midmark

Preva Dental X-ray System

User Manual

00-02-1576
Revision ZB1
March 2021

Contents

Introduction

Intended Use

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

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 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.
- 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.
- Replace sensors only when a patient is not in contact with the machine or the operator.

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

- 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., IEC[1], NEC[2], or VDE[3] standards concerning provisions of an additional protective earth (ground) terminal for power supply connection.
- Before cleaning or disinfecting, this equipment must 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.

[1] International Electrotechnical Commission
[2] National Electrical Code
[3] Verband Deutscher Elektrotechniker (Association of German Electrical Engineers)

Radiation Safety

- Allow only qualified and authorized personnel, observing all laws and regulations concerning radiation protection, to operate this equipment.
- The operator must remain at all times a safe distance from the focal spot and the X-ray beam.
- Utilize all of the equipment's radiation safety features.
- To protect both the patient and the operator from X-ray radiation, employ all available radiation protection devices, accessories, and procedures.

Device Disposal

To ensure compliant and safe disposal of waste electrical and electronic equipment, contact the Midmark dealer or local regulatory or public health authorities.

Warnings/Precautions

The instructions contained in this manual must be read and followed when operating the Preva system. The l**ocal** Midmark dealer can assist in placing the system in operation**.**

E

xplosion Safety

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

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 in the Installation Guide 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.

X-Ray Protection

Do not operate the device 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-ray radiation. However, no practical design can provide complete protection from radiation or completely prevent operators from exposing themselves or others to unnecessary radiation.

Product Description

The Preva Dental X-ray System is a high-frequency intra-oral X-ray machine. It consists of six components, as shown in Figure 1: 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.

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 142, 167, 193, 208 cm (56, 66, 76 and 82 in).

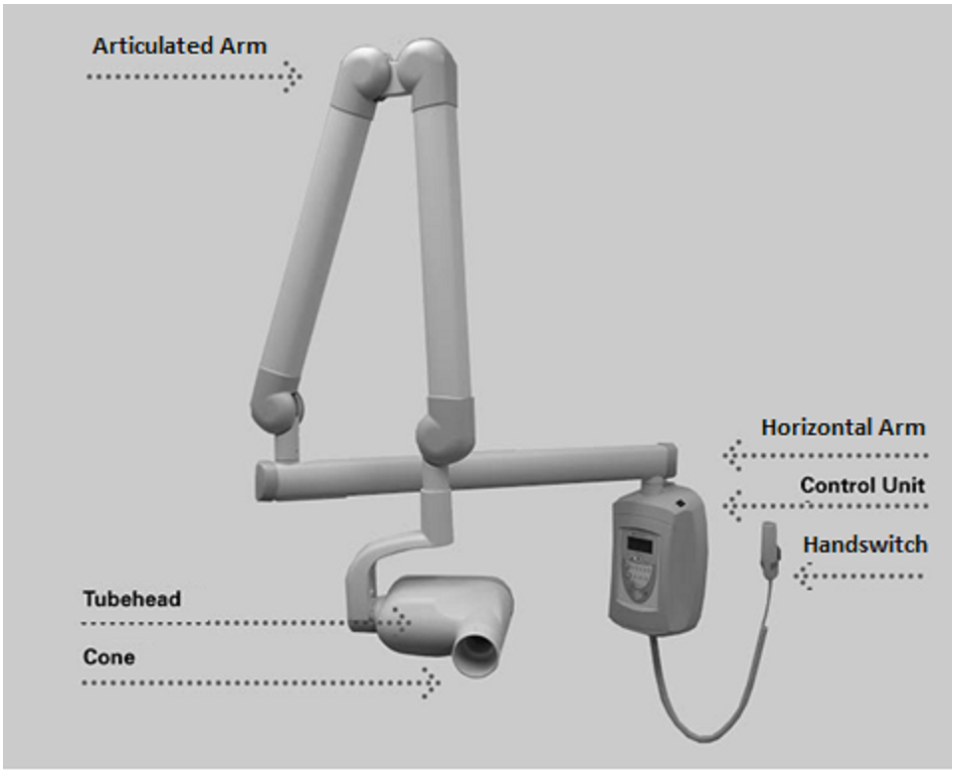

Figure 1 Component Diagram

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

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

20 cm (8-inch) Cone attached to the Tubehead. An optional 30 cm (12-inch) Cone is available[4].

Handswitch

Exposures can be made with the exposure button or with the optional Handswitch (30-A2040).

Tubehead

The Tubehead contains the X-ray tube, high voltage circuit, and a round Cone. The tubehead is shipped assembled to the Articulated Arm.

⚠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.

Model Configurations

The Preva is available as either a wall-mounted or a mobile unit. See the Preva Installation and Service Manual (PN 00-02-1577) mounting instructions.

Installation and Service

Allow only Midmark-approved personnel to install or service Preva equipment. Contact Midmark for assistance in locating an approved dealer. Contact information is on the back cover.

[4] See *About the 20 cm and 30 cm Cones* on page 19 for ordering information.

Certified Components

Component	Reference Number
Tubehead	30-A1027
Control Unit. Preva	30-A0010
Control Unit. Preva Mobile	30-A0013
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
Modular BLD, Base, Gray	30-A2205
Modular BLD, Spacer, Gray	30-A2206
Modular BLD, Spacer, White	30-A2208

Authorized Representatives

North America

Midmark Corporation
1001 Asbury Dr.
Buffalo Grove, Illinois 60089 U.S.A.
Phone: 800-MIDMARK (800-643-6275)
Fax: 847-415-9801

Key to Symbols Used

	Type B: Protection against electric shock (IEC 60601.1-1988)
	Information useful to an operator, not related to safety.
	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 the 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 Medical device risk classification – Class II (FDA) Protection against electrical shock – Class I (IEC 60601) Degree of protection against electrical shock Type B applied part – Pass (UL) Type BF applied part (ClearVision sensor only) – Pass (UL) Degree of protection against ingress of water (ClearVision sensor only) – 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 (ClearVision sensor only) – 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

⚠WARNING

- Mobile RF communications equipment can affect the performance of medical electrical equipment. (The Preva Dental X-ray System is not considered life-supporting equipment.) Midmark advises against using the Preva system adjacent to other devices. If it must be used near other devices, carefully adjust their configuration to ensure that electromagnetic interference (EMI) does not degrade performance. Test both devices for normal operation. See the EMC tables on the next two pages for detailed information.
- Use of accessories, transducers, or cables other than those provided by 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.
- Usage limitation: The Preva Dental X-ray System, when integrated with ClearVision sensors, must be used with IEC-60950- or IEC-60601-compliant computers. Also, any device between the integrated Preva system and the computer (USB hub) must be compliant with IEC 60950 or IEC 60601. If not, electromagnetic compatibility may be degraded.

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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
1001 Asbury Dr.
Buffalo Grove, Illinois 60089 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

Power On Settings

When powering on the Preva Dental X-ray System, the Operator Panel displays the selections from the system's last exposure.

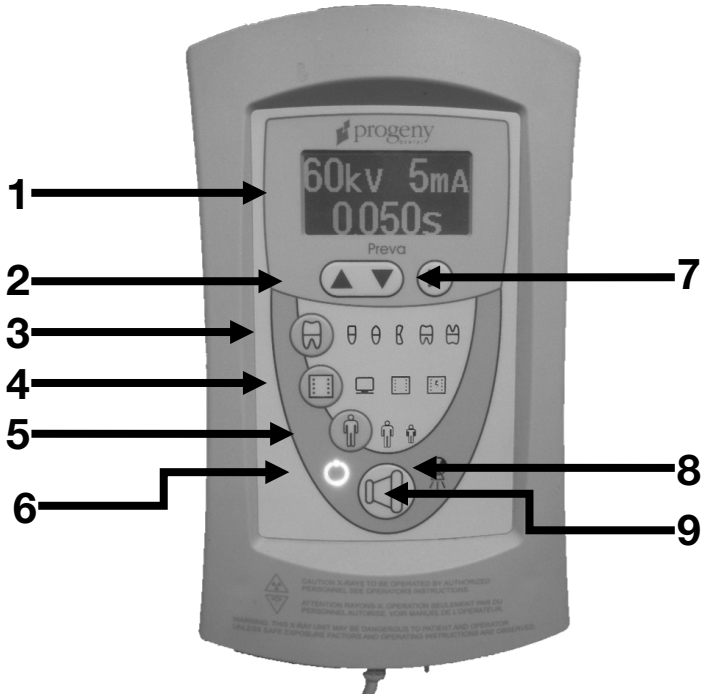


Figure 2 Preva Operator Panel

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 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 default exposure settings, refer to the Default Exposure Settings tables on page 30.

Adjusting Exposure Settings

Preset exposure settings can be adjusted before making an exposure. Use the right arrow to select the exposure setting to adjust. Use the up and down arrows to adjust the value. To save new presets, see the System Configuration Mode section on page 28.

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

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. No exposure can be made while the Ready Indicator is flashing.

Exposure Button and Radiation Indicators

The Exposure button initiates an X-ray exposure. For a complete exposure, the button must be pressed and held until the Radiation Indicator goes off and the audible signal stops. Releasing the Exposure button will immediately terminate 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. • 30 cm during an examination can expose a patient to non-diagnostic X-rays. Automatic shutdowns can be caused by overcurrent relays (caused by excess electricity flowing to the tubehead) or thermal cut-out (caused by the tubehead exceeding acceptable temperature specifications).

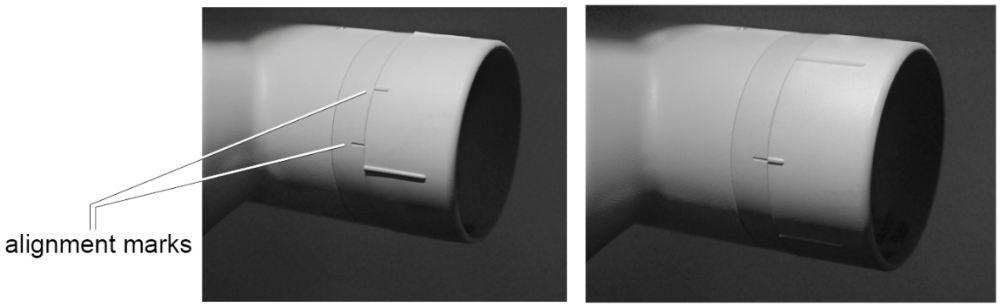
Interlock

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

Changing a Cone

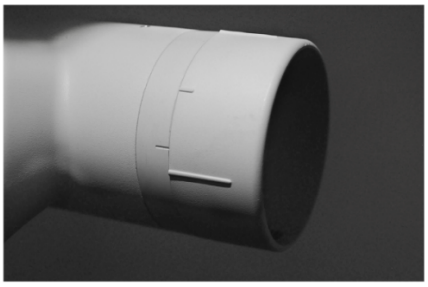
The Preva system has a variety of cone options (see Certified Components on page 8). Follow this procedure to replace a cone:

1. To remove a cone, rotate it until the marks on the tubehead and the cone align.



2. Remove the cone. The parts are magnetized so there will be a slight resistance.

3. Reverse the steps to attach the new cone. Secure it by rotating it clockwise about 30° clockwise until the first detent is felt.



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 will be 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, the preset exposure settings selected in steps 2-4 can be adjusted before making an exposure. (Skip this step when using the default exposure settings.) While exposure settings are being adjusted, the Tooth Selection, Image Receptor Type, and Patient Size buttons will be turned off. Use the right arrow to select the exposure setting to be adjusted. Use the up and down arrows to adjust the value.
6. Position the Tubehead 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 (6.6 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 audio-visual communication between them.

7. Take the X-ray. Press and hold the Exposure button until the audible signal stops and the Radiation Indicator goes 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 operatory when using the coil-cord handswitch. To follow established safety practices and comply with regulations, the technique factors must be visible to the operator from the remote location.

8. Return the Tubehead to the storage position.

⚠CAUTION	Do not strike the tubehead on anything when returning it to the storage position.

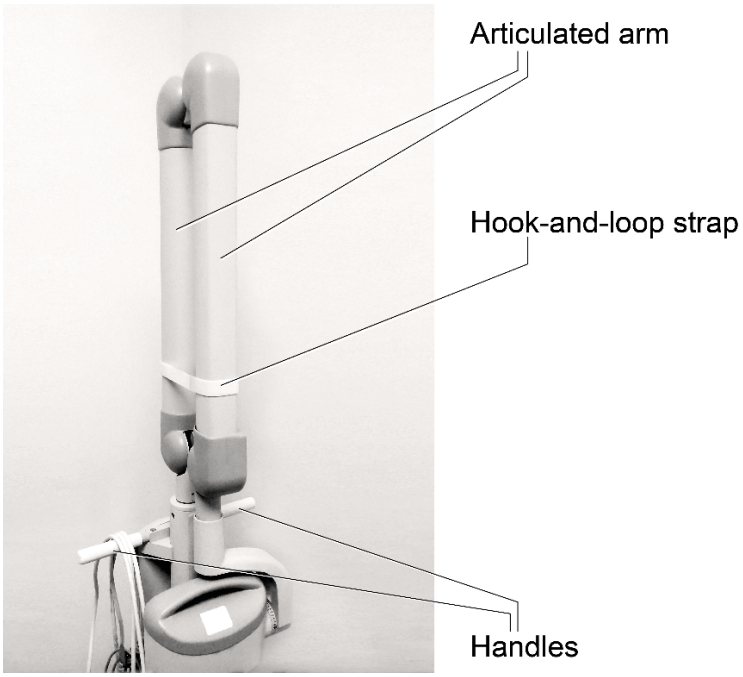
It may be necessary to increase or decrease the kV, mA, or time from the preset values. To do this:

1. Press the Enter button to highlight the value being changed.
2. Use the up or down arrows 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 the Dose Information section on page 43.

Transporting the Device

To avoid injury and damage to the tubehead when transporting the device to a different location within the user facility, collapse the articulated arm and secure it with the hook and loop strap[5] that was used during shipping. Maneuver the device by grasping the device's two handles. Avoid hitting the tubehead on walls, doorways, etc. and be careful not to damage the cable with the wheels during transport.



About the 20 cm and 30 cm Cones

The System is factory configured for use with the standard, supplied 20 cm (8 in.) Round Cone[6]. A 30 cm (12 in.) Round Cone[7] is also available.

Using the longer cone will require longer exposure times. For instructions on configuring the system for use with the longer cone, see the System Configuration Mode section on page 28.

[5] Part number 30-S0037
[6] Part number 30-A2195
[7] Part number 30-A2200

Maintenance

Regular Maintenance

In the interest of equipment safety, a regular maintenance program must be established. Include annual system function checking in this program. It is the owner's responsibility to arrange for this service and to assure that the personnel performing service procedures are fully qualified.

Cleaning and 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 barriers, perform these cleaning and disinfecting steps between each patient:

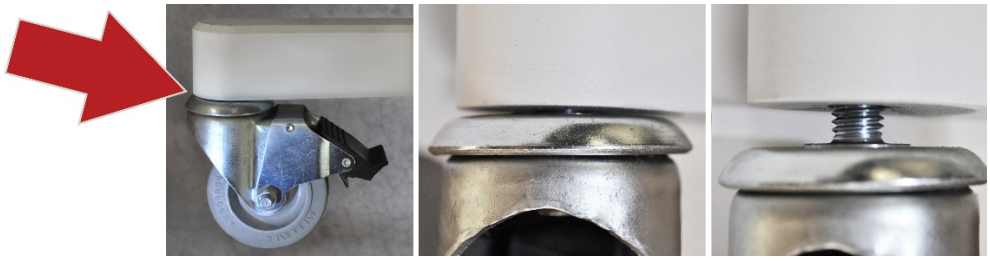
1. Remove gross bio-burden from the cone, handles, and structure with a disposable towel moistened with water.
2. Dry the cone, handles, and structure with disposable towels.
3. Wipe the cone, handles, and structure with a germicidal broad-spectrum disinfectant.
4. Clean any remaining disinfectant residue 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. • Follow the manufacturer's instructions when using germicidal disinfectants.

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.

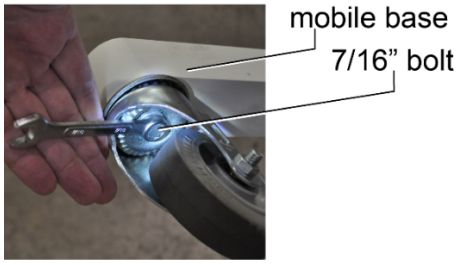
1. Casters attach to the mobile base, as shown in the left photograph below. When correctly seated, a caster will be snug against the base (middle). If the caster begins loosening, threads will be visible between it and the mobile base (right).



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:

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.

⚠CAUTION	Two people are required to perform this step.

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 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 Preva Installation and Service Manual (00-02-1577) or contact Midmark's Technical Support.

System Function Checklist

Component	Directions	✓
Wall Mounting	Verify that the wall support is adequate and that the system is properly mounted to the wall.	
Labels	Verify 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. If necessary, replace the Tubehead.	
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 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.	
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.	
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 handswitch is used, inspect the switch housing and coil cord for damage or wear. Replace them if there is any evidence of damage.	
User Information	Verify that the owner of the system has received the user manual.	

Seasoning X-ray Tubes

X-ray tubes which sit dormant for several months can become electrically unstable. To remedy this condition, perform a new 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 two months.

1. Verify system operation.
2. Energize the system.
3. Select 60 kilovolts [kV], 7 milliamperes [mA], and a one-second exposure.
4. Make five exposures at this level, observing the normal cooling time.
5. Select 65 kilovolts, 7 milliamperes, and a one-second exposure time.
6. Make five exposures at this level, observing the normal cooling time.
7. Select 70 kilovolts, 6 milliamperes, and a one-second exposure time.
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 section on page 26. 2. Verify the kilovoltage and tube current during an exposure using the diagnostic mode, as explained in the System Configuration section. Alternatively, a non-invasive meter can be used to evaluate kilovoltage and exposure time. 3. Inspect the condition of the remaining imaging chain components such as the film, chemistry and processor, and 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 button will cause a pre-termination error, resulting in an underexposed image. After five seconds, the system will return to the normal operating condition. See Exposure Button and Ready Indicator on page 16 for more information

Technical Support

If the steps above do not resolve error issues, stop using the X-ray unit and contact Midmark Technical Support for assistance.

Contact	Midmark Corporation 1001 Asbury Dr. Buffalo Grove, Illinois 60089 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

Default Exposure Times

These tables show the 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 on page 28.

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 Dose Information on page 42.

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. (See Figure 3) A menu screen will appear after about 5 seconds.
2. Use the down arrow to highlight “Configure Unit” then press the right arrow key to select it.
3. “Select Languages” 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.

Figure 3
Preva Operator Panel

System Configuration Mode

About System Configuration Mode

The System has a software-driven configuration mode. These procedures can be performed in configuration mode.

- Adjusting the display
- Changing default exposure settings
- Changing the extension 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 five seconds. The Main System Configuration menu will appear, as shown in Figure 4. 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.
3. After selecting an option, use the up and down arrows to increase or decrease values.

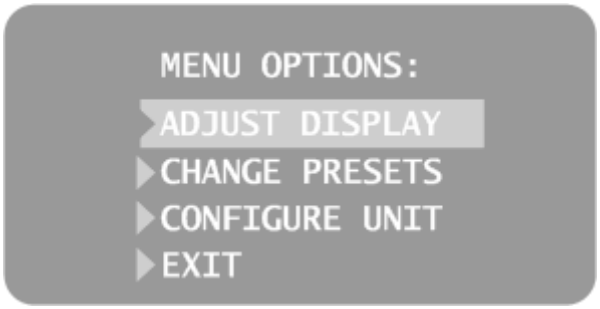


Figure 4
Main System Configuration Menu

Adjusting the Display

Contrast and foreground/background tones can be adjusted by the operator.

The Display Options Menu

1. From the system configuration main menu, shown in Figure 4, select ADJUST DISPLAY. The Display Options menu, shown in Figure 5, will appear.
2. Select EXIT to return to the Main System Configuration menu shown in Figure 4.

Adjusting Contrast

1. Select ADJUST CONTRAST from the menu. The Progeny logo will be displayed.
2. Use the up and down arrows to increase or decrease the contrast between the menu text and the background.
3. Press the right arrow to save the changes.

Reversing the Image

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

Figure 5 Display Options Menu

Changing Default Exposure Settings

The operator can adjust image density for all of a receptor's presets simultaneously or change each of the technique factors individually. Default settings can also be restored. For charts of the factory default settings, refer to the Default Exposure Times section on page 26.

If the 30 cm (12 inch) cone is to be used, configure the device for use with it before changing default exposure settings. This will reset exposure settings to the defaults used with the 30 cm cone.

Before changing presets, use one of the Exposure Settings tables (page 32 for the 20 cm/8 in. cone, page 33 for the 30 cm/12 in. cone) to record the presets being programmed.

Displaying the Preset Options Menu

1. From the Main System Configuration menu (see Figure 4), select CHANGE PRESETS. The Preset Options menu shown in Figure 6 will be displayed.
2. Select EXIT to return to the Main System Configuration menu.

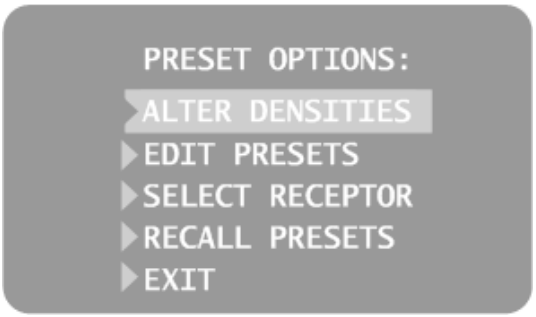


Figure 6
Preset Options Menu

Changing All Receptor Settings Globally

1. Select ALTER DENSITIES from the Preset Options menu. The first Image Receptor Type will be displayed showing the selected Image Receptor Type and the current density.
2. Use the Image Receptor Type button to select the image receptor to adjust.
3. Use the up and down arrows to specify the percentage by which densities will be increased or decreased for the selected receptor. Densities can be increased or decreased according to the values on the display.
4. Press Enter to save the changes.

Changing All Receptor Settings Globally

1. Select ALTER DENSITIES from the Preset Options menu. The first Image Receptor Type will be displayed showing the selected Image Receptor Type and the current density.
2. Use the Image Receptor Type button to select the image receptor to adjust.
3. Use the up and down arrows to specify the percentage by which densities will be increased or decreased for the selected receptor. Densities can be increased or decreased according to the values on the display.
4. Press Enter to save the changes.

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 arrow 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 “Saving Settings” message will be displayed briefly. The system will then return to the normal operational mode.

Note: When 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 five seconds.
3. Select EDIT PRESETS from the Preset Options menu. Entering Edit Preset Mode will be displayed and Tooth Size, Image Receptor Type, and Patient Size will be illuminated.
4. Use the Tooth Selection, Image Receptor Type, and Patient Size Selection buttons to select which preset to change. The display shows the current values for the preset.
5. Use the right arrow to highlight the technique factor to be changed (tube voltage in kilovolts [kV], tube current in milliamps [mA], or duration in seconds [s]).
6. Use the up and down arrows to change the value for the selected technique factor.
7. Repeat steps 2-4 to change additional presets.
8. After the new values have been entered, press the Tooth Selection and Patient Size Selection buttons simultaneously for five seconds to record the changes.

Recalling Presets

1. Turn the system on.
2. Push and hold the Tooth and Patient selection switches. A menu screen will appear after about five seconds.
3. To return all presets to their default values, select RECALL PRESETS from the Preset Options menu. The menu will ask the user to confirm the choice.
4. Use the up arrow to select YES. All custom presets will be erased and values will revert to their defaults.
   or
   Use the down arrow to select NO. All current presets will be retained.

User-Adjusted Exposure Settings for the 20 cm (8 in.) Cone

If the default exposure settings do not produce the density desired, adjust the settings using System Configuration mode. Record the settings in this table.

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						

User-Adjusted Exposure Settings for the 30 cm (12 in.) Cone

If the default exposure settings do not produce the density desired, adjust the settings using System Configuration mode. Record the settings in this table.

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 the Current System Configuration

The 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. The Configuration menu shown in Figure 7 will be displayed.
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.

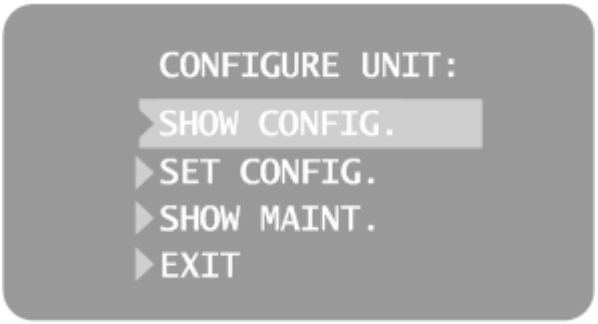


Figure 7 Configuration Menu

Changing the Cone Extension Size

Select SET CONFIG. from the Configuration menu, shown in Figure 7, to display the Set Configuration menu, Figure 8, with the cone size options. The system's default is for use with the supplied 20 cm (8 in.) cone. A 30 cm (12 in.) cone is available (see About the 20 cm and 30 cm Cones on page 18). Using the longer cone requires longer exposure times. The system automatically selects when the cone size is changed 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.

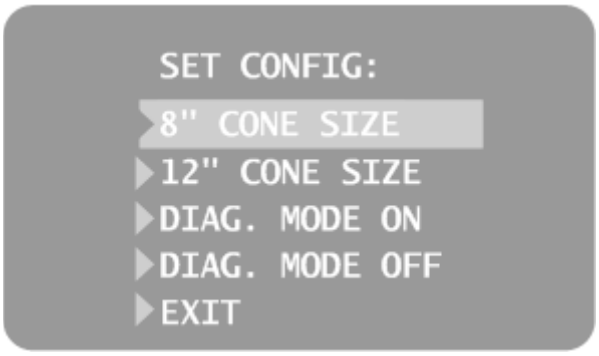


Figure 8
Set Configuration Menu

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

Parameter	Description
Line Voltage	AC 110 V to 230 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	20 cm (8 in.) 30 cm (12 in.)
Focal Spot	0.4 mm (per IEC 60336)
Temperatures	
Operating	+10 °C to +35 °C (+50 °F to +95 °F)
Storage	-35 °C to +66 °C (-31 °F to +151 °F)
Transport	0 °C to +50 °C (+32 °F to +122 °F)
Atmospheric Pressures	
Operating	70 kPa to 106 kPa
Storage	70 kPa to 106 kPa
Transport	70 kPa to 106 kPa
Maximum Altitude	3,000 m (9,843 ft.)
X-ray Beam Dimension	Diameter of 6 cm (2.36 in.) at the end of the 8-inch cone. Cones with smaller diameter or rectangular beams are available.
Humidity Range (Operation & Storage)	10 to 80% non-condensing
U.S. Patents	D470237, D469182, D470589, and 6,837,468

Statements and Information According to 21 CFR Sub Chapter	
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 41. 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

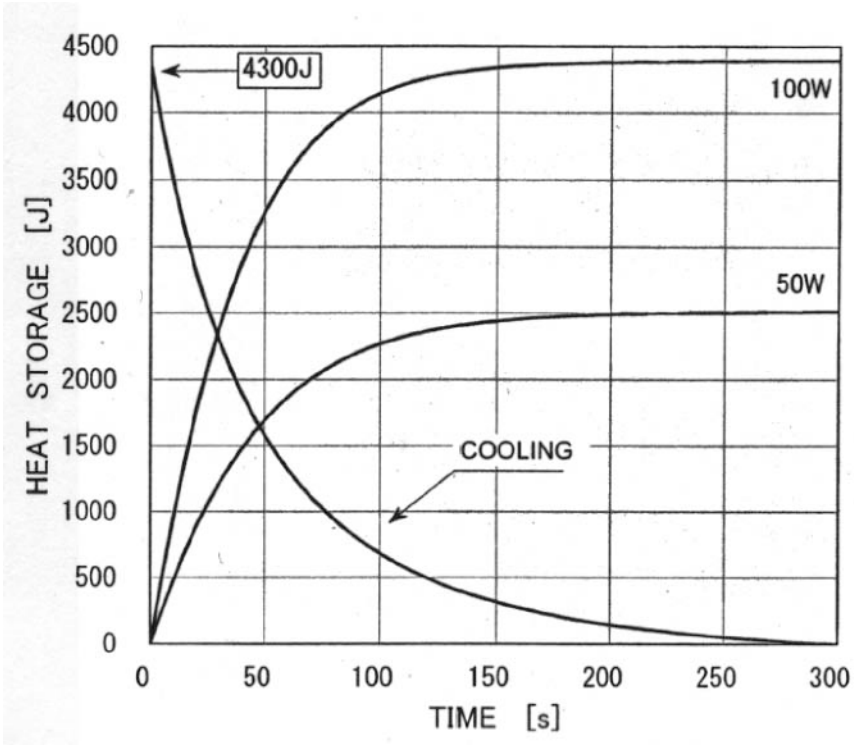


Figure 9
Canon (Toshiba)
Tube Rating Chart

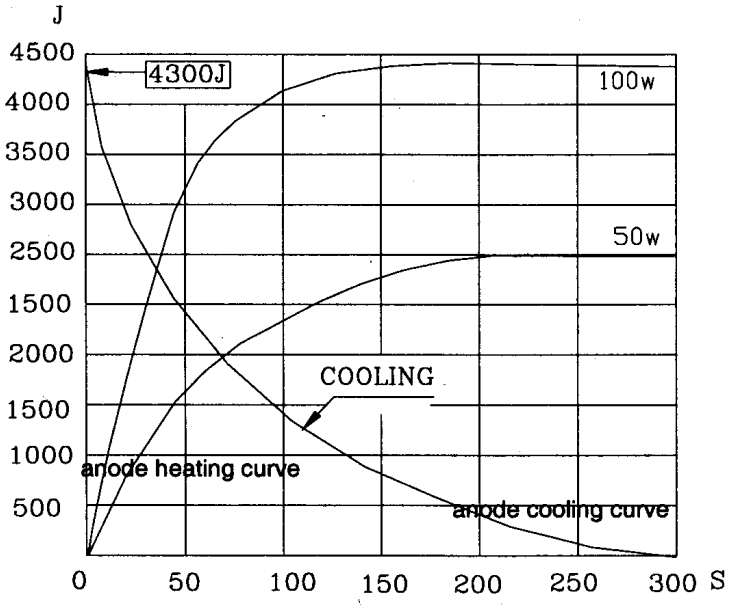


Figure 10
Kailong Tube Rating
Chart

Thermal Characteristics Chart

Statements and Information According to Canadian Radiation Emitting Devices Regulations

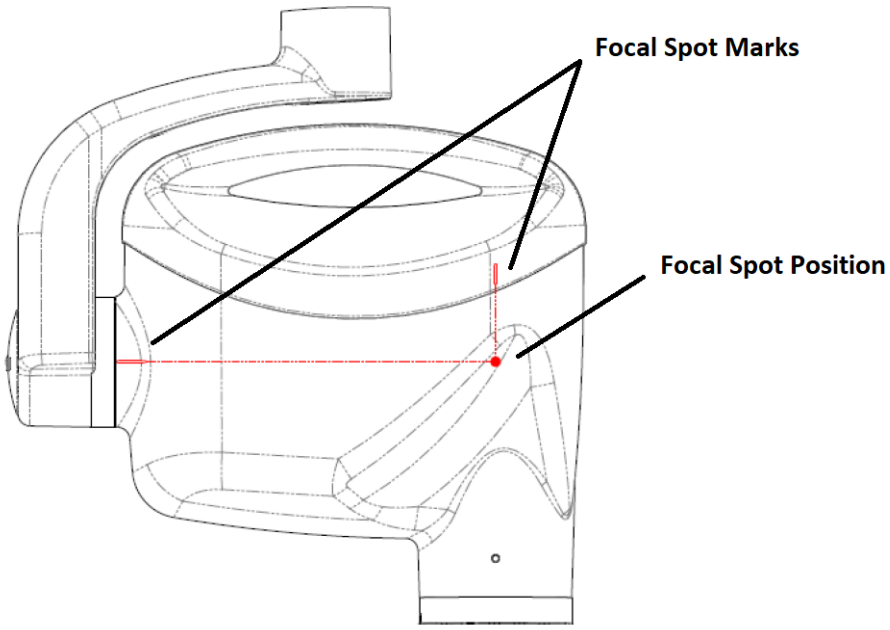
Part II of Schedule II

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 on page 37.
- 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 on page 26.

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 on page 6 and listed by part number in the Certified Components section on page 8. Information on the effectiveness of the BLDs is provided in the Dose Information section on page 42. 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 on page 8.

3(b)(ii) Nominal X-ray image receptor air kerma range that is needed for the intended use: refer to the Dose Information section on page 42. 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 on page 42.

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 on page 8.

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 on page 42.

3(e)(ii) The maximum deviation of the air kerma: refer to the Dose Information on page 42.

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·mA^{-1}·s^{-1}	1.560 mGy·mA^{-1}·s^{-1}	1.783 mGy·mA^{-1}·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

Kerma Area Product

Kerma[8], *K*, is the quotient of dE_{tr} divided by d*m* where

dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass of material

d*m* is the mass of the material

K is the kerma in J/kg, expressed in the SI unit *gray (Gy)*

When the material is air, the quantity is referred to as air kerma.

Kerma area product, abbreviated KAP, has replaced the older terminology, dose area product (DAP).

The air kerma-area product, expressed in the SI units mGy·cm^2, is a commonly used quantity associated with the amount of X-ray used in dental panoramic and CBCT radiography. It is calculated with this formula:

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

Modular BLD Cone Dimensions				
Part Number	**Length (cm)**	**Width**		**Opening Area (cm^2)**
		(mm)	**(cm)**	
30-A2196	20	60	6	18.84
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			

[8] As defined by the International Commission on Radiation Units and Measurements

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