VILLA SISTEMI MEDICALI

ENDOS DC

CE 0434

User's Manual

Release 16 April 2003 (Rev. 0)

Contents

1. INTRODUCTION

NOTA:
This manual is updated to the product status it is sold with, to guarantee the user an adequate reference when using the equipment and for everything connected with its use safety. The manual may not reflect product variations without any impacts on operative mode and safety.

The intraoral radiographic ENDOS DC, produces high quality intraoral X-rays, thanks to the exam repetitiveness combined with reduced exposure times and the small dimensions of the focal spot.

ENDOS DC is designed exclusively for performing intraoral X-rays.

The equipment has the following features:

- very good quality X-rays pictures
- user friendly
- ergonomic design.

The purpose of this manual is to provide the user with instructions that will allow him to run the equipment safely and efficiently.

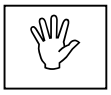
The equipment must be used according to the procedures in the manual and never for different purposes from the ones for which it has been designed.

1.1 Icons in the manual

Indicates a "NOTE"; we recommend particular attention in reading the subjects identified with this icon.

Indicates a "WARNING"; subjects identified with this icon concern safety aspects regarding the patient and/or the operator.

2. SAFETY ASPECTS



WARNING:
Read this chapter very carefully.

Villa Sistemi Medicali design and make their equipment according to safety requirements; moreover, they supply all necessary information for appropriate use and warnings relating to dangers connected with X-ray generators.

The manufacturer does not accept any responsibility for:

- use of ENDOS DC equipment for purposes other than those for which it has been designed,
- damages to the equipment, the operator, the patient caused both by wrong installations and maintenance that do not follow the procedures contained in the User's and Service Manuals provided with the equipment, and by wrong operating techniques,
- mechanical and / or electrical changes, made during and after installation, that differ from the ones in the Service Manual.

Only personnel authorised by the manufacturer may carry out technical work on the equipment.

Only authorised personnel can remove the tubehead from its support and/or gain access to live parts.

2.1 Warnings

The equipment must be used according to the procedures in this manual and never for different purposes from the ones for which it has been designed.

Before carrying out any maintenance disconnect the equipment from the power line using the circuit breaker provided.

ENDOS DC is an electro-medical device and for this reason can be used only under the supervision of highly qualified medical staff in possession of all the necessary knowledge about X-ray protection.

The user is responsible for fulfilling all the legal requirements connected with the possession, installation and use of the equipment itself.

ENDOS DC is built for continuous running with intermittent load; for this reason the planned duty cycle must be observed.

Appropriate accessories, such as lead aprons, must be used, where necessary, to protect the patient from radiation.

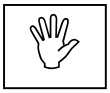
Although the equipment is designed to provide a reasonable degree of protection from electromagnetic interference, according to IEC International regulations, it must be installed at an adequate distance from electricity transformer rooms, static continuity units, two-way amateur radios and cellular phones. The latter can be used only at a minimum distance of 1.5m from any part of the equipment.

Any instrumentation or equipment for professional use located near ENDOS DC must conform to Electromagnetic Compatibility regulations. Non conforming equipment, with known poor immunity to electromagnetic fields, must be installed at a distance of at least 3m from ENDOS DC and supplied by a dedicated electric line.

ENDOS DC must be turned off when using electro-cautery or similar equipment in the vicinity of the equipment itself.

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

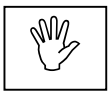
Equipment parts which may come into contact with the patient must be cleaned regularly according to the instructions given later in this document.



WARNING:
For safety reasons, it is forbidden to overload the extension arm or the scissors arm in an anomalous way, for example by leaning on them.

2.2 Protection from X-rays

Although dosage given by modern X-ray equipment is low on average, during the execution of the exposure, the operator must take all precautions to protect the patient and himself in compliance with the regulations in force.



WARNING:
Protection from X-ray radiation is regulated by law. The equipment must be used by specialised personnel only.

a) The film (or the digital sensor) must be put into the patient's mouth manually or using the appropriate supports. If possible it must be held by the patient himself.

b) During X-ray exposure, the operator must not come into contact with the tubehead or the collimator cone.

c) During exposure, the operator must be at a certain distance from the X-ray source (at least 2 metres), in the opposite direction to X-ray beam.

d) During exposure, the operator and the patient are the only people allowed in the room.

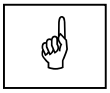
e) The lead aprons should be used to reduce the undesirable effect of secondary radiation on the patient.

2.3 Environmental risks and disposal

Some parts of the equipment contain material and fluids which must be disposed of in special areas designated by the local health authorities at the end of the equipment's life cycle.

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

- **Tubehead:** external packages in non-biodegradable plastic, dielectric oil, lead, copper, brass, aluminium, resin, tungsten, beryllium
- **Power supply and remote control:** external packages in non biodegradable plastic, iron, copper, plastic reinforced by fibre glass
- **Tubehead extension:** iron, aluminium, copper.



NOTE:
The Manufacturer and the Distributor do not accept any responsibility for the disposal of equipment or parts discarded by the user and the related costs.

2.4 Symbols in use

The following symbols are used in this manual and on ENDOS DC:

Symbol	Description
	Equipment with Type B applied parts
~	Alternate current
N	Connecting point to the neutral conductor
L	Connecting point to the live conductor
	Protection ground
	Functional ground
	OFF ; equipment not connected to the electric line
|	ON ; equipment connected to the electric line
	Permission key to exposure; the permitted exposure status is displayed by switching on the corresponding green symbol
	Focal spot according IEC 336
	X-ray emission

3. CLEANING AND DISINFECTION

The following procedures should be observed carefully in order to guarantee accurate hygiene and cleaning:

- **Before cleaning the equipment disconnect it from the line using the cut-out switch which must be provided when setting up. This operation is necessary as some internal parts remain live even after it has been switched off from the on-board switch.**

- Be careful not to let water or other fluids enter the equipment in order not to cause a short circuit and corrosions.

- Never use solvents (alcohol, petrol, Trichloroethylene), corrosive or abrasive substances when cleaning.

External surfaces

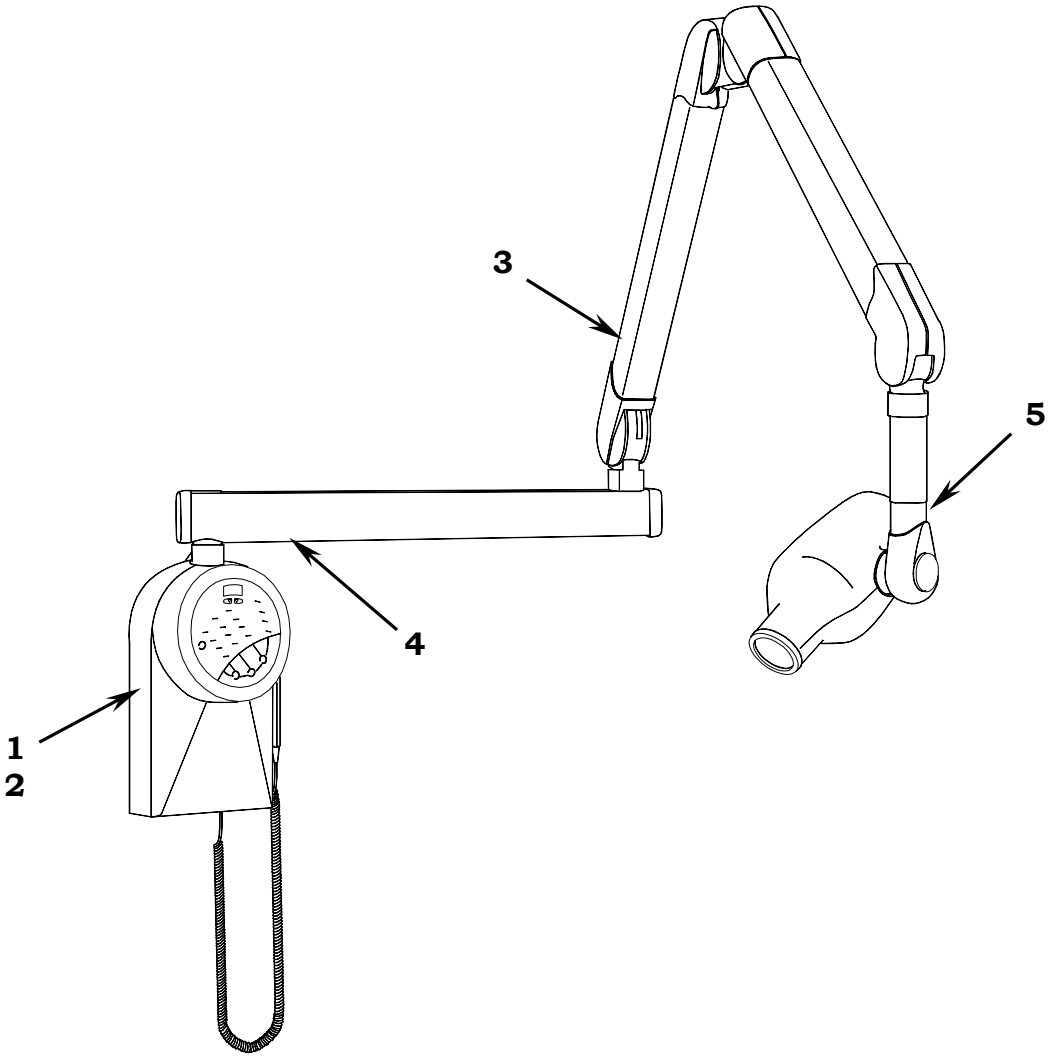
Use a soft cloth and, for a stronger action, a neutral soap to prevent damaging painted surfaces.
During cleaning operations, prevent surplus detergent and/or fluids entering the equipment or staying on painted surfaces.

Parts that come into contact with the patient's skin

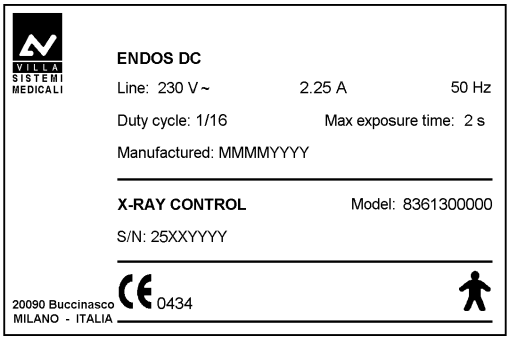
These parts should be disinfected at regular intervals with a 2% Glutaraldeide solution to guarantee hygiene.

4. DESCRIPTION

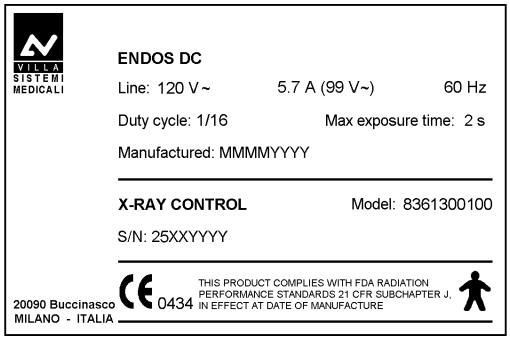
4.1 Identification labels



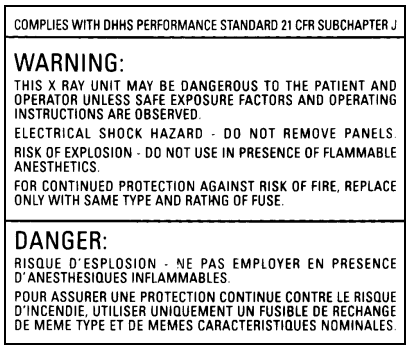
1a
ENDOS DC label (230V version)



1b
ENDOS DC label (120V version)

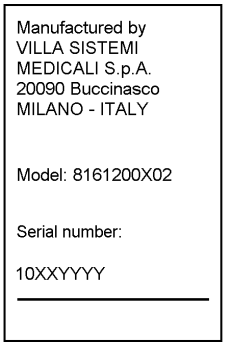


2
"WARNING" label
(only for 120V version)

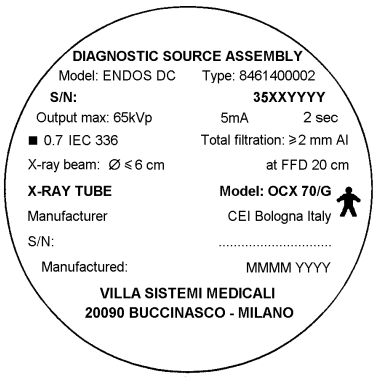


3
DP arm
label

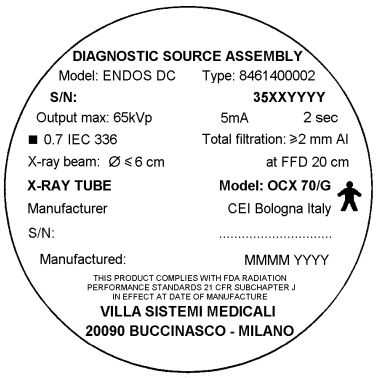
4
Extension arm
label



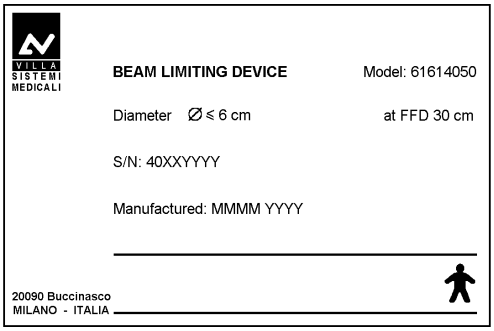
5a
Tubehead label (230V version)



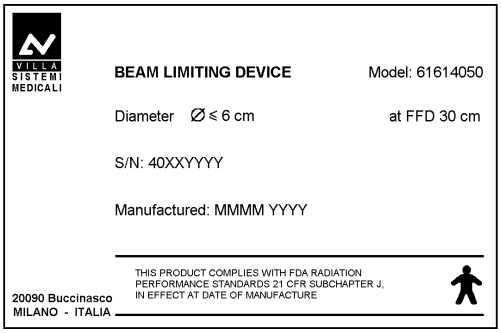
5b
Tubehead label (120V version)



6a
Collimator 30cm label
(optional – 230V version)



6b
Collimator 30cm label
(optional – 120V version)



4.2 Functions

4.2.1 ENDOS DC

ENDOS DC is able to produce excellent quality X-rays thanks to parameters repeatability and has very short exposure times and a very small focal spot.

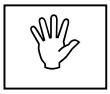
ENDOS DC X-ray equipment is compatible with VIDEORADIOGRAPHY equipment systems (Digital image acquisition equipment) and incorporates the latest digital X-ray intraoral technology.

If you do not possess VIDEORADIOGRAPHY equipment you are recommended to use high-speed films or EKTASPEED films (Kodak) in order to limit the dosage absorbed by the patient.

The working mode can be selected using the control keyboard, with the possibility of choosing between two films of a different speed (sensibility), the digital sensor or a mode that can be customised by the user, called "Custom".

ENDOS DC equipment can use the optional 30cm collimator cone (to be ordered separately with 6161405000 code); the change from standard cone (20 cm) to 30 cm cone (or vice versa) is possible using a special key; the "long cone inserted" selection is displayed by the LED (**23**) start-up.

The change from standard cone (20 cm) to long cone (30 cm) is made by touching keys "film speed" (**13**) and "increase" (**2**) at the same time and it is indicated by the LED (**23**). In this selection, pre-set exposure times in anatomic selection are automatically increased by a multiplication factor equal to 2.
Vice versa, the change from long cone to standard cone is achieved by touching keys "film speed" (**13**) and "decrease" (**1**) at the same time.



WARNING:
ENDOS DC equipment does not automatically detect the presence of the type of cone: it is the operator's responsibility to check that the luminous sign does actually indicate the true situation.

4.2.2 High frequency generator (or HF)

ENDOS DC is composed of a generator, a tubehead including a collimator, a CPU card (or logic) which controls the equipment functions and a keyboard used to select exposure parameters. The standard configuration provides a keyboard directly connected to the CPU card, while an optional configuration allows the keyboard to be set up in remote control; in this case, instead of the X-ray button you can use the key provided directly on the keyboard itself.

The HF generator, driven by remote control, linked with the tubehead, uses microcontroller technology know-how to get very good quality X-rays and, at the same time, reducing the X-ray dose to the patient. Conventional equipment generally uses the intrinsic skill of the RX generator tube to conduct electric current in only one way. In this way you get the generation of a "train" of RX pulses. Vice versa ENDOS DC apparatus, uses the "constant tension" technology generating a continuous and steady exposure. Moreover, the emission of soft X-rays is so small that it ensures that emission parameters, kVp and mA are constant throughout exposure time. The control microprocessor ensures that exposure times remain constant and that they can be repeated; exposure voltage and exposure times depending on the patient's size and the selected tooth can be selected simply by pressing a key.

The HF tubehead is much smaller thanks to the back positioning of the X-ray tube; the length is only 27 cm, while the focus-skin distance remain at the standard 20 cm. Because the tubehead is so light (only 4.5 Kg.) the arm is remarkably easy to handle.

4.3 Configurations

4.3.1 Standard configuration

ENDOS DC is manufactured in standard configuration (9461000013 code) composed of the parts defined in the following picture:

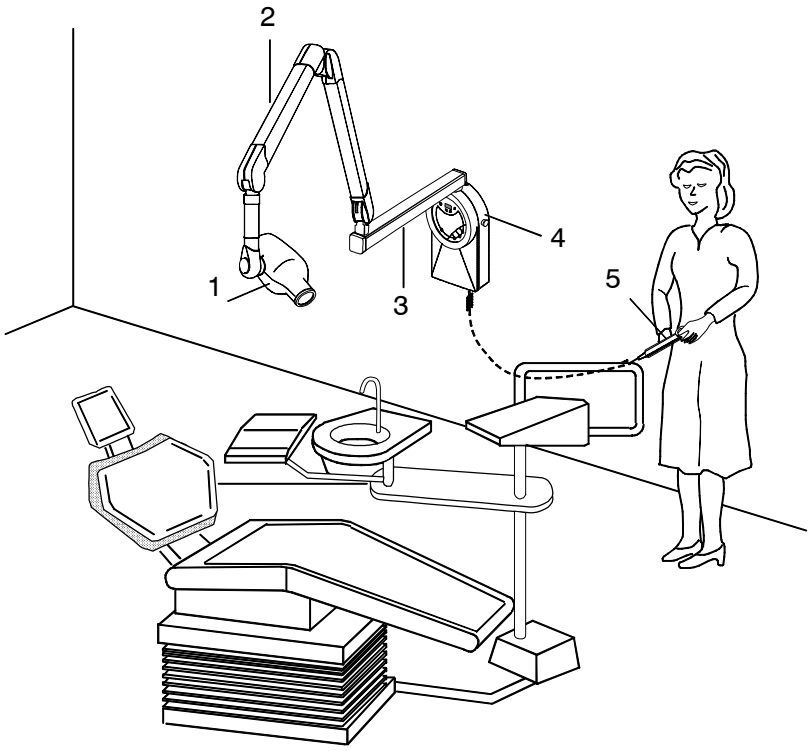


Figure 1

1 Tubehead
2 Scissors arm
3 Extension arm
4 Timer with high frequency generator
5 X-ray button

4.3.2 Mobile stand configuration

ENDOS DC can be assembled on a mobile stand; this configuration gives greater flexibility of use.

NOTE:
The mobile stand version must be requested when ordering. The conversion from wall version to mobile stand version is not provided.

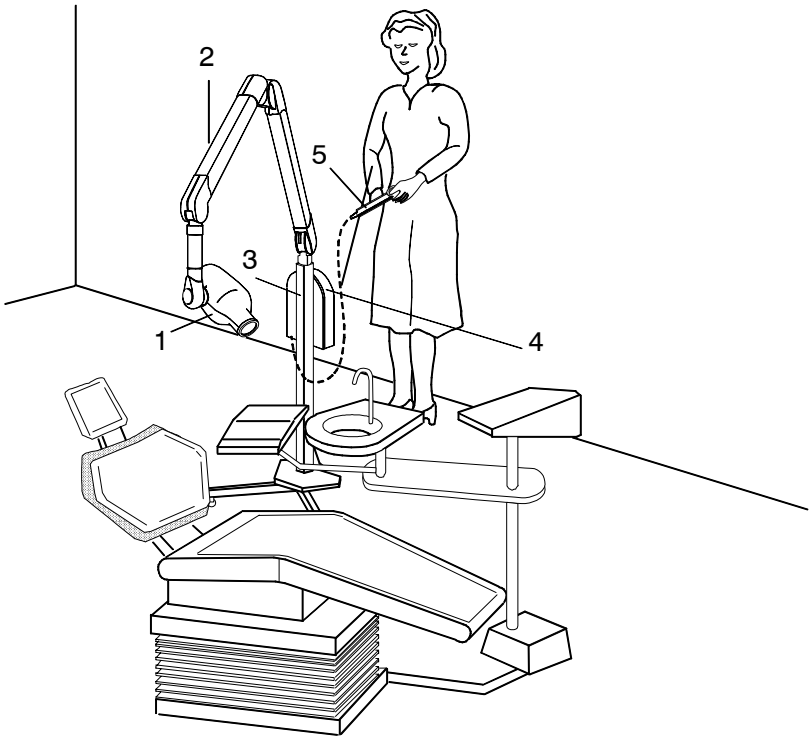


Figure 2

1 Tubehead
2 Scissors arm
3 Mobile stand
4 Timer with high frequency generator
5 X-ray button

4.3.3 Remote keyboard configuration

It is possible to get a remote keyboard configuration, outside the exam room.
Moreover, the apparatus provides two separate contacts for connection with external signaling devices. One contact signals the equipment is ON and ready for use while the second one signals the presence of X-rays. The connection mode and the necessary signal device requirements are reported in the "Service Manual".

NOTE:
In this configuration you are recommended to install the remote keyboard in a place that is reserved for the exclusive use of specialised technical personnel and not in a place that is accessible to unauthorised persons.

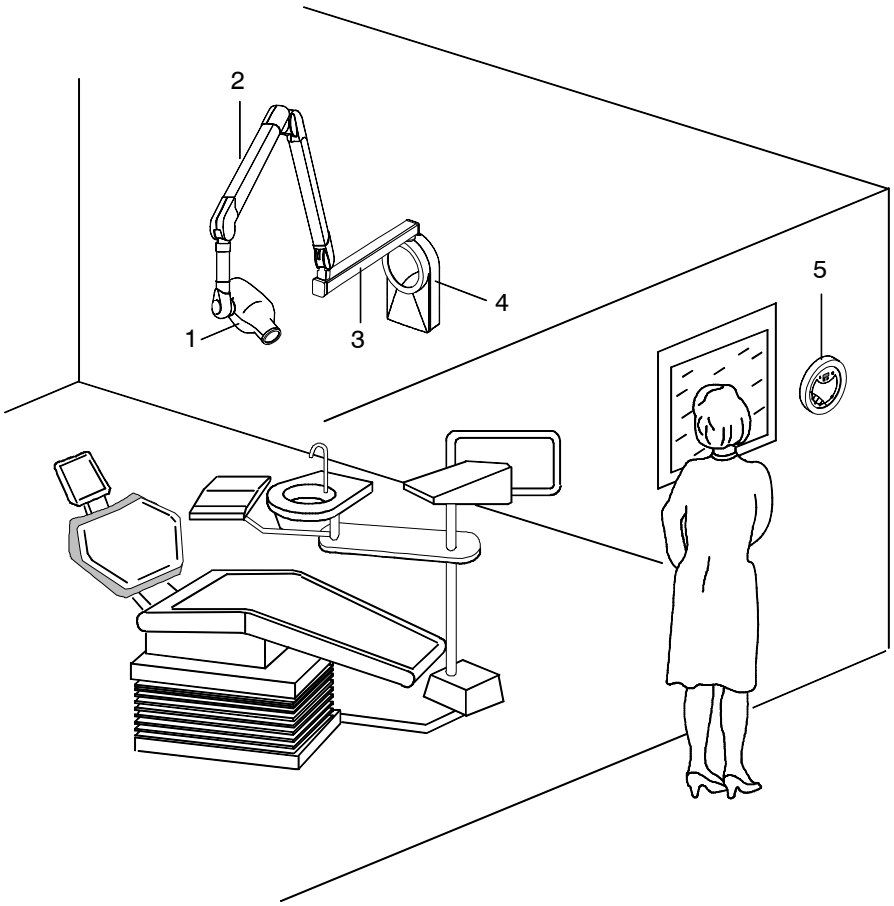


Figure 3

1 Tubehead
2 Scissors arm
3 Extension arm
4 High frequency generator
5 Remote timer

5. TECHNICAL FEATURES

Technical features		
Equipment	ENDOS DC	
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italia	
Class	Class I° with type B applied (EN 60601-1 classification) 	
Protection level	Standard apparatus IP20	
Line voltage	**198 ÷ 264 V~**	**99 ÷ 132 V~ (*)**
Line frequency	50 – 60 Hz	
Rated current	0.2 Arms continuous, 2.25 Arms impulsive **@** 230 V~	0.4 Arms continuous, 5,7 Arms impulsive @ 99 V~ **(*)**
Power consumption	50 VA continuous, 0.55. kVA impulsive **@** 230 V~	50 VA continuous, 0.55. kVA impulsive **@** 120 V~
Max. apparent line resistance	0,8 Ω max	**(*)**
Line voltage regulation	-	< 3 % at 99 V
Main fuse	3 AT	6 AT
Preset exposure times	from 0.01 to 2s in 35 steps	
Automatic selection	60 pre-set times	
Time accuracy	±5 % or ± 2 ms	
Circuit type	constant potential	
High voltage value	65 kV_p	
Tubehead current	4 and 5 mA selectable	
kV accuracy	± 5 %	
Tubehead (anode) current accuracy	± 5 %	
Max. exposure time	2 s	
Electronics box dimension	345x195x100mm	

(*) *The unit can be operated with the line voltage 100 V ± 10 %, under the condition that line resistance is lower than 0.4 Ω (complies with IEC 601-1). Max line current absorption at 100 V –10 % is 6 A.*

Tubehead features	
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italia
Rated voltage	65 kV_p
Tubehead power	325 W max.
Total filtration	≥ 2 mm Al **@** 65 kV_p
HVL (Half Value Layer)	> 1.5 mm Al eq.
Transformer insulation	Oil bath
Interval between exposures / duty cycle	15 times X-ray time / 1 : 15 (adaptive)
Focal spot	0.7 (IEC 336) @ 5 mA
Minimum focus to skin distance	20 cm (optional 30 cm)
X-ray diameter (@ 20cm focus)	6 cm (optional 35 x 45 mm)
Cooling	Convection
Radiation leakage at 1 m	< 0.25 mGy / h
Technical factors for radiation leakage	65 kV - 5mA - 1s / Duty cycle 1 : 15
X-ray tube features	
Manufacturer	CEI Bologna (Italy)
Type	OCX / 70-G
Inherent filtration	0.5 mm Al eq. a 70 kV_p
Anode tilt	19°
Anode material	Tungsten
Rated voltage	70 kV
Maximum filament current	2.8 A
Maximum filament voltage	4.1 V
Anode thermal capacity	6 kJ
Anode cooling capacity (max)	90 W

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
Weight of equipment and detachable parts	
Gross weight including packing	35 kg
Net weight of equipment in standard configuration	22 kg
60 cm extension arm (standard)	2.9 kg
80 cm extension arm	3.5 kg
30 cm extension arm	1.9 kg
Scissors arm	9 kg
Wall plate with generator	5 kg
Tubehead	4.5 kg

NOTE ABOUT COOLING TIME:
ENDOS DC equipment is designed to guarantee the best efficiency of use for the operator; this feature also includes a low tube cooling time, in order to limit the waiting time between one exposure and the next even when the equipment is being used intensively. In order to guarantee the useful life of the equipment, cooling time varies according to the conditions in which the equipment is used and it can assume even 1 : 30 values (30 s waiting every 1 s exposure) or 1 : 45 (45 s waiting every 1 s exposure). The calculation algorithm preset in the equipment takes into account the usage conditions and applies the correct value for the pause between two consecutive exposures.
Considering all this, you are advised not to switch the ENDOS DC off immediately after an exposure.

5.1 Method of measuring technical factors

NOTE:
The best way to measure technical factors is by taking a direct measurement of radiological parameters. This is also called the invasive method. This method requires access to live parts so it can be performed by personnel authorised by the Manufacturer only.

The measurement method using non invasive tools, for instance the kV_p/t meter, is acceptable, even though it usually gives a less accurate result. In fact, measuring the high tension tube value using non invasive tools is strictly correlated to the method chosen by the manufacturer of the tool himself; generally this method is less accurate than the direct method and it may also require two consecutive exposures.
Similarly, anode current measurement using the indirect method is affected by systematic errors, as it is very often based on the current/time product measurement, dividing the measurement by the time measured by this method.

The logic card (CPU) has 3 test points (TP kV, TP mA and TP GND) to which the tool used for the measurement is connected, typically a digital multimeter with an entry resistance of more than 10 MΩ or memory oscilloscope.

- **High tension value to the tube**

  Connect the positive prod on TPkV and the negative one on TPGND; select a 1 s exposure time and read the value measured by DVM considering 1VDC = 20 kV; you must measure a 3.25 V DC ± 160 mV (3.09 ÷ 3.41) value.

- **Anode current value**

  Connect the positive prod on TPmA and the negative one on TPGND; select a 1 s exposure time and read the value measured by DVM considering 1VDC = 2 mA; you must measure a 2.5 V DC ± 125 mV [2.375 ÷ 2.625 V] value for 5 mA anode current, while for 4 mA you must have 2 V DC ± 100 mV (1.9 ÷ 2.1 V).

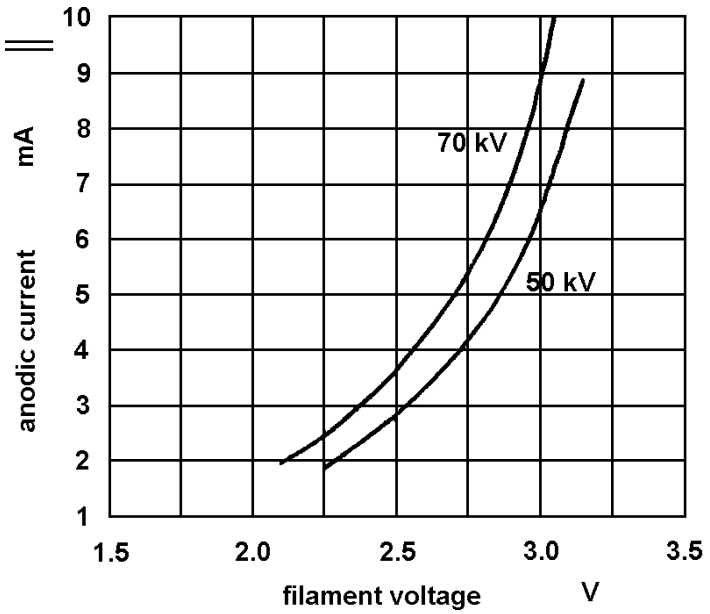
- **Exposure time measurement**

  Use a memory oscilloscope, connecting the hot point of the sound to TPkV and the mass to TPGND. Set the oscilloscope to wave form storage, with the trigger on the positive side. Select the required exposure time and make an exposure. The exposure time is **defined as the interval between the moment when Kv value goes above 75% of the stationary value and the fall under this value: exposure time accuracy must be ± 5% or ± 2 ms if bigger.**
  When using a non invasive tool, such as a kV_p/time meter, there may be a bigger error, depending on the measurement tool used.

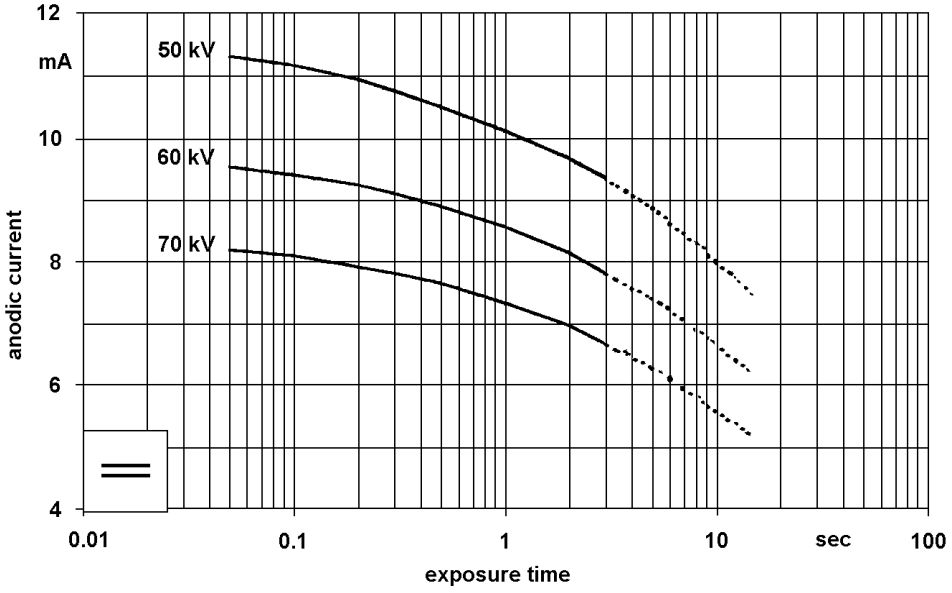
5.2 Curves tube features

OCX / 70-G

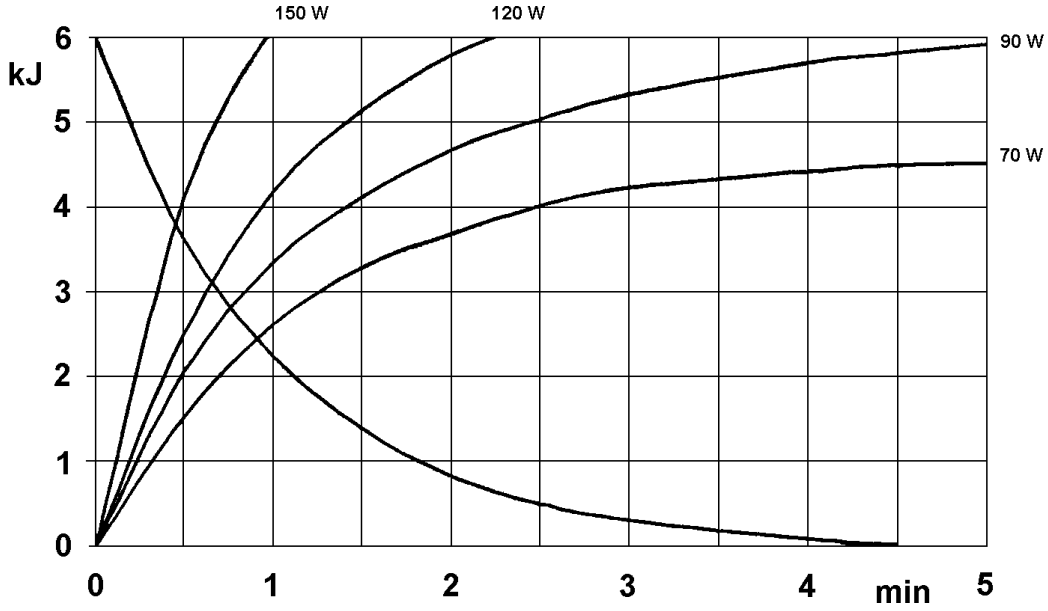
Emission feature



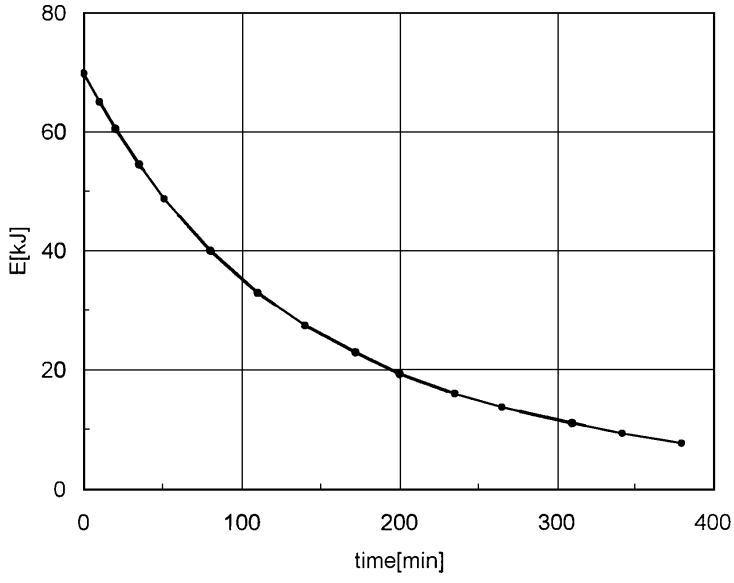
Load



Curve anode cooling



Curve tubehead cooling



5.3 Standard and regulations

ENDOS DC equipment complies with the following regulations:

- EN 60601-1 (IEC 601-1)
- EN 60601-1-1 (IEC 601-1-1)
- EN 60601-1-2 (IEC 601-1-2)
- EN 60601-1-3 (IEC 601-1-3)
- EN 60601-2-28 (IEC 601-2-7)
- EN 60601-27 (IEC 601-2-7)

- CFR 21 Subchaper J for version operating at rated line voltage 99-132 V.

CE symbol certifies the compliance of ENDOS DC to 93/42/CEE legal directives.

5.4 Overall dimensions

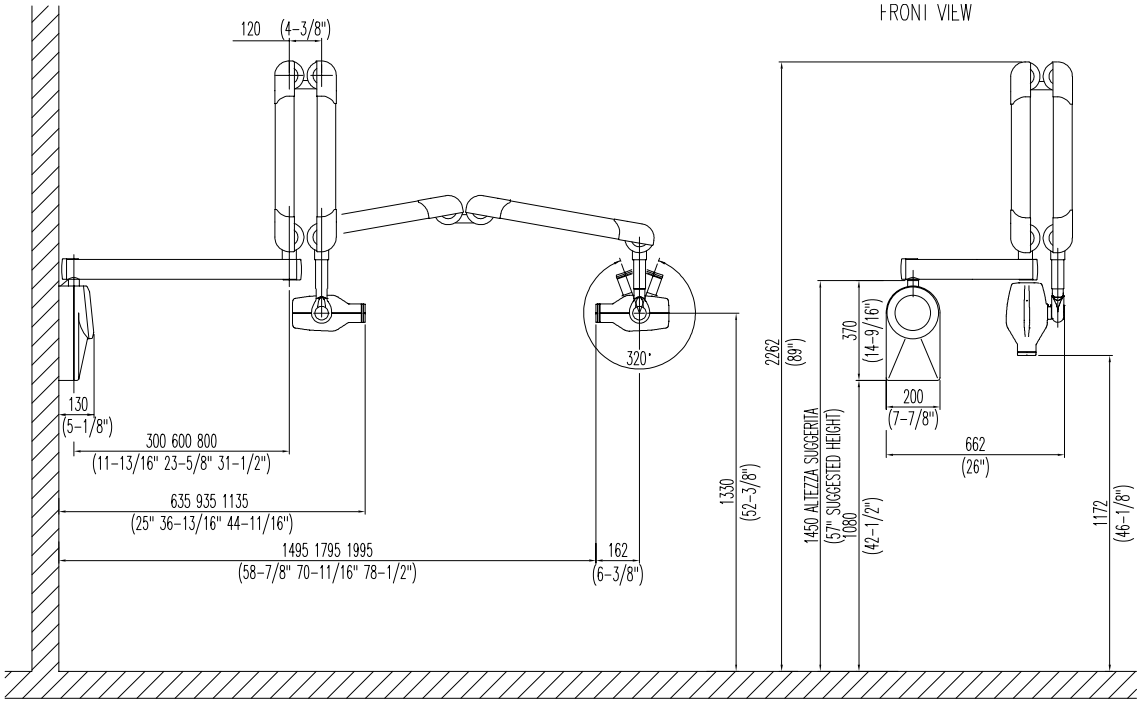


Figure 4: Wall version overall dimensions

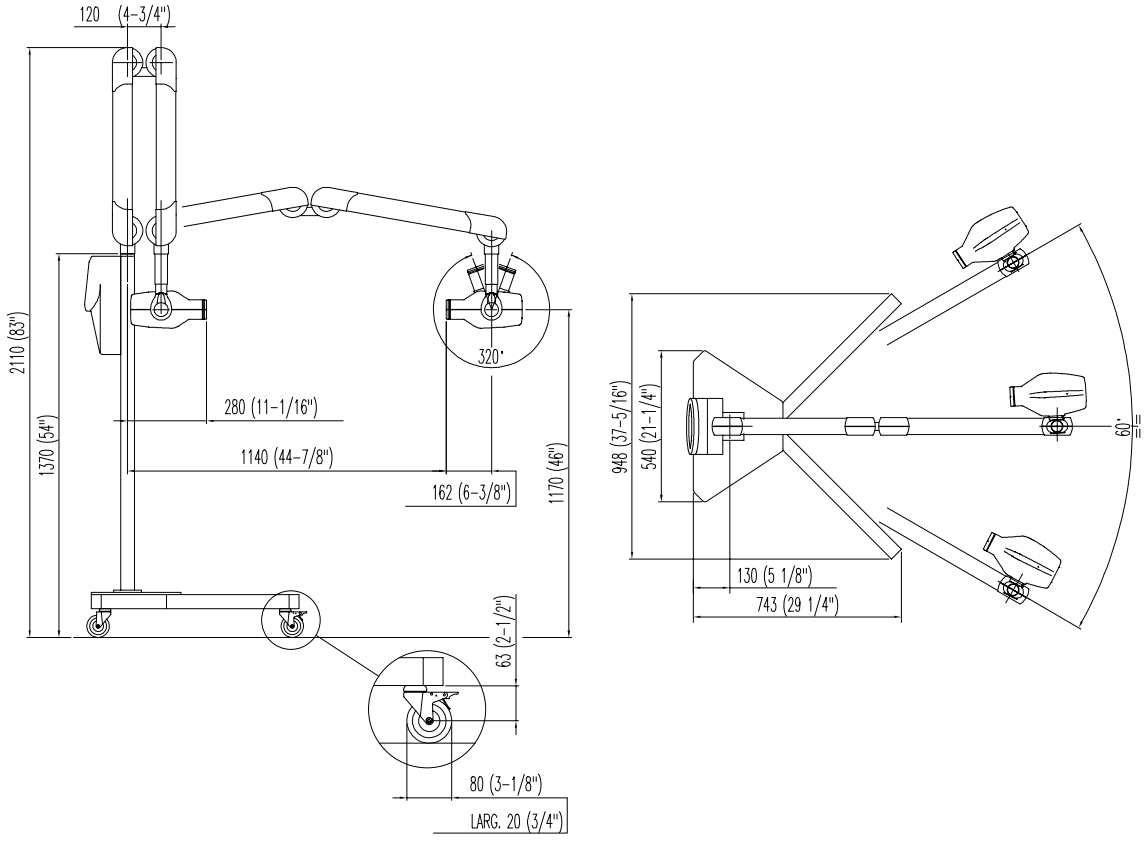


Figure 5: Mobile Stand version overall dimensions

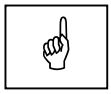
6. GENERAL USE INSTRUCTIONS

6.1 Equipment start-up

a) Press the main switch located on the bottom part of the generator cover to start the "CHECK" function which begins when the keyboard and display LED come on.

b) After the "CHECK" function the machine sets itself by default in the configuration corresponding to the last selection executed.

From this moment the apparatus is in the waiting condition.



NOTE:

- The "ready for X-rays" condition is signalled when the corresponding green LED (**21**) comes on; the condition is achieved by pressing one of the anatomic or manual selection keys.
- The "ready for X-rays" condition is active for about 15 s. If no exposure is taken during this period, the equipment returns to the waiting condition. In this case, if you want to take an exposure, press one of the anatomic selection key again.
- Pressing one of the anatomic selection keys enables the toggle of the corresponding choices.
- **Exposure will be activated by keeping the X-ray button pressed.**
- **When setting up the remote keyboard (optional) exposure can be controlled by the key located on the keyboard itself.**

NOTE:
The procedures shown in the following paragraphs refer to Figure 15 at the end of this chapter.
To look up this picture easily, open the page to read it while reading the other pages of the manual.

6.2 Special keyboard functions

ENDOS DC keyboard is designed to facilitate selection operations, so normally you must touch one single key to select a function; on the other hand, pressing a combination of two keys simultaneously gives access to special functions, such as.

6.2.1 Change from Focus Film Distance (FFD) 20 cm to FFD 30 cm

This is achieved by pressing the "Film speed" and "Increase" keys at the same time.
When 30 cm FFD is selected, the exposure time values selected are multiplied by the multiplication value 2. The "long cone" LED signal switches on (**23**).

WARNING:
The equipment does not automatically detect when a standard or long cone is being used, so it is the user's responsibility to check that the visual display actually corresponds to the true conditions of the equipment.

6.2.2 Change from FFD 30 cm to FFD 20 cm

This is achieved by pressing the "film speed" (**13**) and "decrease" (**1**) keys.
The "long cone" selection LED (**23**) is switched off.

WARNING :
The equipment does not automatically detect when a standard or long cone is being used, so it is the user's responsibility to check that the visual display actually corresponds to the true conditions of the equipment.

6.3 Preset / Manual exposure

It is possible to choose whether to work in pre-set selection (or anatomical) i.e. with the values pre-set by the manufacturer according to the size and the type of tooth, or whether to perform an exposure manually, i.e. with the possibility of varying the pre-set times.
In anatomical selection it is possible to select the receptor type used (different film types or digital radiography).

6.3.1 Selection of receptor type for anatomic exposure mode

The device allows to select the type of receptor used: 4 selections are possible through key (**13**) which toggles the selections among LED (**14**), (**15**), (**16**) and (**17**).
Selections (**14**) and (**15**) are set for film types D and E.
Selection (**16**) is for digital radiography.
Selection (**17**) allows to use preselected exposure times configured directly by the customer (see paragraph 6.4).

6.3.2 Anatomical preset exposure

When the previous exam was performed in manual exposure, to go to preset exposure just press one of the anatomic selection keys.
In preset mode it is possible to vary the size (key **3**) and the type of tooth (key **7**).
By pressing the size key (**3**), which emits an acoustic signal, you can change the patient size selection Large patient (**4**) / Normal patient (**5**) / Small patient (**6**).
Use key (**7**) to vary the selection of the tooth type. Each time this key is pressed, the type of tooth selected is displayed visually by the LEDs (**8** to **12**).

Based on the selected film type, preset exposure time are given in Table 1.

	Film selection 1 (LED14)			**Film selection 2 (LED15)**		
Size	**Large**	**Normal**	**Small**	**Large**	**Normal**	**Small**
Upper molars	0.48	0.36	0.24	0.30	0.22	0.15
Premolars	0.30	0.22	0.15	0.20	0.15	0.10
Incisors/canines	0.24	0.18	0.12	0.15	0.12	0.08
Lower molars	0.38	0.28	0.19	0.24	0.18	0.12
Bite wing	0.24	0.18	0.12	0.15	0.12	0.08

Table 1

NOTE:
The values reported above concern type D film (film selection 1, LED **14**) and type E (film selection 2, LED **15**). The above selection automatically chooses a 5mA anode current (shown by the start-up of LED **18**), which guarantees good quality images with reduced exposure times.

ENDOS DC equipment is designed also to use ultra-sensitive films (speed F). The possibility to select this film type can be configured by the Service Engineer at installation.

If you want to change the combination of films in use, you must call the Technical Service to set-up the proper configuration.

Exposure times for type F film are:

	Film type F		
	Large	**Normal**	**Small**
Upper molars	0.19	0.15	0.10
Premolars	0.12	0.09	0.06
Incisors/canines	0.10	0.08	0.05
Lower molars	0.15	0.12	0.08
Bite wing	0.10	0.08	0.05

Table 2

Exposure times for digital radiography (LED **16**) are given in Table 3.

	Digital sensor		
Size	**Large**	**Normal**	**Small**
Upper molars	0.15	0.10	0.06
Premolars	0.09	0.06	0.06
Incisors/canines	0.08	0.05	0.05
Lower molars	0.12	0.08	0.08
Bite wing	0.08	0.05	0.05

Table 3

This selection automatically sets a value of 4 mA anode current, signalled by the corresponding LED (**19**).

NOTE:
This selection is designed for the use with a CCD-type sensor; if a sensor with a different sensitivity is in use (for instance permanent phosphorus sensor), this can be configured by the Service Engineer at installation or during a service call.

Phosphorous sensor times are given in Table 4.

	Phosphorous sensor		
Size	**Large**	**Normal**	**Small**
Upper molars	0.30	0.20	0.12
Premolars	0.18	0.12	0.12
Incisors/canines	0.16	0.10	0.10
Lower molars	0.24	0.16	0.16
Bite wing	0.16	0.10	0.10

Table 4

6.3.3 Manual exposure

ENDOS DC makes it possible to work not only in the anatomic mode already described above but also in the manual mode.

To access the manual mode just press one of the two keys "increase" (**2**) or "decrease" (**1**). In this way the system exits the "automatic exposure times selection" mode by switching off the LED corresponding to the type of tooth and size.

The alphanumeric display (**22**) will show the last automatic selected time mode; to vary it, just press the "decrease" or "increase" keys again until you get the requested value.

A buzzer sounds every time a time variation is made; it is also possible to make a quick variation of exposure times (4 units a second) by keeping either keys (**13**) or (**14**) pressed for more than 2 seconds.

NOTE:
Exposure times can vary from a minimum of 0.01 seconds to a maximum of 2 seconds according to the following table:

0.01– 0.02 – 0.03 –0.04 – 0.05 – 0.06 –0.07 – 0.08 - 0.09 – 0.10 – 0.12 – 0.14 – 0.16 – 0.18 – 0.20 – 0.22 – 0.25 – 0.28 – 0.32 – 0.36 – 0.40 – 0.45 – 0.50 – 0.56 – 0.63 – 0.71 – 0.80 – 0.90 – 1.00 – 1.10 – 1.25 – 1.40 – 1.60 –1.80 – 2.00

Table 5: Manual exposure times

NOTE:
For exposure times lower than 0.04 s, the <25% limit between the value of different selections is not observed (EN60601-2-7 regulation).Values lower than 0.10 s are generally used with digital sensors.

6.4 Modification of customisable table

ENDOS DC has the possibility of customising anatomical exposure times to adapt them to the user's actual usage conditions. This is possible by using a customisable table, or "custom", shown on the keyboard of the corresponding symbol and LED (**17**).

At the beginning the "custom" table is set to the same values as the digital table; to access the table itself and modify it use the following procedure:

a) Press the "film selection" key (**13**) to bring the choice on "custom" (**17**) (if not already selected); press at the same time keys (**13**) and (**7**) to enter editing mode of the custom exposure times. The editing condition is shown by the custom LED flashing (**17**); the time for the selected tooth/size combination is displayed on the display in flashing mode; the anode current LED in use is flashing.

b) Pressing the "size selection" key (**3**) or "tooth selection" key (**7**) will show the relevant exposure time (blinking) for the combination; time is modified using "increase" (**2**) or "decrease" keys (**1**).

c) Pressing at the same time the "film selection" key (**13**) and "increase" (**2**) or "decrease" key (**1**) changes the anodic current to be used for that size-tooth combination, as shown by the anodic current blinking.

d) Repeat the steps **b)** and **c)** to change other times in the table.

e) Confirm the set conditions **by pressing the main X-ray button or key. When the display/LED stops flashing this means that storage has been completed.**

f) To exit the configuration of the customized table without storing data it is necessary to turn off the device.

6.5 Preparation of the tubehead

a) Set the tubehead with an angle suitable for the exposure and positioning requested (see Figure 6, Figure 7, Figure 8, Figure 9).

b) Put the film into the patient's mouth according to the chosen way (bisecting or parallel). For this purpose, see paragraph 6.6.

c) Move the tubehead cone towards the patient and focus it exactly towards the tooth to X-ray referring to the following Figures.

NOTE:
If you want to use the cone with rectangular collimator 35x45mm, assemble it by clicking it onto the end of the present cone, positioning it as requested.

LOWER JAW (MANDIBLE)

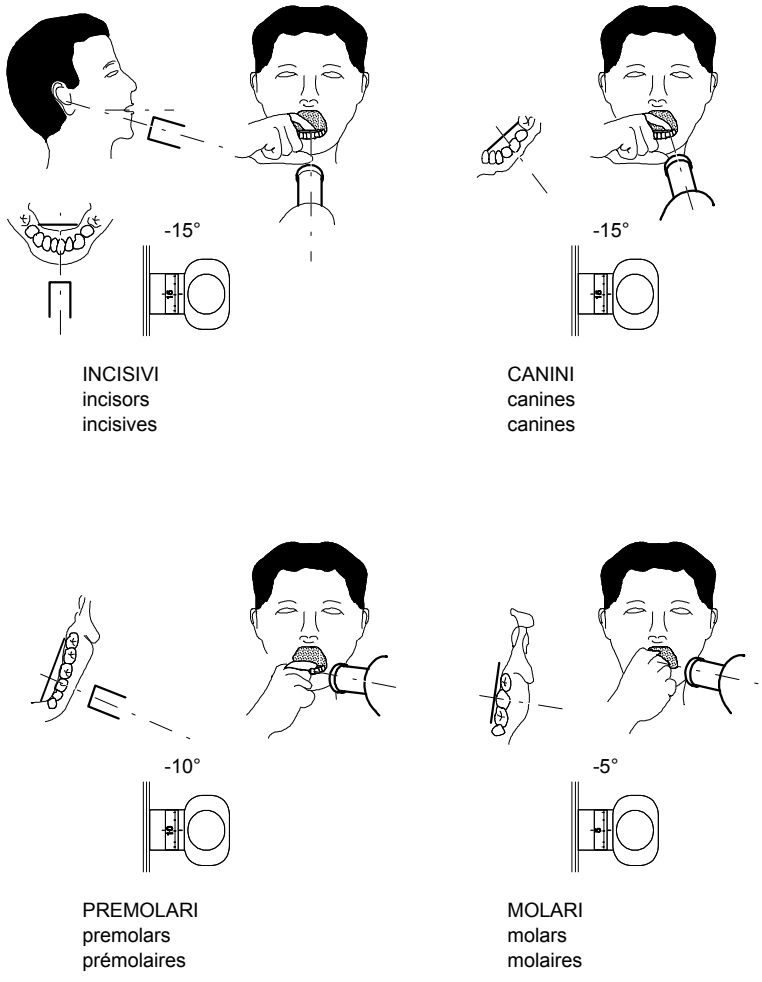


Figure 6

UPPER JAW

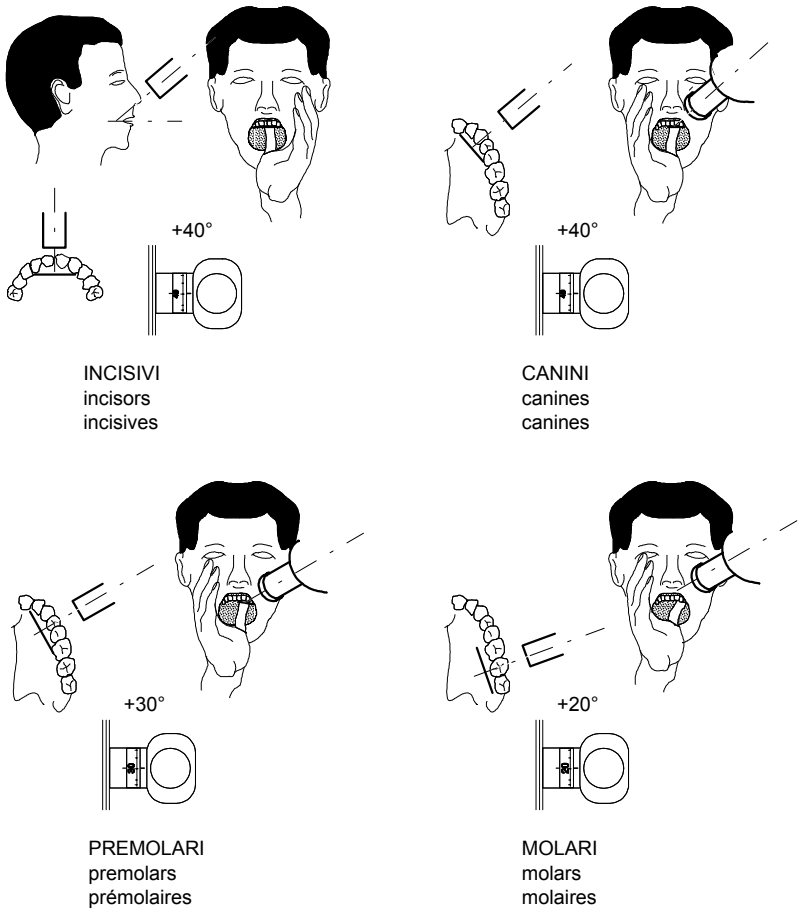


Figure 7

OCCLUSAL

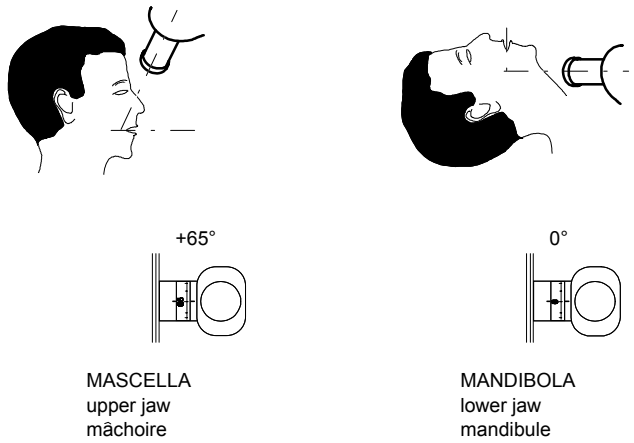


Figure 8

BITE WING

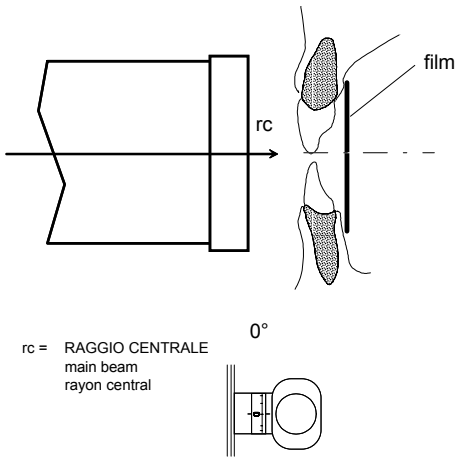


Figure 9

6.6 Exposure techniques

This paragraph describes the different techniques generally used for intraoral exposure.

6.6.1 Bisecting technique

Incidence X-ray beam – Vertical angle

To get a real image of the tooth, the X-ray must be perpendicular to the bisecting line of the angle formed by the longitudinal axis of the tooth and by the film.
After positioning the X-ray beam and the patient's head according to these criteria, it is possible to apply an average vertical incidence for each area. The incidence angle of the X-ray beam can be correctly measured by the graded scale applied to the tubehead.

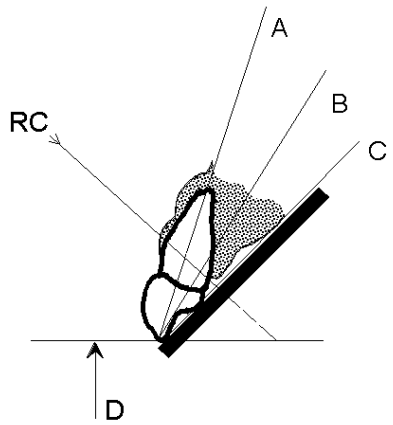


Figure 10

Legend Figure 10:

A - *Tooth longitudinal axis*

B - *Bisecting line*

C - *Film level*

D - *Occlusal level*

RC - *X-ray beam*

X-ray beam incidence – Horizontal direction

The X-ray beam must be set horizontally, in particular in the ortho-radial direction regarding inter-proximal spaces (see Figure 11), in order to avoid a superimposition of the structures (see Figure 12).

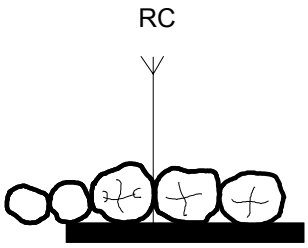


Figure 11
(Correct position)

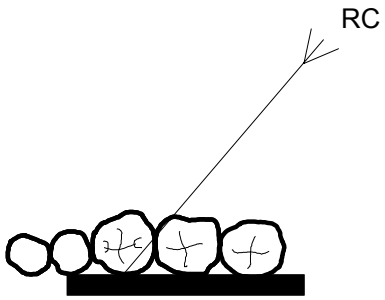


Figure 12
(Wrong position)

Legend Figure 11 and Figure 12

RC - X-r*ay beam*

6.6.2 Parallel technique

Using this technique, the film level is placed parallel to the tooth axis. Owing to anatomic factors, the film is generally kept away from the lingual surface of the tooth, except for molars.
When it is introduced into the patient's oral cavity, the film is fixed on a support to prevent distortion. The patient holds the support itself near the teeth.
Various types of supports are available on the market, to match the different types of teeth. This technique enables you to get more accurate and more easily repeatable X-rays compared with the bisecting technique (see Figure 13 and Figure 14).

HORIZONTAL SECTION

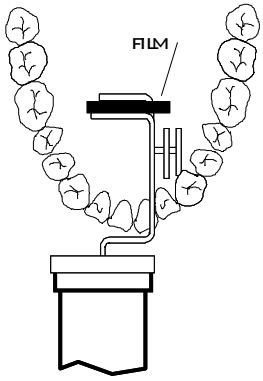


Figure 13

VERTICAL SECTION

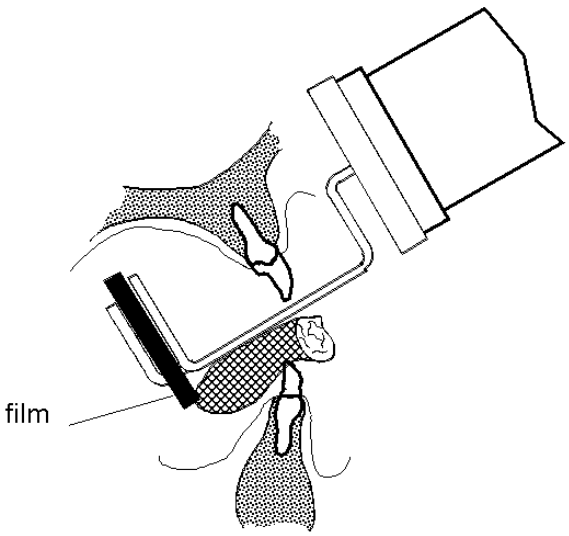


Figure 14

6.7 Execution of exposure

WARNING:
In standard configuration, i.e. with wall assembly, the X-ray button (**24**) on the keyboard is disabled for safety reasons. In fact, if enabled, the user would not be able to move away from the equipment and to go outside the radius of the primary X-ray beam.
In this configuration only the X-ray button provided with extensible spiral cable can be used.

The keyboard X-ray key can be used only for remote keyboard installations. Only authorised personnel can enable the implementation of this feature.

a) Set exposure time as described in paragraph 6.3.

b) Move as far away as the X-ray button cable will allow in the opposite direction to emission.

c) Press the X-ray button holding it pressed for the whole exposure.

d) The start of the exposure is shown both visually, by the X-ray signal LED (**20**), and acoustically, by an uninterrupted buzzer.

e) At the end of the exposure three horizontal segments appear on the screen representing the automatic cooling pause of the tubehead. This pause is equal, by default, to 15 times the exposure time; during this period it is not possible to perform a new exposure or to re-set new data.

NOTE:
The cooling time may vary according to the workload of the equipment. Refer to the information given in the notes in chapter 5.

WARNING:

- The exposure button is a "dead man" control; so it must be held pressed during the whole exposure. If the patient should move during the examination, the button must be released immediately interrupting the emission of X-rays. The message **A02** or **A03** will appear on the remote control alphanumeric display.
- **The message A02 identifies that the exposure procedure has been interrupted when the exposure has already started; in this case, the film must be replaced before proceeding with a new exposure and you must wait until the automatic pause has finished.**
- **If a further exposure is performed without replacing the film, you would obtain non-diagnostic results due to a double exposure.**
- Message **A03** refers to an interruption in the exposure during preheating: no dose has been delivered.
- If an error message appears on the screen at the end of the exposure, indicating the letter "**E**" followed by a number **and the buzzer persists, switch off the system immediately since you may be in the presence of undesired emissions. Accidental exposure is, in any case, interrupted by the generator's safety system; this happens before a real hazard occurs for the patient and/or operator.**

The ENDOS DC system is designed to display the delivered dose in the last exposure. This function can be switched on by configuring the system and can be modified by the service technician.
The value of the delivered dose is displayed at the end of the exposure and remains on the screen for a period of 5 seconds; after this time, the system returns to the controls waiting condition or tube cooling condition without any display.

WARNING:
The dose displayed on the screen, expressed in mGy, is calculated according to an empirical parameter calculated with type tests performed on some equipment representative of the normal production and is an approximate value that may vary even by ± 25% compared with the value of the dose actually delivered.

THE DELIVERED DOSE VALUE IS CALCULATED AT 20 cm FROM THE FOCAL POINT AND IS THEREFORE VALID ONLY FOR STANDARD 20 cm CONE.

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6.8 Command keyboard

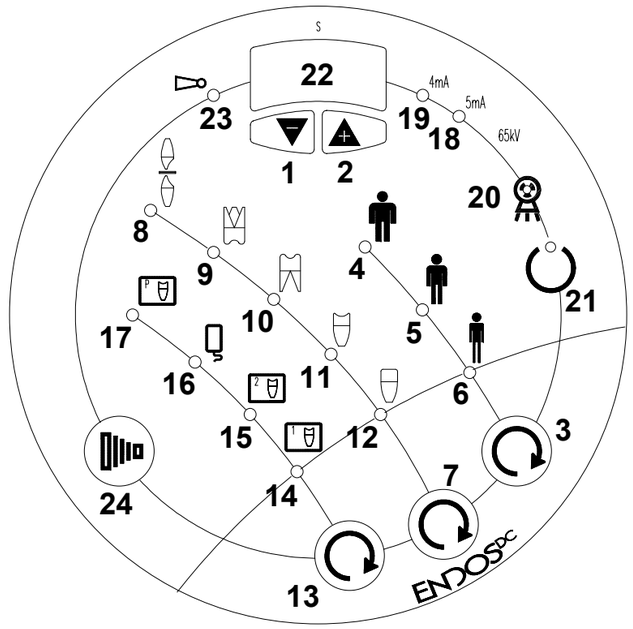


Figure 15: Command key

1 Key for manually decreasing exposure times

2 Key for manually increasing exposure times

3 Anatomic selection key
Large patient / Normal patient / Thin patient

4 Large patient selection LED

5 Normal patient selection LED

6 Small patient selection LED

7 Automatic tooth selection key

8 Automatic Bite wing selection LED

9 Upper molars automatic selection LED

10 Lower molars automatic selection LED

11 Pre-molars automatic selection LED

12 Incisor-canine automatic selection LED

13 Film type selection key

14 Type 1 film selection key

15 Type 2 film selection key

16 Digit radiovideography selection LED

17 Customisable selection LED (Custom)

18 5 mA anodic current selection LED

19 4 mA anodic current selection LED

20 “Emission underway” warning LED

21 “Ready for X-rays” warning LED to indicate that you can the emission procedure by pressing the appropriate button

22 3-digit exposure time display

23 Long cone inserted warning LED

24 X-rays key

7. ERROR MESSAGES ON THE SCREEN

ENDOS DC is completely controlled by a microprocessor which not only controls the programming of emission parameters but also identifies the different machine statuses and possible anomalies and errors on the screen by means of coded messages.
The following tables illustrate the meaning of the various messages which might appear on the screen and also explains their cause and remedies.

Error messages are divided into three different groups, classified according to the seriousness of the anomaly found and the possible effect on the operators' safety and/or the equipment.

7.1 Fatal alarms during start-up

These alarms do NOT allow any exam to be performed.

It is possible to try to switch the equipment on and off, but if the alarm is repeated you must call the technical assistance service.

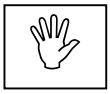
Displayed Message	ANOMALY type	ACOUSTIC signaling
CH0	Checksum error of memories (EEPROM+EPROM)	Absent
CH1	Configuration writing error on memory (EEPROM + EPROM)	Absent
CH2	Checksum error on program memory	Absent
E01	X-ray button pressed at start-up	Absent
E02	A key pressed at start-up (not X-ray button)	Absent
E03	Multiple keys pressed at start-up	Absent

7.2 Alarms during exposure

Any anomalies that occur during exposure always stop the exposure itself. The acoustic signal (present or absent) depends on the time the breakdown occurred and the success of the exposure interruption.

These errors cannot be removed without turning off the equipment and in most cases indicate a failure or deterioration of the equipment requiring technical assistance.

Displayed Message	ANOMALY type	ACOUSTIC signaling
E11	Filament circuit failure	Absent
E12	RX ON too slow in the rise	Absent
E13	Emission even after the end of exposure	Present until RX ON is active
E14	Back-up timer intervention	Present until RX ON is active
E15	PFC overvoltage safety intervention	Present until RX ON is active
E16	PFC undervoltage safety intervention	Present until RX ON is active
E17	Feedback kV beyond upper limit	Present until RX ON is active
E18	Feedback mA under lower limit	Present until RX ON is active
E19	Feedback mA over upper limit	Present until RX ON is active
E20	Current overload of filament	Present until RX ON is active
E21	Anode overload	Present until RX ON is active
E22	kV overvoltage signal	Present until RX ON is active
E23	Found undesired emission (RX ON present)	Present until RX ON is active
E24	RX ON drop before exposure end	Present until RX ON is active



WARNING:
Always switch the equipment off when an alarm appears and the buzzer is active. In any case the back up timer will stop exposure.

7.3 Alarms not affecting further exposures

Situations which do not directly affect the safety of the operator, patient or equipment are considered as re-settable anomalies. The situation which caused the alert condition is always displayed by a flashing green LED and the corresponding error message, which, in these cases, has the "Axx" syntax. The error condition prevents further exposures until it is reset by pressing any key; in this case the display on the screen and keyboard reflects the last selection made.

Displayed Message	ANOMALY type	ACOUSTIC signaling
A01	X-ray button already pressed at the touch of any key exiting IDLE-ON status	Absent
A02	X-ray button release during exposure	Present until RX ON is active
A03	X-ray button release during pre-heating phase (2° time not present yet)	Absent

WARNING:
In the event of an A02 signal, the X-ray button has been released with considerable emission, so the film must be replaced in order to obtain diagnostic images.

In the event of an A01 signal, you must release the X-ray button; if this is not pressed, it identifies a breakdown, so call the Technical Assistance service.

8. CHECK AND CORRECTION OF POSSIBLE ERRORS IN DENTAL X-RAYS

8.1 Typical faults in intraoral X-rays

- **Too pale X-rays**

  Possible causes:
  - Inadequate exposure to X-rays (short time)
  - Inadequate development time
  - Damaged developer
  - Developer temperature lower than the requested value
  - Wrong dilutions of developing fluids.

- **Too dark X-rays**

  Possible causes:
  - Excessive exposure to X-rays
  - Excessive development time
  - Developer temperature over the requested value
  - Wrong dilution of developing fluids.

- **Out-of-focus X-rays (impossibility to see details)**

  Possible causes:
  - The patient moved
  - The tubehead moved.

- **X-rays with fishbone marks**

  Some intraoral films have a thin lead layer in the box with some fishbone marks engraved in the lower part. These films can be exposed to radiation only on one side. If the film is exposed to the wrong side, the lead layer will absorb a large amount of radiation during exposure. The result will be a lighter X-ray and the film will show fishbone marks.

- **Partially exposed X-rays**

  Possible causes:
  - X-rays directed far from the medial section of the film
  - Low fluid level, with subsequent partial development of the film
  - Two or more films one close to the other in the developer.

- **Darkened X-rays**

  Possible causes:
  - The film has been in the warehouse for too long (check expiry date)
  - Accidental exposure of the film to X-ray
  - Accidental exposure of the film to other sources of natural or artificial light.

- **Dark line on X-rays**

  This line appears when the film is excessively folded.

- **X-rays with marks of electrostatic electricity**

  When the film is excessively compressed and the air is dry, electrostatic electricity can be released so it can run down to compression points, where black marks form.

- **X-rays with chemical spots**

  The scattering of developing or fixing fluid on the film before development and fixing procedures causes spots on the X-rays; these spots are:
  - Dark if caused by the developing fluid
  - Light if caused by the fixing bath.

- **X-rays with emulsion loss**

  If the film is kept in a warm water bath too long (for instance, all night), the emulsion can soften and partially come off the base of the film. After development, the film will be scratched.

8.2 Typical faults caused by wrong positioning

- **X-rays with extended or shortened images**

  The X-ray beam is not perpendicular to the bisecting line of the angle formed by the longitudinal axis of the tooth and by the film.

- **X-rays with extended apex of the tooth**

  Probably caused by excessive folding of the film in the patient's mouth.

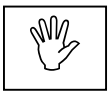
9. MAINTENANCE

Like all electrical equipment, this unit requires not only correct use, but also maintenance and checks at regular intervals. This precaution will guarantee that the equipment works safely and efficiently.

Periodic maintenance consists in checks carried out directly by the operator and/or by the Technical Service.

The operator can carry out the following checks himself:

- check the labels are intact and well attached
- check there are no oil marks on the tubehead
- check the remote control cable is not broken or scratched
- check there are no external damages to the equipment which could make it unsafe in terms of protection from radiation
- check the scissors arm balance
- check that the X-ray beam is centred
- check proper functioning of X-ray exposure LED and exposure buzzer.



WARNING:
If you find irregularities or damages the operator must inform the Technical Service immediately.

MAINTENANCE OPERATIONS RECORD

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 .....

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

Cause .....

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