EZ Sensor

User/Installation Manual

VATECH

This manual covers the installation and operating procedures of the EzSensor.
Unless otherwise specified, all the information contained in this manual is applicable equally to all EzSensor types.

Notice to users

For the improvement of product performance, supplementation, and the follow-up of information, the contents of this manual are subject to change without prior notice.

Please note that our company bears no responsibility for accidental damage nor will be obligated to perform warranty service for any damage to equipment due to user error. Please follow the instructions in this manual closely. Become familiar with the safety precautions and usage procedures for this product. Note that the product may differ slightly from the contents of this manual, depending on individual product specifications.

The following symbols are used throughout this manual to provide instructions on the effective use of this product.

Indicates useful information and tips on how to use our software and products.

Indicates important instructions. If not observed, malfunction or damage to the system or other property may occur.

Indicates warnings and instructions for safety. If not adhered to, there is a serious risk of injury to the patient and/or the operator.

United States federal law restricts this device to use by or on the order of a physician.

The device must be installed and used in accordance with the safety regulations and instructions supplied in this user manual only for the purposes and applications for which it is intended.

Indications for Use
EzSensor, an Intra-oral Imaging System, 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.

Before each usage, check the outer surface of the EzSensor for any signs of physical damage or defect. The surface of the EzSensor should have a smooth finish, with no evidence of chipping or damage. Otherwise, contact your local VATECH product distributor for further instructions on how to proceed.

To ensure the correct usage of the EzSensor device in a clinical environment, for which the intended purposes correspond to its design and application, only dentists or their designated operators are authorized to operate this system.

Modifications and/or additions to the device must be conducted exclusively by VATECH personnel or by parties expressly authorized to do so by VATECH. Any modifications or additions must always comply with the standards and generally recognized rules of good workmanship.

It is the user's responsibility to ensure compliance with all local safety regulations in effect in the jurisdiction of installation.

Electrical safety

The covers of the device may be removed only by qualified and authorized technical personnel.

This device can only be used in rooms or areas which comply with all laws and regulations applicable to electrical safety on medical premises, such as CEI standards for the use of an additional ground terminal for equipotential connections. This device must always be disconnected from the power supply before cleaning or disinfecting.

This device should be connected with the product which is complied with IEC 60601-1.

Water and other liquids must not be permitted to penetrate the device. Liquids may cause corrosion or the device to short circuit. No protection is offered against liquid penetration.

Explosion safety

This device is not recommended for use in the presence of flammable gases or vapours. Some disinfectants evaporate and form explosive or flammable mixtures. If disinfectants of this kind are used, it is important to let the vapours disperse before using the device again.

For the improvement of product performance, supplementation, and follow-up of information, the contents of this manual are subject to change without prior notice.

X-ray protection

The rules of dental radiography apply to digital X-ray systems. Please continue to use protection for your patients. As a clinician, clear the immediate area when exposing the sensor.

Symbols Descriptions

Item	Symbol	Description
1		Type B applied part
2		Indicates to the user to check the accompanying documents (this User Guide) for more information about EzSensor
3		Conforms to CE MDD 93/42/EEC (European Communities) concerning medical devices
4		Waste Electrical and Electronic Equipment
5		Handle with care
6		Fragile, handle with care
7		This way up
8		Intended for a single use.

WEEE information according to directive 2002/96/EC

(Waste Electrical and Electronic Equipment)

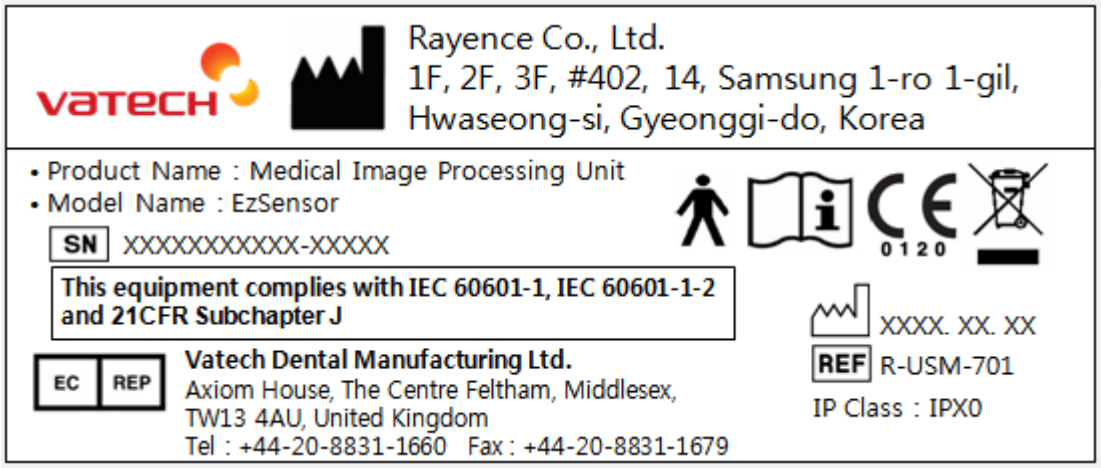
The crossed-out wheeled bin symbol, that is present on the device, means that within the European Union the product must be taken to separate collection at the product end-of life. Therefore, at the end of the life-cycle of the device, the user should deliver the device to the proper collection facilities of the Electric and Electronic Equipments. Alternatively, the user can return the device to the seller, on a one-to-one basis, as long as he or she is buying a new one of equivalent type and that fulfills the same functions as the old one.

Disposing of the device separately avoids possible negative consequences for the environment and health deriving from inappropriate disposal and enables the constituent materials to be recovered to obtain significant savings in energy and resources.

Who disposes any Electric and Electronic Equipment, reporting the above symbol, as unsorted municipal waste, instead of collecting it separately, incurs the administrative sanctions in accordance with law.

Label Location

The VATECH logo and the following label can be found on the EzSensor device.



Contents

Chapter 1 Introduction

1.1 System Description

EzSensor is a modern digital imaging solution for intraoral dental radiography. Its advanced CMOS technology provides excellent image quality. For patient comfort, the ergonomic design is based on human intraoral anatomy.

EzSensor is a digital X-ray imaging system designed specifically for dental radiography within the oral cavity. The system captures X-ray images and makes them available for display and storage across your computer network.

EzSensor is connected by a 'USB A-A' cable (supplied separately) to a compatible Windows XP or Windows Vista or Windows 7 PC. EzSensor is provided the power from PC. Support for the EzSensor is provided by compatible software programs such as EasyDent.
For other custom applications, a programmer's guide is available.

The EzSensor includes a detachable holder that can be mounted on the wall or other stable surface.

The EzSensor comes with the following features:

- Excellent image quality based on advanced CMOS technology
- More comfortable sensor ergonomic shape for the human oral structure
- Lower dose exposure
- Enhanced durability
- Easy-to-use USB interface

<Table 1. Specifications >

Parameter	Description
Detector Structure	Low Noise Hybrid CMOS
Dimensions (W x L x T)	Size 1.0: 1.03 x 1.45 x 0.19 inch (26.1 x 36.8 x 4.95 mm) Size 1.5: 1.14 x 1.52 x 0.19 inch (29.2 x 38.7 x 4.95 mm) Size 2.0: 1.24 x 1.69 x 0.19 inch (31.5 x 42.8 x 4.95 mm)
Pixel Pitch	0.035 mm
Active Pixel Array	Size 1.0: 572 x 858 pixels (20.02 x 30.03 mm) Size 1.5: 686 x 944 pixels (24.01 x 33.04 mm) Size 2.0: 744 x 1030 pixels (26.04 x 36.05 mm)
Grayscale	4096 gray levels
Resolution	14.2 lp/mm (theoretical)
USB Cable length between Controller and PC	3m
Electrical rating	DC 5V, 500mA
Operation mode	Continuous
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
EU classification	Medical Devices 93/42/EEC as a class IIa
Protection against shock	Type B applied part
Protection against water/matter	IPX0

The sensor has to install and transportation and storage in the permissible environmental conditions. And sensor is not suitable to be operated in explosive environments. Use the provided protective package for transporting or storage.

Also sensor should not operate in oxygen rich or explosive environments.

1.2 System Components

The EzSensor device installer should check the following items listed in the table below before system installation. If the serial numbers of the individual parts do not match, do not install the system. Contact your local distributor or agent for support.
This device should be connected with the product which is complied with IEC 60601-1.

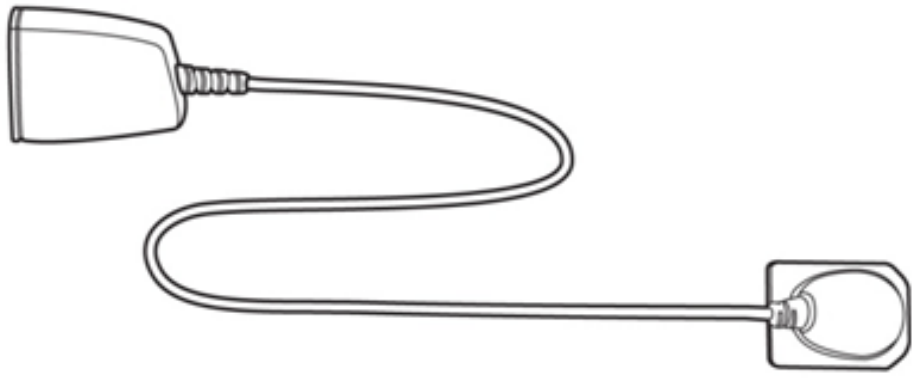
<Table 2. EzSensor system components>

No	Components	Remarks
1.	Sensor Module*	
2.	Control Board Box	
3.	USB PC Interface Cable (3M)	
4.	Holder for Sensor	
5.	Silicon cover*	
6.	Wrap* (Hygienic Sleeves)	
7.	S/W Installation CD	EasyDent + EzSensor Driver
8.	EzSensor Manual	Document

* Patient applied part (Inside Patient environment)

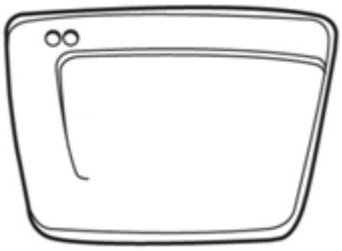
1. Sensor Module:

   Consists of a special CMOS sensor specifically designed for use in radiography and enclosed in a hermetically sealed ergonomic capsule. The sensitive surface of the sensor is covered with a thin layer of scintillating phosphorous, through which X-ray radiation is converted into light and then into an electric charge.



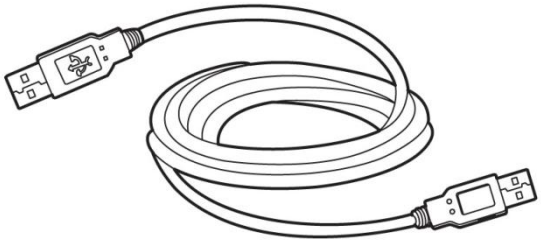
2. Control Board Box:

Provides power to the sensor, timing and synchronization of sensor signals, signal pre-amplification, analogue/digital signal conversion, USB port interface and optical insulation of all connections.



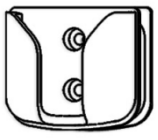
3. USB PC Interface Cable:

Used to transmit the output signal from the control board box to the computer.



4. Holder for Sensor:

Used to stow the sensor when not in use



5. Silicon cover:

Used to protect from external shock.

6. Wrap (Hygienic Sleeves):

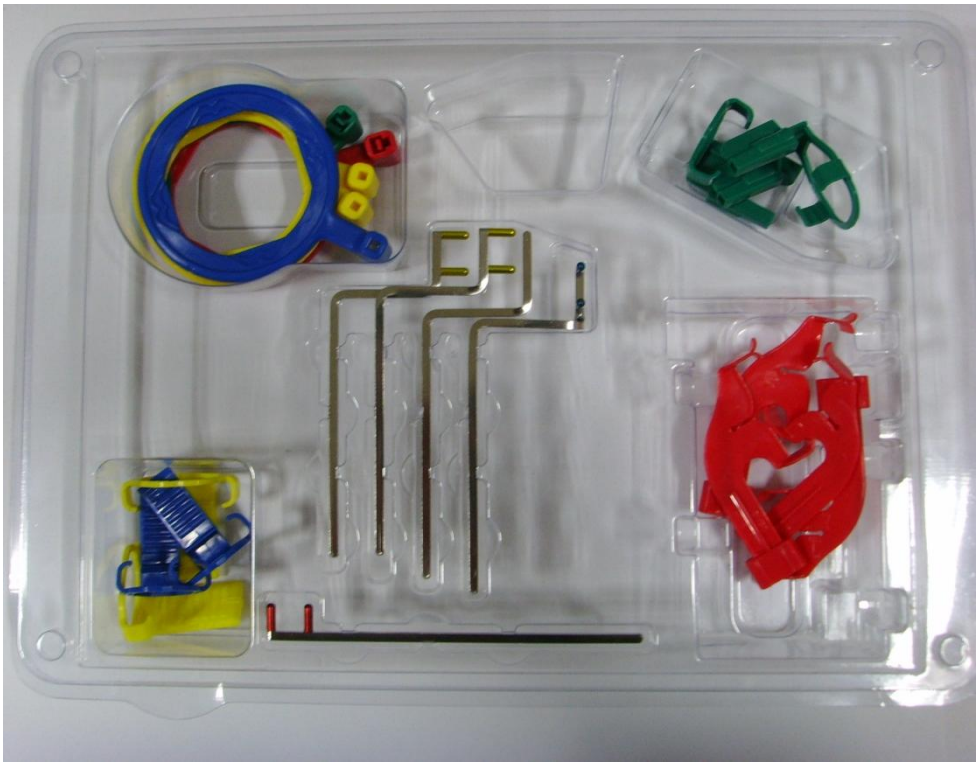
The sensor is supplied in a non sterile state. Single-use wrap must cover the sensor before placing it in the patient's mouth. The once used wrap shall be

disposed. These wrap are conform to the ISO 10993-1.

7. S/W Installation CD

1.3 Sensor positioning aid accessories (optional)

The positioning system is an intraoral positioning device specifically designed to support and align the sensor with the X-ray source when positioned along the upper or lower jaw.



NOTE

Please refer to the Appendix for more information (pages 49~51).

Chapter 2 Hardware Installation

2.1 What you should do before use

To operate the intraoral sensor, you need to install the EzSensor driver. This device should be connected with the product which is complied with IEC 60601-1.

2.2 Specifications

We cannot guarantee that EasyDent will work properly with an unregistered copy of Microsoft Windows. Therefore, you should use registered, genuine version of Microsoft Windows.

2.2.1 PC Specifications

① Operating System

- Microsoft Windows XP 32bit
- Microsoft Windows Vista 32bit
- Microsoft Windows 7 32bit

②Hardware requirements

- Main CPU: Intel Pentium IV 3.0 GHz
- Main Memory: 1GB of RAM (DDR2)
- Video Memory: 64 MB
- HDD: 80 GB (or better)
- CD-ROM (prefer CD-RW)
- USB Port
- Network Card: 1 EA
- Monitor: Min. resolution: 1024*768
- Keyboard/Mouse

Turn off the Windows Firewall service for proper communication across the network for the installed database and file servers.

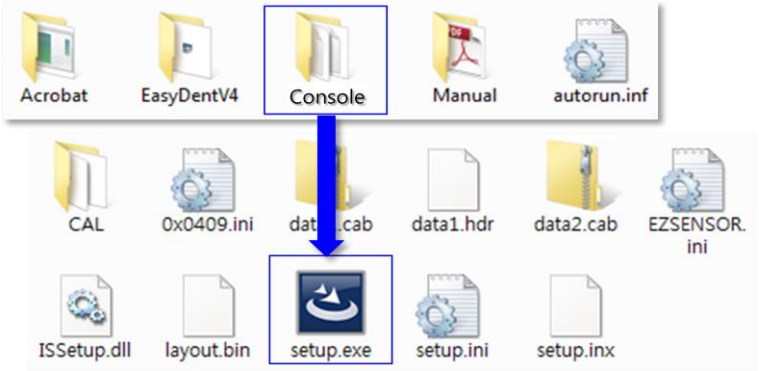
If you need to install additional software on your computer, please install only those that are internationally authorized. Take extra precaution when installing any Active-X controls.

2.2.2 EzSensor Driver Setup

This step is necessary for the installation of EzSensor. Capturing software and Calibration data for the EzSensor will be installed along with the Windows device driver. A Twain driver is also installed during this step.

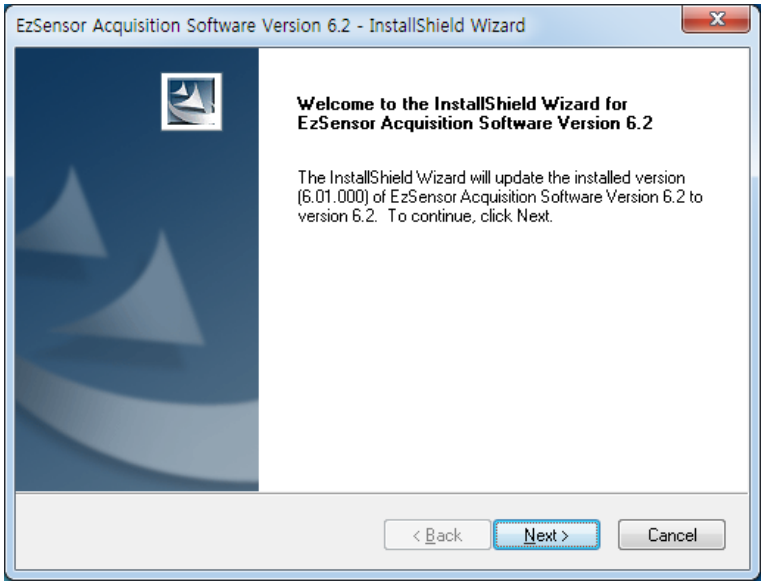
Step 1

Insert the S/W Installation CD in the CD-ROM. Setup should start automatically.
If it does not, click **Start** > **Run** and type
D:\Console\setup.exe or
D:\EzSensor\setup.exe.



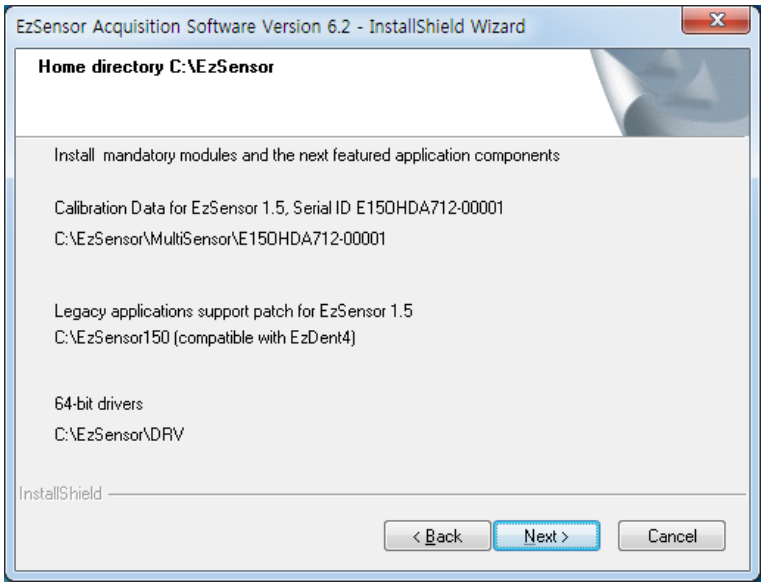
Step 2

The install program for 'EzSensor Acquisition Software Version 6' will appear. Click the 'Next' button.



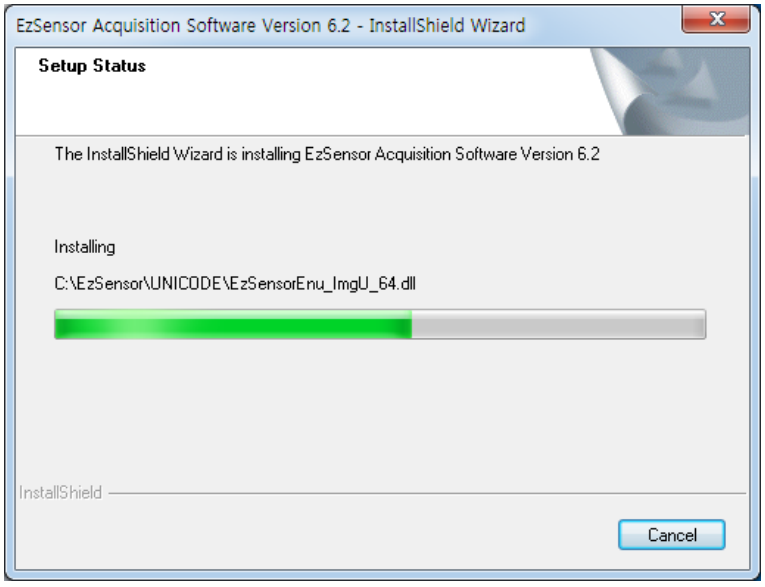
Step 3

Check the EzSensor installation directory and then click the ‘Next’ button.



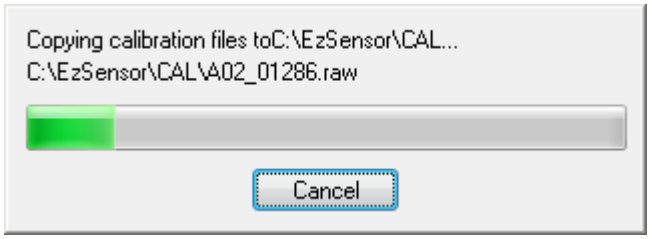
Step 4

The Installshield Wizard will start configuring the installation parameters.



Step 5

The InstallShield wizard will copy the EzSensor calibration files to your workstation(PC).

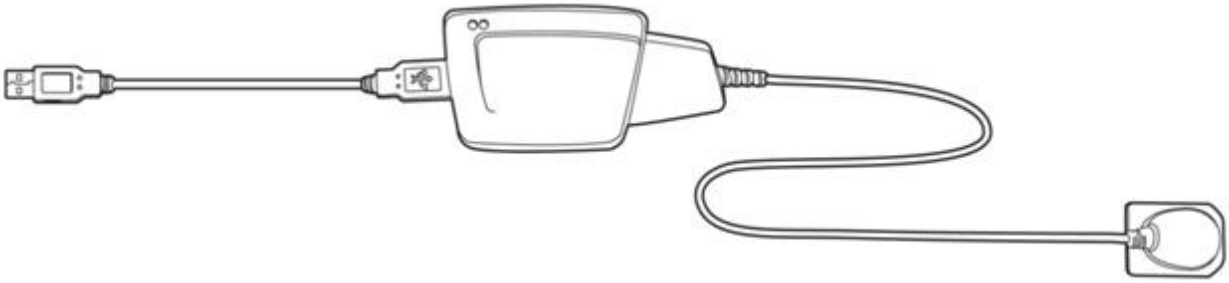


2.3 Cable Connection & Driver Installation

Do not connect the EzSensor and USB PC Interface cable to your computer until you have successfully installed the setup program.

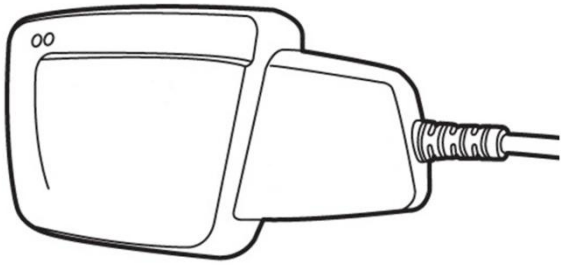
Be sure to connect the EzSensor module to the control board box before connecting the USB PC Interface cable to your computer.

Connect only item that has been specified as part of the Medical Equipment System.



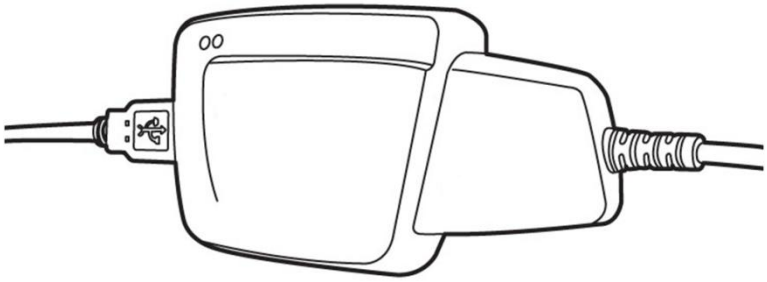
Step 1

Connect the EzSensor Module to the Control Board box.



Step 2

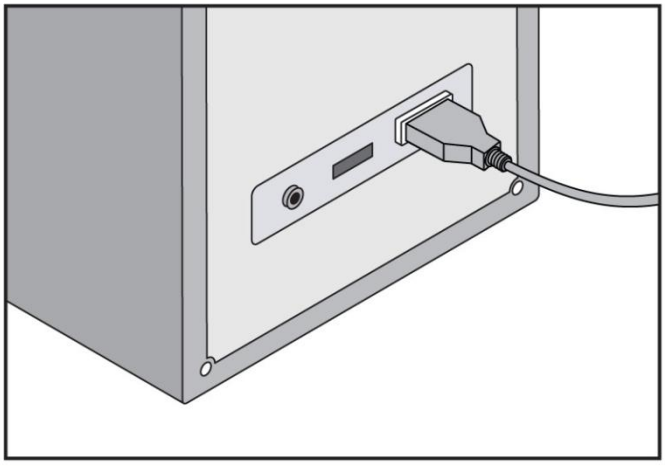
Connect the USB PC Interface Cable to the Control Board box.



Step 3

Connect the USB PC Interface cable connector to the USB port on the PC.

Be sure to connect the USB port on backside for accurate operation.



Step 4

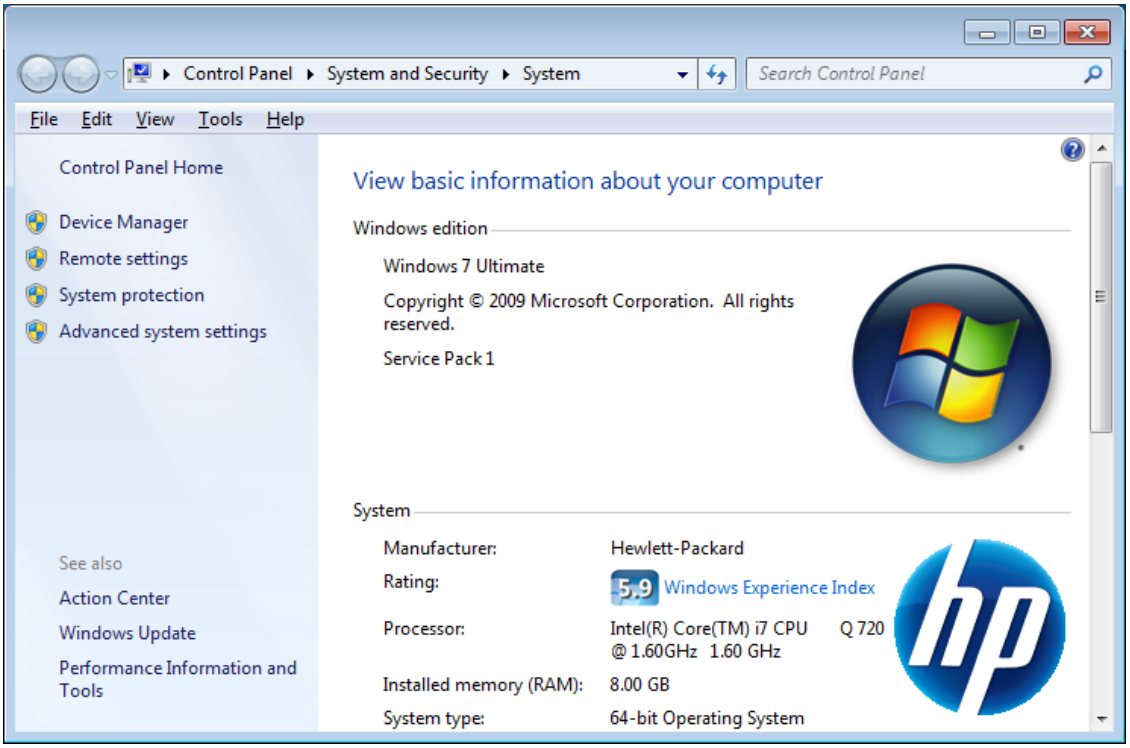
Confirmation of Driver installation at the Device Manager.

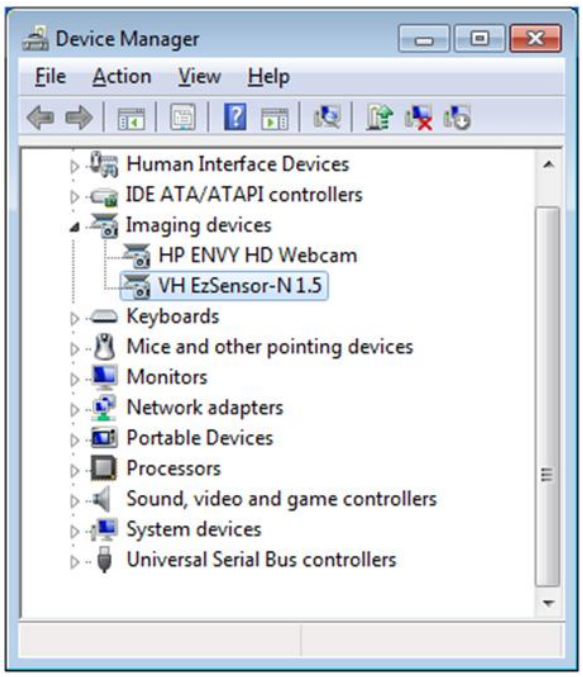
Method of Confirmation:

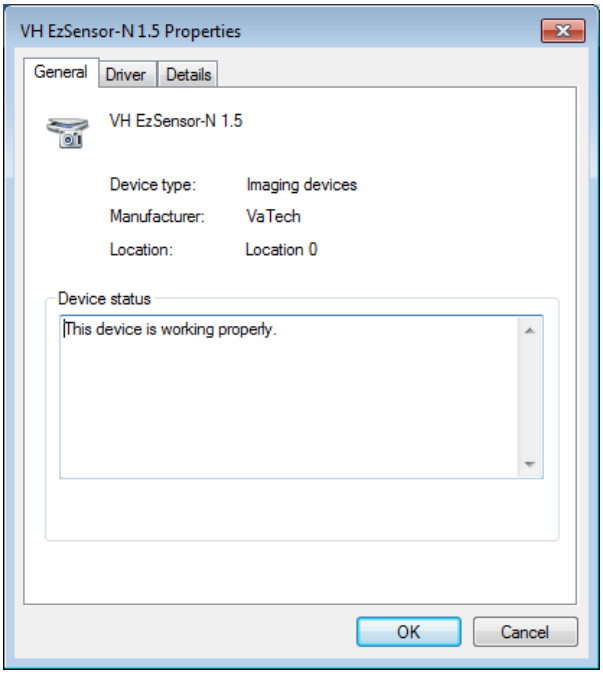
Windows 7 : Control Panel → System and Security →System → Device Manager

Windows XP : Settings → Control Panel → System→ Hardware →Device manager

Select 'VH EzSensor-N x.x', located under Imaging Devices. You should see the message, "This device is working properly".







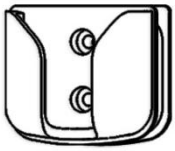
CAUTION

EzSensor is supplied the power and transported data via USB port of PC.
Do not disconnect during usage.

2.4 Installation of the EzSensor Holder

The EzSensor holder is used for mounting the EzSensor to the wall when not in use.
When choosing where to install the EzSensor, locate an area that offers easy access and visibility during patient examinations.

① Position the holder on a stable, flat surface. Using the holes at the back of the holder as guides, fasten the holder securely to the wall using two dry wall screws (included).



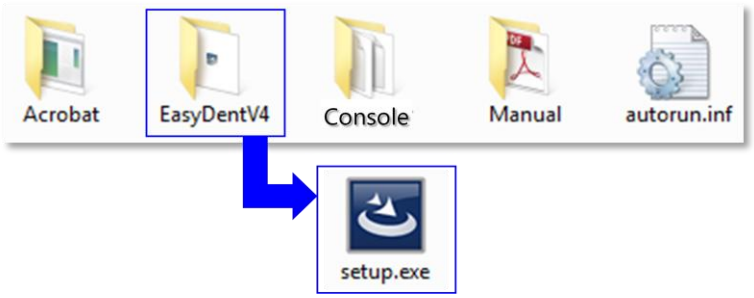
Chapter 3 Installing the software

3.1 Installation of EasyDent

In this step, EasyDent(viewer) will be installed. Alternatively, software which supports the Twain interface can be used instead of EasyDent.

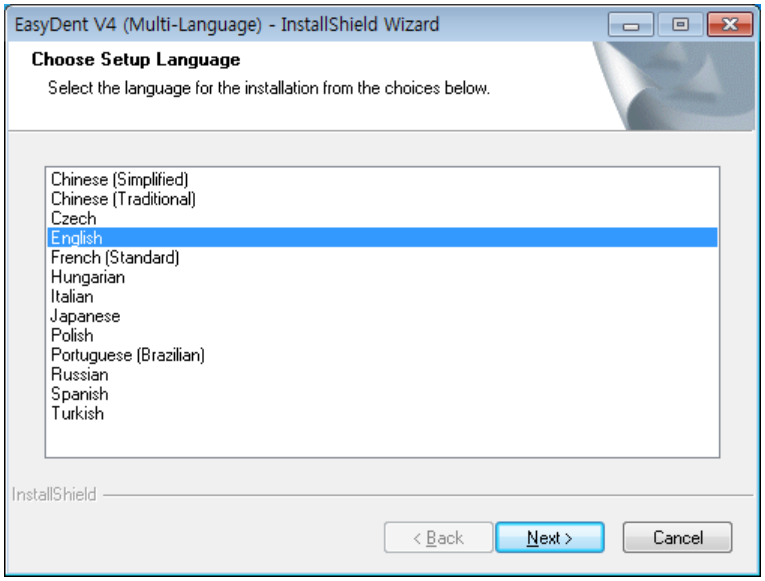
Step 1

Insert the S/W installation CD in the CD-ROM drive. ***D:\EasyDentV4\setup.exe.*** Press 'Enter'.



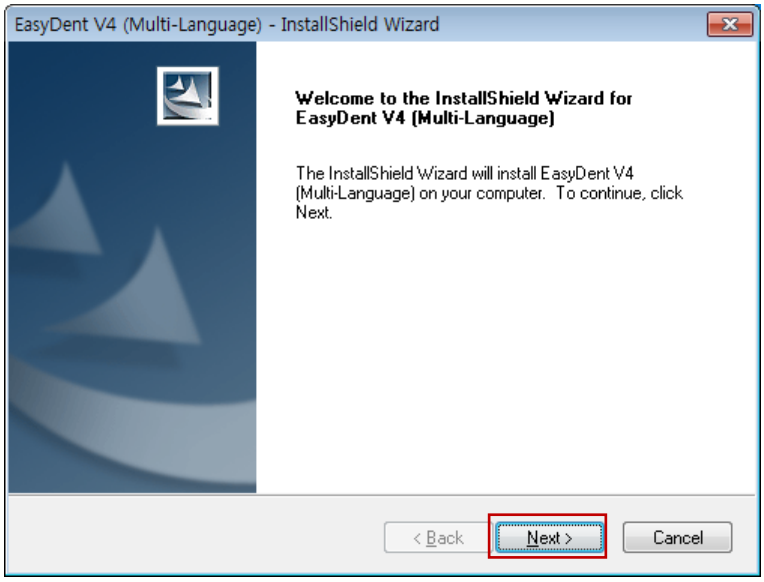
Step 2

Select the language you want to install and then click 'Next'.



Step 3

The 'EasyDentV4 InstallShield Wizard' will appear. Click the 'Next' button.

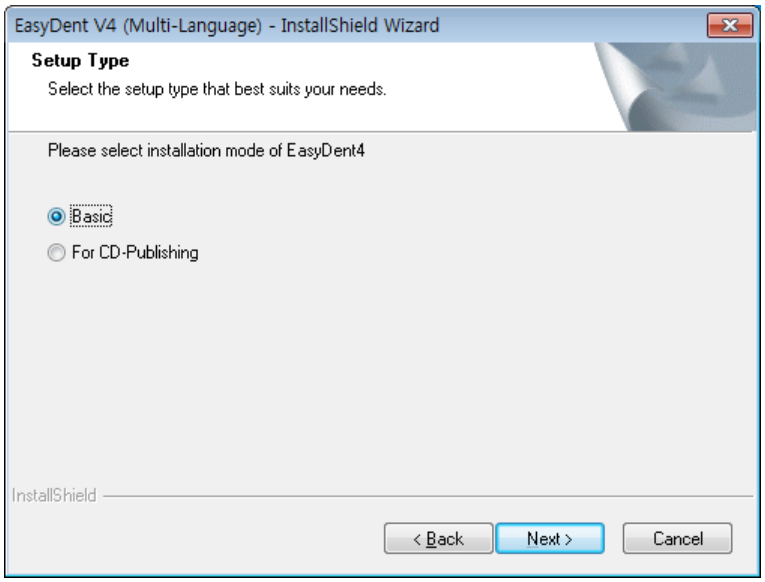


Step 4

Select the setup type that best suits your needs.
Click the 'Next' button.

Basic : Installs the basic version of EasyDent V4

CD-Publishing : Installs the basic version of EasyDent V4 along with CD-Publishing capabilities (optional)



NOTE

For the EasyDent server, select all items.

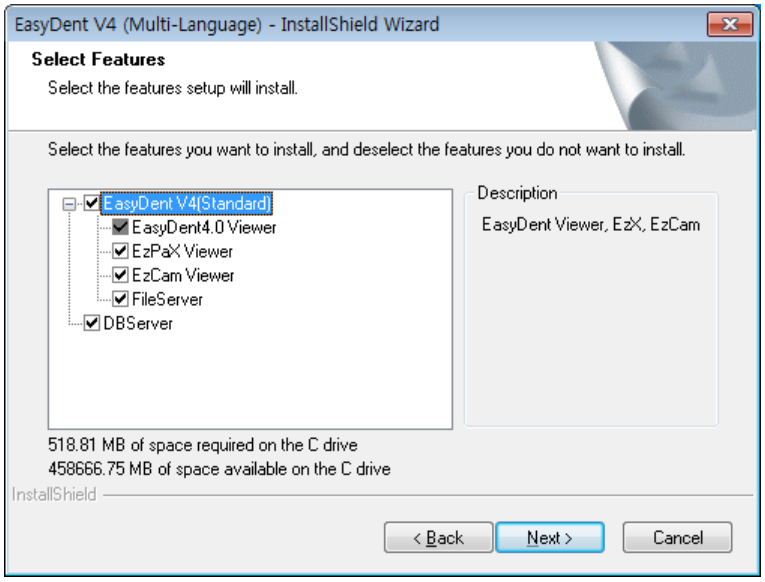
For PC being used for viewer : Select only the items except for DB & File servers.

For the detailed installation, refer to the EasyDent installation manual.

Step 5

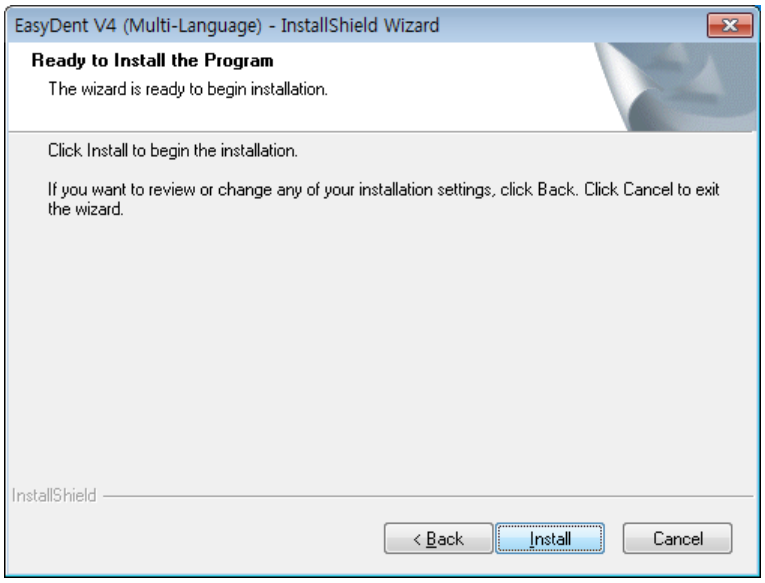
Select the features that you want to install. Click the ‘Next’ button.

EasyDent Viewer is the minimum requirement for EzSensor use.



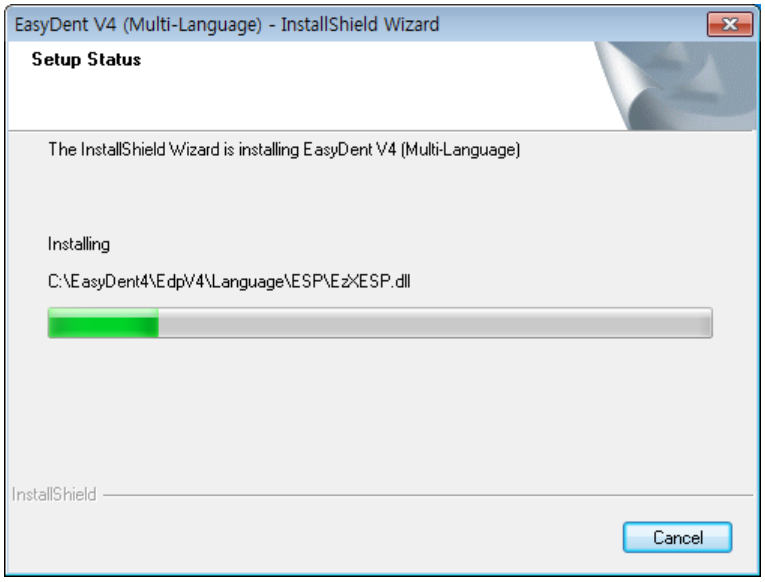
Step 6

Now you are ready to install. If you would like to review any of your installation settings, click ‘Back’. To proceed with the installation, click ‘Install’. Click ‘Cancel’ to exit the wizard.



Step 7

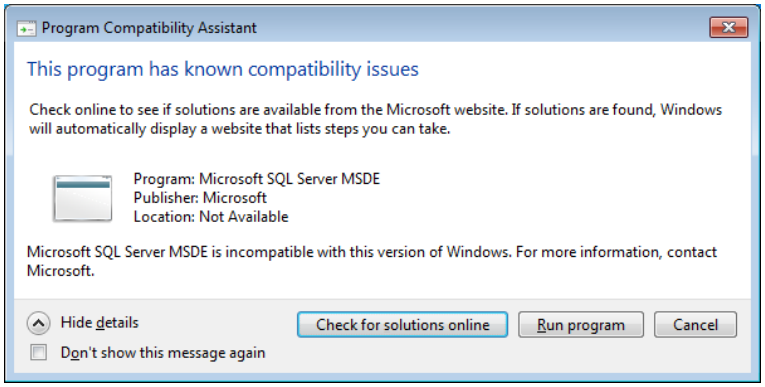
Installing EasyDentV4



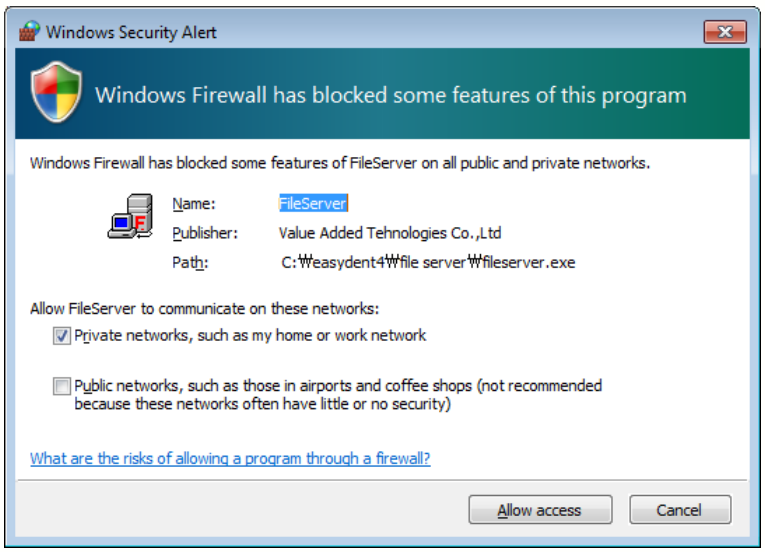
Step 8

The program compatibility and Windows Firewall alarm messages are shown.

Click 'Run program' button on the program compatibility message.

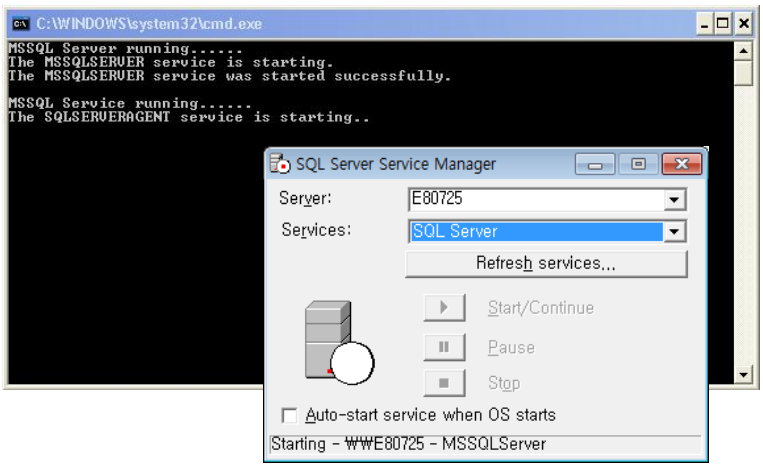


And click 'Allow access' button on the windows security message.



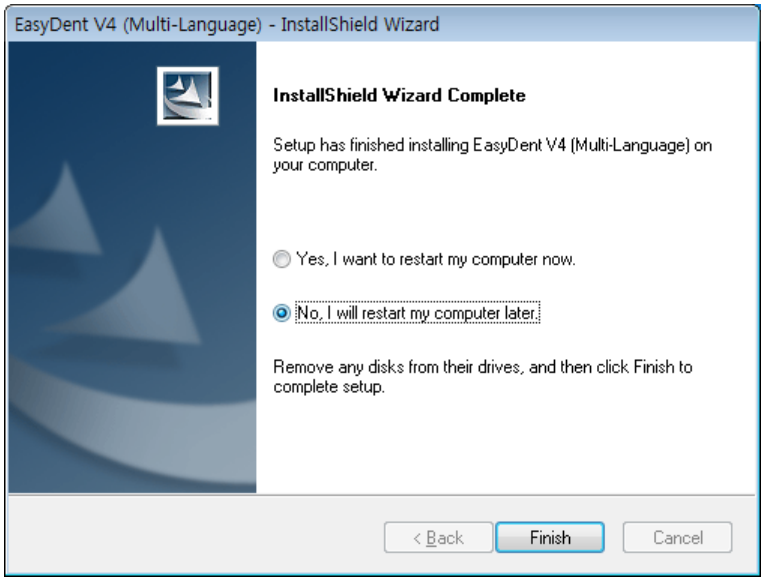
Step 9

MSDE(Microsoft SQL server Desktop Engine) is installed automatically.
Close the SQL Server Service Manager.



Step 10

Select ‘No, I will restart my computer later’, and then click ‘Finish’.



3.2 Preparing for Image Acquisition with the EzSensor

① Turn on the computer.

② Run the EasyDent . (refer to P25)

③ Configure the required X-ray parameters (exposure time, etc.) for the X-ray generator.

④ Put a new wrap on the EzSensor and connect this to the sensor positioning system.

⑤ Position the EzSensor at the appropriate area in the mouth. The flat receptor side of the sensor must face the X-ray source. Note that the receptor side is marked with a label for ease of recognition.
The use of the sensor positioning aid is recommended to guarantee that the sensor is parallel to the tooth and at the appropriate angle for exposure.

⑥ The use of the parallel technique with a positioning system, if possible, is highly recommended.

⑦ After preparing the sensor for exposure in EasyDent, acquire an image by pressing the exposure button for your X-ray source.

Using the EzSensor with intraoral X-ray

Using the EzSensor with a Sensor positioning system(optional)

3.3 Running the EasyDent

Shot functions are available after patient registration and device selection. Single shot, multi shot, sequence shot are used frequently. You must be fully aware of the explanations before capturing image.

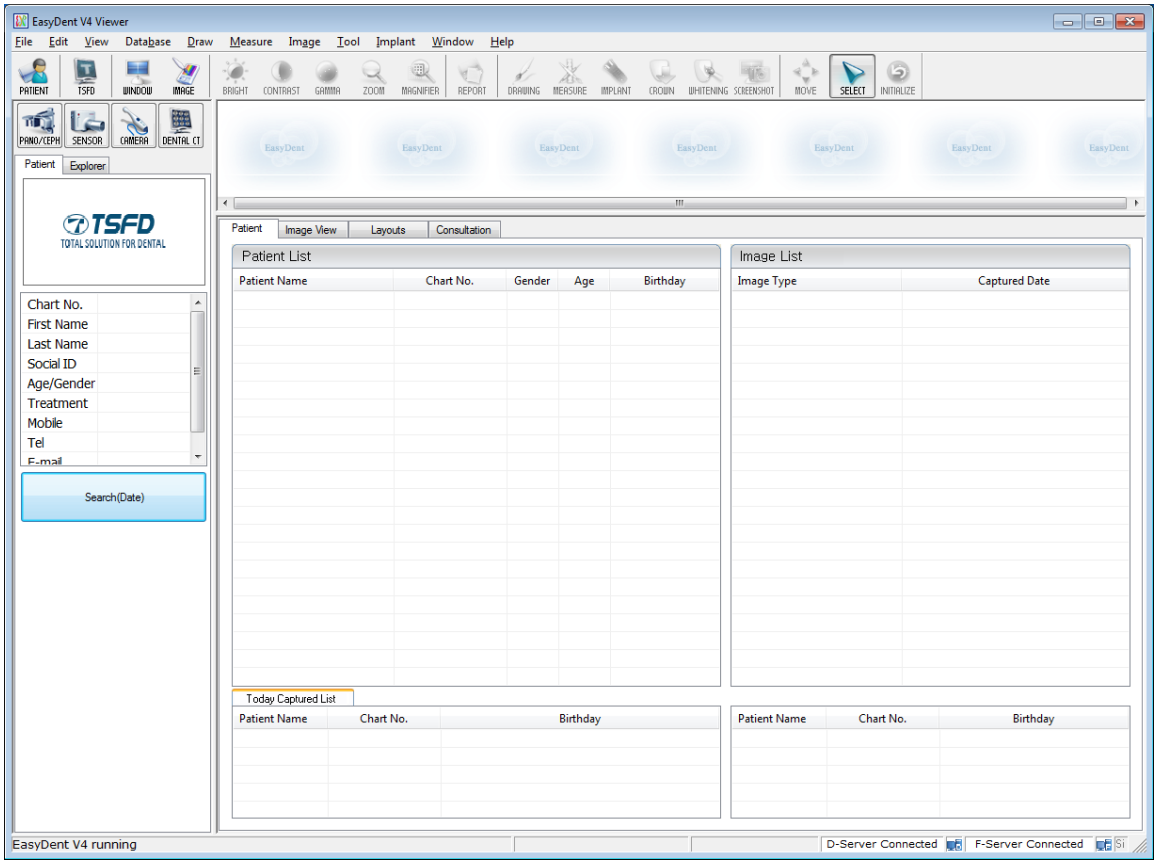
3.3.1 Patient Registration and Device Selection

Step 1

Turn on the PC.

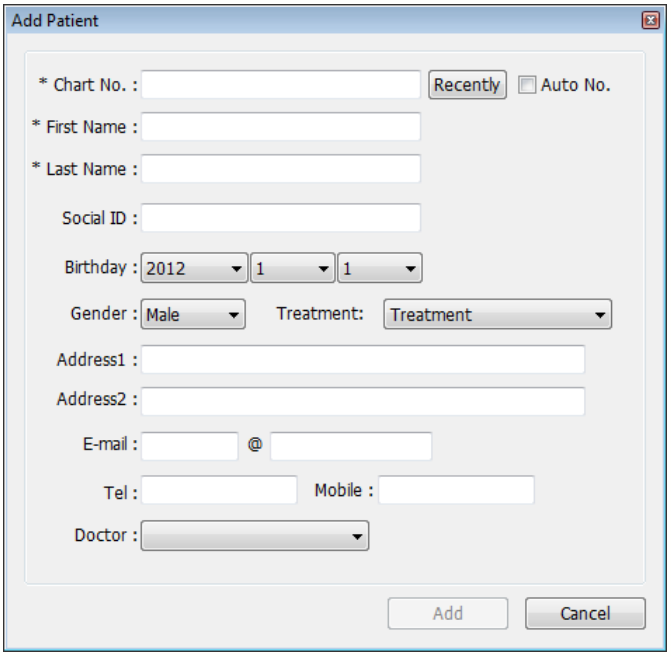
Run EasyDent4 Viewer. Click the 'Patient (

)' button to register a new patient.



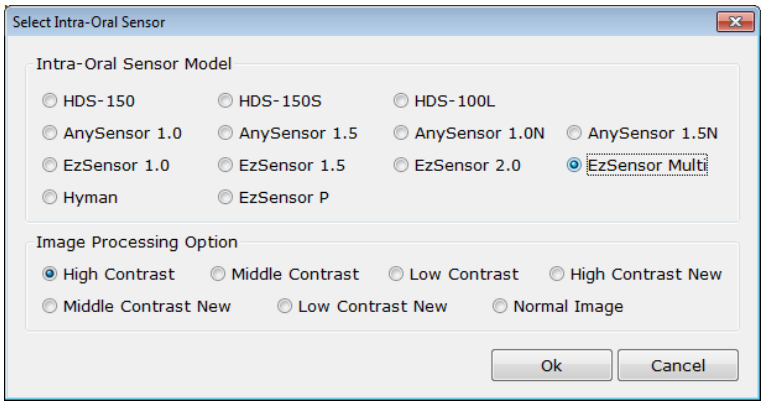
Step 2

The new patient registration window will appear. You are asked to register the new patient and click “Add”.



Step 3

Click ‘Help > Intra-Oral Sensor Setting > Select Device’ on the menu bar.
Select your capture device. At this time, you are asked to select the device and image quality.
The sensor model and image processing setting information is stored internally. Change these settings when using another sensor or changing the image processing option.



① High Contrast (Default)
② Middle Contrast
③ Low Contrast
④ High Contrast New
⑤ Middle Contrast New
⑥ Low Contrast New
⑦ Normal Image

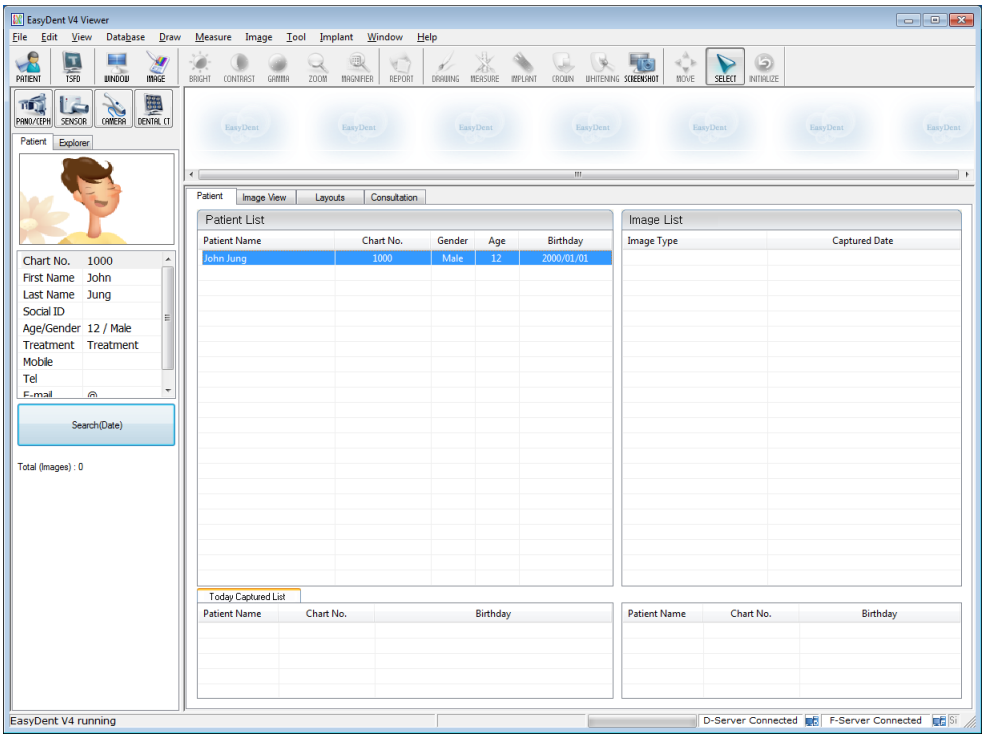
3.3.2 Single Shot

Capture a single image.

Step 1

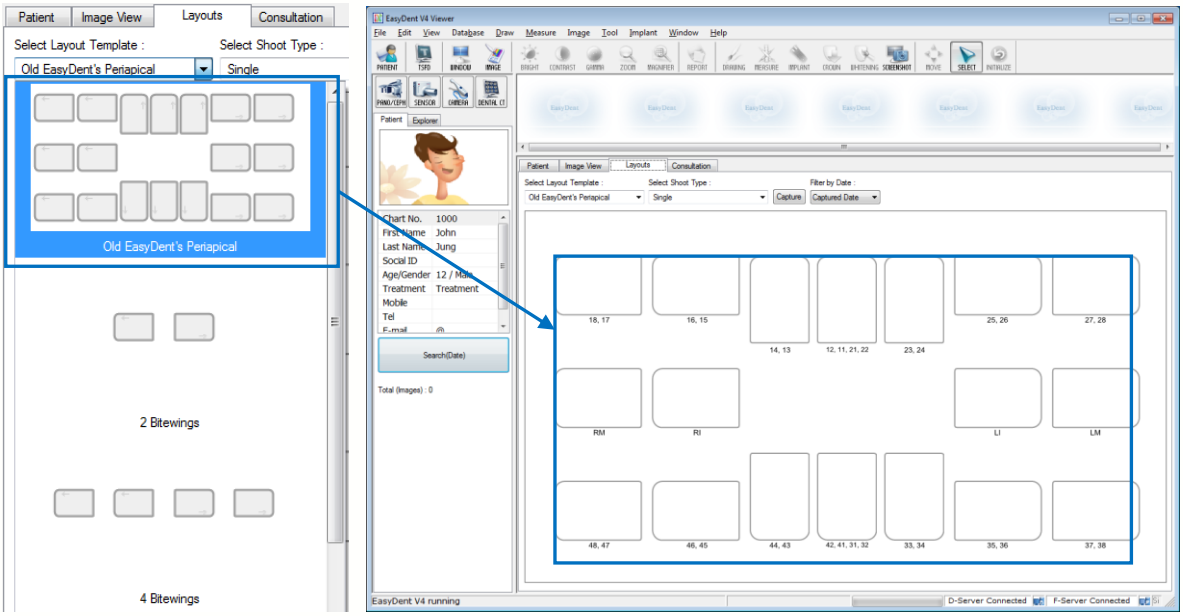
Start EasyDent by clicking the EasyDent V4 Viewer on the desktop.

Search and enter the appropriate patient information.



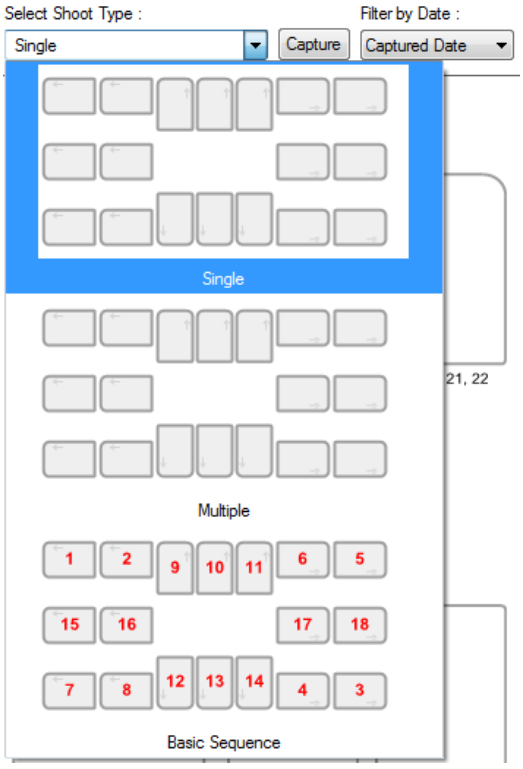
Step 2

Click the ‘Layouts’ tab. Select your favorite layout from the Layout template list.
The Layout Template can be customized. Please refer to the EasyDent manual.



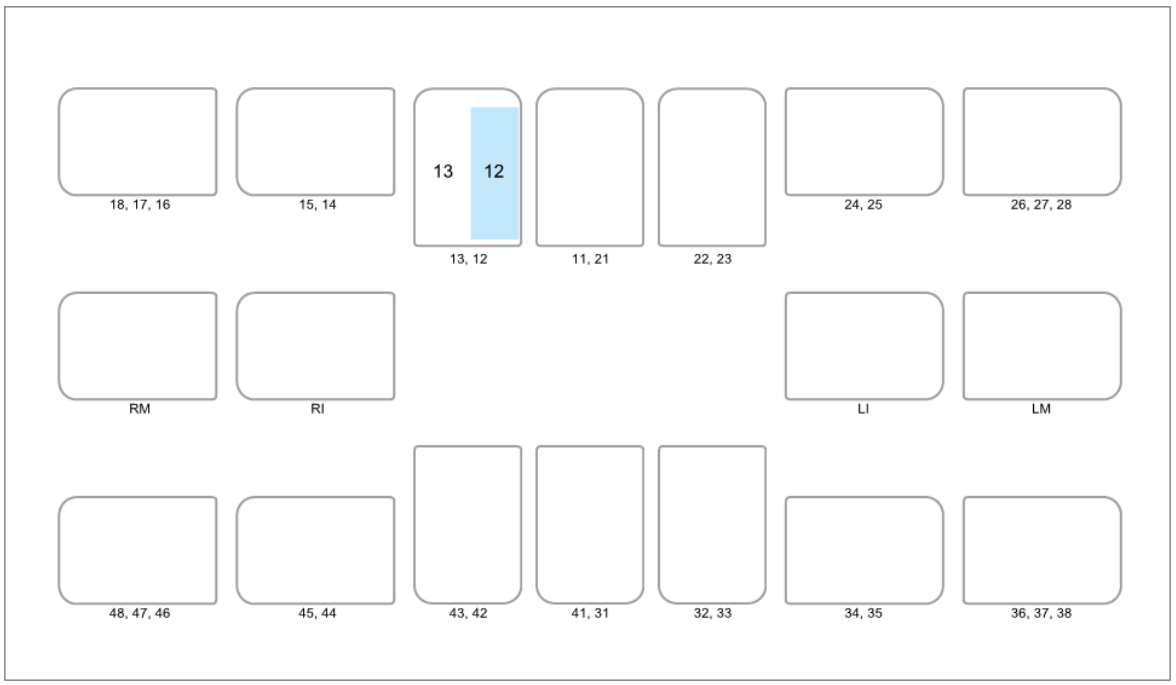
Step 3

Select the ‘Single’ from the Shoot Type list.



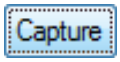
Step 4

Select the tooth position to capture. The tooth box is selected in blue.



Step 5

Click the ‘SENSOR (

)’ button or ‘Capture (

)’ button.

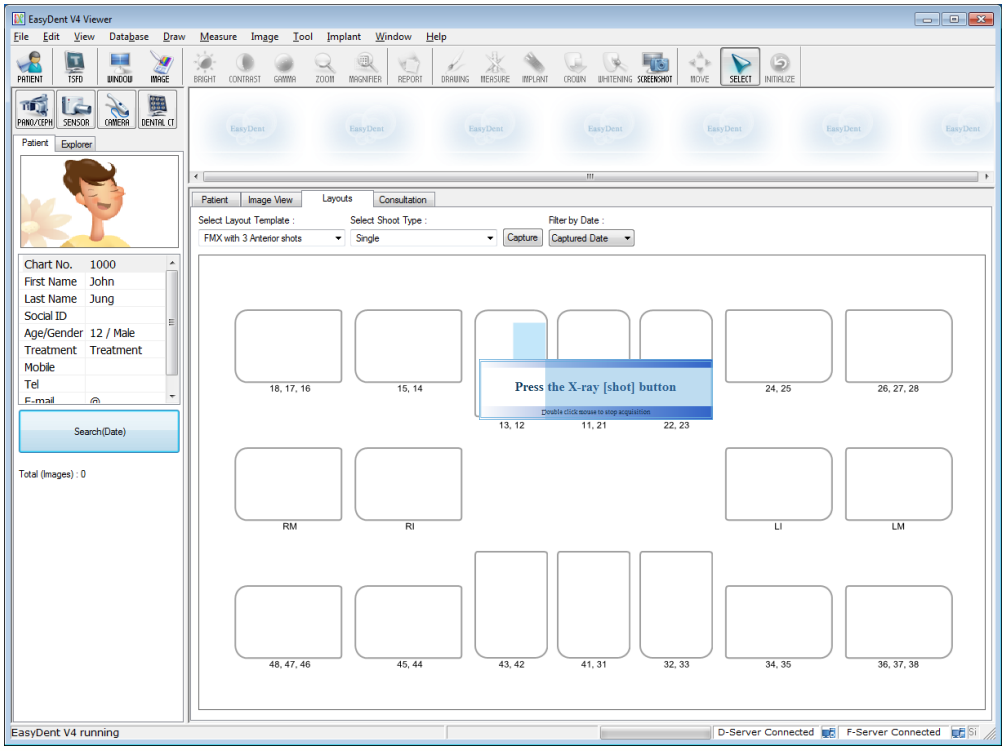
Step 6

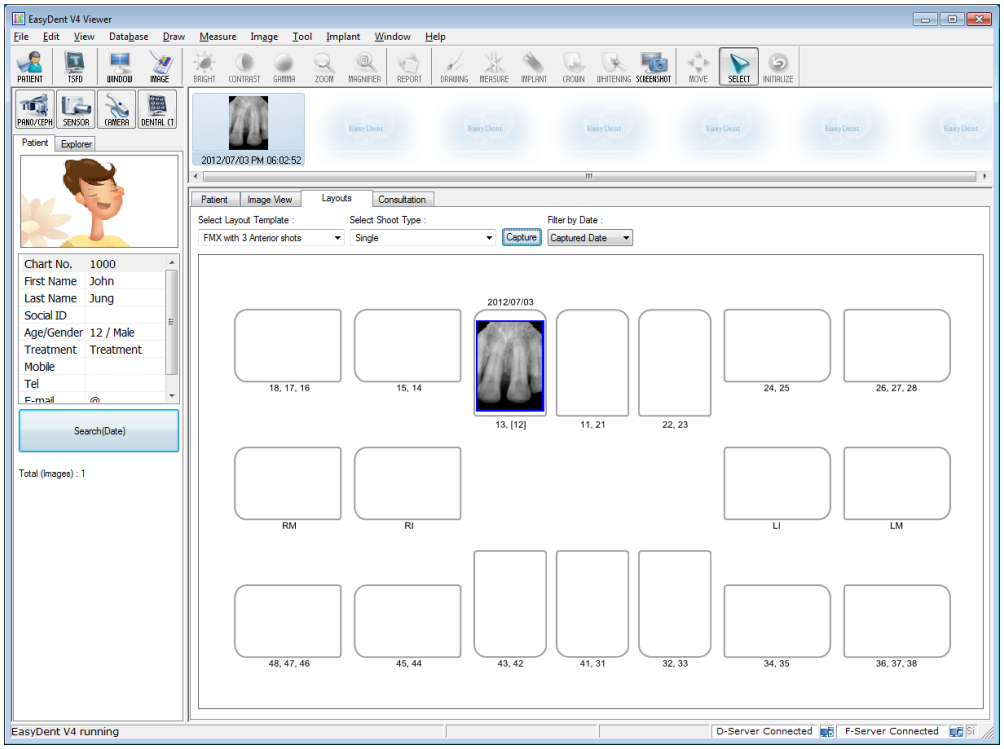
Position the sensor correctly.

Step 7

After checking the sensor is in the correct position, expose the X-ray after the “Please expose X-ray” message appears.

The message, “Optimizing Image… Please wait” appears while the image is being optimized. The image will appear after optimization is complete.



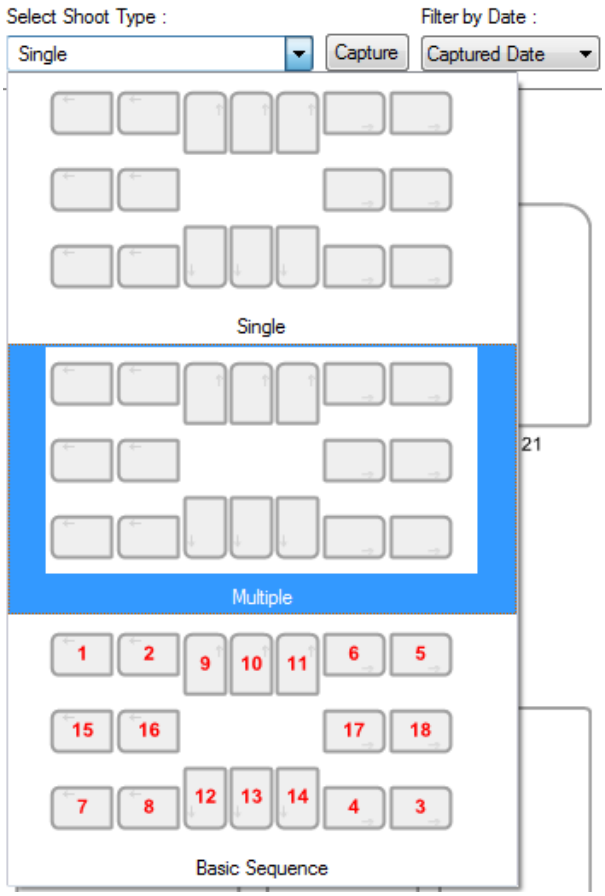


3.3.3 Multi Shot

You can capture multiple images continuously until you click stop. Click and drag the image to its appropriate position after stopping capture.

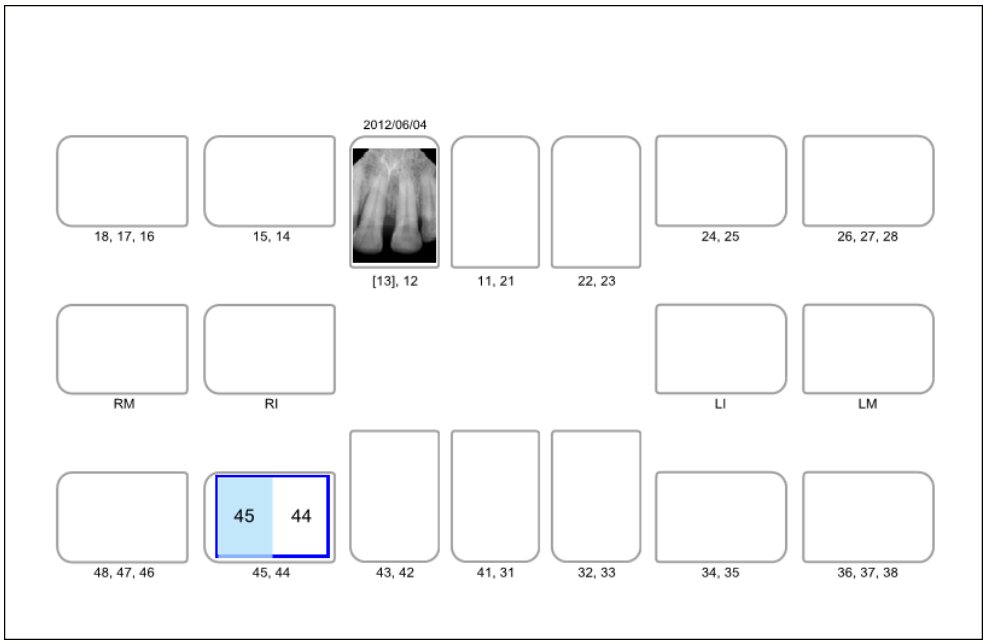
Step 1

Select the ‘Multiple’ from the Shoot Type list.



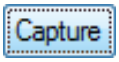
Step 2

Select the tooth position to capture. A blue rectangle will be drawn on the tooth box.



Step 3

Click the ‘SENSOR (

)’ button or ‘Capture (

)’ button.

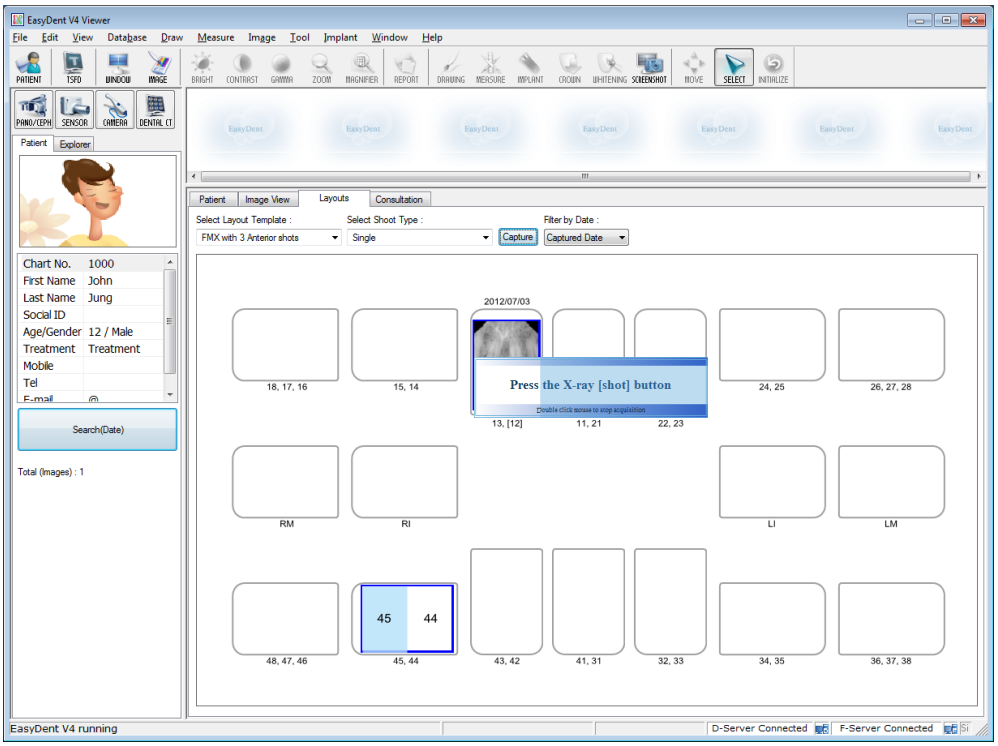
Step 4

Position the sensor correctly.

Step 5

Expose the X-ray after the “Please expose X-ray” message appears.

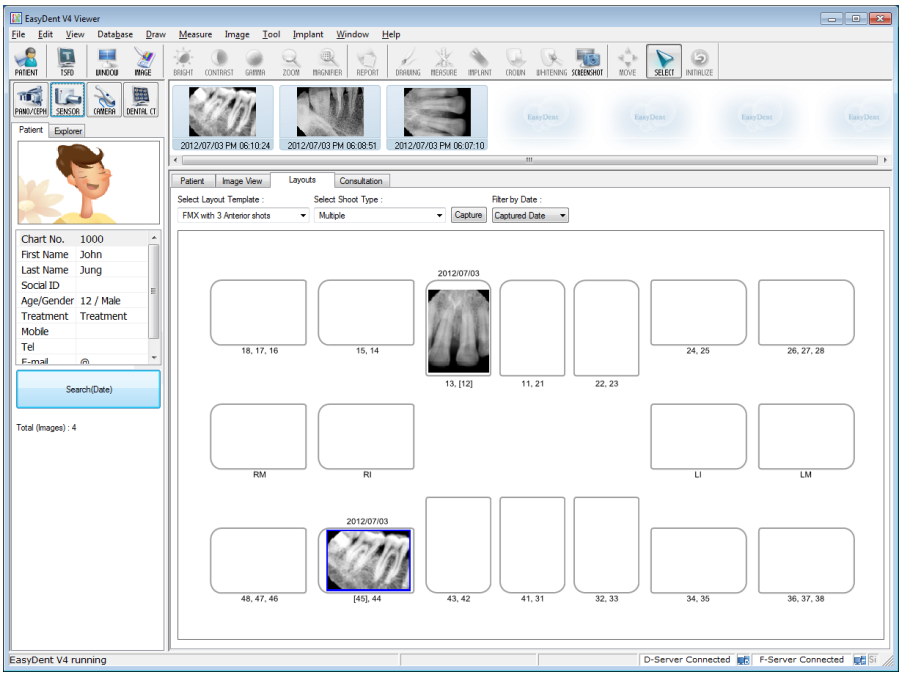
The message, “Optimizing Image… Please wait” appears while the image is being optimized.



Step 6

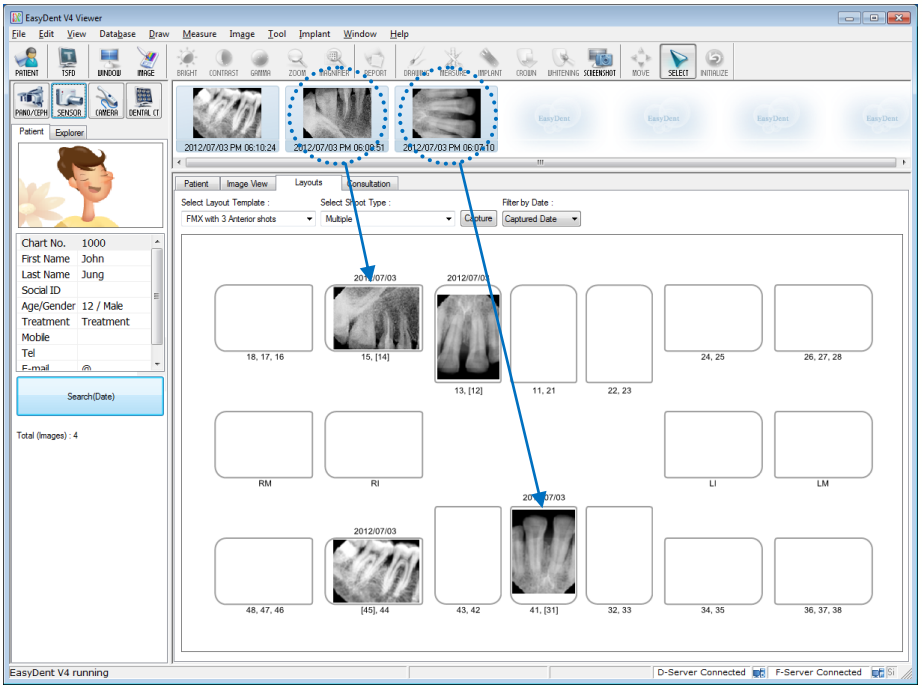
If you want to acquire more images, continue to expose the x-ray when the 'Press the X-ray (shot) button' message appears.

To finish, double click on the 'Press the X-ray (shot) button' message box. And then the image will appear after optimization is complete.



Step 7

Click and drag the image to its appropriate position.

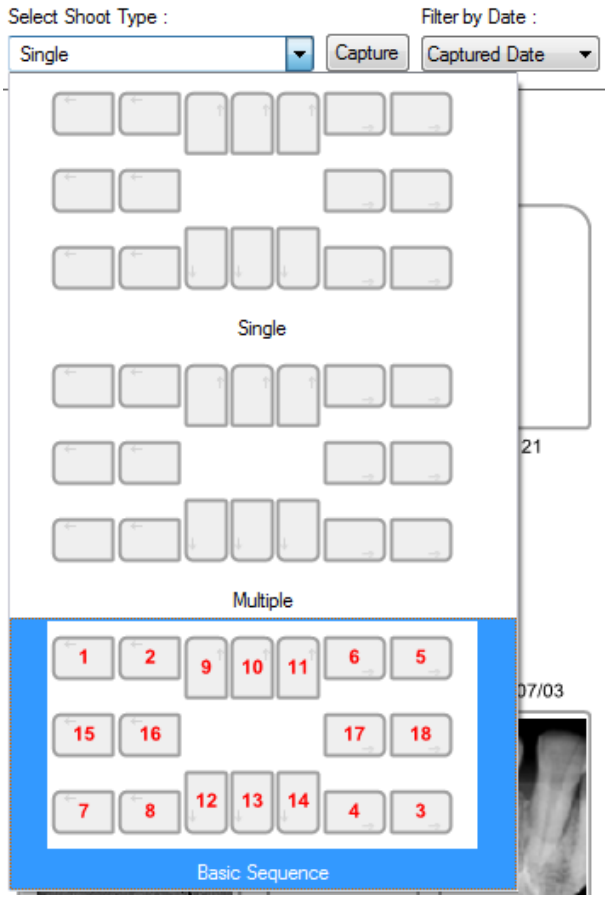


3.3.4 Sequence Shot

You can capture multiple images according to a pre-saved order. Capturing according to the order will ensure the images appear automatically in the correct positions.

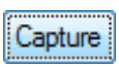
Step 1

Select your favorite sequence from the Shoot Type list. Red numbers are represented the capture order.
The Sequence shot can be customized. Please refer to the EasyDent manual.



Step 2

Click the 'SENSOR (

)' button or 'Capture (

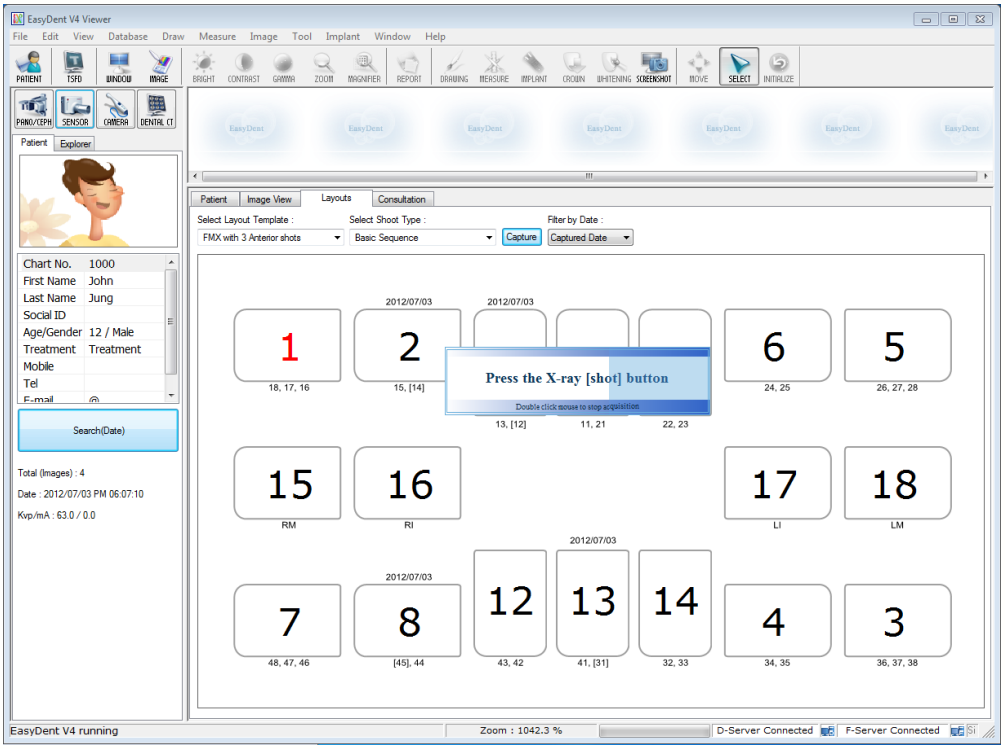
)' button.

Step 3

Position the sensor correctly.

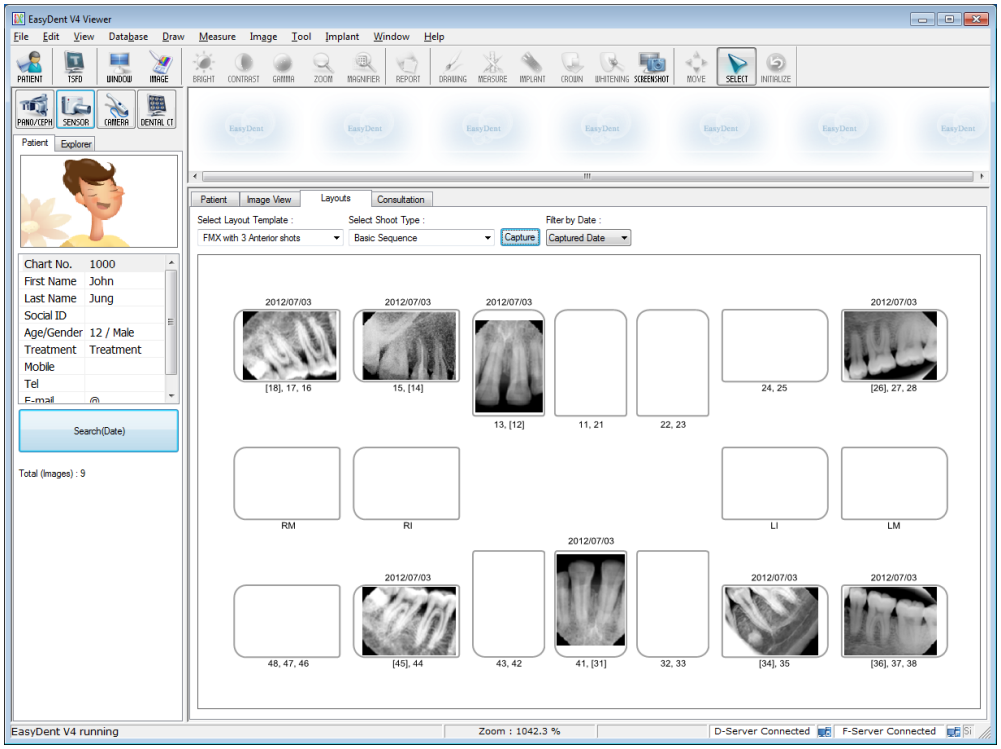
Step 4

Capturing according to the order, the images appear automatically in the correct positions.
Expose the X-ray after the “Please expose X-ray” message appears.
The message, “Optimizing Image… Please wait” appears while the image is being optimized.



Step 5

If you want to finish, double click the ‘Press the X-ray (shot) button’ message box. And then according to the capturing order, the images appear automatically in the correct positions.



NOTE

All images are saved in the Database server automatically.

With double click on the image, the image is shown as large size at any function’s table.

Chapter 4 Maintenance

For optimal performance, Rayence recommends that the working area be kept clean. There are no specific cleaning requirements for the EzSensor beyond normal care and attention for aesthetic appearances.
Caution: Federal law restricts this device to sale by or on the order of a physician.

4.1 Visual Inspection

Like all electrical systems, EzSensor requires not only correct usage, but also visual inspection prior to operation, as well as routine checks at regular intervals. These precautions will help ensure that the system operates accurately, safely, and efficiently.
Before use, the operator should check the system for any signs of physical damage or defect. If something out of order is suspected, contact your local VATECH product distributor for further instructions on how to proceed.

4.2 Periodic Maintenance

Periodic maintenance should be performed as necessary, and at least once a month. Maintenance should consist of various checks performed by the operator or by a qualified service technician.

- Check that all cables connected to the EzSensor are undamaged.
- Check for external damage to the EzSensor that may compromise its ability to be safely operated. If EzSensor is defective, the sensor will be returned to the manufacturer for repair.
- Arrange the sensor and control box USB cable to prevent the damage of the cable's rubber tube. For example, do not press the cable under the legs of the table or the people.

4.3 Care and Cleaning

Wipe the front plate of the sensor unit with ethanol or glutaraldehyde solution to disinfect it each time a different patient uses the instrument, in order to prevent infection. If you are using disinfectant other than those specified above, or you are mixing another disinfectant with ethanol, please also consult a specialist, because they may harm the front plate.

To clean the EzSensor, use either of the following solutions listed below and observe the precautions noted. (Do not use any type of solvent, such as alcohol or benzene.)

- Mild soap and water
- Isopropyl alcohol (70%)
- Most alcohol and ammonia based cleaners
- Mild, non-abrasive cleaners

Do not soak or immerse the system and be sure to dry it completely after cleaning.
Clean the surface of the system by moistening it with a soft cotton swab dipped in either of the cleaning solutions listed above. Gently wipe the surface from end-to-end in straight lines, without applying any pressure. Make sure that liquid does not penetrate the system through the USB cable or the sensor cable connectors.
After cleaning the surface of the EzSensor, use a clean lint-free cloth to dry the system, as required, until the surface is clean.

※Clean the silicone cover using the same method.
※ Do not use the following cleaning materials.

- Hard brushes or scrapers of any kind
- Strong acids or alkaloids

4.4 Precautions

- Do not soak the sensor in the water or alcohol.
- Authorized service personnel can repair about calibration.
- Service personnel cannot handle the problem which is not mentioned in this manual. So, in this case please request the repair to manufacturer through VATECH dealer.
- This equipment and accessories are to be disposed safely at the end of the product life cycle and national regulation must be observed.

4.5 Product complaint

Any health care professional (e.g., customer or user of this system of products) who has any complaints should notify your distributor first. They will handle them.

If the device may have caused or contributed to a serious injury of a patient, your distributor should be notify immediately by telephone, fax, or written correspondence to the manufacturer. And then the manufacturer shall report them to the government of each country according to their reporting process.

Do not modify this equipment without authorization of the manufacturer.

Chapter 5 Warranty

VATECH hereby warrants EzSensor™ (“Product”) against defects in material and workmanship under normal usage and service for a period of 24 months from the date of installation.
If Buyer promptly notifies VATECH or Seller regarding any parts that fail to perform as specified under normal usage during the Warranty Period and VATECH determines that such failure resulted from a defect in materials or workmanship during the Warranty Period, then VATECH, at its option, shall repair, rebuild or adjust the affected parts.

VATECH shall have no obligation for any defects to the extent that such defect arises out of (i) normal and fair wear and tear or Product which has been modified without VATECH's approval, (ii) Product which has not been installed in strict conformity to the VATECH's directions or which have been subjected to electrical or other abuse, or damaged by improper handling, storage or use by Buyer or a third party, (iii) use of Product in combination with devices or products not purchased from VATECH; (iv) use or application of Product in a field or in an environment for which such Product was not designed or contemplated; (v) use of any parts or material not provided by VATECH for warranty service; or (vi) the third party’s maintenance not certified by VATECH; or (vii) force majeure such as natural disaster.

Repaired, rebuilt or adjusted component parts are warranted for 90 days or the remainder of the Warranty Period, whichever is longer. This Warranty extends solely to Buyer and shall not extend to any person that purchases the Products from Buyer or any other person, whether an entity or a natural person, in the chain of the use or distribution of the Products.

The warranty period for Product shall including replacement of Non-Consumable parts and the labor to correct warranty issues.

Buyer will make all reasonable efforts to advise VATECH of the use of any non-VATECH authorized Items, components, or parts in Product. If, after troubleshooting, it is determined that repairs (including replacement of any Items, components, or parts) to Product under warranty are a result of a non-VATECH authorized Item, component, or part, VATECH will be paid for all costs associated with the repair service rendered.

This expresses all of VATECH's responsibilities regarding the Product, including the sale of the Product, the events giving rise to the sale of the Product, defects in the Product, and the failure of the Product to meet or perform in accordance with specifications or as intended. The remedies contained in this warranty are Buyer's exclusive remedies. VATECH shall not, in any event or under any circumstances, be responsible for damages or other sums in excess of the total purchase price actually paid by Buyer to Seller i.e., VATECH or VATECH's dealer. Without limiting the generality of the foregoing under no circumstance shall VATECH be responsible or liable in any regard with respect to damages from loss of use, loss of time, loss of data, inconvenience, commercial loss, lost profits or savings, or other incidental, special or consequential damages claimed by Buyer to arise out of the use or inability to use the Product, even if Buyer has been advised of the possibility of such damages.

If the Buyer fails to pay any amounts due to the Seller, whether related to the Products or otherwise, VATECH shall have the right to refuse to provide any services to the Buyer under this Warranty until such payment has been received by the Seller.

In the event that the product is returned to VATECH after the warranty has expired, VATECH reserves the right to invoice a reasonable fee for the repair services provided to Buyer.

VATECH shall make the sole final determination about whether the fail to perform occurred in normal usage (under warranty) or not (excluded from warranty). If the dealer or the Buyer doesn't accept the result of VATECH's investigation, the burden of proof is on them.

Warranty Procedure

If Buyer needs to make a claim based on this Warranty, Buyer should advise Seller in writing immediately at the following address:

RAYENCE Co., Ltd.

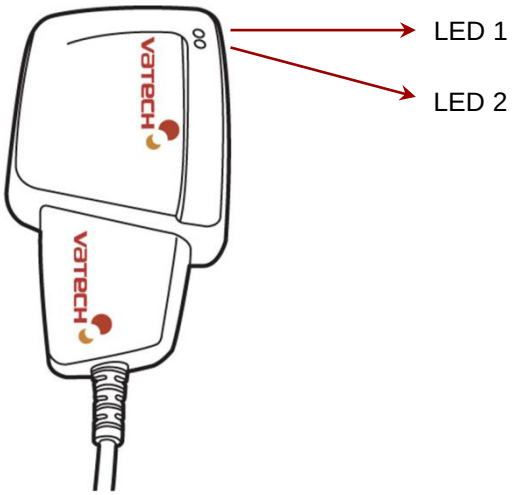
1F, 2F, 3F, #402, 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea

Appendix

A.1 LED Indicators

The EzSensor Hardware Controller has two LED indicators that show its functional status.

The location of the LED lights is as shown in the following illustration and described in Table 3.



<Table 3. Description of LED Indicators>

Operational State	LED State		Functional Status Confirmation
	LED 1	LED 2	
Initial State	Green	Off	USB Connection
Standby	Green	Green	Capture standby
Trigger (X-ray On)	Orange	Green	X-ray On and Sensor Trigger On
Data Transmission with the USB PC interface cable	Green	Orange	Confirm data transmission with the sensor board
Image acquisition	Green	Off	Completion of data transmission (Return initial state)

A.2 X-ray Exposure Guide

The required X-ray dose for the best image is dependent on the following:

- X-ray source (tube assembly, manufacturer, AC/DC, etc.)
- Distance between beam focus and sensor
- Tooth (object) to be X-rayed
- Bone density and age of patient
- Miscellaneous circumstances, etc.

The X-ray dose influences image quality. Based on fundamental laws of physics, an insufficient dose generally means higher image noise, which leads to poorer detail discrimination. On the other hand, an excessively high dose can cause the sensor to be overexposed. This is also perceptible by a decrease in detail discrimination, specifically in darker areas.

The effect of image processing reduces the difference between image qualities of different doses. Users can adjust brightness and contrast in the option menu.

The recommended exposure dose is from 300μGy to 600μGy when measuring without an object. Exposure time corresponding to the dose may vary depending on the X-ray equipment used. Recommended exposure times according to positions are as shown in the Recommendation on Exposure Time Table.

The X-ray dose is maintained through tube voltage (kVp) and current (mA), as well as exposure time according to the signal level.

Since the exposure time depends on the diagnostic problem as well as the clinical situation, the selection of an adjustment is the responsibility of the treating physician.

Image degradations caused by overexposure of the sensor cannot be compensated but by insufficient dose can be partially compensated through image processing.

< Table 4. Recommendation on Exposure Time >

Exposure condition	Dose (μGy)	60kvp 6mA	60kVp 2mA	65kVp 5mA
Patient		Adult	Adult	Adult
SID		**28cm**	**18cm**	**28cm**
Intra Oral X-ray Unit (Model name)	No Filter	*VX 70*	*AnyRay*	*ESX*
		Approximate Exposure Time (sec)		
Incisor & Canine	300 ~ 500	0.12 ~ 0.2	0.1 ~ 0.2	0.18 ~ 0.28
Molar	400 ~ 600	0.16 ~ 0.25	0.15 ~ 0.25	0.24 ~ 0.34

* SID : Source to imaging receptor Distance

NOTE

For larger body types : increase the source current by 25%
For children : reduce the source current (or Exposure time) by 20%
For edentulous patients : reduce the source current by 20%.

CAUTION

The X-ray dose required for image acquisition can vary depending on the X-ray source and environmental circumstances. You must maintain the exposure time and change the kVp and mA values according to the signal level. In addition, if the X-ray source and the distance to the sensor were changed during the initial installation, the distance (from cone to detector) must be changed to the 80mm setting.
The exposure time may vary depending on the age, gender and bone density of the patient.

A.3 Error Message

1. USB device driver is not installed.
   - Solution: Please install the device driver again.

2. Control box cannot be initialized.
   - Solution: Check and re-connect the USB PC interface cable.

3. USB device driver is not working properly.
   - Solution: Re-install the driver.

4. Capture program is already running.
   - Solution: Please close any other programs.

5. Detector response time-out.
   - Check and re-connect the USB PC interface cable. Please try again.
     If the same message is displayed again, contact Customer Service.

6. Data communication error.
   - Solution: Re-connect the USB PC interface cable.

7. Canceled image capturing.
   - This means that the user canceled image capture. Please try again.

8. Cannot find dark frame.
   - Solution: Restore the EzSensor's calibration data from the S/W installation CD or re-calibrate the sensor. If the same message is displayed again, contact Customer Service.

9. Cannot find bright frames for calibration.
   - Solution: Reinstall the EzSensor driver.

10. Bad Pixel Map correction error.
    - Solution: Restore the EzSensor's calibration data from the S/W installation CD or re-calibrate the sensor. If the same message is displayed again, contact Customer Service.

11. Wrong image processing parameters.
    - Solution: Check the X-ray source. If the problem persists, call for technical assistance.

12. Cannot load 'EzSensor.dll'.
    - Solution: Please re-install the acquisition software.

13. Require 'EzSensor.dll' was damaged.
    - Solution: Please re-install the acquisition software.

A.4 Troubleshooting

If you experience any problems regarding the EzSensor system during operation, please refer to the troubleshooting table below for corrective measures. If the problem persists, please contact your local VATECH product distributor.

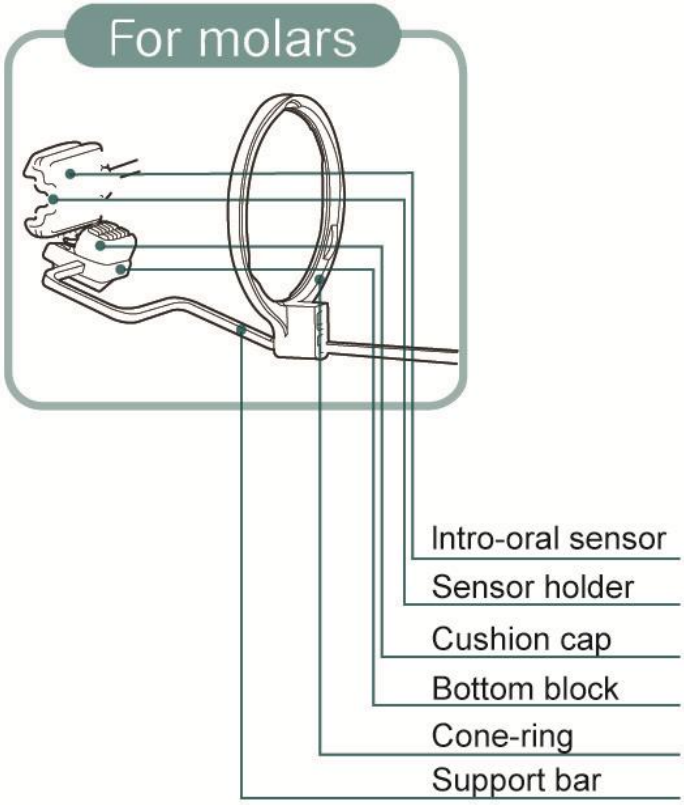
<Table 5. Troubleshooting Table>

Item	Description	Corrective Measure
1	LED 1 on the control board box does not illuminate after installing the device.	Check that the USB PC interface cable is plugged in correctly at the control board box and on the console PC.
2	LED 1 on the control board box continuously illuminates an ORANGE light during image acquisition.	Check that the Sensor is properly connected. Unplug the USB PC interface cable from the control board box and then reconnect it.
3	LED 2 on the control board box continuously illuminates a RED light during image acquisition.	Unplug the USB PC interface cable from the control board box and then reconnect it. Open the Windows Device Manager and check that the device is installed correctly. Alternatively, try another USB port on your computer.
4	A 'PID 2XXX NO; interface #0 (Check Connection)' error message is displayed.	Unplug the USB PC interface cable from the control board box and then reconnect it. Open the Windows Device Manager and check that the device is installed correctly. Alternatively, try another USB port on your computer.

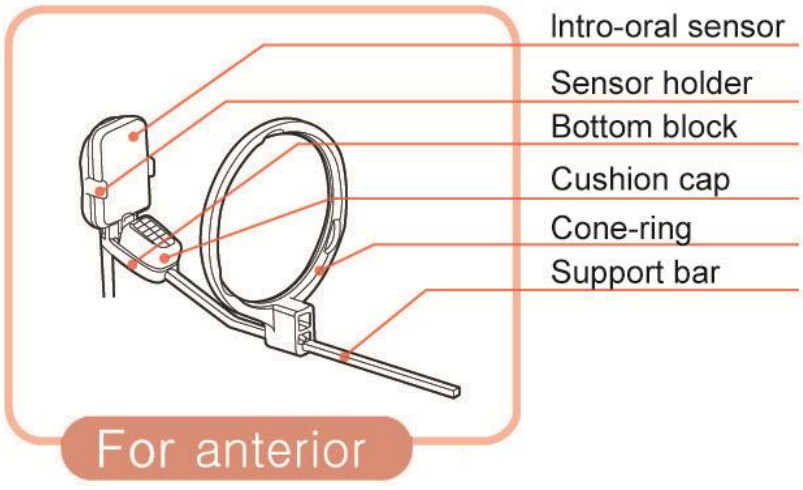
A.5 How to use the sensor positioning system

- Sensor position aids:

① Sensor positioning system for molars

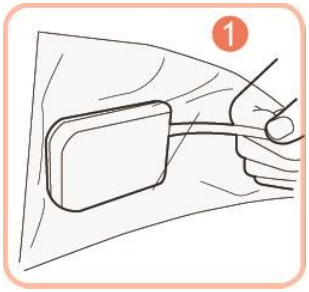


② Sensor positioning system for anterior

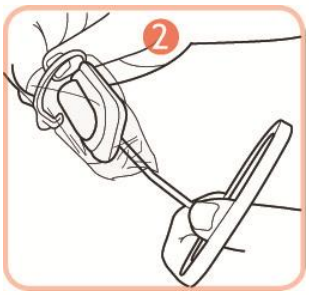


- Usage Method:

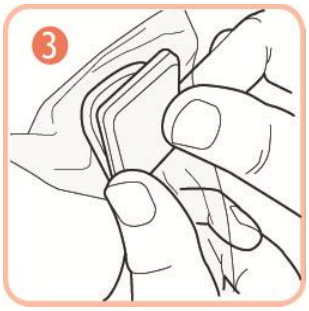
① Insert the sensor into the wrap provided.
At this time, it is normally recommended to cover the sensor with the silicon cover.



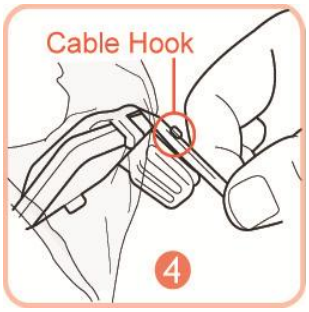
② Pass the sensor through the cone ring and into the sensor holder.



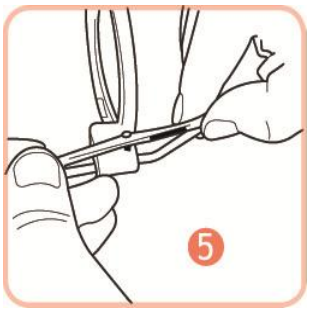
③ Fix the sensor firmly to the sensor holder.



④ Put the sensor cable in the cable-holder located at the side of the bottom block.



⑤ Fasten the sensor cable on the cone ring with the cable hook.



⑥ Put the cushion cap on the top of the bottom block.

A.6 Electromagnetic field information according to IEC601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model EzSensor is intended for use in an electromagnetic environment as specified below. The customer or the user of the Model EzSensor should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The model EzSensor 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.
RF emissions CISPR 11	Class A	The model EzSensor is suitable for use in all establishments, including domestic establishments, and those directly connected to a personal computer USB port used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic emissions			
The model EzSensor is intended for use in an electromagnetic environment as specified below. The customer or the user of the model EzSensor should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tiles. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 60601-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 6 cycles 70 % U_T (30 % dip in U_T) for 30 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 6 cycles 70 % U_T (30 % dip in U_T) for 30 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model EzSensor requires continued operation during power mains interruptions, it is recommended that the model EzSensor be powered from an uninterruptible power source or battery**.**
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note : U is the A.C. mains voltage prior to the application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The model EzSensor is intended for use in an electromagnetic environment as specified below. The customer or the user of model EzSensor should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the model EzSensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m 80 MHz to 2.5GHz	Recommended separation distance $d=[3.5/V1]\sqrt{P}$ $d=[3.5/E1]\sqrt{P}$ 80MHz to 800MHz $d=[7/E1]\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer, and d is the recommended separation distance in meters(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

[a] **Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model EzSensor is used exceeds the applicable RF compliance level above, normal operation of the model EzSensor must be verified. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the model EzSensor.**

[b] **Over the frequency range of 150kHz to 80MHz, field strengths should be less than [V1] V/m.**

The information in this document is subject to change without notice and does not represent a commitment on the part of the vendor.

If you do not properly set the device setting, causing the device to malfunction or fail, we cannot guarantee any responsibility.

Rayence Co., Ltd.
Web Site ▸ www.rayence.com
Head Office & Factory ▸ 1F, 2F, 3F, #402, 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea

CE 0120

CE symbol grants the product compliance to the European Directive for Medical Devices 93/42/EEC as a class IIB device. Authorized by **SGS United Kingdom Ltd**

EC Representative; VATECH Dental Manufacturing Ltd.
Axiom House, The Centre Feltham, Middlesex, TW13 4AU, United Kingdom
Tel: +44 (0)208-831-1660, Fax: +44 (0)208-831-1679

Document No. R-USM-701
Release Version 4.4
Dated Aug. 8th. 2013

Rayence Co., Ltd.
1F, 2F, 3F, #402, 14, Samsung 1-ro 1-gil, Hwaseong-si,
Gyeonggi-do, Korea