



JB-70 Dental X-Ray System

User Manual

00-02-1568 Rev A

Progeny Dental

1407 Barclay Boulevard
Buffalo Grove, Illinois 60089 U.S.A.
Phone: (888) 924-3800 Fax: (847) 459-5175
WWW.progenydental.com

Table of Contents

General Information.....	3
Product Description.....	3
Compliance with Applicable Standards	5
Certified Components	5
EC Declaration of Conformity	6
Authorized Representatives	7
Safety.....	7
Explanation of Symbols on Technical Labels	8
Obtaining Technical Support	8
Operating the JB-70 Dental X-Ray System.....	9
Operator Panel Controls.....	9
Taking an X-Ray	10
Using the 12 in Cone (30-A2033)	11
Recommended Maintenance	12
Regular Maintenance	12
Cleaning and Disinfecting.....	12
Checking System Functions.....	12
System Function Checklist	13
Solving Performance Issues.....	14
Performance Issues	14
Obtaining Technical Support	14
Setting Pre-programmed Exposure Times	15
Power On Settings	15
Pre-programmed Exposure Times	15
Changing Programmed Exposure Times.....	17
Specifications	18
JB-70 Dental X-Ray System.....	18

General Information

Product Description

	<p>The JB-70 Dental X-Ray System is a state-of-the-art intra-oral x-ray machine. The JB-70 consists of five components, as shown in Figure 1 Component Diagram: the Control Unit, the Tubehead, the Articulating Arm, the Horizontal Arm and the Cone.</p>
Control Unit	<p>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.</p>
Tubehead	<p>The Tubehead contains the x-ray tube, high voltage transformer, and Cone. The Tubehead is shipped already assembled to the Articulating Arm.</p> <p>Note: There is a small hole in the plastic handle covering the back of the Tubehead. Under no circumstances should this hole be blocked as it provides an air vent to allow the Tubehead oil to expand and contract as the unit is operated.</p>
Articulating Arm	<p>The Articulating Arm provides the articulation support for the Tubehead and the reach and coverage of the Tubehead to the patient. The Articulating Arm allows smooth movement for precise positioning and does not drift or vibrate when left in position.</p>
Horizontal Arm	<p>The Horizontal Arm helps provide the necessary reach for the JB-70. The Horizontal Arm pivots smoothly around a shaft inserted in the top of the Control Unit. The Horizontal Arm contains an access cover to connect the cable from the Horizontal Arm to the Control Unit. The Horizontal Arm is available in two lengths, one that provides a 76 inch reach and one that provides a 66 inch reach.</p>
Cone	<p>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 JB-70 is shipped with the standard 8 inch Cone attached to the Tubehead. A 12 inch Cone (30-A2033) can be ordered as an option.</p>
Installation and Service	<p>The JB-70 Dental X-Ray System should only be installed and serviced by approved Progeny dealer personnel. Contact Progeny at (888) 924-3800 if you need assistance locating an approved dealer.</p>

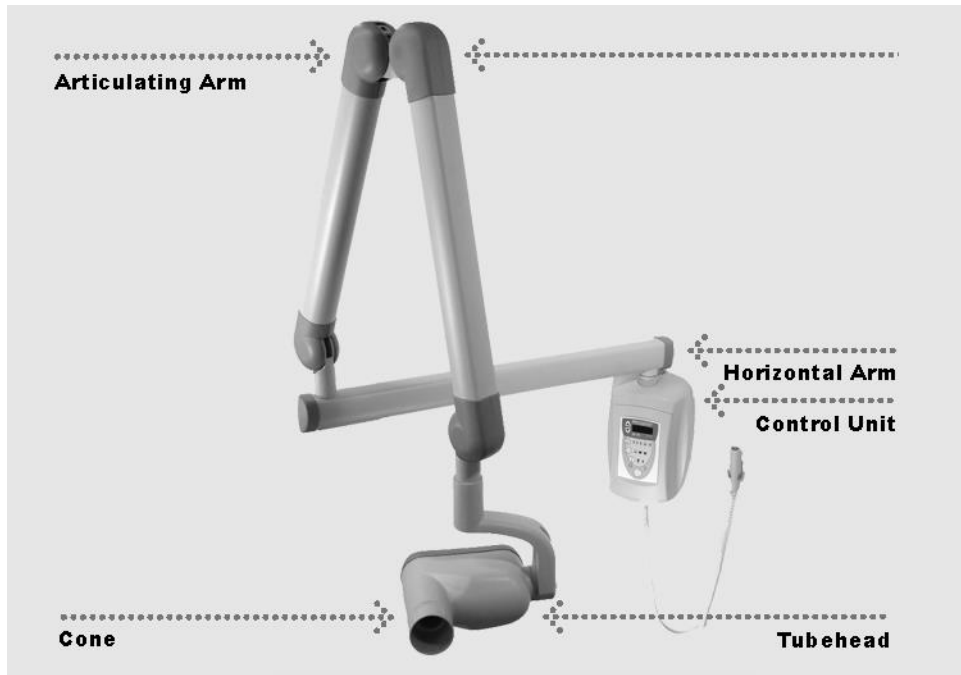


Figure 1
Component
Diagram

Compliance with Applicable Standards

Radiation Protection

The certified components of the JB-70 Dental X-Ray System comply with Radiation Performance Standards 21 CFR, Subchapter J, at the time of manufacture.

The certified components of the JB-70 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, IEC60601-2-7, IEC60601-2-28.

EMI/EMC

IEC60601-1-2

Certified Components

120V System

Component

Tubehead
Control Unit
Cone 8 in.
Cone 12 in.

Reference Number

30-A0005
30-A0001
30-A2016
30-A2033

230V System

Component

Tubehead
Control Unit
Cone 8 in.
Cone 12 in.

Reference Number

30-A1007
30-A0003
30-A2016
30-A2033

EC Declaration of Conformity

Name and Description of Product

Progeny JB-70

Catalog Model	I7017, 76 inch reach, 120Volt 30-A0001, Control, 120Volt 30-A2025, Extension Arm, Long
Catalog Model	I7016, 66 inch reach, 120Volt 30-A0001, Control, 120Volt 30-A2034, Extension Arm, Short
Catalog Model	I7027, 76 inch reach, 230Volt 30-A0003, Control, 230Volt 30-A2025, Extension Arm, Long
Catalog Model	I7026, 66 inch reach, 230Volt 30-A0003, Control, 230Volt 30-A2034, Extension Arm, Short
Class:	IIb

Reference Numbers to which Conformity is Declared

The following regulatory documents apply:
 21CFR
 UL 2601-1
 IEC 60601-1-2
 IEC 60601-1-3
 IEC 60601-2-7
 IEC 60601-2-28
 IEC 60601-2-32
 Medical Device directive
 ISO 13485
 EN46001

Declaration

Progeny, Inc. declares that the products described herein meet all the applicable Essential Requirements of the EC Medical Device Directive 93/42/EEC in Annex I. For Class IIb products described herein, the product is manufactured, inspected, tested and released in accordance with the approved quality assurance system established in accordance with ISO 9001, EN 46001 and Annex II of the EC Medical Device Directive under the Supervision of the British Standards Institution, a Notified Body carrying the Notified Body No. 0086.

Contact

Alan Krema
 Product Development
 Progeny, Inc.

Authorized Representatives

North America

PROGENY DENTAL
1407 Barclay Blvd.
Buffalo Grove, IL 60089
Phone: 888-924-3800
Fax: 847-459-5175

Europe

CE Partner 4U
Nijverheidsstraat 5
2624 BA Delft
Netherlands
Phone: +31-15.2576682
Fax: +31-15.2576683

Safety

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 6ft. (2m) 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

- Only qualified and authorized service personnel should remove covers on the equipment.
- 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 JB-70 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.

Explanation of Symbols on Technical Labels

	Type B: Protection against electric shock (IEC 60601.1-1988)
	Consult written instructions in User's Manual.
	ATTENTION RAYONS-X: OPERATION SEULEMENT PAR DU PERSONNEL AUTORISE. VOIR MANUEL DE L'OPERATEUR.
	WARNING X-RAY THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.
	<i>X-RAY EMISSION</i>
L	Mains HOT WIRE
N	Mains NEUTRAL WIRE
	Earth Ground

Obtaining Technical Support

Contact	PROGENY DENTAL 1407 Barclay Blvd. Buffalo Grove, IL 60089 Phone: 888-924-3800 Fax: 847-459-5175
----------------	---

Operating the JB-70 Dental X-Ray System

Operator Panel Controls

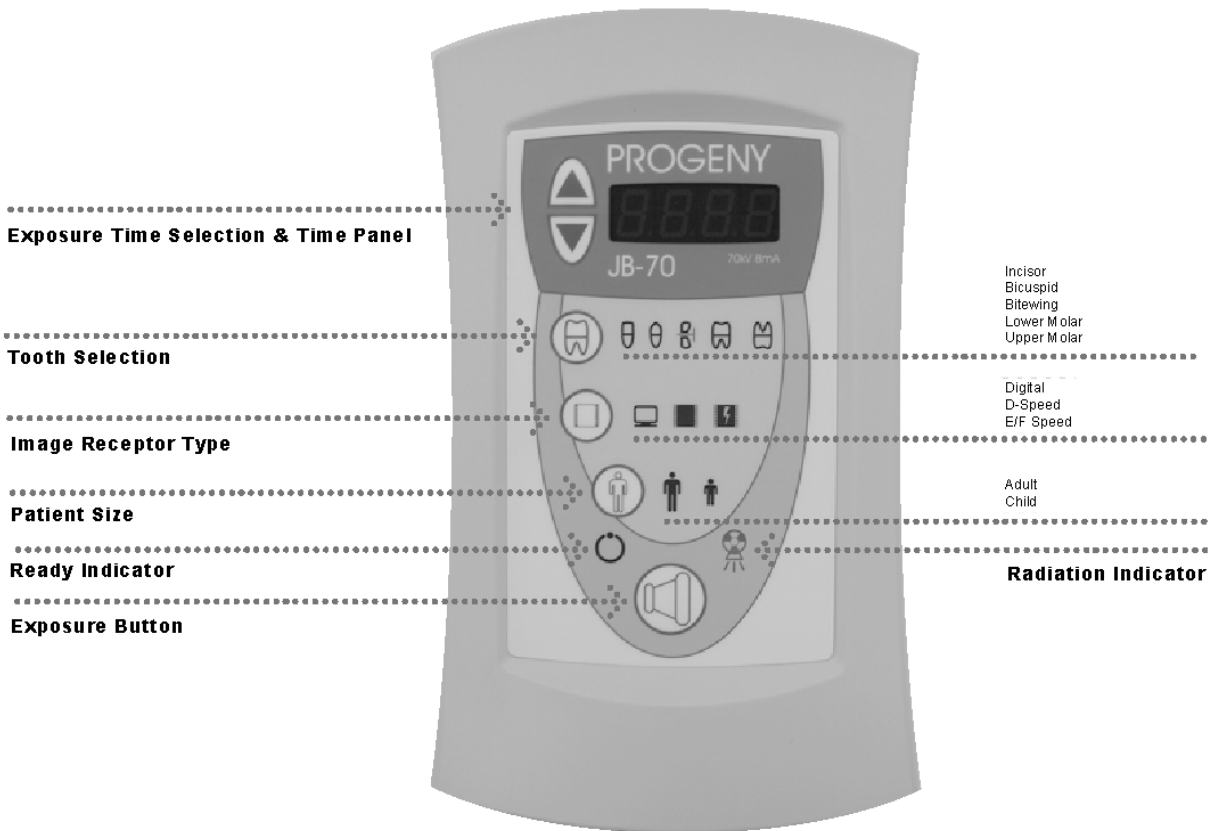


Figure 2 JB-70 Operator Panel

Exposure Time Selection

The JB-70 Dental X-Ray System has 30 pre-programmed exposure times. The exposure time that is used when taking an x-ray is determined by the combination of the Tooth Selection, Image Receptor Type and Patient Size that is selected on the Operator Panel. The pre-set exposure times can also be adjusted using the up and down Exposure Time arrows.

- For a table of the pre-programmed exposure times set at the factory, refer to the Pre-programmed Exposure Times table later in this manual.
- For a procedure for modifying pre-programmed exposure times, refer to Changing Programmed Exposure Times later in this manual.

Exposure Button

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.

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 JB-70 has a visible and an audible Radiation Indicator. When an exposure is in progress, the Radiation Indicator on the Operator Panel is illuminated and a 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 on the base of the Control Unit, to the "On" position. The Ready Indicator on the front of the Operator Panel will light.
2. Exposure time can be selected by either using the pre-programmed exposure times or by simply adjusting the time manually up or down to the desired time. If selecting the time manually, skip steps 3-5.
3. 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.
4. 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.
5. 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.
6. If desired, the Exposure Time Selection up or down buttons can be used to change the pre-set exposure time.
Note: When the Time Selection buttons are used, the Tooth Selection, Image Receptor Type and Patient Size buttons are turned off.
7. Position the Tubehead to the patient using standard accepted positioning procedures.
8. 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 bang the Tubehead on the wall when returning it to the storage position.

Using the 12 in Cone (30-A2033)

The JB-70 is set at the factory for use with the standard supplied 8 in (20 cm) cone. The 12 in (30 cm) long cone (30-A2033) is recommended when using the paralleling film positioning technique. Using the long cone requires the use of longer exposure times, which can be programmed into the system by changing an internal electrical setting. Only a qualified Progeny Dental service agent should perform this modification. Contact your Progeny Dental service agent to make the change.

Recommended Maintenance

Regular Maintenance

In the interest of equipment safety, a regular maintenance program must be established. This maintenance program should consist of cleaning and disinfecting as well as 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 Progeny Dental x-ray equipment.

Cleaning and Disinfecting

All external and cleanable surfaces can be cleaned and/or disinfected using the following list of commonly used solutions:

- Isopropyl alcohol
- Phenylphenl
- Benzyl-P-Chlorophenol
- Iodophor

Note: Use bleach or glutaraldehydes only occasionally.

Verify the contents of any cleaning or disinfecting solution against the list above before applying it to any surface of the JB-70 Dental X-Ray System.

Checking System Functions

Important Notice

The following checks must be performed at the installation of the JB-70 Dental X-Ray System and as part of the recommended maintenance at least every twelve months after installation. Failure to perform these checks may result in an installation that does not comply with U.S. Radiation Performance Standards 21 CFR Subchapter J.

If the JB-70 Dental X-Ray System does not perform the functions below, see the Troubleshooting section of this manual or contact Progeny Dental's Technical Support. Do not use the system until the problems are resolved.

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.	
Indication of Technique Factors	Verify that the "70 kV – 8 mA" is legible on the label of the Operator Panel.	
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 movement.	
Suspension	Check that all movements are smooth and quiet. Verify that the Tubehead is properly counterbalanced for vertical drift and that the Horizontal and Articulating 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 base of the Control Unit, in the ON position, verify that a time indicates on the Operator Panel. Also, check the function of the selection buttons for Exposure Time, 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 an exposure of 1.65 seconds (2.0 seconds for the 50 Hz system) using the Exposure Time buttons. Initiate an exposure but release the Exposure button after a brief period of time before the timer terminates the exposure. Verify that exposure terminates immediately upon release of the Exposure button.	
Coil-cord Hand Switch (Optional)	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 a copy of the User Manual.	

Solving Performance Issues

Performance Issues

Light X-Ray

If the x-rays are lighter than desired, check the following:

1. Verify that the exposure time is appropriate for the examination. If using pre-programmed exposure times, make sure that the proper image receptor type is selected.
2. Verify proper operation of the film processor.

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.

Obtaining Technical Support

Contact

PROGENY DENTAL
1407 Barclay Blvd.
Buffalo Grove, IL 60089
Phone: 888-924-3800
Fax: 847-459-5175

Setting Pre-programmed Exposure Times






Power On Settings






When the JB-70 Dental X-Ray System is powered on, the Operator Panel selections are those that were in use when the system was last powered off.

Pre-programmed Exposure Times

The table below shows the pre-programmed exposure times for each combination of Tooth, Image Receptor Type and Patient Size on the Operator Panel. These exposure times can be modified using the procedure that follows the table.

Times for 8 inch (20 cm) Cone in Seconds 60 Hz (50 Hz times shown in parentheses)

		Digital Receptor		D-speed Film		E/F Speed Film	
		Adult	Child	Adult	Child	Adult	Child
	Incisor	0.067 (0.080)	0.050 (0.060)	0.200 (0.240)	0.100 (0.120)	0.117 (0.140)	0.067 (0.080)
	Bicuspid	0.083 (0.100)	0.050 (0.060)	0.267 (0.320)	0.133 (0.160)	0.167 (0.200)	0.083 (0.100)
	Bitewing	0.100 (0.120)	0.050 (0.060)	0.233 (0.280)	0.133 (0.160)	0.117 (0.140)	0.067 (0.080)
	Lower Molar	0.133 (0.160)	0.067 (0.080)	0.233 (0.280)	0.117 (0.140)	0.167 (0.200)	0.083 (0.100)
	Upper Molar	0.167 (0.200)	0.083 (0.100)	0.333 (0.400)	0.167 (0.200)	0.117 (0.140)	0.067 (0.080)

Times for 12 inch (30 cm) Cone in Seconds 60 Hz (50 Hz times shown in parentheses)							
		Digital Receptor		D-speed Film		E/F Speed Film	
Anatomy		Adult	Child	Adult	Child	Adult	Child
	Incisor	0.133 (0.160)	0.100 (0.120)	0.417 (0.500)	0.200 (0.240)	0.233 (0.280)	0.117 (0.140)
	Bicuspid	0.167 (0.200)	0.083 (0.100)	0.533 (0.640)	0.267 (0.320)	0.333 (0.400)	0.167 (0.200)
	Bitewing	0.200 (0.240)	0.100 (0.120)	0.467 (0.560)	0.233 (0.280)	0.233 (0.280)	0.117 (0.140)
	Lower Molar	0.233 (0.280)	0.133 (0.160)	0.467 (0.560)	0.233 (0.280)	0.333 (0.400)	0.167 (0.200)
	Upper Molar	0.333 (0.400)	0.167 (0.200)	0.667 (0.800)	0.333 (0.400)	0.233 (0.280)	0.117 (0.140)

Changing Programmed Exposure Times

The JB-70 Dental X-Ray System has a programming mode during which the exposure times can be modified.

Note: When the system is in programming mode, it ignores the x-ray exposure circuit such that when the Exposure button is pressed no x-ray is made. When in programming mode, pressing the Exposure button stores the current Operator Panel settings.

1. To enter programming mode, press and hold the Image Receptor Type button while turning ON the power. The Ready Indicator will flash to indicate that the system is in programming mode.
2. Select the combination of technique factors whose exposure time is to be changed.
 - a. Use the Image Receptor Type button to select the receptor type.
 - b. Use the Tooth Selection button to select a tooth.
 - c. Use the Patient Size button to select the patient size.
3. Use the Time Selection buttons to change the exposure time for the combination of tooth, image receptor type and patient size.

Note: When the Time Selection buttons are used, the Tooth Selection, Image Receptor Type and Patient Size buttons are turned off.
4. After the exposure times have been set, press the Exposure button to store the exposure times.
5. Repeat steps 2 and 4 until exposure times have been set for all combinations of image receptor, tooth and patient size.
6. When the exposure times have been stored, power off the system. To return the system to normal operational mode, power it on without holding any selection buttons.

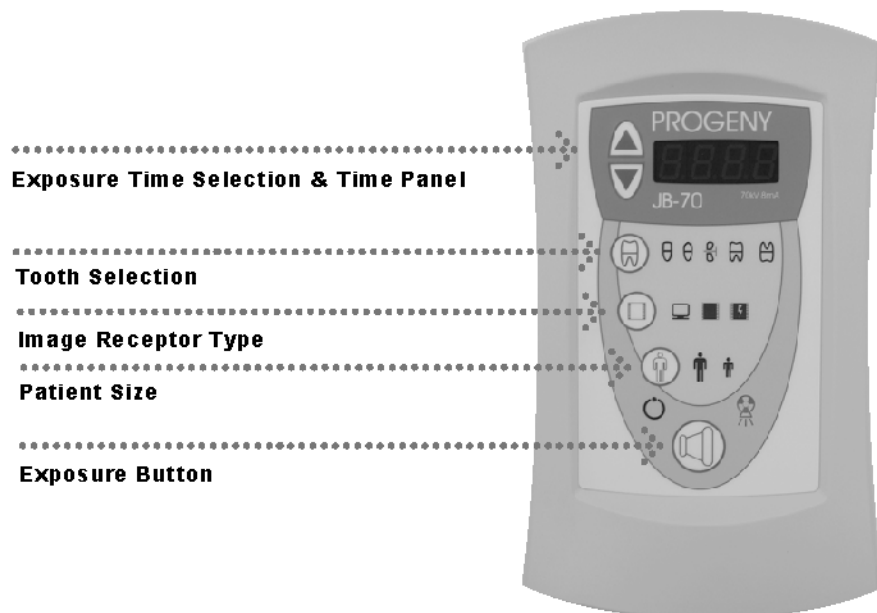


Figure 3
Exposure Time
Selection Buttons

Specifications

JB-70 Dental X-Ray System

The following specifications contain information required to be provided to the user per Federal Regulation 21 CFR.

Line Voltage	120 VAC +/- 10% 50/60 Hz	Max line current is 10 Amps
	230 VAC +/- 10% 50/60 Hz	Max line current is 5 Amps
	Load Regulation Must not exceed 6%	
Tube Potential	70 kVp +/-10%	
Tube Current	8 mA +/- 2 mA	
Exposure Time Selections	50 ms through 1.65 seconds for 60 Hz operation 60 ms through 2.0 seconds for 50 Hz operation.	
Timer Accuracy	+/- 34 ms	
Source to Skin Distance	8 inch (20 cm) 12 inch (30 cm)	
Radiation Output	Approximately 800 mR at the following sets 70 kVp 8 mA 1.0 sec 20 cm SID	
Minimum Inherent Filtration	2 mm Aluminum equivalent	
Minimum Half Value Layer	1.7 mm Aluminum equivalent at 70 kVp	
Focal Spot	0.7 mm (IEC 336)	
Duty Factor	1:60	
Leakage Technique Factors	0.25 mA at 70 kVp	
Target Angle	20 degrees	
Operating Temperature	+50 F/+113 F (+10 C/+45 C)	
Storage Temperature	-31F/+150 F (-35 C/+66 C)	
Maximum Altitude	12,000 ft	
Cone Focal Length	8 inch(20 cm) for bisecting angle technique 12 inch(30 cm) for paralleling technique	
Diameter of X-Ray	2.7 inch (6.9 cm) at the end of the Cone	

Measurement Bias

Each exposure is preceded by a filament warm up time of about 0.175 seconds. During this time, a low level of radiation is produced. The peak tube potential varies during the filament warm up from approximately 60 to 80 kVp. Although the amount of radiation produced during this time is small, it is useful and contributes to forming the image on the film.

When the exposure time starts, the first several x-ray pulses will be high kVp (about 80), low mA (about 2), and will settle out to 70 kVp and 8 mA (nominal) after 5-10 pulses.

Tube Rating Charts

