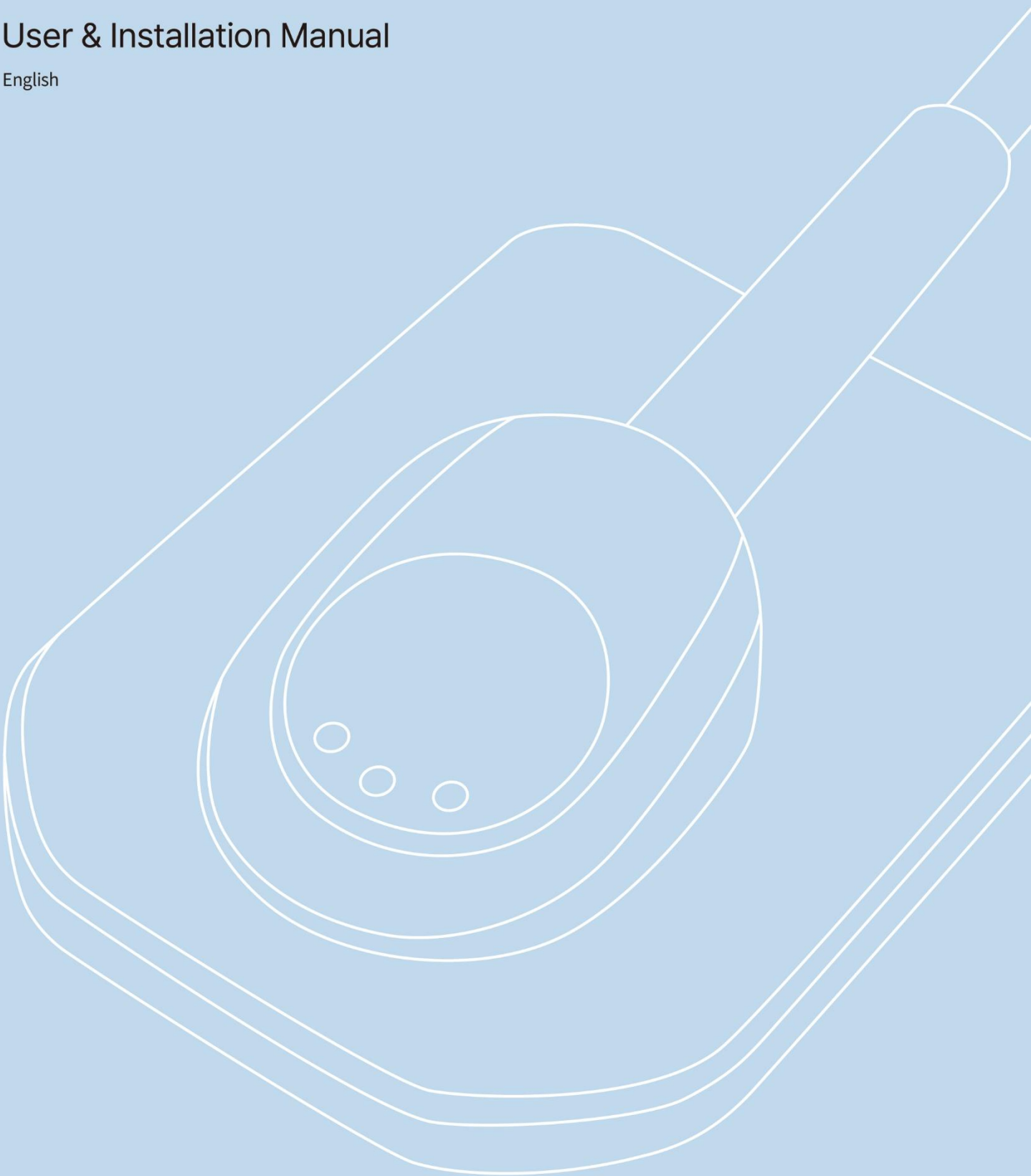
EzSensor HD

User & Installation Manual

English



This document should be used as a guide only to instruct on the EzSensor HD

For further assistance on this user's manual or Intra Oral Sensor, contact your dealer.

The User Manual that comes with the product may not contain the most updated information on the product.

Indication for use

The EzSensor HD 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.

R-USM-712

Version: 5.0

Date: 2026-03-31

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User Manual

PART I. User Manual

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Introduction

Notice

To improve Product performance and to provide updates and additional information, the contents of this manual are subject to change without prior notice.

Please note that our company assumes no responsibility for accidental damage nor are we obligated to provide warranty service for any equipment damage resulting from user error. Please follow the instructions in this manual closely. Familiarize yourself 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 specific Product specifications.

Conventions and Symbols

Convention

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

	**WARNING** Indicates warnings and safety instructions. Failure to comply may result in serious injury to the patient and/or the operator.

	**CAUTION** Indicates important instructions. Failure to follow these instructions may result in malfunction or damage to the Product or other property may occur.

	**NOTICE** Indicates useful information and tips for using our software and Products.

For U.S. users: United State federal law restricts this device to use by or on the order of a physician.

For users in other countries: This device may be used only by or on the order of a licensed person (e.g., doctor, nurse, dentist, X-ray technician, or radiologist) under the applicable laws of each country.

Symbols Descriptions

Item	Symbol	Description
1		Handling procedures for Electro-Static Discharge (ESD)
2		Handle with care
3		Fragile, handle with care
4		This way up
5		Storage/Ship Temperature
6		Transport/Storage Humidity
7		Transport/Storage Atmospheric Pressure
8		Manufacturer
9		Indicates the item is a medical device
10		Type B applied part
11		Waste Electrical and Electronic Equipment (WEEE)
12		Conforms to 2017/745 medical device regulation (CE MDR)
13		Refer to the instruction manual/booklet

14	SN	Serial number
15		Date of manufacture
16	UDI	Indicates a carrier containing unique device identifier (UDI) information
17	EC REP	Authorized representative in the European Community
18		Indicates that the Wrap is a non-reusable component supplied with the device to ensure hygiene and prevent cross-contamination

Safety Instructions

Intended Use

Intra-Oral Sensor 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

Clinical Benefit

The intraoral X-ray sensor, in combination with associated image processing software, provides radiographic image information that supports dentists and other dental clinicians in the assessment of oral structures and conditions that cannot be adequately evaluated through visual examination alone.

The device supports diagnostic decision-making by providing image information suitable for dental diagnosis. Any patient-related outcomes result from clinical management decisions made by qualified healthcare professionals and are not directly attributable to the device itself. intraoral imaging device intended to collect dental x-ray photons and convert them

Intended Patient Population

<table>
<tr><th>Item</th><th>Description</th></tr>
<tr><td>Age</td><td>The device is intended for use on patients aged 6 years and older who are able to cooperate with standard Intraoral X-ray imaging procedures.
<table>
<tr><th>Age Group</th><th>Age</th><th>Applicability</th></tr>
</table>
</td></tr>
</table>

Item	Description		
	Infant/Young children	0 – 5	Excluded
	Children	6 – 13	Included
	Adolescent/Adult	≥ 13	Included
Weight	Not relevant		
Gender	Not relevant		
Health	Not relevant		
Nationality	Multiple		
Patient Group	Patients aged 6 years and older requiring intraoral X-ray imaging for dental diagnosis.		

Pediatric Considerations

CAUTION

- Pediatric patient within the intended patient population may have limited cooperation. Additional operator assistance may be required. The decision to perform intraoral imaging in these patients should be based on clinical judgment.

It is the user's responsibility to ensure compliance with all applicable local safety regulations in force at the installation site.

Patient Cooperation

CAUTION

- The device is intended for use in patients who are able to cooperate with standard intraoral imaging procedures.
- If the patient cannot cooperate (e.g., excessive movement, gag reflex), stop the procedure and reassess.

	CAUTION
	• Before each use, inspect the outer surface of the EzSensor Classic for any signs of physical damage or defects. The surface of the EzSensor Classic should have a smooth finish, with no evidence of chipping or cracking. If any damage is detected, contact your local Product distributor for further instructions. • To ensure proper use of the EzSensor Classic device in a clinical or other professional healthcare environment, and in accordance with its design and application, only licensed dentists or operators expressly designated by them are authorized to operate this Product • Modifications and/or additions to the device must be conducted only by the MANUFACTURER or by parties expressly authorized by the MANUFACTURER. Any modifications or additions must comply with applicable standards and generally recognized rules of good workmanship. • Use of this equipment adjacent to or stacked with other equipment should be avoided, as it may result in improper operation. If such use is necessary, this equipment and the other equipment must be observed to confirm that they are operating normally. • Use of components and accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

It is the user's responsibility to ensure compliance with all applicable local safety regulations in force at the installation site.

Electrical safety

	CAUTION
	• The covers of the Product may be removed only by qualified and authorized technical personnel. • This Product may be used only in rooms or areas that comply with all applicable laws and regulations governing electrical safety in medical facilities, such as IEC standards requiring an additional ground terminal for equipotential connections. This Product must be disconnected from the power supply before cleaning or disinfection. • This Product must be connected to a PC that complies with applicable IEC or ISO safety standards. Immerse the sensor in one of the cleaning solutions listed in Section 5.3 Care and Cleaning for no longer than 60 seconds. After immersing the sensor in disinfectant, wipe it dry with a clean, dry cloth. Use of other disinfectants may cause discoloration but will not affect the functional performance of the sensor.

Electrical safety

	CAUTION
	• The covers of the Product may be removed only by qualified and authorized technical personnel. • This Product may be used only in rooms or areas that comply with all applicable laws and regulations governing electrical safety in medical facilities, such as IEC standards requiring an additional ground terminal for equipotential connections. This Product must be disconnected from the power supply before cleaning or disinfection. • This Product must be connected to a PC that complies with applicable IEC or ISO safety standards. Immerse the sensor in one of the cleaning solutions listed in Section 5.3 Care and Cleaning for no longer than 60 seconds. After immersing the sensor in disinfectant, wipe it dry with a clean, dry cloth. Use of other disinfectants may cause discoloration but will not affect the functional performance of the sensor.

Explosion safety

	CAUTION
	• This Product is not recommended for use in the presence of flammable gases or vapors. Some disinfectants may evaporate and form flammable or explosive mixtures. If disinfectants of this kind are used, it is important to let the vapors disperse before using the Product again. • To improve Product performance and to provide updates and additional information, the contents of this manual are subject to change without prior notice.

X-ray protection

	CAUTION
	• The rules of dental radiography apply equally to digital X-ray systems. Appropriate radiation protection measures must continue to be used for patients. As a clinician, ensure that all non-essential personnel are clear of the immediate area when the sensor is exposed.

Biocompatibility / Infection Control

	CAUTION
 	• Because of the possibility of infection, only components and accessories recommended and approved by Rayence Co., Ltd. must be used with the sensor. • The wrap (hygienic sleeve) used with the sensor is intended for single use only. • Warning - Infection Risk: Reuse of the wrap is not permitted. Reusing the wrap may increase the risk of cross-contamination and infection

	and may result in harm to the patient or user. Put on a new wrap before inserting the sensor into the mouth for each use.

Indications

- Intra-Oral Sensor is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.

Contraindications

- The intra-oral sensor is contraindicated in patients who exhibit severe gag reflex or have anatomical anomalies of the oral cavity that may cause significant discomfort.

Side Effects

- No serious adverse effects directly related to the use of the intraoral sensor have been reported in clinical literature or post-market data.
- However, the following side effects may occur or are possible during normal use:
  - Oral discomfort or pressure pain, especially in patients with small oral cavities or during prolonged use.
  - Activation of the gag reflex, particularly in pediatric, anxious, or sensitive patients.
  - Minor mucosal irritation due to improper sensor positioning or repeated contact.
  - Cross-contamination or infection if appropriate hygienic measures (e.g.,disposable wraps/barrier protection) are not followed.
  - Improper reuse of disposable components (e.g., hygiene wraps) may lead to cross-contamination or increased risk of infection. This risk is mitigated through clear instructions in the IFU regarding single-use components and hygiene protocols.

Disposal of the Product

WEEE information in accordance with directive 2002/96/EC

(Waste Electrical and Electronic Equipment)

The crossed-out wheeled bin symbol shown on the Product indicates that, within the European Union, the Product must be disposed of via separate collection at the end of its service life. Therefore, at the end of the Product's service life, the user should deliver the device to an authorized collection facility for Waste Electrical and Electronic Equipment (WEEE). Alternatively, the user may return the Product to the seller, on a one-to-one basis, provided they are purchasing new equipment of an equivalent type and that performs the same functions as the original device.

Disposing of the Product separately prevents potential negative impacts on the environment and human health resulting from inappropriate disposal. Furthermore, it enables constituent materials to be recovered, leading to obtain significant savings in energy and resources.

Anyone who disposes of WEEE bearing the above symbol as unsorted municipal waste, rather than utilizing separate collection, is subject to the administrative sanctions in accordance with law.

Label Location

The label is located on the EzSensor HD device and packaging box.

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System Overview

System Description

This manual covers the installation and operating procedures for the ***EzSensor HD (IOS-U20IF, IOS-U15IF, IOS-U10IF), collectively or individually referred to as EzSensor HD or the Product***.

IOS-U20IF and IOS-U20VF models are Size 2.0, IOS-U15IF and IOS-U15VF models are Size 1.5, and IOS-U10IF and IOS-U10VF models are Size 1.0.

Unless otherwise specified, all information contained in this manual applies equally to all EzSensor HD types.

The product meets the following performance claims

1. The images produced are of diagnostic quality
2. The radiation dose is equivalent to or lower than traditional film

Table 1 Specifications

Parameter	Description
Detector Structure	CMOS Photodiode Array
Dimensions (W x L x T)	Size 1.0: 1.44 x 1.00 x 0.19 inch (36.8 x 25.4 x 4.8 mm) Size 1.5: 1.55 x 1.15 x 0.19 inch (39.5 x 29.2 x 4.8 mm) Size 2.0: 1.69 x 1.28 x 0.19 inch (42.9 x 31.3 x 4.8 mm)
Pixel Pitch	High Resolution mode: 0.0148 mm Normal resolution mode: 0.0296mm
Active Pixel Array	Size 1.0: 1.18 x 0.79 inch (30.01 x 20.01 mm) 2028 x 1352 pixels @ High Resolution mode 1014 x 676 pixels @ Normal Resolution mode Size 1.5: 1.30 x 0.94 inch (33.00 x 23.98 mm) 2230 x 1620 pixels@ High Resolution mode 1115 x 810 pixels @ Normal Resolution mode Size 2.0: 1.42 x 4.02 inch (35.99 x 25.99 mm) 2432 x 1756 pixels @ High Resolution mode 1216 x 878 pixels @ Normal Resolution mode

Parameter	Description
USB Cable Length between Controller and PC	2.7m
Electrical Rating	DC 5 V, 500 mA
Operation Mode	Global shutter
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 Regulation 2017/745 as a Class IIa device
Protection against Shock	Type B applied part
Ingress Protection	IP68

	CAUTION
	The Product must be installed, transported and stored within the permissible environmental conditions. Use the provided protective package for transporting or storage. Additionally, the Product must not be operated in oxygen-rich or explosive environments.

Product Components

The ***EzSensor HD*** installer must verify all items listed in the table below are present before installation. If the serial numbers of the individual parts do not match, do not install the Product. Contact your local distributor or authorized agent for support.

This Product should be connected with to a device that complies with IEC 60601-1.

Table 2 Ezsensor HD Product components

No	Components	Remarks
1	Sensor Module	2.7 m USB cable is all in one
2	Wrap (Hygienic Sleeves)	Single use only
3	Sensor Holder	Optional
4	Silicon Cover*	External Impact Protection
5	USB Memory	EzDent-i (Console SW) Install-package for sensor Product Manual

* Patient applied part

Sensor Module

The sensor module consists of a specialized CMOS sensor designed for radiographic applications and enclosed in a hermetically sealed, ergonomic capsule. The sensitive surface of the sensor is covered with a thin layer of scintillating phosphorous, which converts X-ray radiation into light and subsequently into an electrical charge.

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PC Specifications

Recommended Server PC Specifications

- Program language: ANSI C, C++
- Hardware Platform: IBM-PC Compatibility

  Minimum and recommended system requirements to run EzDent-i is described below.

- Server

Item	Minimum	Recommended
CPU	Dual-Core Processor @3.40GHz	Quad-Core Processor @3.4GHz or Higher
RAM	4GB	8GB or Higher
Display	1280 × 1024	1920 × 1080 or Higher
Network	100M Ethernet LAN (CAT 5 cable) or 802.11n Wireless Network	1G Ethernet LAN (CAT 5E cable) or Higher or 802.11ac Wireless Network or Higher

- Client

Item	Minimum	Recommended
CPU	Dual-Core Processor @2.7GHz	Dual-Core Processor @3.2GHz or Higher
RAM	4GB	4GB or Higher
Display	1024 × 768	1920 × 1080 or Higher
Network	100M Ethernet LAN (CAT 5 cable) or 802.11n Wireless Network	1G Ethernet LAN (CAT 5E cable) or Higher or 802.11ac Wireless Network or Higher

- Operating system: Windows 10 or higher
- Off-the-shelf: Commercial Program OS

	CAUTION
	We cannot guarantee that EzDent-i will work properly on an unregistered or non-genuine copy of Microsoft Windows. Therefore, a registered, genuine version of Microsoft Windows must be used.

	NOTICE
	• Disable the Windows Firewall service to ensure proper network communication 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.

Installation of Software Driver

	NOTICE
	• To operate the intraoral sensor, you must install the EzSensor HD Driver. • This Product must be connected with to a device that complies with IEC60601-1

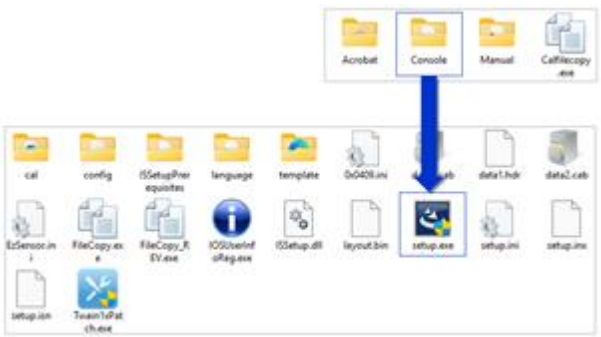
Setup for sensor Install-package

The EzSensor HD supports manual installation. ***Manual Installation***

This step is necessary for the installation of the EzSensor HD. The capturing software and calibration data for the EzSensor HD are installed and downloaded, along with the Windows device driver. A Twain driver is also installed during this step.

Step 1:

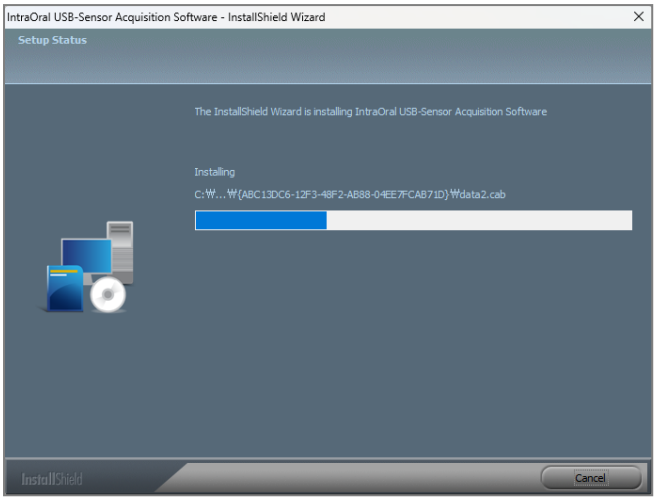
Insert the USB drive containing the software installation files. Connect the USB to the PC and run the setup.exe file.



Homedirectory:\Console\setup.exe

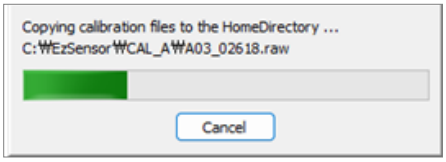
Step 2:

The install program for 'IntraOral USB-Sensor Acquisition Software' will appear, and the installation process will begin.



Step 3:

After the Software (EzSensor) installation is complete, the calibration files are copied to the PC.



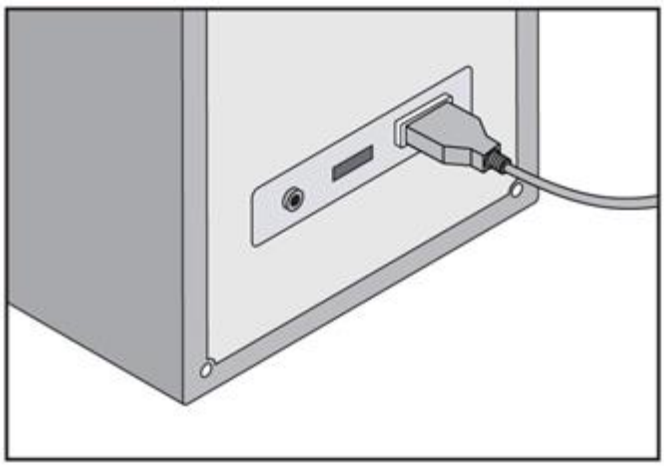
Cable connection & Driver Installation

	WARNING
	Connect only the components specified as part of the Medical Equipment System.

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

Step 1:

Connect the EzSensor HD USB Connector to the USB port on the PC.



Be sure to connect the USB port on the rear panel for proper operation.

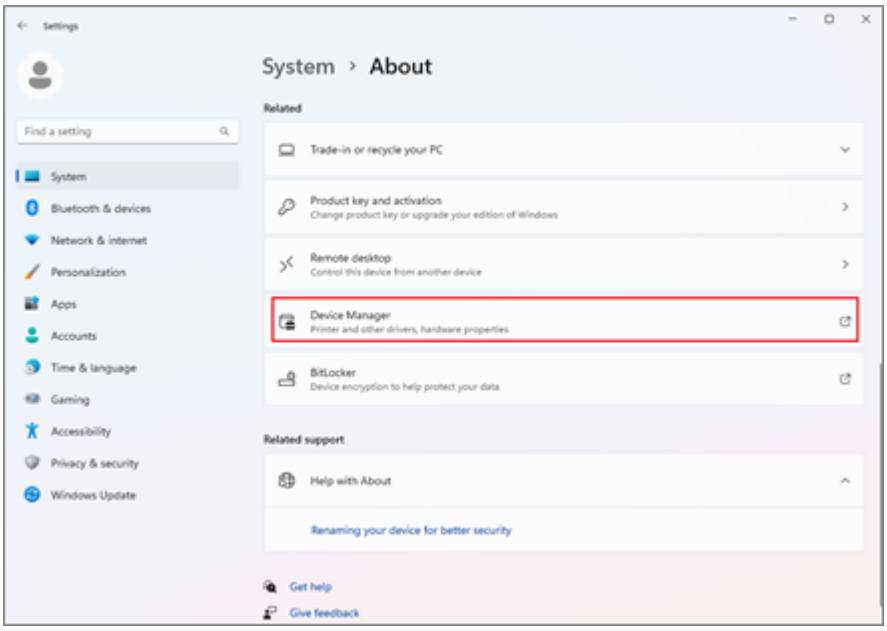
Step 2:

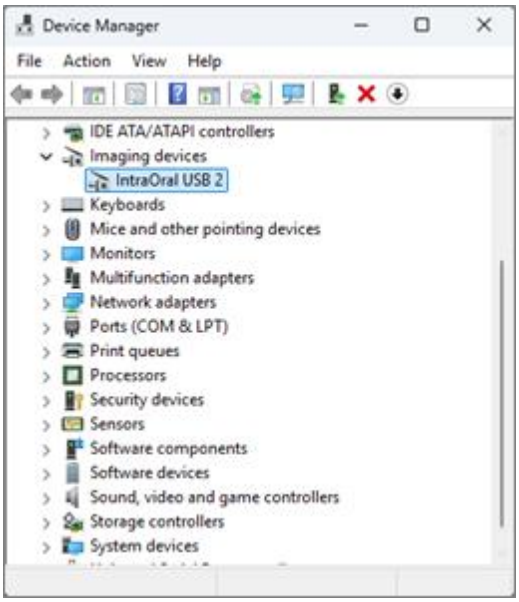
Confirm the driver installation at the Device Manager.

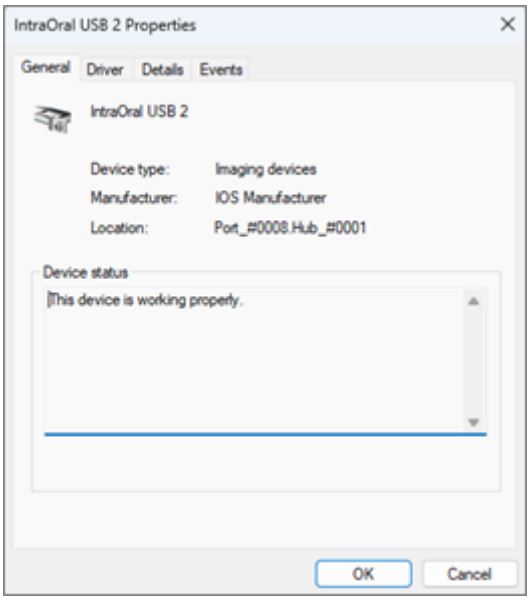
Method of Confirmation:

Windows 11: Settings → System → About → Device Manager

Select "IntraOral ~", located under Imaging Devices. You should see the message, "This device is working properly".







	CAUTION
	The EzSensor HD is supplied to the power and transports data via the USB port of the PC. Do not disconnect during usage.

Installation of the EzSensor HD Holder

The EzSensor HD holder is used for mounting the EzSensor HD to the wall when the device is not in use.

When choosing the installation location, select 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 included drywall screws.

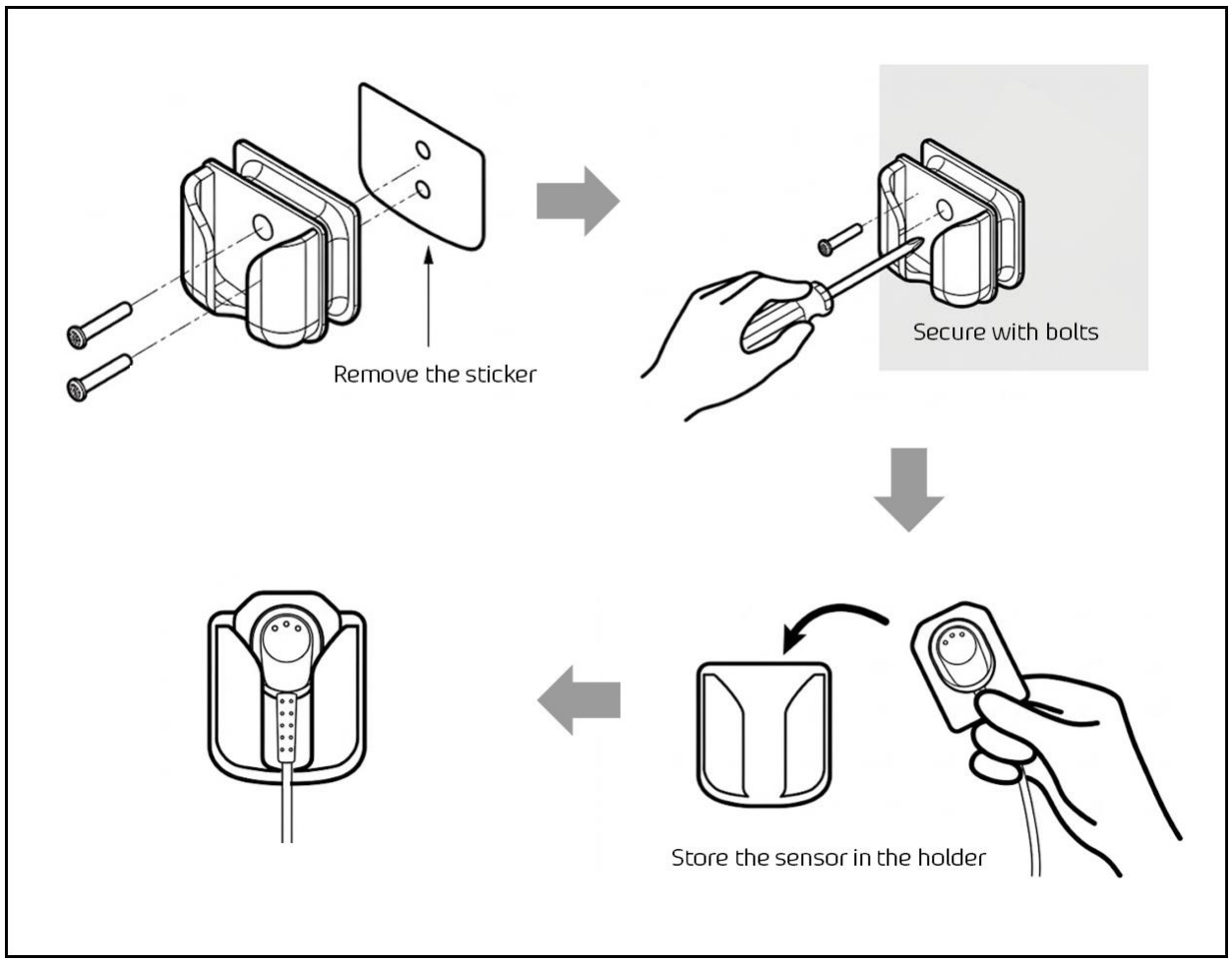


Image Acquisition Overview

	NOTICE
	This intraoral sensor package includes Console Software called EzDent-i and the accompanying user manual. Basically, the usage of EzDent-i is recommended. The detailed information for the user guide of EzDent-i is provided in EzDent-i user manual on the computer.

1. Turn on the computer.
2. Launch the EzDent-I software.
3. Configure the X-ray parameters (e.g., exposure time) on the X-ray generator.
4. Before using the sensor, perform an operation test by tacking an X-ray of a coin placed on the flat receptor side.
5. Position the ***EzSensor HD*** in the appropriate intraoral area. The flat receptor side must face the X-ray source. Using a sensor positioning aid is highly recommended to ensure the sensor is parallel to the tooth and at the correct exposure angle.
6. Press the exposure button on your X-ray source to acquire the image.

	NOTICE
	Normal Resolution Mode: Optimized for general diagnostic use, providing normal resolution with enhanced data readout speeds.

Care and Maintenance

For optimal performance, the MANUFACTURER recommends the working area be kept clean. Beyond standard care for maintaining aesthetic appearance, the ***EzSensor HD*** has no specific additional cleaning requirements.

Using the Sensor

Handle with care Avoid dropping or applying excessive force to the sensor.

Use a hygienic sleeve Always use a hygienic sleeve and change it for every patient.

Hold the connector when unplugging Do not pull the cable when disconnecting the sensor.

Place the sensor in the holder when not in use This helps prevent the cable from twisting or tangling and protects the cable from damage.

Do not twist the cable Twisting the cable may cause internal wire stress and lead to cable damage.

Prevent the patient from biting the cable Biting the cable may damage the cable insulation and internal wires.

Do not let the cable hang on the floor or near drawers The cable may be stepped on or pinched, which can lead to cable failure.

Do not pull the cable to remove the sensor Hold the sensor body or connector when removing it from the holder or hygienic sheath.

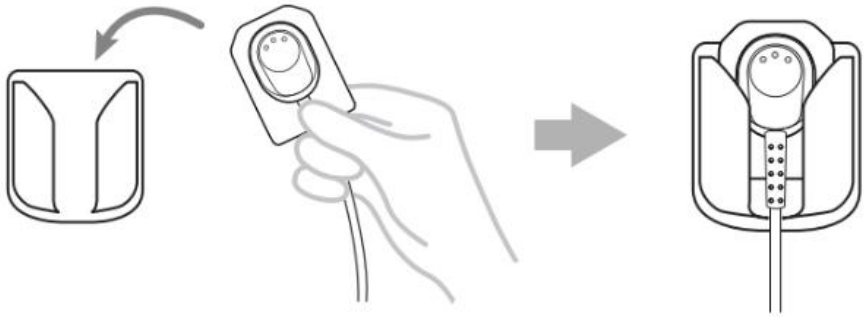
Do not coil the cable for storage Coiling the cable may cause permanent bending or internal wire damage.

Do not twist the hygienic sleeve around the cable Twisting may cause cable damage.

	NOTICE
	When applying a disposable hygienic sleeve to the sensor cable, ensure the cable is not twisted or kinked.

Storage

When the sensor is not in use, store it in the wall-mounted holder. Place the sensor securely in the holder and allow the cable to hang freely. Keeping the cable straight without twisting or coiling helps prevent cable damage and ensures long-term reliability.



	NOTICE
	When storing the cable, avoid coiling it to prevent permanent bending or internal damage.

Periodic Maintenance

Periodic maintenance should be performed as necessary and in accordance with monitored frequency in the table below. Maintenance may include various checks performed by the operator or by a qualified service technician.

- Check that all cables connected to the EzSensor HD are undamaged.
- Check for any external damage to the EzSensor HD that may compromise its ability to be safely operated. If the EzSensor HD is defective, it should be returned to the MANUFACTURER for repair.
- Arrange the sensor and control box USB cable to prevent damage to the cable's rubber tube. They should not be stepped on, bent sharply, or pressed under table legs.

NOTICE

A qualified service technician is a person authorized by the Manufacturer or its distributors.

Test List

Test Item	Frequency	Equipment
Connection	Daily	Sensor & PC
Cable	Monthly	Cable
Resolution	Annually	Resolution phantom (e.g., Gammex RMI)

Connection

Object

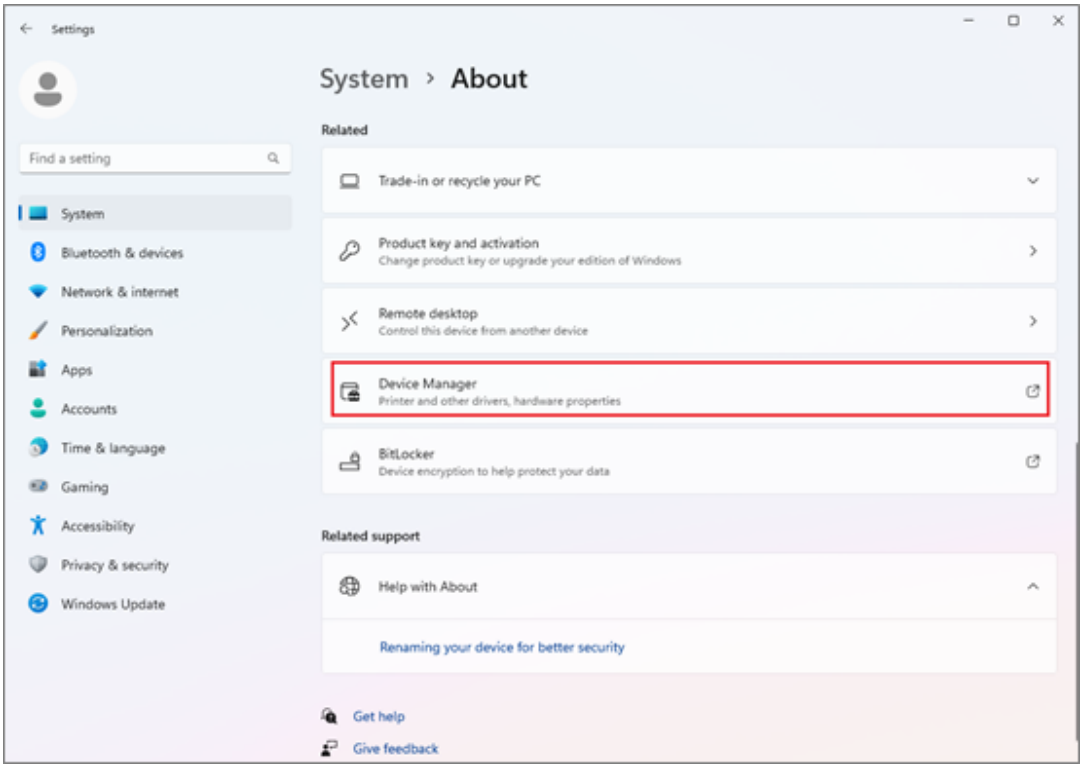
Check that the PC operates normally when the sensor is connected

Procedure

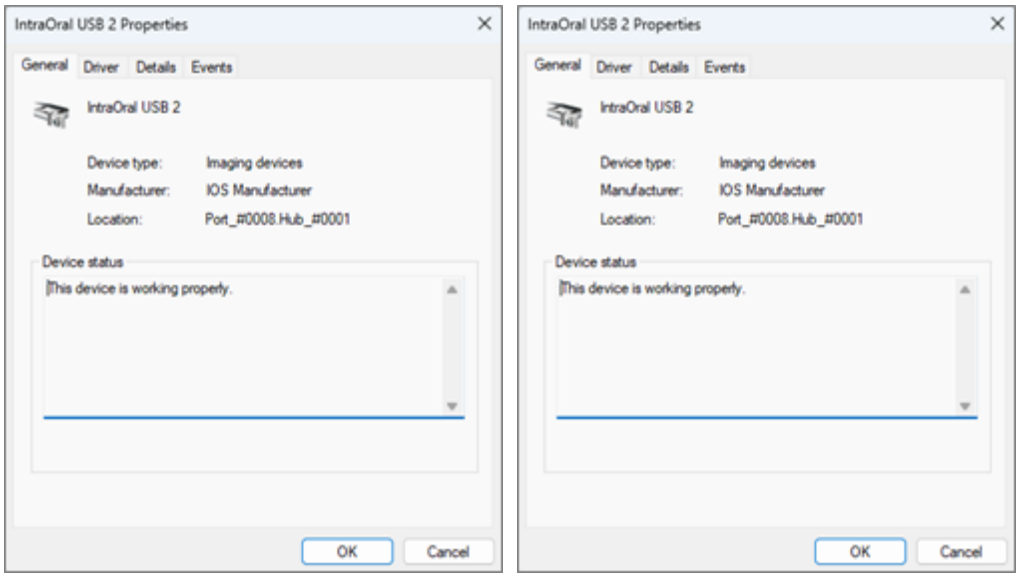
1. Connect the X-sensor USB connector to the USB port

2. Confirm the driver installation at the Device Manager Method of Confirmation:

   - Windows 11: Control Panel → System → About → Device Manager



3. Select "IntraOral USB x", located under Imaging Devices. You should see the message, “This device is working properly”.



Cable

Object

To prevent sensor malfunction caused by external cable stress.

Procedure

1. Arrange the sensor and control box USB cable to prevent damage to the cable's rubber tube. They should not be stepped on, bent, or pressed under table legs.
2. Check that all cables connected to EzSensor HD are undamaged.

Resolution

Object

Verify the resolution of the EzSensor HD

Procedure

1. Run EzDent-i with connecting EzSensor HD.
2. Attach the resolution phantom (e.g., Gammex RMI) to the detector in a diagonal orientation.
3. Set the X-ray exposure conditions to 60~70 kVp, 50 mAs, and SID to 28 cm.
4. Confirm that the resolution is over 8 lp/mm.

Cleaning

In order to prevent infection, wipe the front plate of the sensor unit with ethanol or a glutaraldehyde solution each time the device is used on a different patient. If you plan to use a disinfectant other than those specified above, or to mix another disinfectant with ethanol, consult a specialist, as it may damage the front plate.

To clean the EzSensor HD, use one of the cleaning solutions listed below. Please observe the precautions noted.

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

Do not soak or immerse any part of the Product. Ensure that the product is completely dry after cleaning.

Clean the surface of the Product by moistening it with a soft cotton swab dipped in one of the cleaning solutions listed above. Gently wipe the surface from end to end in straight lines without applying any pressure. Ensure that no liquid enters the Product through the USB cable or the sensor cable connectors.

After cleaning the surface of the EzSensor HD, use a clean lint-free cloth to dry the Product, as required, until the surface is clean.

NOTICE

- The device is designed for repeated use for up to 7 years under normal conditions. The silicone cover is intended for repeated use and should be maintained according to the Care and Cleaning instructions in the Instruction for Use to ensure safe use throughout its reusable lifecycle.
- 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

Precautions

- Do not soak the sensor in water or alcohol.
- Only authorized service personnel may repair calibration issues.
- Service personnel may not handle problems not mentioned in this manual.
- Please request repairs from the MANUFACTURER through a VATECH dealer.
- Equipment and accessories are to be disposed of safely at the end of the Product's service life. National regulations must be observed.

Product Complaint

Any health care professional (e.g., a customer or user of Product or system) with a complaint should notify his or her distributor first, who will handle such issues.

If the Product may have caused or contributed to a serious injury of a patient, the distributor should immediately notify the MANUFACTURER by telephone, fax, or written correspondence. The MANUFACTURER will report the incident to the government according to their reporting process.

WARNING

Do not modify this equipment without authorization of the MANUFACTURER.

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Warranty

The MANUFACTURER hereby warrants EzSensor HD (“Product”) against defects in materials and workmanship under normal usage and service for the period specified in the purchase agreement from the date of installation.

If the Buyer promptly notifies the MANUFACTURER or the Seller regarding any parts that fail to operate as specified under normal usage during the Warranty Period and the MANUFACTURER determines that such failure resulted from a defect in materials or workmanship during the Warranty Period, then the MANUFACTURER, at its option, shall repair, rebuild or adjust the affected parts.

The MANUFACTURER shall have no obligation for any defects that arise from (i) normal and fair wear and tear; the Product being modified without the MANUFACTURER's approval, (ii) installation not performed in strict conformity with the MANUFACTURER 's directions or having been subjected to electrical damage or other abuse, or damaged by improper handling, storage, or used by a third party, (iii) use of the Product in combination with devices or products not purchased from the MANUFACTURER; (iv) use or application of the Product in a field or in an environment for which such the Product was not designed or intended; (v) use of any parts or materials not provided by the MANUFACTURER for warranty service (vi) maintenance by a third party not certified by the MANUFACTURER; or (vii) force majeure events such as natural disasters.

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

The warranty period for the Product shall include the replacement of non-consumable parts and the labor required to correct warranty issues.

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

This Warranty constitutes the entirety of the MANUFACTURER’s responsibilities regarding the Product, including the sale of the Product, the events giving rise to the sale of the Product, any 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 the Buyer’s exclusive remedies. The MANUFACTURER 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 the Buyer to the Seller (i.e., MANUFACTURER or the MANUFACTURER’s dealer). Without limiting the generality of the foregoing, under no circumstances shall the MANUFACTURER be liable for damages related to loss of use, loss of time, loss of data, inconvenience, commercial loss, lost profits or savings, or other incidental, special or consequential damages that arise out of the use or inability to

use the Product, even if the 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 specified, the MANUFACTURER 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 the MANUFACTURER after the warranty has expired, the MANUFACTURER reserves the right to charge a reasonable fee for the repair services provided to Buyer.

The MANUFACTURER shall be the sole arbiter in determining whether the failure occurred under normal usage (covered under warranty) or not (excluded from warranty). If the dealer or the Buyer disputes the result of the MANUFACTURER's investigation, the burden of proof shall rest on them.

Warranty Procedure

If the Buyer needs to submit a claim under this Warranty, the Buyer should immediately notify the MANUFACTURER or the Seller in writing at the following address:

Rayence Co., Ltd..

Website: www.rayence.com

14, Samsung 1-ro 10gil, Dongtan-gu, Hwaseong-si, Gyeonggi-do, Korea

User Manual

PART II. Appendix

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X-ray Exposure Guide

The required X-ray dose for achieving the best image depends on the following factors:

- X-ray source (tube assembly, MANUFACTURER, AC/DC, etc.)
- Distance between the beam focus and sensor
- Target tooth (object) for imaging
- Bone density and age of patient
- Other miscellaneous factors

The X-ray dose directly influences image quality. Based on fundamental laws of physics, an insufficient dose generally increases image noise, resulting in poor detail discrimination. Conversely, an excessively high dose may cause the sensor to be overexposed. This condition is also perceptible as a reduction in detail discrimination, particularly in the low-density (darker) areas.

Image processing can mitigate differences in quality resulting from varying doses. Users can adjust brightness and contrast in the Options menu.

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

The X-ray dose is controlled by tube voltage (kVp) and current (mA), and exposure time according to the signal level.

	WARNING
	Image degradations caused by sensor overexposure cannot be corrected, whereas an insufficient dose can be partially compensated through image processing.

	NOTICE
	As exposure settings depend on the specific clinical situation, determining the final X-ray parameters is the sole responsibility of the treating physician.

Table 3 Recommendations on Exposure Time

Exposure Condition	Dose(µGy)	60 kVp 6 mA	60 kVp 2 mA	60 kVp 7 mA
Patient		Adult	Adult	Adult
SID		28 cm	18 cm	20 cm
IntraOral X-ray Unit (Model name)	No Filter	VX 70	AnyRay	EzRayP
		Approximate Exposure Time (sec)		
Incisor & Canine	300–500	0.12 –0.2	0.1–0.2	0.07–0.10
Molar	400–600	0.16–0.25	0.15–0.25	0.13–0.14

* SID: Source-to-imaging Receptor Distance

*Recommendations on Exposure Time are limited to the IntraOral X-ray Unit in the above table

NOTICE

- For larger body types: increase the tube current (mA) or exposure time by 25%
- For children (≥6 years): reduce the tube current (mA) or exposure time by 20%
- For edentulous patients: reduce the tube current (mA) by 20%.

NOTICE

- Since the X-ray exposure condition may vary depending on the patient age, gender, and bone density, pediatric exposure settings should be determined based on expert clinical judgment
- For further information, please refer to the FDA Pediatric X-ray Imaging webpage, http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm298899.htm

WARNING

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

Error Messages

- USB device driver is not installed.
  - Solution: Reinstall the EzSensor HD driver..
- Control box cannot be initialized.
  - Solution: Check and reconnect the USB cable.
- USB device driver is not working properly.
  - Solution: Reinstall the EzSensor HD driver.
- Capture program is already running.
  - Solution: Please close any other conflicting programs.
- Detector response timeout.
  - Check and reconnect the USB cable. If the issue persists, contact Customer Service.
- Data communication error.
  - Solution: Reconnect the USB cable.
- Canceled image capturing.
  - The user canceled the image capture process, Please try again.
- Cannot find dark frame.
  - Solution: Restore the EzSensor HD calibration data from the installation media(USB) or recalibrate the sensor. If the error persists, contact Customer Service.
- Cannot find bright frames for calibration.
  - Solution: Reinstall the EzSensor HD driver or perform a recalibration.
- Bad Pixel Map correction error.
  - Solution: Restore the calibration data from the installation media or recalibrate the sensor.
- Wrong image processing parameters.
  - Solution: Check the X-ray source. If the problem persists, contact Technical Support.
- Cannot load 'EzSensor.dll'.
  - Solution: Reinstall the acquisition software.
- Require 'EzSensor.dll' is damaged.

- Solution: Reinstall the acquisition software.

Troubleshooting

If you experience any problems regarding the X-sensor during operation, please refer to the troubleshooting table below for corrective measures. If the problem persists, please contact your local Product distributor.

Table 4 Troubleshooting Table

Item	Description	Corrective Measure
1	A "PID 2XXX NO; #0 (Check Connection)" error message is displayed.	Unplug the USB PC cable from the PC connector. Open the Windows Device Manager and verify that the device is installed correctly. Alternatively, try a different USB port.

Electromagnetic Compatibility Information

Guidance and MANUFACTURER's declaration – electromagnetic emissions		
The EzSensor HD is intended for use in an electromagnetic environment as specified below. The customer or the user of the Product should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The EMISSIONS characteristics of EzSensor HD make it suitable for use in industrial areas and Professional healthcare facility environment (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Conducted emissions CISPR 11 Group1 Class A	Group 1 Class A	
Harmonics emission IEC 61000-3-2	A	The EzSensor HD is suitable for use in all establishments other than domestic environments, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided that the following warning is observed: **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the EzSensor HD, or shielding the installation location
Voltage fluctuations/Flicker IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The EzSensor HD is intended for use in an electromagnetic environment as specified below. The customer or user of the EzSensor HD 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	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air	Floors should be wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF Electromagnetic Field Immunity IEC 61000-4-3	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	When an image can be abnormal near a device using WPT, RFID, NFC and when this symptom is detected, distance or turn around enough." Please use it
Immunity to Proximity Fields from RF Wireless Communications Equipment IEC 61000-4-3	28 V/m Max. 385-5785 MHz In according to table 9 in IEC 60601-1-2	28 V/m Max. 385-5785 MHz in According to Table 9 in IEC 60601-1-2	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EzSensor HD including cables specified by Qpix solutions. Otherwise, degradation of the performance of this equipment could result.
Proximity Magnetic Felds IEC 61000-4-39 EN 61000-4-39	134.2 kHz, 65 A/m 13.56 kHz, 7.5 A/m	134.2 kHz, 65 A/m 13.56 kHz, 7.5 A/m	When an image can be abnormal near a device using WPT, RFID, NFC and when this symptom is detected, distance or turn around enough." Please use it
Electrical Fast Transient/Burst IEC 61000-4-4	AC Mains ± 2 kV, 100 kHz repetition frequency	AC Mains ± 2 kV, 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or dental hospital environment.
	Patient connected ± 1 kV, 100 kHz Repetition frequency	Patient connected ± 1 kV, 100 kHz Repetition frequency	

Surge IEC 61000-4-5	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV	Mains power quality should be that of a typical commercial or dental hospital environment.
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 60601-4-11	0 % UT:0.5cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0º	0 % UT: 0.5cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0º	Mains power quality should be that of a typical commercial or dental hospital environment. If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply (UPS) or battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m 50 Hz & 60 Hz	30 A/m 50 Hz & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC61000-4-6	3 V	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Product, including cables, than the recommended separation distance, calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
	0.15-80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	0.15-80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	
Radiated RF IEC61000-4-3	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz-2.7GHz 80% AM at 1kHz	Recommended Separation Distance $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 M $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 G 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) U_T is the A.C. mains voltage prior to applying the test level.

Note2) At 80 MHz and 800 MHz, the higher frequency range applies.

Note3) 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 radiotelephones (cellular/cordless), land mobile radios, amateur radio, and AM and FM radio broadcasts and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment created by fixed RF transmitters, an electromagnetic site survey should be conducted. If the measured field strength at the location where the Product is used exceeds the applicable RF compliance level above, the Product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or relocating the Product.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Product.

The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user The Product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The Product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74

1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for 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.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Product, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Rayence Co., Ltd.
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CE 1639

CE symbol grants the product compliance to the Medical Devices regulation 2017/745 as a class IIa device. Authorized by SGS Belgium NV, Notified Body.

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