

AZTECH 65

with CCD timer



User's manual

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1. INTRODUCTION

This manual is intended to assist the user in the safe and efficient operation of the equipment described.

The equipment must be used in accordance with the procedures contained in the manual and must not be used for purposes other than those which are described herein.

The equipment should be operated only by qualified personnel having the necessary knowledge of radiation protection.

The user is responsible for complying with the legal requirements regarding the installation and operation of the equipment.

If the equipment is not operated properly or if the user does not maintain the equipment properly, the manufacturer cannot be held responsible for any damage, injury and malfunction.

2. WARNING

- This equipment complies with DHHS performance standard 21 CFR Subchapter J.
- This X ray unit may be dangerous to the patient and operator unless safe exposure factors and operating instructions are observed.
- Electrical shock hazard. Do not remove panels.
- Risk of explosion. Do not use in presence of flammable anesthetics.
- For continued protection against risk of fire, replace only with same type and rating of fuse.

On this manual and on the equipment, the following symbols are used to signal grounding terminals



X-Ray emission command



X-Ray emission signaling



Exposure time step decrement



Exposure time step increment

The scissors arm has been designed to work correctly with a minimum operating angle of 20 degree; therefore the arm has to be used with an aperture angle grater than 20 degree.

3. CLEANING AND DISINFECTING PROCEDURES

MATERIAL REQUIRED FOR STERILIZATION

- 1) Cold sterilization solution :
 - a) water and soap for metal and plastic components
 - b) cleaner and disinfectant (e.g. Birex)
- 2) Cotton wool
- 3) Gloves

PROCEDURE

1. Water or other liquids must not be allowed to enter the equipment because they can cause short circuits and corrosion
2. Gently clean metal and plastic components with water and soap
3. After use on each patient, disinfect collimator nose with a cleaner and disinfectant (e.g. Birex), to fight bacteria and spores

4. SAFETY PRECAUTION

1. Only qualified service personnel are authorized to remove the covers and to access the internal components.
2. This equipment is not designed for use in the presence of explosive gases or vapors such as flammable anesthetics.
3. After using on each patient, disinfect collimator nose with a cleaner and disinfectant (e.g. Birex), to fight bacteria and spores. Metal and Plastic Components have to be cleaned with cloth, water and soap.
4. Water or other liquids must not be allowed to enter the equipment because they can cause short circuits and corrosion.
5. Only qualified service personnel is authorized to remove the diaphragm and the X-Ray tube assembly from their support.
6. Personnel working in the examination room must observe the applicable radiation protection regulations.
7. To protect the patient from X-Ray, radiation protection accessories must be used where necessary, such as standard leaded aprons.
8. No other person other than the patient and the operator must be present in the examination room during the X-Ray exposures.
9. The operator during the X-ray emission must not hold or touch the tubehead cover or the collimator cone.
10. The film must be introduced into the patient's mouth manually or by means of special holders; the patient and not the operator must hold the receptor in place if necessary.
11. **For safety purposes, nobody should be allowed to hang down from the extension arm or scissors arm.**

5. DESCRIPTION

Aztech 65

The Aztech 65 X-Ray tubehead generates radiographs of excellent quality, in part due to the fine repeatability of the examinations combined with the very short exposure times and a small focal spot

The following are the features of this equipment:

- radiographs of higher quality
- easy to use
- ergonomic design

The system is microprocessor controlled enabling a high repeatability of exposure time and is composed by the following parts:

- a - SCISSORS ARM ASSEMBLY**
- b - TUBEHEAD WITH COLLIMATOR**
- c - CCD TIMER**

SCISSORS ARM ASSEMBLY

This is an arm with double joint enabling linear and upward extension. The Tubehead remains balanced in all positions. A horizontal arm extension can be added (12, 29 1/2 and 35 1/2 inches) to facilitate different tubehead/arm reach.

TUBEHEAD

The TUBEHEAD with its 65 kVp and 8 mA reduce exposure time; therefore less x-rays are absorbed by patients. The X-Ray Head is fitted with a collimator with 8" (20 cm) min. focus to skin distance and 6 cm (2 3/8") beam diameter. The Tubehead is connected to the arm by a sliding contact enabling 360 degrees rotation horizontally and 160 degrees vertically.

CCD TIMER

The CCD is a microprocessor controlled digital timer, with manual time selection. There are 31 possibilities for time selection, starting from 0.03 sec minimum up to 3 seconds.

The most important feature is automatic time compensation in regard to input line voltage variations within a range of voltage changes from -10% to +10%. The CCD uses a sophisticated algorithm to compensate the line voltage fluctuations in order to obtain a constant contrast; thereby, the name Computer Controlled Density or CCD.

The CCD can be used for the following nominal voltage: 120 V

5.1. Standard configuration

AZTECH 65 has been designed in a standard configuration having the following features:

Tubehead
Wall plate complete with timer with CCD microprocessor
Control box with external spiral cable
Scissors arm
Extension arm of 90 cm
16" on center wall plate mounting

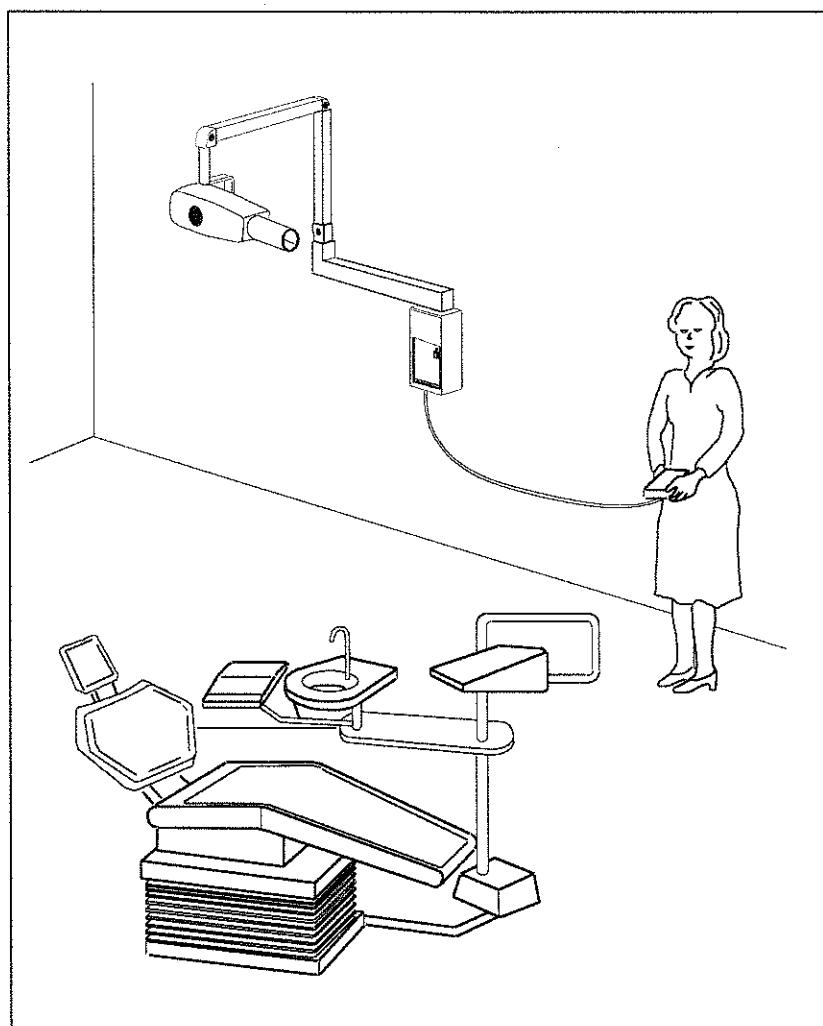


Figure 1

Optional Configuration

A remote-control configuration, with a structure similar to the standard one, but which offers the possibility of operating the remote hand control outside the work room, is also available. A special kit is available to enable this type of installation. This kit contains a special wire harness. The picture herein after features an example of this kind of installation.

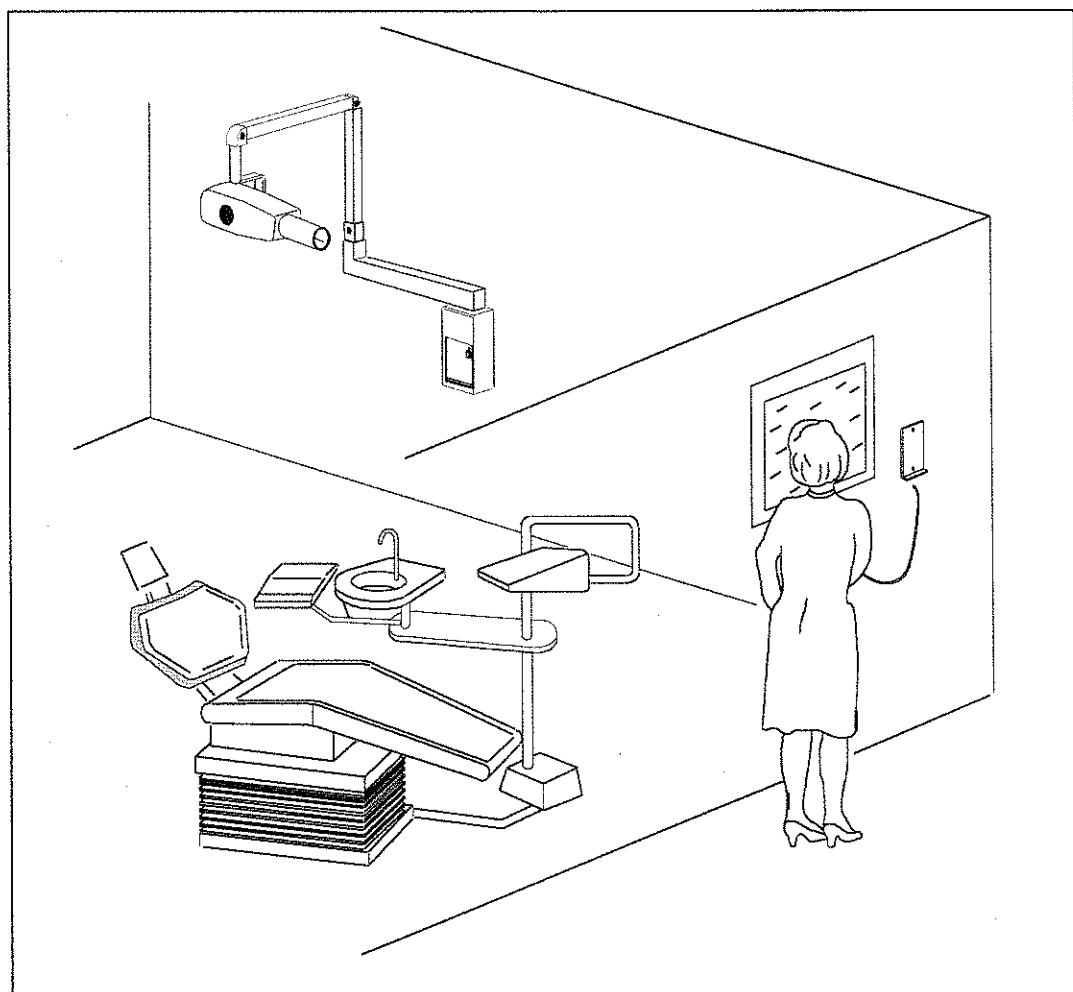


Figure 2

6. TECHNICAL DATA

APPARATUS	AZTECH 65
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MILAN) ITALY
Class	I type B
Rated Line Voltage	120 V \pm 10 %
Line Frequency	60 Hz
Line Current	6 A (120 V)
Power Consumption	0.8 kVA
Apparent Line Resistance	0.2 Ω max. 120 V
Line Voltage Regulation	\leq 3 %
Main fuse	10 A F (120 V)
Exposures Times	31 exposure times, with manual selection, from 0.03 s to 3 s
Control Exposures	Microprocessor controlled Timer, with automatic compensation of line voltage fluctuation
TIMER ACCURACY on the PRE-SELECTED EXPOSURE TIME (This is the value of the timer setting the operator pre-selects which is displayed prior to exposure)	The absolute maximum deviations can be +180% -100% when line voltage changes within rated voltage range (see note below). Inaccuracy is +/- 5% or 30ms (whichever is greater) at 120V At different voltages within the rated voltage range this inaccuracy has to be added to the deviations due to line voltage changes. (see note below)
TIMER ACCURACY on the CORRECTED EXPOSURE TIME (This is the <u>actual</u> time of exposure, displayed on the CCD timer during emission, and indicated as long as the emission button is depressed)	+/- 5% or 30ms (whichever is greater) on the corrected actual exposure time as determined by the internal algorithm as a function of the line voltage (see note below)
Timer box dimensions	310 x 170 x 100 mm (12 x 14 x 4 inches)
Remote Hand Control Dimensions	175 x 60 x 25 mm (7 x 2.5 x 1 inches)

TUBEHEAD

Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MILAN) Italy
Rated Output Voltage	65 kV _p \pm 15%
High Voltage Circuit	Single-phase, self rectifying
Rated Output Current	8 mA
Rated Power	0.8 kW
Total Filtration	2 mm Al eq.
Transformer Insulation	Oil bath
Cooling	Environmental
Minimum focal spot to skin distance	20 cm (7 7/8")
X ray beam diameter	6 cm (2 3/8")
Radiation leakage at 1 m	< 50 mR/h
Technique factors for radiation leakage	65 kV, 8 mA, 1 s
Maximum deviation of output current	\pm 2 mA

Exposure interval	duty cycle 1/60
X-RAY TUBE	
Manufacturer	CEI - Bologna, Italy
Type	OCX 70 G
Focal spot	0.8 mm (IEC 336)
Inherent Filtration	0.5 mm Al eq.

WARNING

The duty cycle of 1/60 has to be intended as follows:

Exposure time	Interval Time between exposures
from 0.03 to 0.1 second	10 seconds
from 0.12 to 1.00 second	1 minute
from 1.30 to 3.00 second	3 minutes

The interval time between exposures has to be respected in order to assure the proper tubehead life.

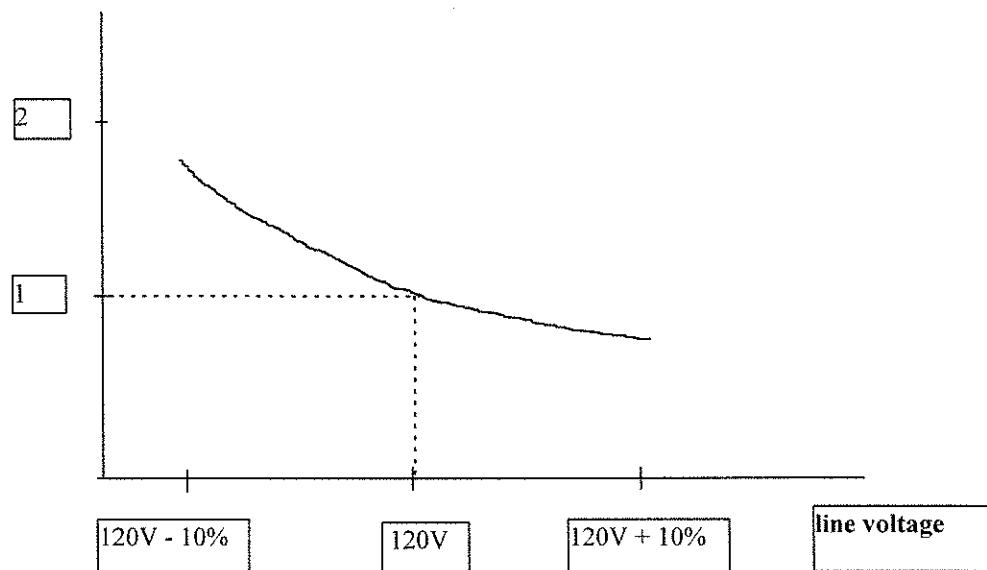
NOTE: Selected Exposure time and 'corrected actual exposure time'. The Aztech 65 CCD timer carries a special feature called Computer Controlled Density which allows to automatically correct the selected exposure time in case the line voltage has drifted from 120V. A change in the line voltage affects the peak voltage applied to the X-Ray tube and the value of high voltage affects significantly the spectrum of the radiation, which finally affects the optical density of the image on the film. Purpose of the Computer Controlled Density correction is to provide basically the same optical density on the film in front of any variation of the line voltage, within the standard accepted limits of rated voltage (120V +/- 10%). This feature allows the user to get basically the same quality of the image without caring about possible variations of the line voltage, which are quite common in many areas, and very difficult to monitor.

The automatic correction of the exposure time works with the following sequence: the internal voltmeter of the CCD timer monitors continuously the line voltage while the user selects the desired exposure time. Once the user has selected the exposure time that is thought adequate to obtain the proper quality of the image for that specific test, the user presses the X-Ray button and the CCD timer displays the corrected actual exposure time that has been determined by the CCD timer itself, on the basis of the line voltage measured just prior to press the Xray button, and that shall be used for that specific test.

The corrected exposure time is the actual exposure time used by the device; it is calculated applying a correction factor to the selected exposure time, based on an empirical law that correlates the optical density of the film with the high voltage peak and consequently with the line voltage.

The qualitative relationship between the multiplying factor and the line voltage is shown in the following picture

Multiplying factor of selected exposure time



The Following table allows to establish real exposure times as a function of preselected times and line voltage:

line voltage	108V		112V		116V		124V		128V		132V	
	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to electronic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to electronic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to electronic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to electronic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to electronic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to electronic inaccuracy
line voltage correction factor:	1,75		1,45		1,24		0,89		0,79		0,7	
preselected time (ms)												
30	53	83	44	74	37	67	27	57	24	54	21	51
		23		0		0		0		0		0
60	105	135	87	117	74	104	53	83	47	77	42	72
		75		57		44		23		17		0
100	175	205	145	175	124	154	89	119	79	109	70	100
		145		115		94		59		49		40
200	350	380	290	320	248	278	178	208	158	188	140	170
		320		260		218		148		128		110
400	700	735	580	610	496	526	356	386	316	346	280	310
		665		550		466		326		286		250
800	1400	1470	1160	1218	992	1042	712	748	632	664	560	590
		1330		1102		942		676		600		530
1000	1750	1838	1450	1523	1240	1302	890	935	790	830	700	735
		1663		1378		1178		846		751		665
1200	2100	2205	1740	1827	1488	1562	1068	1121	948	995	840	882
		1995		1653		1414		1015		901		798
1500	2625	2756	2175	2284	1860	1953	1335	1402	1185	1244	1050	1103
		2494		2066		1767		1268		1126		998
2000	3500	3675	2900	3045	2480	2604	1780	1869	1580	1659	1400	1470
		3325		2755		2356		1691		1501		1330
2500	4375	no exposure	3625	3806	3100	3255	2225	2336	1975	2074	1750	1838
		no exposure		3444		2945		2114		1876		1663
3000	5250	no exposure	4350	no exposure	3720	3906	2670	2804	2370	2489	2100	2205
		no exposure		no exposure		3534		2537		2252		1995

(1) IT IS THE VALUE DISPLAYED BY THE TIMER SO LONG AS THE X-RAY BUTTON IS KEPT PRESSED

no exposure = the timer does not allow exposure times longer than 4 sec

HOW TO ASSESS TECHNICAL FACTORS

kVp The kVp is defined as the stationary high voltage value which settles under load after pre-heating time.
The kV_p are assessed with a non-invasive instrument having a $\pm 2\%$ accuracy, at a nominal input line voltage.
A direct measurement of the high voltage can only be carried out by specialized technicians in a suitable testing laboratory which would require disassembling of the tubehead.

mA The output current is defined as the average value of the stationary current which settles after pre-heating time.
The output current is measured with a digital voltmeter by assessing DC voltage drop on terminals of 1k Ohm resistance (measurement accuracy $\pm 2\%$) mounted on the tubehead. To access the resistance, remove the tubehead plastic covers loosening the four recessed screws. The voltmeter has to be connected in parallel to the resistance (DC, 10V).

t The exposure time is defined as the time measured with non invasive kV_p/t meter. Accuracy is granted by using an RTI PMX II instrument, set with the following parameters:
Parameter :sec
LF.HF :LF
SE/LO : SE
Di :2
CAL: :1
To perform the measurement, the "RAD" probe of the instruments has to be placed at the end of the beam limiting device (Focus to Detector Distance = 20 cm) in a manner to cover completely the sensitive area.

6.1. Tube Characteristics

The following figures are the main characteristics of the X-Ray tube OCX 70 G used on the Aztech 65.

OCX 70 G

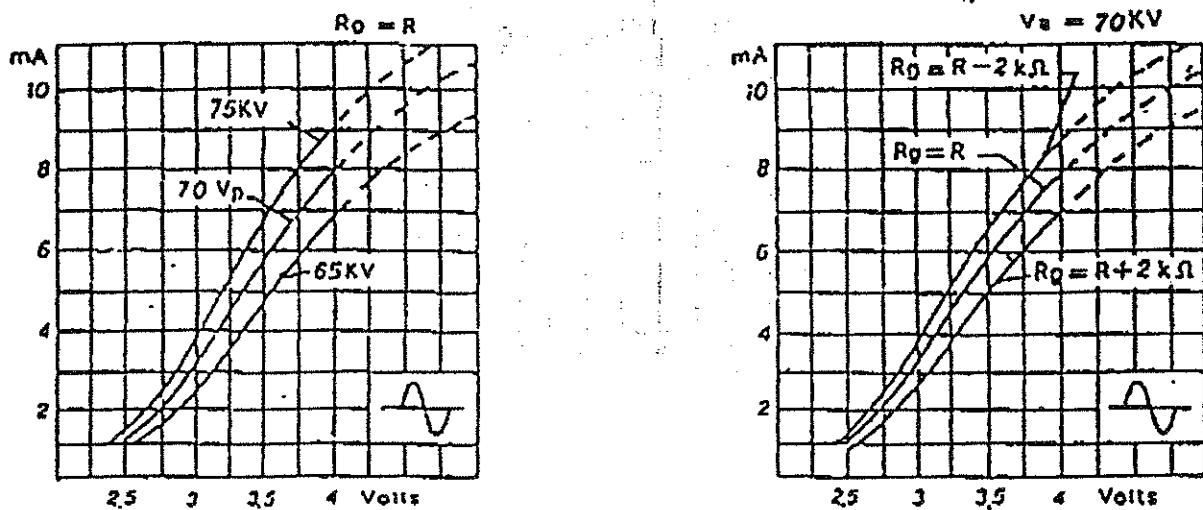


Figure 3 Emission Characteristics

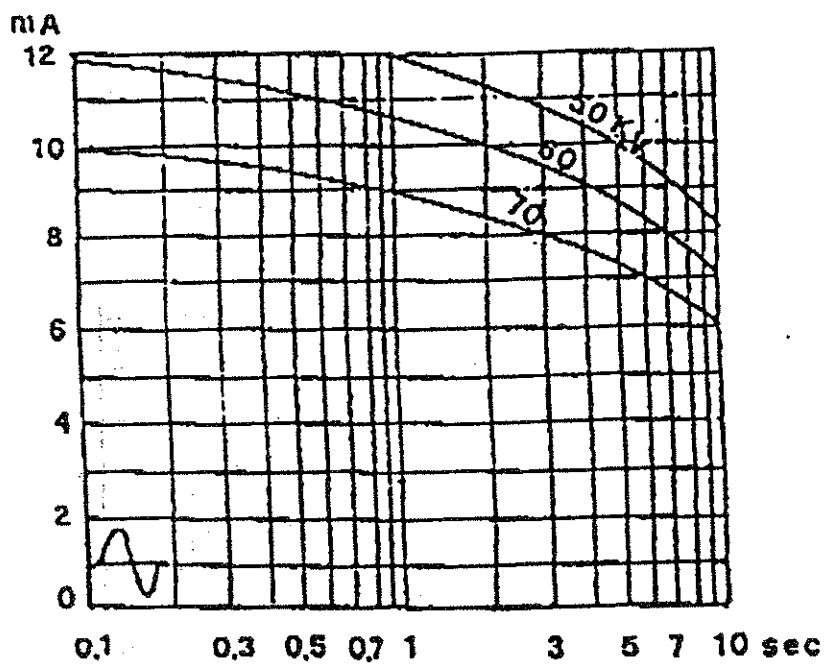


Figure 4 Ratings

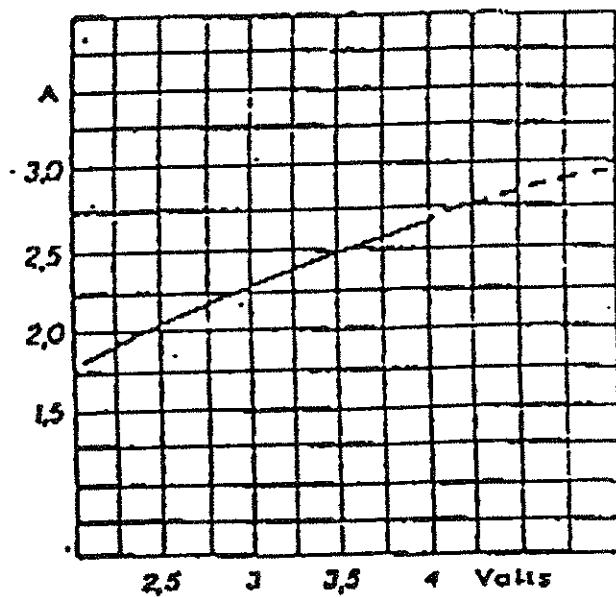


Figure 5 Filament characteristics

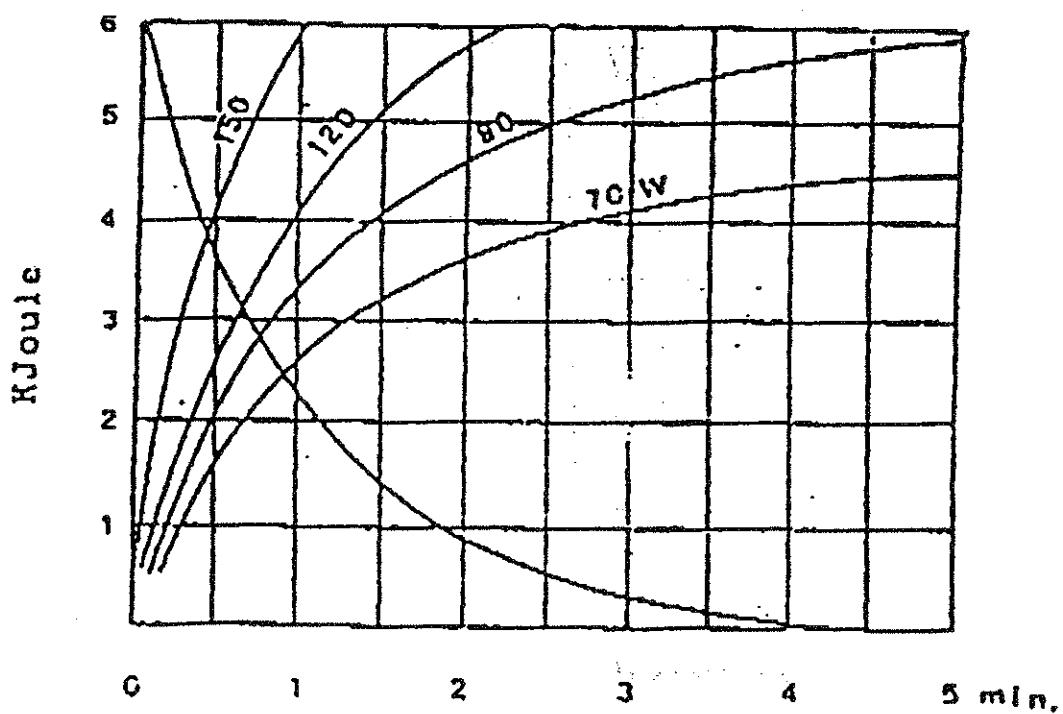


Figure 6.1 TUBE RATING CHARTS AND COOLING CURVES FOR ANODE

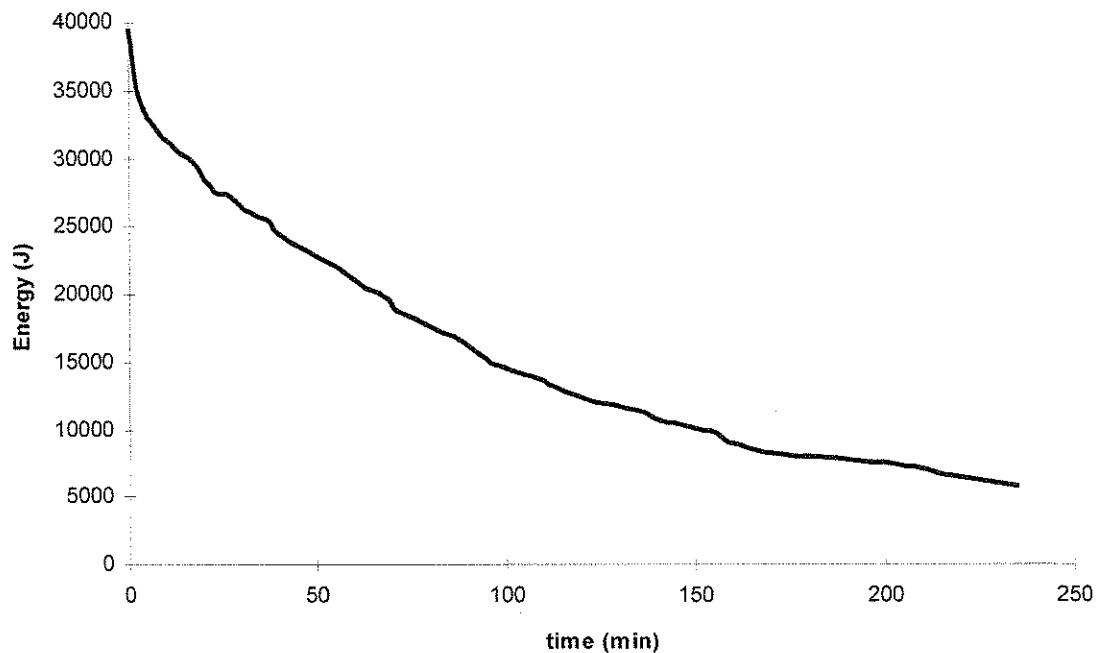


Figure 6.2 COOLING CURVE OF TUBEHEAD

7. OPERATING GENERAL INSTRUCTION

AZTECH 65

With reference to Figure 3 on Page 17

1. Timer Box
2. Hand Control
3. Power Switch

Hand Control

4. Display
5. Button to increase selected exposure times
6. Button to decrease the selected exposure times
7. X-Ray exposure button (Dead man type)
8. X-Ray emission signaling LED

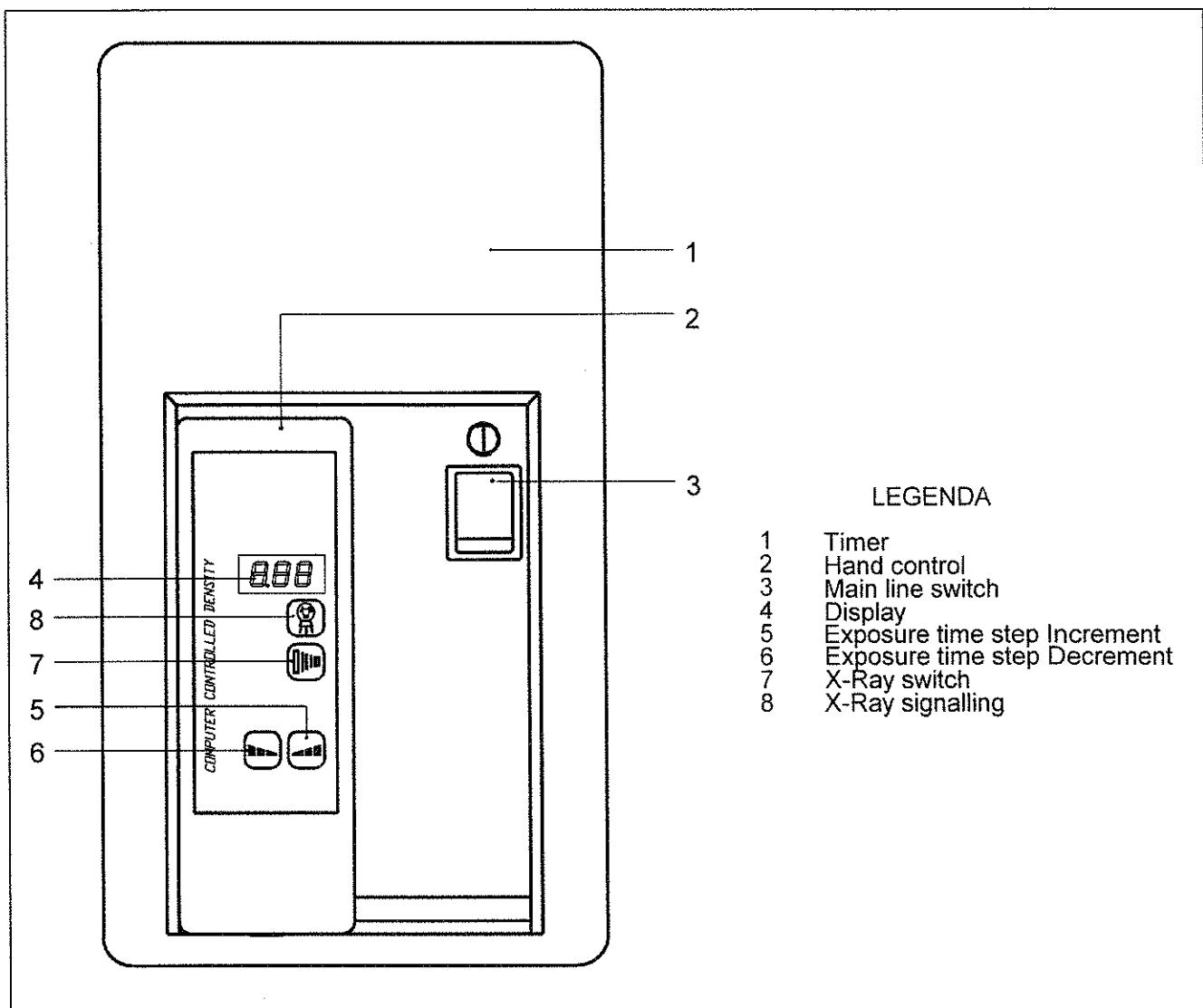


Figure 3 Aztech 65 Timer

7.1. Turning the power on

- a) Depress the start up switch (“3” on Figure 3 on Page 17) placed in the upper front part of the cover; this turn on the self check function indicated by glowing of the remote hand control LED’s showing “888”.
- b) Having accomplished the self check function, the equipment set itself for default to the last exposure time selected during the last exposure.

THE EQUIPMENT IS READY FOR OPERATION

7.2. Exposure time selection

- a) If not already on, depress the start up switch “3” (Figure 3 on Page 17) to power on the timer. When the system is powered, after a short self check the system shows the exposure time selected.
- b) The exposure time will increase by depressing button “5” and decrease by button “6”. By holding one of the two buttons depressed, time settings will increase or decrease very quickly, down or up, to full scale. To increase or decrease time by one step at a time, depress one of the buttons several times; a beep signal will indicate time changing. There are 31 individual times that may be selected, from 0.03 s minimum to 3.00 s maximum (see Table 2 on Page 19). Select an appropriate exposure time according to the film used. Table 1 on Page 19 shows exposure times for Kodak Ultraspeed (“D type”).
- c) The exposure is initiated by depressing and holding the emission button also called the X-Ray switch “7” (Figure 3 on Page 17).
- d) The emission is signaled by acoustic signal on the timer box and by a glowing LED “8” on the hand control.

Type of tooth	Size	Suggested Exposure times
Incisors Canines Upper jaw	A	0.50
	C	0.33
Premolars Upper jaw	A	0.60
	C	0.40
Molars Upper jaw	A	0.80
	C	0.50
Incisors/Canines Lower jaw	A	0.33
	C	0.20
Premolars Lower jaw	A	0.40
	C	0.26
Molars Lower jaw	A	0.60
	C	0.40
Occlusal	A	1.00
	C	0.60
Bite wing	A	0.50
	C	0.33

A = Adult C = Child

Table 1 : Suggested Exposure Times

0.03 - 0.04 - 0.05 - 0.06 - 0.07 - 0.08 - 0.09 - 0.10 - 0.12 - 0.14 - 0.16 - 0.18 - 0.20 - 0.23 - 0.26 -
0.30 - 0.33 - 0.36 - 0.40 - 0.45 - 0.50 - 0.60 - 0.70 - 0.80 - 0.90 - 1.00 - 1.30 - 1.60 - 2.00 - 2.50 -
3.00

Table 2: Exposure Times allowed on the CCD Timer

7.3. PREPARING THE TUBE-HEAD

- a) Arrange Tubehead according to an angle suitable for type of exposure and positioning required (see Figure 4, Figure 5, Figure 6 and Figure 7 from Page 21 and following)
- b) Introduce the film into patient's mouth according to the technique to be used (bisecting or parallel techniques). Please refer to chapter 7.4 on Page 25.
- c) Bring Tubehead Cone to patient and direct exactly to the tooth to be radiographed using the reference lines.
- d) Take the Remote Control handswitch timer assembly ("2" of Figure 3 on Page 17) and walk in the opposite direction to X-Ray emission.

Once exposure has been selected and Tubehead accurately positioned on the patient, depress X-Ray button "7" (Figure 3 on Page 17); X-Ray signaling LED "8" will glow and a sound signal will be heard as long as X-rays are emitted. If X-Ray button is kept depressed, actual exposure time (including line voltage changes during exposure) will be displayed. When this button is released, the Remote Hand Control will return to the last selection made.

WARNING:

X-Ray button "7" is a "Dead-Man" control; therefore, it must be kept depressed throughout the exposure. When released, the action is automatically terminated. In case of excessive line voltage fluctuations which may require the timer selection to be set for 4 seconds or longer, the system will not execute the exposition. When line voltage exceeds the set limits (-10% and +10%) with regard to rated line voltage, "666" and "999" will be displayed, while the first indicates a "low" voltage and the second a "high" voltage conditions.

MANDIBLE



Figure 4

MAXILLA

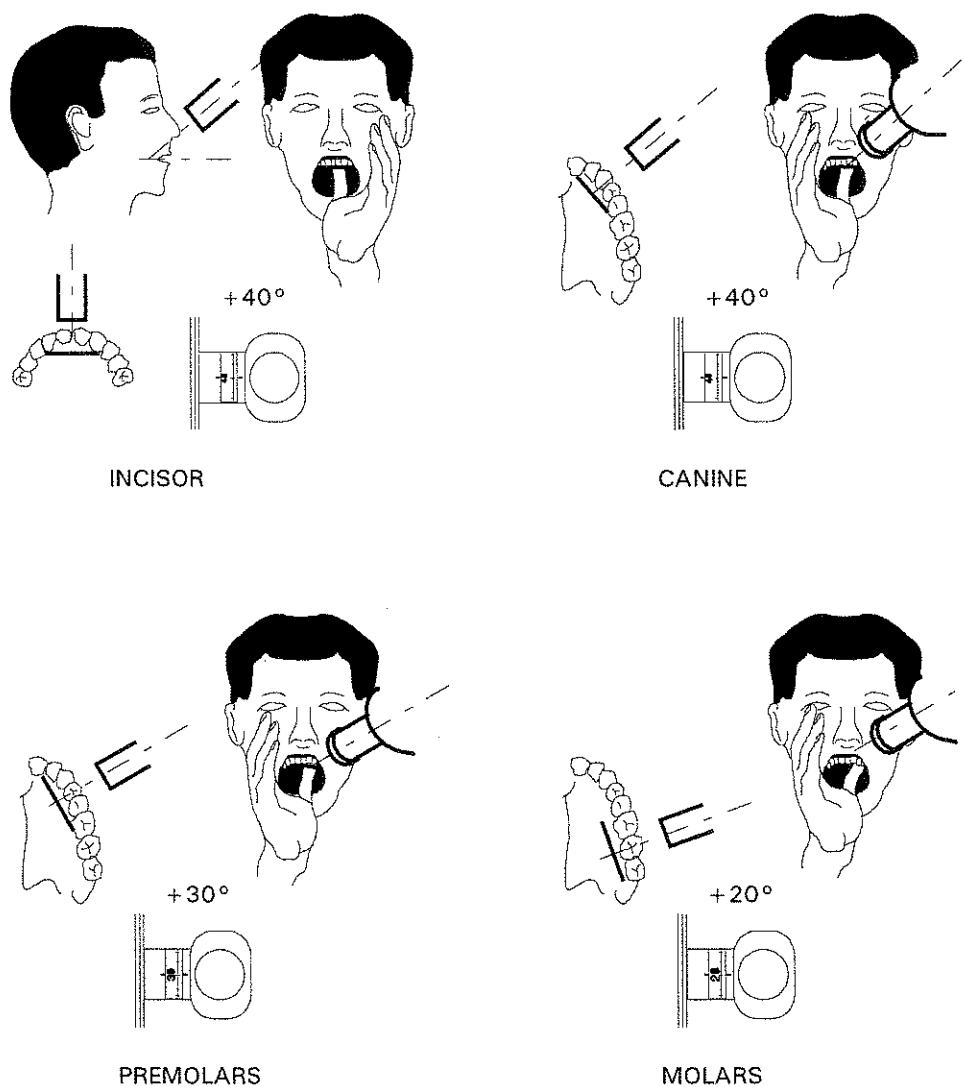


Figure 5

OCCLUSAL

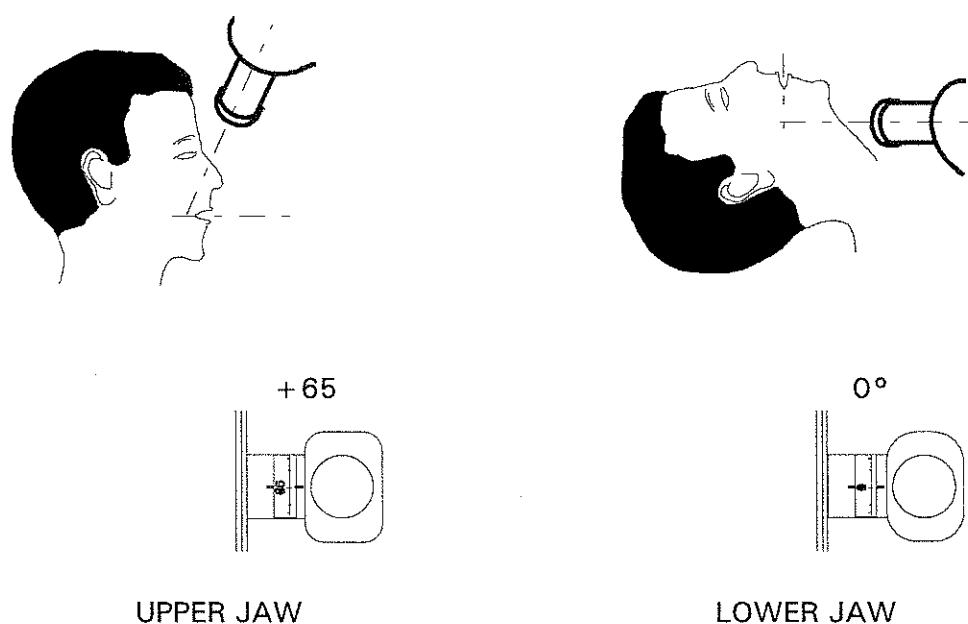


Figure 6

BITE-WING

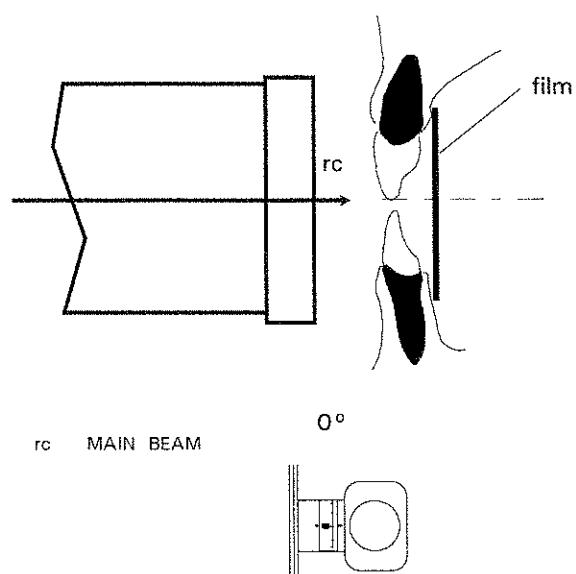


Figure 7

7.4. X-RAY EXPOSURE TECHNIQUE

In this chapter are described the different techniques normally used for intraoral X-rays exposure

7.4.1. Bisecting technique

Main Beam Incidence-Vertical Angle

To obtain a true image of a tooth, the main beam must be perpendicular to the bisecting plane of the angle formed by the longitudinal axis of the tooth and the film.

Once head and film positions have been set, according to this principle, an average vertical incidence can be used for each area. The angle of incidence of the main beam may be properly assessed by means of the graduated scale affixed onto the X-Ray tube assembly.

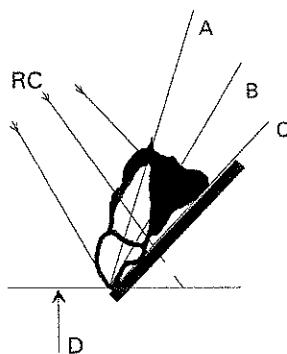


Figure 8

Main Beam Incidence-Horizontal Direction

The main beam must be correctly adjusted horizontally, in particular in an orthoradial direction as regards interproximal spaces. This to prevent structures from overlapping (see Figure 14).

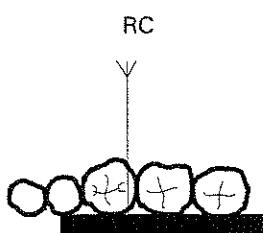


Figure 9

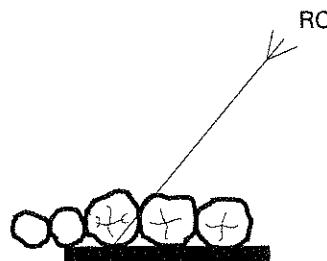


Figure 10

KEY TO FIGURES to Figure 8, Figure 9 and Figure 10

- A - Longitudinal axis of tooth
- B - Bisector
- C - Film plane
- D - Occlusal plane
- RC - Main Beam

7.4.2. Long cone technique

By this technique, the film plane is arranged parallel to the main axis of teeth. Due to anatomic factors, usually the film is positioned away from the lingual surface of teeth, lower molars excepted. The film rests on a support when introduced into the mouth to prevent distortion. The patient holds the support with his/her teeth. A range of supports suiting different types of teeth is available on the market. This technique gives more accurate radiographs and can be repeated more easily than the bisector technique (see Figure 11 and Figure 12).

HORIZONTAL SECTION

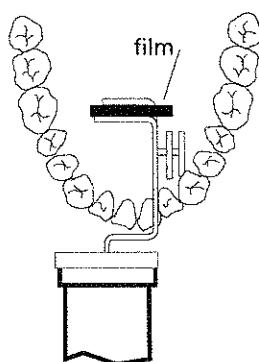


Figure 11

VERTICAL SECTION

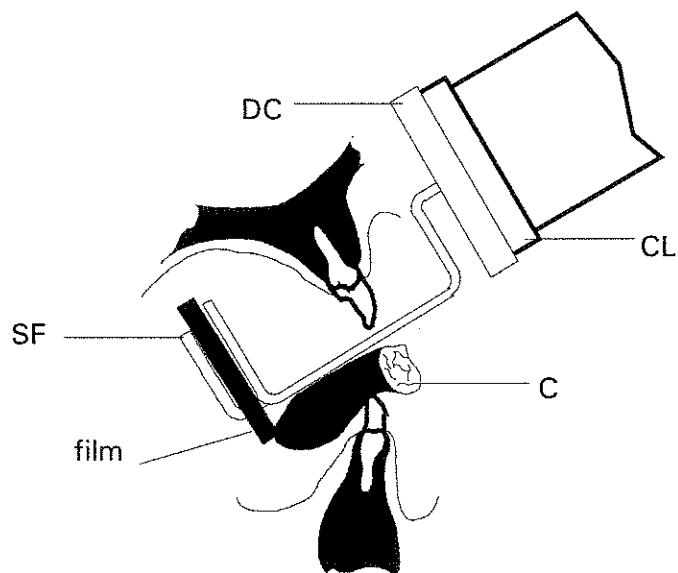


Figure 12

7.5. MAKING EXPOSURE

- a) Grip the remote control and select time setting as described in paragraph 7.2 on Page 16
- b) Get as far as the hand control cable allows it, in the beam emission opposite direction.
- c) Depress the X-Ray button "7" (Fig. 7 page 16) keeping it depressed throughout the exposure.
- d) The exposure start up is indicated both visually with the X-Ray pilot lamp "8" glowing and an audible signal with a sound higher then the standard data modification signal tone.

WARNINGS:

X-Ray button is a "Dead-Man" control. Therefore, as previously described, it must be kept depressed throughout the exposure. If the patient should move during the examination, the button must be released, thereby interrupting the emission.

8. PROTECTION AGAINST RADIATION

NOTE: Radiation protection is generally prescribed or regulated by local, State or Federal regulatory agencies. These regulations are beyond the scope of this manual. Operation and use of the device should be limited to trained personnel.

- a) For X-Ray exposure we suggest the use of Ultraspeed (Kodak) D type films.
- b) The film must be introduced into the patient's mouth manually or by means of special supports. The patient and not the operator must hold it.
- c) During radiation exposure, the operator must not be in contact with Tubehead and Collimator.
- d) During radiation exposure, the operator must keep away from X-Ray source, in a direction opposite to that of emission.
- e) During radiation exposure, no people other than the operator and patient should be present.
- f) To reduce the unwanted effect of secondary radiation on the patient, we suggest using lead aprons.

9. CHECKS AND CORRECTION OF POSSIBLE FAULTS IN DENTAL RADIOGRAPHS (Trouble shooting)

9.1. Typical defects of intra-oral radiology

- **Light radiographs:**

Causes

- Insufficient exposure to X-Ray
- Insufficient development time
- Deteriorated developer
- Developer's temperature below recommended value
- Incorrect developer dilution

- **Dark radiographs:**

Causes

- Excessive exposure to X-Ray
- Excessive development time
- Developer's temperature above recommended value
- Incorrect developer dilution

- **Blurred radiograph (no details visible):**

Causes

- The patient moved
- The tube-head moved

- **Radiographs with Herringbone Marks:**

There are intra-oral films that may be exposed to radiation on one side only. If a film is exposed to X-rays on the wrong side (that facing the X-Ray tube), the lead layer will absorb a large quantity of radiation during exposure. This will result in a light, soft radiographs, the back of the lead sheet will carry herring cone marks which become visible on the film when its underside is exposed to x-rays.

- **Partially Exposed Radiographs:**

Possible causes

- X-Ray directed off films mid section.
- Low developer level, therefore partial film development.
- Two or more films placed against each other during development

- **Clouded radiographs:**

Possible causes

- Protracted shelf life
- Film accidentally exposed to X-Ray
- Film accidentally exposed to other light sources such as daylight, faulty lamp in the dark room, etc.

- **Radiographs showing a black line:**

This black line appears when the film is excessively folded.

- **Radiographs showing sign of electrostatic electricity**

When a film is compressed too much and the air is dry static electricity may be released discharging in the compression points which therefore exhibit black marks. Other black marks may fan out.

- **Radiographs with chemical spots:**

Developer and fixing liquid spattered onto the film before development and fixing procedure spots on the radiograph:

- Dark, when caused by developer
- Light, when caused by fixing liquid

- **Radiographs with emulsion coming off:**

If a film is kept in a warm water bath too long (e.g. through the night), the emulsion may turn softer and partially come off the film base. After development the film will exhibit scratches.

9.2. Typical defect caused by incorrect positioning

- **Radiographs with Elongated or Shortened Image:**

The main beam is not perpendicular to the bisector of the angle formed by the longitudinal axis of tooth and film.

- **Radiographs with Stretched-out Tip of Teeth:**

Probably caused by excessive film folding inside patient's mouth.

10. MAINTENANCE

As with any electric appliance this equipment not only requires proper operation but also regular maintenance and servicing. These precautions serve to maintain the system in good order and operational reliability

The servicing required consists of visual checks which can be performed directly by the user (see table below) as well as preventive and/or corrective maintenance which has to be performed personnel from your dental dealer.

If components which have a direct or indirect influence on safety or radiation protection are replaced, it is essential that only genuine spare parts be used and the replacement be performed by qualified personnel authorized by the manufacturer

Warning: Before operating, the operator must check that the apparatus does not have any apparent problems. Should irregularities or failures be observed or experienced, the operator should call your dental dealer.

Frequency	Type of checks
Once a year	<ul style="list-style-type: none">• Check that labels on control Console and Tube-head are intact and properly secured.• Check that Tubehead is free from oil residues.• Check that X-Ray control box is not broken or scored• Check for external damage on the apparatus which may prejudice protection against radiation• Check balance of scissors arm• Check that mounting plates are intact and correctly attached• Make sure the remote-control cable shows no signs of breakage or abrasions• Check functionality of dead-man switch• Check integrity of LEDS and mains switch lamp• Check the efficiency of the screw frictioning the horizontal movement ("A" Figure 15, page 24 of Installation Manual)

10.1. MAINTENANCE RECORD

Installation: Date Technician

Maintenance: Date Technician

Cause



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Code

69609172 (Rev. 5 on 18.05.99)