FLASHRAY

User Manual

FlashRay Sensor

DENTERPRISE INTERNATIONAL, INC

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Manual Date 20181010

FLASHRAY

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1 Introduction

You have just received your **FlashRay** digital intra-oral radiology kit. We thank you for purchasing our product and for the confidence you have in us and hope that our product will give you complete satisfaction.

We recommend that you read this manual thoroughly before installation; following the guidelines from installation and usage described in it will exclude risks to the patient and the care team.

Your sensor uses an x-ray sensitive electronic detector that replaces the conventional film used for the acquisition of radiological intra-oral images. The x-rays are automatically detected by the sensor which triggers image acquisition. The acquired image is displayed almost instantaneously on the screen of the computer to which the sensor is connected. These digital images can then be manipulated, analyzed, saved as files or printed.

The development process of conventional films is thus completely eliminated as well as the possible influences on image quality; such as the type and age of the chemical product, the temperature of the baths or the development time.

The sensor is available in two sizes; depending on the kit you have ordered you received a size 1, a size 2 sensor or both:

- The size 1 sensor allows you to acquire the majority of intra-oral images both vertically and horizontally.
- The size 2 sensor allows you to easily acquire horizontal “bitewing” images.

The instructions and information in this manual refer to both sensor sizes, unless specifically stated.

Caution: Federal law restricts this device to sale by or on the order of a dentist

1.1 Indication for Use

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

1.2 Product Description

An X-ray image sensor is positioned in the patient’s mouth just like intraoral film. There is no electrical or physical connection between **FlashRay** and the x-ray generator. Images are automatically acquired when x-rays are present in a dose which is perceptible to the sensor.

Digital x-ray images are quickly displayed on the screen. Images can be optimized for viewing via imaging software, stored as image files, and printed out on a suitable printer if desired. **Apteryx** software is one example of a dedicated software that employs a number of utilities for optimizing viewing and printing of images.

Denterprise offers technical support for this device to ensure proper operation and to answer any questions regarding the function of the device.

The type of x-ray systems that integrate with the FlashRay sensor are wall-mounted x-ray generators (both AC and DC) with a tube current between 1 and 15 mA inclusive, and with a tube voltage

between 50 and 100 kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time.

This device and software cannot act as an x-ray generator controller. All control of x-ray generation is done by controls built into the generator itself. **There is no connection between the subject device and the x-ray generator. The subject device does not control the generator, it is a receiver.**

The **FlashRay** must be connected to a PC through the standard USB 2.0 port.

1.3 Unpacking your FlashRay Sensor

The **FlashRay** sensor is carefully inspected and packaged prior to shipment. If the sensor was shipped to you, please remove the contents of the shipping container and be sure to identify and directly locate each of the components listed below.

NOTE: If the package arrives with any damage or missing components, please notify your dealer immediately (within 24 hours) and you will be instructed as to how this should be handled.

CHECK LIST BEFORE USE

Make sure the kit is complete with the following items: Sensor, Sensor Holder Trial Kit, Sensor Covers, Wall Bracket, USB Card with Software, Drivers, Sensor Correction File, and Acceptance Form. Please notify the dealer immediately if the kit is incomplete.

Once the system is installed make sure to complete the Acceptance Form and send this in to activate your warranty.

1.4 Symbols Used in the Manual

Warning Alerts the operator that failure to follow the procedure could cause bodily injury or death.

Caution Alerts the operator that failure to follow the procedure could cause damage to the equipment or cause loss of data.

Important Provides advice for the operator regarding use of the device or a process.

NOTE Highlights important or unusual points.

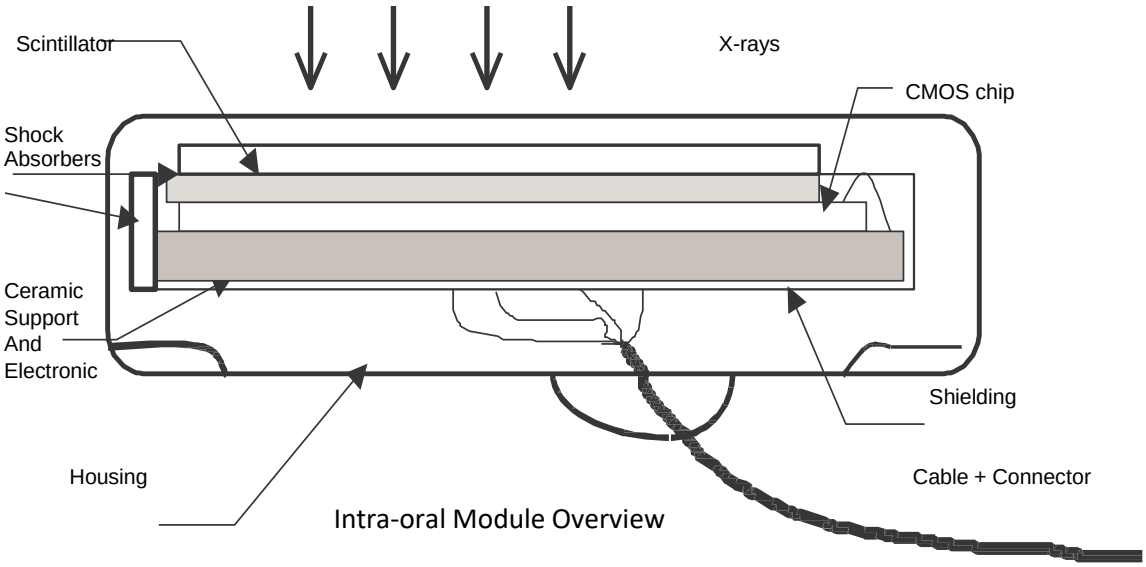
1.5 General Description

The S11684-12 / Size 1 and S11685-12 / Size 2 are CMOS area image sensors developed for X-ray imaging. The image sensors have a monitoring photodiode for monitoring and detecting X-ray irradiation. FOP (fiber optic plate) used as the input window ensures high image quality and long sensor life even under exposure to X-rays.

The S11684-12 and the S11685-12 supports USB 2.0. These sensors are designed to be dust and water proof, equivalent to IP67

The intra oral sensor includes the following sub elements:

- CMOS image sensor chip
- Scintillator
- Electronic substrate (electronic circuitry carrier + proximity electronics)
- Flexible cable with end connector
- Watertight housing
- Shielding foils and shock absorbers



Intra-oral Module Overview

1.6 Cable

Cable consists of PVC, ETFE, copper, plug connector and sensor connector
Cable diameter: ϕ3.7 ± 0.3
Cable length: 2 meters

1.7 Housing

Housing material is ABS and the flammability is HB if YK-94 (UL File No. 49895).
The color sample of the finished ABS housing is: CABS- 7247C (Black).
Envelope protection rating: IP67 (6 = Totally protected against dust and 7 = Protected against the effect of immersion between 15cm and 1m).

2 Contents

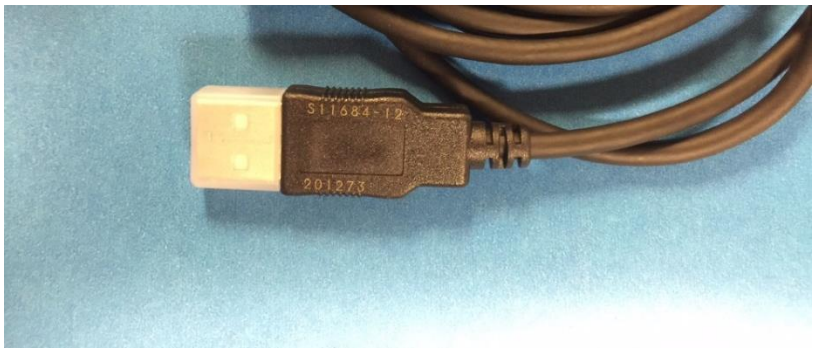
S 11684-12
Size 1.0 = Image area / outer dimensions

S 11685-12
Size 2.0 = Image area / outer dimensions

= 20 mm x 30 mm
= 39.0 ± 0.3 x 25.0 ± 0.3

= 26 mm x 34 mm
= 41.9 ± 0.3 x 30.4 ± 0.3

NOTE: The **FlashRay** sensor is individually marked with a **serial number**. (See picture below)



When you receive the FlashRay sensor, if the kit is not complete or you have any damage due to shipping, please notify us immediately at Denterprise International, Inc. 800-323-2690.

2.1 Label

FLASHRAY

Size 1 and Size 2 **Assembled in USA**

70 kVp tube voltage
6 mA tube current
Temperature 140°F
Humidity 90%

Intended for dental radiographic examination and diagnosis of disease of the teeth, jaw, and oral structure.




IP67

Denterprise International, Inc.
100 E. Granada Blvd., Suite 219
Ormond Beach, FL 32176
800-323-2690

Caution: *Federal law restricts this device to sale by or on the order of a dentist.*

2.2 Label Information

Description

Manufacturer name: Denterprise International, Inc.

Address: 100 East Granada Blvd. Suite 219

Ormond Beach, FL 32176

Tel: 1-800-323-2690

Fax: 1-855-235-7902

www.denterpriseintl.com info@denterpriseint.com

Label Traceability	Label Containing:
FlashRay Sensor	Product name
	Serial Number of Sensor
	Date Manufactured
	Consult instructions for use
	BF Type Equipment
	Product must be collected separately
IP 67	Dust resistant; Water resistant
	Caution: Failure to follow procedures could cause damage to equipment or cause loss of data.

2.3 Packaging and Environment

Transport, storage and environment: the **FlashRay** sensor is delivered in a non- sterile package. It is shipped in a protective package to prevent the sensor from physical impact or damage.

S 11684-12 / Size 1 and S 11685-12 / Size 2

Absolute maximum ratings

Parameter	Symbol	Condition	Min.	Typ.	Max.	Unit
Supply voltage	V_{BUS}	Ta=25 °C	4.75	5	5.25	V
Operating temperature	Topr	No dew condensation*1	0	-	35	°C
Storage temperature	Tstg	No dew condensation*1	-20	-	70	°C
Incident X-ray energy	Ex-ray		20	70	90	kVp
Total dose irradiation	D	Ta=25 °C, 60 kVp	-	-	57.6	Gy

When there is a temperature difference between a product and the surrounding area in high humidity environment, dew condensation may occur on the product surface. Dew condensation on the product may cause deterioration in characteristics and reliability.

Note: Exceeding the absolute maximum ratings even momentarily may cause a drop in product quality. Always be sure to use the product within the absolute maximum ratings.

Should a return to the distributor be necessary, make sure to package the FlashRay sensor in the original packaging.

All sensors are shipped with its documentation. Please contact your distributor for a replacement manual if this documentation is lost.

3 Safety and Disposal Procedures

The **FlashRay** sensor must be installed and used in accordance with the safety regulations and instructions for use supplied in this User Manual, for the purposes and applications for which it is intended.

Modifications and/or additions to the **FlashRay** must always comply with standards and recognized rules of good workmanship.

3.1 Electrical Safety

This product must be used only in rooms or areas which comply with all laws and regulations applicable to electrical safety in medical premises, such as IEC standards regarding use of an additional ground terminal for potential connections.

- The **FlashRay** sensor conforms to electrical and safety standard IEC 60601-1:2005 (Medical Electrical Equipment, Part I: General requirements for basic safety and essential performance).

- The **FlashRay** sensor conforms to electrical and safety standard IEC 60601-1-2:2007 (Medical Electrical Equipment, Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests).

  The **FlashRay** sensor conforms to electrical and safety standard IEC 62220-1:2003, (Medical electrical equipment – Characteristics of digital X-ray imaging devices—Part 1: Determination of the detective quantum efficiency).

- **FlashRay** sensor is not suitable to be operated in an anesthetic gas environment.

- All IT components are to be placed OUTSIDE the patient environment. IT components placed INSIDE the patient environment, due to customer site requirement, must conform to other basic standards. IEC 60601-1 defines the "Patient environment" as "any volume in which intentional or unintentional contact

can occur between a patient and parts of the ME Equipment or ME System or between a Patient and other persons touching parts of the ME Equipment or ME System."

Warning

DO NOT CONTINUE TO USE THE SENSOR IF THERE IS VISIBLE DAMAGE TO THE SENSOR HOUSING AND/OR CABLE.

3.2 X-ray Protection

The rules of dental radiography still 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.

3.3 Prevention of Cross-Contamination

To help prevent cross-contamination between patients, place a new hygienic barrier on the sensor for each new patient. The hygienic barrier must cover the sensor and at least 3-4 inches (7-10 cm) of the cable.

3.4 Product Disposal

The sensor contains a small amount of lead, similar to the lead foil used in dental intraoral x-ray film. The sensor head needs to be disposed of carefully, so please contact your dealer or supplier for further information about product disposal at the end of the product's lifetime. The cable and connector have to be recycled by an electronic waste processing facility.

3.5 Prevention of Environmental Contamination

Dispose of sheaths and other consumables following the normal dental office procedure for biomedical waste.

4 Power Supply

The power to the **FlashRay** sensor is provided directly by the power supply of the USB cable connecting it to the computer.

The USB port shall support USB 2.0 High speed mode.

5 Operators and Liability

*The **FlashRay** sensor must be used by a dental practitioner and trained technical staff.*

- The connection box should never be opened by the user. Only the manufacturer is authorized to open and make repairs to the sensor or box. Return the equipment to your distributor in case of malfunction.

The manufacturer will not be liable if:

- **Interventions or repairs have been made by persons without the authorization of the manufacturer or distributor and are not part of accepted interventions.**

- **The equipment is used with an installation that is not compliant with the applicable standards and decrees—in particular when not compliant with the stands relating to the security rules for electro medical systems. Make sure the installation of the equipment is compliant with the applicable regulations.**

6 Installation

Installation precautions

As the intra-oral sensor is situated inside the patient environment, your computer must necessarily comply with standard IEC 60601-1, or your installation including the computer must have been rendered compliant with standard IEC 60601-1. You can connect the sensor to your computer without additional precautions once your complete installation is compliant with standard IEC 60601-1-1.

The **FlashRay** sensor is an electrical medical device requiring special precautions regarding electromagnetic compatibility. Please observe the recommendations in this manual during the commissioning and use of the equipment. **NOTE:** To avoid interferences in the image, do not use the system close to strong magnetic fields and avoid proximity to electrostatic emission sources.

The sensor must be handled with care, minimizing the twisting, pulling and bending of the attachment cable. **DO NOT** step or roll on the cable. **DO NOT** pull on the cable itself but on the connection plug to disconnect the USB cable.

To avoid interferences in the image, do not use the system close to strong magnetic fields and avoid proximity to electrostatic emission sources.

NOTE: The use of cables or accessories other than those specified in this manual can cause an increase in the emissions or a reduction in the immunity of the **FlashRay** sensor.

Important Any computer configuration that does not comply with the minimal recommended configuration can prevent the starting or proper functioning of the sensor. Verify the specifications of the computers before the installation.

Installation Process

CONTACT YOUR DEALER FOR INSTALLATION. We want to provide you with an installation service to ensure that this product is set up and installed correctly for optimal use. We will walk you through the process and answer questions and provide training for correct usage of this device.

6.1 Setup Guidelines

The computer and the screen with which the sensor is connected to should preferably be situated close to the chair, within the field of vision of the practitioner, to allow for immediate use. This will allow the practitioner to provide visual access to the patient and be able to share the radiological information with him/her.

The screen must be placed so as to avoid any reflections or direct overhead illuminations that could be detrimental to the visualization of the radiological images. It must be set up (contrast and brightness) to display as many grey levels as possible in the image.

The x-ray generator has a great influence on the quality of the acquired images. The **FlashRay** is compatible with any kind of generator, be it high-frequency or conventional. The generator must be equipped with an electronic timer (allowing for very short exposure times) and must emit a dose sufficient for the acquisition of a good image (with sufficient contrast). Make sure that your x-ray generator is in good repair and has been calibrated and tested recently (as per your states regulation). The energy emitted by a generator diminishes over time; when in doubt have your generator checked by a qualified technician.

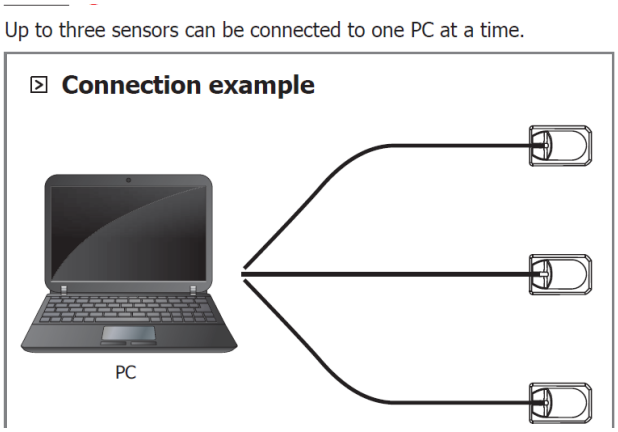
6.1 Exposure Time Chart

Parts of tooth		Classification		Exposure time	Exposure time set
Upper	Incisor 	Film	Adult	0.7 ~ 0.8 Sec	0.7 Sec
			Child	0.4 ~ 0.6 Sec	0.5 Sec
		Sensor	Adult	0.2 ~ 0.3 Sec	0.2 Sec
			Child	0.14 ~ 0.2 Sec	0.16 Sec
	Canine 	Film	Adult	0.9 ~ 1.0 Sec	0.9 Sec
			Child	0.6 ~ 0.8 Sec	0.7 Sec
		Sensor	Adult	0.3 ~ 0.4 Sec	0.35 Sec
			Child	0.1 ~ 0.2 Sec	0.1 Sec
	Molar 	Film	Adult	1.1 ~ 1.2 Sec	1.1 Sec
			Child	0.8 ~ 0.9 Sec	0.8 Sec
		Sensor	Adult	0.4 ~ 0.5 Sec	0.4 Sec
			Child	0.2 ~ 0.3 Sec	0.2 Sec
Lower	Incisor 	Film	Adult	0.5 ~ 0.6 Sec	0.5 Sec
			Child	0.2 ~ 0.3 Sec	0.2 Sec
		Sensor	Adult	0.14 ~ 0.25 Sec	0.2 Sec
			Child	0.08 ~ 0.14 Sec	0.1 Sec
	Canine 	Film	Adult	0.6 ~ 0.7 Sec	0.6 Sec
			Child	0.3 ~ 0.4 Sec	0.3 Sec
		Sensor	Adult	0.2 ~ 0.3 Sec	0.2 Sec
			Child	0.14 ~ 0.2 Sec	0.16 Sec
	Molar 	Film	Adult	0.7 ~ 0.8 Sec	0.7 Sec
			Child	0.4 ~ 0.15 Sec	0.4 Sec
		Sensor	Adult	0.25 ~ 0.35 Sec	0.3 Sec
			Child	0.16 ~ 0.25 Sec	0.2 Sec

Controls built into your specific generator will control the sensor. Here is a table provided to assist you with your settings (the time table is based on a 3mA portable device). Your specific generator may need to be adjusted for this sensor and during the integration of the device our technical support department will assist you to make the necessary adjustments for your generator. Denterprise International, Inc. may be reached at 877-509-3180 for technical support.

6.2 Multiple Sensors Setup

Multiple **FlashRay** sensors are supported on a single PC.



In the event of multiple sensor installation, after each sensor is connected, the user is responsible to verify that it is recognized and communicating with the PC.

If the newly connected sensor does not appear on the list, make sure the USB port that the sensor is plugged into is connected to the PC on which the installation of the **QucikRay HD** is running (and is not, for example, on a USB hub which is connected to a different PC). If the sensor is connected to the correct PC but does not appear on the sensor drop-down list, contact your Dealer for technical support for further assistance.

Operators should consult the appropriate software user manual for the procedure that verifies the presence of a connected sensor. If required, contact Customer Support (contact information provided in that particular manual).

6.3 Portability

The **FlashRay** sensor can be easily moved from one dental chair to another. Once disconnected from the USB port of the computer, the sensor may be positioned near a second dental chair and connected to a USB port nearby.

7 Integrating your device

The type of x-ray generator that integrates with the FlashRay sensor are wall mounted intraoral x-ray generators both AC and DC. The tube current is between 1 and 15 mA and the tube voltage is between 50 and 100 kV inclusive. Generators allow variable mA/kV to

be selected, as well as exposure time. The operator/technician will set the desired exposure parameters form the generator control panel.

The software with the FlashRay is supported on the following:

- Windows XP
- Vista
- Windows 7, 8, 8.1 and 10.

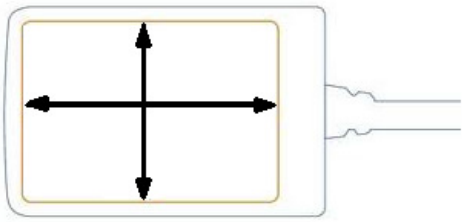
Requirement for PC hardware are as follows:

- Hardware and software would need to be a minimum of Pentium4 or better processor.
- At least 1 GB of RAM
- 200MB of hard drive space for the software, plus additional space for the user database (40GB minimum recommended).
- USB 2.0 or 3.0.
- 100 MB wired Ethernet connection is needed if networked.

8 Positioners

The universal positioner allow for the positioning of the sensor in the mouth with the technique of parallel positioning. The universal positioner allows for the acquisition of any type of radiographic image and can be used with the size 1 and size 2 sensors without having to change the type of positioner.

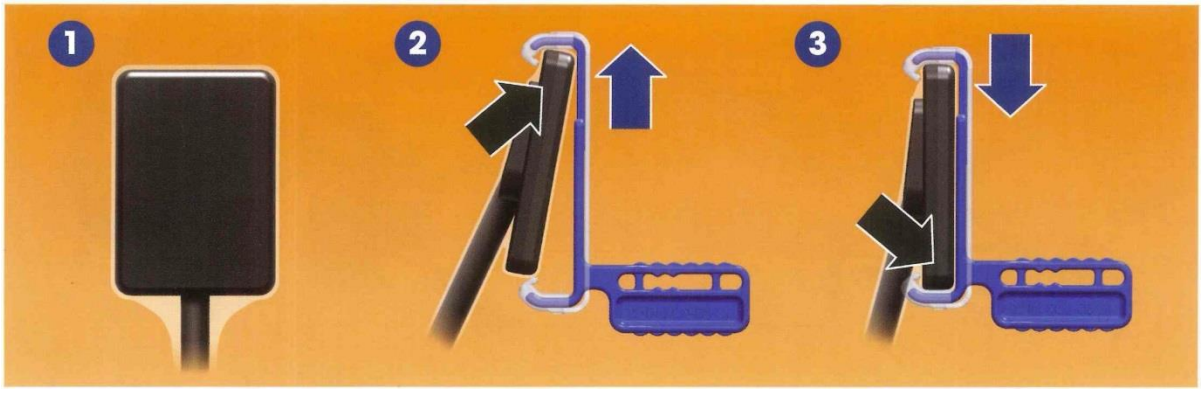
The sensor is clipped to the head of the positioner; a rotation of the sensor in the positioner allows the user to position the sensor depending on the tooth or teeth to be x-rayed.



The sensitive area of the sensor is indicated by the arrows in the picture. The area outside of the gold line is not sensitive to x-rays.

NOTE: Make sure the sensitive area is positioned towards the x-ray source when positioning the sensor in the mouth and that the whole sensitive area is irradiated.

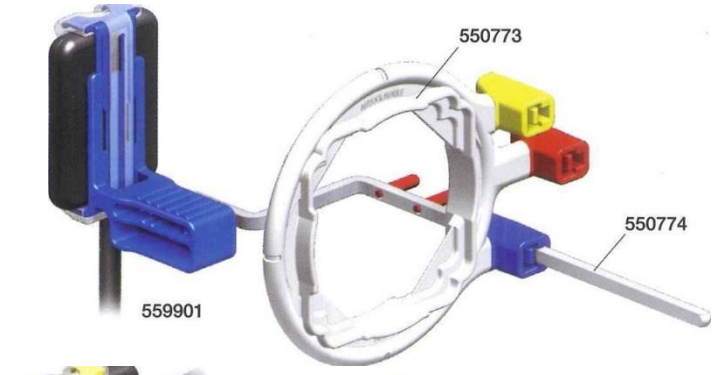
area that is not sensitive) to unclip it from the positioner or sensor connection cable.



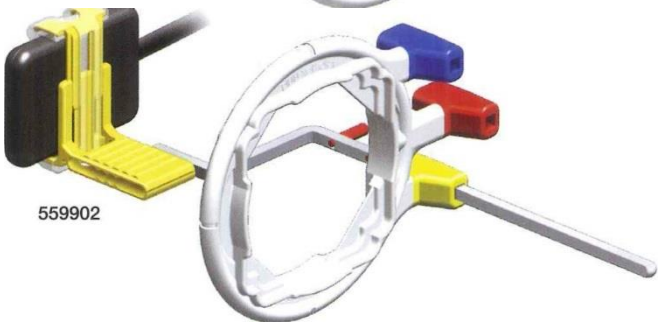
8.1 Positioner Instructions

1. Place a protective cover over the **FlashRay** sensor.
2. Load sensor into appropriate biteblock for the area to be imaged by holding sensor firmly and pressing edge of sensor against the movable clip.
3. Insert opposite sensor edge and release clip.
4. Insert positioning arm into the appropriate color-coded channel of the aiming ring and attach biteblock according to Positioning Guide.
5. Correctly assembled, the sensor should be centered when viewed through the aiming ring.
6. Position holder in patient's mouth and slide aiming ring close to patient's face.
7. Align x-ray tube to aiming ring.
8. Take exposure.
9. Change as needed for the next desired image.

8.2 Type of Positioners recommended with this sensor



Anterior



Poster

Bitewing

8.3 Sensor Precautions

Make sure the sensitive surface (the flat surface) of the sensor is directed towards the x-ray generator. The back of the sensor (rounded) does not react to x-rays and does not produce an image on-screen.

The sensor must be manipulated with care, minimizing the twisting, pulling and bending of the attachment cables. Do not step or roll on the cable.

Even though the sensor is resistant to impacts, it is strongly recommended to not let it fall on the floor. If a physical impact should happen, contact your distributor and do not try to intervene yourself.

Do not tell the patient to bite on the sensor or cable. Instead, **ask the patient to close their mouth around the sensor and relax the muscles of the jaw.**

Additional Precautions for Use

- Use a disposable sterilized cover to avoid various infections among patients.
- Check whether the product operates properly before using. Do not use the product when there is something wrong before using. Stop using the product immediately when it is found to be in fault while in use, such as overheating or cracking.
- Do not modify or overhaul the product by yourself.
- Verify your own application software. Improper command sequence, improper arguments and any other improper operation may result in unintended behavior.
- If the product is used in an environment with temperature of 35° C, equal to 95° F, for a period of time, it is possible that the maximum temperature of the surface of this product could reach 45° C, equal to 113° F. Pay attention to the temperature when using this product.

- Do not twist, bend, pull and pinch the cable strongly. These actions can cause damage to the cable.
- Connect and disconnect the USB connector by holding the body of the sensor, never pull it by the cord.
- Check that the USB connector is not wet and dirty before you connect it.
- Do not touch the pins of the USB connector because the product can be damaged due to static electricity.
- Do not drop or strike the product.
- Do not apply any pressure (example, tight holders or biting) on the product because it might be damaged.
- Obey local laws when you use or dispose the product.
- If you use the product beyond the estimated useful life, check the performance of the product carefully before using.
- Take measures against computer viruses and verify antivirus measures.

9 Care Instructions

Dental intraoral X-ray sensors are sophisticated electronic products incorporating advanced technologies. As such, they have to be handled with a high degree of care.

9.1 Cleaning and Disinfecting Instructions

THE DENTAL INTRA-ORAL SENSORS ARE NOT STERILE MEDICAL DEVICES.

Hygiene is important with the sensor so be sure to change the disposable sheaths for every sensor usage between different patients to prevent risk of cross infection.

IMPORTANT: Disinfect the image sensor before its first use and whenever there is a risk of contamination.

Store disposable sanitary sheaths in a clean, dry place not exposed to sunlight or UV rays.

It is mandatory to carefully follow the disinfecting and cleaning recommendations in order not to damage the sensors

DO THIS: (See picture below)

- Use protective gloves for using, cleaning or disinfecting the sensor.
- To disinfect the sensor head and the cable near the sensor head, wipe them with a cloth with 70% isopropyl alcohol after you finish using the product.
- Do not keep immersing the product in any liquid. However, you can immerse the sensor head in only water for a few seconds each time.
- Do not expose the product to any unspecified liquid.
- Use a new disposable protective sheath for every sensor usage.
- Do not sterilize the product by heating, autoclaves or UV.

- **When the product is not in use, we recommend that you put it into the packing box we sent to avoid the damage of static electricity.**
- Keep the product away from direct sunlight, dust, or corrosive gases such as chlorine or fluorine, etc.
- Do not apply pressure on the product during storage.

Protective sheath on sensor

Recommended storage when not in use

DO NOT DO THIS:

- Sterilize the sensor using autoclave or UV oven.
- Wipe the cable surface with a moistened compress with a disinfecting solution.
- Immersion in bleach or an alcohol content solution.
- Immerse connector in disinfecting solutions.
- Clean the sensor using non appropriate instruments.

9.2 Mechanical Damage Prevention

DO THIS:

- Always manipulate the sensor with a high degree of care.
- Always use the sensor with the proper holder.
- Plug and unplug the sensor holding the connector by the molded body and never by the cord.
- Use the holder and the method recommended by your distributor.
- To remove from the holder, grip the sensor carefully and withdraw holder.
- Make sure the sensor cable is not tangled, as damage may occur if not properly used.
- Make sure the sensor never strikes a hard surface.

Incorrect method of handling

Correct method of handling

USE THE APPROVED HOLDERS SENT WITH YOUR SENSOR OR OTHR APPROVED HOLDERS.

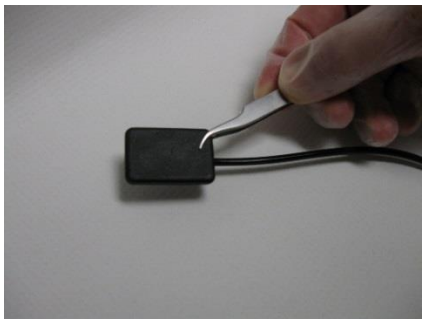
DO NOT DO THIS: (See pictures on next page)

- Pinch sensor or cable.
- Pull or kink cable.
- Unplug sensor by pulling on cable.
- Remove protective sheath by pulling the cable.
- Drop sensor.
- Leave cable on the floor.
- Rolling over the cable with a chair or walking over it, this could damage the cable.
- Bite sensor or cable.
- Do not touch the pins of the USB connector because the product can be damaged due to static electricity.

DO NOT pinch sensor or cable

Important:

DO NOT USE A HEMOSTAT OR ANY TYPE OF CLAMP TO HOLD THE SENSOR. THIS WILL CAUSE DAMAGE THAT IS NOT COVERED UNDER THE WARRANY.

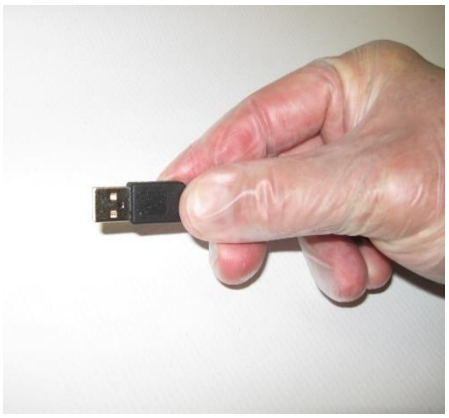


DO NOT use a clamp to hold sensor

9.3 Protection from Electrical Damage

DO NOT DO THIS:

- Immerse connector in disinfecting solutions.
- Use a sensor that has a nick on the sensor head or on the cable.
- Do not pull on the cable itself when disconnecting the USB cable (See picture below).



Correct method of handling

Incorrect method of handling

10 Maintenance

The **FlashRay** sensor does not require any special maintenance other than regular cleaning and disinfection.

Clean your monitor screen, mouse and keyboard frequently.

Set monitor brightness and contrast properly. Be sure to use a video mode recommended for use with **FlashRay.**

11 Troubleshooting

This section supplies information for some simple tests which the user may perform in the event the sensor malfunctions. Refer to the PC manual and the software manual for information on other types of malfunctions.

If the system does not acquire x-ray images:

- Check the USB connection.
- Check that the **FlashRay** is not disabled in the software program.
- Make sure that the correction file USB Card for the connected sensor is installed successfully.
- Make sure that the active side of the sensor is facing the source of the x-ray and the active area is aligned with the x-ray beam.
- Check the x-ray exposure settings and ensure that the x-rays were emitted.

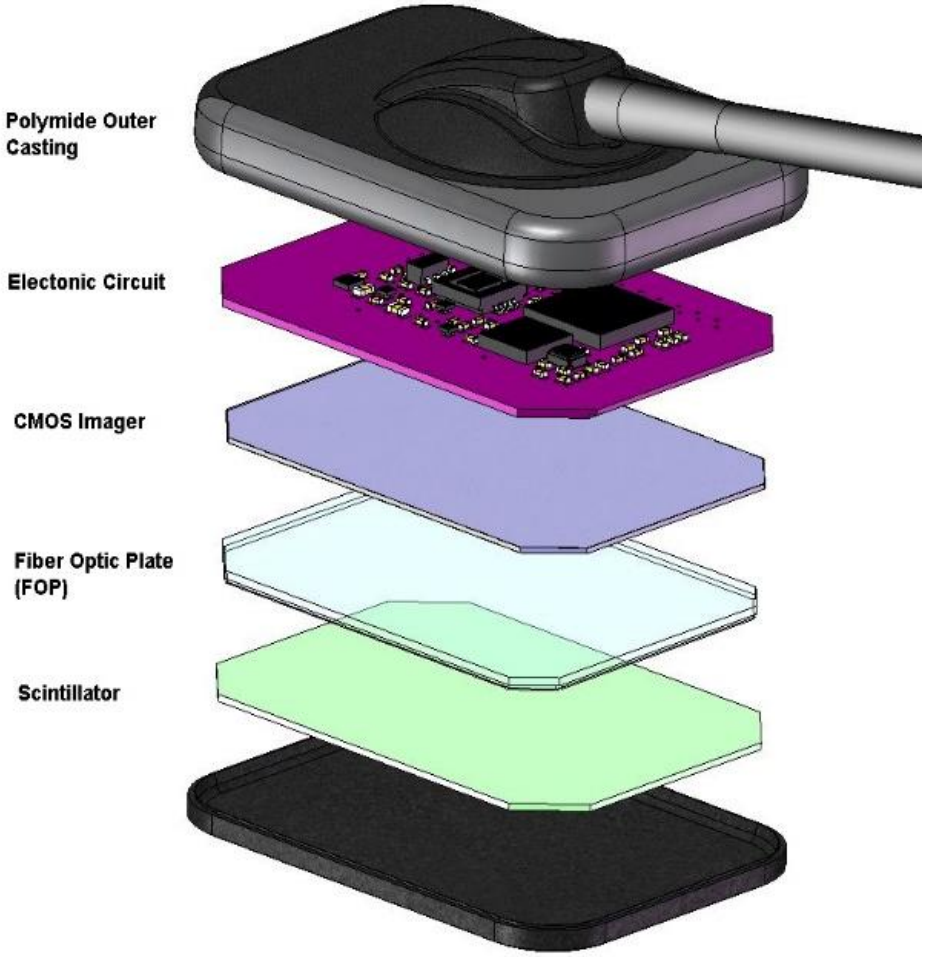
Consult your software user manual for additional assistance. If the problem cannot be resolved, contact your Dealer or Customer Support (information provided in your manual).

12 Specifications

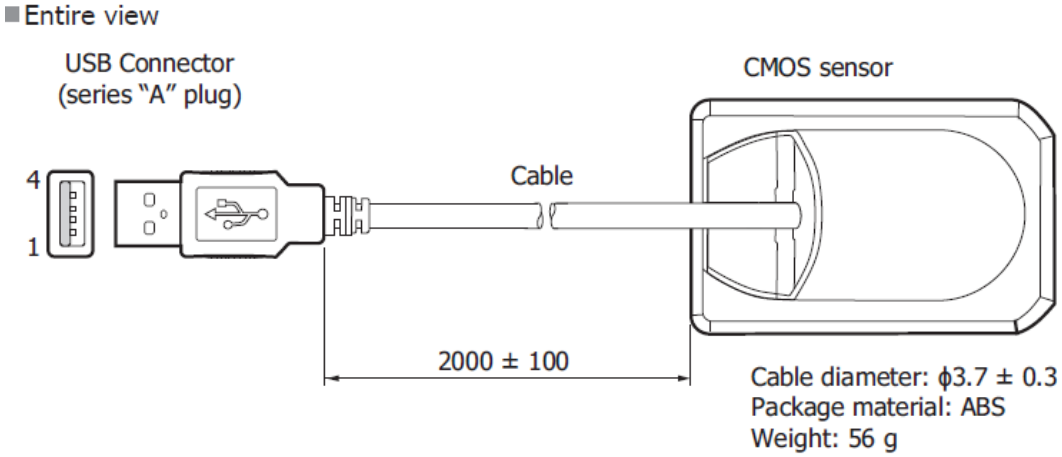
Structure

Parameter	S11684-12/-62 (Size 1)	S11685-12/-62 (Size 2)	Unit
	Min Typ Max	Min Typ Max	
Image size (H x V)	20 x 30	26 x 34	mm
Pixel size	20 x 20	20 x 20	µm
Pixel pitch (H x V)	20	20	µm
Number of total pizels (H x V)	1000 x 1506	1300 x 1706	pixels
Number of effective pixels	1000 x 1500	1300 x 1700	pixels
Number of light-shielded pixels	Upper part: 766, 768, 770	Upper part: 756, 758, 790	pixels
Number of light-shielded pixels	Lower part: 1000 x 3	Lower part: 1300 x 3	pixels
Scintillator Type	CsI(TI)-12 / GOS-62	CsI(TI)-12 / GOS-62	
Interface	USB 2.0	USB 2.0	

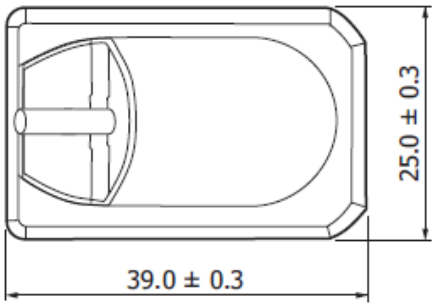
12.1 Sensor Architecture

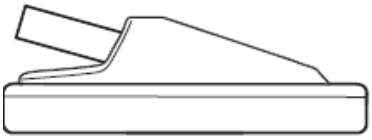


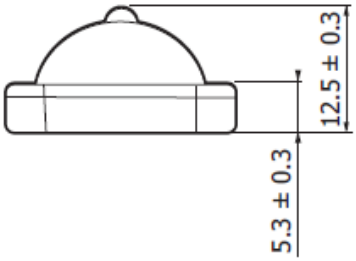
12.2 Mechanical Dimensions Sensor Size 1



CMOS sensor



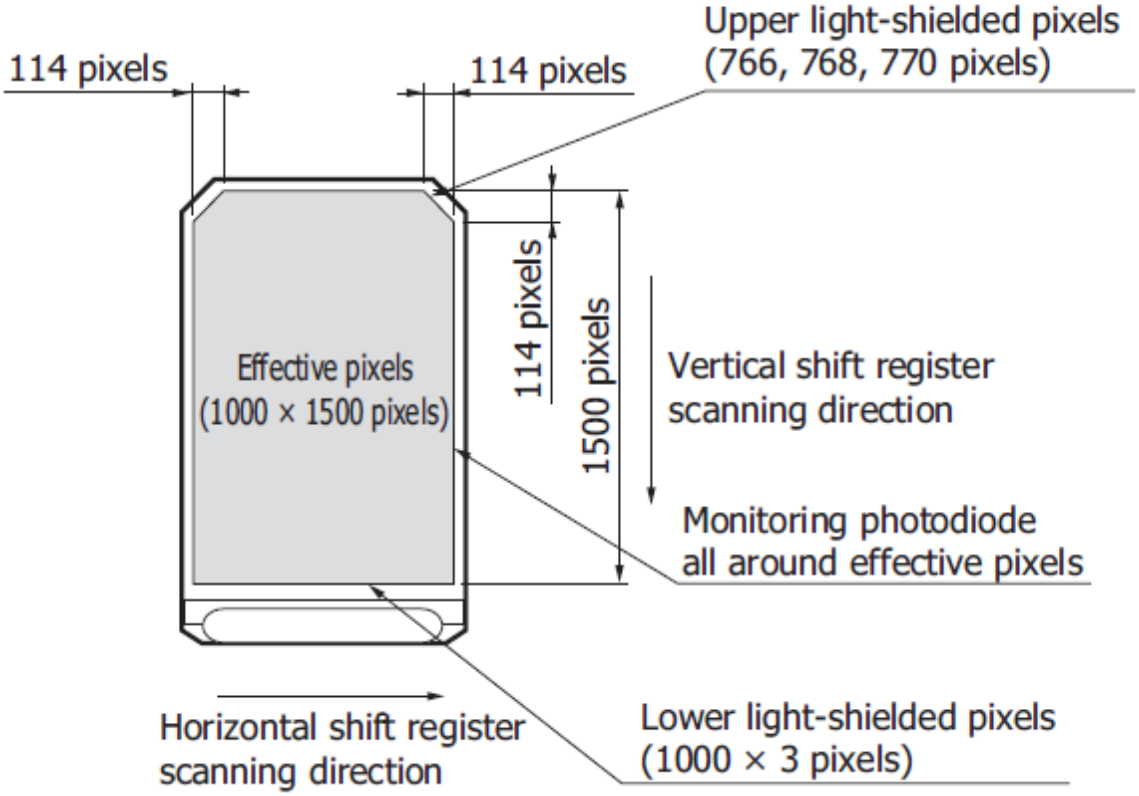




Standard packing:
polypropylene box in moisture-proof bag
[1 product/bag, bag size;150 (W) × 200 (H) × 50 (D) mm,
gross weight: approx. 320 g]

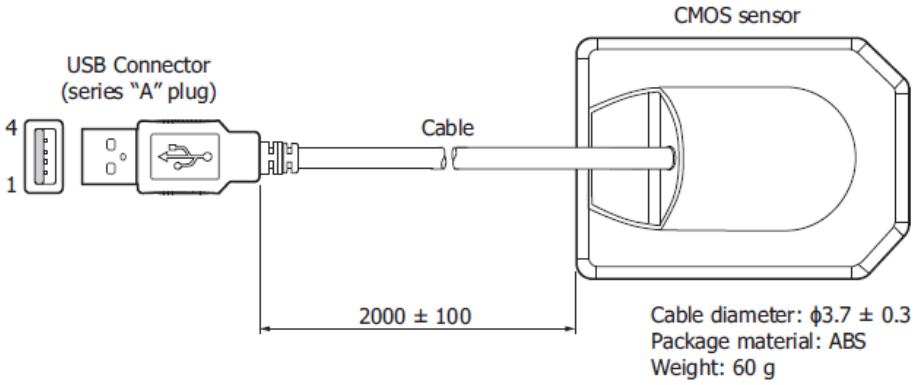
12.3 Image Sensing Area / Actual Image Area Size #1

Effective photosensitive area

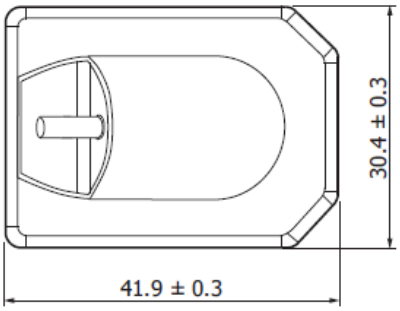


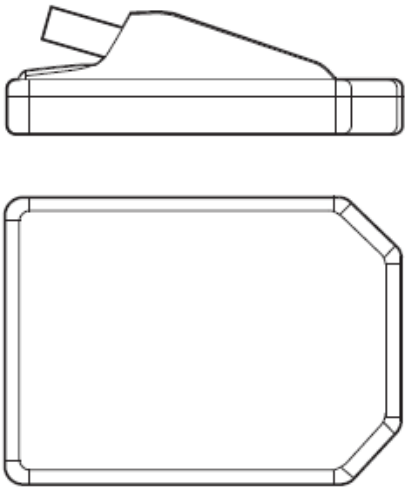
12.4 Mechanical Dimensions Sensor Size #2

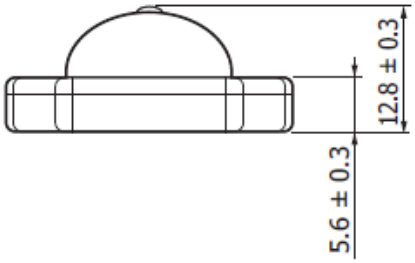
Entire view



CMOS sensor



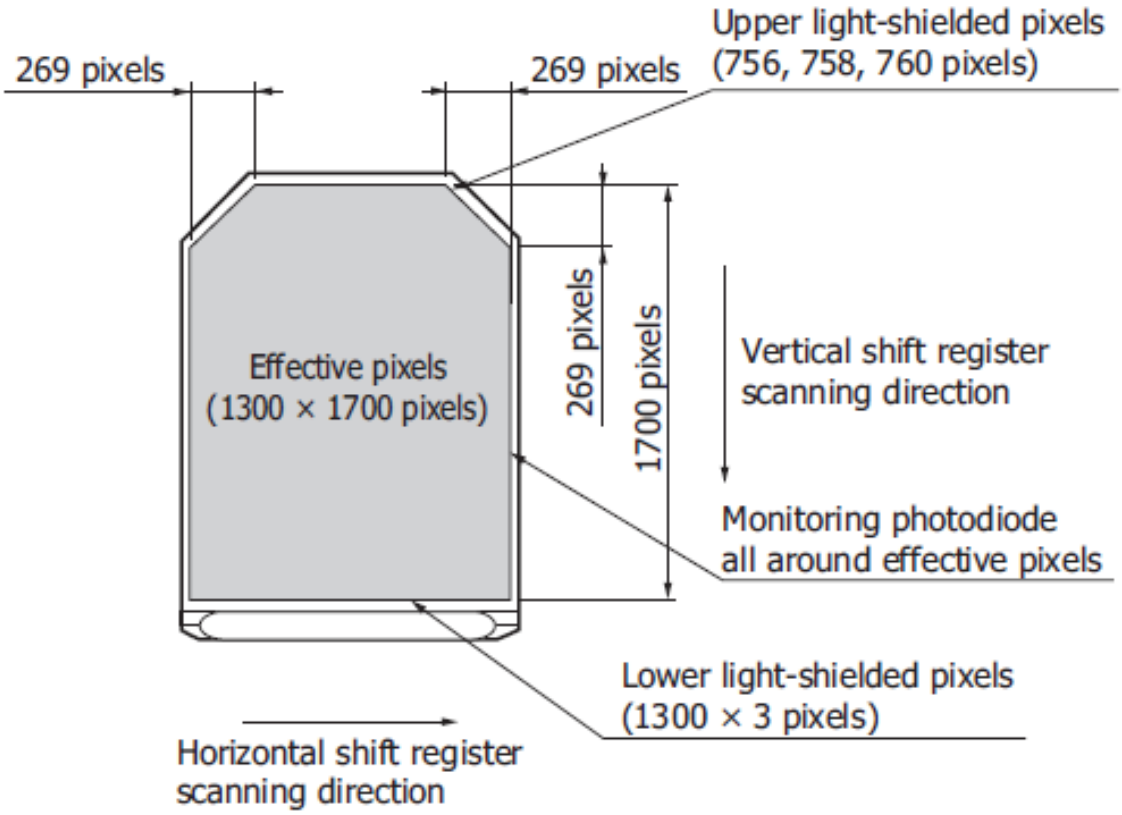




Standard packing:
polypropylene box in moisture-proof bag
[1 product/bag, bag size: 150 (W) × 200 (H) × 50 (D) mm,
gross weight: about 320 g]

12.5 Image Sensing Area / Actual Image Area Size #2

Effective photosensitive area



13 Sensor Images

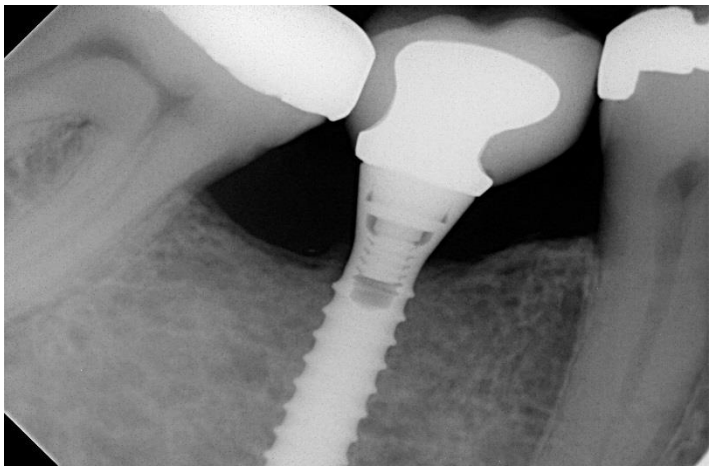


Image #1 Posterior PA showing an implant

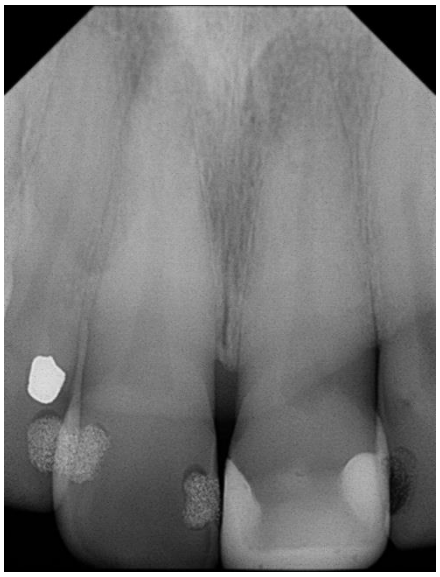


Image #2 Upper Anterior PA

Image #3 Lower Anterior PA

13.1 Image Quality Assurance

Image quality of the **FlashRay** sensor depends on several factors:

- The quality of the X-ray source (kV, focal spot size, distance)

- The alignment of the X-ray source to the anatomic region
- The applied X-ray dose / exposure time
- The settings of the computer monitor

It is recommended that you establish a procedure for periodic review of the image quality. If image quality is not satisfactory, check the manufactuerer guidelines of your genertor to make sure it is not a software problem. Then **contact customer service support at 877-509-3180.**

Display Image: Refer to the software manual for guidance on how to ensure good display settings and image dispay properties.

13.2 Electro Optical Performances

General Test conditions for performances under X-ray specification:

- X-rays generator 70 k Vp tube voltage
- Pixel: 20 µm x 20 µm
- Scintillator: CSI deposited on fiber-less substrate
- Performance given with dark image subtracted
- Analog: gain 2
- Threshold level 250 mV

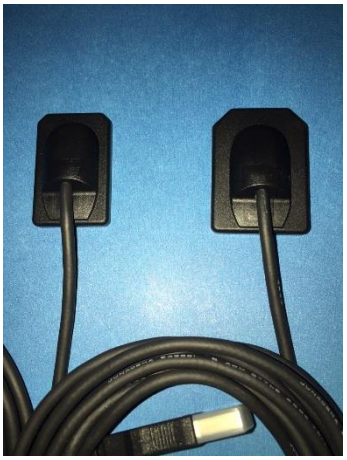


Image of sensors:

Size 1 (in photo on left)

Size 2 (in photo on right)

13.3 Electrical and Optical characteristics S11684 / Size 1 and S11685 / Size 2

Electrical and optical characteristics (image sensor, Ta=25 °C, VBUS=5 V)

Parameter			Symbol	S11685-12			S11685-62			Unit
				Min.	Typ.	Max.	Min.	Typ.	Max.	
X-ray sensitivity*2			Sx-ray	13	19	25	10	14	19	LSB/µGy
Saturation output			Dsat	3280	4900	-	3280	4900	-	LSB
Saturation dose*2			Lsat	130	260	380	170	350	500	µGy
X-ray response nonuniformity*2 *3 *4			XRNU	-	-	±30	-	-	±30	%
Dark output*3			Ddark	-	350	900	-	350	900	LSB/(pixel·s)
Readout noise			DNread	-	7	21	-	7	21	LSB rms
Dynamic range*5			DR	44	57	-	44	57	-	dB
X-ray resolution*2			RESOx-ray	15	20	-	8	12	-	line pairs/mm
Blemish*2	Point defect*6	White spot	-	-	0	20	-	0	20	-
		Black spot	-	-	0	20	-	0	20	-
	Cluster defect*7		-	-	0	3	-	0	5	-
	Column defect*8		-	-	0	0	-	0	1	-
Defect line*2 *9			DL	-	0	1	-	0	3	lines
Reliability*10			-	-	125000	-	-	125000	-	shots

S11684-12 /Size 1

Electrical and optical characteristics (monitoring photodiode, Ta=25 °C, Vdd=5 V)

Parameter	Symbol	S11684-12			S11684-62			Unit
		Min	Typ	Max	Min	Typ	Max	
Sensitivity*2	S_MPD	-	56	-	-	38	-	LSB/(µGy/ms)*11
Saturation output*12	Dsat_MPD	-	1023	-	-	1023	-	LSB
ADC offset	Ooffset_MPD	-	430	-	-	430	-	LSB
Random noise	Nrnd_MPD	-	2	-	-	2	-	LSB rms

S11685-12 / Size 2

Electrical and optical characteristics (monitoring photodiode, Ta=25 °C, VBUS=5 V)

Parameter	Symbol	S11685-12			S11685-62			Unit
		Min.	Typ.	Max.	Min.	Typ.	Max.	
Sensitivity*2	S_MPD	-	63	-	-	46	-	LSB/(µGy/ms)*11
Saturation output*12	Dsat_MPD	-	1023	-	-	1023	-	LSB
ADC offset	Ooffset_MPD	-	430	-	-	430	-	LSB
Random noise	Nrnd_MPD	-	2	-	-	2	-	LSB rms

13.4 Temperature Range

Operating Temperature : 0° C to 35°C / 32°F to 95°F

Storage Temperature : -20° C to 70°C / 68°F to 158°

14 Warranty

- The warranty is limited to replacement or repair of any defective product due to defects in workmanship or materials used in manufacture. The warranty does not cover loss or damage caused by natural disaster, misuse (including modifications and any use not complying with the environment, application, usage and storage conditions described in this manual, or total radiation dose over 50 Gy (incident X-ray energy: 70 kVp) even within the warranty period.

15 Summary

- Used by a dental professional
- Installation by contacting your dealer to interface software
- Sensor powered by the USB 2.0 port
- Use X-ray protection
- Use protective sheaths on sensor
- Use positioners
- Instruct the patient, “Do Not Bite on the Sensor”
- Make sure sensitive surface of sensor is directed towards x-ray generator
- Handle sensor with high degree of care
- Do not twist cable
- Clean with 70% isopropyl alcohol

The summary is not intended to replace complete user instructions. The entire user manual should be read before the device is operated.

16 Index