Wireless Digital Flat Panel Detector

Mars1717VS

User Manual

Document Version: A0

Document ID: 119-201-01

Release Date: 2019.09.16

CE 0197

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

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

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

E

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.

About SAR

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

To Customers

Congratulations on your purchase of the Fixed Digital Flat Panel (hereinafter referred to as Mars1717VS) which is manufactured by iRay Technology Co.Ltd. (Hereinafter referred to as iRay).

At iRay, we strive to not only make the world-class products that deliver the best value possible to our customers but also offer the highest quality of service and customer care. Please take time to read through this user guide in order to utilize the product effectively. We hope you enjoy the experience with iRay Mars1717VS.

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

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

Notes on usage and management of the equipment

1. Read all of the instructions in the user guide before your operation. Give particular attention to all safety precautions.
2. Only a physician or a legally certified operator should use this product.
3. The equipment should be maintained in a safe and operable condition by maintenance personnel.
4. Use only computers and image display monitors complying with IEC 60601-1 or IEC 60950-1. For details, consult our sales representative or local iRay dealer.
5. Use only the dedicated cables. Do not use any cables other than those supplied with this product.
6. Request your sales representative or local iRay dealer to install this product.

Caring for your environment

This symbol indicates that this product is not to be disposed of with your residential or commercial waste.

Recycling iRay Equipment

Please do not dispose of this product with your residential or commercial waste. Improper handling of this type of waste could have a negative impact on health and on the environment. Some countries or regions, such as the European Union, have set up systems to collect and recycle electrical or electronic waste items. Contact your local authorities for information about practices established in your region. If collection systems are not available, call iRay Customer Service for assistance.

Disclaimer

iRay shall not be liable to the purchaser of this product or third parties for any damage, losse, or injury incurred by purchaser or third parties as a result of fire, earthquake, any accident, misuse or abuse of this product.

iRay shall not be liable to any damage, loss, or injury arising from unauthorized modifications, repairs, or alterations to this product or failure to strictly comply with iRay′ s operating and maintenance instructions.

iRay shall not be liable for any damage or loss arising from the use of any options or consumable products other than those dedicated as Original iRay Products by iRay Technology.

It is the responsibilities of the user/attending physicians for maintaining the privacy of image data and providing medical care services. iRay shall not be responsible for the legality of image processing , reading and storage nor it shall be responsible for loss of image data for any reason.

Information regarding specification, compositions, and appearance of this product is subject to change without prior notice.。

Copyright

Trademarks

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

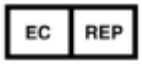
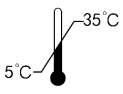
Symbols and Conventions

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 personal injury.
	This notice is used to identify conditions under which improper use of the product may cause minor personal 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 contents of the labels and markings on iRay Mar1717VS product are indicated below:

Symbol	Guide
	Caution: please refer to the instructions in the user manual.
	This symbol is used to indicate that the equipment has passed CE testing and it is followed by the CE number.
	This symbol is used to identify the manufacture series number which is after, below or adjacent to the symbol. The series number of our products is usually made of nineteen digits as shown below: A1A2A3A4 B1B2 C1C2 L M1M2 D1D2 Y1Y2 X1X2X3X4 Numerical Order Year Date Month Production site Version Derived classes 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 iRay authorized representative in the European region.
	This symbol is used to indicate consultation of the user guide for general information.
	Safety Signs: please refer to the user guide for safety instructions.
	Safety Signs：Dangerous Voltage.
	Handled with care.
	This symbol is used to indicate the operational temperature limits.
	This symbol indicates the product radiates wireless signal.

	Package symbol, fragile.
	Package symbol, keep away from sunlight.
	Package symbol, keep dry.
	Package symbol, keep the equipment up right.
	Package symbol, do not roll the transportation package.
	Type-B applied part
	Package symbol, this symbol is used to indicate stacking limit number.
	IPX3 for working surface only

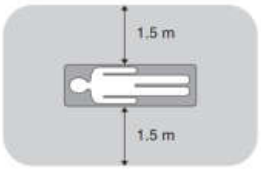
1. Safety

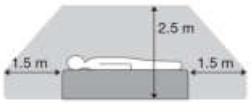
1.1 Safety Precautions

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

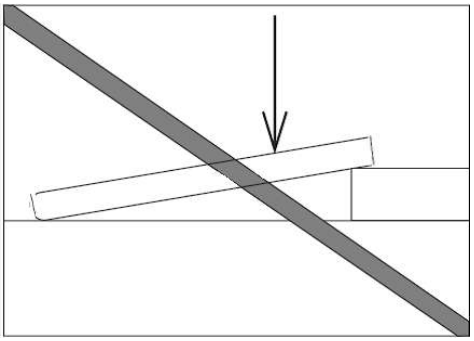
WARNING	
Installation and environment of use   	• **Do not use or store the equipment near flammable chemicals such as alcohol, thinner, benzene, etc.** If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the equipment. Also, some disinfectants are flammable. Be sure to take care when using them. • **Do not connect the equipment with anything other than specified.** Doing so may result in fire or electric shock. • **All the patients with active implantable medical devices should be kept away from the equipment.**
Power supply  	• **Do not operate the equipment using any type of power supply other than the one indicated on the rating label.** Otherwise, it may result in fire or electric shock. • **Do not handle the equipment with wet hands.** You may experience electric shock that could result in death or serious injury. • **Do not place heavy object such as medical equipment on cables and cords. Do not pull, bend, bundle, or step on them to prevent their sheath from being damaged, and do not alter them neither.** Doing so may damage the cords which could result in fire or electric shock. • **Do not supply power to more than one piece of equipment using the same AC outlet.** Doing so may result in fire or electric shock. • **Do not turn ON the system power when condensation has formed on the equipment.** Doing so may result in fire or electric shock. • **Do not connect a multiple portable socket-outlet or extension cord to the system.** Doing so may result in fire or electric shock. • **To avoid the risk of electric shock, this equipment must only be connected to power supply with protective earth.** Not doing so may result in fire or electric shock.
	• **Securely plug the power cord into the AC outlet.** If contact failure occurs, or if metal objects come into contact with the exposed metal prongs of the plug, fire or electric shock may result. • **Be sure to turn OFF the power to each piece of equipment before connecting or disconnecting the cords.** Otherwise, you may get an electric shock that could result in death or serious injury. • **Be sure to hold the plug or connector to disconnect the cord.**

	If you pull the cord, the core wire may be damaged, resulting in fire or electric shock.
WARNING	
Handling  	• **Never disassemble or modify the equipment. No modification of this equipment is allowed. Parts of the Mar1717VS that are not serviced or maintained while in use with the patient.** Doing so may result in fire or electric shock. Also, since the equipment incorporates parts that may cause electric shock as well as other hazardous parts, touching them may cause death or serious injury. • **Do not place anything on top of the equipment.** The object may fall and cause an injury. Also, if metal objects such as needles or clips fall into the equipment, or if liquid is spilled, it may result in fire or electric shock. • **Do not hit or drop the equipment.** The equipment may be damaged if it receives a strong jolt, which may result in fire or electric shock if the equipment is used without being repaired. • **Do not put the equipment and pointed objects together.** The equipment may be damaged. If so, the equipment should be used in bucky.
	• **Have the patient take a fixed posture and do not let the patient touch parts unnecessarily.** If the patient touches connectors or switches, it may result in electric shock or malfunction of the equipment.
When a problem occurs	• **Should any of the following occurs, immediately unplug the power cord of Control Box, and contact your sales representative or local iRay dealer:** When there is smoke, an odd smell or abnormal sound. When liquid has been spilled into the equipment or a metal object has entered through an opening. When the equipment has been dropped and damaged.
Maintenance and inspection  	• **Please turn OFF the power of the equipment and unplug the power cord of adaptor before cleaning.** • **NEVER use alcohol, ether and other flammable cleaning agent for safety. NEVER use methanol, benzene, acid and base because they will erode the equipment.** • **DON'T dip the equipment into the liquid.** • **Please make sure that the equipment's surface & plugs are dry before turning ON.** Otherwise, it may result in fire or electric shock.
	• **Clean the plug of the power cord periodically by unplugging it from the AC outlet and removing dust or dirt from the plug, its periphery and AC outlet with a dry cloth.** If the cord is kept plugged in for a long time in a dusty, humid or sooty place, dust around the plug will attract moisture; this could cause insulation failure that may result in a fire. • **For safety reasons, be sure to turn OFF the power to each piece of equipment when performing inspections indicated in this manual.** Otherwise, electric shocks may occur.

<table>
<tr><th colspan="2">CAUTION</th></tr>
<tr><td>Installation and environment of use</td><td>
• Do not install the equipment in any of the locations listed below. Doing so may result in failure, malfunction, equipment falling, fire or injury.
Close to facilities where water is used
Where it will be exposed to direct sunlight
Close to the air outlet of an air-conditioner or ventilation equipment
Close to heat source such as a heater
Where the power supply is unstable
In a dusty environment
In a saline or sulfurous environment
Where temperature or humidity is high
Where there is freezing or condensation
In areas prone to vibration
On an incline or in an unstable area
• Take care that cables do not become tangled during use. Also, be careful not to get your feet caught by cable.
Otherwise, it may cause a malfunction of the equipment or injury of the user due to tripping over the cable.




</td></tr>
<tr><td>Power supply</td><td>
• Always connect the three-core power cord plug to a grounded AC power outlet.
• To make it easy to disconnect the plug at any time, avoid putting any obstacles near the outlet. Otherwise, it may not be possible to disconnect the plug in an emergency.
• Be sure to ground the equipment to an indoor grounded connector. Also, be sure to connect all the grounds for the system to a common ground.
• Do not use any power source other than the one provided with this equipment.
Otherwise, fire or electric shock may be caused due to leakage.
</td></tr>
<tr><td>Handling</td><td>
• Do not spill liquid or chemicals onto the equipment. In case the patient is injured, it is not allowed to contact with blood or other body fluids.
Doing so may result in fire or electric shock.
In such a situation, protect the equipment with a disposable cover as necessary.
• Turn OFF the power and pull out the plug to each piece of equipment for safety when not used.
</td></tr>
</table>

CAUTION	
Handling	• **Handle the equipment carefully.** • **Do not submerge the equipment in water.** • **The internal image sensor may be damaged if something hits against it or it is dropped.** • **Do not place excessive weight on the equipment.** • **Otherwise, the internal image sensor may be damaged and image may be incorrect.** • • **<Load Limit>** • **Uniform load：150 kg over the whole area of the detector surface.** • **Local load：100 kg on an area 4 cm diameter.** • **Be sure to use the equipment on a protected foam. Otherwise, the internal image sensor may be damaged. Be sure to securely hold the detector while using it in upright positions. Otherwise, the detector may fall over, resulting in injury to the user or patient, or may flip over, resulting in damage to the inner device.**  Keep the same load (same pressure) on the detector when acquiring the image. Otherwise, the image will be incorrect.
CAUTION	
CAUTION	• **Do not close to fire, do not use in high temperature** • **Do not invert positive and negative pole** • **Do not contact with metal in case of short circuit** • **Do not insert sharp objects into battery** • **Do not beat battery** • **Do not stand on battery** • **Do not use battery out of rules** • **Do not dispose battery or change internal structure** • **Do not submerge battery in water, please keep dry in storage and do not contact with water in use** • **Please charge battery with charger following IEC60601-1 & IEC62133 Standards provide by us** • **Do not mix battery with ones not provided by our company** • **Do not charge battery with broken charger.**

1.2 Notes for Using of FPD

When using the equipment, take the following precautions. Otherwise, problems may occur and the equipment may not function correctly.

Before exposure

- Be sure to check the equipment daily and confirm that it works properly.
- Be sure there be a battery installing on the Mars1717VS to avoid the power off suddenly
- Sudden heating of the room in cold areas will cause condensation to form on the equipment. In this case, wait until the condensation evaporates before performing an exposure. If the equipment is used while condensation is formed on it, problems may occur in the quality of captured images. When an air-conditioner is used, be sure to raise/lower the temperature gradually so that a difference of temperature in the room and equipment does not occur, to prevent condensation.
- The detector should warm up for 15 minutes before exposure or updating the gain map or defect map.

During exposure

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

Disinfection and Cleaning (When in portable usage)

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

1.3 Notes for Using of Battery

- Battery is shipped with detector, remaining capacity should be charged greater than or equal to 50% but less than 60%. If storage without use, charge greater than or equal to 50% but less than 60% every 3 month, or it causes damage to battery.

- Battery is shipped in package without detector, remaining capacity should be charged greater than or equal to 20% but less than 30%, If storage without use, charge greater than or equal to 20% but less than 30% every 2 month, or it causes damage to battery.

  If battery remaining capacity is lower than 20%, delivery is not allowed, or it is possible to be over discharge.

  Battery storage and working environment should strictly follow specification. If there is any objection, there is possibility to damage performance

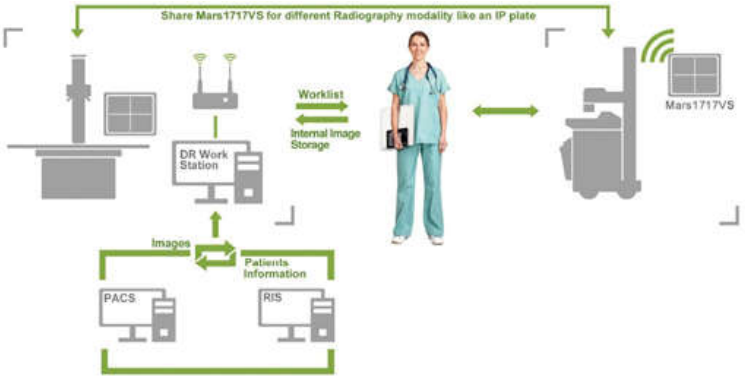
  If battery is not used in detector, please detach it.

2. General Description

Mars1717VS is a cassette-size wireless X-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It is developed to provide the good quality of radiographic image, which contains an active matrix of 3070×3070 with 139um pixel pitch. Panels' scintillator is CsI (Cesium Iodide). Mars1717VS supports wireless communication between panel and Workstation, and can be used as a real portable panel.

2.1 Scope

This manual contains information about the Mars1717VS. Information in the manual, including the illustrations, is based on prototype. If your configuration does not have any of these items, information about these items does not apply to your panel.



2.2 Intended Use

Mars1717VS Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures. This panel provides digital X-ray imaging for diagnosis of disease, injury, or any applicable health problem. The image is obtained as the result of X-ray passing through the human body and detected by detector.

iRay would provide hardware and software support for integration of system.

This panel is not intended for mammography or dental applications.

2.3 Essential Performance

According to the Mars1717VS series INTENDED USE and the result of risk management, image acquisition and data transmission are defined as ESSENTIAL PERFORMANCE.

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

2.4 Application Specification

PATIENT population:

Age: except for children

Weight: not relevant

Health: not relevant

Nationality: multiple

Gender: except for pregnant women

Intended OPERATOR:

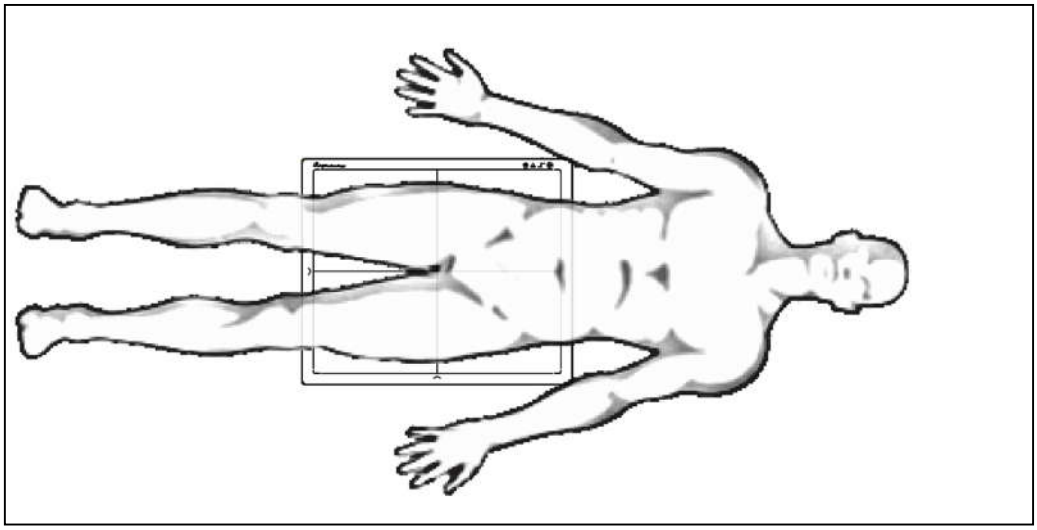
All of use, maintenance and operation steps should be carried out by the operator who has accepted the professional training offered by the company's customer service staff.

Life-time:

Life-time: 5 years without frequency limit

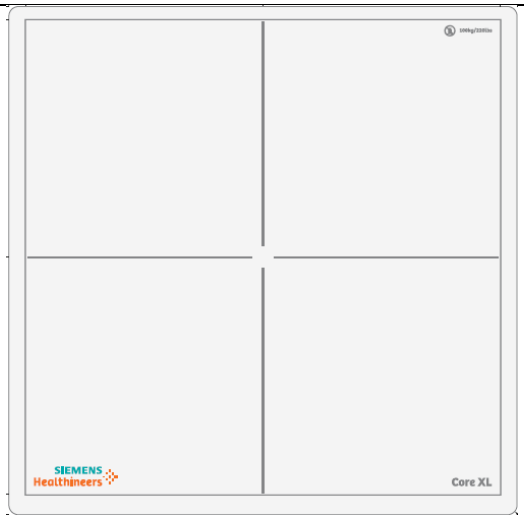
2.5 The Relative Position Between Patient And Detector

Because of the crosstalk effect of Amorphous silicon flat-panel detector, Pay attention to the relative position of patient and detector, the recommended position as shown below, Otherwise, the image is prone to abnormal light lines.



2.6 Product Components

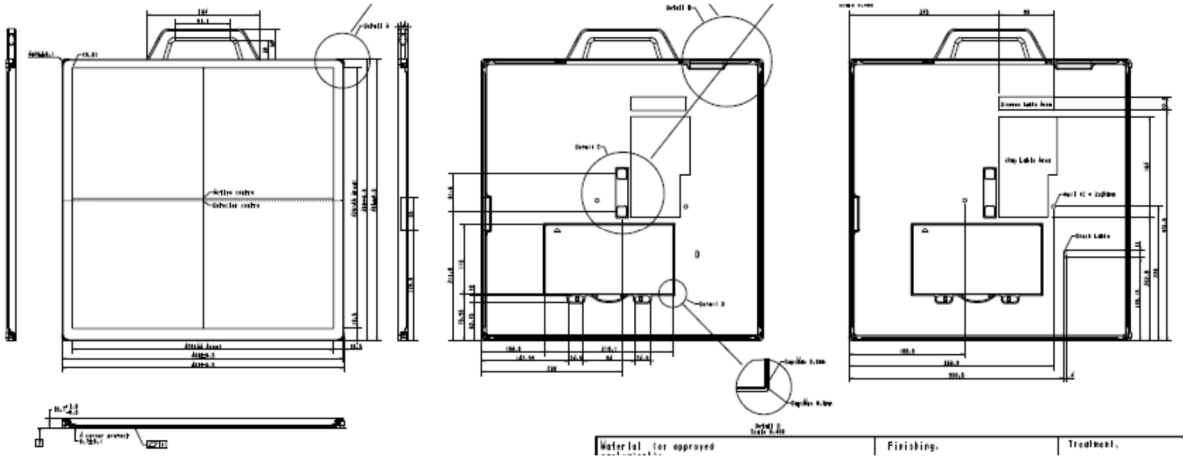
Mars1717VS comes with battery package. Once powered on, it would build a connection with Workstation through Ethernet cable (only for service) or Wireless connection.

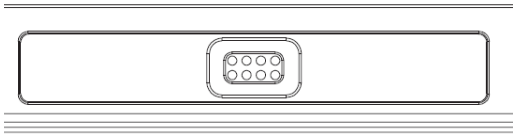
Item		Description
Detector		1pcs Main Unit
Battery		1pcs Battery pack

Ethernet Cable (Only for service)		1pcs 1 m
Ethernet Adapter		1pcs
Battery Charger		1pcs

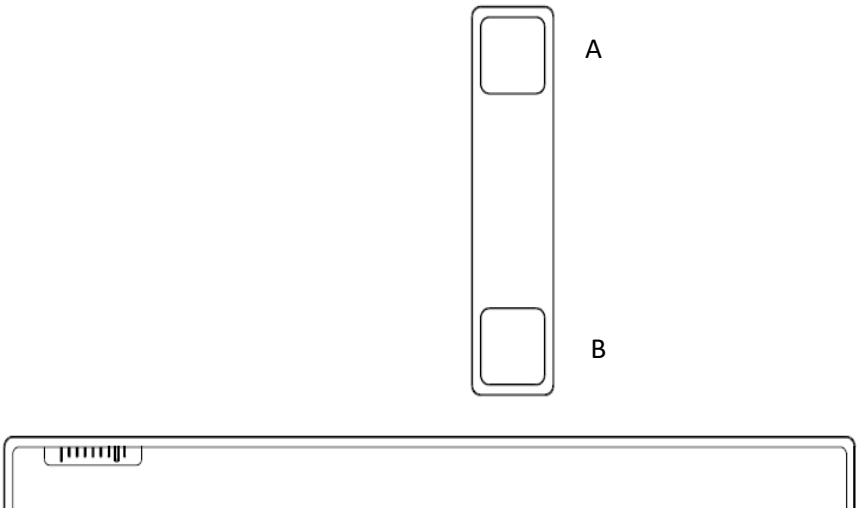
2.7 Components Description And Specification

2.7.1 Detector





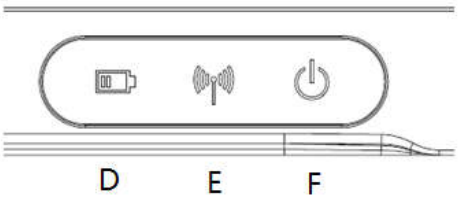
External Signals Input



External Power Input

No.	Item	Description

A	Positive Pole	NA
B	Negative Pole	NA



Indicator

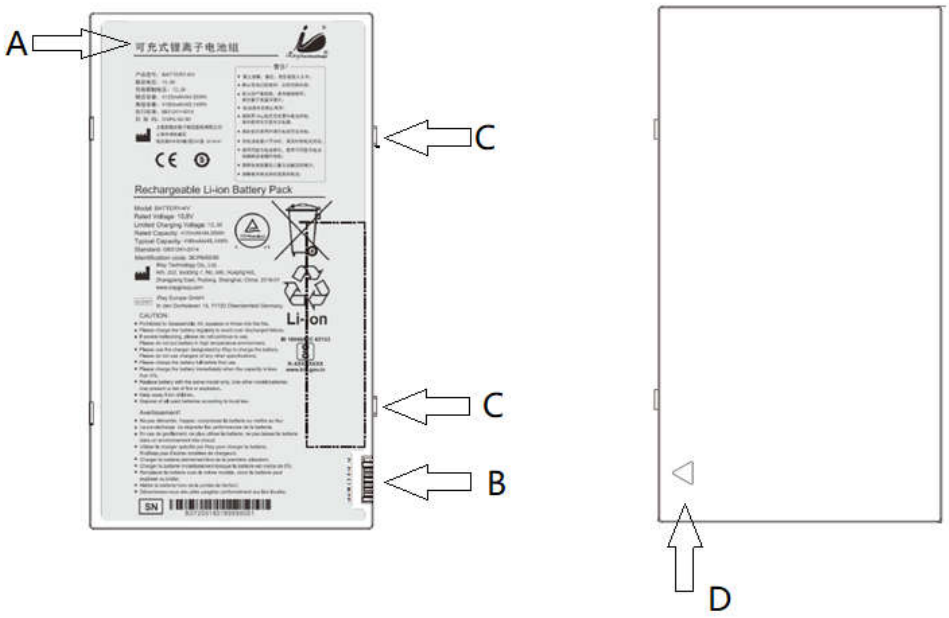
No.	Item	Description
D	Power	Power button of control panel
E	Link	Link button of control panel
F	Status	Status button of control panel

Detector Specification

Item	Specification
Model	Mars1717VS-VSI (CsI)
Image Sensor	a-Si (Amorphous Silicon) TFT
Pixel Size	139μm
Effective Array	3070 x 3070
Effective Area (H x V)	426.7mm x 426.7mm
Gray scales	16bit
Limiting Spatial Resolution	3.6 Lp/mm without phantom or grid
Image Acquisition Time ~~(Wireless)~~ Client mode~~(5G)~~	Preview: 2.5 sec. Processed: 7 sec.
Cycle Time	Min. 9s
Power Consumption	Max. 20W
Dimension (L × W × H)	461 x 461 x 15.7 mm(Without Handle)

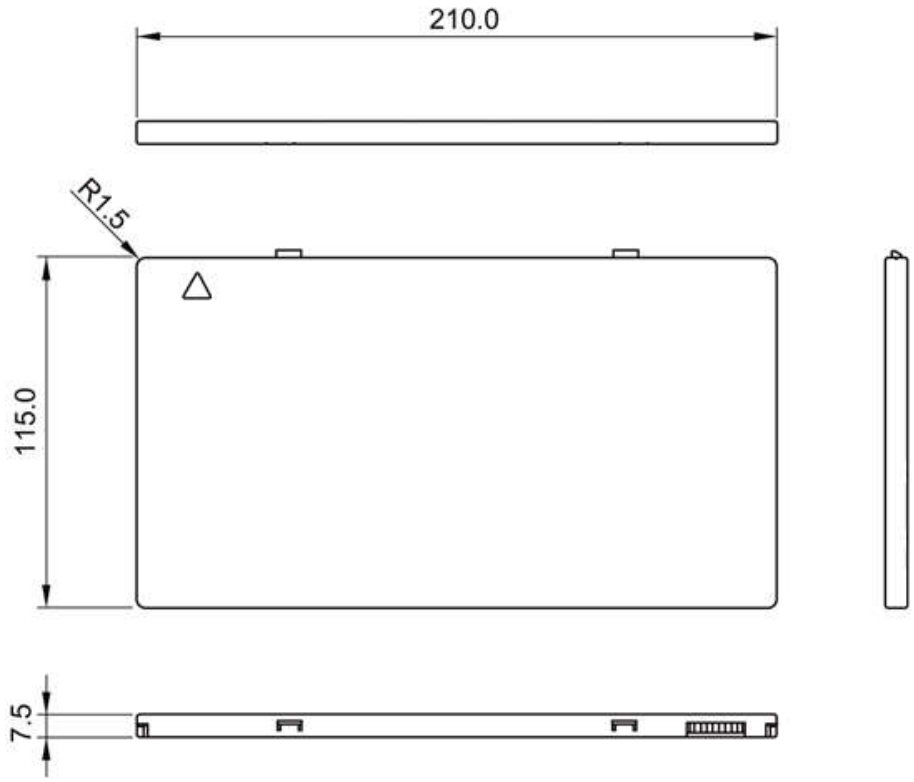
Weight (with one battery)	≤4.2 kg
Image Transfer	Wireless: IEEE802.11 a/b/g/n/ac
Wireless Frequency Range	2.412~2.472GHz, 5.18~5.22GHz; 5.745~5.85GHz
Data Transmission Power	13dBm (Typ.) @802.11a 16dBm (Typ.) @802.11b 14dBm (Typ.) @802.11g 13dBm (Typ.) @802.11n HT20 11dBm (Typ.) @802.11n HT40 16dBm@2.4GHz 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
X-ray Energy	40kV to 150kV

2.7.2 Battery



Item	Name	Description
A	Battery Label	/
B	Battery Interface	8 Pin Battery connector
C	Pilot Pin	/
D	Indicator	Installation direction indicator

Dimension and Specification

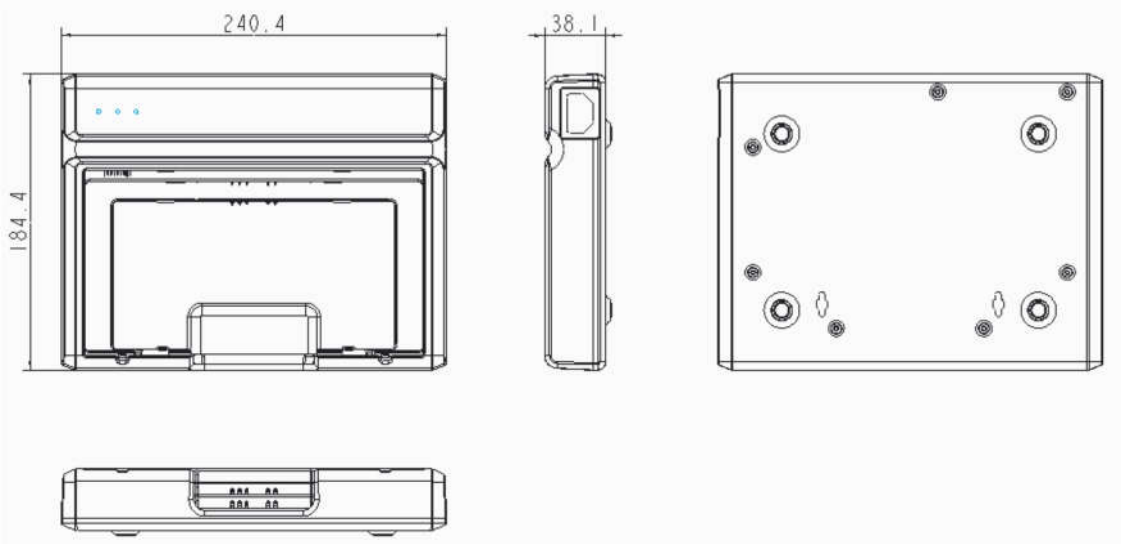


Item	Specifications
Model	Battery-KV
Rated Capacity	Typ. 4180mAh @ Discharge 0.2C
Nominal Voltage	10.8V
Charge Voltage	12.6±0.05V
Discharged End Voltage	9V
Charging Method	CC-CV
Operating Temperature	Charge 0℃-+60℃, Discharge-10℃-+60℃
Storage Temperature	≤3 month -20℃-+45℃ ≤6 month -20℃-+35℃
Relative Humidity	5%~95%
Dimension (L × W × H)	210 x 115 x 7.5 mm
Weight	0.28kg

2.7.3 Battery Charger

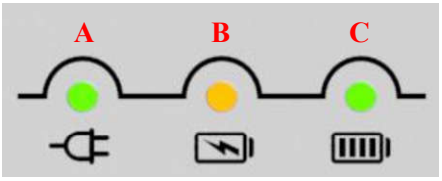
Item	Name	Description
A	Battery Interface	8 Pin Battery connector
B	Capacity Indicator	The indicator definition is as follow
C	Power Indicator	The indicator definition is as follow
D	Hand Pull Position	/
E	The limit ball plug	/
F	DC Jack	24V DC input

Dimension and Specification

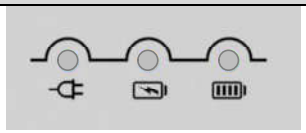
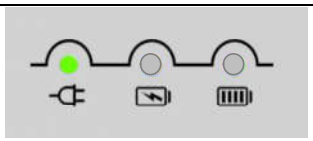
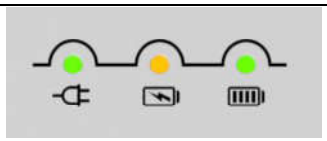
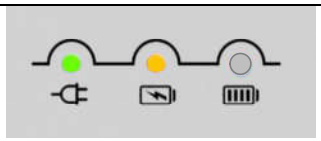
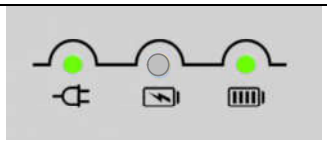
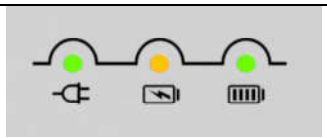


Item	Specifications
Model	Charger-Combo
Simultaneous Charging	1 battery packs
Full charging time	≤3 hours
Rated power supply	90~264V(AC)
Dimension (L × W × H)	240 x 184 x 38 mm
Weight	0.55 kg

The battery charger indicator definition:



Item	Name	Description
A	Power Indicator	/
B	Charging Indicator	/
C	Charge Full Indicator	/

X Indicator	Lighting Status	Operating Status
All off		No power input
A indicator on		● AC Power input ● Multiple batteries inserted
A indicator on B and C alternately blink 2 times		Battery insertion self-test
A and B indicator on		Battery Charging
A and C indicator on		Battery capacity full, charging stops
A indicator on B and C alternately blinking		Battery charging abnormal

Two or more battery charging at the same time is prohibited, if inserted at the same time, the charger will automatically stop working.

2.7.4 Power supply

Mars1717VS supports both DC Power and Battery package input.

Item	Specifications
DC Power	24V(DC), 0.75A
Battery Package	10.8V(DC),1.5A

2.7.5 Recommended Application Condition

Item	Description
Operating System	Windows 7 32/64bit
CPU	Intel Core i7 3.6G
Memory	4G DDR3
Hard Disk	640 G
LAN Card	Intel Pro EXP9301CT PRO Gigabit Network Adapter with PCIe interface

2.7.6 Use Environment

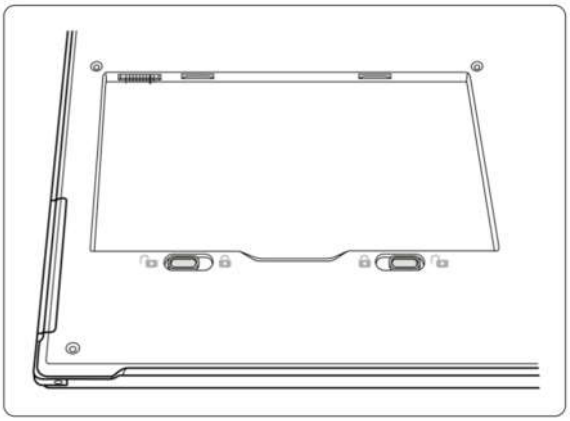
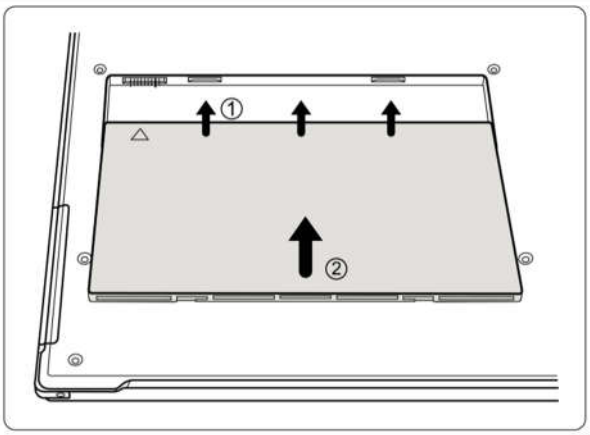
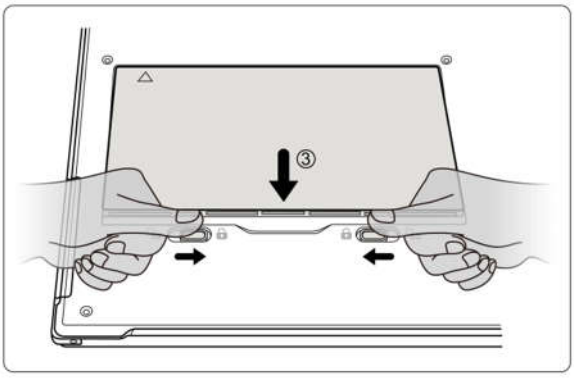
	Temperature	Temperature change	Humidity	Atmospheric Pressure	Pressure Change
Operating	5~35℃	<1k/min	10%~90% RH	700~1060hPa	<10kp/min (1kp=1.0197E-5Pa)
Storage	-10~55℃	<1k/min	10%~90% RH	700~1060hPa	<10kp/min (1kp=1.0197E-5Pa)
The Mars1717VS serial detectors shall operate at an altitude specified not more than 3000m, the environment is only for detector.					

3. Installation

3.1 Panel Installation

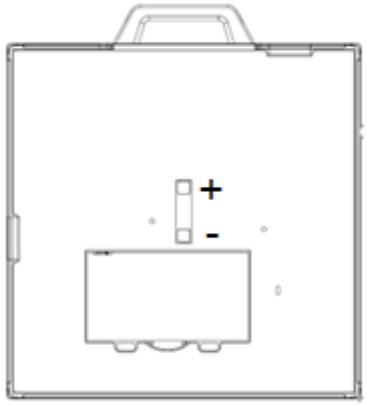
3.1.1 Attach Battery Pack

Mars1717VS can be powered by both battery package and DC power. Once battery package is inserted or DC power is on, Panel would be activated immediately. If none of battery and DC power is on, Mars1717VS would power off. Please see below for battery installation.

● Make sure that the connectors on the battery package are pointed to the cave in battery compartment.	
● Slide battery package into battery compartment（Make sure battery capacity overpass 10%）.	
● Slide the battery lock lever.	

3.1.2 Attach DC Power

Please see below for DC power installation.

● The DC source is connected to the power interface on the back of the detector, the polarity of the power supply is marked in the figure on the right	

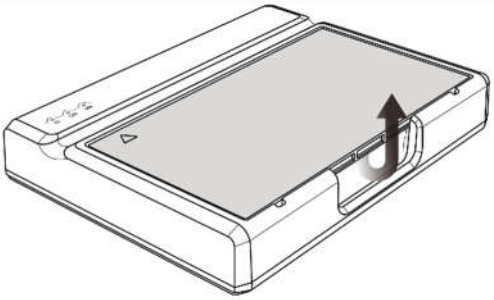
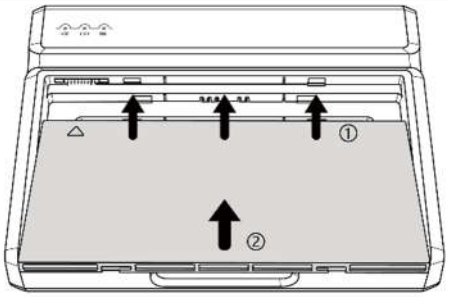
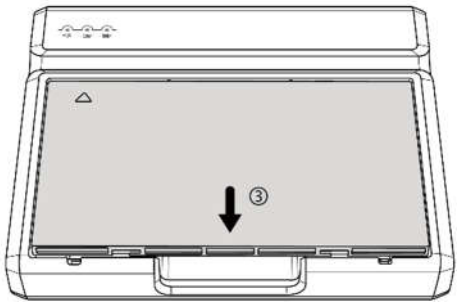
3.1.4 Indicator

After booting up, users can check the status indication of LED as follows.

LED indicator is as table:

Items	Color	Descriptions
Power	Green	Battery capacity is 11%~100%
	Orange	Battery capacity is 6%~10%
	Orange (blinking）	Battery capacity is 0%~5%
	Green(blinking)	The battery is charging
Link	Green	WIFI connecting is normal
	Orange	WIFI link is lost
Status	Green	SDK is OK
	Orange	SDK is disconnect or firmware update
	Green(blinking)	Exposure indication
	Orange (blinking)	FPD Error

3.2 Battery Charger Installation

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

4. Software Setup

4.1 System requirement

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

4.2 Environment setup

Setup files and download url are included in Software Development Kit(hereafter refers as SDK) directory: Tools\env_setup.

1. Please install Microsoft .NET Framework 4.5(Windows XP only can install V4.0). Download from Microsoft web site, please.

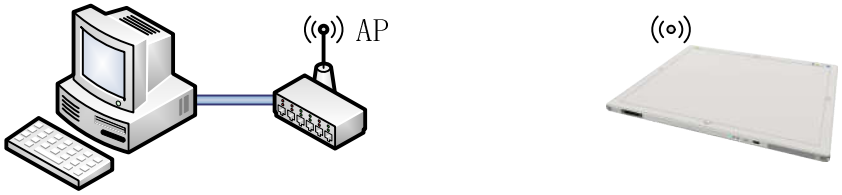
2. Visual C++ redistributed package need to be installed: vcredist_x86_2013(or vcredist_x64_vs2013).

3. For Windows XP, full path should be used in file “bind.txt”.

4.3 Connection Mode

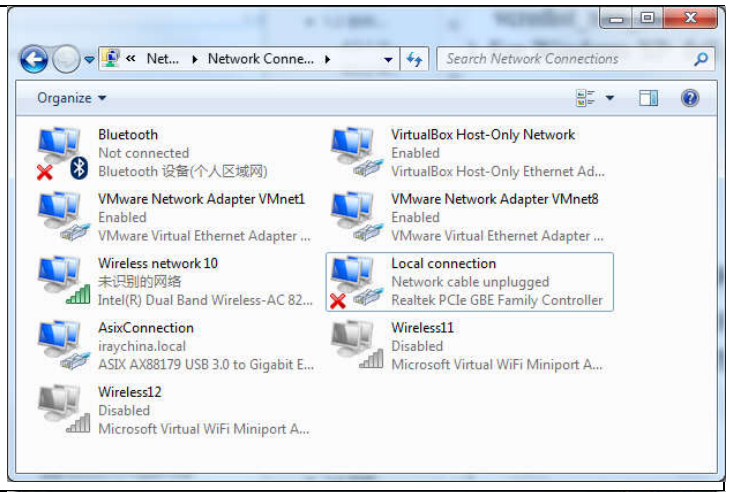
Mars1717VS supports one connection modes as follows, the IP address and other information mentioned below is as the example, user should configure the connection with the specific requirement.

Wireless Client Mode as below.

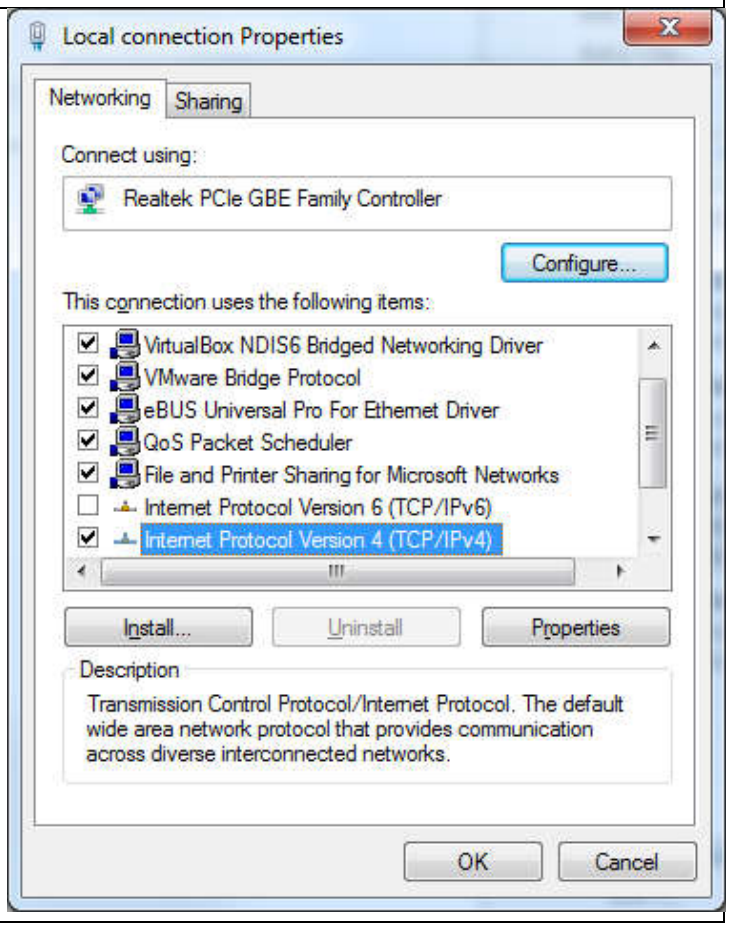


4.4 Wired Connection Setup (Service Only)

- Select wired network adapter that connected to the detector.

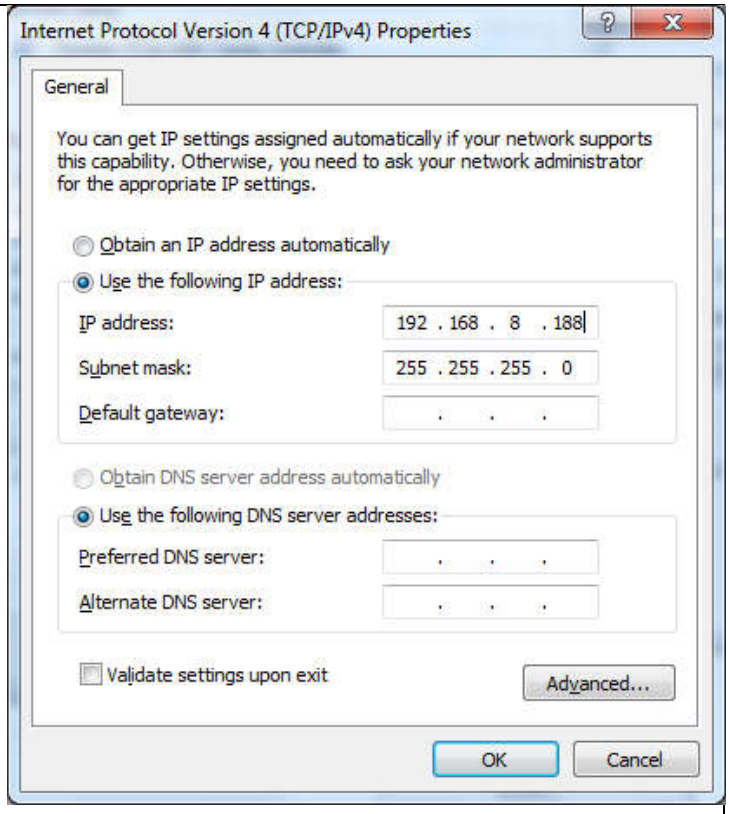


- Right click the network adapter. Then select properties.



<table>
<tr>
<td>

- Double click IPV4 item
- Default IP settings:
- IP address：192.168.8.188
- Subnet mask：255.255.255.0

</td>
<td> 
</td>
</tr>
<tr>
<td>

- The IP address should be identical with Cfg_HostIP item in work_dir\Mar1717VS \config.ini file.

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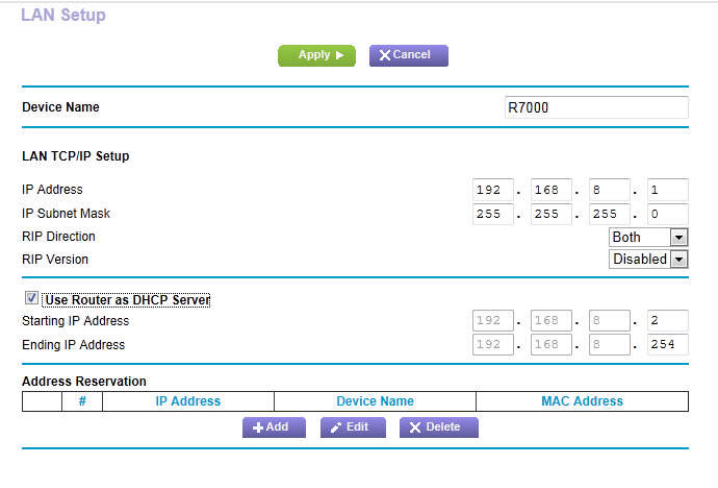
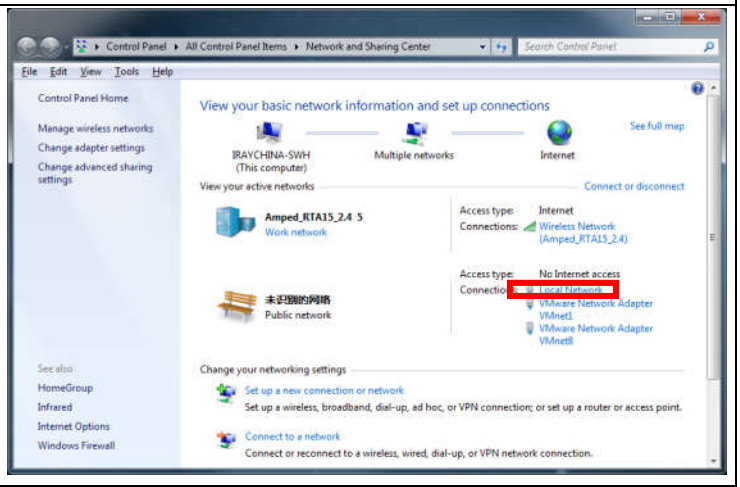
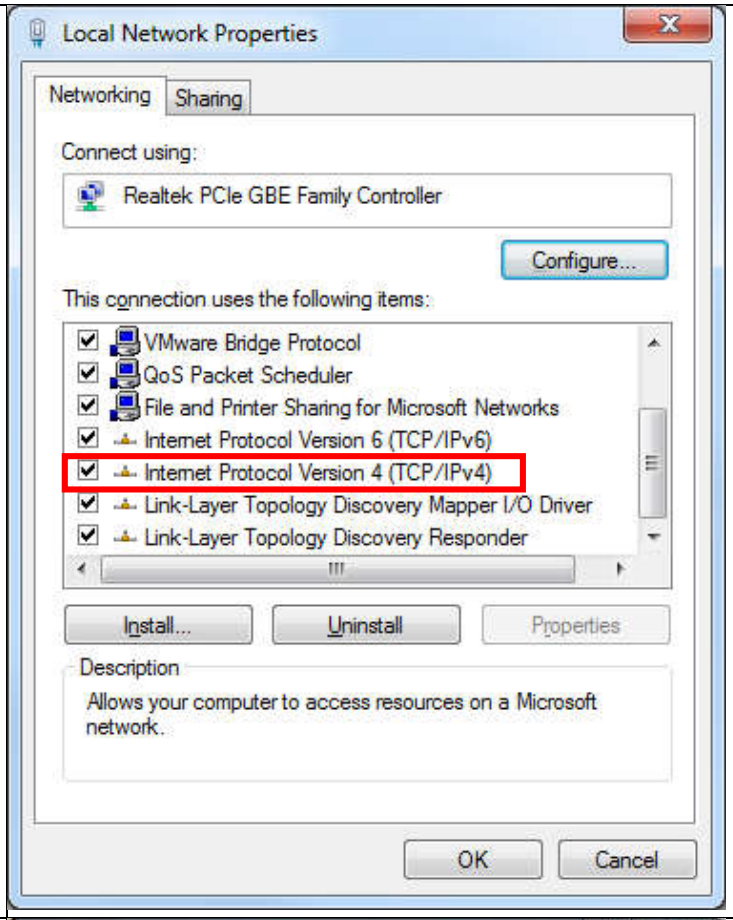
</tr>
</table>

4.5 Client Mode Connection

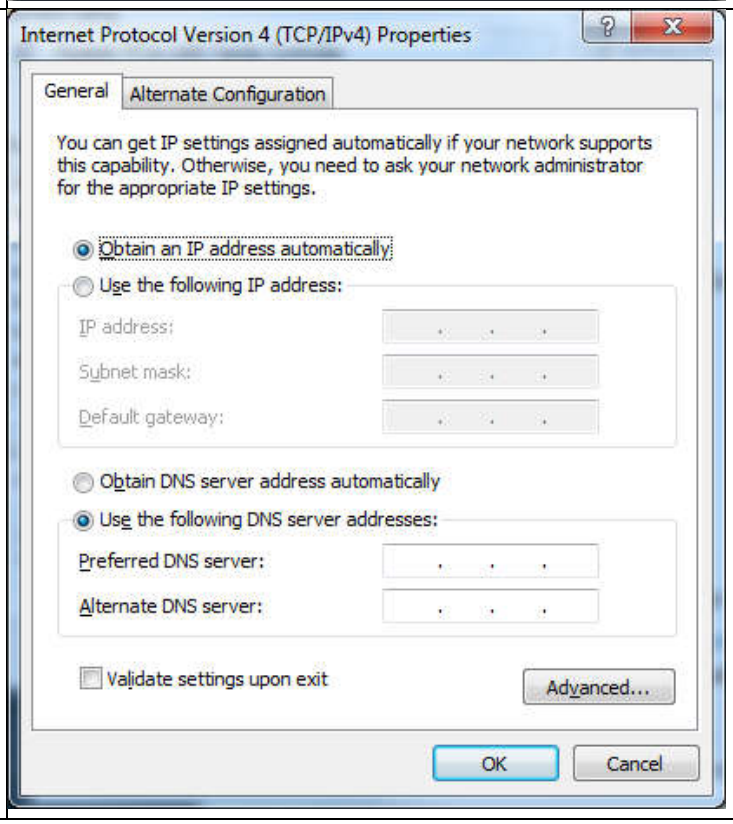
To complete wireless connection configuration, user has to finish actions listed below.

1. Setup physical connection ● Connect one end of Gigabit Ethernet Cable to Workstation, ● Connect another end to LAN port of External	
2. AP setup ● Set up the Wireless AP to: ● IP address 192.168.8.188 ● Subnet Mask 255.255.255.0 ● The setting process will be viable depends on AP model ● Here shows the Netgear Wireless Router setup	
● Open local network management interface	

- Right click the network adapter, select properties and entered the Local connection Properties window as shown left.
- Double click IPV4 item

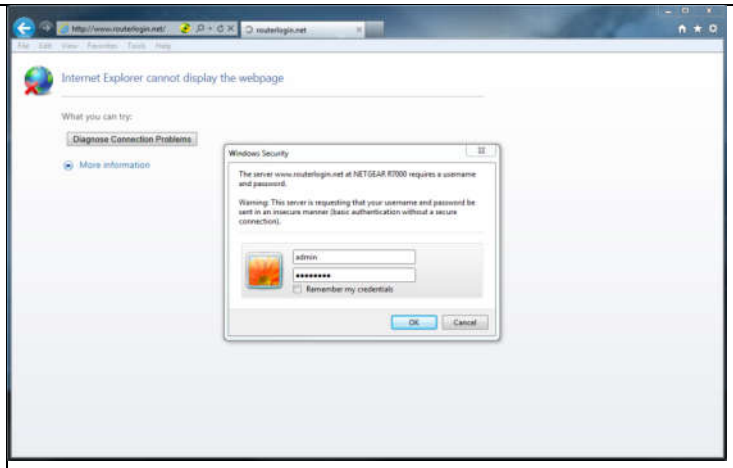


- Select “Obtain an IP address automatically”

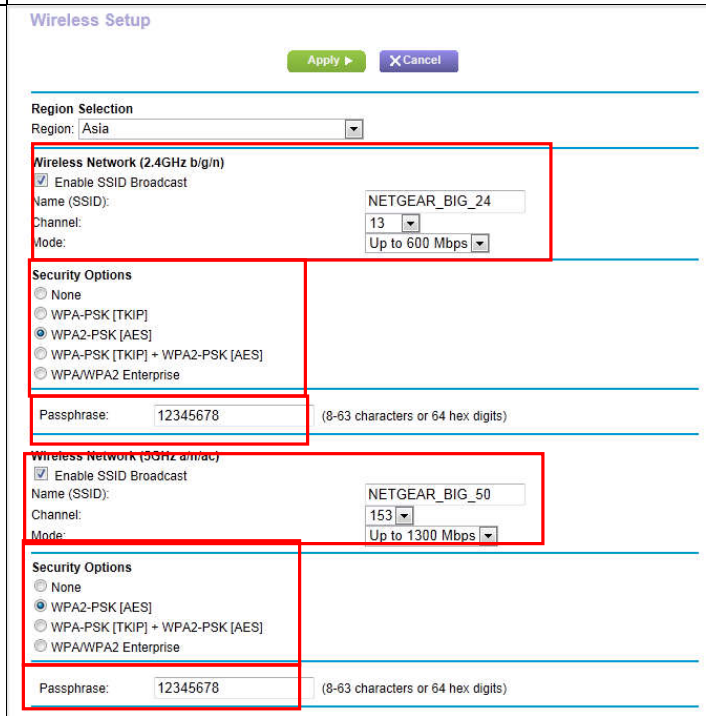


<table>
<tr><td>

- Open browser and type 192.168.1.1
- Log into external wireless AP

</td><td> 
</td></tr>
<tr><td>

- Wireless setup

</td><td> 
</td></tr>
<tr><td>

- Configure 2.4GHz wireless network

</td><td>

- SSID: NETGEAR_BIG_24
- Security: WPA2-PSK
- Password: 12345678
- Channel: [Please check the current Wi-Fi environment, and choose a relatively clean channel]

</td></tr>
<tr><td>

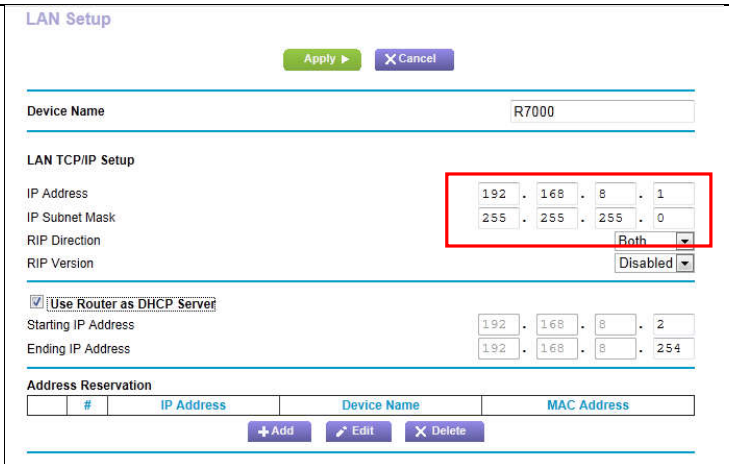
- Configure 5GHz wireless network

</td><td>

- SSID: NETGEAR_BIG_50
- Security: WPA2-PSK
- Password: 12345678
- Channel: [Please check the current Wi-Fi environment, and choose a relatively clean channel]

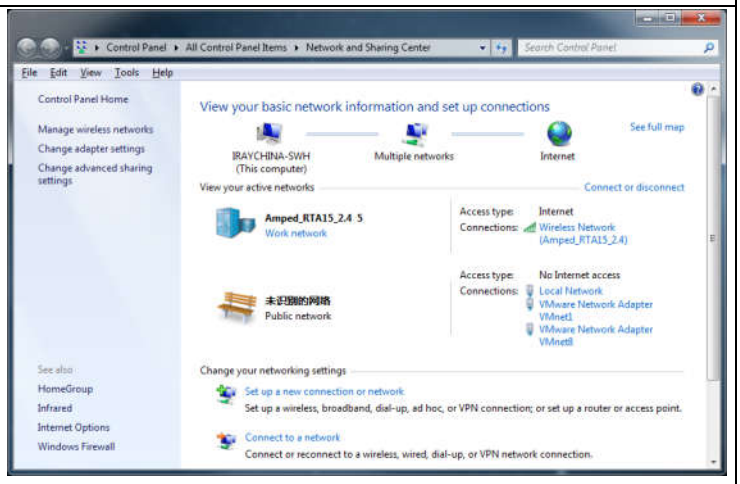
</td></tr>
</table>

- LAN setup
- Configure LAN IP address
- IP address: 192.168.8.1
- Subnet Mask: 255.255.255.0
- The AP setup is done

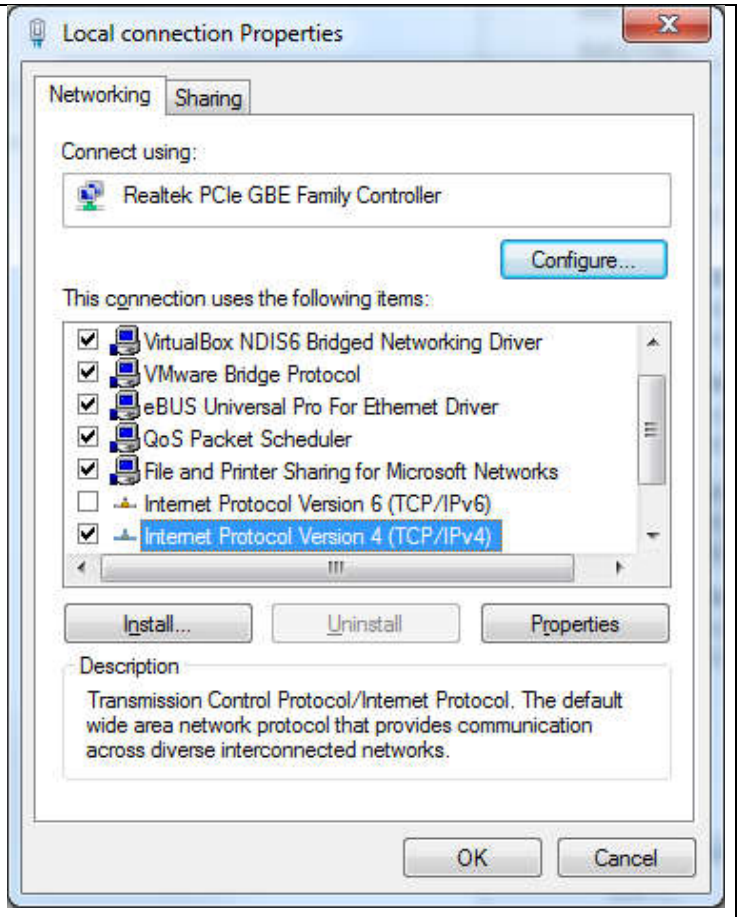


3. Workstation IP setup

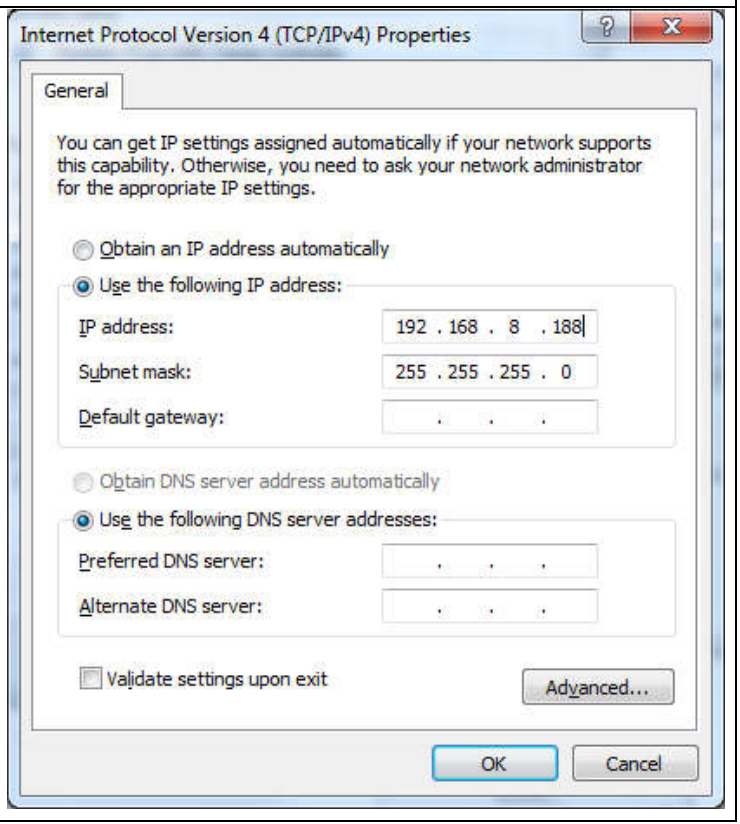
- After AP setup done, the user can setup the Workstation IP address
- Open local network management interface



- Right click the network adapter, select properties and entered the Local connection Properties window as shown left.
- Double click IPV4 item



- Set the Default IP as follows:
- IP address：192.168.8.188
- Subnet mask：255.255.255.0



<table>
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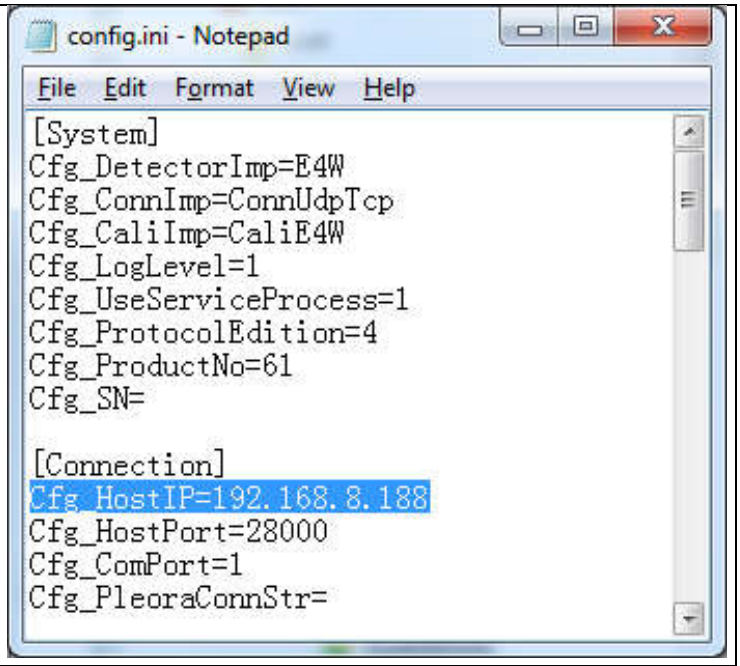
- The IP address should be identical with Cfg_HostIP item in work_dir\Mars1717VS\config.ini file.

</td>
<td>



</td>
</tr>
<tr>
<td>

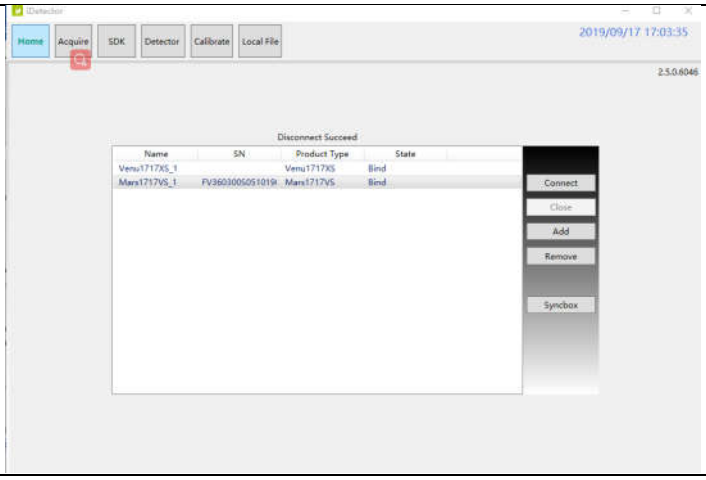
4. Panel setup

- Either Wired Cable or AP mode can be used to configure detector
- To start configuration with wired cable. It is necessary to finish 4.4, then proceed to the steps below.

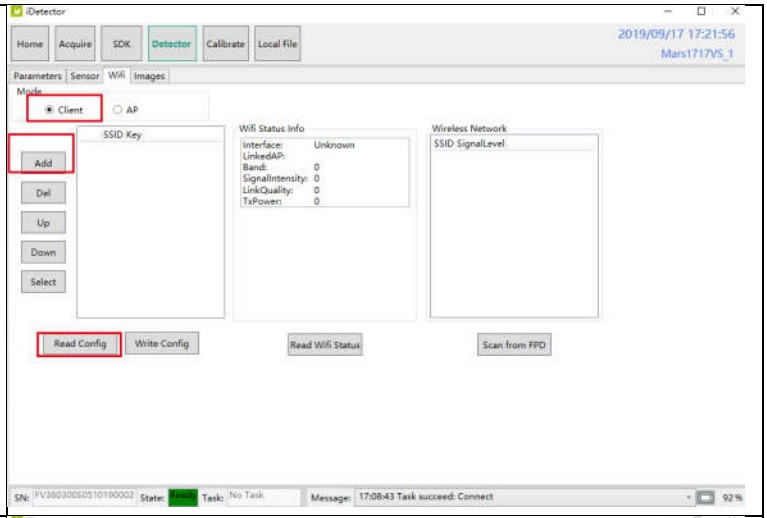
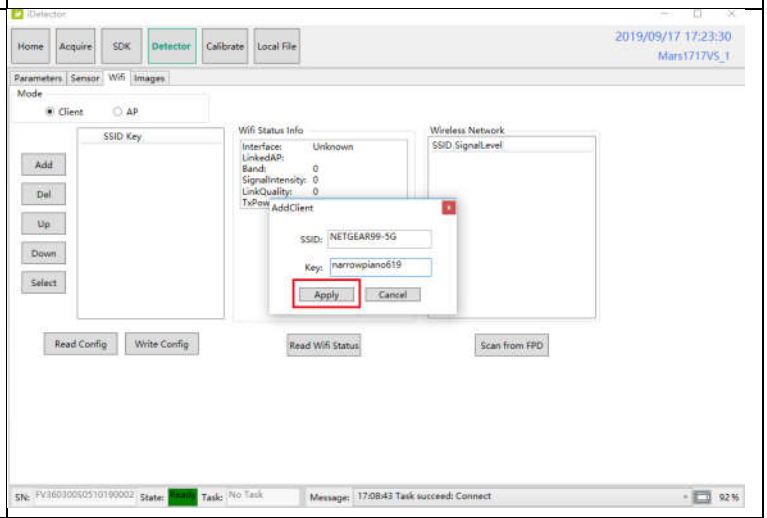
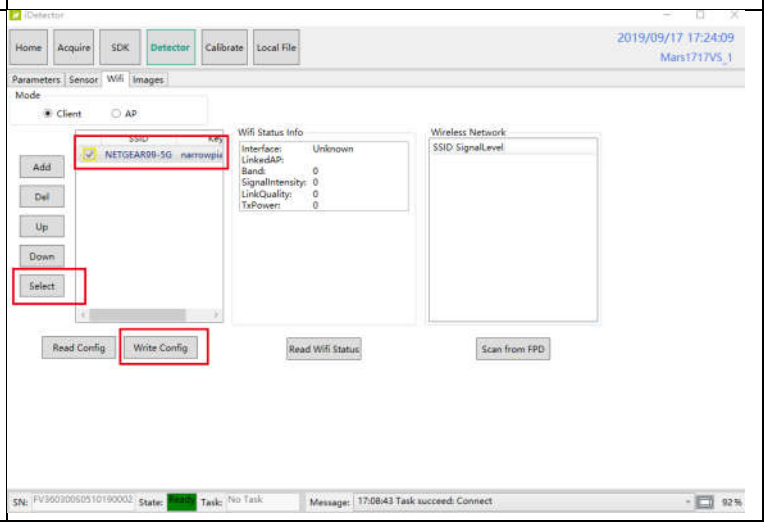
</td>
<td></td>
</tr>
<tr>
<td>

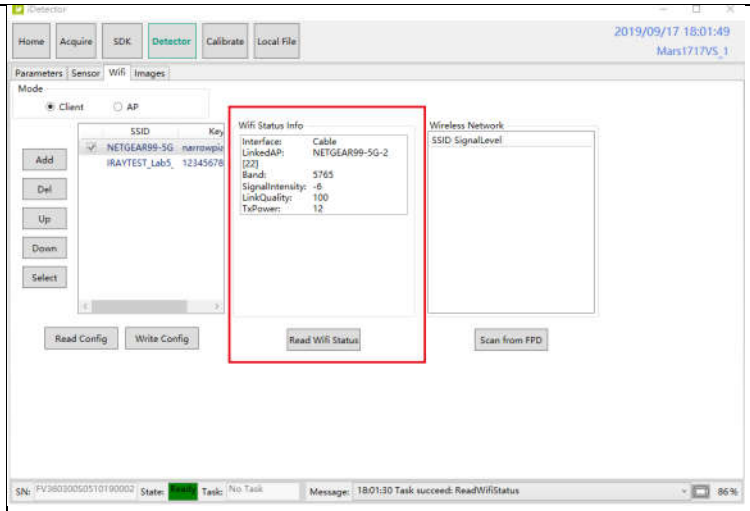
- Connect panel to Workstation like 4.4

</td>
<td>



</td>
</tr>
</table>

● Click “Detector” ● Click “Read Config” ● Choose Client mode	
● Click “Add” ● Type SSID and Password ● Click “Apply”	
● Choose SSID and select (There will be √ occurred) ● Click “write config” to save parameters.	

● Turn on wireless router. ● Make sure there are wired connection between router and work station and IP 192.168.8.188. ● Click “Read WIFI Status” to check wireless transmission status, numerical value occurred means the link is up and available.	

Since we have chosen default SSID and password, it would connect to wireless AP immediately after powered on next time.

4.6 iDetector software

SDK supply iDetector as tool softwore:

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

64-bits iDetector.exe: Tools\iDetector\x64

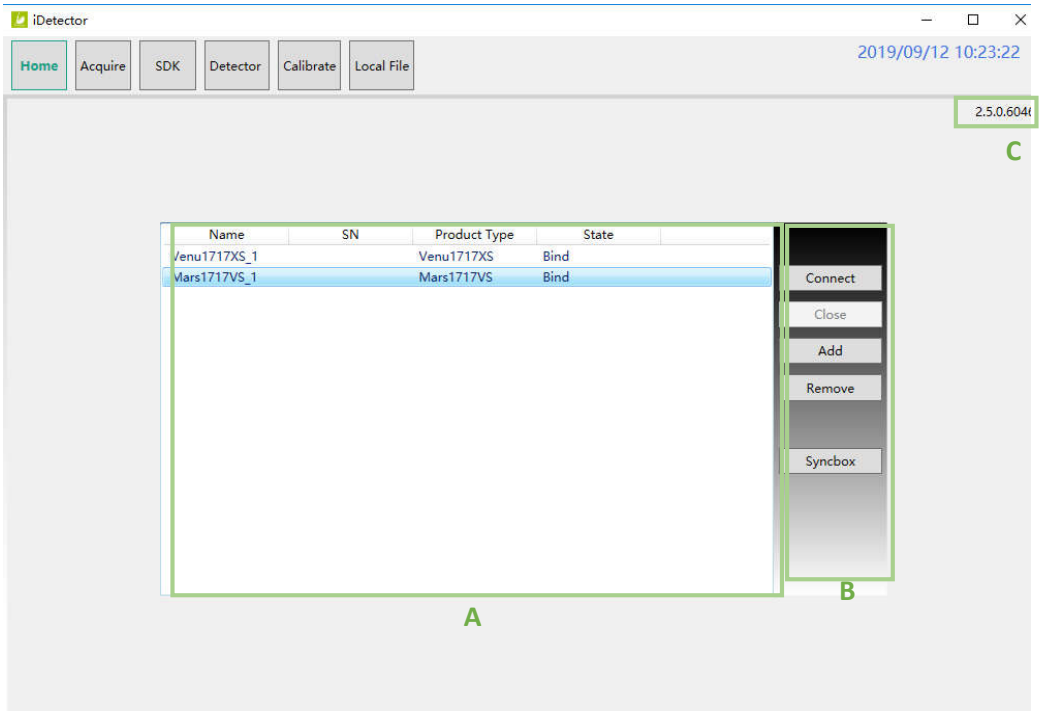
Double click iDetector.exe to run the software. For different software version, the UI maybe have little difference. If change, forgive us for not issuing a separate notice.

Users can refer to 903-341-14_iDetector_UserManual_EN_A4 for specific operation methods.

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

4.7.1 HomePage

The main function in this page is to connect detector.



A

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

B

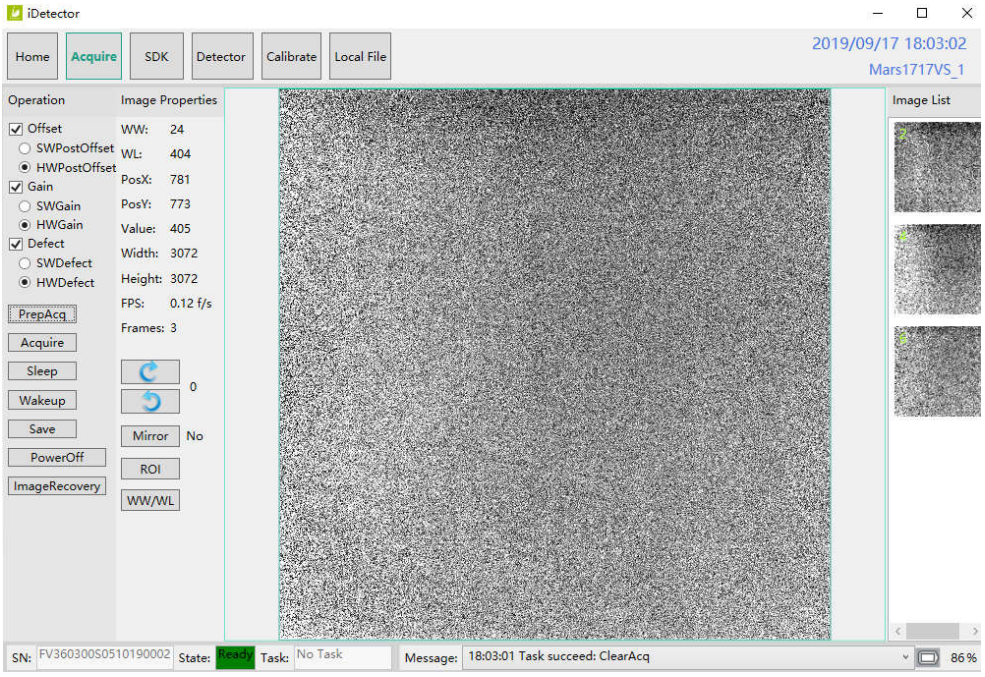
Button	Function description
Connect	Click this button to connect the selected detector.
Close	Click this button to disconnect the selected detector.
Add	Add work directory
Remove	Remove work directory
Syncbox	Open Syncbox configuration window (Optional device)

C

The version of the SDK is displayed here, and the information will vary depending on the SDK version.

4.7.2 Acquire Page

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



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

Item	Description
SN	SN number of current connected detectors
State	Detectors state, e.g. busy, ready
Task	the current task of detector
Message	feedback information of command, e.g. succeed, failed

Functions in this Page.

Correction Menu		Description
Offset	HW-PostOffset	Do hardware PostOffset correction for image if checked (Only for Mars detector)
Gain	HWGain	Do hardware Gain correction for image if selected
Defect	HWDefect	Do hardware defect correction for image if checked (for Mars and Mercu detector)
Acqurie Button		**Description**
PrepAcq		Clear and acquire
Save		Save image, the format is raw and tiff
Poweroff		shutdown detector
Image Properties& Image Process		**Description**
WW		window width
WL		window level
PosX		X coordinates of the current cursor at the point
PosY		Y coordinates of the current cursor at the point
Value		Value of the current cursor at the point
Width		Image width
Height		Image height
FPS		Frame rate
Frames		Display the frame count
		Rotate the image clockwise, 90 degrees every time.
		Rotate the image anticlockwise, 90 degrees every time.
Mirror		Open or close mirror
ROI		ROI tool，to view the image of the AVG, SV, SNR and other parameters. Press "ctrl" key, can create several ROI areas.
WW/WL		Auto adjust WW/WL based on selected area by right button of mouse.
Image List		Show thumbnails

4.7.3 Detector Page

In Detector page, Detector Parameters, Sensor, Wifi and Images tab could be set.

Please refer to 903-341-14_iDetector_UserManual_EN_A4, for specific operation guide.

4.7.4 Calibrate Page

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

Please refer to 903-341-14_iDetector_UserManual_EN_A4, for specific operation guide. Users can also refers to chapter 5.2 for panel Correlation and Calibration tutorial.

4.7.5 Local Page

The idetector Software includes a local images display tool that allows users to look up local images.

Please refer to 903-341-14_iDetector_UserManual_EN_A4 for specific operation methods.

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

a) The operating system is not compatibility;

b) Change or upgrade 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

Mars1717VS provides SDK for user to integrate panel into their DR system. Additionally, it also provides an application for demonstration, i.e. iDetector. User can use iDetector to control panel without DR system.

5.1 Main Operation

To Acquire X-ray image is the main operation of Mars1717VS. Most importantly, panel should build synchronization with X-ray generator.Mars1717VS is born with one way to acquire X-ray image that is Software Mode.

5.1.1 Steps for acquiring image

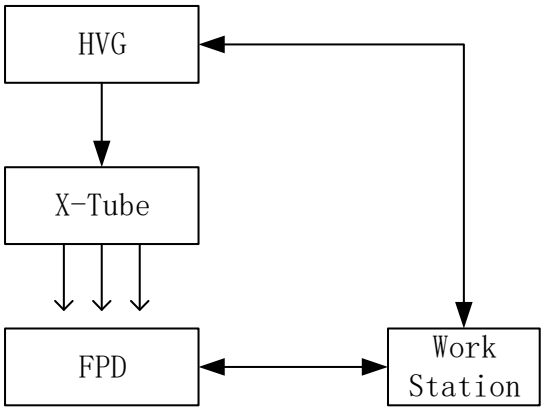
- Make sure the hardware is connected correctly and then power on.
- Once powered off, please wait at least 60s before power on again
- Wait until initialization is complete
- Connect the software
- choose the synchronization mode
- Generate HWPreOffset, Gain and Defect template after the detector reaches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

To Acquire X-ray image is the main operation of Mars1717VS. Most importantly, detector should build synchronization with X-ray generator. Mars1717VS has one synchronization mode to acquire X-ray image, which is Software Mode.

5.1.2 Software Mode

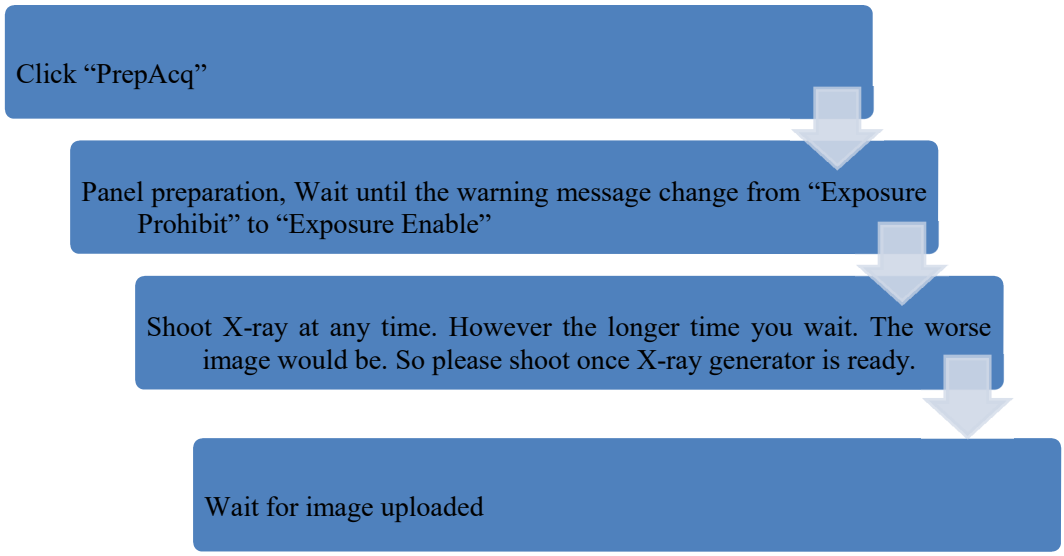
5.1.2.1 Block Diagram

Software mode is the basic way to acquire x-ray image. Please see figure below for general feature



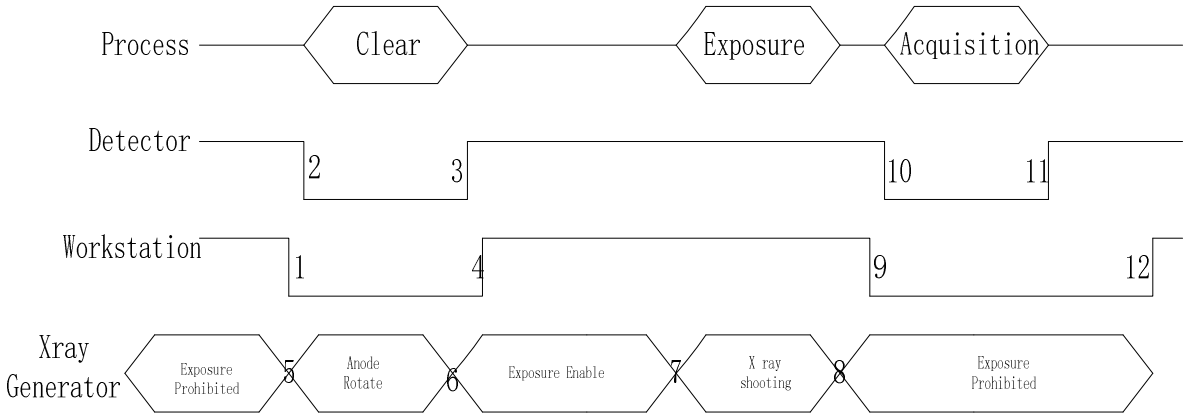
Workstation is a host device installed with iDetector and SDK. Chapter 3 has described how to establish connection between panels and workstation. In software mode, workstation does not control x-ray generator. Users would decide when to shoot x-ray.

5.1.2.2 Work flow



5.1.2.3 Timing Setting

To set a clear scenario for programming, see diagram below for details



1. Workstation receives “prepacquire” request, send command “clear” to panel.
2. Panel receives “clear” from workstation, starts clearing leakage of panel. Meanwhile, panel send a message to workstation “Exposure Prohibited”.
3. Panel finishes “Clear” and send a message to workstation “Exposure Enable”.
4. Workstation shows “Exposure Enable” on the IDetector’s message bar to tell user shoot X-ray now.
5. User triggers X-ray generator to initialize and do anode rotation to prepare for X-ray shooting.
6. X-ray generator finishes preparation for X-ray shooting and reminds user to shoot.
7. X-ray generator starts releasing X-ray.
8. X-ray generator finishes x-ray shooting.
9. Time out, panel acquires data.

10. Panel completes image acquisition and begins to send data to workstation.

11. Workstation receives all image data from panel

If Hardware Post offset and Hardware calibration is selected, image got would be preview image. After step11, panel would do another dark image acquisition. With both light image and dark image, panel completes all the correction and calibration process. Finally, panel uploads processed image to workstation.

5.1.3 After Use

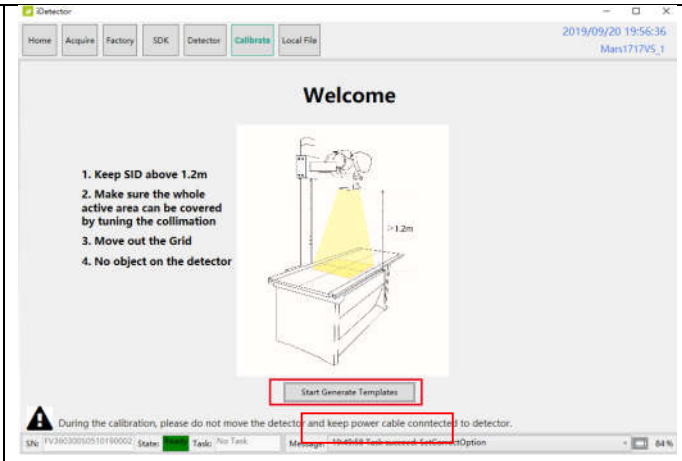
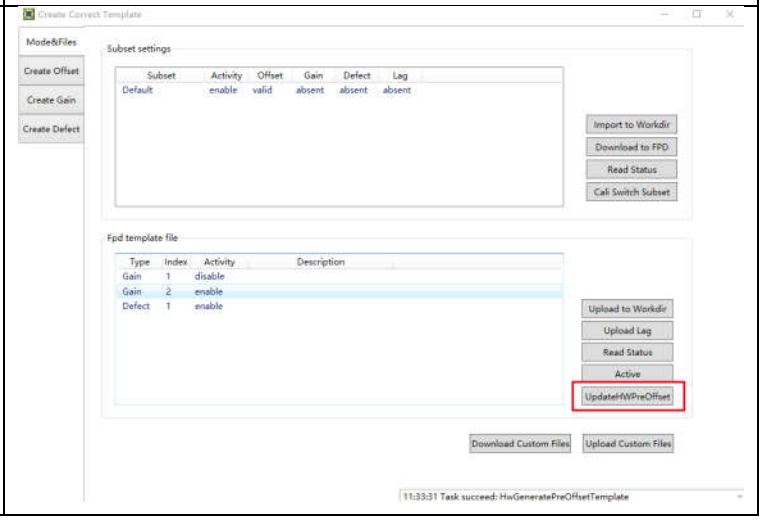
1. Disconnect the software
2. Power off
3. Keep it clean
4. Store under specified conditions

5.2 Correction and Calibration Template Generation

The correction and calibration should be performed after installation and it is recommended to perform the new correction and calibration after any major change on the system settings and hardware configuration. On the other hand, it is also recommended to do the correction and calibration in each 6 months.

5.2.1 Pre-offset Template Generation

If panel is configured to do Pre-offset correction, Pre-offset Template is necessary. See below

Select “Calibrate” Click “Start Generate Templates”	
Click “UpdateHWPreOffset”	

5.2.2 Gain Calibration Template Generation

On Gain template generating page, there are 12 images that need to be got.

The operation process is as follows:

1) Click “start” button;

2) Click “PREP”, and start exposure;

3) After exposure, click “Acquire” to get the light image;

4) If the value meets the expected value, click “Accept”, then get the other 11 images;

5) If the value does not meet the expected value, please do not click the “Accept”, and adjust the exposure dose, then click the “PREP” to get light image again;

6) After getting 12 images, click “Generate” to generate gain template.

Notes: 1 please use hardware post offset correction.

5.2.3 Defect Correction Template Generation

The operation process is as follows:

1) On the “Defect Calibration” page, start exposure, there are 8 images need to be captured;

2) Click “Start” button;

3) Click “PREP”, and start exposure;

4) After exposure, click “Acquire” to get the light image;

5) If the value meets the expected value, click “Accept”, then get the other 7 images;

6) If the value does not meet the expected value, please do not click the “Accept”, and adjust the exposure dose, then click the “PREP” to get light image again;

7) After getting 8 images, click “Generate” to generate gain template.

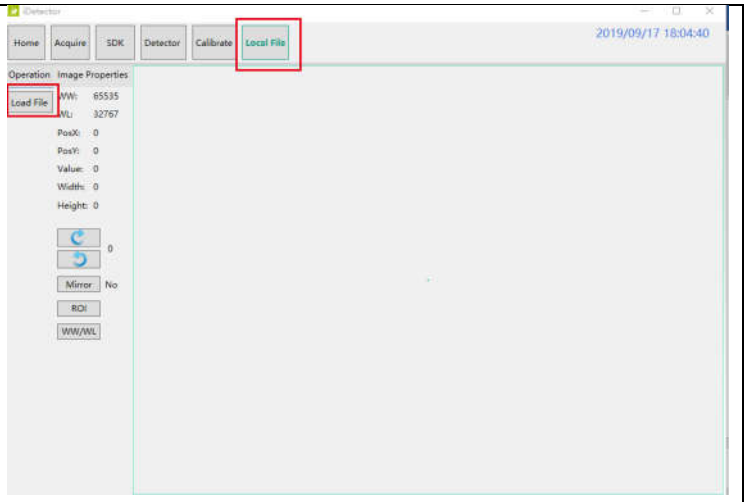
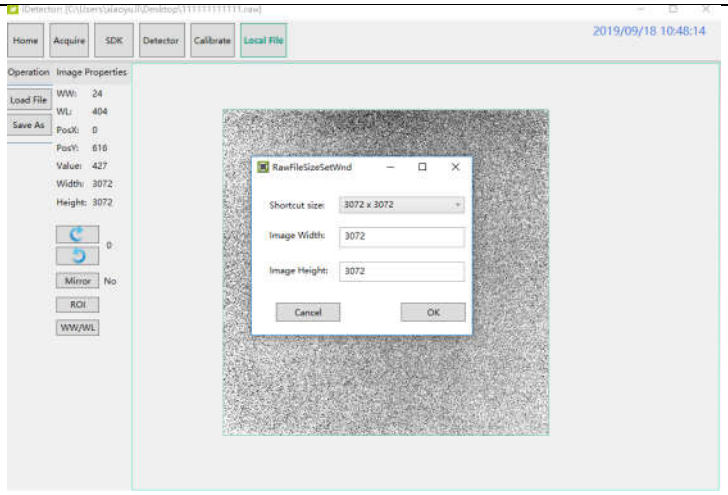
Note:

1. Please use hardware post offset mode.

2. Make sure your x ray dose is right, if your dose is out of the range, iDetector will remind you to adjust the dose. Then you can click “start creating” and try again.

5.3 Local Image Check

“OPEN” provides two features for image check and uploading. Local Image Check, Panel Image Upload. Local Image Check defines function to check image saved in Workstation. Panel Image Upload defines function to upload images stored in panel.

• Click “Local File” button in “Local File” UI, choose the specified file • In this page user can open the image files saved in local, the file format can be 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 daft 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. • Mars1717VS image size: 3070*3070	

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

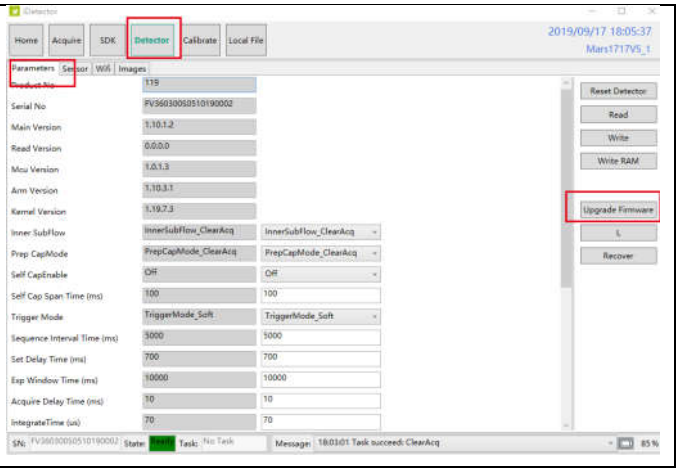
This page provides WW/WL tool as Acquire page . Click this button to auto adjust WW/WL based on selected area by right button of mouse.

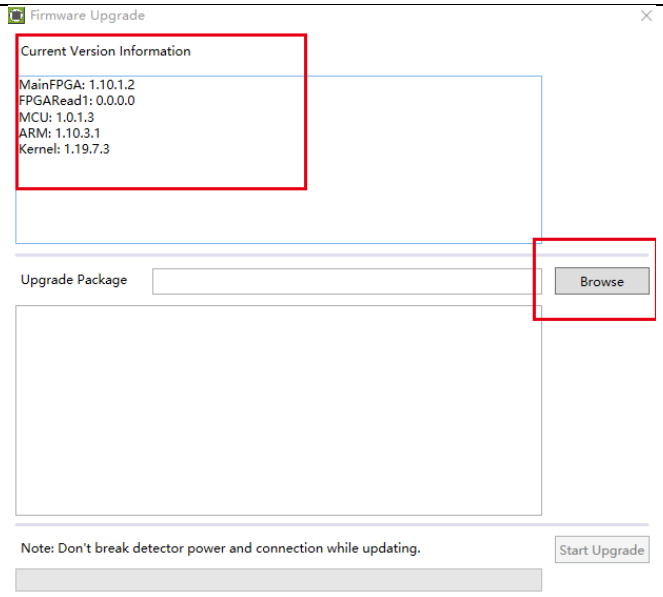
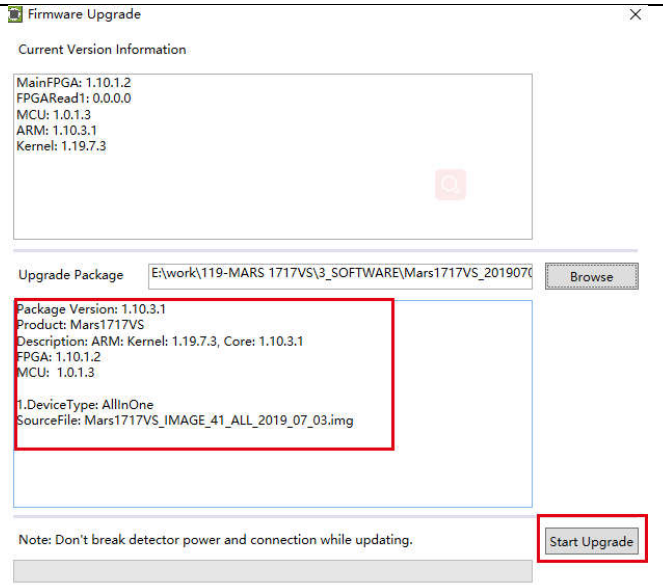
Image Properties& Image Process	Description
WW	window width
WL	window level
PosX	X coordinates of the current cursor at the point
PosY	Y coordinates of the current cursor at the point
Value	Value of the current cursor at the point

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 areas.
WW/WL	Auto adjust WW/WL based on selected area by right button of mouse.

5.4 Firmware Upgrade

Panel supports upgrading firmware with IDetector, also allows the use of the Web way to upgrade the firmware, if a user needs to upgrade the firmware, please complete the following steps.

• After connecting the detector, click the “Parameters” page in “Detector” • User can enter the upgrade UI by clicking “Upgrade Firmware” button	

• The dialog box shows the version of the current firmware • Click “Browse” to choose the firmware file to upgrade, the extension of the file is .ifirm	
• After choosing the file, the lower dialog box shows the version of the new firmware, user should check the information and click “Start Upgrade” • After the upgrade process is finished, power-cycle the detector	

6. Regulatory Information

6.1 Medical equipment safety standards

- Medical equipment classification

Type of protection against electrical shock	External electrical power source equipment Class I Equipment (medical approved adaptor) External electrical power source equipment (battery)
Degree of protection against electrical shock	Type-B applied part
Degree of protection against ingress of water	IPX3
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 r

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
IEC 60601-2-54:2009+A1:2015	Medical electrical equipment –Part 2-54: 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: 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
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

6.2 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 affect 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”

◆ Important information regarding Electromagnetic Compatibility (EMC)

Mars1717VS 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. Mars1717VS 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.

Mars1717VS 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 Mars1717VS 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	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

6.3.1 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 an 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.

a) Reorient or relocate the antenna.

b) Increase the separation between the panel and receiver.

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

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

6.4 Battery Safety Standards

Standards	Description
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

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 Info

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.

9. Appendix

9.1 Appendix A Information of Manufactures

COMPANY: iRay Technology Taicang Ltd.

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

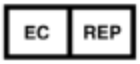
ZIP CODE: 215434

TELEPHONE: +86 0512-53690872

FAX: +86 0512-53690872

HOMEPAGE: *WWW.IRAYGROUP.COM*

9.2 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

ZIP CODE: /

WEBSITE: *WWW.IRAYGROUP.COM*

CC 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

1.1 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 is 0.106W/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.

1.2 IC Notice

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.

This Class B digital apparatus complies with Canadian ICES-003.

IC:25116-01070189

IC Radiation Exposure Statement

This EUT is in compliance with SAR for general population/uncontrolled exposure limits in IC RSS-102 and had been tested in accordance with the measurement methods and procedures specified in IEEE 1528 and IEC 62209. This equipment should

be installed and operated with minimum distance of 0 cm between the radiator and your body. This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.

Cet appareil est conforme aux Normes RSS d'Industy Canada. Son utilisation est soumise à deux conditions:

(1) Ce dispositif ne peut pas provoquer d'interférences, et

(2) Ce dispositif doit accepter toutes les interférences reçues, y compris les interférences susceptibles de provoquer un fonctionnement non souhaité.

Cet appareil de classe B est conforme à la norme canadienne ICES-003.

IC:25116-01070189

Déclaration d'exposition IC

Cet EUT est conforme aux valeurs SAR à la norme SAR pour le grand public ainsi qu'aux limites d'exposition non règlementée IC RSS-102 et a été testé selon les méthodes et procédures spécifiées par les Normes IEEE 1528 et IEC 62209. Cet appareil devrait être installé et utilisé en respectant une distance minimale de 0 cm avec votre corps. Cet appareil et son (ses) antenne (s) ne doivent pas être situés à proximité l'un de l'autre et ne doivent pas fonctionner en même temps qu'une autre antenne ou qu'un autre émetteur.

- UNII I is in door use only
- Les dispositifs RL-EL sont restreints à une utilisation à l’intérieur seulement dans la ba nde de 5 150 à 5 250 MHz.

Cet appareil est conçu et fabriqué de façon à ne pas dépasser les limites d'émission pour l'exposition à l'énergie de radiofréquence (RF) fixées par la Federal Communications Commission des États-Unis et Industrie Canada.

Au cours des essais SAR, cet appareil est configuré pour transmettre des données à son niveau de puissance le plus élevé à toutes les bandes de fréquences testées et placées dans l'ensemble des positions simulant l'exposition aux radiofréquences contre la tête et près du corps, avec une séparation de 0 mm. Bien que le DAS soit déterminé par le niveau de puissance le plus élevé, le niveau SAR réel de l'appareil en fonctionnement peut être bien inférieur à la valeur maximale indiquée. Cela est dû au fait que l'appareil est conçu pour fonctionner à plusieurs niveaux d'alimentation, pour s'adapter aux capacités des différents réseaux électriques. De manière général, plus vous vous trouverez pès d'une station sans fil, plus la fréquence de transmission sera basse.

La norme d'exposition pour les dispositifs sans fil employant une unité de mesure est connue sous le nom de taux d'absorption spécifique (SAR). La limite SAR fixée par la FCC est de 1,6 W / kg et de 1,6 W / kg par Industry Canada.

Cet appareil est conforme à la norme SAR pour le grand public ainsi qu'aux limites d'exposition non règlementées ANSI / IEEE C95.1-1992 et Canada RSS 102, et a été testé conformément aux méthodes et procédures spécifiées par les Normes IEEE1528 et Canada RSS 102. Ce dispositif a été testé et respecte les directives FCC et IC sur l'exposition aux radiofréquences lorsqu'il est testé en contact direct avec le corps.

Pour cet appareil, la valeur SAR la plus élevée pour une utilisation près du corps est de

0.106 W/kg.
Bien qu'il puisse exister des différences entre les niveaux de SAR selon les dispositifs et les emplacements où ils sont utilisés, tous répondent aux exigences Gouvernementales.
La valeur SAR déclarée conforme est une distance de 0 mm entre l'unité et le corps humain. Eloignez cet appareil à une distance d'au moins 0 mm de votre corps pour vous assurer que le niveau d'exposition aux RF est conforme ou inférieur au niveau indiqué. Vous pouvez également opter pour un étui ne contenant aucun composant métallique, pour maintenir une séparation de 0 mm entre cet appareil et votre corps.
Pour tout appareil contenant du métal, la conformité de l'exposition aux radiofréquences n'a pas encore été testée / certifiée de manière précise.

End of document