CE 0197

# Digital Intra-oral X-Ray Imaging System
# Pluto0001X /Pluto0002X
# User's Manual

Document Version: A0
Document ID: 111-201-02
Release Date: 2020-12-08

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.

# To Customers

Congratulations on your purchase of the Pluto0001X/ Pluto0002X Digital Intro-oral X-Ray Imaging System (Hereinafter referred to as Pluto0001X/Pluto0002X) which is manufactured by iRay Technology Co. Ltd. (Hereinafter referred to as iRay).

At iRay, we strive to not only make the world-class products that deliver the good value possible to our customers but also offer the highest quality of service and customer care. Please take time to read through this user guide in order to utilize the product effectively. We hope you enjoy the experience with iRay Pluto0001X/Pluto0002X.

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

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**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.

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**Copyright**



**Trademarks**

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

**Symbols and Conventions**

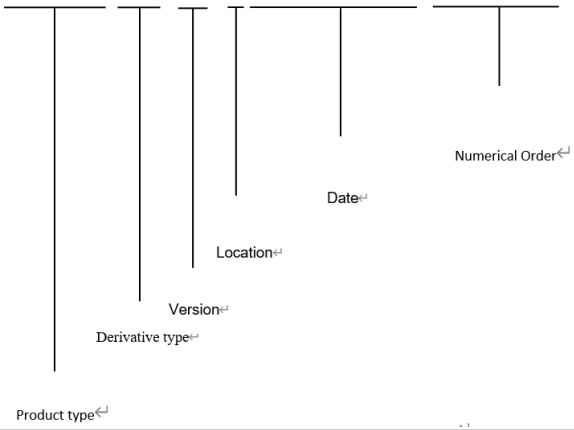
The following symbols and conventions are used throughout the user guide.

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

Labels and markings on the equipment

The contents of the labels and markings on iRay Pluto0001X/ Pluto0002X product are indicated below:

| | |
|---|---|
| | Caution: please refer to the instructions in the user manual. |

| | |
|---|---|
| SN | This symbol is used to identify the manufacture's series number which is after, below or adjacent to the symbol. The series number of iRay products is usually made of 19 digits as shown below:<br>  <br> |
| | This symbol is used to indicate the name, address of the manufacturer.<br>The date of manufacture, as well as the name and address of the manufacturer, is combined in this symbol. |
| EC REP | This symbol is used to indicate the name and address of iRay authorized representative in the European Union. |
| | This symbol is used to indicate consultation of the user guide for general information. |
| | Safety Signs: please refer to the user guide for safety instructions. |
| | Use-by date, Indicates the date after which the medical device is not to be used. |
| | Type BF applied part |

| | |
|---|---|
| IP68 | IP Grade of the sensor according to IEC60529 |
| Rx only | Caution: Federal law restricts this device to sale by or on the order of a physician. |
|  | Package symbol, fragile, handle with care |
|  | Package symbol, keep away from rain |
|  | Package symbol, keep away from sunlight |
|  | Package symbol, keep the way up, it shows the correct upright position of the distribution packages for transport and storage. |
|   | Package symbol, stacking limit by number, it shows the maximum number of identical transport package which may be stacked on the bottom one, where “n” is the limiting number. |
|  | Package symbol, indicates the package shall be stored, transported, and handled within temperature limits. |
|   | Package symbol, indicates the range of humidity to which the medical device can be safely exposed. |
| CE 0197 | CE marked product |

# CONTENTS

# 1. Safety Information

1.1 Safety precautions

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

| WARNING | |
|---|---|
| Installation and environment of use<br>  <br> | Do not use or store the equipment near flammable chemicals such as thinner, benzene, etc.<br>If chemicals are spilled or evaporate, it may result in fire or product damage through contact with electric parts inside the equipment.<br>Do not connect the equipment with anything other than specified.<br>Doing so may result in personal injury or product damage.<br>Do not install or use in the following environment, or it may cause fire, personal injury or product damage:<br>Facilities near water sources<br>In direct sunlight<br>Close to air condition or ventilation<br>Dusty to a heat source as a heater<br>In a salty or acidic environment<br>High temperature and high humidity<br>Ice or condensation<br>In the environment easy to vibrate<br>On a slope or in an unstable area<br>▪ Ensure that the cable is not knotted or wound during use.<br>Or it may cause the equipment damage or personal injury. |
| **WARNING** | |
| Handling<br>  <br> | ▪ Never disassemble or modify the equipment. No modification of this equipment is allowed.<br>▪ Follow the below instructions to prevent damage to the sensor and cable<br>Do not twist, bend, pull and pinch the cable strongly<br>Do not strike or drop the equipment.<br>Do not touch the pin of the USB connector<br>Do not put the equipment and pointed objects together. |
| When a problem occurs | Please unplug the USB connector when a problem happened and contact the supplier or local dealer:<br>▪ When there is smoke, an odd smell or abnormal sound.<br>▪ When liquid has been spilled into the equipment or a metal object has entered through an opening.<br>▪ When the equipment has been dropped and damaged. |

| | |
|---|---|
| Maintenance and inspection  | ▪ Check the sensor and cable for any damage or abnormal conditions<br>▪ Check that the PC and software are working properly |
| **CAUTION** | |
| Hygienic protection and cleaning  | ▪ Hygienic protection<br>The sensor should be covered with hygiene sheath when you apply the sensor to a patient<br>Note that a hygiene sheath whose is single use only. The bag should be renewed for each patient to prevent any possible transmission of infective agents.<br>Use a hygiene bag whose size fit the size of the sensor<br>Purchase the medical purpose sheath via formal purchase channels:<br>Dental Intraoral Camera Sheaths<br>▪ Cleaning<br>Pay special attention to avoid the risk of damage when cleaning the sensor<br>The sensor should be cleaned frequently. Wipe the sensor and the cable with soft cloth which is damped with 70% isopropyl alcohol when the USB connector is not connected.<br>Do not apply any liquid or disinfectant to the product except 70% isopropyl alcohol.<br>Do not immerse the sensor in disinfectants or any other chemicals<br>Do not sterilize the product by heating, autoclaving or UV |
| **CAUTION** | |
| ⚠ CAUTION | No valuable clinical obtained after exposure due to operational reasons or failure of the device<br>The sensor performance was abnormal, no valuable clinical images obtained after exposure due to the interference of the equipment which is not conforming to IEC60601-1-2standard. |
| | The sensor is used in conjunction with the registered x-ray machine. Installation and software operation of this product, please refer to the product user's manual. For the other operation, please refer to the operation manual of the x-ray machine. |

## 1.2 Notes for Using

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

***Before using***

- Please check whether the USB connector is dry or clean before connecting the USB connector
- Please hold the control box of the USB when plugging the USB connector, do not touch the pin of USB connector

***During using***

- Do not move the USB connector during the use of the sensor
- When the sensor is working, the temperature of the sensor will increase. Please pay attention to the temperature of the sensor to avoid the risk of injury.
- The detector should warm up for 15 minutes before exposure or updating the gain map or defect map.

***During exposure***

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

***After using***

- After the USB port is pulled out, please take care of the USB connector to avoid the risk of damage.

The sensor should be stored in a place free of chemicals or gases and free from adverse factors such as pressure, high temperature, humidity, direct sunlight, dust, oxides or sulfides.

When the sensor is out of using, it is recommended to put it into the product package box, to avoid damage.

## 1.3 Storage and Operation Environment

Ensure that the sensor is stored and used in the following environment:

| | Temperature | Temperature variation | Humidity | Barometric pressure | Barometric change |
|---|---|---|---|---|---|
| Operation | 10~35℃ | ≤1℃/min | 20~90% RH | 700~1060mbar | ≤10 mbar/hour |
| Storage | -10~55℃ | ≤1℃/min | 10~95% RH | | ≤20 mbar/hour |

▪ Do not operate the sensor at an altitude more than 3000m, the system connected with the sensor also can operate at an altitude less than 3000m.

▪ Do not expose the sensor to a hot and humid environment, otherwise it may result in product damage

# 2. General Introduction

## 2.1 Indications for Use

The Digital Intra-Oral X-Ray Imaging System (Pluto0001X/ Pluto0002X) is used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination and the diagnosis of structural diseases. The product is expected to be used in hospitals and clinics, operated and used by trained professionals under the guidance of doctors.

This device is not intended for mammography and conventional photography applications.

This device is suitable for providing dental radiography imaging for both adult and pediatric.

According to the expected use of Pluto0001X/Pluto0002X and the result of risk assessment, the product essential performance is identified: image acquisition of X-ray sensor and image process.

This manual contains information about Pluto0001X/ Pluto0002X. All users should read and understand this manual before using the product. All information in this manual,

including illustrations, is based on the device prototype. If the device does not contain these contents, they will not apply to this device.

2.2 Component of the imaging system

The component of digital intraoral X-ray imaging system are sensor and image acquisition software iRayDR.

2.2.1 Image acquisition workstation

The image acquisition software iRayDR is used to acquire and display the image, patient management, examination management, image storage and image printing administration.

Note: the detail description of the image acquisition workstation are showed in the user manual of the iRayDR.

2.2.2 Sensor

The pluto0001X and Pluto0002X feature a 20 μm pixel pitch CMOS sensor with directly deposited CsI:Tl scintillator which ensures optimal resolution. Made from a strong sealed Kevlar shell, the sensor has an ergonomic design with smooth edges, rounded corners, and a flexible cable for maximum patient comfort. An easy to use hi-speed direct USB interface enables a simple connection to a PC without need for an additional control box. The optional iRay intra-oral software application makes it easy to acquire, enhance, analyze, view and share images from the Pluto 0001X/Pluto0002X sensor.

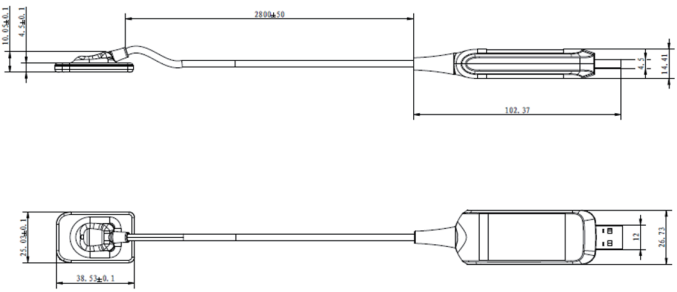


Fig.1 Pluto0001X outline(unit: mm)

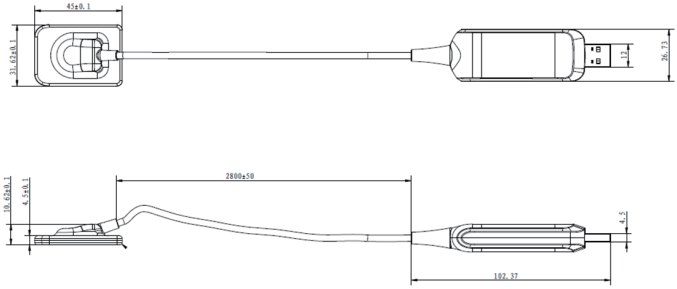



Fig.2 Pluto0002X outline(unit: mm)

## Technical Specification

| Item | Detailed information | |
|---|---|---|
| Pixel matrix | 1500×1000 | 1800×1300 |
| Pixel Pitch | 20μm | |
| Scintillation Screen | CsI | |
| Sensor size | 38.5mm×25mm×5mm | 40mm× 31mm×5mm |
| AD Conversion | 16bits | |
| Spatial resolution | Limited: 25lp/mm<br>Typical: >14.5lp/mm | |
| Ingress Protection | IP68<br>(the highest point of enclosures with a height greater than 1000mm below the surface of water, and the duration of the test is more than 30 minutes) | |
| Sensitivity | >50lsb/uGy | |
| Trigger sensitivity | <100μGy/s | |
| Max linearity dose | >400uGy | |
| Length of cable | <3m | |
| interface | Direct USB, USB2.0 | |
| Power | <2W | |

## 2.3 Timing and Electrical characteristics

| | Condition | Min | Type | Max | Unit |
|---|---|---|---|---|---|
| Integration time | | 0.05 | | 4 | s |
| Current consumption | Image sensor head | | 30 | 50 | mA |
| | USB driver | | 200 | 350 | mA |
| Readout time | | | 1 | 1.5 | s |

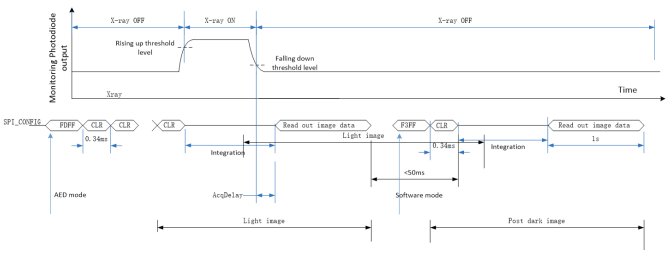
| | | | | | |
|---|---|---|---|---|---|
| AcqDelay | Can be Configured | | | 50 | ms |
| Image cycle time | | | | 6 | s |

- Trigger Mode

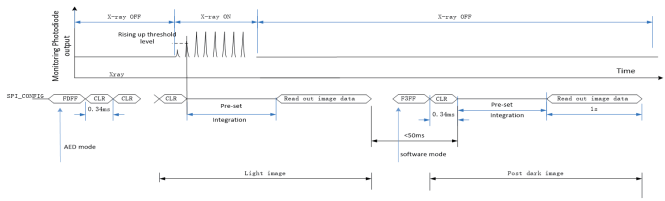
One is be triggered by the sensor automatically, the other is trigged by the software command by an operator. Software trigger mode is only used for debug and can be used by service engineer who is authorized by iRay.

| Type | DC X-tube | AC X-tube |
|---|---|---|
| mechanism | Automatically detect x-ray start and x-ray end | Only detect x-ray start; x-ray end is pre-set by integration time |
| Integration time | Depend on X-ray width | Pre-set and fixed, 0.5s, 1s or 1.5s |

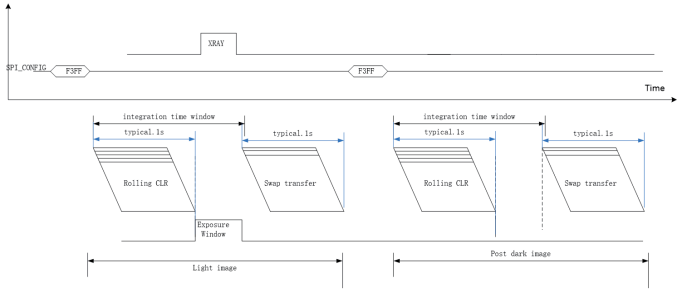
- AED(auto exposure detection) mode-DC x-ray tube




- AED(auto exposure detection) mode-AC x-ray tube



- Software mode




## 2.4 AED trigger sensitivity

The AED trigger sensitivity should be matched with X-ray source dose rate(correlated to power capacity) to achieve the minimum X-Ray width, because the X-Ray during the AED cycle time will not contribute to the image integration.

| AED Trigger sensitivity Level choose | AED cycle time(ms) |
|---|---|
| 20 | 5.5 |
| 50 | 2.3 |
| 100 | 1.5 |
| 150 | 1.0 |
| 200 | 0.7 |
| 300 | 0.5 |
| 500 | 0.3 |

The x-ray machine used with intra-oral sensor in the current is 60-70kV and 1-8mA. For different type of x-ray machine, it is recommended to select the appropriate trigger threshold according to the following tables:

| kV | mA | SID (mm) | Equivalent filter | Skull size | Min Entrance Dose Rate(uGy/s) | Recommend Trigger Level(uGy/s) | Max Entrance Dose Rate(uGy/s) | mA (up to) |
|---|---|---|---|---|---|---|---|---|
| 60 | 1 | 250 | 2mm Al | | 256 | 50 | 1000 | 4 |
| | | | 8mm Al | Standard | 69 | | | |
| | | | 10mm Al | Fat | 51 | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 65 | 1 | 250 | 2mm Al | | 306 | 50 | 1000 | 3.2 |
| | | | 8mm Al | Standard | 91 | | | |
| | | | 10mm Al | Fat | 69 | | | |
| 70 | 1 | 250 | 2mm Al | | 358 | 50 | 1000 | 3 |
| | | | 8mm Al | Standard | 226 | | | |
| | | | 10mm Al | Fat | 90 | | | |

| kV | mA | SID (mm) | Equivalent filter | Skull size | Min Entrance Dose Rate(uGy/s) | Recommend Trigger Level(uGy/s) | Max Entrance Dose Rate(uGy/s) | mA (up to) |
|---|---|---|---|---|---|---|---|---|
| 60 | 3.2 | 250 | 2mm Al | | 927 | 150 | 3000 | 8 |
| | | | 8mm Al | Standard | 251 | | | |
| | | | 10mm Al | Fat | 186 | | | |
| 65 | 3.2 | 250 | 2mm Al | | 1115 | 150 | 3000 | 8 |
| | | | 8mm Al | Standard | 333 | | | |
| | | | 10mm Al | Fat | 253 | | | |
| 70 | 3.2 | 250 | 2mm Al | | 1311 | 200 | 4000 | 8 |
| | | | 8mm Al | Standard | 425 | | | |
| | | | 10mm Al | Fat | 330 | | | |

Note: The dose rate may be different between different x-ray machines with same exposure parameter, which need to adjust according the actual dose rate.

## 2.5 PC configuration

| System | Recommand configuration | Minimum configuration |
|---|---|---|
| System configuration | CPU: IntelCore i3 (R) frequency≥ 2.5G | CPU: IntelPentium(R) frequency≥ 2.0G |
| | Memory: 4GDDR3/4 | Memory: 4GDDR3/4 |
| | Preview Monitor: 1920×1080 | Preview Monitor: 1280×768 |
| Other hardware | Support Serial port communication: USB2.0 port | |
| OS | Win7, Win8, Win10 | |

PC connected to the sensor must be approved by local authorities: for example, by IT equipment safety certificate, NRTL approval, etc..

# 3. Information on Operation

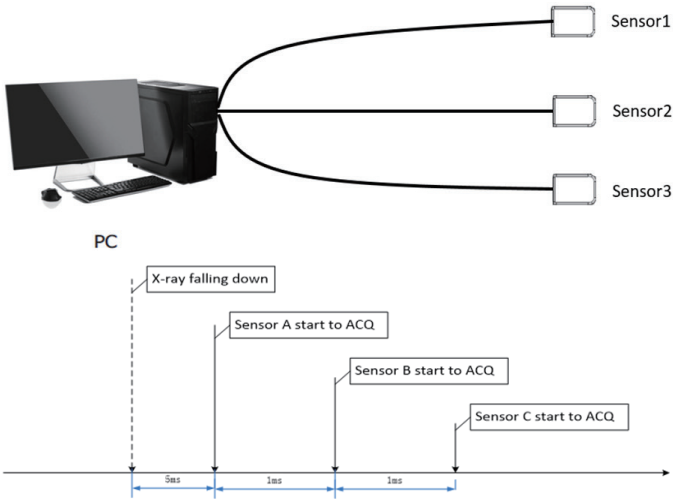
## 3.1 Installation and operation

This chapter mainly introduces the use of DEMO software iDetector(service engineer) to connect the sensor and realize the basic image acquisition and image processing functions.

The detector is connected to the computer via USB, and the image data is transmitted via USB protocol.

## 3.2 Multi-sensor

Multi sensors can be supported by USB ports on PC, or using self-power USB Hub. It up to 9 sensors.




Also, the snesor can be supported to connect by USB-Hub, which can be powered by computer or external power.

## 3.3 Connect Sensor

Double-click to run the “iDetector.exe” in the SDK directory..\Tools\iDetector\x64, to enter into the Home window, see figure 3.3.1.

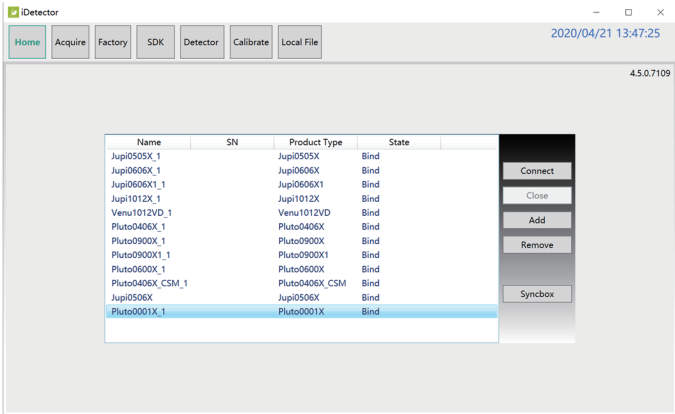



Figure 3.3.1 Home interface

Note: select w32 or x64 according to the computer system.

After sensor is connection successfully, the Acquire tab will be entered, see figure 3.3.2.

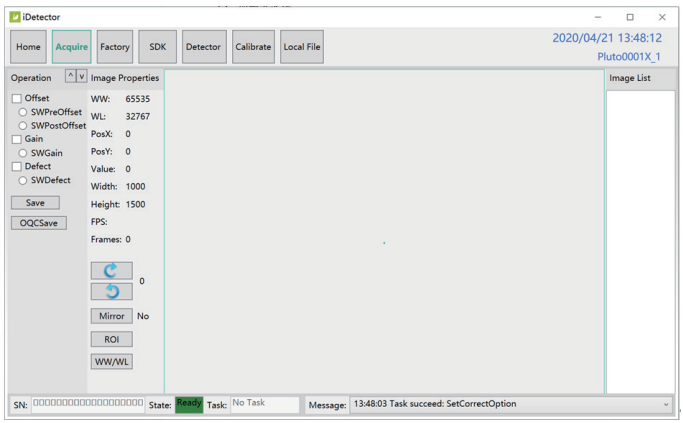
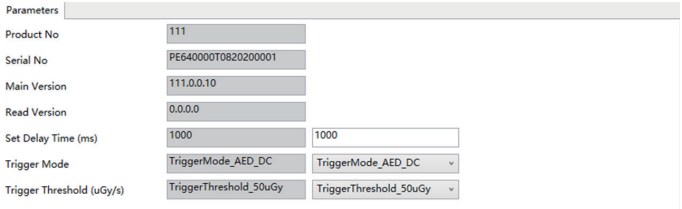


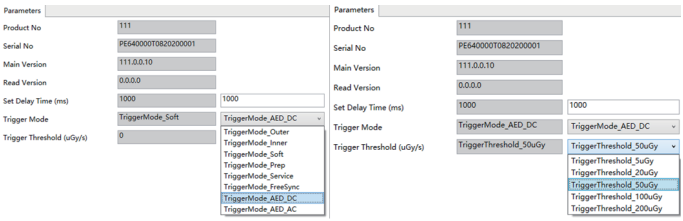

Figure 3.3.2 Acuire interface

## 3.4 Get the first image

After the sensor connected successfully, you can set the AED trigger mode in Detector interface according to the x-ray device.




| Parameters | Description | Note |
|---|---|---|
| Product No | Product number | Read only |
| Serial No | Sensor serial number | Read only |
| Main Version | The Firmware version number | Read only |
| Read Version | | Read only |
| Set Delay Time(ms) | Delay time | Set before exposure and only work in AC mode |
| Trigger Mode | Trigger Mode | Three trigger mode: AED_DC, AED_AC and software. |
| Trigger Threshold(uGy/s) | Trigger threshold | Trigger threshold with different integration time |

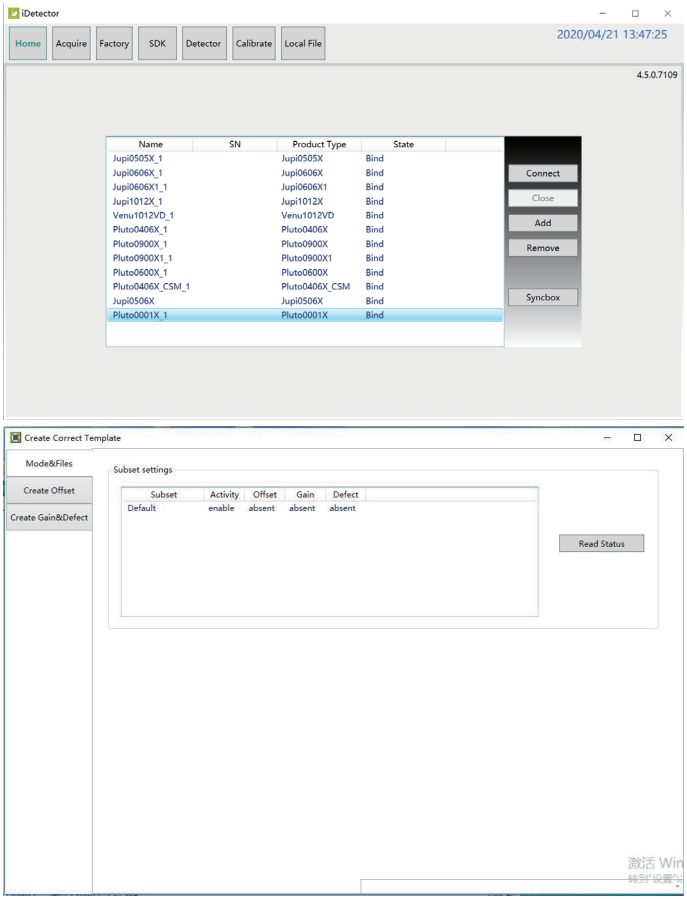



## 3.5 Create correction templates:

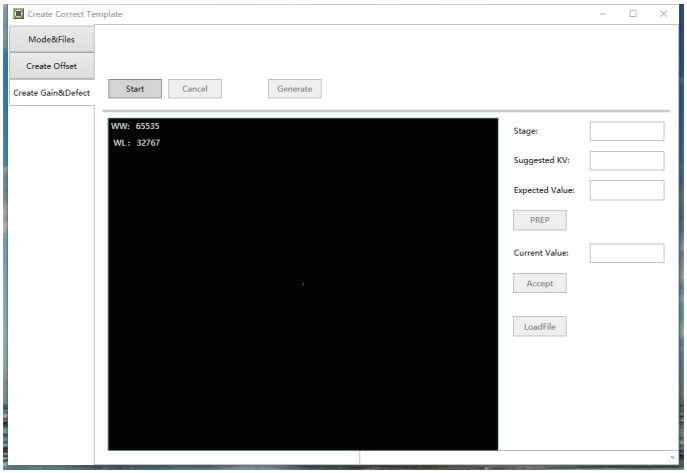
The creation steps of gain and defect are as follows:

1. Double-click iDetector.exe to open image acquisition software, select detector from the list, select “Pluto0001X” and click “Connect”, wait for successful connection.

Select calibrate tab to enter template generation page.



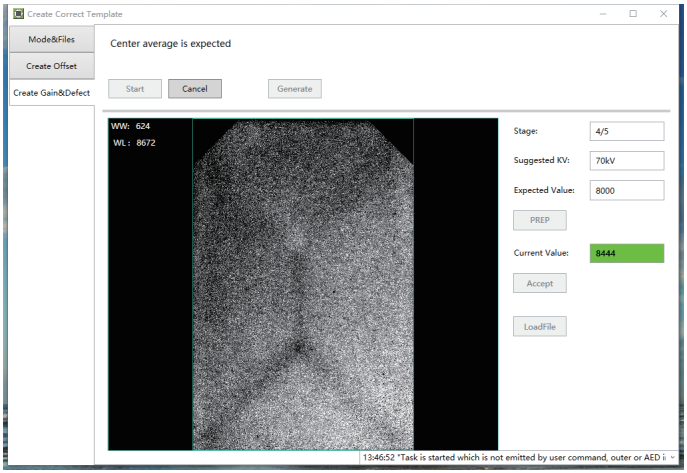

2. Click “Create Gain&Defect” to enter the template creation interface.



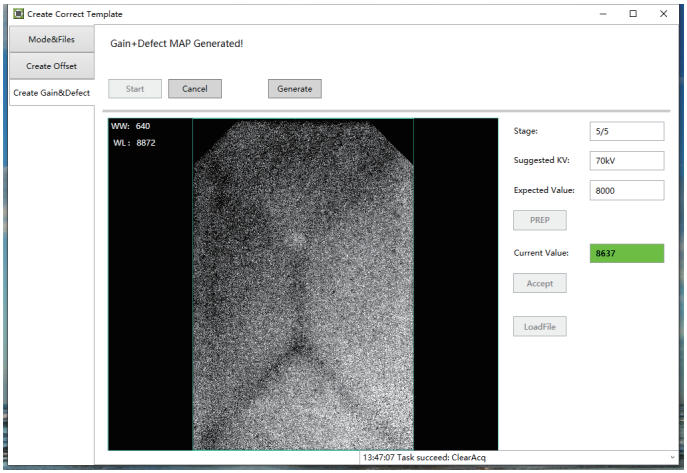

3. Click “Start” to enter the template creation process.

Start to exposure according to the expected parameters

Change the X-ray on time and re-exposure until the gray value meet the expected value. Click “Accept” and enter into next step.



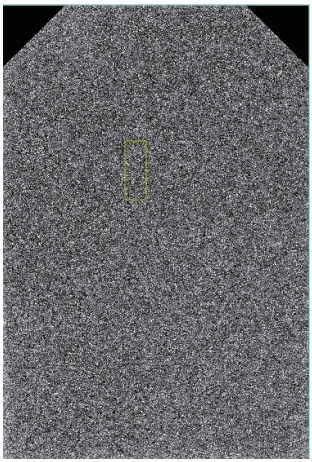

4. Follow the same step to accomplish the other 4 steps; after 5 steps finished, click “Generate” to create template.




It is forbidden to move the sensor during calibration.

## 3.6 Load template

In “Acquire” interface, select Offset as SWPostoffset, Gain as SWGain and Defect as SWDefect”. The image so acquired is a full correction diagram.



CORRECTION TEMPLATE VALIDITY CHECK

The validity of template can be checked in the calibrate

interface:


| Template type | Period of validity |
|---|---|
| Offset | Updated each shot |
| Gain | 1year |
| Defect | 1year |

## 3.7 Defect template modification

The factory default Defect template is also in CD for the user. User can modify the Defect template to add new of previously undetected faulty line and dead pixels.

1. Enter the Local File page, click Load File button and select .dft file to open.

2. After opening file, dead pixels and faulty line setting window will pop up as shown in Figure 3.7.1 below. Type in the coordinate in point area, click Add button to add dead pixels and click Delete button to delete dead pixels;

3. Type in coordinate values of vertical or horizontal line in Line area, click Add button to add faulty line and click Delete button to delete faulty wire;

4. Click Save button to see the modification results in image preview.

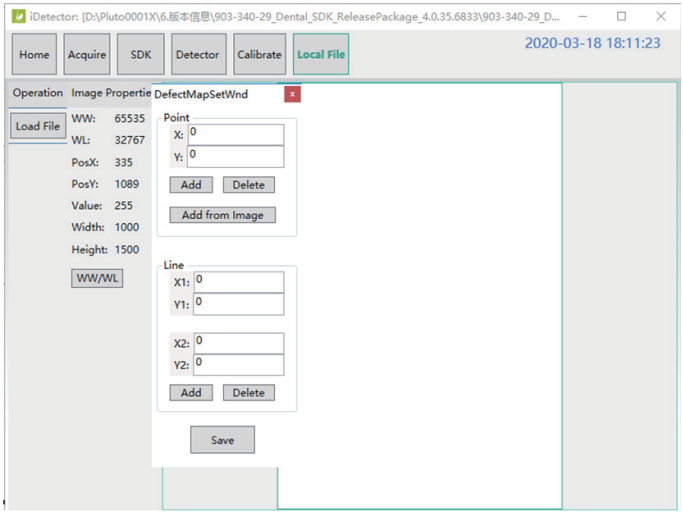



Figure 3.7.1 Defect modification window

You should know some basic electronic knowledge and computer skill to read this user's manual. Users should know how to use iDetector.

If you have any question that not mentioned in this manual, please contact our customer service department (service@iRaygroup.com). We will provide you with the best service.

# 4. Troubleshooting

## 4.1 Log

Users can read the main operation information of the detector from the log. The store path of log is ..\Tools\iDetector\x64\work_dir\Pluto0001X \detector.log, in debug mode, please set the Cfg_LogLevel=0 in config.ini for more detail

## 4.2 Quick troubleshooting

The following table lists the symptom, cause and corrective action.

| Symptom | Cause | Correction active |
|---|---|---|

| | | |
|---|---|---|
| Can not connect sensor | Can not find device | No sensor connection<br>The USB connector is damage<br>Re-plug the USB connector<br>Change the USB port and re-plug<br>Check the cable and sensor for damage or other abnormallities<br>Reinstall the usb driver |
| | It prompts cannot find device | Delete the “Cfg_USBConnStr” in ..\ \Tools\iDetector\x64\work_dir\Pluto0001X\config.ini<br>Delete the “SN” in ..\ \Tools\iDetector\x64\work_dir\Pluto0001X\config.ini |
| No image display | No sensor connection<br>Sensor or cable is damged<br>X-ray dose is too low<br>Exposure time is too short | Check the sensor and cable<br>Increase the distance between tube and sensor<br>Increase mA<br>Increase exposure time<br>Replug the sensor and try again |
| Image from x-ray exposure is pale and grainy | The sensor is moving during exposure<br>X-ray is instability<br>The imaging surfaceofsensor is not facing the x-ray device | Fix the sensor before exposure<br>Check the x-ray machine<br>Check the sensor position |

If the symptom still exists, please contact the service.

Product regulatory information includes safety, EMC and other related regulation requirements of the product and its accessories.

# 5. Information on Safety Regulations

## 5.1 Medical Equipment Safety Standards

- Medical equipment classification

| | |
|---|---|
| Protection type against electrical shock | Not Class I equipment;<br>Not Class II equipment;<br>Not internally power equipment. |

| | |
|---|---|
| Protection degree against electrical shock | With type BF applied part |
| Protection degree against water penetration | IP68 (intraoral sensor part)<br>IPX0 (control box) |
| Mode of operation | Continuous operation |
| Flammable anesthetics | Not suitable for use in situation with flammable anesthetic mixture with air, oxygen or nitrous oxide<br>Not suitable for use in oxygen-rich situation |
| Both Pluto0001X and Pluto0002X are only one power supply and signal input and output part, both the power and signal via a USB port to connect to a PC. | |

- Safety standards reference

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

| | |
|---|---|
| IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) | Medical electrical equipment –Part 1: General requirements for basic safety and essential performance |
| EN 60601-1:2006 + A11:2011 + A1:2013 + A12:2014 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| ANSI/AAMI ES60601-1:2005/ (R)2012 + A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| CAN/CSA-C22.2 No.60601-1:14 | Medical electrical equipment –Part 1: General requirements for basic safety and essential performance |
| KS C IEC 60601-1 | Medical electrical equipment –Part 1: General requirements for basic safety and essential performance |

| | |
|---|---|
| IEC 60601-2-65:2012+A1:2017 | Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment |
| IEC 60601-1-6:2010+A1:2013 | Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability |
| CAN/CSA-C22.2 NO. 60601-1-6:11+A1:2015 | Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability |
| KS C IEC 60601-1-6:2011 | Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability |
| EN 60601-1-6:2010+A1:2015 | Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability |
| IEC 60601-1-2:2014 | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic disturbances– Requirements and tests |
| EN 60601-1-2:2015 | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic disturbances– Requirements and tests |
| EN 62304:2006/ AC:2008 | Medical device software – Software life-cycle processes |
| EN 62366:2008 | Medical devices – Application of usability engineering to medical devices |
| ISO 15223-1:2016 | Medical devices-symbols to be used with medical device labels, labeling and information to be supplied–Part1:General requirements |

## 5.2 Guidance and manufacture's declaration for EMC

### 5.2.1 EMI Compliance Table

- Emissions

| Phenomenon | Compliance | Electromagnetic environment |
|---|---|---|
| RF emissions | CISPR 11 Group 1, ClassB | Professional healthcare facility environment |

### 5.2.2 EMS Compliance Table

- Enclosure USB Port

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|---|---|
| | | Professional healthcare facility environment |
| Electrostatic Discharge | IEC 61000-4-2 | ±8 kV contact<br>±2kV, ±4kV, ±8kV, ±15kV air |
| Radiated RF EM field | IEC 61000-4-3 | 3V/m<br>80MHz-2.7GHz<br>80% AM at 1kHz |
| Near fields from RF wireless communications equipment | IEC 61000-4-3 | Refer to table “Near fields from RF wireless communications equipment” |
| Rated power frequency magnetic fields | IEC 61000-4-8 | 30A/m<br>50Hz or 60Hz |

- Near fields from RF wireless communications equipment

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

- Recommended separation distances between portable or

mobile RF communication device and detector:

Portable RF communications equipment, including antennas, can effect medical electrical equipment. The warning should include a use distance such as “be used no closer than 30 cm (12 inches) to any part of the Pluto0001X and Pluto002X, including cables specified by the manufacturer”.

- Cable provided for EMC

| Cable | Recommended length | Recommended length | Number | Cable classification |
|---|---|---|---|---|
| Cable | 2.8m | shielded | 1 piece | DC power and SIP/ SOP |

- Electromagnetic Compatibility (EMC)

The Pluto0001X and Pluto002X digital intraoral X-ray imaging system need special precautions regarding EMC, and should be installed by authorized personnel and follow EMC guidance in the user manual. The PlutoX series product when in use may interfere with portable and mobile RF communication devices such as mobile (cellular) telephones. Electromagnetic interference may result in incorrect operation of the system and a potentially dangerous situation.

The PlutoX series digital intraoral X-ray imaging system should not be stacked with or adjacent to other devices. If inevitable, verify the product.

The PlutoX series digital intraoral X-ray imaging system conforms to the IEC60601-1-2:2014 and EN60601-1-2:2015 standard on both immunity and emissions.

Accessories, transmitters and cables other than those specified by the user manual or sold together with product may result in increased emissions or decreased immunity of the product.

5.3 Environmental Directive

Europe WEEE directive

ROHS (2011/65/EU)

PFOS legislation (No.757/2010)
REACH legislation (No.1907/2006)
Cadmium legislation (Controlled substance: Annex XVII)
REACH legislation (No.1907/2006) (SVHC: Annex XVII)
EU Packaging Directive (94/62/EC)

# 6.Product Maintenance

## 6.1 Expected Service Life

Estimated product lifetime is 5 years with regular inspection and maintenance.

## 6.2 Regular Inspection and Maintenance

The detector needs regular inspection at least once a year not only for the safety of patients, the operator and third parties, but also for performance and reliability. If necessary, contact service office or local dealer for regular inspection or maintenance.

In order to ensure the safety of patients, operators or other third parties, and to maintain the good performance and reliability of the equipment, it is necessary to conduct regular inspections at least once a year. If necessary, clean up equipment, adjust parameters or replace consumables according to the safety requirements in the preface of this manual.

### 6.2.1 Daily inspection

Before and after using, the following check items shall be implement.

| Inspection items | Inspection actions |
|---|---|
| Intraoral sensor | Make sure that the detector has no cracks<br>Ensure that no dust and impurities adhere to the USB interface |
| cable | Ensure that the cables are not damaged and the cable casing is not torn |

### 6.2.2 Monthly and annual inspections

| Inspection items | frequency | Inspection actions |
|---|---|---|

| | | |
|---|---|---|
| Resolution | Monthly/Yearly | Check the resolution of the detector through the resolution graph or use a phantom |
| Linearity range | Monthly/Yearly | Evaluate by checking the image gray value |
| correction | Monthly/Yearly | When the X-ray generator, tube, collimator or exposure environment changes |

6.3 Repair

If a problem cannot be solved, contact your sales representative or local dealer. Please provide the following information:

Product Name:

Series Number:

Description of Problem: as clearly as possible

6.4 Care and Cleaning

In order to prevent infection, wipe the front plate of the sensor unit with ethanol to disinfect it each time a different patient uses the instrument. If you plan to use a disinfectant other than those specified above, or you are mixing another disinfectant with ethanol, please consult a specialist because it may damage the plate.

To clean the sensor shall use the 70% isopropyl alcohol. Please observe the precautions noted.

Do not soak or immerse any part of the Product, and be sure to dry it completely after cleaning.

Clean the surface of the Product by moistening it with a soft cotton swab dipped in one of the cleaning solution. Gently wipe the surface end-to-end in straight lines, without applying any pressure. Make sure the liquid does not penetrate the Product through the USB cable or the sensor cable connectors.

After cleaning the surface of the sensor, use a clean lint-free cloth to dry the Product, as required, until the surface is clean.

**Do not use the following cleaning materials.**

- **Hard brushes or scrapers of any kind**
- **Strong acids or alkaloids**

# Appendix

A. Information of Manufacture

**COMPANY:** iRay Technology Co., Ltd
**ADDRESS:** Rm. 202, Building 7, No. 590, Ruiqing Rd., Zhangjiang East, Pudong, Shanghai, China
**ZIP CODE:** 201201
**TELEPHONE:** +86-21-50720560

**EUROPEAN REPRESENTATIVE**
**COMPANY:** iRay Europe GmbH
**ADDRESS:** In den Dorfwiesen 14, 71720 Oberstenfeld Germany
**TEL:** +49-7062-977 88 00
**FAX:** +49-7062-976 05 71
**Email:** S.feng@iraygroup.com

B. Recommended exposure time

| Protocol | | Patient | x-Ray mahcine | Exposure time |
|---|---|---|---|---|
| Maxilla | Incisors | Child | 70kV/8mA | 0.032 |
| | | Adult | 70kV/8mA | 0.040 |
| | Premolars and Canines | Child | 70kV/8mA | 0.040 |
| | | Adult | 70kV/8mA | 0.050 |
| | Molars | Child | 70kV/8mA | 0.050 |
| | | Adult | 70kV/8mA | 0.063 |

| | | | | |
|---|---|---|---|---|
| | Incisors | Child | 70kV/8mA | 0.025 |
| | | Adult | 70kV/8mA | 0.032 |
| | Premolars and Canines | Child | 70kV/8mA | 0.032 |
| | | Adult | 70kV/8mA | 0.040 |
| | Molars | Child | 70kV/8mA | 0.040 |
| | | Adult | 70kV/8mA | 0.050 |

Note: X-ray sources: 70kV/8mA when using a 20cm SID

**Important**

Recommended exposure time can vary depending on the patient's body size, age, sex, and thickness of the position to be photographed.

Please adjust exposure time according to patient.

- Forlarger body types: increase the source current by25%
- For children(5~21age): reduce the source current (or Exposure time) by20%
- For edentulous patients : reduce the source current by20%.

Since the X-ray exposure condition can be changed depending on the age, gender and bone density of the patient, in case of Pediatric, X-ray exposure condition can be changed by expert's judge.

For further information, please refer to FDA Pediatric X-ray Imaging webpage, http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm298899.htm)