Digital Flat Panel Detector

Mars1717XF

User Manual

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

This equipment complies with FCC exposure limits set forth for an uncontrolled environment.

Sterilization and Shelf Life

This does not apply.

Notes on usage and management of equipment

1. Read all instructions in the 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 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 dealer.
5. Use dedicated cables. Do not use cables other than those supplied with the product.
6. Do not open the cover of the product without approval.
7. Request your sales representative or local dealer to install this product.

Caring for your environment

This symbol indicates that the product cannot be disposed of with your residential or commercial waste.

Recycling Equipment

Please do not dispose of this product with your residential or commercial waste. Improper handling of this type of waste will have a negative impact on health and 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 official dealer for assistance.

Disclaimer

- Manufacturer shall not be liable for any damage, loss, or injury incurred to the purchaser and the third parties as a result of fire, earthquake, any accident, misuse or abuse of the product.
- Manufacturer shall not be liable for any damage, loss, or injury arising from unauthorized modifications, repairs, or alterations or failure to strictly comply with operation and maintenance instructions.
- Manufacturer shall not be liable for any damage or loss arising from use of any option or consumer goods other than those dedicated as original products.
- It is the responsibility of users and physicians to maintain the privacy of image data and provide a medical care service. Manufacturer shall not be responsible for the legality of image processing, reading and storage, nor shall it be responsible for loss of image data for any reason.
- Information regarding specifications, components, and appearance of the 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

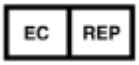
The following symbols and conventions are used throughout the user guide.

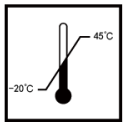
	This symbol is used to identify conditions under which improper use of the product may cause death or serious injury.
	This notice is used to identify conditions under which improper use of the product may cause minor injury.
	This notice is used to identify conditions under which improper use of the product may cause property damage.
	This is used to indicate a prohibited operation.
	This is used to indicate an action that must be performed.
	This is used to indicate important operations and restrictions.
	This is used to indicate operations for reference and complementary information.

Labels and markings on the equipment

The labels and markings on the product are indicated below:

Marking	Description

	Caution: please refer to instructions in the user manual.
	This symbol is used to indicate that equipment has passed CE testing, and it is followed by a CE number.
	This symbol is used to identify the manufacturing series number which is after, below or adjacent to the symbol. The series number of the product is usually composed of 13 digits as shown below: A1A2A3A4 C1C2 M DD Y XXX Numerical Order Year Date Month Version Product Code
	This symbol is used to indicate the name and address of the manufacturer.
	This symbol is used to indicate the name and address of authorized representatives in the European region.
	This symbol is used to indicate the need to consult the user guide for general information.
	Safety Signs: please refer to the user guide for safety instructions.
	Safety Signs: Dangerous voltage levels.
	Stand-by.
	Handle with care.

	FPD is allowed to withstand 100kg on its 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 upright.
	Package symbol: do not roll package.
	Package symbol: this symbol is used to indicate stacking limit number.

	Detector symbol: the device passes IPX4 test
Rx Only	Device is for prescription use only.

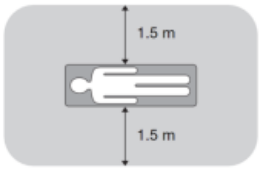
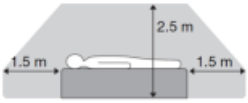
1 Safety Information

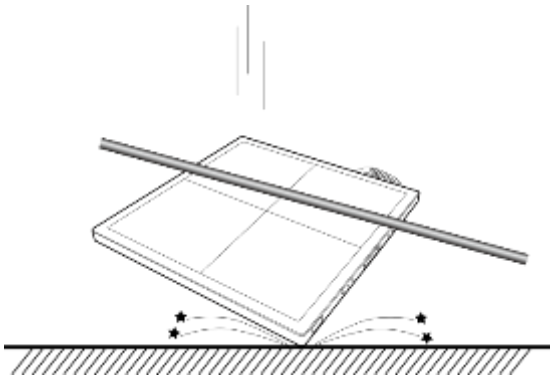
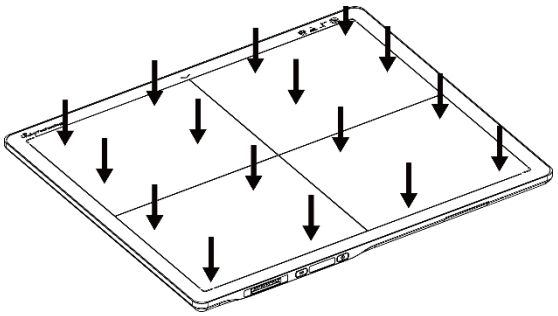
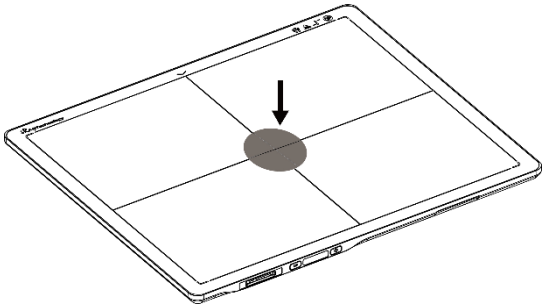
1.1 Safety Precautions

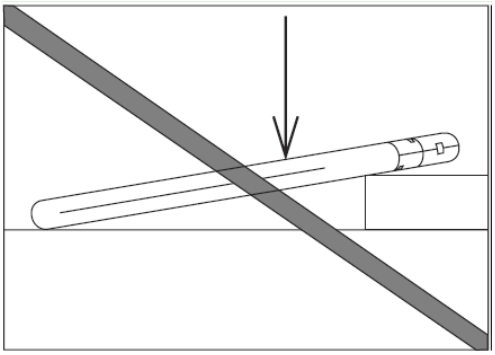
Follow these safety guides and properly use the device to prevent injury and damage.

WARNING	
Installation and environment of use  	**Do not use or store the device near flammable chemicals such as alcohol, thinner, benzene, etc.** If chemical is spilled or evaporates, it may result in fire or electric shock through contact with electric parts inside the device. Also, some disinfectants are flammable. Be sure to take care when using them. **Do not connect the device with anything other than those specified.** Doing so may result in fire or electric shock. **All patients with active implantable medical devices should be kept away from the device.**
Power supply  	**Do not operate using any type of power supply other than those 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 objects such as medical equipment on cables and cords. Do not pull, bend, bundle, or step on the cables and cords to prevent the sheath from being damaged, and do not alter the cables and cords either.** 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 system power when condensation has formed on the device.** 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 a power supply with a 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 the plug, this may result in fire or electric shock. **Be sure to turn off power to each piece of the 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 the device. No modification is allowed.** Doing so may result in fire or electric shock. Also, since the 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 the 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 the 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 being repaired. **Do not put the device and pointed objects together.** It may be damaged. The device is recommended to be used in Bucky.
	**Have the patient take a fixed posture and only let them touch the parts of the device they need to touch.** If patients touch connectors or switches, it may result in electric shock or malfunction.
When problem occurs 	**Should any of the following occur, immediately unplug the power cord, and contact a sales representative or local dealer:** When there is smoke, odd smell or abnormal sound. When liquid has been spilled inside or a metal object has entered through an opening. When the device has been dropped and damaged.
Maintenance and inspection  	**Please turn off the power of the device and unplug the adaptor power cord before cleaning.** **For safety reasons, never use alcohol, ether and other flammable cleaning agent. Never use methanol, benzene, acid and base because they will erode the device.** **Don't dip the device into liquid.** **Please make sure that the device's surface and plug are dry before turning the device 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 the 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 fire. **For safety reasons, be sure to turn off the power to each piece of the device when performing inspections indicated in this manual.** Otherwise, an electric shock may occur.
CAUTION	
Installation and environment of use	**Do not install the device in any of the 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 an air outlet of an air-conditioner or ventilation equipment Close to a heat source such as a heater Where the power supply is unstable In a dusty environment In a saline or sulfurous environment Where the temperature or humidity is high Where there is freezing water or condensation In areas prone to vibration On an incline or unstable area **Take care that cables do not become tangled during use. Also, be careful not to get your feet caught by the cable.** Otherwise, it may cause a malfunction of the device or injury of the user due to tripping over the cable. **Non-medical equipment such as a battery charger and access point cannot be used in the patient's vicinity.**  
Power supply	**Always connect the three-core power cord plug to the 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 be impossible to disconnect the plug in an emergency.** **Be sure to ground the device to an indoor grounded connector. Also, be sure to connect all the grounds of the system together.** **Do not use any power source other than that provided.** Otherwise, fire or electric shock may be caused due to leakage.
Handling	**Do not spill liquid or chemicals onto the device. In case the patient is injured, do not allow blood or other body fluids to contact the device.** Doing so may result in fire or electric shock. In such situation, protect the device with a disposable cover as necessary. **Turn off the power and pull out the plug to each piece of the device for safety when not used.**

CAUTION	
Handling	**Handle carefully.** **Do not submerge the device in water.** **The internal image sensor may be damaged if something hits it or is dropped. If it is dropped, the shock label inside will turn red and the device will not be warranted by Manufacturer.**  **Do not place excessive weight on the device.** Otherwise, the internal image sensor may be damaged and images may be incorrect  Uniform load：150 kg over the whole area of the detector surface  Local load：100 kg on an area 4 cm in diameter Be sure to use the equipment on a flat surface so it will not bend. Otherwise, the internal image sensor may be damaged. Be sure to securely hold the detector while using it in upright positions. Otherwise, the detector may fall over, resulting in injury to the user or patient, or may flip over, resulting in damage to the device.

	 Keep the same load (the same pressure) on the detector when acquiring an 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.

1.2 Notes for Use

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

Before exposure

- Be sure to check the device daily and confirm that it works properly.
- Be sure there is a battery installed in the product to avoid a sudden power off

- Sudden heating of the room in cold areas will cause condensation to form on the 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 an air-conditioner is used, be sure to raise/lower the temperature slowly so that a difference in temperature in the room and the device does not occur, to prevent condensation.
- The detector should be warmed for more than 20 minutes before exposure or updating gain or defect template.

During exposure

- Do not move the power cable during exposure as it may cause image noise or artifacts, or even incorrect images.
- Do not use the equipment near detectors generating strong magnetic fields. Otherwise, it may cause image noise, artifacts or even incorrect images.
- Do not make an exposure within 60 seconds after 4 full range exposures. Otherwise, the image will be incorrect. Do not make an exposure within 30 seconds after a full-range exposure. The larger the dose used, the longer the wait should be before the next exposure.
- During image acquisition, product should not be influenced in a physical or electrical way.

After exposure

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

Disinfecting and Cleaning

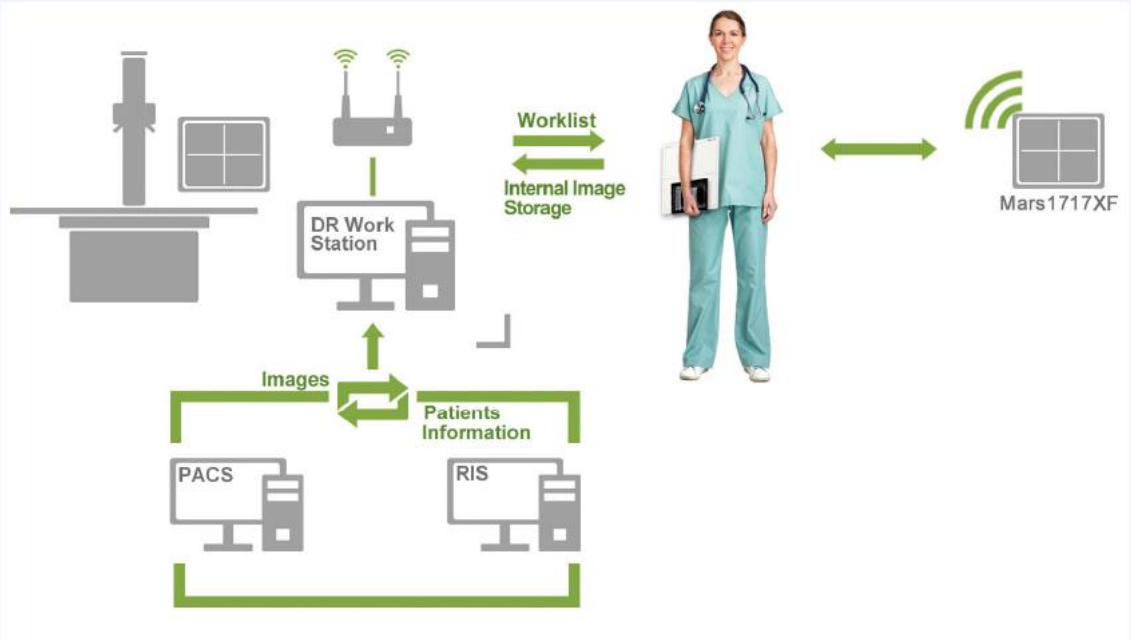
- After every examination, wipe the patient contact surfaces with disinfectants such as Benzalkonium chloride or Benzalkonium bromide, to prevent the risk of infection. For details on how to sterilize the device, consult a specialist.
- Do not spray the detector directly with disinfectants or detergents.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

2 General Description

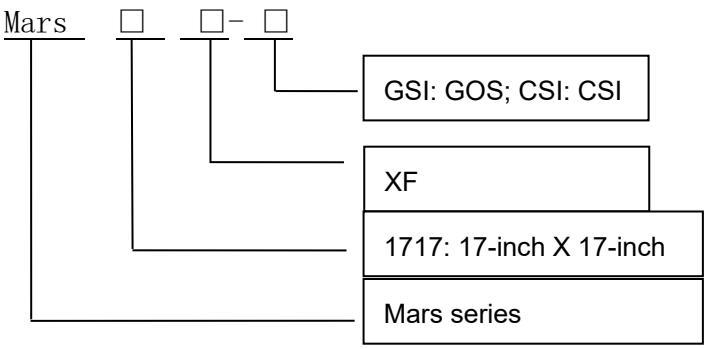
The product is a cassette-size wireless X-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It is developed to provide the highest quality of radiographic images, and contains an active matrix of 2832×2836 with 150um pixel pitch. The detector's scintillator has two options: GOS (Gadolinium Sulfoxylate) and CsI (Caesium Iodide). However, the greatest improvement is wireless communication between the detectors and PC. In addition, it can be powered with a battery for portable panel use.

2.1 Scope

This manual contains information about the Mars1717XF. All operators must read and understand this manual before using the device. All information in this manual, including illustrations, is based on an 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 Lineup



2.3 Characteristics

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

2.4 Intended Use

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

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

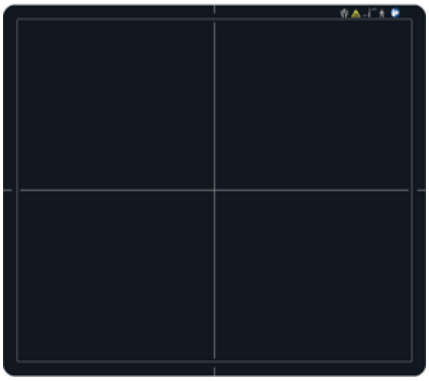
According to product's intended use and results of risk management, essential performance is identified and described as the following:

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

2.5 Product Components

The product is configured with the components below

Item	Description

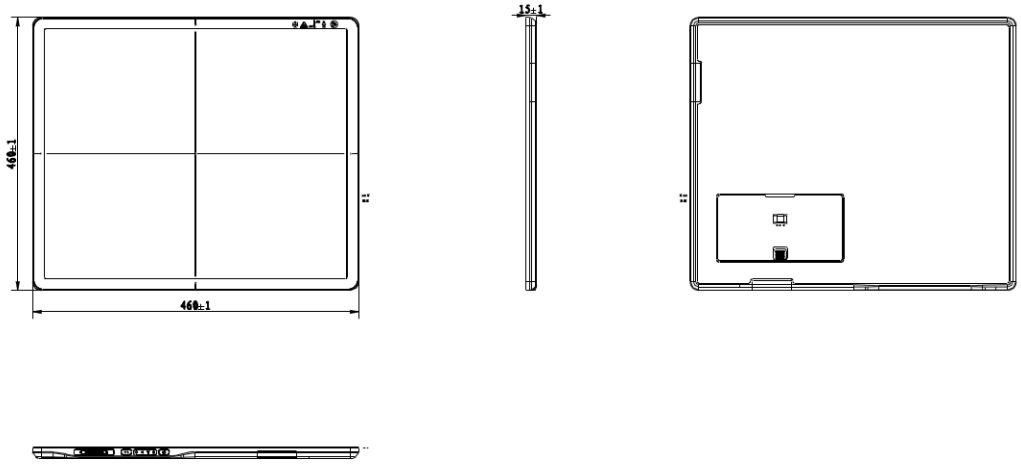
Mars1717XF Detector		Mars1717XF GSI/CSI
Medical adapter for detector and battery charger		24V (DC) power adapter
Battery pack		7.6V battery pack
Gigabit ethernet cable		Ethernet cable for wireless router
AC power cable		AC cable for adapter

Battery charger		Battery charger
User Manual		Paper print
CD-ROM		User Manual Service tool

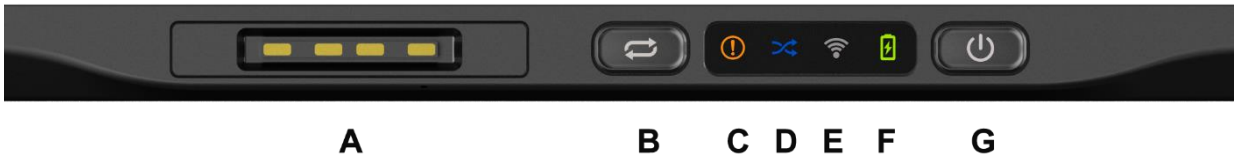
Note: The product package may be different based on requirements.

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

2.6.2 Battery 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

2.6.3 Battery Charger

Item	Item	Description
A	Battery Slot	3 batteries inserted
B	Capacity Indicator	The indicator definition is as below
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

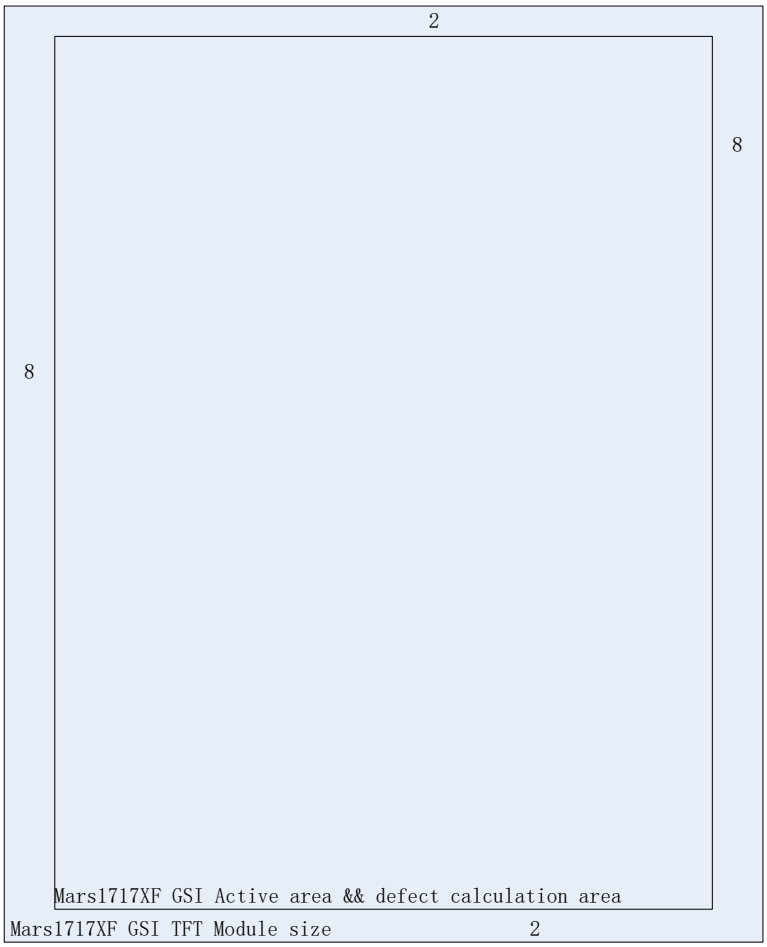
2.7 Product Specifications

2.7.1 Detector

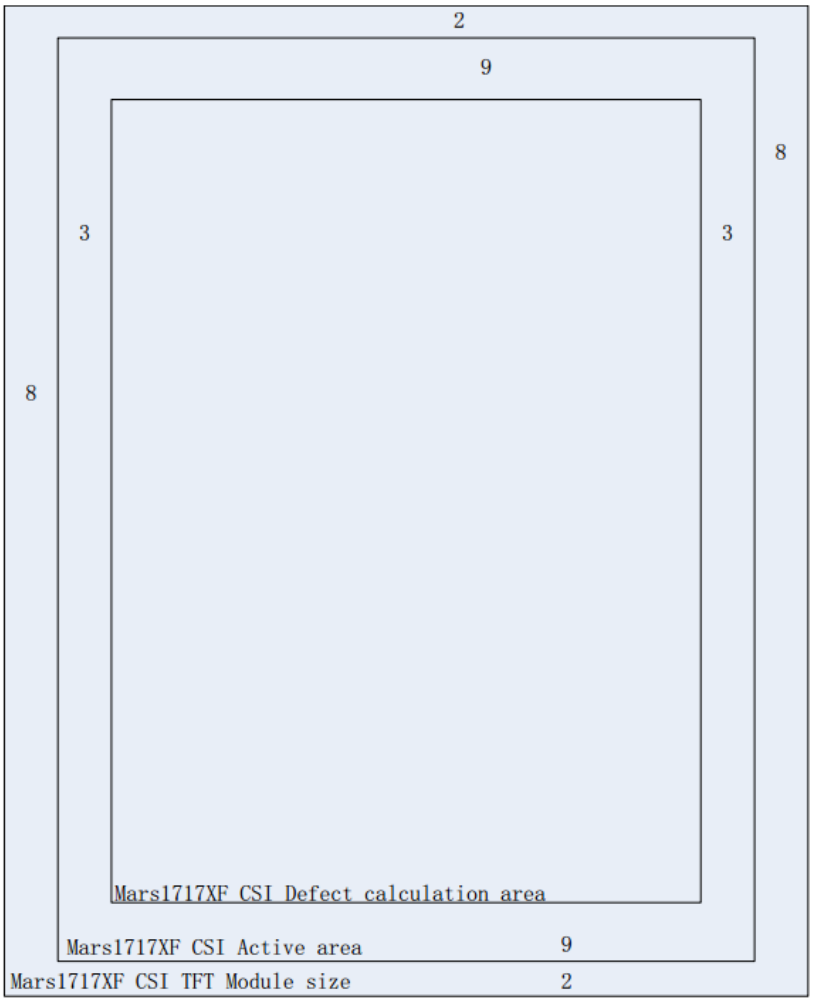
Item	Specification
Model	Mars1717XF-GSI (GOS) Mars1717XF-CSI (CsI)
Pixel Size	150 μm
Effective Array	2832 x 2836 (Note)
Effective Area (H x V)	424.8mm x 425.4mm
Greyscales	16 bit
Image Transfer	Wireless: IEEE802.11a/b/g/n
Wireless Frequency Range	2.412~2.472GHz, 5.18~5.22GHz; 5.745~5.85GHz
Data Transmission Power	13dBm (Typ.) @802.11a 16dBm (Typ.) @802.11b

	14dBm (Typ.) @802.11g 13dBm (Typ.) @802.11n HT20 11dBm (Typ.) @802.11n HT40 16dBm@2.4GHz 13dBm@5.8GHz
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

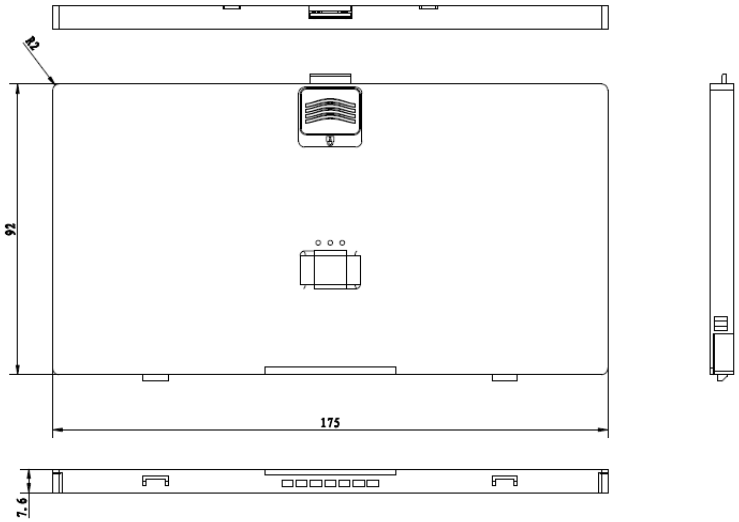
Note: The Mars1717XF-GSI's active area and defect calculation area is 2832 x 2836; the TFT module size is 2848 x 2840. Please see figure below



The Mars1717XF-CSI defect calculation area is 2826 x 2818, the active area is 2832 x 2836 and the TFT module size is 2848 x 2840



2.7.2 Battery



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

2.7.3 Battery Charger

Item	Specifications
Model	Charger-KX

Simultaneous Charging	3 battery packs
Full Charging Time	2.5 hours

2.7.4 Environment

	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)

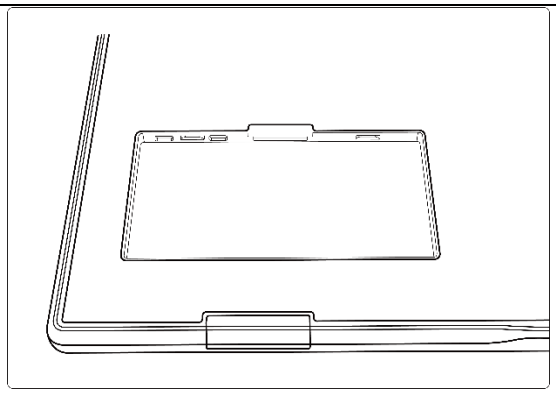
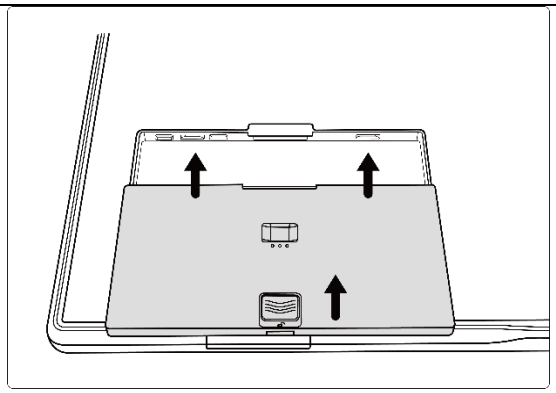
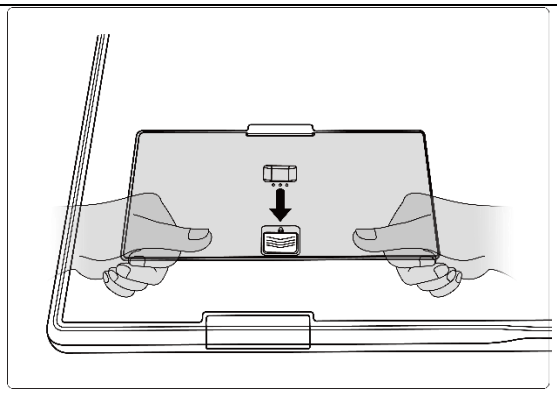
- Detectors should operate at altitudes of not more than 3,000m; the requirement is only for the detector.
- If storing with a battery, the temperature should be in the range of -20℃~45℃ when the expected storage time is less than 3 months. For -20℃~25℃, the storage time is 12 months.

3 Preparation

3.1 Detector Installation

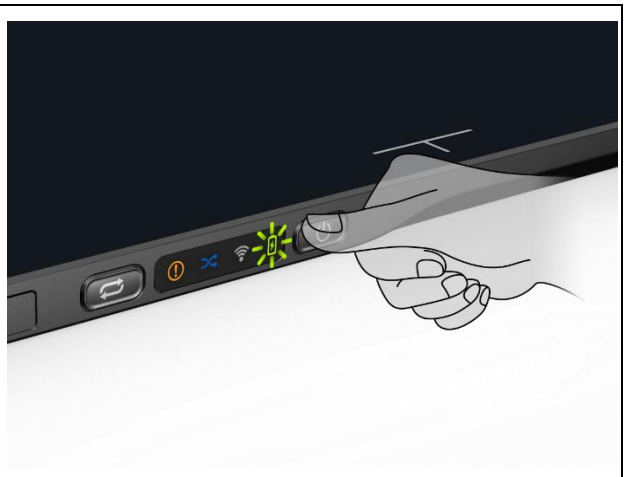
3.1.1 Attach Battery Pack

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%).	
Slide the battery lock lever.	

3.1.2 Booting Up

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

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. When the detector is powered on, the user presses the button for 4 seconds to shut down the detector. On the other hand, it can also be used as a reset internal control IC when the button is activated for 8 seconds.	

After booting up, users can check the indicator of the 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 mode

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 enabled
Green ON		Wired connection is enabled (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 prohibited
Green ON		Ready for exposure
Orange blinking		Safety Mode
Orange ON		Fatal Error

Green blinking		Wireless configuration reset

3.1.3 Adapter

The detector supports an externally powered It gets CB certificate No. SG PSB-MD-00005 and NRTL certificate No. U8V 093768 0016. 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 the safety and function requirements of the detector, standard components are recommended.

	AC Adapter

4 Operation

The detector provides user SDK for integration into the DR system. Additionally, it also provides application demonstration, i.e., iDetector.

4.1 Main Operation

The detector mainly acquires X-ray images. More importantly, the detector should build

synchronization with the X-ray generator, i.e., Software Mode and AED Mode.

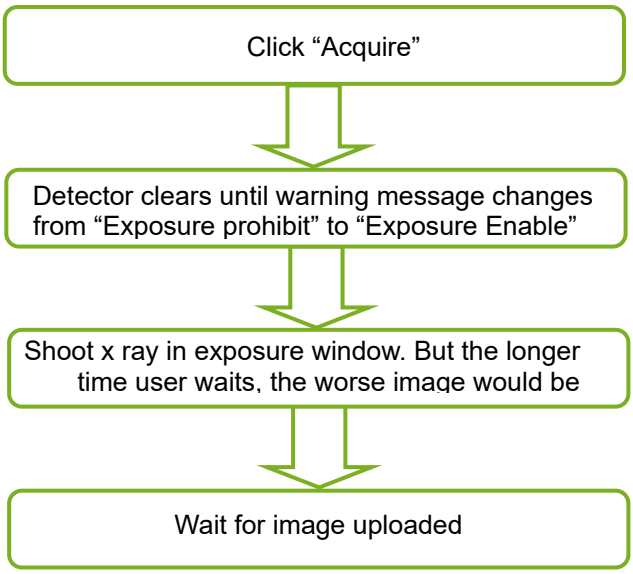
4.1.1 Software Mode

4.1.1.1 Block Diagram

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

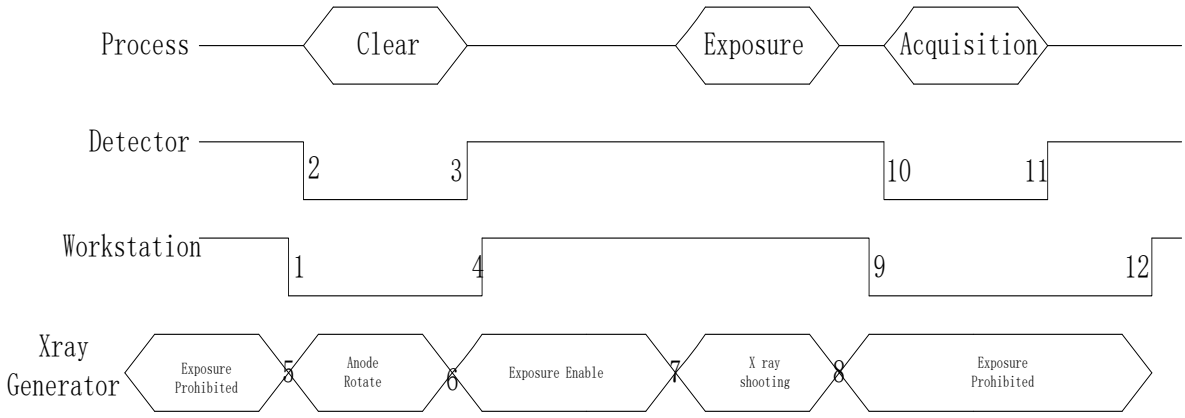
The workstation hosts the PC device installed with FDR SE Console or iDetector. Chapter 3.3 describes how to establish connection between detectors and the workstation. In Software mode, the workstation does not control the X-ray generator; users decide when to take an X-ray.

4.1.1.2 Work flow



4.1.1.3 Timing Setting

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



1. Workstation receives “Acquire” request, send command “Clear” to detector.
2. Detector receives “clear” from workstation and begins 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 takes 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 taking X-rays.
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 images.

Images received will be preview images; preview images are those without much correction which causes some stripes; they cannot be used for final diagnosis.

The detector will make another dark image acquisition for offset correction. If Hardware Post offset and Hardware calibration are selected, the detector uploads the processed image to the workstation after offset, gain and defect calibration.

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

Note: If the wireless condition is bad, the detector cannot send even one package in 30s. It will stop trying to send image packages. Users have to retrieve images from the detector when the wireless condition is good enough.

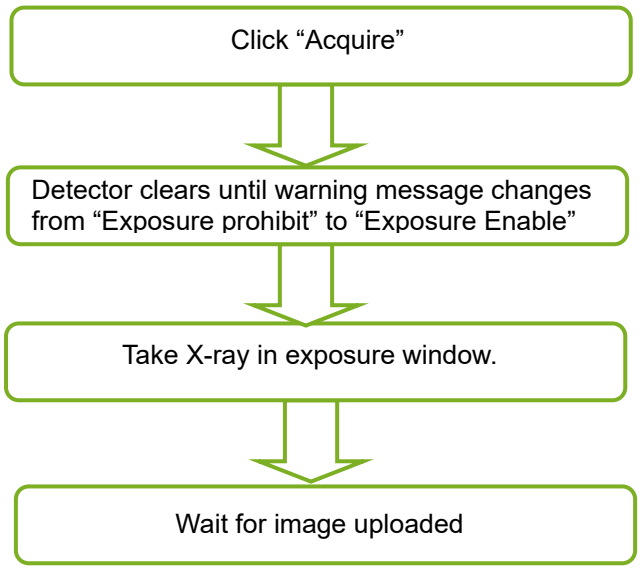
4.1.2 AED Mode

4.1.2.1 Block Diagram

Please see the figure below for general features. AED mode is configured by selecting “inner” in Trigger mode and “cycleacq” in inner trigger subflow.

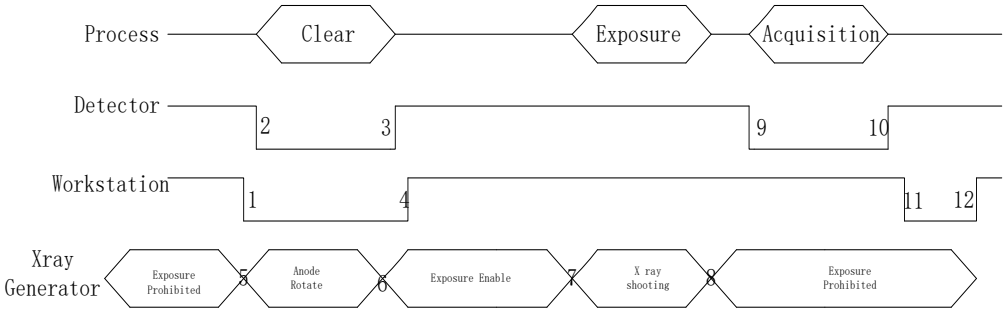
The workstation hosts the PC device installed with FDR SE Console or iDetector. Chapter 3.3 describes how to establish the connection between detectors and the workstation. In AED mode, the workstation does not control the X-ray generator; the user decides when to take the X-ray.

4.1.2.2 Work Flow



4.1.2.3 Timing Setting

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



1. Workstation receives “Acquire” request and sends “Clear” to detectors.
2. Detector receives “clear” from workstation and begins 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 takes 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 taking X-rays.
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.

Images received will be preview images. Preview images are those without much correction which causes some stripes; they cannot be used for final diagnosis.

The detector will make another dark image acquisition for offset correction. If Hardware Post offset and Hardware calibration are selected, the detector uploads the processed image to the workstation after offset, gain and defect calibration.

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

Note: If the wireless condition is bad, the detector cannot even send one package in 30 seconds. It will stop trying to send an image package. Users have to retrieve images from the detector when the wireless is good enough.

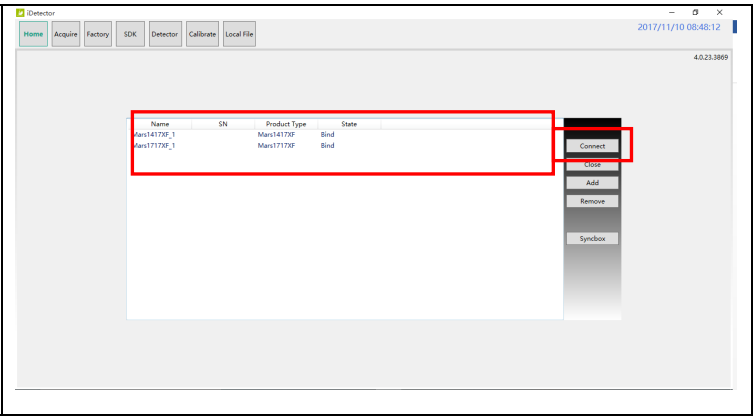
4.1.2.4 Abnormal Action

If users do not want to take an X-ray, it is possible to cancel the exposure window manually.

4.1.2.5 Exposure Window

The 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	

Notes:

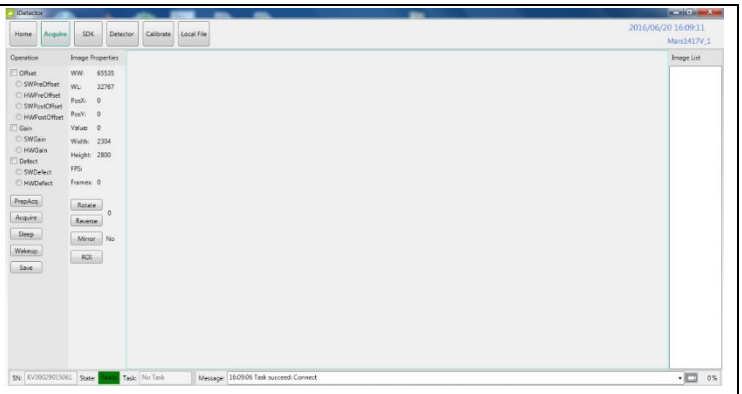
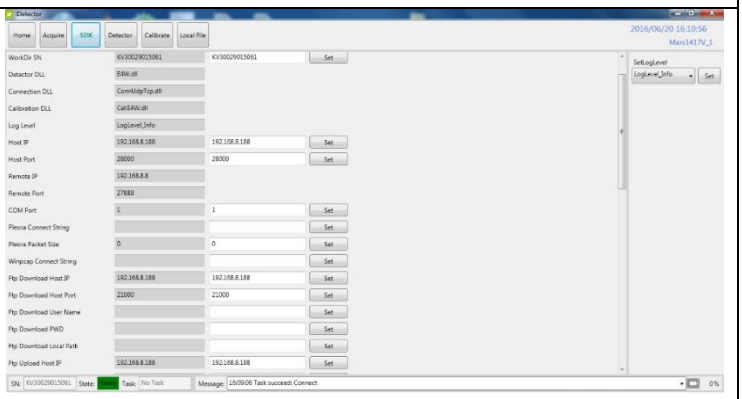
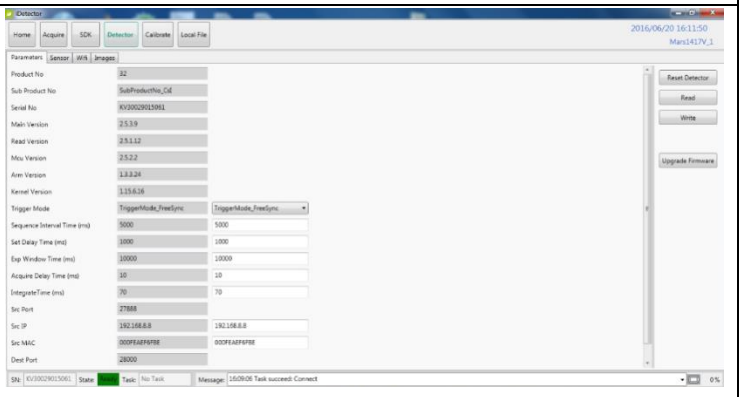
1. Users must re-connect the detector with a different IP address when changing the connection from a different net card.

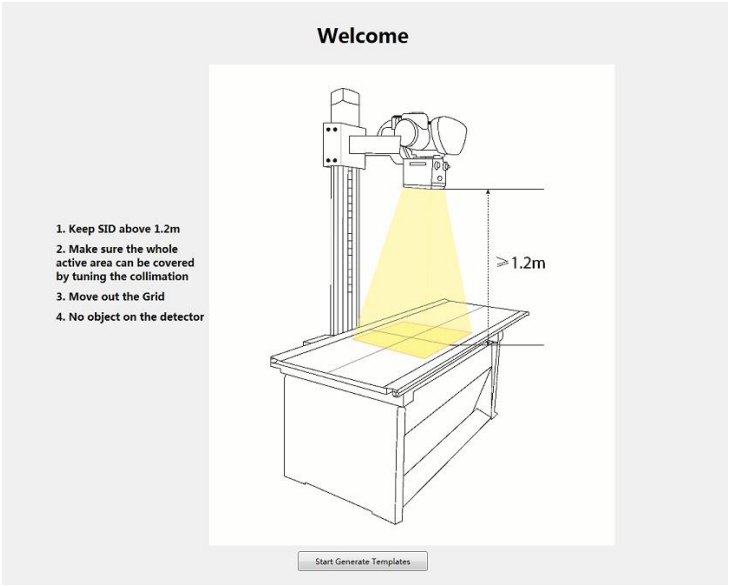
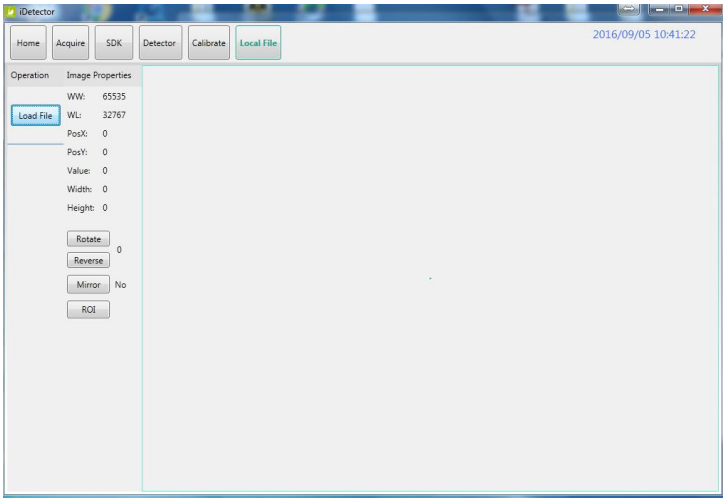
2. Switching between wired and wireless connection does not need any extra operation.

3. The rule of multi-share is based on the IP address. The second terminal with a different IP address is not allowed to operate when the first is connected. If there is no command transmission between the detector and the workstation (FDR SE Console or iDetector) over 5 minutes, the 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 so on	
“SDK” module: IP address, MAC address and so on	
“Detector” module: Trigger module, wireless configuration and so on	

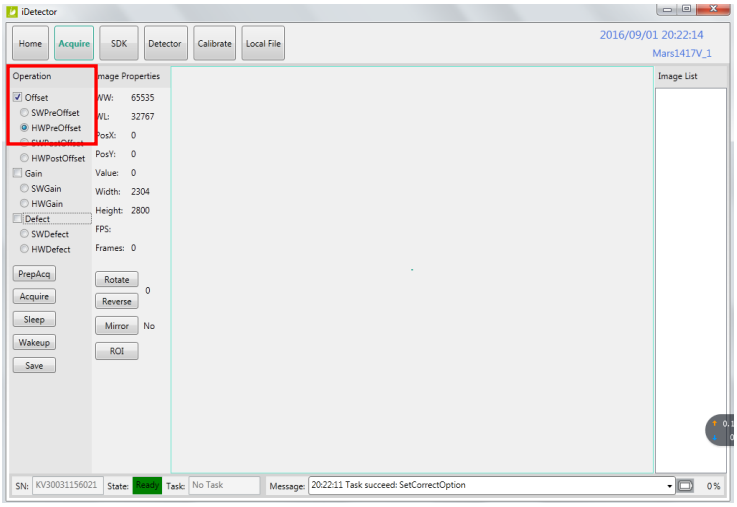
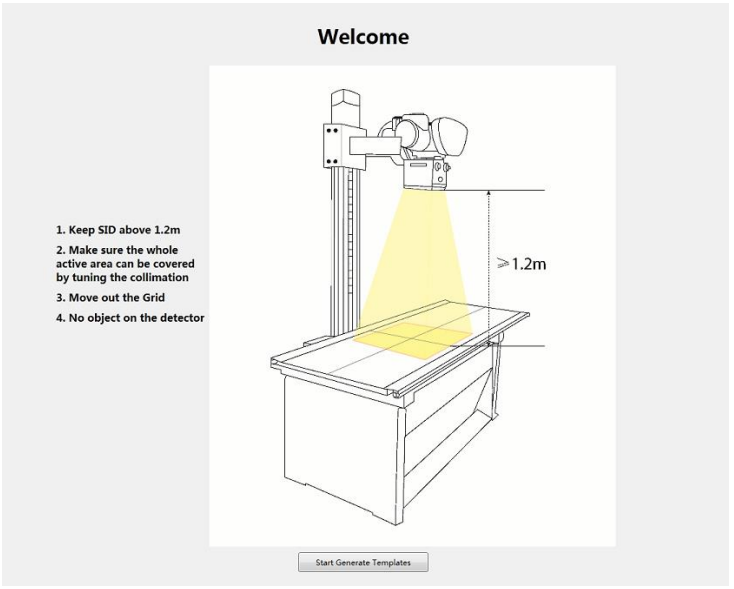
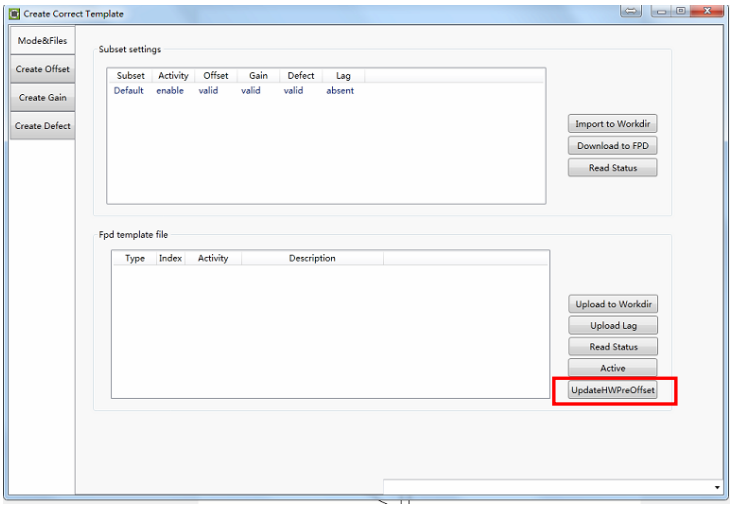
“Calibrate” module: Template generation and management.	
“Local File” module: Read raw or dcm image	

4.4 Correction Template Generation

Manufacturer 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 every 6 months.

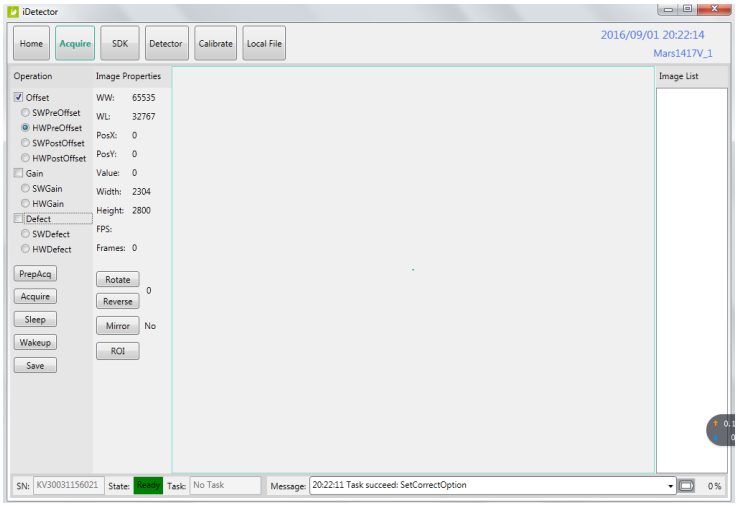
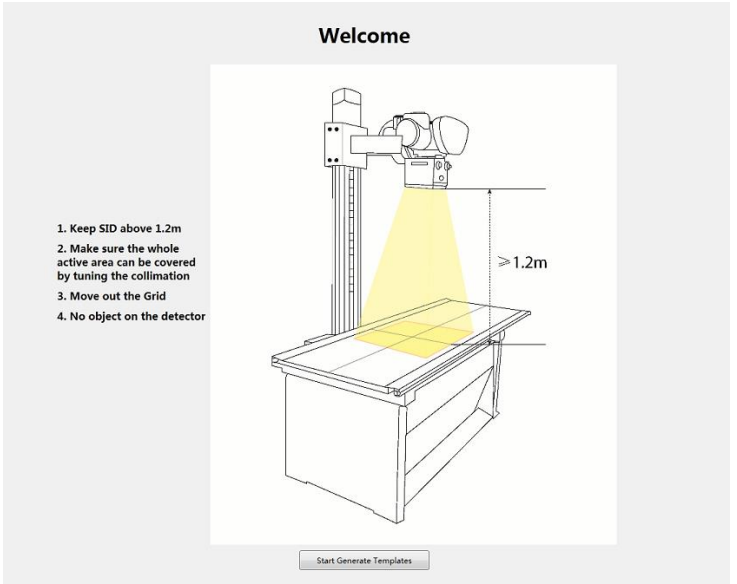
4.4.1 Pre-offset Template Generation

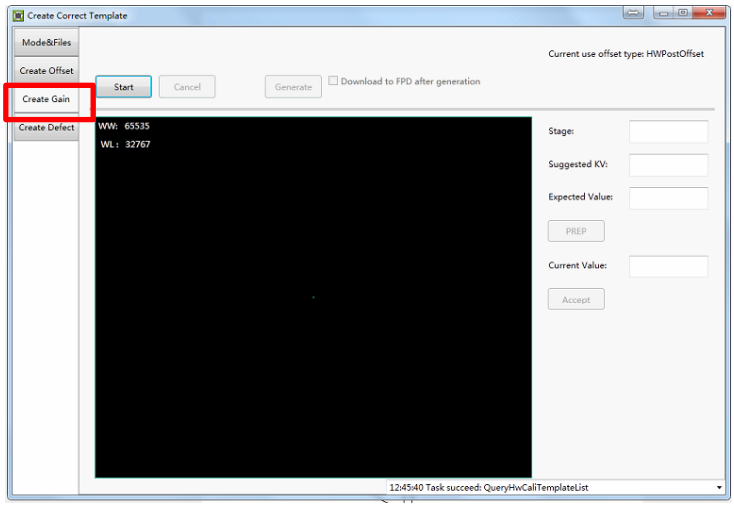
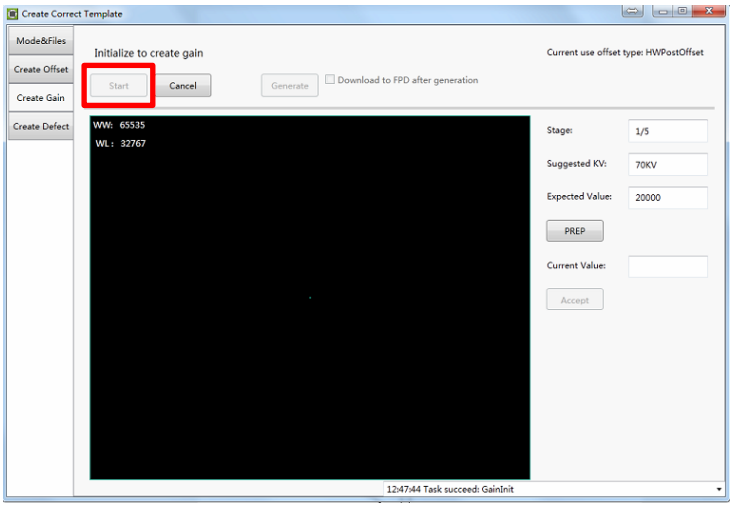
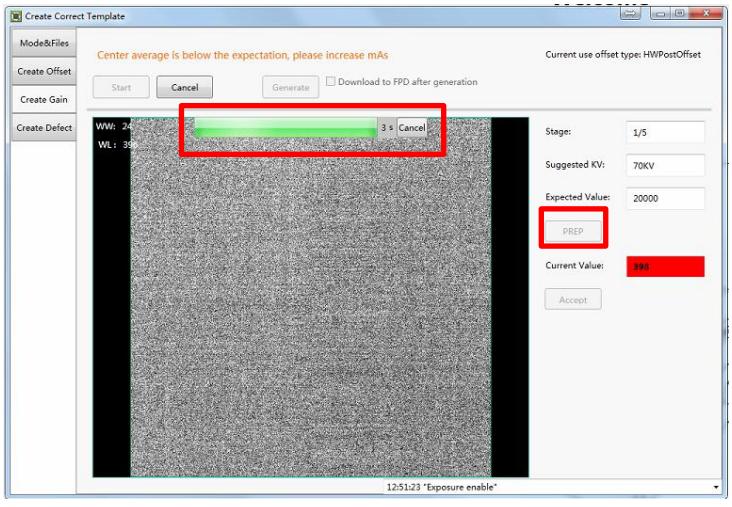
The pre-offset template is necessary for preview image. See below

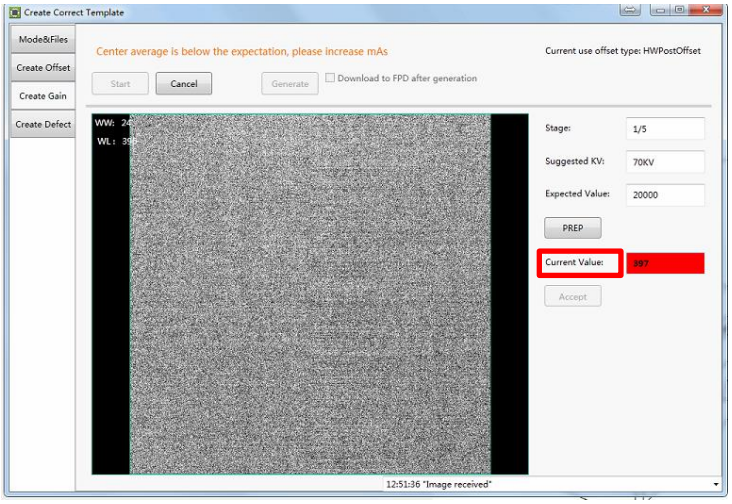
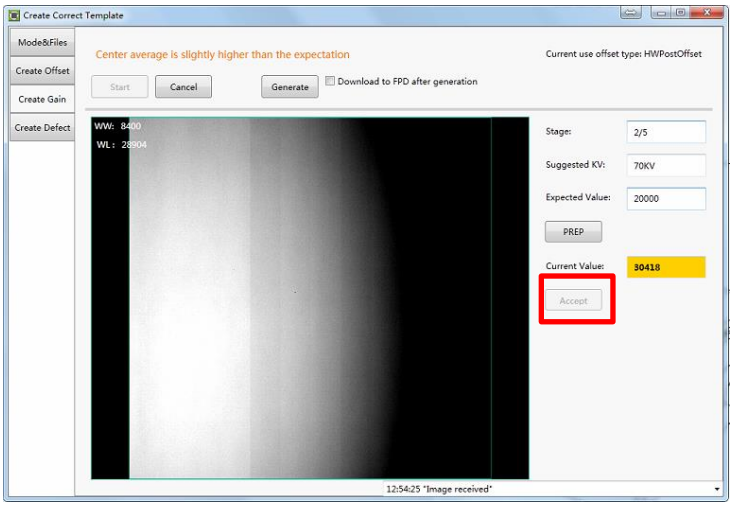
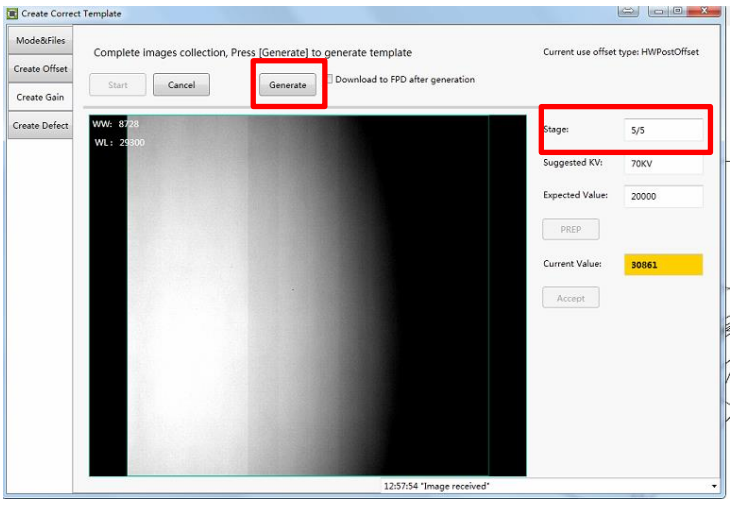
Go to “Acquire” module, choose “HWPostOffset”	
Go to “Calibrate” module, click “Start Generate Templates”	
Click “UpdateHWPreOffset”, wait until image acquisition ends	

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 to count down. Before window ends, take X-ray.	

There will be a prompt in the region of the current value if the dosage is incorrect. **(Note 1)** Change dosage and exposure again until image is accepted.	
Click “Accept” if box is green, Click “PREP” to start another X-ray take.	
Gain calibration template needs 5 X-ray images. After 5 images acquired, click “Generate”, wait until “Task succeed:FinishGenerationProcess”	

Note:

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

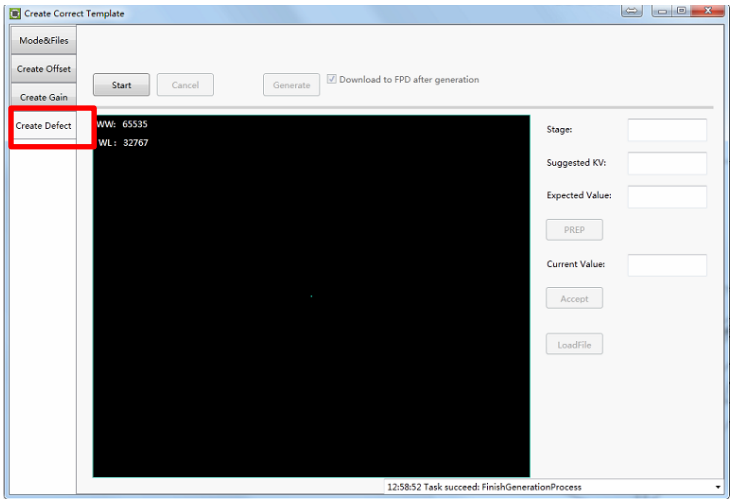
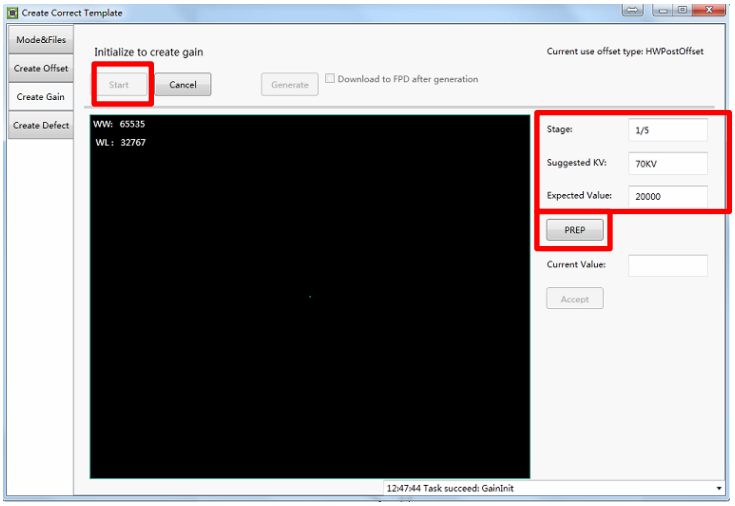
   Green means image meets requirements.

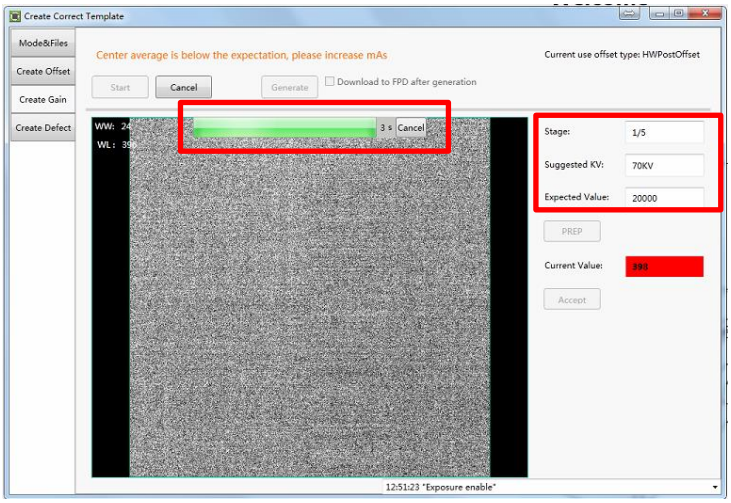
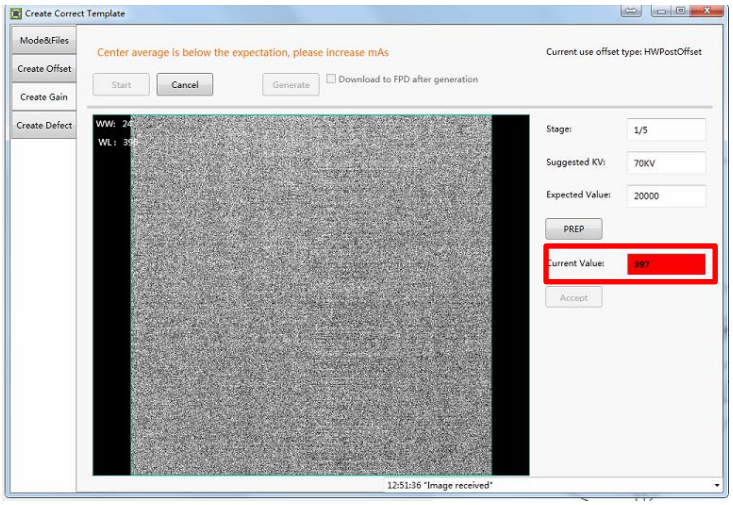
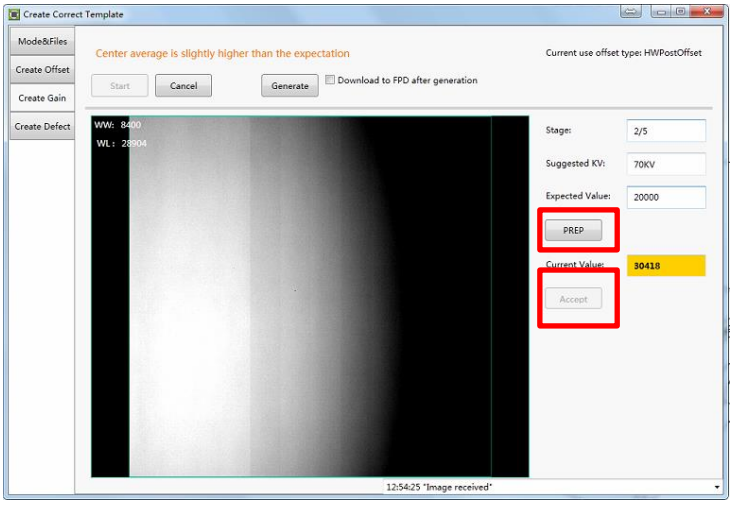
Yellow means image does not meet requirements, but can generate template.

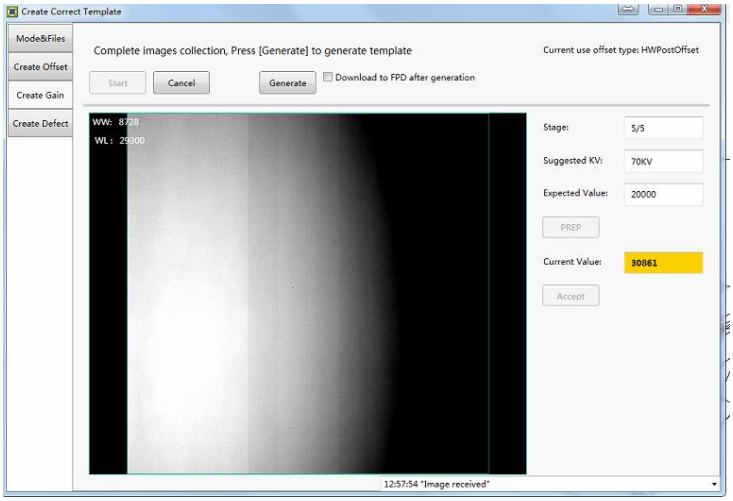
Red means image does not meet requirements, cannot generate template, must be taken again.

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 to count down. Before window ends, take X-ray.	
There will be a prompt in the box if the 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 take.	

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.

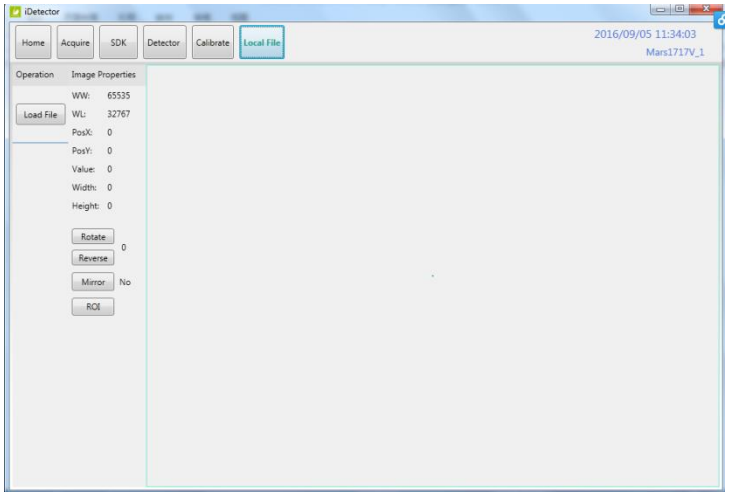
   Yellow means image does not meet requirements, but template can be generated.

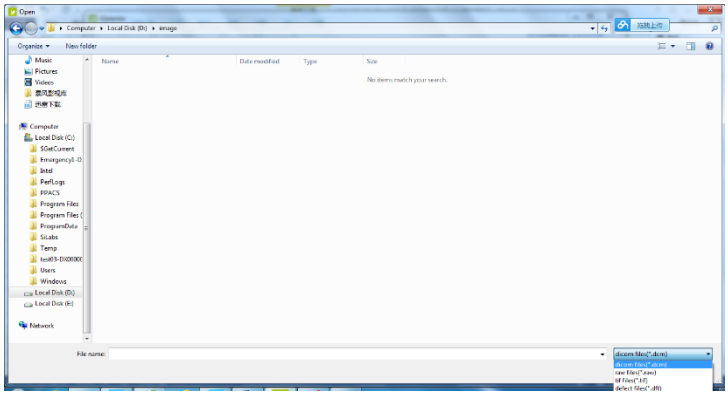
   Red means image does not meet requirements, template cannot be generated, must take another shot.

4.5 Image Check and Upload

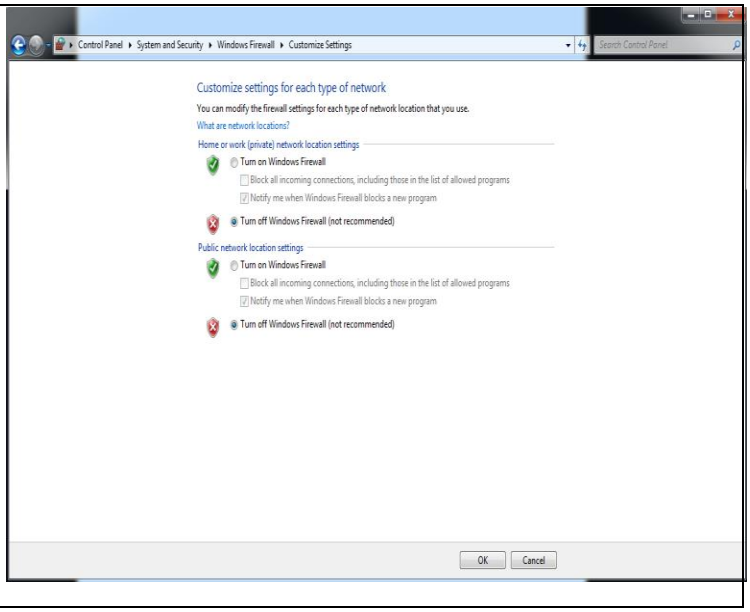
“Local Image Check” defines the function checking image saved in the workstation (FDR SE Console or iDetector). “Panel Image Upload” defines function uploading images stored in the detector.

4.5.1 Local Image Check

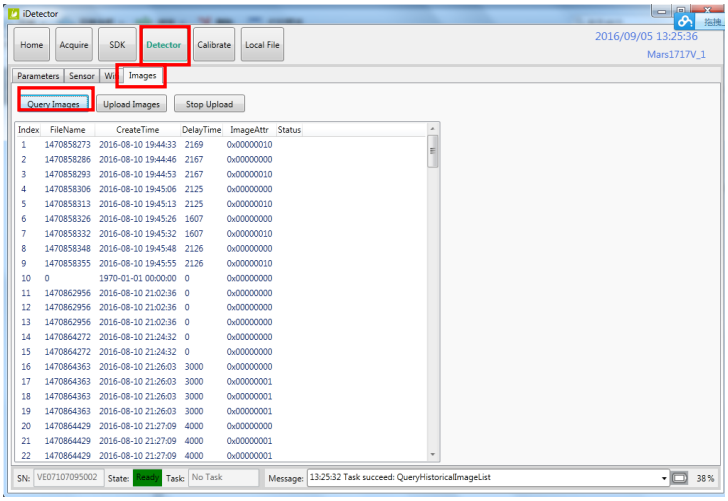
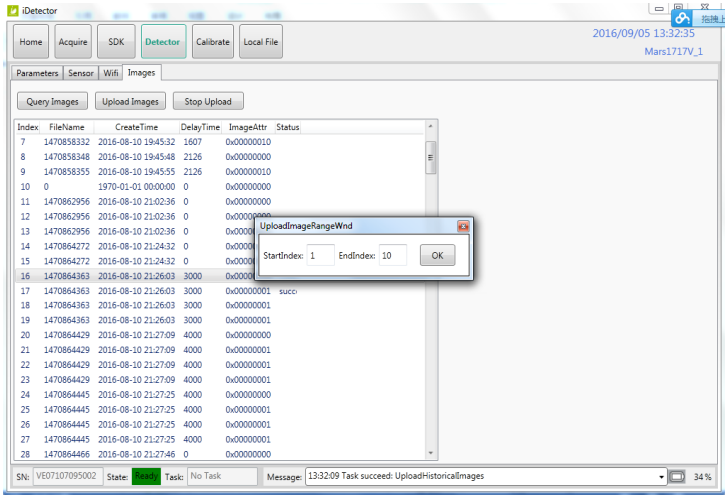
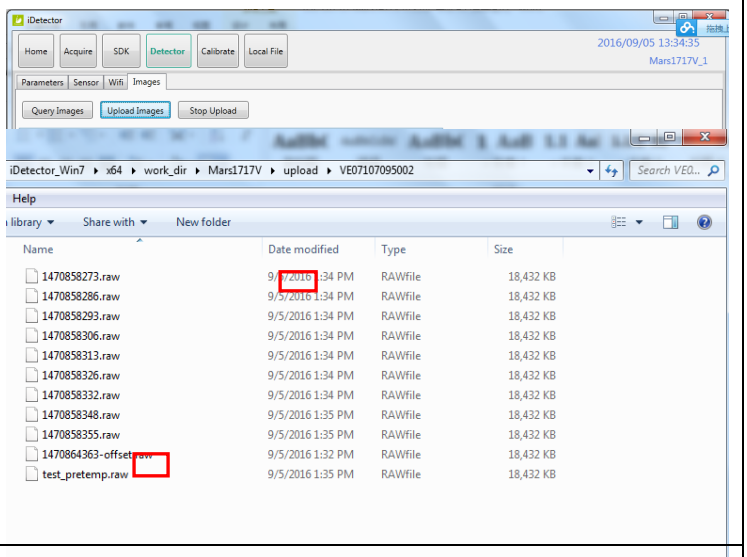
Choose “Local File”	

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

4.5.2 Panel Image Upload

Double-check firewall is closed	

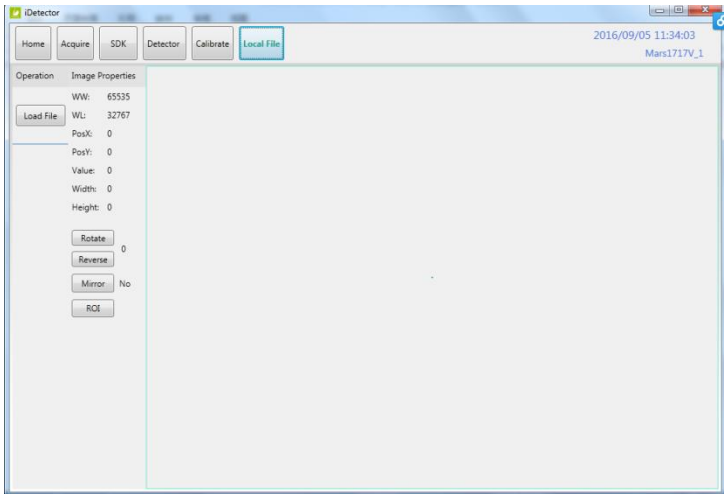
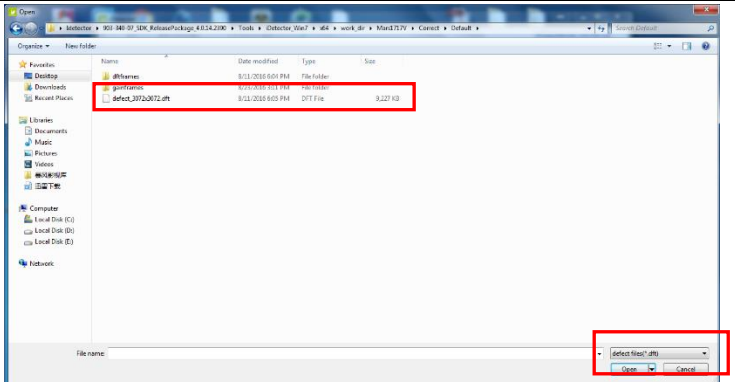
Panel Image is uploaded as below.

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 \ Mars1717XF_Client \ upload \serial number"	

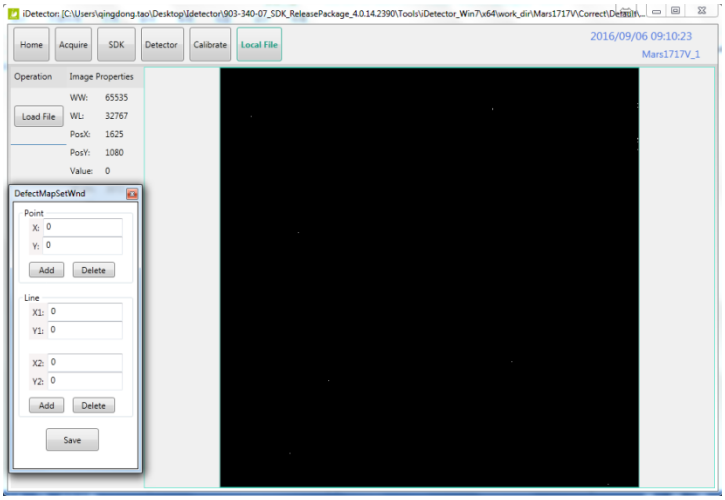
4.5.3 Defect Template Check and Modification

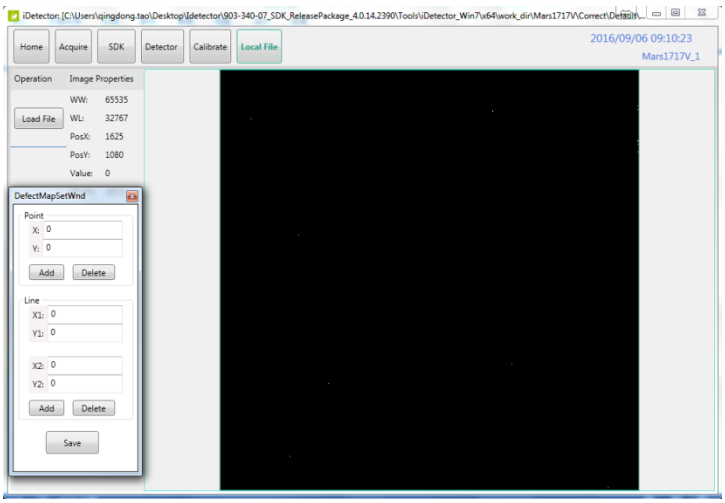
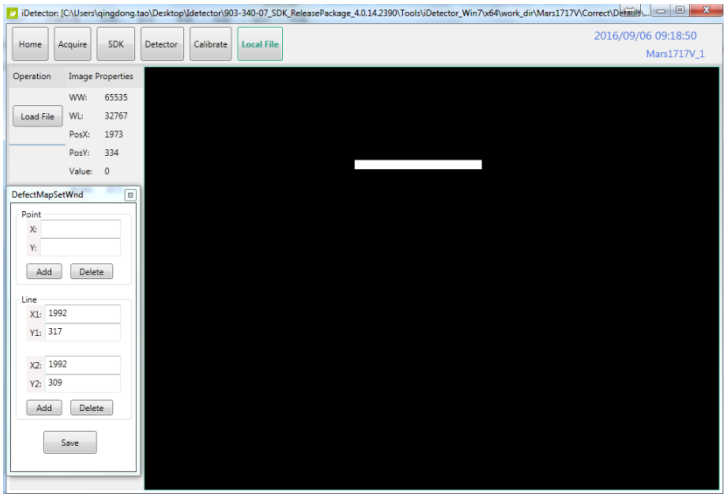
iDetector provides function checking defect template. If the defect template has updates, the user can add and delete defect pixels or lines.

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

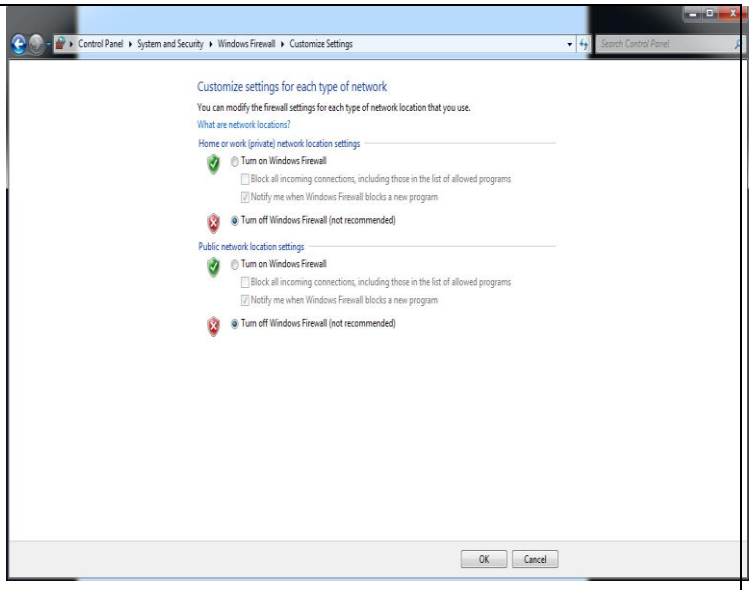
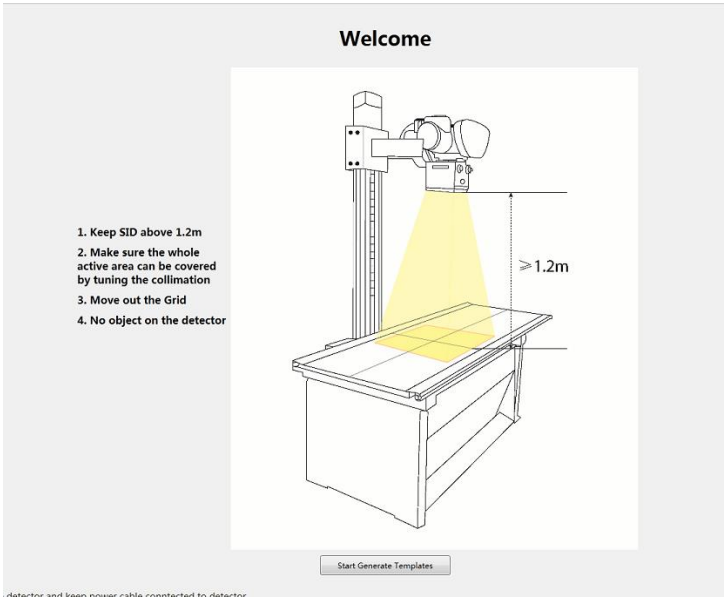
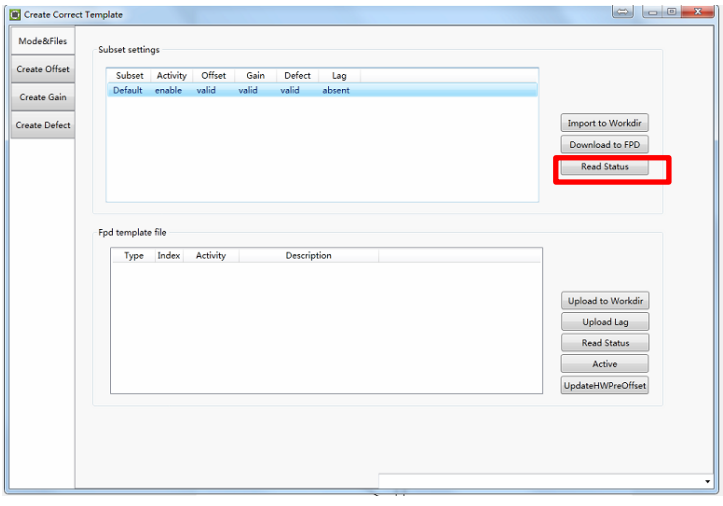
Open defect template	

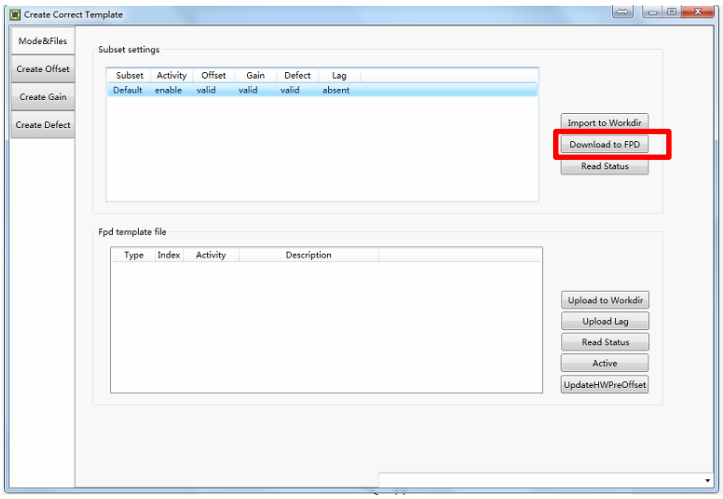
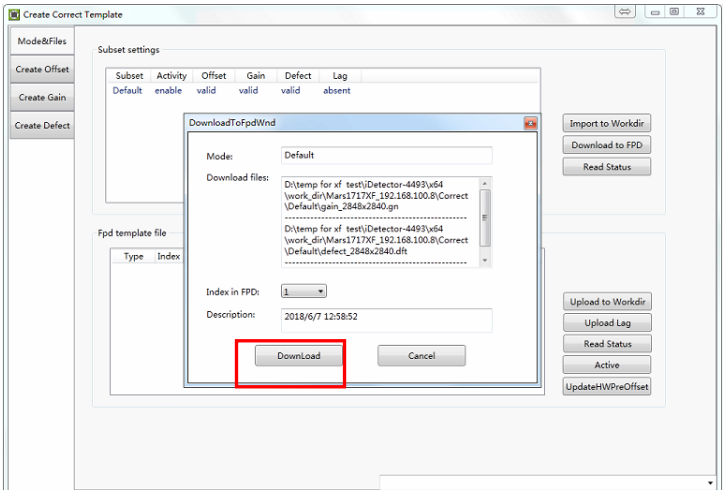
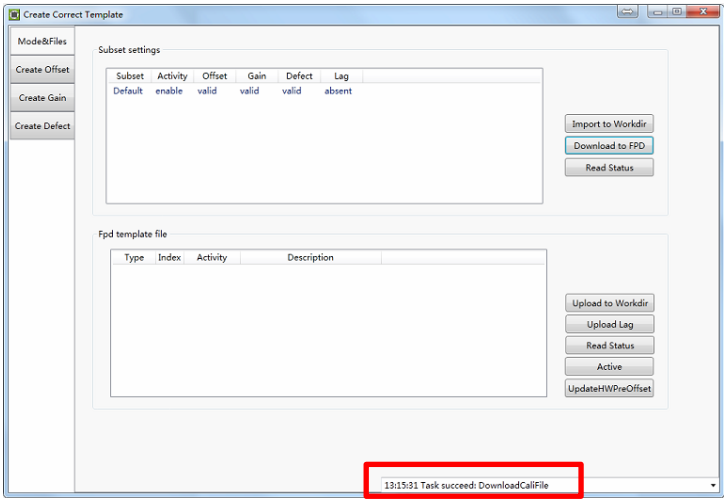
If there are new defect pixels, type in coordinates, click "Add". If defect templates have dummy lines, type in coordinates, click "Delete".	
If there are new defect lines, type in starting and ending coordinates, click "Add". If defect templates have dummy lines, type in coordinates, click "Delete".	
Click "Save" to save modified defect template.	

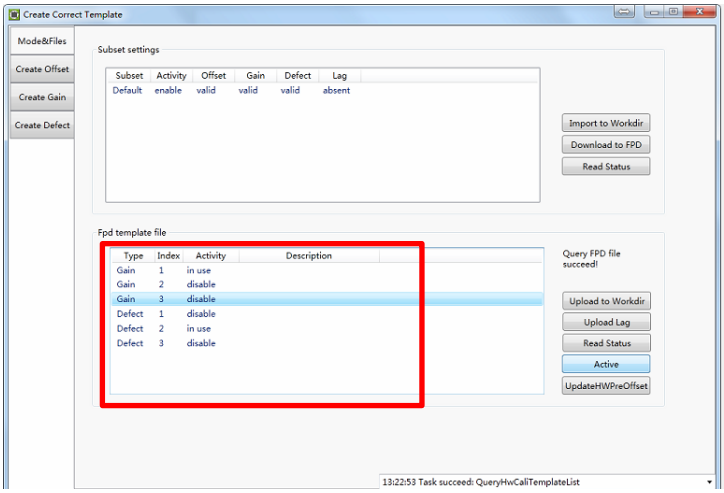
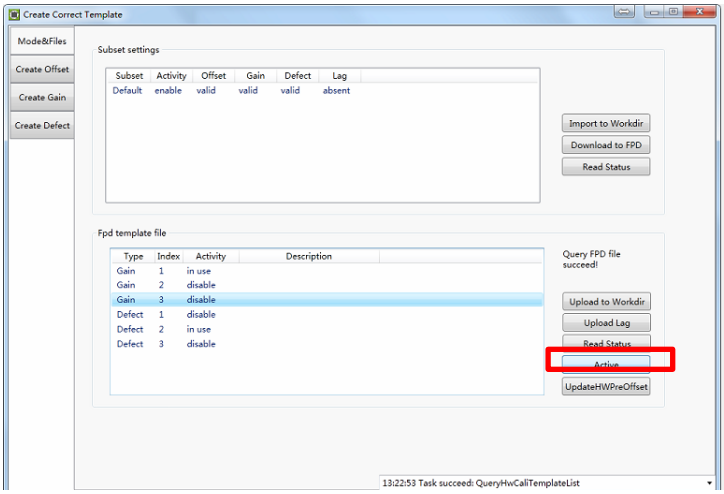
4.6 Correction Template Management

4.6.1 Template Synchronization

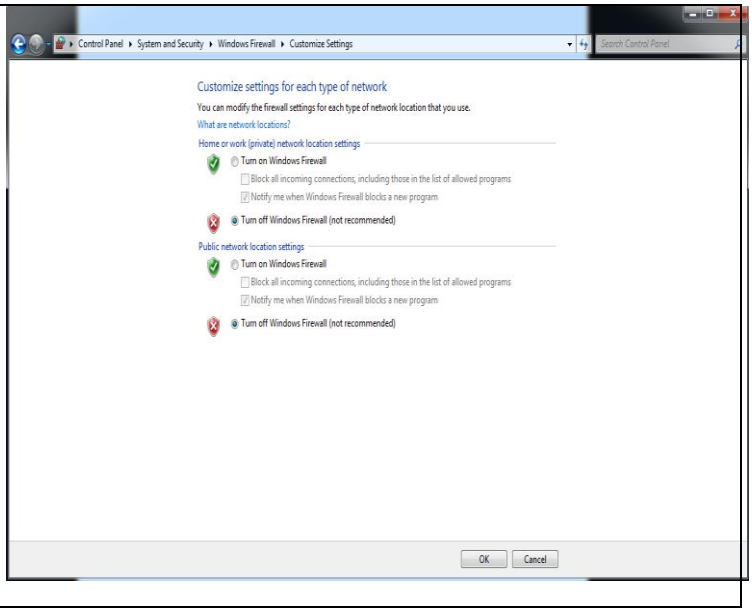
The detector supports correction template storage, which means templates can be transmitted not only from the detector to the workstation(FDR SE Console or iDetector), but also from the workstation(FDR SE Console or iDetector) to the detector.

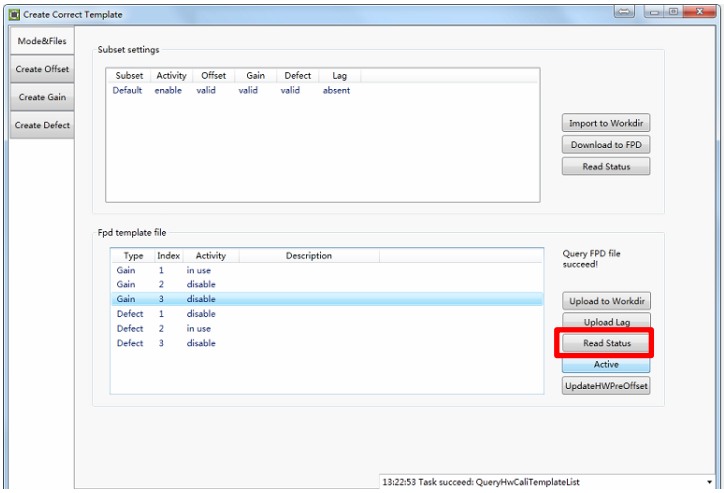
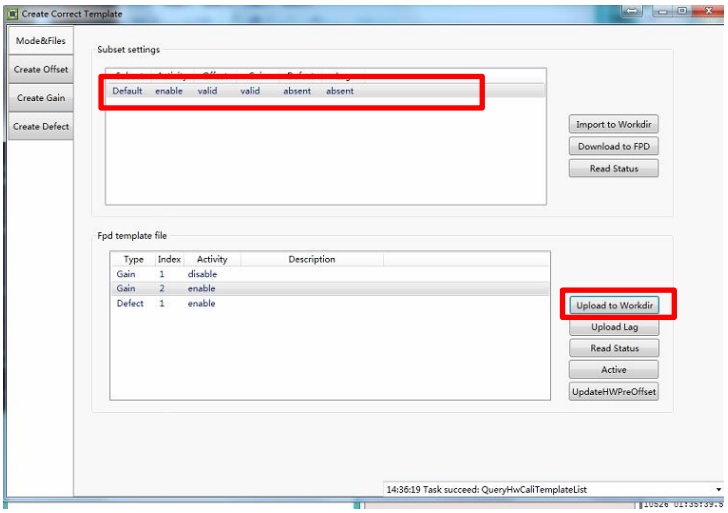
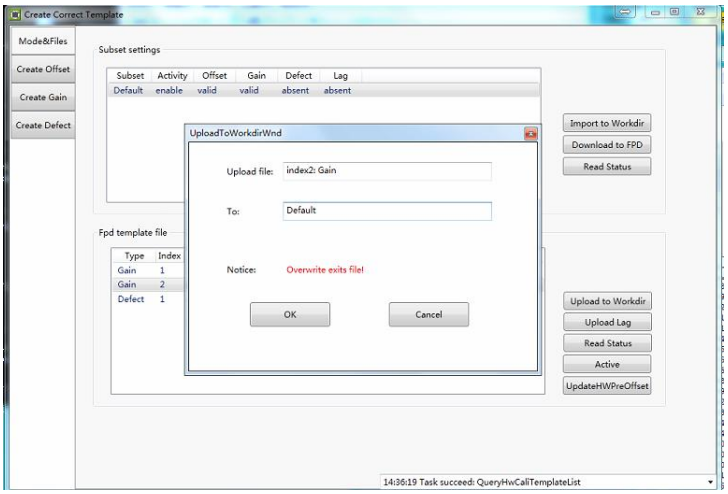
Make sure the firewall is turned off	
Choose “Calibrate”, Click “Start Generate Templates”	
Click “Read Status” besides “Subset settings”	

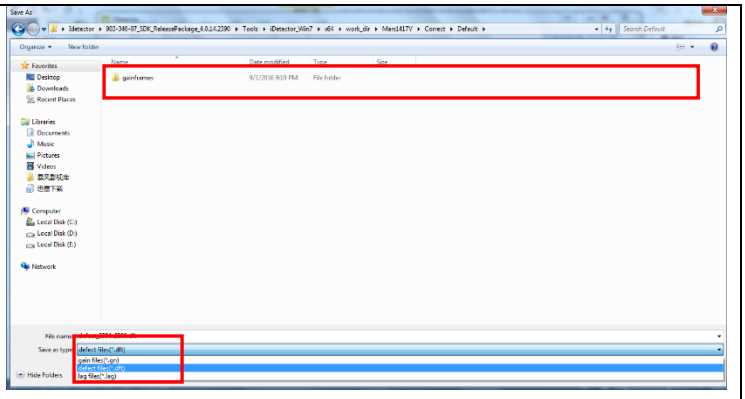
Click the template to be downloaded Click “Download to FPD”	
Check whether information is right. Change Index in FPD if necessary. Click “Download”.	
Wait until “Task succeed: Download CaliFile”	

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	

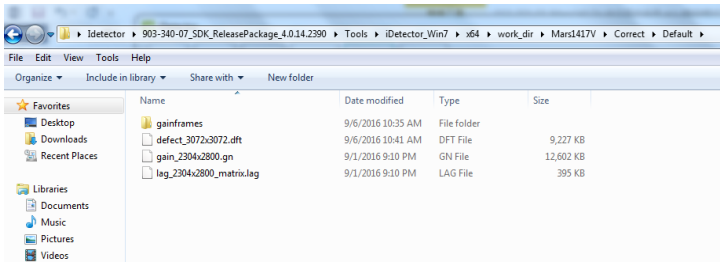
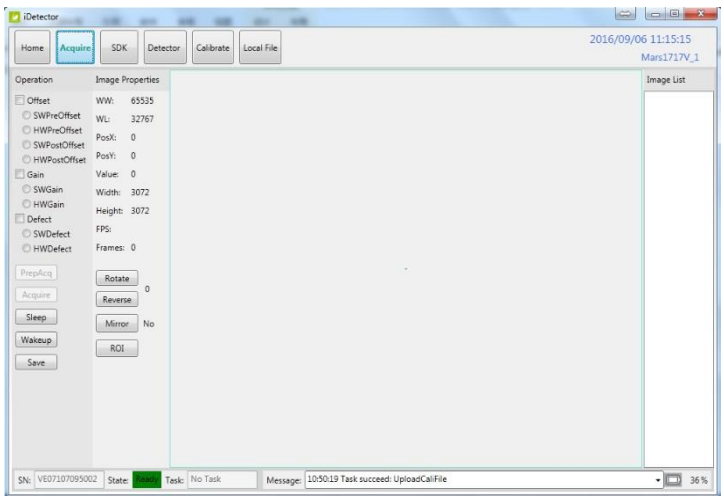
Choose “Calibrate”, Click “Start Generate template” Click “Read status” besides FPD template file. Click template which needs to be uploaded.	
Click subset settings Click “upload to Workdir”.	
If information listed is right, click “OK”. Wait until “Upload FPD file succeed!”	

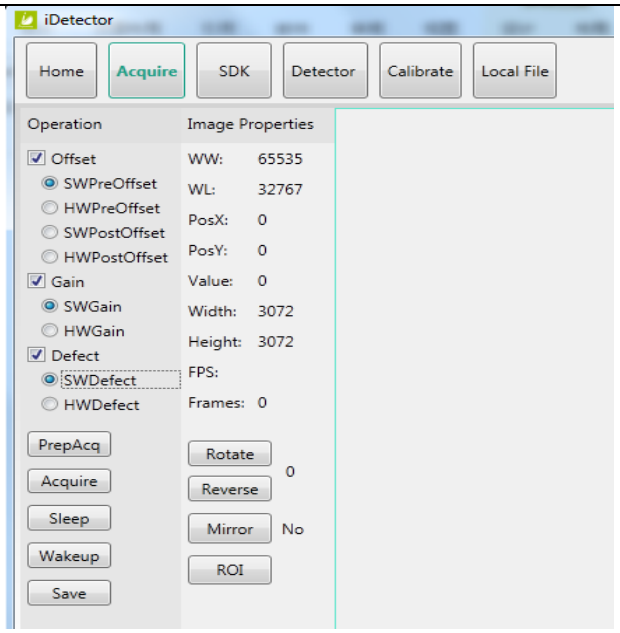
Check template uploaded in “work_dir\Mars1717XF_192.168.100.8\ Correct\Default”	

4.6.2 Correction Activation

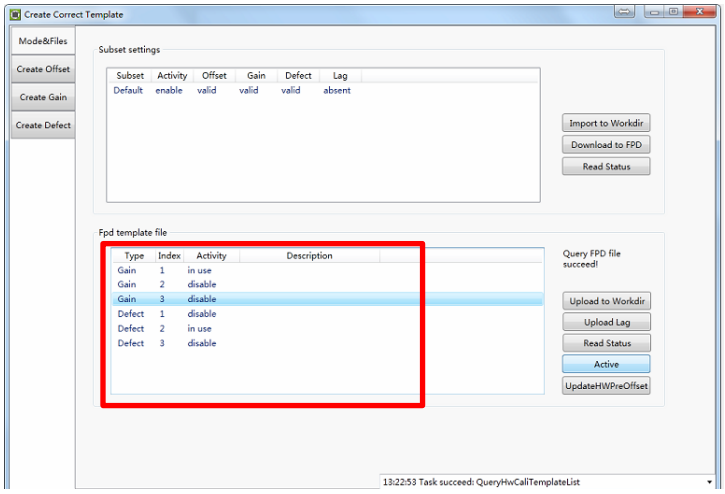
The detector supports two ways to do corrections. Software correction defines a scenario in which the workstation(FDR SE Console or iDetector) finishes a correction. If the detector does itself, that is hardware correction and calibration.

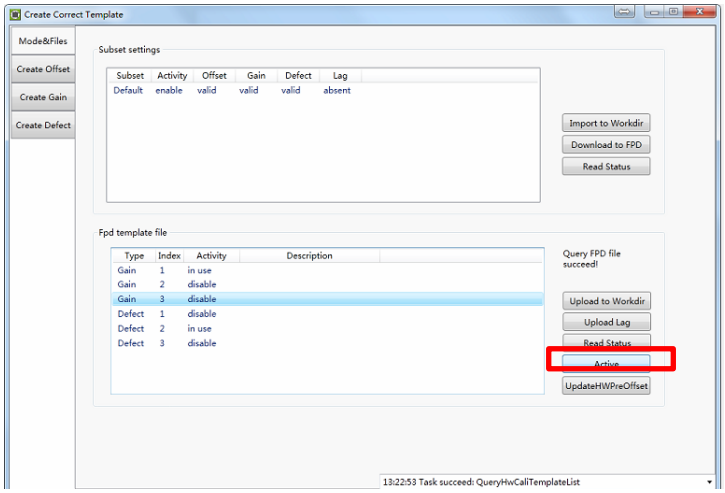
4.6.2.1 Software Correction

Make sure templates are saved in “work_dir\Mars1717XF_192.168.100.8\ Correct\Default”	
Choose “Acquire”	

Offset mode “SWPostOffset”, Gain mode “SWGain”, Defect mode “SWDefect”	

4.6.2.2 Hardware Correction

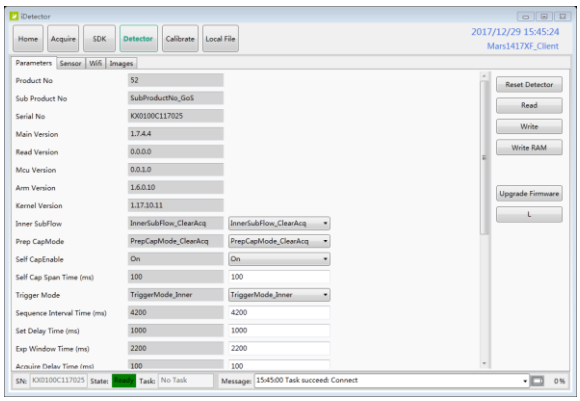
Click “Read Status” to read template	

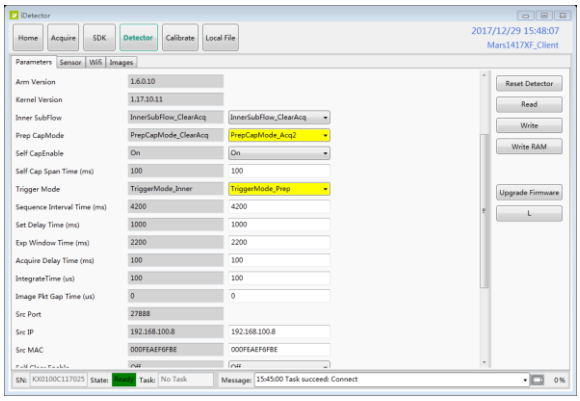
Choose template number according to requirements Click “Active” to activate template	
Offset mode “HWPostOffset” Gain mode “HWGain” Defect mode “HWDefect”	/

4.7 Firmware Update

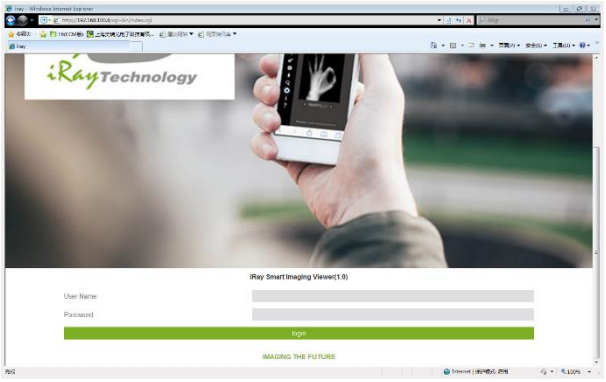
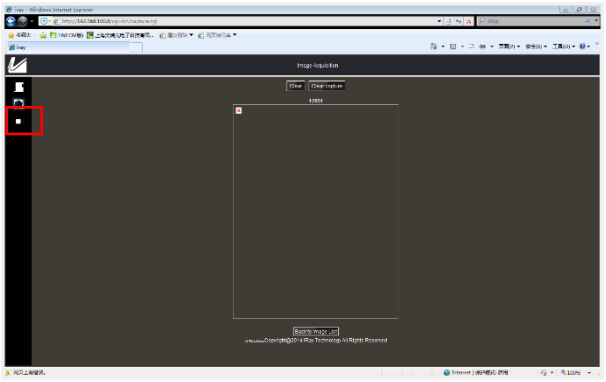
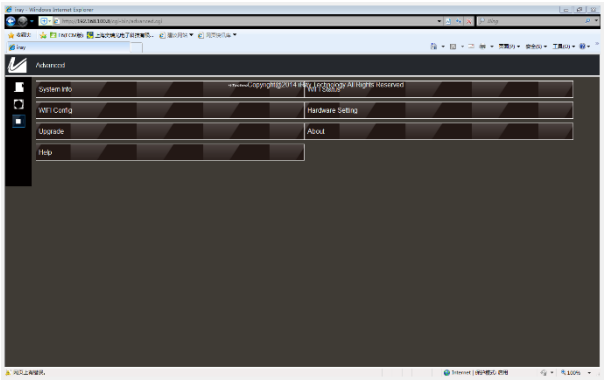
The detector supports firmware updating with the website; if the user needs to update firmware, please follow the steps below

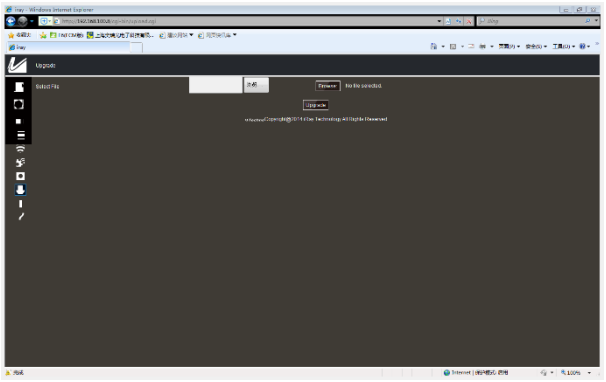
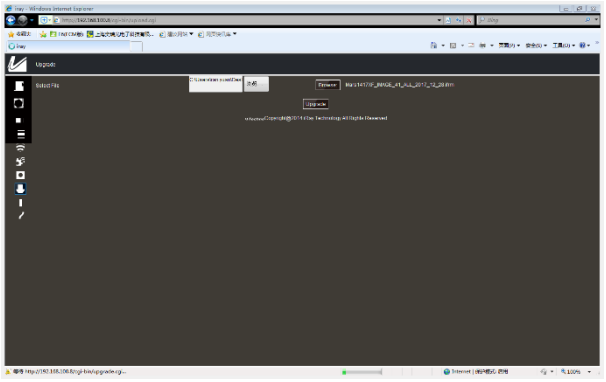
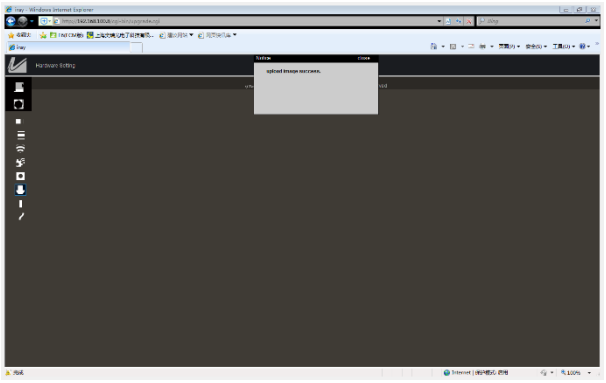
Preparation before updating

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” Mars1717XF_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 the battery (more than 25%) in the detector, in case power is down when upgrading. On the other hand, the detector should reboot after updating.

4.8 Short cut

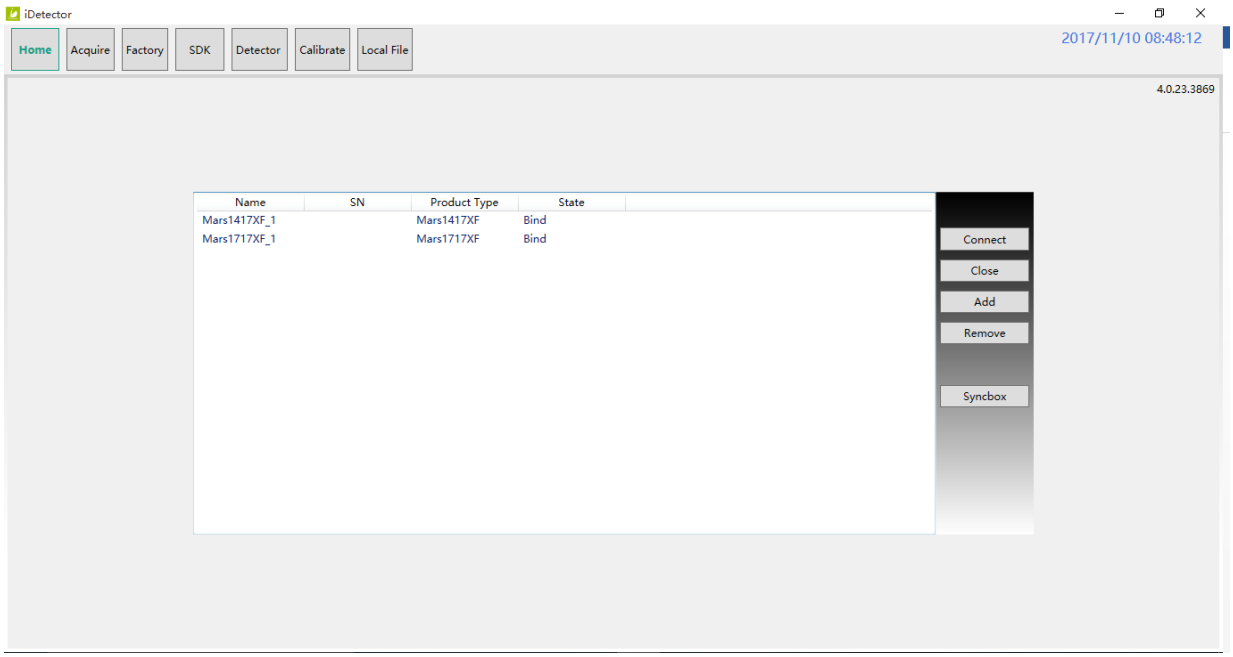
iDetector supports some shortcuts as follows:

- 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 the screen. See the table below for a 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 are shown as follows.

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 mainly for image acquisition. In the “operation” box, the user chooses the image correction method according to requirements. “image properties” shows simple information of the image acquired. “Image list” shows the last 5 images; if the user wants to check an image, then double click. The user can rotate images and do other image processing with “ROI”.

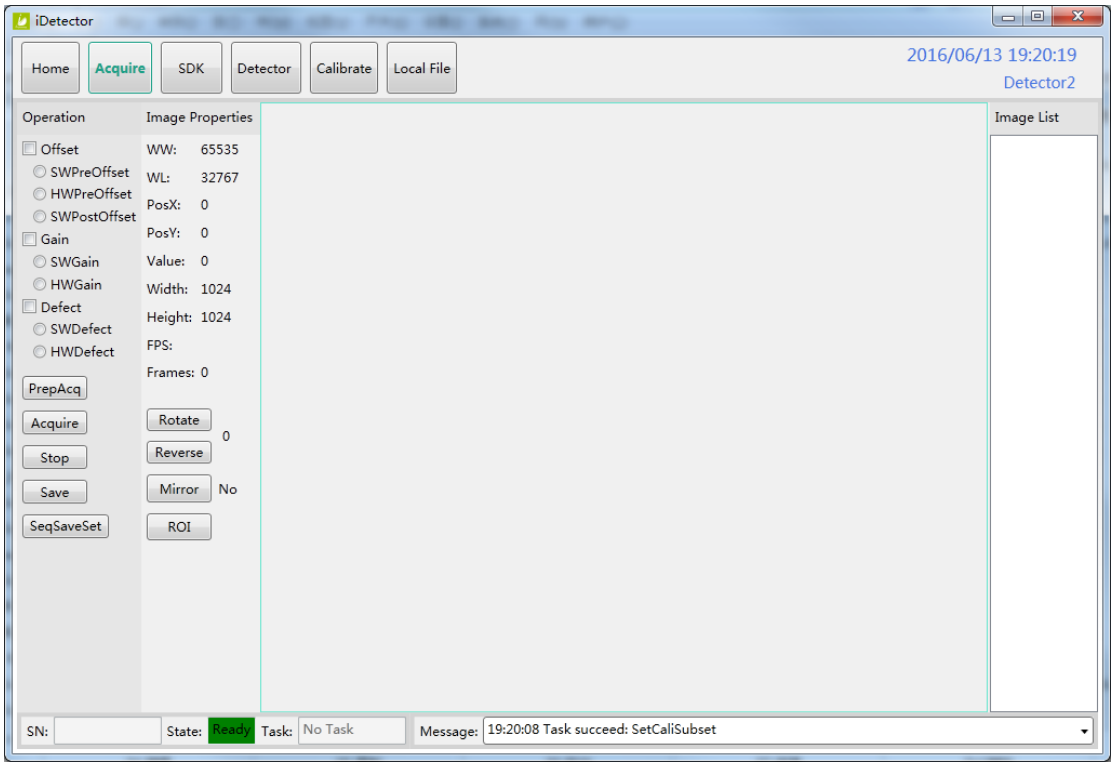


Figure 4.13.2

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

Item	Function description
SN	Connected detector SN number

State	Detector status, such as Busy or Ready
Task	What detector is doing
Message	Feedback of detector action, such as succeeded or failed

Image operation and property of SDK is shown below

Correction Menu		**Function description**
Offset	SWPreOffset	Reserved
	HWPreOffset	Reserved
	SWPostOffset	DR Software does post offset correction
	HWPostOffset	Detector does post offset correction
Gain	SWGain	DR Software does gain correction
	HWGain	Detector does gain correction
Defect	SWDefect	DR Software 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 (document type and path can 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

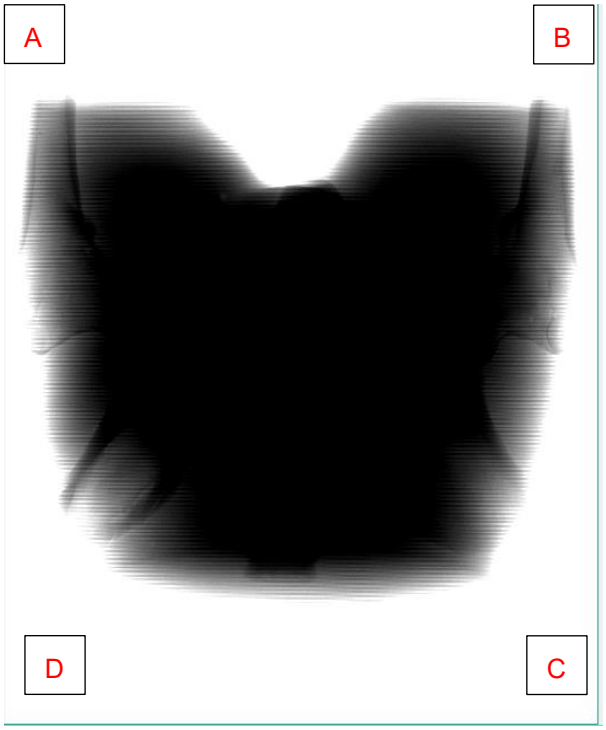
Height	Image height
FPS	Frame rate
Frames	Frame number
Rotate	Rotate image 90 degrees in clockwise direction
Reverse	Rotate image 90 degrees in counterclockwise direction
Mirror	Mirror image horizontally
ROI	Statistic of image such as AVG and SV
Image List	Latest 5 images

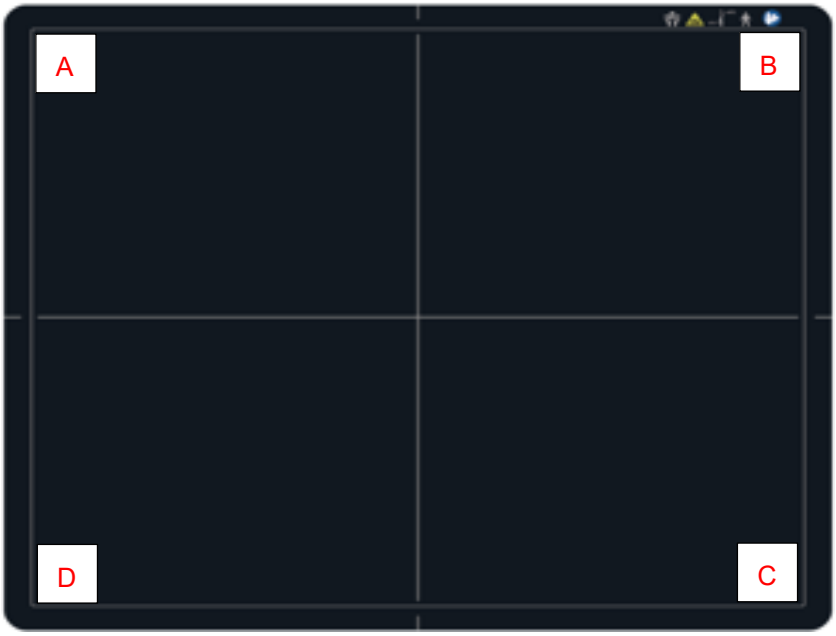
Image preview shortcut is stated below：

- 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

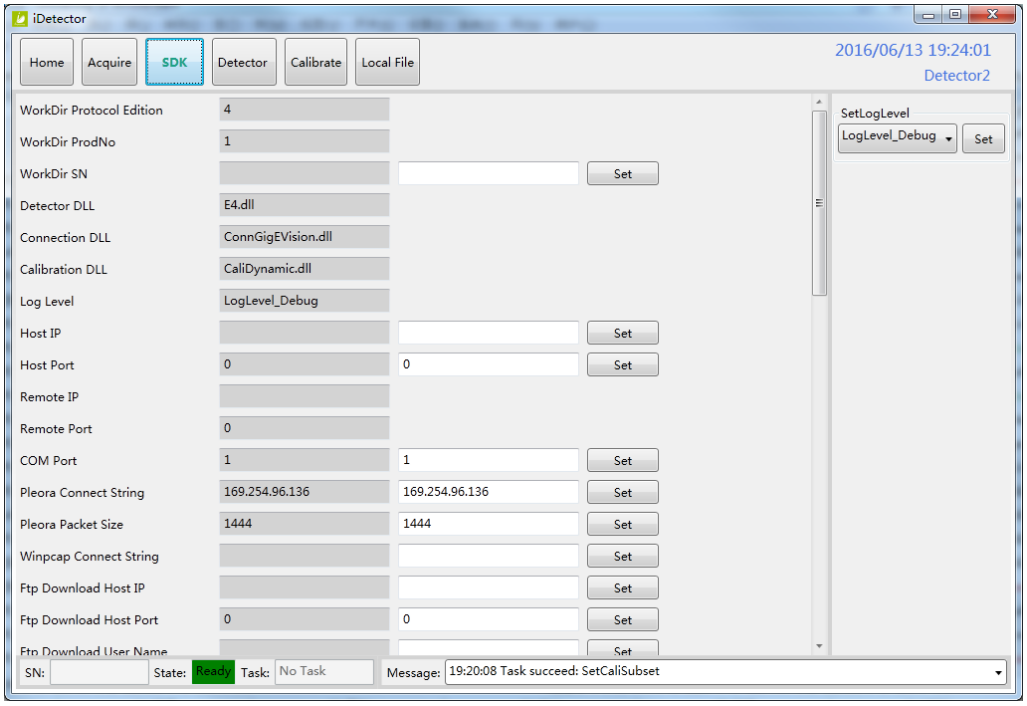
Image	Panel
A	A
B	D
C	C
D	B





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 the page are defined as follows:

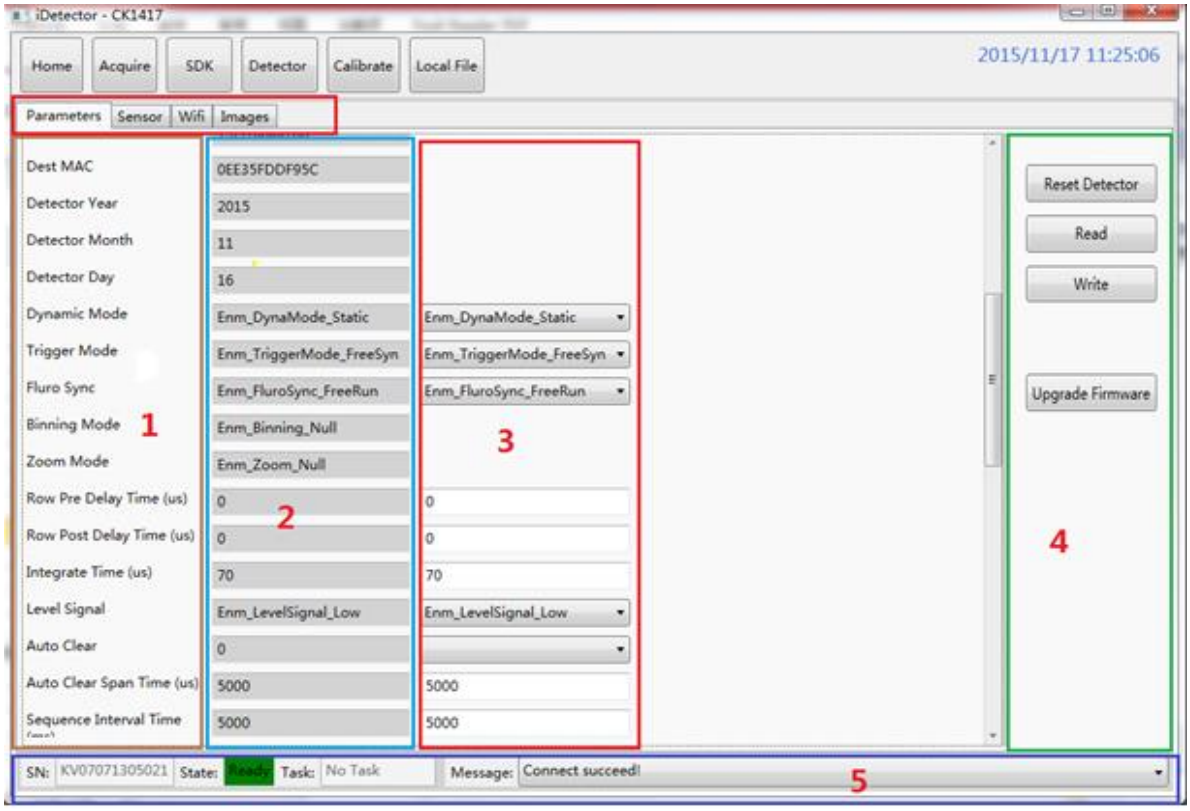
Zone 1: parameters

Zone 2: parameters reading from detector

Zone 3: parameters 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

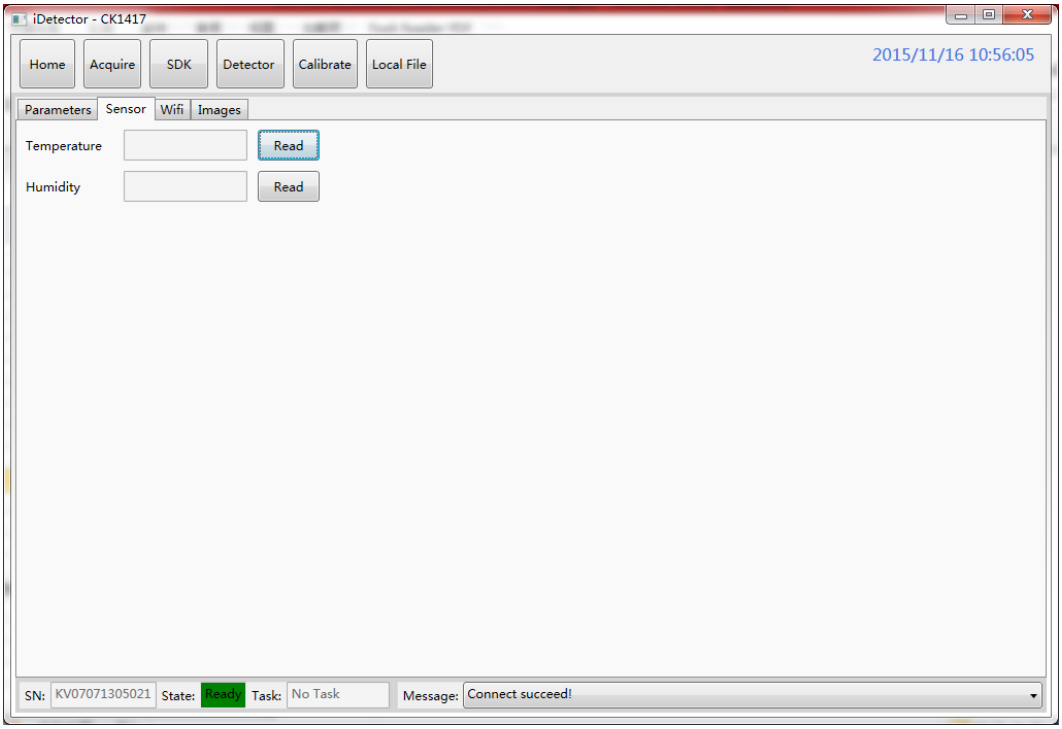
Function Button	Description
Reset Detector	Reboot detector

Read	Read configuration
Write	Write configuration
Upgrade Firmware	Reserved

4.9.5.2 Sensor

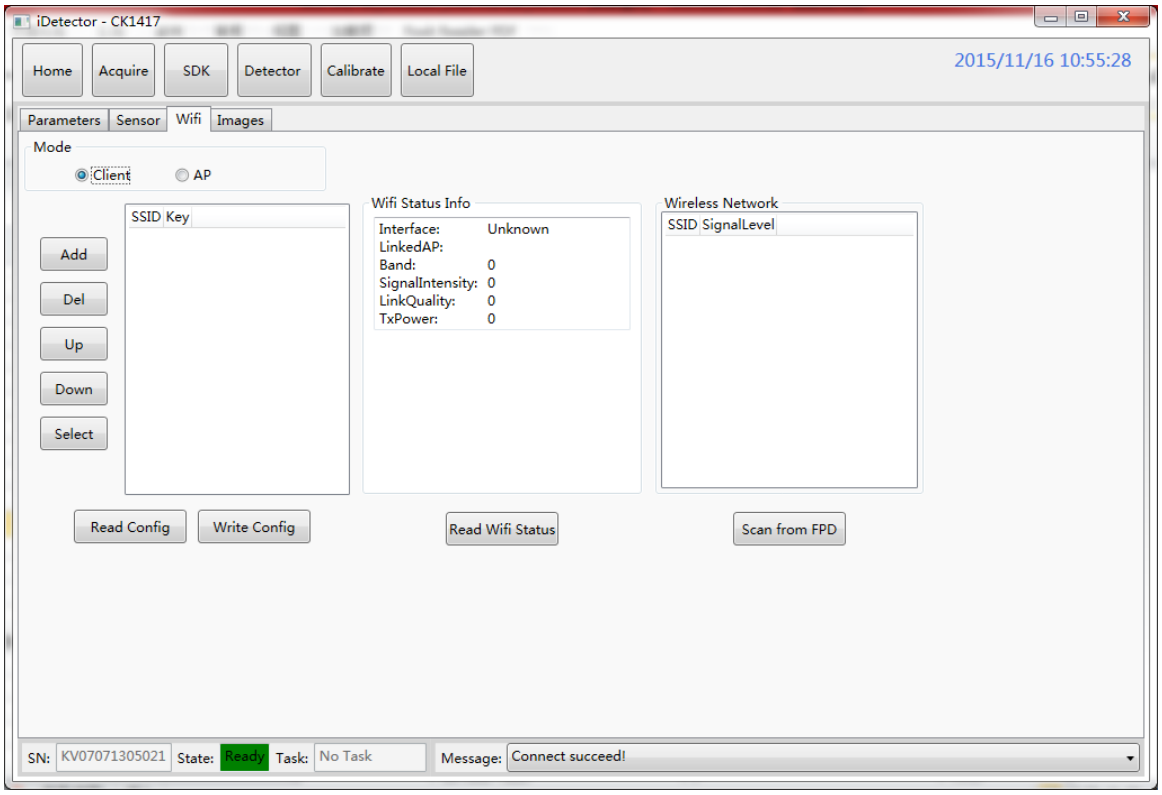
This page includes temperature and humidity information.

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



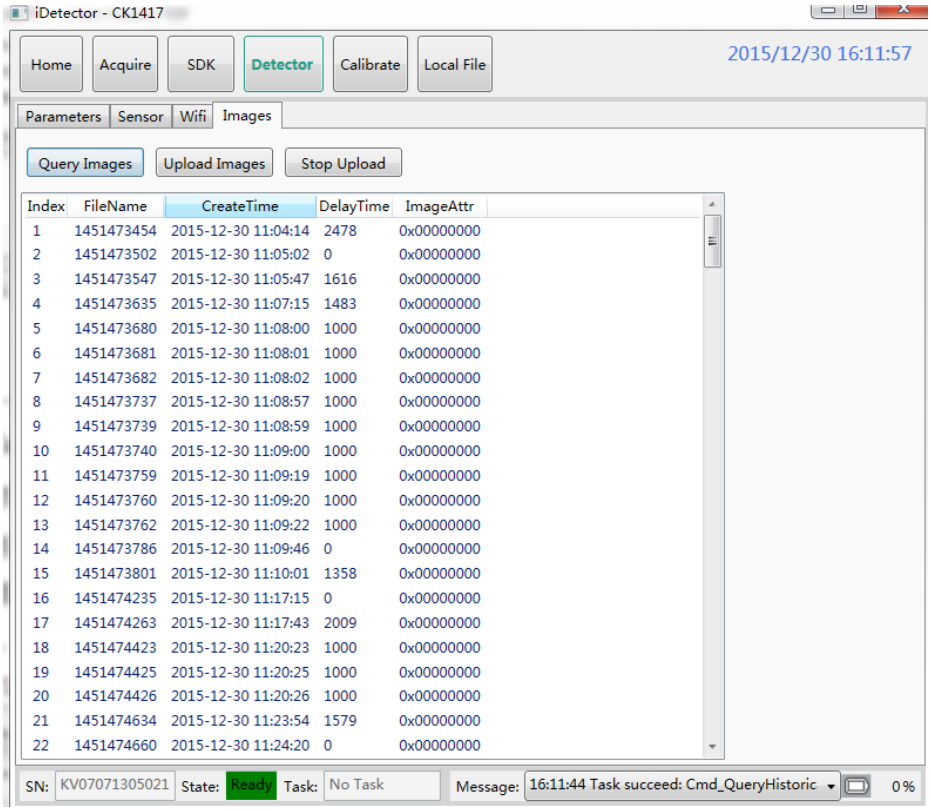
4.9.5.3 Wireless configuration

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 will 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 are shown in this area

4.9.5.4 Images



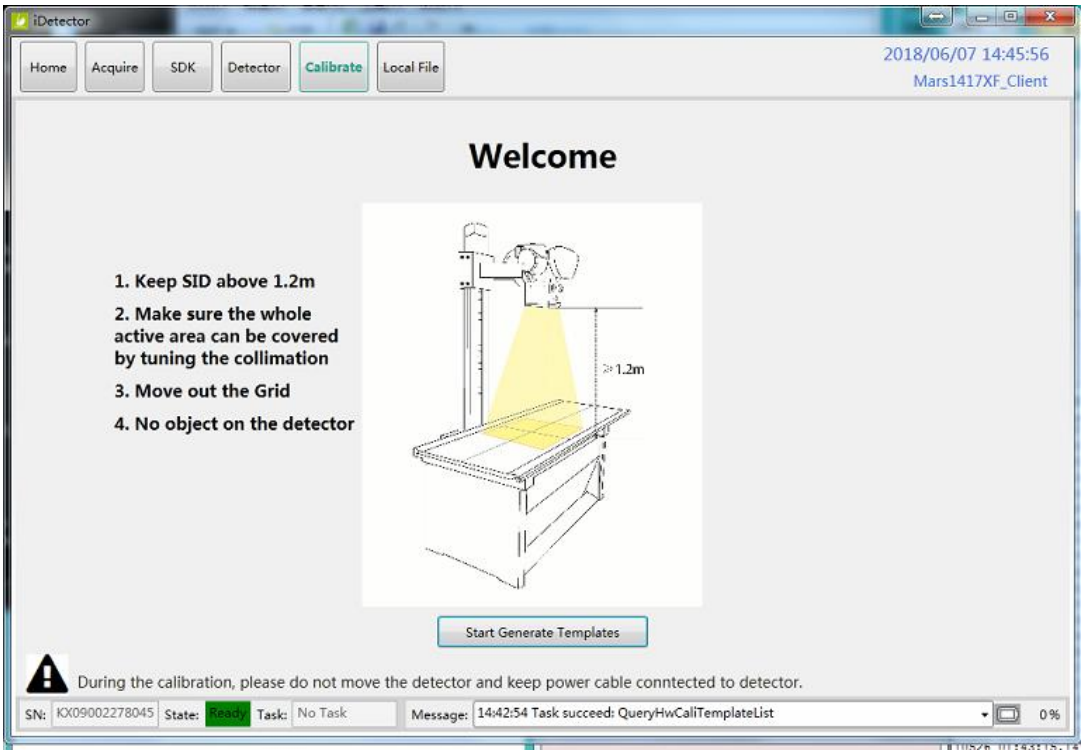
Parameters	Description
Query images	Query image list in detector
Upload images	Upload specific images in detector
Stop upload	Stop uploading accidently
Index	Item No. which is roll counting
Filename	Image No. which is defined and saved in detector
Create time	Time image is saved
Delay time	Acquisition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

Note:

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

4.9.6 Calibrate Page

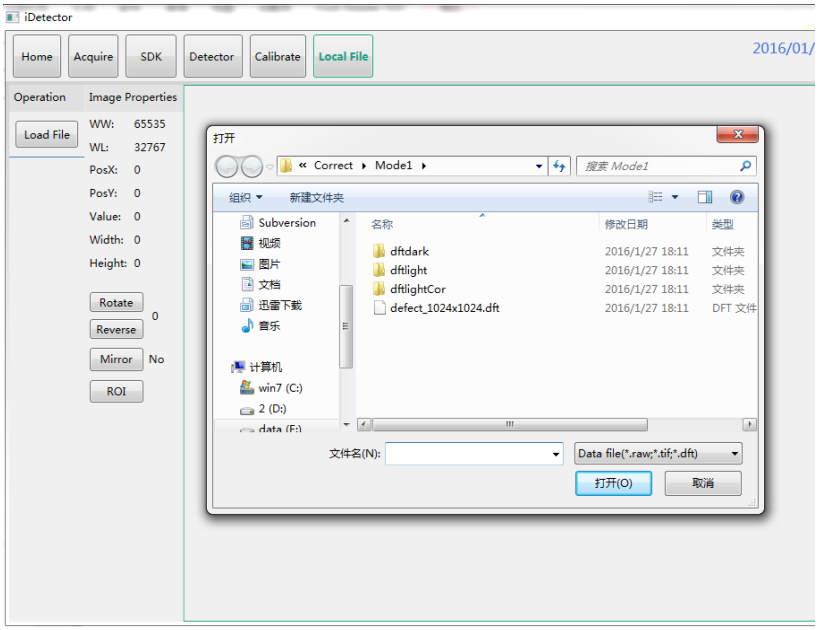
This page works for template management and generation.



Function Button	Description
Start to Generate Templates	Start template generation and template management

4.9.7 Local File Page

This page works for local image check.



Function Button	Description
Rotate	Rotate image 90 degrees in a clockwise direction
Reverse	Rotate image 90 degrees in a 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 the detector and the workstation(FDR SE Console or iDetector) 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

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

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

4.10.4 Technical specifications(Only for CE)

Image Transfer	Wireless: IEEE802.11a/b/g/n
Wireless frequency range	2.412~2.472GHz, 5.18~5.22GHz;5.745~5.85GHz
Data Transmission Power	13dBm (Typ.) @802.11a 16dBm (Typ.) @802.11b 14dBm (Typ.) @802.11g 13dBm (Typ.) @802.11n HT20 11dBm (Typ.) @802.11n HT40

	16dBm@2.4GHz 13dBm@5.8GHz
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

The detector sends image data acquired to the workstation (FDR SE Console or iDetector). The workstation(FDR SE Console or iDetector) sends users' commands to the detector.

4.10.6 Hazardous Situations Resulting from Failure of the IT Network

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

4.10.7 Warning

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

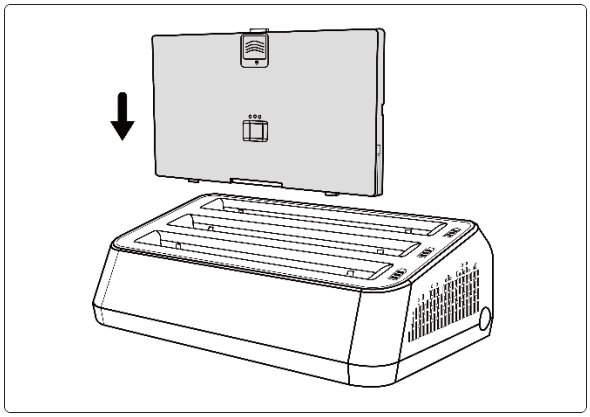
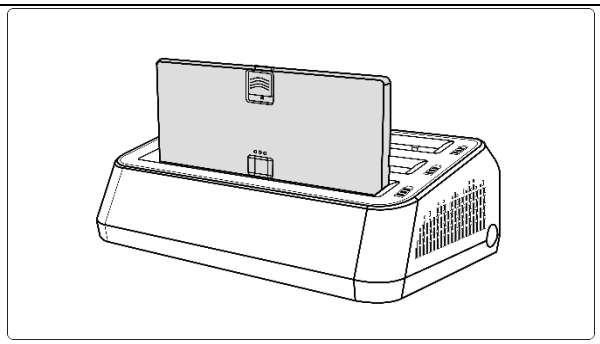
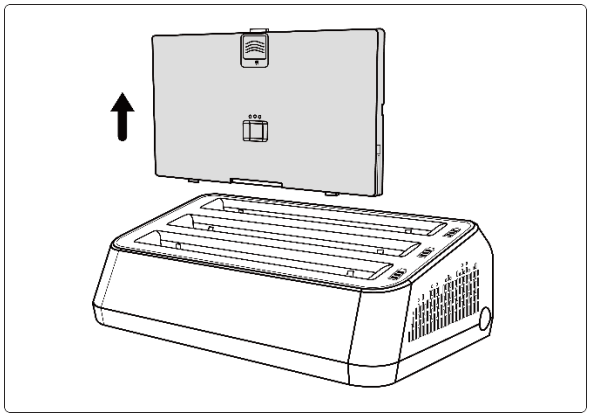
The manufacturer of the X-ray machine should identify, analyze, evaluate and control these risks.

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

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 in figure	
Make sure the battery is inserted to the bottom of the opening	
Unload battery from charger after charging completes.	

6 Regulatory Information

Product safety regulatory information includes safety of the detector, charger and other accessories.

6.1 Manufacturer's Information

COMPANY: iRay Technology Co., Ltd

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

ZIP CODE: 201201

TELEPHONE: +86-21-50720560

European Representative

COMPANY: iRay Europe GmbH

ADDRESS: In den Dorfwiesen 14, 71720 Oberstenfeld Germany

www.irayeurope.com

TEL: +49-7062-977 88 00

FAX: +49-7062-976 05 71

Email: S.feng@iraychina.com

6.2 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[Note1]
Protection degree against water penetration	IPX4 (Detector) IPX0 (Charger-KX)

Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in situation with flammable anesthetic mixture with air, oxygen or nitrous oxide Not suitable for use in oxygen-rich situation
The detector has two power supply modes (power adaptor and battery pack) and a single way for signal transmission (wireless)	

Note 1.When connected to patient, it was only allowed be powered by battery and shall disconnect adapter cord

◆ Safety standards reference

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

MDD (93/42/EEC)	Medical Device Directive
Directive 2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)
EN ISO 13485:2016	Medical devices– Quality management systems– Requirements for regulatory purposes
EN ISO14971: 2012	Medical device – Application of risk management to medical devices
IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
EN 60601-1:2006+A11:2011+A1:2013+A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
BS EN 60601-1:2006+A11:2011	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1:2005/(R)2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
CAN/CSA-C22.2 No.60601-1:14	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance

KS C IEC 60601-1	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
JIS T0601-1:2012	Medical electrical equipment– Part 1: General requirements for basic safety and essential performance
SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
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
CAN/CSA-C22.2 NO. 60601-2-54:11	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
SS-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
IEC 60601-1-6:2010+A1:2013	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+A1:2015	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 60601-1-6:2010+A1:2015	Medical electrical equipment Part 1-6: General requirements for basic safety and essential

	performance — Collateral standard: Usability
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic disturbances– Requirements and tests
IEC 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. 60601-1-14	Medical Electrical Equipment – Part 1: General requirements for 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

6.3 Guidance and manufacture's declaration for EMC

6.3.1 EMI Compliance Table

◆ Emissions

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2	Professional healthcare facility environment

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

6.3.2 EMS Compliance Table

◆ Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Near fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table “Near fields from RF wireless communications equipment”
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

◆ Near fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		

1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

◆ Input 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°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°
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/Unshielded	Number	Cable classification
AC power cable	1.8m	Unshielded	1 piece	AC power
DC power cable	3m	Unshielded	1 piece	DC power

◆ Electromagnetic Compatibility (EMC)

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

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

The Mars1717XF series wireless flat panel detector conforms to this EN60601-1-2:2007 standard on both immunity and emissions.

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

6.4 Radio Frequency Compliance Information

Country	Item
U.S.A.	KDB 865664 D01 47 CFR part 15, subpart B 47 CFR part 15，subpart C 15.247 47 CFR part 15，subpart C 15.407 47 CFR §2.1091 KDB447498 D01 General Exposure Guidance v06
European Union	EN 301 489-1 V 2.1.1 EN 301 489-17 V 3.1.1 EN 300 440 V 2.1.1

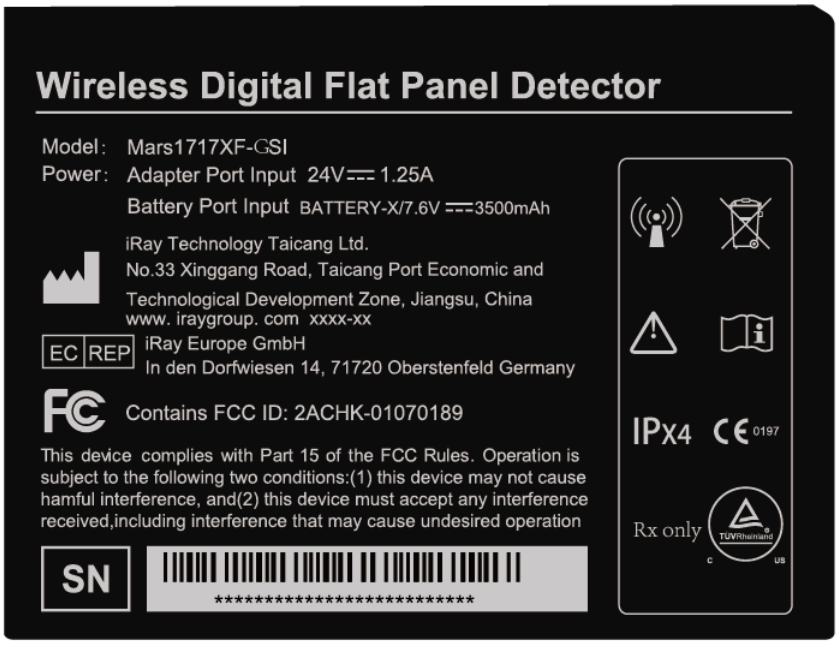
	EN 300 328 V 2.1.1; EN 301 893 V 2.1.1 EN 62311:2008 EN 62209-2:2010 EN 50566:2017 EN 62476:2010 EN 55032:2015 EN 61000-3-2:2014 EN 61000-3-3:2013

6.5 Battery Safety Standards

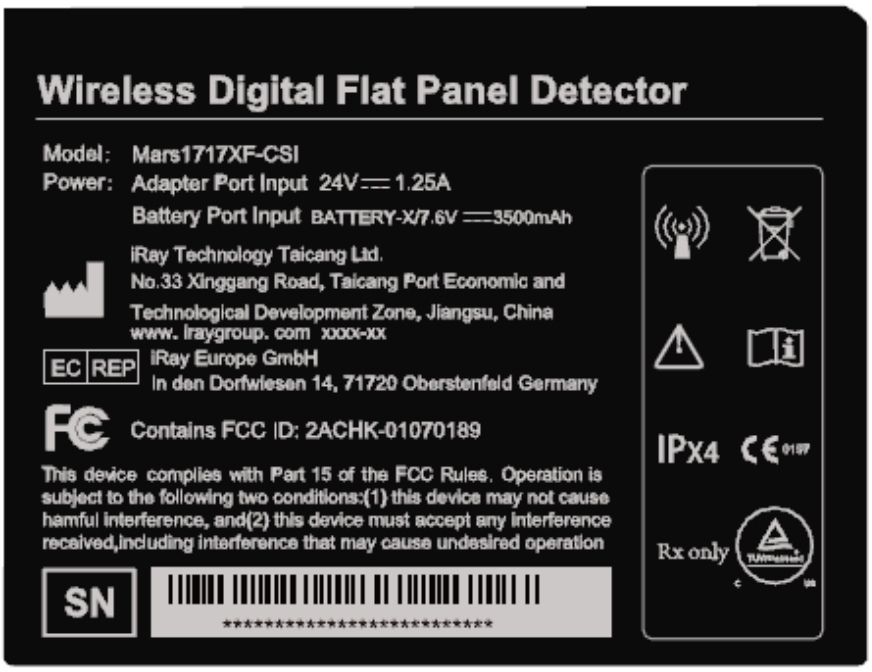
Standards	Description
UL1642	Component recognition on secondary Li-ion cells
UL 2054:2004 R9.11	Household and commercial batteries
IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes
UN38.3	United Nations Recommendations on the Transport of dangerous goods Manual of tests and Criteria ST/SG/AC.10/11/Rev.5/Amend.1&Amend.2

6.6 Product Label

Mars1717XF-GSI Detector Label

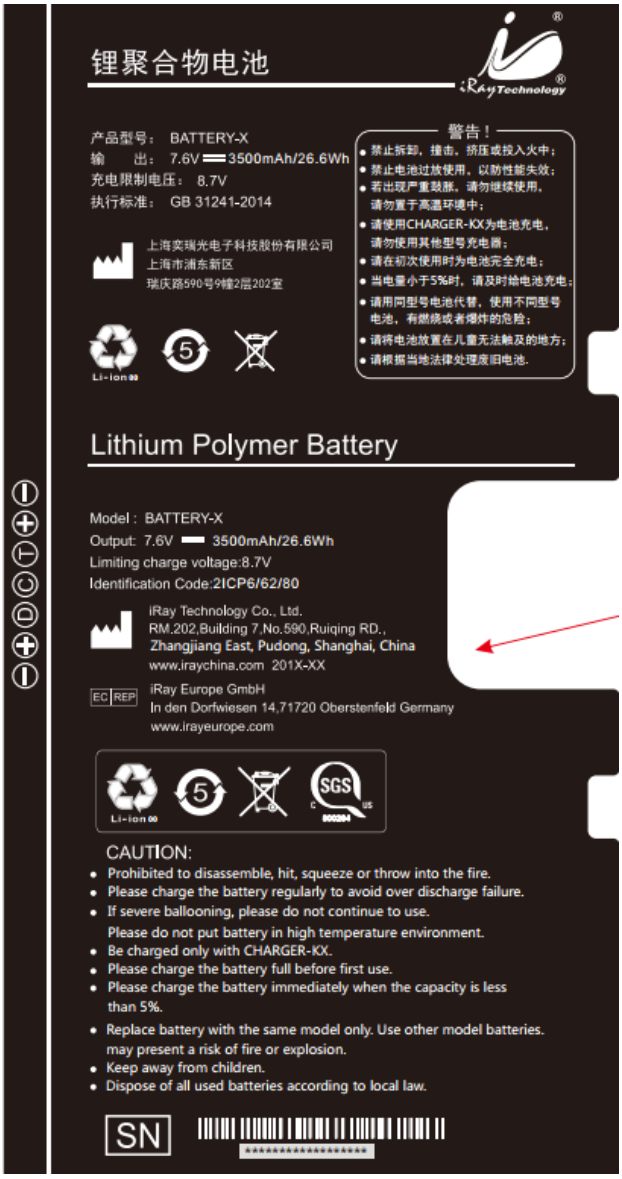


Mars1717XF CSI Detector Label



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
上海奕瑞光电子科技股份有限公司
上海市浦东新区
瑞庆路590号9幢2层202室
警告！
• 禁止拆卸，撞击，挤压或投入火中；
• 禁止电池过放使用，以防性能失效；
• 若出现严重鼓胀，请勿继续使用，请勿置于高温环境中；
• 请使用CHARGER-KX为电池充电，请勿使用其他型号充电器；
• 请在初次使用时为电池完全充电；
• 当电量小于5%时，请及时给电池充电；
• 请用同型号电池代替，使用不同型号电池，有燃烧或者爆炸的危险；
• 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.
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.590,Ruiqing RD.,
Zhangjiang East, Pudong, Shanghai, China
www.iraychina.com 201X-XX
EC REP
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 Troubleshooting

Please refer to the service manual. If the problem remains unsolved, turn off the detector and contact the Fujifilm service department. We will provide the best service possible.

8 Product Maintenance

8.1 Expected Service Life

Estimated product lifetime is 7 years with regular inspection and maintenance.

8.2 Regular Inspection and Maintenance

The detector needs regular inspection at least once a year not only for the safety of patients, the operator and third parties, but also for performance and reliability. If necessary, contact Fujifilm service office or local dealer for regular inspection or maintenance.

There is a lithium battery in the detector whose lifetime is more than 5 years; the battery needs to be replaced when it finishes. Contact Fujifilm after-sales service departments or authorized product distributors.

8.3 Repair

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

Product Name:

Series Number:

Description of Problem: as clearly as possible.