

Digital Flat Panel Detector

# Venu1012V(A17)

## User Manual



Version : A0

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Medical device registration certificate no:

Registered product standard no:



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

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

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

E



## To Customers

Congratulations on your purchase of the Fixed Digital Flat Panel (hereinafter referred to as VENU1012V) which is manufactured by iRay Technology Co.Ltd. (Hereinafter referred to as iRay).



Please take time to read this user guide in order to utilize the product effectively. We hope you enjoy the experience with iRay VENU1012V.

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

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## 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. Maintenance personnel should maintain the equipment in a safe and operable condition.
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.
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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.
6. Venu1012V has no applied parts. 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.
7. The voltage DIP, interruption or variation of the system power supply may have impact on Venu1012V. So the uninterruptible power supply should be considered.
8. Venu1012V is forbidden to use under oxygen-enriched conditions.
9. Venu1012V is forbidden to use near flammable objects.

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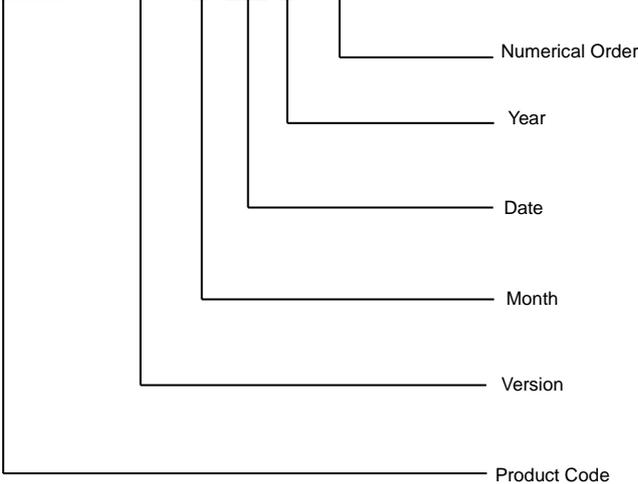
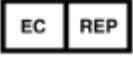
## Symbols and Conventions

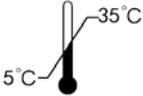
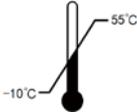
The following symbols and conventions are used throughout the user guide.

	<p>This symbol is used to identify conditions under which improper use of the product may cause death or serious personal injury.</p>
	<p>This notice is used to identify conditions under which improper use of the product may cause minor personal injury.</p>
	<p>This notice is used to identify conditions under which improper use of the product may cause property damage.</p>
	<p>This is used to indicate a prohibited operation.</p>
	<p>This is used to indicate an action that must be performed.</p>
	<p>This is used to indicate important operations and restrictions.</p>
	<p>This is used to indicate operations for reference and complementary information.</p>

## Labels and markings on the equipment

The contents of the labels and markings on iRay Venu1012V product are indicated below:

图标	含义
	Caution: please refer to the instructions in the user manual.
	This symbol is used to indicate that the equipment has passed CE testing and it is followed by the CE Notified Body number.
	<p>This symbol is used to identify the manufacturer's series number which is after, below or adjacent to the symbol. The series number of iRay products is usually made of thirteen digits as shown below:</p> <p style="text-align: center;"> <u>A1A2A3A4</u>    <u>C1C2 M</u>    <u>DD Y</u>    <u>XXX</u> </p> <div style="display: flex; justify-content: center; align-items: center; gap: 20px;"> <div style="text-align: center;">  </div> <div style="text-align: right;"> <p>Numerical Order</p> <p>Year</p> <p>Date</p> <p>Month</p> <p>Version</p> <p>Product Code</p> </div> </div>
	This symbol is used to indicate the name and address of the manufacturer.
	Manufacturing date of this product.
	Expiring date of this product.
	This symbol is used to indicate the name and address of iRay authorized representative in the European region.

	<p>This symbol is used to indicate consultation of the user guide for general information.</p>
	<p>This product is not to be disposed of with your residential or commercial waste.</p>
	<p>Safety Signs: please refer to the user guide for safety instructions.</p>
	<p>Safety Signs: Dangerous Voltage.</p>
	<p>This symbol indicates load limit.</p>
	<p>Handled with care.</p>
	<p>This symbol is used to indicate the operational temperature limits.</p>
	<p>This symbol is used to indicate the storage temperature limits.</p>
	<p>Package symbol, fragile.</p>
	<p>Package symbol, keep away from sunlight.</p>
	<p>Package symbol, keep dry.</p>
	<p>Package symbol, this symbol is used to indicate the humidity limits.</p>

	Package symbol, keep the equipment up right.
	Package symbol, do not roll the transportation package.
	Package symbol, this symbol is used to indicate stacking limit number.

## Contents

<b>TO CUSTOMERS</b> .....	<b>1</b>
<b>CONTENTS</b> .....	<b>7</b>
<b>1 SAFETY INFORMATION</b> .....	<b>10</b>
1.1 SAFETY PRECAUTIONS.....	10
1.2 NOTES FOR USING .....	15
<b>2 GENERAL DESCRIPTION</b> .....	<b>18</b>
2.1 SCOPE .....	18
2.2 MODEL .....	18
2.3 CHARACTERISTIC.....	19
2.4 INTENDED USE .....	19
2.5 PRODUCT SPECIFICATION.....	19
2.6 ENVIRONMENT REQUIREMENTS.....	20
2.7 PRODUCT COMPONENTS.....	21
2.8 COMPONENTS DESCRIPTION.....	22
<b>3 SOFTWARE INSTRUCTIONS</b> .....	<b>26</b>
3.1 SYSTEM REQUIREMENT.....	26
3.2 ENVIRONMENT .....	26
3.3 WIRED CONNECTION.....	26
3.4 NETWORK CONFIGURATION .....	29
3.5 USER INTERFACE.....	30
3.6 CALIBRATION .....	31
<b>4 OPERATION</b> .....	<b>41</b>
4.1 STEPS FOR ACQUIRING IMAGE.....	41
4.2 INNER MODE OPERATION.....	41
4.3 FREESYNC MODE OPERATION.....	44
4.4 AFTER USE.....	46
<b>5 REGULATORY INFORMATION</b> .....	<b>48</b>
5.1 MEDICAL EQUIPMENT SAFETY STANDARDS.....	48
5.2 GUIDANCE AND MANUFACTURE’S DECLARATION FOR EMC .....	49
5.3 PRODUCT LABEL.....	52
<b>6 SERVICE INFORMATION</b> .....	<b>54</b>
6.1 PRODUCT LIFETIME .....	54

6.2	REGULAR INSPECTION AND MAINTENANCE .....	54
6.3	REPAIR.....	54
<b>APPENDIX A INFORMATION OF MANUFACTURES .....</b>		<b>56</b>

# 1 SAFETY INFORMATION

1.1	SAFETY PRECAUTIONS.....	10
1.2	NOTES FOR USING .....	15

# 1 Safety Information

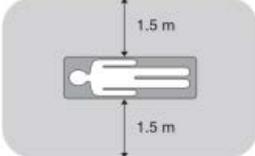
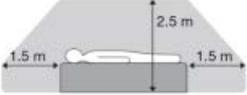
## 1.1 Safety Precautions

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

<b>WARNING</b>	
<p><b>Installation and environment of use</b></p>  <p>Prohibited</p>  <p>Prohibited</p>	<ul style="list-style-type: none"> <li>• <b>Do not use or store the equipment near flammable chemicals such as alcohol, thinner, benzene, etc.</b> 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.</li> <li>• <b>Do not connect the equipment with anything other than specified.</b> Doing so may result in fire or electric shock.</li> <li>• <b>All the patients with active implantable medical devices should be kept away from the equipment.</b></li> </ul>
<p><b>Power supply</b></p>  <p>Prohibited</p>	<ul style="list-style-type: none"> <li>• <b>Do not operate the equipment using any type of power supply other than the one indicated on the rating label.</b> Otherwise, it may result in fire or electric shock.</li> <li>• <b>Do not handle the equipment with wet hands.</b> You may experience electric shock that could result in death or serious injury.</li> <li>• <b>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.</b> Doing so may damage the cords which could result in fire or electric shock.</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 turn ON the system power when condensation has formed on the equipment.</b> Doing so may result in fire or electric shock.</li> </ul>

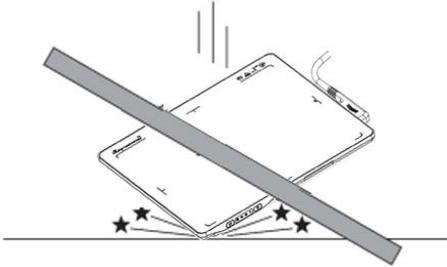
<p><b>Power supply</b></p>  <p>Prohibited</p>	<ul style="list-style-type: none"> <li>• <b>Do not connect a multiple portable socket-outlet or extension cord to the system.</b> Doing so may result in fire or electric shock.</li> <li>• <b>To avoid the risk of electric shock, this equipment must only be connected to power supply with protective earth.</b> Not doing so may result in fire or electric shock.</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Securely plug the power cord into the AC outlet.</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>Be sure to turn OFF the power to each piece of equipment before connecting or disconnecting the cords.</b> Otherwise, you may get an electric shock that could result in death or serious injury.</li> <li>• <b>Be sure to hold the plug or connector to disconnect the cord.</b> If you pull the cord, the core wire may be damaged, resulting in fire or electric shock.</li> </ul>
<b>WARNING</b>	
<p><b>Handling</b></p>  <p>Prohibited</p>	<ul style="list-style-type: none"> <li>• <b>Never disassemble or modify the equipment. No modification of this equipment is allowed. Parts of the VENU1012V that are not serviced or maintained while in use with the patient.</b> 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.</li> <li>• <b>Do not place anything on top of the equipment.</b> 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.</li> <li>• <b>Do not hit or drop the equipment.</b> 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> <li>• <b>Do not put the equipment and pointed objects together.</b> The equipment may be damaged. If so, the equipment should be used in bucky.</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Have the patient take a fixed posture and do not let the patient touch parts unnecessarily.</b></li> </ul> <p>If the patient touches connectors or switches, it may result in electric shock or malfunction of the equipment.</p>
<p><b>When a problem occurs</b></p>	<ul style="list-style-type: none"> <li>• <b>Should any of the following occurs, immediately unplug the power cord of Control Box, and contact your sales representative or local iRay dealer:</b></li> </ul> <p>When there is smoke, an odd smell or abnormal sound.</p> <p>When liquid has been spilled into the equipment or a metal object has entered through an opening.</p> <p>When the equipment has been dropped and damaged.</p>
<p><b>Maintenance and inspection</b></p>  <p>Prohibited</p>	<ul style="list-style-type: none"> <li>• <b>Please turn OFF the power of the equipment and unplug the power cord of adaptor before cleaning.</b></li> <li>• <b>NEVER use alcohol, ether and other flammable cleaning agent for safety. NEVER use methanol, benzene, acid and base because they will erode the equipment.</b></li> <li>• <b>DON'T dip the equipment into the liquid.</b></li> <li>• <b>Please make sure that the equipment's surface &amp; plugs are dry before turning ON.</b></li> </ul> <p>Otherwise, it may result in fire or electric shock.</p>
	<ul style="list-style-type: none"> <li>• <b>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.</b></li> </ul> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>For safety reasons, be sure to turn OFF the power to each piece of equipment when performing inspections indicated in this manual.</b></li> </ul> <p>Otherwise, electric shocks may occur.</p>

<b>CAUTION</b>	
<p><b>Installation and environment of use</b></p> 	<ul style="list-style-type: none"> <li> <p><b>Do not install the equipment in any of the locations listed below. Doing so may result in failure, malfunction, equipment falling, fire or injury.</b></p> <p>Close to facilities where water is used</p> <p>Where it will be exposed to direct sunlight</p> <p>Close to the air outlet of an air-conditioner or ventilation equipment</p> <p>Close to heat source such as a heater</p> <p>Where the power supply is unstable</p> <p>In a dusty environment</p> <p>In a saline or sulfurous environment</p> <p>Where temperature or humidity is high</p> <p>Where there is freezing or condensation</p> <p>In areas prone to vibration</p> <p>On an incline or in an unstable area</p> </li> <li> <p><b>Take care that cables do not become tangled during use. Also, be careful not to get your feet caught by cable.</b></p> <p>Otherwise, it may cause a malfunction of the equipment or injury of the user due to tripping over the cable.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> </li> </ul>
<p><b>Power supply</b></p>	<ul style="list-style-type: none"> <li> <p><b>Always connect the three-core power cord plug to a grounded AC power outlet.</b></p> </li> <li> <p><b>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.</b></p> </li> <li> <p><b>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.</b></p> </li> <li> <p><b>Do not use any power source other than the one provided with this equipment.</b></p> </li> </ul> <p>Otherwise, fire or electric shock may be caused due to leakage.</p>

<b>Handling</b>	<ul style="list-style-type: none"> <li>• <b>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.</b></li> </ul> <p>Doing so may result in fire or electric shock.</p> <p>In such a situation, protect the equipment with a disposable cover as necessary.</p> <ul style="list-style-type: none"> <li>• <b>Turn OFF the power and pull out the plug to each piece of equipment for safety when not used.</b></li> </ul>
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**CAUTION**

<b>Handling</b> 	<ul style="list-style-type: none"> <li>• <b>Handle the equipment carefully.</b></li> <li>• <b>Do not submerge the equipment in water.</b></li> <li>• <b>The internal image sensor may be damaged if something hits against it or it is dropped.</b></li> </ul> <div style="text-align: center;">  </div> <ul style="list-style-type: none"> <li>• <b>Do not place excessive weight on the equipment.</b></li> <li>• <b>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.</b></li> </ul> <p>Keep the same load (same pressure) on the detector when acquiring the image. Or the image will be incorrect.</p>
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**CAUTION**

 <b>CAUTION</b>	<ul style="list-style-type: none"> <li>• <b>Do not close to fire, do not use in high temperature</b></li> <li>• <b>Do not invert positive and negative pole</b></li> <li>• <b>Do not contact with metal in case of short circuit</b></li> </ul>
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## 1.2 Notes for Using

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 exposure rate is over 900nGy/s @70KV.
- 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.

### 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 bleeding patient.

## 2 GENERAL DESCRIPTION

2.1	SCOPE .....	18
2.2	MODEL .....	18
2.3	CHARACTERISTIC.....	19
2.4	INTENDED USE .....	19
2.5	PRODUCT SPECIFICATION .....	19
2.6	ENVIRONMENT REQUIREMENTS.....	20
2.7	PRODUCT COMPONENTS.....	21
2.8	COMPONENTS DESCRIPTION.....	22

## 2 General Description

Venu1012V is a digital X-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It is developed to provide the highest quality of radiographic image, which contains an active matrix of 2000×2400 with 125um pixel pitch.

### 2.1 Scope

This manual contains information about the Venu1012V. Information in the manual, including the illustrations, is based on prototype. If your configuration does not have any of these items, information about these items does not apply to your panel.

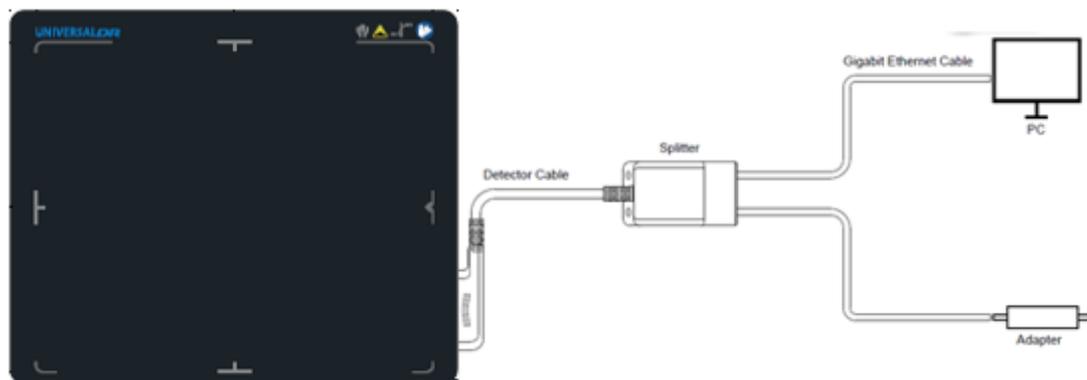
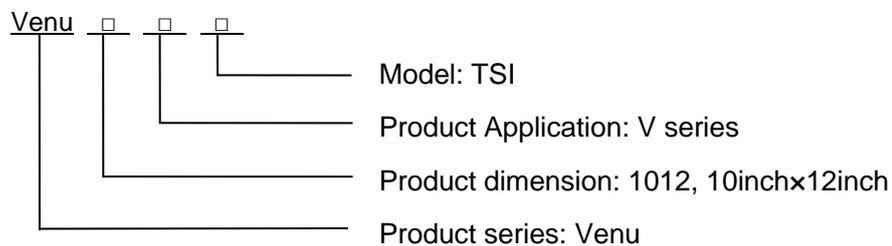


Figure 3.1.1

### 2.2 Model



## 2.3 Characteristic

- Static flat panel detector used for general radiography.
- Sync-shot exposure trigger
- CsI scintillation screen

## 2.4 Intended use

Venu1012V serial Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis for podiatry use. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures.

This panel is not intended for mammography, and prohibited for pregnant women and children.

According to the Venu1012V intended use and the result of risk management, identifying and describing the essential performance as the following:

- a) To get image of dark field, the Venu1012V shall not be influenced to the imaging acquisition;
- b) To keep the data transmission function, the Venu1012V shall not be influenced to the data and signal transmission.

## 2.5 Product Specification

Item	Specification
Scintillator	CsI-TSI
Effective area	250mm x 300mm
Pixel matrix	2048*2448 (row*column)
Pixel matrix (effective)	2000x2400 (row*column)
Pixel pitch (resolution)	125um
AD conversion	16bit
Trigger mode	Inner, Freesync
The length of the X-ray window	Typ. ≤ 1s
Image Acquisition Time	Preview Time: Typ. 3s Full image Time: Typ. 6s
Cycle Time	9s without image processing
Image Transfer	Gigabit Ethernet

Used kV	45kV to 55kV
Power Consumption	Max. 20W
Weight	2.5kg
Degrees of protection provided by enclosure	IPX0

## 2.6 Environment requirements

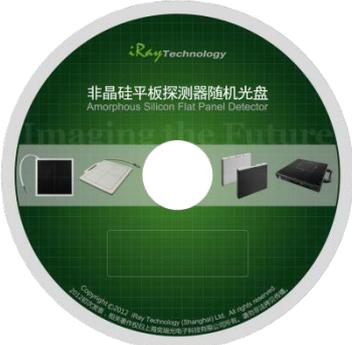
### 2.6.1 Operation requirements

Item	Specification
Temperature	Min 5 °C Max 35°C
Temperature variation	Max ± 0.5 °C / min
Humidity (no condensing)	Min 30 %RH Max 80 %RH
Pressure	Min 700 mbar Max 1060 mbar
Altitude	Max 3000m

### 2.6.2 Transport and storage requirements

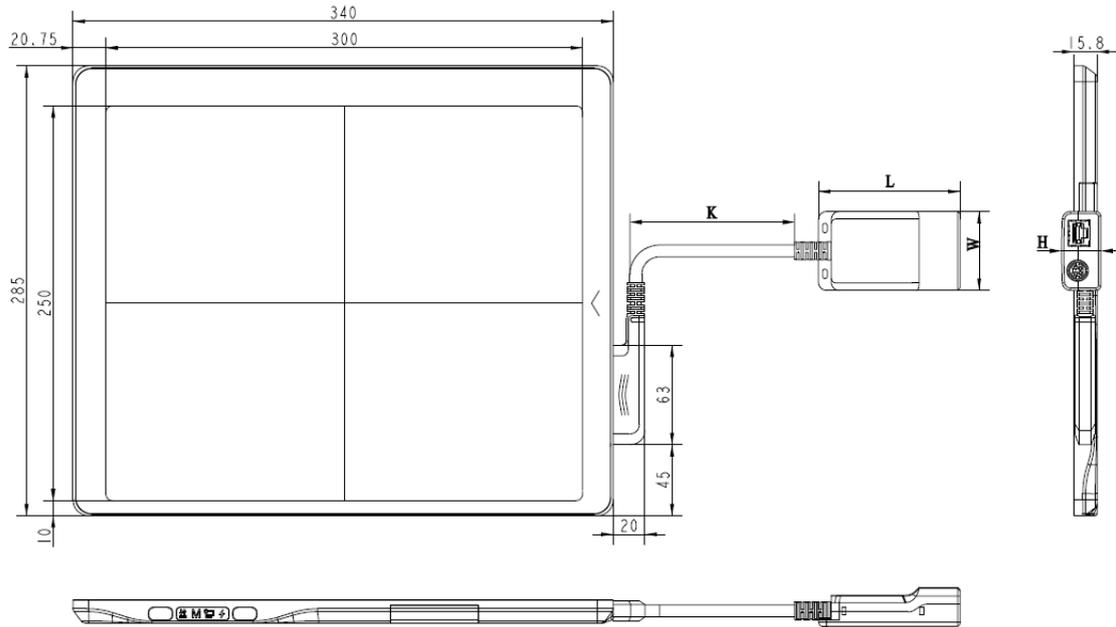
Item	Specification
Temperature	Min -10 °C Max 55°C
Temperature variation	Max ± 1°C / min
Humidity (no condensing)	Min 10 %RH Max 90 %RH
Pressure	Min 700 mbar Max 1060 mbar
Altitude	Max 3000m

## 2.7 Product Components

	Item	Description
Venu1012V Detector with Detector Cable	 <p>The image shows a black rectangular detector unit with a small screen at the top displaying 'INTERALLOM' and some icons. A white cable labeled 'Detector Cable' is connected to the side of the unit, leading to a small white rectangular component labeled 'Splitter'.</p>	<p>1pcs Main Unit The Detector Cable is replaceable.</p>
Medical Adapter	 <p>The image shows a black rectangular power adapter with two cables. One cable has a standard three-prong AC power plug, and the other has a cylindrical DC power connector.</p>	<p>1 pcs DC 24V</p>
Gigabit Ethernet Cable	 <p>The image shows a coiled white Gigabit Ethernet cable with RJ45 connectors on both ends.</p>	<p>1pcs 3 m</p>
AC Power Cable	 <p>The image shows a coiled black AC power cable with a standard three-prong AC power plug on one end and a DC power connector on the other.</p>	<p>1 pcs</p>
CD-Rom	 <p>The image shows a CD-ROM with a green background. The text on the CD includes 'RayTechnology', '非晶硅平板探测器随机光盘', and 'Amorphous Silicon Flat Panel Detector'. There are also small images of the detector unit and other components.</p>	<p>1pcs Gain correction data Defect correction map SDK Manual</p>

## 2.8 Components Description

### 2.8.1 Detector



Item	Description	Comment
L	Length of Splitter	Refer to 2.8.3
W	Width of Splitter	Refer to 2.8.3
H	Height of Splitter	Refer to 2.8.3
K	Length of the cable	~ 3m

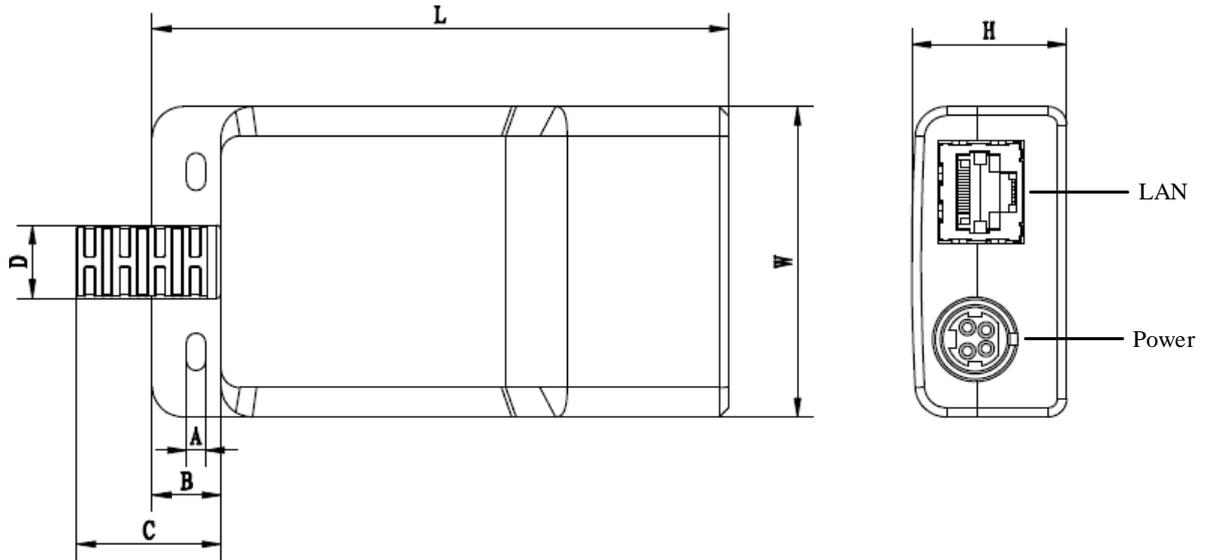
### 2.8.2 Detector Cable

The detector cable is replaceable and can be replaced if necessary. It is fixed to the detector by two screws. So a screwdriver shows below or alike is available when needed.



### 2.8.3 Splitter

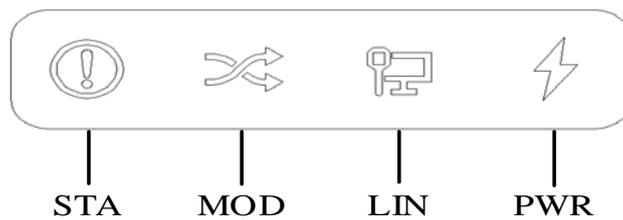
The Splitter should be fixed steady.



Item	Dimension (mm)	Item	Dimension (mm)
A	3	L	92
B	11	W	50
C	23	H	25
D	12		

### 2.8.4 LED Indicator

Once powered on, user can check the status through LED indicator.



Item	Description
PWR	Power Indicator
LIN	Link Indicator
MOD	<b>Reserved</b>

STA	Status Indicator	
Power Indicator	Lighting Status	Description
OFF		<ul style="list-style-type: none"> <li>Power OFF</li> </ul>
Green ON		<ul style="list-style-type: none"> <li>Power ON</li> </ul>
Link Indicator	Lighting Status	Description
OFF		<ul style="list-style-type: none"> <li>Power OFF</li> <li>No connection</li> </ul>
Green ON		<ul style="list-style-type: none"> <li>Physical layer connection is established</li> </ul>
Status Indicator	Lighting Status	Description
OFF		<ul style="list-style-type: none"> <li>Power OFF</li> <li>Exposure Disable</li> </ul>
Green ON		<ul style="list-style-type: none"> <li>Exposure Enable</li> </ul>
Orange blinking		<ul style="list-style-type: none"> <li>Safe mode</li> </ul>
Orange ON		<ul style="list-style-type: none"> <li>Error</li> </ul>

## 2.8.5 Power Adapter

Item	Specification
AC IN	100-240Vac., 50/60Hz 2.5A Max.
DC OUT	24.0Vdc 5.0A

## 3 SOFTWARE INSTRUCTIONS

3.1	SYSTEM REQUIREMENT.....	26
3.2	ENVIRONMENT .....	26
3.3	WIRED CONNECTION.....	26
3.4	NETWORK CONFIGURATION .....	29
3.5	USER INTERFACE.....	30
3.6	CALIBRATION .....	31

### 3 Software Instructions

Venu1012V provides SDK for user to integrate panel into their DR system. Additionally, it also provides an application for demonstration, i.e. iDetector. User can use iDetector to control panel without DR system.

For detailed introduction, please refer to “\Help\Doc”

903-341-13\_SDK\_ProgrammingGuide

903-341-14\_iDetector\_UserManual

#### 3.1 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. The computer should have at least 4 GB memory. In addition, the firewall should be shut down to avoid communication issue.

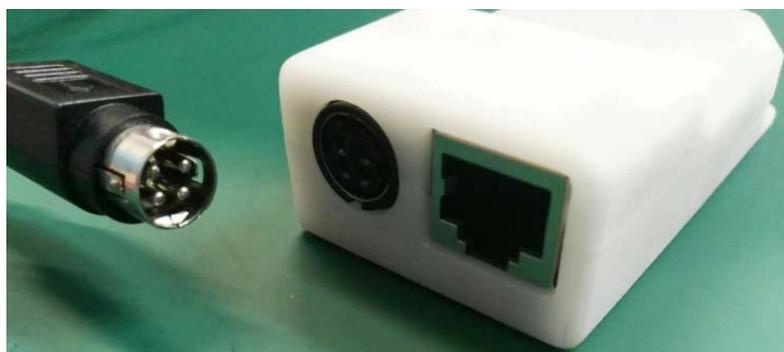
#### 3.2 Environment

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”.

#### 3.3 Wired Connection

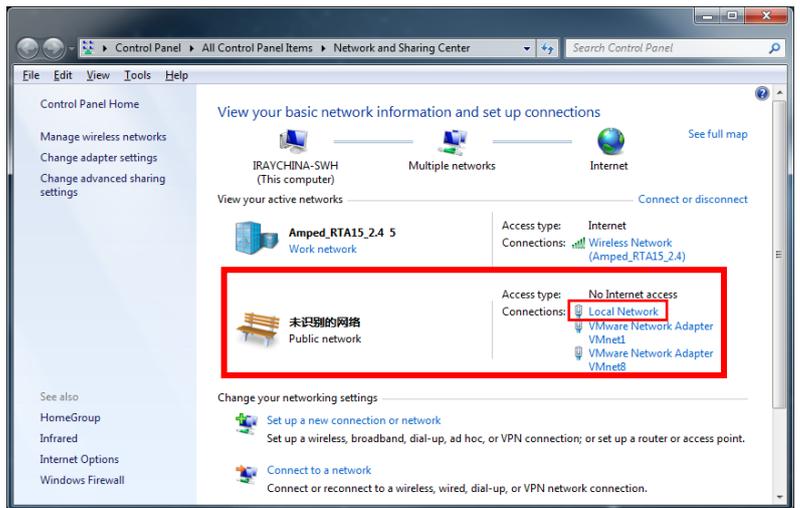
Connect the power cable



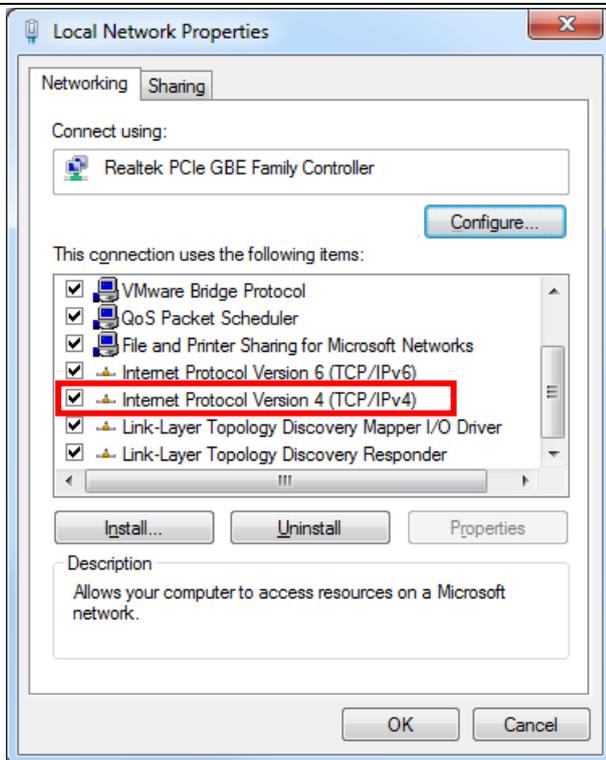
Connect the Ethernet cable



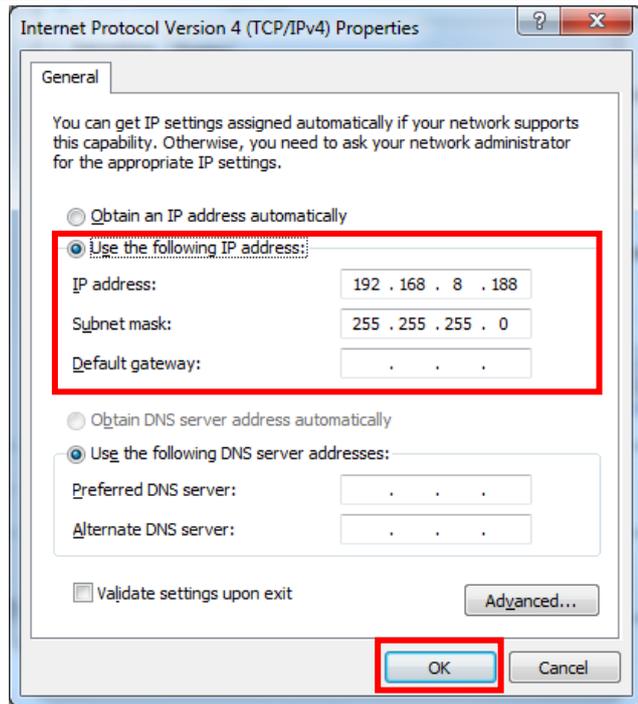
1. Wait until physical layer connection is established
2. Open local network management interface



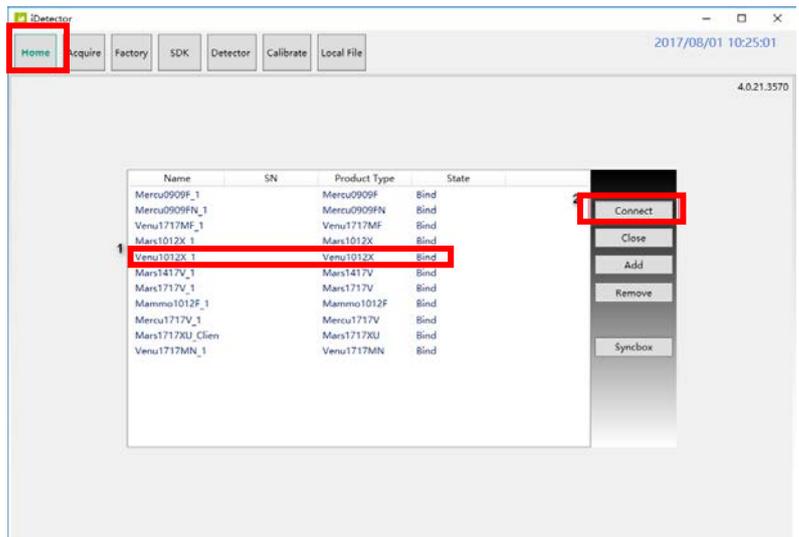
Double click "TCP/IPv4"



1. Enter the IP address and Subnet mask as follow:  
 IP address: 192.168.8.188  
 Subnet mask: 255.255.255.0
2. Click "OK".

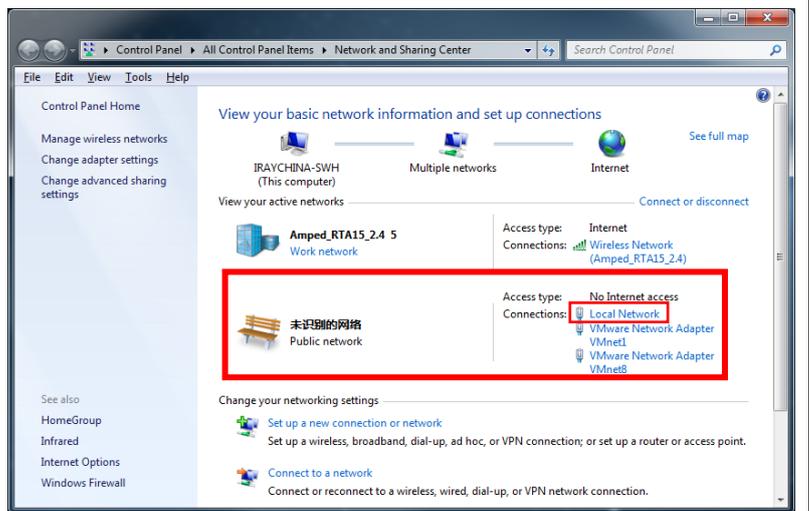


1. Open SDK
2. Click "Home"
3. Click "Venu1012V\_1"
4. Click "Connect"

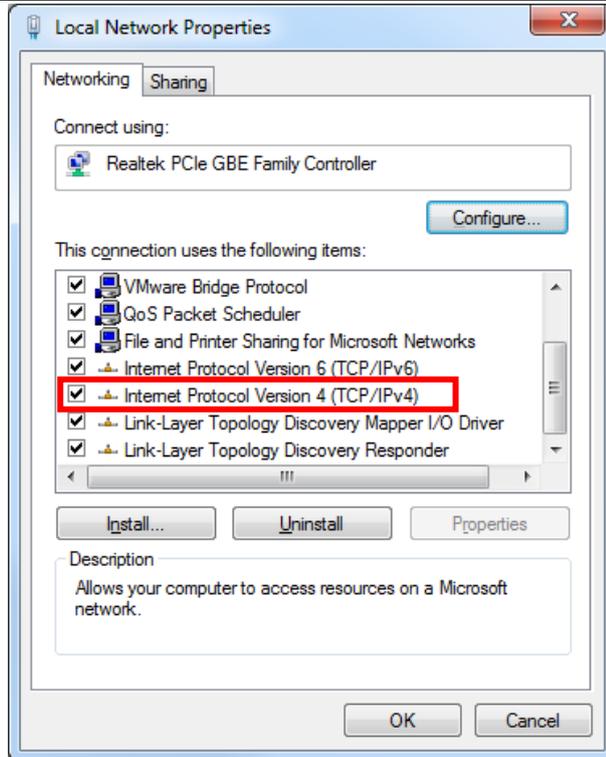


### 3.4 Network Configuration

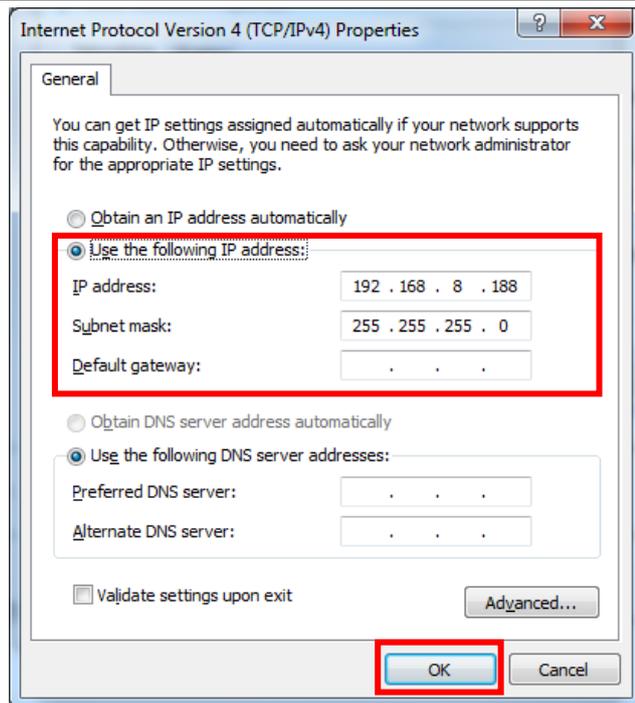
- 1. Wait until physical layer connection is established
- 2. Open local network management interface



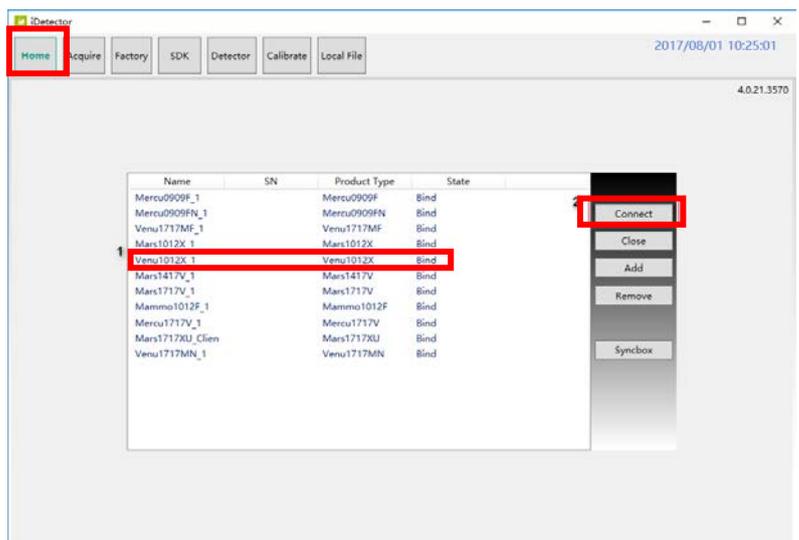
Double click "TCP/IPv4"



1. Enter the IP address and Subnet mask as follow:  
 IP address: 192.168.8.188  
 Subnet mask: 255.255.255.0
2. Click "OK".



5. Open SDK
6. Click "Home"
7. Click "Venu1012V\_1"
8. Click "Connect"



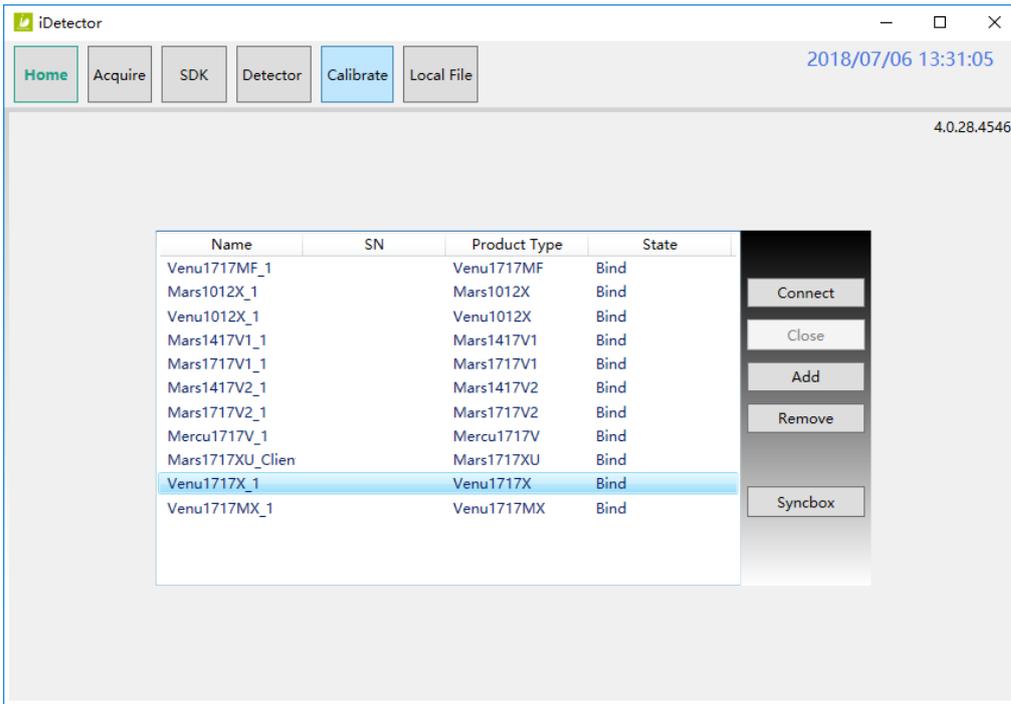
### 3.5 User Interface

SDK supply iDetector as tool software:

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

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

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



Tab Function description

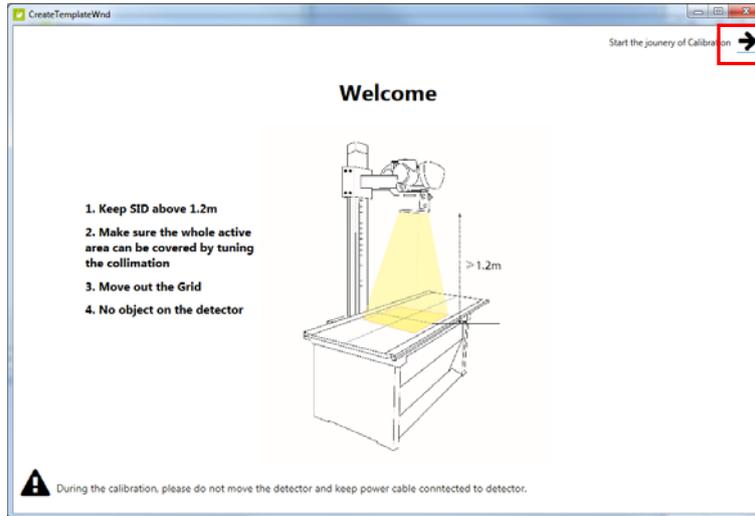
Tab	Function description
Home	Connect FPD and view the connect state
Acquire	Acquire image, select correction mode, save image and process image
SDK	config.ini setting, log level setting
Detector	Configure parameters for detector.
Calibrate	Generate calibration files and manage the calibration files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

## 3.6 Calibration

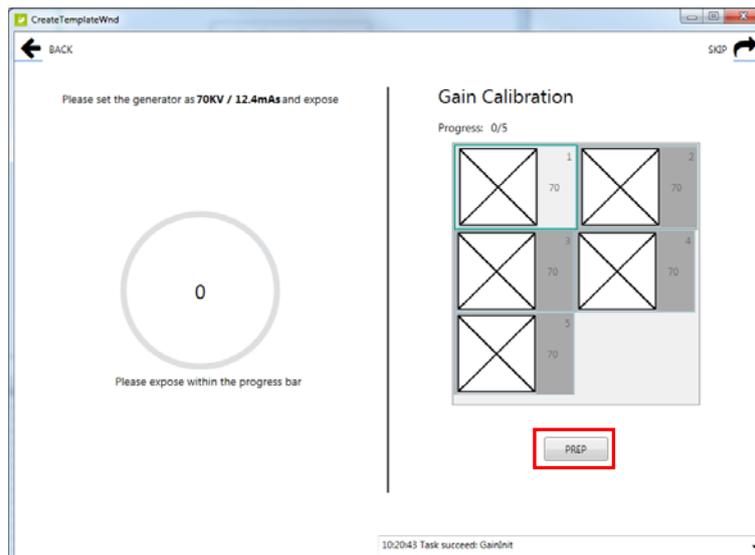
### 3.6.1 Generate Gain Template

1. Select **HWPostOffset** option on “Acquire” page. Otherwise, the generated gain template maybe not good.
2. The FDD (Focus to Detector Distance) should be higher than 1.2m. Ensure the whole active area is covered by the X-ray beam and no objects between the X-ray source and Detector.

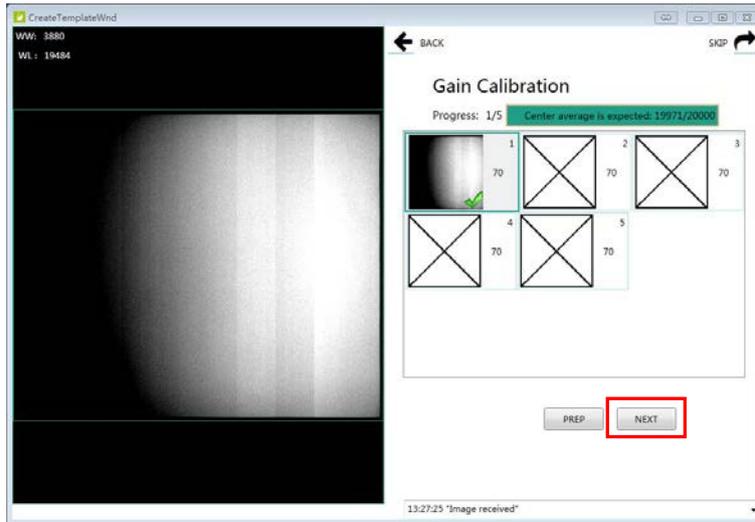
3. Click arrow icon to enter Gain Calibration Interface.



4. Click "PREP" button.



5. Exposure and acquire images. If gray value of the image does not meet the requirement, the mAs of X-ray generator need to be adjusted. A green tips box will be displayed if the gray value is acceptable.



6. Repeat step 4, step 5 until all images are captured.

7. Generating Gain template file.

Note:

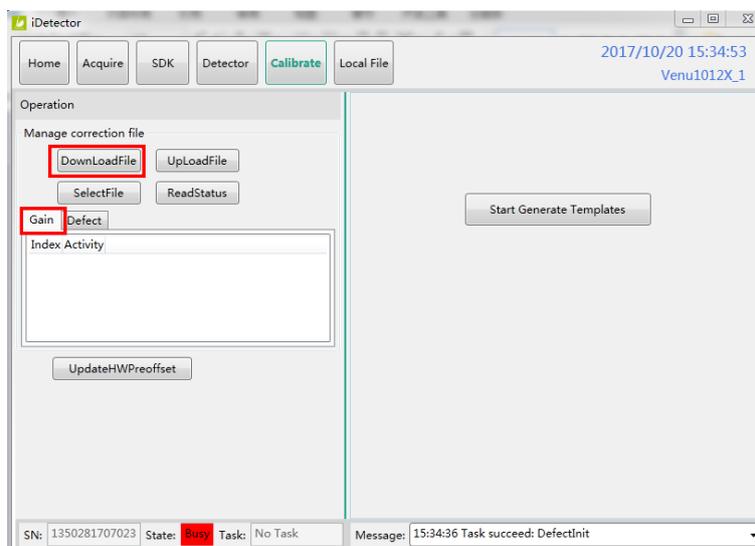
1. In order to achieve better performance, new gain template should be used when the kV of the X-ray generator is changed.

2. In order to achieve better performance, new gain template should be used when the position of the detector is changed.

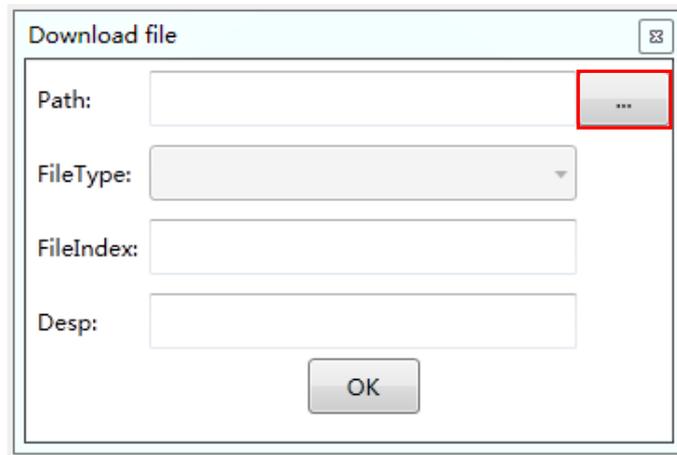
3. In order to achieve better performance, new gain template should be used when the FDD is changed.

### 3.6.2 Download Gain Template

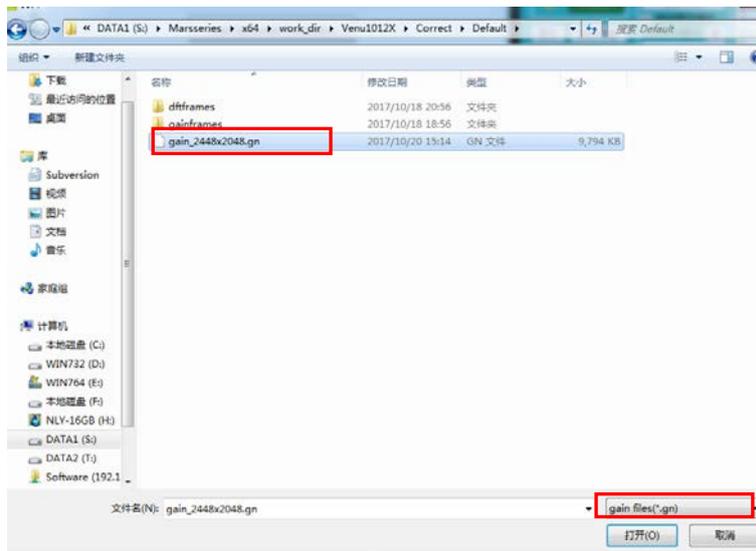
1. Click “Gain”, then Click “DownloadFile” button.



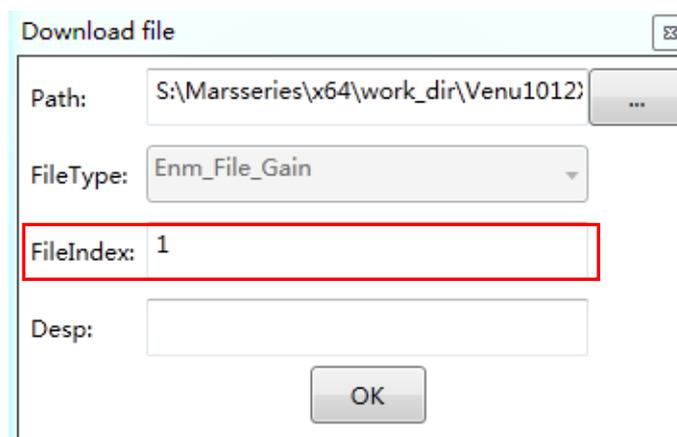
2. Click “...” to choose the path.



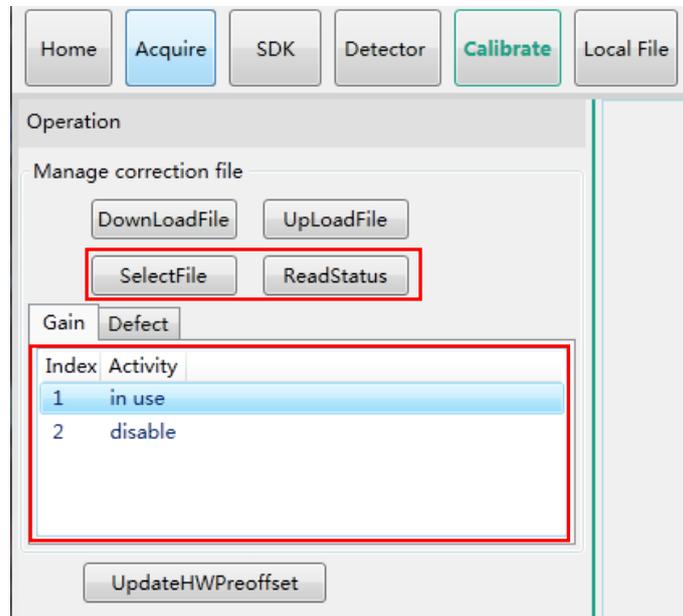
3. Select the “.gn”file and click “Open(O)” button.



4. Input the File Index. For example, input “1”. Click “OK” button until the file is downloaded successfully.



5. Click “ReadStatus” button, choose the right index and click “SelectFile” button.

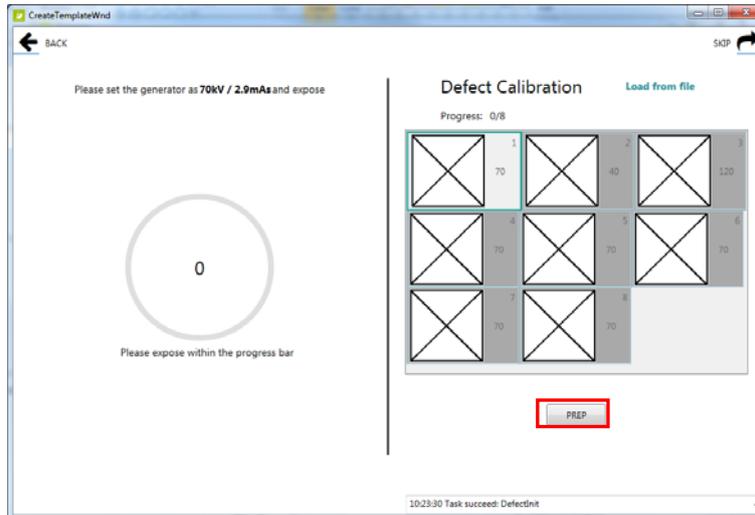


### 3.6.3 Generate Defect Template

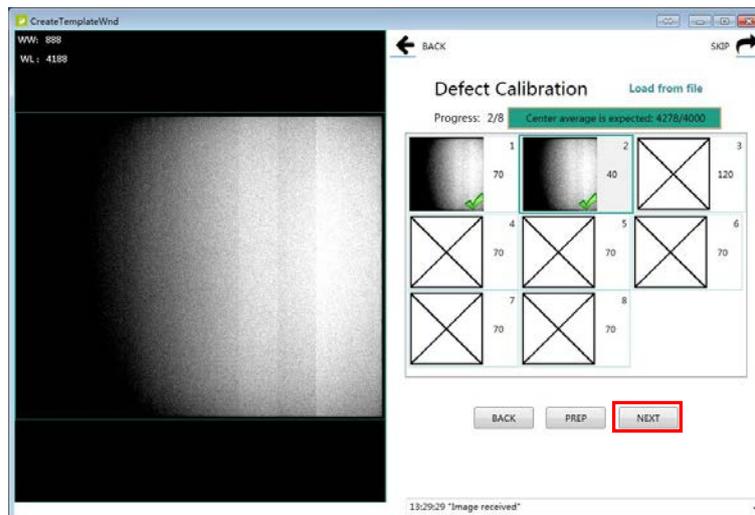
1. Select **SWPostOffset** option on “Acquire” page.
2. The FDD (Focus to Detector Distance) should be higher than 1.2m. Ensure the whole active area is covered by the X-ray beam and no objects between the X-ray source and Detector.
3. Click arrow icon to enter Defect Calibration Interface.



4. Click “PREP” button.



5. Exposure and acquire images. If gray value of image does not meet the requirement, the mAs of X-ray generator need to be adjusted. A green tips box will be displayed if the gray value is acceptable.



6. Click “Next” button. Repeat step 4, step 5 until all images are captured.

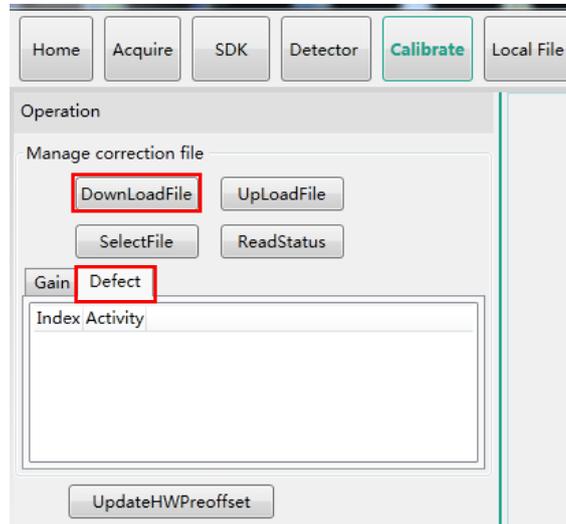
7. Click “Next” button(on right-top corner of window) to generate defect template file.

Note: It is no necessary to update the defect template unless new defect point or defect line is found.

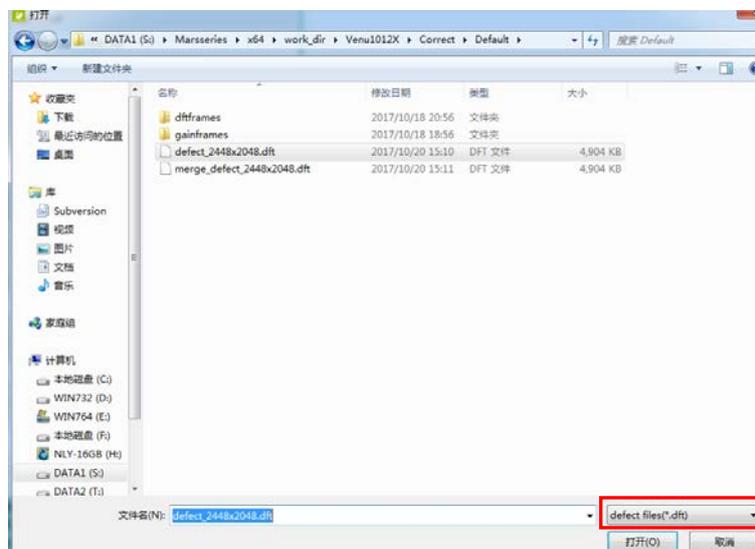
### 3.6.4 Download Defect Template

It is very similar to the steps about how to download gain template.

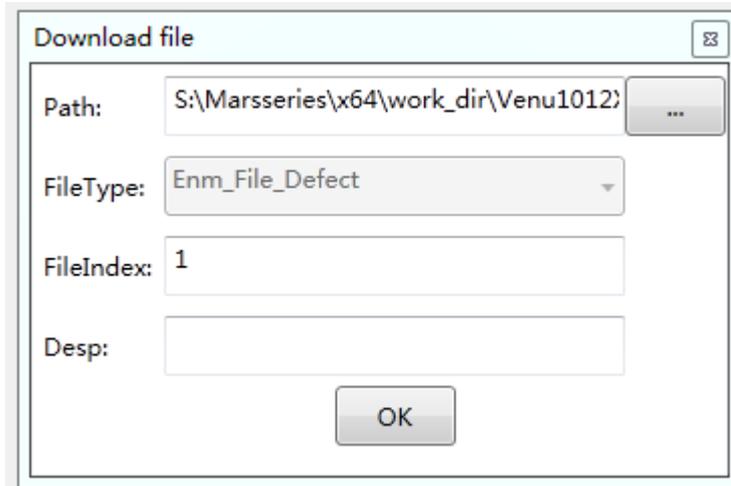
1. Click “Defect”, then Click “DownloadFile” button.



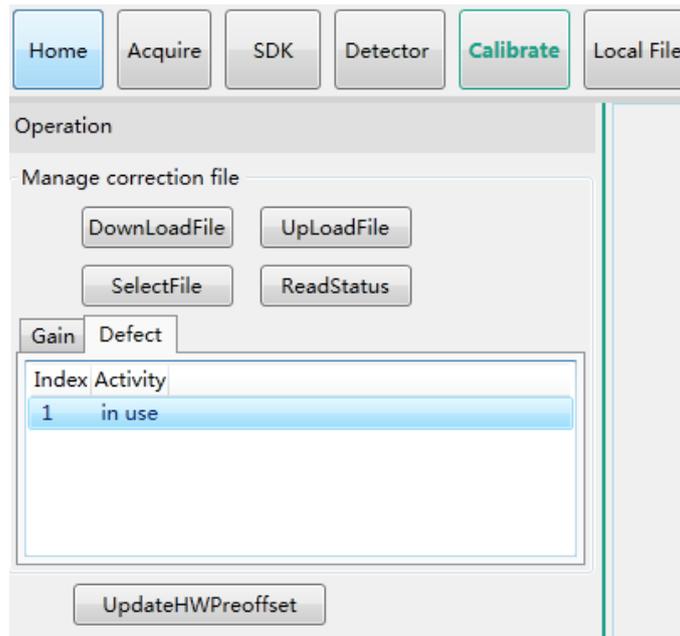
2. Select the “.dft” file and click “Open(O)” button.



3. Input the File Index. For example, input “1”. Click “OK” button until the file is downloaded successfully.



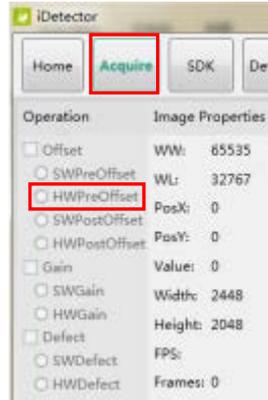
4. Click “ReadStatus” button, choose the right index and click “SelectFile” button.



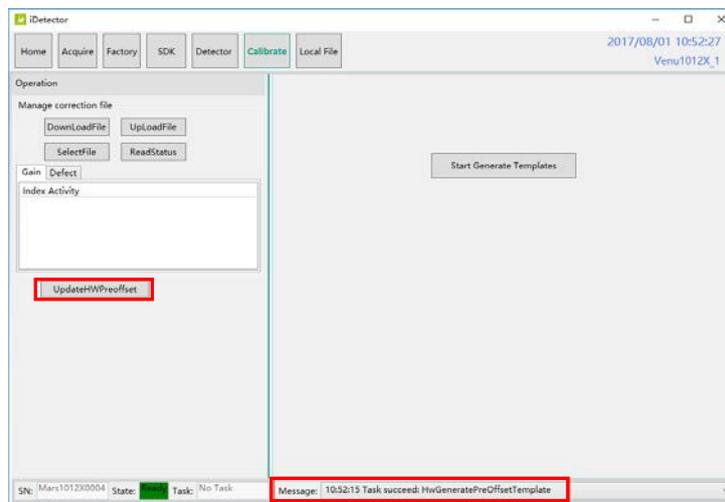
### 3.6.5 Pre-offset Template Update

The pre-offset template can't be updated automatically. And it may effect the uniformity of the corrected image when the pre-offset template is invalid. The operator can update the template within two steps.

1. Select "HWPreOffset" in "Acquire" interface.



2. Click "UpdateHWPreoffset" button and wait until the message box shows "Task succeed".



## 4 OPERATION

4.1	STEPS FOR ACQUIRING IMAGE.....	41
4.2	INNER MODE OPERATION.....	41
4.3	FREESYNC MODE OPERATION.....	44
4.4	AFTER USE.....	46

## 4 Operation

### 4.1 Steps for acquiring image

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

To Acquire X-ray image is the main operation of Venu1012V. Most importantly, detector should build synchronization with X-ray generator. Venu1012V has Inner mode and FreeSync mode.

### 4.2 Inner Mode Operation

Workstation is a host PC device installed with iDetector and SDK. In Inner mode, workstation does not control x ray generator. The operator should complete the exposure within “Exposure Window Time”.

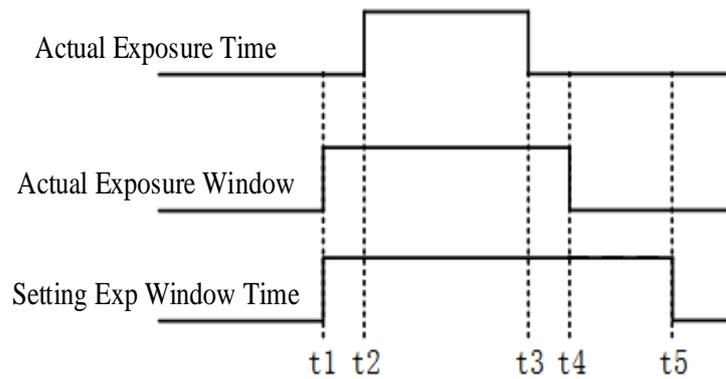
#### 4.2.1 Parameters Setting

When connected, parameters can be set through “Detector” interface. Please DO NOT change the parameters casually. Incorrect parameters may lead to bad image quality or not work properly.

Item	Description	Default
Exp Window Time	Exposure window. For Inner mode, exposure need be completed in exposure window. Otherwise, image will loss dose.	5000(ms)
Acquire Delay Time	The time span between the end of exposure and the start of acquisition.	10(ms)

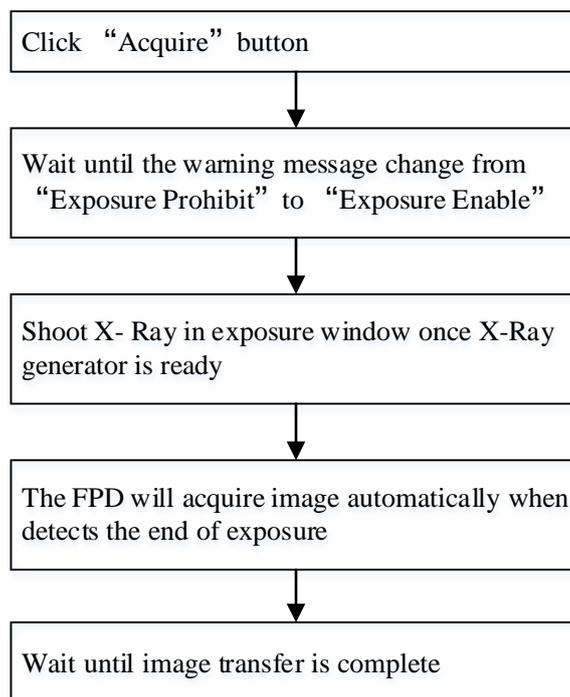
Exp Window Time(ms):  $t_5-t_1$ . The time span that detector can accept X-ray, can be set from 1000ms to 5000ms.

Acquire Delay Time(ms):  $t_4 - t_3$ . The time span between the end of exposure and the start of acquisition.

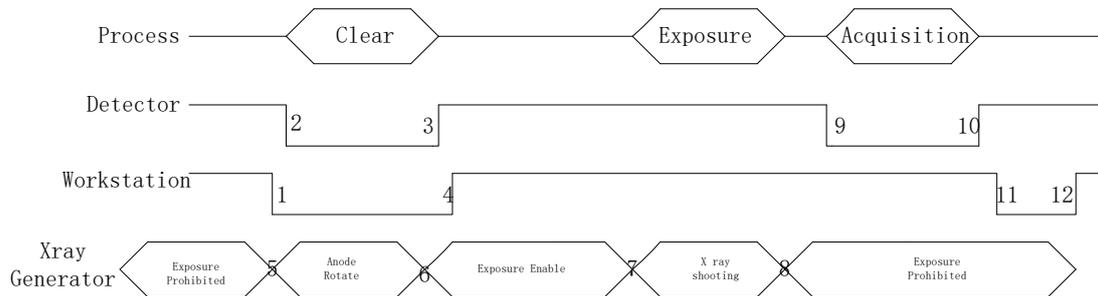


## 4.2.2 Work Flow

When connected, select “HWPostOffset”, “HWGain” and “HWDefect”. Then image can be acquired by clicking “Acquire” button.



## 4.2.3 Timing Setting



1. Workstation receives "Acquire" request and sends "Clear" to the panel.
2. Panel receives "clear" from Workstation, start clear operation. Meanwhile, panel would send "Exposure Prohibited" to Workstation.
3. Panel finishes "Clear" operation and send "Exposure Enable" to Workstation.
4. Workstation shows "Exposure Enable" on the iDetector's message bar to tell user shoot X ray.
5. User triggers x ray generator to initialize and do anode rotation to prepare for X ray shooting
6. X-ray generator finishes preparation and reminds users.
7. X ray generator begins releasing x ray
8. X ray generator finishes x ray shooting.
9. X ray sensor in panel triggers panel to start image acquisition operation.
10. Panel completes image acquisition and begins to send data to Workstation.
11. Workstation starts receiving image data from panel.
12. Workstation receives preview image data from panel and display the preview image.

If Hardware Pre-offset and Hardware calibration is selected, image got is the final image.

If Software Pre-offet and Software Calibration is selected, image got would be raw image, Workstation would finish image processing and image is shown on screen.

If Hardware Post offset and Hardware calibration is selected, image got from panel will be preview image . After step12, panel would do another dark image acquisition. With both light and dark image, panel completes correction and calibration process. Finally, panel uploads processed image to Workstation and image is shown on screen.

If Software Post offset and Software calibration is selected, image got from panel would be preview image. After step12, Workstation sends another “clear Acquire” to panel , panel would do dark image acquisition and uploads dark image to Workstation. With both light and dark image, Workstation completes correction and calibration process. Finally, processed image is shown on screen.

Hardware post offset, hardware gain and hardware defect should be selected in normal operation .

However, software post offset should be selected when generate the defect template.

#### 4.2.4 Abnormal Action

Action1: after Step4, if user wants to cancel X ray exposure cycle, iDetector provides an “Abort Exp” function to close exposure window.

Action2: after Step4, if user does not shoot x ray until the exposure window time is run out, panel would close exposure window automatically and send a message to Workstation that waiting for X ray shooting is overtime. Meanwhile, panel would also start image acquisition. After acquisition, panel sends image to Workstation.

### 4.3 Freesync Mode Operation

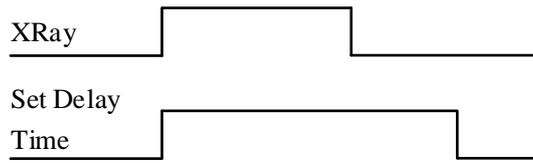
Workstation is a host PC device installed with iDetector and SDK. In Freesync mode, workstation does not control x ray generator. The FPD will detect the start of X-Ray and acquire the image automatically.

#### 4.3.1 Parameters Setting

When connected, parameters can be set through “Detector” interface. Please DO NOT change the parameters casually. Incorrect parameters may lead to bad image quality or not work properly.

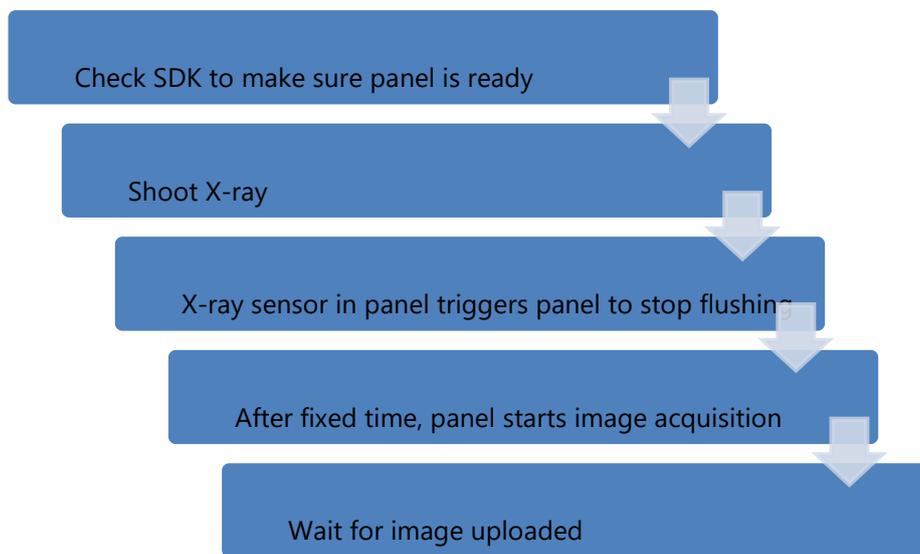
Item	Description	Default
Set Delay Time	When X-Ray is detected, the detector will start to acquire image after Set Delay Time.	1000(ms)

Set Delay Time: Can be set to 1000 and 2000.

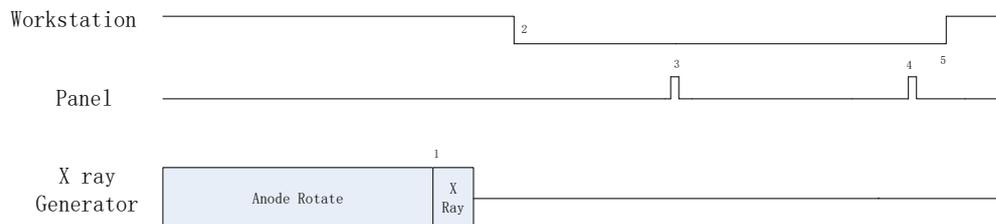


### 4.3.2 Work Flow

When connected, select “HWPostOffset”, “HWGain” and “HWDefect”. Once X-Ray is detected, the FPD will acquire the image automatically.



### 4.3.3 Timing Setting



1. X-ray generator is ready for X-ray shooting and begins to release X-ray.
2. Workstation receives “Exposure Prohibited” from Panel.
3. Panel starts uploading preview image to Workstation. If hardware offset is selected, panel would do offset first, and then upload preview image (2X2 binning).
4. Panel starts uploading Post-dark image to Workstation. If hardware offset is chosen, panel would do correction and calibration first, then upload processed image to Workstation.
5. Workstation receives “Exposure Enable” from Panel.

## 4.4 After use

- Disconnect the software
- Power off
- Keep it clean
- Store under specified conditions

## 5 REGULATORY INFORMATION

5.1	MEDICAL EQUIPMENT SAFETY STANDARDS.....	48
5.2	GUIDANCE AND MANUFACTURE'S DECLARATION FOR EMC.....	49
5.3	PRODUCT LABEL.....	52

## 5 Regulatory Information

### 5.1 Medical equipment safety standards

#### ◆ Medical equipment classification

Type of protection against electrical shock	External electrical power source equipment Class I Equipment
Degree of protection against electrical shock	<b>No Applied Parts.</b>
Degree of protection against ingress of water	IPX0
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide Not suitable for use in the oxygen rich environment

#### ◆ Product safety standards

MDD (93/42/EEC)	Medical Device Directive
EN ISO 13485:2012/EN ISO 13485:2012/AC:2012	Medical devices --- Quality management systems --- Requirements for regulatory purposes
EN 60601-1:2006/A1:2013/ IEC 60601-1:2005/A1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
AAMI / ANSI ES60601-1:2005/(R)2012+A1:2012, C1:2009/(R)2012 +A2:2010/(R)2012	(Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod).
CAN/CSA-C22.2 NO. 60601-1:14	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)
EN 60601-1-2:2015/ IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: 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
EN 60601-2-54:2009+A1:2015 /IEC60601-2-54:2009+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 ISO 14971:2012	Medical device – Application of risk management to medical devices
EN ISO 15223-1:2016 /ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

## 5.2 Guidance and Manufacture’s Declaration for EMC

### EMI & EMS Compliance Table

Table 1 - Emission

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

### EMS Compliance Table

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications	IEC 61000-4-3	Refer to table 3

equipment		
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, $\pm 5$ kHz 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		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
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 and 70% UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 cycles

\* Professional healthcare facility environment.

\* A description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES

\* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

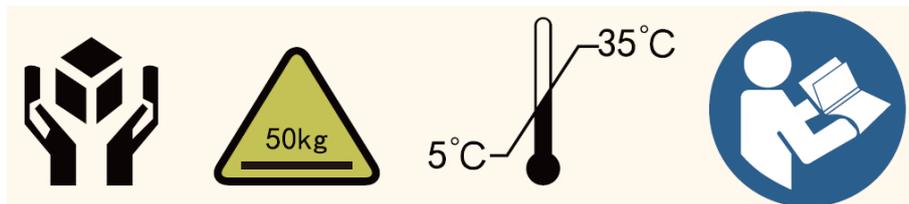
\* A list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable.

Name	Length	Shielding or not	Quantity	Classify
AC Power Cable	1.8m	No shielding	1	AC Power
Ethernet Cable	15m	Shielding	1	Signal

\* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

\* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Venu012V, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## 5.3 Product Label





### 平板探测器及其影像系统

产品型号: Venu1012V-TSI  
 接入电源: 适配器供电输入 24V  1.2A  
 附属设备: Venu1012V-TSI GB9706.14-1997

 上海奕瑞光电子科技股份有限公司  
 上海市浦东新区  
 瑞庆路590号9幢2层202室

其它内容详见说明书



  
20XX-XX





  
20XX-XX-XX

## Flat Panel Detector

Model: Venu1012V-TSI  
 Power: Adapter Port Input 24V  1.2A

iRay Technology Co., Ltd.  
 Rm.202, Building 7, No. 590, Ruiqing Rd. ,  
 Zhangjiang East, Pudong, Shanghai, China  
[www.iraygroup.com](http://www.iraygroup.com)

 iRay Europe GmbH  
 In den Dorfwiesen 14, 71720 Oberstenfeld Germany

  
20XX-XX







SN

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## 6 SERVICE INFORMATION

6.1	PRODUCT LIFETIME .....	54
6.2	REGULAR INSPECTION AND MAINTENANCE .....	54
6.3	REPAIR.....	54

## **6 Service Information**

### **6.1 Product Lifetime**

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

### **6.2 Regular Inspection and Maintenance**

In order to ensure the safety of patients and operator, 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.

### **6.3 Repair**

If problem cannot be solved even taking the measures indicated in troubleshooting, 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.

## APPENDIX

APPENDIX.....	56
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## Appendix A Information of Manufactures



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