
ENDOGRAPH DC 0051



Service Manual

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1	04.09.13	12, 13, 28, 31, 36, 42, 86, 88, 90	FDA approved revision. Added note on spacer insertion during stand arm set assembling. Mains plug on mobile stand version no more supplied. Spare Parts update. (Ref. RDM 7723, RDM 7763, RDM 7773, RDM 7797, RDM 7836)

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This Manual in English is the original version.

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1. INTRODUCTION



NOTE:

This manual is updated for the product it is sold with, in order to guarantee an adequate reference to use the product properly and safely. The manual may not reflect changes to the product that do not affect operating modes or safety.

The Endograph DC intra-oral X-ray unit takes high quality intra-oral X-rays thanks to reduced exposure times and the small dimensions of the focus spot.

Endograph DC is intended exclusively for intra-oral X-rays.

System operation is managed by a microprocessor, which permits high reproducibility of the exposure times.

The system consists of the following parts:

- timer: Endograph DC complete with the wall support
- extension arm (30cm, 60 cm or 80cm for the wall version)
- Scissors arm (DP)
- Tube-head (60-65-70) kV ; 6 mA

The aim of this manual is to instruct the user on the safe and effective use of the device.

The device must be used in compliance with the procedures described, and never be used for purposes different from those herewith indicated.

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.

1.2 How to contact VILLA SISTEMI MEDICALI technical service

For any technical queries please contact the following:

- Telephone number +39 02 48859.1
- Fax number +39 02 48859222
- E-mail: dentalservice@villasm.com

2. SAFETY ASPECTS



WARNING:

Please read this chapter thoroughly.

VILLA SISTEMI MEDICALI designs and builds the devices in compliance with the safety requirements; furthermore it supplies all information necessary for correct use, and the warnings related to danger associated with X-ray generating units.

The manufacturer cannot be held responsible for:

- use of Endograph DC equipment different from the purpose for which it was originally designed,
- damage to the unit, the operator or the patient, caused both by incorrect installation and maintenance procedures different from those described in this user and service manuals supplied with the unit, and by wrong operations,
- mechanical and/or electrical modifications performed during and after the installation, different from those described in the service manual.

Only personnel authorised by the manufacturer may carry out technical operations on the unit.

Only authorised personnel can remove the tube-head from its support and/or access the components under tension.

2.1 Warnings

The device must be used in compliance with the procedures described and never be used for purposes different from those herewith indicated.

Before performing any maintenance operation, disconnect the unit from the power supply using the provided circuit breaker.

Endograph DC is an electro-medical device and therefore it can be used only under the supervision of suitably qualified medical personnel, with the necessary knowledge on X-ray protection.

The user is responsible for the fulfilment of the legal requirements regulating the ownership, installation and use of the equipment itself.

Endograph DC has been built to support continuous operation at intermittent load; therefore please follow the described use cycles.

Wherever necessary, use the appropriate accessories, such as the leaded aprons, to protect the patient from radiation.

Endograph DC must be turned off when using electrosurgical devices or similar equipment near the unit.

This device has not been designed to be used in environments where anaesthetic mixtures flammable with air, oxygen or nitrous oxide can be detected.

In order to prevent risks of short-circuit and corrosion, avoid the entry of water or other liquids in the equipment.

The parts of the unit that can come into contact with the patient must be cleaned regularly according to the instructions provided below in this document.



WARNING:

For safety reasons, it is prohibited to abnormally overload the extension arm or the scissors arm, for example by leaning on it.

2.1.1 Electromagnetic emissions

In accordance with the IEC 60601-1-2 standard, Endograph DC is suitable for use in the electromagnetic environment specified below. The customer or user of the system must ensure that it is used in the said environment.

Emissions test	Conformity	EMC environment of use
RF emissions CISPR 11	Class B	Endograph DC is suitable for use in all domestic environments and in environments directly connected to the mains power supply at low voltage that supplies buildings for domestic use.
	Group I	Endograph DC uses RF power only for its internal functioning. As a result, its RF emissions are very low and most likely will not cause any interference in electronic devices located nearby.
Harmonic emissions IEC 61000-3-2	Class A	
Flicker/voltage fluctuation emissions IEC 61000-3-3	In compliance	

2.1.2 Electromagnetic immunity

In accordance with the IEC 60601-1-2 standard, Endograph DC is suitable for use in the electromagnetic environment described below. The customer or user of the system must ensure that it is used in the said environment.

Immunity test	Test level IEC 60601-1-2	Compliance level	EMC environment of use
Electrostatic discharges (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV in air	± 6 kV contact ± 8 kV in air	The flooring must be wood, concrete or ceramic tile. If the flooring is covered with synthetic material, the relative humidity must be at least 30%.
Transients/sequence of rapid electric impulses IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	The quality of the mains voltage must be the same as a typical commercial or hospital environment.
Overvoltages IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and earth	± 1 kV between phases ± 2 kV between phase and earth	The quality of the mains voltage must be the same as a typical commercial or hospital environment.
Voltage dips, short breaks and voltage variations of the power supply feed line IEC 61000-4-11	0 % U_t for 0.5 cycles 40 % U_t for 5 cycles 70 % U_t for 25 cycles 0 % U_t for 5 s	0 % U_t for 0.5 cycles 40 % U_t for 5 cycles 70 % U_t for 25 cycles 0 % U_t for 5 s	The quality of the mains voltage must be the same as a typical commercial or hospital environment. If the Endograph DC user requires continuous operation during interruptions in the mains voltage, it is recommended to power the Endograph DC with an uninterrupted power supply or batteries.
Magnetic field at the main frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	The levels of the magnetic fields at mains frequency must be the same as a typical commercial or hospital environment.
Note: U_t is the a.c. mains voltage prior to the application of the test level.			

Immunity test	Test level IEC 60601-1-2	Compliance level	EMC environment of use
			The RF portable and mobile communications units should not be used closer to any part of the Endograph DC, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \times \sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ from 800 MHz to 2.5 GHz
Conducted RF IEC 61000-4-6	3 V from 150 kHz to 80 MHz	3 V	$d = 1.2 \times \sqrt{P}$
			where "P" is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). The field strength of the fixed RF transmitters, determined by an on-site electromagnetic survey, should be lower than the compliance level in each frequency range. Interference may be verified near devices marked with the following symbol: 

2.1.3 Recommended separation distances to portable and mobile radio equipment

Endograph DC is designed to operate in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or user of the system can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communication devices (transmitters) and Endograph DC as recommended in the following table in relation to the maximum output power of the radio devices.

Maximum rated output power of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)		
	from 150kHz to 80MHz $d = 1.2 \times \sqrt{P}$	from 80MHz to 800MHz $d = 1.2 \times \sqrt{P}$	from 800MHz to 2.5GHz $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters maximum rated output not shown in the table, the recommended separation distance "d" in meters (m), can be calculated using the equation applicable to the frequency of the transmitter, where "P" is the highest rated output of the transmitter in watts (W) according to the manufacturer of the transmitter. Note 1: at 80 MHz and 800 MHz, apply the separation distance for the higher frequency interval. Note 2: these guidelines may not apply to all situations. Electromagnetic propagation depends on the absorption and reflection of structures, objects and people.			

2.2 Protection from X-rays

Although the dose supplied by modern X-ray units is quite low, the operator must adopt the precautions and/or suitable protection for the patient and himself according to current regulations, during the execution of radiography.



WARNING:

Protection against radiation is regulated according to law. The equipment may only be used by specialised personnel.

- a)** The film (or the digital sensor) must be placed in the patient's mouth either manually or using the specific supports, and must be held in position by the patient if necessary.
- b)** During exposure to the rays, the operator must not be in contact with the tube-head or the collimator cone.
- c)** During exposure, the operator must maintain a certain distance from the source of the rays (at least 2 metres) in the opposite direction of the emission.
- d)** During exposure, only the operator and the patient may be present in the room.
- e)** Use the specific leaded aprons to reduce the undesired effect of secondary radiations for the patient.

2.3 Environmental risks and disposal

Some of the device's components contain material and liquids that, at the end of the equipment life-cycle, must be disposed of at the recycling centres appointed by the local health units.

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

- **Tube-head:** non biodegradable plastic materials, glass, dielectric oil, lead, tungsten, aluminium, copper.
- **Other parts of the device:** non biodegradable plastic materials, metal materials, printed circuits, iron-plastic materials.

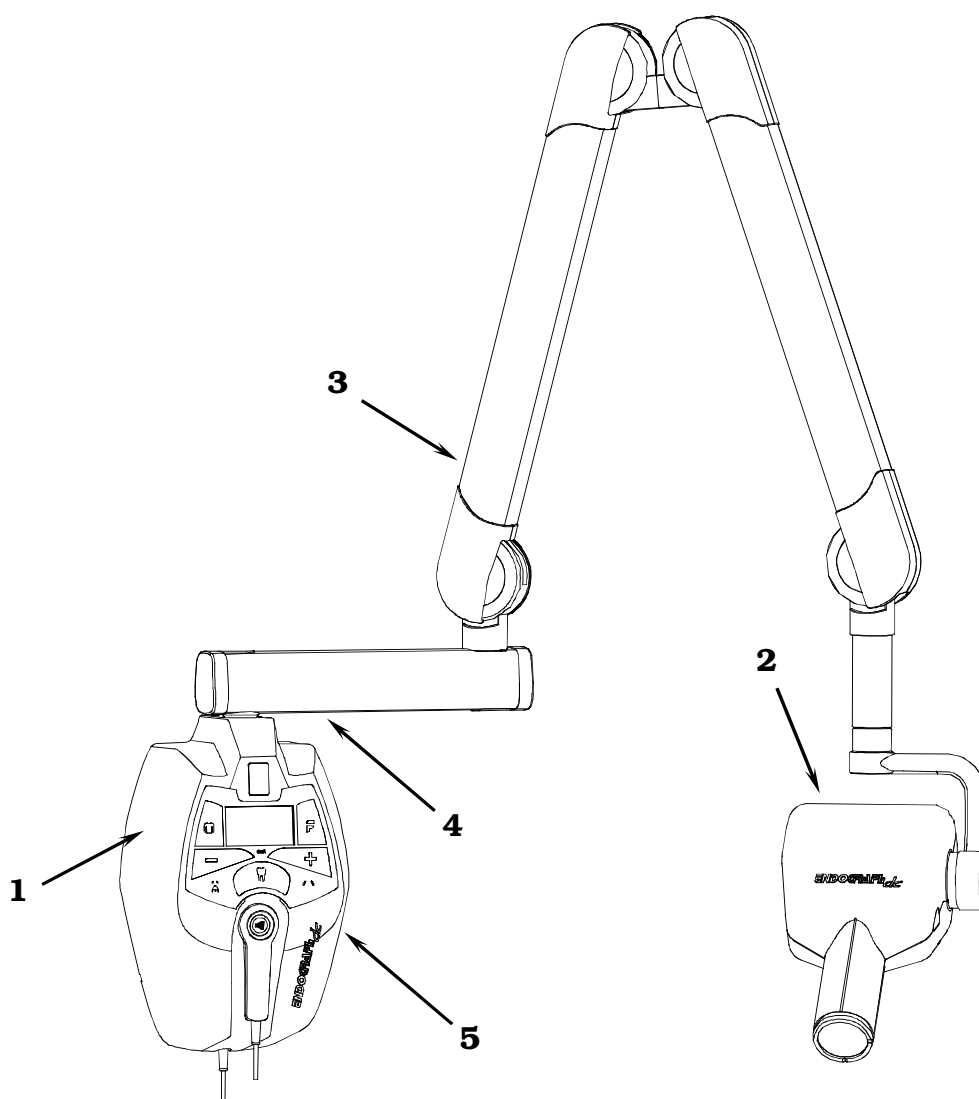
2.4 Symbols in use

In this manual and on the Endograph DC itself, apart from the symbols indicated on the keypad, also the following icons are used (see chapter 6 of User's Manual):

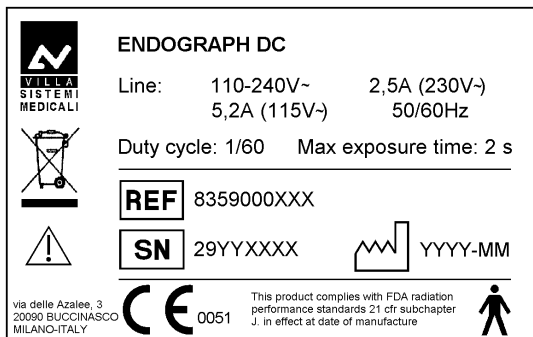
Symbol	Description
	Device with type B applied parts
	In some of its parts, the device contains materials and liquids that, at the end of the lifespan of the unit, must be disposed of at the appropriate disposal centres
~	Alternating Current
N	Connection point to the neutral conductor
L	Connection point to the line conductor
	Earth protection
	Operation earthing
○	OFF; device not connected to the mains
	ON; device connected to the mains
	Exposure enabling key; the exposure enabled status is indicated by the switching on of the corresponding green symbol
	Ray Emission
	Focus spot according to IEC 336
	Warning: see the accompanying documentation
	Product identification code
	Serial number
	Date of manufacture (year and month)
	Manufacturer's name and address
	Filtration
	Tube-head
	X-ray tube
CE 0051	Conformity to the EC 93/42 Directive and subsequent amendments and additions
CE 0051	Guarantees wireless switch for Endograph DC compliance with Directive R&TTE 1995/5/EC

3. DESCRIPTION

3.1 Identification plates

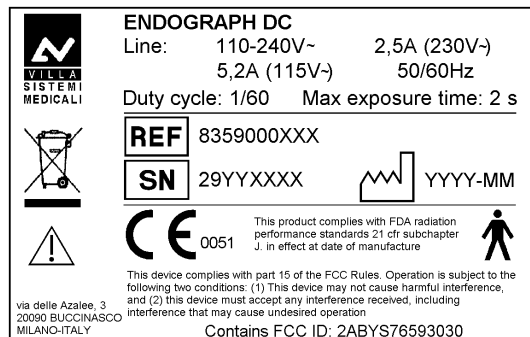


1a
Endograph DC plate



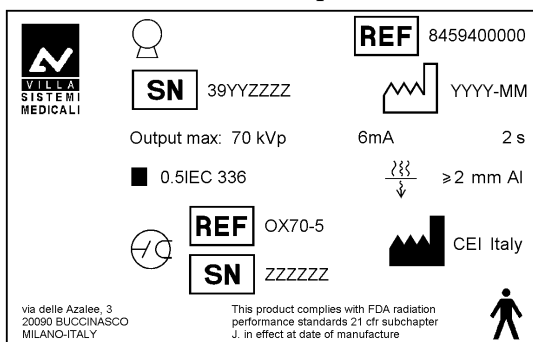
ENDOGRAPH DC
Line: 110-240V~ 2,5A (230V~)
5,2A (115V~) 50/60Hz
Duty cycle: 1/60 Max exposure time: 2 s
REF 8359000XXX
SN 29YYXXXX YYY-MM
via delle Azalee, 3
20090 BUCCINASCO
MILANO-ITALY
CE 0051 This product complies with FDA radiation performance standards 21 cfr subchapter J, in effect at date of manufacture

1b
Endograph DC plate for
configuration with Wireless X-ray button



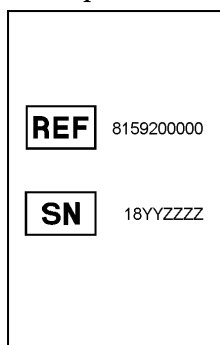
ENDOGRAPH DC
Line: 110-240V~ 2,5A (230V~)
5,2A (115V~) 50/60Hz
Duty cycle: 1/60 Max exposure time: 2 s
REF 8359000XXX
SN 29YYXXXX YYY-MM
via delle Azalee, 3
20090 BUCCINASCO
MILANO-ITALY
CE 0051 This product complies with FDA radiation performance standards 21 cfr subchapter J, in effect at date of manufacture
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation
Contains FCC ID: 2ABYS76593030

2
Tube-head plate



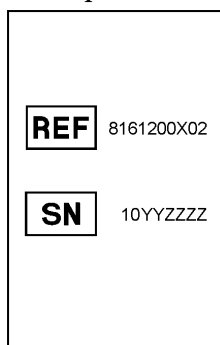
REF 8459400000
SN 39YYZZZZ YYY-MM
Output max: 70 kVp 6mA 2 s
0.5IEC 336 ≥ 2 mm Al
REF OX70-5
SN ZZZZZZ
via delle Azalee, 3
20090 BUCCINASCO
MILANO-ITALY
This product complies with FDA radiation performance standards 21 cfr subchapter J, in effect at date of manufacture

3
DP arm
plate



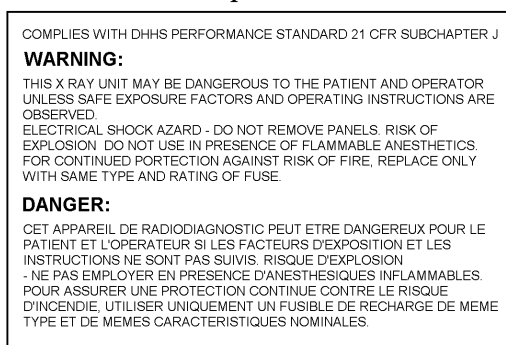
REF 8159200000
SN 18YYZZZZ

4
Extension arm
plate



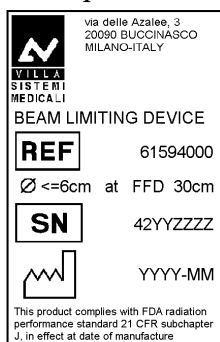
REF 8161200X02
SN 10YYZZZZ

5
WARNING
plate



COMPLIES WITH DHHS PERFORMANCE STANDARD 21 CFR SUBCHAPTER J
WARNING:
THIS X RAY UNIT MAY BE DANGEROUS TO THE PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.
ELECTRICAL SHOCK AZARD - DO NOT REMOVE PANELS. RISK OF EXPLOSION DO NOT USE IN PRESENCE OF FLAMMABLE ANESTHETICS. FOR CONTINUED PROTECTION AGAINST RISK OF FIRE, REPLACE ONLY WITH SAME TYPE AND RATING OF FUSE.
DANGER:
CET APPAREIL DE RADIODIAGNOSTIC PEUT ETRE DANGEREUX POUR LE PATIENT ET L'OPERATEUR SI LES FACTEURS D'EXPOSITION ET LES INSTRUCTIONS NE SONT PAS SUIVIS. RISQUE D'EXPLOSION - NE PAS EMPLOYER EN PRESENCE D'ANESTHESIQUES INFLAMMABLES. POUR ASSURER UNE PROTECTION CONTINUE CONTRE LE RISQUE D'INCENDIE, UTILISER UNIQUEMENT UN FUSIBLE DE RECHARGE DE MEME TYPE ET DE MEMES CARACTERISTIQUES NOMINALES.

6
Collimator 30 cm (optional)
plate



via delle Azalee, 3
20090 BUCCINASCO
MILANO-ITALY
BEAM LIMITING DEVICE
REF 61594000
 $\varnothing \leq 6$ cm at FFD 30cm
SN 42YYZZZZ YYY-MM
This product complies with FDA radiation performance standard 21 CFR subchapter J, in effect at date of manufacture

7
Wireless X-ray button (optional)
plate



Wireless switch for Endograph DC
REF 7659303000
SN 30YYXXXX
Via delle Azalee 3
20090 Buccinasco
MI - Italy
CE 0051
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation
Contains FCC ID: 2ABYS76593030

3.2 Functions, Models and Versions

The Endograph DC intra-oral X-ray unit makes it possible to obtain consistently high quality X-rays thanks to the reproducibility of the unit parameters with very short exposure times and a very small focus spot.

The Endograph DC intra-oral X-ray unit is compatible for being combined with digital image acquisition systems, thereby obtaining the maximum benefits of today's digital intra-oral radiologic technology. If you do not currently have a digital system, the use of high-speed film or film in the EKTRASPEED (Kodak) category is recommended in order to limit the dose absorbed by the patient. A button on the control keypad is used to select the operating mode and it is possible to select films with different speeds (sensitivity), the phosphor sensor, the digital sensor or a customised user mode "Custom mode".

The Endograph DC X-ray unit has an LCD display with dimensions of 84mm x 45mm (240x128 pixel) which makes it easier for the operator to perform all operations, guaranteeing the immediate and complete display of the exposure parameters.

The Endograph DC system can use the optional 30 cm collimator cone (to be ordered separately with code 6159400000). The "long cone inserted" selection is signalled by the specific symbol on the display. In this configuration, the exposure times that were pre-set in the anatomic selection are automatically increased by a multiplicative factor of 2.

The Endograph DC system includes the following: generator, tube-head complete with collimator, CPU (or logic) card that controls the system functions, keypad, extension arm and scissors arm.



WARNING:

The Endograph DC system does not automatically detect the presence of a cone or other item: the operator is responsible for checking the congruity between the indication on the display and the actual situation of use.

3.2.1 High Frequency (HF) Generator

The remote controlled HF generator, together with the tube-head, uses state-of-the-art microelectronic technology to obtain optimal quality X-rays while reducing the patient dose of rays. Conventional systems generally use the intrinsic capacity of the RX generator tube to conduct the electric current in one direction only. This generates a "train" of RX impulses. The Endograph DC unit instead uses constant-voltage technology that generates continuous and stable emission of X-rays. This reduces the emission of soft rays, guaranteeing the constancy of the emission parameters, kVp and mA.

The microprocessor-based control ensures constant and repeatable exposure times; by simply pressing a button it is possible to automatically select the exposure times based on the size of the patient and the selected tooth.

3.2.2 Extension arm and scissors arm

This consists of an arm with a double joint, which permits horizontal and upward extension. The tube-head remains balanced in all positions.



NOTE:

The scissors arm was designed to work correctly with a maximum opening angle of 160°; therefore, an opening angle of less than 160° is required for its use.

A horizontal extension arm can also be added, which is available in different sizes (30 / 60 / 80 cm) to satisfy all requirements.

3.2.3 Tube-head

The tube-head makes it possible to select one of three different high voltage values: 60 / 65 / 70 kVp.

The radiogenic unit is equipped with a collimator with a focus skin distance of 20 cm and a ray emission diameter of 6 cm at the cone exit. The tube-head is connected to the arm by a guide, which permits 390° horizontal rotation and 290° vertical rotation.

3.2.4 Timer

The timer consists of an LCD display (240x128 pixel), two LEDs (yellow: X-rays in progress– green: ready for X-rays) and 5 buttons that are used to select from among 3 different patient sizes, 3 types of sensors (film, phosphor or digital) and 7 different pre-set anatomical structures (incisor, canine, premolar, lower molar, upper molar, front bite-wing and rear bite-wing).

There are 36 fixed times available for manual selection which vary from a minimum of 0.01 seconds up to a maximum of 2 seconds.

The timing is managed in order to guarantee exact precision of the exposure times.



NOTE:

The configuration can be set using the remote X-ray control outside the examination room. This consists of a wall support onto which the X-ray button is connected with an extendable cable.



NOTE:

The unit provides two separate contacts for the possible connection with external signalling devices. One contact signals the status of the unit as operative and ready to be used, the second emits the X-rays. The connection methods and the requirements necessary for the signalling devices are described in the "Service Manual".

3.3 Configurations

3.3.1 Standard configuration

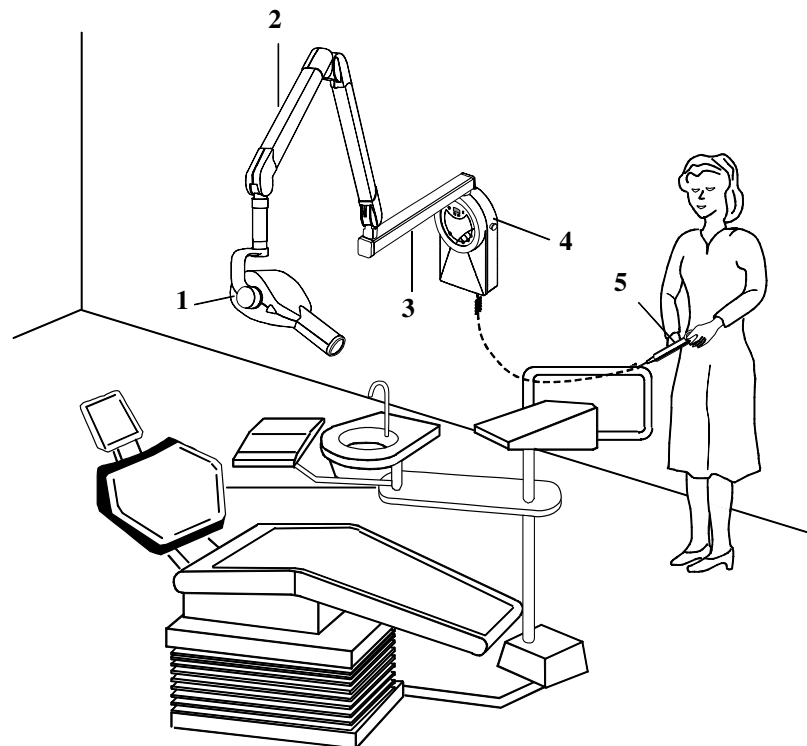


Figure 3-1

- 1** Tubehead
- 2** Scissors arm
- 3** Extension arm
- 4** Timer
- 5** X-ray button

3.3.2 Remote timer configuration

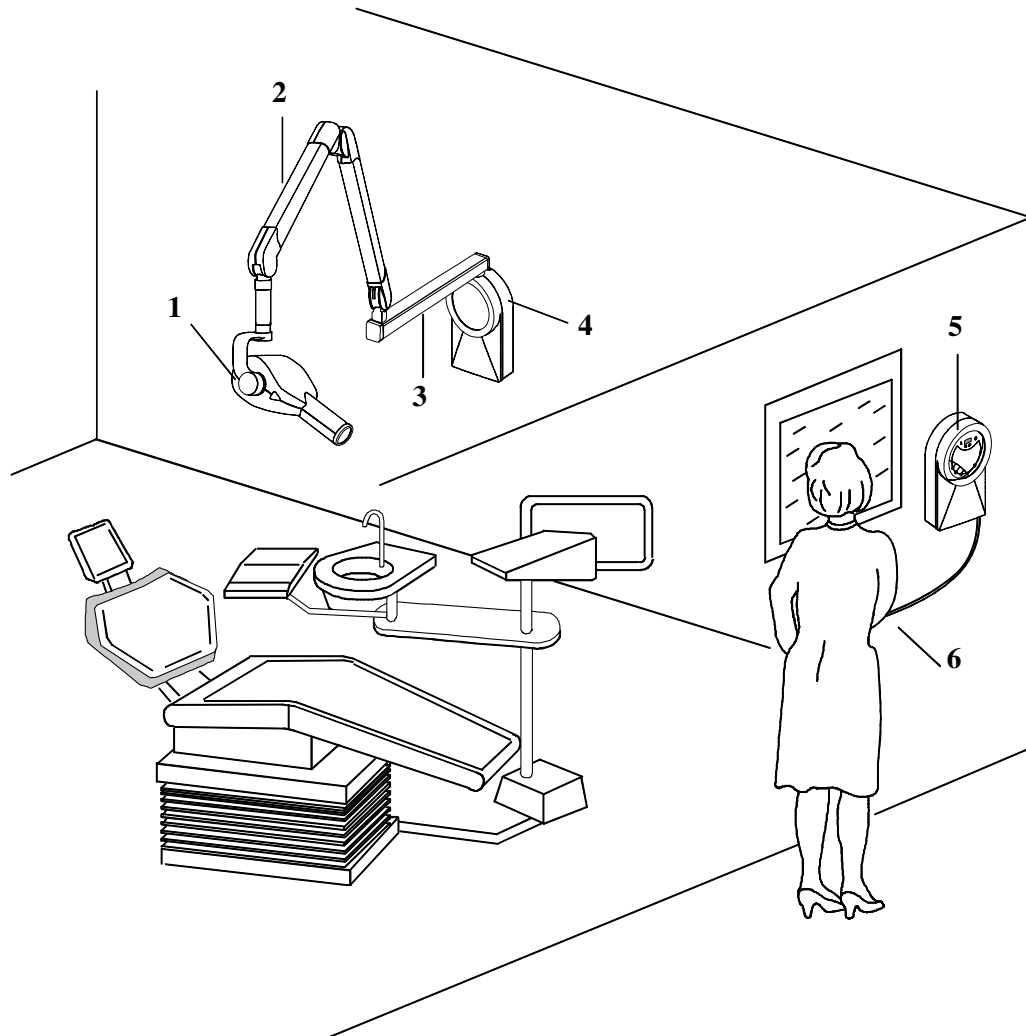


Figure 3-2

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

3.3.3 Mobile stand configuration

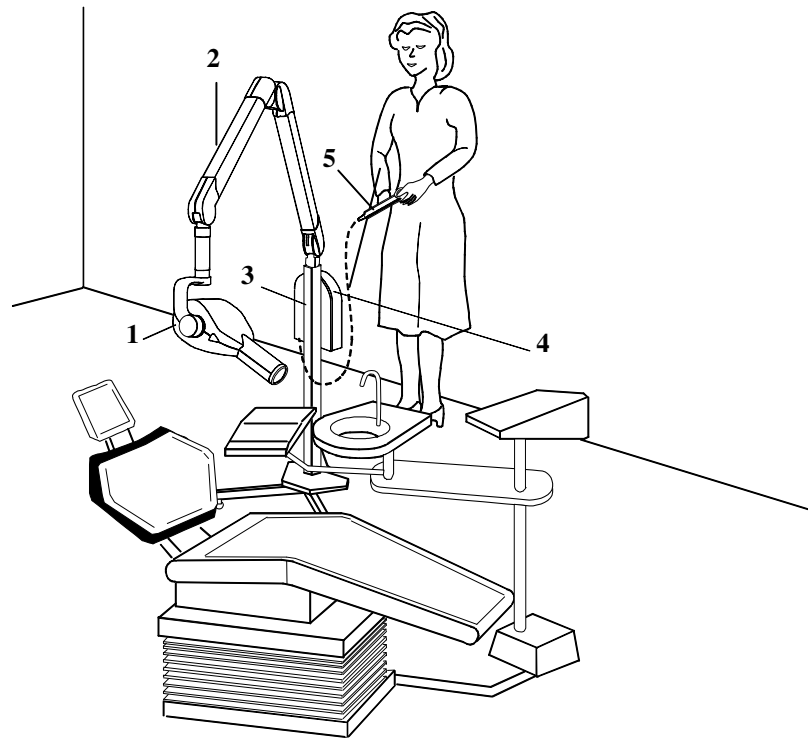


Figure 3-3

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

3.3.4 Remote X-ray button configuration

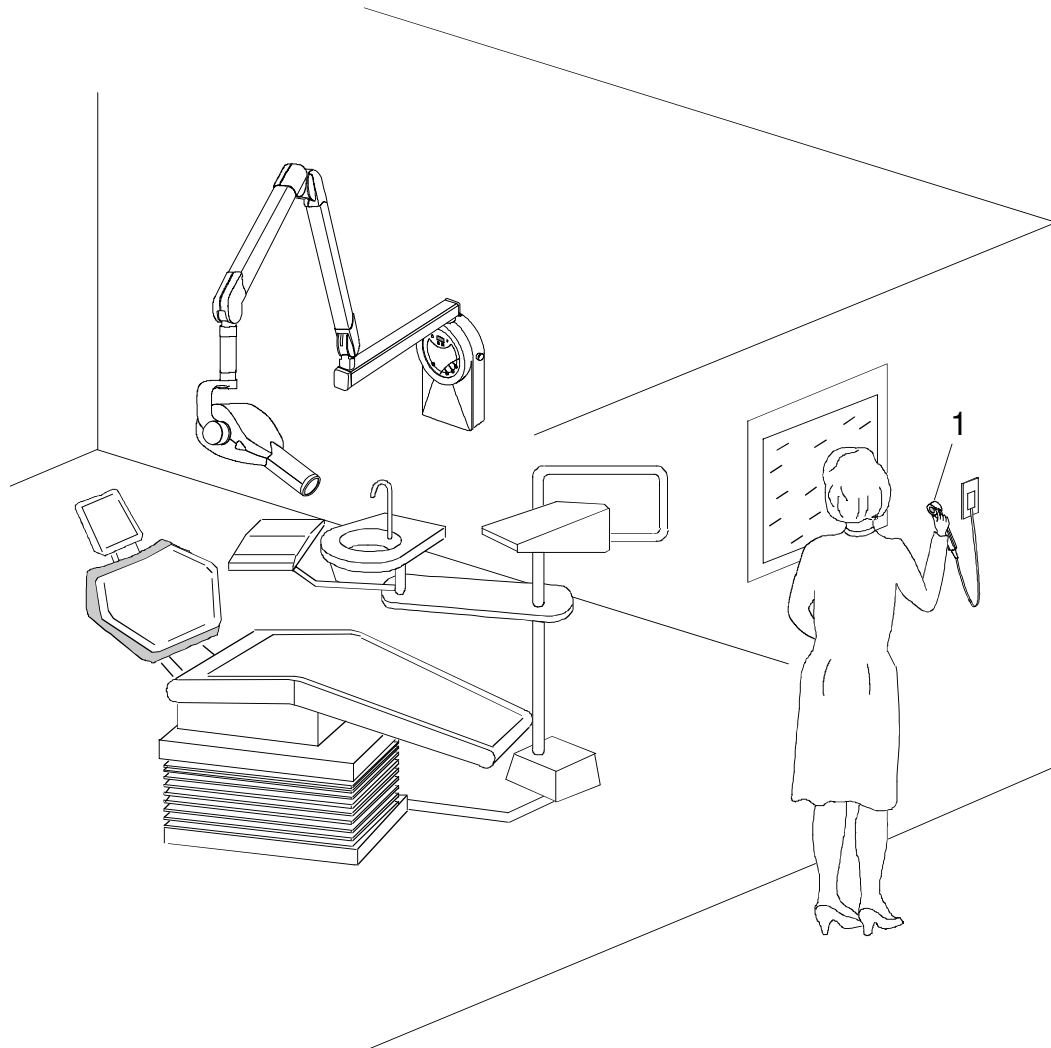


Figure 3-1

- 1** Remote X-ray button (optional)

3.3.5 Configuration with wireless X-ray button

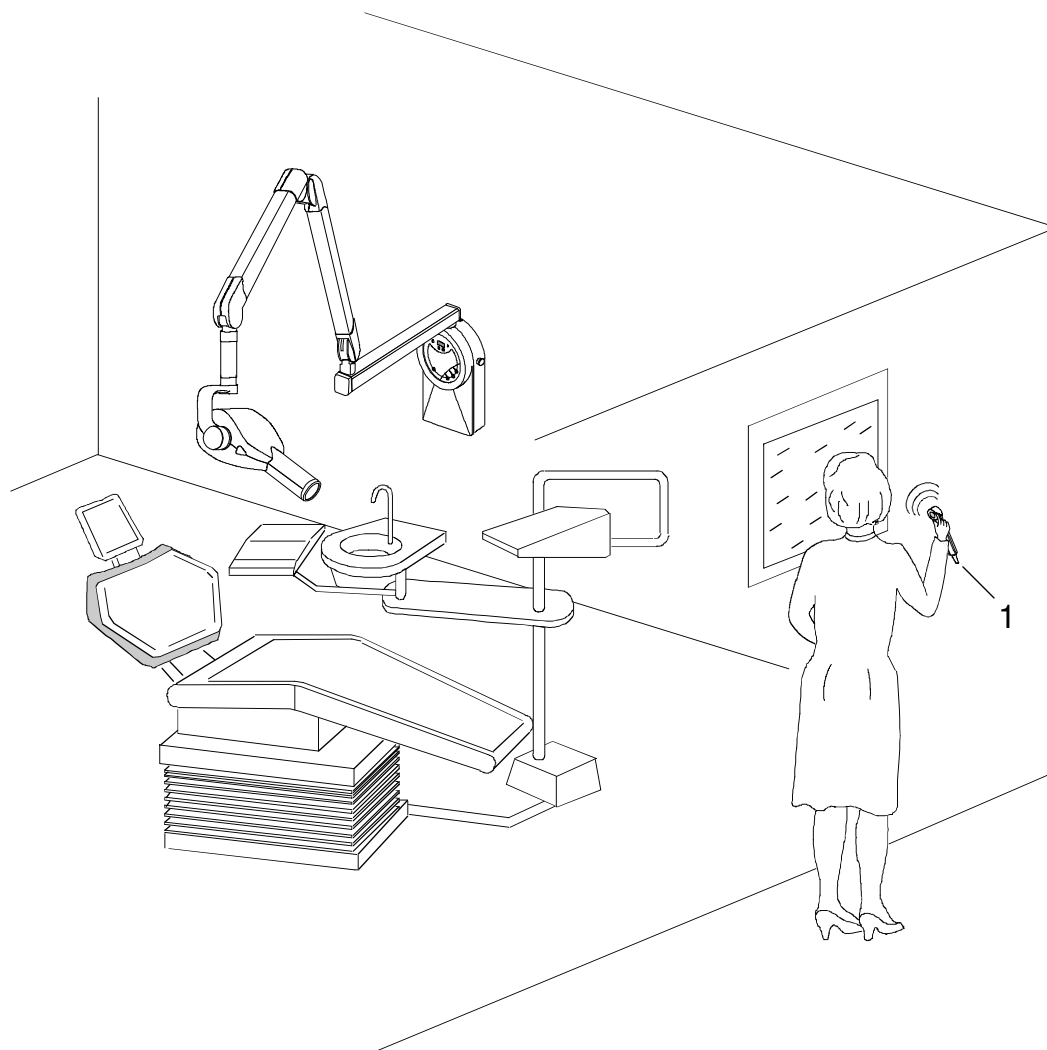


Figure 3-2

1 Wireless X-ray button (optional)

4. TECHNICAL DATA

Technical characteristics		
Equipment	Endograph DC	
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italia	
Class	Class I with type B applied parts (according to EN 60601-1 classification)	
Protection degree	IPX0 standard device	
Line voltage	99-264 V~	
Rated voltage	110-240 V~	
Line frequency	50 / 60 Hz	
Maximum line current	5.2 A rms impulsive @ 115 V ~	2.5 A rms impulsive @ 230 V ~
Technical factors for maximum line current	70kV, 6mA	
Absorbed power	583W (584VA)	566W (570VA)
Maximum apparent line resistance	0.4 Ω (99-132 V~)	0.8 Ω (198-264 V~)
Mains fuse	6.3 AT	
Selectable times	from 0.01 to 2.00 s in 36 steps	
Automatic selection	882 pre-programmed times (7 anatomic - 3 sizes - 3kV - 2 SID- 3 receptors)	
Time accuracy	$\pm 5 \% \pm 2$ ms	
High voltage values	60-65-70 kVp selectable	
Tubehead current	6 mA	
kV accuracy	$\pm 8 \%$ @ rated voltage	
Tubehead anodic current accuracy	$\pm 10 \%$ @ rated voltage	
Maximum exposure time	2.0 s	
Timer size	284×253×123.3 mm	

Tube-head characteristics	
Manufacturer	CEI Bologna (Italy)
Rated voltage	60-65-70 kV _p (selectable)
Tubehead power	420 W
Total filtration	≥ 2.5 mm Al eq. @ 70 kV
HVL (Half value Layers)	> 2 mm Al eq.
Transformer insulation	Oil bath
Interval between the exposures / duty cycle	60 times the X-ray time / 1 : 60
Focus size	0.5 (IEC 336)
Minimum focus to skin distance	20 cm (optional 30 cm cone)
X-ray diameter (@ 20cm focus)	≤ 6 cm (35x45 mm + 25x35 mm + 20x30 mm optional)
Cooling	Convection
Leakage radiation at 1 metre	< 0.25 mGy/h
Technical factors for leakage radiation	70 kV, 6 mA, 1 s duty cycle 1 exposure every 60 seconds
X-ray tube characteristics	
Manufacturer	CEI Bologna (Italy)
Type	OX/70-5
Inherent filtration	0.5 mm Al equivalent to 70 kV
Anode tilt angle	19°
Anode material	Tungsten
Rated voltage	60-65-70 kV (selectable)
Filament max voltage	3.1 V
Filament max current	2 A
Anode thermal capacity	7 kJ
Anode cooling capacity (max)	110 W

Environmental conditions	
Operating temperature range	+10°C ÷ +40°C
Relative working humidity (RH) range	30% ÷ 75%
Temperature range for transport and storing	-20°C ÷ +70°C
Humidity range for transport and storing	<95 % non-condensing
Minimum atmospheric pressure for storing and transport	630hPa
Weight of the unit and the removable parts	
Gross weight including packaging	30 kg
Net weight of the unit in the standard configuration	23 kg
Extension arm 60 cm (standard)	2.9 kg
Extension arm 80 cm	3.5 kg
Extension arm 30 cm	1.9 kg
Scissors arm with tube-head support	10 kg
Timer + wall support	5.05 kg
Tube-head	5 kg

4.1 Method for measuring technical factors

The measuring method with non-invasive instruments, for example kV_p/t meter, is accepted, even if it generally provides less accuracy. In fact, the measurement of the high voltage at the tube with non-invasive instruments is closely correlated to the method selected by the instrument manufacturer; in general, this method is more inaccurate than the direct method and may also require two subsequent exposures. In the same way, the method of measuring the anodic current with the indirect method is affected by systematic errors, as they are often based on the measurement of the current/time product, dividing the measurement by the time measured with the said method.

- **High voltage value at the tube (kVp)**

The kVp value is defined as the stationary value of the high voltage applied at the tube that is stabilised under load after the pre-heating time.

Measure the value of the kVp with a non-invasive instrument (with 2% accuracy), setting the exposure time to 1 second.

- **Measuring the exposure time**

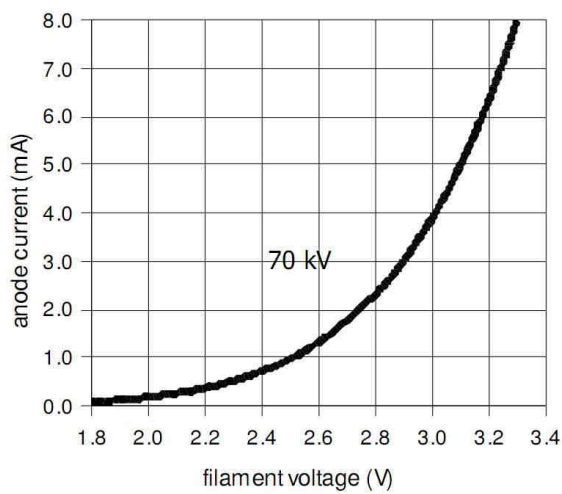
The exposure time must be measured using a non-invasive instrument.

In compliance with standard IEC 60601-2-7, the exposure time is measured as the interval of time between the moment in which the high voltage has reached for the first time a value equal to 75% of the peak value and the moment in which it goes down below this value.

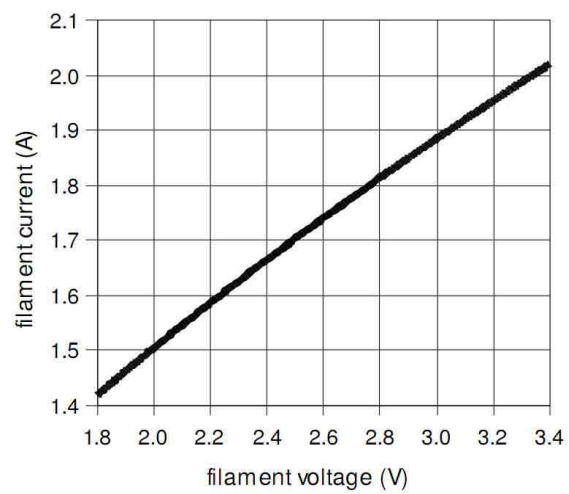
4.2 Curves tube features

OX/70-5

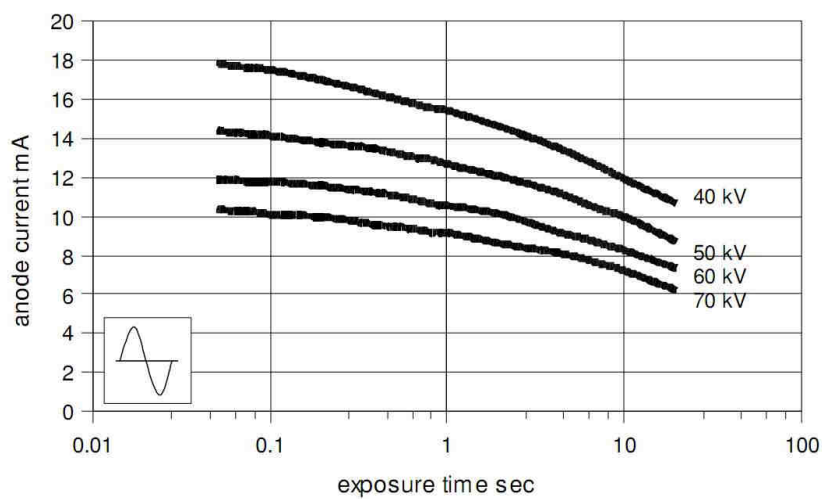
Emission characteristics



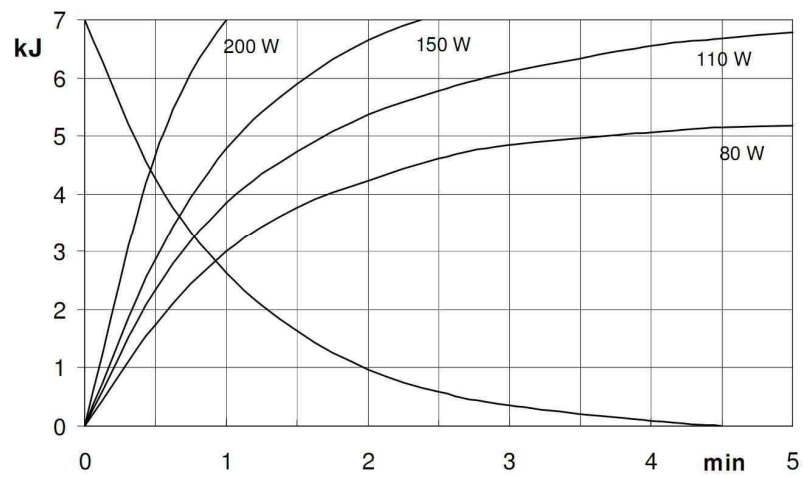
Filament characteristics



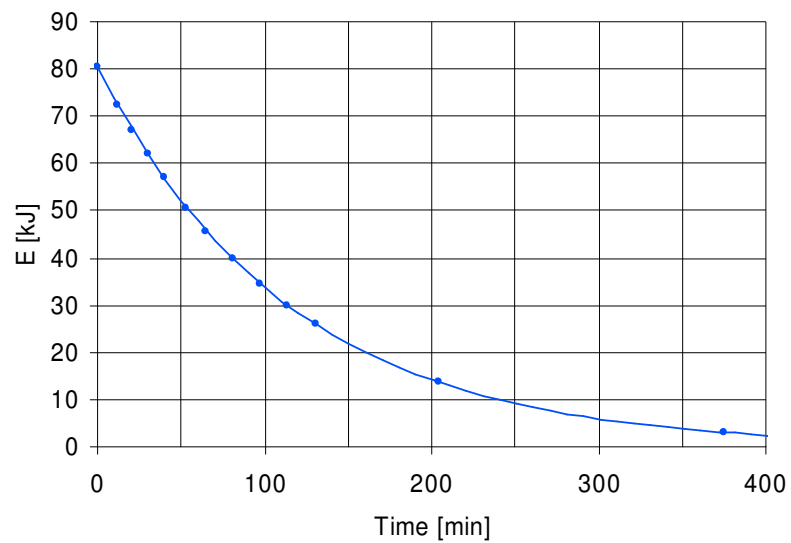
Load



Anode cooling curve



Tube-head cooling curve



4.3 Reference standard

Endograph DC complies with the following standards:

IEC 60601-1:1988 + A1:1991 + A2:1995

Medical Electrical Equipment – Part 1: General requirements for safety.

IEC 60601-1-6:2004

Medical electrical equipment - Part 1: General requirements for safety - collateral standard: Usability.

IEC 60601-1-2:2001+ A1

Electromagnetic Compatibility Requirements and Tests.

IEC 60601-1-3:1994

Gen. Requirements for Radiation Protection in Diagnostic X-ray Equipment.

IEC 60601-2-7:1998

Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators.

IEC 60601-2-28:1993

Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis.

IEC 62304:2006 + Ac:2008

Medical device software - Software life-cycle processes.

ISO 14971:2007

Medical Devices - Application of Risk Management to Medical Devices.

CAN/CSA C22.2 No. 601.1-M90 (2nd edition) +A1 + A2

Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

UL 60601-1 (1st edition)

Medical Electrical Equipment - Part 1: General Requirements for Safety

 0051 Guarantees Endograph DC compliance with Directive 93/42 and as amended. (subsequent amendments and additions)

CFR 21

Code Federal Regulation. Sub Chapter J

Canadian Medical Device Regulations

4.3.1 Reference standards related to wireless switch

Endograph DC contains radio module with FCC ID: 2ABYS76593030

The wireless switch for Endograph DC complies with the following standards:

ETSI EN 300 220-2 v.2.3.1

ETSI EN 301 489-3 v.1.4.1

Electromagnetic Compatibility and Radio Spectrum matters (ERM).

CE 0051 Guarantees wireless switch for Endograph DC
compliance with Directive R&TTE 1995/5/EC

CFR title 47 part 15

Subpart C-Intentional Radiators 15.231

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

4.4 Dimensions

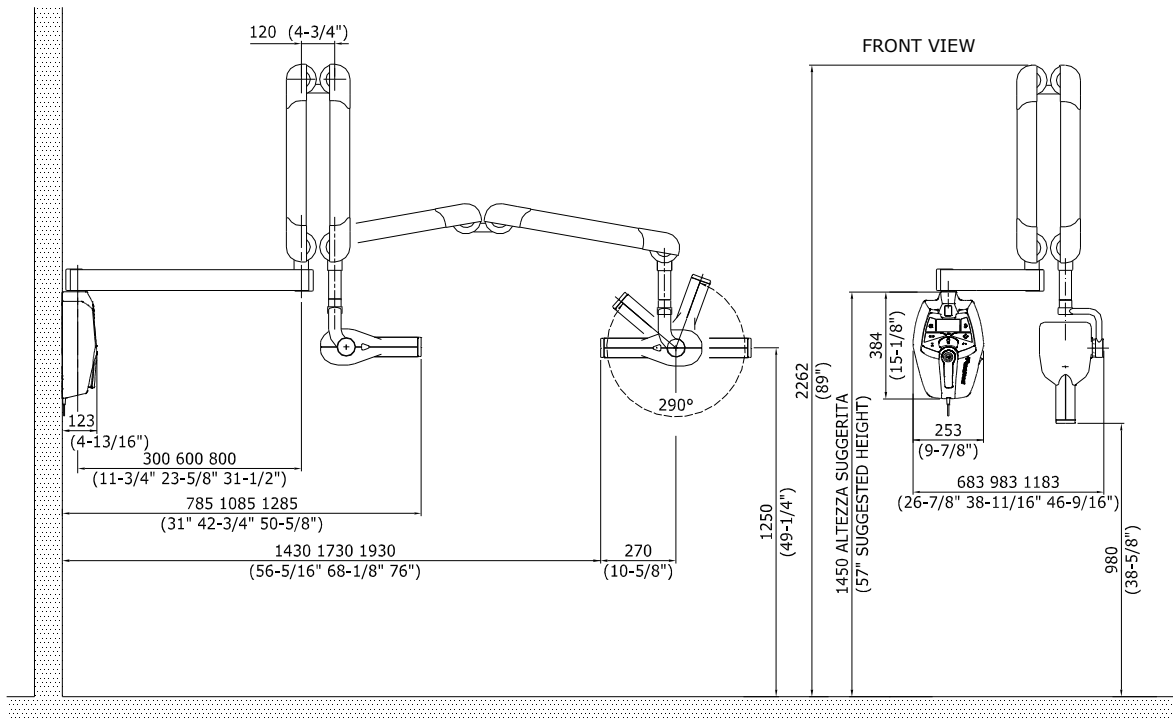


Figure 4-1: Dimensions of the wall version

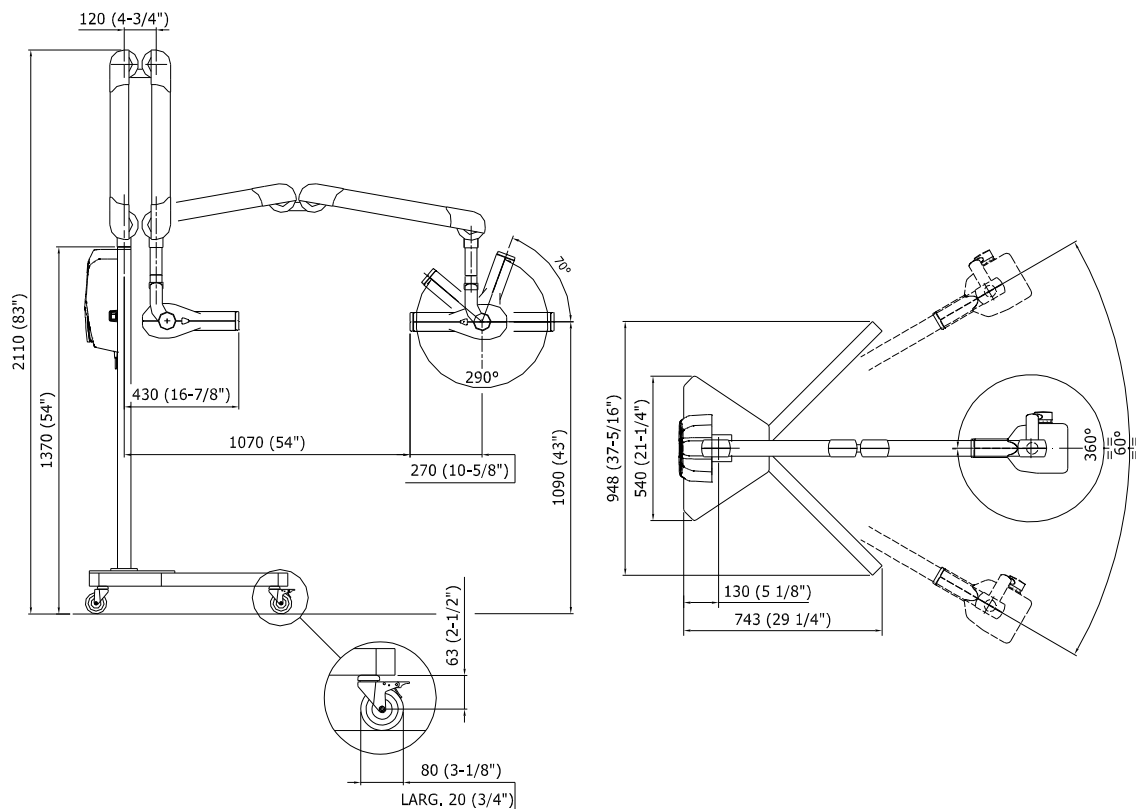


Figure 4-2: Dimensions of the mobile stand version

5. PRE-INSTALLATION

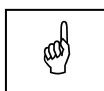
Endograph DC does not ask for special pre-installation works, still it is necessary to grant an adequate grounding for EMC compatibility and safety.

Section of grounding cable must be at least equal or greater than the section of line cables. It is advisable to use a grounding cable with section 2.5mm².

If cables are going to be positioned inside the wall, it is better that ducts are already positioned, taking into account where the device will be installed, taking care that cables exit in correspondence of the hole on the lower side of the wall plate.

The Manufacturer can assist technically in the pre-installation phase, but preparation works are a customer's responsibility.

5.1 Mounting methods



NOTE:

This chapter is valid for Wall version. The user does not need to assess the consistency of the wall for Stand version.

The installer is responsible for assessing the consistency of the wall. The extraction load on each screw is 446 N (46 kg) for the wall version standard assembly (3 mounting screws), 634 N (65 kg) for the wall version "single stud" assembly (5 mounting screws).

For each type of wall use the appropriate mounting method complying with the following specifications which guarantee a safety factor 4:

- Wooden uprights: self-threading screws 8x70 A 4.8 (provided with the installation kit)
- Full or concrete bricks: screw anchors (provided with the installation kit) in cast iron M8 or chemical screws WURTH (not provided)
- Hollow bricks: chemical screws (not provided).

A counter-plate must be used with walls with a lower resistance.

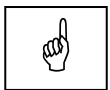


WARNING:

The Manufacturer is not responsible for any installations that do not comply with the specifications stated above.

5.2 Electric pre-setting

- | | |
|--|--|
| • Single-phase supply + ground | 110-240 V~ ±10% |
| • Frequency | 50 – 60 Hz |
| • Max absorbed current during emission | 5.2 A rms impulsive @ 115 V~
2.5 A rms impulsive @ 230 V~ |
| • Apparent line resistance | 0.4 Ω @ 99-132 V~
0.8 Ω @ 198-264 V~. |



NOTE:

The device is intended for permanent installation.

It is forbidden to connect the system by a plug in a wall socket for safety reasons.

Mobile version has to be requested on order and it is not possible to transform wall mounted version into a mobile version in field.



NOTE:

A circuit breaker with overcurrent protection must be connected to the intraoral X-ray equipment with the following features:

- Nominal current: 10A
- Differential sensitivity: 0.03A.

Section of line cables must be not lower than 1.5 mm².

Grounding of the system must meet requirement of the laws; a bad grounding can be dangerous for the operator and can generate malfunctioning of the device.



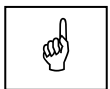
NOTE:

The mobile stand is supplied without the mains plug to permit the free connection at every socket.

Is in charge to the installer supply a mains plug compatible with the local electrical network with follow features: connection 2P+Earth protection, minimum working voltage compliant with the power supply in use, minimum rated current 10A.

Then install the mains plug on the cable by connecting the Y/G wire in the earth protection connector and the others conductors in the others free connectors.

The mains plug must be in compliance with the laws and directive in force of the Country of use and report at least one quality/safety mark released by a recognized Notified Body.



NOTE:

Endograph DC can be connected to signaling devices outside the installation room; please make reference to chapter 6.4.1.

It is also possible to mount the system with remote keyboard: in this case it is necessary to use a RJ45 cable provided by the Manufacturer.

6. INSTALLATION

6.1 Wall installation

Endograph DC intraoral X-ray equipment is shipped pre-assembled in sub-assys.

Mechanical assembly work consists solely in assembling these units.

All the mechanical components are therefore adjusted before delivery;

not only is there no need to carry out any adjustment on these parts but it would also cause the equipment to malfunction; any adjustment must be carried out by authorised personnel only.

6.1.1 Timer set up (standard configuration)

1. To be sure that the equipment is in the correct position we recommend you put the provided template code 39599100 (**3** - Figure 6-1) in the requested position, in this way identifying the requested wall-mounting position. Considering the overall dimensions of the equipment, put the top part of the template at 1450 mm from the floor.



WARNING:

The installer will assess the consistency of the wall taking into consideration the screw extraction load specified in paragraph 5.1.

2. Mark the mounting points and make the respective holes with a diameter corresponding to the chosen screws.
Making reference to the template, use holes "A" for standard installation. Use holes "B" for single stud installation.
3. Remove the plastic timer cover (**1** - Figure 6-1) loosening the two sealing screws (**2** - Figure 6-1) placed on the top part.
Do not remove completely the screws and the relevant plate (4 - Figure 6-1); with the extension arm in place, will not be possible to reassemble the plate.
To make the operation easier, disconnect all wires between wall plate and cover.
4. Fix the timer to the wall using the relevant screws verifying the perpendicularity of both axes with respect to the wall.

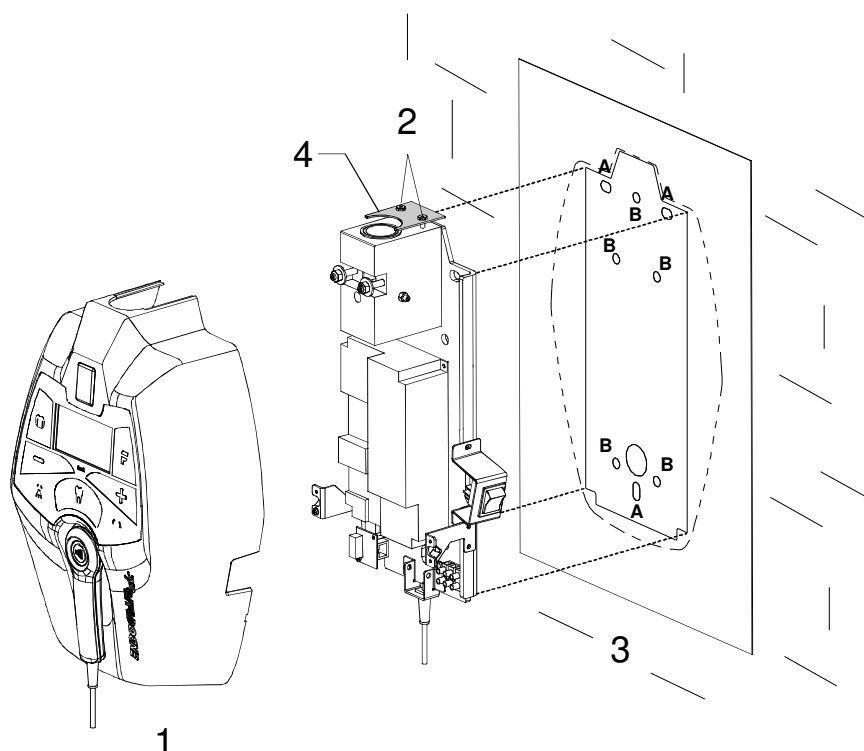


Figure 6-1

6.2 Assembling the mobile stand and timer installation

1. Cross the two base tubes (**1** - Figure 6-2) into the provided cut, fixing them together with the screw (**2** - Figure 6-2) and relevant nut (**3** - Figure 6-2). Do not tighten the screw completely.
2. Position the base plate (**4** - Figure 6-2) and fix it with the four screws (**5** - Figure 6-2). If necessary, reposition the two base tubes (**1** - Figure 6-2) slightly in order to align the relevant holes on the plate.
3. Lock the nut (**3** - Figure 6-2) in order to block the base tubes (**1** - Figure 6-2) permanently.
4. Assemble the stand column (**6** - Figure 6-2) on the base plate (**4** - Figure 6-2) with the four screws (**7** - Figure 6-2).

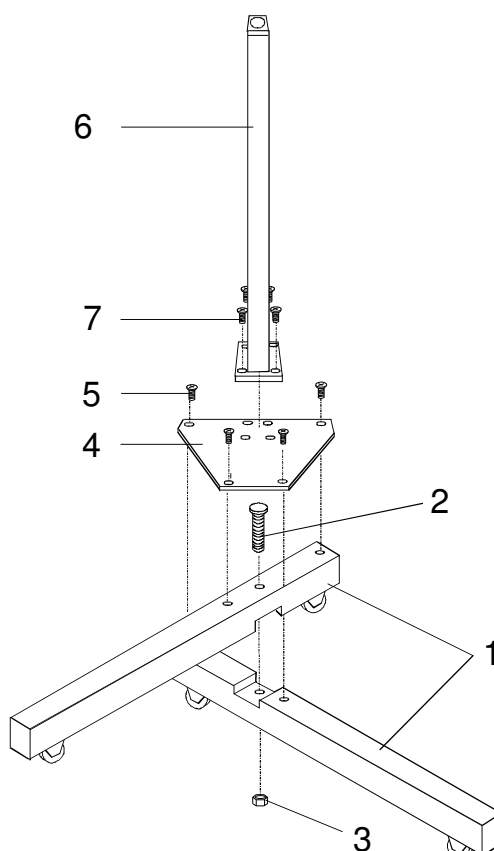


Figure 6-2

5. Assemble the timer support plate (**8** - Figure 6-3) to the stand column, fixing it with the two screws (**9** - Figure 6-3) present on the stand column.



WARNING:

The timer must be fixed to the support plate after assembling the scissors arm (see paragraph 6.3.3).

6. Remove the plastic timer cover (**10** - Figure 6-3) by loosening the two sealing screws (**12** - Figure 6-3) placed on the top.
To make the operation easier, disconnect all cables connecting the timer and the plastic cover.
7. Fix the timer onto the support plate with the two screws (**14** - Figure 6-3) taking care to thread the supply cable and the cables coming from the scissors arm inside the hollow one (**15** - Figure 6-3). Check that the upper level is level using a bubble level.

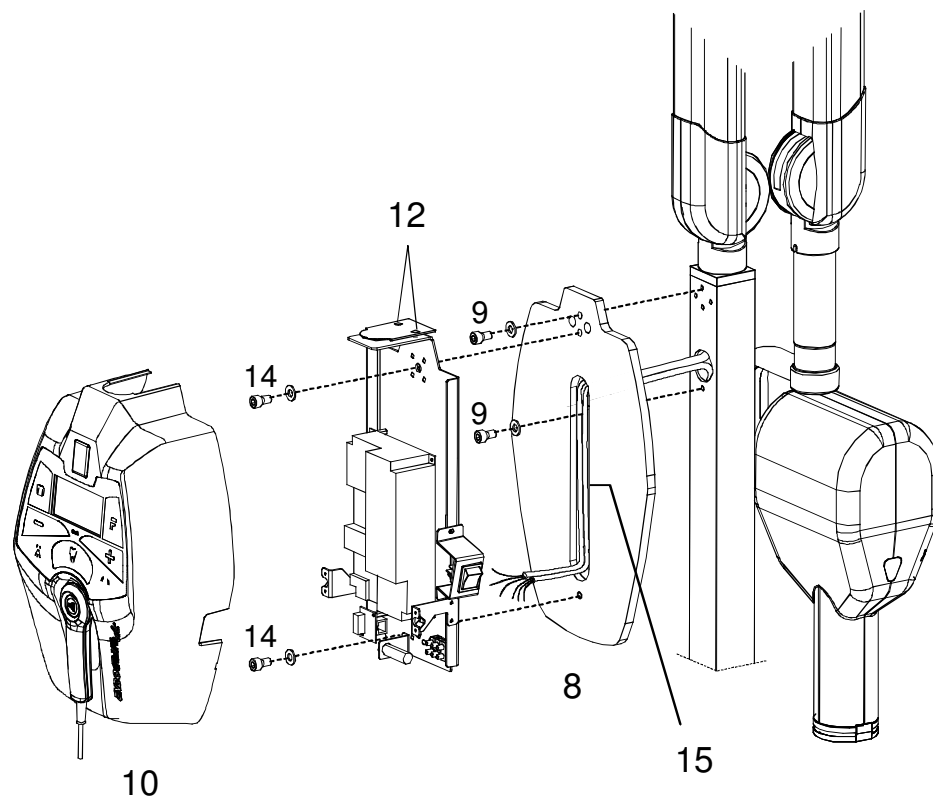


Figure 6-3

6.3 Assembling the arms

6.3.1 Assembling the extension arm

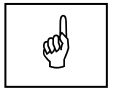
1. Insert the extension arm into the arm support block which is an integral part of the wall support plate.



NOTE:

You must keep the arm orthogonal to the plate to be able to insert the shaft into the bush placed inside the support.

2. Assemble the extension arm frictioning mechanism block (**1** – Figure 6-4); this frictioning mechanism (code 6159300100) is included in the mounting hardware packaging.
3. Assemble the arm rotation stop screw (**2** - Figure 6-4) in the hole present on the shaft; this screw (code 2100014800) is included in the mounting hardware packaging.
4. Tighten the two lateral screws (**3** - Figure 6-4 – one on each side) ensuring that they block the arm rotation without interfere with the extension arm pin.



NOTE:

The purpose of the frictioning mechanism and the rotation stop pin is to prevent the extension arm from becoming detached.

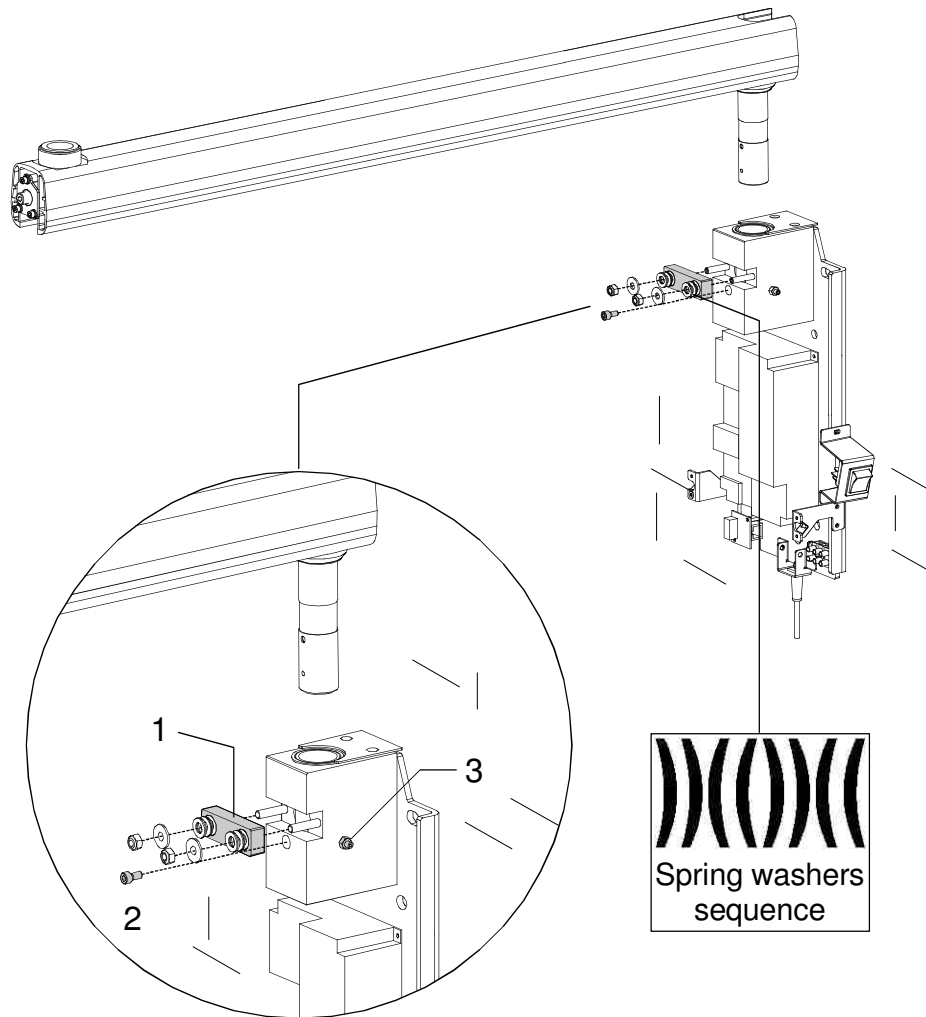
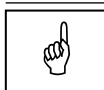


Figure 6-4

6.3.2 Assembling the scissors arm (DP arm)



NOTE:

To help assembly Endograph DC is shipped with the tubehead already mounted on the scissors arm; it is recommended to let the tape wrapping the arm in place. In case it is removed, besides making more difficult the assembly it is possible that the installer is hurt or the arm damaged.

1. Remove the friction group fixing plate fixed to the extension arm with three screws (scissor arm side). Take note that the upper screw is shorter than the other two and has to be mounted in the same position.

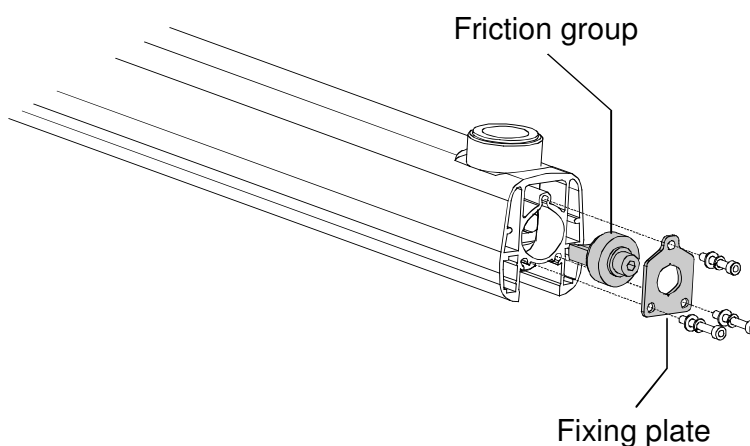


Figure 6-5

2. Remove also the friction taking care not to loose the spring washer. Here following is indicated the right sequence of the washers.

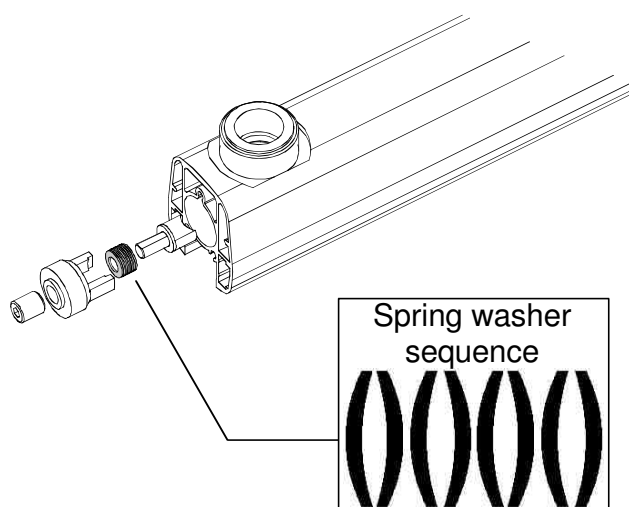


Figure 6-6

3. Remove the fixing bushing. This operation will permit an easier insertion of the scissor arm group into the extension arm.

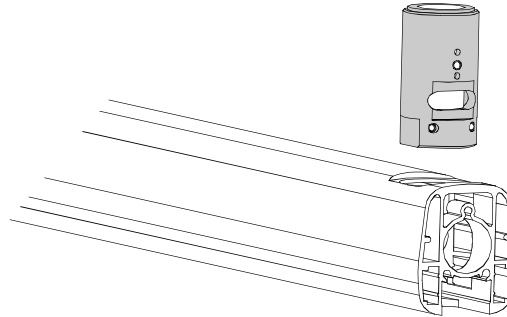


Figure 6-7

4. Insert the extension arm pin in the bushing; during insertion take care to the O-Rings present in the bushing. The friction group fixing holes must be toward tube head support.

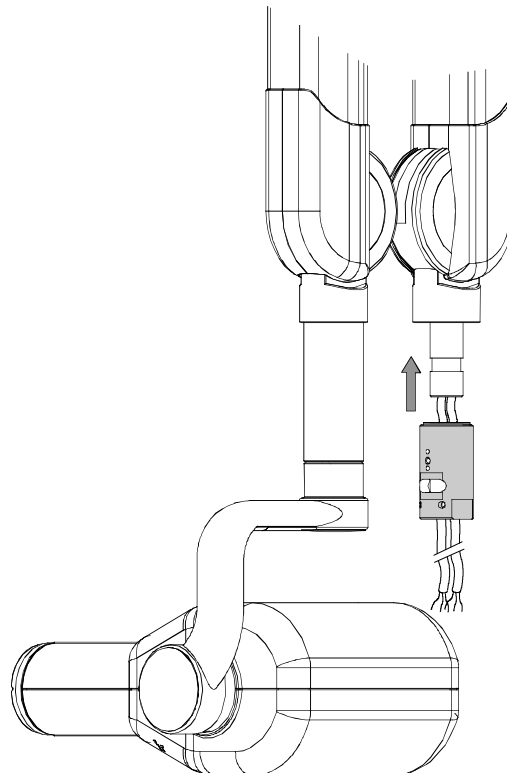


Figure 6-8

5. Insert the scissor arm into the extension arm, aligning the bushing fixing holes to the extension arm screws. Power cable, signal cable and grounding cable must be let out freely from the extension arm.

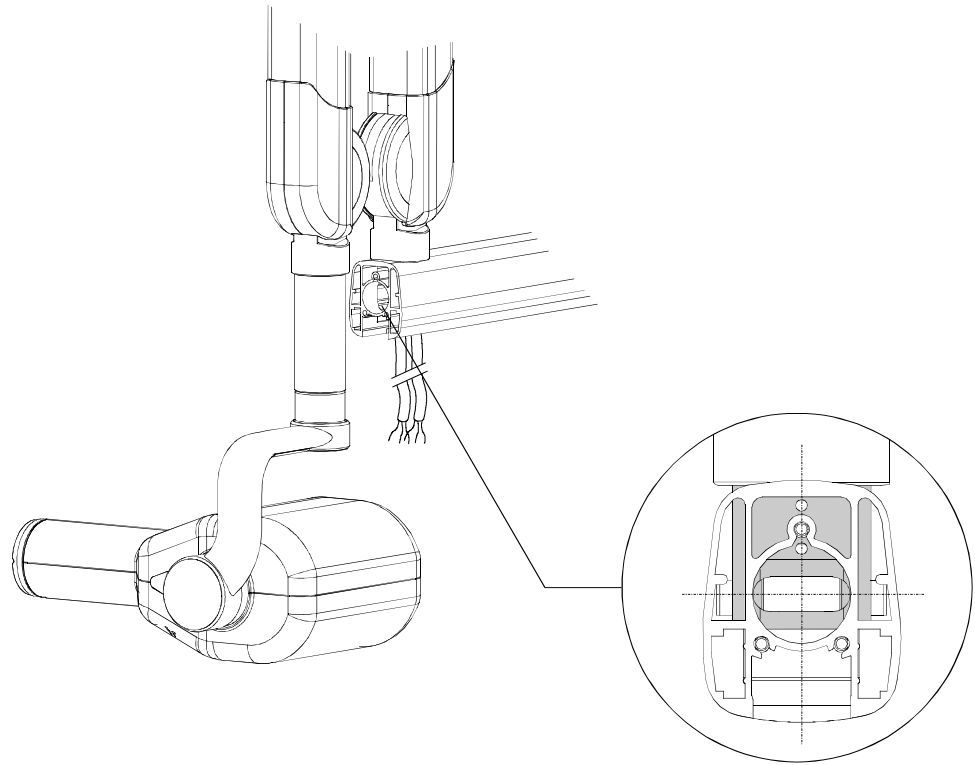
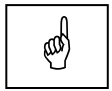


Figure 6-9

6. Mount the friction group and fix the plate using the shorter screw in the top hole (Figure 6-5). Tighten the grub screw until it is frictioned but don't force the friction. It has to be adjusted only if necessary.
7. Remove the safety clamp and completely open the scissors arm to locate the position where the cable is more recovered inside the arm itself.



NOTE:

The following operations must be done with the scissors arm completely open.

8. Holding this position, gently pull the cables coming from the scissors arm down to avoid excess cable in the arms.

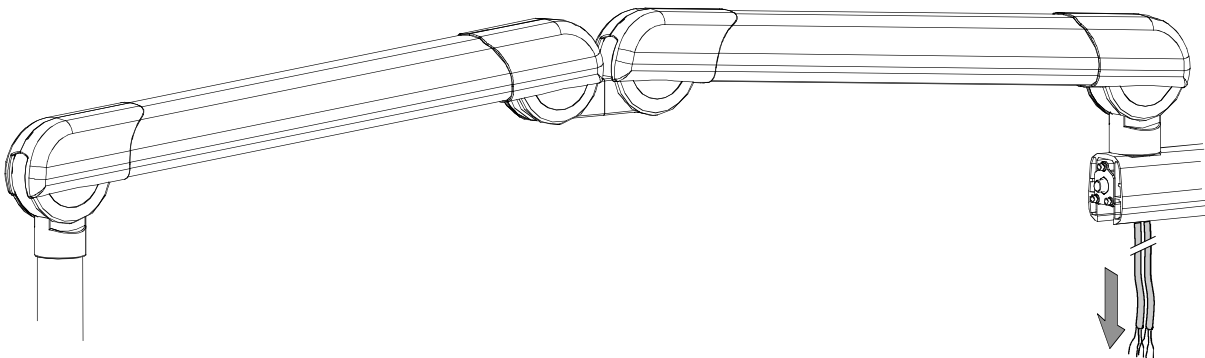


Figure 6-10

9. Insert the cables inside the extension arm (power cable on one side and filament cable and the grounding cable on the other side) following the drawing in Figure 6-11 (fase 1); this will make sure that the cables are not tensioned during use. To make this easier, wrap together the grounding and filament cables with tape.
10. Run the cables inside the extension arm until they come completely out at the opposite end.
11. Insert the cables inside the rotation pin as shown in the following figure (fase 2 and 3).

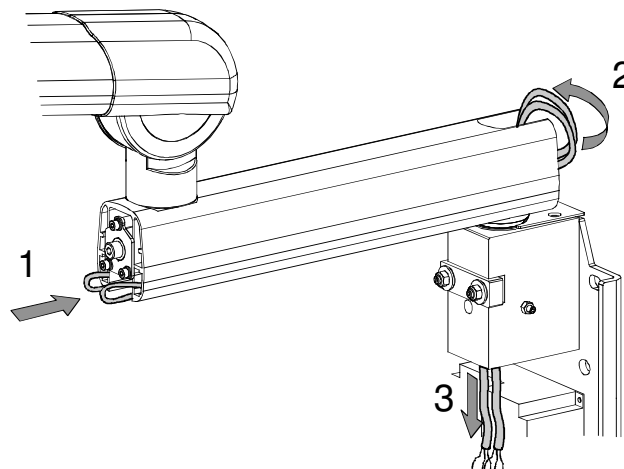


Figure 6-11

- 12.** Push the cables inside the extension arm (scissors arm side), so that no excess is left at the extremity. When doing this, firmly pull the cables on the other end of the extension arm (timer side).

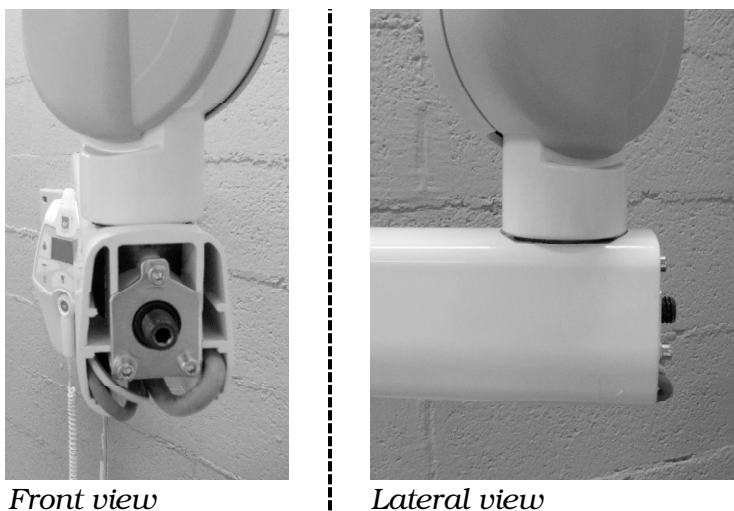


Figure 6-12

- 13.** Make sure that cables don't push the end cap when opening and closing the scissors arm. Repeat this operation several times in all the arm positions.
If necessary, repeat step 12 and carefully adjust the excess cable.
- 14.** Check that the DP arm is perfectly inserted; check that the rotation of the scissors arm inside the extension arm is the one ergonomically requested by the operator, otherwise work on the frictioning mechanism (**1** - Figure 7-2) until you get the requested run.



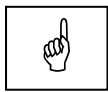
NOTE:

This frictioning mechanism is also used to prevent the scissors arm from becoming detached and for this reason it must never be loosened completely.

- 15.** Check the ergonomics of the arm opening movement, otherwise adjust the tension of the arm balance springs (see paragraph 7.1.3).
- 16.** Assemble the front covers of the extension arm included in the mounting hardware packaging.

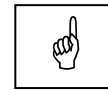
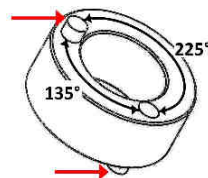
6.3.3 Assembling the stand arms set

1. Loose the two screws (**1** - Figure 6-13) to allow the positioning of the scissors arm.
2. Assemble the scissors arm (there is no extension arm in this configuration), being careful to insert the spacer (**2** - Figure 6-13) into the rotation pin. The spacer (code 6161305600) is included in the mounting hardware packaging.



NOTE:

Be sure that the two pins are inserted into the spacer as showed in the drawing.



NOTE:

Keep the arm perfectly orthogonal to the pole when inserting the extension arm rotation pin.
Do not release the scissors arm from their sealing packing.

3. Secure the arm tighten the two screws (**1**).

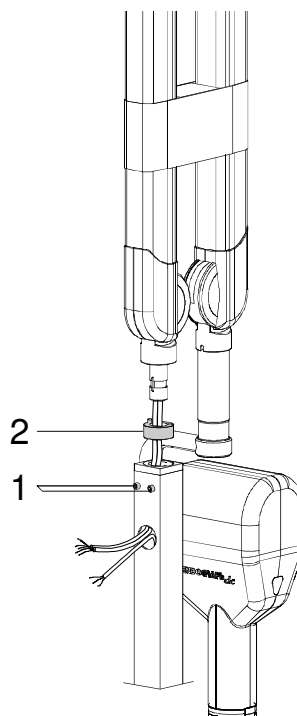


Figure 6-13

6.4 Installation of the optional parts

6.4.1 External signaling devices

Endograph DC allows connecting additional signaling devices outside the room, as specified here below:

- A signaling device indicating "READY" and "RX ON" status can be connected to X11 connector of the "External signal" board A5 (Figure 6-14).
- To use signaling devices it is necessary to prepare connections using 4 wires having a section of 0.5 mm².

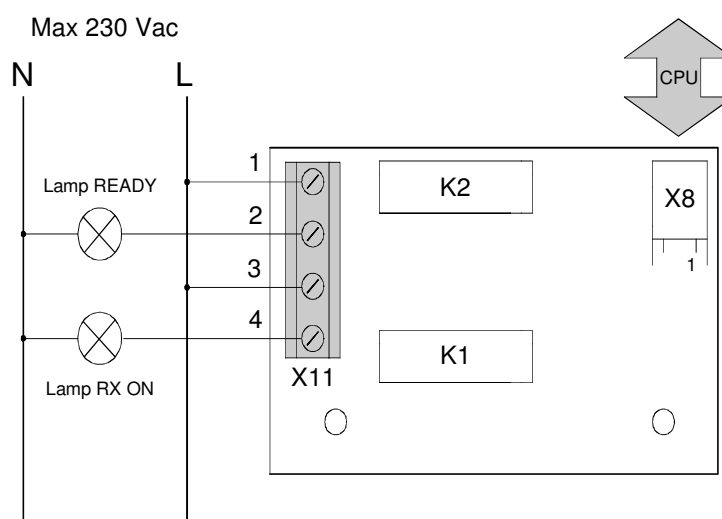


Figure 6-14

6.4.2 Remote X-ray button



NOTE:

Whatever remote X-ray button installation is implemented, the front panel of the timer must be visible from the remote button location to allow the user to see technical factors before starting an exposure.

There are two possible alternative for remote X-ray button:

1. A door bell X-ray button (not provided by Villa Sistemi Medicali) can be installed following the instruction here below.



NOTE:

The connecting cable between Timer and Remote X-ray button, passing into the wall or external, must always be put into a metal conduct to avoid any kind of disturbance to the signals passing through the cable. The cable can be a maximum of 15 meters long and consequently the distance between Timer and X-ray button must be shorter than this length.

The connecting cable must have a 1mm² minimum section and must be connected to the X6.1 and X6.2 connectors on the CPU board A2 (see chapter 12).

The remote X-ray button can be connected in parallel to the standard X-ray button supplied with the timer, using the same connectors.

Safety regulations stipulate that a button enabled by an appropriate safety key must be used.

2. The kit P/N 6659120000 provides a way to install remotely the X-ray button supplied with the timer.
The kit includes a wall support plate with a terminal strip.



NOTE:

The connecting cable between Timer and remote X-ray button (not provided by Villa Sistemi Medicali) must have a 1mm² minimum section. The connecting cable must always be put inside a metal conduct to avoid any disturbance to the signals passing through the cable.

Remove the X-ray button from the Timer disconnecting the cable from X6.1 and X6.2 connectors.
Assemble the button on the wall support plate connecting the cable on the terminal strip.

The connecting cable between Timer and remote X-ray button must be connected to X6.1 and X6.2 connectors (Timer side) and to the terminal strip of the support plate.

The support plate has to be fixed on the wall using the fisher type screws provided.

6.4.3 Wireless X-ray button

6.4.3.1 Wireless X-ray button –battery assembling

To insert the battery inside the wireless X-ray button, proceed as follow:

- 1.** unscrew the two screws located on the back of the button
- 2.** open the two half-shells, keeping the green button facing upwards and paying attention to the electronics located inside
- 3.** insert the batteries respecting the indicated polarities
- 4.** reclose the two half-shells and tighten the screws.

6.4.3.2 Wireless upgrade kit assembling



NOTE:

This procedure has to be performed in case of field upgrade. System coming with wireless X-ray button are pre-assembled in factory.

The wireless upgrade kit (code 7659303000) includes:

- Wireless X-ray button
- 2 x AAA batteries
- A6 Radio board
- X7 connecting cable.

To assemble the parts proceed as follow:

1. Remove the plastic timer cover (see paragraph 6.1.1 – point 3) and disconnect the cables between timer and cover.
2. Remove the CPU board from the timer cover.
3. Assemble the hexagonal spacer on the CPU board A2 (component side) as shown in Figure 6-15 and Figure 6-16.

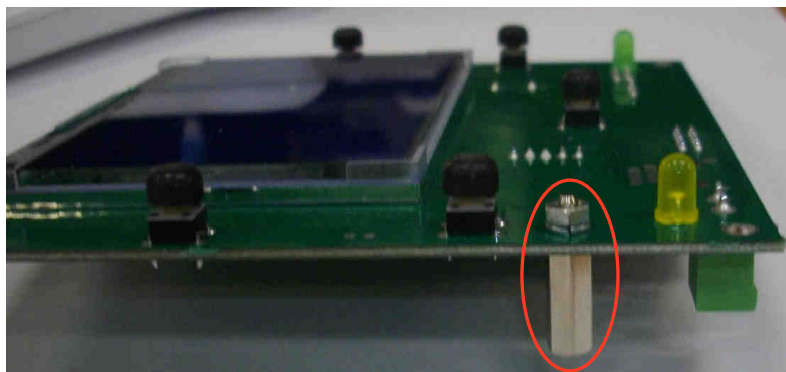


Figure 6-15

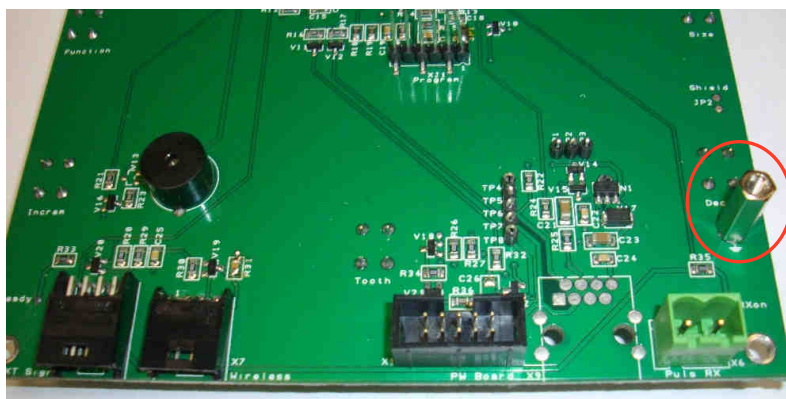


Figure 6-16

4. Assemble the A6 Radio board on the CPU board using the provided screw (Figure 6-17).

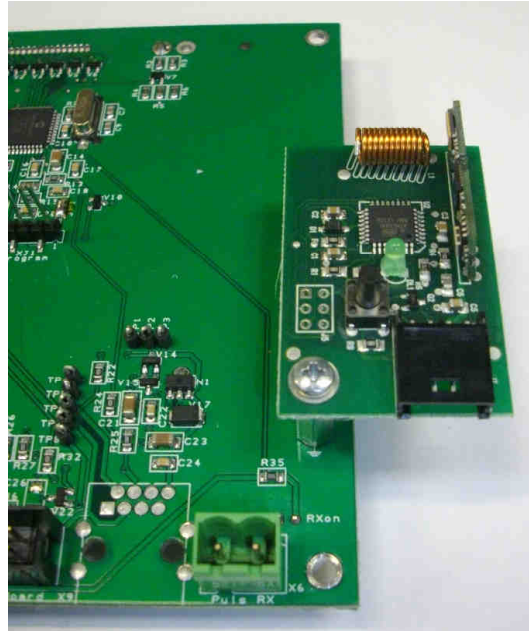
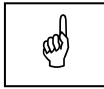


Figure 6-17

5. Reassemble the CPU board on the timer cover.
6. Connect the X7 cable between CPU board – connector X7 - and Radio board – connector J7.
7. Reconnect the cables between timer and CPU board and reassemble the plastic timer cover.

6.4.3.3 Wireless X-ray button – Timer matching



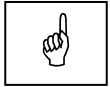
NOTE:

This procedure has to be performed in case of wireless X-ray button replacement or in case of matching lost.

To match wireless X-ray button and timer, proceed as follow:

- 1.** Switch on the equipment and verify that it is into ready mode.
- 2.** Press and hold pressed the wireless X-ray button until the green LED switches on (about 6 seconds).
- 3.** Press and release the wireless X-ray button: the green LED blinks slowly for three times. If the LED blinks quickly, the matching failed; repeat the procedure.

6.4.4 Remote Timer configuration



NOTE:

The mains power supply has to be provided only on wall support side.



NOTE:

**The connection cable between wall support and remote timer supplied in the Remote Timer kit (code 6659300100) is 20 meters long, ending with RJ45 connector.
The maximum distance between wall support and timer must not exceed the cable length.**

6.4.4.1 Wall support set-up

For the Remote Timer wall support set-up follow the instruction listed in paragraph 6.1.1 – Timer set-up (standard configuration).

6.4.4.2 Remote Timer set up

- 1** To be sure that the equipment is in the correct position we recommend you put the provided template code 39599101 (**3** - Figure 6-18) in the requested position, in this way identifying the requested wall-mounting position. Considering the overall dimensions of the equipment, put the top part of the template at 1450 mm from the floor.
- 2** Mark the mounting points and make the relevant holes with the diameter corresponding to the chosen screws.
- 3** Remove the plastic timer cover (**1** - Figure 6-18) by loosening the two sealing screws (**2** - Figure 6-18) placed on the top part.
- 4** Fix the timer to the wall using the provided screws (**4** - Figure 6-18) verifying its perpendicularity with the wall accordingly to both axis.

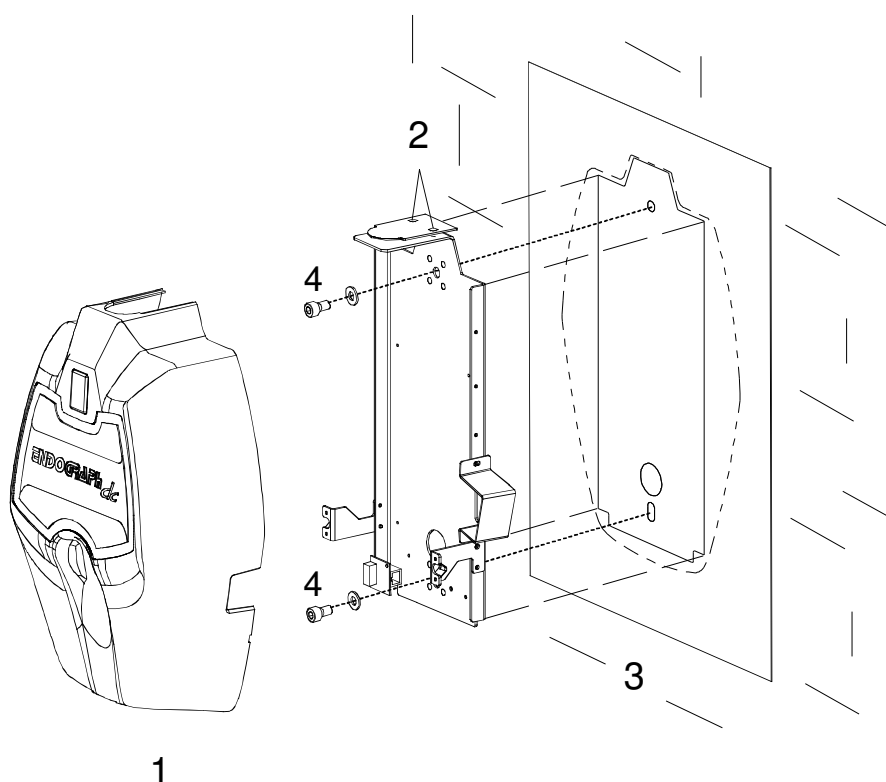


Figure 6-18

6.4.5 Installation of chemical screws

You are recommend to use chemical screws when installing the equipment on hollow bricks.

6.5 Electrical connection

6.5.1 Electrical connection for standard and mobile stand versions



NOTE:

Cables coming from the tubehead are supplied for the 80 cm extension arm.

For the 30 cm and 60 cm extension arm and for mobile stand version, the surplus part of the cables must be positioned to the top of the timer with a suitable loop, without passing over the Driver board area. Fix the cables with the provided strip.

1. Connect the power cables from the tubehead to the Driver board wiring the cables to the connector X4 (OUTPUT) and shield to screw W2, following the positions as in the table:

Tubehead wires colour	Tubehead wires identification	Driver board
Green	1	X4.1
Brown	2	X4.2
White	3	X4.3
Yellow/Green	Ground	X4.GND
Black	Shield	Screw W2

2. Connect the signal cable of the tubehead to the Driver board wiring the cables to the connector X2 (HEATER) following the position as in the table:

Tubehead wires colour	Tubehead wires identification	Driver board X2 terminal
White/Yellow	+	+
Green/Brown	-	-

3. Make the connection between the general switch and the terminal strip of the timer using a bipolar cable plus ground, section 1.5 mm² (16 AWG). Fix the cable to the terminal strip following the positions as shown (L = line, N = neutral, Ground = yellow/green cable). The conductors have to be secured to the timer base.
4. Assemble the two pins lock (1 - Figure 6-19) on the timer cover; these pins (code 2100511300) are included in the mounting hardware packaging.

5. Connect the cables between timer and cover: flat cable between CPU board – connector X1 – and Driver board – connector X1 (CONTROLS); X-ray button cable to CPU board – connector X6.
6. Place the cover on the timer taking care that the cover is positioned under the upper plate (4 – Figure 6-1). Push the cover against the locking pins and tighten the two upper screws (2 – Figure 6-1).

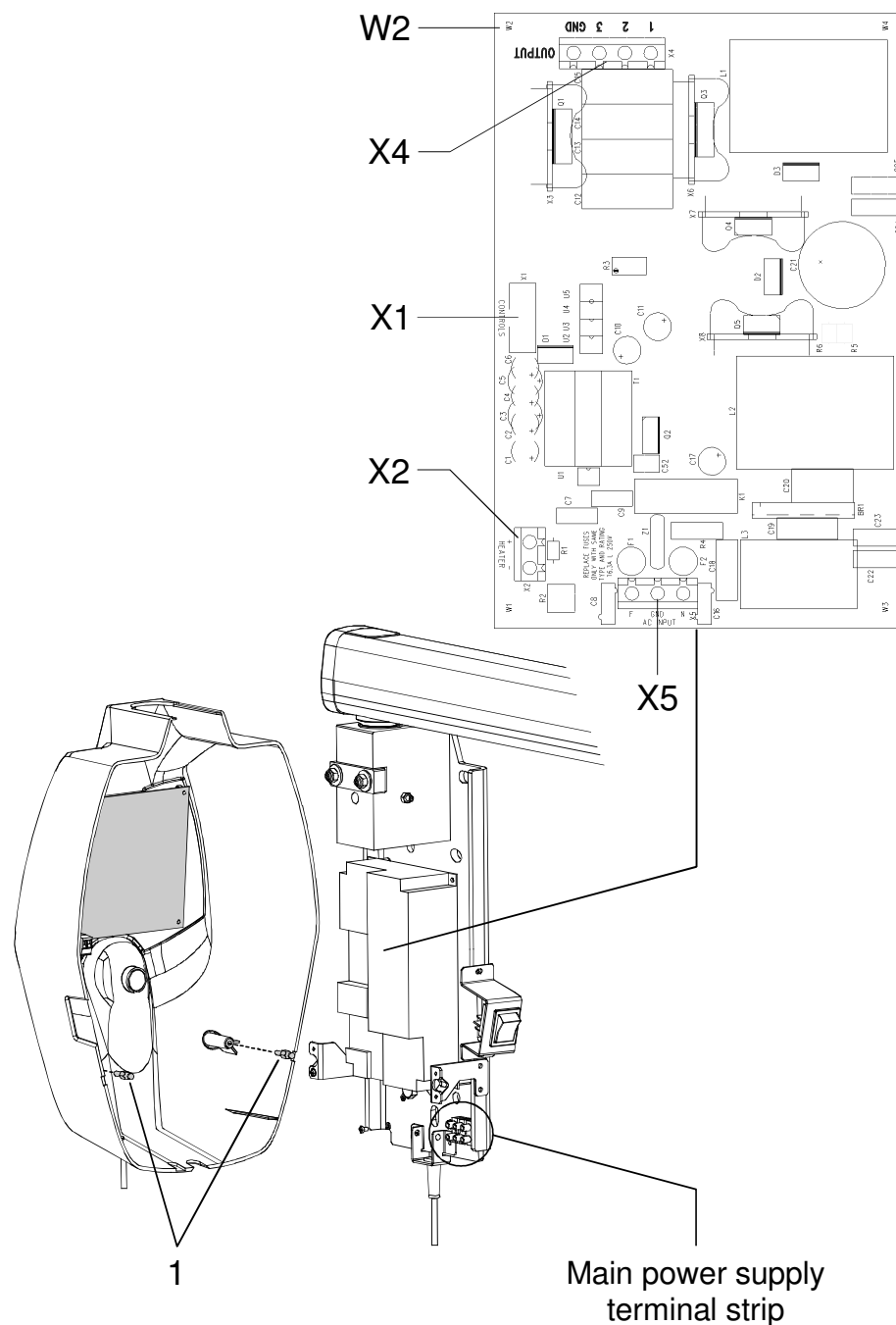


Figure 6-19

6.5.2 Electrical connection for Remote Timer version

6.5.2.1 Wall support connection

1. Remove the X-ray button complete of its support from the timer.
2. Connect the timer following the procedure listed in paragraph 6.5.1, steps from 1 to 3.
3. Assemble the Remote Interconnection Timer board (A8), included in the Remote Timer box, on the timer as shown in Figure 6-20.
4. Connect the flat cable, supplied with the Remote Timer box, between Driver board – connector X1 (Figure 6-19) – and A8 board – connector X1 (Figure 6-20).
5. Connect the RJ 45 cable to the A8 board – connector X9 (Figure 6-20).
6. Assemble the two pins lock (**1** - Figure 6-20) on the Remote Timer cover (**1** - Figure 6-18); these pins (code 2100511300) are included in the mounting hardware packaging.
7. Place the cover on the timer taking care that the cover is positioned under the upper plate (**4** - Figure 6-1). Push the cover against the locking pins and tighten the two upper screws (**2** - Figure 6-1).

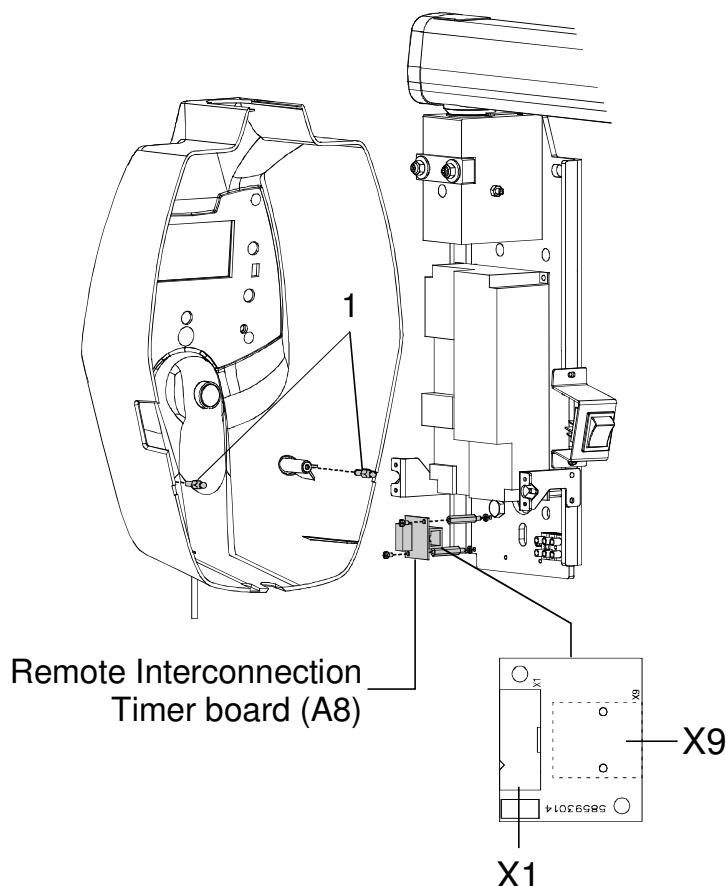


Figure 6-20

6.5.2.2 Remote Timer connection

1. Assemble the X-ray button complete of its support (**2** - Figure 6-21) on the Remote Timer plate.
2. Connect the RJ 45 cable to the Remote Interconnection Timer board (A9) – connector X9 (Figure 6-21).
3. Assemble the two pins lock (**1** - Figure 6-21) on the Timer cover (**1** - Figure 6-1); these pins (code 2100511300) are included in the mounting hardware packaging.
4. Connect the flat cable between CPU board – connector X1 – and A9 board – connector X1. Connect the X-ray button cable to the connector X6 on the CPU board.
5. Place the cover on the remote support taking care that the cover is positioned under the upper plate (**3** - Figure 6-21). Push the cover against the locking pins and tighten the two upper screws.

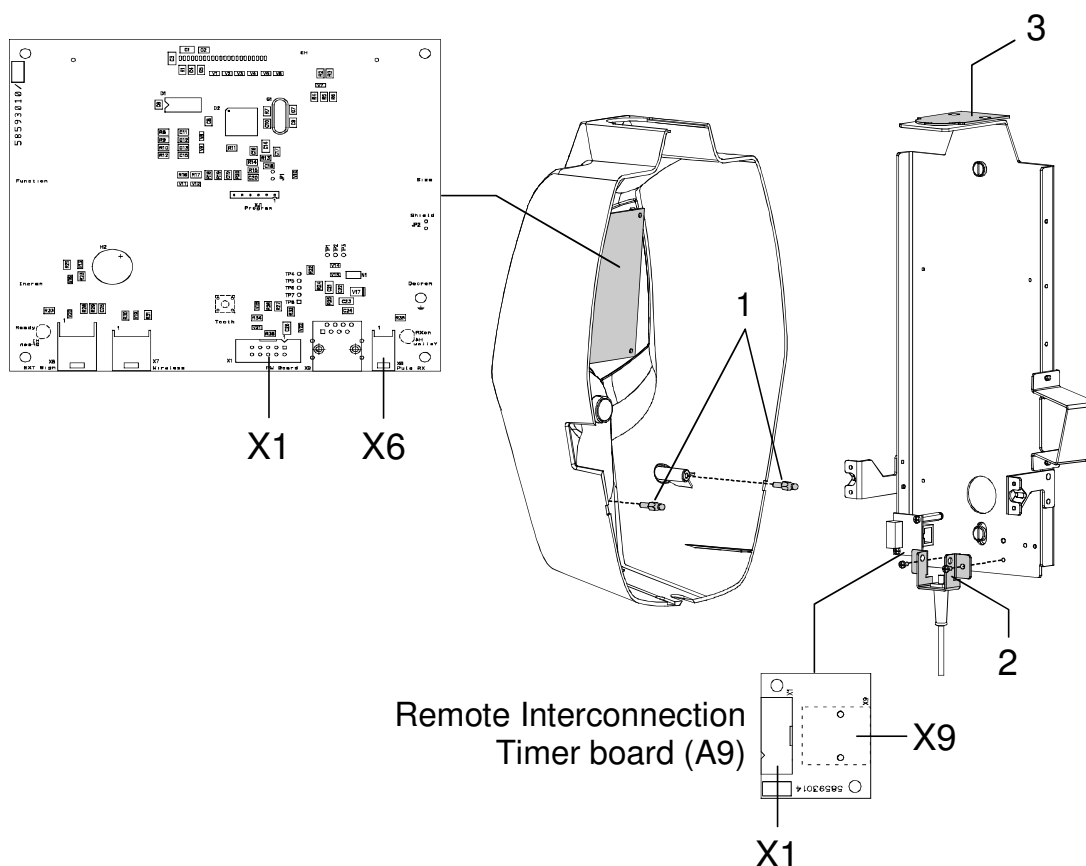


Figure 6-21

6.6 Power-up sequence

At start-up the timer automatically checks all the internal hardware and particularly:

- Display lights ON
- LEDs light for 2 seconds
- CHECKSUM check of the storage program and display of the words "CH0" if the check result is negative or in the event of non-initialized memory
- Buzzer check (rings)
- Check of all buttons and X-ray buttons in particular, no button must be pressed. If any buttons are pressed an error code message will appear on the display
- Showing of software and hardware versions (HW: X.XX – SW: X.XX).



NOTE:

During the first start-up, the volatile memory may not be programmed and therefore the "CH0" message will appear. In this case, press "F" key to restore the factory default setting. The "CH0" message must not be displayed any more.

If this happens again, replace the EEPROM on the CPU board and proceed to the set-up sequence.



WARNING:

Replacing the EEPROM, all the custom tables will be lost.

7. CHECKS, CALIBRATIONS AND ADJUSTMENTS

The device is calibrated in the factory during final testing carried out at the manufacturer's site.

Some adjustments (for example the friction mechanisms of the scissors arm and extension arm) may need to be done once the installation has been completed and are described in the installation chapter 6.

7.1 Arm adjustment

The arms may need adjusting in the following cases:

- the movement of the extension arm combined with the scissors arm is not considered to be ergonomic by the end user; in this case it will be necessary to adjust the extension arm frictioning mechanism.
- the scissors arm is not perfectly balanced; in this case you must adjust the springs.

7.1.1 Adjusting the extension arm support frictioning mechanism

The device to adjust the arm support frictioning mechanism is placed on the front of the wall support. To make this adjustment you have to proceed as follows.

- 1.** Remove the plastic timer cover by loosening the two sealing screws (**1** - Figure 7-1) placed on the top part of the wall plate. Be careful to the cables connecting the timer and the plastic cover.
- 2.** Using a 10 mm wrench, adjust the frictioning mechanism nuts (**2** - Figure 7-1) until the movement of the arm is ergonomic.
- 3.** Reposition the plastic cover when you have finished.

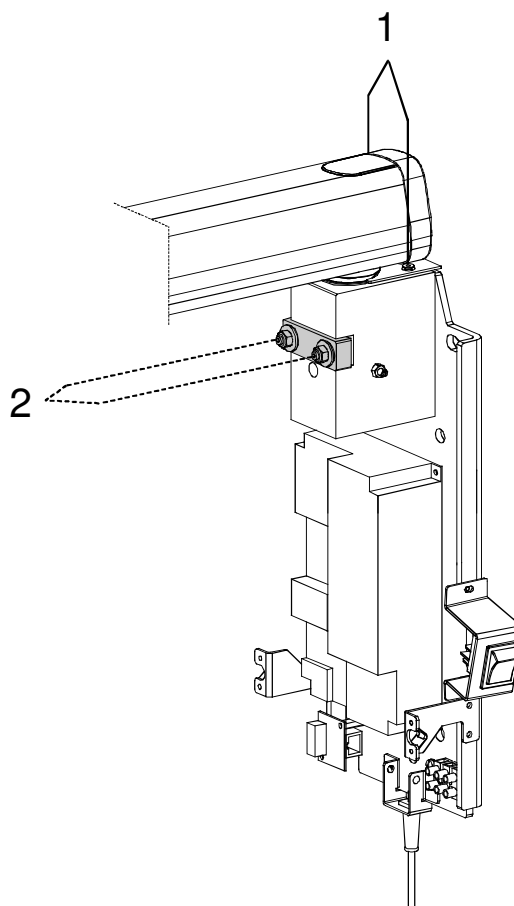


Figure 7-1

7.1.2 Adjusting the extension arm frictioning mechanism

1. Remove the small front extension arm cover, working carefully.
2. Adjust the frictioning mechanism (**1** - Figure 7-2) using a 5 mm hexagon wrench checking the rotation of the scissors arm.



NOTE:

The purpose of this frictioning mechanism is to prevent the scissors from becoming detached, so it must not be loose.

3. Assemble the cover again.

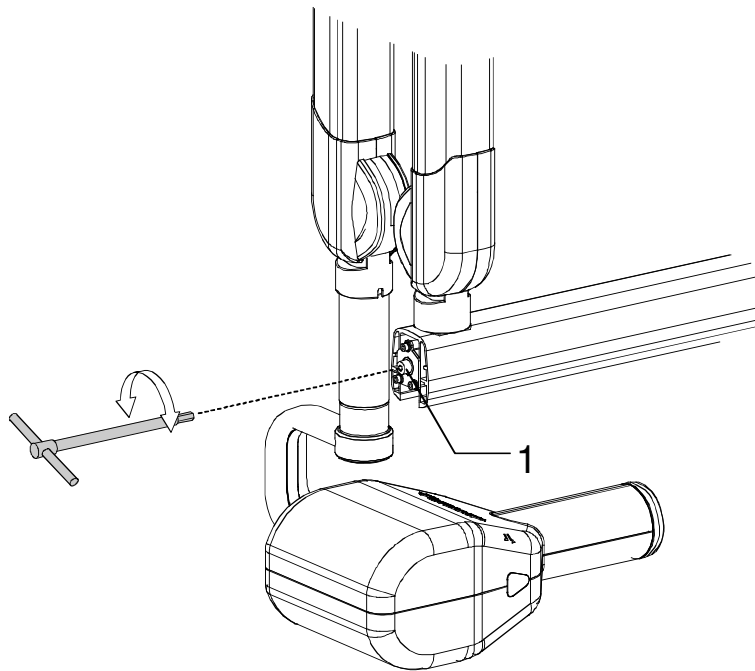


Figure 7-2

7.1.3 Adjusting the balance scissors arm

- **Adjusting the second arm**

Proceed as follows to adjust the scissors arm:

- **Adjusting the friction (for small corrections - picture A)**

1. Put the arm in a horizontal position; remove the plastic coordinator covers. **This must be done carefully to avoid breaking the covers themselves.**
2. Using a 2.5mm hexagon wrench, loosen the dowel (1).
3. Using two 13 wrenches, adjust the frictioning mechanism by rotating one of the wrenches $\frac{1}{4}$ of a turn each time.
4. When you have finished the adjustment, tighten the previously loosened dowel and reassemble the plastic covers.

- **Adjusting the spring (picture B)**

If adjustment of the friction is not enough, you can adjust the spring to optimise the balance:

- 1 Put the arm in a horizontal position; remove the plastic coordinator covers. **This must be done carefully to avoid breaking the covers themselves.**
- 2 Insert a 6mm hexagon wrench (about 200mm long – contained in the kit P/N 6661209900). **This wrench must rotate clockwise if the arm tends to go down compared to the release position; anticlockwise if it tends to go up.**
- 3 When you have finished the adjustment, reposition the plastic covers.

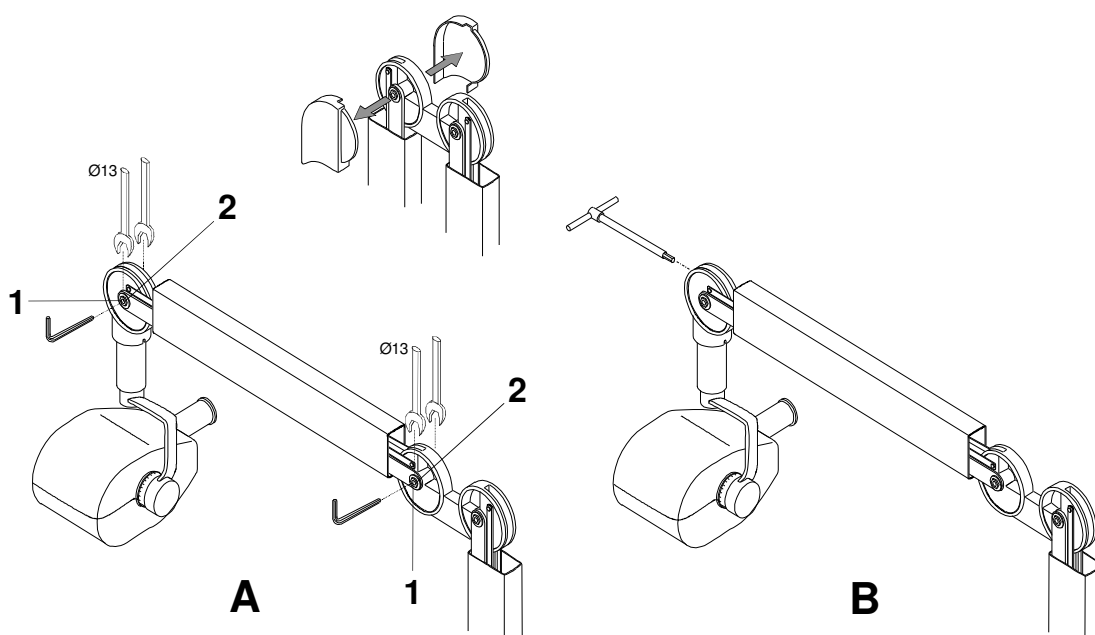


Figure 7-3

- **Adjusting the first arm**

If the first arm also needs to be adjusted:

- **Adjusting the friction (for small corrections - picture A)**
 - 1 Close the arm scissors arm; remove the plastic co-ordinator covers. **This must be done carefully to avoid breaking the covers themselves.**
 - 2 Using a 2.5mm hexagon wrench, loosen the dowel (1).
 - 3 Using two 13 wrenches, adjust the frictioning mechanism by rotating one of the wrenches $\frac{1}{4}$ of a turn each time.
 - 4 When you have finished the adjustment, tighten the previously loosened dowel and reassemble the plastic covers

- **Adjusting the spring (picture B)**

If adjustment of the friction is not enough, you can adjust the spring to optimise the balance:

1. Put the arm in a horizontal position; remove the plastic co-ordinator covers. **This must be done carefully to avoid breaking the covers themselves.**
2. Insert a 6mm hexagon wrench (about 200mm long – contained in the kit P/N 6661209900). **This wrench must rotate clockwise if the arm tends to go down compared to the release position; anticlockwise if it tends to go up.**
3. When you have finished the adjustment, reposition the plastic covers

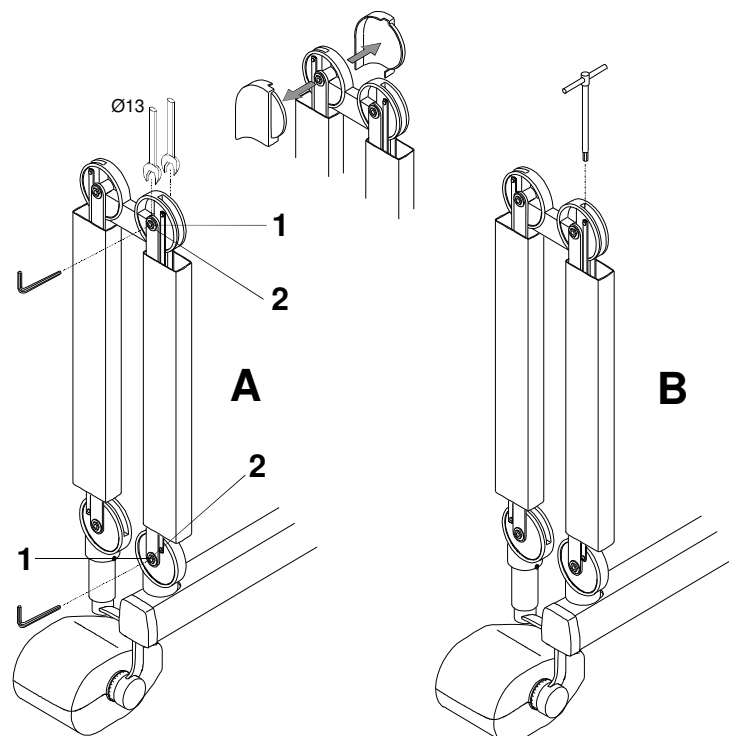


Figure 7-4

8. SET-UP

The Endograph DC system has a modifiable configuration that can be adapted to specific usage needs.

To enter the "set-up" function press the "Increase"  and "Decrease"  keys simultaneously during the software / hardware version display phase; the display will show:

System Setup

PXX: *selected parameter description*
Value = *selected parameter value*

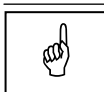
Press "Function"  key to go to the following parameter; touch either the "Increase" or "Decrease" keys to change the displayed parameter value. Press "Function" key and then confirm (Increase key) or cancel (decrease key) the new setting.

Press and hold pressed the "Function" key to exit the setup program, the system will restart.

P00: Stand-by timeout (min)

This parameter indicates the time in minutes after that the system enter in "sleep" condition.

With "Value = 0", the system is always in the "Ready for X-rays" conditions. The selectable value changes between 0 and 5 (default 2).



NOTE:

When Value = 0, the green "Ready for X-rays" LED is always ON.

P01: Duty cycle

This is the value of parameter K (value selectable between 0 and 80) which, multiplied by the current value of exposure time, calculates the value of the cool down time between consecutive exposures.

$$\text{COOL DOWN BETWEEN EXPOSURES} = \text{Exposure time} \times K$$

Default value = 60 (sixty times the exposure time).



WARNING:

This parameter must not be changed from the factory configuration. Changing on this parameter may effect on the equipment life time.

P02: Exposure Counter

This parameter shows the number of the performed exposure. The counter can be reset to zero by pressing the "Size Selection"  and "Tooth automatic selection"  keys together; the operation requires confirmation, by pressing the "Increase"  key.

P03: Film sensitivity

This parameter adapts the exposure times associated to Anatomic and Size selections to the film speed used by the user. The available values are shown in the following table:

Value (multiplies the pre-set exp. time)	Film type
0.75	--
1.00	F
1.25	E
1.50	--
2.00	D

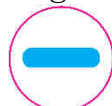
Default value = 1.00 (F)

P04: Long cone (FFD = 30cm)

When you use a 30 cm limiter cone, the exposure times in the preset tables must be multiplied by a 2 factor to get a correct dose. The default value is "OFF", which corresponds to the standard cone (Film Focus Distance = 20cm). The change from standard cone to long cone times is made by selecting "ON". This setting is available also in normal working or out of set-up program modes, and it is available to the user.

P05: Display back light

This parameter makes it possible to vary the display back light, in order to compensate any differences in environmental light. Values are

changed by "Increase"  and "Decrease"  keys.

P06: Dose Correction Factor

This parameter is used only during factory test.



NOTE:
Do not modify factory configuration.

P07: Language

Using "Increase" and "Decrease" keys, select the desired language between: English, Italian, French, Spanish, German, Portuguese, Russian, Dutch, Arabic, Turkish, Chinese (traditional), Chinese (simplified), Symbols only (visualize only the tooth symbol).

P08: Manufacturer's Logo

This parameter allows to visualize / hide Villa logo at system start-up.

Default value = Show Logo.

P09: Disable X-Rays (demo mode)

This parameter make it possible to enable / disable the X-Rays emission.

Default value = X-Rays ENABLED (ON).

P10: Display mode reverse

This parameter allows to change the display between white text on blue background and blue text on white background.

Default value = OFF (white text on blue background).

P11: LCD Contrast Adjustment

This parameter makes it possible to vary the contrast of the display, in order to compensate any differences in environmental light.

Two adjustments are possible:

- Press "Tooth automatic selection"  key for a coarse regulation. Default value = 2
- Press "Increase"  and "Decrease"  keys for a fine regulation. Default value = 24.

P12: Beep on keypress

This parameter makes it possible to enable / disable the acoustic sound on key press.

Default value = ON

P13: Exposure extra time

This parameter is used only during factory test.



NOTE:
Do not modify factory configuration.

P14: Restore Factory Settings

Select value = ON to restore the system configuration and the custom time tables to factory default.

After confirmation, the system will restart with factory settings.



NOTE:
All custom settings will be lost.

The following table displays the values of programmable parameters

Display	Parameters	Set Value	New setting	WARNING
P00	Stand-by timeout	2 min		
P01	Duty cycle	60		(1)
P02	Exposure Counter	////		
P03	Film sensitivity	1.00		
P04	Long cone	OFF		
P05	Display back light	////		
P06	Dose Correction Factor	////		
P07	Language	////		
P08	Manufacturer's Logo	Show logo		
P09	Disable X-Rays	X-ray enabled (ON)		
P10	Display mode reverse	OFF		
P11	LCD Contrast Adjustment	////		
P12	Beep on keypress	ON		
P13	Exposure extra time	0		(1)
P14	Restore Factory Settings	////		



WARNING:

Parameters shown with (1) in the previous table can not be changed; the perfect running of the system or its compliance with Directive CE 93/42 cannot be guaranteed if any change is made.

9. TROUBLESHOOTING



WARNING:

The system must be switched off before performing integrity checks on fuses and components.

System	F1	F3
110 – 240 V wall version	6.3 AT 250 V	-
110 – 240 V stand version	6.3 AT 250 V	6.3 AT 250 V

- **Symptom:**

Display off when main switch is ON

- **Action:**

- check if the LED on the keyboard are ON and pressing the keyboard buttons you can hear any beep.

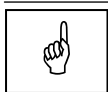
If the keyboard doesn't work, switch OFF the equipment and verify:

- the flat cable connecting the CPU and the Driver board
- integrity of fuses F1 and F3 (if present)
- measure the presence of the main power supply.

If no anomalies are found, start replacing boards in the following order: CPU, Driver board (including tubehead).

9.1 Error messages on the display

As described in chapter 3, the Endograph DC is totally controlled by a microprocessor which, not only checks the programming of exposure parameters but also signals the various machine statuses and any anomalies and errors, by messages in code on the display unit. The following tables contain the various messages which may appear on the display, their meanings, their cause and how to behave.



NOTE:

Error messages belong to three different groups, classified according to the seriousness of the anomalies found and their possible effect on the safety of the operators' and/or the system.

9.1.1 Fatal errors upon power-up and in the ready, idle and cooling statuses

These signals DO NOT allow any examination to be performed.

Displayed message	ANOMALY type	Corrective actions
E01	X-ray button pressed at start-up	Switch the system off and on again; if the message is still present, replace the X-ray button.
E02	A key pressed at start-up (different from X-ray button)	The pressed button is identified by an hexadecimal code according to Table 1 Verify that the relevant button is not really pressed. Switch the system off and on again; if the message is still present, replace the CPU board.
E03	More keys pressed at start-up	The pressed button is identified by an hexadecimal code according to Verify that the relevant button is not really pressed. Switch the system off and on again; if the message is still present, replace the CPU board.
E05	Unwanted X-ray emission	Switch the system off and on again; if the message is still present, replace the tubehead and the Driver board.

The main key codes used to identify the pressed button are listed in the following table:

Code	Description
0001	Function key (F)
0002	Increment key (+)
0004	Tooth key
0008	Decrement (-) key
0010	Size key

Table 1

All other key codes identify a combination of two or more pressed buttons.

9.1.2 Fatal errors during X-ray emission

Possible anomalies during exposure always interrupt the exposure itself. Whether there is an acoustic signal or not depends on the time the fault occurred and on the success of the X-ray interruption procedure.

Displayed message	ANOMALY type	Corrective actions
E04	No emission (breakage in the filament circuit)	Measure the impedance value between "+" and "-" of Driver board - connector X2 (HEATER); this value must be lower than 20 ohm. If the value is greater than 20 ohm, remove the tubehead plastic covers and measure the impedance value between J3.IN+ and J3.IN- of Filament Voltage Regulator board. If the value is still greater than 20 ohm, disconnect the cables J3.Fil+ and J3.Fil- from the Filament terminal strip and measure the impedance value between them. If the measured value is lower than 20 ohm, replace the DP arm, otherwise replace tubehead and Driver board.
E06	Activation of the back-up timer	Check integrity of the flat cable connecting the CPU to the Driver board. Switch the system off and on again; if the message is repeated after an exposure, replace the Driver board and the tubehead.
E07	Protection intervention	Switch the system off and on again; if the message is still present, replace the Driver board and the tubehead.



WARNING:

When an error signal appears and the buzzer sounds, always switch the system off. In any case when the back-up timer is triggered it always interrupts X-ray emission.

9.1.3 NON fatal errors

Situations which do not directly effect the safety of the operator, patient or the system are considered as re-settable anomalies.

The error condition prevents additional exposures until it is reset

by pressing the "Increase"  key.

Displayed message	ANOMALY type	Corrective actions
CH0	Memory checksum error (EEPROM)	If present at the first start-up of the equipment after replacing EEPROM, follow the displayed procedure. On the contrary, if present during normal working, replace the EEPROM, if not enough, replace CPU board.
E11	X-ray button active after the cooling phase	Release the X-ray button and follow the displayed procedure. If the X-ray button is not pressed, switch off the system and replace the button.
E12	Release of X-ray button during emission	Reset the error and repeat exposure. Make sure NOT to release the X-ray button before the buzzer stops. If the message is still present, replace the X-ray button.
E13	Release of X-ray button during pre-heating phase	Reset the error and repeat exposure. Make sure NOT to release the X-ray button before the buzzer stops. If the message is still present, replace the X-ray button.

10. REPLACING PARTS



NOTE:

The Service Engineer has to take special care for all what concerns electrical safety of the device and must make sure of restoring all provisions for electrical safety which may be affected during a service intervention and to solicit the customer to have the electrical safety tests repeated every time the intervention has caused the replacement of important parts or the intervention has significantly affected safety provisions of the device.

10.1 Replacing the tubehead and the Driver board



WARNING:

The tubehead and the Diver board are matched in the factory and therefore **MUST** be replaced as a couple.



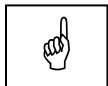
WARNING:

Before proceeding with the replacement of the tubehead, close and tie the two sections of the scissors arm together.
Failure to follow these instruction may harm both the technician and damage the arm itself.



NOTE:

Before carrying out the following operations, disconnect the equipment from the line.



NOTE:

No specific actions are required after replacing the tubehead and the Driver board.

10.1.1 Replacing the tubehead



NOTE:

The spare tubehead is always shipped with a new set of plastic covers and with a new identification plate, giving the new serial numbers of the tubehead itself and of RX tube.

1. Remove the tubehead covers removing the front fixing ring of the extension cone and loosening the two screws (one on each part) located under the lateral triangular labels; gently open the two plastic covers.
2. Disconnect the cables coming from the scissor arm.
3. Holding the tubehead, unscrew the extension cone and remove the four fixing screws fixing the tubehead itself to the support. Remove the tubehead.
4. Take the new tubehead and assemble it on the support.
5. Connect the cables coming from the arm with the corresponding connectors on the tubehead.
6. Assemble the new plastic covers set.

10.1.2 Replacing the Driver board

1. Remove the plastic timer cover loosening the two sealing screws placed on the top part. Pull the cover to release the locking pins. To make the operation easier, disconnect all wires between wall plate and cover. The flat cable connecting the CPU board and the Driver board has to be removed from the connector on the Driver board.
2. Disconnect cables from connectors X2, X4 (including shield W2) and main power supply cable from connector X5 (Figure 6-19).
3. Remove the board and assemble the new one, fixing it.
4. Connect the cables disconnected at step 2.
5. Connect all the connections cables between wall plate and cover; close the timer again.

10.2 Replacing the CPU board



NOTE:

Before carrying out the following operations, disconnect the equipment from the line.

1. Remove the plastic timer cover loosening the two sealing screws placed on the top part. Pull the cover to release the locking pins. To make the operation easier, disconnect all wires between wall plate and cover. The flat cable connecting the CPU board and the Driver board has to be removed from the connector on the CPU board.
2. Remove the failed CPU board and replace it with the new one.



NOTE:

If the system is equipped with the wireless X-ray button, remove from the failed CPU board the A6 Radio board (Figure 6-17) complete of cable X7 and exagonal spacer support and assemble it on the new CPU board as described in paragraph 6.4.3.2, steps 3 and following.

3. Connect all the connections cables between wall plate and cover; close the timer again.
4. Switch the system on and enter the setup procedure (chapter 8). Check all configuration parameters.



NOTE:

It is possible to save the stored customized table, removing the EEPROM from the old CPU to the new one.

10.3 Replacing the keypad

Replacing the keypad consists in replacing the adhesive membrane: remove the timer covering panel, remove the old membrane carefully and clean the surface where the membrane was attached.



NOTE:
Do not use solvent, but only alcohol.

Attach the new membrane.

10.4 Replacing the scissors arm

10.4.1 Replacing the scissors arm with wall timer (standard configuration)



WARNING:

Before to remove the tubehead, close and tie the two sections of the scissors arm together.
Failure to follow these instruction may harm both the technician and damage the arm itself.



NOTE:

Before carrying out the following operations, disconnect the equipment from the line.

1. Remove the tubehead as described in paragraph 10.1.1, steps from 1 to 3.
2. Remove the plastic timer cover loosening the two sealing screws placed on the top part. Pull the cover to release the locking pins. To make the operation easier, disconnect all wires between wall plate and cover.
3. Remove the front covers of the extension arm.
4. Disconnect cables from connectors X2 and X4 (including shield W2) (Figure 6-19). Remove the cables from the extension arm completely.
5. Remove the friction group on the extension arm as described in paragraph 6.3.2, steps 1 and 2; remove the arm.
6. Assemble the new arm as described in paragraph 6.3.2, steps 3 and following.
7. Connect the cables as described in paragraph 6.5.1.
8. Reassemble the tubehead as described in paragraph 10.1.1, steps from 4 to 6.

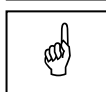
10.4.2 Replacing the scissor arm on mobile stand



WARNING:

Before to remove the tubehead, close and tie the two sections of the scissors arm together.

Failure to follow these instruction may harm both the technician and damage the arm itself.



NOTE:

Before carrying out the following operations, disconnect the equipment from the line.

1. Remove the tubehead as described in paragraph 10.1.1, steps from 1 to 3.
2. Remove the plastic timer cover loosening the two sealing screws placed on the top part. Pull the cover to release the locking pins. To make the operation easier, disconnect all wires between wall plate and cover.
3. Disconnect cables from connectors X2 and X4 (including shield W2). Disconnect the main power supply cable from the main power supply terminal strip (Figure 6-19).
4. Remove the timer from the support plate.
5. Remove the scissor arm.
6. Assemble the new arm as described in paragraph 6.3.3.
7. Fix the support plate and the timer as described in paragraph 6.2, steps 5 and following.
8. Connect the cables as described in paragraph 6.5.1.
9. Reassemble the tubehead as described in paragraph 10.1.1, steps from 4 to 6.

11. 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 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 centered
- check proper functioning of X-ray exposure LED and exposure buzzer
- check the plates are intact and well attached.

The Service Engineer, during preventive maintenance, besides the checks listed above, will verify also:

- correct adjustment of the rotation friction mechanism of the extension arm and of the scissors arm
- correct balancing of scissors arm, making proper adjustment when necessary.



NOTE:

The Service Engineer has to take special care for all what concerns electrical safety of the device and must make sure of restoring all provisions for electrical safety which may be affected during a service intervention and to solicit the customer to have the electrical safety tests repeated every time the intervention has caused the replacement of important parts or the intervention has significantly affected safety provisions of the device.



NOTE:

Interventions carried out by the Service Engineer must be noted in the Maintenance Record page at the end of the User Manual, with a short description of the actions done

12. SCHEMATICS AND DRAWINGS

1. ENDOGRAPH DC – General connection diagram

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13. SPARE PARTS

1 – TIMER: ENDOGRAPH DC

2 – EXTENSION ARM / SCISSOR ARM

3 – MOBILE STAND

4 – TUBEHEAD

5 – OPTION

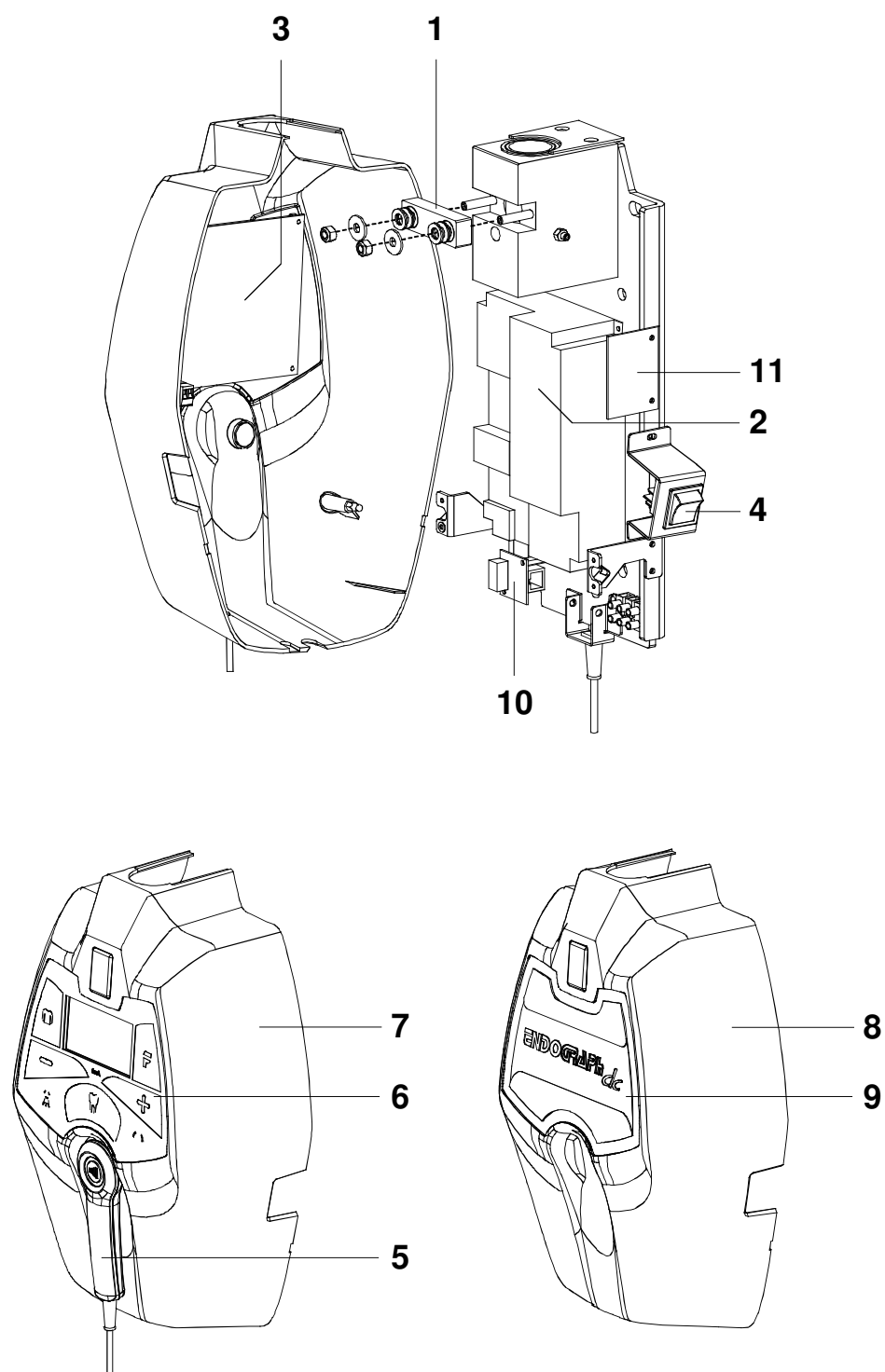
1 – TIMER: ENDOGRAPH DC



WARNING:

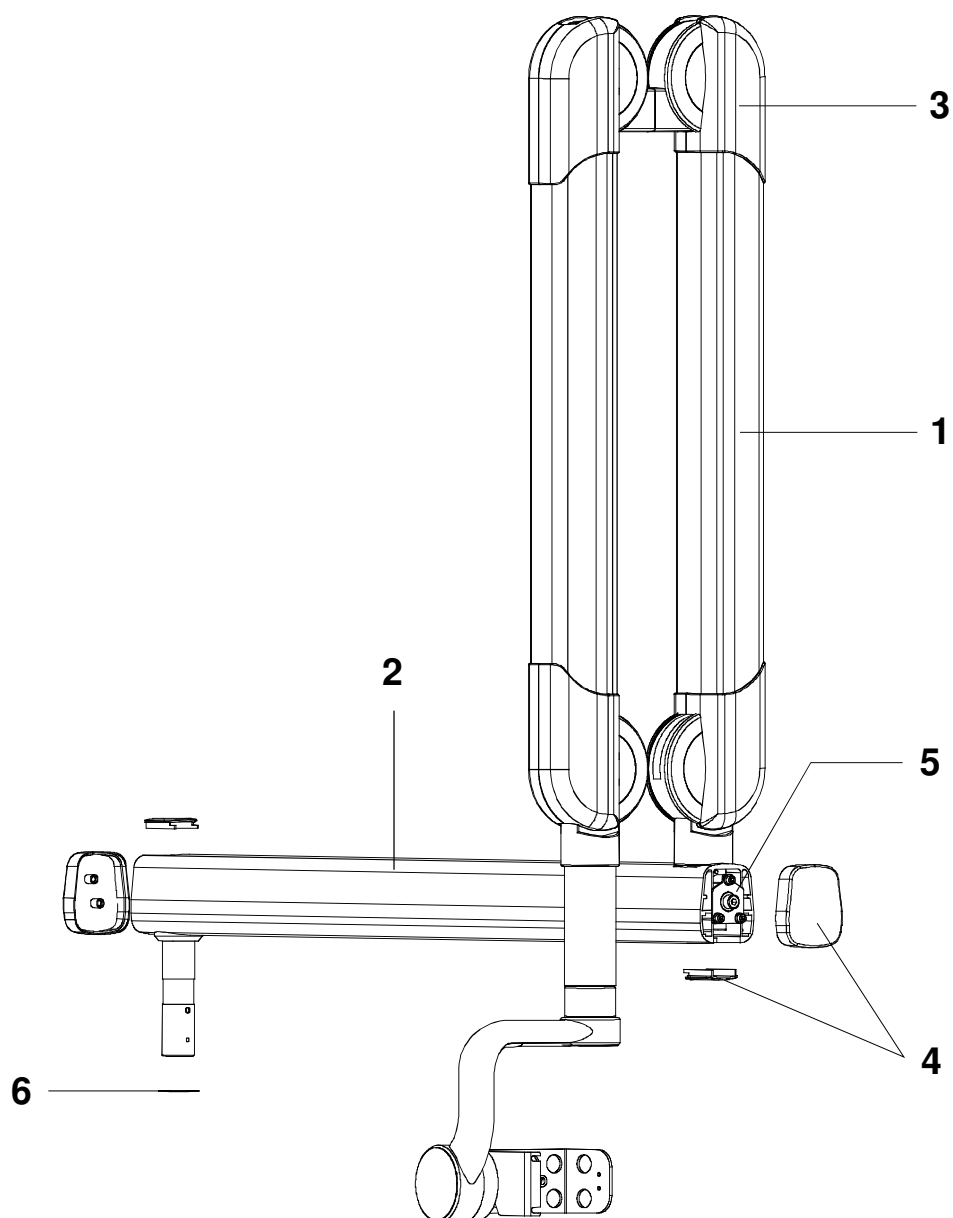
The Driver board and the tubehead are matched in the factory and therefore **MUST** be replaced as a couple.

Ref.	VSM code	Description	Note
1	6159300100	Frictioning mechanism assy	
2	6659400000	A2 Driver board and Tubehead assembly	
3	5859301000	A2 CPU board	
	4695463800	A6 Radio board	Present only with wireless X-ray button
--	6259300300	Flat cable CPU-Driver board	
4	4291420900	ON/OFF switch	
5	6659300500	X-ray push button	
	6659300600	Wireless X-ray push button	
6	5459301200	Timer keypad	
7	6659300200	Timer front cover complete of keypad	
8	5459301600	Remote timer keypad	
9	6659300400	Remote timer front cover complete of keypad	
10	5859301400	A8 / A9 Remote Interconnection control board	Present only with Remote Timer version
11	5859301200	A5 External signal board	Optional
F1	2300997200	Fuse 6.3 A T 6.3x32 250V	Mounted on Power PCB
F3	2300997200	Fuse 6.3 A T 6.3x32 250V	For mobile version
-	4560311800	Fuse holder	For mobile version
	4560311900	Cap for fuse holder	



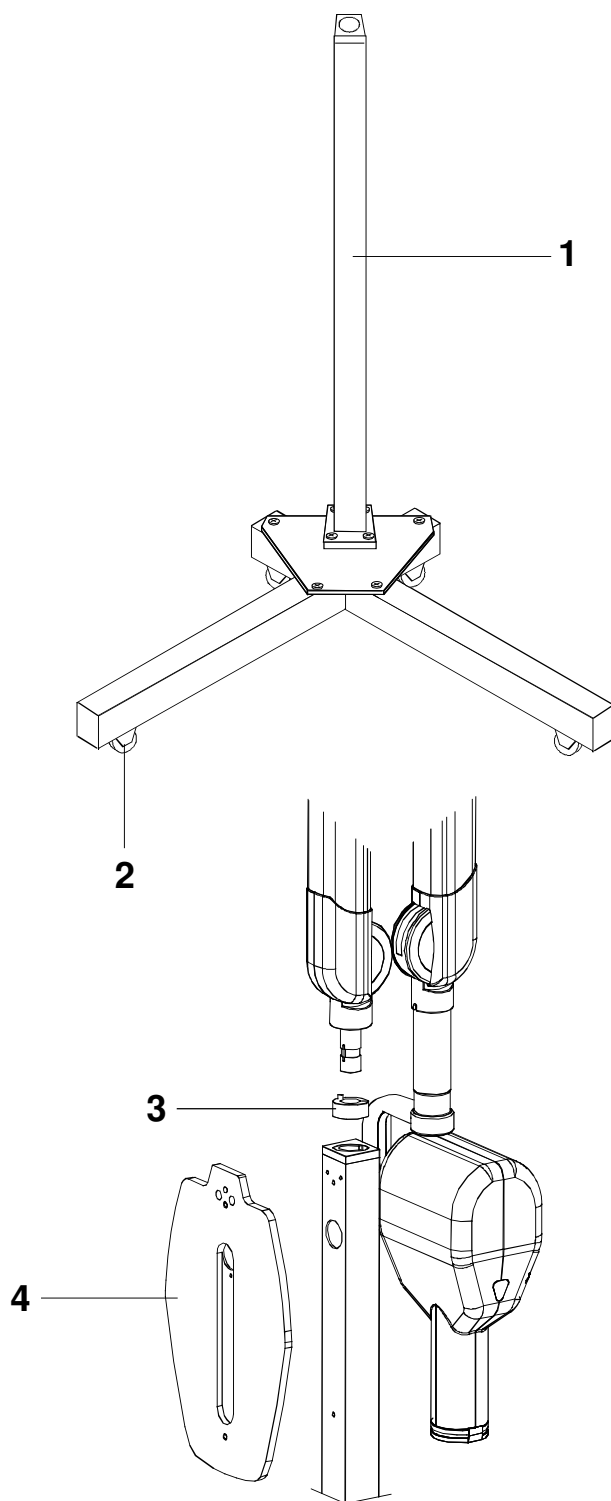
2 – EXTENSION ARM / SCISSOR ARM

Ref.	VSM code	Description	Note
1	8159200000	Scissor arm complete of tubehead support	
2	8161200302	Extension arm 30 cm	
	8161200502	Extension arm 60 cm	
	8161200402	Extension arm 80 cm	
3	6661210013	Scissor arm joint covers kit (DX + SX)	
4	6659210013	Extension arm end-covers kit	
5	6659210100	Extension arm frictioning mechanism	
6	5160249500	Busher Ø 28 mm	



3 – MOBILE STAND

Ref.	VSM code	Description	Note
1	8160120000	Mobile stand complete	
2	4890310400	Wheel with brake 80x24	
	4890307000	Wheel 80x24	
3	6661305600	Mobile stand spacer	
4	5259300105	Timer fixing plate	



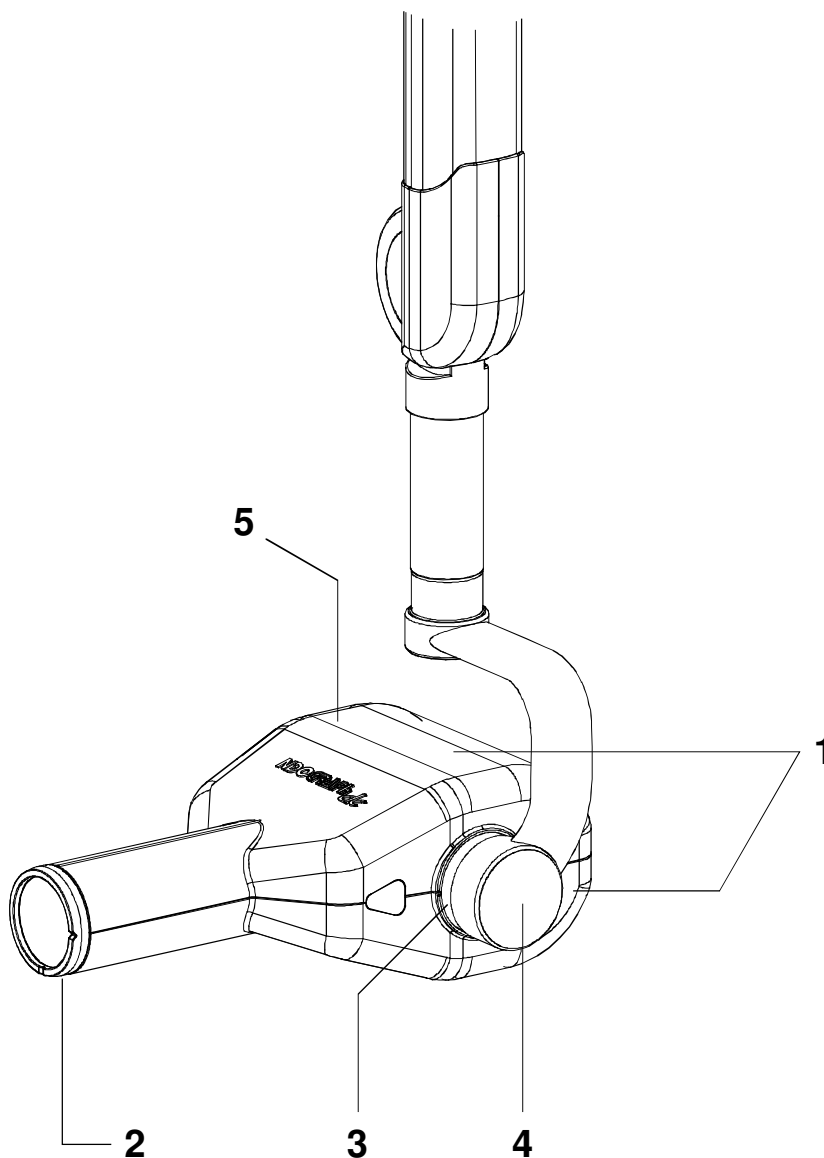
4 – TUBEHEAD



WARNING:

The tubehead and the Diver board are matched in the factory and therefore **MUST** be replaced as a couple.

Ref.	VSM code	Description	Note
1	6659400105	Tubehead covers kit (without plate)	
2	5460461813	Front fixing ring	
3	5160423813	Angle indicator	
4	5460420813	Tubehead lateral cover	
5	6659400000	Tubehead complete assembly including Driver board	



5 – OPTION

Ref.	VSM code	Description	Note
1	6659300100	Remote Timer kit	
2	6659120000	Remote X-ray button support	
3	7659303000	Wireless upgrade kit for wired X-ray button.	
4	7659303100	External lamp connection kit	
5	6159400000	Extension cone for 30cm Source to Image Distance	
6	6159410000	Rectangular beam limiting device 45x35mm	
7	6159410100	Rectangular beam limiting device 25x35mm	
8	6159410200	Rectangular beam limiting device 20x30mm	
9	6659200100	Allen wrenches kit	

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14. FIXING TEMPLATES

The system is equipped with a set of templates, composed of the following elements:

Code	Description
39599100	Template for standard version
39599101	Template for remote version

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Cod. 6959900703_Rev.1



VILLA SISTEMI MEDICALI S.p.A.
Via Delle Azalee, 3
20090 Buccinasco (MI) – ITALY
Tel. (+39) 02 48859.1
Fax (+39) 02 4881844