midmark

Midmark® Intraoral Digital Sensor

User and Installation Manual

003-10565-00
Revision AA6
April 2023

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

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Contents

Introduction

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About This Manual

Welcome to advanced dental imaging technology from Midmark.

This manual describes the Midmark® Intraoral Digital Sensor (or “the Sensor"). It explains system components and provides instructions on getting started, installing the software and calibration files, acquiring images, and disinfecting the device.

Safety-Related Notation

⚠WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
⚠CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	Addresses practices and issues not related to personal injury.
SAFETY INSTRUCTIONS	Indicates specific safety-related instructions, procedures, or locations of safety equipment.

Related Manuals

Title	Description
00-02-1598: User Guide- Progeny Imaging	Designed to help acquire and work with images using Progeny® Imaging.
00-02-1604: Installation Guide- Progeny Imaging	Describes how to install Progeny Imaging, use the configuration utility, and upgrade Progeny Imaging.
00-02-1658: Progeny Imaging User Guide (Spanish)	Designed to help acquire and work with images using Progeny® Imaging. Presented in Spanish.
00-02-1659: Progeny Imaging User Guide (French)	Designed to help acquire and work with images using Progeny® Imaging. Presented in French.
003-10566-00: Midmark Preva User Manual	Identifies requirements for using the Preva Dental X-ray System, as well as quality control, cleaning, and disposal.

Indications for Use

The Sensor is intended to be used by dentists and other qualified professionals for producing diagnostic X-ray radiographs of dentition, jaws, and other oral structures.

The Sensor consists of a sensor head, cable, and USB connector. It is recommended to be used in conjunction with a patient positioner, sensor holder, and sensor sheaths.

Guidelines for Patient Selection

Guidelines for using the Sensor are described in the American Dental Association/Food and Drug Administration (ADA/FDA) Guide to Patient Selection for Dental Radiographs. The Sensor must only be operated for the intended use as indicated by the prescription of a qualified dental practitioner.

The device may be applied to the general patient population, including pediatric patients.

See the upcoming "Dose Data" beginning on page 108 for detailed exposure information.

Contraindications

None known.

Adverse Reactions

None known.

⚠WARNING	The Sensor may affect patients with pacemakers. The safety risk related to such use has not been analyzed.

Indications of Sterility

This product is not provided sterile.

SAFETY INSTRUCTIONS	For patient safety, **always** cover the Sensor with a disposable hygienic protective cover prior to use. A new cover must be used for each patient. It is recommended to disinfect the Sensor between uses. Refer to the Using the Sensor Sheaths section.

Warnings and Precautions

Read the following warnings and precautions before operating the Sensor. Not following the instructions in this manual may cause harm to the patient, operator, or others.

Midmark's Sensor must be prescribed by a dental practitioner skilled in the art of applying radiography in dentistry. Midmark's Sensor must be applied only by a qualified person, based on clinical examination, the consideration of the patient's signs, symptoms, oral and medical histories, and consideration of the patient's vulnerability to environmental factors that may affect oral health. The danger to X-ray use requires the prescriptions to include individual justification of the related risk factors and apply the device only when the additional diagnostic information is expected to improve patient care. The risk is estimated to be more significant for pediatric patients and pregnant women.

Examine radiological images and consider whether the diagnostic information sufficiently supports the diagnosis or planned treatment. If its information is insufficient, use supplemental information from other X-ray modalities or reapply the Sensor.

The certified components of the Sensor comply with Radiation Performance Standards 21 CFR, Part I, Subchapter J.

⚠WARNING	Do not modify the Sensor without manufacturer authorization. Modifying the safety mechanisms could result in previously unidentified risks to operators, patients, and third parties.

Radiation Safety

⚠WARNING	X-rays may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed. Only qualified and authorized personnel may operate the Sensor, observing all laws and regulations concerning radiation protection.

- Stand at least 2 m (approx. 7 ft) away from the focal spot and out of the X-ray beam path during radiography. No significant zone of occupancy is defined.
- Make full use of all radiation safety equipment features, accessories, and procedures available to protect the patient and operator from X-ray radiation.

NOTICE	Use a rectangular cone and sensor positioning devices whenever possible in order to reduce the X-ray dose to the patient.

NOTICE	Maintain audio-visual communication with the patient during X-ray exposure.

NOTICE	Verify the device operation with a radiological image test of a phantom or a test object after installation, servicing, or maintenance.

Warnings and Precautions (Cont.)

Electrical Safety

The Sensor is powered by the USB port.

- The Sensor is not serviceable. Contact Midmark Technical Support for service.
- Do not replace the Sensor when the patient is in the vicinity of the computer. Do not touch the patient when connecting or disconnecting the Sensor.
- The Sensor cable should be handled with care. Do not sharply bend or crimp the Sensor cable. Doing so could permanently damage the Sensor.
- The device installation must comply with all local legal requirements concerning electrical safety in rooms used for medical purposes.
- Before cleaning or disinfecting, this equipment must always be disconnected from the electrical supply.
- The computer and any other associated equipment (like USB hub) shall be placed outside the patient's environment (i.e., more than 1.8 meters away from the chair). The operator shall not access the patient and such devices at the same time.
- The computer and any other associated equipment shall be compliant with IEC 62368 or IEC 60601 (latest edition).
- The Sensor is sensitive to ultraviolet (UV) light. Therefore, the Sensor should never be exposed to direct sunlight for extensive periods of time. The storage location should be protected from direct sunlight.
- The Sensor enclosure meets IP68 per standard IEC 60529. This allows the Sensor to be placed in cleaning solution for up to 30 minutes. Do not immerse the USB connector. Reference "Appendix A: Cleaning and Disinfection" on page 96.

Warnings and Precautions (Cont.)

Electromagnetic Compatibility

⚠WARNING

- 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 all are operating normally.
- Using accessories or cables other than those specified in Sensor product documentation or provided by Midmark could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable radio frequency (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 Sensor, including network and power cables. Otherwise, degradation of the performance of this equipment could result.
- Interference may occur in the vicinity of equipment marked with this symbol  . Stop using or reposition the disturbing device if image distortion occurs.

NOTICE

The medical use of the Intraoral Digital Sensor is exempt from the specific technical standards and other requirements contained in Federal Communications Commission (FCC) Part 15. This exemption requires the user to stop operating the device upon a finding by the Commission or its representative that the device is causing harmful interference.

The Sensor is intended for use in all establishments, including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Disturbance	Standard	Compliance Level	Guidance
RF emission	CISPR 11:2019	Group 1, Class B	The Sensor is unlikely to cause interference to other medical devices intended to provide electromagnetic compatibility similar to this device.
Harmonic distortion	IEC 61000-3-2:2009	Class A	
Voltage fluctuations/ flicker emission	IEC 61000-3-3:2013	Class A	

The device is designed to be resistant to electromagnetic interferences typical for domestic, commercial, or hospital environments, and it is unlikely to cause interference to other medical devices designed to operate in the same environment.

Immunity	Standard	Compliance Level	Guidance
Electromagnetic discharge: − Contact − Air	IEC 61000-4-2:2008	± 8 kV ± 15 kV	The floor must be wood, concrete, or ceramic tile. It is recommended to maintain the relative humidity above 30 % when the floor is covered with synthetic material not treated to reduce the accumulation of static charges.
Electrical fast transient/burst: − Power supply lines − Input/output lines	IEC 61000-4-4:2012	± 2 kV ± 1 kV	
Surge: − Line to line − Line to earth − Input/output lines	IEC 61000-4-5:2017	± 1 kV ± 2 kV ± 1 kV	
Voltage dips, short interruptions, and voltage variations on power supply input lines	IEC 61000-4-11:2017	0 % * U_T for 0.5 cycles 0 % * U_T for 1 cycle 70 % * U_T for 0.5 s 0 % * U_T for 5 s	It is recommended to use an external uninterruptable power supply if continuous device operation is required.
Power frequency magnetic field:	IEC 61000-4-8:2009	30 A/m	Stop using or reposition the disturbing device if image distortion occurs.
Conducted RF: − 150 kHz to 80 MHz − ISM band	IEC 61000-4-6:2013	3 V 6 V	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 Sensor, including network and power cables. Otherwise, degradation of the performance of this equipment could result. Stop using or reposition the disturbing device if image distortion occurs.
Radiated RF: − 80 MHz to 2.7 GHz − Proximity fields from RF wireless communications equipment	IEC 61000-4-3:2010	3 V/m —	Interference may occur in the vicinity of equipment marked with symbol  . Stop using or reposition the disturbing device if image distortion occurs.

Explosion Safety

The device is not intended for use in oxygen-rich environments, critical care units, and in the presence of flammable and potentially explosive fluids, gases, or vapors. The safety risk related to such use has not been analyzed. Such use may cause personal injury and damage to the equipment. If flammable disinfectants are used, the vapor must be allowed to disperse before using the equipment.

Warnings and Precautions (Cont.)

Thermal Safety

- The maximum Sensor temperature in the patient's mouth may reach a temperature of 10 °C higher than the patient's temperature.
- The Sensor surface may remain above 41 °C (106 °F) for up to 10 minutes after the Sensor is removed from the patient's mouth.

Damage and Injury

Prevent damage and injury by observing the following:

- General
  - Follow all instructions within this manual.
  - Do not use any materials which are not directly approved.
  - Do not attempt to modify or repair the Sensor. Modification of the device could damage it and void the warranty.
  - Do not use the Sensor if it is suspected to be unsafe. Contact Technical Support.
  - Keep packaging out of reach of children.
  - Do not use an autoclave or a UV oven to sterilize the Sensor.
  - Do not allow the temperature of applied parts to exceed 45°C (113°F) in normal conditions.
  - Leave the Sensor plugged in the computer (if possible).
- Handling
  - Do not drop the Sensor or allow it to strike a hard surface. Do not pinch it severely. Handle the Sensor with care.
  - Avoid contact with solvents, flammable liquids, and sources of strong heat, which can damage the plastic enclosure of the Sensor, the cable, and the connector.
  - Use protective gloves when using and disinfecting the Sensor.
  - Do not bite the Sensor or cable.
  - Handle the Sensor carefully when removing it from a positioning system.
- Operation
  - Do not use the Sensor unless authorized and trained.
  - Remain at a proper distance from the X-ray beam.
  - Do not use the device in an inflammable anesthetic gas environment.
  - Place computer and other associated equipment out from the patient area (more than 1.8m (5.9ft)).
  - Use electromechanically safe certified computers (IEC 62368-1 or IEC 60601 compliant).
  - Keep the patient within your field of view while the Sensor is in the patient's mouth.

  - Do not leave the Sensor inside a patient's mouth for longer than 10 minutes.
  - Use a positioning system if there is enough space in the patient's mouth. Follow the manufacturer's instructions for use.
  - Do not touch the patient and computer/associated equipment at the same time.
  - Double-check the Sensor/X-ray output tube position to reduce the need to reshoot and thus reduce X-ray doses received by the patient.
- Safety and integrity of the cable
  - Do not pull, bend, or pinch the cable severely.
  - Plug and unplug the Sensor by holding the USB connector, not the cable.
  - Do not allow the cable to lay on the floor or across a passageway.
  - Coil the cable in large loops (1 or 2 loops) if needed during storage and transport. Do not wrap the cable in tight loops (e.g., around your hand).
  - Do not use computer furniture with drawers that can pinch the cable.
  - Ensure the cable is not tangled when using the Sensor.
  - Do not pull the cable when removing protection sleeves/sheaths.
  - Do not walk over the cable or roll a chair over it.
- Storage
  - Store the Sensor on a holder or a hook fixed on the wall if possible (with no more than 2 sensors on the same hook). Do not coil the cable around the holder.
  - If storing the Sensor in a wallet, choose a package that allows large cable loops (20cm diameter if possible). Do not use a very tight wallet to store the Sensor.
  - Do not store the Sensor freely on a table or a shelf.

Imaging Software

- The Sensor is designed to interoperate with imaging software through direct integration or by using TWAIN. Recall the last image if the software interface fails.

⚠CAUTION	Incorrect patient name and tooth number identification may lead to diagnosis or treatment errors. Verify and correct the marking on the recalled image.

Connectivity to IT Networks

- The Sensor, computer, and provided cables comprise a medical electrical system. The computer is not intended to be located in the patient environment (within a 1.5m radius of the patient).
- The Sensor requires a high-speed USB port for power and communication. Connect to the USB port of a computer or the dedicated port of the Midmark intraoral X-ray source if you purchased an integrated system.
- The intraoral sensors are designed to work together in a system with a wide range of equipment, and the following minimum safety requirements must be met for safe operation:

  - The USB connectivity must meet the requirements of the USB 2.0 or later standard, as evident, for example, by the USB.org logo.
  - The computers and IT equipment must comply with IEC 62368-1 or IEC 60601-1 standards, as evidenced by the marking on the device or by the manufacturer-provided declaration of conformity.
  - System installation shall be in accordance with the requirements of IEC 60601-1, the Standard for Safety Requirements of Medical Electrical Systems.
- Note that the sensor interoperation was evaluated with multiple off-the-shelf devices, and the safety of various systems was considered as described in this manual. However, Midmark cannot analyze the safety risk of all available choices, and the responsible organization must ensure the correct and safe equipment interoperation after any non-Midmark device installation or service.

Environmental Conditions

Operational Environment

The Sensor is intended to operate in temperature-controlled locations, where heating or cooling may be switched off for periods, but the occurrence of extremely low temperatures is prevented. The expected operational environment is:

Description	Value
Temperature	+ 5 °C to + 35 °C (+ 41 ºF to + 95 ºF)
Relative humidity	5 % to 85 %, non-condensing
Atmospheric pressure	70 kPa to 106 kPa
Maximum altitude	3000 m (9842 ft)

To maintain this environment:

- Use appropriate heating or cooling equipment.
- Use additional humidification where necessary to avoid extremely dry conditions.
- Use dehumidification where necessary to avoid extremely humid conditions.

Transportation Environment

The Sensor is intended to be transported for a limited time in weather-protected, heated, and ventilated conditions, or ventilated weather-protected conditions without heating in the general open-air climates, excluding Cold and Cold Temperate climates. The expected transportation environment is:

Description	Value
Temperature	− 25 °C to + 60 °C (− 13 ºF to + 140 ºF)
Relative humidity	5 % to 95 %, non-condensing
Atmospheric pressure	70 kPa to 106 kPa

Storage Environment

The Sensor is intended to be stored in enclosed locations with no control over humidity. The expected storage environment is:

Description	Value
Temperature	− 40 °C to + 70 °C (- 40 ºF to + 158 ºF)
Relative humidity	10 % to 90 %, non-condensing
Atmospheric pressure	70 kPa to 106 kPa

To maintain this environment, use heating to raise low temperatures, especially where there is a large difference between the conditions of this class and the open-air climate.

Units of Measure

Numeric indications of parameters on the Sensor are expressed in International System of Units (SI) units. Symbols ′ and ″ may be used for marking the angle units, minute and second of angle. When provided, approximate converted values in U.S. customary units are listed in parentheses. The distances in customary units use the abbreviations "ft" and "in" to denote foot and inch units.

Disclaimer

Midmark pursues a policy of continual product development. Although every effort is made to produce up-to-date product documentation, this publication should not be regarded as an infallible guide to current specifications. Midmark reserves the right to make changes without prior notice.

The original language of this manual is English. Translations to other languages are also available.

Warranty

A Warranty Registration Form has been included with your system. Please complete and return it immediately to validate your warranty. Failure to return the completed Warranty Registration Form may result in delays when contacting Technical Support for assistance.

For warranty information, visit https://www.midmark.com/warranty-information/dental-warranty.

Obtaining Technical Support

Upon request, qualified installation personnel can obtain part lists, descriptions, and additional Midmark® Intraoral Digital Sensor information from Midmark. Contact Midmark for a list of authorized installers.

Midmark Corporation

1001 Asbury Drive, Buffalo Grove, IL 60089 U.S.A.

Phone: 1.800.MIDMARK (1.800.643.6275)
Direct: + 1.844.856.1231 Opt. 3
Fax: + 1.847.415.9801

imagingtechsupport@midmark.com

Hours: 8:00 a.m. to 5:00 p.m. Central Time

To facilitate your service call, the following information should be ready and available:

- Computer operating system
- Version of Progeny Imaging software
- Serial number of your Sensor
- Type of Progeny Imaging installation (standalone, peer-to-peer network, client-server network)

Symbols Glossary

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Symbol	Description
⚠WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
⚠CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	Addresses practices and issues not related to personal injury.
SAFETY INSTRUCTIONS	Indicates specific safety-related instructions, procedures, or locations of safety equipment.
	Warns of ionizing radiation.
	Signifies that the instruction manual must be read.
	Identifies the location where the operator's manual is stored. Identifies information that relates to the operating instructions. Indicates that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	Identifies a type BF applied part complying with IEC 60601-1.
	Class II equipment – provides double isolation to protect against electric shock
IP68	Degree of protection. IP68 means that sensor casing is totally protected against dust and protected against the effect of immersion as specified in “Appendix A: Cleaning and Disinfection” on page 96.
REF	Identifies the product catalog number or model.
SN	Identifies the product serial number.
	Indicates the date on which a product was manufactured.
	Identifies the manufacturer of a product.

Symbol	Description
	Indicates that the marked item or its material is part of a recovery or recycling process.
	Indicates the maximum and minimum temperature limits at which the item shall be stored, transported, or used.
	Indicates the acceptable upper and lower relative humidity limits for transport and storage.
	Indicates the acceptable upper and lower atmospheric pressure limits for transport and storage.
	Indicates that the items shall not be vertically stacked.
	Indicates that the contents of the transport package are fragile, and the package shall be handled with care.
	Indicates that the transport package shall be kept away from rain and in dry conditions.
	Indicates mass.
	Indicates the correct upright position of the transport package.

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Midmark® Intraoral Digital Sensor Labels

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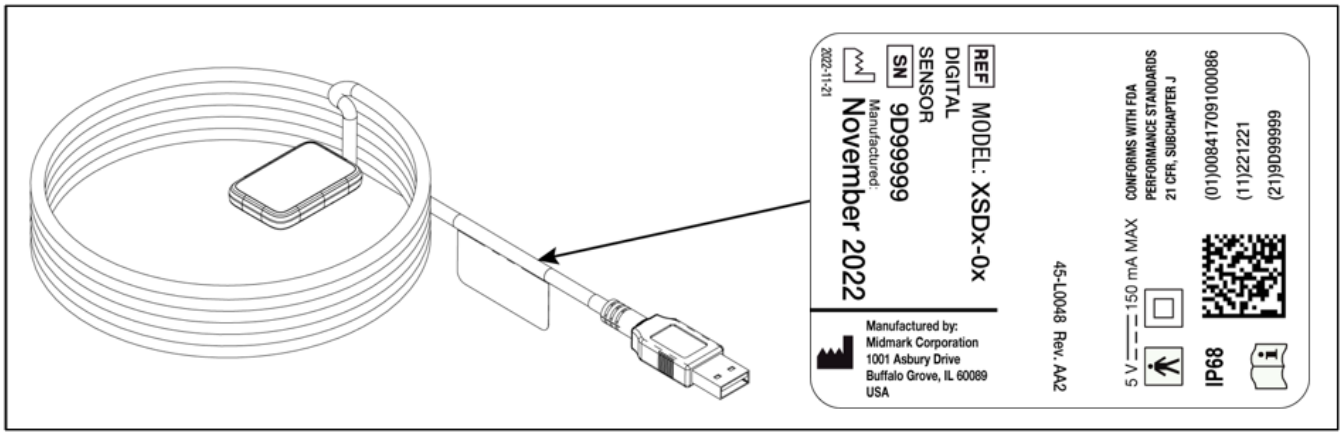
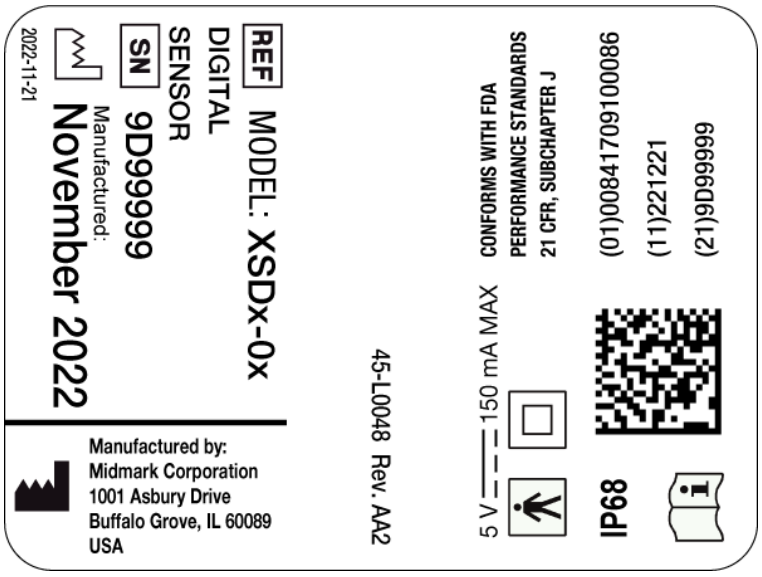
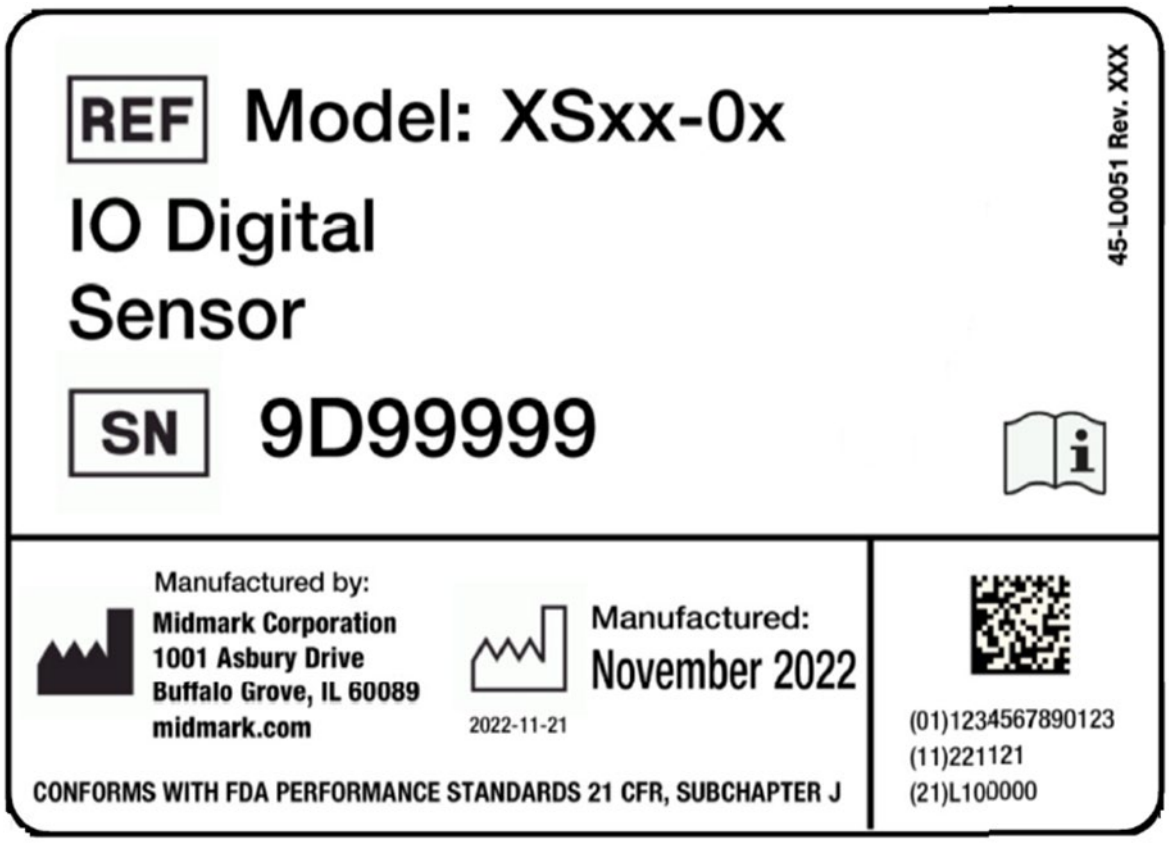
Sensor Labels



Sensor Label Placement Overview



Flag Label on Sensor Cable



Label on Sensor Box

Glossary of Terms

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Term	Meaning
Active Area	The equivalent sensor area used to produce an image, measured in square millimeters (mm^2). The larger the number, the larger the active area.
Beam-limiting Device (BLD)	A device that provides a means to restrict the dimensions of the X-ray field.
Collimator	See [Beam-limiting Device] above.
Connection Type	Specifies the connection type used to attach the sensor system to the computer.
Dynamic Range	Represents the largest output of the device as a ratio to the smallest output, measured in decibels (dB). A larger number shows a greater X-ray exposure range in which the X-ray sensor system can produce an image without degradation.
Exposure (of an object)	See [Irradiation] below.
Exposure (of an X-ray tube)	See [Loading] below.
Exposure Switch	See [Irradiation Switch] below.
Exposure Time (to radiation)	See [Irradiation Time] below.
Field of View (FOV)	The anatomical area included in the imaged volume or the area of the patient that is irradiated.
Film Size Equivalent	The size of the X-ray sensor active area in relation to traditional film-based X-ray systems available to the dentistry profession.
Flash Memory	A non-volatile, reprogrammable memory used for data and program storage.
Interlock	A device preventing the start or the continued operation of equipment unless certain pre-determined conditions prevail.

Term	Meaning
Intermediate-Level Disinfectant	Agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.
Irradiation	In radiology, exposing a living being or matter to ionizing radiation.
Irradiation Switch	In radiological equipment, a control device provided to initiate and stop irradiation.
Irradiation Time	The duration of irradiation determined according to specific methods, usually the time a rate of a radiation quantity exceeds a specified level.
Loading	In an X-ray generator, the act of supplying electrical energy to the anode of an X-ray tube.
Loading Factors	A factor influencing by its value the X-ray tube load, such as X-ray tube current, loading time, continuous anode input power, X-ray tube voltage, and percentage ripple.
Low-Level Disinfectant	Agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores.
Number of Pixels	The total number of pixels in the sensor active area. It has no unit value; however, a larger number results in a finer image.
Patient Database	An organized collection of data stored and accessed electronically that contains medical information about individual patients.
Patient Information	An informational record that uniquely describes each patient. It contains the patient's first name, last name, and ID.
Pixel Size	The size of the smallest discrete picture element used in the process of image acquisition, measured in micrometers (µm). The smaller the pixel size, the finer the image.
Region of Interest (ROI)	Localized part of an image that is of particular interest at a given time.
Sensor Cable	Identifies the type and length of the sensor cable.

Term	Meaning
Technique Factors	See [Loading Factors] above.
Theoretical Resolution	Measures the maximum level of detail that the sensor system is capable of acquiring, measured in line-pairs per millimeter (lp/mm). The larger the number, the finer the image.
Useful Beam (X-ray Imaging Device)	The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch is activated.
X-ray Tube	An electron tube, which is designed for the conversion of electrical energy into X-ray energy.

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Midmark® Intraoral Digital Sensor Types

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Sensor Configurations

The Sensor is available in multiple sizes and configurations:

- Size 1 – external size of 36.2 x 24.1 x 5.9 mm
- Size 2 – external size of 42.8 x 30.5 x 5.7 mm
- Short cable – 1.1m
- Long cable – 3m
- Standalone system – A system in which the Sensor is plugged into a USB port on a computer.
- Integrated system – A system in which the Sensor is plugged into the USB port on the intraoral X-ray device. (Note: Refer to 003-10566-00, the user manual for Midmark's Preva Dental X-Ray System, for catalogue numbers of integrated systems.)

The following standalone configurations are available:

Catalogue Number	Description
XSDN-05	Midmark IO DR Sensor, Size 1, 1.1M Cable, Dental
XSDS-05	Midmark IO DR Sensor, Size 1, 3M Cable, Dental
XSDS-05/L	Midmark IO DR Sensor, Size 1, 3M Cable, w/laptop, Dental
XSDN-06	Midmark IO DR Sensor, Size 2, 1.1M Cable, Dental
XSDS-06	Midmark IO DR Sensor, Size 2, 3M Cable, Dental
XSDS-06/L	Midmark IO DR Sensor, Size 2, 3M Cable, w/laptop, Dental
XSDS-0D	Midmark IO DR Sensor, Size 1 & 2, 3M Cable, Dental
XSDS-0D/L	Midmark IO DR Sensor, Size 1 & 2, 3M Cable, w/laptop, Dental

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Key Components

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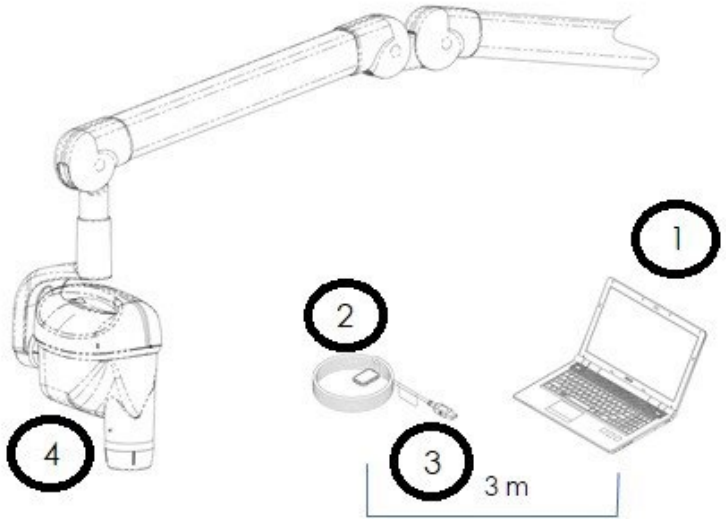
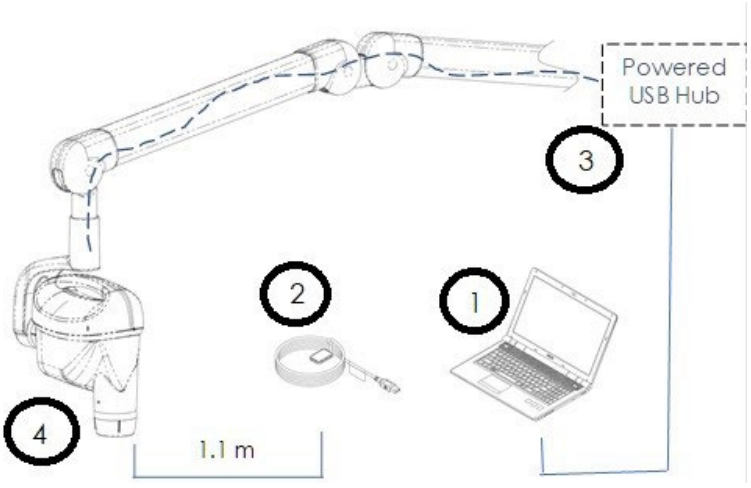
Overview

The Sensor is a digital imaging system for dental radiographic application. The product is to be used for routine dental radiographic examinations. Two different sized sensors (size 1 and size 2) are utilized to image different anatomy and for different patient sizes. The Complementary Metal Oxide Semiconductor (CMOS) sensor connects directly to a USB connection in a personal computer (PC) without the need for an intermediate electrical interface. The Sensor works with a standard dental intraoral X-ray source without any connection to the X-ray source. The Sensor captures an image automatically upon sensing the production of X-ray, and after the X-ray is complete, transfers the image to an imaging software program on the PC. Disposable sheaths are used with each use to prevent cross-contamination between patients. The Sensor is a state-of-the-art intraoral X-ray detector intended for digital imaging of teeth and the oral cavity. The components of the Sensor system are a computer, the Digital Sensor, USB connectivity, and an X-ray source.



Key components of a standalone system.



Key components of an integrated system.

1 Computer

A computer with imaging software used to initiate radiography, view radiographs, and store the images together with patient data in a database.

2 Digital Sensor

The digital sensor is designed to transform a two-dimensional X-ray picture into an electrical signal. The structure of the Sensor is assembled with a first layer of phosphor material (scintillator) which, when exposed by incident X-rays, emits a luminous radiation. This light is then transferred to the photo sensitive elements of the Sensor, where it is transformed to electrical potential. The electrical signal is sent to the computer for processing.

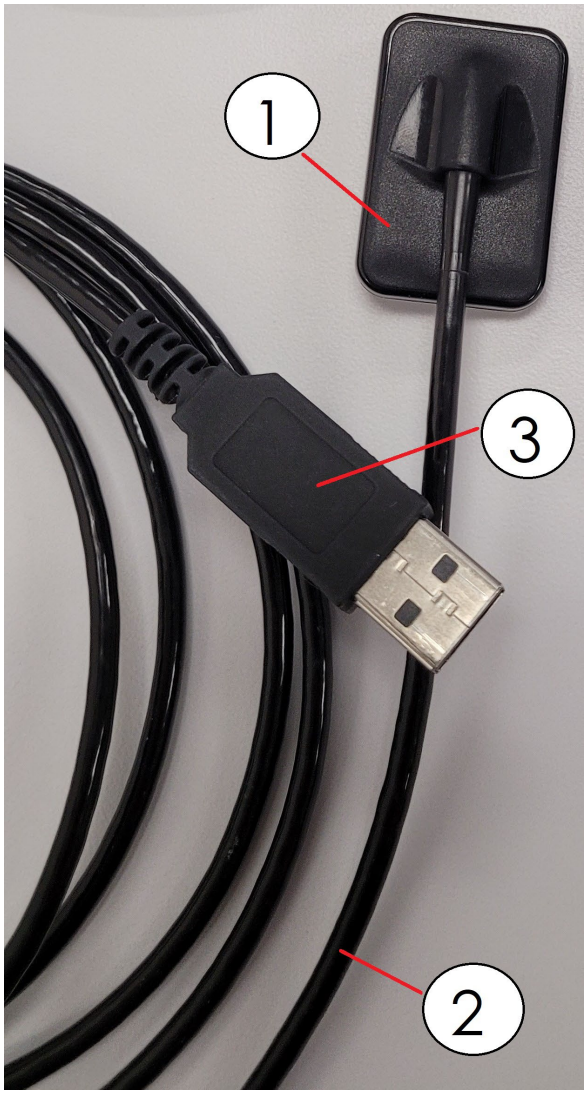
3 USB Connectivity

The means by which the Sensor connects to a power source and the imaging software. The USB connector at the end of the Sensor cable is inserted into a USB port on either a computer (standalone system) or the intraoral X-ray device (integrated system)

4 X-Ray Source

The source of the X-ray radiation used to create the radiographic image; i.e., the intraoral X-ray device.

Digital Sensor



1 Imaging Receptor

The imaging receptor is the portion of the device that is placed in the patient's mouth to receive X-rays and transform them into an electrical signal. (Also sometimes referred to as just "the sensor.")

2 Sensor Cable

The sensor cable is the portion of the device that transmits the electrical signal from the imaging receptor to the computer for processing.

3 USB Connector

The USB connector is the portion of the device that connects the Sensor to a USB port on either a computer (standalone system) or the intraoral X-ray device (integrated system).

Accessories and Supplemental Parts

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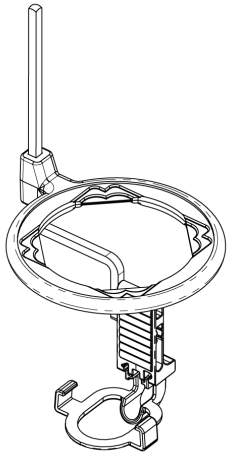
Accessories

Part	Description
	*Protective Sheath – PN 500-434 (size #1 sample pack)* *– PN 500-435 (size #2 sample pack)* *– PN 500-432 (size #1 500 CT pack)* *– PN 500-433 (size #2 500 CT pack)* Protective liner sheaths that provide a safe and effective barrier between the Sensor and the patient. They are consumable, non-sterile, and come in two different sizes to accommodate the two available Sensor sizes.
	*Positioner – PN 002-10787-00* Accessory to assist with correct positioning of the Sensor inside the patient's mouth.
	*X-Ray Source* Any intraoral X-ray source suitable for producing diagnostic X-ray radiographs of dentition, jaws, and other oral structures. Refer to 003-10566-00, the user manual for Midmark's Preva Dental X-Ray System, for Midmark part numbers.

Supplemental Parts

Part	Description
	*Sensor Holder – PN 45-A2018, 45-A2018-W, 45-A2019, or 45-A2019-W* Plastic holder to store the Sensor when not in use. Available with either a straight back or a curved back for mounting on either a flat surface or a curved surface (e.g., articulated arm). Available in both gray and white.
	*Laptop with Installed Progeny Imaging – PN 30-08180* A laptop that comes with Progeny Imaging software pre-installed for use with the Sensor.

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Applied Parts From Risk Management

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Applied Parts

Because the Sensor is covered with a sheath during use, there are no applied parts. However, the Sensor head and the first 10cm of the cable are treated as applied parts. Refer to Figure 1 below.

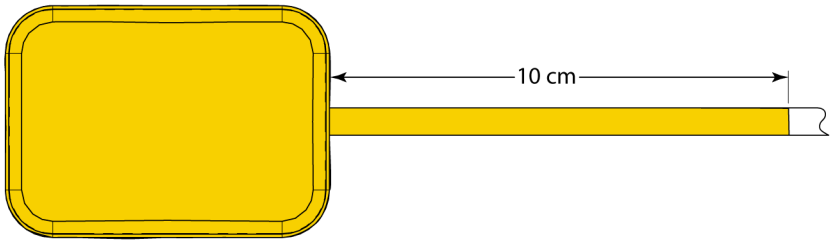

Figure 1. Applied parts (highlighted).

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Installation

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Overview

> **NOTICE** It is recommended that the installing technician review the complete instructions before attempting to install or upgrade any component.

The Sensor is an intraoral digital sensor used with an intraoral X-ray generator to capture digital images of dentition and the surrounding skeletal structures. The Sensor is available in two configurations:

- Standalone – Sensor, connected directly to a PC. (Note: This Sensor can be used with any intraoral X-ray source.)
- Integrated – Integrated into and part of the Preva Plus system or provided separately and connected to Preva 2.0.

If using a laptop that was purchased from Midmark as part of a combination sensor/laptop catalogue number, the following steps have already been completed at the factory and can be skipped:

- Installing the Midmark Device Suite
- Installing Progeny Imaging

Before You Begin

Computer and Software

You must have a dedicated computer with a 64-bit Windows operating system and have at least one **High-speed** USB port available. The computer requirements are listed in Table **1** below.

> **NOTICE** The installer must have administrator privileges on the computer (or the administrator must be available to enter admin credentials) in order to install the software.

Image capture and management software must be installed on all computers that will host the Sensor. The performance of that software is affected by the amount of random access memory (RAM) and storage memory available to the system for acquisition, displaying, storing, and printing digital X-ray images. The recommended requirements are listed as a guideline only.

The host computer used with the Sensor must have a declaration of conformity for class A compliance with CISPR 32 or EN 55032 and their national deviations for the market in which the Sensor was distributed.

> **NOTICE** Be aware that the patient volume and the specific demands of your practice may require adjusting these guidelines accordingly. The system requirements of other programs operating on the same computer or network may affect these guidelines as well.

Component	Requirement
Windows Operating System	• Windows 10 Pro or Enterprise (64) • Windows 2008 R2 Server & above
Processor	Intel i3 (or greater)
Memory	8 GB RAM (or greater)
Storage	250GB Hard Drive (or greater)
Video	32 bit, 1920 X 1080 Resolution Capable
Display	1920 X 1080, 32 true bit color
USB Ports	High Speed USB

Table 1. Recommended system requirements.

Midmark requires the use of Progeny Imaging and Midmark Device Suite software. It must be installed on every computer that will interface with the Sensor. If you are not intending to use Progeny Imaging, then compatible image capture and management software must be installed on all computers to be used. This software may support direct integration with the Sensor or may use TWAIN interface through the Midmark Device Suite software.

For installation and use of Progeny Imaging software, refer to the Progeny Imaging Installation Manual or contact Technical Support.

For installation and use of third-party software that supports direct integration, refer to that software installation and user manuals.

Check System Contents

Verify that all items listed on the Packing List are contained in your system order. If any item appears to be missing, contact Technical Support immediately. Use Figure 1 below as a guide.

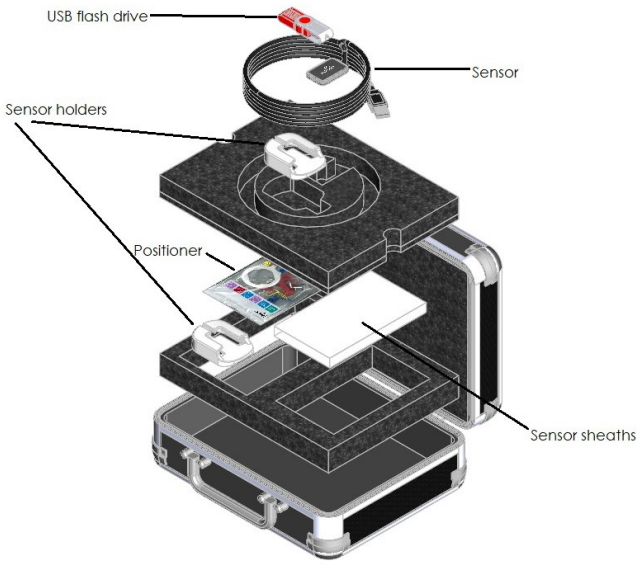


Figure 1. Guide to system order contents.

Tools Required

No tools are required to install the Sensor.

Installation Procedure

Installing Midmark Device Suite Together with Progeny Imaging Software

When installing the Sensor drivers and associated software, it is assumed that previous versions of the Midmark Device Suite and Progeny Imaging image management software are not present.

NOTICE

Proper operation requires any previous version of Midmark Device Suite and Progeny Imaging to be removed (uninstalled) prior to the installation process to begin.

IMPORTANT: If both Midmark Device Suite and Progeny Imaging are installed, Progeny Imaging must be uninstalled BEFORE Midmark Device Suite is uninstalled. Uninstalling Midmark Device Suite first will cause an error that prevents Progeny Imaging from being uninstalled.

Execute the following steps:

- Insert the USB flash drive into an available USB port on your computer and allow the computer to recognize the flash drive.

- If the software on the USB flash drive does not start automatically, navigate to Windows Explorer™ and select the “Progeny” drive letter. Browse to the content of the flash drive and double-click on “Setup.exe”. Refer to Figure 2 below. This step begins the installation process.

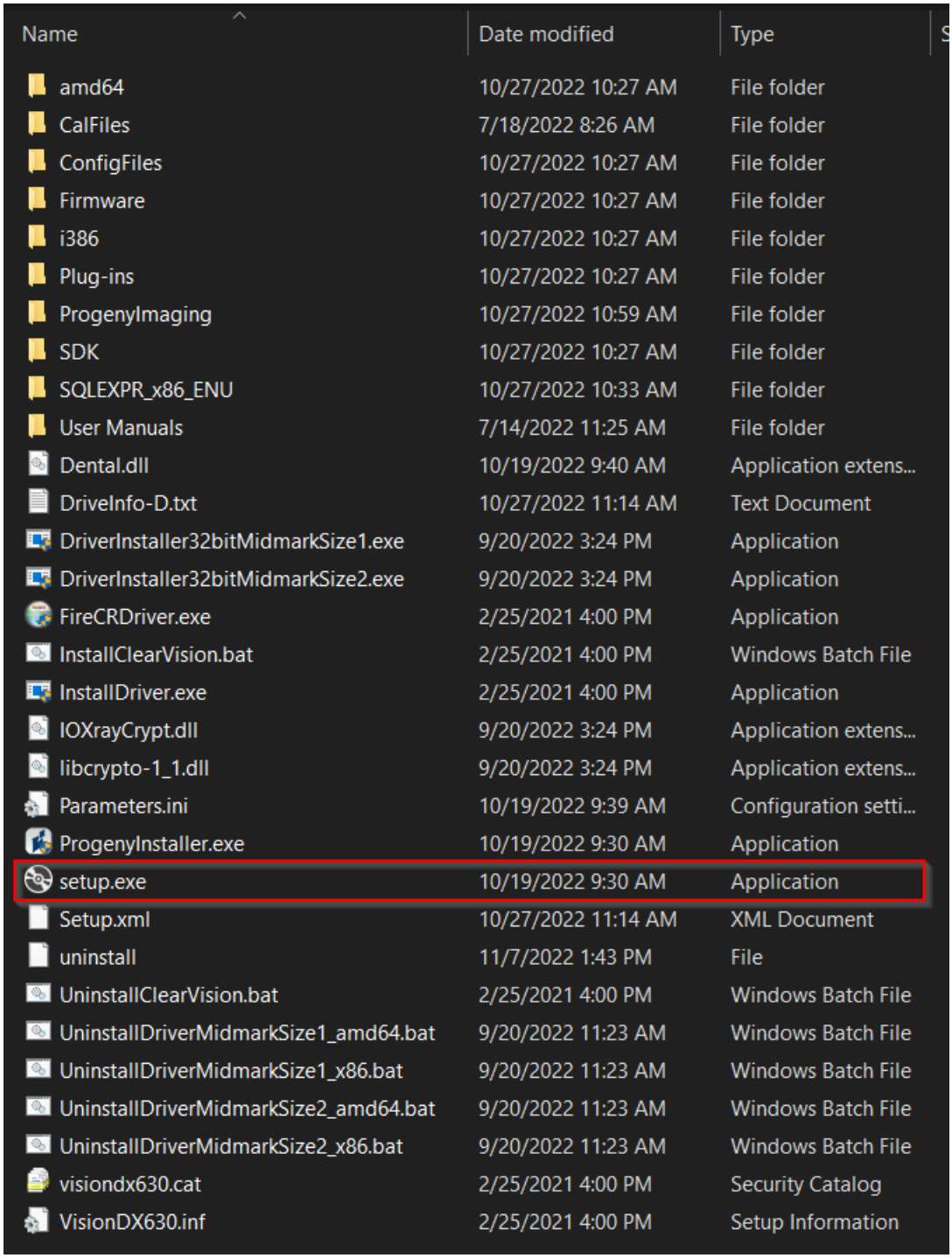


Figure 2. Contents of the Progeny flash drive.

NOTICE The installation software requires Microsoft .NET Framework revision 4.0. This software will be installed if it is not yet present to the operating system. Follow all on-screen prompts.

- A “User Account Control” pop-up window appears confirming your choice to make changes to your device. Click “Yes.” See Figure 3 below.

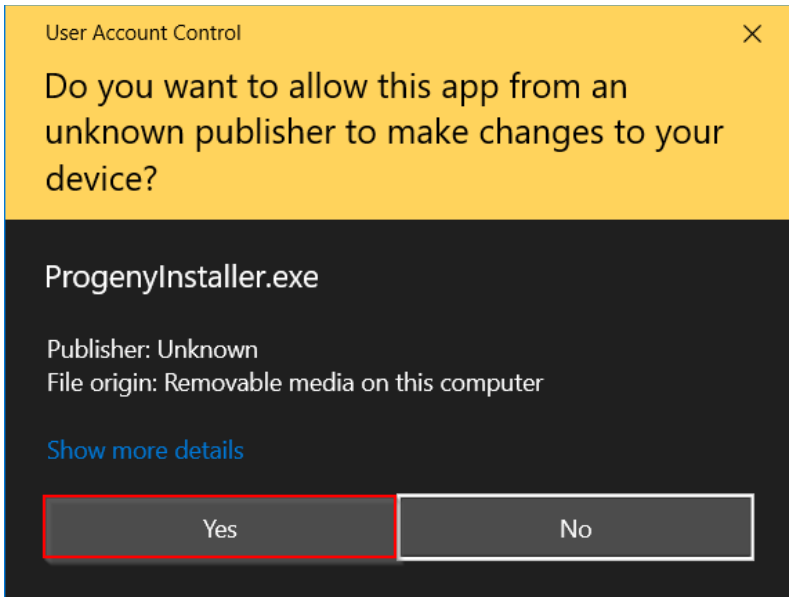


Figure 3. The User Account Control pop-up window.

- The main screen of the installation software opens. Click on the “Install Midmark Device Suite” button (see Figure 4 below).

Figure 4. The main screen of the installation software.

NOTICE The installed software requires multiple software components that may already be available in your system. These components will be installed if they are not yet present. Follow all on-screen prompts.

- The “Select Devices To Install” pop-up will be displayed. Check the option for “Midmark IO Digital Sensor” (and, if applicable, any other device families that have to be supported by the imaging software). An “Install” button will then appear. Click that. See Figure 5 below.

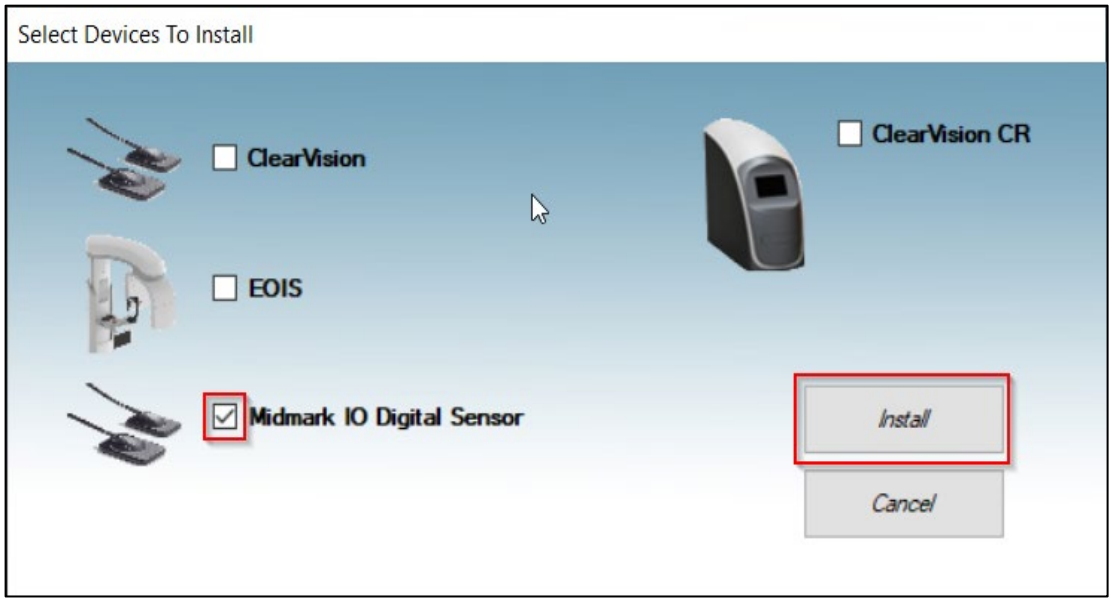


Figure 5. Selecting the device families to be installed.

- The “Driver Installation” pop-up appears with a green progress bar that extends to the right as installation occurs. Wait for the bar to fully load. See Figure 6 below.

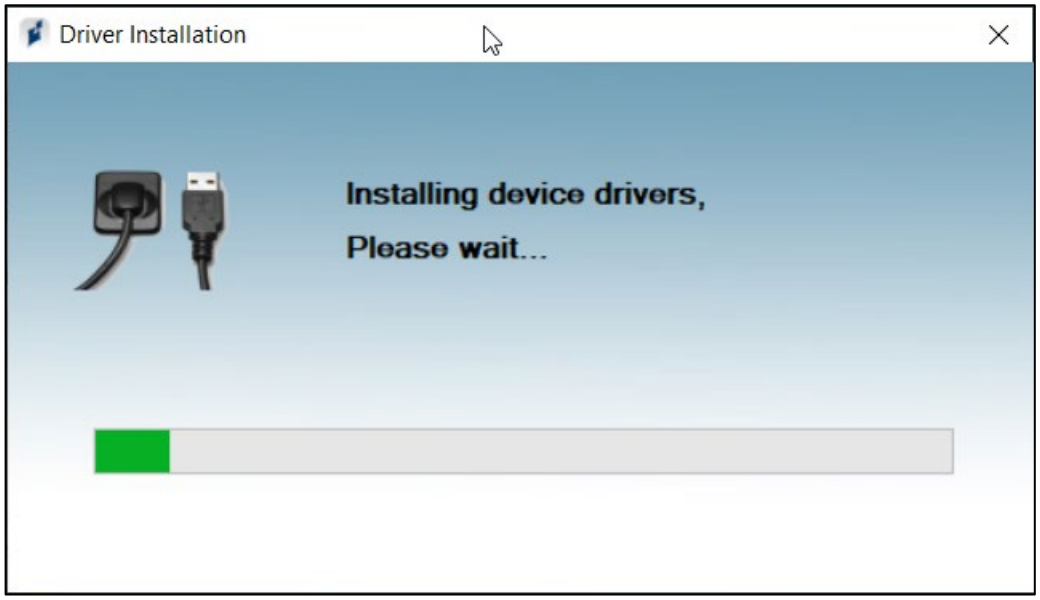


Figure 6. The Driver Installation pop-up.

- When the green bar has fully loaded, the driver installation window will automatically close out, and the setup wizard window will appear. Click on the “Next” button. See Figure 7 below.

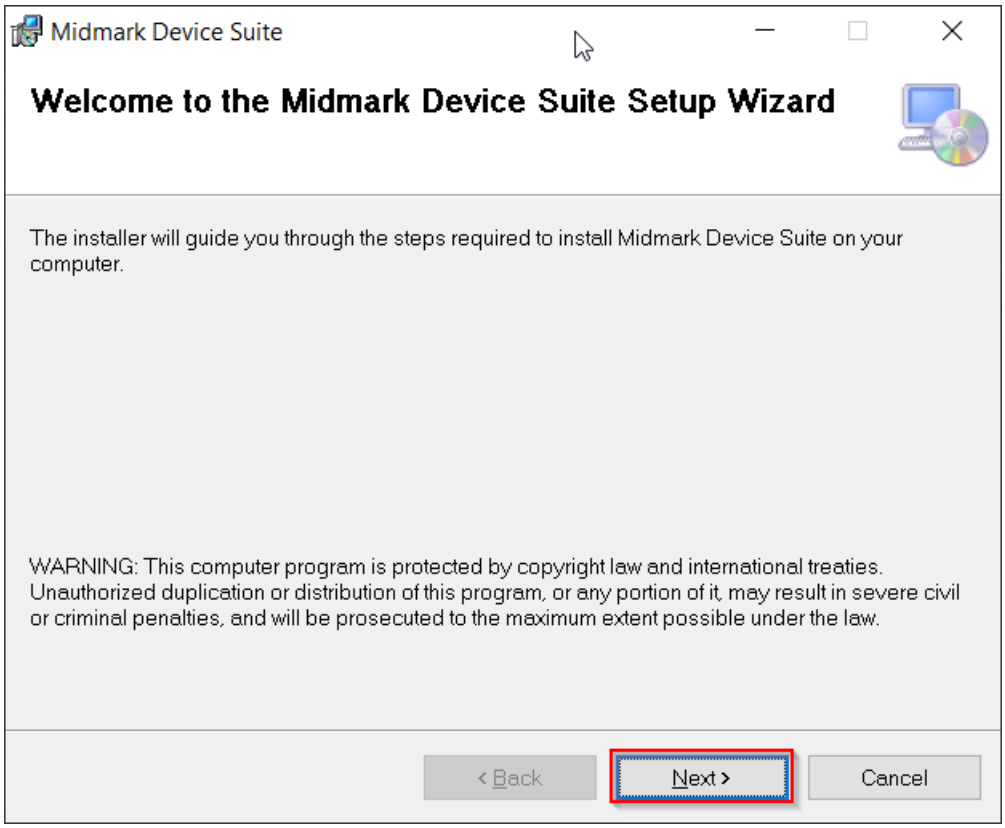
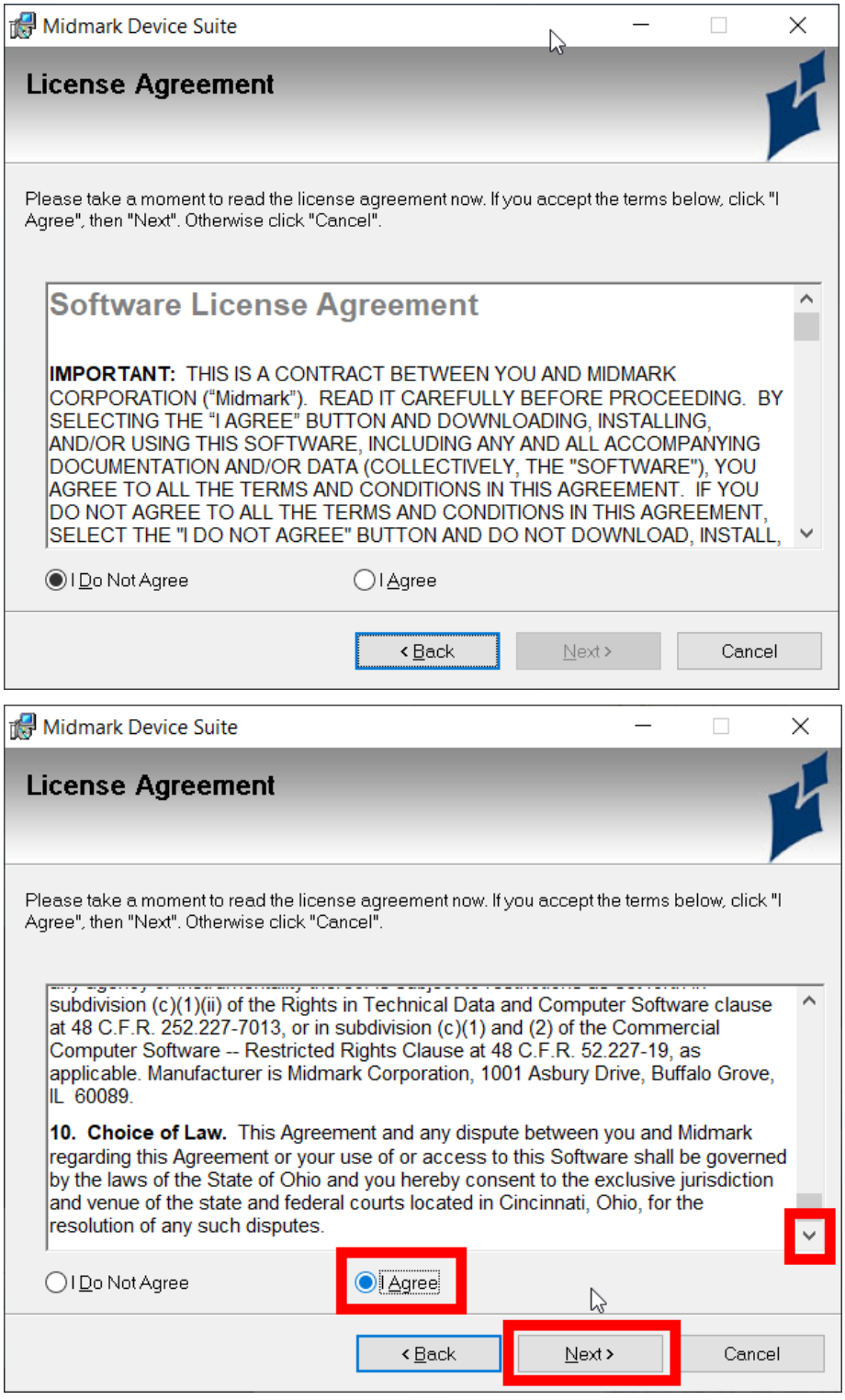


Figure 7. The Midmark Device Suite setup wizard.

- The license agreement pop-up appears with the default of “I Do Not Agree” selected and the “Next” button grayed out. Scroll through the agreement and read it by clicking the downward arrow towards the right-side edge of the window. If you accept the terms, click the radio button next to “I Agree,” then click the “Next” button. See Figures 8 below.



Figures 8. The license agreement windows.

- The pop-up window shown below in Figure 9 appears. Default options are populated automatically as shown below. These options can be changed according to user preference. When satisfied with the selections, click the “Next” button.

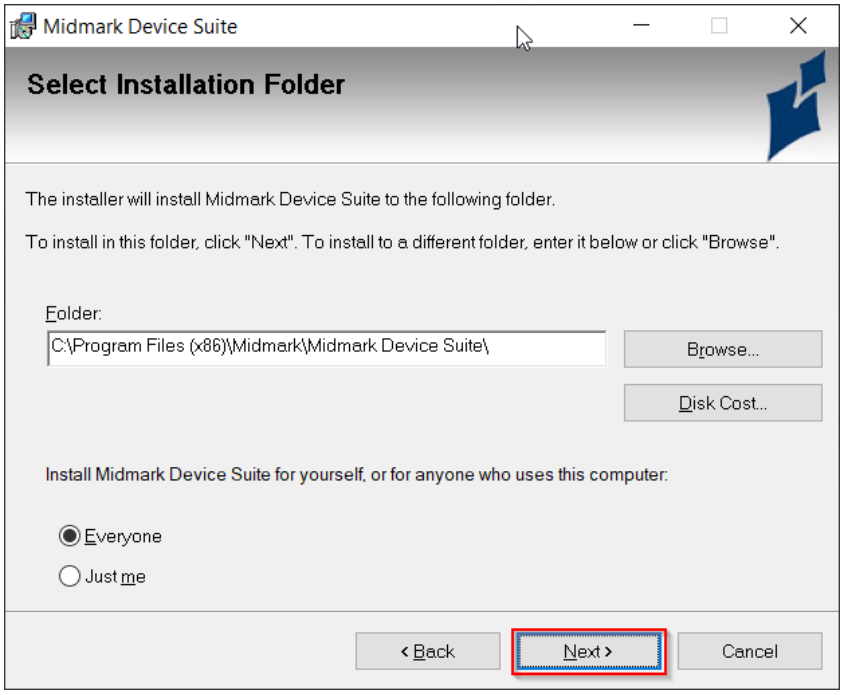


Figure 9. Pop-up to select location of the Midmark Device Suite installation.

- The “Confirm Installation” pop-up window appears. Click the “Next” button. See Figure 10 below.

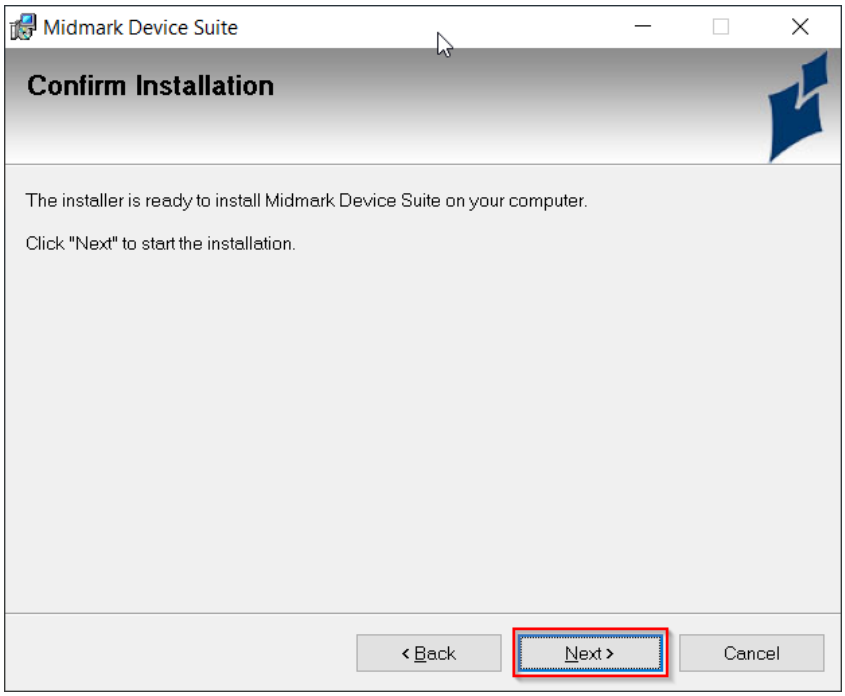


Figure 10. The “Confirm Installation” window.

- When the installation is complete, the pop-up shown in Figure 11 below appears. Click the "Close" button.

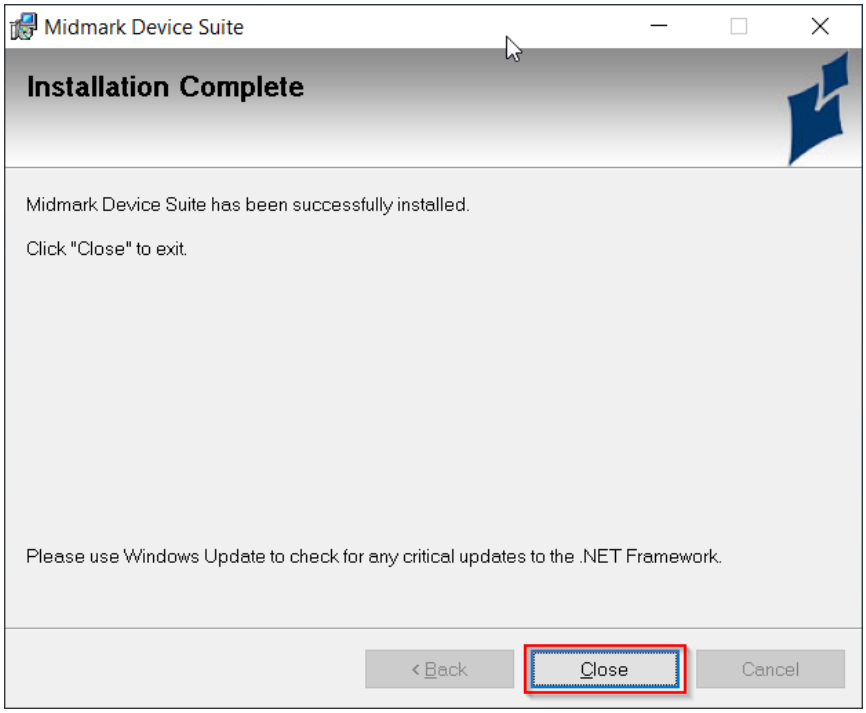


Figure 11. The "Installation Complete" window.

- On the main installation screen, there will now be a green check mark next to "Install Midmark Device Suite," indicating that the installation is complete. (See Figure 12 below.) Continue by clicking on the "Install Progeny Imaging" button to install Progeny Imaging software.

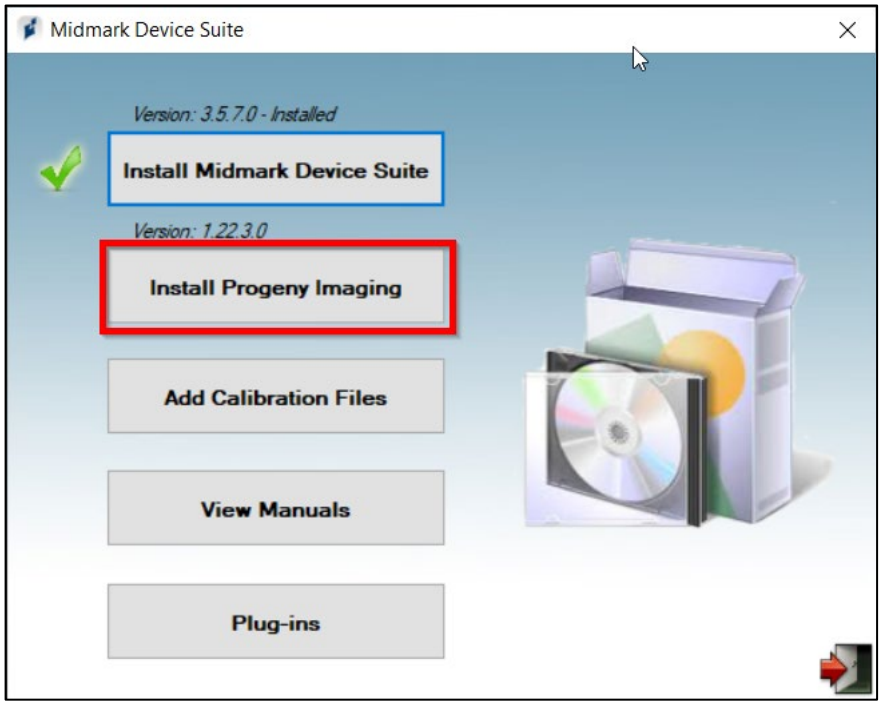
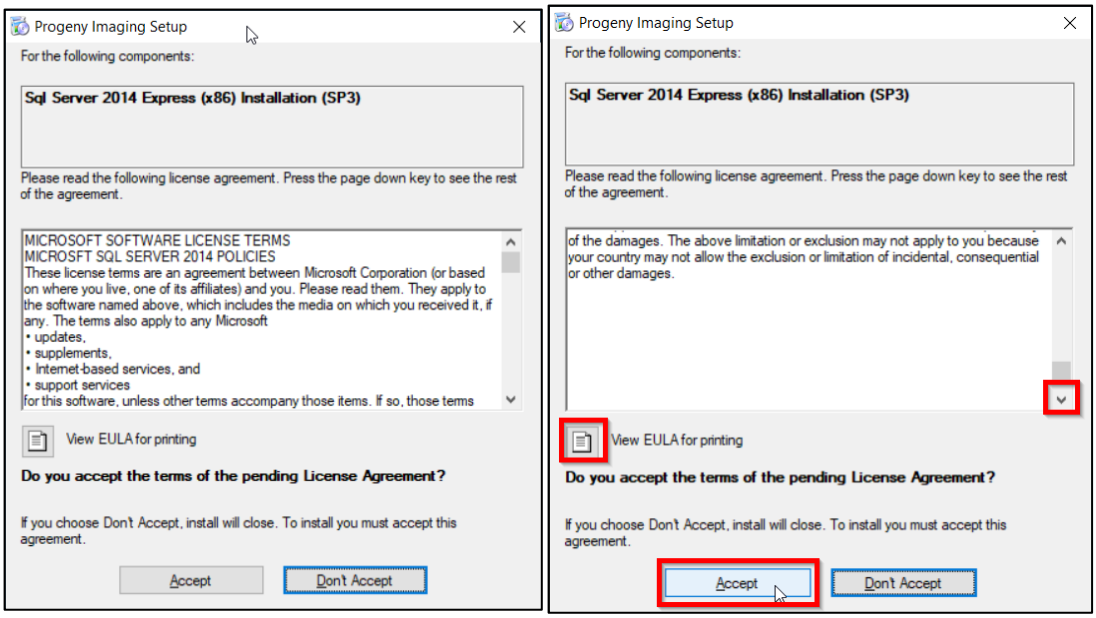


Figure 12. Installation of the Midmark Device Suite is complete; starting the Progeny Imaging installation.

- The “Progeny Imaging Setup” pop-up appears to show the license agreement. The “Don’t Accept” option is selected by default. To read the license agreement, click the downwards arrow towards the right-side edge of the window to scroll to the bottom. (Alternatively or if desired, the agreement can be printed by clicking the paper icon next to “View EULA for printing.”) If you agree with the terms of the agreement, click the “Accept” button. See Figures 13 below.



Figures 13. Progeny Imaging license agreement.

- The “Progeny Imaging Setup” pop-up window appears. A green bar moves from left to right to indicate progress. Wait for the process to complete. When it does, this pop-up will automatically close out with no user action needed. (See Figure 14 below.) A similar pop-up window (not pictured) will appear and close out for Progeny Imaging configuration.

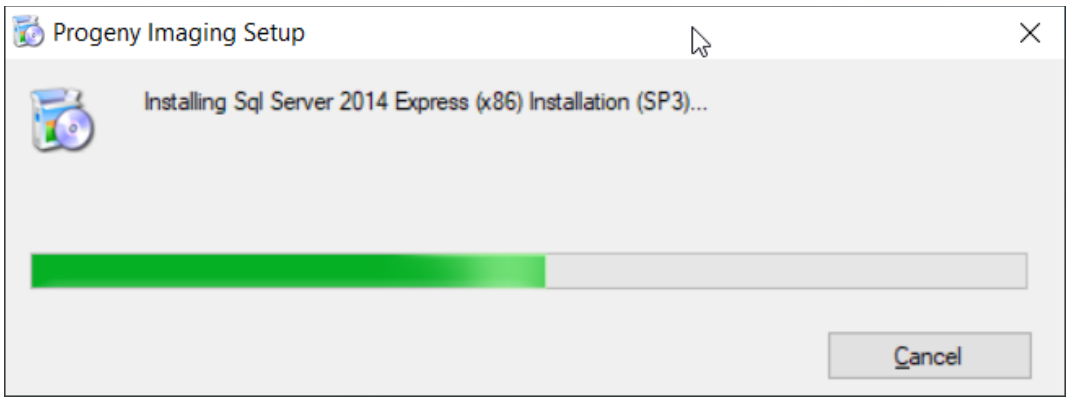


Figure 14. The “Progeny Imaging Setup” pop-up window.

- The main installation screen will now show a green checkmark next to “Install Progeny Imaging” in addition to “Install Midmark Device Suite” to indicate that both are now installed. Click on the door icon in the lower-right corner to close out the window. See Figure 15 below.

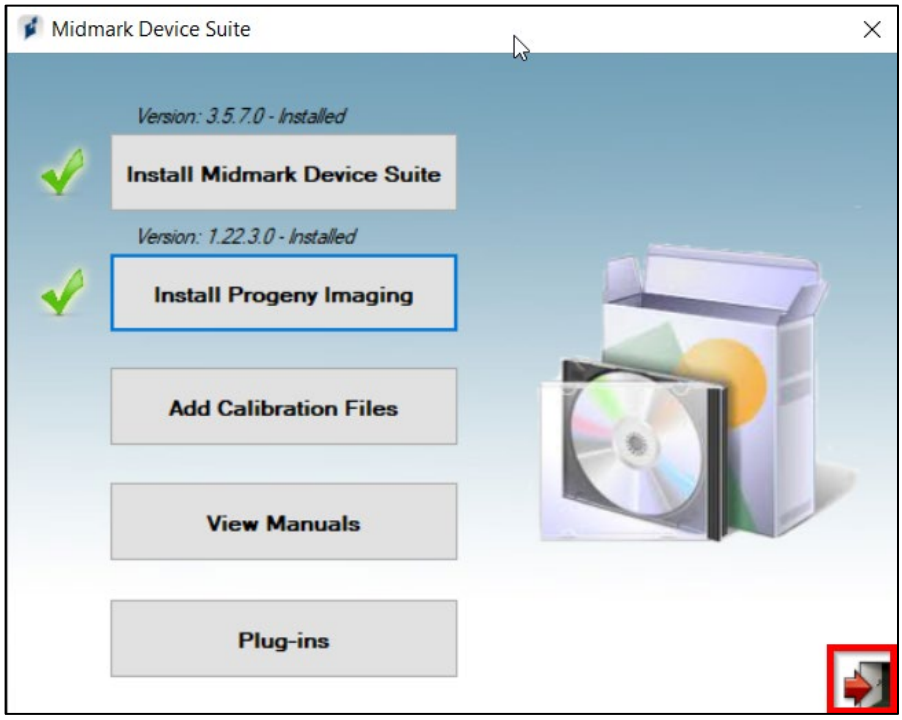


Figure 15. Midmark Device Suite and Progeny Imaging have been successfully installed.

NOTICE	The USB flash drive contains the operation instructions and the sensor support software. Do not discard or reuse. Save and store the USB flash in a convenient location to allow future references to its content.

Installing the Sensor Holder

- Choose a location for the sensor holder. This is where the sensor will be stored when not in use. The location is flexible based on user preference. However, it should be confirmed that the intended holder location is close enough to the intended USB port that the cable can reach between the two.
- The Sensor is sensitive to intense ultraviolet (UV) light. Therefore, the Sensor should never be exposed to direct sunlight for extensive periods of time. Accordingly, if it is intended to use the sensor holder for long-term storage, the chosen location should not be in the path of direct sunlight.
    - If installing a standalone system, this location will likely be near the computer that has the sensor support software installed.
    - If installing an integrated version, this location will likely be on the articulated arm of the X-ray-emitting device.
- Ensure that the chosen location is clean, dry, and free of debris.

- Select a sensor holder based upon the chosen location. The sensor holders are available in two shapes depending upon the surface of the chosen location. See Figure 16 below.

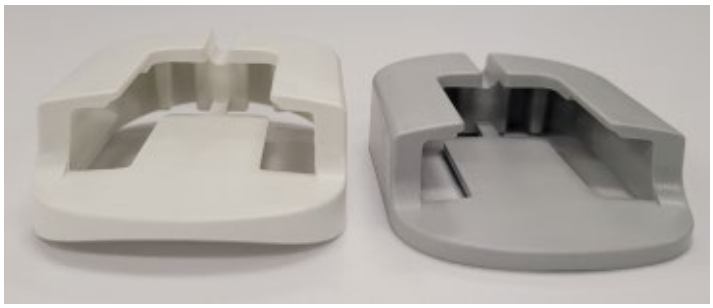


Figure 16. The sensor holders are available with both a curved back and a straight back (left and right respectively in the photograph).

- Remove the backing from the sensor holder.
- Press the sticky side of the sensor holder against the chosen location. Refer to Figure 17 below for an example.

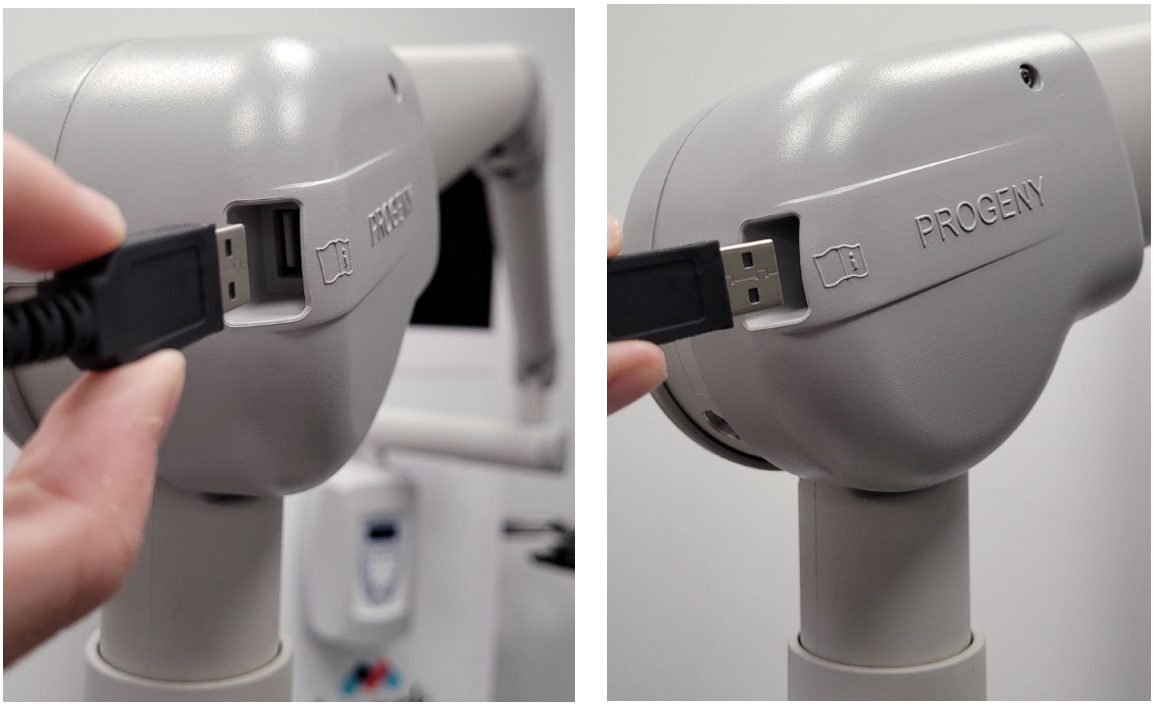
Figure 17. An example of a sensor holder installed on an articulated arm (pictured here with a Sensor inside).

Installing the Sensor Calibration Files

The Sensor requires a calibration file to be installed for each Sensor to operate correctly. This calibration file is unique for each Sensor, and it is provided on the Sensor itself.

- Use the sensor holder as the Sensor storage location.
- Plug the Sensor into an available high-speed USB port.
    - If installing a standalone system, plug the Sensor into an available high-speed USB port on the computer that has the sensor support software installed.

- If installing an integrated system, plug the Sensor into the USB port available at the end of the articulated arm (near to the tubehead; refer to Figures 18 below). Also verify that a high-speed cable on the control unit is connected to the PC that has the imaging software. That connection has to be present for the Sensor to be operational.



Figures 18. Plugging the Sensor into the USB port on the articulated arm for an integrated system.

- Start the Progeny Imaging program by double-clicking on the “Progeny Imaging” shortcut on the desktop. There may be a slight delay before it opens. Refer to Figure 19 below.

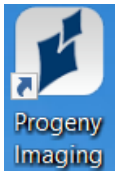


Figure 19. The Progeny Imaging desktop shortcut.

- A username/password box appears. Click in the “Username” box and type “administrator,” then click the “Login” button. No password is needed. Refer to Figure 20 below.

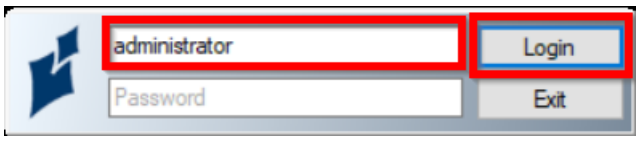


Figure 20. The username/password box in Progeny Imaging.

- In the toolbar at the top of the Progeny Imaging screen, locate the drop-down field that is next to the circular red device status indicator. “<None>” is displayed in the field. Click on the drop-down arrow to the right of this field. See Figure 21 below.

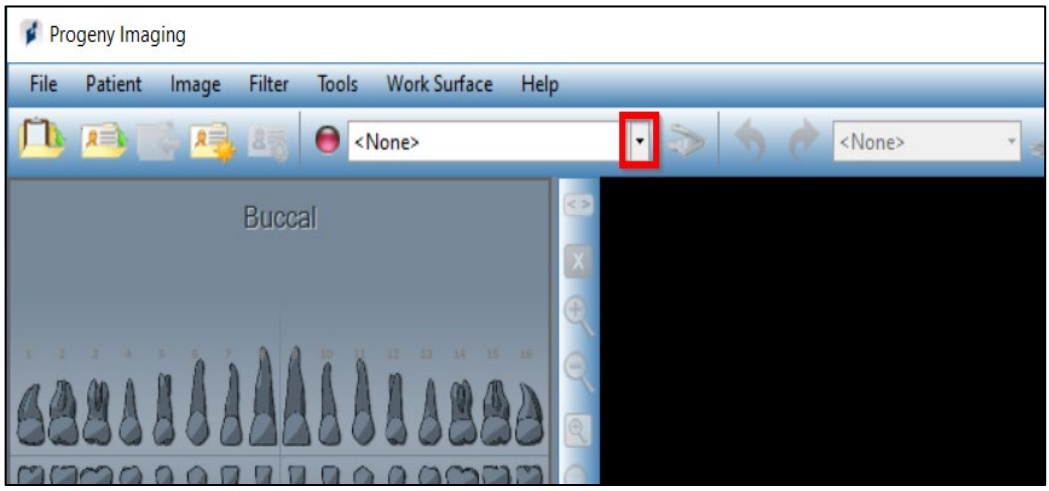


Figure 21. The drop-down arrow next to the device status indicator in Progeny Imaging.

- A drop-down menu appears with a list of devices. Click on the name that corresponds to the device that was just plugged in. (I.e., “Midmark IO Digital Sensor.”) See Figure 22 below.

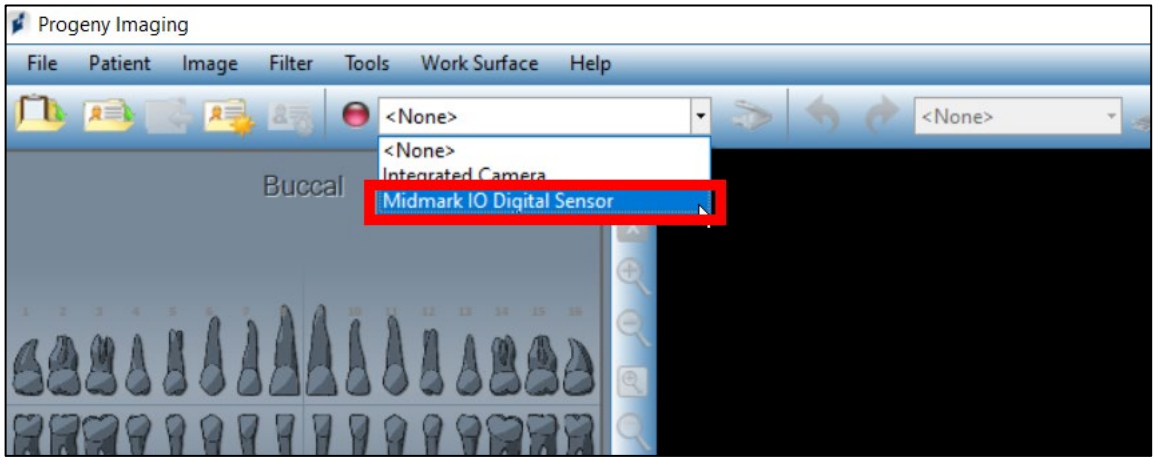


Figure 22. The device selection drop-down in Progeny Imaging.

- A pop-up window appears showing the progress of the calibration file download. Wait for the download to complete. The “Downloading” window will automatically close when it is done. Refer to Figure 23 below.

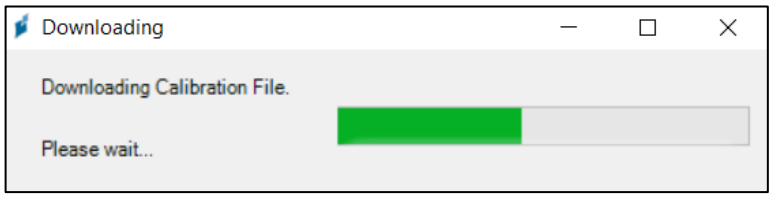


Figure 23. The calibration file download window.

- The circular device status indicator is now green. (See Figure 24 below.) This confirms that the Sensor is now connected to the computer and the calibration files are now downloaded.

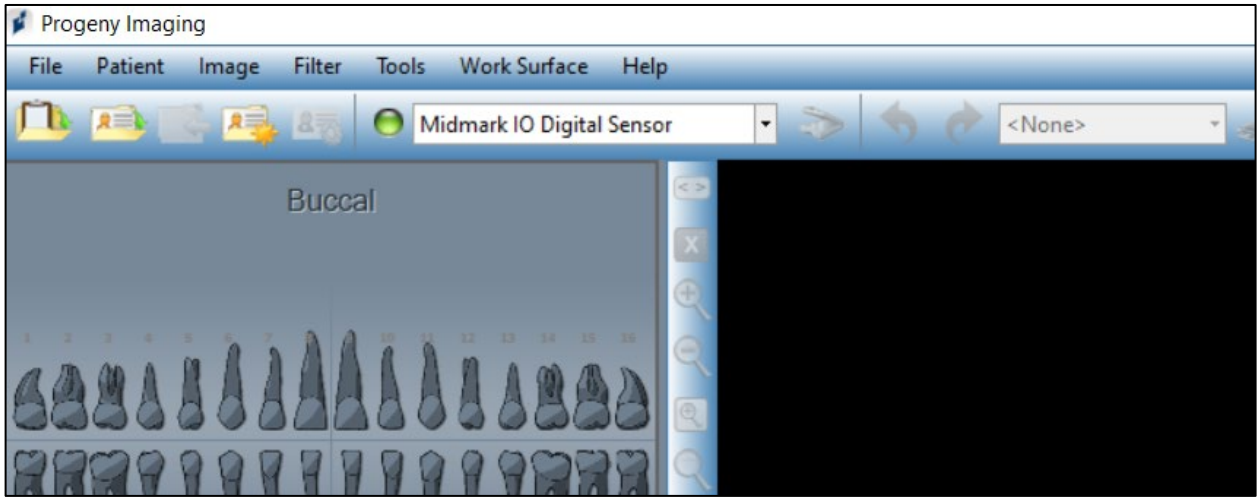


Figure 24. The circular device status indicator is now green.

Device Configuration

- Click on the green device status indicator. See Figure 25 below.

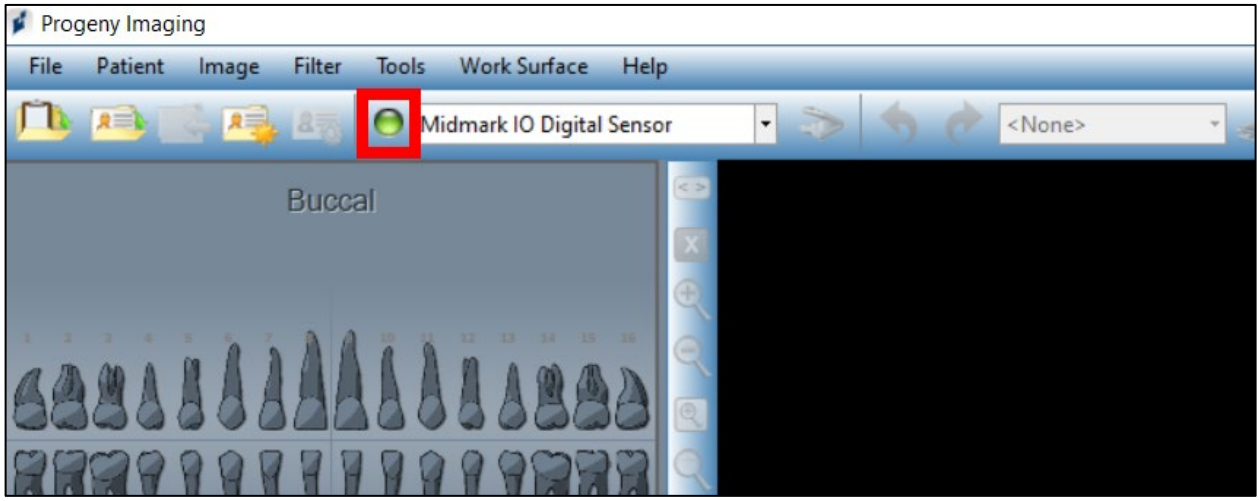


Figure 25. Clicking on the green device status indicator.

- The “Device Configuration Screen” opens. See Figure 26 below.

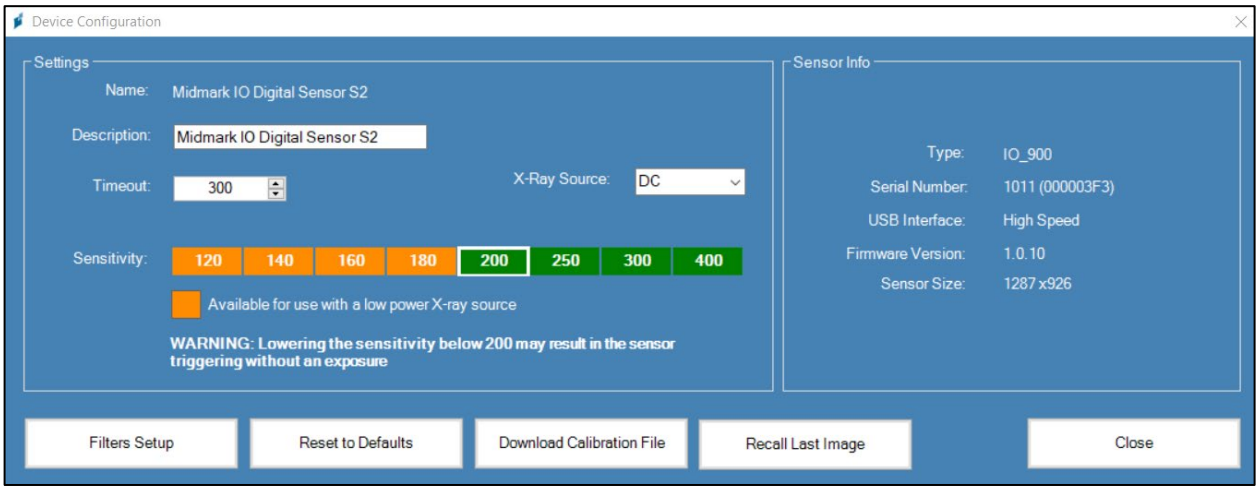


Figure 26. The Device Configuration Screen.

- Make changes to the configuration settings as desired. The available options are described and explained in Table 2 below.

Settings options:	
Name:	This is the Sensor name that will appear in the Device Menu. (This field cannot be changed.)
Description:	This allows user to enter more information about the Sensor.
Timeout:	This option allows the user to adjust the length of the timeout period (in seconds). If image is not taken within the timeout period, the sensor returns to "unarmed" state.
X-Ray Source:	This option allows the user to change the X-ray source (AC or DC).
Sensitivity:	This option allows the users to adjust the "Trigger Level" (sensitivity) of the Sensor. The "Sensitivity" (Selector) is default to the setting of "200." (Note: This setting is useful when acquiring images with a "low-emitting" X-ray source; however, lowering the sensitivity below 200 may result in the sensor triggering without an exposure.)
Sensor Info:	
Type:	Displays the Sensor type
Serial Number:	Displays the serial number
USB Interface:	Displays the USB Interface
Firmware Version:	Displays the firmware version
Sensor Size:	Displays the Sensor Size
Screen Buttons:	
Filters Setup:	This allows the user to configure the filter settings that are applied automatically to an image upon acquisition.
Reset to Defaults:	This allows the user to restore the "Device Configuration" (Window) to default factory settings.
Download Calibration File	Can be used to manually download the calibration files in the case that the Sensor becomes disconnected during the calibration process or that the calibration files are not automatically downloaded.
Recall Last Image	This will retrieve the last image taken and import said image to the currently opened Patient.
Close	This closes the "Device Configuration" window.

Table 2. Device configuration options.

- If the user makes changes and then clicks "Close," a pop-up will appear asking to confirm whether changes should be applied. Select the desired option. See Figure 27 below.

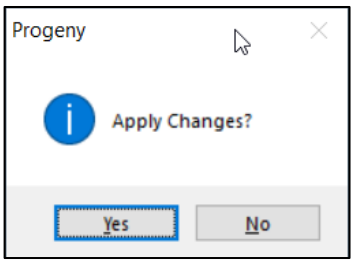


Figure 27. The confirmation pop-up for changes made to device configuration settings.

Device Operation Verification

Once installed, device operation must be verified with a radiological image of a test phantom or test object. See section “Maintenance Schedule” for instructions and details.

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Using the Sensor Sheaths

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Using the Sensor Sheaths

Overview

NOTICE The following procedures are examples only. Procedures may differ slightly based on the manufacturer of the sheath used. Always consult the manufacturer's instructions for sheath use and placement.

Use a new sanitary sheath for each patient. The sheath must be biocompatible following the standard ISO 10993-1. Sheaths provided by Midmark meet this standard.

A sample pack of sanitary sheaths is included with your Midmark® Intraoral Digital Sensor. (Refer to Figure 1 below.) Sheaths come in one of two different sizes depending upon the size of the Sensor ordered.

Figure 1. Sample packs of sensor sheaths.

Sheaths are necessary to avoid patient cross contamination. Care must be exercised when placing sheaths on Sensors or in a positioning device. If you suspect the sheath integrity has been compromised, do not use the affected sheath; discard it and replace with a fresh one.

The sheaths are not sterile and are intended as a single-use item. Dispose of used sheaths appropriately.

To order more sheaths, contact Midmark or your Midmark dealer.

Placing a Sensor in a Sheath

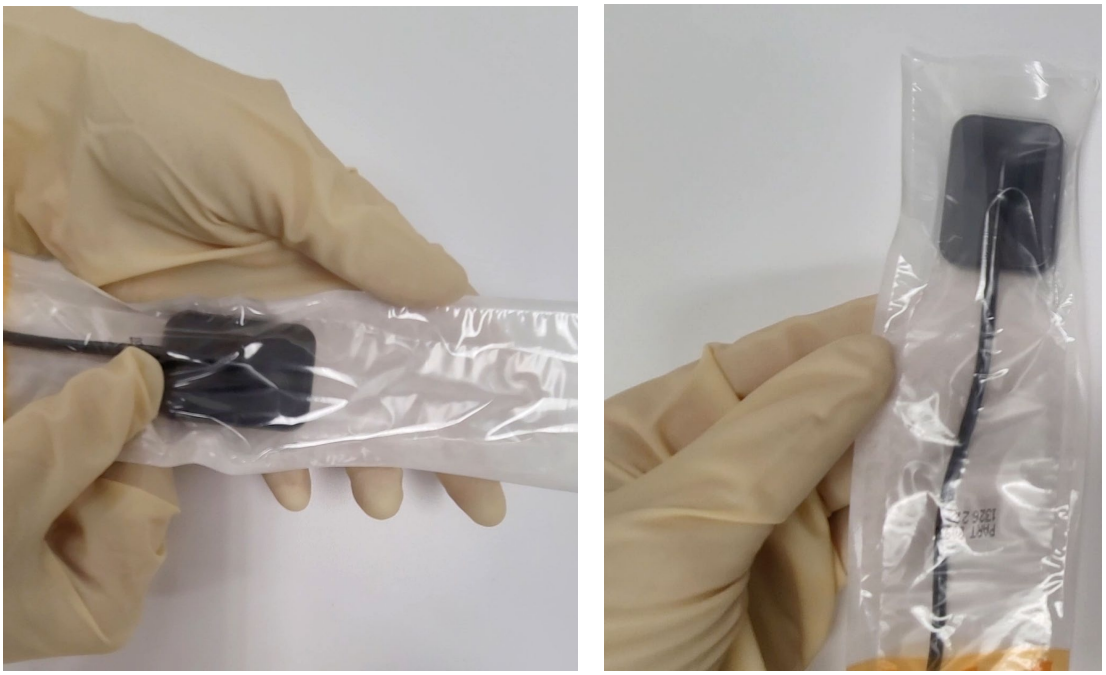
Follow the procedure below prior to every use of the Sensor.

⚠WARNING Gloves should be worn when placing the Sensor in a sheath.

1. Obtain a sheath and inspect it for any holes, tears, or other integrity issues. Discard and obtain a fresh sheath if any issues are identified.
2. Hold the sheath and insert the Sensor into the opening between the white tab and the paper. See Figure 2 below.

Figure 2. Inserting the Sensor into the opening of the sheath.

3. Gently slide the Sensor into the sheath until it reaches the tip of the sheath. Do not force it. See Figures 3 below.

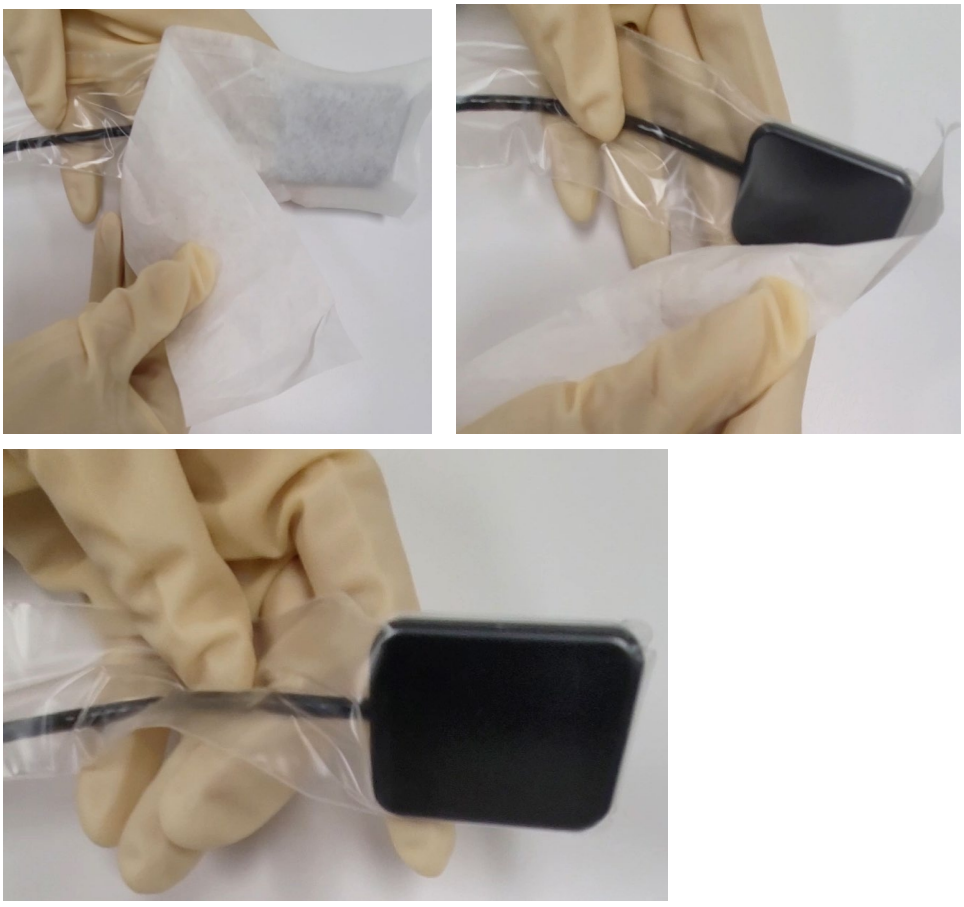


Figures 3. Sliding the Sensor to the tip of the sheath.

4. Peel back and remove the protective cover. See Figures 4 below.

Figures 4. Removing the protective cover from the sheath.

5. Peel away the paper backing. See Figures 5 below.



Figures 5. Removing the paper backing from the sheath.

NOTICE It may be helpful to wrap the loose sheath material around the Sensor cable. If so, take care not to twist the cable itself.

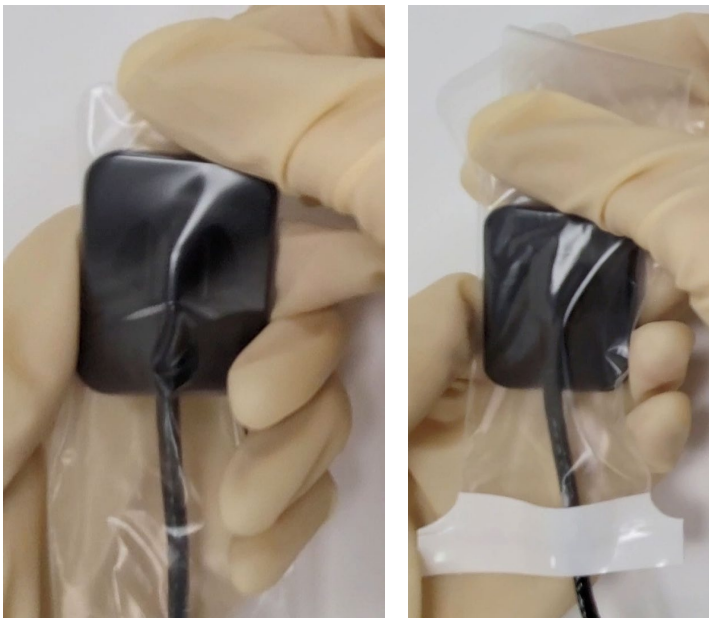
Figure 6. Loose sheath material wrapped around the Sensor.

6. Double-check the sheath for any holes, tears, or other integrity issues. Discard and obtain a fresh sheath if any issues are identified.
7. The Sensor is now protected and ready for normal use.

Removing a Sensor from a Sheath

⚠WARNING Gloves should be worn when removing the Sensor from a sheath.

1. If the loose sheath material was wrapped around the Sensor cable, gently untwist it, taking care not to twist the cable itself.
2. Using the thumb, delicately slide the Sensor out of the sheath. DO NOT pull the cable while removing the protective sheath; damage to the Sensor can result. See Figures 7 below.



Figures 7. Removing the Sensor from a sheath.

3. Dispose of the sheath properly.

NOTICE

Wastes containing blood and saliva used in dental procedures are considered regulated waste. Such waste must be placed in containers which are:

- Closable
- Puncture resistant
- Leakproof on sides and bottom
- Labeled or color-coded per 29 CFR§1910.1030(g)(1)
- Closed before removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

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Using a Sensor Positioning Device

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Using a Sensor Positioning Device

To facilitate correct positioning of the Sensor in the patient's mouth, it is **recommended** a positioning device be used. Refer to the manufacturer's manual for instructions for optimal usage.

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Operating the Midmark® Intraoral Digital Sensor – Acquiring Images

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Operating the Midmark® Intraoral Digital Sensor – Acquiring Images

Prerequisites

- Install the imaging software following the installation steps provided with the product.
- It is recommended to use the sensor positioning device that is included in the Sensor package. Always follow the manufacturer's instructions for use and disinfection.
- The Sensor has undergone image verification using a test phantom or test image after installation.

Connect the Sensor

1. Connect the Sensor to the computer (standalone configuration) or to the USB interface connector on the Preva articulated arm or elsewhere as applicable (integrated system configuration).

NOTICE	Always attach the Sensor and the integrated system to a USB port that complies with the USB specification and supports **high-speed** transfer. Use only USB certified components that support **high-speed** transfer if an additional USB hub or USB cable is needed. Attaching the Sensor to a different port or using different components and cables will prevent the imaging software from recognizing the Sensor. (Contact Midmark technical support for further information.)

Taking Images

1. Refer to the specific imaging software manual for X-ray image acquisition.

NOTICE	Midmark recommends the use of Progeny Imaging image management software. Incompatible software will not allow Sensor operation.

2. Verify that the X-ray system exposure parameters are adequate for the desired examination. Refer to the dose table in this manual for guidance.
3. Insert the Sensor into a sensor sheath. Refer to the "Using the Sensor Sheaths" section of this manual.
4. Position the Sensor inside the patient's mouth in the desired position.
5. Position the tubehead of the X-ray system to the patient using standard positioning procedures.
6. Activate the Sensor via the imaging software (refer to the software manual).
7. Radiate the Sensor.
8. Repeat steps 1-7 for additional images.

Taking Images using a "Low Emitting" X-Ray Source

1. Refer to your specific "Low Emitting" X-Ray Source manual for X-ray image acquisition settings.

2. Verify that the X-ray system exposure parameters are adequate for the desired examination.
3. Insert the Sensor into a sensor sheath.
4. Position the Sensor inside the patient's mouth in the desired position.
5. Position the X-ray system to the patient using standard positioning procedures.
6. Activate the Sensor via the imaging software (refer to the software manual).
7. Radiate the Sensor.
8. Repeat steps 1-7 for additional images.

NOTICE	See the Device Configuration Screen within the Installation section of this manual to adjust the sensitivity (trigger level) of the Sensor.

After Using the Sensor

1. Once all desired images are acquired, remove and discard the sensor sheath. (Refer to the section "Removing a Sensor from a Sheath.")
2. Disinfect the Sensor. (Refer to the section "Cleaning and Disinfection.")
3. Place the Sensor back in the sensor holder.

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Appendices

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Appendix A: Maintenance

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Overview

The maintenance schedule of the Sensor to be performed by the user is defined in the “Maintenance Schedule” section. Disinfection is recommended between every use.

The Sensor does not require periodic calibration.

Required cleaning and disinfecting described in this appendix may be performed by a person designated by the responsible organization. That person needs to be knowledgeable about the Sensor operation and the clinical practices adopted by the dental office.

Maintenance Schedule

Action	Frequency
Imaging receptor operation inspection	At least semi-annually
Sensor cable integrity	At least monthly
On-product labeling inspection	Annually
Imaging performance verification	Quarterly, with a frequency specified by the user based on the risk related to the performed treatments and whether the sensor has been dropped, mishandled, or bitten by a patient.

For operation inspection, ensure the Sensor is reliably detected by the software and reliably captures images of the test object. Consult this manual for troubleshooting.

For cable verification, verify the cable jacket is not damaged and there is no exposed wire. Replace the Sensor if the cable is pinched or visibly damaged.

For label verification, verify that the text is legible. Contact Technical Support if the label is damaged.

For imaging performance verification, purchase qualification phantom per IEC 61223-3-4. Replace the Sensor if the performance does not meet the minimum performance specified in the standard.

Hygiene

The applied parts listed in the “Applied Parts” section above require cleaning and disinfection after every patient, including the Sensor head and the first 10cm of the cable.

The methods described here protect operators and patients and also will not damage the Sensor.

- Wear disposable gloves when taking X-ray patient scan images.
- Wear disposable gloves when performing cleaning and disinfection procedures.
- Clean and disinfect patient positioners per manufacturer’s instruction if reused.
- Clean and disinfect the Sensor and the first 10cm of the cable.

Parts Breakage

⚠CAUTION	Handle and store the Sensor with care to prevent breaking it during use or storage. Replace broken parts before the next use.

The Sensor's enclosure is designed to minimize X-ray attenuation and may break more easily during cleaning or use.

Cleaning and Disinfection

NOTICE	Disinfection of the Sensor is the sole responsibility of the user according to their practice's protocol and the instructions, requirements, and limitations of the disinfecting agent being used as per the manufacturer of the agent.
NOTICE	Do not use an autoclave or a UV oven to sterilize the Sensor. Doing so may damage the electronics and closure, thus voiding the warranty.
⚠CAUTION	Always use protective gloves when disinfecting the Sensor.
⚠WARNING	Before cleaning or disinfecting, this equipment must always be disconnected from the electrical supply.

When to Clean/Disinfect the Sensor

- After each instance of installation, servicing, or use of the device.
- Prior to each usage with a new patient.
- Clean and periodically disinfect parts that may accidentally have come into contact with patients' skin or been cross-contaminated by the operator.

Selecting a Disinfectant

- Do not use cleaning or disinfecting chemicals that produce flammable and potentially explosive fluids, gasses, or vapors on the device or in its vicinity. If such use is needed, wait for the flammable and potentially explosive fluids, gasses, or vapors to evaporate before using the device.
- Centers for Disease Control and Prevention (CDC) recommends using an Environmental Protection Agency- (EPA-) registered hospital disinfectant with a low-level to intermediate-level activity after each patient. (Refer to the Glossary of Terms section of this manual.)
- For all surfaces visibly contaminated with blood, CDC recommends using an intermediate-level disinfectant. (Refer to the Glossary of Terms section of this manual.)

- Preferred disinfectants:
  - Sani-cloth AF3
  - Cavi-Wipes
  - Opti-Cide3 Wipes
  - Opti-Cide3 Spray
  - Clorox Healthcare wipes
  - Clorox Healthcare spray
- Forbidden products:
  - ALCOHOLS (Isopropyl Alcohol, Methanol, etc.)
  - SEKUSID-N™ (ECOLAB PARAGERM Laboratories)
  - SEKUSEPT Easy™ or Aktiv™ (Ecolab Paragerm Labs)
  - FD333™ or FD322™ (DÜRR DENTAL Laboratories)
  - Bleach
  - Autoclaves and UV ovens

Cleaning/Disinfection Process

- Put on fresh gloves before cleaning the Sensor.
- Clean surfaces of all applied parts for any apparent contaminants before disinfecting. Always disinfect the applied parts listed in the “Applied Parts” section, including the parts after removing the protective sheath. To clean or remove any gross bioburden, use a soft disposable towel moistened with water.
- There are two methods for disinfecting the sensor: wiping and immersion.
- Wiping disinfection:
  - Apply disinfecting solution on a sterile compress. Do not use an abrasive material.
  - With the sterile compress, wipe all surfaces of the Sensor’s head. Take care to wipe the part between the cable and the Sensor shell.
  - With the sterile compress, wipe the first 10cm of the Sensor cable.
  - Respect recommendations provided by the manufacturer of the disinfecting solution.
- Immersion disinfection:
  - Inspect the Sensor’s head for nicks. If any are present, do NOT use the immersion method.
  - Prepare the disinfection solution according to the manufacturer’s recommendation. Respect the accurate titration.
  - Immerse the Sensor head according to the manufacturer’s recommendation. Do NOT immerse the end with the USB connector.
  - It is not recommended to exceed a maximum immersion time of 35 minutes.
  - Respect recommendations provided by the manufacturer of the disinfecting solution.
- Whichever disinfection method is used, following disinfection, clean any remaining disinfectant and cleaning product from surfaces using a soft disposable towel moistened with warm water.

- Dry the Sensor before placing it in the next sheath.

Post-Disinfection Requirements

- Inspect the labels affixed to the applied and patient or operator-accessible parts. Verify that all product labels remain intact and are legible.
- Wastes containing blood and saliva used in dental procedures are considered regulated waste. If any such waste is generated as a result of cleaning/disinfecting the device, the waste must be placed in containers which are:
    - Closable
    - Puncture resistant
    - Leakproof on sides and bottom
    - Labeled or color-coded per 29 CFR§1910.1030(g)(1)
    - Closed before removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
- Always change gloves between patients to avoid cross-contamination risks.

Safe Disposal Methods

Wastes containing blood or saliva used in dental procedures are considered regulated waste and must be placed in containers that are:

- Closable.
- Puncture resistant.
- Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping.
- Labeled/color-coded per OSHA requirement 29 CFR§1910.1030(g)(1).
- Close before removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. Consult other local, state, territorial, and national requirements.

Caution must be applied when disposing of a medical device containing patient information. This includes files on the imaging workstation.

The Sensor (and workstation, if provided) are electrical equipment. Contact your waste disposal service provider, your distributor or dealer where the Sensor was purchased, or your local regulatory or public health authority for information on the safe electrical and electronic equipment disposal that complies with local, state, territorial, and national requirements.

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Appendix B: Technical Specification

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Electrical Specification

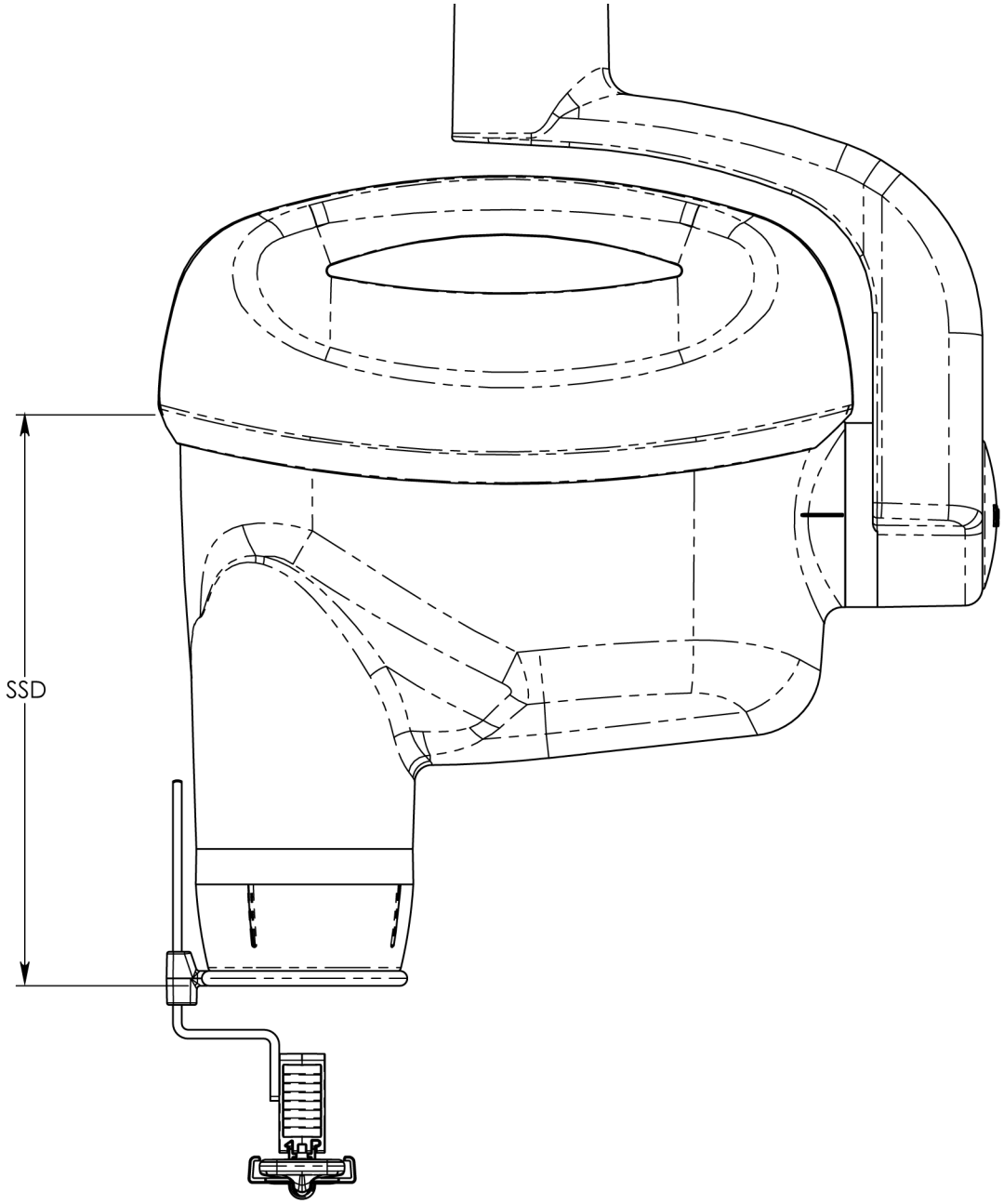
Parameter	Specification
Sensor Cable	3 m or 1.1 m
Connection Type/Computer Interface	High-Speed USB. This includes ports marked as USB SS (superspeed).
Power Supply	+5 V, per USB 2.0 specification
Level of Protection	IP68 (sensor only, per IEC 60529)
Degree of Protection for the Applied Parts	Class II, Type BF

X-Ray Sensor

Parameter	Specification
Film Size Equivalent	Size 1: 37 mm x 24 mm Size 2: 43 mm x 30 mm
Active Area	Size 1: 578.39 mm^2 Size 2: 920.48 mm^2
Number of Pixels	Size 1: 2.53 million Pixels Size 2: 4.77 million Pixels
Pixel Size	14 µm x 14 µm

Source to Skin Distance (SSD)

Parameter	SID Specification
Short cone (standard)	minimum 20 cm (8 in)
Long cone (optional)	minimum 30 cm (12 in)



Imaging Workstation Specification

Parameter	Specification
Windows Operating System	• Windows 10 Pro or Enterprise (64) • Windows 2008 R2 Server & above
Processor	Intel i3 (or greater)
Memory	8 GB RAM (or greater)
Storage	250 GB hard drive (or greater)
Video	32 bit, 1920 X 1080 Resolution Capable
Display	1920 X 1080, 32 true bit color
USB Ports	High Speed USB 2.0 or higher

Monitor Specification

Parameter	Specification
Resolution	1280 pixels × 1024 pixels

Intraoral X-ray Sources

Parameter	Specification
Compatible parts	Any intraoral X-ray source suitable for producing diagnostic X-ray radiographs of dentition, jaws, and other oral structures.

Sensor Positioning Devices

Parameter	Specification
Compatible parts	Any sensor positioner suitable for dental intraoral X-ray radiography and designed to support X-ray imaging sensors with size of 36 × 24 mm (1.4 × 0.9 in) or 43 × 31 mm (1.7 × 1.2 in).

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Appendix C: Dose Data

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Dose Information

The following table provides recommendations for typical loading factors at specified distances between the focal spot and the skin to achieve the nominal X-ray image receptor air kerma range (in mGy) needed for the intended use of the Sensor.

With X-ray tube setting at 65kV and 7mA

Anatomy	Settings	20 cm (8 in) Cone		30 cm (12 in) Cone	
		Adult	Child	Adult	Child
					
Incisor 	s	0.050	0.025	0.100	0.050
	mGy	0.546	0.273	0.485	0.243
Bicuspid 	s	0.050	0.025	0.100	0.050
	mGy	0.546	0.273	0.485	0.243
Bitewing 	s	0.080	0.040	0.160	0.080
	mGy	0.874	0.437	0.776	0.388
Lower Molar 	s	0.100	0.050	0.200	0.100
	mGy	1.092	0.546	0.971	0.485
Upper Molar 	s	0.100	0.050	0.200	0.100
	mGy	1.092	0.546	0.971	0.485

Appendix D: Troubleshooting Procedures

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Error Message Conventions

Error messages appear as pop-up windows in the format shown in Figure 1 below.

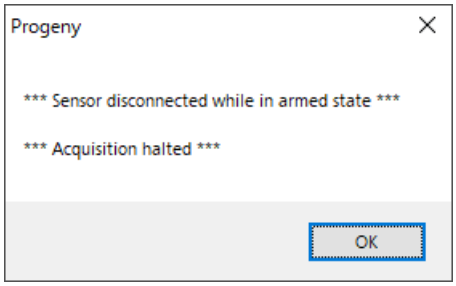

Figure 1. Example of an error message.

Some error messages guide possible suitable action to resolve the condition. Arrange for service if the issue persists or is not resolved after following the displayed guidance.

Error Messages

Error Name	Description and Recommended Action
Low Disk Space	**Message: "Sensor cannot arm due to less than 100 MB of free hard drive space available. Please free up more hard drive and try again."** 1. Create more disk space to arm Sensor. 2. If there is more than 100 MB of remaining disk space, the sensor will arm.
Disconnected in armed state	**Message: "*** Sensor disconnected while in armed state. Acquisition halted ***"** 1. If the Sensor is armed and ready for X-ray, and then the Sensor abruptly disconnects, a message will appear notifying the user that the Sensor was disconnected while in an armed state. 2. Reconnect the Sensor and try again.
Sensor timeout	**Message: "Sensor acquisition error: timed out."** 1. If the Sensor is in an armed state and meets the maximum timeout period (default: 5 minutes), the Sensor will disarm and notify the user that the Sensor timed out. 2. Ensure all equipment is turned on and ready, then try again.
Sensor USB Speed	**Message: "Sensor cannot arm due to being connected to a USB port lower than USB 2.0. Please connect the device to a USB 2.0 or higher port and/or hub."** 1. If the USB speed is less than "High Speed," or USB 2.0, a message will notify the user that the Sensor cannot arm due to slow USB speeds. 2. Connect the Sensor to a USB port/hub that meets the stated requirements.
Recall Last Image	**Message: "No image present in cache for recall."** 1. If the user requests to recall last image, but there is no image in the cache, it will notify the user that there is nothing to recall. 2. No action needed. Take images in order for images to be present in the cache.
Device used by another process	**Message: "Device Used By Another Process."** 1. If another application or process is using the device, the user will be notified. 2. Close any other applications that are using the Sensor.
Device Transfer Failed	**Message: "USB Transfer Failed."** 1. If, during an image transfer, the device fails to continue sending data, the user will be notified of the failed transfer. 2. Check Sensor connections. 3. Take another image if deemed appropriate.

Error Name	Description and Recommended Action
Max temperature reached	**Message: "Device Auto Disarmed Max Temp"** 1. If the device has reached the maximum allowable operating temperature (48 degrees Celsius), the Sensor will not arm, preventing the user from taking an acquisition. 2. Lower the temperature in the surrounding area, or move the Sensor to an area with lower ambient temperatures.

Midmark Technical Support

Upon request, qualified installation personnel can obtain part lists, descriptions, and additional Midmark® Intraoral Digital Sensor information from Midmark. Contact Midmark for a list of authorized installers.

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