REMEDI™

User Manual

R-SENSOR

(Model name: IoDS-2401/IoDS-

2402)

Intra-oral Digital X-ray Sensor

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Document Version 5

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This User Manual may be revised for the improvement of the product, without prior notification. Images in this User Manual may differ from the actual product.

Table of Content

1. About User Manual

This User Manual is provided to the user along with the IoDS-2401/2402.

This User Manual only pertains to the IoDS-2401/2402 and does not serve for any other products of the

company. In the event of loss of or damage to this User Manual, please contact to service center of REMEDI Co., Ltd..

This User Manual describes the precautions and possible risks that the user should be aware of and give attention to prior to use the IoDS-2401/2402. Please read carefully all the precautions before you start using the device.

Please refer to the Table of Contents to easily find the information that you need.

If you have any inquiries or need detailed information on the product, please refer to the contact information or call our customer service center.

1.1 Cautions

This document contains proprietary information that is protected by copyright.

Under copyright law, this document cannot be reproduced, modified or otherwise amended without prior approval.

1.2 Quality Assurance

The contents of this document may be revised without notification.

The company will not be responsible for any consequential problems, loss or damage arising from the use of any performance specification or information that differs from the information contained in this User Manual.

1.3 Revision History

The part numbers and revision number indicated in this document represent the current version.

The revision number will not be changed even if any sub-documents are revised.

The revision number may be changed when there is a major change in part numbers or technical information in the document.

1.4 Symbols

Symbols are indicated on the exterior, packaging of the product and in this User Manual.

The symbols represent important cautions and advice to the user. Please read the following symbols carefully and be well informed of them for the use and storage of the product.

⚠	WARNING	This symbol represents "WARNING." It is associated with possible matters that may harm or cause irreversible damage to the product or the patient.
⚠	CAUTION	This symbol represents "CAUTION." It is associated with possible matters that may damage the product or harm the patient.

* This User Manual may differ from the actual product in terms of functionality.

* If deemed necessary, the company may make any improvement to the product to enhance its performance, without prior notification, and the company has no obligation to apply the same specification change to the products already sold.

* This user manual is written in English.

* Countries other than English shall be produced in the language of the country in accordance with the translation guidelines of REMED Co., Ltd.

2. Precautions

2.1 General Cautions

⚠CAUTIONS

1.	Please read and understand the instructions carefully and then use your device.
2.	No modification of this equipment is allowed. If the product is modified or used for any purpose other than those specified in this User Manual, REMEDI Co., Ltd. will not be responsible for the safe operation of the device.
3.	Please check the sensor if not use for a long time

4.	It can be provide any needed technical information to whom it may concern of maintenance service
5.	Do not pull the USB cable.
6.	Alerts the operator that failure to follow the procedure could cause damage to the equipment or cause loss of data.
7.	Do not continue to use the sensor if there is visible damage to the sensor housing and/or cable
8.	As the intra-oral sensor is situated inside the patient environment, your computer must necessarily comply with standard IEC 60601-1, or your installation including the computer must have been rendered compliant with standard IEC 60601-1. You can connect the sensor to your computer without additional precautions once your complete installation is compliant with standard IEC 60601-1.
9.	The sensor is an electrical medical device requiring special precautions regarding electromagnetic compatibility. Please observe the recommendations in this manual during the commissioning and use of the equipment.
10.	The sensor must be handled with care, minimizing the twisting, pulling and bending of the attachment cable. Do not step or roll on the cable. Do not pull on the cable itself but on the connection plug to disconnect the USB cable.
11.	To avoid interferences in the image, do not use the system close to strong magnetic fields and avoid proximity to electrostatic emission sources.

2.2 General Prohibitions

PROHIBITIONS

1.	Do not use it out of intended use.
2.	Do not attempt to modify the unit.

2.3 General warnings

WARNINGS

1.	This device should be used in accordance with doctor's instructions and instruction.

2.	The other equipment may malfunction due to the electromagnetic waves generated by this device. This device may malfunction due to electromagnetic interference generated by other equipment. Do not use it adjacent to other equipment or load other equipment do. Do not connect the USB cable to supply mains with wet hands.
3.	This device must be used by the intended user. Patients and users may be at risk from a variety of hazards when using the device by someone other than the intended user.
4.	If intentionally ignore the cautions, warnings, and safety signs specified in this manual, patient and user may be at risk from various hazards.
5.	Alerts the operator that failure to follow the procedure could cause bodily injury or death.

3. Appearance

3.1 Intended Use

- IoDS-2401/2402 is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.

- IoDS-2401/2402 is located in the patient's mouth and used together with a separate medical device, X-ray generator, used once for one patient, and can be used for another patient by replacing the designated protective cover after use. IoDS-2401 / 2402 should only be used by dentists.

- Patient group

Age: Not relevant

Health: Not relevant

Patient condition: Not relevant, However, that special care must be taken to ensure safety when the system is used to examine pregnant patients.

Patients who require radiographic imaging to diagnose diseases

Medical radiation exposure of pregnant woman is in accordance with ICRP-60 5.3.3

Radiation exposure against the pregnant woman executes only in case that it is necessary.

Abdominal radiation does are limited to less than 2 mSv when used in pregnant women

- Disease to be diagnosed: To diagnose diseases of the patient's teeth. (Example: Caries, tooth arrangement, etc)

3.2 Specification

Product name	Intra-oral digital X-ray sensor
Brand name	R-SENSOR
Model	IoDS-2401, IoDS-2402 (Model name is different according to the sensor head size.)
Classification	Class IIa (Annex IX, Rule 16, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)
Protection type from electrical shock	- ClassⅡ equipment - B type Applied part
Rating	5 Vd.c., 0.5 A (via USB cable connected to PC)
Expected service life	7 years
Essential performance	No essential performance
Software for IoDS-2401/2402	- Type: Standalone software (USB) - S/W name: REMEDIC - S/W version: V1.00
Harmonized Safety Standards	
IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: usability
IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

3.3 Product description

- An X-ray image sensor is positioned in the patient's mouth just like Intra-oral film. There is no electrical or physical connection between IoDS-2401/2402 and the x-ray generator. Images are automatically acquired when x-rays are present in a dose which is perceptible to the sensor.

- Digital x-ray images are quickly displayed on the screen. Images can be optimized for viewing via imaging software, stored as image files. Specified software is one example of a dedicated software that employs a number of utilities for optimizing viewing and printing of images.

- REMEDI offers technical support for this device to ensure proper operation and to answer any questions regarding the function of the device.

- The type of x-ray systems that integrate with the IoDS-2401/2402 are wall-mounted x-ray generators (both AC and DC) with a tube current between 1 and 15 mA inclusive, and with a tube voltage between 50 and 100 kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time.

- This device and software cannot act as an x-ray generator controller. All control of x-ray generation is done by controls built into the generator itself. There is no connection between the subject device and the x-ray generator. The subject device does not control the generator, it is a receiver.

- IoDS-2401/2402 must be connected to a PC through the standard USB 2.0 port.

3.4 Appearance

- Details size of IoDS-2401
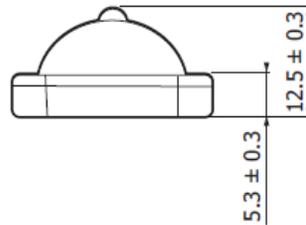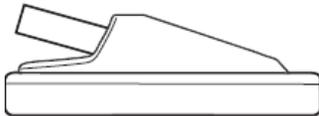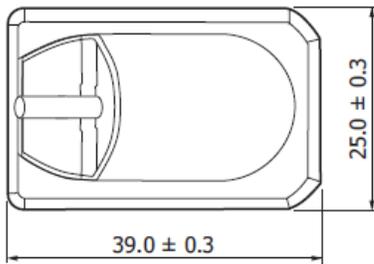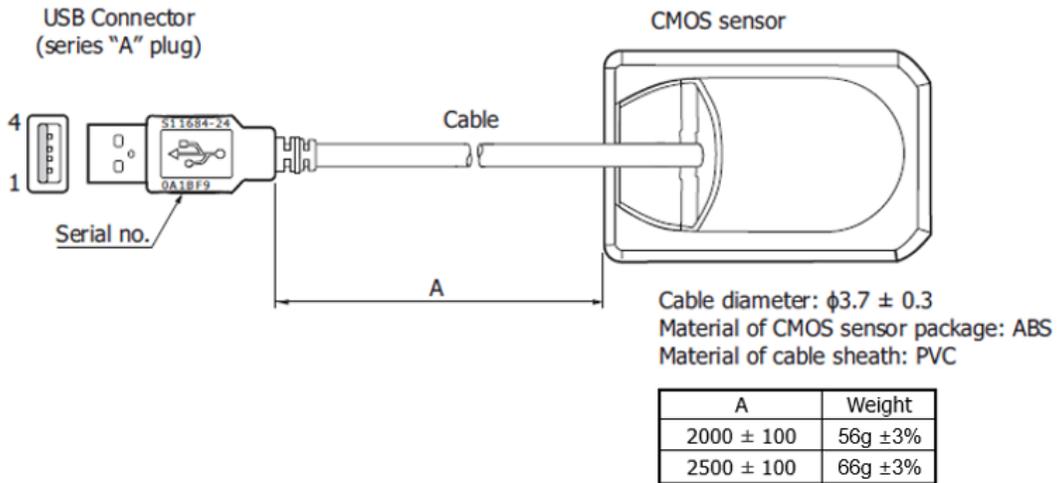
USB Connector
(series "A" plug)

CMOS sensor

Cable

4

S11684-24

1

0A1BF9

Serial no.

A

Cable diameter: $\phi 3.7 \pm 0.3$
Material of CMOS sensor package: ABS
Material of cable sheath: PVC

A	Weight
2000 ± 100	56g ±3%
2500 ± 100	66g ±3%

25.0 ± 0.3

39.0 ± 0.3

12.5 ± 0.3

5.3 ± 0.3

Standard packing:
polypropylene box in moisture-proof bag
[1 product/bag, bag size;150 (W) × 200 (H) × 50 (D) mm,
 gross weight: approx. 320 g]

- Details size of IoDS-2402

USB Connector
(series "A" plug)

CMOS sensor

Cable

4

S11684-24

0A1BF9

1

Serial no.

A

Cable diameter: $\phi 3.7 \pm 0.3$
Material of CMOS sensor package: ABS
Material of cable sheath: PVC

A	Weight
2000 ± 100	60g ±3%
2500 ± 100	70g ±3%

CMOS sensor

30.4 ± 0.3

41.9 ± 0.3

12.8 ± 0.3

5.6 ± 0.3

Standard packing:
polypropylene box in moisture-proof bag
[1 product/bag, bag size: 150 (W) × 200 (H) × 50 (D) mm,
gross weight: about 320 g]

.
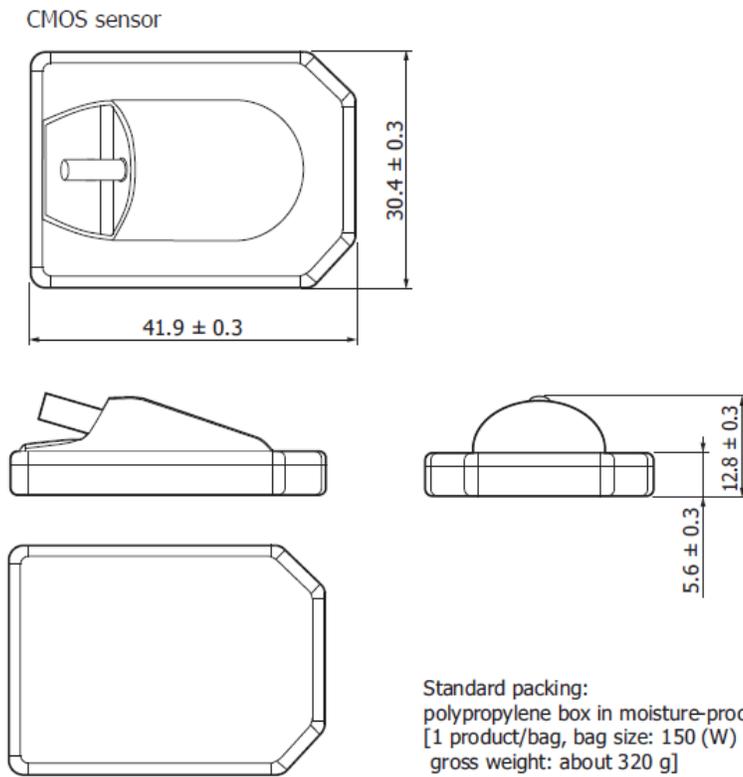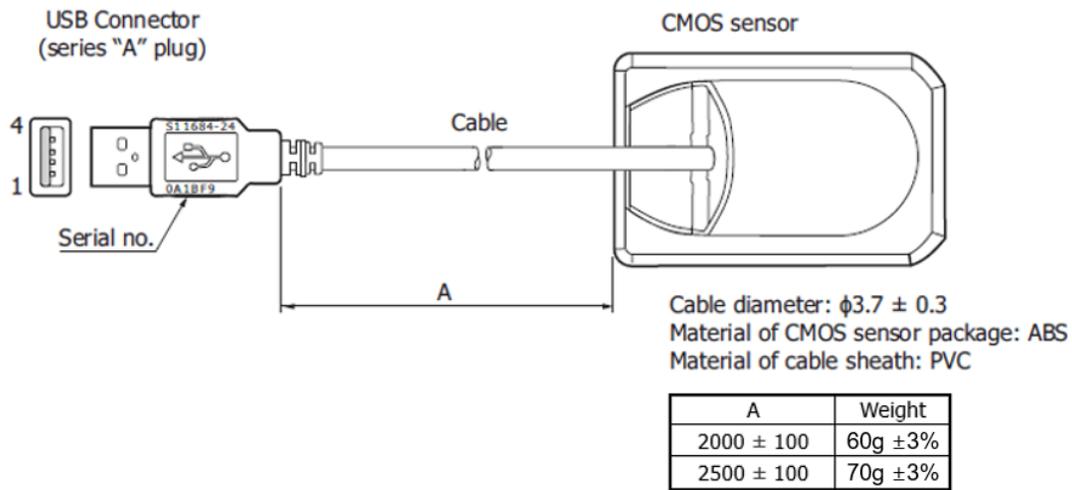
- The IoDS-2401(Sensor1) and IoDS-2402(Sensor2) are CMOS area image sensors developed for X-ray imaging. The image sensors have a monitoring photodiode for monitoring and detecting X-ray irradiation. FOP(fiber optic plate) used as the input window ensures high image quality and long sensor life even under exposure to X-rays.

- The IoDS-2401/2402 supports USB 2.0. These sensors are designed to be water proof, equivalent to IPX7.

- The intra oral sensor includes the following sub elements:

. CMOS image sensor chip

. Scintillator

. Electronic substrate (electronic circuitry carrier + proximity electronics)

. Flexible cable with end connector

. Watertight housing

. Shielding foils and shock absorbers

Scintillator

X-rays

CMOS chip

Shock
Absorbers

Ceramic
Support
And
Electronic

Shielding

Housing

Cable + Connector

Intra-oral Module Overview

Polymide Outer Casting
Electonic Circuit
CMOS Imager
Fiber Optic Plate (FOP)
Scintillator
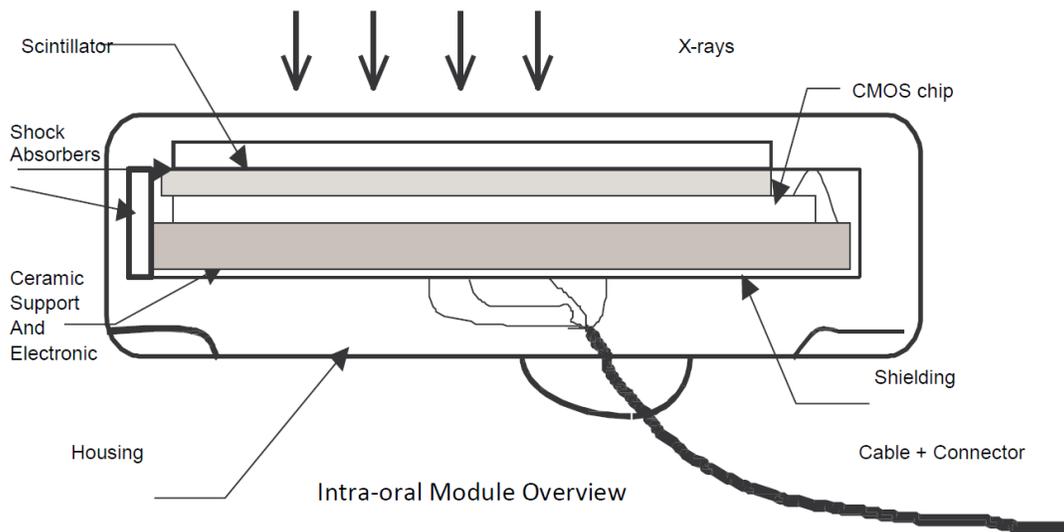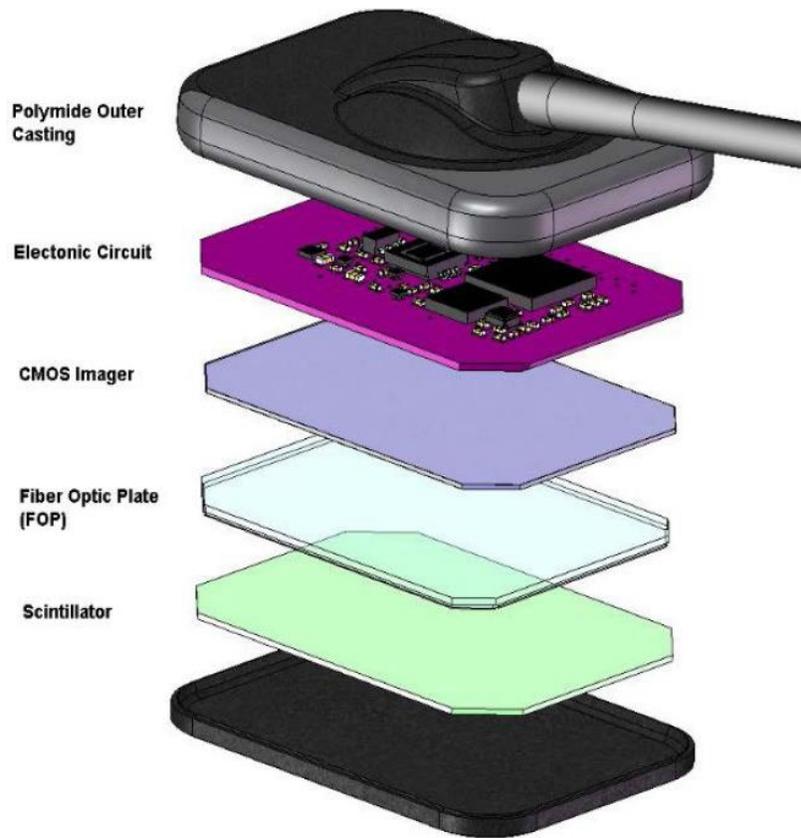
- Cable

   . Consists of PVC, ETFE, copper, plug connector and sensor connector

   . Diameter: φ3.7 ± 0.3

   . Length: 2 / 2.5 meters

- Housing

  . Housing material is ABS and the flammability is HB if YK-94(UL File No. 49895). The color

  sample of the finished ABS housing is: CABS- 7247C (Black).

  . Envelope protection rating: IPX7 (7=Protected against the effect of immersion between 15cm

  and 1m).

- X-ray protection

  . The rules of dental radiography still apply to digital x-ray systems. Please continue to use

  protection for your patients. As a clinician, clear the immediate area when exposing the sensor.

- Prevention of Cross-Contamination

. To help prevent cross-contamination between patients, place a new hygienic barrier on the sensor

for each new patient. The hygienic barrier must cover the sensor and at least 3-4 inches (7-10 cm) of

the cable.

3.5 Accessory

① Sensor holder

- An instrument that hangs the sensor after using the sensor

- size: 42 × 50 mm

- weight: 27g
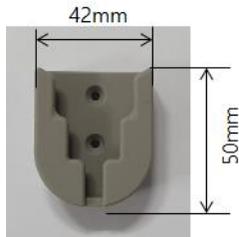
② USB : USB with program

- It is install on a PC   and display the signal transmitted from the sensor on the monitor to process the image.

- size: 18 × 41 mm

- weight: 3g

3.6 Operating condition

- Temperature: 0 ℃ ~ 35 ℃

- Related Humidity: 30 %R.H. ~ 75 %R.H. (Non-condensing)

- Atmospheric pressure: 76 kPa ~ 106 kPa

- Altitude: Less than 2,000 m

- Incident X-ray energy: 20 kVp ~ 90 kVp

3.7 Storage and transportation condition

- Temperature: -20 ℃ ~ 70 ℃

- Related Humidity: 10 %R.H. ~ 90 %R.H. (Non-condensing)

- Atmospheric pressure: 76 kPa ~ 106 kPa

3.8 Symbols

The following are descriptions of the symbols located on the outside and packaging of the product.
Please read carefully before using the product.

No	Symbol	Description	Location
1	SN	Serial Number	Product Label
2		Date of manufacture	Product Label
3		TYPE B applied part	Product Label
4		Follow instructions for use	Product Label
5		General Caution, Warning (safety sign)	User manual
6		General Prohibition (safety sign)	User manual
7		Alternating current	Product Label
8		Keep dry	Package

9		Keep away from sunlight	Package
10	EC REP	EC representative	Package Product Label
11		Manufacturer	Package Product Label
12	35℃ / 0℃	Operating temperature range	Product Label
13	70℃ / -20℃	Storage temperature range	Package
14	75%R.H / 30%R.H	Operating humidity range	Product Label
15	90%R.H / 10%R.H	Storage humidity range	Package
16	106kPa / 76kPa	Operating Atmospheric pressure range	Product Label
17	106kPa / 76kPa	Storage Atmospheric pressure range	Package
18		WEEE Mark	Package Product Label
19	CE	CE marking	Package Product Label
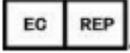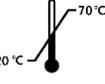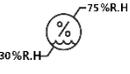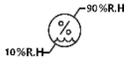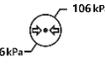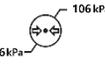
3.9 Labels of Sensor(Laser printing)

< Label location: Sensor front >

3.10 Label of Package
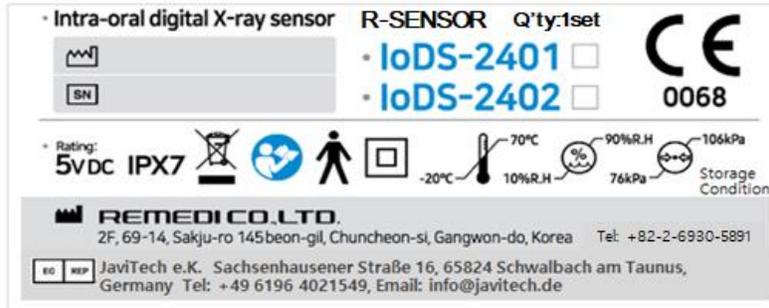
3.11 Applied part symbol

- (B type applied part) symbol was marked on the label

4. How to use (Start-up and Shutdown procedure)

4.1 Frequently used functions

- Check the sensor head for damage.

- Cover the sensor head with a wrap.

- Determine the location to exposure X-ray and place the sensor on the tooth to be imaged.

- Enter patient information or search for a patient.

- Operate the image. (Magnification, rotation, inversion, length measurement, etc.)

- Save the image.

- Remove the sensor from the patient mouth.

- Discard the wrap, clean the sensor, and store it in the designated location.

4.2 Pre-procedure

- Check the patient's condition.

- Put a wrap on the sensor.

- Determine the location to exposure X-ray.

- The Protective sheath uses 100L / 100S products from a licensed Pac-Dent International, Inc.

(Pac-Dent International, Inc FDA 510K No. K151123)

4.3 Setup guidelines

   - The computer and the screen with which the sensor is connected to should preferably be situated close to the chair, within the field of vision of the practitioner, to allow for immediate use. This will allow the practitioner to provide visual access to the patient and be able to share the radiological information with him/her.

   - The screen must be placed so as to avoid any reflections or direct overhead illuminations that could be detrimental to the visualization of the radiological images. It must be set up (contrast and brightness) to display as many grey levels as possible in the image.

   - The x-ray generator has a great influence on the quality of the acquired images. The IoDS-2401/2402 is compatible with any kind of generator, be it high-frequency or conventional. The generator must be equipped with an electronic timer (allowing for very short exposure times) and must emit a dose sufficient for the acquisition of a good image (with sufficient contrast). Make sure that your x-ray generator is in good repair and has been calibrated and tested recently (as per your states regulation). The energy emitted by a generator diminishes over time; when in doubt have your generator checked by a qualified technician.

4.4 Operation procedure

4.4.1 Precautions for Sensor ⚠

- Make sure the sensitive surface (the flat surface) of the sensor is directed towards the x-ray generator. The back of the sensor (rounded) does not react to x-rays and does not produce an image on-screen.

- The sensor must be manipulated with care, minimizing the twisting, pulling and bending of the attachment cables. Do not step or roll on the cable.

- Even though the sensor is resistant to impacts, it is strongly recommended to not let it fall on the floor. If a physical impact should happen, contact your distributor and do not try to intervene yourself.

- Do not tell the patient to bite on the sensor or cable. Instead, ask the patient to close their mouth around the sensor and relax the muscles of the jaw.

4.4.2 Precautions for Use

- Use a disposable sterilized cover to avoid various infections among patients.

- Check whether the product operates properly before using. Do not use the product when there is something wrong before using. Stop using the product immediately when it is found to be in fault while in use, such as overheating or cracking.

- Do not modify or overhaul the product by yourself.

- Verify your own application software. Improper command sequence, improper arguments and any other improper operation may result in unintended behavior.

- Do not twist, bend, pull and pinch the cable strongly. These actions can cause damage to the cable.

- Connect and disconnect the USB connector by holding the body of the sensor, never pull it by the cord.

- Check that the USB connector is not wet and dirty before you connect it.

- Do not touch the pins of the USB connector because the product can be damaged due to static electricity.

- Do not drop or strike the product.

- Do not apply any pressure (example, tight holders or biting) on the product because it might be damaged.

- Obey local laws when you use or dispose the product.

- If you use the product beyond the estimated useful life, check the performance of the product carefully before using.

- Take measures against computer viruses and verify antivirus measures.

4.5 How to Use

Only PCs that meet the specifications listed below should be used. Failure to do so may result in equipment damage or unacceptable risk to the patient or operator.

- IEC 60950-1 approved PCs

- OS: Window XP, 7, 8, 8.1, 10

- CPU: Pentinum4 or better process

- RAM: at least 1 GB

- Storage: 200 MB for software, 40 GB for user database

- USB 2.0 or 3.0

📖 Monitor resolution: at least FHD

⚠	The sensitive area of the sensor is indicated by the arrows in the picture. The area outside of the gold line is not sensitive to x-rays.	
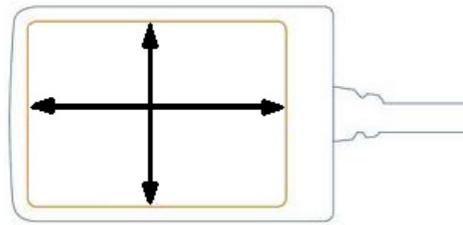
4.5.1 Installation of Software Driver

(1) Preparation

Complete package of the R-Sensor includes follows.

1) R-Sensor

2) Software USB

(2) Configuration of R-Sensor

- There are different ways to connect R-Sensor and your PC.

- R-Viewer is a dedicated software which allows you to save and acquire the image

- Through the imaging sensor.

- R-Sensor supports TWAIN and TWAIN compatible software.

(3) Software

Connect the included USB of the product to the PC and the folder will run

이름 ^	수정한 날짜	유형	크기
📁 Cal_Data	2019-08-27 오전 1...	파일 폴더	
📁 HAMAMATSU	2020-11-03 오전 9...	파일 폴더	
📁 R-VIEWER Setup	2020-08-11 오후 2...	파일 폴더	
📁 Sensor_Driver	2020-08-11 오후 2...	파일 폴더	
📄 User Manual_IO Sensor.pdf	2020-08-11 오후 2...	Adobe Acrobat D...	1,793KB

Menu	Description
R-Viewer Setup	R-Viewer for single PC use
Sensor_Driver	R-Sensor device driver

(4) Twain and device driver installation

The TWAIN driver is provided under the terms of the contract and please contact your seller.

(5) R-Viewer install

1) Connect the USB included with the product to your PC.

2) Enter the R-VIEWER Setup folder.

3) Double-click and run the RMD Setup file.

4) Select [All] and then click the [install] button when the screen below is displayed.
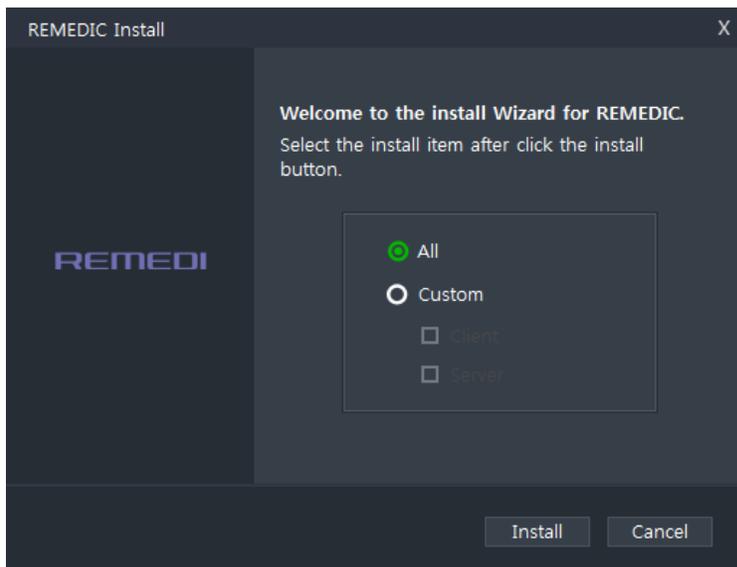
5) The installation proceeds automatically in this order: Client, DB Server, and File Server.
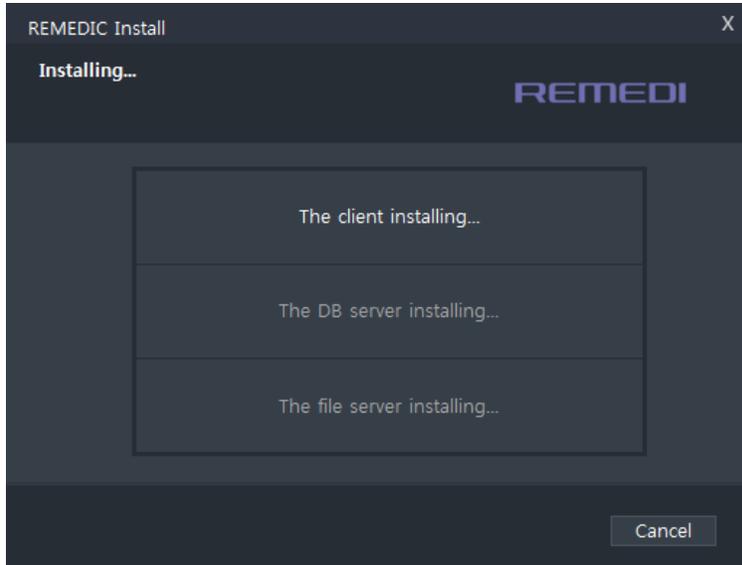
Note: The server consists of a DB server that manages information and a File server that

manages images.

6) When the installation is complete, the screen below will be displayed and the PC will reboot

when you click the [OK] button.

(6) R-Sensor driver install

1) Connect the USB included with the product to your PC.

2) Enter the Sensor_Driver folder.

3) Enter the folder to match the OS to the PC you want to install.

4) Double-click on the installation file to run it.
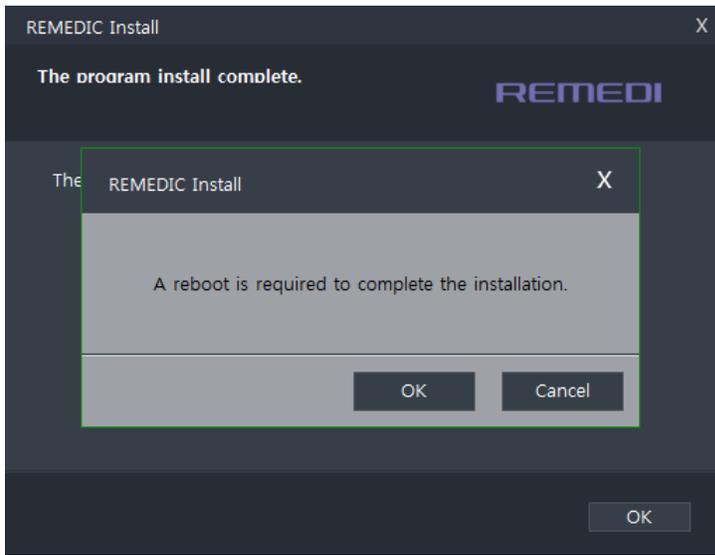
5) Please press OK as below.
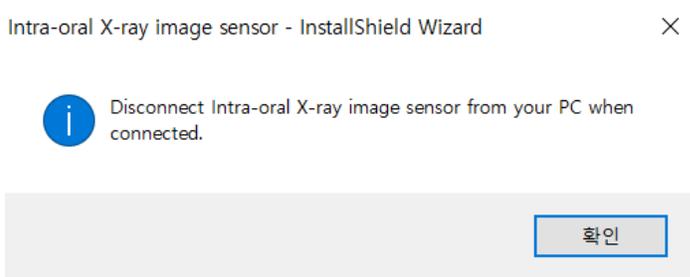
6) Click next.
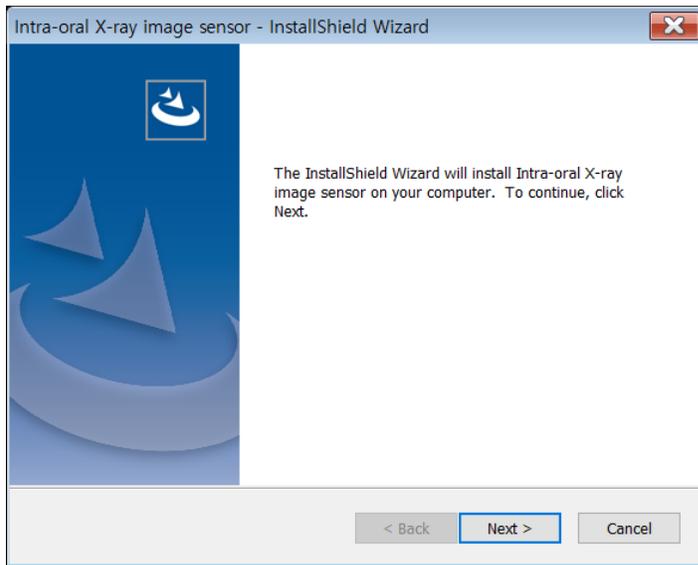
7) Click Yes
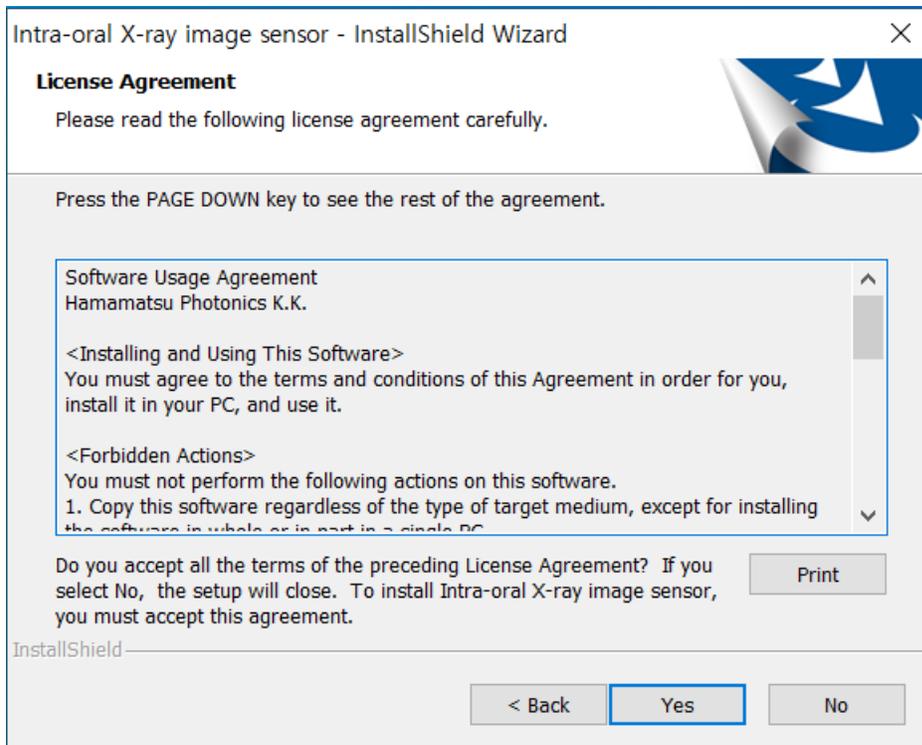
8) Click next.

Intra-oral X-ray image sensor - InstallShield Wizard   ✕

Choose Destination Location

Select folder where setup will install files.

Setup will install Intra-oral X-ray image sensor in the following folder.

To install to this folder, click Next. To install to a different folder, click Browse and select another folder.

Destination Folder

C:₩...₩IntraOralXrayImageSensor₩driver₩   Browse...

InstallShield

< Back   Next >   Cancel
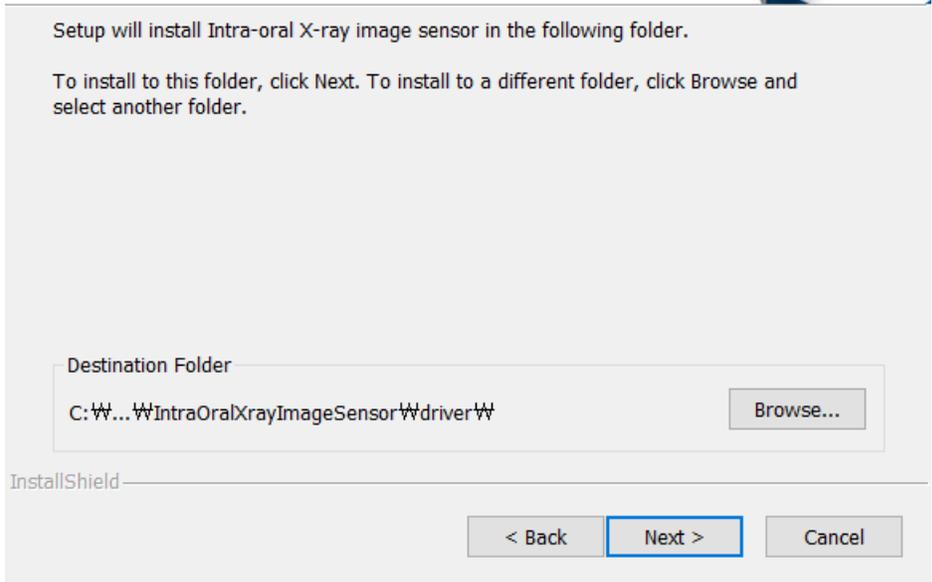
9) Click Finish and reboot to finish the installation.

Intra-oral X-ray image sensor - InstallShield Wizard

InstallShield Wizard Complete

The InstallShield Wizard has successfully installed Intra-oral X-ray image sensor. Before you can connect Intra-oral X-ray image sensor to your PC, you must restart your computer.

⦿ Yes, I want to restart my computer now.

◯ No, I will restart my computer later.

< Back   Finish   Cancel
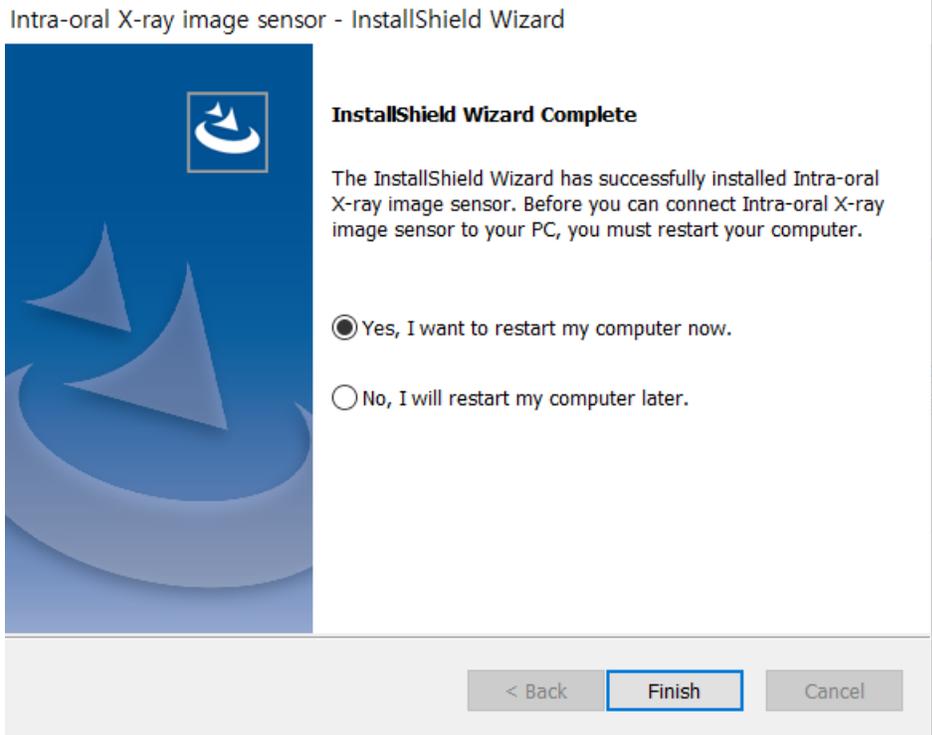
(7) Image acquisition by using r-viewer

1) Patient Add and Search Mode
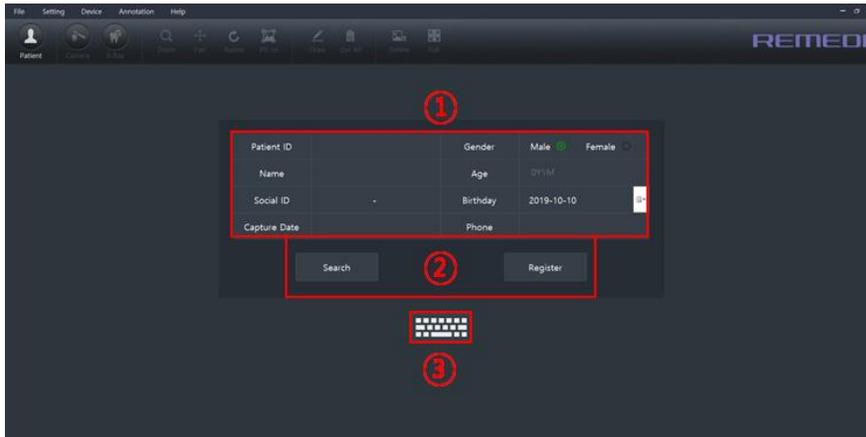
① Patient Information Input Window : Entering Patient Information to Add or Search

② Search and Add Button

③ Virtual Keyboard: Display Windows Virtual Keyboard

2) Patient Selection Mode

The list of patients searched or added is displayed.
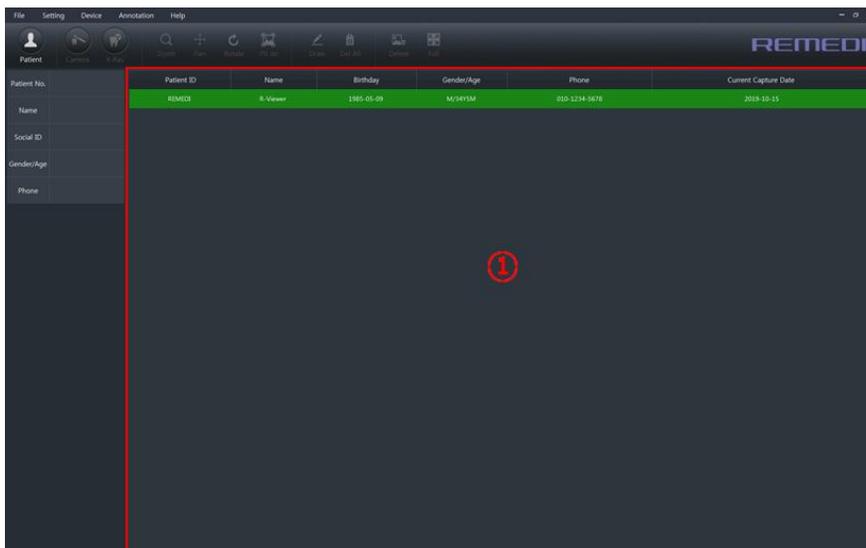
① Patient List: Displaying a list of patients searched or added

3) Imaging and Viewing Mode

View images of selected patients or take images of oral cameras or oral sensors.

It consists of the patient's information display window, the image data list, the Periodical view and

thumbnail, and the Image View window.
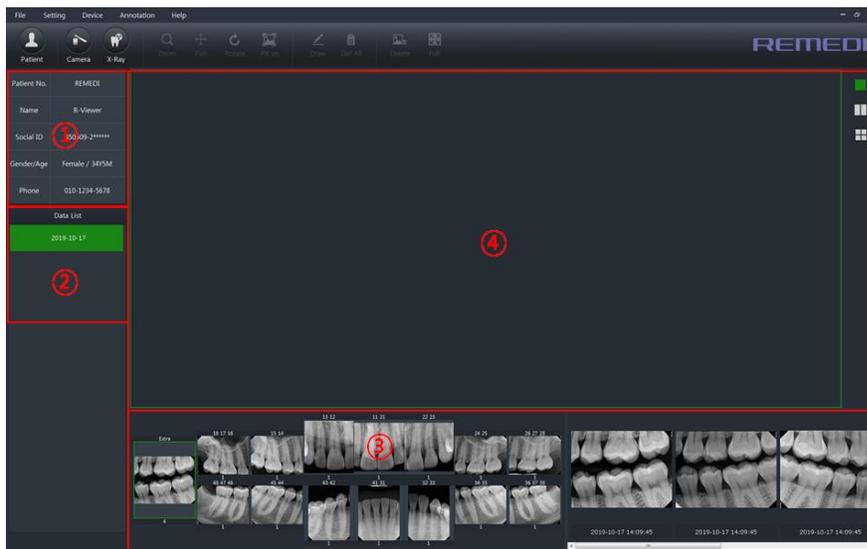
① Patient Information: Displaying information for selected patients

② Data List: List of date of imaging

③ Periodical & Thumbnail: Displaying the location of the shoot and viewing the

thumbnail

④ Image View: Display Selected Image Window

4) Oral sensor shooting

Filming method

- Click on the Oral Sensor Filming button - X-Ray Survey

- Clicking on the Oral Sensor Filming button displays the Oral Sensor Filming window shown below.

- After placing the sensor in the patient's mouth, the X-Ray is investigated and the image is automatically taken.
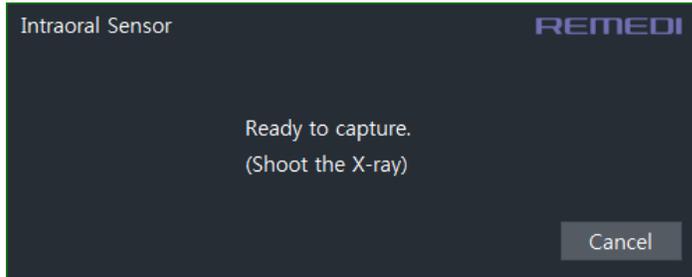
- When the oral sensor has been successfully photographed, the images are displayed in the Periodical View as shown below.
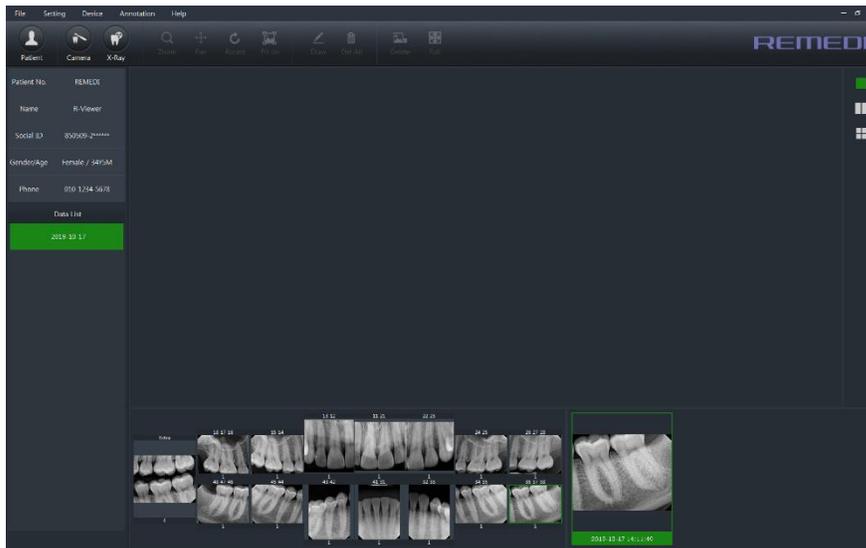
If the sensor is not connected, the message below will be displayed.

After clicking the Cancel button, please check the sensor connection.
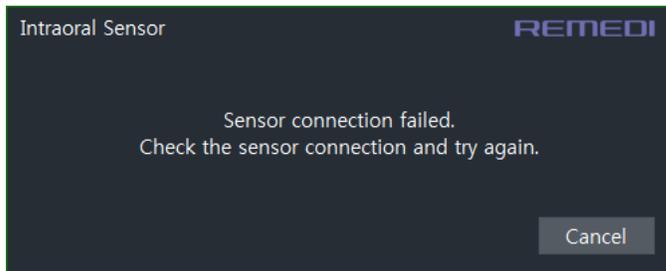
5) Cancels oral sensor shooting

Press the Cancel button with the oral sensor shooting window displayed to cancel the shooting
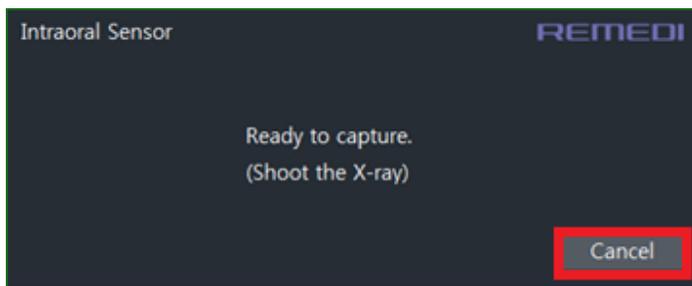
4.6 Shutdown procedure

- Remove the sensor from the patient mouth.

- Discard the wrap, clean the sensor, and store it in the designated location.

- Turn off the PC.

4.7 After using this device

- Turn the PC power switch off and separate the USB cable of IoDS-2401/2402.

- Please contact our headquarters or a nearby sales representative for any problems with the device

4.8 Storage and Cleaning after use

- The dental intra-oral sensors are not sterile medical devices.

- Hygiene is important with the sensor so be sure to change the disposable sheaths for every sensor usage between different patients to prevent risk of cross infection.

- Disinfect the image sensor before its first use and whenever there is a risk of contamination.

- Store disposable sanitary sheaths in a clean, dry place not exposed to sunlight or UV rays.

- It is mandatory to carefully follow the disinfecting and cleaning recommendations in order not to

damage the sensors.

- Do the following(See picture below)

        • Use protective gloves for using, cleaning or disinfecting the sensor.

        • To disinfect the sensor head and the cable near the sensor head, wipe them with a cloth with 70% isopropyl alcohol after you finish using the product.

        • Do not keep immersing the product in any liquid. However, you can immerse the sensor head in only water for a few seconds each time.

        • Do not expose the product to any unspecified liquid.

        • Use a new disposable protective sheath for every sensor usage.

        • Do not sterilize the product by heating, autoclaves or UV.

        • When the product is not in use, we recommend that you put it into the packing box we sent to avoid the damage of static electricity.

        • Keep the product away from direct sunlight, dust, or corrosive gases such as chlorine or fluorine, etc.

        • Do not apply pressure on the product during storage.

Recommended storage when not in use

- Do not do the following(See picture below)

  • Sterilize the sensor using autoclave or UV oven.

  • Wipe the cable surface with a moistened compress with a disinfecting solution.

  • Immersion in bleach or an alcohol content solution.

  • Immerse connector in disinfecting solutions.

  • Clean the sensor using non appropriate instruments.

4.9 Mechanical damage prevention

- Do the following(See picture below)

  • Always manipulate the sensor with a high degree of care.

  • Always use the sensor with the proper holder.

  • Plug and unplug the sensor holding the connector by the molded body and

never by the cord.

  • Use the holder and the method recommended by your distributor.

  • To remove from the holder, grip the sensor carefully and withdraw holder.

  • Make sure the sensor cable is not tangled, as damage may occur if not properly

used.

  • Make sure the sensor never strikes a hard surface.

- Do not do the following(See picture below)

        • Pinch sensor or cable.

        • Pull or kink cable.

        • Unplug sensor by pulling on cable.

        • Remove protective sheath by pulling the cable.

        • Drop sensor.

        • Leave cable on the floor.

        • Rolling over the cable with a chair or walking over it, this could damage the

cable.

        • Bite sensor or cable.

        • Do not touch the pins of the USB connector because the product can be

damaged due to static electricity.

        • Do not use a hemostat or any type of clamp to hold the sensor. This will cause

damage that is not covered under the warranty.

4.10 Protection from electrical damage

- Do not do the following(See picture below)

• Immerse connector in disinfecting solutions.

• Use a sensor that has a nick on the sensor head or on the cable.

• Do not pull on the cable itself when disconnecting the USB cable (See picture below).

5. Technical Data

5.1 Specifications - Performance

	IoDS-2401	IoDS-2402
Image size (H X V)	20 ㎜ X 30 ㎜	26 ㎜ X 34 ㎜
Pixel size (H X V)	20 ㎛ X 20 ㎛	
Pixel pitch (H X V)	20 ㎛	
Number of total pixels (H x V)	1000 pixels X 1506 pixels	1300 pixels X 1706 pixels
Number of effective pixels	1000 pixels X 1500 pixels	1300 pixels X 1700 pixels
Scintillator Type	CsI(Tl)-12/GOS-62	
Interface	USB 2.0	

- Effective photosensitive area of IoDS-2401
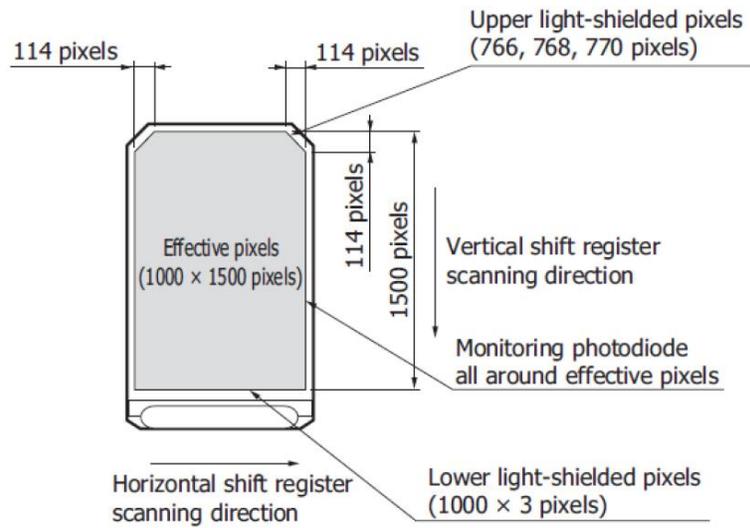
- Effective photosensitive area of IoDS-2402
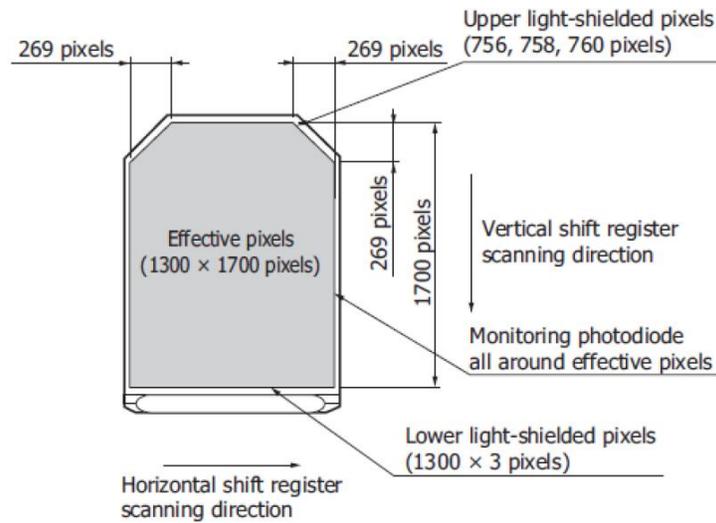
5.2 Exposure time chart

Parts of tooth		Classification	Exposure time	Exposure time set
Upper	Incisor	Adult	0.2 − 0.3 s	0.2 s
		Child	0.14 − 0.2 s	0.16 s
	Canine	Adult	0.3 − 0.4 s	0.35 s
		Child	0.1 − 0.2 s	0.1 s
	Molar	Adult	0.4 − 0.5 s	0.4 s

		Child	0.2 − 0.3 s	0.2 s
Lower	Incisor	Adult	0.14 − 0.25 s	0.2 s
		Child	0.08 − 0.14 s	0.1 s
	Canine	Adult	0.2 − 0.3 s	0.2 s
		Child	0.14 − 0.2 s	0.61 s
	Molar	Adult	0.25 − 0.35 s	0.3 s
		Child	0.16 − 0.25 s	0.2 s

5.3 Image quality assurance

- Image quality of the IoDS-2401/2402 sensor depends on several factors:

• The quality of the X-ray source (kV, focal spot size, distance)

• The alignment of the X-ray source to the anatomic region

• The applied X-ray dose / exposure time

• The settings of the computer monitor

- It is recommended that you establish a procedure for periodic review of the image quality. If image quality is not satisfactory, check the manufacturer guidelines of your generator to make sure it is not a software problem. Then contact customer service support.

- Display Image: Refer to the software manual for guidance on how to ensure good display settings and image display properties.

5.4 Electro Optical Performances

- General Test conditions for performances under X-ray specification:

• X-rays generator 70 kVp tube voltage

• Pixel: 20 μm x 20 μm

• Scintillator: CSI deposited on fiber-less substrate

• Performance given with dark image subtracted

• Analog: gain 2

• Threshold level 250 mV

5.5 Portability

   - The IoDS-2401/2402 can be easily moved from one dental chair to another. Once disconnected from the USB port of the computer, the sensor may be positioned near a second dental chair and connected to a USB port nearby.

6. Maintenance

6.1   Disposal of Equipment

   - This equipment has been applied the standard of the Waste Electrical and Electronic equipment(WEEE)

   - Ask repair service to manufacturer in case of product problem or weaken negative pressure. Do not repair randomly.

6.2 Problem solving

   - This section supplies information for some simple tests which the user may perform in the event the sensor malfunctions. Refer to the PC manual for information on other types of malfunctions.

   - If the system does not acquire x-ray images:

               • Check the USB connection.

               • Check that the IoDS-2401/2402 is not disabled in the software program.

               • Make sure that the correction file USB for the connected sensor is installed

   successfully.

               • Make sure that the active side of the sensor is facing the source of the x-ray

   and the active area is aligned with the x-ray beam.

               • Check the x-ray exposure settings and ensure that the x-rays were emitted.

   - If the problem cannot be resolved, contact your Dealer or Customer Support (information provided in this manual).

6.3 Replacement of parts by service personnel

⚠ Do not replace any parts of the device. Replacement of specific parts is possible only by the designated service personnel. Replacement of parts by unauthorized persons may

cause electrical hazards.

6.4 Maintenance

   - The IoDS-2401/2402 does not require any special maintenance other than regular cleaning and disinfection.

   - Clean your monitor screen, mouse and keyboard frequently.

   - Set monitor brightness and contrast properly. Be sure to use a video mode recommended for use with IoDS-2401/2402.

7. Statements and tables for EMC

Table 1 - Enclosure port

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		Professional healthcare facility environment
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields a)	IEC 61000-4-3	3 V/m f) 80 MHz − 2,7 GHz b) 80 % AM at 1 kHz c)
RATED power frequency magnetic fields d) e)	IEC 61000-4-8	30 A/m g) 50 Hz or 60 Hz

a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.

b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1). f) Before modulation is applied.

g) This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

Table 2 – Input a.c. power PORT: Not applicable (No Aa.c. power port)

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		Professional healthcare facility environment
Electrical fast transients/bursts a	IEC 61000-4-4	Not applicable ± 2 kV 100 kHz repetition frequency
Surges a) b) j) o) Line-to-line	IEC 61000-4-5	Not applicable ± 0,5 kV, ± 1 kV
Surges a) b) j) k) o) Line-to-ground	IEC 61000-4-5	Not applicable ± 0,5 kV, ± 1 kV, ± 2 kV

Conducted disturbances induced by RF fields c) d) o)	IEC 61000-4-6	Not applicable 3 V m) 0,15 MHz − 80 MHz 6 V m) in ISM bands between 0,15 MHz and 80 MHz n) 80 % AM at 1 kHz e)
Voltage dips f) p) r)	IEC 61000-4-11	Not applicable 0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° q)
		Not applicable 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0°
Voltage interruptions f) i) o) r)	IEC 61000-4-11	Not applicable 0 % UT; 250/300 cycle h)

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).

k) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.

l) Direct coupling shall be used.

m) r.m.s., before modulation is applied.

n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.

q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.

r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range. See Table 1 Note c) for examples calculations.

Table 3 – Input d.c. power PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		Professional healthcare facility environment
Electrical fast transients/bursts a) g)	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges a) b) g) Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges a) b) g) Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV

Conducted disturbances induced by RF fields a) c) d) i)	IEC 61000-4-6	3 V m) 0,15 MHz − 80 MHz 6 V m) in ISM bands between 0,15 MHz and 80 MHz n) 80 % AM at 1 kHz e)
Electrical transient conduction along supply lines f)	ISO 7637-2	Not applicable

a) The test is applicable to all d.c. power PORTS intended to be connected permanently to cables longer than 3 m.

b) All ME EQUIPMENT and ME SYSTEM cables shall be attached during the test

c) INTERNALLY POWERED ME EQUIPMENT is exempt from this test if it cannot be used during battery charging, is of less than 0,4 m maximum dimension including the maximum length of all cables specified and has no connection to earth, telecommunications systems, any other equipment or a PATIENT.

d) The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems

g) Direct coupling shall be used.

h) r.m.s., before modulation is applied.

i) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

j) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 4− Patient coupling PORT: Not applicable (No Patient coupling port)

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		Professional healthcare facility environment

ELECTROSTATIC DISCHARGE c)	IEC 61000-4-2	Not applicable ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted disturbances induced by RF fields a)	IEC 61000-4-6	Not applicable 3 V b) 0,15 MHz − 80 MHz 6 V b) in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

a) The following apply:

− All PATIENT-COUPLED cables shall be tested, either individually or bundled

− PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.

− No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.

− Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

− Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.

− If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

− The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b) r.m.s., before modulation is applied

c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table 5− SIP/SOP PORT: Not applicable (No SIP/SOP port)

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		Professional healthcare facility environment

ELECTROSTATIC DISCHARGE e)	IEC 61000-4-2	Not applicable ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transients / bursts b) f)	IEC 61000-4-4	Not applicable ± 1 kV 100 kHz repetition frequency
Surges a) b) g) Line-to-ground	IEC 61000-4-5	Not applicable ± 2 kV
Conducted disturbances induced by RF fields b) d) g)	IEC 61000-4-6	Not applicable 3 V h) 0,15 MHz − 80 MHz 6 V h) in ISM bands between 0,15 MHz and 80 MHz i) 80 % AM at 1 kHz c)

a) This test applies only to output lines intended to connect directly to outdoor cables.

b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Calibration for current injection clamps shall be performed in a 150 Ω system.

e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

f) Capacitive coupling shall be used.

g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

h) r.m.s., before modulation is applied.

i) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

8. Product Warranty Policy

This product is guaranteed for two years from the date of purchase.

We will repair the product free of charge during the warranty period.

Damage caused by the customer's negligence, even during the warranty period, does not apply to free

repair.

This product has undergone stringent quality management and has passed testing procedures in accordance with KGMP standards. This warranty will cover for damages or abnormalities that occur during normal conditions of operation

Please submit your warranty to a REMEDI Co., Ltd. service center or sales representative for after service and receive assistance regarding repairs

If the sales representatives or place of purchase does not offer repairs please contact the service center or hotline as shown on the bottom of the warranty

If this warranty is sent via fax to our headquarters, we will make a phone call to confirm the device number and register the device in our database. For all other cases, the warranty begins on the day the device is sent out for delivery from our headquarters

Contact Us: You can reach us through the following contact points to get detailed information on our services and products.

[Manufacturer / Customer Service Team]: REMEDI Co., Ltd.,
#24232, 2F, 69-14, Sakju-ro 145beon-gil, Chuncheon-si, Gangwon-do, Korea
Tel: +82-2-6930-5891, Fax: +82-2-6930-5892, E-mail: sales@remedihc.com
Homepage: http://www.remedihc.com

REMEDI Co., Ltd. homepage is available to you and provides a page where you can let us know if you have any complaints. If you have experienced any inconveniences during the use of our product or have any suggestions for improvement, except for product defects, please feel free to contact us and help us incorporate your ideas.

[EU Representative]: JaviTech e.K.
Address: Sachsenhausener Straße 16, 65824 Schwalbach am Taunus ,Germany

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