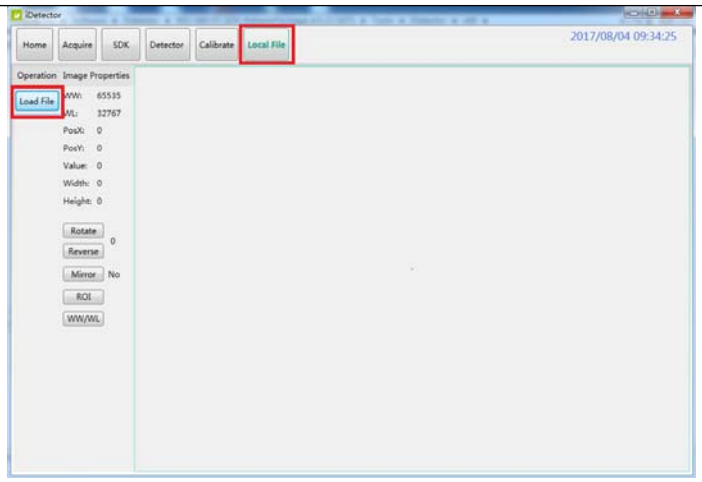
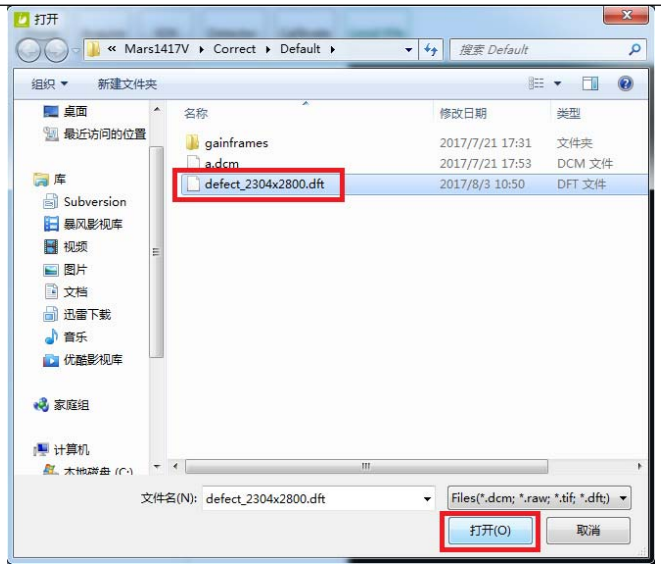
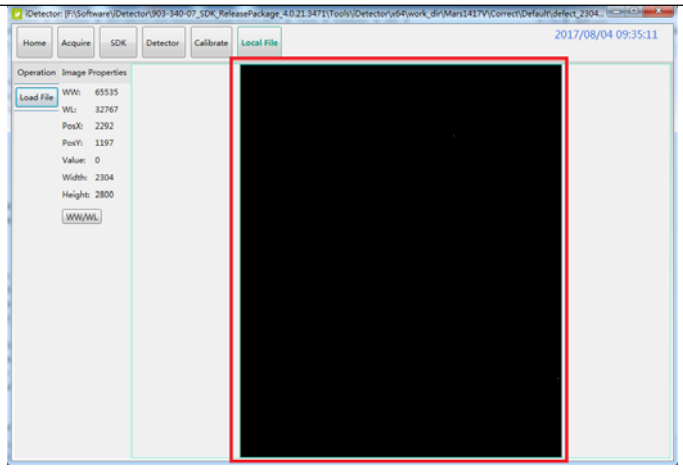
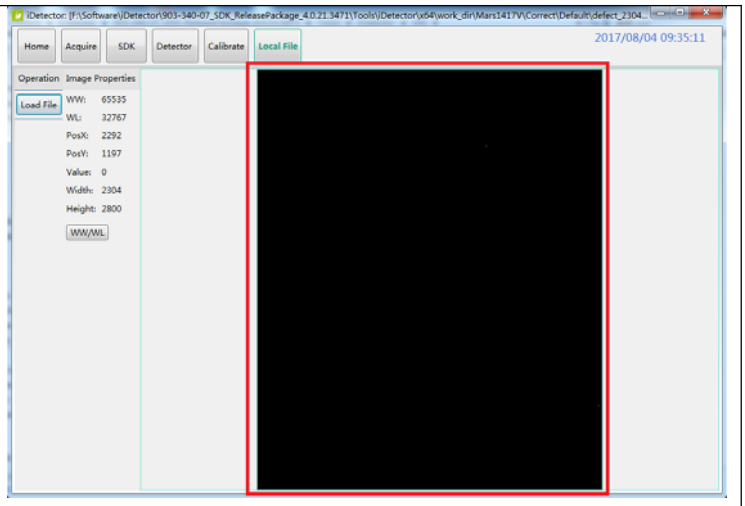
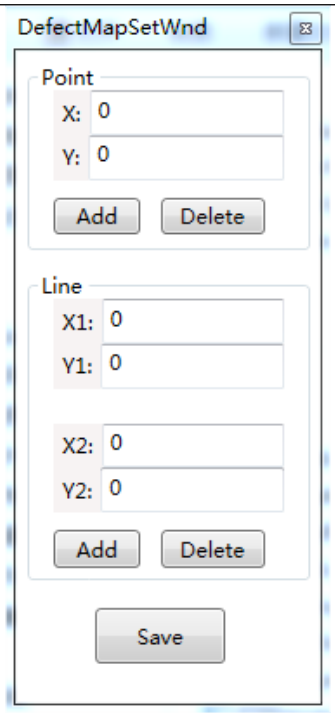
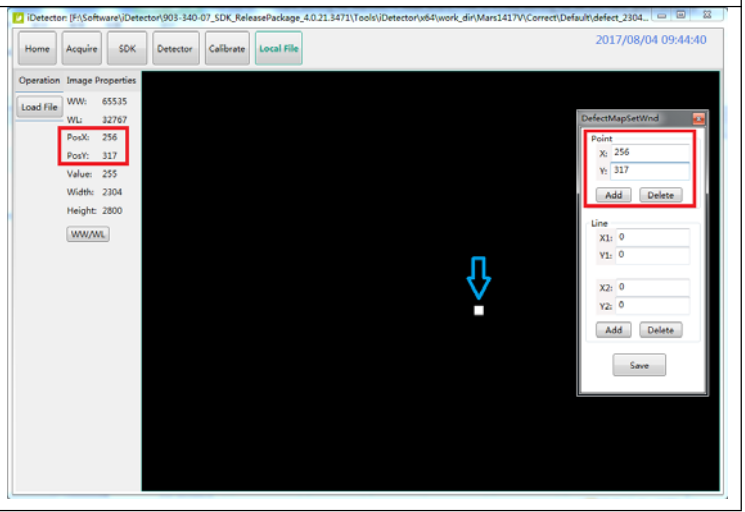
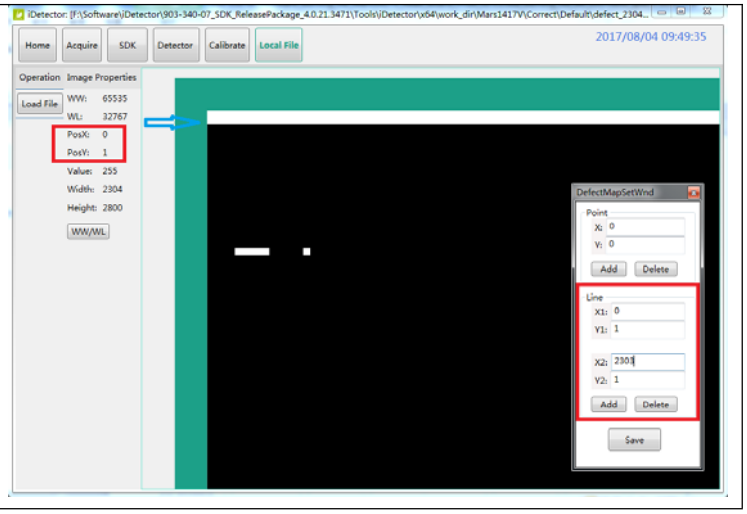
4.6.1. Defect Template Check

Click “LoadFile” on “LocalFile” page	
Choose the specified defect template, and click “Open”	
The defect template will showed on the UI	

4.6.2. Defect Template Modification

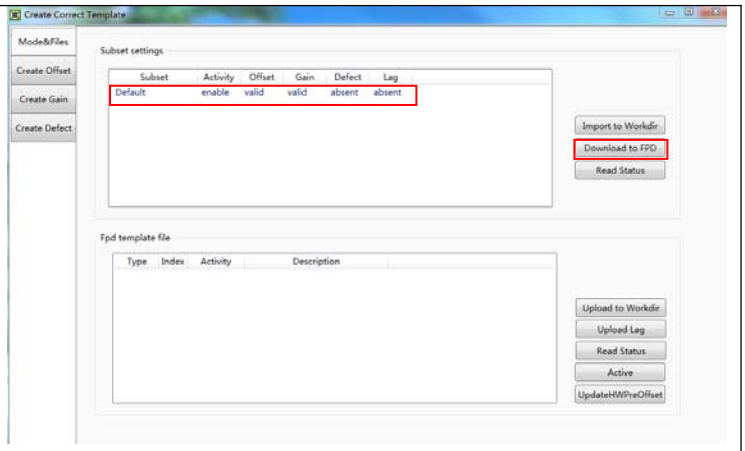
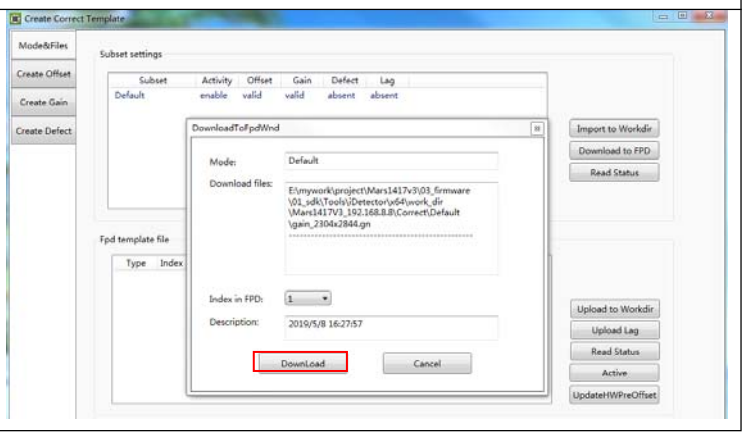
Open the specified defect template	
The defect management dialog box will be showed	
Find the pixel that needs to be managed, type the coordinate of the pixel and click “Add”, the information will be added to the template If click “Delete”, the information will be deleted Click “Save”	

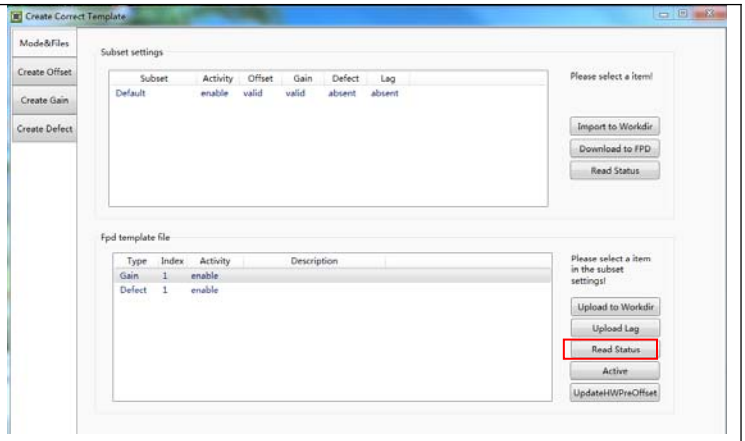
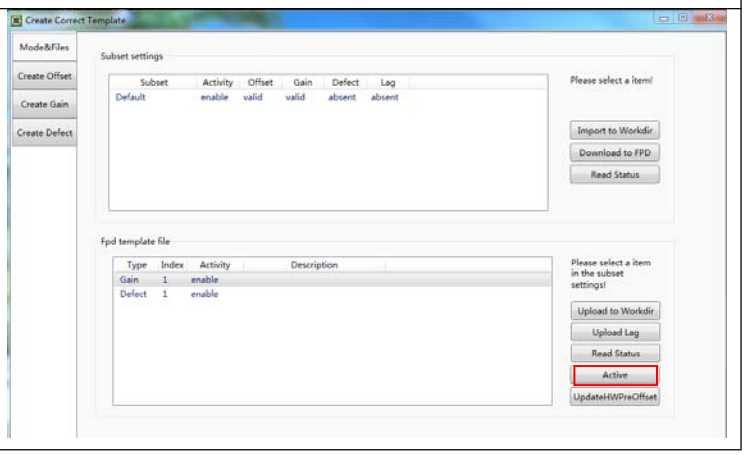
It is similar to manage the defect pixel, If user need to add the defect line, type the coordinate of the line and click “Add” If the information needs to be deleted, click “Delete”	

4.7. Correction and Calibration Management

4.7.1. Correction and Calibration template synchronization

Panel supports correction and calibration template storage. So template in panel could be uploaded to Workstation, and template in Workstation could also be downloaded to panel.

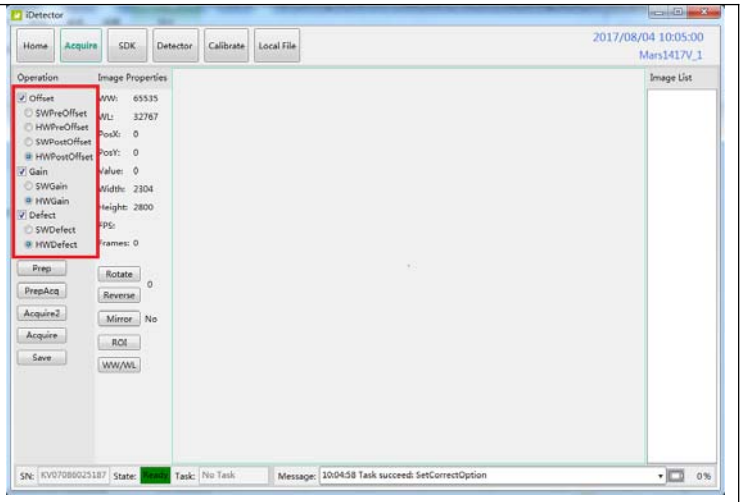
After generating the offset ,gain and defect templates, select the templates and click “Download to FPD”	
Click “DownLoad”	

Click “Read Status”	
If the activity shows disenable, please select the one and click “Active” to enable it	

4.7.2. Correction and Calibration management

Panel supports two ways to do correction and calibration. Software Correction and Calibration defines the scenario that Workstation completes all correction and calibration. If panel complete all correction and calibration by itself, it is named as Hardware Correction and Calibration.

User can set the calibration method on “Acquire” page	

Choose “HWPostOffset”, “HWGain”, “HWDefect”, the hardware-based calibration is on	
Choose “SWPostOffset”, “SWGain”, “SWDefect”, the software-based calibration is on	

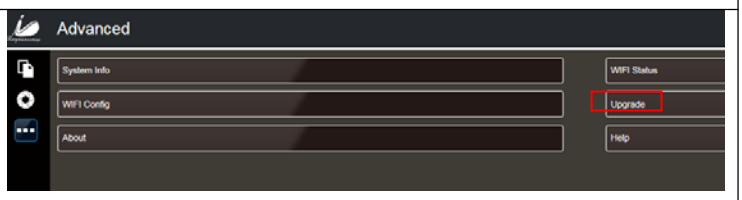
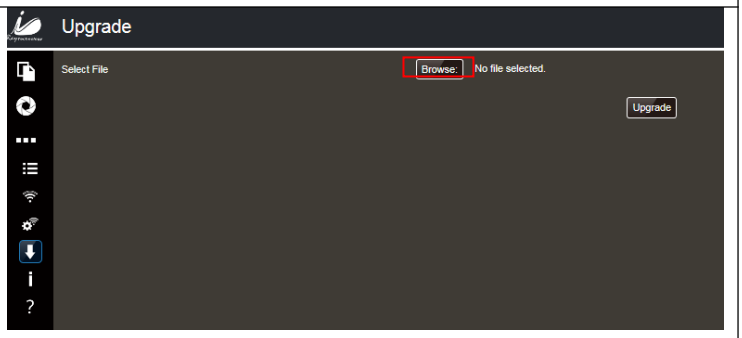
4.8. Firmware Update

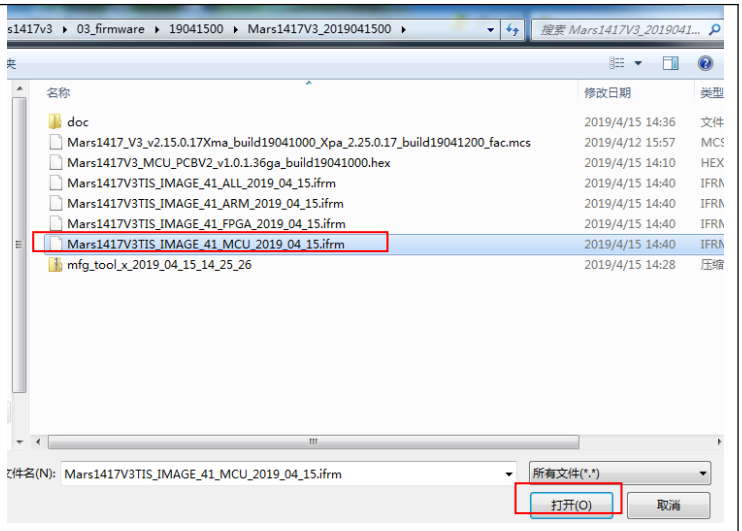
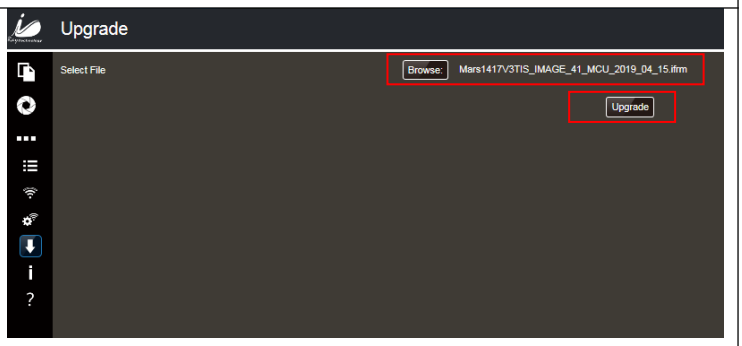
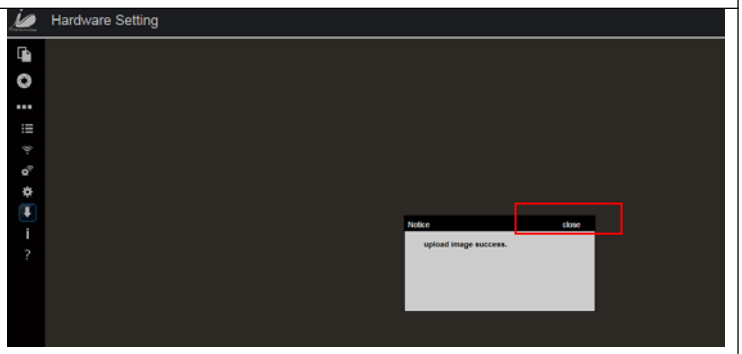
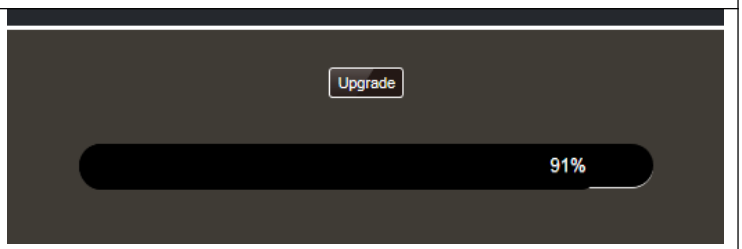
Panel supports the use of the Web way to upgrade the firmware, if a user needs to update the firmware, please complete the following steps.

Before update, please make sure that the battery capacity is more than 80% or the DC power is connected.

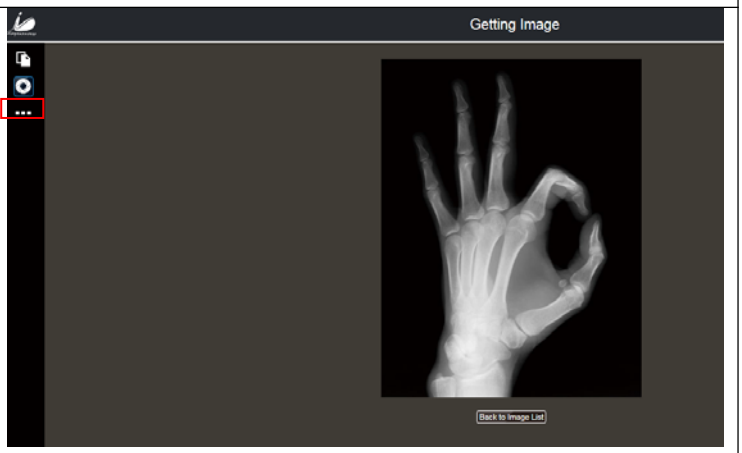
4.8.1. MCU Update

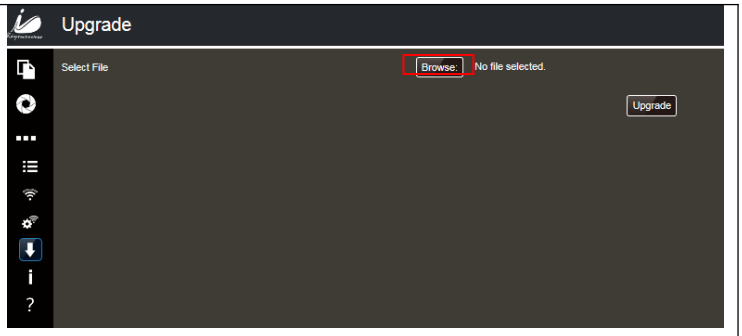
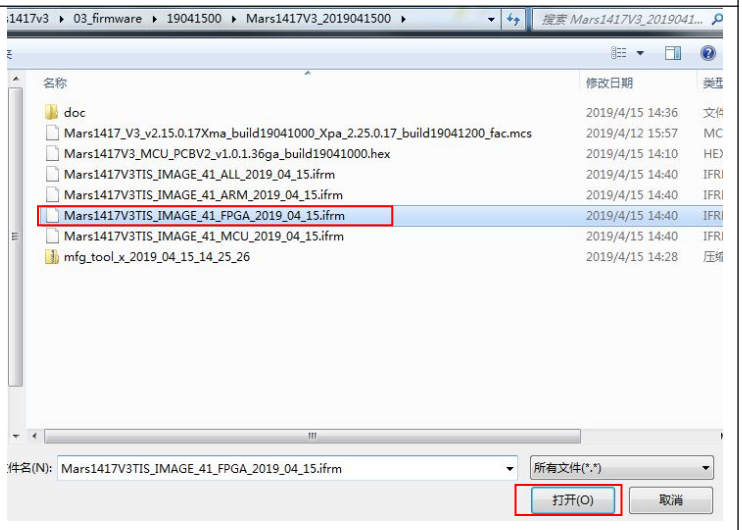
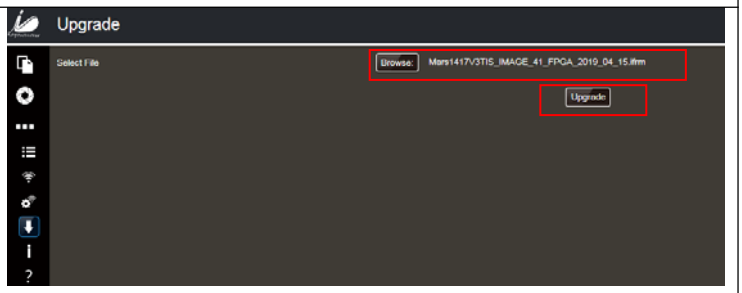
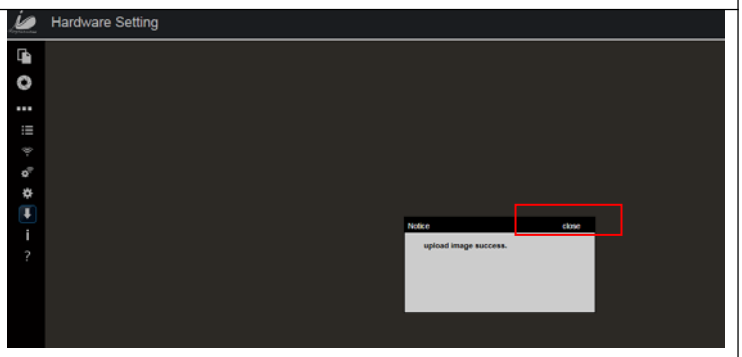
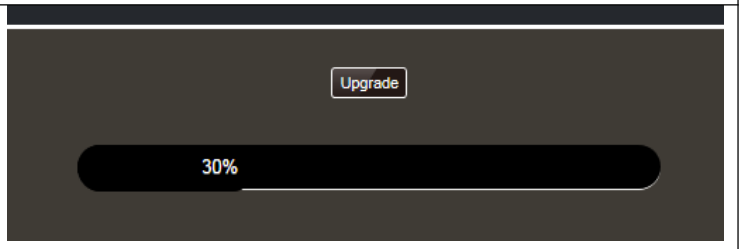
Connect the panel to PC	/
Open a browser, and type “192.168.8.8” in the search bar, then click the “Enter” button	

User name: admin Password: iray Click “login”	
Click “[redacted]”	
Click “Upgrade”	
Click “Browse”	

Find the MCU file, select it and open it	
The selected file name will be displayed on the interface. Click “Upgrade”	
Click “close”	
There will show the progress bar.	
If upgrade success, the interface as shown in the picture on the right will be displayed. Otherwise, it means failure.	

4.8.2. FPGA Update

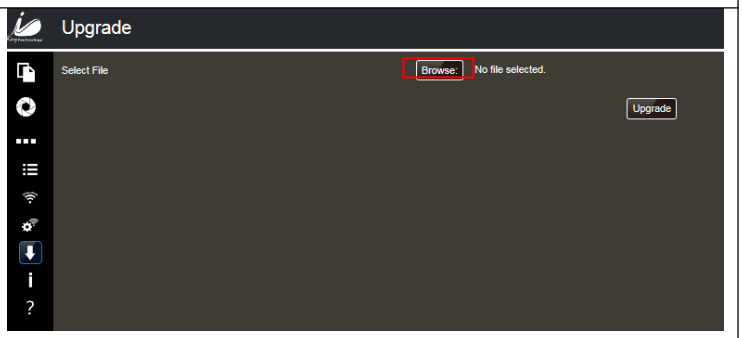
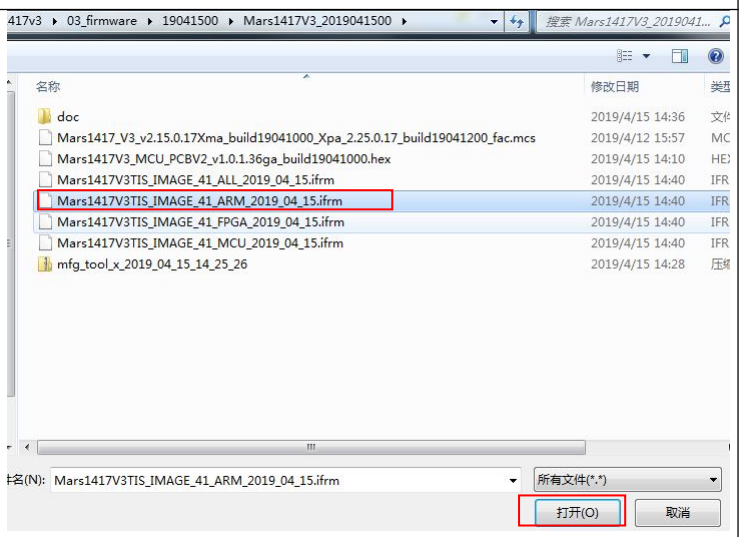
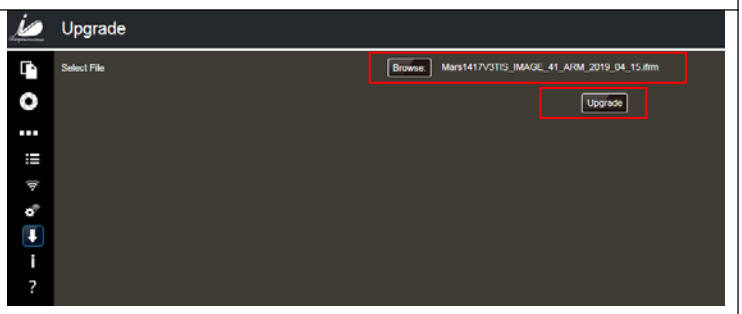
Connect the panel to PC	/
Open a browser, and type “192.168.8.8” in the search bar, then click the “Enter” button	
User name: admin Password: iray Click “login”	
Click “[redacted]”	
Click “Upgrade”	

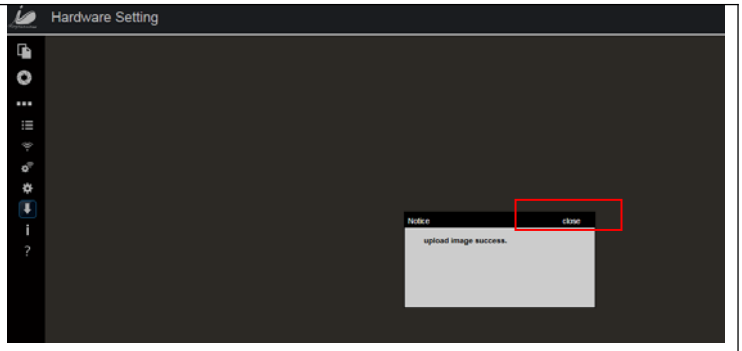
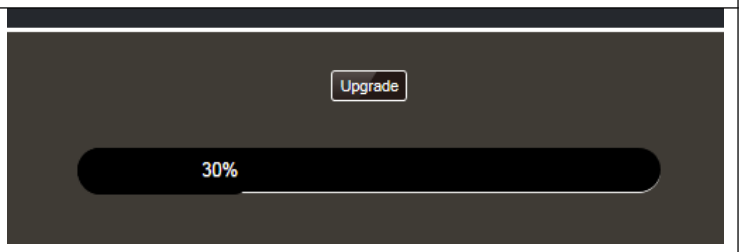
Click “Browse”	
Find the FPGA file, select it and open it	
The selected file name will be displayed on the interface. Click “Upgrade”	
Click “close”	
There will show the progress bar.	

If upgrade success, the interface as shown in the picture on the right will be displayed. Otherwise, it means failure.	

4.8.3. ARM Update

Connect the panel to PC	/
Open a browser, and type “192.168.8.8” in the search bar, then click the “Enter” button	
User name: admin Password: iray Click “login”	

Click “[redacted]”	
Click “Upgrade”	
Click “Browse”	
Find the ARM file, select it and open it	
The selected file name will be displayed on the interface. Click “Upgrade”	

Click “close”	
There will show the progress bar.	
If upgrade success, the interface as shown in the picture on the right will be displayed. Otherwise, it means failure.	

4.8.4. ALL FIRMWARE Update

All of the firmware (MCU, FPGA, and ARM) can be upgraded at the same time, if the file selected is like “Mars1417V3TIS_IMAGE_41_ALL_2019_04_15.ifm”. And the upgrade steps please refer the steps above.

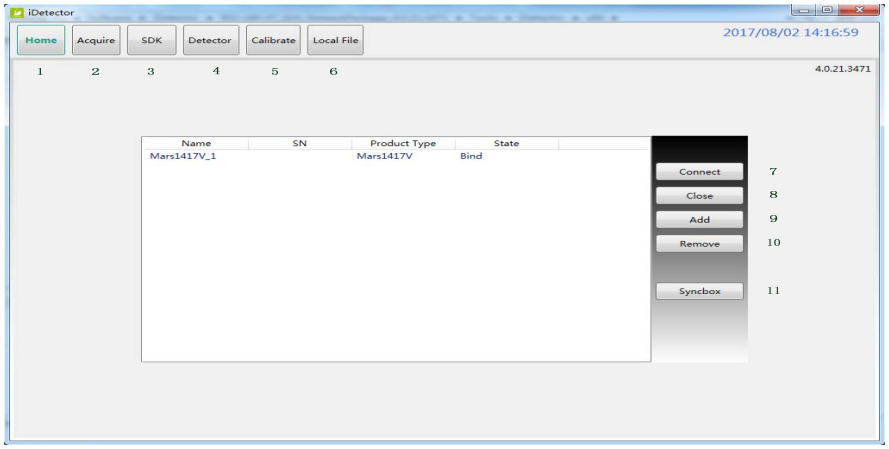
4.9. Short cut

iDetector supports some shortcuts as follows:

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

4.10. Software

4.10.1. Main GUI



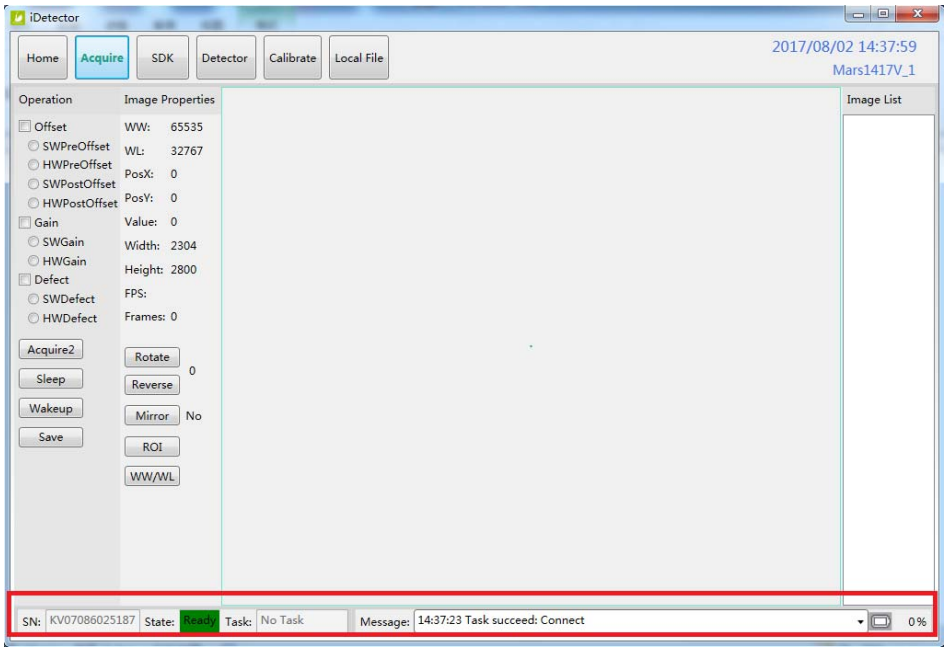
iRay provides test tools, such as iDetector for testing the basic performance of detector. It can connect the detector, acquire image, image correct and calibrate.

Function description of regions and buttons within the main window as follows:

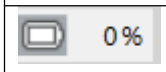
1	Home	Home page, shows the list of the detectors
2	Acquire	Acquire images, free for use after connecting the detector
3	SDK	Configure UI for SDK, free for use after connecting the detector
4	Detector	Configure UI for detector, free for use after connecting the detector
5	Calibrate	Calibration UI, for generation and management of the calibration template
6	Local File	Image management, free for use at any time
7	Connect	Button for connecting the detector
8	Close	Button for disconnecting the detector
9	Add	Button for add the instance for one detector
10	Remove	Button for delete the instance for one detector
11	Syncbox	Management for syncbox

4.10.2. Message Box

4.10.2.1. Status Box



Status box defines the current status of panel.

SN	Serial Number of the detector
Status	Status of the detector, busy or ready
Task	The current task being executed
Message	Information
	Remaining power of the battery, showed as percentage

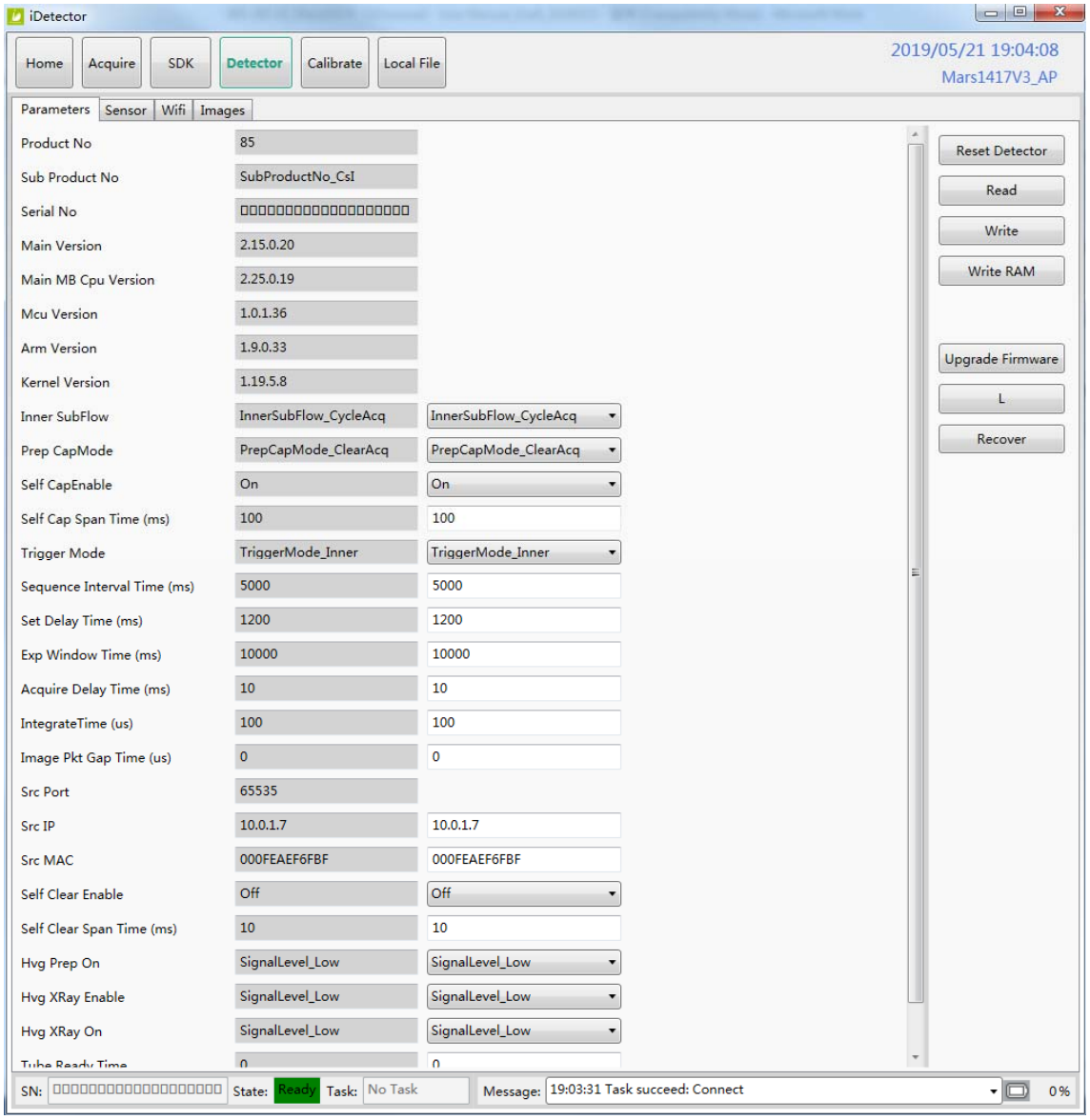
4.10.2.2. Progress Bar

Progress Bar defines as following.

If progress bar is Green when shooting X ray, image quality is acceptable, otherwise image quality would degrade.

4.10.3. Configuration GUI

4.10.3.1. General Settings

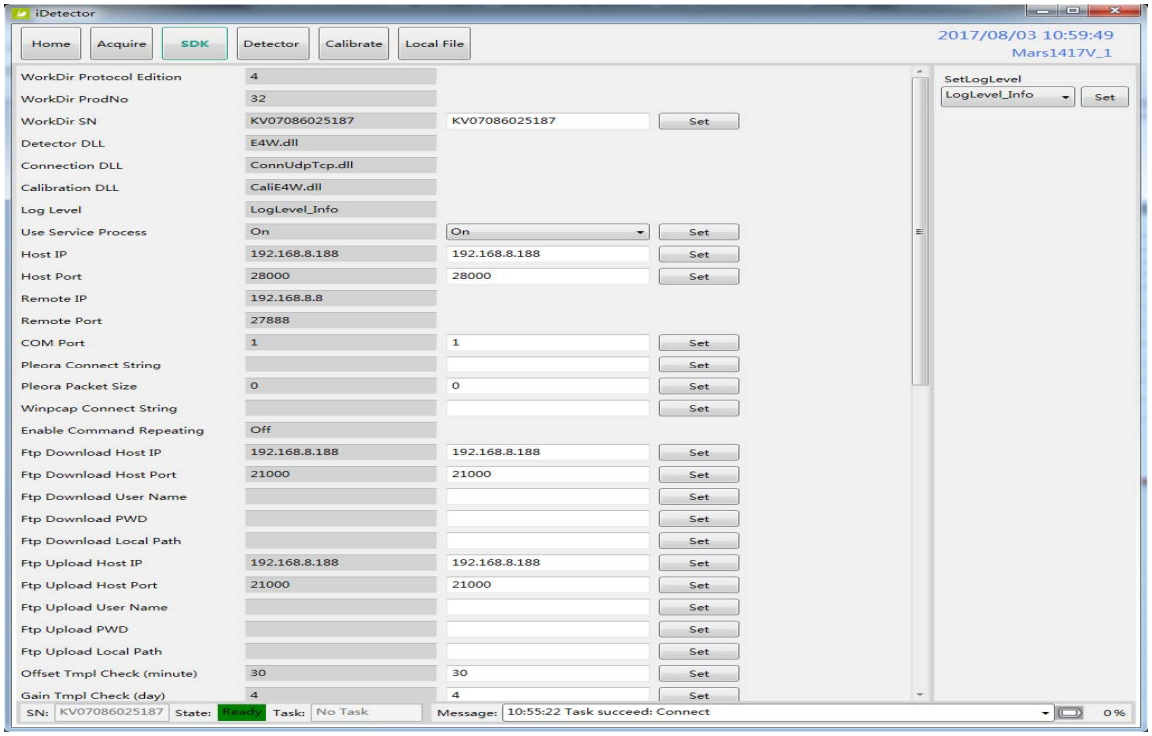


Except the following parameters, the value should not be modified for other parameters.

Description		Modify
Product No	Type number of the detector	NO
Sub Product No	Sub-type of the detector	NO
Serial No	Serial number of the panel	NO
Main Version	Version of the firmware of Main FPGA	NO
Main MB Cpu Version	Version of the MB Cpu of Main FPGA	NO
MCU Version	Version of the firmware of MCU	NO
Arm Version	Version of the App of ARM	NO
Kernel Version	Version of the Kernel of ARM	NO
Inner Subflow	Sub work-flow	Yes

Prep CapMode	Reserved	Yes
Self CapEnable	Reserved	YES
Self Cap Span Time	Should not be modified, and keep the original value	YES
Trigger Mode	Trigger mode	YES
Sequence Interval Time	Should not be modified, and keep the original value	YES
Set Delay Time	Exposure window for Freesync mode	YES
Exp Window Time	Exposure Window for Software/Inner mode, the value should not be large than 10s	YES
Acquire Delay Time	Reserved	YES
Integrate Time	Should not be modified, and keep the original value	YES
Src Port	Port number for detector	NO
Src IP	IP address for detector	YES
Src MAC	MAC address for detector	YES
Dest Port	Port number for PC	NO
Dest IP	IP address for detector	NO
Self Clear Enable	Related to Prep CapMode, the value should be configured as “On” if Prep CapMode is configured as PrepCapMode_ClearAcq, otherwise should be “Off” If the Trigger Mode is Software/Inner, the value should be “On”	YES
Self Clear Span Time	Should not be modified, and keep the original value	YES
Hvg Prep On	Reserved	YES
Hvg XRay Enable	Reserved	YES
Hvg XRay On	Reserved	YES
Tube Ready Time	Reserved	YES
Image Pkg Gap Time	Reserved	YES
Out Mode Cap Trigger	Reserved	YES

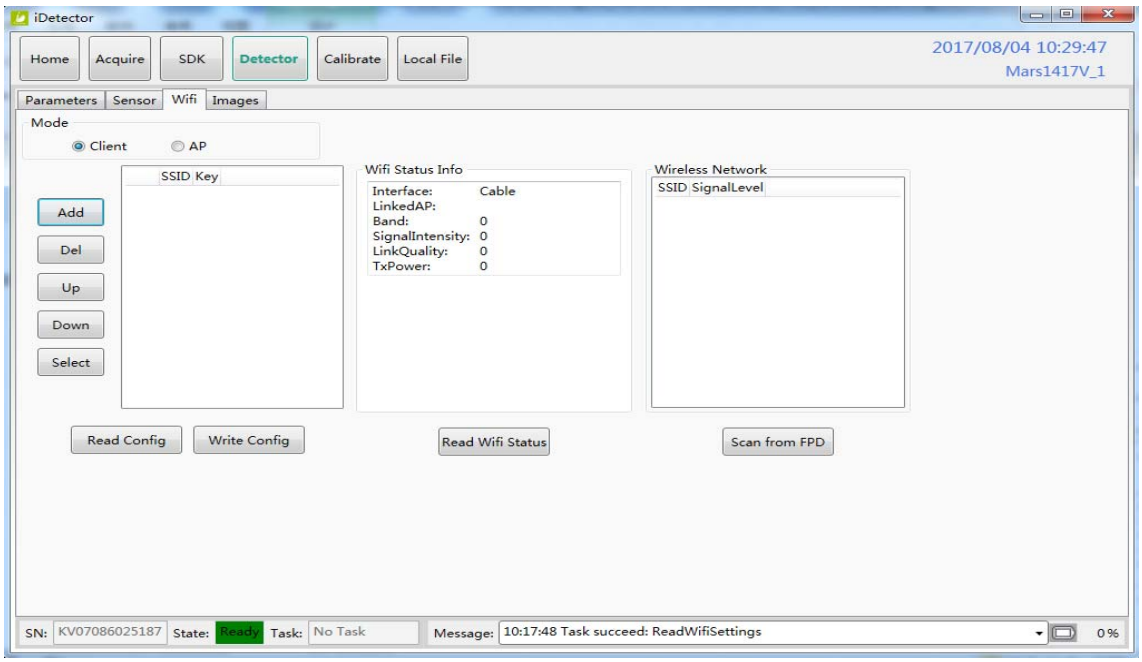
4.10.3.2. SDK Settings



Only the following parameters need to be concerned

Description		Modify
Host IP	IP Address of local workstation	YES
Host Port	Port of local workstation	YES
Ftp Download Host IP	FTP download server IP, keep the same as Host IP	YES
Ftp Download Host Port	FTP download server Port, keep the same as Host Port	YES
Ftp Upload Host IP	FTP upload server IP, keep the same as Host IP	YES
Ftp Upload Host Port	FTP upload server Port, keep the same as Host Port	YES

4.10.3.3. Network Settings



Description		Modify
Add	Add the information of SSID and Key of the AP	/
Del	Delete the information of SSID and Key of the AP	/
Up	Move up the AP information	/
Down	Move down the AP information	/
Select	Select the AP	/
Read Config	Read the parameters of the AP information when the detector is set as AP	/
Write Config	Write the parameters of the AP information when the detector is set as AP	/
Read Wifi Status	Read the wifi status of the current detector	/
Scan from FPD	Scan the AP	/

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

1) The operating system is not compatibility;
2) Change or update the software failed;
3) The compatibility of the interface;
4) The data transfer protocol error;
5) The inconsistent of interface or format leads to data distortion;
6) The data output failed;

5. REGULATORY INFORMATION **83**

5.1. Medical equipment safety standards 83

5.2. The compliance for each EMISSIONS and IMMUNITY standard or test specified by IEC60601-1-2 standard 84

5.3. Radio Frequency Compliance Information 87

5.3.1. FCC Compliance 87

5.4. Battery Safety Standards 88

5. Regulatory Information

5.1. Medical equipment safety standards

Medical equipment classification

Type of protection against electrical shock	External electrical power source equipment Class I Equipment (medical approved adaptor) Internal electrical power source equipment (battery)
Degree of protection against electrical shock	Type-B applied part
Degree of protection against ingress of water	IPX1
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide Not suitable for use in the oxygen rich environment

Product safety standards

MDD (93/42/EEC)	Medical Device Directive
ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
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 62133:2012	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
IEC 62220-1:2003 EN 62220-1:2004	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency
IEC 62304:2006/AMD1:2015	Medical device software - Software life-cycle processes
IEC 62366-1:2015/IEC 62366:2007/EN 62366:2008	Medical devices –part 1: Application of usability engineering to medical devices
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN ISO14971: 2012	Medical device – Application of risk management to medical devices
ANSI/AAMI ES60601-1:2005/(R)2012+A1:2012+C1:2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005,

009/(R)2012+A2:2010/(R)2012	MOD)
CAN/CSA-C22.2 No.60601-1:14	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
ISO 15223-1:2016/ EN ISO 15223-1:2016	Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied—Part 1: General requirements

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

EMI Compliance Table

Emission

Phenomenon	**Compliance**	**Electromagnetic environment**
RF emissions	CISPR 11 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

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
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table “Proximity fields from RF wireless communications equipment”
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Proximity 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 AC 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

Input DC 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
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

Signal input/output parts 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
Electrical fast transients/burst	IEC 61000-4-4	±1 kV 100kHz repetition frequency
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

The following shows information on reference cables provided against EMC

Cable	**Recommended cable length**	**Shielded or Unshielded**	**Number**	**Cable classification**
AC Power Cable	3m	Unshielded	1 pcs	AC Power
DC Power Cable	3.5m	Unshielded	1 pcs	DC Power
LAN Cable (configuration mode)	3m	Shielded	1 pcs	Signal

- Important information regarding Electromagnetic Compatibility (EMC)

Mars1417V 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. Mars1417V 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. The minimum distance between the panel and other equipment should be larger than 12 inch.

Mars1417V 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 Mars1417V as replacement parts for inner components, may result in increased emission or decreased immunity.

5.3. Radio Frequency Compliance Information

Country	Item
U.S.A	FCC Part 15.107 Sub part (b) / 15.109(g) Sub part B FCC Part 15 Sub part E 15.407 FCC Part 15 Sub part C 15.247
European Union	ETSI EN 301 489-1 V1.8.1 (EMC) ETSI EN 301 489-17 V2.1.1 (EMC) EN 300 328 V.1.7.1; EN 301 893 V1.6.1 (RF) EN 62311:2008 (RF Exposure) ETSI EN 300 328 V1.7.1; EN 301 893, V1.5.1 (Radio Spectrum)

5.3.1. FCC Compliance

- 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 measure.

  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.

5.4. Battery Safety Standards

Standards	Description
CAN/CSA E62133:13 1st Ed. Rev.	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 First Edition
UL 62133, 1st Ed. Rev.	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 First Edition
UL 2054	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. TROUBLE SHOOTING.....**90**

6. 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.

7. SERVICE INFORMATION **92**

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7.4. Replacement Parts Support 92

7. Service Information

7.1. Product Lifetime

The estimated product lifetime is up to 7 years under appropriate regular inspection and maintenance (battery 5 years).

7.2. 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.

7.3. 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.

7.4. 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.

Appendix

APPENDIX A INFORMATION OF MANUFACTURES.....**94**

APPENDIX B INFORMATION OF MEDICAL DEVICE DIRECTIVE EUROPEAN REPRESENTATIVE.....**95**

Appendix A Information of Manufactures

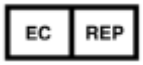
Company: iRay Technology Taicang, Ltd.

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

ZIPCODE: 215434

TELEPHONE: +86-0512-53690872

Appendix B Information of Medical Device Directive European Representative



iRay Europe GmbH

Address: In den Dorfwiesen 14, 71720 Oberstenfeld Germany

Tel: +49-7062-977 88 00

Fax: +49-7062-976 0571

FCC Regulations:

Contains module's FCC ID：2ACHK-01070189

- 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.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

  —Reorient or relocate the receiving antenna.

  —Increase the separation between the equipment and receiver.

  —Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

  —Consult the dealer or an experienced radio/ TV technician for help.
- Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
- W52/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.

For this device, the highest FCC reported SAR value for usage against the head is 0.152W/kg, and for usage near the body is 0.137W/kg.

the highest CE SAR value for usage against the body is 0.093W/kg.

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.