Model RPS500

RIOScan

Digital Imaging Plate System

User Manual

This user manual contains information for appropriate use of RIOScan.

The operator must read this manual carefully before using the product.

The operator must follow instructions and safety regulations described in the user manual to prevent any injury to the operator and the patient or damage to the product.

Caution (US only): This product must only be sold to dentists or oral health professionals as stated by the federal law.

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This manual is valid for following software revisions: RIOView Ver. 1.1 or higher
This manual is subject to change without prior notice.

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

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EC REP

CE 0120

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User Manual Information

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1 User Manual Information

This user manual provides information for your basic understanding of the RIOScan (also referred to as the “product”) as well as detailed steps to explain the product usage.

1) Do not discard this manual and keep it for future reference.
2) Read the safety information before using the product.
3) If you have a problem using the product, refer to troubleshooting in chapter 8.
4) All illustrations in this manual may differ from your product depending on its options or model you purchased.
5) The screenshots in this manual may differ from your experience of the product depending on the version of your product’s firmware or driver.

1.1 Conventions

Terms in this manual are used interchangeably:

1) “Product” refers to the scanner and its components.
2) “Machine” or “device” refers to the scanner or the imaging plate scanner.
3) “Image plate” or “IP” refers to the imaging plate.

1.2 Symbols and safety notices

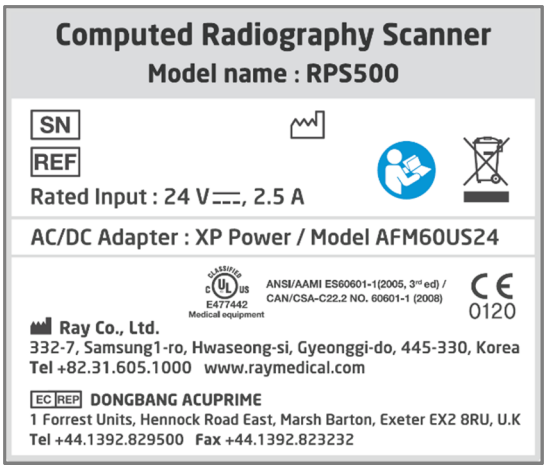
These symbols are included to prevent injury to you and others, and to prevent any potential damage to the product.

Symbols	Description
	This symbol indicates manufacturer.
	This symbol indicates the date of manufacture.
	This symbol indicates Authorized Representative in the European Community.
 Warning	This symbol indicates general warning sign to identify conditions or actions which cause personal injury or substantial property damage if the instructions are ignored.
 Caution	This symbol indicates general caution sign to alert the operator to exercise careful attention to any operation, procedure, or practice which if not followed may result in damage or destruction to the product and imaging plates.
	This symbol indicates that the operator should take precautions for handling electrostatic sensitive devices.
	This symbol illustrates the item is for single use only by the operator for safety reasons.
	This symbol indicates mandatory action required by operator.
	This symbol indicates essential information to the operator.
	This symbol refers to precautions for electromagnetic interference.

	This symbol indicates dangerous voltage.
	This symbol indicates compliance of guidelines and instructions in the manual for safe operation of the equipment.
	This symbol indicates prohibited action for the safety of the operator.
	This symbol indicates that the product may include industrial waste materials.

1.3 Label

The following label is located at the rear of the scanner and on the packaging box.



Safety and Regulatory precautions

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2 Safety and Regulatory precautions

This chapter contains safety information that must be thoroughly read and understood prior to operating to the product.

Be sure to read and understand all of these instructions before using the product. After reading this section, keep the manual in a safe place for future reference.

The product is intended for use by qualified personnel only.
The owner shall ensure that all precautions and safety measures are taken place as well as maintenance events.

It is recommended to use genuine manufacturer's parts and components. Service or repair required as a result of using non-genuine parts or non-genuine components will not be covered under the product's warranty.

Do not modify this equipment without authorization from the manufacturer.

2.1 Intended use

The RIOScan (Model RPS500) is a digital intraoral dental radiographic imaging system intended for use by dentists and dental or oral health professionals. The system captures, digitizes, displays, and stores diagnostic intraoral radiographic images.

2.2 Safety

2.2.1 Operation

Please be alert and cautious to ensure safe usage of the product.

Before using the product, check for any malfunctions or abnormalities. Do not use the product when then product needs repairing, contact qualified personnel.

Do not leave the patient alone while the product is operating.

2.2.2 EMC and ESD

Electromagnetic compatibility (EMC) requirement and Electrostatic discharge (ESD) protective measures must be 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 Appendix B 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 static can be done by touching the ground wire or metallic objects.

2.2.3 Environment

Place the product in an environment where it meets the operating temperature and humidity specifications.

Do not use the scanner when it is below freezing temperature or has recently been moved from a location below freezing temperature. Doing so may damage the scanner. Only operate the scanner when the internal temperature of the scanner is within the operating temperature and humidity specifications.

Do not use the product in places where chemicals are stored or where gas is generated.

Do not place the product in an area with dust, humidity, or water leaks. This could result in electric shock or fire.

Choose a flat and stable surface with enough space for ventilation to place the product. Please avoid sources of direct light, heat, chemicals, gases, or excess humidity.

- Do not place the product near any heat sources or radiators.
- Do not place the product on an unstable surface. The product could fall, causing injury or product damage.
- Do not put a cover over the scanner or place it in an unventilated location, such as a closet. If the scanner is not well ventilated, this could result in fire.
- Do not use the product if the power cord is damaged or if the electrical outlet is not grounded. This could result in electric shock or fire.
- Do not place anything on top of the product (e.g. fluids, small metals, heavy objects, candles, lit cigarettes, etc.). This could result in electric shock or fire.

- If the scanner overheats, releases smoke, makes noise, or generates an odd odor, immediately turn off the power switch and unplug the scanner from any electrical source.

- The user should always have access to the power outlet in case of emergencies that require the user to pull out the plug to prevent electrical shock or fire.

- Do not bend, step on, or place heavy objects on the power cord. Stepping on or crushing the power cord with heavy objects could result in electric shock or fire.

- Do not remove the plug by pulling on the cord. Do not handle the plug with wet hands. This could result in electric shock or fire.

2.2.4 Handling of the product

1) It is recommended to store the product in its original box in order to avoid any damages when it is not in use for a week or longer.

2) If the product has been dropped, or if the outer case of the scanner appears damaged, unplug the scanner from all interface connections and request assistance from your sales representative or qualified service personnel. Otherwise, this could result in electric shock or fire.

3) If the scanner does not operate properly after these instructions have been followed, unplug the scanner from all interface connections and request assistance from your sales representative or qualified service personnel. Otherwise, this could result in electric shock or fire.

4) Do not disassemble, repair, or rebuild the scanner by yourself. It can damage the scanner. Call your sales representative or a certified technician when the scanner needs repairing.

5) To clean and operate the product, strictly follow the user manual provided with the product. Otherwise, you could damage the product.

6) Do not clean the product with benzene, paint thinner, or alcohol and do not spray water directly into the product. This could result in electric shock or fire.

7) Do not forcefully pull the imaging plate out during scanning. It can cause damage to the scanner or to the image plate.

8) Do not block or push objects into the imaging plate inlet or the imaging plate outlet of the scanner.

9) Do not forcefully insert the imaging plate into the inlet during scanning. It can cause damage to the imaging plate or distortion on the X-ray image.

10) Do not turn off the scanner during scanning or transmitting data. It can cause loss of the X-ray image.

11) Do not touch the pins of the LAN connector.

12) The PC and other devices connected to the scanner must use an isolated power source which has patient protection measures. The PC and other devices must be grounded.

13) Do not overload wall outlets and extension cords. This can diminish performance, and could result in electric shock or fire.

14) The scanner must use the power level which is specified on the label. If you are unsure or want to check the power level you are using, contact your local electrical utility company.


Warning

Make sure you plug the power cord into a grounded electrical outlet (supply mains with protective earth). Otherwise, this could result in electric shock or fire.

2.2.5 Radiation

1) Only qualified personnel should operate this product. Suitable measures for X-ray protection (ex. Lead apron) must be considered when using X-rays.

2) You must observe all local radiation safety and exposure regulations when using this product with an X-ray source and when exposing patients to X-rays.

2.2.6 Laser

1) The product is certified to conform to the requirements for Class 1 laser products. Class 1 laser products are considered to be non-hazardous. The product and its laser system are designed so patients are not exposed to laser radiation above a Class 1 level during safe and normal operation.

2) Never operate or service the scanner with the cover removed from the product assembly. If you open the cover, laser beam that is class 3B power will be emitted. The direct or reflected laser beam which is invisible can damage your eyes.

3) Laser information

Items	Specification
Material Laser safety classification (IEC 60825-1: 2014)	3B
Wavelength	658 nm (Typ.)
Output power	26 mW (Max.)

Warning

When using this product, follow these safety precautions to reduce risk of injury.

2.3 Disposal

This symbol on the product, accessories or literature indicates that the product and its accessories (e.g. charger, headset, USB cable) should not be disposed with other household waste at the end of their working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other waste and recycle them responsibly to promote the sustainable reuse of material resources.

Contact your supplier and check the terms and conditions of the purchase contract. This product and its electronic accessories should not be mixed with other commercial wastes for disposal.

2.4 Hygienic protection and cleaning

2.4.1 Hygienic protection

Before using the imaging plate on a patient, the imaging plate must be covered with a new protective cover and new barrier envelope. Note that the protective cover and the barrier envelope are single use only. Both protective covers and barrier envelopes must be newly replaced for each patient to prevent from any transmission of infective agents.

Use the appropriately sized protective cover and barrier envelope for the size of the imaging plate. Protective covers and barrier envelops can be purchased from the manufacturer or your sales representative.

Take appropriate hygienic measures to prevent cross contamination between patients or operators.

2.4.2 Cleaning

Do not sterilize the product via heating, autoclaving, or UV light.

1) Imaging plate

Pay special attention to avoid the risk of damage when cleaning the imaging plate. Excessive force to the imaging plate during cleaning may cause damage.
To clean the plate, wipe with a dry soft cloth (lint free cotton).

Do not immerse the imaging plate in any disinfectants or other chemicals.

2) Scanner

If X-ray image quality problems occur or if the product is kept in a dusty environment, you may need to clean and maintain your product regularly in order to use the product in its best condition and to use the product to its maximum life span.

Cleaning the product with cleaning materials containing large amounts of alcohol, solvents, or other strong substances can discolor or distort the product.

If your product or the surrounding area becomes contaminated, we recommend cleaning with a soft cloth or tissue dampened with 70% isopropyl alcohol.

During the scanning process, dust particles can accumulate inside the scanner. This buildup can cause image quality problems. Cleaning the inside of the scanner clears dust reduces these problems.

In order to maintain the image quality of the scanner, clean the inside of the scanner once a week. Clean the inside of the scanner immediately when dust particles or foreign objects are found in the X-ray images or on the imaging plate. See details in chapter 3.3.

Maintenance and Quality control

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3 Maintenance and Quality control

Maintenance procedure and quality control procedure shall be performed periodically by observing the following instructions and local regulation.
The owner or operator is responsible for periodic maintenance and quality control to reduce and identify any potential problems.

3.1 Maintenance

Items	Description
Daily maintenance	Inspect if there is any damage or abnormal condition on the scanner and imaging plates. Check if the PC and the software are working properly. Check if the X-ray source (system) is operating properly.
Before each patient	Check if the imaging plate is cleaned appropriately.
Weekly maintenance	Clean the inside (feeder module) of the scanner.
Within every 6 months	Perform a quality control check.

Periodic maintenance could prevent deterioration of the product performance or product failure.

3.2 Quality control

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

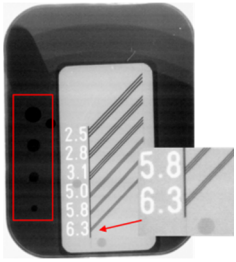
Items	Description
Qualification of controller	Operator or physician who have read this instruction for use.
Frequency of QC	Every six months.
Required tools	"Quart" phantom or similar.
Testing criteria	1) Test for low level contrast of X-ray image: 4 contrast objects (Ø1.0, 1.5, 2.0, 2.5mm) should be 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 "Quart" Phantom or similar.

1) Run "RIOView".
2) Capture the X-ray image of the "Quart" phantom or similar.
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	Number of the low contrast objects identified in the X-ray image: 4	Pass
Line pair resolution(LP/mm)	Line pair resolution: 6lp/mm or higher	Pass



Caution

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

3.3 Cleaning inside (feeder module) the scanner

3.3.1 Cleaning instructions

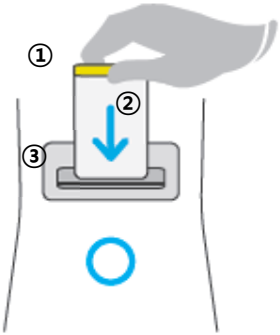
1) Prepare a cleaning sheet clip(①), cleaning sheet(②) and cleaning sheet guide(③).

2) Place the cleaning sheet guide onto the scanner.

3) On the touch screen menu, select the cleaning function.

4) Prepare the cleaning sheet and clip the holder at one end.

5) Touch the screen and insert the cleaning sheet as below image.



6) Cleaning will automatically proceed when the cleaning sheet is inserted. When cleaning is complete, the sheet will automatically remove itself from the scanner.

7) Repeat the cleaning process two or three times to completely remove dust or other foreign substances in the scanner.

3.3.2 Cleaning period

1) It is recommended to clean the product once a week, but the cleaning schedule can be adjusted to accommodate the frequency of use or the operation environment.

2) Immediately clean the inside of the scanner when dust or other substances are found on the X-ray images or imaging plates.


Caution

Please use cleaning sheets provided by manufacturer when cleaning the inside of the scanner. Using non genuine cleaning sheets or incorrect cleaning process can cause image quality loss or technical issues.

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Technical Specifications

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4 Technical Specifications

4.1 Specifications

Items	Specification
Available Imaging plate	Size: 0, 1, 2, 3, 4*
Imaging plate size (W X H)	Size 0: 22 x 35 mm Size 1: 24 x 40 mm Size 2: 31 x 41 mm Size 3: 27 x 54 mm Size 4: 57 x 76 mm
Gray scale resolution	14 bit
Resolution(Theoretical)	SHR: 21 lp/mm HR: 16 lp/mm HS: 9 lp/mm
Erasing	Auto
Display	4.3” Touch screen
Dimensions(W x H x D)	170 x 260 x 278 mm
Weight	3.5 kg
Connection	Fast Ethernet
Laser safety classification	Class 1 Laser product
Power supply	100 – 240VAC, 50/60Hz (24VDC, 2.5A, AC/DC adapter)

* Size 4 imaging plate is an optional item in the Occlusal kit.

4.2 Environment

Items	Specification
Operation environment	Temperature: 10 ~ 35 ℃ Humidity: 20 ~ 80 %Atmospheric pressure: 800hPa ~1060hPa
Storage condition	Temperature: -20 ~ 50 ℃ Humidity: 10 ~ 90 % Atmospheric pressure: 800hPa ~1060hPa

4.3 RIOView system requirement

Items	Recommended Specification
CPU	Intel i5 or higher
RAM	4GB or more
HDD space	200GB or more
Resolution	1280 X 800 or higher
Video	Video Card with over 512MB RAM
USB port	USB port 2.0
LAN port	100M Ethernet
Peripherals	CD/DVD ROM drive
Operating System	Microsoft Windows® 7 Microsoft Windows® 8 Microsoft Windows® 10

The PC and all other equipment connected to the scanner must have the CE marking (IEC approval) or UL/CSA approval.

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Product Information

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5 Product Information

5.1 Images of scanner, parts, and components

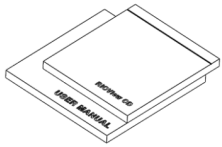
Scanner

AC adapter

Power cord

Ethernet cable

Software Installation CD and user manual



Imaging plate

Protective cover

Barrier envelopes

IP guide

Size 0~3

Size 4 (Option)

IP Storage box and pad

The actual scanner and components may differ from the images above. Some components may change depending on the models and changes in specifications.

5.2 Items

Actual items, quantity, or packaging in your kit may differ from the list depending on your country or options for your purchase.

5.2.1 Standard Kit

1) Scanner box

- Scanner: 1ea

2) Imaging plate box

- Imaging Plate Kit(Size 0): 1 kit (2 pcs)
- Imaging Plate Kit(Size 2): 1 kit (2 pcs)
- Barrier Envelopes(Size 0): 1 box (200 pcs)
- Barrier Envelopes(Size 2): 1 box (200 pcs)
- Protective Covers(Size 0): 1 box (100 pcs)
- Protective Covers(Size 2): 1 box (100 pcs)

3) Components box

- AC Adapter: 1 ea
- Power cord: 1 ea
- Ethernet Cable: 1 ea
- Imaging plate tray: 1 ea
- Imaging plate guide(Size 0~3 type): 1 ea
- Imaging storage box: 1 ea
- Imaging storage box pad: 1 ea
- Software Installation CD: 1 ea

- User manual: 1 ea
- Cleaning sheet
- Cleaning sheet guide
- Cleaning sheet clip

5.2.2 Occlusal Kit (Optional item)

- Imaging plate guide (Size 4 type): 1 ea
- Imaging plate kit (Size 4): 1 kit (1 pcs)
- Barrier Envelopes (Size 4): 1 box (100 pcs)
- Protective covers (Size 4): 1 box (100 pcs)

5.3 Component name and function

Items	Description
①Touch screen	The touch screen displays information. It can be operated by the user's fingertips or a touch screen stylus pen.
②Imaging plate guide	Imaging plate guide enables users to insert the imaging plate properly. There are two different types of guides: one for size 0-3 and another for size 4 (optional). **Caution: Be sure to use the appropriately sized guide for each imaging plate.**
③Power button	The user can turn the scanner on or off using the power button. The LED indicates the power status. No light: Scanner off Blue light: Scanner on Blinking light: Power save mode
④Imaging plate tray	The imaging plate drops onto the imaging plate tray after the image has been read or erased. **Caution: Please keep the imaging plate clean from dust or other contaminants.**

⑤**AC adapter jack**	The AC adapter jack connects the AC adapter to the scanner. Please connect one end of the power cord to the AC adapter then connect to the wall power supply. **Note: Power cords can vary from region to region.** **Caution: Be sure to only use the AC adapter provided by the manufacturer.**
⑥**Ethernet port**	Ethernet cable connects to the Ethernet port (RJ45).

5.4 Component

5.4.1 Imaging plate

- X-ray exposure will create and save an image onto the imaging plate.
- The imaging plate has two sides: the active (blue) and inactive (printed) side. The active side (blue) must be exposed to X-rays.
- Use the scanner to attain or erase images on the imaging plate.
- There is an orientation marker (“r”) on the bottom left corner of the imaging plate. Refer to this marker when taking X-ray images.

If the active side (blue) of the imaging plate has scratches or other kinds of damages, please replace it with a new one.

It is important to scan the image from the plate as soon as possible after taking the X-ray image. The image quality deteriorates as time passes. The image must be developed within thirty minutes from when the image was taken while it is still inside the barrier envelope. Manually erase (See details in chapter 7.5 Erase.) the imaging plate if it has not been used within the past 24 hours.

5.4.2 Protective cover

- The protective cover shields the plate from physical damage and data loss caused by external sources of light.

To prevent image data loss caused by exposure to external light sources, do not remove the imaging plate from the protective cover until inserting into the scanner for image reading.

Protective cover is for single use only. Do not reuse.

5.4.3 Barrier envelopes

- Barrier envelopes protect imaging plates from contamination caused by external factors.
- Barrier envelopes prevent image data loss in the imaging plate caused by external light sources.

The imaging plate must be inserted into the barrier envelope before use. In order to prevent cross contaminations between scanner operators and patients, please keep and use barrier envelopes in sterile condition.

Barrier envelopes are for single use only. Do not reuse. To prevent infection and contamination, please properly dispose barrier envelopes after each use.

It is recommended to use genuine manufacturer's components such as imaging plates, protective covers, barrier envelopes, and cleaning sheets. Using non-genuine components may result in malfunction and poor image quality which will require servicing or repair and will not be covered under the product's warranty.

5.4.4 Imaging plate storage box

The imaging plate storage box is where the imaging plates are stored. Imaging plates should always be kept in its storage box when not in use to protect them from physical damage or contamination.

5.4.5 Imaging plate storage box pad

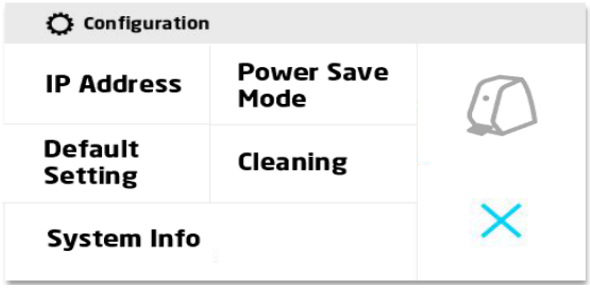
When handling imaging plates, handle them over the imaging plate storage box pad to prevent damages from drops or scratches. It is also recommended to grab them carefully to not cause any physical damages.

5.5 Touch screen of scanner

5.5.1 Home Screen

Items	Description
Network connection status	Network connection status is shown on the touch screen by icons. : Network connected : Network disconnected
QuickScan	X-ray images are saved in the internal memory of the scanner. **Note: QuickScan is useful when "7.2 Normal scanning" is impossible due to PC or network issues.**
Erase	Manually erases the data on the imaging plate.
Configuration	IP address, Power save mode, Default setting, Cleaning and System information are set or adjusted.

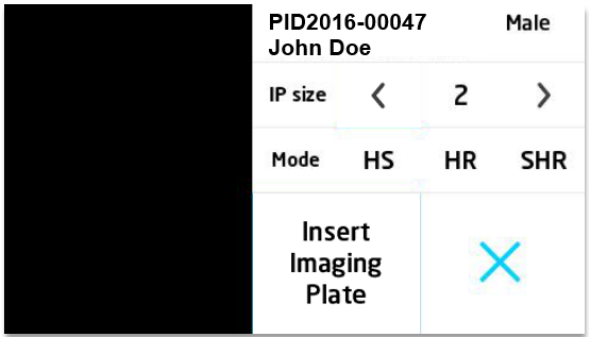
5.5.2 Configuration Screen



Items	Description
IP address	The IP address, subnet mask, and default gateway are set using the number buttons.
Power Save Mode	There are four intervals for power save mode: never (turns off power save mode), 10 minutes, 30 minutes, and 60 minutes. **Note: The scanner converts to power save mode after a period of inactivity which is indicated by a blinking blue LED light.** **To deactivate (or wake) the scanner from power save mode, tap the touch screen or power button, or operate the software on the PC that is connected to scanner.**
Default Setting	Sets the default values for ScanReady Screen. IP size: 0, 1, 2, 3, 4(Optional) Mode: SHR(Super high resolution), HR(High resolution), HS(High speed)
Cleaning	Initiates the cleaning procedure to clean inside (feeder module) the scanner. The procedure removes dust or other contaminants inside the scanner. The scanner should be cleaned on a regular basis to maintain image quality.
System info	Displays the scanner name, IP address, serial number, and firmware version.
	Demonstrates the basic functions of the scanner. A pre-saved demo image is displayed on the preview screen.
X	Returns to the home screen.

5.5.3 Scan Ready Screen

The below image appears on the touch screen when [Scan] button is activated on RIOView.

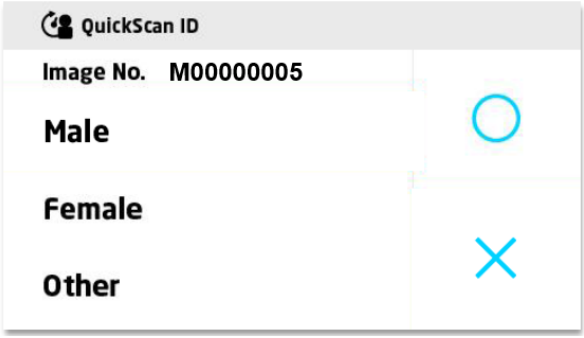


Items	Description
Patient information	Patient information (ID, name, gender) selected from the PC software will appear on the touch screen.
IP size	Imaging plate size can be adjusted by tapping [<] and [>] buttons.
Mode	HS (High speed), HR (High resolution), and SHR (Super high resolution) modes are provided.
Insert Imaging plate	This area displays messages and status of the scanner during operation and the operator can initiate scanning procedure by tapping on the area. “Insert Imaging plate”: Displays the message when the scanner is ready for insert of a imaging plate. “Touch to Scan”: Displays the message when the scanner is ready to scan. The operator can tap on the message to begin scanning. “Scanning, “Erasing”, and “Transferring Image”: These messages displays to indicate the current stage of the scanning process.
Preview	The scanned image will display on the touch screen for preview.
X	Cancels the imaging plate reading. Tap on [X] to remove the imaging plate from the scanner without image reading or erasing when the status is ‘Touch to Scan’.

Caution

Scanning over a previously canceled imaging plate can cause image quality loss due to exposure to external light sources and other environmental factors.

5.5.4 QuickScan ID Screen



Items	Description
Image No.	The serial number on the image saved into the scanner via QuickScan mode.
Male	Select when scanning a male patient.
Female	Select when scanning a female patient.
Other	Select when the imaging plate contains other types of images.
O	Select to return to the Scan Ready screen.
X	Cancels QuickScan mode and returns to the home screen.

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Installation

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6 Installation

The scanner should be installed by a qualified technician who received training on installation and management of the device.

6.1 Pre-installation cautions

6.1.1 Shipping and packaging

1) Inspect the condition of the packaging for damages that may have occurred during shipping and handling.
2) Protect the scanner from strong impact.
3) Immediately after opening the box, check the quantity of the basic components and packing conditions. Make sure all listed components are included in the package.

6.1.2 Installation site

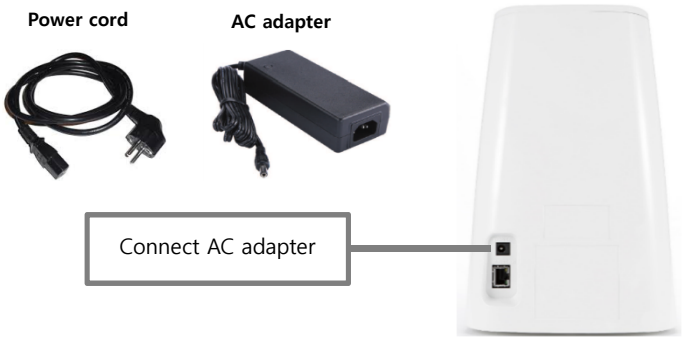
1) Avoid places with strong ambient light or direct sunlight.
2) Place the scanner away from the vicinity of wireless or portable devices which may emit electromagnetic waves. The waves may harmfully interfere with the operations of the scanner which may result in malfunctions.
3) Vibrations can affect image data during scanning. Avoid areas with vibrations.
4) Install the scanner on a stable surface that is at least 50cmx50cm and can support 5kg.
5) Do not move the scanner during operation.
6) Do not impact the scanner with strong forces.

6.2 Product installation

6.2.1 Power supply connection

During initial installation, make sure the power supply from the installation site conforms to the requirements indicated in “4. Technical Specifications”.

First connect the power cord to the AC adapter, then connect the AC adapter jack to the scanner.



If the power cord that came with the package cannot be used in your area, please contact your distributor.

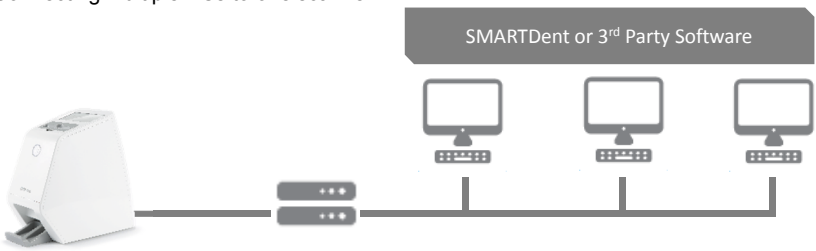
6.2.2 Network connection

The following are different network configurations for setting up RIOScan.

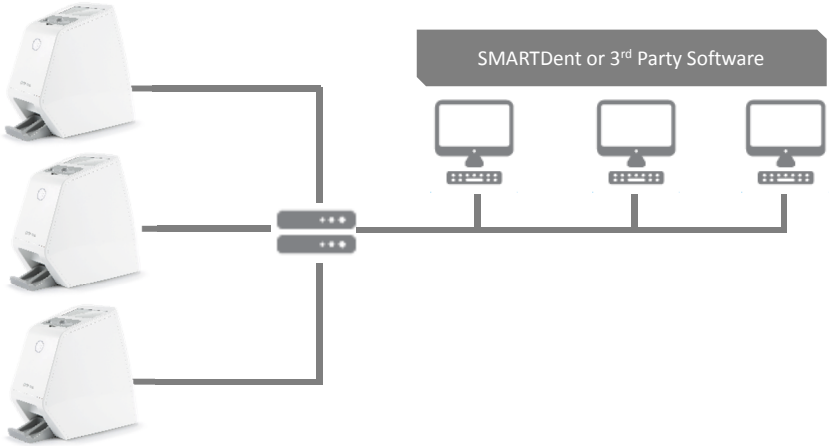
1) Directly connecting one PC to one Scanner.

Note: When directly connecting the PC to the scanner, please set a static IP address on the PC. The static IP address should be different from the IP address applied on the scanner.

2) Connecting multiple PCs to one scanner.



3) Connecting multiple scanners to multiple PCs.



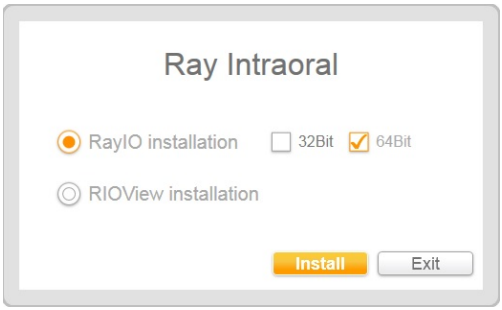
6.3 Software installation

RayIO and RIOView can be installed using the installation CD that is included in the package. In order to connect your PC to the scanner, RayIO must be installed. RIOView program can only be used when one scanner is directly connected to one PC.

6.3.1 RayIO installation

Below are the instructions for RayIO installation.

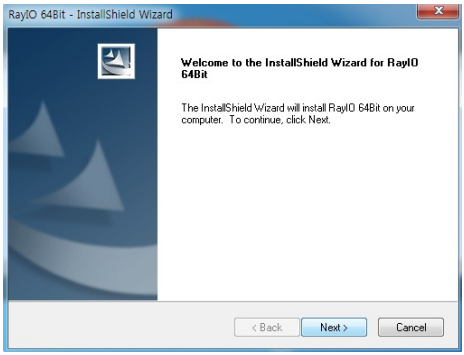
1) Insert the software installation CD into the CD-ROM drive of the PC.
2) Run Setup.exe, then select [RayIO installation].
   32bit or 64bit will be automatically selected according to the operating system of your PC. If Net framework 4.0 is not installed properly, “Initialization Error” message window will appear. To correct this, manually install Net framework 4.0 using the installation program on the CD.
3) Click [Install].



Items	Description
RayIO installation	RIOScan Image Acquisition module RIOScan device driver TWAIN Data Source RIOScan Image Acquisition Module, RIOScan Device Driver and TWAIN Data Source.
RIOView installation	Installs RIOView program for patient and image data management. Install RIOView program only if one PC is directly connected to one scanner.

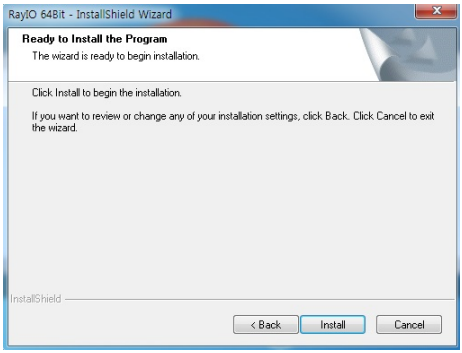
If the imaging software only supports TWAIN 32 bit, RayIO 32 bit must be installed even in a Windows 64 bit environment.

4) Click [Next] to proceed with the RayIO installation.

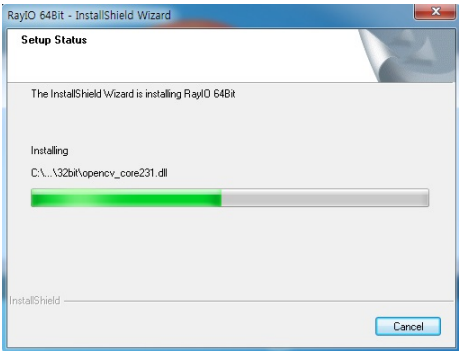


If Microsoft Visual C++ 2013 Redistributable Package is not installed, proceed installation referring to the instructions on the screen.

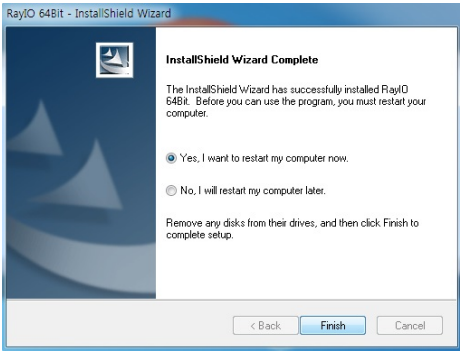
5) Select [Install] to install RayIO.



6) RayIO installation will proceed.



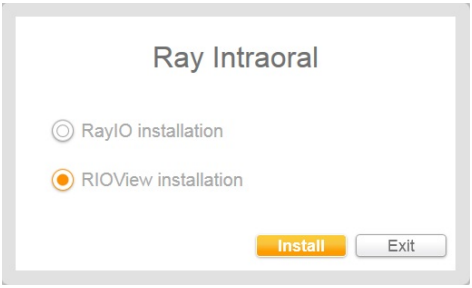
7) When the RayIO installation is complete, click [Finish] and the PC will automatically reboot.



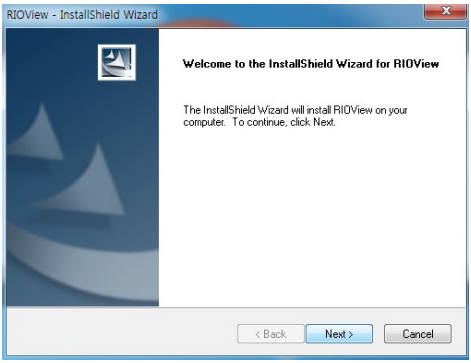
To operate the scanner and share images within the clinic's network, install RayIO and link it with SMARTDent imaging software, a 3rd party imaging software, or a practice management software. For detailed instructions, please refer to the software manual.

6.3.2 RIOView installation

1) In order to install RIOView, run Setup.exe, select [RIOView installation] and click [Install].

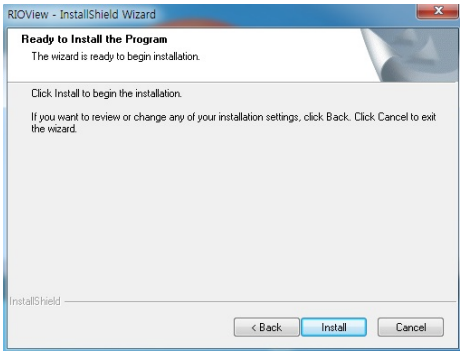


2) Click [Next] to proceed with the RIOView installation.

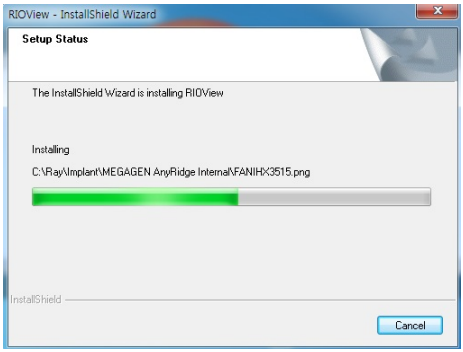


If Microsoft Visual C++ Redistributable Package, BlendWPFSDK, MSXML 4.0 SP3, MS Access DB Engine 2010 are not installed, proceed installation referring to the instructions on the screen.

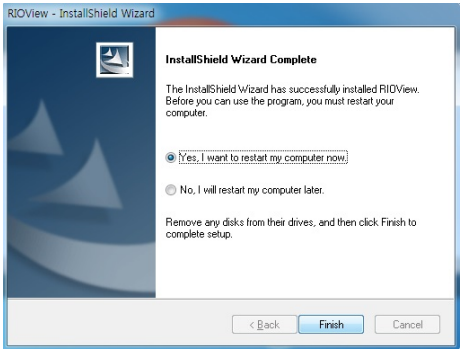
3) Click [Install] to start RIOView installation.



4) RIOView installation will proceed.

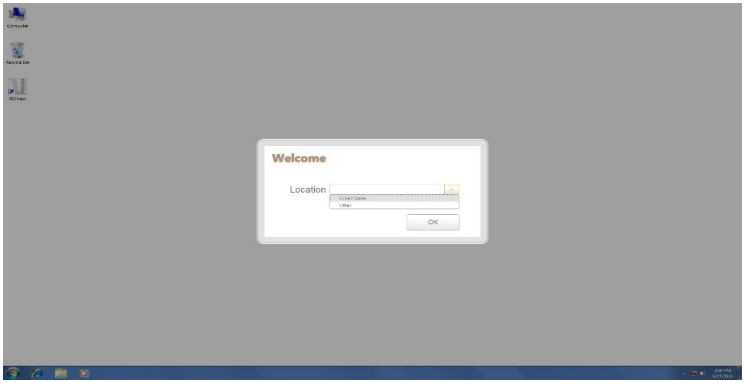


5) When RIOView installation is complete, click [Finish] to end the procedure.

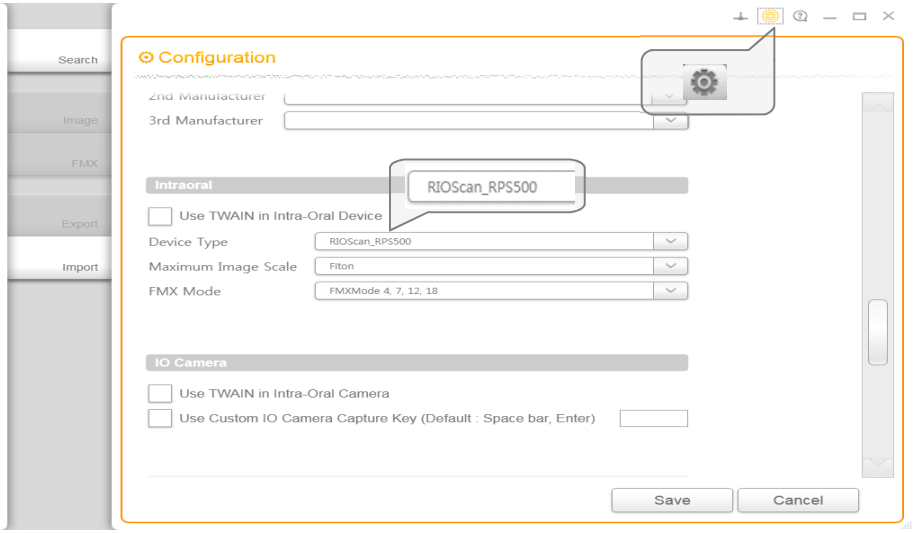


6) The below icon will appear on the desktop if RIOView is properly installed.

7) Run RIOView, select a location, and click [OK] to save.



8) Click [ ] icon from the configuration menu to move into intra-oral sensor category. Select [RIOScan] as the sensor type and click [Save].



6.4 Network connection and setting

6.4.1 Network connection checklist

1) A network connection between the PC and the scanner is necessary for communication and image transfer between devices.

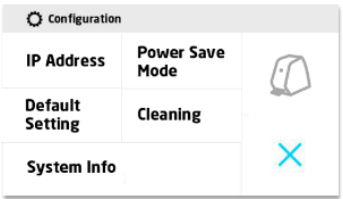
2) Connect the Ethernet cable which is included in the package to the network terminal at the back of the scanner.

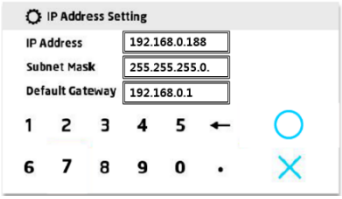
3) Make sure the cable is not twisted and plugged in correctly.

If the Ethernet cable is disconnected or has an unstable connection, this could result in image loss or error. Do not move the network device including the Ethernet cable, hub, and router or change the network setting while operating of the scanner.

6.4.2 Setting IP Address

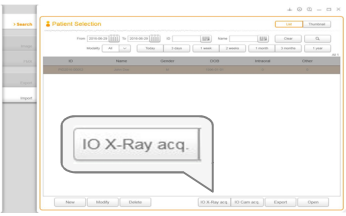
Below are the instructions for setting the scanner's IP address.

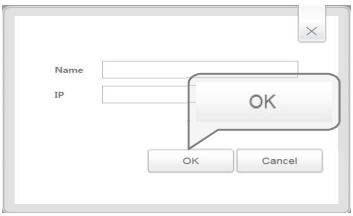
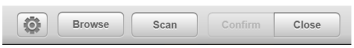
No.	Figure	Description
1		Select [Configuration] on the home screen.
2		Select [IP Address] on the Configuration screen.

3		Enter the IP address, subnet mask, and default gateway using the numbers shown on the screen, then tap on [O]. To cancel setting the IP address, tap on [X]. **Note: To acquire network setting Information, contact your network service provider.**
4		When network setting is complete, the scanner will automatically reboot and return to the home screen.

6.4.3 RIOView IP address setting

In order to connect the PC to the scanner for operation, the scanner IP address should be set using RIOView as shown below.

No.	Figure	Description
1		Select an existing or new patient and then click [IO X-ray acq.] button.
2		Click the [⚙] button to open the Configuration window.

3		Click [New] to add a new IP address. **Note: IP addresses can be edited using the [New], [Modify], and [Delete] buttons located below.**
4		Enter the name and IP address that were set on the scanner and then click [OK].
5		Double check the name and IP address. If correct, click [OK].
6		Select the registered device from the drop-down menu on the upper left side of the image acquisition screen.
7		Click [Scan] to connect to the scanner.
8		When the scanner is connected, the [Scan] button will change to [Scanning]. The touch screen on the scanner will display the “Scan Ready” screen.

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Operation

7

7 Operation

7.1 Power on & off

Off On

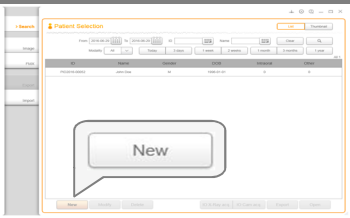
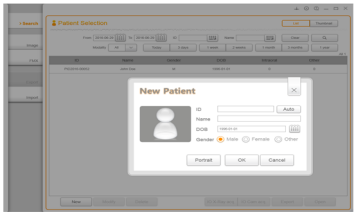
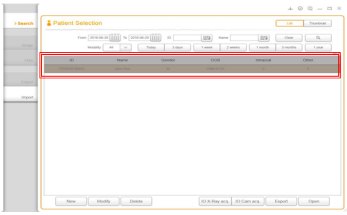
1) Press the power button for over 3 seconds to power on. The blue light will turn on.
2) Press the power button for above 3 seconds to power off. The blue light will turn off.

The scanner automatically goes into power save mode after a period of inactivity. The power save mode is indicated by a blinking blue light. By tapping on the touch screen, power button, or connecting to the scanner via the software from your PC, the scanner will return to normal mode. If you are not using the scanner for a long period of time, disconnect the AC adapter from the scanner.

7.2 Standard Imaging

7.2.1 Patient registration

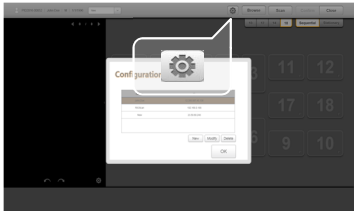
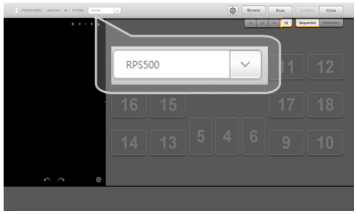
The following instructions show how to register new patients into RIOView.

No.	Figure	Description
1		Click [NEW] at the bottom of the front page.
2		Enter the patient ID, patient name, date of birth, and gender, then click [OK] button in the New Patient window.
3		Once complete, the newly registered patient can be found on the patient list.

7.2.2 Preparation of image acquisition

Select a patient, then click [IO X-Ray acq.] button or click the FMX tab, then click (IO X-Ray acq) button on top of the screen.

The image acquisition process is shown below.

No.	Figure	Description
1		Select a patient and click [IO X-ray acq.] from the menu on the bottom.
2		To add, edit, or delete the IP address of a scanner, click [⚙] at the top of the menu.
3		Choose a device to connect to from the installed device list on the upper left corner.
4		Click the [Scan] button on the upper right corner to connect to the scanner.
5		When the scanner is connected, the [Scan] button will change to [Scanning]. The touch screen will display the “Scan Ready” screen.

7.2.3 Imaging plate usage

1) The following are instructions for the use and care of your imaging plates.

Caution

Always wear sterile gloves when handling imaging plates.

- Grip the imaging plates by the edges. Do not touch the active side.

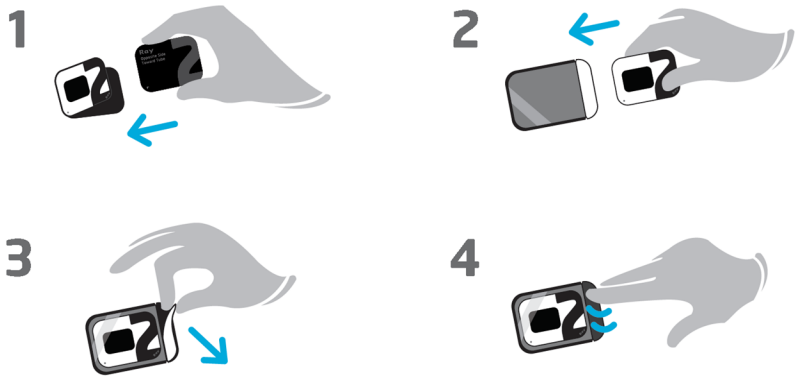
- Clean the imaging plates with dry, non-abrasive, Lint-free cotton when contaminated.
- Keep the imaging plates away from strong light.
- Erase the imaging plates before use when it has prolonged exposure to light.
- Store the imaging plates inside the imaging plate storage box.

2) The following are instructions and precautions for the use of the protective covers and the barrier envelopes.

- The protect covers and the barrier envelopes are single use only. Re-using the imaging plate can result in cross-contamination between patients and staff.
- Keep away from dust and humidity.
- Keep away from direct sunlight.

3) Imaging plate preparation

- Prepare the imaging plates using the appropriately sized protective covers and barrier envelopes.



① Place the imaging plate into the protective cover with the active side (blue) facing towards the black side of the protective cover. Make sure the orientation mark (“r”) is properly aligned.

Caution

The printed and active (blue) sides of the imaging plate must be in the correct orientation. A proper image cannot be achieved when incorrectly placing the image plate.

② Insert the imaging plate into the barrier envelope so that the printed side of the protective cover is facing the transparent side of the barrier envelope.

③ Peel off the adhesive strip from the barrier envelope.

④ Seal the barrier envelope.

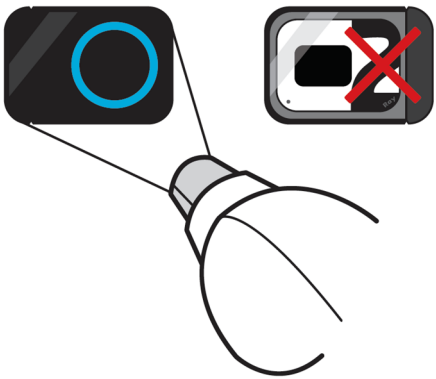
7.2.4 X-ray scanning

1) Place the imaging plate in the correct position for image acquisition.
2) Use the imaging plate holder for proper positioning.
3) Place the X-ray source and the imaging plate according to the intraoral radiography method.

Caution

Image errors can occur when the imaging plate and X-ray source is not correctly positioned.

4) The X-ray should be emitted to the active side (blue) of the imaging plate.
5) Once the imaging plate is placed inside the barrier envelope, the X-ray tube should be directed towards the black side of the barrier envelope.



When acquiring images, make sure the orientation marker (“r”) is located at the bottom of the imaging plate. The user is able to display and arrange the placement of acquired images in the RIOView FMX.

7.2.5 Imaging plate insertion to the scanner

1) After X-ray scanning, remove the imaging plate from patient's mouth and wipe out contaminants including saliva.

2) Tear along the cutting line of the adhesive seal to remove the barrier envelope.

3) Remove the protective cover and the imaging plate. Be careful not to expose the imaging plate to external light sources.

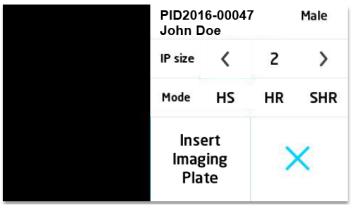
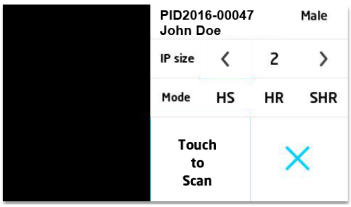
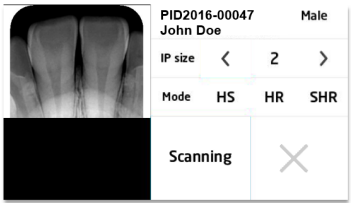
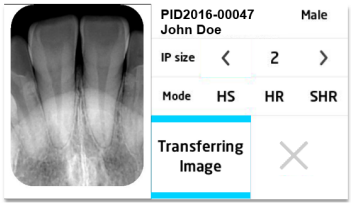
4) Insert the imaging plate into the scanner with the printed side of the protective cover facing toward the front of the scanner.

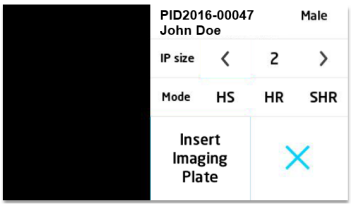
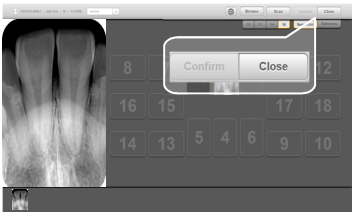
5) Once the imaging plate is recognized by the scanner, it will automatically move to the scanning location.

Insert the imaging plate into the imaging plate guide until it is detected. When detected, the imaging plate will automatically roll into the scanner.

Do not force the imaging plate into the imaging plate guide. This may cause flaws or distortions in the scanned images.

7.2.6 Image scanning and storing

No.	Figure	Description
1		This screen will appear on the scanner after clicking [Scan] from the RIOView software. **Note: If you are using the imaging plate guide in the Occlusal Kit, you will see <4> in the list of IP sizes.**
2		After inserting the imaging plate, tap [Touch to Scan] to begin scanning. **Note: In case the user taps on [X], the scanner returns to the home screen and the imaging plate is removed without being read or erased.**
3		The order of the scanning process is Scanning, Erasing, then Transferring. The scanner will display a preview X-ray image in the left preview window. No button activates during the scanning process.
4		Images are transferred after scanning. The scanner will return to the “Scan Ready” screen. **Note: To scan multiple images, insert the next imaging plate after scanning is completed.**

5		When you are finished scanning, tap the [X] button and the scanner will return to the home screen.
6		Store images by clicking [Confirm] button after adjusting the position of the images and rotation information. Click [Close] button when image storing is not necessary.

Do not remove the imaging plate guide before the “Transferring Image” procedure is completed.

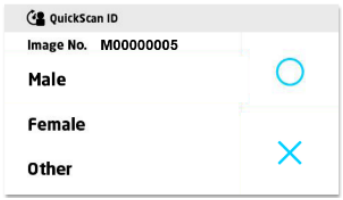
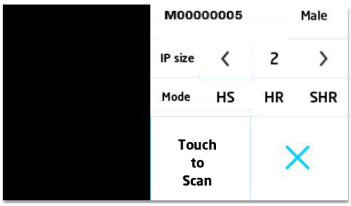
Always tap the [X] button after an imaging plate scanning session. Other PCs cannot connect to the scanner when it is in a “Scan Ready” status.

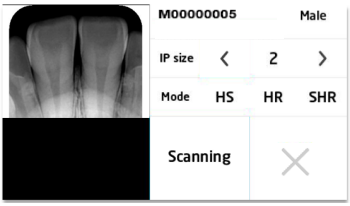
7.3 QuickScan

QuickScan is used for capturing and saving images into the internal memory of the scanner in case the scanner cannot connect to the PC due to network errors.

7.3.1 QuickScan image acquisition

For information on image acquisition by QuickScan, refer to the below description.

No.	Figure	Description
1		Select [QuickScan] on the home screen.
2		Select gender and tap [O]. An Image No. (A serial number) is automatically assigned. Tap [X] to return to the home screen.
3		Select an IP size and a mode. Then, insert the imaging plate to start scanning. Tap the [X] button to return to the home screen. **Note: If you are using the imaging plate guide in the Occlusal Kit, you will see <4> in the list of IP sizes.**
4		After inserting the imaging plate, tap [Touch to Scan] to begin scanning. **Note: In case the user taps on [X], the scanner returns to the home screen and the imaging plate is removed without being read or erased.**

5		The order of the scanning process is Scanning, Erasing, then Saving Image. The scanner will display a preview X-ray image in the left preview window. No button activates during the process. **Note: To scan multiple images, insert the next imaging plate after scanning is completed.**
6		Make sure to tab [X] after QuickScan is completed.

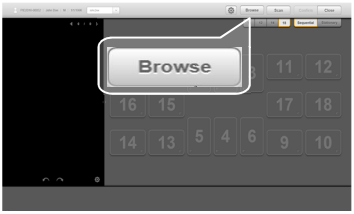
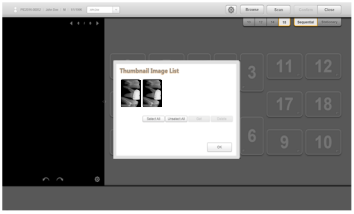
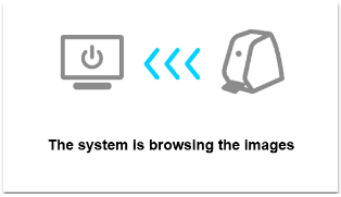
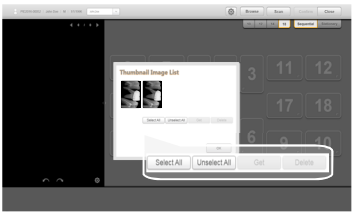
Always tap the [X] button after an imaging plate scanning session. Other PCs cannot connect to the scanner when it is in a “Scan Ready” screen.

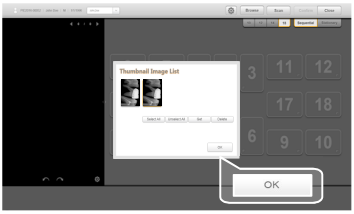
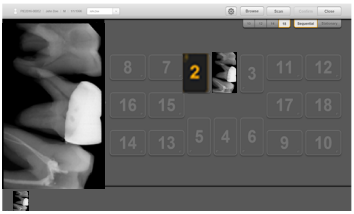
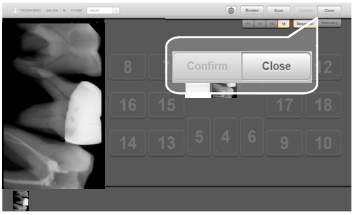
Do not remove the imaging plate guide before the “Saving Image” procedure is complete.

The below message will appear when there is not enough memory for the QuickScan. The user must download the stored images into the PC by using the Browse function of RIOView.

7.3.2 QuickScan image storing and deleting

Stored images in the scanner through QuickScan can be transferred to RIOView (PC).

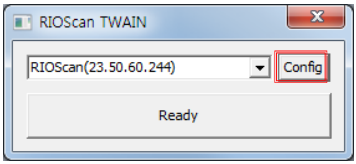
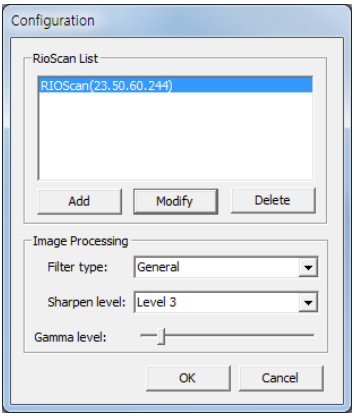
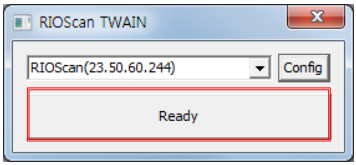
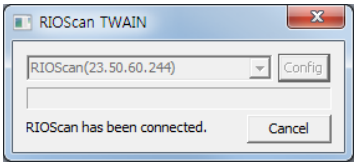
No.	Figure	Description
1		Select a patient and click [IO X-ray acq.] at the bottom. **Note: Refer to the "7.2.2 patient registration" to register a new patient.**
2		Choose a Scanner on the upper left side to retrieve an image. Click [Browse] on the upper right side.
3		Images from the connected scanner are shown on the thumbnail image list.
4		"The system is browsing the images" message will appears on the Touch Screen of the scanner, while the scanner browses.
5		Select the thumbnail of an image you desire and click [Get]. Click [Delete] to discard the image.

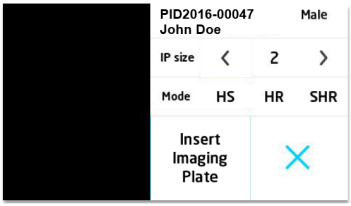
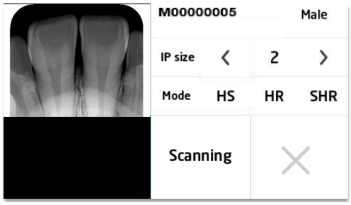
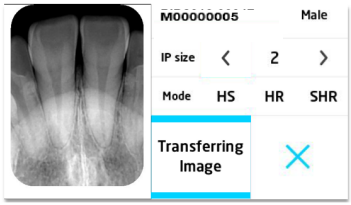
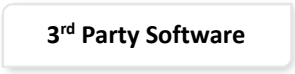
6		After retrieving or deleting, close the thumbnail list window by clicking the [OK] button.
7		Check if the retrieved image is displayed on the FMX view.
8		Adjust the orientation and the position of the images. Store images by clicking [Confirm]. Click [Close] to close without saving.

The more the scanner stores images in its internal memory, the longer it will take to receive images through the Browse function.

7.4 Taking images through TWAIN

Please refer to the following instructions for taking images from third party software using TWAIN.

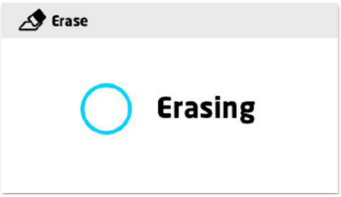
No.	Figure	Description
1		Run the RIOScan TWAIN and click [Config].
2		Select a scanner from the RIOScan list and click [Modify]. Next, insert the IP address that is set by the scanner. Use “Image Processing” to optimize images for diagnostic purposes by applying a filter type and adjusting the sharpness and the gamma level.
3		Click [Ready] to connect with the selected scanner.
4		When the scanner is connected, the message ‘RIOScan has been connected.’ will appear at the bottom.

5		In the Scan Ready screen, select an IP size and a mode. Then, insert the imaging plate to scan. When the imaging plate is inserted, the scanner will display a message [Touch to Scan]. Click the [Touch to Scan] to begin scanning. **Note: In case the user taps on [X], the scanner returns to the home screen and the imaging plate is removed without being read or erased.**
6		The order of the scanning process is Scanning, Erasing, then Transferring. The scanner will display a preview X-ray image in the left preview window. No button activates during the process.
7		When scanning is completed, the image will transferred to the PC and the scanner will return to the “Scan Ready” screen. **Note: To scan multiple images, insert the next imaging plate after scanning is completed.**
8		When acquisition is completed, adjust and save the image. **Note: Please refer to the manual of the third party software for operating TWAIN Data Source.**

Always tap the [X] button after an imaging plate scanning session. Other PCs cannot connect to the scanner when it is in the “Scan Ready” screen.

7.5 Erase

Please erase images on the imaging plates before use if it was cancelled during the scanning process or has not used been used within the past 24 hours.

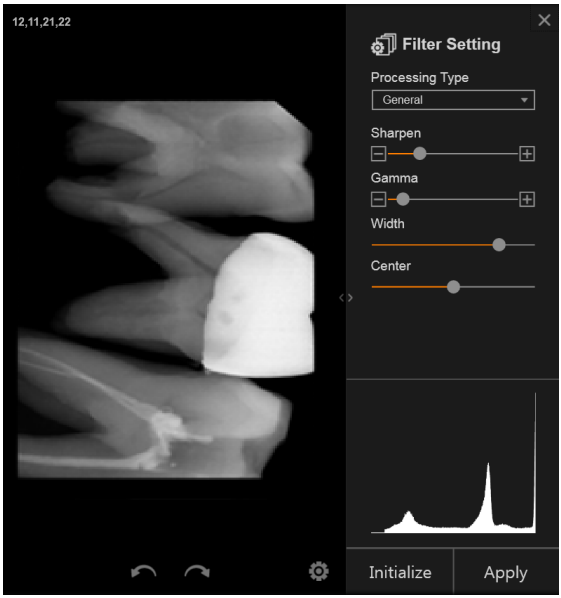
No.	Figure	Description
1		Select [Erase] on Home Screen.
2		Insert the imaging plate through the imaging plate guide.
3		Once the imaging plate is rolled into the scanner, the message “Erasing” will appear on the touch screen.
4		When erasing is complete, the touch screen will return to the home screen.

When exposed to light, the imaging plate should be erased before use.

7.6 Customizing image quality

You may choose an image processing type and adjust the sharpness, gamma, and window width or center of your X-ray image to your preferences.

Click [Setting] on bottom right corner of “Image Preview”. “Filter setting” window appears as below.



Change the filter setting to your preferences. Select ‘Processing Type’ and adjust ‘Sharpen’ level, Gamma, Width, Center, then click [Apply]. On the next acquisition, the new image filter will be automatically applied.

The histogram on the bottom right displays the current X- ray levels of the X-ray image. Adjust the exposure time to find the X-ray image level of your preference.

The Intra Oral Image Processing Config (IOImageProcessingConfig) is a tool for you to check out different image filters and to see its effects on the X-ray images in advance before you change image filters in your third party imaging software. Run IOImageProcessingConfig by executing “IOImageProcessingConfig.exe” found in “C:\Ray\RayIO\”.

Troubleshooting

8

8 Troubleshooting

Symptom	Possible Cause	Solution
Unable to turn power on Scanner does not power on	Power is not connected properly.	Check the conncection between the power cord and AC adapter jack.
	The power button was not pressed longer than 3 seconds.	Press the power button longer than 3 seconds.
	The AC adapter is damaged.	Please unplug the adapter from the power outlet and contact your distributor.
Unable to view scanned images	The inactive side was facing the wrong direction when inserted.	Please insert the imaging plate in the correct orientation. Erase the imaging plate before rescanning to achieve optimized image.
	The imaging plate was exposed to external light sources.	In the future, scan the imaging plate as soon as possible.
	Scanner does not work normally due to technical issues.	Please contact your retailer or technical service provider.e
	The X-rays were not emitted to the imaging plate.	Check the exposure option or properly align the X-ray tube with the imaging plate.
	Amount of X-ray dose is not sufficient due to low battery capacity of the X-ray generator.	Re-charge the X-ray generator.
	The X-rays were not emitted due to damaged X-ray generator.	. Please contact your X-ray generator distributor or technical service provider.
Ghost image or multiple layers of images appear in the scanned image	Previous image was not erased from the imaging plate.	Erase the imaging plate mannually before use.
	The imaging plate was scanned multiple times by the X-ray generator.	In the future, scan the imaging plate only once per image. Erase the imaging plate before emitting the X-rays.
	Previously scanned image in the imaging plate was not deleted completely.	Contact the local representative or technical service center of the X-ray generator if the problem repeats.
Shadow or stripes appear in the scanned image.	The imaging plate was exposed to external light sources before it was scanned.	Do not use the imaging plate without using a protective cover.
		Please scan the imaging plate as soon as possible after removing the barrier envelope from the imaging plate,.

		Keep the scanner away from direct sunlight.
	Imaging plate was exposed to other radiation sources (e.g. scattered X-rays or natural background radiation)	If the imaging plate was not used within the past 24 hours, please erase the imaging plate before use.
	The imaging plate was damaged, scratched, or contaminated.	Please clean the imaging plate if contaminated.
		Please replace the imaging plate if damaged or scratched.
Contrast of the scanned image is too high or low.	The imaging plate is not exposed long enough to the X-rays (The image is too bright).	Increase the exposure time or See Appendix A.
	The imaging plate was exposed to the X-rays for too long (The image is too dark).	Reduce the exposure time or See Appendix A.
The scanned image is blurry.	The patient was not stable when taking the image.	Check the exposure time then position the patient properly before taking the image.
The software cannot recongnize the device.	Power is not connected, or power is not on.	Check the power connection, and press power button for more than 3 seconds.
	There was an error on the network setting of the PC.	Refer to '6.4 Network connection and setting' and re-set the network.

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Message

9

9 Message

9.1 Scanner message

Message	Possible Cause	Solution
[8000] Imaging plate inserted incorrectly.	Imaging plate is not inserted correctly.	Insert the imaging plate into the scanner, while printed side is facing the front part of the scanner. Only use imaging plates provided by the manufacturer.
	Insertion panel is not placed accurately, or contaminated with foreign substance.	Place the insertion panel accurately.
	Insertion panel is contaminated.	Clean the insertion panel.
[8001] Insertion panel is not recognized.	Insertion panel is not placed accurately, or contaminated with foreign substance.	Place the insertion panel accurately.
[8002] Incompatible insertion panel size.	Improper insertion panel is placed on the scanner.	Replace with the proper insertion panel.
[8003] The RIOScan storage is full. There is insufficient memory to save an image selected.	Memory is full.	Connect the scanner to RIOView and transfer the images to the PC. Afterwards, delete the images in the scanner.
[8200] Updating system configuration, Please wait for reboot.	Scanner will automatically reboot after settings are saved.	Wait until the automatically reboots.
[8205] The back cover is opened. The system will be shut down soon.	Back cover is open or not properly assembled.	Stop operation and contact technical service center.
[8206] The network connection has been disconnected.	Network is disconnected.	Check network connection.
[8207] The system cannot be specified. Please call service.	Product type does not match.	Stop operation and contact sales representative or technical service center.
The system is browsing the images.	Browsing function is running.	Run browsing function.
Firmware update in progress, this may take a while. Please do not turn off the power.	Firmware is being downloaded.	Wait until firmware download is complete.
The update completed successfully, Please Wait for reboot.	Firmware download is complete.	Wait until scanner reboots.
Checking the Feeder module, this may take a while	Feeder module is being examined.	Wait until feeder module examination is complete.

9.2 RIOView message

Message	Possible Cause	Solution
Failed to connect RIOScan	Scanner is not connected to the network.	Check whether scanner power is on, and network is connected.
	IP address is not set properly.	Check the IP address et on the scanner. Insert the correct IP address on the PC software.
RIOScan is connecting with other PC. (Computer Name)	Selected scanner is connected with a different PC.	Check whether PC is connected with a different PC. Press [X] button to disconnect previous connection and move to home screen.
Failed to get Images.	Connection with scanner is unstable.	Check network environment.
	Scanner connection is ramdomly disconnected.	Check whether scanner power got off or network got disconnected while acquiring image.
Failed to delete the selected image.	Connection with scanner is unstable.	Check network environment.
	Scanner connection is ramdomly disconnected.	Check whether scanner power got off or network got disconnected while acquiring image.
Failed to get RIOScan Image.	Connection with scanner is unstable.	Re-connect with the scanner.
	Cancel connection with the scanner.	Check connection between scanner and PC.
Error occurred during the scanning process.	Connection with scanner is unstable.	Check network environment.
	Power supply issue occurred during scanning.	Check power connection and reboot the scanner.
	There was a malfunction on the scanner while scanning.	Reboot the scanner and re-try the procedure.
Image processing has failed.	Version of image processing file or OS environment is not adequate.	Check OS environment and re-install the adequate program.

Appendix A. Exposure value recommendation

Protocol		Patient	Exposure values (sec)	
			Standard X-ray	Portable X-ray
Maxilla	Incisors	Adult	0.10 ~ 0.14	0.20 ~ 0.30
		Child	0.06 ~ 0.10	0.14 ~ 0.20
	Premolars and Canines	Adult	0.12 ~ 0.16	0.30 ~ 0.40
		Child	0.10 ~ 0.16	0.10 ~ 0.20
	Molars	Adult	0.16 ~ 0.20	0.40 ~ 0.50
		Child	0.12 ~ 0.16	0.20 ~ 0.30
Mandible	Incisors	Adult	0.08 ~ 0.12	0.14 ~ 0.25
		Child	0.05 ~ 0.08	0.08 ~ 0.14
	Premolars and Canines	Adult	0.10 ~ 0.14	0.20 ~ 0.30
		Child	0.08 ~ 0.12	0.14 ~ 0.20
	Molars	Adult	0.14 ~ 0.18	0.25 ~ 0.35
		Child	0.10 ~ 0.14	0.16 ~ 0.25

- Recommendation of exposure setting (kV and mA).
  - Standard X-ray sources: 70kV/7mA when using a 20 cm (8”) cone.
  - Portable X-ray sources: 60kV/2mA.
- Recommended exposure values can vary depending on the patient’s body size, age, sex, and thickness of the soft tissue. Please adjust the exposure values accordingly to the patient.

Appendix B. Electromagnetic compatibility

1) 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.

2) 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.

3) Protecting the equipment from external electromagnetic waves.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The RPS500 is intended for use in the electromagnetic environment specified below.
The customer or the user of the RPS500 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The RPS500 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The RPS500 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 used 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 RPS500 or shielding the location.</td></tr>
<tr><td>Harmonic
emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage
fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity declaration			
The RPS500 is intended for use in the electromagnetic environment specified below. The customer or the user of the RPS500 should assure that is used in such an environment.			
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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line ±2 kV line(s) to earth	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RPS500 requires continued operation during power main interruptions, it is recommended that the RPS500 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 levels characteristic of a typical location in a typical commercial or hospital environment.

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity declaration</th></tr>
<tr><td colspan="4">The RPS500 is intended for use in the electromagnetic environment specified below. The customer or the user of the RPS500 should assure that is used in such an environment.</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>0.15~80 MHZ
3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the RPS500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = [\frac{3,5}{V1}]\sqrt{p}$
$d = [\frac{3,5}{E1}]\sqrt{p}$ 80 MHz to 800 MHz
$d = [\frac{7}{E1}]\sqrt{p}$ 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 surveys, 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:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3V/m
80 MHz to 2.5 GHz</td><td>3 V/m
80 MHz to 2.5 GHz</td></tr>
</table>

TABLE: Recommended separation distances between portable and mobile RF communications equipment and the equipment

The RPS500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RPS500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the RPS500as 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√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√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.

Note1	At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.
Note2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.