Wireless Digital Flat Panel Detector

# Mars1717X

## User Manual

Version ： A1

Doc ID ： 053-201-02

Release Date:： 2020.08.11

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

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

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

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## 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

Congratulations on your purchase of the Flat Panel Detector (hereinafter referred to as Mars1717X) which is manufactured by iRay Technology Company Ltd. (Hereinafter referred to as iRay).

Please take time to read through this user guide in order to utilize the product effectively. We hope you enjoy the experience with iRay Mars1717X.

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

## To Customers

Congratulations on your purchase of the Fixed Digital Flat Panel (hereinafter referred to as Mars1717X) 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 Mars1717X(configuration： Mars1717X).

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

## 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

1. iRay shall not be liable to the purchaser of this product or third parties for any damage, loss, or injury incurred by purchaser or third parties as a result of fire, earthquake, any accident, misuse or abuse of this product.
2. 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.
3. 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.
4. 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.
5. Information regarding specification, compositions, and appearance of this product is subject to change without prior notice.

## Copyright



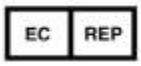
## Trademarks

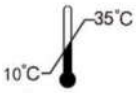
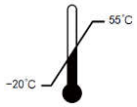
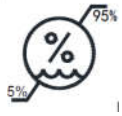
## Symbols and Conventions

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

| | |
|---|---|
|  | Identify the conditions under which improper use of the product may cause death or serious personal injury. |
|  | Identify conditions under which improper use of the product may cause minor personal injury. |
|  | Identify conditions under which improper use of the product may cause property damage. |
|  | Indicate a prohibited operation. |
|  | Indicate an action that must be performed |
|  | Indicate important operations and restrictions. |
|  | Indicate operations for reference and complementary information. |

## Labels and markings on the equipment

| Symbol | Description |
|---|---|
|  | Caution: please refer to the instructions in the user manual. |
|  | Indicates that the equipment has passed CE testing and the CE Notified Body number follows it. |
|  | Serial number of the product. |
|  | Name and address of the manufacturer. |
|  20XX-XX-XX | Expiring date of this product. |
|  | Name and address of iRay authorized representative in the European region. |
|  | Consultation of the user guide for general information. |
|  | This product is not to be disposed of with your residential or commercial waste. |
|  | Safety Signs:<br>Please refer to the user guide for safety instructions. |
|  | B Type. |
|   | Load limit. |

| | |
|---|---|
|  | Handled with care. |
|  | Operational temperature limits. |
|  | Storage temperature limits. |
|  | Fragile |
|  | Keep away from sunlight |
|  | Keep dry |
|  | Humidity limits. |
|  | Keep the equipment up right. |
|  | Do not roll the transportation package. |
|  | Stacking limit number. |
| IP56 | IP56 for detector |
| Rx only | Detector symbol : device is for prescription use only |

# Contents

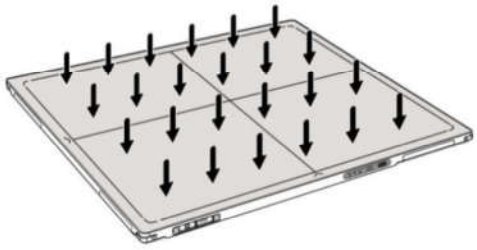
# 1. General Description

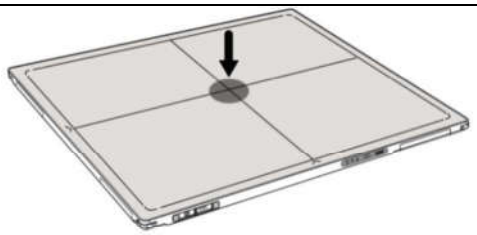
## 1.1. Safety Precautions

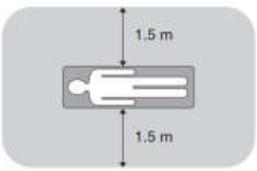
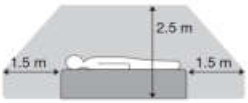
Follow these safeguards and properly use the equipment to prevent injury and damage to any equipment/data

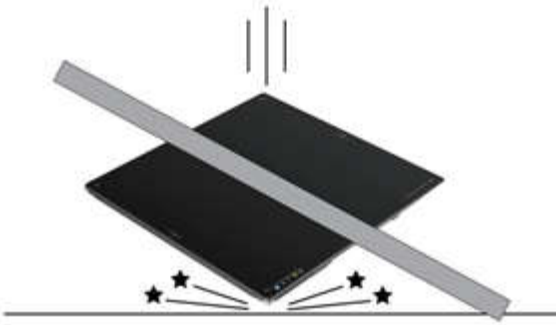
| WARNING | |
|---|---|
| Installation and environment of use<br>  <br> | **Do not use or store the equipment near flammable chemicals such as alcohol, thinner, benzene, etc.**<br>If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the equipment. Also, some disinfectants are flammable. Be sure to take care when using them.<br>**Do not connect the equipment with anything other than specified.**<br>Doing so may result in fire or electric shock.<br>**All the patients with active implantable medical devices should be kept away from the equipment.** |
| Power supply<br>  <br> | **Do not operate the equipment using any type of power supply other than the one indicated on the rating label.**<br>Otherwise, it may result in fire or electric shock.<br>**Do not handle the equipment with wet hands.**<br>You may experience electric shock that could result in death or serious injury.<br>**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.**<br>Doing so may damage the cords, which could result in fire or electric shock.<br>**Do not supply power to more than one piece of equipment using the same AC outlet.**<br>Doing so may result in fire or electric shock.<br>**Do not turn ON the system power when condensation has formed on the equipment.**<br>Doing so may result in fire or electric shock. |

| | |
|---|---|
| Power supply<br>  <br> | **Do not connect a multiple portable socket-outlet or extension cord to the system.**<br>Doing so may result in fire or electric shock.<br>**To avoid the risk of electric shock, this equipment must only be connected to power supply with protective earth.**<br>Not doing so may result in fire or electric shock. |
|  | **Securely plug the power cord into the AC outlet.**<br>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.<br>**Be sure to turn OFF the power to each piece of equipment before connecting or disconnecting the cords.**<br>Otherwise, you may get an electric shock that could result in death or serious injury.<br>**Be sure to hold the plug or connector to disconnect the cord.**<br>If you pull the cord, the core wire may be damaged, resulting in fire or electric shock. |
| WARNING | |
| Handling<br>  <br> | **Never disassemble or modify the equipment. No modification of this equipment is allowed. Parts of the Mars1717X that are not serviced or maintained while in use with the patient.**<br>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.<br>**Do not place anything on top of the equipment.**<br>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.<br>**Do not hit or drop the equipment.**<br>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.<br>**Do not put the equipment and pointed objects together.**<br>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.**<br>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:**<br>When there is smoke, an odd smell or abnormal sound.<br>When liquid has been spilled into the equipment or a metal object has entered through an opening.<br>When the equipment has been dropped and damaged. |
| Maintenance and inspection<br>  | **Please turn OFF the power of the equipment and unplug the power cord of adaptor before cleaning.**<br>**NEVER use alcohol, ether and other flammable cleaning agent for safety. NEVER use methanol, benzene, acid and base because they will erode the equipment.**<br>**DON'T dip the equipment into the liquid.**<br>**Please make sure that the equipment's surface & plugs are dry before turning ON.**<br>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.**<br>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.<br>**For safety reasons, be sure to turn OFF the power to each piece of equipment when performing inspections indicated in this manual.**<br>Otherwise, electric shocks may occur.<br><Load Limit><br>Uniform load: 300kg over the whole area of the surface<br>  <br>Local load: 150kg on an area 4cm diameter |



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

| | |
|---|---|
| Power supply | **Always connect the three-core power cord plug to a grounded AC power outlet.**<br>**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.**<br>**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.**<br>**Do not use any power source other than the one provided with this equipment.**<br>Otherwise, fire or electric shock may be caused due to leakage. |
| Handling | **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.**<br>Doing so may result in fire or electric shock.<br>In such a situation, protect the equipment with a disposable cover as necessary.<br>**Turn OFF the power and pull out the plug to each piece of equipment for safety when not used.** |
| CAUTION | |
| Handling | **Handle the equipment carefully.**<br>**Do not submerge the equipment in water.**<br>**The internal image sensor may be damaged if**<br>  <br>**something hits against it or it is dropped.**<br>**Do not place excessive weight on the equipment.**<br>**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.**<br>Keep the same load (same pressure) on the detector when acquiring the image. Or the image will be incorrect. |
| CAUTION | |

| | |
|---|---|
| CAUTION | **Do not operate close to fire, do not use in high temperatures**<br>**Do not invert positive and negative poles**<br>**Do not contact with metal in case of a short circuit**<br>**Do not insert sharp objects into the battery**<br>**Do not hit the battery**<br>**Do not stand on the battery**<br>**Do not use the battery for purposes other than those stipulated in the rules**<br>**Do not dispose of the battery or change its internal structure**<br>**Do not submerge the battery in water; please keep it dry in storage and do not contact with water while in use**<br>**Please charge the battery with the charger provided by Manufacturer**<br>**Do not mix the battery with ones not provided by Manufacturer**<br>**Do not charge the battery with a broken charger.**<br>**Charge the battery regularly to avoid over-discharge failure.**<br>**Do not use the battery when it is severe ballooning.** |

## 1.2. Notes for Use

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

### Before exposure

- Be sure to check the connection of all the parts are set properly & check the detector is kept in insulated cover that operator or patient can't touch the detector directly before powered up.
- Be sure to check the product daily and confirm it work properly.
- Sudden heating of the room in cold areas will cause condensation on the product. In this case, wait until the condensation evaporates before performing an exposure. If it is used when condensation is formed, problems may occur in the quality of captured images. When an air-conditioner is used, be sure to raise/lower the temperature gradually to prevent condensation.

- The product should be warmed up for 15 minutes before exposure or updating the gain map and defect map.
- Make sure wave form of the energy going to the X ray tube is square not pulse.
- Be cautious with circumstance that someone has radio isotope recently injected into them, it may cause panel transmit image without x ray.
- Once powered off, please wait at least 60s before power on again

### During exposure

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

### After Usage

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

# 2. General Description

Mars1717X（configuration：Mars1717X, hereinafter referred as Mars1717X） 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 4267×4267 with 100μm pixel pitch. The scintillator of Mars1717X is CsI(Caesium Iodide) which is direct deposit. Since Mars1717X supports multiple trigger modes, it can satisfy both of the general DR system and retrofit DR system.

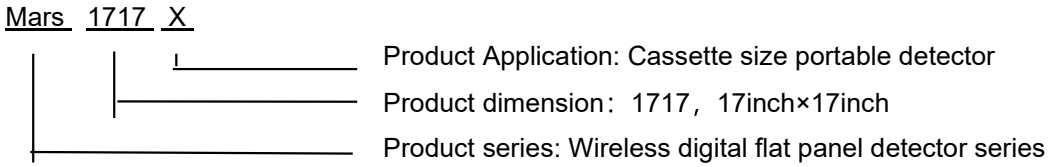
## 2.1. Scope

This manual contains information about iRay Mars1717X product. All operators must read and understand this manual before using equipment. All information in this manual, including the illustrations, is based on equipment prototype. If configuration of your equipment does not have any of these items, information about these items in the manual does not apply to your equipment.

## 2.2. Principle

Detectors contain a layer of scintillator material, which converts the x-rays into light. Directly behind the scintillator layer is an amorphous silicon pixel array contains a photodiode which generates an electrical signal in proportion to the light produced by the portion of scintillator layer in front of the pixel. The signals from the photodiodes are amplified and encoded by additional electronics positioned behind the sensor array in order to produce an accurate and sensitive digital representation of the x-ray image.

## 2.3. Model




Product Type: Battery - KX---------Rechargeable lithium battery

Product Type: Charger - Combo--------Battery charger

## 2.4.Characteristics

- Wireless static flat panel detector
- 17 inch ×17 inch
- Removable handle
- AED
- 802.11 a/b/g/n/ac
- 16-bit AD

## 2.5. Intended Use

Mars1717X is indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. It is intended to replace film/screen systems in all general–purpose diagnostic procedures. The device is not intended for mammography or dental applications.

According to the Mars1717X intended use and the result of risk management, identifying and describing the essential performance as the following:

To get image of dark field, the Mars17X shall be not influenced to the imaging acquisition.

To keep the data transmission function, the Mars1717X shall be not influenced to the data and signal transmission

## 2.6. ESSENTIAL PERFORMANCE

According to the Mars1717X 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”.

The product support DICOM3.0.

## 2.7. Application Specification

**Suitable patient**

It is suitable for providing digital X-ray imaging for DR system to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients, but not intended for mammography or dental applications. The remaining notes depend on the DR system.

**PATIENT population:**

Age: Adult and pediatric patients

Weight: not relevant

Health: not relevant

Nationality: multiple

Gender: except for pregnant women

## Pediatric Use: Guidance & Considerations

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g.less than 50 kg (110 lb) in weight and 150 cm (59 in) in height, measurements which approximately correspond to that of an average 12 year old.

The following ranges of pediatric subpopulations are to be used as a guide for manufacturers in developing medical devices:

| Pediatric Subgroup | Approximate Age Range |
|---|---|
| Newborn (Neonate) | From birth to 1 month of age |
| Infant | Greater than 1 month to 2 years of age |
| Child | Greater than 2 to 12 years of age |
| Adolescent | Greater than 12 through 21 years of age |

Exposure to ionizing radiation is of particular concern in pediatric patients because:

1) for certain organs and tumor types, younger patients are more radiosensitive than adults (the cancer risk per unit dose of ionizing radiation is higher for younger patients);

2) use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients;

3) younger patients have a longer expected lifetime putting them at higher risk of cancer from the effects of radiation exposure.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to

obtain images that are adequate clinically.

Additional guidance and recommendation are provided by the Alliance for Radiation Safety in Pediatric Imaging (Image Gently Alliance) *https://www.imagegently.org/*

**Table 1 : Techniques for Typical Body Parts**

| Body Parts | Patient Size | kVp | mAs | SID | Grid |
|---|---|---|---|---|---|
| **Abdomen AP/PA** | Very Low Birth Weight (Less than 1.5Kg) | 55 | 1 | 1m | No |
| | Low Birth Weight (Between 1.5 and 2.5Kg) | 55 | 1.6 | 1m | No |
| | Newborn (Age is less than 1 month and Weight above than 2.5Kg) | 70 | 1.6 | 1m | No |

| Body Parts | Patient Size | kVp | mAs | SID | Grid |
|---|---|---|---|---|---|
| Abdomen AP/PA | Infant (Age is between 1 month and 2 years) | 73 | 2 | 1m | No |
| | Child (Age is between 2 years and 12 years) | 75 | 7.1 | 1m | Yes |
| | Preadolescent (Age is between 12 years and 13 years) | 75 | 14 | 1m | Yes |
| | Adolescent (Age is between 13 years and 21 years) | 75 | 20 | 1m | Yes |
| | Adult Small | 75 | 18 | 1m | Yes |
| | Adult Medium | 80 | 22 | 1m | Yes |
| | Adult Large | 85 | 32 | 1m | Yes |
| Chest PA/AP | Very Low Birth Weight | 50 | 1 | 1m | No |
| | Low Birth Weight | 55 | 1 | 1m | No |
| | Newborn | 65 | 1 | 1m | No |
| | Infant | 70 | 1.6 | 1m | No |
| | Child | 70 | 1.6 | 1m | No |
| | Preadolescent | 90 | 2 | 1m | Yes |
| | Adolescent | 90 | 2 | 1m | Yes |
| | Adult Small | 110 | 1.8 | 1.8m | Yes |
| | Adult Medium | 110 | 2.8 | 1.8m | Yes |
| | Adult Large | 120 | 4 | 1.8m | Yes |
| **Extremities** | Very Low Birth Weight | 50 | 1 | 1m | no |

| | | | | | |
|---|---|---|---|---|---|
| **AP/PA** | Low Birth Weight | 55 | 1 | 1m | no |
| | Newborn | 57 | 1 | 1m | no |
| | Infant | 57 | 1.2 | 1m | no |
| | Child | 58 | 1.2 | 1m | no |
| | Preadolescent | 62 | 1.6 | 1m | no |
| | Adolescent | 62 | 2 | 1m | no |
| | Adult Small | Regarding adult details techniques of Extremities, please refer to the table "Techniques for Adult Extrimities" | | | no |

**Table 2: Techniques for Adult Extrimities**

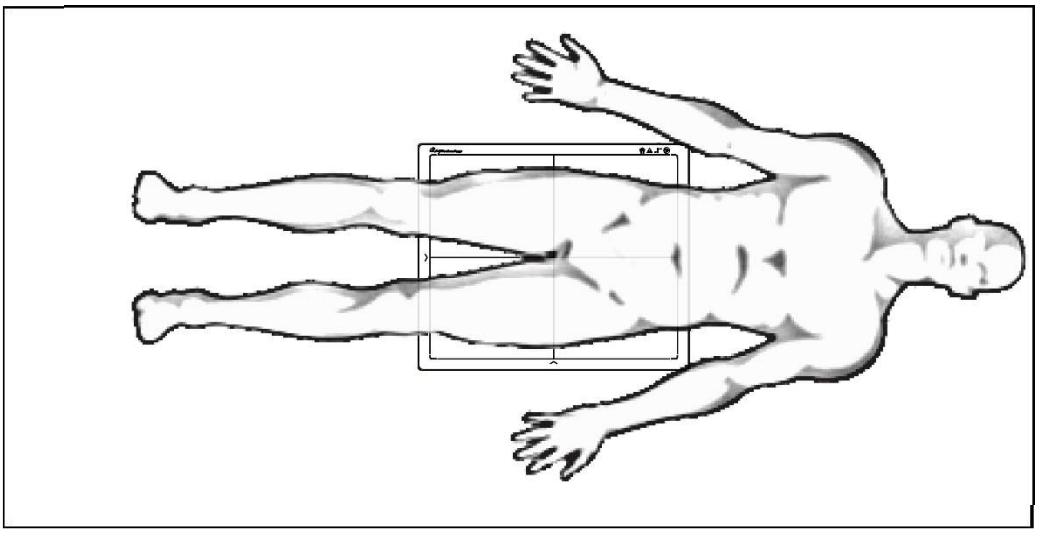
| Adult Extemities List | kVp | mAs | SID | Grid |
|---|---|---|---|---|
| Ankle - AP | 58 | 4 | 1m | no |
| Ankle – Lateral | 58 | 4 | 1m | no |
| Femur – AP | 70 | 16 | 1m | yes |
| Femur – Lateral | 70 | 10 | 1m | yes |
| Hand - AP | 53 | 1.8 | 1m | no |
| Hand – Lateral | 53 | 1.8 | 1m | no |
| Humerus - AP | 75 | 7.1 | 1m | yes |
| Humerus – Lateral | 70 | 3.2 | 1m | yes |
| Knee - AP | 65 | 10 | 1m | yes |
| Knee – Lateral | 65 | 10 | 1m | yes |
| Wrist - PA | 55 | 1.8 | 1m | no |
| Wrist – Lateral | 55 | 1.8 | 1m | no |

**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.

## 2.8. 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.



## 2.9. Product Components

The product is configured with the components below

| Item | Quantity |
|---|---|
| Mars1717X Detector | 1pcs |
| Adapter | 1pcs |
| Battery pack | 2pcs |
| Gigabit Ethernet cable | 1pcs |
| AC power cable | 1pcs |

| | |
|---|---|
| DC power cable | 1pcs |
| Battery charger | 1pcs |
| CD ROM | 1pcs |

## 2.10. Environment

| | Temperature | Temperature Variation | Humidity | Atmospheric Pressure | Atmospheric Pressure Variation |
|---|---|---|---|---|---|
| Operating | 10~35℃ | <1k/min | 5%~90% RH | 700~1060hPa | <10kp/min (1kp=1.0197E-5Pa) |
| Transport &Storage (without battery) | -20~55℃ | <1k/min | 5%~95% RH | 600~1060hPa | <10kp/min (1kp=1.0197E-5Pa) |

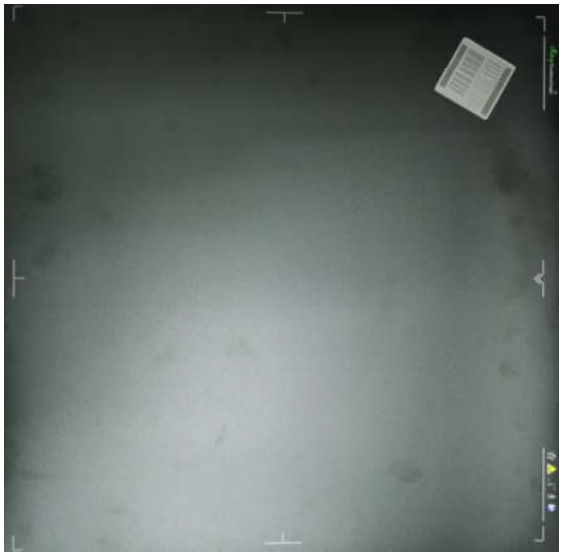
## 2.11. Components Dsecription

### 2.11.1. Detector

### 2.11.2. Button and Indicator


| NO. | Item | Description |
|---|---|---|
| A | DC Input Interface | 24V DC input |
| B | Multi-Function | Multi-Function Button |
| C | Status Indicator | Detector Status indicator |
| D | Mode Indicator | Detector WIFI mode indicator |
| E | Link Indicator | Detector Link indicator |
| F | Power Indicator | Detector Power indicator |
| G | Power Button | Power button |

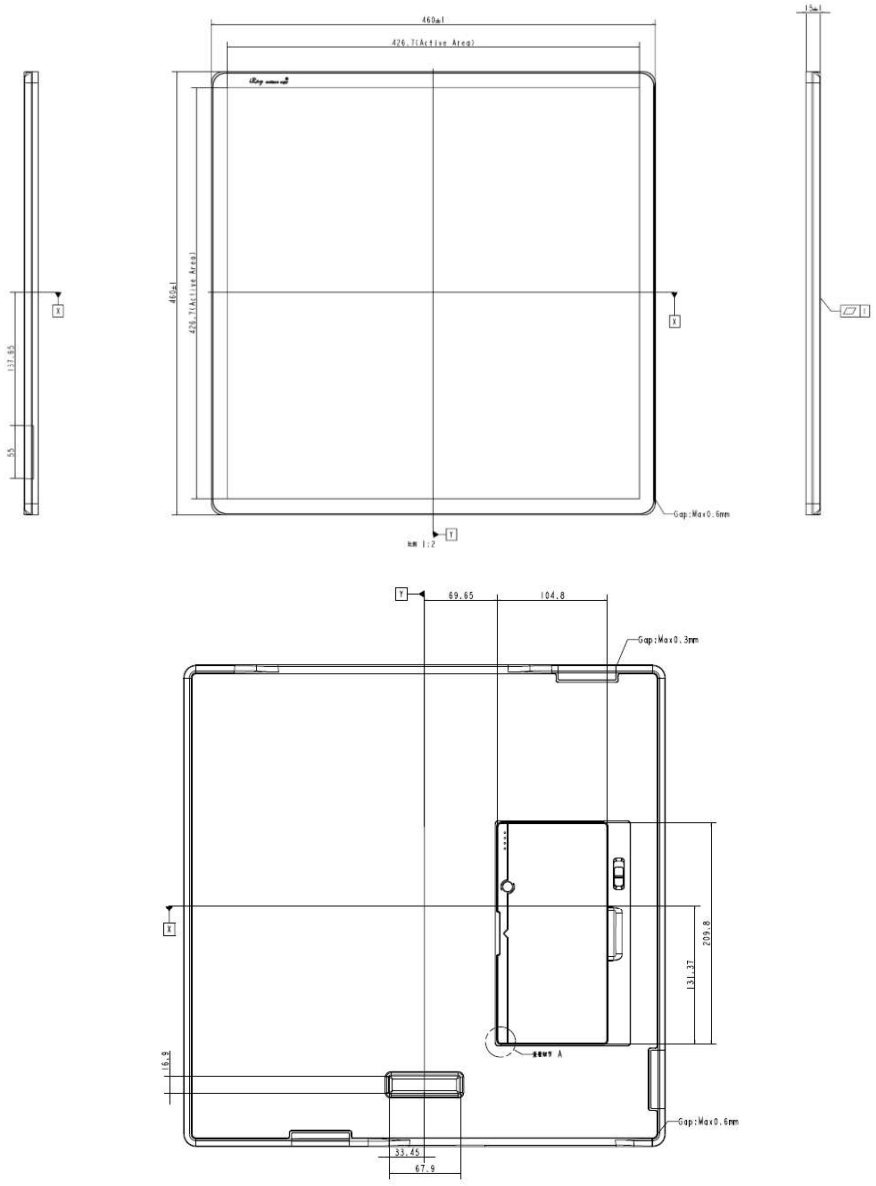
### 2.11.3. Image Dirction



Locate the logo at the top right corner, then the acquired image is mirrored on vertical direction.

## 2.12. Product Specification

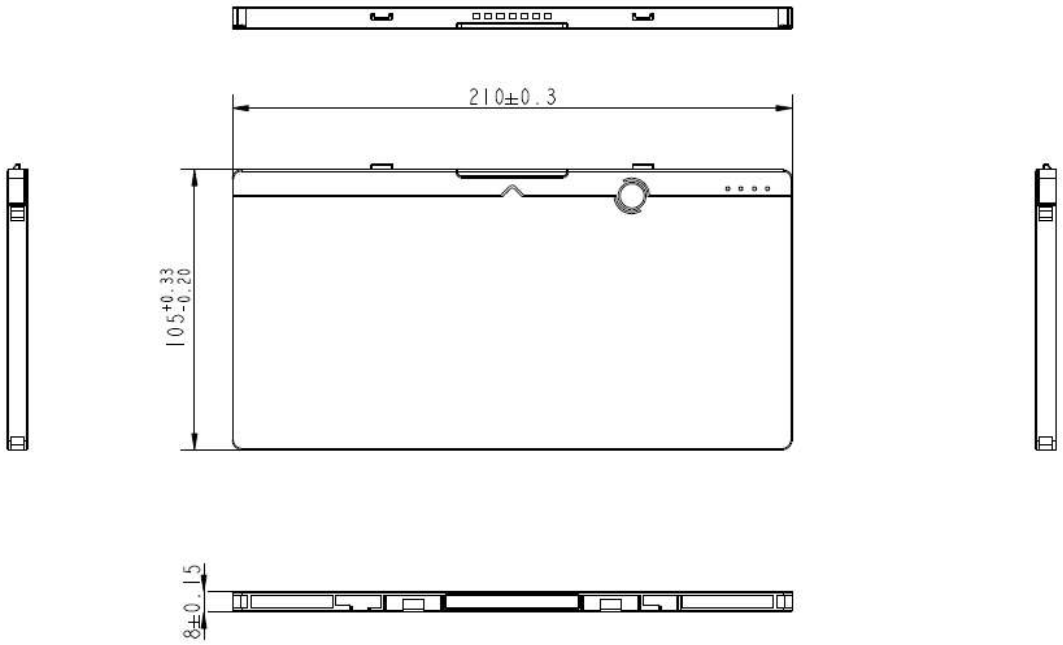
### 2.12.1. Detector



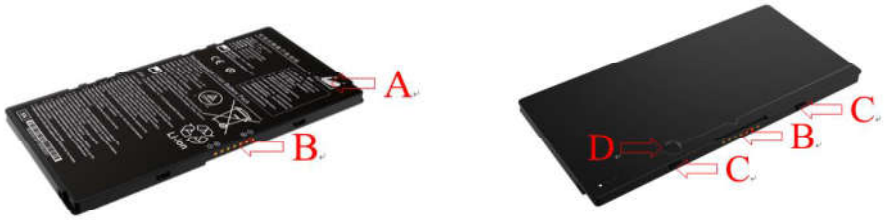

| Item | Specification |
|---|---|
| Model | Mars1717X |
| Image Sensor | a-Si (Amorphous Silicon) TFT |
| Scintillator | CsI |
| Pixel Size | 100um |
| Fill Factor | 60% |

| | |
|---|---|
| Effective Array | 4267x4267 |
| Effective Area (H x V) | 426.7mm×426.7mm |
| Spatial Resolution | Min 4.3 lp/mm |
| Image Transfer | WIFI |
| Full Image Time | <5s |
| Cycle Time | 6s |
| Power Consumption | Max 20W @No battery charging |
| Dimension (L × W × H) | 460mmx460mmx15mm @typ. |
| Weight | Max 3.4kg(with battery) |
| 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<br>16dBm (Typ.) @802.11b<br>14dBm (Typ.) @802.11g<br>13dBm (Typ.) @802.11n HT20<br>11dBm (Typ.) @802.11n HT40<br>16dBm@2.4GHz<br>13dBm@5.8GHz |
| Wireless Modulation | 802.11b: CCK, DQPSK, DBPSK<br>802.11a/g/n: 64QAM, 16QAM, QPSK, BPSK<br>802.11ac: 256QAM, 64QAM, 16QAM, QPSK, BPSK |
| Wireless Band | 2.4GHz≤40MHz<br>5.19GHz≤40MHz<br>5.8GHz≤40MHz |
| X-ray Energy | 40-150kV |
| Panel protection | IP56 |
| SID | 90-180cm |

### 2.12.2. Battery




| Item | Specifications |
|---|---|
| Model | Battery-KX |
| Rated Capacity | Min. 4700mAh, Typ. 4900mAh @ Discharge 0.2C |
| Nominal Voltage | 11.55V |
| Charge Voltage | 13.2V |
| Discharged End Voltage | 9V |
| Charging Method | CC-CV |
| Operating Temperature | Charge 0℃-+60℃, Discharge-10℃-+60℃ |
| Storage Temperature | 1 month-20℃-+50℃<br>3 month -20℃-+45℃<br>6 month -20℃-+35℃ |
| Relative Humidity | 5%~95% |
| Dimension (L × W × H) | 210 x 105 x 8 mm |
| Weight | 0.285kg |

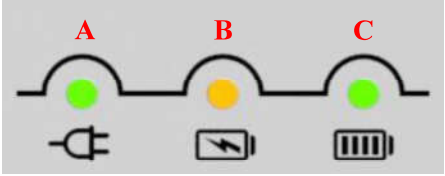



| NO. | Item | Description |
|---|---|---|
| A | Battery Label | / |
| B | Battery Interface | 7-pin battery connector |
| C | Guide Block | / |
| D | Touch Display | Show battery level after touching |

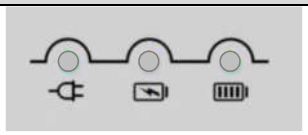
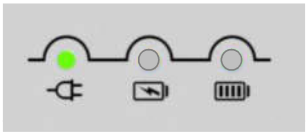
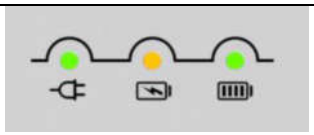
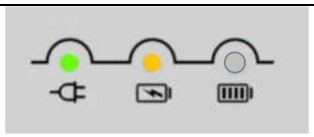
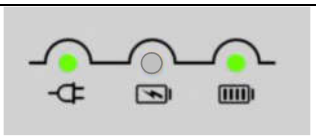
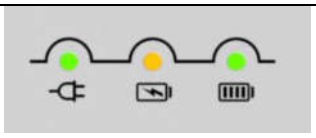
### 2.12.3. Battery Charger


| Item | Specifications |
|---|---|
| Model | Charger-Combo |
| Simultaneous Charging | 1 battery pack |
| Full charging time | ⩽3 hours |
| Rated power supply | 90V~264V(AC) |
| Dimension (L × W × H) | 240.4 x 184.4 x 41.5 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<br>● Multiple batteries inserted |
| A indicator on<br>B and C alternately blink 2 times |  | Battery insertion self-test |
| A and B<br>indicator on |  | Battery Charging |
| A and C<br>indicator on |  | Battery capacity full, charging stops |
| A indicator on<br>B and C alternately blinking |  | Battery charging abnormal |

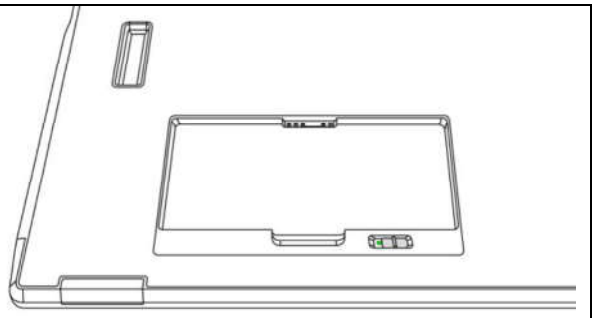
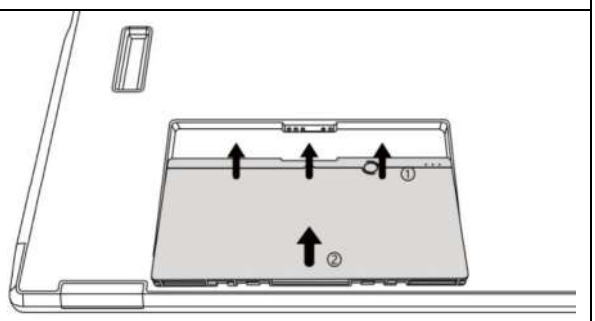
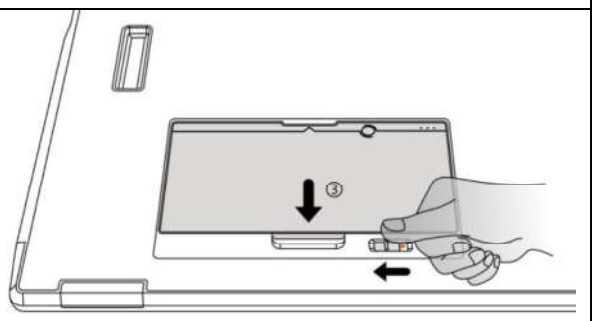
Two or more battery charging at the same time is prohibited, if inserted at the same time, the charger will automatically stop working.

# 3. Basic Operation

## 3.1. Preparation

### 3.1.1. Attach Battery Pack

The product can be powered by both a battery pack and DC power. Once the battery pack is inserted or DC power is connected, detectors will be turned on immediately. If neither battery nor DC power is connected, panel will power off. Please see below for battery installation.

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

### 3.1.2. Adapter

Detector supports an external adapter powered, It gets CB certificate No. SG PSB-MD-00005 and NRTL certificate No. U8V 093768 0016.The ports defined as bellow:

| No. | Definition | Voltage Range |
|---|---|---|
| P1 | DC Power Negative | 0~0.5V |
| P2 | DC Power Positive | 23~25V |
| P3 | DC Power Positive | 23~25V |
| P4 | DC Power Negative | 0~0.5V |

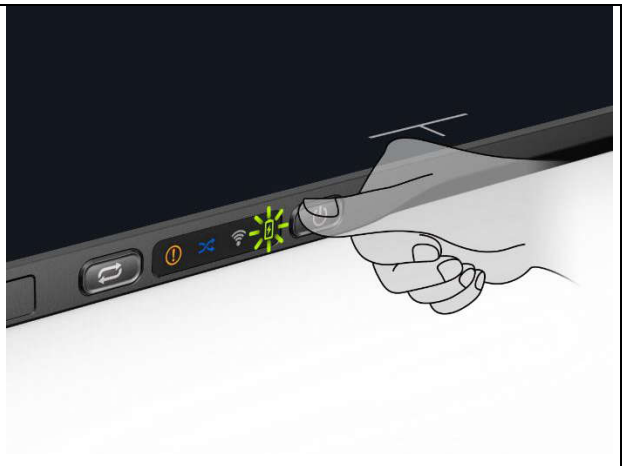
In order to meet the safety and function requirements of the detector, standard components are recommended.

| | |
|---|---|
|  | AC Adapter |

## 3.2. Routine Operation

### 3.2.1. Starting Up

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

| | |
|---|---|
| When the detector is powered down, the user presses the button for 4 seconds to turn on the detector if the battery is inserted and the capacity is not less than 15%, or DC power is connected. |  |

After booting up, users can check the indicator of the detector.

**Power indicator:**

| Power Indicator | Lighting Status | Status | | |
|---|---|---|---|---|
| | | Battery Capacity | DC Input | Description |
| OFF |  | N/A | N/A | Detector is off |
| Green ON |  | N/A | YES | Detector is on |
| Orange Blinking |  | ≥7% & ＜15% | NO | Detector is on |
| Green Blinking |  | ≥95% | YES | Detector is off |
| Green&Orange Blinking |  | ≥15% & ＜95% | YES | Detector is off |

**Link indicator:**

| Link Indicator | Lighting Status | Description |
|---|---|---|
| OFF |  | Detector is turned off<br>Wireless connection is not ready |
| Blue ON |  | AP connection is ready<br>Client WIFI connection is build |
| Blue Blinking |  | Client WIFI connection is not built |
| Green ON |  | Wired connection is enabled (Service Mode) |

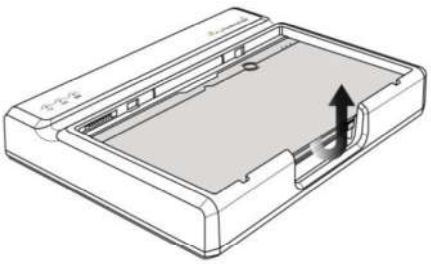
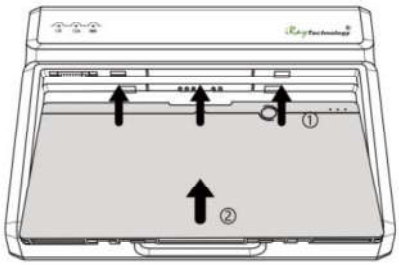
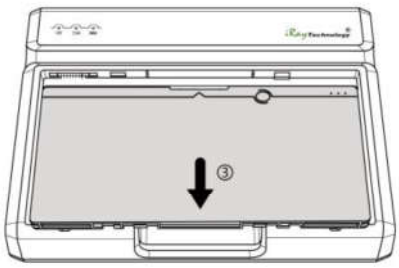
**Mode indicator:**

| Mode Indicator | Lighting Status | Description |
|---|---|---|
| ON |  | Client connection is built |
| ON |  | AP mode is enabled |
| OFF |  | Detector is off<br>Client connection is not built |

**Status indicator：**

| Mode Indicator | Lighting Status | Description |
|---|---|---|
| OFF |  | Detector is off |
| Green ON |  | Exposure is allowed |
| Orange ON |  | Error |

## 3.3. Battery Charger Installation

| Operation | Figure |
|---|---|
| Unload Battery from battery charger. |  |
| Insert battery into battery charger.<br>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. The firewall should be shut down to avoid commuication issue.

## 4.2. Environment setup

Setup files and download url are included in 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).

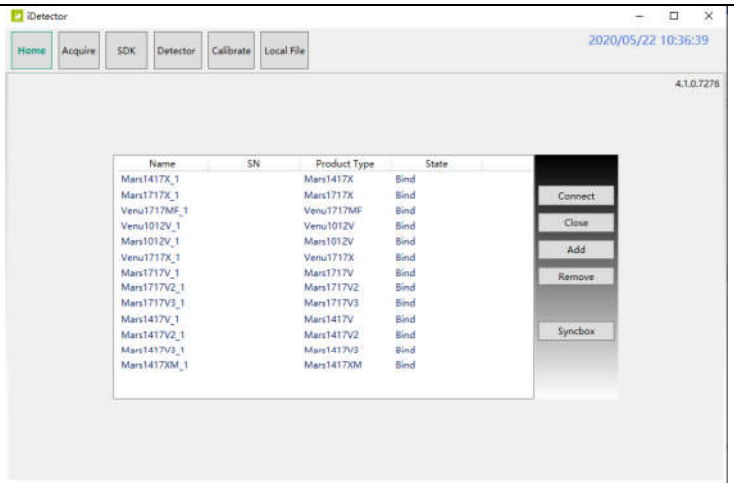
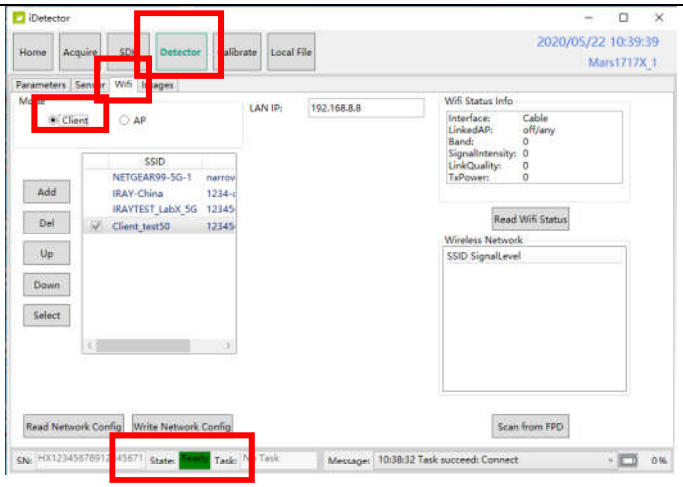
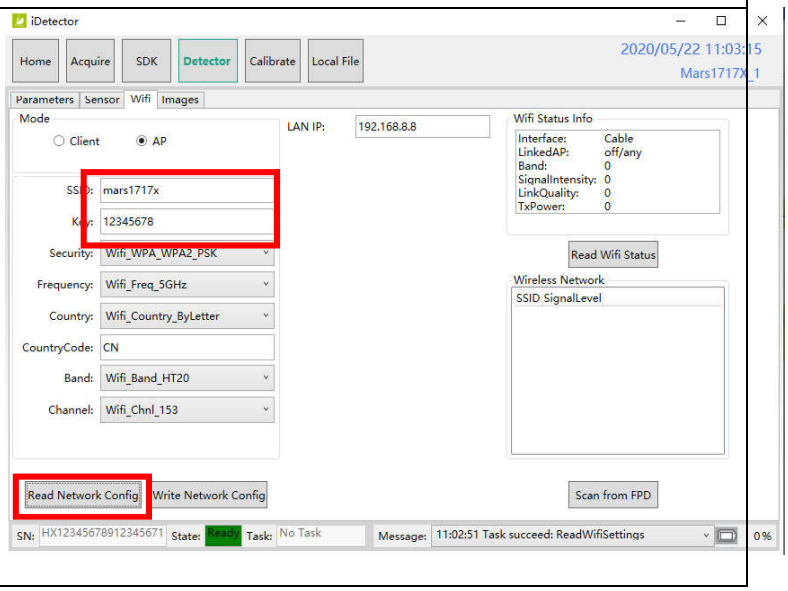
3. For Windows XP, full path should be used in file “bind.txt”.

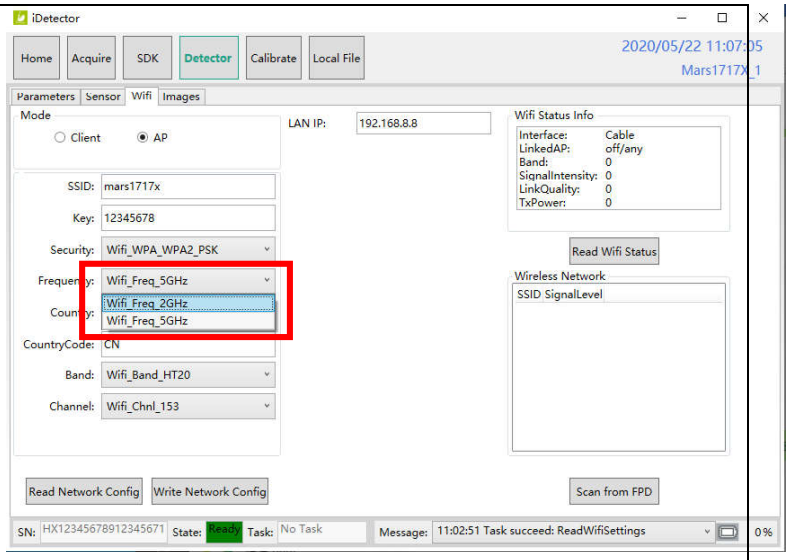
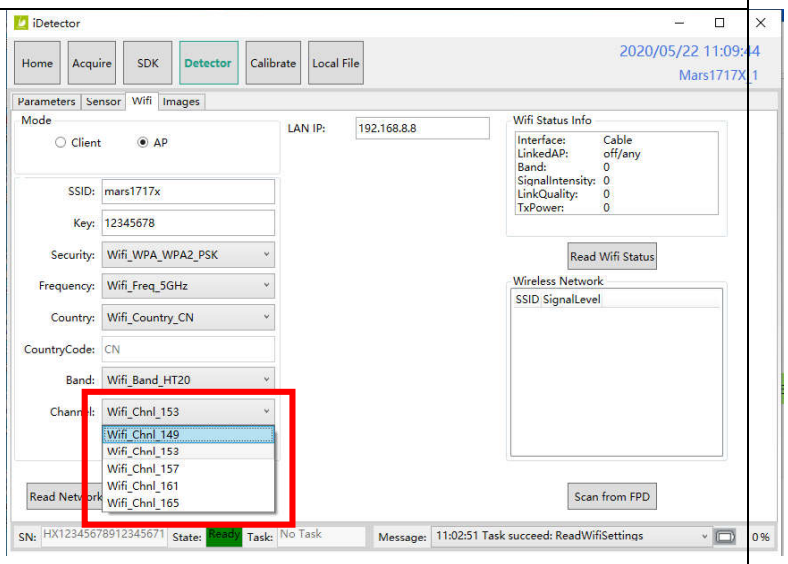
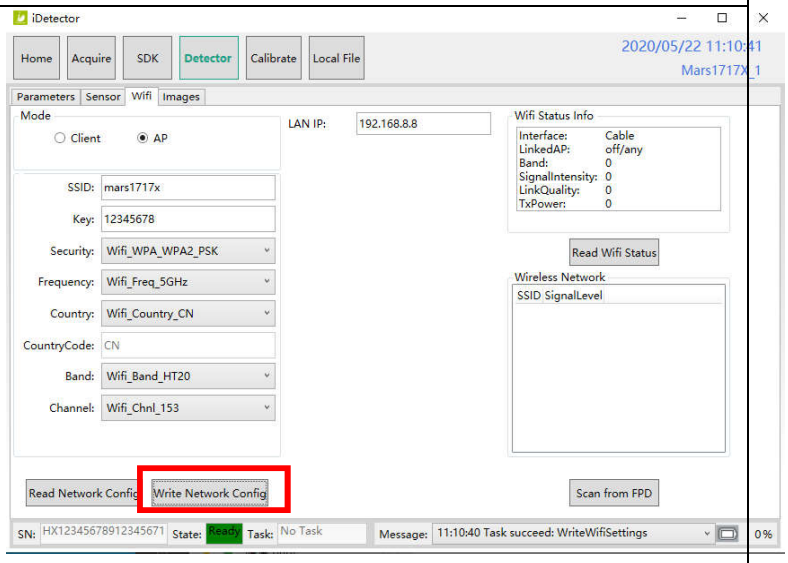
The wifi information should be configured for first use with wired connection. The configuration can be changed when needed.

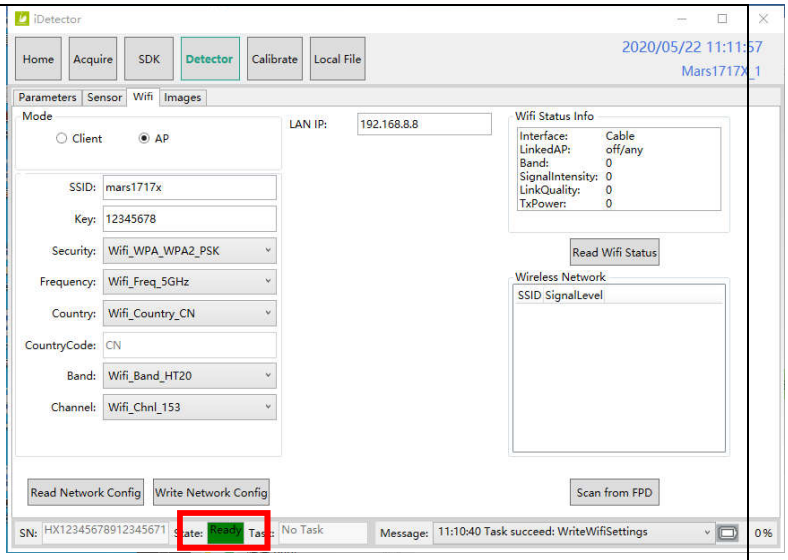
## 4.3. Wireless Connection

The default IP address (IPv4) of the detector is 192.168.8.8, the PC address (IPv4) should be configured as 192.168.8.xxx, which should be the same as the value of parameter “Cfg_HostIP”in file “*\work_dir\Mars1717X\config.ini”

### 4.3.1. AP Mode

| | |
|---|---|
| On the main window of Home page, Select the instance of “Mars1717X” and use the “Connect” button the build the connection. |  |
| After finishing building the connection, click “Read Config”button on the “Wifi”tab of “Detector” pag to get the current wifi configuration. |  |
| Click “Read Network Config” to get default setting.<br>Change SSID and password setting.<br>make sure SSID is different from other already exist; |  |

| | |
|---|---|
| Change channels and frequency setting |  |
| Click "Channel" and choose a clean frequency and channel |  |
| Click "Write Network Config" |  |

| | |
|---|---|
| Waiting FPD status be “Ready” |  |



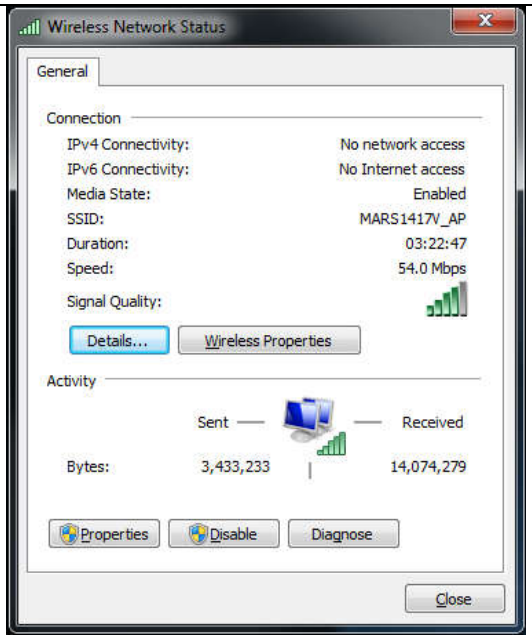
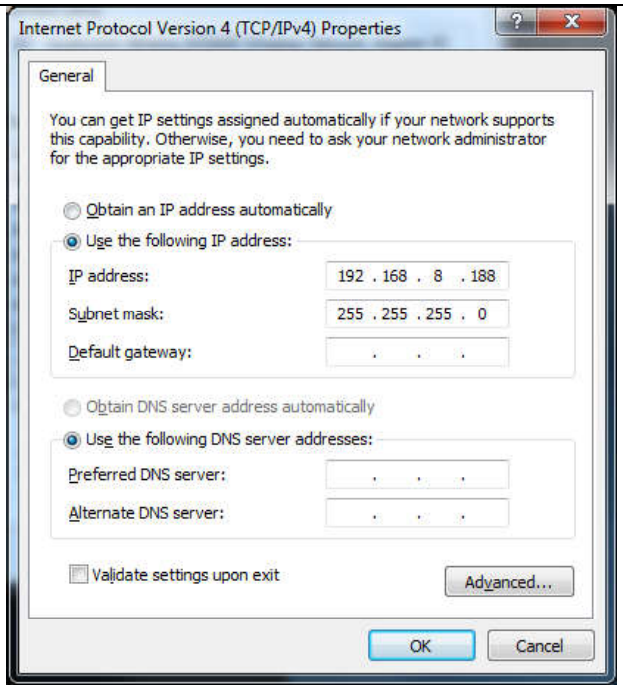
### 4.3.2. Client Mode

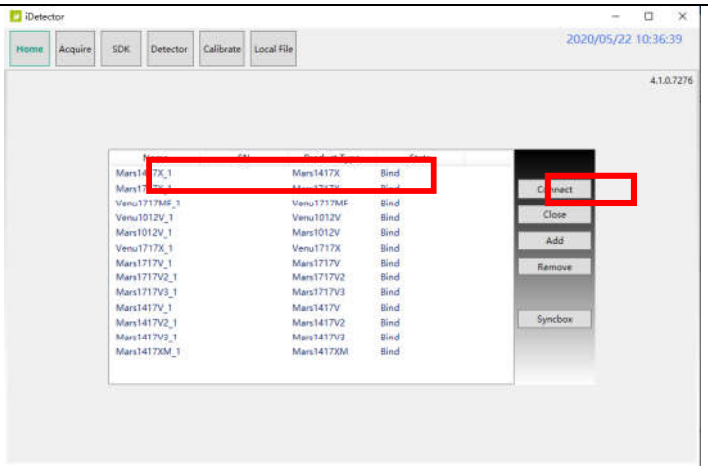
Add: add the information of the access  point, such as SSID and password.

Select: Select the Access Point that needs to be connected to.

### 4.3.3. Configuration of external wireless card

| | |
|---|---|
| Open local wireless signal list |  |

| | |
|---|---|
| Select SSID which belongs to detectors;<br>Input password and log into system |  |
| Open wireless card configuration |  |
| open IPV4 setting |  |
| IP setting as follows<br>IP address: 192.168.8.188<br>Subnet mask: | IP address: 192.168.8.188<br>Subnet mask: 255.255.255.0 |

| | |
|---|---|
| 255.255.255.0 | |
| Open SDK and choose product start connection |  |

## 4.4. Software UI

SDK supply iDetector as tool softwore:

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

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

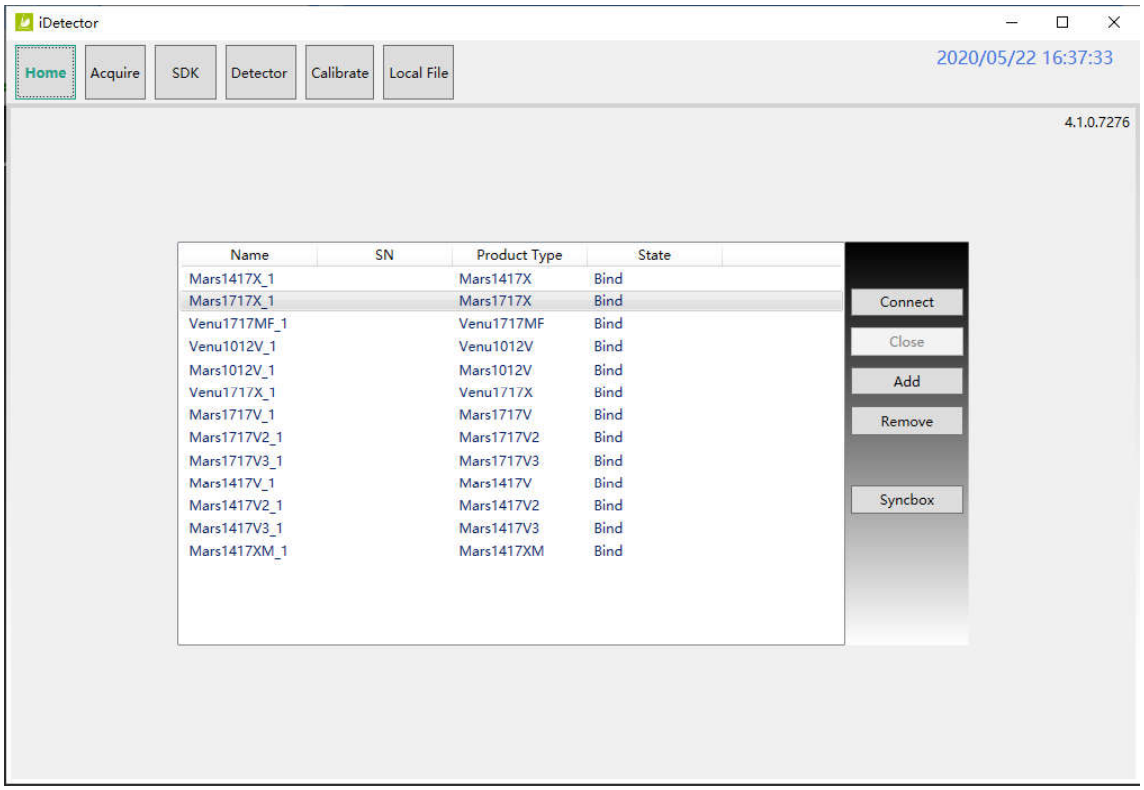
Double click iDetector.exe to run the software. For different software version, the UI maybe has little difference.

For this manual, the example is based on SDK_*_xxxx. This UI is almost the same for different versions of iDetector.

| 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. |

### 4.4.1. HomePage

The main function in this page is to connect detector.

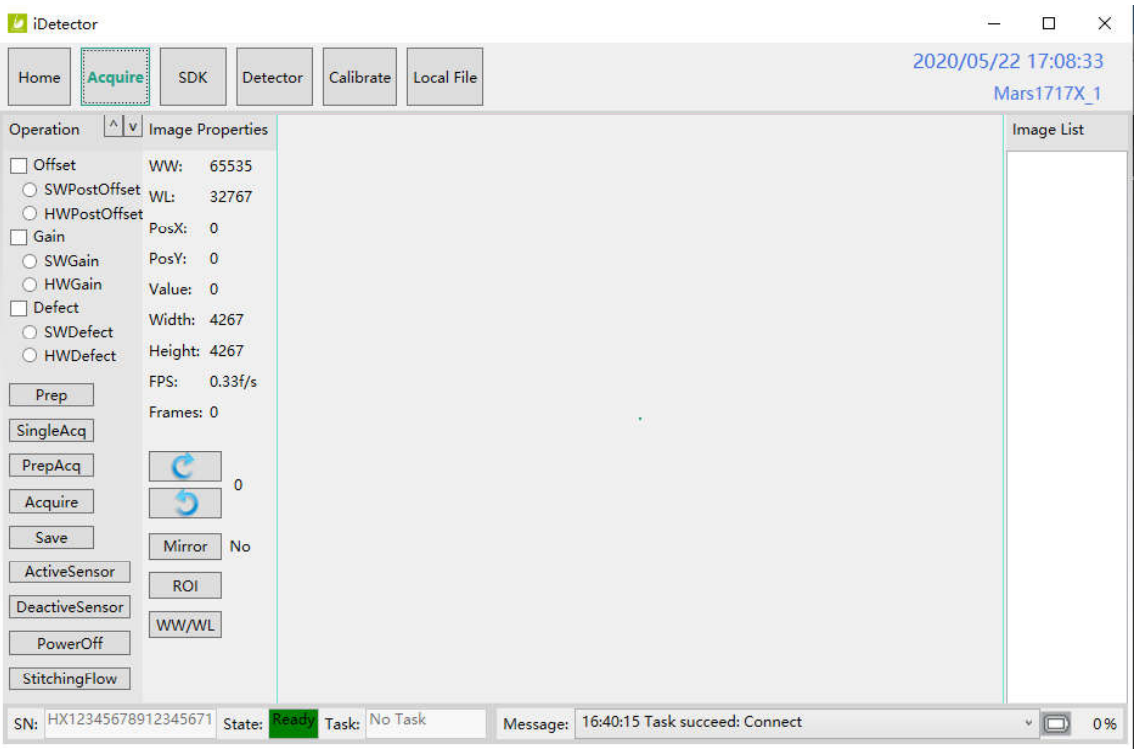



| Item | Function description |
|---|---|
| Name | Display the name of detector |
| SN | Display the SN of detector |
| Product Type | Display the type of detector |
| State | Display the connection state (Bind, Unknown, Ready etc.) |

| 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) |

### 4.4.2. Acquire Page

This page is used to acquire image under different work mode, and user can select correction options too. When acquire image finished there will be a preview image shown on the screen (if the correction option is selected, otherwise only the raw images will be shown).The propertities of image is displayed on the left of image window.And on the right of image window 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 the same.

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

Functions in this Page.

| Correction Menu | | Description |
|---|---|---|
| Offset | HWPostOffset | Do hardware PostOffset correction for image if checked |
| Gain | HWGain | Do hardware Gain correction for image if selected |
| Defect | HWDefect | Do hardware defect correction for image if checked |
| **Acqurie Button** | | **Description** |
| Prep | | Clear. Prepare to integrate. |
| SingleAcq | | Acquire once |
| PrepAcq | | Clear and acquire |
| Acquire | | Seriers acquire images |
| Save | | Save the current image, the format is raw and tiff |
| ActiveSensor | | Active sensor |
| DeactiveSensor | | Deactive sensor |
| PowerOff | | Shutdown detector |
| Stitchingflow | | Image stitching flow |
| **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 |

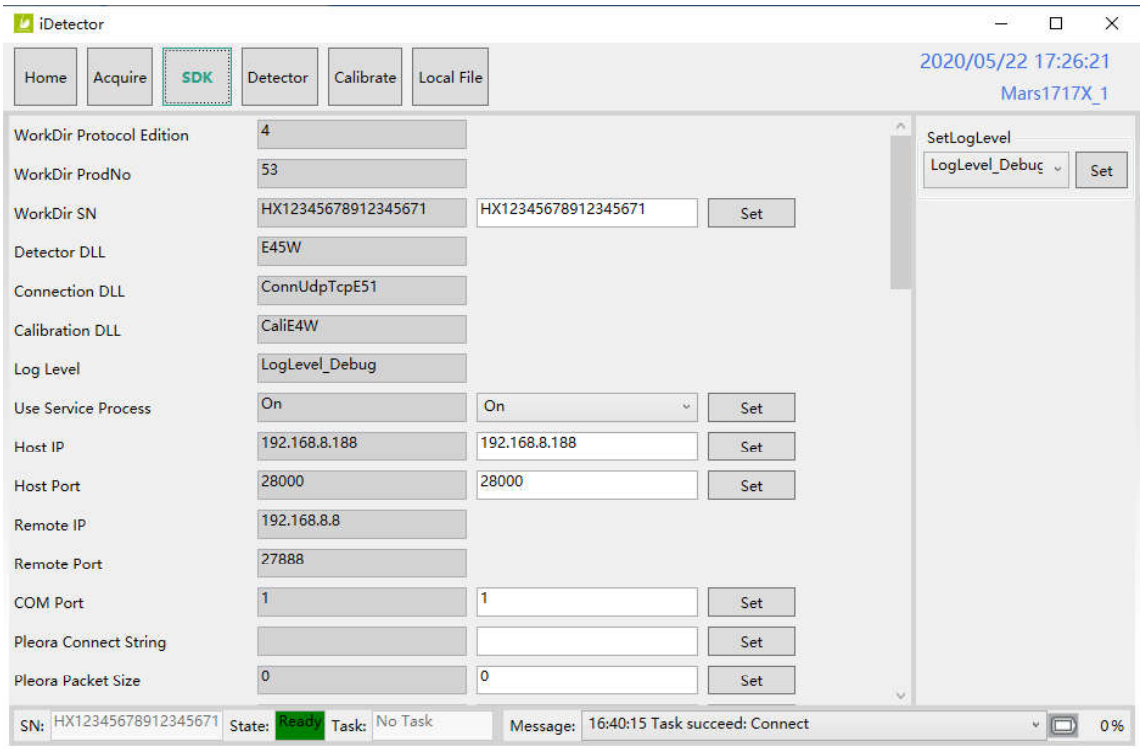
| | |
|---|---|
|  | Rotate the image clockwise, 90 degrees every time. |
|  | Rotate the image anticlockwise, 90 degrees every time. |
| Mirror | Open or close mirror |
| ROI | ROI tool, to view the image of the AVG, SV, SNR and other parameters with right click. Press "ctrl" key, can create several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

When the image is displayed on the screen, maybe the user want to see details by dragging or zoom in/out the image, for convenience, these are some shortcuts.

1. Click the left mouse button: movie playback function operation area display.
2. Double-click the left mouse button: the image display in center and with maximum size;
3. Double-click the right mouse button: restore the window level and width for WL:32767/WW:65535;
4. Drag the left mouse button to drag the image display;
5. Lateral-drag the right mouse button to adjust the window width, and vertical-drag the right mouse button to adjust the window level;
6. F3 Key: Quickly locate the image window width and window level.
7. F4 Key: Adjust window width and window level automatically.

### 4.4.3. SDK Pgae

SDK page is used to set parameters in config.ini and log level.



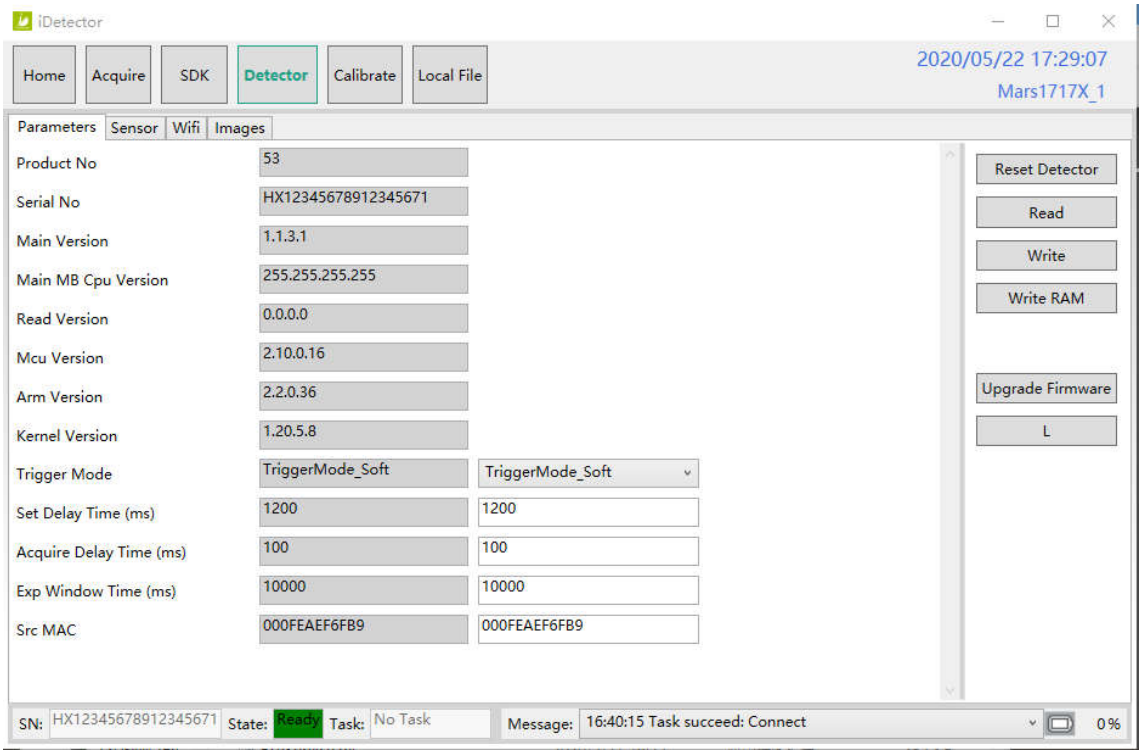

Different log level will show different details. It is recommended to set the log level as Debug

### 4.4.4. Detector Page

In this page, there are Parameters, Sensor and Images tab.

- **Parameters**

1. Enter Detector page, the tab of Paramters is activity by default. There are 5 regions in this page.
2. Parameter name region: lists the paramters.
3. Parameter read region: read the parameters, the values of the parameters are displayed in this area by Read.
4. Parameter write region: write parameter. Entered value of the corresponding parameter in this area can be write to detector.
5. Operation region: functional operation buttons area.
6. Status bar region: status bar for detector state and information of reading or writing parameters, etc.




Configuration parameters description as below:

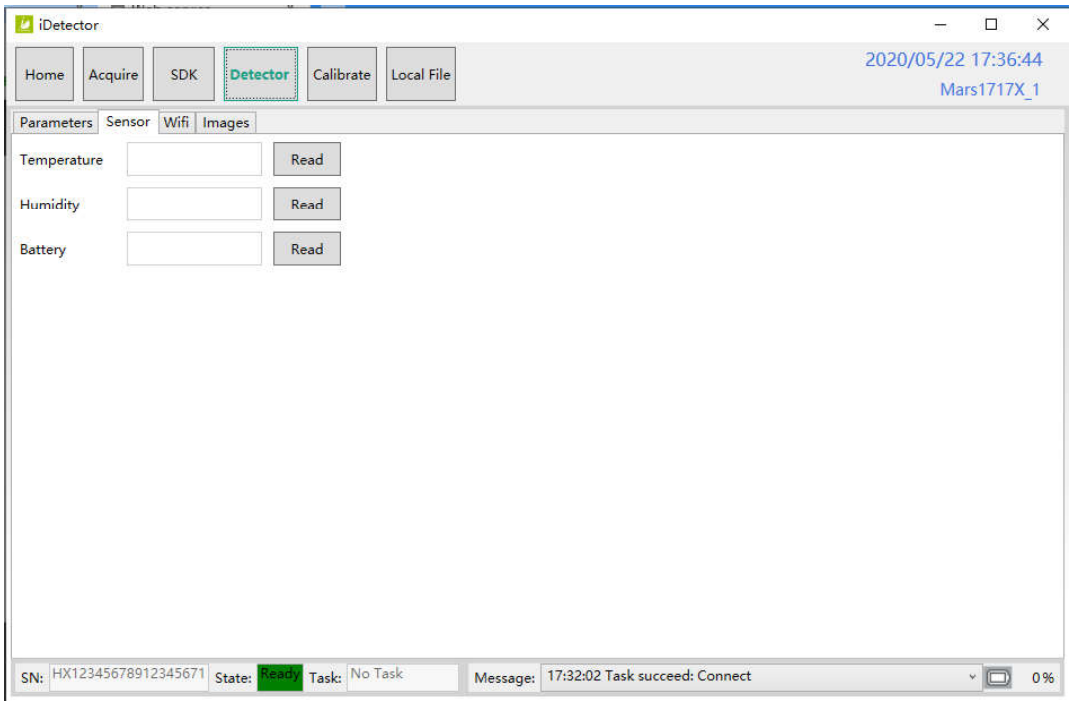
| Name | Description | Configurable |
|---|---|---|
| Product No. | Type of detector product | N |
| Serial No. | Serial number of the detector | N |
| Main Version | Firmware version number of the FPGA | N |
| Read Version | N/A | N |
| MCU Version | Firmware version number of the MCU | N |
| Arm Version | Version number of the ARM App | N |
| Kernel Version | Version number of ARM Kernel | N |
| Trigger Mode | Tirgger mode of the detector | Y |
| Set Delay Time(ms) | Exposure window for AED mode which use a fixed window | Y |
| Acquire Delay Time(ms) | Exposure window for getting image which use a dynamic window | Y |
| Exp Window Time(ms) | Max exposure window for command trigger which use a dynamic window | Y |
| Src MAC | Detector MAC | Y |

Button function description:

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

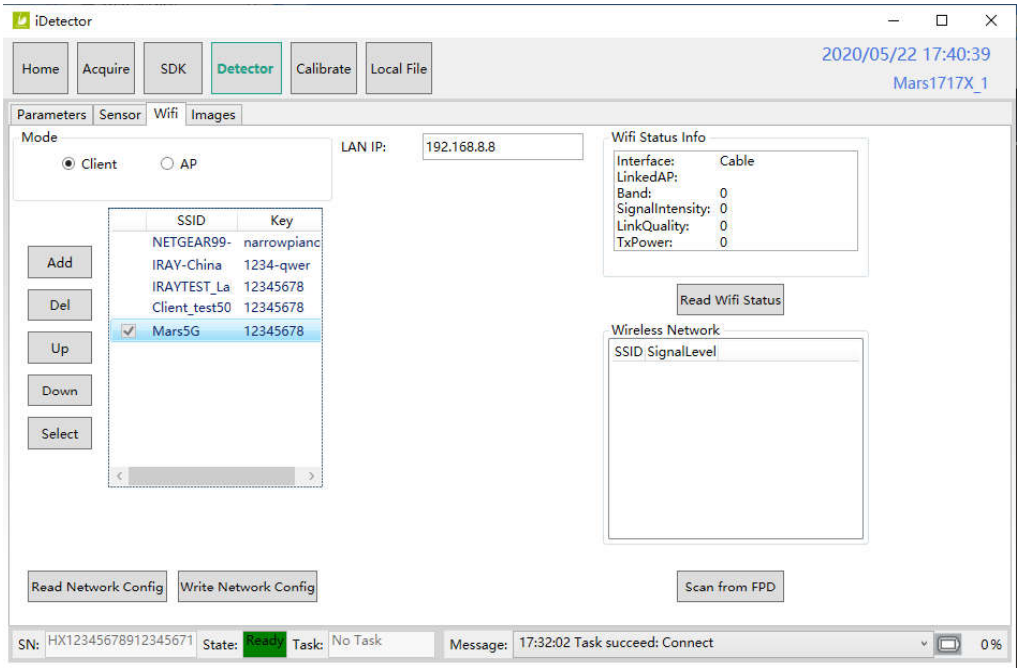
- **Sensor**

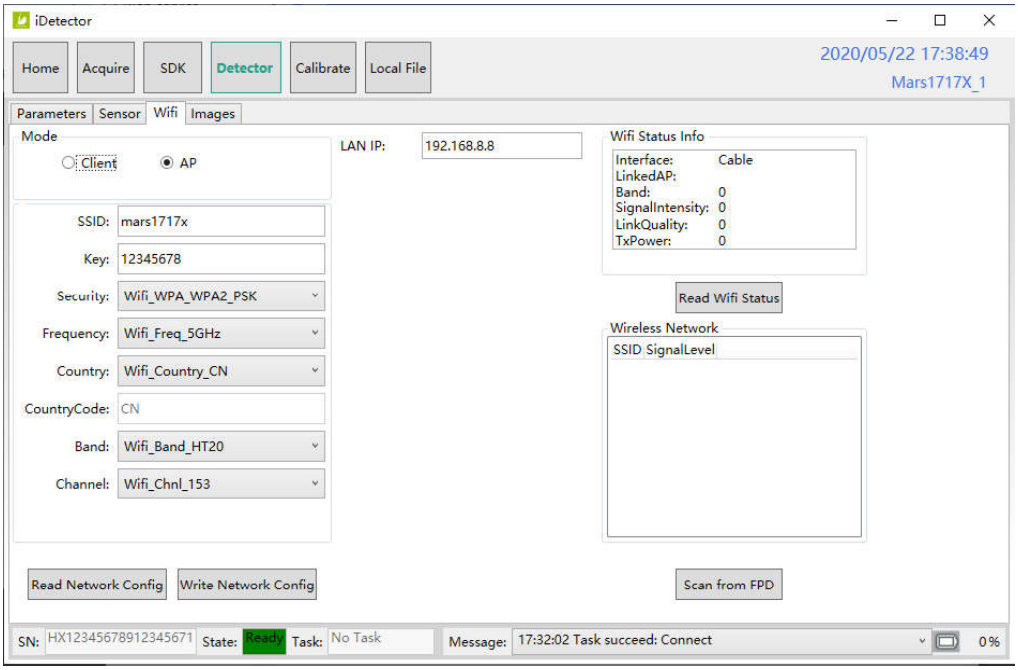
The mainly function in this page is to probe the temperature and humidity of the detector. Click "Read" button to get the value of the temperature or humidity.




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

- **Wifi**

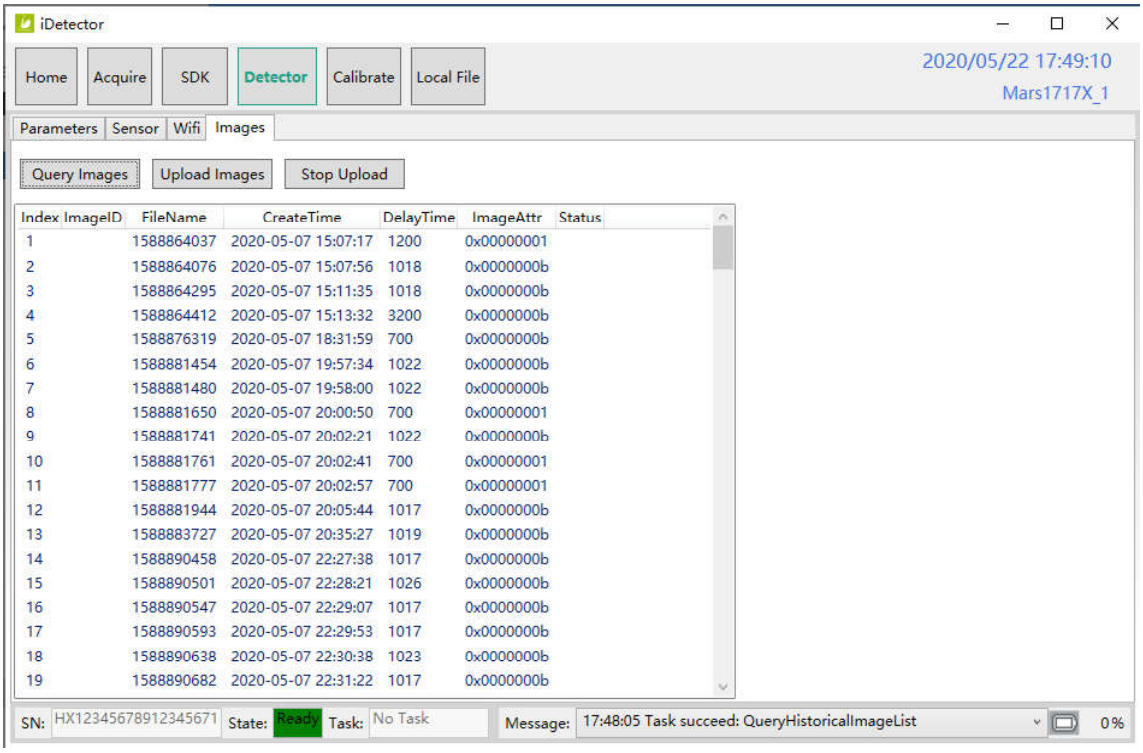



User can config the wireless connect parameters on this tab.

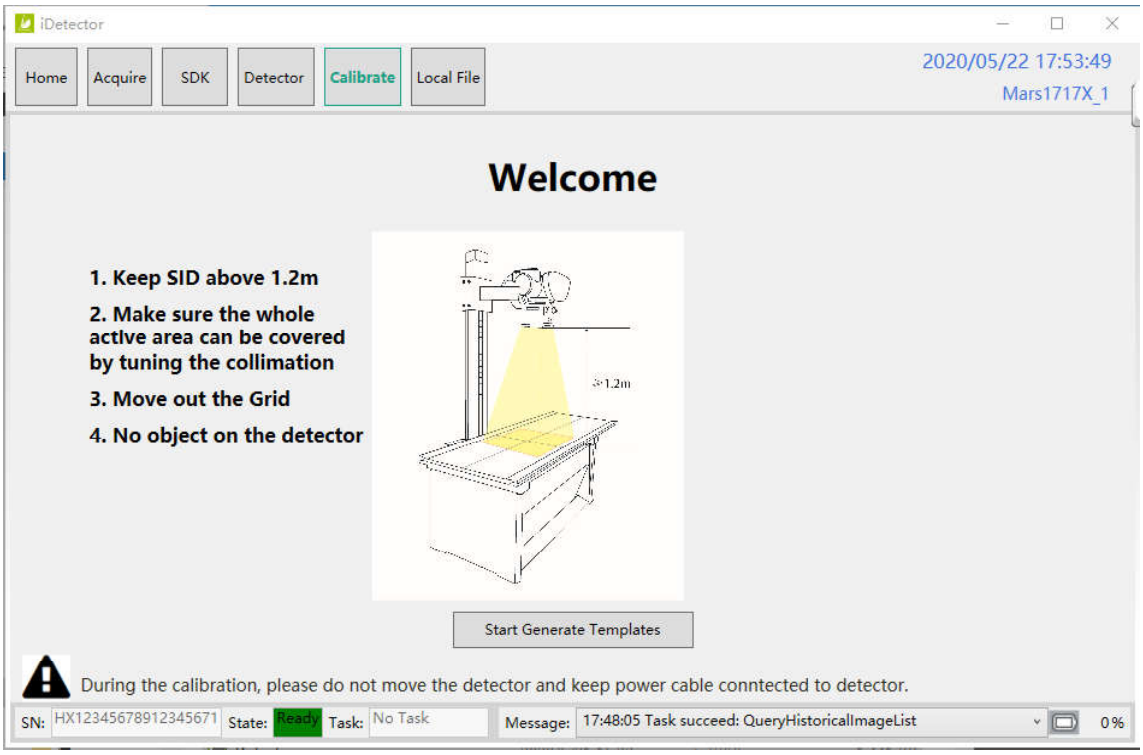
- **Images**

You can Query and upload Images from detector to Workstation.

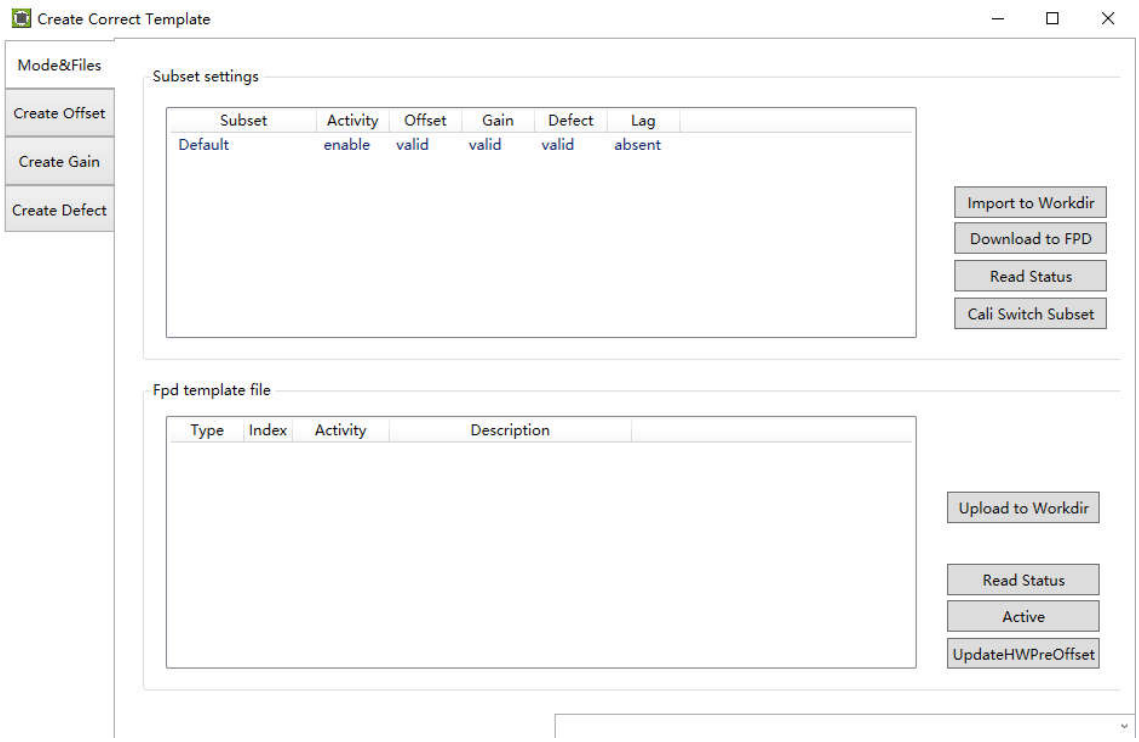



### 4.4.5. Calibrate Page

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




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




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

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

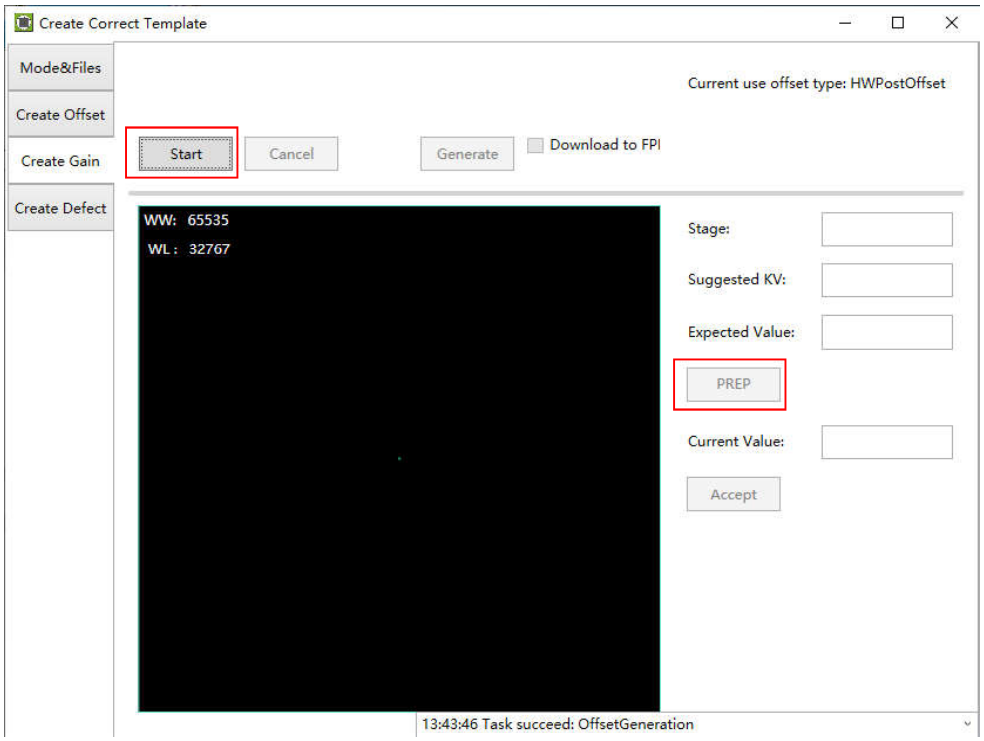
| | |
|---|---|
| UpdateHWPreOffset | Force detector update Offset template |
| ReadStatus | Get the current state of template for hardware correction, enable/disable |

- **Generate Gain Template File**

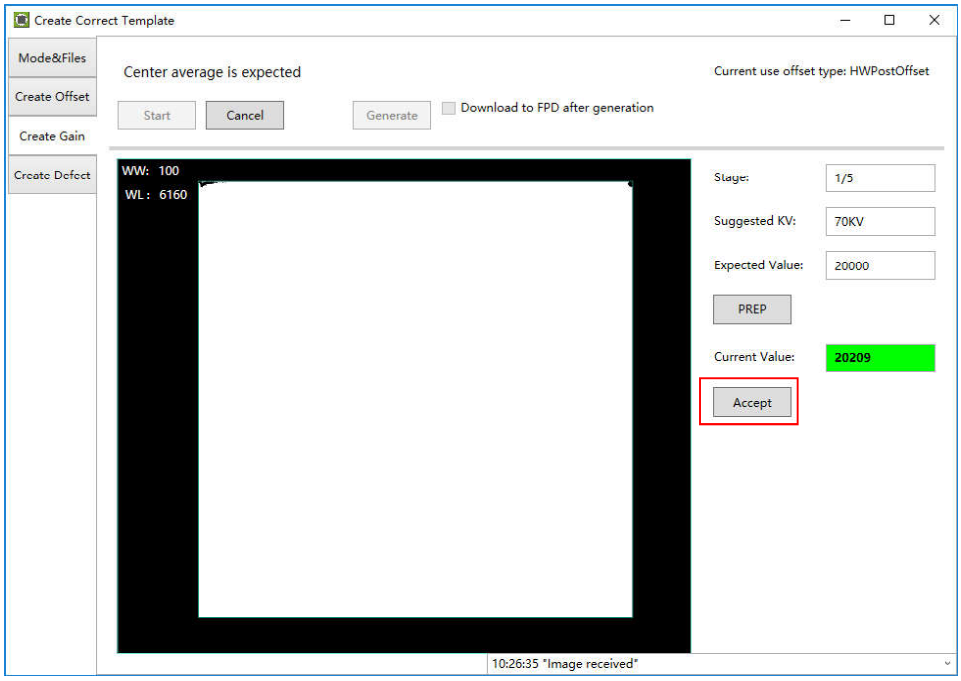
If the relative position between tube and detector changed or KV value changed, it suggest to create gain template file.

1. Enter Create Gain page

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




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




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

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

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

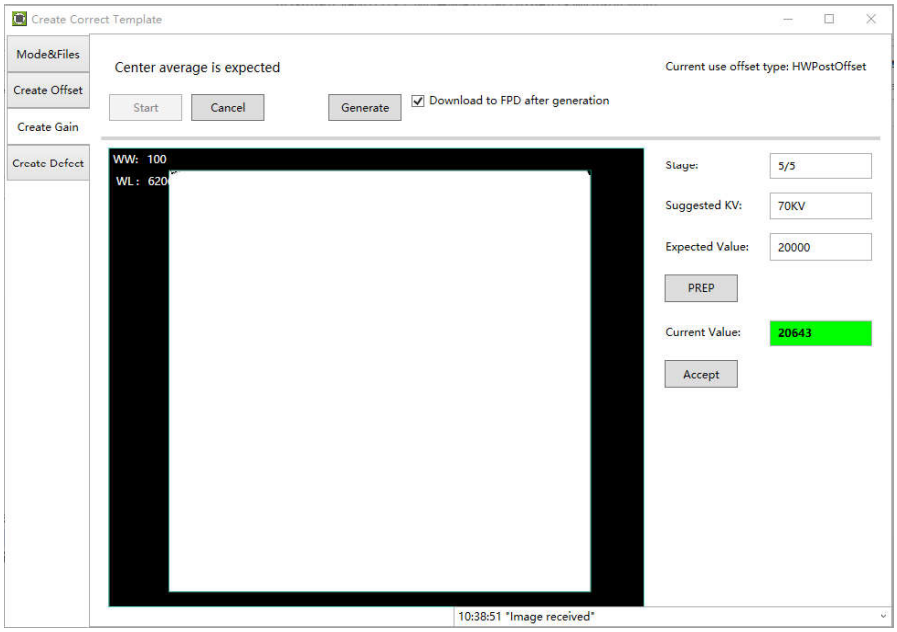
Yellow: The current value is higher or lower than the expected one, user decides if acceptable. For example, the expected value is 20000, and user needs 40000 as the gain piont, the yellow warning can be ignored, and the value can be accepted still.

Green: The value is good.

Red: The value is un-acceptable.

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

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



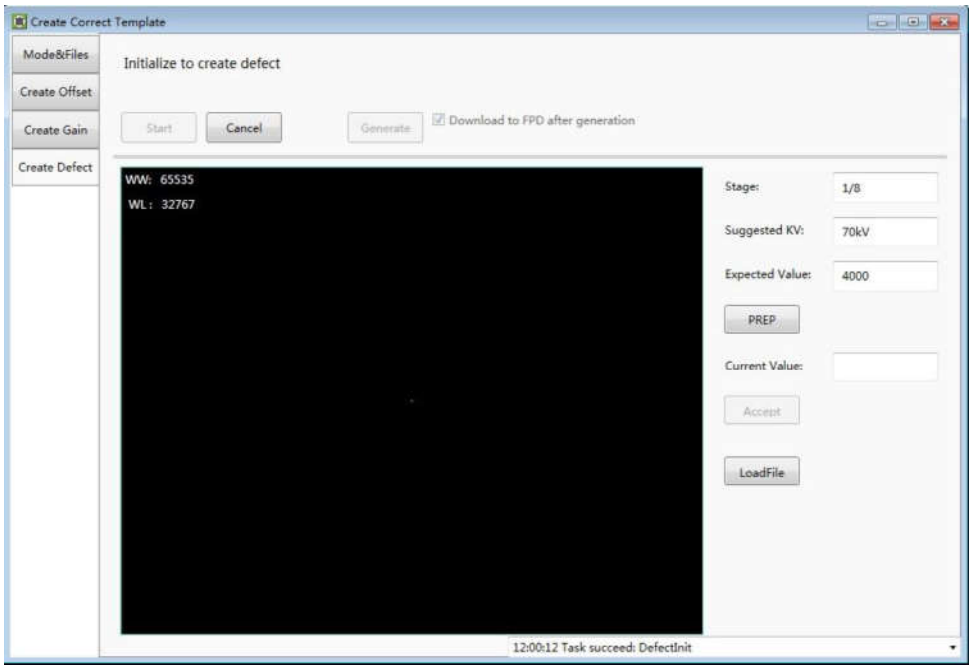

4. When the generating process is finished, the UI will give the message of successful.

- **Generate Defect Template File**

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

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

   And the process can be quit by “Cancel”.

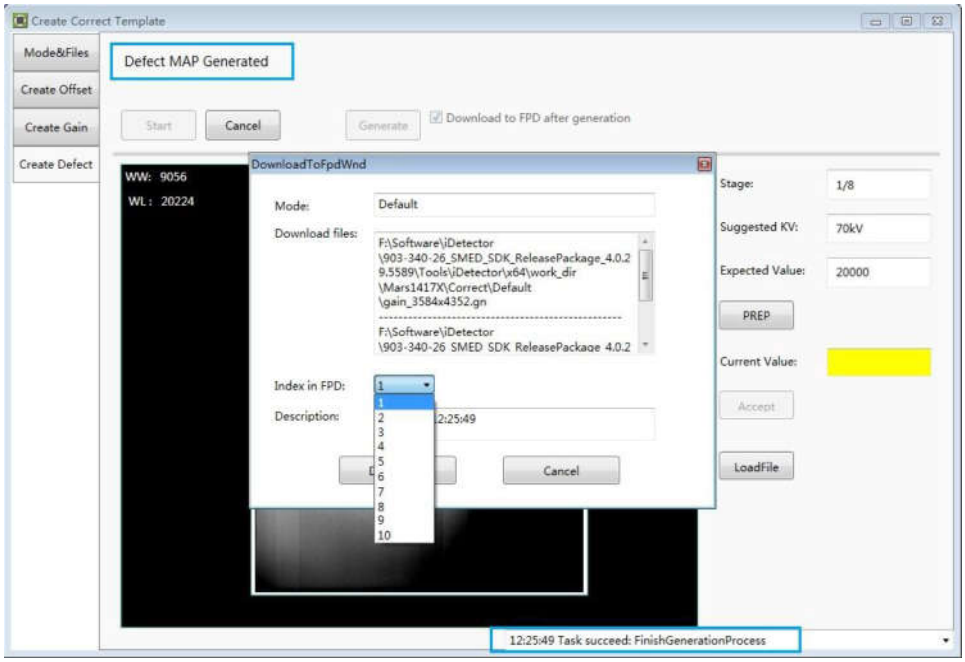


2. There are 8 images that need to be acquired, the UI gives the recommend KV and expected image value, user should refer with them.

3. If the option “Download to FPD after generation” is checked, the download UI will appear after finishing generating the defect map which will takes a little time.

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

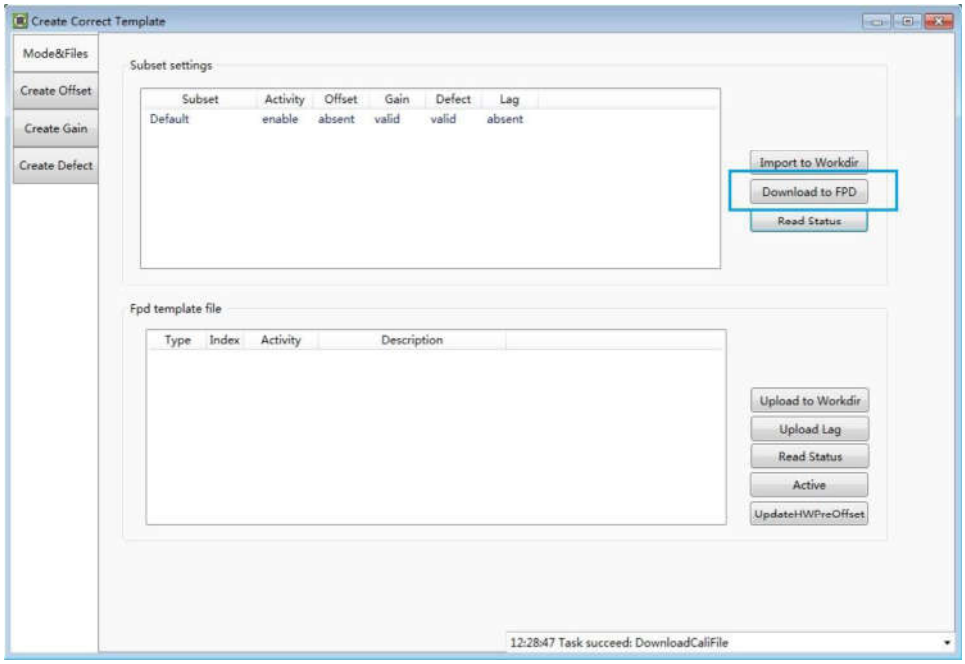
   The “Download files” part show the directory of the generated map stored on the workstation.




4. After choosing the stored index of FPD, the download process can be started by the “Download” button, user should wait the process until it is finished.

5. The correction map also can be managed at anytime on the page of “Mode&Files”.

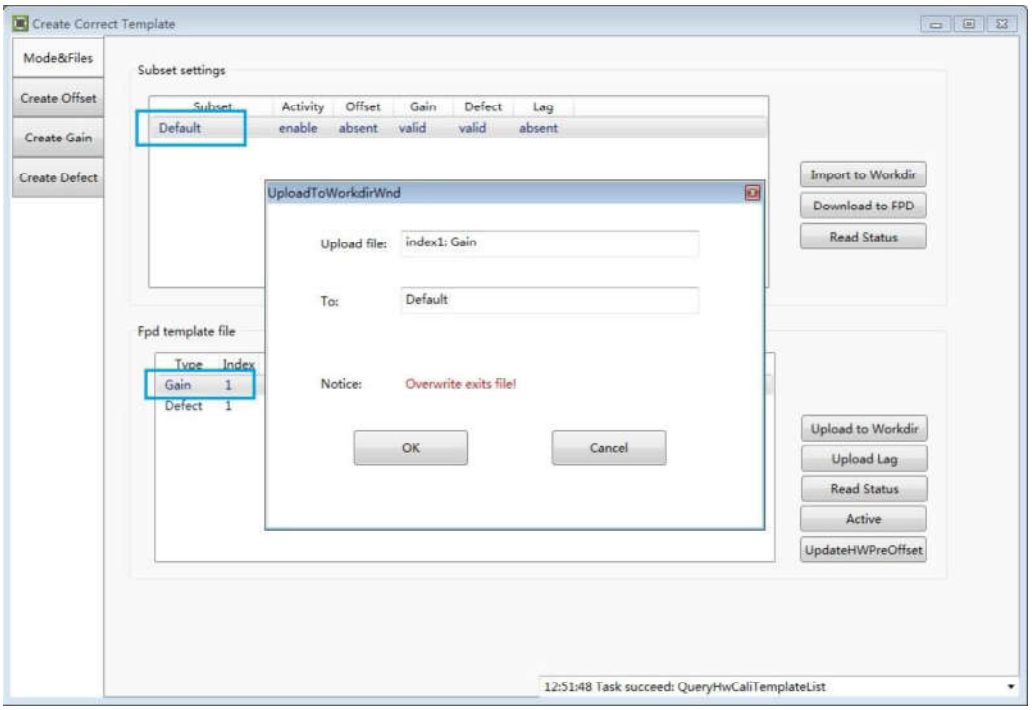
   Choose the item of “Default” in the Subset settings part and click “Download to FPD” to finish downloading the maps into the detector.




- **Upload the correction files**

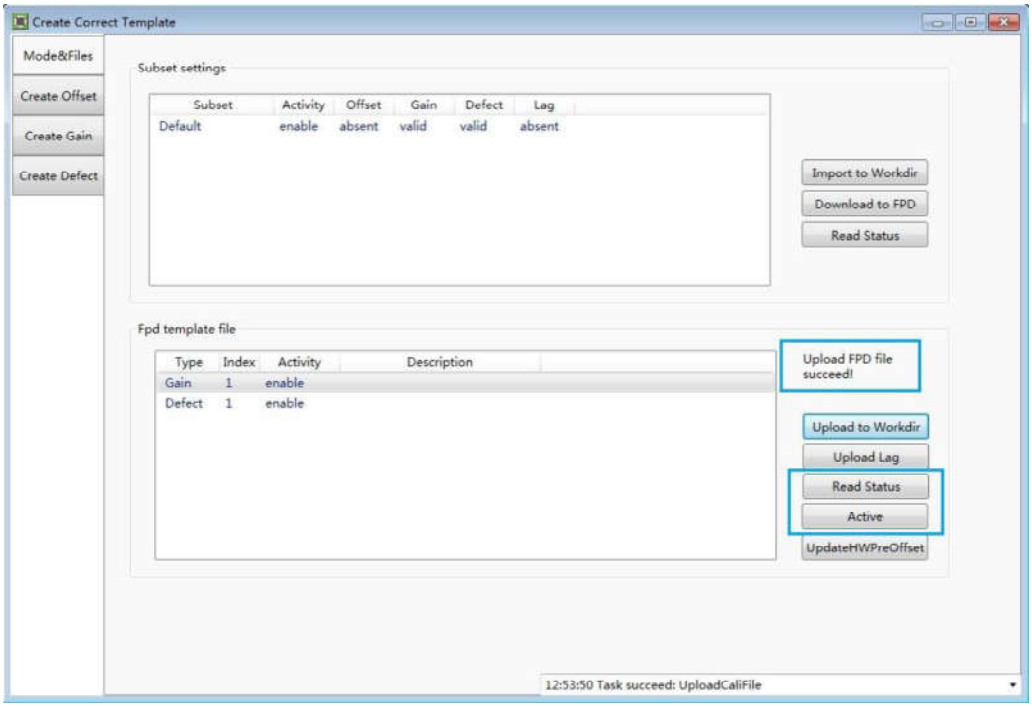
1. The correction maps can be uploaded to the workstation too.

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




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

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




### 4.4.6. Local Page

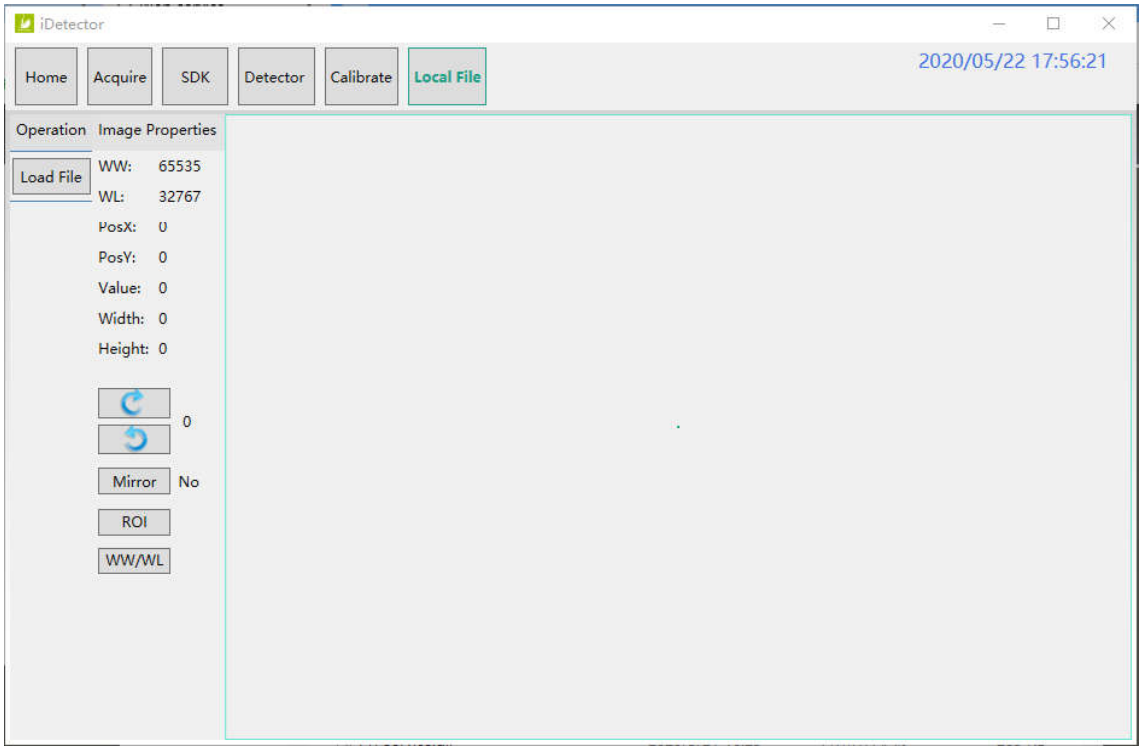
In this page user can open the image files saved in local, the file formate can be dcm, raw, tiff, dft. When the software is disconnected to detector, the file still can be opened.

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

The pixel matrix is defined as below:

Active area : 4267*4267

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




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

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

| Image Properties& Image Process | Description |
|---|---|
| WW | window width |
| WL | window level |
| PosX | X coordinates of the current cursor at the point |
| PosY | Y coordinates of the current cursor at the point |
| Value | Value of the current cursor at the point |
| Width | Image width |
| Height | Image height |
|  | Rotate the image clockwise, 90 degrees every time. |

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

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

a) The operating system is not compatibility;

b) Change or update the software failed;

c) The compatibility of the interface;

d) The data transfer protocol error;

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

f) The data output failed;

# Operation Instructions for Image Acquisition

Mars1717X provides SDK for users to integrate detector into their DR system. Additionally, it also provides an application for demonstration, i.e. IDetector. User can use IDetector to control detector without DR system.

## 4.6. 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

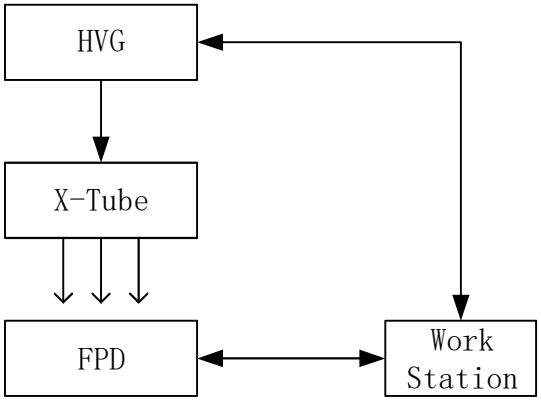
- Wait until initialization is complete
- Connect the software
- choose the synchronization mode
- Generate HWPreOffset, Gain and Defect template after the detector reaches thermal equilibrium
- Acquire images in the selected mode

To Acquire X-ray image is the main operation of Mars1717X. Most importantly, detector should build synchronization with X-ray generator. Mars1717X has one synchronization modes to acquire X-ray image, which is Software Mode.

## 4.7. Software Mode

### 4.7.1. Block Diagram

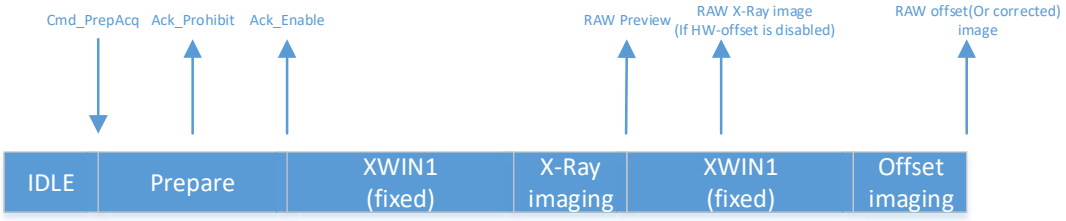
Software mode is the basic way to acquire X-ray image. Please see figure below for general feature. Workstation is a host PC device installed with iDetector and SDK. FPD is the Flat Panel Detector and HVG is the High Voltage Generator. In this mode, Workstation does not have to control X-ray generator.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



### 4.7.2. Work Flow(PrepAcq)

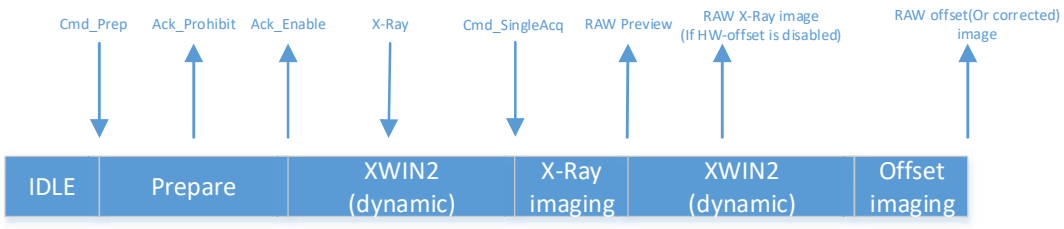
Select HWPostOffset、HWGain、HWDefect. If user need the raw image, please de-select all these correction options.

Also, the software correction is supported.




1. Send Cmd“PrepAcq” on UI “Acquire” page.
2. After receiving the Cmd_PrepAcq, it will start the prepare process, and send back the acknowlage of “Prohibit” and “Enable”, the “XWIN” will be started.
3. The XWIN is configured by parameter “Clear Acq Delay Time” on “SDK” page, the unit is “ms”.
4. User needs to make sure the X-Ray ends within the XWIN.
5. The detector will send the images after the XWIN closed.
6. The preview image will be always sent, which is 4x4 averaging, the raw X-Ray image will be sent if the HW correction is disabled with the raw offset image follows, otherwise, the X-Ray image will not be sent and only the corrected image will be transferred.

### 4.7.3. Work Flow(Prep+Acq)

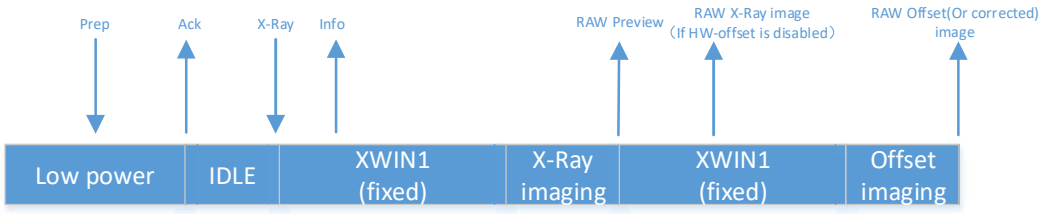



1. Send Cmd“Prep” on UI “Acquire” page.

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

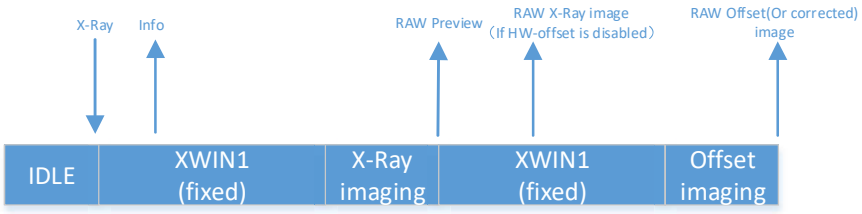
## 4.8. AED Mode

### 4.8.1. Inner




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

### 4.8.2. Freesync Mode




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

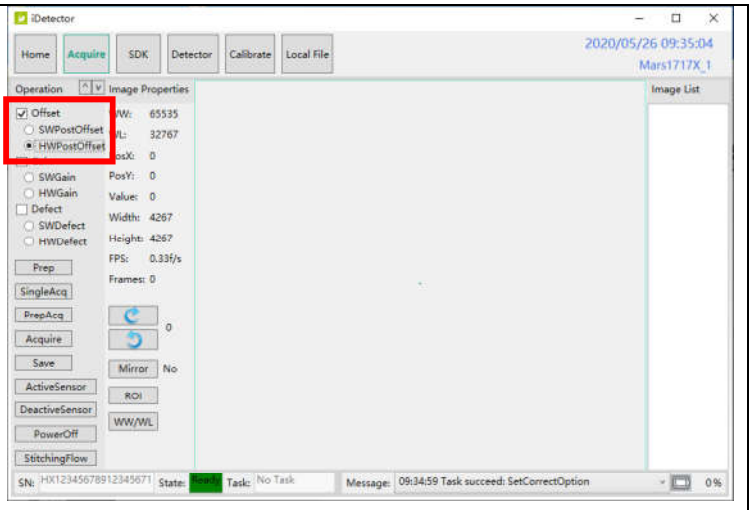
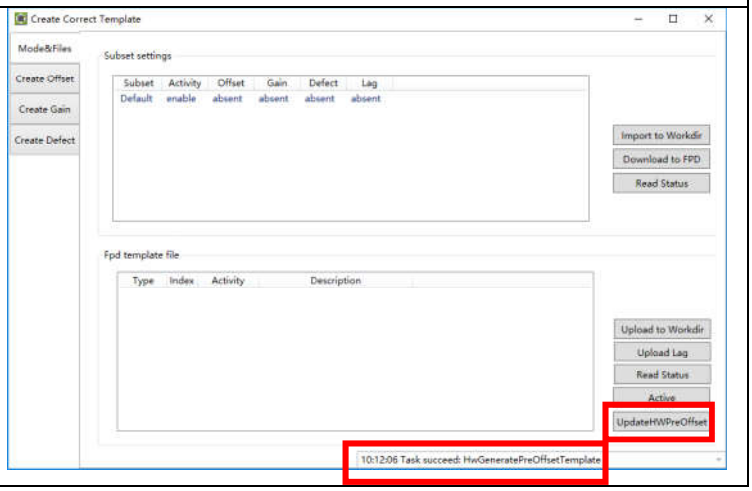
## 4.9. After use

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

## 4.10. Correction and Calibration Template Generation

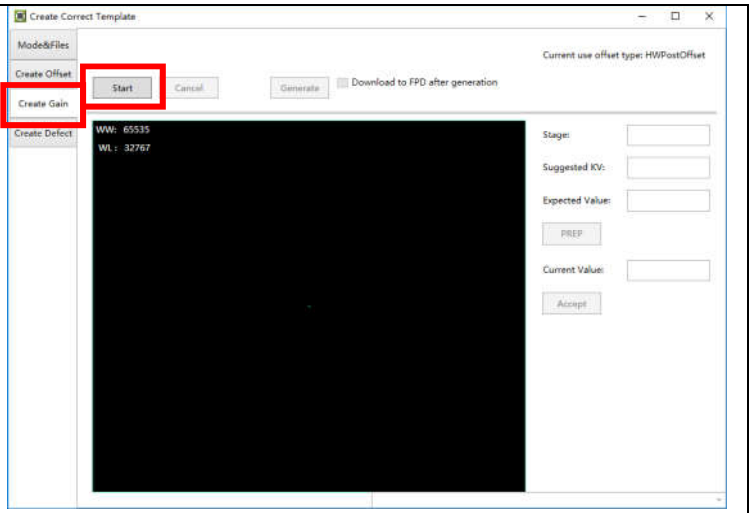
The correction and calibration should be performed after installation and it is recommended to perform the new correction and calibration after any major change on the system settings and hardware configuration. On the other hand, it is also recommended to do the correction and calibration in each 6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

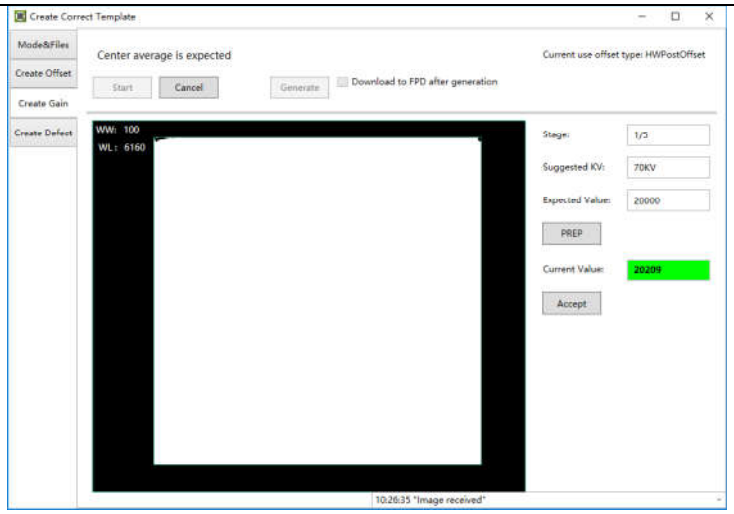
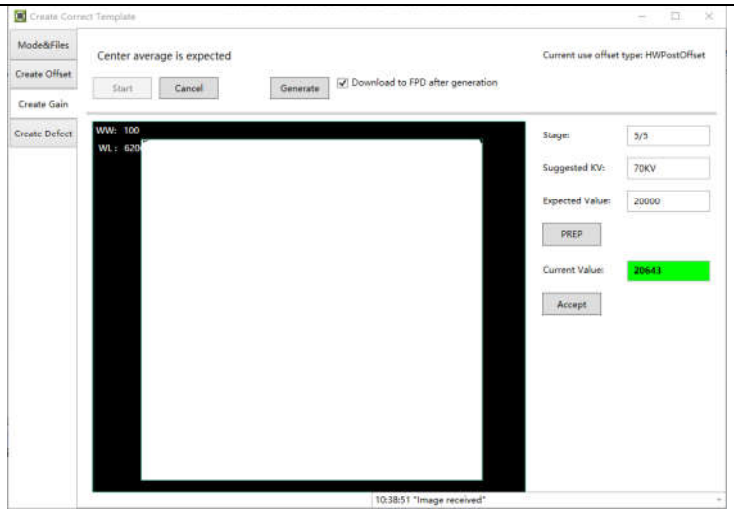
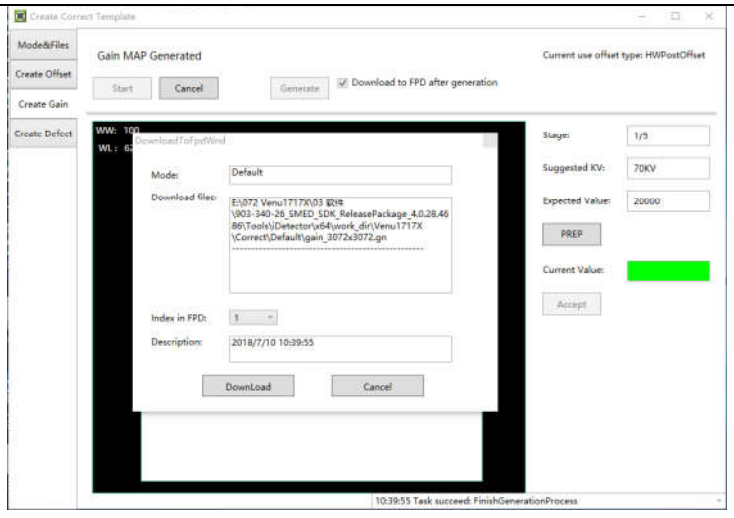
### 4.10.1. HW pre-offset Template Generation

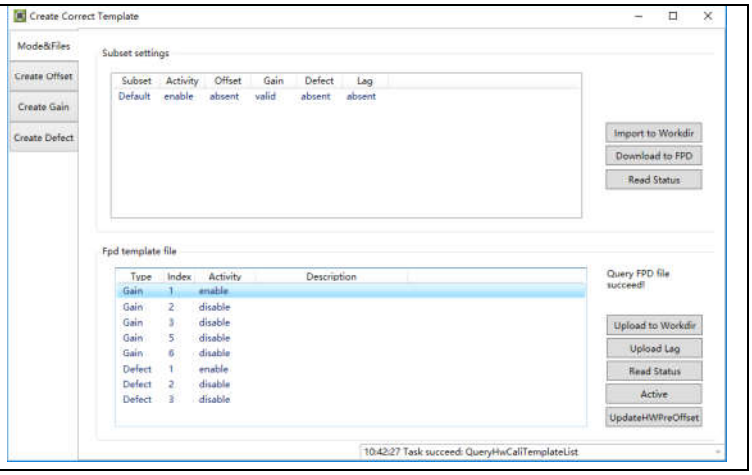
| | |
|---|---|
| Enter Acquire interface, select<br>HWPostOffset option |  |
| Enter Calibrate interface, click<br>UpdateHWPreOffset button.<br>Waiting until status bar displayed:<br>"Task succeed:<br>HwGeneratePreOffsetTemplate" |  |

### 4.10.2. Gain Calibration Template Generation

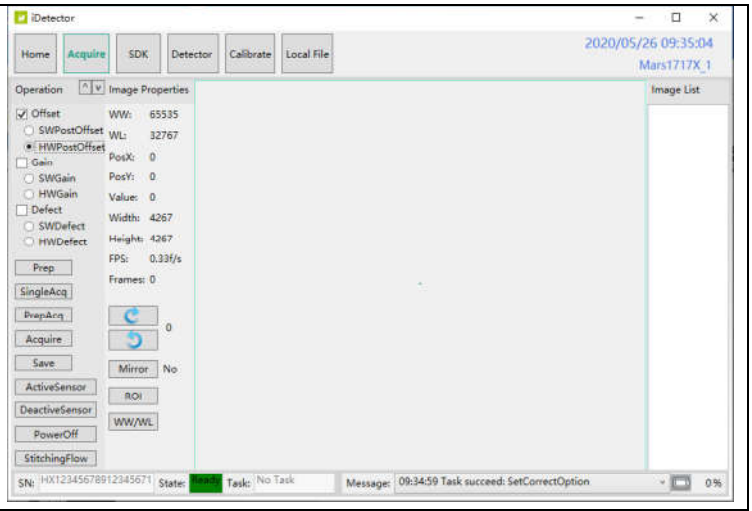
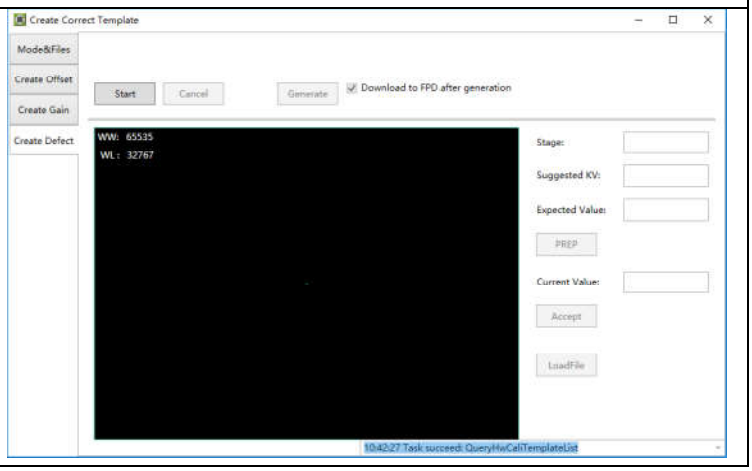
If the relative position between tube and detector changed or KV value changed, it suggest to create gain template file.

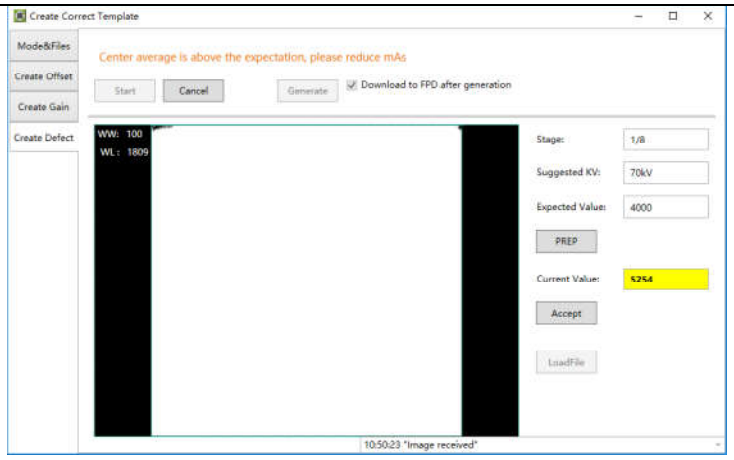
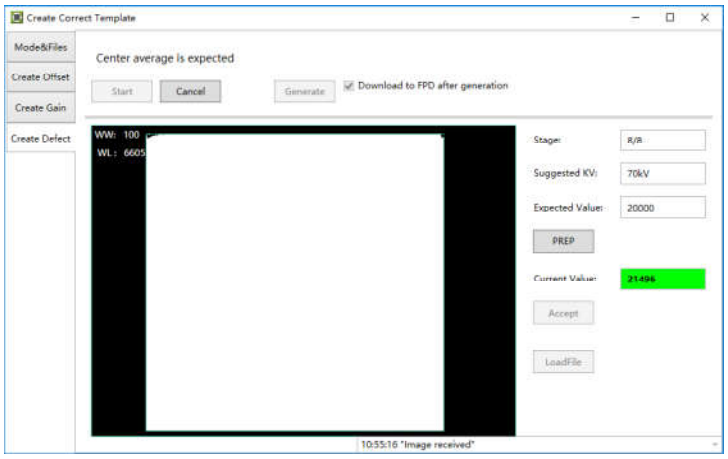
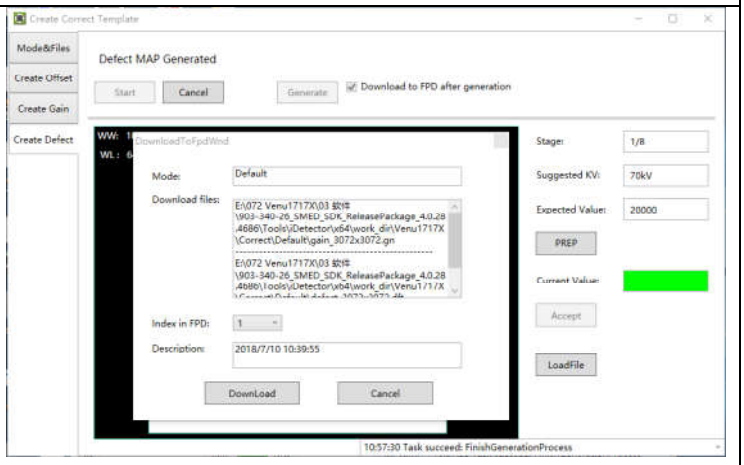
| | |
|---|---|
| Enter Create Gain page<br>Click "Start" button to start process. |  |

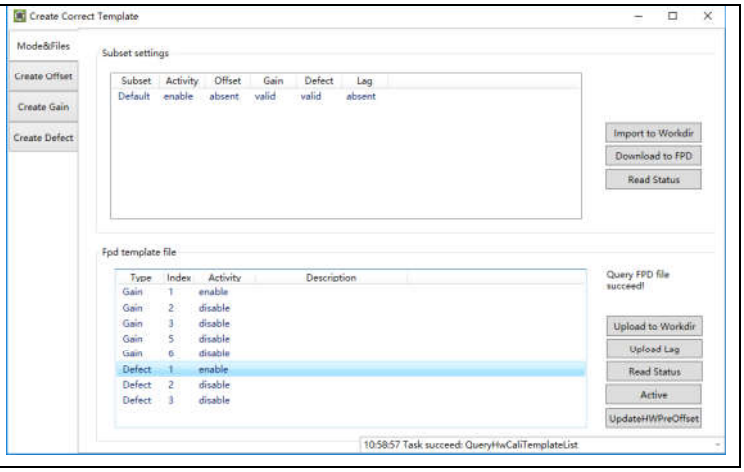
| | |
|---|---|
| Click PREP button, acquire image. Please exposure after Acquire button enable. And click Acquire button to acquire image after exposure end. Click Accept button after acquired image. If Current Value textbox is yellow, click PREP button. Re-acquire images after adjust generator parameters.<br>Note: In different trigger mode, the operation maybe have little difference. Please follow the UI tips.<br><br>**Mind:**<br>If the detector is in inner or Freesync mode, then user should finish the exposure before the time bar counting ends.<br>And the click on Acquire is not necessary for inner or Freesync. |  |
| Create gain template need several images. You can click Generate button to generate Gain template once one image was captured. But it may lead to imperfect template quanlity. |  |
| Download template file dialog will pop up if "Download to FPD after generation" option was checked. Click Download button to download the template into the detector. |  |

| | |
|---|---|
| Select Mode&Files tab. Click Read Status button to check whether just downloaded gain template is enable. If not, please click Active button to enable. |  |

### 4.10.3. Defect Correction Template Generation

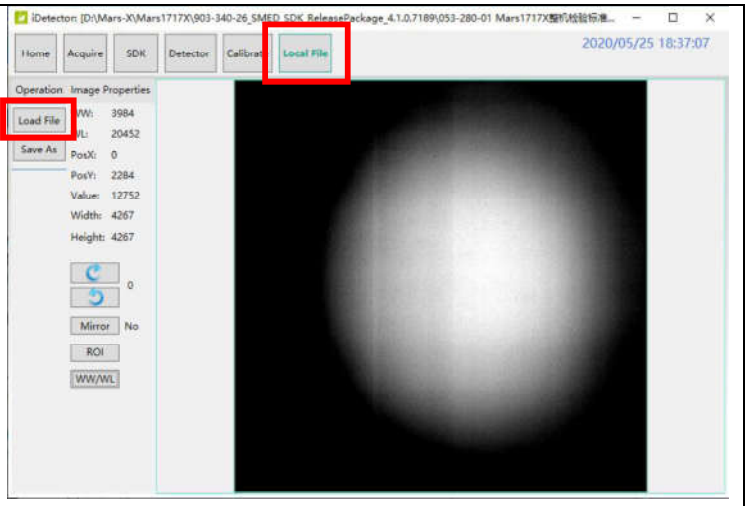
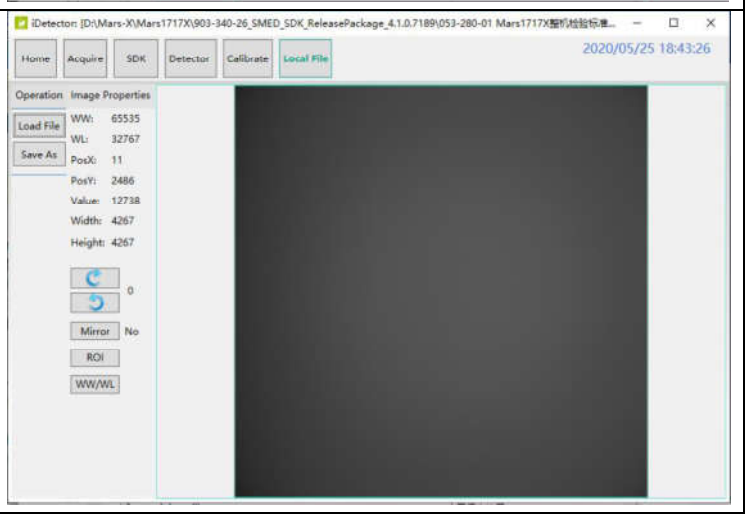
| | |
|---|---|
| Enter Acquire UI. Choose HWPostOffset.<br>Enter Calibrate UI. Select Create Defect tab. |  |
| Click "Start" button to start process.<br>Click PREP button, acquire image. Please exposure after Acquire button enable. And click Acquire button to acquire image after exposure end. Click |  |

| | |
|---|---|
| Accept button after acquired image. If Current Value textbox is yellow , click PREP button. Re-acquire images after adjust generator parameters.<br>Note: In different trigger mode, the operation maybe have little difference. Please follow the UI tips. |  |
| You can click Generate button to generate Gain template after acquired required images. |  |
| Download template file dialog will pop up if "Download to FPD after generation" option was checked. Click Download button to download the template into the detector. |  |

| | |
|---|---|
| Select Mode&Files tab. Click Read Status button to check whether just downloaded gain template is enable. If not, please click Active button to enable. |  |

## 4.11. 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<br>In this page user can open the image files saved in local, the file formate 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 dft file there will be a dialog to select image size. Select correct size to open image files. If the file is not correct user will get an error message.<br>Mars1717X image size: 4267*4267 |  |

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

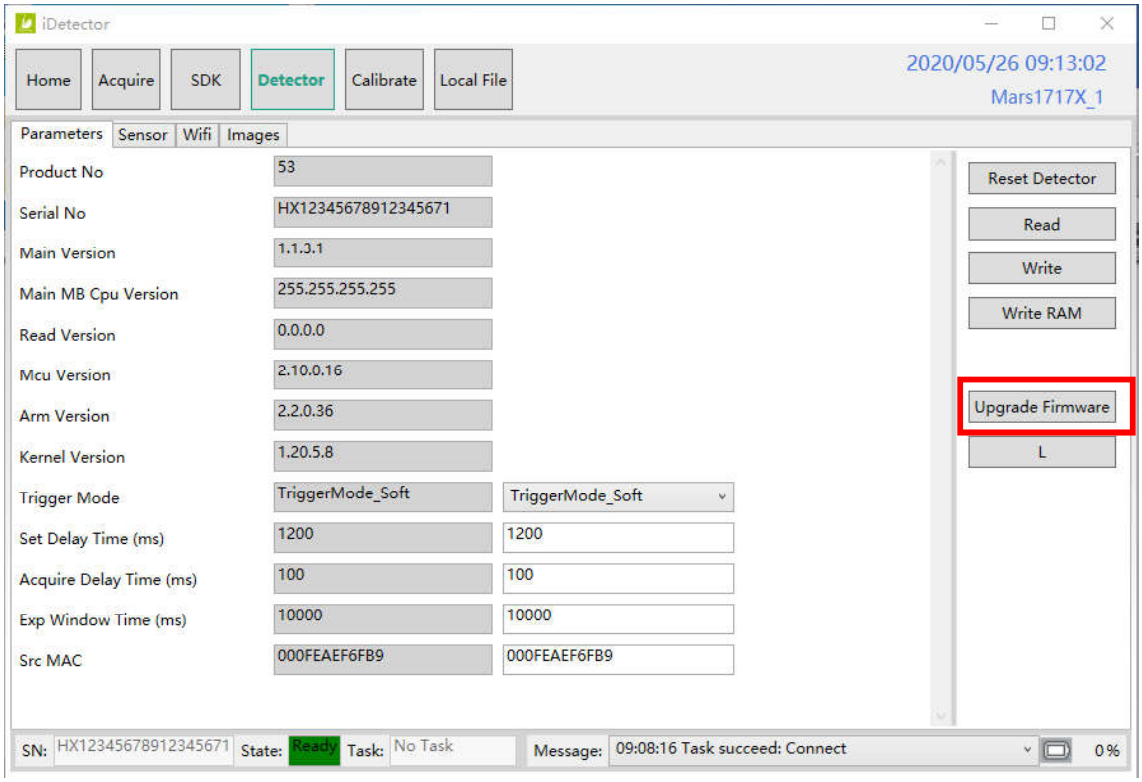
This page provides WW/WL tool as Acquire page . Click this button to auto adjust WW/WL based on selected area by right button of mouse.

| Image Properties& Image Process | Description |
|---|---|
| WW | window width |
| WL | window level |
| PosX | X coordinates of the current cursor at the point |
| PosY | Y coordinates of the current cursor at the point |
| Value | Value of the current cursor at the point |
| Width | Image width |
| Height | Image height |
|  | Rotate the image clockwise, 90 degrees every time. |
|  | Rotate the image anticlockwise, 90 degrees every time. |
| Mirror | Open or close mirror |
| ROI | ROI tool，to view the image of the AVG, SV, SNR and other parameters. Press "ctrl" key, can create several ROI area. |
| WW/WL | Auto adjust WW/WL based on selected area by right button of mouse. |

## 4.12. 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.

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




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

**Mars1717X_IMAGE_44_ALL_20XX_XX_XX.ifrm**

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

**Mars1717X_IMAGE_44_ARM_20XX_XX_XX.ifrm**

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

**Mars1717X_IMAGE_44_FPGA_20XX_XX_XX.ifrm**

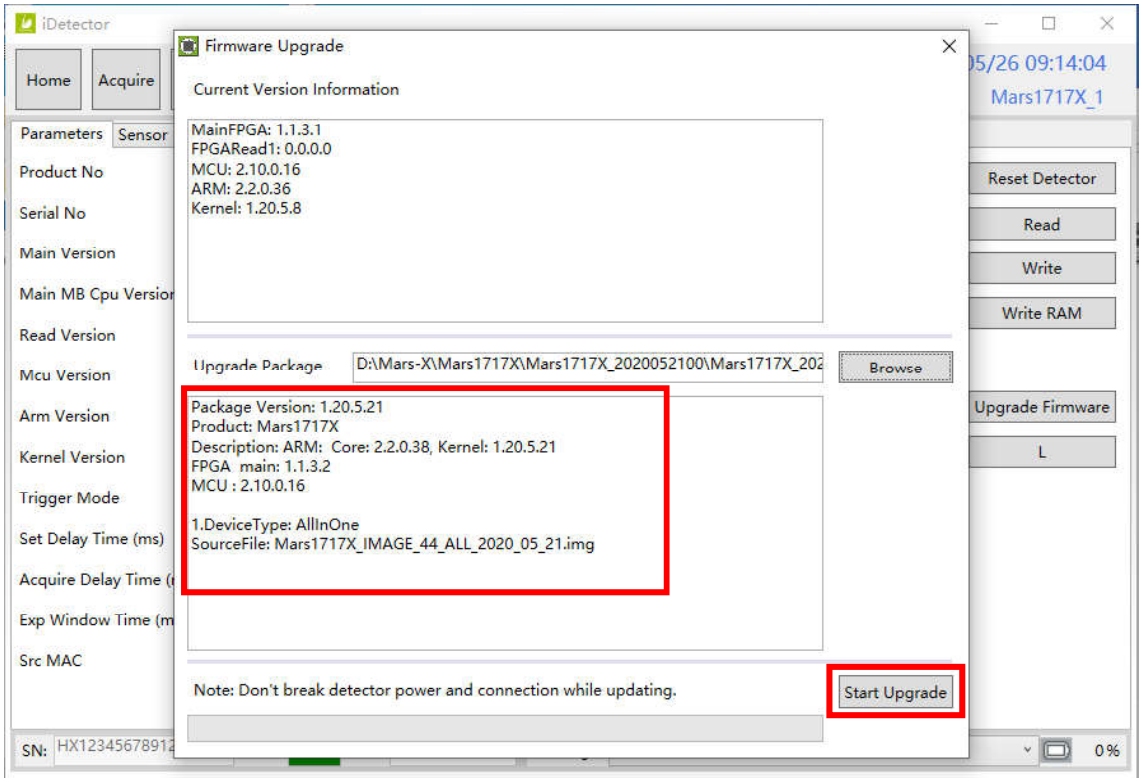
Word “FPGA” indicates the file is only for FPGA.

**Mars1717X_IMAGE_44_MCU_20XX_XX_XX.ifrm**

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

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

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




Note:

1. There is a progress bar for indication. Make sure battery is inserted and battery capacity is over 25%
2. Please make sure that iDetector shows “Ready”. It can also be checked by click “Config” button, there is firmware version.

# 6. Regulatory Information

## 6.1 Medical Equipment Safety Standards

◆ **Medical equipment classification**

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

◆ **Safety standards reference**

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

| | |
|---|---|
| IEC 60601-1:2005+A1:2012 | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| EN 60601-1: 2006+A1:2013 +A11:2011+A12:2014 | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| CAN/CSA-C22.2No.60601-1:14 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| ANSI/AAMI ES60601-1:2005+A2 (R2012)+A1 | C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) |
| KS C IEC 60601-1:2013; | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2014 | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests |
| 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 |
| CAN/CSA-C22.2 No. 60601-1-2:16 | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – |

| | Requirements and tests |
|---|---|
| IEC 60601-2-54:2009+A1:2015 | Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy |
| EN 60601-2-54:2010+A1:2015 | Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy |
| CAN/CSA-C22.2 No. 60601-2-54:11+GI1(R2016)+A1; | Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy |
| KS C IEC 60601-2-54:2012 | Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy |
| IEC 60601-1-6:2010 +A1:2013; | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usibility |
| EN 60601-1-6:2010+ A1:2015; | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usibility |
| CAN/CSA-C22.2 No. 60601-1-6:11+A1; | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usibility |
| KS C IEC 60601-1-6:2011; | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usibility |
| EN ISO 14971: 2019 | Medical device – Application of risk management to medical devices |
| EN ISO 24971: 2010 | Medical devices — Guidance on the application of ISO 14971 |
| ISO 15223-1:2016 | Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied—Part 1: General requirements |
| IEC 62133-2:2017 | Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems |
| EN 1041:2008+A1 | Information supplied by the manufacturer of medical devices |
| ISO 10993-1:2018 | Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process |
| MDD (93/42/EEC) | Medical Device Directive |
| EN ISO 13485:2016 | Medical devices -- Quality management systems -- Requirements for regulatory purposes |

## 6.2 Guidance and Manufacture's Declaration for EMC

### 6.2.1 EMI Compliance Table

◆ **Emissions**

| Phenomenon | Compliance | Electromagnetic environment |
|---|---|---|
| RF emissions | CISPR 11<br>Group 1, Class B | Professional healthcare facility environment |
| Harmonic distortion | IEC 61000-3-2<br>Class A | Professional healthcare facility environment |
| Voltage fluctuations and flicker | IEC 61000-3-3<br>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<br>±2kV, ±4kV, ±8kV, ±15kV air |
| Radiated RF EM field | IEC 61000-4-3 | 3V/m<br>80MHz-2.7GHz<br>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<br>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<br>100kHz repetition frequency |
| Surges<br>Line-to-line | IEC 61000-4-5 | ±0.5 kV, ±1 kV |
| Surges<br>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<br>6V in ISM bands between 0.15MHz and 80MHz<br>80%AM at 1kHz |
| Voltage dips | IEC 61000-4-11 | 0% UT; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° |
| | | 0% UT; 1 cycle<br>and<br>70% UT; 25/30 cycles<br>Single phase: at 0° |
| Voltage interruptions | IEC 61000-4-11 | 0% UT; 250/300 cycles |

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

Portable RF communications equipment, including antennas, can effect medical electrical equipment. The warning should include a use distance such as “be used no closer than 30 cm (12

inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer".

◆ **Cable provided for EMC**

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

◆ **Electromagnetic Compatibility (EMC)**

Mars1717X 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. Mars1717X 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.

Mars1717X 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 Mars1717X 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<br>47 CFR part 15, subpart B<br>47 CFR part 15，subpart C 15.247<br>47 CFR part 15，subpart C 15.407<br>47 CFR §2.1091<br>KDB447498 D01 General Exposure Guidance v06 |
| European Union | ETSTEN 300 328 V2.2.2<br>ETST EN 301 893 V2.1.1<br>ETST EN 300 440 V2.1.1<br>ETSTEN 301 489-1 V2.2.3<br>ETSTEN 301 489-3 V2.1.1<br>ETSTEN 301 489-17 V3.2.4<br>EN 55032:2015+A11:2020 |

| | |
|---|---|
| | EN 55035:2017+A11:2020<br>EN 61000-3-2:2014<br>EN 61000-3-3:2013<br>EN 50566:2017<br>EN 62209-2:2010+A1:2019<br>IEC 62479:2010 |

### 6.3.1 FCC Compliance

Contains module's FCC ID：2ACHK-01070189

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

- Operation is subject to the following two conditions.

The panel may not cause harmful interference.

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

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

  Reorient or relocate the antenna.

  Increase the separation between the panel and receiver.

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

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

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

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

UNII I is in door use only

**Radio Frequency (RF) Energy**

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

During SAR testing, this device was set to transmit at its highest certified power level in all tested frequency bands, and placed in positions that simulate RF exposure in usage

against the body with no separation. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below the maximum value.

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

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

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

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

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

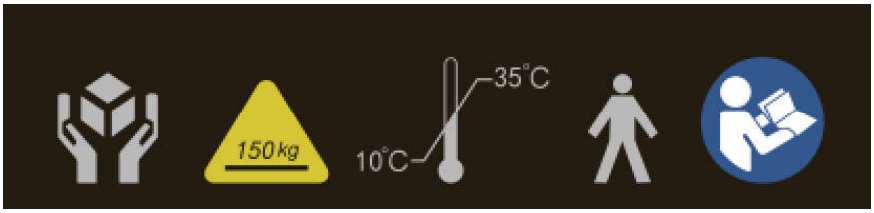
RF exposure compliance with any body-worn accessory, which contains metal, was not tested and certified, and using such body-worn accessory should be avoided.

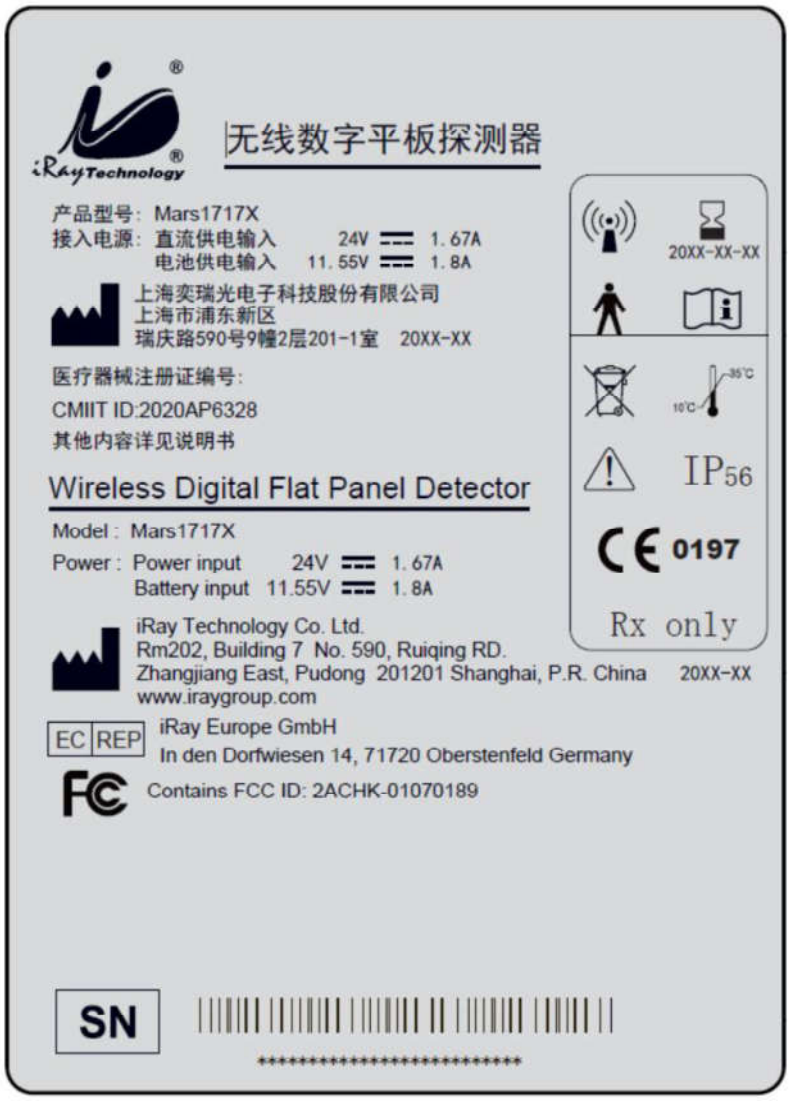
## 6.4 Battery Safety Standards

| Standards | Description |
|---|---|
| IEC 62133:2012 | 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 |

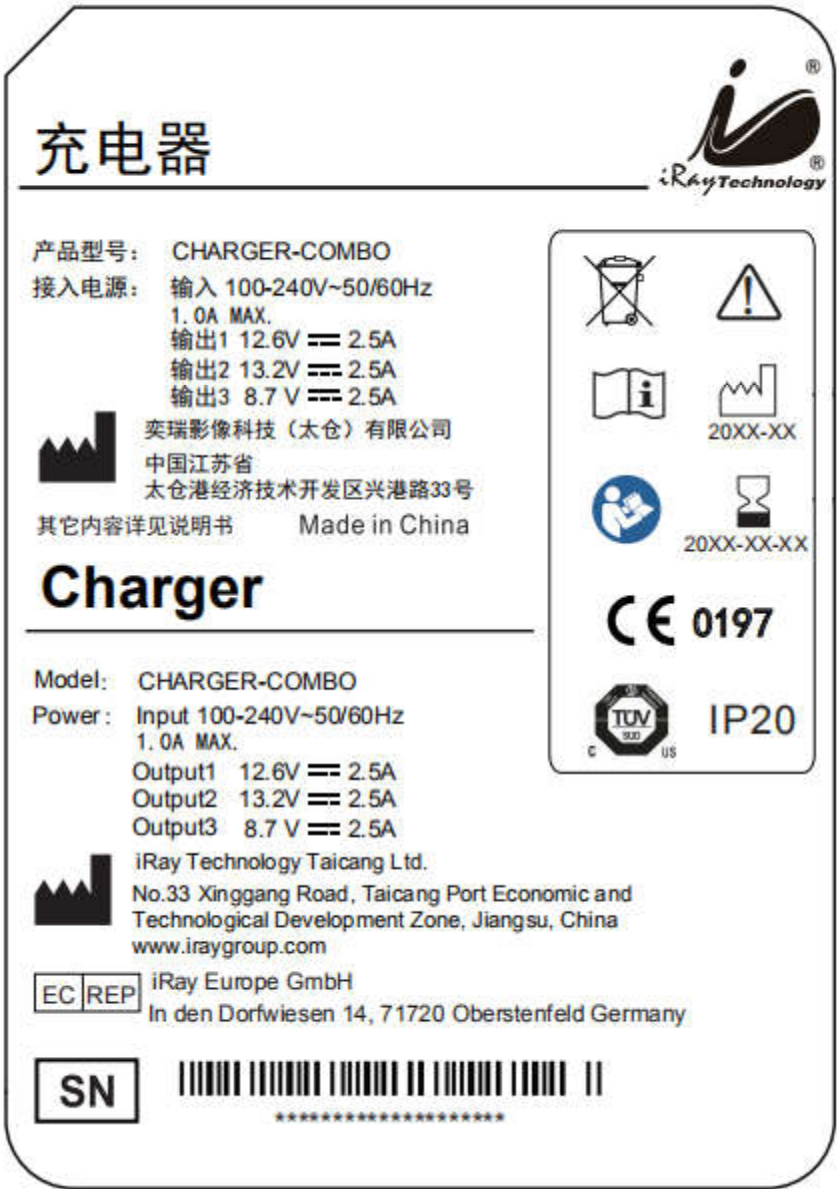
## 6.5 Product Label

Mars1717X Detector Label



**Battery Charger Label**



**Battery Label**

# 7. Trouble Shooting

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

# 8. Service Information

## 8.1 Service Office Information

| Service Office |
| --- |
| Tel：+86 2150720560 |
| Fax：+86 2150720561 |
| E-mail：service@iRaygroup.com |
| Location：RM202, Building 7, No. 590, Ruiqing RD. , Zhangjiang East, Pudong 201201, Shanghai, P.R. China |

## 8.2 Product Lifetime

The estimated product lifetime is up to 7 years without frequency limit.

## 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.

# Appendix A Information of Manufactures

**COMPANY:** iRay Technology Co. Ltd.

**ADDRESS:** Room 201, Building 9, No.590, Ruiqing Rd, Zhangjiang East, Pudong, 201201, Shanghai, P.R. China

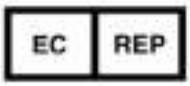
Building 45, No.1000, Jinhai Rd, Pudong, Shanghai, China

**ZIP CODE:** 201201

**TELEPHONE:** +86 21-50720560

**HOMEPAGE:** *WWW.IRAYGROUP.COM*

# Appendix B Information of Europe Representative




| | |
|---|---|
| **COMPANY:** | iRay Europe GmbH |
| **ADDRESS:** | IN DEN DORFWIESEN 14, 71720 OBERSTENFELD GERMANY |
| **ZIP CODE:** | / |
| **TELEPHONE:** | +49-7062-977 88 00 |
| **FAX:** | +49-7062-976 0571 |
| **HOMEPAGE:** | WWW.IRAYEUROPE.COM |