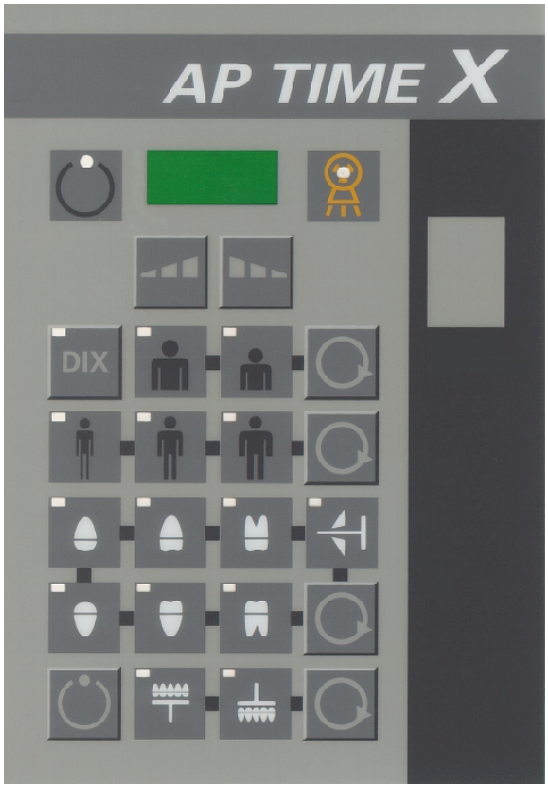
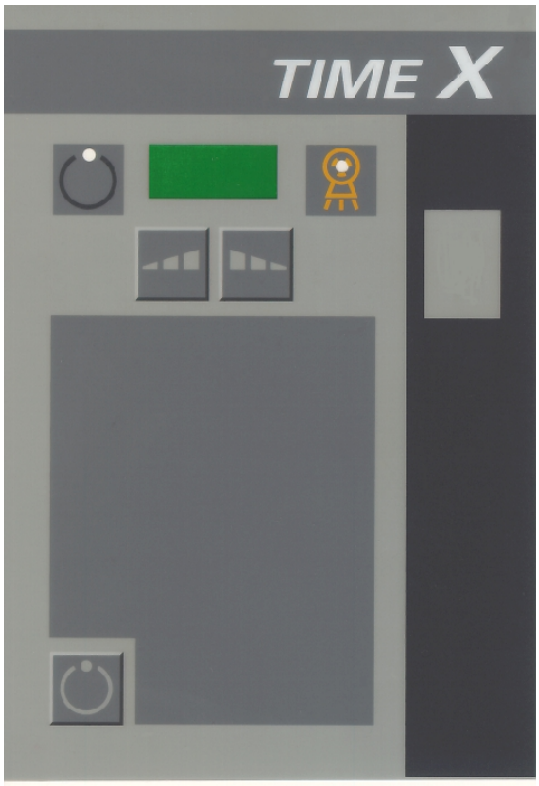
VILLA SISTEMI MEDICALI

EXPLOR-X 70

with AP TIME X – TIME X timer

(120V version)





User's manual

Release 16 March 2001 (Rev. 1)

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1. INTRODUCTION

NOTE:
The present manual is updated for the product it is sold with in order to grant an adequate reference to use properly and safely the product. The manual may not reflect changes to the product not impacting operating modes or safety.

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 repeatibility of exposure times, and is composed of the following parts:

- Timer: AP TIME X or TIME X complete with single stud mount wall plate
- Extension arm:
  - Square: 30cm (11 3/4"), 55cm (21 5/8"), 75cm (29 1/2"), 90cm (35 7/16")
  - Oval: 30cm (11 3/4"), 60cm (23 5/8"), 75cm (29 1/2"), 90cm (35 7/16")
- 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.

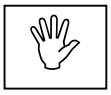
This manual is intended to assist the user in the safe and efficient operation of the equipment described.

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 with 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.

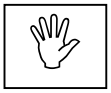
Explor-X 70 must be switched off during the use of High Frequency surgical device or similar instruments placed near the equipment.

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 if required.



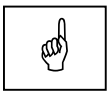
WARNING:
For safety purposes, it is forbidden to overload the extension arm and the scissors arm in an anomalous way, e.g. by hanging down from them.

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

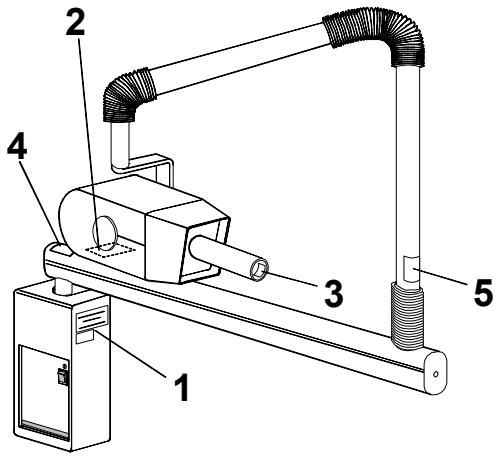
Use a soft cloth and gentle soap, paying attention not to damage painted surfaces.
During cleaning operation, prevent any detergent or other liquid from penetrating into the equipment or remaining on painted surfaces.

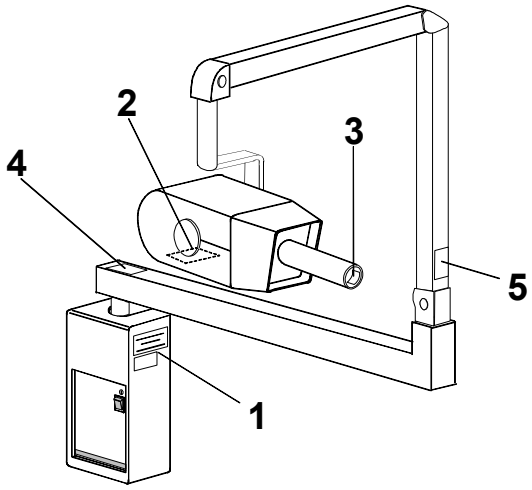
Parts in contact with the patient's skin

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

4. DESCRIPTION

4.1 Identification labels





1a
System timer features label

Made in Italy

Type: EXPLOR X 70

Line: 120 V ~ 8.2 A (at 132V ~) 60 Hz

X RAY CONTROL Model: 836037XX

Technique factors:

Time: from 0.04 to 3.2 s kVp: 70 mA: 8

S/N: 23XXYYYY Manufactured: *MMMM YYYY*

20090 Buccinasco
MILANO - ITALIA

THIS PRODUCT COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR SUBCHAPTER J, IN EFFECT AT DATE OF MANUFACTURE

1b
ETL certification label

ETL LISTED
CONFORMS TO UL STD 2601-1
2001443
CERTIFIED TO CAN/CSA STD C22.2 NO. 601.1

2
Tubehead features label

Made in Italy

TUBE HOUSING ASSEMBLY Model: 84604596

kVp:70 mA:8 Total filtration: 2 mm Aleq

S/N: 31XXYYYY Manufactured: ***MMMM YYYY***

X RAY TUBE Model D082 B

Manufacturer Toshiba JAPAN

Focus:0.8 Inherent filtration:0.5 mm Aleq

S/N: .....

20090 Buccinasco
MILANO - ITALIA

THIS PRODUCT COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR SUBCHAPTER J, IN EFFECT AT DATE OF MANUFACTURE

3
Beam limiting device features label

Made in Italy

BEAM LIMITING DEVICE Model: 61604059

DIAMETER 6 cm AT SSD 20 cm

S/N: **40XXYYYY**

Manufactured: *MMMM YYYY*

20090 Buccinasco
MILANO - ITALIA

THIS PRODUCT COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR SUBCHAPTER J, IN EFFECT AT DATE OF MANUFACTURE

4
Extension arm features label

5
Scissors arm features label

Made in Italy

Model AAAAAAAA

Serial number

BBXXYYYY

20090 BUCCINASCO
MILANO - ITALIA

Settled for

EXPLOR-X 70

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

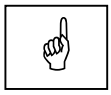
The Explor-X 70 may be equipped with two different types of Timer:

- **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 120V ± 10%.

- **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

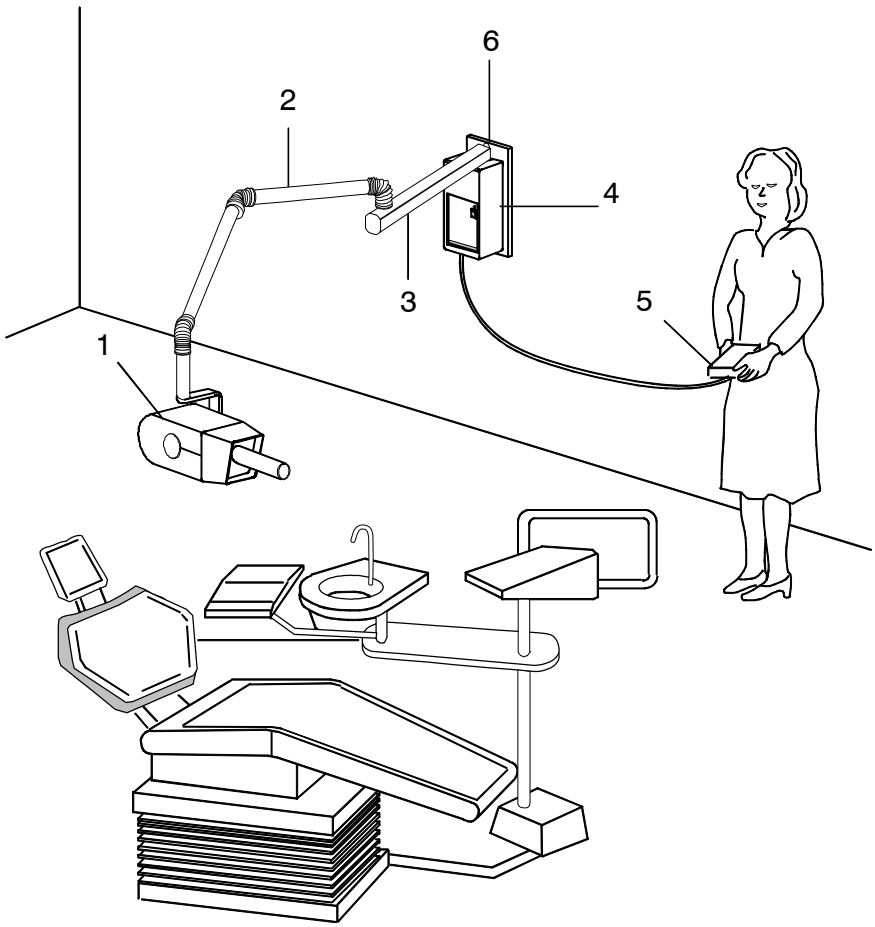


Figure 1

1 Tubehead
2 Scissors arm
3 Extension arm
4 Wall plate + Timer
5 X-ray button
6 Single stud center wall plate

4.3.2 Remote timer configuration

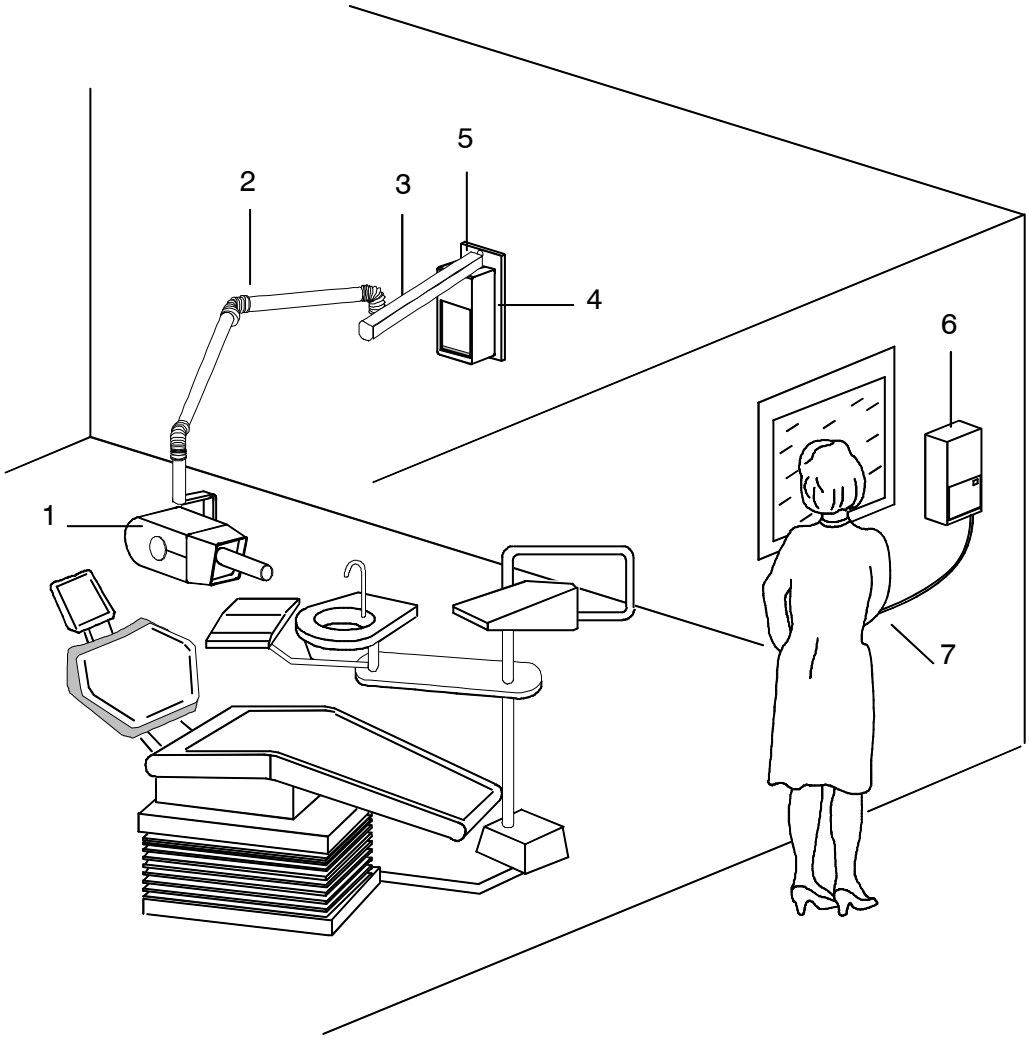


Figure 2

1 Tubehead
2 Scissors arm
3 Extension arm
4 Wall plate
5 Single stud center wall plate
6 Remote timer
7 X-ray button

4.3.3 Mobile stand configuration

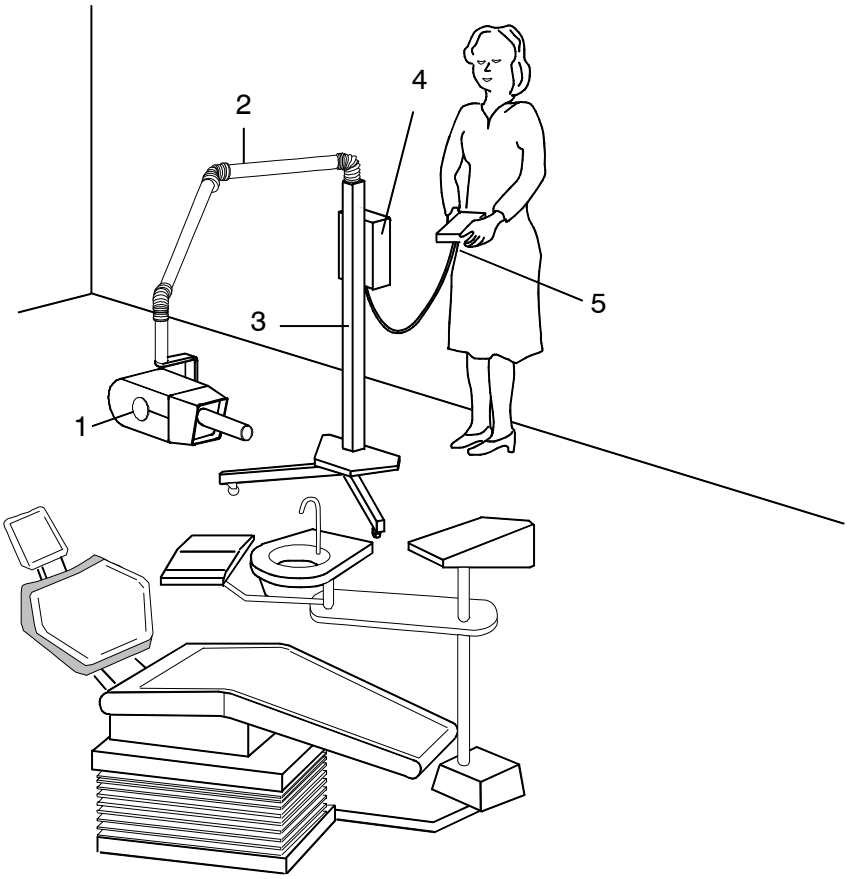


Figure 3

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

4.3.4 Configuration with remote X-ray button

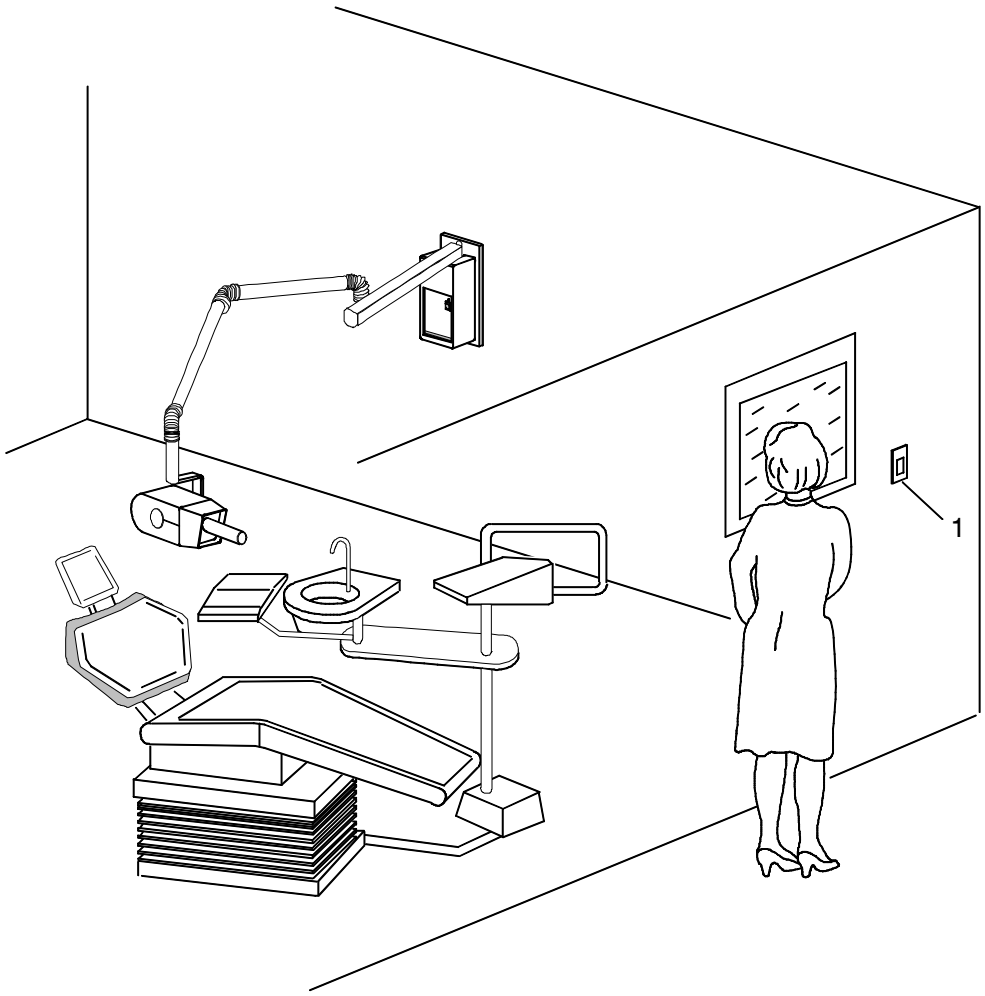


Figure 4

1 X-ray button

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); Class II according to 21 CFR 
Line voltage	120V~ ± 10%
Line frequency	60Hz
Rated current	8.2A rms @ 132V ~
Power consumption	1.1 kVA @ 132V ~
Line Voltage Regulation	≤ 3% at 132V ~
Main fuse	10A 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 control	Microprocessor controlled exposure times, with automatic compensation of line voltage fluctuations.
TIMER ACCURACY on the CORRECTED EXPOSURE TIME (This is the actual time of exposure, pre-indicated on the timer during the enabled status and during emission and determined by the internal algorithm as a function of the line voltage) **See Paragraph 5.1!!!**	± 2 pulses (± 32 ms)
TIMER ACCURACY on the PRE-SELECTED EXPOSURE TIME (This is the value of the timer setting the operator pre-selects)	The absolute maximum deviation can be +200% ; -100% when the line voltage changes within the rated voltage range: it includes intrinsic inaccuracy and correction due to line voltage changes. **See Paragraph 5.1!!!** (The inaccuracy at 120V is ±32ms)
Timer dimension	31x17x10cm (12x7x4 inches)

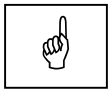
Tubehead features	
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italy
Rated output voltage	70kV$_p$ ±15%
High voltage circuit type	Single phase, self-rectifying
Tubehead current	8mA
Tubehead power	0.8kW
Total filtration	2mm Al eq. @ 70kV$_p$
Transformer insulation	Oil bath
Cooling	Convection
Maximum deviation of output current	±4.5mA
Pre-heating time	250ms
Interval between exposure/duty cycle	60 times X-ray time / 1:60
Minimum focus to skin distance	20cm (7 7/8”)
X-ray beam diameter (@ 20cm focus)	6cm (2 3/8”)
Radiation leakage at 1m	<25 mR/h, duty cycle 1:60 (at 132V~)
Technical factors for radiation leakage	70kV, 8mA, 1s
X-ray tube features	
Manufacturer	Toshiba (Japan)
Type	D-082B
Focal spot	0.8 (IEC 336)
Inherent filtration	0.5mm Al equivalent
Anode thermal capacity	6kJ
Environmental conditions	
Operating temperature range	+50°F ÷ +104°F (+10°C ÷ +40°C)
Operating relative humidity range	30% ÷ 75%
Temperature range for transport and storage	-4°F ÷ +168°F(-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	35kg
Net apparatus weight in standard configuration	30kg
30cm (11 3/4") extension arm	2.9kg
60cm (23 5/8") extension arm	4.3kg
75cm (29 1/2") extension arm	5kg
90cm (35 7/16") extension arm	5.7kg
Scissors arm	6kg
Timer plus wall plate	8.3kg
Tubehead	8.5kg

5.1 Exposure time correction algorithm

The Explor-X 70 timers carries a special feature that allows automatic correction of 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 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 (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.

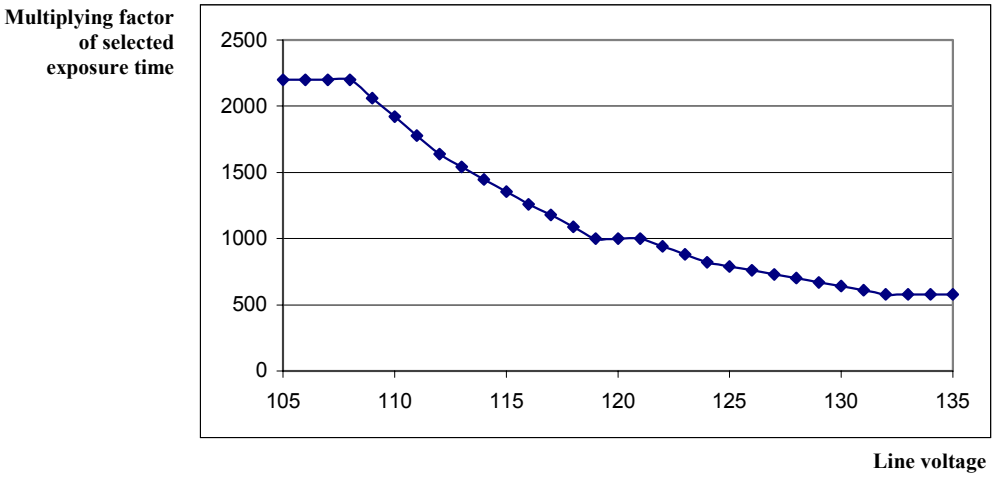
The automatic correction of the exposure time works with the following sequence: the internal voltmeter of the timer monitors continuously the line voltage while the user selects the desired exposure times. Once the user has selected the exposure time that is thought adequate to obtain the proper quality of the image for that specific test, the user presses the "READY" 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. When the user presses the X-ray button, the exposure will start implementing the last displayed pre-indicated time and the display will maintain the indication of the actual exposure time until the X-ray button is released. The actual exposure time of the last exposure can be retrieved any time by pressing the X-ray button without having enabled the system; in this case no X-ray emission is generated and the last exposure time is displayed.



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



The following table allows to establish pre-indicated times and final real exposure times as a function of reselected time and line voltage variation.

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 intrinsic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to intrinsic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to intrinsic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to intrinsic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to intrinsic inaccuracy	corrected exposure time (on the basis of current line voltage) (1)	max/min exposure time due to intrinsic inaccuracy
line voltage correction factor:	2,2		1,64		1,16		0,82		0,7		0,58	
preselected time (ms)												
40	88	120	66	98	46	78	33	65	28	60	23	55
		0		0		0		0		0		0
60	132	164	98	130	70	102	49	81	42	74	35	67
		100		66		38		17		10		3
100	220	252	164	196	116	148	82	114	70	102	58	90
		188		132		84		50		38		26
200	440	472	328	360	232	264	164	196	140	172	116	148
		408		296		200		132		108		84
400	880	912	656	688	464	496	328	360	280	312	232	264
		848		624		432		296		248		200
800	1760	1792	1312	1344	928	960	656	688	560	592	464	496
		1728		1280		896		624		528		432
1000	2200	2232	1640	1672	1160	1192	820	852	700	732	580	612
		2168		1608		1128		788		668		548
1200	2640	2672	1968	2000	1392	1424	984	1016	840	872	696	728
		2608		1936		1360		952		808		664
1500	3300	3332	2460	2492	1740	1772	1230	1262	1050	1082	870	902
		3268		2428		1708		1198		1018		838
2000	4400	no exposure	3280	3312	2320	2352	1640	1672	1400	1432	1160	1192
		no exposure		3248		2288		1608		1368		1128
2500	5500	no exposure	4100	no exposure	2900	2932	2050	2082	1750	1782	1450	1482
		no exposure		no exposure		2868		2018		1718		1418
3000	6600	no exposure	4920	no exposure	3480	3512	2460	2492	2100	2132	1740	1772
		no exposure		no exposure		3448		2428		2068		1708
(1) IT IS THE PREINDICATED VALUE OF EXPOSURE TIME DISPLAYED BY THE TIMER DURING THE ENABLE STATUS												
no exposure = the timer does not allow exposure times longer than 4 sec												

5.2 Technical factors measuring method

kV_p The kV_p is defined as the stationary high voltage value which settles under load after pre-heating time.
The kV_p is assessed with a non-invasive instrument having a ± 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 that 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 ± 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 pulse counter, measuring pulses of the input line voltage during the loading time; this loading time is defined as the time during which the voltage is applied to the tubehead. This loading time is obtained by the sum of the pre heating time (fixed and equal to 250 ms) and the corrected exposure time, displayed on the timer during "exposure enabled" time and during exposure itself. To perform the measurement, the pulse counter has to be connected to terminal X3 and X4 of the power board of the timer.
The number of pulses measured by the instruments has to be converted to exposure time, measured in seconds; to do so, subtract 15 pulses (corresponding to the fixed pre heating time of .25 s) and multiply the result by .017.
As explained before, the time is synchronous with the line frequency, so time round off is possible.

The following table gives example of conversion of exposure time to pulses and vice versa.

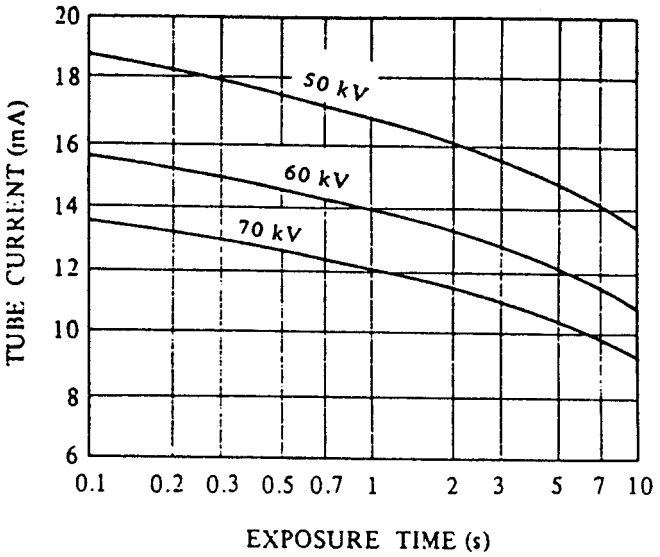
Exposure time	Line Voltage	Multiplying factor	Corrected exposure time	Measured pulses	Measured pulses - 25
0.10	120	1.00	0.100	31	6
0.10	116	1.16	0.116	32	7
0.10	128	0.70	0.070	29	4
1.00	120	1.00	1.00	85	60
1.00	112	1.64	1.64	114	89
1.50	120	1.00	1.50	115	90
2.00	120	1.00	2.00	145	120

5.3 X-ray tubehead curves

TOSHIBA D-082 B

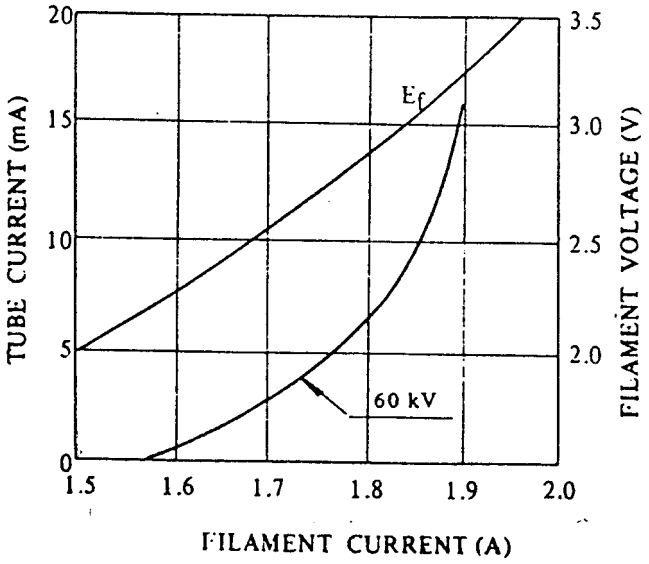
Emission and filament features

Self-Rectified
Focal Spot : 0.8 mm

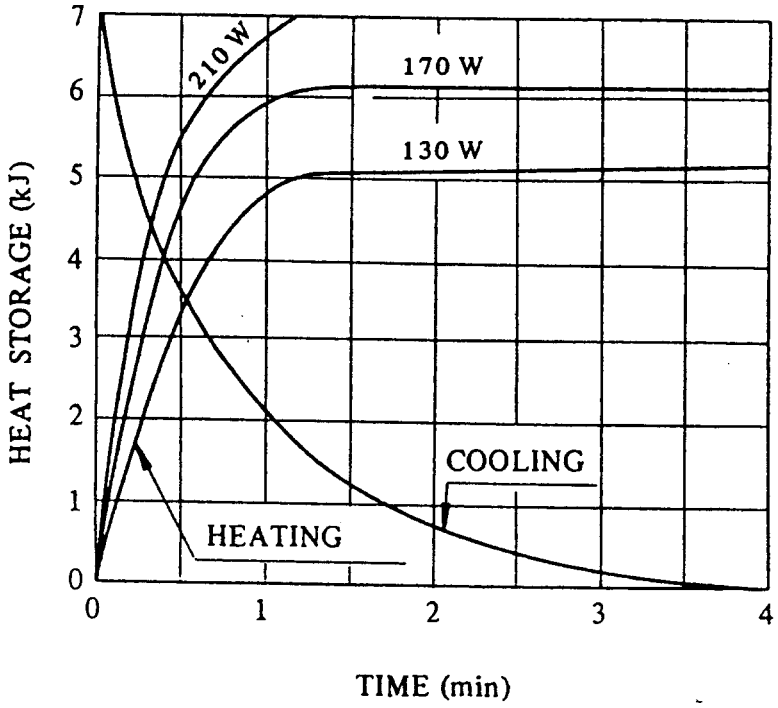


Load

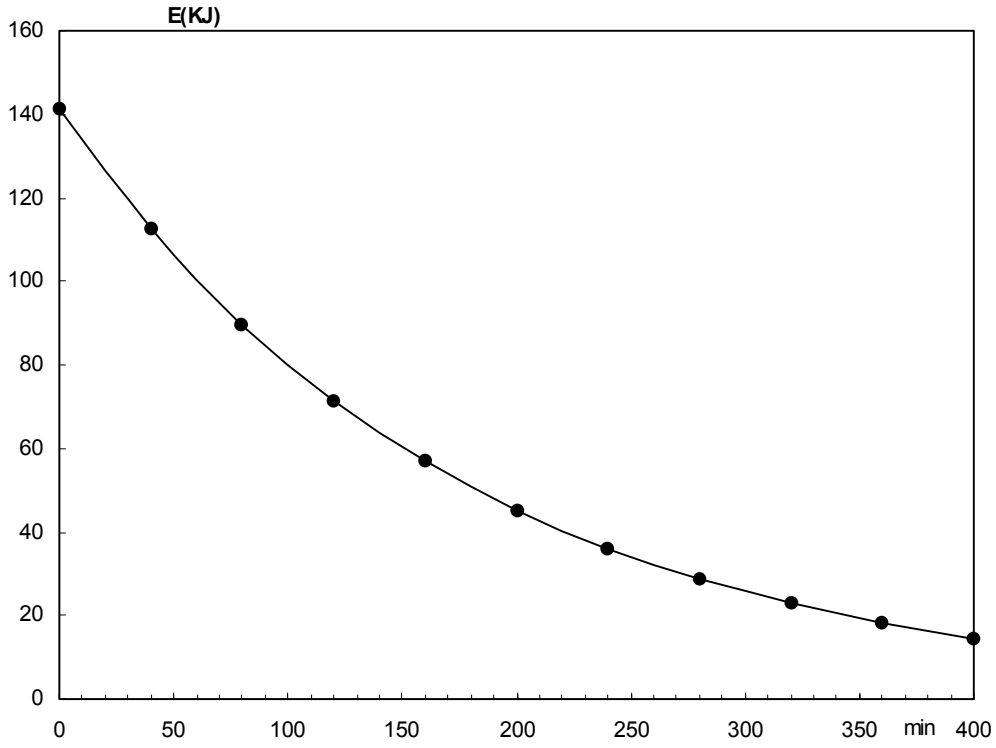
Self-Rectified



Cooling curve



COOLING CURVE OF TUBEHEAD



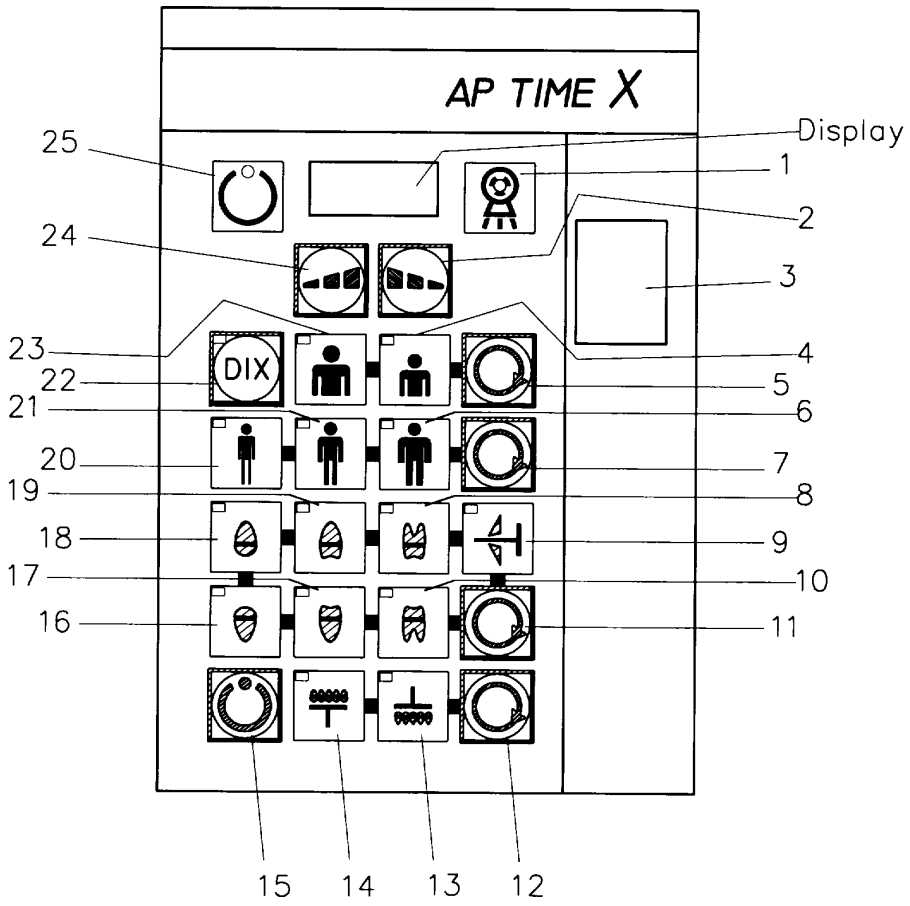
5.4 Standards and regulation

Explor-X 70 is designed and produced to meet the following standards:

- 21 CFR
- UL 187
- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2

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.

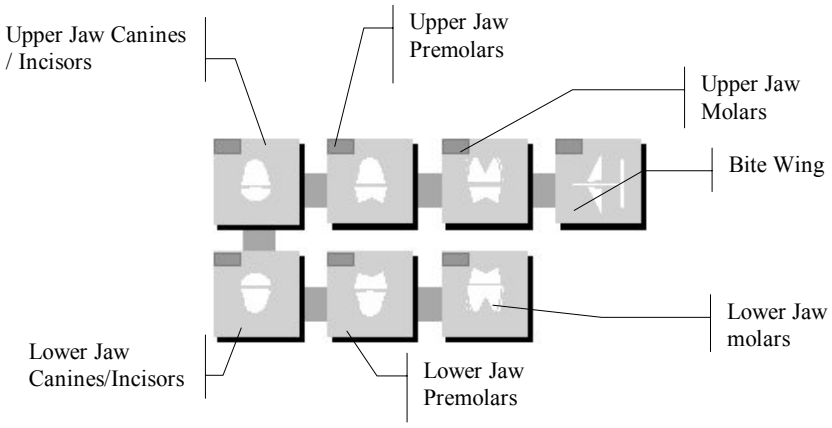
"SIZE" selection key

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.

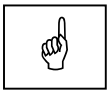


Upper- or Lower-jaw "OCCLUSAL" selection key

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

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), after which the function is disabled and the pressing of the exposure button does not cause X-ray emission.



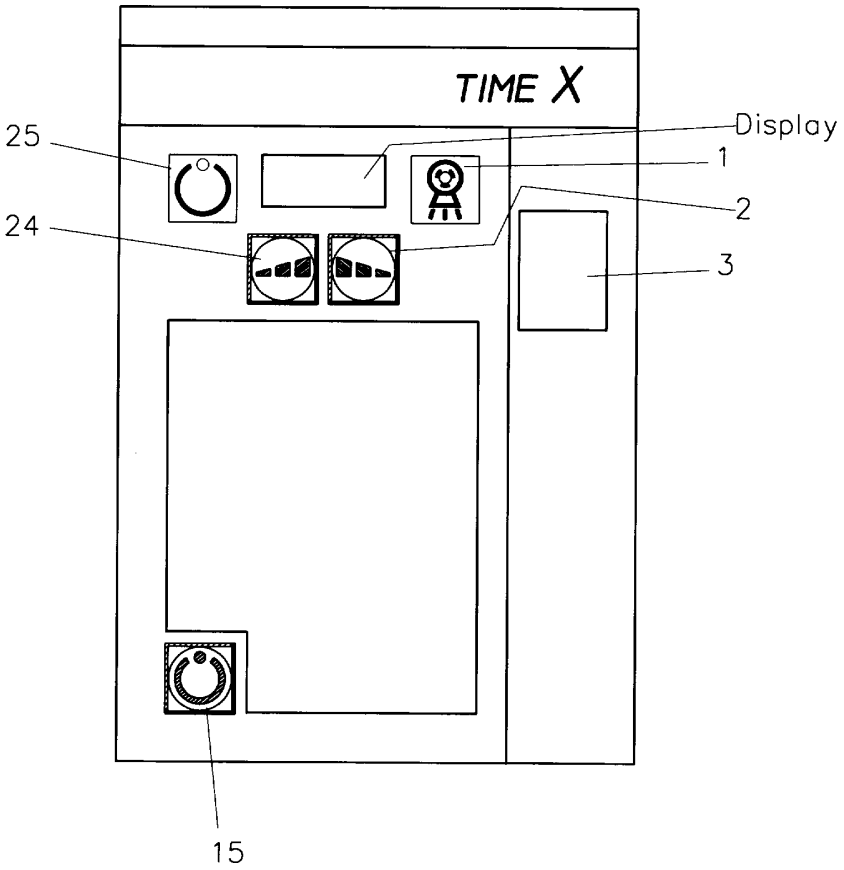
NOTE:
Pressing the "Ready" key, the system will be ready for the exposure and also it will starting showing on the display the exposure time corrected according to the internal line voltage fluctuation algorithm (please see paragraph 5.1).

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 

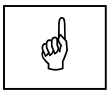
By depressing one of the above keys, the exposure time is selected among the 32 times available.
When the button is pressed once, the time set as default is displayed; to change it, release the button and depress it again; rapid selection is also possible, by keeping the button depressed; this way, the 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 paragraph 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), 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 starting showing on the display the exposure time corrected according to the internal line voltage fluctuation algorithm (please see paragraph 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. 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

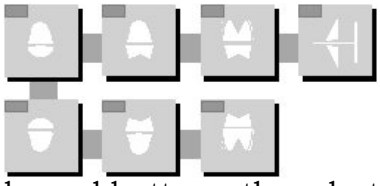
a) Depress Main Switch placed in the front part of the cover. This operation will turn on the system self check function.

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 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.

7.1.2 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 paragraph 5.1 and 5.2.

7.1.3 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 DIX 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 DIX button once again.

7.2 Preparing the tubehead

a) Arrange the tubehead with an angle suitable for the required exposure and positioning (See Figure 5 ÷ Figure 8).

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 beam limited near the patient and direct it exactly towards the tooth under examination by referring to the following figures.

MANDIBLE

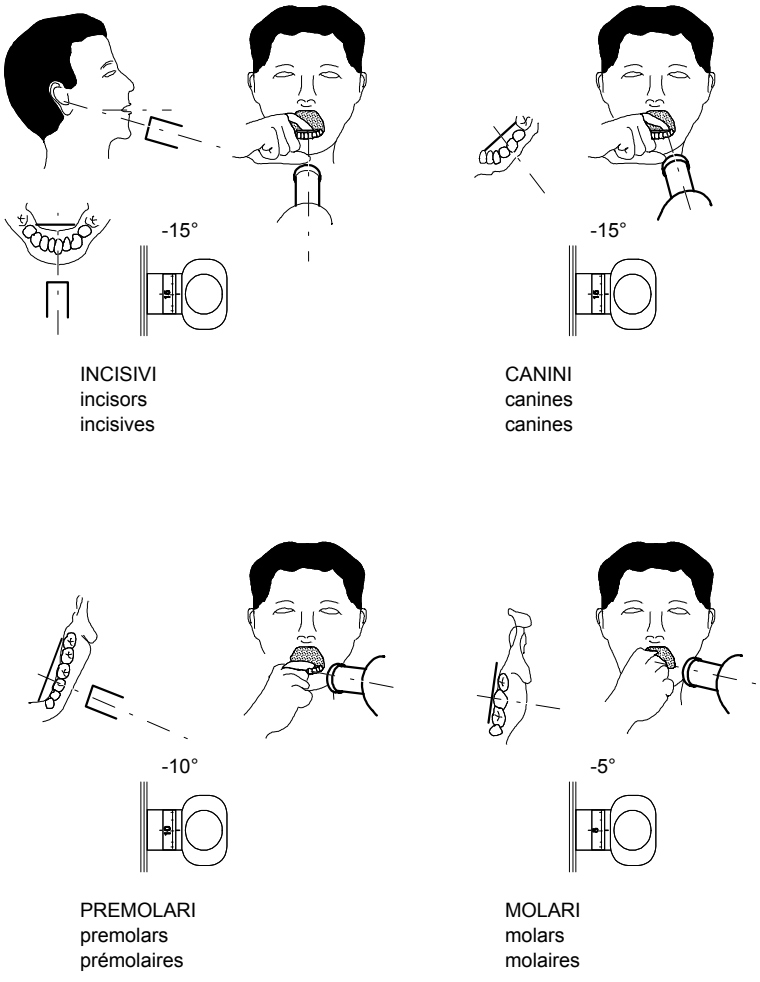


Figure 5

MAXILLA

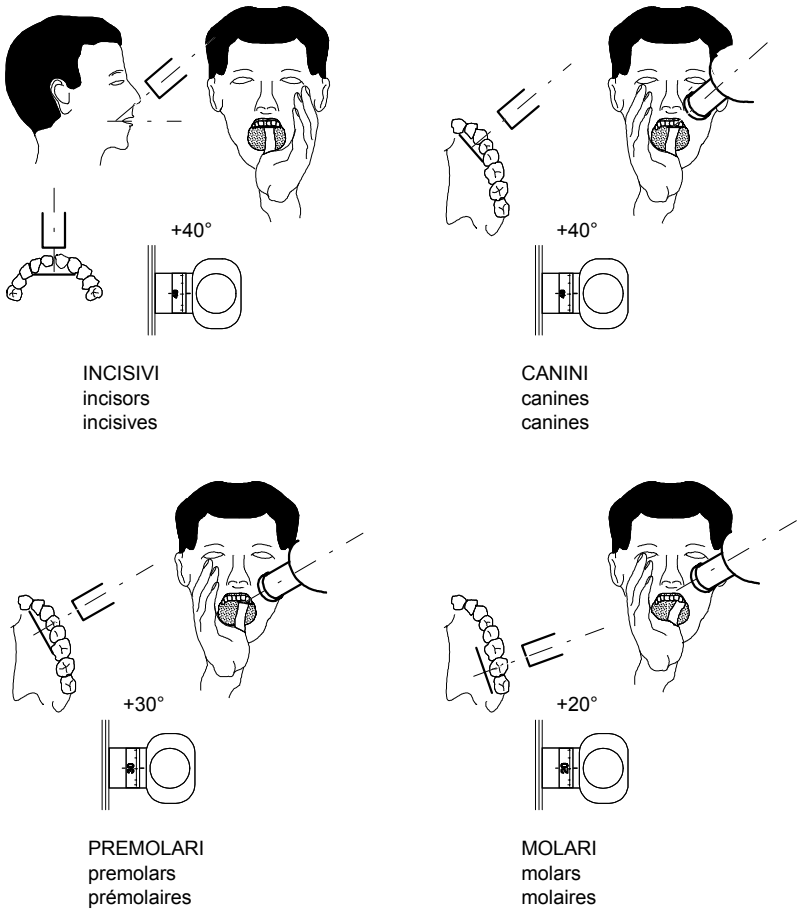


Figure 6

OCCLUSAL

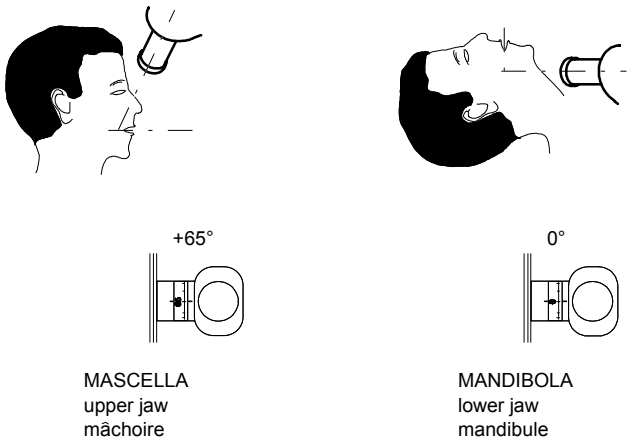


Figure 7

BITE WING

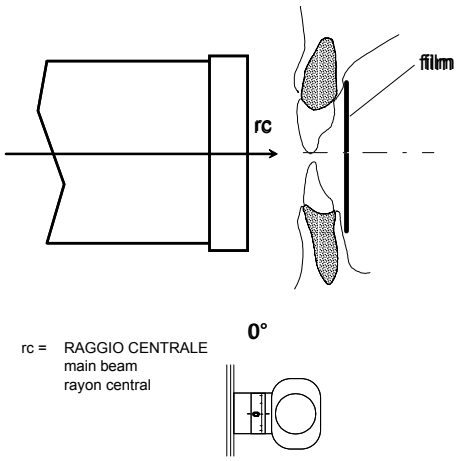


Figure 8

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.

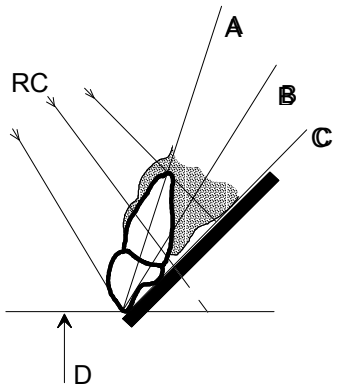


Figure 9

Key to Figure 9:

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 10), in order to prevent structures from overlapping (See Figure 11).

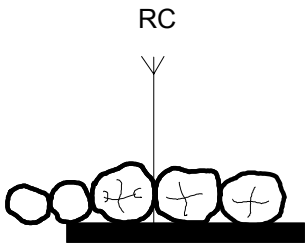


Figure 10
(Correct position)

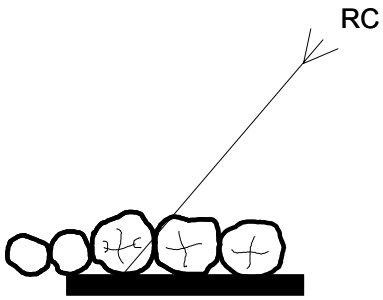


Figure 11
(Wrong position)

Key to Figure 10 and Figure 11

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 Figure 12 and Figure 13).

HORIZONTAL SECTION

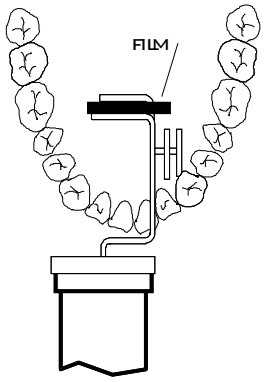


Figure 12

VERTICAL SECTION

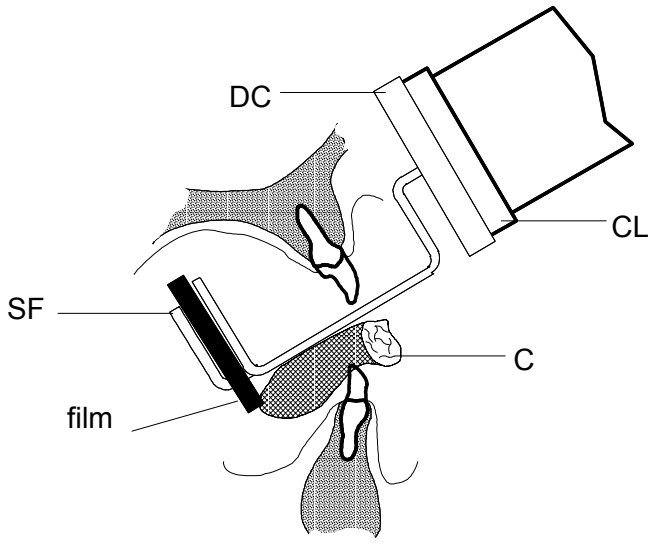


Figure 13

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 paragraph 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

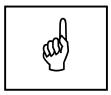
e) The starting of exposure is indicated by the glowing of the green light and by a sound signal.

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 exceeds the set limits (-10% and +10%), 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 it 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

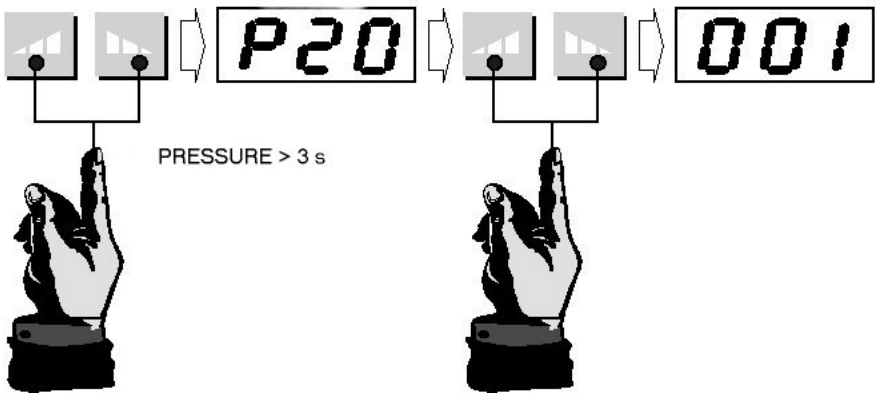
The user has the possibility to display two functional parameters:

7.5.1 Exposure counter

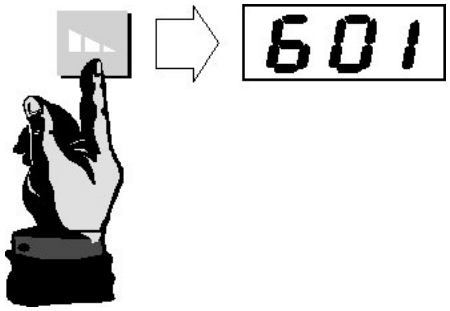
In the Stand-By mode, the number of exposures carried out (since the last counter reset) can be displayed following this procedure:

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 o 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

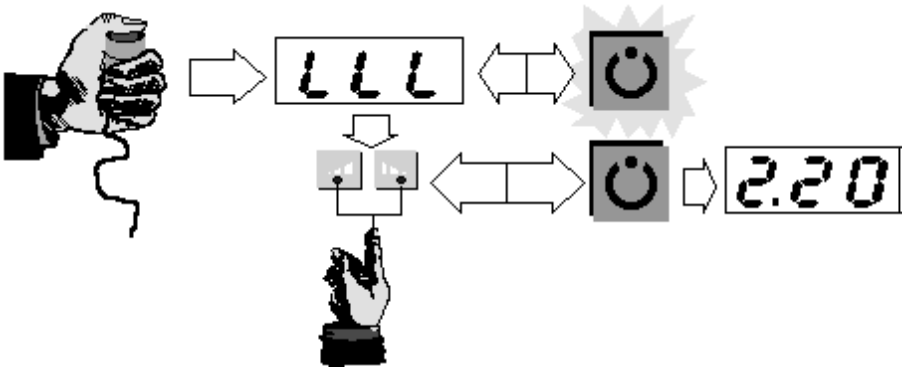
The display of AP TIME X or TIME X timer is used also to visualize messages that explain the status of the unit. These messages are related to conditions that inhibit the emission or errors occurred during the functioning.

10.1 Exposure-inhibiting conditions

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

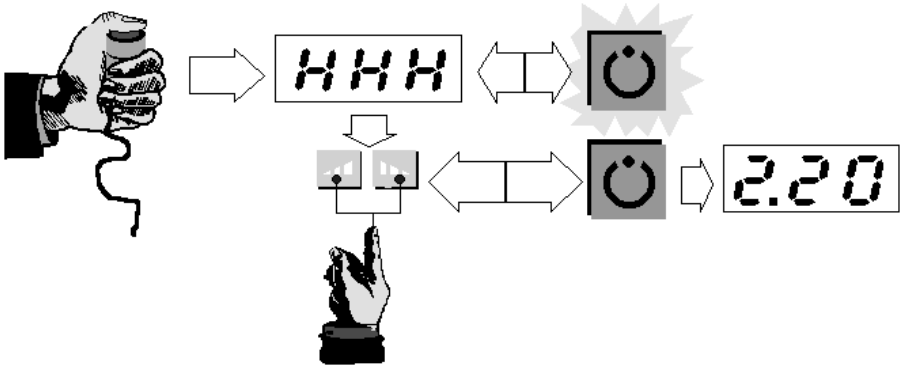
- **Input line voltage below rated voltage by 12.1%**

  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.



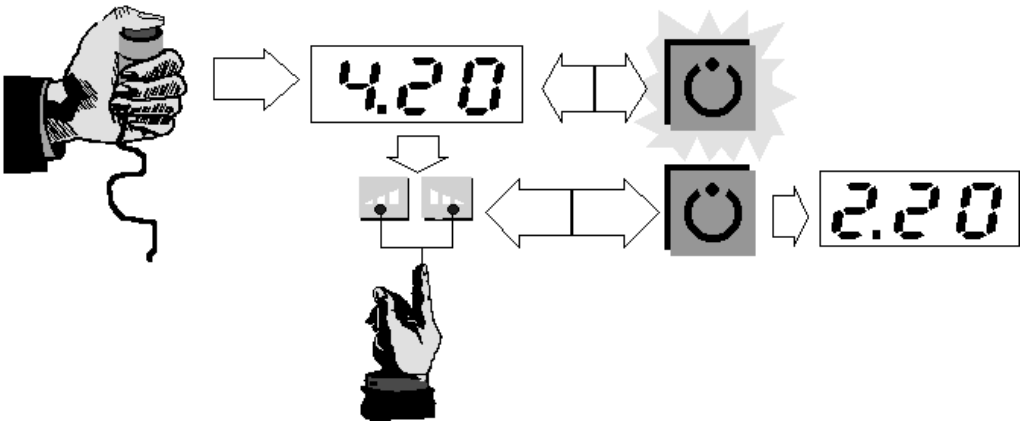
- **Input line voltage above rated voltage by 12.1%**

  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.

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 Primary 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 Remote 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:

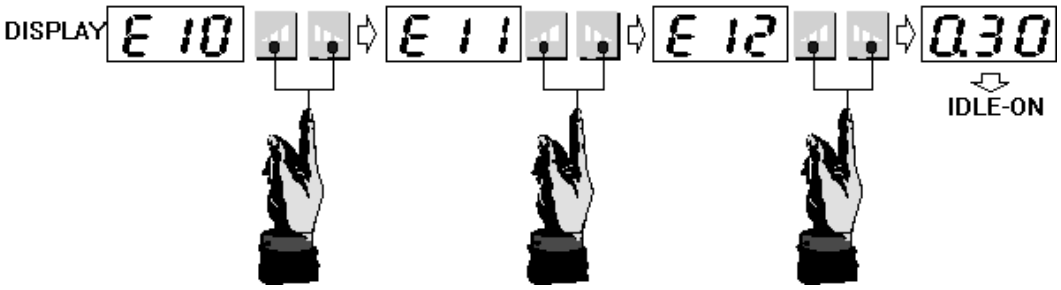
In case of error signal **"E02"**, immediately switch the system off, because unwanted X-ray emission is taking place.

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

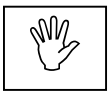
11. MAINTENANCE

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
- check centering of X-ray beam.



WARNING:
Checks must be performed before any operating session.
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 MEDICALI 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 .....

Maintenance: Date ..... Technician .....

Cause .....

Cod. 6960925000_Rev.1

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