new life radiology

EVOLUTION LINE INSTALLATION AND USER MANUAL

Mod. MQI006-0 Doc. HBE090-3

mod. EVOSTYLE N.G.

Index

GENERAL ASPECTS

Introduction

Dear Customer,

thank you for the preference granted to our product. We invite you to attentively read the present instructions that will help you to get the maximum of your X-ray diagnostic information with minimal x-ray use.

This manual has the purpose to provide the User with instructions for proper, safe and efficient operation.

The equipment must be used in accordance with the procedures contained in the manual and never for purposes other than those specified herein.

The User is responsible for what concern the fulfilments in legal matters facing installation and equipment functioning.

The plant can only be used by medical personnel in possession of the related licenses enablers and aware of the risks associated with the use of ionizing radiation sources. The use of X-ray sources for purpose of medical diagnostics is subject to specific authorizations and/or communications to the Authorities responsible for vigilance. The User is responsible for the use unauthorized of the plant. The User of the X-ray plant for dental complementary radiology is also required, without exception, to observe the regulations governing the safety of exposure to ionized radiations sources for workers, for member of the public, for population and patients.

If the equipment is not operated correctly or it is not made proper maintenance, the manufacturer cannot be held responsible for any breakages, lesions and mal functioning.

Descriptions

"CAUTION: Do not modify this equipment without the manufacturer's permission."

EVOSTYLE N.G. radiological unit is an equipment designed to obtain intraoral dental radiographs arranged to be use with acquisition systems (conventional films, phosphor plates and video radiographic).

According to Directive 2007/47/CE (Legislative Decree 37/2010) it is classified in CLASS IIb.

The unit is manufactured in accordance with the actual international standards on the protection of ionizing radiation, electrical safety, mechanical safety and electromagnetic compatibility for electro medical equipment.

The equipment consists of the following parts:

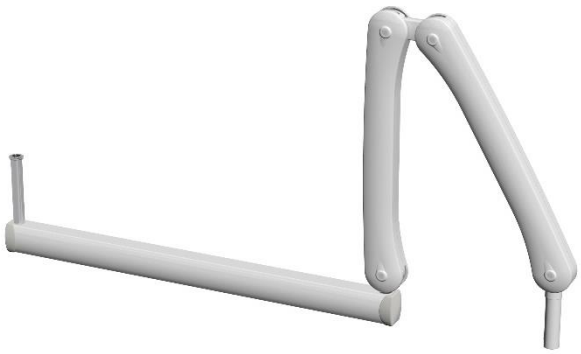
Monoblock

Monoblocs **EVOLUTION x 3000** include the use of x-ray tubes Toshiba (DG-073B-AC) and Kailong KL2.

The EVOSTYLE N.G. complies with European directives on electromagnetic compatibility.

However it may be appropriate to avoid installing the equipment in the immediate vicinity of other electrical equipment with which you could generate mutual electromagnetic interference fields. It is also important to avoid the use of electrical appliances (eg. electrosurgery, cell phones, etc…) near the appliance during its use.

Articulated support double pantograph with wall support or mobile



The monoblock is directed within the installation area by an articulated arm double pantograph; this arm, coupled to the wall support through an extension cable of variable size (mm 400-800-1100), has a maximum extension which varies between 1730 mm and 2430, depending on the extension cord used.

Timer

The timer unit EVOSTYLE N.G. is integrate in the wall plate; it allows the management of exposure times and at the same time guarantees maximum safety in the use of x-ray tubes for electro purposes for intraoral diagnostics;

The timer operation is managed by means of the button with wire. The x-ray delivery is managed through consent to "dead man's switch" so as to ensure maximum security both for the operator and for the patient;

The timer of the control panel is provided with membrane digital keys in order to facilitate the use;

The timer does not allow the use of radiographic in fluoroscopy;

The time scale set with the factory default values complies with R10 scale relative to the norm EN60601-2-7 (IEC 60601-2-7);

The exposure times displayed on the timer display are express in ms.

The maximum time that can be set is 3 s (the display will read 3000) while the minimum time is 40 ms. (the display will read 0040);

EVOSTYLE N.G. has a unique safety system against short circuits or malfunction of the unit, this system is the automatic fuse THERMOSWITCH.

This device intervenes in case of conduction for a time longer than 6 sec. In this situation it blocks the continuity between the control unit and the monoblock, thus preventing the emission of anomalous X-ray.

In case of intervention of the THERMOSWITCH, this will be replaced, this operation requires a service call to technical assistance.

Drawings, schematics, components lists, instructions for repairs:

New Life Radiology is committed to providing, upon request, drawings, circuit diagrams, component parts lists, instructions, or other information that can serve for qualified technical personnel, to perform the repair of any parts that can be repaired.

The Manufacturer reserves the right to make changes at any time without notice.

Technical Data

Classification:	Electromedical equipment Class I With applied part type B	
Head:	single-phase self-righting Monobloc	A) KL2-0.8-70G B) Toshiba DG-073B-AC
Type:		70 kV_p (±5%)
Rated electrical power:		0,430 kW
Supply voltage:		230V~ (50 Hz) single phase
Absorption:		6 A
Focal spot value for the reference axis comply with IEC 60336:		0,8 mm Kailong KL2-0.8-70G; 0,7 mm Toshiba DG-073B-AC
Anode current:		8 mA
Total filtration:		2 mm Al eq.
Time emission/cooling ratio:		1/30
Maximum emission time:		3,00 s
Dispersed radiation:		< 0,25 mGy/h a 1 m by focus
Intermittent functioning:		1 sec. ON / 30 sec. OFF
Control logic:		dead man's switch
Maximum apparent resistance of the supply network:		0.46 Ω
Current / time product:		0,8 mAs
External fuse:		Fast F 6,3 AH
Internal fuse:		F 500 mA
Weight: Mural Mobile		 31 Kg 40 kg
Long cone: ⚠ cod. C.L.01 Remote focus skin: ∅ of the beam at the end of the spacer:		 20 cm 6 cm

Accuracy Load Factors

Voltage accuracy	± 5 %
Current accuracy	± 3 %
Time accuracy	± 5 %
Dose accuracy	± 5 %

Other Data

Maximum current automatic switches for the feeding net	Magnetic thermal switch from 10 A (CEI 23-3)
High voltage measure method:	Not invasive method
Current measure method in the radiogenic pipe:	See page 45
Charge application time determination method:	Not invasive method
Interposition aluminium filter between rays window and cone collimator:	Al 1 mm (AlP99,9 UNI3567)

INSTALLATION AND USE

Use Conditions

The equipment is designed for continuous operation with intermittent charge.

The operating times are with intermittent charge with a duty cycle of 1/30 (1s ON/30s OFF)

Classification according to Directive 2007/47 / EC (Legislative Decree no. 37/2010)	**Class IIb**
Protection against electrical dangers:	Class I
Protection degree against the direct and indirect contacts:	Equipment with parts applied type B
Protection degree against water penetration:	Common equipment IPX0
Use safety degree in presence of inflammable anesthetic mixture:	Equipment not suitable to an use in presence of an inflammable anesthetic mixture with air or with oxygen or with nitrogen protoxide
Use conditions:	Equipment for continuous operation with intermittent charge
Installation:	Permanent e mobile

General symbols

Caution: consult annexed documentation

Ionizing radiation

Apparatus with Type B part applied

Earth protection

O

Switch open(disconnected from mains supply)

I

Switch close(connected to mains supply)

Red point, placed on the cover of the unit, indicate focal spot

Alternating current

Radiation emission symbol

Follow annex instructions

Symbol in conformity with European Directive 2002/96/Ec (Weee). The symbol indicates that this product should not be treated as household waste but should be handed in at the appropriate collection centre for the recycling of electrical and electronic equipment. Discard it according to local regulations for waste disposal.

Manufacturer

CE 0051

Symbol in conformity with Community Legislation. The symbol is followed by a number which identifies the notified organism which certifies and monitors such compliance

REF

Product Code

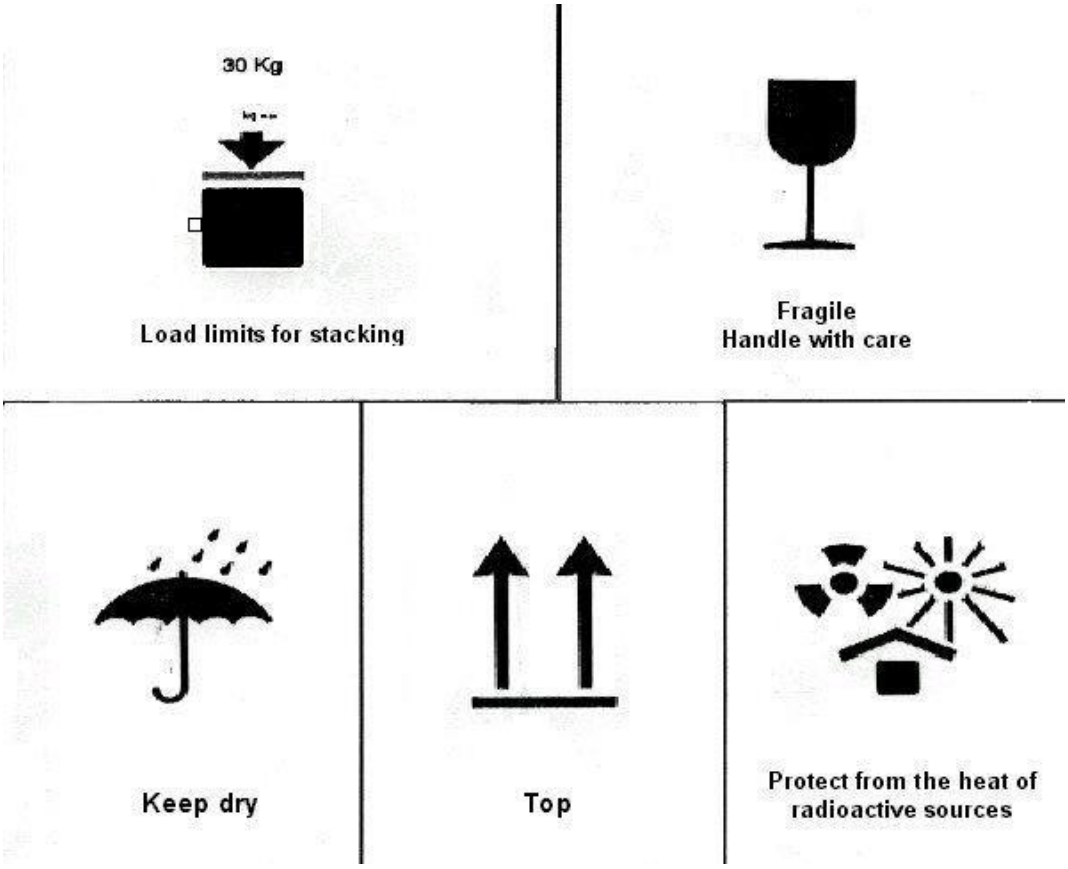
SN

Equipment Serial Number. To be used for all communication with manufacturer / service technician

TUBE

X-ray Tube Serial number

Symbols for transportation and storage



Information for installation

PLASTIC MATERIAL PLUGS NOT ALLOWED

Utensils and tools required for installation (not supplied)

- ✓ 1 multi meter
- ✓ 1 meter
- ✓ 1 fixed key from 13 mm
- ✓ 1 nandle spanner from 5,5 mm
- ✓ 1 set of Allen spanner
- ✓ 1 spirit level
- ✓ 1 plastic mallet
- ✓ 1 percussion drill with points from Ø 3 to Ø 13 mm
- ✓ 1 thin screwdriver for electrical connection
- ✓ 1 medium screwdriver
- ✓ 1 net feeding cable with three wires (2 conductors + 1 ground) of section 1,5 mmq for a reduced length of not over 40 m (for superior lengths use the section cable corresponding to that indicated from the Country actual standards).

Electrical indications

All works for the feeding electric plant must be performed in conformance with the actual reference standards for plants and locals for medical use. (CEI 64-8-710).

A feeding of 230-240 V to 50 Hz. is required. For the phase conductors, neutral and ground, the minimum section must be of 1,5 mmq of copper. It recalls the necessity to perform the ground connection as required by current legislation.

The plant must be performed and tested by qualified personnel.

The warranty excludes damages caused by erroneous connection.

Wiring and connection conductors sections

A three conductors cable (3x1,5 mmq) is expected between the net switch and the equipment. For the assembled versions and in all cases of separate installation from the control unit, a second cable, always 3 x 1.5 sq mm, shall be provided between the control unit and the support. Please note that the radiological groups are supplied without a plug for leaving the buyer free to connect to equipment already on site.

Efficient grounding is a first necessary condition for the proper functioning of the system, respecting the symbols indicated for connection:

F – Line (brown) N – Neutral (blue) T – Ground (yellow-green)

Point A grounded power cord; Point B output external lamp

Check carefully all connection cables, plugs and line contacts.

Remember that the suppliers must support a current of at least 10A.

The connection to the external lamps must be done by connecting the output LAMP indicated with the letter B in the figure above. The lamp must be of value 30W 230-240 Vac. according to the actual reference standard for plants and locals for medical use (IEC 64-8-710).

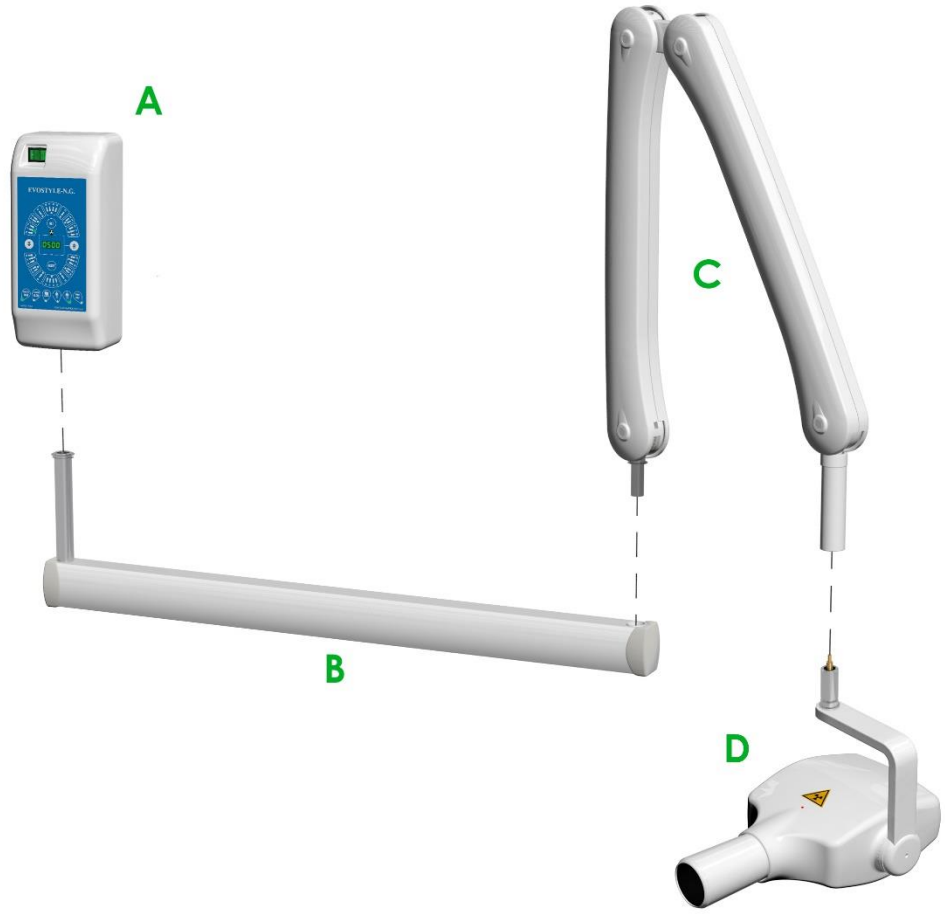
Installation

"CAUTION: To avoid the risk of any electric shock, this device must be connected only to power mains gifted with ground protection."

The installation is provided in both wall and mobile version on column.

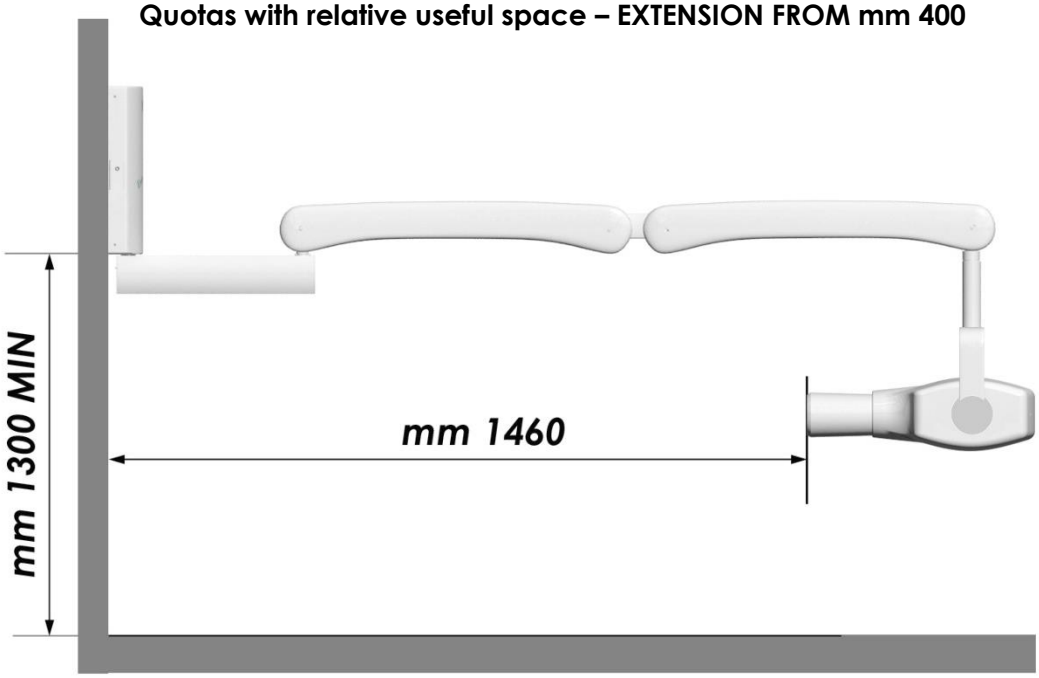
Instructions for installation in wall mode

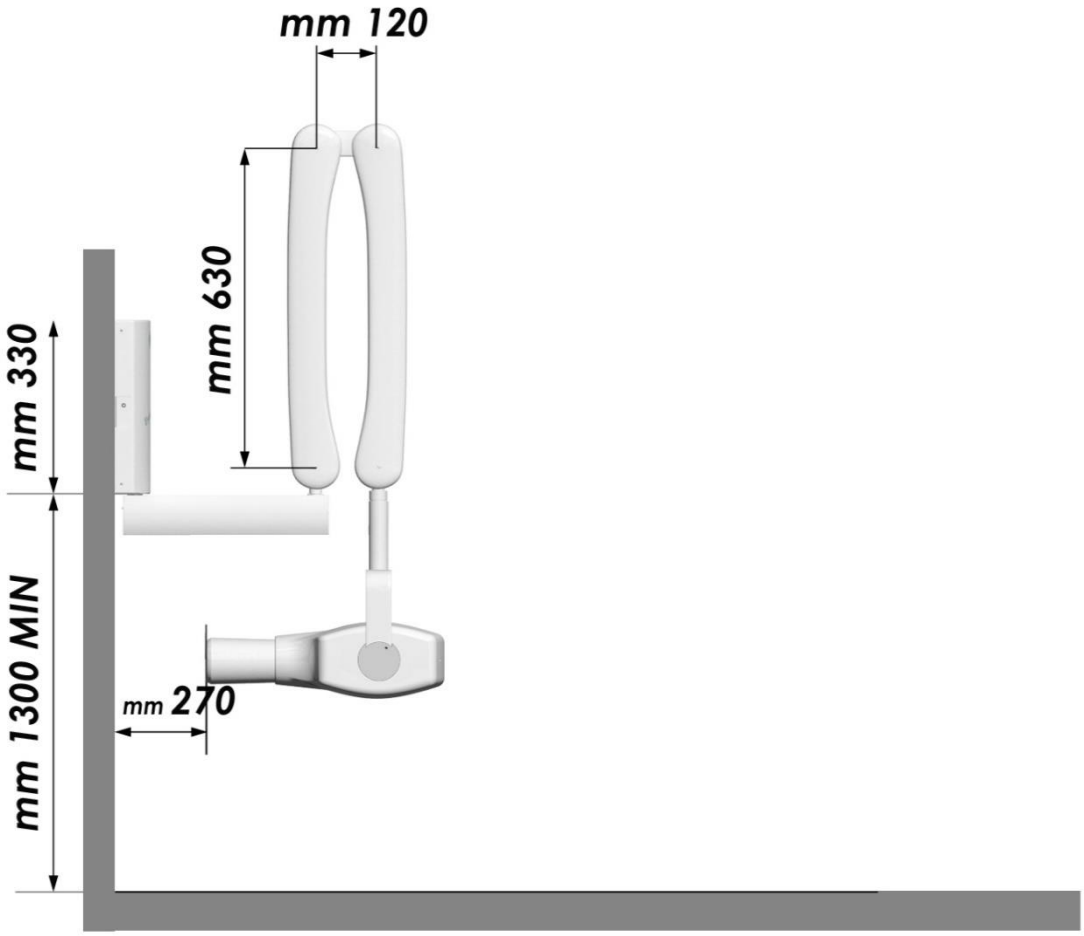
The system in wall version consists of the components shown in the following legend:



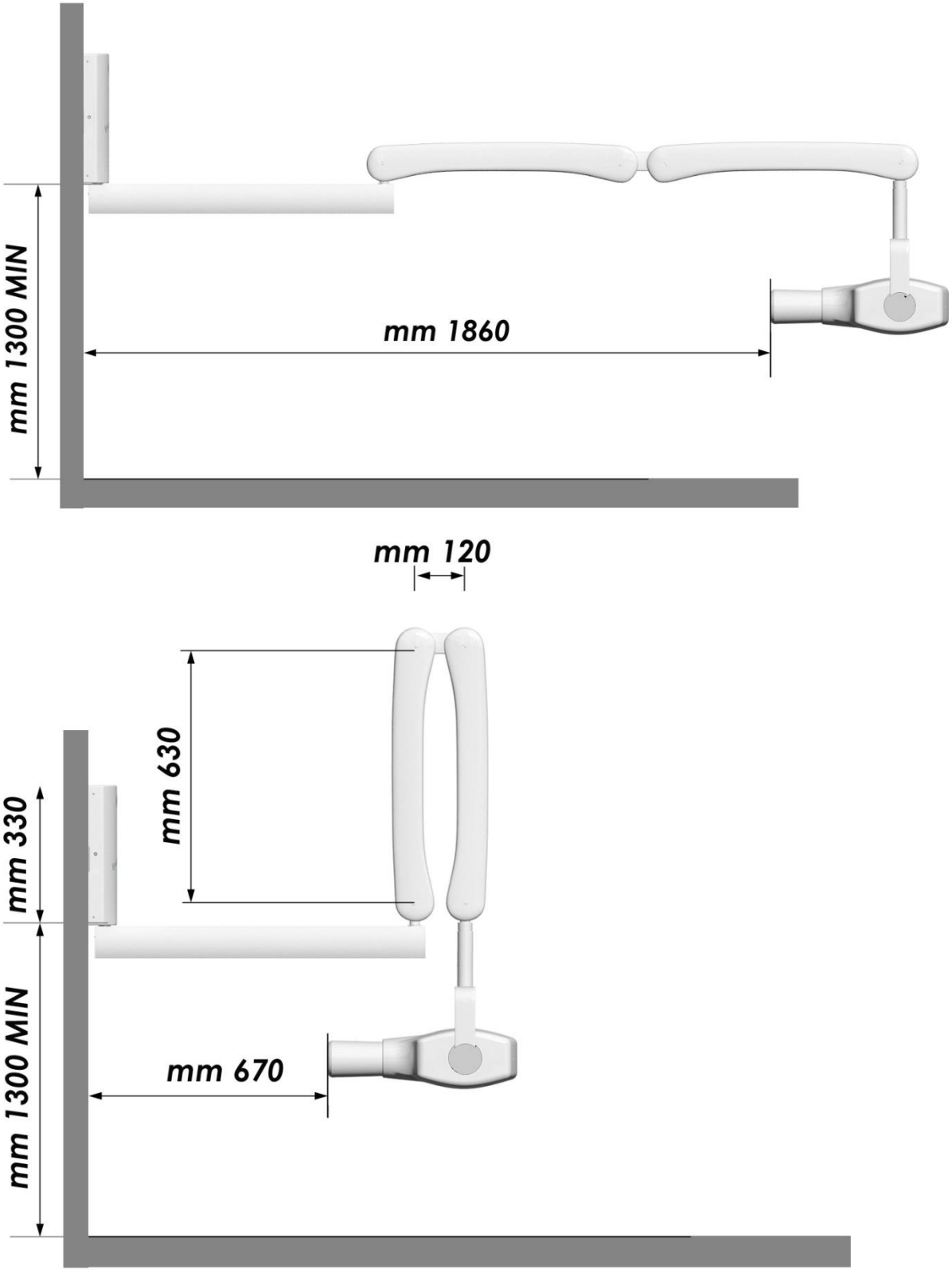
A ***wall plate + timer***
B ***extension***
C ***double pantograph arm***
D ***monoblock***

Quotas with relative useful space – EXTENSION FROM mm 400

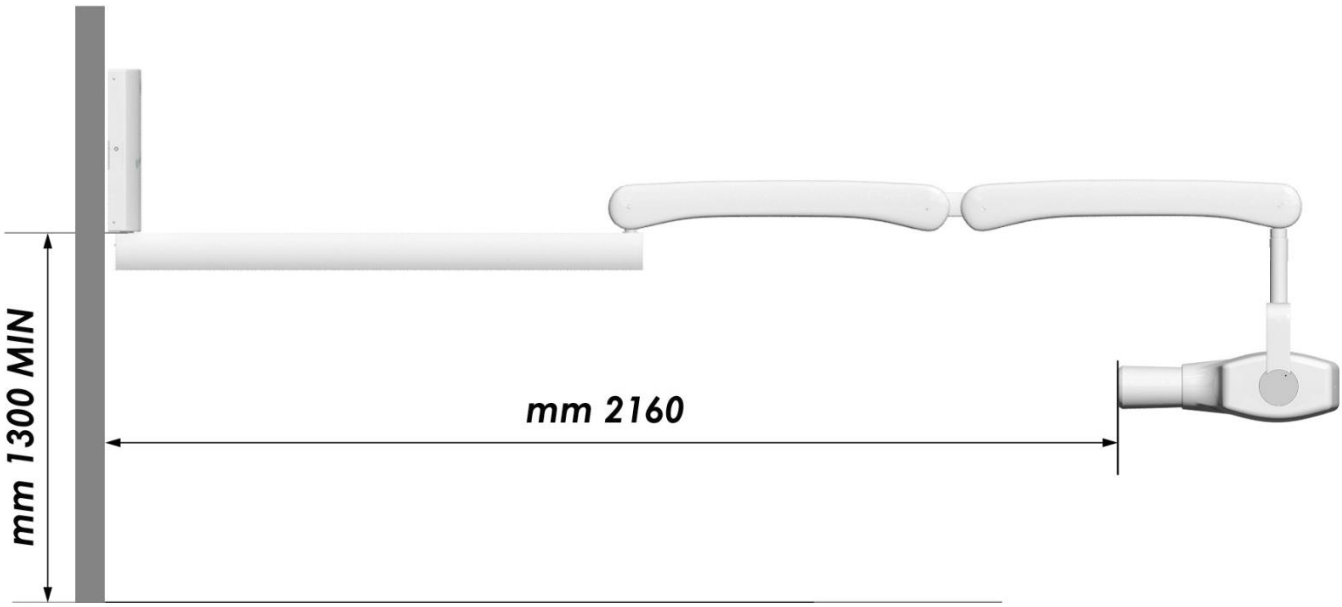


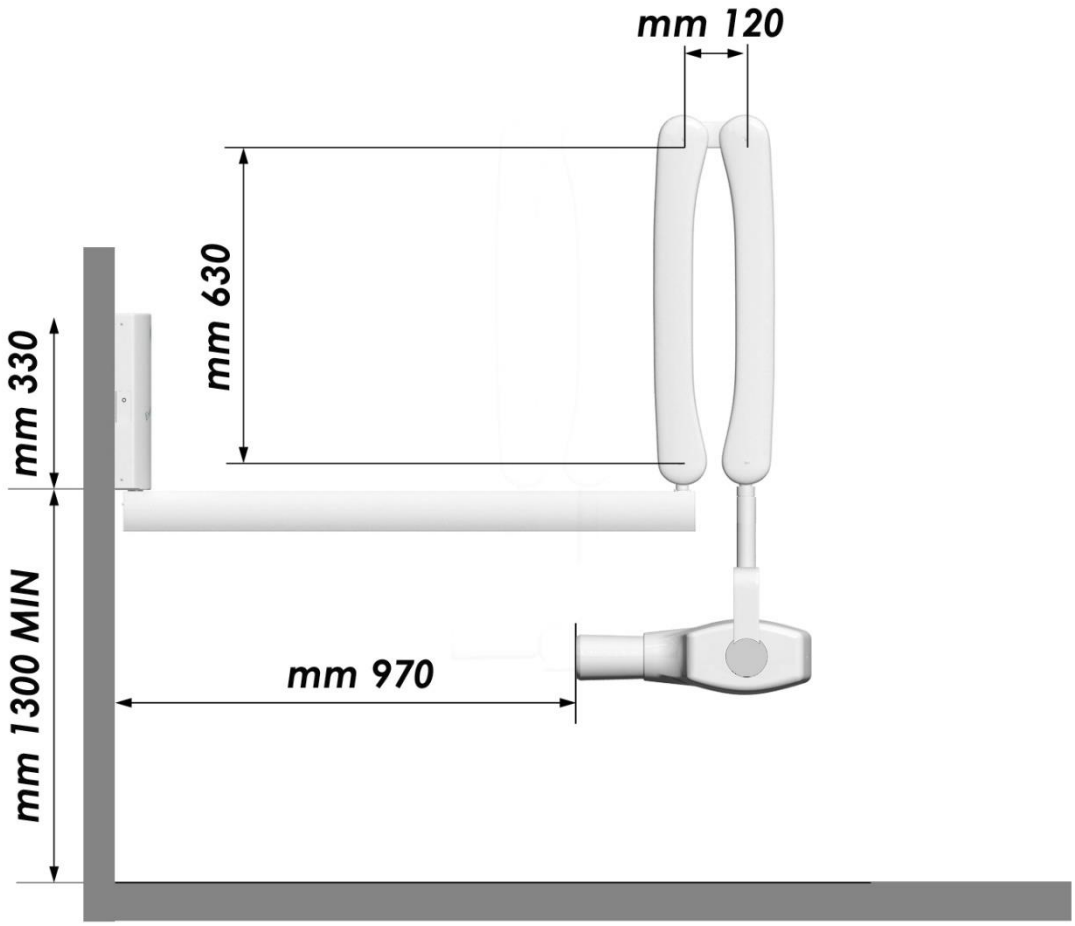


Quotas with relative useful space – EXTENSION FROM mm 800



Quotas with relative useful space – EXTENSION FROM mm 1100





Wall plate installation

- ✓ This device is provided with a plaque for the wall mounting with built-in timer ***(A)***, closed with a plastic cover (fig.1).

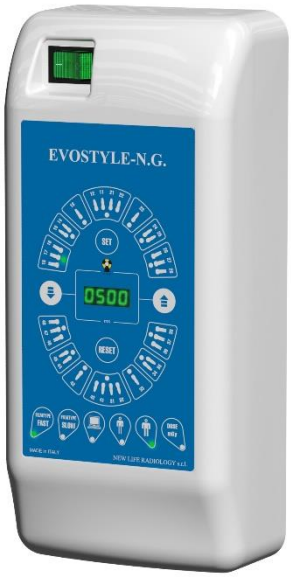


fig. 1

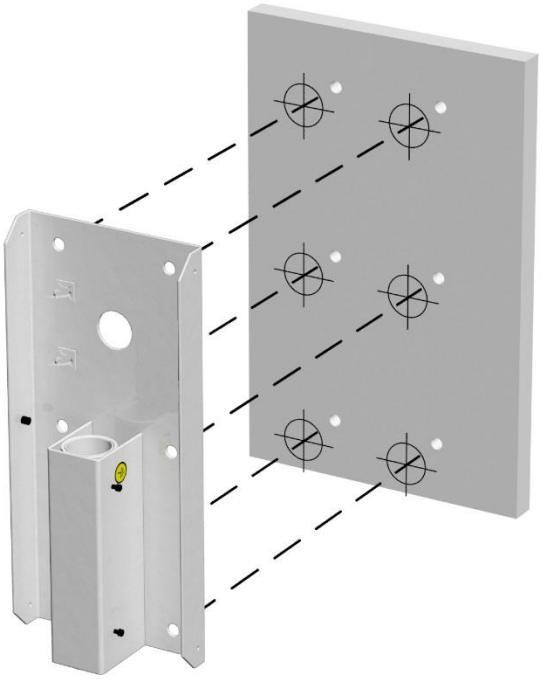


fig. 2

- ✓ Define the position on the wall of the WALL PLATE ***(A)*** with respect to the amplitude of the working field chosen and to the size of the structure that the same can assume right or left of the axis of the wall plate when it is inactive.
- ✓ Plot on the wall the position of the six holes making sure to check the perpendicularity with a plumb line. If the electric plant is recessed, track also the corresponding hole (Fig. 2)
- ✓ Drill six holes on the wall starting with the tip of ∅ 7, enlarging gradually. This to not demolish the stability and maintain under control the interaxes. For walls of full or holed or cement bricks use metallic plugs preferable of ∅ 12 equipped with unmissable female grain and separated screw ∅ 6 with hexagonal head and washer.
- ✓ For types of wall of insufficient reliability it is necessary to resort to the construction of a reinforcement to be defined case by case.
- ✓ Apply the wall plate and bring it closer parallel to the wall by tightening the 6 screws alternately, if the wall is not perfectly flat put adequate thicknesses so as not to deform the wall plate.

Extension installation

- ✓ Extract the SEGER from the extension ***(B)***, and enter it in the wall plate (A), as shown in fig. 3

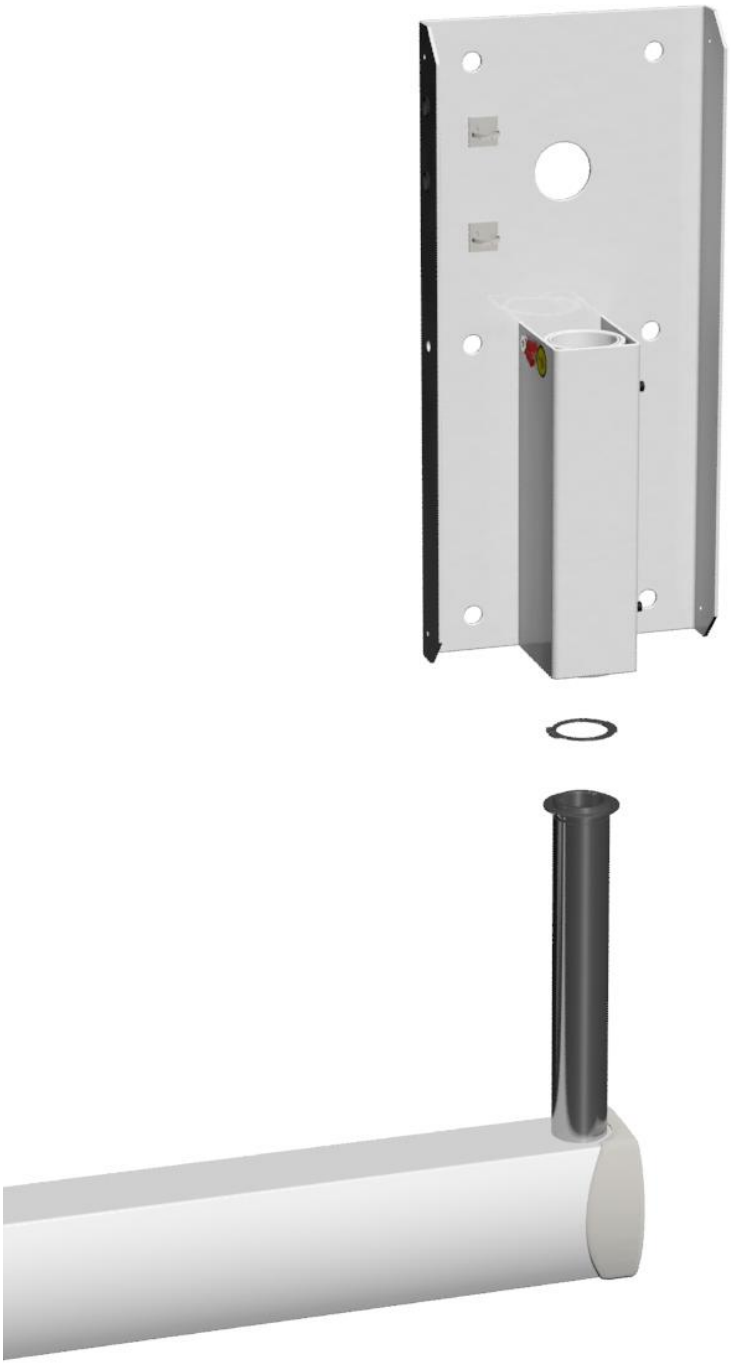


fig. 3

- ✓ Replace the SEGER, unhook the front cover and remove the lower strip cover strips (fig. 4)

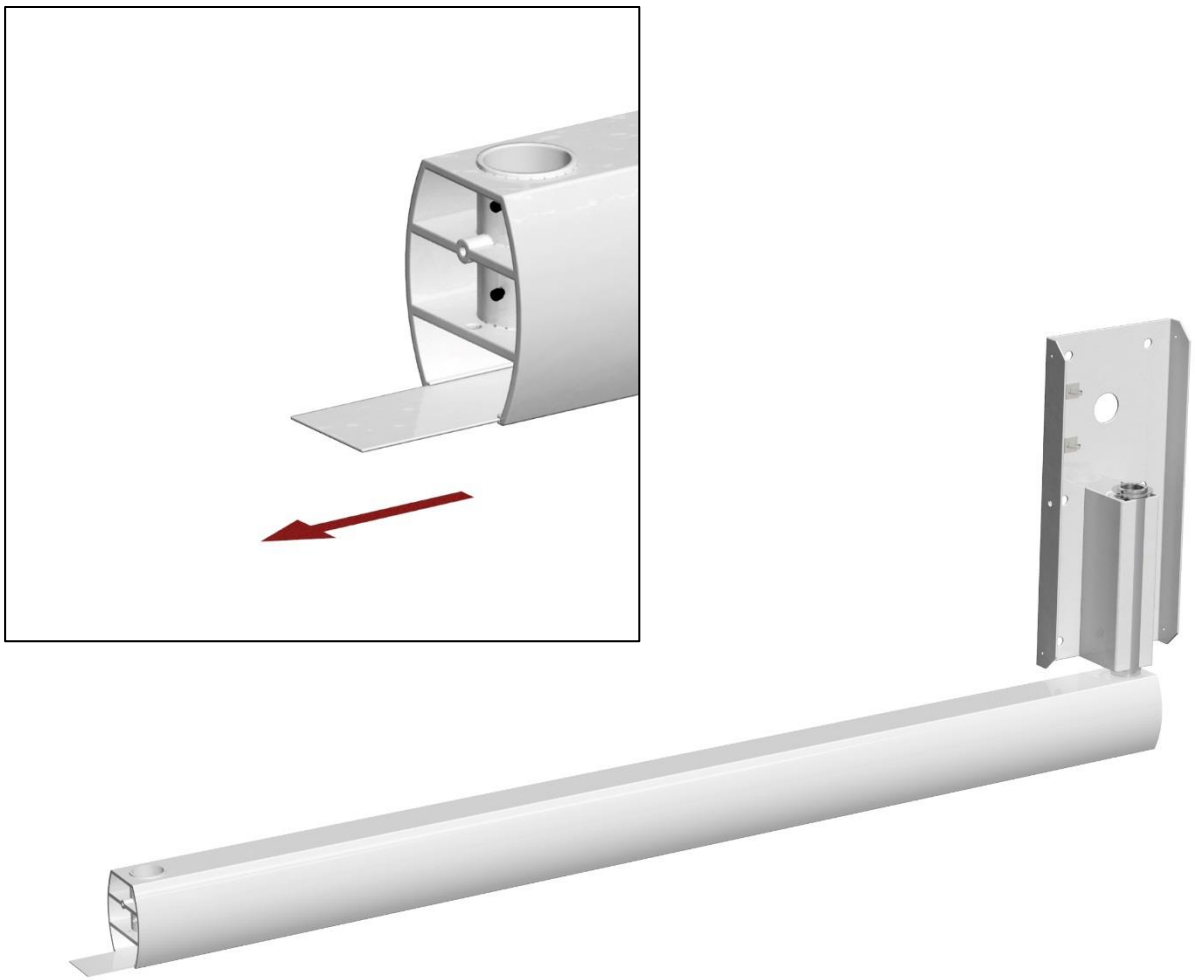


fig. 4

Double pantograph arm installation

- ✓ Enter the double pantograph arm ***(C)*** in the extension ***(B)*** and route the cable as shown in Figure 5. Close the extension repositioning the lower strip cover strips. Connect the cable from the double pantograph arm to output of **THERMOSWITCH** and the ground wire IN in its slot.

fig. 5

Monoblock installation

- ✓ **Before inserting the monoblock *(D)* it is essential to work in safety by opening the double pantograph arm *(C)* as shown in fig. 6, to avoid that it snaps abruptly since it has the springs charged and calibrated to support the weight of the monoblock.**

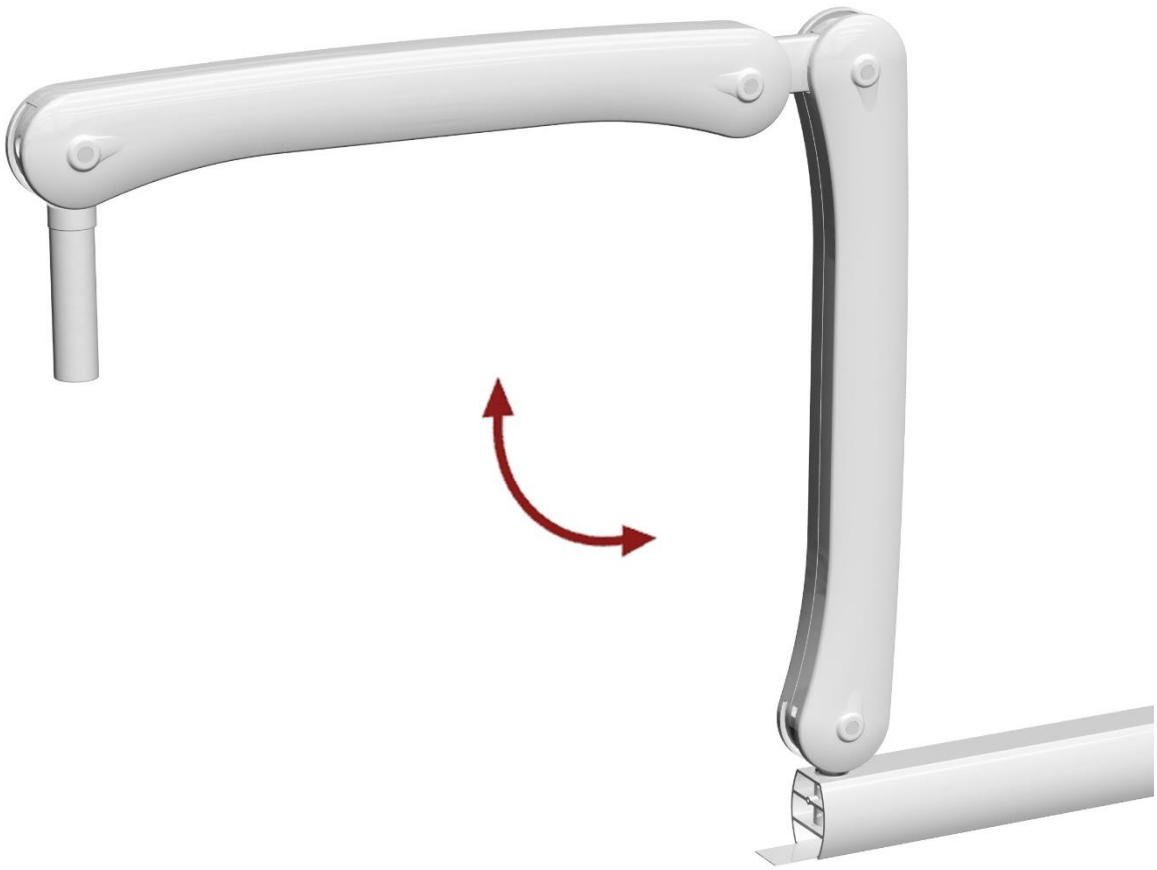


fig. 6

- ✓ Unscrew the screw from the front tubular carrier of the double arm pantograph ***(C)*** by lifting the cylinder and remove the half-moon(fig. 7)

fig. 7

✓ Insert Monoblock ***(D)*** in the double pantograph arm ***(C)*** as shown in Fig. 8

fig. 8

✓ Reinsert the half-moon in its slot. Lower the cylinder, securing the double arm pantograph with the screw.

fig. 9

Settings

After installing the equipment, make a dynamic test to ensure that the movements of the assembly are properly calibrated.

Clutch screws adjustment

- ✓ If necessary adjust the clutch screws of the wall plate ***(A)*** and the extension ***(B)*** as shown in fig.10

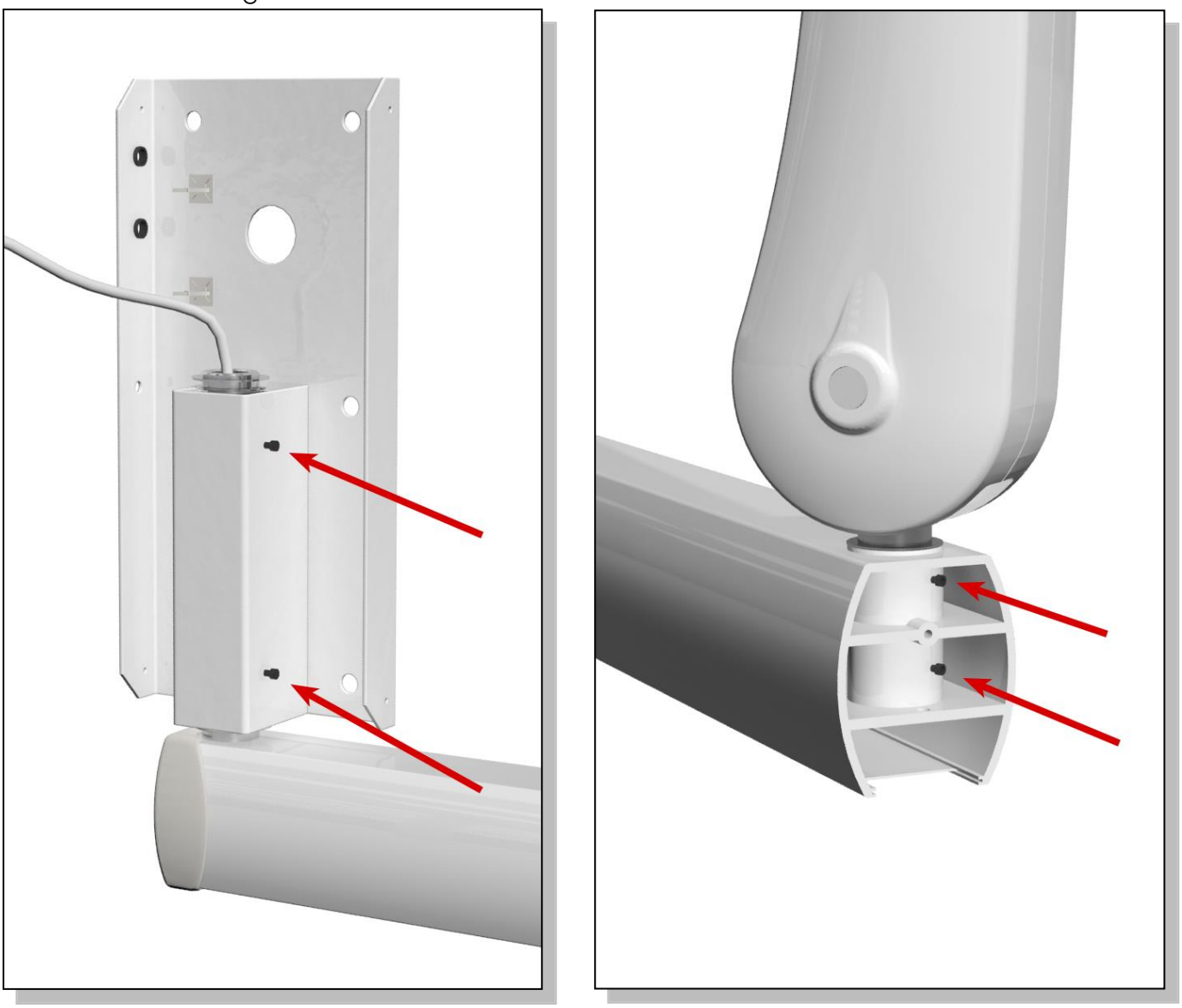


fig.10

- ✓ After making the adjustments necessary to close the wall plate with the respective cover, making sure to replace the lower back lining strip and the front cover of the extension.

Springs adjustment of the double pantograph arm

Do not intervene personally in the arm's settings, have this operation made exclusively by specialized personnel only.

- ✓ In the case in which the double pantograph arm does not remain stationary in all positions wanted by the user, it means that requires some adjustments. The calibration must be performed as follows: with reference to fig. 11, if it was found that the section A is spread when the double pantograph tends to go back, it means that the spring is too tight and in this case we must unscrew slightly the push-spring nut through the socket wrench supplied. To do this, tilt the section A of about 15 ° and insert the socket wrench into the hole 1 and unscrew slightly.
- ✓ If on the contrary it is found that stretching the double pantograph, the stretch A tends to fall forward, it means that the spring must be slightly loaded, then as bifore, tilt the stretch A of 15 ° and insert the socket wrench into the hole 1 and screw slightly.
- ✓ This procedure is identical for the section B in which the adjusting key must be inserted in the hole 2.

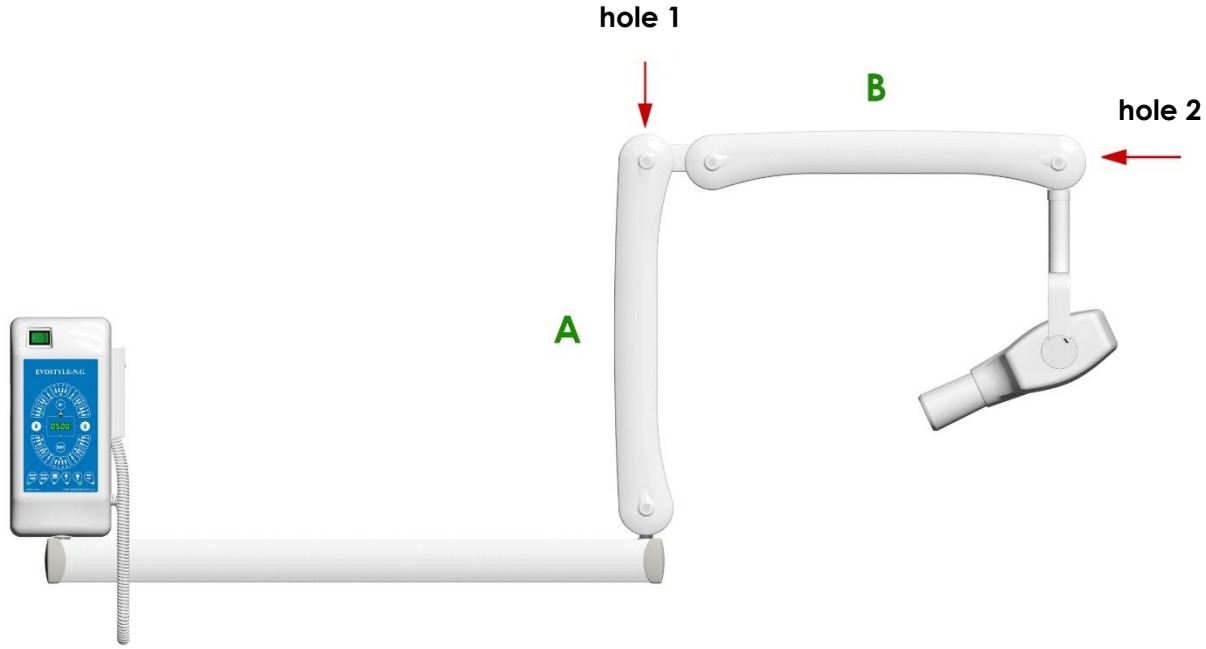


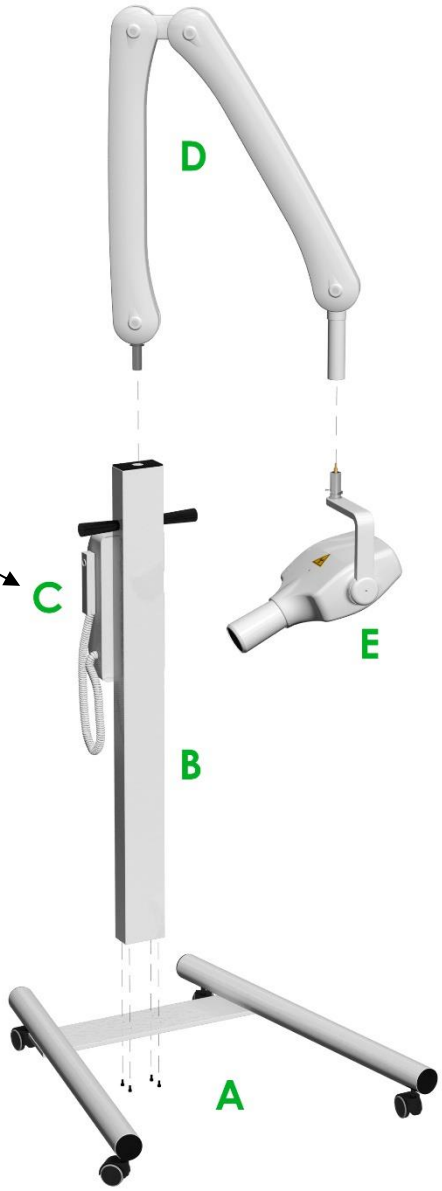
fig.11

Instructions for installation in column mode

This device is not intended for mobile use, the wheels are intended for a better positioning of the main appliance above the patient.

The system in column mode consists of the components shown in the following legend:

Detail C



A	***cart***
B	***vertical support***
C	***plate holder + timer + button with spiral cord***
D	***double pantograph arm***
E	***monoblock***

Quotas with its useful space

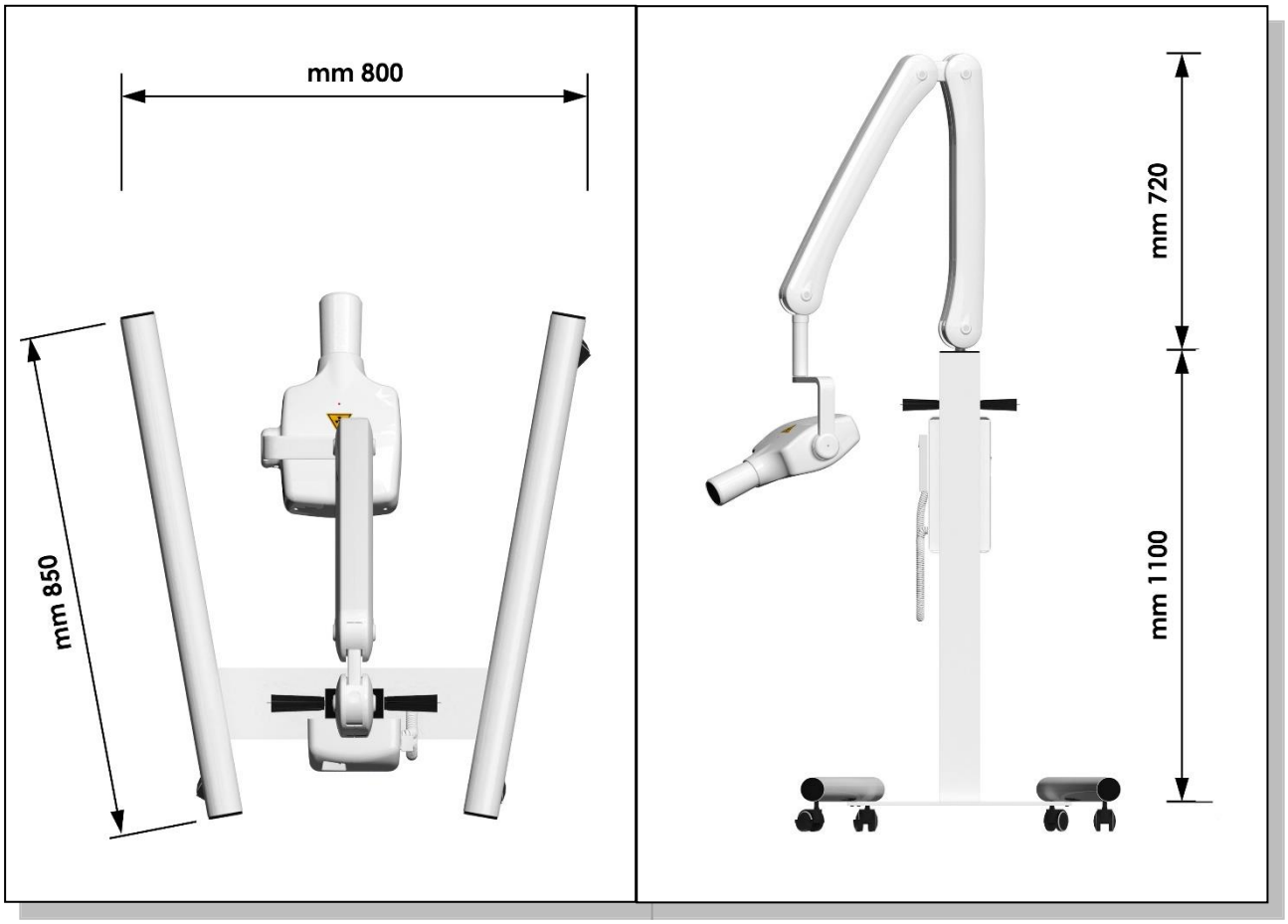


Fig. 12

Column assembly

- ✓ The first procedure to be carried out is to assemble the carriage ***(A)***, this is done by mounting the two tubular "1" and "2" on the base "3" using four screws 8x20, as shown in fig. 13

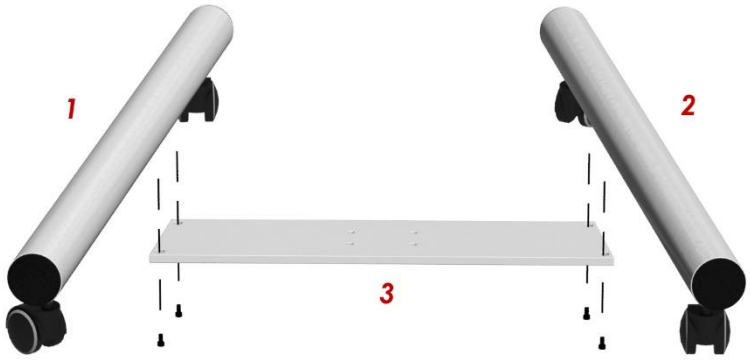


Fig. 13

- ✓ Once assembled the cart ***(A)*** is possible to fix on it the vertical support ***(B)*** using 4 screws 6x20 as shown in fig. 14

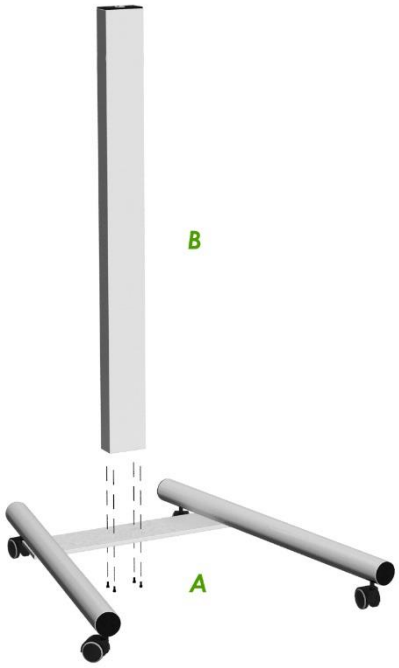


fig. 14

- ✓ Insert the two handles provided into the hole as in fig. 15

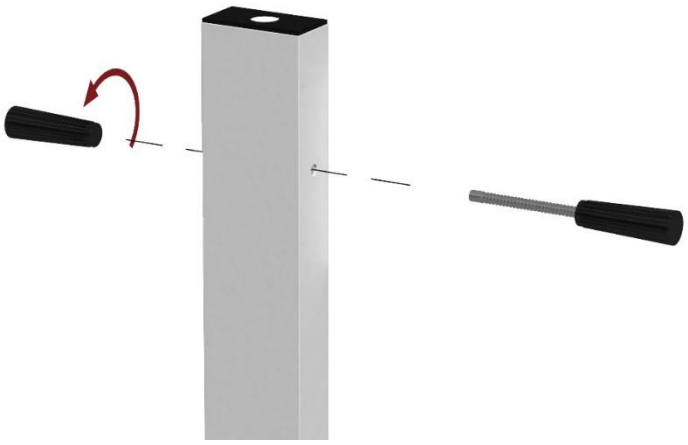


fig. 15

Installing double pantograph arm

- ✓ By passing the power cord coming from the vertical support ***(B)*** through the hole, fix the plate support + timer ***(C)*** to it using four screws 3,5x6,5 as shown in Fig. 16

fig. 16

✓ Insert the double pantograph arm ***(D)*** in the vertical support ***(B)*** as shown in fig. 17

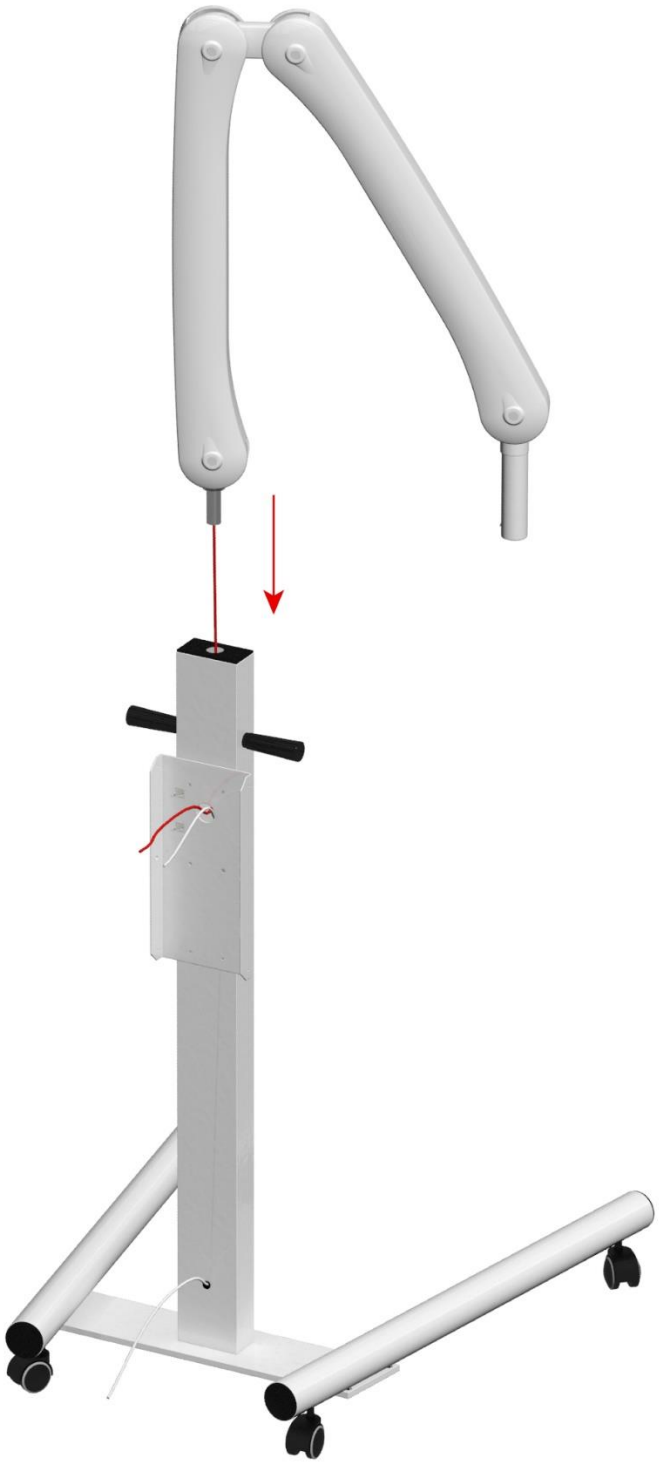


fig. 17

- ✓ Connect the cable coming from the vertical support ***(B)*** to the input of the timer, and the cable coming from the double pantograph arm ***(D)*** to the output of the **THERMOSWITCH** as shown in figure 18:

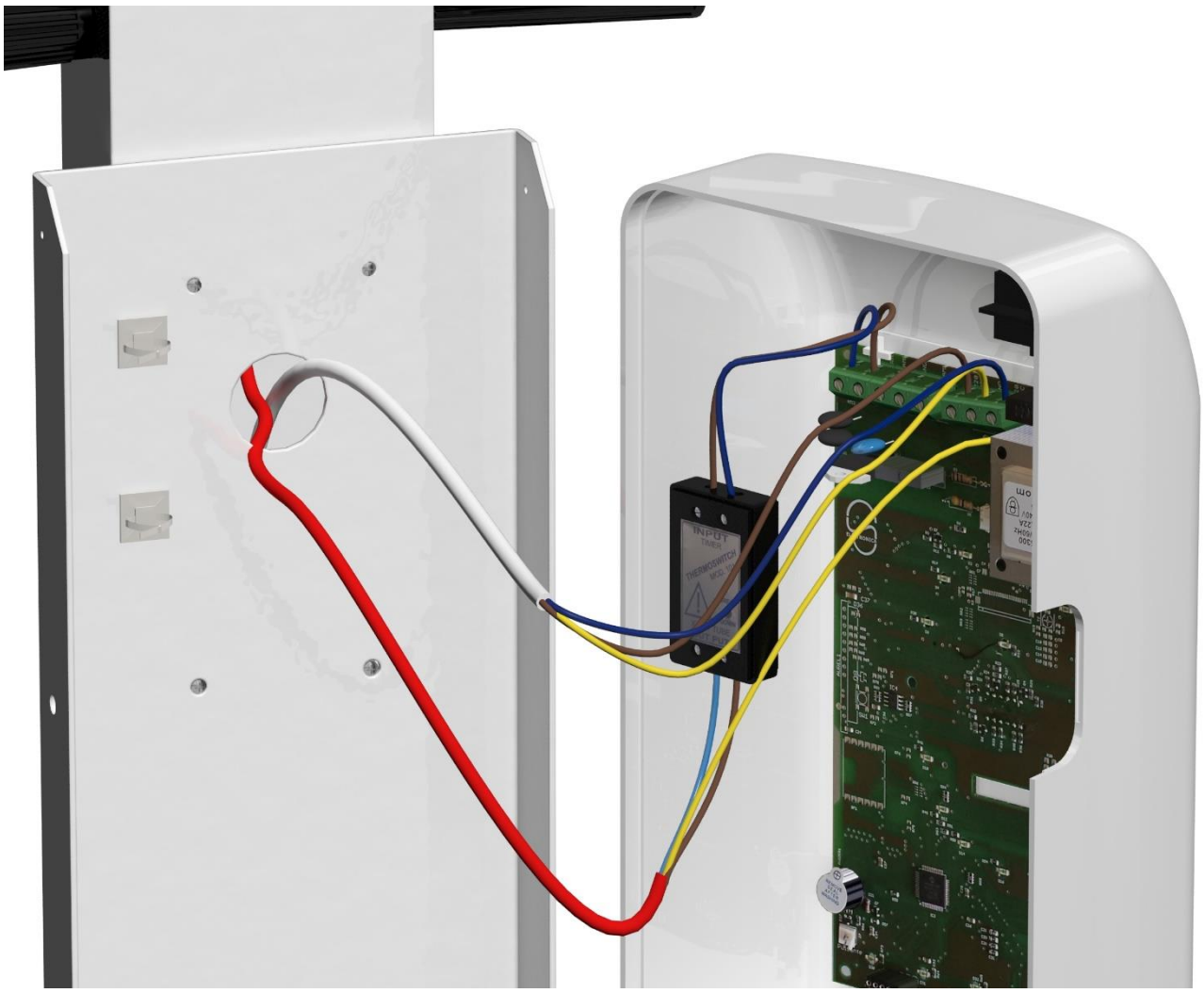


fig. 18

Monoblock installation

- ✓ To install the monoblock refer to the procedure described previously for the wall version from page 20.
- ✓ To adjust the springs of the double pantograph arm refer the procedures for the wall version on page 24.

Timer operation

- ✓ The timer of the device allows the management of the exposure times of the monoblock at the same time guarantees maximum safety in the use of X-ray tubes for electro medical purposes for intraoral diagnostic;
- ✓ The timer control panel is provided with membrane digital buttons so as to facilitate its use;
- ✓ The timer functioning is managed by button with spiral cord to dead man's device in such a way as to ensure maximum safety for both the operator and patient;
- ✓ The timer does not allow the use of X-ray in scopy;
- ✓ The time range set by the factory values complies with R10 range relative to standard EN60601-2-7 (IEC 60601-2-7);
- ✓ The exposure time displayed on the timer are expressed in ms;
- ✓ The maximum time that can be set is 3 s (the display will read 3000) while the minimum time is 40 ms. (the display will read 0040);

Description of the timer control panel

Following is the symbolism used on the front panel of the timer:

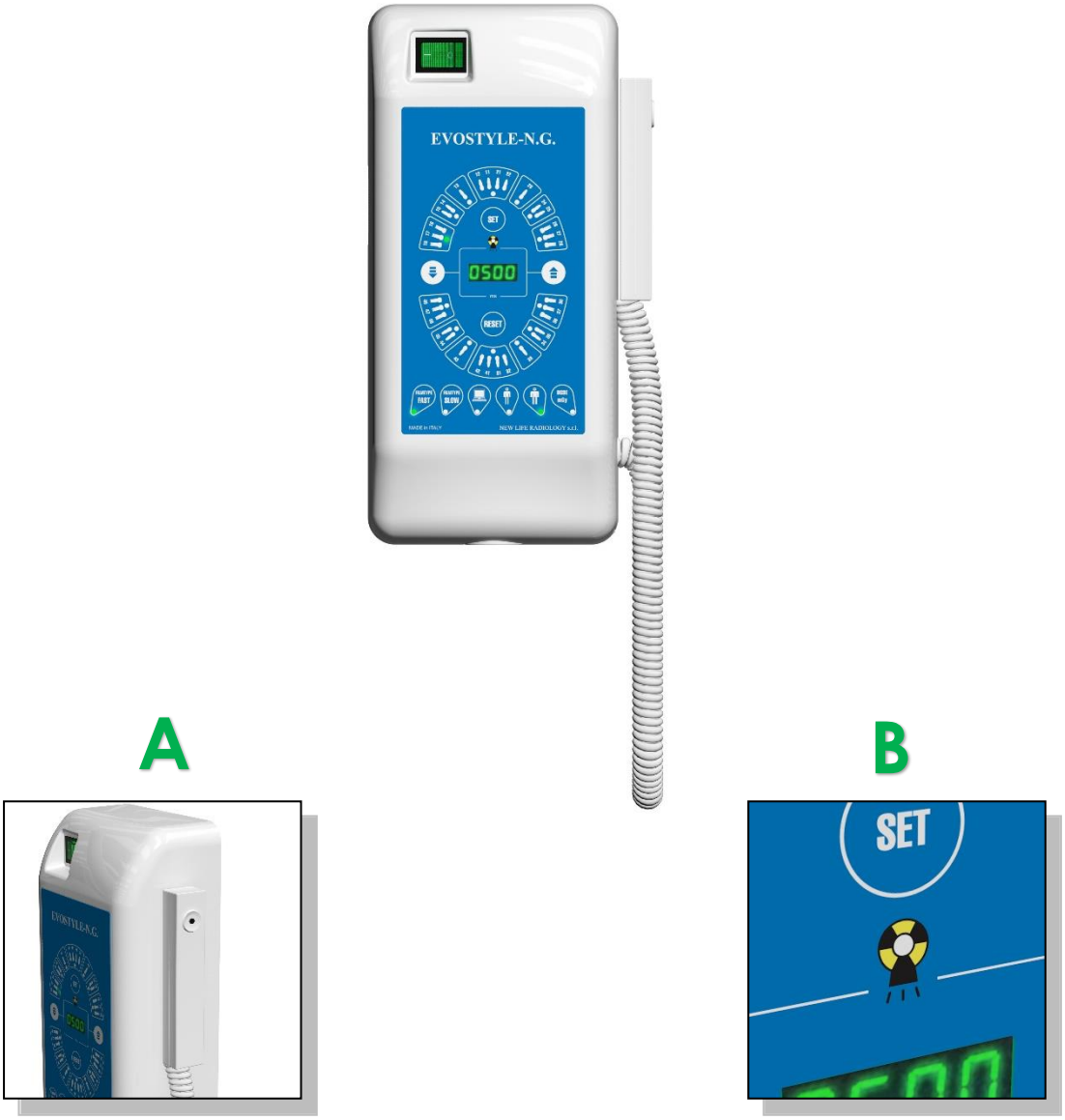


fig.19

A	Button with cable
B	Light emission radiation

Tooth type: Incisor (n. 11 – 12 – 21 - 22 - 31 – 32 - 41 - 42)

Tooth type: Canine (n. 13 – 23 – 33 – 43)

Tooth type: Pre molar (n. 14 – 15 – 24 – 25 – 34 – 35 – 44 – 45)

Tooth type: Molar (n. 16 – 17 – 18 – 26 – 27 – 28 – 36 – 37 – 38 – 46 – 47 – 48)

Selection button: increasing manual mode

Selection button: decreasing manual mode

Patient selection button: Normo-type

Patient selection button: Child

Selection button: Digital radiography

Times memorization button

Selection button Reset: It allows resetting the device to factory defaults

Selection button: Film Type fast

Selection button: Film Type slow

Selection button: Dose mGy

4-digit display (the exposure time expressed in ms)

Timer use instructions

- ✓ **SWITCHING ON**: to switch on the timer set the switch on I as shown in fig.20 for both the mural and column version

fig.20

When you turn, on the display will appear for about one second, the 1_02 number that indicates the version of installed software; subsequently a number which can vary from 0080 to 0220 indicating the optimum start given to the tube (expressed in [ms]), also this value will be visible for about one sec .; and finally the timer will be set with the parameters of the last exposure carried out successful. At this point the timer is ready for use.

FUNCTIONING E TIME SCALE:

On the default timer is installed R10 time scale (in milliseconds [ms]), these values are recommended to obtain with less exposure time the maximum image quality, they can be modified depending on the operator's needs. The tables below show the programmed time scales depending on the type of film or sensor used with the relative dose value, expressed in milligray [mGy] that it has at 20 cm from the focus tube (this value is to be considered an estimate of the emitted dose and it should not be understood as a measure of the same):

Film type Fast 

Upper jaw

	Tooth type			
Patient type				
	160 [ms] 1.23 [mGy]	160 [ms] 1.23 [mGy]	250 [ms] 1.93 [mGy]	320 [ms] 2.47 [mGy]
	100 [ms] 0.77 [mGy]	100 [ms] 0.77 [mGy]	160 [ms] 1.23 [mGy]	200 [ms] 1.54 [mGy]

Lower jaw

	Tooth type			
Patient type				
	160 [ms] 1.23 [mGy]	160 [ms] 1.23 [mGy]	160 [ms] 1.23 [mGy]]	160 [ms] 1.23 [mGy]
	100 [ms] 0.77 [mGy]	100 [ms] 0.77 [mGy]	100 [ms] 0.77 [mGy]	100 [ms] 0.77 [mGy]

Film type Slow 

Upper jaw

	Tooth type			
Patient type				
	400 [ms] 3.09 [mGy]	600 [ms] 4.63 [mGy]	640 [ms] 4.94 [mGy]	800 [ms] 6.18 [mGy]
	260 [ms] 2.00 [mGy]	320 [ms] 2.47 [mGy]	400 [ms] 3.09 [mGy]	500 [ms] 3.86 [mGy]

Lower jaw

	Tooth type			
Patient type				
	400 [ms] 3.09 [mGy]	400 [ms] 3.09 [mGy]]	400 [ms] 3.09 [mGy]	500 [ms] 3.86 [mGy]
	250 [ms] 1.93 [mGy]	250 [ms] 1.93 [mGy]	250 [ms] 1.93 [mGy]	320 [ms] 2.47 [mGy]

RVG 

Upper jaw

	Tooth type			
Patient type				
	120 [ms] 0.92 [mGy]	160 [ms] 1.23 [mGy]	200 [ms] 1.54 [mGy]	260 [ms] 2.00 [mGy]
	60 [ms] 0.46 [mGy]	60 [ms] 0.46 [mGy]	80 [ms] 0.61 [mGy]	100 [ms] 0.77 [mGy]

Lower jaw

	Tooth type			
Patient type				
	120 [ms] 0.92 [mGy]	120 [ms] 0.92 [mGy]	120 [ms] 0.92 [mGy]	160 [ms] 1.23 [mGy]
	60 [ms] 0.46 [mGy]	60 [ms] 0.46 [mGy]	60 [ms] 0.46 [mGy]	60 [ms] 0.46 [mGy]

To set the desired exposure parameters, select the type of tooth, the patient and the appropriate film. If you have the need to change the default time you can do it manually using the button  to decrease it, and key  to increase it, every time pressure is increased / decreased by 20 ms, and you can save that time by pressing the button 

During operation, we recommend the use of protective devices such as collars and aprons.

To perform the exposure once positioned the cone along the monobloc on the area to be

examine. After setting the time, and having moved away to a safe distance from the radiation source (minimum 2 meters), simply press the button (A) holding it down until the time on the display starts blinking, the exposure will be accompanied by a beeping sound and a visual indicator on the timer panel (the led (B) yellow will be lit during the exposure time).

Once the exposure is finished, must wait until the timer runs out the pause time to make the next radiography (the timer is paused until the display will flash the time of the last exposure made).

If the timer is left on without performing any activity for about 15 minutes, it will be on standby. In this mode, the display will be turned off and only the adult patient led will be turned on. To disable the standby mode, simply select any button.

After making an exposure, it is possible to know an estimate of the dose emitted expressed in [mGy] to 20 cm from the focus, by pressing 

this value will remain visible on the display for about 3 seconds, after which the display will be displayed again the last successful exposure time, in this conditions the timer is ready for a new exposure.

ERROR TABLE

The errors are displayed with "ERROR:" followed by an indication of the error:

ERROR CODE	CAUSE	SOLUTION
Err1	The ***(A)*** button turns out to be pressed while pressing the system power button	Turn off and turn on again the device; Should such problem persist, it means that the button is blocked in the "normally closed" mode. Substitute the button;
Err2	The ***(A)*** button is released prior to the end of the exposure time	In order to get out of the error press a button from the keyboard at the end of the cool in procedure;
Err3	The ***(A)*** button is pressed by the user at the end of an exposure and subsequent cooling action	In order to get out of the error release the button key;

Possible failures

- ✓ Below there are some possible failures that might occur, and their recovery procedures

Must always disconnect the unit from the mains supply before starting any maintenance or inspection activities.

TIMER DISPLAY DOES NOT SWITCH ON

If the timer's display does not turn on, first check that the fuses are intact as shown in fig. 21

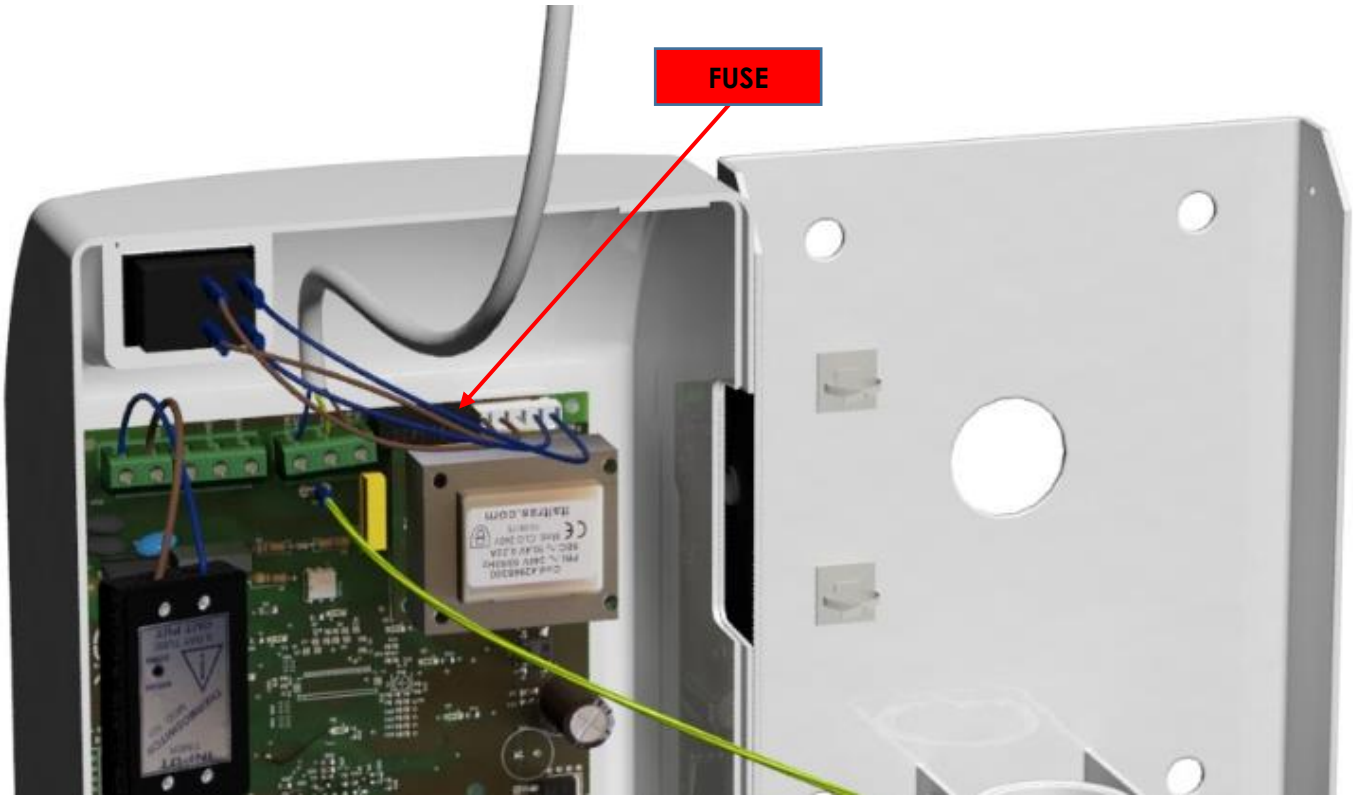


fig.21 (wall / column version)

LOSS OF DATA SET IN THE TIMER

If there is a loss of data set on the timer, a possible solution is to reset it bringing it to the factory settings This operation is effected by holding down the RESET button and turning on the system, all of the teeth LEDs light up and then release the RESET button. Wait until the software version appears and the exposure time. In this way the system is reset and ready for use.

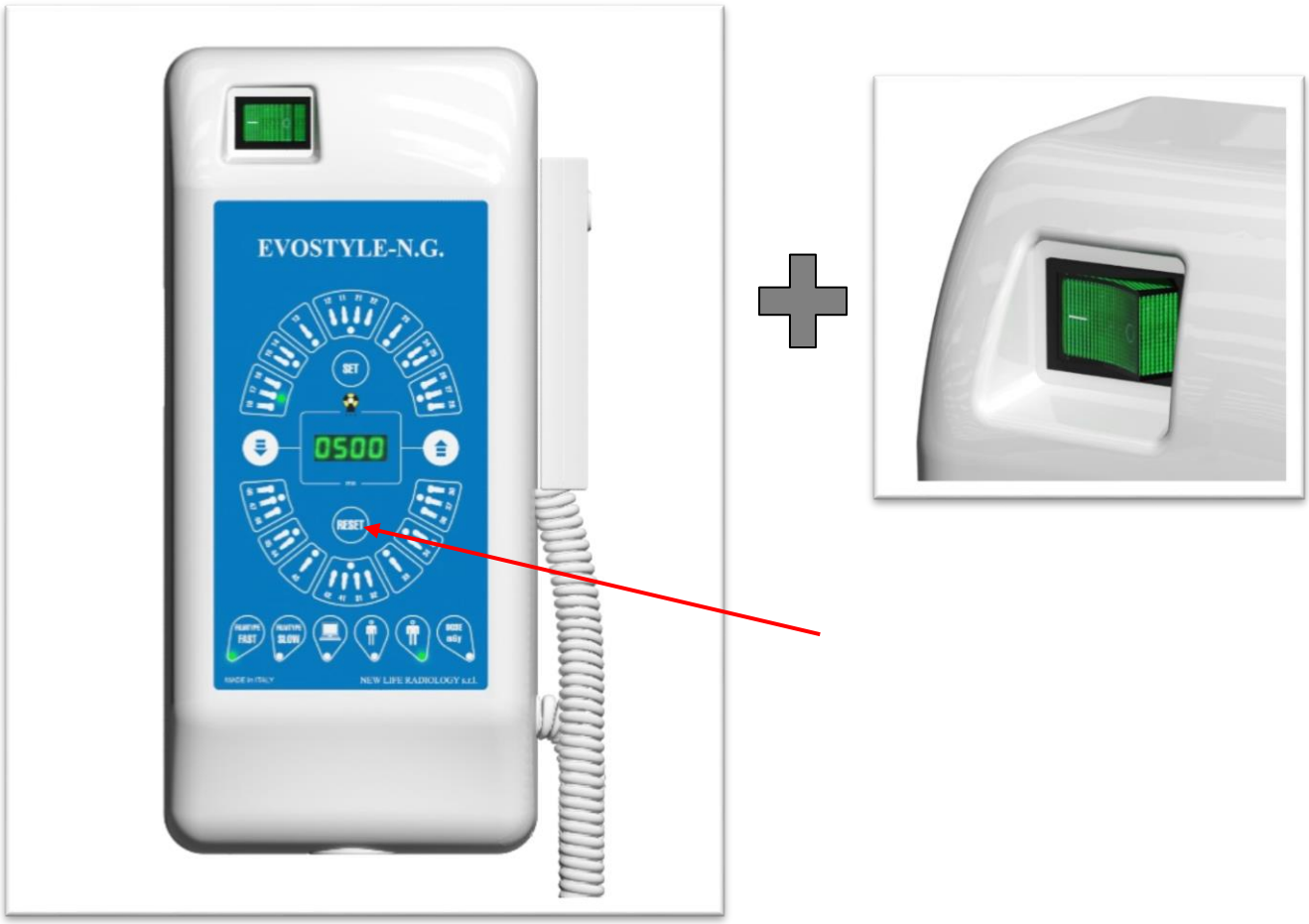


fig. 22 (wall / column version)

THE MONOBLOCK DOES NOT EMIT X-RAYS

If the monoblock does not emit X-rays, as first check the continuity of the **THERMOSWITCH;** if this test is negative, you must bypass it as shown in fig.23

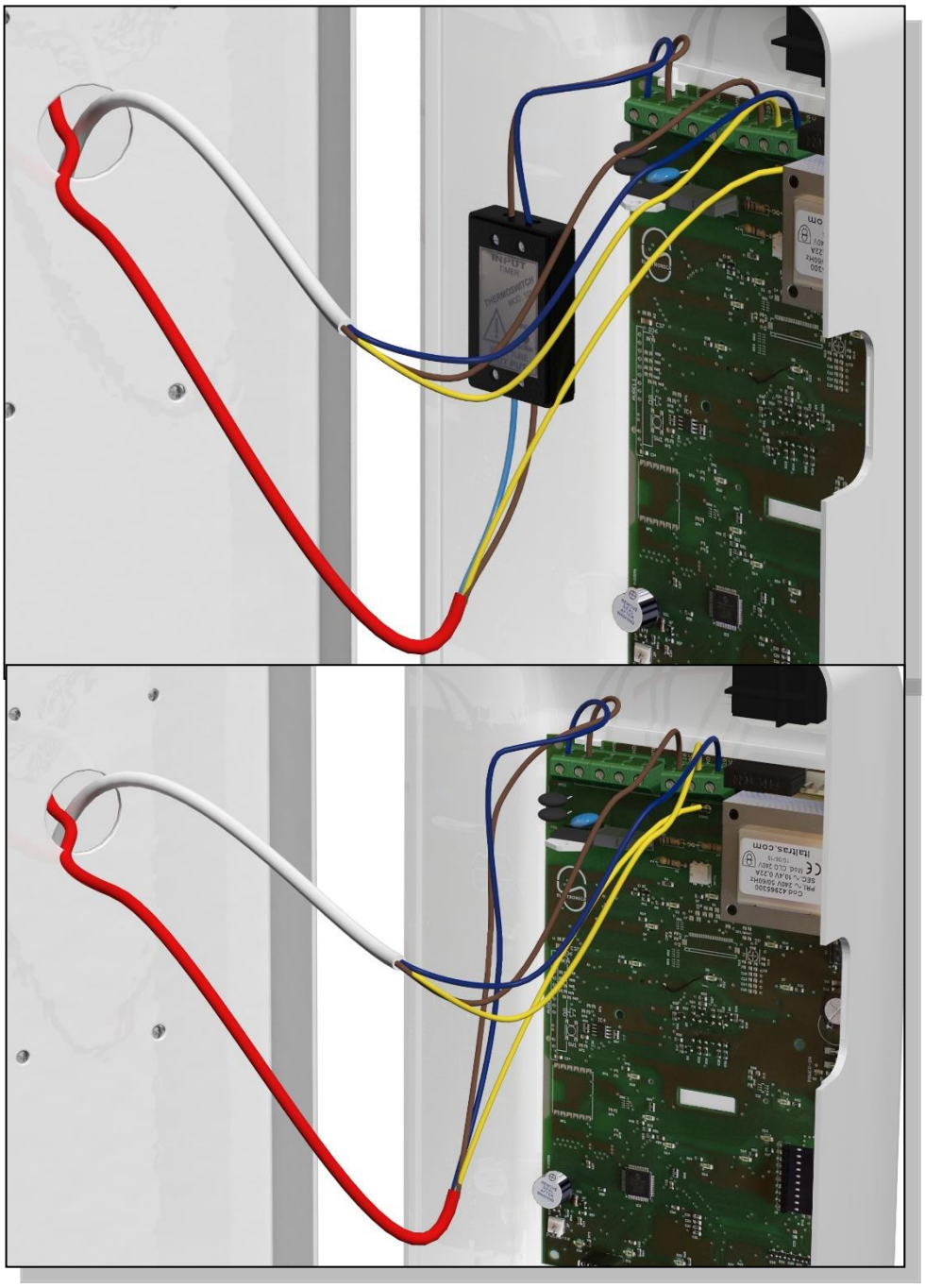


fig. 23

If after this operation there is still no x-ray emission, the problem must be sought through a tester in the continuity of the power cord that goes from the monoblock to the timer. Using a tester to check the continuity between the points A and B as shown in figure 24.

fig.24

Radiant tube's filament pre-heating time variation

Should it be necessary to increase or decrease the pre-heating time of the filament of the radiant tube, proceed as follow:

press the button  and at the same time, turn on the system. When a number appears on the display, release the button  , Such number is equivalent to the pre-heating time actually present in the memory. In order to vary such time, press the directional button  if you want to increase the pre-heating time , or the directional button  to decrease such time. Once the desired time is reached press the button  , the new value will be saved into the memory and the sign "END" will appear on the display. At this point, turning off and rebooting the system is necessary.

Measurement of the filament current

The measurement of the filament current can be carried out through the use of an oscilloscope or by means of a digital multimeter. To perform this measurement, proceed as follows:

- ✓ After removing the back cover, referring to Fig.25 Unsolder the wire from the connector at point A and connect in series a resistance from 1KΩ

fig. 25

Measurement using the oscilloscope:

Measure across the resistor the voltage value. To make the measurement with an oscilloscope, you need:

Set the time base [SEC/DIV] and Volt time scale [VOLTS/DIV] of the oscilloscope in an appropriate manner, so that the waveform of the measured voltage fills the screen of the oscilloscope, as shown in fig.26 (the order of magnitude of exposure time to perform the current measurement is of a few hundred ms)

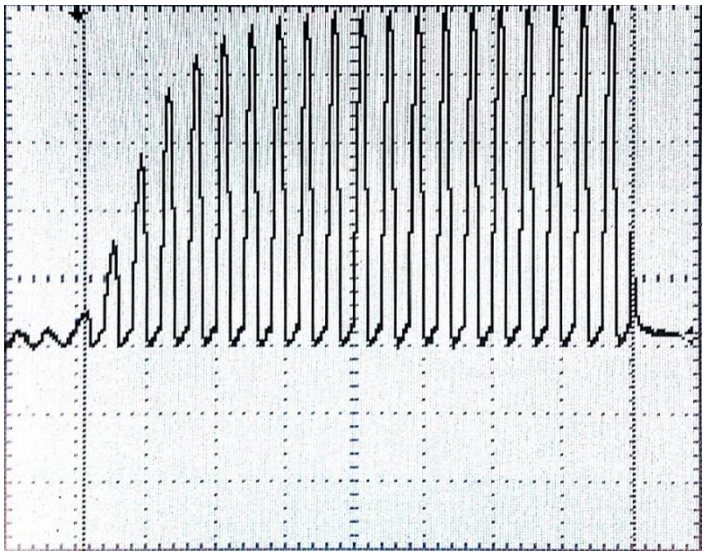


fig. 26

If the measurement is performed correctly it is expected to see an average value of about 8 V (to each V corresponds 1 mA)

Measurement using the digital multimeter:

It is necessary to set the full scale of the multimeter in an appropriate manner in order to measure the voltage across the resistance; then after positioning the end sleeves of the multimeter across the resistor (as shown previously in fig.25) set an exposure time long enough to allow the multimeter to read this voltage (the order of magnitude of the exposure is approximately 1 sec). The value that is expected to read is like in the previous case of about 8 V (to each V corresponds 1 mA)

Procedure for dosimetric measurements:

During an inspection test are carried out dosimetric measurements to verify correct operation. These measures are carried out by a special instrument cluster with the following procedure:

- ✓ The instrument used for dosimetric measurements is the RTI ELECTRONICS PIRANHA 255;
- ✓ Is positioned the instrument at a distance of 50 cm from the fire hose and found the dose values expressed in mGy;
- ✓ It checks the performance of the X-ray tube is in compliance with the project specifications;
- ✓ The tests are stored in digital format and made available for those who request them;

Plates positioning

- ✓ Below, in fig.27 it shows the layout plates positioning on EVOSTYLE N.G.

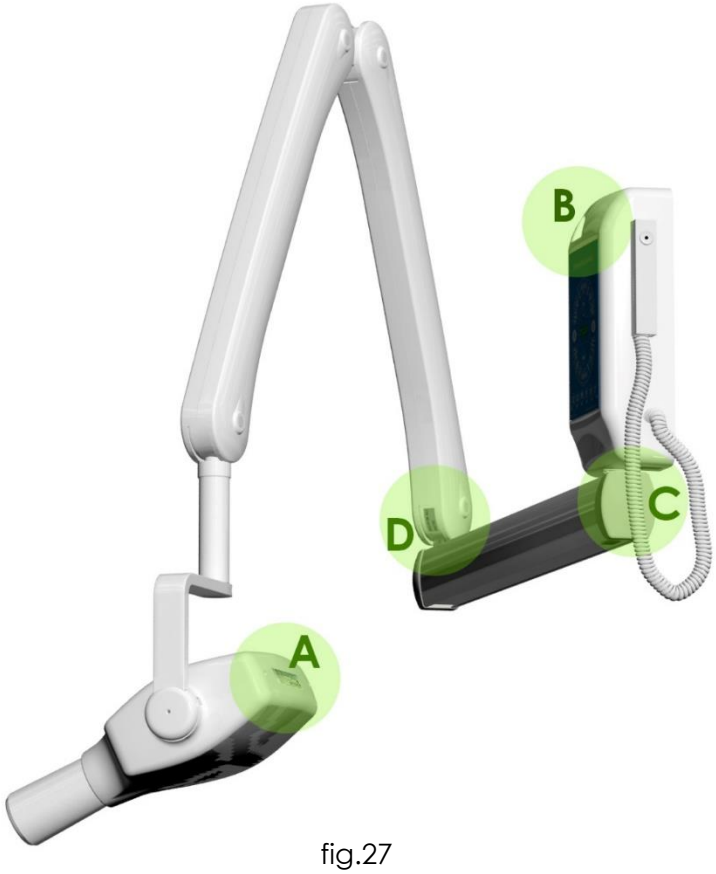


fig.27

Description plate fields:

1. TUBE:

It indicates the model of the X-ray tube used;

2. MAT: XXXXXXXX

It indicates the serial number of the X-ray tube;

3. TIMER: XX.E XYZ

XX It indicates the year of manufacture;

E XYZ It indicates the number of the timer series;

4. S/N XX.XY.XYZ (It represents the device serial number)

XX It indicates the year;

XY It indicates the month;

XYZ indicates the serial sequential number;

("A" wall version)

("B" column version)


EVOSTYLE-

("B")


MADE in ITALY
MOD S01 SN AD2
Mod.T034
MOD M01 SN AD.2
Mod.T035

("C")

("D")

Preventive maintenance

CARRIED OUT BY THE DENTAL LABORATORY OPERATOR, WITH ANNUAL CADENCE

Informations for programming routine maintenance on the plant are provided to ensure the best conditions of use by fully exploiting the diagnostic potential, without compromising any safety and reliability aspect that characterize the Company.

The verifications and controls are divided into blocks and the operator before starting the procedures of controls must ensure the availability of the instruction manual:

Radiogenic head monoblock:

plate integrity with the identification data;

Ionizing radiations warning signals integrity;

oil leaks absence verification;

complex integrity: covers shells, spacer cone attachment, rotation system;

monoblock's correct anchoring verification at the pantograph;

verify the correct 360 ° rotation of the monoblock;

Wall and column support,and pantograph:

verify the correct fixing of the wall support (only for wall version);

move the pantograph in all directions to verify the stability and bilance;

verify that the movement of the complex is fluid, flexible, without obstacles and that it is not hardening;

check for drawings from fluidifying liquid;

Supply unit

plate integrity with the identification data;

verify the integrity of the snap command and its spiral cable;

integrity of the signal lights (yellow);

integrity of the acoustic signaling system;

If that anomalies are found on the plant during all of the above checks, these should be reported to your distributor maintenance technician's New Life Radiology.

The extraordinary maintenance interventions are not carried out by the operator

Extraordinary maintenance

CARRIED OUT BY THE NEW LIFE RADIOLOGY SRL TECHNICAL ASSISTANCE IN CASE OF NEED AND IN ANY CASE AFTER RELEVANT REPAIRS .

We provide a guideline on controls, on minimum checks that are to be performed in any technical intervention on the plant:

monoblock, support and pantograph stability;

wear of the joints of rotation, of the plant balance and of the springs;

power supply's sliding contact of the head;

power cord of the head and of the control unit;

TESTING SERVICES

The frequency of checks carried out by a qualified expert on the performance of the X-ray (high voltage values, the dose rate, etc ..) will allow to always obtain perfect images.The X-ray, and in particular the single unit, does not contains parts subject to maintenance or external assistance.

Manufacturer responsibility

- ✓ The manufacturer is responsible for the effects of safety, reliability and performance of the equipment only if:
- ✓ assembly and any intervention on the equipment have been made by specialists;
- ✓ if the environment electrical system in which the equipment is installed is in compliance with current standards in the field of plant safety;
- ✓ if the equipment is used in accordance with use

Parts of input and output signal

It is not provided for the equipment connections with other parts of entry and exit signal outside.

Cleaning and disinfection of the unit and the parts in contact with the patient

You should always disconnect the unit from the mains power supply before starting cleaning activities and / or disinfection.

The method used for disinfection must meet the regulations and the recommendations in force, including those regarding the prevention of risks of explosion.

Cleaning and disinfection of the parts in contact with the patient

- ✓ The parts in contact with the patient are represented by the cone collimator (cod. CL01). This part should be carefully disinfected after the use through disposable disinfectant wipes category "medical surgical".

Cleaning and disinfection of the unit

- ✓ For these operations can be used a cloth moistened with neutral water-based detergent products. Make sure that no liquid seeps inside the equipment because it may cause short circuits and corrosion. Do not use abrasive polishing.
- ✓ The accessories and connection cables must be disinfected only with a cloth soaked in disinfectant solution. Do not use solvents or corrosive disinfectants.

- ✓ Spray disinfectants are not recommended because they may enter into the device and cause short circuits and corrosion. If the spray use is essential, take the following precautions:
- ✓ If the room where the appliance is installed is subjected to disinfection treatment, the same must be carefully covered with a protective sheet, taking care to turn it off well in advance so as to cool completely.
- ✓ After the dispersion of the vaporized disinfectant, remove the protective sheet and disinfect the device as described above.
- ✓ Do not use the device in the presence of disinfectants which vaporize to form explosive mixtures and wait until the vapors have dissipated before using it.

Environmental protection

- ✓ The monoblock unit is made of lead parts and contains oil. The disposal at end-of-life of these parts must be done in a controlled way through authorized disposal companies according to current regulations.
- ✓ In case of monoblock's damage for impact or crushing with a consequent oil leaking, prevent dispersal into the environment, proceeding to disposal as indicated above.

Characteristics of the X-ray tubes KL2-0.8-70G and Toshiba DG-073B-AC

X-ray tube Technical description

Target material that characterizes the radiation spectrum :	Tungsten
Reference axis for target angle and focal spot characteristics:	Orthogonal to the anode-cathode axis
Target angle compared to the reference axis:	19° from the axis Kailong KL2-0.8-70G; 20° from the axis Toshiba DG-073B-AC
Focal spot value for the reference axis comply with IEC 60336:	0,8 mm Kailong KL2-0.8-70G; 0,7 mm Toshiba DG-073B-AC
Filtration:	eq. 1 mm + 1 mm Al added, not removable without tools
X-ray tube nominal voltage:	70kV
Current intensity and frequency:	8mA 50 Hz
Operating cycle:	1/30

X-ray tube- sheath assembly technical description

Reference axis for angle of the target and characteristics of the focal spot:	Orthogonal to the anode-cathode axis
Target angle compared to the reference axis:	19° from the axis Kailong KL2-0.8-70G; 20° from the axis Toshiba DG-073B-AC
Focal spot value for the reference axis comply with IEC 60336:	0,8 mm Kailong KL2-0.8-70G; 0,7 mm Toshiba DG-073B-AC
Load factors values concerning radiation leakage:	1/30
Classification:	Class IB (IEC 60601-1)
Data for high voltage connections:	See detailed figures
High voltage connection polarity:	Phase and Neutral (sinusoidal alternating current)
Precautions to be observed to installation completed before the first load:	None

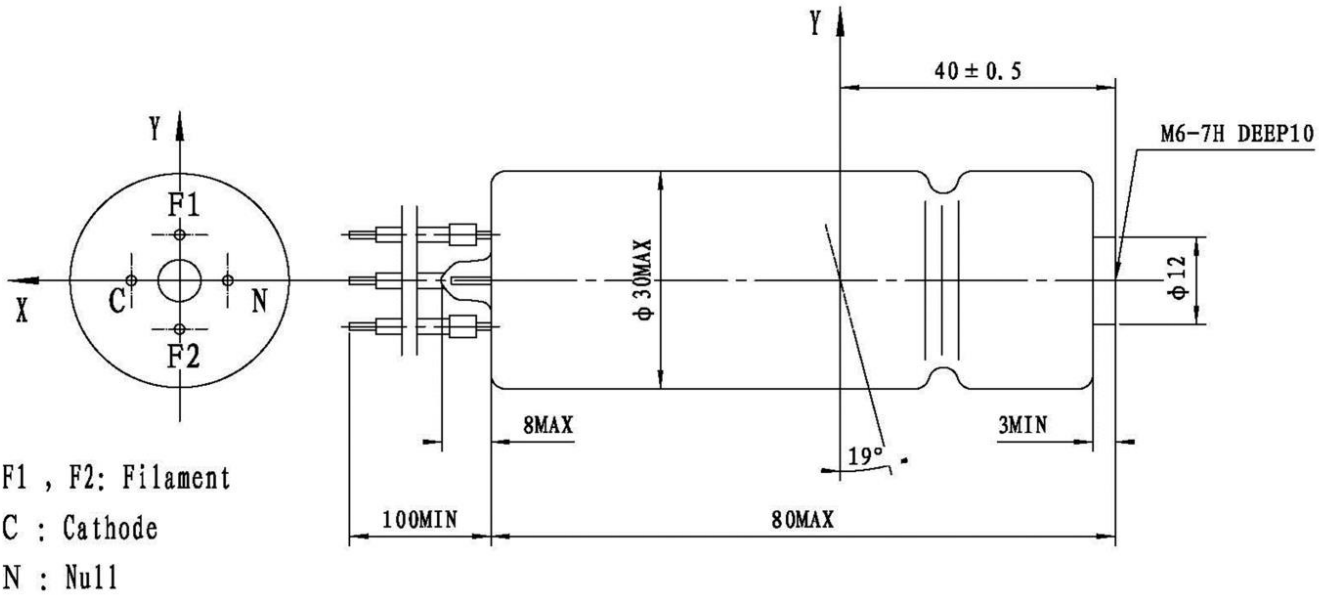
Beam limiting devices technical description

Limiter beam (cone collimator) coated in lead:	distance FFD 200 mm max ∅ 60 mm mod. C.L.01

Technical description of the X-ray radiant complex for diagnostic

Reference axis at which the slope of the anode and the characteristics of the focal spot refer:	Orthogonal to the anode-cathode axis
Anode slope compared to the specific reference axis:	19° from the axis Kailong KL2-0.8-70G; 20° from the axis Toshiba DG-073B-AC
Focal spot position on the reference axis:	See detailed figures
Focal spot value for the reference axis comply with IEC 60336:	0,8 mm Kailong KL2-0.8-70G; 0,7 mm Toshiba DG-073B-AC

X-ray tube type kailong KL2-0.8-70G

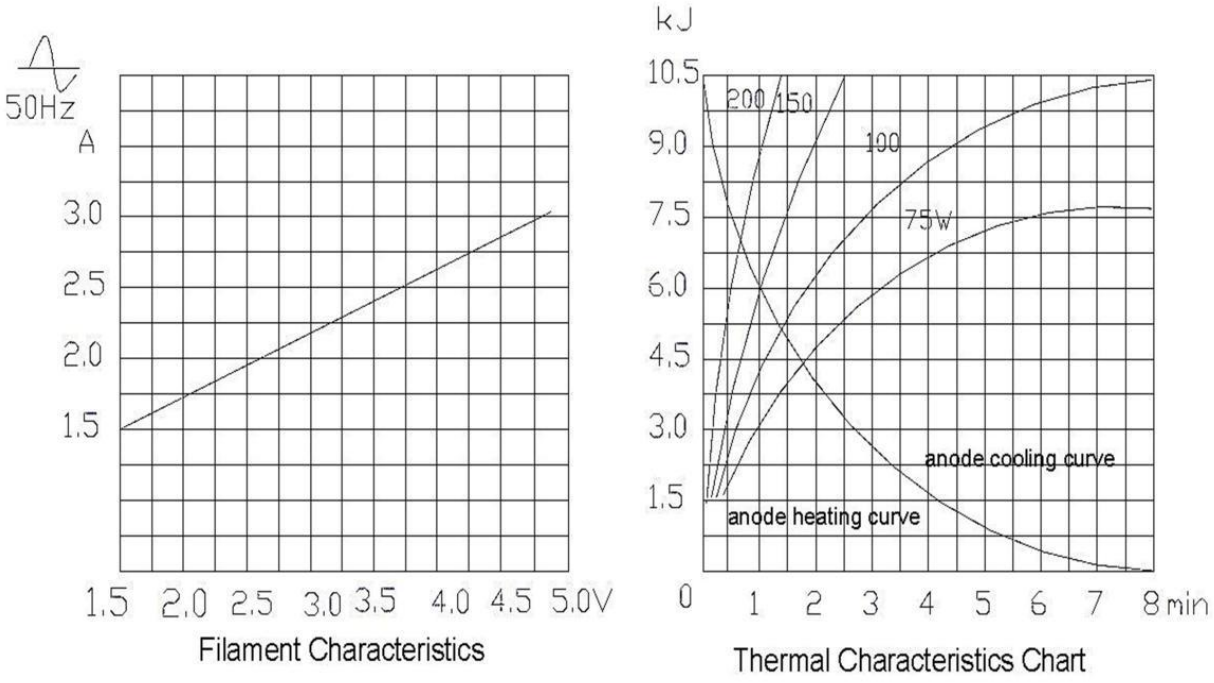


X axis :horizontal Y axis :vertical

OUTLINE DRAWING

(KL2-0.8-70G)

fig.28


50Hz
A
3.0
2.5
2.0
1.5
1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0V
Filament Characteristics
kJ
10.5
9.0
7.5
6.0
4.5
3.0
1.5
0
200 150
100
75W
anode cooling curve
anode heating curve
1 2 3 4 5 6 7 8 min
Thermal Characteristics Chart

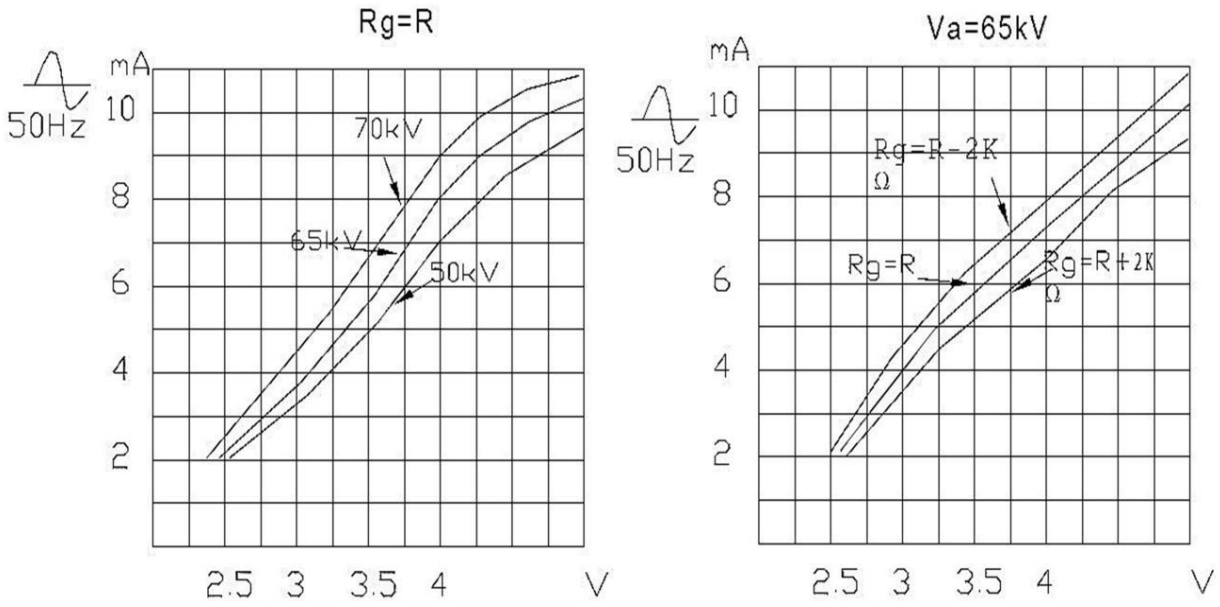
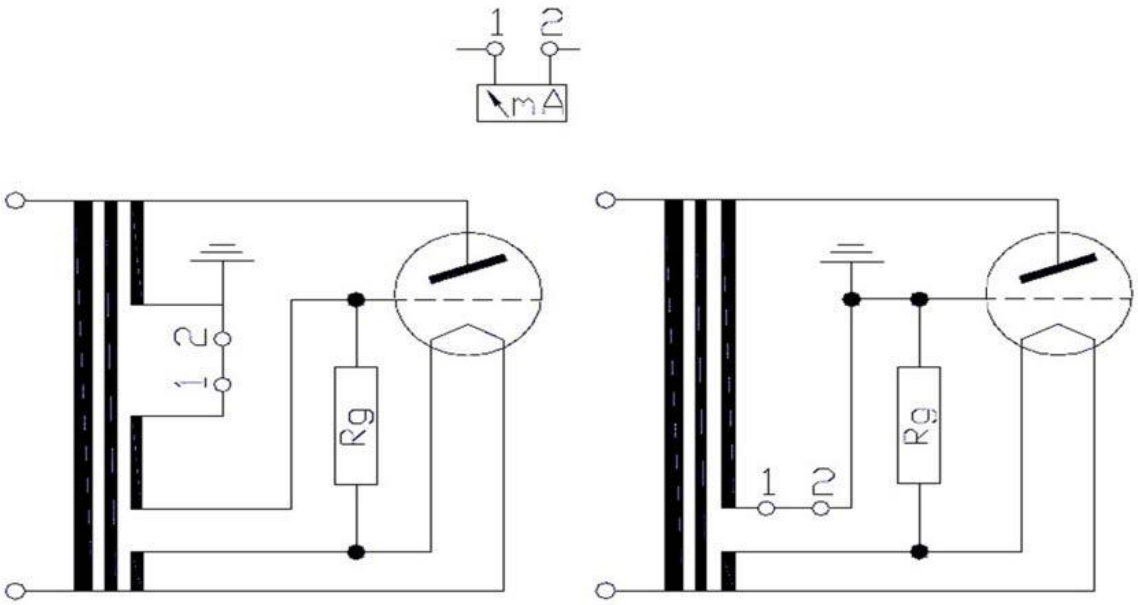

Rg=R
50Hz
mA
10
8
6
4
2
70kV
65kV
50kV
2.5 3 3.5 4 V
Va=65kV
mA
50Hz
10
8
6
4
2
Rg=R-2K Ω
Rg=R
Rg=R+2K Ω
2.5 3 3.5 4 V

fig.29



Basic Circuit

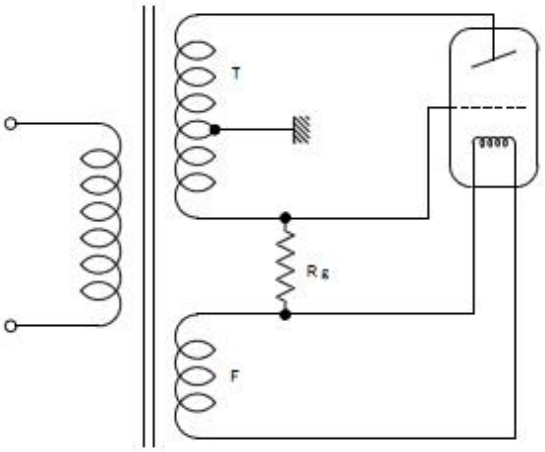
R=Rg value recommended by manufacturer for any tube

fig.30

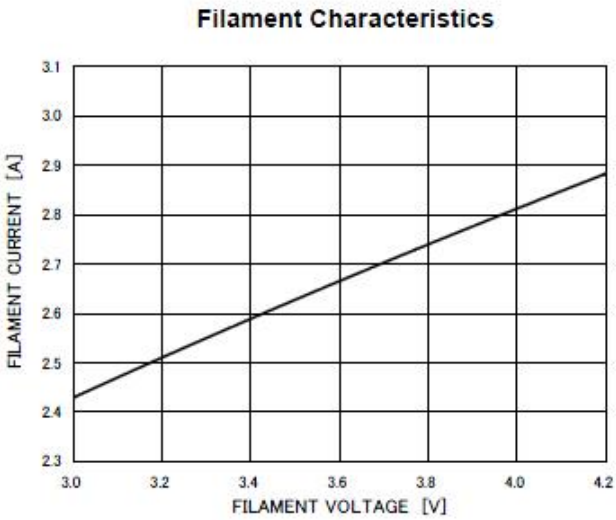
X-ray tube type Toshiba DG-073B-AC

Reference curves

One-Peak High-Voltage Generator (Self-rectified)



T: Transformer F: Filament Transformer Rg: Bias Resistor



Note 1) This graph indicates typical characteristics.
Note 2) Refer to IEC60613:2010

fig.31

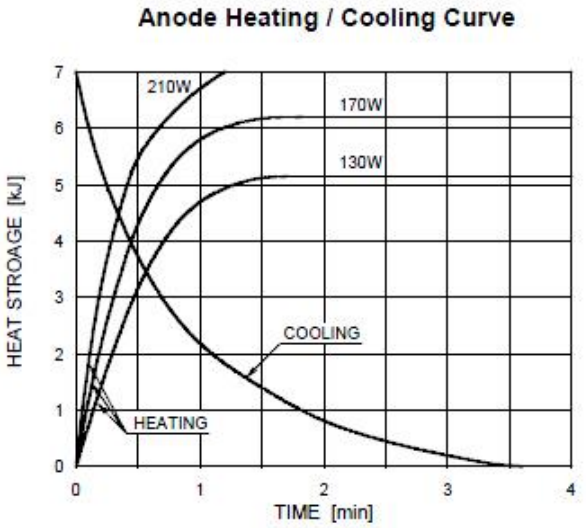


fig.32

Safety aspects

- ✓ The equipment is not designed to be used in the presence of explosive gases or vapours.
- ✓ It is forbidden to pour water or other liquids on the equipment so as not to cause short circuits and corrosion
- ✓ Only service technicians are authorized to remove the monoblock from its support.
- ✓ The personnel authorized to the radiological examinations performance must observe the protection rules against radiation.
- ✓ To protect the patient from diffused radiations, it is recommended the adoption of protective clothing for dental use.
- ✓ While executing x-ray examinations, there must not be other people in the room in addition to the patient.
- ✓ All personnel present during an x-ray examination must comply with safety regulations concerning protection against radiation. For their own safety, the operator must always keep a distance of more than 2 meters and out of the path of the x-ray beam, in order to avoid the exposition to the stray radiation.
- ✓ The plate must be placed in the oral cavity of the patient, and must be kept on site by the patient.
- ✓ Before using this x-ray system please refer to the regulation in force in your area concerning paediatric patients, pregnant women and anyone with health issues that contraindicate the use of x-rays. Investigate and make sure of this condition before starting the exposure.

Possible drawbacks found in the intraoral radiographs results

Clear image

Possible causes:

- Exhausted development liquid
- Excessive dilution of the developing liquid
- Too short exposure time to X-rays
- Insufficient development time
- Exposure liquid temperature below the recommended range

Dark image

Possible causes:

- Wrong dilution of developing liquid
- Too long exposure time to X-rays
- Excessive development time
- Exposure liquid temperature higher than the recommended

Not detailed image

Possible causes:

- Patient movement
- Monoblock movement

Radiography partially exposed

Possible causes:

- Error in the centering between rays's beams and film
- Liquid development too low with a consequent film partial development
- Contact between two or more films during development

Veiled Image

Possible causes:

- Films that exceeded the expiration date
- Film accidental exposure to rays
- Film accidental exposure to heat sources
- Film accidental exposure to daylight or safety lamp darkroom no longer suitable

Black line occurrence on X-rays

Possible causes:

- A sharp film folding can be the cause of the appearance of a black line on the film

Radiography with elongated apexes of the teeth

Possible causes:

- Excessive film folding in the oral cavity

Recommendations

For maximum radiological image quality with minimal X-ray dose, we recommend the use of films with high sensitivity and the respect of development time proposed by the manufacturer of the films, shaking continuously films during the development itself. If the image thus obtained is too dark, it is necessary to decrease the X-ray exposure time and not the development duration.

In the case of manual development it is good to know that the developer liquid preserves its efficiency in average for a week regardless of the number of films processed. Please note that the treatment liquids are harmful to the environment and must be disposed of as indicated by the manufacturer

Film positioning

During normal operation, the film must be positioned at 90 ° with respect to the cone collimator, as shown in fig.33

Upper jaw *Lower jaw*

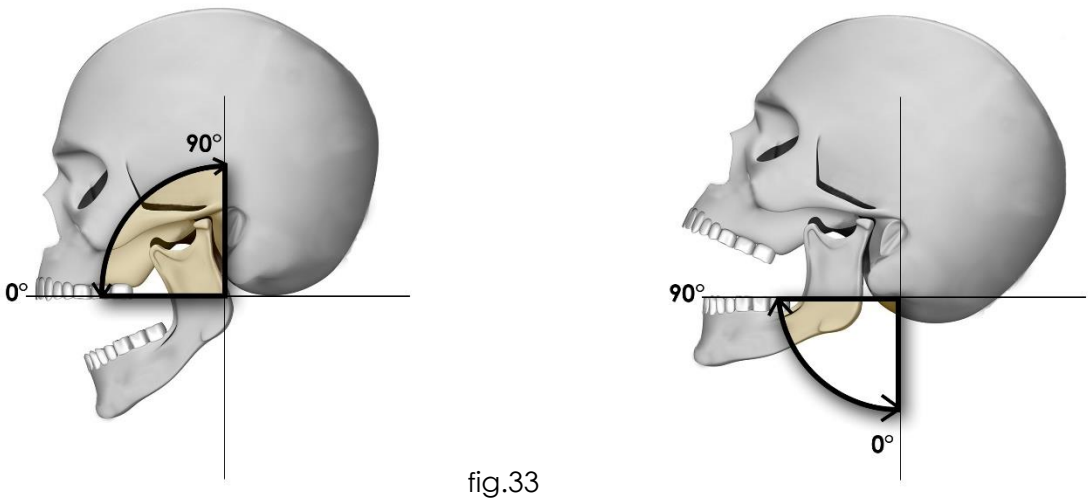


fig.33

Although every effort is made to ensure the accuracy of the information contained in this manual, the **New Life Radiology** does not assume responsibility for any mistakes, omissions or inaccuracies.