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Preva Dental X-ray System

User Manual

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Preva Dental X-ray System

User Manual

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General Information

Intended Use

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

Warnings / Precautions

Radiation Safety

- Only qualified and authorized personnel may operate this equipment observing all laws and regulations concerning radiation protection.
- The operator at all times must remain at a safe distance from the focal spot and the X-ray beam for operator protection.
- Full use must be made of all radiation safety features on the equipment.
- Full use must be made of all radiation protection devices, accessories and procedures available to protect the patient and operator from X-ray radiation.

Electrical Safety

⚠WARNING	To avoid electric shock, connect this equipment only to supply mains with protective earth.

- Because the design of the Preva power supply circuit may momentarily draw high current, **do not use this device with any wall outlet that has a GFCI (Ground Fault Circuit Indicator)**. Outlets with GFCI breakers are designed to trip when they sense a small amount of current passing from the line to earth ground. Outlets with GFCI could compromise the operation of the intra-oral X-ray device and the GFCI circuit itself.
- Only qualified and authorized service personnel should remove covers on the equipment.
- All maintenance that requires removing of protective covers must be executed by service personnel when the patient is not present.
- The sensor shall only be replaced when the operator and any part of the machine does not touch the patient.

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

- This equipment must only be used in rooms or areas that comply with all applicable laws and recommendations concerning electrical safety in rooms used for medical purposes, e.g., IEC, US National Electrical code, or VDE standards concerning provisions of an additional protective earth (ground) terminal for power supply connection.
- Before cleaning or disinfecting, this equipment must always be disconnected from the main electrical supply.
- The Preva Dental X-ray System 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.

Explosion Safety

This equipment must not be used in the presence of flammable or potentially explosive gases or vapors, which could ignite, causing personal injury and/or damage to the equipment. If such disinfectants are used, the vapor must be allowed to disperse before using the equipment.

Attention:
The equipment must only be installed and operated in accordance with the safety procedures and operating instructions given in this manual and in the Installation Guide for the purposes and applications for which it was designed. Modifications and/or additions to the equipment may only be carried out by Midmark Corporation or by third parties expressly authorized by Midmark Corporation to do so. Such changes must comply with legal requirements as well as with the generally accepted technical rules. It is the responsibility of the user to ensure that existing legal regulations regarding installation of the equipment with respect to the building are observed.

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

X-Ray Protection

X-ray equipment may cause injury if used improperly.

The device must not be operated in the significant zone of occupancy. The operator of an intraoral dental X-ray device must remain 2 meters (6.6 feet) away from the focal spot and out of the path of the X-ray beam.

The Preva Dental X-ray System provides a high degree of protection from unnecessary X-radiation. However, no practical design can provide complete protection nor prevent operators from exposing themselves or others to unnecessary radiation.

The instructions contained in this manual must be read and followed when operating the Preva. Your Midmark Sales Corporation dealer will assist you in placing the Preva in operation.

Product Description

The Preva Dental X-ray System is a high-frequency intra-oral X-ray machine. The Preva consists of five components, as shown in Figure 1 Component Diagram: the Control Unit, the Tubehead, the Articulated Arm, the Horizontal Arm, the Cone, and the Remote Control option.

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, kVp control, and exposure time control. The Control Unit consists of the mounting base and Operator Panel.
Tubehead	The Tubehead contains the X-ray tube, high voltage circuit, and a round Cone. The tubehead is shipped already assembled to the Articulated Arm.

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

Articulated Arm	The Articulated Arm provides the articulation support for the Tubehead and the reach and coverage of the Tubehead to the patient.
Horizontal Arm	The Horizontal Arm helps provide the necessary reach for the Preva. It pivots around a shaft inserted in the top of the Control Unit and contains an access cover to connect the cable from the Horizontal Arm to the Control Unit. It is available in four lengths on wall mount units providing reaches of 56, 66, 76 and 82 inches [142, 167, 193, 208 cm].
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 circle at its end. The Preva is shipped with the standard 8-inch [20 cm] Cone (30-A2195) attached to the Tubehead. A 12-inch [30 cm] Cone (30-A2200) can be ordered as an option.
Handswitch	To make exposures in addition to or replacing the use of the exposure button, an optional Handswitch (30-A2040) can be ordered.
Model Configurations	The Preva is available as both a wall mount and mobile unit. See the Preva Installation and Service Manual for installation and mounting instructions.
Installation and Service	The Preva Dental X-ray System should only be installed and serviced by approved Midmark dealer personnel. If you need assistance locating an approved dealer, contact Midmark Corporation using the information on the back cover of this manual.

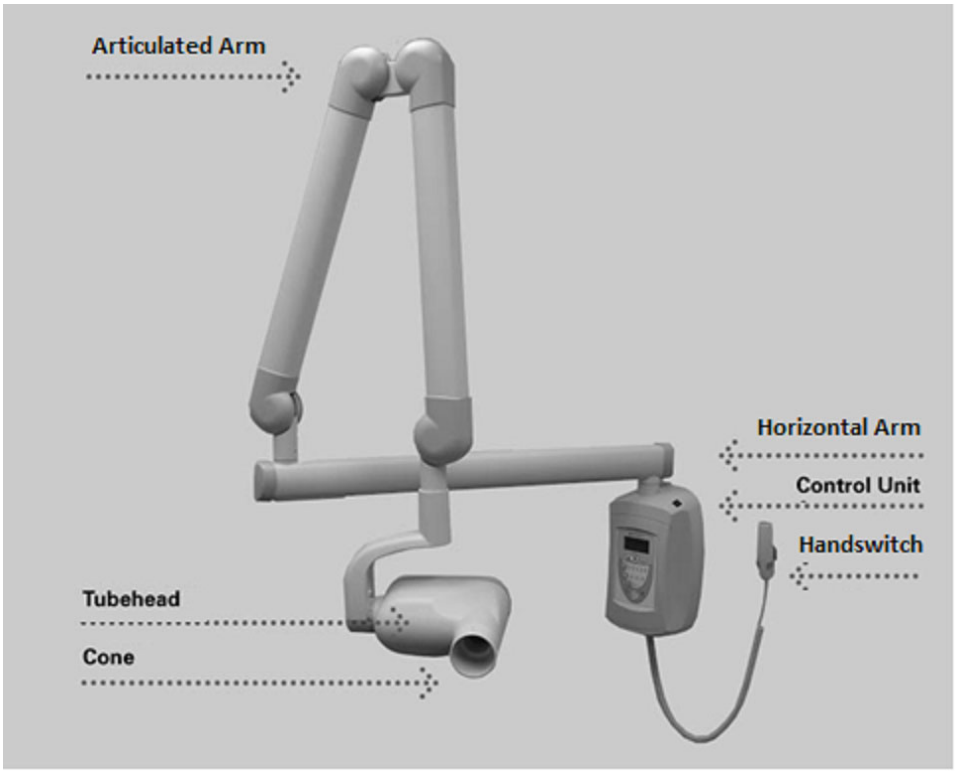


Figure 1 Component Diagram

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

Certified Components

System	Component	Reference Number
	Tubehead	30-A1027
	Control Unit. Preva	30-A0010
	Control Unit. Preva Mobile	30-A0013
	Modular BLD, 20 cm Lg., 70 mm Cone, Gray	30-A2195
	Modular BLD, 30 cm Lg., 70 mm Cone, Gray	30-A2200
	Modular BLD, 20 cm Lg., 60 mm Cone, White	30-A2196
	Modular BLD, 30 cm Lg., 60 mm Cone, White	30-A2201
	Modular BLD, 30 cm Lg., 60 mm Cone, Gray	30-A2229
	Modular BLD, 20 cm Lg., 30x40 mm Cone, White	30-A2198
	Modular BLD, 30 cm Lg., 30x40 mm Cone, White	30-A2203
	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, Base, Gray	30-A2205
	Modular BLD, Spacer, Gray	30-A2206
	Modular BLD, Spacer, White	30-A2208

Authorized Representatives

North America	Midmark Corporation 675 Heathrow Dr. Lincolnshire, Illinois 60069 U.S.A. Phone: 800-MIDMARK (800-643-6275) Fax: 847-415-9801
Europe	CE Partner 4U Esdoornlaan 13 3951DB Maarn The Netherlands www.cepartner4u.eu

Explanation of Symbols on Technical Labels

The symbols appearing on the product and/or in the technical manuals.

	Type B: Protection against electric shock (IEC 60601.1-1988)
	A hazardous situation which, if not avoided, could result in minor or moderate injury.
	A hazardous situation which, if not avoided, could result in serious injury or death.
	Consult written instructions in User Manual.
	WARNING X-RAY THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.
	*X-RAY EMISSION*
L	Mains HOT WIRE
N	Mains NEUTRAL WIRE
	Earth Ground
	Waste Electrical and Electronic Equipment (WEEE). WEEE distributed in the European Economic Area (EEA) must be collected and disposed of separately from other waste, per WEEE Directive 2012/19/EU. Contact the equipment dealer for information on local compliance schemes.

Compliance with Applicable Standards

The following regulatory documents apply:

Radiation Protection	The certified components of the Preva Dental X-ray System comply with Radiation Performance Standards 21 CFR, Subchapter J, at the time of manufacture. The certified components of the Preva Dental X-ray System comply with IEC 60601-1-3 Radiation protection/X-ray equipment.
UL 2601-1 File Number: E181750	Classified by Underwriters Laboratories Inc. with respect to electrical shock, fire and mechanical hazards only in accordance with UL 2601-1, and CAN/CSA C22.2 NO, 601.1-M90, and to the following particular standards, IEC 60601-2-7, IEC 60601-2-28.
General Safety	IEC 60601-1:1995 Protection against electrical shock – Class II Degree of protection against electrical shock – Type BF Applied Part Degree of protection against ingress of water – IP67 Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
EMI/EMC	IEC 60601-1-2:2007
Degree of Protection	IEC 60529:2001 Degree of protection against ingress of water – IP67
Imaging Performance	IEC 61223-3-4:2000 Line pair resolution – better than 8 lp/mm Low contrast resolution – all holes visible
EMC Statement	**Information regarding potential EMC interference and advice for avoidance** • The Preva Dental X-ray System is considered as non-life-supporting equipment. While using Preva Dental X-ray System adjacent to other equipment, configuration should be carefully adjusted to ensure that electromagnetic interference (EMI) does not degrade performance. Specifically, mobile RF communications equipment can effect medical electrical equipment. Please refer to the EMC table below. • Usage limitation: Preva Dental X-ray System when integrated with ClearVision Sensors shall be used with IEC 60950 or IEC 60601 compliant computers. Also, any device between the integrated Preva Dental X-ray System and the computer (USB Hub) shall be compliant with IEC 60950 or IEC 60601. If not, this may result in degraded electromagnetic compatibility.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Preva Dental X-ray System is intended for use in the electromagnetic environment specified below. The customer or the user of the Preva Dental X-ray System should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emission CISPR 11	Group 1	The Preva Dental X-ray System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Preva Dental X-ray System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Preva Dental X-ray System is intended for use in the electromagnetic environment specified below. The customer or the user of the Preva Dental X-ray System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a transient/ burst supply lines typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable.	
Voltage dips, interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle < 40% U_T (60% dip in U_T) for 5 cycles < 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	Not Applicable.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Preva Dental X-ray System is intended for use in the electromagnetic environment specified below. The customer or the user of the Preva Dental X-ray System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Preva Dental X-ray System equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz	3 V	$d = 1.2 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Preva Dental X-ray System is used exceeds the applicable RF compliance level above, the Preva Dental X-ray System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Preva Dental X-ray System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and Preva Dental X-ray System			
The Preva Dental X-ray System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the sensor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \times \sqrt{P}$	80 MHz to 2.5 GHz $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Obtaining Technical Support

Contact

Midmark Corporation
675 Heathrow Dr.
Lincolnshire, Illinois 60069 U.S.A.
Phone: 800-MIDMARK (800-643-6275)
Fax: 847-415-9801
imagingtechsupport@midmark.com
Hours: 8:00 a.m. – 5:00 p.m. Central Time

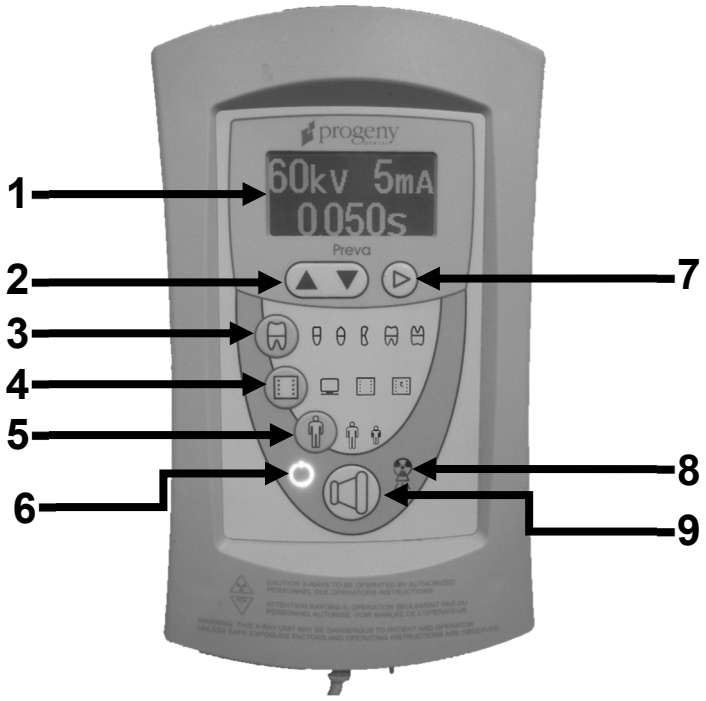
Operating Instructions

Using the Operator Panel

Power On Settings

When powering on the Preva Dental X-ray System, the Operator Panel displays the selections from the most recent exposure taken prior to powering off the system.

Figure 2
Preva Operator Panel



Icons

1. Large, 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 change kV, mA and time settings.
3. Tooth Icon: Pressing this button allows the user to select Incisor, Bicuspid, Bitewing, Upper or Lower Molar.
4. Receptor Icon: Choices are: Digital, D Speed film, E/F Speed Film. If using phosphor plates, select E/F Speed Film Setting.
5. Patient Size Icon: Press to select Large or Small
6. Ready Indicator: Circle lights up to indicate that the system is ready to produce X-ray.
7. Right Arrow Button: Use this button to move between kV, mA and time selections. This button is also used as an “Enter” key when the system is in menu mode.
8. Radiation Indicator: This symbol lights up when an X-ray is produced.
9. Exposure Button: Pressing this button will produce an X-ray exposure.

Exposure Settings

When the system is powered on, the operator panel, Figure 2, displays the exposure settings (kV, mA, and seconds) for the currently selected tooth, image receptor type, and patient size. Use the Tooth Selection, Image Receptor Type, and Patient Size buttons to select other exposure settings.
For a table of the factory-programmed exposure settings, refer to the Preprogrammed Exposure Settings tables in this manual.

Adjusting Exposure Settings

Preset exposure settings can be adjusted prior to making an exposure. Use the right arrow to select the exposure setting to adjust. Then use the up and down arrow buttons to adjust the value.
To save new presets, see the System Configuration Mode information in this manual.

Exposure Button and Ready Indicator

The Exposure button is used to initiate an X-ray exposure. For a complete exposure, the button must be pressed and held until the Radiation Indicator no longer illuminates and the audible signal is no longer heard. Releasing the Exposure button immediately terminates the X-ray exposure.

⚠CAUTION	An incomplete exposure caused by prematurely releasing the exposure button may require the operator to make another radiograph. When the exposure button has been released prematurely, the system will notify the operator momentarily and then return to operating mode.

Ready Indicator

The Ready Indicator illuminates 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. When the Ready Indicator is flashing, no exposure can be made.

Radiation Indicators

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

Taking an X-ray

1. Turn the power switch, located at the upper right of the Control Unit, to the “On” position. The Ready Indicator on the front of the Operator Panel, (Figure 2), will light.
2. Verify that the unit is set for the correct Image Receptor Type. The icon for the currently selected Image Receptor Type is illuminated. To change the Image Receptor type, press the Image Receptor Type button until the correct Image Receptor Type is selected.
3. Verify that the system is set for the appropriate Patient Size. The icon for the currently selected Patient Size is illuminated. To change the Patient Size, press the Patient Size button until the correct Patient Size is selected.
4. Verify that the unit is set for the Tooth to be imaged. The icon for the currently selected Tooth is illuminated. To change the Tooth Selection, press the Tooth Selection button until the correct Tooth is selected.
5. If desired, preset exposure settings for the combination of Image Receptor Type, Tooth Selection, and Patient size, selected in steps 2-4, can be adjusted prior to making an exposure. Use the right arrow to select the exposure setting to adjust. Then use the up and down arrow buttons to adjust the value. Skip this step if you are using preprogrammed exposure settings.
   Note: When exposure settings are being adjusted, the Tooth Selection, Image Receptor Type, and Patient Size buttons are turned off.
6. Position the Tubehead to the patient using standard accepted positioning procedures.
7. Prepare to take an X-ray.

   The device must not be operated in the significant zone of occupancy. The operator of an intraoral dental X-ray device must remain 2 meters (6.6 feet) away from the focal spot and out of the path of the X-ray beam..

8. Take an X-ray. Press and hold the Exposure button until the audible signal is no longer heard and the Radiation Indicator is no longer illuminated. Releasing the Exposure button or coil-cord hand switch at any time will immediately terminate the exposure.
   Note: When using the coil-cord hand switch, it is recommended that the operator exit the operatory if possible.
   Note: In order to comply with regulations and good safety practices, the technique factors must be visible to the operator from the remote location.
9. Return the Tubehead to the storage position.
   Note: Be careful not to strike the Tubehead on anything when returning it to the storage position.

It may be necessary to increase or decrease the kV, mA, or time from the preset values for one exposure. To do so:

1. Press the Enter button to highlight the value to change.
2. Use the up or down button to increase or decrease the value (no lights on the display will be lit to indicate the preset values).
3. Press the Exposure button.
4. Press any other button (Tooth, Film or Patient Size) to return the display to the preset values.

For information on estimated radiation doses for all Technique Factors combinations using the 20 cm cone, refer to “Dose Information” section in this manual.

About the 20cm Cone (30-A2195) and the 30 cm Cone (30-A2200)

The Preva Dental X-ray System is factory set for use with the standard supplied 8-inch [20 cm] Round Cone [30-A2195].

A 12-inch [30 cm] Round Cone [30-A2200] is also available.

Using the longer cone requires longer exposure times.

For instructions to set the system to use the longer cone, see the System Configuration information in this manual.

Recommended Maintenance

Regular Maintenance

In the interest of equipment safety, a regular maintenance program must be established. This maintenance program should consist of annual system function checking. It is the owner's responsibility to arrange for this service and to assure that the personnel performing this are fully qualified to service Midmark Corporation X-ray equipment.

Cleaning and Disinfecting

Cleaning / Disinfecting

Employ personal protective equipment to prevent the spread of infections.
Clean the outside of the system using a damp towel or non-alcohol based disinfectant.

⚠CAUTION	• Do not allow liquids to drip into the system electronics. • Do not spray cleaner or disinfectant directly onto the machine. • Protect the system from contamination using barriers available from dental distributors. • Follow the disinfectant manufacturer's recommendations when using their cleaner or disinfectant.

Cleaning Methods

If not using a barrier, between each patient, perform the following cleaning and disinfecting steps.

1. Remove gross bio-burden from the cone, handles and structure with a disposable towel moistened with water.
2. Dry the cone, handles and structure with disposable towels.
3. Wipe the cone, handles and structure with a germicidal broad spectrum disinfectant product following the disinfectant manufacturer's instructions.
4. Clean any remaining disinfectant residue from the system with a disposable towel moistened with water. This additional step prevents possible product discoloration or corrosion.
5. Dry the cone, handles and structure with paper towels.

⚠CAUTION	The Preva Dental X-ray System is not waterproof. Clean it only with moistened, not saturated, towels.

Inspecting the Casters

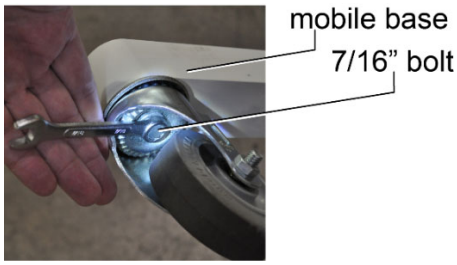
Repeatedly rolling the system over rough surfaces such as thresholds or rough floors can cause casters to loosen. Inspect them monthly and, if necessary, follow this procedure to tighten them.

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).

Visual inspection of the casters

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

2. Using a 7/16” 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.)



Inspecting the Casters

Optional:

⚠CAUTION	Two people are required to perform this step.

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

Mobile base elevated

3. Test the operation of the casters by moving the X-ray system in different directions.

   For systems manufactured before October 2017, a service kit is available which will prevent casters from loosening. Refer to Technical Advisory Notice 003-10221-00, available through the Midmark Technical Library.

Checking System Functions

The following checks must be performed to complete the installation of the Preva Dental X-ray System 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	Do not use the Preva Dental X-ray System if it cannot perform the functions in the System Function Checklist. Refer to the Troubleshooting section of the Installation Guide or contact Midmark's Technical Support.

System Function Checklist		✓
Wall Mounting	Ensure that the wall support is adequate and that the system is properly mounted to the wall.	
Labels	Ensure that all certified components bear labels that include the model and serial number, date of manufacture and a statement of certification as noted elsewhere in this manual.	
Tubehead	Check for oil leaks or other evidence that could indicate internal damage. Replace the Tubehead, if necessary.	
Tubehead Rotation	Ensure that the Tubehead maintains its position around the horizontal axis while remaining easy to rotate and position. Also check the vertical pivot of the Tubehead for easy movement while remaining in position after moving.	
Suspension	Check that all movements are smooth and quiet. Verify that the Tubehead is properly counterbalanced for vertical drift and that the Horizontal and Articulated Arms do not drift horizontally.	
Power Switch	Verify that the switch is working properly and that the Ready Indicator is illuminated when the power switch is in the ON position.	
Operator Panel Controls	With the power switch, located at the upper right of the Control Unit, 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 should cause indicator lamps to indicate the selected item.	
Exposure Button	Verify that the Exposure button on the Operator Panel is functioning properly. To make an exposure, press and hold the Exposure button until the Radiation Indicator is extinguished and the audible signal is no longer heard.	
Exposure Indicators	Make several exposures and 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 after a brief period of time before the timer terminates the exposure. Verify that the display indicates “Pre-termination Error” and returns to normal operating mode.	
Coil-cord Hand Switch Option	If a coil-cord hand switch is used, inspect the switch housing and coil cord for damage or wear. Replace if evidence of damage is present.	
User Information	Make certain that the user of the system has received the User Manual.	

New Tube Seasoning Procedure

X-ray tubes that sit dormant for several months can become electrically unstable. To remedy this condition, it is recommended you perform a new tube seasoning procedure. This process establishes stable high voltage operation and will ultimately extend the life of the tube. Repeat this procedure before returning to normal operation any time the system has been unused for more than two months.

1. Verify system operation.
2. Energize the system.
3. Select 60 kilovolts [kV], 7 milliamperes [mA], and the exposure time of one second.
4. Make five exposures at this level, observing the normal cooling time.
5. Select 65 kilovolts, 7 milliamperes, and the exposure time of one second.
6. Make five exposures at this level, observing the normal cooling time.
7. Select 70 kilovolts, 6 milliamperes, and the exposure time of one second.
8. Make five exposures at this level, observing the normal cooling time.

Solving Performance Issues

Performance Issues

Light or Dark X-ray Images	1. Adjust the selected exposure time, kilovoltage [kV] or tube current to produce an acceptable image. If necessary, reprogram the technique factors, as explained in the System Configuration information in this manual. 2. Verify the kilovoltage and tube current during an exposure using the diagnostic mode, as explained in the System Configuration section (pg. 25) of this manual. Alternatively, you may employ a non-invasive meter to evaluate kilovoltage and exposure time. 3. Inspect the condition of the remaining imaging chain components such as the film, chemistry and processor, or the condition of the X-ray sensor and computer.
No X-ray	If no X-ray is produced, 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.
Pre-termination Error	Early release of the exposure switch will cause a pre-termination error to occur. After five seconds, the system will return to the normal operating condition. Be advised that this will result in an underexposed image.

Obtaining Technical Support

If the above steps do not resolve any of the error issues that you are experiencing, suspend use of the X-ray unit and contact Midmark Technical Support for assistance.

Contact	Midmark Corporation 675 Heathrow Dr. Lincolnshire, Illinois 60069 U.S.A. Phone: 1-800-MIDMARK (800-643-6275) Fax: 847-415-9801 imagingtechsupport@midmark.com Hours: 8:00 a.m. – 5:00 p.m. Central Time

System Configuration

Preprogrammed Exposure Times

The tables below show the factory default exposure settings for each combination of Tooth, Image Receptor Type, and Patient Size on the Operator Panel. These exposure settings can be modified using the System Configuration mode. For details, see the System Configuration Mode section.

8-inch Cone (20 cm)

Setting		Progeny®		Schick		Dexis®		Kodak		Sirona		PSP		D Speed		E/F Speed	
		Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Incisor	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.125	0.064	0.080	0.050	0.125	0.064	0.080	0.050	0.080	0.064	0.160	0.080	0.320	0.160	0.160	0.080
Bicuspid	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.125	0.064	0.080	0.050	0.125	0.064	0.125	0.080	0.080	0.064	0.160	0.080	0.320	0.160	0.160	0.080
Bitewing	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.160	0.080	0.100	0.064	0.160	0.080	0.125	0.080	0.100	0.080	0.200	0.100	0.400	0.200	0.200	0.100
Lower Molar	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.160	0.080	0.100	0.064	0.160	0.080	0.160	0.080	0.100	0.080	0.200	0.100	0.400	0.200	0.200	0.100
Upper Molar	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.200	0.100	0.125	0.080	0.200	0.100	0.200	0.125	0.125	0.080	0.250	0.100	0.500	0.200	0.250	0.100

12-inch Cone (30 cm)

Setting		Progeny®		Schick		Dexis®		Kodak		Sirona		PSP		D Speed		E/F Speed	
		Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Incisor	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.250	0.125	0.160	0.100	0.250	0.125	0.160	0.100	0.160	0.125	0.320	0.160	0.640	0.320	0.320	0.160
Bicuspid	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.250	0.125	0.160	0.100	0.250	0.125	0.250	0.160	0.160	0.125	0.320	0.160	0.640	0.320	0.320	0.160
Bitewing	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.320	0.160	0.200	0.125	0.320	0.160	0.250	0.160	0.200	0.160	0.400	0.200	0.800	0.400	0.400	0.200
Lower Molar	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.320	0.160	0.200	0.125	0.320	0.160	0.320	0.160	0.200	0.160	0.400	0.200	0.800	0.400	0.400	0.200
Upper Molar	kV	60	60	65	65	60	60	65	65	60	60	60	60	60	60	60	60
	mA	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	sec	0.400	0.200	0.250	0.160	0.400	0.200	0.400	0.250	0.250	0.160	0.500	0.200	1.000	0.400	0.500	0.200

Note: *To see the dosages for kV and mA combinations, see the "Dose Information" section of this manual.*

Changing Language

Five languages are preprogrammed in the display panel. To change follow the steps below.

1. Push and hold the Tooth and Patient selection switches, a menu screen will appear after about 5 seconds. (See Figure 3)
2. Using the down arrow highlight “Configure Unit” and press the right arrow key. (See Figure 3)
3. “Select Languages” on the next screen is highlighted press the right arrow key.
4. Select the desired language and press the right arrow key. If you do not see your desired language listed arrow down to “More” and press the right arrow key.
5. After selection arrow down to Exit and press the right arrow key then repeat this procedure to return to the main screen.

Figure 3
Preva Operator Panel

System Configuration Mode

About System Configuration Mode

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

- Adjusting the Display
- Changing Preprogrammed Exposure Settings
- Changing the Cone Size
- Showing Current System Configuration
- Displaying Diagnostic Data

Using System Configuration Mode

1. To enter system configuration mode, depress the Tooth Selection and Patient Size Selection buttons on the Operator Panel simultaneously for 5 seconds. The display shows the Main System Configuration menu, as shown in Figure 4, and the Ready Indicator blinks.
2. To select menu items while in system configuration mode, use the up and down arrows to highlight a menu option. Then use the right arrow button as an Enter button to select the highlighted option. When changing presets, the right arrow button is also used to select the technique factor.
3. After selecting a menu option, use the up and down arrows to increase or decrease values.

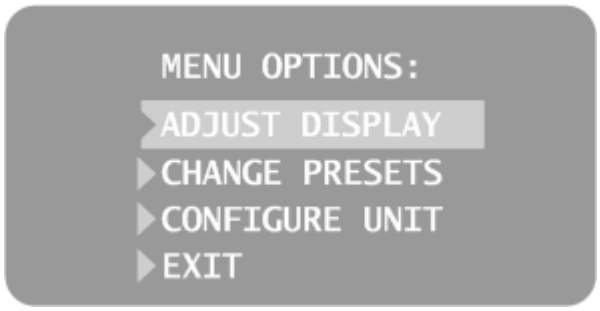


Figure 4
Main System Configuration Menu

Adjusting the Display

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

1. From the system configuration main menu, shown in Figure 4, select ADJUST DISPLAY. You will see the Display Options menu shown in Figure 5.
2. Selecting EXIT returns the display to the Main System Configuration menu shown in Figure 4.

Adjusting Contrast

1. Select ADJUST CONTRAST from the menu. You will see the Progeny® logo.
2. Use the up and down arrows to increase or decrease the contrast between the menu text and the display background.
3. Press the right arrow to save your settings.

Reversing the Image

1. Select REVERSE IMAGE from the menu. The text and display background colors will be swapped.
2. Press the right arrow to save your settings.

Figure 5 Display Options Menu

Changing Preprogrammed Exposure Settings

The Preva Dental X-ray System allows the operator to increase or decrease image density for all presets for a receptor simultaneously or to change each of the technique factors for a preset individually. You can also restore factory default settings. For charts of the factory default settings, refer to Factory Preprogrammed Exposure Settings section in this manual.

Note: If the 12-inch [30 cm] cone is going to be used, configure the Preva for use with the 12-inch cone before changing preprogrammed exposure settings. Configuring the Preva for use with the 12-inch cone will reset exposure settings to the default settings used with the 12-inch cone.

Note: Before changing presets, use one of the Record your Exposure Settings tables provided in this manual to record the presets you are programming. Make sure to use the correct table (for 8-inch cone or 12-inch cone) based on the cone size being used.

Displaying the Preset Options Menu

1. From the Main System Configuration menu, shown in Figure 4, select CHANGE PRESETS. You will see the Preset Options menu shown in Figure 6.
2. Selecting EXIT returns the display to the Main System Configuration menu shown in Figure 4.

Figure 6
Preset Options Menu

Changing All Receptor Settings Globally

1. Select ALTER DENSITIES from the Preset Options menu. The first Image Receptor Type illuminates. The display shows the selected Image Receptor Type and current density.
2. Using the Image Receptor Type button, select the image receptor to adjust.
3. Use the up and down arrow buttons to specify a percentage by which densities will be increased or decreased for the selected receptor. Densities can be increased or decreased according to values provided on the display.
4. Press Enter to save your settings.

Preprogramming to Digital Sensors

1. Turn the system on.
2. Push and hold the Tooth and Patient selection switches, a menu screen will appear after about 5 seconds.
3. Select CHANGE PRESETS from the Menu Options screen.
4. Select SELECT RECEPTOR from the Preset Options menu (Figure 6).
5. Press the up or down button to highlight the sensor or phosphor plate to change, and press Enter.
6. Select YES or NO on the Verification screen.
7. Exit the Preset Options menu.
8. Exit the Menu Options menu. A message of “Saving Settings” will display briefly, and then the system will return to the normal operational mode.

Note: When you are working in service mode, the green light next to the exposure button will blink.

Changing Presets Individually

1. Turn the system on.
2. Push and hold the Tooth and Patient selection switches, a menu screen will appear after about 5 seconds.
3. Select EDIT PRESETS from the Preset Options menu. The display notifies you that you are entering Edit Preset Mode, and Tooth Size, Image Receptor Type, and Patient Size are illuminated.
4. 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.
5. Use the right arrow button to highlight the technique factor (tube voltage in kilovolt [kV], tube current in milliamp [mA] or duration in seconds [s]) to change.
6. Use the up and down arrow buttons to set the value for the selected technique factor and preset.
7. Repeat steps 2-4 to change additional presets.
8. When you have completed all changes, press the Tooth Selection and Patient Size Selection buttons simultaneously for 5 seconds to record the change.

Recall Presets

1. Turn the system on.
2. Push and hold the Tooth and Patient selection switches, a menu screen will appear after about 5 seconds.
3. To return all presets to factory defaults, select RECALL PRESETS from the Preset Options menu. The menu will ask you to confirm your choice.
4. 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.**
5. Select NO using the down arrow button and retain current presets.

Record Your Exposure Settings (8” [20 cm] Cone)

If the preprogrammed exposure settings do not produce the density desired, adjust the settings using System Configuration mode. Record your settings in the table below.

8-inch (20 cm) Cone		Digital Receptor		D-speed Film		E/F Speed Film	
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						

Record Your Exposure Settings (12” [30 cm] Cone)

If the preprogrammed exposure settings do not produce the density desired, adjust the settings using System Configuration mode. Record your settings in the table below.

12-inch (30 cm) Cone		Digital Receptor		D-speed Film		E/F Speed Film	
Tooth Selection	Setting	Adult	Child	Adult	Child	Adult	Child
Incisor 	kV						
	mA						
	seconds						
Bicuspid 	kV						
	mA						
	seconds						
Bitewing 	kV						
	mA						
	seconds						
Lower Molar 	kV						
	mA						
	seconds						
Upper Molar 	kV						
	mA						
	seconds						

Showing Current System Configuration

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

1. From the Main System Configuration menu, shown in Figure 4, select CONFIGURE UNIT. You will see the Configuration menu shown in Figure 7.
2. Select SHOW CONFIG. The display will show:
   - Current software version
   - Cone size
   - Diagnostic mode on or off
3. Press any button on the Operator Panel to return to the Configuration menu.

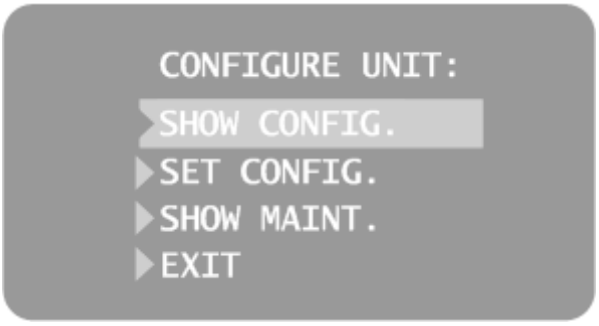


Figure 7 Configuration Menu

Changing the Cone Size

Selecting SET CONFIG. from the Configuration menu, shown in Figure 7, displays the Set Configuration menu, Figure 8, with options to change the cone size. The Preva Dental X-ray System is factory set for use with the standard supplied 8-inch [20 cm] Cone. The 12-inch [30 cm] Cone [30-A2200] is available. Using the longer Cone requires longer exposure times, which the Preva automatically selects when you change the Cone size in the Set Configuration menu.

Using a 12-inch [30 cm] Cone

1. From the Main System Configuration menu, shown in Figure 4, select CONFIGURE UNIT. You will see the Configuration menu shown in Figure 7.
2. Select SET CONFIG. You will see the Set Configuration menu, shown in Figure 8.
3. From the Set Configuration menu, use the up and down arrows to highlight 12” CONE SIZE.
4. Press the right arrow button to select the 12” CONE. The display warns you that selecting the 12-inch Cone will override custom presets with the default factory settings for the 12-inch Cone.
5. Using the up arrow, select YES to install presets for the 12-inch Cone.

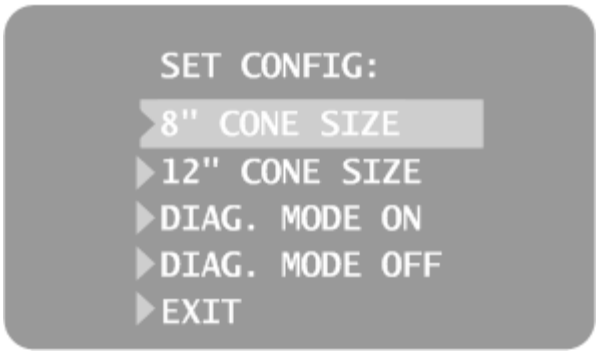


Figure 8
Set Configuration Menu

Diagnostic Mode

About Diagnostic Mode

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

Showing the Maintenance Summary

1. From the Main System Configuration menu, shown in Figure 4, select CONFIGURE UNIT. You will see the Configuration menu shown in Figure 7.
2. Select SET CONFIG. You will see the Set Configuration menu, shown in Figure 8.
3. To display a summary of maintenance data, highlight select SHOW MAINT from the Configuration menu. The following maintenance data are displayed:
    - Total kJ (kilojoules—total system heat on X-ray tube)
    - Exposure Count
    - Reboots (power up cycles)
    - OT Counts (over-threshold counts)
4. Press any button on the Operator Panel to return to the Configuration menu.

Showing Feedback Values After an Exposure

If you take an X-ray (following the steps in “Taking an X-ray”) while in diagnostic mode, the display shows feedback values for that exposure. Until you exit diagnostic mode, the display will continue to show feedback values after each exposure.

1. From the Main System Configuration menu, shown in Figure 4, select CONFIGURE UNIT. You will see the Configuration menu shown in Figure 7.
2. Select SET CONFIG. You will see the Set Configuration menu, shown in Figure 8.
3. From the Set Configuration menu, use the up and down arrows to highlight DIAG MODE ON. Press the right arrow button to turn on diagnostic mode.
4. Exit System Configuration mode by highlighting and selecting EXIT in the Configuration and Main menus.
5. Prepare to take an X-ray.

   The device must not be operated in the significant zone of occupancy. The operator of an intraoral dental X-ray device must remain 2 meters (6.6 feet) away from the focal spot and out of the path of the X-ray beam..

6. Take an X-ray.
   The display will show the following feedback values:
    - kV
    - mA
    - Filament current
7. Press any button on the Operator Panel to clear the feedback values from the display.
8. To exit diagnostic mode, press the Tooth Selection and Patient Size Selection buttons simultaneously for 5 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. On the Set Configuration menu, highlight and select DIAG MODE OFF.

Specifications

Preva Dental X-ray System

Line Voltage	AC 100 V to 250 V, 50 Hz or 60 Hz
Line Load	250 V, UL Recognized – It is recommended that branch circuit does not exceed 15A
Tube Potential	60 kV, 65 kV, 70 kV
Tube Current	4 mA, 5 mA, 6 mA, 7 mA (7 mA is not available at 70 kV)
Irradiation Time	20 ms through 2 s
Maximum Deviation from Indicated Values	Peak tube potential, maximum deviation: ±5% Tube current, maximum deviation: ±1 mA Exposure time: min 20 ms, max. 2 s, max. deviation: ±5%+1 ms
Minimum Source to Skin Distance	8-inch cone (20 cm) 12-inch cone (30 cm)
Focal Spot	0.4 mm (per IEC 60336)
Operating Temperature	+50 °F to +95 °F (+10 °C to +35 °C)
Storage Temperature	-31 °F to +150 °F (-35 °C to +66 °C)
Maximum Altitude	12,000 ft (3,657 m)
X-ray Beam Dimension	Diameter of 2.72 inches (7 cm) at the end of the 7 inch Cone. Cones with smaller diameter or rectangular beams are available.
Humidity Range (Operation & Storage)	10 to 80 % non-condensing

Statements and Information According to 21 CFR Sub Chapter J

1020.30 (h) (1) (i)	Instructions for the use of the Preva and precautionary statements are part of this User's Manual.
1020.30 (h) (1) (ii)	As described in the Recommended Maintenance section, the Preva should be serviced on an annual basis to ensure proper functionality. It is the owner's responsibility to arrange for this service and to assure that the personnel performing this service are fully qualified to service Midmark Corporation X-ray equipment.
1020.30 (h) (2) (i)	Leakage technique factors: 70 kV, 0.4 mA Minimum filtration (half-value layer) in useful beam: 1.7 mm Al equivalent at 70 kV
1020.30 (h) (2) (ii)	The cooling curve charts for the anode can be found on page 38. Please note that due to the integrated design of the Preva, there is no meaningful separate cooling curve for the tube housing.
1020.30 (h) (2) (iii)	Since the Preva operates as a complete system in only one mode as a high frequency X-ray system, there is no need to provide a tube rating chart.
1020.30 (h) (3) (i)	Rated nominal line voltage: 110 V – 230 V Line voltage regulation: 10% of the nominal line voltage
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 (1.2 kW). Operation at higher input voltage will reduce the maximum current (5 A at 240 V). The technique factors producing the maximum momentary line current are 65 kV, 7 mA, 2 s.
1020.30 (h) (3) (v)	Generator rating at maximum technique factor of 65 kV, 7 mA is 455 W. Duty cycle is 1:15.
1020.30 (h) (3) (vi)	Maximum deviation from indicated values: a) Peak tube potential, maximum deviation: ±5% b) Tube current, maximum deviation: ±1 mA c) Exposure time: min 20 ms, max. 2 s, max. deviation: ±5%+1 ms
1020.30 (h) (3) (viii)	The measurement criteria for all technique factors used in paragraphs (h) (3) (iii), and (h) (3) (vi) is 90% of the selected peak tube voltage.

Thermal Characteristics Charts

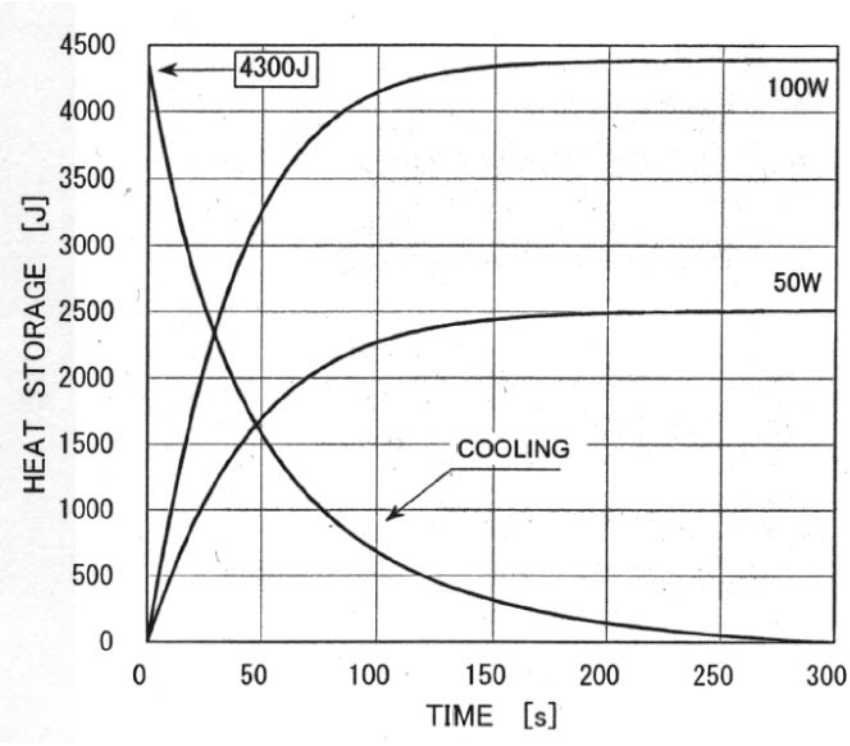


Figure 9
Canon (Toshiba)
Tube Rating Chart

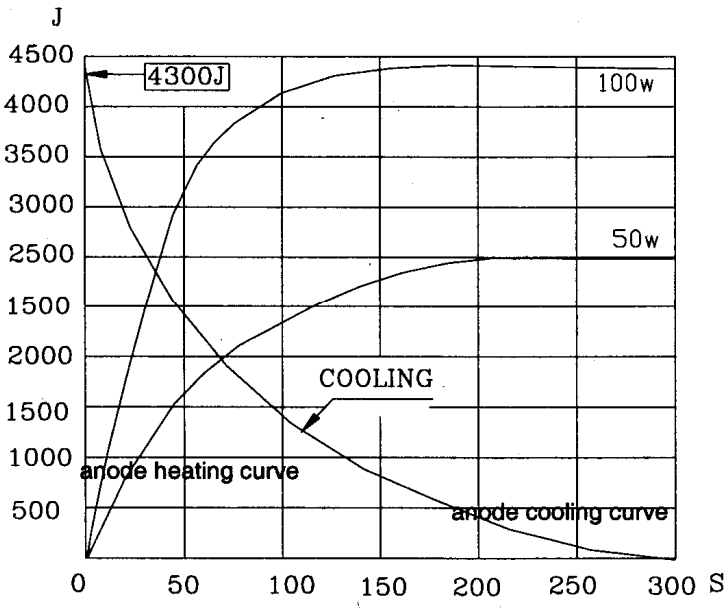


Figure 10
Kailong Tube Rating
Chart

Thermal Characteristics Chart

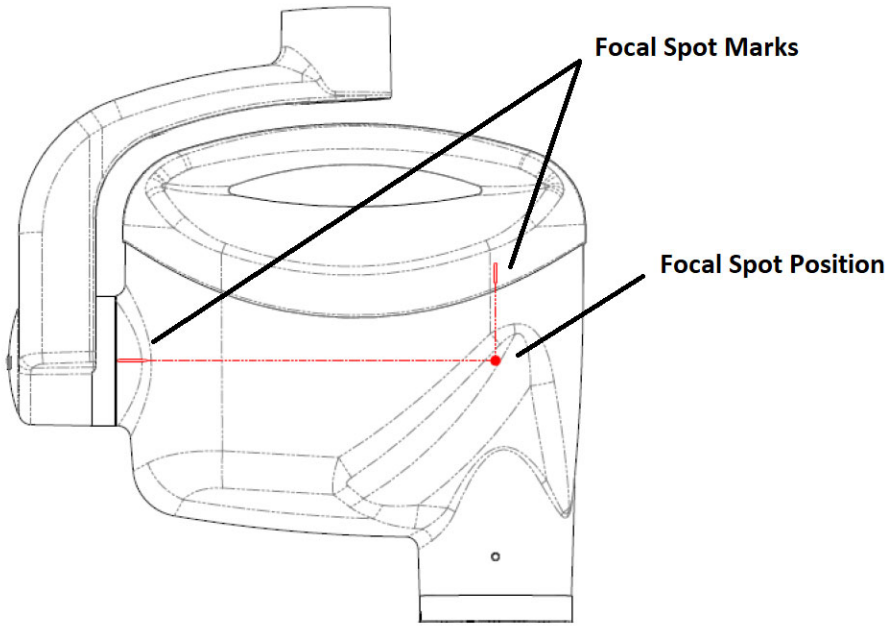
Statements and Information According to Canadian Radiation Emitting Devices Regulations, Part II of Schedule II

Specifications Preva

2(h)(i)-(iv)

For each X-ray tube assembly:

- Nominal focal spot size: is 0.4 mm.
- Cooling curves for the anode and X-ray tube housing: refer to the Thermal Characteristics Charts in the **Specifications** section of this manual.
- X-ray tube rating charts: refer to the tube rating figures within the **Specifications** section of the *Preva Installation and Service Manual* (00-02-1577).
- Focal spot position: the following illustration shows the focal spot position and the focal spot marks on the Preva tubehead.



2(i)

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

2(j)

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

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

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 **System Configuration** section of this user manual.

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	60kV, 65kV, 70kV	±5%
Tube Current	4mA, 5mA, 6mA, 7mA Note: 7mA is not available for 70kV.	±20%
Exposure Duration	min 20 ms, max. 2 s	±5% of 20ms, whichever is greater

2(q)

Removable protective devices: the modular beam-limiting devices (BLDs) available for use with Preva are described in the **Product Description** section and listed by part number in the **Certified Components** section of this user manual. Information on the effectiveness of the BLDs is provided in the **Dose Information** section. Instructions for BLD replacement are provided in Technical Advisory Notice (TAN) 55-60-004, available in the Midmark.com Technical Library.

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 **Certified Components** section of this user manual.

3(b)(ii)

Nominal X-ray image receptor air kerma range that is needed for the intended use: refer to the **Dose Information** section of this user manual. For dose administered when using the ClearVision sensor, refer to the **Dose Information** section of the *ClearVision Installation and User Manual* (00-02-1663).

3(b)(iii)

Recommendations for typical loading factors at specified distances between the focal spot and the skin of 20 cm to achieve the air kerma referred to in subparagraph (ii): refer to the **Dose Information** section of this user 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 **Certified Components** section of this user 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 **Dose Information** section of this user manual.

3(e)(ii)

The maximum deviation of the air kerma: refer to the **Dose Information** section of this user manual.

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.

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

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

The Preva X-ray tube output is not calibrated to the listed values and may change over the life of the product. The presented data are based on statistical analysis of limited number of measurements made on a limited number of Preva intraoral X-ray systems. The maximum deviation of the estimate does not exceed 40% with confidence 99.9%. Calibrated measurement equipment must be used periodically, and at least annually, to obtain precise values for the X-ray tube output and air kerma for each individual machine at the technique factors of interest.

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

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

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

Exposure Time	60 kV				65 kV				70 kV		
	4 mA	5 mA	6 mA	7 mA	4 mA	5 mA	6 mA	7 mA	4 mA	5 mA	6 mA
0.020 s	0.110 mGy	0.137 mGy	0.165 mGy	0.192 mGy	0.125 mGy	0.156 mGy	0.187 mGy	0.218 mGy	0.143 mGy	0.178 mGy	0.214 mGy
0.025 s	0.137 mGy	0.172 mGy	0.206 mGy	0.240 mGy	0.156 mGy	0.195 mGy	0.234 mGy	0.273 mGy	0.178 mGy	0.223 mGy	0.267 mGy
0.032 s	0.176 mGy	0.220 mGy	0.264 mGy	0.308 mGy	0.200 mGy	0.250 mGy	0.300 mGy	0.349 mGy	0.228 mGy	0.285 mGy	0.342 mGy
0.040 s	0.220 mGy	0.275 mGy	0.330 mGy	0.385 mGy	0.250 mGy	0.312 mGy	0.374 mGy	0.437 mGy	0.285 mGy	0.357 mGy	0.428 mGy
0.050 s	0.275 mGy	0.344 mGy	0.412 mGy	0.481 mGy	0.312 mGy	0.390 mGy	0.468 mGy	0.546 mGy	0.357 mGy	0.446 mGy	0.535 mGy
0.064 s	0.352 mGy	0.440 mGy	0.528 mGy	0.616 mGy	0.399 mGy	0.499 mGy	0.599 mGy	0.699 mGy	0.456 mGy	0.571 mGy	0.685 mGy
0.080 s	0.440 mGy	0.550 mGy	0.660 mGy	0.769 mGy	0.499 mGy	0.624 mGy	0.749 mGy	0.874 mGy	0.571 mGy	0.713 mGy	0.856 mGy
0.100 s	0.550 mGy	0.687 mGy	0.824 mGy	0.962 mGy	0.624 mGy	0.780 mGy	0.936 mGy	1.092 mGy	0.713 mGy	0.892 mGy	1.070 mGy
0.125 s	0.687 mGy	0.859 mGy	1.031 mGy	1.202 mGy	0.780 mGy	0.975 mGy	1.170 mGy	1.365 mGy	0.892 mGy	1.114 mGy	1.337 mGy
0.160 s	0.879 mGy	1.099 mGy	1.319 mGy	1.539 mGy	0.998 mGy	1.248 mGy	1.498 mGy	1.747 mGy	1.141 mGy	1.426 mGy	1.712 mGy
0.200 s	1.099 mGy	1.374 mGy	1.649 mGy	1.924 mGy	1.248 mGy	1.560 mGy	1.872 mGy	2.184 mGy	1.426 mGy	1.783 mGy	2.140 mGy
0.250 s	1.374 mGy	1.718 mGy	2.061 mGy	2.405 mGy	1.560 mGy	1.950 mGy	2.340 mGy	2.730 mGy	1.783 mGy	2.229 mGy	2.675 mGy
0.320 s	1.759 mGy	2.198 mGy	2.638 mGy	3.078 mGy	1.997 mGy	2.496 mGy	2.995 mGy	3.494 mGy	2.282 mGy	2.853 mGy	3.423 mGy
0.400 s	2.198 mGy	2.748 mGy	3.298 mGy	3.847 mGy	2.496 mGy	3.120 mGy	3.744 mGy	4.368 mGy	2.853 mGy	3.566 mGy	4.279 mGy
0.500 s	2.748 mGy	3.435 mGy	4.122 mGy	4.809 mGy	3.120 mGy	3.900 mGy	4.680 mGy	5.460 mGy	3.566 mGy	4.458 mGy	5.349 mGy
0.640 s	3.517 mGy	4.397 mGy	5.276 mGy	6.156 mGy	3.994 mGy	4.992 mGy	5.990 mGy	6.989 mGy	4.564 mGy	5.706 mGy	6.847 mGy
0.800 s	4.397 mGy	5.496 mGy	6.595 mGy	7.694 mGy	4.992 mGy	6.240 mGy	7.488 mGy	8.736 mGy	5.706 mGy	7.132 mGy	8.558 mGy
1.000 s	5.496 mGy	6.870 mGy	8.244 mGy	9.618 mGy	6.240 mGy	7.800 mGy	9.360 mGy	10.920 mGy	7.132 mGy	8.915 mGy	10.698 mGy
1.250 s	6.870 mGy	8.588 mGy	10.305 mGy	12.023 mGy	7.800 mGy	9.750 mGy	11.700 mGy	13.650 mGy	8.915 mGy	11.144 mGy	13.373 mGy
1.600 s	8.794 mGy	10.992 mGy	13.190 mGy	15.389 mGy	9.984 mGy	12.480 mGy	14.976 mGy	17.472 mGy	11.411 mGy	14.264 mGy	17.117 mGy
2.000 s	10.992 mGy	13.740 mGy	16.488 mGy	19.236 mGy	12.480 mGy	15.600 mGy	18.720 mGy	21.840 mGy	14.264 mGy	17.830 mGy	21.396 mGy

Note: *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 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*

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