BLUEX

IntraOs 70
X-Ray Equipment

Operator's Manual

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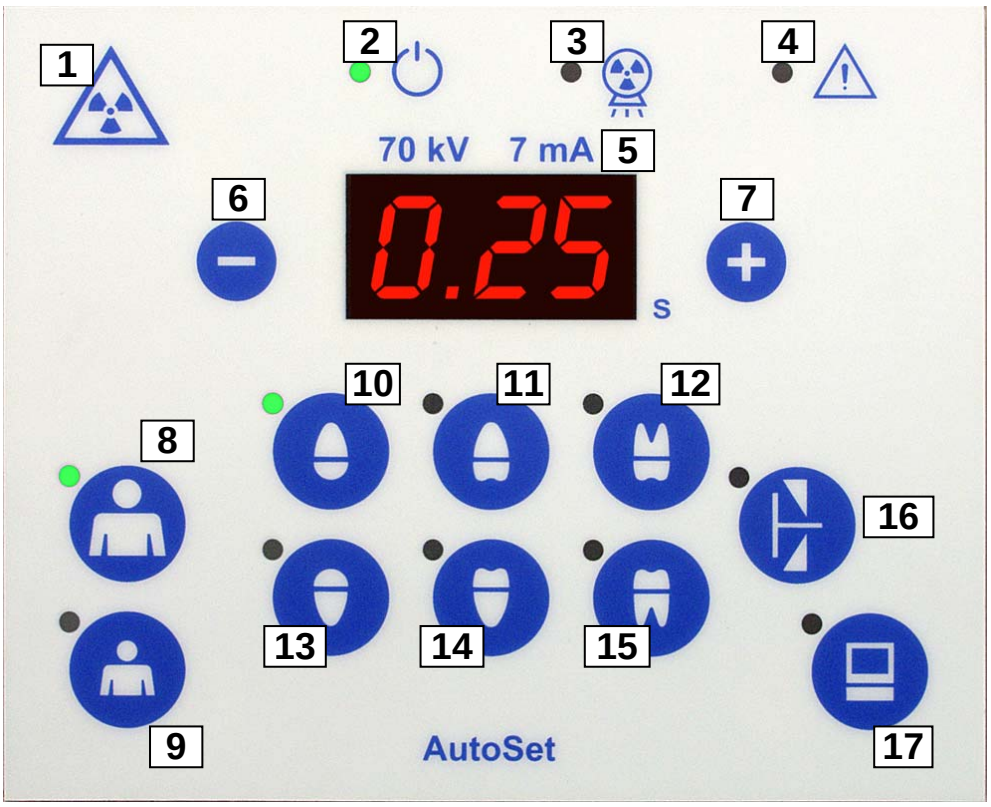
Control panel and exposure pushbutton



1	Device for emission of ionizing radiation on request
2	Indication of system turned on and ready
3	Irradiation
4	Alarm
5	mAs display, the controlled technique factor
6	Manual decrease of controlled technique factor
7	Manual increase of controlled technique factor
8	Patient size adult/large
9	Patient size child/small
10	Maxillary incisor
11	Maxillary canine or premolar
12	Maxillary molar
13	Mandibular incisor
14	Mandibular canine or premolar
15	Mandibular molar
16	Bite-wing premolar
17	Digital detector
18	Radiation exposure pushbutton

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

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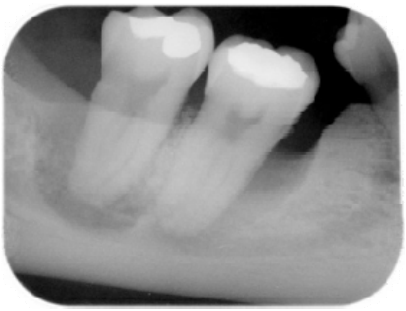


1. INTRODUCTION

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 systems can be configured for wall or mobile solutions.

The available features make the use simple and grant long life with minimum maintenance requirements.

The Operator's Manual and the Service and Installation Manuals supplied with the system are integral part of the product. The original language of the Operator's Manual is English.

1.3 Equipment Classification

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

1.4 Obligations 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.

1.5 Warning

X-ray equipment produce ionising radiation that may be harmful if not properly controlled. It is recommended that the equipment be operated by trained personnel only, in accordance with the existing laws.

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.

1.6 Safety Recommendations

- Electrical.
  - Trained and qualified service 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 disconnect it from line voltage supply (with the room switch) before cleaning or disinfecting the unit.
- Mechanical.
  - Check regularly (at least once a year) the status of supports and arms of the suspension system, in case having necessary maintenance performed by a service technician.
- 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.

2. TECHNICAL DATA

2.1 System Supply

Line Voltage	115 V (from 99 V to 132 V in sub-ranges depending on THA mounted) 230 V (from 198 V to 264 V in sub-ranges depending on THA mounted)
Line Voltage Working Range	Limited to the working range of the THA: 108 - 132 V for 93 202 01300 207 - 253 V for 93 202 01700
Line Fuse	Slow Blow: 6.3 A at 115 V, 4 A at 230 V, second fuse to be activated in case of two phases supply or mobile unit
Line Frequency	50/60 Hz ± 2 Hz
Line resistance	≤ 0.4 Ohm at 115 V, ≤ 0.8 Ohm at 230 V

2.2 Tube Housing Assemblies

Nominal Line Voltage	120 V for type 93 202 01300 230 V for type 93 202 01700
Nominal Line Current	6 A at 120 V for type 93 202 01300 4 A at 230 V for type 93 202 01700
Line Voltage Working Range	120 V ± 10% for type 93 202 01300, 230 V ± 10% for type 93 202 01700
Anode Voltage (peak tube potential)	70 kVp ± 8% at nominal line voltage 66 kVp ± 8% at nominal line voltage – 10% 74 kVp ± 8% at nominal line voltage+ 10%
Anode Current (tube current)	7.0 mA ± 15% at at nominal line voltage 5.3 mA ± 15% at nominal line voltage – 10% 8.3 mA ± 15% at nominal line voltage + 10%
Maximum Load	70 kVp, 7 mA, 3.2 s
X-ray Insert	3 electrodes, grid control action models: OCX/70-G, RFG070
Anode Material	Tungsten
Anode Angle	19° to the tube axis
Focal Spot	0.8 (EN 60336:1995-04)
Inherent Filtration	> 2.5 mm Al
Duty Cycle	1/30
Radiation Leakage	< 0.1 mGy/h a 1 m (< 11.5 mR/h a 1 m)

2.3 Beam Limiting Device

Round BLD	Metal cone with near-focus section
	Focus skin distance (FSD) 8.27"(21 cm)
	Circular radiation field size 2.35" diameter (6 cm)

Rectangular BLD	Metal body with near-focus section
	Focus skin distance (FSD) 8.27"(21 cm)
	Rectangular radiation field size 1.26"x1.65" (3.2x4.2 cm)

2.4 AutoSet Timer

Supply Voltage	115 V ± 15% for type 93 300 60200 230 V ± 15% for type 93 300 60100					
Exposure factor	Exposure time in s, 18 steps from 0.06 s to 3.2 s (R10 scale)					
	0.06	0.12	0.25	0.50	1.00	2.00
	0.08	0.16	0.32	0.64	1.25	2.50
	0.10	0.20	0.40	0.80	1.60	3.20
	Time in seconds is converted to number of mains pulses with 1 pulse precision (20 ms at 50 Hz, 16.6 ms at 60 Hz.					
Precision	± 0.02 s or 5% (whichever the greater)					
Exposure factor setting	Automatic setting through tooth type selection and patient size, for use with traditional film or digital sensor, or manual setting moving up or down the scale with plus and minus keys.					
Irradiation signal	Yellow light on hand-switch and on control panel plus acoustic buzzer					
Hand-switch	Hand-switch with 3 m coiled cord, with remote mounting optional kit					
Overall size	6" (15 cm) width, 9"½ (24 cm) height, 3"½ (9 cm) depth					
Other features	Microprocessor controlled functionality Traditional film speed setting Digital sensor speed setting Zero-crossing power switching 3 s minimum waiting time Energy management for cool down time Optional kit with 33 ft (10 m) cable for remote mounting					

2.5 Mechanical Suspension System

Wall Support	4.72" (12 cm) width, 9.45" (24cm) height, 3.54" (9 cm depth)
Extension Arm Length	Short: 11.8" (30 cm), medium:23.6" (60 cm), long: 31.5" (80cm),
Folding Arm Useful Reach	54.3" (138 cm) with short extension arm 66.1" (168 cm) with medium extension arm 74" (188 cm) with long extension arm
Mobile Stand	29" (74 cm) width, 24"½ (62 cm) depth 42" (107 cm) height, 65" (165 cm) total height with folding arm

2.6 Weights

Timer	3.7 lb (1.7 kg)
Tube-Head	14.5 lb (6.6 kg)
Round BLD	0.22 lb (0.1 kg)
Rectangular BLD	0.44 lb (0.2 kg)
Folding Arm	25.8 lb (11.7 kg)
Short Extension	6.2 lb (2.8 kg)
Medium Ext.	8.8 lb (4.0 kg)
Long Ext.	10.6 lb (4.8 kg)
Wall Support	2.9 lb (1.3 kg)
Mobile Stand	64.8 lb (29.4 kg)

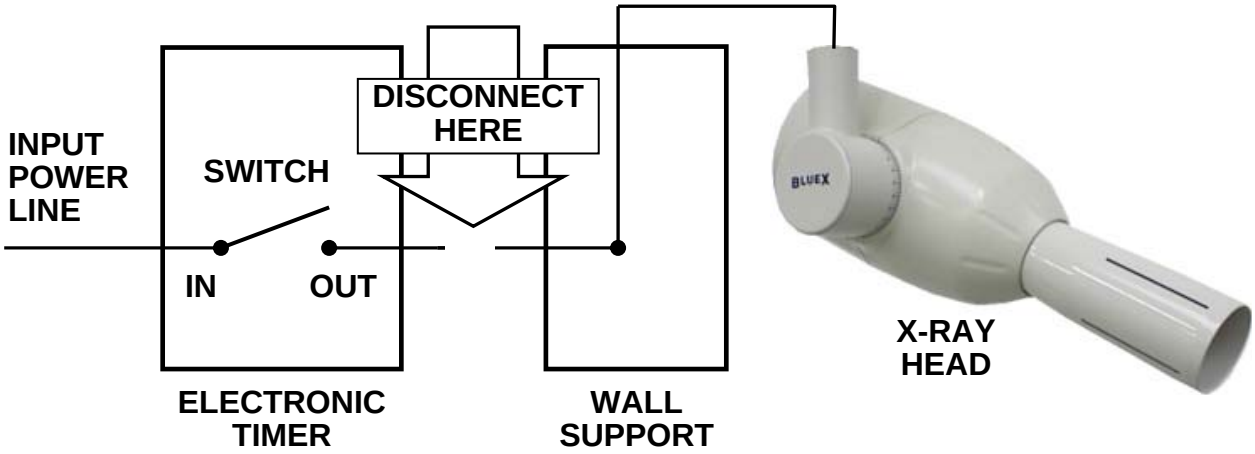
3. OPERATING INSTRUCTION

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.

This task 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 rectangular BLD is available as an option.

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 user is recommended to bring the rim of the collimator in touch with the film holder or with the face of the patient to reduce possible blurring due to some movement during irradiation.

3.3 The AutoSet Control Panel

The control panel (see picture at page 2) allows for setting the exposure time in s through selection of type of tooth and size of patient plus, in case, indication of use of digital detector.

At bottom, on the left the keys for selection of patient size, in the middle those for tooth type, incisor, canine or premolar, and molar, for maxillary or mandibular areas, on the right the selection of bite-wing in premolar area and lower the key for selection of digital receptor as alternative to the film.

The display in the middle indicates the exposure time in s as applicable to the selected conditions and the plus or minus keys can be used to change such a value when desired (manual mode).

At top the green light of system ready, the yellow one indicating irradiation and the red one for alarm condition.

3.4 User Functionality of the AutoSet Timer

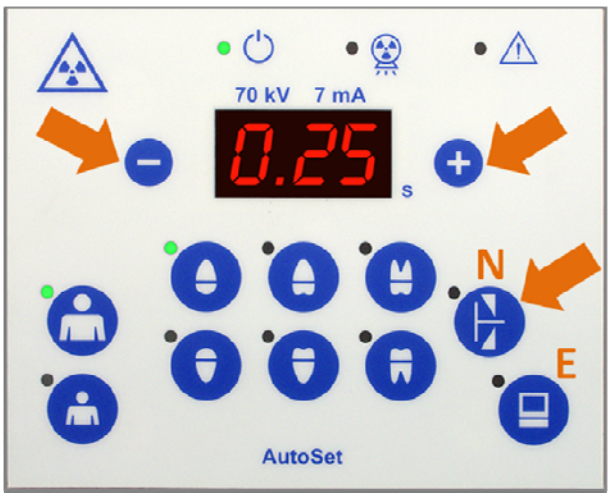
Before using the timer make sure that the proper film speed indication and length of the beam limiting device have been properly set into the memory of the timer.

FILM SPEED INDEX								
0.32	0.40	0.50	0.64	0.80	1.00	1.25	1.60	2.00
		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 control radiation dose changes due to sudden and strong fluctuations of the line voltage supply for a 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 here reported.

- 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 mode is 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 (E) input mode (back to normal operation) or the ♪ key to pass to next (N) 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 (E) input mode (back to normal operation) or the ♪ key to pass to next (N) selection.
- Actual Exposure Time. The message on the display, either "on" or "OFF", tells whether the actual corrected time in s or the selected one will be displayed. Press the ⊕ or ⊖ keys to change the value. Press the ▭ key to exit (E) input mode (back to normal operation) or the ♪ key (E) to go back to first selection.

3.5 Use of the AutoSet Timer

To operate the systems turn the timer "ON" with the switch 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 ligths 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 (maxillary) or lower (mandibular) incisor
- Upper (maxillary) or lower (mandibular) canine /premolar
- Upper (maxillary) or lower (mandibular) molar
- Inter-proximal bite-wing on molar/premolar

In case of use of 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					
0.06	0.12	0.25	0.50	1.00	2.00
0.08	0.16	0.32	0.64	1.25	2.50
0.10	0.20	0.40	0.80	1.60	3.20

Each step changes the radiation energy of a visible level 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 is over the nominal voltage level) or longer (when the line voltage is below it). This function is thus granting blackening consistency even in presence of mains voltage fluctuations (less retakes).

During the exposure the yellow lights of X-ray On, on the control panel and on the hand-switch, light and the internal buzzer sounds to indicate radiation emission.

As additional safety feature the timer is provided of an independent back-up device 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. A minimum waiting time of 3 s is implemented.

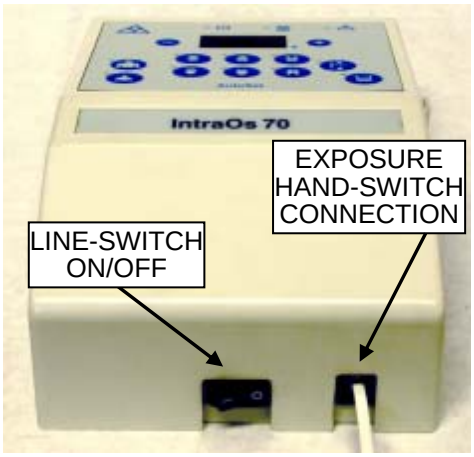
During the cool-down time the digits of the selected time on the display keep flashing and operation of the system is inhibited. Once cooled down the digits on the display become steady and the system is ready again.

3.6 Moving the mobile unit

The folding arm has to be closed in parking position every time the mobile unit is relocated from one place to another one.

3.7 Operation

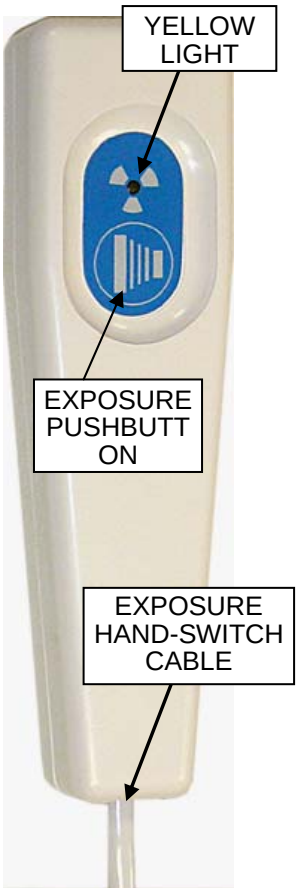
1 Turn on the line voltage supply with the switch below the timer



2 Position the image receptor where needed and orientate the BLD accordingly. Operate with the rim of the collimator in touch with the film holder or with the face of the patient

3 Select the desired time-current product (exposure factor) with keys for patient size, type of tooth and type of receptor, or set values manually moving up or down the scale.

4 Take the exposure hand-switch and move to a convenient position of at least 2 m far from the patient.



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 and the buzzer are switched OFF to indicate the end of the exposure.

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

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.

3.8 Functional Check

After installation the following check is recommended.

- Switch-on line voltage supply switch (below the unit) and check that the green light ⏻ 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 (refer to the Service & Installation Manual):
  - 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.

3.9 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 liquids enter into the equipment.

Plastic covers can be wiped with a soft cloth and light detergent. Avoid the use solvents or corrosive detergents.

3.10 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.

3.11 Maintenance

Maintenance for the IntraOs 70 systems to be done regularly by a service technician at least once every 24 months, in addition to regular checks performed by the operator every year.

4. DISPOSING OF OBSOLETE EQUIPMENT

A radiological 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 tank of the X-ray tube.

The "crossed-out wheeled bin" symbol on the product indicates that the product at the end of its useful life must not be disposed of as unsorted municipal waste but has to be collected separately and delivered to specialized operators for recycling or disposal of waste of electrical and electronic equipment (WEEE), in compliance with existing laws.

By doing in this way possible negative effects on human health and environment are prevented, and recycling of the component materials is promoted.

Penalties are applicable to illicit disposal.

Blue X Imaging and its local Dealers commit to fulfill obligations related to the management of WEEE of professional nature, according to the provisions of the European directives 2002/96/EC and 2003/108/EC.

Appendix A
System Components

IntraOs 70 – Intraoral X-ray System

Article	Type Code
Wall Adaptor	93 100 11000
Support Arm 30 cm	93 150 17100
Support Arm 60 cm	93 150 17200
Support Arm 80 cm	93 150 17300
Scissor Arm	93 150 12010
Tube Head 120 V G120N	93 202 01300
Tube Head 230V G230N	93 202 01700
Round BLD	91 300 00020
Rectangular BLD	91 300 00040
AutoSet Timer 115 VAC	93 300 60200
AutoSet Timer 230 VAC	93 300 60100
Mobile Stand	93 150 20080
Mobile Stand UL/CSA	93 150 20090
Wall Plate 16"	86 100 11500

Appendix B
Icons

	IEC Type B Equipment		Compliance to European Community Requirements
	X-ray On Irradiation		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	N	Neutral Point (for equipment permanent connected to line)
	Upper Molar	L	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

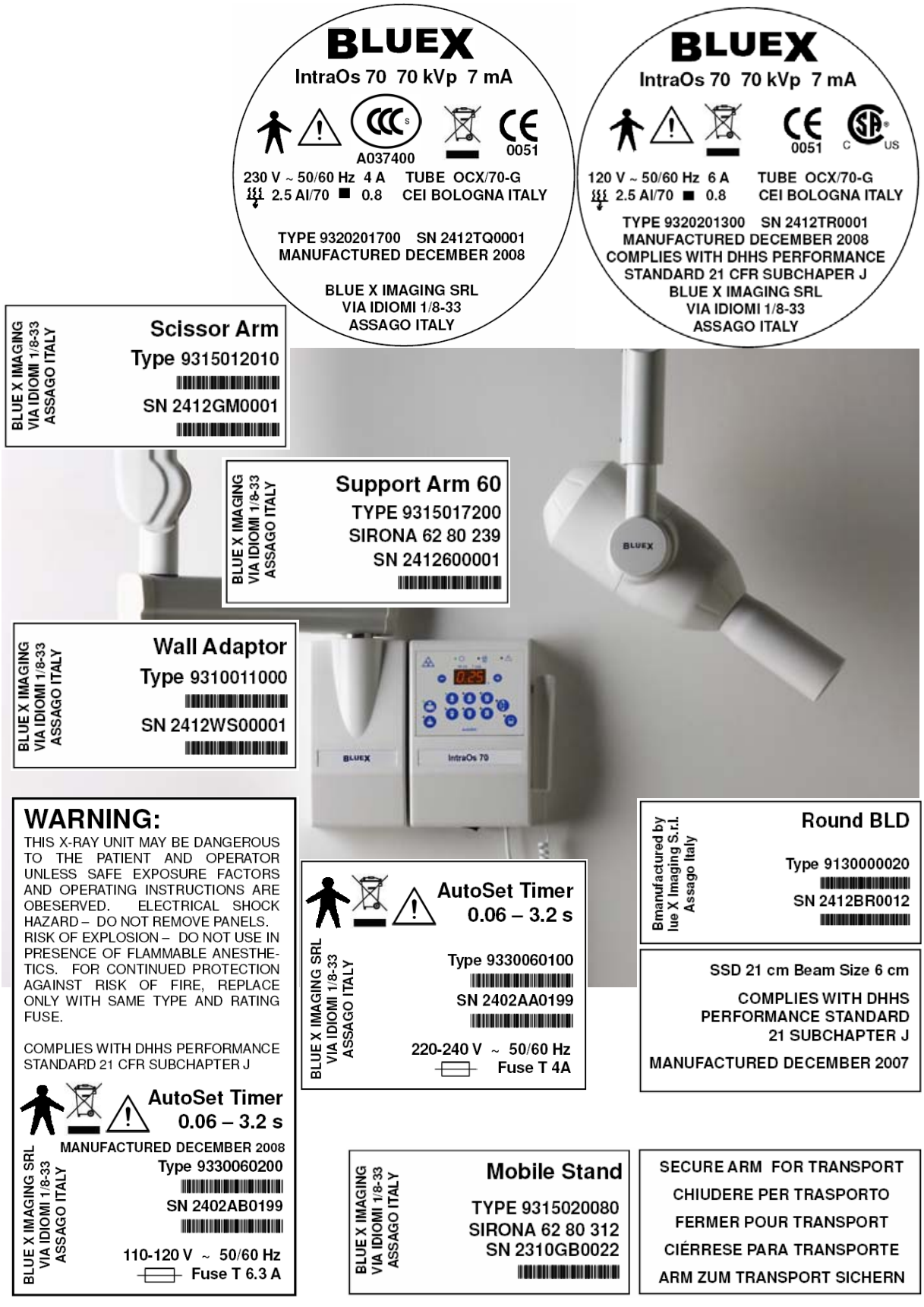
Appendix C
Exposure Table

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

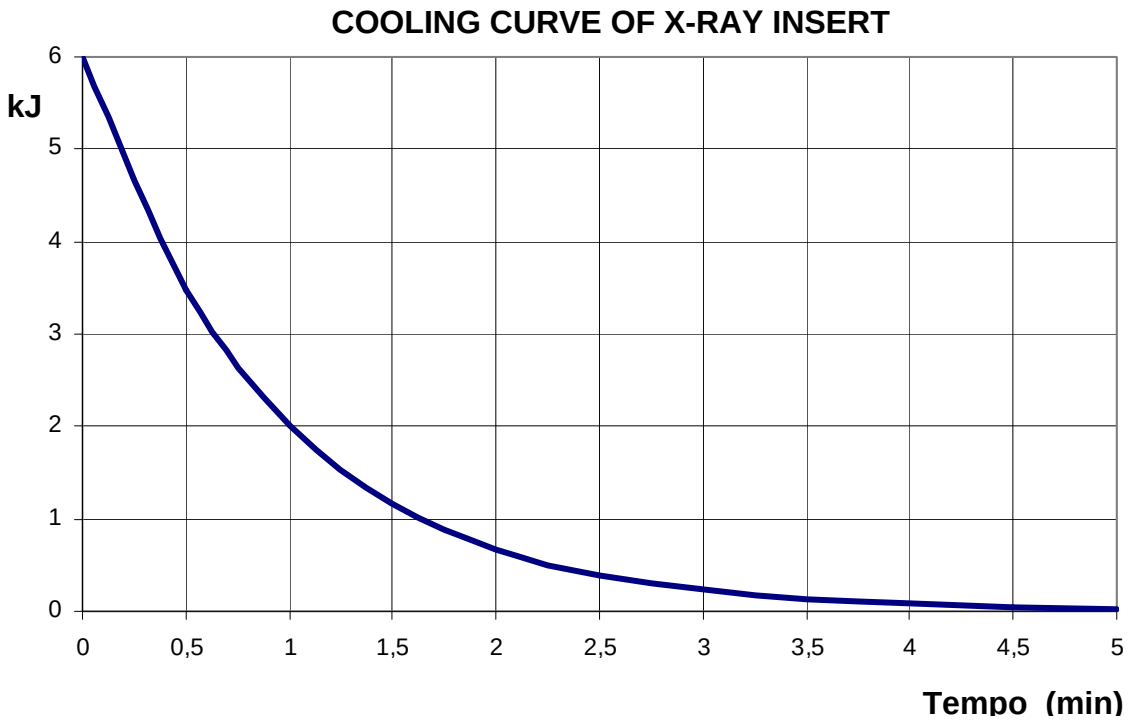
Appendix D
Alarm Conditions

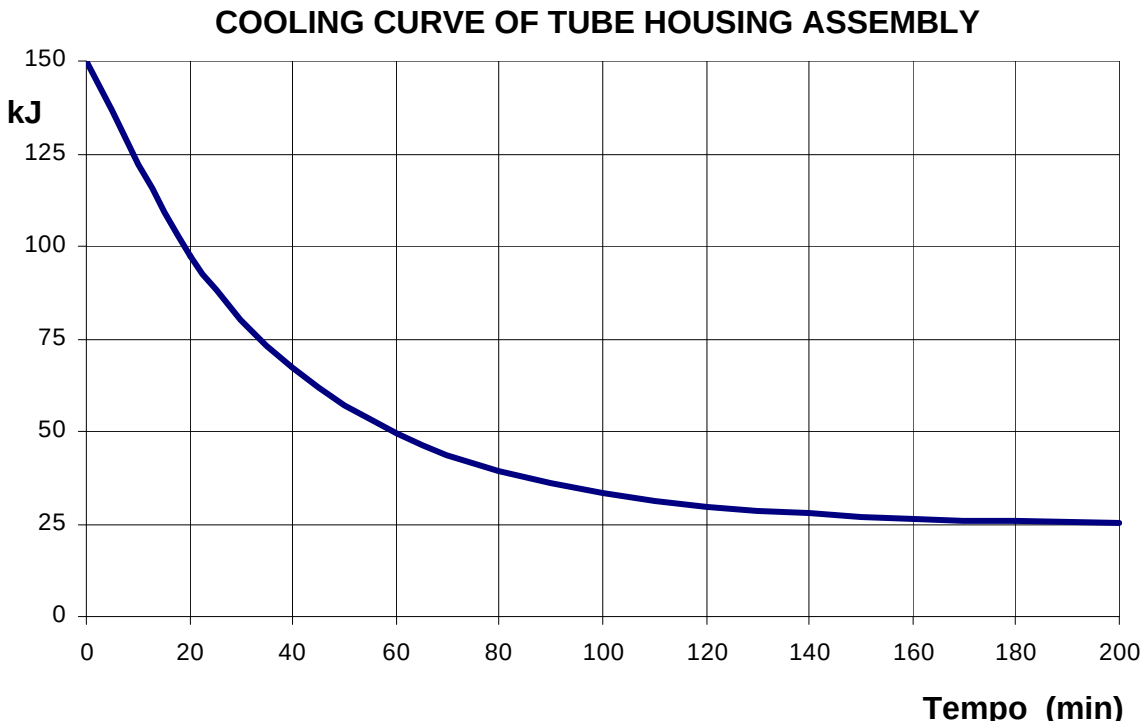
AutoSet Timer Alarm Conditions				
Code	**Fault /Error**	**Signal**	**Action**	**Reset**
A 01	X-ray requested during cool-down period	Green lamp (System Ready) flashing	System inhibited	By acknowledgement on the panel or when system cooled down
A 02	Line voltage below lower limit	Green lamp (System Ready) 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	Computed exposure factor lower than minimum	Green lamp (System Ready) and red lamp (Alarm) flashing	Minumum exposure factor forced	By acknowledgement on the panel
A 05	Corrected exposure factor greater than maximum	Green lamp (System Ready) and red lamp (Alarm) flashing	Maximum exposure factor 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 99	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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