BRASSELER USA®

GEM™

DIGITIAL X-RAY SENSORS

INSTRUCTIONS FOR USE

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INTRODUCTION

Brasseler GEM10, GEM15, and GEM20 sensors are digital x-ray sensors that are designed specifically for intraoral x-ray imaging upon human patients for diagnostic use. Intraoral x-rays are captured using standard intraoral x-ray imaging techniques as performed by trained dentists and associated care providers.

No physical, mechanical, or electrical connection exists between the Brasseler GEM sensors and the x-ray source. The sensor is initialized via software to wait for and detect onset of exposure from the x-ray source; and creates a digital image after being exposed with x-rays; and delivers the sensor data to the PC that the sensor is coupled to via USB connection.

No modification of any kind is allowed to the Brasseler GEM Digital Sensor System. Any repair must be performed exclusively by Brasseler or a Brasseler authorized vendor.

Essential Performance

The essential performance of the Brasseler GEM Sensor System is the sensor's integration with an imaging software (PACS) and the sensor's ability to capture intraoral x-ray images that allow visual recognition of dental anatomical structures and pathologies as well as abnormal dental conditions. The digital x-ray images are used for diagnosis, treatment, and monitoring of the dental structures, pathologies, and conditions in child and adult dental patients.

Product Description

The Brasseler GEM Digital Sensor System is an indirect converting x-ray detector. A scintillating material converts the incident x-ray flux into visible light photons, this light is coupled optically and directed to a CMOS technology light detection imager via a fiber optic faceplate, and then converted to digital data.

Once the sensor is initialized via software command; the design of the sensor assembly supports automatic detection of the onset of incoming x-rays flux and which then the sensor integrates and generates the intraoral digital x-ray image.

Brasseler GEM Digital Sensor System implements a dedicated and encapsulated electronic assembly including a housing, an image sensor, a permanently attached USB cable, and a software driver. The data is delivered via the USB cable connection to the PC. The power for the electronic assembly is supplied via USB connection.

Indications for Use

Brasseler GEM is a USB-driven digital intraoral x-ray sensor which is intended to acquire dental radiographic images. Brasseler GEM must be operated by healthcare professionals who have been trained and are competent using various methods of acquiring radiographic images of dental anatomy. Brasseler GEM can be used with dental positioning devices and holders to assist with aligning an x-ray source beam with the sensor and anatomy. Brasseler GEM can also be aligned by hand with assistance of patient.

Take precautions to protect yourself from radiation. Please refer to Instructions for Use of the intraoral x-ray equipment being used with the Brasseler GEM Digital Sensor System.

Under no circumstances should operator of system hold sensor by hand during x-ray exposure.

Instruct patient not to bite on a sensor. Use positioning techniques to minimize ability for patient to bite sensor. Biting a sensor may damage the internal components, affecting image quality and performance, and resulting damage may void the Brasseler GEM Digital Sensor System warranty.

Intended Use: Brasseler GEM is intended for any dental practice that uses x-ray equipment for intraoral diagnostic purposes. Brasseler GEM can be used by trained dental professionals for patients receiving intraoral x-ray examinations and produces digital images for patients receiving intraoral x-ray examinations for diagnostic purposes. When Brasseler GEM is to be used in a dental practice, an optional software will be necessary. Brasseler GEM is a USB-driven digital intraoral x-ray sensor which is intended to acquire dental radiographic images. Brasseler GEM must be operated by healthcare professionals who have been trained and are competent using various methods of acquiring radiographic images of dental anatomy. Brasseler GEM can be used with dental positioning devices and holders to assist with aligning an x-ray source beam with the sensor and anatomy.

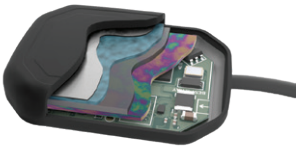
There are no known contraindications.

Device Overview

A sensor is first connected to a PC running Windows operating system through the standard Universal Serial Bus (USB) port. The sensor is then positioned in the patient's mouth by a trained dental professional. There is no physical or electrical connection between the GEM and the x-ray source, however once sensor is armed via software command the sensor will detect and convert incident x-rays into a digital image, as long as the x-ray source exposing the sensor to a minimum detectable dose.

Digital x-ray images are displayed on the computer monitor within seconds after exposing the sensor. Images can be optimized per a user's requirements via accompanying imaging software and are stored as image files in the users imaging software (PACS) database.

SENSOR CONNECTED TO USB CABLE



INTERNAL COMPONENTS VIEW

Proficiency with the Brasseler GEM Digital Sensor System

It is critical that all operators of a Brasseler GEM Digital Sensor System read and understand this user guide and become familiar with the Brasseler GEM Digital Sensor System prior to using on patients. Practicing the techniques for intraoral imaging prior to use on patients is strongly recommended.

For new users of intraoral imaging or digital x-ray imaging and software, training is highly recommended. This manual is not intended to serve as a training substitute or as a continuing education course for intraoral imaging. Reading this manual thoroughly and then carefully practicing with the equipment will prepare users for intraoral imaging on a patient, but these activities must be paired with additional intraoral imaging training and/or experience.

Computer skills and an basic understanding of the Windows operating system, along with an understanding of the imaging software (PACS) being utilized are assumed in this user manual. If a user does not have any of the above skills a computer training course or other aides are very highly recommended and may be necessary to avoid issues.

Conventions Used in the Manual

The following conventions are used to bring the operator's attention to important information:

	**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.
	**X-RAY** Alerts the operator that this section references the external radiation source and damage to the operator that may result from improper use.
IMPORTANT:	Provides advice for the operator regarding use of the device or a process.
PLEASE NOTE:	Highlights important or unusual points.

INSTALLATION, CARE, AND MAINTENANCE

Many errors originate from inadequate attention to hardware installation. Poor care of the Brasseler GEM Digital Sensor System can result in damage to, or destruction of, the fragile electronic components. Poor attention to sensor, PC, or imaging equipment maintenance procedures including adjustment of the x-ray source, can lead to unacceptable image quality.

PLEASE NOTE: Please call Brasseler GEM Technical Support at 1-877-958-1625.

Installation should be carried out by a trained and qualified computer specialist or network technician.

Brasseler GEM Digital Sensor System units are highly sophisticated equipment that must be handled with care and maintained in accordance with the manufacturer's recommendations.

When calling technical support, please ensure that you have access to the computer which is commonly used with a sensor.

Failure to maintain cybersecurity can result in compromised device functionality, loss of data, or exposure of other connected devices or networks to security threats.

Description of Product Symbols

Please refer to "Product Symbols" in Appendix C of this document.

Hardware Requirements

IMPORTANT: For regulatory reasons, all IT components used in connection with Brasseler GEM Digital Sensor System need to be in compliance with applicable safety standards. Refer to Appendix B, "Conformance to Standards."

Current hardware system requirements are available on the Brasseler website. Technology and system requirements may change. Please consult your IT professional or Brasseler prior to the purchase of new hardware to make sure that it will be compatible with your Brasseler GEM Digital Sensor System.

Systems meeting but not exceeding the minimum requirements may fail to deliver a satisfactory experience for some users or in some installations. Systems with faster processors, more memory, bigger hard drives, and high-quality monitors will significantly enhance performance.

It is highly recommended to always back-up all data prior to any changes and use a certified computer professional to make any system and/or network changes. Always back-up data and store it off-site. Before assuming that your back-up efforts have been

successful, make sure that you understand the back-up process and practice the restore process at least once on a test system. Verify that both the operating system and data have been accurately preserved. Consult with your IT support team for questions.

Installing the Brasseler GEM Digital Sensor System

PLEASE NOTE: Brasseler GEM Digital Sensor Systems do not require calibration. Any calibration files are pre-loaded in a sensor's physical on-board non-volatile memory and therefore the installer does not need to install calibration files onto each PC, and which is often the case with other brands of sensors.

Installation includes:

1. Installing the device driver if it is not already available on that computer.
2. Connecting the sensor to a computer.

Installing Device Driver for Sensor

1. Ensure that the computer to which you are connecting the sensor to has a compatible imaging software installed.
2. If the compatible imaging software doesn't install the GEM sensor device driver it can be downloaded from BrasselerUSADental.com/GEMSoftware. After downloading, run the installer [GEMDriverSetlup.exe] and follow the instructions that appear on the screen.

PLEASE NOTE: For additional installation guidance and resources, visit http://BrasselerUSADental.com/GEMSoftware

Connect a GEM Sensor

1. Carefully plug the USB end of the GEM sensor cable into the computer's USB port. Do not use force. Ensure that the plug is properly oriented with the USB port. Try rotating the USB plug if it does not easily insert into the USB port.
2. When the sensor is plugged into the computer the Windows operating system will detect that a USB device has been plugged in.
3. Follow the installation instructions that appear on the screen
4. After use is complete, unplug the USB end of the sensor cable from the USB port to disconnect the GEM sensor.

Adjusting the X-Ray Source

Brasseler GEM Digital Sensor System are generally compatible with any dental intraoral x-ray unit. Digital sensors normally require much shorter exposure times than film does thanks to the high sensitivity of the sensor technology. For this, Direct Current (DC), or high frequency x-ray generators are recommended for optimal use. These generators provide stabilized tube voltage (kV) and reproducible exposure doses even with the very short exposure times. Please refer to your x-ray generator manual for the recommended exposures times for digital sensors as x-ray exposure values vary by make and model.

IMPORTANT: X-ray generators, even among the same brands, may differ greatly in their performance based on generator values, age, use rate, and many other factors. In addition, on newer x-ray machines, the "digital" setting on the x-ray interface may not be the ideal setting. Users should determine the best settings per x-ray head based on desired image results.

Conformance to Standards

All x-ray equipment for the dental intraoral radiography used with Brasseler GEM Digital Sensor System must conform to IEC 60601-2-65.

Brasseler GEM Sensor Systems conform to the safety standard IEC 60601-1.

All IT components electrically connected to the Brasseler GEM Sensor System must conform to IEC 60950-1.

Normally, the IT components are placed outside the patient environment. IT components placed inside the patient environment, due to customer site requirements, must also conform to IEC 60601-1.

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 Medical Equipment (ME) or ME System or between a Patient and other persons touching parts of the ME Equipment or ME System."

US Federal law restricts this device to sale by or on the order of a dentist or other licensed practitioner.

Safety Considerations

All external surfaces of the sensor, sensor cable, sensor holders, and the sensor sheaths are considered to be Type BF applied parts and are safe for normal or accidental patient contact during use.

Brasseler GEM Digital Sensor System do not have serviceable parts. Do not open the device to service it. All aspects of the sensor that are meant to be attended to by the operator are accessible without opening the internal components of the device. If there is a service problem, contact a qualified service representative from whom you purchased your Brasseler GEM Digital Sensor System

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.

Mains Isolation
Disconnection from the supply mains occurs at the input to the computer. The sensor can also be disconnected from the computer.

Prevention of Cross-Contamination

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

For information about cleaning the sensor, please refer to the Care Instructions in Appendix D.

Sensor Inspection
Always inspect the sensor, cable, and position devices for physical damage prior to every use. See Care Instructions in Appendix D for more information.

Remove sensor from service if damage to the cable or housing is observed, otherwise exposure to elevated surface temperature or improper functionality may result.

Disposal

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste. It must be collected separately and must be disposed as per local regulations. Contact your authorized representative for information concerning the decommissioning of your equipment.

X-Ray Generator Settings

The radiation of x-ray tubes is controlled by the settings of:

- Exposure time (milliseconds) or pulses
- Voltage (kV or KVp)

- Current (mA)
- Distance between the x-ray generator and the sensor

Some controls allow for the modification of all the above, others have fixed settings for current and voltage. Follow the instructions of the x-ray source/generator to set the desired dose values.

There is a correlation between the distance of the cone to the sensor and the dose received by the GEM unit. The radiation that reaches the sensor decreases with the square of the distance. If you double the distance, the sensor receives only ¼ of the radiation.

Proper Care of the Brasseler GEM Digital Sensor System

Prior to taking x-rays, each staff member should be fully trained and have a complete understanding of how to care for a sensor. Not adhering to the following rules to protect the sensors may potentially result in malfunction or permanent damage.

- Store the sensor in a safe place when not in use
- Do not allow the patient to bite down on the sensor or sensor cable
- Do not roll over the cable with any wheeled items such as carts or stools
- Do not allow the sensor cable to be pinched in a drawer, door, or cabinet
- Do not twist, coil, or wrap the sensor cable tightly around any object
- Do not insert foreign objects into the sensor or cable connector
- Do not drop the sensor
- Do not clamp the sensor with devices that exert excessive force (for example: hemostats or clamps of any type)
- Do not autoclave the sensor
- Disinfect the sensor and cable in accordance with the CDC and/or other responsible regulatory parties including standards such as OSAP for infection control
- Use a new sheath for every patient

Do not autoclave the sensor. Autoclaving a sensor will cause permanent damage.

The sheath must be removed after each patient. The sensor must be cleaned and disinfected after each patient use by following the Cleaning Agent guidelines. Do not use any cleaning agents not contained within the approved list of cleaning agents.

Abuse or misuse of the sensor components may result in voiding the manufacturer warranty. The manufacturer warranty does not cover visible damage to any of the Brasseler GEM Digital Sensor System components.

See Care Instructions in Appendix D for more information.

Image Quality Assurance

Image quality depends on several factors, such as, but not limited to, the following:

- The quality of the x-ray source (kV, mA, focal spot size, distance to sensor, etc.)
- The alignment of the x-ray source to the anatomical region
- The applied x-ray dose (exposure time)
- The patient not moving during exposure
- The settings of the computer monitor

It is recommended that an operator establishes a procedure for periodic review of the image quality. If image quality is not satisfactory, or degrading, please check the contributing system parts and speak with a certified dental x-ray technician or Brasseler GEM Technical Support.

APPENDIX A - EMC INFORMATION

The Brasseler GEM Digital Sensor System, like any electronic device, is subject to electromagnetic interactions with other electronic devices. Care must be taken when operating this equipment around other electrical equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device.

The EMC information in this chapter is provided for the medical system established by connecting the GEM unit to a computer. This computer must be compliant with IEC 60950-1 (if located outside the patient environment) or IEC 60601-1 (if located inside the patient environment). Please consult the documentation of the computer for completing the EMC information.

This Medical Equipment is deigned to comply with IEC 60601-1-2: 2014. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the user instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Consult your authorized dealer for help

The Brasseler GEM Digital Sensor System is suitable for use in hospitals except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of the EM disturbance is high.

IMPORTANT: Portable/mobile radio frequency communications equipment can affect the function of the GEM unit as well as any other electronic medical equipment. This affect may result in image failure or image quality degradation.

Brasseler GEM Sensor Systems are USB compliant devices and shall be used with USB compliant cables suitable for high speed/USB 2.0 cables. Such cables are either marked “USB 2.0” or “USB High Speed.” USB certified hubs can be used to extend the distance to the USB host/computer. The length of the cable connection to the hub or between hubs shall not exceed 5 meters.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of the equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Using non-USB compliant cables or hubs, or exceeding the maximum count of USB hub devices for extending the distance, can degrade the immunity of the GEM unit to electromagnetic fields or increase the emission of electromagnetic fields from the GEM unit.

For cable extensions, use a USB Cable Extender (3 feet) or an Active USB Extender Cable (15 feet).

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.

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 Brasseler GEM Sensor Systems, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Brasseler GEM Digital Sensor System, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the Brasseler GEM Sensor System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The sensor is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A (*)	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies (*)	

(*) Computer used with the Brasseler GEM Sensor system must meet this rating.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Brasseler GEM Sensor system, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the Brasseler GEM Sensor system should assure 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 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Complies (*)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 common mode	Complies (*)	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0o, 45o, 90o, 135o, 180o, 225o, 270o, and 315o 0% UT; 1 cycle 70% UT; 25/30 cycles for 50 Hz and 60 Hz, respectively Single phase: at 0o 0% UT; 250/300 cycle for 50 Hz and 60 Hz respectively Single phase: at 0o	Complies (*)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the sensor requires continued operation during power mains interruptions, it is recommended that the sensor be power from an uninterruptible power supply or a battery.
	VDI specs per 3rd edition: <5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in atypical commercial or hospital environment.

NOTE 1 UT is the mains voltage prior to application of the test level.

(*) Computer used with the Brasseler GEM Sensor system must meet this rating.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Brasseler GEM Sensor system, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the Brasseler GEM Sensor system should assure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	AC Mains: 3 V, 0.15 MHz – 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz SIP/SOPS: 3 V, 0.15 MHz – 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Complies (*)	Portable and mobile RF communications equipment should be used no closer to any part of the Brasseler Gem sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3 ed3.0 (with A1:2007+A2:2010)	3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	Complies (*)	Recommended separation distance: 150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2.5 GHz V1 = 3 Vrms E1 = 3 V/m Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The ISM (Industrial, Scientific and Medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 4,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FI-XRS systems used exceeds the applicable RF compliance level above, the Brasseler GEM Sensor Systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Brasseler GEM Sensor System.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

(*) Computer used with the Brasseler GEM Sensor system must meet this rating.

Recommended separation distances between portable and mobile RF communications equipment and the Brasseler GEM Sensor System

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

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (Meters)		
	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	3.69	3.69	7.38
100	11.67	11.67	23.33

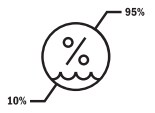
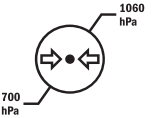
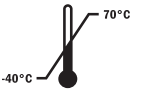
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

APPENDIX B — SPECIFICATIONS AND STANDARDS

Sensor Architecture	Indirect converting dental intraoral CMOS x-ray sensor Image Pixel Size: 19.5µm Image Resolution: 20+ visible lp/mm Maximum Gray Levels: 16,384 (14 bit)
X-Ray Parameters	Sensor can be used with dental x-ray generators in the range of 60 to 70 kV; at minimal 40 µGy incident dose
Electrical Rating	DC 5V, 0.5W ⎓
Connection to PC	USB 2.0 compliant
Cable Length	1.9m
Degree of Protection Against Shock	Type BF Applied part 
Mode of Operation	Continuous
Method of Sterilization	Sensor not suitable for sterilization or autoclave
Type of Protection Against Electrical Shock	Class II
Suitability for Use in an OXYGEN RICH ENVIRONMENT	Not intended for use in an Oxygen Rich Environment
Protection Against Harmful Ingress of Water	IPX8 (Protected against the effects of continuous immersion in water at 1.1 meters for up to 35 minutes)
Sensor Technology	CMOS

	External Dimensions (mm)	Active Imaging Area (mm)	Active Image Area (px)
GEM10 - Size 1	36.36 x 24.53 x 12.52	30.01 x 20.01	1539 x 1026
GEM15 - Size 1.5	38.83 x 29.63 x 13.01	32.99 x 25.82	1692 x 1324
GEM20 - Size 2	41.80 x 30.48 x 13.02	35.92 x 25.82	1842 x 1324

Environmental Conditions	Humidity	Air Pressure	Ambient Temperature
Usage Brasseler Gem units are not suitable to be operated in oxygen rich and/or explosive environments	30% to 75%	700 hPa to 1060 hPa in altitudes up to 3000 meters	5° to 30°C
Transportation and Storage Transport in the supplied protective pack	10% to 95%		-40° to 70°C
Packaging Labels			
EU Classification	Class IIa medical device according to MDD 93/42/ECC		

APPENDIX C — PRODUCT SYMBOLS

Symbol	Title of the Symbol	Reference Number	Standard Containing the Symbol	Fuction/ Description per Standard	Manufacturer Interpretation
	Type BF applied part	5333	IEC 60417	To identify a type BF applied part complying with IEC 60601-1	To identify a type BF applied part complying with IEC 60601-1
	Direct Current	5031	IEC 60417	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals	Direct Current
	General warning sign	W001	ISO 7010	To signify a general warning	Warning
	Radioactivity and ionizing radiation	W003	ISO 7010	To warn of radioactive materials or ionizing radiation	Radiation Warning
	Caution	0434B	ISO 7000	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	Please refer to the written instructions in this manual
	Do not reuse	1051	ISO 7000	To indicate that the item is for single use only and must not be used more than once, for example, on packages of medical disposables	Please contact your supplier for further information about the product disposal at the end of the product's lifetime
	Marking of electrical and electronic equipment	N/A	BS EN 50419	This symbol on the products and/ or accompanying documents means that the used electrical and electronic products should not be mixed with general household waste	Please contact your supplier for further information about the product disposal at the end of the product's lifetime
	Manufacturer	3082	ISO 7000	To identify the manufacturer of a product. This symbol shall be used filled in all applications to differentiate it from ISO 7000-2497	Manufacturer

	Date of manufacture	2497	ISO 7000	To indicate the date on which a product was manufactured	Date of manufacture
	Distributor	3724	ISO 7000	To identify the distributor of a product.	Distributor
	Catalogue number	2493	ISO 7000	To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.	Catalogue number
	Serial number	2498	ISP 7000	To identify the manufacturer's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.	Serial number
	Consult instructions for use or consult electronic instructions for use	1641	ISO 7000	Indicates the need for the user to consult the instructions for use When the instructions for use and patient information are located within the same electronic instructions for use, a manufacture may choose to use this symbol to indicate both.	Follow the operating instructions for use
	N/A	N/A	N/A	N/A	IPX8 (Protected against the effects of continuous immersion in water at 1.1 meters for up to 35 minutes)
	Atmospheric pressure limitation	2621	ISO 7000	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage	Atmospheric pressure limitation
	Humidity limitation	2620	ISO 7000	To indicate the acceptable upper and lower limits of relative humidity for transport and storage	Humidity limitation

	Temperature limit	0632	ISO 7000	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used	Temperature limitation
	This way up	0623	ISO 7000	To indicate correct upright position of the transport package	This end up
	N/A	N/A	ISO 7000	N/A	Stocking Unit
	Keep away from rain	0626	ISO 7000	To indicate that the transport package shall be kept away from rain and in dry conditions	Keep Dry
	Fragile, handle with care	0621	ISO 7000	To indicate that the contents of the transport package are fragile and the package shall be handled with care	Fragile, handle with care
	Prescription device	801.109	FDA Title 21	Caution: US Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner	Clinical use only

APPENDIX D - CARE INSTRUCTIONS

This section contains the proper handling for the GEM intraoral dental sensors. Failure to follow these care instructions may result in voiding of the Warranty.

Handling

- Do not use force to pull the sensor out of the USB port it is plugged into. The joint between cable and housing can withstand more the 500 pulling cycles with a pulling force of 30 N. The USB connector for the sensor has an endurance of 5,000 insertion / pulling cycles.
- Do not drop a sensor onto, or let it knock against, a hard surface. Even without obvious outward damage being visible, internal damage can occur.
- The sensor capsule and cable can withstand minimal biting (up to 50 N) as it may happen during the intended usage, however biting is not recommended.
- The sensors are not suitable for sterilization. Do not autoclave.
- The operating ambient temperature shall not exceed 30°C for a sustained period of time. However it can go to 37°C for less than 2 minutes.

Cleaning

The sensor surfaces/coatings, including the cable and all other material, are subject to hygienic considerations (excluding the USB connector) as defined below for Cleaning and Wet Disinfection:

In the scope of this requirement, Cleaning is defined as soft wiping the sensor and/or cable surfaces with either a soft cotton towel immersed with a disinfection liquid or a commercial available disinfection wipe. All surfaces of the sensor / cable may come into contact with the disinfection liquid and the disinfection "occurs" while the liquid is present / drying. This wiping procedure is typically random in movement and intermittent; hence, the total wiping time is stated within this requirement.

Material / Cleaner	**Total Wiping Time**
Isopropyl Alcohol (70%)	15 seconds
CaviCide® (Manufactured by Metrex)	15 seconds
CaViWipes™ (Distributed by Metrex)	15 seconds
ProSpray C-60™ (Manufactured by Certol)	15 seconds
Sani-Cloth® Plus, HB (Manufactured by PDI)	15 seconds

- The design can withstand up to 10,000 Cleanings for all materials listed above using the defined wiping time.

Material / Cleaner	**Submersion Time**
Isopropyl Alcohol (70%)	15 minutes
CaviCide® (Manufactured by Metrex)	15 minutes
ProSpray C-60™ (Manufactured by Certol)	15 minutes

- The sensor can withstand a total of 1,250 Wet Disinfections for all of the materials listed above using the defined insertion time per cycle.

Examples of Damage / Abuse

Below are examples of typical customer damage

Acceptance Levels	Acceptance Criteria	Acceptance Definitions
Target condition	As shipped condition, close to perfect	Desirable condition
Acceptable condition	Bite mark 1 – minor Bite mark 2 – medium Housing damage 1 – minor	Condition is not necessarily perfect but maintains integrity and reliability of the assembly E.g. Minor scratches, minor bite marks, minor cosmetic damage, etc.
Reject condition	Bite mark 3 – severe Cable cut Cable damaged Cable kinked Housing cracked Housing damaged Housing dented	A defect condition that impacts form, fit and function of the assembly. E.g. Heavy housing damage, deep scratches, deep bite marks, cracked housing, damaged USB connector, tool markings, broken cable strain relief, kinked cable, cut cable, etc.

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