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This manual is the English translation of the Italian original manual version.

1. INTRODUCTION

The intra-oral x-ray equipment Explor-X 70, manufactured by VILLA SISTEMI MEDICALI S.p.A., performs high-quality intra-oral radiographs, ensured by the repeatability of examination combined with reduced exposure times and with the small focal spot.

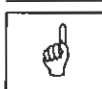
Explor-X 70 is conceived to perform only intra-oral x-ray.

The equipment displays the following features:

- High-quality radiographs
- Easy to use
- Ergonomic design.

The functioning of the system is microprocessor controlled, thus ensuring high repeatability of exposure times, and is composed of the following parts:

- Timer: AP TIME X or TIME X complete with wall plate
- Extension arm (60cm - 23 5/8" oval or 55cm - 21 5/8" square, 75cm - 29 1/2" or 90cm - 35 7/16" for wall version and 30cm - 11 3/4" for ceiling and dental chair version)
- Scissors arm
- 70kV 8mA tubehead.



NOTE:

The extension and scissors arms may be provided in both square and oval versions; a square extension arm can only be combined with a square scissors arm, and the same holds for the oval versions.

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

1.1 Icons appearing in the manual



Indicates a "NOTE"; the utmost attention shall be devoted to the reading of paragraphs marked by this icon.



Indicates a "WARNING"; paragraphs marked with this icon cover patient and/or operator safety aspects

2. SAFETY INFORMATION



WARNING:

Read this chapter very carefully.

VILLA SISTEMI MEDICALI designs and manufactures equipment in compliance with safety requirements; moreover, it provides all the necessary information for correct utilization as well as warnings related to risks associated to x-ray generators.

Villa Sistemi Medicali shall not be responsible for:

- any use of the Explor-X 70 equipment different from that for which it has been designed,
- any damage to the equipment, the operator or the patient caused either by incorrect installation and maintenance not compliant with the procedures contained in the relevant user's and installation manuals provided with the equipment, or by incorrect operation techniques,
- any mechanical and/or electrical changes effected during or after installation, different from those reported in the service manual.

Only qualified service personnel, authorized by VILLA SISTEMI MEDICALI is allowed to perform technical interventions on the equipment.

Only authorized personnel is allowed to remove the tubehead from its support and access the internal components.

2.1 Warnings

The equipment must be used in compliance with the procedures contained in the present manual and shall never be used for purposes different from those envisaged by it.

Before performing any maintenance intervention, the equipment must be disconnected from the input line voltage by means of the relevant magnetic-thermal switch.

Explor-X 70 is a medical imaging equipment and must therefore be used only under the supervision of qualified medical staff, having the necessary knowledge in the field of protection against radiation.

The user bears legal responsibility related to the possession, installation and use of the equipment.

Explor-X 70 is designed for continuous operation with intermittent load; compliance with the envisaged utilization cycles is therefore required.

To protect the patient from x-ray , radiation protection accessories, such as standard leaded aprons, must be used.

Although the equipment has been designed to ensure a satisfactory degree of protection against electromagnetic interference, in compliance with IEC European regulations, the unit must be positioned at an adequate distance from electric power transformation plants, UPS, amateur and cellular telephone transmitters and receivers. The use of cellular telephone communication devices is allowed only at a distance higher than 1.5m (59") from any element of the equipment.

Any other instrument or equipment for professional use placed near the Explor-X 70 must comply with Electromagnetic Compatibility regulations. Non-complying instruments, known to have a low immunity to electromagnetic fields, must be installed at a distance of at least 3m (118") from the Explor-X 70 and must be supplied through a dedicated power line.

Explor-X 70 must be switched off during the use of High Frequency surgical device or similar instruments placed near the equipment.

The equipment has not been designed to be used in the presence of anaesthetic mixtures inflammable with air, oxygen or nitrous oxide.

Parts of the apparatus which may be in contact with the patient must be regularly cleaned following the instructions provided in this manual.

Although the x-ray doses provided by modern equipment are reduced on average, during exposure the operator must take all the necessary precautions and/or protection measures for the patient and for himself, in compliance with existing regulations.

The film must be introduced in the patient's mouth either manually or by means of the relevant holders; it must never be held by the operator, and only the patient may hold it during exposure if required.



WARNING:

For safety purposes, it is forbidden to overload the extension arm and the scissors arm in an anomalous way, e.g. by hanging down from them.

2.2 Environmental risk and disposal

The equipment contains - in some of its parts - solid and liquid substances which must be disposed at the recycling centers appointed by local regulations at the end of the equipment's life cycle.

In particular, the equipment contains the following materials and/or components:

- **Tubehead:** non-biodegradable plastic materials, metal, glass, dielectric oil, lead, tungsten.
- **Other parts of the equipment:** non-biodegradable plastic materials, metal, printed circuits, iron and plastic materials









NOTE:

VILLA SISTEMI MEDICALI is not responsible for eventual disposal of the apparatus or parts thereof and for the related expenses.

2.3 Symbols used

Besides the symbols present on the keyboard (see Chapter 6), in this manual and on the Explor-X 70 the following symbols are used:

Symbol	Description
	Equipment with Type B applied parts
~	AC
N	Connection to neutral conductor
L	Connection to line conductor
	Protection grounding
	Functional grounding
○	OFF ; equipment not connected to power line
	ON ; equipment connected to power line
	Exposure enabling; enabled exposure status is revealed by the glowing of the relevant green symbol.
	Focal spot in compliance with IEC 336
	X-ray emission

3. **CLEANING AND DISINFECTING PROCEDURES**

In order to ensure accurate hygiene and cleaning of the equipment, the following procedures must thoroughly be respected:

- **Before proceeding to equipment cleaning, disconnect it from the input line by means of the general line switch envisaged during the installation phase. Such operation is required because some internal parts of the equipment remain connected to mains voltage even when this has been switched off by means of the on-off button.**
- Water or other liquids must not be allowed to enter the equipment because they can cause short circuits and corrosion.
- Do not use alcohol, petrol or other inflammable, corrosive or abrasive substances for equipment cleaning.

External surfaces

Use a soft cloth and gentle soap, paying attention not to damage painted surfaces.

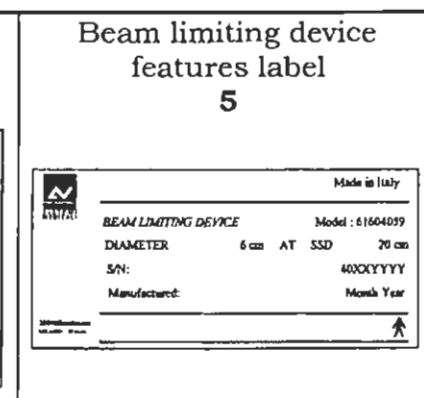
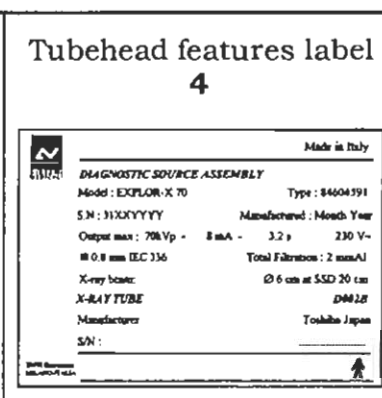
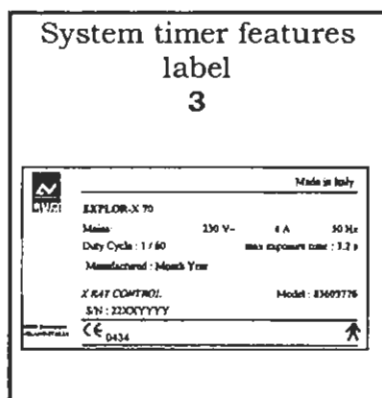
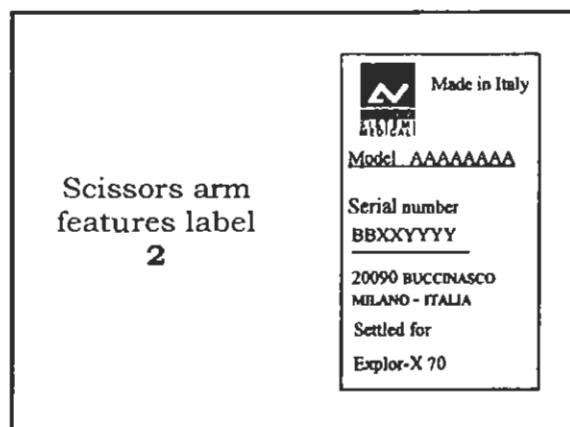
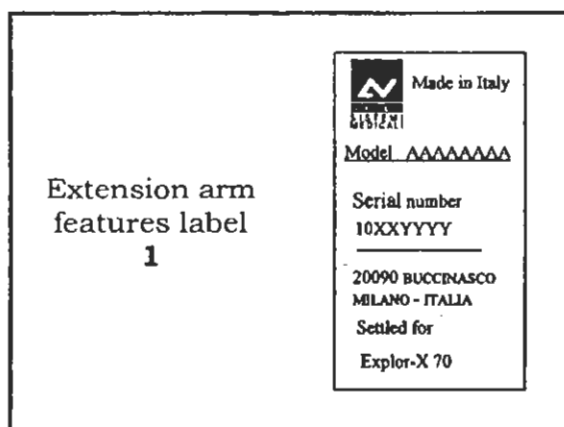
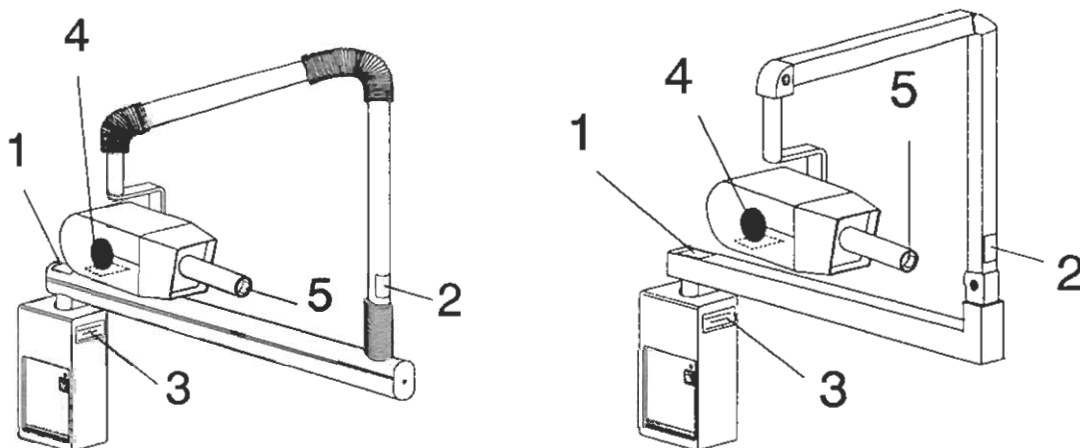
During cleaning operation, prevent any detergent or other liquid from penetrating into the equipment or remaining on painted surfaces.

Parts in contact with the patient's skin

To ensure hygiene of these parts, periodic disinfecting with a disinfectant solution (e.g. 2% solution of Glutharaldehyd, etc.) is recommended.

4. DESCRIPTION

4.1 Identification labels

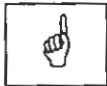


4.2 Functions, Models and Versions

The Explor-X 70 intra-oral x-ray equipment is composed of the following parts:

4.2.1 Extension arm and scissors arm (Square or Oval)

The scissors arm is an arm with double joint, enabling linear and upward extension. The tubehead remains balanced in all positions.

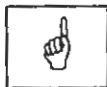


NOTE:

The scissors arm is intended to operate correctly with a minimum angle of 20°; hence, its use requires an opening angle larger than 20°.

A horizontal extension arm must be provided; it is available in different sizes to meet all possible requirements.

Both the extension arm and the scissors arm may be either square or oval.



NOTE:

A square extension arm can only be combined to a square scissors arm. The same holds true for oval arms configurations.

4.2.2 Tubehead

Its 70 kVp voltage and 8 mA current reduce exposure times and the amount of radiation absorbed by the patient. The tubehead is equipped with a collimator with a 20cm (7 7/8") focus to skin distance and a 6cm (2 3/8") beam diameter at the cone output. The tubehead is connected to the arm by means of a sliding contact, allowing 360° horizontal rotation and 290° vertical rotation.

4.2.3 Timer

The Explor-X 70 may be equipped with two different types of Timer:

- **AP TIME X**

AP TIME X is a microprocessor-controlled digital timer allowing both manual and automatic selection of exposure times.

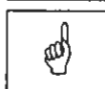
Automatic selection allows to choose among 54 pre-set times according to the type of patient (adult or child), his/her size (small, medium, large) and to the type of tooth.

Fixed times available for manual selection are 32 and may range from 0.04 seconds minimum to 3.20 seconds maximum.

The key feature of this timer is automatic time compensation according to input line voltage variations within a range of $\pm 10\%$ of nominal value.

- **TIME X**

TIME X displays the same features as the AP TIME X Timer, with the exception of automatic and digital anatomic selection. In other words, this timer allows only manual selection of exposure times.



NOTE:

A configuration with remote x-ray switch, outside the examination room, is also available.

The equipment provides two separate contacts for possible connection to external signalling devices. One contact reveals that the equipment is functioning and ready to use, whereas the second reveals x-ray emission. The connection modality and the requirement for signalling devices are provided in the "Service Manual".

4.3 Configurations

4.3.1 Standard configuration

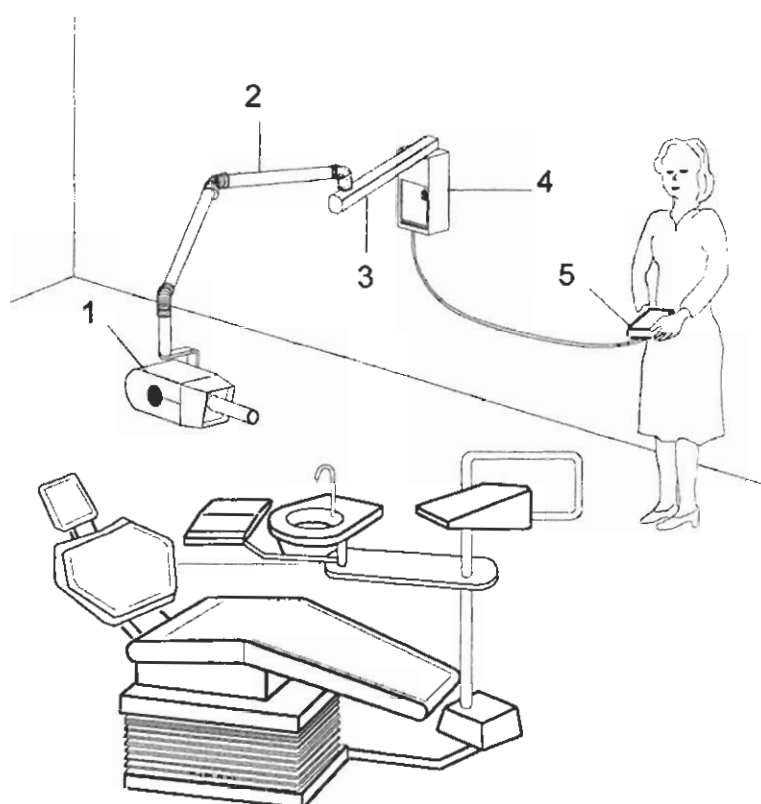


Figure 1

- 1 Tubehead
- 2 Scissors arm
- 3 Extension arm
- 4 Wall plate + Timer
- 5 X-ray button

4.3.2 Remote timer configuration

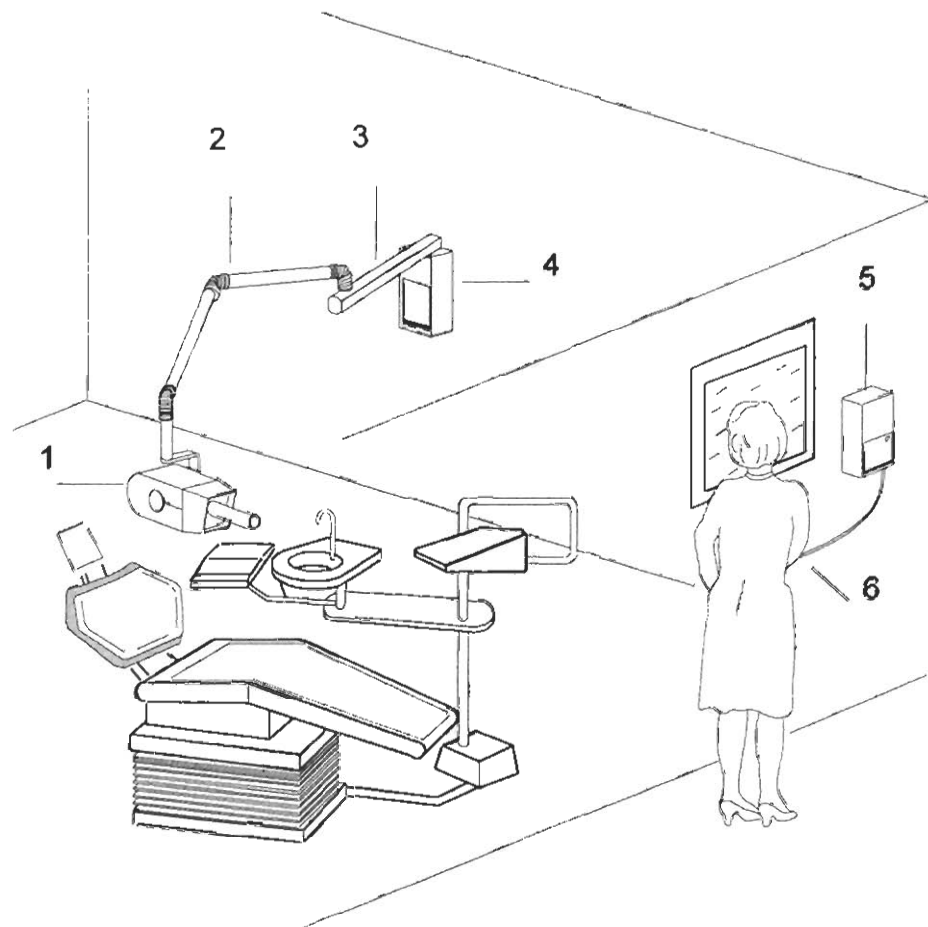


Figure 2

- 1 Tubehead
- 2 Scissors arm
- 3 Extension arm
- 4 Wall plate
- 5 Remote timer
- 6 X-ray button

4.3.3 Dental chair configuration

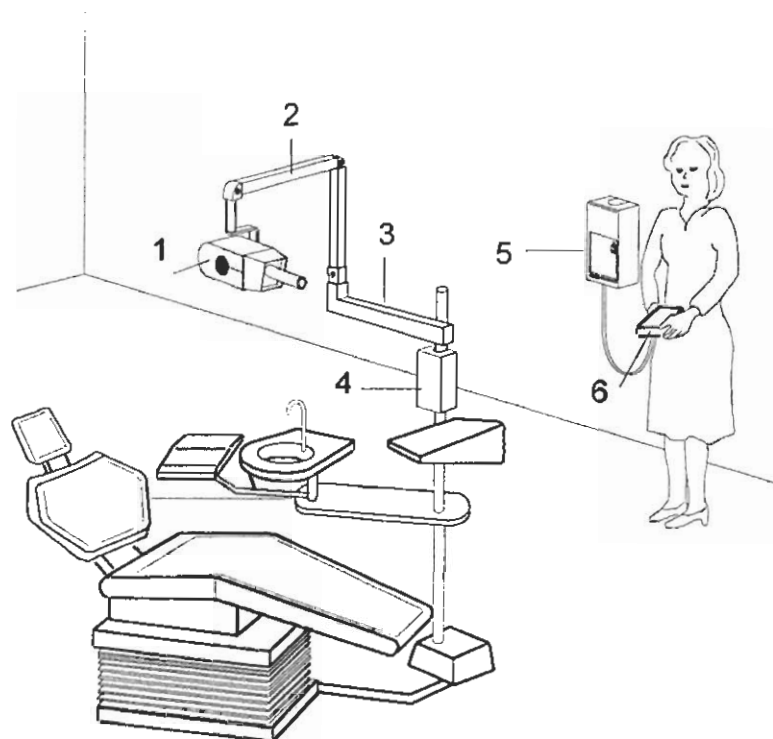


Figure 3

- 1** Tubehead
- 2** Scissors arm
- 3** Dental chair extension arm
- 4** Dental chair connection
- 5** Remote timer
- 6** X-ray button

4.3.4 Ceiling suspension configuration

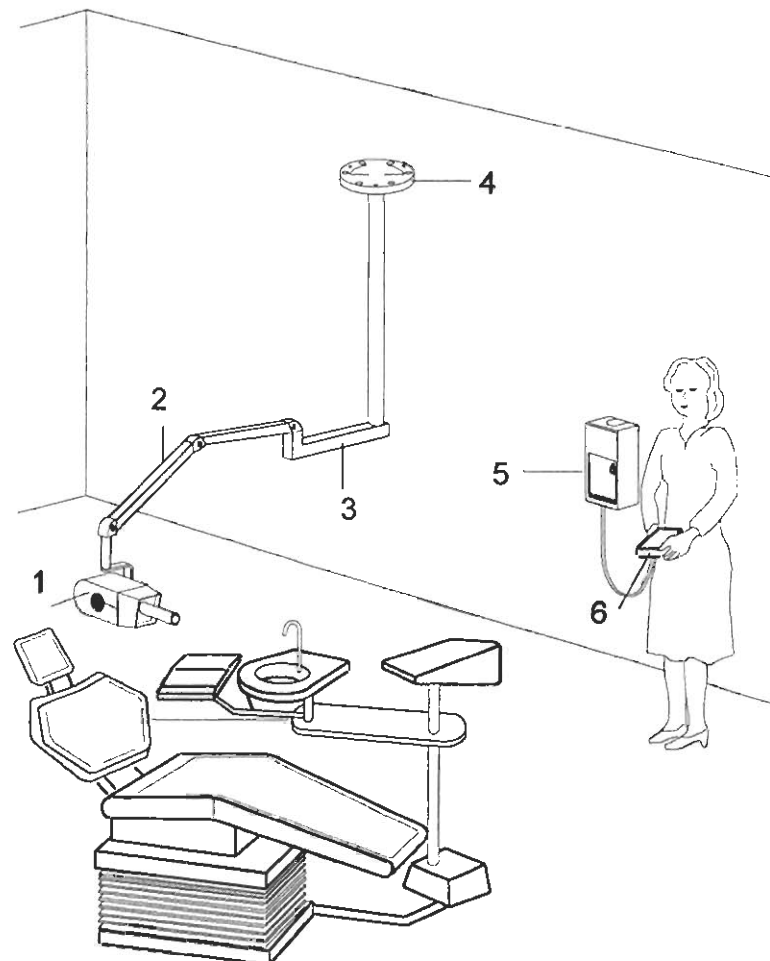


Figure 4

- 1** Tubehead
- 2** Scissors arm
- 3** Ceiling extension arm
- 4** Ceiling suspension plate
- 5** Remote timer
- 6** X-ray button

4.3.5 Mobile stand configuration

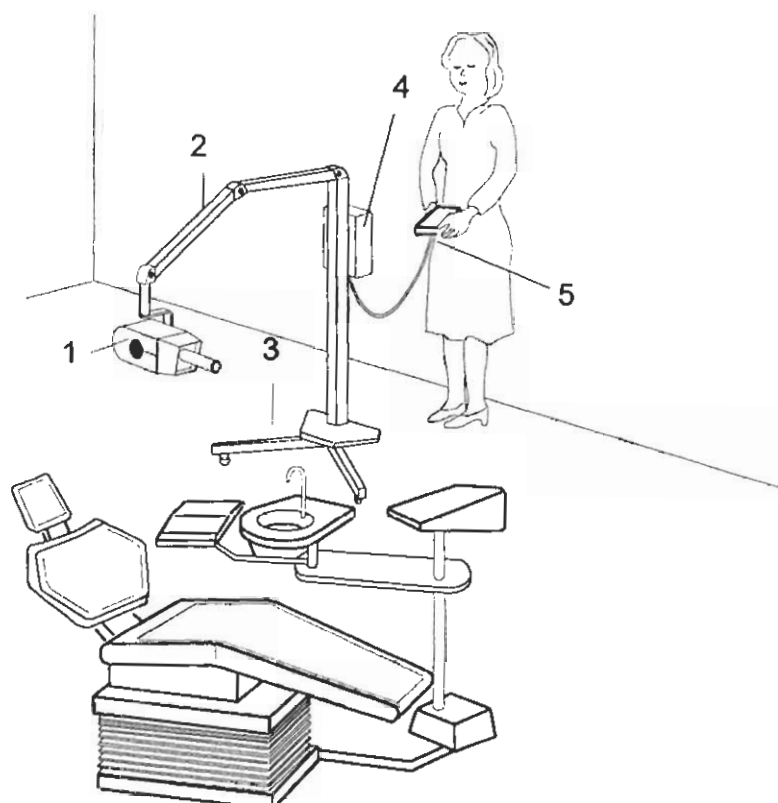


Figure 5

- 1 Tubehead
- 2 Mobile stand scissors arm
- 3 Mobile stand
- 4 Timer
- 5 X-ray button

4.3.6 Configuration with remote x-ray button

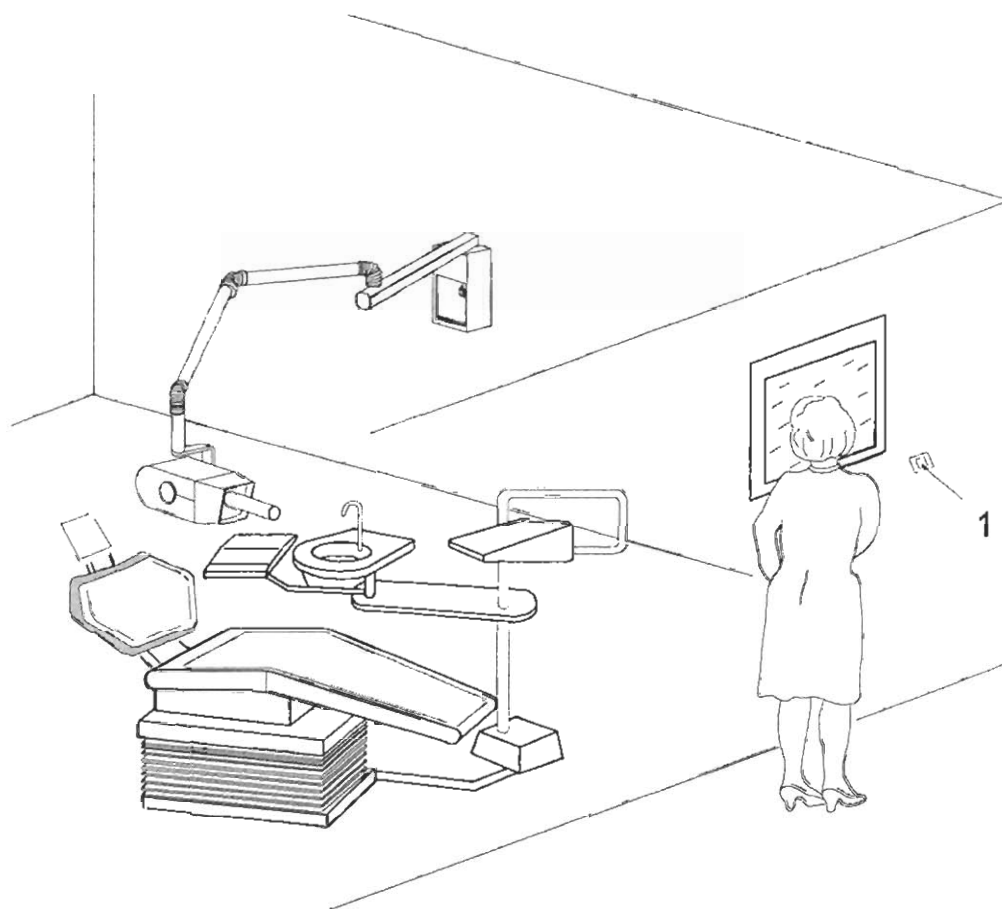


Figure 6

1 X-ray button


4.4 Identification of versions

The different versions of the system are identified by using the following configuration coding system.

4.4.1 Code generation

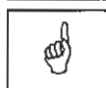
94	60	0	7X	X	X	X
						Line voltage
						0=220V
						2=240V
						3=230V
						Timer
						4=AP TIME X
						5=TIME X
						6=AP TIME X remote
						7=TIME X remote
						Scissors arm
						0=Square wall mounting 75cm (29 1/2")
						1=Square mobile
						2=Square ceiling
						3=Oval wall mounting 75cm (29 1/2")
						4=Oval mobile
						5=Oval ceiling
						6=Square wall mounting 55cm (21 5/8")
						7=Square wall mounting 90cm (35 7/16")
						8=Oval wall mounting 60cm (23 5/8")
						9=Oval wall mounting 90cm (35 7/16")
						Model
						70=Explor-X 70 kV Toshiba x-ray tube
						Fixed = 0
						Product type
						60=intra orali
						ID number
						94=Intra oral selling code

5. TECHNICAL FEATURES

Technical features	
Equipment	Explor-X 70
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italy
Class	Class I with type B applied parts (IEC 601-1 classification) 
Protection level	Standard apparatus IP20
Line voltage	220/230/240V~ (According to the installed tubehead)
Line frequency	50Hz
Rated current	4A rms impulsive @ nominal voltage
Power consumption	880VA impulsive @ 220V ~ 920VA impulsive @ 230V ~ 960VA impulsive @ 240V ~
Max. apparent line resistance	0.8 Ω max. @ nominal voltage
Main fuse	6A F
Preset exposure times	from 0.04 to 3.2s in 32 steps
Anatomic selection (for AP TIME X only)	54 pre-set times
Exposure time accuracy	$\pm 10\%$ or $\pm 20\text{ms}$ (whichever is greater)
High voltage circuit type	Single phase, self-rectifying
kV selection	70 kVp
Tubehead current	8 mA
kV accuracy	$\pm 8 \%$
Tubehead (anode) current accuracy (at nominal voltage)	$\pm 15 \%$
Ref. current - exposure time product	0.8 mAs (8 mA - 0.1 s)
Max. exposure time	3.2 s
Timer dimension	310x170x100mm (12x7x4 inches)

Tubehead features	
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italy
Rated voltage	70 kV _p
Tubehead power	430 W
Pre-heating time	240 ms
Total filtration	2 mm Al eq. @ 70 kV
Transformer insulation	Oil bath
Interval between exposure / duty cycle	60 times x-ray time / 1 : 60
Minimum focus to skin distance	20 cm (7 7/8")
X-ray beam diameter (@ 20cm focus)	≤ 6 cm (2 3/8")
Cooling	Convection
Radiation leakage at 1m	< 0.25 mGy/h, duty cycle 1 : 60
Technical factors for radiation leakage	70 kV, 8 mA, 1 s
X-ray tube features	
Manufacturer	Toshiba (Japan)
Type	D-082B
Focal spot	0.8 (IEC 336)
Inherent filtration	min. 0.5 mm Al equivalent at 70 kV
Anode tilt	20°
Anode material	Tungsten
Rated voltage	70 kV
Maximum filament current	1.9 A
Maximum filament voltage	3 V
Anode thermal capacity	7 kJ
Environmental conditions	
Operating temperature range	+10°C ÷ +40°C
Operating relative humidity range	30% ÷ 75%
Temperature range for transport and storage	-20°C ÷ +70°C
Max. relative humidity for transport and storage	<95 % non condensing
Min. atmospheric pressure for storage and transport	630hPa

Apparatus and detachable parts weight	
Gross weight including packing	35 kg
Net apparatus weight in standard configuration	30 kg
75cm (29 1/2") extension arm (standard)	5 kg
90cm (35 7/16") extension arm	5.7 kg
Scissors arm	8.5 kg
Timer plus wall plate	8.3 kg
Tubehead	8.5 kg



NOTE:

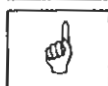
The timer works in synchronism with the line voltage.
 For exposure times lower than 0.08s the 25% limit between the value of the different selections (EN60601-2-7 regulation) cannot be respected because smaller variations would not have any appreciable effect on the generated x-ray dose (EN60601-2-7).

5.1 Exposure time correction method

The Villa Sistemi Medicali x-ray intraoral equipment is equipped with a special feature called "Computer Controlled Density" that allows to automatically correct the exposure time according to the fluctuation of the mains voltage from its nominal value.

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 timer 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 (+/-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 timer monitors continuously the line voltage, while the user selects the desired exposure times. 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 button to enable the system and the timer displays the corrected actual exposure time that is calculated by the timer itself, on the basis of the line voltage measured every half a second by the internal voltmeter.

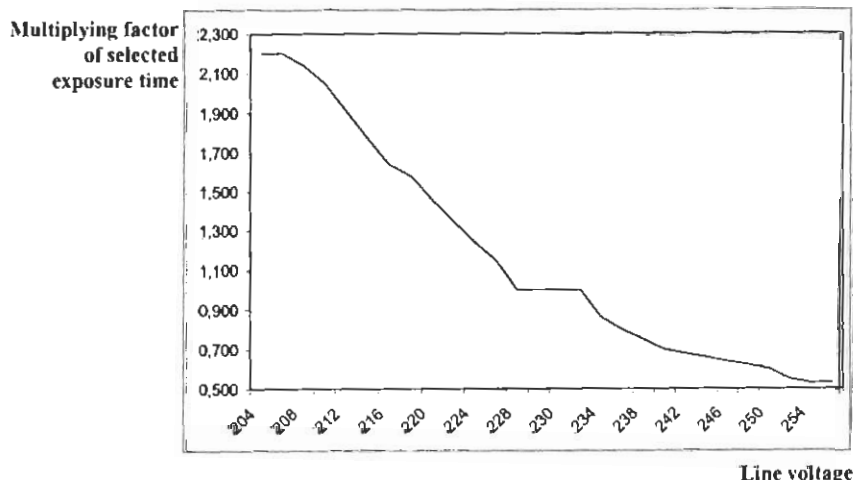


NOTA:

AP TIME X and TIME X timers works synchronously with the power line, so the calculated time is always rounded off to a multiple of pulses.

The corrected exposure time shown once the timer has been enabled by the "Ready" button and during the exposure is the time used by the equipment: it is calculated applying a correction factor to the selected exposure time, based on an empirical law that correlates the dose with the high voltage peak and consequently with the line voltage.

The qualitative trend of the multiplying factor and the line voltage is shown in the following picture (for a time set to operate at 230V):



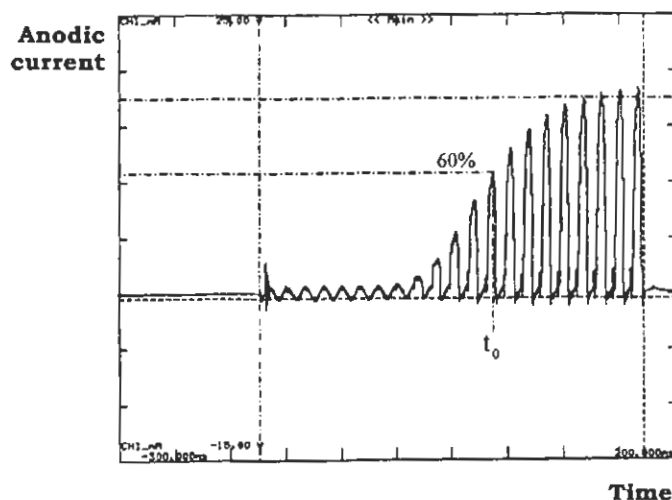
5.2 Technical factors measuring method

- kV_p** The value of kV_p is defined as the stationary value of high voltage applied to the tube, that stabilises under load after the pre-heating time. The value of kV_p is measured by means of a non-invasive instrument, having an accuracy over 2%, at the rated value of input line voltage. Direct measurement of high voltage may be carried out only by disassembling the tubehead.
- mA** The value of anode current is defined as the average value of stationary current stabilising under load after the pre-heating time. The value of anode current is measured by means of a digital voltmeter and by measuring voltage drops at the ends of 1 kΩ resistance, 1% mounted on the tubehead. To access this resistance, plastic tubehead protection covers must be removed. The digital voltmeter must be in the DC mode, and the transformation ratio is 1 mA = 1V.
- t** The value of exposure time is the time during which a significant amount of x-rays is generated; it is measured by counting the number of half-waves where the value of anode current peak is over 60% of the steady-state value. The time required to reach such condition is called "pre-heating time".
Measurement must be effected under rated input voltage conditions, by measuring the wave shape of anode current on the 1kΩ resistance and by means of a memory oscilloscope.
Measurement of exposure times by means of non-invasive instruments may lead to non-quantifiable systematic errors of measurement related to the instrument used (please see chapter 5.3).

5.3 Proper use of the dosimeters when assessing exposure times

The use of non-invasive instruments for the measurement of the exposure parameters of the intraoral equipment may lead to some problems when interpreting the result of the measurement of the exposure times.

The origin of this problem is related to the raising curve of the anodic current of the x-ray tube, as shown in the next graph:



According to the EN60601-2-7 standard, "the exposure time of 1 or 2 peak generators is measured by counting the number of cycles or half-cycles during which a significant quantity of radiation is emitted". In the case of the Villa Sistemi Medicali intraoral equipment, the measuring methods consists of the measurement of the peaks that exceed the 60% of the level reached at the steady-state. This method is defined as an invasive method as the current trend can be measured by reading current flowing the 1Ω resistor within the tubehead case.

The non-invasive methods, based on the use of instruments that measure the dose, are clearly much easier and quicker to use than the invasive method, but can introduce significant errors when measuring exposure times. This is due to the fact that some of these instruments start counting the exposure time as soon as a small quantity of radiation is detected by the sensor thus calculating exposure times longer than the ones declared by the manufacturer that instead tests and certifies the equipment by using the invasive method.

The determinations achieved with these non-invasive instruments can lead to the conclusion that the timer of the equipment under test is not accurate while the inaccuracy is clearly explained by a different definition of exposure time as shown in the following.

Examples

Next table shows the comparison of the times obtained by using the non-invasive method (measuring instrument Solidose 308 RTI PMX-1D) and the times obtained by using the invasive method according to the rule that the counting of the exposure time starts when the anodic current reaches the 60% of the steady-state value.

Time indicated by the timer during the exposure (obtained has described above)	Time measured with the non-invasive method
220 ms	305 ms
300 ms	425 ms
440 ms	545 ms
560 ms	665 ms
650 ms	745 ms
780 ms	885 ms
890 ms	984 ms

As clearly shown in the table, there is a constant discrepancy for all the exposure times; this difference is given by the raising time of the current as the non-invasive instrument starts measuring the time as soon as a small quantity of dose is detected. The result of this behaviour is that all exposure times are longer than the time declared by the definition of when current reaches the 60% of the steady-state.

Corrective actions

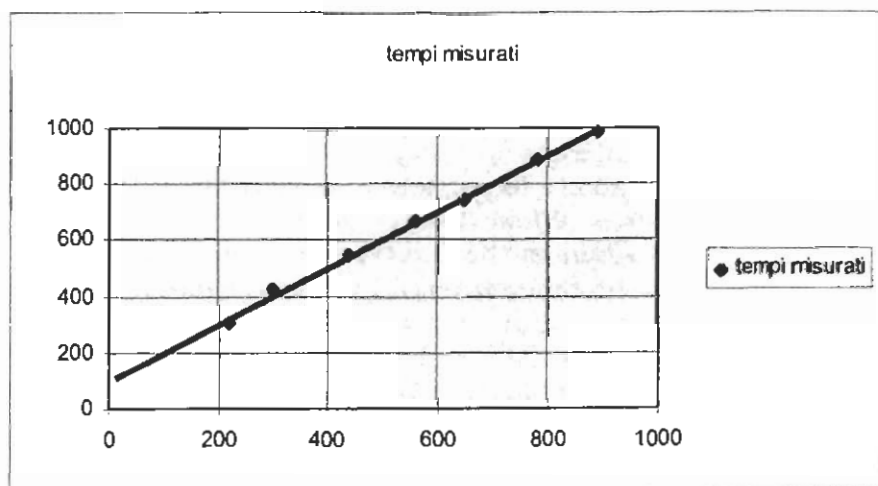
Among the different non-invasive instruments, some include a special feature that allows to perform a more accurate measurement of the exposure times. When this special function is activated, the measuring instrument requires the execution of 2 measurements: the first one determines the time required by the equipment to reach a given significant dose value, the second one counts the time interval between the time assessed during the first measurement and the end of the exposure. The result of this second measurement is the exposure time. The measurement of the exposure times carried out with instruments that include this special feature matches quite well with the times assessed by the invasive method (see next table).

Time indicated by the timer during the exposure (obtained has described above)	Time measured with the non-invasive method (measuring instrument RTI PMXII set in "lock mode")
100 ms	103 ms
250 ms	264 ms
400 ms	401 ms
500 ms	503 ms
700 ms	703 ms
1000 ms	1003 ms
2000 ms	1960 ms

When using non-invasive instruments not including this special feature, a practical method can be used to overcome this problem, as described here after:

- Set on a graph the times measured by the non-invasive instrument versus the corrected times displayed by the timer; interpolate the points on the graph by a straight line (if possible by means of the least square algorithm method, otherwise in graphical way)
- Determine the intercept of the straight line with respect to the Y axis: this intercept value can be considered the time that the non-invasive instrument adds to any measurement (offset value), due to the fact that it is triggered by the first dose that reaches its sensor instead of starting the count when reaching the 60% of the steady-state anodic current value
- Subtract this offset value from each measurement displayed by the instrument and compare the times so obtained with the times shown by the timer.

The use of this method with the data shown in the first example allows to confirm that the measurement become consistent well within the limits given by the rules. Infact, the offset value of the first example is approximately 100ms; once this offset is subtracted from the measured values the results become very similar to the preset times.

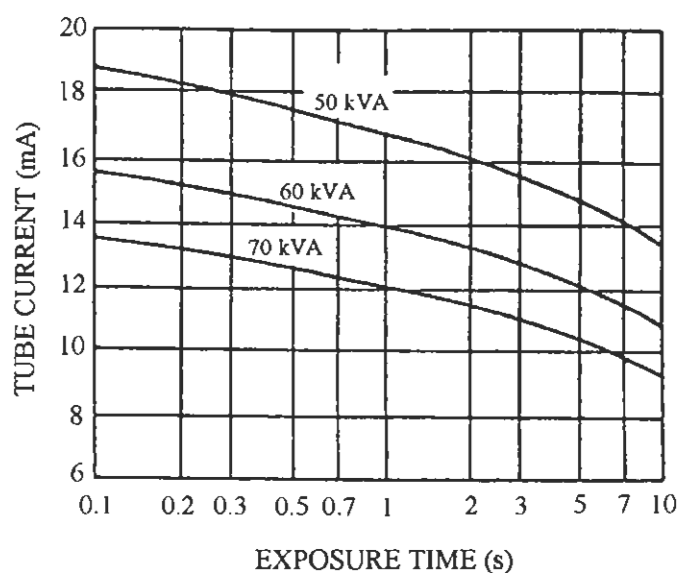


5.4 X-ray tubehead curves

TOSHIBA D-082 B

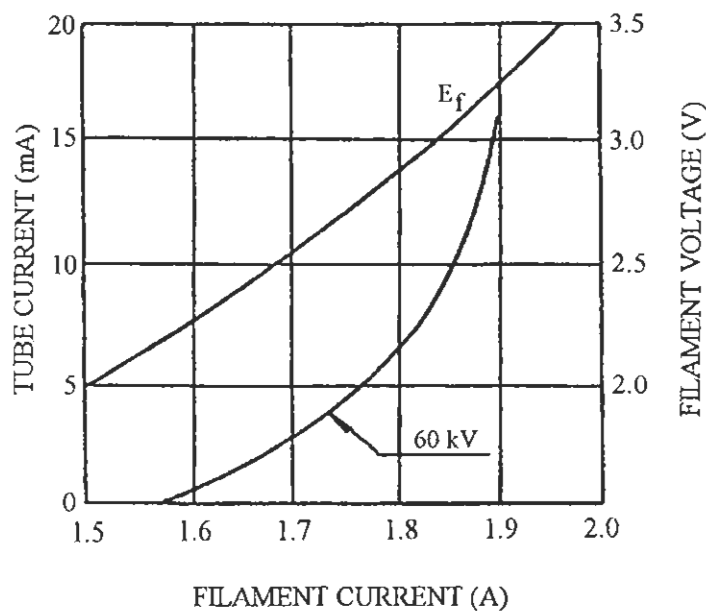
Emission and filament features

Self-Rectified
 Focal Spot : 0.8 mm

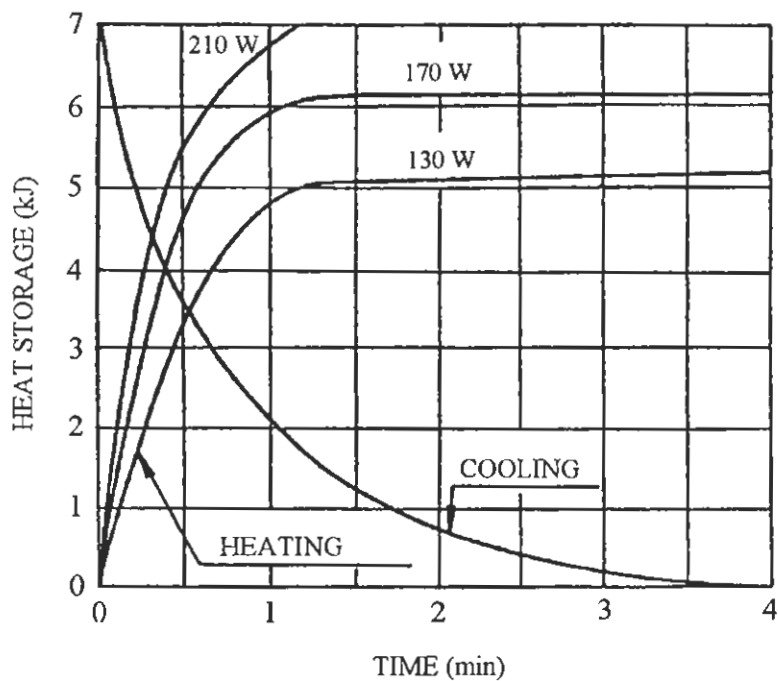


Load

Self-Rectifier



Cooling curve



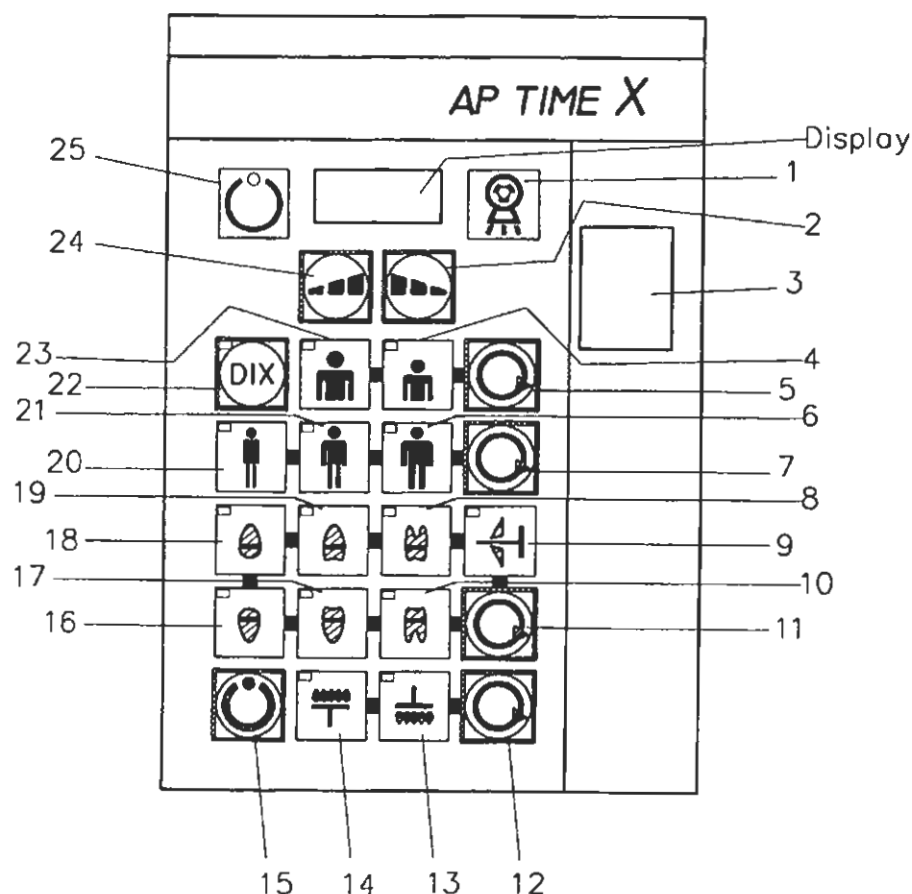
5.5 Standards and regulation

Applicable regulations:

EEC 93/42: EN 60601-1
EN 60601-1-1
EN 60601-1-2
EN 60601-1-3
EN 60601-1-4
EN 60601-2-7
EN 60601-2-28

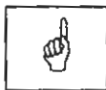
6. OPERATING INSTRUCTIONS

6.1 "AP TIME X" timer



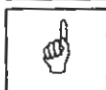
LEGEND:

1 X-ray emission LED	10 Lower Molar LED	18 Upper incisor LED
2 Decrease key	11 Tooth type selection key	19 Upper canine LED
3 Mains switch	12 Occlusal selection key	20 Small size LED
4 Child LED	13 Lower Occlusal LED	21 Medium size LED
5 Adult/Child selection key	14 Upper Occlusal LED	22 Digital radiography selection key
6 Large size LED	15 Exposure enabling key	23 Adult LED
7 Size selection key	16 Lower incisor LED	24 Increase key
8 Upper Molar LED	17 Lower canine LED	25 «Ready for x-ray» Green LED
9 Bite-wing LED		



NOTE:

All automatic selections are revealed by the switching on of the relevant light signal, placed to the left of the symbol.



NOTE:

The AP TIME X timer is equipped with a Stand-By function, by which - if no button on the keyboard is pressed for at least 5 minutes - the timer turns to a stand-by mode (low consumption), revealed by the presence of only the decimal point on the right hand side. Press any key to return to operating conditions.

Exposure times INCREASE KEY



Exposure times DECREASE KEY





By depressing one of the above buttons, it is possible to switch from automatic to manual selection. This way, all signals related to automatic selection (Adult/Child, Patient Size, Tooth or Occlusal Selection) are switched off. Selection of times shall therefore take place in manual mode.

When the button is pressed once, the time set as default is displayed; to change it, release the button and depress it again; rapid selection is also possible, by keeping the button depressed; this way, the variation is effected rapidly.



To go back to automatic time selection, press one Selection key (Size, Adult/Child, Tooth, Occlusal).

“ADULT/CHILD” selection key

By depressing the  button placed beside the   symbols,


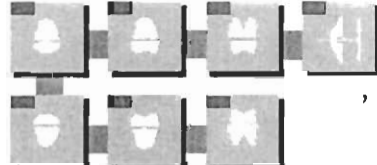
the rotation switch between Adult  and Child  mode is effected; thus exposure times may be changed.

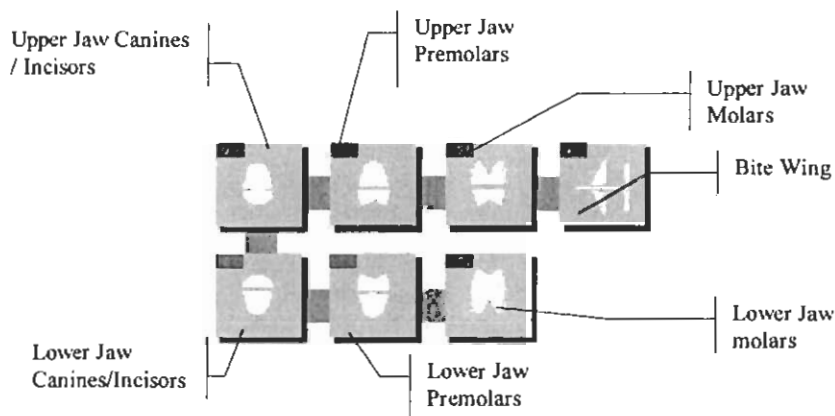
“SIZE” selection key

By depressing the  button placed beside the  symbols, rotation selection between the different patient sizes - small, medium and large (left to right) is effected. Exposure times are changed in this case as well.

A sound signal lasting abt. ½ sec is heard every time a button is depressed, and the led related to the selected function is switched on.

“ANATOMIC TOOTH” selection button


By depressing the  button placed beside , rotation selection among the exposure times pre-set for the different teeth is effected. The meaning of symbols is explained in the following paragraphs.



Upper- or Lower-jaw “OCCLUSAL” selection key

By depressing the  button placed beside the  symbols,

upper- or lower-jaw occlusal exposure selection is effected; the selection is displayed by the glowing of the relevant LED, whereas all signals related to the tooth type are switched off. The Adult/Child and Size selections remain active. To go back to tooth anatomic selection, depress

the  button placed beside tooth symbols.

System enabling key

For additional safety, the AP TIME X timer is equipped with the "Exposure Enabling" function, particularly useful in the case of remote emission button. X-ray emission

can take place only once the  button has been depressed; the


signal for enabled system is displayed on the keyboard by the glowing of the relevant green signal. Such enabling lasts during a preset time (which can be varied in the installation phase between 10 and 30 seconds: default 15 seconds), after which the function is disabled and the pressing of the exposure button does not cause x-ray emission.



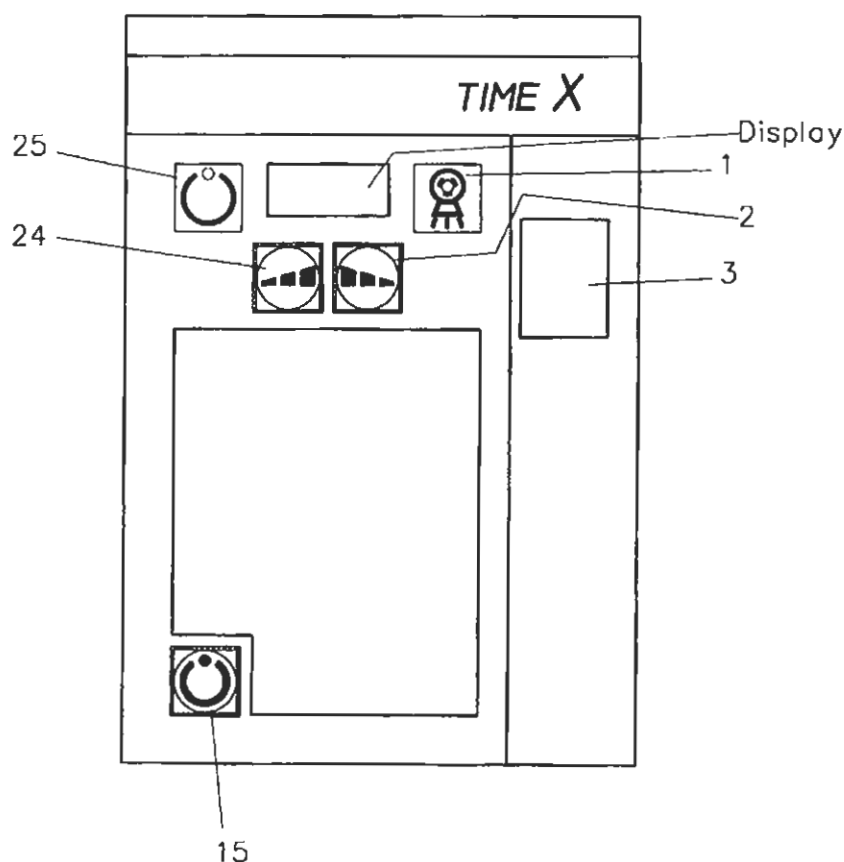
NOTE:

Pressing the "Ready" key, the system will be ready for the exposure and also it will start showing on the display the exposure time corrected according to the internal line voltage fluctuation algorithm (please see chapter 5.1).

Digital selection key

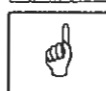
The  button enables automatic exposure for Digital Radiology, reducing exposure times to values suitable for the use of digital sensors.

6.2 "TIME X" timer



LEGEND:

- 1** X-ray emission LED
- 2** Decrease key
- 3** Mains switch
- 15** Exposure enabling key
- 24** Increase key
- 25** "Ready for x-ray" Green LED



NOTE:

The TIME X timer is equipped with a Stand By function, by which - if no button on the keyboard is pressed for at least 5 minutes - the timer turns itself into a stand-by mode (low consumption), revealed by the presence of only the decimal point on the right hand side. Press any key to return to operating conditions.

Exposure times INCREASE KEY



Exposure times DECREASE KEY



By depressing one of the above keys, the exposure time is selected among the 32 times available.

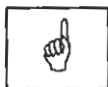
When the button is pressed once, the time set as default is displayed; to change it, release the button and depress it again; rapid selection is also possible, by keeping the button depressed; this way, the variation is effected rapidly.

System enabling key

For additional safety, the TIME X timer is equipped with the "Exposure Enabling" function, particularly useful in the case of remote emission button. X-ray emission

can take place only once the  button has been depressed; the

signal for enabled system is displayed on the keyboard by the glowing of the relevant green signal. Such enabling lasts during a preset time (which can be varied in the installation phase between 10 and 30 seconds), after which the function is disabled and the pressing of the exposure button does not cause x-ray emission.




NOTE:

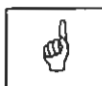
Pressing the "Ready" key, the system will be ready for the exposure and also it will starting showing on the display the exposure time corrected according to the internal line voltage fluctuation algorithm (please see chapter 5.1).

6.3 Visual signals

System enabling signal

When switched on, the green signal  , placed in the right top

corner of the keyboard, indicates the "Ready for x-ray" condition, in which pressing the x-ray button marks the starting of exposure. Such exposure enabling condition lasts until the end of exposure or during a pre-set time (which can be varied in the installation phase between 10 and 30 seconds: default 15 seconds), after which the function is disabled; it can be re-enabled by pressing the relevant key once again.



NOTE:


Pressing the "Ready" key, the system will be ready for the exposure and also it will start showing on the display the exposure time corrected according to the internal line voltage fluctuation algorithm (please see chapter 5.1).



NOTE:

The pressing of the x-ray button with enabling function not active does not effect any exposure; at the same time, the display shows the last actual exposure time

"ACTIVE X-RAY EMISSION" signal

The yellow light  , active in case of x-ray emission, marks actual emission. Moreover, the emission is signaled by an sound signal.

Exposure times visualization display

The display, placed in the upper central part of the keyboard, has multiple functions.

1. During the exposure preparation phase, it displays the selected exposure time in automatic or manual mode.
2. Immediately after having enabled the system by the "Ready" button and during the exposure phase, it displays the exposure time adjusted by the system to compensate fluctuations in the input line voltage, whereas at the end of exposure it displays the time remaining before the end of the tubehead cooling phase.
3. Finally, if the x-ray button is pressed with disabled emission, the display shows the last actual exposure time.

7. SYSTEM OPERATION






- a) Depress Main Switch placed in the front part of the cover.
This operation will turn on the system self check function.
- b) Once the self check has been completed (possible anomalies are signaled by error messages described in Chapter 10), the system automatically sets on Adult, Medium Size and Incisor/Canine of jaw, displaying the relevant exposure time.

THE SYSTEM IS NOW READY FOR OPERATION.

7.1 Preparing the apparatus

7.1.1 Setting the timer for exposure in x-ray mode with automatic selection of exposure time (for AP TIME X version only)

To enable automatic selection, set the patient by choosing between

the   keys and the patient size keys   .

Subsequently, the type of tooth under examination must be set by

choosing among the     projections. By    projections. By

depressing the control panel buttons, the selection is confirmed by an sound signal and by the glowing of the LED related to the button pressed. The preset Size/Tooth combination, will cause the display to show the basic exposure time (see table 1). The suggested exposure times are given for Kodak Ultra Speed (Type D) films.


















						
						
	0.25	0.32	0.50	0.12	0.16	0.23
	0.32	0.50	0.70	0.18	0.25	0.36
	0.36	0.63	0.80	0.23	0.32	0.45
	0.25	0.32	0.50	0.12	0.16	0.23
	0.36	0.50	0.70	0.18	0.25	0.36
	0.30	0.40	0.60	0.12	0.16	0.23
	0.23	0.30	0.45	0.12	0.16	0.23
	0.60	0.80	1.00	0.30	0.40	0.60
	0.45	0.60	0.90	0.23	0.30	0.45

Table 1



NOTE:


In case different film types are used (e.g., type E), automatic selection must take place with prior change in the multiplying factor. Such change can be carried out by the Service Engineer during the installation phase or directly by the user (Paragraph 7.5.2).


The multiplying factor reported on the documentation provided by the film manufacturer must be set.

7.1.4 Setting the Timer for exposure in x-ray mode with manual selection of exposure time

Enable manual selection by depressing the  and  keys.

When enabling manual selection the preset time will be increased by

depressing the  button and will be decreased by depressing

the  button. To increase or decrease times one step at time

depress one of the keys several times; a sound signal will indicate time changes. By holding one of the keys depressed, time settings will rapidly increase or decrease down to full scale. Manually selectable times are 32, ranging from 0.04 sec. minimum to 3.20 sec. maximum (see Table 2)

0.04	-	0.06	-	0.08	-	0.10	-	0.12	-	0.14	-	0.16	-	0.18	-	0.20	-	0.23	-	0.25	
-	0.30	-	0.32	-	0.36	-	0.40	-	0.45	-	0.50	-	0.54	-	0.60	-	0.63	-	0.70	-	0.80
-	0.90	-	1.00	-	1.25	-	1.30	-	1.40	-	1.60	-	2.00	-	2.50	-	3.00	-	3.20		

Table 2



NOTE:

See chapter 5.1, 5.2, 5.3.



7.1.5 Setting the Timer for exposure in Videoradiography mode with automatic selection of exposure times in digital dental x-ray mode (for AP TIME X version only)



NOTE:

This automatic program can be used only when a digital intra-oral system is available.

Further details on use and patient positioning are described in the relevant manual.

- a) Depress the  button; the relevant signal turns on and the times displayed are reduced compared to use of the system with films and shall be in line with the selection performed. (Adult/Child, Size, Tooth, Occlusal).
- b) Exposure for digital radiology can be selected automatically, by selecting one of the available times.
- c) To go back to radiographic mode with automatic selection, depress the  button once again.

7.2 Preparing the tubehead

- a) Arrange the tubehead with an angle suitable for the required exposure and positioning (See Figures 7÷10).
- b) Introduce the film into the patient's mouth according to the chosen technique (bisecting or parallel). Please refer to paragraph 7.3.
- c) Move the cone near the patient and direct it exactly towards the tooth under examination by referring to the following figures.

MANDIBLE



Fig. 7

MAXILLA

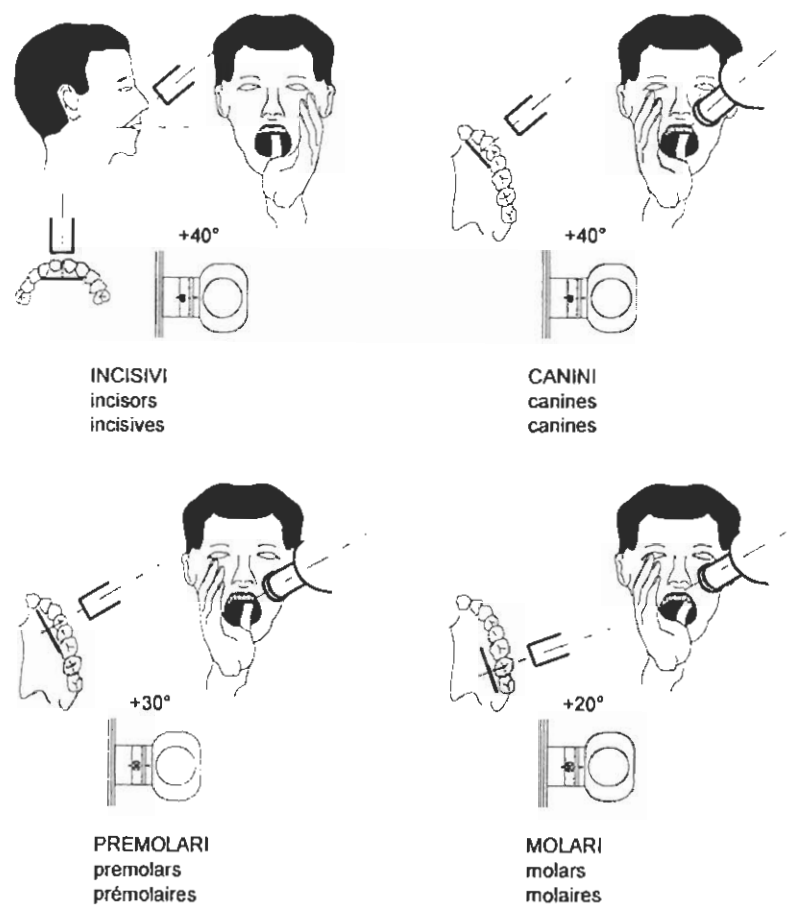


Fig. 8

OCCLUSAL

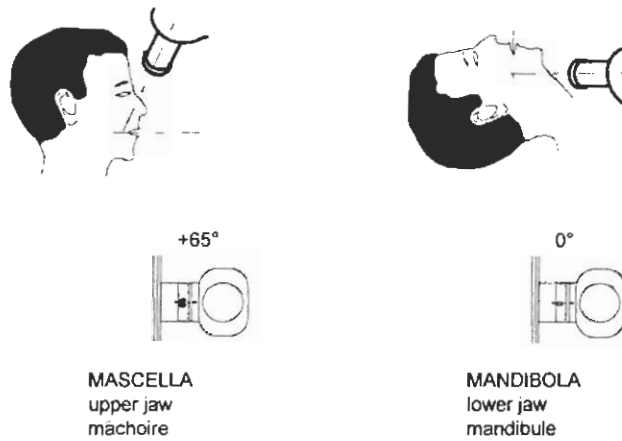


Fig. 9

BITE WING

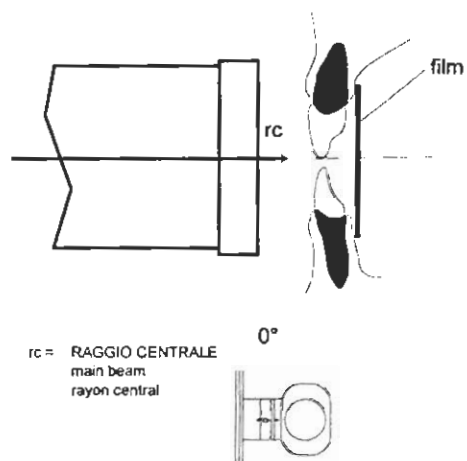


Fig. 10

7.3 Exposure techniques

This chapter describes the different techniques normally used for intra-oral x-ray exposure.

7.3.1 Bisecting technique

Main beam incidence - Vertical angle

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

Once head and film positions have been set according to these criteria, an average vertical incidence can be used for each area. The angle of incidence of the main beam can be correctly measured by means of the graduated scale fixed onto the tubehead.

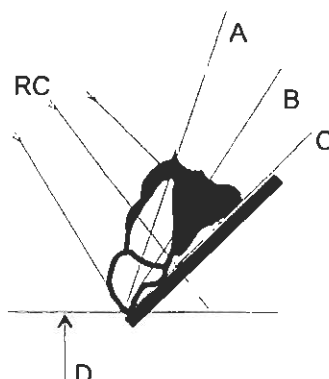


Fig. 11

Key to figure 11:

A - Longitudinal axis of tooth

B - Bisector

C - Film plane

D - Occlusal plane

RC - Main beam

Main beam incidence - Horizontal direction

The main beam must be correctly adjusted horizontally, in particular in an orthoradial direction as regards interprossimal spaces (See Figure 12), in order to prevent structures from overlapping (See Figure 13).

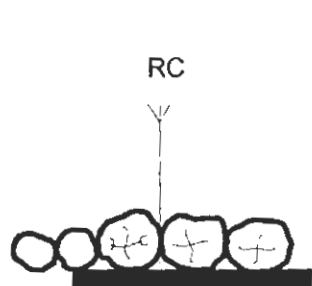


Fig. 12
(Correct position)

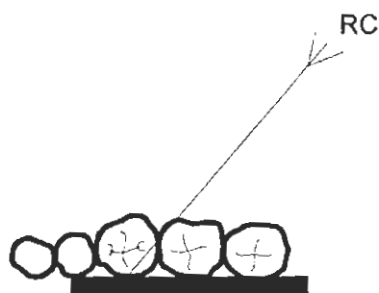


Fig. 13
(Wrong position)

Key to figures 12 and 13

RC - Main beam

7.3.2 Parallel Technique

By this technique, the film plane is placed parallel to the main axis of tooth. Owing to anatomic factors, the film is usually positioned away from the lingual surface of teeth, except in the case of molars. When introduced into the patient's mouth, the film rests on a support to prevent distortion. The patient holds the support with his/her teeth. A full range of supports suitable for the different types of teeth is available on the market. This technique provides more accurate and easily repeatable radiographs compared to the bisecting technique (See Figures 14 and 15).

HORIZONTAL SECTION

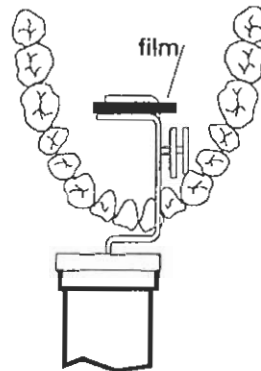


Fig. 14

VERTICAL SECTION

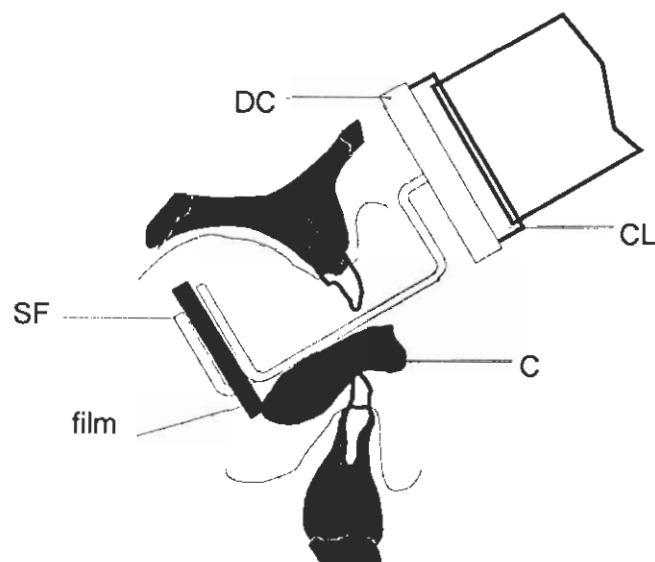

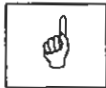


Fig. 15

7.4 Exposure

- a) By operating on the main keyboard, select the exposure time as described in paragraph 7.2, according to the selected mode.
- b) Enable exposure by depressing the  button.



NOTE:

Pressing the "Ready" key, the system will be ready for the exposure and also it will starting showing on the display the exposure time corrected according to the internal line voltage fluctuation algorithm (please see chapter 5.1).

- c) Get as far as the hand control cable allows, in a direction opposite to beam emission.
- d) Depress the x-ray button and hold it depressed throughout exposure
- e) The starting of exposure is indicated by the glowing of the green light and by a sound signal.

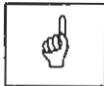


WARNINGS:

- The x-ray button is a 'Dead man' control; it must therefore be kept depressed during the whole exposure.
By releasing the button before the end of exposure, the operation is automatically interrupted; this situation is signaled by the intermittent glowing of the exposure time display, while other light signals on the keyboard are switched off. This signal lasts until one of the time increase buttons is depressed.
- In case of an excessive line voltage variation which, due to the exposure the automatic compensation features, would require an actual exposure time of 4 sec. or more, the system will not perform exposure. In this case, the display shows the re-adjusted exposure time according to line voltage fluctuations.
- In case the line voltage is outside the acceptable range, the display will show 'LLL' (if voltage is too low) and 'HHH' (if voltage is too high) respectively.
- Depressing the x-ray button with disabled exposure will display the actual exposure time of the last exposure performed, or the time selected in case of first exposure.

- f) At the end of exposure, the system starts the tubehead cooling cycle (60 times the exposure time); this condition is revealed by the intermittent glowing of the system enabling light, while the display shows the time remaining before the end of the cycle.

- g) In case the exposure enabling button is depressed when the x-ray button is already depressed, exposure is inhibited and the relevant error is signaled.



NOTE:

The actual exposure time adjusted according to line voltage variations does not include the pre-heating time required for the anode current to reach 60% of its final value.

7.5 Special functions

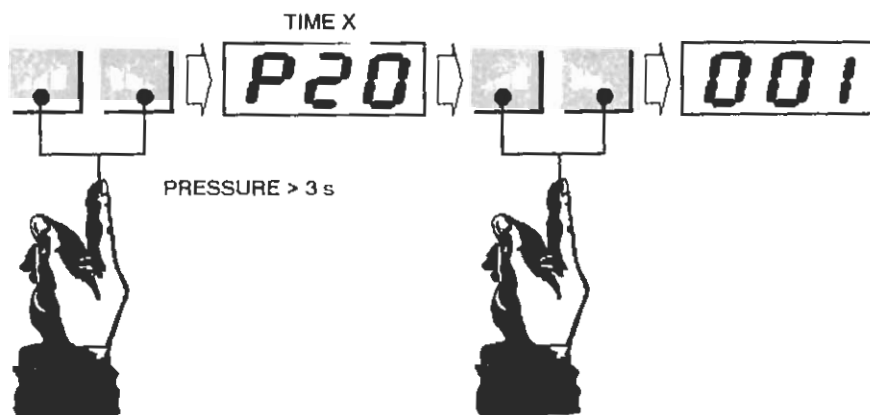
The user has the possibility to display two functional parameters:

7.5.1 Exposure counter

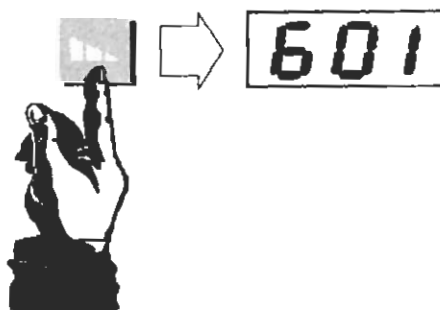
мерная карточка

In the Stand-By mode, the number of exposures carried out (since the last counter reset) can be displayed following this procedure:

1. Simultaneously depress and hold depressed the "increase" and "decrease" buttons for over 3 seconds; the display will show the message **"P20" (Now release the two buttons).**
2. To visualize thousands (e.g. **"001"**) depress the "increase" or "decrease" button.



3. Depress the "decrease" button to display the numbers between 0 and 999.



The above example shows a reading of 1601 exposures (001+601=1601)

To go back to Stand-By mode, depress the  button.

7.5.2 Selection of the multiplying factor for different film types



NOTE:

This parameter is displayed only in the "AP TIME X" version, since the "TIME X" version does not envisage the use of "automatic" selection.


This particular function allows the operator to change the duration of x-ray emission according to film speed (thus affecting image quality). Film speed is reported on the film box.

The value displayed is an **X multiplying factor** which adjusts exposure times in **STANDARD RADIOLOGY** (non-digital), **WITH AUTOMATIC ANATOMIC SELECTION**.

The different X multiplying factors available are reported in the following table:


X Multiplying Factor
0,2
0,4
0,5
0,6
0,7
0,8
0,9
Default value = 1,0
1,4

For the appropriate factor, please consult the film manufacturer.

To display this parameter, turn the equipment off, turn it back on and when the display shows the software version message - depress the 

button for a few seconds. The value related to the set multiplying factor will be displayed.

To decrease that multiplying factors, depress the "decrease" button; to increase it, depress the "increase" button.

Once proper selection has been made, press again the  button to store the selected multiplying factor.

8. PROTECTION AGAINST RADIATION

**WARNING:**

Radiation protection is generally regulated by law. These regulations are beyond the scope of the present manual. Operation and use of the equipment must be allowed to trained personnel only.

- a) The film must be introduced into the patient's mouth manually or by means of the relevant holders; it must be held by the patient himself.
- b) During radiation exposure, the operator must not be in contact with the tubehead or the collimator.
- c) During radiation exposure, the operator must keep at a certain distance from the x-ray source (at least 2m or 78 3/4"), in a direction opposite to that of x-ray emission.
- d) During radiation exposure, no one other than the operator and the patient must be present in the room.
- e) To reduce the unwanted effects of secondary radiation on the patient, we suggest using the relevant leaded aprons.

9. CHECKS AND CORRECTION OF POSSIBLE FAULTS IN DENTAL RADIOGRAPHS

9.1 Typical defects of intra-oral radiology

- **Light radiographs:**

Possible causes:

- Insufficient exposure to x-ray (short time)
- Insufficient development time
- Deteriorated developer
- Developer temperature below recommended value
- Incorrect developing fluid dilution.

- **Dark radiographs:**

Possible causes:

- Excessive exposure to x-ray (long time)
- Excessive development time
- Developer temperature above recommended value
- Incorrect developing fluid dilution.

- **Blurred radiographs (details not visible):**

Possible causes:

- The patient moved
- The tubehead moved.

- **Radiographs with herringbone marks:**

Some intra-oral films are provided with a thin lead foil having a herringbone type mark on its lower side. These films may be exposed to radiation on one side only. If the film is exposed on the wrong side, the lead foil will absorb a large amount of radiation during exposure. The result shall be a lighter radiograph and the film will carry herringbone marks.

- **Partially exposed radiographs:**

Possible causes:

- X-ray directed off the film's mid section
- Low development fluid level, with consequent partial film development
- Two or more films placed against each other during development.

- **Clouded radiographs:**

Possible causes:

- Excessive film shelf life (check expiration date)
- Film accidentally exposed to x-ray
- Film accidentally exposed to other natural or artificial light sources.

- **Radiographs showing a black line:**

This line appears when the film is excessively folded.

- **Radiographs showing signs of electrostatic electricity:**

When a film is compressed too much and the air is dry, static electricity may be released discharging in the compensation points, which display black marks.

- **Radiographs with chemical spots:**

Development and fixing fluid spattered on the film before development and fixing procedures produces spots on the radiograph; such spots are:

- Dark, when caused by development fluid
- Light when caused by fixing fluid.

- **Radiographs with emulsion coming off:**

If the film is kept in a hot water bath too long (e.g. throughout the whole night), the emulsion may become softer and partially come off the film base. After development, the film will show scratches.

9.2 Typical defects caused by incorrect positioning

- **Radiographs with elongated or shortened image:**

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

- **Radiographs with stretched out tip of tooth**

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

10. MESSAGES ON DISPLAY

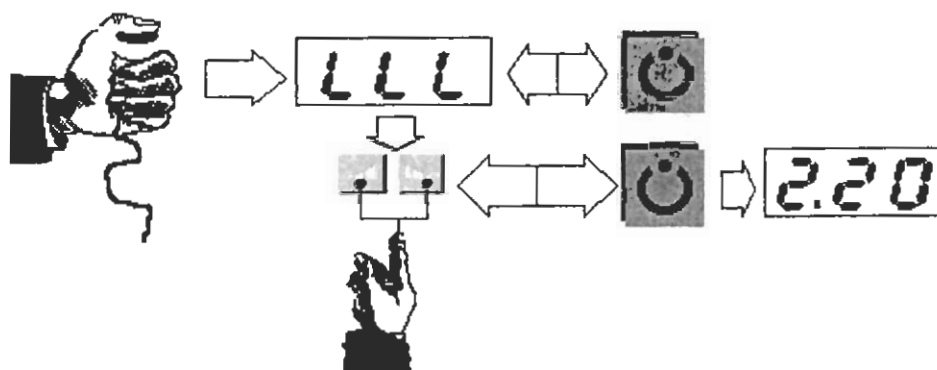
The display of AP TIME X or TIME X timer is used also to visualize messages that explain the status of the unit. These messages are related to conditions that inhibit the emission or errors occurred during the functioning.

10.1 Exposure-inhibiting conditions

The x-ray cycle is not enabled or is interrupted for the following reasons:

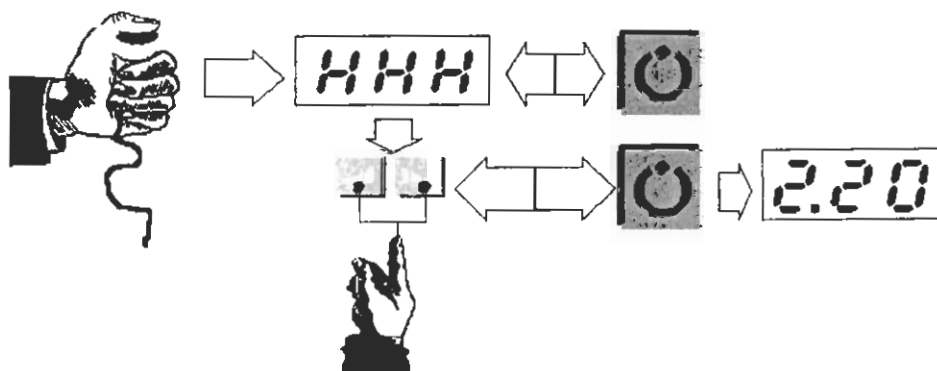
- **Input line voltage below rated voltage by 12.1%**

Before performing the exposure a check of the input line voltage is performed. If voltage is below rated voltage by 12.1% , the display shall show the code "LLL" combined to glowing of the green operation LED. To reset this alarm, press the "INCREASE" or "DECREASE" button.



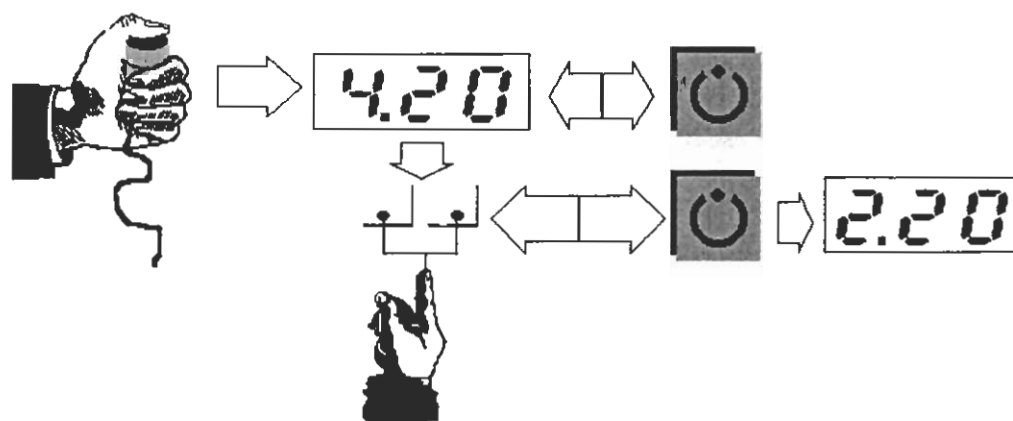
- **Input line voltage above rated voltage by 12.1%**

Before performing the exposure a check of the input line voltage is performed. If voltage is above rated voltage by 12.1% , the display shall show the code "HHH" combined to glowing of the green operation LED. To reset this alarm, press the "INCREASE" or "DECREASE" button.



- **Calculated exposure time above 4 seconds**

In the cycle-Start phase (x-ray button depressed), the actual exposure time is calculated according to variations in the line voltage. If the time detected is above 4 seconds, the display will show the value of calculated time (e.g. 4.20 seconds) and the green operation LED will simultaneously glow. To reset this alarm, press the "INCREASE" or "DECREASE" button.



NOTE:

In case of a Software problem, a safety timer is envisaged at the hardware level, which stops x-ray emission after a maximum of 5.5 seconds.

В случае возникновения программного сбоя, предусмотрена таймер, который предотвратит продолжение излучения максимум через 5,5 секунд.

10.2 Error messages

The AP TIME X and the TIME X timers are equipped with a sophisticated diagnosis function, allowing the monitoring of the whole emission phase and of the relevant safety measures.

Error messages displayed can be divided into three categories:

- errors in the power-on phase requiring Service Engineer intervention;
- resettable errors in power-on phase;
- errors detected during the emission phase

The first type of errors are detected during the system power-on phase; if the system encounters a non-resettable alarm condition, it stops and does not allow any operation. Such status is cancelled only by switching the system off and back on or by following the instructions provided in the table on the following page. These anomalies have an error code between **"E01"** and **"E09"**.

Resettable alarm conditions inhibit some of the system's functions, thus allowing minimum operation. These anomalies have an error code between **"E11"** and **"E13"**.

Errors detected during the emission phase can cause the timer to block the following exposures. These anomalies have an error code between **"E20"** and **"E25"**.

For any error typology, please refer to the following descriptions.

10.2.1 Non resettable errors

DISPLAY Signal	Type of ANOMALY	SOUND Signal	Checks and operations to be carried out
CHS	Memory Checksum Error (EEPROM + EPROM) and RAM test (1)	None	Contact Technical Service
E01	X-ray relay closed at power-on	None	Contact Technical Service
E02	Tubehead Supply Active at power-on	ACTIVE	Contact Technical Service
E03	External x-ray emission enabling <u>Primary</u> button depressed at power-on	None	Check that the primary x-ray button is depressed or in short-circuit, in this case contact Technical Service
E04	External x-ray emission enabling <u>Remote</u> button depressed at power-on	None	Check that the remote x-ray button is depressed or in short-circuit, in this case contact Technical Service
E05	Both external x-ray emission enabling buttons depressed at power-on	None	Check that both x-ray buttons are depressed or in short-circuit, in this case contact Technical Service
E06	System enabling button depressed at power-on	None	Check key board and contact Technical Service if required
E07	Digital selection button depressed at power-on (3)	None	Check key board and contact Technical Service if required
E08	"Increase" button depressed at power-on	None	Check key board and contact Technical Service if required
E09	"Decrease" button depressed at power-on	None	Check key board and contact Technical Service if required

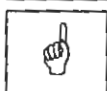


WARNING:

In case of error signal **"E02"**, immediately switch the system off, because unwanted x-ray emission is taking place.

10.2.2 Non-fatal errors during power-on phase

If, during the TEST phase, one of the anomalies considered "**RESETTABLE**" is detected, the system keeps the Anomaly signal on the display until the "increase" or the "decrease" button is depressed, thus bringing the system back to its Stand-By mode, displaying the exposure time.

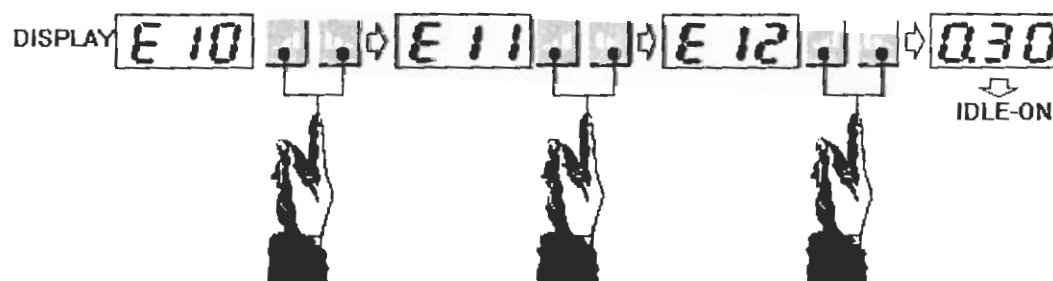


NOTE:

In case the system detects more than one Anomaly at a time, simultaneous depressing of the "increase" and "decrease" buttons shall display the sequence of errors detected. The system shall turn to its Stand-By mode only after the last value displayed has been reset and therefore pointed out to the user.

EXAMPLE:

ADULT/CHILD, SIZE and ANATOMIC TOOTH selection buttons already depressed upon Power-on (TEST) will lead to:



The display shows the user the kind of misfunctioning detected as follows:

DISPLAY Signal	Type of ANOMALY	SOUND Signal
E10	ADULT/CHILD selection button depressed at power-on	None
E11	SIZE selection button depressed at power-on	None
E12	Anatomic tooth button depressed at power-on	None
E13	OCCLUSAL selection button depressed at power-on	None

10.2.3 Errors during exposure phase

Non closing of x-ray selection

DISPLAY Signal	Type of ANOMALY	X-ray emission	Checks and operations to be carried out
E20	X-ray relay not closing within the set time	Emission not started	Contact Technical Service

Non-opening x-ray relay

DISPLAY Signal	Type of ANOMALY	X-ray emission	Checks and operations to be carried out
E21	X-ray relay not opening within 50 msec	Emission stopped by safety timer. Continuous BUZZER signal	Contact Technical Service

Non-closing of x-ray control

DISPLAY Signal	Type of ANOMALY	X-ray emission	Checks and operations to be carried out
E22	X-ray triac not closing within 50 msec	Emission not started	Contact Technical Service

Non-opening of x-ray triac

DISPLAY Signal	Type of ANOMALY	X-ray emission	Checks and operations to be carried out
E23	X-ray triac not opening within 50 msec	Emission stopped by safety timer. Continuous BUZZER signal	Contact Technical Service

X-ray relay closed upon cycle enabling

DISPLAY Signal	Type of ANOMALY	X-ray emission	Checks and operations to be carried out
E24	X-ray relay closed before x-ray cycle enabling	Emission not started	Contact Technical Service

Hardware timer intervention

DISPLAY Signal	Type of ANOMALY	X-ray emission	Checks and operations to be carried out
E25	Hardware timer intervention	Emission stopped by the hardware timer	Turn the system off and back on; if the problem persists contact Technical Service

11. MAINTENANCE

As any other electric appliance, this unit requires not only proper operation, but also regular maintenance and servicing. These precautions shall ensure safe and effective functioning of the system.

Periodic maintenance consists of checks directly effected by the operator and/or by Technical Service.

Checks directly effected by the operator may be:

- check that labels are intact and properly secured
- check that tubehead is free from oil residues
- check that the hand control cable is not broken or worn out
- check for external damage on the apparatus, which may prejudice protection against radiation
- check scissors arm balancing
- on the square arm check that, when the 2 sections of the arm are fully open (e.g. first arm in vertical position, second arm in horizontal position) they are perpendicular each other.

If instead the angle between the 2 sections of the arm is lower than 85°, check the position of the pivot holding the tube-head as follows:

- if it is perpendicular to the floor (angle between the pivot and the second section of the arm $>90^\circ$), perpendicularity between the 2 sections of the arm can be obtained by performing the Square arm balancing procedure (see paragraph 7.2.1)
- if the pivot holding the tube-head is not perpendicular to the floor (angle between the pivot and the second section of the arm $\neq 90^\circ$), then the arm needs refurbishing as, probably, the junction mechanism and the covers are worn out. This condition can be confirmed by the fact that the second arm has an evident mechanical play bringing it from rest position to horizontal position.



WARNING:

In case of irregularities or failures, the operator shall contact Technical Service.

MAINTENANCE LOG-BOOK

This log-book has to be filled in by the authorized VILLA SISTEMI MEDICAL engineer after installation and after performing the preventive or corrective maintenance visits.

Installation: Date Technician

Maintenance: Date Technician

Cause

Maintenance: Date Technician

Cause

Maintenance: Date Technician

Cause

Maintenance: Date Technician

Cause

Maintenance: Date Technician

Cause

Maintenance: Date Technician

Cause

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