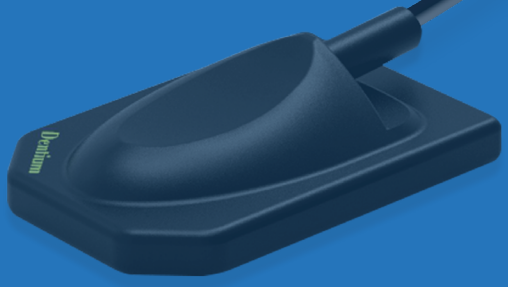
IOX Intra-oral Sensor

User Manual



Dentium
For Dentists By Dentists

CE 0068

Table of Contents

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

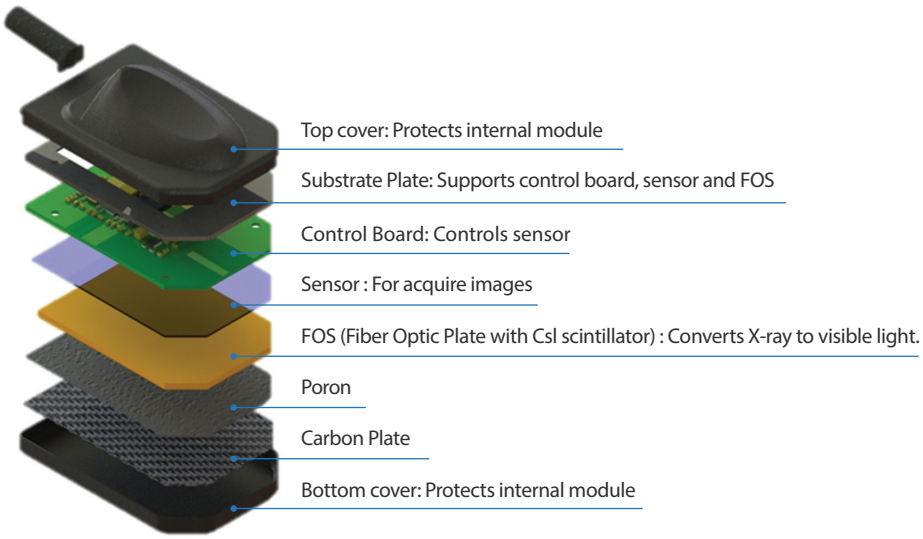
1.1. Product description and purpose of use

1.1.1. Product Description

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

1.1.3. Purpose of use

The Intraoral Sensor is a medical device that uses 2 ~ 3 teeth in high resolution for precise diagnosis.

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 degrades 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.

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 exceeds 41°C (reach up to 41.1°C). Do not directly touch the product for a long period of time with the power turned on.
- 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.

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

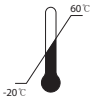
In order to use the device efficiently, this manual uses the following symbols to fully understand and comply with the meanings of the symbols. To avoid personal injury and property damage, please observe the safety precautions specified in the documentation.

Symbol	Symbol Title	Description
	NOTE	Provides information and instructions for using the device.
 Caution	CAUTION	Important instructions for using the device. It can cause serious damage to the device and human body.
 Warning	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

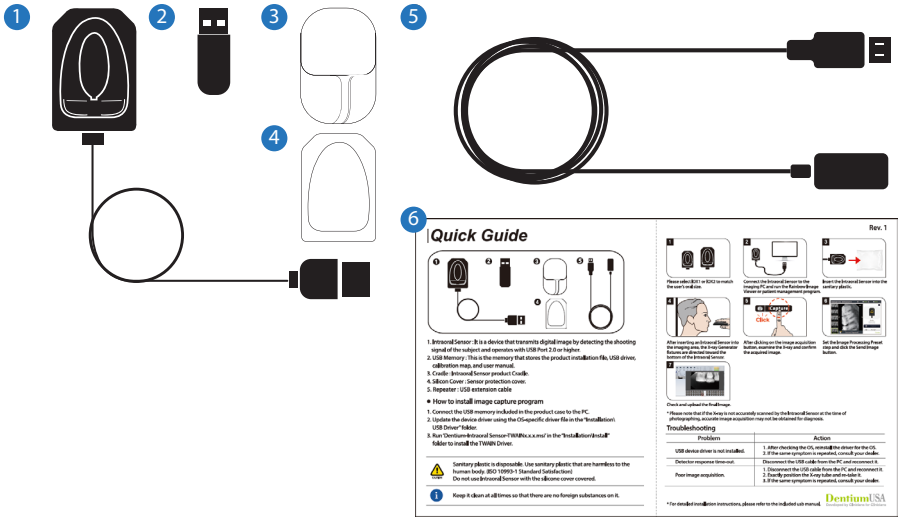
Symbol	Description
	Indicates the need for the user to consult the instructions for use
	Identifies a type B applied part complying with IEC 60601-1
	Indicates the need for the user to consult the instructions of use for important information such as warnings and cautions
IP68	Protected against access 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
EC REP	Indicates the authorized representative in the European union. Symbol is accompanied by the name and address of the authorized representative adjacent to the symbol.
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 0068	CE marking indicates that a product complies with applicable European Union regulations
℞ Only	Federal law prohibits dispensing without prescription

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 medial 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 5.1 mm	29.1 x 42.6 x 5.1 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 ℃ to 30 ℃ (Usage) - 20 ℃ to 60 ℃ (Transportation and Storage)	
Relative Humidity	30 % to 95 % (Usage) 10 % to 95 % (Transportation and Storage)	
Air Pressure	700 to 1060 hPa	
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	

- 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

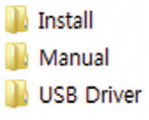
The Intraoral Sensor provides an integrated installer that installs USB driver and TWAIN Driver.

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



7.1.2 Installing USB Driver

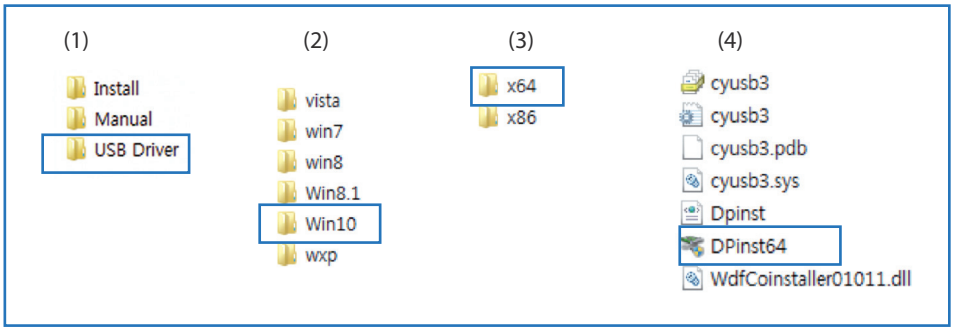
1) Move to the corresponding path of USB memory. Path: Installation\USB Driver

2) Select the folder suitable for the operating system of the installation PC. (From Vista, 7, 8, 8.1, 10, XP)

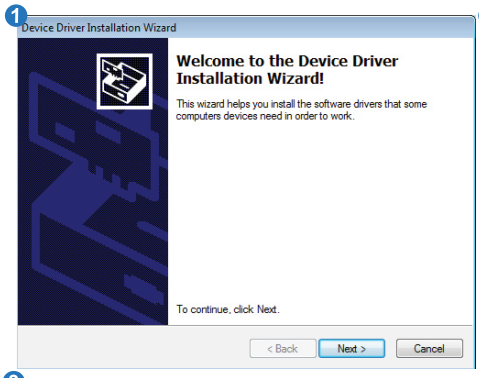
3) Select a folder that matches the bit of the operating system. (32-bit: x86, 64-bit: x64)

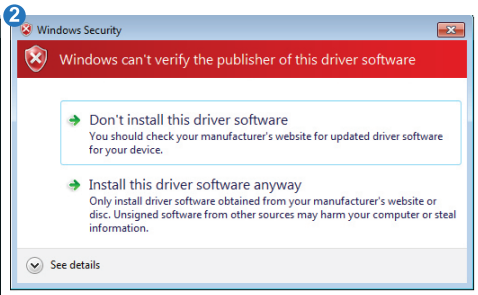
4) Run the installation file. (32-bit: DPInst32.exe, 64-bit: DPInst64.exe)

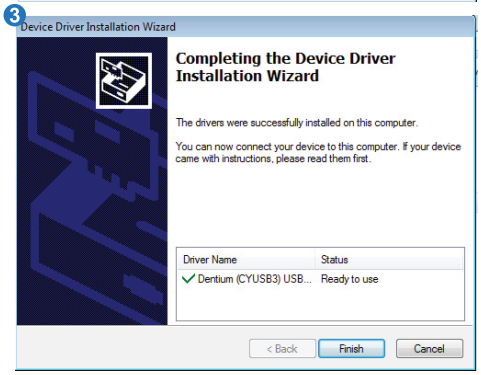
5) Please click "Next" button to complete the installation.



7.1.3 USB Driver setup screen description





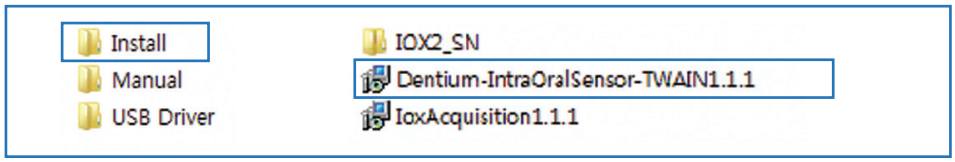


1. When the Run screen appears, click the "Next" button.
2. The driver installation confirmation window appears and click "Install this driver software" to proceed with the installation.
3. When installation is complete, click "Finish" to exit.

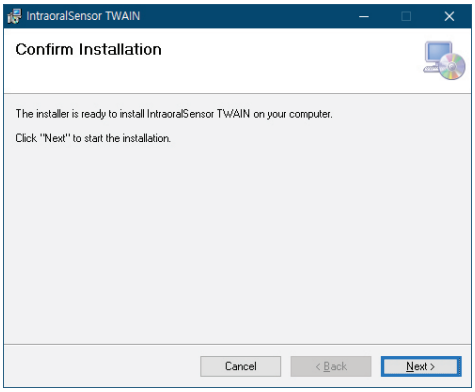
7.1.4 Installing IOX Acquisition and TWAIN Driver

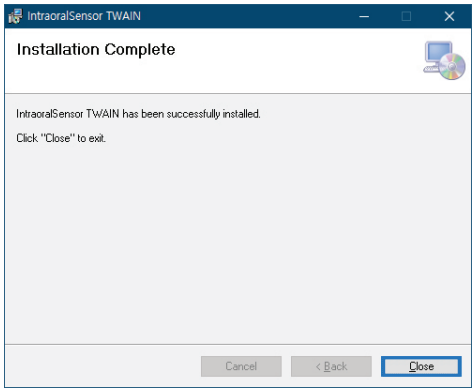
The Intraoral Sensor can acquire images using TWAIN-compliant applications. In order to use this function, the image management and patient management program must support the TWAIN interface.

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



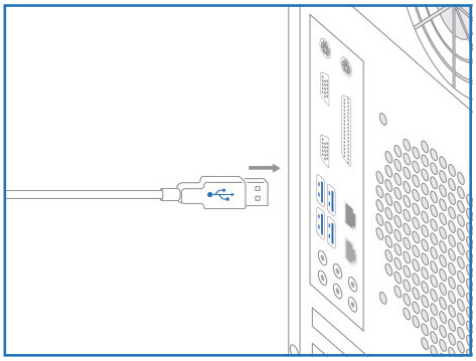
* Continue to click the "Next" button to complete the installation.

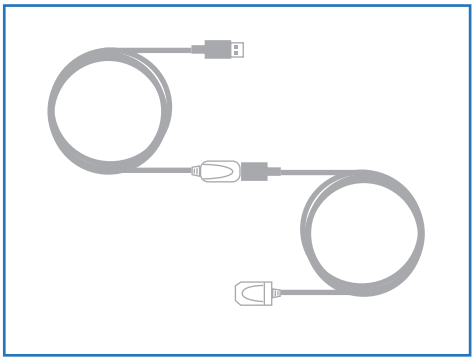




7.1.5 Cable connection

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.

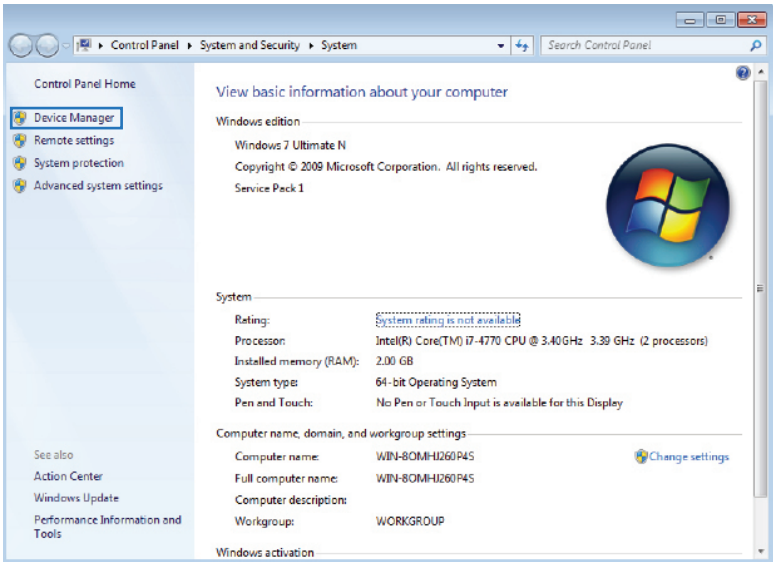
7.1.6 Device driver verification

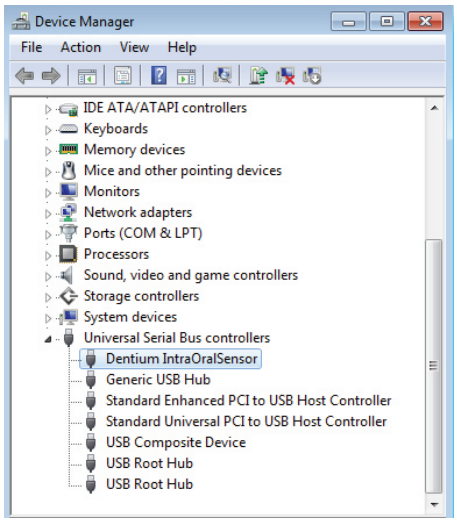
Run Device Manager in Control Panel on Windows systems. If you see "Dentium IntraOralSensor" in the "Universal Serial Bus Controller", the driver is working normally.

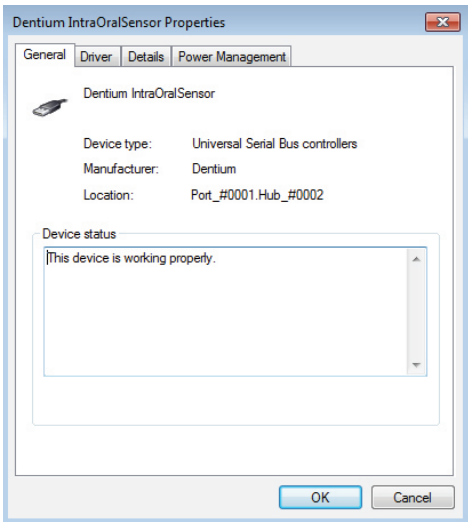
Verification method:

1) Windows 7 or 10: Control Panel -> System and Security -> System -> Device Manager

2) Windows XP: Settings -> Control Panel -> System -> Hardware -> Device manage





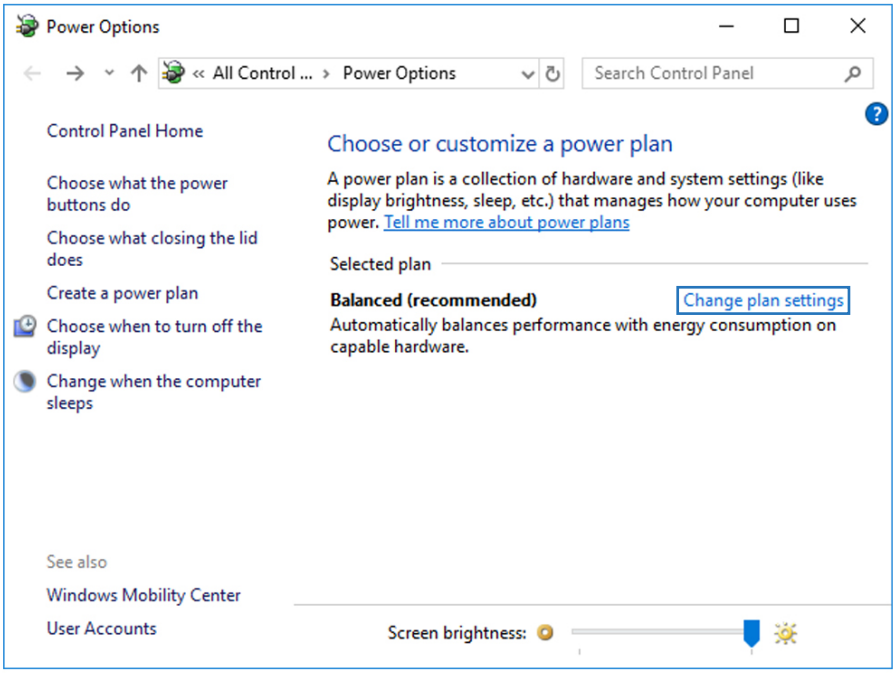


* If the driver is not installed properly, please contact Dentium Service Department or request Sevice Call

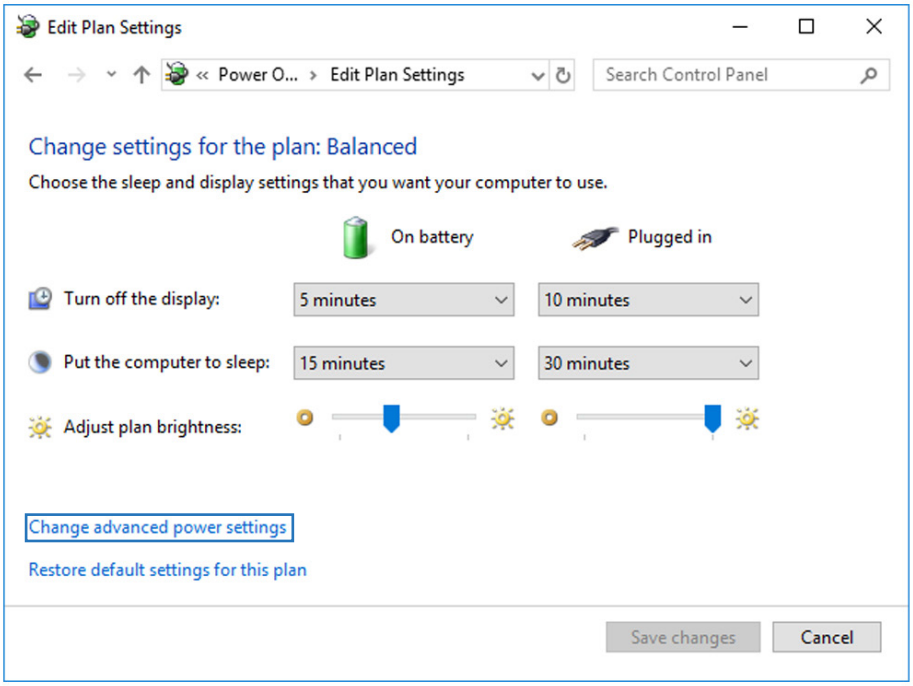
7.1.7 Power settings when using a laptop or tablet PC

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

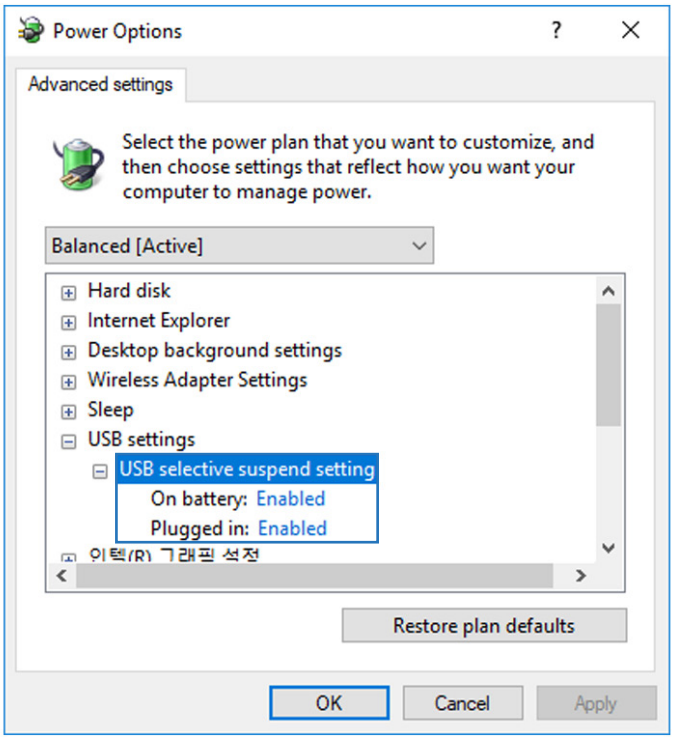
1) Press the Windows key + R to open the Run box. Type powercfg.cpl and press Enter.
2) When the 'Power Options' windows opens, click the Change plan settings link to the right of your current power plan.



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.



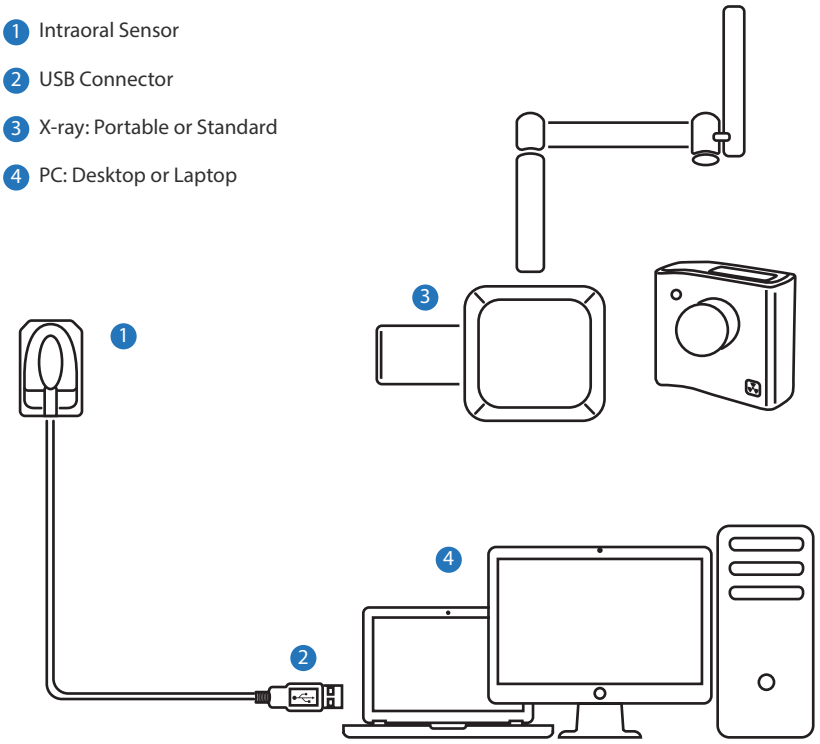
08
Image Acquisition

8.1 System configuration

To acquire the image of the Intraoral Sensor (1), connect the USB data communication connector (2) to the PC or Labtop (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.

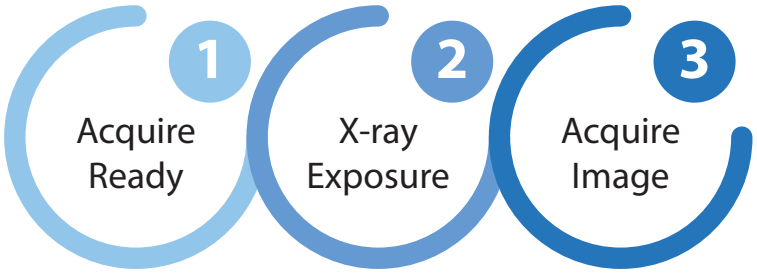
Warning	• Use an input power source certified by IEC60950-1 for PC and X-ray generator. Electric shock protection class: Type B applied parts Degrees of protection provided by enclosures: IP68

1 Intraoral Sensor
2 USB Connector
3 X-ray: Portable or Standard
4 PC: Desktop or Laptop



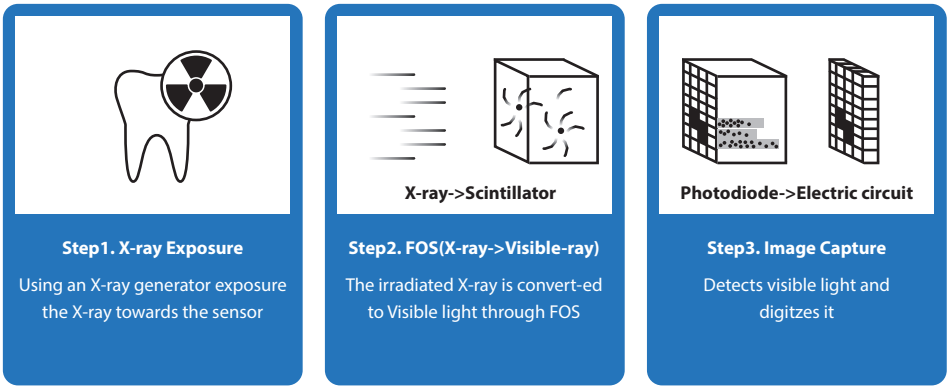
8.2 Image acquisition process

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.



Step1. X-ray Exposure

Using an X-ray generator exposure the X-ray towards the sensor

X-ray->Scintillator

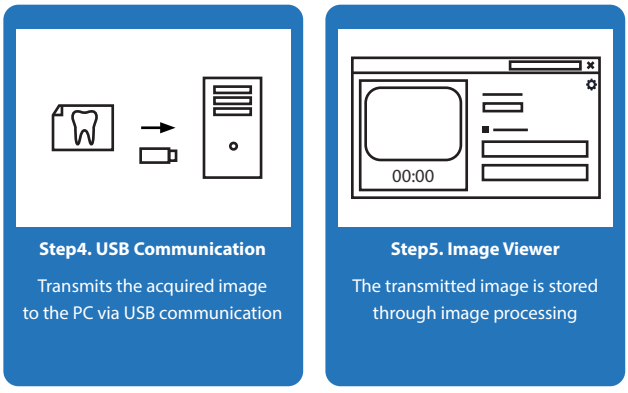
Step2. FOS(X-ray->Visible-ray)

The irradiated X-ray is convert-ed to Visible light through FOS

Photodiode->Electric circuit

Step3. Image Capture

Detects visible light and digitzes it



Step4. USB Communication

Transmits the acquired image to the PC via USB communication

Step5. Image Viewer

The transmitted image is stored through image processing

8.4 How to use Dentium “rainbow Image Viewer”

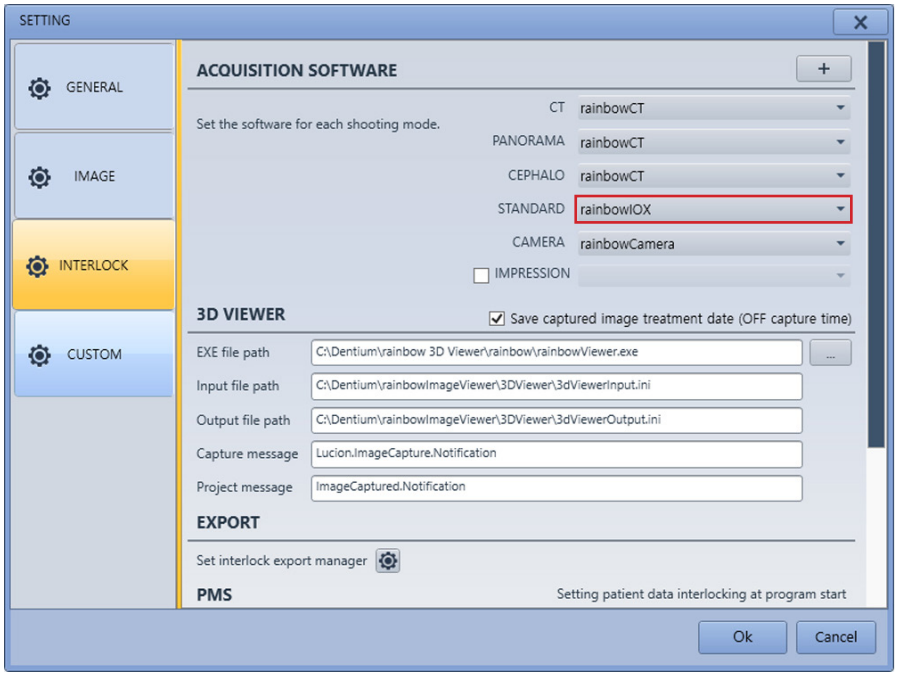
Please refer to the user manual for basic installation and usage of the ‘rainbow Image Viewer’.

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.

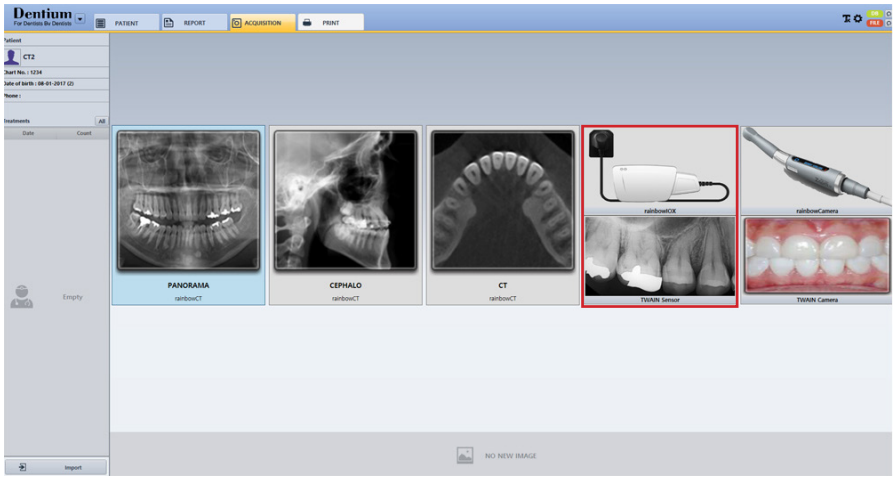
8.4.2 Verifying the installation of the Intraoral Sensor

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



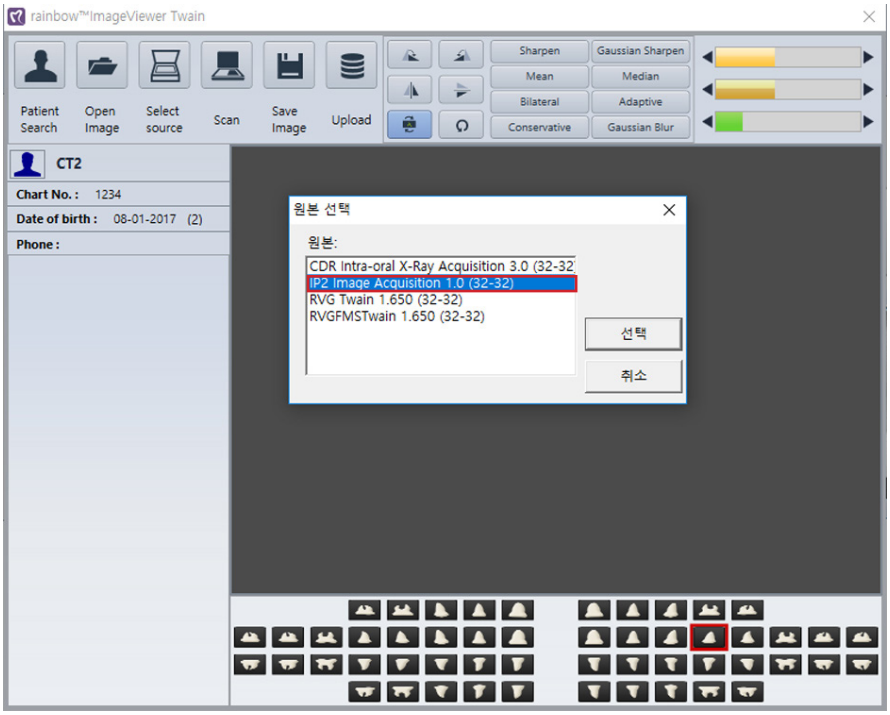
8.4.3 Execute “rainbow Image Viewer”

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

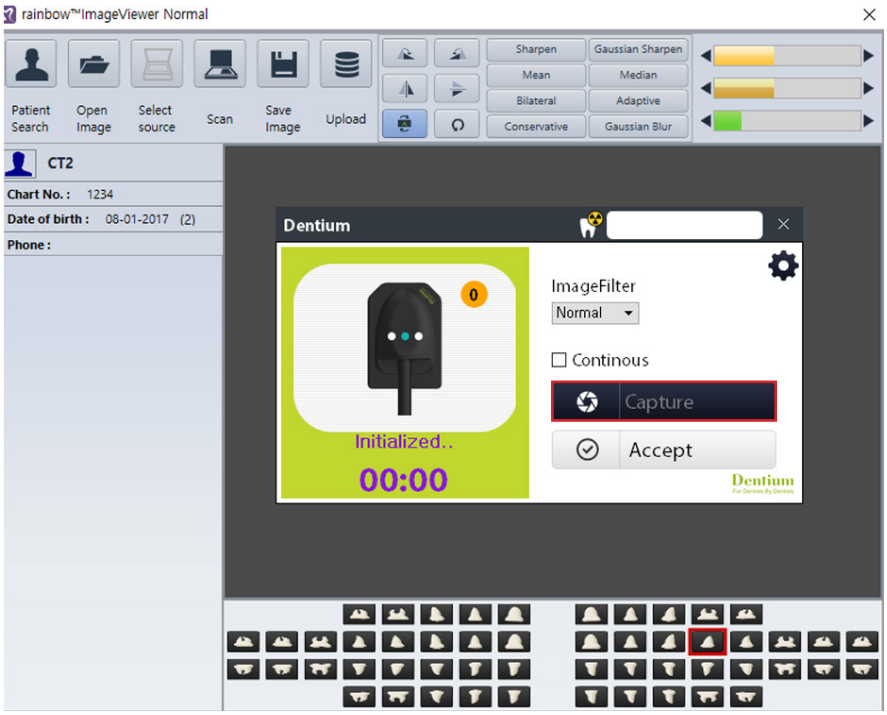
Prepare a portable x-ray generator or standard x-ray generator for the exposure.

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

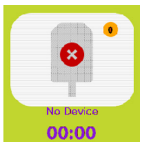
With the device in position, click the "Capture" button to run the capture program. In this step, the device is ready to acquire an X-ray image.



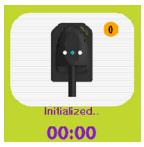
Warning	* The setup button (⚙) on the top right of the capture program can only be used by the administrator. Never should be used by the user.

8.4.8 Status description:

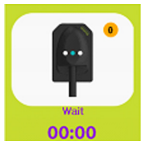
The status of device information is divided into 6 levels.



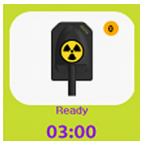
No Device
Indicates that the cable of the device is disconnected.



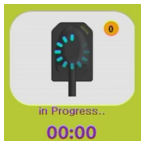
Initialize
Initialization is in progress after the device is connected to the PC. When the cable is disconnected, the connection is made only once for the first time.



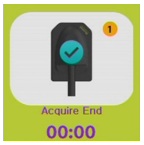
Wait
Device initialization is completed normally and preparing to acquisition.



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



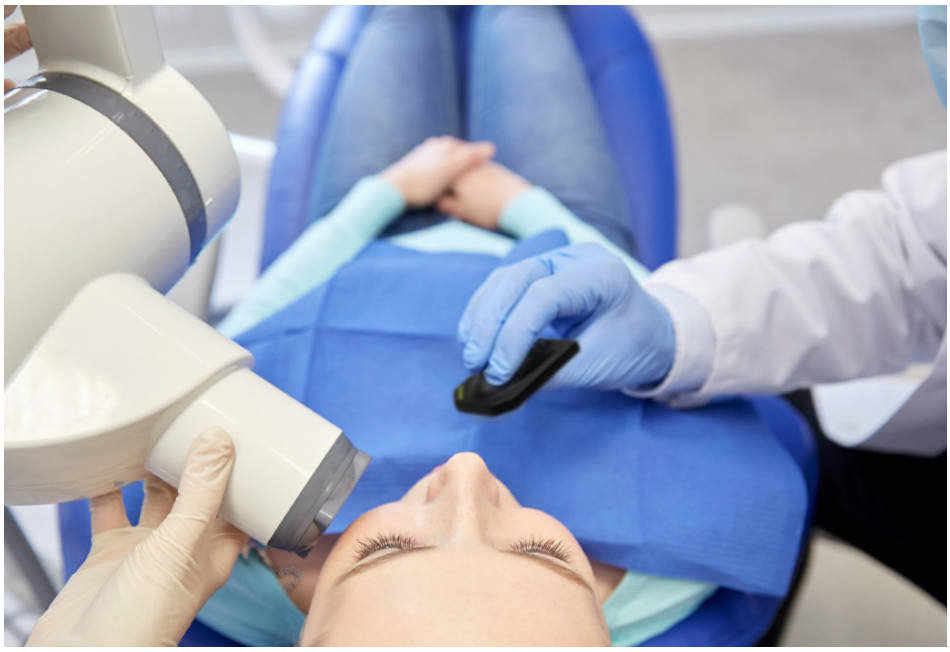
In progress
Indicates the image acquisition step after x-ray exposure is completed.



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

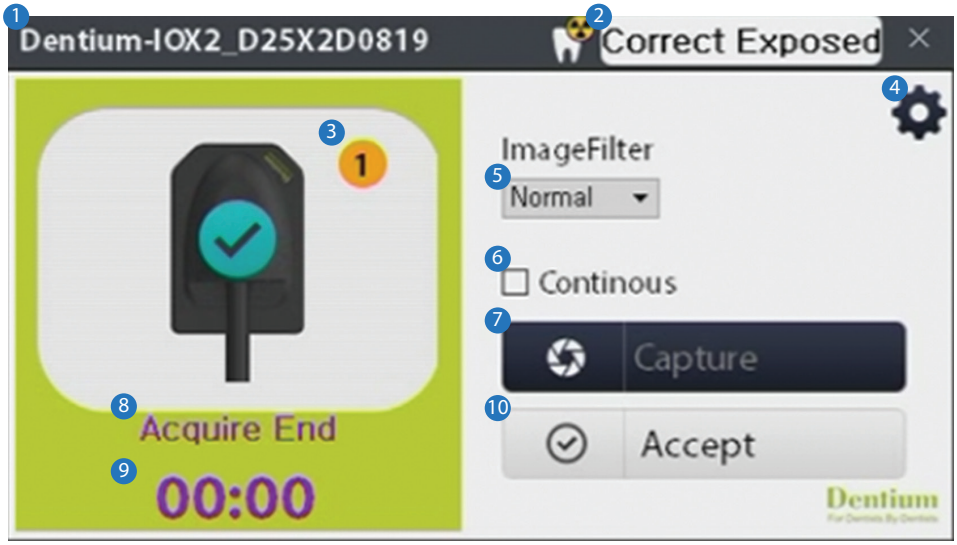
When the device is properly positioned for the patient's capture area and clicks the "Capture" button, the device is ready to acquire images. Exposure X-ray after setting the appropriate conditions according to the patient's condition.



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 fuctions 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 exposuring in 3 steps.
   1)Under Exposed: Lack of dose
   2)Correct Exposed: Appropriate level
   3)Over Exposed: Excess of dose

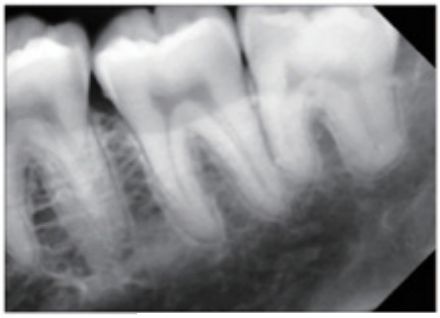
   

3. Number of acquired image: Check the number of acquired images.
4. Acquisition setting menu: Check and change detailed sensor settings. Do nou use it other than the administrator.
5. Preset step adjustment: Five step of calibration setting can be selected.
6. Contiunous acquisition: Choose if you need contiunous 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.

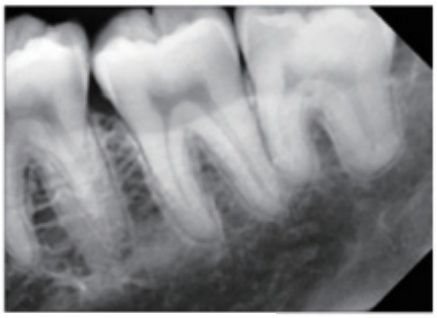
8.4.11 Preset step adjustment about image processing

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.

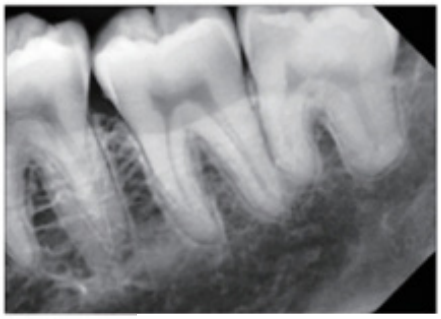
Sample images with image processing filter applied are shown below.



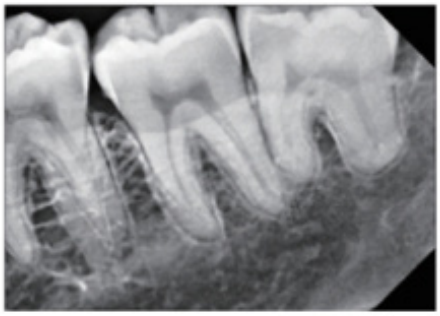
Smooth +



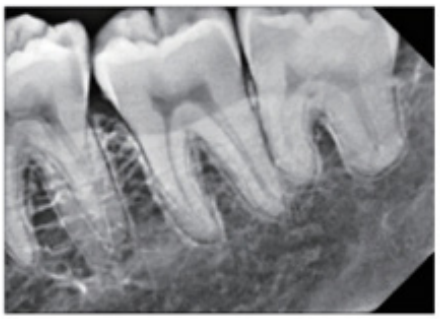
Smooth



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

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	
Patient	Children	Adult
SID	200 mm	
Anterior / Canine	130 ~ 150 µGy	400 ~ 450 µGy
	0.02 ~ 0.03 s	0.06 ~ 0.10 s
Molar	150 ~ 200 µGy	500 ~ 600 µGy
	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.

10 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.

10.1 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 alkaloids.

10.2 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.

11
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

11.1 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

Handling of errors during

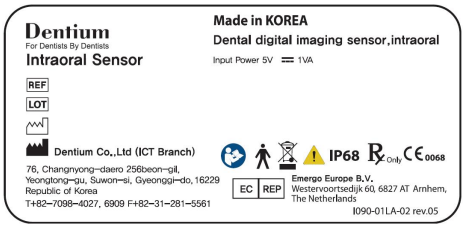
Warning	The following are the simple things you can do. If the problem persists, please contact Dentium Service Department or request a Service Call.

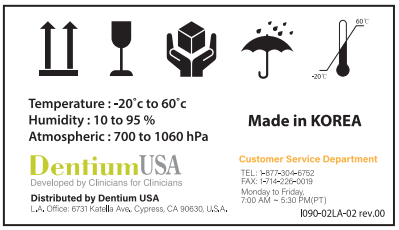
Error	Cause and solution	
USB device recognition failed	Cause	1) Connector contact fault 2) Extension cable fault
	Solution	1) Check the PC connection. 2) Check the repeater's power adapter connection 3) Rerun the installation file. 4) If the symptom cannot be solved, contact Dentium Service Department 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.

13
Label location

13.1 Packaging box

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





13.2 Sensor module

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

14

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.
Mains terminal disturbance voltage CISPR 11	Group 1 Class A	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.
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)"

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 0º 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.			

15 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.

15.1 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.

16 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: (031-281-5561) When you claim under this warranty, you must present the warranty to the manufacturer.
If you can't get free warranty

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

Dentium

For Dentists By Dentists

Intraoral Sensor

User Manual

Dentium

For Dentists By Dentists

Document NO. I090-01MU-04

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