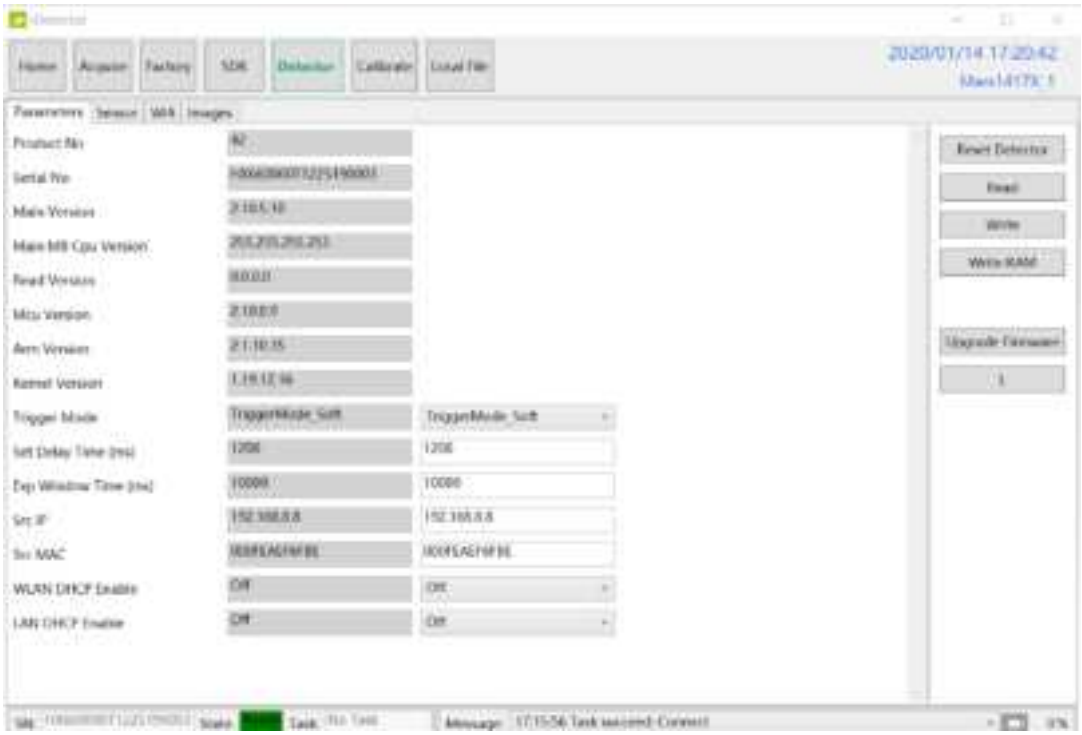
3. Parameter read region: read the parameters, the values of the parameters are displayed in this area by Read.
4. Parameter write region: write parameter. Entered value of the corresponding parameter in this area can be write to detector.
5. Operation region: functional operation buttons area.
6. Status bar region: status bar for detector state and information of reading or writing parameters, etc.



Configuration parameters description as below:

Name	Description	Configurable
Product No.	Type of detector product	N
Serial No.	Serial number of the detector	N
Main Version	Firmware version number of the FPGA	N
Read Version	N/A	N
MCU Version	Firmware version number of the	N

	MCU	
Arm Version	Version number of the ARM App	N
Kernel Version	Version number of ARM Kernel	N
Trigger Mode	Tirgger mode of the detector	Y
Set Delay Time(ms)	Exposure window for AED mode which use a fixed window	Y
Exp Window Time(ms)	Max exposure window for command trigger which use a dynamic window	Y
Src IP	Detector IP	Y
Src MAC	Detector MAC	Y
WLAN DHCP Enable	DHCP, Client, not set as on with LAN DHCP enabled at the same time.	Y
LAN DHCP Enable	DHCP, Client, not set as on with WLAN DHCP enabled at the same time.	Y

Button function description:

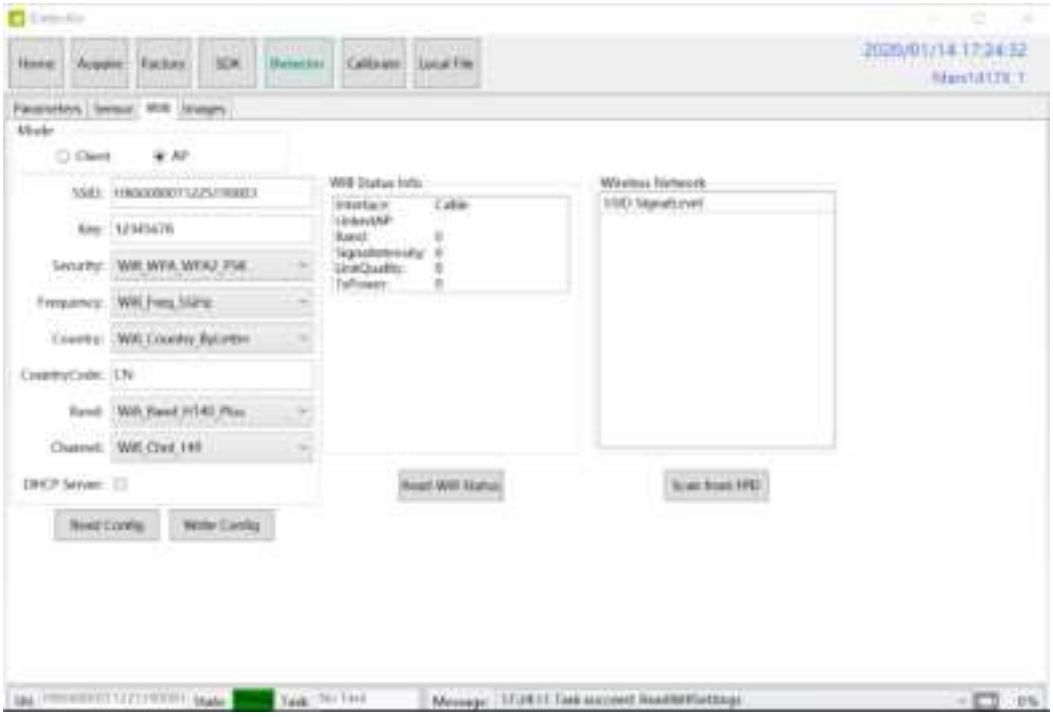
Function Button	Description
Reset Detector	Reset Detector
Read	Read parameters
Write	Write parameters
Write RAM	Write parameters into RAM(will lost changes after reset)
Upgrade Firmware	Upgrade firmware
L	Upload detector log to the specified directory

- **Sensor**

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

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

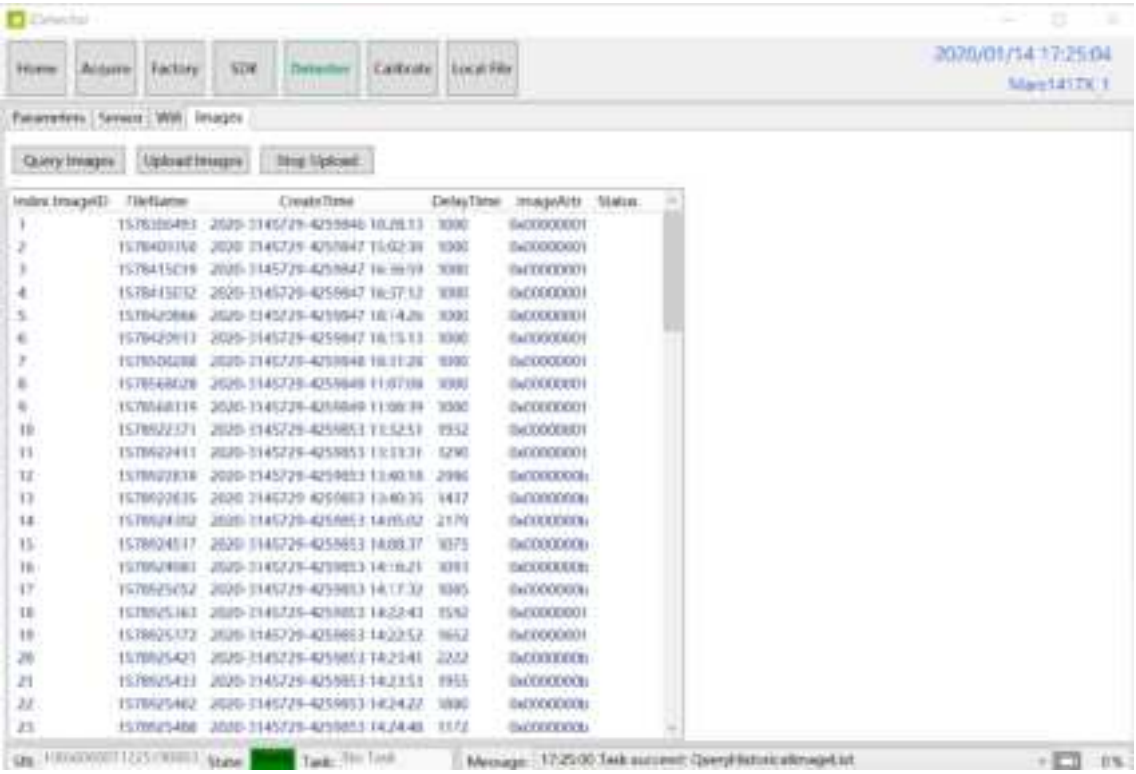
- **Wifi**



User can config the wireless connect parameters on this tab.

- **Images**

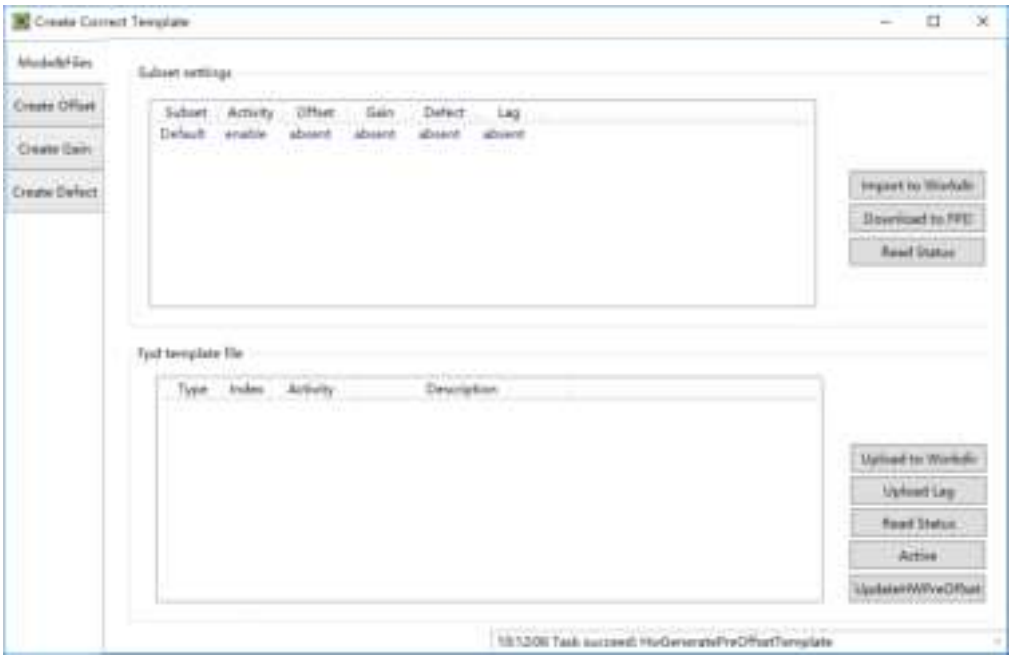
You can Query and upload Images from detector to Workstation.



4.4.5. Calibrate Page

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

Click “Start Generate Templates” to enter generating templates page.



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

Mode&Files page	Description
Import to Workdir	Copy template file into current calibration directory.
Download to FPD	Select one item first. Then click this button to download selected template file(s) into detector.
UpLoad to Workdir	Select one item in Fpd template file control and select one item in Subset settings control. Click this button to upload selected template from detector into specified calibration directory.

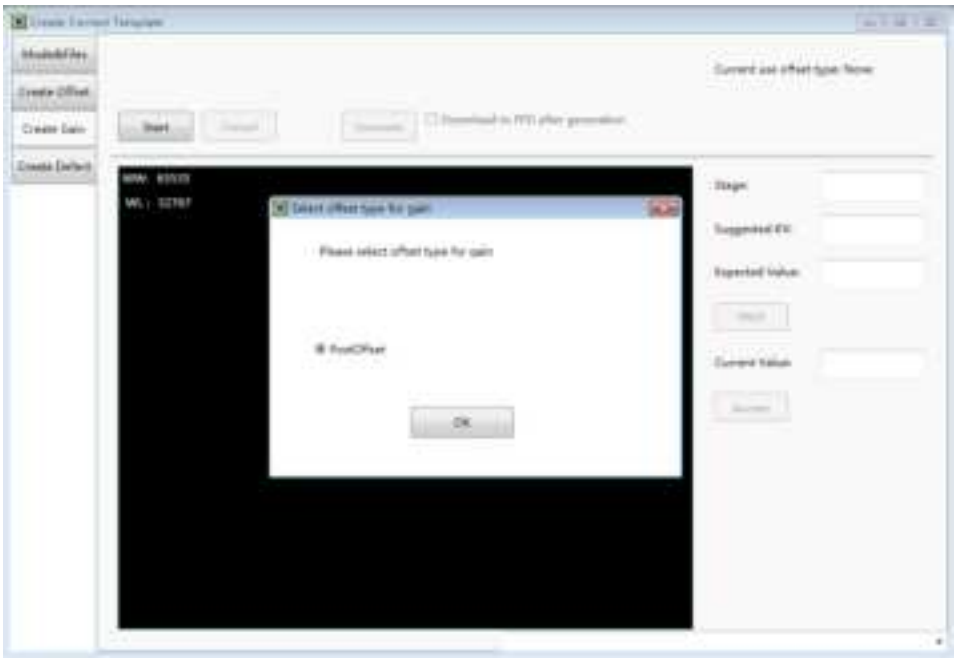
Upload Lag	Upload Lag into SDK current directory
Active	Select one item in list. Click this button to activate selected template for hardware correction.
UpdateHWPreOffset	Force detector update Offset template(not needed for postoffset flow)
ReadStatus	Get the current state of template for hardware correction, enable/disable

- **Generate Gain Template File**

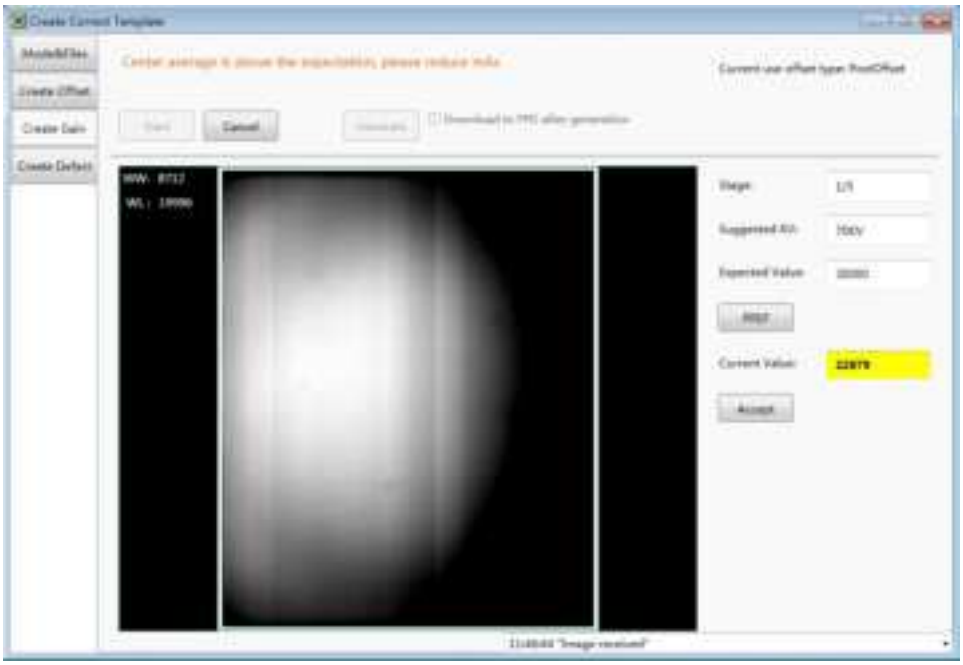
If the relative position between tube and detector changed or KV value changed, it suggest to create gain template file.

1. Enter Create Gain page

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

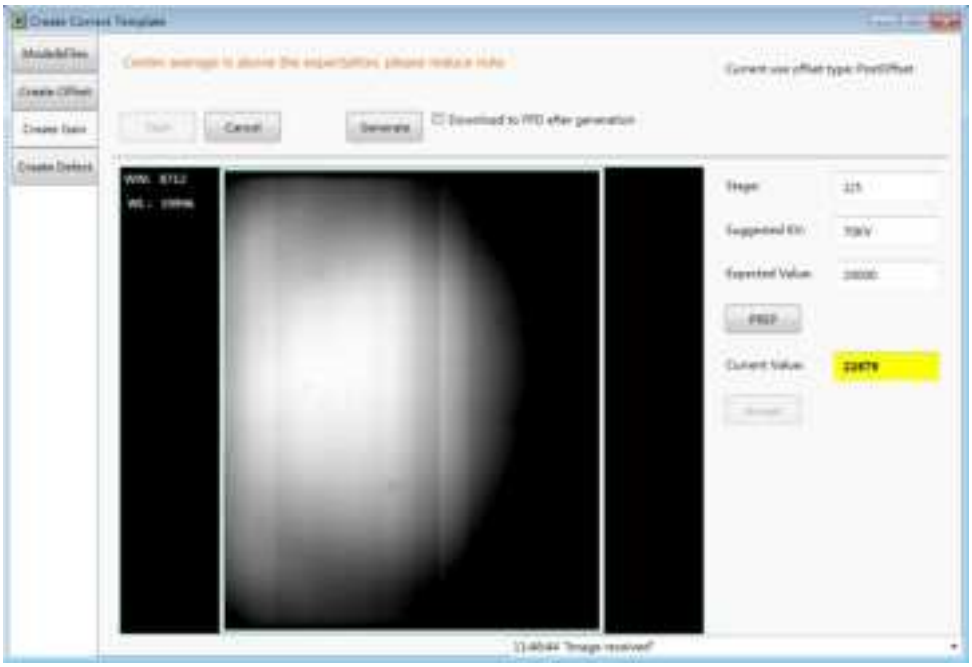


2. Click PREP button, then exposure after Acquire button enable. After receving the PREP request, the detector needs some time to be ready, the decounting bar will apear when the exposure window is opened. After exposure user can click Acquire button to acquire the X-Ray image.



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

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



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

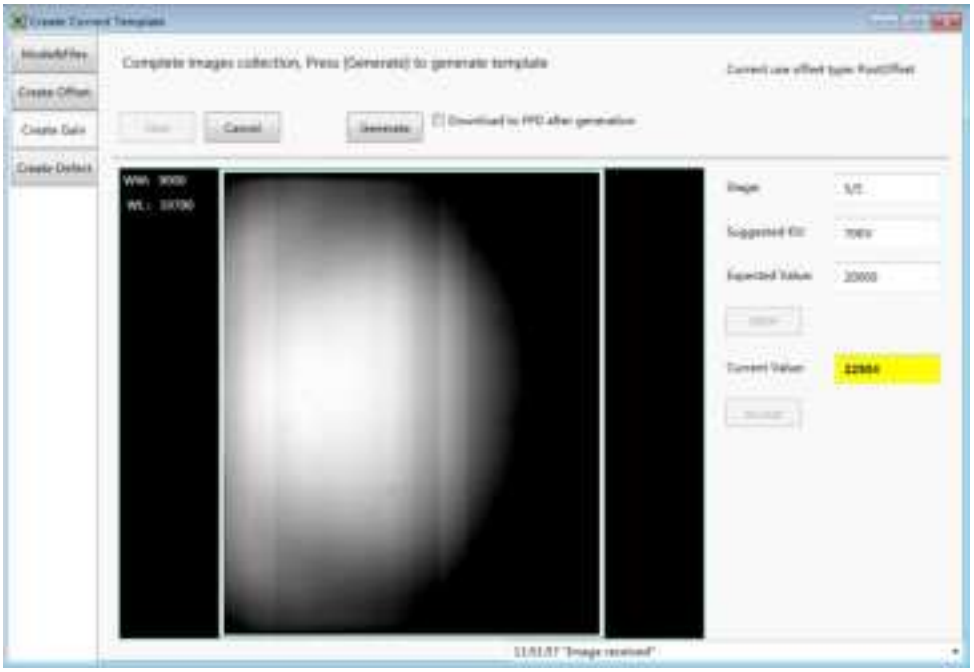
Yellow: The current value is higher or lower than the expected one, user decides if acceptable. For example, the expected value is 20000, and user needs 40000 as the gain piont, the yellow warning can be ignored, and the value can be accepted still.

Green: The value is good.

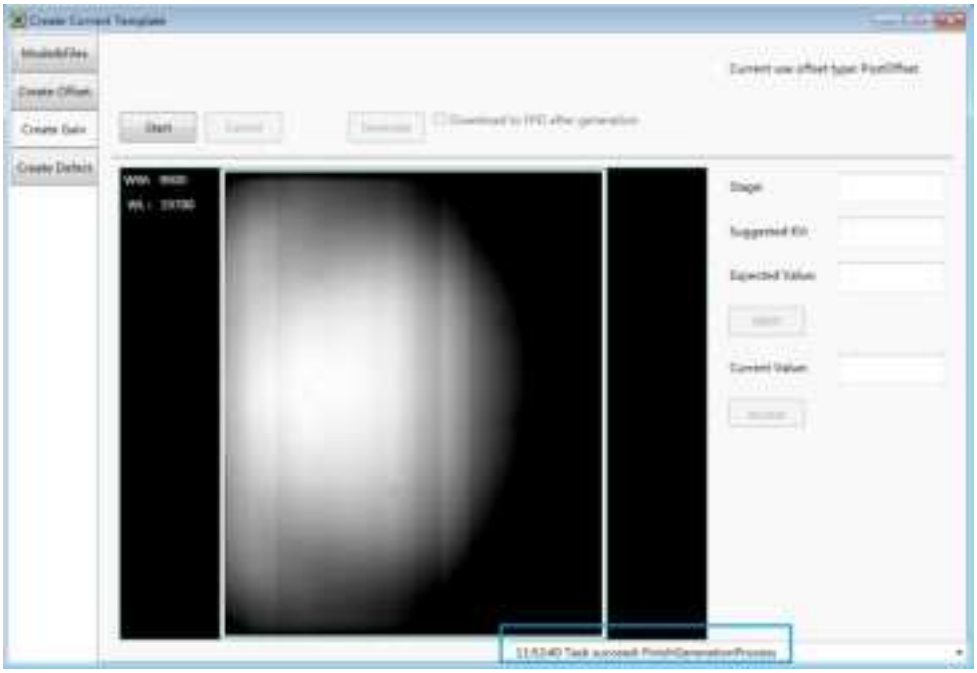
Red: The value is un-acceptable.

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

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



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

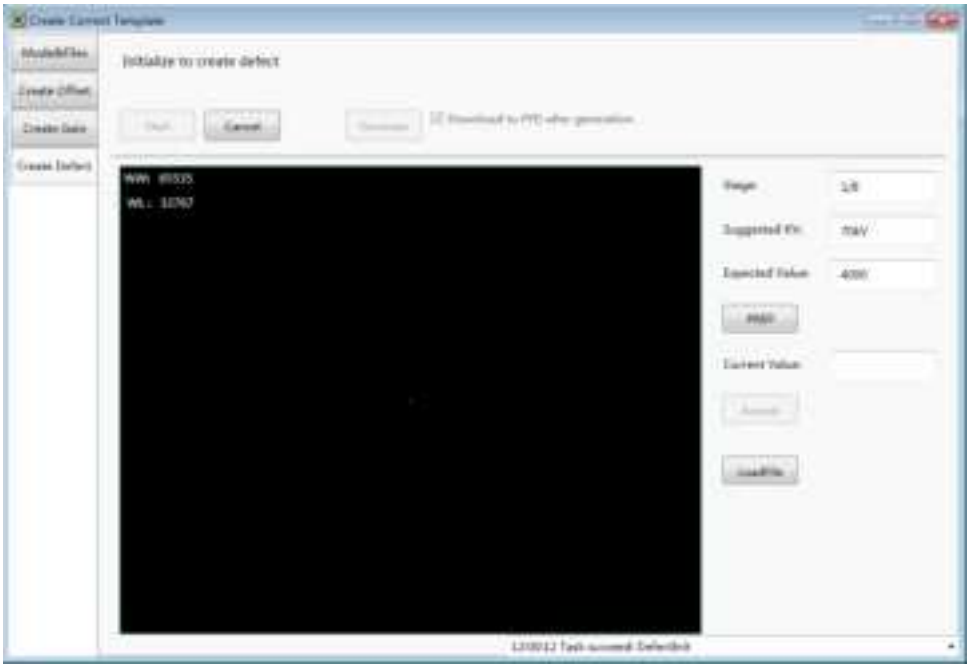


- **Generate Defect Template File**

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

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

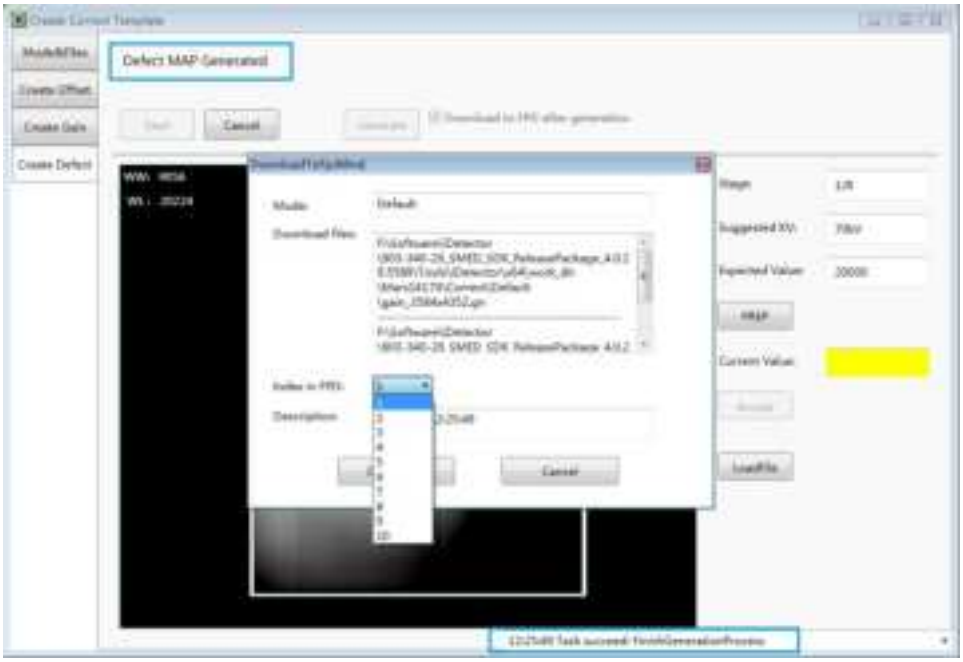
   And the process can be quit by “Cancel”.



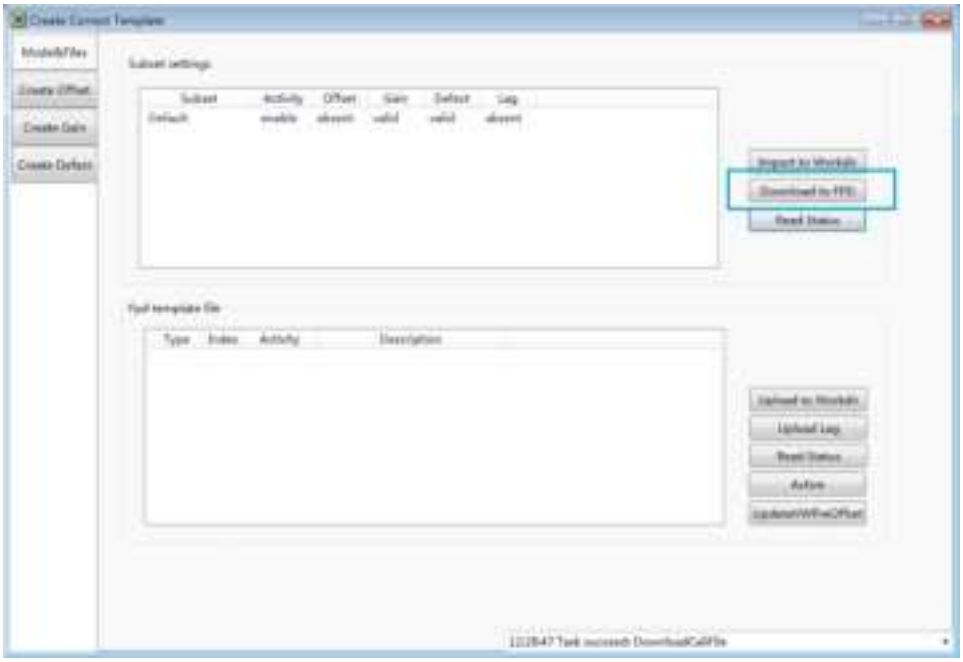
2. There are 8 images that need to be acquired, the UI gives the recommend KV and expected image value, user should refer with them.
3. If the option “Download to FPD after generation” is checked, the download UI will appear after finishing generating the defect map which will takes a little time.

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

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



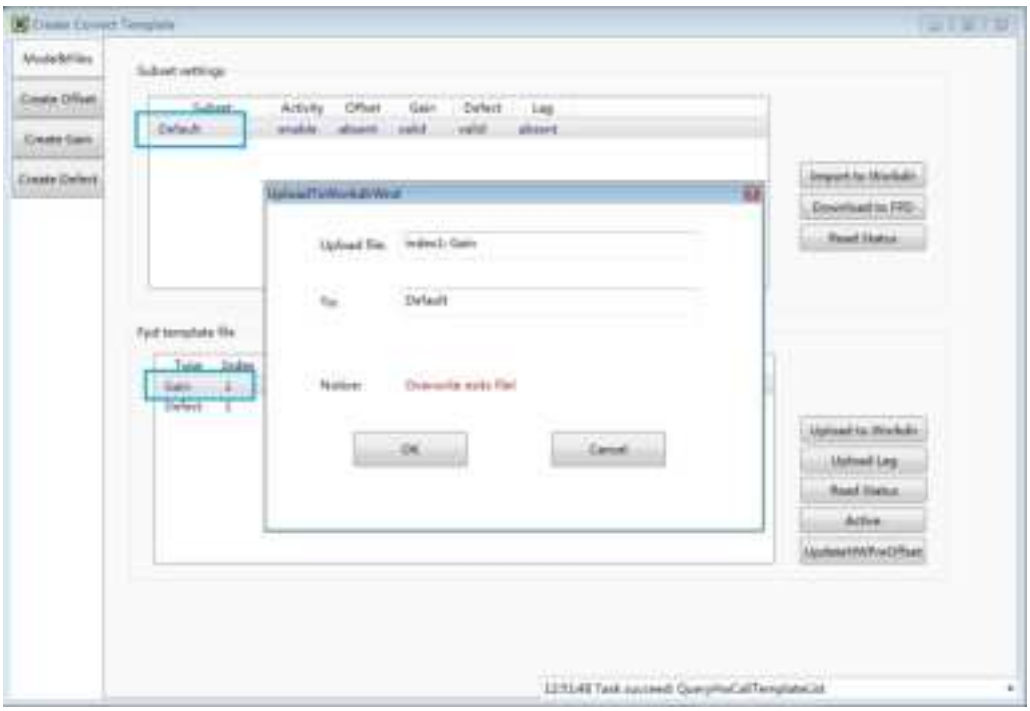
4. After choosing the stored index of FPD, the download process can be started by the “Download” button, user should wait the process until it is finished.
5. The correction map also can be managed at anytime on the page of “Mode&Files”. Choose the item of “Default” in the Subset settings part and click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



- **Upload the correction files**

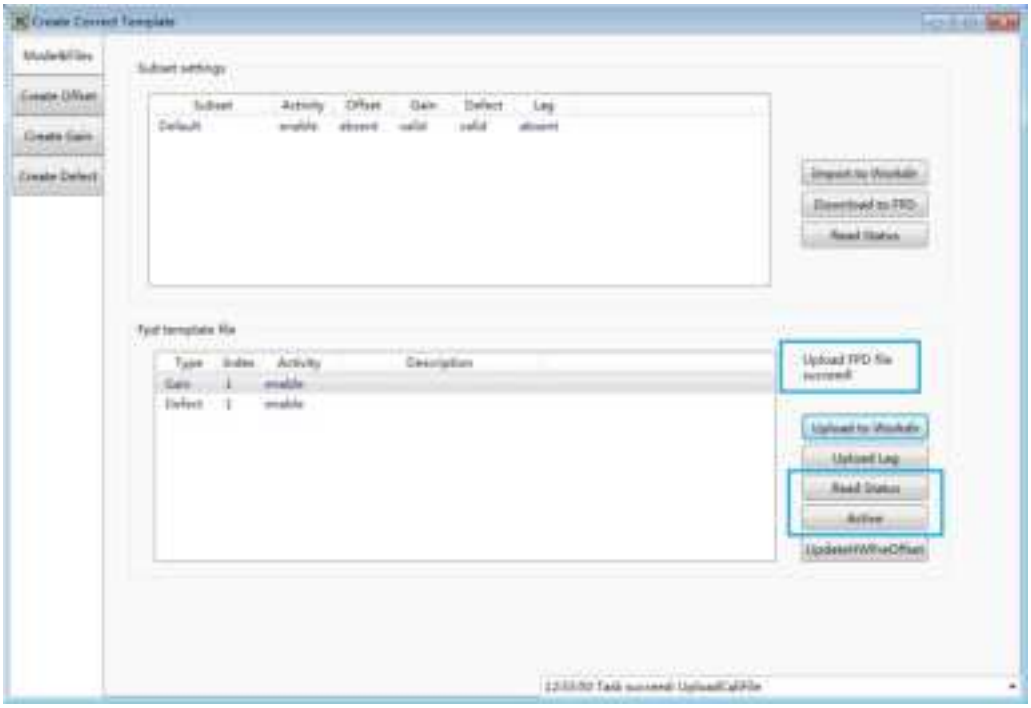
1. The correction maps can be uploaded to the workstation too.

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



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

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



4.4.6. Local Page

In this page user can open the image files saved in local, the file formate can be dcm, raw, tiff, dft. When the software is disconnected to detector, the file still can be opened.

Click “Load File”, there will be an open file wizard. Select file and click open or double click the file. The tiff file will be opened directly. For the raw file or dft file there will be a dialog to select image size. Select correct size to open image files. If the file is not correct user will get an error message.

The pixel matrix is defined as below:

Active area : 3500*4300

TFT includes active area and dummy pixels: 3524*4330

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

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

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

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

Image Properties& Image Process	Description
WW	window width
WL	window level
PosX	X coordinates of the current cursor at the point
PosY	Y coordinates of the current cursor at the point
Value	Value of the current cursor at the point

Width	Image width
Height	Image height
	Rotate the image clockwise, 90 degrees every time.
	Rotate the image anticlockwise, 90 degrees every time.
Mirror	Open or close mirror
ROI	ROI tool，to view the image of the AVG, SV, SNR and other parameters. Press "ctrl" key, can create several ROI area.
WW/WL	Auto adjust WW/WL based on selected area by right button of mouse.

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

a) The operating system is not compatibility;

b) Change or update the software failed;

c) The compatibility of the interface;

d) The data transfer protocol error;

e) The inconsistent of interface or format leads to data distortion;

f) The data output failed;

5. Operation Instructions for Image Acquisition

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

5.1. Steps for acquiring image

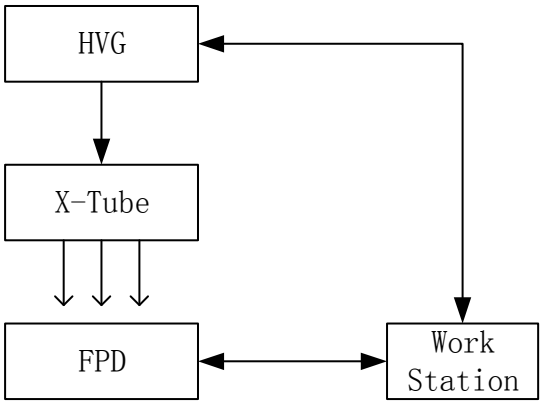
- Make sure the hardware is connected correctly and then power on.
  Once powered off, please wait at least 60s before power on again
- Wait until initialization is complete
- Connect the software
- choose the synchronization mode
- Generate HWPreOffset, Gain and Defect template after the detector reaches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

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

5.2. Software Mode

5.2.1. Block Diagram

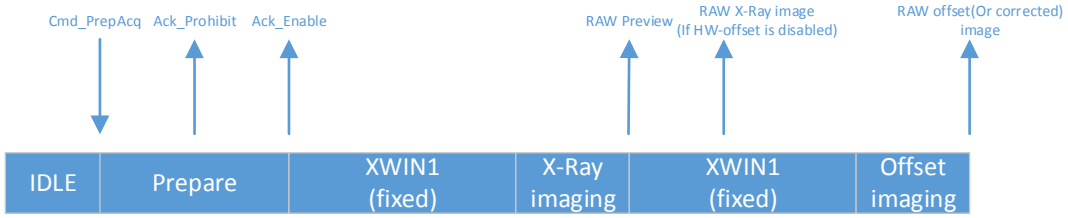
Software mode is the basic way to acquire X-ray image. Please see figure below for general feature. Workstation is a host PC device installed with iDetector and SDK. FPD is the Wireless Digital Wireless Digital Flat Panel Detector and HVG is the High Voltage Generator. In this mode, Workstation does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



5.2.2. Work Flow(PrepAcq)

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

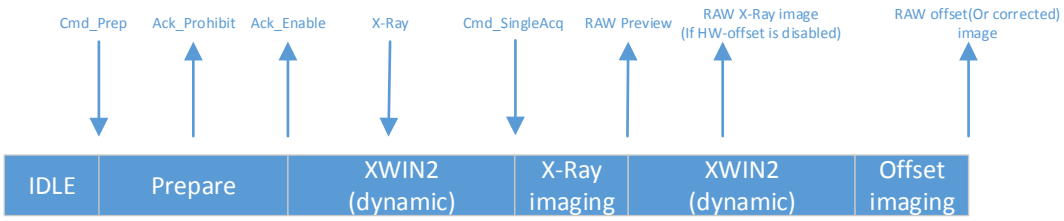
Also, the software correction is supported.



1. Send Cmd“PrepAcq” on UI “Acquire” page.
2. After receiving the Cmd_PrepAcq, it will start the prepare process, and send back the acknowlage of “Prohibit” and “Enable”, the “XWIN” will be started.
3. The XWIN is configured by parameter “Clear Acq Delay Time” on “SDK” page, the unit is “ms”.
4. User needs to make sure the X-Ray ends within the XWIN.
5. The detector will send the images after the XWIN closed.

6. The preview image will be always sent, which is 4x4 averaging, the raw X-Ray image will be sent if the HW correction is disabled with the raw offset image follows, otherwise, the X-Ray image will not be sent and only the corrected image will be transferred.

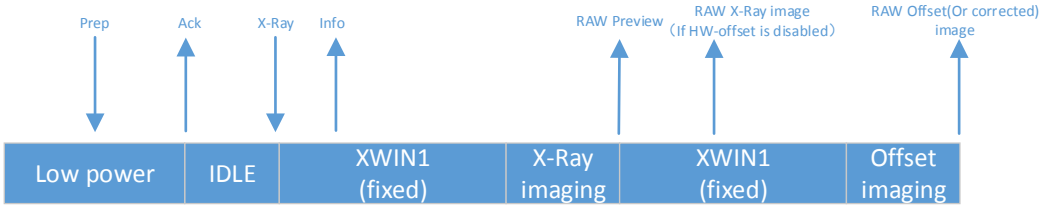
5.2.3. Work Flow(Prep+Acq)



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

5.3. AED Mode

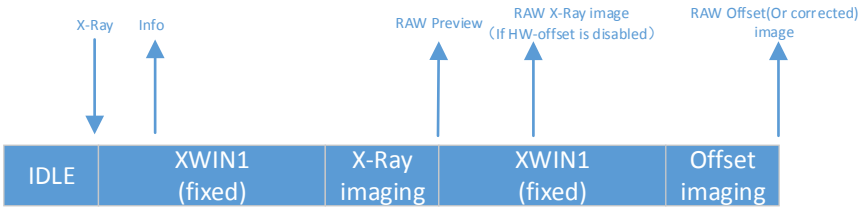
5.3.1. Inner



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

5.3.2. Freesync Mode

5.3.3.



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

5.4. After use

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

5.5. Firmware Upgrade

On “Detector” Page，“Parameter” Tab，user can upgrade firmware by entrance button

“Upgrade Firmware”.

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

Mars1417X_IMAGE_44_ALL_20XX_XX_XX.ifrm

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

Mars1417X_IMAGE_44_ARM_20XX_XX_XX.ifrm

Word “ARM” indicates the file is only for ARM.

Mars1417X_IMAGE_44_FPGA_20XX_XX_XX.ifrm

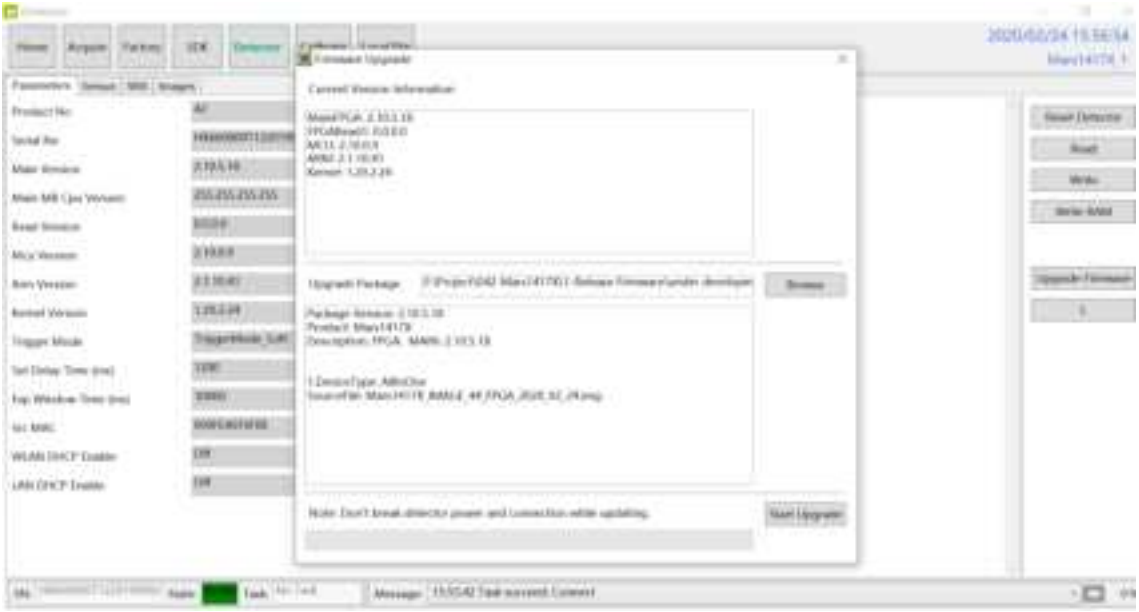
Word “FPGA” indicates the file is only for FPGA.

Mars1417X_IMAGE_44_MCU_20XX_XX_XX.ifrm

Word “MCU” indicates the file is only for MCU.

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

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



6. Regulatory Information

6.1. Medical Equipment Safety Standards

◆ **Medical equipment classification**

Protection type against electrical shock	Class I equipment, using medically approved adaptor supply Internally powered equipment, using battery power supply
Protection degree against electrical shock	B Type
Protection degree against water penetration	IP56 (Detector) IP20 (Charger-Combo)
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in situation with flammable anesthetic mixture with air, oxygen or nitrous oxide Not suitable for use in oxygen-rich situation
The detector has two power supply modes (power adaptor and battery pack) and a single way for signal transmission (wireless)	

◆ **Safety standards reference**

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

IEC 60601-1:2005/AMD1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014/EN60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-2-54:2015/EN 60601-2-54:2015	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
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 (IEC 60601-1:2005, MOD)
CAN/CSA-C22.2No.60601-1:14	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

6.2. Guidance and Manufacture's Declaration for EMC

6.2.1. EMI Compliance Table

◆ **Emissions**

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

6.2.2. EMS Compliance Table

◆ **Enclosure Port**

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

◆ **Near fields from RF wireless communications equipment**

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m

450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		

2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

◆ Input a.c. power port

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

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

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

◆ Cable provided for EMC

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

◆ **Electromagnetic Compatibility (EMC)**

Mars1417X requires special precautions regarding EMC and needs to be installed only by iRay or authorized personnel and put into service according to EMC information provided in the user manual. Mars1417X in use may be susceptible to electromagnetic interference from portable and mobile RF communications such as mobile (cellular) telephones. Electromagnetic interference may result in incorrect operation of the system and create a potentially unsafe situation.

Mars1417X conforms to this EN60601-1-2:2015 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

The use of accessories, transmitters and cables other than those specified by this User Manual, with the exception of accessories and cables sold by iRay of Mars1417X as replacement parts for inner components, may result in increased emission or decreased immunity.

6.3. Radio Frequency Compliance Information

Country	Item
U.S.A.	KDB 865664 D01 47 CFR part 15, subpart B 47 CFR part 15，subpart C 15.247 47 CFR part 15，subpart C 15.407 47 CFR §2.1091 KDB447498 D01 General Exposure Guidance v06
European Union	ETSTEN 300 328 V2.2.2 ETST EN 301 893 V2.1.1 ETST EN 300 440 V2.1.1 ETSTEN 301 489-1 V2.2.3 ETSTEN 301 489-3 V2.1.1 ETSTEN 301 489-17 V3.2.4 EN 55032:2015+A11:2020 EN 55035:2017+A11:2020 EN 61000-3-2:2014 EN 61000-3-3:2013 EN 50566:2017 EN 62209-2:2010+A1:2019 IEC 62479:2010

6.3.1. FCC Compliance

Contains module's FCC ID：2ACHK-01070189

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

- Operation is subject to the following two conditions.

The panel may not cause harmful interference.

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

- The panel generates, uses, and radiates radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the panel does cause harmful interference to radio or television reception, which can be determined by turning the panel off and on, the user is encouraged to correct the interference by one or more of the following measures.

Reorient or relocate the antenna.

Increase the separation between the panel and receiver.

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

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

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation

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

UNII I is in door use only

Radio Frequency (RF) Energy

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

During SAR testing, this device was set to transmit at its highest certified power level in all tested frequency bands, and placed in positions that simulate RF exposure in usage against the body with no separation. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below

the maximum value.

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

The exposure standard for wireless devices employing a unit of measurement is known as the Specific Absorption Rate, or SAR. The SAR limit recommended by the ICNIRP used by the general public is 2.0W/kg averaged over ten grams of tissue and, is 1,6W/kg Averaged over one gram of tissue by IEEE Std 1528.

The FCC has granted an Equipment Authorization for this product with all reported SAR Levels evaluated as in compliance with the FCC RF exposure guidelines.

While there may be differences between the SAR levels of various product and at various positions, they all meet the government requirements.

SAR compliance for body-worn operation is based on a separation distance of 0 mm between the unit and the human body. Carry this device at least 0 mm away from your body to ensure RF exposure level compliant or lower to the reported level. To support body-worn operation, choose the belt clips or holsters, which do not contain metallic components, to maintain a separation of 0 mm between this device and your body.

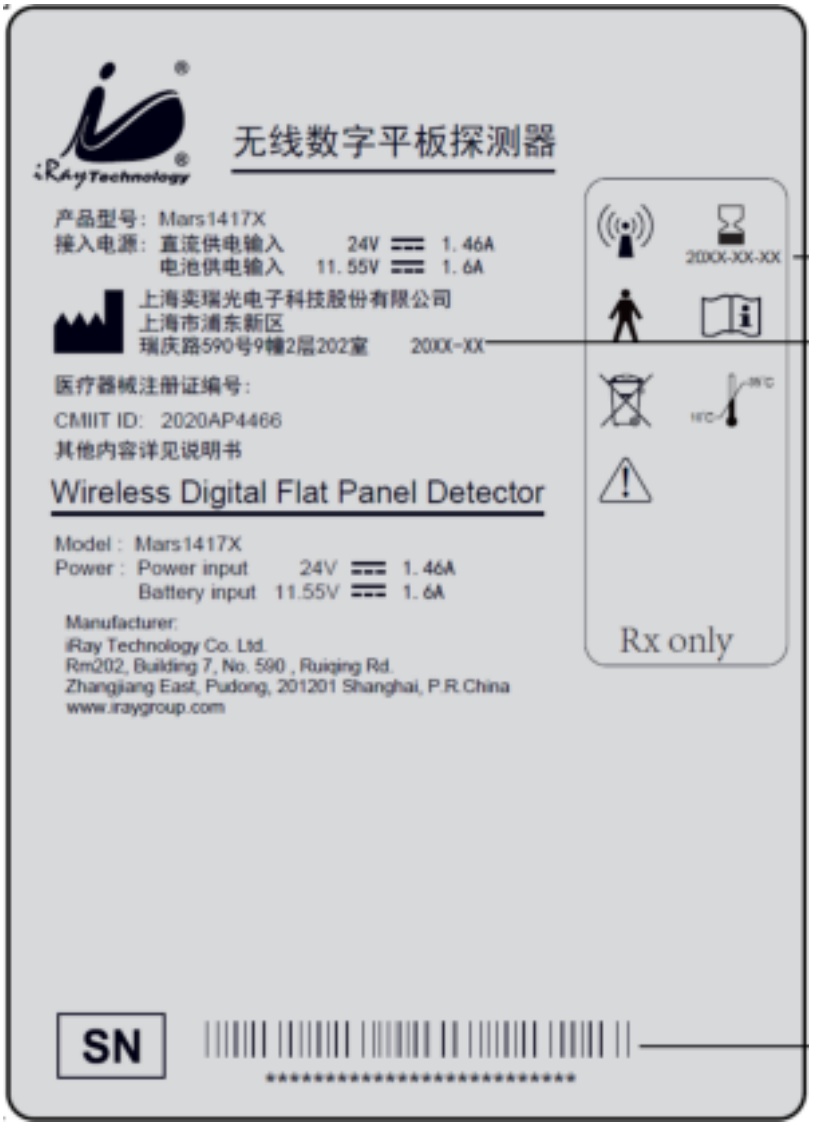
RF exposure compliance with any body-worn accessory, which contains metal, was not tested and certified, and using such body-worn accessory should be avoided.

6.4. Battery Safety Standards

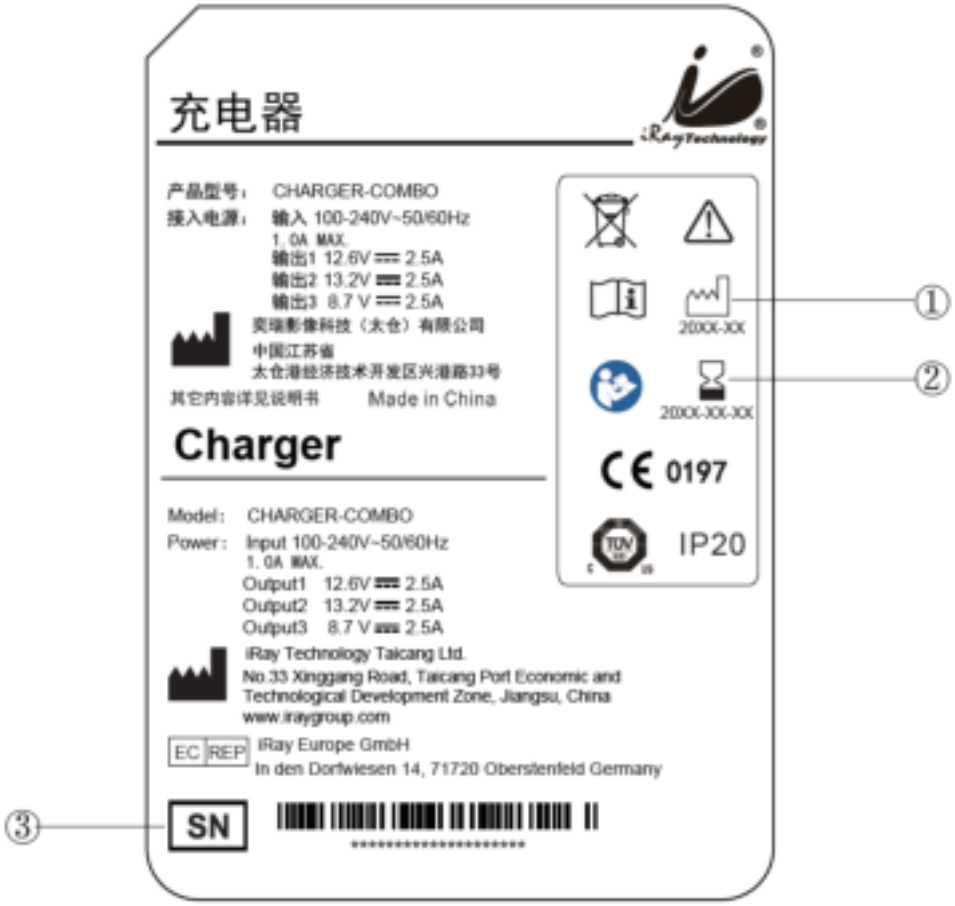
Standards	Description
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
UN38.3	United Nations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

6.5. Product Label

Mars1417X Detector Label


无线数字平板探测器
产品型号：Mars1417X
接入电源：直流供电输入 24V 1.46A
电池供电输入 11.55V 1.6A
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
20XX-XX
医疗器械注册证编号：
CMIIT ID: 2020AP4466
其他内容详见说明书
Wireless Digital Flat Panel Detector
Model : Mars1417X
Power : Power input 24V 1.46A
Battery input 11.55V 1.6A
Manufacturer:
iRay Technology Co. Ltd.
Rm202, Building 7, No. 590 , Ruiqing Rd.
Zhangjiang East, Pudong, 201201 Shanghai, P.R.China
www.iraygroup.com
20XX-XX-XX
Rx only
SN

Battery Charger Label



Battery Label

7. Trouble Shooting

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

8. Service Information

8.1. Service Office Information

Service Office
Tel: +86 21 50720560
Fax: +86 21 50720561
E-mail: service@iraygroup.com
Location: No.33 Xinggang Road, Taicang Port Economic and Technological Development Zone, Jiangsu, China PC: 215434

8.2. Product Lifetime

The estimated product lifetime is up to 5 years under appropriate regular inspection and maintenance.

8.3. Regular Inspection and Maintenance

In order to ensure the safety of patients and operator, to maintain the performance and reliability of the panel, be sure to perform regular inspection at least once a year. If necessary, clean up the panel, make adjustments or replace consumables such as fuses etc. There may be cases where overhaul is recommended depending on conditions. Contact iRay service office or local iRay dealer for regular inspection or maintenance.

8.4. Repair

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

Product Name:

Series Number:

Description of Problem: as clearly as possible.

8.5. Replacement Parts Support

Main parts (parts required to maintain the function of the product) of this product will be stocked for 5 years after discontinuance of production for repairing.

COMPANY: iRay Technology Taicang Ltd.

ADDRESS: No.33 Xinggang Road, Taicang Port Economic and Technological Development Zone, Jiangsu, China

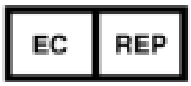
ZIP CODE: 215434

TELEPHONE: +86 0512-53690872

FAX: +86 0512-53690872

HOMEPAGE: *WWW.IRAYGROUP.COM*

Appendix A Information of Manufactures



Appendix B Information of Europe Representative

COMPANY: iRay Europe GmbH

ADDRESS: IN DEN DORFWIESEN 14, 71720 OBERSTENFELD GERMANY

ZIP CODE: /

TELEPHONE: +49-7062-977 88 00

FAX: +49-7062-976 0571

HOMEPAGE: WWW.IRAYEUROPE.COM