midmark

Preva Dental X-Ray System

User Manual

003-10566-00
Revision AB1
March 2024

Caution: Federal law restricts this system 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 intraoral dental imaging technology from Midmark.

This manual describes the Preva Dental X-ray System and how to use it to generate X-rays for intraoral radiographs. It also explains Preva components and provides instructions on getting started, quality control, resolving issues, as well as cleaning and disposal.

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.

Related Manuals

Title	Description
003-10567-00: Midmark Preva Installation and Service Manual	Identifies requirements for installation and servicing for Preva Dental X-ray System.
003-10565-00: Midmark Intraoral Digital Sensor User and Installation Manual	Describes the Midmark Intraoral Digital Sensors, how to use them, and how to install them.
003-10678-00: User and Installation Manual – Midmark Imaging Software	Describes how to install Midmark Imaging, acquire and work with images using Mimdark Imaging, and generally how to use the features of Midmark Imaging.

Indications for Use

The intended use of the Preva X-Ray System is to act as a diagnostic source for radiographic dental imaging.

Guidelines for Patient Selection

Guidelines for using the Preva are described in the ADA/FDA Guide to Patient Selection for Dental Radiographs. Preva must only be operated for the intended use as indicated by the prescription of a qualified dental practitioner.

See the upcoming section "Dose Data" beginning on page 123 for detailed exposure information.

Contraindications

None known.

Adverse Reactions

None known.

⚠WARNING

- Preva may affect patients with pacemakers. Midmark has not analyzed this risk.
- Preva uses an audible indicator when emitting an X-ray. This may startle some patients. Earplugs may be used for patients with sensory disorders.

Indications of Sterility

This product is not provided sterile.

Warnings and Precautions

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

Midmark's Preva must be prescribed by a dental practitioner skilled in the art of applying radiography in dentistry. Midmark's Preva 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 Preva.

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

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

⚠WARNING Do not block the small hole in the plastic handle that covers the back of the Tube Head. It provides an air vent to allow the Tube Head oil to expand and contract as the unit is operated.

Radiation Safety

⚠WARNING This X-ray unit 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 Preva, observing all laws and regulations concerning radiation protection.

The X-ray tube is charged to a peak potential between 60 kV and 70 kV to provide tube currents between 4 mA and 7 mA for exposure durations of 0.02 s to 2 s. For more detailed exposure information, see the upcoming section "Dose Data" beginning on page 123.

- 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. Reference 003-10567-00, the Installation and Service Manual for stray radiation information.
- Make full use of all radiation safety equipment features, accessories, and procedures available to protect the patient and operator from X-ray radiation.
- The device is equipped with circuits that monitor the proper device operation during X-ray and will shut down the X-ray output if failure is detected. The X-ray can be terminated also by releasing of the Exposure Button.
- Execute the Seasoning Procedure on page 100 when Preva is not used for six months.

Warnings and Precautions (Cont.)

⚠CAUTION	Do not touch the USB connector on the articulated arm.

Electrical Safety

The Preva uses electrical energy from power mains for this operation.

⚠CAUTION	Preva requires a reliable connection to a protective earth/ground (Class I protection against electrical shock). Connect only to supply mains with protective earth/ground terminal, for example, a receptacle marked with a green dot or a label “hospital-grade” or “hospital only.”

- Do not replace X-ray sensors while a patient is in contact with the device or the operator.
- Allow only qualified and authorized service personnel to remove Preva covers and service the equipment.
- Service personnel must follow the instructions in the Installation and Service Manual during servicing.
- Do not service when the patient or non-service personnel is present.
- The power cord and power mains switch are power disconnect devices. Disconnect the power cord from the receptacle or turn the power switch OFF.
- Position mobile units to allow the power cord to be easily disconnected from the wall outlet.
- The service disconnect switch must be in the on position to operate the device. Depressing the power switch to the off position will immediately disconnect the device from the electrical mains.
- Preva is ordinary medical equipment without protection against ingress of liquids. Do not allow any water or other liquid to leak inside.
- Because the design of the Preva power supply circuit may momentarily draw high current, do not use this device with wall outlets having GFCIs (Ground Fault Circuit Interrupters). Outlets with GFCI are designed to trip when they sense a small amount of current passing from the line to earth ground. Outlets with GFCI can compromise the operation of the intra-oral X-ray device and the GFCI circuit itself.
- Turn off Preva before cleaning or disinfecting the control unit, display, or exposure switch/remote exposure station. These parts are not protected against ingress of liquids and must be wiped instead of sprayed.

Warnings and Precautions (Cont.)

Electromagnetic Compatibility

Preva 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.

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.

The medical use of Preva is exempt from the specific technical standards and other requirements contained in 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.

⚠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 Preva 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 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 Preva, 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.

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. 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.)

Damage and Injury

Prevent damage and injury by doing the following:

- Tampering with movements of Preva parts may result in damage to Preva or injury to service technicians, operators, or patients.
- Use caution and avoid dropping any Preva accessories.

Connectivity to IT Networks

- Preva does not require connectivity to IT networks to operate. Connectivity for the sensor system is embedded within the integrated models of Preva.
- When the sensor is used within an integrated Preva, the X-ray source, sensor, computer, and provided cables comprise a medical electrical system. The computer is not intended to be located in the patient environment (within a 1.5 m radius of the patient).
- For the integrated Preva systems, the high-speed USB connection with the sensor is created by connecting the sensor to the sensor port at the end of the articulated arm and by connecting the computer to the internal USB hub.
- The intraoral sensor connectivity is designed to work with Midmark intraoral sensors and may utilize a wide range of USB-capable equipment. 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

Preva 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	+ 10 °C to + 35 °C (+ 50 ºF to + 95 ºF)
Relative humidity	10 % to 80 %, non-condensing
Atmospheric pressure	70 kPa to 106 kPa
Maximum altitude	3000 m (9843 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. Do not allow condensation to form on the unit.

Transportation Environment

Preva 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	− 35 °C to + 66 °C (− 31 ºF to + 151 ºF)
Relative humidity	10 % to 80 %, non-condensing
Atmospheric pressure	70 kPa to 106 kPa

Storage Environment

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

Description	Value
Temperature	− 35 °C to + 66 °C (− 31 ºF to + 151 ºF)
Relative humidity	10 % to 80 %, 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 specified conditions and the open-air climate.

Units of Measure

Numeric indications of parameters on Preva 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, converted values in English 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.

Obtaining Technical Support

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

Midmark Corporation

60 Vista Drive, Versailles, OH 45380 U.S.A.

Phone: 1.800.MIDMARK (1.800.643.6275)
Direct: 1.844.856.1231 Opt. 3
imagingtechsupport@midmark.com

Hours: 8:00AM to 5:00PM Central Time

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.
	General warning sign.
	Warns of ionizing radiation.
	Warns of electricity.
	Heavy device can fall.
	Signifies that the mains plug must be disconnected from electrical outlet for the purposes of maintenance, in case of malfunction, or when left unattended.
	Signifies that the instruction manual must be read.
	Signifies that the earth terminal must be connected.
	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.
	An NRTL mark for compliance with IEC 60601-1.
	Identifies a type B applied part complying with IEC 60601-1.
L	Marks a terminal connected to the power mains' hot (not grounded) conductor.
N	Marks a terminal connected to the power mains' neutral (grounded) conductor.

Symbol	Description
	Identifies a terminal connected to an external conductor for protection against electric shock in case of a fault or the terminal of a protective earth (ground) electrode.
	Equipment is suitable for alternating current only.
	| – indicates the position of the power mains switch that connects Preva to the power mains (i.e., “power on”) ◯ – indicates the position of the power mains switch that disconnects Preva from the power mains (i.e., “power off”)
	Indicates a reference to the X-ray tube model.
	Indicates a value of filtration of the X-ray beam.
	Indicates a value of focal spot size of the X-ray tube.
	Indicates X-radiation emission (light with **YELLOW** color).
	Stand-by or preparatory state. When lighted with steady **GREEN** color, the system is in a Ready state and will emit X-ray when the Exposure button is pressed. When lighted with a flashing **GREEN** color, the system is in a Stand-by/preparatory state and the system will not emit X-ray when the Exposure button is pressed.
	Identifies the product catalog number or model.
	Identifies the product serial number.
	Indicates the date on which a product was manufactured.
	Identifies the manufacturer of a product.
	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.

Symbol	Description
	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 no more than three of the items should be vertically stacked on top of each other.
	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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Preva Labels

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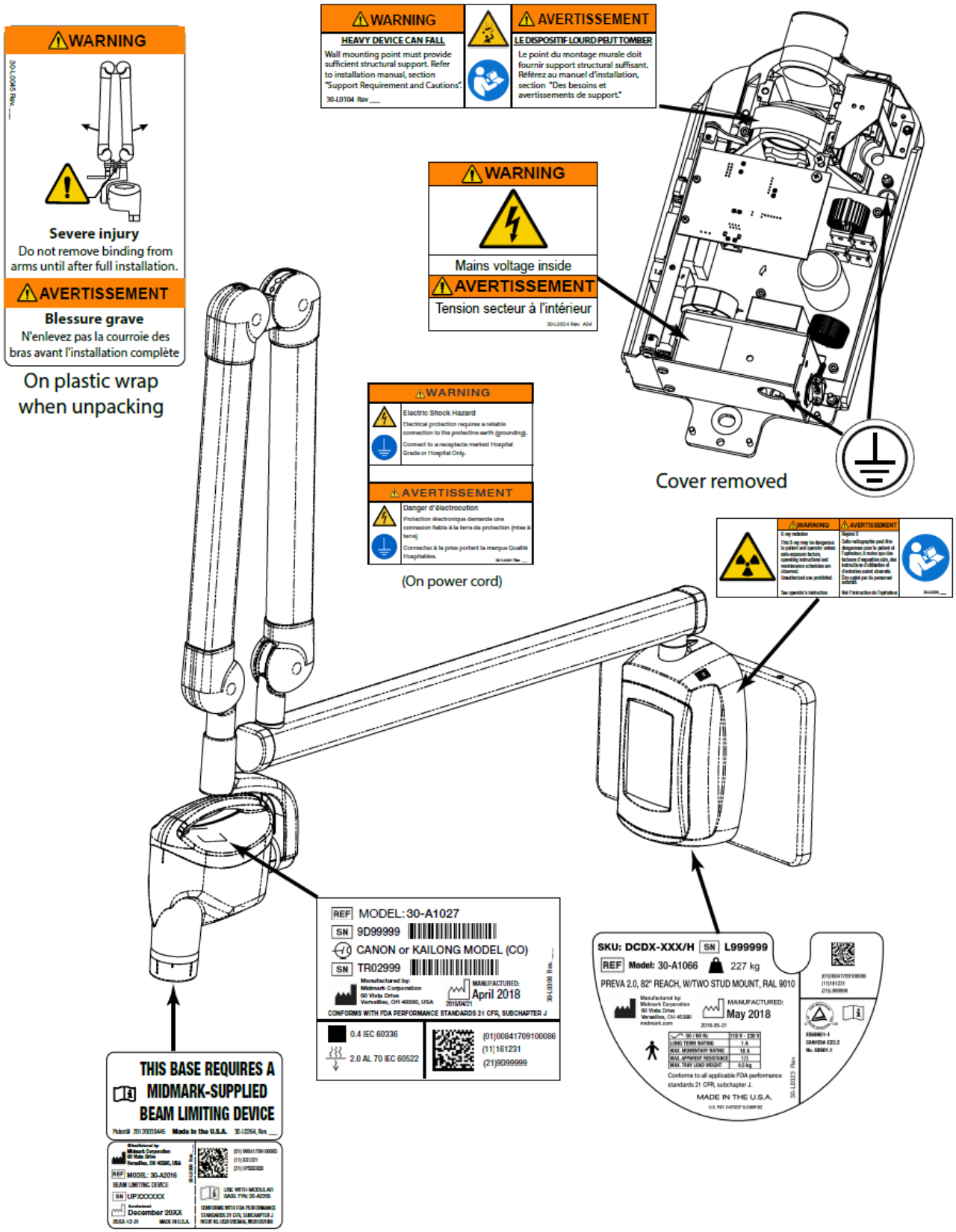
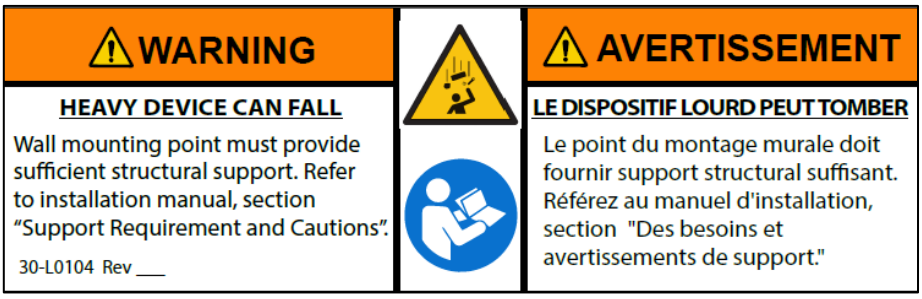
Wall-Mount Configuration

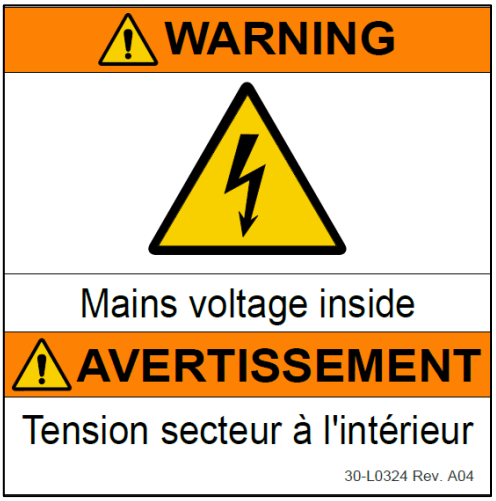


Overview of Wall-Mount Configuration Preva Labels

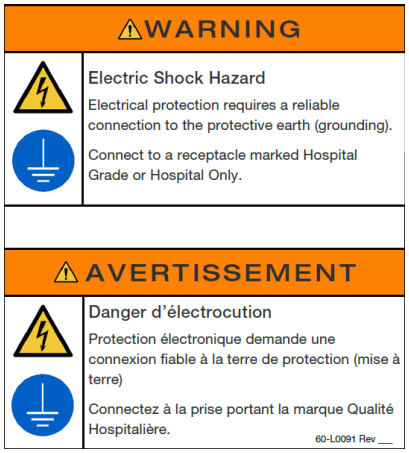
Plastic Wrap Label



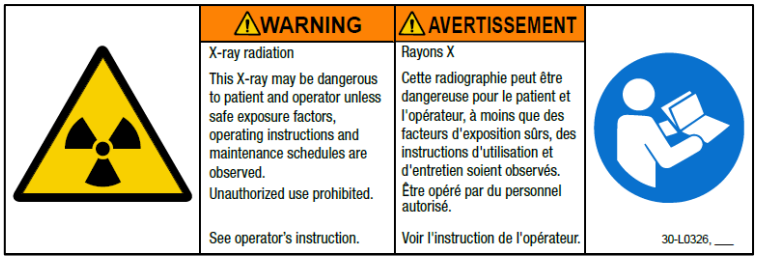
Safety Warning Label



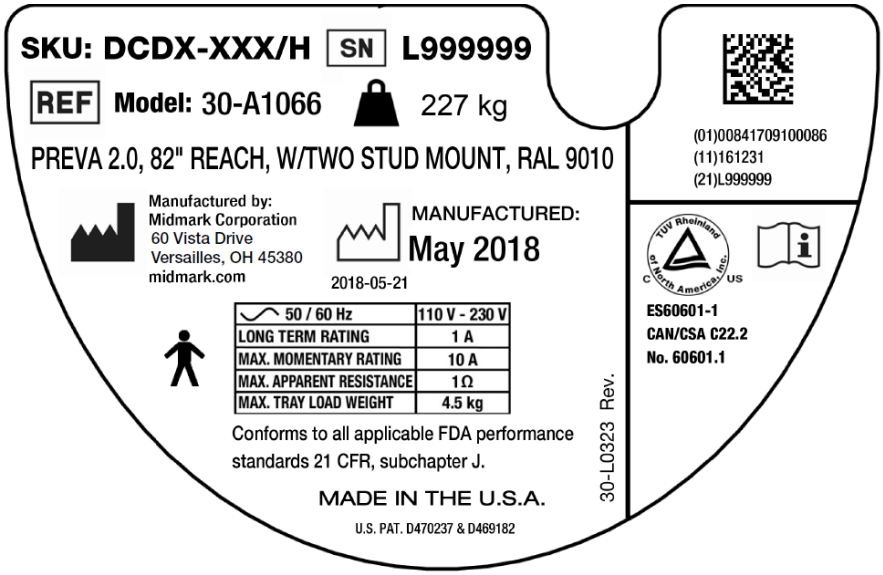
Dangerous Voltage Warning Label (For Service Only)



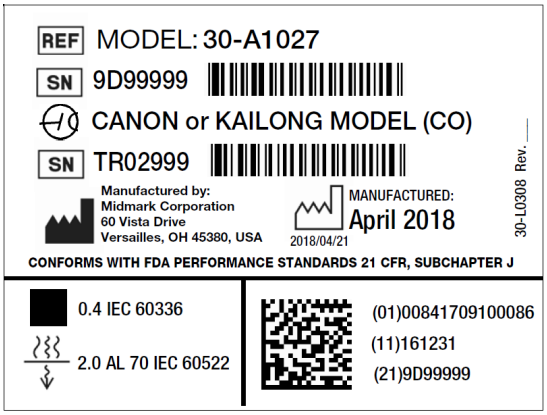
Power Cord Label



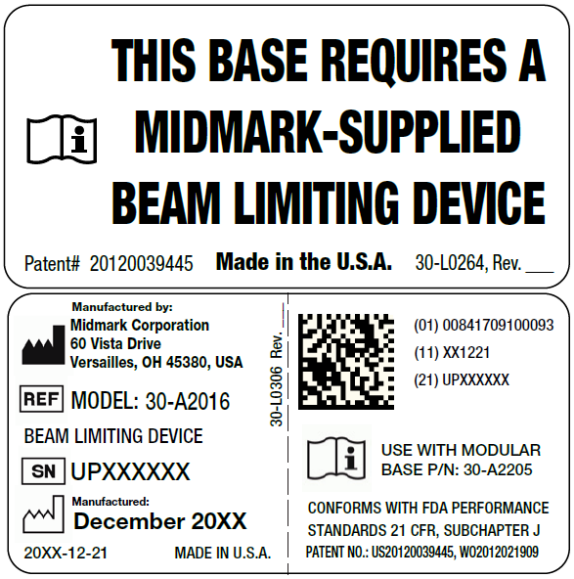
X-ray Warning Label



Intraoral System Serial Label

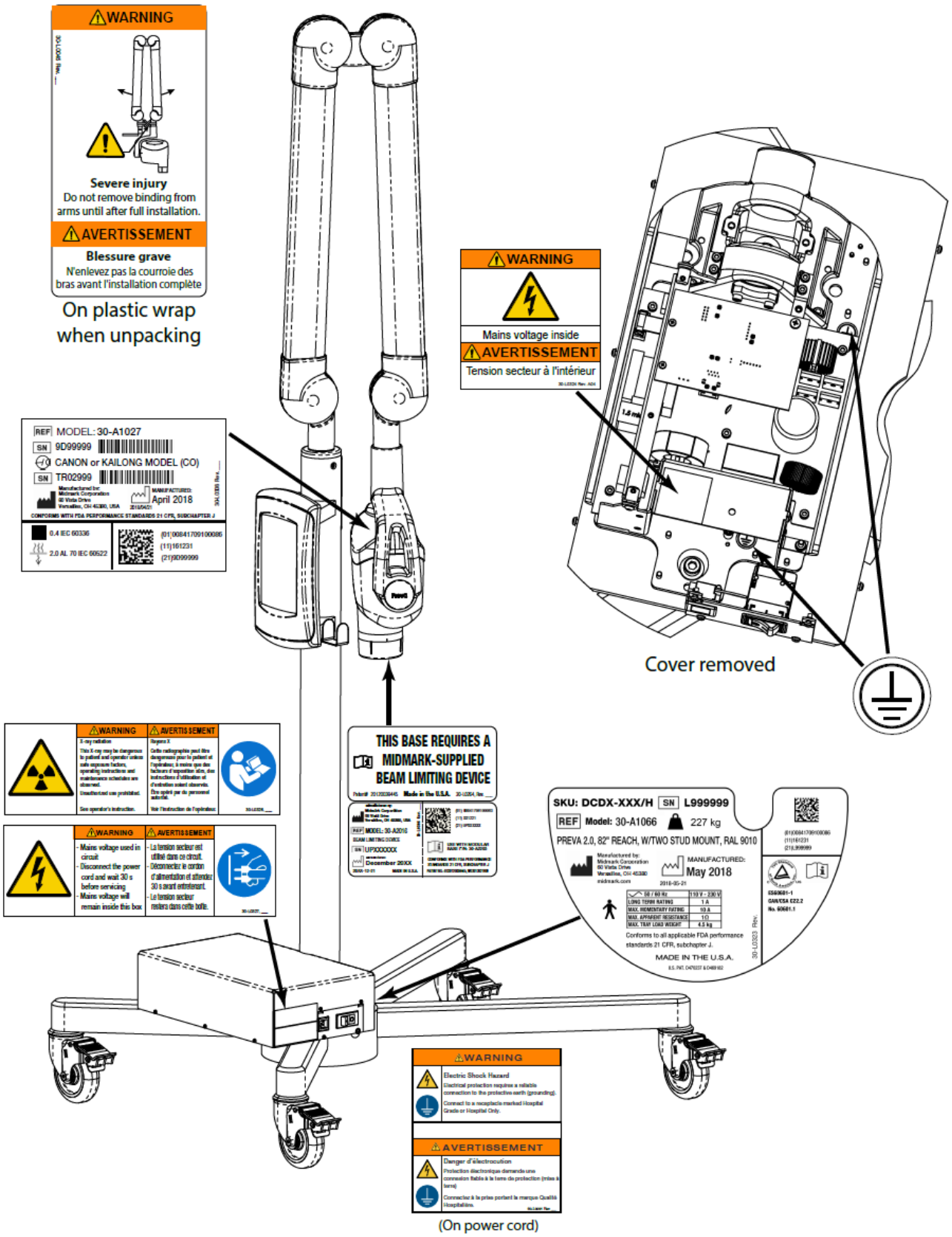


Tube head Serial Label



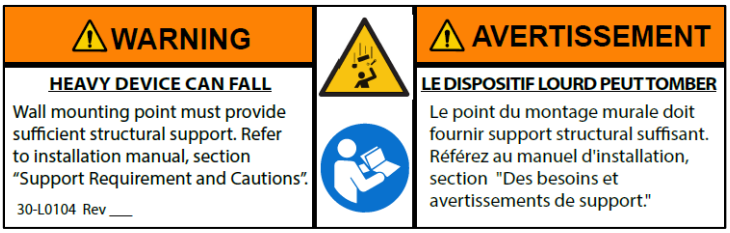
Beam-Limiting Device Serial Label

Mobile Configuration

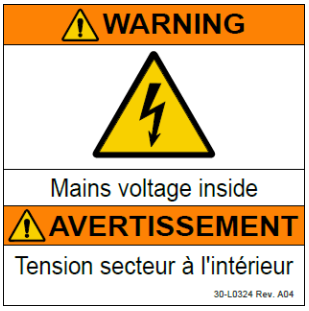


Overview of Mobile Configuration Preva Labels

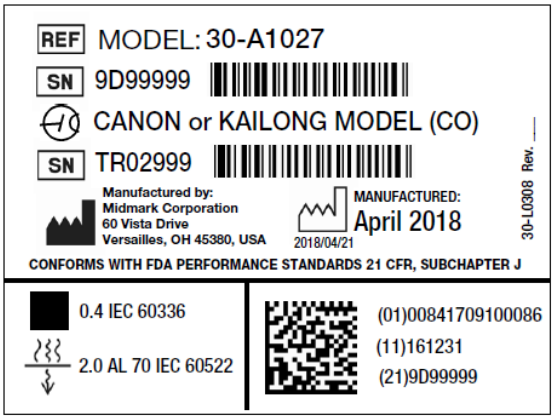
Plastic Wrap Label



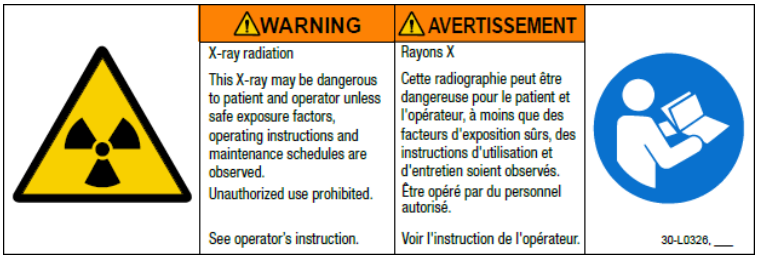
Safety Warning Label



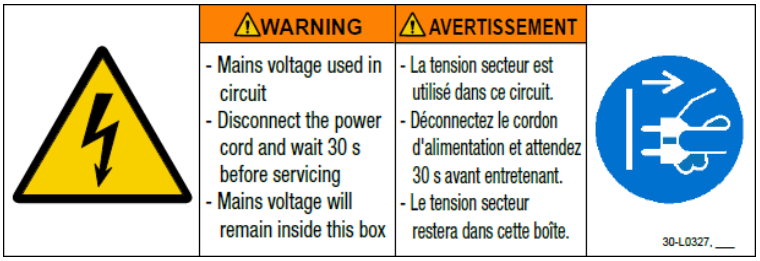
Dangerous Voltage Warning (For Service Only)



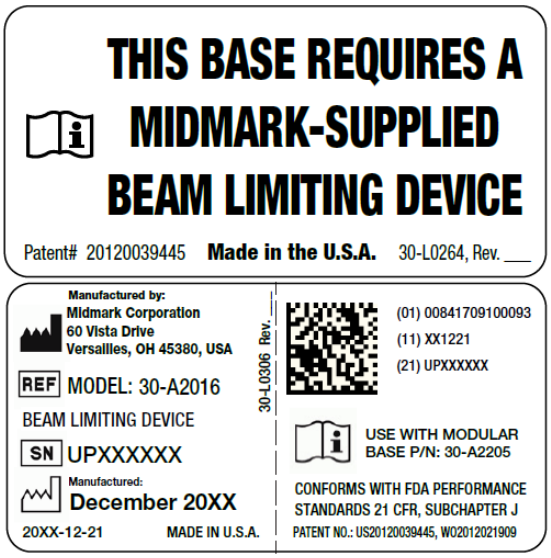
Tube head Serial Label



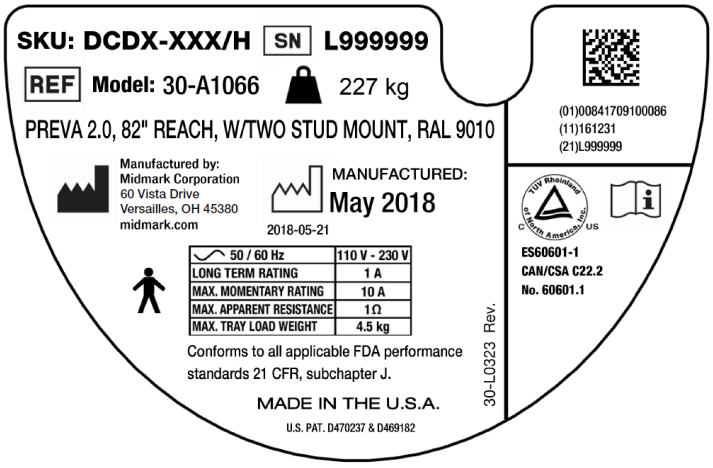
X-ray Warning Label



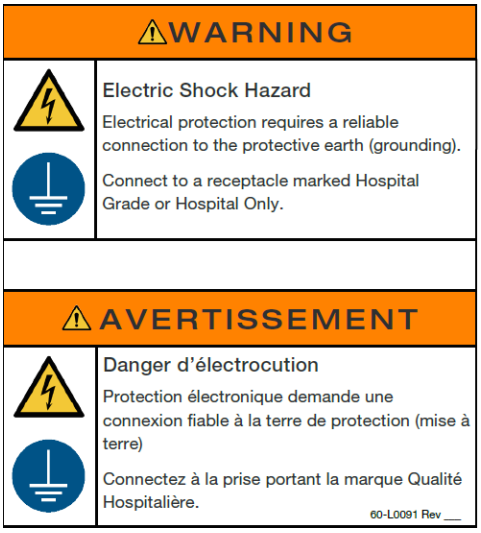
Dangerous Voltage – Unplug Before Service Label



Beam-Limiting Device Serial Label



Intraoral System Serial Label



Power Cord Label

Glossary of Terms

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Term	Meaning
Beam-limiting Device (BLD)	A device that provides a means to restrict the dimensions of the X-ray field.
Cone	See [Beam-limiting Device] above.
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.
Interlock	A device preventing the start or the continued operation of equipment unless certain pre-determined conditions prevail.
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.
Protective Earth (Ground)	A not normally carrying current connection to a common potential near to the earth's surface potential that is provided for safety purposes.

Term	Meaning
Technique Factors	See [Loading Factors] above.
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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Preva Models

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Preva Configurations

Preva is available in multiple configurations based on the following variables:

- Arm Reach – 142 cm (56 in), 168 cm (66 in), 193 cm (76 in), and 208 cm (82 in)
- Color Scheme – White and gray
- Mount – Single stud, double stud, metal stud, and mobile unit. Refer to the “Accessories and Supplemental Parts” section beginning on page 48.
- BLD/Cone – *20 cm length*: ▭ 20 mm × 30 mm, ▭ 30 mm × 40 mm, ▭ 35 mm × 45 mm, ⌀ 60 mm; *30 cm length*: ▭ 20 mm × 30 mm, ▭ 30 mm × 40 mm, ▭ 35 mm × 45 mm, ⌀ 60 mm. Refer to the “Accessories and Supplemental Parts” section beginning on page 48.
- Accessory – None, Handswitch, Remote Exposure Station, Two-stud Mount, Metal Stud Mount, Laptop Tray, Laptop
- Sensor – None, Size 1, Size 2 (the sensors, if included, will have short cable length)

The table on the following page describes the Preva models available for purchase.

Type of Preva	Part # - Gray	Part # - White	Description
Preva Plus with #1 Sensor	DCD7-G1Z/S1	DCD7-W1B/S1	193 cm (76 in) reach, single stud mount
	DCD6-G1Z/S1	DCD6-W1B/S1	168 cm (66 in) reach, single stud mount
	DCD5-G1Z/S1	DCD5-W1B/S1	142 cm (56 in) reach, single stud mount
	DCD8-G2Z/S1	DCD8-W2B/S1	208 cm (82 in) reach, double stud mount
	DCD7-G2Z/S1	DCD7-W2B/S1	193 cm (76 in) reach, double stud mount
	DCD6-G2Z/S1	DCD6-W2B/S1	168 cm (66 in) reach, double stud mount
	DCD5-G2Z/S1	DCD5-W2B/S1	142 cm (56 in) reach, double stud mount
Preva Plus with #2 Sensor	DCD7-G1Z/S2	DCD7-W1B/S2	193 cm (76 in) reach, single stud mount
	DCD6-G1Z/S2	DCD6-W1B/S2	168 cm (66 in) reach, single stud mount
	DCD5-G1Z/S2	DCD5-W1B/S2	142 cm (56 in) reach, single stud mount
	DCD8-G2Z/S2	DCD8-W2B/S2	208 cm (82 in) reach, double stud mount
	DCD7-G2Z/S2	DCD7-W2B/S2	193 cm (76 in) reach, double stud mount
	DCD6-G2Z/S2	DCD6-W2B/S2	168 cm (66 in) reach, double stud mount
	DCD5-G2Z/S2	DCD5-W2B/S2	142 cm (56 in) reach, double stud mount
Preva Plus Combination System with #1 and #2 Sensor	DCD7-G1Z/SB	DCD7-W1B/SB	193 cm (76 in) reach, single stud mount
	DCD6-G1Z/SB	DCD6-W1B/SB	168 cm (66 in) reach, single stud mount
	DCD5-G1Z/SB	DCD5-W1B/SB	142 cm (56 in) reach, single stud mount
	DCD8-G2Z/SB	DCD8-W2B/SB	208 cm (82 in) reach, double stud mount
	DCD7-G2Z/SB	DCD7-W2B/SB	193 cm (76 in) reach, double stud mount
	DCD6-G2Z/SB	DCD6-W2B/SB	168 cm (66 in) reach, double stud mount
	DCD5-G2Z/SB	DCD5-W2B/SB	142 cm (56 in) reach, double stud mount
Preva Plus Mobile	DCDM-G0Z/HS1	DCDM-W0B/H/S1	Mobile with #1 Sensor
	DCDM-G0Z/HS2	DCDM-W0B/H/S2	Mobile with #2 Sensor
	DCDM/G0Z/H/SB	DCDM-W0B/H/SB	Mobile with #1 and #2 Sensor
Preva 2.0 Intraoral X-Ray System	DCD7-G1Z	DCD7-W1B	193 cm (76 in) reach, single stud mount
	DCD6-G1Z	DCD6-W1B	168 cm (66 in) reach, single stud mount
	DCD5-G1Z	DCD5-W1B	142 cm (56 in) reach, single stud mount
	DCD8-G2Z	DCD8-W2B	208 cm (82 in) reach, double stud mount
	DCD7-G2Z	DCD7-W2B	193 cm (76 in) reach, double stud mount
	DCD6-G2Z	DCD6-W2B	168 cm (66 in) reach, double stud mount
	DCD5-G2Z	DCD5-W2B	142 cm (56 in) reach, double stud mount
	DCDM-G0Z/H	DCDM-W0B/H	Mobile
Preva DC Intraoral X-Ray System	P7017	PE7017	193 cm (76 in) reach, single stud mount
	P7016	PE7016	168 cm (66 in) reach, single stud mount
	P7015	PE7015	142 cm (56 in) reach, single stud mount
	P7018-P	PE7018-P	208 cm (82 in) reach, double stud mount
	P7017-P	PE7017-P	193 cm (76 in) reach, double stud mount
	P7016-P	PE7016-P	168 cm (66 in) reach, double stud mount
	P7015-P	PE7015-P	142 cm (56 in) reach, double stud mount
	P7017GM	PE7017M	Preva DC Mobile System
Preva DC Intraoral System with 6 cm (60 mm) Long Cone Gray	DPD7-G1Q	N/A	193 cm (76 in) reach, single stud mount, long cone
	DPD7-G2Q	N/A	193 cm (76 in) reach, two stud mount, long cone
	DPD6-G2Q	N/A	168 cm (66 in) reach, two stud mount, long cone
	DPD5-G2Q	N/A	142 cm (56 in) reach, two stud mount, long cone

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Key Components

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Key Components

The Preva Dental X-ray System is a high-frequency intra-oral X-ray machine. Its primary components include, at minimum, the Control Unit, the Tube head, the Articulated Arm, the Operator Panel, the Yoke, and the Cone. The configuration of these components depends upon whether a given device is a wall mount or a mobile unit.

Key Components – Wall Mount Configuration

⚠CAUTION	Do not hang lead aprons on the horizontal extension arm.

Articulated Arm

The Articulated Arm provides the articulation support for the Tube head and the reach and coverage of the Tube head to the patient.

Yoke

The Yoke connects the Articulated Arm to the Tube head.

Tube head

The Tube head contains the X-ray tube and high-voltage circuit. It has a provision for attaching the Cone. The Tube head is shipped assembled to the Articulated Arm.

⚠WARNING	There is a small hole in the plastic handle covering the back of the tube head. Under no circumstances should this hole be blocked as it provides an air vent to allow the tube head oil to expand and contract as the unit is operated.

Cone or Modular Beam-Limiting Device (BLD)

The Cone establishes the distance from the X-ray tube to the patient's skin. It provides positioning assistance and collimates the X-ray beam to within a defined shape at its end. The Preva is shipped with the standard 20 cm (8-inch) Cone attached to the Tube head. Multiple different Cones are available, including an optional 30 cm (12-inch) Cone. Refer to the "Accessories and Supplemental Parts" section beginning on page 48 for more information.

Horizontal Arm

The Horizontal Arm helps provide the necessary reach for the Preva. It pivots around a shaft inserted in the top of the Control Unit and contains an access cover to connect the cable from the Horizontal Arm to the Control Unit. It is available in four lengths on wall mount units, providing reaches of 142, 167, 193, or 208 cm (56, 66, 76, or 82 inches).

Control Unit

The Control Unit provides for the input power connection and control of the Tube head and Operator Panel. It provides automatic line voltage compensation, kVp control, and exposure time control. In the wall-mount configuration, it also serves as a mounting base for the Operator Panel.

Operator Panel

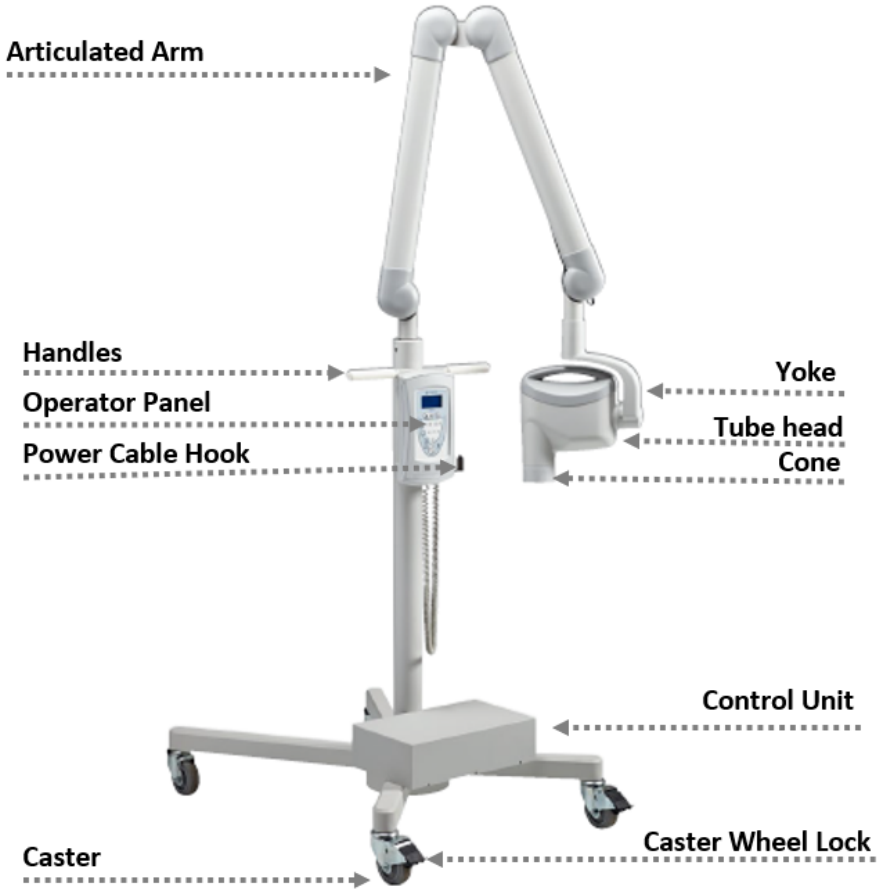
The Operator Panel is a touchpad through which the user interacts with the Preva. It consists of indicator lights; a screen which displays menus, technique factors, and other information; and buttons which can be used to navigate menus and change settings. Refer to the Control Interface section of this manual beginning on page 64 for details.

Hand Switch and Remote Exposure Station (not pictured)

Exposures can be made with the exposure button, with the optional hand switch, or with the optional remote exposure station. For installations requiring two exposure switches, the device can be configured in one of three ways:

1. One operator panel and one remote exposure station
2. Remote Exposure Station with Series Switch
3. One operator panel and one hand switch

Key Components – Mobile Configuration



Articulated Arm

The Articulated Arm provides the articulation support for the Tube head and the reach and coverage of the Tube head to the patient.

Handles

Projections by which the Preva should be gripped when moving the device.

Operator Panel

The Operator Panel is a touchpad through which the user interacts with the Preva. It consists of indicator lights; a screen which displays menus, technique factors, and other information; and buttons which can be used to navigate menus and change settings. Refer to the Control Interface section of this manual beginning on page 64 for details.

Power Cable Hook

A metal hook around which the power cable can be looped when the Preva is not in use.

Caster

The wheels at the base of the unit which allow the Preva to be transported.

Caster Wheel Lock

A lock which can be engaged to prevent rotation of the wheels (and therefore movement of the unit).

Yoke

The Yoke connects the Articulated Arm to the Tube head.

Tube head

The Tube head contains the X-ray tube and high-voltage circuit. It has a provision for attaching the Cone. The Tube head is shipped assembled to the Articulated Arm.

Cone or Modular Beam-Limiting Device (BLD)

The Cone establishes the distance from the X-ray tube to the patient's skin. It provides positioning assistance and collimates the X-ray beam to within a defined shape at its end. The Preva is shipped with the standard 20 cm (8-inch) Cone attached to the Tube head. Multiple different Cones are available, including an optional 30 cm (12-inch) Cone. Refer to the "Accessories and Supplemental Parts" section beginning on page 48 for more information.

Control Unit

The Control Unit provides for the input power connection and control of the Tube head and Operator Panel. It provides automatic line voltage compensation, kVp control, and exposure time control.

Hand Switch (not pictured)

Exposures can be made with the exposure button or the optional hand switch. For installations requiring two exposure switches, the mobile device can be configured in one way:

1. One operator panel and one hand switch

Accessories and Supplemental Parts

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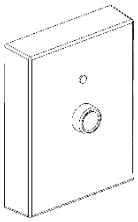
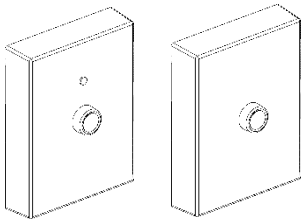
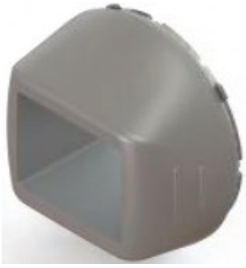
Exposure Switches

The exposure switches control the exposure during radiography.

Part	Description
	*Exposure Switch Option:* *Hand Switch, PN 30-A2040 or 30-A2040-W* Usually used with mobile devices or when the operator must remain near the patient. Available in gray or white.
	*Exposure Switch Option:* *Remote Exposure Station, PN 60-A2181* Usually used outside of the room to ensure that the operator is protected by distance or a protective barrier.
	*Exposure Switch Option:* *Remote Exposure Station with Series Switch, PN 002-10938-00* Contains two switches usually installed behind a protective barrier and is used to ensure that the operator remains in a specific position during the X-ray emission. This arrangement requires two-handed operation.

Beam-Limiting Devices

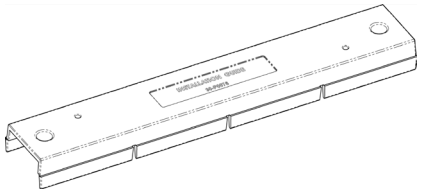
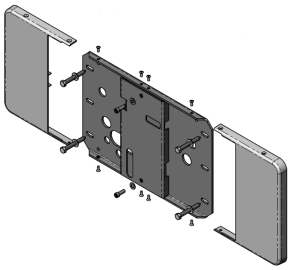
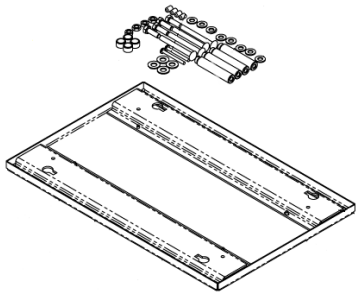
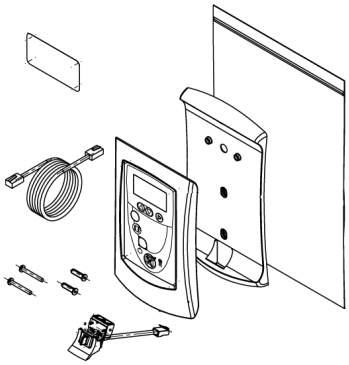
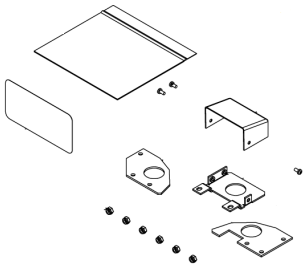
The beam-limiting devices (BLD) reduce the patient X-ray exposure by collimating the beam to the shape of the BLD. The beam-limiting devices also provide a spacer between the X-ray tube and the patient's skin. The length of the spacer is listed as 20 cm or 30 cm long in the table below.

Part	Description
	*Modular BLD, 20 cm Long:* *⌀60 mm Cone, White, PN 30-A2196* A white round cone providing 20 cm of source to object distance with a diameter of 60 mm.
	*Modular BLD, 20 cm Long:* *⌀60 mm Cone, Gray, PN 30-A2228* A gray round cone providing 20 cm of source to object distance with a diameter of 60 mm.
	*Modular BLD, 20 cm Long:* *30×40 mm Cone, White, PN 30-A2198* A white rectangular cone providing 20 cm of source to object distance with size of 30 mm by 40 mm.
	*Modular BLD, 20 cm Long:* *20×30 mm Cone, White, PN 30-A2199* A white rectangular cone providing 20 cm of source to object distance with size of 20 mm by 30 mm.
	*Modular BLD, 20 cm Long:* *35×45 mm Cone, Gray, PN 30-A2221* A gray rectangular cone providing 20 cm of source to object distance with size of 35 mm by 45 mm.

Part	Description
	*Modular BLD, 20 cm Long:* *35×45 mm Cone, White, PN 30-A2222* A white rectangular cone providing 20 cm of source to object distance with size of 35 mm by 45 mm.
	*Modular BLD, 30 cm Long:* *35×45 mm Cone, Gray, PN 30-A2223* A gray rectangular cone providing 30 cm of source to object distance with size of 35 mm by 45 mm.
	*Modular BLD, 30 cm Long:* *35×45 mm Cone, White, PN 30-A2224* A white rectangular cone providing 30 cm of source to object distance with size of 35 mm by 45 mm.
	*Modular BLD, Base (Gray), PN 30-A2205* A gray replacement base used with the modular cones providing mounting of the modular BLDs.
	*Modular BLD, Spacer (Gray), PN 30-A2206* A gray replacement base used with the modular cones providing 30 cm source to object distance.
	*Modular BLD, Spacer (White), PN 30-A2208* A white replacement base used with the modular cones providing 30 cm source to object distance.

Installation Options

These items assist with the device installation in various environments.

Part	Description
	*Installation Option:* *Single-Stud Mount, Installation Guide, 30-P0076* A tool assisting the proper mounting in a single-stud configuration (wooden stud walls).
	*Installation Option:* *Two-Stud Mount, 30-A2042* A mount allowing installing of the device on two wooden studs.
	*Installation Option:* *Metal Stud Mount, 30-A2043* A mount allowing installing of the device on walls constructed with metal studs.
	*Installation Option:* *Dual Operator Panel Kit, 30-A2114 and 30-A2114-W* A kit intended for passthrough installations where a single Preva unit is mounted in a cabinet between two operatories. The kit allows an Operator Panel to be installed in each operatory. There will be a switch on the Control Unit to select which Operator Panel is active.
	*Installation Option:* *4×4 Mount Kit, 30-A2099* A kit intended to provide cover for cables in cases where the wires for power mains must enter on the center line of the Control Unit.

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Applied Parts

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Applied Parts

No parts of Preva have to be in contact with the patient during the device operation. The tube head, cone, yoke, and/or arm may make incidental contact with the patient.

When Preva is used as part of an integrated system with the Midmark Intraoral Sensor, that sensor and the first 10 cm (4 in) of the cable are applied parts.

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Startup and Shutdown

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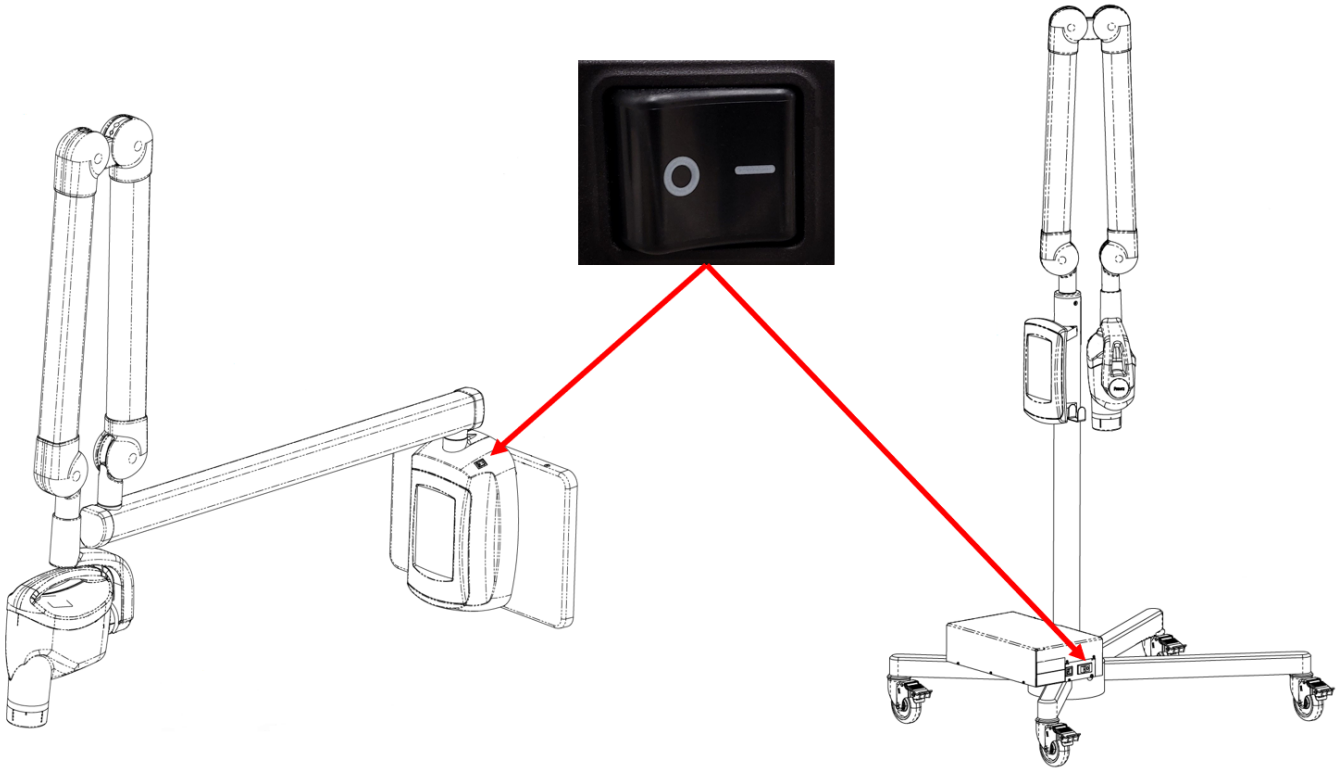
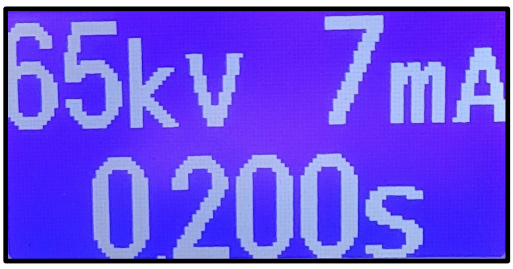
Turning Preva On

1. Locate the power switch. (Note: This is also referred to as the service disconnect switch.) On a wall-mount Preva (below, left), it will be on top of the control unit mounted to the wall. On a mobile Preva (below, right), it will be on the side of the control unit at the base.

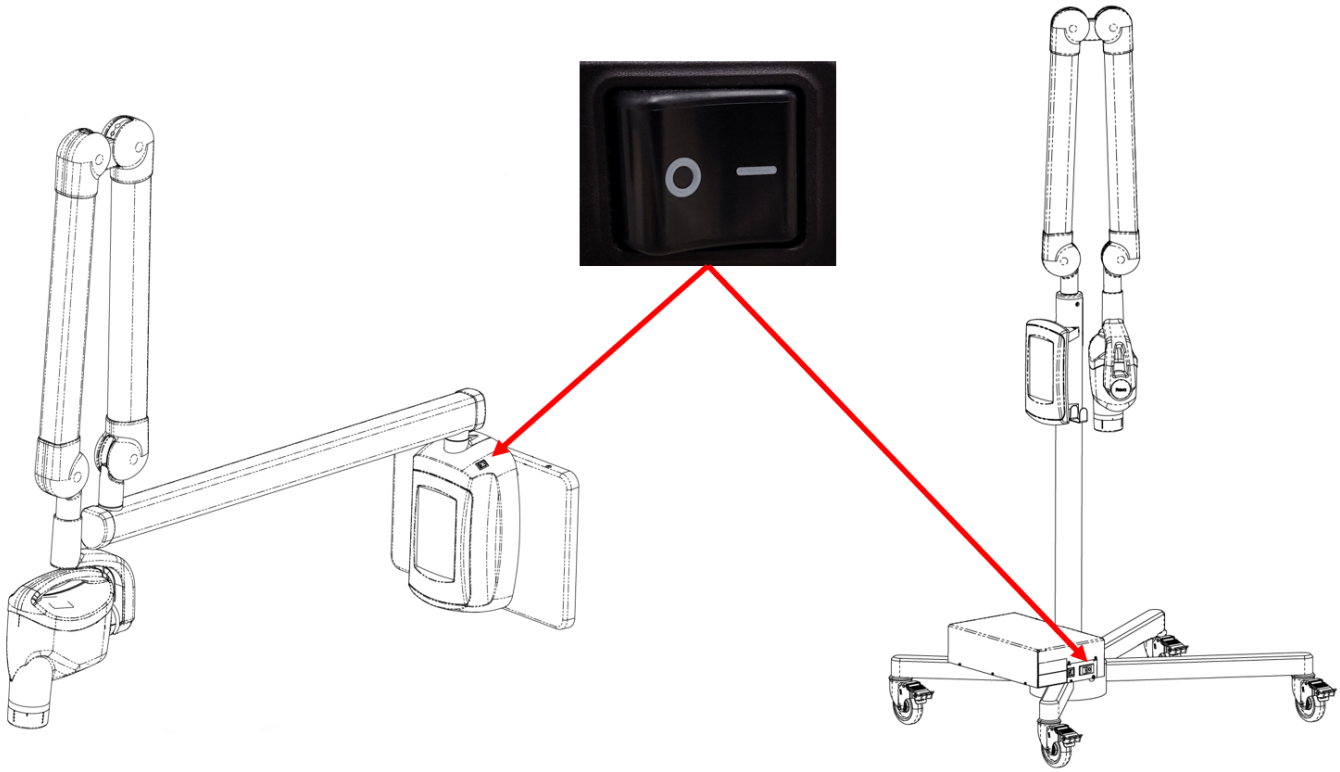


2. To turn unit power on, press the power switch so that the | side is depressed. Refer to the section “Symbols Glossary” beginning on page 16.
3. The operator panel lights up. The Ready Indicator illuminates, and the display briefly shows the Midmark logo (below, left), followed by the selections from the system’s most recent exposure (below, right – example only). If the most recent exposure was taken using preset settings, then the applicable Tooth, Receptor, and Patient Size icons also illuminate.



Turning Preva Off

1. Locate the power switch. On a wall-mount Preva (below, left), it will be on top of the control unit mounted to the wall. On a mobile Preva (below, right), it will be on the side of the control unit at the base.



2. To turn unit power off, press the power switch so that the ◯ side is depressed. Refer to the section “Symbols Glossary” beginning on page 16.
3. The operator panel lights turn off.

Control Interface

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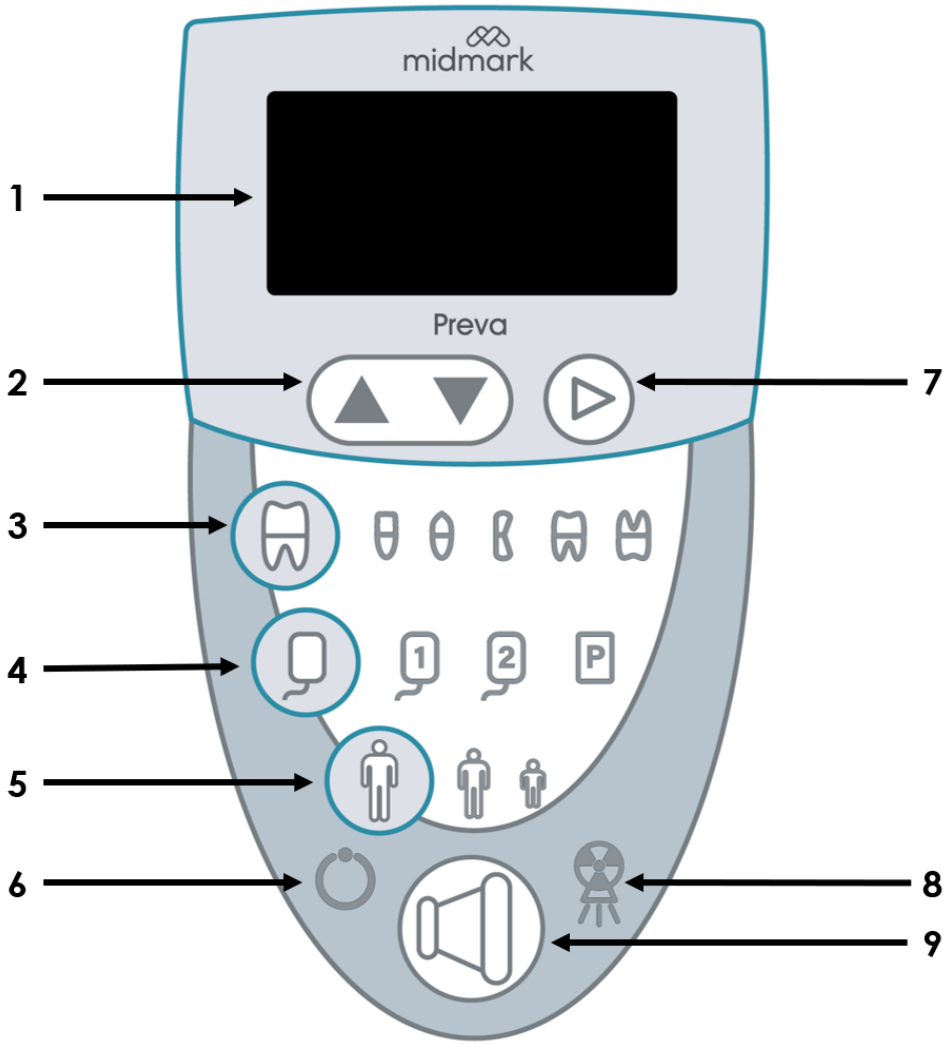
Preva Operator Panel

When the Preva Dental X-ray System is powered on, the Operator Panel displays the selections from the system's most recent exposure.



Icons

1. An LED screen displays technique factors. It also displays menu selections when the system is in menu mode.
2. Up and Down arrows are used to navigate menus and change kV, mA, and time settings.
3. Tooth Icon: Pressing this button allows the user to select Incisor, Bicuspid, Bitewing, Upper Molar, or Lower Molar.
4. Receptor Icon: Used to select one of two different digital receptor settings or phosphor plate.
5. Patient Size Icon: Press to select Large or Small.
6. Ready Indicator: Symbol lights steadily to indicate that the system is ready to produce X-ray or flashes to indicate system is cooling.
7. Right Arrow Button: Use this button to move between kV, mA, and time selections. This button is also used as an "Enter" key when the system is in menu mode.

8. Radiation Indicator: This symbol lights when X-rays are being produced.
9. Exposure Button: Press this button to initiate an X-ray exposure.

Technique Factors

When the system is powered on, the operator panel (see previous page) displays the technique factors (kV, mA, and seconds) from the system's most recent exposure. Use the Tooth Selection, Image Receptor Type, and Patient Size buttons to select other technique factors.

For a table of the default technique factors, refer to the Default Exposure Times tables on page 127.

Changing Technique Factors

It may be necessary to increase or decrease the kV, mA, or time from the preset values. For details, refer to the "Adjusting Technique Factors" section beginning on page 73 of this manual. High-level instructions are as follows:

1. Press the right arrow button to highlight the value being changed.
2. Use the up or down arrows to increase or decrease the value. (The lights on the display that indicate the preset values will no longer be lit.)
3. Press any other button (Tooth, Receptor, or Patient Size) to return the display to the preset values.
4. The procedure for changing pre-programmed settings is available in the "Changing Pre-Programmed Technique Factors" section beginning on page 84 of this manual.

Radiation Indicators

The Preva has a visible and an audible Radiation Indicator. When an exposure is in progress, the Radiation Indicator on the Operator Panel is illuminated (pictured below), and an audible tone is heard. The exposure is complete when the Radiation Indicator is extinguished and the audible tone is no longer heard.

Ready Indicator

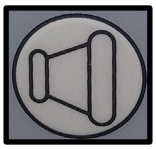
The Ready Indicator illuminates (pictured below) when the system is ready to make an exposure. Immediately after an exposure, the Ready Indicator flashes until the X-ray tube cools down

sufficiently to make the next exposure. The Ready Indicator also flashes when the system is on a menu screen. No exposure can be made while the Ready Indicator is flashing.

NOTICE The cooling time is either 10 seconds or 15 times the length of the exposure, whichever is longer. The Ready Indicator flashes green during the cooling time and illuminates in a steady green when the cooling time has been completed.

Exposure Button and Radiation Indicators

The Exposure Button (pictured below) initiates the X-ray output, and the button must be pressed for the complete duration of the desired irradiation time. The X-ray output is indicated by the yellow illumination of the Radiation Indicator, and the termination of the X-ray is evident by the cessation of the audible signal. The button must be pressed and held until the audible signal stops. Releasing the Exposure Button during exposure will immediately terminate the X-ray exposure.



⚠CAUTION Accidental release of the Exposure Button during radiography causes additional X-ray exposure. The button release terminates the X-ray before the selected exposure time expires, causing reduced dose to be emitted. As a result, the imaging receptor may not receive sufficient X-ray energy to provide an image with diagnostic quality, and the radiography may need to be repeated.

Interlock

NOTICE It is the owner's responsibility to provide any visual interlock indicators required by local ordinances.

Operating Instructions

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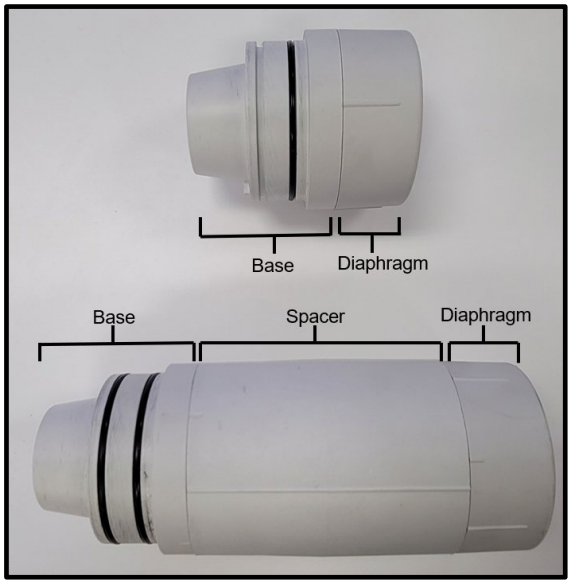
About the 20 cm and 30 cm Cones

The system is factory-configured for use with the standard, supplied round cone which provides 20 cm (8 in) source-to-image distance and is 60 mm in diameter. Other cone options are available. Refer to the “Accessories and Supplemental Parts” section beginning on page 48 for a list of available cones.

Using the 30 cm (12 in) source-to-image distance cones will require longer exposure times. For instructions on configuring the system for use with the longer cones, see the Changing the Cone Size section beginning on page 94 of this manual.

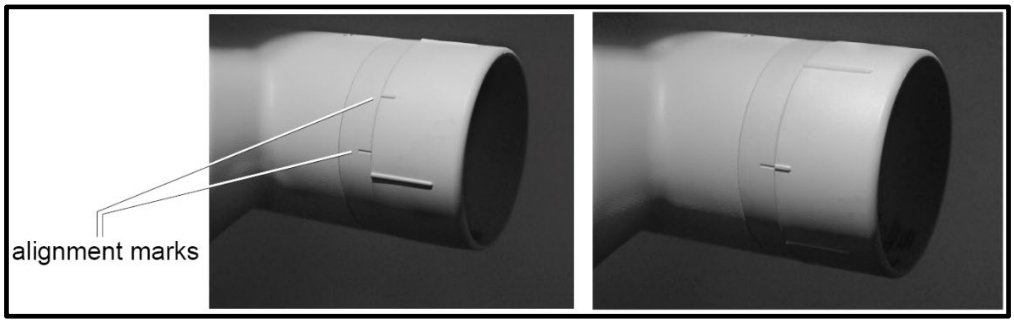
Cones are comprised of a base and a diaphragm. In the case of the 30 cm (12 in) cone, a spacer is permanently affixed to the base. Refer to the photograph below.



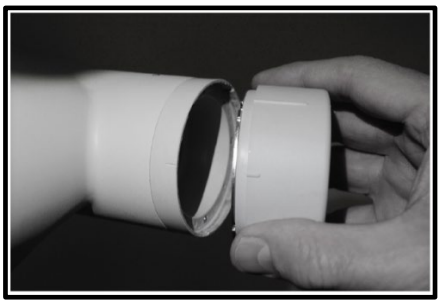
Changing a Cone Diaphragm

The Preva system has a variety of cone options (see the “Accessories and Supplemental Parts” section beginning on page 48). Follow this procedure to replace a cone diaphragm:

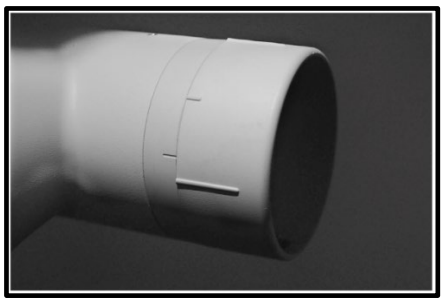
1. To remove a cone diaphragm, rotate it until the short marks on the base (or spacer, if applicable) and the cone diaphragm align.



2. Remove the cone diaphragm by pulling it out. There will be a slight resistance because the parts are magnetized.

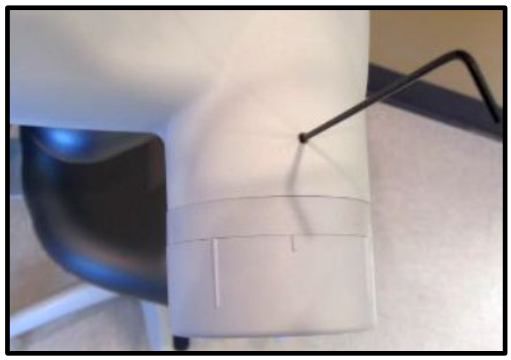


3. Reverse the steps to attach the new cone diaphragm. Secure it by rotating it clockwise about 30° until the first catch is felt. After the first catch, it can be rotated further if desired (for example, in the case of a rectangular-shaped diaphragm when it is desired to align the orientation of the diaphragm with the orientation of a sensor).



Changing from a 20 cm Cone to a 30 cm Cone

1. Remove the set screw from the Preva tube head and pull out the cone base.



2. On the new cone to be installed, remove the O-ring that is the farther of the two from the diaphragm.

3. Insert the cone into the tube head. Ensure it is flush and tighten the set screw.

4. Move the tube head into various positions. Ensure that there is no binding and that the tube head does not drift when placed at various angles.

5. The exposure times must be reconfigured as a result of the longer cone. Refer to the Changing the Cone Size section beginning on page 94 of this manual.

Adjusting Technique Factors

Preset technique factors can be adjusted before making an exposure.

1. Use the right arrow to select the technique factor to adjust. When the right arrow is first pressed, the kV setting will be highlighted (below, left). Pressing the right arrow a second time

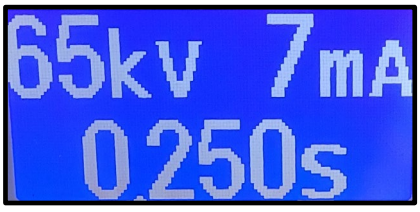
will highlight the mA setting (below, middle), and pressing it a third time will highlight the time/seconds setting (below, right). Pressing the right arrow a fourth time will begin the cycle again.

NOTICE

- After the right arrow is pressed, the icons on the panel will no longer be illuminated. This indicates that the preset values are no longer selected.
- If time is the only setting desired to be changed, the right arrow does not need to be pressed. Pressing the up and down arrows will automatically highlight and change the time if neither of the other settings are highlighted.

2. When the desired setting is highlighted, use the up and down arrows to adjust the value. In this example, the time setting has been increased from 0.200 sec to 0.250 sec.

3. After a few seconds have passed without pressing a button, the highlighting will disappear, leaving the selected settings displayed on the screen and ready to use.



4. Press any other button (Tooth, Receptor, or Patient Size) to return the display to the preset values.
5. To save new presets, see the “Changing Pre-Programmed Technique Factors” section beginning on page 84 of this manual.

Taking an X-Ray

1. Turn the power switch to the “On” position. Refer to the section “Turning Preva On” beginning on page 61 of this manual.
2. Verify that the unit is set for the Tooth to be imaged. The icon for the currently selected Tooth is illuminated in blue. To change the Tooth Selection, press the Tooth Selection button until the correct Tooth is selected.
3. Verify that the unit is set for the correct Image Receptor Type. The icon for the currently selected Image Receptor Type is illuminated in blue. To change the Image Receptor type, press the Image Receptor Type button until the correct Image Receptor Type is selected.
4. Verify that the unit is set for the appropriate Patient Size. The icon for the currently selected Patient Size is illuminated in blue. To change the Patient Size, press the Patient Size button until the correct Patient Size is selected.
5. If desired, the technique factors can be selected manually. (Skip this step when using the default technique factors.) Refer to the section “Adjusting Technique Factors” beginning on page 73 for more information.
6. Position the Tube Head and image receptor for the patient’s X-ray using standard accepted positioning procedures.

⚠CAUTION	Do not operate the device in the significant zone of occupancy. The operator must remain at least 2 meters (7 feet) away from the focal spot and out of the path of the X-ray beam. In locations in which the patient is isolated from the operator during X-ray exposures, it is the owner’s responsibility to provide for audiovisual communication between them.

7. Take the X-ray. Press and hold the Exposure Button until the audible signal stops and the Radiation Indicator light turns off. Releasing the Exposure button or coil-cord hand switch at any time will immediately terminate the exposure.

⚠CAUTION	It is recommended that the operator exit the room when using the coil-cord hand switch. To follow established safety practices and comply with regulations, the technique factors must be visible to the operator from the remote location.

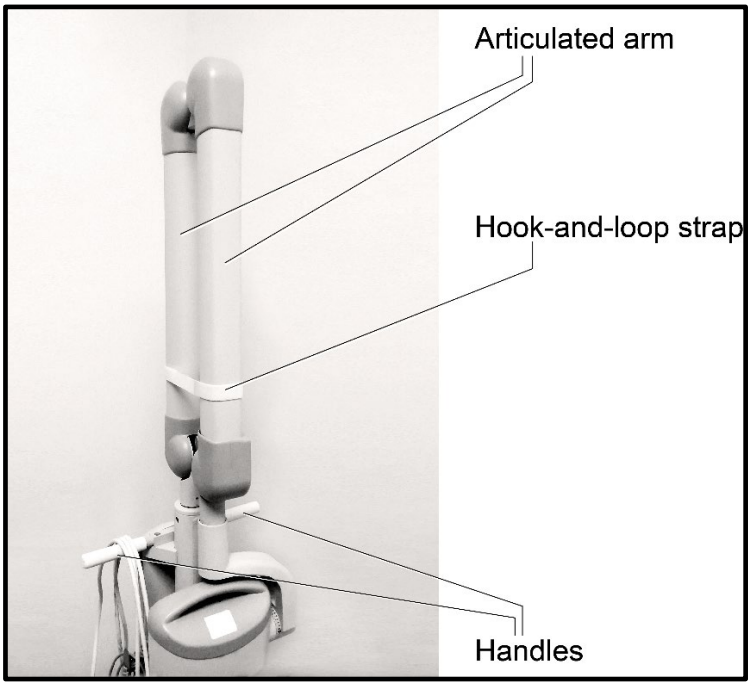
8. Allow the unit to cool down before taking another exposure. The cooling time is either 10 seconds or 15 times the length of the exposure, whichever is longer. The Ready Indicator flashes green during the cooling time and illuminates in a steady green when the cooling time has been completed.
9. Repeat steps 2 – 8 for each additional exposure that is needed.
10. When finished acquiring images, return the tube head to the storage position. To do this, position the articulated arm so that both segments are pointing straight up.

⚠CAUTION

- The mobile Preva configuration is more likely to tip over if not stored properly. Pay particular attention to the storage position for mobile units.
- Do not strike the Tube Head on anything when returning it to the storage position.

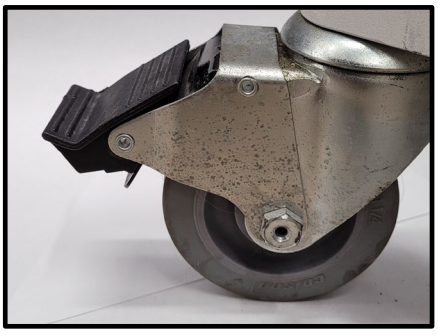
Transporting the Mobile Device

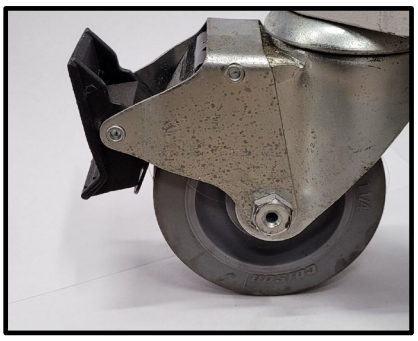
To avoid injury and damage to the Tube Head when transporting the device to a different location within the user facility, collapse the articulated arm and secure it. Maneuver the device by grasping the device's two handles. Avoid hitting the Tube Head on walls, doorways, etc., and be careful not to damage the cable with the wheels during transport.



⚠CAUTION Engage the wheel caster locks when the device is not being transported.

The following images show the wheel caster locks in the unlocked (below, left) and the locked (below, right) positions.





System Configuration Mode

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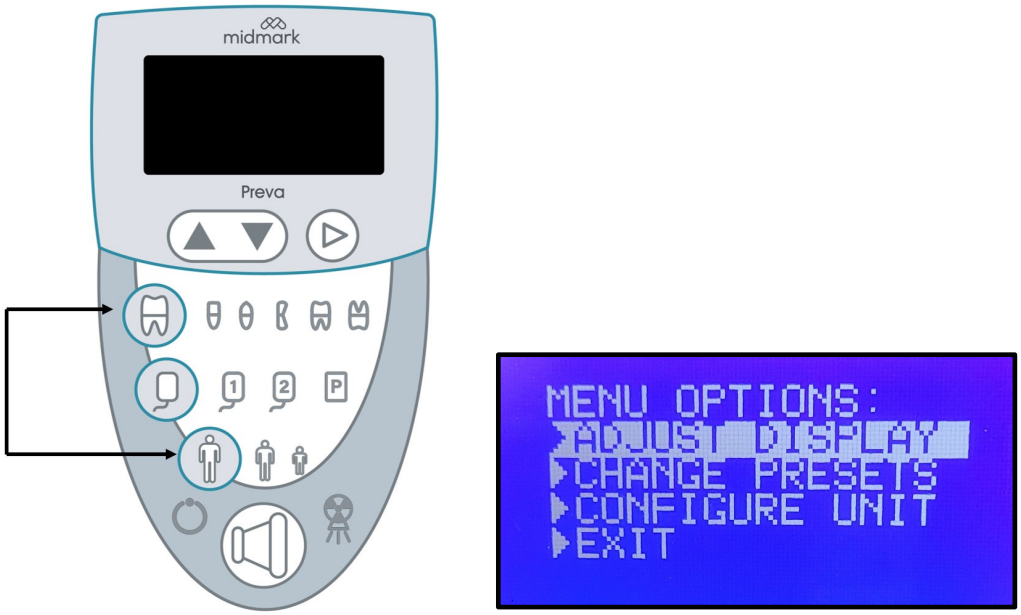
System Configuration Mode

The Preva Dental X-ray System has a software-driven system configuration mode. When the Preva is in system configuration mode, the following procedures can be performed:

- Adjust the display
- Change default technique factors
- Change the extension cone size
- Show current system configuration
- Display diagnostic data

Using System Configuration Mode

1. To enter System Configuration mode, press the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for five seconds (below, left). The Main System menu will appear as shown below (right). The Ready Indicator will blink.



2. To make a selection from the menu, use the up and down arrows to highlight an option. Select the option by pressing the right arrow. Each of the options will be shown in detail in the following sections.
3. After selecting an option, use the up and down arrows to increase or decrease values. Use the right arrow as an enter key.

Adjusting the Display

The Display Options Menu

The Preva Dental X-ray System allows the operator to adjust the display image.

1. To enter System Configuration mode, press the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for five seconds (below, left). The Main System menu will appear as shown below (right). The Ready Indicator will blink.

2. From the Main System menu, select ADJUST DISPLAY (highlighted above). The Display Options menu shown below will appear.

3. Select EXIT to return to the Main System Configuration menu.

Adjusting Contrast

1. On the DISPLAY OPTIONS menu, scroll to ADJUST CONTRAST. Press the right arrow button.

2. The Midmark logo will appear.

3. Use the up and down arrows to increase or decrease the contrast between the menu text and the background. Below are some examples showing the spectrum of this setting.

4. When satisfied with the appearance of the display, press the right arrow to save the changes.

Reversing the Image

1. On the DISPLAY OPTIONS menu, scroll to REVERSE IMAGE.

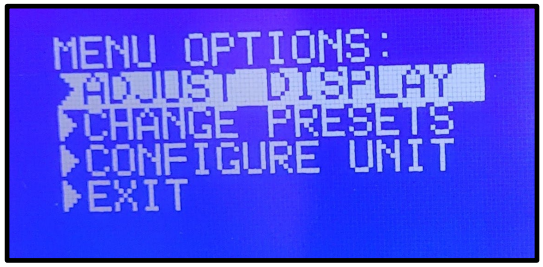
2. Press the right arrow button. The text and background colors will be swapped.

3. Scroll down to EXIT and press the right arrow button.

Changing Languages

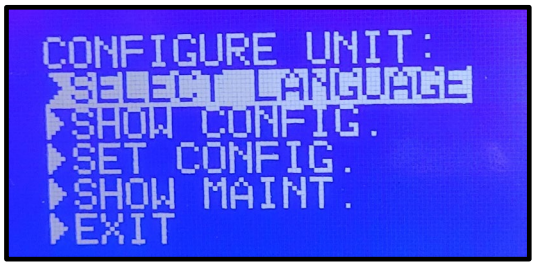
Five languages are programmed in the display panel. Follow these steps to change the language.

1. Push and hold the Tooth and Patient selection buttons simultaneously (below left). After about 5 seconds, a menu screen (below right) will appear.

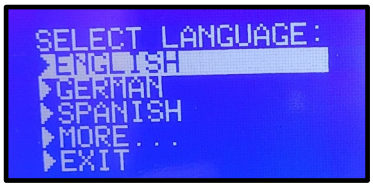


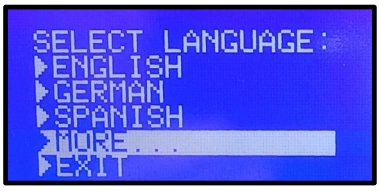
2. Use the down arrow to highlight “CONFIGURE UNIT,” then press the right arrow key to select it.

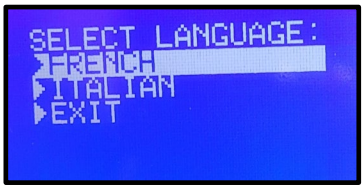
3. “SELECT LANGUAGE” on the following screen will be highlighted. Press the right arrow key.



4. Select the desired language and press the right arrow key. If the desired language is not displayed, press the down arrow to reach “MORE...” Press the right arrow.







5. Press the down arrow key to reach “EXIT,” then press the right arrow key to select it. Repeat this step to return to the main screen.

Changing Pre-Programmed Technique Factors

The Preva Dental X-ray System allows the operator to increase or decrease image density for all presets for a receptor simultaneously or to change each of the technique factors for a preset individually. You can also restore factory default settings. For charts of the default settings, refer to the tables in the System Configuration – Default Exposure Times section on page 127.

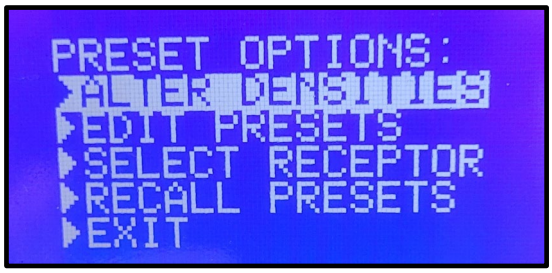
NOTICE

If the 30 cm (12 in) cone will be used, configure the Preva for use with the 30 cm cone before changing preprogrammed technique factors. Configuring the Preva for use with the 30 cm cone will reset technique factors to the default settings used with the 30 cm cone.

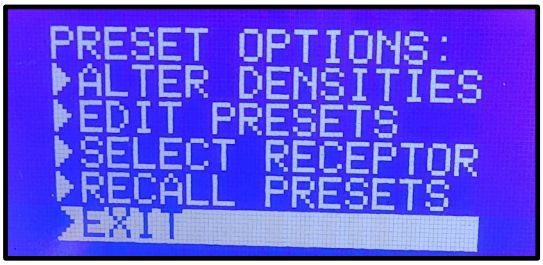
Displaying the Change Presets Menu

1. From the Main System menu shown in the “Using System Configuration Mode” section above, select CHANGE PRESETS.

2. The PRESET OPTIONS menu shown below appears.

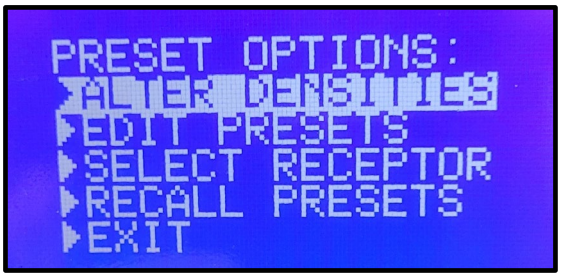


3. Selecting EXIT returns the display to the Main System menu.

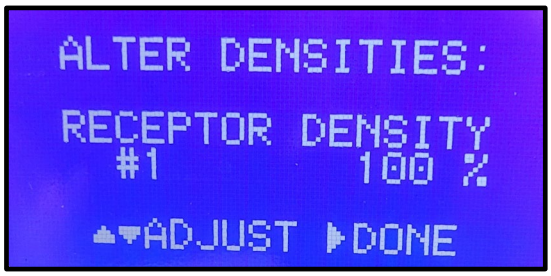


Changing All Receptor Densities Globally

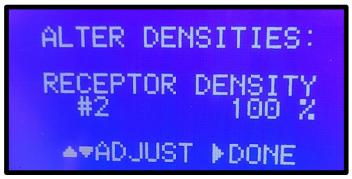
1. From the PRESET OPTIONS menu, select ALTER DENSITIES.



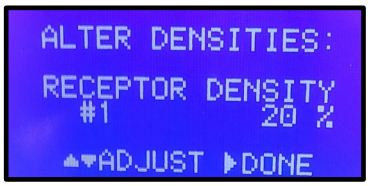
2. The first Image Receptor Type illuminates. The display shows the selected Image Receptor Type and current density. In this example, receptor #1 is shown at 100% density.

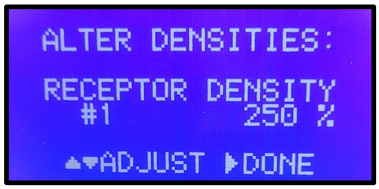


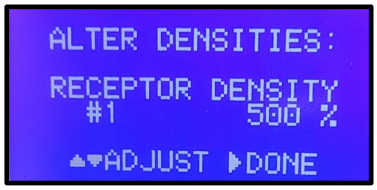
3. Using the Image Receptor Type button, select the Image Receptor to adjust. As each one is selected, the display will show it as depicted below and the corresponding icon will be illuminated on the operator panel.



4. Use the up and down arrow buttons to specify a percentage by which densities will be increased or decreased for the selected receptor. Below are some examples of possible values.







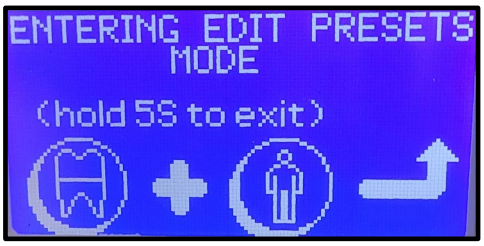
5. Press the right arrow to save the settings.

Changing Presets Individually

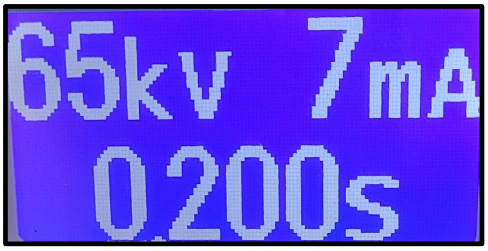
1. From the PRESET OPTIONS menu, select EDIT PRESETS.

2. The display notifies the user that they are entering Edit Preset Mode and that the Tooth Icon and Patient Size Icon can be held simultaneously for five seconds to exit (shown below). The icons for Tooth, Image Receptor Type, and Patient Size are illuminated. The message will

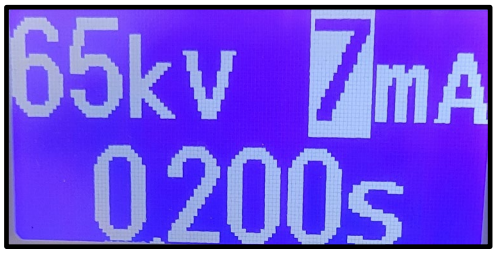
automatically disappear after a few seconds, but the Ready Indicator will blink in green to indicate that the system is in the EDIT PRESETS mode.



3. Use the Tooth Selection, Image Receptor Type, and Patient Size Selection buttons to select the preset to change. The display shows the current values for the preset. The below is an example only; numbers will vary depending upon the Tooth, Image Receptor Type, and Patient Size selected.



4. Use the right arrow button to highlight the technique factor to change. (The choices are kV, mA, and time/seconds.) In the example below, the mA value has been highlighted.

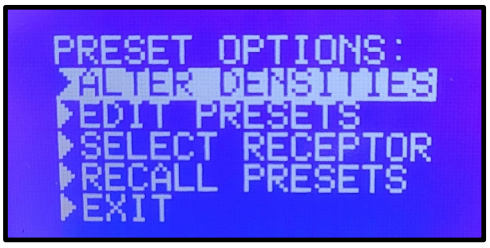


5. Use the up and down arrow buttons to set the value for the selected technique factor and preset. The examples below show the mA value being changed.

NOTICE If time is the factor needing to be changed, this can be done without pressing the right arrow first. Pressing the up and down arrows will automatically adjust the time if neither of the other factors are highlighted.

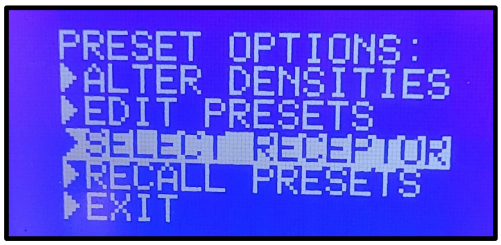
6. Repeat steps 3-5 to change additional presets.

7. When you have completed all changes, press the Tooth Selection and Patient Size Selection buttons simultaneously for 5 seconds to record the change. The display will return to the PRESET OPTIONS menu.

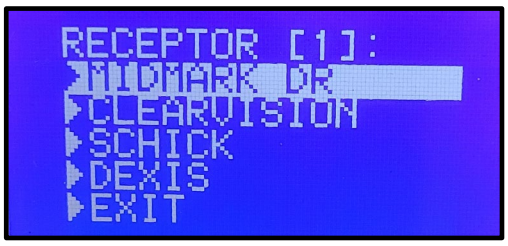


Restoring Factory Presets for Individual Digital Sensors

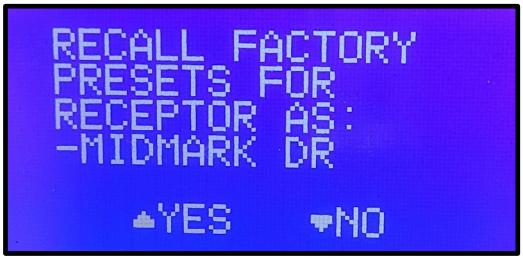
1. From the PRESET OPTIONS menu, select SELECT RECEPTOR.



2. Select the desired digital receptor, 1 or 2, by pressing the receptor button. Both options are shown below. The LED indicator will toggle between the two options.



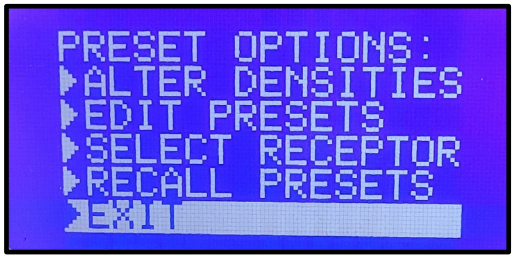
3. Press the up or down button to highlight the sensor to change. Press the right arrow button.
4. Select YES or NO on the verification screen.



NOTICE

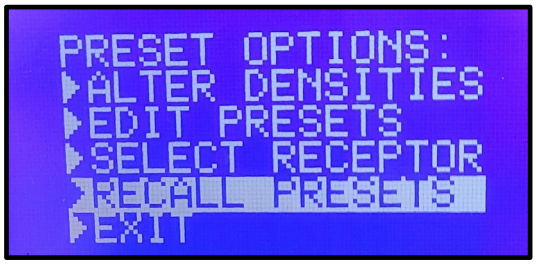
The system defaults to Receptor 1. If the user selects NO on the verification screen and the display returns to the PRESET OPTIONS menu, the system will default back to Receptor 1 if the user again selects SELECT RECEPTOR, even if the user was previously working with Receptor 2. Verify that the correct icon is illuminated on the operator panel if recalling factory presets for multiple sensors.

5. Exit the Preset Options menu.

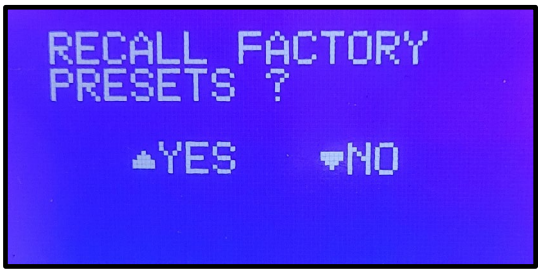


Return to All Factory Default Presets

1. To return all presets to factory defaults, select RECALL PRESETS from the Preset Options menu.



2. The menu will ask the user to confirm their choice. Select YES using the up arrow button and return all presets to factory default settings. Selecting YES will erase any custom presets that have been set up. Select NO using the down arrow button to retain current presets.



User-Adjusted Technique Factors for the 20 cm (8 in) Cone

If the default technique factors do not produce the density desired, adjust the settings using System Configuration Mode. Record the settings in this table.

20 cm (8 in) Cone		Digital Receptor 1		Digital Receptor 2		Phosphor Plate P	
Tooth Selection	Setting	Adult	Child	Adult	Child	Adult	Child
Incisor	kV						
	mA						
	seconds						
Bicuspid	kV						
	mA						
	seconds						
Bitewing	kV						
	mA						
	seconds						
Lower Molar	kV						
	mA						
	seconds						
Upper Molar	kV						
	mA						
	seconds						

User-Adjusted Technique Factors for the 30 cm (12 in) Cone

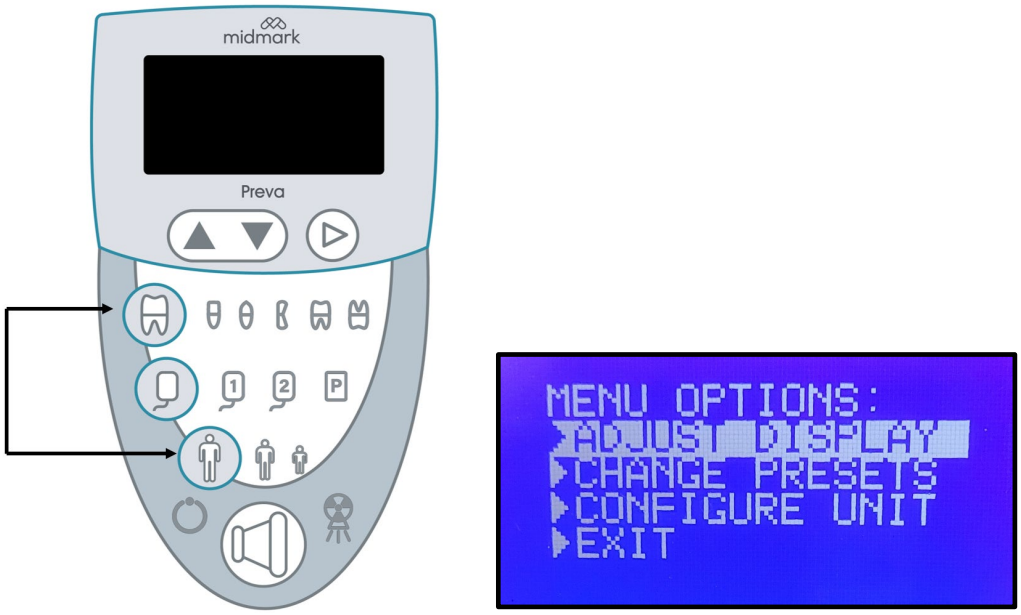
If the default technique factors do not produce the density desired, adjust the settings using System Configuration Mode. Record the settings in this table.

30 cm (12 in) Cone		Digital Receptor 1		Digital Receptor 2		Phosphor Plate P	
Tooth Selection	Setting	Adult	Child	Adult	Child	Adult	Child
Incisor	kV						
	mA						
	seconds						
Bicuspid	kV						
	mA						
	seconds						
Bitewing	kV						
	mA						
	seconds						
Lower Molar	kV						
	mA						
	seconds						
Upper Molar	kV						
	mA						
	seconds						

Showing the Current System Configuration

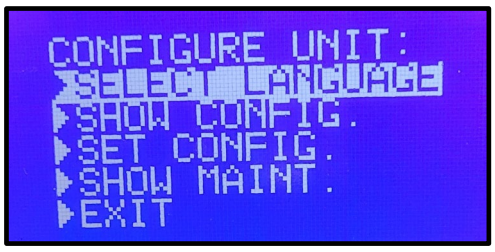
The Preva Dental X-ray System displays the current system configuration. This display is informational only.

1. To enter system configuration mode, press the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for five seconds (below left). The Main System menu will appear as shown below (right). The Ready Indicator will blink.

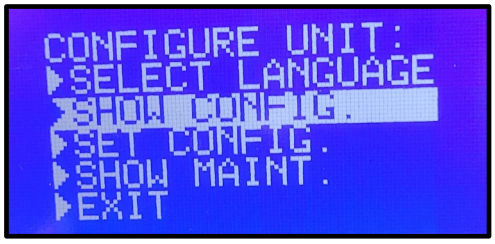


2. From the Main System menu, select CONFIGURE UNIT.

3. The CONFIGURE UNIT menu shown below will be displayed.

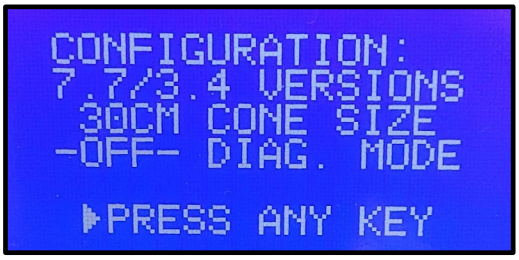


4. Select SHOW CONFIG.



5. The display will show:
   - Current software version
   - Cone size
   - Diagnostic mode, on or off

   The image below shows example values for illustration purposes only.



6. Press any button on the Operator Panel to return to the Configuration menu.

Changing the Cone Size

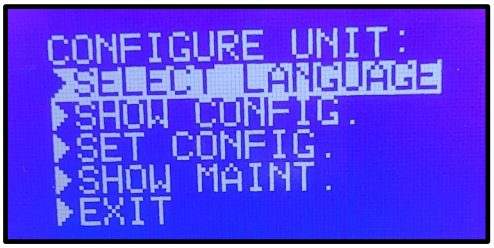
The Preva Dental X-ray System is preset for use with the standard supplied 20 cm (8 in) Cone. A 30 cm (12 in) Cone is available. Using the longer Cone requires longer exposure times, which the Preva automatically selects when the Cone size is changed in the Set Configuration menu. The Set Configuration menu displays the cone size options.

Using a 30 cm (12 in) Cone

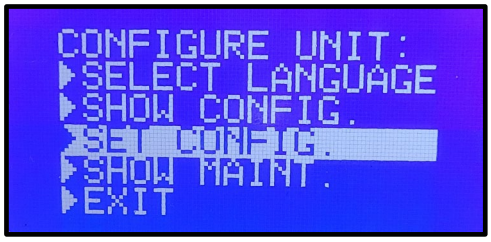
1. To enter system configuration mode, press the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for five seconds (below left). The Main System menu will appear as shown below (right). The Ready Indicator will blink.

2. From the Main System menu, select CONFIGURE UNIT.

3. The CONFIGURE UNIT menu shown below will be displayed.

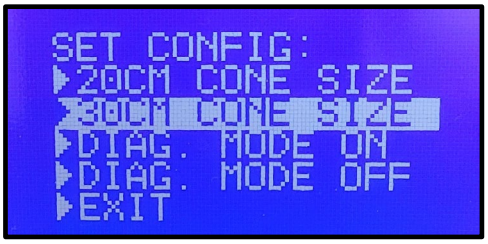


4. Select SET CONFIG.



5. The Set Configuration menu shown below will be displayed.

6. From the Set Configuration menu, use the up and down arrows to highlight “30CM CONE SIZE.”



7. Press the right arrow button to select the 30 cm Cone. The display warns that selecting the 30-cm Cone will override customer presets with the default factory settings for the 30-cm Cone.

8. Follow the instructions on the display. If it is desired to proceed with changing the cone size, use the up arrow to select YES to install presets for the 30-cm Cone. If it is not desired to proceed with changing the cone size, use the down arrow to select NO to exit this screen.

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Quality Control (QC)

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X-ray Source Performance QC

Certified Components

The certified components of Preva comply with Radiation Performance Standards 21 CFR, Part I, Subchapter J, with respect to those characteristics authorized by Variance Number FDA-2018-V-2208, effective July 10, 2018.

The related certified components are listed in the table below:

Component	Reference Number
Tube Head	30-A1075, 30-A1078
Control Unit. Preva	30-A1025, 30-A1035, 30-A1062, 30-A1065
Control Unit. Preva Mobile	30-A1032, 30-A1066
Modular BLD, 20 cm Lg., 60 mm Cone, White	30-A2196
Modular BLD, 20 cm Lg., 30x40 mm Cone, White	30-A2198
Modular BLD, 20 cm Lg., 20x30 mm Cone, White	30-A2199
Modular BLD, 20 cm Lg., 35x45 mm Cone, Gray	30-A2221
Modular BLD, 20 cm Lg., 35x45 mm Cone, White	30-A2222
Modular BLD, 30 cm Lg., 35x45 mm Cone, Gray	30-A2223
Modular BLD, 30 cm Lg., 35x45 mm Cone, White	30-A2224
Modular BLD, 20 cm Lg., 60 mm Cone, Gray	30-A2228

These components are also designed to meet the requirements of IEC 60601-2-63 as certified by TUV (NRTL). The sensor part numbers are not included here because they are described in their own user manual. Refer to 003-10565-00, the Sensor User and Installation Manual.

Performance Factors

The operation of the X-ray source in Preva is qualified based on the technique factor accuracy, linearity, and reproducibility of the X-ray tube output, half-value layer (HVL), and beam alignment.

The acceptance and quality control of Preva is based on AAPM Report No. 175, Acceptance Testing and Quality Control of Dental Imaging Equipment (2016), https://doi.org/10.37206/160.

Midmark recommends establishing a Quality Control (QC) program to ensure that the Preva performs as per its specification and meets the regulatory requirements. The guidance of NCRP Report No. 177, Radiation Protection in Dentistry and Oral & Maxillofacial Imaging (2019), can be particularly useful.

X-ray Source Performance QC (Cont.)

Qualification Procedure

Leakage radiation measurements are not required as all radiation shielding is encapsulated into the tube head, which is unlikely to be damaged. A leakage measurement may be performed by placing a suitable, highly sensitive radiation detector over the suspected location and then adjacent to it. Measurements made after exposures at the two locations should be similar.

The HVL, technique factor accuracy, linearity, and reproducibility of the X-ray tube output may be measured with the Radcal Accu-Gold radiation measurement device. Alternatively, perform the measurements per IEC 60601-2-65 using a radiation measurement device suitable for intraoral X-ray sources.

The dose-area product may be measured with the Radcal 10X6-60DAP chamber attached to the Radcal Accu-Gold radiation measurement device. Alternatively, use a suitable dose-area product (DAP) meter or measure the X-ray beam size and dose separately and calculate the kerma-area product (KAP).

Seasoning Procedure

NOTICE X-ray tube seasoning is required when Preva is not used for six months.

X-ray tubes which sit dormant for several months can become electrically unstable. To remedy this condition, perform a tube seasoning procedure. This will establish stable high voltage operation and will extend the life of the tube. Repeat this procedure before returning to normal operation any time the system has been unused for more than six months.

1. Turn the Preva on and confirm it illuminates as appropriate.
2. Select 60 kilovolts (kV), 4 milliamperes (mA), and a one-second exposure.
3. Make five exposures at this level, observing the normal cooling time.
4. Select 65 kilovolts, 4 milliamperes, and a one-second exposure time.
5. Make five exposures at this level, observing the normal cooling time.
6. Select 70 kilovolts, 4 milliamperes, and a one-second exposure time.
7. Make five exposures at this level, observing the normal cooling time.

Appendices

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Appendix A: Commissioning and Maintenance

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Commissioning and Maintenance

Preva must be serviced as specified in the “Periodic Maintenance Schedule” section beginning on page 109 of this manual to ensure proper functionality.

Once per year, a medical physicist needs to be employed to evaluate Preva and all office safety mechanisms related to X-ray imaging.

Preva does not require periodic calibration unless technique factors are found to be out of specification.

It is the owner’s responsibility to arrange for this service and assure that the personnel performing this service are fully qualified to service Midmark Corporation X-ray equipment according to the requirements detailed in Midmark Preva Installation and Service Manual (P/N: 003-10567-00).

Required maintenance, cleaning, and disinfecting described in this appendix may be performed by a trained service technician or another person designated by the responsible organization. That person needs to be knowledgeable about the Preva operation and the clinical practices adopted by the dental office.

After any service or maintenance procedure, the technician must verify the operation of Preva with a radiological image test of a phantom or test object.

The technician must clean the device from any residue or contamination introduced during the executed service or maintenance procedure. Then, the technician must verify the operation of all installed X-ray irradiation switches and X-ray irradiation interlocks.

Do not service or perform maintenance on Preva in the presence of a patient.

Hygiene

The sensor (if used) requires cleaning and disinfection after every patient. The Preva should be cleaned and disinfected periodically.

The methods described here protect operators and patients yet in a manner that will not damage Preva.

- Wear disposable gloves when taking X-ray patient scan images.
- Wear disposable gloves when performing cleaning and disinfection procedures.

Parts Breakage

⚠CAUTION	Handle parts with care to prevent breaking them during use. Replace broken parts before the next use.

The following parts are designed to minimize X-ray attenuation and may break more easily during cleaning or use:

- Cone (i.e., beam-limiting device or BLD)

Cleaning and Disinfection

NOTICE	Do not spray liquids directly onto any Preva surface. Apply the cleaning or disinfecting solution to a wipe and use the wipe to complete the task.

The sensor cleaning and disinfection instructions are described in 003-10565-00, the Sensor User and Installation Manual.

- Put on fresh gloves before cleaning Preva.
- Shut down Preva before cleaning and disinfecting. Cleaning and disinfecting the tube head or arm may be performed without shutting down Preva.
- Clean all surfaces for any apparent contaminants and then disinfect periodically to prevent cross-contamination between patients and operators.
- Always wipe instead of spray. With exception of arm and tube head, the enclosures do not provide protection against ingress of liquids.
- To clean or remove any gross bioburden, use a soft disposable towel moistened with warm water.
- To disinfect, use a soft cloth to wipe the surfaces to be cleaned with an EPA-registered hospital-grade intermediate level disinfectant with a tuberculocidal claim or equivalent. Midmark recommends CaviWipes (in the United States or Canada) and CaviWipes-AF (in the United States only). Follow the disinfectant manufacturer’s instructions for application and wet-contact time.
- To clean any remaining disinfectant and cleaning product from surfaces, use a soft disposable towel moistened with warm water.
- Dry contact areas with soft disposable towels.
- Verify that all product labels remain intact and are legible.

Function Readiness Checklist

Performing the tasks on this checklist verifies the electrical, mechanical, and software readiness of Preva. Refer to the Periodic Maintenance Schedule section for frequency of the below tasks.

> **⚠CAUTION** Radiation will be emitted for the tasks that require an exposure to be taken. Take proper precautions, including ensuring that at anybody present is least 2 m (approx. 7 ft) away from the focal spot and out of the X-ray beam path.

Task Area	Description	✓
Labels	Ensure that all certified components bear legible labels, including the model and serial number, date of manufacture, and a certification statement.	
Device Support	Inspect the adequacy of the wall support and verify that the Preva system is securely attached to the wall (if applicable).	
Electrical Safety	Verify the integrity of the power line, its connections, and the connection to earth ground.	
Power Switch	Verify that the power switch is working and that the operator panel illuminates when the power switch is in the ON position.	
Operator Panel Controls	With the power switch in the ON position, verify that technique factors appear on the Operator Panel. Also, check the function of the selection buttons for Tooth Selection, Image Receptor Type, and Patient Size. Pressing a selection button will cause indicator lamps to indicate the selected item.	
Mechanical Safety	Visually inspect the adequacy of the arm attachment and verify that the mechanical link is structurally sound.	
Suspension	Check that all movements are smooth and quiet. Verify that the Tube Head is properly counterbalanced for vertical drift and that the Horizontal and Articulated Arms do not drift horizontally.	
Mechanical Safety	Inspect casters (mobile units only) to ensure they are not becoming detached from the base.	
Tube head	Check for oil leaks.	
Tube Head Rotation	Ensure that the Tube Head maintains its position around the horizontal axis while remaining easy to rotate and position. Also check the vertical pivot of the Tube Head for easy movement while remaining in position after moving.	
Diagnostic Source Assembly	Inspect the integrity of collimator attachment and fasteners.	

Function Readiness Checklist (Cont.)

Task Area	Description	✓
Accessories	Verify that the following accessories are in working order: handswitch and remote switch (as applicable).	
Intended function, imaging	Produce a couple of exposures using a test object and verify the correct imaging operation.	
Exposure Button	Verify that the Exposure button on the Operator Panel functions properly. To make an exposure, press and hold the Exposure button until the Radiation Indicator goes off and the audible signal stops. Verify that the Radiation Indicator illuminates, and the audible signal is heard.	
Handswitch Button (if applicable)	Verify that the Handswitch functions properly. To make an exposure, press and hold the Handswitch button until the Radiation Indicator goes off and the audible signal stops. Verify that the Radiation Indicator illuminates, and the audible signal is heard. Inspect the switch housing and coil cord for damage or wear. Replace them if there is any evidence of damage.	
Remote Exposure Station Button (if applicable)	Verify that the Exposure button on the Exposure Station functions properly. To make an exposure, press and hold the Exposure button until the Radiation Indicator goes off and the audible signal stops. Verify that the Radiation Indicator illuminates, and the audible signal is heard.	
Premature Termination	Select the longest exposure time possible using the up and down arrows. Initiate an exposure, but release the Exposure button quickly (before the timer terminates the exposure). Verify that the display indicates “Pre-termination Error” and returns to normal operating mode.	
User Information	Verify that the owner of the system has received the user manual.	

Periodic Maintenance Schedule

The Preva System requires the following maintenance. Refer to the Function Readiness Checklist section beginning on page 107 and the sections following this table for details on how to conduct these tasks.

> **⚠CAUTION** Radiation will be emitted for the tasks that require an exposure to be taken. Take proper precautions, including ensuring that at anybody present is least 2 m (approx. 7 ft) away from the focal spot and out of the X-ray beam path.

#	Description	Frequency
1	Irradiation interlocks operation verification	Bi-weekly
2	Caster inspection (mobile units only; see next section)	Monthly
3	Imaging performance verification	Quarterly*
4	Device support inspection	Annually
5	Mechanical integrity inspection	Annually
6	Electrical integrity inspection	Annually
7	On-machine labels inspection	Annually
8	Air kerma/dose confirmation (see Appendix C)	Annually
9	X-ray performance QA by a Qualified Physicist	Every 3 years

*NOTE: Select the imaging performance verification frequency based on the risk related to the performed treatments and used modalities.

Irradiation interlocks operation verification

The irradiation interlock circuit safeguards the X-ray function of Preva by inhibiting its operation when a designated safety switch opens, for example, when a door is open. Occasionally, the interlock may consist of multiple switches that individually activate the interlock to inhibit Preva operation. Execute the following procedure individually for each interlock circuit:

- Visually inspect the irradiation interlock circuit and the related exposed wiring for damage.
- Turn Preva power on.
- Wait for the operator control panel to start and verify that it illuminates as appropriate.
- Open the interlock switch.
- Prepare Preva to acquire an Intraoral image. Point the tube head in a safe direction.
- Press the exposure button and confirm that no audible indicator is heard and that the X-ray indicator () does not illuminate.
- Move to a designated safe location behind the interlock.
- Close the interlock switch.
- Verify the Ready indicator is illuminated with **GREEN** light.

- Press and hold the exposure switch button to initiate X-ray irradiation and allow Preva normal operation. Ensure that the X-ray indicator () illuminates with **YELLOW** light and the audible indicator emits constant sound.
- Open the interlock switch midway through the procedure and verify that the X-ray indicator () stops illuminating with a **YELLOW** light.
- Verify that the X-ray irradiation terminates immediately, as indicated by the deactivation of the X-ray visual and audible indicators, and the operator control panel reports the pre-termination condition.

Imaging performance verification

The imaging performance verification is intended to check whether Preva performs as intended.

- Perform at least one radiograph of a test object.

Device support inspection

The structural integrity of the Preva wall attachment is essential for maintaining machine safety.

- If applicable, inspect the adequacy of the wall support and verify that the Preva system is securely attached to the wall.

Mechanical integrity inspection

The verification of mechanical integrity of Preva includes the Control Unit, Horizontal Arm, Articulated Arm, Yoke, Tube Head, and attachment points for each.

- Visually inspect the adequacy of the above mechanical elements and verify that the mechanical links are structurally sound, without excessive wear or mechanical wobbling.

Electrical integrity inspection

The verification of electrical integrity of Preva includes the power cord (if used), power switch, X-ray irradiation switches, and operator panel.

1. Power cord
   - Unplug the power cord. Visually inspect the adequacy of the power cord and the outlet where it is connected. Specifically, examine the means for protective earth (ground) connection.
2. Power switch
   - Visually inspect and verify the operation of the power switch. The operator panel will only be illuminated when the power switch is in the ON position.
3. Exposure Switches
   - Ensure that the tube head is positioned in a way that no one is in the path of the X-ray beam. Press and hold the Exposure Button. Verify that a single exposure is executed without error.
4. Operator panel

- Cycle Preva power off and on by using the power switch.
- Verify that after Preva power is turned on, the operator panel displays a start screen with the Midmark logo, then displays technique factors.
- Verify that the operator panel functions respond when buttons are pressed (except the Exposure Button, which was verified above).

On-machine labels inspection

Device on-machine labels communicate important safety messages and must remain legible.

- Inspect the legibility of all labels described in the “Preva Labels” section beginning on page 22 of this manual.

X-ray performance QA by a Qualified Physicist

The X-ray performance of Preva is essential for performing the intended functionality.

- Arrange an X-ray performance inspection to be performed by a Qualified Physicist following the “Qualification Procedure” described on page 100 of this manual.

Inspecting the Casters (Mobile Units Only)

Repeatedly rolling the system over rough surfaces such as thresholds or rough floors can cause casters to loosen. Inspect them monthly and, if necessary, follow this procedure to tighten them.

1. Casters attach to the mobile base, as shown in the left photograph below. When correctly seated, a caster will be snug against the base (middle). If the caster begins loosening, threads will be visible between it and the mobile base (right).

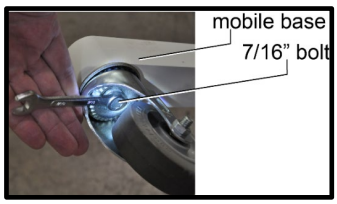
⚠CAUTION If caster threads are visible, stop moving the X-ray system.

2. Lift the mobile base at one of the casters and slide something stable and at least 11.4 cm (4.5 in) thick under it. In this example, three reams of standard copier paper were used.

⚠CAUTION Two people are required to perform this step.

NOTICE This step is optional. However, while the caster can be tightened without it, this step is considerably easier if the mobile base is elevated so the wheel is off the floor slightly.

3. Using a 7/16 in box end wrench, tighten any loose caster bolts. This is done by reaching under the arm of the mobile base and positioning the wrench over the caster bolt. (Bolts will not be visible during this procedure, but this photograph shows a properly positioned wrench.)



4. If applicable, remove the items that were placed underneath the mobile base.
5. Test the operation of the casters by moving the X-ray system in different directions.

Safe Disposal Methods

Wastes containing blood or saliva generated 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 Preva imaging workstation.

Preva is an electrical equipment that contains dielectric oil; therefore, precautions must be taken during the disposal of Preva. Contact your waste disposal service provider, your distributor or dealer where Preva 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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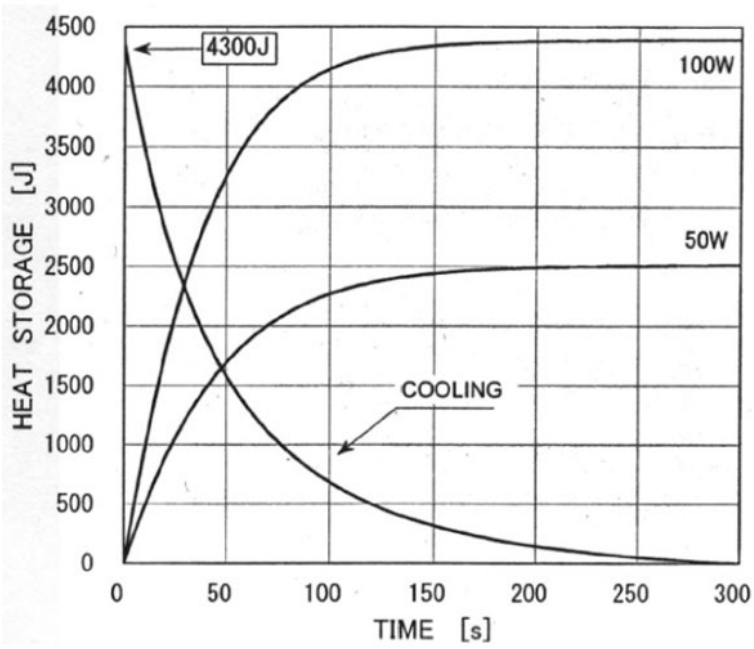
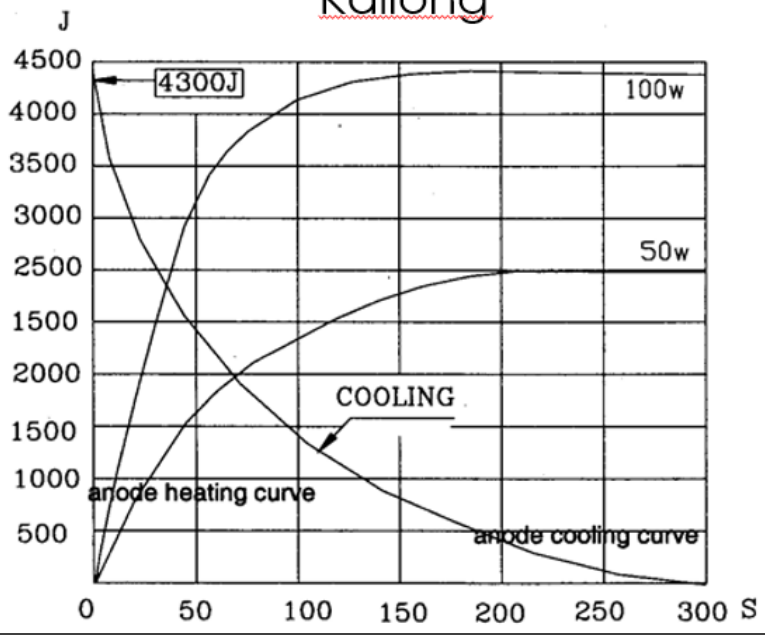
Electrical Specification

Parameter	Specification
Supply Mains	dedicated, a.c., single phase, continuous operation with intermittent loading
Rated Line Voltage	110 V to 230 V
Rated Line Frequency	50 Hz or 60 Hz
Rated Line Current	max 1 A, long-time current max 10 A, momentary current
Mains Breaker	It is recommended that the unit be installed with a dedicated electrical line connected to a breaker with a minimum 15 amp rating.
Permissible Apparent Resistance	Max 1 Ω (110 V)
Disconnect Device	No additional disconnect device is required. Use the power switch to power off the machine and/or disconnect the power cord from the power outlet to de-energize Preva during service.
Technique Factors for Maximum Line Current	65 kV, 7 mA, 2.0 s continuous X-ray
Degree of Protection for the Applied Parts	Class I, Type B
Enclosure Classification	IPX0 (no protection against ingress of dust and liquids)

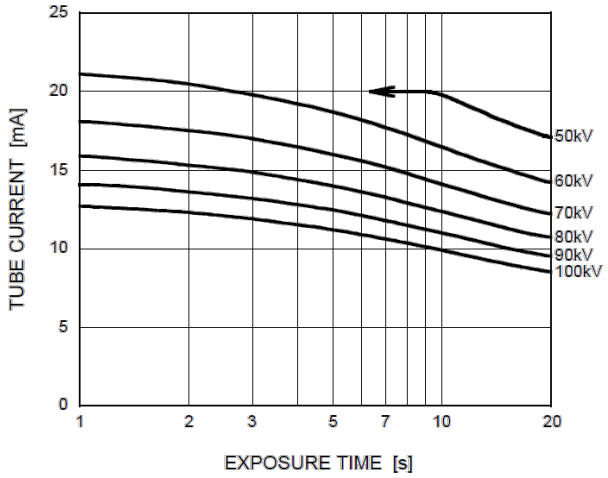
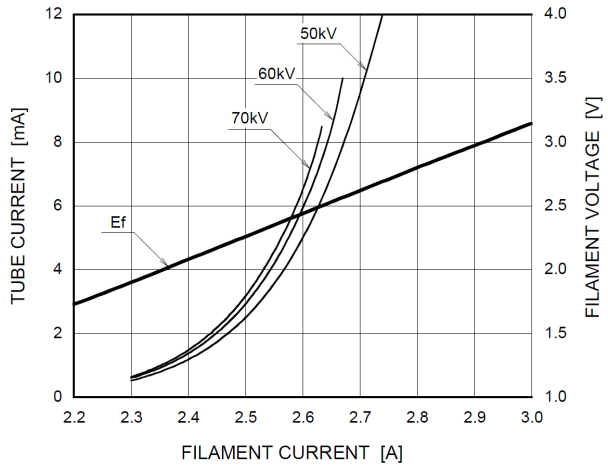
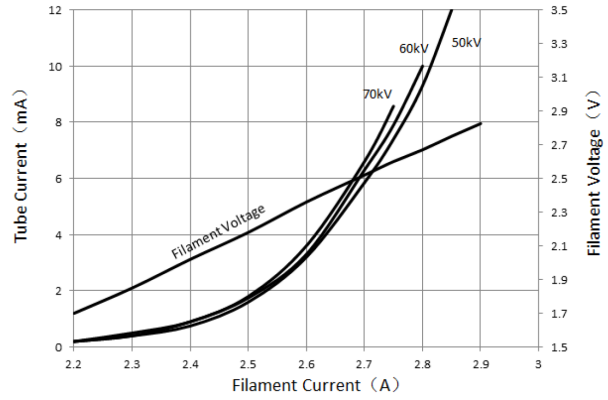
X-ray Source Specification

Parameter	Specification
Rectification type	High frequency, DSP controlled
Duty cycle	Continuous operation with intermittent loading; automatically enforced duty cycle that depends on the device use.
Nominal tube voltage rating	60 kV, 65 kV, and 70 kV
Maximum deviation from the tube voltage indication	10 % of the indicated value
Nominal tube current rating	4 mA, 5 mA, 6 mA, and 7 mA Note: 7 mA not available for tube voltage of 70 kV
Maximum deviation from the tube current indication	20 % of the indicated value
Nominal exposure time rating	0.020 s to 2.0 s
Maximum deviation from the exposure time indication	5 % of the indicated value or 0.020 s, whichever is greater
Nominal focal spot size	0.4 mm
Technique Factors for Maximum Line Current	65 kV, 7 mA, 2.0 s
Technique Factors that Contain the Lowest Current-Time Product	4 mA, 0.020 s
X-ray filtration (Minimum filtration (half-value layer) in useful beam)	2 mm Al equivalent at 70 kV

X-ray Source Specification (Cont.)

Parameter	Specification
Anode heating and cooling curves for X-ray tube	Canon  Kailong 

X-ray Source Specification (Cont.)

Parameter	Specification
Minimum Source-to-Skin Distance	20 cm (8 in) 30 cm (12 in)
X-ray Beam Dimension	Diameter of 6 cm (2.36 in) at the end of the 20 cm (8 in) cone. Cones with smaller diameter or rectangular beams are available.
Rating charts for X-ray tube	
Emission and filament characteristics for X-ray tube	Canon:  Kailong: 

Source to Object Distance

Modular BLD Cone Dimensions				
Part Number	Length (cm)	Width		Opening Area (cm²)
		(mm)	(cm)	
30-A2196	20	60	6	28.27
30-A2228	20			
30-A2198	20	30 × 40	3 × 4	12.00
30-A2199	20	20 × 30	2 × 3	6.00
30-A2221	20	35 × 45	3.5 × 4.5	15.75
30-A2222	20			
30-A2223	30			
30-A2224	30			

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Appendix C: Dose Data

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Dose Information

The X-ray tube output is defined as the quotient of the air kerma at a specified distance from the X-ray tube focus by the tube current–exposure time product. The Preva X-ray tube output at 20 cm is shown in the following table. Divide the values in the table by 2.25 for 30 cm cones.

Table 1: Preva X-ray tube output at 20 cm from the X-ray tube focus

Peak X-ray Tube Voltage	60 kV	65 kV	70 kV
X-ray Tube Output	1.374 $mGy \cdot mA^{-1} \cdot s^{-1}$	1.560 $mGy \cdot mA^{-1} \cdot s^{-1}$	1.783 $mGy \cdot mA^{-1} \cdot s^{-1}$

The Preva X-ray tube output is not calibrated to the listed values and may change over the product's life. The data are based on statistical analysis of limited number of measurements made on a limited number of Preva systems. The maximum deviation of the estimate does not exceed 30 %. The owner (Responsible Organization) must verify at least annually that Preva X-ray output is within the specified error by using dose measurement equipment with sufficient accuracy, for example, Radcal 10X6-60 connected to a Radcal Accu-Gold system. Arrange for Preva to be serviced when the quality control indicates insufficient X-ray performance accuracy.

The incident air kerma is defined as the kerma to air from an incident X-ray beam measured on the central beam axis at the position of the patient surface. Only the radiation incident on the patient or phantom and not the backscattered radiation is included.

The incident air kerma for Preva at 20 cm from the X-ray tube focus is shown in the following table. The values are calculated based on the X-ray tube output.

Table 2: Preva incident air kerma at 20 cm from the X-ray tube focus

Exposure Time	60 kV				65 kV				70 kV		
0.020 s	0.110	0.137	0.165	0.192	0.125	0.156	0.187	0.218	0.143	0.178	0.214
0.025 s	0.137	0.172	0.206	0.240	0.156	0.195	0.234	0.273	0.178	0.223	0.267
0.032 s	0.176	0.220	0.264	0.308	0.200	0.250	0.300	0.349	0.228	0.285	0.342
0.040 s	0.220	0.275	0.330	0.385	0.250	0.312	0.374	0.437	0.285	0.357	0.428
0.050 s	0.275	0.344	0.412	0.481	0.312	0.390	0.468	0.546	0.357	0.446	0.535
0.064 s	0.352	0.440	0.528	0.616	0.399	0.499	0.599	0.699	0.456	0.571	0.685
0.080 s	0.440	0.550	0.660	0.769	0.499	0.624	0.749	0.874	0.571	0.713	0.856
0.100 s	0.550	0.687	0.824	0.962	0.624	0.780	0.936	1.092	0.713	0.892	1.070
0.125 s	0.687	0.859	1.031	1.202	0.780	0.975	1.170	1.365	0.892	1.114	1.337
0.160 s	0.879	1.099	1.319	1.539	0.998	1.248	1.498	1.747	1.141	1.426	1.712
0.200 s	1.099	1.374	1.649	1.924	1.248	1.560	1.872	2.184	1.426	1.783	2.140
0.250 s	1.374	1.718	2.061	2.405	1.560	1.950	2.340	2.730	1.783	2.229	2.675
0.320 s	1.759	2.198	2.638	3.078	1.997	2.496	2.995	3.494	2.282	2.853	3.423
0.400 s	2.198	2.748	3.298	3.847	2.496	3.120	3.744	4.368	2.853	3.566	4.279
0.500 s	2.748	3.435	4.122	4.809	3.120	3.900	4.680	5.460	3.566	4.458	5.349
0.640 s	3.517	4.397	5.276	6.156	3.994	4.992	5.990	6.989	4.564	5.706	6.847
0.800 s	4.397	5.496	6.595	7.694	4.992	6.240	7.488	8.736	5.706	7.132	8.558
1.000 s	5.496	6.870	8.244	9.618	6.240	7.800	9.360	10.920	7.132	8.915	10.698
1.250 s	6.870	8.588	10.305	12.023	7.800	9.750	11.700	13.650	8.915	11.144	13.373
1.600 s	8.794	10.992	13.190	15.389	9.984	12.480	14.976	17.472	11.411	14.264	17.117
2.000 s	10.992	13.740	16.488	19.236	12.480	15.600	18.720	21.840	14.264	17.830	21.396

Notes:

1. All air kerma values are in mGy.

Dose Units

The quantity as defined by the International Commission on Radiation Units and Measurements (ICRU). The kerma, K, is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus

$$K = \frac{\mathrm{d}E_{tr}}{\mathrm{d}m}$$

in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as “air kerma.”

The röntgen (R), the legacy unit of quantity exposure, was used prior to the use of air kerma. Values of exposure in röntgen can be converted to air kerma in gray using the conversion factor 0.876×10^{-2} Gy/R. Similarly, air kerma values in gray can be converted to exposure in röntgen using the conversion 114 R/Gy.

The integral of the air-kerma free-in-air (i.e., in the absence of backscatter) over the area of the X-ray beam in a plane perpendicular to the beam axis. In many medical publications, the acronym used for this quantity is KAP. The older terminology is the dose-area product (DAP).

The air kerma-area product, provided in mGy·cm², is a commonly used quantity associated with the amount of X-ray utilized in dental radiography. It is calculated with this formula:

KAP = (air kerma) × (area of the cone opening)

System Configuration – Default Exposure Times

The following tables show the default technique factors for each combination of Tooth, Image Receptor Type, and Patient Size on the Operator Panel. These technique factors can be modified either permanently or on a case-by-case basis. For details, see the Changing Pre-Programmed Technique Factors section beginning on page 84 and the Adjusting Technique Factors section beginning on page 73.

20 cm (8 in) Cone		Midmark DR		ClearVision		Schick		Dexis		Ph. Plate	
		Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Incisor	kV	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.050	0.025	0.125	0.064	0.080	0.050	0.125	0.064	0.160	0.080
Bicuspid	kV	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.050	0.025	0.125	0.064	0.080	0.050	0.125	0.064	0.160	0.080
Bitewing	kV	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.080	0.040	0.160	0.080	0.100	0.064	0.160	0.080	0.200	0.100
Lower Molar	kV	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.100	0.050	0.160	0.080	0.100	0.064	0.160	0.080	0.200	0.100
Upper Molar	kV	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.100	0.050	0.200	0.100	0.125	0.080	0.200	0.100	0.250	0.100

30 cm (12 in) Cone		Midmark DR		ClearVision		Schick		Dexis		Ph. Plate	
		Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Incisor	kv	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.100	0.050	0.250	0.125	0.160	0.100	0.250	0.125	0.320	0.160
Bicuspid	kv	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.100	0.050	0.250	0.125	0.160	0.100	0.250	0.125	0.320	0.160
Bitewing	kV	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.160	0.080	0.320	0.160	0.200	0.125	0.320	0.160	0.400	0.200
Lower Molar	kV	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.200	0.100	0.320	0.160	0.200	0.125	0.320	0.160	0.400	0.200
Upper Molar	kV	65	65	60	60	65	65	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7
	sec	0.200	0.100	0.400	0.200	0.250	0.160	0.400	0.200	0.500	0.200

Note: To see the dosages for kV and mA combinations, see Dose Information.

Appendix D: Troubleshooting Procedures

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Solving Performance Issues

X-ray Images that are Too Light or Too Dark

The image darkness depends on the performance matching between the imaging receptor and the X-ray source. Certain receptors require more X-ray than others. Always adjust the imaging receptor first and then the technique factors on the X-ray source to minimize as far as possible the amount of X-ray used for each radiograph (as low as reasonably achievable (ALARA) principle).

1. Adjust the imaging receptor to the maximum sensitivity suitable for the desired radiograph.
2. Based on the image anatomy, the sensor performance, and the desired quality, adjust the technique factors of the X-ray source – selected exposure time [s], tube voltage [kV], or tube current [mA] to produce an acceptable image.
   - It is generally recommended to increase technique factors when images are too light and to decrease them when images are too dark.
   - Time is typically the first technique factor to be changed. Time and mA tend to have the greatest impact on images that are too light or too dark.
   - kV tends to have the greatest impact on image contrast.
3. Consult with the designated Qualified Expert. (For more information, read NCRP Report No. 177, Radiation Protection in Dentistry and Oral & Maxillofacial Imaging, National Council on Radiation Protection and Measurements, ISBN 9781944888183 (2019).)
4. If necessary, reprogram the technique factors, as explained in the Changing Pre-Programmed Technique Factors section beginning on page 84.

> **NOTICE** Digital intraoral sensors often have a software function that equalizes the image brightness for a wide range of technique factors. Thus, changing the technique factors will not affect the image brightness. Consult with the sensor software for details.

5. If the steps above do not resolve the issue, refer to 003-10567-00, the Installation and Service Manual.

No Power

If the Operator Panel display is not on, check the following:

1. Verify that the line cord (if one is in use) is properly connected.
2. Verify that the power switch is in the ON position. That is, the side of the power switch with the following symbol should be in the downward position:

Pre-termination Error

Early release of the exposure button will cause a pre-termination error, resulting in an underexposed image. After five seconds, the system will return to the normal operating condition.

Electromagnetic Interference

Preva and digital X-ray devices are designed to minimize electromagnetic interference. If interference is suspected, disconnect and reconnect the sensor, move the interfering device away from the Preva unit, or remove the interfering device from the room. Contact Midmark Technical Support if the problem persists.

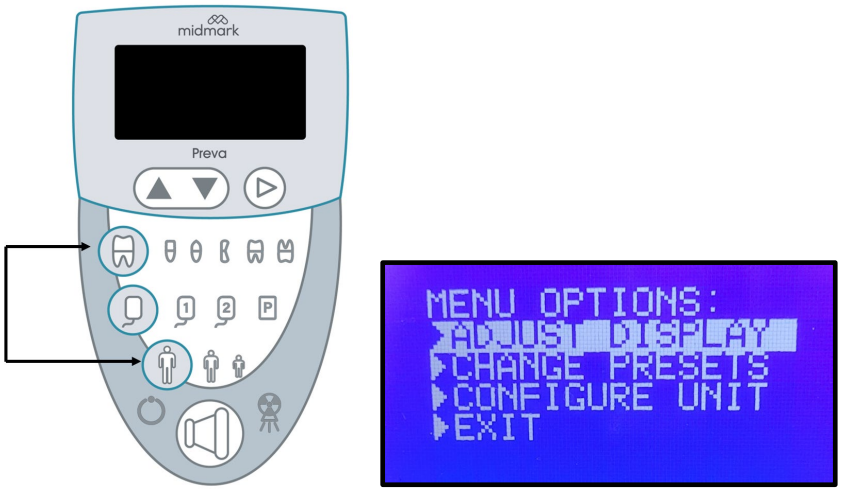
Diagnostic Mode

About Diagnostic Mode

The Preva Dental X-ray System has a diagnostic mode which displays a summary of maintenance data or display feedback values after each exposure.

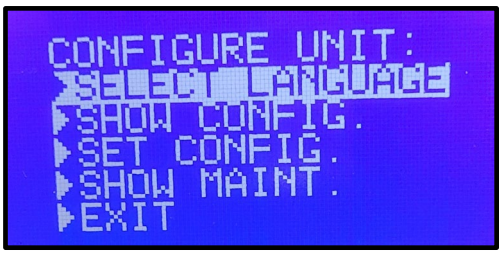
Showing the Maintenance Summary

1. To enter System Configuration mode, press the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for five seconds (below, left). The Main System menu will appear as shown below (right). The Ready Indicator will blink.

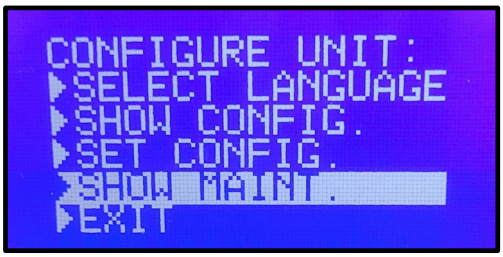


2. Select CONFIGURE UNIT.

3. The CONFIGURE UNIT menu displays as shown below.



4. To display a summary of maintenance data, highlight and select SHOW MAINT. from the CONFIGURE UNIT menu.



5. The following maintenance data will be displayed:
   - Total kJ (kilojoules – total system heat on X-ray tube)
   - Exposure Count
   - Reboots (power up cycles)
   - OT Counts (over-threshold counts)

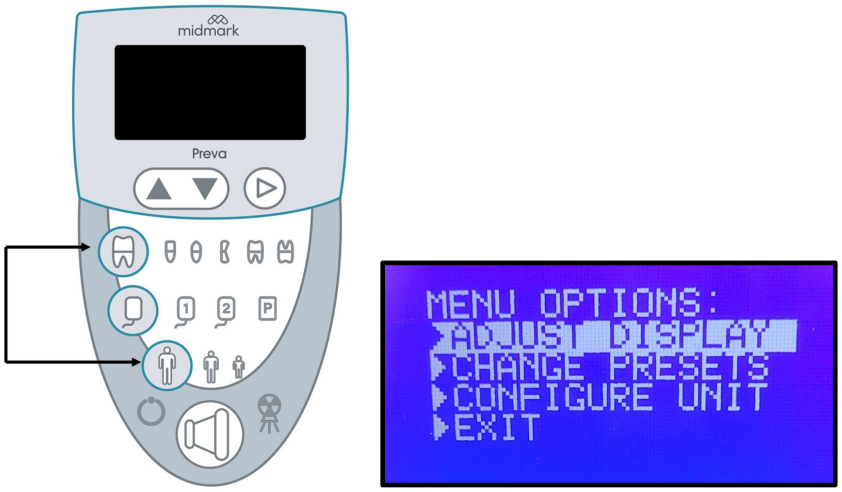
   The below image shows example values for illustration purposes only.

6. Press any button on the Operator Panel to return to the Configuration menu.

Showing Feedback Values After an Exposure

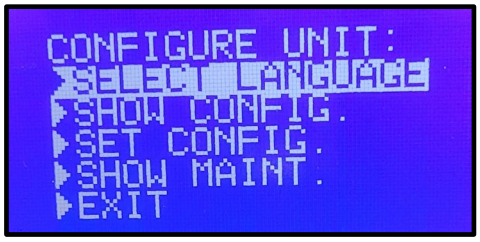
If an X-ray is taken (following the steps in “Taking an X-Ray” beginning on page 75) while in diagnostic mode, the display shows feedback values for that exposure. Until diagnostic mode is exited, the display will continue to show feedback values after each exposure. Follow the steps described on the following pages.

1. To enter System Configuration mode, press the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for five seconds (below, left). The Main System menu will appear as shown below (right). The Ready Indicator will blink.

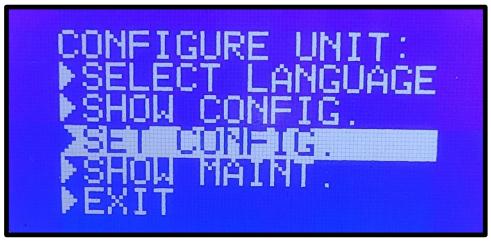


2. Select CONFIGURE UNIT.

3. The Configure Unit menu will appear as shown below.



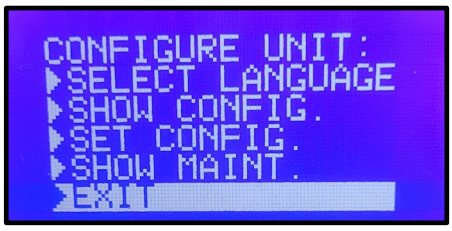
4. Select SET CONFIG.



5. The Set Configuration menu will appear as shown below.

6. From this menu, use the up and down arrows to highlight DIAG MODE ON. Press the right arrow button to turn on diagnostic mode.

7. Exit System Configuration mode by highlighting and selecting EXIT in the Configuration and Main menus.



8. Prepare to take an exposure.

⚠CAUTION	X-rays will be emitted. The operator must remain 2 meters (7 feet) away from the focal spot and out of the path of the X-ray beam.

9. Take an exposure. The display will show the following feedback values:
   - kV
   - mA
   - Filament current

   Values in the image below are examples for illustration purposes only.

The display will also contain options for the following actions:

- ADJUST
- SEE ERRORS
- DONE

10. The up arrow button on the Operator Panel can be pressed to adjust the kV. However, this option is typically used by qualified servicer technicians rather than users. Reference 003-10567-00, the Installation and Service Manual.
11. Press the down arrow button on the Operator Panel to see errors.

12. Press the right arrow button on the Operator Panel to clear the feedback values from the display.
13. To exit diagnostic mode, press the Tooth Selection and Patient Size Selection buttons simultaneously for five seconds to display the Main System Configuration menu. From the Main System Configuration menu, highlight and select CONFIGURE UNIT. Then highlight and select SET CONFIG. (See steps 1-5 above for illustrations of these steps.) On the Set Configuration menu, highlight and select DIAG MODE OFF.

Error Messages

Error Messages	Suggested Action
At power-up, the operator display freezes on the “Preva” screen	If any of these error messages are displayed and do not resolve on their own, contact Midmark Technical Services.
“Error – Serial Communications”	
“Pre-termination Error”	
“kV Too High”	
“kV Too Low”	
“mA Too High”	
“mA Too Low”	

More information about error messages is available in the Installation and Service Manual.

Appendix E: Regulatory Compliance

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Statements to FDA 21 CFR Subchapter J Compliance

1020.30(h)(1)(i)

Instructions for the use of the Preva Dental X-Ray System and precautionary statements are part of this User Manual. For more information, see the section “Introduction” beginning on page 6.

1020.30(h)(1)(ii)

As described in chapter “Commissioning and Maintenance,” “Periodic Maintenance Schedule” beginning on pg. 109, the Preva should be serviced at the specified intervals to ensure proper functionality. It is the owner’s responsibility to arrange for this service and assure that the personnel performing this service are fully qualified to service Midmark Corporation X-ray equipment, according to local servicing requirements.

1020.30(h)(2)(i)

Leakage Technique Factors: 70 kV, 0.4 mA

Minimum filtration (half-value layer) in useful beam: 2.0 mm Al equivalent at 70 kV

1020.30(h)(2)(ii)

The cooling curve chart for the anode and X-ray tube housing assembly can be found in the section “X-ray Source Specification,” which begins on page 118 of this manual.

1020.30(h)(2)(iii)

The Tube Rating chart for the tube housing assembly can be found the section “X-ray Source Specification,” which begins on page 118 of this manual. The device generates X-rays continuously.

1020.30(h)(3)(i)

Rated nominal line voltage: 110 V to 230 V, 50 Hz or 60 Hz

Line voltage regulation: 10% of the nominal line voltage

Maximum Apparent Resistance: 1 Ω (110 V)

1020.30(h)(3)(ii) and (iii)

The maximum momentary line current (less than 5 s) of the Preva is 10 A when operated on 120 V power mains. Operation at a higher input voltage reduces the maximum current to 1 A at 240 V. The technique factors producing the maximum momentary line current are 65 kV, 7 mA, and 2.0 s.

Statements to FDA 21 CFR Subchapter J Compliance (Cont.)

1020.30(h)(3)(v)

Generator rating at maximum technique factor of 65 kV, 7 mA is 455 W. Duty cycle does not exceed 1:15.

1020.30(h)(3)(vi)

Maximum deviation from indicated values:

- Peak tube potential, ± 10 % of selected tube loading voltage.
- Tube current, ± 20 % of selected tube loading current.
- Irradiation time, ± 0.020 s or ± 5 % of the selected irradiation time, whichever is greater.

1020.30(h)(3)(viii)

Refer to the section “Qualification Procedure” in the Quality Control section beginning on page 100.

1020.30(h)(4)(i)

The leakage technique factors within section 1020.30(h)(2)(i) apply for the device X-ray operational range.

1020.30(h)(4)(ii)

The beam-limiting devices do not provide additional filtration to the X-ray beam.

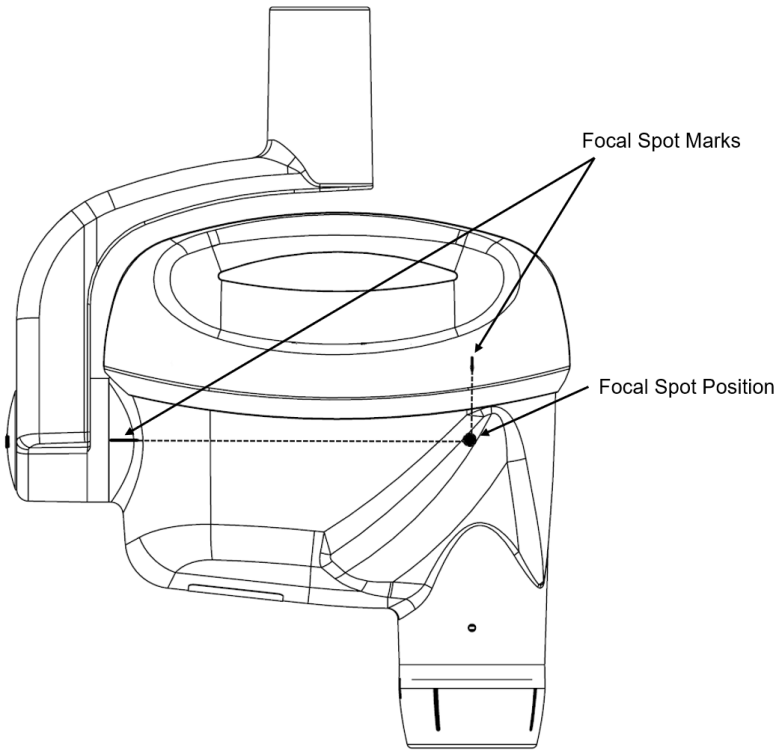
Statements to Canadian Radiation Emitting Device Regulation

Part II of Schedule II – Specifications Preva

2(h)(i)-(iv)

For each X-ray tube assembly:

- The nominal focal spot value is 0.4 mm.
- Cooling curves for the anode and X-ray tube housing assembly: refer to the section “X-ray Source Specification” beginning on page 118.
- X-ray tube rating charts: refer to the section “X-ray Source Specification” beginning on page 118.
- Focal spot position: the following illustration shows the focal spot position and the focal spot marks on the Preva Tube Head.



2(i)

- Duty cycles: 1:15.
- Rectification type: Constant potential, high-frequency.
- Generator rating: 60 kV, 65 kV, and 70 kV.

2(j)

To operate the equipment at the maximum line current, the following are necessary:

- Nominal line voltage, 110 V to 230 V. 50 Hz or 60 Hz
- Maximum line current: 10 A
- Line voltage regulation: 10% of the nominal line voltage.

Statements to Canadian Radiation Emitting Device Regulation (Cont.)

2(k)

Loading factors that constitute the maximum line current condition for the X-ray generator: 65 kV, 7 mA, 2 s

2(l)

Recommended loading factors for each patient size: refer to the section “System Configuration – Default Exposure Times” beginning on page 127.

2(o)

The operating range and the maximum deviation for any setting within the operating range for each loading factor are summarized below:

Factor	Nominal Value	Deviation
Peak Tube Potential	60 kV, 65 kV, and 70 kV	10 % of the indicated value
Tube Current	4 mA, 5 mA, 6 mA, and 7 mA Note: 7 mA is not available for 70 kV	20 % of the indicated value
Irradiation Duration	0.020 s to 2 s	0.020 s or ± 5 % of the indicated irradiation time, whichever is greater

2(q)

Removable protective devices: the modular beam-limiting devices (BLDs) available for use with Preva are described in the Accessories and Supplemental Parts section beginning on page 48. Information on the effectiveness of the BLDs is provided in the Dose Information section beginning on page 125. Instructions for BLD replacement are provided in the Operating Instructions section beginning on page 69 of this manual.

3(a)

Shape and dimension of the exit field: the shape and dimension of the exit field is determined by the size of the BLD. For a list of available BLD sizes, refer to the Accessories and Supplemental Parts section beginning on page 48.

3(b)(ii)

Nominal X-ray image receptor air kerma range that is needed for the intended use: refer to the Dose Information section beginning on page 125. For dose administered when using a digital X-ray sensor, refer to the manual for the digital X-ray sensor.

3(b)(iii)

Recommendations for typical loading factors at specified distances between the focal spot and the skin of 20 cm to achieve the air kerma referred to in subparagraph (ii): refer to the Dose Information section beginning on page 125.

3(c)

The method by which the distance between the focal spot and the skin can be determined using the focal spot indicators is determined by the length of the BLD. For a list of available BLD sizes, refer to the Accessories and Supplemental Parts section beginning on page 48.

3(e)(i)

For the air kerma at a given distance from the focal spot for every selectable combination of loading factors, refer to the System Configuration – Default Exposure Times section beginning on page 127.

3(e)(ii)

The maximum deviation of the air kerma: refer to the Dose Information section beginning on page 125.

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Midmark Technical Support

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

Midmark Corporation

Phone: 1.800.MIDMARK (1.800.643.6275)
Direct: 1.844.856.1231 Opt. 3
imagingtechsupport@midmark.com

Hours: 8:00AM to 5:00PM Central Time

Manufacturer:
Midmark Corporation
60 Vista Drive
Versailles, OH 45380 USA
Phone: 1.847.415.9800
midmark.com

Technical Library
technicallibrary.midmark.com

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