midmark

Preva Dental X-Ray System

Installation and Service Manual

003-10567-00
Revision AA2
February 2023

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

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Introduction (Cont.)

About This Manual

Welcome to intraoral dental imaging technology from Midmark.

This manual describes the Preva Dental X-ray System and how to install and service it. The instructions contained in this manual must be read and followed when installing, servicing, or operating the Preva. A Midmark Dental dealer will assist in placing the Preva in operation.

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
003-10566-00: Midmark Preva User Manual	Identifies requirements for using the Preva Dental X-ray System, as well as quality control, cleaning, and disposal.
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.

Continued

Introduction (Cont.)

Indications for Use

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

Contraindications

None known.

Adverse Reactions

None known.

⚠WARNING	Preva may affect patients with pacemakers. Midmark has not analyzed this risk.

Indications of Sterility

This product is not provided sterile.

Product Description

The Preva Dental X-ray System is a state-of-the-art, high-frequency intra-oral X-ray machine. Its primary components include, at minimum, the Control Unit, the Tubehead, 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. The following two sections will show the configuration of these components and describe them in more detail.

Continued

Introduction (Cont.)

Key Components – Wall Mount Configuration

> **⚠CAUTION** Do not hang objects on the horizontal extension arm.

Articulated Arm

The Articulated Arm provides the articulation support for the Tubehead and the reach and coverage of the Tubehead to the patient. The Articulated Arm allows smooth movement for precise positioning and does not drift or vibrate when left in position.

Yoke

The Yoke connects the Articulated Arm to the Tubehead.

Tubehead

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

> **⚠WARNING** There is a small hole in the plastic handle covering the back of the tubehead. Under no circumstances should this hole be blocked as it provides an air vent to allow the tubehead 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

Continued

Introduction (Cont.)

Preva is shipped with the standard 20 cm (8-inch) Cone attached to the Tubehead. Multiple different Cones are available, including an optional 30 cm (12-inch) Cone. Refer to the section “Accessories and Supplemental Parts” beginning on page 57 of this manual for more information.

Horizontal Arm

The Horizontal Arm helps provide the necessary reach for the Preva. It pivots smoothly 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 in).

Control Unit

The Control Unit provides for the input power connection and control of the Tubehead and Operator Panel. It provides automatic line voltage compensation, tube voltage 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 section “Control Interface” beginning on page 153 of this manual 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

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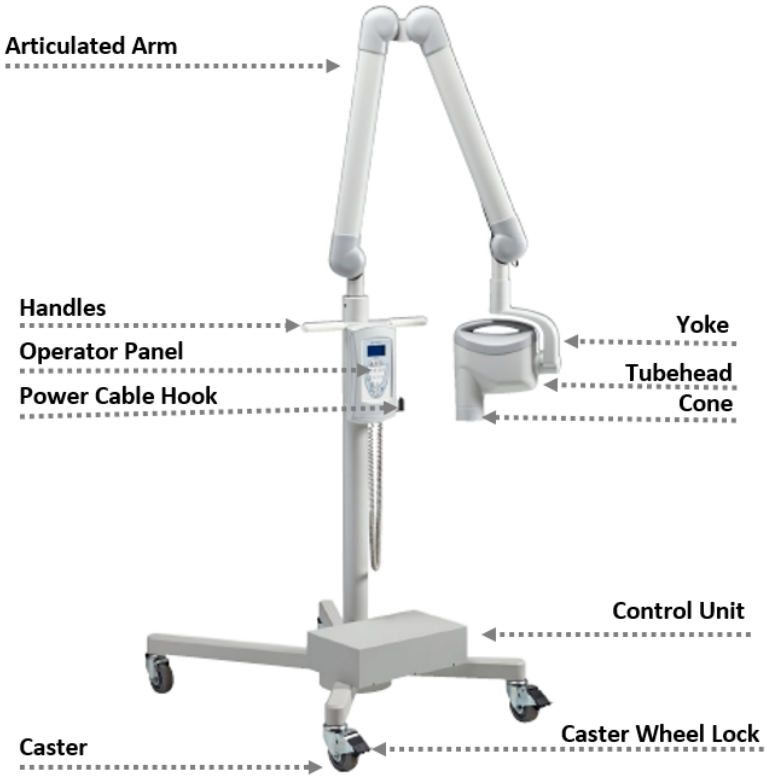
Introduction (Cont.)

Key Components – Mobile Configuration



Articulated Arm

The Articulated Arm provides the articulation support for the Tubehead and the reach and coverage of the Tubehead to the patient. The Articulated Arm allows smooth movement for precise positioning and does not drift or vibrate when left in position.

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 section “Control Interface” beginning on page 153 of this manual 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).

Continued

Introduction (Cont.)

Yoke

The Yoke connects the Articulated Arm to the Tubehead.

Tubehead

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

> **⚠WARNING** There is a small hole in the plastic handle covering the back of the tubehead. Under no circumstances should this hole be blocked as it provides an air vent to allow the tubehead 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 Tubehead. Multiple different Cones are available, including an optional 30 cm (12-inch) Cone. Refer to the section "Accessories and Supplemental Parts" beginning on page 57 of this manual for more information.

Control Unit

The Control Unit provides for the input power connection and control of the Tubehead and Operator Panel. It provides automatic line voltage compensation, tube voltage 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 device can be configured in one way:

1. One operator panel and one hand switch

Model Configurations

The Preva is available as either a wall-mounted or a mobile unit. It 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 section "Accessories and Supplemental Parts" beginning on page 57 of this manual for more information.
- 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 section "Accessories and Supplemental Parts" beginning on page 57 of this manual for more information.

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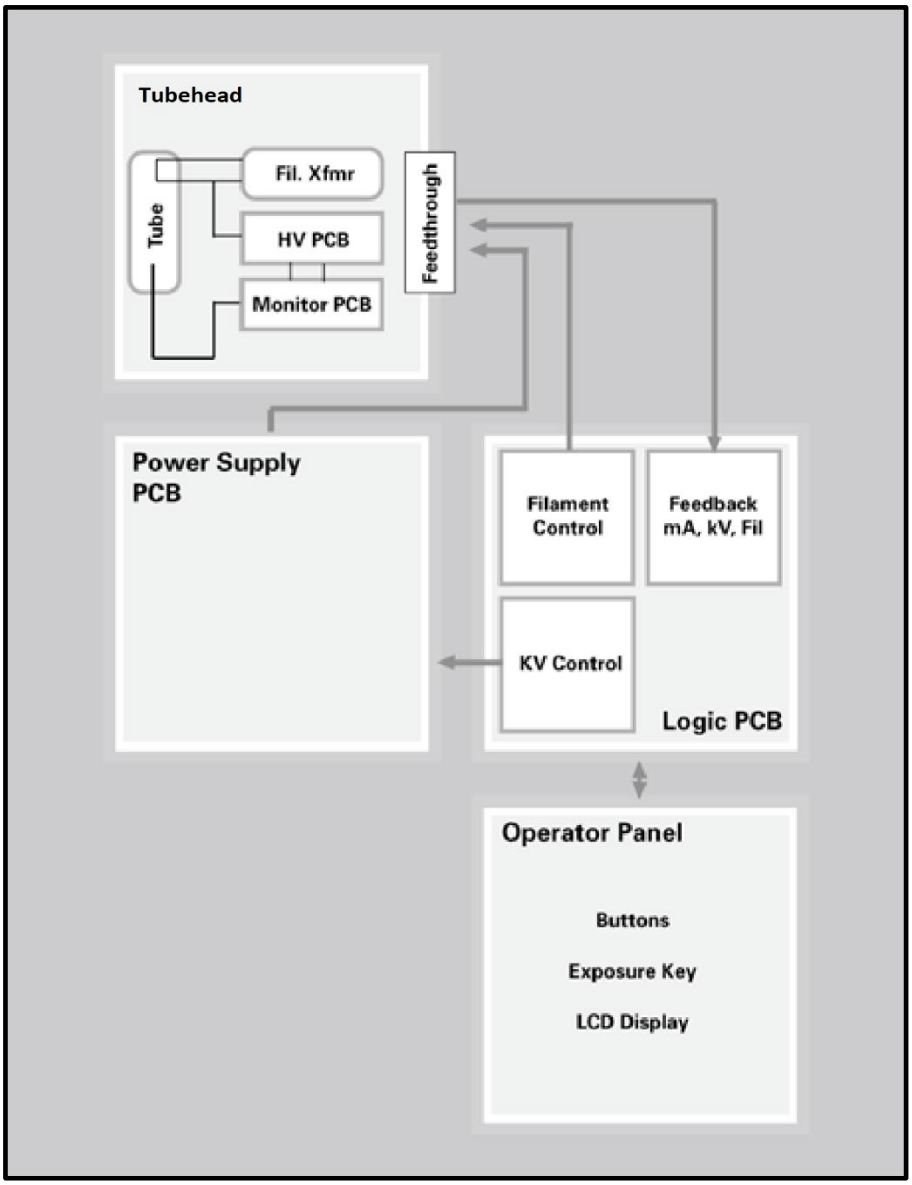
Introduction (Cont.)

- 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)

Installation procedures may vary depending upon the particular Preva configuration.

Electronics Block Diagram



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Introduction (Cont.)

Installation and Service

The Preva Dental X-ray System should only be installed and serviced by approved Midmark dealer personnel. Contact Midmark Corporation at 800.MIDMARK for assistance locating an approved dealer.

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Introduction (Cont.)

Warnings and Precautions

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

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 Tubehead. It provides an air vent to allow the Tubehead oil to expand and contract as the unit is operated.

Mechanical Safety

When using lag screws as the method of attachment, it is imperative to consider the full scope of the task. Several factors must be considered for safe, permanent installations. Some of the key issues are:

- Lumber commonly used in construction projects can be different from location to location.
- The grade, age, position, and overall condition can vary greatly.
- The attachment stud may have additional, hidden loads.
- The location of the pilot hole with respect to the center of the stud will affect the load-bearing ability.
- The size of the pilot hole required for the lag screw will be different based on the grade, age, and condition of the lumber.
- Never over-tighten the lag screw as this will weaken the mechanical connection.
- Lumber with splits or cracks should not be used for attachment.
- Plywood, particle board, or similar construction materials should not be used for attachment.
- Consider lumber dryness or moisture when attaching to exterior framing studs.
- Midmark mechanical designs will exert up to 127 kg.m (920 ft·lbf) of loading on the supporting structure.
- Midmark provides fasteners for average installations. Based on specific installation conditions, it may be necessary to choose an alternate fastener or fastening methods.
- If the surface of the Installation Guide falls below the surface of the wall, a correspondingly longer fastener must be chosen.

Continued

Introduction (Cont.)

- Seek the advice of a professional structural engineer to clarify any issues before the installation.
- Inspect the attachment method 30 days after the installation and every 6 months thereafter.
- Lag screws are not intended to be used as an attachment method for metal supports such as those found in center island pass-through cabinets. Midmark provides machine screws, large flat washers, and nylock nuts to use when fastening the system to metal supports.

Safe Installation and Operation

The equipment must be installed and operated only in accordance with the safety procedures and operating instructions in this manual and only for the purposes and applications for which it was designed. Modifications or additions to the equipment may be made only by Midmark Corporation or by third parties expressly authorized by Midmark Corporation. Such changes must comply with the rules and legal requirements of the authority having jurisdiction. It is the responsibility of the owner to ensure that existing legal regulations regarding installation of the equipment with respect to the building are observed.

Radiation Safety/X-Ray Protection

⚠WARNING	X-ray equipment can cause injury if used improperly. 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 271.

- 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 the section “Typical X-ray Scatter Dose Rates” beginning on page 32 of this manual.
- The Preva system provides a high degree of protection from unnecessary X-ray radiation. However, no practical design can provide complete protection from radiation or completely prevent operators from exposing themselves or others to unnecessary radiation. Make full use of all radiation safety equipment features, devices, accessories, and procedures available to protect the patient and operator from unnecessary 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” found on page 247 of this manual when Preva is not used for six months.

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Introduction (Cont.)

Warnings and Precautions (Cont.)

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

Responsibilities for the Installer and Service Engineer

- Verification of machine performance after installation must be performed according to the guidelines identified in the section “Function Readiness Checklist” beginning on page 255 of this manual.
- Verification of machine performance after maintenance or repair must be performed according to the guidelines identified in the section “Function Readiness Checklist” beginning on page 255 of this manual. Calibration instructions are identified in the section “Calibration” beginning on page 192 of this manual.
- Radiation safety practices must be observed when making exposures for troubleshooting.

Support Requirements

The Preva Dental X-ray System is designed to mount on a single wood 5 cm × 10 cm (2 in × 4 in) drywall stud or equivalent wall support. It can also be mounted on concrete or other similar wall construction. **Mounting to a plywood or particle board wall is not acceptable.** Verifying the wall support capability and the selection of the proper mounting hardware is the responsibility of the installer.

Note that a two-stud wall plate assembly (30-A2042 or 30-A2042-W) is available to mount on two wooden studs. A metal stud mounting kit (30-A2043 or 30-A2043-W) is available.

The wall support and mounting hardware must withstand a 45.4 kg (100 lb.) shear load and a 227 kg (500 lb.) withdrawal force at each of the mounting bolts. The wall fabrication and attachments to the building structure must be capable of withstanding a load moment of 127 kg.m (920 ft·lbf).

> **⚠WARNING** The listed support requirements are recommended minimums. The structural integrity must be verified by the customer’s structural engineer.

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.”

- This equipment must be used only in rooms or areas complying with all applicable laws and recommendations concerning electrical safety in rooms used for medical purposes, e.g.,

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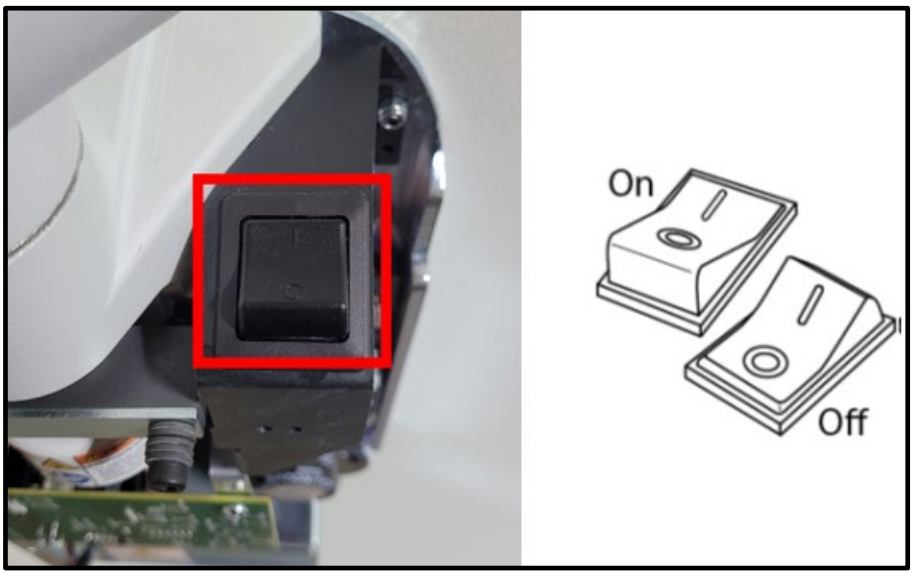
Introduction (Cont.)

International Electrotechnical Commission (IEC), National Electrical Code (NEC), or Verband Deutscher Elektrotechniker (VDE; Association of German Electrical Engineers).

- Replace X-ray sensors only when a patient is not in contact with the machine 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 this 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.
- Unplug mobile units before opening their covers.
- Allow only qualified and authorized service personnel to remove equipment covers.
- All maintenance requiring the removal of protective covers must be executed by service personnel only when patients are not present.

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

- 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.



- Connect only parts and accessories specified by Midmark as compatible with the Preva Dental X-ray System. Use of parts or accessories not specified by Midmark may result in previously

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Introduction (Cont.)

unidentified risks to patients, operators, or third parties. The responsible organization must identify, analyze, and control these risks.

- 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.
- The Preva is ordinary-type medical equipment without protection against ingress of liquids. To protect against short-circuit and corrosion, no water or any other liquid should be allowed to leak inside the equipment.

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Introduction (Cont.)

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.

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Introduction (Cont.)

Standard	Description	Compliance Level	Guidance	Method
CISPR 11, Class B, 2019	RF Emission	Class B, Group 1	230V/50Hz and 110V/60Hz	Per Standard at 230V/50Hz and 110V/60Hz
IEC61000-3-2: IEC 61000-3-2:2005 +A1:2008 +A2:2009	Harmonic Distortion	Class A	230V/50Hz	Per Standard at 230V/50Hz
IEC61000-3-3: 2013	Voltage Fluctuations / flicker emission	Class A	230V/50Hz	Per Standard at 230V/50Hz
IEC61000-4-2: 2008	Electromagnetic discharge -Contact -Air	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	230V/50Hz	Per Standard at 230V/50Hz
IEC61000-4-3: 2006 +A1:2007 +A2:2010	Radiated RF: -80 MHz to 2.7 GHz -Proximity fields from RF wireless communications equipment	3 V/m (80 MHz -2.7 GHz) 80 % AM at 1 kHz	230V/50Hz	Per Standard at 230V/50Hz
IEC61000-4-4: 2012	Electrical fast transient/burst: -Power supply lines -Input/output lines	± 2 kV @ 100 kHz Rep. (AC Mains) ± 1 kV @ 100 kHz Rep. (I/O Ports)	230V/50Hz	Per Standard at 230V/50Hz
IEC61000-4-5: 2014+A1:2017	Surge: -Line to line -Line to earth -Input/output lines	± 0.5 kV, ± 1 kV L-L ± 0.5 kV, ± 1 kV, & ± 2 kV L-PE	230V/50Hz	Per Standard at 230V/50Hz
IEC61000-4-6: 2013	Conducted RF: -150 kHz to 80 MHz -ISM band	3V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 Hz	230V/50Hz	Per Standard at 230V/50Hz
IEC61000-4-8: 2009	Power frequency magnetic field	30 A/m, 60 Hz	230V/50Hz	Per Standard at 230V/50Hz
IEC61000-4-11: 2004 +A1:2017	Voltage dips on power supply	0 % UT for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°.	110V/60Hz, 230V/50Hz	Per Standard at 110V/60 Hz, and 230V/50 HZ
		0 % UT for 1 cycle 70 % UT for 25/30 cycles Single phase: at 0° Notes: 30 cycles for 60 Hz		
	Voltage Interruptions on power supply	0% UT for 250/300 cycles Notes: 30 cycles for 60 Hz		
Sublcause 8.10, Radiated Susceptibility	Immunity to proximity fields from RF wireless communication equipment	Per Table 9	230V/50Hz	N/A

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Introduction (Cont.)

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.

Continued

Introduction (Cont.)

Warnings and Precautions (Cont.)

Damage and Injury

Prevent damage and injury by considering 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 be 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 1.5m 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.

Continued

Introduction (Cont.)

Reach and Coverage

The reach of the system is measured from the tip of the Cone with the arm fully extended and the Cone pointing back toward the pivot of the wall plate. This measurement method accommodates the normal positioning of the Tube head to the patient. A patient can, therefore, be positioned without difficulty within a radius outward from the pivot point to the dimensions shown in the diagrams.

Horizontal Arm Lengths

The Preva Horizontal Arm is available in four lengths. Each length gives the system a different reach.

- Reach of 142 cm (56 in).
- Reach of 168 cm (66 in).
- Reach of 193 cm (76 in).
- Reach of 208 cm (82 in).

The diagrams in the rest of this section show P/N P7018-P with an 82-inch reach. For other models, apply the following conversions:

- For models with a 193 cm (76 in) reach, reduce the dimensions by 20 cm (8 in).
- For models with a 168 cm (66 in) reach, reduce the dimensions by 46 cm (18 in).
- For models with a 142 cm (56 in) reach, reduce the dimensions by 71 cm (28 in).

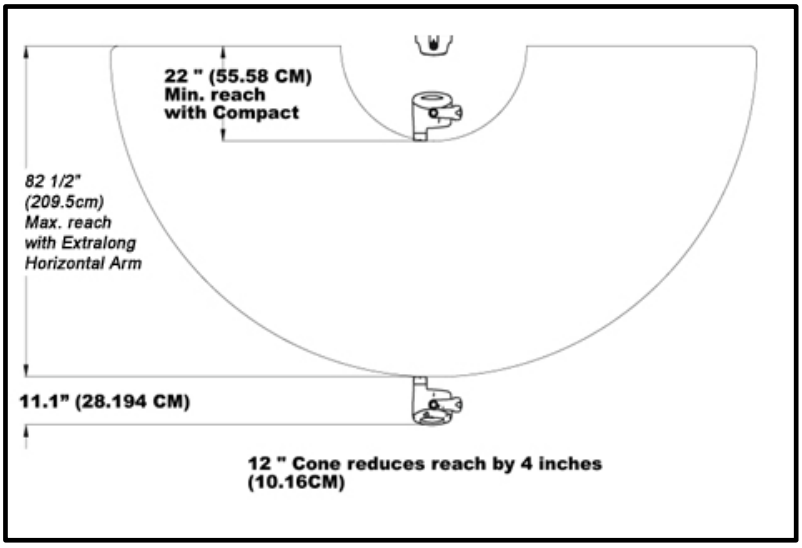
Optional 30 cm (12 in) Cone

The 208 cm (82 in) reach for Catalog P7018-P assumes the use of the 20 cm (8 in) Cone that is supplied with the system. If the optional 30 cm (12 in) Cone is used, the reach is reduced by 10 cm (4 in).

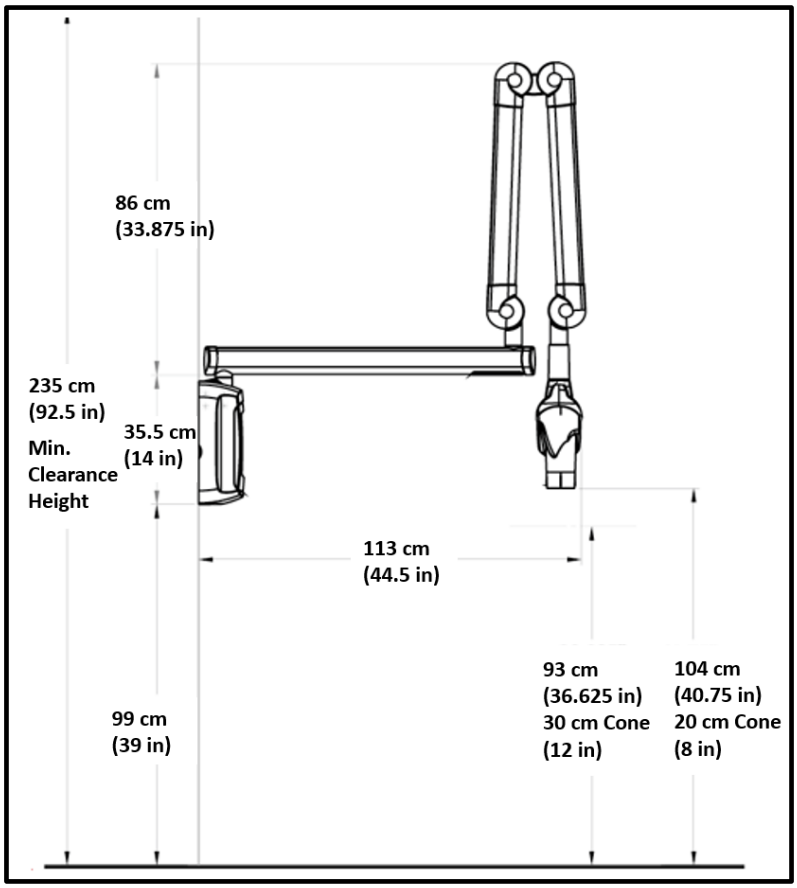
Continued

Introduction (Cont.)

Reach and Coverage Diagram



Cabinet Mounting Dimensions

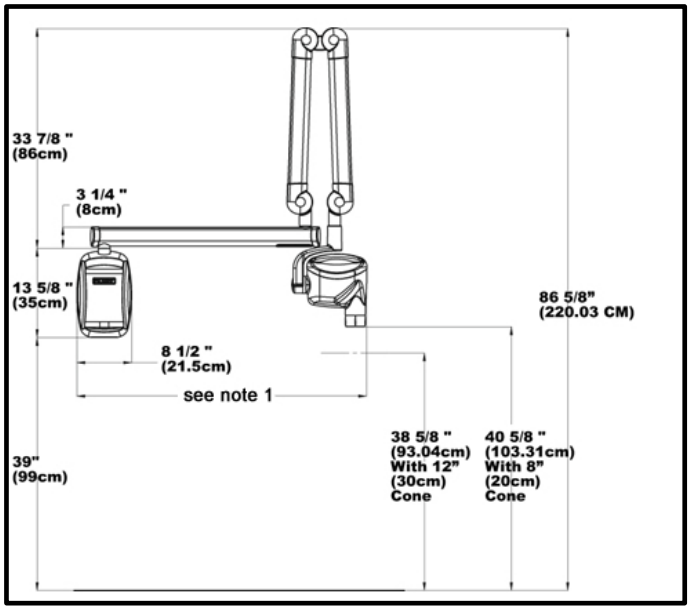


NOTICE 208 cm (82 in) reach not recommended for cabinet mount.

Continued

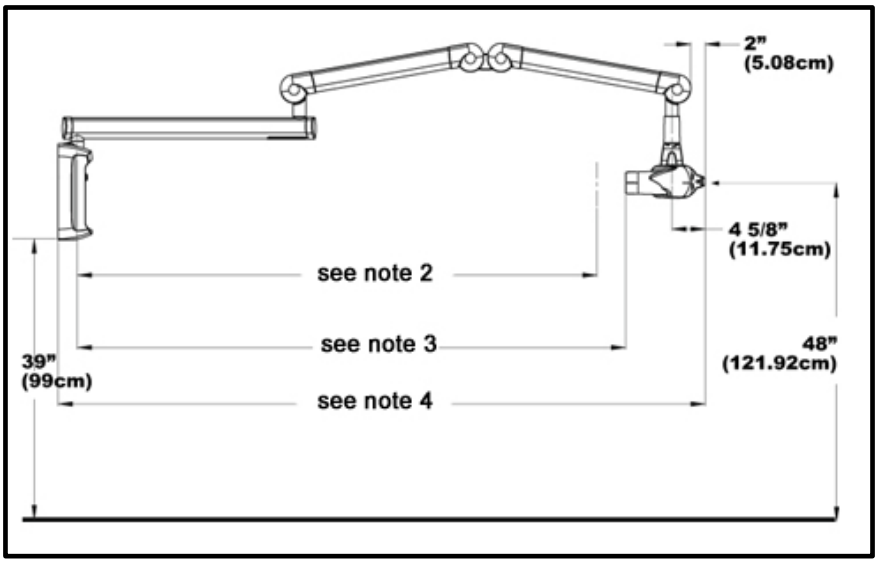
Introduction (Cont.)

Retracted Wall Mount



Note 1 Horizontal Dimension Add 12.7 cm (5 in) for Two Stud Mount	P7015-P 62.5 cm (24 5/8 in)
	P7016-P 88 cm (34 5/8 in)
	P7017-P 114 cm (44 5/8 in)
	P7018-P 128.5 cm (50 5/8 in)

Extended Position Wall or Cabinet Mount



With 30 cm (12 in) Cone	
Note 2	P7015-P 133 cm (52 1/2 in)
	P7016-P 159 cm (62 1/2 in)
	P7017-P 184 cm (72 1/2 in)
	P7018- 199 cm (781/2 in)

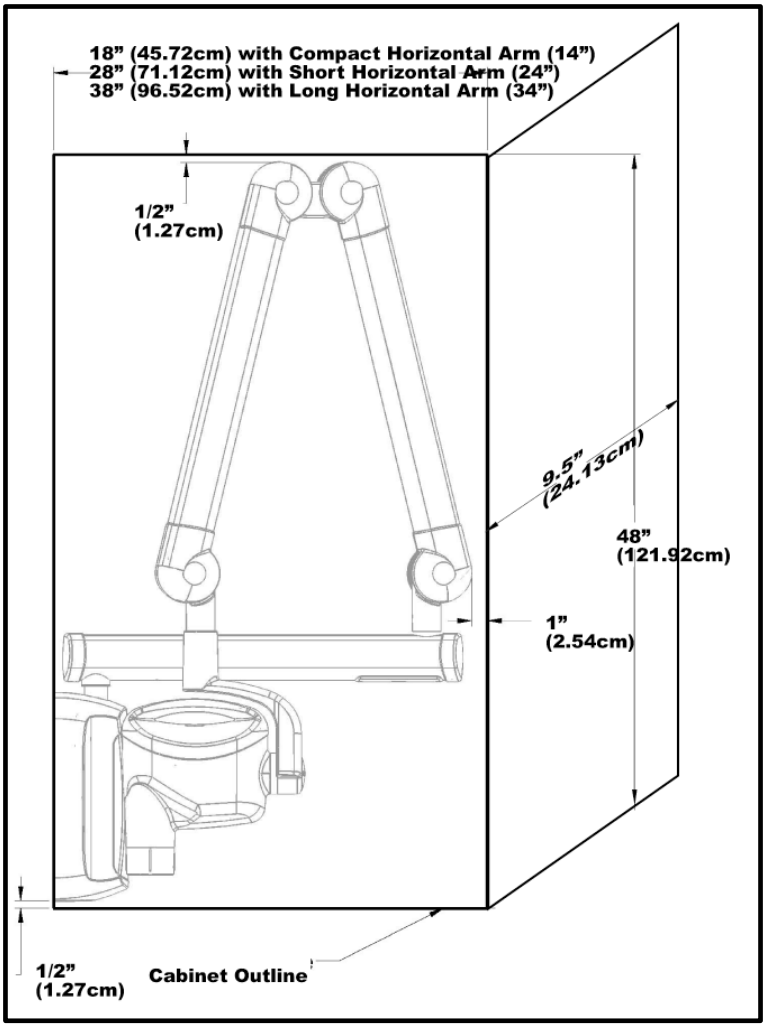
With 20 cm (8 in) Cone	
Note 3	P7015-P 143.5 cm (56 1/2 in)
	P7016-P 169 cm (66 1/2 in)
	P7017-P 194.5 cm (76 1/2 in)
	P7018-P 209.5 cm (82 1/2 in)

To handle	
Note 4	P7015-P 178.5 cm (70 3/8 in)
	P7016-P 204 cm (80 3/8 in)
	P7017-P 229.5 cm (90 3/8 in)
	P7018-P 244.5 cm (96 3/8 in)
(add 2.5 cm (1 in) for Two Stud mount)	

Continued

Introduction (Cont.)

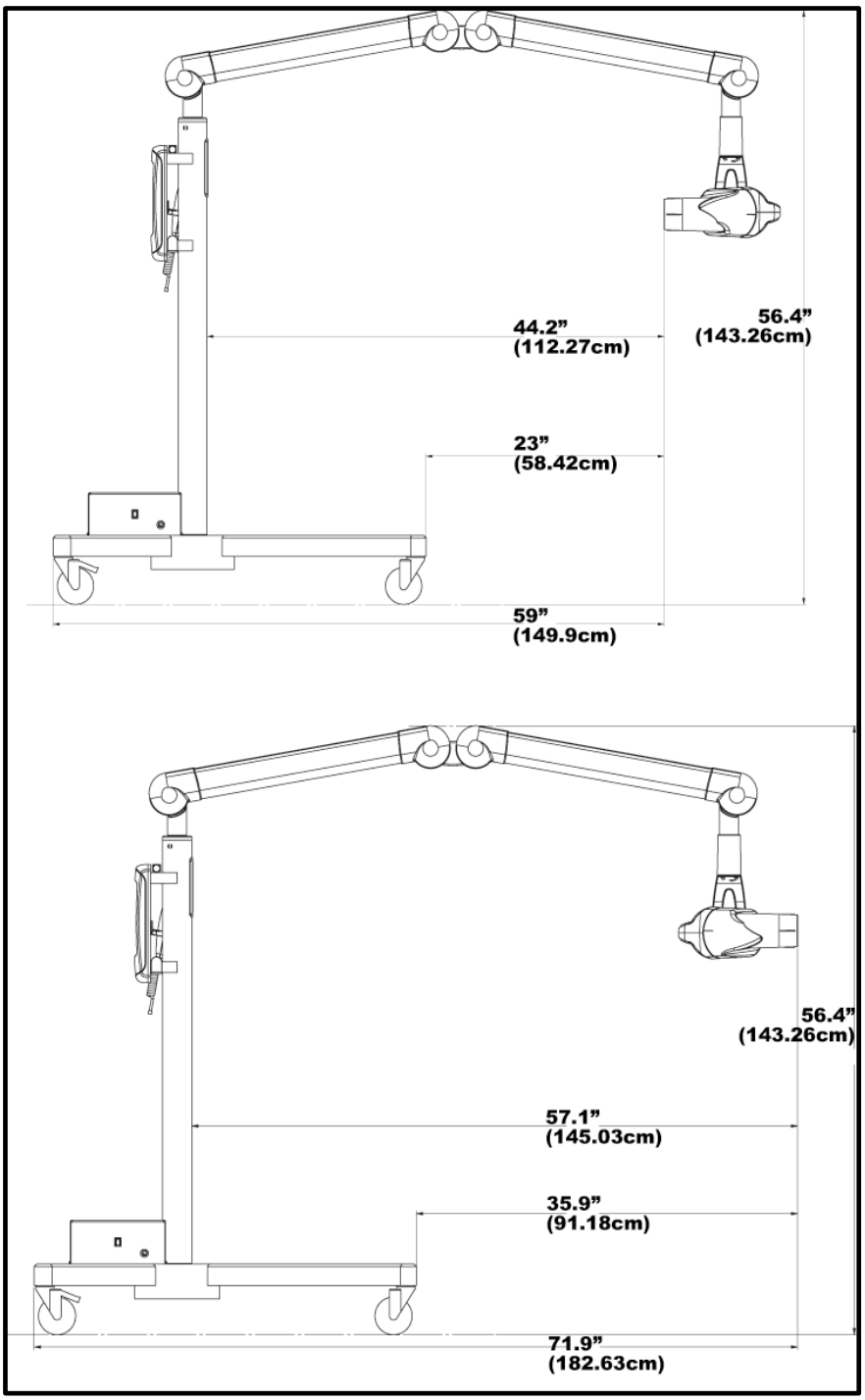
Retracted Position for a Cabinet Mount



Continued

Introduction (Cont.)

Mobile Unit Extended

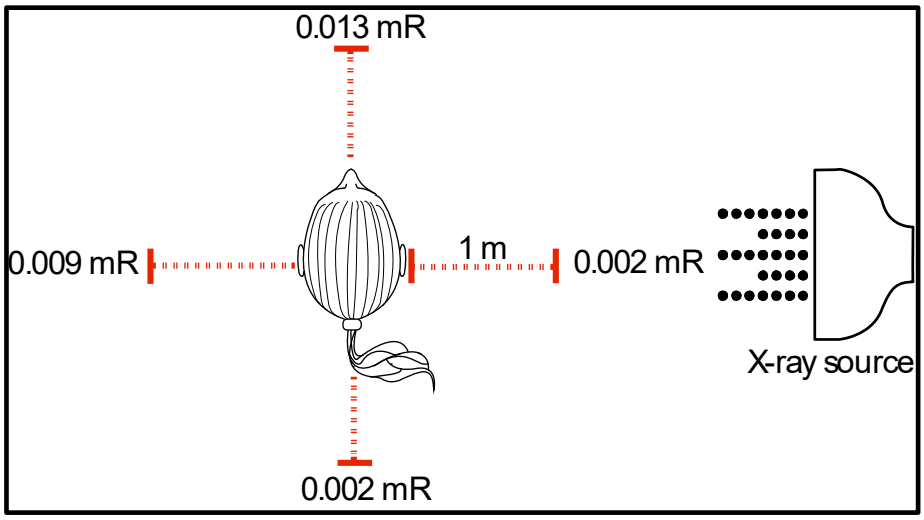


Continued

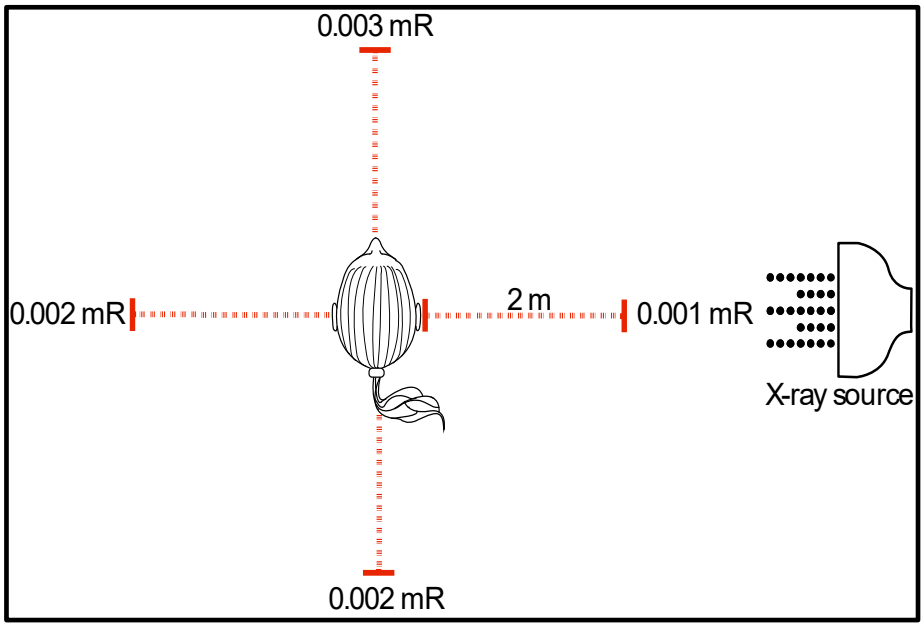
Introduction (Cont.)

Typical X-ray Scatter Dose Rates

For room planning purposes, these illustrations show X-ray scatter dose rates that are typical of the Preva system. This data was developed using a common, commercially available human head phantom in the normal patient position to produce the required X-ray scatter. A Rad-Cal model 160 cm^3 ion-chamber (µRem) meter was used to integrate the doses. Measurements were taken at distances of 1 and 2 meters from the X-ray target, 127 cm (50 in) from the horizontal plane of the floor.



Exposures: molar protocol; 70 kV, 6 mA, 1 s.; measurements at 1 meter (39 in) from the X-ray target.



Exposures: molar protocol; 70 kV, 6 mA, 1 s.; measurements at 2 meters (79 in) from the X-ray target.

Continued

Introduction (Cont.)

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

Continued

Introduction (Cont.)

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.

Electrical Requirements

Mains Power Supply

The Preva Dental X-ray System requires 3-wire single phase AC power mains that contain line conductor, neutral conductor, and protective earth conductor. It is recommended that the unit be installed with a dedicated electrical line connected to a breaker with a minimum 15 amp rating. The wiring must provide for a permanently grounded power line configuration.

The installer must determine the suitability of installing the Preva with a line cord. If a line cord is used, use the one provided with the unit.

Line Voltage

AC 110 V to 230 V, 50 Hz or 60 Hz (See complete specifications in Appendix B, Technical Specification beginning on page 263 of this manual.)

Max Line Resistance

For normal function of the Preva Dental X-ray System, the resistance of the power line should not exceed 0.4 Ω at nominal line voltage.

⚠WARNING

- Mobile radiofrequency (RF) communications equipment can affect the performance of medical electrical equipment. Midmark advises against using the Preva system adjacent to other devices. If it must be used near other devices, adjust their configuration to ensure that electromagnetic interference (EMI) does not degrade performance. Test both devices for normal operation.
- Use of accessories, transducers, or cables other than those provided or specified by Midmark can result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment. This can result in improper operation.
- Use portable RF communications equipment (including peripherals such as antenna cables and external antennas, including cables specified by Midmark) no closer than 30 cm (12 in) to any part of the Preva system. Otherwise, performance of the equipment may be degraded.
- When integrated with sensors, must be used with IEC 60950 or IEC 60601 compliant computers. Also, any device between the integrated system and the computer (USB hub) must be compliant with IEC 60950 or IEC 60601. If not, electromagnetic compatibility may be degraded.

Continued

Introduction (Cont.)

Interlock

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

Compliance with Applicable Standards

Radiation Protection

At the time of manufacture, the certified components of the Preva Dental X-ray System comply with Radiation Performance Standards 21 CFR, Subchapter J.

The certified components of the Preva Dental X-ray System comply with IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment.

Basic Safety and Essential Performance

Certified by TUV Rheinland of North America (TRNA) to:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- CAN/CSA C22.2 No. 60601-1-14:2014
- IEC 60601-1-3:2008/A1:2013
- CAN/CSA C22.2 No. 60601-1-3A-09
- IEC 60601-1-6:2010/AMD1:2013
- IEC 60601-2-65:2012/AMD1:2017
- CAN/CSA C22.2 No. 60601-2-65A:15

EMI/EMC

IEC 60601-1-2:2014+AMD1:2020

Imaging Performance

- IEC 61223-3-4:2000
- Line pair resolution: better than 8 lp/mm per IEC 61223-3-4:2000 acceptance criteria
- Low contrast resolution: all holes visible per IEC 61223-3-4:2000 acceptance criteria

> **NOTICE** Imaging performance metrics are not affected by differences among imaging receptors.

Continued

Introduction (Cont.)

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

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

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

imagingtechsupport@midmark.com

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

midmark.com/service-support

Technical Library

technicallibrary.midmark.com

Symbols Glossary

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Symbols Glossary (Cont.)

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.

Continued

Symbols Glossary (Cont.)

Symbol	Description
N	Marks a terminal connected to the power mains' neutral (grounded) conductor.
	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.

Continued

Symbols Glossary (Cont.)

Symbol	Description
	Indicates that the marked item or its material is part of a recovery or recycling process.
	Indicates the maximum and minimum temperature limits at which the item shall be stored, transported, or used.
	Indicates the acceptable upper and lower relative humidity limits for transport and storage.
	Indicates the acceptable upper and lower atmospheric pressure limits for transport and storage.
	Indicates that 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

Wall-Mount Configuration 45
Mobile Configuration 49

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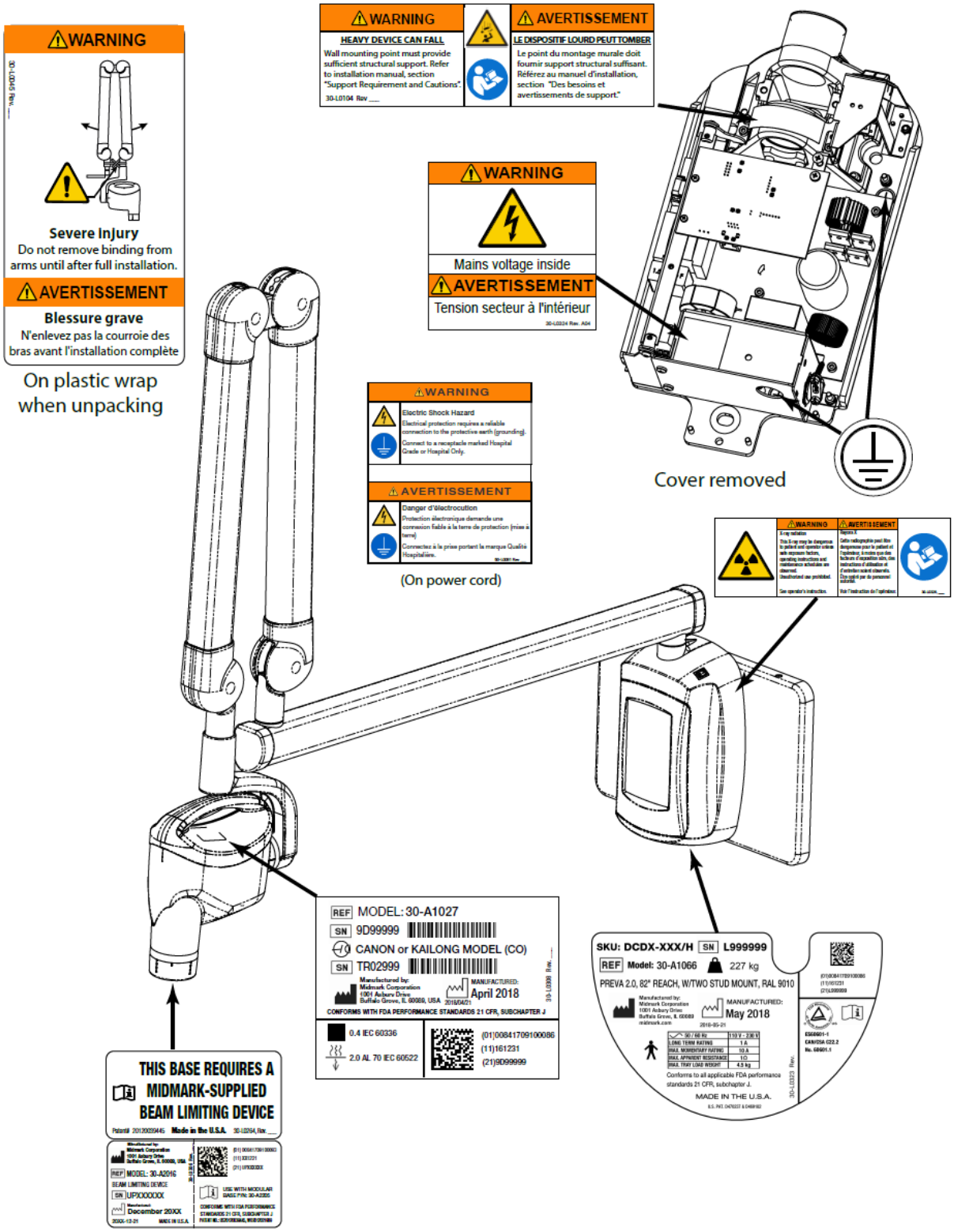
Preva Labels (Cont.)

Wall-Mount Configuration

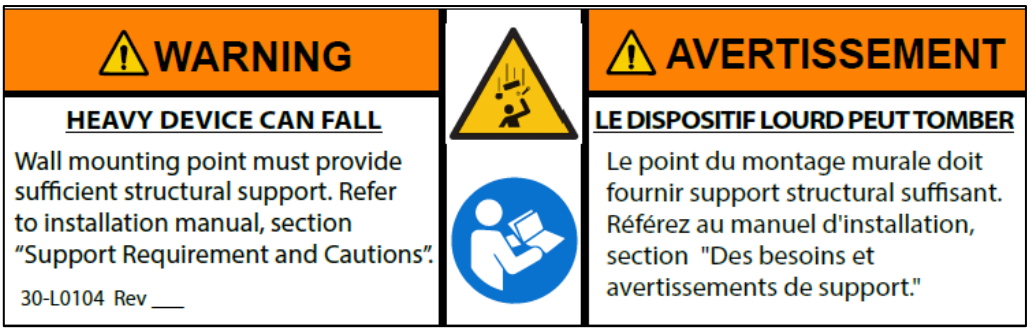


Overview of Wall-Mount Configuration Preva Labels

Continued

Preva Labels (Cont.)

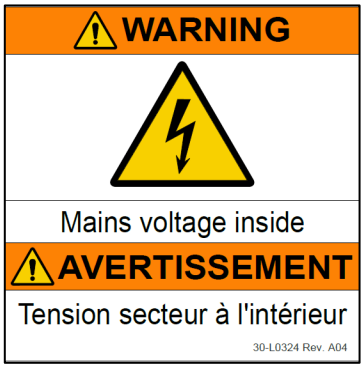
Plastic Wrap Label



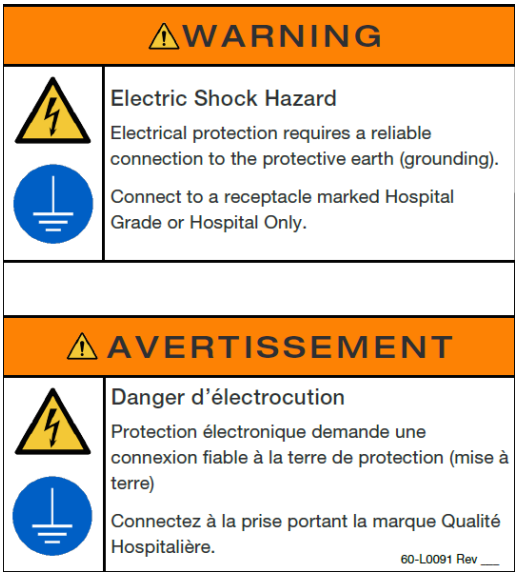
Safety Warning Label

Continued

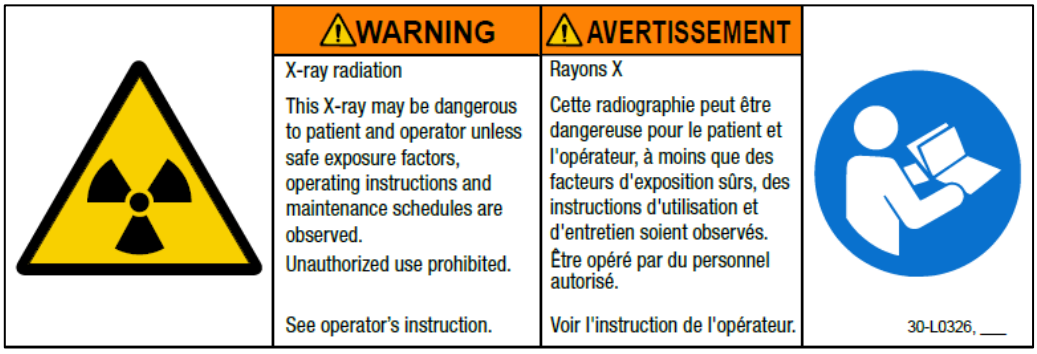
Preva Labels (Cont.)



Dangerous Voltage Warning Label (For Service Only)



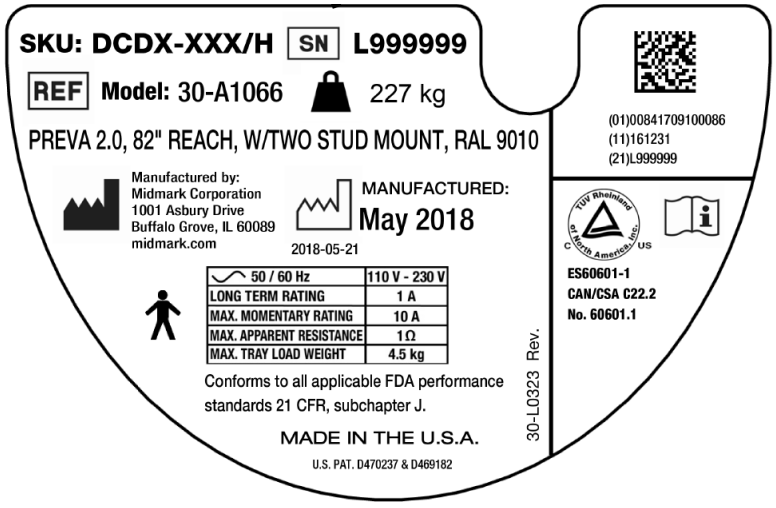
Power Cord Label



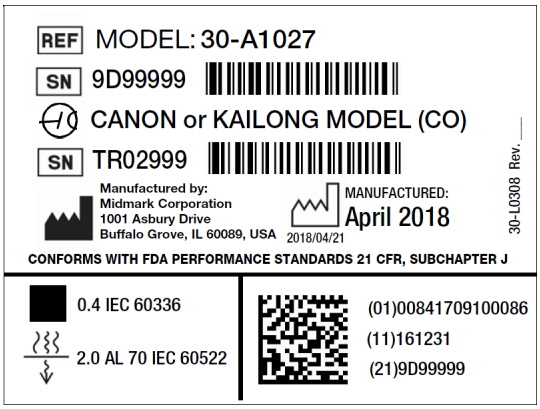
X-ray Warning Label

Continued

Preva Labels (Cont.)



Intraoral System Serial Label



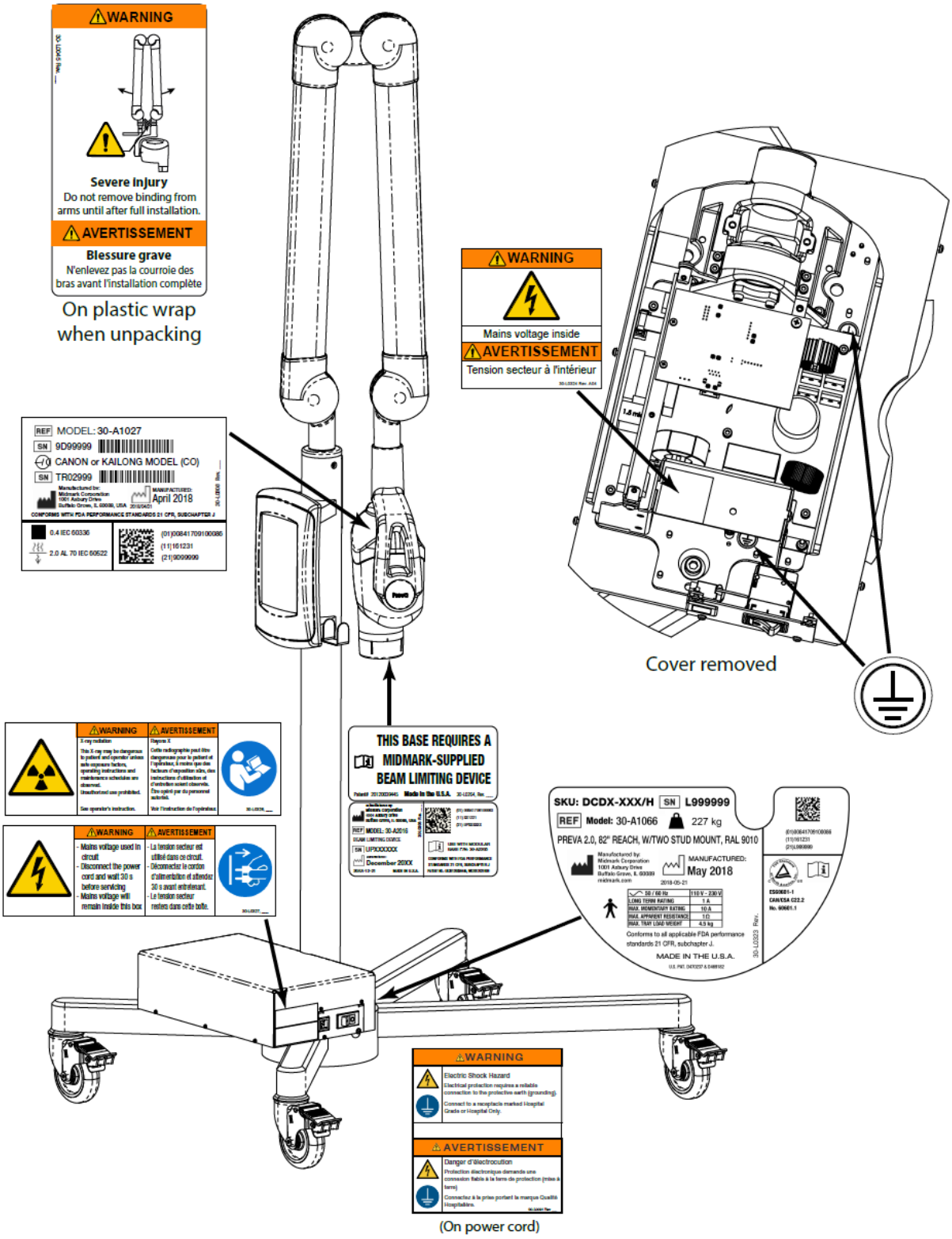
Tubehead Serial Label

Beam-Limiting Device Serial Label

Continued

Preva Labels (Cont.)

Mobile Configuration

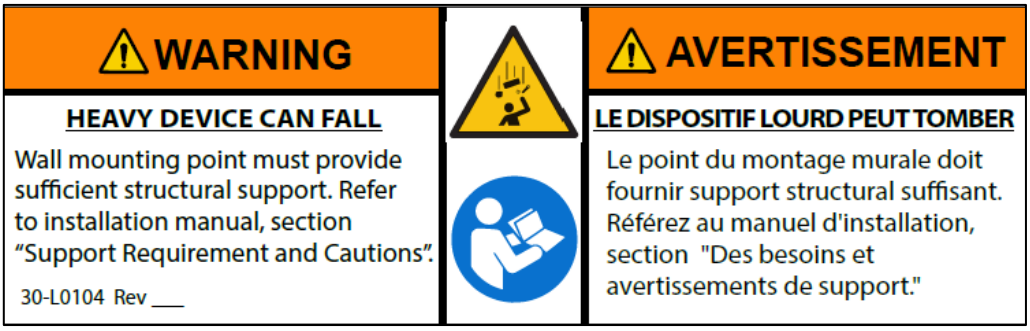


Overview of Mobile Configuration Preva Labels

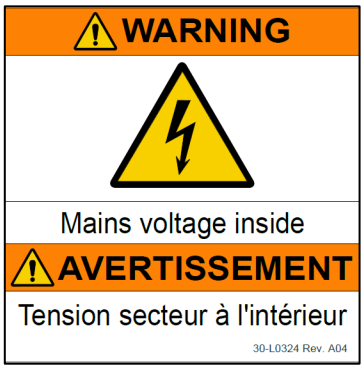
Continued

Preva Labels (Cont.)

Plastic Wrap Label



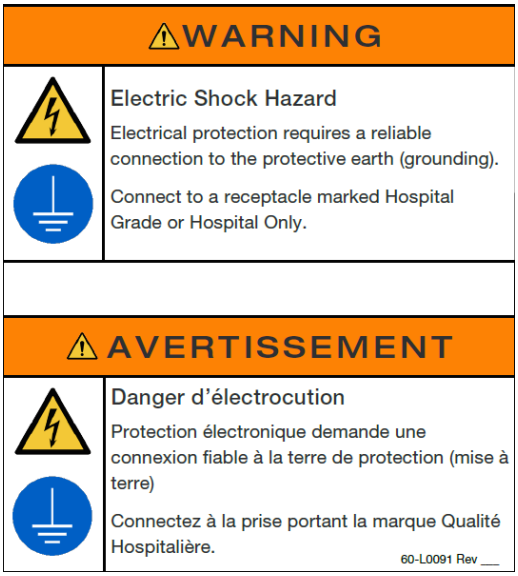
Safety Warning Label



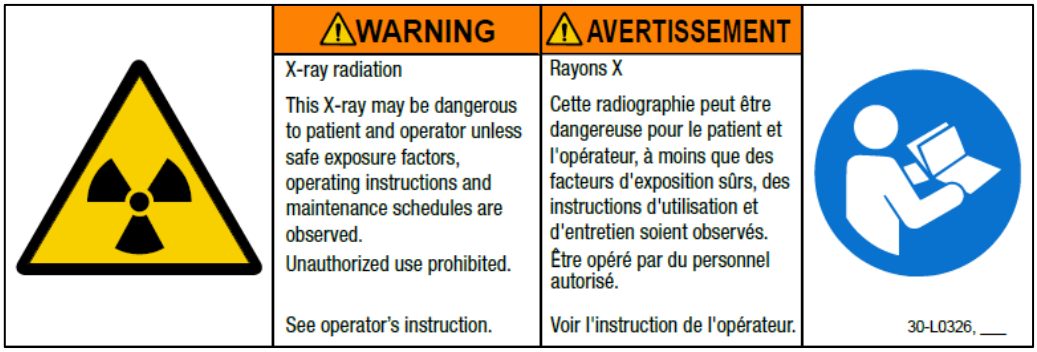
Dangerous Voltage Warning (For Service Only)

Continued

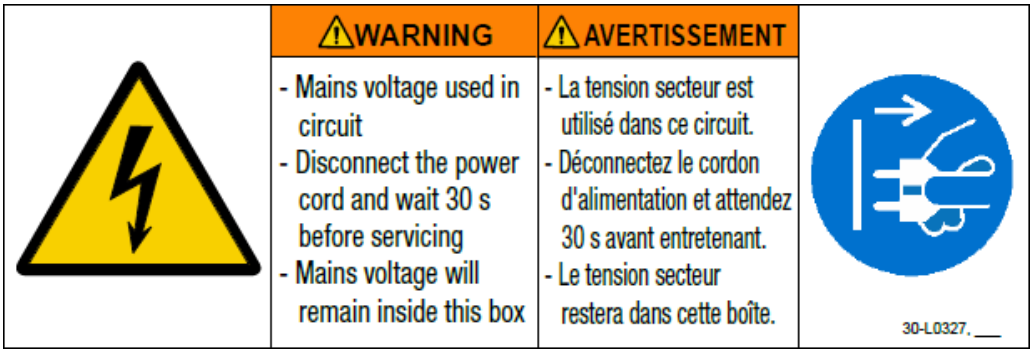
Preva Labels (Cont.)



Power Cord Label



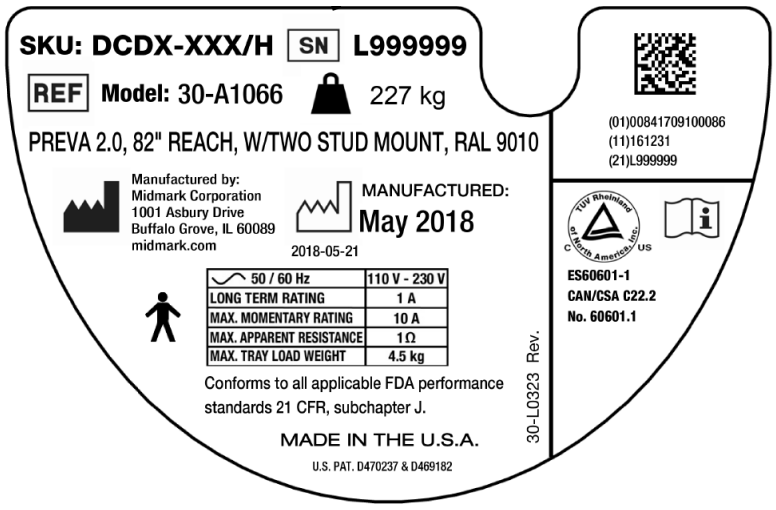
X-ray Warning Label



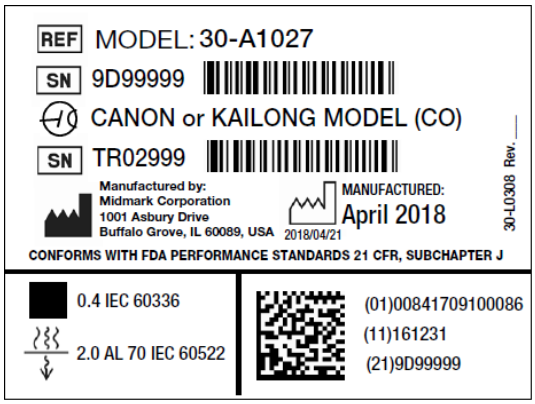
Dangerous Voltage – Unplug Before Service Label

Continued

Preva Labels (Cont.)



Intraoral System Serial Label



Tube head Serial Label

Beam-Limiting Device Serial Label

Glossary of Terms

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Glossary of Terms (Cont.)

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.

Continued

Glossary of Terms (Cont.)

Term	Meaning
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.
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.

Accessories and Supplemental Parts

Exposure Switches 59
Beam-Limiting Devices 60
Installation Options 62

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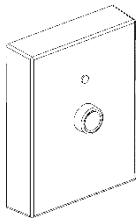
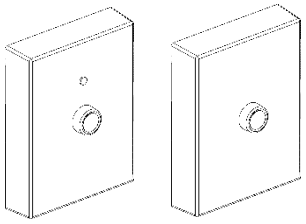
Accessories and Supplemental Parts (Cont.)

Exposure Switches

The exposure switches control the exposure during radiography.

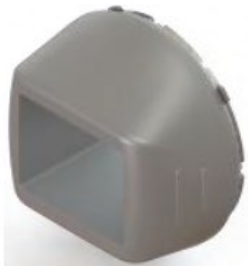
Part	Description
	*Exposure Switch Option:* *Hand Switch, PN 30-A2040 or 30-A2040-W* Usually used with mobile devices or when the operator must remain near the patient. Available in gray or white.
	*Exposure Switch Option:* *Remote Exposure Station, PN 60-A2181* Usually used outside of the room to ensure 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.

Continued

Accessories and Supplemental Parts (Cont.)

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.

Continued

Accessories and Supplemental Parts (Cont.)

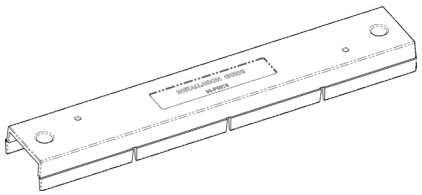
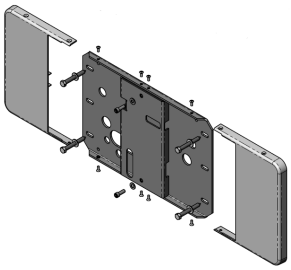
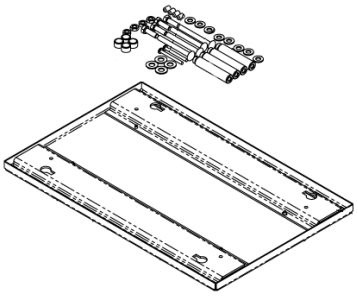
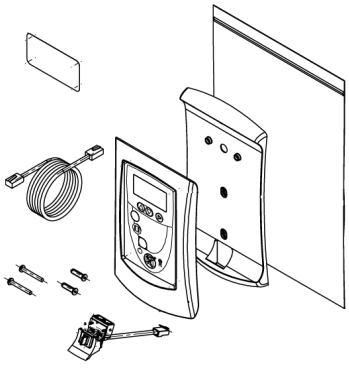
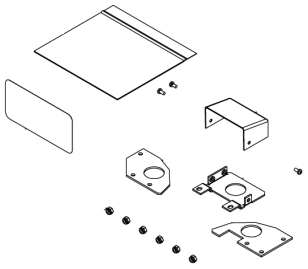
Part	Description
	*Modular BLD, 20 cm Long:* *35×45 mm Cone, White, PN 30-A2222* A white rectangular cone providing 20 cm of source to object distance with size of 35 mm by 45 mm.
	*Modular BLD, 30 cm Long:* *35×45 mm Cone, Gray, PN 30-A2223* A gray rectangular cone providing 30 cm of source to object 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.

Continued

Accessories and Supplemental Parts (Cont.)

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.

Continued

Accessories and Supplemental Parts (Cont.)

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Applied Parts

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Applied Parts (Cont.)

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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Installation Options

Mounting Configurations 70
Single Wood Stud Wall, Solid Wall, or Reinforced Wood Cabinet 71
Dual Wood Stud Wall 74
Metal Stud Wall 75
Installing the 4×4 Mount 76
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Operator Panel Locations 80
On Control Unit 80
Remote Operator Panel 80

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Installation Options (Cont.)

Mounting Configurations

This section gives instructions for installing the Preva Dental X-ray System in the three available wall-mounting configurations: single stud, dual stud, and metal stud wall.

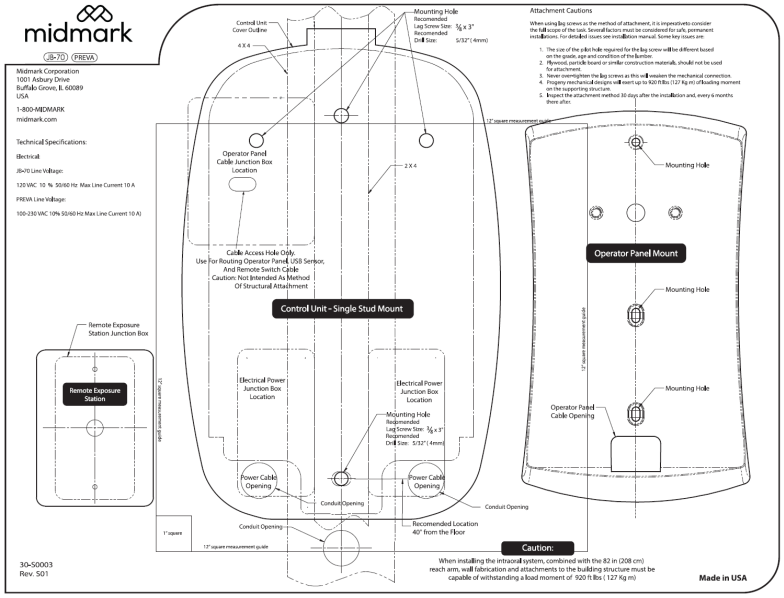
⚠CAUTION

- When installing the Preva combined with the 208 cm (82 in) reach arm, the wall fabrication and attachments to the building structure must be capable of withstanding a load moment of 127 kg-m (920 lb-ft).
- Do not use lag screws as an attachment method for metal supports such as those found in center island pass-through cabinets. Midmark provides machine screws, large flat washers, and nylock nuts for fastening the system to metal supports.

NOTICE

The purpose of this section is to give an overview of instructions and considerations to be aware of before beginning wall-mount installation processes. The detailed installation instructions are contained in the section “Installation Procedures – Wall-Mount Configurations” beginning on page 81 of this manual. Do not begin the installation process until reading that section.

Use 30-S0003, the mounting template shown below. A copy of this template is included in the box. Use the front side for single-stud installations. Reverse the template for dual-stud installations.



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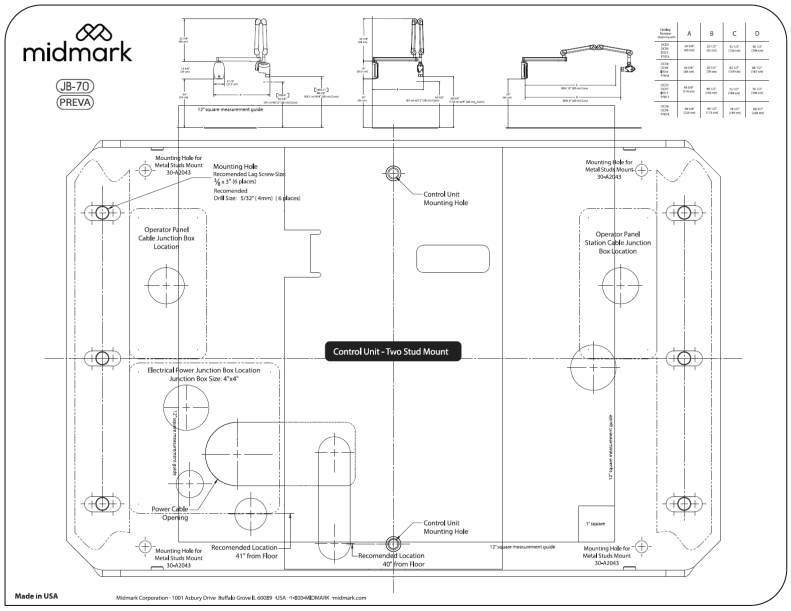
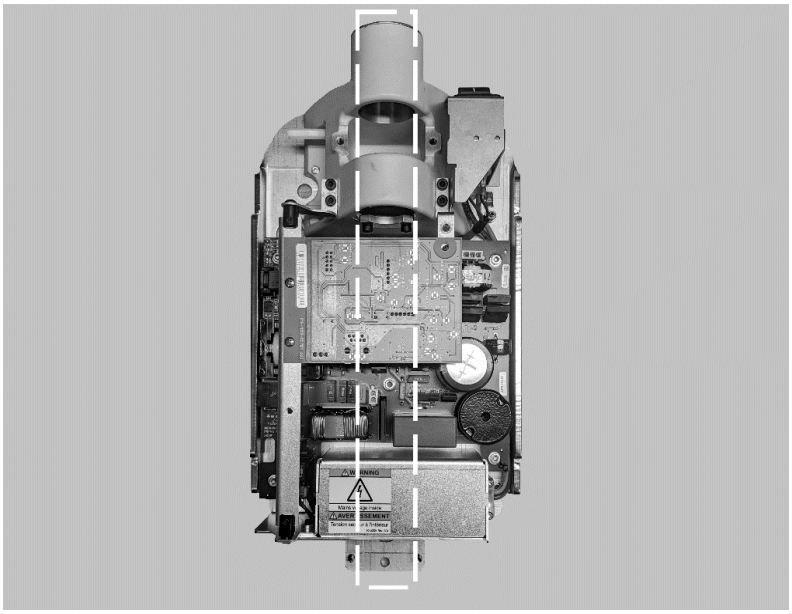
Installation Options (Cont.)



Single Wood Stud Wall, Solid Wall, or Reinforced Wood Cabinet

⚠WARNING Do not attach the 208 cm (82 in) reach system to a wall in the single-stud configuration. Refer to the dual-stud configuration sections of this manual.

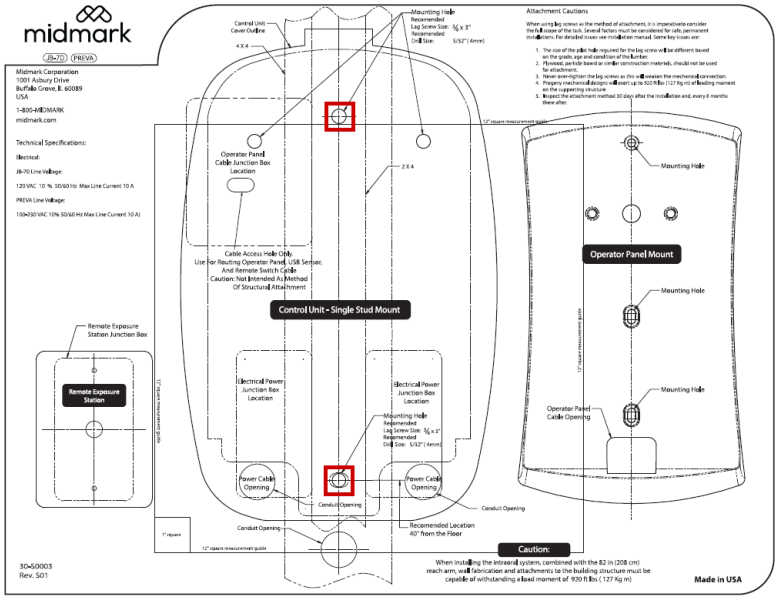
The Control Unit is recommended to be located at a height of 99 cm (39 in) from the floor to the bottom of the control, mounted on the wood stud, as shown below. However, the large range of travel of the Articulated Arm provides some flexibility in the vertical position if needed.



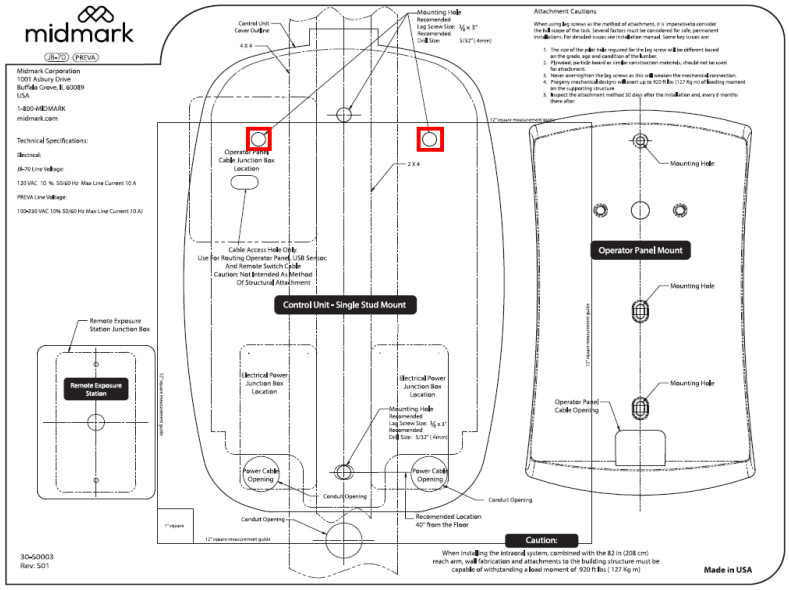
Continued

Installation Options (Cont.)

Two mounting holes are provided. Refer to the supplied mounting template for specific locations. Use Installation Guide 30-P0076. These same two mounting holes should also be used for a reinforced cabinet; however, cabinets need to be sufficiently reinforced. See the image below.



In order to mount to a solid, masonry-type wall, the same mounting holes and mounting template as the single-wood wall stud are used, plus the additional mounting holes indicated in the picture below. The installer must supply appropriate fasteners.



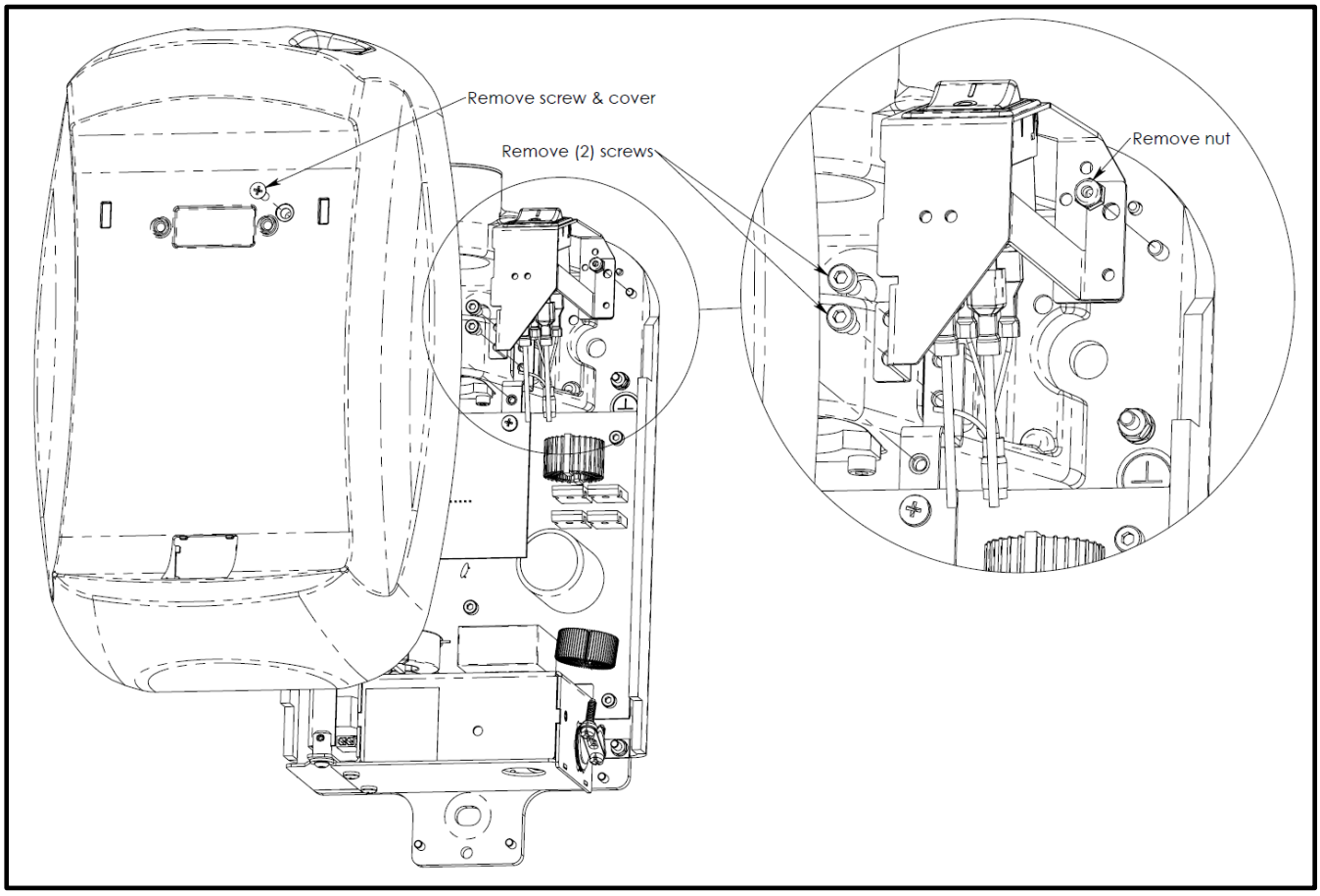
Additional steps are needed to access the hole to the right side of the main mounting holes. Refer to the following steps and the diagram that follows:

1. Remove the two screws and one nut from the power switch bracket.

Continued

Installation Options (Cont.)

2. Remove the power switch bracket and clear the way for the bolt.
3. Attach mounting fastener through the exposed hole.
4. Reattach the power switch bracket, the two screws, and the nut.

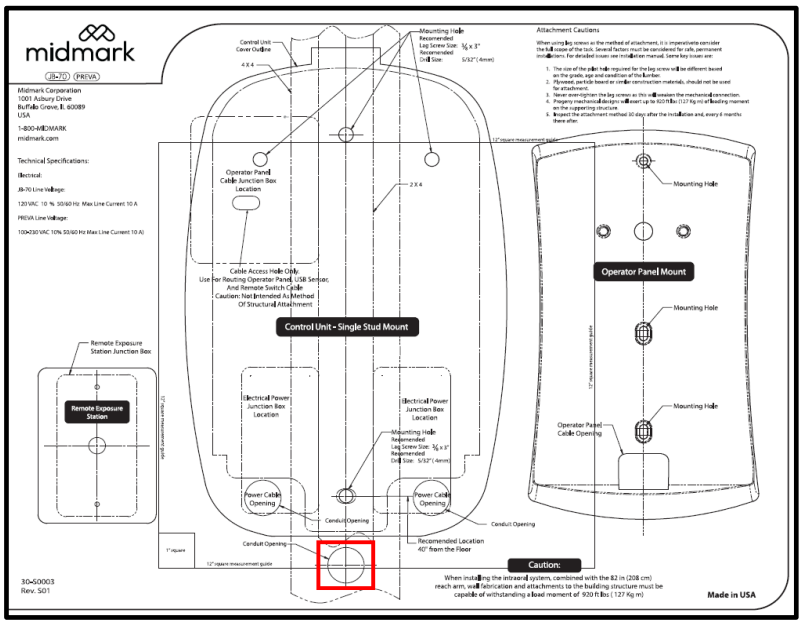


The power supply should be routed on the right of the stud, and the controls should be routed to the left of the stud. The installation must follow the local electrical code. Alternatively, the power supply can be installed on the left and the control on the right; however, additional care must be taken to separate the control cables from the power cables.

NOTICE	A 4×4 junction box will not be covered by the Control Unit. Refer to the supplied mounting template for specific location. (Relevant area is highlighted in the image below.)

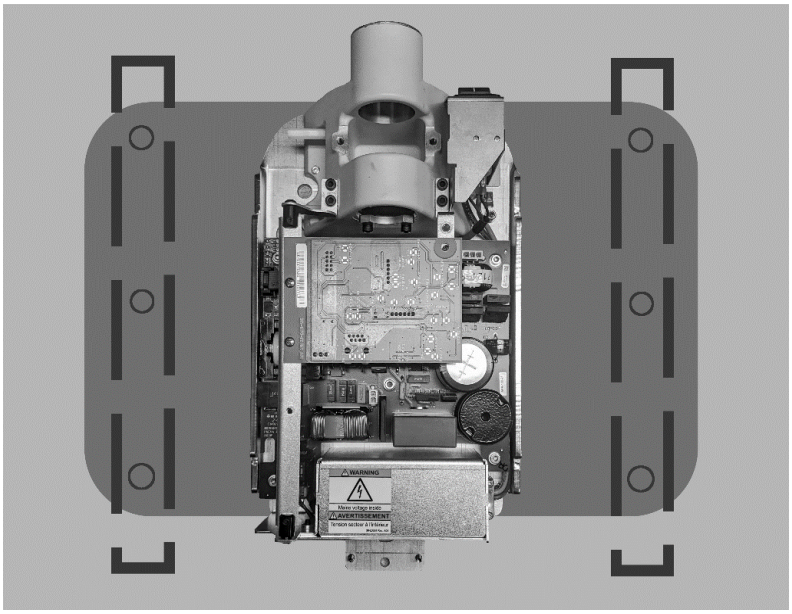
Continued

Installation Options (Cont.)



Dual Wood Stud Wall

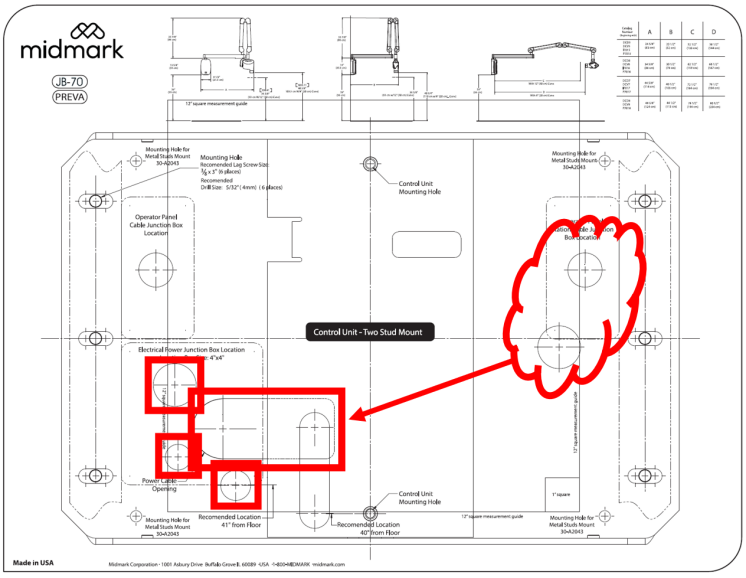
When installing the Preva Dental X-ray System on two 40 cm (16 in spaced on center) wood studs, the Control Unit is mounted to a wall plate (Two-Stud Mounting Kit 30-A2042), which mounts to the wood studs, as shown below. Fasteners are provided with the wall plate.



In mounting configurations using the dual-stud wall plate, there are several holes available for incoming line power. This is to provide for various locations of existing power boxes when installing as a replacement unit. Refer to the reverse side of the mounting template, 30-S0003, for hole locations. See below.

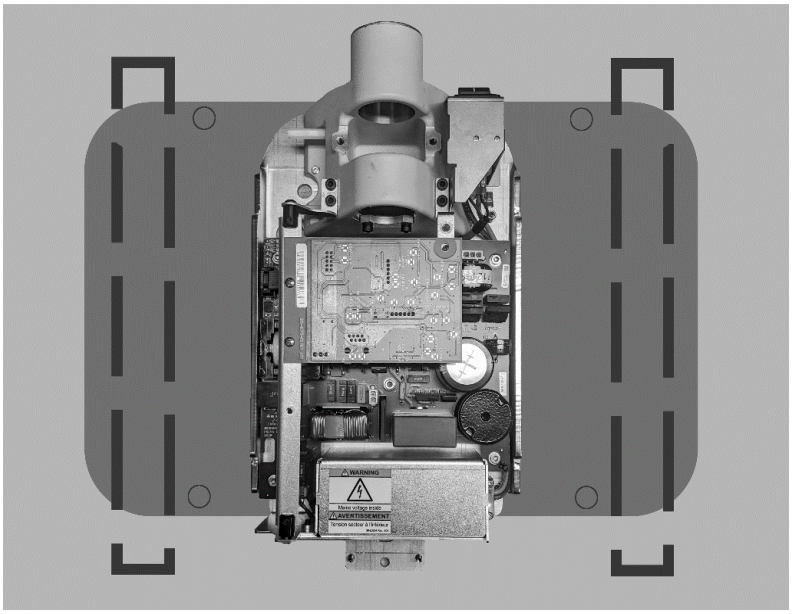
Continued

Installation Options (Cont.)



Metal Stud Wall

When installing the Preva Dental X-ray System on a metal stud wall, the Control Unit is mounted using Metal Stud Support Plate Kit 30-A2043. One plate is positioned behind the wall and one plate is positioned in front of the wall. See below.

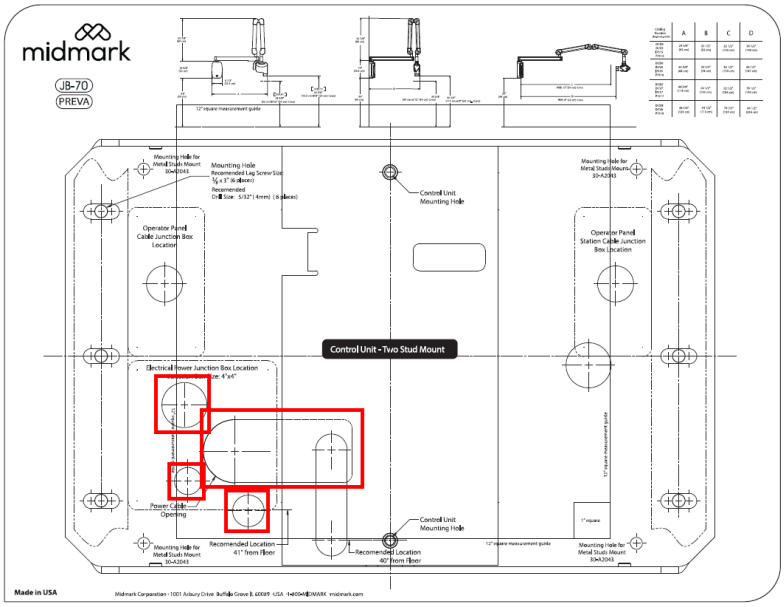


Fasteners are provided with the wall plate and support plate. The wall fabrication and attachments to the building structure must be capable of withstanding a load moment of 127 kg.m (920 ft·lbf). If the wall on which the Preva is to be installed does not meet this requirement, it must be reinforced.

Continued

Installation Options (Cont.)

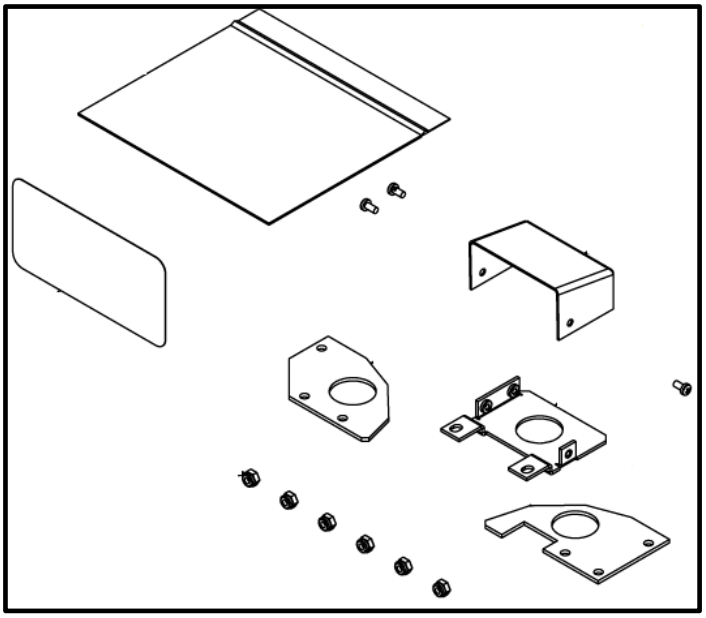
In mounting configurations using the dual-stud wall plate, there are several holes available for incoming line power. This is to provide for various locations of existing power boxes when installing as a replacement unit. Refer to the mounting template, 30-S0003, for hole locations.



Installing the 4×4 Mount

NOTICE Do not use this option if working with a flexible metal conduit.

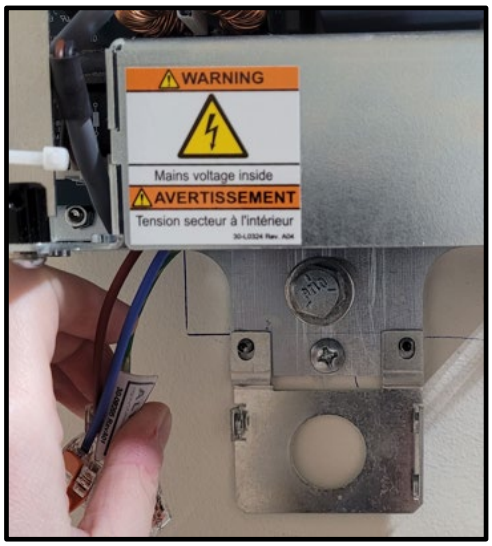
In cases where the wires for power mains must enter on the center line of the Control Unit, the 4×4 Mount Kit (30-A2099), shown below, is available.



Continued

Installation Options (Cont.)

1. Place the power line bracket assembly on the two bottom-most threaded studs at the base of the Control Unit as shown below.



2. Trace the inside of the circle and remove the power line bracket assembly.

3. Drill out the drywall within the circle.

Continued

Installation Options (Cont.)

4. Feed the power mains cable through the hole in the power line bracket assembly. Place the power line bracket assembly back on the screws at the base of the Control Unit and secure it with two nuts.

5. Screw the junction box cover in place.

Continued

Installation Options (Cont.)

6. Position the Control Unit cover in place.
7. Put the power cord cover in place and secure with three screws.

Wall Mounting Above a Countertop

When mounting the control unit above a horizontal surface such as a countertop, allow sufficient distance between it and the bottom of the control unit to allow the product label to be read.

Continued

Installation Options (Cont.)

Operator Panel Locations

The Operator Panel for the Preva Dental X-ray System can be installed on the Control Unit or mounted remotely on a wall.

On Control Unit

The Operator Panel snaps on to the front of the Control Unit. Installation of the Operator Panel on the Control Unit may require the purchase and use of the coil-cord hand switch option (30-A2040 or 30-A2040-W).

Remote Operator Panel

The Operator Panel is mounted on the wall remote from the Control Unit. If the Operator Panel is mounted separate from the Control Unit, a supplied cable must be run from the Control Unit to the Operator Panel. Where local codes require, a separate 2×4 junction box should be mounted to the left of the mounting stud above the power supply box. Refer to the supplied mounting template for specific location. A cradle is provided to mount the Operator Panel in the desired location.

Installation Procedures – Wall-Mount Configurations

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- Gather Tools 83
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Installing Plastic Covers 122

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Installation Procedures – Wall-Mount Configurations (Cont.)

Preparing to Install the Preva

Check Pre-Installation Requirements

Prior to beginning the installation, be sure that all pre-installation requirements have been completed. This includes confirming that the wall support requirements are adequate for mounting the unit and that the electrical power requirements and wire locations are proper. Refer to the “Introduction” section of this manual as well as the section “Installation Options” beginning on page 68 of this manual.

NOTICE Midmark recommends that the Preva be connected to dedicated wiring and permanently grounded. The installer must determine the suitability of using a line cord at the time of installation, ensuring proper grounding technique.

Gather Tools

Items needed for all types of mounts:

- Stud finder
- Bubble level (torpedo level)
- Masking or other tape for placing the mounting template on the wall
- Awl
- Drill driver and drill bits appropriate to type of wall mounting
- Metric hex key set
- Screwdrivers (flat blade and Phillips)
- Torque wrench, 0-5.5 kg-m (0-40 lb-ft) or equivalent
- Sockets and ratchet driver appropriate to type of wall mounting
- Fluke model 73 DVM equivalent or better
- Small test clips (such as Pomono Electronics Minigrabber Test Clip Model 6248 or Radio Shack Mini-Hook Adapters catalog #270-334)

Items needed only for the metal stud wall mount:

- 2.5-cm (1-in) hole saw
- Dry wall saw
- 0.64 cm (1/4-in) diameter, 30.5-cm (12-in) drill bit
- Two 4×4 wood studs
- Drywall screws

Continued

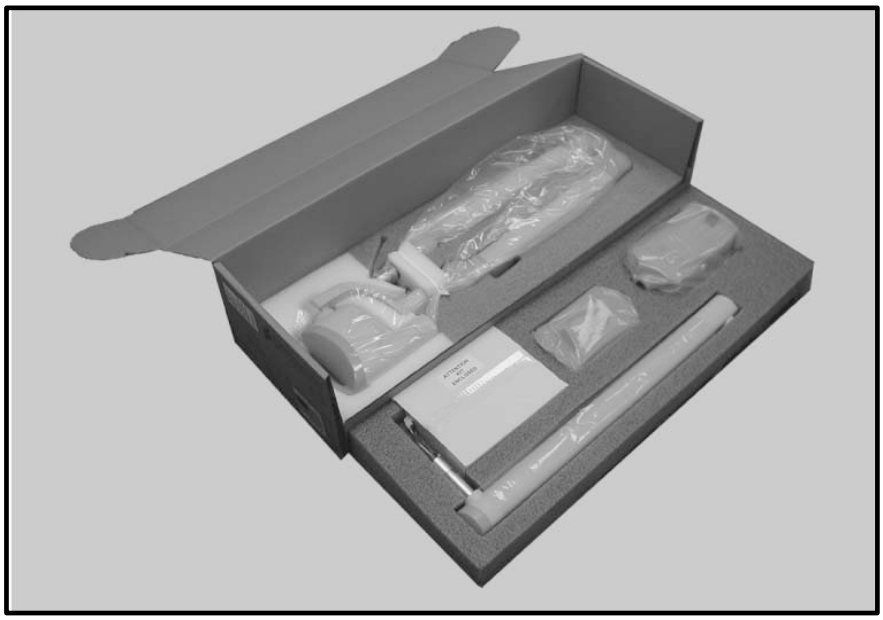
Installation Procedures – Wall-Mount Configurations (Cont.)

Installation Time

The Preva Dental X-ray System has been designed to be installed by one person in less than one hour, assuming that all pre-installation requirements have been met.

Open the Shipping Carton

The Preva is shipped in a convenient two-level carton as shown below.



The first level contains the items needed for the first part of the installation, including the Control Unit, Operator Panel, Horizontal Arm, mounting template, documentation, cables, packets containing the mounting hardware, brake assembly, plastic covers, and additional hardware.

The second level contains the Articulated Arm and the Tube head Assembly. These parts can remain in the shipping carton until installation.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

Packing List

Part Number	Description	Quantity
30-A1028	Articulated Arm and Tube head Assembly	1
30-A1025	Control Unit Assembly	1
30-A2076	Operator Panel	1
30-P0029	Operator Panel Mounting Cradle	1
30-A2244	Preva Mounting Hardware Kit	1
30-A2156	Preva Plastic Covers / Brake Kit	1
30-A2077	Two-Stud Mount Assembly (Optional)	1
30-A2040	Hand Switch Assembly (Optional)	1
E1-13052	Line Cord 1.83 m (6 ft)	1
30-A2228	Modular BLD, 60 mm Cone	1
30-A2221	Modular BLD, 35 mm × 45 mm Cone	1
E1-13004	Cable, 8 Cond. 15 cm (0.5 ft)	1
E1-13003	Cable, 8 Cond. 762 cm (25 ft)	1
30-A2218	Preva Documentation Kit	1
Note: Shipment contains one of the following Extension Arms Per Order		
30-A2071	Extension Arm, Long	1
30-A2073	Extension Arm, Short	1
30-A2074	Extension Arm, Compact	1
30-A2164	Extension Arm, Extra Long	1
Options		
E1-13049	8 Cond. RJ45 to RJ45 15 m (50 ft)	1
60-A2182	Remote Exposure Station Assembly	1
30-A2198	20 cm (8-in) Rectangular Cone, 30 × 40 mm	1
22-11466	8 mm (0.3 in) Adjustment Wrench	1
22-11467	Fluorescent Screen	1
30-A2099	4×4 Mount Kit	1

Installing the Control Unit

Single-Stud Wood Wall Installation

Installation Guide 30-P0076 (shown below) is an aid for positively locating the center of 2×4 wooden studs. The Installation Guide is a necessary part of the installation and ***must*** be used whenever single-stud installations are performed.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

The Installation Guide is equipped with side tabs which can be removed if its placement is obstructed by an electrical box. During installations that include attachment to a 4×4 wooden stud, all of the tabs on one side of the Installation Guide can be removed to facilitate placement and attachment.

⚠WARNING

- Do not attach a system with a 208 cm (82 in) reach to a wall in the single-stud configuration. Refer to the dual-stud configuration sections of this manual.
- Use the provided fasteners to fasten the system to metal supports. Do not use lag screws. Refer to the metal stud wall sections of this manual.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

1. Locate the wooden stud.

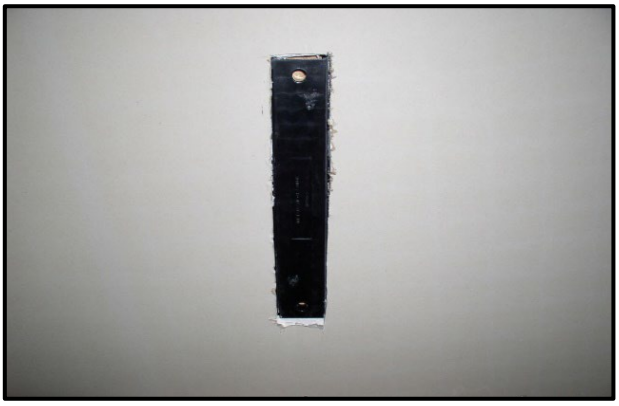
2. Make a small opening in the wall to positively identify the position of the wooden stud.

3. Draw an outline of the Installation Guide 30-P0076 on the wall, ensuring that the vertical height matches the requirements set forth on the Wall Mount Template (30-S0003). Use a level as needed to ensure the placement is straight. Open the wall so that the installation guide can rest directly on the wooden stud.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

4. Place the Installation Guide 30-P0076 on the wooden stud. Use a hammer to embed the built-in nails into the stud.



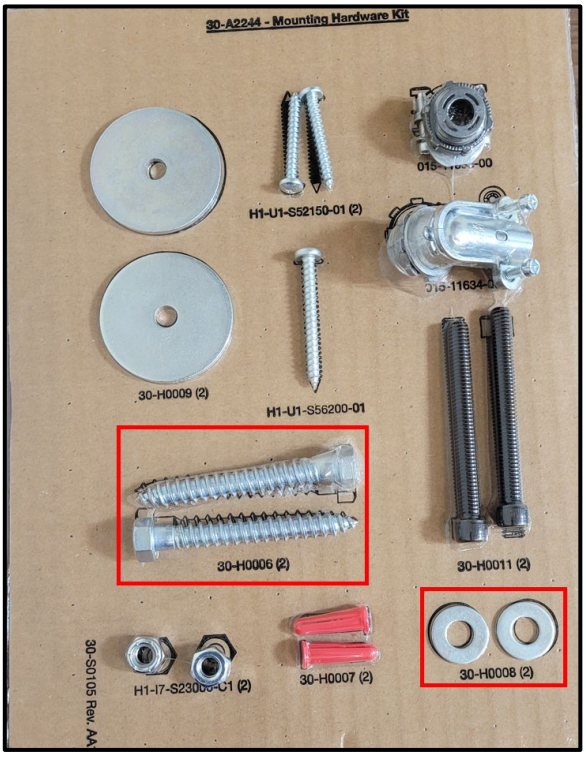
5. Drill two 6 mm (1/4-in) diameter holes using the Installation Guide as a drill template. Leave the Installation Guide in place.

⚠WARNING To avoid drilling into electrical wiring behind the drywall, drill only through the Installation Guide.

6. Locate the Control Unit in the first level of the shipping carton.
7. Remove the Phillips screw from the front cover of the Control Unit. Carefully remove the front cover. Place the front cover and the screw in a safe location for later reassembly.
8. From hardware kit 30-A2244, select the 1 cm × 7.6 cm (3/8 in × 3 in) long lag screws (30-H0006) and washers (30-H0008). See image below.

Continued

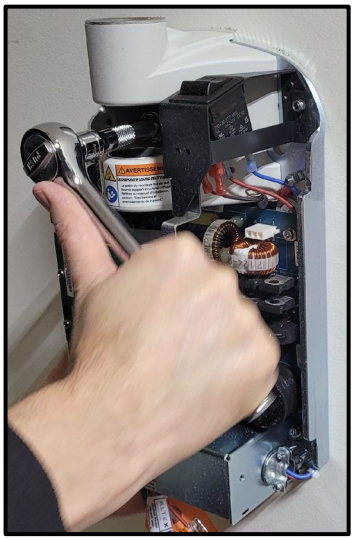
Installation Procedures – Wall-Mount Configurations (Cont.)



NOTICE

- If the surface of the Installation Guide falls below the surface wall, a correspondingly longer fastener must be chosen.
- For concrete walls, the installer must supply the appropriate mounting bolts.

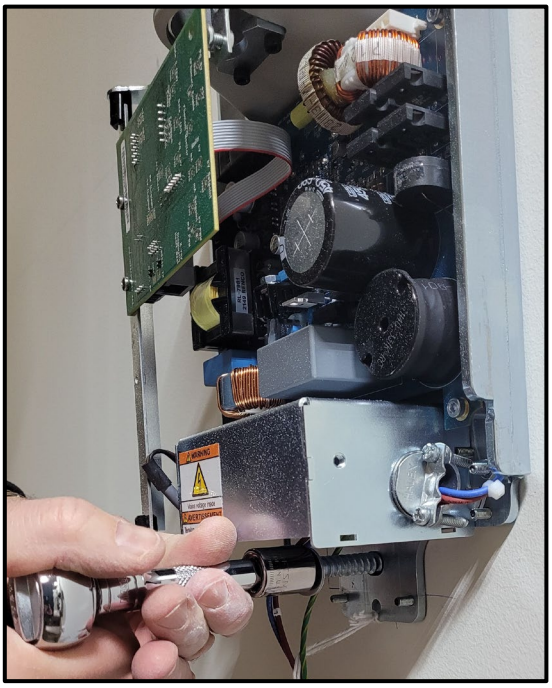
9. Put a lag screw and washer through the upper mounting hole of the Control Unit.
10. Ensuring that the Installation Guide is still in place, place the Control Unit on the wall and loosely tighten the upper mounting bolt.



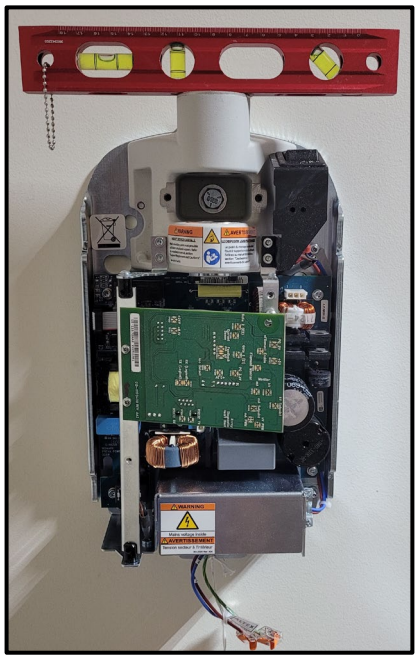
Continued

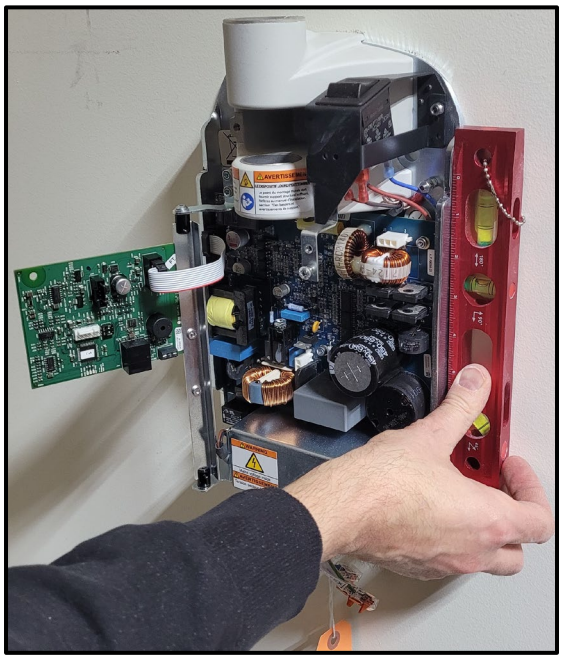
Installation Procedures – Wall-Mount Configurations (Cont.)

11. Put the remaining lag screw and washer through the lower mounting hole of the Control Unit and loosely tighten. Ensure that the power wire extends through the opening at the bottom of the Control Unit.



12. Place a level on the Control Unit bearing parallel to the wall as shown below. Level the Control Unit.





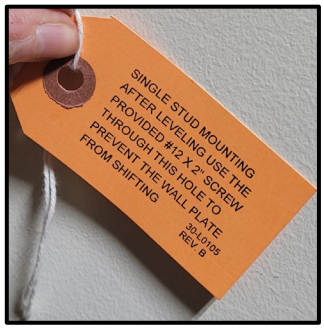
13. Tighten the upper and lower lag screws to 19 N·m — 24 N·m (14 lbs-ft — 18 lbs-ft).

Continued

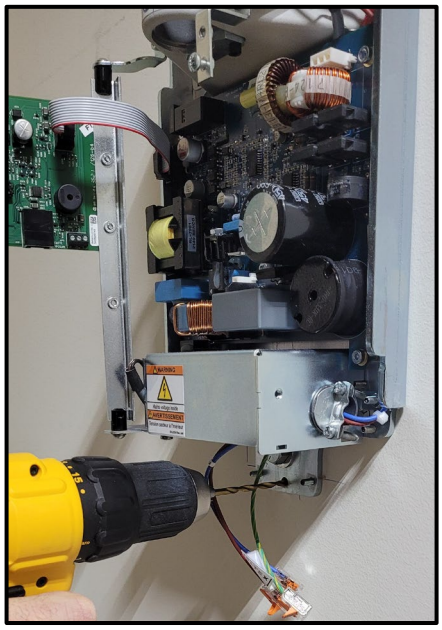
Installation Procedures – Wall-Mount Configurations (Cont.)

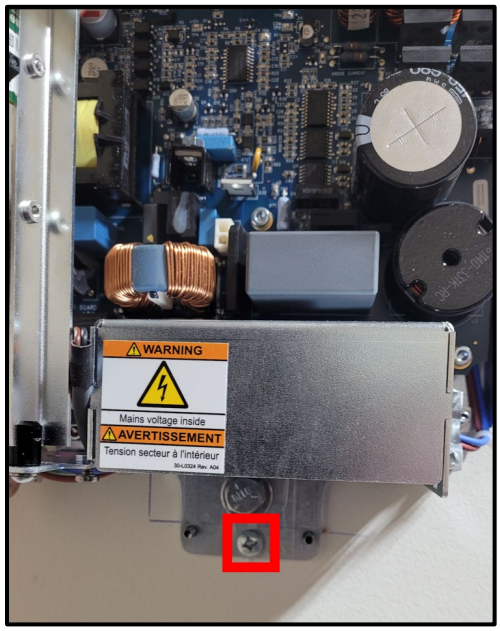
> **⚠CAUTION** Over-tightening the lag screws will damage the wooden stud and reduce the holding force. Do not over-tighten them.

14. Remove the string and orange tag hanging from the bottom of the Control Unit.



15. Drill a hole for a #12 wood screw below the lower lag screw as shown below. The bit size is 4 mm (5/32 in). Install and tighten the wood screw (H1-U1-S56200-01) to prevent the unit from shifting.





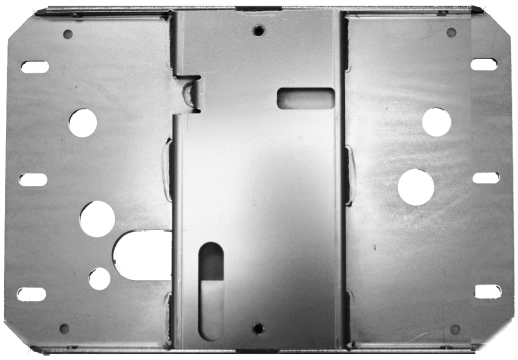
16. Continue to the section “Installing Horizontal Arm and Brake” beginning on page 95 of this manual.

Dual-Stud Wood Wall Installation

In the dual-wood wall stud installation, the Control Unit is bolted to a wall plate (30-A2042) that has been installed on two wood studs.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



The mounting template (30-S0003) is used to locate the wall plate mounting holes. Carefully placing the mounting template for two-stud mount installations on the wall will help ensure correct installation of the mounting plate and, hence, the Control Unit.

1. Use a stud finder to locate the center of the studs on which the wall plate will be mounted.
2. Place the mounting template for the two-stud mount on the wall with the lower mounting holes 102 cm (40 in) above the floor.
3. Place a level parallel to the vertical lines on the mounting template and adjust the mounting template until it is plumb.
4. Tape the mounting template to the wall.
5. Using an awl or other sharp object, punch through the mounting template to mark the location of the mounting holes.
6. Drill 6 mm (1/4 in) pilot holes (for common pine studs) at the marked locations.
7. Remove the mounting template from the wall and save for future use.
8. Select the 3/8 in × 3 in long lag screws (30-H0006) and washers (30-H0008).
9. Put the lag screws and washers through the mounting holes on the wall plate and into the holes drilled into the walls using the mounting template. Loosely tighten. Be sure that the power wire extends through the opening in the wall plate.
10. Level the wall plate.
11. Tighten the lag screws to 2.0 – 2.5 kg-m (14 – 18 lb-ft).

⚠CAUTION	Over-tightening the lag screws will damage the wooden stud and reduce the holding force. Do not over-tighten them.

12. Locate the Control Unit in the first level of the shipping carton.
13. Remove the Phillips screw from the front cover of the Control Unit. Carefully remove the front cover. Place the front cover and the screw in a safe location for later reassembly.
14. Select the 5/16 in-18 × 7/8 in long socket cap screws (H1-15-S23088-01) and washers (H1-NA-S12000-01).

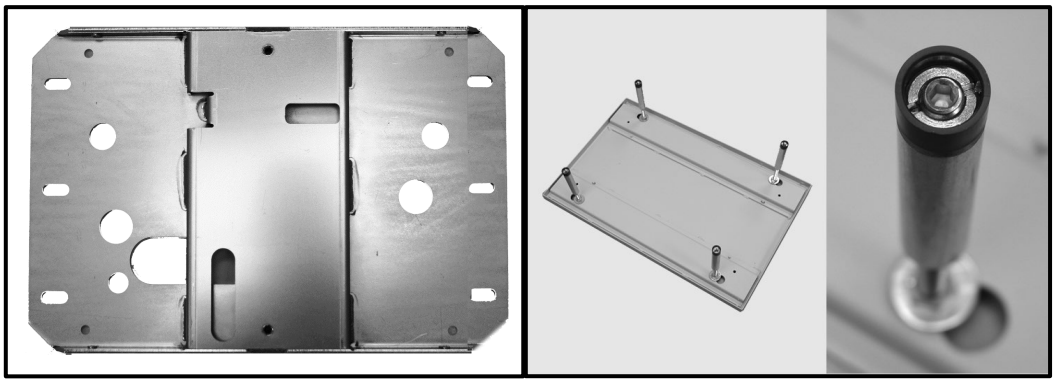
Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

15. Put one screw and washer through the upper mounting hole of the Control Unit.
16. Place the Control Unit on the wall and loosely tighten the upper screw.
17. Put the other screw and washer through the lower mounting hole of the Control Unit and loosely tighten. Be sure that the power wire extends through the opening at the bottom of the Control Unit.
18. Place a level on the Control Unit bearing parallel to the wall. Level the Control Unit.
19. Tighten the upper and lower screws.
20. After the control unit is installed, slide covers on the wall plate and fasten with the provided eight screws (H1-64-S17050-01).
21. Continue to the section “Installing Horizontal Arm and Brake” beginning on page 95 of this manual.

Metal Stud Wall Installation

In the metal wall stud installation, the Control Unit is bolted to a wall plate (below, left) that has been installed to the support plate (below, right). The wall and support plates are shipped separately from the Preva unit.



The mounting template (30-S0003) is used to locate wall plate and support plate mounting holes. Carefully placing the mounting template on the wall will help ensure correct installation of these plates and, hence, of the Control Unit.

1. Use a stud finder to locate the center of the studs on which the Control Unit will be mounted.
2. Place the mounting template for the dual-stud mount on the wall with the lower mounting holes 102 cm (40 in) above the floor.
3. Place a level parallel to the vertical lines on the mounting template and adjust the mounting template until it is plumb.
4. Tape the mounting template to the wall.
5. Using an awl or other sharp object, punch through the mounting template to mark the location of the mounting holes.
6. Drill 6 mm (1/4 in) pilot holes at marked locations.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

7. Drill 2.5 cm (1 in) clearance holes.
8. Remove the mounting template from the wall and save for future use.
9. Cut a 15 cm × 25 cm (6 in × 10 in) access hole between the clearance holes.
10. Insert two wooden studs or other filler material in the access hole. The filler material prevents the metal stud wall from being crushed during installation. Attach the studs to the rear drywall surface with drywall screws.

> **⚠CAUTION** The metal stud wall must be secure to hold a load of 127 kg.m (920 ft·lbf).

11. Put the small, then the larger washers and nut on each of the four carriage bolts.
12. Insert the carriage bolts into the support plate holes.
13. Screw the threaded standoffs onto the carriage bolts with the slotted ends away from the back plate.
14. Place the plastic sleeve bearings in the slotted ends of the carriage bolts.
15. Using a 5/32 in Allen key, insert a set screw into each threaded standoff. Screw the set screw until just below the slot in the threaded standoff, but do not tighten.
16. Using two sheet metal screws, mount and level the support plate through the pilot holes on the back side of the wall. Tighten the sheet metal screws with the screwdriver.
17. On the front side of the wall, use a flat screwdriver to adjust the threaded standoffs until the plastic part is flush with the drywall.
18. Tighten the set screws in the threaded standoffs to lock them in place.
19. Select the 5/16-18 in × 1 in long hex bolts (H1-00-S23100-01).
20. Put the hex bolts through the mounting holes on the wall plate and loosely tighten. Be sure that the power wire extends through the opening in the wall plate.
21. Level the wall plate.
22. Tighten the hex bolts.
23. Remove the Control Unit from the first level of the shipping carton.
24. Remove the socket flathead screw from the front cover of the Control Unit. Carefully remove the front cover. Place the front cover and the screw in a safe location for later reassembly.
25. Select the 5/16 in-18 × 7/8 in long socket cap screws (H1-15-S23088-01) and washers (H1-NA-S12000-01).
26. Put one screw and washer through the upper mounting hole of the Control Unit.
27. Place the Control Unit on the wall and loosely tighten the upper screw.
28. Put the other screw and washer through the lower mounting hole of the Control Unit and loosely tighten. Be sure that the power wire extends through the opening at the bottom of the Control Unit.
29. Place a level on the Control Unit bearing parallel to the wall. Level the Control Unit.

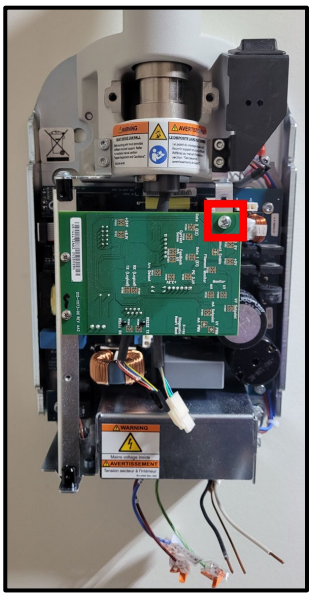
Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

30. Tighten the upper and lower screws.
31. After the control unit is installed, slide covers on the wall plate and fasten with the provided (8) screws (H1-64-S17050-01).

Installing Horizontal Arm and Brake

1. Remove the Horizontal Arm from the top level of the shipping carton.
2. Remove the red tag from the Horizontal Arm. Do not yet remove the braided sleeve around the wires.
3. Remove the screw from the logic control board. Swing the board outwards and out of the way.



4. Insert the braided sleeve into the shaft of the Horizontal arm.

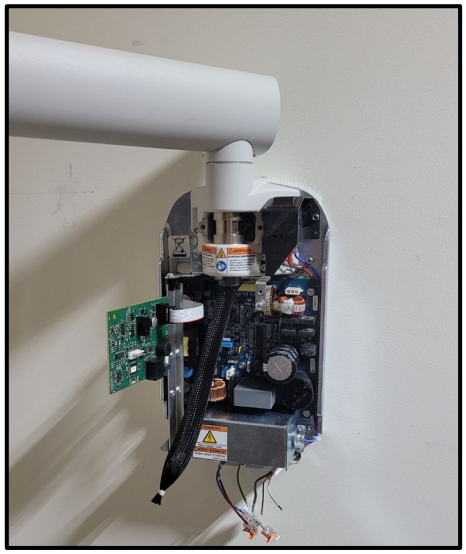
NOTICE	Do not lubricate the shaft of the Horizontal Arm or bearings in the Control Unit.

5. Insert the braided sleeve enclosing the wires into the opening in the top of the Control Unit.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

6. Insert the Horizontal Arm completely into the Control Unit as shown below. Ensure that the Horizontal Arm is firmly seated in place.



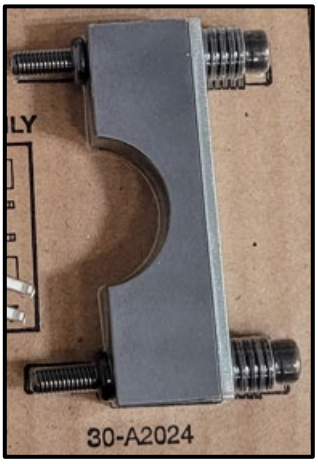
7. Remove the braided sleeve to free the wires. Discard the braided sleeve.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

NOTICE Do not make the wire connections at this time.

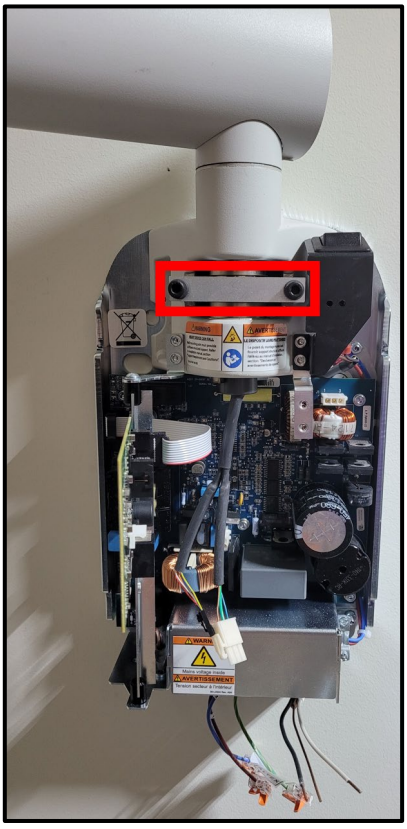
8. Locate the brake assembly 30-A2024 in the kit pack 30-A2244.



9. As shown below, install and loosely tighten the brake assembly in order to put a small amount of drag on the rotation of the Horizontal Arm and to keep the Horizontal Arm from lifting out.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



Installing Articulated Arm and Tube Head

The Tube head and Articulated Arm are installed as a single unit.

1. Remove the top-level packing material from the shipping carton to gain access to the Articulated Arm and Tube head Assembly.
2. Remove the red tag, but do not yet remove the plastic covering, the braided sleeve enclosing the cable wires, or the tie holding the Articulated Arm closed.
3. Remove the Articulated Arm and Tube head Assembly from the shipping carton.

⚠CAUTION	The Articulated Arm will spring open and potentially cause personal injury if the tie is removed. Do not remove the tie holding the Articulated Arm closed.

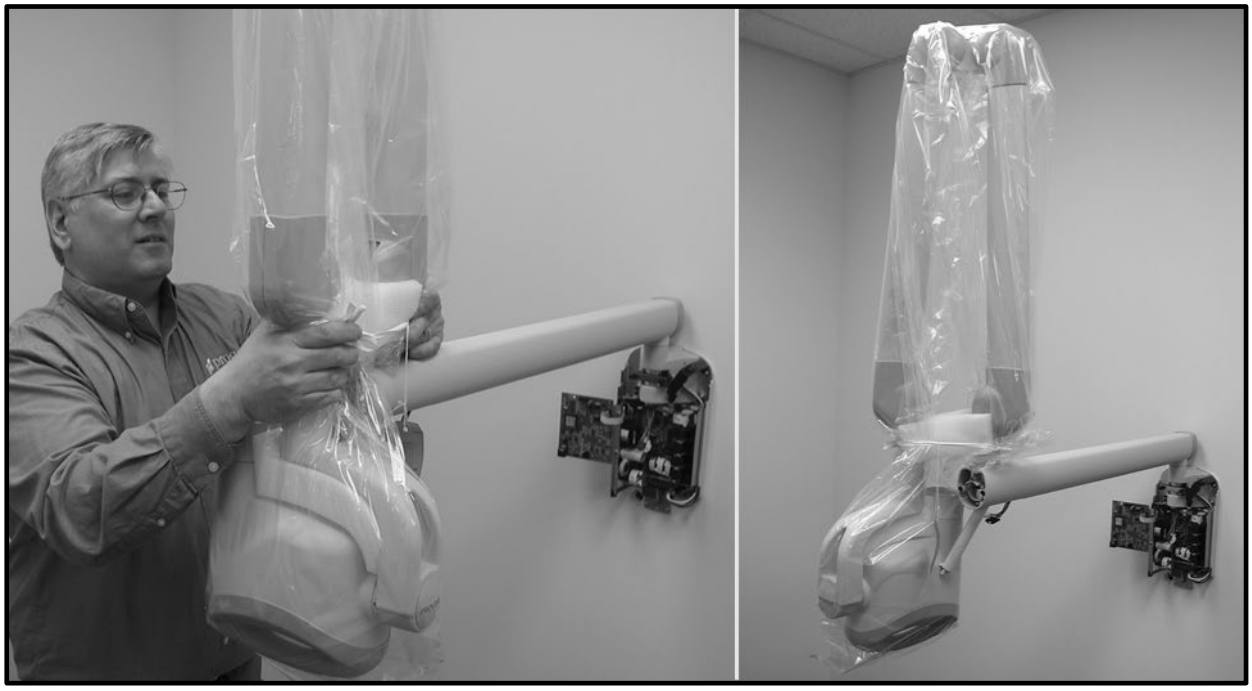
NOTICE	Do not lubricate the shaft of the Articulated Arm or the bearings in the Control Unit.

4. Position the Articulated Arm above the Horizontal Arm.
5. Carefully route the braided sleeve with the arm cable plug through the opening in the Horizontal Arm.

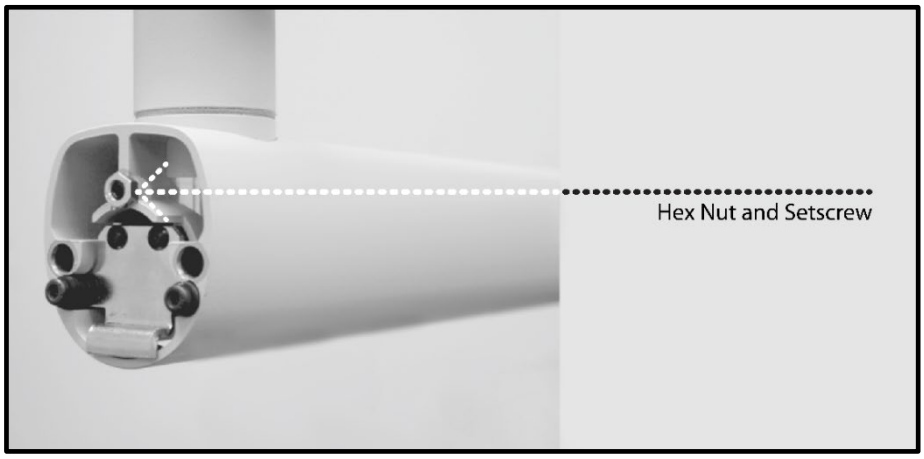
Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

6. Insert the shaft of the Articulated Arm into the opening in the Horizontal Arm as shown below.



7. Press down until the shaft is completely seated in the Horizontal Arm.
8. Remove the braided sleeve to free the wires. Discard the braided sleeve.
9. Untie the Articulated Arm and remove the plastic covering.
10. Locate the Articulated Arm brake assembly (30-A2068).
11. Insert the M6 × 25 mm (1 in) long set screw as shown below. Using a 3 mm hex key, tighten the screw fully, then back off 1/4 of a turn and secure with the hex nut.

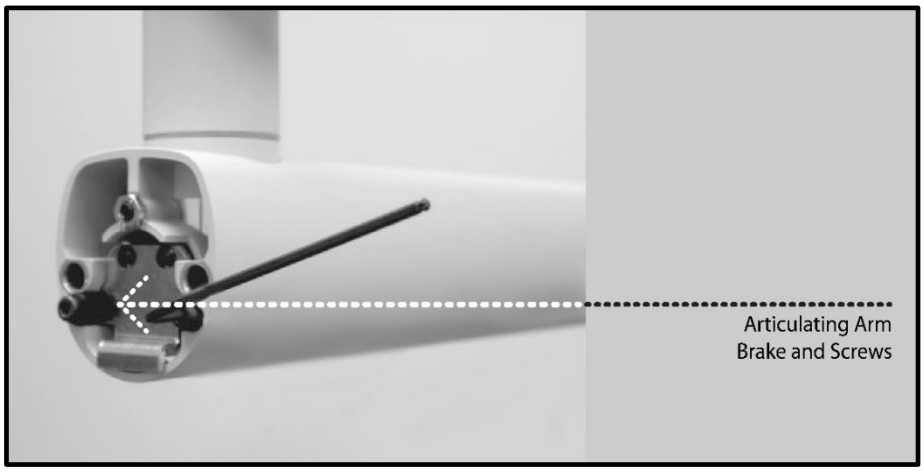


12. Using a 3 mm hex key, install the Articulated Arm brake. Tighten screws until the Articulated Arm brake contacts the shaft of the Articulated Arm. If additional friction is required to prevent

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

drifting, turn the two screws evenly approximately 1/4 of a turn at a time until drift stops, as shown below.



13. See the section “Mechanical Adjustments” beginning on page 225 of this manual for procedures to correct drift in the Articulated Arm.

Connecting the Cables

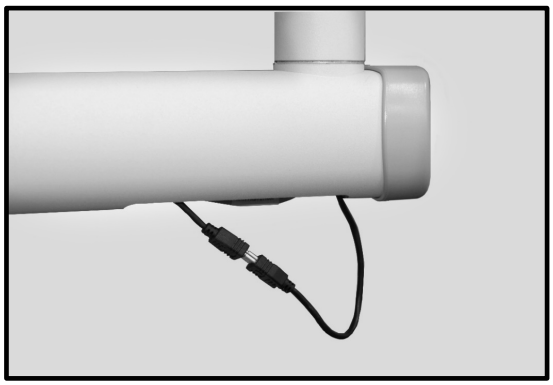
⚠CAUTION	Verify that the power switch is off before proceeding.

1. Connect the Articulated Arm cable to the Horizontal Arm cable as shown below.

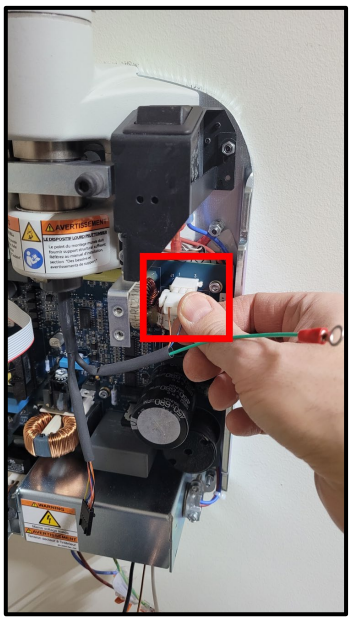
2. If present, connect the black sensor cable as shown below. (Note: Not all models will have this cable.)

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



3. Once the connections are made, dress the cables and push them into the opening in the Horizontal Arm.
4. Attach the white connector from the Horizontal Arm to point J1 on the Power Supply Board (30-08197), as shown below.

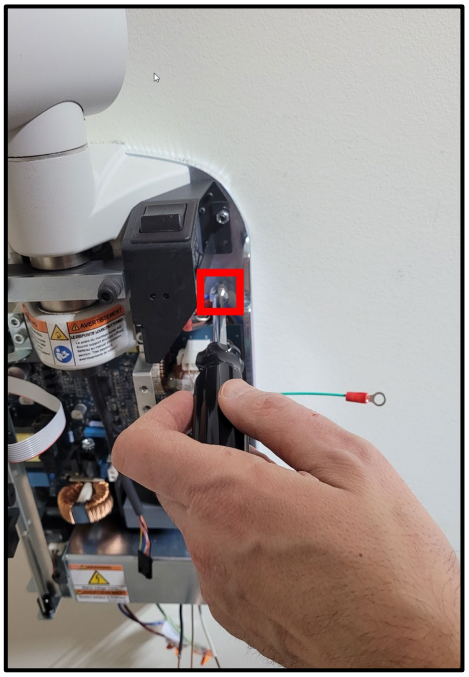


NOTICE The plug must be properly oriented. The tab must align with the latch.

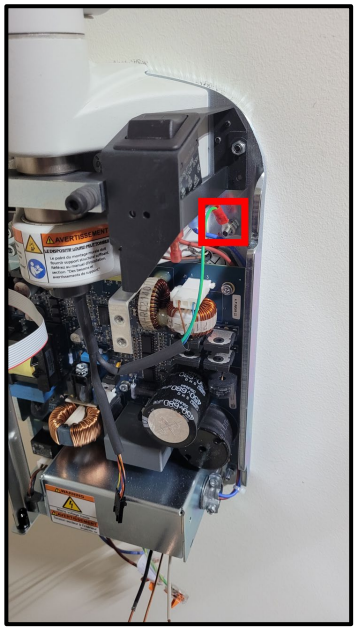
5. Remove the nut and the washer on the upper right side of the Control Unit as shown below. Keep them in a safe place for the next step.

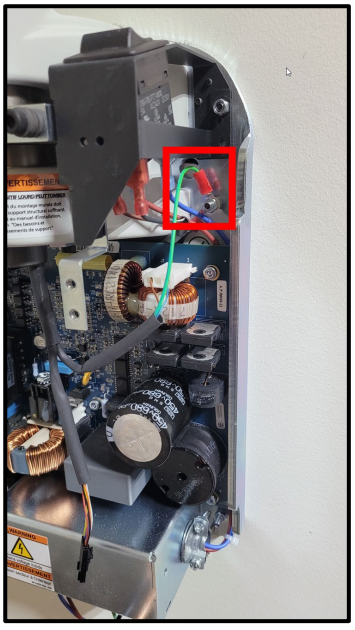
Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



6. Attach the ground ring terminal from the horizontal arm to the chassis as shown below. Reattach the washer and then the nut that were removed in step 5.

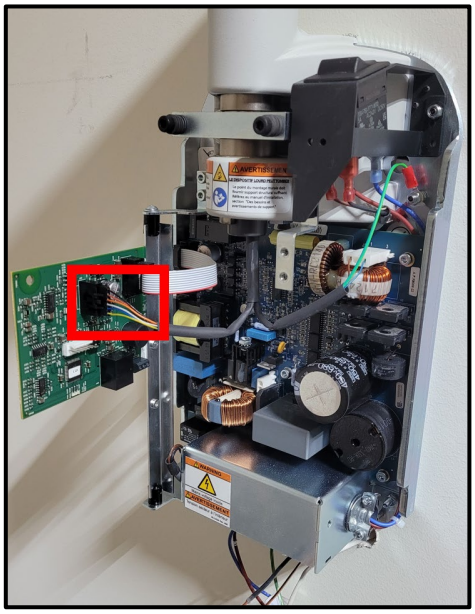




7. Attach the black connector from the Horizontal Arm to point J201 of the Logic Board (015-11172-00) as shown below.

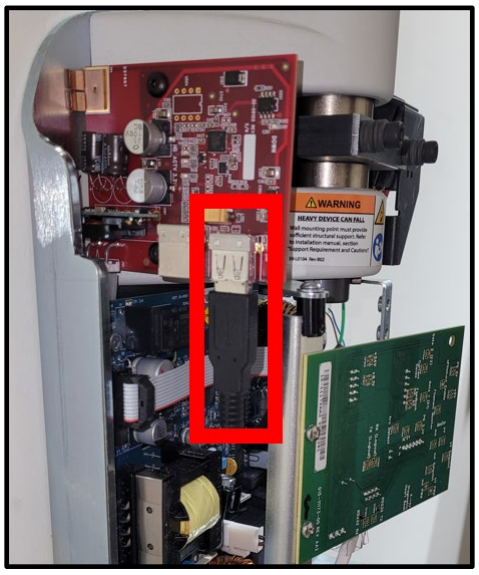
Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



NOTICE The plug must be properly oriented. The tab must align with the latch.

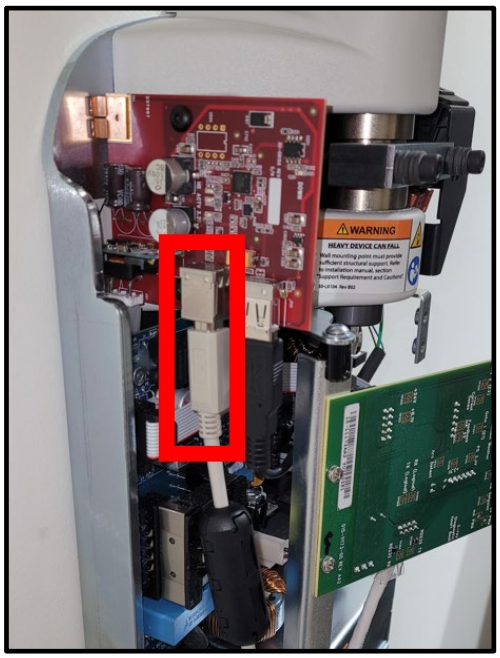
8. If the optional integrated sensor cable is present, plug it into the USB hub as shown below and proceed through the following steps. If not installing an integrated system, skip to step 12 below.



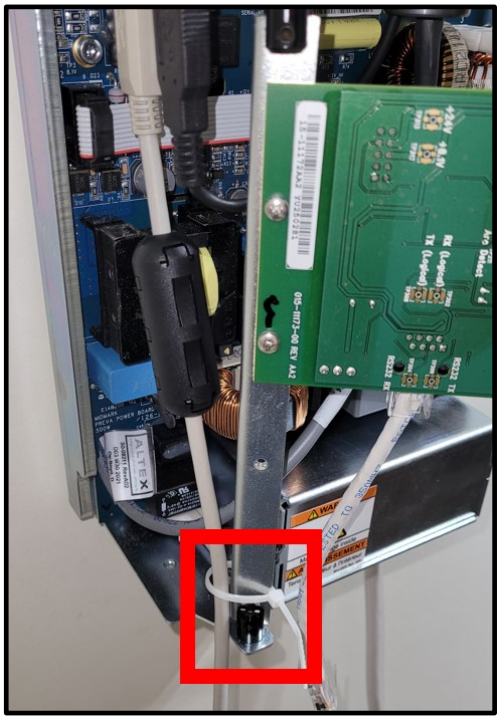
9. If installing an integrated system, connect the USB cable that will connect to the computer into the USB hub.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



10. If installing an integrated system, tie the USB cable to the base of the logic board bracket as shown below. Trim excess zip tie if appropriate.

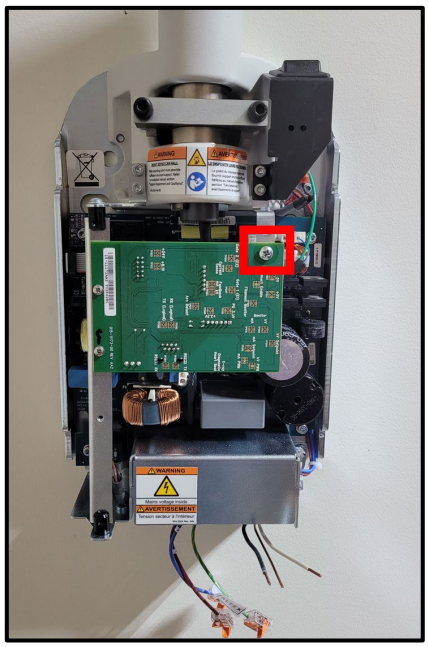


11. If installing an integrated system, use pliers to remove the notch in the middle of the bottom of the control unit cover as shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

12. Swing the logic board inward and reattach the screw. See below.



Connecting Power

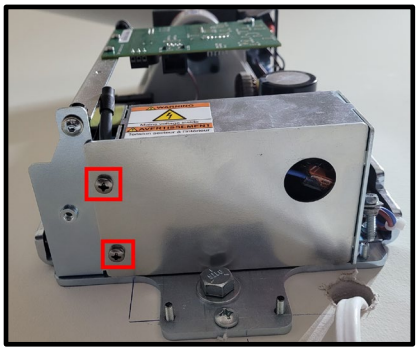
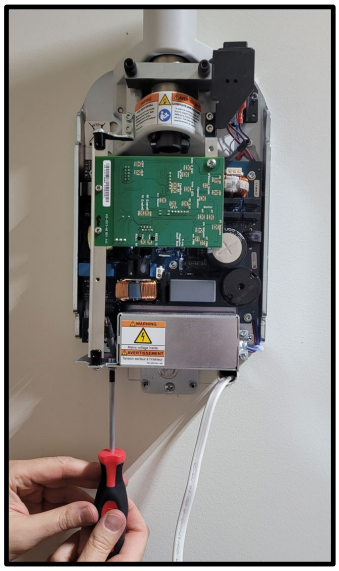
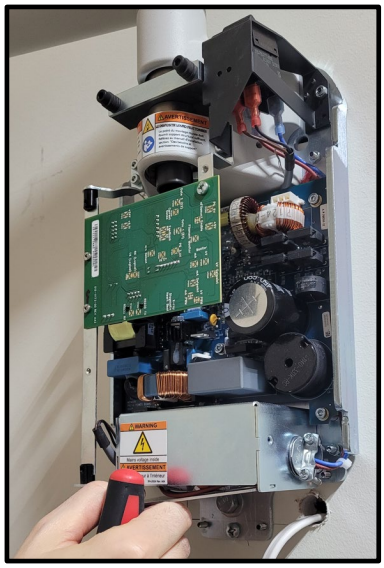
Connection to mains power must be performed by a qualified electrician. Follow all local safety regulations.

There are many similarities between installing a permanently wired system and installing a cord-connected system. The following steps are applicable to both types of installations.

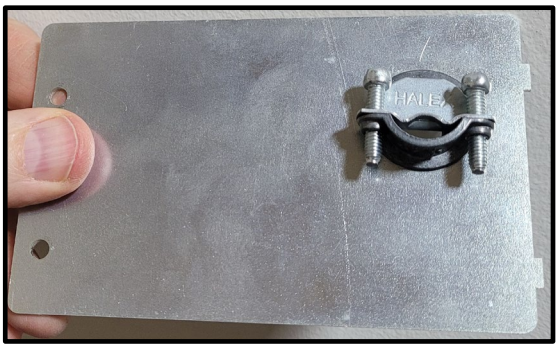
Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

1. Before beginning, power must be turned off at the circuit breaker.
2. Remove the appropriate cable clamp from the hardware kit. For a jacketed cable or the line cord provided with the unit, this will be a squeeze clamp (015-11633-00). For a flexible metal conduit, this will be 90deg Connector (015-11634-00). Depending on the type of wiring or cable used to carry the mains power to the unit, it is also possible that the installer may need to provide the correct clamp/connector.
3. Using a Phillips head screwdriver, remove the junction box cover (30-F4058) by removing the two screws as shown below.

4. Attach the appropriate clamp to the 1.3 cm (1/2 in) knockout located in 30-F4058 as shown below. (This example shows 015-11633-00.)

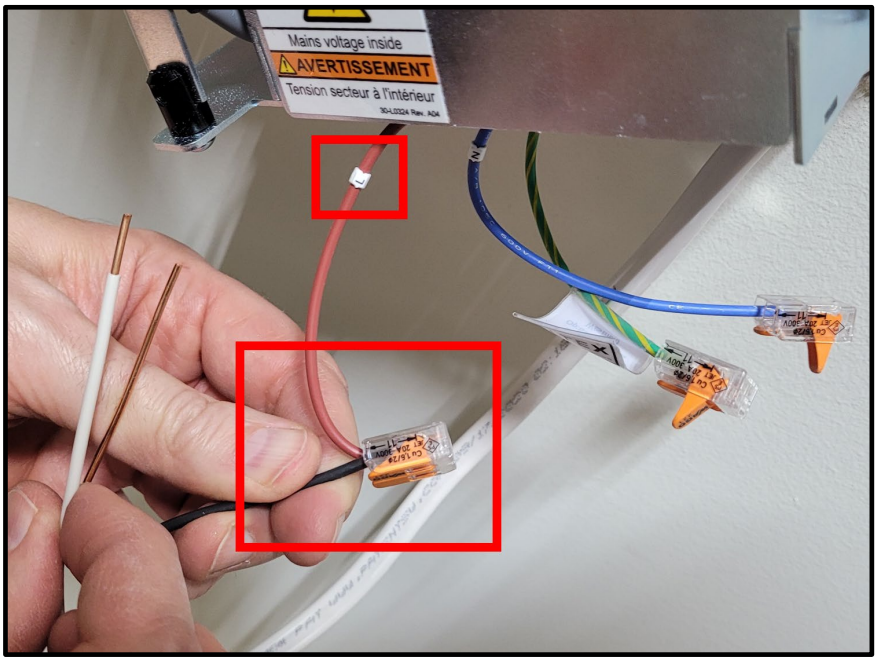



5. Route the line cord or wiring through the clamp.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

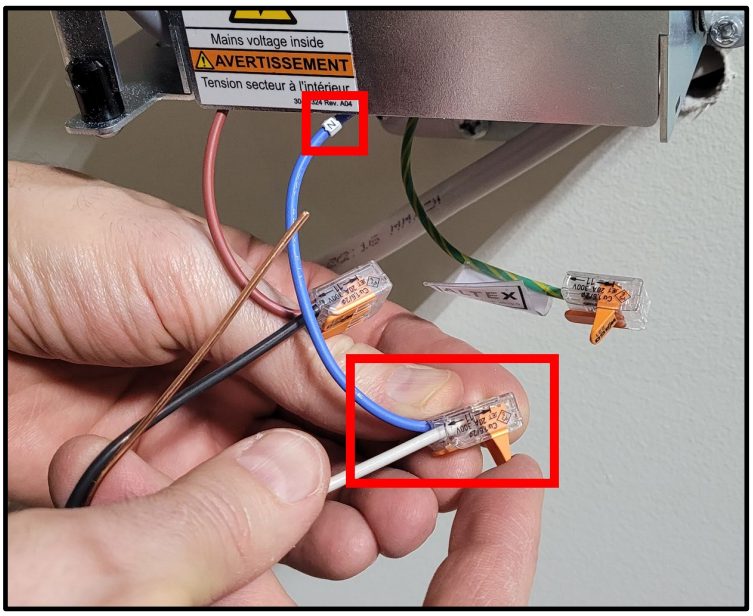
6. Attach the hot (black or brown) wire of the mains to the brown connection identified as L inside the junction box. Flip up the levers of the splicing connector (015-11629-00) to insert the wire as shown below. Once inserted, flip the level down to secure the connection.



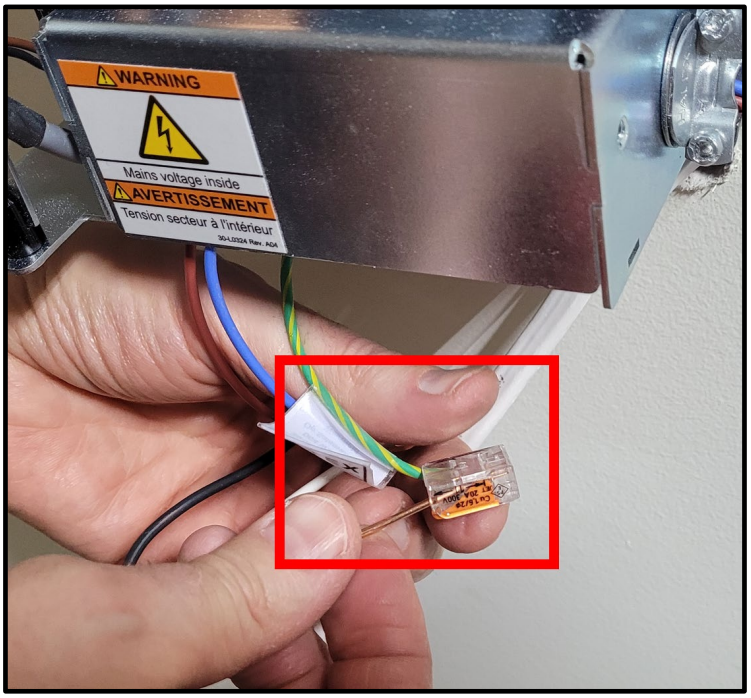
7. Attach the neutral (white or blue) wire of the mains to the blue connection identified as N inside the junction box as shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



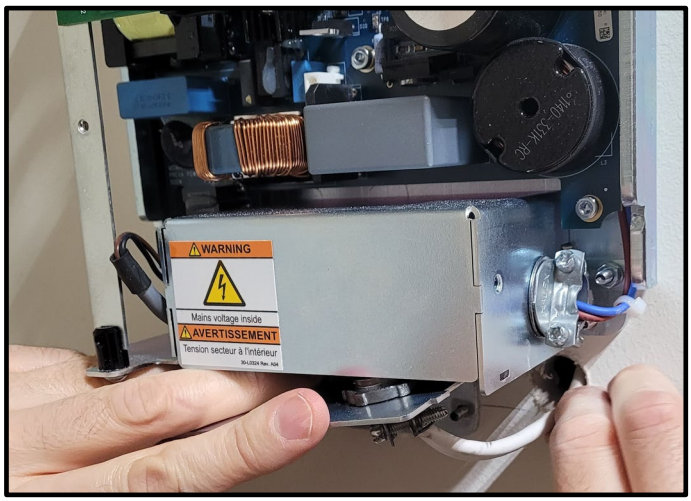
8. Attach the ground (e.g., bare copper or green/yellow) wire of the mains to the green-and-yellow-striped connection inside the junction box as shown below.



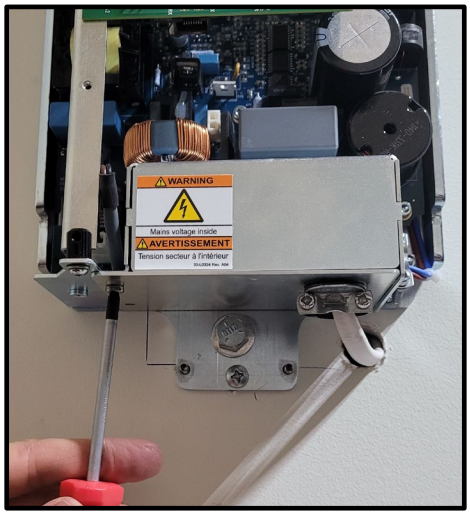
9. Carefully dress the cables as needed. Push the connections into the junction box and the mains cable into the wall as shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



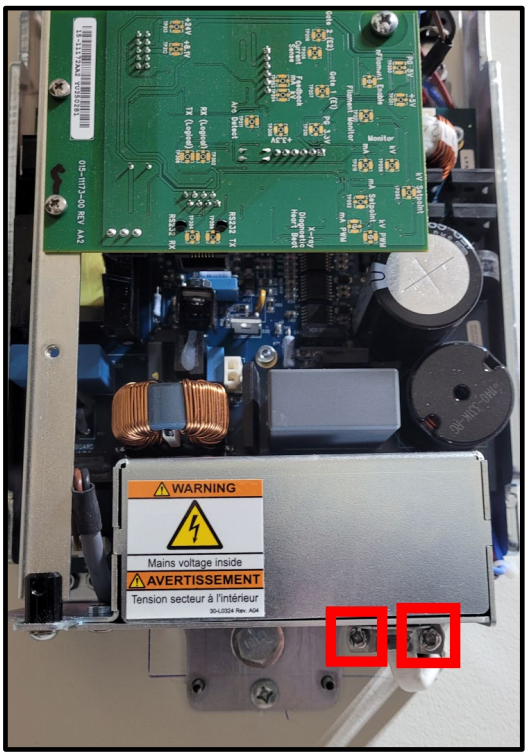
10. Reattach the junction box cover (30-F4058) to the junction box and secure it with the two screws that were previously removed.



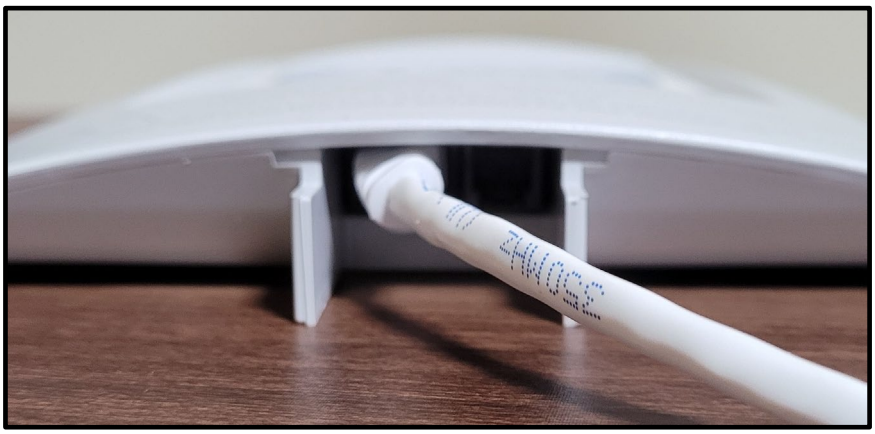
11. Use a screwdriver to secure the two screws on the cable clamp shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



12. Identify the Operator Panel and the 7.6 m (25 ft) interconnect cable.
13. Plug the cable into the left socket at the base of the Operator Panel as shown below (Operator Panel viewed from below).



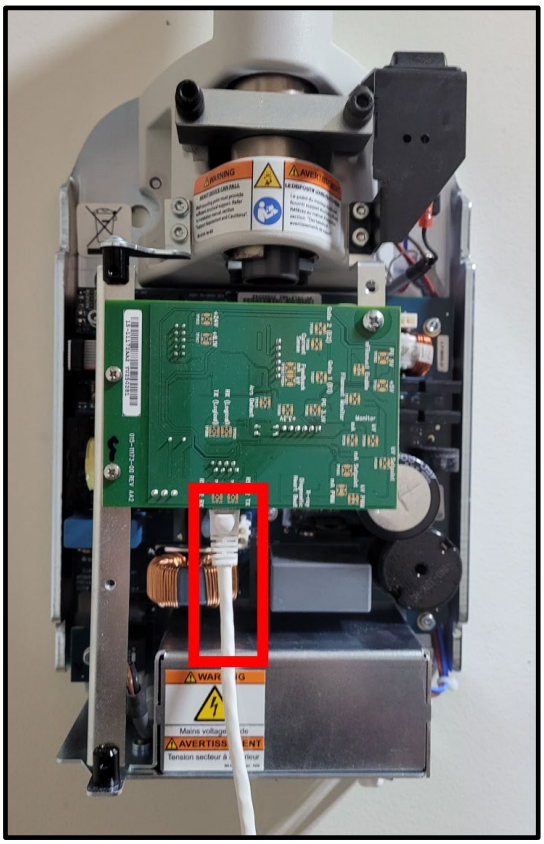
NOTICE

The Operator Panel is required during initial power-up and verification. The connection to the 7.6 m (25 ft) interconnect cable is temporary in the case of Operator Panels installed on the control unit. The Operator Panel will be connected in its final position for use later.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

14. Plug the other end of the cable into connector J401 on the Logic Board 015-11172-00 as shown below.



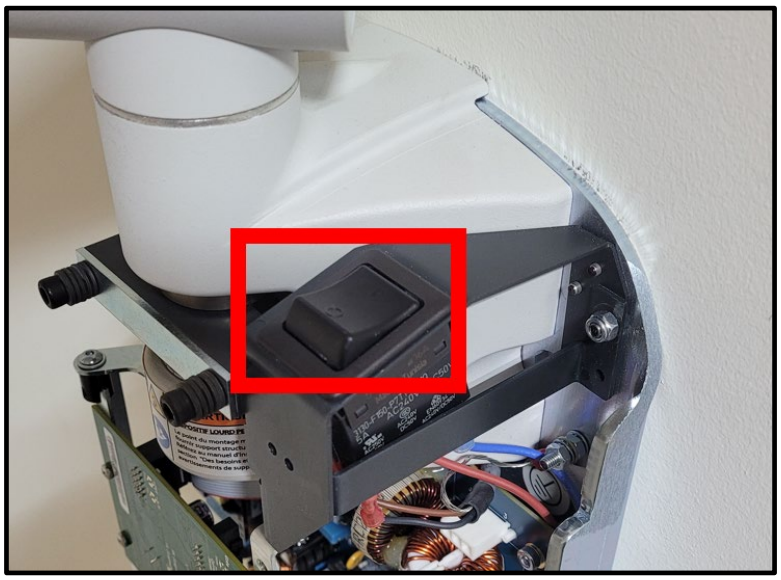
Electrical Verification

NOTICE Calibration of the Preva is preset at the factory and is not required during initial installation. Service replacement of the Logic Board 015-11172-00 or the Tube head may require calibration. See the section “Calibration” beginning on page 192 of this manual.

1. Turn on the Preva using the power switch as shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



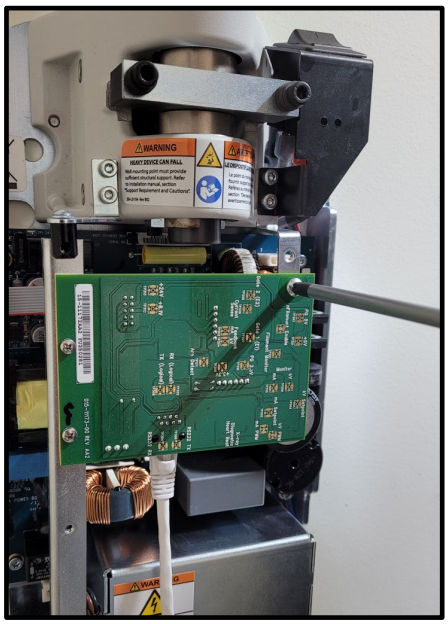
2. On the Operator Panel (see below), the product display screen will show the software version. Then it will display the default technique factors. Icons will illuminate.

⚠CAUTION	The power supply board (30-08197) contains high electrical energy when energized. Avoid contact with this board. After the system is turned off, electrical energy will remain in the power supply board for several minutes. Before performing any service on this board, first verify that voltage has dissipated.

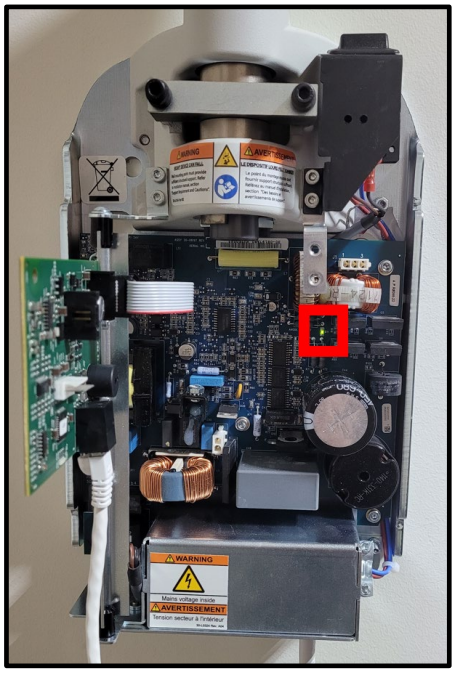
3. Remove the screw holding the Logic Board in place and swing the logic board outwards.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



4. On Power Supply Board 30-08197 (shown below), verify that LED D11 is illuminated. The illuminated LED indicates that supply voltage is present.

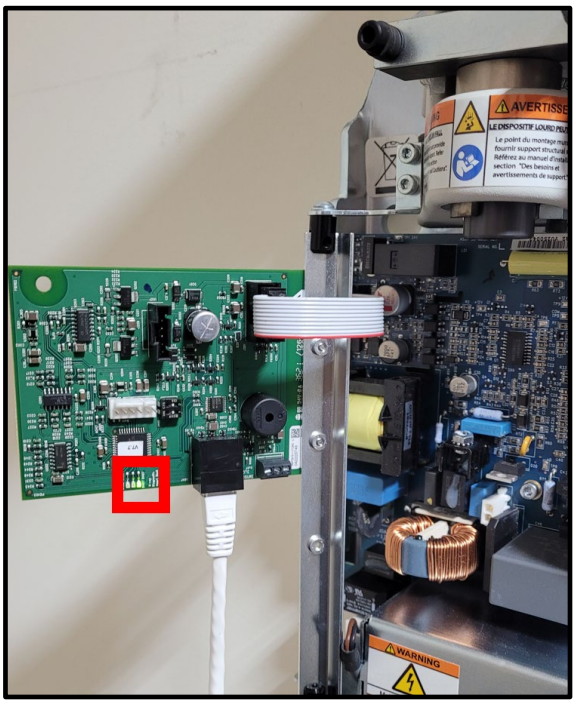


NOTICE Stored electrical energy is present whenever D11 is illuminated.

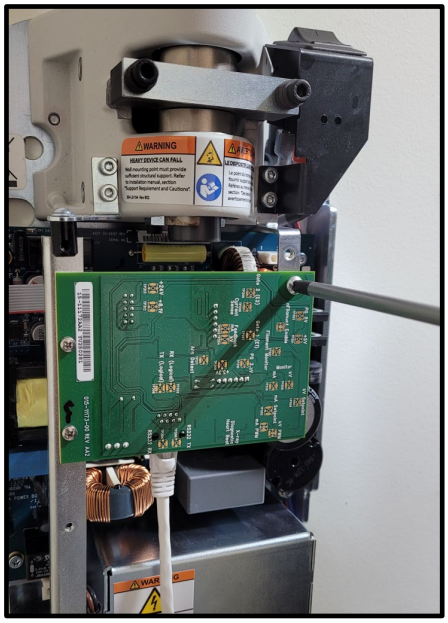
5. On the Logic Board 015-11172-00, verify that LED D402 is flashing as shown below. If the LED is not flashing, refer to the “Power is ON but no Operator Display” procedure beginning on page 199 of this manual.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



6. Swing the Logic Board inwards. Replace and secure the screw to hold it in place.



7. Turn off the Preva using the power switch as shown at the beginning of this section.

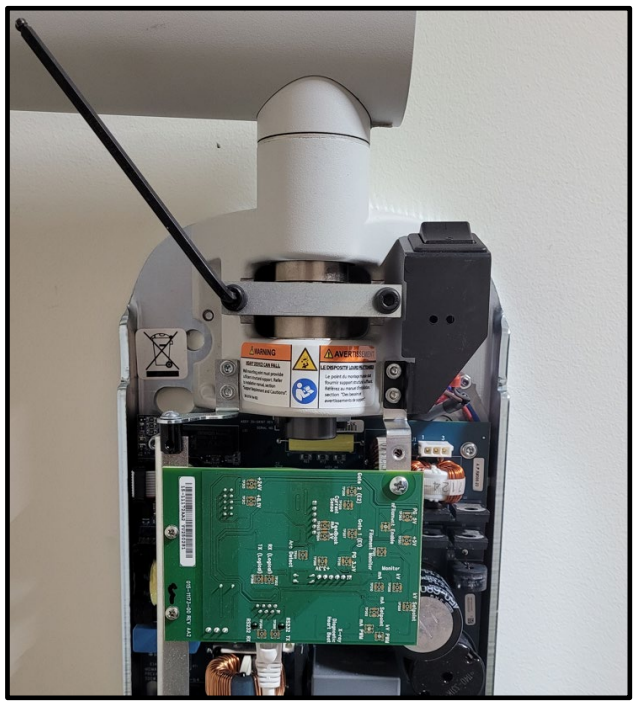
Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

Mechanical Adjustments

Horizontal Arm Adjustment

1. Locate the brake assembly at the top of the Control Unit. The brake assembly has a screw on either side of a clamping bar over the Horizontal Arm pivot post.
2. Using a 4 mm hex key, as shown below, tighten the screws equally to apply adequate braking to the pivot post so that the Horizontal Arm begins to move after the Articulated Arm.



Additional Adjustments

The balance and friction of the Articulated Arm are pre-set at the factory. During the installation process, check the balance and friction. When moving the Tube head, the Articulated Arm should be steady in all positions and move before the Horizontal Arm. If adjustments are necessary, follow the adjustment procedures in the section “Mechanical Adjustments” beginning on page 225 of this manual.

NOTICE	Do not use mechanical adjustments to compensate for a system that is not properly leveled on the wall.

Installing Control Unit Cover and Operator Panel

The Operator Panel can be installed on the Control Unit or in a separate location. Installation of the Operator Panel on the Control Unit may require the purchase and use of the coil-cord hand switch option (30-A2040 or 30-A2040-W).

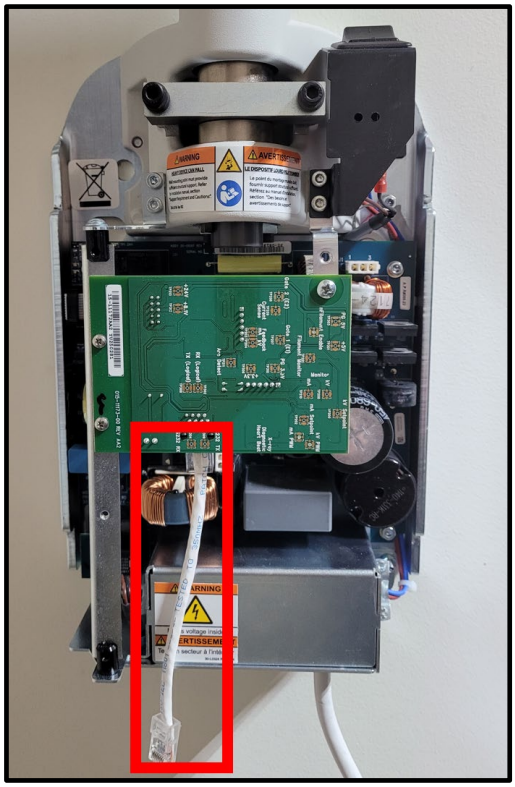
Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

NOTICE In order to comply with the regulations and proper X-ray practices, the Operator Panel must be located where the operator can view both the patient and the exposure factors prior to the exposure.

Installing Operator Panel on the Control Unit

1. Connect the short cable at point J401 on the Logic Board 015-11172-00.



2. Feed the cable through the front cover of the Control Unit.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

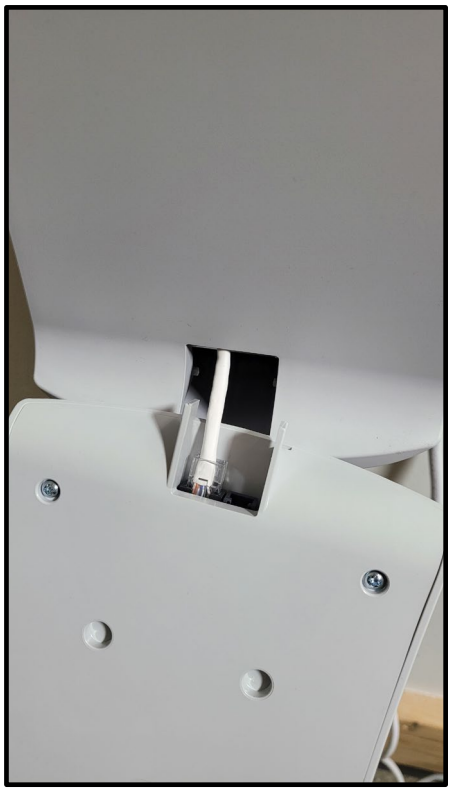
3. Replace the Control Unit cover beginning at the top, being careful of the power switch and cover alignment, as shown below.

4. Replace the screw on the front cover of the Control Unit.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

5. Plug the cable into the bottom of the Operator Panel.



6. Snap the Operator Panel into place on the front cover of the Control Unit as shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

Installing Operator Panel Remotely

For remote Operator Panel installations, a mounting cradle is used for wall attachment.

1. Place and level the mounting template (30-S0003) at eye level in the location where the Operator Panel is to be installed. Tape the mounting template to the wall.
2. Using an awl or other sharp object, punch through the mounting template to mark the location for the screws for the Operator Panel mounting cradle.
3. Drill pilot holes at marked locations. With a drywall knife, cut an opening as shown on the mounting template.
4. Remove the mounting template from the wall.
5. Using the anchors and screws from the mounting hardware packet, install the Operator Panel mounting cradle in the position marked.
6. Locate the 7.6 m (25 ft.) remote control cable.
7. Route the remote control cable, in compliance with local codes, from the intended location of the remote Operator Panel to the back of the Control Unit.

> **NOTICE** The cable can also be run to an electrical box or opening at the top left of the wall plate assembly. A sufficient length of cable should be left available to bring the remote cable out to the bottom front of the Control Unit.

8. Plug the remote control cable into the bottom of the Logic Board 015-11172-00.
9. Attach the Control Insert into the Control Unit Cover as shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

10. Replace the Control Unit cover beginning at the top as shown below, being careful of the power switch and cover alignment.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

11. Replace the screw on the front cover of the Control Unit.

12. Attach the Panel Insert Plug to the Control Unit Cover so that the Midmark logo is oriented as shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)

13. Locate the Operator Panel in the top portion of the shipping carton.
14. Connect the other end of the remote cable to the right plug (as viewed from the back) on the bottom of the Operator Panel.
15. Carefully dress the white cable back into the wall.
16. Snap the Operator Panel to the mounting cradle as shown below.

Installing Plastic Covers

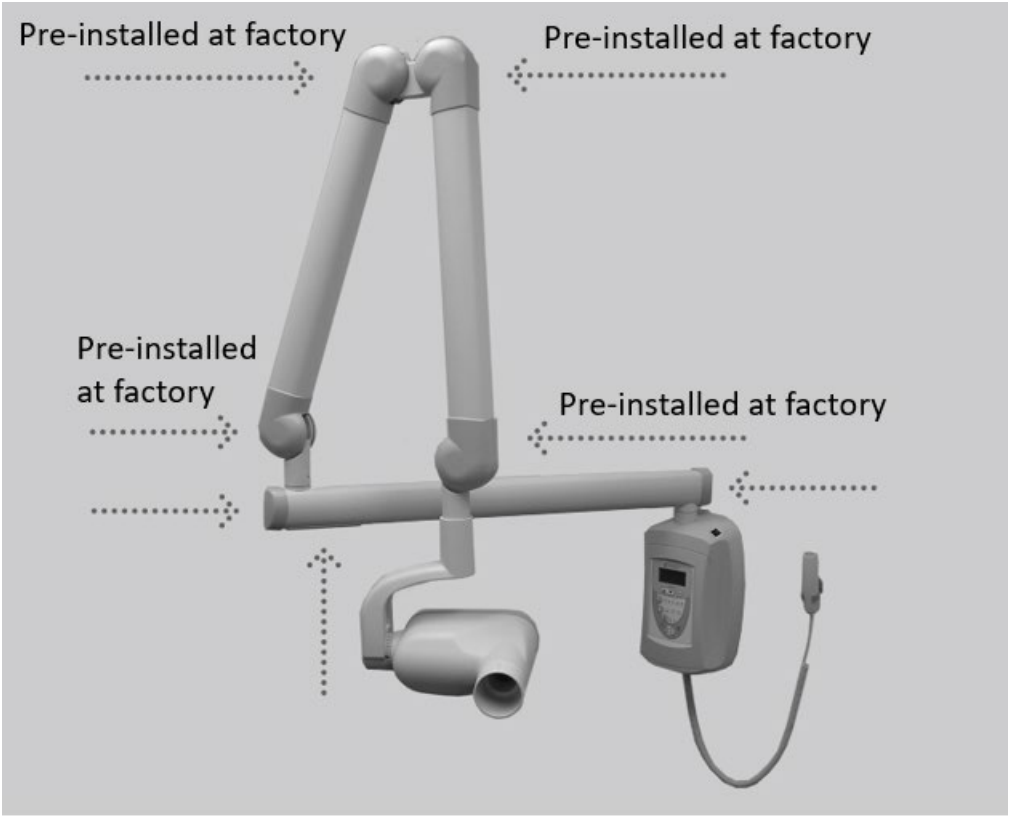
The end cap for the Horizontal Arm is shipped in the kit of plastic parts and is put on as part of the installation procedure. The cable access cover is placed over the cable connection underneath the Horizontal Arm.

End caps for the Articulated Arm are shipped installed but are removable to perform mechanical adjustments.

Cover locations are shown below.

Continued

Installation Procedures – Wall-Mount Configurations (Cont.)



1. Place the plastic covers from the kit on the ends of the Horizontal Arm.
2. Install the cable access cover over the Horizontal Arm opening using two Phillips flat-head screws.
3. If any of the optional installation procedures are being utilized, proceed to the next section. If installation is complete, proceed to the section “Function Readiness Checklist” beginning on page 255 of this manual.

Installation Procedures – Mobile Configuration

Mobile Assembly Parts List 126
Assembling the Mobile Unit 127
Tools Required 127
Instructions 127

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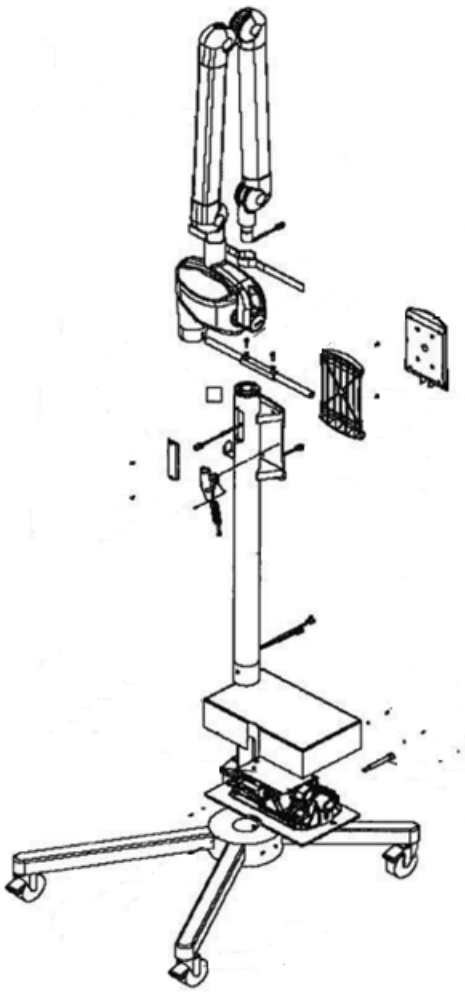
Installation Procedures – Mobile Configuration (Cont.)

Mobile Assembly Parts List



Description	Part Number	Quantity
Velcro Strap	30-A2093	1
Screw	H1-15-M16020-10	2
Mobile Stand Handle w/Grips	30-A2111	1
Operator Panel	30-A2076	1
Screw	H1-61-M13008-01	2
Cradle	30-M3010	1
8 Conductor RJ45 to RJ45 Cable, 2 m	E1-13029	1
Column	30-M0045	1
Screw	H1-61-M05008-01	5
Washer	H1-P2-M04000-01	5
Column Screw	30-M0046	1
Caster, Swivel w/Brake	30-S0036	4
Mobile Stand Base	30-A2078	1
Control	30-A1032	1
Hand Switch	30-A2040	1
Screw	H1-63-M09008-17	2
Access Cover	30-P0017	1
Brake	30-A2109	1
Line Cord (not shown)	015-11668-00	1

Continued

Installation Procedures – Mobile Configuration (Cont.)

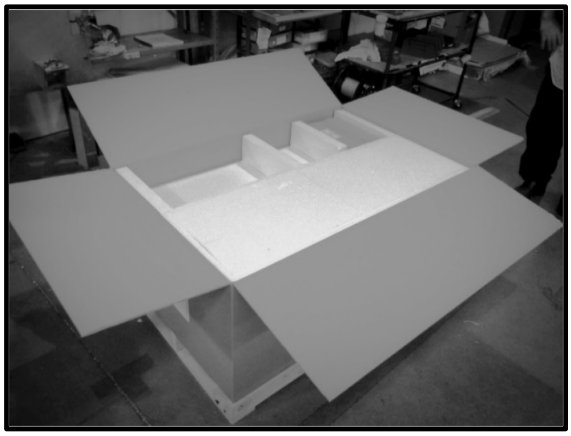
Assembling the Mobile Unit

Tools Required

- 9.5 mm (3/8 in) square drive hex key 10 mm
- 9.5 mm (3/8 in) square hex key × 15 cm (6 in) extension
- 9.5 mm (3/8 in) square drive ratchet
- No. 1 Phillips screwdriver
- 7 mm nut driver
- Small flat-blade screwdriver
- 4 mm hex key
- 5 mm hex key
- Utility Knife
- Portable Power Drill

Instructions

1. Open the box from the top side.

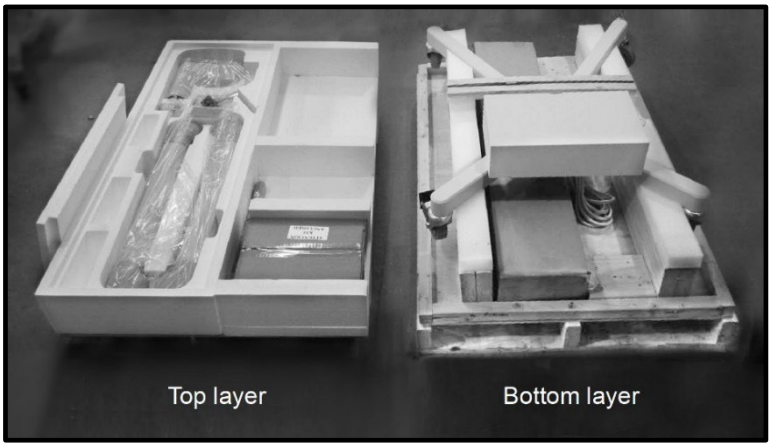


2. Remove all transportation screws from the base of the crate (qty: 10).

Continued

Installation Procedures – Mobile Configuration (Cont.)

3. Lift the shipping box and separate from the crate. There are two layers of parts. Separate the top layer and place on the floor or remove each piece individually.



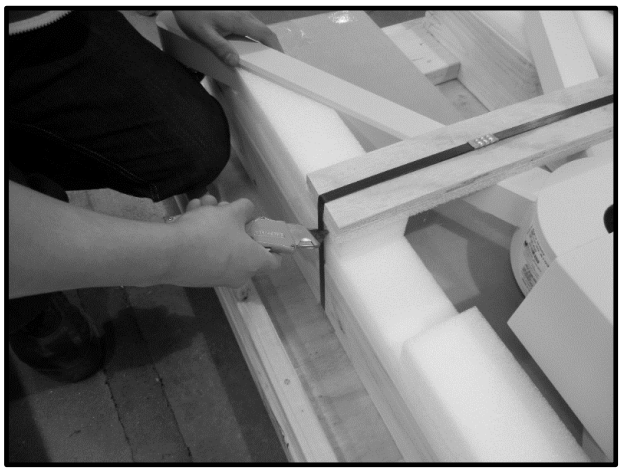
⚠CAUTION	This is a two-person job. The base is heavy and requires two people to lift. Observe proper lifting precautions.

NOTICE	To prevent damage to the Tube Head, take care when handling the Articulated Arm assembly.

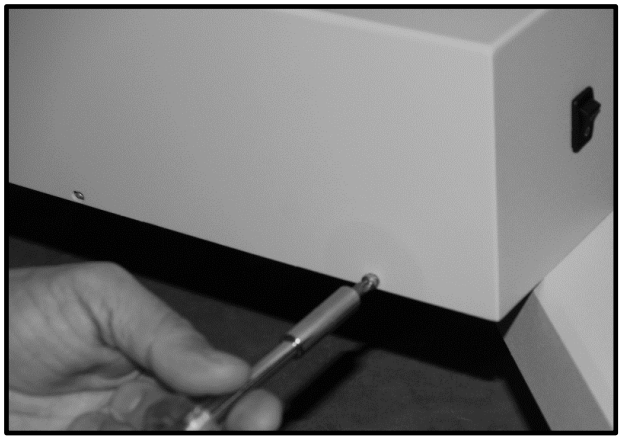
4. Cut the transportation band from the lower layer that holds the mobile base.

Continued

Installation Procedures – Mobile Configuration (Cont.)



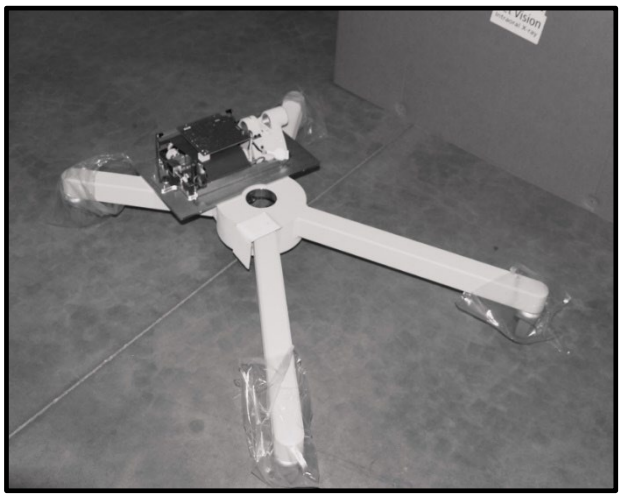
5. Remove the top cover of the Control Unit by removing screws located at the base of the cover.



6. Separate the mobile unit base from the pallet.

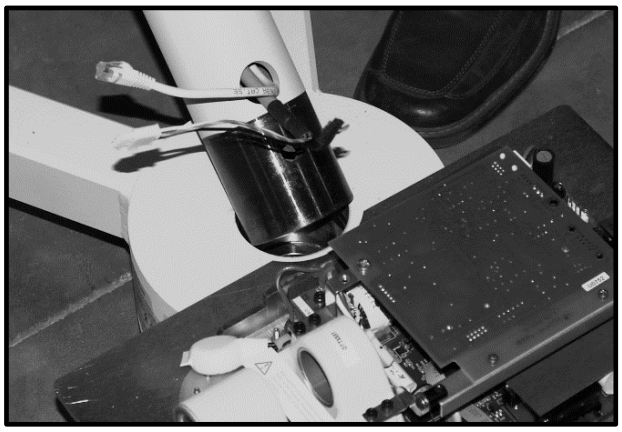
Continued

Installation Procedures – Mobile Configuration (Cont.)



⚠CAUTION The base is heavy and requires two people to lift. Observe proper lifting precautions.

7. Locate the mobile unit post (located in the top layer of parts removed earlier) and insert into the mobile base as shown.

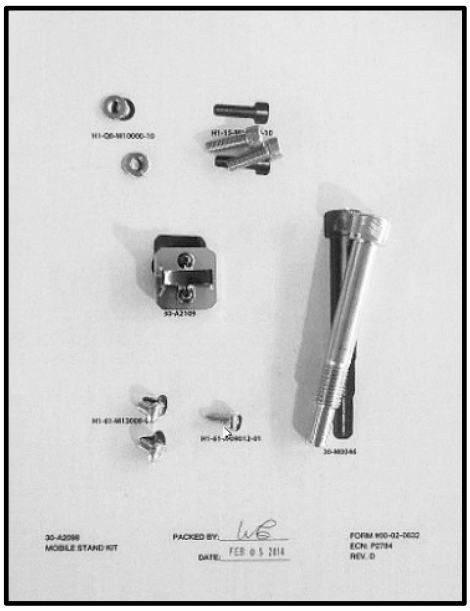


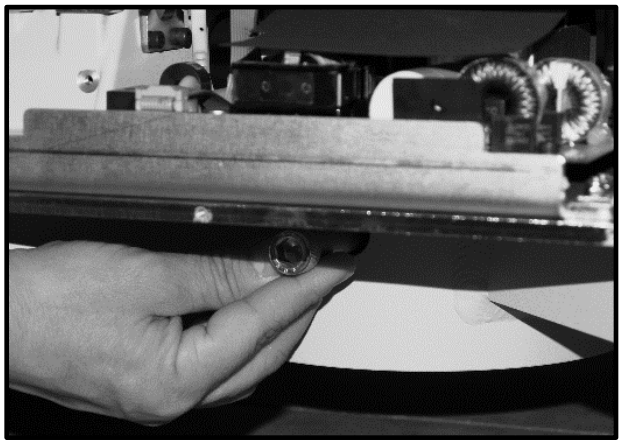
NOTICE Take care not to pinch the Cat 5 cable or the Tube Head connectors.

8. In the “Kit, Mobile Stand” package (30-A2098), locate and insert the bolt used to secure the post to the mobile base. Requires 10 mm hex key.

Continued

Installation Procedures – Mobile Configuration (Cont.)



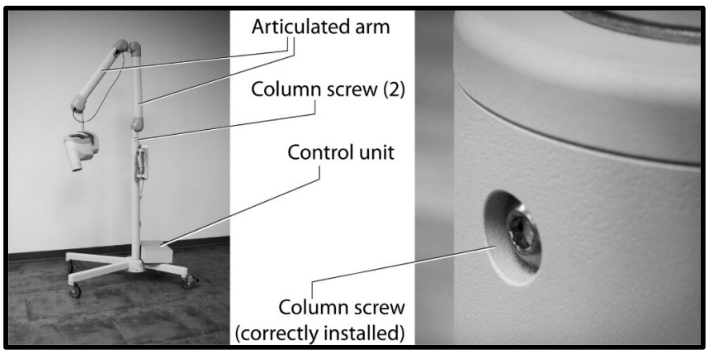


9. Back out the Allen bolts used to secure the Articulated Arm to the post (quantity: 2). This allows the Articulated Arm to be inserted completely into the post.

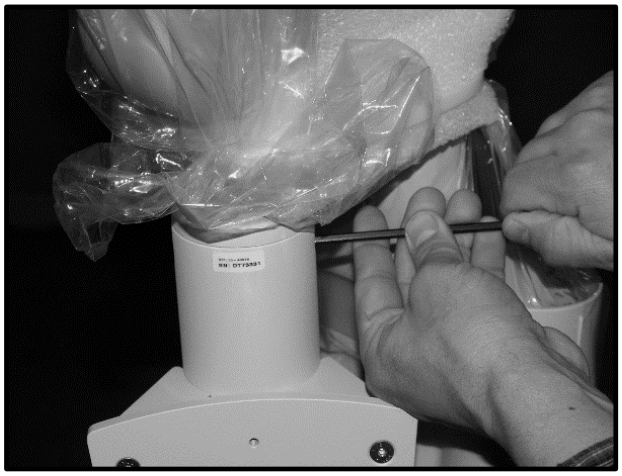
10. Locate the Articulated Arm/Tube Head assembly. Remove the red transportation label. Pull back the plastic packaging to expose the shaft. Remove the braided sleeve protecting cables and connectors.
11. Lift the arm/Tube Head carefully and guide the cables through the top of the post. Carefully insert the Articulated Arm, taking care not to pinch or damage the connectors.

Continued

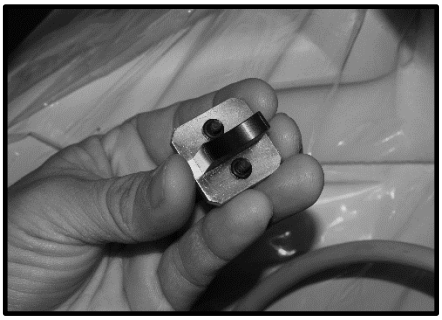
Installation Procedures – Mobile Configuration (Cont.)



12. Secure the Articulated Arm assembly to the post with the two Allen bolts that were backed out earlier.



13. Locate and install the Articulated Arm brake assembly. Install and adjust by tightening to the point where the Articulated Arm does not drift when the arm is lightly pushed.



14. Connect the Tube Head cables (gray and black connectors).

Continued

Installation Procedures – Mobile Configuration (Cont.)

15. If the unit is an integrated model, connect the USB cables (black connectors).

16. Insert cables into the post.

Continued

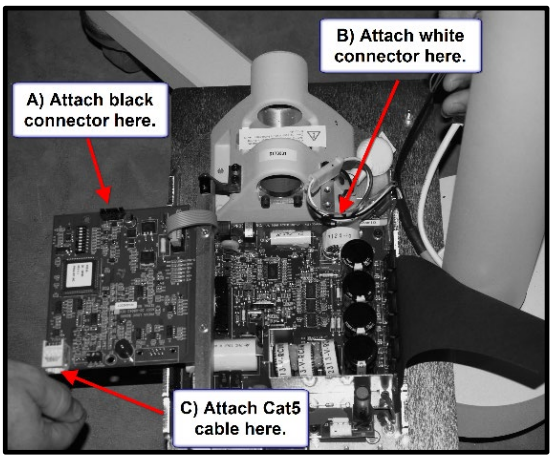
Installation Procedures – Mobile Configuration (Cont.)

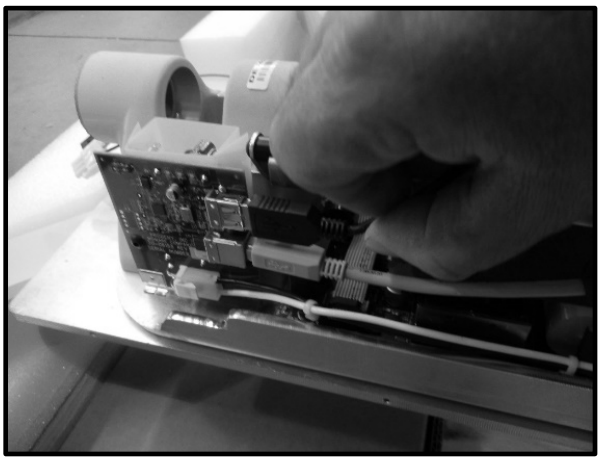
17. Install the cover plate.

18. Remove the screw that locks down the Logic Board. Swing out the Logic Board and connect the connections as shown below.
    - Black connector (feedback from Tube Head)
    - White connector (Power to Tube Head)
    - Cat5 (network cable)
    - USB (for integrated units)

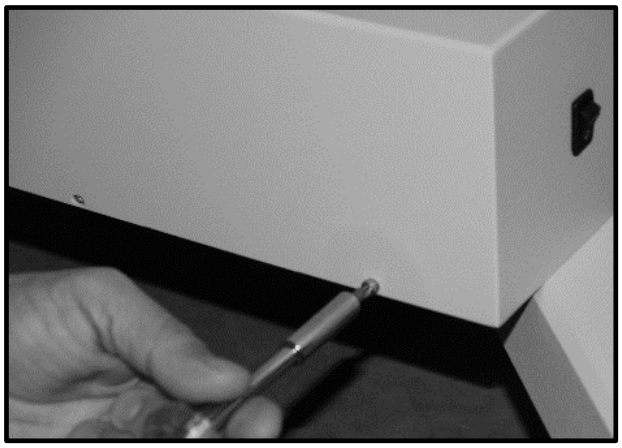
Continued

Installation Procedures – Mobile Configuration (Cont.)

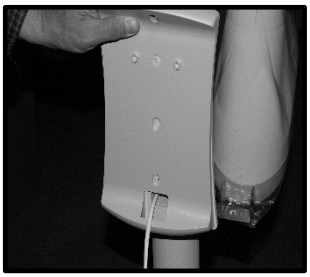


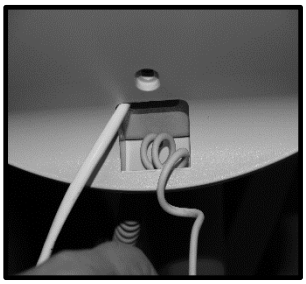


19. Attach the Control Unit cover.



20. Feed the Cat5 cable through the Operator Panel's cradle. Feed remote exposure cable through the bottom of the cradle.



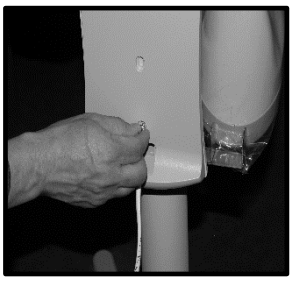


NOTICE Allow a few coils of slack for strain relief.

21. Attach the cradle with supplied hardware.

Continued

Installation Procedures – Mobile Configuration (Cont.)



22. Connect Cat5 cable and remote switch to the Operator Panel. Mount the Operator Panel into the cradle.

23. Install the mobile unit handle with the supplied hardware.

Continued

Installation Procedures – Mobile Configuration (Cont.)

24. Attach the remote switch holster by removing the adhesive backer and attaching to the frame.

25. Proceed to the section “Function Readiness Checklist” beginning on page 255 of this manual.

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Optional Installation Procedures

Selecting Exposure Switch Configurations 141
Installing the Hand Switch Option 142
- Operator Panel on Control Unit 142
- Operator Panel in Remote Location 142

Installing the Remote Exposure Station 143
- Single Switch Configuration 143
- Two Switches in Series at Remote Location 144

Installing the 30 cm (12 in) Cone Spacer 147

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Optional Installation Procedures (Cont.)

Selecting Exposure Switch Configurations

Preva supports the following exposure switch configurations:

- Single exposure switch on the Operator Panel
- Two exposure switches acting in parallel (pressing either one will activate the exposure); one of the switches is on the Operator Panel and the other can be a hand switch or remote switch. The hand switch or remote switch may have to be purchased separately.
- Two exposure switches acting in series (pressing both switches is required to activate the exposure); one of the switches is on the Operator Panel and the other can be a hand switch or remote switch. The hand switch or remote switch may have to be purchased separately.
- Two remote exposure switches acting in series (pressing both switches is required to activate the exposure). This option requires purchasing of a kit.
- One exposure switch and interlock switch. The switch is on the Operator Panel, and the interlock switch must be purchased separately.

To configure the Operator Panel for the selected exposure switch configuration, follow the steps below. The factory default configuration is a single exposure switch on the Operator Panel; if the default configuration is selected, this section is not applicable.

1. Turn the power off.
1. Remove the Operator Panel from its mount on the Control Unit or cradle.
2. Unplug the cable that connects the Operator Panel to the Control Unit.
3. With a Phillips screwdriver, remove the 4 screws from the back of the Operator Panel. Put the screws in a safe location for later use.
4. Remove the back cover from the Operator Panel.
5. Lift out the Operator Panel Board 30-08213.
6. Locate point J17 and J18 on the Operator Panel Board 30-08213. Refer to the chart below and place the jumpers in the positions corresponding to the desired switch closure.

J17 and J18 - Exposure Switch Jumper Settings	
Jumper Position	Switch Closure Required for Exposure
J17 Open, J18 Open	Remote Switch or Panel Switch (parallel)
J17 Open, J18 Shorted	Remote Switch and Panel Switch (series)
J17 Shorted, J18 Open	Interlock enabled

7. Put the Operator Panel Board 30-08213 back in position.
8. Put the cover on the back of the Control Panel using the 4 screws.

If any of the other optional installation procedures are being utilized, proceed to the applicable section. If installation is complete, proceed to the section “Function Readiness Checklist” beginning on page 255 of this manual..

Continued

Optional Installation Procedures (Cont.)

Installing the Hand Switch Option

The Preva can be installed with a coil-cord hand switch (30-A2040 or 30-A2040-W). The coil-cord hand switch is used to make exposures, in addition to the exposure button on the Operator Panel. Installation of the coil-cord hand switch involves connecting the hand switch into the connector on the bottom of the Operator Panel.

NOTICE Adding the coil-cord hand switch will not disable the exposure switch on the control panel. Contact Technical Support if local laws require the disabling of the Exposure button on the control panel.

Operator Panel on Control Unit

1. Remove the screw holding the front cover of the Control Unit in place. Put the screw in a safe location for later use.
2. Remove the front cover.
3. Cut out the notch on the base of the Control Unit front cover.
4. Route both the Operator Panel cable and the coil-cord hand switch through the hole in the bottom of the Control Unit front cover.
5. Place a loop of the coil cord into the notch.
6. Carefully reassemble the Control Unit front cover, keeping the coil-cord in the notch. Secure the front cover with the screw that was removed in step 1.
7. Connect the coil-cord hand switch to the left plug socket (as viewed from the back) on the bottom of the Operator Panel. Connect the short white cable to the right plug socket.
8. Carefully dress the two cables back into the front cover of the Control Unit.
9. Snap the Operator Panel into place on the front cover of the Control Unit.
10. Mount the bracket for the coil-cord hand switch in a convenient location.
11. Stow the coil-cord hand switch.
12. Proceed to the section “Function Readiness Checklist” beginning on page 255 of this manual.

Operator Panel in Remote Location

1. Route the cable from the coil-cord hand switch through the hole in the wall mounting cradle.
2. Place a loop of the coil cord into the notch.
3. Connect the coil-cord hand switch to the left plug socket (as viewed from the back) on the bottom of the Operator Panel. Connect the control cable to the right plug socket.
4. Carefully dress the control cable into the wall.
5. Snap the Operator Panel into place on the wall mounting cradle.
6. Mount the bracket for the coil-cord hand switch in a convenient location.

Continued

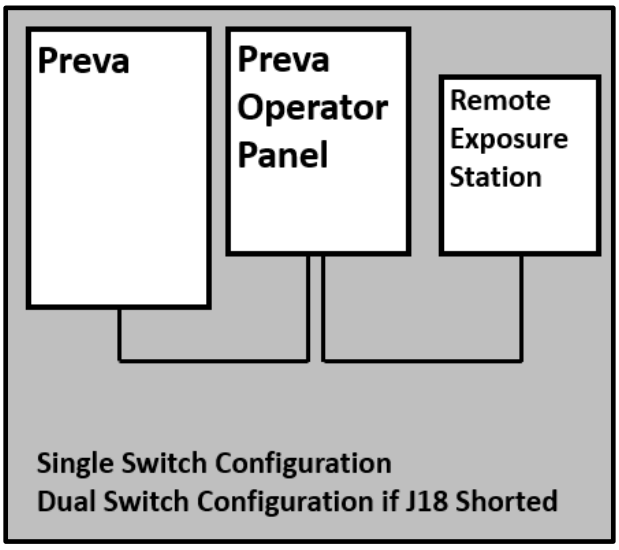
Optional Installation Procedures (Cont.)

7. Stow the coil-cord hand switch.
8. Proceed to the section “Function Readiness Checklist” beginning on page 255 of this manual.

Installing the Remote Exposure Station

The Remote Exposure Station is an option for the Preva that allows the operator to make the exposure from a fixed location remote from the main unit.

The image below shows possible configurations. Either a single Remote Exposure Station can be used, or the Operator Panel can be used in series or in parallel with the Remote Exposure Station. In the series configuration, both switches are required to be pressed simultaneously to make an exposure. In the parallel configuration, only one needs to be pressed to make an exposure.



The following tools are required to install the switch:

- Phillips screwdriver
- Flat-blade screwdriver
- Telephone cable stripper (for dual switch configuration only)
- Wire stripper (for dual switch configuration only)

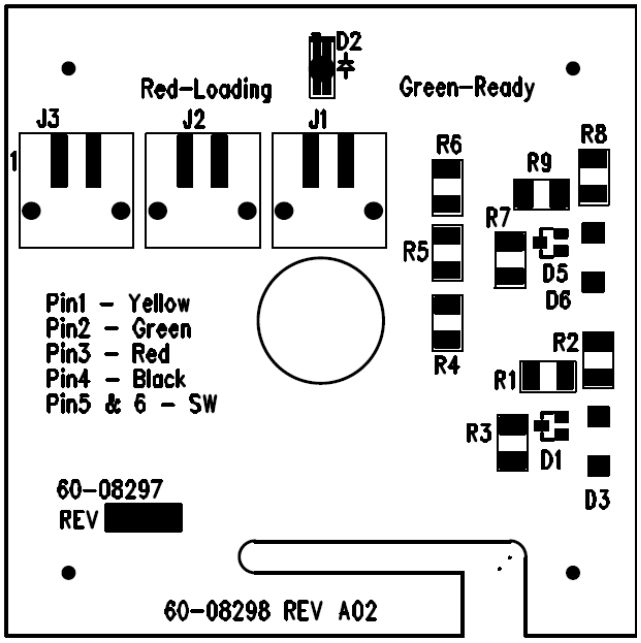
Single Switch Configuration

1. Route the cable for the Remote Exposure Switch from the Preva Operator Panel mounting location (either Control Unit or Wall Mounting Cradle) to the Remote Exposure Switch mounting location. This can be done in the wall with or without conduit or on the wall surface. A 5 cm × 10 cm (2 in × 4 in) junction box may be used where the Remote Exposure Switch is to be mounted.
2. Thread the cable end with the handset connector through the opening in the wall mount cover from the inside and connect it to the Operator Panel. If the cable is routed on the surface of the wall, it should enter the wall mount cover through the notch on the left of the power switch.

Continued

Optional Installation Procedures (Cont.)

3. Connect the cable conductors on the opposite end of the cable to terminal blocks J3 and J2 on the PCB in the switch enclosure as shown below.



4. Make sure the two gray wires from the pushbutton are connected to terminals 1 and 2 of J1.
5. Screw the inner section of the enclosure to the junction box using the two screws provided. If the cable is routed on the surface of the wall, make sure it sits in the notch on the bottom of the enclosure. Confirm that no wires are being pinched between the junction box and the enclosure.
6. Hook the outer section of the enclosure and fasten the two pieces at the bottom with the 6-32 x 5/16 in screw.
7. Refer to the table below to configure series or parallel operation.

J17 and J18 - Exposure Switch Jumper Settings	
Jumper Position	Switch Closure Required for Exposure
J17 Open, J18 Open	Remote Switch or Panel Switch (parallel)
J17 Open, J18 Shorted	Remote Switch and Panel Switch (series)
J17 Shorted, J18 Open	Interlock enabled

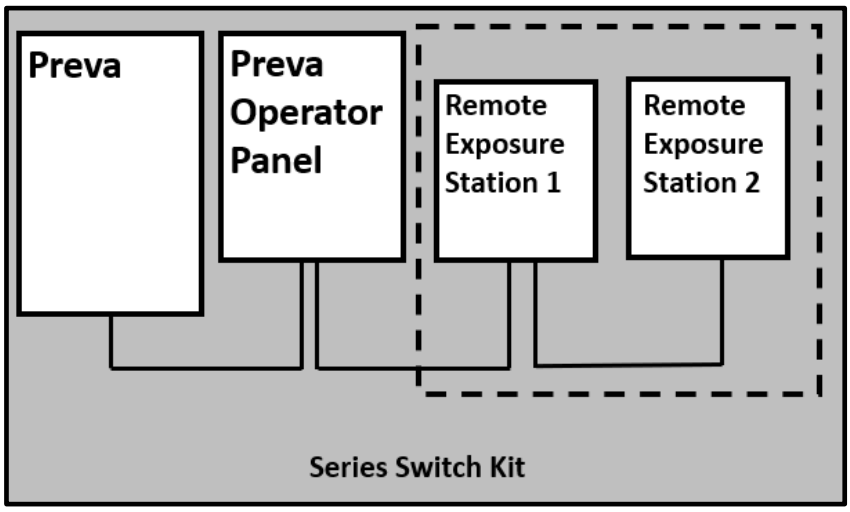
8. If any of the other optional installation procedures are being utilized, proceed to the applicable section. If installation is complete, proceed to the section “Function Readiness Checklist” beginning on page 255 of this manual.

Two Switches in Series at Remote Location

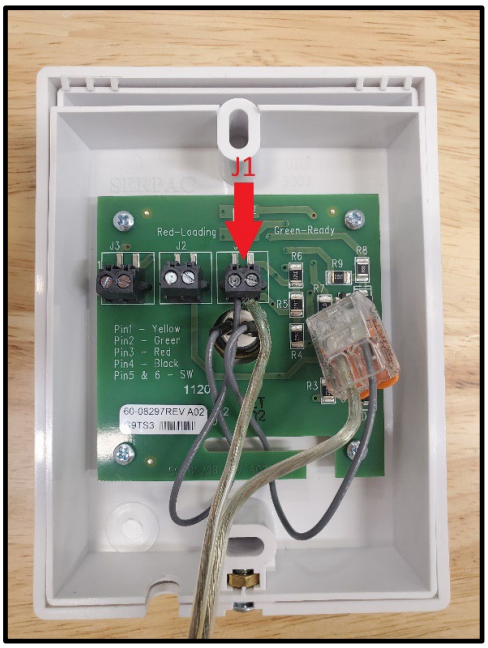
The dual-switch configuration consists of a remote exposure station and a series switch extension. Both switches must be pressed simultaneously to take an exposure.

Continued

Optional Installation Procedures (Cont.)



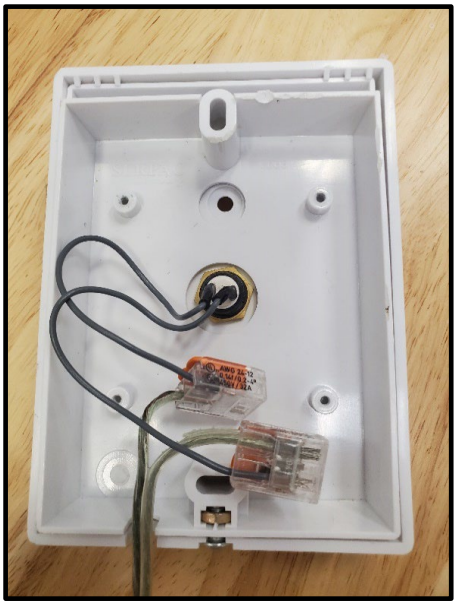
1. Route one cable from the Preva to the first switch location either through conduit or on the surface of the wall.
2. Route the other cable from the first switch location to the second switch location either through conduit or on the surface of the wall.
3. Thread the first cable end with the handset connector through the opening in the wall mount cover from the inside and connect it to the Operator Panel. If the cable is routed on the surface of the wall, it should enter the wall mount cover through the notch on the left of the power switch.
4. On the Remote Exposure Station, remove one wire from J1 as shown below.



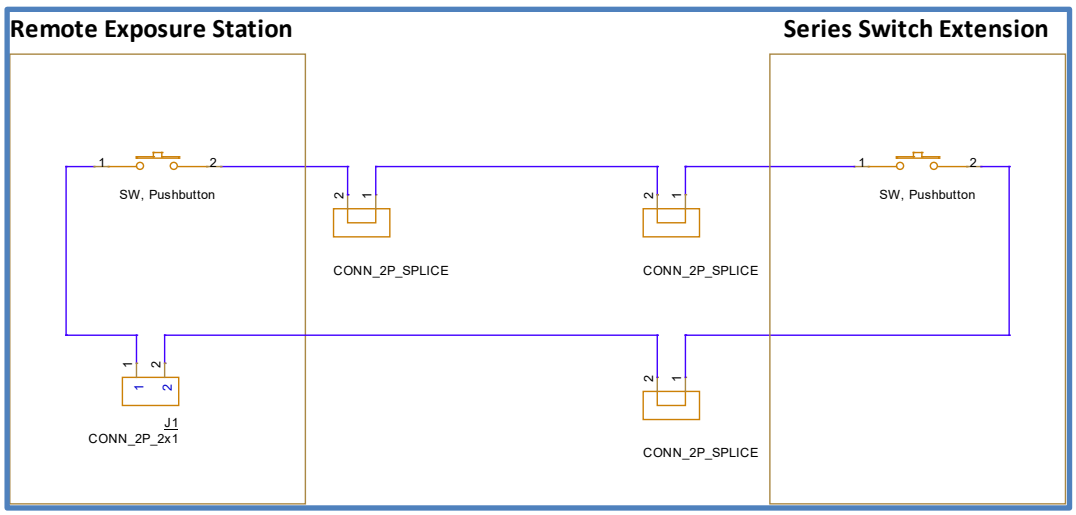
Continued

Optional Installation Procedures (Cont.)

5. Use a splice connector to connect the free wire from J1 and one wire from the two-wire cable as shown below.



6. On the Series Switch Extension, use splice connectors to connect each wire from the switch to a wire on the two-wire cable. See below. The two switches are now connected in series.



7. Screw the inner section of enclosure #2 to the junction box using the two screws provided. If the cable is routed on the surface of the wall, make sure it sits in the notch on the bottom of the enclosure. Confirm that no wires are being pinched between the junction box and the enclosure.
8. Hook the outer section of the enclosure onto the inner section at the top. Push the wires all the way into the enclosure and fasten the two pieces at the bottom with the 6-32 × 5/16 in screw.

Continued

Optional Installation Procedures (Cont.)

9. If any of the other optional installation procedures are being utilized, proceed to the applicable section. If installation is complete, proceed to the section “Function Readiness Checklist” beginning on page 255 of this manual.

Installing the 30 cm (12 in) Cone Spacer

The Preva is factory-set for use with the standard supplied 20 cm (8 in) Cone. The 30 cm (12 in) Cone (30-A2200) is recommended when using parallel film positioning techniques.

Using the longer cone requires longer exposure times. Therefore, installation of the longer cone requires both a physical installation of the cone as well as system configuration changes to set the longer exposures times. Refer to section “Changing from a 20 cm to a 30 cm Cone Spacer” beginning on page 162 for physical installation instructions and to section “Changing the Cone Size” beginning on page 184 for system configuration instructions.

If installation is complete, proceed to the section “Function Readiness Checklist” beginning on page 255 of this manual.

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Startup and Shutdown

Turning Preva On 151
Turning Preva Off 152

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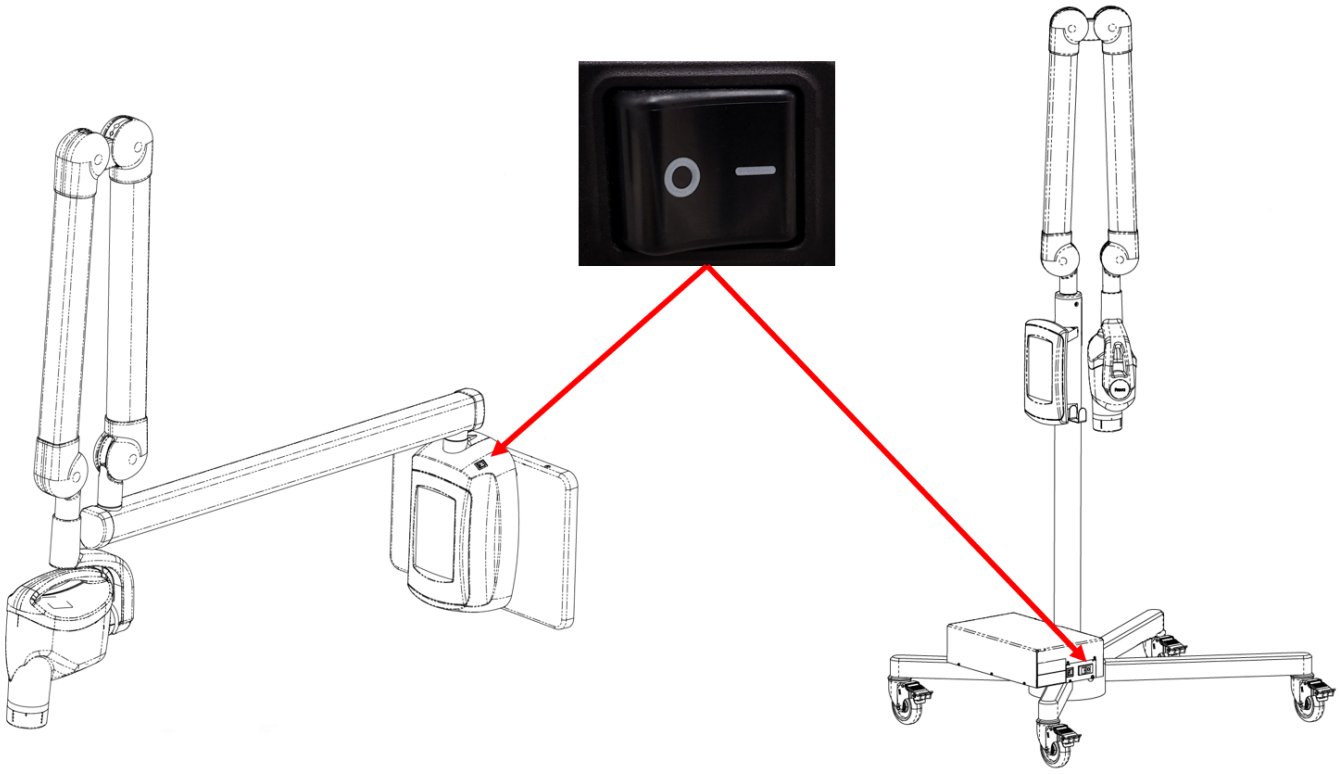
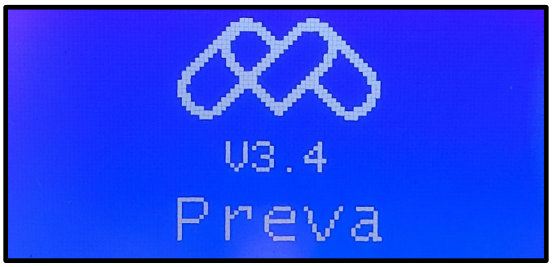
Startup and Shutdown (Cont.)

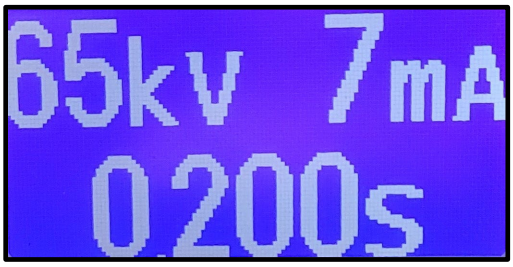
Turning Preva On

1. Locate the service disconnect switch. (Note: This is also referred to as 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 on, press the power switch so that the | side is depressed. Refer to the section “Symbols Glossary” beginning on page 37.
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.



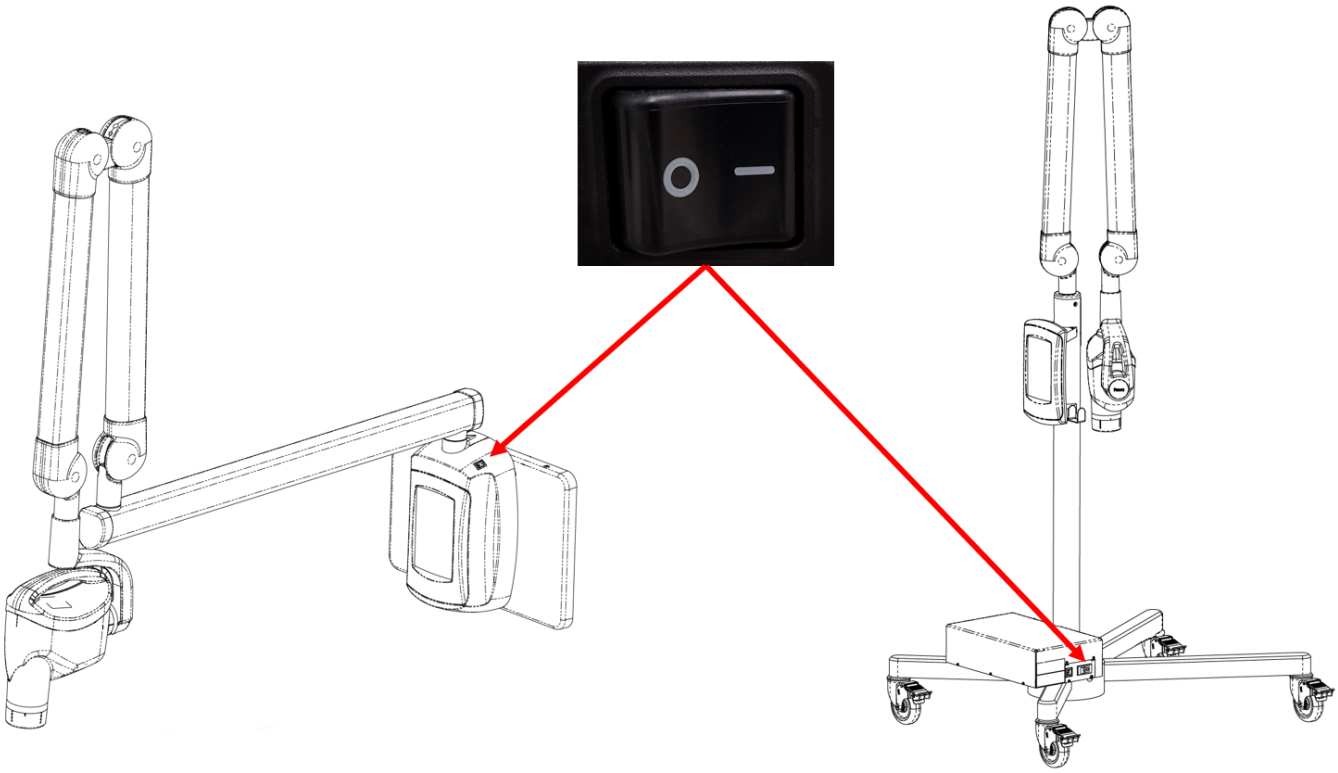


Continued

Startup and Shutdown (Cont.)

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 37.
3. The operator panel lights turn off.

Control Interface

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Interlock 158

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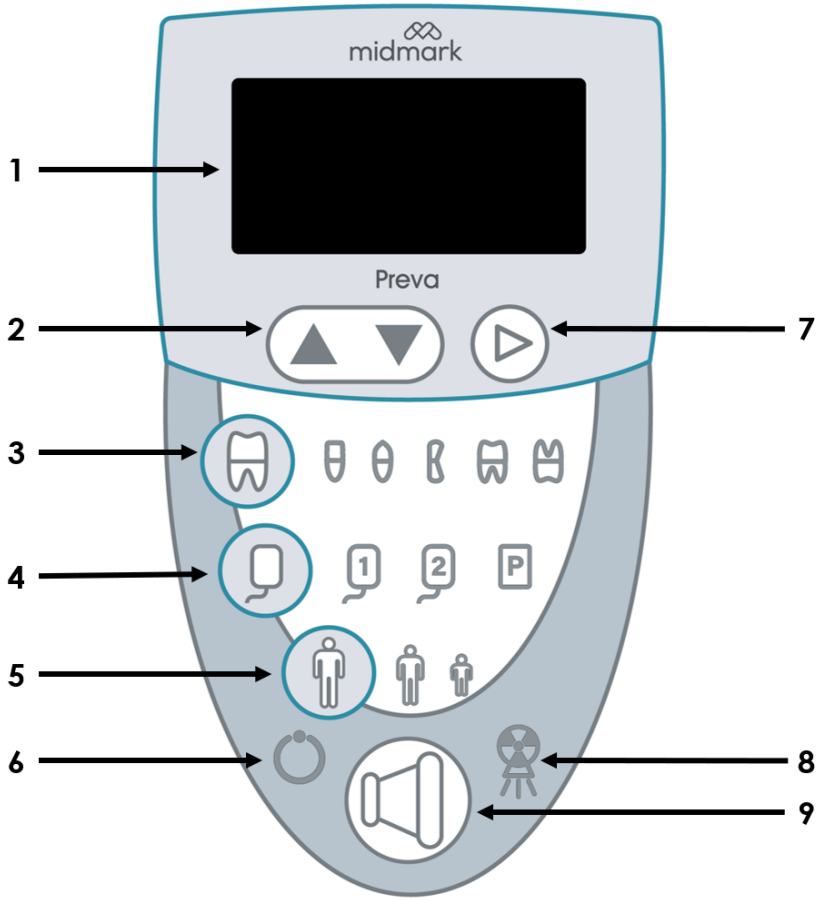
Control Interface (Cont.)

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 settings. 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.

Continued

Control Interface (Cont.)

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 (tube voltage-kV, tube current-mA, and exposure time-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 tables in the section "System Configuration – Default Exposure Times" beginning on page 275 of this manual.

Changing Technique Factors

Use the Tooth Selection, Image Receptor Type, and Patient Size buttons to select from various pre-programmed technique factors.

It may be necessary to increase or decrease the kV, mA, or time from the preset values. For details, refer to the section "Adjusting Technique Factors" beginning on page 163 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 preprogrammed settings is available in the section "Changing Pre-Programmed Technique Factors" beginning on page 174 of this manual.

Continued

Control Interface (Cont.)

Radiation Indicators

The Preva has a visible and an audible Radiation Indicator. When an exposure is in progress, the Indicator on the Operator Panel is illuminated (pictured below), and a 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.

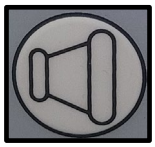
Exposure Button and Radiation Indicators

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

Continued

Control Interface (Cont.)

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 needs 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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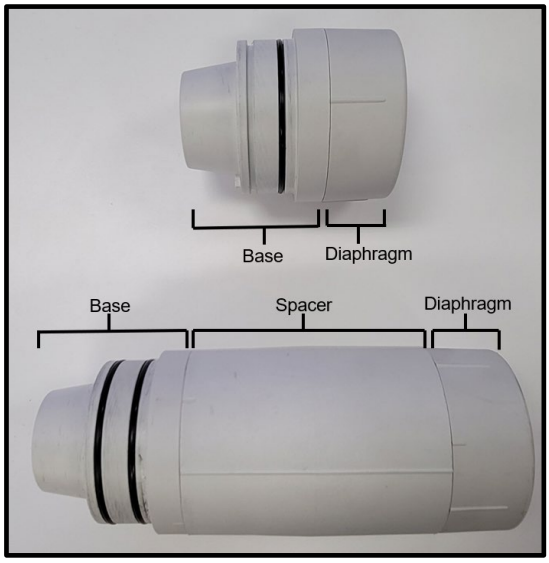
Operating Instructions (Cont.)

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. See the section “Accessories and Supplemental Parts” beginning on page 57 of this manual 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 section “Changing the Cone Size” beginning on page 184 of this manual.

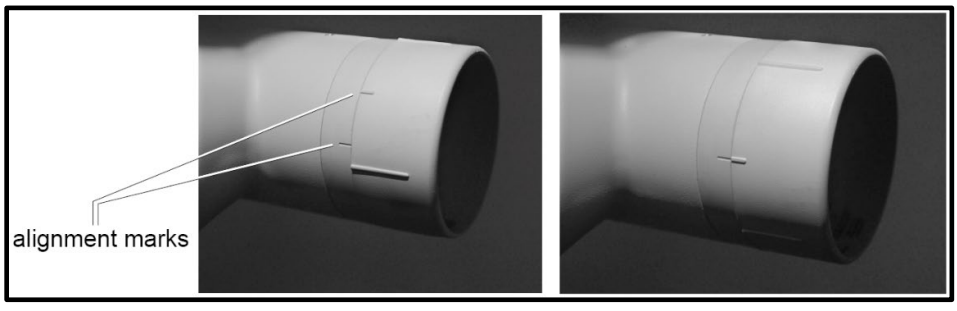
Cones are comprised of a base and a diaphragm. In the case of the 30 cm (12 in) cone, a spacer is permanently affixed to the base. Refer to the photograph below.



Changing a Cone Diaphragm

The Preva system has a variety of cone options (see the section “Accessories and Supplemental Parts” beginning on page 57 of this manual). Follow this procedure to replace a cone diaphragm:

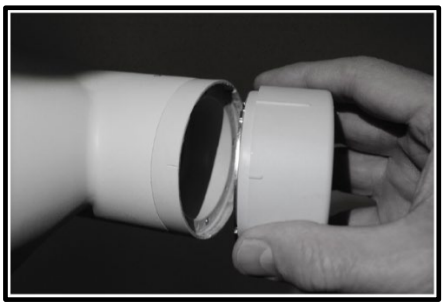
1. To remove a cone diaphragm, rotate it until the short marks on the base (or spacer, if applicable) and the cone diaphragm align.



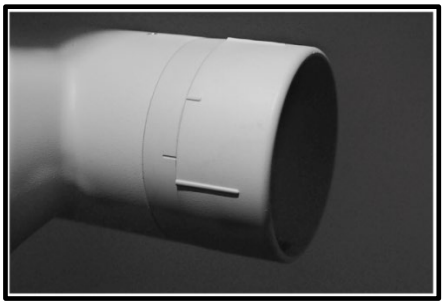
Continued

Operating Instructions (Cont.)

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 to a 30 cm Cone Spacer

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

Continued

Operating Instructions (Cont.)

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 section “Changing the Cone Size” beginning on page 184 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

Continued

Operating Instructions (Cont.)

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 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.

1. 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 s to 0.250 s.

2. 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.

3. Press any other button (Tooth, Receptor, or Patient Size) to return the display to the preset values.
4. To save new presets, see the “Changing Pre-Programmed Technique Factors” section beginning on page 174 of this manual.

Continued

Operating Instructions (Cont.)

Taking an X-Ray

1. Turn the power switch to the “On” position. Refer to the section “Turning Preva On” in 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” above 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.

Continued

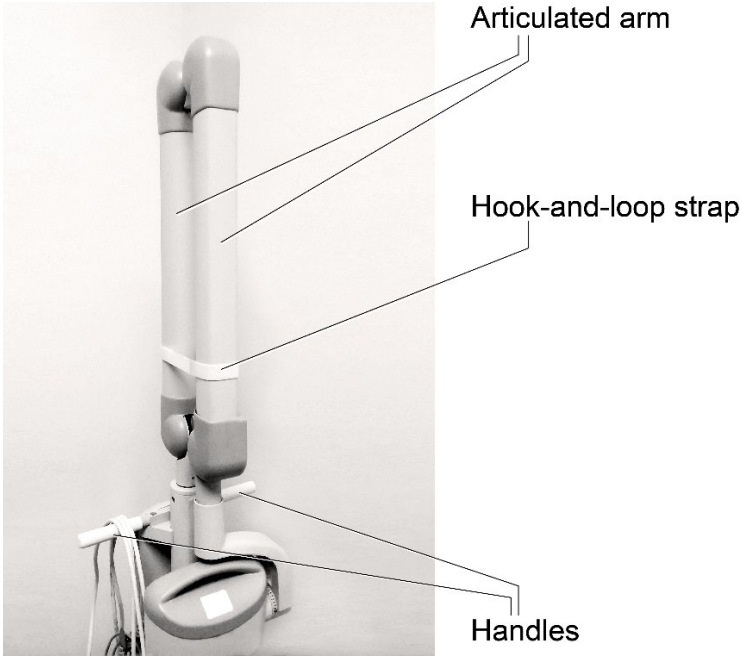
Operating Instructions (Cont.)

⚠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.

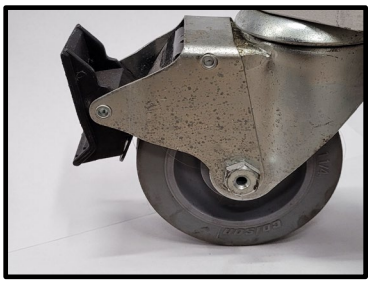
Transporting the Mobile Device

To avoid injury and damage to the mobile Preva unit when moving it, 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 remove cables that may be in the path of the mobile Preva unit.



⚠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.



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System Configuration Mode

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System Configuration Mode (Cont.)

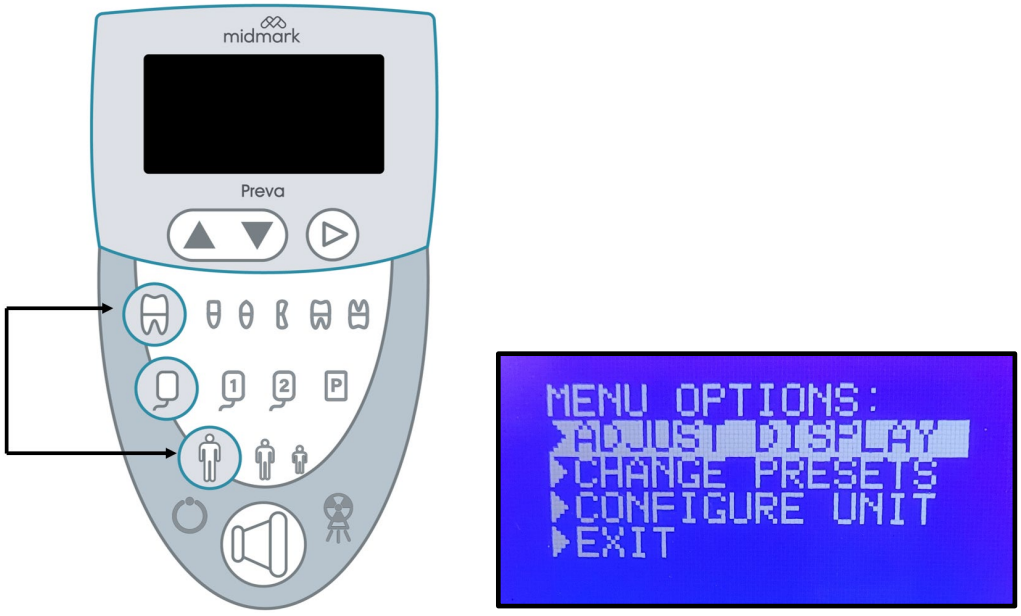
System Configuration Mode

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:

- Adjusting the display
- Changing default technique factors
- Changing the cone size
- Showing current system configuration
- Displaying 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.

Continued

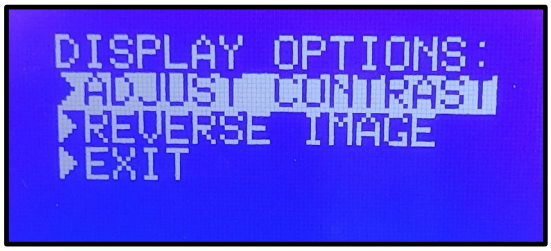
System Configuration Mode (Cont.)

Adjusting the Display

The Display Options Menu

1. To enter System Configuration mode for adjusting the display image, 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.

Continued

System Configuration Mode (Cont.)

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.

Continued

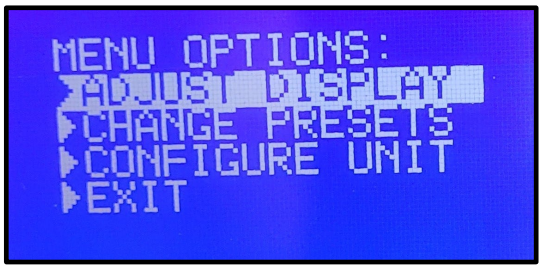
System Configuration Mode (Cont.)

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.

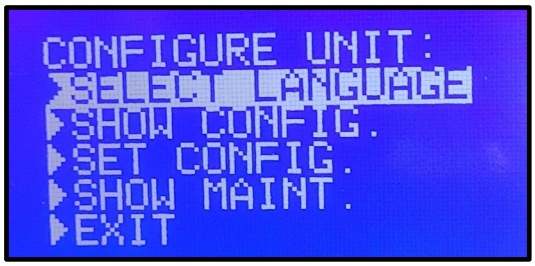


2. Use the down arrow to highlight “CONFIGURE UNIT,” then press the right arrow key to select it.

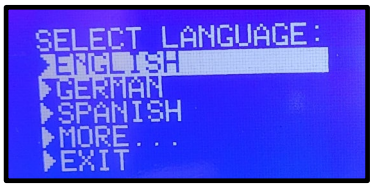
Continued

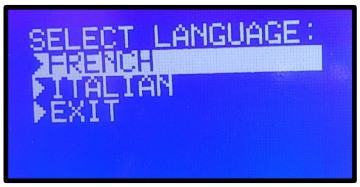
System Configuration Mode (Cont.)

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

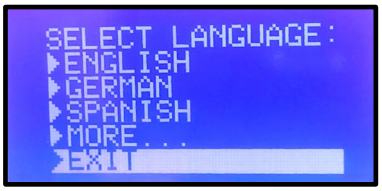


4. Select the desired language and press the right arrow key. If the desired language is not displayed, press the down arrow to reach “MORE...” Press the right arrow.





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. Default factory default settings can also be restored. For charts of the default settings, refer to the section “System Configuration – Default Exposure Times” beginning on page 275 of this manual.

Continued

System Configuration Mode (Cont.)

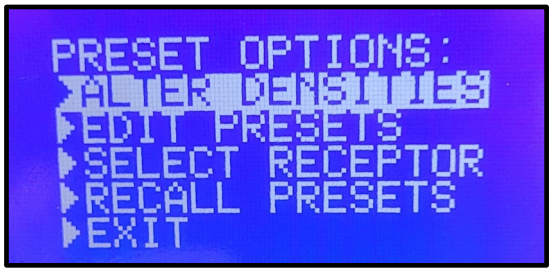
NOTICE

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.

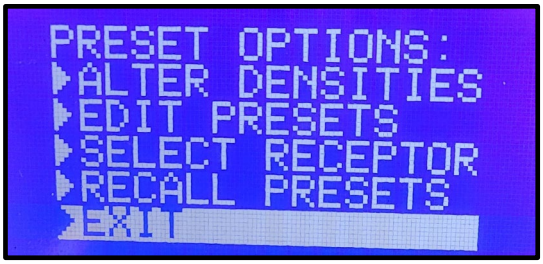
Displaying the Change Presets Menu

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.

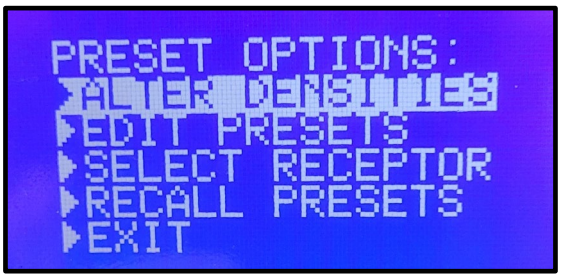


Changing All Receptor Densities Globally

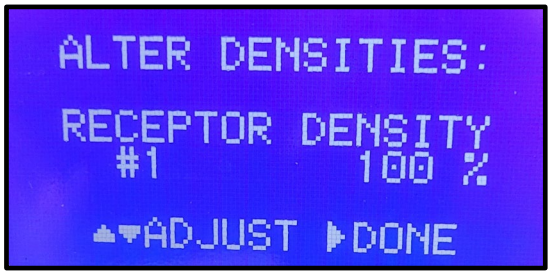
1. From the PRESET OPTIONS menu, select ALTER DENSITIES.

Continued

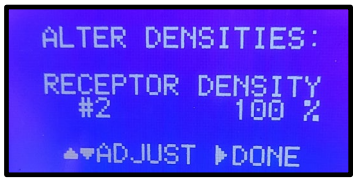
System Configuration Mode (Cont.)



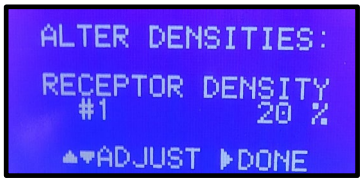
2. The first Image Receptor Type illuminates. The display shows the selected Image Receptor Type and current density. In this example, receptor #1 is shown at 100% density.

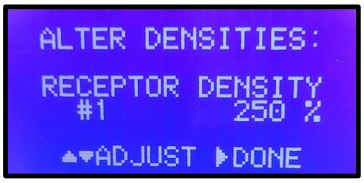


3. Using the Image Receptor Type button, select the Image Receptor to adjust. As each one is selected, the display will show it as depicted below and the corresponding icon will be illuminated on the operator panel.



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.





NOTICE For receptors 1 and 2, densities can be decreased in predetermined increments to a minimum of 20% and increased in predetermined increments to a maximum of 500%. For the phosphor plate, the range is 13% to 400%.

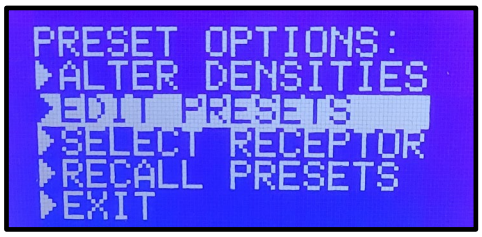
5. Press the right arrow to save your settings.

Continued

System Configuration Mode (Cont.)

Changing Presets Individually

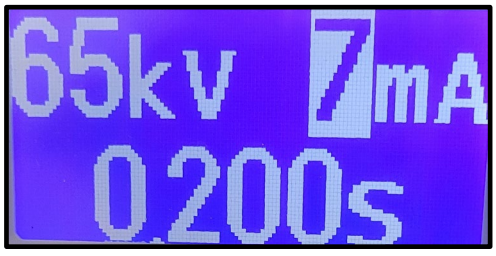
1. From the PRESET OPTIONS menu, select EDIT PRESETS.



2. The display notifies you that you 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.



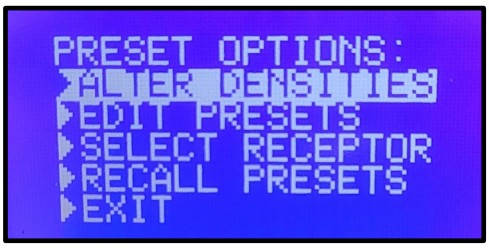
Continued

System Configuration Mode (Cont.)

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.

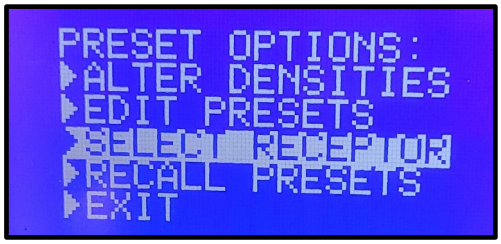
NOTICE If time is the factor needing to be changed, this can be done without pressing the right arrow first. Pressing the up and down arrows will automatically adjust the time if neither of the other factors are highlighted.

6. Repeat steps 3-5 to change additional presets.
7. When all changes have been completed, 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

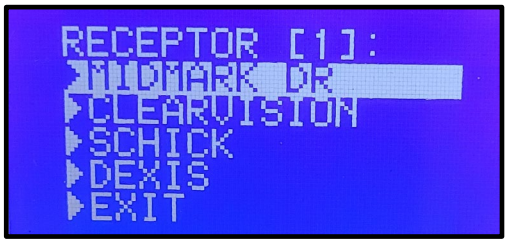
1. From the PRESET OPTIONS menu, select SELECT RECEPTOR.



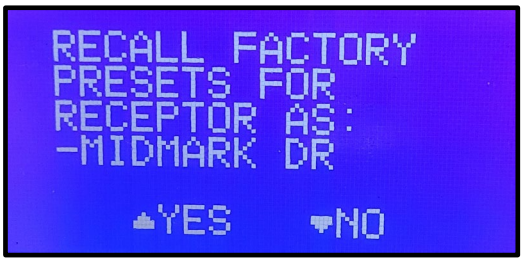
2. Select the desired digital receptor, 1 or 2, by pressing the receptor button. Both options are shown below. The LED indicator will toggle between the two options.

Continued

System Configuration Mode (Cont.)



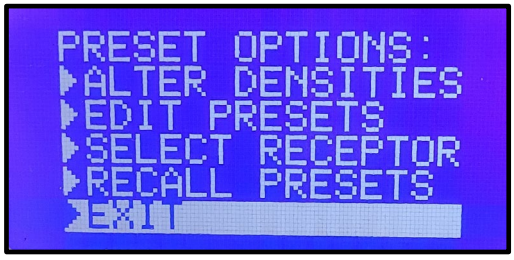
3. Press the up or down button to highlight the sensor to change. Press the right arrow button.
4. Select YES or NO on the verification screen.



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.



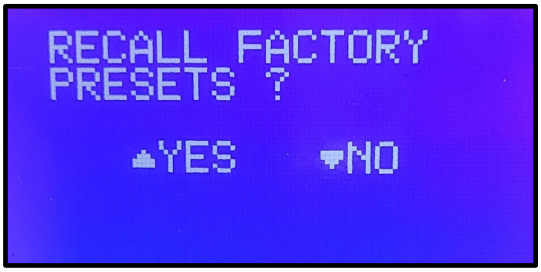
Return to All Factory Default Presets

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

Continued

System Configuration Mode (Cont.)

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.



Continued

System Configuration Mode (Cont.)

Adjust Technique Factors for 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						

Continued

System Configuration Mode (Cont.)

Adjust Technique Factors for 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						

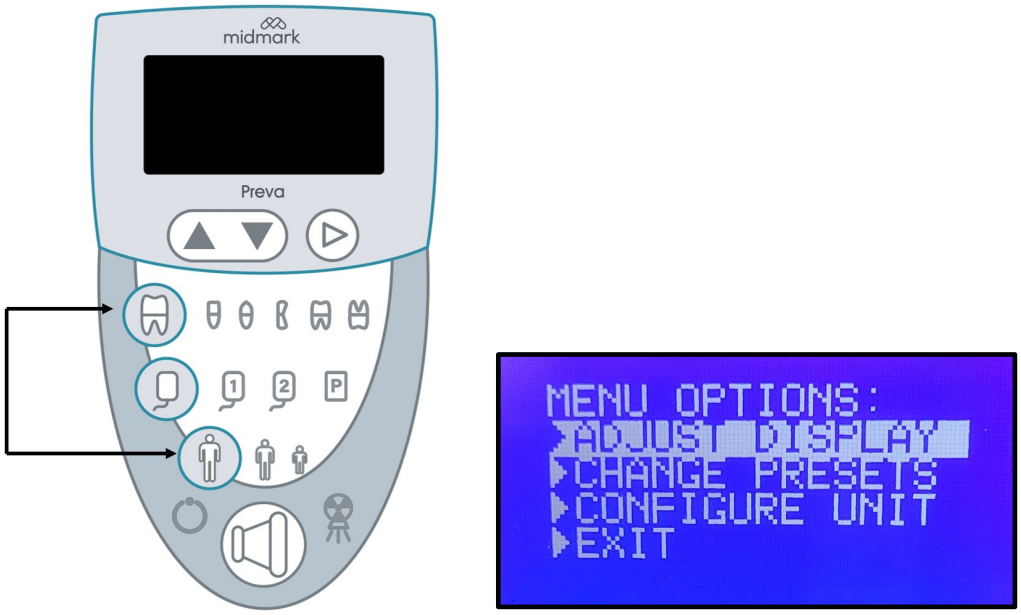
Continued

System Configuration Mode (Cont.)

Showing the Current System Configuration

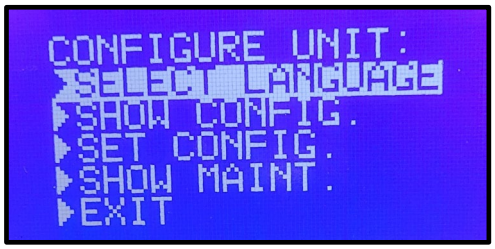
The Preva Dental X-ray System displays the current system configuration. This display is informational only.

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.

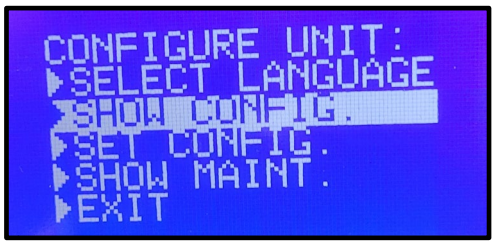
3. The CONFIGURE UNIT menu shown below will be displayed.



4. Select SHOW CONFIG.

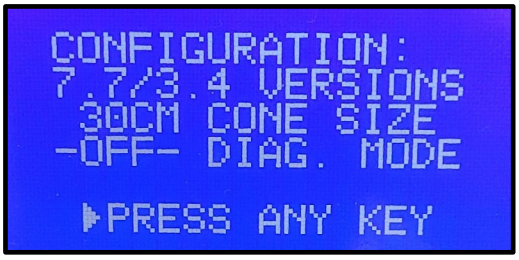
Continued

System Configuration Mode (Cont.)



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

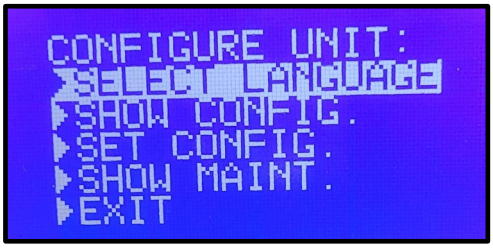
1. To enter system configuration mode, press the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for five seconds (below left). The Main System menu will appear as shown below (right). The Ready Indicator will blink.

Continued

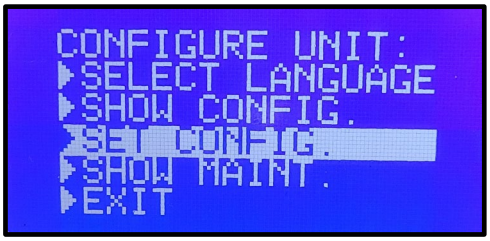
System Configuration Mode (Cont.)

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

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



4. Select SET CONFIG.



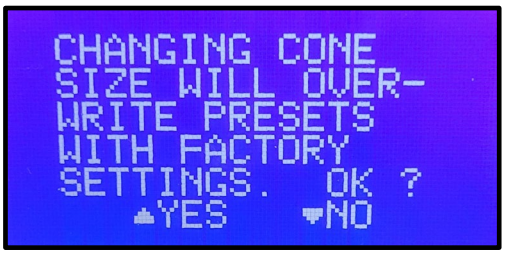
Continued

System Configuration Mode (Cont.)

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.

Continued

System Configuration Mode (Cont.)

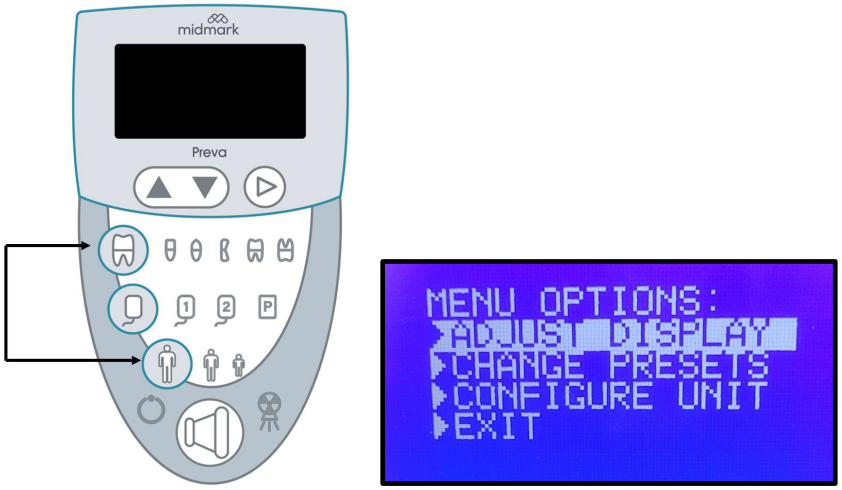
Diagnostic Mode

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.

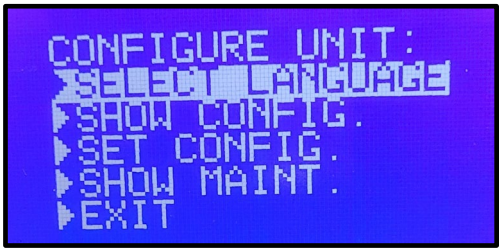
Showing the Maintenance Summary

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.

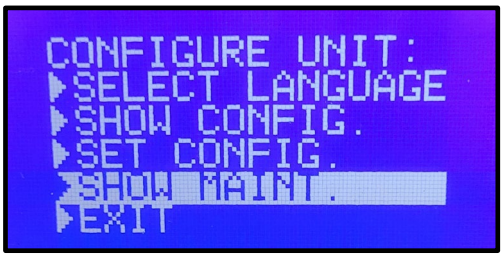
3. The CONFIGURE UNIT menu displays as shown below.



Continued

System Configuration Mode (Cont.)

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 165) 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.

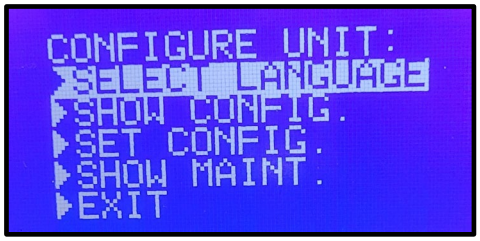
1. To enter System Configuration mode, press the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for five seconds (below, left). The Main System menu will appear as shown below (right). The Ready Indicator will blink.

Continued

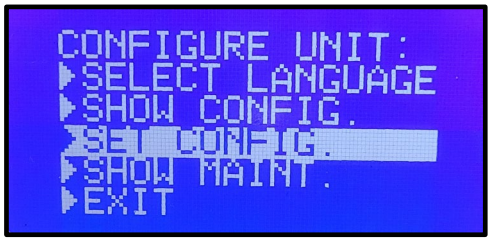
System Configuration Mode (Cont.)

2. Select CONFIGURE UNIT.

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



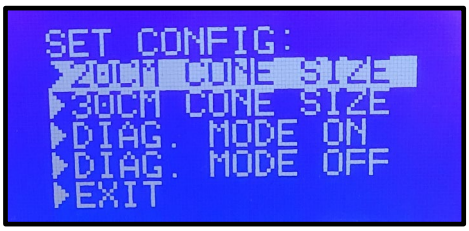
4. Select SET CONFIG.



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

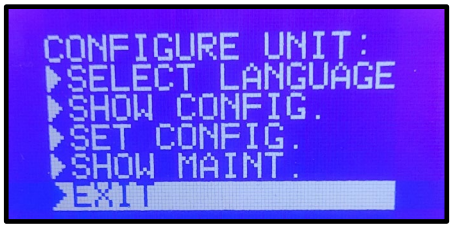
Continued

System Configuration Mode (Cont.)



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.

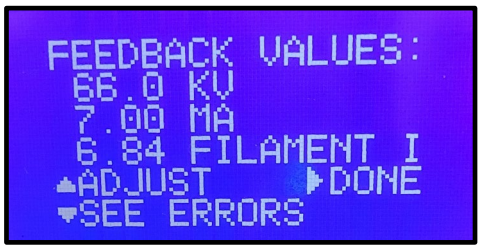
⚠CAUTION	X-rays will be emitted. The operator must remain 2 meters (7 feet) away from the focal spot and out of the path of the X-ray beam.

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.

Continued

System Configuration Mode (Cont.)



NOTICE Feedback values are approximate.

The display will also contain options for the following actions:

- ADJUST
- SEE ERRORS
- DONE

10. Press the up arrow button on the Operator Panel to adjust. This feature is explained in more detail in the section “Calibration” beginning on page 192 of this 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.

Continued

System Configuration Mode (Cont.)

Calibration

Occasionally, it may be necessary to calibrate kilovoltage (kV). The tube current and irradiation time cannot be calibrated. Approximate mA and kV levels can be observed using the Diagnostic Mode feature of the Preva. If the kV needs calibration, follow these steps.

This procedure requires an X-ray kV meter such as Radcal Accugold or similar. Set the meter to perform in a dental mode and to ignore the pre-heat pulses.

1. Turn on Diagnostic Mode by following the applicable steps in section “Showing Feedback Values After an Exposure” beginning on page 188 of this manual.
2. When the menus have been exited and the display has been returned to operational mode, set the technique factors as follows:
   - Tube voltage: the voltage that is desired to be calibrated (60 kV, 65 kV, or 70 kV)
   - Tube current: 5 mA
   - Irradiation duration: 0.250 s
3. Make an exposure.

> **⚠CAUTION** Follow normal radiation protection procedures before and during the exposure.

4. Observe the voltage reading of the X-ray measurement equipment.
5. Press the Up arrow to activate the Adjust feature. This displays the Current kV Modulation Level Screen.

6. Press the Up or Down buttons while observing the Counts indicator. Adjust the Counts in small increments. (In general guidance, about four counts for each 1 kV discrepancy.)
7. Press the right arrow button to exit and return to operational mode.
8. Make an exposure and observe the feedback.
9. Repeat steps 4-8 until the desired kV level is reached.
10. Deactivate the calibration session by following the final step in the section “Showing Feedback Values After an Exposure” above. Alternatively, turn the power off and then on again.

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Troubleshooting Electrical Performance Issues (Cont.)

General Information

Cautions and Notes

⚠CAUTION

- High voltage – risk of electric shock. The Preva system has the capacity to store electrical energy during operation and after the system has been turned off. The Preva system will store energy for approximately three minutes after removal from power lines.
- Before attempting service within the system, observe the green LED “D11” of the Power Supply Board. Illumination represents the presence of stored energy. Do not touch while this light is on.
- As an added safety practice, it is recommended to measure for the presence of DC voltage across TP8 and TP5 of the Power Supply Board.

⚠CAUTION

Observe radiation safety practices when making exposures for troubleshooting.

NOTICE

- If the Operator Panel is replaced, any customized technique factors must be reprogrammed. Instructions for carrying out this reprogramming are explained in the section “System Configuration Mode” section beginning on page 168 of this manual.
- If the Logic Board 015-11172-00 or the Tube head is replaced, it may be necessary to recalibrate tube voltage. See the section “Calibration” beginning on page 192 of this manual.

Test Equipment

Electrical measurements require specific meter test probes. Use small test clips, such as Pomona Electronics Minigrabber Test Clip Model 6248 or Radio Shack Mini-Hook Adapters catalog #270-334, or the equivalent.

⚠WARNING

Test leads should be CAT II or higher.

Dose measurement equipment with sufficient accuracy, for example, Radcal 10X6-60 connected to a Radcal Accu-Gold system.

Replacement and Service Parts

Below is a list of available replacement and service parts. For convenience, many parts are grouped into Field Replacement Unit (FRU) kits to reduce the number of orderable parts.

Continued

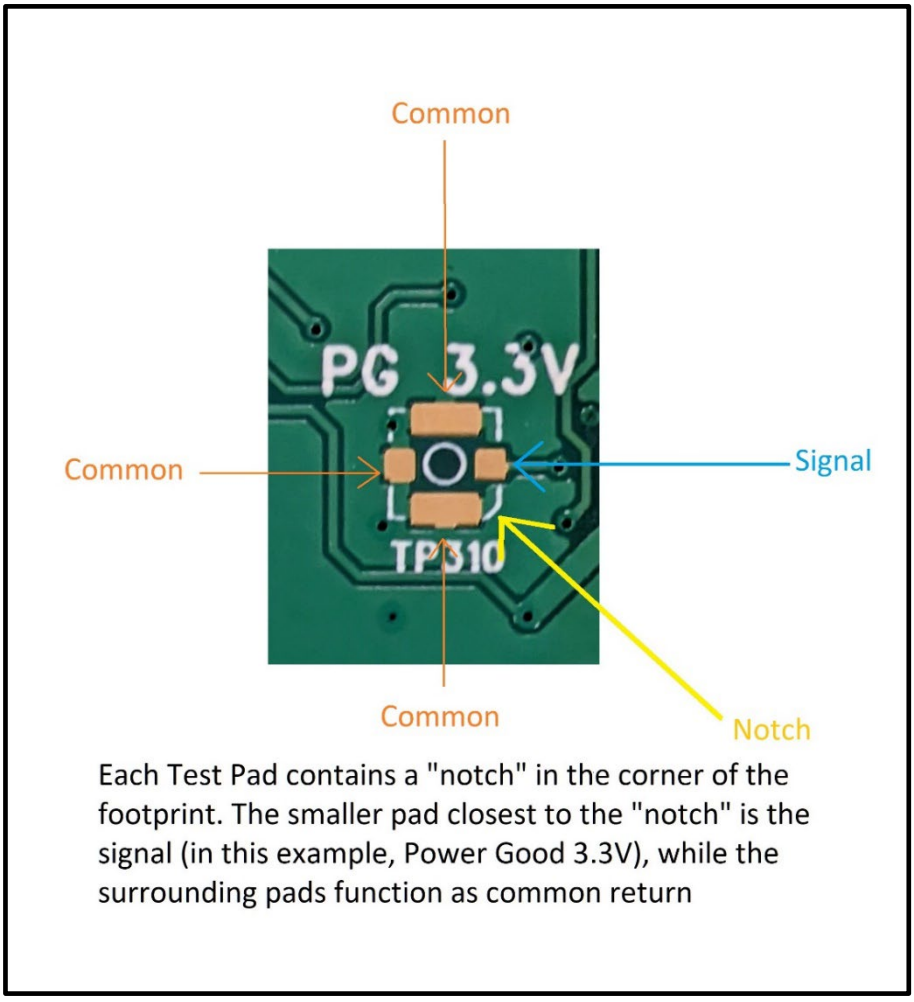
Troubleshooting Electrical Performance Issues (Cont.)

Kit/Part Number	Kit/Part Description
002-10536-00	Mobile To Wall Required Service Items
002-10790-00	FRU Kit, Logic Board
002-10825-00	FRU Kit, Mounting Hardware
002-10910-00	FRU Kit, Power Board
002-10912-00	FRU Kit, Power Switch
002-10913-00	FRU Kit, USB Hub
002-10914-00	FRU Kit, Mobile Power Switch
002-10915-00	FRU Kit, Ground Wire
002-10916-00	FRU Kit, Power Cord
002-10917-00	FRU Kit, Mobile Power Cord
002-10926-00	FRU Kit, Mobile Power Switch, White
002-10950-00	FRU Kit, Wall Mount Cover, Gray
002-10951-00	FRU Kit, Wall Mount Cover, White
002-10952-00	FRU Kit, Tube Head, Gray
002-10953-00	FRU Kit, Tube Head, White
002-10954-00	FRU Kit, Handle Covers, Gray
002-10955-00	FRU Kit, Handle Cover, White
30-08166-L055	Horizontal Arm Cable, 550 mm
30-08166-L080	Horizontal Arm Cable, 800 mm
30-08166-L106	Horizontal Arm Cable, 1060 mm
30-08166-L120	Horizontal Arm Cable, 1200 mm
30-08167-L187	Articulated Arm Cable Assembly
30-A1071-5	Intraoral Arm Cable FRU Kit, Compact Arm, 142 cm (56 in)
30-A1071-6	Intraoral Arm Cable FRU Kit, Short Arm, 168 cm (66 in)
30-A1071-7	Intraoral Arm Cable FRU Kit, Long Arm, 193 cm (76 in)
30-A1071-8	Intraoral Arm Cable FRU Kit, Mobile or Extra Long Arm, 208 cm (82 in)
30-A2076	Operator Panel, Gray
30-A2076-W	Operator Panel Kit, White
30-T0124	Tube Head Spanner Wrench
E1-13003	7.6 m (25-foot) Communication Cable
E1-13004	15 cm (6-inch) Communication Cable

Continued

Troubleshooting Electrical Performance Issues (Cont.)

Identification of Test Point Pad “Notch”



Each Test Pad contains a "notch" in the corner of the footprint. The smaller pad closest to the "notch" is the signal (in this example, Power Good 3.3V), while the surrounding pads function as common return

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:

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

Continued

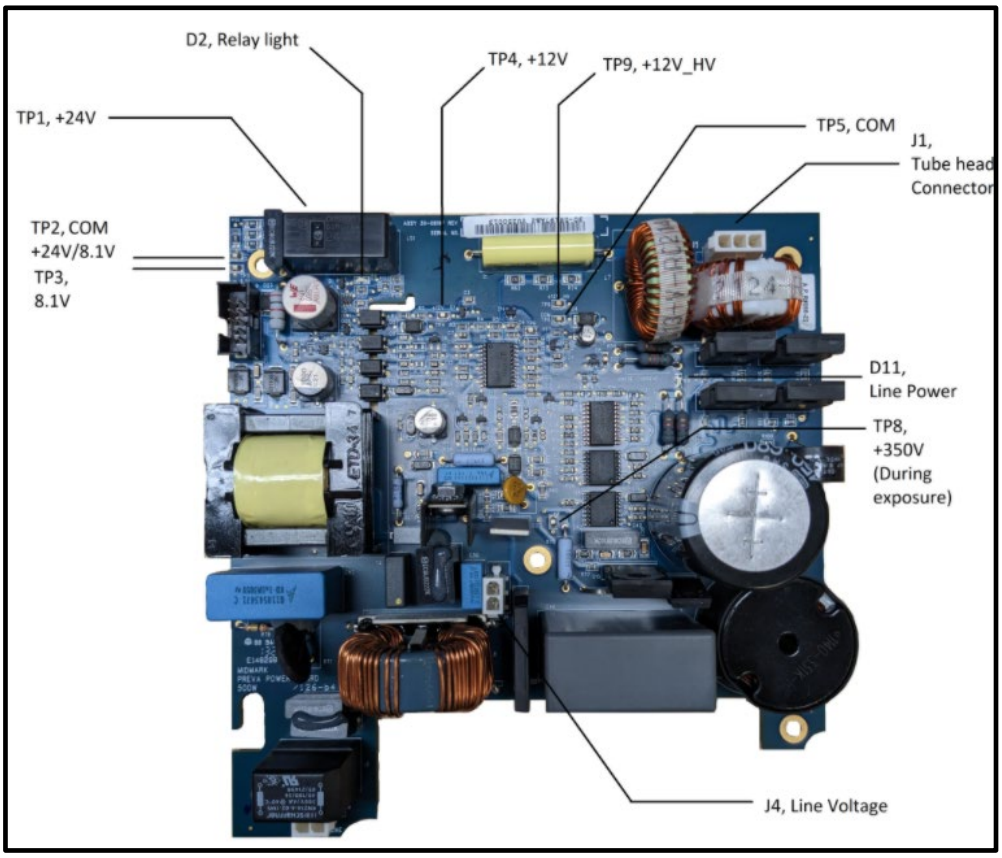
Troubleshooting Electrical Performance Issues (Cont.)

the Preva unit, or remove the interfering device from the room. Contact Midmark Technical Support if the problem persists.

Power is ON but no Operator Display

⚠WARNING Dangerous voltage.

1. On the Power Supply Board 30-08197, check for the presence of 100 to 230 volts AC at J4, USB Hub Power connector, as shown below. It will also be indicated by the green illumination of D11. If a cable is connected at J4, it may be disconnected to make the measurement. If power is absent, check that the Preva is connected to line power.

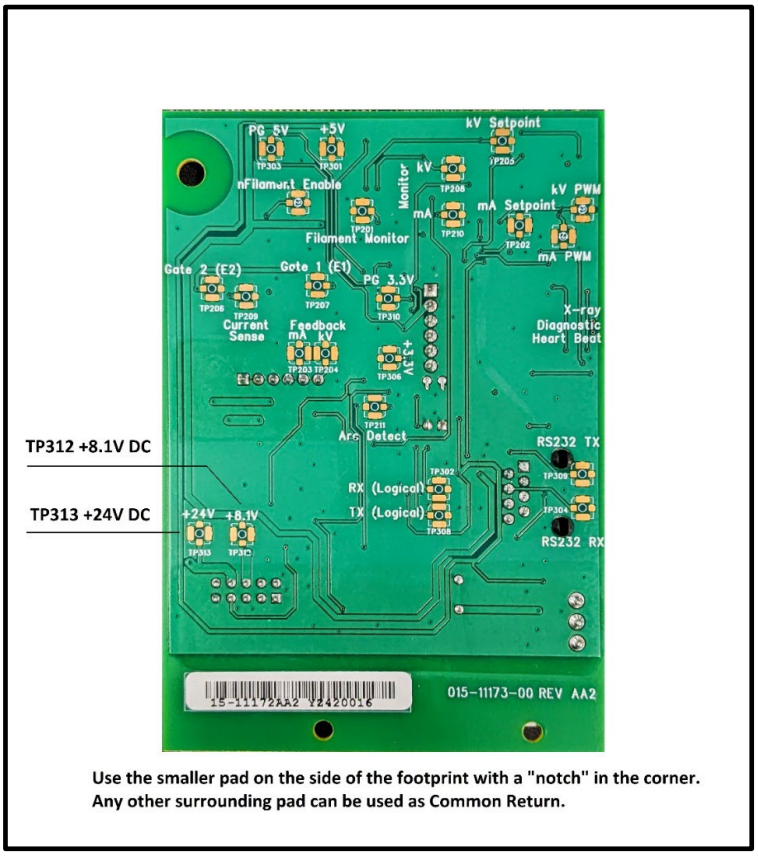


2. Confirm that the connections to mains voltage are intact. Voltage at the input side of the switch, but not at the output, requires replacement of the Service disconnect switch, (FRU kit 002-10912-00 for wall mount; FRU kit 002-10914-00 or FRU kit 002-10926-00 (white) for mobile).
3. Inspect the condition of the communication cable between the Logic Board and the Operator Panel. Midmark includes two communication cables with each Preva system. Should the installed communication cable be suspect, temporarily substitute the other cable as a test tool.

Continued

Troubleshooting Electrical Performance Issues (Cont.)

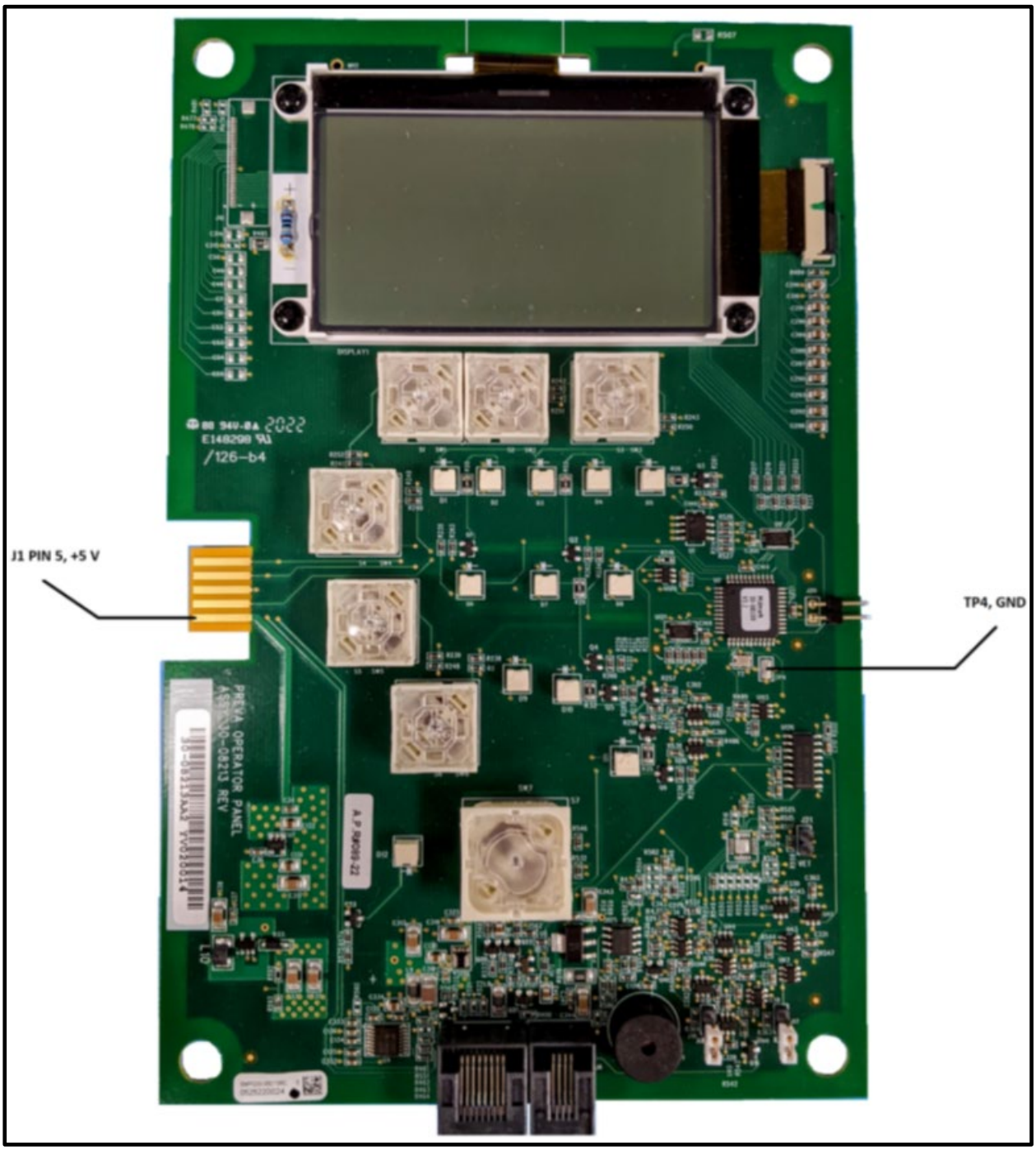
4. If the power switch is on, there is no operator display, and a faint buzzing sound is also detected, check the ribbon cable installed between the Power Supply Board and the Logic Board. If the cable is not properly seated, reinsert it. If it is damaged, replace the cable.
5. On the Logic Board, measure voltages at TP312 (+8.1V) and TP313 (+24V) as shown below. Use the surrounding pads on the test points as common return. Refer to the section “Identification of Test Point Pad “Notch”” on page 198 above for measurement instructions. If any of these voltages are not present after power is applied, next check voltages on the Power Supply Board.



6. On the Power Supply Board, use TP2 as a common test point and check TP1 +24 volts DC and TP3 8.1 volts DC, as shown in the image accompanying step 1 above. Then use TP5 as the common return to check TP4 for the presence of +12 volts DC. Should any of these voltages not be present, replace the Power Supply Board. If each voltage is present, inspect the condition of the ribbon cable between the Power Supply Board and the Logic Board. If the cable is undamaged and seated properly, replace the Logic Board.
7. If the power supply voltages are present, and the ribbon cable and communication cable are found acceptable, open the Operator Panel case and measure for the presence of +5 volts DC across J1 PIN 5 and TP4 of the Operator Panel Board as shown below. Absence of this voltage indicates the need to reconfirm the power supply voltages and communication cable. Presence of the voltage requires the replacement of the Operator Panel Board.

Continued

Troubleshooting Electrical Performance Issues (Cont.)



Too Light or Too Dark X-ray Images

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).

Continued

Troubleshooting Electrical Performance Issues (Cont.)

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.
3. It is generally recommended to increase technique factors when images are too light and to decrease them when images are too dark.
4. 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.
5. kV tends to have the greatest impact on image contrast.
6. 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).)
7. If necessary, reprogram the technique factors, as explained in the section “Changing Pre-Programmed Technique Factors” beginning on page 174 of this manual.

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.

If the steps above do not resolve the issue, proceed to the following steps:

8. Verify the kilovoltage and tube current during an exposure using Diagnostic Mode, as explained in section “Showing Feedback Values After an Exposure” beginning on page 188 of this manual. Alternatively, a non-invasive meter may be employed to evaluate kilovoltage and exposure time.
9. Check for a flickering of the operator panel during exposure. If this is happening, replace the Logic Board.
10. A light image can be caused by the Logic Board. This is characterized by a short pulse of exposure as viewed on the display followed by an error. Replace the Logic Board.
11. Full fluorescence with light image may require adjustment of the preprogrammed exposure settings.
12. Inspect the condition of the remaining imaging chain components by following the instructions of those manufacturers.

Operator Panel Freezes On “Preva” Screen

1. Disconnect any additional exposure switches that could be connected to either the Operator Panel or the Logic Board. Attempt to power up the unit again. If the unit powers up successfully, inspect the wiring of the external switches and replace the switch and/or the wiring if necessary.

Continued

Troubleshooting Electrical Performance Issues (Cont.)

2. If the problem persists after step 1, replace the Operator Display Board (30-08213).

Continuous Beep at Power-Up

If the display is backlit but does not display the technique factors (or if there is no display), replace the Operator Display Board (30-08213) or the Logic Board (015-11172-00), or both.

If the display is normal, replace the Logic Board (015-11172-00).

Buzzing Noise at Power-Up

1. Check the ribbon cable installed between the Power Supply Board and the Logic Board. If the cable is not properly seated, reinsert it. If it is damaged, replace the cable.
2. If step 1 does not resolve the problem, replace the Logic Board (015-11172-00).

“Error – Serial Communication” Displays

This error indicates that there is no communication between the Logic Board and the Operator Panel.

1. If the Cat 5 communication cable is open between the Logic Board and Operator Panel boards, replace the cable.
2. If step 1 does not resolve the issue, replace the Logic Board and the Operator Panel Board.

“Pre-Termination Error” Displays Without Cause

Early release of the exposure button will cause a pre-termination error, resulting in an underexposed image and the error screen pictured below. Under normal conditions, the system will return to the normal operating condition after five seconds.

If early exposure release is not the cause, this error can also be caused by a high-voltage breakdown in the Tube Head and is characterized by a snapping or popping noise within the Tube Head.

1. Inspect the condition of the feedback cable.
2. Inspect the condition of the communication cable.

Continued

Troubleshooting Electrical Performance Issues (Cont.)

3. If used, inspect the remote exposure switch wiring for a loose connection.

Refer to the High-voltage Breakdown section “High-Voltage Breakdown” beginning on page 212 of this manual for detailed instructions.

Device Ready, but No Radiation Produced

Two different audible exposure indicators are employed within the Preva system. One indicator is embedded in the Operator Panel and will initiate when any exposure switch is pressed. The second audible indicator initiates when the Logic Board begins the exposure sequence. During normal operation, the Operator Panel indicator will sound first followed shortly thereafter by the Logic Board indicator. It is important to recognize the sequence for troubleshooting purposes.

1. Open the Operator Panel and configure it for a single switch and no interlock.

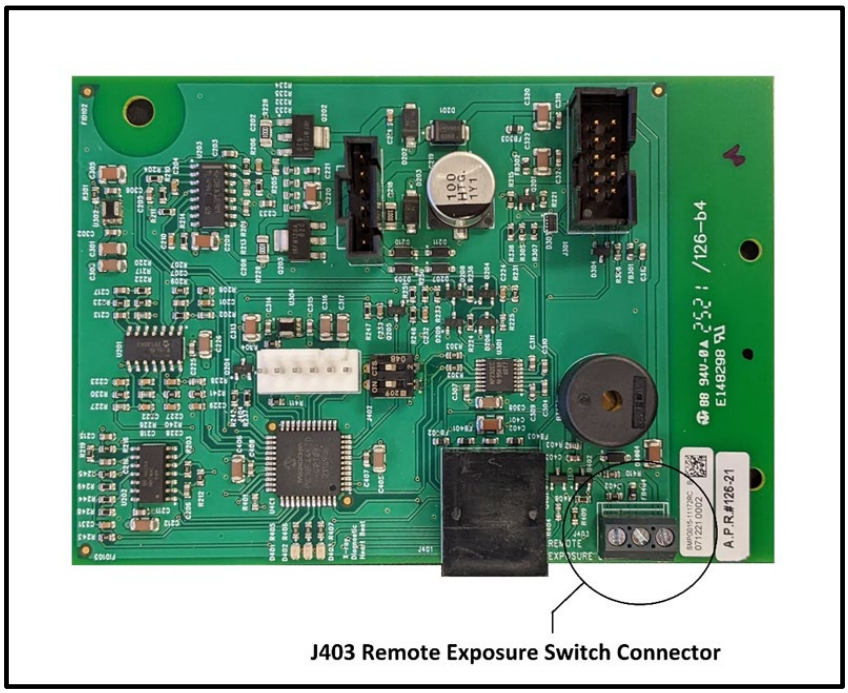
J17 and J18 - Exposure Switch Jumper Settings	
Jumper Position	Switch Closure Required for Exposure
J17 Open, J18 Open	Remote Switch or Panel Switch (parallel)
J17 Open, J18 Shorted	Remote Switch and Panel Switch (series)
J17 Shorted, J18 Open	Interlock enabled

2. Check whether the Ready Indicator on the Operator Panel is illuminated with green light when the Preva is on and idle.
3. If the Ready Indicator is illuminated in green, observe relay and D2 on the Power Board, press the exposure switch, and confirm that the exposure is activated by hearing the relay click or observing the light output from D2 on the Power Board. Observe also whether D401 on the Logic Board illuminates during the exposure attempt.
4. Make subsequent exposures and listen for the audible indicator on the Logic Board and Operator Panel.
5. If the Operator Panel indicator does not sound, inspect the condition of any remote exposure switches. Substitution is the preferred method to test these switches. However, an alternative

Continued

Troubleshooting Electrical Performance Issues (Cont.)

method is to momentarily apply a jumper wire across the contacts of J403 on the Logic Board (015-11172-00) as shown below to simulate an exposure switch closure.

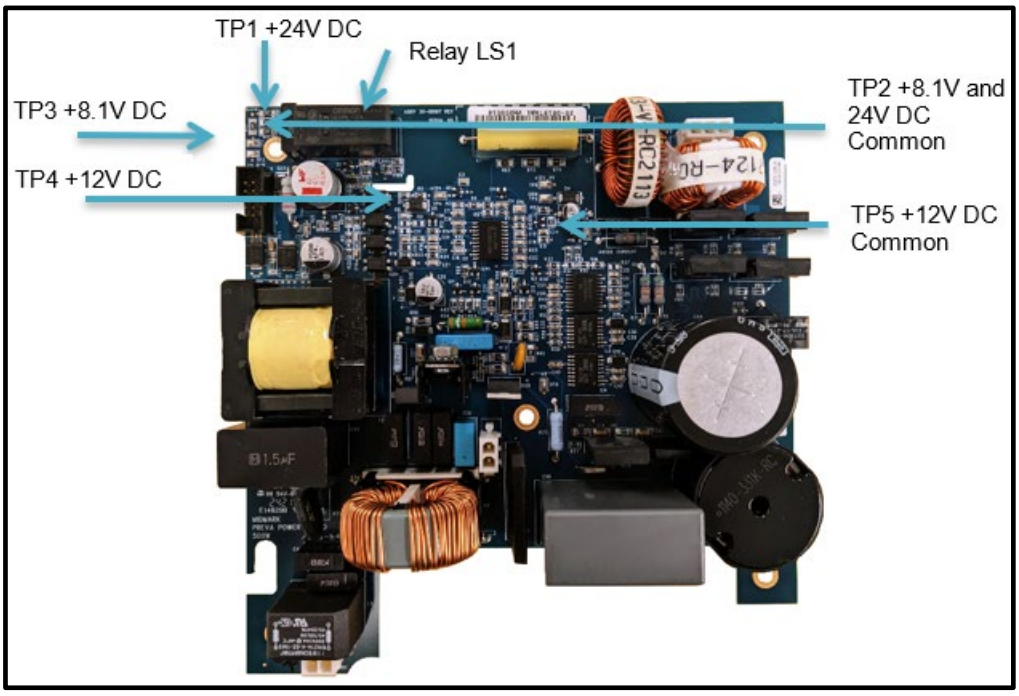


6. If “D2” and “D401” do not illuminate, this indicates that the exposure signal conductor in the Cat 5 communication cable is open. Connect a substitute communication cable to test for this condition and replace the cable if needed.
7. If the Operator Display indicator sounds but the Logic Board indicator does not activate and the Power Board indicator does not activate, inspect the condition of the ribbon cable between

Continued

Troubleshooting Electrical Performance Issues (Cont.)

the Power Supply and the Logic Boards. If the ribbon cable is acceptable, replace the Logic Board.



8. If applicable, reconfigure the exposure switch and interlock circuit as suitable for the user.

No X-ray, but Exposure Indicators Detected

When no X-ray is produced, the Preva may still operate the exposure indicators. The procedure to troubleshoot a no-X-ray condition depends upon which exposure indicators are detected.

1. Activate Diagnostic Mode as explained in the section “Showing Feedback Values After an Exposure” beginning on page 188 of this manual.
2. Take an exposure.
3. Follow the appropriate procedure below:
   - If no kV is produced, go to the section “No kV Produced” beginning on page 206 of this manual.
   - If no mA is produced, go to the section “No mA Produced” beginning on page 209 of this manual.

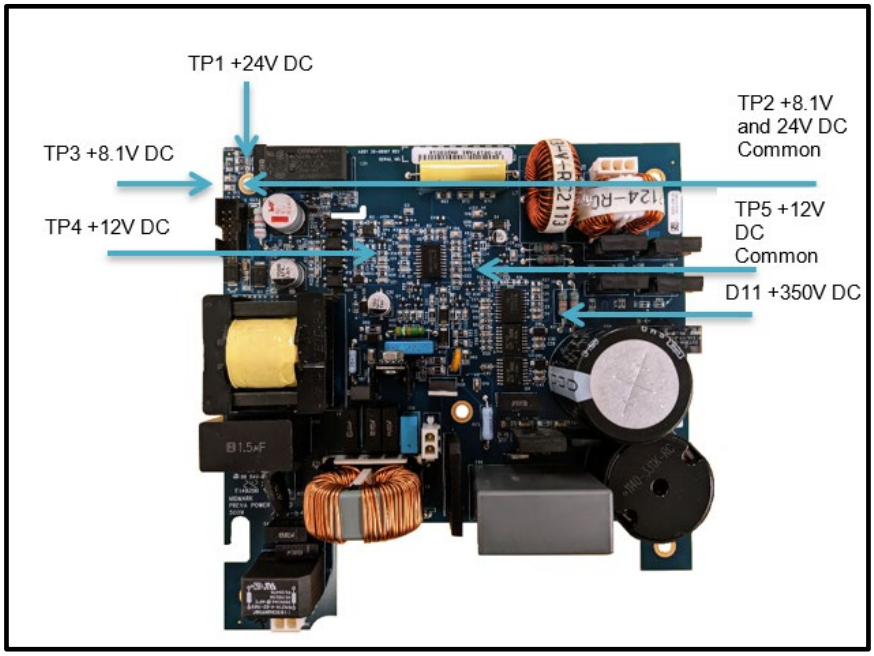
No kV Produced

This section applies when the Operator Panel displays a message that kV is too low.

Continued

Troubleshooting Electrical Performance Issues (Cont.)

1. Verify that the D11 light is illuminated on the Power Board. Replace the Power Board if it is not. If it is illuminated, proceed to step 2.
2. On the Power Supply Board (30-08197), measure the voltage across TP5, the Common Return, and TP8, + 350 V DC, as shown below. This voltage will be acceptable if measured between 330 V and 390 V DC while an exposure is being taken. Values above or below this range indicate the need to replace the Power Supply Board.

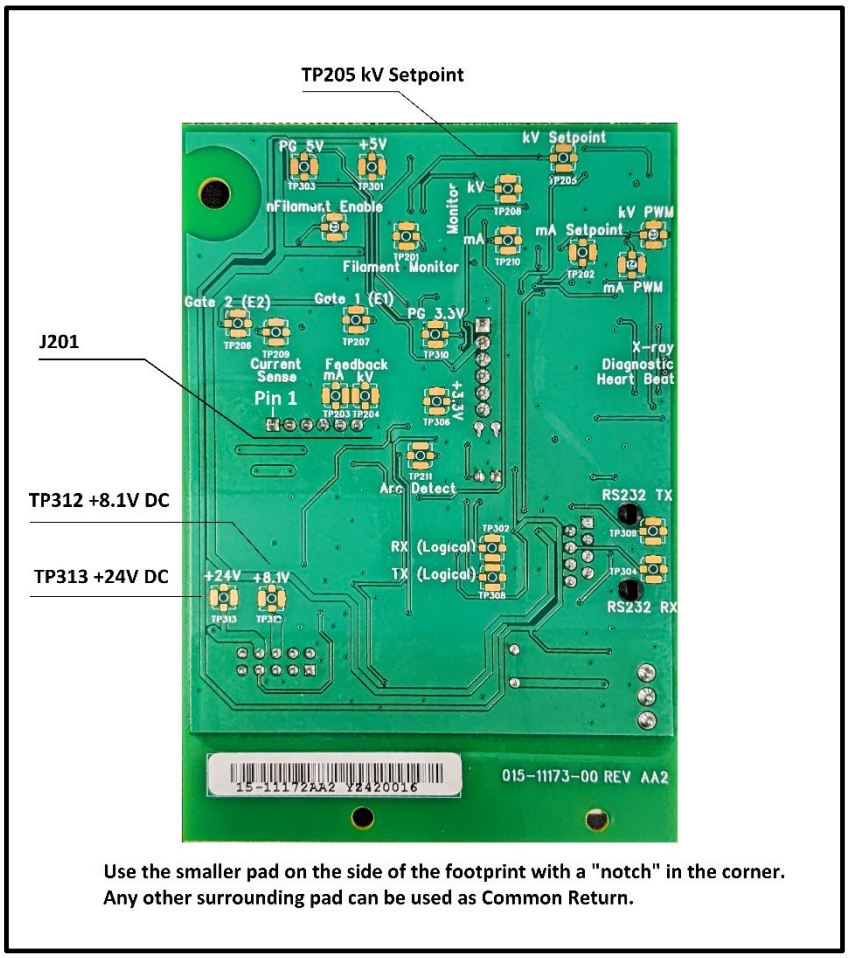


3. On the Logic Board (015-11172-00), measure voltages at TP312 (+8.1 V) and TP313 (+24 V) as shown below. Use the surrounding pads on the test points as common return. (Refer to the section “Identification of Test Point Pad “Notch”” beginning on page 198 for measurement

Continued

Troubleshooting Electrical Performance Issues (Cont.)

instructions.) If any of these voltages are not present after power is applied, next check voltages on the Power Supply Board.

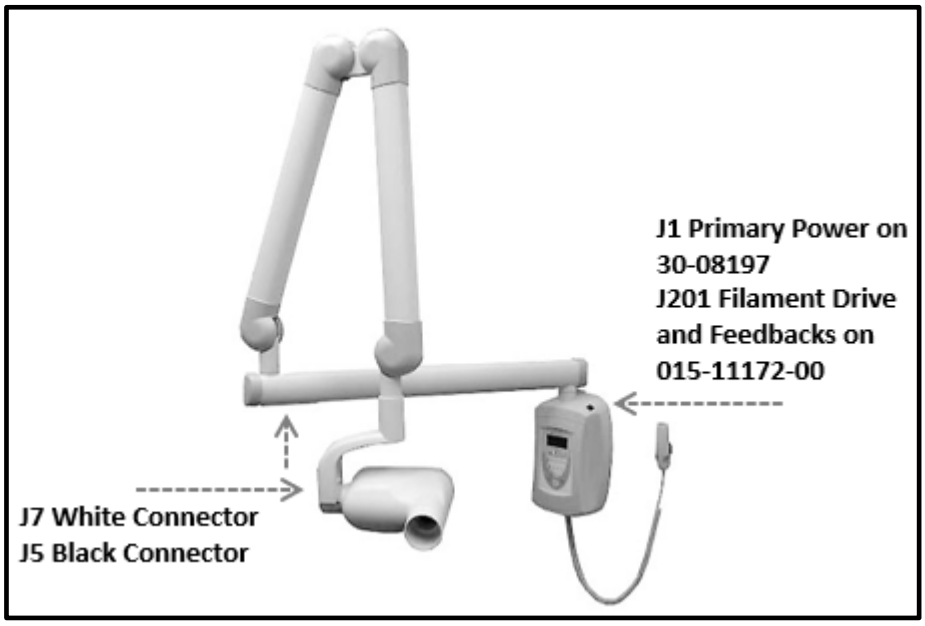


4. On the Power Supply Board, use TP2 as a common test point to check TP1 +24 volts DC and TP3 8.1 volts DC. Then use TP5 as the common return to check TP4 for the presence of +12 volts DC as shown in the image accompanying step 1 above. If any of these voltages are not present, replace the Power Supply Board. If each voltage is present, check other voltages on the Logic Board.
5. On the Logic Board, measure between the surrounding test point pads and TP205, kV Setpoint as shown in the image accompanying step 2 above. This voltage should be between 3 and 4 volts DC. If this voltage is not present, replace the Logic Board. If this voltage is correct, inspect the condition of the ribbon cable between the Power Supply Board and the Logic Board. If the cable is undamaged and seated properly, replace the Logic Board.
6. Check the condition of the cables between the Control Unit and the Tube Head assembly. If no X-ray occurs and no errors are displayed, the problem may lie within the conductors of the white connector (which is primary power to the Tube Head Assembly). If no X-ray occurs and the attempt is accompanied by a “snap” sound, the problem may lie with the conductors of the black connector (which is transmitting the feedback signals). Connections for this cable begin with controls at J1 of the Power Supply Board and J201 of the Logic Board. As shown below,

Continued

Troubleshooting Electrical Performance Issues (Cont.)

an internal set of connections will be accessed below the distal side of the Horizontal Arm and at the inside top of the Tube Head Yoke. The final set of connections is accessed by removing the Pivot Cap located at the attachment point of the Tube Head to the Yoke.



7. If D11 on the Power Supply Board is illuminated, power supplies are in order, and the cable connections are correct, place an AC voltmeter across the Tube Head connector J1 (white connector) on the black and white conductors, turn off error checking (Logic Board J402 in off position), request an exposure time of at least 1.5 s, and measure the resulting voltage during the exposure. Presence of 130 V AC will require the replacement of the Tube Head Assembly. Absence of 130 V AC will require re-inspection of the interconnect cables for open conductors.

No mA Produced

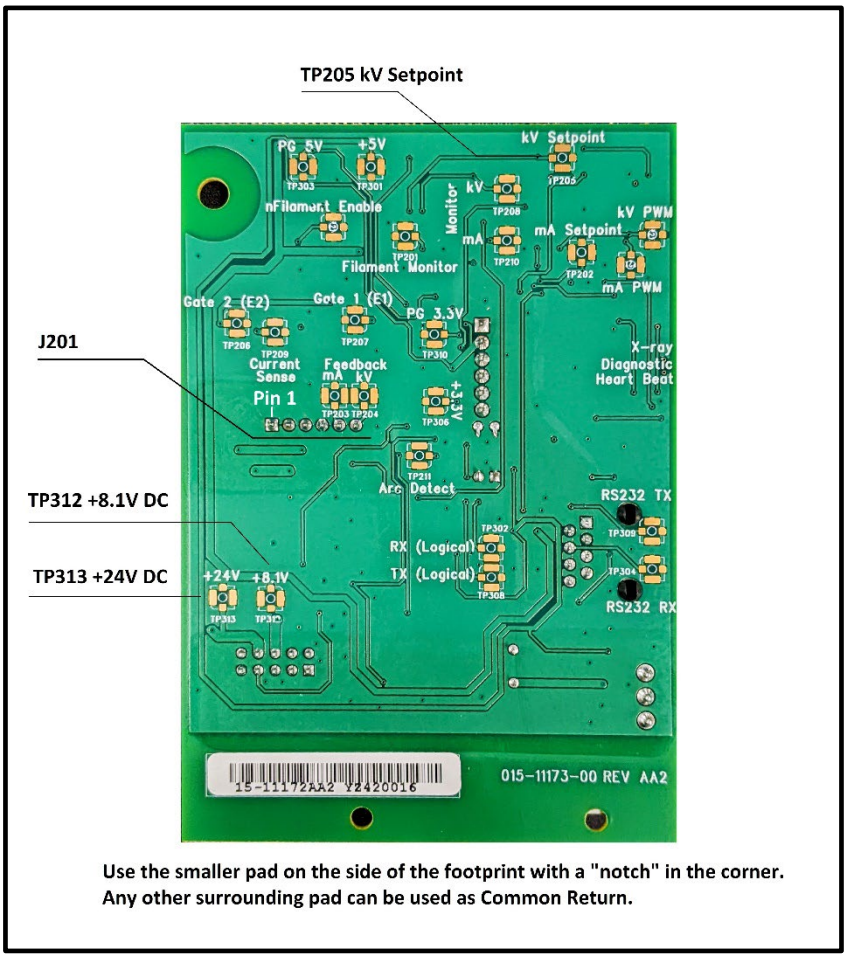
This section applies when the Operator Panel displays a message that mA is too low.

1. On the Logic Board (015-11172-00), measure voltages at TP312 (+8.1V) and TP313 (+24V) as shown below. Use the surrounding pads of the test points for common return. Refer to the section “Identification of Test Point Pad “Notch”” beginning on page 198 for measurement

Continued

Troubleshooting Electrical Performance Issues (Cont.)

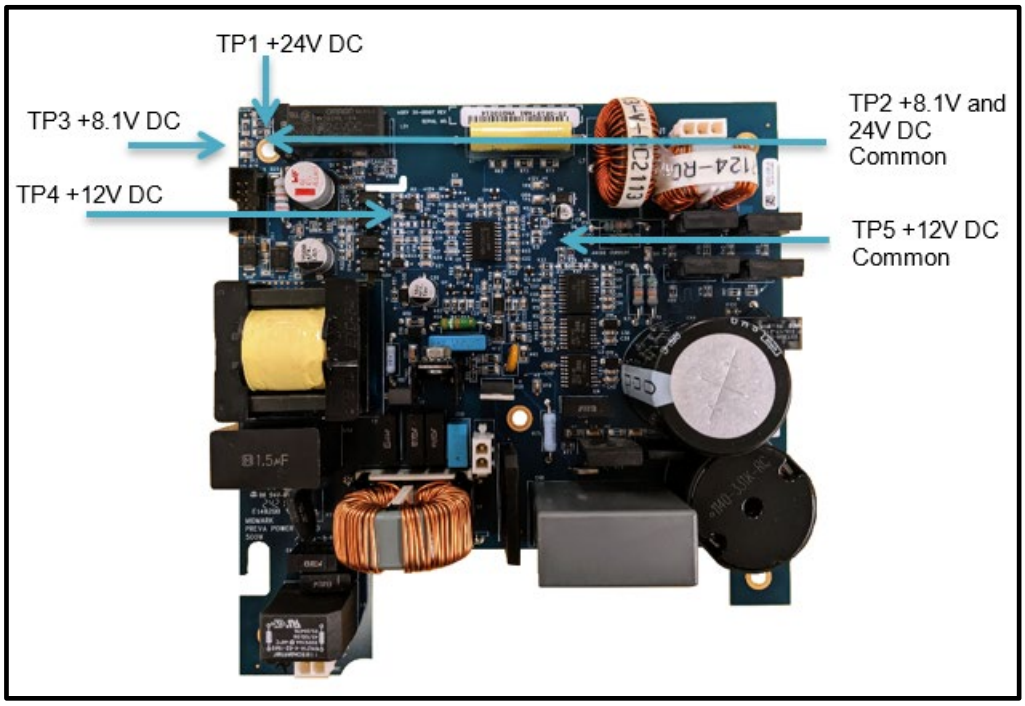
instructions. If any of these voltages are not present after power is applied, next check voltages on the Power Supply Board.



Continued

Troubleshooting Electrical Performance Issues (Cont.)

2. On the Power Supply Board (30-08197), use TP2 as a common test point to check TP1 +24 volts DC and TP3 8.1 volts DC as shown below. Then use TP5 as the common return to check TP4 for the presence of +12 volts DC.

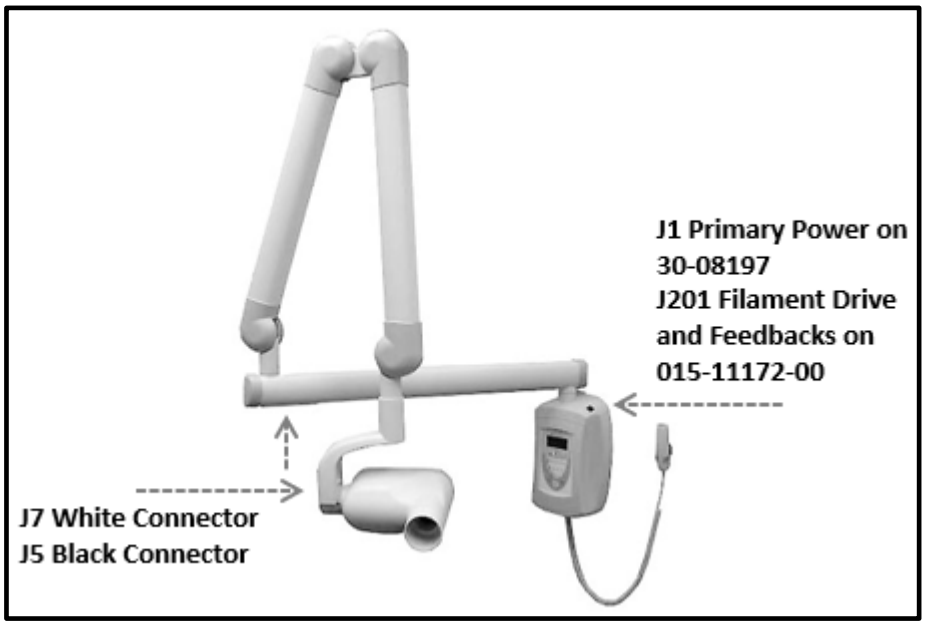


3. If any of these voltages are not present, replace the Power Supply Board. If these voltages are correct, next check voltages on the Logic Board.
4. On the Logic Board, measure the DC voltage between the surrounding test point pads and TP202, mA Setpoint. This reading should be between 1 volt and 2 volts. If this voltage is not correct, replace the Logic Board.
5. If this voltage is correct, select 1.5 seconds of exposure time and measure AC voltage across pin 1 and pin 2 of the Logic Board at the connector J201. During exposures, this value should be 24 volts. Also measure AC voltage across pin 2 and pin 3 of J201. This value should be 24 volts. If either voltage is missing, replace the Logic Board.
6. If these voltages are present, measure for the same values at the Tube Head Assembly at the connector J5 (black) on the blue and gray conductors and the blue and brown conductors. If the voltages are not present, inspect the inter-connect cables between the control and Tube Head Assembly.
7. Connections for this cable begin with controls at J1 of the Power Supply Board and J201 of the Logic Board. As shown below, an internal set of connections will be accessed below the distal side of the Horizontal Arm and at the inside top of the Tube Head Yoke. The final set of

Continued

Troubleshooting Electrical Performance Issues (Cont.)

connections is accessed by removing the Pivot Cap located at the attachment point of the Tube head to the Yoke.



8. If the voltages are present, replace the Tube Head Assembly.

High-Voltage Breakdown

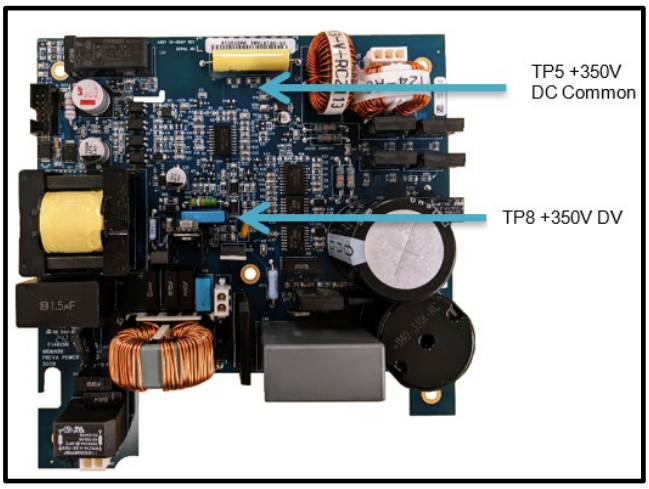
High-voltage breakdown is characterized by a loud snap during an exposure attempt.

> ⚠CAUTION High voltage present.

1. Turn the power switch off and on to reset the circuit breaker. This will recover the power to the board if the circuit breaker was activated during the previous exposure.
2. Verify that the D11 light is illuminated on the Power Board. Replace the Power Board if it is not. If it is illuminated, proceed to step 3.
3. On the Power Supply Board (30-08197), measure the voltage across TP5, the Common Return, and TP8, + 350 V DC, as shown below. This voltage will be acceptable if measured between 330 V and 390 V DC while an exposure is being taken. Values above or below this range indicate the need to replace the Power Supply Board.

Continued

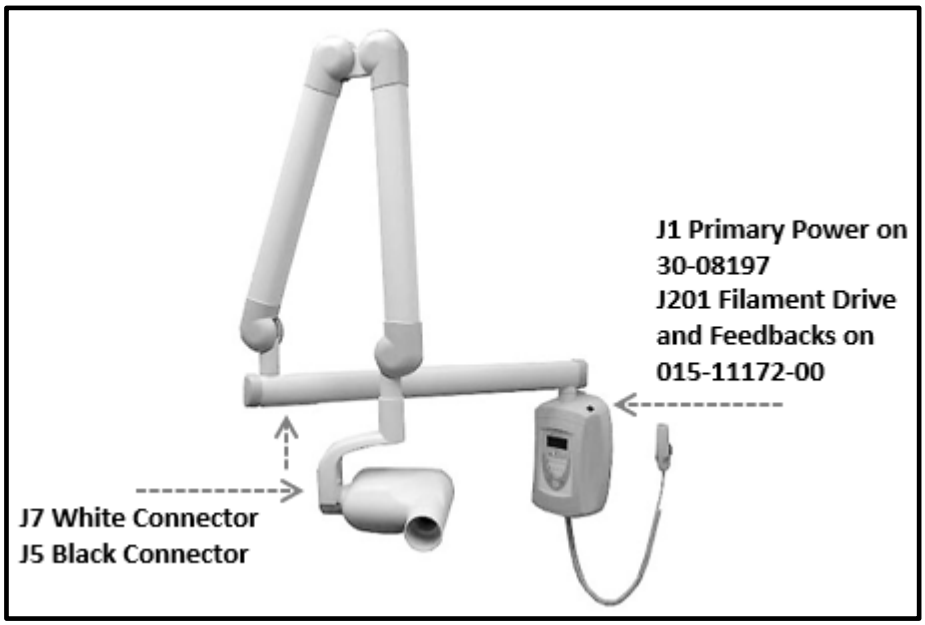
Troubleshooting Electrical Performance Issues (Cont.)



4. If the voltage is correct, inspect the condition of the cabling between the Power Supply Board, Logic Board, and Tube Head Assembly.

⚠CAUTION	High voltage present.

Of particular importance are the conductors held by the black connectors. These conductors transmit the feedback values from the Tube Head Assembly and directly affect the control of power to the Tube Head Assembly. Connections for this cable begin with controls at J1 of the Power Supply Board and J201 of the Logic Board. As shown below, an internal set of connections will be accessed below the distal side of the Horizontal Arm and at the inside top of the Tube Head Yoke. The final set of connections is accessed by removing the Pivot Cap located at the attachment point of the Tube Head to the Yoke.

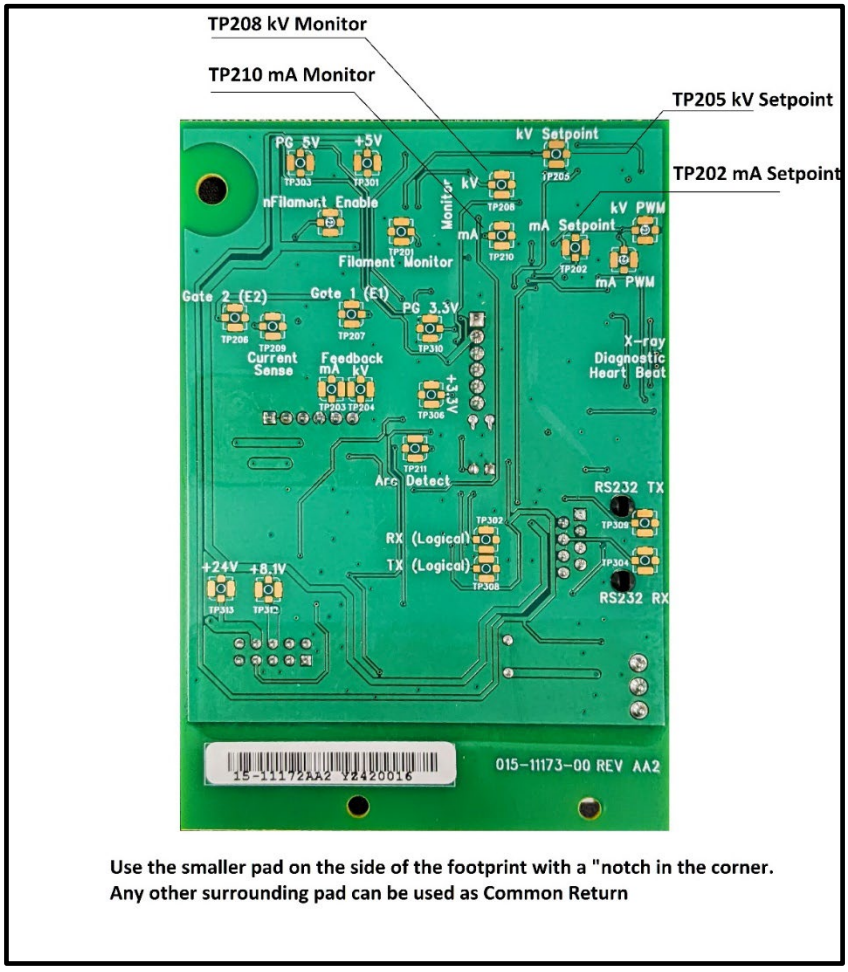


Continued

Troubleshooting Electrical Performance Issues (Cont.)

5. If the cabling is found acceptable, select 1.5 seconds of exposure time and, placing a DC voltmeter on the surrounding pads of the test points of Logic Board 015-11172-00, measure the feedback values at TP210 mA Monitor and TP208 kV Monitor, as shown below. Refer to the section “Identification of Test Point Pad “Notch”” beginning on page 198 for measurement instructions. Look for the following values:

   - TP210 – mA Monitor. This voltage should be between 1.5 V and 3.5 V DC during exposure attempts. The voltage should not oscillate between 1.5 and 3.5; instead, the measurement should come to a specific value and stabilize. Oscillating values or absent values will indicate the need to replace the Tube Head Assembly.
   - TP208 – kV Monitor. This voltage should be between 3 V and 4 V DC during exposure attempts. The voltage should not oscillate between 3 and 4; instead, the measurement should come to a specific value and stabilize. Oscillating values or absent values will indicate the need to replace the Tube Head Assembly. If the feedback voltages are present and stable, replace the Logic Board.



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Replacing and Adjusting Preva Components

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Determining the Necessary Adjustment 225
Tube Head Movement Horizontal Arm Adjustment 226
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Outside Articulated Arm Vertical Movement 228
Control Side of Articulated Arm Balance Adjustment 228
Articulated Arm Friction Adjustments 230
Replacing the Power Cord on a Mobile Device 231
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Replacing and Adjusting Preva Components (Cont.)

Preva Tube Head Removal and Replacement

Tube Heads are shipped with the yoke cable assembly already pre-mounted to the Tube Head. This guide provides instructions for the installation technician on how to remove the original head, install the replacement Tube Head, and how to calibrate the replacement Tube Head.

⚠CAUTION	The Articulated Arm will spring open and can cause serious injury if it is not secured. The spring tension is adjusted to account for the weight of the Tube Head. Do not remove the Tube Head until the Articulated Arm assembly has been secured.

Required Tools

- Spanner wrench (30-T0124)
- Needle-nose pliers
- Metric hex keys
- #2 Phillips head screwdriver
- #1 Phillips head screwdriver
- Fluorescent screen (22-11467)

Instructions

1. Remove the end cap from the side of the Tube Head that is currently on the arm.

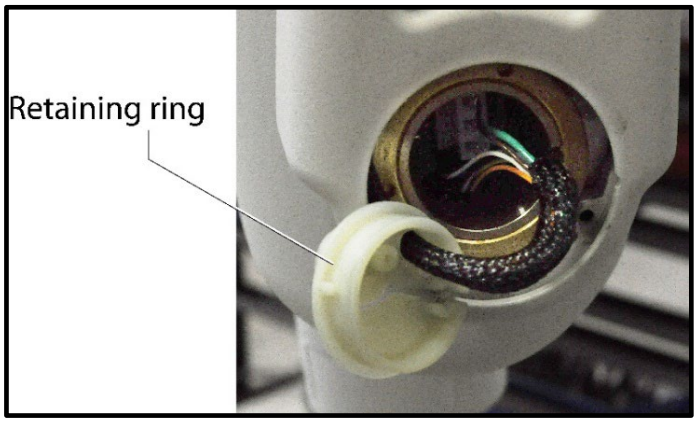
Continued

Replacing and Adjusting Preva Components (Cont.)

2. Remove the small Phillips head screw that holds the cable restraint and remove the restraint.

3. Remove the larger Phillips head screw.

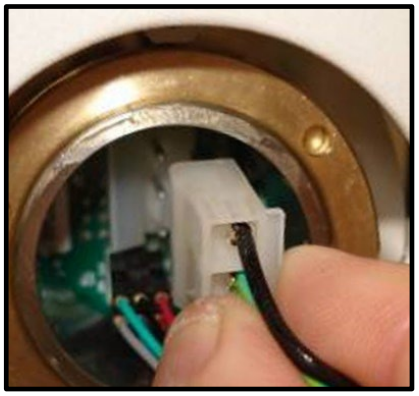
4. Remove the retaining ring by pulling it out with a pair of needle-nose pliers.

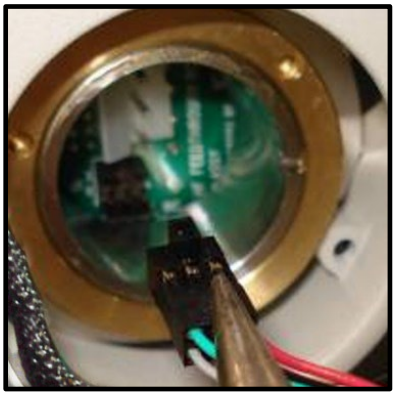


Continued

Replacing and Adjusting Preva Components (Cont.)

5. Unplug the white and black connectors located inside the Tube Head.

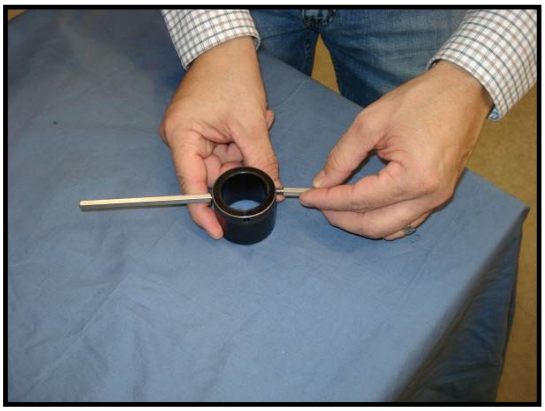




6. Secure the articulated arm.

⚠WARNING The Articulated Arm will spring open and can cause serious injury if it is not secured. Do not remove the Tube Head until this step has been completed.

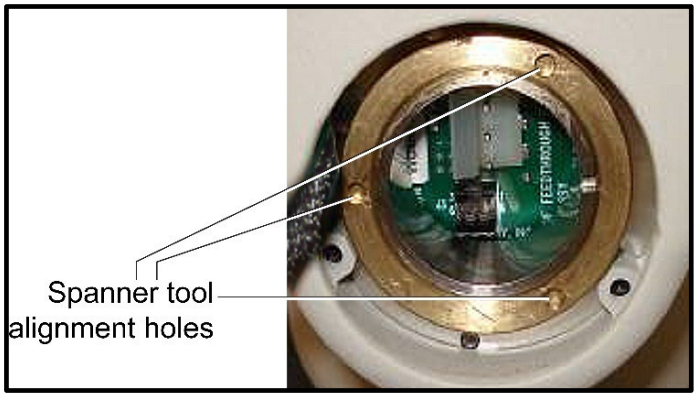
7. Assemble the spanner wrench by threading the two leverage arms into the base of the spanner wrench.



Continued

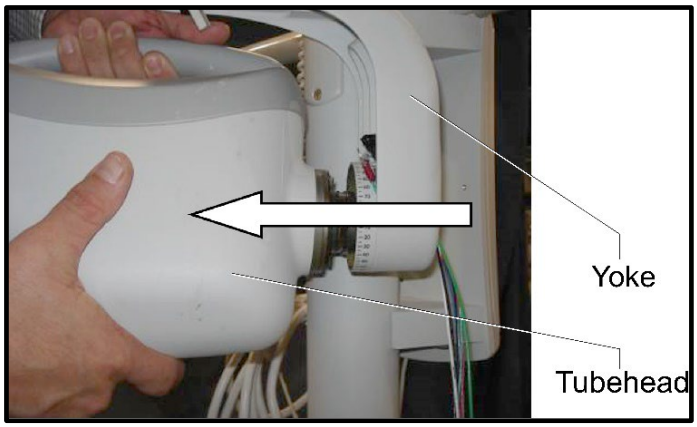
Replacing and Adjusting Preva Components (Cont.)

8. Align the three pins on the spanner tool with the alignment holes in the brass friction nut.



9. Loosen the friction nut by turning the spanner wrench counterclockwise.

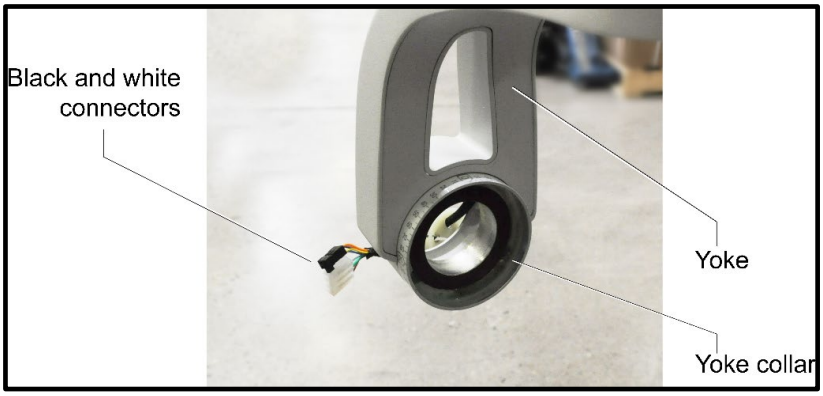
10. Repeat steps 8 and 9 to remove the second friction nut.
11. Carefully remove the Tube Head from the yoke.



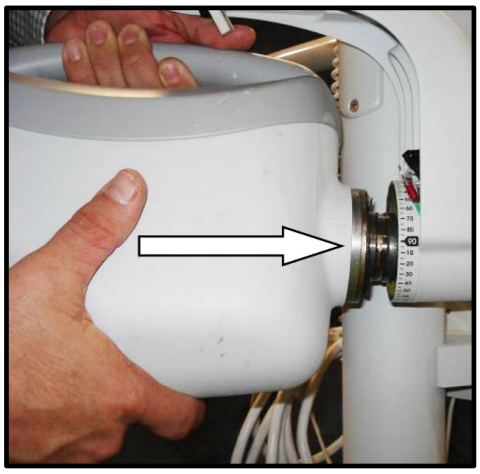
Continued

Replacing and Adjusting Preva Components (Cont.)

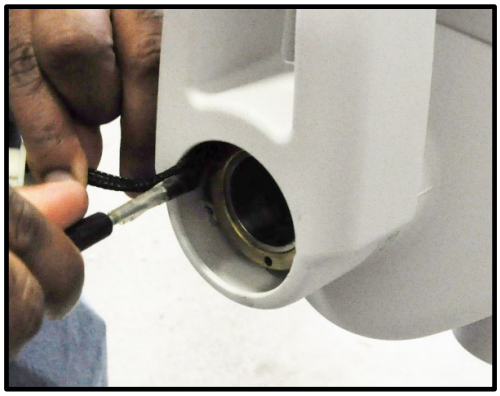
12. The black and white connectors and the yoke collar will remain with the yoke.



13. Insert the new Tube Head into the yoke collar.



14. Manually thread the friction nut on the Tube Head shaft. Insert a small screwdriver into one of the alignment holes to spin the friction nut until snug.

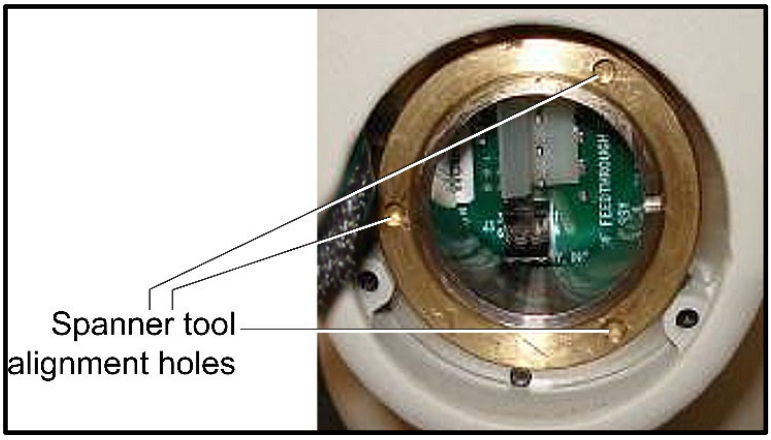


NOTICE Take care not to pinch or cut the cable.

Continued

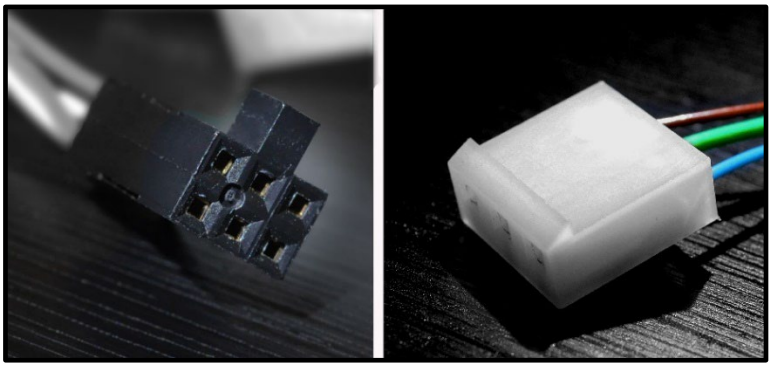
Replacing and Adjusting Preva Components (Cont.)

15. Align the three pins on the spanner wrench with the three holes in the friction nut.



16. Tighten the friction nut.

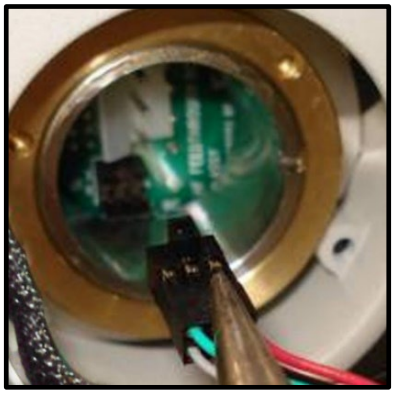
17. Repeat steps 14 through 16 for the second friction nut.
18. Note that the black and white connectors are tabbed so they can be connected in only one orientation.

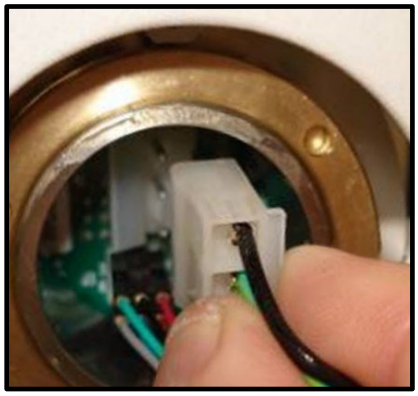


Continued

Replacing and Adjusting Preva Components (Cont.)

19. Reconnect both connectors that were disconnected earlier in this procedure.





20. Snap the retaining ring into the center of the friction nut. Orient the retaining ring with the larger screw hole at the nine o'clock position.

21. Secure the retaining ring with the larger Phillips head screw.

Continued

Replacing and Adjusting Preva Components (Cont.)

22. Secure cable restraint.

23. Place the cap back on the Tube Head.

24. Calibrate the tube head. Refer to the section “Calibration” beginning on page 192 of this manual.

Mechanical Adjustments

Determining the Necessary Adjustment

The balance and friction of the Articulated Arm and the friction of the Tube head are initially set at the factory. During the installation process, check the balance and friction. When moving the Tube Head, the Articulated Arm should be steady in all positions and move before the Horizontal Arm.

NOTICE	The mechanical adjustments should not be used to compensate for a system that is not properly leveled on the wall.

Continued

Replacing and Adjusting Preva Components (Cont.)

Tube Head Movement Horizontal Arm Adjustment

NOTICE If performing this adjustment as part of the initial installation of the Preva, skip steps 1 – 3.

1. Remove the screw from the Control Unit front cover.
2. Carefully remove the front cover. If the Operator Panel is installed on the Control Unit, carefully keep the Operator Panel together with the front cover.
3. Set the front cover aside.
4. Locate the brake assembly at the top of the Control Unit. The brake assembly has a screw on either side of a clamping bar over the Horizontal Arm pivot post.

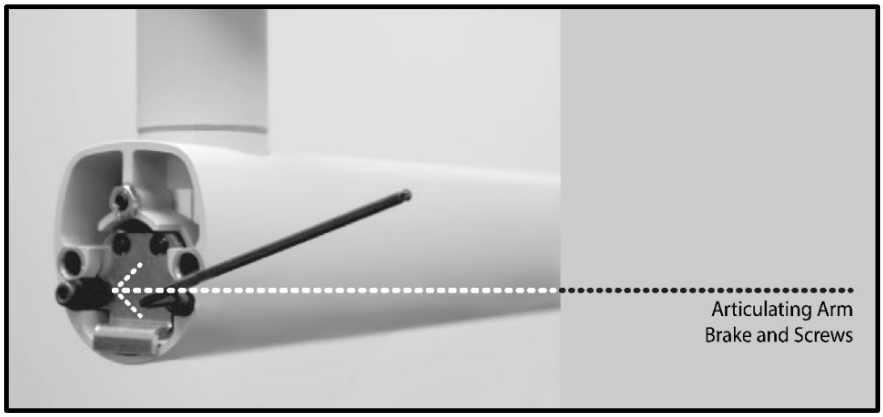
5. Using a 4 mm hex key, tighten the screws equally to apply adequate braking to the pivot post so that Horizontal Arm begins to move after the Articulated Arm.
6. Replace front cover of the Control Unit. Replace the screw on the front cover.

Continued

Replacing and Adjusting Preva Components (Cont.)

Adjusting the Horizontal Arm Brake Assembly

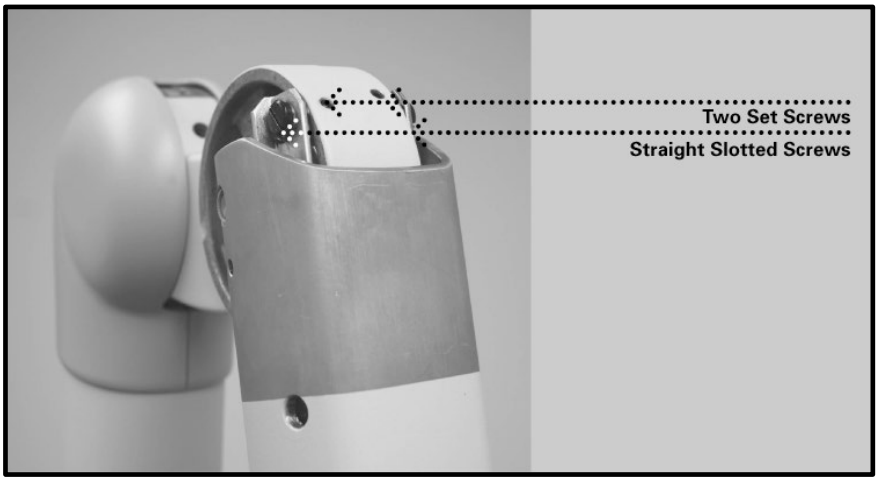
Locate the friction assembly screws. Using a 3 mm hex key as shown below, tighten or loosen screws as necessary to get proper movement without unwanted horizontal movement of the Articulated Arm.



⚠CAUTION Do not attempt to adjust any other screws in the Horizontal Arm.

Adjusting the Articulated Arm

Follow this procedure ONLY if the yoke assembly does not stop on its own and contacts the Horizontal Arm. Refer to the image below while following this procedure.



1. Loosen the two set screws indicated in the picture, but do not remove them completely.
2. Loosen the two straight-slotted screws indicated in the picture, but do not remove them completely. (Note: The picture shows only one of the two screws; the other is located on the opposite side of the arm.)
3. Move the Articulated Arm into the position where it is desired for it to stop before it makes contact with the Horizontal Arm.

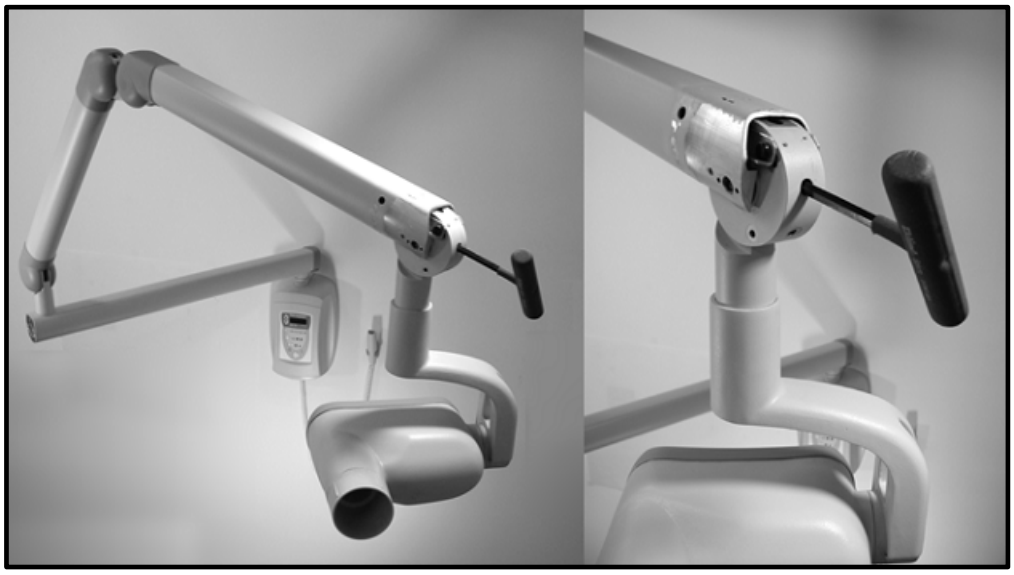
Continued

Replacing and Adjusting Preva Components (Cont.)

4. Tighten the two straight-slotted screws.
5. Tighten the two set screws.

Outside Articulated Arm Vertical Movement

1. Remove the plastic trim covers from the end of the Articulated Arm nearest to the Tube Head.
2. Position the Articulated Arm with the arm nearest the Tube Head fully upward.
3. Loosen set screws as described in the section “Articulated Arm Friction Adjustments” beginning on page 230 of this manual.
4. Insert a 23 cm (9 in) long 8 mm hex key (T-handle) into the adjustment nut as shown below. Turning the wrench clockwise will cause the Control Unit side of the Articulated Arm to lift. Turning it counterclockwise will cause it to drop.



5. Adjust as necessary until the Control Unit side of the Articulated Arm no longer drifts.
6. Tighten set screws as described in the section “Articulated Arm Friction Adjustments” beginning on page 230 of this manual to achieve desired Articulated Arm motion.
7. Replace the plastic covers on the end of the Articulated Arm.

Control Side of Articulated Arm Balance Adjustment

1. Remove the plastic covers at the top of the Articulated Arm.
2. Position the Articulated Arm at a 45-degree angle.
3. Loosen set screws as described in the section “Articulated Arm Friction Adjustments” beginning on page 230 of this manual.

Continued

Replacing and Adjusting Preva Components (Cont.)

4. Place a 23 cm (9 in) long 8 mm hex key (T-handle) into the adjustment nut inside the Articulated Arm as shown below.

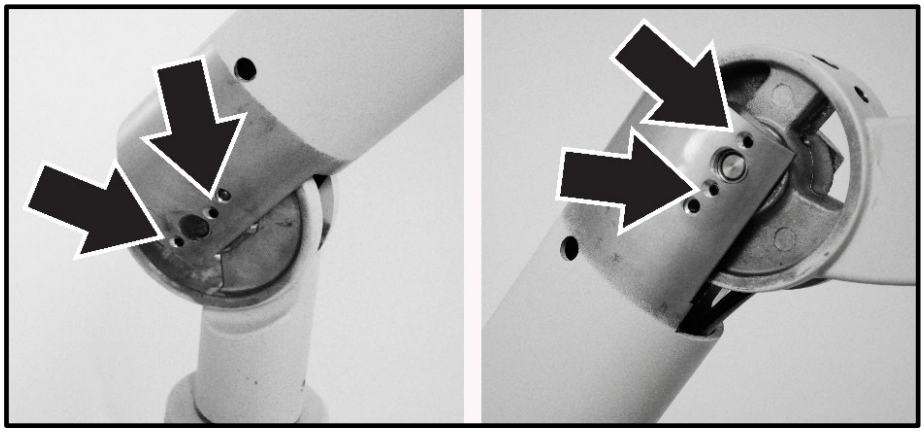
5. Turning the wrench clockwise will cause the Control Unit side of the Articulated Arm to lift. Turning it counterclockwise will cause it to drop. Adjust as necessary until the Control Unit side of the Articulated Arm no longer drifts.
6. Tighten set screws as described in the section “Articulated Arm Friction Adjustments” beginning on page 230 of this manual to achieve desired Articulated Arm motion.
7. Replace the plastic covers on top of the Articulated Arm.

Continued

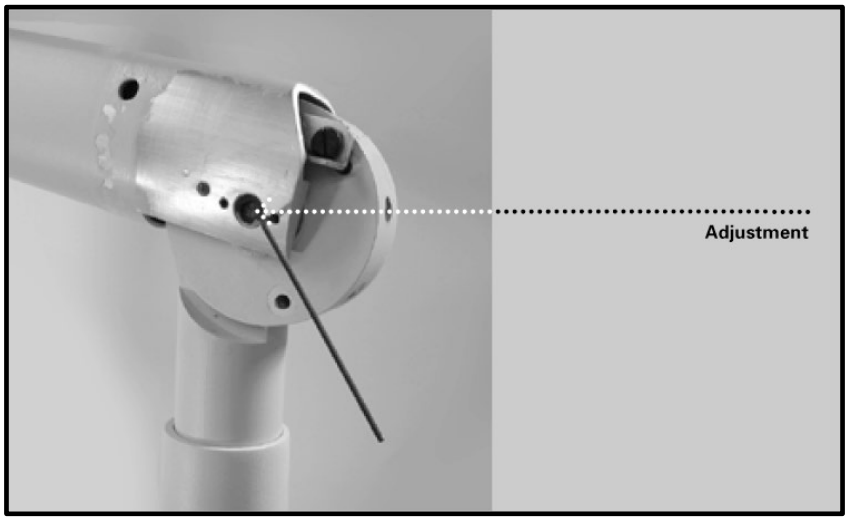
Replacing and Adjusting Preva Components (Cont.)

Articulated Arm Friction Adjustments

The Preva has four friction adjustment points located at the four pivot points of the Articulated Arm. These friction points can be adjusted to reduce or increase the force needed to position the Articulated Arm.



1. Remove the plastic covers on the Articulated Arm to access the adjustment points.
2. Using a 2 mm hex key as shown below, tighten both screws evenly at each adjustment point until the movement of the Articulated Arm is as desired. Do not loosen adjustment points so far as to allow the Articulated Arm to drift.



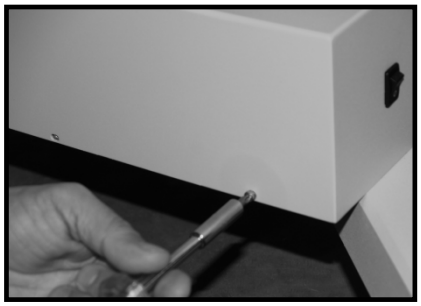
Continued

Replacing and Adjusting Preva Components (Cont.)

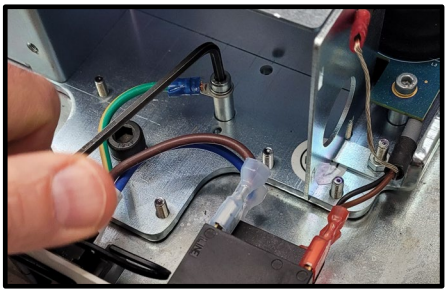
Replacing the Power Cord on a Mobile Device

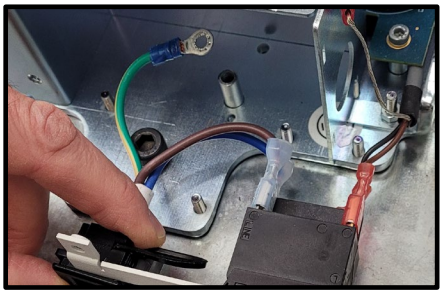
Tools required: Phillips screwdriver, 3 mm hex key, needle-nose pliers.

1. Remove the six screws that secure the Control Unit cover. Remove the cover.

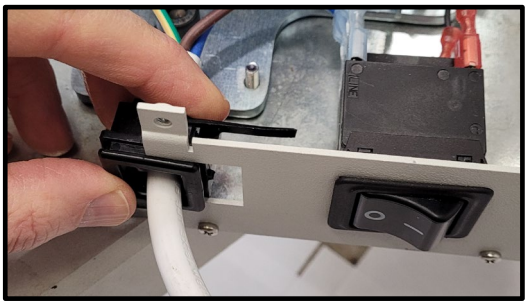


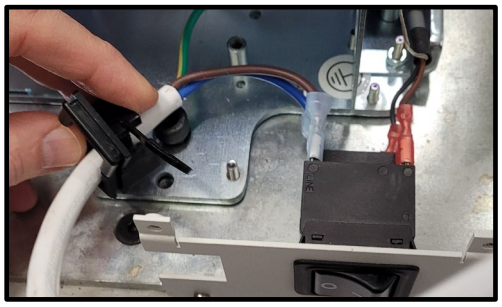
2. Using the 3 mm hex key, loosen and remove the nut and lock washer that secure the green-and-yellow ground wire.





3. Slide the strain relief out of the metal slot.

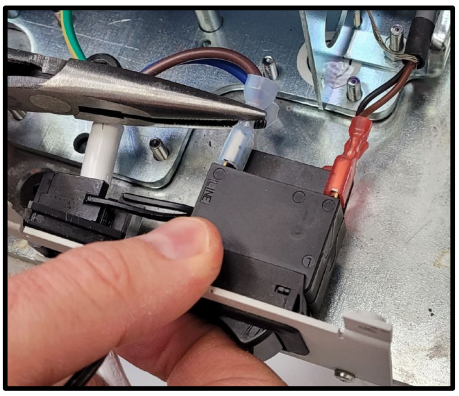
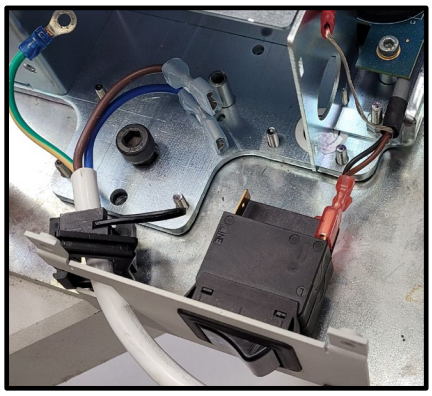




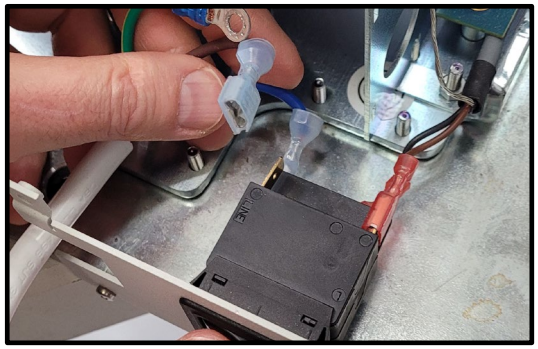
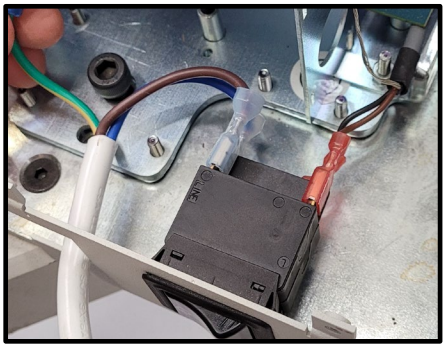
Continued

Replacing and Adjusting Preva Components (Cont.)

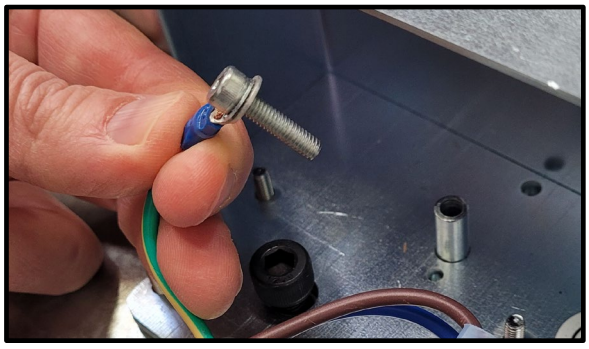
4. Using the pliers, remove the blue neutral conductor and brown line conductor connections from the power switch.

5. The power cord being removed is now free. Remove it and discard.
6. Locate the new power cord. Connect the blue neutral conductor and brown line conductors to the power switch as shown below. The blue wire goes on the bottom and the brown wire goes on the top.

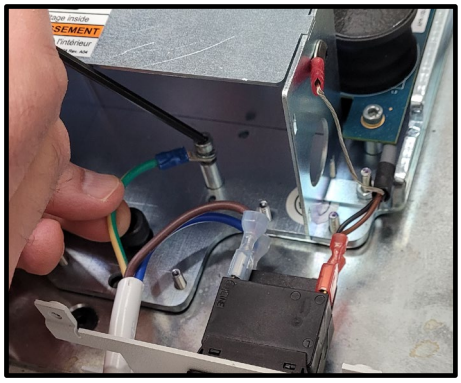
7. Slide the lock washer onto the screw, then slide the screw through the ring on the green-and-yellow ground wire.



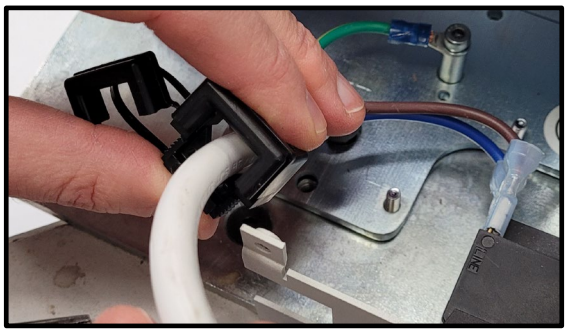
Continued

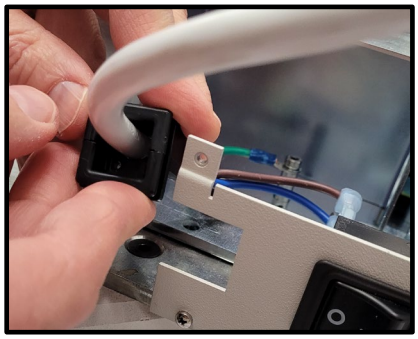
Replacing and Adjusting Preva Components (Cont.)

8. Secure the ground wire using the 3 mm hex key.

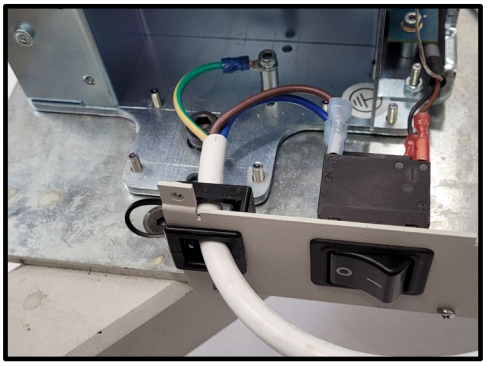


9. Snap the strain relief onto the new power cord.





10. Slide the strain relief into the bracket slot.



11. Reinstall the Control Unit cover.
12. Plug the power cord into a wall outlet and test the system for normal operation.

Replacing a Cone

Refer to the section Operating Instructions beginning on page 159 of this manual.

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Component Diagrams

Arm and Tube Head Diagram 237
Horizontal Arm Diagram 238
Mounting Plates Diagram 238
Operator Panel Diagram 239
Control Unit Diagram 240
Hand Switch Diagram 242

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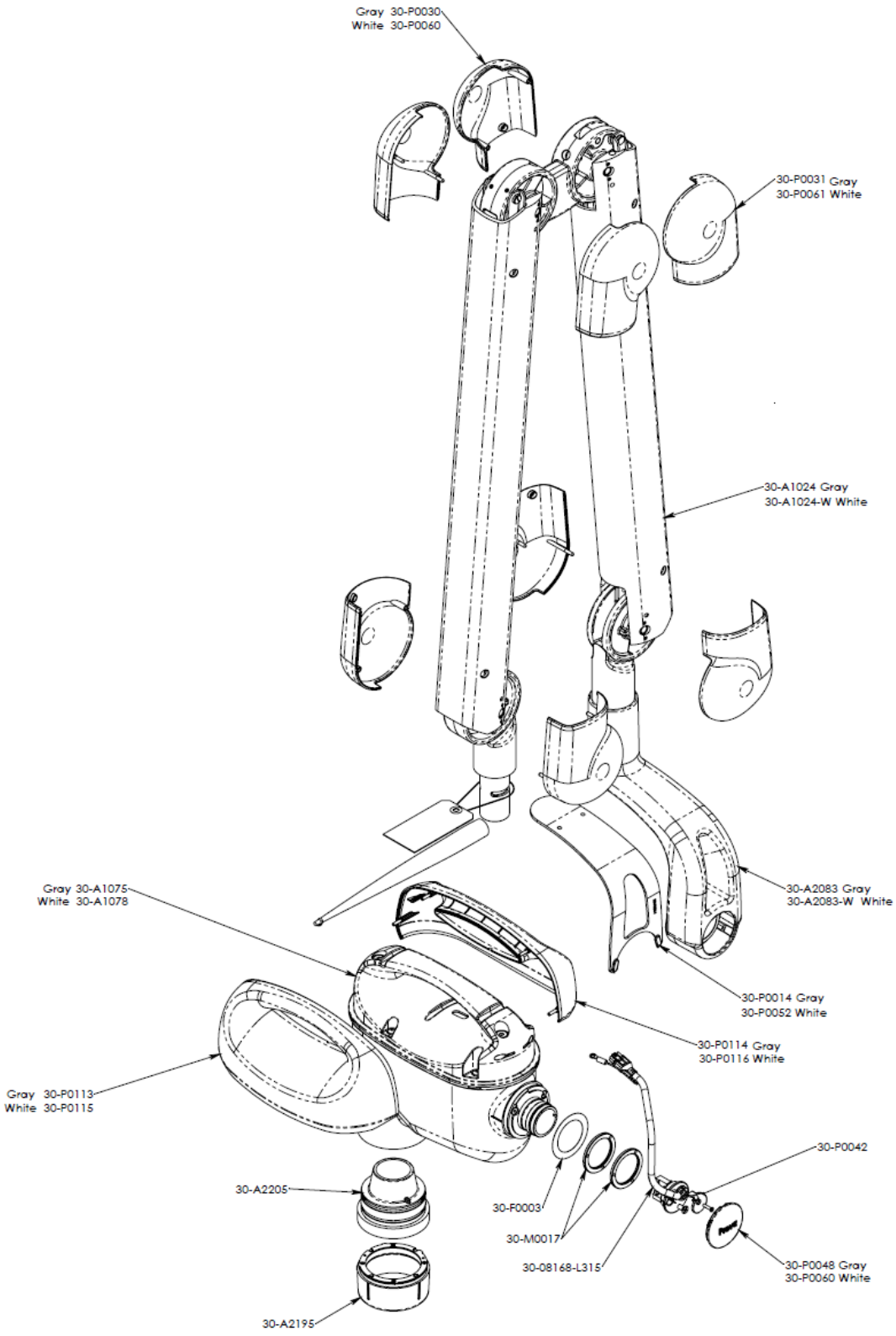
Component Diagrams (Cont.)

Arm and Tube Head Diagram



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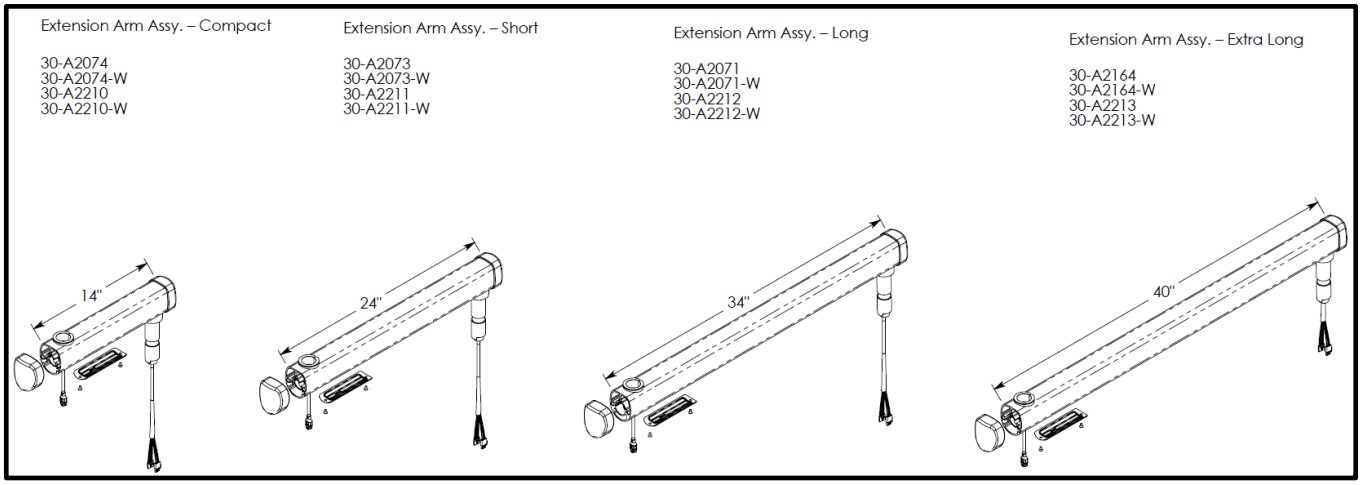
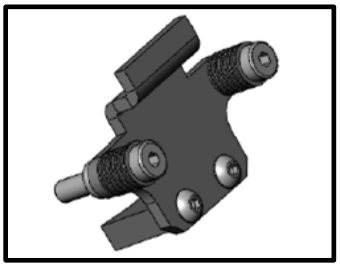
Component Diagrams (Cont.)

Horizontal Arm Diagram

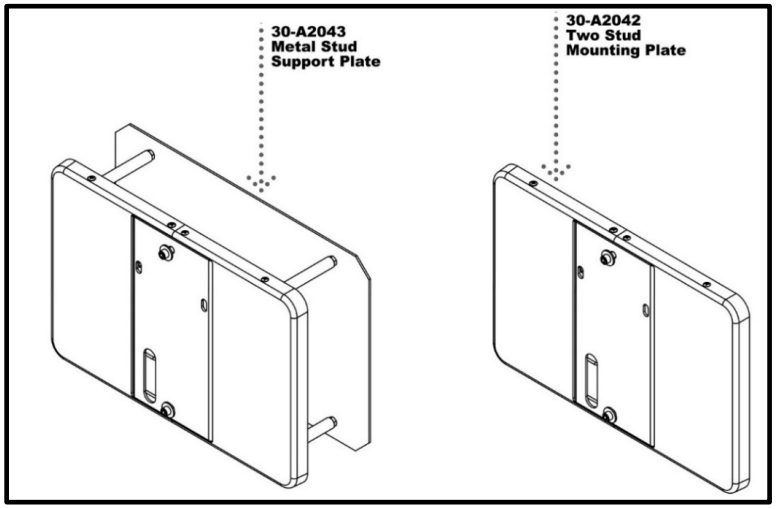


Horizontal Arms



Articulated Arm Brake

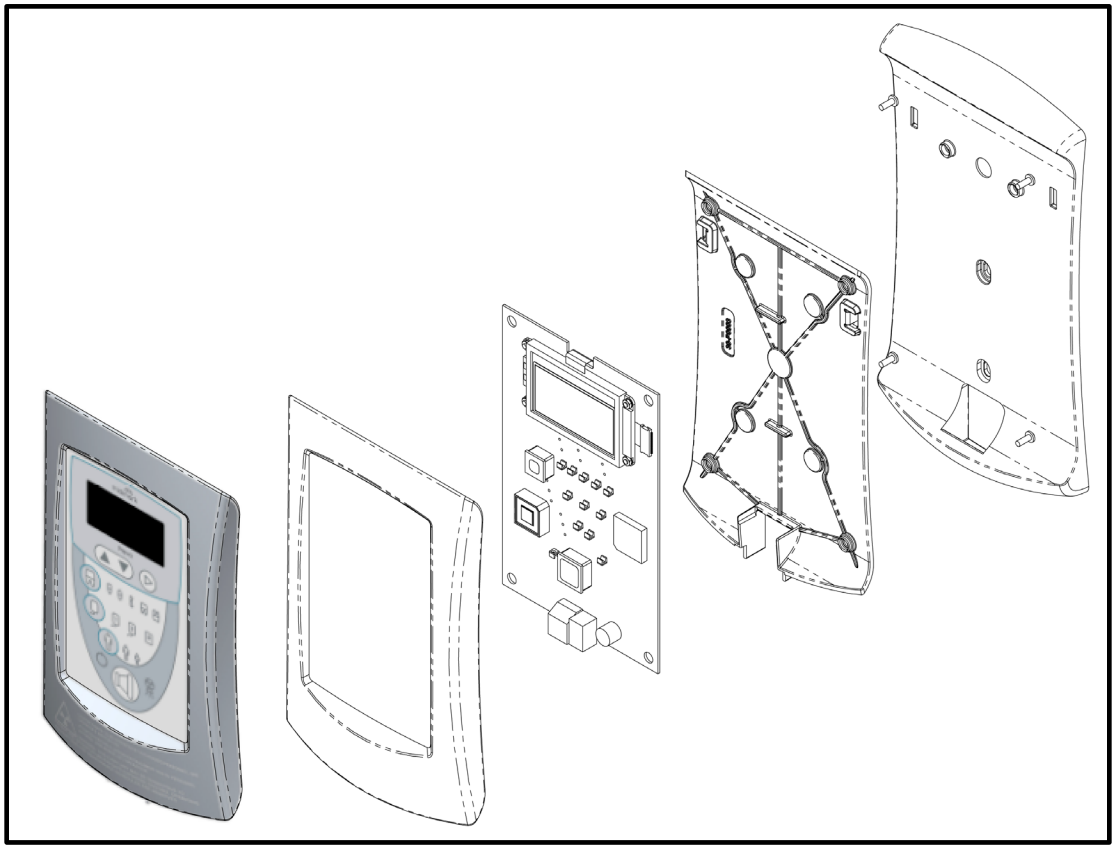
Mounting Plates Diagram



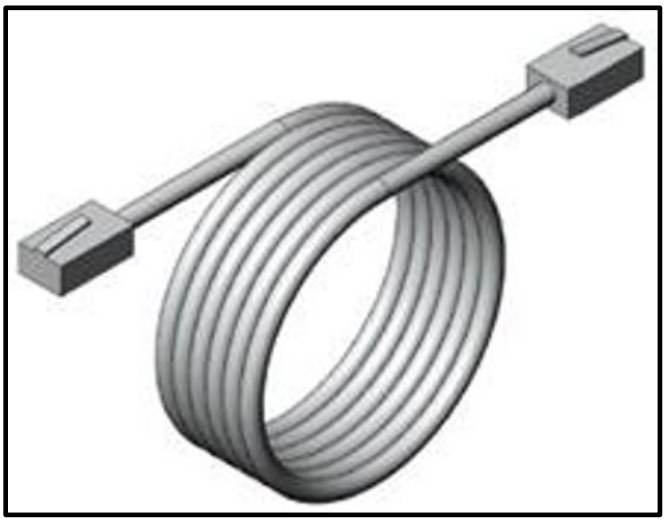
Continued

Component Diagrams (Cont.)

Operator Panel Diagram



Operator Panel

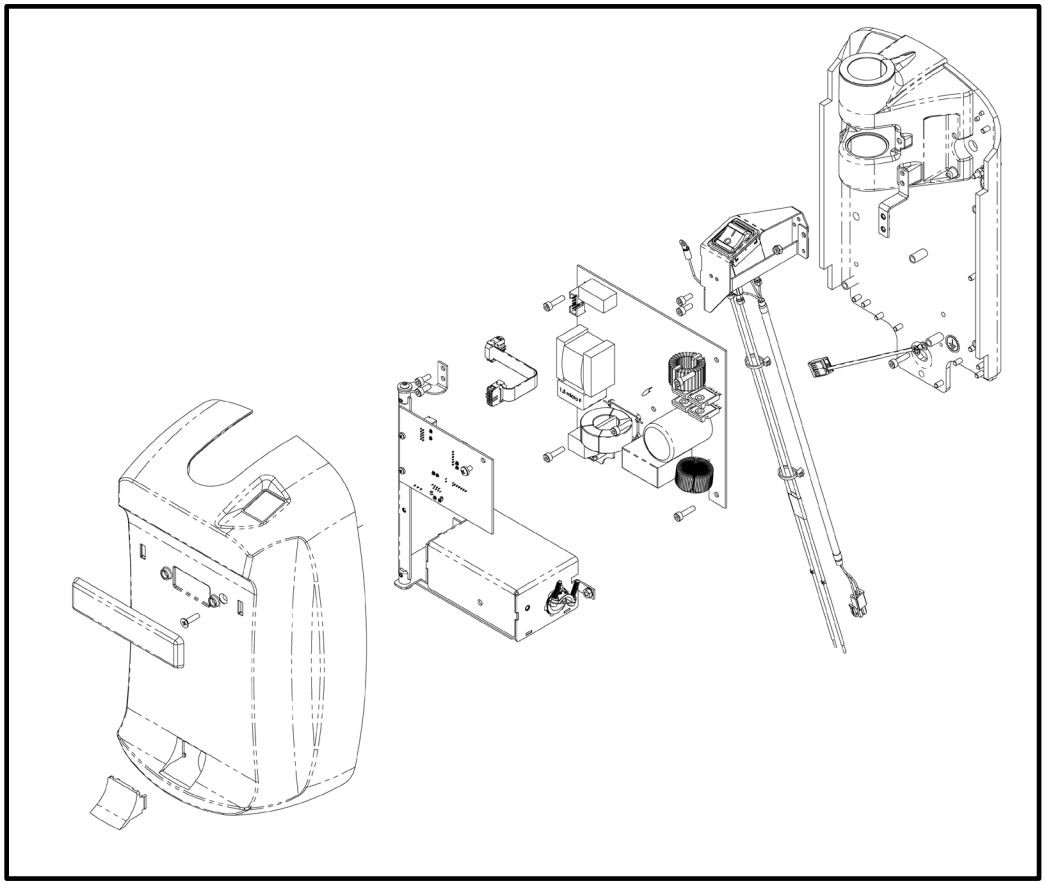


Cables: Cat 5 15 m (50 ft) E1-13034
Cat 5 7.6 m (25 ft) E1-13003
Cat 5 15 cm (6 in) E1-13004
Exposure Cord Pigtail 30-08035

Continued

Component Diagrams (Cont.)

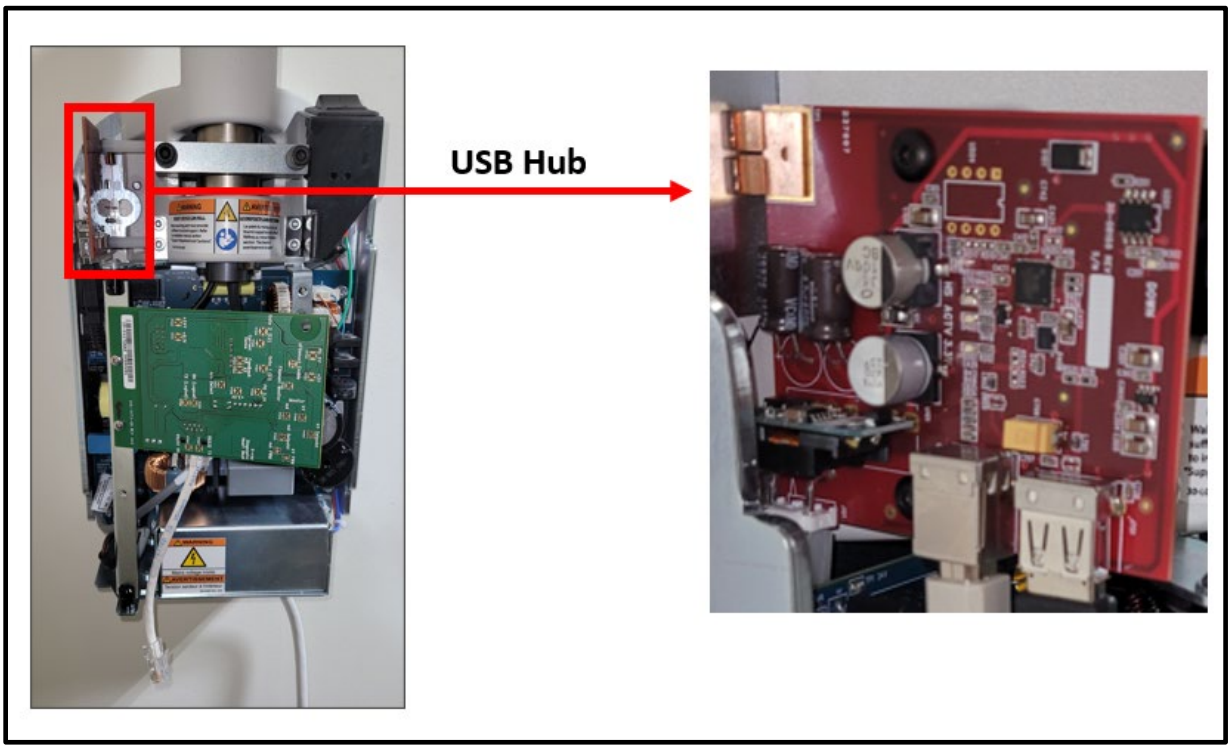
Control Unit Diagram



Control Unit Assembly

Continued

Component Diagrams (Cont.)

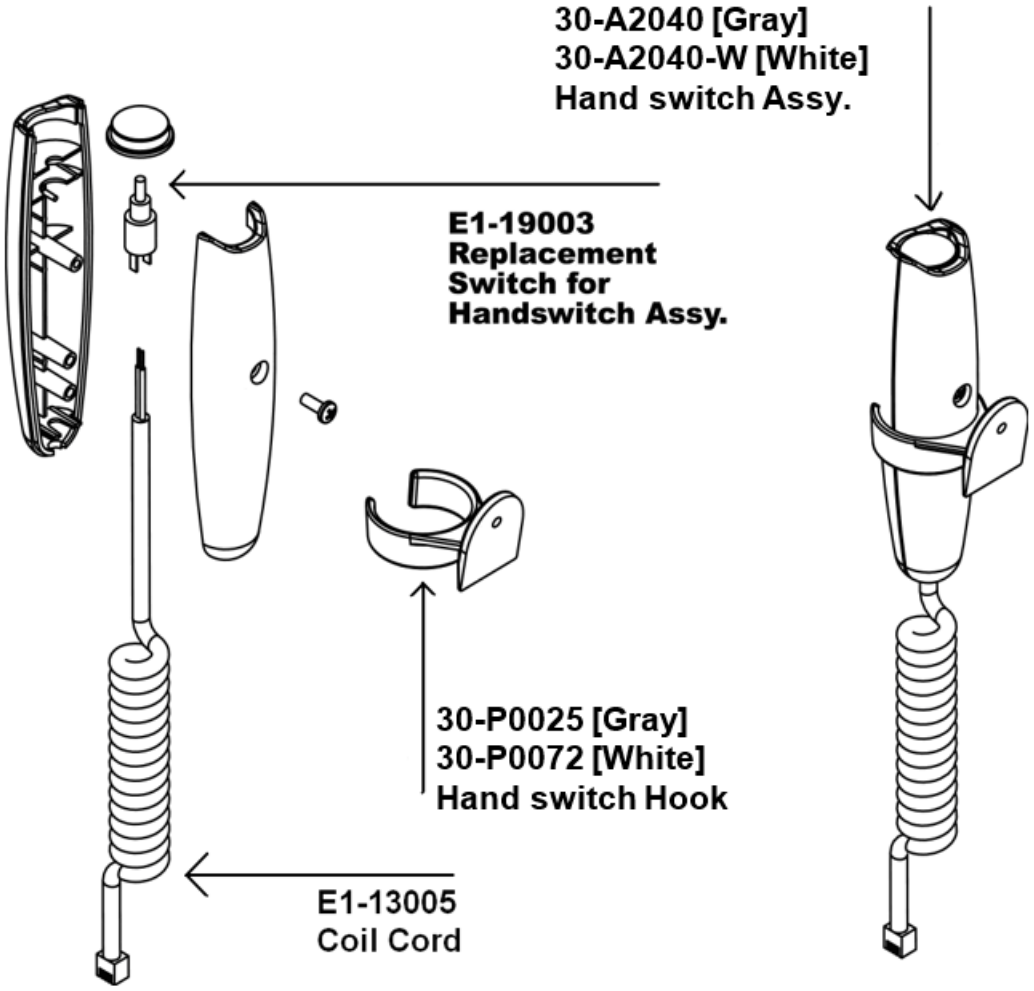


USB Hub

Continued

Component Diagrams (Cont.)

Hand Switch Diagram



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Quality Control (QC)

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Certified Components 246
Performance Factors 246
Qualification Procedure 247
Seasoning Procedure 247

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Quality Control (QC) (Cont.)

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.

Continued

Quality Control (QC) (Cont.)

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.
- This procedure is not needed immediately after Tube Head replacement. Instead, refer to the section “Calibration” beginning on page 192 of this manual.

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.

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Appendix A: Commissioning and Maintenance

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Appendix A: Commissioning and Maintenance (Cont.)

Preva must be serviced as specified in this Appendix 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 this manual.

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 performing cleaning and disinfection procedures.

Appendix A: Commissioning and Maintenance (Cont.)

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 patient contact areas with soft disposable towels.
- Verify that all product labels remain intact and are legible.

Appendix A: Commissioning and Maintenance (Cont.)

Function Readiness Checklist

Performing the tasks on this checklist verifies the electrical, mechanical, and software readiness of Preva. Refer to the section “Periodic Maintenance Schedule” beginning on page 257 for frequency of the below tasks and further detail on how to carry them out.

The following checks must be performed to complete the installation of the Preva and as part of the recommended maintenance as indicated in the User Manual. Failure to perform these checks may result in an installation that does not comply with U.S. Radiation Performance Standards 21 CFR Subchapter J.

⚠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.
- If the Preva does not perform the functions below, advise the owner that the system is not to be used. See the section “Troubleshooting Electrical Performance Issues” beginning on page 194 of this manual or contact Midmark’s Technical Support.

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 and properly 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.	

Continued

Appendix A: Commissioning and Maintenance (Cont.)

Function Readiness Checklist (Cont.)

Task Area	Description	✓
Tube head	Check for oil leaks or other evidence that could indicate internal damage. If necessary, replace the tube head.	
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.	
Task Area	Description	
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.	

Appendix A: Commissioning and Maintenance (Cont.)

Periodic Maintenance Schedule

The Preva System requires the following maintenance. Refer to the section “Function Readiness Checklist” beginning on page 255 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.

Continued

Appendix A: Commissioning and Maintenance (Cont.)

- 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), circuit breaker and 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. Circuit breaker & power switch
   - Visually inspect and verify the operation of the circuit breaker & power switch. The operator panel will only be illuminated when the circuit breaker & power switch are in the ON position.
3. Exposure Switches

Continued

Appendix A: Commissioning and Maintenance (Cont.)

- 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 43.

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 instructions in the section “Qualification Procedure” beginning on page 247 of this manual.

Appendix A: Commissioning and Maintenance (Cont.)

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.

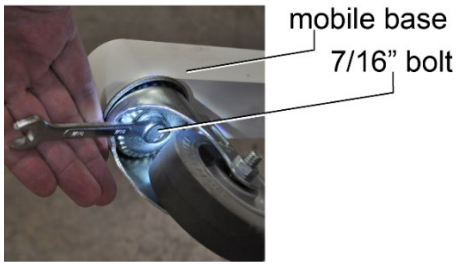
⚠CAUTION	Two people are required to perform this step.

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.

Continued

Appendix A: Commissioning and Maintenance (Cont.)

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.

Continued

Appendix A: Commissioning and Maintenance (Cont.)

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.

Appendix B: Technical Specification

Electrical Specification 265
X-ray Source Specification 266
Source to Object Distance 269

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Appendix B: Technical Specification (Cont.)

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)

Continued

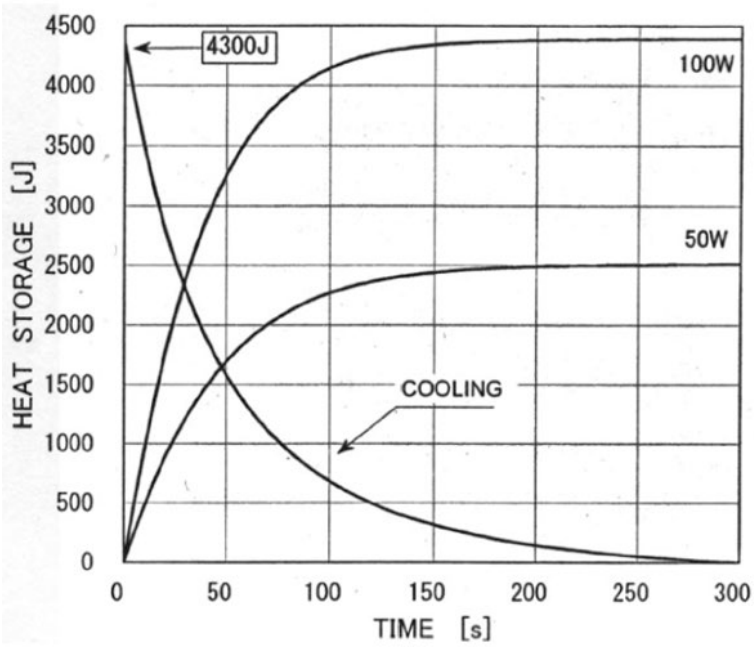
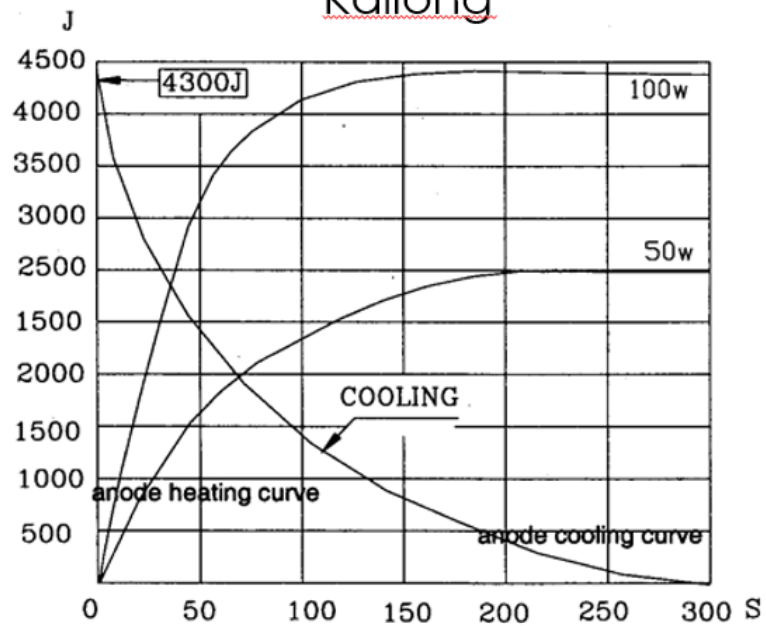
Appendix B: Technical Specification (Cont.)

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

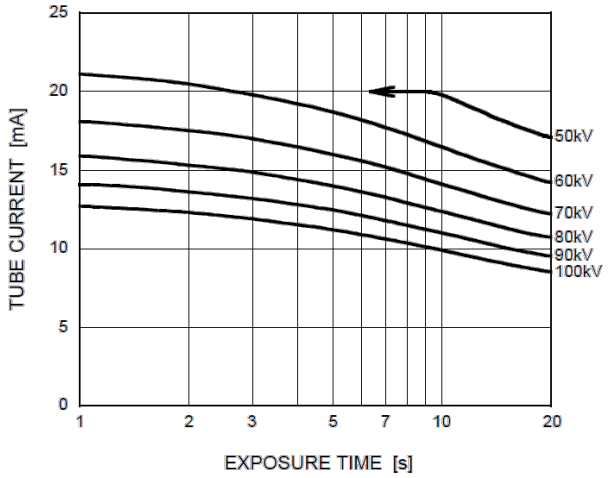
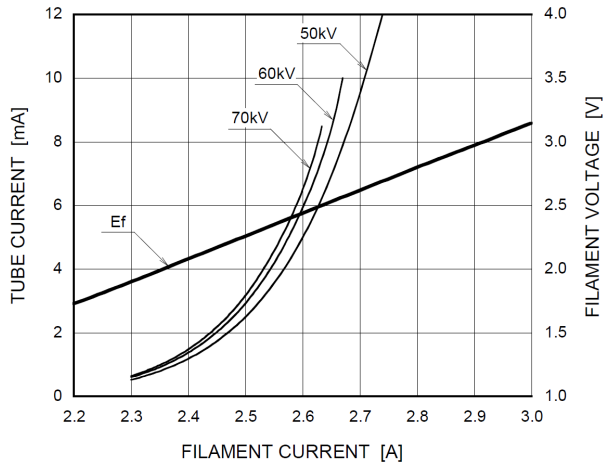
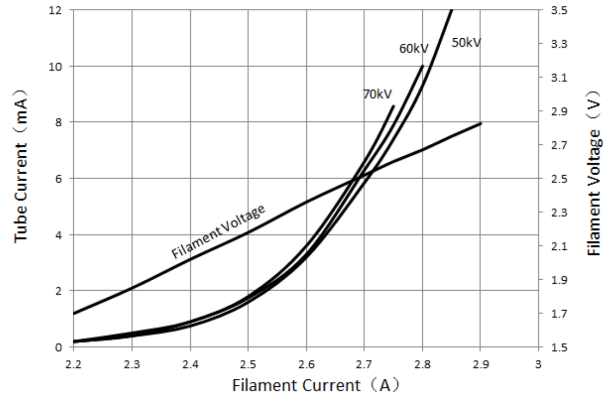
Continued

Appendix B: Technical Specification (Cont.)

Parameter	Specification
Anode heating and cooling curves for X-ray tube	Canon  Kailong 
Minimum Source-to-Skin Distance	20 cm (8 in) 30 cm (12 in)
X-ray Beam Dimension	Diameter of 6 cm (2.4 in) at the end of the 20 cm (8 in) cone. Cones with smaller diameter or rectangular beams are available.

Continued

Appendix B: Technical Specification (Cont.)

Parameter	Specification
Rating charts for X-ray tube	
Emission and filament characteristics for X-ray tube	Canon:  Kailong: 

Continued

Appendix B: Technical Specification (Cont.)

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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Dose Units 274
System Configuration – Default Exposure Times 275

Appendix C: Dose Data

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Appendix C: Dose Data (Cont.)

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 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 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 device 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. Service the device if the quality control indicates insufficient X-ray performance.

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

Exp.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

Note: All air kerma values are in mGy.

Continued

Appendix C: Dose Data (Cont.)

Dose Units

The quantity as defined by the International Commission on Radiation Units and Measurements (ICRU). The kerma, K, is the quotient of $\mathrm{d}E_{tr}$ by $\mathrm{d}m$, where $\mathrm{d}E_{tr}$ is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass $\mathrm{d}m$ 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)

Appendix C: Dose Data (Cont.)

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 section “Changing Pre-Programmed Technique Factors” beginning on page 174 and the section “Adjusting Technique Factors” beginning on page 163.

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.

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Appendix D: Regulatory Compliance

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Statements to Canadian Radiation Emitting Device Regulation 281

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Appendix D: Regulatory Compliance (Cont.)

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 Installation and Service Manual. For more information, see the section “Introduction” beginning on page 8.

1020.30(h)(1)(ii)

As described in chapter “Commissioning and Maintenance,” section “Periodic Maintenance Schedule” beginning on pg. 257 of this manual, 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 266 of this manual.

1020.30(h)(2)(iii)

The Tube Rating chart for the tube housing assembly can be found in the section “X-ray Source Specification,” which begins on page 266 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.

Continued

Appendix D: Regulatory Compliance (Cont.)

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 of this manual beginning on page 247.

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.

Appendix D: Regulatory Compliance (Cont.)

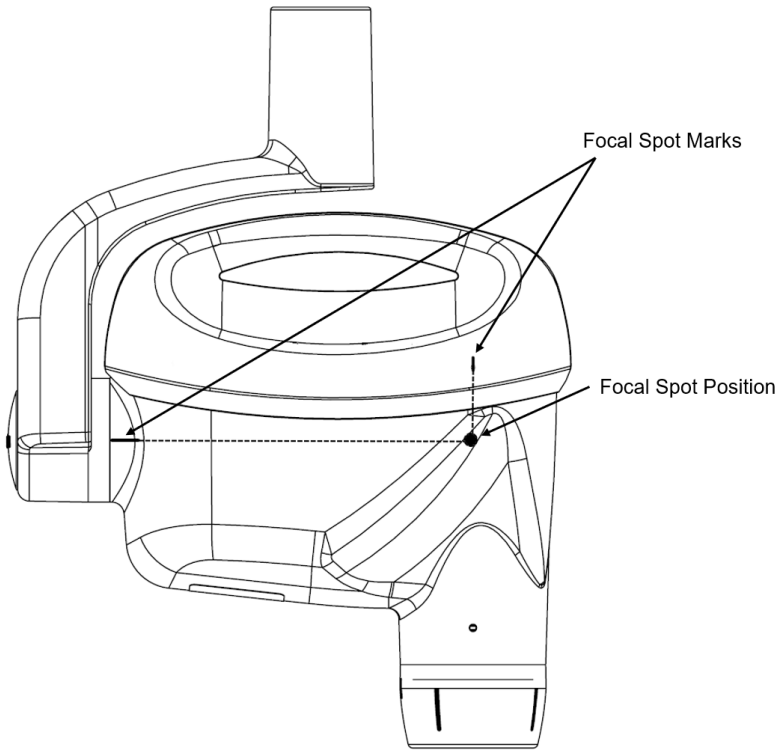
Statements to Canadian Radiation Emitting Device Regulation

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,” which begins on page 266 of this manual.
- X-ray tube rating charts: refer to the section “X-ray Source Specification,” which begins on page 266 of this manual.
- 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.

Continued

Appendix D: Regulatory Compliance (Cont.)

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.

Continued

Appendix D: Regulatory Compliance (Cont.)

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 275.

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 section “Accessories and Supplemental Parts” beginning on page 57 of this manual. Information on the effectiveness of the BLDs is provided in the section “Dose Data” beginning on page 271 of this manual. Instructions for BLD replacement are provided in the section Operating Instructions beginning on page 159 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 section “Accessories and Supplemental Parts” beginning on page 57 of this manual.

3(b)(ii)

Nominal X-ray image receptor air kerma range that is needed for the intended use: refer to the section “Dose Data” beginning on page 271 of this manual. For dose administered when using a digital X-ray sensor, refer to the manual for the digital X-ray sensor.

Continued

Appendix D: Regulatory Compliance (Cont.)

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 section “Dose Data” beginning on page 271 of this manual.

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 section “Accessories and Supplemental Parts” beginning on page 57 of this manual.

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 section “Dose Data” beginning on page 271 of this manual.

3(e)(ii)

The maximum deviation of the air kerma: refer to the section “Dose Data” beginning on page 271 of this manual.

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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.

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