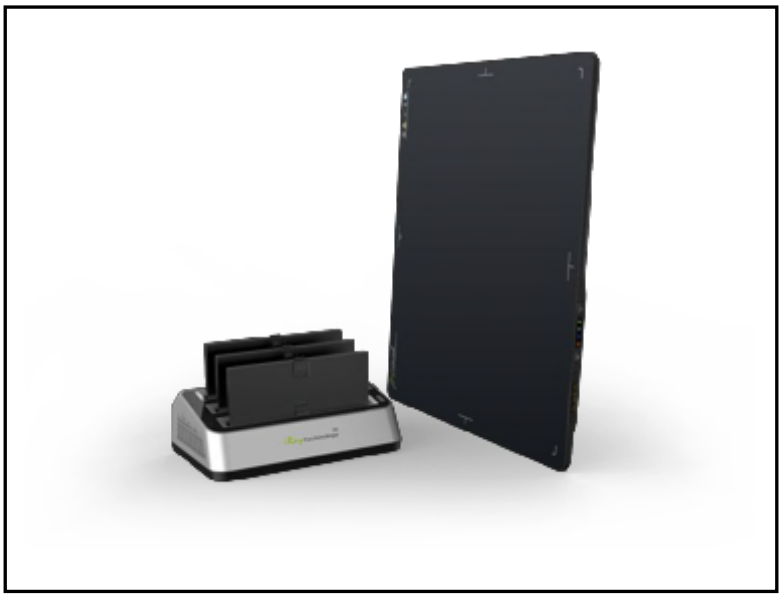
Digital Flat Panel Detector

Mars1417XF

User Manual



Before operating, please read this user manual and pay attention to all safety precautions. Please ensure that user manual is properly maintained so that it can be accessed at any time. Please use correctly on the basis of full understanding of content.

To Customers

Congratulations on your purchase of Mars1417XF wireless digital flat panel (hereinafter referred to as Mars1417XF) which is manufactured by iRay Technology Co. Ltd. (Hereinafter referred to as iRay).

At iRay, we strive to not only make the world-class product that delivers the best value to our customers but also offer the highest quality of service and customer care. Please take time to read user guide in order to utilize product effectively. We hope you enjoy experience with Mars1417XF.

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

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

About FCC

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;

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

Attention that changes or modification not expressly approved by the party responsible for compliance could 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 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.

About SAR

After the laboratory measurement, the max SAR value is 0.058mW/g for 2.4G WLAN and max SAR value is 0.277mW/g for 5G WLAN which satisfies the RF exposure requirement.

Notes on usage and management of equipment

1. Read all instruction in user guide before operation. Pay 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 safe and operable condition by maintenance person.
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 dedicated cables. Do not use cables other than those supplied with product.
6. Do not open cover of product without authority.
7. Request your sales representative or local iRay dealer to install this product.

Caring for your environment

This symbol indicates that product cannot 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 would produce a negative impact on health and environment. Some countries or regions, such as European Union, has 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 any damage, loss, or injury incurred to purchaser and the third parties as a result of fire, earthquake, any accident, misuse or abuse of product.
- iRay shall not be liable to any damage, loss, or injury arising from unauthorized modifications, repairs, or alterations or failure to strictly comply with iRay's operation and maintenance instruction.

- iRay shall not be liable to any damage or loss arising from use of any option or consumer goods other than those dedicated as Original iRay product.
- It is the responsibilities of users and physicians for maintaining the privacy of image data and providing medical care service. iRay shall not be responsible for legality of image processing, reading and storage nor shall it be responsible for loss of image data for any reason.
- Information regarding specification, components, and appearance of product is subject to change without prior notice.。

Copyright

Trademarks

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

Symbols and Conventions

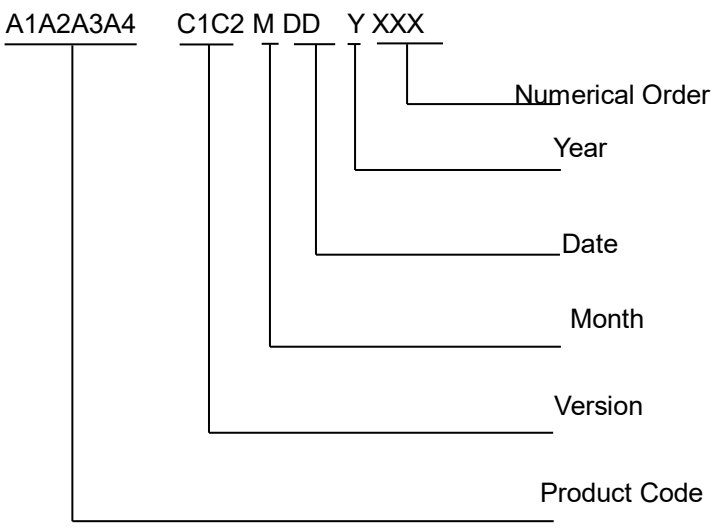
The following symbols and conventions are used throughout user guide.

	This symbol is used to identify condition under which improper use of product may cause death or serious human injury.
	This notice is used to identify condition under which improper use of product may cause minor human injury.
	This notice is used to identify condition under which improper use of product may cause property damage.
	This is used to indicate a prohibited operation.
	This is used to indicate an action that must be performed.

Important	This is used to indicate important operation and restriction.
Information	This is used to indicate operation for reference and complementary information.

Labels and markings on the equipment

The labels and markings on Mars1417XF product are indicated below:

Marking	Description
	Caution: please refer to instruction in user manual.
CE	This symbol is used to indicate that equipment has passed CE testing and it is followed by CE number.
SN	This symbol is used to identify manufacture series number which is after, below or adjacent to symbol. The series number of iRay product is usually made of thirteen digits as shown below: 
	This symbol is used to indicate name and address of manufacturer.
EC REP	This symbol is used to indicate name and address of iRay authorized representative in European region.
	This symbol is used to indicate consultation of user guide for general information.

	Safety Signs: please refer to user guide for safety instructions.
	Safety Signs：Dangerous Voltage.
	Stand-by.
	Handle with care.
	FPD is allowed to withstand 100kg on surface
	This symbol is used to indicate operation temperature range.
	This symbol is used to indicate storage temperature range.
	Non-ionizing radiation
FCC	Federal Communications Commission certificate
	Package symbol: fragile.
	Package symbol: keep away from sunlight.
	Package symbol: keep dry.

	Package symbol: this symbol is used to indicate humidity range.
	Package symbol: keep equipment up right.
	Package symbol: do not roll package.
	Package symbol: this symbol is used to indicate stacking limit number.
IPX4	Detector symbol: the device passes IPX4 test

Contents

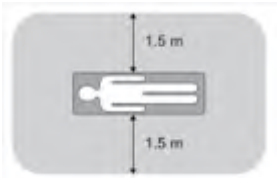
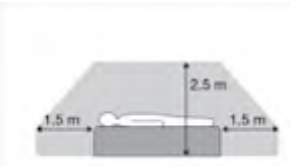
1 Safety Information

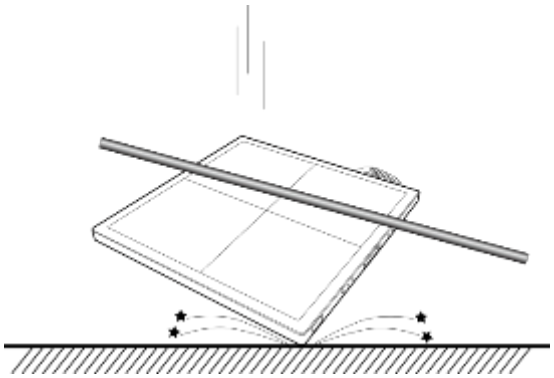
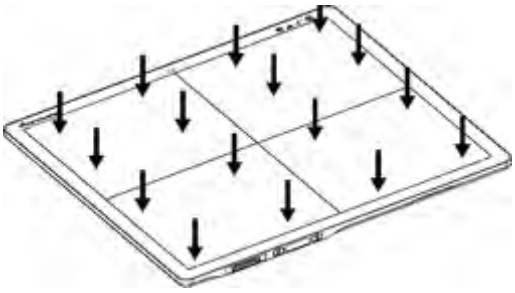
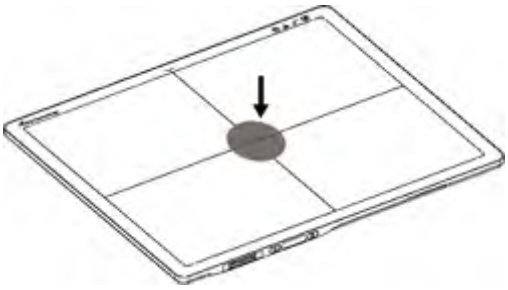
1.1 Safety precautions

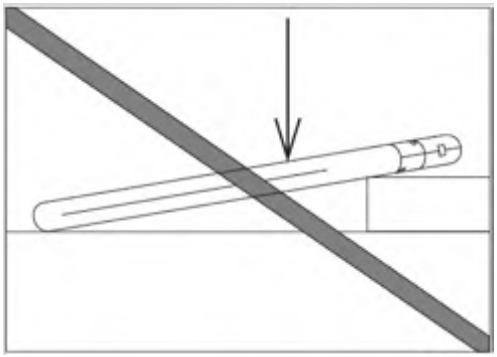
Follow these safe guides and properly use device to prevent injury and damage.

WARNING	
Installation and environment of use  	**Do not use or store device near flammable chemical such as alcohol, thinner, benzene, etc.** If chemical is spilled or evaporated, it may result in fire or electric shock through contact with electric parts inside device. Also, some disinfectant is flammable. Be sure to take care when using them. **Do not connect device with anything other than specified.** Doing so may result in fire or electric shock. **All patients with active implantable medical devices should be kept away from device.**
Power supply  	**Do not operate using any type of power supply other than indicated on rated label.** Otherwise, it may result in fire or electric shock. **Do not handle 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 sheath from being damaged, and do not alter them neither.** Doing so may damage 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 system power when condensation has formed on the devie.** Doing so may result in fire or electric shock. **Do not connect multiple portable socket-outlets or extension cords to system.** Doing so may result in fire or electric shock. **To avoid the risk of electric shock, the device must be connected to power supply with protective earth.** Not doing so may result in fire or electric shock.

	**Securely plug power cord into AC outlet.** If contact failure occurs or metal objects contact with exposed metal prongs of plug, may result fire or electric shock. **Be sure to turn off power to each piece of device before connecting or disconnecting cords.** Otherwise, you may get electric shock that could result in death or serious injury. **Be sure to hold plug or connector to disconnect cord.** If you pull cords, the core wire may be damaged, resulting in fire or electric shock.
WARNING	
Handling  	**Never disassemble or modify device. No modification is allowed.** Doing so may result in fire or electric shock. Also, since device contains components that may cause electric shock and other hazardous parts, touching them may cause death or serious injury. **Do not place anything on top of device.** The object may fall and cause an injury. Also, if metal objects such as needles or clips fall inside, it may result in fire or electric shock. **Do not hit or drop device.** The device may be damaged if receiving a strong jolt, which may result in fire or electric shock if the device is used without repairing. **Do not put device and pointed objects together.** It may be damaged. Device is recommended to be used in Bucky.
	**Have the patient take a fixed posture and do not let patient touch unnecessary parts.** If patients touch connectors or switches, it may result in electric shock or malfunction.
When problem occurs 	**Should any of the following occurs, immediately unplug the power cord, and contact sales representative or local iRay dealer:** When there is smoke, odd smell or abnormal sound. When liquid has been spilled inside or metal object has entered through an opening. When the device has been dropped and damaged.
Maintenance and inspection  	**Please turn off the power of device and unplug 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 device.** **Don't dip the device into liquid.** **Please make sure that the device's surface & plug is dry before turning on.** Otherwise, it may result in fire or electric shock.
	**Clean the plug of power cord periodically by unplugging it from AC outlet and removing dust or dirt from plug, its periphery and AC outlet with dry cloth.**

	If 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 fire. **For safety reasons, be sure to turn off power to each piece of device when performing inspections indicated in this manual.** Otherwise, electric shock may occur.
CAUTION	
Installation and environment of use	**Do not install device in any of locations listed below. Doing so may result in failure, malfunction, falling, fire or injury.** Close to facilities where water is used Where it will be exposed to sunlight directly Close to air outlet of air-conditioner or ventilation equipment Close to heat source such as heater Where power supply is unstable In dusty environment In saline or sulfurous environment Where temperature or humidity is high Where there is freezing or condensation In areas prone to vibration On incline or 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 malfunction of device or injury of user due to tripping over cable. **Non-medical equipment such as battery charger and access point cannot be used in patient's vicinity.**  
Power supply	**Always connect three-core power cord plug to grounded AC power outlet.** **To make it easy to disconnect plug at any time, avoid putting any obstacles near outlet. Otherwise, it may be impossible to disconnect plug in emergency.** **Be sure to ground device to indoor grounded connector. Also, be sure to connect all ground of system together.** **Do not use any power source other than provided.** Otherwise, fire or electric shock may be caused due to leakage.
Handling	**Do not spill liquid or chemicals onto device. In case the patient is injured, iti is not allowed to contact with blood or other body fluids.** Doing so may result in fire or electric shock. In such situation, protect device with a disposable cover as necessary. **Turn off power and pull out plug to each piece of for safety when not used.**
CAUTION	

Handling	**Handle carefully.** **Do not submerge device in water.** **The internal image sensor may be damaged if something hits against it or dropped. If itis dropped, shock label inside would turn red and device would not be warranted by iRay.**  **Do not place excessive weight on device.** Otherwise, internal image sensor may be damaged and image may be incorrect  Uniform load：150 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 flat surface so it will not bend. Otherwise, the internal image sensor may be damaged. Be sure to securely hold detector while using it in upright positions. Otherwise, the detector may fall over, resulting in injury to user or patient, or may flip over, resulting in damage to device.

	 Keep the same load (the same pressure) on detector when acquiring image. Or image will be incorrect.
CAUTION	
CAUTION	Do not close to fire, do not use in high temperature Do not invert positive and negative pole Do not contact with metal in case of short circuit Do not insert sharp objects into battery Do not beat battery Do not stand on battery Do not use battery out of rules Do not dispose battery or change internal structure Do not submerge battery in water, please keep dry in storage and do not contact with water in use Please charge battery with charger provided by iRay Do not mix battery with ones not provided by iRay Do not charge battery with broken charger. Charge battery regularly to avoid over discharge failure. Do not use battery when it is severe ballooning.

1.2 Notes for Using

When using device, take the following precautions. Otherwise, problems may occur and there would be malfunction.

Before exposure

- Be sure to check device daily and confirm that it works properly.
- Be sure there is battery installed on Mars1417XF to avoid power off suddenly
- Sudden heating of room in cold areas will cause condensation to form on device. In this case, wait until condensation evaporates before performing an exposure. If it is used while condensation is formed, problems may occur in the quality of captured images. When air-conditioner is used, be sure to raise/lower the temperature slowly so that difference of temperature in room and device does not occur, to prevent condensation.
- The detector should be warmed more than 20 minutes before exposure or updating gain or defect template.

During exposure

- Do not move power cable during exposure, or it may cause image noise or artifacts, even incorrect images.
- Do not use equipment near detector generating strong magnetic field. Otherwise, it may cause image noise, artifacts or even incorrect images.
- Do not exposure in 60s after 4 times of full range exposure. Otherwise, image would be incorrect. Neither do exposure in 30s after a full range exposure. The larger dose using, the longer time should be waited before next exposure.
- During image acquisition, Mars1417XF should not be influenced by physical or electrical way.
- If detector receives dose which is close to full range, clipping data lines appear in full range area.

After exposure

If detector would not be used in 5 days, it is required to take out battery. If battery would not be used at long time, it must be charged to 30%~50% every 3 month or 50%~70% every 6 month.

Disinfection and Cleaning

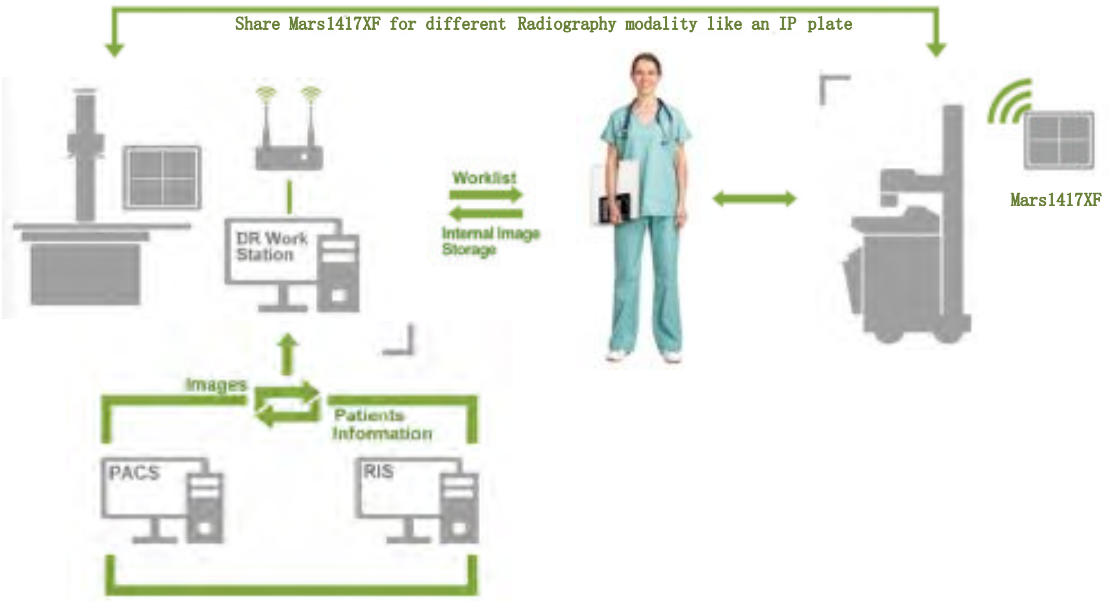
- After every examination, wipe patient contact surfaces with disinfectants such as ethanol, to prevent the risk of infection. For details on how to sterilize, consult a specialist.
- Do not spray detector directly with disinfectants or detergents.
- Wipe it with cloth slightly damped with neutral detergent.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

2 General Description

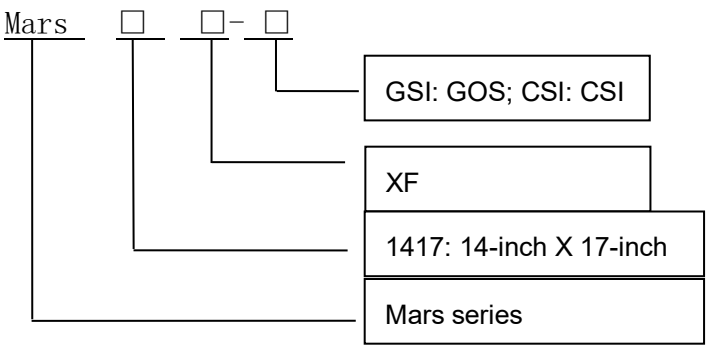
Mars1417XF is a cassette-size wireless X-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It is developed to provide the highest quality of radiographic image, which contains an active matrix of 2336×2836 with 150um pixel pitch. Detectors' scintillator has two options which are GOS (Gadolinium Sulfoxylate) and CsI (CaesiumIodide). However, the greatest improvement is wireless communication between detectors and PC. Meanwhile it can be powered with battery for portable panel use.

2.1 Scope

This manual contains information about Mars1417XF. All operators must read and understand this manual before using. All information in this manual, including illustrations, is based on equipment prototype. If your configuration does not have any of these items, information about these items in the manual does not apply to your detector.



2.2 Model



2.3 Characteristic

- Wireless static Flat Panel Detector used for general radiography.
- 14 × 17 inch
- AED trigger
- Easy to change cable and charge in tray.
- Battery recycling
- IPX4

2.4 Intended use

Mars1417XF Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography or dental applications.

The detector could be used for general X ray diagnosis of usual body part. It is not intended for mammography, dental applications, neonatal and fluoroscopy. More care should be taken when diagnosis with allergic constitution. Not only this but also prohibited for pregnant women and children. Shield of none inspection body part is necessary during x ray exposure. There is no contraindication.

According to Mars1417XF intended use and result of risk management, essential performance is identified and described as following:

- To acquire dark image, Mars1417XF shall be not influenced to imaging acquisition.
- To maintain data transmission, Mars1417XF shall be not influenced to data and signal transmission.

2.5 Product Components

Mars1417XF is configured with components bellowing

Item	Description

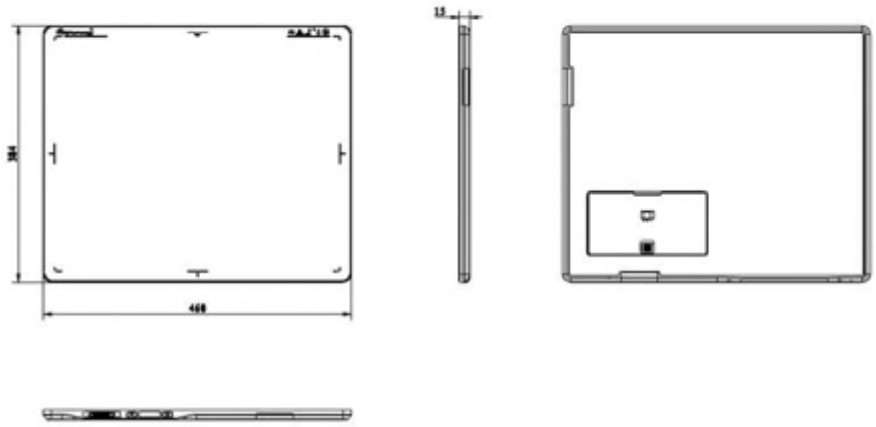
Mars1417XF Detector		Mars1417XF GSI/CSI
Medical adapter for detector and battery Charger		24V (DC) power adapter
Battery Pack		7.6V battery pack
Gigabit Ethernet cable		Ethernet cable for wireless router
AC Power Cable		AC Cable for adapter

Battery Charger		Battery charger

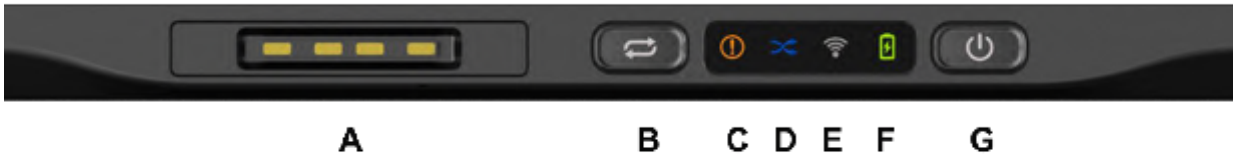
Note: Mars1417XF package may be different based on requirement.

2.6 Components Description

2.6.1 Detector



External Signals Input and Control Panel



Control Panel

NO.	Item	Description
A	DC Input Interface	24V DC input
B	Reserved	Reserved
C	Status Indicator	Detector Status indicator

D	Reserved	Reserved
E	Link Indicator	Detector Link indicator
F	Power Indicator	Detector Power indicator
G	Power Button	Power button

2.6.2Battery Pack

NO.	Item	Description
A	Battery Label	/
B	Battery Interface	7 Pin Battery connector
C	Guide block	/
D	Latch	Attach the battery lock to the detector

E	Touch Display	Show battery level after touching

2.6.3Battery Charger

Item	Item	Description
A	Battery Slot	3 Batteries inserted
B	Capacity Indicator	The indicator definition is as follow
C	DC Jack	24V DC input

The battery charging capacity indicator definition:

Indicator	Lighting Status	Operating Status

OFF		No battery Insert
Green blinking		Battery Insert with capacity ≤95%，charging
Green ON		Battery Insert with capacity >95%
Orange blinking		Battery slot malfunction

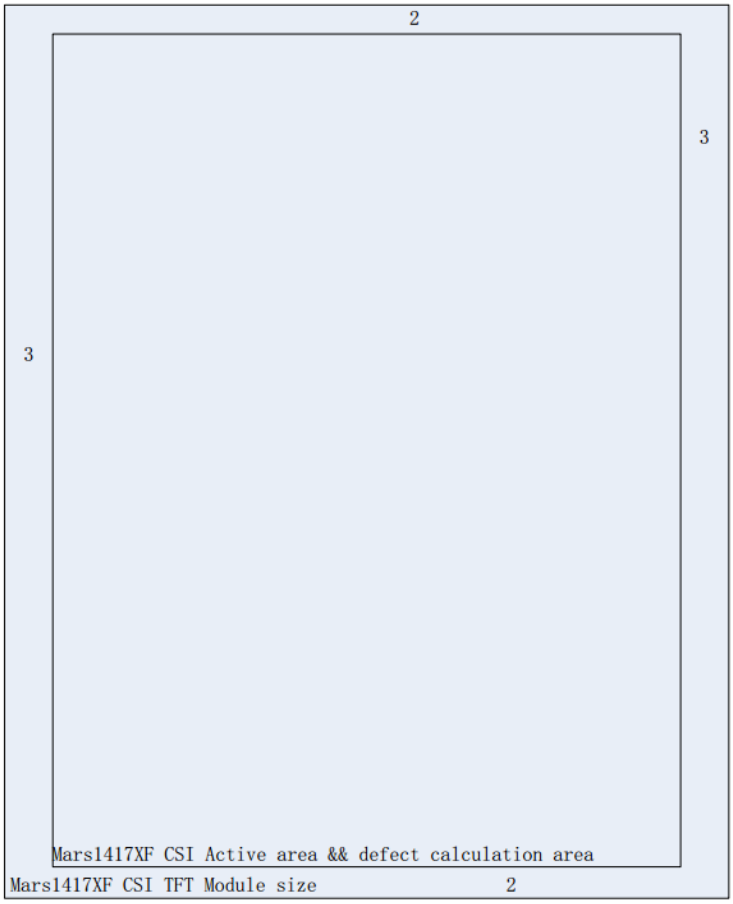
2.7 Product Specification

2.7.1Detector

Item	Specification
Model	Mars1417XF-GSI (GOS) Mars1417XF-CSI (CsI)
Pixel Size	150 μm
Effective Array	2336 x 2836(Note)
Effective Area (H x V)	350.4mmx 425.4 mm
Greyscales	16 bit
Image Transfer	Wireless : IEEE802.11a/b/g/n
Wireless frequency range	2.412~2.462GHz, 5.18~5.24GHz;5.745~5.825GHz
Data Transmission Power	13dBm(Typ.) @802.11a 14dBm(Typ.) @802.11b

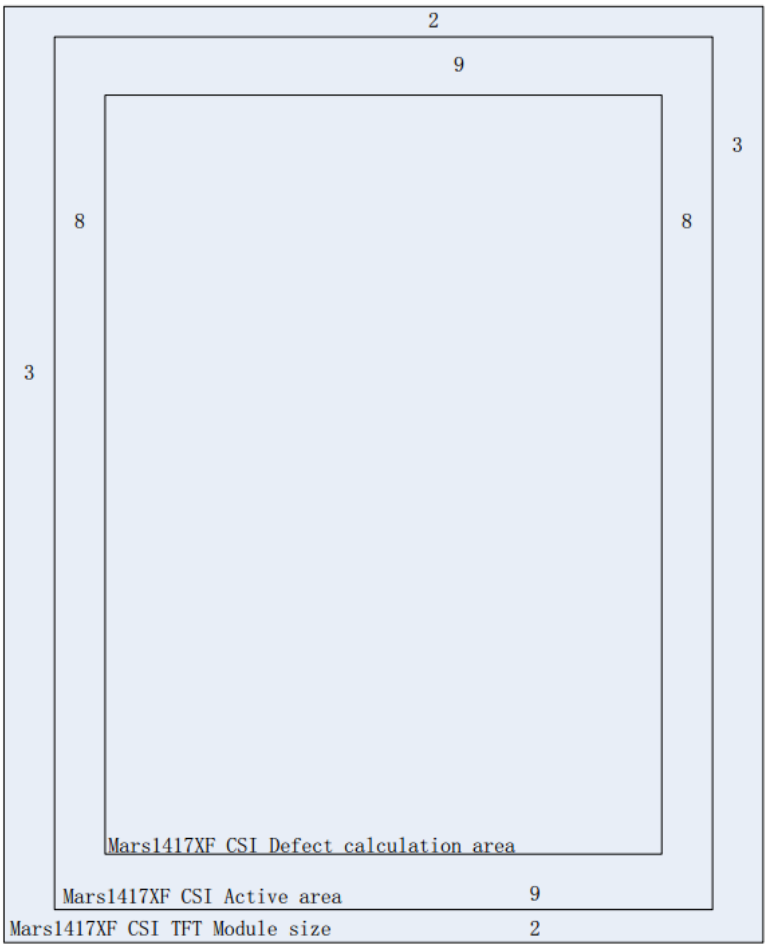
	13dBm(Typ.) @802.11g 13dBm(Typ.) @802.11n HT20 12dBm(Typ.) @802.11n HT40 11.5dBm(Typ.) @ 802.11n AC20 11.5dBm(Typ.) @802.11n AC40
Wireless Modulation	11b: DSSS (DBPSK, DQPSK and CCK) 11a/g/n: OFDM(BPSK,QPSK,16QAM,64QAM)
Wireless Band	2.4GHz≤40MHz 5.19GHz≤40MHz 5.8GHz≤40MHz

Note: Mars1417XF-GSI active area and defect calculation area 2336*2836, TFT module size is 2342*2840. Please see figure below

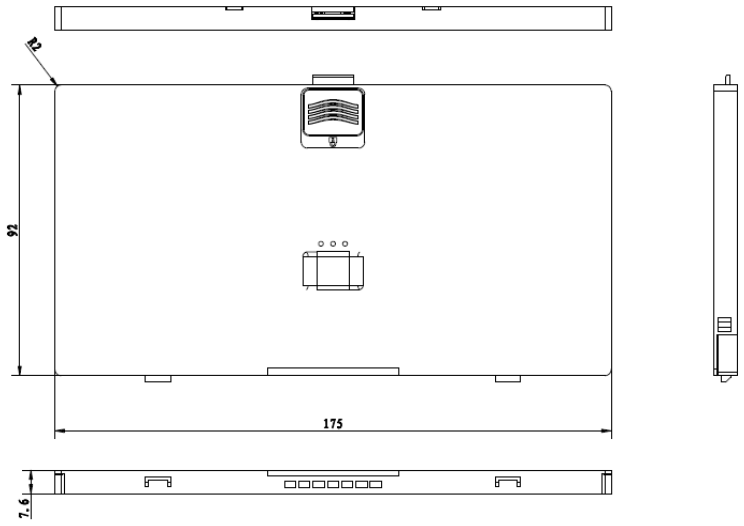


Mars1417XF-CSI defect calculation area is 2320*2818, active area is 2336*2836, TFT module size

is 2342*2840



2.7.2Battery



Item	Specifications
Model	Battery-KX
Rated Capacity	Min. 3500mAh, Typ.3800mAh @ Discharge 0.5C
Rated Voltage	7.6V

2.7.3Battery Charger

Item	Specifications
Model	Charger-KX
Simultaneous Charging	3 battery packs
Full charging time	2.5 hours

2.7.4SDK Recommended Condition

Item	Description
Operating System	Windows 7 32/64bit
CPU	Intel Core i5 3.6GHz
Memory	8G DDR3
Hard Disk	640 G
LAN Card	Intel Pro EXP9301CT PRO

2.7.5Environment

	Temperature	Temperature Variation	Humidity	Atmospheric Pressure	Atmospheric Pressure Variation
Operating	5~30℃	<1k/min	10%~80% RH	700~1060hPa	<10kp/min (1kp=1.0197E-5Pa)
Storage (without battery)	-20~50℃	<1k/min	10%~90% RH	700~1060hPa	<10kp/min (1kp=1.0197E-5Pa)

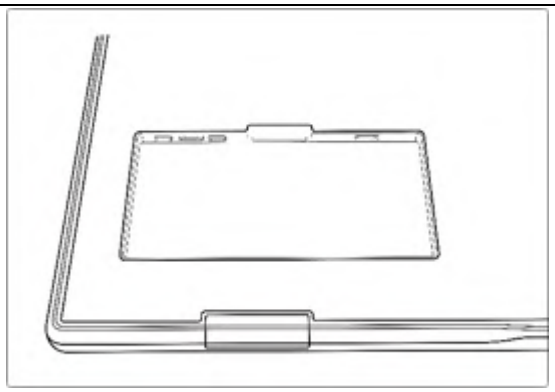
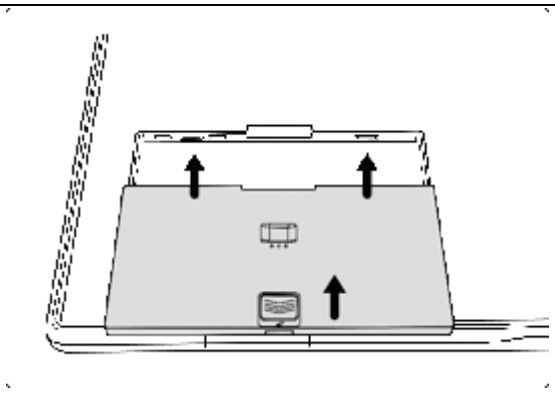
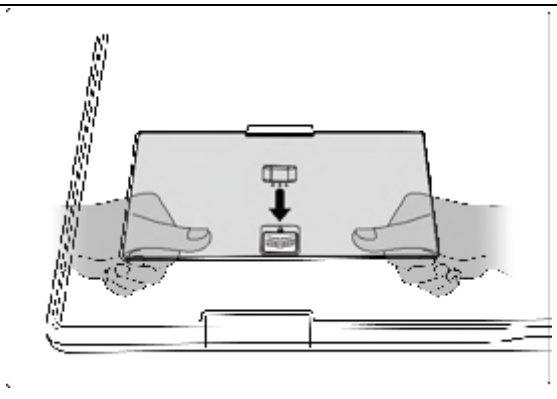
- Mars1417XF detectors should operate at altitude specified not more than 3000m, the requirement is only for detector.
- If storage with battery, temperature should be in the range of -20℃~45℃ when expected time is less than 3 months. Meanwhile, -20℃~25℃ for 12 months.

3 Installation

3.1 Detector Install

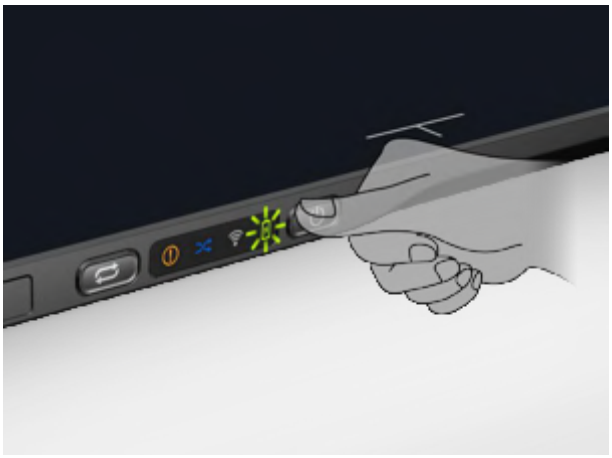
3.1.1Attach Battery Pack

Mars1417XF could be powered by both battery pack and DC power. Once battery pack is inserted or DC power is connected, Detectors would be turned on immediately. If neither battery nor DC power is connected, Mars1417XF would power off. Please see below for battery installation.

Make sure that connectors on battery pack are pointed to the cave in battery compartment.	
Slide battery package into battery compartment (Make sure battery capacity overpass 15%).	
Slide the battery lock lever.	

3.1.2Booting Up

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

When detector is powered down, users press button and hold on 4 seconds to turn on detector if battery is inserted and capacity is not less than 15%, or DC power is connected. When detector is powered on, users press button and hold on 4 seconds to shut down detector. On the other hand, it can also be used as reset internal control IC when button is activated for 8 seconds.	

After booting up, users can check indicator of detector.

Power indicator

Power Indicator	Lighting Status	Status		
		Battery Capacity	DC Input	Description
OFF		NO	NO	Detector is turned off
Orange ON		≥7% & ≤15%	NO	Detector is turned on
Green ON		>15%	NO	Detector is turned on
		NO	YES	
Orange Blinking		≥7% & ＜15%	YES	Detector is turned on
Green Blinking		≥15% & ＜95%	YES	Detector is turned on or detector is in sleep

Link indicator:

Link Indicator	Lighting Status	Description
OFF		• Detector is turned off • Wired connection broken and wireless connection not ready

Blue ON		• wireless connection is built
Green ON		Wired Connection is built(Service Mode)
Blue blinking		• Detector Initialization • Wireless configuration reset
Green blinking		Wireless configuration reset

Mode indicator:

Mode Indicator	Lighting Status	Description
Blue ON		Default
OFF		Detector is turned off

Status indicator:

Status Indicator	Lighting Status	Description
OFF		• Detector is turned off • Exposure prohibit
Green ON		Ready for exposure
Orange blinking		Safety Mode
Orange ON		Fatal Error
Green blinking		Wireless configuration reset

3.1.3Adapter

Mars1417XF supports external adapter powered, port defined as bellowing:

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 safety and function requirements of detector, the standard component is recommended：

	LXCP120-0240625(C005)

3.2 Software Installation

In case of iDetector malfunction, please install Microsoft .NET Framework 4.5 firstly，then install vcredist_x86_2013 or vcredist_x64_vs2013.

3.3 Detector Installation

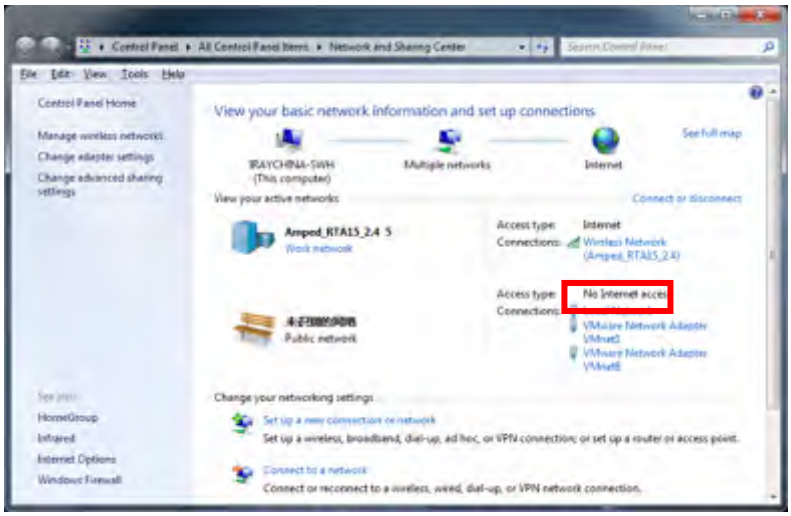
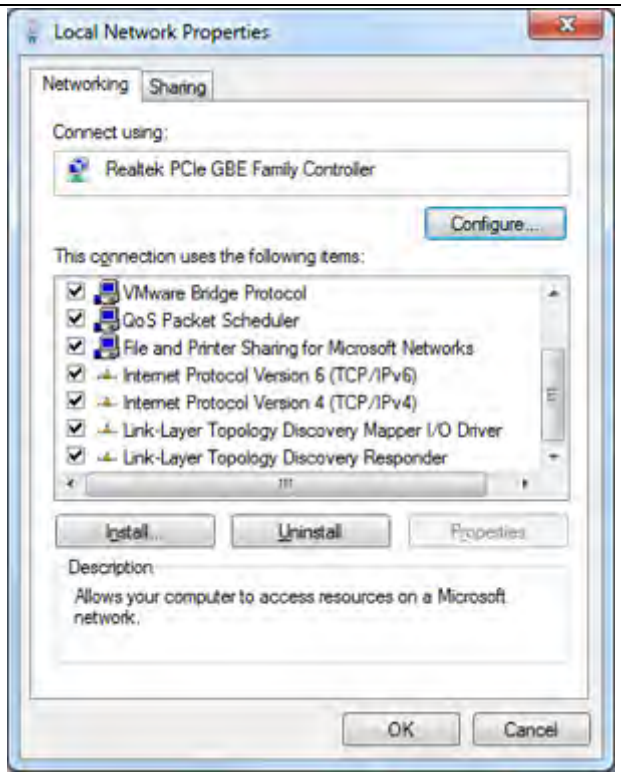
To complete Wireless configuration, users must follow steps bellowing.

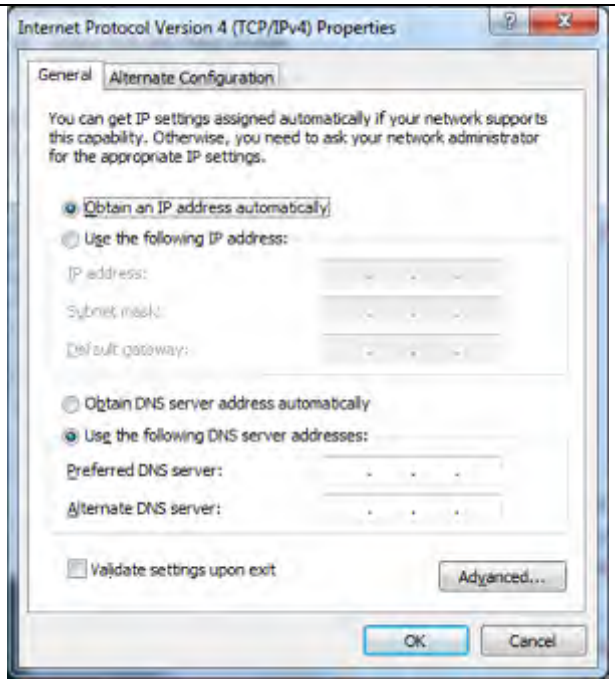
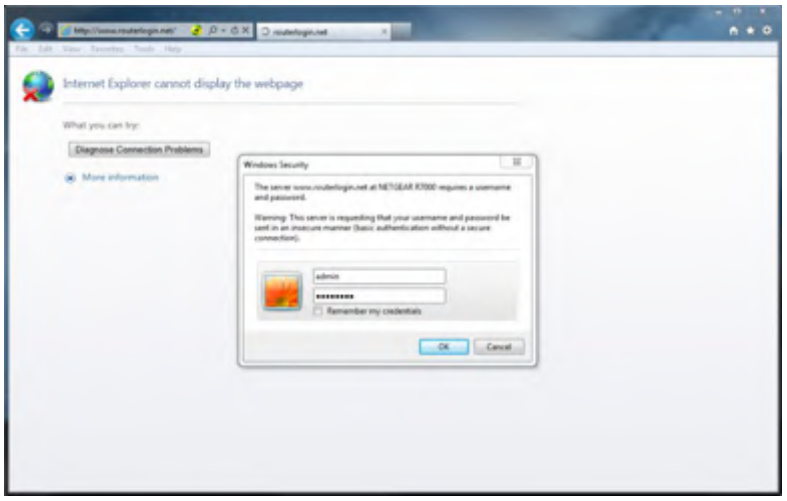
Detector default mode: Client mode

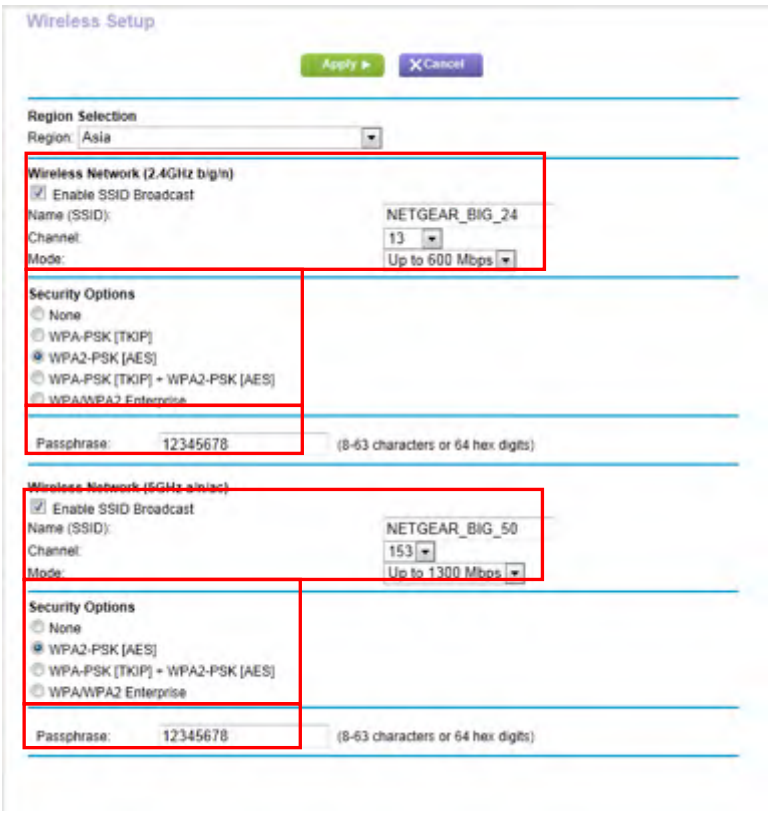
Detector default SSID: XF-SN-5G (Serial NO. of detector)

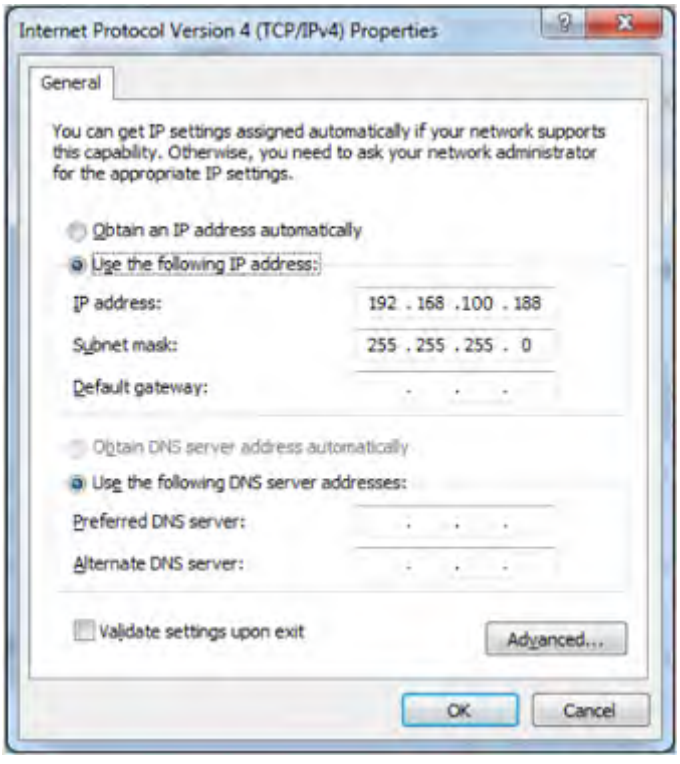
Detector default Password：12345678

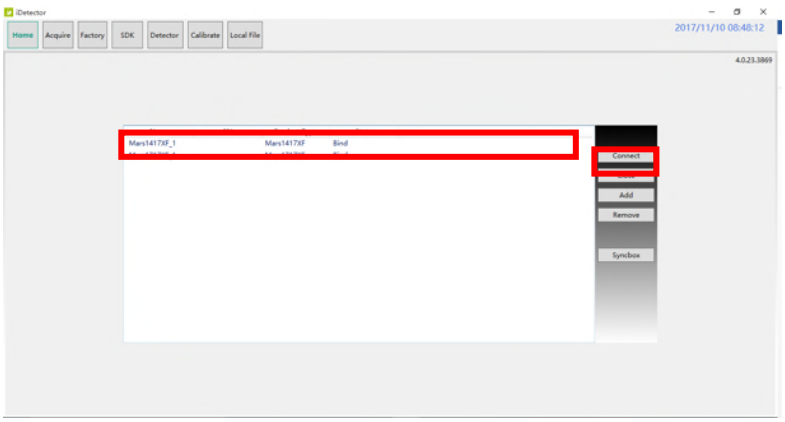
3.3.1 Configuration of External wireless AP

Connect one end of Gigabit Ethernet Cable to PC, Connect the other end to LAN port of External wireless AP	/
Open local network management interface	
Open local network configuration	

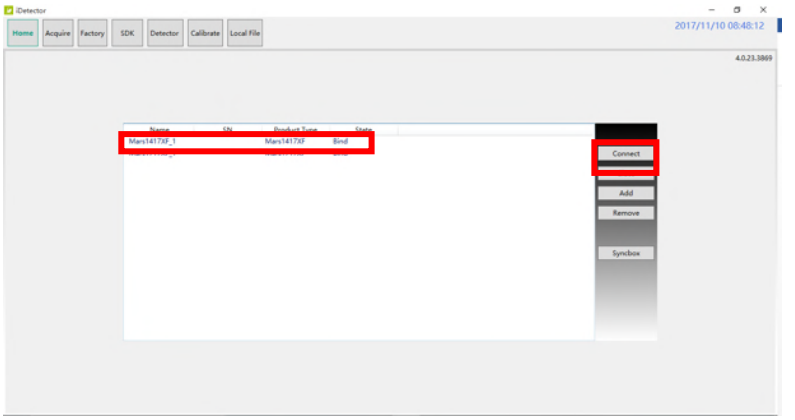
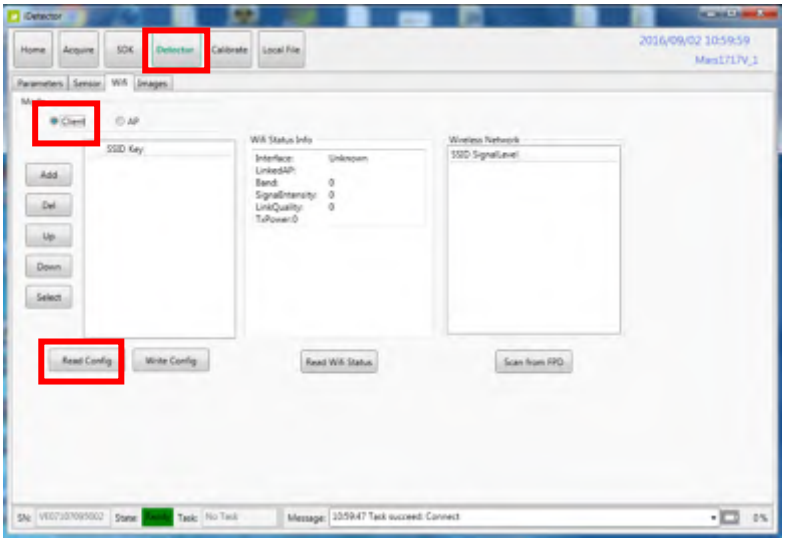
Open IPV4 setting	
IP setting Network mask setting	Select “Obtain an IP address automatically”
Open browser and type in 192.168.1.1 Log into external wireless AP	

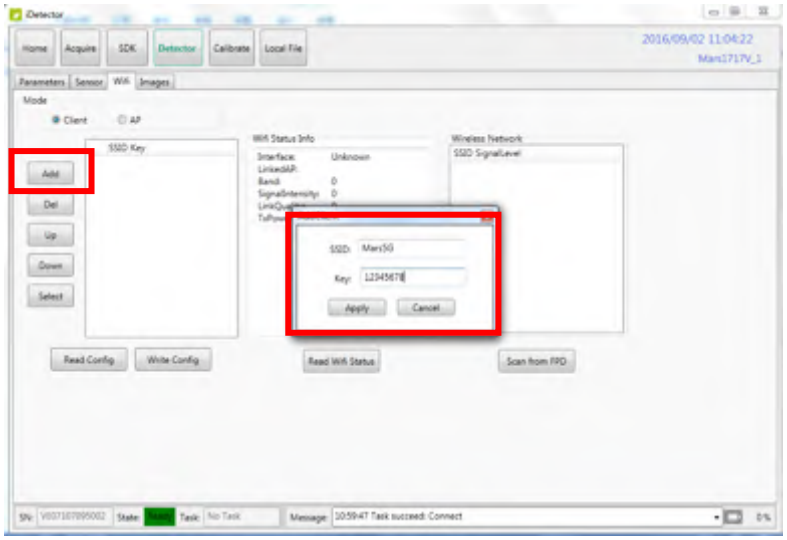
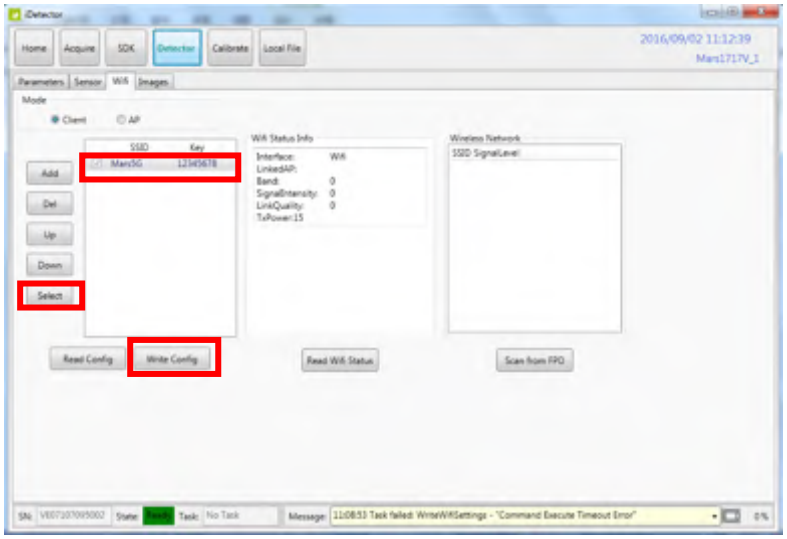
Wireless setup	
Configure 2.4GHz wireless network	SSID: XF-SN-2G (No conflict in the air) Security: WPA2-PSK Password: 12345678 Channel: (Check Wi-Fi in the air, and choose a relatively clean channel)
Configure 5GHz wireless network	SSID: XF-SN-5G (No conflict in the air) Security: WPA2-PSK Password: 12345678 Channel: (Check Wi-Fi in the air, and choose a relatively clean channel)

LAN setup	
Configure LAN IP address	IP address: 192.168.100.1 Subnet Mask: 255.255.255.0
Reboot router	Reboot router after setting
Recover Local Network IPv4 setting of PC wired Ethernet card	
IP setting Network mask setting	IP address: 192.168.100.188 Subnet mask: 255.255.255.0

Open iDetector Click “Connect” based on product name “Mars1417XF_Client”	

3.3.2 Wireless configuration of detector (if necessary)

Connect panel in wireless mode	
Click “Detector” Click “Read Config” Click “Client mode”	

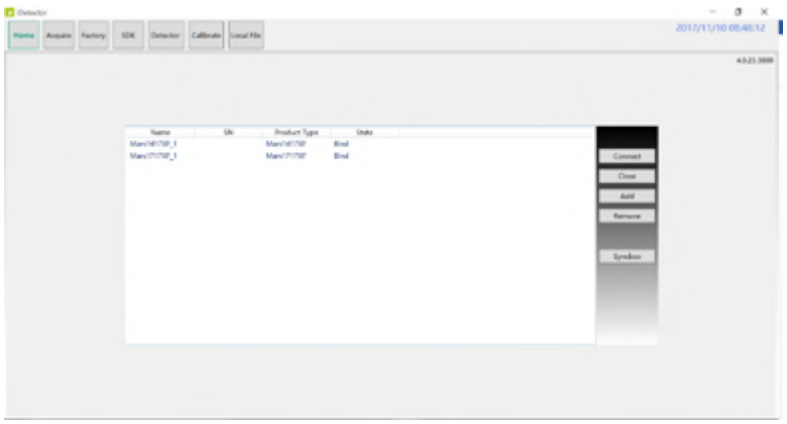
Click “Add” Type in SSID and Password Click “Apply”	
Click new SSID and then click “Select”, new SSID would be activated. Click “Write config” to save parameter.	

Wireless setting would be activated immediately. Default SSID and password is configured, detector would connect to wireless router after powered on next time.

3.3.3 Wireless configuration reset

If users don’t know wireless configuration of detector. There provides a way to reset configuration

Power on detector, wait for 60 seconds.	
Press mode shift button. Hold on until status indicator blinks.	

Press power button. Hold on until it is powered off. Wait for 5 seconds. Press power button. Hold on until it is powered on.	
Scan Wireless SSID in air, there would be “XF-SN” Connect it with password “12345678”	/
Change IP address of wireless card in workstation to “192.168.8.8”	/
Connect detector with iDetector. Select with”Mars1417XF_AP”	
The same as chapter 3.3.2	/

Note: If users don’t want to use default IP address of workstation to build the connection, it is necessary to close iDetector before changing IP address of workstation and iDetector configuration.

4 Operation

Mars1417XF provides users SDK for integration into DR system. Additionally, it also provides application demonstration, i.e. iDetector.

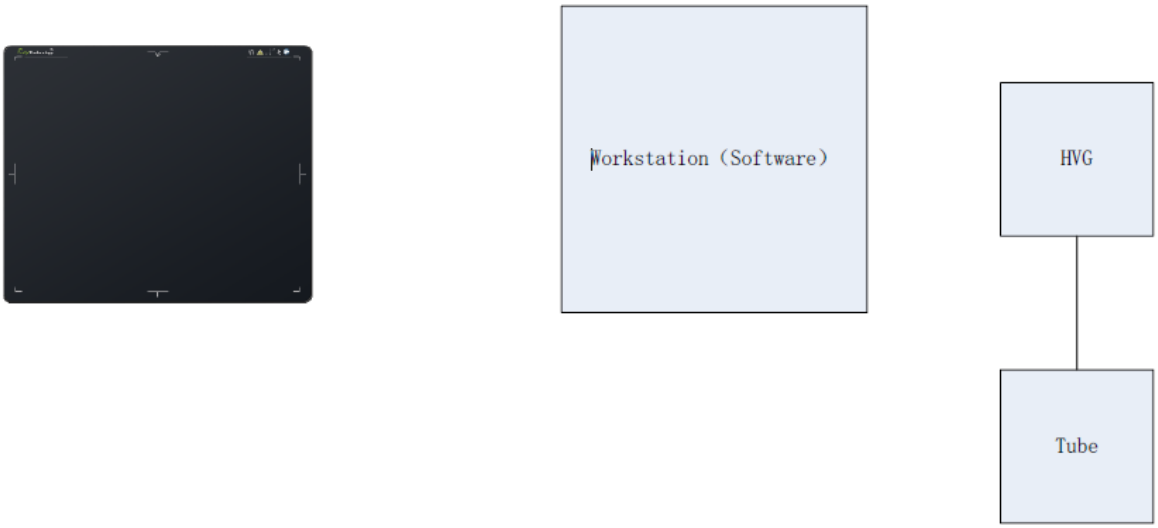
4.1 Main Operation

Mars1417XF mainly acquires x ray image. More importantly, detector should build synchronization with X-ray generator, i.e. Software Mode and AED Mode.

4.1.1 Software Mode

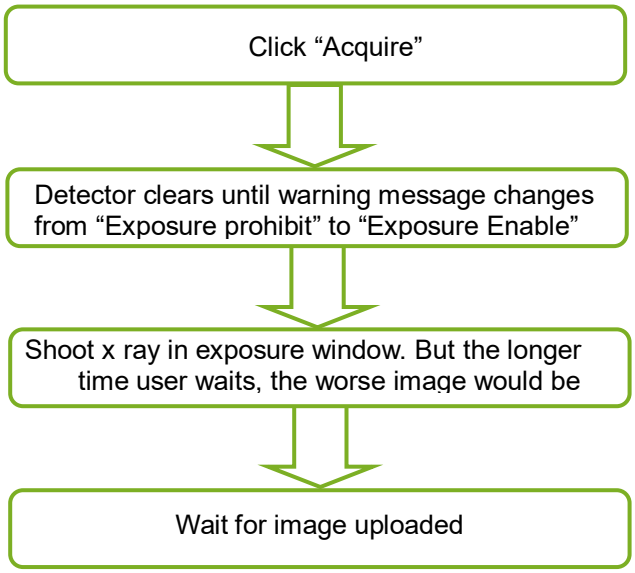
4.1.1.1 Block Diagram

Software mode builds the first x ray image acquisition step. Please see figure below for general feature, Software mode is configured by selecting “prep” in Trigger mode and “prepcapmode_acq2” in Prep capmode.



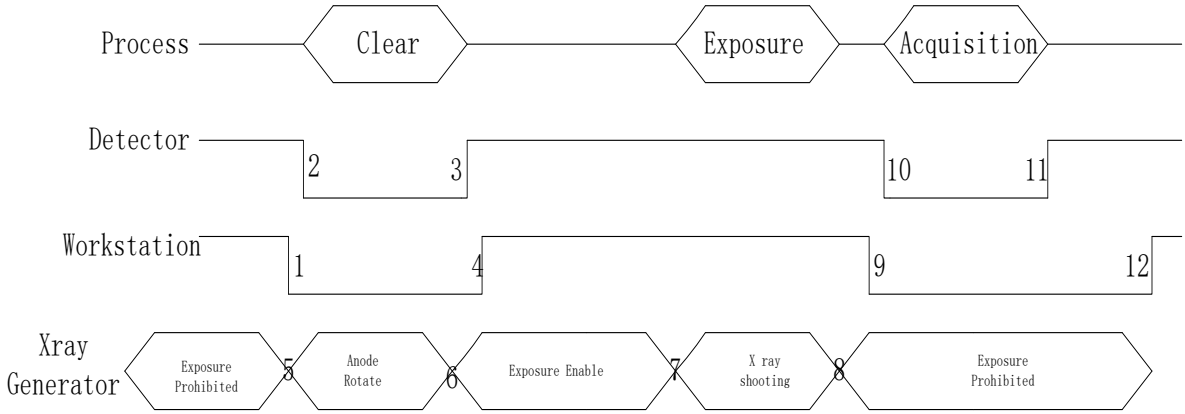
Workstation means host PC device installed with iDetector or SDK. Chapter 3.3 has described how to establish connection between detectors and workstation. In Software mode, workstation does not control X-ray generator, users decide when to shoot X-ray.

4.1.1.2 Work flow



4.1.1.3 Timing Setting

To get a clear view of workflow, see diagram below for details



1. Workstation receives “Acquire” request, send command “Clear” to detector.
2. Detector receives “clear” from workstation and begin flushing panel. Meanwhile, replies to workstation “Exposure Prohibited”.
3. Detector finishes “Clear” and sends message “Exposure Enable”
4. “Exposure Enable” is shown on iDetector’s bar, user shoots X-ray.
5. User triggers X-ray generator to initialize and do anode rotation to prepare for X-ray.
6. X-ray generator finishes preparation and replies to user
7. X-ray generator begins releasing X-ray
8. X-ray generator finishes X-ray shooting.
9. Workstation prepares receiving image.
10. Detector begins data acquisition after time limits.
11. Detector completes image acquisition and begins image transmission.

12. Workstation receives all image.

Image received would be preview image, preview image is image without much correction which causes them some stripes, it cannot be used for final diagnosis.

Detector would do another dark image acquisition for offset correction. If Hardware Post offset and Hardware calibration is selected, detector uploads processed image to workstation finally after offset, gain and defect calibration.

If Software Post offset and Software calibration is selected, corrected image is shown on screen after workstation finishes offset, gain and defect calibration.

Note: If wireless circumstance is bad, detector couldn't send even one package in 30s. It would stop trying sending image package. Users have to retrieve images from detector when wireless is good enough.

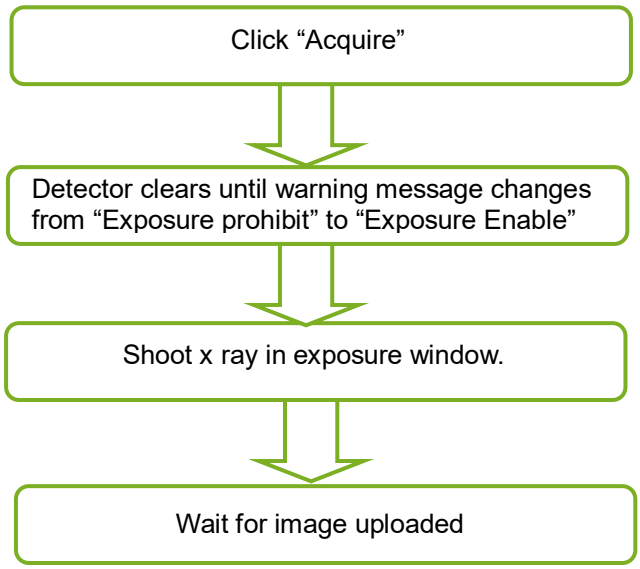
4.1.2 AED Mode

4.1.2.1 Block Diagram

Please see figure below for general feature. AED mode is configured by selecting "inner" in Trigger mode and "cycleacq" in inner trigger subflow.

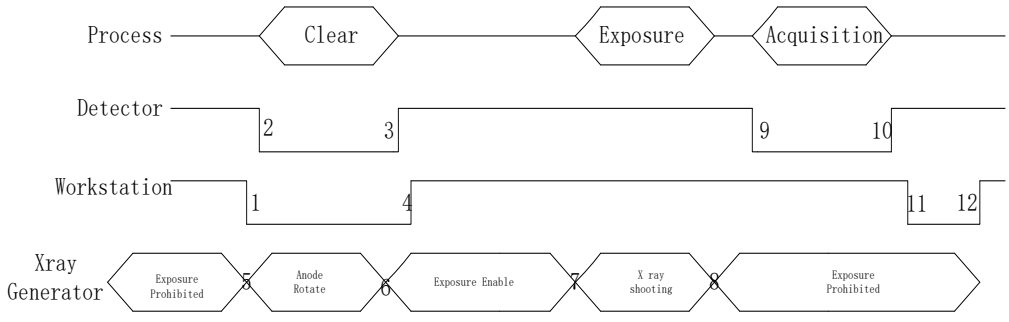
Workstation means host PC device installed with iDetector or SDK. Chapter 3.3 has described how to establish connection between detectors and workstation. In AED mode, workstation does not control X-ray generator, user decides when to shoot X-ray.

4.1.2.2 Work Flow



4.1.2.3 Timing Setting

To get a clear view of workflow, see diagram below for detail



1. Workstation receives “Acquire” request and sends “Clear” to detectors.
2. Detector receives “clear” from workstation and begin flushing panel. Meanwhile, replies to workstation “Exposure Prohibited”.
3. Detector finishes “Clear” and sends message “Exposure Enable”.
4. “Exposure Enable” is shown on iDetector’s bar, user shoots X-ray.
5. User triggers X-ray generator to initialize and do anode rotation to prepare for X-ray.

6. X-ray generator finishes preparation and replies to user
7. X-ray generator begins releasing X-ray
8. X-ray generator finishes X-ray shooting.
9. Detector begins data acquisition after time limits.
10. Detector completes image acquisition and begins image transmission.
11. Workstation begins receiving all images.
12. Workstation finishes receiving all images.

Image received would be preview image, preview image is image without much correction which causes them some stripes, it cannot be used for final diagnosis.

Detector would do another dark image acquisition for offset correction. If Hardware Post offset and Hardware calibration is selected, detector uploads processed image to workstation finally after offset, gain and defect calibration.

If Software Post offset and Software calibration is selected, corrected image is shown on screen after workstation finishes offset, gain and defect calibration.

Note: If wireless circumstance is bad, detector couldn't send even one package in 30s. It would stop trying sending image package. Users have to retrieve images from detector when wireless is good enough.

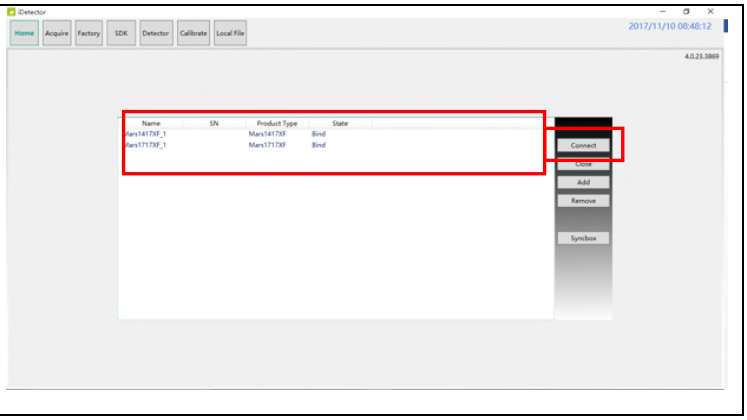
4.1.2.4 Abnormal Action

If users do not want to shoot X-ray, it is available to cancel exposure window manually.

4.1.2.5 Exposure Window

Exposure window can be configured with: 0.7s, 1.2s, 2.2s, 3.2s, 4.2s.

4.2 Connection Build

Open iDetector and click "Connect" based on product name	

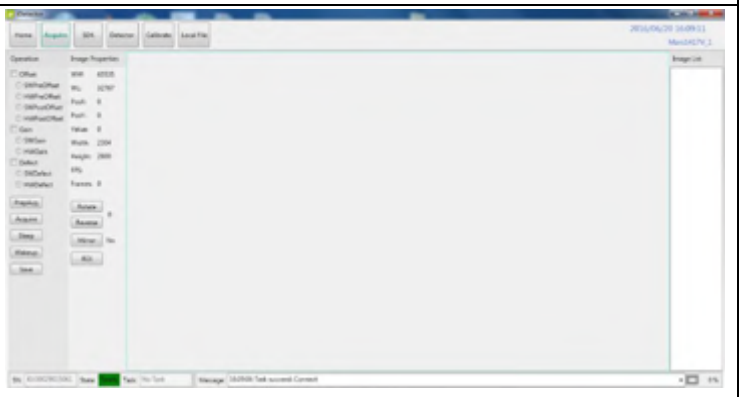
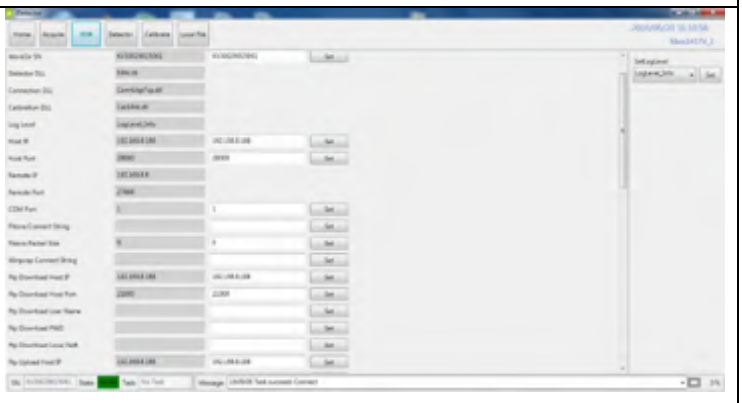
Note:

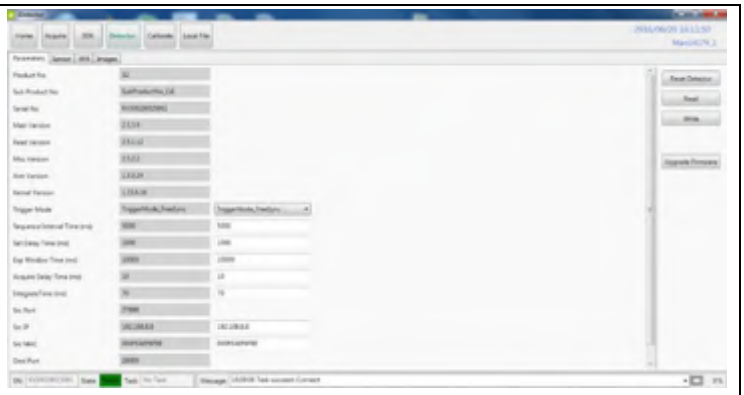
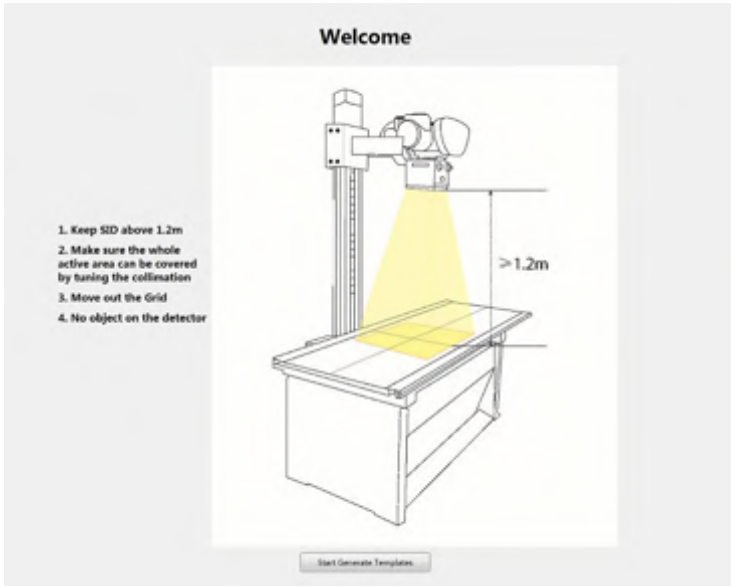
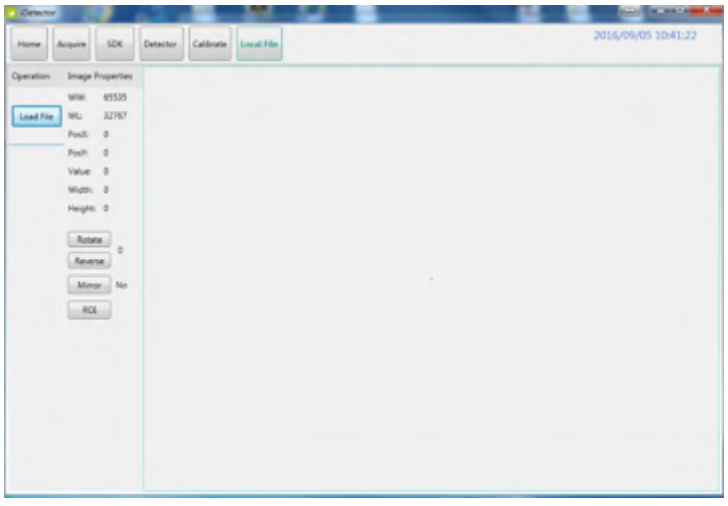
1. Users must re-connect detector with different IP address when changing connection from different net card.

2. Switching between wired and wireless connection does not need any extra operation.

3. The rule of multi-share is based on IP address. The second terminal with different IP address is not allowed to operate when the first is connected. If there is no command transmission between detector and workstation over 5 minutes, detector releases access authority.

4.3 Panel Configuration

Choose iDetector menu related modules	
“Acquire” module: Choose offset mode, load gain and defect template Acquire images: “Prepacq”, “Acquire” and son on	
“SDK” module: IP address, MAC address and so on	

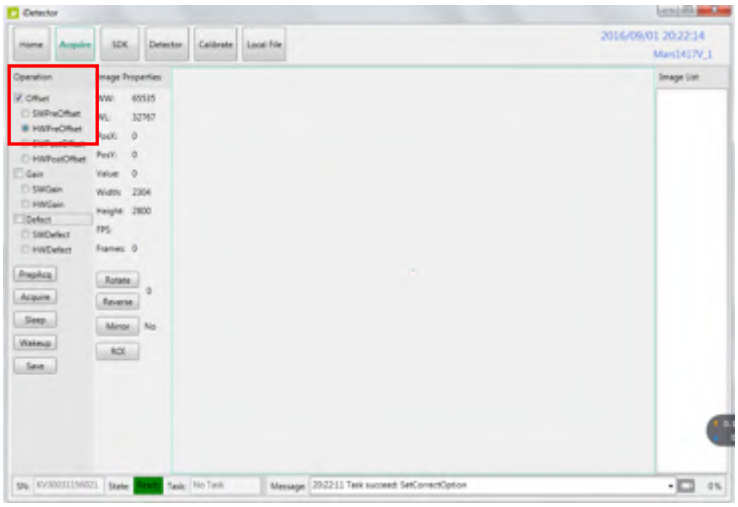
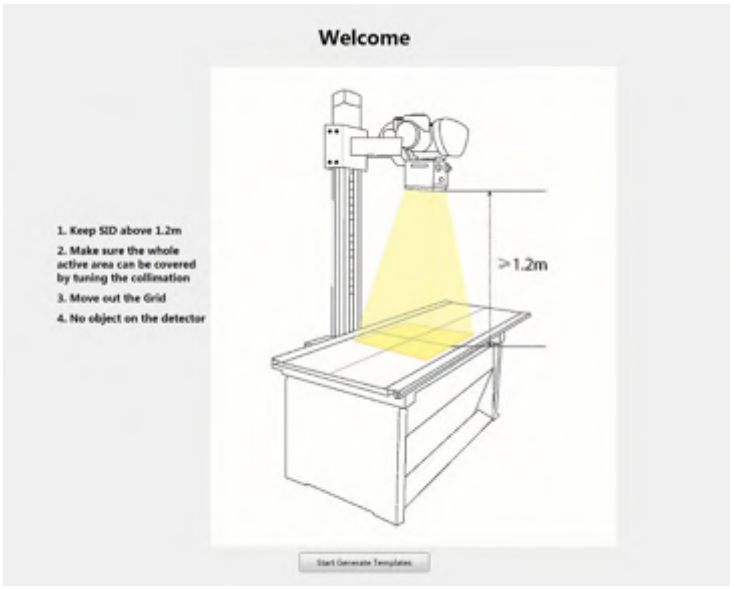
“Detector” module: Trigger module, wireless configuration and so on	
“Calibrate” module: Template generation and management.	
“Local File” module: Read raw or dcm image	

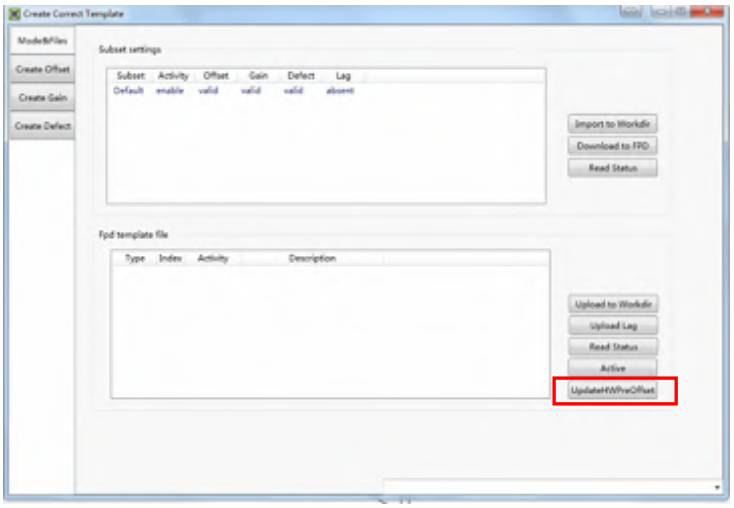
4.4 Correction Template Generation

iRay recommends users correction template generation after installation, any major change on system settings or hardware configuration. On the other hand, it is also recommended to do template generation each 6 month.

4.4.1 Pre-offset Template Generation

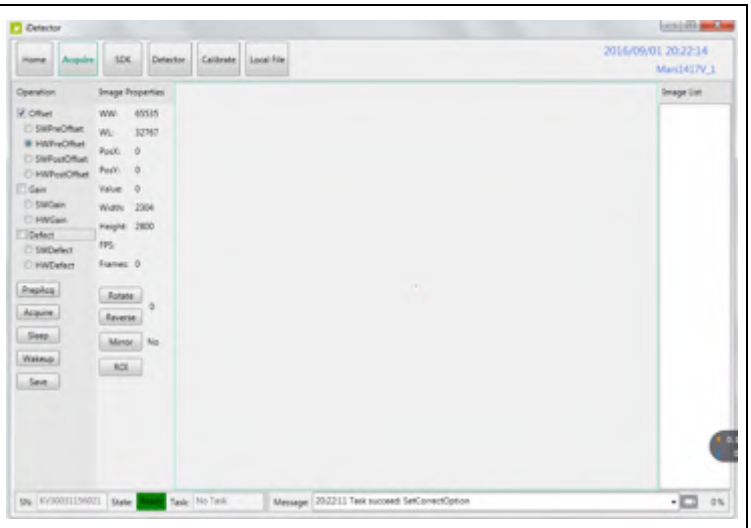
Pre-offset template is necessary for preview image. See below

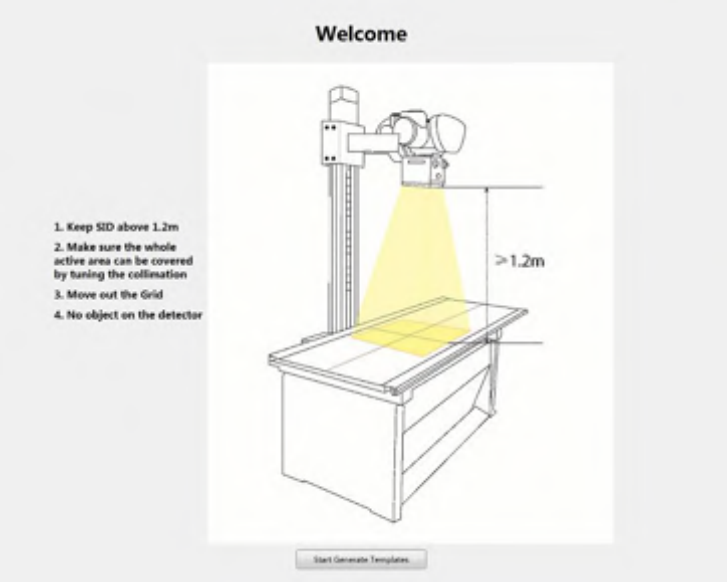
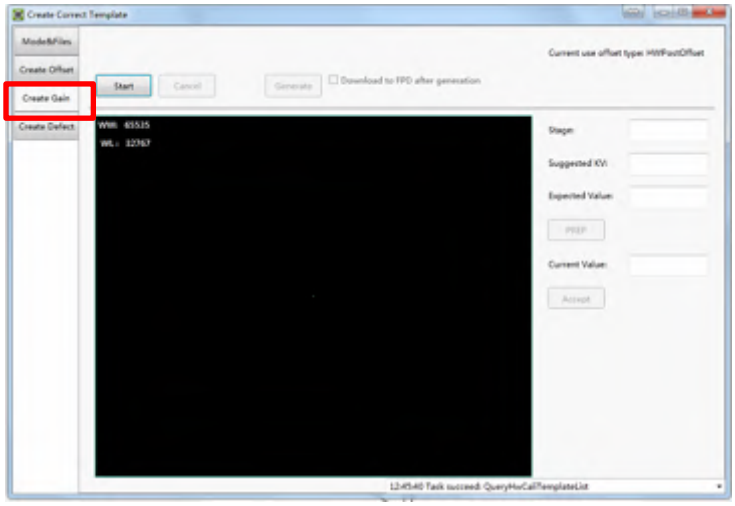
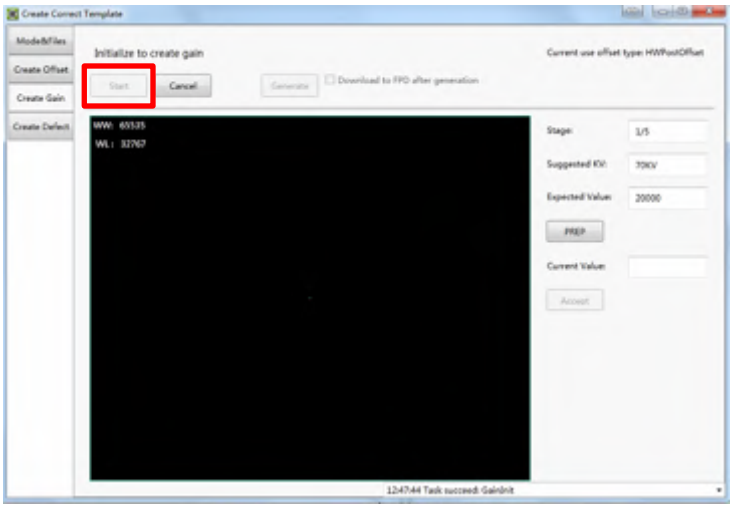
Go to “Acquire” module, choose “HWPostOffset”	
Go to “Calibrate” module, click “Start Generate Templates”	

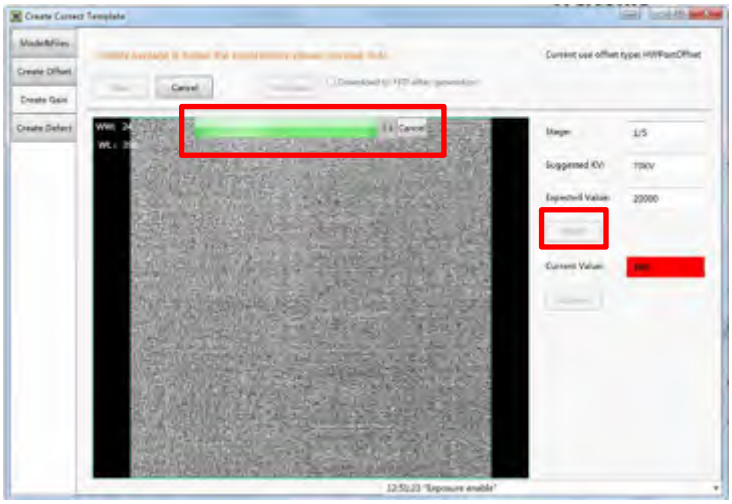
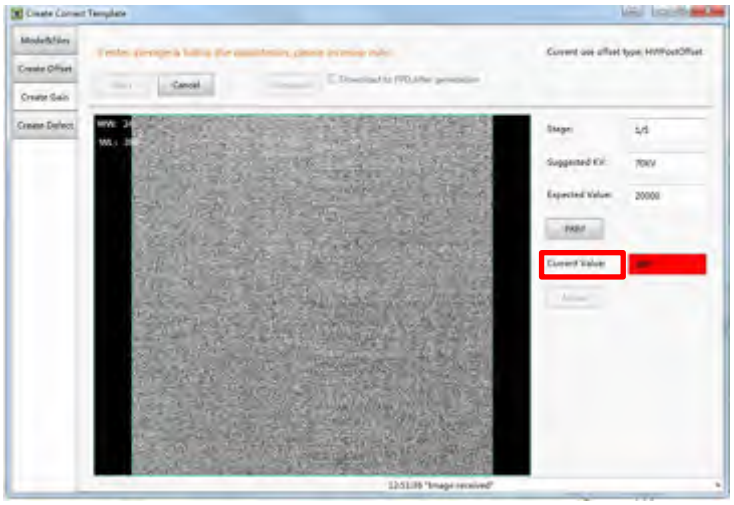
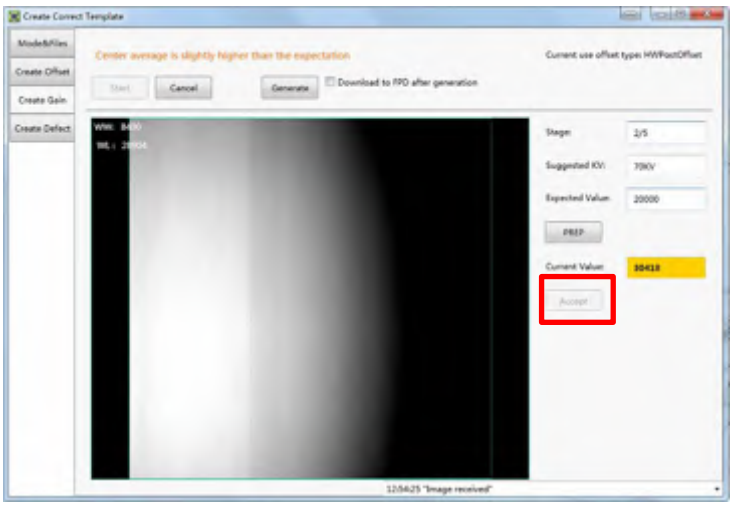
click “UpdateHWPreOffset”, wait until image acquisition ends	

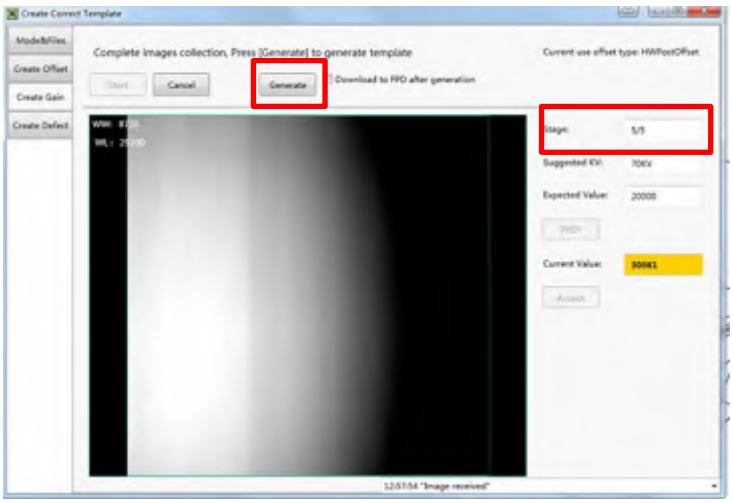
4.4.2 Gain Template Generation

Before Gain template generation, make sure SID=1.2m, no copper is required,

Go to “Acquire” module, choose “HWPostoffset”	

Go to “Calibrate” module, click “Start Generate Templates”	
Click “ Create Gain”	
Click “Start”	

Set x ray dose to meet the expected value. Click “PREP”, wait for exposure bar is counting down. Before window ends, shoot x ray.	
There would be prompt in the region of current value if dosage is improper. **(Note 1)** Change dosage and exposure again until image is accepted.	
Click “Accept” if box is green, Click “PREP” to start another X ray shoot.	

Gain calibration template needs 5 x ray images. After 5 images acquire, click “Generate”, wait until “Task succeed:FinishGenerationProcess”	

Note:

1. X ray image has three states: green, yellow and red.

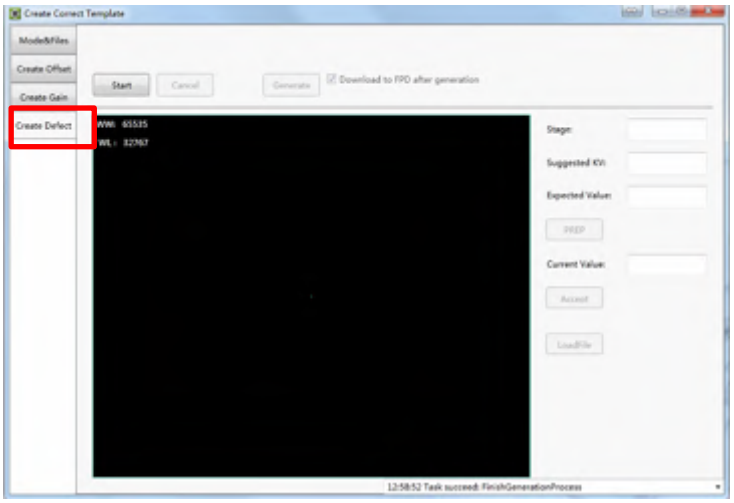
   Green means image meets requirements.

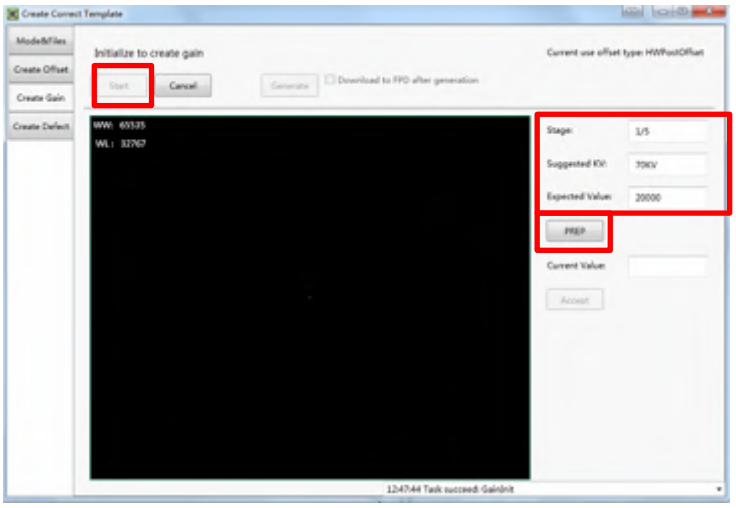
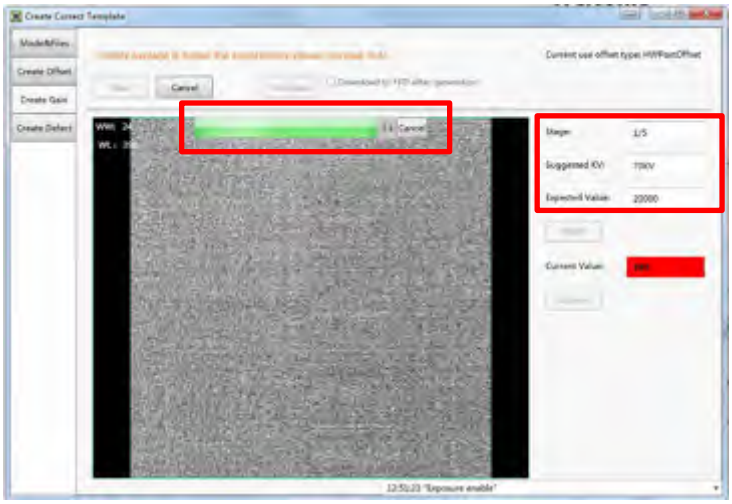
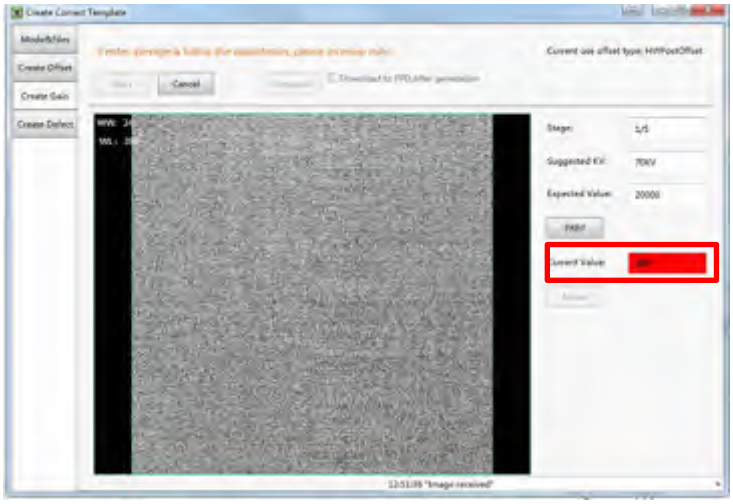
   Yellow means image does not meet requirements, but can generate template.

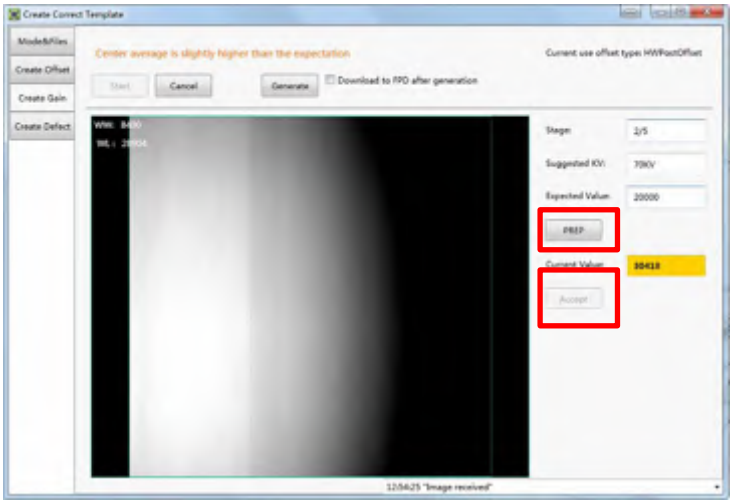
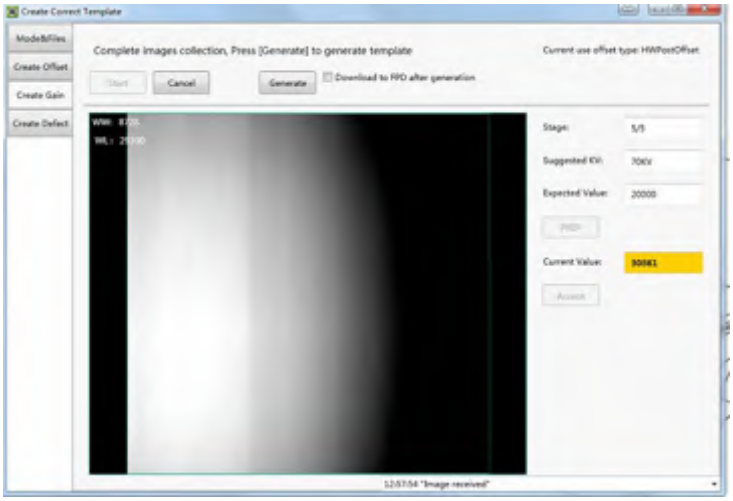
   Red means image does not meet requirements, cannot generate template, must be taken again.

4.4.3 Defect Template Generation

Before Defect template generation, make sure SID=1.2m, no copper is required,

Click” Create Defect”	

Click “Start”, Defect template needs 8 x ray images.	
Set X ray dose according to expected value. Click “prep”, wait for exposure bar is counting down. Before window ends, shoot x ray.	
There would be prompt in the box if dosage is improper. (Note 1) Change dosage and exposure again until image is accepted.	

Click “Accept” if box is green, Click “PREP” to start another X ray shoot.	
Calibration template needs 8 x ray images. After images acquire, click “Generate”, wait until “Task succeed:FinishGenerationProcess”	

. **Note:**

1. X ray image has three states: green, yellow and red.

   Green means image meets requirements.

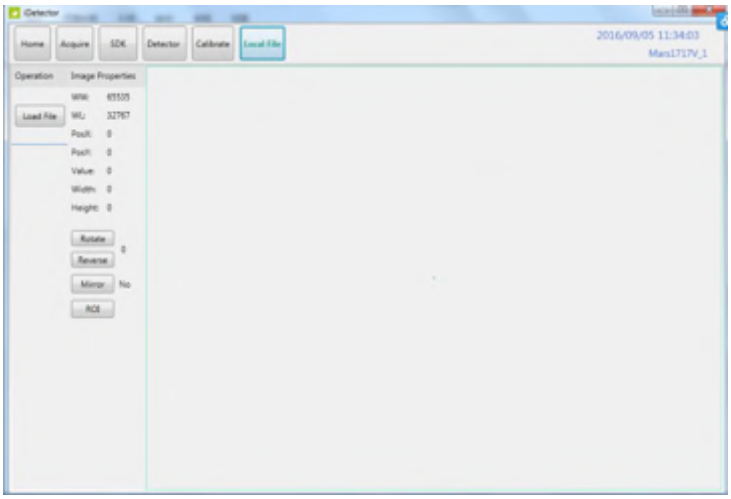
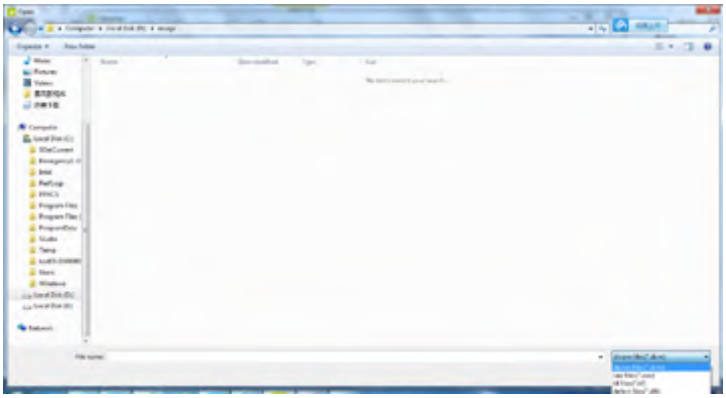
   Yellow means image does not meet requirements, but template can be generated.

   Red means image does not meet requirements, template cannot be generated, must take another shot.

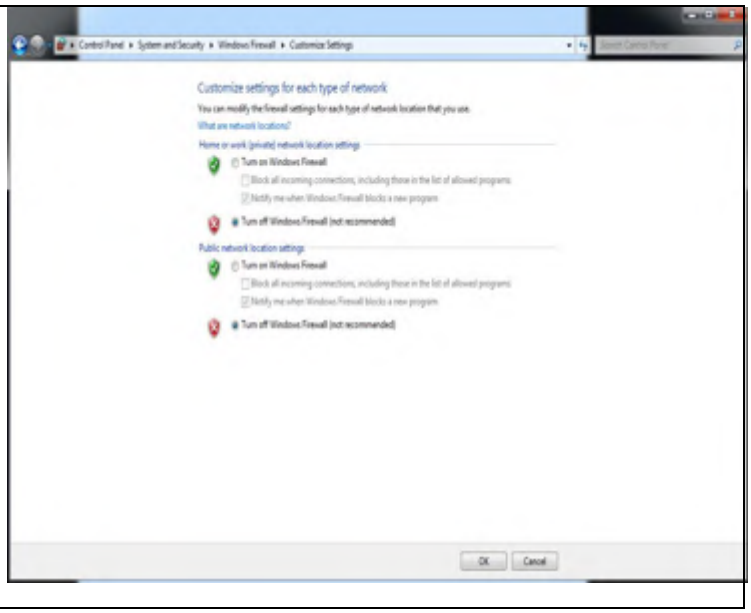
4.5 Image Check and upload

“Local Image Check” defines function checking image saved in Workstation. “Panel Image Upload” defines function uploading images stored in detector.

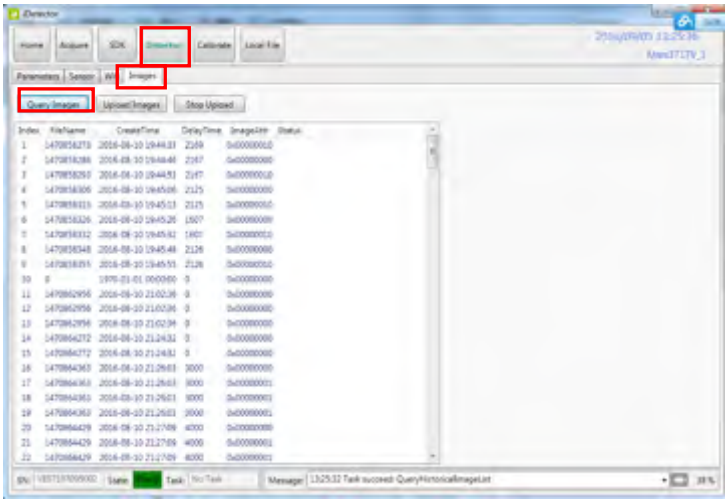
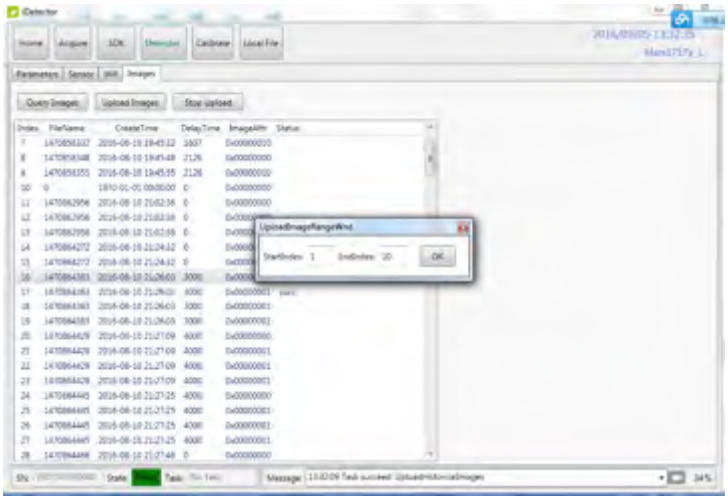
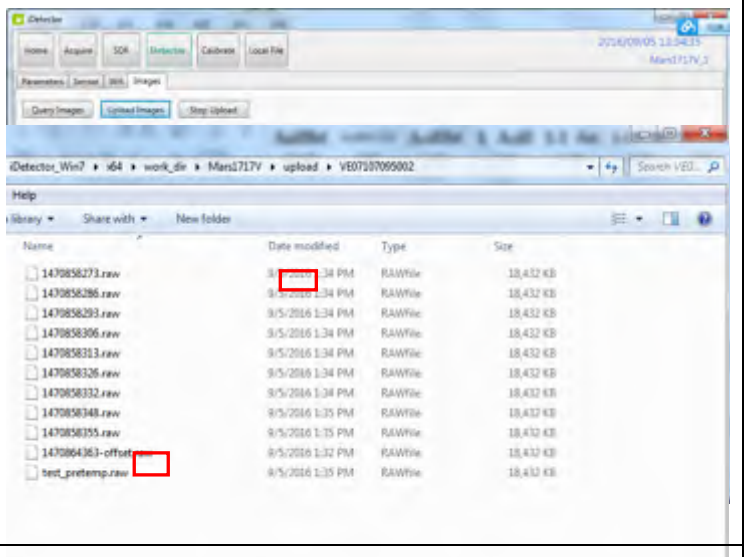
4.5.1 Local Image Check

Choose “Local File”	
Click “Local File” to open dicom, Raw and tif file	
Click “Open”	/

4.5.2 Panel Image Upload

Double check firewall is closed	

Panel Image is uploaded as following.

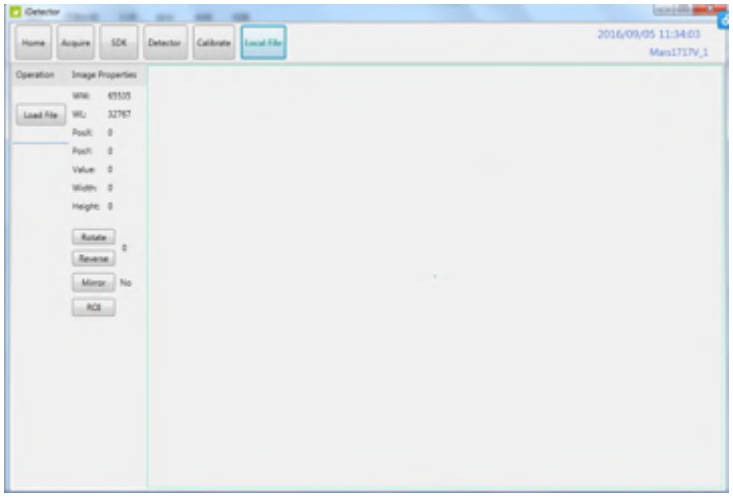
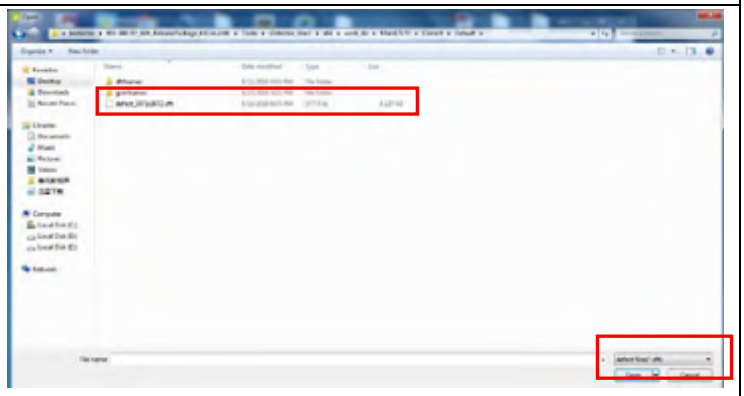
Choose “Detector” -> “Images” Click “Query Images”, image info listed below	
Click “Upload Images” Input the index number of images Click “OK”	
Waiting for status from "Busy" into "Ready" Check upload images Click "Stop Uploading" to stop image upload	
Images uploaded is stored in "work_dir \ Mars1417XF_Client \ upload \serial	

number"	

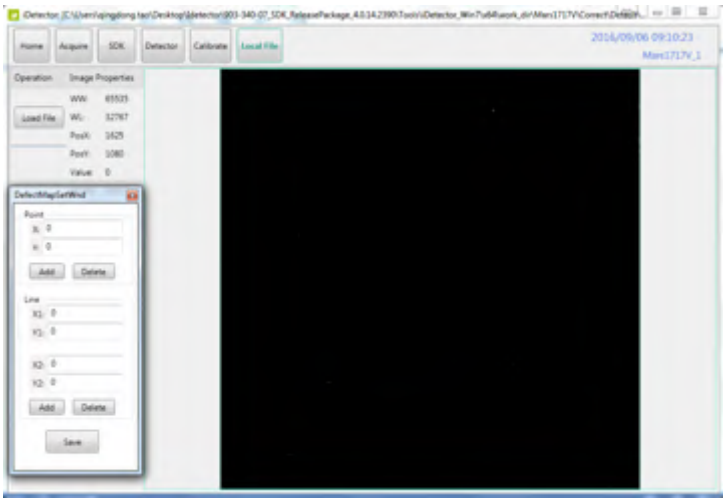
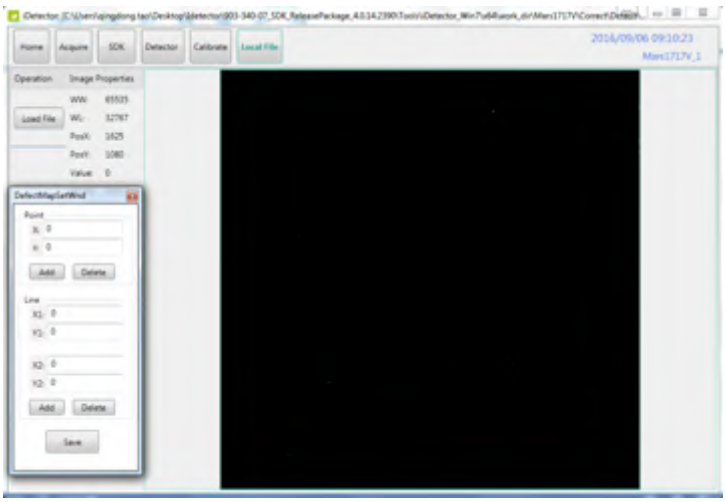
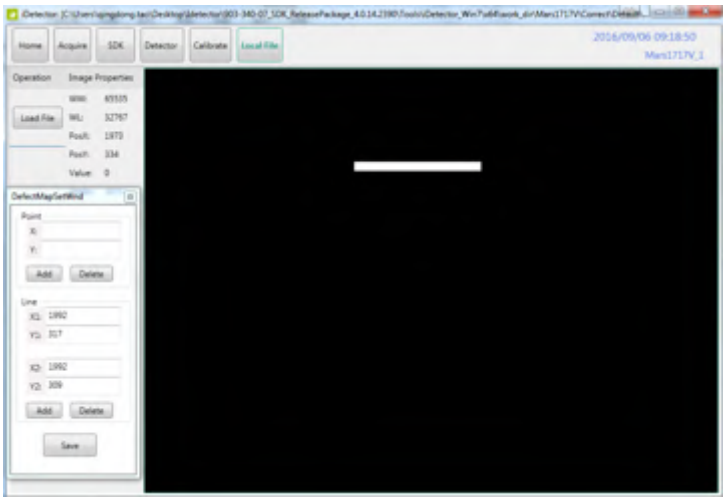
4.5.3 Defect Template Check and Modification

iDetector provides function checking defect template. If defect template has updates, user could add and delete defect pixel or lines.

4.5.3.1 Defect Template Check

Select “Local File” module Click “Local File”	
Choose template type “*.dft”, open it	

4.5.3.2 Defect Template Modification

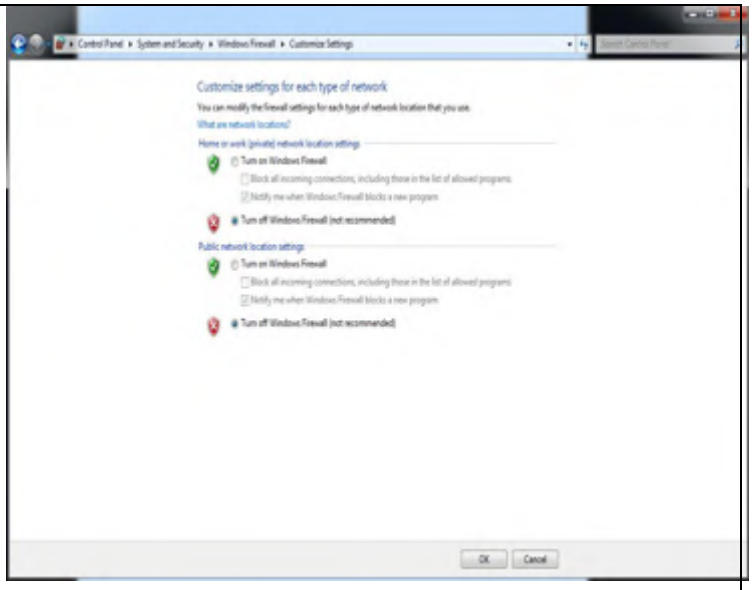
Open defect template	
If there are new defect pixels, type in coordinates, click "Add"; If defect templates have dummy lines, type in coordinates, click "Delete"	
If there are new defect lines, type in starting and ending coordinates, click "Add". If defect templates have dummy lines, type in coordinates, click "Delete";	

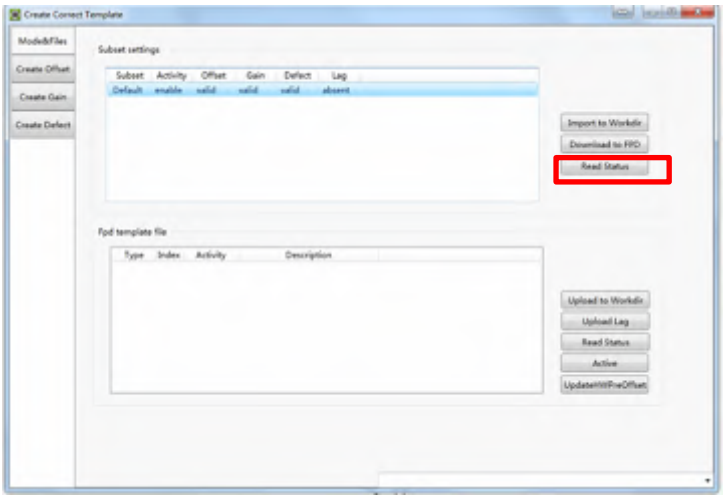
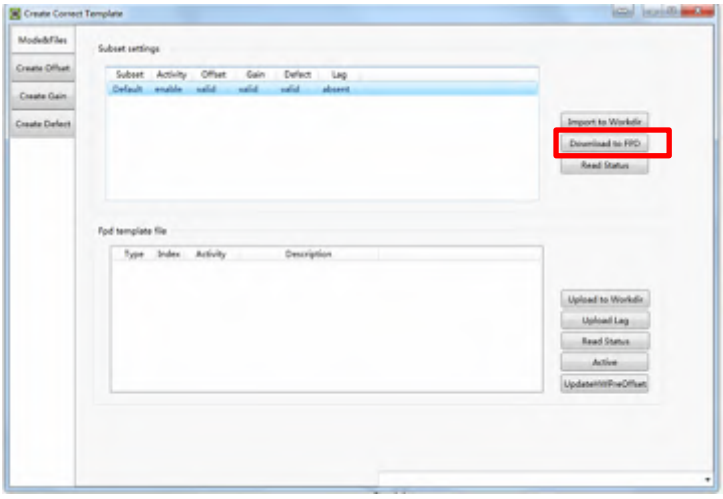
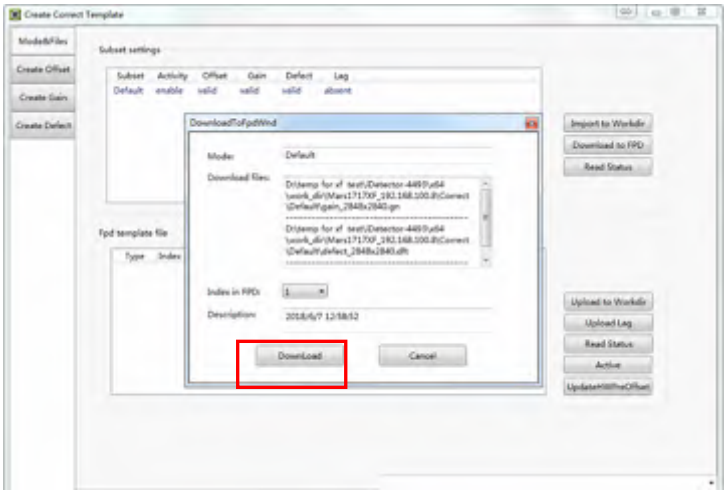
Click "Save" to save modified defect template	

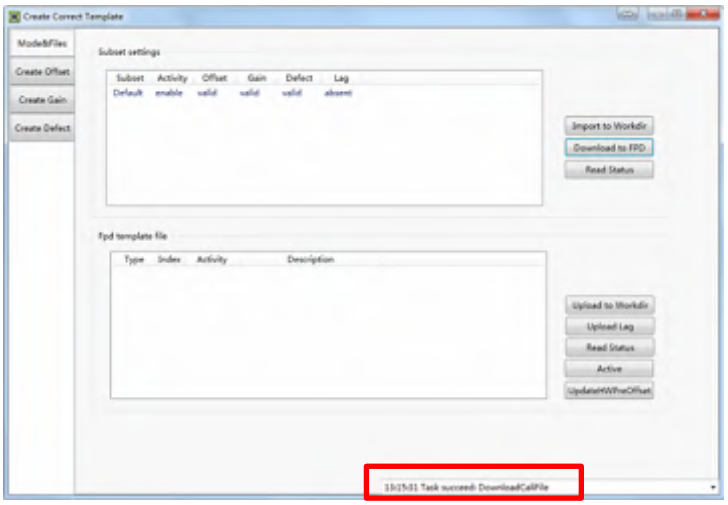
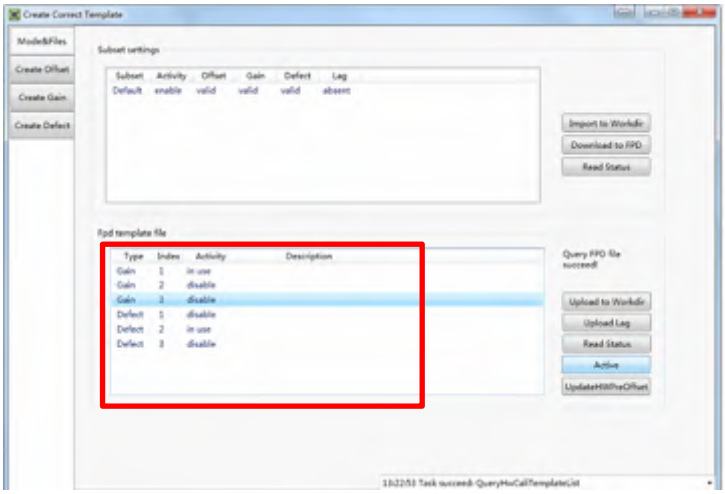
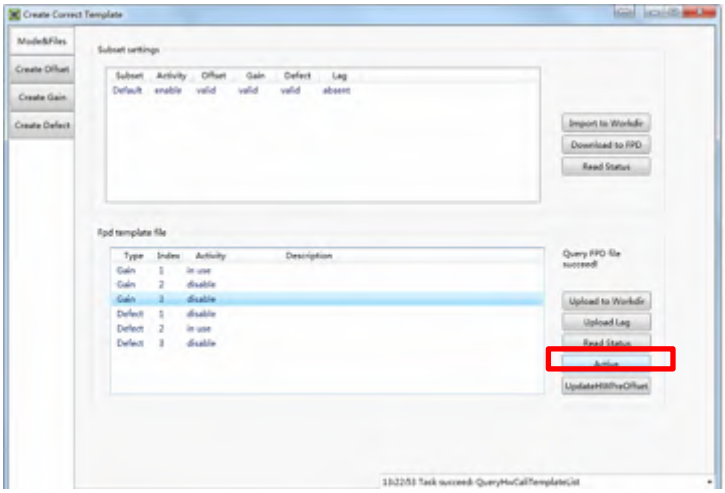
4.6 Correction Template Management

4.6.1 Template Synchronization

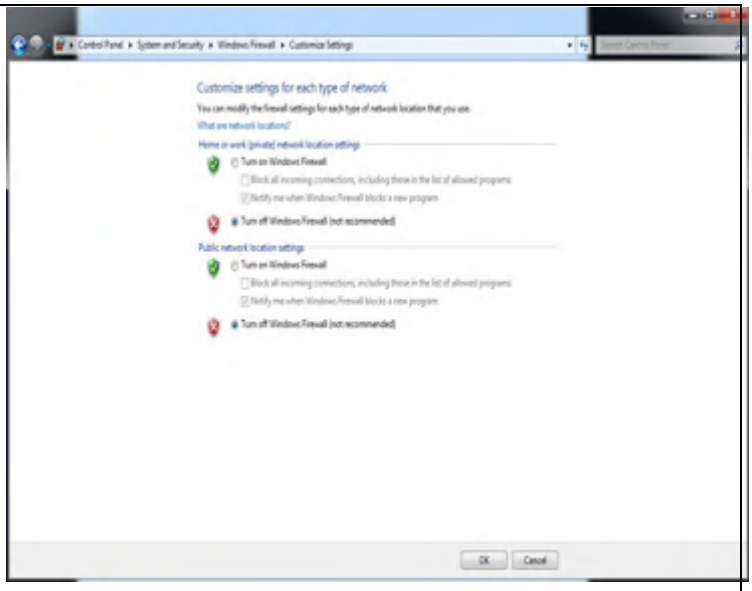
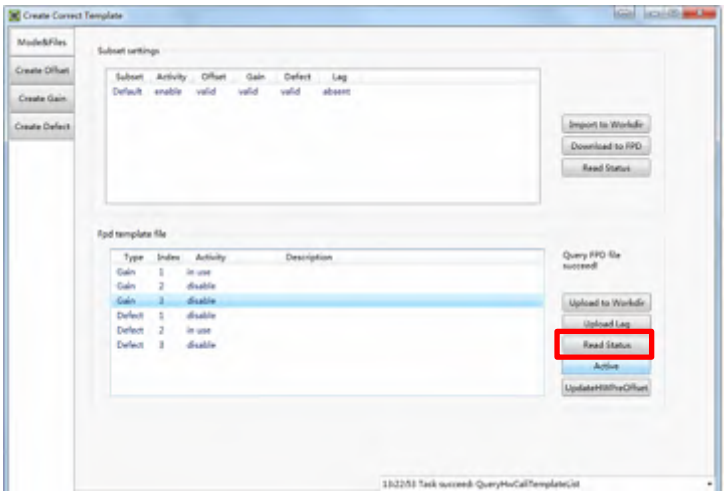
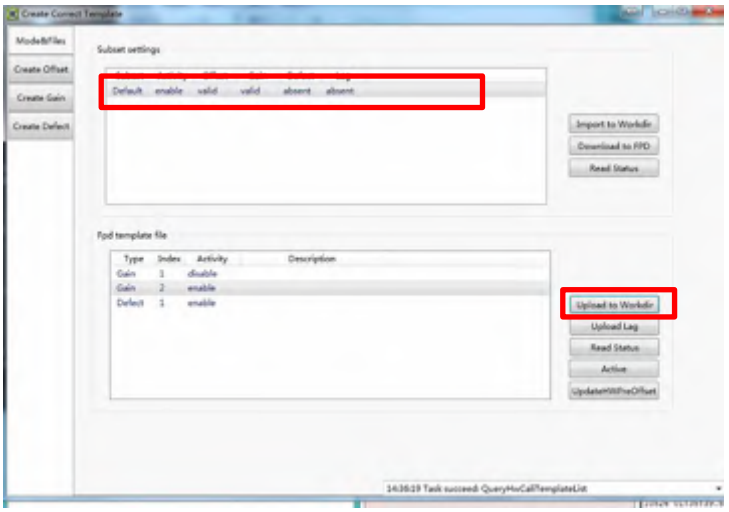
Detector supports correction templates storage which means templates could be transmitted not only from detector to workstation, but also from workstation to detector.

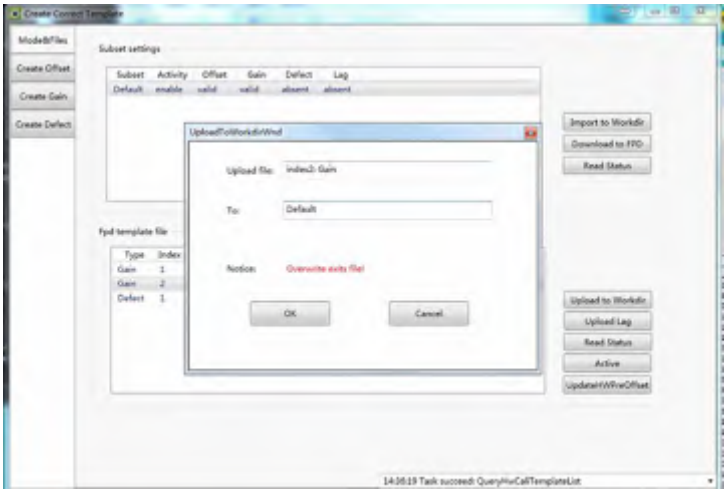
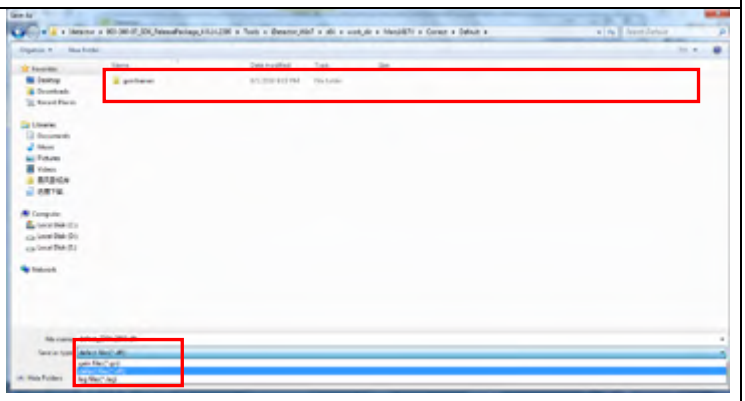
Make sure firewall is turned off	
Choose “Calibrate”, Click “Start Generate Templates”	

Click “Read Status” besides “Subset settings”	
Click the template to be downloaded Click “Download to FPD”	
Check information whether it is right. Change Index in FPD if necessary. Click “Download”.	

Wait until “Task succeed: Download CaliFile”	
Click “Read Status” to read template	
Choose template number according to requirements Click “Active” to activate template	

Upload templates

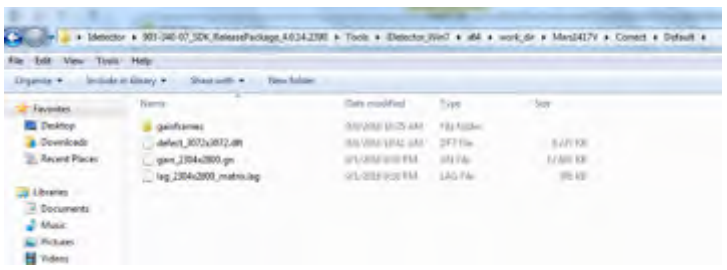
Make sure firewall is turned off	
Choose “Calibrate”, Click “Start Generate template” Click “Read status” besides FPD template file. Click template which needs to be uploaded.	
Click Subset settings Click “upload to Workdir”.	

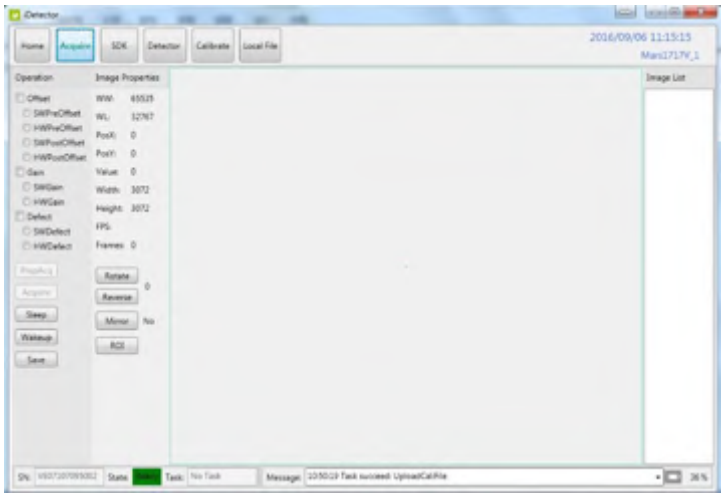
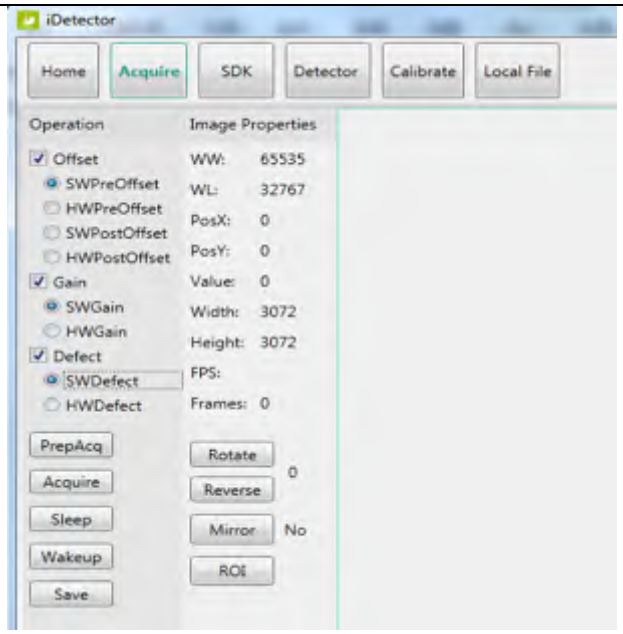
If information listed is right, click “OK”. Wait until “Upload FPD file succeed!”	
Check template uploaded in “work_dir\Mars1417XF_192.168.100.8\ Correct\Default”	

4.6.2 Correction Activation

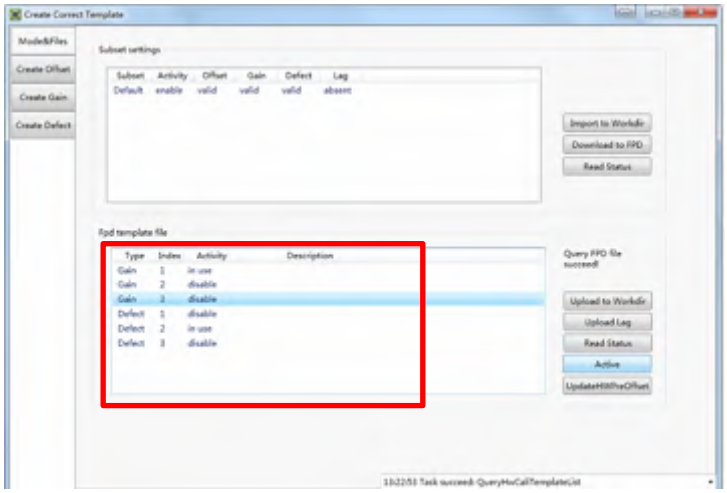
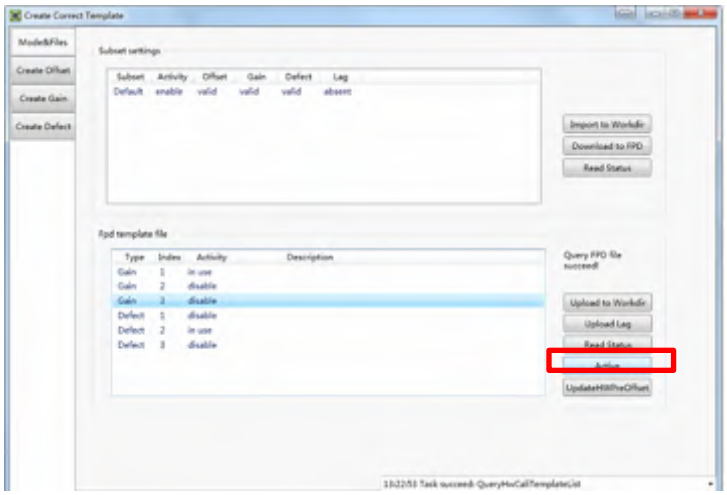
Detector supports two ways to do correction. Software correction defines scenario that workstation finishes correction. If detectors do itself, that’s hardware Correction and Calibration.

4.6.2.1 Software Correction

Make sure templates saved in “work_dir\Mars1417XF_192.168.100.8\ Correct\Default”	

Choose “Acquire”	
Offset Mode:“SWPostOffset”, Gain mode “SWGain”, Defect mode “SWDefect”	

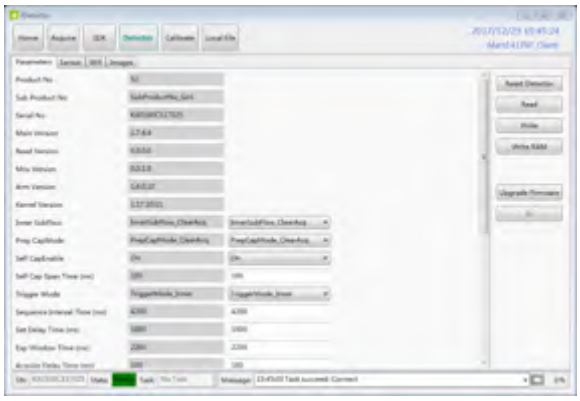
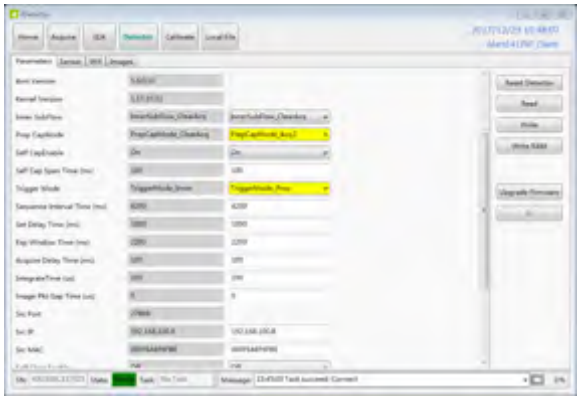
4.6.2.2 Hardware Correction

Click “Read Status” to read template	
Choose template number according to requirements Click “Active” to activate template	
Offset Mode “HWPostOffset” Gain mode “HWGain” Defect mode “HWDefect”	/

4.7 Firmware Update

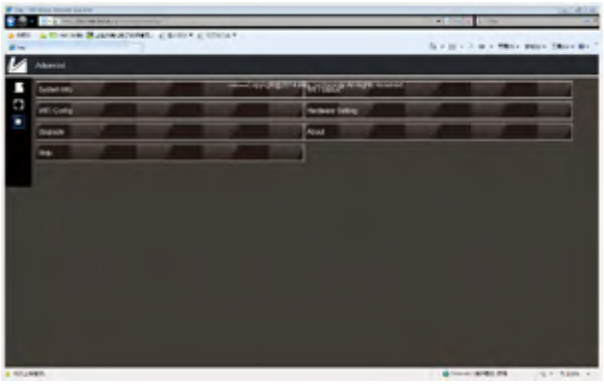
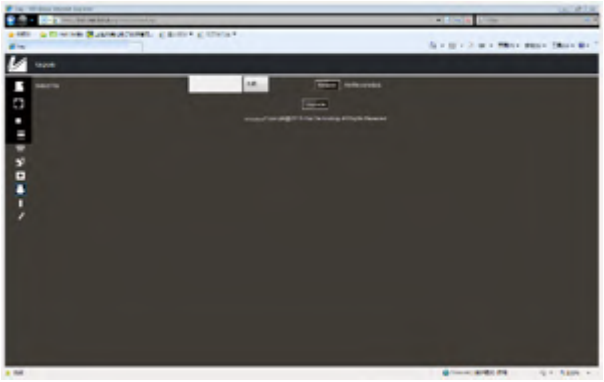
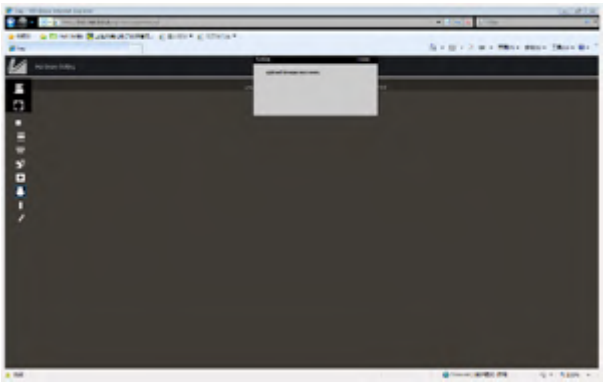
Detector supports firmware updating with website, if user needs update firmware, please follow steps below

Preparation before updating

Go to page “Detector”	
Change Trigger mode to “TriggerMode_Prep” Change Prep Capmode to “PrepCapMode_Acq2” Click “Write”	

Firmware updating

Open IE browser. Input 192.168.100.8 User name: admin Password: iray	
Click button in red box	

Choose “upgrade”	
Click “browse” on the right	
Choose” Mars1417XF_IMAGE_41_ALL_XXXX_XX_XX.ifrm” Click “upgrade”	
Click “close” when “upload image success” pops up Wait until upgrade is done.	

Note:

1. please insert battery (more than 25%) in detector, in case power is down when upgrading. On the other hand, detector should reboot after updating.

4.8 Short cut

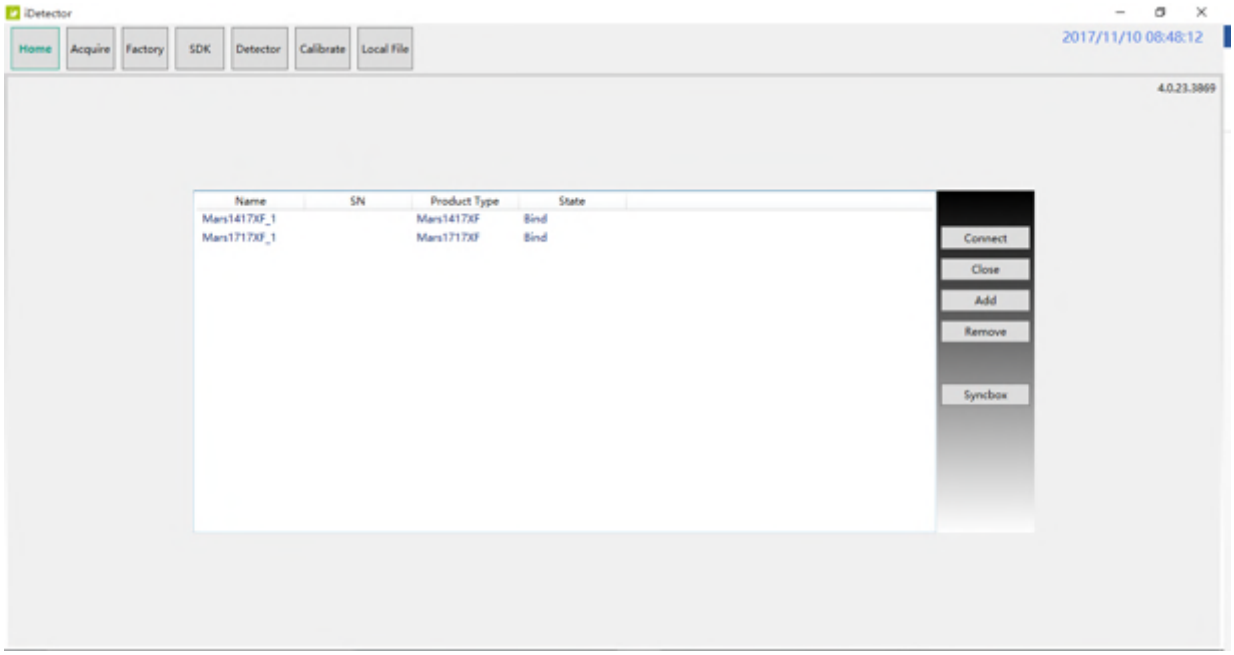
iDetector supports some shortcuts as follows:

- •Double-click left mouse: image displayed in center with maximum size.
- •Press and drag left mouse: drag image displayed.
- •“F3”: Quickly adjust the image window width and window level.

4.9 Software

4.9.1 Main GUI

Double-click iDetector, main interface is shown on screen. See table below for detailed function description.



Item	Function description
Home	Connect detector, check connection status
Acquire	Image acquisition, correction mode, image storage and processing
SDK	Config.ini setting and Log level setting
Detector	Detector configuration, synchronization methods, etc
Calibrate	Correction template generation and management
Local File	Local image check and image processing

4.9.2 Home Page

Item and button description is shown as following.

Item	Function description
Name	Detector name
SN	Detector SN number
Product Type	Product type
State	Three states: Bind, Unknown, Ready
Button	**Function description**
Connect	Build connection with specific detector
Close	Disconnect with specific detector
Add	Add additional working directory
Remove	Delete working directory

4.9.3 Acquire Page

This page works for image acquisition mainly. In “operation” box, user chooses image correction method according to requirements. “image properties” shows simple information of image acquired. “Image list” shows lasted 5 images, if user wants to check some image, double click. User can rotate images and do other image processing with “ROI”.

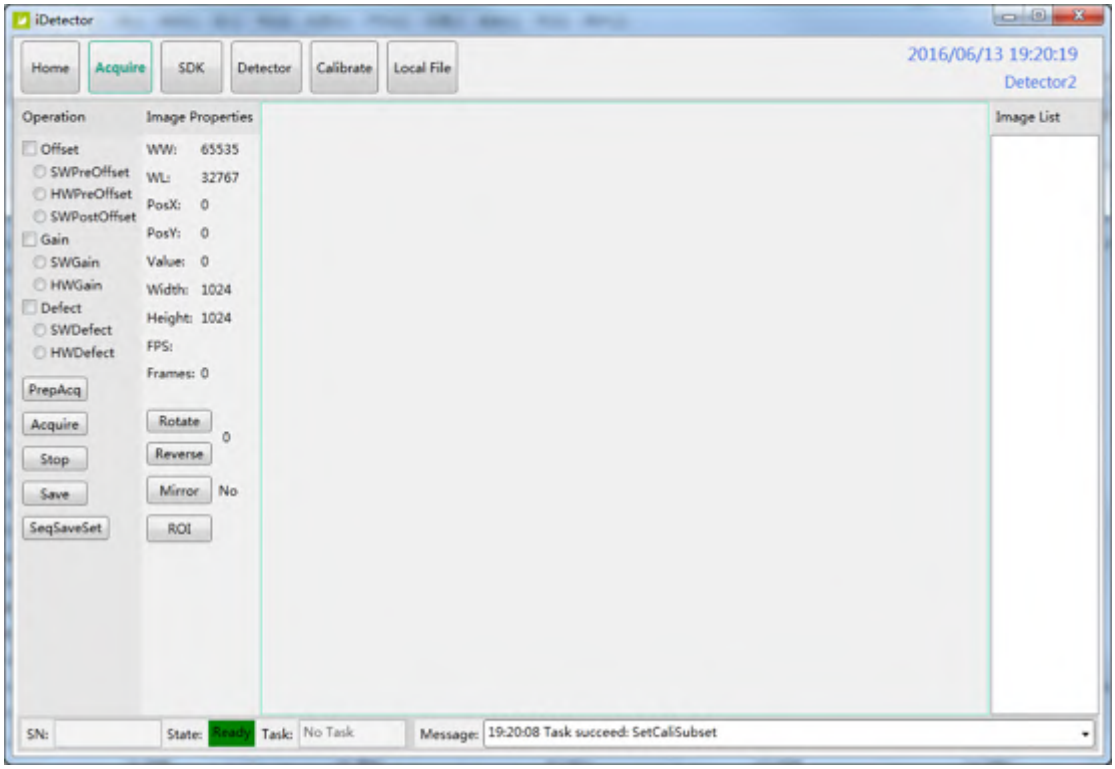


Figure 4.13.2

State of detector, SN and Message is on the bottom of page.

Item	Function description
SN	Connected detector SN number
State	Detector status, such as Busy or Ready
Task	Event that detector is doing
Message	Feedback of detector action, such as succeed or failed

Image operation and property of SDK is shown below

Correction Menu		Function description
Offset	SWPreOffset	Reserved
	HWPreOffset	Reserved
	SWPostOffset	Workstation does post offset correction
	HWPostOffset	Detector does post offset correction
Gain	SWGain	Workstation does gain correction
	HWGain	Detector does gain correction
Defect	SWDefect	Workstation does defect correction
	HWDefect	Detector does gain correction
Acquisition		**Functional description**
PrepAcq		Flush the panel and then do image acquisition
Acquire		Start image acquisition
Stop		Stop continuous image acquisition
Save		Save images
SeqSaveSet		Save image frames in continuous image acquisition mode(documents type and path could be set)
Image Properties/ Image Process		**Functional description**
WW		Window width
WL		Window level

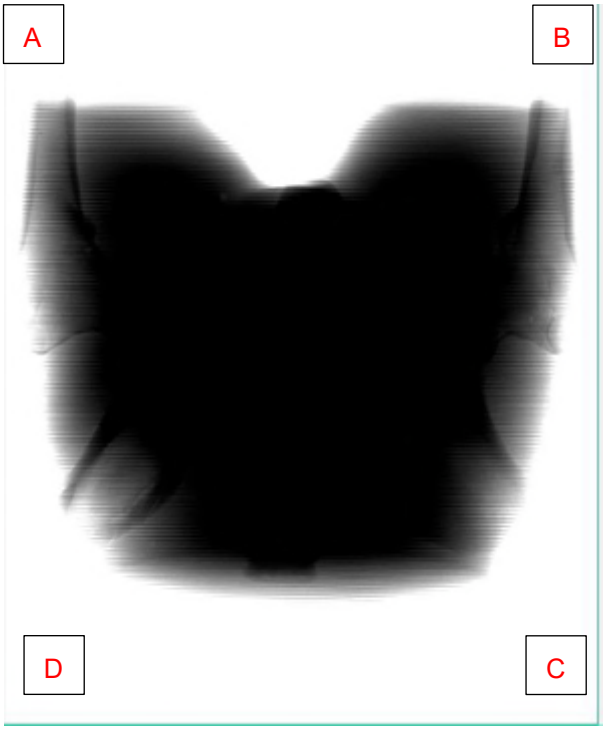
PosX	Cursor X coordination
PosY	Cursor Y coordination
Value	Value of cursor
Width	Image width
Height	Image height
FPS	Frame rate
Frames	Frame number
Rotate	Rotate image 90 degrees at clockwise direction
Reverse	Rotate image 90 degrees at counterclockwise direction
Mirror	Mirror image horizontally
ROI	Statistic of image such as AVG and SV
Image List	Latest 5 images

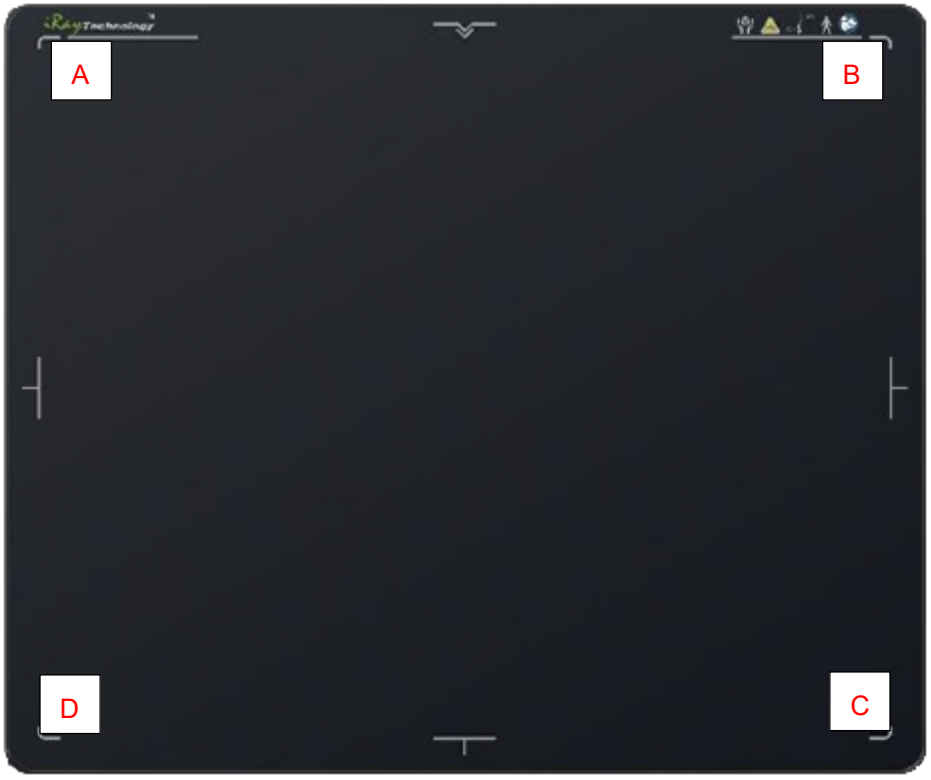
Image preview shortcut is stated below：

- Double left click: image displayed in center with maximum size.
- Double right click: window level and width adjusted to WL: 32767/WW: 65535.
- Drag left mouse: drag image displayed.
- Lateral drag right mouse: adjust window width
- Vertical drag right mouse: adjust window level
- F3: Quickly adjust window width and level.

Note: correlation between image acquired and physical panel direction

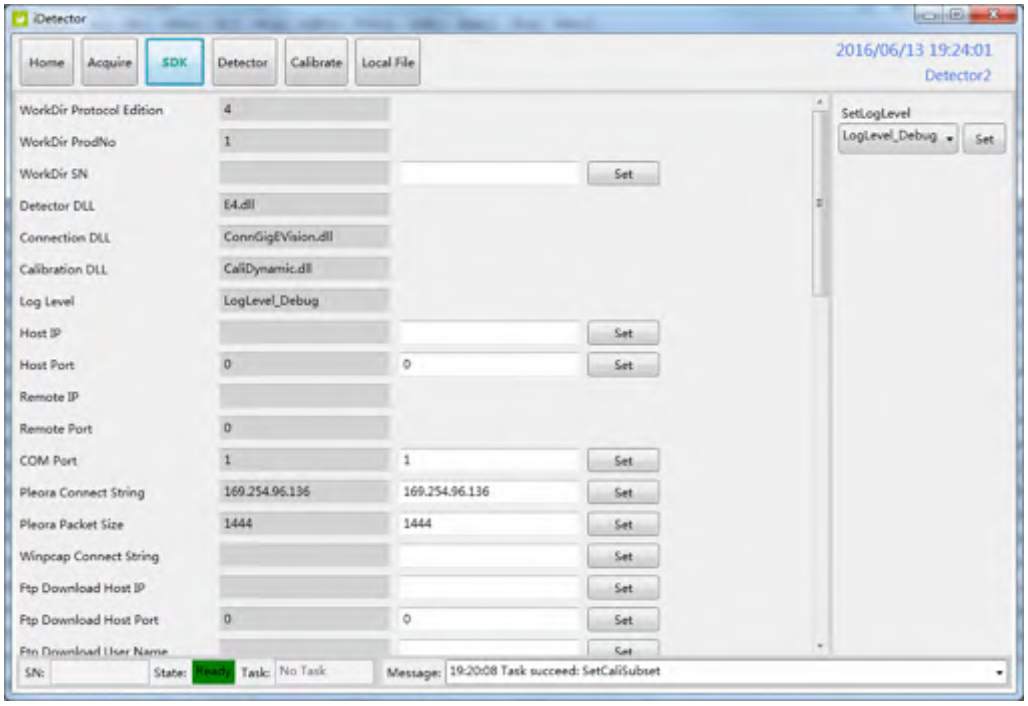
Image	Panel
A	A
B	D
C	C
D	B





4.9.4 SDK Page

The page is used to configure config.ini and set log level in real time, as shown below



4.9.5 Detector Page

4.9.5.1 Parameters

Parameter tab is activated in default. Five boxes on page are defined as following:

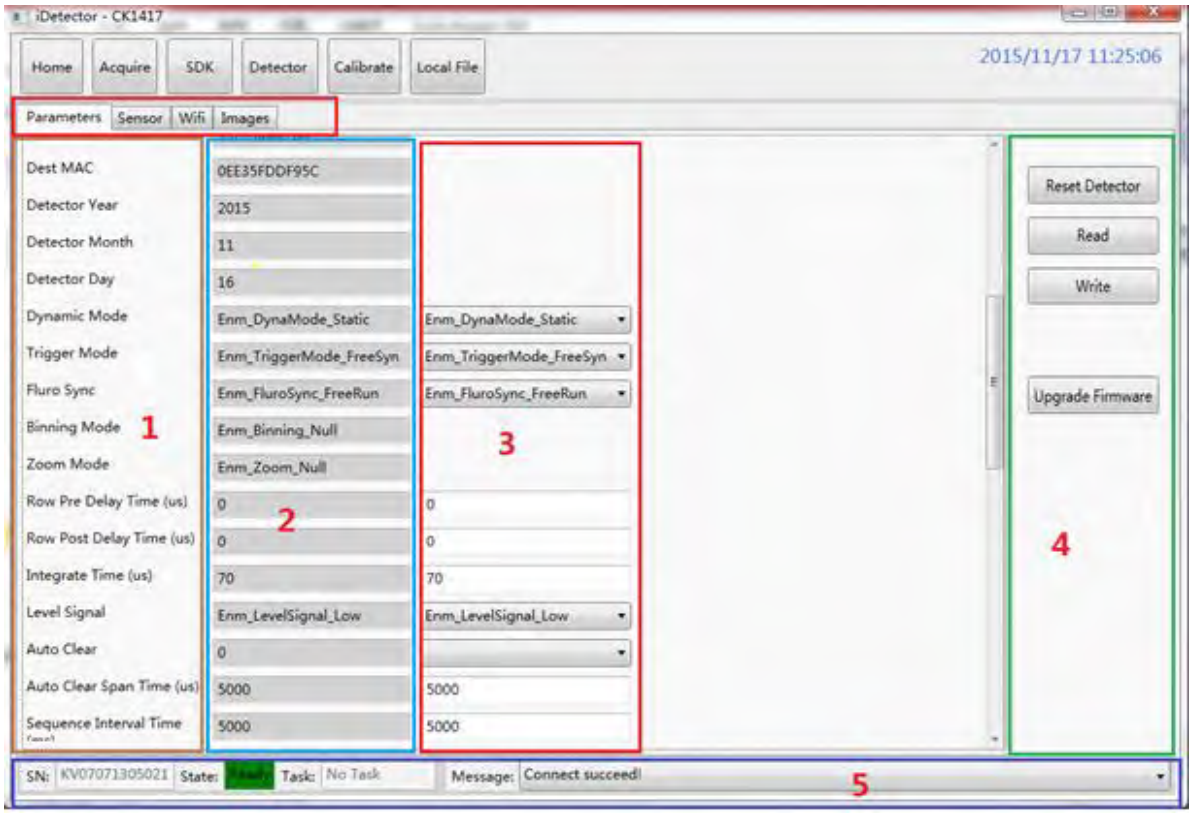
Zone 1: parameters

Zone 2: parameters reading from detector

Zone 3: parameters which are written into detector

Zone 4: function button

Zone 5: simple message from detector and state



Configuration parameter items

ParmName	Description	Modifiable
Main Version	Detector FPGA version	NO
Read Version	Detector Read version	NO
Product No	Product number	NO
SN	Serial number	NO
Trigger Mode	Static X ray synchronization mode	YES
Fluro Sync	Dynamic X ray synchronization mode	YES
Set Delay Time	Delay time for “prepacq”	YES
Acquire Delay	Reserved	YES
Integrate Time	Reserved	YES
Tube Ready	Reserved	YES

Function button description

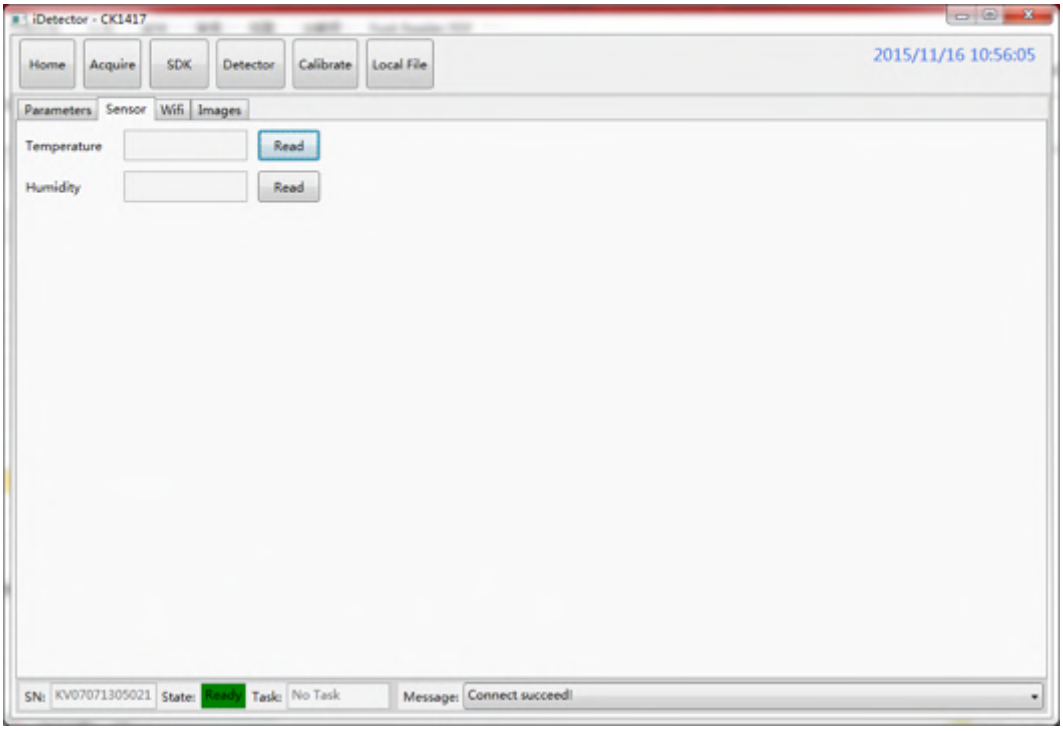
Function Button	Description
Reset Detector	Reboot detector

Read	Read configuration
Write	Write configuration
Upgrade Firmware	Reserved

4.9.5.2 Sensor

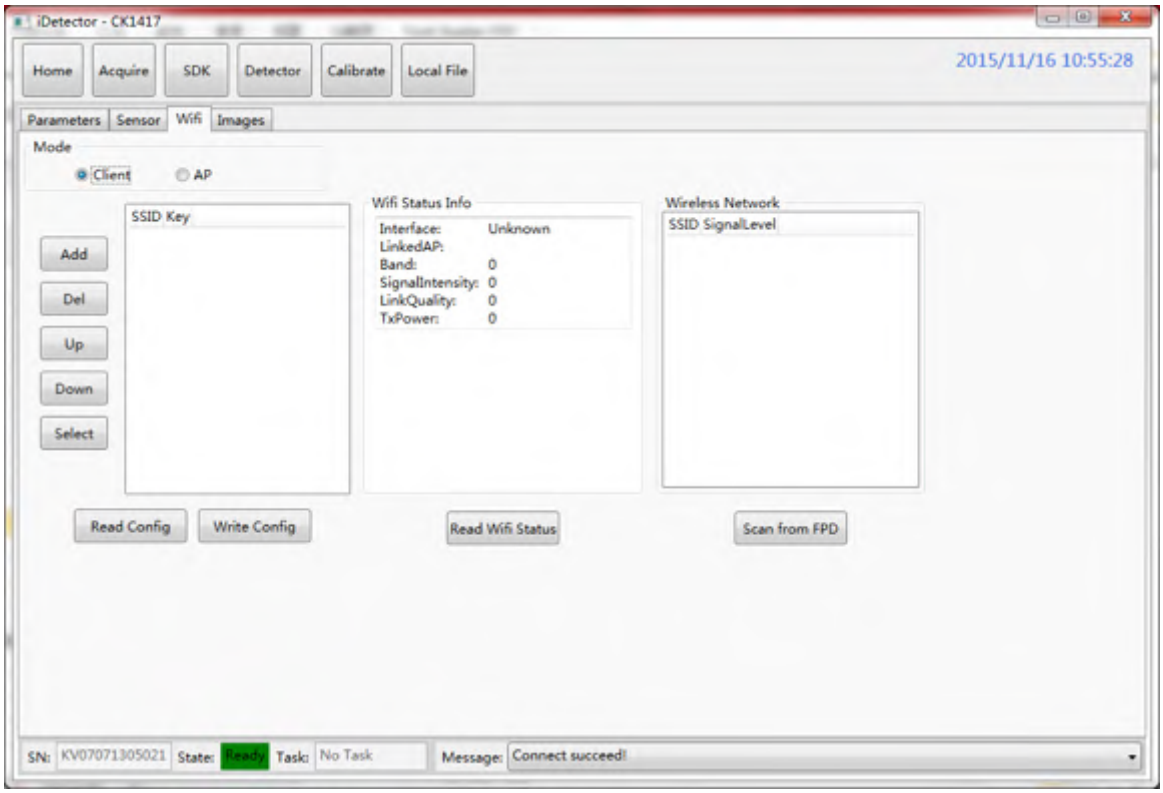
This page includes temperature and humidity information.

Sensor	Description	Modifiable
Temperature	Read temperature in detector	NO
Humidity	Read humidity in detector	NO



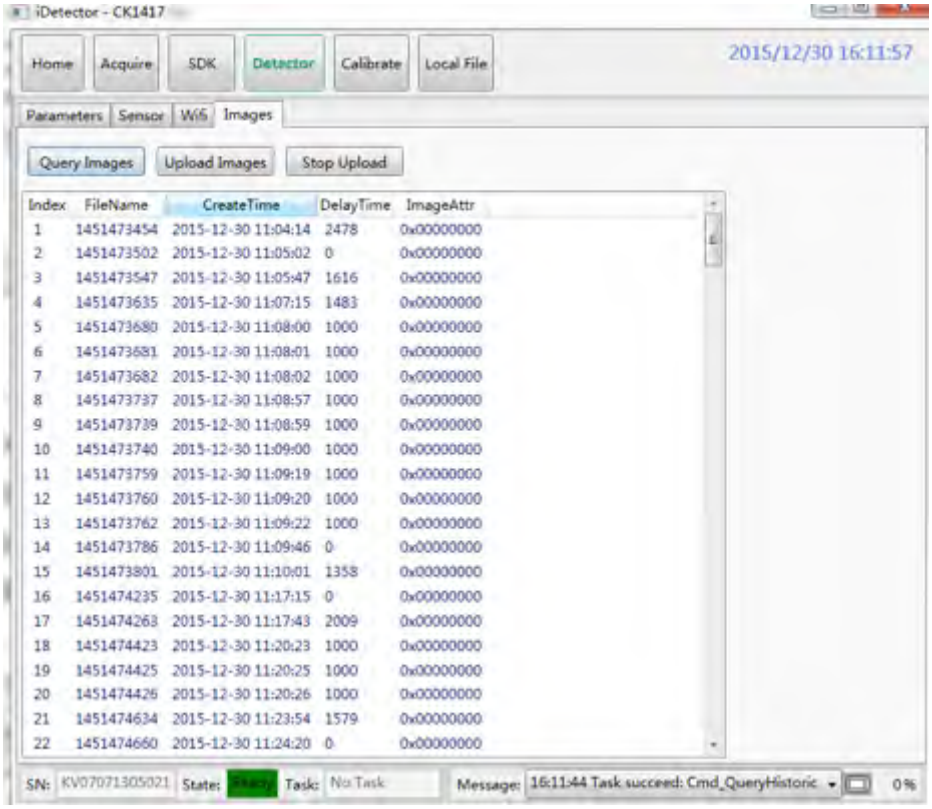
4.9.5.3 Wireless configuration

Mode should be checked with Client.



Parameters	Description
Client	
Add	Add default SSID in wifi list
Del	Delete specified SSID in wifi list
Up	Move up
Down	Move down
Select	Set specified SSID as default one which means it would be loaded automatically after powering up
SSID Key	List 10 optional SSID names
Others	
Read Config	Read wireless configuration from detector
Write Config	Write wireless configuration to detector
Read WiFi Status	Check wireless link status in detector
Scan from FPD	Scan SSID in air with FPD wifi module
Wifi Status Info	Wireless link status is shown in this area
Wireless Network	Available wireless networks is shown in this area

4.9.5.4 Images



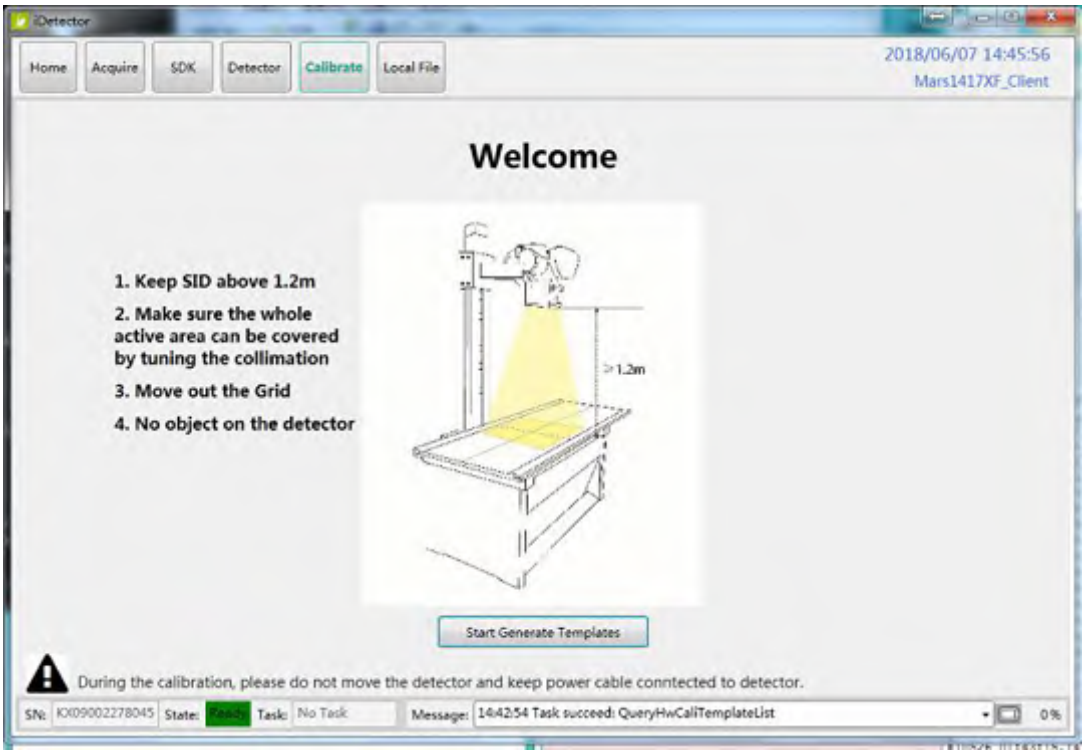
Parameters	Description
Query images	Query image list in detector
Upload images	Upload specific images in detector
Stop upload	Stop uploading accidently
Index	Item NO. which is roll counting
Filename	Image NO. which is defined and saved in detector
Create time	Time image is saved
Delay time	Acquisition delay time
Image attr	Image type

Note:

1. If “HWPostoffset” is chosen, image saved in detector would be corrected one. If not or “SWPostoffset” is chosen, it would be incorrected one.

4.9.6 Calibrate Page

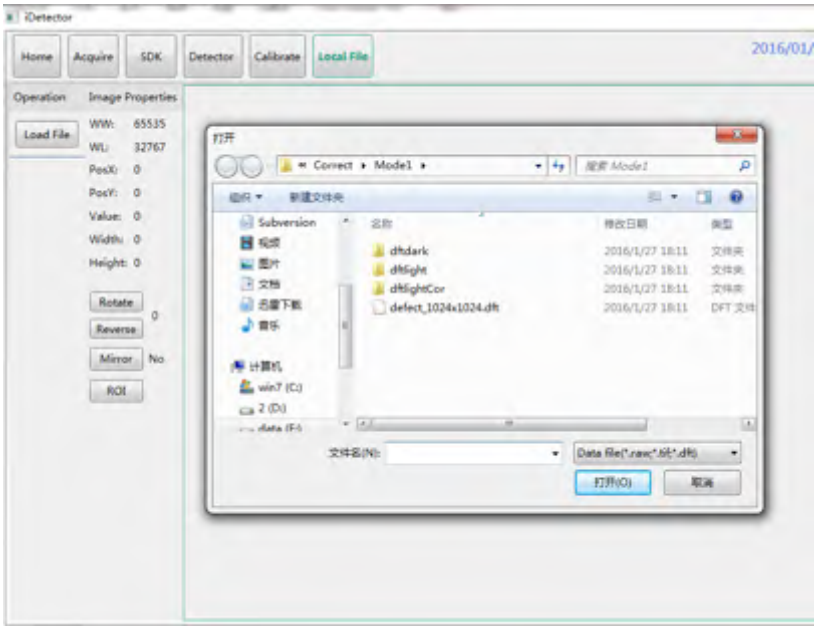
This page works for template management and generation.



Function Button	Description
Start Generate Templates	Start templates generation and templates management

4.9.7 Local File Page

This page works for local image check.



Function Button	Description
Rotate	Rotate image 90 degree at clockwise direction
Reverse	Rotate image 90 degree at counterclockwise direction
Mirror	Mirror image horizontally
ROI	Region of interest image statistic such as AVG and SV Right press mouse draw a box

4.10 IT-network

4.10.1 Purpose for IT-network

Transmission between Detector and workstation is image data and command/status communication.

4.10.2 Required characteristics

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

It supports at least 2 routers.

4.10.3 Required configuration

Wireless card and detector must works on the same IP segment such as 192.168.100.XXX

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

4.10.4 Technical specifications

Image Transfer	Wireless : IEEE802.11a/b/g/n
Wireless frequency range	2.412~2.462GHz, 5.180~5.240GHz;5.745~5.825GHz
Data Transmission Power	14dBm(Max.) @802.11a 15dBm(Max.) @802.11b 14dBm(Max.) @802.11g 14dBm(Max.) @802.11n HT20 13.5dBm(Max.) @802.11n HT40 13.5dBm(Max.) @802.11n AC20/AC40

Wireless Modulation	11b: DSSS (DBPSK, DQPSK and CCK) 11a/g/n: OFDM(BPSK,QPSK,16QAM,64QAM)
Wireless Band	2.4GHz≤40MHz 5.19GHz≤40MHz 5.8GHz≤40MHz

4.10.5 Intended information flow

Detector sends image data acquired to workstation. Workstation sends users' command to detector.

4.10.6 hazardous situations resulting from failure of the IT-network

- failure of completing essential performance
- failure of finishing configuration of product
- The operating system is not compatibility;
- Change or update software failed;
- Compatibility of interface;
- The data transfer protocol error;
- The inconsistent of interface or format leads to data distortion;
- The data output failed;

4.10.7 Warning

connection of main unit to an IT-network that includes other equipment could result in previously unidentified risks.

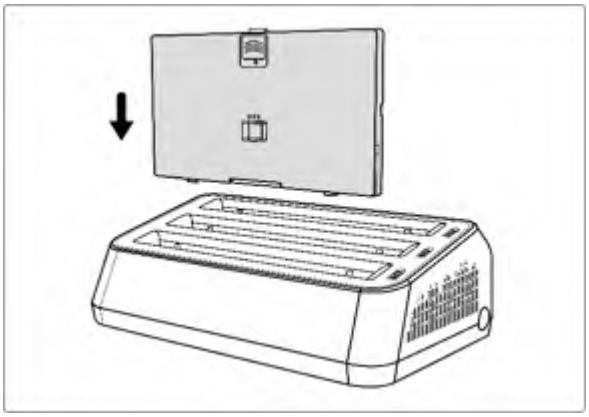
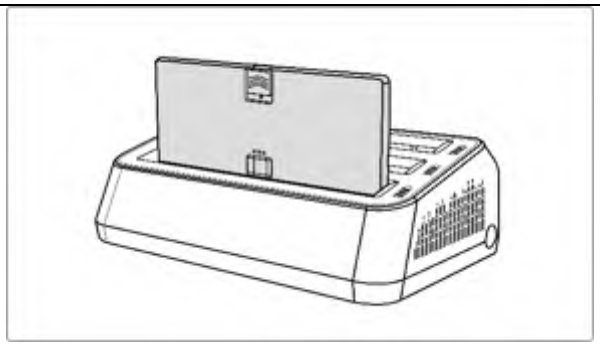
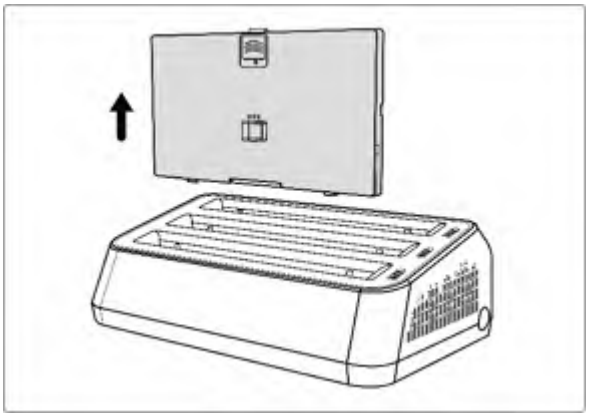
manufacturer of x-ray machine should identify, analyze, evaluate and control these risks.

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

4.10.8 Changes to IT-network include:

- changes in IT-network configuration;
- connection of additional items to IT-network;
- disconnecting items from IT-network;
- update of equipment connected to IT-network;

5 Charger Installation

Insert battery into battery charger Note: insert direction as figure	
Make sure battery is inserted on the bottom of cave	
Unload battery from charger after charging completes.	

6 Regulatory Information

Mars1417XF safety regulatory includes safety of detector, charger and other accessory.

6.1 Information of Registration

REGISTRANT: iRay Technology Co., Ltd

ADDRESS: Rm. 202, Building 7, No. 590, Ruiqing Rd., Zhangjiang East, Pudong, Shanghai, China

TELEPHONE: +86-21-50720560

SERVICE: Service Department of iRay

SERVICE TEL: +86-21-50720560

6.2 Information of Manufactures

COMPANY: iRay Technology Co., Ltd

ADDRESS: Rm. 202, Building 7, No. 590, Ruiqing Rd., Zhangjiang East, Pudong, Shanghai, China

ZIPCODE: 201201

TELEPHONE: +86-21-50720560

6.3 Medical equipment safety standards

◆ Medical equipment classification

Protection type against electrical shock	Class I Equipment, using medical approved adaptor supply Internally powered Equipment, using battery power supply
Protection degree against electrical shock	B Type
Protection degree against ingress of water	IPX4 (Mars1417XF series panel) IPX0 (Charger-KX)
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in situation with flammable anesthetic mixture with air, oxygen or nitrous oxide

	Not suitable for use in oxygen rich situation
The detector is born with two power supply modes(power adaptor and battery pack) and a single way of signal transmission(wireless)	

◆ Safety standards reference

Mars1417XF series wireless detector safety standards cover detector, charger, battery pack and other accessory.

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
EN 60601-1:2006/A1:2013 IEC60601-1:2005/A1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance IEC60601-1:2005
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility disturbances – Requirements and tests IEC60601-1-2:2014
EN 60601-2-54:2009	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
ANSI/AAMI ES60601-1:2005+ Amendment 1:2012+ Amendment 2:2010	Medical Electrical Equipment – Part 1: General requirements for safety and essential performance
CAN/CSA C22.2 No. 60601-	Medical Electrical Equipment – Part 1: General requirements for

1-14	safety and essential performance
ISO 15223-1:2016	Medical devices-symbols to be used with medical device labels, labeling and information to be supplied-Part1:General requirements

6.4 Guidance and manufacture's declaration for EMC

6.4.1 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

6.4.2 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% U_T; 0.5 cycle

		At 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o and 315^o
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0^o
Voltage interruptions	IEC 61000-4-11	0% U_T; 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	Shield/Unshield	Number	Cable classification
AC power cable	1.8m	Unshielded	1 pcs	AC power
DC power cable	3m	Unshielded	1 pcs	DC power

◆ Electro Magnetic Compatibility (EMC)

Mars1417XF series wireless flat panel detector needs special precautions regarding EMC, be installed by iRay or authorized personnel and follows EMC guide in user manual. Mars1417XF series product in use may interfere with portable and mobile RF communication device such as mobile (cellular) telephones. Electromagnetic interference may result in incorrect operation of system and potentially danger situation.

Mars1417XF series wireless flat panel detector should not be stacked with or adjacent to other device. If inevitable, verify detector.

Mars1417XF series wireless flat panel detector conforms to this EN60601-1-2:2007 standard on both immunity and emission.

Accessories, transmitters and cables other than those specified by User Manual or sold by iRay may result in increased emission or decreased immunity of detector.

6.5 Radio Frequency Compliance Information

Country	Item
U.S.A	FCC Part 15.107 Subpart (b) / 15.109(g) Subpart B FCC Part 15 Subpart E 15.407 FCC Part 15 Subpart C 15.247 SAR
European Union	EVSI EN 301 489-1 V1.8.1 (EMC) EVSI EN 301 489-17 V2.1.1 (EMC) EN 300 328 V.1.8.1; EN 301 893 V1.6.1 (RF) EN 62311:2008 (RF Exposure)

6.6 Battery Safety Standards

Standards	Description
UL1642	Component Recognition on the Secondary Li-ion cell
UL 2054:2004 R9.11	Household and commercial Batteries
IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes
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

6.7 Product Label

Mars1417XF-GSI Detector Label

Mars1417XF CSI Detector Label

Battery Charger Label

Battery Label


锂聚合物电池
产品型号： BATTERY-X
输 出： 7.6V 3500mAh/26.6Wh
充电限制电压： 8.7V
执行标准： GB 31241-2014
警告！
Lithium Polymer Battery
Model: BATTERY-X
Output: 7.6V 3500mAh/26.6Wh
Limiting charge voltage:8.7V
Identification Code:2ICP6/62/80
iRay Technology Co., Ltd.
RM.202,Building 7,No.596,Ruqing RD.,
Zhangjiang East, Pudong, Shanghai, China
www.iraychina.com 201X-XX
iRay Europe GmbH
In den Dorfwiesen 14,71720 Oberstenfeld Germany
www.irayeurope.com
CAUTION:
Prohibited to disassemble, hit, squeeze or throw into the fire.
Please charge the battery regularly to avoid over discharge failure.
If severe ballooning, please do not continue to use.
Please do not put battery in high temperature environment.
Be charged only with CHARGER-KX.
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.
SN

7 Trouble shooting

Please refer service manual. If problem unsolved, turn off detector and contact iRay service department (**service@iraychina.com**). We would provide the best service.

8 Product Maintenance

8.1 Regular inspection and Maintenance

Not only for safety of patients, operator and the third parties, but also performance and reliability, detector needs regular inspection at least once a year. If necessary, clean up, calibration and replace components such as fuses, detector cable. There would be case that overhaul is recommended depending on conditions. Contact iRay service office or local iRay dealer for regular inspection or maintenance.

There is a lithium battery in detector whose lifetime is more than 5 years, battery needs to be replaced when time is over. Contact Shanghai IRay after-sales service departments or authorized product distributors.

8.2 Repairment

If problem cannot be solved, contact your sales representative or local iRay dealer. Please provide following information:

Product Name:

Series Number:

Description of Problem: as clearly as possible.

8.3 Replacement support

Performance parts (parts to maintain performance of product) will be stocked for 5 years after discontinuance of production