



# **Luna1012X**

## **Wireless Digital Flat Panel Detector**



## **User Manual**

Document Version: A1  
Document ID: 166-201-02  
Release Date: 4/2/2022

## To Customers

Thanks you for purchasing the Luna1012X (hereinafter referred to as Luna1012X) Digital Flat Panel Detector from iRay Technology Co., Ltd. (hereinafter referred to as iRay).

This manual contains all the general information about the Luna1012X, which is intended to provide users with instructions on installation, use and maintenance.

All information in this manual, including illustrations, is based on the equipment prototype. If your equipment does not match with these contents, they will not apply to your equipment.

Information regarding the specifications, compositions, appearance, etc. of this product is subject to change without prior notice.

Store this manual safely so that you can access it in the future.

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## Trademarks



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## Environmental Protection



This symbol indicates that this product cannot be disposed as domestic or commercial waste. Improper handling of this type of waste may result in a negative impact on health and environment.

Some countries or regions, such as the European Union, have set up systems to collect and recycle electrical or electronic waste items. Please contact your local authorities for information about practices established in your region. If collection systems are not available, call iRay Customer Service for assistance.

## For Your Safety




- To avoid personal injury or product damage, be sure to read the user manual and all accompanying information carefully and pay attention to all safety information before installing and using the detector.
- The installation, debugging, addition, modification and maintenance of this product can only be carried out by operators who has accepted the professional training offered by the iRay's customer service staff.
- The equipment should be maintained in a safe and operable condition by maintenance personnel.
- Only a physician or a legally certified operator is allowed to use this product.
- 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. For details, consult our sales representative or local iRay dealer.



## Disclaimer

- iRay will not bear any responsibilities for any abnormality, equipment damage and personal injury caused due to your failure to follow the warnings and operating instructions in this manual.
- 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.
- iRay shall not be liable to any damage, loss, or injury arising from unauthorized modifications, repairs, or alterations to this product or failure to strictly comply with iRay's operating and maintenance instructions.
- iRay shall not be liable for any damage or loss arising from the use of any options or consumable products other than those dedicated as original iRay products.
- During X-ray imaging, collecting, processing, reading and storing of image data, the user should comply with the law of the countries where the product is used.
- The users and operators of the product shall protect the privacy of image data.
- The clinician is responsible for providing medical service and erroneous treatment due to misdiagnosis.

## Warning Symbols

The warning symbols that appear in this user manual are classified as follows for better comprehension of their meanings. Make sure that you fully understand them and obey the instructions they contain.

 <b>WARNING</b>	This indicates a potentially hazardous situation which, if ignored, may result in severe personal injury, death, or substantial product damage.
 <b>CAUTION</b>	This indicates a potentially hazardous situation which, if ignored, may result in minor personal injury, death, or product damage.
 <b>PROHIBITED</b>	This symbol is used to indicate a prohibited operation.

 <b>NOTE</b>	This emphasizes or supplements important information about the main text.
 <b>REFERENCE</b>	This symbol is used to indicate “please refer to accompanying documents attached to the CD disk”.

## Abbreviations

Abbreviations	Explanation
AC	Alternating Current
AED	Automatic Exposure Detection
AP	Access Point
DC	Direct Current
DR	Digital Radiography
EMC	Electro Magnetic Compatibility
FPD	Flat Panel Detector
FTP	File Transfer Protocol
HVG	High Voltage Generator
IP	Internet Protocol
IT	Information Technology
LAN	Local Area Network
LED	Light Emitting Diode
PC	Personal Computer
ROI	Range of Interest
RF	Radio Frequency
SAR	Specific Absorption Rate
SDK	Software Development Kit
SN	Serial Number
SSID	Service Set Identifier
TFT	Thin Film Transistor
UI	User Interface
WL	Window Level
WW	Window Width

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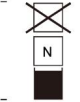



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# 1 Safety Information

## 1.1 Product Symbols

### 1.1.1 Symbols on the Package Box

Symbol	Explanation	Symbol	Explanation
	This symbol is used to indicate "Keep the equipment up right".		This symbol is used to indicate "Fragile, handle with care".
	This symbol is used to indicate that a medical device that needs to be protected from moisture.		This symbol is used to indicate the maximum number of stacks up to N layers (for details, refer to the package box).
	This symbol is used to indicate that the temperature range to which the medical device can be safely exposed.		This symbol is used to indicate that the humidity range to which the medical device can be safely exposed.
	This symbol is used to indicate "Keep away from direct sunlight".		







### 1.1.2 Symbols on the Product Label

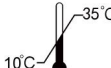

The label in the figure below is only an example and does not represent the actual label. Please refer to the label on the detector host.







Symbol	Explanation
<div style="border: 2px solid black; padding: 5px; display: inline-block; margin-bottom: 10px;"> <b>SN</b> </div>	<p>This symbol is used to identify the manufacture series number which is made of 19 digits as shown below:</p> <p style="text-align: center;"> <math>A_1 A_2 A_3 A_4 B_1 B_2 C_1 C_2 L M_1 M_2 D_1 D_2 Y_1 Y_2 X_1 X_2 X_3 X_4</math> </p> <div style="display: flex; justify-content: space-between;"> <div> <p>Production Series No.</p> <p>Production Date</p> <p>Production Site</p> <p>Production Version No.</p> <p>Derivative Type</p> <p>Production Type</p> </div> </div>

Symbol	Explanation	Symbol	Explanation
	This symbol indicates the name and address of manufacturer.		Caution: please refer to the instructions in the user manual.
	This symbol represents reference to the user manual for general information.		This symbol is used to represent nonionizing electromagnetic radiation.
	This product is not to be disposed of with your residential or commercial waste.	 20XX-XX-XX	This symbol is used to indicate the expiration date.



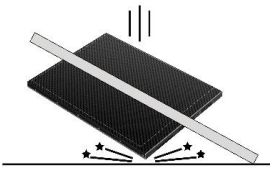
Symbol	Explanation	Symbol	Explanation
	This symbol is used to indicate operational temperature limits.	IP <sub>67</sub>	This symbol is used to indicate the protection classification.
Rx only	Device is for prescription use only		This symbol represents the application part of type B, indicating that the product has a patient contact part.

## 1.2 Safety Precautions

### 1.2.1 Operation and Storage Environment



 WARNING	<ul style="list-style-type: none"> <li><b>Do not operate or store the equipment in or around flammable or corrosive gases, gas mixtures, liquids, chemicals, or other substances.</b> Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.</li> </ul>
 CAUTION	<ul style="list-style-type: none"> <li><b>Do not operate the detector in a location with the following conditions. Ignoring this warning may result in equipment failure, fire, or personal injury.</b> <ul style="list-style-type: none"> <li>Close to fluid or places where fluid is used</li> <li>Where is will be exposed to direct sunlight</li> <li>Close to the air outlet of an air-conditioner or ventilation equipment</li> <li>Close to a heat source such as a heater</li> <li>Where the power supply is unstable</li> <li>In a dusty environment</li> <li>In a saline or sulfurous environment</li> <li>Where temperature or humidity is high</li> <li>Where there is freezing or condensation</li> <li>In an area prone to vibration</li> <li>On an incline or in an unstable area</li> </ul> </li> <li><b>Non-medical equipment, such as battery chargers, wireless routers, and infrared devices, should not be used near patients.</b></li> <li><b>All patients using active implantable medical devices should stay away from this product.</b></li> <li><b>Do not turn on the power switch when there is condensation on the detector or any of its components or accessories.</b> Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.</li> </ul>

## 1.2.2 Equipment, Interface, Power Source, and Cables

 <b>WARNING</b>	<ul style="list-style-type: none"> <li>Be sure to connect non-product components to the equipment according to the label and user manual.</li> <li>Do not connect the detector to any component or accessory other than the manufacturer's specified ones. Do not use any power source other than the one provided with the equipment. Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.</li> <li>Be sure to turn OFF the power of the detector, including turning off the power supply or removing the battery (if applicable) before connecting or disconnecting the cables or accessories.</li> <li>Do not touch the power supply, battery pack, detector, cable, connector, or any other components with wet hands. Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.</li> <li>To avoid the risk of electric shock, this equipment must be connected to a power supply with protective earth.</li> <li>Use only dedicated cables for the device. Do not use any other cables.</li> </ul>
 <b>CAUTION</b>	<ul style="list-style-type: none"> <li>Observe and follow all safety information in this manual and on the warning labels on the battery (if applicable). Ignoring warnings could result in personal injury or product damage.</li> <li>Do not modify the cables or subject the cable to external stress or damage. Avoid placing anything heavy, including the detector, on the cable, stepping on the cable, pulling the cable, or subjecting the cable to excessive bending or bundling. Ignoring this warning may result in cable failure, which may result in personal injury, death, or product damage.</li> <li>Do not place excessive heavy objects on the equipment. Otherwise, the internal sensor may be damaged and the equipment may not work normally to acquire images.</li> <li>Do not exceed the maximum uniform load weight of 300 kg distributed across the surface of the X-ray detector.</li> <li>Do not exceed the maximum load weight of 150 kg distributed on an area of 40 mm in a diameter of the X-ray detector surface.</li> <li>Do not hit or drop the equipment. The equipment may be damaged if it receives a strong jolt, which may result in fire or electric shock if the equipment is used without being repaired.</li> </ul>  <ul style="list-style-type: none"> <li>Do not use any power source other than the one provided with this equipment. Otherwise, improper power connection may lead to fire or electric shock.</li> </ul>


	<ul style="list-style-type: none"> <li>• <b>Only dedicated cables can be used on this equipment. Do not use any cable other than those supplied with this product.</b></li> <li>• <b>The power cord plug must be firmly inserted into the power socket.</b> 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.</li> <li>• <b>Do not supply power to more than one piece of equipment using the same AC outlet.</b> Doing so may result in fire or electric shock.</li> <li>• <b>Do not connect a multiple portable socket-outlet or extension cord to the equipment.</b> Otherwise, it may result in fire or electric shock.</li> <li>• <b>To make it easy to disconnect the plug at any time, avoid putting any obstacles near the outlet.</b> Otherwise, it may not be possible to disconnect the plug immediately in case of an emergency.</li> <li>• <b>Be sure to disconnect the power cable by holding the plug or connector, not by pulling the cable.</b> If you pull the cable too hard, the core wire may be damaged, resulting in fire or electric shock.</li> </ul>
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### 1.2.3 Handling



 <b>WARNING</b>	<ul style="list-style-type: none"> <li>• <b>Personnel not authorized by iRay are prohibited to open the equipment enclosure.</b> Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.</li> <li>• <b>Do not touch the interface and power unit or cable and the patient at the same time. Do not let the patient touch the interface and power unit or cable. Have the patient take a fixed posture and do not let the patient touch parts unnecessarily.</b> Ignoring this warning may cause electrical shock and/or unknown hazards, which may result in severe personal injury, death, or substantial product damage.</li> </ul>
 <b>PROHIBITED</b>	<ul style="list-style-type: none"> <li>• <b>Do not handle the equipment with wet hands.</b> Otherwise, it may result in electric shock that could result in death or serious injury.</li> <li>• <b>Make sure the equipment is used on a flat and stable surface to prevent bending and deformation of the equipment.</b> Otherwise, the internal image sensor may get damaged.</li> <li>• <b>If the detector is placed vertically or in any tilted position, the X-ray detector must be securely placed in the Bucky tray or securely fastened to the X-ray detector enclosure or support structure.</b> Otherwise, the detector may tip over, causing injury to the patient, or damage to internal equipment.</li> <li>• <b>Keep the detector under even load (same pressure) during image acquisition.</b> Otherwise, the quality of acquired images is not guaranteed.</li> <li>• <b>Do not spill liquids or chemicals onto the equipment. Do not let the equipment come into contact with the patient's blood or other body fluids.</b> Otherwise, it may result in fire or electric shock. For avoiding such contact, the disposable protective covers should be used to protect the equipment.</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Do not place any superfluous objects within the moving range of the parts of this product.</b></li> <li>• <b>Disconnect the power supply when the equipment is not used for the sake of safety.</b></li> </ul>
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### 1.2.4 Failure Handling



 CAUTION	<ul style="list-style-type: none"> <li>• <b>Turn off the detector, unplug the adapter or battery power cord immediately and contact your sales representative or local iRay distributor if any of the following occurs:</b> <ul style="list-style-type: none"> <li>• When there is smoke, an odd smell or abnormal sound</li> <li>• When liquid has been spilled into the equipment or a metal object has entered the equipment through an opening</li> <li>• When the equipment has been dropped and is damaged</li> </ul> </li> <li>• <b>When liquid has been spilled into or on any part of the X-ray detector or power supply (if applicable), or when the X-ray detector, its component, or accessory is dropped, unplug the power supply from the AC outlet, and immediately contact your sales representative or local iRay distributor.</b></li> </ul> <p>Further use under abnormal conditions may result in severe personal injury, death, or substantial product damage.</p>
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### 1.2.5 Battery

 CAUTION	<ul style="list-style-type: none"> <li>• <b>If the enclosure is broken or overheating, or emits unusual odors, smoke, or leaks anything. Avoid contact with any material leaking from the battery pack.</b> If any liquid comes into contact with your skin or eyes, wash the affected area with clean running water and seek immediate medical attention.</li> <li>• <b>Do not hit or squeeze the battery. Do not insert any object into the battery or use any device to pry open the battery pack case.</b> Attempting to do so will damage the battery case, which may cause the battery to release toxic and hazardous substances, resulting in injuries such as electric shock, burns, or fire, and render the battery unusable.</li> <li>• <b>Replacement of battery by unauthorized users or incorrect replacement of battery may cause electric shock, burns, or fire, and render the battery unusable.</b></li> </ul>
 PROHIBITED	<ul style="list-style-type: none"> <li>• <b>Keep the battery away from fire, do not use it at high temperature, and do not charge the battery near flammable materials.</b></li> <li>• <b>Do not invert positive and negative poles.</b></li> <li>• <b>Do not touch the battery with metal to prevent short circuit.</b></li> <li>• <b>Do not use non-standard batteries.</b></li> <li>• <b>Do not change the internal structure of the battery.</b></li> <li>• <b>Do not immerse the battery in water or other liquids, keep it dry when using the battery.</b></li> <li>• <b>Do not use batteries not provided by iRay.</b></li> <li>• <b>Do not charge damaged batteries or charge batteries with damaged chargers.</b></li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Do not use the battery charger around the patient.</b></li> <li>• <b>Please remove the battery when the detector is not used for a long time.</b></li> </ul>
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### 1.2.6 Maintenance and Inspection

 <b>WARNING</b>	<ul style="list-style-type: none"> <li>• <b>Be sure to turn off the power of detector when the inspections indicated in this manual are going to be performed. If the detector is powered by AC power supply, turn off the power switch and/or unplug the AC power cord. If the detector is powered by a battery, remove the battery.</b> Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.</li> <li>• <b>NEVER use alcohol, ether and other flammable cleaning agent to clean the equipment for the sake of safety. NEVER use methanol, benzene, acid, alkali or other corrosive liquids to clean the equipment.</b></li> <li>• <b>The X-ray detector must be repaired by X-ray detector manufacturer authorized personnel only.</b> Ignoring this warning may result in explosion, fire, electric shock, or unknown hazards, which may result in severe personal injury, death, or substantial product damage.</li> </ul>
 <b>CAUTION</b>	<ul style="list-style-type: none"> <li>• <b>Clean the plug of power cord periodically by unplugging it from the AC outlet and remove dust and dirt from the plug, its periphery and AC outlet with a dry cloth.</b> If the power cord is left plugged in for an extended period of time in a dusty, dark and humid environment, the dust around the outlet will absorb moisture, possibly causing insulation failure and a fire.</li> <li>• <b>Make sure that the equipment's surface &amp; plugs are dry before turning ON the power.</b> Otherwise, it may result in fire or electric shock.</li> </ul>

## 1.3 Notes for Using the Equipment

Pay attention to the following precautions when using the equipment. Otherwise, the equipment 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 equipment daily and confirm that it works properly.
- When room is heated up suddenly in cold areas, it will cause condensation on the equipment. In this case, wait until the condensation evaporates before performing an exposure. If condensation occurs during the use of the equipment, the images captured may suffer from quality problems. When an air-conditioner is used, be sure to

raise/decrease temperature gradually to ensure that the temperature difference between room and equipment will not cause condensation.

- The detector should be warmed up for 20 minutes before exposure or creation of calibration template.
- 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

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- Do not move the power cable or Ethernet cable during exposure. Otherwise, it may cause image noise, artifacts or incorrect images.
- Do not use the equipment in areas with strong magnetic field. Otherwise, it may cause image noise, artifacts or incorrect images.
- Do not use the equipment in areas with vibration. Otherwise, it may cause image noise, artifacts or incorrect images.

## ■ After Exposure

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Turn off the power to the detector when the flat panel detector is not used.

## ■ Disinfection and Cleaning

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After every examination, wipe the patient contact surfaces of the detector using disinfectants such as ethanol, to prevent the risk of infection. For details on how to sterilize, consult a specialist.

- ① Do not spray the detector directly with disinfectants or detergents.
- ② Wipe it with a cloth slightly damped with a neutral detergent. Do not use solvents such as alcohol, thinner, benzene, acid and base. Doing so may damage the surface of the equipment.
- ③ It's recommended to use a waterproof non-woven cover as the isolated layer between detector and the bleeding patient.

## 2 Regulatory Information

### 2.1 Medical Equipment Classification

The detector has two power supply modes (power adaptor and battery pack) and two ways of signal transmission (wireless or wired transmission).	
Protection Type Against Electrical Shock	Class I equipment, using medically approved adaptor supply Internally powered equipment, using battery power supply
Degree of Protection Against Electrical Shock	B Type
Mode of Operation	Continuous operation
Flammable Anesthetics	Not suitable for use in situation with flammable anesthetic mixture with air, oxygen or nitrous oxide Not suitable for use in oxygen-rich situation

### 2.2 Safety Standard Reference

The applicable safety standards for this product covers the product host, battery charger, rechargeable battery (if applicable) and other accessories.	
IEC 60601-1-1-2-2014	Medical electrical equipment-Part 1-2 General requirements for basic safety and essential performance-Collateral Electromagnetic Disturbances-Requirements and tests (Edition4.0)
IEC 60601-1-2012	Medical electrical equipment-Part 1: General requirement for basic safety and essential performance (Edition3.1)
IEC 60601-2-54-2018	Medical electrical equipment-Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (Edition1.2)
IEC 60601-1-6-2013	Medical electrical equipment-Part1-6: General requirements for basic safety and essential performance-collateral standard: Usability (Edition3.1)

### 2.3 Guidance and Manufacturer's Declaration For EMC

#### 2.3.1 EMI Compliance Table

##### ■ Emissions



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

### 2.3.2 EMS Compliance Table

#### ■ Enclosure Port

Phenomenon	Basic EMC Standard	Immunity Test Levels		
		Professional Environment	Healthcare	Facility
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air		
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz		
Near fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table “Near Fields from RF Wireless Communications Equipment”		
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz		

#### ■ Near Fields from RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)	Immunity Test Levels		
		Professional Environment	Healthcare	Facility
385	380-390	Pulse modulation 18Hz, 27V/m		
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m		
710	704-787	Pulse modulation 217Hz, 9V/m		
745				
780				
810	800-960	Pulse modulation 18Hz, 28V/m		
870				
930				
1720	1700-1990	Pulse modulation 217Hz, 28V/m		
1845				
1970				
2450	2400-2570	Pulse modulation 217Hz, 28V/m		
5240	5100-5800	Pulse modulation 217Hz, 9V/m		
5500				
5785				

## ■ Input AC Power Port

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

## 2.4 Battery Safety Standards

Standards	Description
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes- Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications-Part2: Lithium systems (Edition1.0)
UN38.3	ST/SG/AC.10/11/Rev. 6 Amend. 1 38.3 UNITED NATIONS “Recommendations on the TRANSPORT OF DANGEROUS GOODS” Manual of Tests and Criteria ST/SG/AC. 10/11/Rev.6 Amend. 1 Section 38.3

## 2.5 FCC Compliance

Contains FCC ID: 2ACHK-01070189

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of

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

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

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

## 2.6 Radio Frequency (RF) Energy

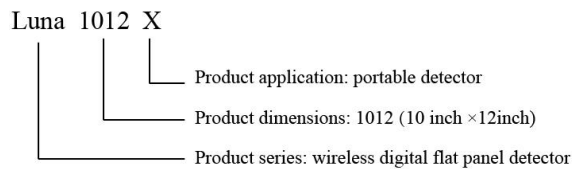
This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the United States.

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 general public 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.

### 3 Product Introduction



Battery type: Battery - KX (Rechargeable lithium battery)

Battery charger: Charger - Combo

#### 3.1 Overview

Luna1012X is a wireless digital X-ray flat panel detector based on amorphous flexible silicon thin-film transistor technologies, which contains an active matrix of 3152×2502 with 100um pixel pitch.

It renders high quality radiographic images with the CSI (Caesium Iodide) scintillator which is direct deposit. Since Luna1012X supports multiple trigger modes, it can satisfy both of the general DR system and retrofit DR system.

#### 3.2 Scope of Application

It is suitable for providing digital X-ray imaging for DR system to provide general radiographic diagnosis for human anatomy, but not intended for mammography or dental applications.

Use of this equipment in pregnant women is prohibited.

The remaining notes depend on the DR system.

#### 3.3 Intended Use

This equipment provides digital X-ray imaging for diagnosis of disease, injury, or any applicable health problem of human. The image is obtained as the result of X-ray passing through the human anatomy and detected by the equipment. iRay will provide equipment and software support for integration of system.

### 3.4 Essential Performance

According to the Luna 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”.

### 3.5 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.

### 3.6 Basic Features

- Wireless static flat panel detector
- AED
- 802.11ac
- 16-bit AD

### 3.7 Packing List

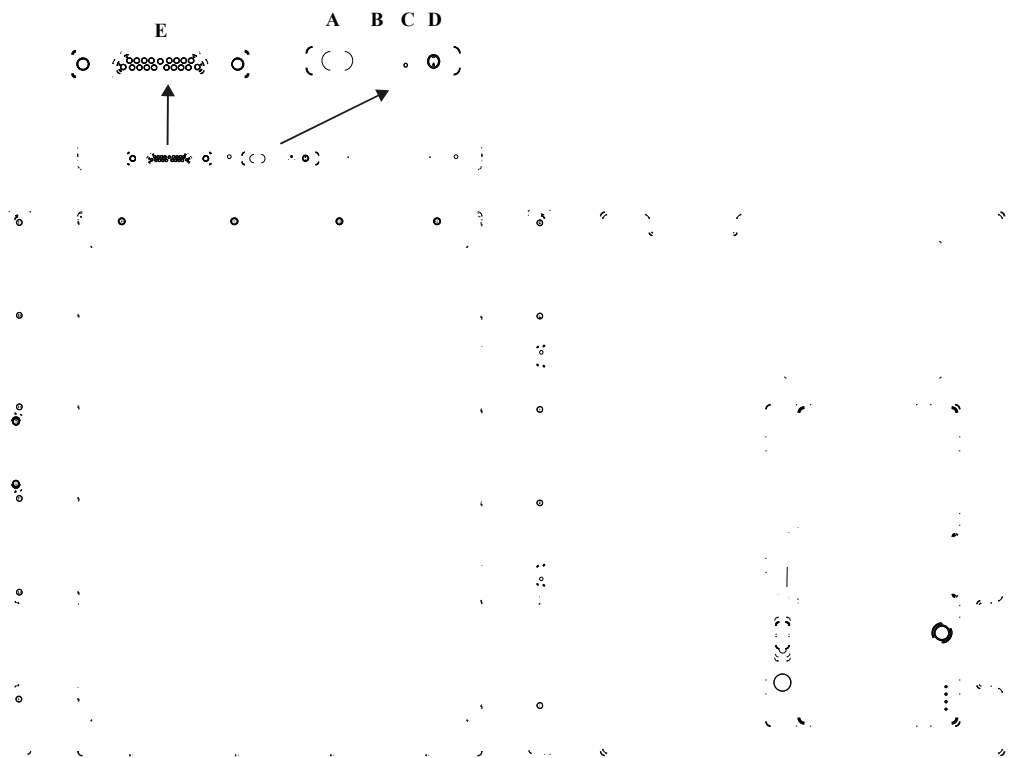
Check the list below to verify that all the items have been included. Contact your iRay dealer if anything is missing or damaged.

Item	Qty. (unit: piece)	Remarks
Luna1012X Detector	1	Default
Power adapter	1	
Battery pack	2	
Battery charger	1	
Gigabit Ethernet cable	1	
AC power cable	2	
Control box	1	

Item	Qty. (unit: piece)	Remarks
CD ROM	1	
Handle (with 2 screws)	1	Option
Dongle	1	
Syncbox	1	

3.8 Component Description

3.8.1 Detector



- A

Status indicator
- B


Link indicator
- C

Power indicator
- D

Power button
- E

24V DC input interface
- F




Detector label






NOTE

The whole main unit encloser is defined as applied part that is accessible to the patient.






### ■ Status Indicator

Status Indicator	Color	Description
OFF		Detector is off
Green ON		Exposure is allowed
Orange ON		Error

### ■ Link Indicator

Link Indicator	Color	Description
OFF		Detector is turned off Wired connection broken and wireless connection not ready
Blue ON		Wireless connection is enabled
Green ON		Wired connection is enabled (Service Mode)

### ■ Power Indicator

Power Indicator	Color	Status		
		Battery Capacity	DC Input	Description
OFF		N/A	N/A	Detector is OFF
Green ON		N/A	Yes	Detector is ON
Orange Blinking		$\geq 7\% \ \& \ < 15\%$	No	Detector is ON
Green Blinking		$\geq 15\% \ \& \ < 95\%$	Yes	Detector is ON
Green & Orange Blinking		$< 95\%$	Yes	Detector is OFF

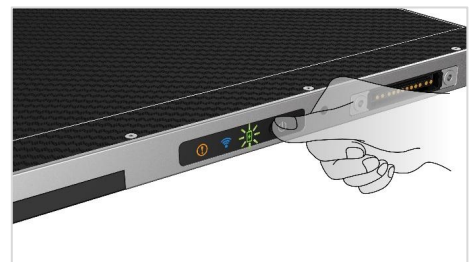
### ■ Power Button

Press the power button to turn on or off the detector.

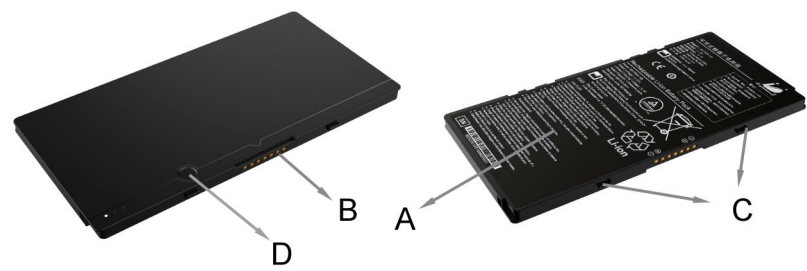
**Startup:** when the detector battery is installed and the power is not less than 7% or the detector is connected with the DC power supply, you can press the button for 4 seconds to turn on the detector.

**Shutdown:** when the detector is turned on, you can press the button and hold for 4 seconds to turn off the detector.

**Reset:** press the button for 8 seconds to reset the internal control core piece.



3.8.2 Battery Pack



- A

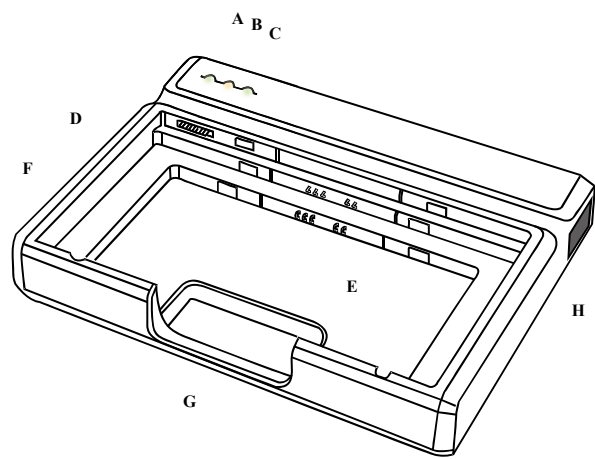
Battery label
- C

Guide block
- B

7-pin battery connector
- D

Touch display

3.8.3 Battery Charger



- A

Power indicator
- E

5-pin Battery connector
- B

Charging indicator
- F

Anti-drop latch
- C

Charge full indicator
- G

Battery removal position
- D

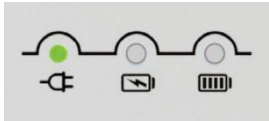

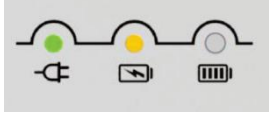
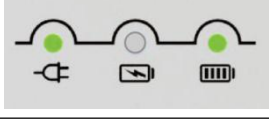
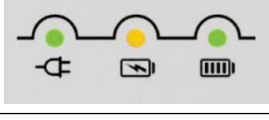
8-pin Battery connector
- H

AC power interface

■ LED Indicators

Indicator	Status	Operating Status
All off		No power input



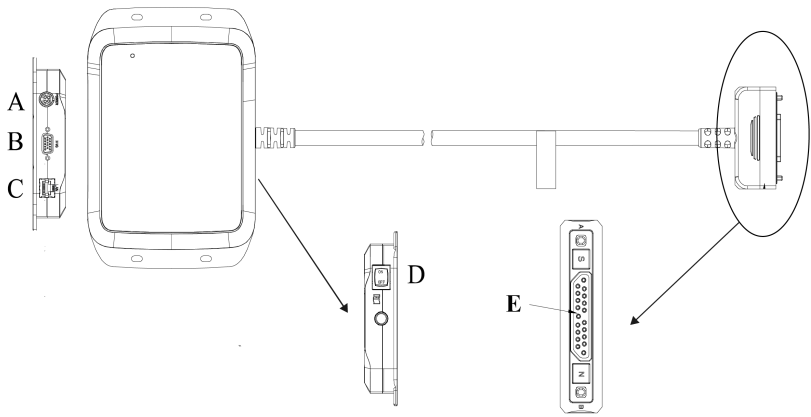
Indicator	Status	Operating Status
Indicator A on		AC Power input Multiple batteries inserted
Indicator A on B and C alternately blink 2 times		Battery insertion self-test
Indicator A and B on		Battery charging
Indicator A and C on		Battery capacity full, charging stops
Indicator A on B and C alternately blinking		Battery charging abnormal



NOTE

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

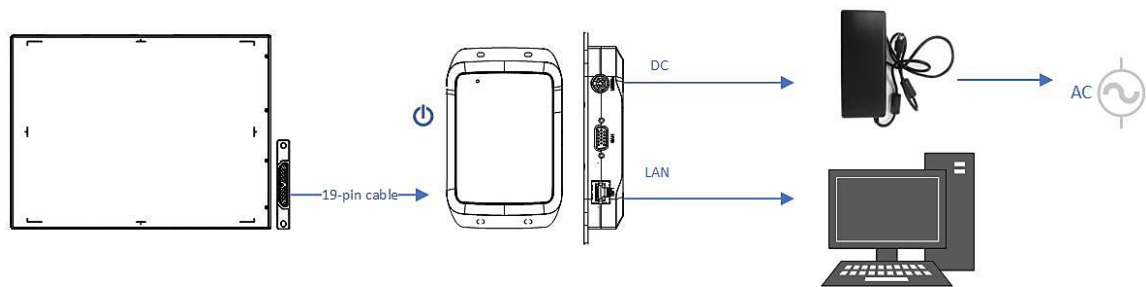
3.8.4 Control Box



- A Power interface
- B Reserved
- C LAN interface

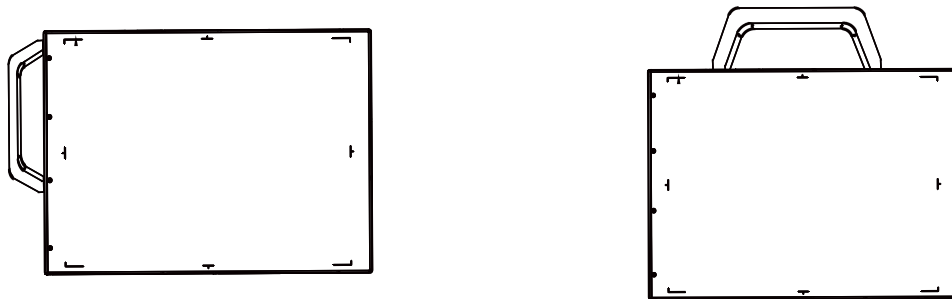
- D Switch
- E 19-pin interface

### ■ Control Box Connection Diagram



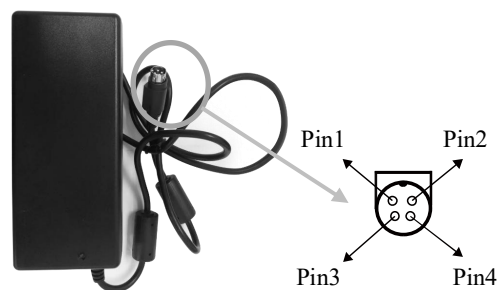
### 3.8.5 Handle

The detector handle is equipped with two screws and can be installed in the following two ways:



### 3.8.6 Power Adapter

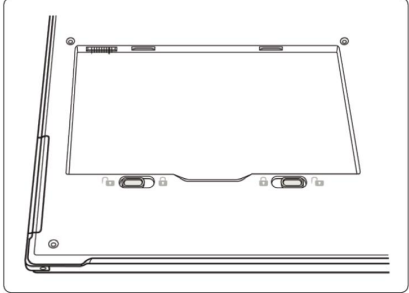
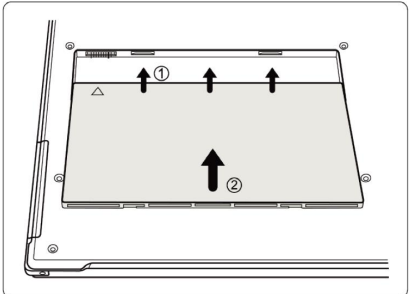
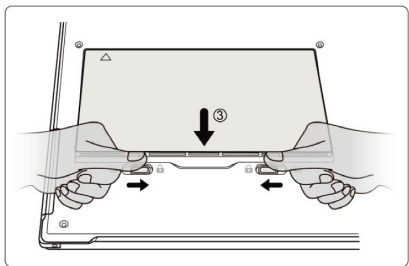
Detector supports an external adapter powered. It gets CB certificate No. SG PSB-MD-00005 and NRTL certificate No. U8V 093768 0016. The ports defined as below:



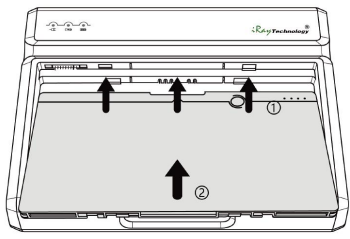
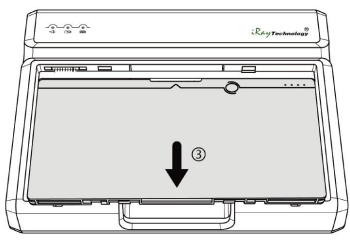
No.	Definition	Voltage Range	Rated Current
P1	DC Power Negative	0~0.5V	0~0.42A
P2	DC Power Positive	23~25V	0~0.42A
P3	DC Power Positive	23~25V	0~0.42A
P4	DC Power Negative	0~0.5V	0~0.42A

## 3.9 Product Installation

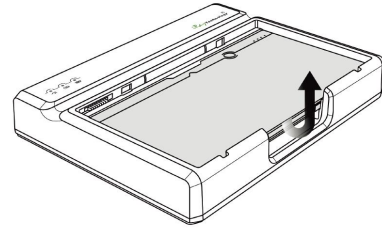
### 3.9.1 Attaching Battery to Detector

<p>① Make sure that connectors on the battery pack are pointed to the opening in the battery compartment.</p>	
<p>② Slide battery package into battery compartment (Make sure battery capacity overpass is 15%).</p>	
<p>③ Slide the battery lock lever in the direction shown until fully locked.</p>	

### 3.9.2 Installing the Battery into Battery Charger

<p>① Insert battery into battery charger in the direction shown right.</p>	
<p>② Press the battery down into the battery compartment.</p>	

- ③ After the battery is fully charged, unload the battery from the battery charger.



## 4 Software Installation and Configuration

### 4.1 System Requirement

**Operating System:** Windows 7/ Windows 10

**Memory:**  $\geq 4$  GB



The firewall should be shut down to avoid communication issue.

### 4.2 Software Installation

Setup files and download url are included in SDK directory: [Tools\env\\_setup](#)

- ① Install Microsoft NET Framework 4.5 (Windows XP only can install V4.0 ). Download it from Microsoft website.
- 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.

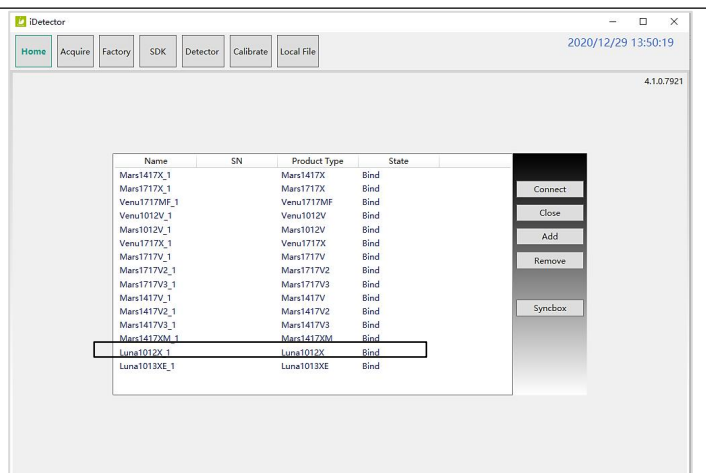
### 4.3 Wireless Connection

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

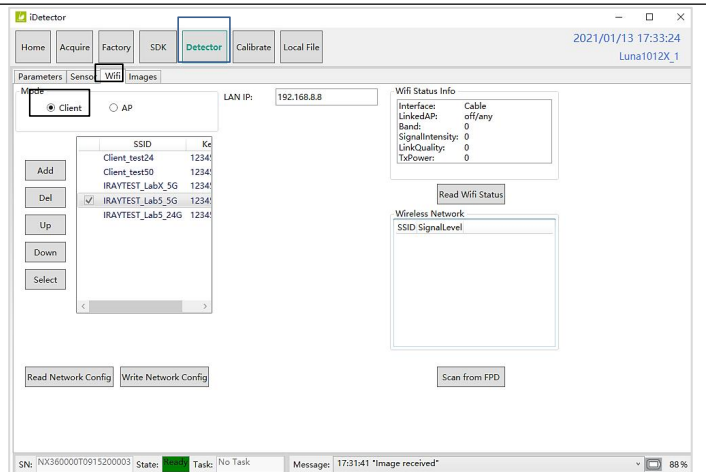
[\\*|work\\_dir\Luna1012X\config.ini](#).

### 4.3.1 AP Mode

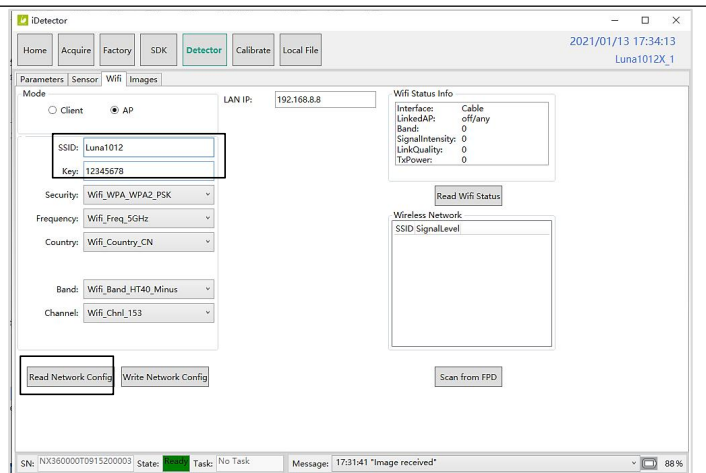
- ① On the Home page, select the [Luna1012X] and click [Connect] button the build the connection.

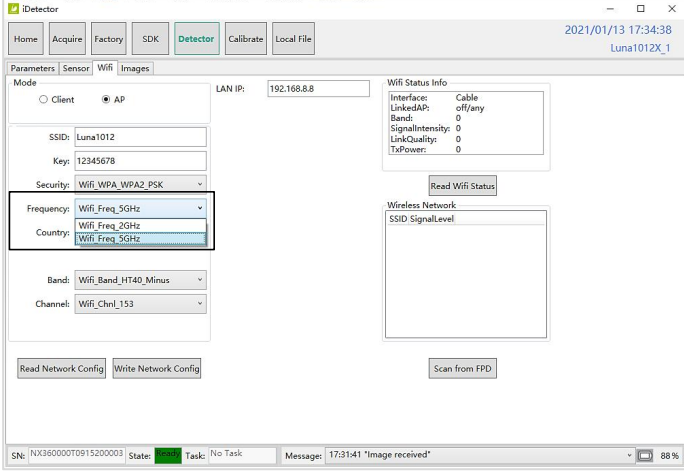
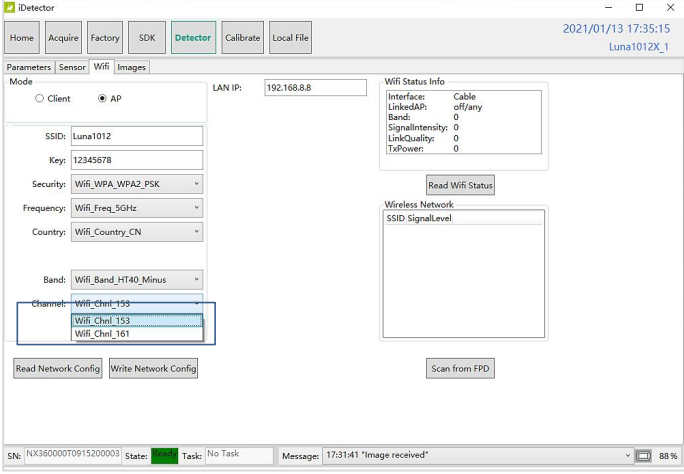
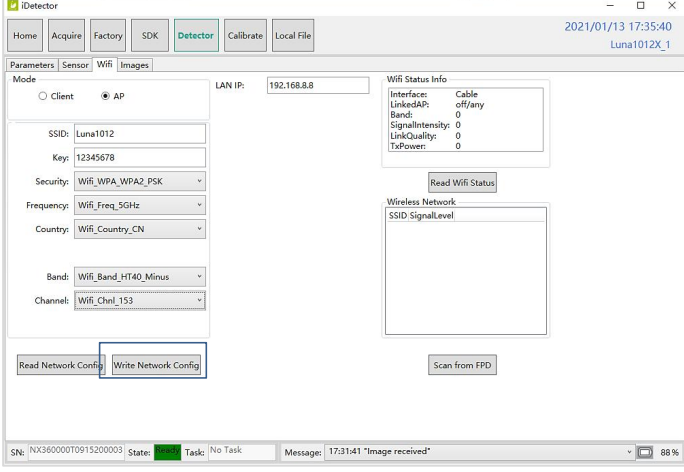


- ② And then click [Read Config] on the Wifi tab of the Detector page to get the current wifi configuration.



- ③ Click [Read Network Config] to get default setting. Change SSID and password setting. Make sure SSID is different from other already exist.



<p>④ Change channels and frequency setting.</p>	
<p>⑤ Click [Channel] and choose a clean frequency and channel.</p>	
<p>⑥ Click [Write Network Config]</p>	

⑦    Waiting FPD status be “Ready”.

Home

Acquire

Factory

SDK

Detector

Calibrate

Local File

Parameters

Sensor

Wifi

Images

Mode

Client

AP

SSID: Luna1012

Key: 12345678

Security: Wifi\_WPA\_WPA2\_PSK

Frequency: Wifi\_Freq\_5GHz

Country: Wifi\_Country\_CN

Band: Wifi\_Band\_HT40\_Minus

Channel: Wifi\_Chnl\_153

Read Network Config

Write Network Config

LAN IP: 192.168.8.8

Wifi Status Info

Interface: Cable

LinkAdp: off/any

Band: 0

SignalIntensity: 0

LinkQuality: 0

TxPower: 0

Read Wifi Status

Wireless Network

SSID: SignalLevel

Scan from FPD

SN: NX360000T091520000

State: 

Ready

Task: No Task


Message: 17:31:41 "Image received"

88 %


4.3.2    Client Mode

■    Configuration of External Wireless Card

①    Open local wireless signal list.



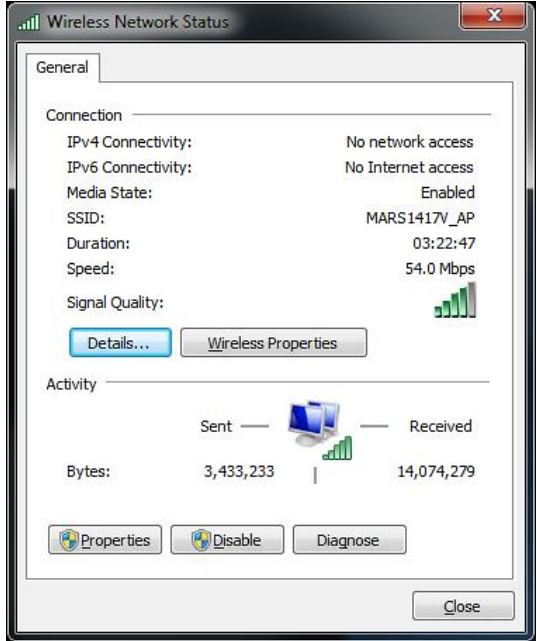
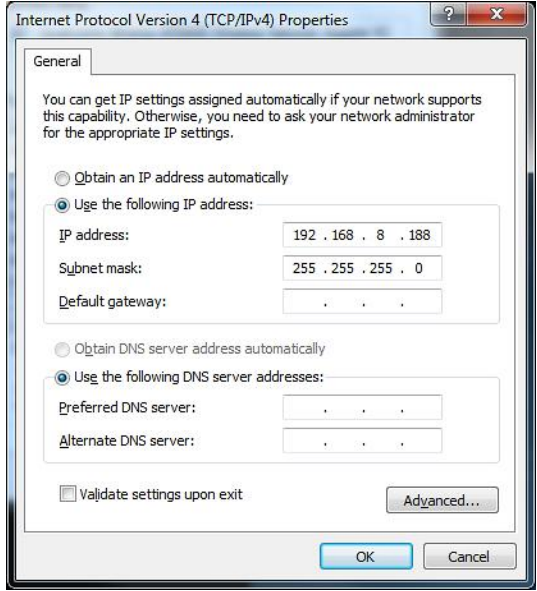
②    Select SSID which belongs to detectors, type password and log into system

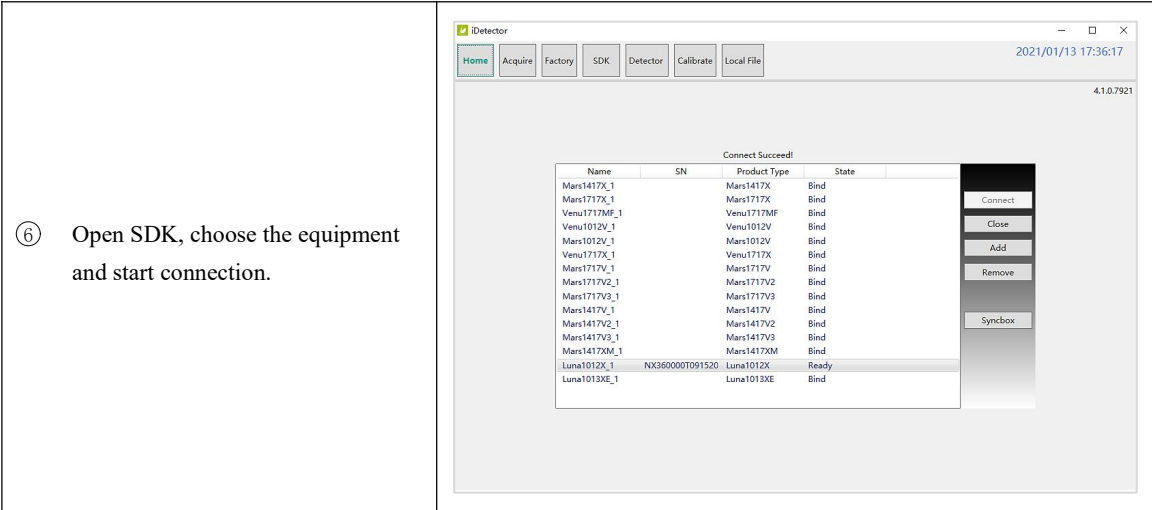


25

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<p>③ Open wireless card configuration</p>	 <p>The screenshot shows the 'Wireless Network Status' window. Under the 'General' tab, the 'Connection' section displays: IPv4 Connectivity: No network access; IPv6 Connectivity: No Internet access; Media State: Enabled; SSID: MARS1417V_AP; Duration: 03:22:47; Speed: 54.0 Mbps; and Signal Quality: represented by a green bar graph. The 'Activity' section shows 'Sent' bytes as 3,433,233 and 'Received' bytes as 14,074,279. Buttons at the bottom include 'Details...', 'Wireless Properties', 'Properties', 'Disable', 'Diagnose', and 'Close'.</p>
<p>④ Open IPV4 setting</p>	 <p>The screenshot shows the 'Internet Protocol Version 4 (TCP/IPv4) Properties' window. Under the 'General' tab, the text states: 'You can get IP settings assigned automatically if your network supports this capability. Otherwise, you need to ask your network administrator for the appropriate IP settings.' The 'Use the following IP address:' radio button is selected. The IP address is set to 192.168.8.188, the Subnet mask is 255.255.255.0, and the Default gateway is blank. The 'Use the following DNS server addresses:' radio button is also selected, with Preferred and Alternate DNS servers both blank. There is a checkbox for 'Validate settings upon exit' and an 'Advanced...' button. 'OK' and 'Cancel' buttons are at the bottom.</p>
<p>⑤ IP setting</p> <p>IP address: 192.168.8.188</p> <p>Subnet mask: 255.255.255.0</p>	



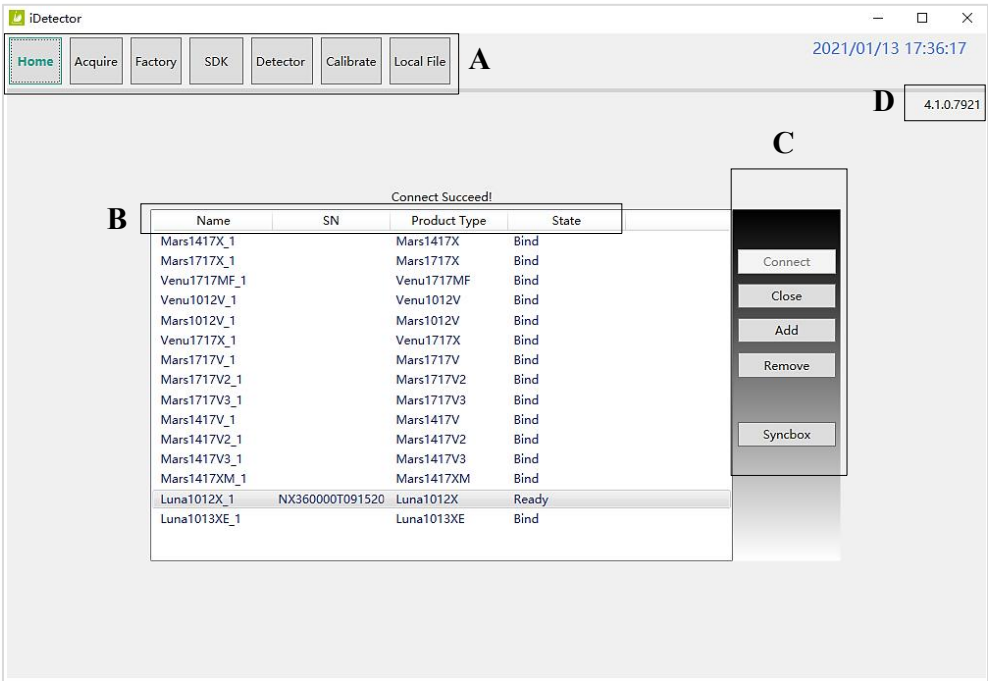
4.4 Introduction to iDetector Interface

Luna1012X provides iDetector software as a basic testing tool, and its SDKS include:

- 32-bit system, idetector. exe , location: Tools\iDetector\w32
- 64-bit system, idetector. exe, location: Tools\iDetector\x64

Double-click idetector. exe to run the software. The UI may not differ much from software version to software version.

4.4.1 Home Page



A Tab	Function Description
-------	----------------------

A Tab	Function Description
Home	Connect FPD and view the connect state
Acquire	Acquire image, select calibration mode, save and process images
SDK	Config.ini setting and log level setting
Detector	Configure parameters and acquisition mode
Calibrate	Generate and manage the calibration files
Local File	Open and view local images

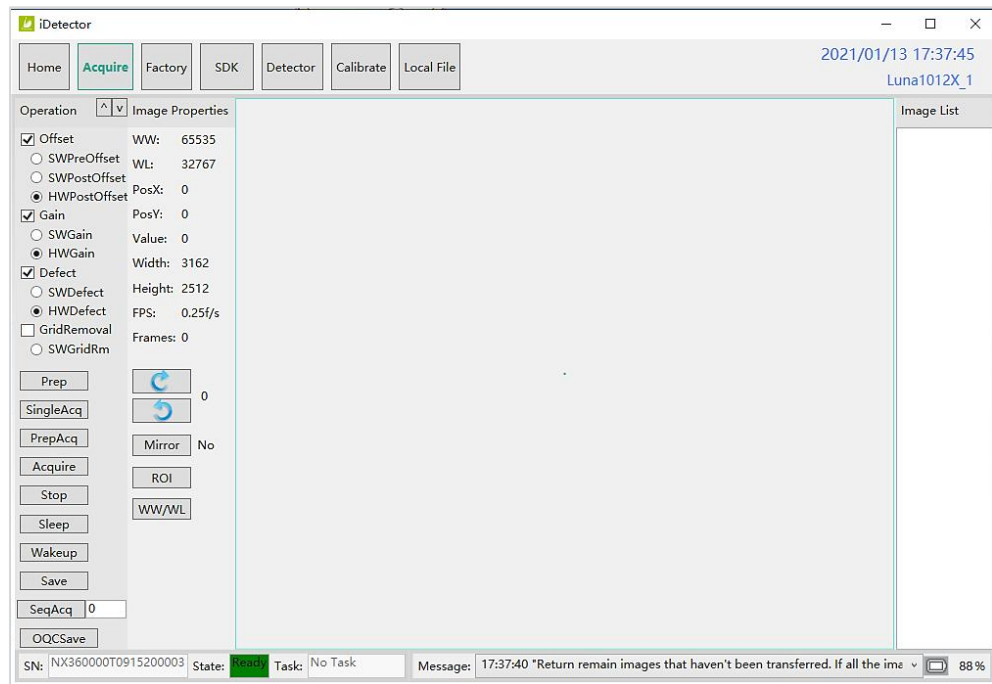
B Item	Function Description
Name	Display the name of detector
SN	Display the SN of detector
Product Type	Display the model of detector
State	Display the connection state of detector (bind, unknown, ready, etc.)

C 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	Delete work directory
Syncbox	Open Syncbox configuration window

D
The version of the SDK is displayed here and the information will vary based on the SDK version.

#### 4.4.2 Acquire Page

On the Detector page, you can perform image acquisition, calibration mode selection, image storage and processing and other operations. See the figure below for the page.





The following table describes main functions of the Acquire page:

State Bar	Function Description
SN	SN number of the currently-connected detector
State	Detector state, e.g. busy, ready
Task	The current task of the detector
Message	Feedback information of command, e.g. succeed, failed

Correct Menu		Function Description
Offset	HWPPostOffset	Select to perform hardware PreOffset calibration on the acquired image
Gain	HWGain	Select to perform hardware Gain calibration on the acquired image
Defect	HWDDefect	Select to perform hardware Defect calibration on the acquired image

Acquire Button	Function Description
Prep	Clear
SingleAcq	Acquire once
PrepAcq	Clear and acquire
Acquire	Acquire images
Save	Save the current image in .raw or .tiff format

Acquire Button	Function Description
ActiveSensor	Active sensor
DeactiveSensor	Deactive sensor
PowerOff	Detector shutdown

Image Properties&Image Process	Function Description
WW	Window width
WL	Window level
PosX	X coordinate of the current cursor location
PosY	Y coordinate of the current cursor location
Value	Gray value of the current cursor location
Width	Image width
Height	Image height
FPS	Frame rate
Frames	Display the number of frames acquired
	Rotate the image clockwise, 90 degrees every time.
	Rotate the image anticlockwise, 90 degrees every time.
Mirror	Enable or disable the mirror function of images
ROI	ROI tool, which can be used to view the image of the AVG, SV, SNR and other parameters
WW/WL	Right-click to adjust WW/WL automatically according to the selected area
Image List	Display the five newly acquired images

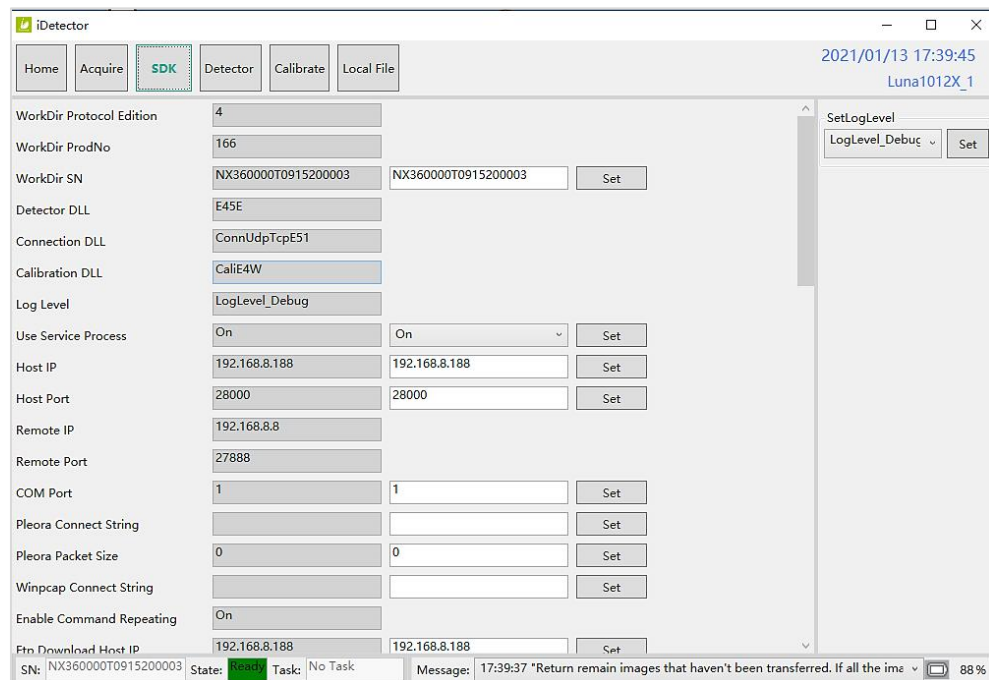
When the image is displayed on the screen, maybe the user want to see details by dragging or zoom in/out the image, for convenience, these are some shortcuts.

- 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 Page

Click [SDK] to enter the SDK page, which you can complete software-related configurations, as shown in the figure below.

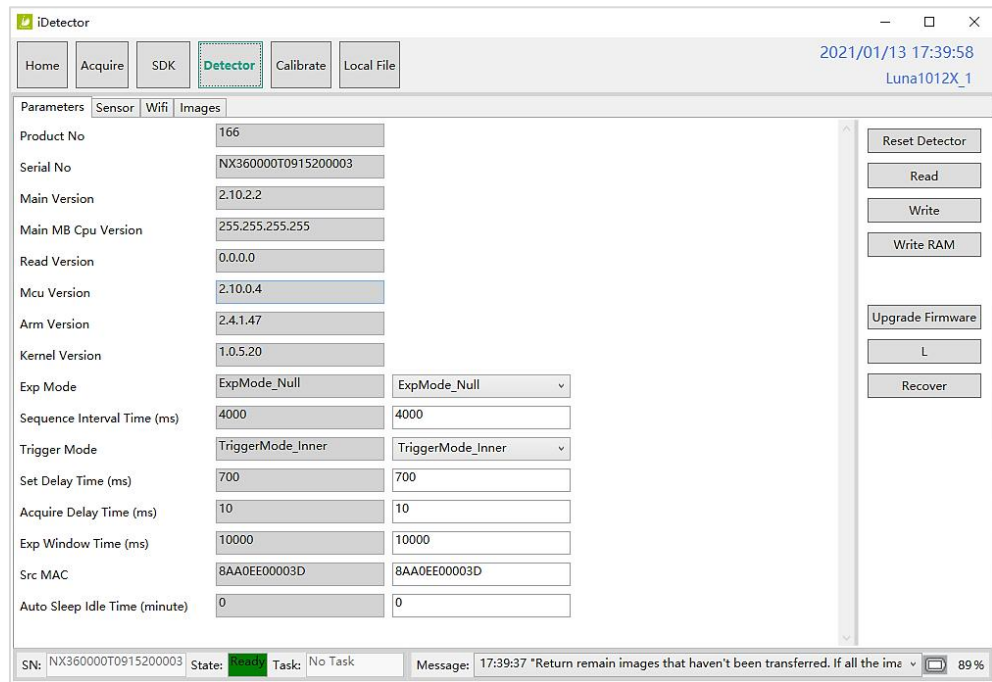


NOTE

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

### 4.4.4 Detector Page

On the Detector page, you can read and set the parameters of the detector, and the parameters in the screenshot are only examples. The specific parameters need to be configured according to the actual application. See this page below:



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

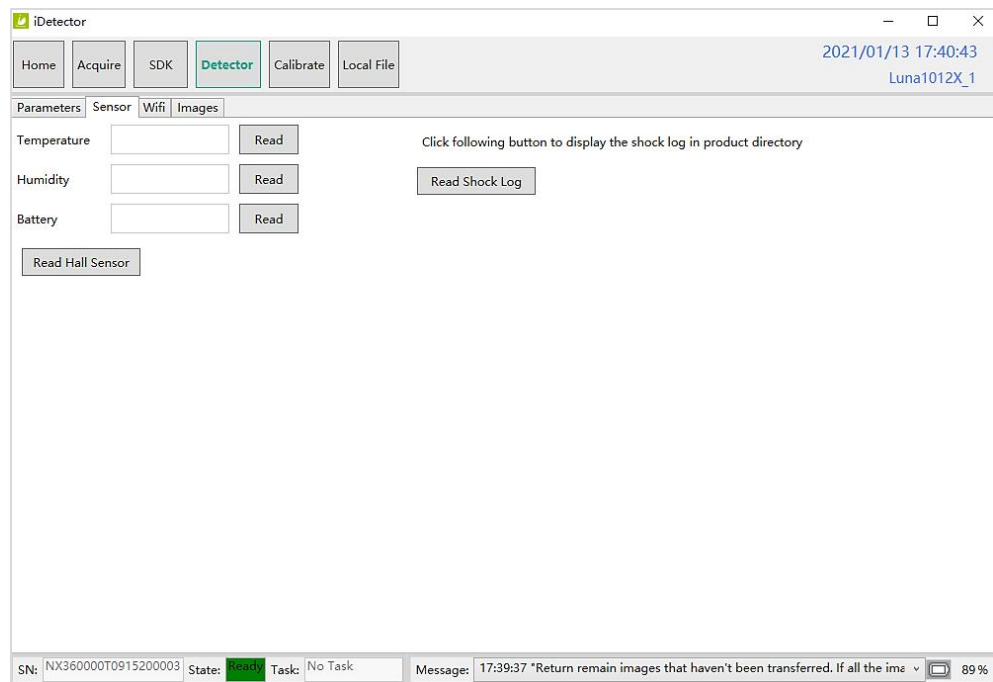
## ■ Parameters

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	Trigger 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	Y

Name	Description	Configurable
	which use a dynamic window	
Exp Window Time (ms)	Max exposure window for command trigger which use a dynamic window	Y
Src MAC	Detector MAC	Y

## ■ 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

You can configure the wireless connect parameters on this tab.

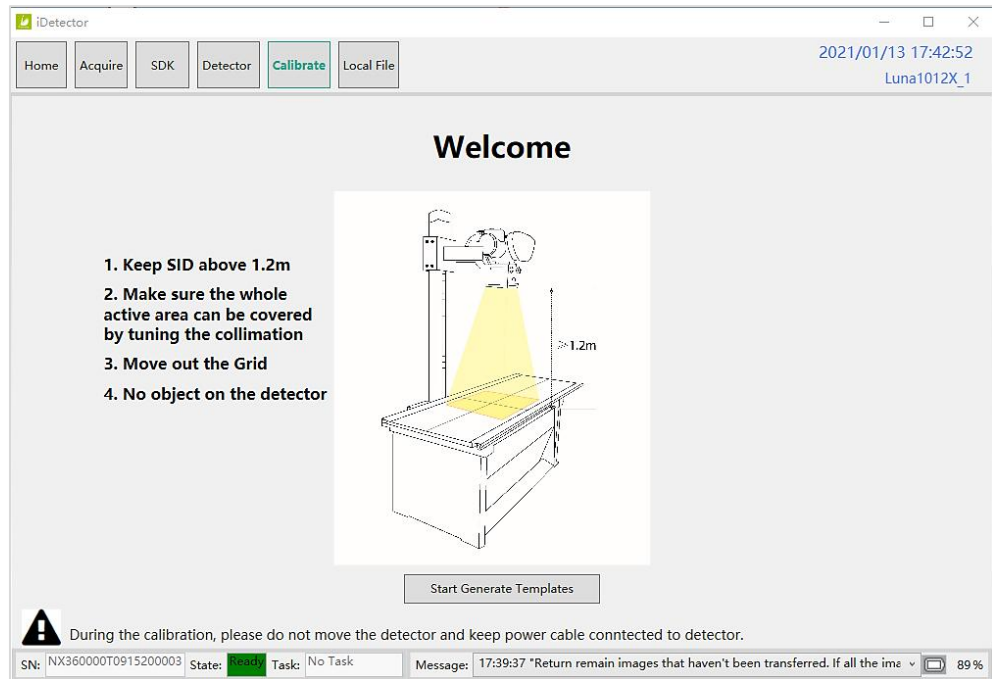




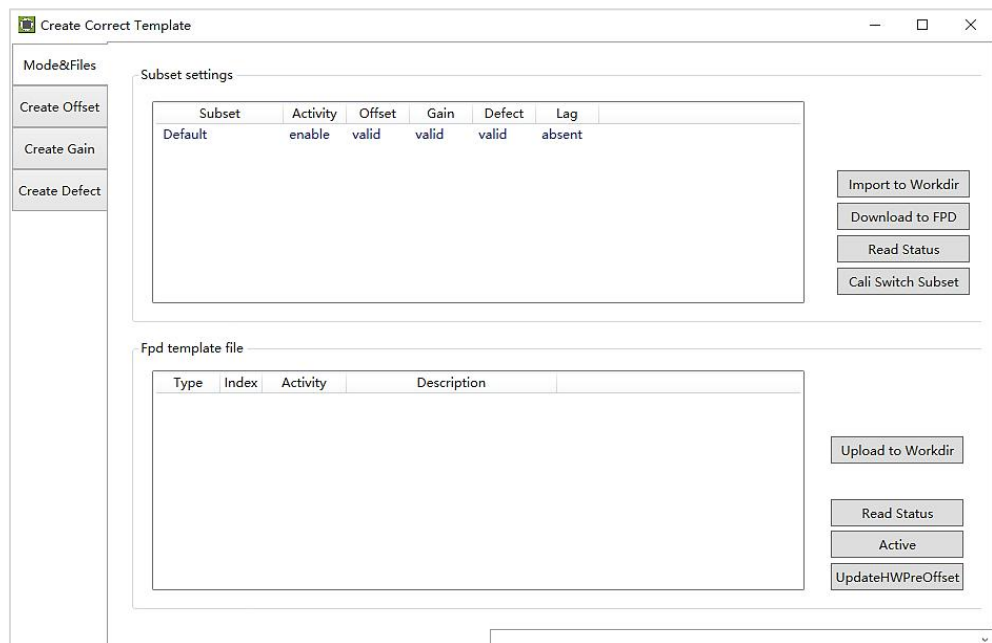
You can query and upload images from detector to workstation.



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



Click [Start Generate Templates] to enter Create Correct Template page.



The main functions of Create Correct Template page are described in the following table:

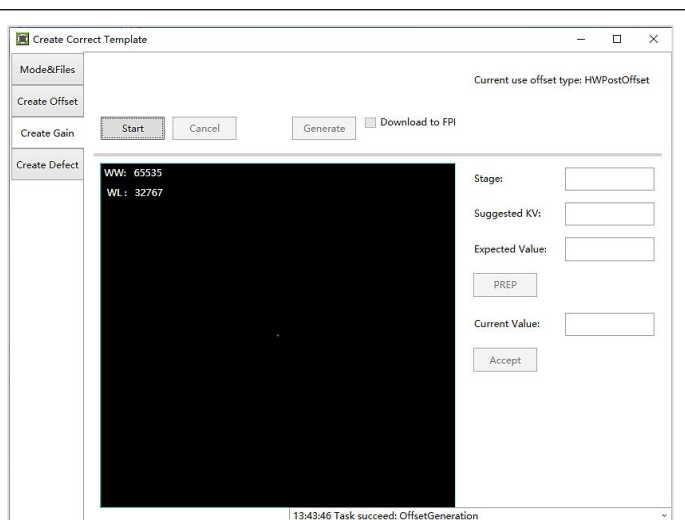
Tab	Description
Mode&Files	Manage template files
Create Offset	Create Offset template
Create Gain	Create Gain template
Create Defect	Create Defect template

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

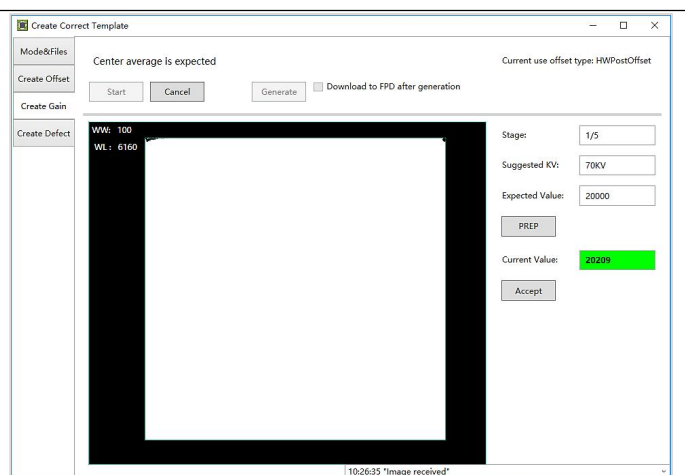
## ■ Generating Gain Template File

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

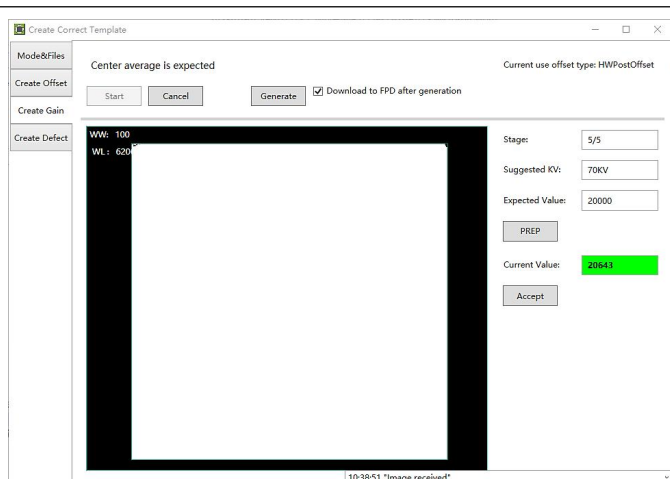
- ① Enter Create Gain page, Click [Start] button to start process, the offset type should be selected, then start to acquire the images.



- ② Click [PREP] button, then exposure after Acquire button enable. After receiving the PREP request, the detector needs some time to be ready, the decoupling bar will appear when the exposure window is opened. After exposure, you can click [Acquire] button to acquire the X-Ray image.



- ③ After acquiring 5 images, you can generate the Gain template by clicking [Generate] button, and the process can be exited from at anytime by clicking [Cancel] button.



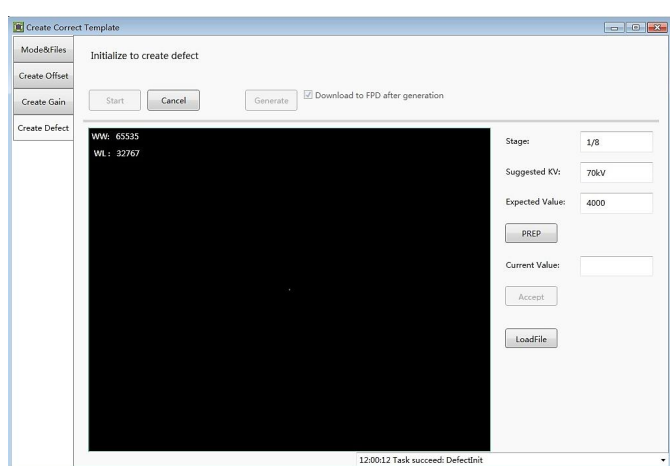
- ④ When the generating process is finished, the UI will pop up “Image Generated”.

## ■ Generate Defect Template File

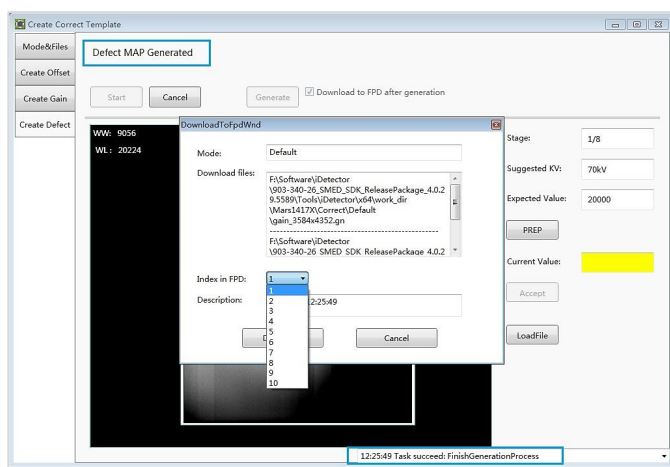
The process of generate defect map is quite similar with the one of gain map.

- ① On the Create Defect page, you can start the generating process by clicking [Start] button. And the process can be quit by clicking [Cancel].

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



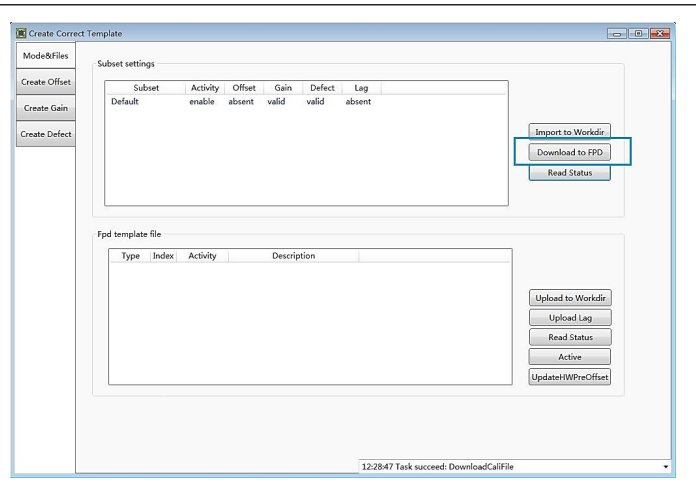
- ② If the option “Download to FPD after generation” is checked, the download UI will appear after finishing generating the defect map which will takes a little time. The field of “Index in FPD” means that the detector can store several correction maps and choose one set to active as user wants. The “Download files” part show the directory of the generated map stored on the workstation.



- ③ 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.

- ④ The correction map also can be managed at anytime on the page of “Mode&Files”.

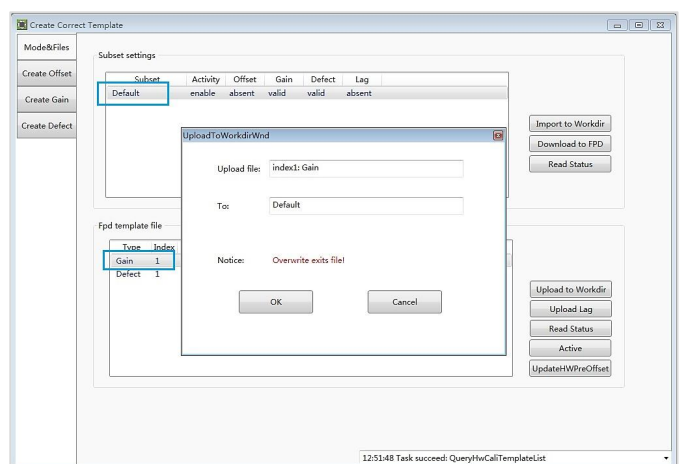
Choose the item of “Default” in the Subset settings part and click “Download to FPD” to finish downloading the maps into the detector.



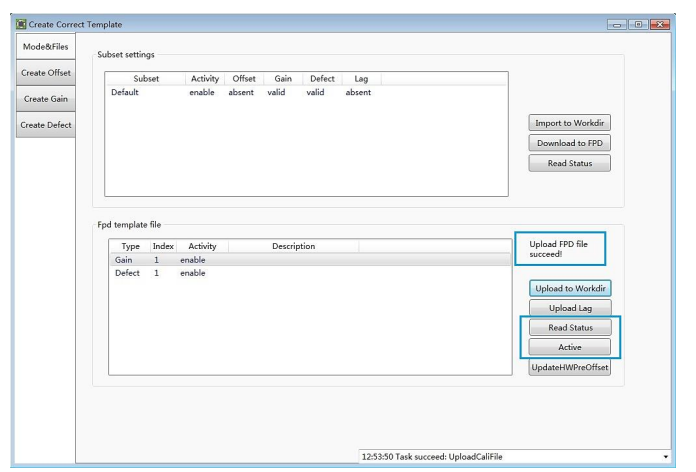
## ■ Uploading the correction files

The correction maps can be uploaded to the workstation too.

- ① 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 File Page

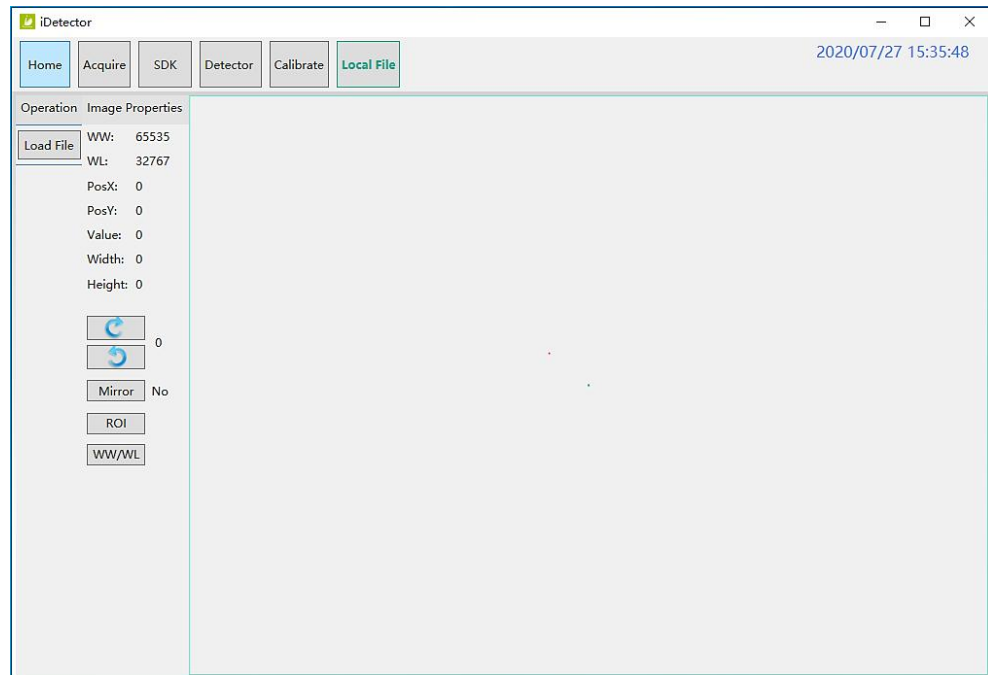
In this page, you can open the image files saved in local. The file format can be .dcm, .raw, .tiff, and .dft. When the software is disconnected to detector, the file still can be opened.

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 : 3162x2512



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.



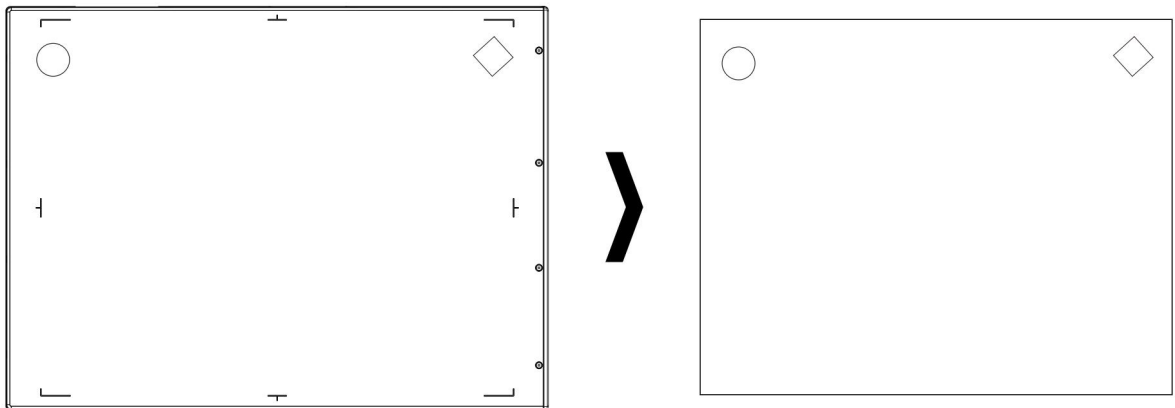
This page provides ROI tool, which can see the AVG, SNR, and other properties of the choosen image area by right mouse button.

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	Function Description
WW	Window width
WL	Window level
PosX	X coordinate of the current cursor location
PosY	Y coordinate of the current cursor location
Value	Gray value of the current cursor location
Width	Image width
Height	Image height

Image Properties&Image Process	Function Description
	Rotate the image clockwise, 90 degrees every time.
	Rotate the image anticlockwise, 90 degrees every time.
Mirror	Enable or disable the mirror function of images
ROI	ROI tool, which can be used to view the image of the AVG, SV, SNR and other parameters
WW/WL	Right-click to adjust WW/WL automatically according to the selected area

#### 4.4.7 Imaging Direction



## 5 IT Network

### 5.1 Purpose for IT Network

Transmission between the detector and the workstation is image data and command/status communication.

### 5.2 Required Characteristics

Wireless communication follows IEEE 802.11a/b/g/n protocol. It works on 2.4GHz and 5GHz.

It supports at least 2 routers.

### 5.3 Required Configuration

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

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

### 5.4 Technical Specifications

Image Transfer	Wireless: IEEE802.11a/b/g/n
Wireless Frequency Range	2.412~2.472GHz, 5.18~5.22GHz;5.745~5.85GHz
Data Transmission Power	13dBm (Typ.) @802.11a 16dBm (Typ.) @802.11b 14dBm (Typ.) @802.11g 13dBm (Typ.) @802.11n HT20 11dBm (Typ.) @802.11n HT40 16dBm@2.4GHz 13dBm@5.8GHz
Wireless Modulation	11b: DSSS (DBPSK, DQPSK and CCK) 11a/g/n: OFDM (BPSK, QPSK, 16QAM, 64QAM)
Wireless Band	2.4GHz≤40MHz 5.19GHz≤40MHz 5.8GHz≤40MHz



## 5.5 Intended Information Flow

The detector sends image data acquired to the workstation. The workstation sends users' commands to the detector.

Please refer to the operation manual of the console for detail.

## 5.6 Hazardous Situations Resulting from Failure of the IT Network

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

## 5.7 Warning

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

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

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

## 5.8 Changes to IT Network

Changes to IT Network include:

- Changes in IT network configuration
- Connection of additional items to IT network
- Disconnecting items from IT network
- Update of equipment connected to IT network

## 6 Workflow

Luna1012X 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.

### 6.1 Startup Procedure

The steps to power on the detector are as follows:

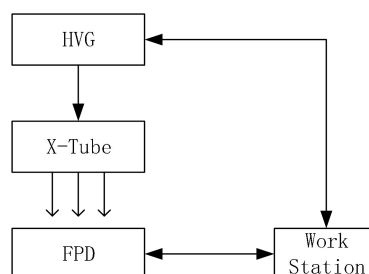
①	Make sure the hardware is connected correctly and then power on. Once powered off, please wait at least 60s before power on again.
②	Wait until initialization is complete.
③	Connect the software.
④	Choose the synchronization mode.
⑤	During cold start, preheat for more than 20 minutes. Generate HWPreOffset, Gain and Defect template after the detector reaches thermal equilibrium.
⑥	Acquire images in the selected mode.

### 6.2 Software Mode

Luna1012X has one synchronization modes to acquire X-ray image, which is Software Mode.

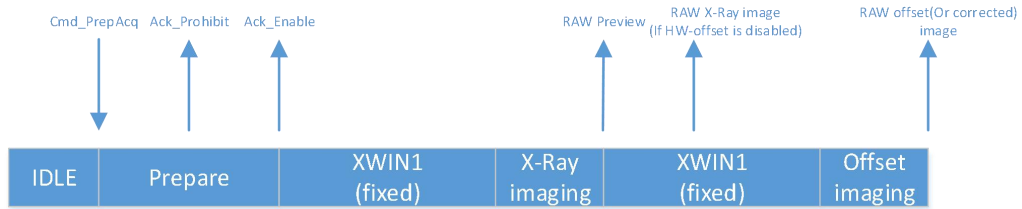
#### 6.2.1 Block Diagram

Software mode is the basic way to acquire X-ray image. Please see figure below for general feature. Workstation is a host PC device installed with iDetector and SDK. FPD is the 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.



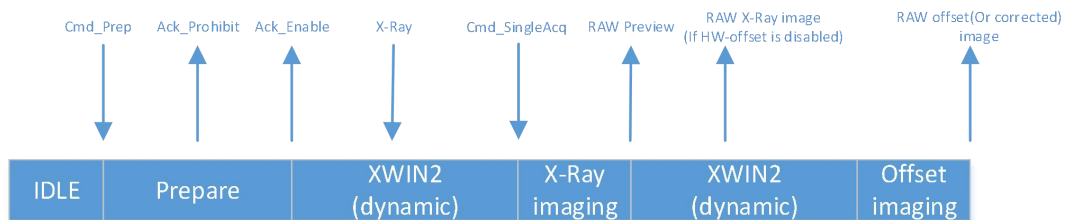
### 6.2.2 Workflow (PrepAcq)

Select HWPostOffset、HWGain、HWDefect. If you 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 acknowledge 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.

### 6.2.3 Workflow (Prep+Acq)



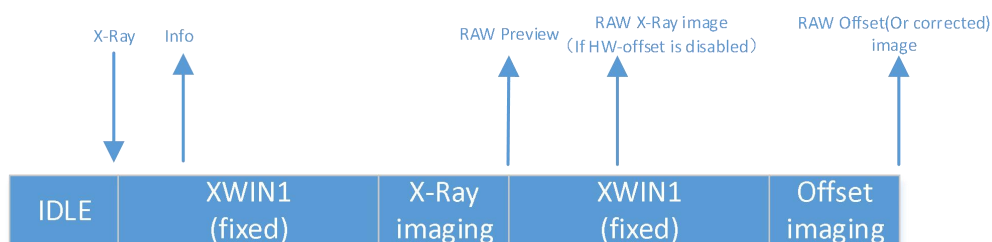
- ① Send Cmd“Prep” on UI “Acquire” page.
- ② After receiving the Cmd\_Prep, it will start the prepare process, and send back the acknowledge of “Prohibit” and “Enable”, the “XWIN” will be started.
- ③ The max XWIN is configured by parameter “Exp Window Time” on “Detector” page “Parameter” tab, the unit 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.

## 6.3 AED Mode

### 6.3.1 Inner Mode

- 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 automatically, 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.

### 6.3.2 Freesync Mode

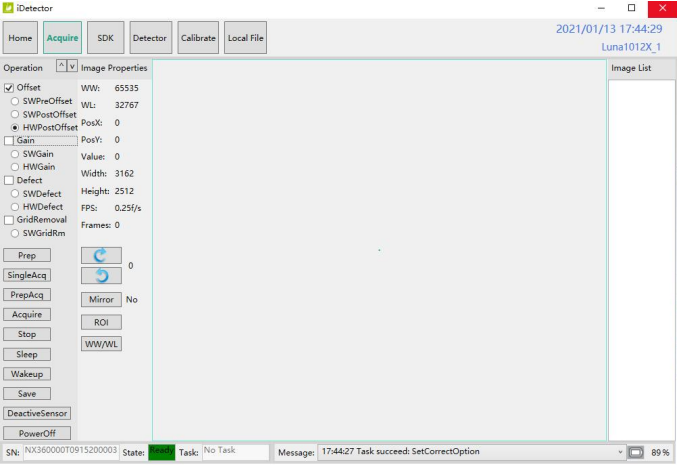
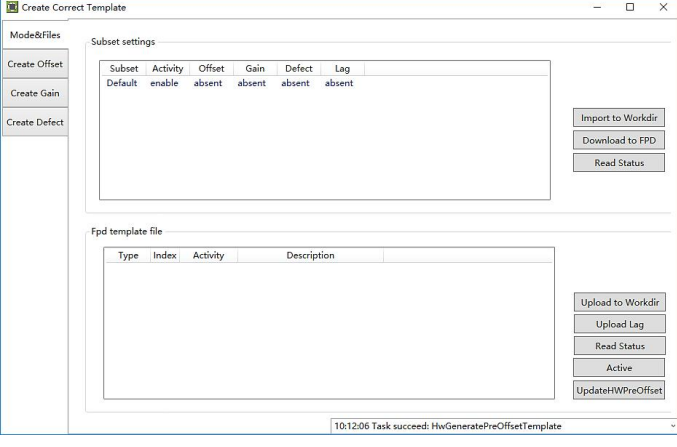


- ① For Freesync mode, there is no low power state.
- ② When the detector is Idle, user can start the exposure flow any time.
- ③ When the X-Ray starts, the detector will sense the X-Ray automatically, the XWIN is configured by parameter “Set Delay Time” on “Detector” page “Parameter” tab, the unit is “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.

## 6.4 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.

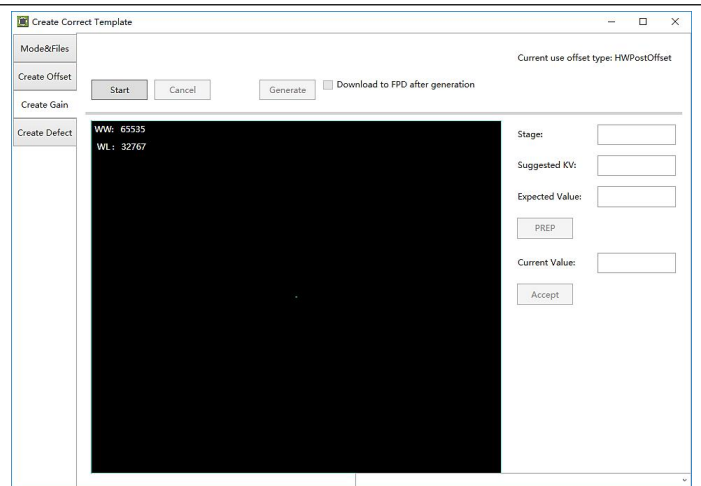
### 6.4.1 Generating HWPreOffset Template

<p>① Enter Acquire interface, select HWPostOffset option</p>	
<p>② Enter Calibrate interface, click [UpdateHWPreOffset] button. Waiting until status bar displayed: "Task succeed: HwGeneratePreOffsetTemplate"</p>	

### 6.4.2 Generating Gain Calibration Template

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

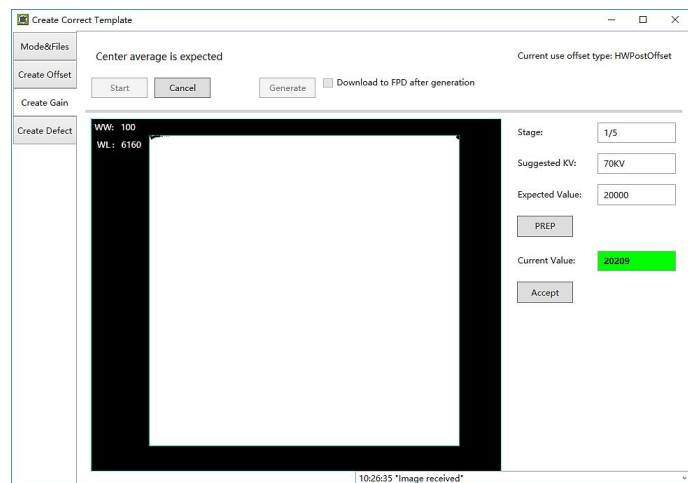
- ① Enter Create Gain page, and click "Start" button to start process.



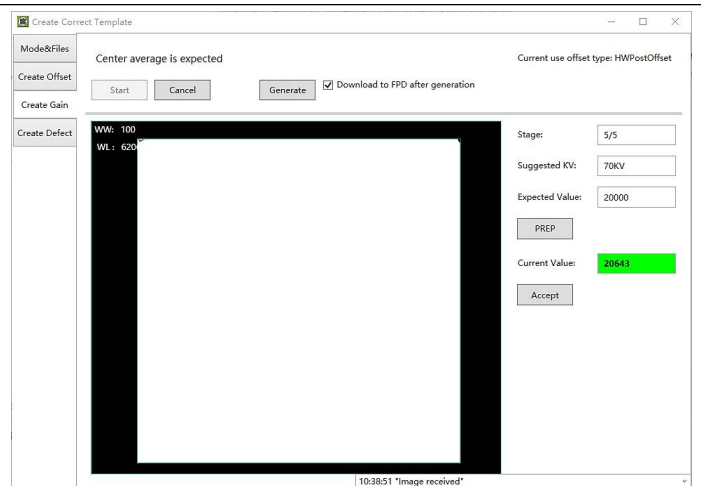
- ② Click PREP button, acquire image. Please exposure after Acquire button enable. And click Acquire button to acquire image after exposure end. Click Accept button after acquired image. If Current Value textbox is yellow, click PREP button. Re-acquire images after adjust generator parameters.

Note: In different trigger mode, the operation maybe have little difference. Please follow the UI tips.

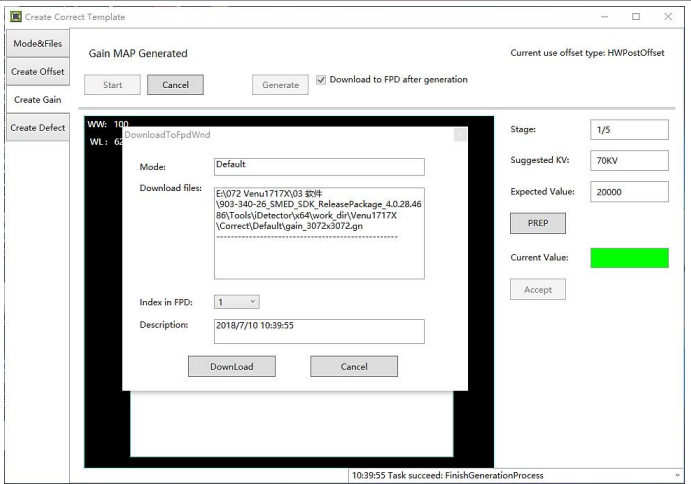
If the detector is in inner or Freesync mode, then user should finish the exposure before the time bar counting ends. And the click on Acquire is not necessary for inner or Freesync.



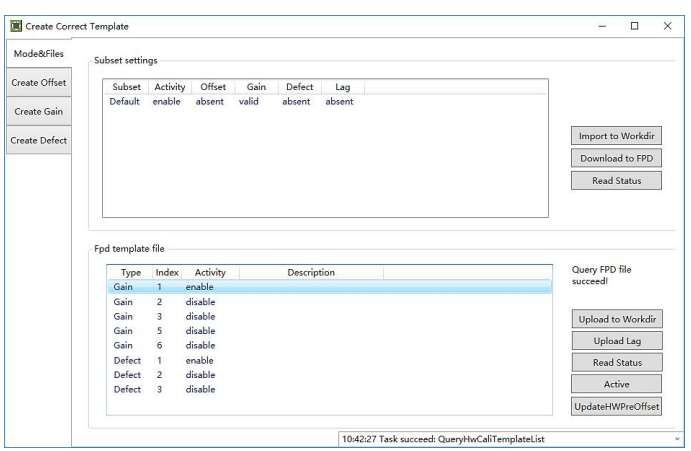
- ③ Create gain template need several images. You can click Generate button to generate Gain template once one image was captured. But it may lead to imperfect template quantity.



④ 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.

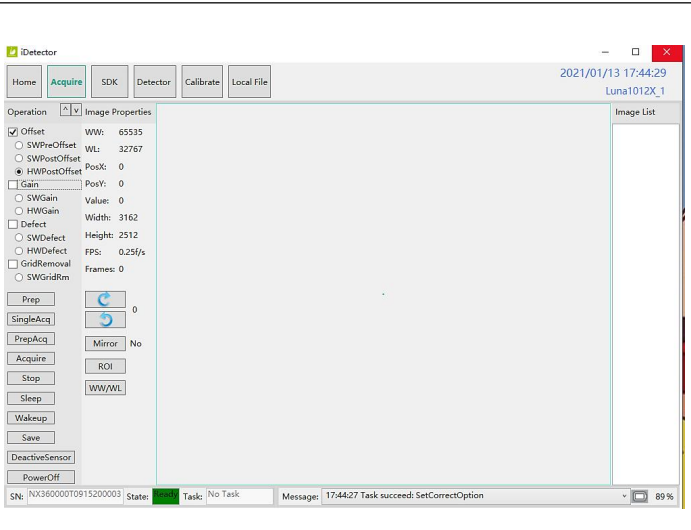


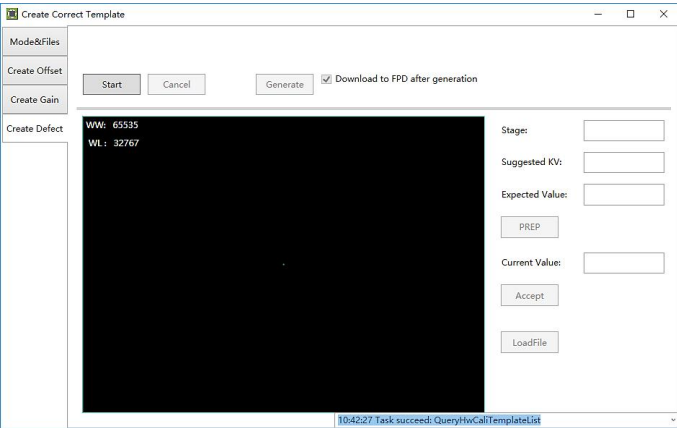
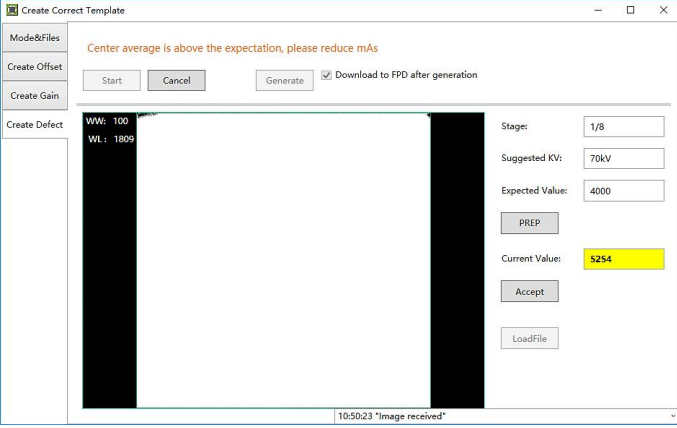
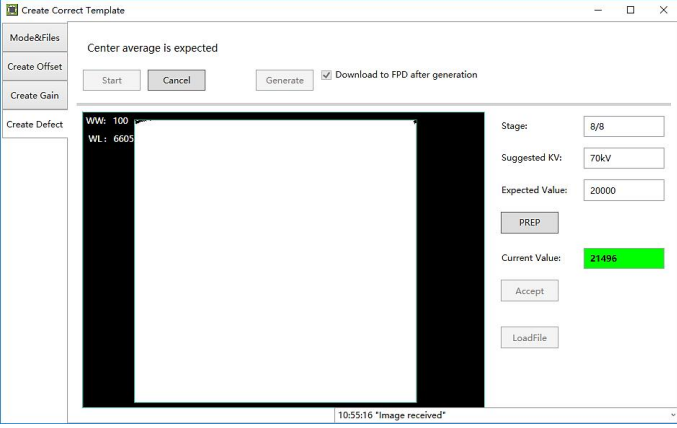
⑤ Select Mode&Files tab. Click Read Status button to check whether just downloaded gain template is enable. If not, please click Active button to enable.



### 6.4.3 Generating Defect Calibration Template

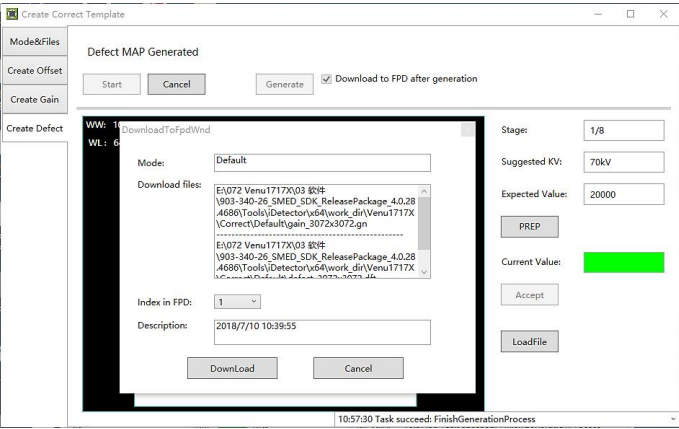
① Enter Acquire UI. Choose HWPPostOffset. Enter Calibrate UI. Select Create Defect tab.



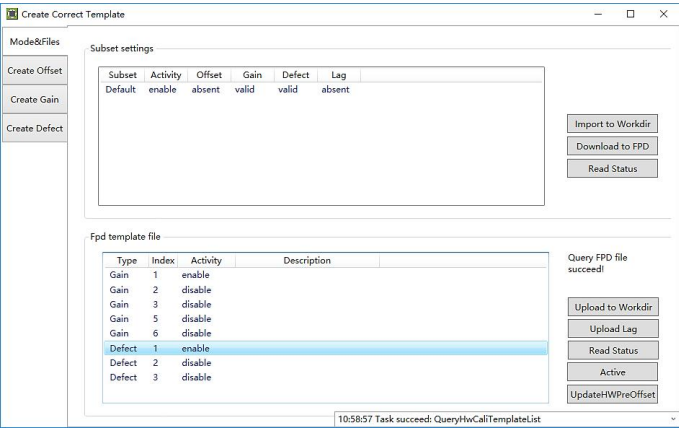
<p>② Click "Start" button to start process. Click PREP button, acquire image. Please exposure after Acquire button enable. And click Acquire button to acquire image after exposure end.</p>	
<p>③ Click Accept button after acquired image. If Current Value textbox is yellow, click PREP button. Re-acquire images after adjust generator parameters.</p> <p>Note: In different trigger mode, the operation maybe have little difference. Please follow the UI tips.</p>	
<p>④ You can click Generate button to generate Gain template after acquired required images.</p>	



⑤ 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.



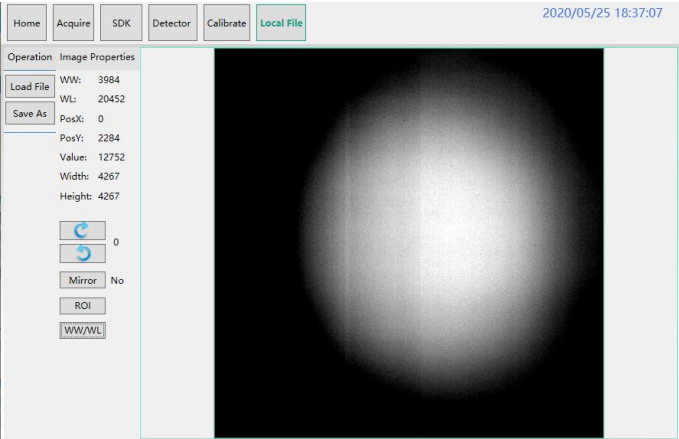
⑥ Select Mode&Files tab. Click Read Status button to check whether just downloaded gain template is enable. If not, please click Active button to enable.



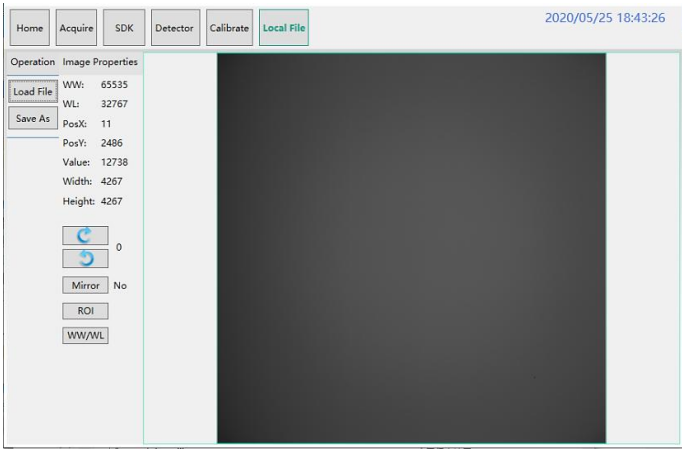
## 6.5 Local Image Check

“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.

① Click “Local File” button in “Local File” UI, choose the specified file. In this page user can open the image files saved in local, the file format can be raw, tiff, dft. When the software is disconnected to detector, the file still can be opened.



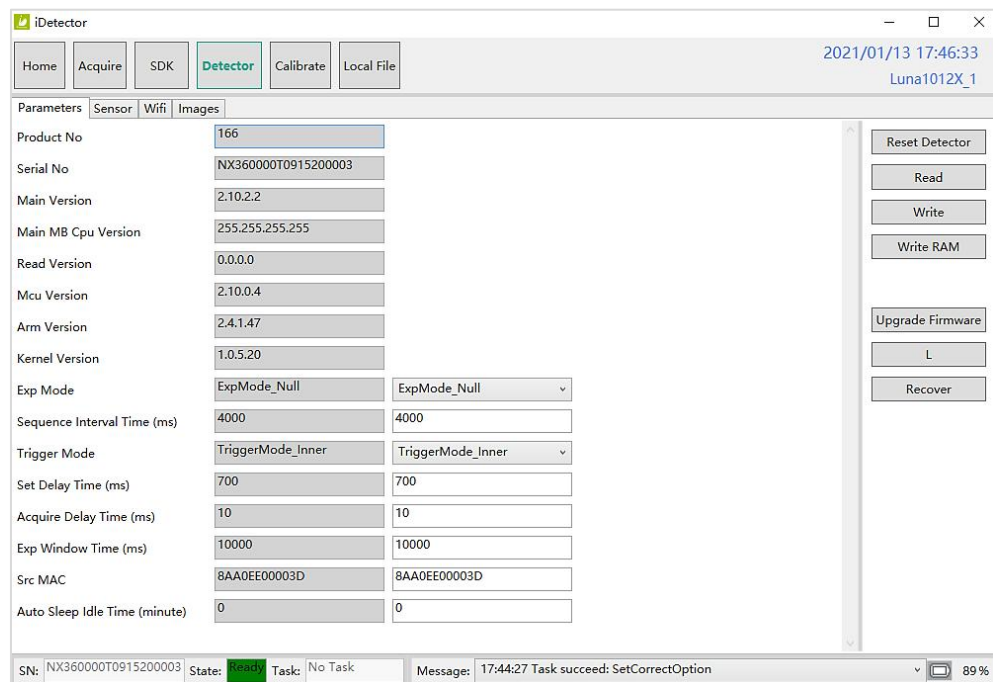
② Click “Load File”, there will be an open file wizard. Select file and click open or double click the file. The tiff file will be opened directly. For the raw file or dft file there will be a dialog to select image size. Select correct size to open image files. If the file is not correct user will get an error message.



## 6.6 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.

Luna1012X\_IMAGE\_44\_ALL\_20XX\_XX\_XX.ifrm

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

Luna1012X\_IMAGE\_44\_ARM\_20XX\_XX\_XX.ifrm

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

Luna1012X\_IMAGE\_44\_FPGA\_20XX\_XX\_XX.ifrm

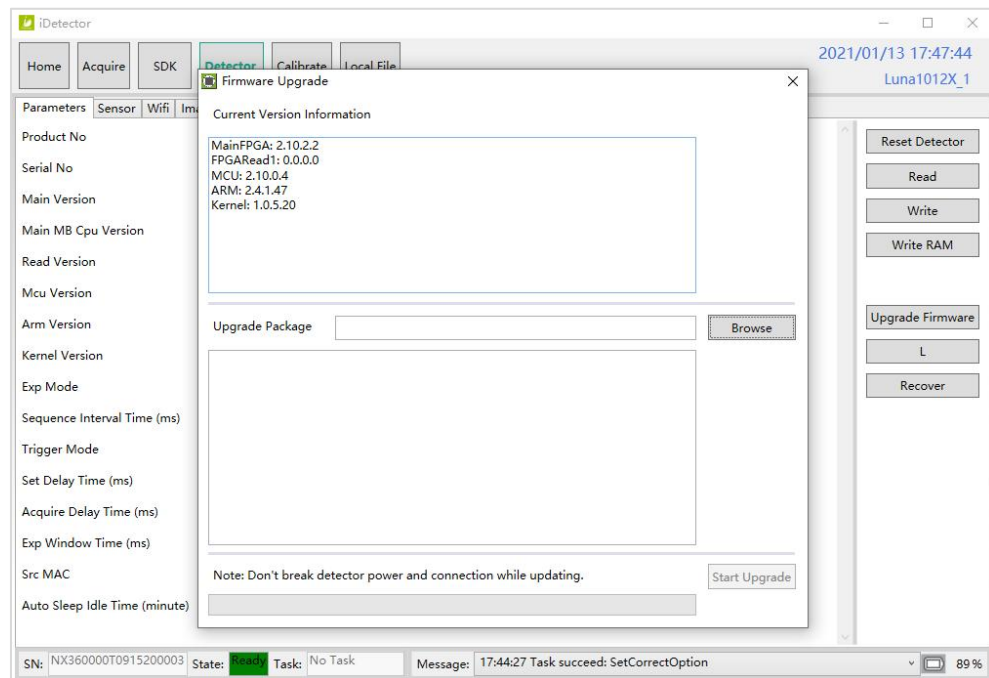
Word “FPGA” indicates the file is only for FPGA.

Luna1012X\_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.

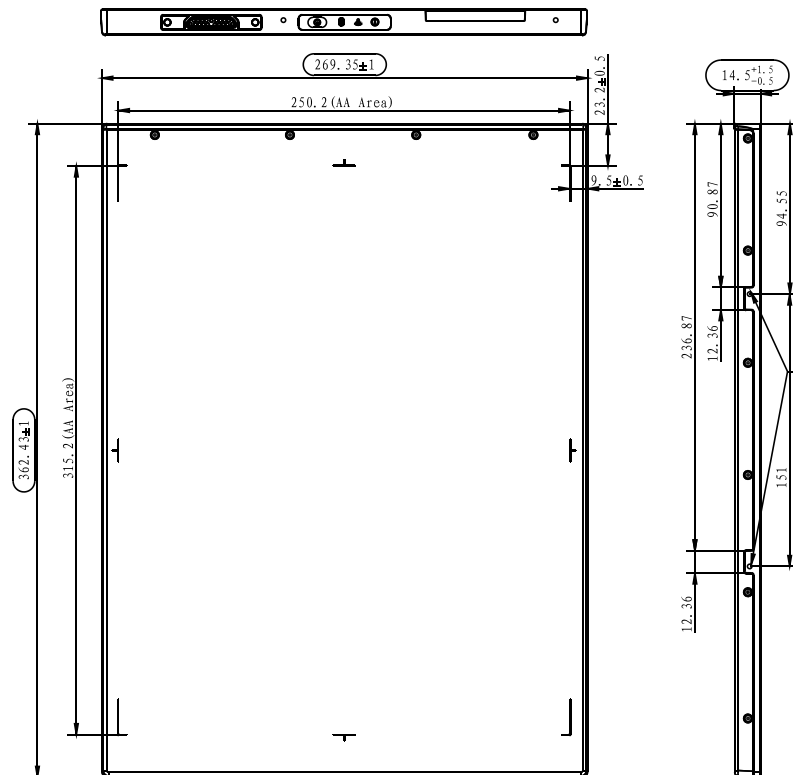


NOTE

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

## 7 Technical Specifications

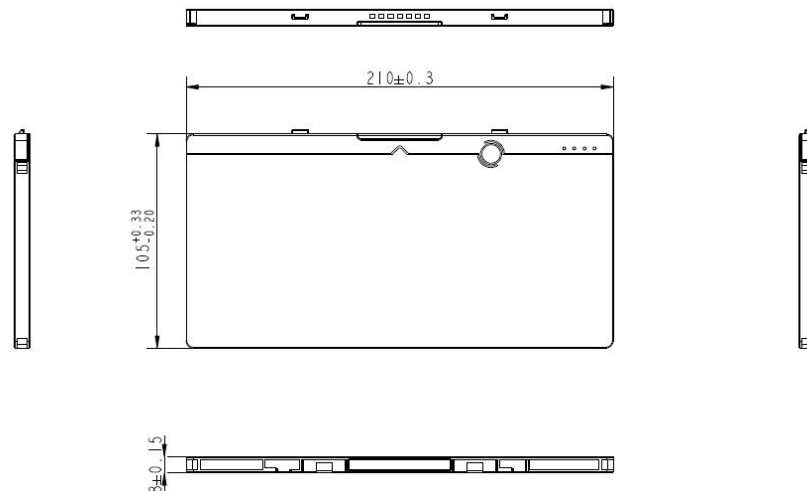
### 7.1 Detector



Item	Specification
Model	Luna1012X
Image sensor	a-Si (Amorphous Silicon) TFT
Scintillator	CsI
Pixel size	100um
Fill factor	60%
Effective array	3152*2502
Effective area (H x V)	315.2 mm*250.2mm
Image transfer	WIFI
Cycle time	6s
Power consumption	18W
Dimension (L × W × H)	362.1x269.2x15mm @typ.

Item	Specification
Weight	2kg
Image transfer	Wireless: IEEE802.11 a/b/g/n/ac
Wireless frequency range	2.412~2.472GHz, 5.18~5.22GHz; 5.745~5.85GHz
Data transmission power	13dBm (Typ.) @802.11a 16dBm (Typ.) @802.11b 14dBm (Typ.) @802.11g 13dBm (Typ.) @802.11n HT20 11dBm (Typ.) @802.11n HT40 16dBm@2.4GHz 13dBm@5GHz
Wireless modulation	11b: DSSS (DBPSK, DQPSK and CCK) 11a/g/n: OFDM (BPSK, QPSK, 16QAM, 64QAM)
Wireless band	2.4GHz≤35MHz 5.GHz≤50MHz
X-ray energy	40-150kV
Trigger mode	Software/AED
SID	0-180cm

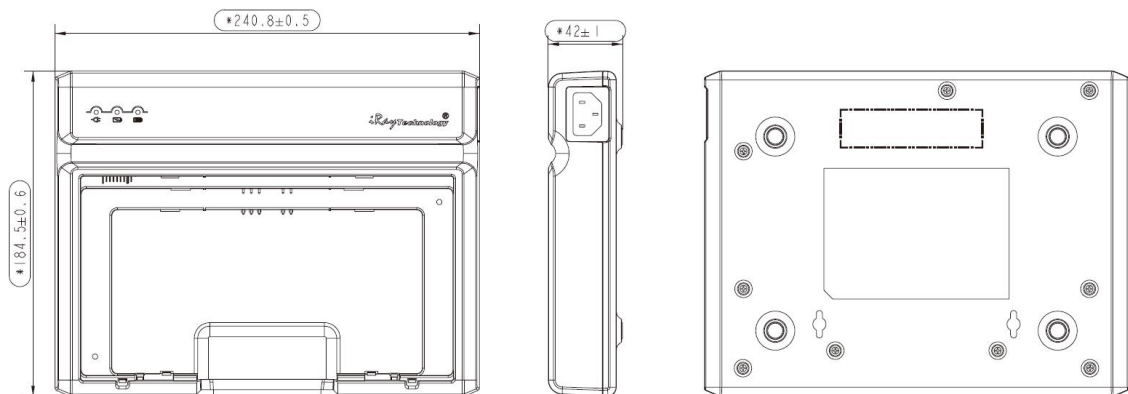
## 7.2 Battery



Item	Specification
Model	Battery-KX
Rated Capacity	Min. 4700mAh, Typ. 4900mAh @ Discharge 0.2C
Nominal Voltage	11.55V

Item	Specification
Charge Voltage	13.2V
Discharged End Voltage	9V
Charging Method	CC-CV
Operating Temperature	Charge 0°C~+60°C Discharge -10°C~+60°C
Storage Temperature	1 month -20°C~+50°C 3 month -20°C~+45°C 6 month -20°C~+35°C
Relative Humidity	5%~95% RH
Dimension (L × W × H)	210 x 105 x 8 mm
Weight	0.285kg

### 7.3 Battery Charger



Item	Specification
Model	Charger-Combo
Simultaneous Charging	1 battery pack
Full charging time	≤4 hours
Rated power supply	90V~264V(AC)
Dimension (L × W × H)	240 x 284 x 38 mm
Weight	0.55 kg


## 7.4 Environment Requirements

	Temperature	Humidity	Pressure
Operation	10~35°C	5%~90% RH	700~1060mbar
Storage	-20~55°C	5%~95% RH	700~1060mbar

## 8 Service Information

### 8.1 Product Life

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

 NOTE	<ul style="list-style-type: none"> <li>• The product life cycle is decided by the life cycle of the detector.</li> <li>• For other replaceable parts, their service life will not affect the life cycle of the whole product.</li> <li>• 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.</li> </ul>
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### 8.2 Regular Inspection and Maintenance

In order to ensure the safety of patients, operating person and third parties, and to maintain the performance and reliability of the equipment, be sure to perform regular inspection at least once a year. If necessary, clean up the equipment, make adjustments, or replace consumables such as fuses, detector cable, 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.

#### 8.2.1 Daily Inspection

The following checks should be performed before and after use of this product.

Item	Operation
Detector	Make sure there are no loose screws or cracks in the detector Make sure there is no dust and impurities attached to the battery connection pins Make sure there are no cracks or short circuits at the battery connection pins
Cables	Ensure that the cable is not damaged and the cable shell is not torn Verify that the power cord is reliably connected to the power socket of the detector
Battery	Make sure there is no short circuit at the battery connection pins Make sure the battery is not expanding



### 8.2.2 Monthly and Yearly Inspection

Item	Frequency	Operation
Resolution	Monthly/yearly	Check detector resolution by resolution graphic or using phantom
Linear	Monthly/yearly	Evaluate by examining the gray value of images
Calibration	Monthly/yearly	When the X-ray generator, tube, collimator or exposure environment changes



For the maintenance and overhaul involving the disassembly of the equipment shell, contact qualified service engineers. Please contact iRay's Customer Service Department or your product distributors.

## 8.3 Troubleshooting

Failure
1. Incompatible with the operating system
2. Incompatible with the interface
3. Software changes or upgrades failed.
4. The data transfer protocol error
5. Inconsistent interfaces or formats may cause data distortion
6. Data output failed
If any fault occurs, contact Shanghai iRay's Customer Service Department ( <a href="mailto:service@iraygroup.com">service@iraygroup.com</a> ) for professional technical support and provide the following information as per the product label: ① Name and model of product; ②Product SN; ③ Description of product failure as detailed as possible.

## 8.4 Customer Service

CS Dept.:	Service Office of iRay Technology Co. Ltd.
Address:	Building 45, No. 1000, Jinhai Rd., Pudong New Area, Shanghai, 201206, P. R. China
Telephone:	+86-21-50720560
Fax:	+86-21-50720561
Email:	<a href="mailto:service@iraygroup.com">service@iraygroup.com</a>
Website:	<a href="http://www.iraygroup.com">www.iraygroup.com</a>

## 8.5 Manufacturer Information



Manufacturer:	iRay Technology Co., Ltd.
Address:	Rm., Building 7, No. 590, Ruiqing Rd., Zhangjiang East, Pudong 201201 Shanghai, P. R. China
Telephone:	+86-21-50720560
Fax:	+86-21-50720561
Website:	<a href="http://www.iraygroup.com">www.iraygroup.com</a>

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