EzSensor i

User & Installation Manual

- English

rayence

This document should be used as a guide only to instruct on the ***EzSensor i***.
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.

R-USM-706
Version: 2.0
Date: 2020-02-10

Preface

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

If you do not properly set the Product, which in turn causes the Product to malfunction or fail, we cannot guarantee any responsibility.

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PART I. User Manual

1. Introduction

1.1. Notice

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

Notice to users

For the improvement of product performance, supplementation, and 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 we be obligated to provide 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.

1.2. Conventions and Symbols

1. Convention

The following symbols are used throughout this manual to provide certain indications for an effective use of this product.

	Indicates useful information and tips on how to use our software and Products.
 CAUTION	Indicates important instructions. If not observed, malfunction or damage to the Product or other property may occur.

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

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

For other countries users: This device to use by or on the order of a licensed person (eg. doctor, nurse, dentist, X-ray professional, and radiologist) under the related laws in each country.

2. Symbols Descriptions

Item	Symbol	Description
1		Type B applied part
2		Refer to instruction manual/ booklet
3	CE 1639	Conforms to CE MDD 93/42/EEC (European Communities) concerning medical devices
4		Waste Electrical and Electronic Equipment
5		Manufacturer
6		Date of manufacture
7	SN	Serial number
8	EC REP	Authorized representative in the European Community

9		Handle with care not to wet
10		Handle with care
11		Fragile, handle with care
12		This way up
13		Intended for a single use.

1.3. Safety Instructions

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.

Indication for Use

***EzSensor i*, 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.

 CAUTION	Before each usage, check the outer surface of the ***EzSensor i*** for any signs of physical damage or defect. The surface of the ***EzSensor i*** should have a smooth finish, with no evidence of chipping or damage. Otherwise, contact your local product distributor for further instructions on how to proceed.
 CAUTION	To ensure the correct usage of the ***EzSensor i*** device in a clinical environment such as professional healthcare environment, for which the intended purposes correspond to its design and application, only dentists or their designated operators are authorized to operate this system
 CAUTION	Modifications and/or additions to the device must be conducted exclusively by MANUFACTURER or by parties expressly authorized to do so by MANUFACTURER. Any modifications or additions must always comply with the standards and generally recognized rules of good workmanship.
 CAUTION	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
 CAUTION	Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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

- **Electrical safety**

 CAUTION	The covers of the device may be removed only by qualified and authorized technical personnel..
 CAUTION	This device can only be used in rooms or areas that comply with all laws and regulations applicable to electrical safety on medical premises, such as IEC 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.
 CAUTION	This device should be connected with the product which is complied with IEC 60601-1. Water and other liquids must be kept at a distance to avoid penetration of the device. Liquids may cause corrosion or the device to short circuit. No protection is offered against liquid penetration..

- **Explosion safety**

 CAUTION	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.

- **Contraindications**
  - Display of cartilage structures
  - Display of soft tissue

- **Side Effect**
  - Using disposable wrap to avoid disinfection

1.4. Disposing of the Product

1. 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 a 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 Waste Electrical and Electronic Equipment Directive (WEEE Directive). Alternatively, the user can return the device to the seller, on a one-to-one basis, as long as he or she is buying a new one of equivalent type and has the same functions as the old one.

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

Anyone who disposes any electronic equipment as unsorted municipal waste rather than collecting it separately violates the administrative sanctions in accordance with the law.

2. Label Location

The label can be found on the ***EzSensor i*** device.

2. System Overview

2.1 System Description

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

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

The ***EzSensor i*** comes with the following features:

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

The product achieves performance claims with the followings;

1) The image produced is of diagnostic quality
2) The radiation dose is equal or reduced compared to film
3) That digital radiology techniques are compatible with various x-ray generators

Parameter	Description
Detector Structure	Low Noise Hybrid CMOS
Dimensions (W x L x T)	Size 1.0: 1.03 x 1.45 x 0.19 inch (26.1 x 36.8 x 4.95 mm) Size 1.5: 1.14 x 1.52 x 0.19 inch (29.2 x 38.7 x 4.95 mm) Size 2.0: 1.24 x 1.69 x 0.19 inch (31.5 x 42.8 x 4.95 mm)
Pixel Pitch	0.035 mm
Active Pixel Array	Size 1.0: 572 x 858 pixels (20.02 x 30.03 mm) Size 1.5: 686 x 944 pixels (24.01 x 33.04 mm) Size 2.0: 744 x 1030 pixels (26.04 x 36.05 mm)
Grayscale	4096 gray levels
Resolution	14.2 lp/mm (theoretical)
USB Cable length between Controller and PC	3m
Electrical rating	DC 5V, 500mA
Operation mode	Continuous
Ambient Temperature	10℃ to 30℃ (Usage) -20℃ to 60℃ (Transportation and Storage)
Relative Humidity	30% to 80% (Usage) 10% to 80% (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 matter/water	IPX0

***** *Specifications are subject to be changed without prior notice.*

< Table 1. Specifications >

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

2.2 System Components

The ***EzSensor i*** device installer should check the following items listed in the table below prior to 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 in compliance with IEC 60601-1.

No	Components	Remarks
1.	Sensor Module	
2.	Control Board Box	
3.	USB PC Interface Cable (3M)	
4.	Holder for Sensor	
5.	Silicon cover*	
6.	Wrap* (Hygienic Sleeves)	Single use only, Option
7.	USB Memory	EzDent-i (Console SW) Install-package for sensor Product Manual

* Patient applied part (Inside Patient environment)

<Table 2. *EzSensor i* System components>

1. Sensor Module:

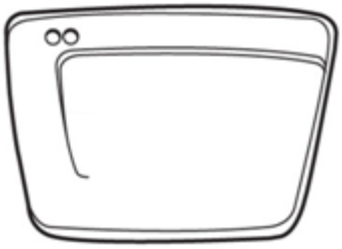
Consists of a special CMOS sensor, specifically designed for use in radiography, and is enclosed in a hermetically sealed ergonomic capsule. The sensitive surface of the sensor is covered with a thin layer of scintillating phosphorous, in which X-ray radiation is converted into light and then into an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

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. This conforms to the ISO 10993-1.

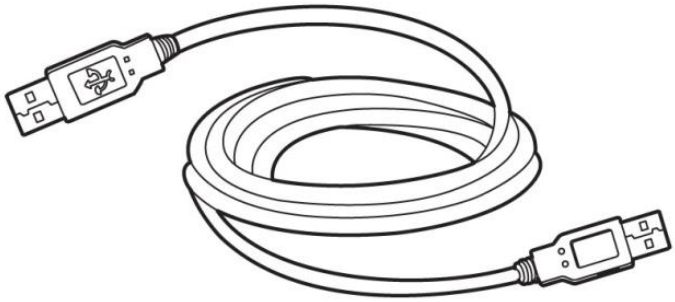
2. Control Board Box:

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



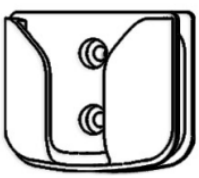
3. USB PC Interface Cable:

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



4. Holder for Sensor:

Used to stow the sensor when not in use



5. Silicon cover:

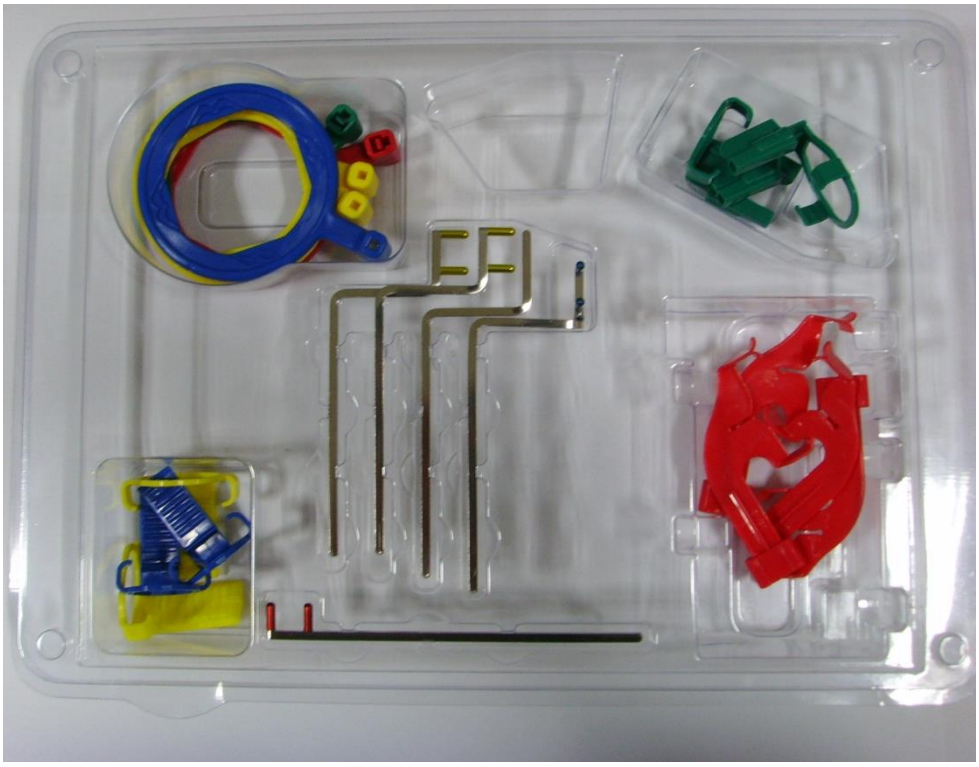
Used for protection from external shock.

6. Wrap (Hygienic Sleeves):

The sensor is supplied in a non-sterile state. Single-use wrap must cover the sensor before placing it in the patient's mouth. The used wrap should be disposed immediately. This conforms to the ISO 10993-1.

2.3 Sensor positioning accessories (optional)

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



Please refer to the Appendix for more information.

3. Installation

3.1 Prior to Usage

To operate the intraoral sensor, installation of the ***EzSensor i*** driver is required.
The device should be connected with the product in compliance with IEC 60601-1.

3.2 Specifications

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

3.2.1 PC Specifications

1. Operating System

- Microsoft Windows XP 32bit
- Microsoft Windows Vista 32bit
- Microsoft Windows 7 32bit
- Microsoft Windows 8(8.1) 32bit & 64bit
- Microsoft Windows 10 32bit & 64bit

2. Hardware requirements

- Main CPU: Intel Pentium IV 3.0 GHz
- Main Memory: 1GB of RAM (DDR2)
- Video Memory: 64 MB
- HDD: 80 GB (or better)

- CD-ROM (prefer CD-RW)
- USB Port
- Network Card: 1 EA
- Monitor: Min. resolution: 1024*768
- Keyboard/Mouse

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

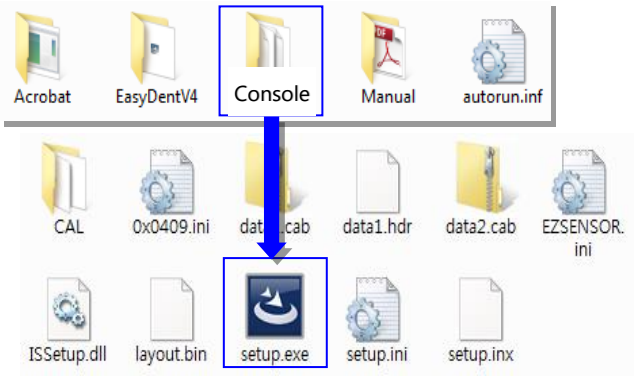
If you need to install additional software on your computer, please install only those that are internationally authorized. Take extra precaution when installing any Active-X controls.

3.2.2 *EzSensor i* Driver Setup

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

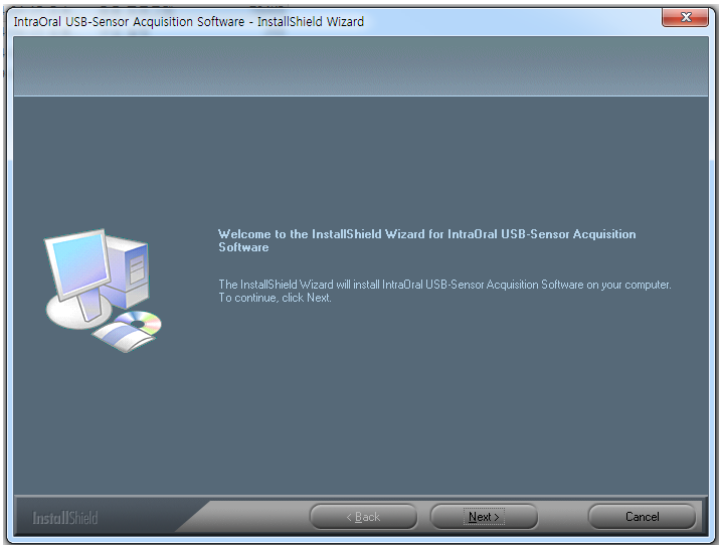
Step 1

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



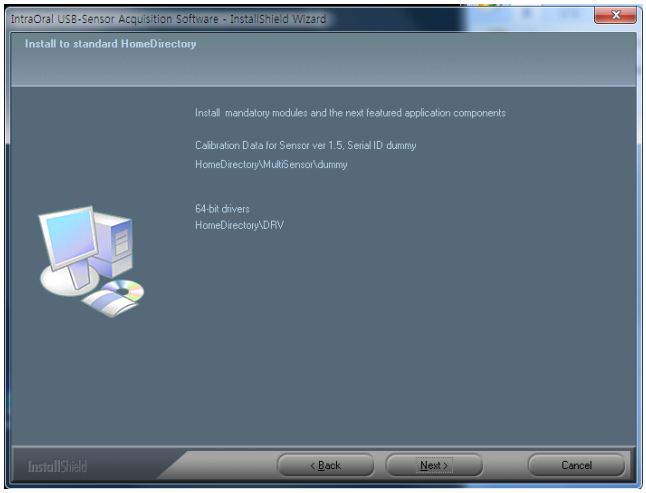
Step 2

The install program for 'IntraOral USB-Sensor Acquisition Software' will appear. Click the 'Next' button



Step 3

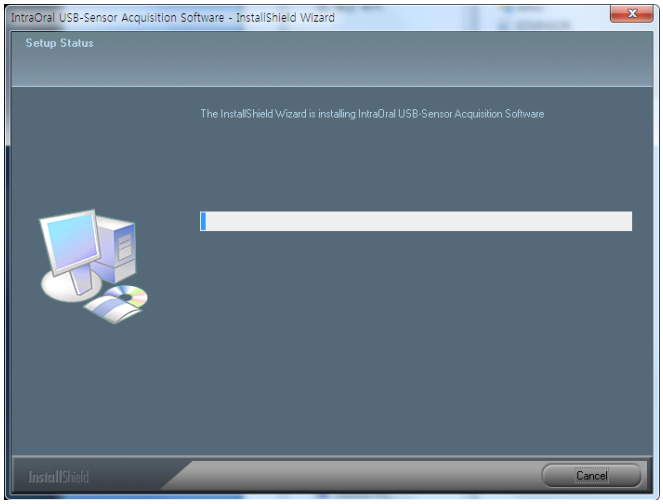
Check the ***EzSensor i*** installation directory and then click the 'Next' button..



Step 4

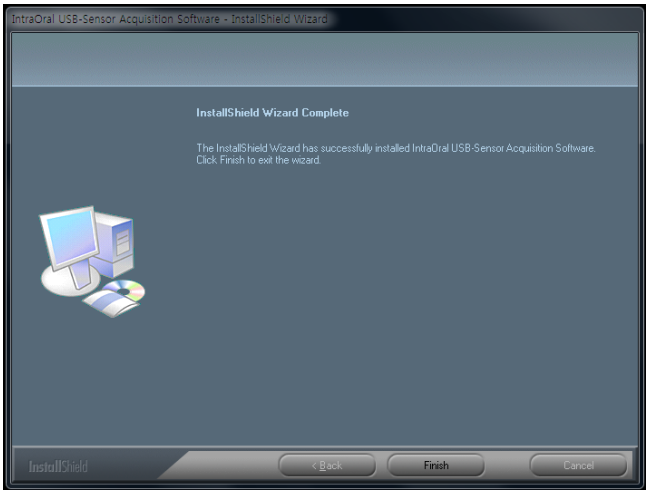
The Installshield Wizard will start configuring the installation parameters.

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



Step 5

The InstallShield wizard will be done.



3.3 Cable Connection & Driver Installation

CAUTION

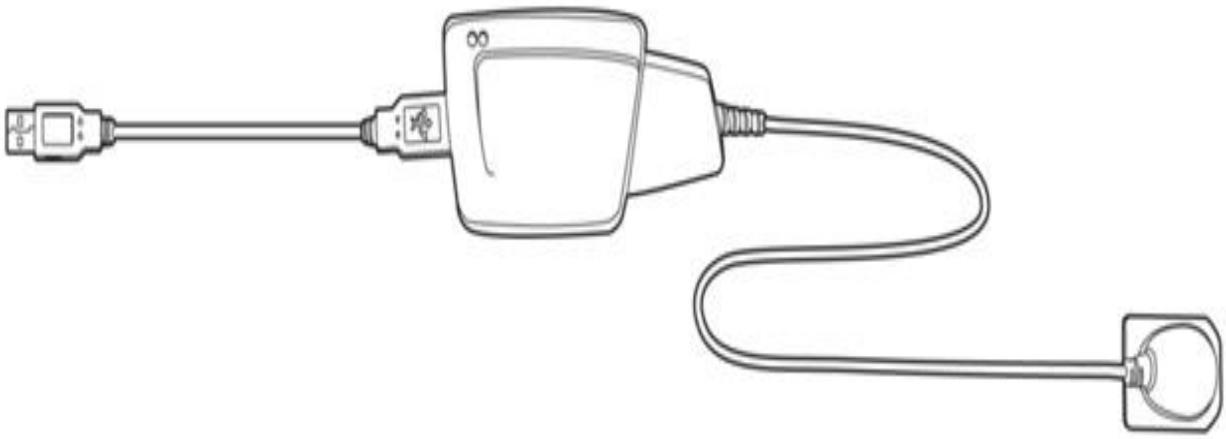
Do not connect the ***EzSensor i*** and USB PC Interface cable to your computer until you have successfully installed the setup program.

CAUTION

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

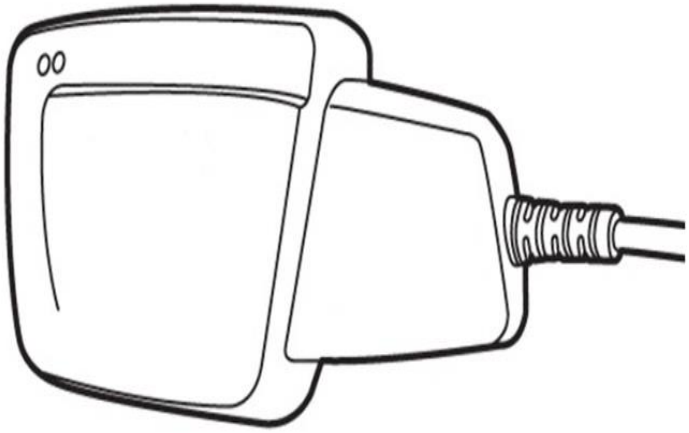
CAUTION

Only connect the item that has been specified as part of the Medical Equipment System.



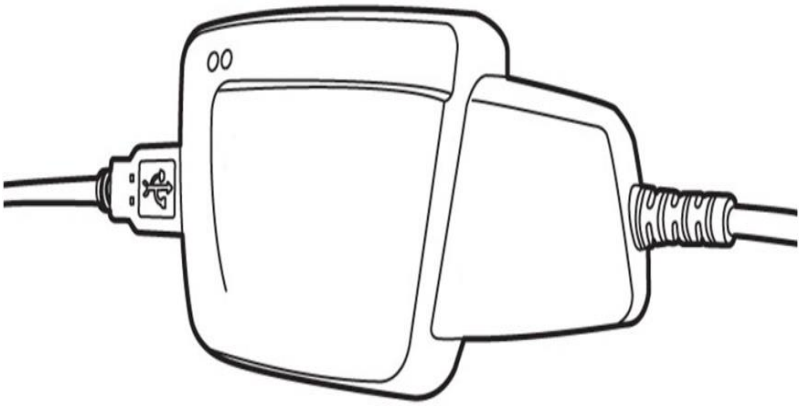
Step 1

Connect the ***EzSensor i*** Module to the Control Board box.



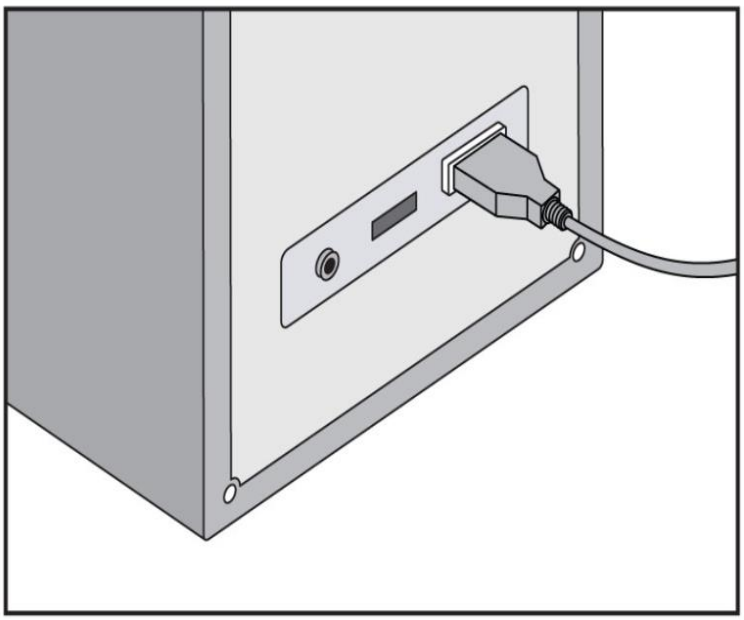
Step 2

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



Step 3

Connect the USB PC Interface cable connector to the USB port on the PC. **Be sure to connect the USB port on the backside for accurate operation.**



Step 4

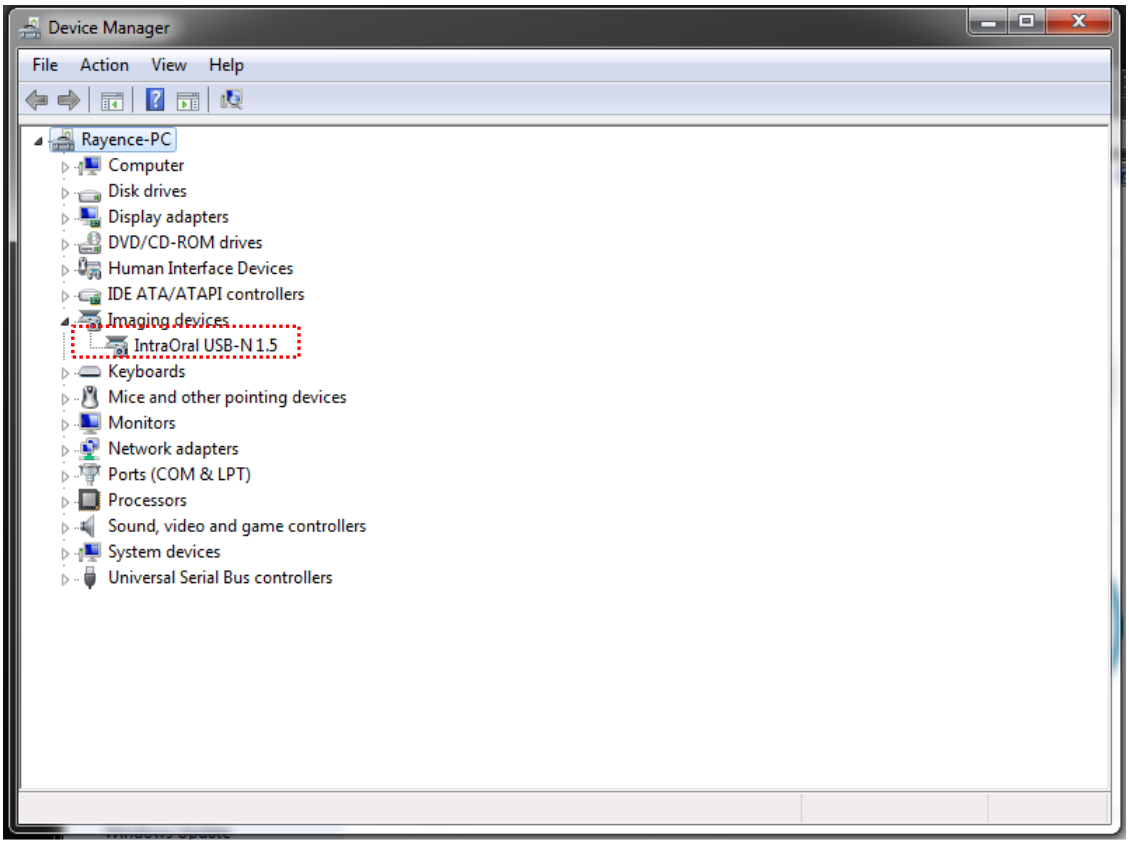
Confirmation of Driver installation at the Device Manager.

Method of Confirmation:

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

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

Select '**IntraOral USB-N xx'**, located under Imaging Devices. You should see the message, "This device is working properly".



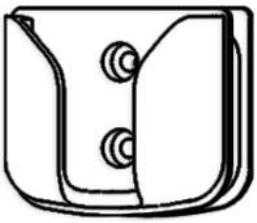
CAUTION

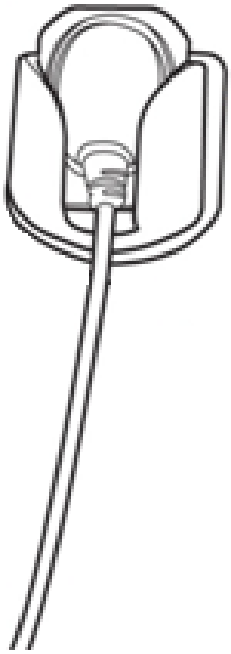
EzSensor i is supplied to the power and transports data via the USB port of the PC. Do not disconnect during usage.

3.4 Installation of the *EzSensor i* Holder

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

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





4. Image Acquisition Overview

This package for intra-oral sensor includes Console Software called EzDent-i with manual. Basically, the usage of EzDent-i is recommended. The detailed information for the user guide of EzDent-i is described to EzDent-i manual

① Turn on the computer.

② Run the ***EzDent-i***

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

④ Put a new wrap on the ***EzSensor i*** and connect it to the sensor positioning system.

⑤ Position the ***EzSensor i*** at the appropriate area in the mouth. The flat receptor side of the sensor must face the X-ray source. Note that the receptor side is marked with a label for ease of recognition.

The use of the sensor positioning aid is recommended to guarantee that the sensor is parallel to the tooth and is at the appropriate angle for exposure.

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

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

Using the *EzSensor i* with an intraoral X-ray

Using the EzSensor i with a Sensor positioning system (optional)

5. Maintenance

For optimal performance, MANUFACTURER recommends the working area be kept clean. There are no specific cleaning requirements for the ***EzSensor i*** beyond normal care and attention for aesthetic appearances.

5.1 Visual Inspection

Like all electrical systems***, EzSensor i*** 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 defects. If something out of order is suspected, contact your local VATECH product distributor for further instructions on how to proceed.

5.2 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 i*** are undamaged.
- Check for any external damage to the ***EzSensor i*** that may compromise its ability to be safely operated. If the ***EzSensor i*** is defective, the sensor should be returned to the manufacturer for repair.
- Arrange the sensor and the control box USB cable to prevent damage of the cable’s rubber tube. They should not be stepped on nor bent and pressed under table legs.

5.3 Care and Cleaning

In order to prevent infection, wipe the front plate of the sensor unit with ethanol or glutaraldehyde solution to disinfect it each time a different patient uses the instrument. If you plan to use a disinfectant other than those specified above, or you are mixing another disinfectant with ethanol, please consult a specialist because it may damage the plate.

To clean the ***EzSensor i***, the following solutions are 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 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 one of the cleaning solutions listed above. Gently wipe the surface end-to-end in straight lines, without applying any pressure. Make sure the liquid does not penetrate the system through the USB cable or the sensor cable connectors.

After cleaning the surface of the ***EzSensor i,*** 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

5.4 Precautions

- Do not soak the sensor in water or alcohol.
- Authorized service personnel can repair calibration issues.
- Service personnel cannot handle problems that are not mentioned in this manual.
- Please request repairs to the manufacturer through a VATECH dealer.
- Equipment and accessories are to be disposed safely at the end of the product life cycle. National regulation must be observed.

5.5 Product complaint

Any health care professional (e.g., a customer or user of this system of products) who has any complaints should notify his or her distributor first, who will handle such issues.
If the device may have caused or contributed to a serious injury of a patient, your distributor should immediately notify the manufacturer by telephone, fax, or written correspondence. The manufacturer will report it to the government according to their reporting process.

Do not modify this equipment without authorization of the manufacturer.

6. Warranty

MANUFACTURER hereby warrants ***EzSensor i***™ (“Product”) against defects in material and workmanship under normal usage and service for a period of 24 months from the date of installation.

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

MANUFACTURER shall have no obligation for any defects that arise from (i) normal and fair wear and tear; the Product being modified without MANUFACTURER 's approval, (ii) not being installed in strict conformity to 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 MANUFACTURER; (iv) use or application of the Product in a field or in an environment for which such the Product was not designed or contemplated; (v) use of any parts or material not provided by MANUFACTURER for warranty service (vi) the third party’s maintenance not certified by MANUFACTURER; 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 the Buyer and shall not extend to any person that purchases the Products from the 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 the Product shall including replacement of Non-Consumable parts and labor to correct warranty issues.

The Buyer will make all reasonable efforts to advise MANUFACTURER of the use of any non- MANUFACTURER authorized items, components, or parts in 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, MANUFACTURER charge for all costs associated with the repair service rendered.

This expresses all of MANUFACTURER'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 the Buyer's exclusive remedies. 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 Seller i.e., MANUFACTURER or MANUFACTURER's dealer. Without limiting the generality of the foregoing, under no circumstance shall MANUFACTURER 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 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, 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 MANUFACTURER after the warranty has expired, MANUFACTURER reserves the right to invoice a reasonable fee for the repair services provided to Buyer.

MANUFACTURER 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 MANUFACTURER's investigation, the burden of proof is on them.

Warranty Procedure

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

RAYENCE Co., Ltd.

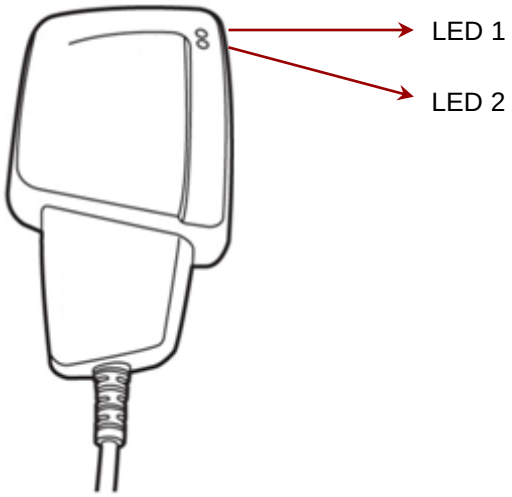
14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea

PART II. Appendix

1. LED Indicators

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

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



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

<Table 3. Description of LED Indicators>

2. X-ray Exposure Guide

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

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

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

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

The recommended exposure dose is from 300μGy to 600μGy when measuring without an object. Exposure time corresponding to the dose may vary depending on the X-ray equipment used. Recommended exposure times according to positions are as shown on the 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 an insufficient dose can be partially compensated through image processing.

Exposure condition	Dose (µGy)	60kvp 6mA	60kVp 2mA	60kVp 7mA
Patient		Adult	Adult	Adult
SID		**28cm**	**18cm**	**28cm**
Intra Oral X-ray Unit (Model name)	No Filter	*VX 70*	*AnyRay*	*ESX*
		Approximate Exposure Time (sec)		
Incisor & Canine	300 ~ 500	0.12 ~ 0.2	0.1 ~ 0.2	0.18 ~ 0.28
Molar	400 ~ 600	0.16 ~ 0.25	0.15 ~ 0.25	0.24 ~ 0.34

* SID : Source to imaging receptor Distance

*Recommendation on Exposure Time is limited to Intra Oral X-ray Unit in the above table

<Table 4. Recommendation on Exposure Time >

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

CAUTION

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

3. Error Message

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Trouble shooting

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

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

<Table 5. Troubleshooting Table>

5. Electromagnetic field information according to IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions		
The Product 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 Product uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class A	The Product is suitable for use in all establishments, including domestic establishments, and those directly connected to a personal computer USB port used for domestic purposes. **NOTE**: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonics emission IEC 61000-3-2	A	
Voltage fluctuation IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions			
The Product 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.			
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, relative humidity should be at least 30%.
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 hospital environment.
	Patient connected	Patient connected	

	± 1 kV, 100 kHz Repetition frequency	± 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 hospital environment.
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 60601-4-11	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0º	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0º	Mains power quality should be that of a typical commercial or 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 source 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 0.15-80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15-80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz	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** $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated RF IEC61000-4-3	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	**Recommended separation distance** $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

			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 deter-mined 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 application of 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 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 the location in which 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 necessary, such as re-orienting or relocating the Product. b Over the frequency range 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.

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