EZSensorP User/Installation Manual



This manual covers the installation and operating procedures of the EzSensor P. Unless otherwise specified, all the information contained in this manual is applicable equally to all EzSensor P 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 P, 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 P for any signs of physical damage or defect. The surface of the EzSensor P 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 P 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.

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

Symbols Descriptions



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-toone 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 P package.



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Chapter 1 Introduction

1.1 System Description

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

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

The EzSensor P 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 1.5: 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	0.02 mm
Active Pixel Array	Size 1.5: 1200 x 1650 pixels (24 x 33 mm) Size 2.0: 1300 x 1800 pixels (26 x 36 mm)
Grayscale	4096 gray levels
Resolution	25 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 P 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 P system components>

No	Components	Remark
1.	Sensor Unit (CMOS Sensor* + USB Box + Cable* (3M))	
2.	Holder for Sensor	
3.	Silicon cover*	
4.	Wrap*(Hygienic Sleeves)	
5.	S/W Installation CD	EasyDent + EzSensor P Driver
6.	EzSensor P Manual	Document

* Patient applied part (Inside Patient environment)

1. Sensor Unit:

The Sensor Unit consists of the CMOS sensor part and a USB Box.

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.



The USB 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. It also transmits an output signal from the sensor to the computer through a cable.



2. Holder for Sensor:

Used to stow the sensor when not in use.



3. Silicon cover:

Used to protect from the external shock.

4. 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.

5. S/W Installation CD





Chapter 2 Hardware Installation

2.1 What you should do before use

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

2.2 Specifications



2.2.1 PC Specification

- ① Operating System
 - Microsoft Windows XP 32bit
 - Microsoft Windows Vista 32bit
 - Microsoft Windows 7 32bit
- ② Hardware requirement
 - 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 P Driver Setup

This step is necessary for the installation of EzSensor P. Capturing software and Calibration data for the EzSensor P 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.

EzSensor Acquisition Software Version 6.2 - InstallShield Wizard	×		
Home directory C:\EzSensor	No.		
Install mandatory modules and the next featured application compo	nents		
Calibration Data for EzSensor 1.5, Serial ID E150HDA712-00001			
C:\EzSensor\MultiSensor\E150HDA712-00001			
Legacy applications support patch for EzSensor 1.5			
C:\EzSensor150 (compatible with EzDent4)			
64-bit drivers			
C:\EzSensor\DRV			
InstallShield			
<u> </u>	Next > Cancel		

Step 4

The Installshield Wizard will start configuring the installation parameters.

EzSensor Acquisition Software Version 6.2 - InstallShield Wizard
Setup Status
The InstallShield Wizard is installing EzSensor Acquisition Software Version 6.2
Installing
C:\EzSensor\UNICODE\EzSensorEnu_ImgU_64.dll
InstallShield
Cancel

Step 5

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

Copying calibration files toC:\EzSensor\CAL C:\EzSensor\CAL\A02_01286.raw		
Cancel		

2.3 Cable Connection & Driver Installation



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



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



Step 1

Connect the USB Box of EzSensor P to the USB port on the PC.

Recommend to connect the USB port on backside for accurate operation.



Step 2

Confirmation of Driver installation at the Device Manager.

Method of Confirmation:

Windows 7 : Control Panel \rightarrow System and Security \rightarrow System \rightarrow Device Manager



Windows XP : Settings \rightarrow Control Panel \rightarrow System \rightarrow Hardware \rightarrow Device manager Select 'VH EzSensor-N x.x', located under Imaging Devices. You should see the message, "This device is working properly".



🚔 Device Manager 📃 🗖 💌	VH EzSensor-N 1.5 Properties
<u>File Action View H</u> elp	General Driver Details
	VH EzSensor-N 1.5
Human Interface Devices	Destastance in testastance
De ATA/ATAPI controllers	Device type: Imaging devices
a 🔚 Imaging devices	Manufacturer: VaTech
HP ENVY HD Webcam	Location: Location 0
VH EzSensor-N 1.5	
Keyboards	Device status
Mice and other pointing devices	This device is working properly.
Monitors	
Network adapters	
Portable Devices	
	-
Sound video and some controllers	
Sound, video and game controllers	
System devices	
Universal Serial Bus controllers	
-	
	OK Cancel

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



2.4 Installation of the EzSensor P Holder

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

 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'.

EasyDent V4 (Multi-Language) - Installs Choose Setup Language Select the language for the installation fr	Shield Wizard		
Chinese (Simplified) Chinese (Traditional) Czech French (Standard) Hungarian Italian Japanese Polish Portuguese (Brazilian) Russian Spanish Turkish			
InstallShield —	< <u>B</u> ack	<u>N</u> ext >	Cancel



The 'EasyDent V4 InstallShield Wizard' will appear. Click the 'Next' button.



Step 4

EasyDent V4 (Multi-Language) - InstallShield Wizard х Setup Type Select the setup type that best Select the setup type that best suits your needs. suits your needs. Please select installation mode of EasyDent4 Click the 'Next' button. 💿 Basic For CD-Publishing Basic : Installs the basic version of EasyDent V4 **CD-Publishing:** Installs the basic version of EasyDent V4 along with CD-Publishing capabilities. (optional) < <u>B</u>ack <u>N</u>ext > Cancel

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.

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

EasyDent Viewer is the minimum requirement for EzSensor P use.

EasyDent V4 (Multi-Language) - InstallShield Wizard Select Features Select the features setup will install.	
Select the features you want to install, and deselect the I	eatures you do not want to install. Description EasyDent Viewer, EzX, EzCam
518.81 MB of space required on the C drive 458666.75 MB of space available on the C drive InstallShield ————————————————————————————————————	ck Next > Cancel

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.

EasyDent V4 (Multi-Language) - InstallShield Wizard			
Ready to Install the Program The wizard is ready to begin installation.			
Click Install to begin the installation.			
If you want to review or change any of your installation settings, click Back. Click Cancel to exit the wizard			
InstallShield			
< <u>B</u> ack Install	Cancel		



Step 7

Installing EasyDent V4.



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.





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

Manager.

C:\WINDOWS\system32\cmd.exe		- 🗆 ×
MSSQL Server running The MSSQLSERVER service is starting. The MSSQLSERVER service was started successf	ally.	
MSSQL Service running The SQLSERVERAGENT service is starting		
D SQL Server Ser	vice Manager 📃 🗉 💌	
Ser <u>v</u> er:	E80725	
Se <u>r</u> vices:	SQL Server	
	Refres <u>h</u> services	
	▶ <u>S</u> tart/Continue	
	■ <u>P</u> ause	
	Stop	-
☐ <u>A</u> uto-start se	rvice when OS starts	
Starting - WW E80	725 - MSSQLServer	

Step 10

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

asyDent V4 (Multi-Language) - InstallShield Wizard				
	InstallShield Wizard Complete Setup has finished installing EasyDent V4 (Multi-Language) on your computer. Yes, I want to restart my computer now. No, I will restart my computer later. Remove any disks from their drives, and then click Finish to complete setup.			
	< <u>B</u> ack Finish Cancel			



3.2 Preparing for the Image Acquisition with the EzSensor P

- ① Turn on the computer.
- 2 Run the EasyDent. (refer to P22)
- ③ Configure the required X-ray parameters (exposure time, etc.) for the X-ray generator.
- ④ Put a new wrap on the EzSensor P and connect this to the sensor positioning system.
- (5) Position the EzSensor P at the appropriate area of 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.
- After preparing the sensor for exposure in EasyDent, acquire an image by pressing the exposure button for your X-ray source.



Using the EzSensor P with intraoral X-ray



Using the EzSensor P 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.

EasyDent V4 Viewer		
<u>File Edit View Database Drav</u>	w <u>M</u> easure Im <u>ag</u> e <u>T</u> ool Implant <u>W</u> indow <u>H</u> elp	
PATIENT TSFD WINDOW IMAGE	BRIGHT CONTRAST GRIMMA ZOOM MAGNIFER REPORT DRAWING MERSURE MIPLINT CROWN WHTEN	ING SCHERKSHOT MOVE SELECT INTIFLIZE
PRINZ/CEPH SENSOR CAMERA DENTAL (T Patient Explorer	EasyDeat EasyDeat EasyDeat EasyDeat	t EasyDeat EasyDeat EasyDeat
		٨
	Patient Image View Layouts Consultation	
TOTAL SOLUTION FOR DENIAL	Patient List	Image List
	Patient Name Chart No. Gender Age Birthday	Image Type Captured Date
Chart No.		
	Patient Name Chart No. Birthday	Patient Name Chart No. Birthday
EasyDent V/ running		



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

Add Patient	
* Chart No. : Recently 🕅 Auto No.	
* First Name :	
* Last Name :	
Social ID :	
Birthday : 2012 • 1 • 1 •	
Gender : Male Treatment: Treatment	
Address1 :	
Address2 :	
E-mail : @	
Tel : Mobile :	
Doctor :	
Add Cancel	

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.

Select Intra-Oral Sensor	
Intra-Oral Sensor Model	1 High Contrast (Default)
© HDS-150 ◎ HDS-150S ◎ HDS-100L	2 Middle Contrast
AnySensor 1.0 AnySensor 1.5 AnySensor 1.0N AnySensor 1.5N	3 Low Contract
Ezsensor 1.0 Ezsensor 1.5 Ezsensor 2.0 Ezsensor Multi	
	(4) High Contrast New
High Contrast Middle Contrast Low Contrast High Contrast New	⑤ Middle Contrast New
⊘ Middle Contrast New ⊘ Low Contrast New ⊘ Normal Image	6 Low Contrast New
Ok Cancel	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.

EasyDent V4 Viewer ile Edit View Database Drav	w Measure Image Tool Im	plant Window H	elp			
		MAGNHER REPORT	DRAUING MERSURE MA		IG SCHEENSHOT MOVE SELECT IN	5) INLIZE
Patient Explorer	EasyDent	EasyDent	EasyDent	EasyDent	EnsyDent	EasyDent EasyDen
				m		
	Patient List	outs Consultation			Image List	
	Patient Name	Chart No.	Gender Age	Birthday	Image Type	Captured Date
Chart No. 1000 First Name Jung Social ID Age/Gender 12 / Male Treatment Treatment Treatment Geologic Tel Famal Search(Date) Total (images) : 0	John Jung	1000	Male 12	2000/01/01		
	Today Captured List					
	Patient Name Chart	No.	Birthday		Patient Name Chart I	Vo. Birthday



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.



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



Step 5

Click the 'SENSOR (SENSOR)' button or 'Capture (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.





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



Step 3

Click the 'SENSOR (SENSOR)' button or 'Capture (Capture)' button.
---------------------	--------	--

Step 4

Position the sensor correctly.

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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.





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.



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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 represent 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.



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.



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.





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 P 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 P are undamaged.
- Check for external damage to the EzSensor P that may compromise its ability to be safely operated. If EzSensor P is defective, the sensor will be returned to the manufacturer for repair.
- Arrange the sensor and USB Box 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 P, 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 P, 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 P[™] ("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 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 300μ Gy to 600μ Gy 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.



Exposure	Dose	60kvp	60kVp	65kVp
condition	(µGy)	бМА	2mA	SMA
Patient		Adult	Adult	Adult
SID		28cm	18cm	28cm
Intra Oral X-ray Unit	No	VX 70	AnyRay	ESX
(Model name)	Filter	Approxir	mate Exposure Tir	me (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

< Table 4. Recommendation on Exposure Time >

* SID : Source to imaging receptor Distance



CAUTION

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%

The X-ray dose required for image acquisition can vary depending on the Xray 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.

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A.2 Error Message

- 1. USB device driver is not installed.
 - Solution: Please install device driver again.
- 2. Control box can't be initialized.
 - Solution: Check and re-connect USB Box.
- 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's response time-out.
 - Check and re-connect USB Box. Please try again. If the same message displayed again, contact Customer Service.
- 6. Data communication error.
 - Solution: Re-connect USB Box.
- 7. Canceled image capturing.
 - This means that the user canceled image capture. Please try again.
- 8. Can't find dark frame.
 - Solution: Restore the EzSensor P's calibration data from the S/W installation CD or recalibrate the sensor. If the same message displayed again, contact Customer Service.
- 9. Can't find bright frames for calibration
 - Solution: Reinstall the EzSensor P driver.
- 10. Bad Pixels' Map correction error
 - Solution: Restore the EzSensor P's calibration data from the installation CD or recalibrate the sensor. If the same message 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. Can't load 'EzSensor.dll'.
 - Solution: Please re-install acquisition software.
- 13. Require 'EzSensor.dll' was damaged.
 - Solution: Please re-install acquisition software.

A.3 Troubleshooting

If you experience any problems regarding the EzSensor P 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 Action
	A 'PID 2XXX NO; interface #0 (Check	Unplug the USB Box and then reconnect it.
	Connection)' error message is	Open the Windows Device Manager and
1	displayed.	check that the device is installed correctly.
		Alternately, try another USB port on your
		computer.



A.4 Electromagnetic field information according to IEC 601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions

The Model EzSensor P is intended for use in the electromagnetic environment specified below. The customer or the user of the Model EzSensor P should assure that it is used in such an environment.			
Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	The model EzSensor P uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The model EzSensor P is suitable for use in all establishments including domestic and those directly connected to a personal computer USB port that supplies used for domestic purposes.	

Guidance and manufacturer's declaration – electromagnetic emissions					
The model EzSensor P is intended for use in the electromagnetic environment specified below. The customer or the user of the model EzSensor P should assure that it is used in such an environment.					
Immunity test	IEC 60601	Compliance	Electromagnetic environment –		
	test level	level	guidance		
Electrostatic discharge (ESD) IEC 61000-4-2	\pm 6 kV contact \pm 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.		
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	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 cycle 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 cycle 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 P requires continued operation during power mains interruptions, it is recommended that the model EzSensor P be powered from an uninterruptible power supply 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 application of the test level.					

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Guidance and manufacturer's declaration – electromagnetic immunity					
The model EzSensor P is intended for use in the electromagnetic environment specified below. The customer or the user of model EzSensor P should assure that it is used in such an environment.					
Immunity test	IEC 60601 test	Compliance	Electromagnetic environment –		
	level	level	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 P, 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]√P		
	2.30112 2.30112	2.00112	d=[3.5/E1]√P 80MHz to 800MHz		
			d=[7/E1]√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:		
			$\left(\left((\bullet)\right)\right)$		

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 P is used exceeds the applicable RF compliance level above, the model EzSensor P should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the model EzSensor P.

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



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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 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, TW 13 4AU, United Kingdom Tel: +44 (0)208-831-1660, Fax: +44 (0)208-831-1679

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