GENORAY

Intraoral Imaging System

GIX-1

For Veterinary Only

User Manual

UM-603 CE VET

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Preface

This manual provides information on the introduction and operation of **GIX-1** (hereinafter "**Product**") and is written based on standard specifications. Some contents may differ depending on the purchased product and specifications, and some contents may be changed without prior notice to improve product performance.

If you have any questions about this product and manual, please refer to the manufacturer or vendor information on the back cover of the document and contact the representative.

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1. Overview

This chapter describes the following: the definition of the manual, notations, warnings, overview of the device, user information, warnings in the manual, and labels and symbols on the device.

1.1) Overview of the manual

This section provides information regarding the definition of the manual, notations, warnings, signs, and the contents of the manual.

1.1.1) Definition of the manual

All the intended user of this manual should read this manual carefully, understand it thoroughly, and then operate the device. Keep this manual at an easily accessible location so that you can refer to the manual whenever needed.

This manual is provided together with shipment of the product.

This manual is applicable to the standard product specifications available at the time of shipping. For this reason, some contents herein may be different from features of the product delivered to your company.

1.1.2) Notations in the manual

"Notation" refers to special symbols or rules used in a user's manual.

This manual uses the following notation to allow the user to easily understand the contents of the manual.

Item	Description
" "	Used to indicate references. e.g., Refer to "Chapter 1 ____."
Bold	Used to indicate items displayed on the GUI, such as menu names and button names. e.g., Click the **Save** button.
>	Used to arrange several menu items or buttons in order. e.g., Click **Import** > **Open** button.
▪ ABC ▪ ABC ▪ ABC	Used to classify or organize equivalent items based on specific conditions.
1 ABC **2** ABC **3** ABC	Used to arrange the steps of a task procedure in order.
❶ ❷ ❸	Used to describe the names or details of components in an image.
① ② ③	Used to describe the order of actions in an image.

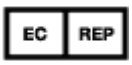
1.1.3) Warnings in the manual

Warnings in this manual are symbols that are intended to allow the user to easily understand the severity of personal injury or product damage that may occur during use of the product. Its color and statement differ depending on the risk level.

This manual defines warning signs as follows to allow the user to easily understand the level of risk.

	Failure to follow instructions marked with this sign may cause an accident or severe injury. Make sure that the user follows the instructions marked with a "Warning" sign.
	Failure to follow instructions marked with this sign may damage the product or embedded software or cause data loss. Make sure that the user follows the instructions marked with a "Caution" sign.
	This sign indicates instructions that must be checked by the user. Make sure that the user checks and follows the instructions marked with a "Notice" sign.
	This sign indicates instructions that must be noted by the user.

1.1.4) Symbols used in the manual

Symbol	Description	Location
	Type-B Applied Part	Label
	Type-BF Applied Part	Label
	WEEE Mark	Label
	Refer to instruction manual	Label
	Name of Manufacturer and Address	Label
	Manufactured Date	Label
	Device Serial Number	Label
CE 2460	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/ EEC as amended by 2007/47/EC as a class IIb device.	Label Manual
	Authorized Representative in the European community	Manual
	Authorized Representative in the Swiss community	Label Manual

1.1.5) Contents of the manual

This manual is composed of 5 chapters and an Appendix. A brief description of each chapter is shown below.

- Chapter 1. Overview

  Provides general information regarding the manual and the product.

- Chapter 2. Safety Instructions

  Provides information regarding the precautions the user must take for safe use of the product.

- Chapter 3. Image Acquisition

  Provides instructions to acquire images from the product.

- Chapter 4. Troubleshooting

  Provides details on how to troubleshoot problems that occur during the use of the product how to resolve the troubles.

- Chapter 5. Product Specification

  Provides the information regarding the standard of the product, its specifications, dimensions, environment of use, etc.

- Appendix

  Provides the information regarding the operation of the product.

1.2) Overview of the product

This section provides an overview of the product, including a brief description, the intended use, user classification, product labels, and information security.

1.2.1) Introduction of the Product

This product is an **Intraoral Sensor** to acquire an image for dentistry developed by Genoray Co., Ltd.

This product acquires the images using portable X-ray devices used by dentistry.

Product type

Model		Manufacturer
 GIX-1 PortView (Size 1)	 GIX-1 PortView (Size 2)	GENORAY
 EV71JU215 (Size 1)	 EV71JU213 (Size 2)	E2V

1.2.2) Purpose of use

This product is intended to acquire digital X-ray images of the patients for dentistry.

Do not use this product for any other purpose.

1.2.3) How to Use the Software

For detailed instruction on how to use the software, refer to the Software Manual.

1.2.4) User information

User classification

GENORAY classifies users as follows, depending on the scope of the product operation and use:

Type	Scope
Operator	Refers to the users that operate the product to acquire images. ▪ Professionals that acquire and review images Veterinarian or radiologists
Product administrator	Refers to the users that perform regular inspection and other maintenance of the product hardware and software. ▪ Medical or imaging professionals that perform quality assurance tests
Service manager	Refers to the service technicians of GENORAY that perform technical services on the product, including failure diagnosis, module repair, and component replacement. ▪ Maintenance staff that perform maintenance of the product, such as installation, configuration, setup, and calibration

NOTICE

Do not perform what is not permitted for the user role category you belong to.

User requirements

The product users require an understand and/or qualifications following items:

Item	Requirement
Education	Veterinarian's license, radiologist's license, or equivalent license (national license) or degree in the field.
Knowledge	▪ Understanding of the veterinary diagnosis and treatment ▪ Understanding of the terminology and instructions regarding the diagnostic medical X-ray device ▪ Understanding of the installation, operation, and configuration of the product ▪ Capability to diagnose using the diagnostic medical X-ray device ▪ Understanding of the purpose and the effect of the treatment
Language	Capability to read and understand the manual written in Korean, English, or other language.

Training program

GENORAY Co., Ltd. takes no responsibility for any damage or accidents caused due to inappropriate operation of the product.

Every user should be trained on the usage instruction of the product before using it. The user should contact the manufacturer or the vendor for more information regarding usage training.

1.2.5) Medical device classification and compliance

This section provides information regarding the class of the device and the standard of compliance.

Conformity notified for medical device

- Good Manufacturing Practice
- Common Standards for Electrical and Mechanical Safety of Medical Device
- Common Standards for Electromagnetic Safety of Medical Device
- Standards for Medical Device [Attachment 2] appliance and machinery 56. Diagnostic X-ray Device

Medical device classification

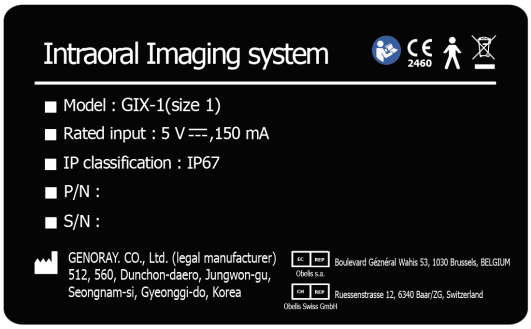
Item	Description
Protection against electric shock	▪ Class I medical device ▪ Type B applied part  ▪ Type BF applied part 

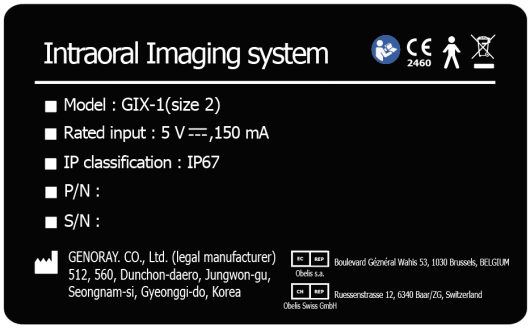
Standards and regulations

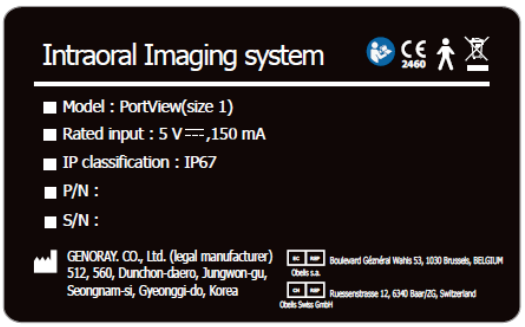
This device is designed and developed in compliance with the following international standards and regulations:

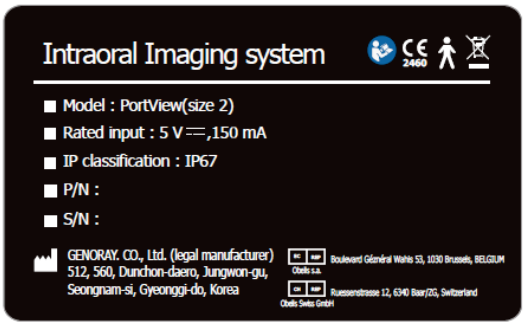
Standard	No.
IEC / EN	IEC / EN 60601-1
	IEC / EN 60601-2
	IEC / EN 60601-3
	IEC / EN 60601-2-45

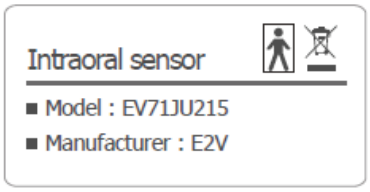
1.2.6) Labeling

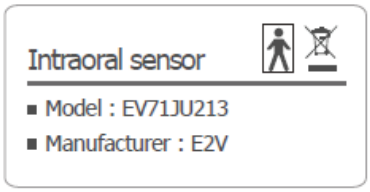












2. Safety precautions

This chapter lists the precautions and the types of safety products inside the product that the user must know to ensure safe use of the product, and provides details on how to operate and check the safety products.

2.1) General safety precautions

The following are the precautions regarding general risk factors that must be taken:

If any abnormality is found on a body part of a patient that came in contact with the product, immediately provide the patient with guidance on how to consult a dermatologist.

- Be cautious and ensure that clothing, accessories, or other objects are put near the product.
- Do not store the product in a humid environment or near liquids.
- Keep an eye on the patient's condition when acquiring images.
- If the patient or product shows any sign of abnormality, immediately stop operation of the product to ensure safety.
- Ensure that any accessory or component of the product is not put around the area of X-ray exposure.
- This product is not appropriate to be used in a location where there is flammable anesthetics or oxygen.

2.2) Radiation safety precautions

The user should comply with the laws and regulations of the radiation safety and protection of the country and region of use.

The device is prohibited to personnel who are not legally qualified to handle X-ray device.

- During exam, use the face guard to minimize the patient's exposure to radiation.
- While image acquisition is in progress, the user should stay at least 2 m (6 ft) away from the device. For more information on the dose, refer to **"Appendix 2 Dose information."**
- Be careful to refrain from going inside the radiation area except for the patient's body part that requires diagnosis.

- Only qualified users, who finished the special training or were assigned the job from the product manager, can handle the product.
- Without the user's observation of the safe value for exposure and the correct operation steps, the X-ray device can cause danger to both the user and the patient.
- When using the product, all users should wear radiation prevention device.
- Perform exam accurately to prevent additional exams, so that the patient is not excessively exposed to radiation.

2.3) Precautions before using

Please check the following precautions before using the Intraoral Sensor.

- Use it by following user's age, gender, body conditions, take care not to exceed the time required for diagnosis.
- Keep checking whether products and patient has problem. If products and patient have problem, keep the patient safe and stop operating.

Modifications and/or additions to the product 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. And using of unauthorized parts that cause product malfunctions of the intraoral sensor can affect product and user's safety.

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

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.

If your product is recognized as unsafe, immediately stop using it and check its condition. If any abnormality of the product is confirmed, contact the manufacturer or the sales company.

- Make sure to use a new disposable sanitary cover all the time.

  This protection cover complies with the biocompatibility standard ISO 10993-1.
- When you remove the sanitary cover on the product, be careful not to damage it.

- For a defective sanitary cover, replace it with a new one and dispose of the old one.
- Wrap the cover around the product as the following picture.

2.4) Precautions when using

Please check the following precautions before using the product.

- The hottest spot at the first 1.5 m part of the cable should not be hotter than 48 °C.
- The capture of the intraoral images should take no longer than 10 minutes.

Intraoral sensor has been determined to be in accordance with international safety standards and is deemed suitable for use within the patient area. To comply with these standards, do not operate non-medical device (such as a PC workstation) inside the patient area. Outside the patient area, the presence of approved non-medical grade device and Listed /Approved / IEC 60950-1 certified Information Technology Device (ITE) computer device is acceptable.

- The operator of this product should abide by applicable regulations of radiation safety and protection while using it in the patient's mouth. Due to the rigidity of the product, the patient may need time to adapt.
- The capturing positions depend more on the shape inside the patient's mouth, the operator's style of practice, and what is needed to be captured, rather than the position of the teeth.
- Use the product following the limitations decided by the external parameters.
- It is recommended for the operator to purchase a separate sensor holder to fix it, regardless of him/her holding the product with fingers to position the product to the capturing position inside the patient's mouth.

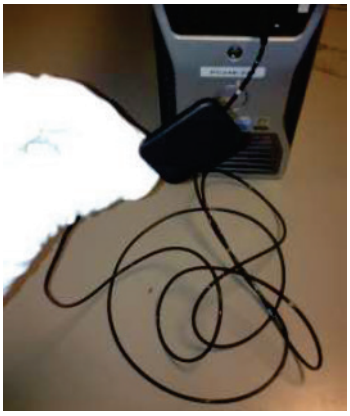
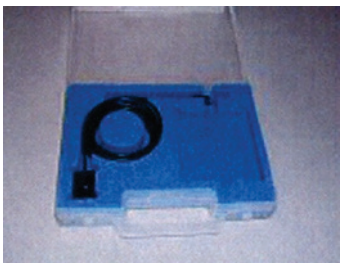
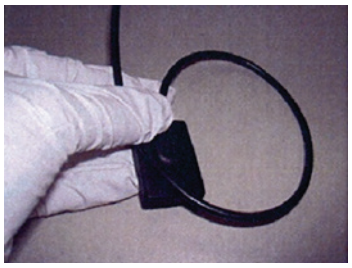
Water and other liquids must be kept at a distance to avoid penetration of the Product. Liquids may cause corrosion or the Product to short circuit. No protection is offered against liquid penetration.

How to Use the Product Properly

Here are several tips to use the product safer, thus longer.

Handling the product, check the followings:

- Be careful when using the product all the time.
- Refrain from hitting it on a solid surface.
  - E.g.: Falling it on a floor.
- Do not let the cable get tangled. Make sure to organize the cable when not using the product.


- Be careful not to damage the product while removing it from the positioning product.

CAUTION

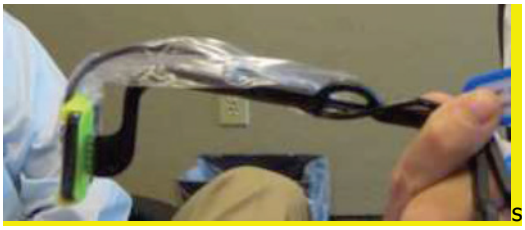
When the product is in the patient's mouth, let the patient keep looking at the operator.

Cases of Improper Use of the Product

The following situations can lead to malfunction of the product, so try to avoid such situations:

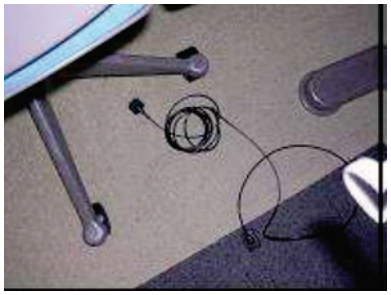
- Pressing hard on the cable;

- Pulling or bending the cable;



- Pulling the cable to unplug the product;
- Pulling the cable to remove the protective cap;
- Falling the product on the floor;
- Leaving the product or its cable on the floor;

  The cable may get tangled with a chair and trip someone while walking;



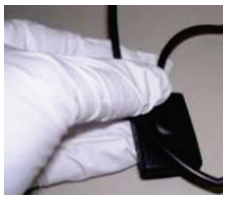
- Pinching the product or its cable.

2.4.1) Instructions for Cleaning

This product is not sterile medical product. Comply with the instructions for cleaning and disinfection and be careful not to damage the product.

CAUTION

Before cleaning and disinfection, put on a pair of protective gloves.



CAUTION

Do not disinfect the product in an environment with flammable anesthetic gas.

Recommended Disinfectant

For proper cleaning and disinfection, use the following recommended disinfectants:

Preferred disinfectant liquids	▪ ANIOXY TWINTM ANIOS Laboratories ▪ PHAGOCID DTM PHAGOGENE DEC.Laboratories
Other authorized disinfectant liquid	▪ CIDEX OPATM JOHNSON&JOHNSON ▪ DENTASEPT ultraTM ANIOS Laboratories ▪ RELYON PERASAFETM PHAGOGENE DEC. Laboratories
Forbidden products	▪ Alcohols Isopropyl Alcohol, Methanol ▪ SEKUSID-NTM ECOLAB PARAGERM Laboratories ▪ SEKUSEPT EasyTM ECOLAB PARAGERM Laboratories ▪ SEKUSEPT AktivTM ECOLAB PARAGERM Laboratories ▪ FD333TM DURR DENTAL Laboratories ▪ FD322TM DURR DENTAL Laboratories

Instructions for Cleaning and Disinfection

Check the followings when you clean and disinfect the product.

- Before applying the product to each patient, make sure to disinfect the product and the first 10 cm of the cable.
- Wipe the surface of the product using a cloth applied with disinfectant.
- It is recommended to disinfect the product by immersing it in the disinfectant. However, make sure to check the proper time of application recommended by the manufacturer of each disinfectant before the disinfection.

Cases of Improper Cleaning of the Product

- When you disinfect the connector, do not immerse it in the disinfectant.

- Make sure that there is no scratch or any damage on the surface of the product or the cable before disinfecting it. If you fail to comply with this instruction, it may lead to the malfunction of the product.
- The cover of the product is fragile enough to be damaged by impacts. Do not use improper cleaning tools.

2.5) Maintenance

Visual inspection

- Like any electrical system or product, this product requires visual inspection as well as proper use.
- Pre-operation and regular periodic inspection. These precautions will help keep your product safe and efficient.
- Before use, the user should check the product for any physical damage or defects. If any abnormality of the product is confirmed, contact the manufacturer or the sales company.

Regular maintenance

Regular maintenance should be performed according to need and frequency of use. Maintenance should consist of various checks performed by the user or a qualified service technician.

2.6) Instructions for Storage

To maintain the product safely, refer to the following instructions.

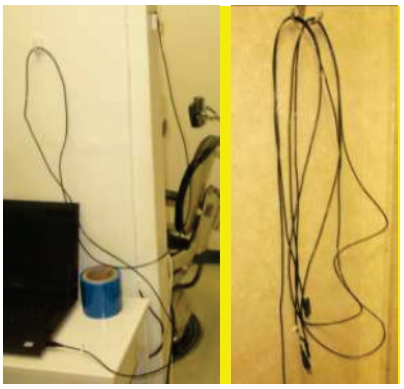
CAUTION

The original packaging provided with the product guarantees the optimal protection of the product. Use the packaging to protect the product while moving it or storing it.

Instructions for Proper Storage

- Fix the holder to the wall to store the product.

- For the cable, coil it around two hooks to organize.



- In case of moving the product, follow the following procedure:
  a. Remove the product carefully from the holder fixed to the wall.
  b. Keep the cable coiled around two hooks to keep organized.
  c. Keep the product with the holder on the wall at a new location.
- When keeping the product in the box, keep it in the following picture.

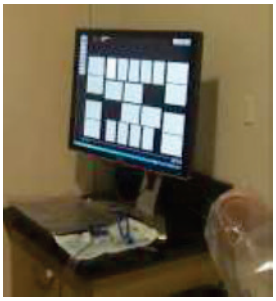
Cases of Improper Storage

Note that most of the accidents occur while the product is left unattended. If you do not coil the cable to organize, it can fall on the floor due to its weight. Be careful.

These are some examples of improper storage:

- Storing the product in a bag with not enough space;

- Leaving the product unattended on a shelf;



- Storing several sets of the product with the same hook;

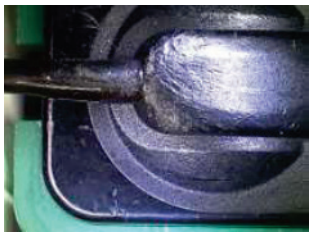
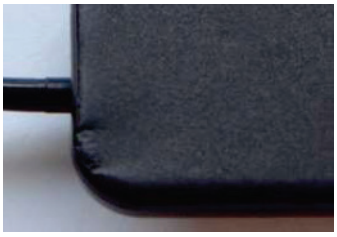
- Coiling the cable of the product around only one hook;

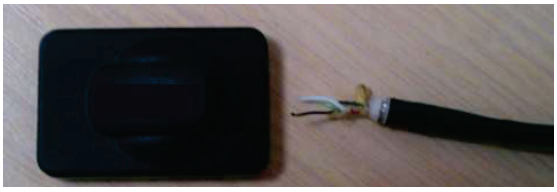
2.6.1) Cases of Breakage due to User's Negligence

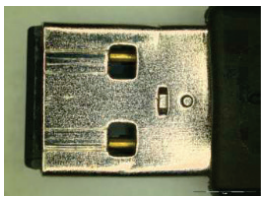
When the malfunction of or damage to the product is due to the user's negligence, such case is not entitled to a warranty. Please comply with all of the following while using the product.

Outside the Product

For the cover, cable, USB connector, etc., it is possible to identify the cause of damage from the aspect of such damage.

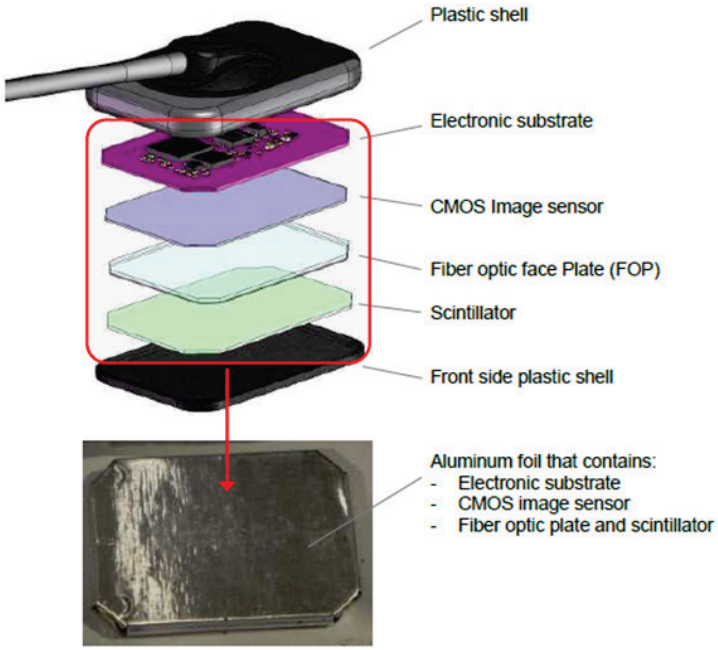
Cover damage due to user's negligence	
 Trace of impact	 Trace of crush
 Deformation and holes	 Holes and damage
Trace of the unapproved holder	Damage due to the use of prohibited disinfection methods, such as alcohol, bleach, heat, UV, etc.

Cable damage due to user's negligence	
 Deformation due to excessive twist	 Crack due to excessive twist
 Torn off	 Separation of the cable due to twist
 Separation of the cable	

USB connector damage due to user's negligence	
 Separation of the cable	 Deformation of the connector
 Deformation of the connector	 Deformation of the connector
 Deformation of the connector	Trace of contact to water

Inside the Product

The surface of the product is composed of plastics while the inside is with aluminum foil. In the aluminum foil, it contains the electronic substrate, CMOS image sensor, FOP, scintillator.



Depending on the condition of the aluminum foil, the use of the product can be affected.

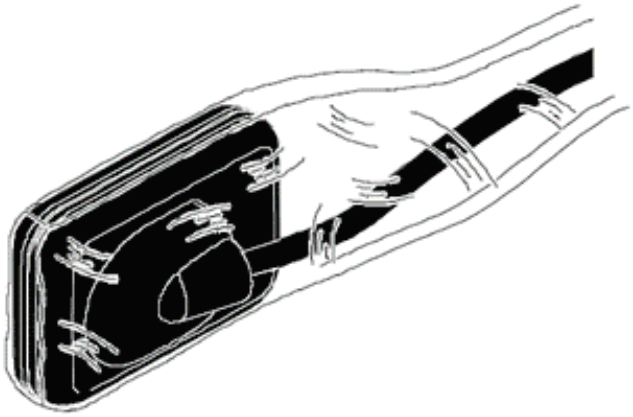
- If the product is pinched, it may leave a record mark on the aluminum foil.
- If excessive force is applied to the product, it may damage the inside of the product. Be careful.
- It is possible to identify the cause of damage to the interior of the product, the cable, and the connector from the aspect of such damage.
- The X-ray test can figure out if the cable and the connector are suitable to use.

3. Image Acquisition

This chapter provides how to acquire images.

3.1) Image acquisition method

1. Cover with a disposable hygienic sleeve (which can buy separately) specifically designed for each sensor size.



CAUTION

To prevent cross-contamination, use a new hygienic barrier for each new patient. (Recommendation to use approved biocompatibility product)

2. Set the exposure value (kV, mA, Sec) of the portable X-ray product appropriately for the patient.
3. Insert the product into the patient's oral cavity and set the imaging position.

NOTE

- The product is inserted into the oral cavity for approximately 5 to 10 seconds.
- When using the product with the Cone index installed, it is more convenient to set the intraoral shooting position.
- Sanitary cover and cone index are not separately supported.

4. Check the acquired patient image using the software. Edit, transmit, save, and output image as needed.

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4. Troubleshooting

This chapter describes how to resolve problems that may occur during use of the product.

NOTICE

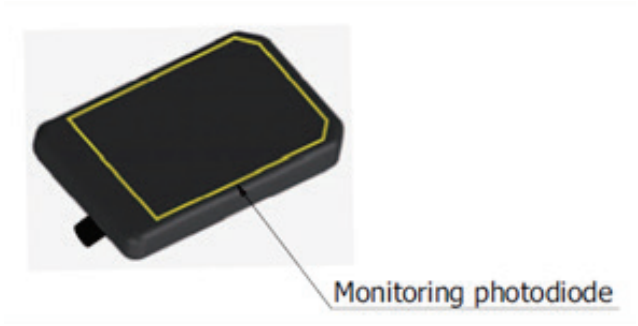
If the product still does not work properly after taking the following troubleshooting measures, contact GENORAY and follow the instructions of the service manager.

4.1) Solutions for failed image acquisition

This is a countermeasure in case an image is acquired without X-ray exposure or if image acquisition fails during X-ray exposure only when the Intraoral Sensor is connected to the USB port of a hospital computer without connecting it to PORT-X IV.

4.2) Failure of Image acquisition or Image acquisition without X-ray exposure.

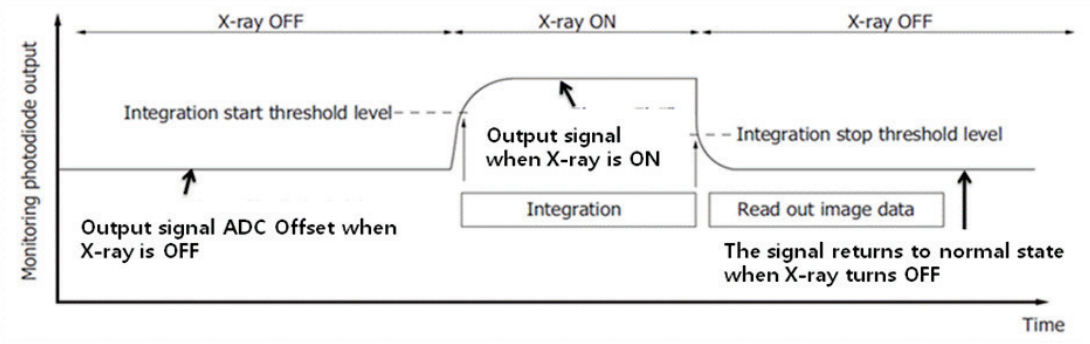
- The intraoral sensor will be used with a connection to the hospital PC which supplies the power to it.
  - Accordingly, the output characteristics of the sensor may be affected by the stability and quality of the computer power applied.
  - If the output characteristic of the sensor is affected, the image may be acquired or the image acquisition may fail without X-ray exposure.



- The intraoral sensor detects incoming X-ray signals within the effective area of the Monitoring Photodiode as shown above.

  After that, the X-ray start point and the X-ray endpoint are sensed and transmitted between them.

- The intraoral sensor captures the start of the X-ray signal (Integration start threshold level, Rising Edge), and the X-rays irradiated from that moment begin to integrate the signal and sense until the end of the X-ray (Integration stop, threshold level, Falling Edge) and the cumulative signal is output as an image.
  - The signal output from the sensor is expressed as an ADC offset signal.
  - This series of processes is called AED (Auto Exposure Detection) and is shown below.



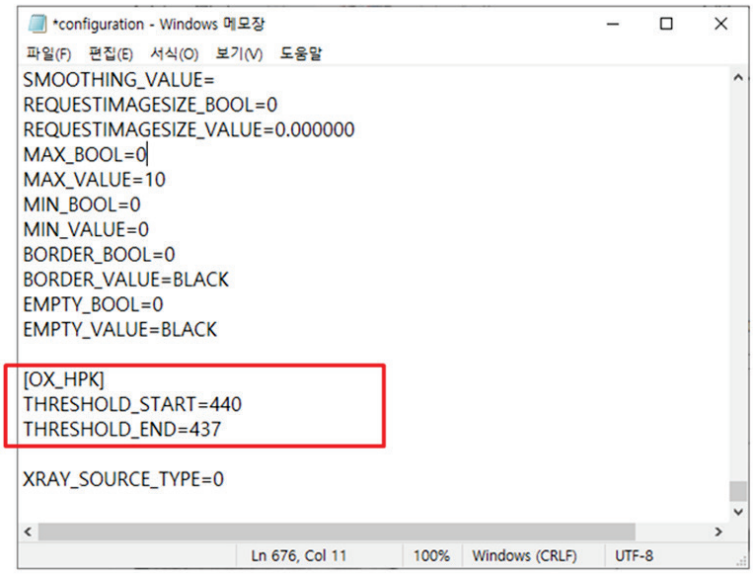
- It is recommended to set the signal value and threshold for each step as follows.

NOTE

Sensor output signal when X-ray off

ADC offset < Integration stop threshold level < Integration start threshold level < When X-ray on ADC offset.

  - Integration Start Threshold level and Integration End Threshold level can be set in the ini file.
  - The ADC offset value of the sensor depends on computer power stability.
  - For the first time installation, measure the ADC offset without X-ray exposure and the Threshold value is set to a range that allows the sensor to operate properly.



EX. Configuration.ini file

4.3) How to measure ADC offset and set threshold when X-ray is OFF

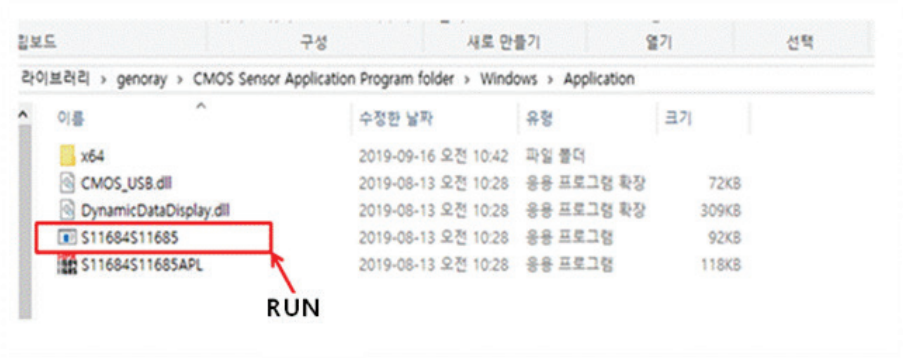
ADC offset is normal

- Connect the The GIX-1 will be used with a connection to the hospital PC which supplies the power to it.

1. to the USB port of the PC you want to install and run S11684S11685.exe.

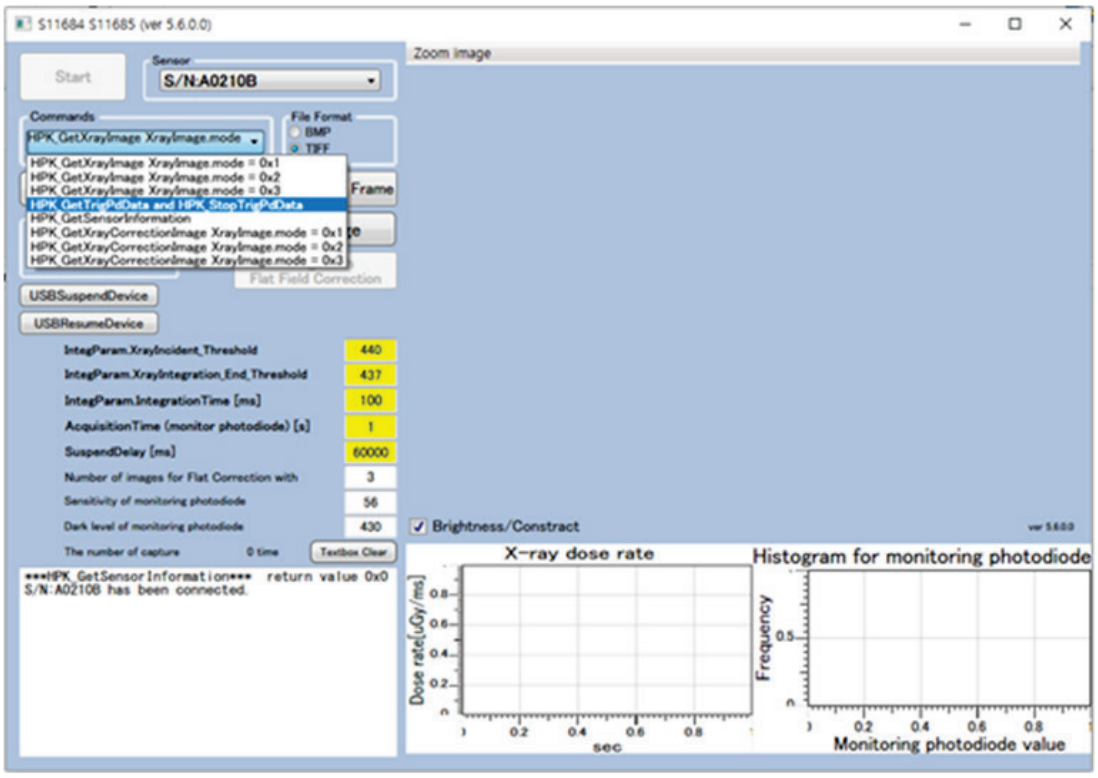
- The execution path is as follows :

  \\CMOS sensor application program folder/Windows/Applications/S11684S11685.exe

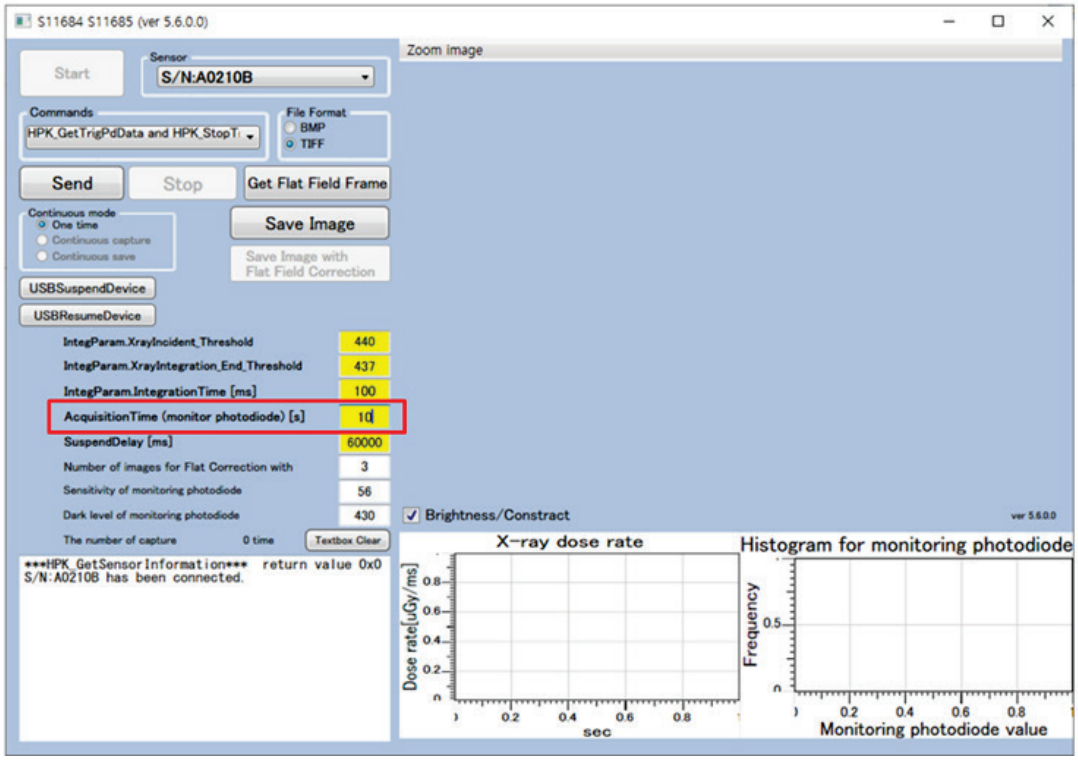


NOTE You can connect using a simple USB extension.

2. In the Command window, select HPK GetTrigPdData and HPK StopTrigPdData mode.



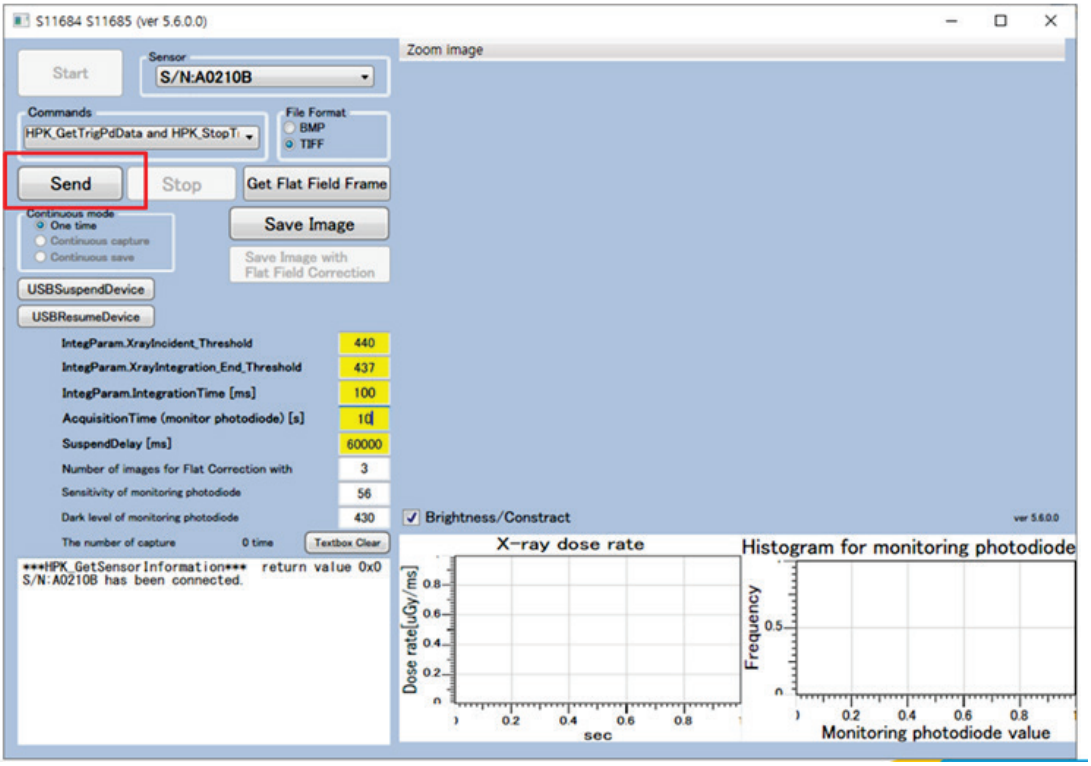
3. Change the Acquisition time[s] setting to 10 sec.



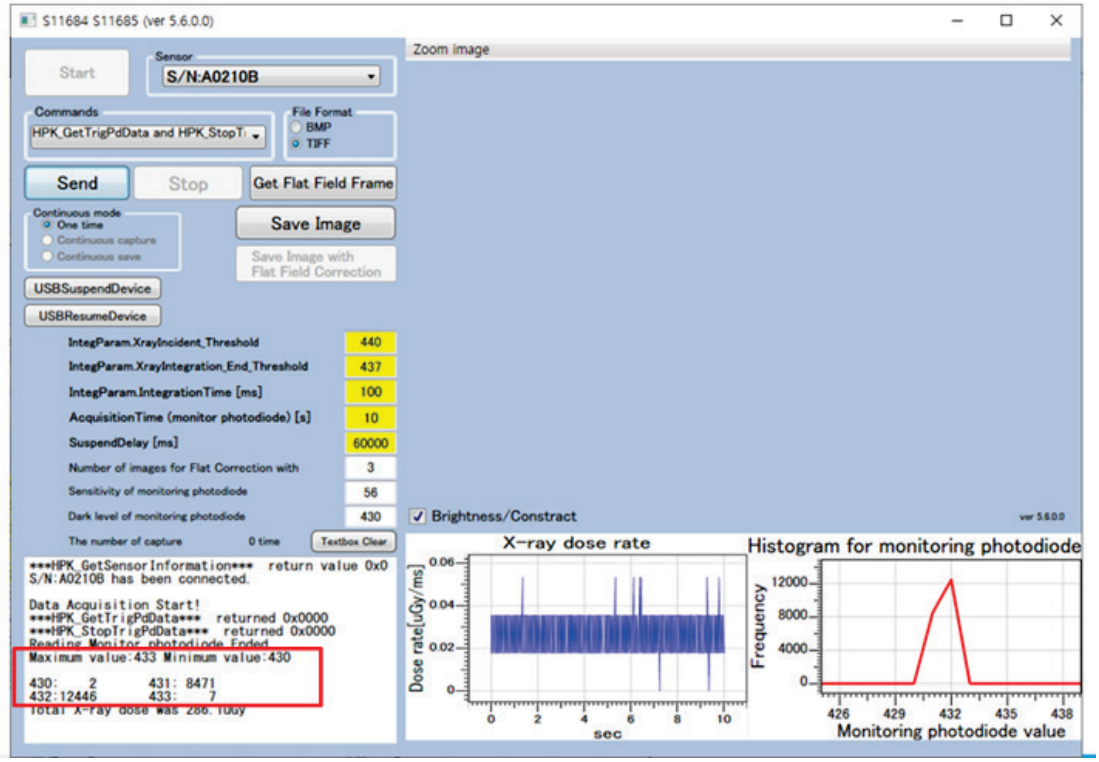
NOTE

The default value is 1 second.

4. Press the [Send] button.



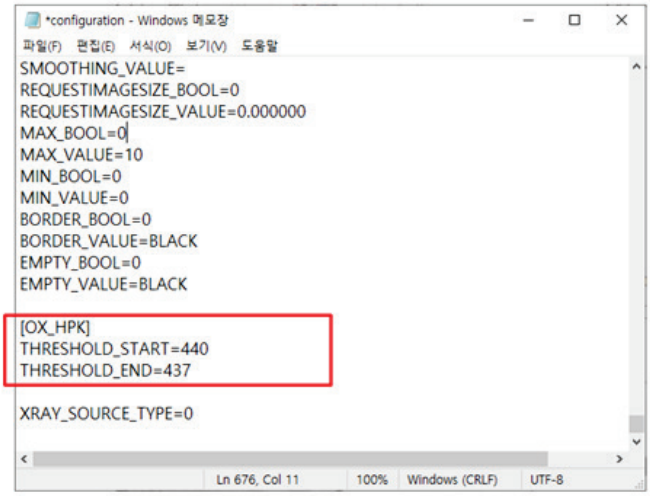
5. Check the ADC Offset value. The figure below shows the measured values from 430 to 433.



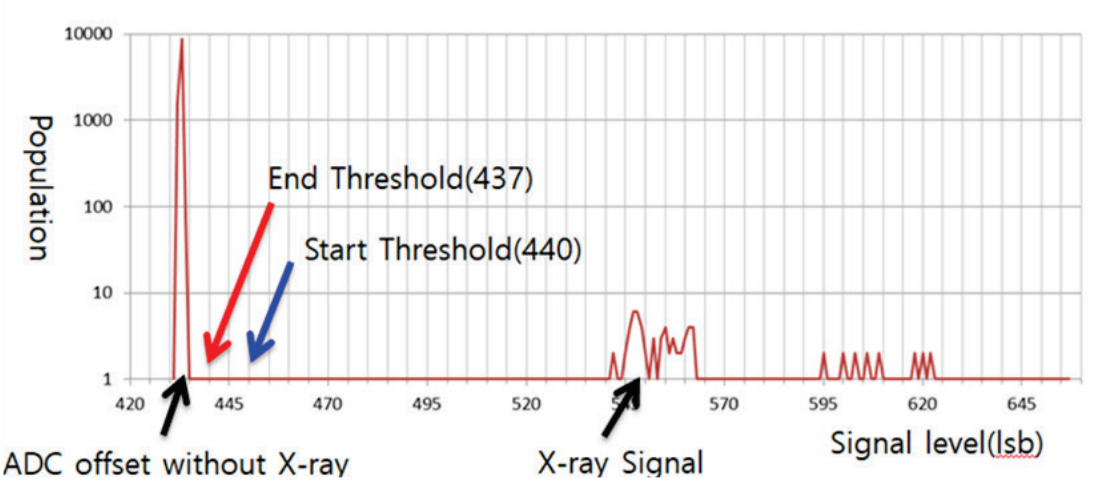
- It is recommended that the ADC Offset value is in the range of 425 ≤ ADC Offset ≤ 437.
- If it is out of the range, refer to **"4.4) In case of image acquisition failure during X-ray exposure after raising the ADC offset setting from the default value."** to take action.

6. The threshold value is set as following guide.

Integration Start Threshold is set by adding 5 to the ADC value maximum, Integration End Threshold is set by adding 2 to the ADC Offset value maximum.



7. If the ADC offset value is output normally, Threshold value can be set as below.

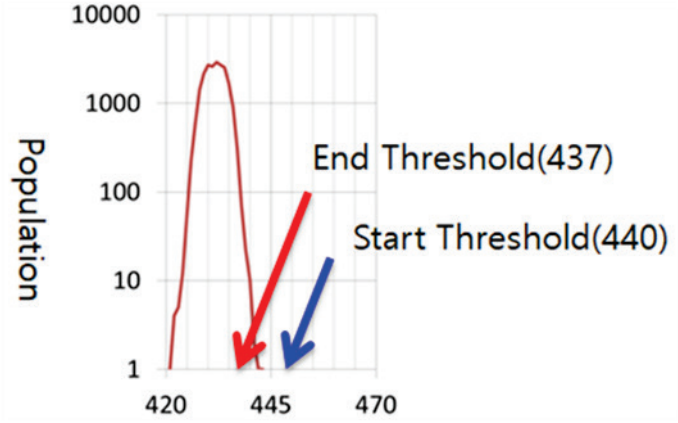


NOTE

The value below is when the ADC offset maximum is 435.

ADC Offset is abnormal

- The ADC offset value of the GIX-1 sensor is affected by the power stability of the connecting computer.
- The ADC Offset value can be output as a different value depending on the specific GIX-1 Sensor.
- Even the same sensor may output different values depending on the type of computer connected.
- If the ADC offset value is unstable on certain computers and sensors, for example:
  - In case that the connected computer USB port power is unstable.
  - In case that Ripple noise of power causes ADC offset instability of the sensor.
  - As shown in the figure, if the ADC offset range is measured wide as in the rage of about 421~443, it will deviate from the recommended ADC offset range. And it is more likely that it violates the Threshold setting conditions below.



NOTE

Sensor output signal when X-ray off

ADC offset < Integration stop threshold level <Integration start threshold level < When X-ray on ADC offset.

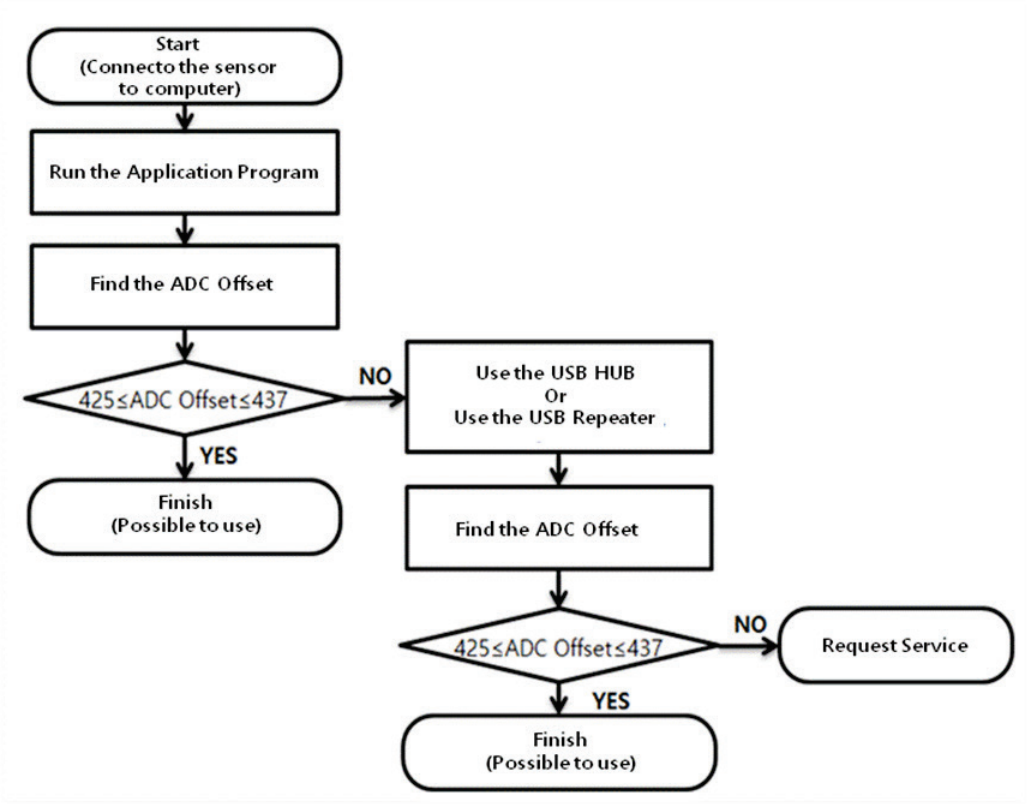
- The threshold value is set as following guide.

NOTE

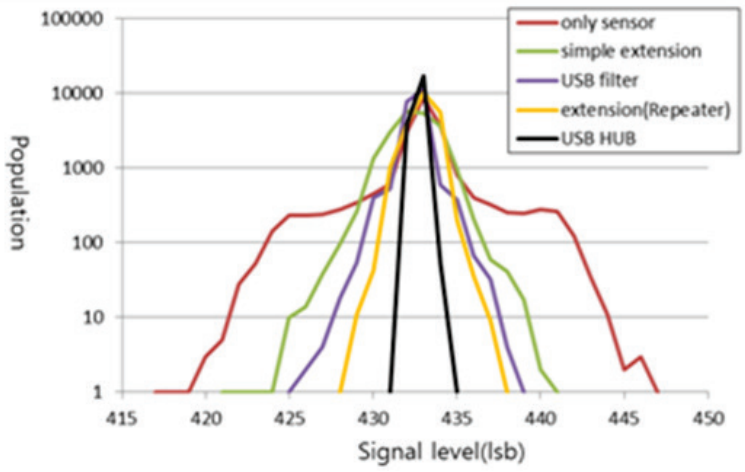
Integration Start Threshold is set by adding 5 to the ADC value maximum,

Integration End Threshold is set by adding 2 to the ADC Offset value maximum.

Field response method



- If the ADC offset value is abnormal, we recommend using USB HUB or USB Repeater.
- The figure below shows experimental results that can improve the output pattern of the ADC offset values.



- Below are the USB HUB and USB Repeater tables listed in the best-performing order by experimental results.

NOTE

Depending on the ground situation of a particular building, the performance orders may vary.

Connection type	Model number	ADC offset level(lsb)		Image
USB HUB(powered) Power connection is essentially required.	ipTime®	4	431 ~ 435	 
Repeater (active, powered, 5m) Power connection is essentially required.	Daewon TMT USB2.0 DW-SUBE-5M	10	428 ~ 438	
USB filter	iSilencer 3.0®	14	425 ~ 439	
Only sensor		30	417 ~ 447	-
Simple USB extension (1m)	Cable mate USB2.0 AM-AF	20	421 ~ 441	

4.4) In case of image acquisition failure during X-ray exposure after raising the ADC offset setting from the default value.

In case of image acquisition failure during X-ray exposure.

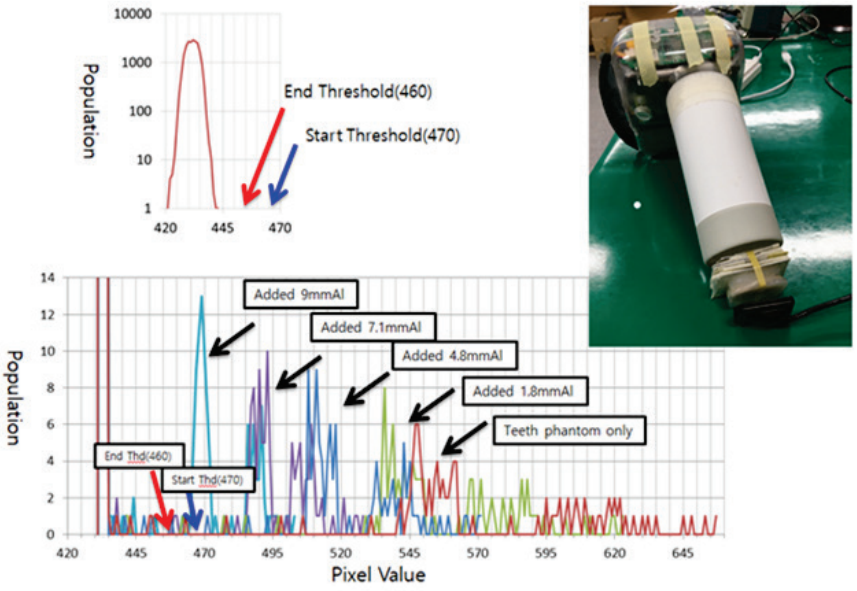
Sometimes X-ray exposure fails to acquire images because the ADC offset values is unstable, the Integration Start/End Threshold is set up higher to meet the conditions as shown in the table below.

NOTE

Sensor output signal when X-ray off

ADC offset < Integration stop threshold level <Integration start threshold level < When X-ray on ADC offset.

- Reason for the the status :
  - If the X-ray signal, which is irradiated to the GIX-1 sensor through the subject, is too low, the sensor doesn't receive the X-ray signal and cannot capture the moment when the X-ray occurs.
  - If the subject you want to check is too thick, there will be a lot of X-ray attenuation, and the transmitted X-ray signal may become smaller.
  - Integration start threshold > It fails image acquisition even if X-ray is exposure when sensor condition of output value occurs (when X-ray is ON)
- Countermeasure :
  - Re-exposure the X-ray to the subject being checked by re-adjusting the subject thinness to the possible thinnest location within the clinically acceptable range.
- Integration Start Threshold > Sensor output value when X-ray is ON.



5. Specifications

This chapter provides information regarding the specifications of the product, and environmental requirements for use.

5.1) Intraoral Sensor Specifications

Manufacturer: GENORAY

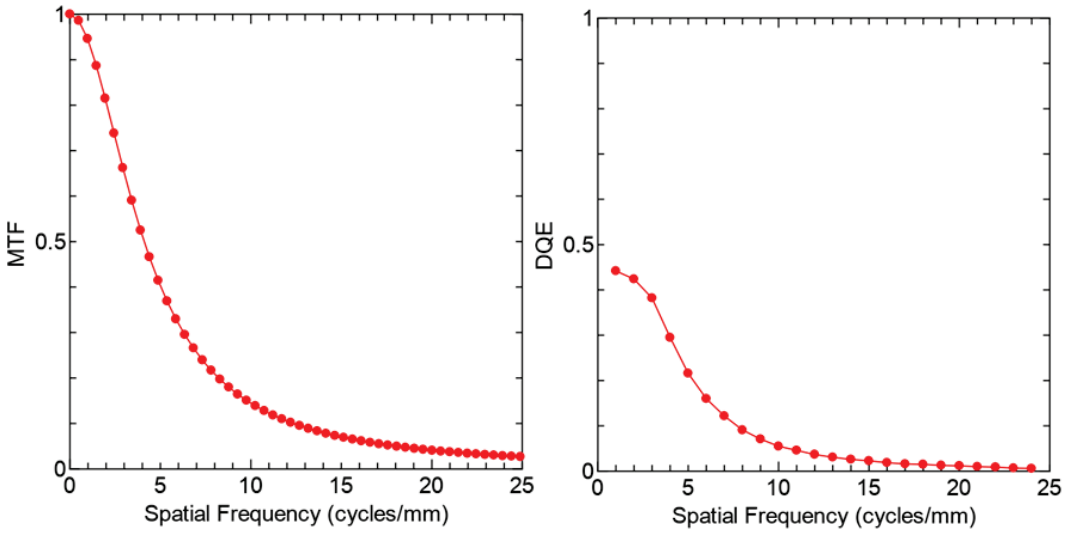
Model	Specification	
GIX-1 PortView Size 1	Sensor Technology	CMOS Type
	Pixel size	20 um
	Sensor plate thickness	5.3 mm
	Area array size	20 mm x 30 mm
	Resolution	>20-line pair/mm actual
	Dynamic Range	16-bit (0 to 5000)
	Interface	USB 2.0
	Cable Length	2.0 m
GIX-1 PortView Size 2	Sensor Technology	CMOS Type
	Pixel size	20 um
	Sensor plate thickness	5.6 mm
	Area array size	26 mm x 34 mm
	Resolution	>20-line pair/mm actual
	Dynamic Range	16-bit (0 to 5000)
	Interface	USB 2.0
	Cable Length	2.0 m

Manufacturer: E2V

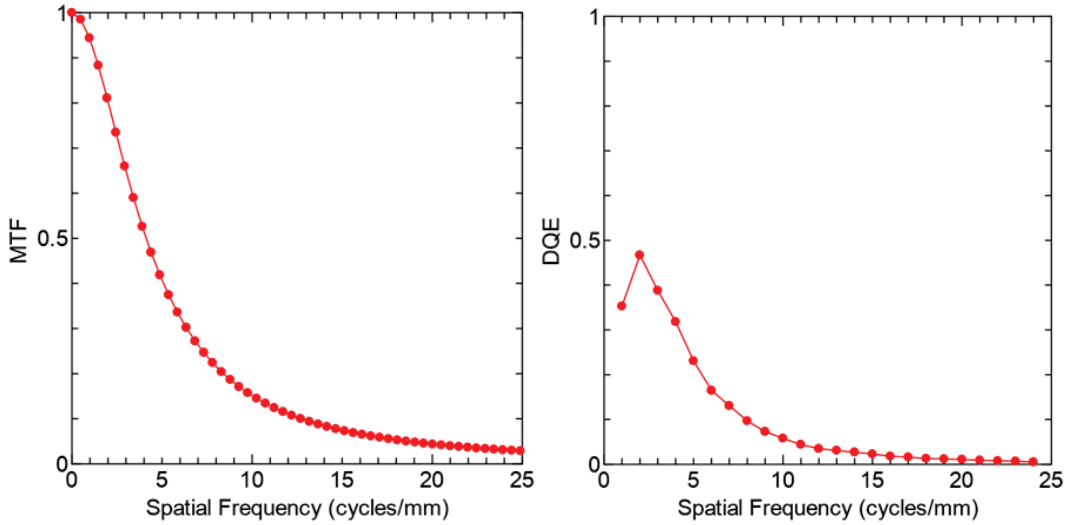
Model	Specification	
EV71JU215 Size 1	Sensor Technology	CMOS Type
	Pixel size	19 um
	Sensor plate thickness	5.4 mm
	Area array size	19.95 mm x 30.02 mm
	Resolution	26.3 lp/mm theoretical, >20-line pair/mm actual
	Dynamic Range	12-bit (0 to 4095)
	Interface	USB 2.0
	Cable Length	3.0 m
EV71JU213 Size 2	Sensor Technology	CMOS Type
	Pixel size	19 um
	Sensor plate thickness	5.4 mm
	Area array size	25.99 mm x 36.00 mm
	Resolution	26.3 lp/mm theoretical, >20-line pair/mm actual
	Dynamic Range	12-bit (0 to 4095)
	Interface	USB 2.0
	Cable Length	3.0 m

Specification-MTF/DQ

- Size 1



- Size 2



5.2) Intraoral Sensor Usage Environment

- Optimal temperature and humidity
  - Temperature: 0-35 °C
  - Relative Humidity: 70 % or less
  - Atmospheric pressure: 700~1060 hPa (70~106 kPa)
- Move & Storage Environment
  - Temperature: -20-+70 °C
  - Relative Humidity: 70 % or less
  - Atmospheric pressure: 700~1060 hPa (70~106 kPa)

To avoid damaging the product's cables and connectors, do not store or use the product near strong heat and fire.

Appendix 1.Waste treatment method

It must be disposed of in an environmentally friendly manner to prevent environmental pollution in accordance with the disposal regulations and guidelines of each country and region. Dispose of it by referring to the table below.

Item	Material	Industrial Waste	Recycling	Hazardous
Intraoral Sensor	-	●		
Cables and Connectors	-		●	
Packaging material	PVC		●	
	Paper		●	
	Plastic		●	

NOTE

Disposal When disposing, please observe the disposal regulations and guidelines of each country and region. For more information, please contact the manufacturer or sales company.

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Appendix 2.Dose information

This is the condition of exposure recommended to use the product. For the details, refer to the following table.

[unit: μGy]

Type		Big	Middle	Child
Maxillary	Incisor	566.5	515	412
	Canine	643.75	566.5	463.5
	Molar	721	643.75	566.5
Mandibular	Incisor	412	360.5	257.5
	Canine	463.5	412	360.5
	Molar	566.5	515	463.5

The condition of the X-ray exposure is the recommended condition of exposure to use the product. The actual condition of exposure can vary depending on the specification of the product or the environment of use.

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Appendix 3.Calibration

Provides the instructions for calibrating the equipment. Depending on which portable equipment you are going to connect with this, refer to the followings.

A.3.1) Port-X II

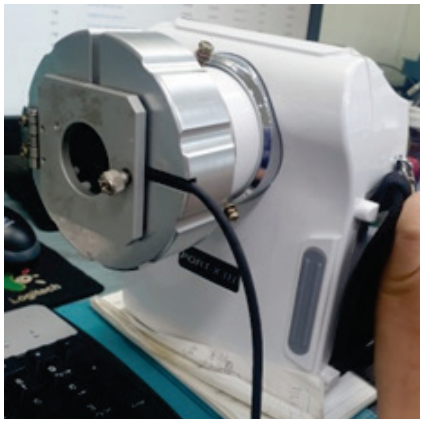
NOTICE

Ask the manufacturer or the seller of the Calibration data file.

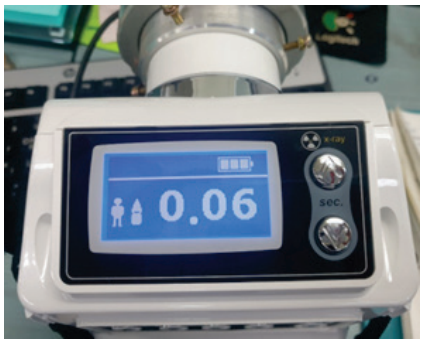
A.3.2) Port-X III

Provides the instructions for calibrating Port-X III.

1. Install the intraoral sensor and the calibration jig in front of the beam limiting device of the equipment.



2. Configure the X-ray exposure condition for calibration.

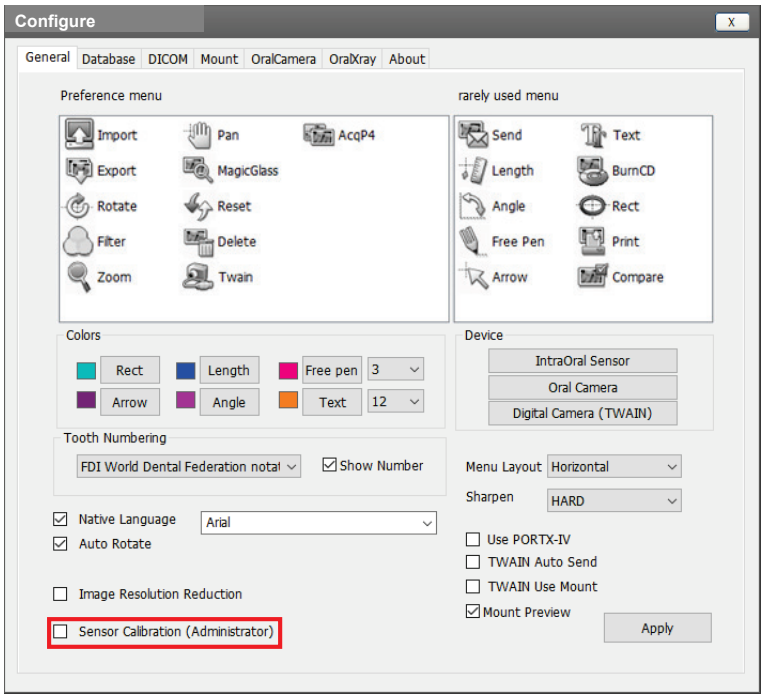


NOTICE

The exposure condition is as follows:

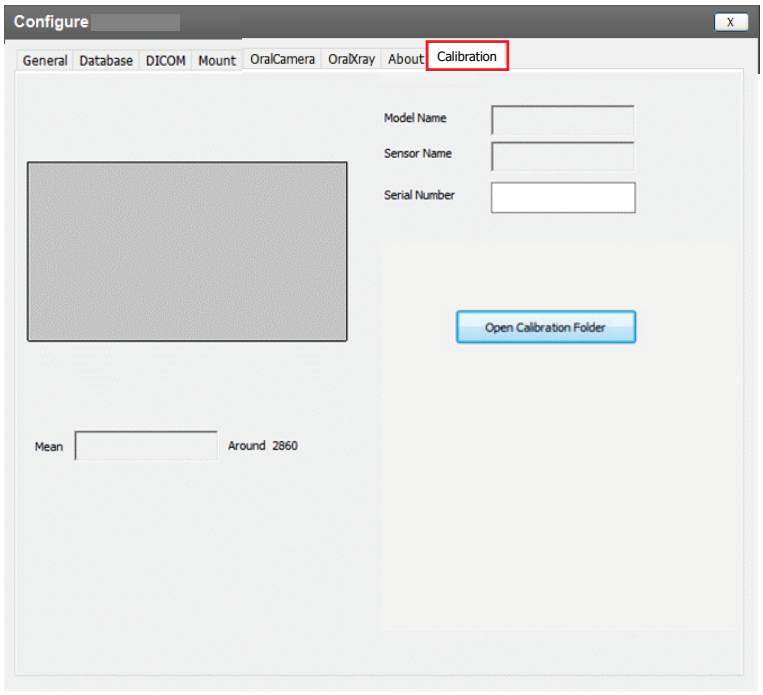
- 80 m sec (70 kV, 2 mA is the default).

3. Run the program window and check Configuration > Sensor Calibration.

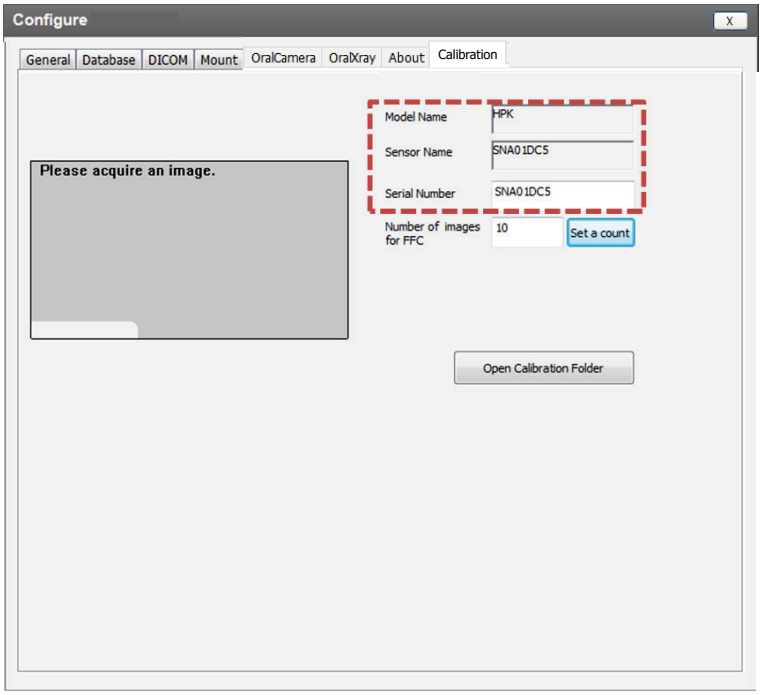


4. Click the [Apply] button and close the configuration.

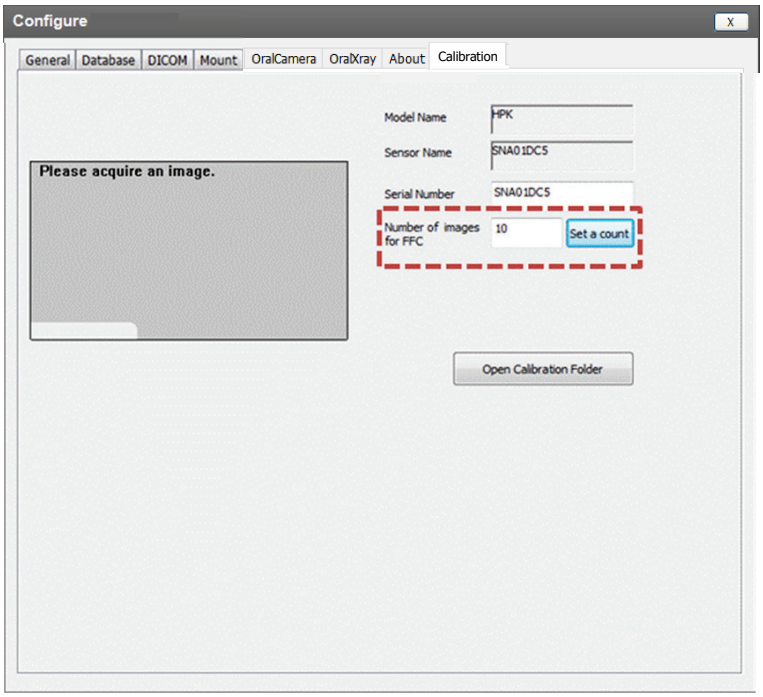
5. Rerun the configuration window and click the Calibration tab.



6. When you fill in the Serial Number of the equipment, the [Model Name] and the [Sensor Name] will be populated automatically.



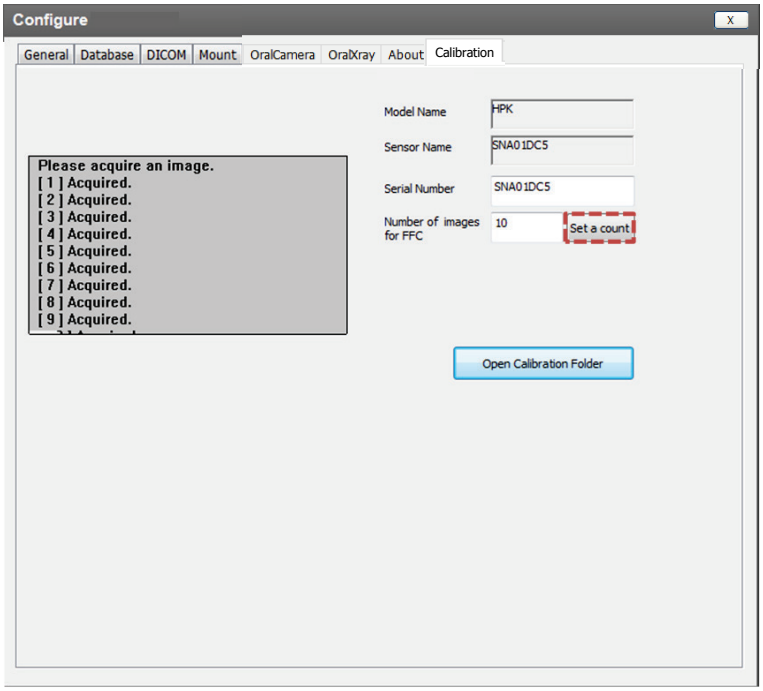
7. Input the image acquisition count at [Number of images for FFC].



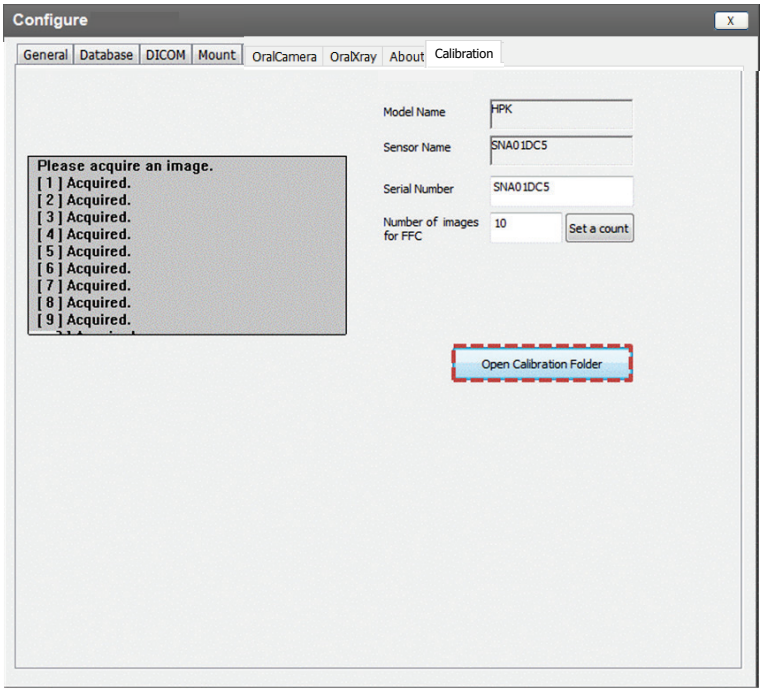
NOTE

10 times of acquisition are recommended for the calibration.

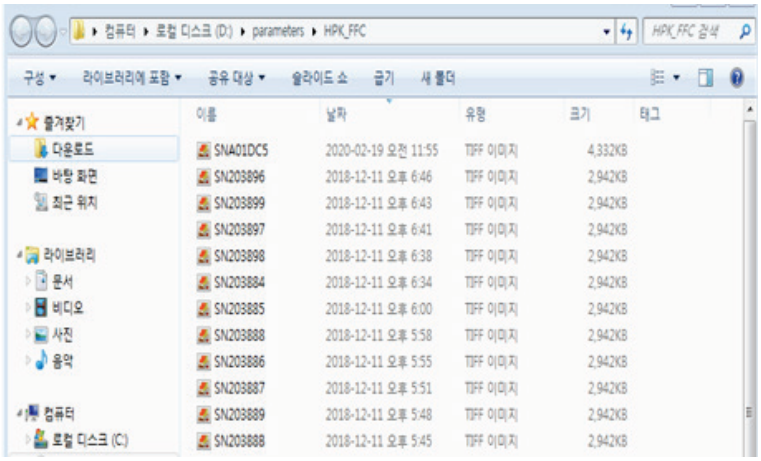
8. When you click the [Set a count] button, the system begins capturing images and the calibration starts automatically.



9. Click the [Open Calibration Folder] button.



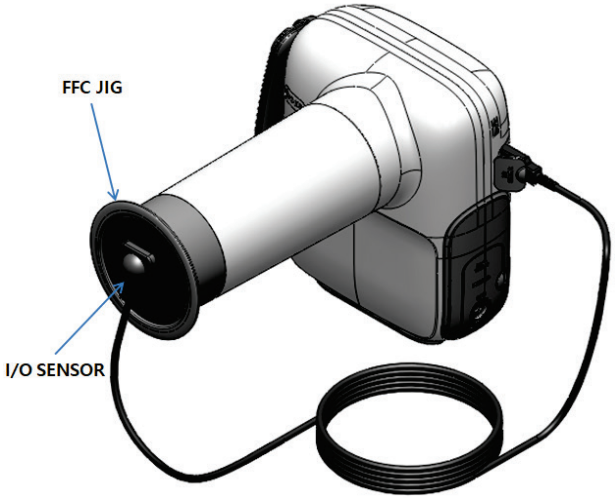
10. Check that the FFC files are created and finish the calibration.



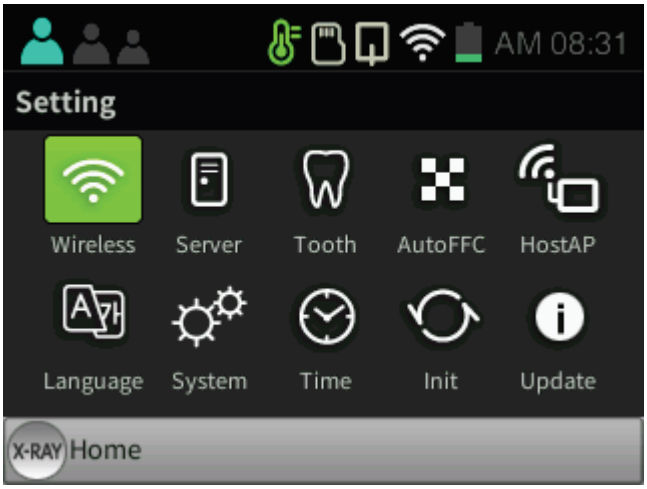
A.3.3) Port-X IV (Port-X IVe, ZEN-PX4, ZEN-PX4e)

Provides the instructions for calibrating Port-X IV (Port-X IVe, ZEN-PX4, and ZEN-PX4e).

1. Install the intraoral sensor and the calibration jig in front of the beam limiting device of the equipment.



2. Click the [Menu] > [Configuration] > [Create FFC].



WARNING

Note that the X-ray is exposed automatically as you create an FFC file.

3. When you click the [Create FFC] button, the FFC feature is performed automatically.

A.3.4) Other Portable Equipment

Refer to the manual of the corresponding equipment.

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