

BLUEX

IntraOs 70 X-ray Equipment Operator's Manual



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IntraOs 70 X-ray Equipment
Operator's Manual – English Edition USA

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Table of Contents

1.	Introduction	4
1.1	Congratulations.....	4
1.2	Purpose	4
1.3	Equipment Classification.....	4
1.4	Applicable Standards.....	4
1.5	Obligation of the Installer.....	5
1.6	Obligation of the User	5
1.7	Warning	5
2.	Technical Data.....	6
2.1	Tube-Head G	6
2.2	Beam Limiting Device	7
2.3	Mechanical System.....	7
2.4	Weights.....	8
2.5	AutoSet Timer	9
3.	Operating instructions	10
3.1	Demonstration	10
3.2	Beam Limiting Device	10
3.3	AutoSet Timer	10
3.4	Operation	14
3.5	Safety	15
3.6	Cleaning.....	15
3.7	Disinfecting	16
3.8	Functional Check.....	16
4.	Disposing of obsolete equipment	16
	Appendix A System Components	17
	Appendix B Icons	18
	Appendix C Exposure Table	19
	Appendix D Alarm Conditions.....	20
	Appendix E Identification Labels.....	21
	Appendix F Cooling Curves.....	22

1. INTRODUCTION

1.1 Congratulations

Congratulations! You have purchased a state of the art equipment which will assist in your profession day after day performing consistently for many years.

The unit is manufactured under a Quality Control System which grants full compliance to specifications.

1.2 Purpose

The IntraOs 70 X-ray Equipment is design to fulfil the needs for intra-oral radiography in the general dental practice.

The system can be configured for wall, unit or mobile solutions and different types of timers and tube-heads.

The features of the system make it easy to use, and grant long life with minimum maintenance.



1.3 Equipment Classification

- FDA: IntraOs 70 is a Class II equipment (21 CFR 872-1800).
- IEC: IntraOs 70 is a Class I, type B equipment

1.4 Applicable Standards

The IntraOs 70 system configurations, all equipped with the AutoSet timer, comply with the following standards.

IEC 601-1	General requirements for safety
IEC 601-1-2	Electromagnetic compatibility
IEC 601-1-3	General requirements for radiation protection in diagnostic X-ray equipment
IEC 601-2-7	Particular requirements for the safety of high voltage generators of diagnostic X-ray generators
IEC 601-2-28	Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
21 CFR 1020.30	Diagnostic x-ray systems and their major components
21 CFR 1020.31	Radiographic equipment

1.5 Obligation of the Installer

Obligation of the Installer is:

- To make sure that the line voltage specified by the Manufacturer of the equipment is available and within the specified range.
- For safety reasons verify that a proper switch is available to disconnect from line voltage supply when needed during installation
- To install and test the equipment with due diligence according to the installation instructions from the Manufacturer.
- To provide this Operator’s Manual to the User.



1.6 Obligation of the User

It is the responsibility of the User:

- To use the system following the instructions and recommendations contained in this Operator’s Manual.
- To maintain the equipment in compliance by following the manufacturer’s recommended maintenance schedule. Failure of the user to properly maintain the equipment may relieve the Manufacturer, or his Agent, from responsibility for any injury, damage, or non-compliance which may result.
- To report promptly to the Health Authority in charge and to the Manufacturer or to its Agent any accident involving this medical device or any alteration in features and/or performances which could cause death, injuries or health hazard to Patient and/or Operator.

Important information to be gathered and to be included in the report to the Manufacturer are the type and serial numbers of the involved items which can be retrieved from the technical labels.

1.7 Warning

X-ray equipment produce ionising radiation that may be harmful if not properly controlled.

It is therefore recommended that the equipment be operated by trained personnel only, in accordance with existing law.



Make sure to carefully manoeuvre the suspension arms to position the tube-head in order prevent harm to the fingers in areas where they may be pinched.

Even if compliant to specifications of electromagnetic compatibility, it is recommended not to use the equipment in presence of external electromagnetic fields, such as those generated by cellular phones, which might interfere with the electronic circuits of the system.

2. TECHNICAL DATA

2.1 Tube-Head G

- Line Voltage: $120\text{ V} \pm 10\%$
- Line Frequency: $50/60\text{ Hz} \pm 2\text{ Hz}$
- Line resistance: $\leq 0.4\text{ ohm}$
- Maximum Line Current: 8 A
- Fuse: 8 A slow blow
- X-ray insert: 3 electrodes, grid control action
 - OCX/70-G
 - RF8G070
- Focal Spot: 0.8
- Anode Angle: 19°
- Connection: by coaxial plug, with free horizontal rotation
- High Voltage Potential: $70\text{ kVp} \pm 5\%$ at 120 V line voltage
- Anode Current: $7\text{ mA} \pm 20\%$ at 120 V line voltage
- Duty Cycle: 1/30
- Inherent Filtration: $\geq 2.1\text{ mm Al}$
- Radiation Leakage: $< 0.1\text{ mGy/h}$ at 1 m ($< 11.5\text{ mR/h}$ at 1 m)

2.2 Beam Limiting Device

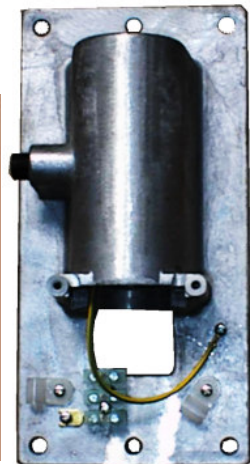
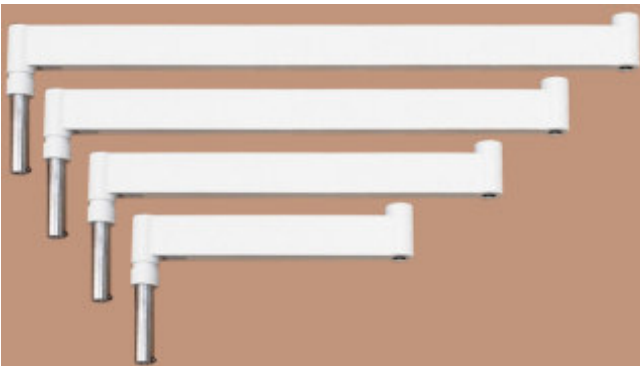
- Circular Output Section
 - Focus Skin Distance: 8.27”(21 cm)
 - Output Radiation Field: 2.35” diameter (6 cm)
- Rectangular Output Section
 - Focus Skin Distance: 8.27”(21 cm)
 - Output Radiation Field: 1.8”x 1.81” (3.5 x 4.6 cm)



2.3 Mechanical System

The wall mounted suspension system includes:

- Wall Support (4.72” width, 9.45” cm height, 3.54” cm depth)
- Extension arms 17”³/₄, 27”¹/₂, 35”¹/₂, and 43”¹/₄ (45, 70, 90, and 110 cm) long





- Folding arm; useful reach of
 - 55" (140 cm) with 17"³/₄ (45 cm) extension arm
 - 65" (165 cm) with 27"¹/₂ (70 cm) extension arm
 - 72"³/₄ (185 cm) with 35"¹/₂ (90 cm) extension arm
 - 80" (205 cm) with 43"¹/₄ (110 cm) extension arm

- The mobile version is composed of:
 - Mobile base: 29" (74 cm) width, 42" (107 cm) height, 24"¹/₂ (62 cm) depth
 - Folding Arm

2.4 Weights

- Tube-head: 14.1 lb (6.4 kg)
- Round BLD: 0.22 lb (0.1 kg)
- Rectangular BLD: 0.44 (0.2 kg)
- Folding Arm: 15.4 lb (7 kg)
- Short Extension Arm: 7.7 lb (3.5 kg)
- Medium Extension Arm: 9.3 lb (4.2 kg)
- Long Extension Arm: 11 lb (5 kg)
- Very Long Extension Arm: 12.7 lb (5.8 kg)
- Wall Support: 2.9 lb (1.3 kg)
- Mobile Base: 55.1 lb (25 kg)

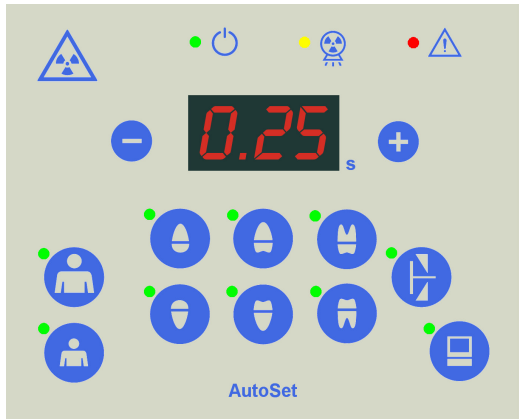


2.5 AutoSet Timer

The timer is working at line voltage of 115 V ± 15%, 50/60 Hz.

Mains features are:

- Microprocessor controlled functionality
- Zero-crossing power switching.
- Film speed setting.
- Automatic setting of exposure time from 60 ms to 3.2 s through object selection.
- Functionality selectable at time of installation for automatic compensation of radiation dose variations due to line voltage fluctuations
- Manual setting possibility of exposure time from 60 ms to 3,2 s in 18 steps. Each step represents the change of the minimum perceptible level of blackening.
- Times are set in seconds by the operator and converted in number of mains pulses by the microprocessor with precision of 1 pulse, corresponding to 20 ms at 50 Hz, 16.6 ms at 60 Hz.



AutoSet exposure times in s					
0.06	0.08	0.10	0.12	0.16	0.20
0.25	0.32	0.40	0.50	0.64	0.80
1.0	1.25	1.60	2.0	2.5	3.2

- Child (small) or adult (large) patient selection
- Low dose setting for use of digital sensors
- Hand-switch is provided with 10 ft/3 m coiled cord. A special installation kit is optionally available for remote installation (33 ft/10 m cable)
- Timer can be remotely mounted.
- Overall size: 6” (15 cm) width, 9”½ (24 cm) height, 3”½ (9 cm) depth

3. OPERATING INSTRUCTIONS

3.1 Demonstration

In order to use of the system for demonstration purposes radiation emission has to be inhibited by disconnecting the supply cables to the tube-head into the wall support or into the timer.



Cables to be disconnected are those leaving the connection block towards the tube-head (“out” connections on the connecting block).

Make sure that the disconnected cables are properly insulated to prevent undesired contacts with live points. Use a spare block to keep them apart.

This has to be done by trained personnel only to avoid the risk of electrical shock.

3.2 Beam Limiting Device

The system is supplied with a Beam Limiting Device which grants a Source Skin Distance of 8.27 inches (21 cm) and has a round output field of 2.35 inches (6 cm) diameter.

A version with rectangular output section of 1.38 x 1.81 inches (3.5 x 4.6 cm) is optionally available.

This device is suitable for either bisecting or paralleling radiographic techniques once conveniently angled by rotating it around the vertical and the horizontal axis.

The tube-head is free to rotate in the horizontal plane (around the vertical axis) and can be rotated plus or minus 135° in the vertical plane (around the horizontal axis) to set the desired angle.



3.3 AutoSet Timer

Before using the timer make sure that the proper film speed combination and length of the beam limiting device have been properly set into the memory of the timer.

Index	0.32	0.40	0.50	0.64	0.80	1.00	1.25	1.60	2.00
Speed			E type			D type			

D type: Kodak Ultraspeed, Agfa Dentus M2 - E type: Kodak Ektaspeed Plus


The timer offers the possibility to correct the exposure time to compensate radiation dose changes due to fluctuations of the line voltage supply, thus granting consistent film blackening. This functionality can be enabled or disabled at time of installation with a dedicated switch (refer to the Service & Installation Manual). When this functionality is enabled, the user is given the possibility to display the actual exposure time after compensation instead of the one requested.


To set the desired working parameters follow the instructions reported here below.

- Enter the set-up menu by switching on the unit while pressing at the same time, and for 2 s, the three keys ⊕, ⊖, and ⊞. The film speed selection modality is thus entered.
 - **Film Speed.** The number on the display represents the index of the speed of the film currently selected (see table above). Press the ⊕ or ⊖ keys to change the value. Press the ⊞ key to exit input mode (back to normal operation) or the ⊞ key to pass to next selection.
 - **Beam Limiting Device.** The number on the display either “20” or “30” represents the length of the BLD in cm. Press the ⊕ or ⊖ keys to change the value. Press the ⊞ key to exit input mode (back to normal operation) or the ⊞ key to pass to next selection.
 - **Actual Exposure Time.** The message on the display, either “on” or “OFF”, tells whether the actual compensated time or the selected one will be displayed. Press the ⊕ or ⊖ keys to change the value. Press the ⊞ key to exit input mode (back to normal operation) or the ⊞ key to go back to first selection.












To operate the systems switch the timer “on” with the button below the unit.


During start-up all the lamps in the panel and the segments of the display, but the yellow light of X-ray On , are blinking for 3 s, to let the operator check that lights in the panel are properly working.



Then the same are switched off all together and the green lamp  will eventually light to indicate System Ready.

Default parameters after installation are: D type film, 20 cm BLD, Adult patient, Upper Premolar (i.e. 0.80 s). Then last parameters used before switching the system off will be proposed at next switch on.

Select the type of patient (child  or adult ) and tooth type:

- Upper  or lower  incisor
- Upper  or lower  canine /premolar
- Upper  or lower  molar
- Inter-proximal bite-wing  on molar/premolar

In case of use of a low-dose digital receptor press the relevant key  to reduce the radiation level.

Should you like to change the pre-set exposure value press the plus key  to increase the exposure time or the minus key  to decrease it. This brings into the manual mode of operation.

The full range of selectable times is of 18 values from 60 ms to 3.2 s.

Range of Selectable Times in s for the AutoSet Timer																	
.06	.08	.1	.12	.16	.2	.25	.32	.4	.5	.64	.8	1	1.25	1.6	2	2.5	3.2

Each step changes the radiation energy of a perceptible level of blackening on the film.

Every 3 steps upward the energy is doubled, every 3 steps downward the energy is halved.

If the functionality to compensate for the effects of fluctuations of the line voltage is activated, the actual exposure time will be shorter (when the line voltage - and kVp consequently - are over the nominal level) or longer (when the line voltage - and kVp consequently - are below the nominal level). This function is intended to grant blackening consistency (less retakes), i.e. the correct X-ray radiation energy as needed for the exposure.

During the exposure the yellow lamp of X-ray On ☠, on the timer and on the hand-switch, lights and the internal buzzer sounds to indicate radiation emission.

As additional safety feature the timer is provided of an independent back-up device (back-up timer and back-up relay) which is going to cut-off radiation in case of failure of the main timer.

Alarm conditions which may occur are signalled by the lights and display messages on the control panel as reported in Appendix D.

In case the buzzers does not quit the sound when the yellow light turns off a fatal conditions to the output relay has occurred.

MANDATORY TO SWITCH-OFF THE SYSTEM USING THE LINE VOLTAGE SWITCH BELOW THE UNIT. STOP USING THE SYSTEM AND CALL TECHNICAL SERVICE TO FIX THE PROBLEM.



The timer implements the dead-man functionality with which radiation emission is stopped if the operator terminates the exposure by releasing the push-button before the requested exposure time has elapsed. An alarm is generated in this condition.

After the exposure the timer takes into account the cool-down period and prevents an immediate exposure which would exceed the energy allowed by the duty cycle.

During the cool-down time the digits of the selected time on the display keep flashing and operation of the system is inhibited. Once cooled down the digits on the display become steady and the system is ready again.

3.4 Operation

1 Turn on the line voltage supply switch on (below the timer) to bring the system ready

2 Position the image receptor where needed and orientate the BLD accordingly.

3 Select the desired exposure time (using the keys or the knob depending on the type of timer connected).

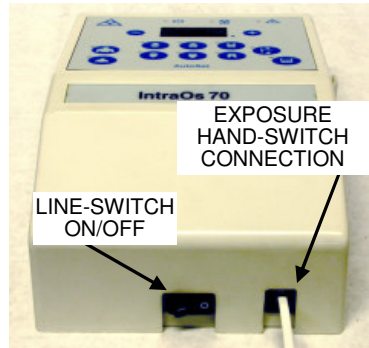
4 Take the exposure switch and move to a convenient position as far from the patient as possible.

5 Press the exposure pushbutton. The exposure yellow light and the buzzer indicate X-ray emission.

Keep the exposure pushbutton pressed until the yellow light is switched off to indicate the end of the exposure.

6 Hook back the exposure hand-switch and process the image receptor.

7 Warning: If the exposure pushbutton is released before the end of the requested time, the radiation emission is terminated and an alarm is generated.



3.5 Safety

- Electrical.
 - Trained and qualified technicians only are authorized to remove covers and have access to power circuits.
 - Power supply lines must comply with safety legislation and have ground terminals for protective earth connection.
 - Switch the equipment off and possibly disconnect it from line voltage supply before cleaning or disinfecting the unit.
- Mechanical.
 - Make sure that fingers or other parts of the patient or of the operator are not pinched during positioning and parking of the equipment.
- Explosion.
 - The equipment cannot be used in presence of flammable gases or vapours.
- Radiation.
 - Trained and qualified personnel only are authorized to operate the equipment always complying with existing law for Radiation Protection.
 - Make sure that the equipment is not left unattended.
- Environmental.
 - The equipment contains components which must be disposed-of following existing law.

3.6 Cleaning

Always disconnect the line voltage supply before cleaning the unit. Use a mild soap to remove finger or other dirty marks paying attention not to have liquid substances enter into the equipment.

Plastic covers can be wiped with a soft cloth and light detergent.

Avoid the use solvents or corrosive detergents which can damage painted surfaces and plastic covers.




3.7 Disinfecting

Parts which can come in touch with the patient must be cleaned with a detergent (such as 2% solution of ammonia) and then disinfected making sure not to use solvents or corrosive disinfectants which can cause cracks on the plastic covers.



3.8 Functional Check

After installation the following check is recommended.

- Switch-on line voltage supply switch (below the unit) and check that the green lamp  of System Ready lights.
- Select any exposure time and position the tube-head so that radiation is directed away without endangering anybody.
- Take the hand-switch, move as far as possible from the unit, press the hand-switch and check that the yellow lamp X-ray on lights and the buzzer sounds during the exposure.
- Select the longest exposure time (3.2 s), press the hand-switch, release it before the selected time is expired and check that the exposure is terminated immediately. An alarm condition is generated due to early termination. Do acknowledge and reset.
- Verify that the tube-head stay in the desired position and if necessary perform the following adjustments:
 - Adjust the friction for rotation around the horizontal axis.
 - Adjust the tension of the spring in the arm.
 - Fine tune the positioning of the wall support.

Refer to Service & Installation Manual for instructions.

4. DISPOSING OF OBSOLETE EQUIPMENT

The IntraOs 70 system is made of different materials which include many kinds of metals, iron, aluminium, lead, copper and others, plastic materials, electronic components and dielectric oil in the tube-head.

Once the system is put out of service such components cannot be abandoned in the environment. They have to be delivered to specialized companies for recycling or disposing of correctly with separate collection.





































Appendix A

System Components

Article System Component	Type Code Catalogue Number
Wall Support	93 100 11000
Extension Arm 45 cm	93 100 17100
Extension Arm 70 cm	93 100 17200
Extension Arm 90 cm	93 100 17300
Extension Arm 110 cm	93 100 17400
Folding Arm	93 100 12010
Tube Head G 120 V	93 200 01300
20 cm Round BLD	91 300 00020
20 cm Rectangular BLD	91 300 00040
AutoSet Timer 115 VAC	93 300 60200
Mobile Base	93 100 20080
Wall Plate	86 100 11500

Appendix B Icons

	IEC Type B Equipment		Compliance to European Community Requirements
	X-ray On		Compliance to Canadian and US Standards
	Examine Annexed Documentation		Line voltage supply On - System Ready
	Increase Exposure Time (one step)		Off (Disconnected from Line voltage Supply)
	Decrease Exposure Time (one step)		On (Connected to Line voltage Supply)
	Child – Small Patient		Alternate Current
	Adult – Large patient		Fuse
	Upper Incisor		Protective Earth
	Upper Canine/Premolar		Neutral Point (for equipment permanent connected to line)
	Upper Molar		Live Point (for equipment permanent connected to line)
	Lower Incisor		Inherent Filtration
	Lower Canine/Premolar		Focal Spot
	Lower Molar		Fragile, Handle With Care
	Bite Wing - Interproximal		Fear of Humidity
	Digital Receptor		Up Do Not Overturn
	Radiography Push Button		Stacking Limit
	Ionizing radiation		Separate Collection, Do Not Dispose

Appendix C Exposure Table

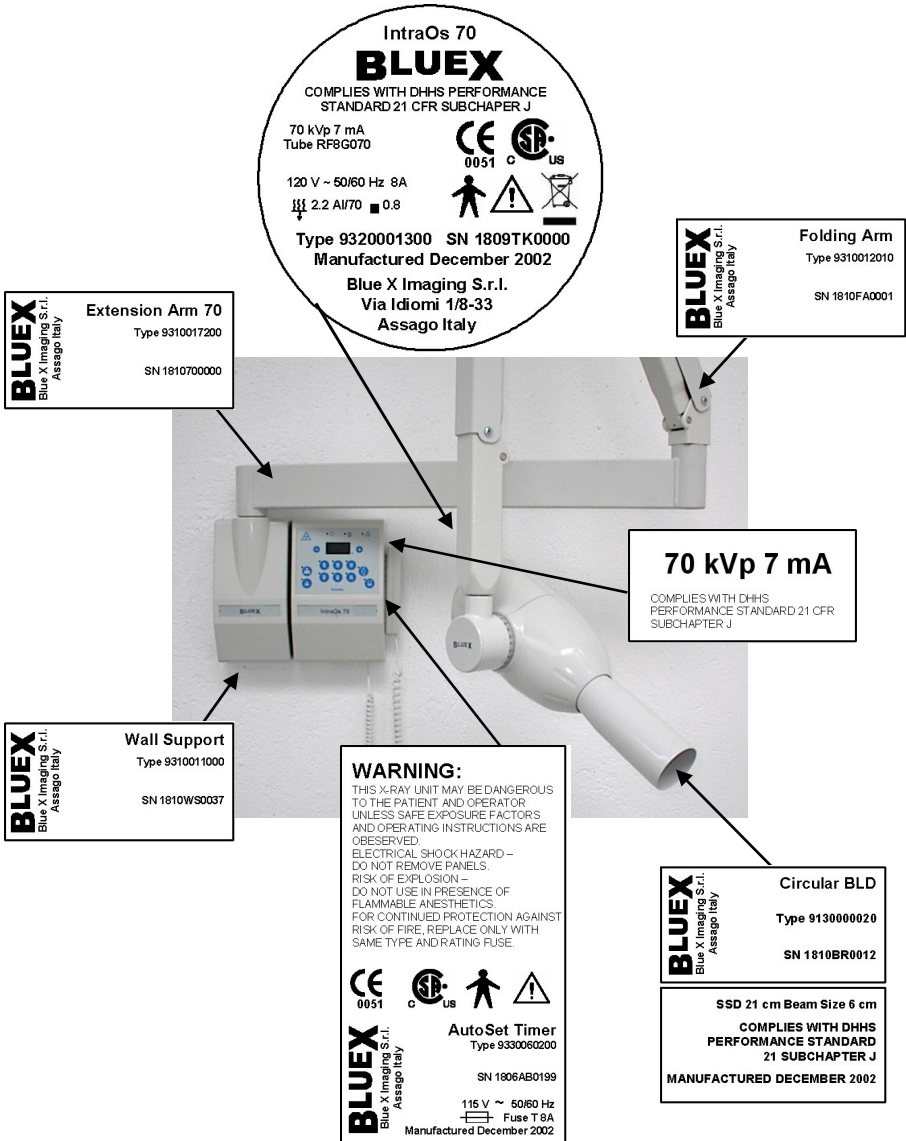
IntraOs 70 - 70 kVp, 7 mA - Exposure Times in s												
Focus-Film Distance 23 cm						D Film			E Film		Digital	Small Patient
					D Film			E Film		Digital		
				D Film			E Film		Digital			Large Patient
	3,20	2,50	2,00	2,60	1,25	1,00	0,80	0,64	0,50	0,40	0,32	
	2,50	2,00	2,60	1,25	1,00	0,80	0,64	0,50	0,40	0,32	0,25	
	2,00	2,60	1,25	1,00	0,80	0,64	0,50	0,40	0,32	0,25	0,20	Upper Molar
	1,60	1,25	1,00	0,80	0,64	0,50	0,40	0,32	0,25	0,20	0,16	Upper Premolar /Canine
Lower Molar	1,25	1,00	0,80	0,64	0,50	0,40	0,32	0,25	0,20	0,16	0,12	Bite Wing
Lower Premolar /Canine	1,00	0,80	0,64	0,50	0,40	0,32	0,25	0,20	0,16	0,12	0,10	Upper Incisor
Lower Incisor	0,80	0,64	0,50	0,40	0,32	0,25	0,20	0,16	0,12	0,10	0,08	
	0,64	0,50	0,40	0,32	0,25	0,20	0,16	0,12	0,10	0,08	0,06	
Focus-Film Distance 33 cm			D Film			E Film		Digital				Small Patient
		D Film			E Film		Digital					
	D Film			E Film		Digital						Large Patient

Appendix D

Alarm Conditions

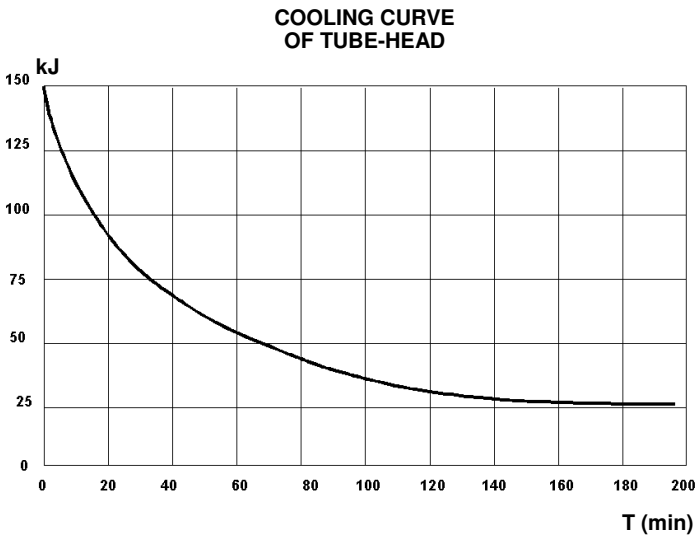
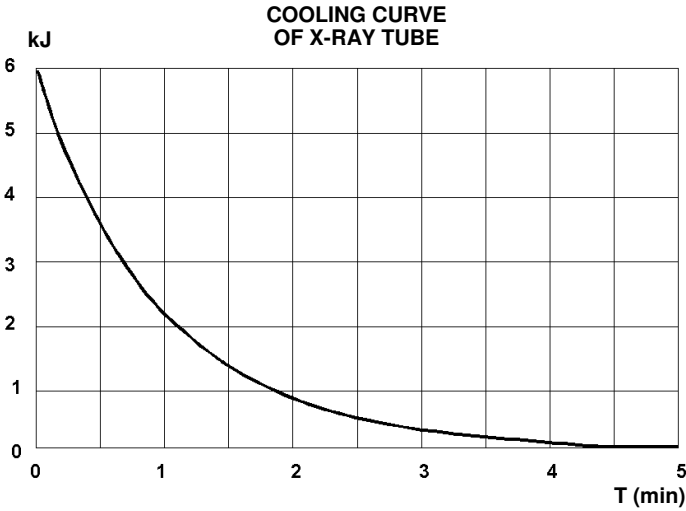
AutoSet Timer Alarm Conditions				
Code	Fault /Error	Signal	Action	Reset
A 01	X-ray requested during cool-down period	Green lamp (System Ready) flashing	System inhibited	By acknowledgement on the panel or when system cooled down
A 02	Line voltage below lower limit	Green lamp (System Ready) and red lamp (Alarm) flashing	System inhibited	Automatically when line voltage back in range
A 03	Line voltage above upper limit	Green lamp (System Ready) and red lamp (Alarm) flashing	System inhibited	Automatically when line voltage back in range
A 04	Corrected exposure time lower than 60 ms	Green lamp (System Ready) and red lamp (Alarm) flashing	0.06 s forced.	By acknowledgement on the panel
A 05	Corrected exposure time greater than 3.2 s	Green lamp (System Ready) and red lamp (Alarm) flashing	3.2 s forced.	By acknowledgement on the panel
A 06	Line Frequency Detection Failure	System Ready (green) lamp and Alarm (red) lamp flashing	System inhibited	By switching system off and on again
A 07	Exposure push button pressed at power on	Red lamp (Alarm) flashing	Exposure inhibited.	By acknowledgement on the panel
A 08	Exposure stopped by the operator	Red lamp (Alarm) flashing	System inhibited	By acknowledgement on the panel or after 1 m
A 09	Exposure stopped by the back-up timer	Red lamp (Alarm) switched on	System inhibited	By switching system off and on again
A 10	Back-up relay failure	Red lamp (Alarm) switched on	System inhibited	By switching system off and on again
A 11	Power switching device failure	Red lamp (Alarm) switched on	System inhibited	By switching system off and on again
A12	Line dips during exposure	Red lamp (Alarm) switched on	Exposure inhibited	By acknowledgement on the panel

Appendix E Identification Labels



Appendix F

Cooling Curves



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Dental X-ray Equipment
Operator's Manual
English Edition USA
Version 3.2



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