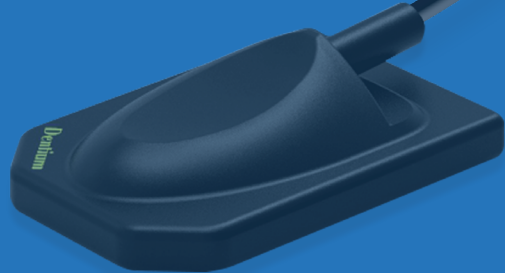


IOX Intra-oral Sensor

User Manual



Dentium

CE 0068

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Notice

Thank you for purchasing *the Dentium Intraoral Sensor* (Dental Image Acquisition Device).
This manual details the usage, handling, care and overall use.

Please read this manual in advance for smooth use of the equipment.
Please keep the Quick guide near the equipment so that you can refer to it at any time.

Manual be changed without notice, depending on product quality upgrade and specification change.

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01

Introduction

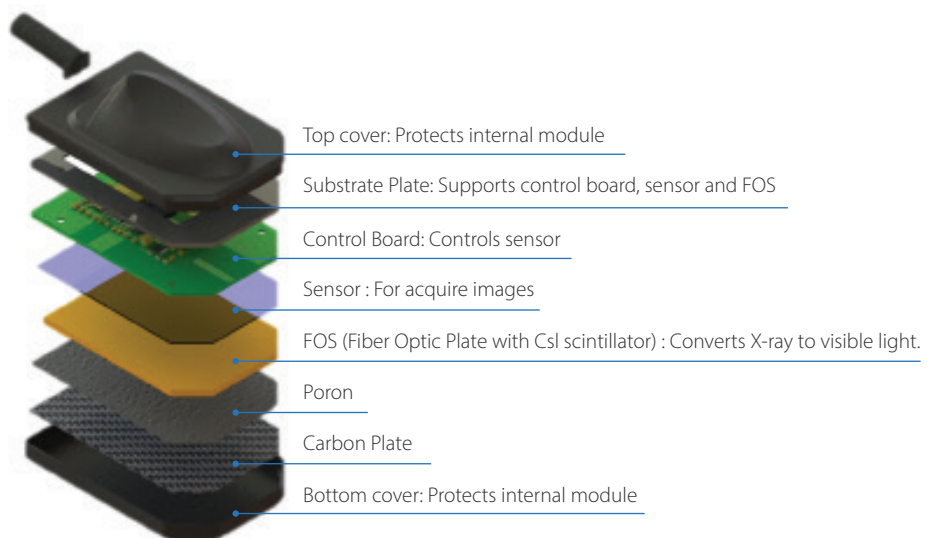
1.1. Product description and purpose of use

1.1.1. Product Description

Dentium Intraoral Sensor is a medical device that acquires digital images by detecting information through X-rays and converting them into electrical image signals to identify teeth and tissues in the mouth. The product consists of the Intraoral Sensor, USB Memory, Sensor Holder, Silicon Cover and Quick Guide.

1.1.2. Intraoral Sensor configuration

The **Intraoral Sensor** consists of Cover(Top, Bottom), Substrate Plate, Control Board, Sensor and FOS.



Components	Description
Cover(Top, Bottom)	Protects internal module
Substrate plate	Supports control board, sensor and FOS
Control Board	Controls sensor
Sensor	For acquiring images
FOS (Fiber Optic Plate with CsI scintillator)	Converts X-ray to visible light
Poron	Microcellular polyurethane foamslight
Carbon plate	Scintillator Protective Cover

1.1.3. Intended use

Intraoral Sensor, an intra-oral imaging device, is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

1.1.4. Life cycle

Control board, Sensor and FOS are key components. Control boards and sensors can be used semi-permanently, but FOS is vulnerable to shock and performance deteriorates as X-rays accumulate. In case of deterioration of images quality, please contact the Dentium branch

1.2. Characteristic of the product



High-resolution images based on CMOS



Easy to use PC compatible with Plug



Supports high speed communication over USB 2.0



Complete waterproof / dustproof construction with IP68



Flexible cable made of silicon



TWAIN (Standard for image acquisition devices) interface

02

Precautions

2.1. Precautions before use

- Ensure that the Intraoral Sensor is operated by a qualified person as a medical device.
- Please read and understand these instructions carefully prior to operating this device.
- Do not place similar medical electrical devices near device. This may degrade the performance of the device. Keep away from other sources of electromagnetic energy to avoid electromagnetic interference.
- Damage to the device due to user's disassembly will not be covered under warranty.
- Pulling or twisting the cable connected to the product may cause performance degradation and failure.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2.2. Use precautions

- After use the Intraoral Sensor should be stored in the sensor holder.
- Dropping, jarring, bumping, or rough handling could result in damage affecting image quality.
- Do not use the device without the plastic cover.
- Patient does not bite the sensor when inserting the device into the mouth.
- Do not disconnect the PC while the device is in operation.
- Do not apply excessive load to the device, as excessive force may cause the equipment to malfunction or degrade performance.
- If you use the product for other use than the recommended one, it may cause the deterioration and malfunction.
- When acquiring images continuously for a long time, the sensor may generate heat. The temperature of the sensor module is less than 40°C.
- The plastic cover is disposable. Please throw it away after use.
- Use the silicon cover only to protect the device, and be sure to remove it when using it.
- X-ray exposure dose affects the image quality. Please adjust it according to recommendation on exposure time.
- Depending on the PC or notebook specifications, the recognition error or the performance of the Intraoral Sensor may be degraded. Please use a product that meets the recommended specifications.
- Please contact Dentium branch or request a service inspection and repair of the device.
- If any error such as recognition error or overheating occurs during use, stop using the device immediately and contact your nearest Dentium Service Department or order a new sensor.
- Use of the equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

2.3. Electrical Precautions

- Do not connect the USB terminal of the Intraoral Sensor to any device other than the designated PC.
- Do not install the device where the USB contact terminal may come in contact with water.
- If the device does not work properly, please contact Service Department or order a new sensor.

2.4. Warnings and cautions

- Do not pour or spray liquid substances such as water or sprays onto this device.
- Do not store flammable materials near the device. It may cause fire or an explosion.
- In the event of an electrical fire, use a fire extinguisher marked for that purpose. Using water or liquids in an electrical fire can seriously damage and damage people and the device. You must disconnect the USB connector before extinguishing a fire to avoid risk of electric shock.
- Do not sterilize or disinfect with spray.

	Never disassemble or modify the product.
---	--

03 Safety guide

3.1. Manual Usage Symbol

In order to use the device efficiently, this manual uses the following symbols to fully understand and comply with the meanings of the symbols. To avoid personal injury and property damage, please observe the safety precautions specified in the documentation.

Symbol	Symbol Title	Description
	NOTE	Provides information and instructions for using the device.
	CAUTION	Important instructions for using the device. It can cause serious damage to the device and human body.
	WARNING	Important instructions for using the device. It can causeserious damage to the device and human body.
	WASTE	Indicates a product should not be disposed of in a landfill the black bar indicates that the equipment was manufactured after 2005.

3.2. Product symbol

Symbol	Description
	Indicates the need for the user to consult the instructions for use
	Identifies a type B applied part complying with IEC 60601-1
	Indicates the need for the user to consult the instructions of use for important information such as warnings and cautions
IP68	Protected against access to hazardous parts. Dust-tight. Protected against the effects of temporary submersion. Customer specification applies and specific testing may be required.
	Indicates the date when the medical device was manufactured
	Indicates the medical device manufacturer
REF	Indicates the manufacturer's catalogue number so the medical device can be identified
LOT	Indicates the manufacturer's lot number so that a specific medical device can be identified
VA	Active electrical Power
	CE marking indicates that a product complies with applicable European Union regulations
	Federal law prohibits dispensing without prescription
	Indicates that the product should not be discarded as unsorted waste but be sent to separate collection facilities for recovery and recycling
MD	Indicates a product is a medical device
UDI	A unique numeric or alphanumeric code that helps identify and track medical devices throughout the healthcare supply chain

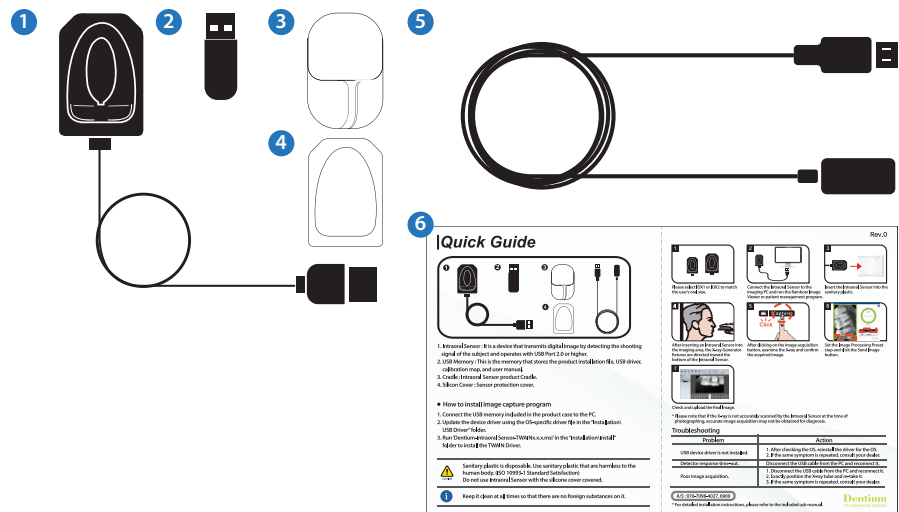
3.3. Packaging symbol

Symbol	Symbol Title	Description
	This way up	Indicates the correct upright position of a package
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	Handle with care	Indicates the package needs to be handled with care.
	Protect from moisture	Indicates a medical device that needs to be protected from moisture
	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed

04

Product Components

The **Intraoral Sensor** consists of a main product(①, Sensor module) and accessories(②, ③, ④, ⑤, ⑥).
The installer should check the items listed in the table below before installing the device.



No.	Symbol Title	Quantity	Description
①	Intraoral Sensor	1 EA	Main device (Sensor module)
②	USB Memory	1 EA	Memory to store device installation file, USB driver, calibration map file and user manual
③	Sensor Holder	1 EA	Sensor holder and protection
④	Silicon Cover	1 EA	Sensor protection cover
⑤	Repeater	1 EA	USB extension cable
⑥	Quick Guide	1 EA	Instructions on how to install and use the device

The control numbers for the product are shown in the table below. Use them when purchasing product services and accessories.

No.	Components	Product code
①	Intraoral Sensor	IOX1 : Intraoral Sensor for children IOX2 : Intraoral Sensor for adult
②	USB Memory	G30000
③	Sensor Holder	G30002
④	Silicon Cover	IOX1 : G30011 IOX2 : G30012
⑤	Repeater	G30003
⑥	Quick Guide	G30010
⑦	Product case	G30007

05

Technology Information

5.1 System Specifications

Items	IOX1	IOX2
Pixel pitch	20 x 20 μm	
Dimensions (W x L x T)	24 x 36.7 x 12.3 mm	29.1 x 42.6 x 12.4 mm
Active area	20 mm X 30 mm	25.6 mm X 36 mm
Number of pixel	1000 X 1500	1280 X 1801
ADC	12 bit	
Frame rate	1 fps	
Data Interface	USB 2.0	
USB Cable length	2.0 m	
Input Voltage	DC 5 V	
Active Power	1 VA	
Ambient Temperature	10 °C to 30 °C (Usage) - 20 °C to 60 °C (Transportation and Storage)	
Relative Humidity	30 % to 95 % (Usage) 10 % to 95 % (Transportation and Storage)	
Air Pressure	70 to 106 kPa	
Protection against Matter/Water	IP68	

5.2 Recommended specifications of PC

Items	Specifications	
	Minimum	Recommended
Operation system	Microsoft Windows 10 (32 bit/64 bit)	
Processor	Dual Core CPU @ 2.0 GHz or Higher	
RAM	2 GB	4 GB
HDD	10GB free hard disk space	
Interface	USB 2.0	
VGA	Video Memory 256 MB	NVIDIA GeForce GTX660 D5 / 1GB
Resolution	1920 x 1080 x 32 bpp	



Warning

- The Intraoral Sensor does not guarantee normal operation in unregistered Microsoft Windows. Therefore, please use the registered genuine version of Microsoft Windows.
- Operating systems other than Windows are not supported.
- It can be used on PCs that are below the minimum specification, but cannot guarantee 100% product performance.

06

Detail of component

6.1 Sensor module



IOX1



IOX2

Tile	Description	Size
IOX1	Universally used by children and adults with a small oral structure	1.0
IOX2	Commonly used adult	2.0

6.2 Detail description



No.	Designation	Designation	Remark
a	Sensor module	Image acquisition device	
b	Relief	Connector with sensor module	
c	Cable	Communications cable	Length : 2 m
d	USB Connector	PC interface	USB 2.0 Type

07

Installation

7.1 Install Software Driver

The Intraoral Sensor provides an integrated installer that installs USB driver and TWAIN Driver.



Warning

- You must install the device driver to operate the Intraoral Sensor. It must be connected to a product or device that complies with IEC60601-1 or IEC 60950-1.

7.1.1 Installation preparation

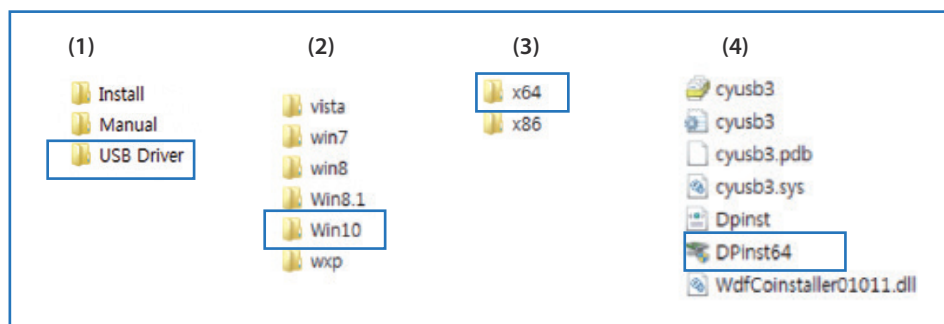
Connect the USB memory to the PC and open the folder.

The configuration of the folder is composed of "Installation", "Calibration", and "manual". The installation program required for image acquisition is provided with two files: Install and USB driver

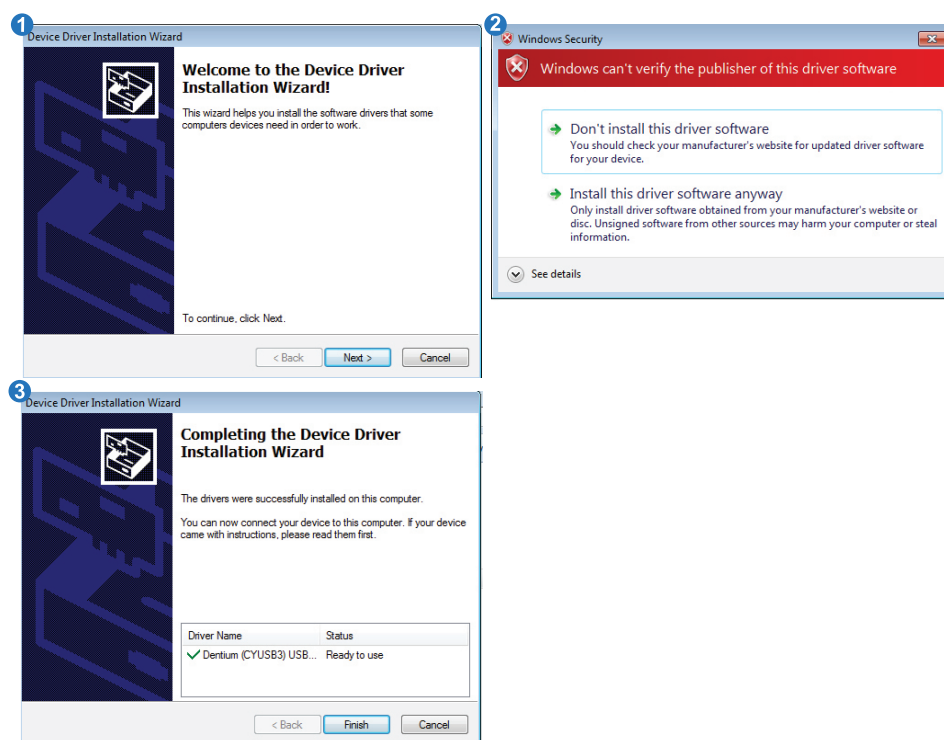
 Install
 Manual
 USB Driver

7.1.2 Installing USB Driver

- 1) Move to the corresponding path of USB memory. Path: Installation\USB Driver
- 2) Select the folder suitable for the operating system of the installation PC. (From Vista, 7, 8, 8.1, 10, XP)
- 3) Select a folder that matches the bit of the operating system. (32-bit: x86, 64-bit: x64)
- 4) Run the installation file. (32-bit: DPInst32.exe, 64-bit: DPInst64.exe)
- 5) Please click "Next" button to complete the installation.



7.1.3 USB Driver setup screen description



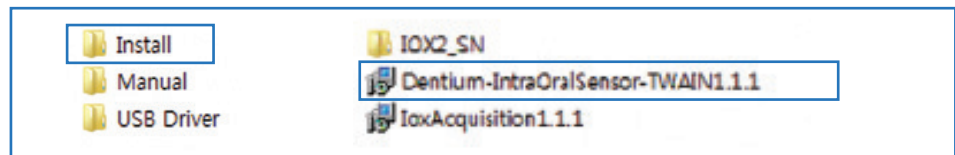
- 1 When the Run screen appears, click the "Next" button.
- 2 The driver installation confirmation window appears and click "Install this driver software" to proceed with the installation.
- 3 When installation is complete, click "Finish" to exit.

7.1.4 Installing IOX Acquisition and TWAIN Driver

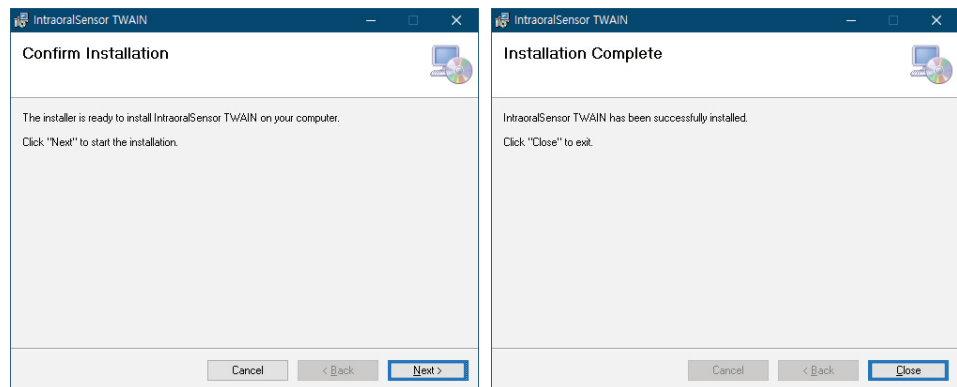
The **Intraoral Sensor** can acquire images using TWAIN-compliant applications. In order to use this function, the image management and patient management program must support the TWAIN interface.

1) IOX Acquisition: If the RainbowImageviewer is provided, install 'IOXAcquisition'. RainbowImageviewer supports IOX acquisition mode, and the procedure is as follows. (For the installation program of RainbowImageviewer, refer to its manual.)

Path: Run the installation \ Install IoxAcquisitionx.x.x.msi



* Continue to click the "Next" button to complete the installation.

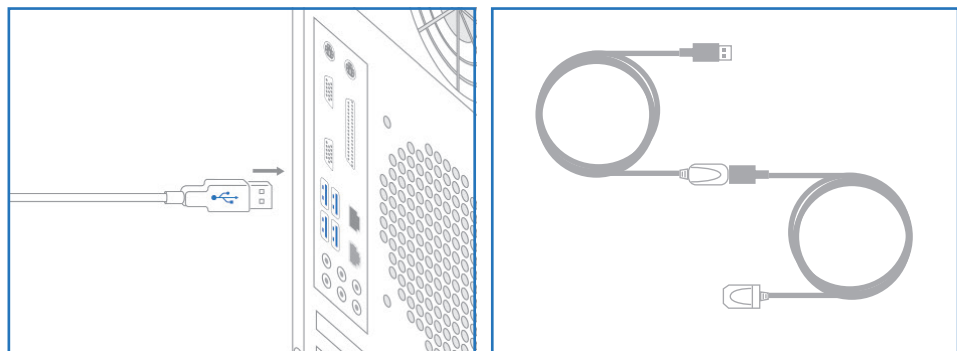


7.1.5 Cable connection

After driver installation is complete, connect the Intraoral Sensor to a USB port on your PC.

-When connecting to USB port, we recommended USB port on the back of the PC.

-Depending on the environment of use, cable extension may be required. In this case, you can use a repeater.



* USB extension cable(Repeater) : USB 2.0 limits the data transmission

distance to 5 m, so it is recommended to use repeater products that amplify signals for stable data transmission when using a extended cable.

-Depending on the environment of use, cable extension may be required. In this case, you can use a repeater.

-The specifications of the repeater are as shown in the table below.

Item	Designation
Cable length	3 m
Interface	USB 3.0
Input voltage	USB bus power
Material	PVC Jacket



Warning

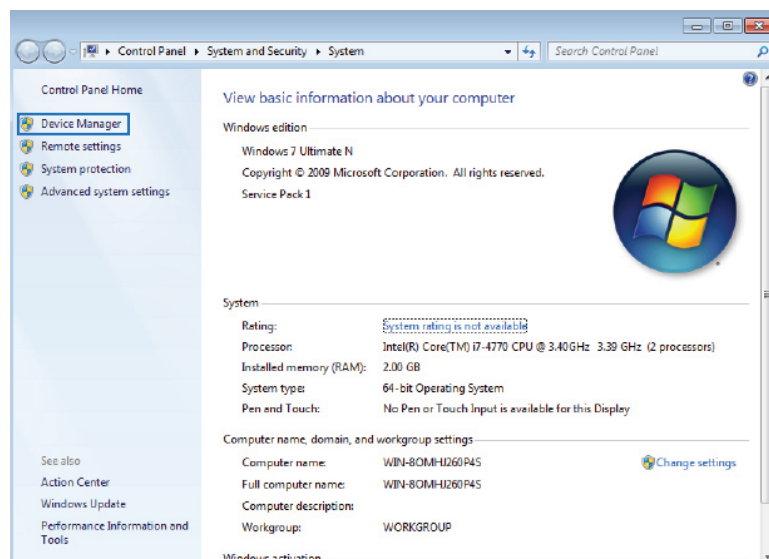
- If you need to purchase additional repeaters, please contact Dentium Service Department or order a new sensor.
- If you need additional other repeater product, use only the adapter power connection type.(The maximum length is limited to 15 m) If there is any problem with the operation after connecting the repeater or extension cable, please contact Dentium Service Department or order a new sensor.

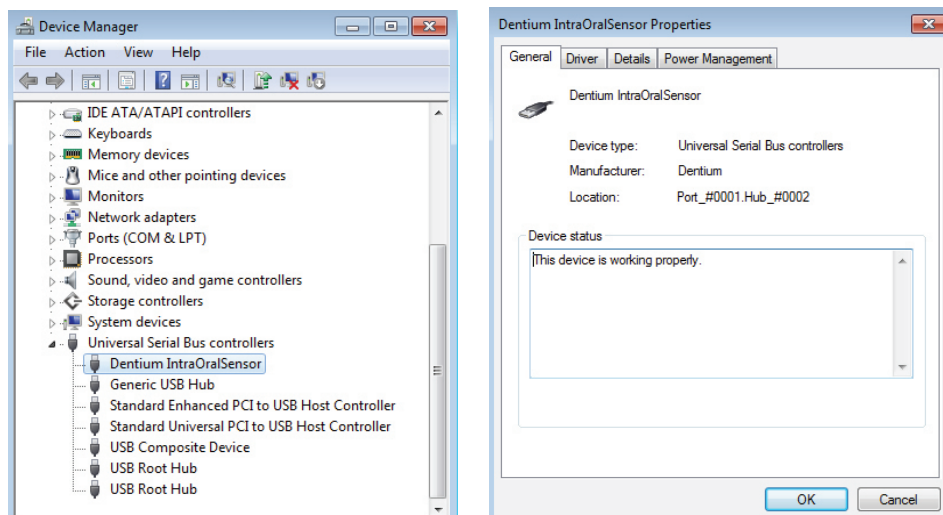
7.1.6 Device driver verification

Run Device Manager in Control Panel on Windows systems. If you see “Dentium IntraOralSensor” in the “Universal Serial Bus Controller”, the driver is working normally.

Verification method:

- 1) Windows 7 or 10: Control Panel -> System and Security -> System -> Device Manager
- 2) Windows XP: Settings -> Control Panel -> System -> Hardware -> Device manage



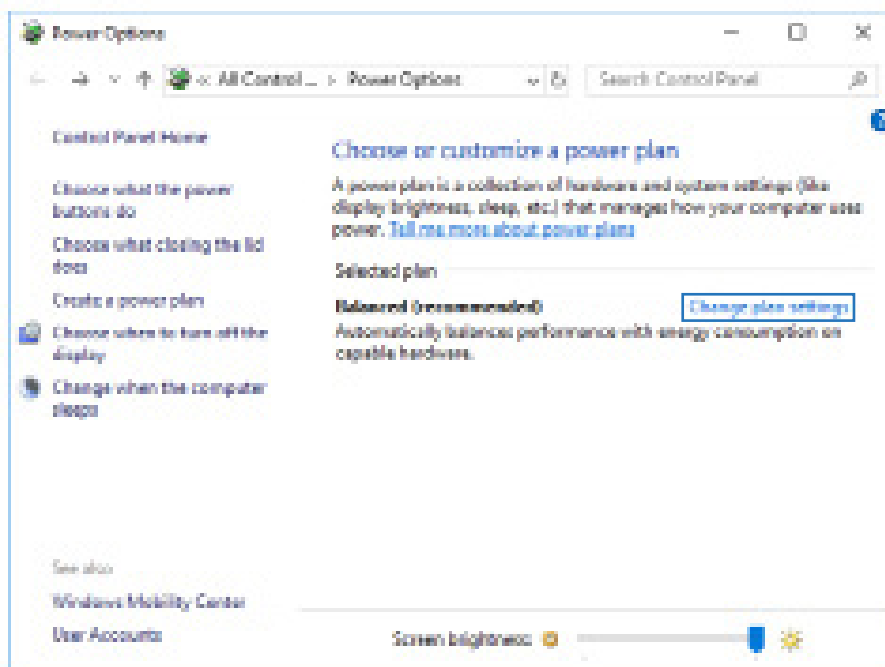


* If the driver is not installed properly, please contact Dentium Service Department or request Service Call

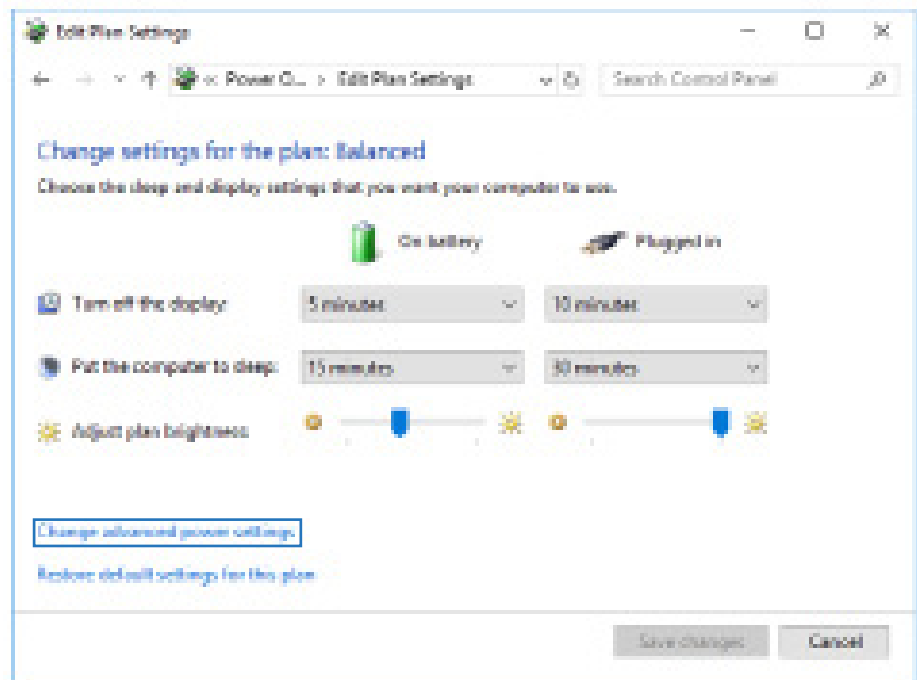
7.1.7 Power settings when using a laptop or tablet PC

When using a laptop or tablet PC, the USB supply power may be unstable. So you need to change the 'USB Selective suspend setting'.

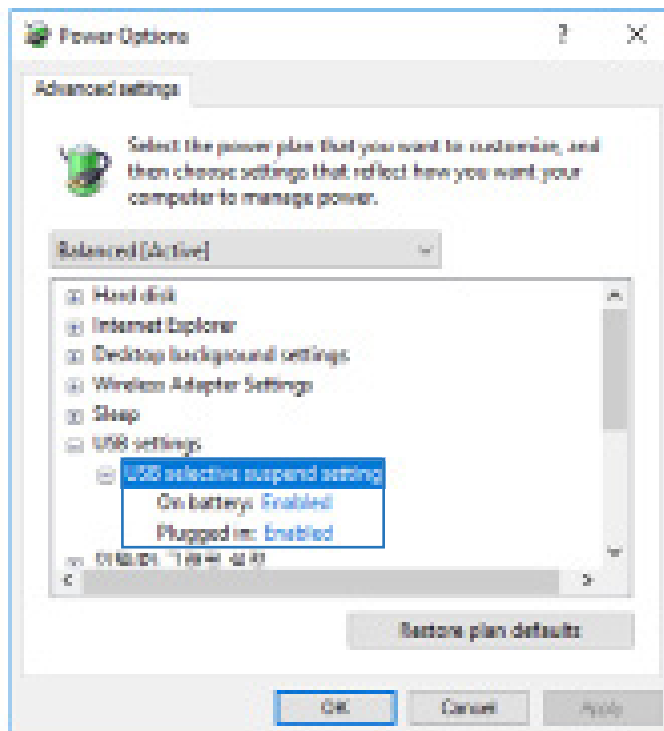
- 1) Press the Windows key + R to open the Run box. Type powercfg.cpl and press Enter.
- 2) When the 'Power Options' windows opens, click the Change plan settings link to the right of your current power plan.



3) Click the 'Change advanced power settings' link.



4) Expand the 'USB settings' and then expand 'USB Selective suspend setting'. Set it to Disabled and Click Apply to save your changes.



08

Image Acquisition

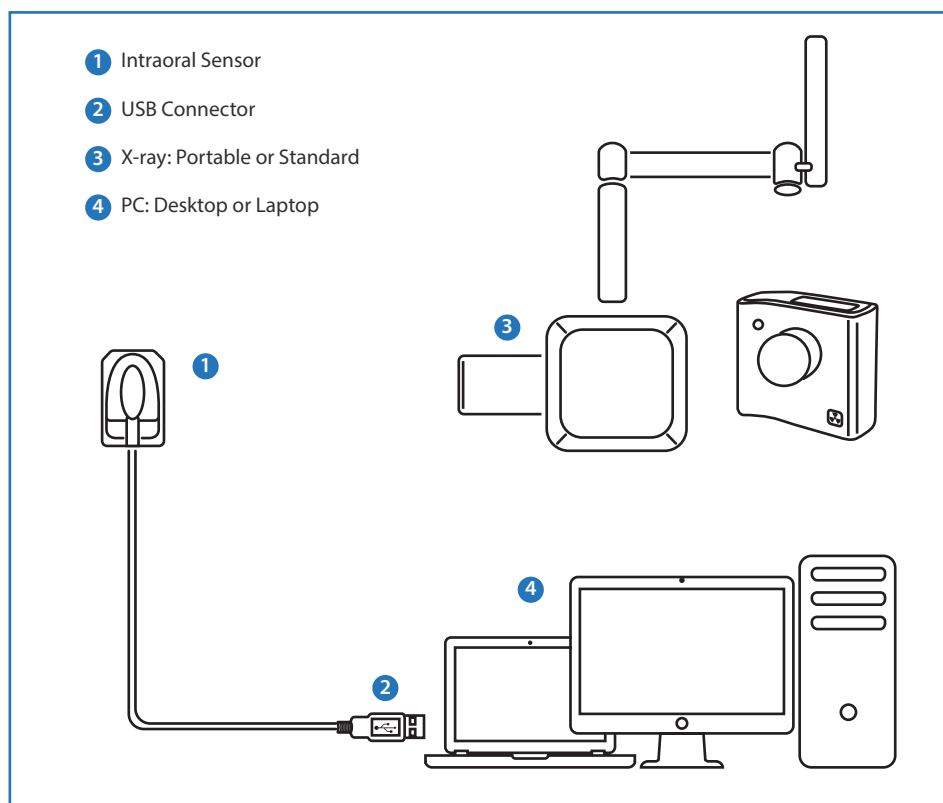
8.1 System configuration

To acquire the image of the Intraoral Sensor (①), connect the USB data communication connector (②) to the PC or Laptop (④) that can control the device and can be viewed images. There are two types of generators that can irradiate X-rays: Portable and Standard (③). When the X-ray is irradiated to the sensor using the X-ray Generator, the image is automatically acquired and can be viewed on a PC or laptop.



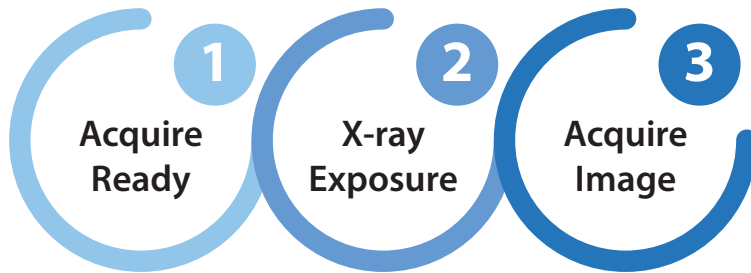
Warning

- Use an input power source certified by IEC60950-1 for PC and X-ray generator.
Electric shock protection class: Type B applied parts
Degrees of protection provided by enclosures: IP68



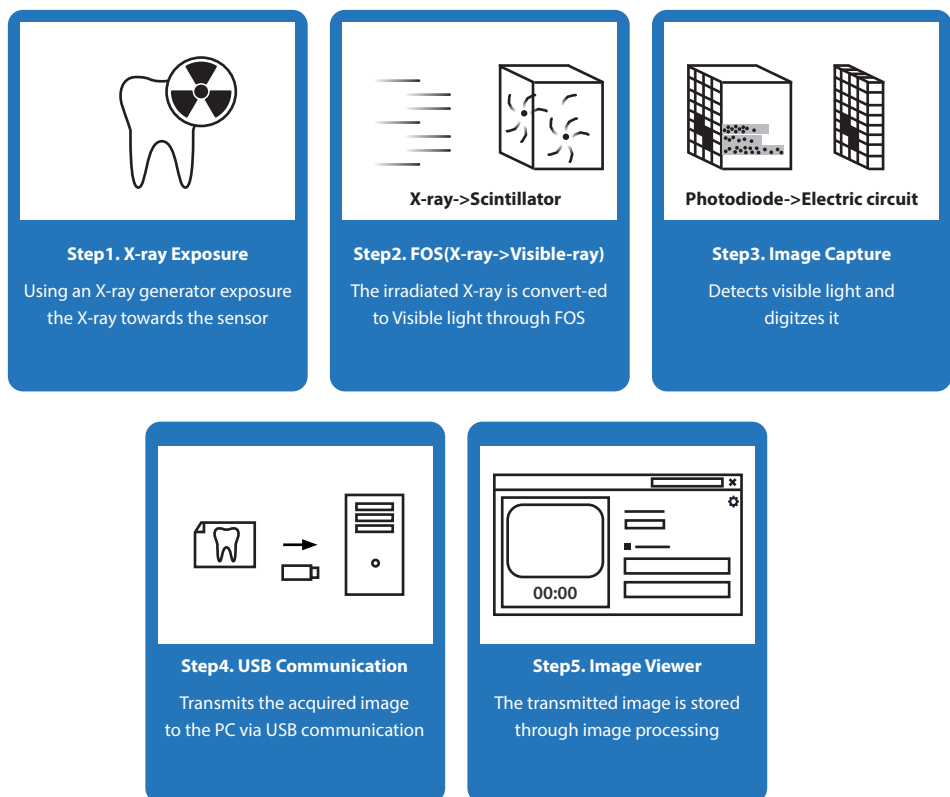
8.2 Image acquisition process

DENTIUM Intraoral Sensor allows you to acquire images in three simple operations. When the Intraoral Sensor is ready to capture, it irradiated X-ray to acquire the image.



8.3 Intraoral Sensor Capture Program

The image acquisition method uses the TWAIN driver. TWAIN is one of the industry standards for common image acquisition interface, and you can acquire images using the Intraoral sensor by using a supporting program. This manual describes how to acquire the Intraoral Sensor images using Dentium's image management program. If you use a third-party program, please refer to its manual. The process of acquiring the image is shown below. When the X-ray is irradiated to Intraoral Sensor, X-ray signal is converted into visible light through the FOS, and the image is detected by the sensor. The acquired image signal is transferred to a PC by USB communication and can be viewed through the image management program.



8.4 How to use Dentium “Rainbow Image Viewer”

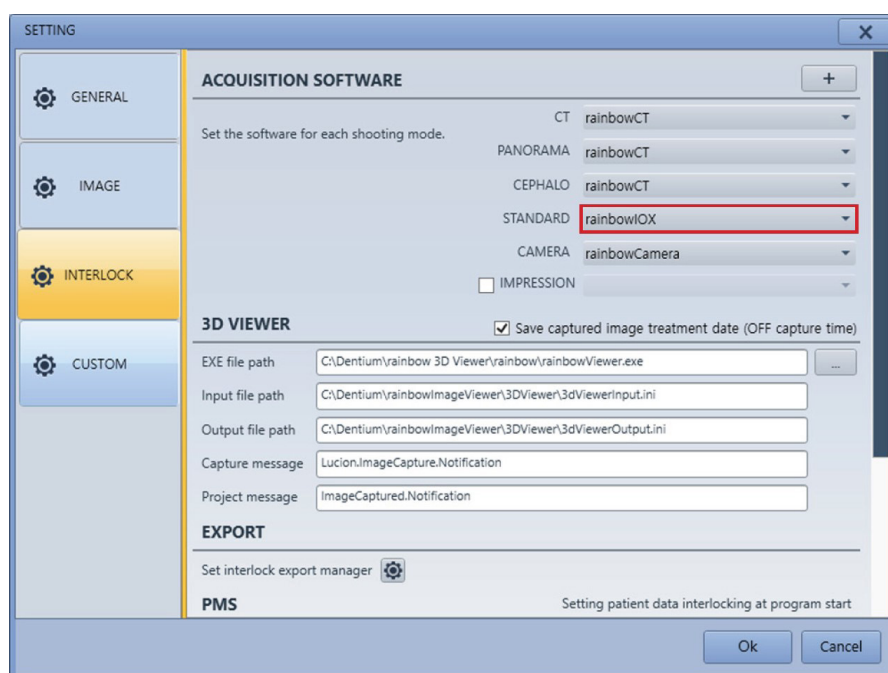
Please refer to the user manual for basic installation and usage of the ‘Rainbow Image Viewer’.

8.4.1 Turn on the PC and check USB connection

Basically, if the USB cable of the Intraoral Sensor is connected to the PC, the image acquisition is possible. Please follow the procedure below while the device is connected.

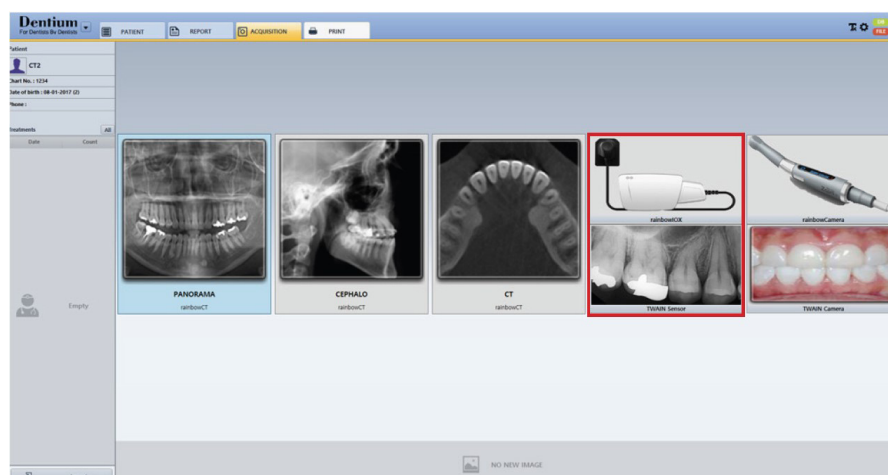
8.4.2 Verifying the installation of the Intraoral Sensor

To check Intraoral Sensor installation, click the Settings button of the Rainbow Image Viewer. On the INTERLOCK tab, check ‘rainbowIOX’ in the STANDARD.



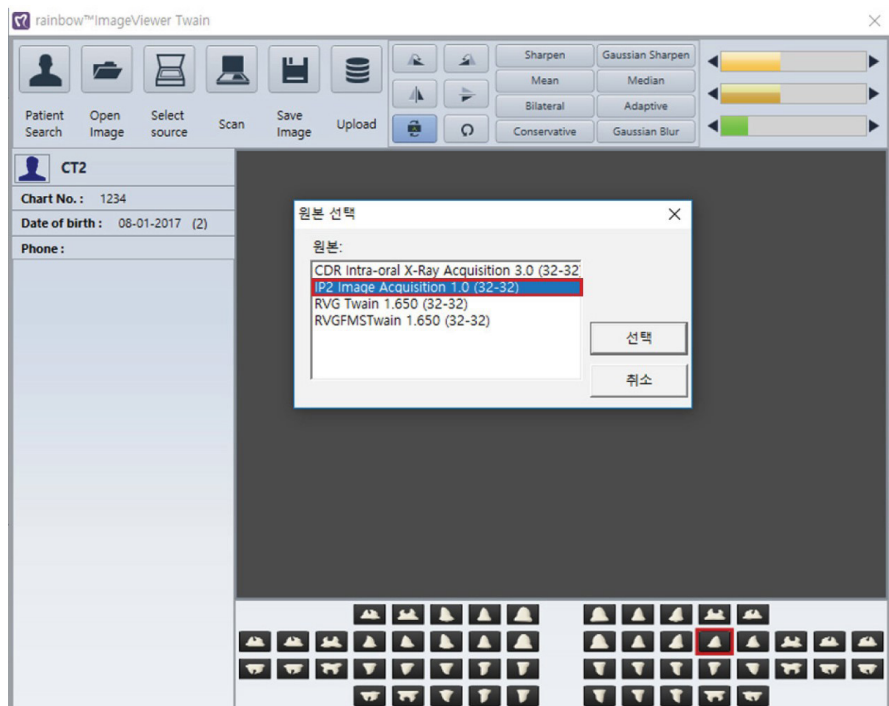
8.4.3 Execute “Rainbow Image Viewer”

After executing Image Viewer, select a patient. Click the ‘ACQUISITION’ tab and then double click on the ‘rainbow IOX’ button.



8.4.4 Preparation for capture

If installing the TWAIN installation file for IOX separately, Click the “Select Source” button to select the desired device (ex. Dentium IOX DS 1.0).



8.4.5 Preparation of x-ray generator

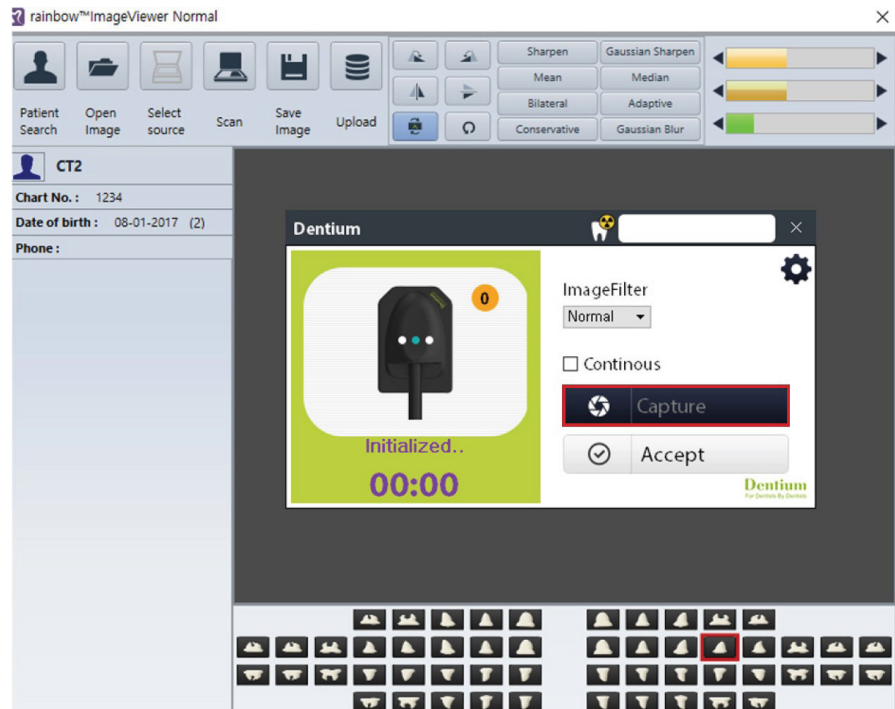
Prepare a portable x-ray generator or standard x-ray generator for the exposure.

8.4.6 Set position for capture

Place the Intraoral Sensor in the patient's mouth to be capture, with the bottom plane of the device facing the x-ray generator.

8.4.7 Run the capture program

With the device in position, click the “Capture” button to run the capture program. In this step, the device is ready to acquire an X-ray image.

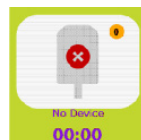


Warning

* The setup button (⚙) on the top right of the capture program can only be used by the administrator. Never should be used by the user.

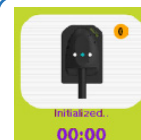
8.4.8 Status description:

The status of device information is divided into 6 levels.



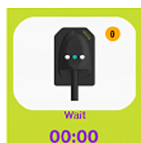
No Device

Indicates that the cable of the device is disconnected.



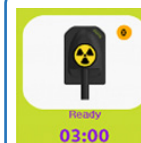
Initialize

Initialization is in progress after the device is connected to the PC. When the cable is disconnected, the connection is made only once for the first time.



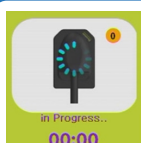
Wait

Device initialization is completed normally and preparing to acquisition.



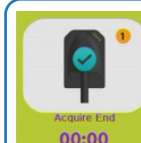
Ready

If you click the "Capture" button while connected, you can acquire an image by exposed x-ray.



In progress

Indicates the image acquisition step after x-ray exposure is completed.

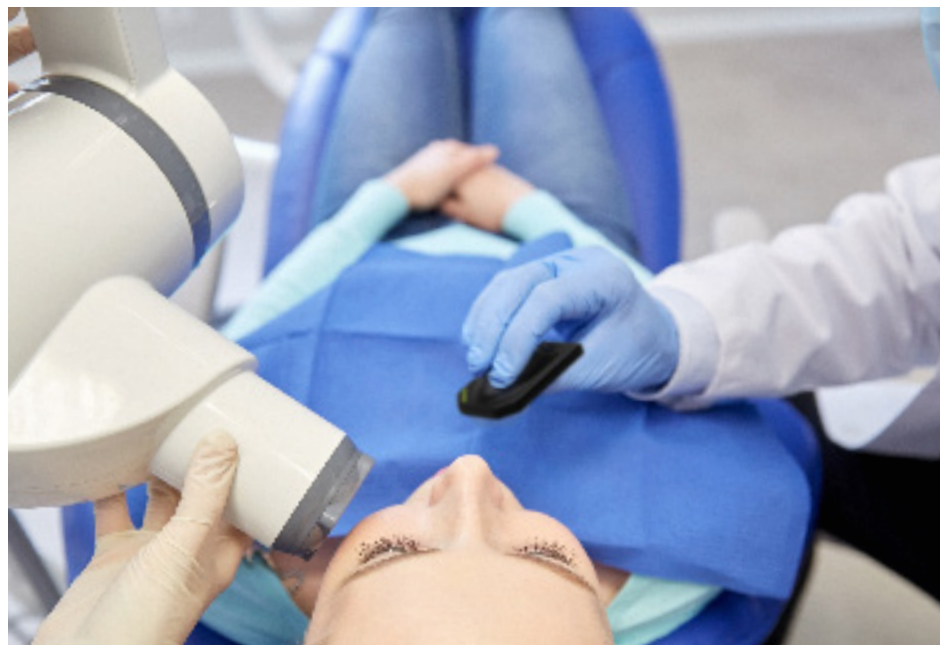


Acquire End

The image has been acquired normally. As soon as image is acquired, it is transferred to the image management program (Rainbow Image Viewer).

8.4.9 X-ray exposure

When the device is properly positioned for the patient's capture area and clicks the "Capture" button, the device is ready to acquire images. Exposure X-ray after setting the appropriate conditions according to the patient's condition.



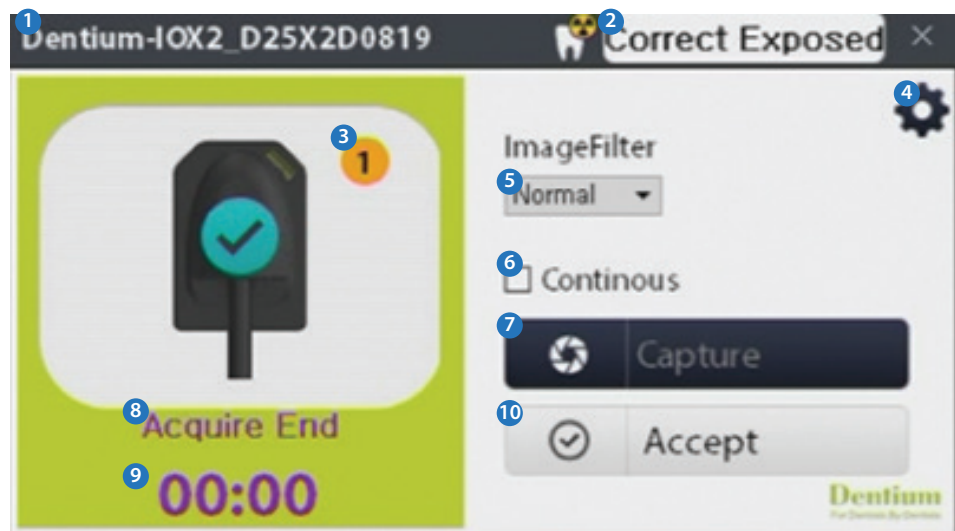
8.4.10 Image acquisition

The image acquired from the device is displayed on the screen as shown below. When the device is properly positioned for the patient's exposure area and clicks the "Capture" button, the device is ready to capture. Exposure X-ray after setting appropriate conditions according to the patient's condition.



Warning

Position the probe on the X-ray generator exactly to the bottom of the device.
Be careful not to move the patient while acquiring image.
When Intraoral sensor is placed in the patient's mouth, be careful not to bite or impact the product.



If you click the “Capture” button, the device will wait for 3 minutes before capture. After acquiring the image, the device will be ready again. The captured image can be previewed and can be viewed by clicking the left / right button. The captured image can be saved by clicking the “Accept” button. (In continuous capture mode, all captured images are saved.)

The detailed functions of the acquisition program are as follow.

- 1 **Device Serial Number:** Serial number and the name of the correction map folder must be matched.
- 2 **X-ray condition guide:** Check X-ray dose irradiated in the exposing in 3 steps.

1)Under Exposed: Lack of dose	Under Exposed!
2)Correct Exposed: Appropriate level	Correct Exposed!
3)Over Exposed: Excess of dose	Over Exposed!
- 3 **Number of acquired image:** Check the number of acquired images.
- 4 **Acquisition setting menu:** Check and change detailed sensor settings.
Do not use it other than the administrator.
- 5 **Preset step adjustment:** Five step of calibration setting can be selected.
- 6 **Continuous acquisition:** Choose if you need continuous acquisition.
- 7 **Device status:** Check the device status.
- 8 **Acquisition waiting time:** Wait up to 3 minutes for acquisition waiting time
- 9 **Image acquisition:** Image acquisition button.
- 10 **Save acquired image:** Save acquired images.

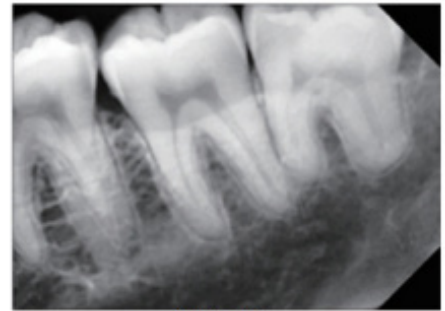
8.4.11 Preset step adjustment about image processing

Acquired images can be selected from a total of five levels of image filters according to preference of user. The default value is set to 'Default', and you can set more sharply from Smooth + (Left) to Sharp + (Right). You can select the filter level before image capturing, and change the filter level after image capturing. In the case of continuous capture mode, the filter can be changed individually in the preview step, and the image is saved as it is.

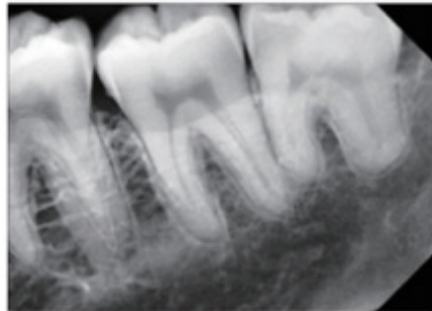
Sample images with image processing filter applied are shown below.



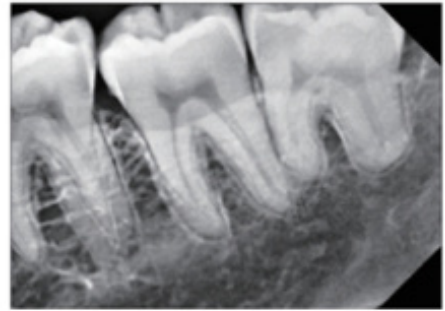
Smooth +



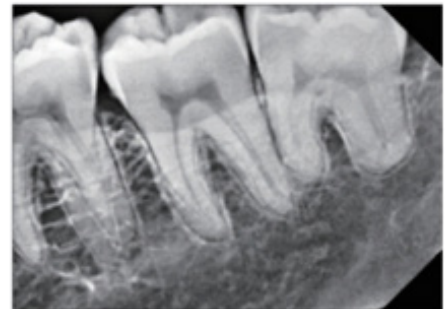
Smooth



Default



Sharp



Sharp+

8.4.12 Check the final image

You can view the saved image through the patient management program. The saved image can be edited by the functions supported by the patient management program. Please check the program's user manual for more details.

09

X-ray exposure guide

9.1. X-ray exposure conditions

The x-ray dose required for the best image acquisition is determined by the following:

- X-ray source: Tube voltage, Tube current, Tube assembly, etc.
- SID (Source to Image Distance): The distance measured between the focal spot target on an x-ray tube to the image receptor of a x-ray cassette
- Target teeth and tissues
- Patient age and bone density

X-ray dose affects image quality. Inadequate dose increases the noise in the image, diminishing detailed discrimination. In contrast, excessively high doses reduce discrimination against dark areas.

X-ray dose is determined by tube voltage (kVp), tube current (mA) and exposure time(s). The exposure time setting for the dose may vary depending on the X-ray Generator. See the table below for the recommended X-ray exposure times for different areas.

Exposure condition	70 kVp, 2 mA	
	Children	Adult
SID	200 mm	
Anterior / Canine	130 ~ 150 μ Gy	400 ~ 450 μ Gy
	0.02 ~ 0.03 s	0.06 ~ 0.10 s
Molar	150 ~ 200 μ Gy	500 ~ 600 μ Gy
	0.03 ~ 0.04 s	0.10 ~ 0.13 s

* SID : Source to Image Distance

* Recommendation on exposure time is limited to Intraoral Sensor in the above table

 Warning	• X-ray exposure condition can be changed by expert's judge. -For larger body types: Increase the source current by 25% -For children(5~21 ages): Reduce the source current by 20% -For edentulous patients : Reduce the source current by 20% • The x-ray dose required to acquire the image may vary depending on the x-ray source and environmental conditions.
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9.2. Check operating conditions

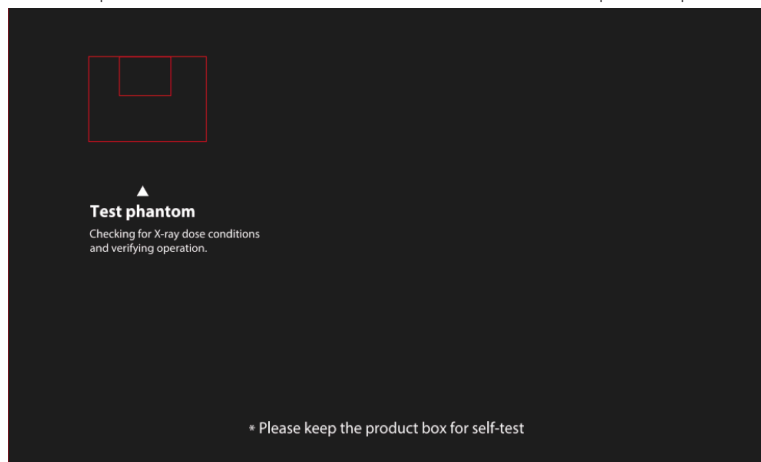
Even if the X-ray generator required for image acquisition has the same specifications, there may be differences in output depending on the product, period of use, battery charge status, and other factors. It supports to check the conditions of use of the X-ray Generator by utilizing the phantom inside the product box. The separately provided program is software that can check usage conditions and verify operation.

9.2.1. Sensor holder using a product box

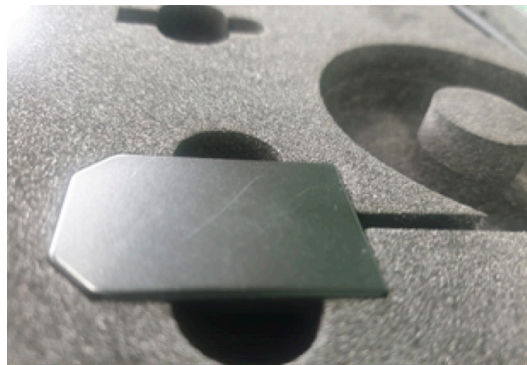
(1) The front of the top of the product box is marked with the 'X-ray Generator ▼' area at the bottom right as shown below. The X-ray Generator's irradiation tool can be located in close contact with the circular center.



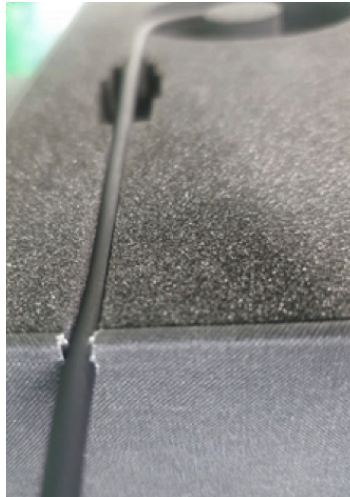
(2) The test phantom location is indicated on the back of the top of the product.



(3) Turn the product upside down on the Intraoral sensor seat in the product box with the bottom of the sensor facing up.



(4) Referring to the figure below, allow the Intraoral sensor to be connected to the Controller while it is mounted on the product box.

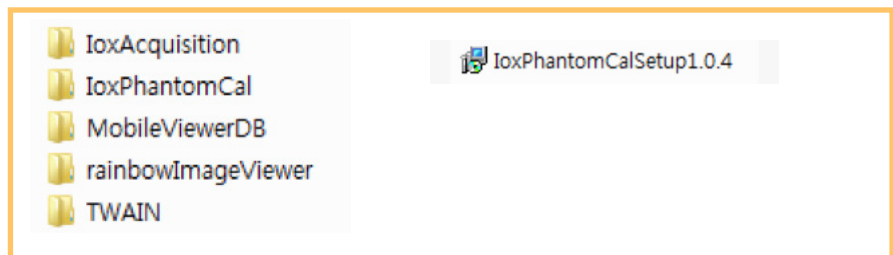


(5) With the Intraoral sensor connected to the Controller, close the cover of the product box and irradiate an X-ray to acquire an image.

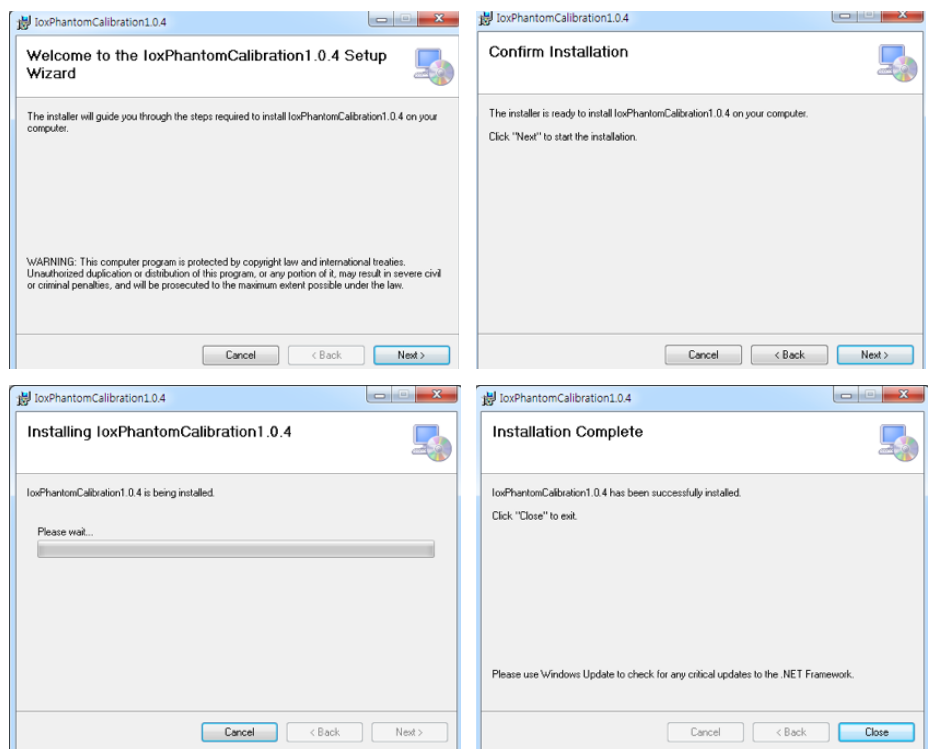
9.2.2. Using the IoxPhantomCal program

(1) Execute the 'IoxPhantomCalSetup.msi' file included in the USB flash drive to install the program.

Path: Run the installation\Install\IoxPhantomCal\IoxPhantomCalSetupx.x.msi file.

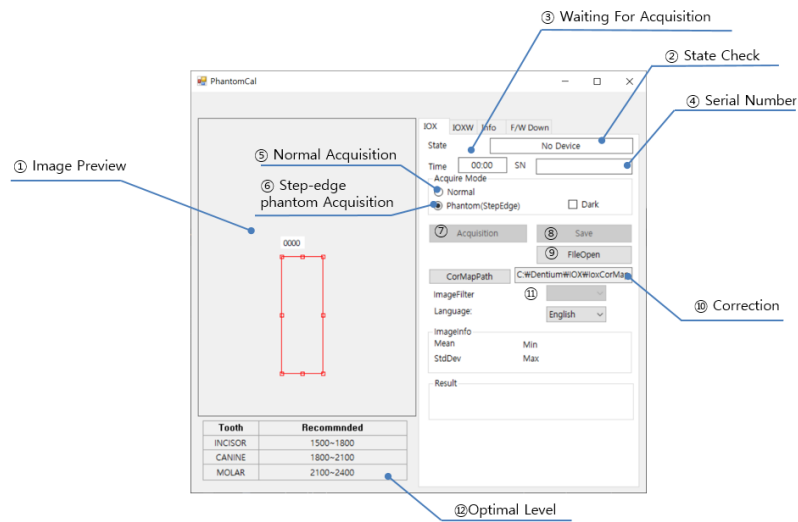


(2) Follow the instructions and click the 'Next' button to complete the installation.



(3) Execute the installed program. Before running the program, connect the sensor to the PC, run the 'PhantomCal.exe' file in the path C:\Dentium\IOX\PhantomCal\.

(4) The function of the program is as follows.



①Image Preview: Check the acquired image.

②State check: Check the operation status.

③Waiting for Acquisition: It waits up to 2 minutes for the waiting time for acquisition the image.

④Serial Number: The unique number of the connected device.

⑤Normal Acquisition: Acquire the corrected image in the same way as the image acquisition using TWAIN.

⑥ This is a dedicated function for test phantom to check the dose condition.

⑦Acquisition: Image acquisition button.

⑧Save: Save the acquired image.

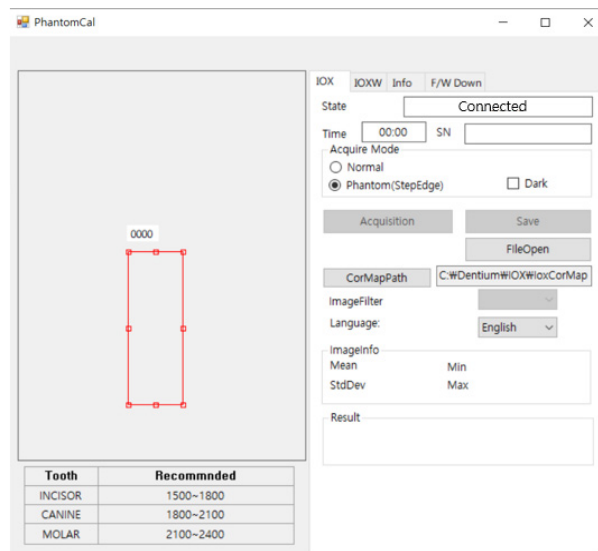
⑨FileOpen: Open the acquired image

⑩Correction Map Storage Folder: Designate the folder where the correction map is saved.

⑪Image Filter: You can specify 5 levels of correction processing for the acquired image.

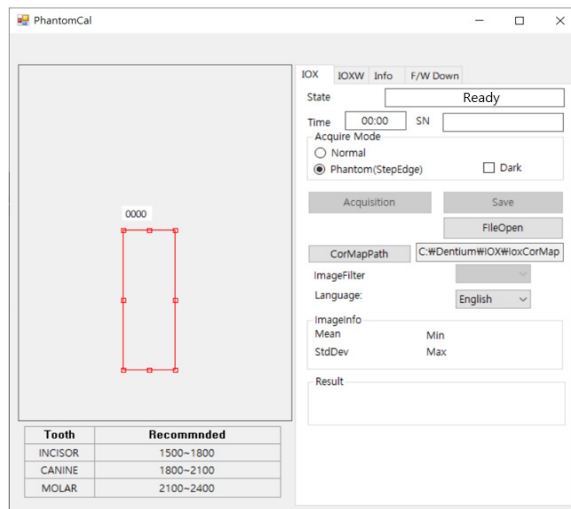
⑫Optimum level: The optimal image level for each tooth area. Please refer to this when checking the dose.

(5) When the Intraoral Sensor is connected, the status changes to 'Connected'.

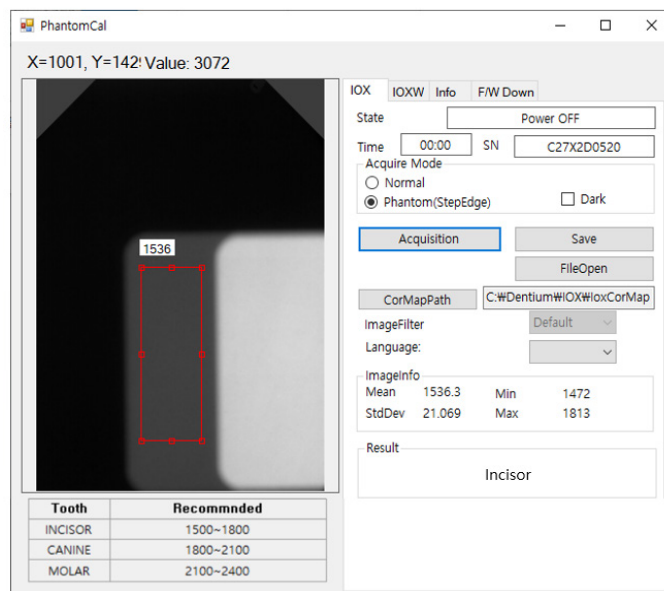


(6) Select 'StepEdge capture' in Mode.

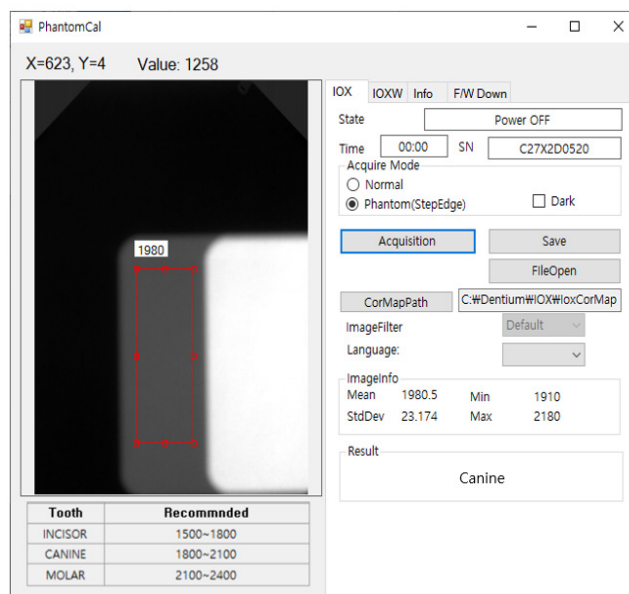
(7) Click the 'Acquisition' button, the status is changed to 'Ready' and the waiting time for acquisition is counted.



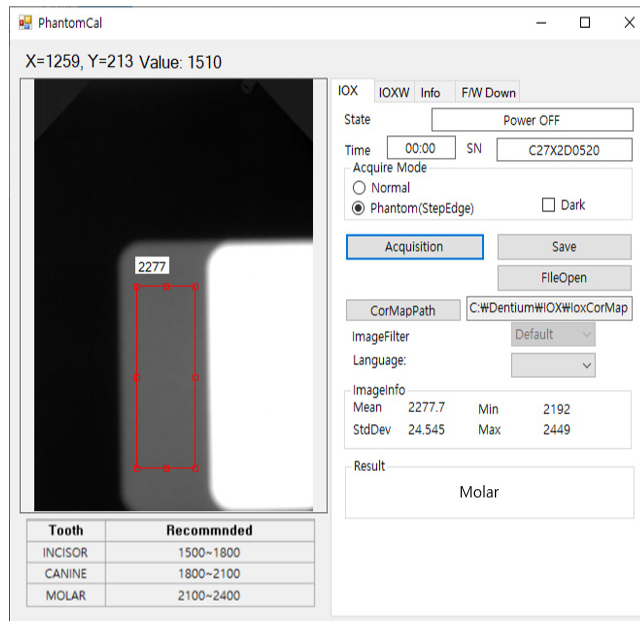
(8) This is an appropriate image level for Incisor Area



(9) This is an appropriate image level for Canine area.

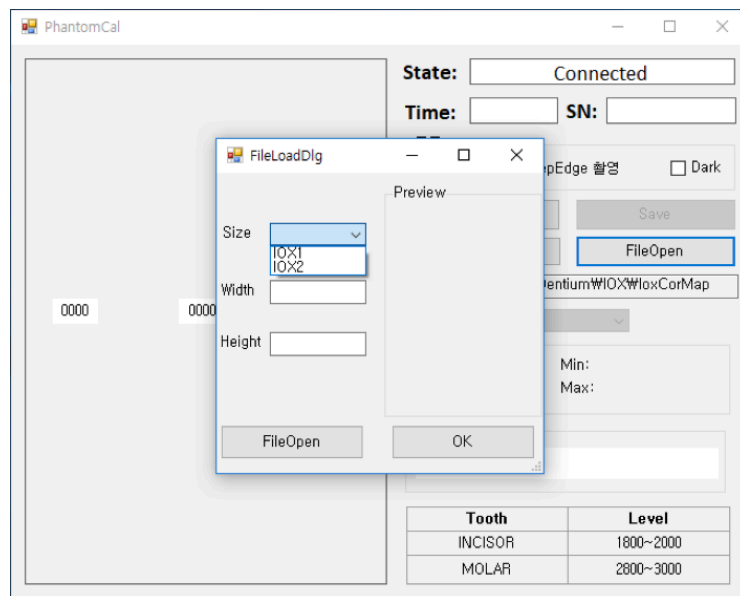


(10) This is an appropriate image level for Molar area.

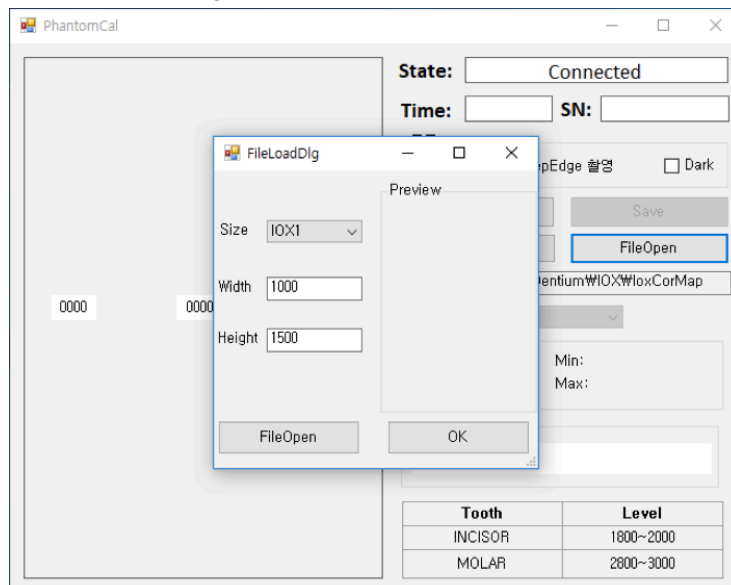


(11) Click the 'FileOpen' button to retrieve and check the acquired image.

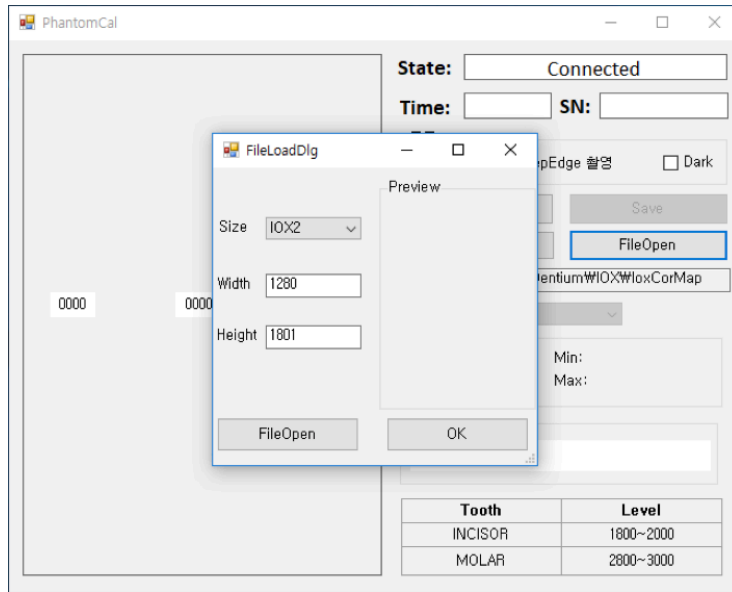
(12) Select IOX1 or IOX2 in 'Size'.



(13) The case of selecting IOX1 is as follows.

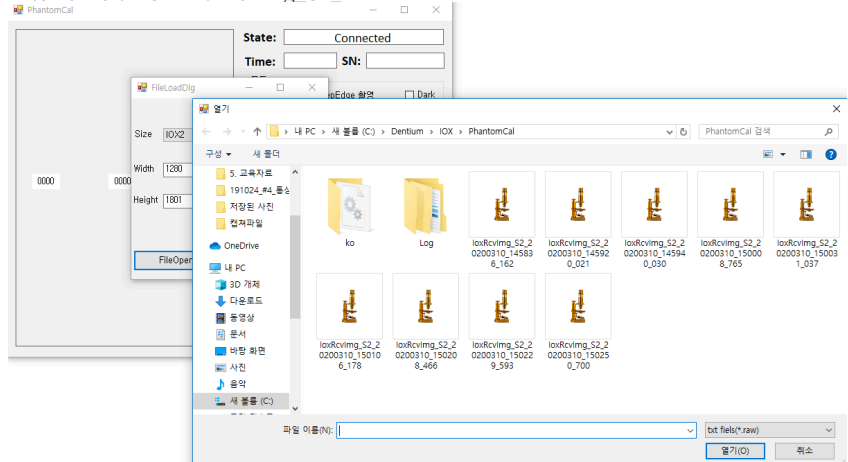


(14) The case of selecting IOX2 is as follows.

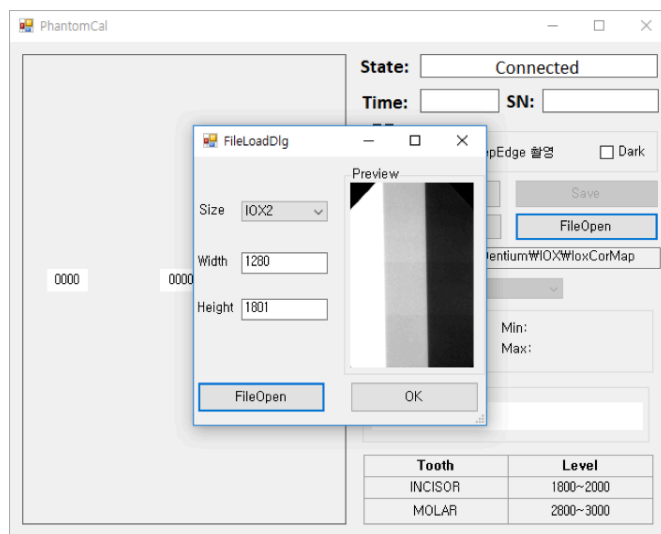


(15) Click the 'FileOpen' button in the lower left corner to select the file.

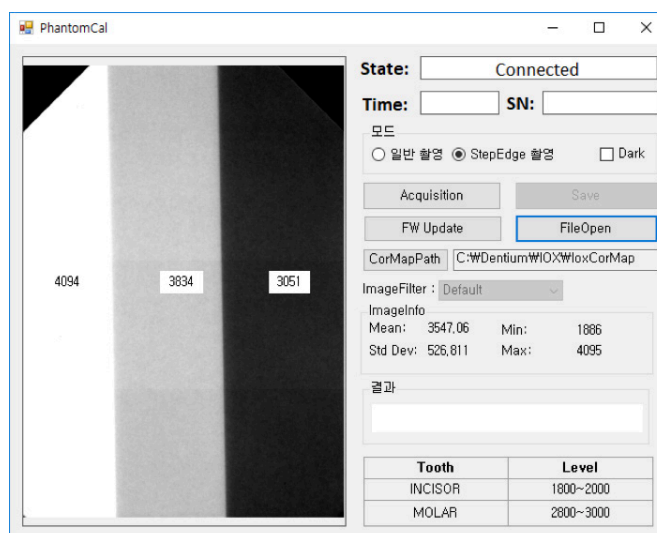
- File name of IOX1: loxRcvlmg_S1_xxxxxxxxx
- File name of IOX2: loxRcvlmg_S2_xxxxxxxxx



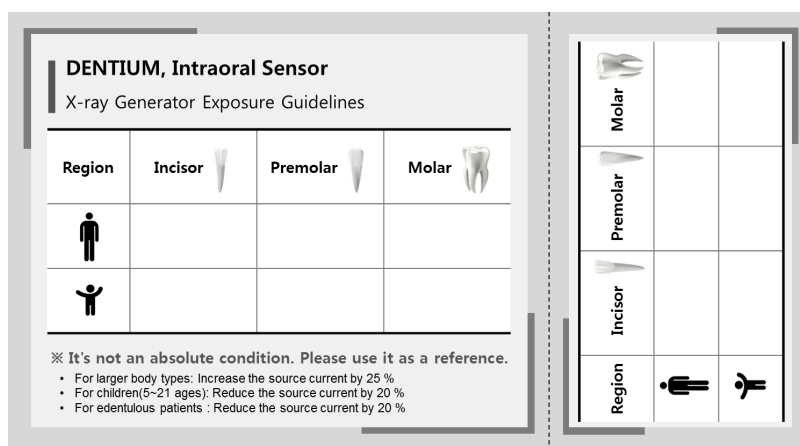
(16) Check the selected image by preview as below.



(17) Click the 'OK' button to check the image level for each area.



(18) Check the irradiation conditions that become the image level for each part based on the image in the right area.



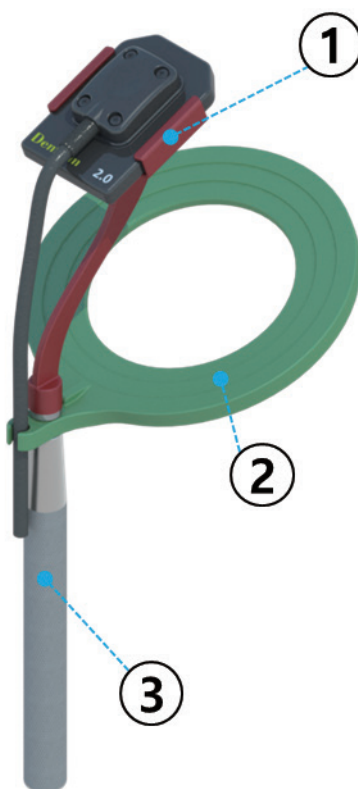
10

Use to Sensor Aligner

It is not easy to accurately position the **Intraoral Sensor** at the location of the teeth when acquiring the image, and it is quite difficult to accurately point the X-ray generator at the location of the sensor. Sensor Aligner designed to hold the **Intraoral Sensor** during the dental radiographic process. By using Sensor Aligner, X-ray exposure through re-shooting can be reduced and time-saving, and high-quality images can be acquired.

10.1. Configuration of Sensor Aligner

The Sensor Aligner can be divided into three parts.



Part	Function
① Sensor connection part	The Intraoral Sensor can be secured and is located in the patient's oral when image acquisition
② X-ray exposure part	Guide the X-ray generator's irradiator towards the sensor
③ Handle part	Sensor Aligner grip handle

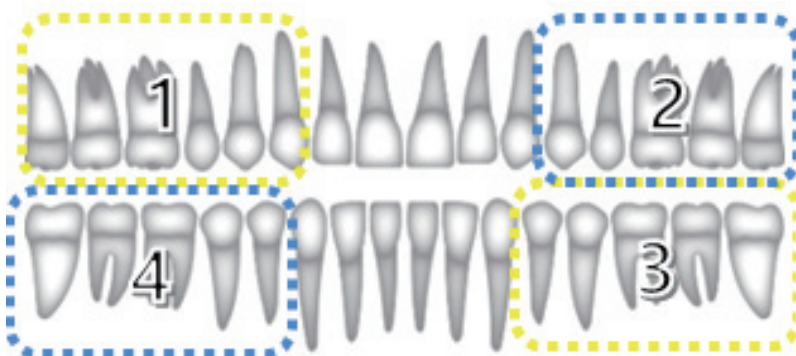
10.2. Sensor Aligner Components

The sensor connection and the X-ray irradiation section are detailed as follows:

10.2.1. Sensor connection part

The sensor connections are divided into four categories, depending on how and where they are taken.

(1) Periapical acquisition: Used for general acquisition, use yellow and blue separately depending on the position of the teeth due to the direction of fastening of the sensor.



Position 1&3



Position 2&4

(2) Bite-wing acquisition: Used for bite-wing acquisition, it is divided into horizontal and vertical directions.



Horizontal type



Vertical type

10.2.2. X-ray exposure part

(1) X-ray exposure part: This is intended to position the X-ray exposure hole and allows accurate X-ray exposure of the sensor location. Below the tightening hole, the sensor's cable can be secured.



(2) Cable holder part: Used when the X-ray exposure guide part is not required and the sensor cable can be secured.



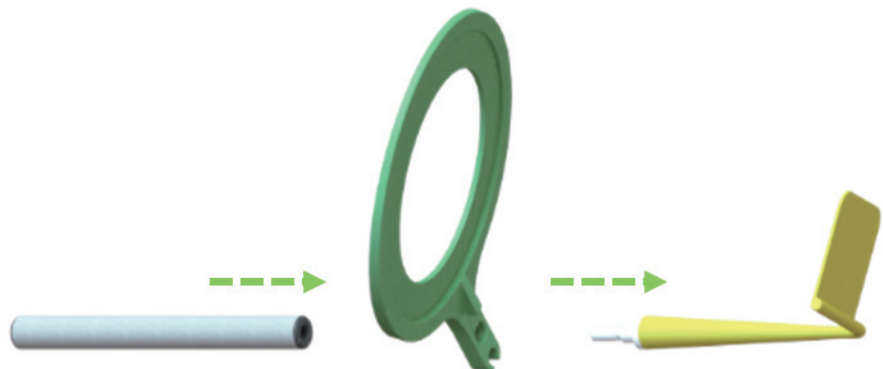
10.2.3. Handle part

The sensor connection part and the X-ray exposure part can be connected.

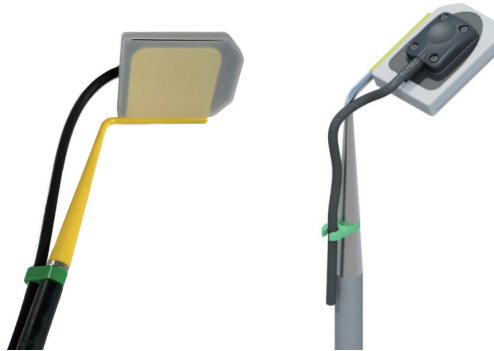


10.2. Sensor Aligner assembly method

(1) When using the X-ray exposure guide part, assemble as follows:



(2) When connecting the sensor to the sensor connection part, use a dedicated silicon cover and insert the sensor connection part into the groove between the silicon cover.



(3) When using cable holder part, tighten as follow:



(4) When using the Sensor Aligner, cover the hygienic cover in the sam way as using the sensor.

11

Cleaning and storage



Warning

- Always clean the electronics accessories after disconnecting the power.
- Do not place a heavy object on cable.
- Do not pull, bend, bundle, or step on cable.
- Do not spray compressed air to clean.

11.1 Cleaning

To prevent infection, the outer surface of the sensor is wiped and sterilized with cleaning solution. If you use a disinfectant other than the designated disinfectant or mix it with other disinfectants or ethanol, the product may be damaged. Use the disinfectant listed below to clean the **Intraoral Sensor**.

- Ethyl or Isopropyl Alcohol (70~90%)
- Sodium hypochlorite (5.25~6.15%)

Clean the product surface with a soft swab moistened with one of the cleaning solutions listed above. Gently wipe the surface in a straight line without applying pressure. After cleaning the surface as necessary, clean and dry the surface with a clean, lint-free cloth.

The Intraoral Sensor meets the IP68, but if it is exposed to alcohol, water, etc. for a long time, it may cause malfunction and damage to the device. Therefore, after washing, dry as quickly as possible.



Warning

- Do not clean the silicone cover as described above.
- Do not use hard brushes or scrapers, strong acids or alkalis.

11.2 Storage

If you do not use this device for a long time, be sure to store it separately from your PC.



Warning

- If it is connected from the PC for a long time, it may cause malfunction.

12

Maintenance

The **Intraoral Sensor** requires not only correct use, but also visual inspection and regular periodic inspection before use. These precautions will help keep your device running correctly, safely, and efficiently. Before use, the device should be checked for physical damage or defects. If you suspect a malfunction, please contact Dentium Service Department or request a Service Call.

- 1) Check if any cable is peeled off and keep it in a circular shape for storage.
- 2) If any abnormality occurs such as heat generation or device recognition failure during use, stop using it immediately and contact Dentium Service Department or request a Service Call.
- 3) When disposing of electronic device accessories, take care of parts that may affect the environment.
- 4) Place where it is not affected by temperature, ventilation, light, dust, salt, etc.
- 5) Avoid inclined or impacted areas
- 6) Do not place in chemical storage or gas storage areas.
- 7) When cleaning the device, lightly rub the surface with a soft, flat dry towel.

12.1 Inspection

Period	Checklists
Daily	• Is the sensor and PC connected properly? • Are there any damage on the surface of the sensor module? • Are sensor surface and sensor cover clean?
Monthly	• Is there any damage to the cable sheath? • Is there any damage to the cable connection(relief)? • Is there any damage to the USB connector that is connected to the PC?
Yearly	• Are there any fixed defects on the image? • Is there a difference in brightness in the image when the X-ray exposure conditions are the same?

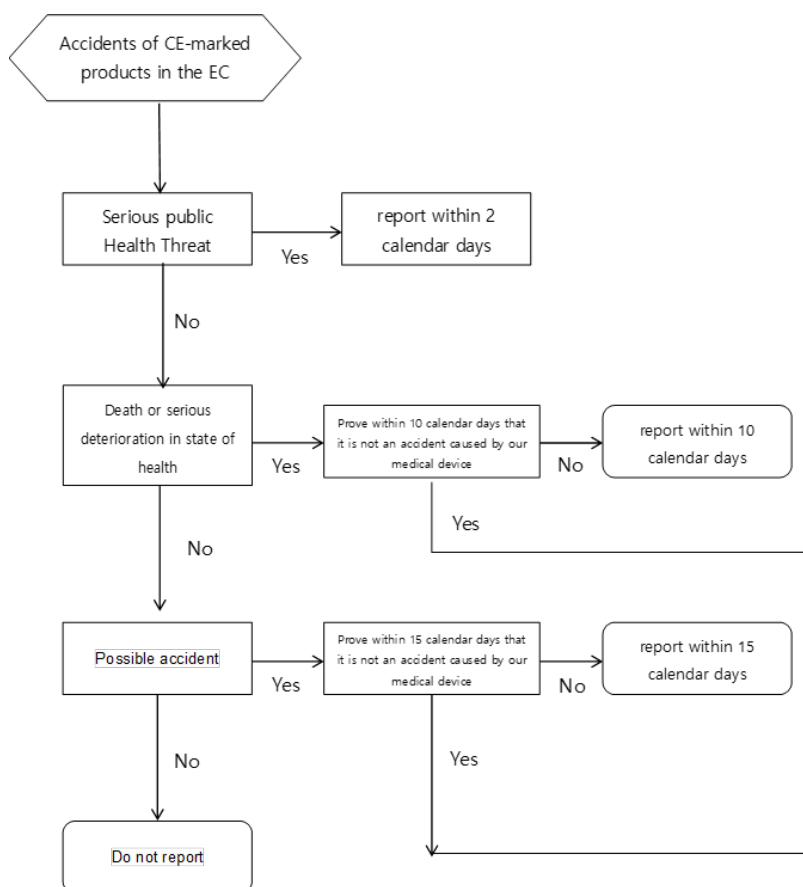


Warning

The sanitary plastic cover must be used when using Intraoral Sensor and should be replaced every time the patient changes for single use.
Use a FDA-approved, safe sanitary plastic cover.
Keep it clean at all times to avoid getting foreign objects.
The sensor cover is for protection, so be sure to remove it before use.

12.2 Vigilance System

Normal image The following decision sheets should be used, for example, whether an accident was caused by a medical device or a device defect.



Personal Responsible for Regulatory Compliance shall submit to the relevant authorities of the country in which the accident occurred as an electronic means (e-mail, online DB system, etc.).

If it corresponds defect of product or information, it shall be notified to NB and AR. In general, the report should be made to the National Competent Authority in the country of occurrence of the INCIDENT unless specified differently in this procedure.

12.3 NATIONAL Management agency

The following decision sheets should be used, for example, whether an accident was caused by a medical device or a device defect.

1) KOREA

- Recall Web page: <https://udiportal.mfds.go.kr/brd/MNU10034>

- Adverse Event: https://udiportal.mfds.go.kr/disps/P03_03

2) USA

- Recall Web page: <https://udiportal.mfds.go.kr/brd/MNU10034>

- Adverse Event: https://udiportal.mfds.go.kr/disps/P03_03

3) ENGLAND

- Web page: <https://www.gov.uk/drug-device-alerts>

4) FRANCE

- Web page: <https://ansm.sante.fr/informations-de-securite/>

13

Handling of errors during



Warning

The following are the simple things you can do. If the problem persists, please contact Dentium Service Department or request a Service Call.

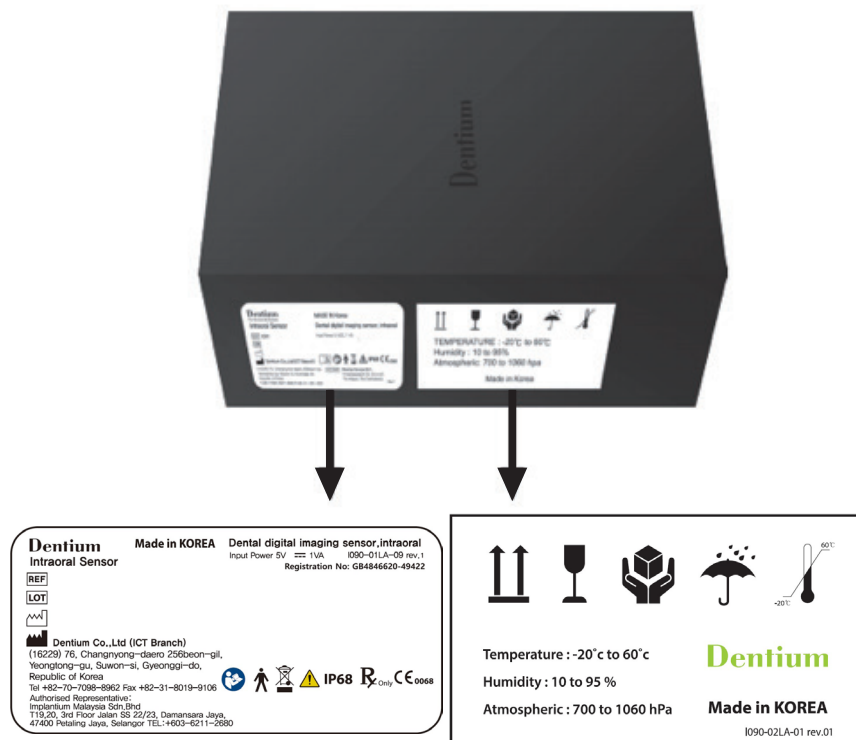
Error	Cause and solution	
USB device recognition failed	Cause	1) Connector contact fault 2) Extension cable fault
	Solution	1) Check the PC connection. 2) Check the repeater's power adapter connection 3) Rerun the installation file. 4) If the symptom cannot be solved, contact Dentium Service Department or request a Service Call.
There is no calibration map	Cause	1) The correction map file is deleted in the installation file folder 2) Calibration map file error
	Solution	1) Check the existence of the file in the correction map folder. 2) Check if calibration map folder name and product S / N match. 3) If the symptom cannot be solved, contact Dentium Service Department or request a Service Call.
Images are automatically acquired without X-ray exposure	Cause	1) Setting value error related to device operation
	Solution	1) Remove the product from the PC and reconnect it. 2) Check if the same symptom is reproduced. 3) If the symptom cannot be solved, contact Dentium Service Department or request a Service Call.
Images of certain areas (ex. Maxillary molar) are not acquired	Cause	1) Insufficient exposure dose 2) Location error of X-ray generator's exposure hole 3) Setting value error related to sensor sensitivity
	Solution	1) Adjust the dose referring to the "X-ray Exposure Guide". 2) Adjust the position of X-ray Generator's exposure hole to face the bottom of sensor correctly. 3) If the symptom is not resolved, contact DentiumService Department or request a Service Call.

14

Label location

14.1 Packaging box

Product and packaging labels are affixed to the sides of the product box.



14.2 Sensor module

The Serial Number label is attached to the USB connector of the **Intraoral Sensor**.



15

Electromagnetic Compatibility Information

Guidance and manufacturer's declaration – electromagnetic emissions		
The Intraoral sensor is intended for use in an electromagnetic environment as specified below. The customer or the user of the Product should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
Radiated disturbance CISPR 11	Group 1 Class A	The Intraoral sensor uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment. The Intraoral sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Mains terminal disturbance voltage CISPR 11	Group 1 Class A	
Harmonics emission IEC 61000-3-2	Class A	
Voltage fluctuation IEC 61000-3-3	Complies	
NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

 NOTE	• "Intraoral Sensor(IOX1, IOX2) meets with the requirements of Electro Magnetic Compatibility according to IEC60601-1-2 : 2014 (4th edition)"
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Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Intraoral sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the Intraoral sensor should assure that it is used in such environment.			
Immunity test	IEC 60601 test	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Discharge by 8 kV direct contact 15 kV of Air-gap discharge	Discharge by 8 kV direct contact 15 kV of Air-gap discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF electromagnetic field immunity IEC 61000-4-3	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	The Intraoral sensor is suitable to use in professional environment (General business, clinic and hospital)

Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	28 V/m Max. 385-5785 MHz in according to table 9	28 V/m Max. 385-5785 MHz in according to table 9	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Intraoral sensor, including cables specified by Dentium. Otherwise, degradation of the performance of this equipment could result
Electrical fast transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for I/O lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for I/O lines 100 kHz repetition frequency	The quality of supplied power should be suitable for general business site or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	The quality of supplied power should be suitable for general business site or hospital environment.
Immunity to conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15-80 MHz 6 V in ISM bands between 0.15 and 80 MHz 80% AM at 1kHz Power supply line & I/O lines	3 V 0.15-80 MHz 6 V in ISM bands between 0.15 and 80 MHz 80% AM at 1kHz Power supply line & I/O lines	The strength of RF field in the frequency range 150 kHz~80 MHz, the strength of the RF field should be smaller than 3 V. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the intraoral sensor.
Voltage dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 Cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30	The quality of supplied power should be suitable for general business site or hospital environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or batter is prepared.

Magnetic field of supply frequency (50/60Hz) IEC 61000-4-8	30 A/m	30 A/m	If degradation of the essential performance occurs, it may be necessary to position the Intraoral sensor further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note UT is the A.C. voltage supply before the test level voltage.			

16

System Disposal Precautions

When you dispose of the device and its accessories, you must dispose of them in accordance with the instructions applicable in your country.



This symbol means that electrical and electronic device waste cannot be disposed of because unsorted municipal waste must be collected separately. Before disposing of the product or parts, please contact Dentium Service Department for instructions for disposal in a safe and proper manner. This device is basically designed to be disposed of without environmental pollution.

16.1 Detailed description of disposal

Part name	Raw materials	Recycled	Hazardous substances
Frame	Aluminum + steel	●	
Cover	Plastic	●	
Relief	Urethane	●	
Control Board	Electronic component + PC	●	
Cable	Silicon	●	
Packaging	Carton + foam	●	

Intraoral Sensor is designed according to medical device regulations and manufactured and inspected according to strict quality control system. Dentium Co., Ltd. warrants that this warranty is in compliance with the international warranty provisions of the Consumer Protection Act.

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Product warranty and service

Dentium Co., Ltd warrants to customer that there are no defects in materials and workmanship under normal use and service for a certain period of one year from the date of purchase of Intraoral Sensor and Accessories. The product warranty is conditioned on the correct use of the product by the customer. During the warranty period, Dentium Co., Ltd will repair or replace defective parts of the product free of charge to the customer. However, if Dentium Co., Ltd determines that the product warranty does not apply, customer shall pay all parts, shipping and labor costs for repair.

Please fill out the following form at the time of purchase and send it to the following fax number: (+82-31-8019-9106) When you claim under this warranty, you must present the warranty to the manufacturer. Free warranty service will not be provided in the following cases:

- 1) Defects or damages due to accident, misuse, abnormal use, abnormal condition, improper storage due to user's negligence.
- 2) Damage or damage caused by external causes such as collisions with objects, fire, flood, sand, earth, storm, lightning, earthquake, weather conditions.
- 3) Defects or damage caused by improper testing, operation, maintenance, installation, service or adjustment not provided or approved by Dentium Co., Ltd.
- 4) Defect or damage caused by disregarding the warning signs in the user's manual (instructions for use)

Product name	Intraoral Sensor	Customer Information (Please complete the form))	
Purchase date		Customer	
Manufacturing date		Address	
Serial Number			
Warranty		Contact information	

BG	ES	CS	DA	DE	ET	EL	EN
							•
FR	GA	HR	IT	LV	LT	HU	MT
NL	PL	PT	RO	SK	SL	FI	KR

Residual Risk Traceability Table			
Recommendations	Description	Page	Risk ID
Caution	Never disassemble or modify the product	8	H-4.2 H-8.10.1
Warning	- The Intraoral Sensor does not guarantee normal operation in unregistered Microsoft Windows. Therefore, please use the registered genuine version of Microsoft Windows. - Operating systems other than Windows are not supported. - It can be used on PCs that are below the minimum specification, but cannot guarantee 100% product performance.	12	H-14.6.2 H-14.7 H-14.8 H-14.9 H-14.11
Warning	You must install device driver to operate the Intraoral Sensor. It must be connected to a product or device that complies with IEC 6061-1 or IEC 60950-1	13	H-7.2.5 H-7.5
Warning	- If you need to purchase additional repeater, please contact Dentium Service Department or order a new sensor. - If you need additional other repeater product, use only the adapter power connection type. (The maximum length is limited to 15m) If there is any problem with the operation after connecting the repeater or extension cable, please contact Dentium Service Department or order a new sensor.	16	H-15.4.1
Warning	- Use an input power source certified by IEC60950-1 for PC and X-ray generator. - Electric shock protection class: Type B applied parts - Degrees of protection provided by enclosures: IP68	19	H-7.2.5 H-7.5
Warning	The setup button(⚙️) on the top right of the capture program can only be used by the administrator. Never should be used by the user.	23	H-14.6.1 H-14.6.2
Warning	Position the probe on the X-ray generator exactly to the bottom of the device. Be careful not to move the patient while acquiring image. When Intraoral sensor is placed in the patient's mouth, be careful not to bite or impact the product.	24	H-9.3
Warning	- X-ray exposure condition can be changed by expert's judge. - For larger body types: Increase the source current by 25% - For children (5~21 ages): Reduce the source current by 20% - For edentulous patients: Reduce the source current by 20% - The x-ray dose required to acquire the image may vary depending on the x-ray source and environmental conditions.	27	H-4.3
Warning	- Always clean the electronics accessories after disconnecting the power. - Do not place a heavy object on cable. - Do not pull, bend, bundle, or step on cable. - Do not spray compressed air to clean.	39	H-5.4 a) H-5.7 H-8.8.4.1

Warning	• Do not clean the silicone cover as described above. • Do not use hard brushes or scrappers, strong acids or alkaloids.	39	H-11.6.6
Warning	• If it is connected from the PC for a long time, it may cause malfunction.	39	H-14.6.2 H-14.7 H-14.8 H-14.9 H-14.11
Warning	• The sanitary plastic cover must be used when using Intraoral Sensor and should be replaced every time the patient changes for single use. Use a FDA-approved, safe sanitary plastic cover. Keep it clean at all times to avoid getting foreign objects. The sensor cover is for protection, so be sure to remove it before use.	40	H-11.6.6
Caution	The following are the simple things you can do. If the problem persists, please contact Dentium Service Department or request a Service Call.	42	H-4.2



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Intraoral Sensor User Manual

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