will cause condensation on the product. In this case, wait until the condensation evaporates before performing an exposure. If it is used when condensation is formed, problems may occur in the quality of captured images. When an air-conditioner is used, be sure to raise/lower the temperature gradually to prevent condensation.
- The product should be warmed up for 15 minutes before exposure or updating the gain map and defect map.
- Make sure wave form of the energy going to the X ray tube is square not pulse.
- Be cautious with circumstance that someone has radio isotope recently injected into them, it may cause panel transmit image without x ray.
- Once powered off, please wait at least 60s before power on again

During exposure

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

After Usage

- After every examination, wipe the patient contact surfaces with disinfectants such as ethanol, to prevent the risk of infection. For details on how to sterilize, consult a specialist.
- Do not spray the product directly with disinfectants or detergents.
- Wipe it with a cloth slightly damped with a neutral detergent. Do not use solvents such as alcohol, benzene and acid. Doing so may damage the surface of the product.
- It's recommended to use a waterproof non-woven cover as the isolated layer between product and the bleeding patient.

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2.1. Product Description

Mars1417X is a cassette-size wireless X-ray Wireless Digital Flat Panel Detector based on amorphous silicon thin-film transistor technology. It is designed to provide the high quality radiography image which contains an active matrix of 3500×4300 with 100um pixel pitch, the TFT module has a pixel matrix of 3584*4352.

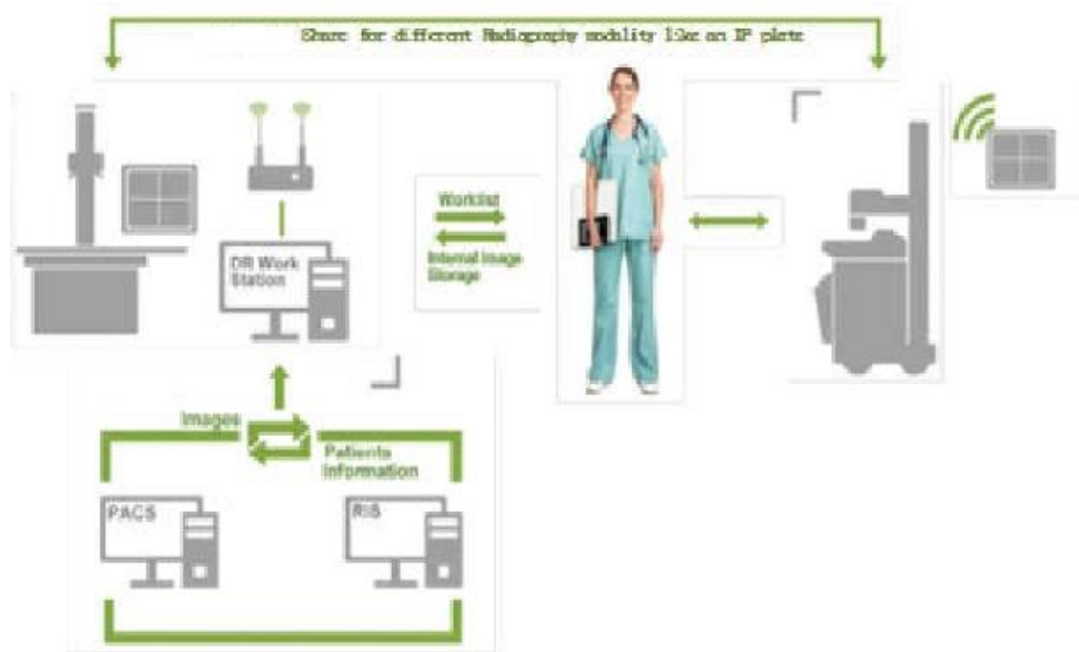
The scintillator of Mars1417X is CsI(Caesium Iodide) which is direct deposit. Since Mars1417X supports multiple trigger modes, it can satisfy both of the general DR system and retrofit DR system.

2.2. Principle

Detectors contain a layer of scintillator material, which converts the x-rays into light. Directly behind the scintillator layer is an amorphous silicon pixel array contains a photodiode which generates an electrical signal in proportion to the light produced by the portion of scintillator layer in front of the pixel. The signals from the photodiodes are amplified and encoded by additional electronics positioned behind the sensor array in order to produce an accurate and sensitive digital representation of the x-ray image.

2.3. Scope

This manual contains information about iRay Mars1417X product. 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.



2.4. Characteristics

- Wireless static flat panel detector
- 14 inch ×17 inch
- Removable handle
- AED
- 802.11ac
- 16-bit AD

2.5 Intended Use

Mars1417X is indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. It is intended to replace film/screen systems in all general-purpose diagnostic procedures. The device is not intended for mammography or dental applications.

Suitable patient

It is suitable for providing digital X-ray imaging for DR system to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients, but not intended for mammography or dental applications. The remaining notes depend on the DR system.

PATIENT population:

- Adult and pediatric patients
- Weight: not relevant
- Health: not relevant
- Nationality: multiple
- Patient state: patient is not user
- Gender: except for pregnant women

Pediatric Use: Guidance & Considerations

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g. less than 50 kg (110 lb) in weight and 150 cm (59 in) in height, measurements which approximately correspond to that of an average 12 year old.

The following ranges of pediatric subpopulations are to be used as a guide for manufacturers in developing medical devices:

Pediatric Subgroup	Approximate Age Range
Newborn (Neonate)	From birth to 1 month of age
Infant	Greater than 1 month to 2 years of age
Child	Greater than 2 to 12 years of age
Adolescent	Greater than 12 through 21 years of age

Exposure to ionizing radiation is of particular concern in pediatric patients because:

- 1) for certain organs and tumor types, younger patients are more radiosensitive than adults (the cancer risk per unit dose of ionizing radiation is higher for younger patients);
- 2) use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients;
- 3) younger patients have a longer expected lifetime putting them at higher risk of cancer from the effects of radiation exposure.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the

amount necessary to obtain images that are adequate clinically.

Additional guidance and recommendation are provided by the Alliance for Radiation Safety in Pediatric Imaging (Image Gently Alliance) <https://www.imagegently.org/>

Table 1 : Techniques for Typical Body Parts

Body Parts	Patient Size	kVp	mAs	SID	Grid
Abdomen AP/PA	Very Low Birth Weight (Less than 1.5Kg)	55	1	1m	No
	Low Birth Weight (Between 1.5 and 2.5Kg)	55	1.6	1m	No
	Newborn (Age is less than 1 month and Weight above than 2.5Kg)	70	1.6	1m	No

Body Parts	Patient Size	kVp	mAs	SID	Grid
Abdomen AP/PA	Infant (Age is between 1 month and 2 years)	73	2	1m	No
	Child (Age is between 2 years and 12 years)	75	7.1	1m	Yes
	Preadolescent (Age is between 12 years and 13 years)	75	14	1m	Yes
	Adolescent (Age is between 13 years and 21 years)	75	20	1m	Yes
	Adult Small	75	18	1m	Yes
	Adult Medium	80	22	1m	Yes
	Adult Large	85	32	1m	Yes
Chest PA/AP	Very Low Birth Weight	50	1	1m	No
	Low Birth Weight	55	1	1m	No
	Newborn	65	1	1m	No
	Infant	70	1.6	1m	No
	Child	70	1.6	1m	No
	Preadolescent	90	2	1m	Yes
	Adolescent	90	2	1m	Yes
	Adult Small	110	1.8	1.8m	Yes
	Adult Medium	110	2.8	1.8m	Yes
	Adult Large	120	4	1.8m	Yes
	Very Low Birth Weight	50	1	1m	no
	Low Birth Weight	55	1	1m	no

Extremities AP/PA	Newborn	57	1	1m	no
	Infant	57	1.2	1m	no
	Child	58	1.2	1m	no
	Preadolescent	62	1.6	1m	no
	Adolescent	62	2	1m	no
	Adult Small	Regarding adult details techniques of Extremities, please refer to the table "Techniques for Adult Extrimities"			no

Table 2: Techniques for Adult Extrimities

Adult Extrimities List	kVp	mAs	SID	Grid
Ankle - AP	58	4	1m	no

Adult Extrimities List	kVp	mAs	SID	Grid
Ankle – Lateral	58	4	1m	no
Femur – AP	70	16	1m	yes
Femur – Lateral	70	10	1m	yes
Hand - AP	53	1.8	1m	no
Hand – Lateral	53	1.8	1m	no
Humerus - AP	75	7.1	1m	yes
Humerus – Lateral	70	3.2	1m	yes
Knee - AP	65	10	1m	yes
Knee – Lateral	65	10	1m	yes
Wrist - PA	55	1.8	1m	no
Wrist – Lateral	55	1.8	1m	no

ESSENTIAL PERFORMANCE

According to the Mars1417X INTENDED USE and the result of risk management, image acquisition and data transmission are defined as ESSENTIAL PERFORMANCE.

Getting dark image proves that ESSENTIAL PERFORMANCE does not influence INTENDED USE. Method for getting dark image in detail refers to section "installation" and "operation"

Intended OPERATOR:

All of use, maintenance and operation steps should be carried out by the operator who has accepted the professional training offered by the company's customer service staff.

Life-time:

Life-time: 7 years without frequency limit

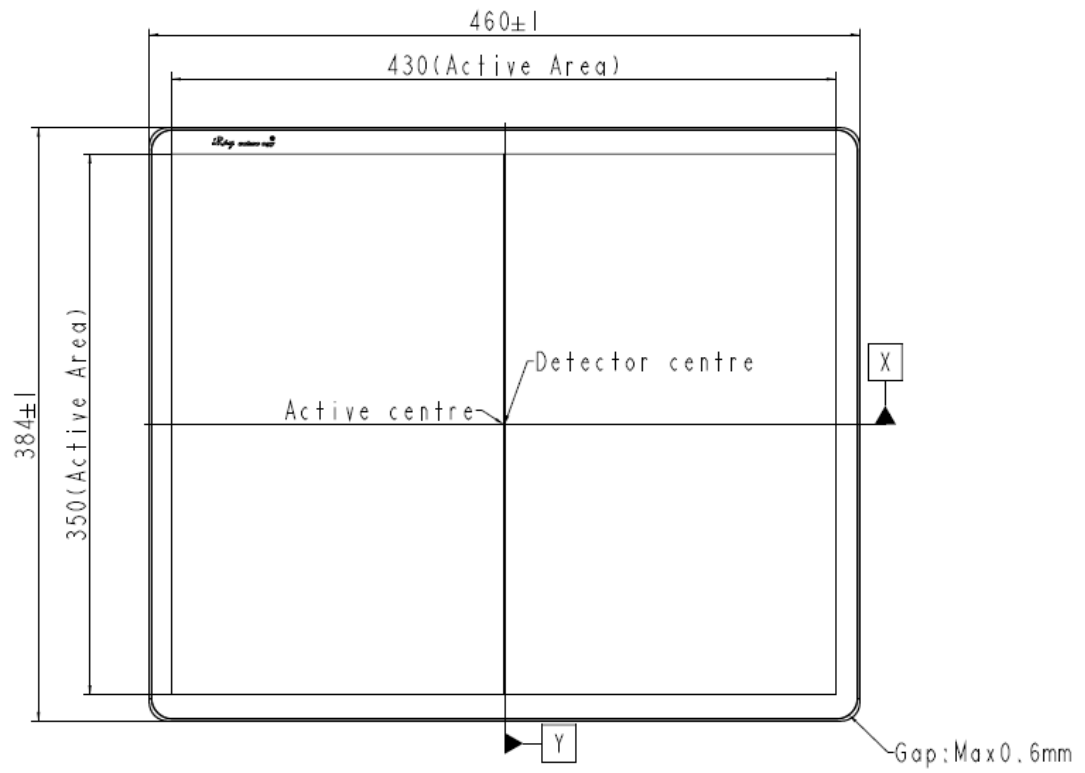
2.6. Environment

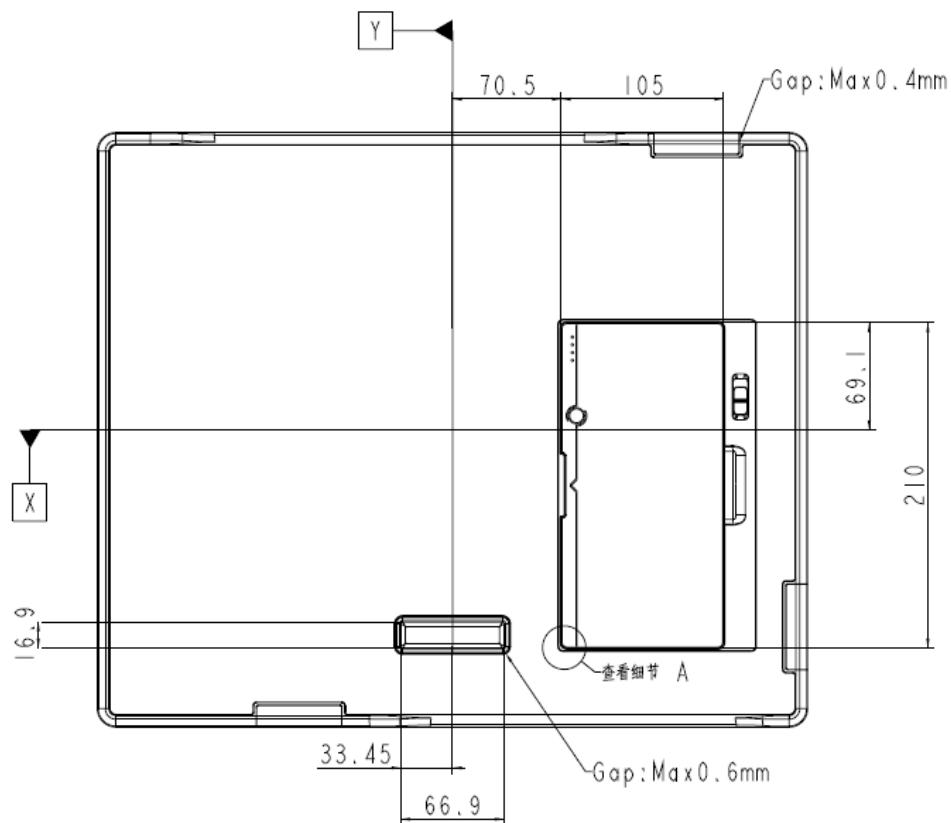
	Temperature	Humidity	Atmospheric Pressure
Operating	10~35℃	5~90% RH	700~1060mbar
Storage	-20~55℃	5~95% RH	600~1060mbar

2.7. Product Components

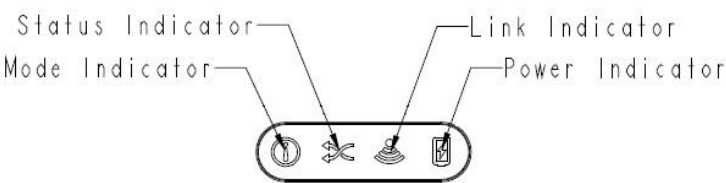
Item	Quantity
Mars1417X Detector	1pcs
Adapter	1pcs
Battery pack	2pcs
Gigabit Ethernet cable	1pcs
AC power cable	1pcs
DC power cable	1pcs
Battery charger	1pcs
CD ROM	1pcs

2.7.1. Detector





2.7.2. Indicator



2.8. Specification

2.8.1. Basic

Item	Specification
Model	Mars1417X
Image Sensor	a-Si (Amorphous Silicon) TFT
Scintillator	CsI
Pixel Size	100um
Fill Factor	60%
Effective Array	3500x4300

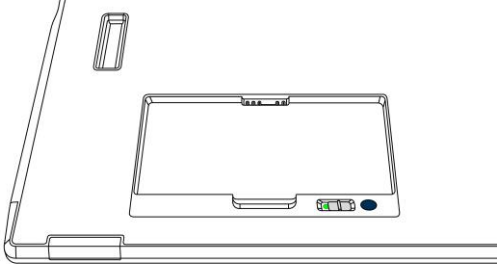
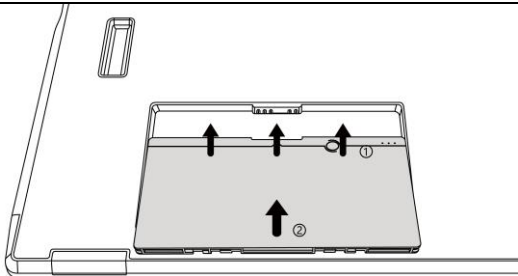
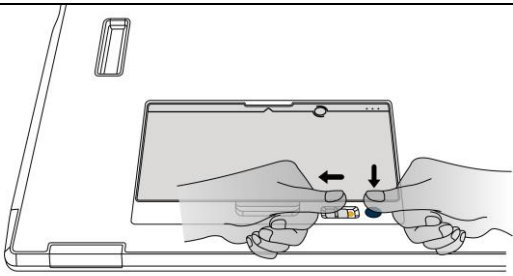
Effective Area (H x V)	35mm×43mm
Spatial Resolution	5.0 lp/mm
Image Transfer	WIFI
Full Image Time	<5.5s (with 1s XWin, from end of XWin)
Cycle Time	<8s
Power Consumption	Max 20W (no battery charging)
Dimension (L × W × H)	460mmx384mmx15mm @typ.
Weight	3kg(with battery)
X-ray Energy	40-150kV
Panel protection	IP56
Trigger Mode	Software/AED
SID	90-180cm

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3.1. Preparation

3.1.1. Attach Battery Pack

The product 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, panel will power off. Please see below for battery installation.

Make sure that connectors on the battery pack are pointed to the opening in the battery compartment.	
Slide battery package into battery compartment (Make sure battery capacity overpass is 15%).	
Press the button and push the locker until the battery is installed well.	

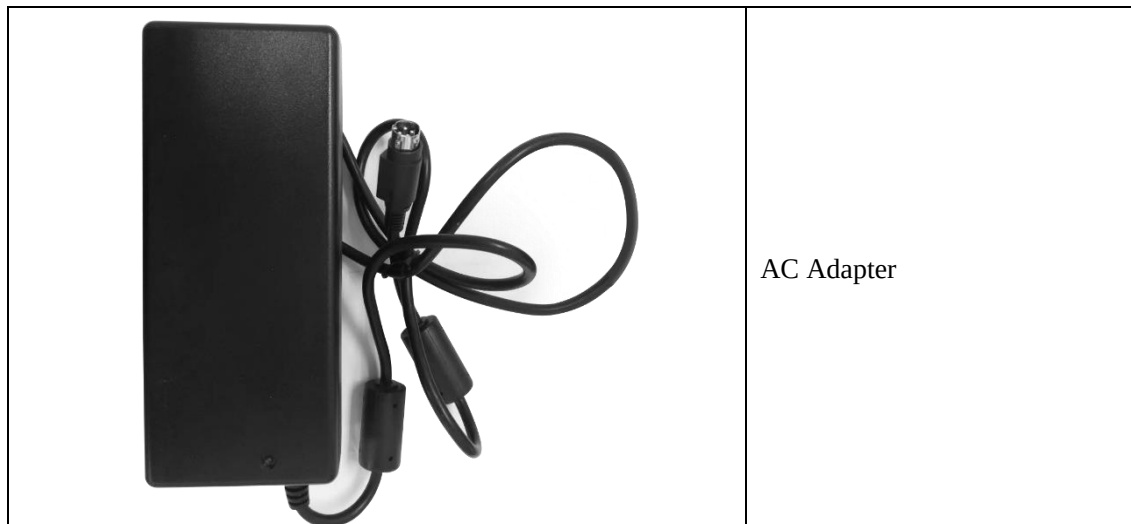
3.1.2. Adapter

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
----	-------------------	--------	---------

In order to meet the safety and function requirements of the detector, standard components are recommended.

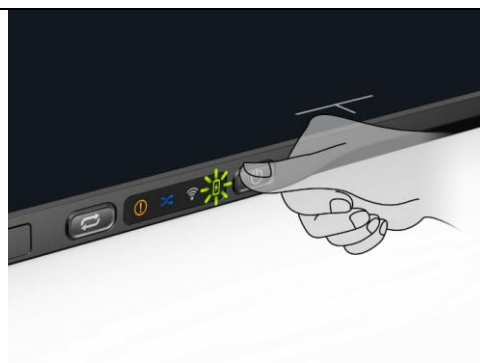


3.2. Routine Operation

3.2.1. Starting Up

On the control panel, users can press the power button to turn on.

When the detector is powered down, the user presses the button for 4 seconds to turn on the detector if the battery is inserted and the capacity is not less than 15%, or DC power is connected.



After booting up, users can check the indicator of the detector.

Power indicator:

Power Indicator	Lighting Status	Status		
		Battery Capacity	DC Input	Description
OFF		N/A	N/A	Detector is off
Green ON		N/A	YES	Detector is on
Orange Blinking	 	≥7% & <15%	NO	Detector is on
Green Blinking	 	≥95%	YES	Detector is off

Green&Orange Blinking		<95%	YES	Detector is off
--------------------------	---	------	-----	-----------------

Link indicator:

Link Indicator	Lighting Status	Description
OFF		Detector is turned off Wireless connection is not ready
Blue ON		AP connection is ready Client WIFI connection is build
Blue Blinking		Client WIFI connection is not built
Green ON		Wired connection is enabled (Service Mode)

Mode indicator:

Mode Indicator	Lighting Status	Description
Blue ON		Client connection is built
Blue Blinking		WIFI mode is set to Client @ detector is in wifi mode switch state
Green ON		AP mode is enabled
Green Blinking		WIFI mode is set to AP @ detector is in wifi mode switch state
OFF		Detector is off Client connection is not built

Status indicator:

Mode Indicator	Lighting Status	Description
OFF		Detector is off
Green ON		Exposure is allowed
Green Blinking		Detector is in WIFI mode switch status
Orange ON		Error

Button	Function	Description
Power	Power On	Press >2s when in power off status
	Power Off	Press >4s when in power on status
	Hardware Reset the Power Management	Press >7s
Mode	AP/Client Switch	Switch the AP or Client mode

■ Power On

When detector is in power off status, user can power on the detector by pressing the power button >2 seconds, and can release it when the power LED start to blink. If the button is pressed >7 seconds, it will result in a power management reset.

■ Power Off

When detector is in power on status, user can power off the detector by pressing the power button >4 seconds, and can release it when the power LED start to blink. If the button is pressed over than 7 seconds, it will result in a power management reset.

■ Power Management Reset

If the power button function does not work, user can try to press the power button >7 seconds which will start a hardware reset, and user can release the button when the power LED start to blink.

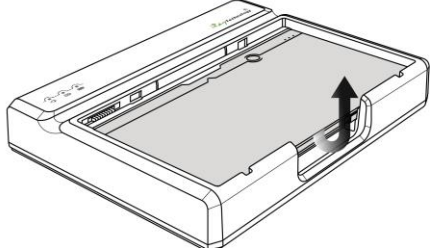
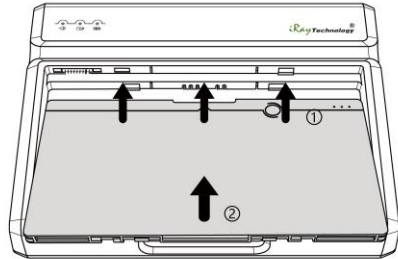
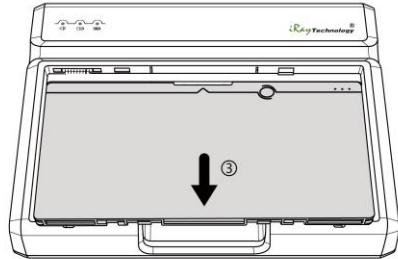
■ AP/Client Switch

User also can switch the WIFI AP/Client mode by the mode button.

- a. Press the mode button about 7 seconds until the status LED indicator start to blink, and then release it.
- b. The mode LED indicator blinks blue means the detector is in Client mode, and green means it is in the AP mode.
- c. Short press on the mode button, the mode LED indicator will blinks from blue to green (or from green to blue), which means the WIFI mode is switched from Client to AP (or AP to Client).

The setting will be valid if there is no more operations on the button for >7 seconds.

3.3. Battery Charger Installation

Operation	Figure
■ Unload Battery from battery charger.	
■ Insert battery into battery charger. ■ Note the interface position as figure.	
■ Press the battery to the bottom of battery compartment.	

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4.1 System requirement

iDetector is developed and deployed on Windows Operation System, it can be run on Windows XP/Windows 7/Windows 8/Windows 10, OS should install latest service pack. And requires computer memory 4 GB minimum. The firewall should be shut down to avoid communication issue.

4.2 Environment setup

Setup files and download url are included in SDK directory: Tools\env_setup

1. Please install Microsoft .NET Framework 4.5(Windows XP only can install V4.0). Download from Microsoft web site, please.
2. Visual C++ redistributed package need to be installed: vc_redist_x86_2013(or vc_redist_x64_vs2013).
3. For Windows XP, full path should be used in file "bind.txt".

The wifi information should be configured for first use with wired connection. The configuration can be changed when needed.

4.3 Wired Connection (for setting&maintenance)

Connect the power cable and data cable to the detector, the cover on the edge can be unscrewed to use the type-c ethernet cable..

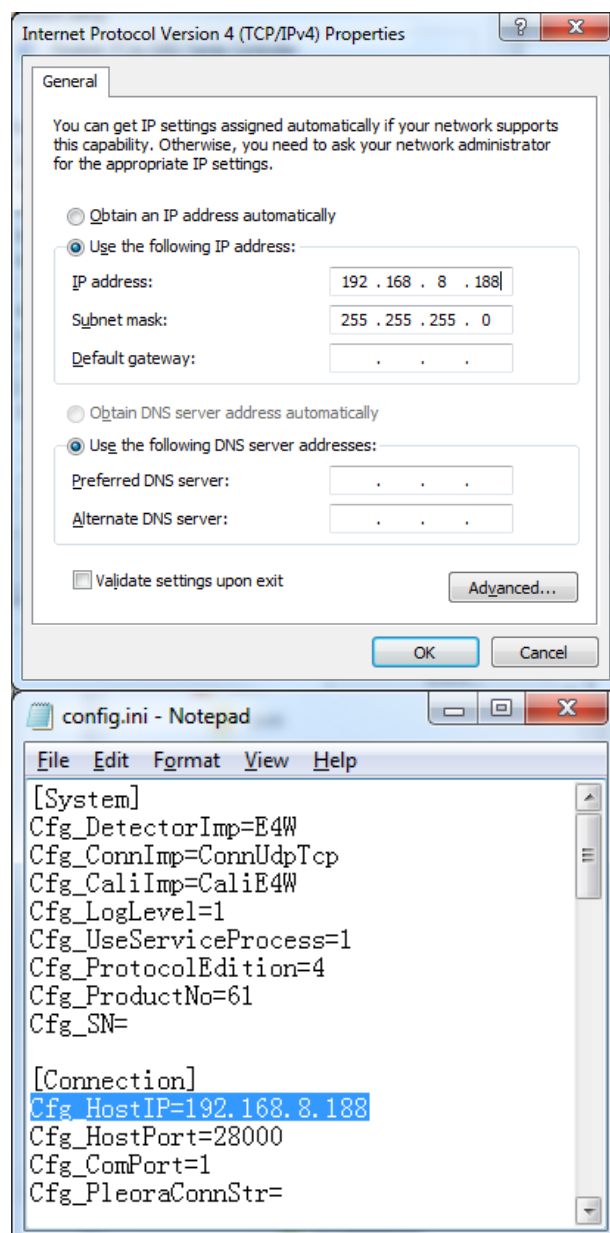


Figure 3-3-2

The default IP address (IPv4) of the detector is 192.168.8.8, the PC address (IPv4) should be configured as 192.168.8.xxx, which should be the same as the value of parameter "Cfg_HostIP" in file "*\work_dir\Mars1417X\config.ini"

Wireless Configuration

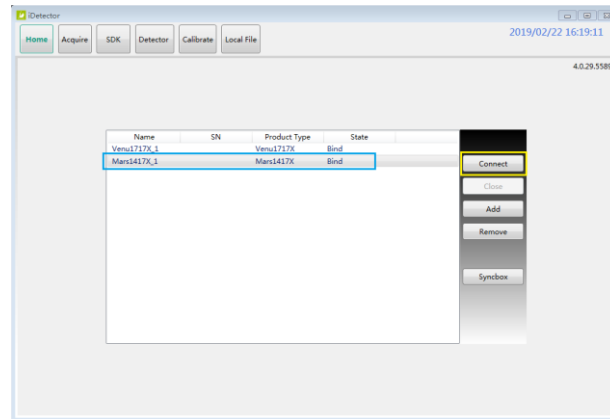


Figure 3-3-3

On the main window of Home page, select the instance of "Mars1417X" and use the "Connect" button to build the connection.

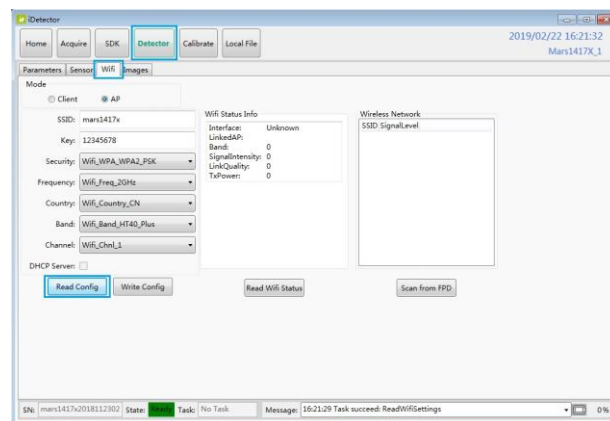


Figure 3-3-4

After finishing building the connection, click "Read Config" button on the "Wifi" tab of "Detector" pag to get the current wifi configuration.

User can set the mode of the wifi for detector, "AP" or "Client".

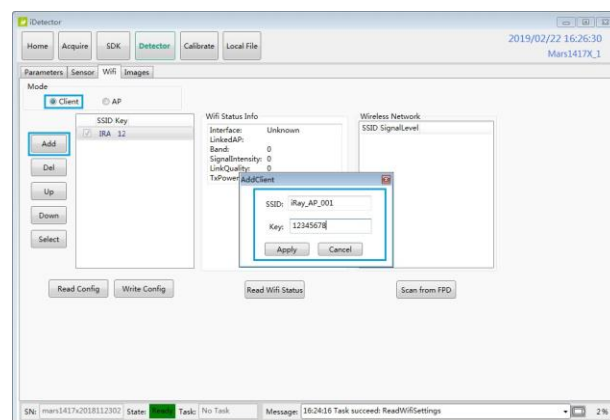


Figure 3-3-5

For Client mode, user can add the information of the access point with button “Add”, and set the default access point that the detector should connects to with button “Select”.

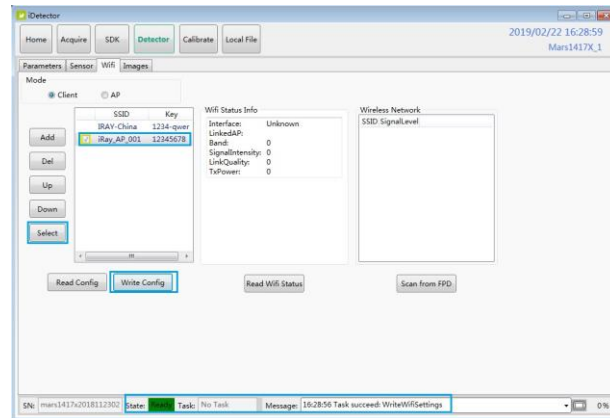


Figure 3-3-6

After click “Write Config” button, the new setting of the wifi will be valid after the status shows succeed.

The detector will connect to the access point when the data cable is removed.

What needs to be noticed is, the wifi frequency set on the “AP” interface will also be valid for “Client” mode.

4.4 Software UI

SDK supply iDetector as tool software:

32-bits iDetector.exe: Tools\iDetector\w32

64-bits iDetector.exe: Tools\iDetector\w64

Double click iDetector.exe to run the software. For different software version, the UI maybe has little difference.

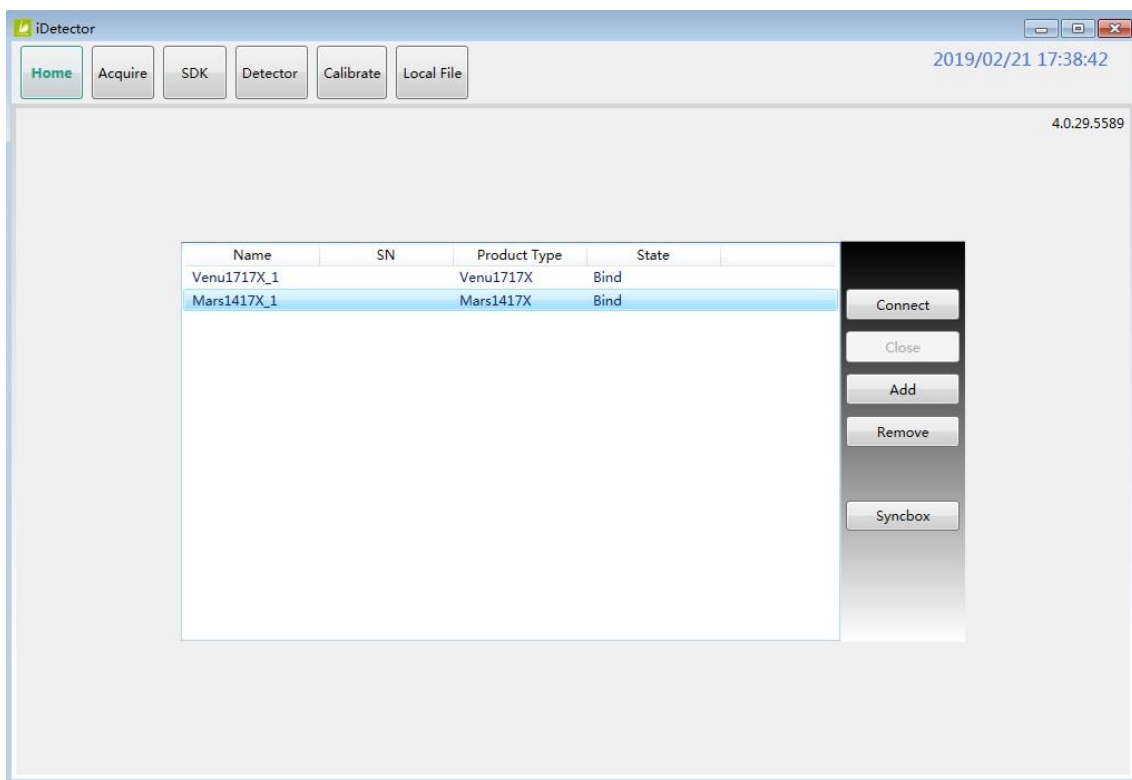
For this manual, the example is based on SDK_*_xxxx. This UI is almost the same for different versions of iDetector.

Tab	Function description
-----	----------------------

Home	Connect FPD and view the connect state
Acquire	Acquire image, select correction mode, save image and process image
SDK	config.ini setting, log level setting
Detector	Configurate parameters for detector.
Calibrate	Generate calibration files and manage the calibration files
Local File	Open and view local images.

4.4.1 HomePage

The main function in this page is to connect detector.



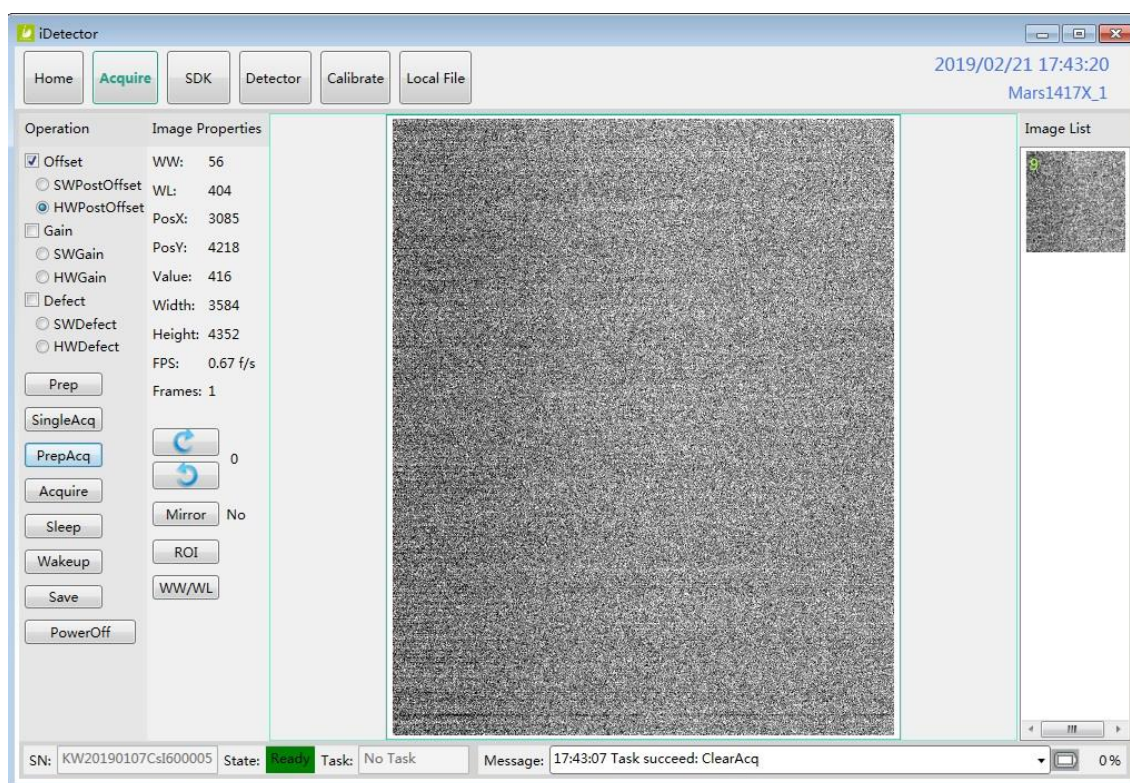
Item	Function description
Name	Display the name of detector
SN	Display the SN of detector
Product Type	Display the type of detector
State	Display the connection state (Bind, Unknown, Ready etc.)

Button	Function description
Connect	Click this button to connect the selected detector.

Close	Click this button to disconnect the selected detector.
Add	Add work directory
Remove	Remove work directory
Syncbox	Open Syncbox configuration window(Optional device)

4.4.2 Acquire Page

This page is used to acquire image under different work mode, and user can select correction options too. When acquire image finished there will be a preview image shown on the screen (if the correction option is selected, otherwise only the raw images will be shown). The properties of image is displayed on the left of image window. And on the right of image window there is a list to show thumbnail of images. User can select it and double click to see for detail. User can rotate, reverse or mirror image. User can get the value of AVG and SNR by ROI tool. The acquired images can be save as raw, tiff or dicom formats. Both raw and tiff formats support single frame and continuous frames save.



Status bar shows detector's serial number, the current task and state of detector, and feedback information of command. Status bar is also can be seen in other pages, and they are all the same.

Item	Description
------	-------------

SN	SN number of current connected detectors
State	Detectors state , eg busy, ready
Task	the current task of detector
Message	feedback information of command, eg succeed, failed

Functions in this Page.

Correction Menu		Description
Offset	HWPostOffset	Do hardware PostOffset correction for image if checked
Gain	HWGain	Do hardware Gain correction for image if selected
Defect	HWDefect	Do hardware defect correction for image if checked
Acquire Button		Description
Prep		Clear. Prepare to integrate.
SingleAcq		Acquire once
PrepAcq		Clear and acquire
Acquire		Acquire once
Sleep		Make the detector enter sleep mode (not supported for samples)
Save		Save the current image, the format is raw and tiff
PowerOff		Turn off the detector via command
Image Properties& Image Process		Description
WW		window width
WL		window level
PosX		X coordinates of the current cursor at the point
PosY		Y coordinates of the current cursor at the point
Value		Value of the current cursor at the point
Width		Image width
Height		Image height
FPS		Frame rate
Frames		Display the frame count
		Rotate the image clockwise, 90 degrees every time.
		Rotate the image anticlockwise, 90 degrees every time.
Mirror		Open or close mirror

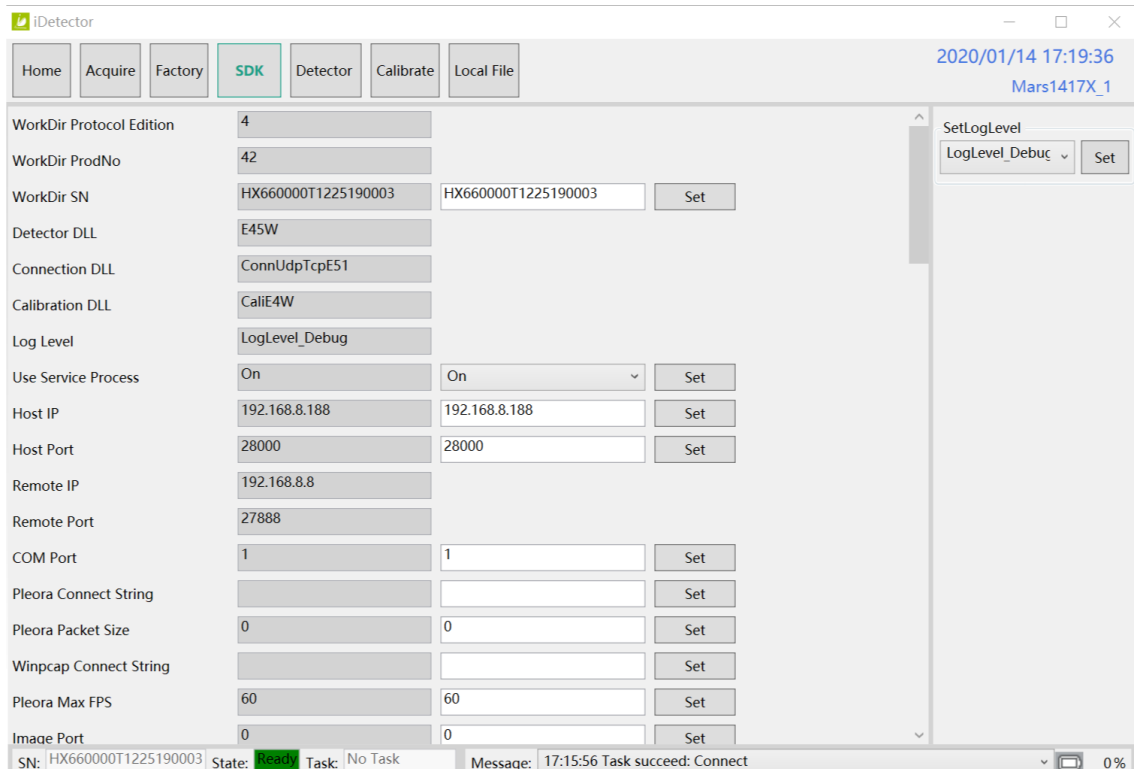
ROI	ROI tool, to view the image of the AVG, SV, SNR and other parameters with right click. Press "ctrl" key, can create several ROI area.
WW/WL	Auto adjust WW/WL based on selected area by right button of mouse.
Image List	Show thumbnails

When the image is displayed on the screen, maybe the user want to see details by dragging or zoom in/out the image, for convenience, these are some shortcuts.

1. Click the left mouse button: movie playback function operation area display.
2. Double-click the left mouse button: the image display in center and with maximum size;
3. Double-click the right mouse button: restore the window level and width for WL:32767/WW:65535;
4. Drag the left mouse button to drag the image display;
5. Lateral-drag the right mouse button to adjust the window width, and vertical-drag the right mouse button to adjust the window level;
6. F3 Key: Quickly locate the image window width and window level.
7. F4 Key: Adjust window width and window level automatically.

4.4.3 SDK Page

SDK page is used to set parameters in config.ini and log level.



Different log level will show different details. It is recommended to set the log level as Debug

4.4.4 Detector Page

In this page, there are Parameters, Sensor and Images tab.

■ Parameters

1. Enter Detector page, the tab of Parameters is active by default. There are 5 regions in this page.
2. Parameter name region: lists the parameters.
3. Parameter read region: read the parameters, the values of the parameters are displayed in this area by Read.
4. Parameter write region: write parameter. Entered value of the corresponding parameter in this area can be written to the detector.
5. Operation region: functional operation buttons area.
6. Status bar region: status bar for detector state and information of reading or writing parameters, etc.

The screenshot shows the iDetector software interface. At the top, there are tabs: Home, Acquire, Factory, SDK, **Detector** (selected), Calibrate, and Local File. The top right corner displays the date and time: 2020/01/14 17:20:42, and the user name: Mars1417X_1. Below the tabs, there are three sub-tabs: Parameters, Sensor, and Wifi. The Parameters tab is active, showing a list of configuration parameters with their current values and input fields for modification. The parameters include Product No, Serial No, Main Version, Main MB Cpu Version, Read Version, Mcu Version, Arm Version, Kernel Version, Trigger Mode, Set Delay Time (ms), Exp Window Time (ms), Src IP, Src MAC, WLAN DHCP Enable, and LAN DHCP Enable. On the right side of the Parameters tab, there are buttons for Reset Detector, Read, Write, Write RAM, Upgrade Firmware, and L. At the bottom, there is a status bar showing the SN: HX660000T1225190003, State: Green, Task: No Task, Message: 17:15:56 Task succeed: Connect, and a progress bar at 0%.

Parameter	Value
Product No	42
Serial No	HX660000T1225190003
Main Version	2.10.5.10
Main MB Cpu Version	255.255.255.255
Read Version	0.0.0.0
Mcu Version	2.10.0.9
Arm Version	2.1.10.35
Kernel Version	1.19.12.16
Trigger Mode	TriggerMode_Soft
Set Delay Time (ms)	1200
Exp Window Time (ms)	10000
Src IP	192.168.8.8
Src MAC	000FEAEF6FBE
WLAN DHCP Enable	Off
LAN DHCP Enable	Off

SN: HX660000T1225190003 State: Green Task: No Task Message: 17:15:56 Task succeed: Connect 0%

Configuration parameters description as below:

Name	Description	Configurable
Product No.	Type of detector product	N
Serial No.	Serial number of the detector	N
Main Version	Firmware version number of the FPGA	N
Read Version	N/A	N
MCU Version	Firmware version number of the MCU	N
Arm Version	Version number of the ARM App	N
Kernel Version	Version number of ARM Kernel	N
Trigger Mode	Trigger mode of the detector	Y
Set Delay Time(ms)	Exposure window for AED mode which use a fixed window	Y
Exp Window Time(ms)	Max exposure window for command trigger which use a dynamic window	Y
Src IP	Detector IP	Y
Src MAC	Detector MAC	Y
WLAN DHCP Enable	DHCP, Client, not set as on with LAN DHCP enabled at the same time.	Y

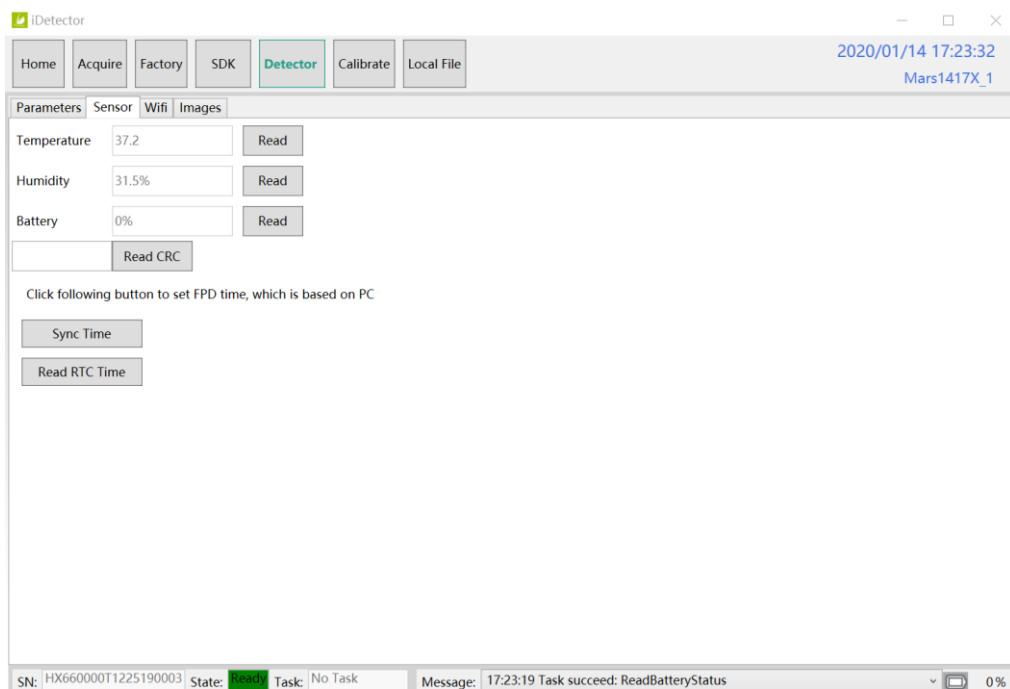
LAN DHCP Enable	DHCP, Client, not set as on with WLAN DHCP enabled at the same time.	Y
-----------------	--	---

Button function description:

Function Button	Description
Reset Detector	Reset Detector
Read	Read parameters
Write	Write parameters
Write RAM	Write parameters into RAM(will lost changes after reset)
Upgrade Firmware	Upgrade firmware
L	Upload detector log to the specified directory

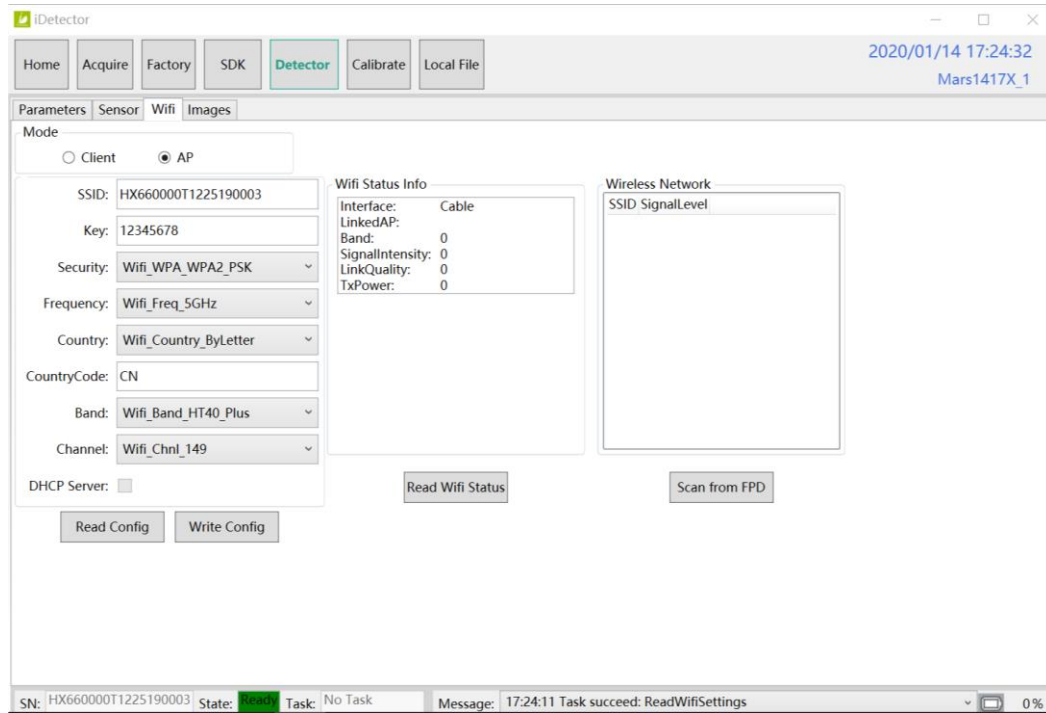
■ Sensor

The mainly function in this page is to probe the temperature and humidity of the detector. Click “Read” button to get the value of the temperature or humidity.



Sensor type	Explanation
Temperature	Read detector temperature
Humidity	Read detector humidity
Battery	Read the capacity of the battery

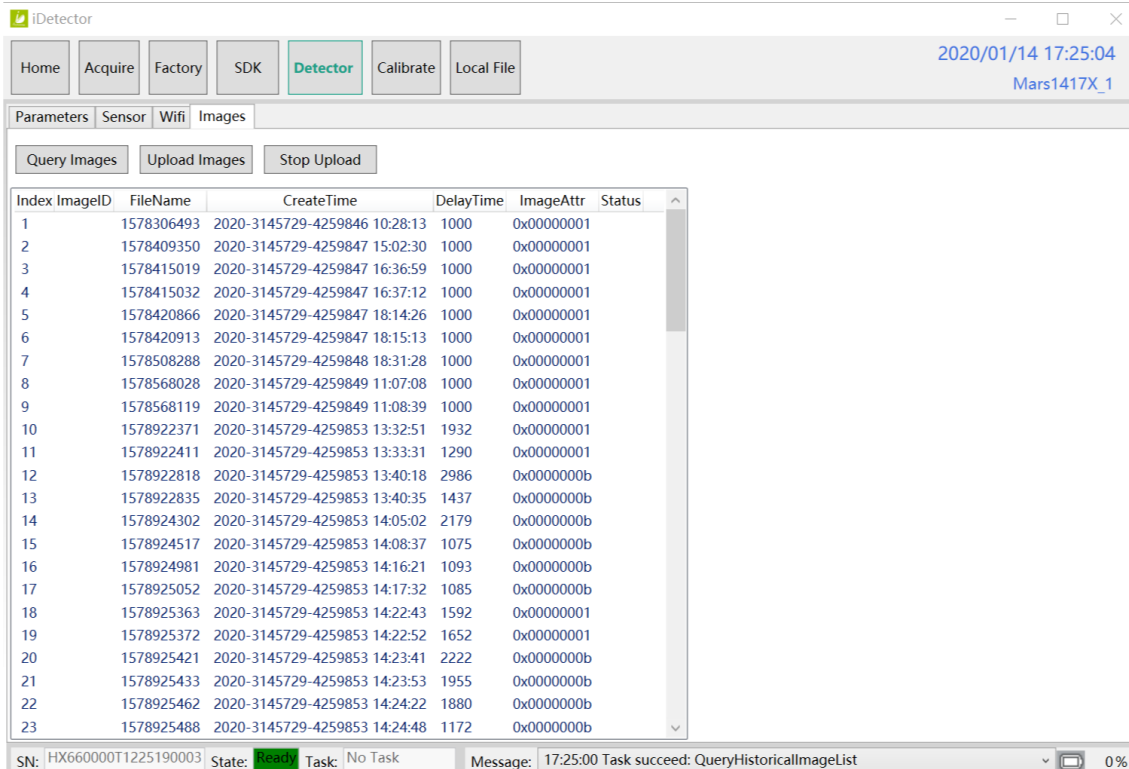
■ Wifi



User can config the wireless connect parameters on this tab.

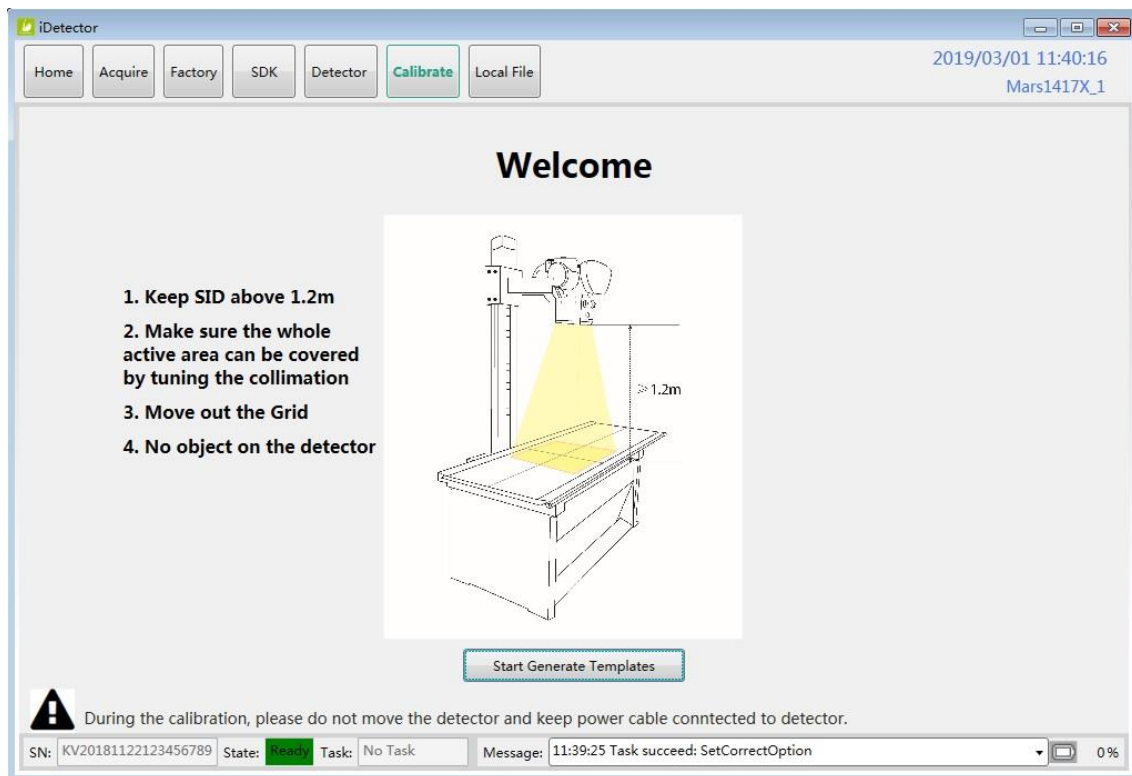
■ Images

You can Query and upload Images from detector to Workstation.

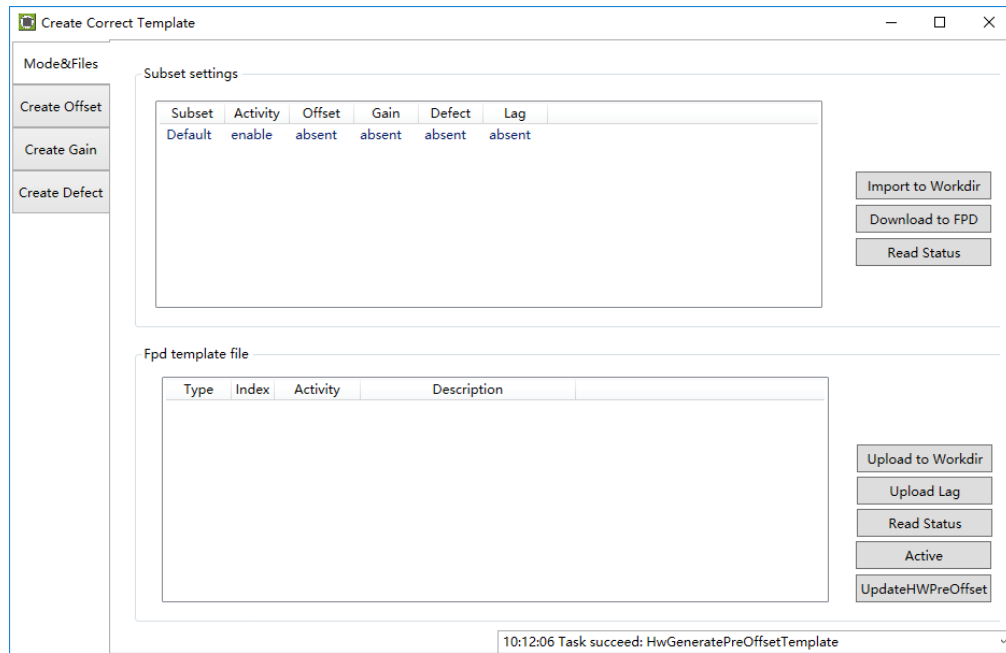


4.4.5 Calibrate Page

Offset, Gain, Defect calibrate files can be generated and managed in this page.



Click "Start Generate Templates" to enter generating templates page.



SubTab	Description
Mode&Files	Manage template files
Create Offset	Create Offset template
Create Gain	Create Gain template
Create Defect	Create Defect template

Mode&Files page	Description
Import to Workdir	Copy template file into current calibration directory.
Download to FPD	Select one item first. Then click this button to download selected template file(s) into detector.
Upload to Workdir	Select one item in Fpd template file control and select one item in Subset settings control. Click this button to upload selected template from detector into specified calibration directory.
Upload Lag	Upload Lag into SDK current directory
Active	Select one item in list. Click this button to activate selected template for hardware correction.
UpdateHWPreOffset	Force detector update Offset template(not needed for postoffset flow)

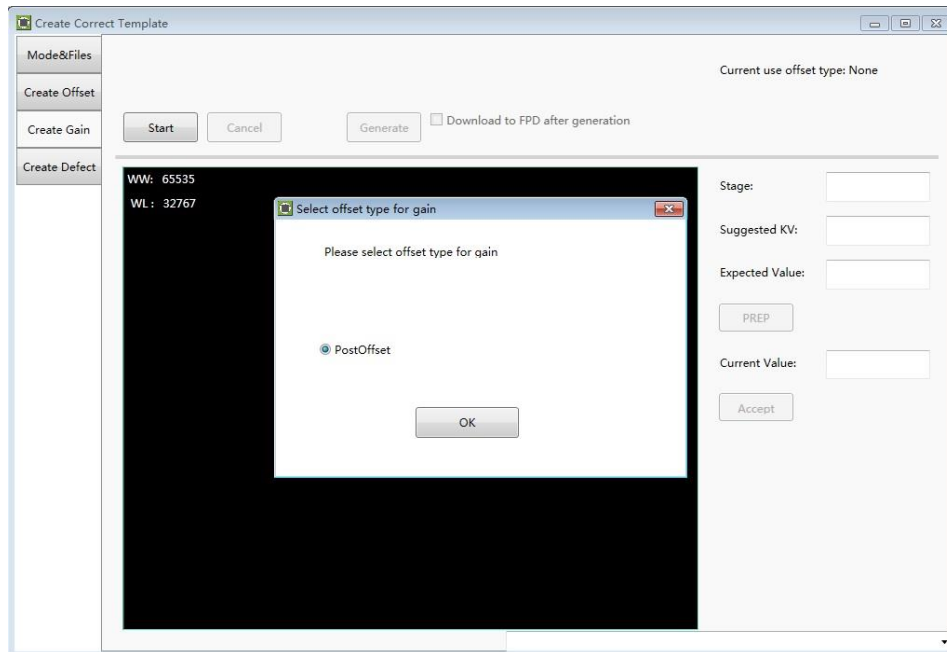
ReadStatus	Get the current state of template for hardware correction, enable/disable
------------	---

■ Generate Gain Template File

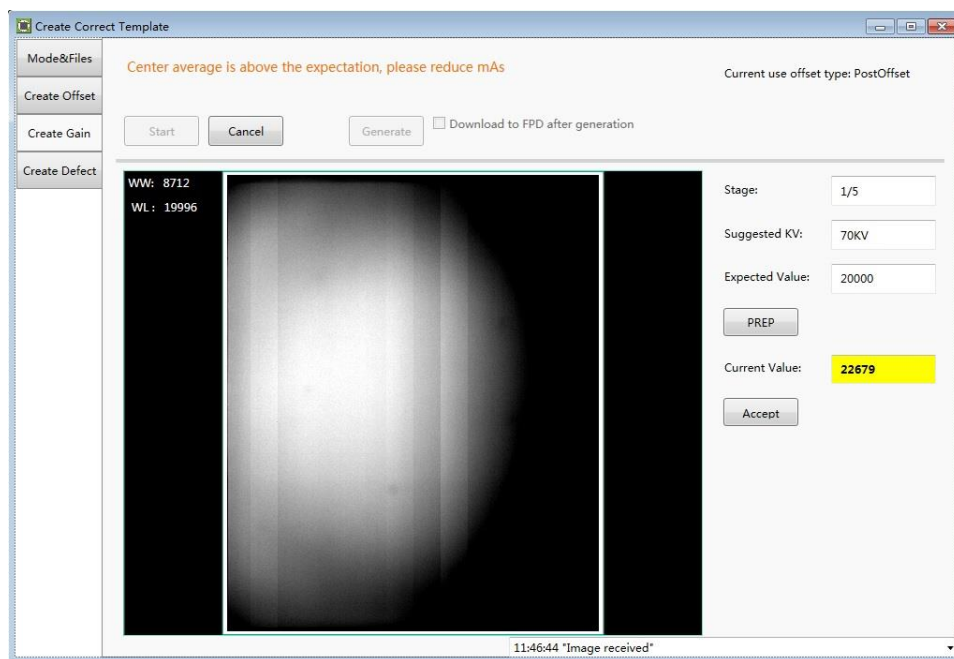
If the relative position between tube and detector changed or KV value changed, it suggest to create gain template file.

1. Enter Create Gain page

Click "Start" button to start process, the offset type should be selected, then start to get the images.

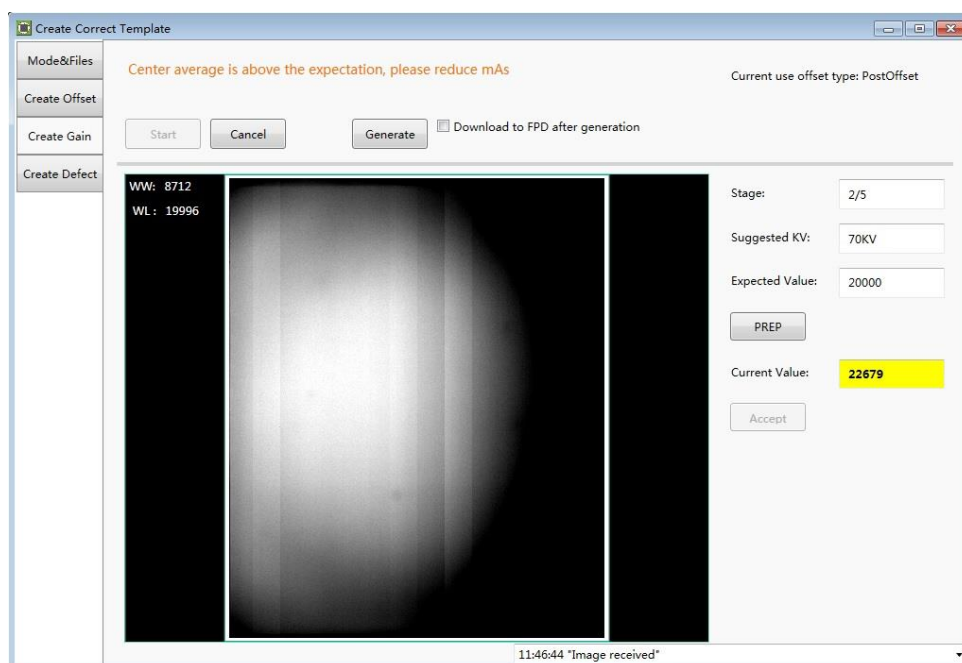


2. Click PREP button, then exposure after Acquire button enable. After receiving the PREP request, the detector needs some time to be ready, the decounting bar will appear when the exposure window is opened. After exposure user can click Acquire button to acquire the X-Ray image.



The gain template generation process needs 5 images total, the UI gives the recommended KV and target value, user can use different ones if needed.

After accepting the current image, the "Stage" will turn to 2/5, 3/5 and so on.



The current value box will show different colors, the definitions are as below:

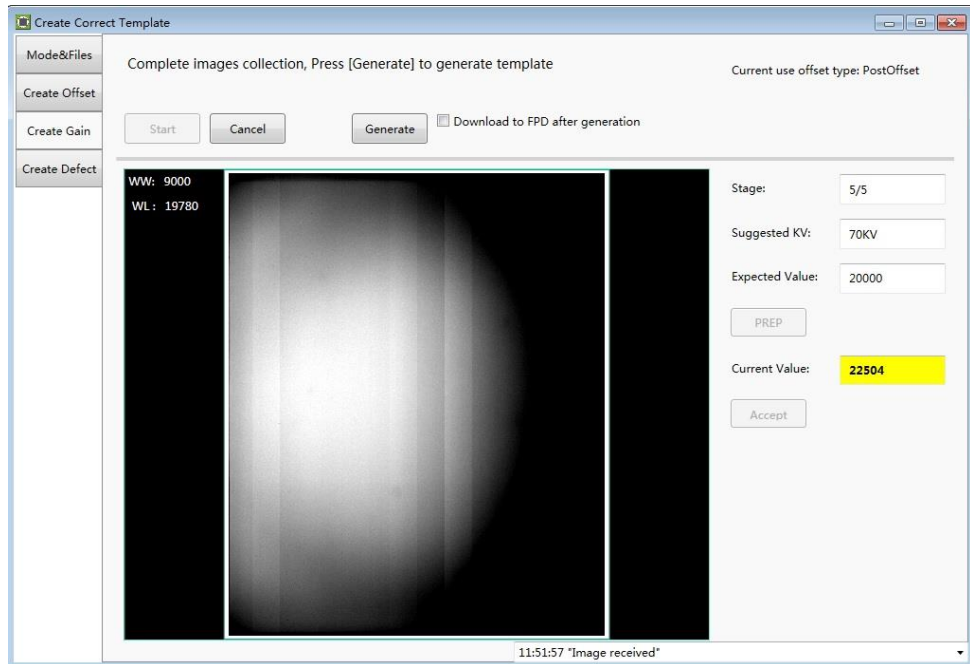
Yellow: The current value is higher or lower than the expected one, user decides if acceptable. For example, the expected value is 20000, and user needs 40000 as the gain point, the yellow warning can be ignored, and the value can be accepted still.

Green: The value is good.

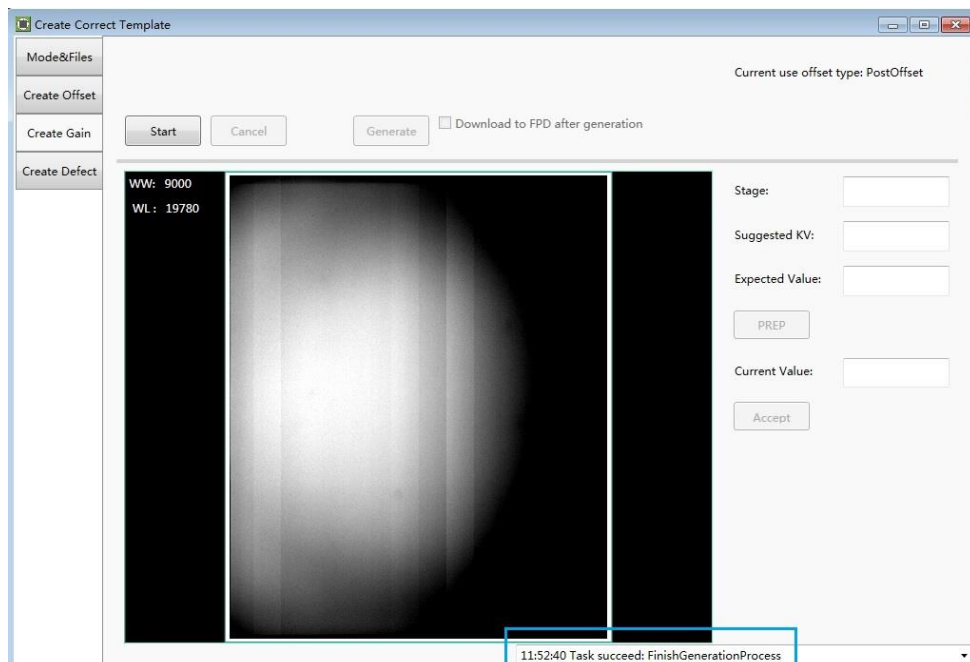
Red: The value is un-acceptable.

- After getting 5 images, user can generate the Gain template by "Generate" button, and the process can be exited from at anytime by using "Cancel" button.

If "Download to FPD after generation" is checked, then the download UI will appear after finishing generating. User can refer to the part of "Generate Defect Template File"



- When the generating process is finished, the UI will give the message of successful.

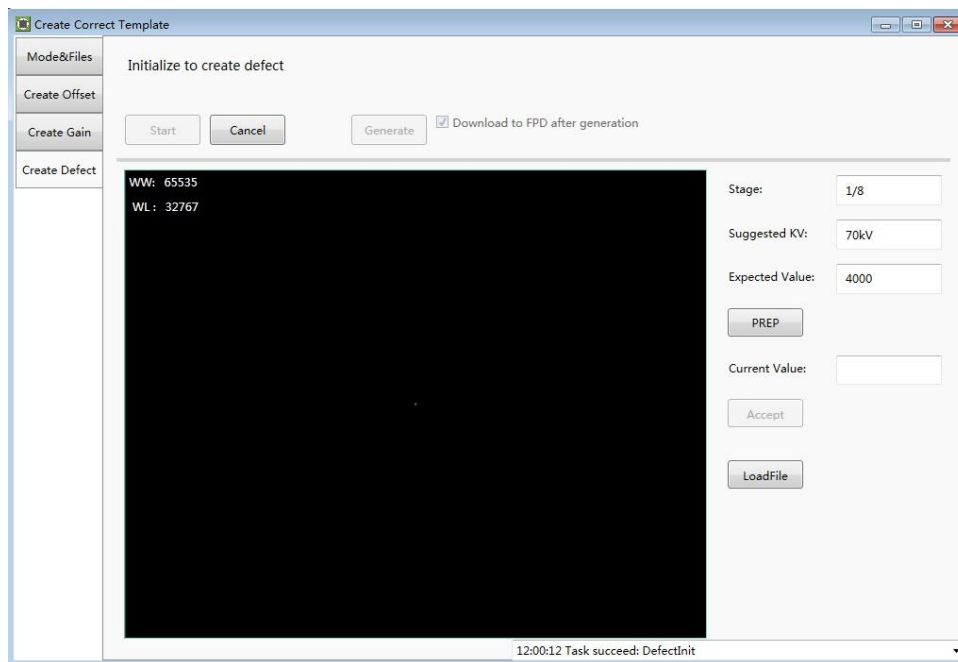


■ Generate Defect Template File

The process of generate defect map is quite similar with the one of gain map.

1. On the “Create Defect” page, user can start the generating process by “Start” button.

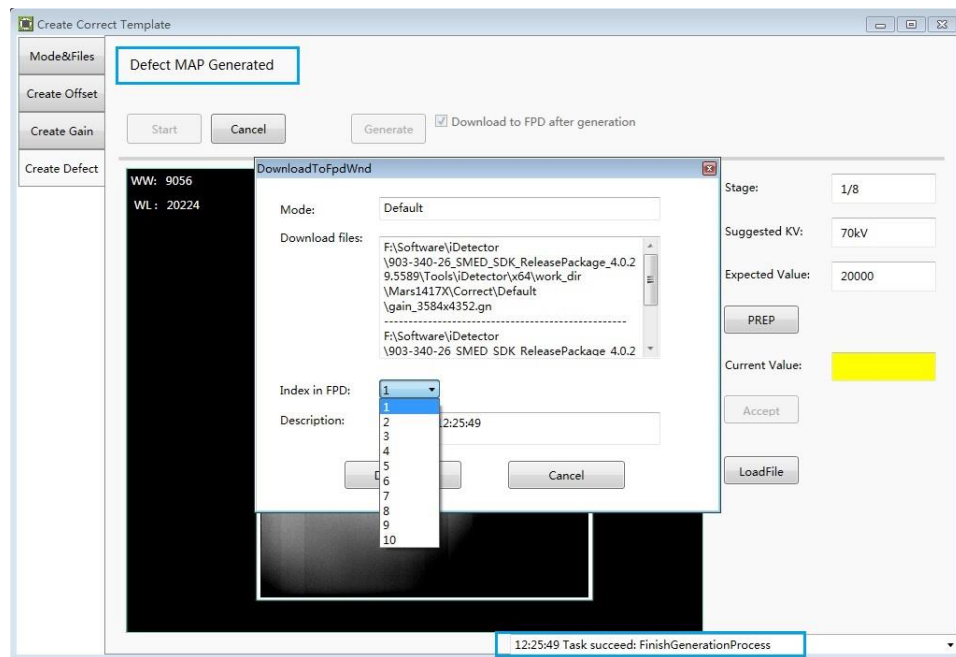
And the process can be quit by “Cancel”.



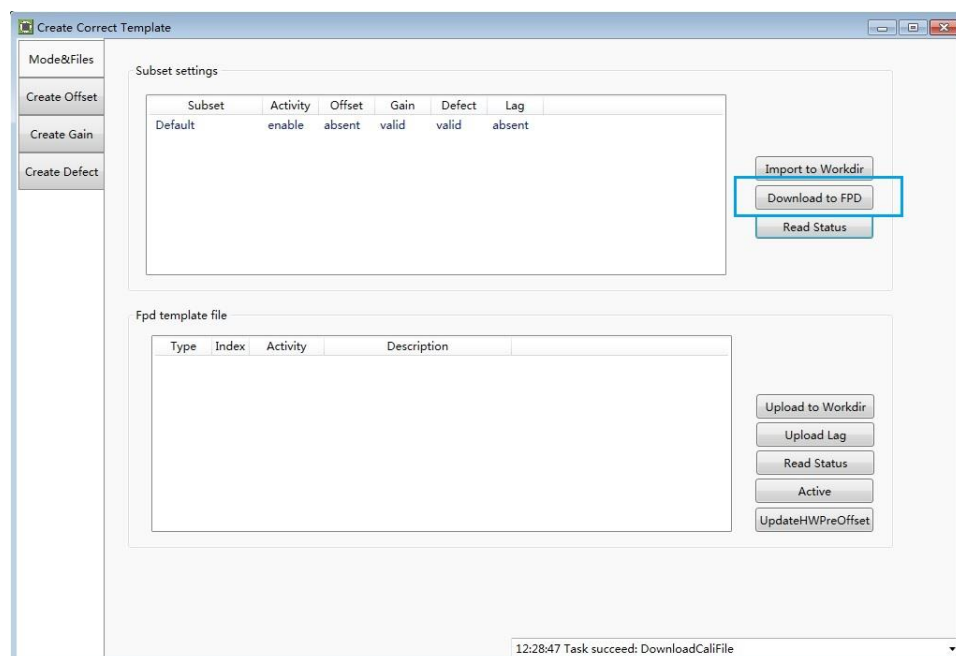
2. There are 8 images that need to be acquired, the UI gives the recommend KV and expected image value, user should refer with them.
3. If the option “Download to FPD after generation” is checked, the download UI will appear after finishing generating the defect map which will takes a little time.

The field of “Index in FPD” means that the detector can store several correction maps and choose one set to active as user wants.

The “Download files” part show the directory of the generated map stored on the workstation.



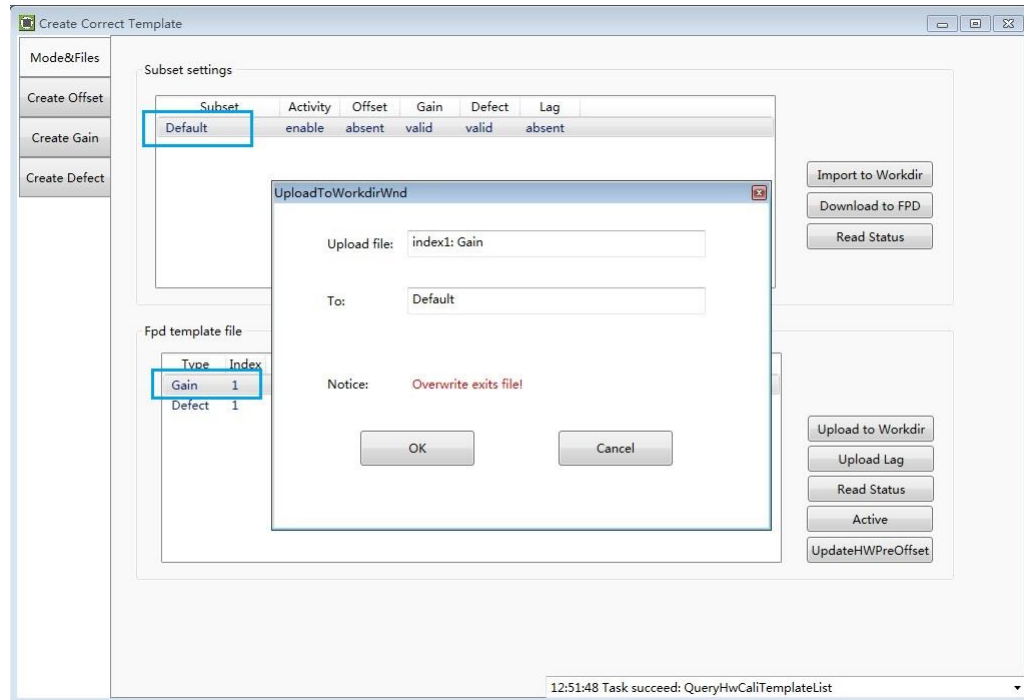
4. After choosing the stored index of FPD, the download process can be started by the "Download" button, user should wait the process until it is finished.
5. The correction map also can be managed at anytime on the page of "Mode&Files". Choose the item of "Default" in the Subset settings part and click "Download to FPD" to finish downloading the maps into the detector.



■ Upload the correction files

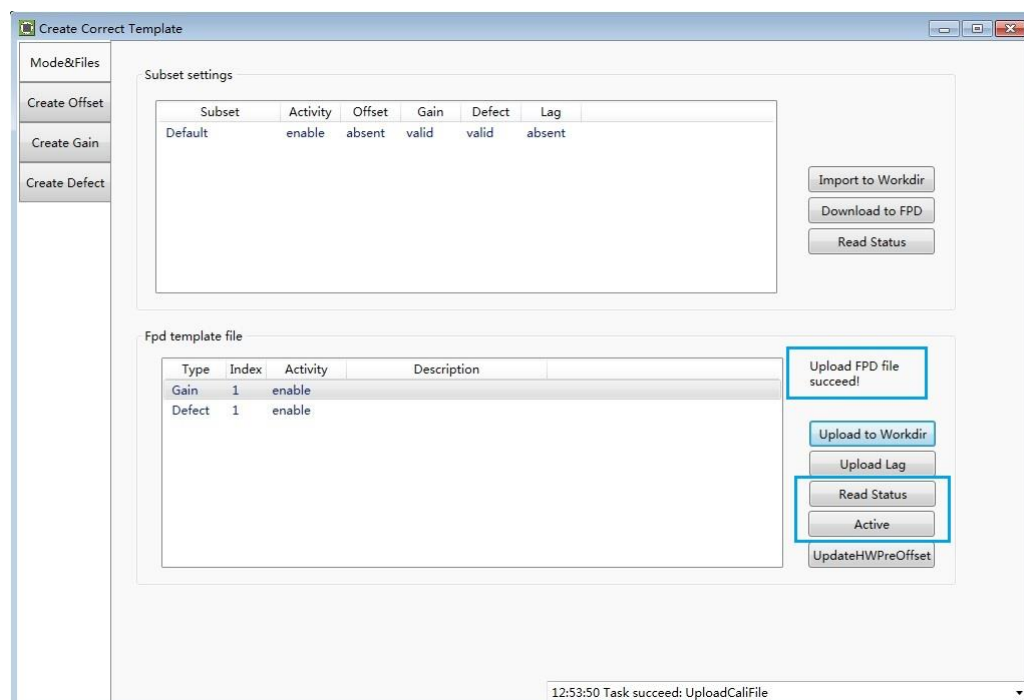
1. The correction maps can be uploaded to the workstation too.

Choose the gain or defect in the “Fpd template files” and the “Default” directory in the “Subset settings”, then click the “Upload to workdir”.



2. When the upload process is finished, the UI will give the message.

The correction maps should be enabled before using hardware correction, read status first, then choose the gain or defect, enable the map by clicking “Active” button.



4.4.6 Local Page

In this page user can open the image files saved in local, the file formate can be dcm, raw, tiff, dft.

When the software is disconnected to detector, the file still can be opened.

Click "Load File", there will be an open file wizard. Select file and click open or double click the file.

The tiff file will be opened directly. For the raw file or dft file there will be a dialog to select image size. Select correct size to open image files. If the file is not correct user will get an error message.

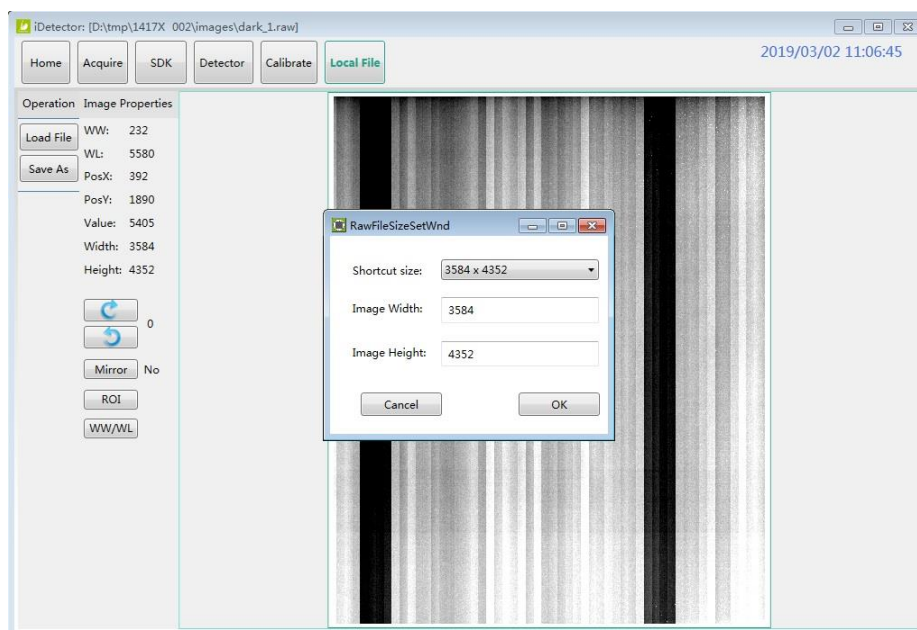
The pixel matrix is defined as below:

Active area : 3500*4300

TFT includes active area and dummy pixels: 3524*4330

Full image includes TFT matrix and empty ROIC channels: 3584*4352

What needs to be notice is only the active area pixels will be displayed when use load file function, the value of dummy pixels and empty channels will be filled by 65535.



This page provides ROI tool, which can see the AVG, SNR, and other properties of the chosen image area by right mouse button.

This page provides WW/WL tool as Acquire page . Click this button to auto adjust WW/WL based on selected area by right button of mouse.

Image Properties& Image Process	Description
WW	window width
WL	window level
PosX	X coordinates of the current cursor at the point
PosY	Y coordinates of the current cursor at the point
Value	Value of the current cursor at the point
Width	Image width
Height	Image height
	Rotate the image clockwise, 90 degrees every time.
	Rotate the image anticlockwise, 90 degrees every time.
Mirror	Open or close mirror
ROI	ROI tool, to view the image of the AVG, SV, SNR and other parameters. Press "ctrl" key, can create several ROI area.
WW/WL	Auto adjust WW/WL based on selected area by right button of mouse.

4.5 List of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK

- The operating system is not compatibility;
- Change or update the software failed;
- The compatibility of the interface;
- The data transfer protocol error;
- The inconsistent of interface or format leads to data distortion;
- The data output failed;

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5.2 Software Mode 59

5.3 AED Mode 61

5.4 After use 62

5.5 Firmware Upgrade..... 62

Mars1417X provides SDK for users to integrate detector into their DR system. Additionally, it also provides an application for demonstration, i.e. IDetector. User can use IDetector to control detector without DR system.

5.1 Steps for acquiring image

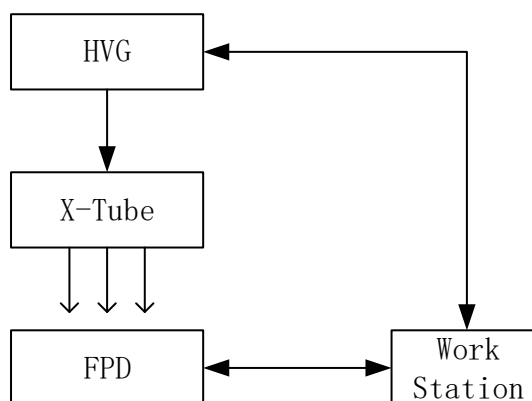
- Make sure the hardware is connected correctly and then power on.
Once powered off, please wait at least 60s before power on again
- Wait until initialization is complete
- Connect the software
- choose the synchronization mode
- Generate HWPreOffset, Gain and Defect template after the detector reaches thermal equilibrium
- Acquire images in the selected mode

To Acquire X-ray image is the main operation of Mars1417X. Most importantly, detector should build synchronization with X-ray generator. Mars1417X has one synchronization modes to acquire X-ray image, which is Software Mode.

5.2 Software Mode

5.2.1 Block Diagram

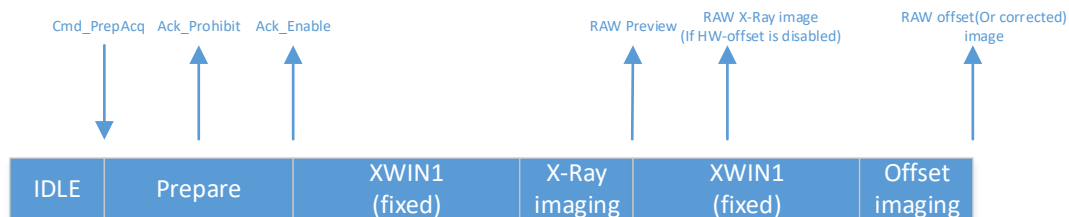
Software mode is the basic way to acquire X-ray image. Please see figure below for general feature. Workstation is a host PC device installed with iDetector and SDK. FPD is the Wireless Digital Flat Panel Detector and HVG is the High Voltage Generator. In this mode, Workstation does not have to control X-ray generator. Users would decide when to shoot X-ray.



5.2.2 Work Flow(PrepAcq)

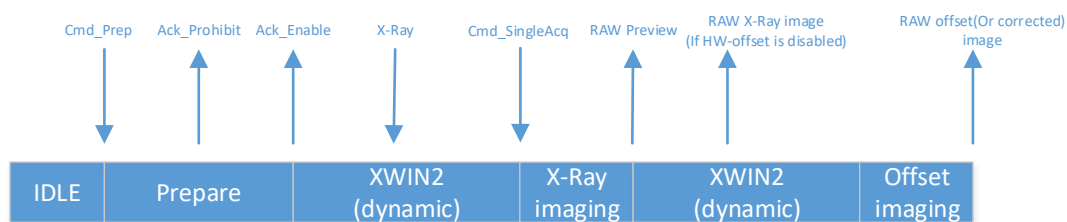
Select HWPostOffset、HWGain、HWDefect. If user need the raw image, please de-select all these correction options.

Also, the software correction is supported.



1. Send Cmd"PrepAcq" on UI "Acquire" page.
2. After receiving the Cmd_PrepAcq, it will start the prepare process, and send back the acknowlage of "Prohibit" and "Enable", the "XWIN" will be started.
3. The XWIN is configured by parameter "Clear Acq Delay Time" on "SDK" page, the unit is "ms".
4. User needs to make sure the X-Ray ends within the XWIN.
5. The detector will send the images after the XWIN closed.
6. The preview image will be always sent, which is 4x4 averaging, the raw X-Ray image will be sent if the HW correction is disabled with the raw offset image follows, otherwise, the X-Ray image will not be sent and only the corrected image will be transferred.

5.2.3 Work Flow(Prep+Acq)

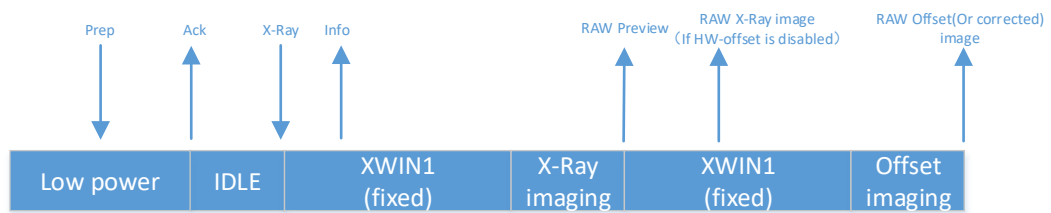


1. Send Cmd"Prep" on UI "Acquire" page.

2. After receiving the Cmd_Prep, it will start the prepare process, and send back the acknowledge of "Prohibit" and "Enable", the "XWIN" will be started.
3. The max XWIN is configured by parameter "Exp Window Time" on "Detector" page "Parameter" tab, the unit is "ms".
4. User starts the X-Ray.
5. Send "SingleAcq" on UI "Acquire" page after the X-Ray is end.
6. The preview image will be always sent, which is 4x4 averaging, the raw X-Ray image will be sent if the HW correction is disabled with the raw offset image follows, otherwise, the X-Ray image will not be sent and only the corrected image will be transferred.

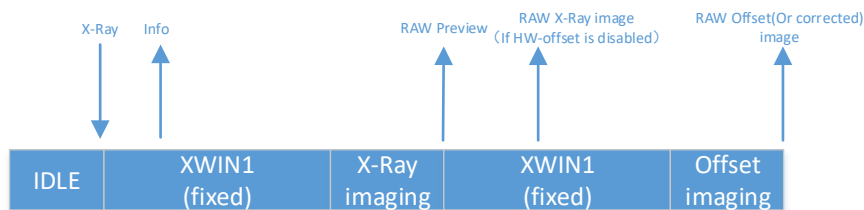
5.3 AED Mode

5.3.1 Inner



1. The detector is in low power state, user needs to send Cmd "Prep" to make the detector exit to idle state which indicated by the acknowledge to Cmd "Prep".
2. When the detector is in idle state, user can start the X-Ray any time.
3. When the X-Ray starts, the detector will sense the X-Ray automatically, the XWIN is configured by parameter "Set Delay Time" on "Detector" page "Parameter" tab, the unit is "ms", user needs to make sure that the XWIN is larger than the X-Ray time.
4. After the XWIN is end, then the detector will start the acquisition flow.
5. The preview image will be always sent, which is 4x4 averaging, the raw X-Ray image will be sent if the HW correction is disabled with the raw offset image follows, otherwise, the X-Ray image will not be sent and only the corrected image will be transferred.

5.3.2 Freesync Mode



1. For Freesync mode, there is no low power state.
2. When the detector is Idle, user can start the exposure flow any time.
3. When the X-Ray starts, the detector will sense the X-Ray automatically, the XWIN is configured by parameter "Set Delay Time" on "Detector" page "Parameter" tab, the unit is "ms", user needs to make sure that the XWIN is larger than the X-Ray time.
4. After the XWIN is end, then the detector will start the acquisition flow.
5. The preview image will be always sent, which is 4x4 averaging, the raw X-Ray image will be sent if the HW correction is disabled with the raw offset image follows, otherwise, the X-Ray image will not be sent and only the corrected image will be transferred.



NOTE

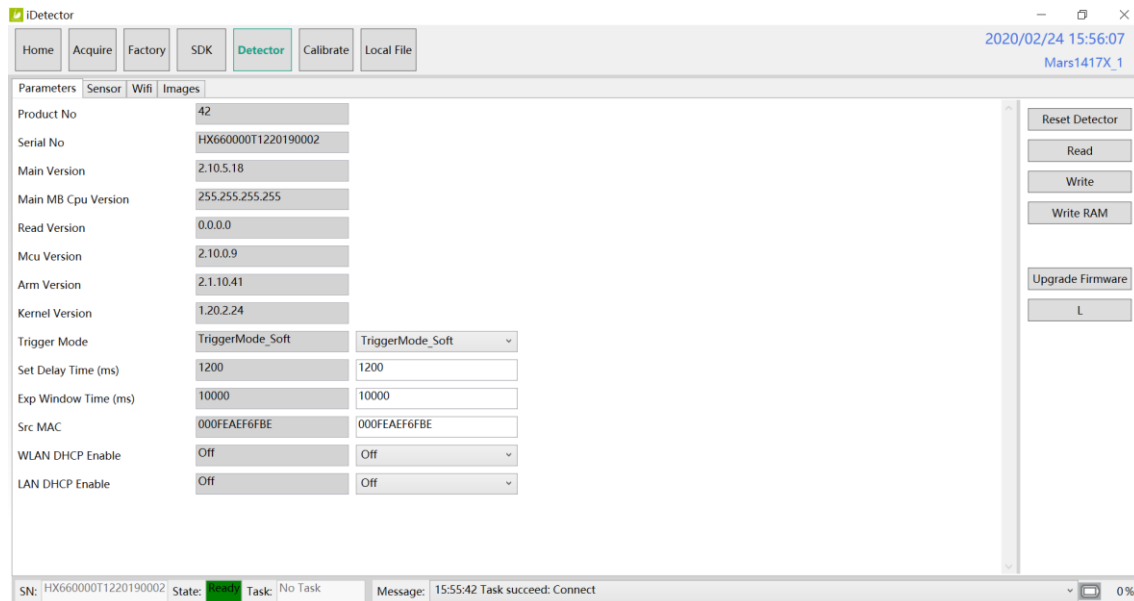
The X-ray triggers in the above workflow diagrams for both Inner and FreeSync modes can be detected by the AED (Automatic Exposure Detection) function, and the current AED version is 4.2.

5.4 After use

1. Disconnect the software
2. Power off
3. Keep it clean
4. Store under specified conditions

5.5 Firmware Upgrade

On "Detector" Page, "Parameter" Tab, user can upgrade firmware by entrance button "Upgrade Firmware".



The firmware upgrade package may contain firmware of several units: ARM, FPGA, MCU.

Mars1417X_IMAGE_44_ALL_20XX_XX_XX.ifrm

Word "ALL" indicates the file contains the firmware upgrade file for all units.

Mars1417X_IMAGE_44_ARM_20XX_XX_XX.ifrm

Word "ARM" indicates the file is only for ARM.

Mars1417X_IMAGE_44_FPGA_20XX_XX_XX.ifrm

Word "FPGA" indicates the file is only for FPGA.

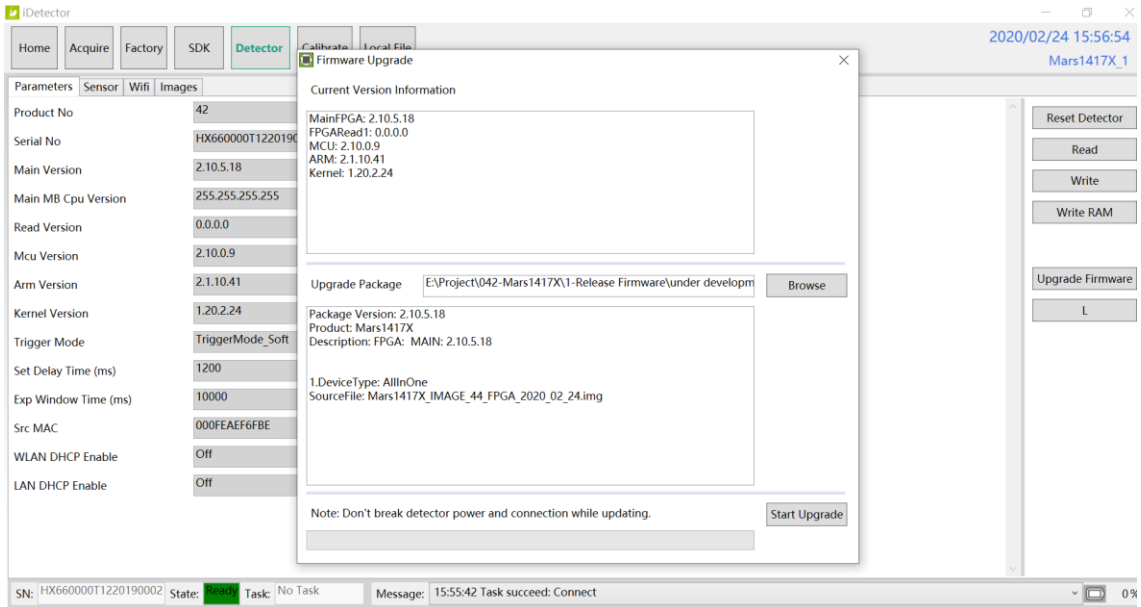
Mars1417X_IMAGE_44_MCU_20XX_XX_XX.ifrm

Word "MCU" indicates the file is only for MCU.

User can choose one of these files as required to start the upgrade.

Choose the file that needs to be upgraded, and must check the package info to confirm if it is correct.

Wireless Digital Flat Panel Detector Mars1417X



6.1	<i>Medical Equipment Safety Standards</i>	66
6.2	<i>Guidance and Manufacture's Declaration for EMC</i>	67
6.3	<i>Radio Frequency Compliance Information</i>	69
	<i>Radio Frequency (RF) Energy</i>	71
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6.5	<i>Product Label</i>	73

6.1 Medical Equipment Safety Standards

◆ Medical equipment classification

Protection type against electrical shock	Class I equipment, using medically approved adaptor supply Internally powered equipment, using battery power supply
Protection degree against electrical shock	B Type
Protection degree against water penetration	IP56 (Detector) IP20 (Charger-Combo)
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
The detector has two power supply modes (power adaptor and battery pack) and a single way for signal transmission (wireless)	

◆ Safety standards reference

Wireless detector safety standards cover the detector, charger, battery pack and other accessories.

IEC 60601-1:2005+A1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1: 2006+A1:2013 +A11:2011+A12:2014	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
CAN/CSA-C22.2No.60601-1:14	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1:2005+A2 (R2012)+A1	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
KS C IEC 60601-1:2013;	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
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
CAN/CSA-C22.2 No. 60601-1-2:16	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-2-54:2009+A1:2015	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy
EN 60601-2-54:2010+A1:2015	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy

CAN/CSA-C22.2 No. 60601-2-54:11+GI1(R2016)+A1;	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy
KS C IEC 60601-2-54:2012	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy
IEC 60601-1-6:2010 +A1:2013;	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
EN 60601-1-6:2010+ A1:2015;	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
CAN/CSA-C22.2 No. 60601-1-6:11+A1;	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
KS C IEC 60601-1-6:2011;	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
EN ISO 14971: 2019	Medical device – Application of risk management to medical devices
EN ISO 24971: 2010	Medical devices — Guidance on the application of ISO 14971
ISO 15223-1:2016	Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied—Part 1: General requirements
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
EN 1041:2008+A1	Information supplied by the manufacturer of medical devices
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
MDD (93/42/EEC)	Medical Device Directive
EN ISO 13485:2016	Medical devices -- Quality management systems - Requirements for regulatory purposes

6.2 Guidance and Manufacture's Declaration for EMC

6.2.1 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	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

6.2.2 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 a.c. 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 and 70% UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 cycles

◆ **Recommended separation distances between portable or mobile RF communication device and detector:**

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	Shielded/Unshielded	Number	Cable classification
AC power cable	1.8m	Unshielded	1 piece	AC power
DC power cable	3m	Shielded	1 piece	DC power
Ethernet cable	3.5m	Shielded	1 piece	Signal

◆ **Electromagnetic Compatibility (EMC)**

Mars1417X requires 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. Mars1417X 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.

Mars1417X 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 Mars1417X as replacement parts for inner components, may result in increased emission or decreased immunity.

6.3 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 C 15.407

European Union	47 CFR §2.1091 KDB447498 D01 General Exposure Guidance v06
	ETSTEN 300 328 V2.2.2 ETST EN 301 893 V2.1.1 ETST EN 300 440 V2.1.1 ETSTEN 301 489-1 V2.2.3 ETSTEN 301 489-3 V2.1.1 ETSTEN 301 489-17 V3.2.4 EN 55032:2015+A11:2020 EN 55035:2017+A11:2020 EN 61000-3-2:2014 EN 61000-3-3:2013 EN 50566:2017 EN 62209-2:2010+A1:2019 IEC 62479:2010

6.3.1 FCC Compliance

Contains module's FCC ID: 2ACHK-01070189

- The panel has been tested to comply with limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

- Operation is subject to the following two conditions.

The panel may not cause harmful interference.

The panel must accept any interference received, including interference that may cause undesired operation.

- The panel generates, uses, and radiates 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 the panel does cause harmful interference to radio or television reception, which can be determined by turning the panel off and on, the user is encouraged to correct the interference by one or more of the following measures.

Reorient or relocate the antenna.

Increase the separation between the panel and receiver.

Connect the panel into an outlet different from the receiver is connected.

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

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

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

UNII I is in door use only

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.

During SAR testing, this device was set to transmit at its highest certified power level in all

tested frequency bands, and placed in positions that simulate RF exposure in usage against the body with no separation. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below the maximum value.

This is because the device is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless Base station antenna, the lower the power output.

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 ICNIRP used by the general public is 2.0W/kg averaged over ten grams of tissue and, 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. To support body-worn operation, choose the belt clips or holsters, which do not contain metallic components, to maintain a separation of 0 mm between this device and your body.

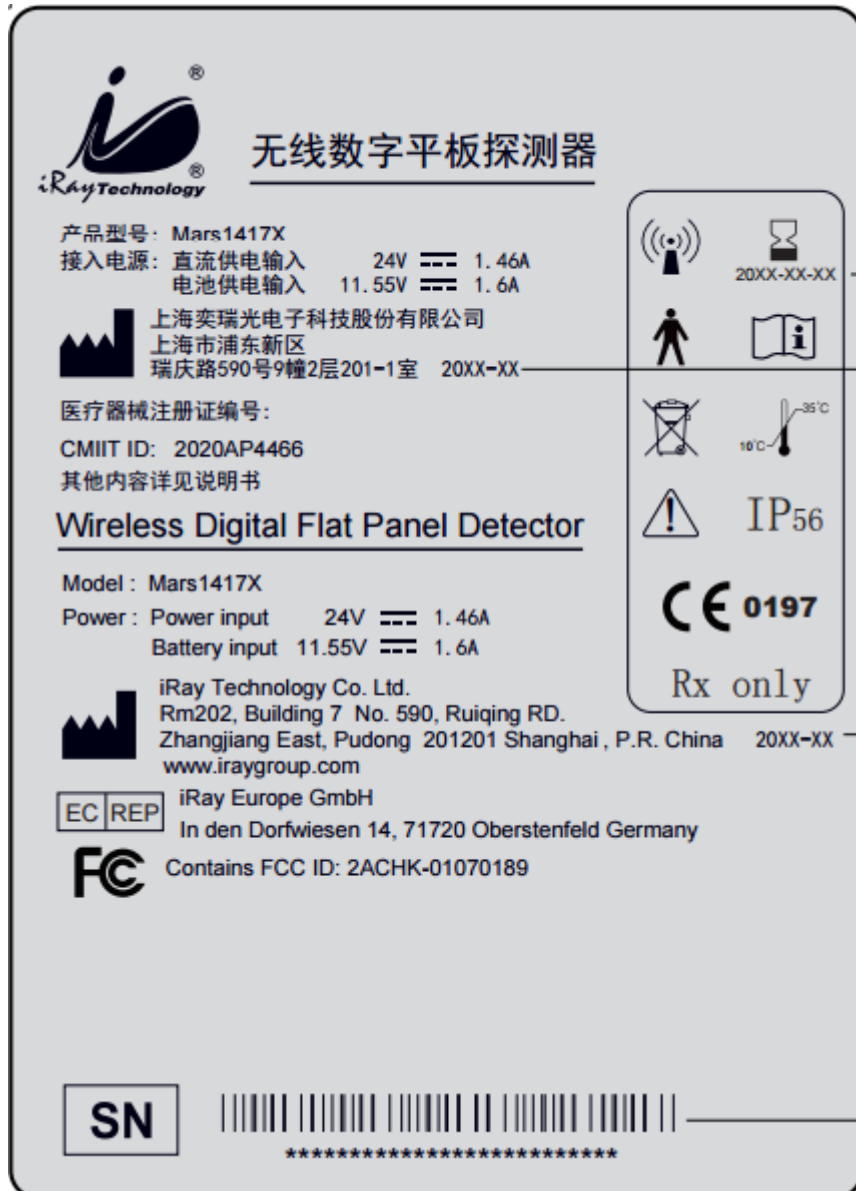
RF exposure compliance with any body-worn accessory, which contains metal, was not tested and certified, and using such body-worn accessory should be avoided.

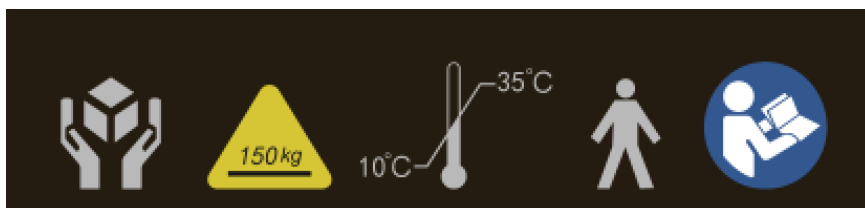
6.4 Battery Safety Standards

Standards	Description
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
UN38.3	United Nations Recommendations on the Transport of dangerous goods Manual of tests and Criteria ST/SG/AC.10/11/Rev.6/Amend.1&Amend.1

6.5 Product Label

Detector label





Battery Charger Label



充电器

产品型号: CHARGER-COMBO
 接入电源: 输入 100-240V~50/60Hz
 1.0A MAX.
 输出1 12.6V == 2.5A
 输出2 13.2V == 2.5A
 输出3 8.7 V == 2.5A



奕瑞影像科技（太仓）有限公司
 中国江苏省
 太仓港经济技术开发区兴港路33号

其它内容详见说明书 Made in China

Charger

Model: CHARGER-COMBO
 Power: Input 100-240V~50/60Hz
 1.0A MAX.
 Output1 12.6V == 2.5A
 Output2 13.2V == 2.5A
 Output3 8.7 V == 2.5A



iRay Technology Taicang Ltd.
 No.33 Xingang Road, Taicang Port Economic and
 Technological Development Zone, Jiangsu, China
www.iraygroup.com

EC REP

iRay Europe GmbH
 In den Dorfwiesen 14, 71720 Oberstenfeld Germany

SN










20XX-XX




20XX-XX-XX

 0197

 IP20

Battery Label

可充式锂离子电池组

产品型号: BATTERY-KX
 额定电压: 11.55V
 充电限制电压: 13.2V
 额定容量: 4700mAh/54.28Wh
 典型容量: 4900mAh/56.59Wh
 执行标准: GB31241-2014
 识别码: 31CP6/65/80

 **iRay Technology**

 宾瑞影像科技(太仓)有限公司
 中国江苏省
 太仓港经济技术开发区兴港路30号 2019-01

警告!

- 禁止拆解、撞击、挤压或投入火中;
- 禁止电池过放使用,以防性能失效;
- 若出现严重膨胀,请勿继续使用;
请勿置于高温环境中;
- 电池浸水后禁止使用!
- 请使用iRay指定充电器为电池充电,
请勿使用其它型号充电器;
- 请在初次使用时请为电池完全充电;
- 当电池电量小于5%时,请及时给电池充电;
- 请用同型号电池替代,使用不同型号电池
有燃烧或者爆炸危险;
- 请将电池放置在儿童无法触及的地方;
- 请根据当地法律处理废旧电池。

Rechargeable Li-ion Battery Pack

Model: BATTERY-KX
 Rated Voltage: 11.55V
 Limited Charging Voltage: 13.2V
 Rated Capacity: 4700mAh/54.28Wh
 Standard: GB31241-2014
 Identification code: 31CP6/65/80

 iRay Technology Taicang Ltd.
 No.33 Xinggang Road,Taicang Port Economic and
 Technological Development Zone,Jiangsu,China 2019-01
 www.iraygroup.com

 iRay Europe GmbH
 In den Dorfriesen 14, 71720 Oberstenfeld Germany

CAUTION:

- Prohibited to disassemble, hit, squeeze or throw into the fire.
- Please charge the battery regularly to avoid over discharged failure.
- If severe ballooning, please do not continue to use,
Please do not put battery in high temperature environment.
- Please use the charger designated by iRay to charge the battery.
Please do not use chargers of any other specifications.
- Please charge the battery full before first use.
- Please charge the battery immediately when the capacity is less
than 5%.
- Replace battery with the same model only. Use other model batteries
may present a risk of fire or explosion.
- Keep away from children.
- Dispose of all used batteries according to local law.

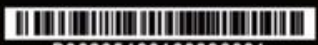
Avertissement!

- Ne pas démonter, frapper, compresser la batterie ou mettre au feu;
- La sur-décharge va dégrader les performances de la batterie;
- En cas de gonflement, ne plus utiliser la batterie, ne pas laisser la batterie
dans un environnement très chaud;
- Utiliser le charger spécifié par iRay pour charger la batterie.
N'utilisez pas d'autres modèles de chargeurs;
- Charger la batterie pleinement lors de la première utilisation;
- Charger la batterie immédiatement lorsque la batterie est moins de 5%;
- Remplacer la batterie avec le même modèle, sinon la batterie peut
exploser ou brûler;
- Mettre la batterie hors de la portée de l'enfant;
- Débarrassez-vous des piles usagées conformément aux lois locales.




Li-ion

SN



B08205190199990001

7.TROUBLE SHOOTING.....	77
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7.Trouble Shooting

Please refer to service manual. If the problem persists, turn off the panel and contact iRay service department (service@iraygroup.com). We would provide the best service.

8.1 *Service Office Information* 79

 a) *Product Lifetime*..... 79

 b) *Regular Inspection and Maintenance*..... 79

 c) *Repair* 79

 d) *Replacement Parts Support* 80

8.1 Service Office Information

Service Office

Tel: +86 21 50720560

Fax: +86 21 50720561

E-mail: service@iraygroup.com

**Location: RM202, Building 7, No. 590, Ruiqing RD. ,
Zhangjiang East, Pudong 201201, Shanghai, P.R. China**

a) Product Lifetime

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

b) Regular Inspection and Maintenance

In order to ensure the safety of patients and operator, to maintain the performance and reliability of the panel, be sure to perform regular inspection at least once a year. If necessary, clean up the panel, make adjustments or replace consumables such as fuses 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.

c) Repair

If problem cannot be solved, contact your sales representative or local iRay dealer for repairs. Please refer to the label and provide the following information:

Product Name:

Series Number:

Description of Problem: as clearly as possible.

d) Replacement Parts Support

Main parts (parts required to maintain the function of the product) of this product will be stocked for 7 years after discontinuance of production for repairing.

<i>APPENDIX A INFORMATION OF MANUFACTURES</i>	<i>82</i>
<i>APPENDIX B INFORMATION OF EUROPE REPRESENTATIVE.....</i>	<i>83</i>

Appendix A Information of Manufactures



COMPANY: iRay Technology Co. Ltd.

ADDRESS: Rm202, Building 7 No.590, Ruiqing RD.Zhangjiang
East, Pudong 201201 Shanghai, P.R China

ZIP CODE: 201201

TELEPHONE: +86 21-50720560

HOMEPAGE: *WWW.IRAYGROUP.COM*

COMPANY: iRay Technology Co. Ltd.

Appendix B Information of Europe Representative



COMPANY: iRay Europe GmbH
ADDRESS: IN DEN DORFWIESEN 14, 71720 OBERSTENFELD
GERMANY
ZIP CODE: /
TELEPHONE: +49-7062-977 88 00
FAX: +49-7062-976 0571
HOMEPAGE: WWW.IRAYEUROPE.COM