Instructions for Use

seethrough SENSOR

XRI-301 XRI-302

XRI-3 - ENG - Rev00

Table of contents

Conformity

SAFETY STANDARDS REFERENCE

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

Standards and Directives	Description
IEC 60601-1: 2005 + A1:2012 + A2:2020	Medical electrical equipment -Part 1: General requirements for basic safety and essential performance
IEC 60601-2-65:2012+AMD1:2017+AMD2:2021	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 + A2:2020	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
EN 60601-1-6:2010 + A1:2013 + A2:2020	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
IEC 60601-1-2:2014 + A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic disturbances-Requirements and tests
EN 62304:2006 + A1:2015	Medical device software – Software life-cycle processes
IEC 62336-1:2015 + A1:2020	Medical devices – Application of usability engineering to medical devices
EN ISO 15223- 1:2021	Medical devices-symbols to be used with medical device labels, labeling and information to be supplied–Part1:General requirements

Environment

Europe WEEE directive	Waste from Electrical and Electronic Equipment
2011/65/EU and 2015/863/EU	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the restriction of the use of certain hazardous substances in electrical and electronic equipment
PFOS legislation (No.757/2010)	COMMISSION REGULATION (EU) No 757/2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III
REACH legislation (No.1907/2006) **REACH legislation (No.1907/2006) (SVHC: Annex XVII)**	Regulation (EC) No 1907/2006 - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Cadmium legislation (Controlled substance: Annex XVII)	COMMISSION REGULATION (EU) No 494/2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium)
EU Packaging Directive (94/62/EC)	European Parliament and Council Directive 94/62/EC on packaging and packaging waste

CLASSIFICATION IN ACCORDANCE WITH IEC 60601-1

Medical equipment classification

Protection degree against water penetration	IP68 (intra-oral sensor part) IPX0 (control box)
Type of protection against electric shock	Not Class I equipment; Not Class II equipment; Not internally power equipment.
Degree of protection against electric shock **Applied part**	With type BF applied part 
Operation mode	Continuous operation
Flammable anesthetics	Not suitable for use in situation with flammable anesthetic mixture with air, oxygen or nitrous oxid. Not suitable for use in oxygen-rich situation

seethrough SENSOR consists of a single unit that includes both the power supply part and signal input/output part. Power and data signals are transmitted via a USB port for connection to a PC.

ELECTROMAGNETIC COMPATIBILITY (EMC)

seethrough SENSOR digital intra-oral X-ray imaging device need special precautions regarding EMC, and should be installed by authorized personnel and follow EMC guidance in the user manual.

seethrough SENSOR 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 device and a potentially dangerous situation.

seethrough SENSOR digital intra-oral X-ray imaging device should not be stacked with or adjacent to other devices. If inevitable, verify the product.

seethrough SENSOR digital intra-oral X-ray imaging device conforms to the IEC60601-1-2:2014 + A1:2020 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.

Cable provided for EMC

Cable	Length (m)	Shield/Unshielded	Number	Cable classification
Cable	2.8	Shielded	1 piece	DC power and SIP/SOP

EMI Compliance Table

Emissions

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

EMS Compliance Table

Enclosure USB Port

Phenomenon	Basic EMC standard or test method	Immunity test levels
		Professional healthcare facility environment
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8 kV contact ± 2, ±4, ± 8, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table "Test specifications for immunity to RF wireless communications equipment" on the next page
Rated power frequency magnetic field	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Test specifications for immunity to RF wireless communications equipment						
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 Hz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						

Test specifications for immunity to RF wireless communications equipment						
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
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 seethrough SENSOR, including cables specified by the manufacturer”.

Symbols and messages

SAFETY SYMBOLS USED IN THIS MANUAL

This symbol is used to identify conditions under which improper use of the product may cause death or serious personal injury.

This notice is used to identify conditions under which improper use of the product may cause minor personal injury.

This notice is used to identify conditions under which improper use of the product may cause property damage.

This is used to indicate a prohibited operation.

This is used to indicate an action that must be performed.

This is used to indicate important operations and restrictions.

This is used to indicate reference and complementary information.

This is used to indicate that the original medical device information has undergone a translation by someone other than the manufacturer (*i.e.*, the distributor)

SYMBOLS ON LABELS (DEVICE AND SHIPPING BOX)

The following symbols are reported on external labels and on the shipping box of the device.

MD	This symbol is used to indicate a Medical Device
#	This symbol is used to indicate the seethrough SENSOR device type or model
	Caution: please refer to the instructions in the user manual
CE 0344	This symbol identifies the notified body that assessed the conformity of the product.
C US	This symbol identifies the Nationally Recognized Testing Laboratory (NRTL).
SN	This symbol is used to identify the manufacture's series number which is after, below or adjacent to the symbol. The series number is usually made of 19 digits as shown below: First digit group: product type Second digit group: derivative types Third digit group: version Fourth digit group: location Fifth digit group: date Sixth digit group: numerical order

UDI	This symbol is used to indicate the UDI of the product.
REF	This symbol is used to indicate the REF of the product.
	This symbol is used to indicate the name and address of the manufacturer. The date of manufacture, as well as the name and address of the manufacturer, is combined in this symbol.
	This symbol is used to indicate the name and address of the distributor.
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 Instructions for Use for general information.
	Safety Signs: please refer to the Instructions for Use for safety instructions.
	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 this 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 that 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.
	This symbol indicates that this product is not to be disposed of with your residential or commercial waste.

	This symbol is used to indicate the name and address of the importer.

Introduction

CONTENTS

This section deals with the following subjects:

About this manual

INTRODUCTION

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

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

⚠ WARNING 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 seethrough SENSOR.

OBLIGATIONS WITH REGARD TO THIS MANUAL

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

MANUAL CONTENT

Congratulations on your purchase of the seethrough SENSOR digital intra-oral X-ray imaging device (hereinafter referred to as seethrough SENSOR) which is manufactured by iRay Group(Hereinafter referred to as iRay) and distributed by W&H Sterilization Srl (hereinafter referred to as W&H).

This manual contains the Instructions for Use of the following versions:

- XRI-301
- XRI-302

Versions differ for size.

DISCLAIMER

Without prejudice to the provisions and obligations set for the manufacturer and distributor of medical devices under Regulation (EU) 2017/745, iRay (in its capacity as manufacturer of this product) and W&H Sterilization Srl (in its capacity as distributor of this product) shall not be liable to the purchaser of this product or third parties for any damage, loss, or injury by purchaser or third parties as a result of fire, earthquake, any reasonably unforeseeable accident using the ordinary diligence, misuse or abuse of this product.

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

iRay and W&H Sterilization Srl shall not be liable for any damage or loss arising from the use of any options or consumable products other than those designated as Original iRay Products by iRay Technology.

All pictures, graphics and illustrations provided in this manual are for the comprehension of the text. They are not meant to be an accurate representation of product details. Thus, they should be taken as indicative only, and may differ from the actual product.

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

For any suggestions or remarks please contact W&H Sterilization Srl or an authorized service partner.

COPYRIGHT NOTICE

TRADEMARKS

The seethrough SENSOR name and seethrough SENSOR logo are registered trademarks of W&H.

Use restrictions

APPLICATION SCOPE/INTENDED USE

seethrough SENSOR is used in conjunction with dental radiography in medical units. The product is used for dental X-ray examination, the diagnosis of structural diseases of teeth, jaws and mouth. The product is expected to be used in hospitals and clinics, operated and used by trained professionals under the guidance of doctors.

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

This manual contains information about seethrough SENSOR. 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 certain features or components are not included in the final device configuration, the corresponding sections of this manual do not apply.

TARGET USERS

seethrough SENSOR is intended to be used by dentists, radiologists and any other legally qualified health care professionals with suitable experience in radiation protection or knowledge of radiation protection, trained in the operation of X-ray equipment.

Contact W&H for further information.

Safety information

CONTENTS

This section deals with the following subjects:

Safety precautions

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

WARNING

Installation and environment of use

- Do not use or store the equipment near flammable chemicals such as thinner, benzene, etc.
- If chemicals are spilled or evaporate, it may result in fire or product damage through contact with electric parts inside the equipment.
- Do not connect the equipment with anything other than specified. Doing so may result in personal injury or product damage.
- Do not install or use in the following environment, or it may cause fire, personal injury or product damage:
  - Facilities near water sources,
  - In direct sunlight,
  - Close to air condition or ventilation,
  - Dusty or close to a heat source as a heater,
  - In a salty or acidic environment,
  - High temperature and high humidity,
  - Ice or condensation,
  - In the environment easy to vibrate,
  - On a slope or in an unstable area.
- Ensure that the cable is not knotted or wound during use. Or it may cause the equipment damage or personal injury.

Handling

- Never disassemble or modify the equipment. No modification of this equipment is allowed.
- Follow the below instructions to prevent damage to the sensor and cable:
  - Do not twist, bend, pull and pinch the cable strongly,
  - Do not strike or drop the equipment,
  - Do not touch the pin of the USB connector,
  - 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:
  - When there is smoke, an odd smell or abnormal sound,
  - When liquid has been spilled into the equipment or a metal object has entered through an opening,
  - When the equipment has been dropped and damaged.

Maintenance and inspection

- Check the sensor and cable for any damage or abnormal conditions,
- Check that the PC and software are working properly.

CAUTION

Hygienic protection

- The sensor should be covered with hygiene sheath when you apply the sensor to a patient
  - 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.
  - Use a hygiene bag whose size fit the size of the sensor
  - Purchase the medical purpose sheath via formal purchase channels: Dental Intraoral Camera Sheaths

Cleaning

- Pay special attention to avoid the risk of damage when cleaning the sensor.
  - 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.
  - Do not apply any liquid or disinfectant to the product except 70% isopropyl alcohol.
  - Do not immerse the sensor in disinfectants or any other chemicals Do not sterilize the product by heating, autoclaving or UV

- No valuable clinical images were obtained after exposure due to operational reasons or failure of the device.
- 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 an X-ray device. Refer to the Instructions for Use of the device for information related to the use of the X-ray device

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 disconnecting the USB connector, handle it carefully to avoid 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.

Getting started

CONTENTS

This section deals with the following subjects:

Requirements

PC CONFIGURATION

System	Recommended configuration	Minimum configuration
System configuration	CPU: IntelCore i3 (R) frequency ≥ 2.5 G	CPU: IntelPentium(R) frequency ≥ 2.0 G
	Memory: 4 GDDR3/4	Memory: 4GDDR3/4
	Preview Monitor: 1920×1080	Preview Monitor: 1280×768
Other hardware	Support Serial port communication, USB 2.0 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..

GROUNDING

The power supply part of the product needs to be well grounded, and the rack fixing the product should also be well grounded.

Product description

IMAGE WORKSTATION

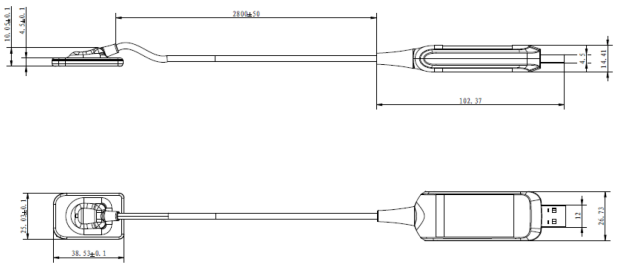
Once the image is acquired, the seethrough studio is used to display the image, patient management, examination management, image storage and image printing administration.

Note: the detail description is shown in the user manual of the seethrough studio.

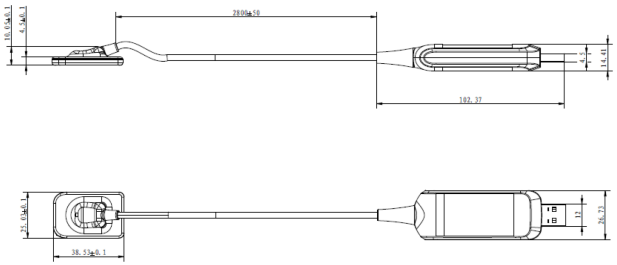
SENSOR

The seethrough SENSOR is 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 seethrough studio software application makes it easy to acquire, enhance, analyze, view and share images from the seethrough SENSOR.

Size 1



Size 2



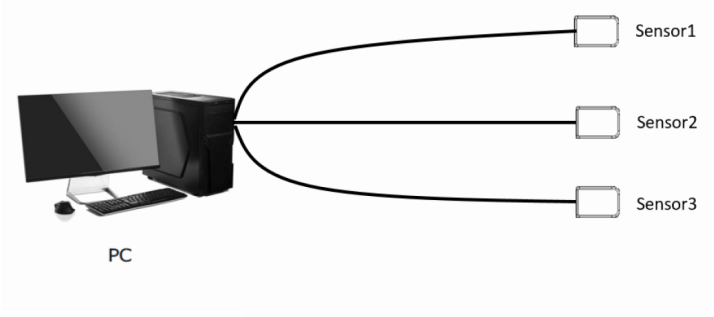
Installing the unit

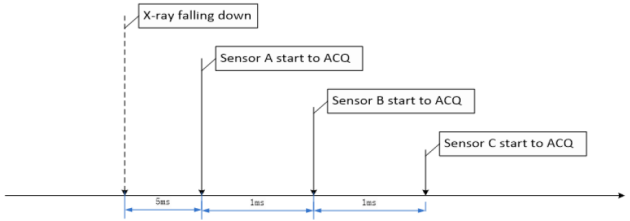
This chapter mainly introduces the use of DEMO software iDetector(service engineer) to connect the sensor and realize the basic image acquisition and image processing functions.

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

MULTI-SENSOR

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





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

USB CORD

The standard cable length of the sensor is 3 m.

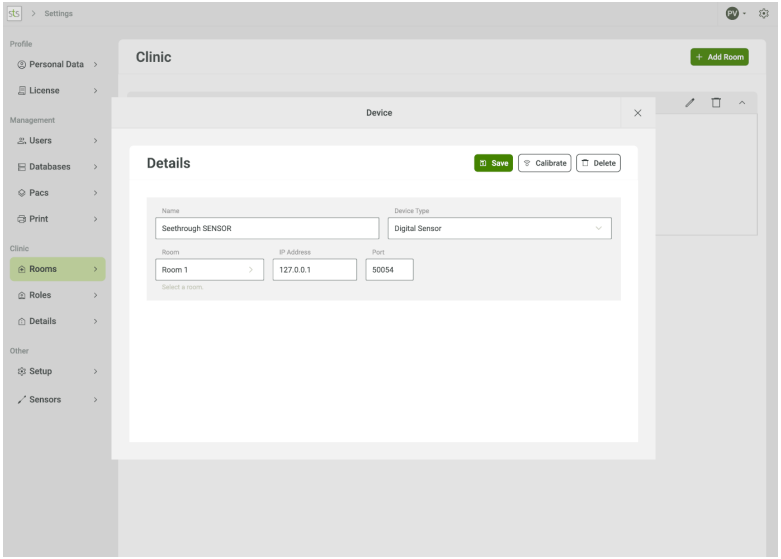
Note: accessories, transmitters and cables other than those specified by the user manual or sold together with device may result in increased emissions or decreased immunity of the device.


USB Hub
Sensor

CONNECT SENSOR

1 Open the seethrough studio and go to the Settings.

Note: refer to seethrough studio guide.

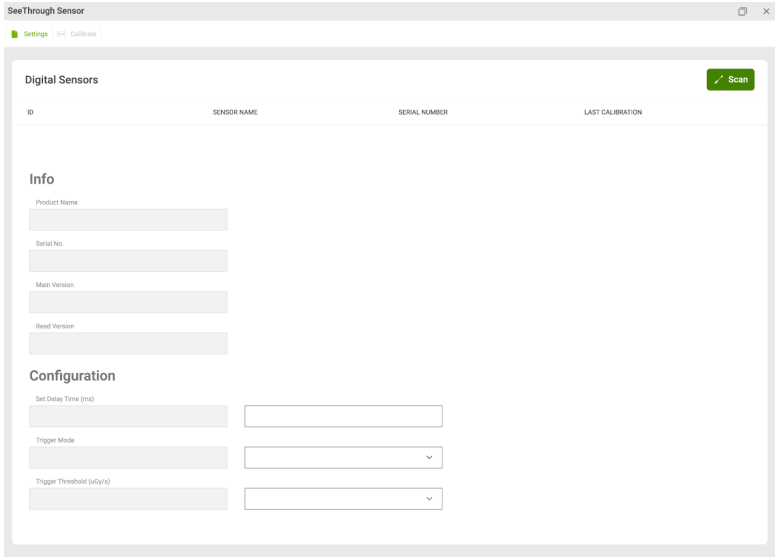


2 Click on "Calibrate" to open the digital sensor module.

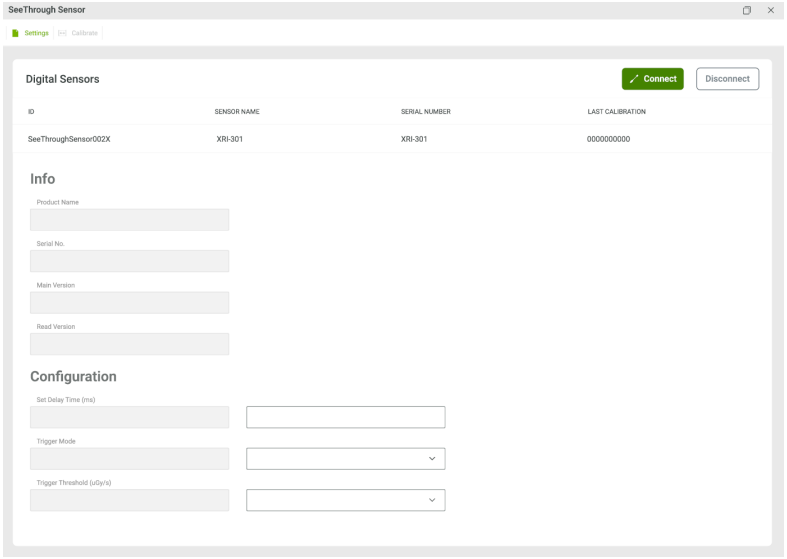
3 The digital sensor module opens.

4 Connect digital sensor to pc via usb port.

5 Click "Scan" to search for the device connected to the PC.

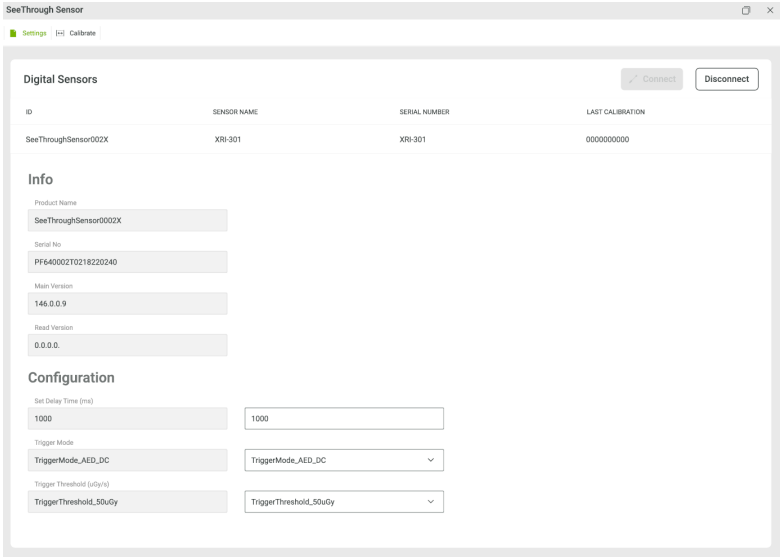


6 Click on "Connect" the available digital sensor



GET THE FIRST IMAGE

1 Set the trigger mode by changing the following parameters:
- delay time: 1000
- Trigger mode: Trigger mode AED DC,
- Trigger threshold: 50uGy

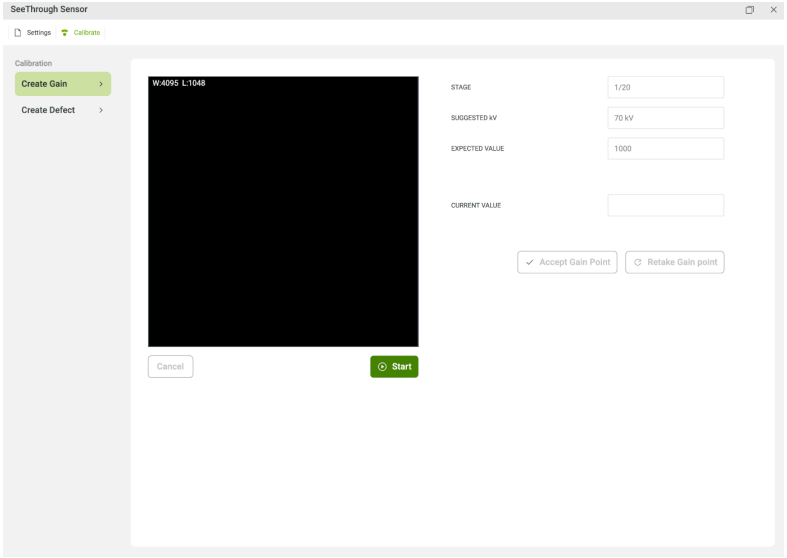


CREATE CORRECTION TEMPLATES

Gain correction

1 Go to "Calibrate" in the upper bar.

2 Enter in the "Create Gain" section.



3 Click on "Start".

4 If the parameters are in the expected range, repeat this procedure 20 times.

Note: a counter is reported in the window.

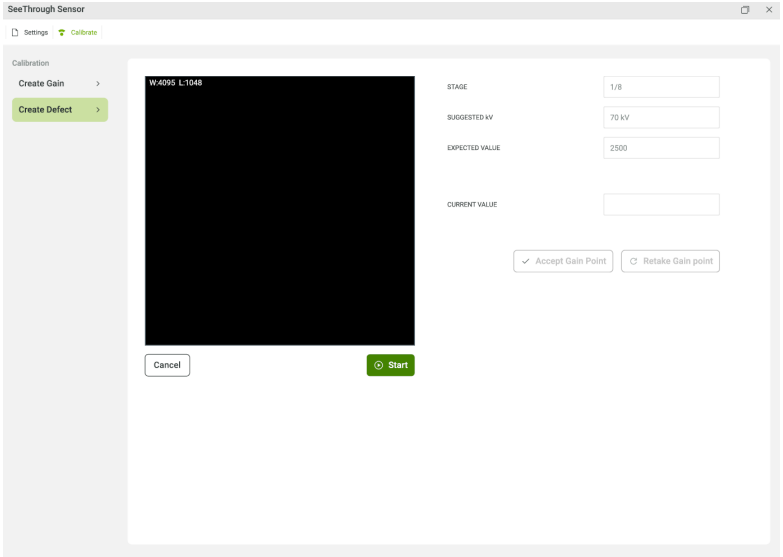
5 If the parameters are outside of the expected range, click on "Retake Gain point".

If the problem persists, contact a technician.

Defect correction

1 Go to "Calibrate" in the upper bar.

2 Enter in the "Create Defect" section.



3 Click on "Start".

4 If the parameters are in the expected range, repeat this procedure 8 times.

Note: a counter is reported in the window.

5 If the parameters are outside of the expected range, click on "Retake Gain point".

If the problem persists, contact a technician.

Operation

CONTENTS

This section deals with the following subjects:

Access and use of seethrough studio

To:

- access seethrough studio,
- create a patient ,
- analyze an exam,
- do a report,
- export an exam,

refer to the software guide.

Recommended exposure time

Radiological parameters	Patient	Unit	Maxilla					
			Incisors	Premolars and canines	Molars	Incisors	Premolars and canines	Molars
70 kV/7 mA	Newborn	s	Less than 0.04					
	Child	s	0.037	0.046	0.057	0.029	0.037	0.046
	Adult	s	0.046	0.057	0.072	0.037	0.046	0.057

Radiological parameters	Patient	Unit	Maxilla					
			Incisors	Premolars and canines	Molars	Incisors	Premolars and canines	Molars
65 kV/7 mA	Newborn	s	Less than 0.04					
	Child	s	0.055	0.069	0.086	0.043	0.055	0.069
	Adult	s	0.069	0.086	0.108	0.055	0.069	0.086

Note: X-ray sources: 70 kV/8 mA and 65 kV/7 mA when using a 200 mm SID.

Important

Exposure time can vary depending on patient's size, age and sex. The thickness of the mouth portion to be scanned may also affect exposure time.

Please adjust exposure time according to patient.

- For larger body types: increase the source current by 25%
- For children(5~21 age): reduce the source current (or Exposure time) by 20%
- 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

Maintenance

CONTENTS

This section deals with the following subjects:

Cautions for maintenance operations

CAUTIONS FOR HYGIENIC PROTECTION AND CLEANING

Hygienic protection

The sensor should be covered with hygiene sheath when you apply the sensor to a patient.
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.
Use a hygiene bag whose size fit the size of the sensor

Cleaning

Pay special attention to avoid the risk of damage when cleaning the sensor
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.
Do not apply any liquid or disinfectant to the product except 70% isopropyl alcohol.
Do not immerse the sensor in disinfectants or any other chemicals
Do not sterilize the product by heating, autoclaving or UV

Ordinary maintenance

EXPECTED SERVICE LIFE

Estimated product lifetime is 7 years with regular inspection and maintenance.

REGULAR INSPECTION AND 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.

If necessary, contact service office or local dealer for regular inspection or maintenance.

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 strong bases.

MAINTENANCE BY THE USER

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

Frequency	Inspection items	Operation
Daily	Inspection items	Make sure that the detector has no cracks. 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.
Monthly/Yearly	Resolution	Check the resolution of the detector through the resolution graph or use a phantom.
	Linearity range	Evaluate by checking the image gray value.
	Correction	When the X-ray generator, tube, collimator or exposure environment changes.

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).

Disposal

DISPOSAL RESPONSIBILITY

- 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 setup 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 W&H for assistance.

Diagnostics

CONTENTS

This section deals with the following subjects:

Troubleshooting

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.

QUICK TROUBLESHOOTING

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

Problem	Possible cause	Solutions
Cannot connect sensor	Cannot find device	No sensor connection The USB connector is damaged Re -plug the USB connector Change the USB port and re -plug Check the cable and sensor for damage or other abnormalities Reinstall the usb driver
	It prompts cannot find device	Delete the “Cfg_USBConnStr” in .. ..\ \Tools\iDetectoriDetector\x64x64\work_ dir\Pluto0001XPluto0001X\config.ini Delete the “SN” in ..\ \Tools\iDetectoriDetector\x64x64\work_dir dir\Pluto0001XPluto0001X\config.ini
No image display	No sensor connection Sensor or cable is damaged X-ray dose is too low Exposure time is too short	Check the sensor and cable Increase the distance between tube and sensor Increase mA Increase exposure time Replug the sensor and try again
Image from X-ray exposure is pale and grainy	The sensor is moving during exposure X-ray output is unstable The imaging surface of sensor is not facing the X-ray device	Fix the sensor before exposure Check the x X-ray machine Ch eck the sensor position

⚠ WARNING If the symptom still exists, please contact the service.

Technical data

CONTENTS

This section deals with the following subjects:

Technical data

POWER SUPPLY SYSTEM

Characteristic	Unit	Data
Pixel matrix		1500 x 1000 Size 1
		1800 x 1300 Size 2
Pixel Pitch	μm	20
Scintillation Screen		CsI
Sensor size	mm	38.5 mm × 25 mm × 4.5 mm Size 1
	mm	45 mm × 31.6 mm × 4.5 mm Size 2
AD Conversion	bits	≥14
Spatial resolution	lp/mm	Limited: 25 Typical: >15
Ingress Protection		IP68 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	lsb/μGy	>40
Trigger dose rate	μGy/s	@50μGy/s，trigger dose range is 50μGy/s ÷ 1000μGy/s @200μGy/s，trigger dose range is 200μGy/s ÷ 4000μGy/s
Max linearity dose	μGy	>300
Length of cable	m	< 3
Interface		Direct USB, USB 2.0
Power	W	<2

STORAGE AND OPERATION ENVIRONMENT

Characteristic	Unit	Data
Operation temperature	°C	10 ÷ 35
Operation temperature variation	°C/min	≤ 1
Operation humidity	R.H.	5 ÷ 90
Operation barometric change	mbar/min	≤ 10
Storage Temperature	°C	-20 ÷ 55
Storage temperature variation	°C/min	≤ 1
Storage humidity	R.H.	5 ÷ 95
Storage barometric change	mbar/min	≤ 20
Barometric pressure	mbar	700 ÷ 1060
Max altitude	m asl	3000

note: do not expose the sensor to a hot and humid environment, otherwise it may result in product damage.

Trigger mode

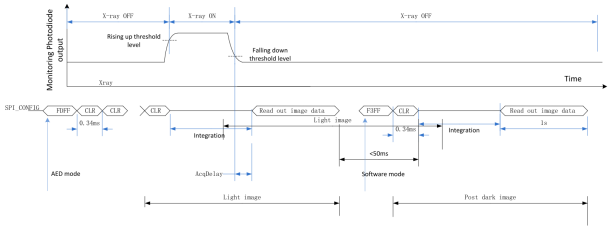
Two trigger modes are available:

- auto exposure detection (AED) mode: triggered by the sensor,
- software mode: triggered by an operator through a software command. This mode is only used for debug and can be used by service engineers authorized by W&H

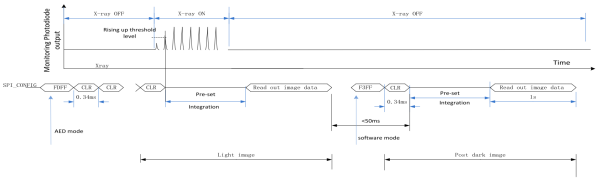
Auto exposure detection (AED) is divided in two type, depending on different dental X-ray sources (DC or AC).

Type	DC X-tube	AC X-tube
Mechanism	Automatically detect X-ray start and X-ray end	Only detect the X-ray start; the X-ray end is pre-set by integration time (controlled by Delay time)
Current consumption	Depend on X-ray width	Pre-set and fixed, 0.5 s, 1 s or 1.5 s

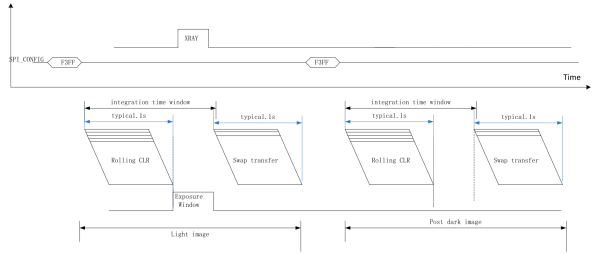
AED(auto exposure detection) mode-DC X-ray tube



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



Software mode



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.

Selected AED Trigger sensitivity level	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

Dose trigger level

The X-ray machine currently used with the intra-oral sensor operates at 60-70 kV and 1-8 mA. 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)	Recommended trigger level (uGy/s)	Max entrance dose rate (uGy/s)	mA (up to)
60	1	250	2 mm Al		256	50	1000	4
			8 mm Al	Standard	69			
			10 mm Al	Large	51			
65	1	250	2 mm Al		306	50	1000	3.2
			8 mm Al	Standard	91			
			10 mm Al	Large	69			
70	1	250	2 mm Al		358	50	1000	3
			8 mm Al	Standard	226			
			10 mm Al	Large	90			

kV	mA	SID (mm)	Equivalent filter	Skull size	Min entrance dose rate (uGy/s)	Recommended trigger level (uGy/s)	Max entrance dose rate (uGy/s)	mA (up to)
60	3.2	250	2 mm Al		256	150	3000	8
			8 mm Al	Standard	69			
			10 mm Al	Large	51			
65	3.2	250	2 mm Al		306	150	3000	8
			8 mm Al	Standard	91			
			10 mm Al	Large	69			
70	3.2	250	2 mm Al		358	200	4000	8
			8 mm Al	Standard	226			
			10 mm Al	Large	90			

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.

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Valid edition of the Instructions for Use: Rev00 of 12/11/2024

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- At the www.wh.com website.
- By calling up the phone number of your authorized W&H service partners, see "Authorized W&H service partners" on page 1
- By scanning the following 2D code