Model RIS500

RIOSensor

User Manual

Ray

This user manual contains information for appropriate use of RIOSensor.

Operator should read this document carefully before using the product. Operator should follow instructions and safety information described herein the user manual to prevent any injury or material damage.

Caution (US only): This product should be sold only to or by the order of a dentist or dental professional by the Federal law.

Publication number : RUG-5001508-EN Revision 5.0 (Revised Aug. 20, 2015)
This manual is valid for following software revisions: RIOView Ver. 1.1.0.1 or higher

This manual is subject to change without prior notice.

For further inquiries, contact your sales representative or customer service of manufacturer.

Table of Contents

1. Introduction

This manual explains how to install the RIOSensor (hereinafter “the product”) and how to use the product.
This chapter provides description of each symbols, safety warnings, and an explanation of labelling involved with the product.

1.1. Symbols and Safety notices

The symbols in table below are indicative of symbols closely related to patient and user safety.

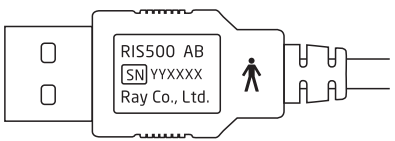
Symbols	Description
	The symbol indicates manufacturer.
	The symbol indicates the date of manufacture.
	The symbol indicates Authorized Representative in the European Community.
	General warning sign to identify conditions or actions which will cause personal injury or substantial property damage if the instructions are ignored.
	The symbol indicates compliance of guidelines and instructions in the manual for safe operation of the equipment.
	The symbol indicates mandatory action requirement by operator.

Symbols	Description
	The symbol indicates the information which operator should be aware of.
 Type B	The symbol indicates that the part of the medical device may come into physical contact with the patient in order for the device to carry out its intended function. The part of the product can be brought into contact with the patient or needs to be touched by the patient. The product is classified as type B equipment and require certain degree of protection against electrical shock , Applied parts of the product are generally not conductive and can be immediately released from the patient.
	The symbol refers to prohibited action for safety reason of the operator.
	The symbol illustrates the product is for single use only by the operator for safety reasons.
	The symbol refers to precautions for electromagnetic interference.
	The symbol indicates that operator should observe precautions for handling electrostatic sensitive devices.
	The symbol indicates that the product may include industrial waste materials

1.2. Label

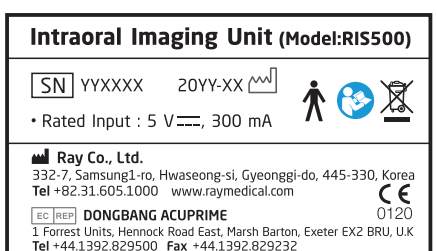
1.2.1. Sensor Label

Sensor label and marking are located on the USB connector of the sensor.



1.2.2. Package Label

Package label and marking are located on the box of RIOSensor.



1.3. Other documents

Refer to the following documents for operating RIOSensor.

- SMARTDent User Manual for network use (except for US/FDA)
- RIOSensor troubleshooting guide

2. Safety and regulatory precautions

This chapter describes the safety information where the user must understand thoroughly prior to usage of the product.

	It is important for the user to read and understand the contents and all instructions in this manual before handling the product.
	The product is intended for use by qualified personnel only. The owner must ensure that all precautions and safety measures are taken place as well as maintenance events.

2.1. Intended use

The product is intended to acquire digital intraoral x-ray image and to store, view, and manipulate for diagnostic use by dentists.

2.2. Safety

2.2.1. Operation

	It is required to be alert to safety when you use the product.
	Before using the product, check whether there is any malfunctions or abnormality. Do not use the product until qualified personnel correct problem if any abnormality is detected.
	Do not leave the patient when the product is in use.
	Do not contact skin over 1 minute with the sensor.

2.2.2. EMC and ESD

	Electromagnetic compatibility (EMC) requirement and Electrostatic discharge (ESD) protective measures are considered when using the product.
	Use of wireless mobile phones and similar wireless devices in the vicinity of this product is prohibited. Use of devices compliant with EMC standards in close proximity can lead to unintended activities due to electromagnetic interference. Read more details in the chapter “8. Electromagnetic compatibility”.
	Destruction or unintended results may occur if electrostatically charged operator or patients touch the product. It is required to take procedures to prevent buildup of electrostatic charge in the user’s body or to discharge the electrostatic charge. Discharging can be done by touching the ground wire or metallic objects.

2.2.3. Environment

	Do not use the product in places where chemicals are stored or where gas is generated. Do not expose the cable to any source of humidity such as damp cloth or spray.
	The product must be used in an ambient temperature which is lower than 35℃.

2.2.4. Handling of the product

Before using	Ensure the USB connecter is not wet and dirty prior to plugging the USB connector. Connect and disconnect the USB connector with holding it by fingers. (Do not hold the cable)
While in use	Do not unplug the USB connector while the product is in use. Pay attention to the temperature of the sensor while in use as the temperature may rise to its maximum of 45.6℃.
After using	Store the sensor in places where there is no chemicals or gas as well as where there are no adverse effects due to pressure, heat, humidity, ventilation, direct sunlight, dust, chloride or sulfide. It is recommended to store the product in its original box in order to avoid any damages, such as static electricity, when it is not in use.
	Follow the below instructions to prevent damage to the sensor and cable. - Do not drop or strike the sensor. - Do not twist, bend, pull and pinch the cable strongly. - Do not touch the pins of the USB connector. - Do not apply any pressure (e.g. tight holders or biting) on the product. - Do not keep anything on the sensor or cable.

	The product should be operated only with the compatible accessary.

2.2.5. Radiation

Only trained personnel should operate this product. Suitable measures for x-ray protection (ex. Lead apron) should be considered when using x-ray. You must observe all local radiation safety and exposure regulations when using this product in conjunction with an x-ray source and when exposing patients to X-Rays.

2.3. Disposal

	Follow the disposal regulations in your country. The sensor must be disposed by environmentally sound manner as it includes industrial waste materials in the composition. Note that an inappropriate disposal of materials can cause environmental pollution.

2.4. Hygienic protection and cleaning

2.4.1. Hygienic protection

	The sensor should be covered with hygiene bag when you apply the sensor to a patient. Note that a hygiene bag 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 fits the size of the sensor. You can purchase a hygiene bag from your local dental supplier.
	Appropriate measures for hygienic protection should be performed to prevent any cross infection among patients, operator and other person.

2.4.2. 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. Do not apply any liquid or disinfectant to the product except 70% isopropyl alcohol.
	Do not let the connector get wet. USB connector of the sensor is sensitive to any liquid. No liquid should penetrate the connector.
	Do not immerse the sensor in disinfectants or any other chemicals. Do not sterilize the product by heating, autoclaving or UV.

3. Maintenance and quality control

Maintenance procedure and quality control procedure should be performed periodically by observing the following instructions and local regulation. The owner or operator has the responsibility to perform periodic maintenance to identify potential problems.

3.1. Maintenance

Daily maintenance	Inspect if there are any damage or abnormal condition on the sensor and cable. Check if the PC and the software are working properly. Check if your x-ray source (system) is properly operating.
Before each patient	Check if the sensor is sterilized appropriately.
Within every 6 months	Perform quality control check.

Periodic maintenance could prevent deterioration of the product performance and cause failure. The deterioration could result in failure of the product which could cause damage to the product.

3.2. Quality control

Quality control may be performed to verify the imaging performance of detector and test the image quality. Your local regulation may require to perform quality control check. Follow the local regulation when required.

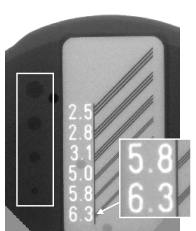
Qualification of controller	Operator or physician who reads this instruction for use
Monitoring frequency	Within every 6 months
Testing tools	"Quart" phantom (Model : Dent/Digitest 2.1) or equivalent.
Testing criteria	1) test for low level contrast of x-ray image : 4 contrast objects(Ø1.0, 1.5, 2.0, 2.5mm) should be observed in the x-ray image
	2) test for line pair resolution(LP/mm) : 6 LP/mm or more should be observed in the x-ray image

Perform the below test procedure using the testing tool.

1) Run "RIOView" to perform the test for low level contrast and for line pair resolution.
2) Capture the image of the "Quart" phantom.
3) Verify the image in the "Image" tap of RIOView by counting the number of the contrast objects shown in the image and by identify the highest line pair resolution.

[Example of test result is below]

Category	Criteria	Result
Low level contrast	Identify the 4 low contrast objects (Ø1.0, 1.5, 2.0, 2.5mm)	Pass
Line pair resolution (LP/mm)	Line pair resolution is 6 LP/mm or higher	Pass



In the event the result of quality control test fails to meet the criteria, do not use the sensor. Contact your sales representative or manufacturer.

4. Technical specifications

4.1. Specifications

RIS500		Size 1	Size 2
Sensor Dimension	Outside	39 x 25 mm	42 x 30 mm
	Image Area	30 x 20 mm	34 x 26 mm
	Number of Pixels	1.5 megapixels	2.2 megapixels
	Weight	56 g	60 g
	Sensor Type	Advanced CMOS with optical fiber	
	Pixel Dimensions	20 x 20 um	
	Scintillator	CsI	
	Resolution	Theoretical 25 lp/mm, Normal > 20 lp/mm	
	Cable Length	2 meters	
	Connection	USB 2.0 high speed	

4.2. Environment

Operation environment	Temperature: 0 ~ 35℃ Humidity : 30 ~ 70 % Atmospheric pressure : 800hPa ~1060hPa
Storage condition	Temperature: -20 ~ 70℃ Humidity : 10 ~ 70 % Atmospheric pressure : 800hPa ~1060hPa

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4.3. RIOView system requirement

	Recommended Specifications
CPU	Intel i5 or higher
RAM	4GB or more
HDD space	200GB or more
Resolution	1280 X 800 or higher
Graphic card	Graphic card with over 512MB RAM
USB port	USB port 2.0
Peripherals	CD/DVD ROM drive
Operating System	Microsoft Windows® 7 (32bit or 64bit) Microsoft Windows® 8 (32bit or 64bit) ("Network server" is only compatible with the Windows 7 Professional 32 or 64 bit)

The PC and other equipment where RIOSensor is connected to must be an approved equipment, such as CE mark (IEC-approval), UL/CSA approval.
The PC must be used in isolation power source which contains patient protective measures for medical devices.
The PC must be protectively earthed.

5. Using RIOSensor

5.1. Preparation

Complete package of the RIOSensor includes follows.

RIOSensor

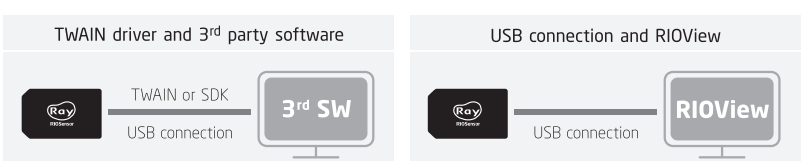
ⓐ Solid-state imaging sensor
ⓑ Software CD

Solid-state imaging sensor

① CMOS sensor
② Cable
③ USB connector

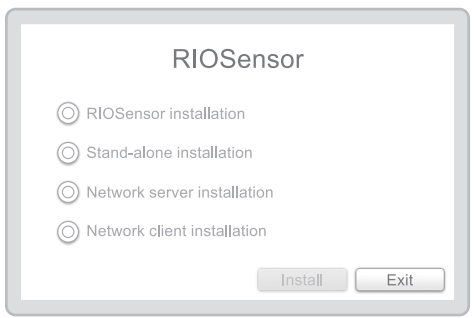
5.2. Configuration of RIOSensor

There are different ways to connect RIOSensor and your PC.
RIOView is a dedicated software which allows you to save and acquire the image through the imaging sensor.
RIOSensor supports TWAIN and TWAIN compatible software.



5.3. Software

List of options will be shown when you run the software CD.

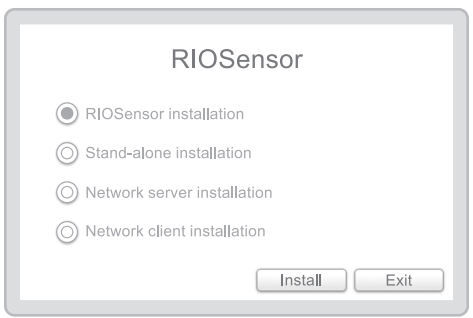


Menu	Description
RIOSensor installation	RIOSensor device driver & TWAIN driver
Standalone installation	RIOView for single PC use

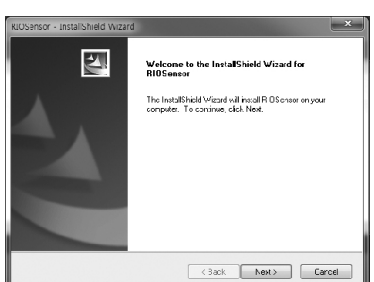
5.4. TWAIN and device driver installation

Install device driver and prerequisite installation package.
"RIOSensor Installation" installs device driver of RIOSensor, TWAIN driver, tool software, and prerequisite software in installation package.

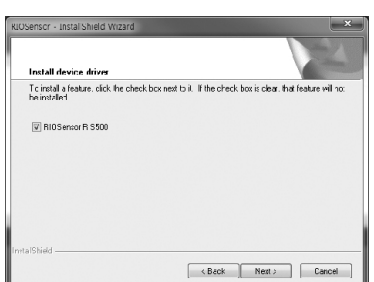
1) Insert the software CD into the CD-ROM drive of the PC.
2) Browse the CD folder and run “Launcher.exe”.
3) Select “RIOSensor installation” and then click “Install”.



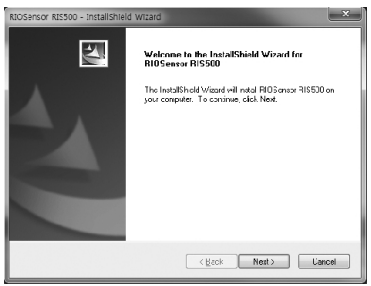
4) Click “Next” to install RIOSensor.



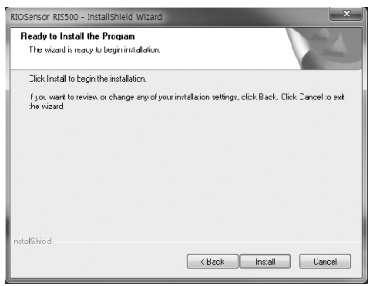
5) Click “Next” to install device driver of RIOSensor.



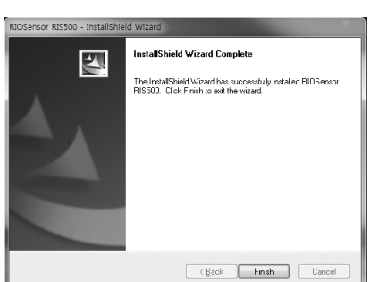
6) Click “Next”.



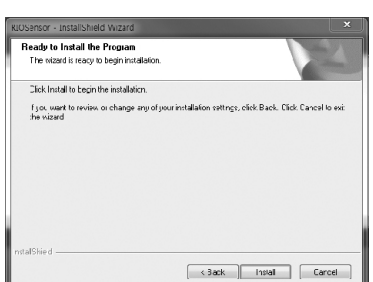
7) Click “Install” to install RIOSensor RIS500.



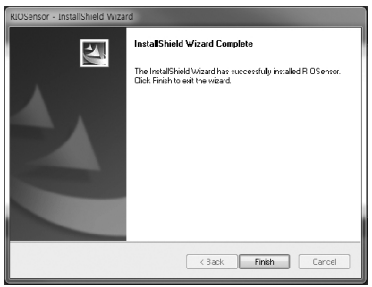
8) Click “Finish”.



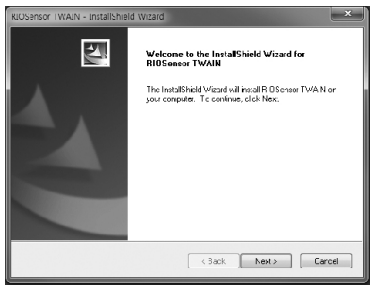
9) Click “Install” to install RIOSensor.



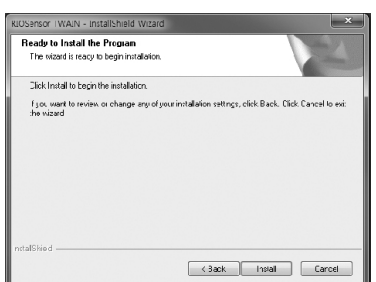
10) Click “Finish”.



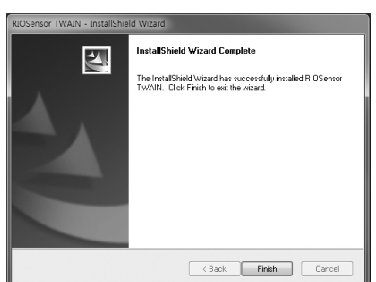
11) Click “Next” to install RIOSensor TWAIN.



12) Click “Install” to install RIOSensor TWAIN.



13) Click “Finish”.

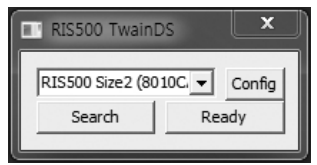


5.5. Image acquisition by using TWAIN

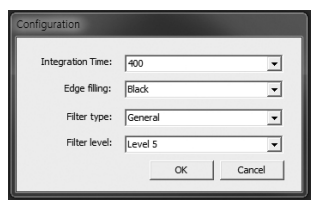
1) In case of using TWAIN, select ‘RIS500 TwainDS’ driver in the driver list.

※ If you select ‘RIS500 TwainDS’ in 3rd party software (For example PMS), TWAIN program of RIOSensor will be run automatically.

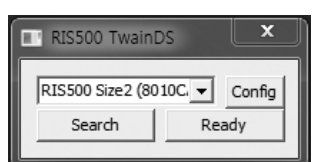
※ If you want to change image filter, click “Config” to begin.



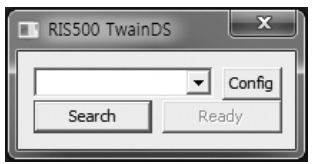
2) In order to change the parameters, click “OK” to save and close ‘Configuration’ window.
If you do not want to change, click “Cancel”.



3) Check “Device List” and click “Ready” to begin.



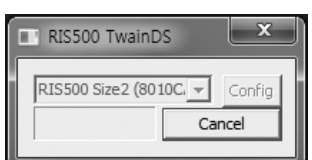
※ If you want to change image filter, click "Config" to begin.



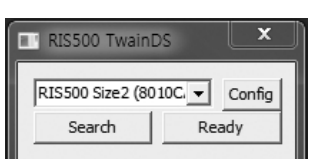
4) Put the sensor into a patient's mouth and move it to proper position.

5) Emit an X-ray to the sensor, image will acquire.

When image acquisition is completed, image will be transmitted to TWIAN client software. Progress bar will appear with the current percentage of acquisition during the process.



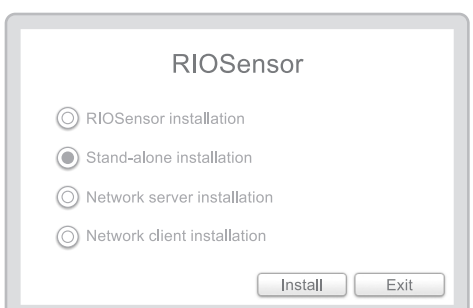
6) Click "X" to exit the program.



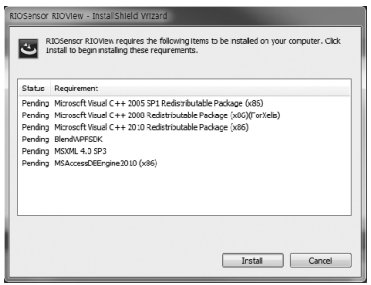
5.6. RIOView installation

When you want to use RIOSensor on a computer without any network connections, the package of "Stand alone installation" is proper solution for you.
It provides both image viewer and acquisition tool for RIOSensor.

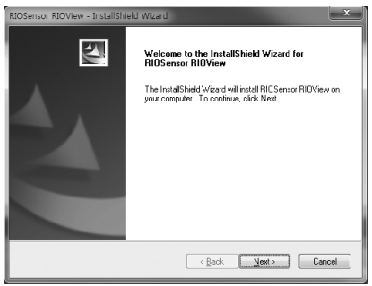
1) Insert the software CD into the CD-ROM drive of the PC.
2) Browse the CD folder and run "Launcher.exe".
3) Select "Stand alone installation" and then click "Install".



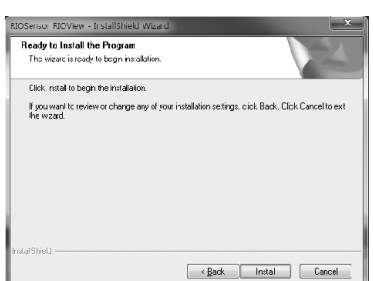
4) When below dialog box is displayed, click “Install”.



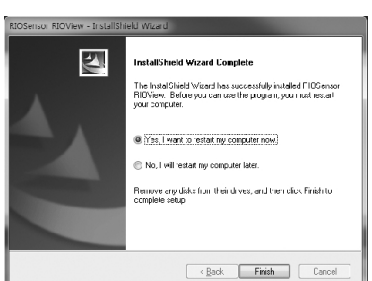
5) Click “Next”.



6) Click “Install” to install RIOView (stand alone software).

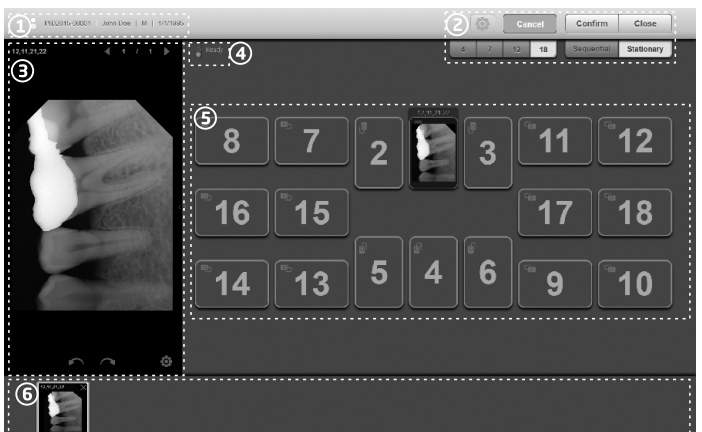


7) Click “Finish” to restart computer.



5.7. Image acquisition by using RIOView

‘Sensor Acquisition View’ is as follows.



	Name	Description
①	Patient Information	Patient ID, name, gender, and DOB
②	Control Button	Acquisition mode, image saving, sensor status control, and setting
③	Image Preview	Large image view with image select, editing, information, and optimizing image quality
④	Sensor Connection	Sensor connection status
⑤	FMX View	FMX 4/7/10/12/14/18 view
⑥	Thumbnail View	Thumbnail image list

Please see 'SMARTDent User Manual' for more details.

Follow the procedure below to use RIOView for image acquisition.

1) Select patient and go to "Sensor Acquisition View" by clicking [Sensor Acq.] button on 'Search' tab or [IO Sensor Acq.] button on 'FMX' tab.
2) Ensure the sensor is connected to the PC and click [Ready] to begin.
3) Place the sensor into the patient's mouth and move it to proper position.
4) Emit X-ray, your image will appear on RIOView.
5) Confirm image and click [Confirm] to save images.

5.8. Customizing image quality

You may choose image processing type and sharpness of x-ray image upon your preference.

1) click [Setting] on right bottom corner of 'Image Preview'.
2) 'Filter Setting' window appears as below.

3) Select 'Processing Type' and 'Sharpen' level, then click [Apply].
   On next acquisition, new image filter will be applied automatically.

In case of using 3rd party software, optimize sensor image quality by running "IOImageProcessingConfig.exe" on "C:\Ray\RayIO\"

6. Guide for x-ray exposure

6.1. Exposure value recommendation

Protocol		Patient	Exposure values (sec)	Dose values (uGy•m2)	Does Tolerance
Maxilla	Incisors	Adult	0.10 ~ 0.14	1.52	±20 %
		Child	0.06 ~ 0.10	0.85	
	Premolars and Canines	Adult	0.12 ~ 0.16	1.86	
		Child	0.10 ~ 0.16	1.69	
	Molars	Adult	0.16 ~ 0.20	2.89	
		Child	0.12 ~ 0.16	1.86	
Mandible	Incisors	Adult	0.08 ~ 0.12	1.19	
		Child	0.05 ~ 0.08	0.52	
	Premolars and Canines	Adult	0.10 ~ 0.14	1.52	
		Child	0.08 ~ 0.12	1.19	
	Molars	Adult	0.14 ~ 0.18	2.20	
		Child	0.10 ~ 0.14	1.52	

- Recommendation of exposure value with 20 cm (8") cones is 70kVp/7mA
- Exposure values vary referring to patient's body, age, sex and thickness of soft tissue. Please adjust the exposure values according to the need.

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6.2. Sensor positioner

The sensor holder (or sensor positioner) allows you to position the sensor with different anatomical angle for your specific needs. Refer to the manual supplied with the sensor holder package.

The below is the list of sensor holders compatible with RIOSensor.

Manufacturer	Model name
RINN	XCP - ORA DS FIT
	XCP - ORA DS FIT Light pack
	Uni-Grip 360

Note that the sensor holders listed above are excluded in the scope of supply. Contact your local sales representative for additional inquiries.

7. Quick troubleshooting

This chapter explains you how to resolve troubles you may have. The following table lists the symptom, cause and corrective action.

Symptom	Cause	Corrective Action
After triggering the x-rays, no image is displayed.	✓ No sensor connection ✓ Insufficient battery on the generator	✓ Ensure the Ready button is active, not grayed out. If the button is grayed out, check the connection of the sensor on the USB 2 port. ✓ Recharge the battery (if handheld device) ✓ If it is connected and the problem persists, contact your representative
Image from x-ray exposure is pale and grainy	✓ Exposure time is short	✓ Increase exposure time. The selected acquisition mode does not correspond to the x-ray dose used. ✓ The generator voltage is too low (<60 kV); have the generator checked. ✓ The generator is too far from the patient with respect to the selected dose. ✓ Check the monitor contrast and brightness settings and ensure there are no reflections on the screen.
The image is dark	✓ Exposure time is long	✓ Lower exposure time. ✓ The selected acquisition mode does not correspond to the x-ray dose used. ✓ Check the monitor settings (contrast and brightness) and ensure there are no reflections on the screen.
The image is blurred	✓ Positioning is not stable	✓ Patient might move during exposure. ✓ X-ray source might not be stable.
The image is white		✓ Active face of sensor was not exposed to x-rays. ✓ X-ray dose is insufficient. ✓ Sensor is not connected, or is improperly connected. ✓ Ensure the generator is producing x-rays; have it checked by a certified technician
Software does not recognize the sensor	✓ Connection error ✓ Insufficient power at USB port	✓ Reconnect the sensor. ✓ Connect the sensor onto the other USB port or USB port at the back of the Desktop PC.

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If the problem persists, contact your sales representative or manufacturer.

For further technical assistance, you may contact your sales representative. When you contact your sales representative, have the following information ready.

- Practice name
- Serial Number: located at the package or USB connector
- Any message displayed on the computer screen.

8. Electromagnetic compatibility

- Use of wireless mobile phones and similar wireless devices in the vicinity of this system is prohibited. Use of devices compliant with EMC standards in close proximity can lead to unintended activities due to electromagnetic interference.

- If system is intended for use on patients having an “Implantable Cardiac Pacemaker ”or “Implantable Defibrillator”, the user is obligated to notify patients having such devices of the possibility of dysfunctions incurred by the machine contributed to continuous pulse shaped X-ray exposure on to the transplanted part of the “Implantable Cardiac Pacemaker” or the “Implantable Defibrillator”. When using this machine, avoid direct X-ray exposure to the “Implantable Cardiac Pacemaker ”or “Implantable Defibrillator” and emit X-ray only for short duration if possible.

- Protecting the equipment from external electromagnetic waves.

The RIOSensor is intended for use in electromagnetic environment specified below. The customer or the operator of the RIOSensor should assure that it is used in such an environment.

8.1. Guidance and manufacturer’s declaration - electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The RIOSensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RIOSensor is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings use for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the RIOSensor or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

8.2. Guidance and manufacturer's declaration - electromagnetic immunity declaration

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Main power quality should be the typical commercial or hospital environment type.
Surge IEC 61000-4-5	±1 kV line(s) to line ±2 kV line(s) to earth	±1 kV ±2 kV	Main power quality should be the typical commercial or hospital environment type.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Main power quality should the typical commercial or hospital environment type. If the user of the RIOSensor requires continued operation during main power interruptions, it is recommended that the RIS500 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at level characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	0.15~80 MHZ 3 V	Portable and mobile RF communication equipment should be used no closer to any part of the RIOSensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHZ $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following Radiated RF symbol: 

8.3. Recommended separation distances

The RIOSensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RIOSensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment and the RIOSensor as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.387	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800MHz, the separation distance for the higher frequency range applies
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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