Dental Line

CE
0051

VILLA

rotograph prime

Service manual

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VILLA

radiology ahead

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Rev.	Date	Page/s	Modification description
P	03.11.15	-	Document preliminary version approval
0	02.12.16		Document update for new cables layout

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Contents

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1. INTRODUCTION

Note
The present 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.

Rotograph Prime, produced by VILLA SISTEMI MEDICALI S.p.A., is an X-ray device for the radiographic analysis of the maxillo-facial complex.
The basic version of the Rotograph Prime performs Panoramic, Sinus and TMJ examinations of the maxillo-facial complex.
The following options are available and must be ordered separately:

- Extended Projection Package; it allow the execution of the following examinations: Emi-panoramic, Reduced dose Panoramic, Frontal dentition, Improved orthogonality Panoramic

Rotograph Prime is intended exclusively for extra-oral X-rays.

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

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

Please read this manual thoroughly before starting to use the unit; it is advisable to keep the manual near the device, for reference while operating.

The user is liable as concerns legal fulfilment related to the installation and the operation of the device.

1.1. Icons appearing in the manual

This icon indicates a "NOTE": please read the items marked by this icon thoroughly.

This icon indicates a "WARNING": the items marked by this icon refer to the safety aspects of the patient and/or the operator.

2. SPECIFICATION OF THE INTENDED USE

2.1. Application and medical purpose

Rotograph Prime is dental extra-oral panoramic X-ray equipment for radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures.

The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals. It can be used with both paediatric and adult patients.

Caution:
Federal law restricts this device to sale by or on the order of a dentist, a radiologist or another legally qualified health care professional.

2.1.1. Intended patient population

Rotograph Prime system can be used with the following typology of patient:

- *Age:* paediatric to geriatric
- *Patient status:*
  - self-sufficient patient (patient can autonomously place himself as requested by the physician)
  - non self-sufficient patient (patient is properly helped to take the exam by medical personnel).
  - In any case the patient must be conscious, not anaesthetized and not incapacitated
- *Nationality:* multiple.

2.1.2. Operator profile

This system may only be operated by persons who have the necessary expertise in radiation protection or knowledge of radiation protection and who have been instructed in the operation of the X-ray equipment.

2.1.3. Application environments

The application environments of the Rotograph Prime are hospitals, private clinics or consultants, other radiology facilities and also residential environment.

Note
In the radiological room, direct audio and visual communication between operator and patient shall be always possible. Otherwise, provide proper support (i.e. lead glass or similar, interphone, etc.).

2.2. Applied parts

During normal use, Rotograph Prime comes in contact with the patient through the handle the chinrest and bite and the temple clamp, classified as Type B applied part.

2.3. Typical doses delivered to the patient during extraoral examinations

The air kerma at the entrance of the x-ray image receptor for the PANORAMIC EXAM is:

mA	2	2.2	2.5	2.8	3.2	3.6	4	4.5	5	5.6	6.3	7.1
kV	Air Kerma [mGy]											
60	2.5	2.8	3.2	3.6	4.1	4.6	5.1	5.7	6.3	7.1	8.0	9.0
62	2.6	2.9	3.3	3.7	4.2	4.8	5.3	6.0	6.6	7.4	8.3	9.4
64	2.9	3.2	3.6	4.0	4.6	5.2	5.7	6.5	7.2	8.0	9.0	10.2
66	3.1	3.4	3.9	4.3	4.9	5.6	6.2	6.9	7.7	8.6	9.7	11.0
68	3.3	3.6	4.1	4.6	5.2	5.9	6.5	7.3	8.1	9.1	10.2	11.5
70	3.5	3.9	4.4	4.9	5.6	6.4	7.1	7.9	8.8	9.9	11.1	12.5

The air kerma for the other exams available on the machine can be calculated using the ratios in the table below:

The Dose per area products delivered by Rotograph Prime to the patient during extraoral examinations are given in the graphical user interface.
The dosimetric indications can be checked by authorised personnel using the instruction reported in paragraph. In case of a discrepancy contact an authorised technician.

Exam	Ratio
Emipanoramic	0.55
Low Dose	0.85
Improved Dentition	0.9
Frontal dentition	0.33
Bitewing L or R	0.24
Bitewing L and R	0.47
TMJ	0.71
Sinus	0.65

Note
The dosimetric indications result from the average of dose measures on a lot of x-rays source assemblies.

The dose is taken at a certain distance from the focal spot of the x-ray source and then reported to the imaging plane.
To get the DAP value, the dose on the imaging plane is multiplied by the x-ray field area measured on the imaging sensor that is 50cm far away from focal spot (the typical size of x-ray beam on the imaging sensor is 140mm x 4.5mm).
The distance between the focal spot and the patient skin is variable during the exam and on average we can assume the mean distance between the focal spot and the patient skin as 264mm.
The overall uncertainty of the indicated value of the air kerma and dose per area product is 50%.

Note
As started in IEC 60601-2-63 standard – no deterministic effects are known with dental extra oral x-ray equipment.

2.4. Description of the system

The evolution of panoramic X-ray provides, in addition to traditional methods of examination (Panoramic, TMJ, Sinus, etc.). the use of three-dimensional images of the patient's maxillofacial complex, so as to allow the doctor the targeted selection of the procedures to use, both during the planning phase of the treatment as well as diagnosis aid.

Rotograph Prime, produced by VILLA SISTEMI MEDICALI S.p.A., is a complete panoramic system that allows the execution of all X-rays commonly used in dentistry and orthodontics (excluding intraoral radiographs).

In this type of device, the linear digital sensor traditionally used in the digital panoramic X-rays has been replaced by a wide range Digital Sensor, also known as the Flat Panel. These sensors allow to capture an area of the maxillofacial complex that include the most important anatomical details, by acquiring a series of two-dimensional images (imaging).

The following options are available that must be ordered separately:

- EVO XP (Additional projection package); allows to perform the following examinations: Emi-panoramic, Improved orthogonality dentition, reduced dose Panoramic, Frontal dentition and Bitewing.

2.5. 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

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3. SAFETY INFORMATION

Warning
Please read this chapter thoroughly.

VILLA SISTEMI MEDICALI designs and builds its 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.

Villa Sistemi Medicali cannot be held responsible for:
• The use of Rotograph Prime different from the intended use
• Damage to the unit, the operator or the patient, caused both by installation and maintenance
procedures different from those described in this Manual and in the Service Manual 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.

Installation and any technical intervention must only be performed by qualified technicians authorised by Villa Sistemi Medicali.

Only authorised personnel can remove the covers and/or have access to the components under tension.

Warning
No modification of this equipment is allowed.

3.1. 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.
Rotograph Prime 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 fulfillment of the legal requirements regulating the ownership, installation and use of the equipment itself.
This device has not been designed to be used in environments where vapours, anaesthetic mixtures flammable with air, or oxygen and nitrous oxide, can be detected.
Do not let water, or other liquids, into the device, as this could cause short-circuits and corrosion.
Before cleaning the device, be sure that the main power supply has been disconnected from the equipment. Pushing the ON/OFF button of the equipment, it mustn't switch on.
Wherever necessary, use the appropriate accessories, such as the leaded aprons, to protect the patient from radiation.
While performing the radiography, no-one, apart from the operator and the patient, must remain in the room.
Rotograph Prime has been built to support a continuous operation at intermittent load; therefore please follow the described use cycles to enable the device to cool down.
Rotograph Prime must be switched off while using electrosurgical devices or similar apparatus.

Warning
For safety reasons, it is prohibited to abnormally overload the patient support arm, for example by leaning on it. The traction force on the handle shall be less than 16kg.

Warning
To avoid risk of electric shock, , this equipment must only be connected to a supply mains with protective earth.

Please clean and disinfect, when necessary, all parts that can be in contact with the patient.
The centering bite or the bite protective sleeve must be replaced after each examination in which they were used.
Never try to rotate the moving arm manually when the unit is switched on, to avoid permanent damage to the unit.
Movement is only possible in case of Error 362 because motors are disabled to permit the patient exit.

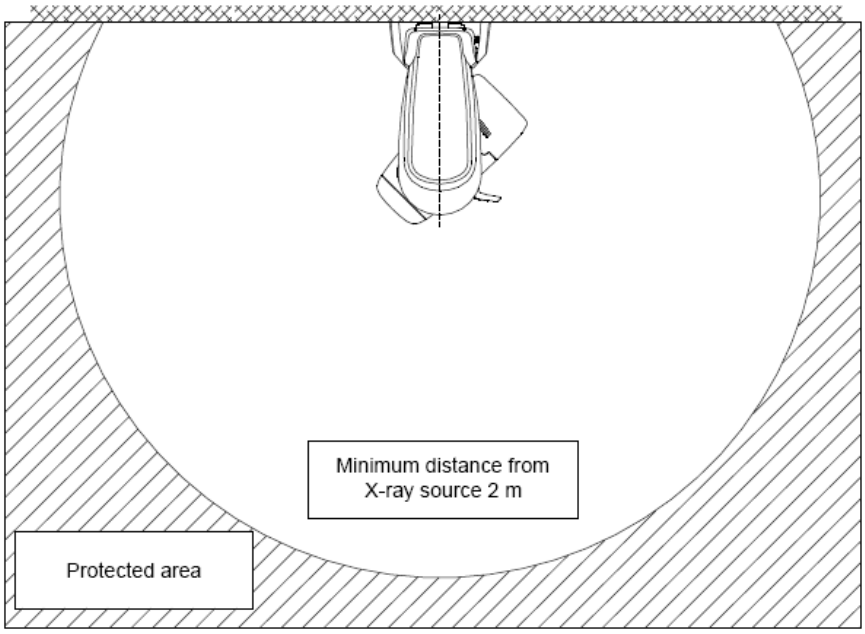
Note
When the unit is switched on, do not move the rotating arm or the tube-head).

3.2. Protection against radiation

Although the dose supplied by dental X-ray units is quite low and distributed on a fairly small surface, the operator must adopt the precautions and/or suitable protection for the patient and himself, during the execution of radiography.

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

It is advisable to control the X-ray emission from a protected area, by means of a remote control. If it is necessary to operate near the patient, stay as far as the remote control cable allows, or at least 2m both from the X-ray source and from the patient, as shown in the following figure.



Warning
Precautions while using laser centring devices

- Always keep the room well lit.
- Do not look into the output windows of laser centring units.
- Do not stare at the reflections of laser pointers.
- Instruct the patient to keep his/her eyes closed as long as the laser pointers are active.
- Before starting an examination, the patient must remove earrings, glasses, necklaces and whatever else could reflect the laser beam or be impressed on the radiographic image.
- Do not clean the openings of laser centring devices with tools that could modify the optics. Any cleaning must be performed only by authorized technicians.
- Operations other than those indicated could cause the ejection of dangerous non-ionizing radiation.

3.2.1 Electromagnetic emissions

In accordance with the IEC 60601-1-2 standard, the Rotograph Prime is suitable for use in the specified electromagnetic environment. The purchaser or user of the system should assure that it is used in an electromagnetic environment as described below.

Emissions test	Compliance	Electromagnetic environment
Radiated and conducted RF emissions CISPR 11	Group I	Rotograph Prime uses RF energy only for its internal function. Therefore, the R.F. emissions is very low and not likely to cause any interference in nearby electronic equipment.
	Class A	Rotograph Prime is suitable for use in all establishments other than domestic and those directly connected to the low voltage power supply network which supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

3.2.2. Electromagnetic immunity

In accordance with the IEC 60601-1-2 standard, the Rotograph Prime is suitable for use in the specified electromagnetic environment. The purchaser or user of the system should assure that it is used in an electromagnetic environment as described below.

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst 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	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV lines to lines ± 2 kV lines to earth	± 1 kV lines to lines ± 2 kV lines to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % Un for 0.5 cycles 40 % Un for 5 cycles 70 % Un for 25 cycles 0 % Un for 5 s	0 % Un for 0.5 cycles 40 % Un for 5 cycles 70 % Un for 25 cycles 0 % Un for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Rotograph Prime requires continued operation during power mains interruptions, it is recommended that the Rotograph Prime be powered from an uninterruptible power supply or battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U_n is the AC mains voltage prior to application of the test level.			

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment
			Portable and mobile RF communications equipment should be used no closer to any part of the Rotograph Prime, 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 80 MHz to 2.5 GHz	3 V/m	d = 1.2 x P 80 MHz to 800 MHz d = 2.3 x P 800 MHz to 2.5 GHz
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz	3 V	d = 1.2 x P
			where "P" is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). Field strength for fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

3.2.1. Recommended separation distances for non-life supporting equipment

Rotograph Prime is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the Rotograph Prime system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitter) and the Rotograph Prime as recommended below, according to the maximum output power of the communications equipment.

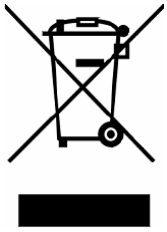
Rated maximum output power of the transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz d = 1.2 x P	80MHz to 800MHz d = 1.2 x P	800MHz to 2.5GHz d = 2.3 x P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at the maximum output power not listed above, the recommended separation distance "d" in meters (m), can be estimated the equation applicable to the frequency of the transmitter, where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. these guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.			

3.3. Environmental risks and displacement

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

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

Note
Information for users of the European Community according to 2012/19/EU Directive on waste electrical and electronic equipment (WEEE)



The symbol of the crossed waste container on the equipment or on the packaging, shows that the product, at the end of its lifecycle, must be collected separately from other type of waste.
The separate collection of this equipment at the end of its lifecycle is organised and managed by the manufacturer. Users who need to dispose of this equipment, should therefore contact the manufacturer and follow the procedure adopted by the manufacturer themselves for the separate collection of the equipment at the end of its lifecycle.
The proper separate collection for the subsequent recycling, treatment and compatible environmental disposal of the equipment, contributes to avoid possible negative effects on the environment and on health and it encourages the reuse or recycling of materials the equipment consists of.
Illegal disposal of the product by the possessor of the equipment, results in the application of administrative sanctions provided by the regulations in force.

3.4. Symbols used

In this manual and on the Rotograph Prime itself, apart from the symbols indicated on the control panel, the following icons are also used:

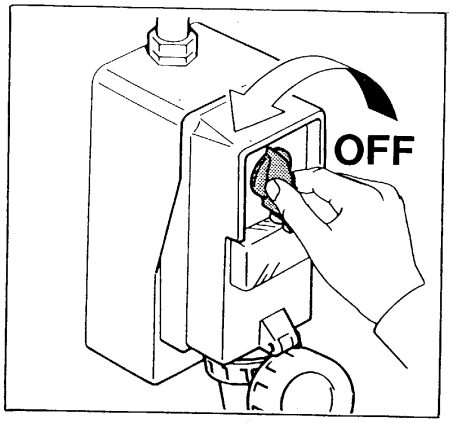
Symbols	Description
	Device with type B applied parts
	The device contains in some of its parts, materials and liquids that at the end of the unit's life, must be disposed of at the appropriate disposal centres
~	A.C.
N	Connection point to the neutral conductor
L	Connection point to the line conductor
	Protection grounding
	Operation grounding
	OFF ; device not connected to the mains
	ON ; device connected to the mains
	Laser
	Laser source output
	Dangerous voltage
REF	Product identification code
SN	Serial number
	Date of manufacturer (year and month)
	Name and address of the manufacturer
	Filtration
	Tube head
	X-Ray tube

Symbols	Description
	Focal spot according to IEC 60336
	Follow instructions for use
CE 0051	Conformity to the 93/42/EEC Directive and its revised version and all other applicable Directives
	exposure enabled status (the corresponding green led is on)
	X-Ray Emission (the corresponding yellow led is on)

4. CLEANING AND DISINFECTION

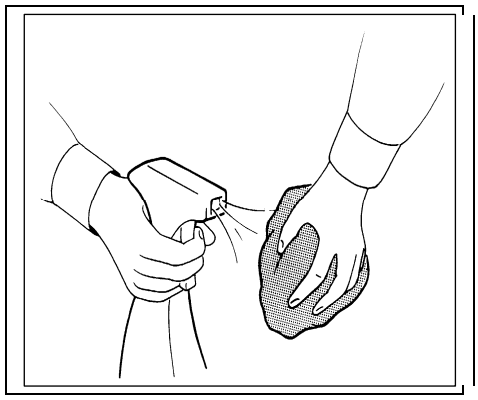
In order to guarantee a good level of hygiene and cleaning, it is necessary to respect the following procedures.

WARNING:
Disconnect the unit from the mains before performing any cleaning.



Do not let water or other liquids enter the unit, as these could cause corrosion or short-circuiting.

Use only a wet cloth and a mild detergent to clean the painted surfaces, the accessories and the connection cables, and then wipe with a dry cloth; do not use corrosive, abrasive solvents (alcohol, benzine, trichloro-ethylene).



The centring bite or the bite protective sleeve must be replaced after each examination in which they have been used.

Thoroughly clean the chin support, resting handles and temple clamps group any time these are used.

The chin support, resting handles and temple clamps group should be disinfected (when considered necessary) with a solution of 2% glutaraldehyde.

NOTE to assure an higher level of hygene the handles of the machine are covered with a special antibacterial paint that thanks to the emission of silver ions prevent the deveolpment of microorganisms.

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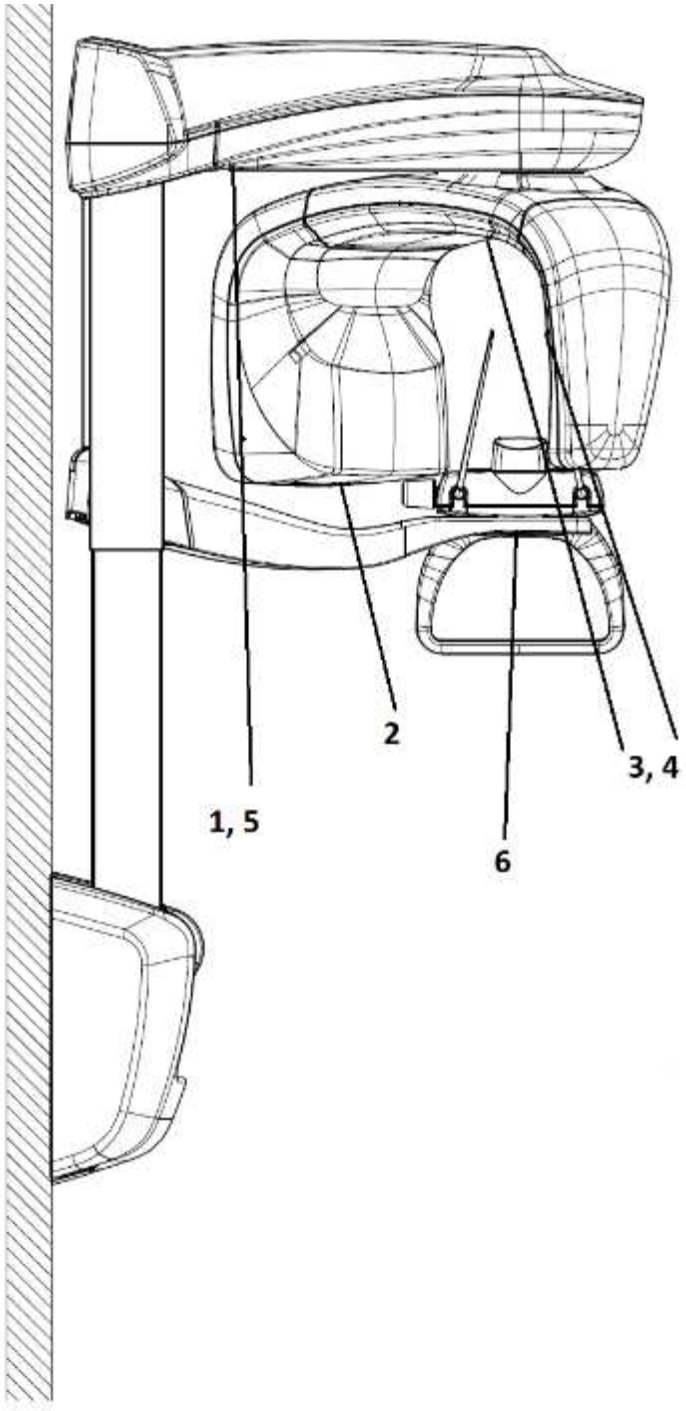
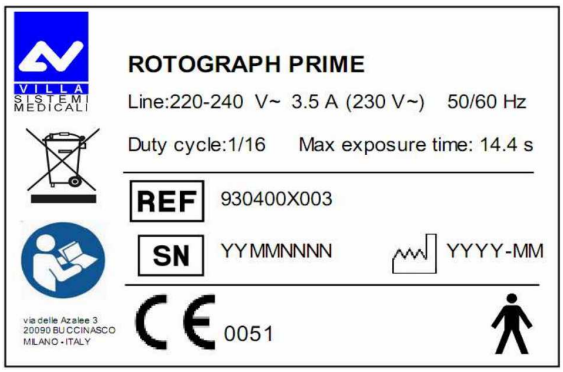
5. DESCRIPTION

5.1. Identification labels and laser labels

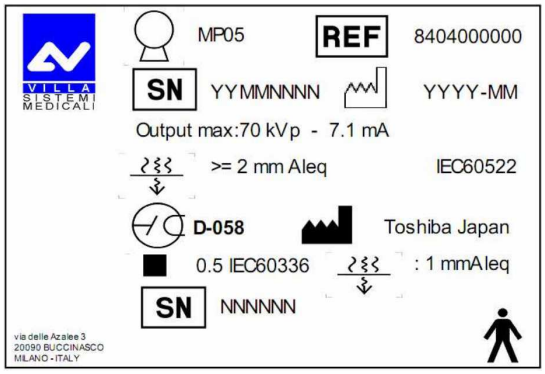


5.1.1. Identification plates and laser labels "220-240V" version

1
Rotograph Prime
identification label



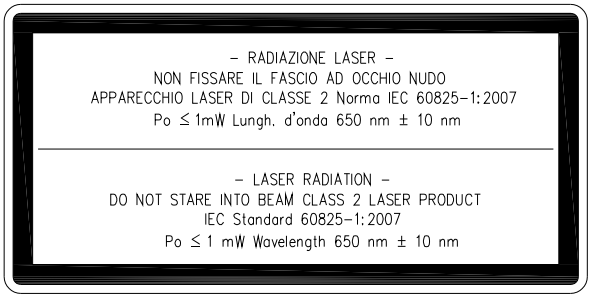
2
Tube-head
identification label



3
(N° 2) Spot Laser
identification label

4
(N° 2) Laser
symbol label

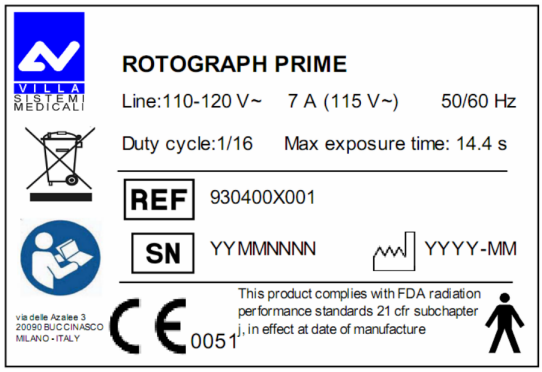
5
Laser WARNING label



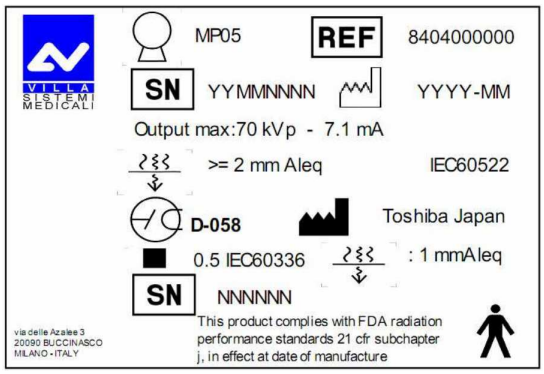
6
XP – Extended Projection Package
identification label

5.1.2. Identification plates and laser labels "110-120V" version

1
Rotograph Prime
identification label



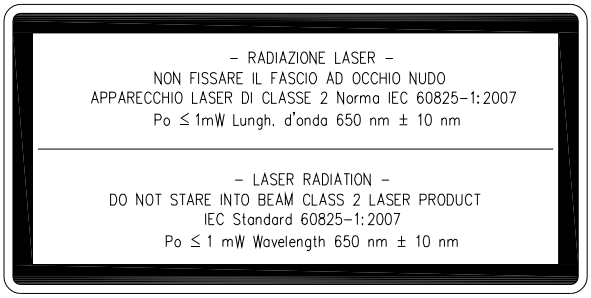
2
Tube-head
identification label



3
(N° 2) Spot Laser
identification label

4
(N° 2) Laser
symbol label

5
Laser WARNING label



6
XP – Extended Projection Package
identification label

5.2. Functions, models and versions

Rotograph Prime, produced by VILLA SISTEMI MEDICALI S.p.A., is a complete panoramic system, which enables to perform all X-rays commonly necessary in dental field (except for endoral x-rays).
In some versions, certain examination modes are not available but the device (thanks to its computerised control system) can be expanded and updated with new releases, directly at the Dentist premises.

The basic version performs Panoramic, Sinus, and TMJ examinations.
Optional functions enable the system to perform the following additional examinations:

- **XP (Extended Projection Package)**
  Allows you to carry out the following additional examinations:
  Emi-panoramic, Reduced dose Panoramic, Frontal dentition, Improved orthogonality Panoramic and bitewing

5.2.1. Basic version

The basic version enables to perform the following examinations:

- Panoramic Adult or Child, with 3 Sizes and 3 Types of biting for a total of 18 combinations in Automatic selection; in manual selection it is possible to select high voltage between 60kV and 70kV, in 2kV steps and anodic current from 2 mA to 7.1 mA in R20 scale steps.
- Sinus enables to perform images of the paranasal sinuses with front projection (postero/anterior).
- TMJ mouth closed/open in lateral projection.

5.2.2. XP function (Extended Projection Package) - Optional

The unit is prearranged to be fitted with the XP (Extended Projection Package) function, which enables to perform the following examinations:

- The right or left Emi-panoramic is used when the patient is known to have a problem only on one side of the arch, in order to reduce the radiation.
- The reduced dose Panoramic reduces the dose radiated on the dentition by excluding the TMJ's ascending rami from the exams.
- The frontal dentition enables to perform examinations of the front part (roughly from canine to canine).
- The Panoramic with improved orthogonality reduces the overlap of the teeth, thereby improving the diagnosis of interproximal decay.
- Bitewing left or right, allows the execution of examination of the lateral dentition (generally from eighth to fourth) with a trajectory that reduces the overlap of the teeth
- Bitewing (left and right) sequentially performs both bitewings, showing them on the same image.

Note
All these examinations can be added to Rotograph Prime systems already installed on filed.

Note
The code inserted into Rotograph Prime to enable the optional examinations is protected by a unique Identification Code (UIC); in the event the UIC is not present or is faulty, an error E107 will be shown. The UIC is simply an identifier if the single Rotograph Prime unit; in order to enable the optional functions it is necessary to request the activations code from Villa Sistemi Medicali, which derives from the Unique Identification Code or from the device serial number.

5.3. Block diagram / Functional description

This paragraph provides a brief description, at block diagram level, of the Rotograph Prime. Aim of this paragraph is to provide a brief description of the system. More details about the electronic circuits which compose the system can be obtained by analyzing the schematics provided in Chapter 14.

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CPU board A1 is the main board that manages directly all the components of the unit.

It is directly connected to the following components :

- Power supply assembly (G1)
- Motors (rotation and Y axes)
- Zero position sensors
- X-ray button
- External signal board (A6)
- Lift motors control rack (G2)
- Generator board (A2) -> (Tubehead),
- Overlay
  -----> (Digital sensor)
- DSPU board (A14) -------|
  -----> (PC)

CPU board, DSPU board and HF board are equipped with a local microcontroller that shares information using a CANBUS transmission line and protocol.

5.3.1. Power supply circuit

It is positioned in the top part of the unit and it is mainly composed by mains switch (S1), line filter (Z1) and a 24Vdc 8,4A switching mode power supply (located under the CPU board) G1 which supply 24 Vdc to the CPU board, that generates the different voltages to the unit.

- Main power supply drives also the up/down motors (M1 and M2) through the motor column driver board (G2) located in the lower part of the unit. Safety switch S2 located in the top side of the unit (red button). In case switch is pressed, the up/down movement is inhibited.
- Main power supply is also provided to the Generator Board A2 used to generate High voltage to the tube head.

The unit does not include a voltage selector circuit for the mains voltage. Therefore, the unit is manufactured in different versions, depending on the line voltage of the installation place.

5.3.2. CPU Board (A1)

It is located on top of the unit.
Main tasks are:

- General controlling of the unit, receiving the signals from the keyboard and from the different optical sensors.
- Driving of the 2 stepper motors which compose the system.
- Managing the signal of position for the lift motors through the Linak motor driver board
- Monitoring the functioning of the motors through the analysis of the signals (zero position) coming from the zero position light sensors.
- Driving of the HF group (Generator board and tubehead) in order to provide the X-ray doses set by the operator on the PC (kV and mA set point) and in the meantime, check the functioning of this group through the managing of the relevant alarm signals.
- Driving of the x-ray button signal and the digital sensor board used to synchronize sensor acquisition with x-ray emission
- Activation of the 2 luminous centering devices.
- Managing of the alarms that can be generated by anomalous conditions present in the unit and caused by the operator or by a fault. These signals are sensed by the local CPUs and signalled using specific CANBus messages.

CPU includes also the configuration and calibration data and the HW key including the data of XP exams.

Adapter board includes the programming data

Serial number board includes the XP data

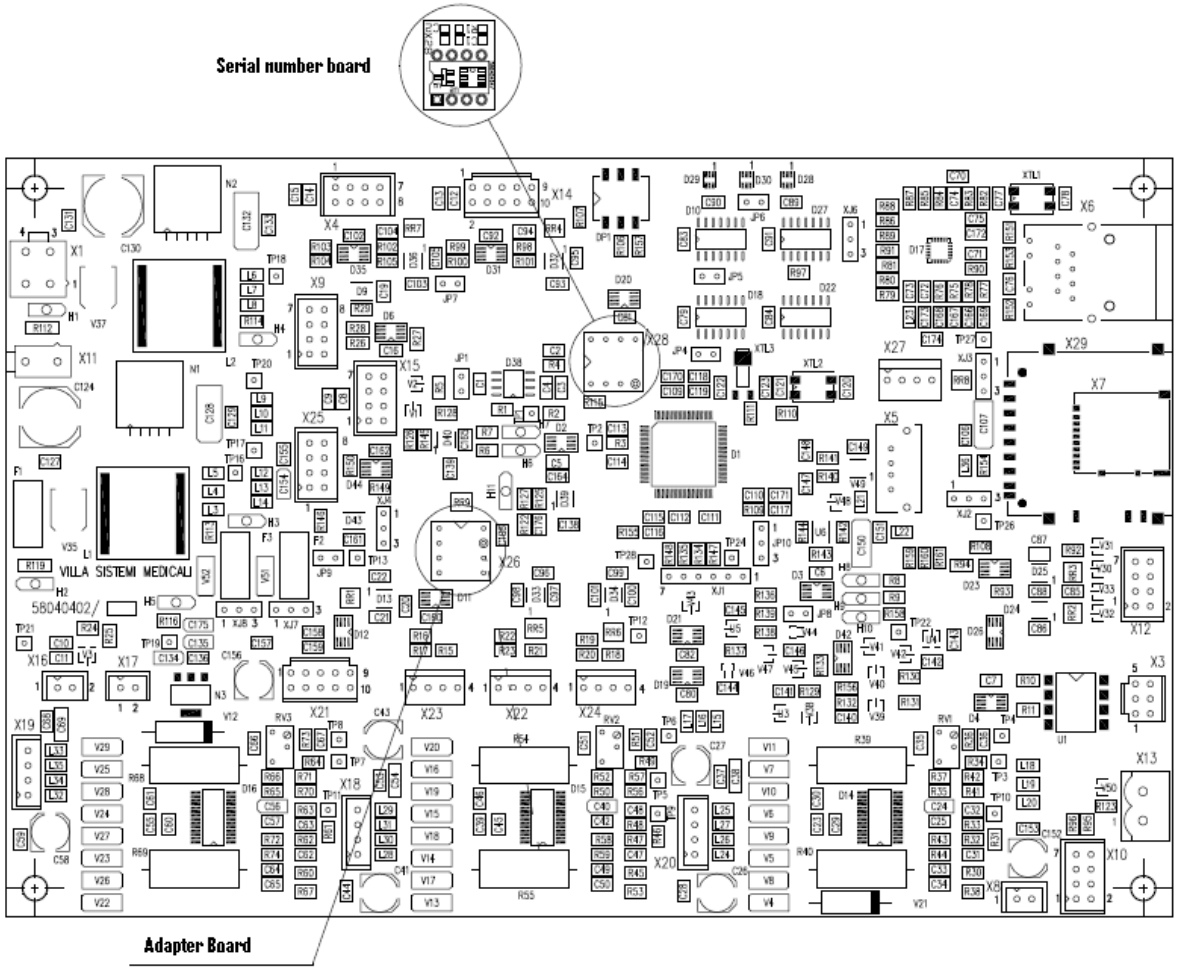

Figura 5-1

5.3.3. Generator Board (A2) and Tubehead

The Generator board and the tubehead are located on the rotating arm, very close to each other. The power supply voltage is directly provided by the mains line.

Generator board includes an integrated CPU that communicate with the main CPU through CAN BUS.cable (X15-X32). This cable also has a dedicated wire to bring the X-ray button signal to this board, so the "dead man switch" method is generated directly on the board.

The high frequency (HF) circuit is based on an inverter circuit working at the frequency about 100kHz, which drives the tubehead through an output stage based on IGBT components.

The Generator board receives the signals concerning the X-ray dose to provide (kV and mA), from the CPU board through CANBus messages; it is the Generator CPU that generates the commands used for the X-ray emission. The Generator board provides to tubehead the voltages that drive the high voltage transformers that then drive anode and filament of the X-ray tube, also giving the relevant timing.

The tubehead is composed by the X-ray tube (Toshiba D-058) inserted in a sealed container, together with the high voltage transformers, filled with dielectric oil.

Checking of proper functioning of the X-ray emitting system is achieved through the analysis of feed back signals generated inside the tubehead and transmitted to the Generator board and relevant Generator CPU. Possible anomalous conditions are then communicated to the main CPU board (A1) which in turn generates error codes to alert the operator

5.3.4. Keyboard (A4)

The keyboard contents only the positioning command, used to set the unit to examination. Complete user interface is in the virtual keyboard managed by the SW installed in the PC (not provided as default)

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6. TECHNICAL CHARACTERISTICS

General features		
Type	Rotograph Prime	
Manufacturer	VILLA SISTEMI MEDICALI S.p.A. Buccinasco (MI) Italia	
Class	Class I with type B applied parts according to IEC 60601-1 classification.	
Protection degree	IPX0 standard device	
Line voltage	99-132V 198-264 V	
Rated line voltage	110-120V 220-240V	
Line frequency	50/60Hz	
Maximum line current	7A @115V 3.5 A @ 230V 50/60Hz	
Technical factors for maximum line current	70kV, 7.1mA	
Power consumption	0.8kVA @ 115V 0.8kVA @ 230V 50/60Hz	
Protection fuse (F1)	10 A T @115V 4 A T @ 230V	
Column protection fuse (F2)	3 A T @115V 1.6 A T @ 230V	
Line apparent resistance	0.4 max (99-132 V) 0.5 max (198-264 V)	
Rated output voltage (kVp)	60 ÷ 70kVp, with 2 kVp steps	
Anodic current	2 ÷ 7.1mA, with R20 scale steps (2, 2.2, 2.5, 2.8, 3.2, 3.6, 4, 4.5, 5, 5.6, 6.3, 7.1)	
Additional filtration	0.60 mm Al eq.	

Exposure times	
Panoramic (PAN)	14.4s Adult / 13.3s Child
EmiPanoramic	7.8s Adult / 7.3 s Child
Improved orthogonality Panoramic	11.9 s Adult / Child
Reduced dose Panoramic	11.9s Adult / 10.8s Child
Frontal dentition	4.4 s Adult / Child
TMJ mouth closed/open	4.8 s per image for left and right joint in open and closed condition
Sinus P/A projection	9.4 s
Exposure time accuracy	± 5 % or ± 20ms whichever is greater
Examination modes	
Examination selection	• Automatic selection for Adult and Child, 3 Sizes • 3 biting modes (in Panoramic) • Manual selection
Panoramic NOTE: Some of these exams are optional and depend on the system configuration.	• Standard Panoramic • Half Panoramic L/R • Improved orthogonality Panoramic • Reduced dose Panoramic • Frontal dentition • Bitewing L/R • Bitewing L and R
TMJ (Temporal Mandibular Joint)	TMJ open and closed mouth
Sinus	Sinus P/A projection

Image magnification	
Panoramic	1: 1.23 (constant)
TMJ	1: 1.20 (medium)
Sinus	1: 1.30 (medium)
Number of images in TMJ (open/closed mouth)	4
Tube-head characteristics	
Model	MP 05
Manufacturer	Villa Sistemi Medicali S.p.A. 20090 Buccinasco (MI) Italia
Maximum tube voltage	70 kVp
kVp accuracy	± 8 %
Maximum anodic current	7.1 mA
Anodic current accuracy	± 10 %
Duty cycle	1 : 16
Reference loading conditions related to maximum energy input to the anode	1125mAs/h @70 kVp
Nominal power	0.50 kW (70 kVp – 7.1 mA)
Total filtration	2.0 mm Al eq. @ 70 kVp
HVL (Half value layer)	> 2.5 mm Al eq. @ 70 kVp
Transformer insulation	Oil bath
Target angle and reference axis	See ***Figure 1***
Cooling	By convection
Leakage radiation at 1 m	< 0.5 mGy/h @ 70 kVp – 7.1 mA – 3s duty cycle 1/16
Tube-head maximum thermic capacity	310kJ

Figure 1: Tubehead target angle (view from the bottom)

X-ray tube characteristics	
Manufacturer	Toshiba
Type	D-058
Nominal focal spot	0.5 EN 60336
Inherent filtration	At least 1.0mm Al eq.
Anode tilt	12.5°
Anode material	Tungsten
Nominal maximum voltage	70 kVp
Filament max current	3 A
Filament max voltage	3.6 V
Anode thermal capacity	13 kJ
Anod thermic capacity in continuous operation	300 W

Laser centring devices	
2 laser beams are used for the patient positioning; beams that align the sagittal and Frankfurt planes (please refer to relevant paragraphs for detailed explanation).	
Wave length	650 nm
Divergence	< 2.0 mRad
Optical power on the working surface	< 1 mW
Laser class	Class 1 laser product according to IEC standard 60825-1:1993 + A1:1997 + A2:2001
Digital Sensor	
Sensible Area (H x L) PAN Sensor	146 x 6 mm
pixel dimension	48 um, 96 um in binning 2x2
Pixel (H) NOTANumber of horizontal pixels depends on examination time	PAN: 1536
Sensor cover attenuation equivalent	< 0.4 mm Al eq.

Mechanical characteristics	
Focal spot to image receptor distance	50 cm (20")
Telescopic motorised column run	66 cm (26")
Maximum total height – Note for the wall mount model this value refers to the recommended installation height	219 cm (86")
Weight	62 kg base version
Column base (optional)	6 kg

Working conditions	
Minimum room size (please refer to the Service Manual)	120x115 cm ("x")
Recommended room size (please refer to the Service Manual)	160x150 cm ("x")
Working temperature range	+ 10° + 40°
Relative working humidity (RH) range	30% 75%
Temperature range for transport and storing	- 20° + 70°
Humidity range for transport and storing	< 95% without condense
Minimum atmospheric pressure for transport and storing	630 hPa

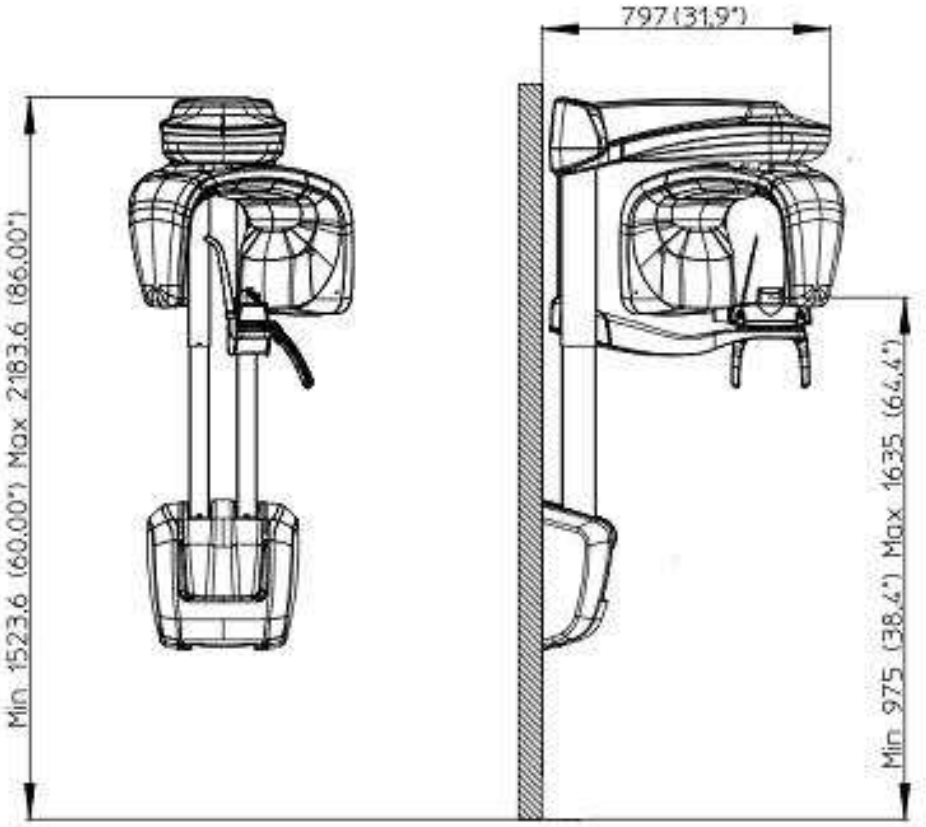
Note
Monitor characteristics: the PC and the monitor are not supplied with the machine.
In order to properly view the images taken with Rotograph Prime the PC monitor must have the following minimum characteristics:

- Resolution: 1366x768 pixels
- Color depht: 16M of colors
- Contrast: 500:1
- Luminosity 200cd/m^2

Note
The handles of the machine are covered with a special antibacterial paint that thanks to the emission of silver ions prevent the deveolpment of microorganisms.

1

6.1. Dimensions



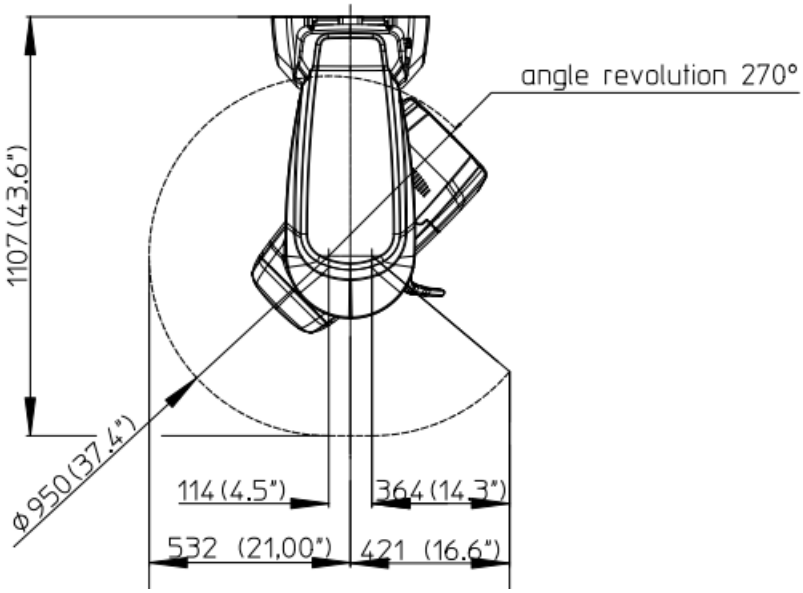
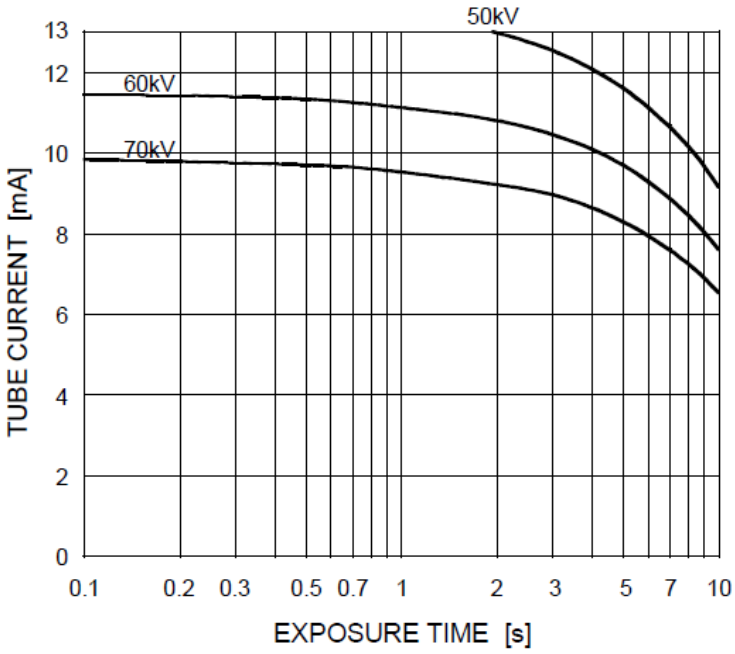


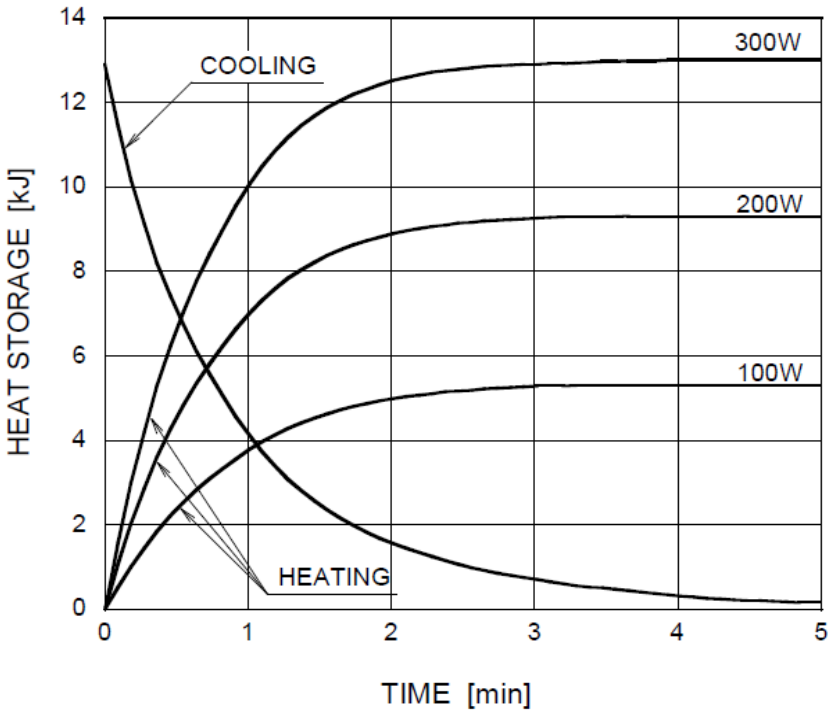
Figure 2: Rotograph Prime wall version dimensions

6.2. Loading curve of the tube and cooling curve of the anode

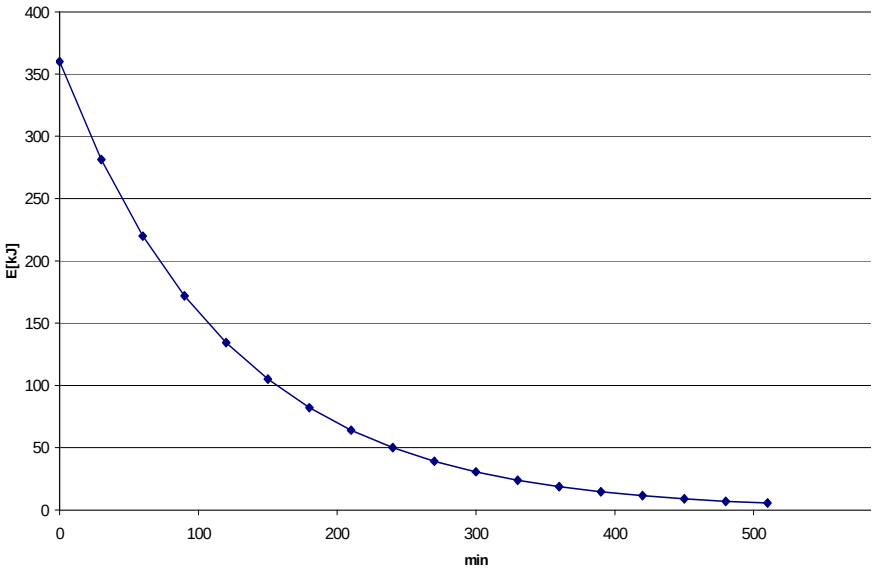
Tube "Toshiba D-058" (0.5 IEC 336)
Load



Anode cooling curve



Tube-head heating and cooling curve



6.3. Reference standards

Medical electrical equipment for dental extraoral radiography Rotograph Prime complies with:

IEC 60601 1: 2005 + Corr.1 (2006) + Corr.2 (2007).
Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6:2010 (3rd Ed.).
Medical electrical equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices.

IEC 60601-1-2:2007 (3rd Ed.).
Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

IEC 60601-1-3:2008 (2nd Ed.).
Medical electrical equipment – Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment.

IEC 60601-2-63:2012
Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.

IEC 62304:2006 + Ac:2008
Medical device software – Software life-cycle processes.

IEC 62366:2007 (1st Ed.)
Medical devices – Application of usability engineering to medical devices.

EN-ISO 14971:2012
Medical Devices – Application of Risk Management to Medical Devices.

CAN/CSA-C22.2 No 60601-1:08
Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.

ANSI/AAMI ES60601-1:2005
Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.

CE 0051 guarantees Rotograph Prime compliance with Directives 93/42/EEC (as amended), 2011/65/EU, 2006/42/EC.

Classifications

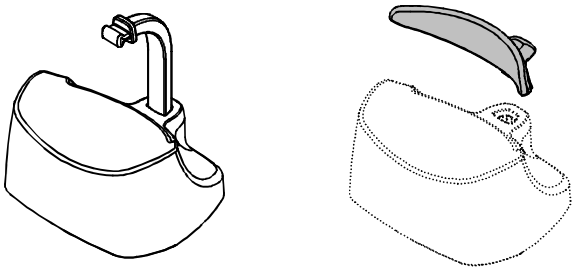
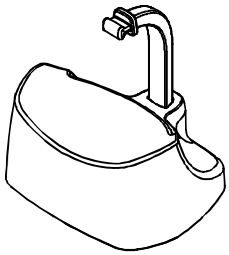
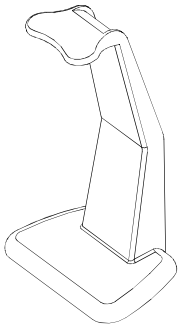
Rotograph Prime is an electro-medical X-ray device belonging to Class I type B as per classifications EN 60601-1, provided for a continuous working at intermittent load.

According to 93/42/EEC Medical Devices Directive the equipment belongs to class II B.

Rotograph Prime has been built to support a continuous operation at intermittent load.

6.4. Separate parts supplied with Rotograph Prime

Rotograph Prime comes with the following removable accessories:

Chin rest for standard panoramic, supplied with removable appendix for edentulous patients	
Reduced height chin rest for standard panoramic	
Lowered chin rest for Sinus, in non volumetric Prime mode	
Standard TMJ positioning support	
Bites, bite protective sleeves	Disposable and non-sterilised parts. Replace after every use.

Note

These removable parts are considered "type B applied parts", in accordance with IEC 60601-1, 3rd edition.
Some of these parts do not carry identification codes due to their small size, but their code is reported on a sheet present in the shipping package. The use of these parts on other devices is not possible, since they are parts designed specifically for the Rotograph Prime.

6.5. Note on constant magnification for dental arch X-ray and TMJ (mouth open/closed) examinations

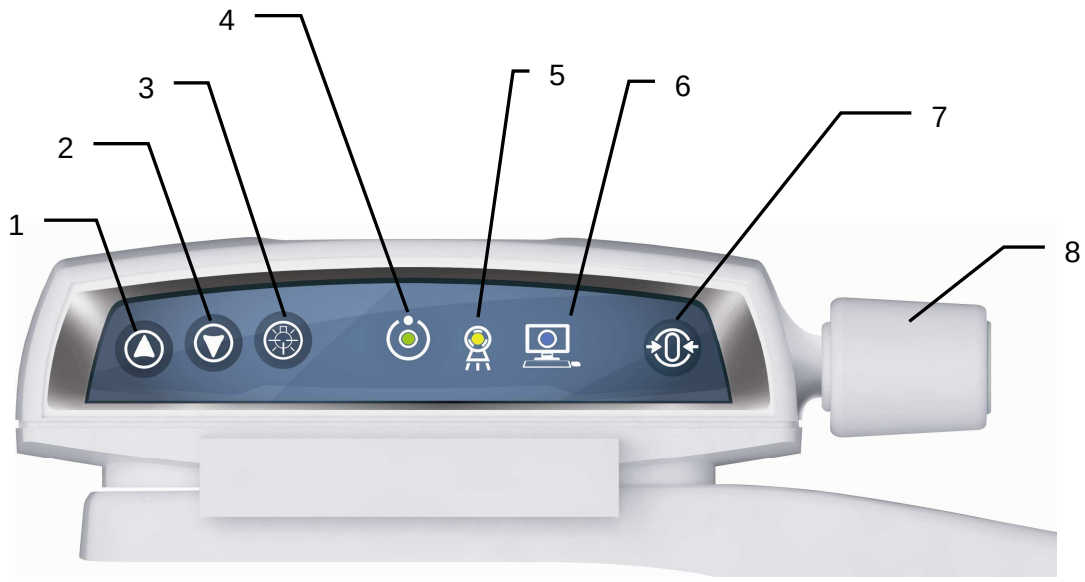
Note

Rotograph Prime is based on a standard dentition and ascending rami shape. This shape, based on statistical studies, establishes a form for the dentomaxillofacial complex, adopted as "standard".
Rotograph Prime follows a roto translation path which maintains constant the magnification factor stated in the Technical Characteristics of each type of exam along this "standard" shape only along the dentition area. The patient's anatomy can differ significantly from the statistical model, so the magnification factor is not maintained and can be different from the value stated. Based on his experience and competence, the user has to judge this variation.

IN ANY CASE, THE TMJ RADIOGRAPHY CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE FILM.

6.6. Control panel - description and functions

The new Rotograph Prime keyboard is presented in the next figure. It shows a general view of the control interface, while details on each functional area are provided in the following pages.



Legend:			
1	"Column movement" up button	5	Light signalling "X-rays in progress"
2	"Column movement" down button	6	Light signalling "Computer connection" status
3	"Centering devices ON" button	7	"Centring/Patient entry" button
4	Light signalling "Ready for X-rays"	8	Temple clasps closing/release knob

Figure 2

The "Centering/Patient Entrance" button is used to:

- start/stop the start examination procedures
- bring the rotation arm to the patient entrance position at the end of the exam..
- In setup mode, this button works as “store parameters”

There are two light indicators; the first one on the top indicates the condition "Machine Ready", indicating the user that by pressing the X-ray button key once more, X-rays emission will start; the second indicates the effective emission of X-rays.

The movement of the column is controlled by the appropriate keys. The speed has two set values. The movements are enabled during equipment setting.
In setup are used to set the parameters

The key "Luminous centering device" helps turn ON/OFF the laser centering devices that allow the correct positioning of the medial-sagittal and Frankfurt planes, by adapting the new Rotograph Prime to the patient's anatomy.

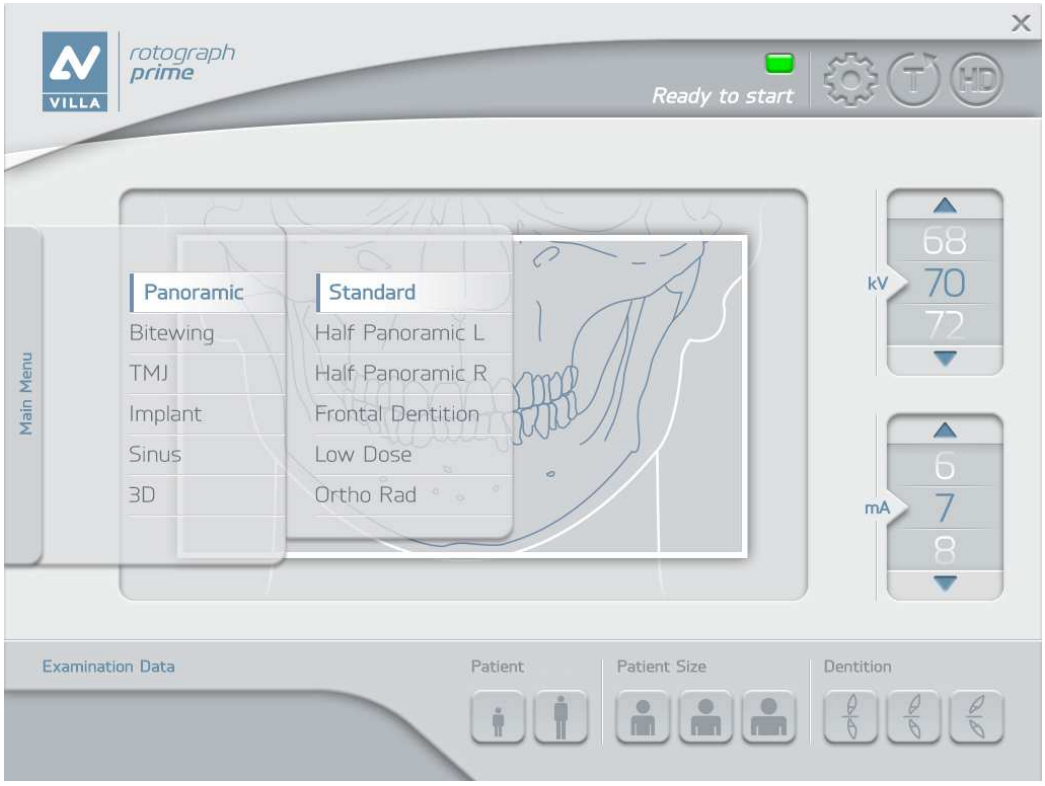
Computer connection status light indicator:

- Blue fixed, computer connection established,
- Blue blinking, waiting for computer connection. No X-ray emission available.

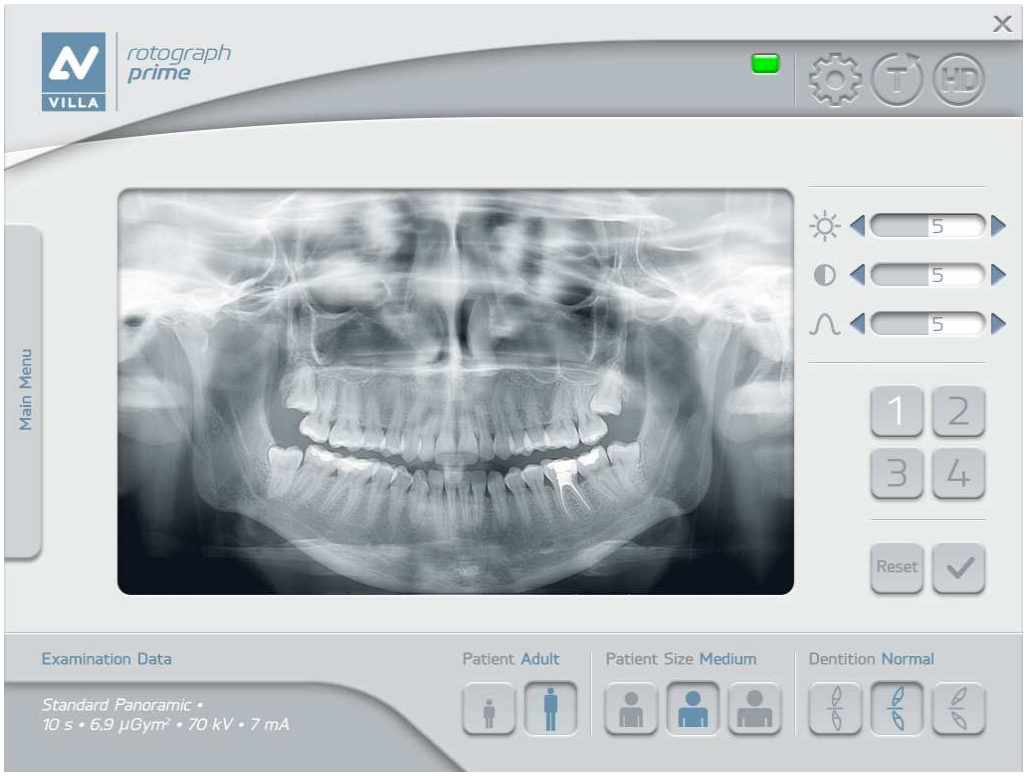
6.7. Graphical User Interface – description and functions

All the unit configuration is made through the virtual keyboard install on the computer.

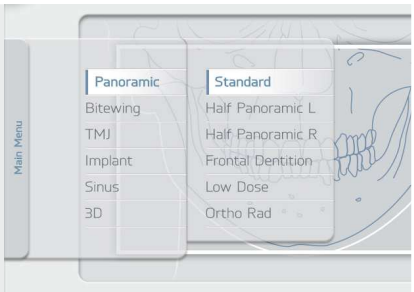
This interface enables the user to configure all the technical features of the unit, to choose and adjust the exam and radiological parameters.
This main window enable the access to the functions describe
The same window with complete programs selection menu in extended view. below.



Optional window with image preset filtered views. Some tool and enhancement filter can be adjustable to modify the image before forwarding it to the dental practice management software linked



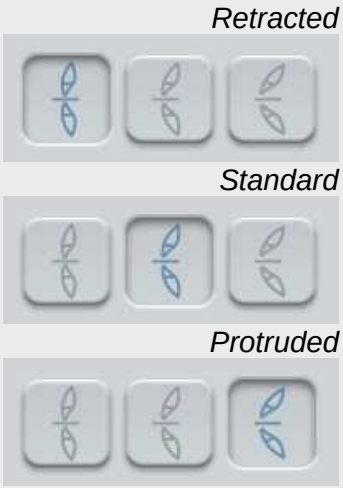
The "Examination Selection Mode" takes place by means of three keys: the first one, the main button, helps select the exam mode between Panoramic, TMJ, Sinus.
The other two, identified by the arrows, help navigate within the exams of each mode.



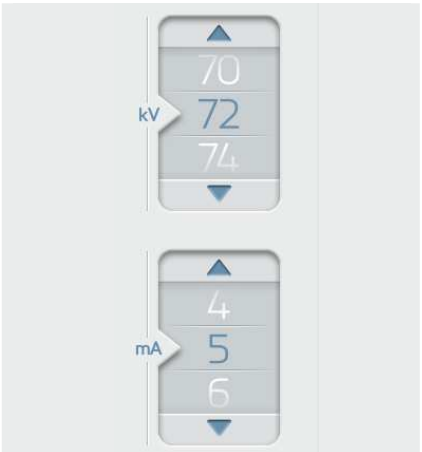
It is possible to select the anatomic mode examinations (anatomic selection), using preset exposure values.
This kind of selection enables to choose between Adult/Child, each with three different sizes (small, medium, large).

NOTE the exam parameter set as default are values to be taken as starting point. The user can optimize the parameters according to their needs and store for each exam their preferred kV and mA.

The Panoramic mode enables to select the patient's type of biting between: protruded, standard or retracted, as indicated within the button.
The arch selection does not influence the values of kV and mA but acts on the position of the focus layer.



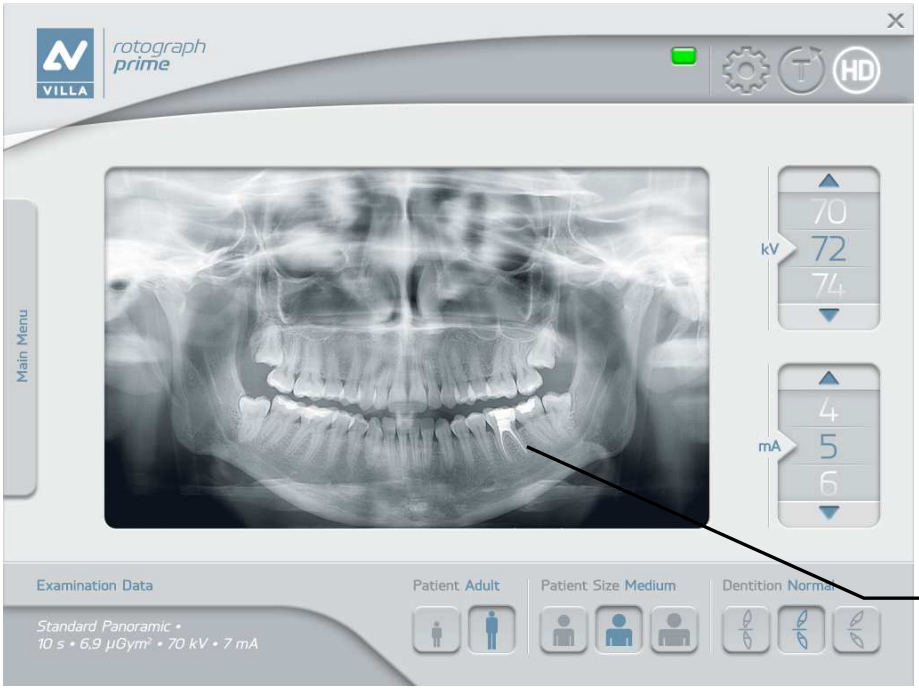
Furthermore there is the possibility to manually select the exposure parameters; in this case, it is possible to set the parameter with the desired value.
The parameters available are: kV and mA. When the exposure parameters are changed manually, the mode indicator switches from "Anatomic" to "Manual". Return to "Anatomic mode" using the main program selection button.



The key "Test" is used to avoid the X-rays emission, in order to check the absence of collisions with the patient.

Unit cooling time indicator: necessary time before the next exposure.

6.7.1. Acquired image display description



Live preview

Once an image has been acquired it is transferred to the computer through the network (if connected).

During acquisition, image is progressively displayed on the computer screen, adjusted to have the whole image, in this control panel software window area.

6.8. Digital Sensor

The new Rotograph Prime is equipped with Sensor PAN: it is a sensor suitable for Panoramic-type imaging, i.e. all images with a 14cm-high field; all Panoramic, TMJ, and Sinus images belong to this type.

The new Rotograph Prime control system takes care of checking the consistency of the safety measures that allow for the correct use of the digital sensor; in particular to prevent the acquisition in case the image management and processing system is not ready to receive the image itself, by displaying the message "Sensor not ready"

6.9. Positioning of chin support

The new Rotograph Prime is equipped with different types of supports: a standard support fitted with a special removable appendix for edentulous patients, a lower one for SINUS examinations and a third one, to be used for TMJ examinations.

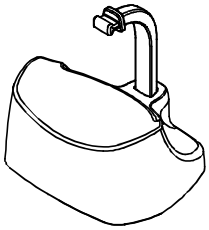
The standard chin support must be used, in panoramic mode, with all the people who can assure a tight grip on the centering bite. The appendix for edentulous patients must be applied only for patients who cannot assure a tight grip on the bite or are not co-operating and might move during the examination.

For the SINUS examinations there is special support that, being in a lower position, ensures a better centering of the interested area in the rays field.

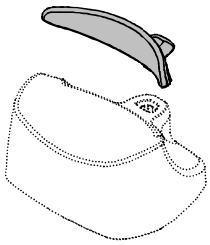
For TMJ examinations, a specific positioner is included, allowing the patient to open and close the mouth without touching any positioner with the chin.

Note

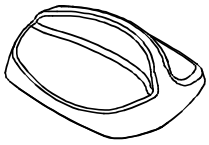
Another chin support, at a low height for standard Panoramic, is provided to ensure a better view of the lower section of the chin for patients with particular anatomy. This chin support is marked by a down arrow "▼on the front of the chin support itself.



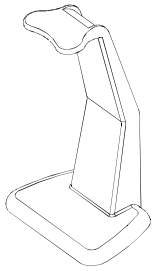
Panoramic standard chin support



Edentulous patients appendix



SINUS chin support



TMJ positioner

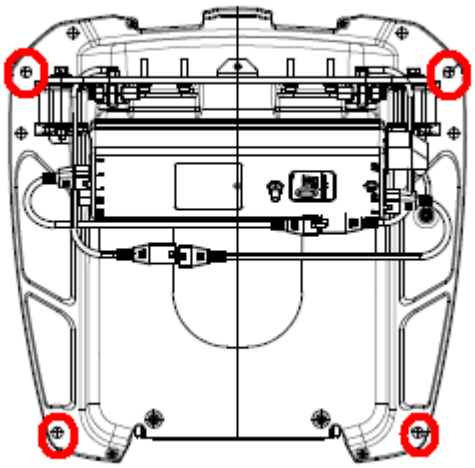
7. PRE-INSTALLATION

The instructions indicated in this and in the following chapter enable to perform a correct installation in order to grant a regular operation of Rotograph Prime.
The supplier can supply the assistance and the necessary technical advice for pre-installation, all masonry works and the pre-installation phase are at the customer's charge and must be performed complying with the indications given below.

The requirements for a correct installation of Rotograph Prime are:

- minimum height of the room: 2.5 m (8.20') and a surface variable according to the configuration of Rotograph Prime to be installed, as indicated in the picture at paragraph 7.3
- a certain distance from heating devices
- the entries in the room, for the transport of the unit, must have a minimum width of 80 cm (31.50").

Note
Fixing to the wall must be done using the 4 holes indicated in the figure



Warning

In its standard versions, Rotograph Prime can be fixed directly to the wall. It is responsibility of the installer to verify the type of wall and use the correct fixing anchor. Here following some suggestion that can help installer to find the correct method depending on wall and installation type.

- **Standard installation** consider to install the unit directly on the wall . Extraction force on each anchor is about 85 Kg.

In case of full concrete (class C20/C25 thickness > 200mm) : Drill with Ø8+ Fischer Anchor FAZ II 8/10 (Villa ordering code 6604100100). Tightening force 20Nm

In case of full bricks : fori Ø14 + chemical Anchors FIS V-BOND 300T + Steel Insert FIS E 11X85 M6 + screws M6x25 (Villa ordering code 6604100200). This solution permit to avoid the use of threated bars. Tightening force 4Nm

In case of hollow brick : Drill Ø16 + chemical Anchors FIS V-BOND 300T Plastic anchor FIS H 16X85 K + Steel Insert FIS E 11X85 M6 (Villa ordering code 6604100200). solution avoiding the use of threated bars). Tightening force 2Nm

Installation with floor support (optional) with unit installed to wall and floor. Extraction force on each anchor is about 72,5Kg each.

In case of full concrete (class C20/C25 thickness > 200mm) : Drill with Ø8+ Fischer Anchor FAZ II 8/10 (Villa ordering code 6604100100). Tightening force 20Nm

In case of full bricks : fori Ø14 + chemical Anchors FIS V-BOND 300T + Steel Insert FIS E 11X85 M6 + screws M6x25 (Villa ordering code 6604100200). This solution permit to avoid the use of threated bars. Tightening force 4Nm

In case of hollow brick : Drill Ø16 + chemical Anchors FIS V-BOND 300T Plastic anchor FIS H 16X85 K + Steel Insert FIS E 11X85 M6 (Villa ordering code 6604100200). solution avoiding the use of threated bars). Tightening force 2Nm

- **Installation to wall with distribution plate (optional)**. Extraction force on each anchor is about 63 Kg each.

In case of full concrete : Drill with Ø8+ Fischer Anchor FAZ II 8/10 ART.094871 FAZ Tightening force 20Nm

In case of hollow brick : Drill Ø16 + chemical Anchors FIS V-BOND 300T ART. 516352 Plastic anchor FIS H 16X85 K + Steel Insert FIS E 11X85 M6 (solution avoiding the use of threated bars)

In case of full bricks : fori Ø14 + chemical Anchors FIS V-BOND 300T + Steel Insert FIS E 11X85 M6 (solution avoiding the use of threated bars)

7.1. Electrical setting up

• Single-phase grounding supply	220-240 V ~ 110-120 V ~
• Frequency	50/60 Hz
• Power consumption	0.8 kVA (at 230 V) 0.9 kVA (at 115 V)
• Current consumption	3.5 A (at 230 V) 8 A (at 115 V)
• Apparent line resistance	0.5 Ω max (for 220-240 V version)
• Line voltage regulation	< 3 % at 99 V (for 110-120 V version)

Note

The device is supplied as a unit to be installed permanently.
Please DO NOT connect the unit to the power using a normal socket, to avoid compromising the electrical safety.

The unit must be connected to a differential magneto-thermal switch, to separate the unit from the supply. This switch must comply with the electrical regulations in force in the country of installation.
The supply conductors must have a 1,5 mm^2 (16 AWG) section.
The general grounding must comply with the rules in force; a wrong quality of the grounding could be dangerous for the operator's safety and cause a bad function of the electrical devices.

Note

Power supply cable is already connected inside the Rotograph Prime

7.2. Packaging

Rotograph Prime is delivered in a single carton-board box.
Package itself became a tool used to install the unit.

PAN only version			
Contents	Packing dimension	Weight	
		Net	Gross
- Complete unit	120x80x67 cm (47.3"x31.5"x26.4")	80 kg (176 lbs)	90 kg (198 lbs)

Note

The box mount shock detectors.
At the receiving and before install the unit, verify that those sensors have not been activated.

Warning

Villa Sistemi Medicali will not bear any responsibility for damages caused to the equipment due to improper unpackaging procedure, and for the relevant costs.

7.3. Space requirements

7.3.1. Version

To be verified

***(*) A** = minimum 600 mm (23.6"), recommended 800 mm (31.5") for service purpose*

Figure 7-3

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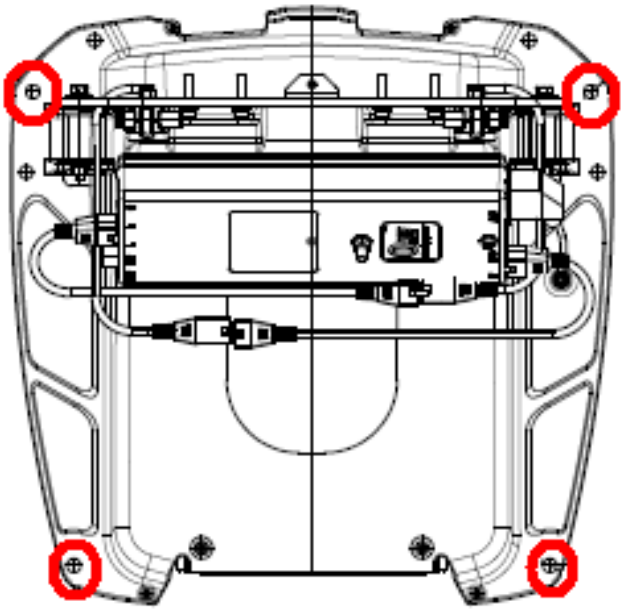
8. INSTALLATION

Note

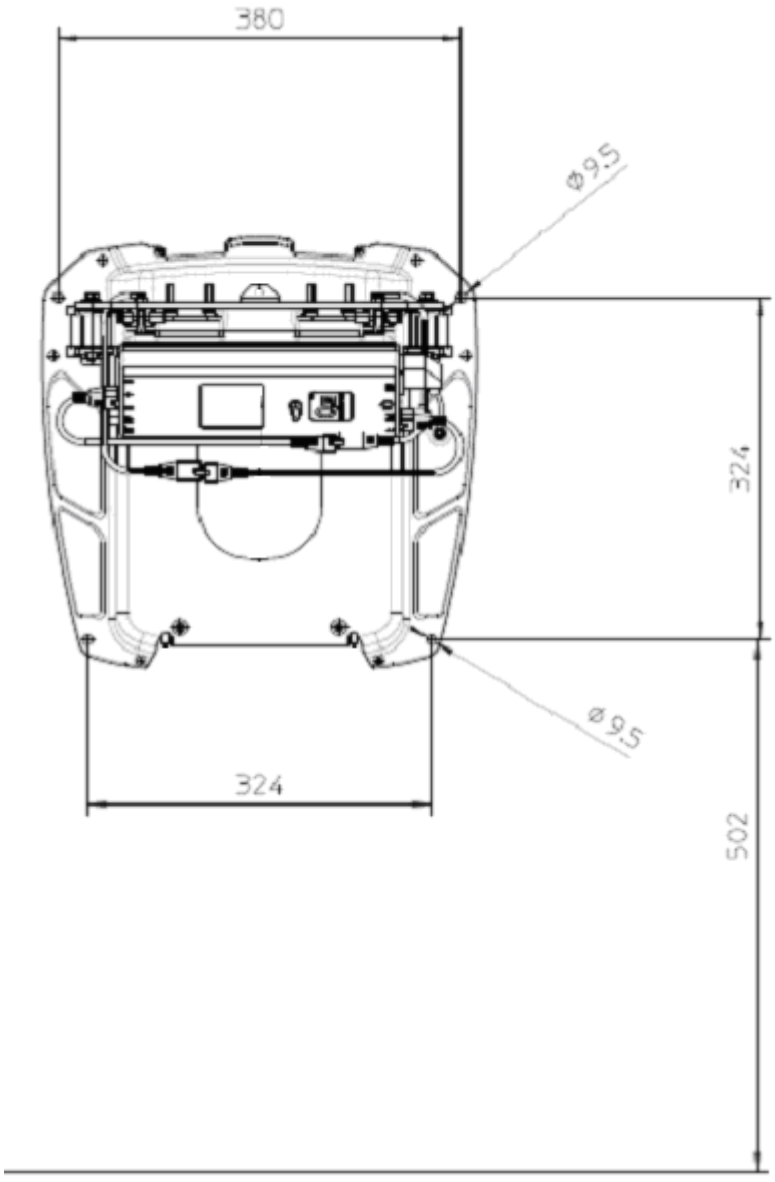
Rotograph Prime is delivered completely pre-mounted; it is contained in a single box. The mechanical mounting consists exclusively in fixing the unit to the wall and complete with few operations the installation. Most of the adjustment are carried out in factory. A single technicians will be able to install the unit as package is used to support the unit during installation.

Note

Fixing to the wall must be done using the 4 holes indicated in the figure



Also if package can be used as tool to install the Rotograph Prime, here following the indication of the drill layout for the standard height in case it is necessary to prepare the room before you receive the unit



Warning

In its standard versions, Rotograph Prime can be fixed directly to the wall. It is responsibility of the installer to verify the type of wall and use the correct fixing anchor. Here following some suggestion that can help installer to find the correct method depending on wall and installation type.

- **Standard installation** consider to install the unit directly on the wall . Extraction force on each anchor is about 85 Kg.

In case of full concrete (class C20/C25 thickness > 200mm) : Drill with Ø8+ Fischer Anchor FAZ II 8/10 (Villa ordering code 6604100100). Tightening force 20Nm

In case of full bricks : fori Ø14 + chemical Anchors FIS V-BOND 300T + Steel Insert FIS E 11X85 M6 + screws M6x25 (Villa ordering code 6604100200). This solution permit to avoid the use of threated bars. Tightening force 4Nm

In case of hollow brick : Drill Ø16 + chemical Anchors FIS V-BOND 300T Plastic anchor FIS H 16X85 K + Steel Insert FIS E 11X85 M6 (Villa ordering code 6604100200). solution avoiding the use of threated bars). Tightening force 2Nm

Installation with floor support (optional) with unit installed to wall and floor. Extraction force on each anchor is about 72,5Kg each.

In case of full concrete (class C20/C25 thickness > 200mm) : Drill with Ø8+ Fischer Anchor FAZ II 8/10 (Villa ordering code 6604100100). Tightening force 20Nm

In case of full bricks : fori Ø14 + chemical Anchors FIS V-BOND 300T + Steel Insert FIS E 11X85 M6 + screws M6x25 (Villa ordering code 6604100200). This solution permit to avoid the use of threated bars. Tightening force 4Nm

In case of hollow brick : Drill Ø16 + chemical Anchors FIS V-BOND 300T Plastic anchor FIS H 16X85 K + Steel Insert FIS E 11X85 M6 (Villa ordering code 6604100200). solution avoiding the use of threated bars). Tightening force 2Nm

- **Installation to wall with distribution plate (optional)**. Extraction force on each anchor is about 63 Kg each.

In case of full concrete : Drill with Ø8+ Fischer Anchor FAZ II 8/10 ART.094871 FAZ Tightening force 20Nm

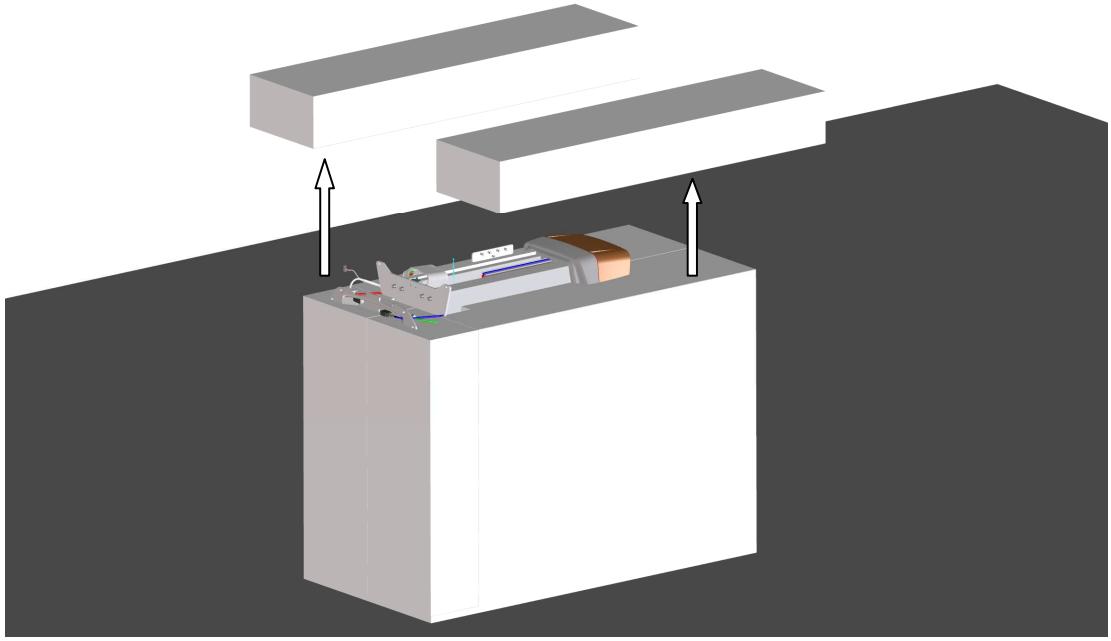
In case of hollow brick : Drill Ø16 + chemical Anchors FIS V-BOND 300T ART. 516352 Plastic anchor FIS H 16X85 K + Steel Insert FIS E 11X85 M6 (solution avoiding the use of threated bars)

In case of full bricks : fori Ø14 + chemical Anchors FIS V-BOND 300T + Steel Insert FIS E 11X85 M6 (solution avoiding the use of threated bars)

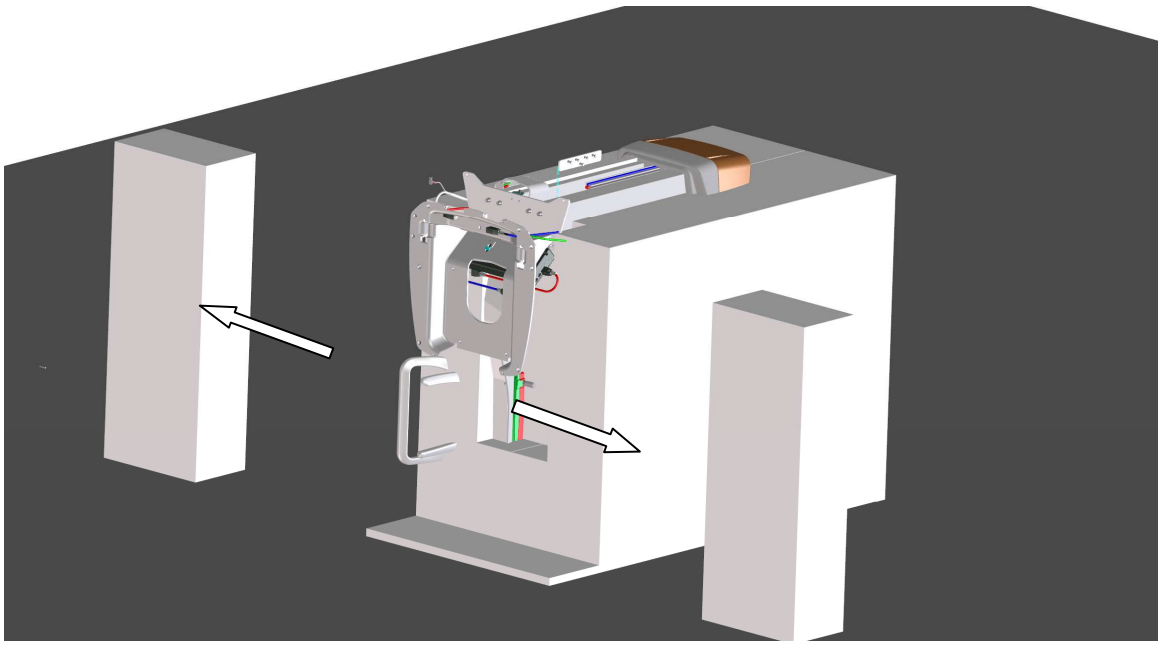
9. SYSTEM INSTALLATION PROCEDURE

9.1. Mechanical installation

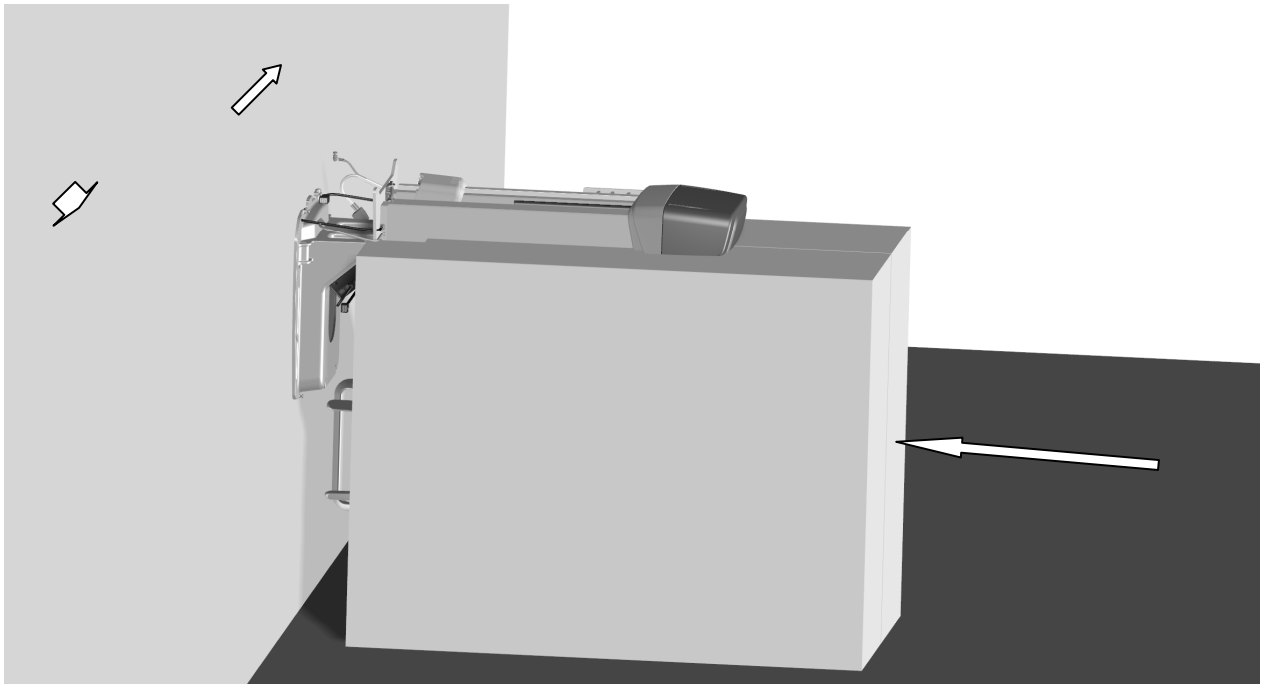
1) Remove the carton box and the higher polystyrene section



2) Remove the front polystyrene section

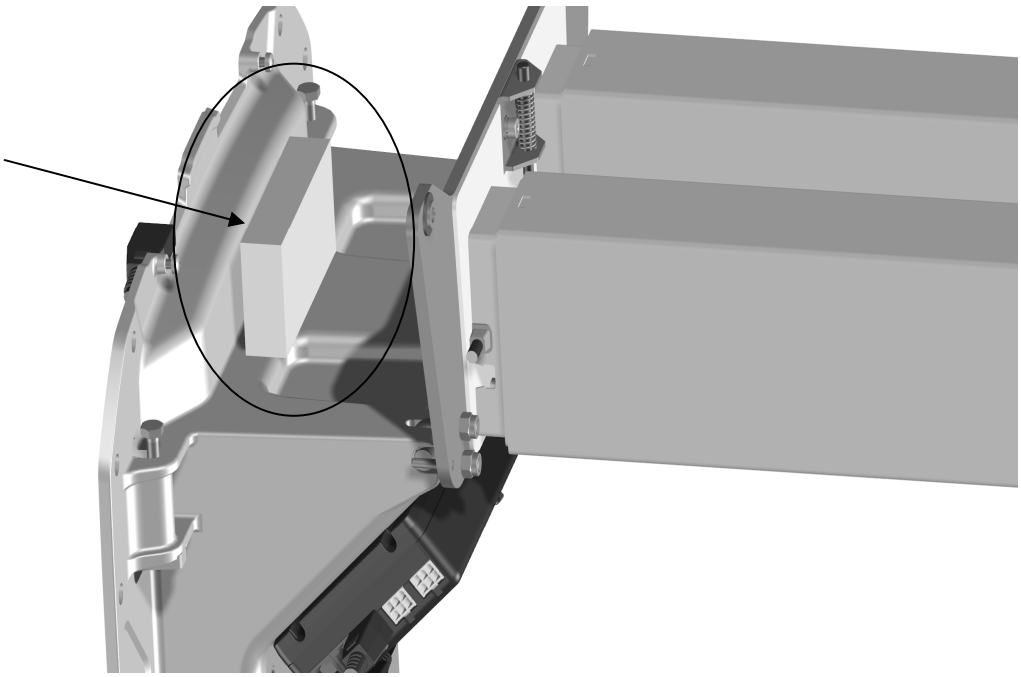


3) Slide the packaging from the polystyrene base close to the wall in the position where the Rotograph Prime will be installed
4) Push the packaging until the System wall plate is against the wall.



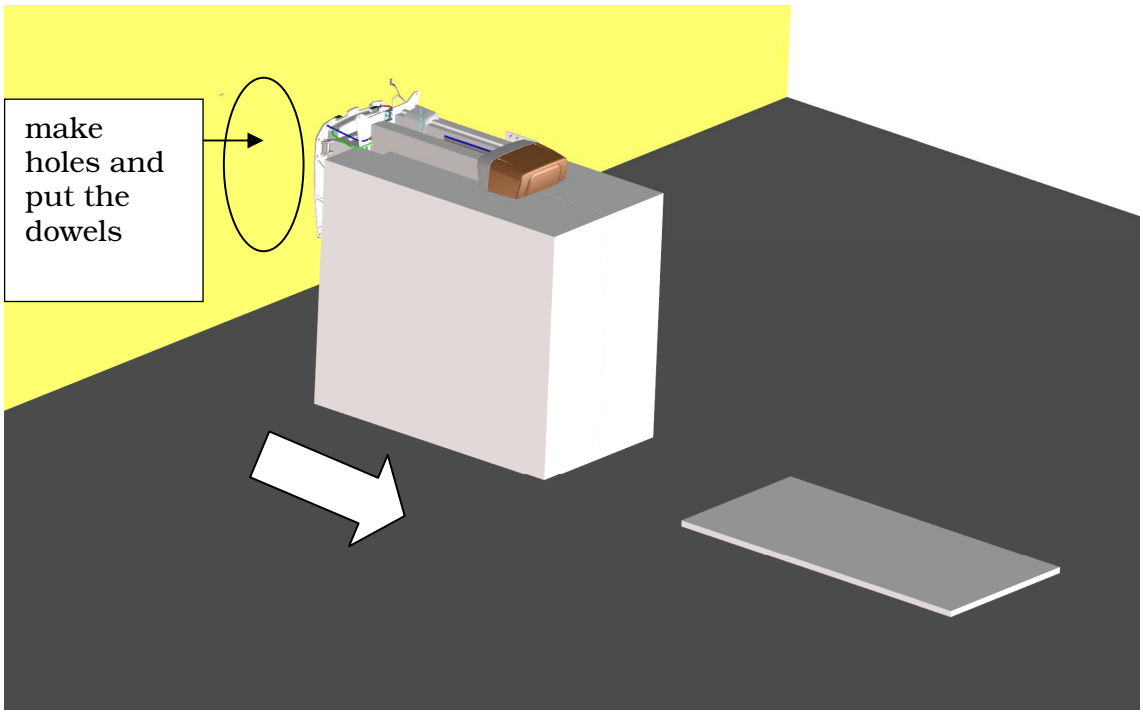
then mark, on the wall, the position of the dowels holes. Verify with an air bubble lever that the plate is horizontal.

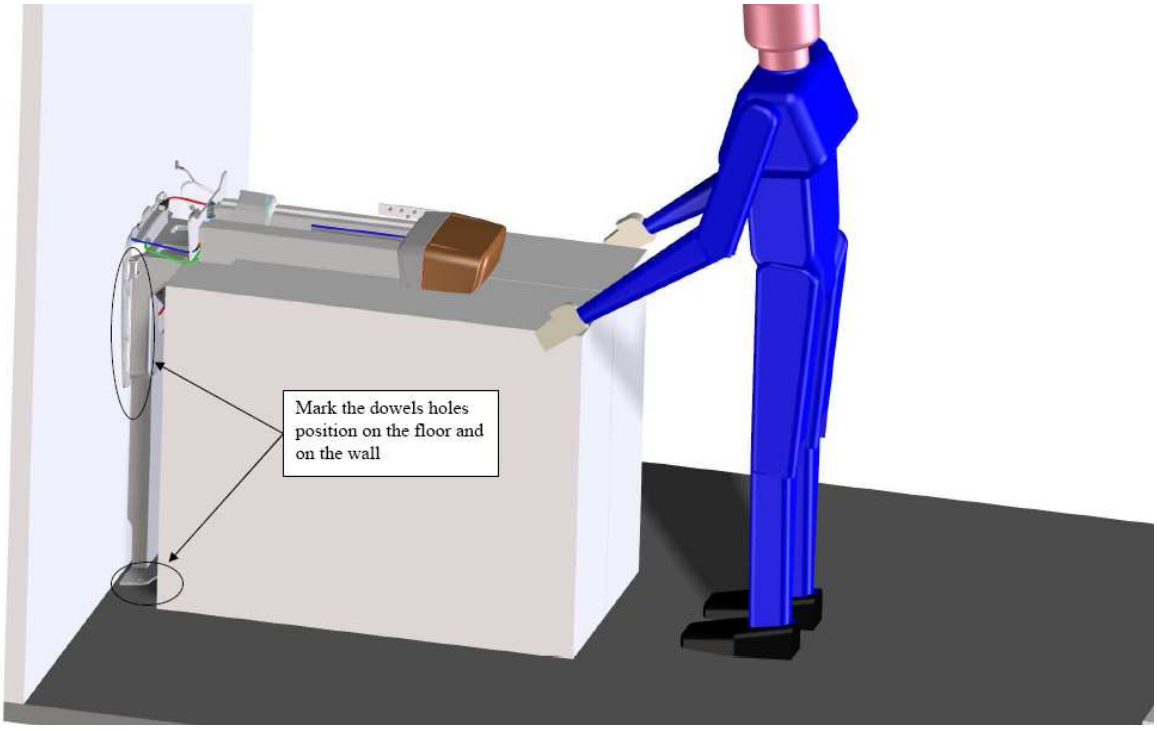
Put the air bubble level in this position over the wall plate



5) Move back the packaging drill the wall, put the dowels, reposition the packaging against the wall and secure the wall plate to the wall with the screw.

WARNING : the exctracting force on each dowel is about 85 kg. It is responsibility of the installer to verify type and solidity of the wall and identify the correct type of fixing method (metallic dowels, plastic dowls, or chemical fixing anchors etc...).

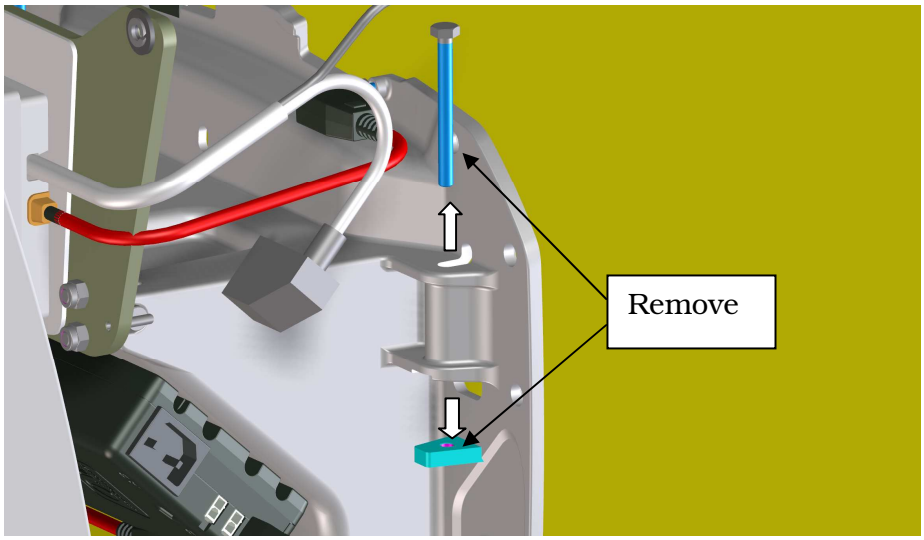


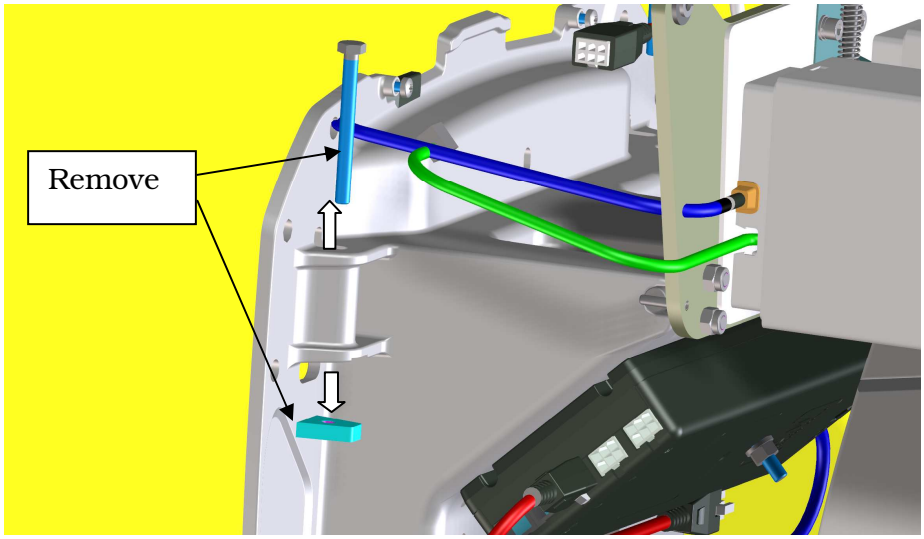


Note: Force to the dowels is: 85 Kg for the wall mounted installation –
72,5 Kg for the wall plate + floor column installation
63 Kg for the wall mounted + 16" extended plate installation

Remove the plastic protection between plate and rotating part

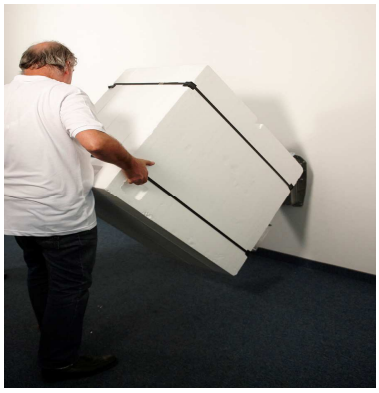
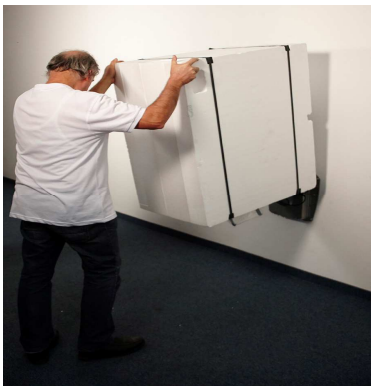
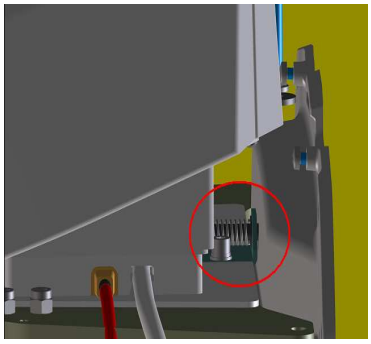
6) WARNING : Once fixed the plate to the wall, remove the tilting plate locking screws, and their nuts, locking the Wall plate.





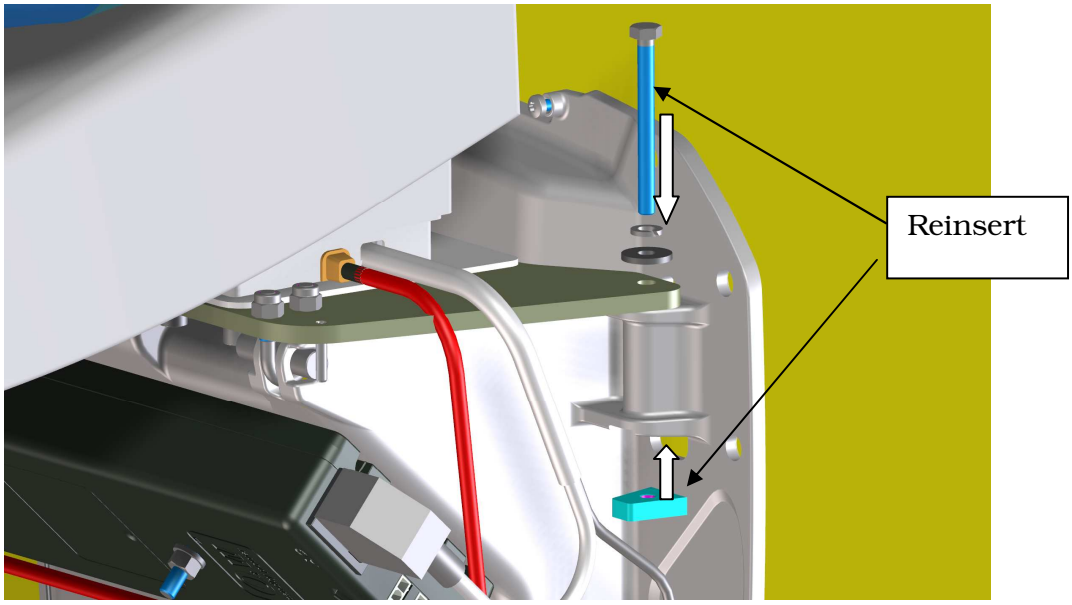
7) Grab the packaging and lift until the insertion of the pin-lock is in its seat (see the picture 1-2-3).
NOTE : The force necessary to lift the Rotograph Prime is about 20kg, so that a single technician can be enough to install the unit

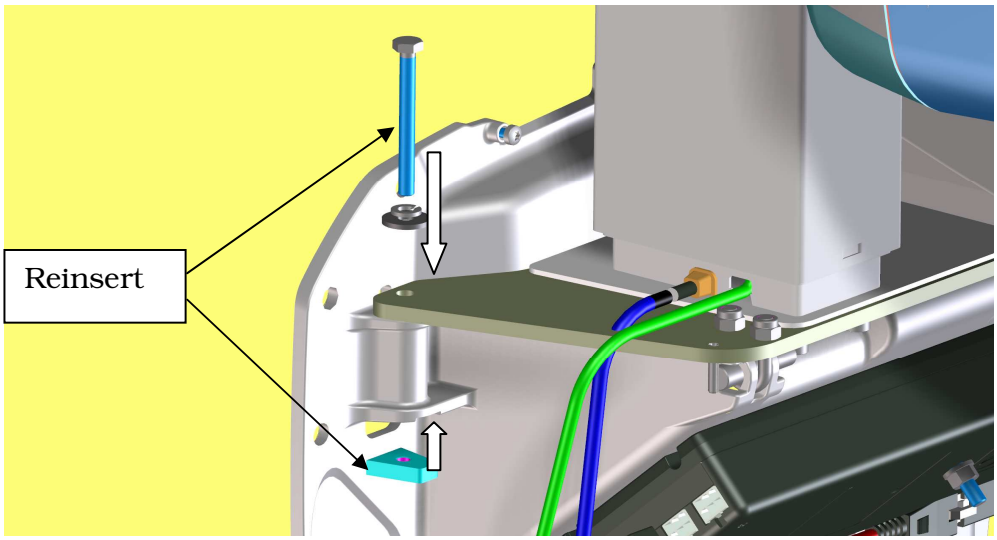


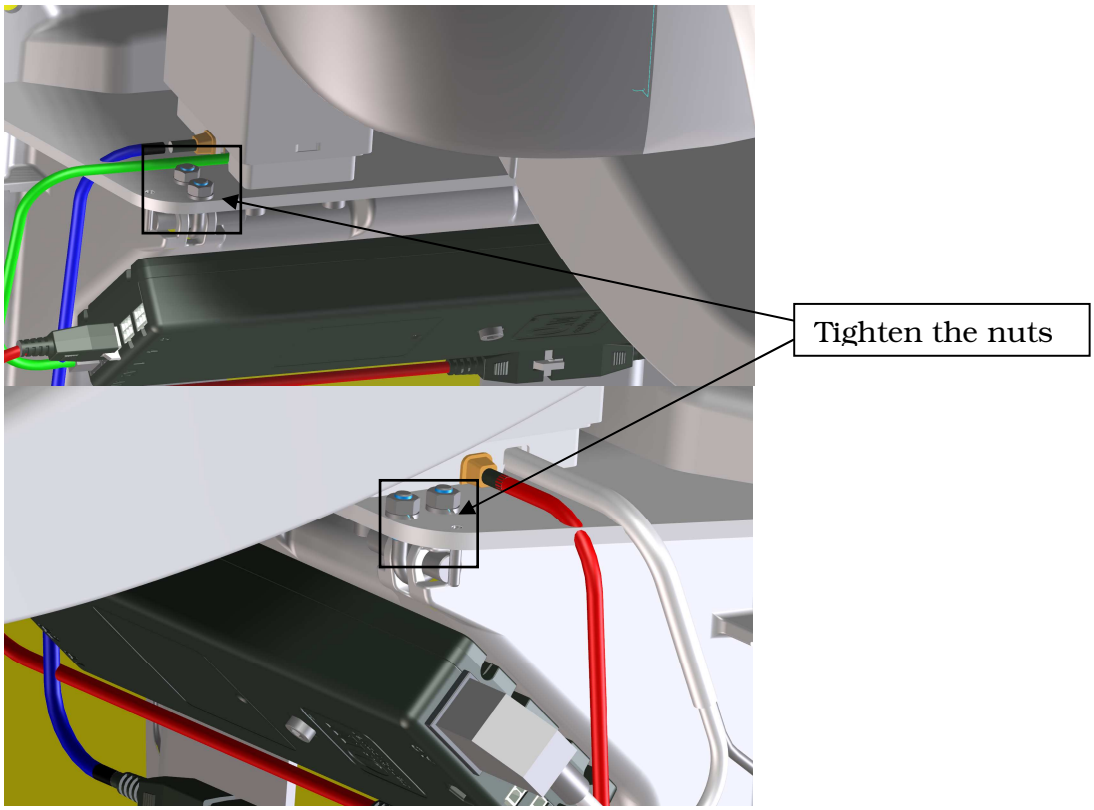
Once the unit reach the final position, be sure that the safety pin is properly locked before to leave the package

8) WARNING! Reinsert immediately the tilting plate locking screws, and their nuts and lock the tilting plate at the wall plate .

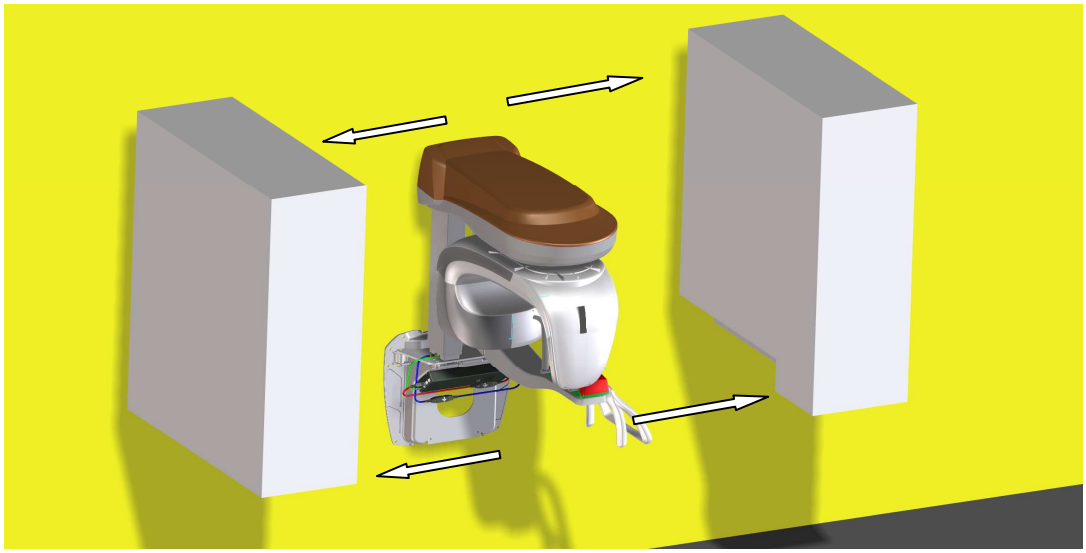




9) Tighten the nuts of the eye bolts of the rotation pins



Warning
In case of dismountling the unit (i.e. after exhibition), it is necessary to loosen these nuts in order to avoid damagements to the hinge during rotation



10) Cut the straps that join the two polystyrene elements and remove them.

WARNING : inside the polystyrene elements, you can find the accessories of the machine and the wall plate cover)

Remove the upper cover releasing the two screws present in the back side (wall direction). Front side of the cover is fixed without screw (locking pins)

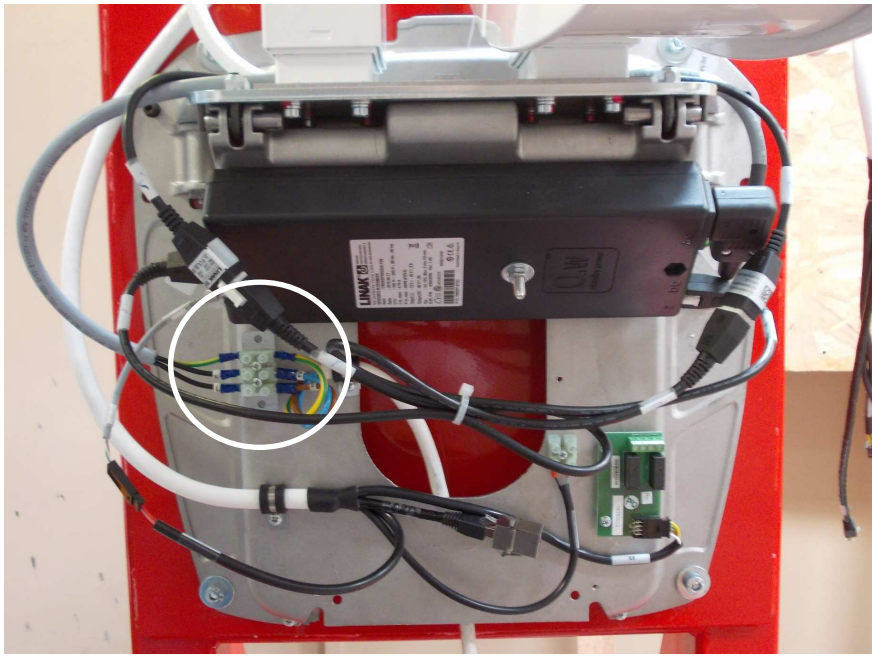
Remove the safety plate used do keep the rotating arm fixed during transportation.

9.2. Electrical connections

Note
Before to connect main power supply, be sure that the main provided by the Customer is according to specification in terms of voltage, line resistance and safety protections.

- **MAIN POWER SUPPLY :** This cable is already connected inside the Rotograph Prime.

It is only necessary to connect it to the dedicated power supply line



- LIGHT SIGNALLING CONNECTION Rotograph Prime, is set to connect, at the entrance of the X-ray room, the following control and warning devices:
- **READY light:** Green light (24V 40W max.), it signals that the machine is ready to perform the exam. (contact N.O.).
- **X-RAYS light:** Yellow light (24V 40 W max.) it signals the entry in the X-ray room is forbidden, since an exposure is on the run (contact N.O.)

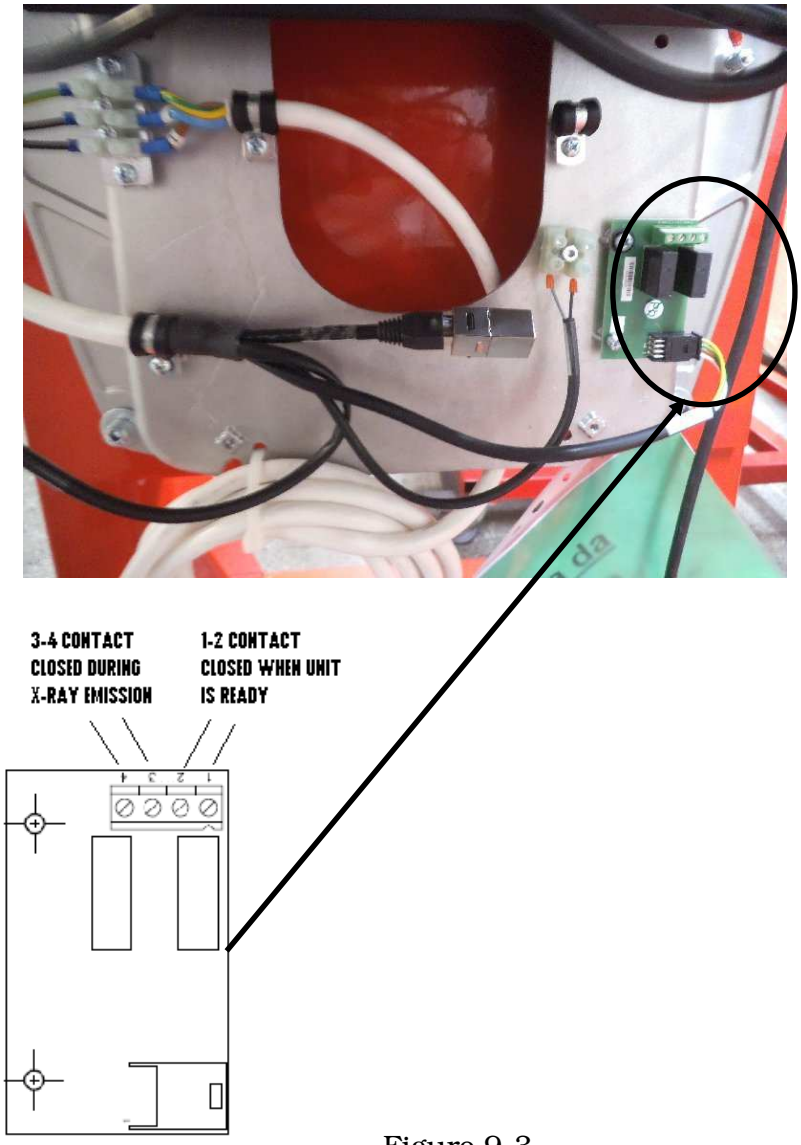


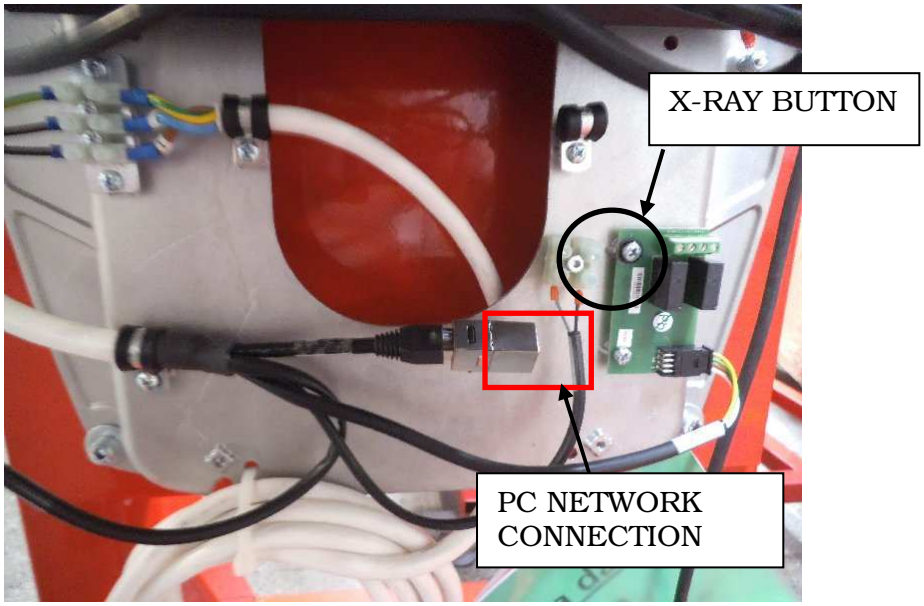
Figure 9-3

Note

The unit only provides the closing contacts relative to the above mentioned functions. Power voltages for the relevant devices have to be provide from outside, making sure not to exceed the indicated ratings.

- **X-RAYS BUTTON :** it is provided a button with the characteristic "dead man switch". Connect it to the indicated terminals. .

In case it is require to add a remote control, (used to perform the exam at a distance, with the operator standing outside the room) it must be "dead man switch" and provide a clean contact



Warning

It is installer's responsibility to check the characteristics of the remote X-ray button
No current or voltage must pass through remote control hand switch.
Wrong connections may damage the CPU

- **ACQUISITION COMPUTER CONNECTION :** it is present a network (RJ45) junction (see square) necessary to connect the network cable of the computer used to acquire the images coming from Rotograph Prime. Computer must be properly configured in terms of IP address and the acquisition SW must be installed. For detailed information check following paragraphs.

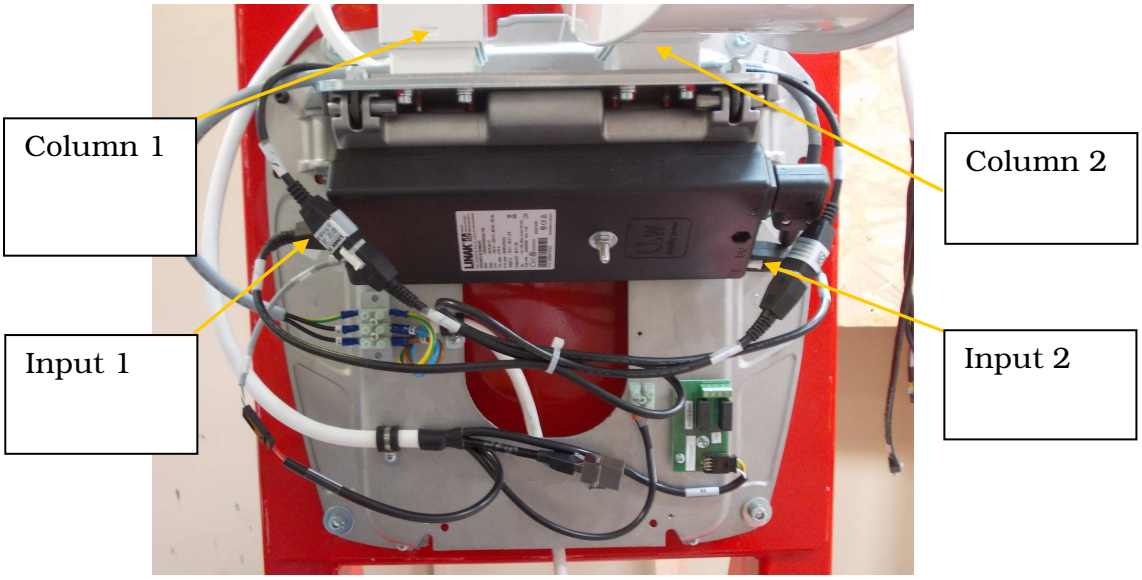
Warning

Never connect the RJ45 cable coming from the computer to other connectors in the unit (i.e. column movement control rack).

Warning

Here following some actions that during installation, maintenance or troubleshooting MUST be avoided as they damage column or control rack

- NEVER DISCONNECT CABLES FROM THE CONTROL BOX IF POWER SUPPLY IS ON
- NEVER SWITCH ON THE EQUIPMENT IF ONE OF THE TWO COLUMNS IS DISCONNECTED
- VERIFY ALWAYS THAT THE COLUMNS ARE CONNECTED TO THE CORRESPONDING PORT IN THE CONTROL BOX



9.3. How to mount the covers

Note
Cover mounting is easier with the unit powered ON, mainly to move the lift.

Wall plate cover

Upper cover

Temple supports

9.4. Unit fully installed

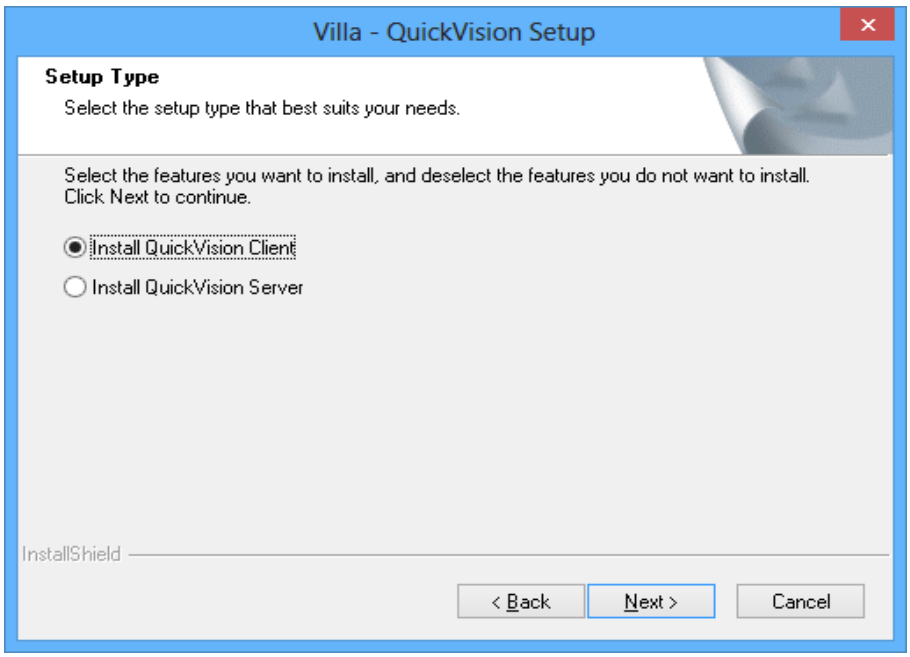
The cables output are from lower side of the Rotograph Prime so that it's possible to position them in a single cable channel on the wall.

9.5. Software Installation

9.5.1. PC set up.Quick Vision Installation

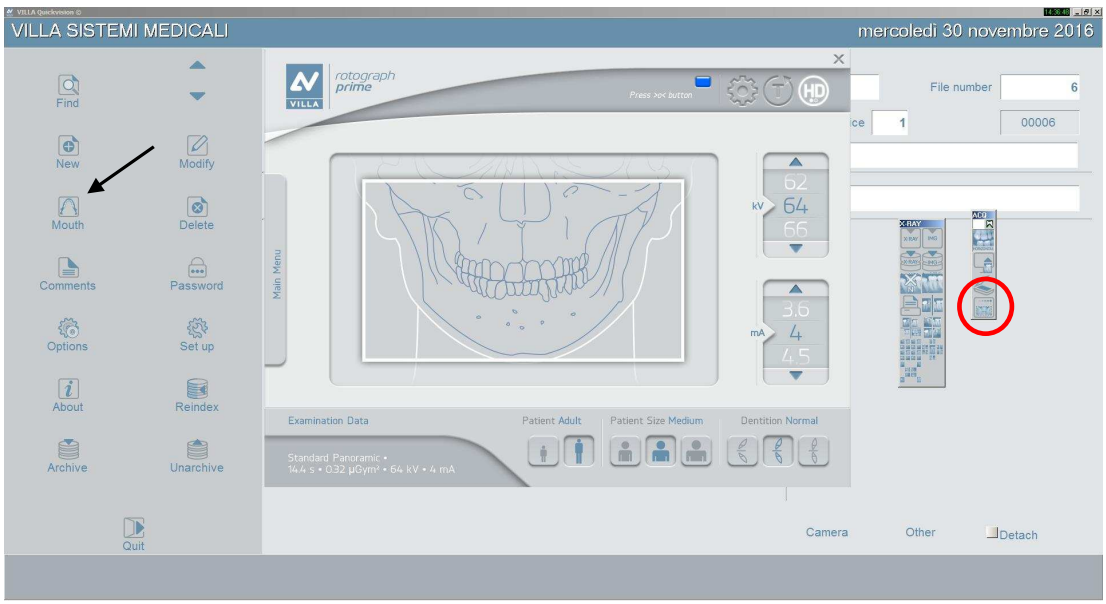
Insert the CD you received with the unit. The autostart will open the following page.

Click on Software to start installation. Select if you system is Client (single PC) or if it is used as Server (PC network), then confirm until the installation is completed



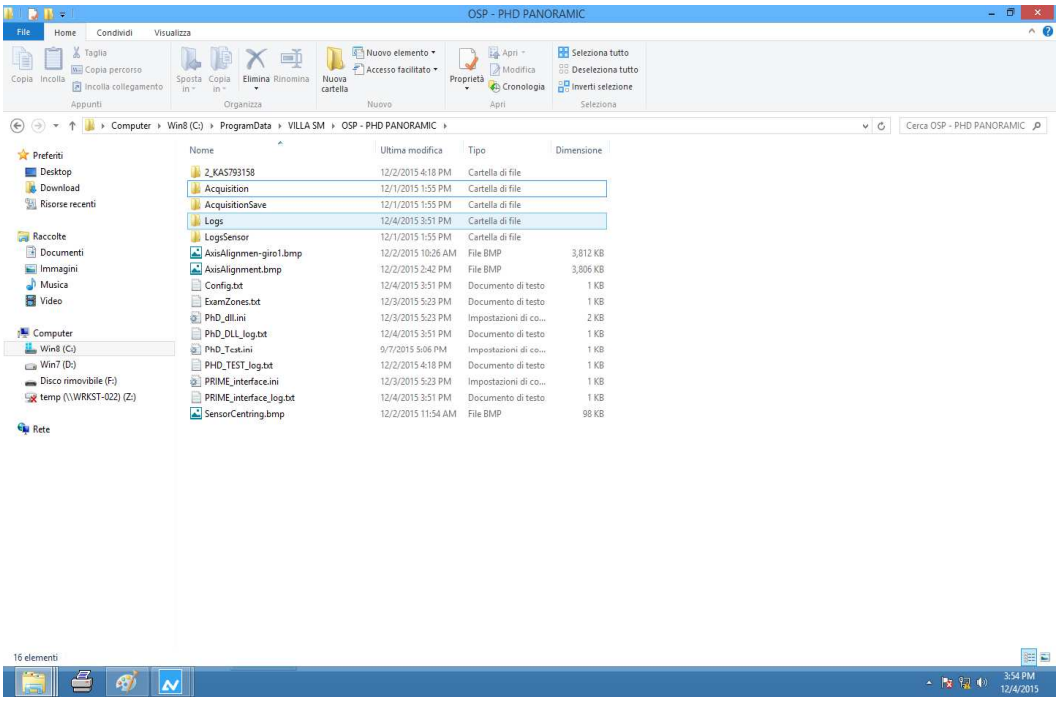
After Software installation, it is necessary to install Drivers for Rotograph Prime

Select Rotograph Prime and confirm to install the Drivers
The digital sensor is set as default with IP address 192.168.0.211.
Set the PC with an IP address of the same family (i.e. 192.168.0.210) before to open virtual keyboard
Opening Quick Vision it is possible to start communication with the unit.
In order to open Virtual Keyboard click on Mouth Symbol (see arrow) and then on keyboard symbol (see circle)



9.5.2. PC - Rotograph Prime Detector Calibration files

Before to start acquisition, it is necessary to save detector calibration files in the directory C:\ProgramData\Villasm\OSP-PHD Panoramic

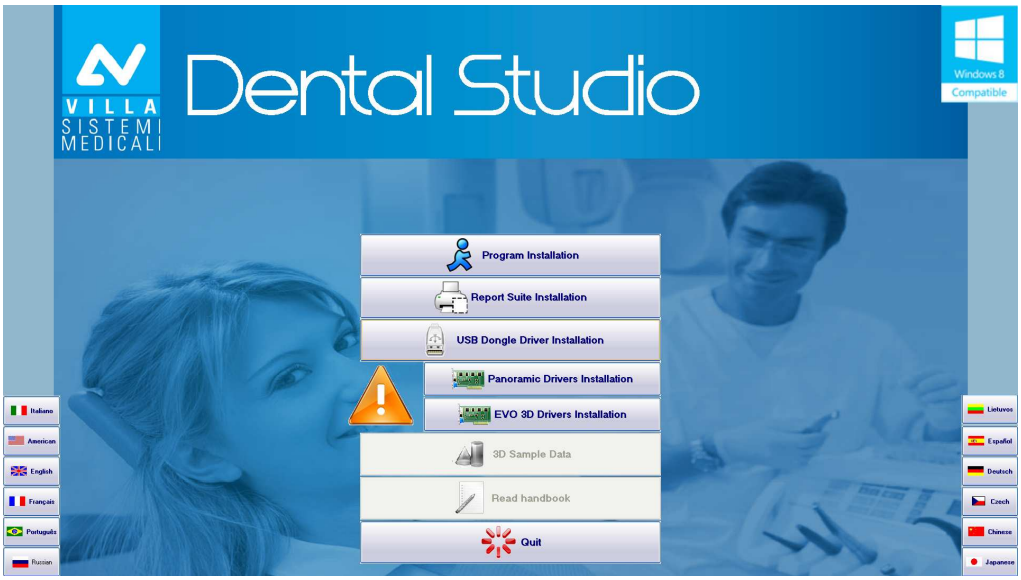


The communication between Rotograph Prime and computer uses a LAN connection. The system is provided with an Ethernet cable in order to permit the PC connection.

In case there is no communication between Rotograph Prime and computer, it is necessary to check the parameters installed in PC and equipment.

9.5.3. PC set up. DentalStudio Plus Installation

For a correct Dental Studio installation it is necessary to insert the CD and follow instruction. Without the USB license key installed.
Select "Program Installation" and after USB Dongle Driver Installation



Switch OFF the computer, insert the USB license key and restart the PC.
After Dental Studio installation, it is necessary to install Drivers for Rotograph Prime, present on the Quick Vision CD.

Select Rotograph Prime and confirm to install the Drivers

At the first use of the SW, it will be required the name of the user. This name will be always stored in the USB key.
In case you need to make some tests, without installing the user name, you can select "Close" without writing any name. The Dicom images will have the warning of "Unregistred license. Only for evaluation" but it will be possible to set the user's data at the next initialization (on customer site).

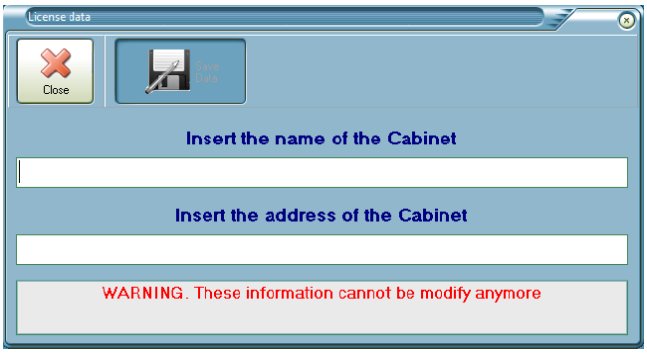


Figure 13-4

The digital sensor is set as default with IP address 192.168.0.211.
Set the PC with an IP address of the same family (i.e. 192.168.0.210) before to open virtual keyboard

Dental Studio Software allows to make measures on images and print them on a Windows printer.
A Dicom additional package is requested to activate the Dicom modalities "Worklist", "Store" and "Print".

To setup Dicom modalities, select "Utilities" icon in Dental Studio home page, the utilities window will be displayed: select "Program setup" and in the next window select "Dicom" icon. From this menu it will be possible configure "Print", "Worklist" and "Store" modalities.

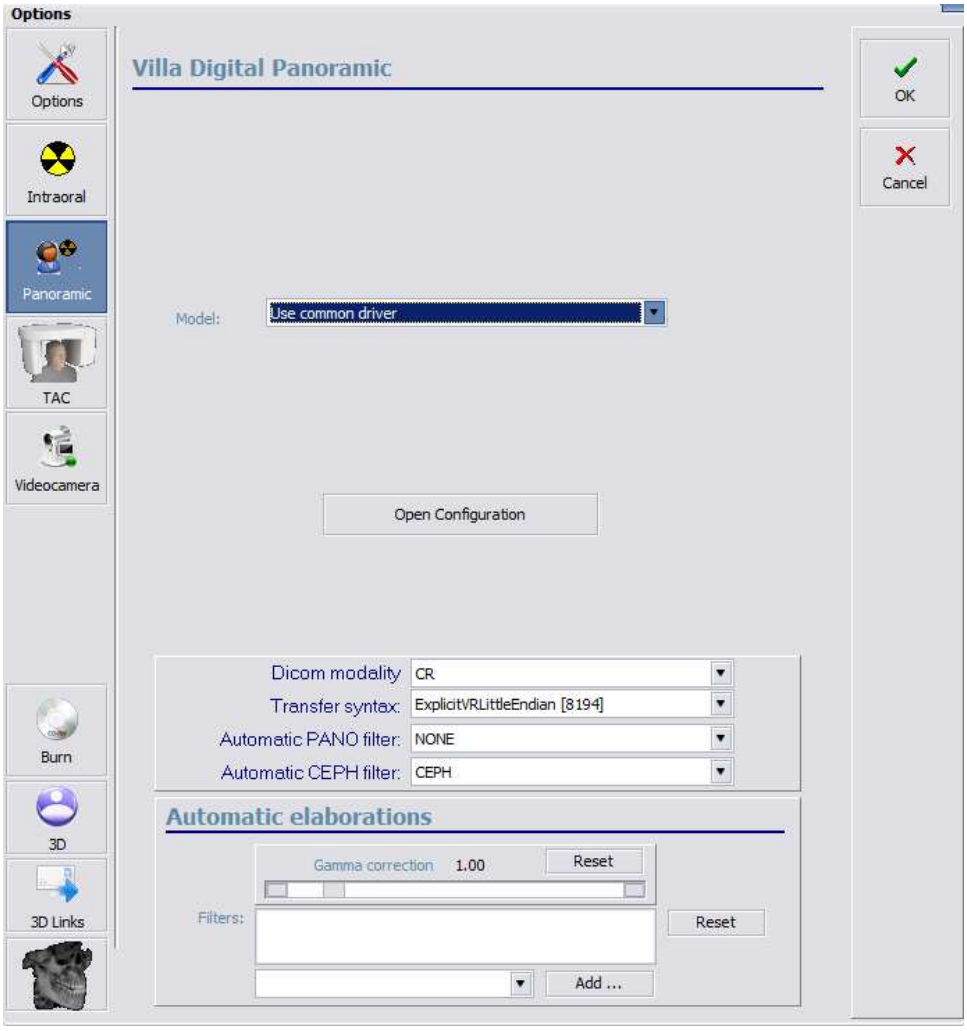
9.6. Image treatment filters setup

To perform filters setup, in the Dental Studio home page, click on "Patients" icon , select a stored patient or create a new one in the Dental Studio database and click on "Images" icon. In the top left side of the program window, select the icon "Options"; select the icon "Panoramic", in the lower part of the displayed window it will be possible to setup the filters used during acquisition; it is suggested to set:

- Sharpen minimum
- Gamma = 1.0

Confirm with "OK".

To setup post processing filters, refer to paragraph 9 of Dental Studio User Manual. It is suggested to use "Sharpen maximum" and "Media standard" filters;



9.6.1. Verification of the PANORAMIC function

WARNING:
X-rays will be emitted during the performance of the following operations. Authorized Technicians are therefore recommended to use the greatest caution and to comply with the safety regulations and laws of their country.

NOTE:
it is recommended that the verification of the exposure parameters is performed annually.

1. Switch on the machine and go to Exam Selection.
2. Open a test patient used to make the test images.
3. Select the GUI icon to open the virtual keyboard and select Pan function.

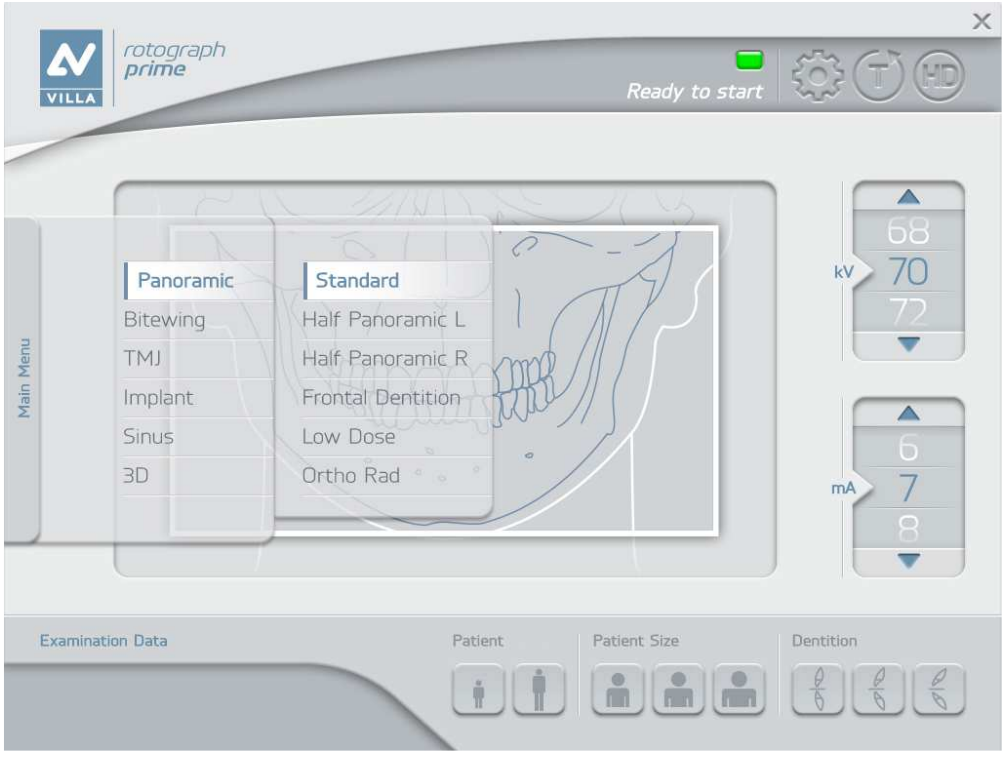


Figure 9-5

Place the centering tool (P/N 6107900200) on the chin rest and the sensor calibration tool (P/N 5607900800) in front of the sensor fixing it with tape.

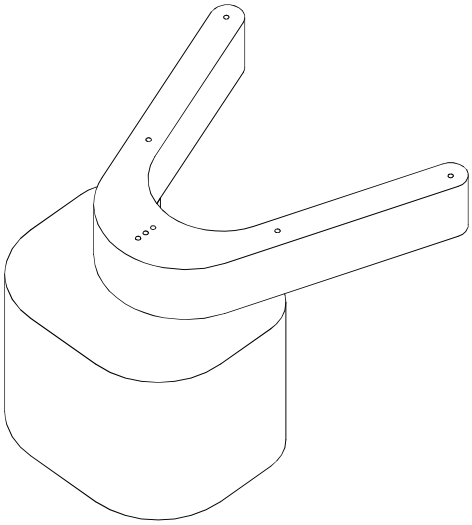


Figure 9-6
Centering tool P/N 6107900200

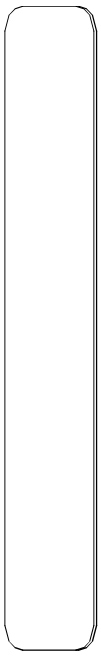
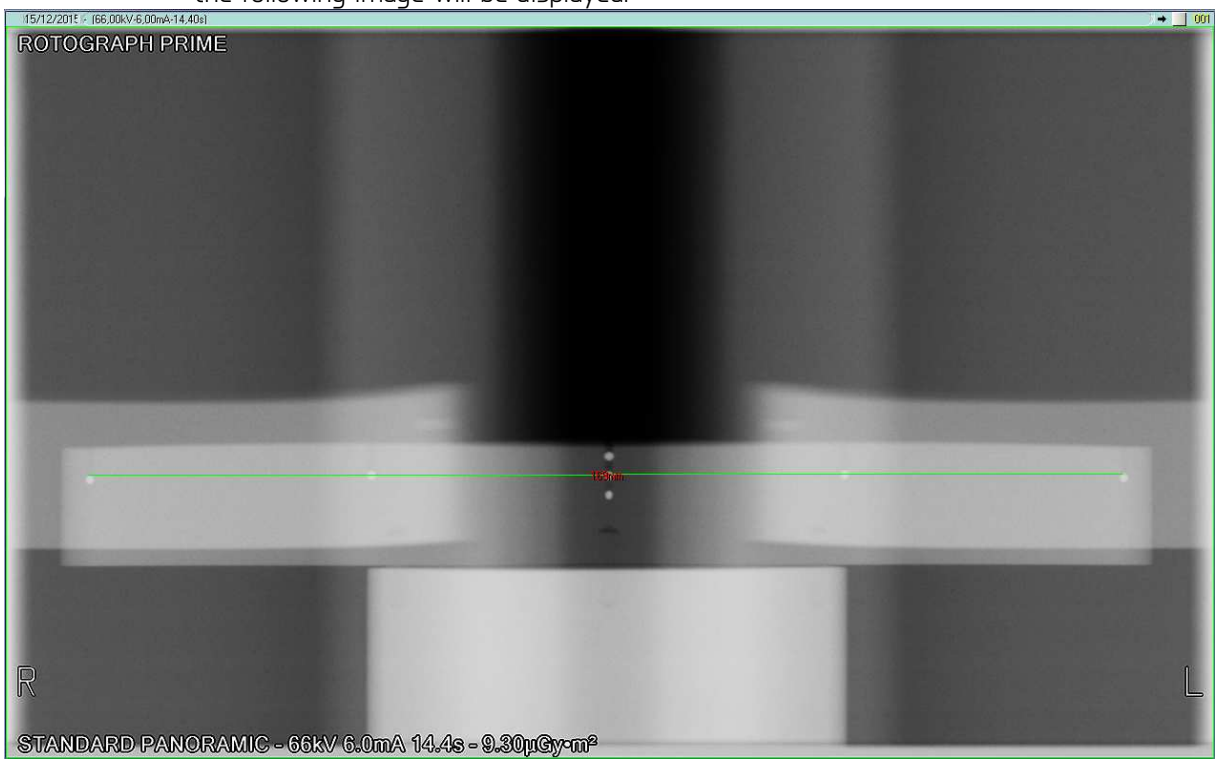


Figure 9-7
Sensor Calibration tool P/N 5607900800

4. Make an exposure in Adult mode at 68kV – 5.6mA using the copper filter or 60kV – 6mA without the copper filter, acquired in the Quick Vision program; the following image will be displayed.



5. Set contrast and brightness level to have good visibility of all centering balls. Select from the menu "Rouler" and measure the dimension of the image using as reference the two external balls. The image has to be 169mm ± 2mm.

6. Measure also the two half of the image in order to check symmetry. The difference has to be max. 1mm.
If there is not symmetry on the image, it is necessary to adjust the rotation offset entering in technical setup
Another verification of the symmetry is the alignment of the three pins in the middle of the image. The central one must be the most focused.

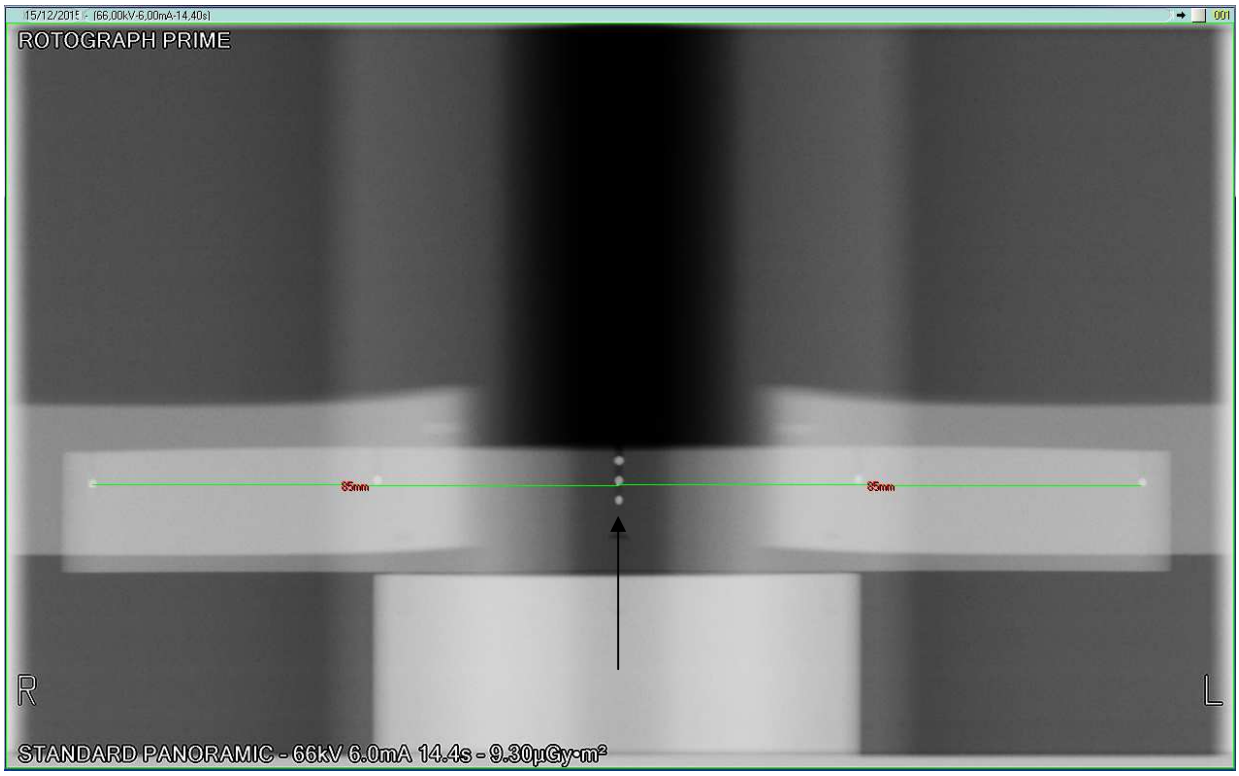


Figure 9-8

9.7. Verification of exposure parameters

Note
It is recommended that the verification of the exposure parameters is performed annually.

The exposure parameters (kV, time and dose) can be checked using two different methods:

- **"non-invasive method"**. Based on measurement with Dose meter. This is the typical method used by Phisician to verify periodically the unit
- **"invasive method"** based on the measurement of the test points on HF board (require the use of multimeter and oscilloscope for time) This method is tipically used during verification done by technical service engineers

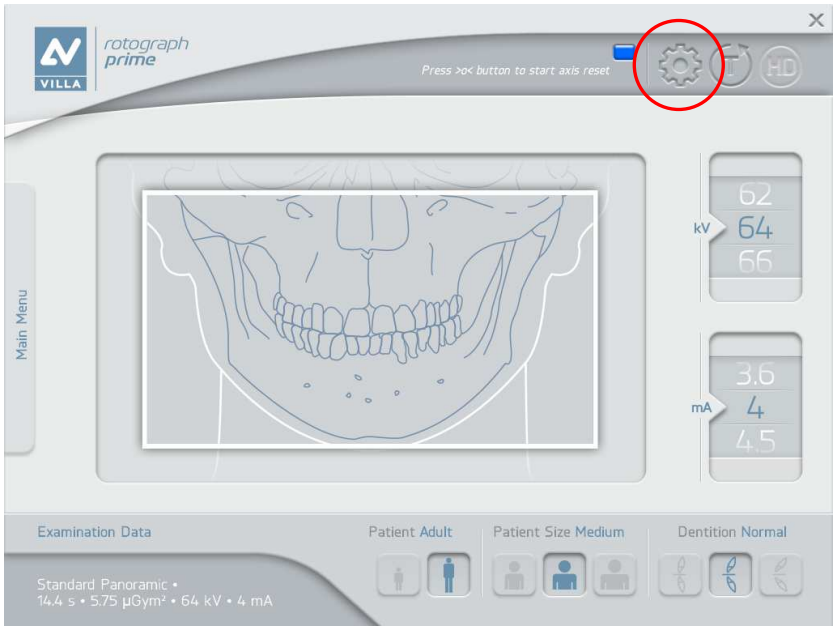
Warning
During the panoramic examination, the set value of kV and tube current varies according to a fixed curve, to compensate the variations in absorption by the patient's tissues; in this way, it is possible to obtain a good uniformity of the image contrast. In particular, the chosen value is lowered during the initial phase, and increased on the canine/incisor zone, in order to compensate the effect of greater attenuation owing to the spine.
The value displayed during the panoramic examination corresponds to the one chosen by the user, while the real value can be different; this fact must be considered if the exposure parameters are checked using standard diagnostic mode.
The accuracy of the exposure parameters kV and mA, stated in the Technical Data section, refers to the accuracy compared with the instantaneous value set by the system.
In any case, the manufacturer guarantees that the accuracy of the exposure parameters is always in compliance with the international standards for the safety of medical devices IEC 60601-1. In particular, in accordance with IEC 60601-2-63, the maximum deviation (including the correction and instrumental doubt) is less than or equal to 10 for kV, while for tube current it is less than or equal to 15%.

For this reason, in order to make easier the exposure parameters, Rotograph Prime has a dedicated modality that permit x-ray exposure without rotating the arm.

Here following the description on how to enter in this modality.

9.7.1. How to make exposure without arm rotation (paragraph for authorised personnel)

1. From Main menu, select the GEAR symbol (configuration).



2. Enter in Technical modality

and type password "TechAccess".

3. Once in setup page, set the exposure parameters and click on “Send Parameters”.

In order to permit the measurement of exposure parameters, it is suggested to set an exposure time of 1 seconds.

The unit is ready to make exposure.

Note
This program allows you to carry out the measuring of the exposure parameters with the tube-head arm in a fixed position (not rotating) without variation due to spine compensation.

9.7.2. Verification of Exposure parameters with NON invasive method (paragraph for authorised personnel)

The exposure parameters (kV, time and dose) can be checked using the so-called "non-invasive method".

Note
It is recommended to perform annually the technical factors measure according to the local rules, checking that the technical factors accuracy is within the limits given in the technical characteristics.

Warning
The device collimator gives a narrow X-ray beam.
Measurements taken with a non-invasive instrument and a narrow beam can be difficult and/or unreliable; it is therefore necessary to use a special probe with a reduced sensitive area. It may be helpful to use a fluorescent screen to locate the X-ray beam, and consequently position the probe of the kV meter.

The exposure time must be measured using a non-invasive instrument.
In compliance with standard IEC 60601-2-63, the exposure time is measured as the interval of time between the moment in which the air Kerma has reached the 50% of the peak value and the moment in which it goes down below this value.

Place carefully the measuring instrument probe in order to be sure x ray beam is reaching the probe.
Measure the exposure parameters .

Here following a suggestion of setting to verify the kV emitted by tubehead.

kV	mA	t (s)	kV acceptance limits	Time acceptance limits
60	3	1	55.2-64.8 kV	0.95-1.05 s
70	6	1	64.4-75.6 kV	0.95-1.05 s

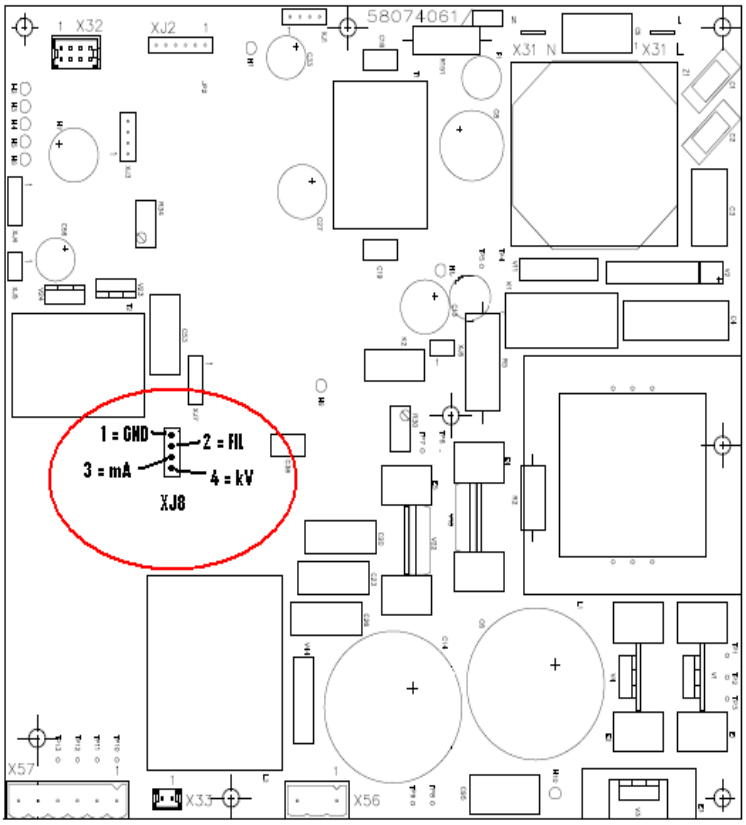
In case the result do not match the indicated values, check accuracy of kV meter sensor position and repeat the test.
If the read values are still out of range, proceed with the invasive method measurement.

9.7.3. Verification of Exposure parameters with invasive method (paragraph for authorised personnel)

Warning
The following operations involve the emission of X-rays, so the Authorised Technician must pay the greatest attention and respect the protection regulations in force in that country.

Note
It is recommended to perform annually the technical factors measure according to the local rules, checking that the technical factors accuracy is within the limits given in the technical characteristics.

Warning
These measurements require the removal of the HF group covers; this means to gain access to internal parts where high voltage are normally present.



Pin 1 is GND
Pin 2 is Filament current
Pin 3 is mA feed back SCALE => 1Vdc = 3mA
Pin 4 is kV feed back SCALE => 1Vdc = 20 kV

Here following a suggestion of setting to verify the kV emitted by tubehead.

kV	mA	t (s)	kV acceptance limits (V) 10%	mA acceptance limits (V) 8%
60	3	3	2.76 – 3.24 V	0.9 – 1.1 V
70	6	3	3.22 – 3.78 V	1.8 – 2.2 V

In case the result do not match the indicated values, verify if error message is present on the GUI and follow troubleshooting to solve the problem

9.7.3.1.1. Time

Verify the accuracy of the exposure time using an oscilloscope connected at the same test points used to measure mA (XJ8 pin 1 for GND and XJ8 pin 3 mA) of the Generator board. The exposure time calculated at about 75% of the maximum kV value, must correspond to the set one ±10%. In case the time is outside the prescribed values, replace the CPU.

9.7.4. Backup

At the end of installation, take note of the following parameters :

IP address of the PC
IP address of Rotograph Prime
Be sure that digital sensor Calibration files CD is archived
Verify that the SW package is archived
Take note of the DICOM configuration, if present (AE title, IP address, etc)

1.1.1.1 Table of pre-set anatomic parameters

PANORAMIC

	Adult	Child
Small	64 kV 5,6 mA	64 kV 4,56 mA
Medium	66 kV 5,6 mA	66 kV 4,5 mA
Large	68 kV 5,6 mA	68 kV 4,5 mA

TMJ open/close mouth

	Adult	Child
Small	64 kV 5,6 mA	64 kV 4,5 mA
Medium	66 kV 5,6 mA	66 kV 4,5 mA
Large	68 kV 5,6 mA	68 kV 64,5 mA

SINUS

	Adult	Child
Small	64 kV 5,6 mA	64 kV 4,5 mA
Medium	66 kV 5,6 mA	66 kV 4,5 mA
Large	68 kV 5,6 mA	68 kV 4,5 mA

Bitewing right/left/bilateral

	Adult	Child
Small	68 kV 5,6 mA	68 kV 5,6 mA
Medium	68 kV 5,6 mA	68 kV 5,6 mA
Large	68 kV 5,6 mA	68 kV 5,6 mA

10. USER PERIODIC MAINTENANCE

This unit, like all other electrical appliances, must be used correctly and also serviced and controlled at regular intervals. This precaution ensures a safe and efficient performance.

The periodical maintenance consists in checks performed by the operator himself and/or by a qualified Technician.

The operator can control the following items:

Frequency	Type of check	Method
Daily	Functioning of the indicator lights	Visual inspection
Daily	Check communication with the PC	Visual inspection
Daily	Check that the cables do not show signs of breaking or wear	Visual inspection
Daily	Check that the unit is not damaged externally as to compromise the safety of protection from radiation	Visual inspection
Daily	Check that there are no traces of oil on the tube-head	Visual inspection
Daily	Check that the arm movement is smooth	Practical inspection
Monthly	Integrity of equipment and labels	Visual inspection

Warning
If the operator detects irregularities or failures, he must immediately call the Technical Service.

MAINTENANCE LOGBOOK

Installation: Date ..... Technician .....

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

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

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

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

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

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

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

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

11. TECHNICIAN PERIODIC MAINTENANCE

As with all electrical appliances, this unit must be used correctly and maintenance and inspections must be made at regular intervals. Such precautions shall guarantee the safe and efficient function of the appliance.

Periodic maintenance consists in inspections made directly by the operator and/or Technical Service Department.

Verify that after installation the unit has been checked in terms of electrical safety according to IEC 62353. Use the values as reference for the next measurements.

Warning

The operator is recommended to perform these inspections before each session of operations.
If the operator detects irregularities or damage, he should immediately inform the Technical Service Department.

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

Frequency	Type of check	
Annually	Correct machine centering	
Annually	Performs sensor calibration	
Annually	Verify that the fixing screws are tightened	
Annually	Verify the exposure parameters	
Each visit	Functioning of the indicator lights	Visual inspection
Each visit	Check communication with the PC	Visual inspection
Each visit	Check that the cables do not show signs of breaking or wear	Visual inspection
Each visit	Check that the unit is not damaged externally as to compromise the safety of protection from radiation	Visual inspection
Each visit	Check that there are no traces of oil on the tube-head	Visual inspection
Each visit	Check that the arm movement is smooth	Practical inspection

The appliance's performance is checked and, where necessary corrected, during the maintenance activities performed by the Technical Service Department, in accordance with the indications provided in the following chapters. Such interventions are recorded in the "Maintenance Logbook" in the Service Manual.

The periodic maintenance performed by the Technical Service Department comprises the performance of the following additional inspection activities to be made yearly:

- general visual inspection
- grounding of all the accessible conductive parts
- condition of the internal and external cables: wear and tear and fastenings
- the tightening of the primary bolts and screws such as the wall fastening systems, the moving mechanisms and the chin rest arm
- the status of cleanness of the console
- the correct functioning of the luminous indicators of the console
- verification of the exposure parameters: kV, mA, time
- verification of the correct function and status of cleanness of the laser centering devices

Warning

The operator is recommended to perform these inspections before each session of operations.
If the operator detects irregularities or damage, he should immediately inform the Technical Service Department.

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.

11.1. Service tools

In order to perform a correct system calibration, is necessary the use of the following tools:

Code	Description	Function
6107900100	Laser centering tool	Used for Panoramic function adjustment and calibration
6107900200	Symmetry check tool	
5209900900	Digital sensor centering tool	Used for Sensor calibration and Cephalometric arm checks
5607900800	Copper filter for Digital sensor	

12. TROUBLESHOOTING

12.1. LEDs description

12.1.1. Generator board LEDs

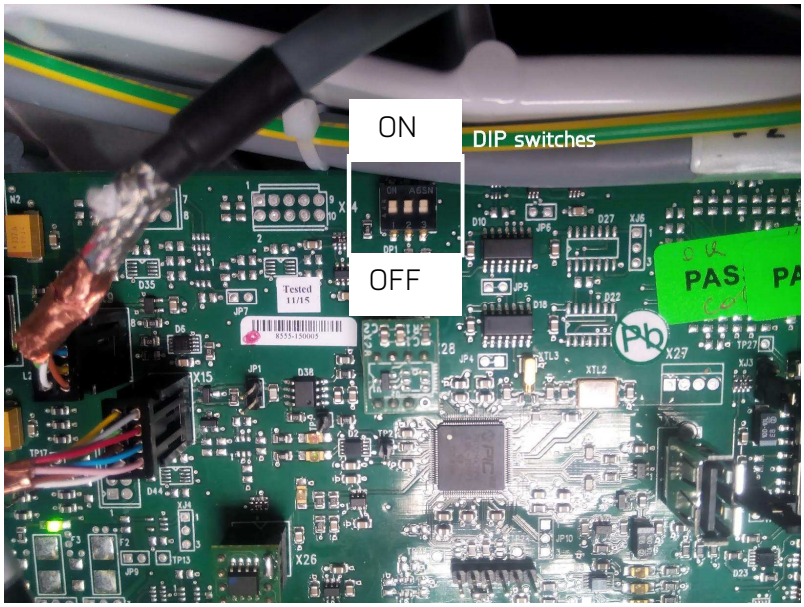
Led	Colour	Std-By status	Status	Function
H1	Green	ON	OFF = Failure	+5Vdc
H2	Green	OFF	ON when exp button pressed	X-Ray button pressed
H3	Green	ON		CanBus
H4	Green	ON		CanBus
H5	Red	OFF	ON = Failure	Filament not working/ No X-Ray emission / H9 ON
H6	Yellow	OFF	ON during x-ray	X-Ray emission active
H8	Green	ON	OFF = Failure	Auxiliary power supply
H9	Red	OFF	ON = Failure	X-Ray exposure too long.
H10	Green	ON	OFF = Failure	Main power supply present

12.1.2. CPU board LEDs

Led	Colour	Std-By status	Status	Function
H6	Green	Flashing	OFF= Failure	CanBus data
H7	Green	Flashing	OFF= Failure	CanBus data
H11	Green	OFF	ON when exp button pressed	X-Ray button pressed
H8- H9- H10		OFF		Not used; only for Service

12.1.3. CPU board DIP switches

1	2	3	Function
OFF	OFF	OFF	Normal mode
OFF	ON	OFF	Exibition Demo mode Allows rotation without x-ray emission
OFF	OFF	ON	Axis Alignment Service Mode – used to check laser centering rotating from 90° and 180° position by pressing >O<
OFF	ON	ON	Allow exposure without rotation. Used to measure KV



12.2. CPU Firmware upgrade

Here below the instructions for the firmware upgrade:
1. unzip the folder PRIME FIRMWARE.zip and copy the content into a USB stick
2. switch-off the Prime
3. insert the USB stick into the usb port of the CPU
4. switch-on the PRIME and wait until the LED close to the USB port will stop to blink
5. switch-off the Prime
6. move the USB stick into the usb port of the DSPU
7. switch-on the PRIME and wait until the two green LED (power and ready) will be lighted (more or less 2 minutes)
8. switch-off the Prime and remove the USB stick

12.3. Displayed messages

Rotograph Prime is fully driven by a microprocessor which controls the programming of the emission parameters and indicates via displayed messages the different conditions of the unit and any defects and errors that occur.

The messages are divided into two groups:

- **Operational messages**: messages that guide the operator in setting up the unit for performing an examination (see User Manual).
- **Error messages**: messages that are displayed when an error occurs. There are three types of error messages:

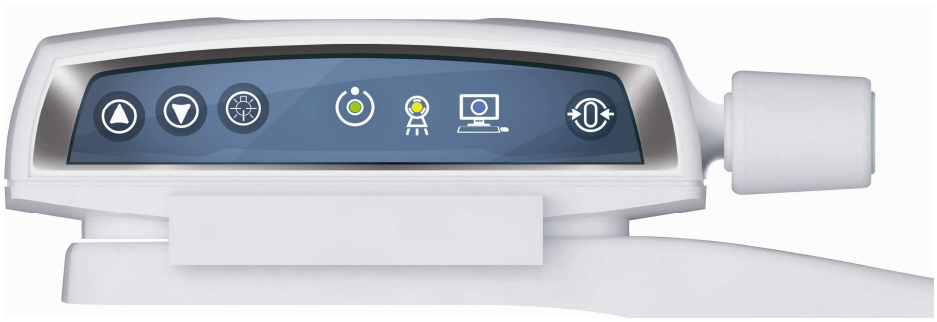
There are two light indicators; the first one on the top indicates the condition "Machine Ready", indicating the user that by pressing the X-ray button key once more, X-rays emission will start; the second indicates the effective emission of X-rays.

Computer connection status light indicator:

- Blue fixed, computer connection established,
- Blue blinking, waiting for computer connection. No X-ray emission available.

1 - Messages that could have been caused by the operator when releasing the X-ray button or pressing key "Patient entrance"

(7)  when a movement is in progress.



Operating conditions are reset by pressing key (7)  .

2 - Messages arising from a system defect. In this case, the Technical Service must

be called.

3 – Messages related to problems regarding the Generator board. In this case, the unit must be switched off. Wait a few seconds for the circuit capacitors to discharge and then switch the unit on again. If the problem persists, call the Technical Service.

The error messages are divided into different areas that can be distinguished by the error number; the following table contains the different errors with meanings.

Main CPU board (A5)		
Code	**Error description**	**Reference chapter**
108	Hardware key A13 fault or missing	**1.1.1.2**
Rotation motor		
Code	**Error description**	**Reference chapter**
200	Zero position optical sensor of rotation axis always activated	**1.1.1.3**
201	Zero position optical sensor never activated	**1.1.1.3**
204	Unexpected activation of rotation optical sensor	**1.1.1.3**
205	Timeout on rotation	**1.1.1.4**
206	Rotation motor collision	**1.1.1.4**
Y motor		
Code	**Error description**	**Reference chapter**
240	Zero position micro Y always active	**1.1.1.6**
241	Zero position micro Y never active	**1.1.1.6**
242	Unexpected activation of Y axis	**1.1.1.6**
243	Timeout on Y axes	**1.1.1.6**
Column UP/DOWN		
Code	**Error description**	**Reference chapter**
260	Movement timeout	**1.1.1.6**
261	Up sensor activation	**1.1.1.6**
262	Down sensor activation	**1.1.1.6**

X-ray Controls		
Code	**Error description**	**Reference chapter**
360	RX button pressed on start-up or before exam	1.1.1.7
361	Remote RX button pressed on start-up or before exam	1.1.1.7
362	RX button released during emission	1.1.1.8
Sensor ready		
Code	**Error description**	**Reference chapter**
370	Sensor ready lost during exposure	1.1.1.10
371	Operation not completed because sensor not ready	1.1.1.11
372	Not possible to execute because cooling time	1.1.1.11
CanBus		
Code	**Error description**	**Reference chapter**
380	Invalid CANBus message	1.1.1.10
DSPU		
Code	**Error description**	**Reference chapter**
400-411	DSPU errors	1.1.1.7
1000-1006	DSPU errors	1.1.1.7

Generator Board A10		
Code	**Error description**	**Reference chapter**
750	Generator board initialization error	**1.1.1.13**
751	Alarm "overvoltage kV"	**1.1.1.14**
752	Alarm "overload on filament" on Generator board	**1.1.1.15**
753	Alarm "overload anodic current"	**1.1.1.15**
754	Alarm "filament not OK"	**1.1.1.16**
755	Alarm "backup timer"	**1.1.1.18**
756	Alarm "PFC not OK"	**1.1.1.17**
758	Alarm "NO X-ray"	**1.1.1.18**
759	Alarm "unexpected emission"	**1.1.1.18**
760	Alarm "NO RX button command"	**1.1.1.19**
761	Alarm "NO X-ray emission"	**1.1.1.18**
762	Alarm "NO X-ray feed back"	**1.1.1.20**
Vertical motor		
Code	**Error description**	**Reference chapter**
800	Timeout on CAN activation for vertical motor	**1.1.1.23**
801	ON/OFF command for vertical motor not changed on planned time	**1.1.1.24**
Keyboard		
Code	**Error description**	**Reference chapter**
850	One or more keycodes are pressed	
851	One or both column keys are pressed	
852	Button <0> pressed during movements	

12.3.1. Errors with code from E000 to E199

All these are errors related to the main CPU board and its internal peripheral.
Power off the unit and, after 1 minute delay, power it ON again; if the error is displayed again, replace the CPU board.

1.1.1.2 E108: Hardware key fault

This error is shown when the firmware of the Rotograph Prime does not sense the presence of the U.I.C. (Unique Identification Code).
The unique code is read, with is check byte, from the control system at the start-up; if the check byte is incorrect, the system displays the above error number.

In case this error is displayed, a pressure of key " Patient entrance " (7)

allows the system to continue its functioning, but only standard base examination will be possible.
Verify the presence of the key and that is well inserted.

In case there is a fault on the hardware key itself, it must be replaced. **All the optional features must be re-enabled with proper codes.** Before requesting a new hardware key, the S/N of the equipment and/or the U.I.C. itself must be recorded and reported to Villa Sistemi Medicali.

12.3.2. Errors with code from E200 to E299

These errors are related to the various axis movements and require the replacement of some parts; only the following error message E206 can be generated by a special condition and can be reset.

1.1.1.3 E200: Zero position optical sensor of rotation always active / E201: Zero position optical sensor of rotation never active / E204: Unexpected activation of zero position rotation sensor

These messages mean that, during the rotation, there is no change or an unexpected activation of the optical sensor B3.
The position of rotation is controlled by the optical sensor B3, that is activated at the start of the rotation travel; if this sensor is found active at the start up phase, and it is never sensed de-activated, the E200 message error is displayed, meaning that the sensor itself is broken or that the motor is not running.
In case that it is never sensed activated, the E201 is displayed, and the reasons are the same.
E204 means that, during some movements, the sensor changes its status to activated in an abnormal condition.

Entering the rotation motor service program it is possible to check the cause of the error.

In normal conditions the display must visualise "X" in place of the character "a".
In all cases, the sensor's functionality can be checked by placing an opaque thin material in the optical path and looking at the voltage coming out from the sensor.
Using the left and right arrows it is possible to rotate the arm, checking if the status of sensor changes accordingly.

1. If there is no variation of the above signals, if the arm does not move or moves with difficulty or jumps:
   - check the belt and verify that it is not broken; if the belt is loose, adjust its tension
   - check cable of stepper motor; there can be a short circuit or a broken wire; check also for a loosen contact. In case of short circuit, replace the cable, verifying also that no damage has been caused to the motor driver on the CPU.

2. If the arm moves, verify the cable up to the CPU board (A5). If it still continues to have no variation of the signals when there is an activation of the switches, change the CPU board.

1.1.1.4 E205 Timeout on rotation

This message means that no change on the rotation's signal is detected; please follow the steps described above.

1.1.1.5 E206 Rotation motor collision

This message means that during rotation an object touch the unit. Typically the problem is due to patient movements with shoulder in touch with rotation arm

1.1.1.6 E240: Zero position sensor for Y axes always active / E241: Zero position sensor Y axes never active/ E242: Unexpected activation of Y axes E243: Timeout of Y axes

These errors are signalling a problem on the Y axis movement.

Entering in the Y-axis service program it is possible to check the cause of the error.

In normal conditions the display must visualize "X" instead of the character "a".

Using the left and right arrows it is possible to rotate the arm, checking if the status of the sensor changes accordingly.

1. If there is no variation of the above signal, if the arm does not move or moves with difficulty or jumps.
   - Check the belt and verify that it is not broken; if the belt is loose, adjust its tension
   - Check cables of the Y axes motor; there can be a short circuit or a broken wire; check also for a loosen contact. In case of short circuit, replace the cable, verifying also that no damage has been caused to the motor driver (D27) on the CPU.

2. If there is no variation of the above signal and the arm moves, verify the cable from the optical sensor up to the CPU board (A5). If still there is no variation of the signals when there is an activation of the switches, change the CPU board.

1.1.1.7 E360 and E361: X-ray button pressed during power on

This message is displayed if, during the power on procedure, the X-ray button, local (E360) or remote (E361) have been sensed as pressed. Release the button if it was pressed: the error condition is reset powering off the unit and on again.
If the error is still present, check the continuity of cables of the interested button. For the local one, S8, it is connected to X18 of the keyboard and it is transferred to the main CPU using the CANBus cable.

- Check that the cable X18-X18 to the main CPU is well inserted and its continuity.
- From the main CPU, the signal is routed to the Generator board (A10), using the CANBus cable X20-X20; check also that this cable is well inserted and its continuity. Replace it if damaged.
- If the error is still present, check the correct insertion of the flat cable between the Generator CPU board (A9) to the Generator board (A10). The cable is labelled X53-X53; replace it if damaged.

WARNING:
On the Generator board (A10) there are dangerous high voltages, 230 VAC and 400 VDC.
Before accessing the Generator CPU and power board (A9 and A10), it is mandatory to switch off the mains and wait up to 2 minutes in order to allow the discharge of the capacitor.

1.1.1.8 E362: X-ray button released during the examination procedure

X-ray emission is commanded using the technique called "dead man's switch", that means that it must be held pressed down until the end of the emission, also during the interrupted emission phase of TMJ.
If this does not happen, the above error message is displayed; the emission is stopped and all motors released in order to allow for the patient's exit.
Press the reset button and restart the operation as suggested by the control system.

1.1.1.9 E370/E371 error on sensor

Error "sensor signal" was lost during exposure or sensor is not ready.
Check connections between CPU and DSPU. May be a cable is damaged and in some angles during rotation interrupt communication between sensor and CPUE372: Exposure not allowed because cooling time not completed

X-ray button has been started while cooling time is still decreasing. Wait until cooling time stop before to try another exposure..

1.1.1.10 E380: Invalid CANBus message (from Generator CPU board A9)

This error is displayed when the main CPU board (A5) receives an invalid message from the Generator board (A10); that is a message which contents is not listed on the valid data dictionary of the unit.
This can be generated by a bad connection or by a fault of the local Generator CPU board (A9).
Check the CANBus cable X20-X20 and replace it if faulty, otherwise replace the Generator CPU board or then the Generator board.

1.1.1.11 E381: Timeout on activating CAN protocol on Generator board / E382: HF not answering to CAN protocol

These two messages have the same meaning, that is a no answer to main CPU from CAN messages, but their occurring is in different times.
E381 is generated during power on, while E382 is displayed after a regular power on sequence.
In both cases, the error can be generated by a bad connection of the CANBus or a fault on the local Generator CPU board or a foult on the Generator board, so the steps above described for E380 are applied.

1.1.1.12 E400-411 E1000-1006: DSPU errors

This range of errors is dedicated to DSPU problems. Verify if DSPU is powered, check connections and in case replace DSPU

12.3.3. Errors with code from E700 to E799

WARNING:
Those errors are related to the X-ray generator, so they can be safety related.
In case of Error messages E759 and E755, the system must be immediately powered off, because there is an unexpected emission (E759) or the emission has not been terminated into the expected time.

WARNING:
On the Generator board (A10) there are dangerous high voltage, 230 V AC and 400 VDC.
Before accessing the Generator CPU and power board (A9 and A10), it is mandatory to switch off the mains and wait up to 2 minutes in order to allow the discharge of the capacitor.

1.1.1.13 E750: No power to the Generator board

This message is signalling that the Generator board (A10) is not powered.

Check that if LED H3 of the Generator board is ON; in affirmative case, check connector X53 insertion and insert it correctly. Check the voltage between TP21 and TP22; it should be 10 V DC 2 V; if the value is inside the range, replace the Generator CPU board (A9). If the value is zero (or very low), replace the Generator board.
If LED H3 is off, perform the appropriate operations as described in the previous chapter.

1.1.1.14 E751: Over voltage kV

This message is displayed when a value higher than expected has been detected on the Generator board (A10).

Check that connector X57 is well inserted. With the connector inserted, measure the resistance between pins 2 and 4 of connector (harness to tubehead) that should be 13.3k ± 2% while is 14.3k ± 2% between pins 4 and 3 of the same connector; if correct values are measured, replace before the tubehead and, eventually, the Generator board.
If incorrect values are measured, replace the tubehead and then the Generator board.

Insulation measure between signals	X57-5/6 e X57-4	Infinieo (scale M)	
Feedback kV +	X57-4 e X57-2	20 k 1%	19,8 20.4 k
Feedback kV -	X57-4 e X57-3	20 k 1%	19,8 20.4 k
Feedback mA	X57-4 e X357-1	330 1%	326 334

1.1.1.15 E752: Filament overload / E753: Overload on Anodic current

These messages are displayed when an abnormal value of filament current or anodic current have been detected.

Replace the tubehead and then the Generator board.

1.1.1.16 E754: Broken filament

This message is displayed when there is a fault on the power circuit of the filament, not only the filament itself.

Check that connector X56 is well inserted.
Check the continuity of wires from X57 to the tubehead.
Verify the correctness of pre heating parameters.
If all OK, replace the tubehead.

Parameter	Measuring points	Value	Limiti
Measure of filament	X57-5 e X57-6	< 0.5	
Measure of primary winding HV	X56-1 e X56-2	< 0.5	
GND measurement	X57-4 and tube head metallic frame	< 0.5	

1.1.1.17 E756: PFC failure

This message is signalling that the PFC (Power Factor Control) circuit is not correctly functioning.

If the error is present in stand-by mode, replace the Generator board (A10).
If the error appears during an exposure, reset the error and repeat the exposure; if the error still appears, replace the Generator board and then the tubehead.

1.1.1.18 E755: Alarm "Backup timer intervention" / E758: Alarm "No X-ray" / E759: Alarm "Unexpected emission" / E761: Alarm "No X-ray emission"

The correctness of X-ray emission is checked by the Generator board (A10) measuring the anodic current against the set nominal value. When the system is in the idle mode, that is in a non emitting state, this signal must be low, and the Generator CPU board (A9) is checking this condition. If this does not happen, the E759 message is displayed.

When the CPU command for the emission, the X-ray on signal is set to on condition when it reaches the 75% of its set value at the beginning and is higher than 25% at the end of emission.
If the first condition is not met, the exam is halted and the system has to be reset, and the **message E758 "No X-ray"** is displayed.
In this case, check the correct insertions of X56 and X57 between the Generator board to the tubehead and X53-X53 (flat cable) between Generator board (A10) and Generator CPU board (A9).
Check the CANBus connection between the Generator CPU board (A9), and the main CPU A5 (cable X20-X20).
If all connections are OK and the fault is repetitive, same as for Led H1 in chapter 12.1.1.

If the second condition is not met, that is, the X-ray emission do not fall under the value in a pre set time, the **message E759 "Unexpected emission"** is displayed. This message can be also displayed if the signal X-ray on is sensed during the idle state.
In this case, check the main CPU board (A5) and the Generator CPU board (A9) and the cable X20-X20. If all OK, replace the Generator board.

The emission is controlled also through a safety backup timer that interrupts the power to the tubehead also in case of a fault (hardware or software) to the Generator CPU board. The intervention of the backup timer, **message E755**, is signalled by a lighting of the red LED H4.
This alarm can be reset only by powering off the unit, wait for few seconds and power it on again. If the LED H4 continues to be ON, replace the Generator board.
If the LED, after the power ON is not lighted, repeat an emission and, if the message is appearing again, replace the Generator board.

1.1.1.19 E760: Alarm "NO RX button command"

This message is displayed when the Generator CPU board (A9) is not detecting the RX button during the emission start-up.

In this case, check the correct insertions of X53-X53 (flat cable) between Generator board and Generator CPU board (A9).
Check the CANBus connection between the Generator CPU board (A9) and the main CPU A5 (cable X20-X20).
If the error is still present, check the cable of the RX button. It is connected to X18 of the keyboard and it is transferred to the main CPU.
If all connections are OK and the fault is repetitive, replace the Generator CPU board (A9).

1.1.1.20 E762: Alarm "NO X-ray feedback"

This message is displayed when the Generator CPU board (A9) is not detecting the X-ray emission feedback signal.

In this case, check the correct insertions of X53-X53 (flat cable) between Generator board and Generator CPU board (A9).
Check the CANBus connection between the Generator CPU board (A9) and the main CPU A5 (cable X20-X20).
Check the correct insertion of X56 and X57 between the Generator board to the tubehead.
If all connections are OK and the fault is repetitive, replace the Generator CPU board (A9).

1.1.1.21 E774: RX button not pressed

This error message is displayed when the Generator CPU board (A9) is not detecting the X-ray button pressed also if the main CPU (A5) has commanded the emission with the corresponding CANBus message.
In this case a possible interruption on cable X20-X20 from main CPU A5 to control CPU A9 is possible.

From the main CPU, the signal is routed to the Generator board, using the CANBus cable X20-X20; check also that this cable is well inserted and its continuity. Replace it if damaged.

If the error is still present, check the correct insertion of the flat cable between the Generator CPU board to the Generator board. The cable is labelled X53-X53; replace it if damaged.

1.1.1.22 E775: RX button released during the emission

This message has the same meaning as the corresponding error E362, but it is generated by the Generator CPU board (A9), that is signalling a possible broken connection with the main CPU (A5).
Repeat the test as per error E774 above.

12.3.4. Errors with code E800 and E801

These messages are signalling an error caused on the column movement.

1.1.1.23 E800: Timeout on CAN activation for vertical motor

This error is displayed when there is no answer to main CPU board (A5) from CAN messages during power on.
The error can be generated by a bad connection of the CANBus or a fault on the Column CPU board (A1).

Check the CANBus cable X11-X11 and replace it if faulty, otherwise replace the Column CPU board.

1.1.1.24 E801: ON/OFF command for vertical motor not changed on planned time

This message is displayed when there is a fault on the column movement.

Check that the column movement power supply fuse F4 is not blown.
Check the safety column movement microswitches work correctly, otherwise replace the microswitches assy (microswitch + cable).
CANBus cable X11-X11 and replace it if faulty, otherwise replace the column CPU board.

12.3.5. Errors with code E850, E851 and E852

These messages are signalling an error caused on the operator's interface.

1.1.1.25 E850: More than one button pressed during power on

During the power on phase, the local control board of the keyboard is controlling that during power on no more than 1 button is pressed.
Only the case of column up/column down is allowed and used to enter the set up procedure, so if this procedure is started without an explicit request, it means that those buttons are pressed.
In this case, replace the keyboard membrane and after the control board.

Otherwise the following message is displayed:

Release the corresponding key if pressed and repeat the power on procedure. Otherwise replace the keyboard membrane and after the control board A4.

1.1.1.26 E851: Column up or Column down pressed at power on

This message is signalling that only one of the two buttons is pressed.
Release the pressed button and power off the system and power on it again. If the message is displayed again, replace first the keyboard membrane and after the control board.

1.1.1.27 E852: One key pressed during the movement

During the system monuments, the keyboard is inactive, but at the pressure of one button all movements are stopped and this message is displayed.
This is useful in case an abnormal motion is detected, for instance the column does not stop at the release of the corresponding button but still continues to move.
Check if one button has been involuntary been pressed and restart the operation with a new power on procedure.
In case there is a stuck key, one of the previous message E850 and E851 must be displayed, so acts accordingly.

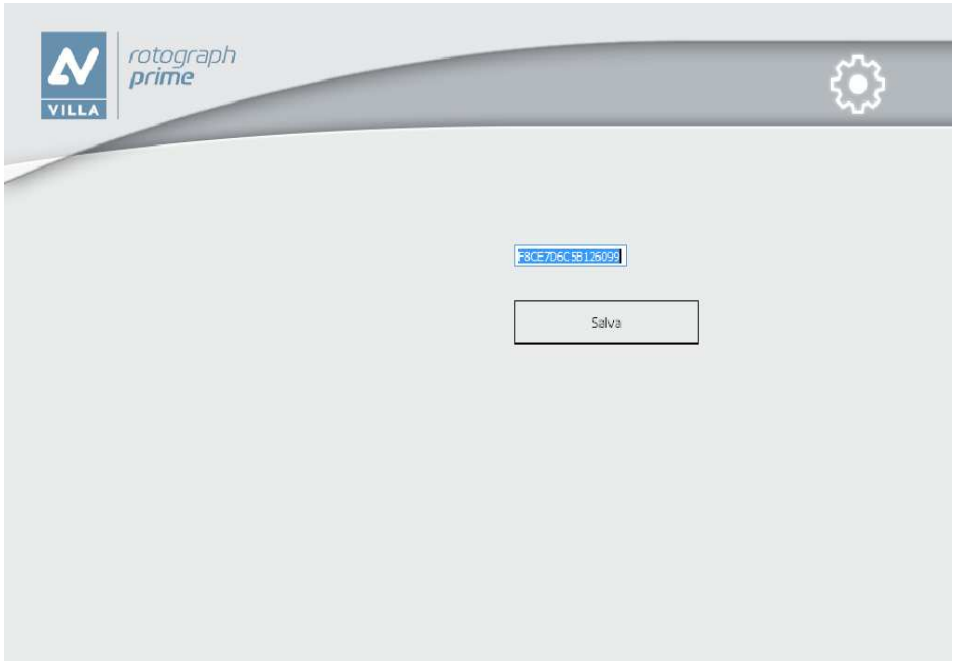
1.1.1.28 E852: One key pressed during the movement

12.4. Service programs descriptions

In order to access Service programs,
from Main Menu select the symbol GEAR (configuration) 

The first page show the SW versions present in the unit. This is useful in case it is required to know the actual versions. This page doesn't require any password.

In order to set up the DXP package, or see if it is active, type the password "PackAccess"



In case you have to set up the code, type it in the window, then click on Save. Exit setup  and switch OFF the unit before to verify if the package has been accepted

In order to enter in Configuration menu, type the password " TechAccess".

This page is reserved only to authorised technicians : it permit access to the different functional parameters

The pages are the following :

- ***Network Setting :*** Permit to set the IP address of the sensor
- ***Exposition:*** permit to read the number of exposure done with the unit
- ***Axis Alignment :*** Permit to adjust motor Offset, used to center rotation offset (for image symmetry), Y axis (for panoramic image size) and Y axes Bitewing (for Bitewing centering)
- ***Preheating :*** Permit to adjust the filament parameters. It is used only in case of tubehead replacement
- ***Centering :*** Permit to make an image without rotation acquiring the image of the x-ray beam on the sensor (used to verify centering)
- ***Logs :*** used to create log files for Service purpose

Each time a parameter is modified, or a different sub menu is selected, the unit will provide the following confirmation page.

12.4.1. Network Setting

Selecting Network Setting it is possible to modify the IP address used to communicate with the Rotograph Prime.

If necessary, change the IP Address according with the one present on the PC (same Subnet mask, but last 3 digits different)

Clicking on Show unit configuration, it is possible to check SW versions

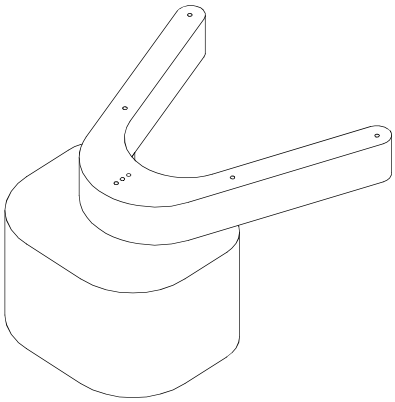
12.4.2. Exposition

This function permit to read the number of exposures done by the unit (not jet available)

12.4.3. Axis Alignment

This function need to verify and adjust x-ray beam alignment , image dimension, laser adjustment, in case of tube head replacement, or CPU replacement, or digital sensor replacement, or if the tests performed after installation are not providing the correct values

To verify the image it is suggested the use of the Centering tool



Centering tool P/N 6107900200

Image acquisition parameters can be set adjusting the parameters in the right side of the screen (in the photo highlighted in red square). Selecting Send Parameters the unit is ready to acquire an
image.

Making exposures with this function, it is possible to make the correct adjustments on the parameters in order to match the specifications.

Here following the description of the parameters highlighted with green square :

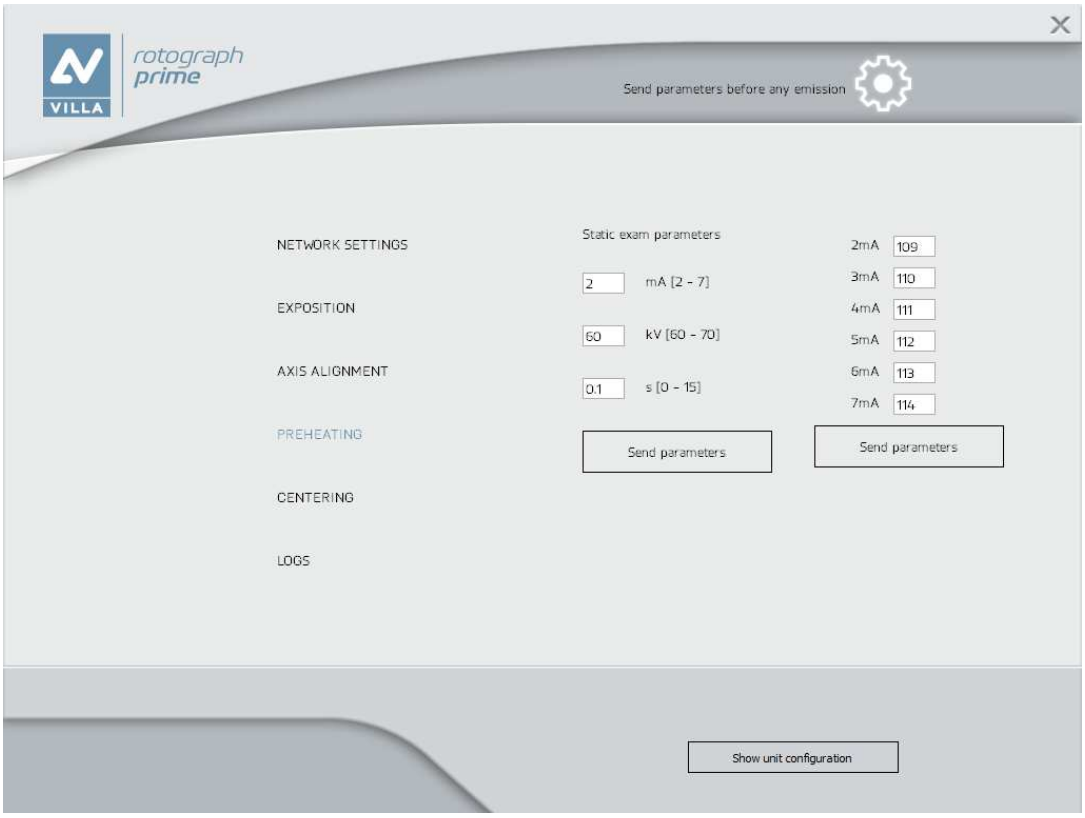
- Adjust on Unit permit to adjust the parameters directly on the unit instead on PC interface. It is useful mainly to verify the laser centering
- Rotation is used to adjust Shymmetry on the image
- Y Axis is used to adjust the size of the image in Panoramic mode
- Y Axis Bitewing is used to adjust the center the image in Bitewing mode
- Send Parameters permit to save the parameters in the Rotograph Prime CPU

Parameters can be adjusted on computer interface, or (mainly in case of laser verification) directly on the unit keyboard. In this case it will be necessary to click on the button Adjust on Unit"

UP/Down buttons change the value. The icon >O< store the values.
Stored values can be read on the PC user interface.

12.4.4. Preheating

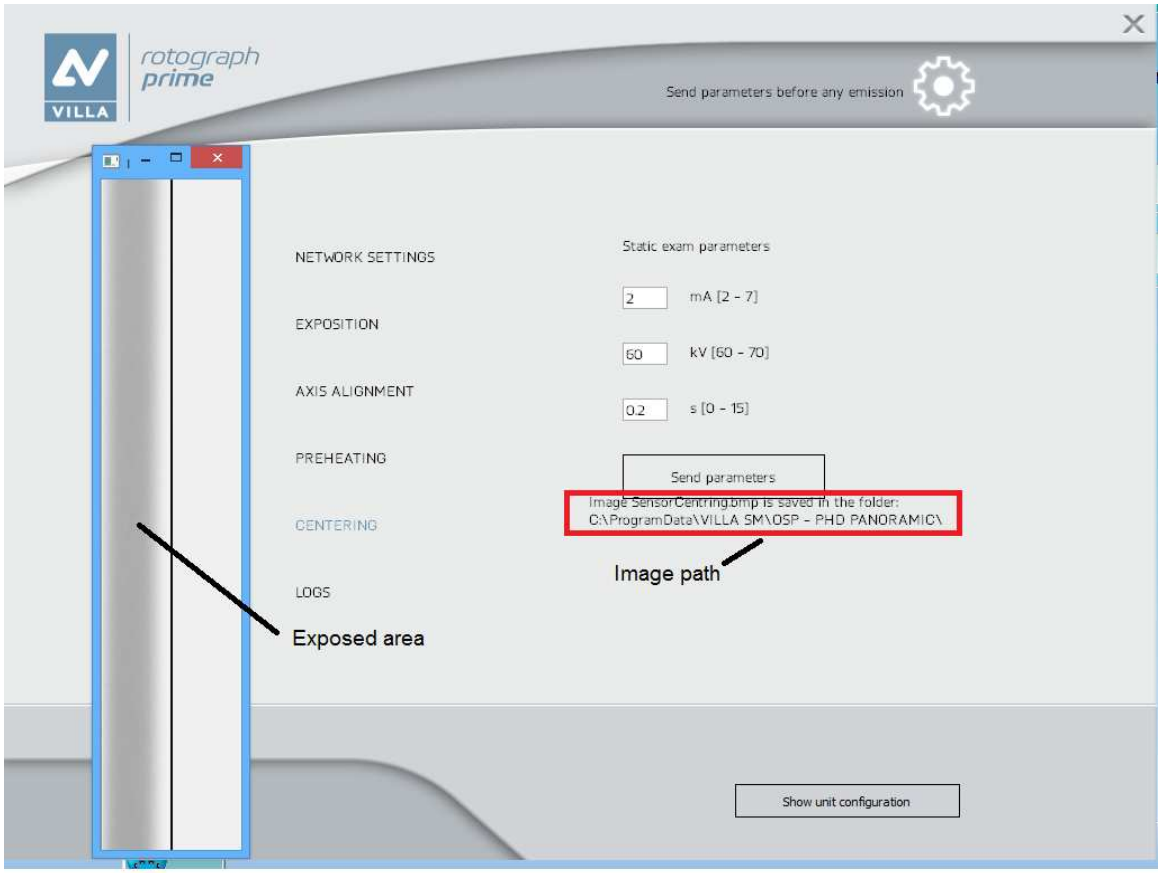
This function permit to adjust and set up the filament current used to emit properly the requested andic current.
This operation has to be done only in case of Tubehead replacement.



Warning
Wrong settings of Preheating parameters may damage x-ray tube.

12.4.5. Centering

This function permit to verify the x-ray beam alignment on the digital sensor, making an exposure without rotating the unit
This function is typically used to measure exposure parameters and in case of digital sensor or tubehead replacement
The image is saved in the directory C:\ProgramData\VILLASM\OSP-PHD Panoramic in bitmap format. and it can be opened in case it is necessary to make measurements or compare the images in order to see if the adjustment has been improved.



12.4.6. **Log files**

This function enable the store of log files, stored in the directory

C:\ProgramData\VILLASM\OSP-PHD Panoramic\Log

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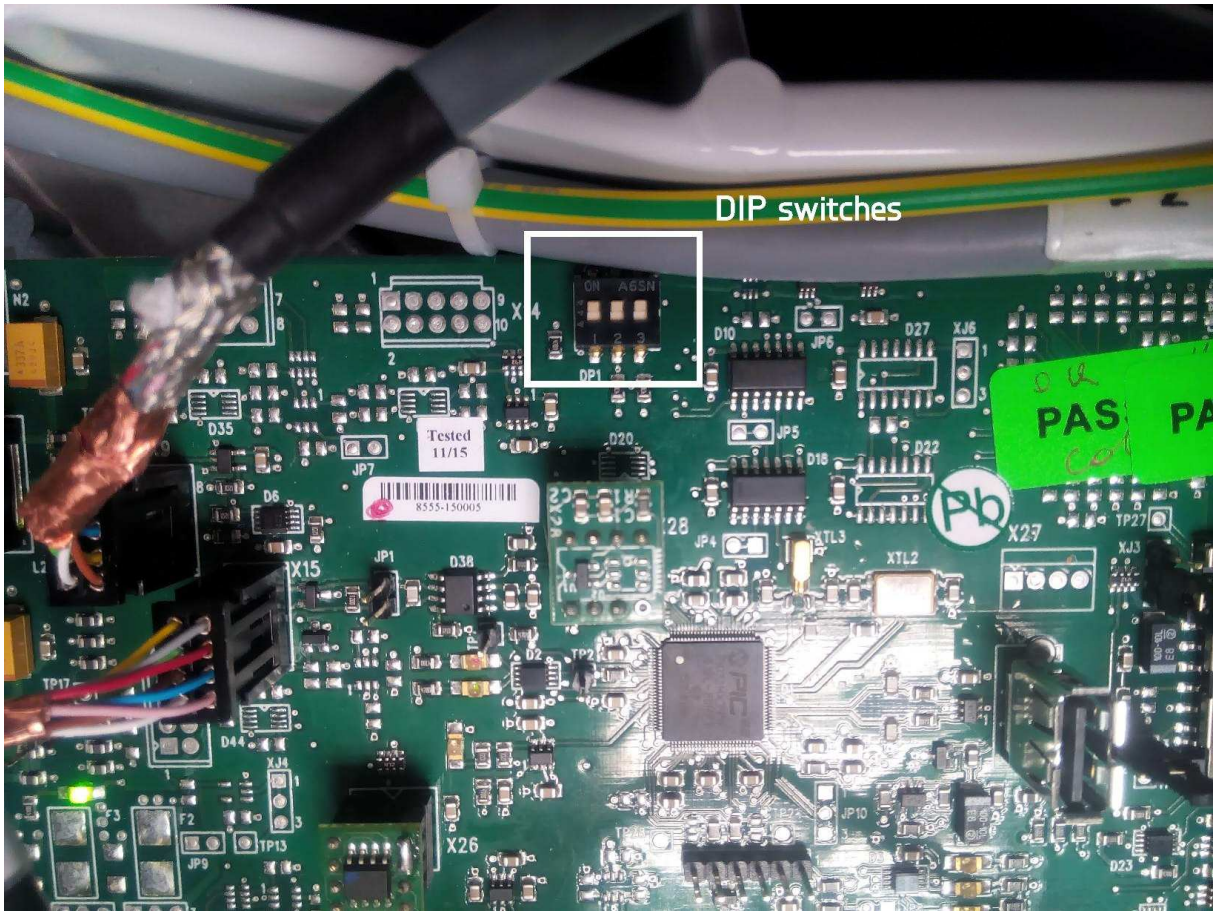
12.5. Exibition mode setup

In case the unit is used as DEMO (exhibition or show room) it is possible to disable the x-ray emission in the following mode :
The Exibition mode is enabled through a dedicated DIP-switches configuration (0-1-0).
Possible configurations are:
0-0-0 = NORMAL MODE
0-1-0 = EXIBITION MODE

DIP switches are physically located in the CPU of the unit (see picture below and annexed).



In this condition the PC is not connected

13. CORRECTIVE MAINTENANCE

In this chapter are included the operation necessary after the replacement of the system main components.

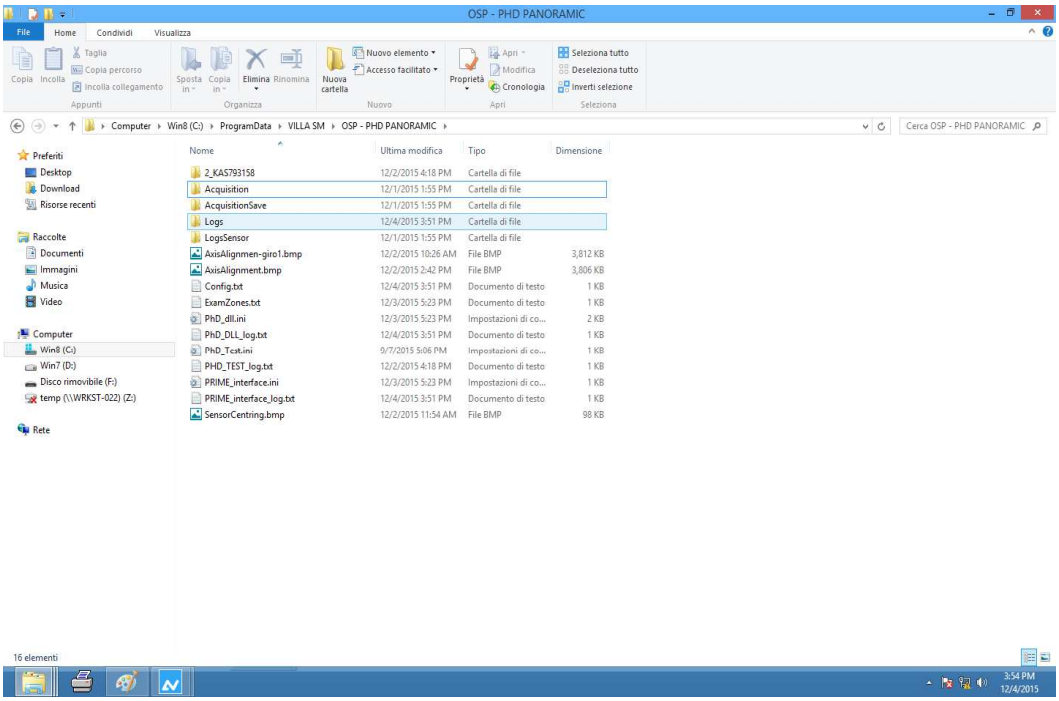
13.1. Digital sensor or Tubehead replacement

13.1.1. Digital sensor replacement

Digital sensor is fixed with two pins, that define the position. No adjustment are allowed in the sensor area.
It is always required to make the standard verification on image quality (see chapter 9.6) before to make examinations with patients.

13.1.2. Calibration file installation

It is important to store the detector calibration files related to the replaced sensor (provided with the sensor on a CD) in the directory
C:\ProgramData\Villasm\OSP-PHD Panoramic

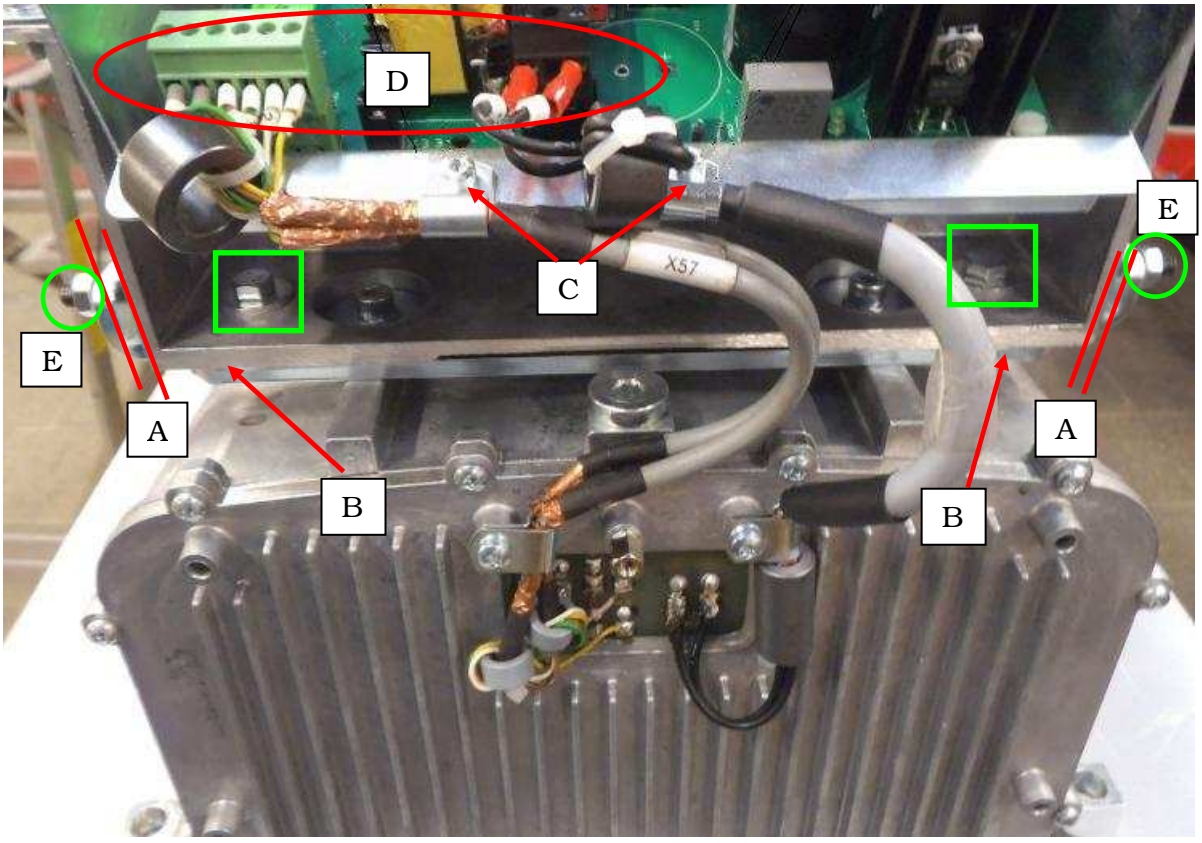


Calibration file is included in the CD provided with the sensor received as spare part

13.1.3. Tube head replacement

Before to remove covers, turn OFF Rotograph Prime.
In case of tubehead replacement, it is necessary to take note of tubehead mechanical position in order to position the new one in a similar position. Measure the distance between support and tubehead plate (ref. A) in both sides.
Measure the distance between tubehead plate and the tubehead support in both extremities (ref. B).
Remove the cables fixing clamps (ref. C) and then disconnect cables from Generator Board (ref. D)
Loosen fine adjustment grub screws from both sides (ref. E)
Remove the hexagonal screws indicated in the square to remove tubehead assembly.

Mount the new tubehead following the opposite procedure and positioning as more as possible in the same position of the original one.
Ùconenct the cables and verify that shielding is well connected to the clamps.
Perform X-ray beam centering verification (see relevant paragraph) and in case the image is not centered to the window, adjust the tubehead position, loosening the screws in the square references and acting on the grub screws indicated in the circles

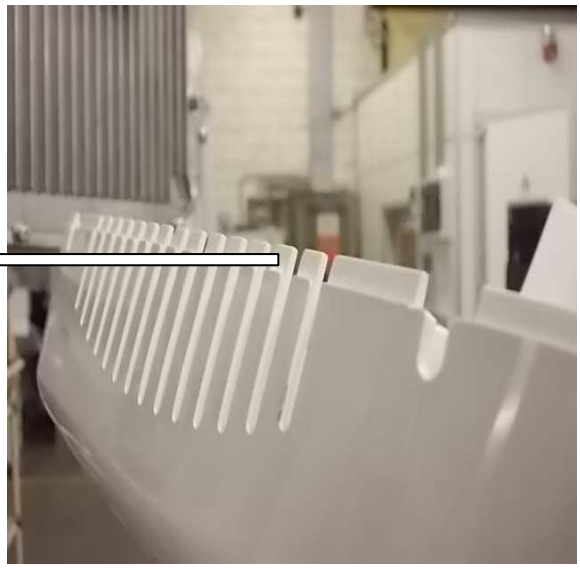


Once x-ray beam has been well centred., tighten the screws,.

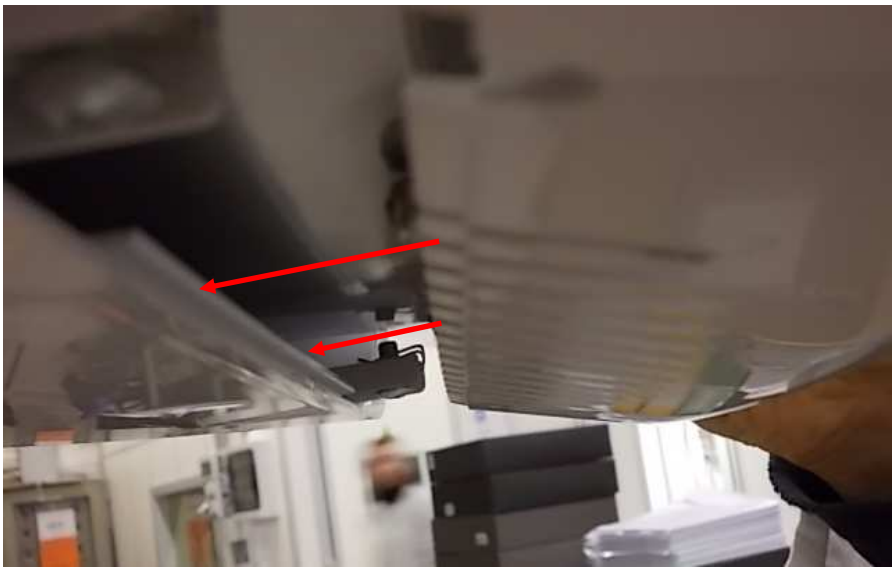
On lateral side of Tube head provided as spare part, it is present a label with written the preheating values of that x-ray tube. Before mounting the covers take note of the values and store them in the CPU memory following instruction in par. 12.4.4 (Preheating)

Warning
Wrong settings of Preheating parameters may damage x-ray tube.

Mount the covers paying attention to position them correctly as here following described.



Pay attention to insert the pins of the tube head back cover inside the guide present in the tube head front cover



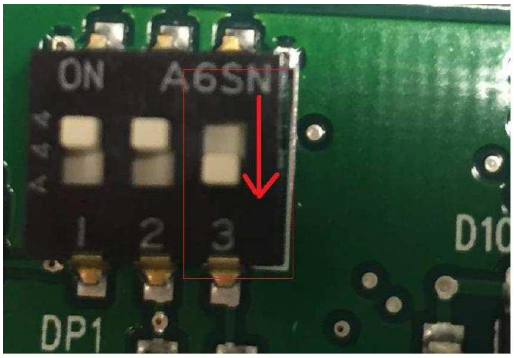
Once inserted lower part of the covers, tilt the back cover and fix the upper part

Perform a Panoramic examination and verify symmetry and image size using the arcate tool

13.1.4. Chin support assy replacement

CALIBRATION REFERENCES

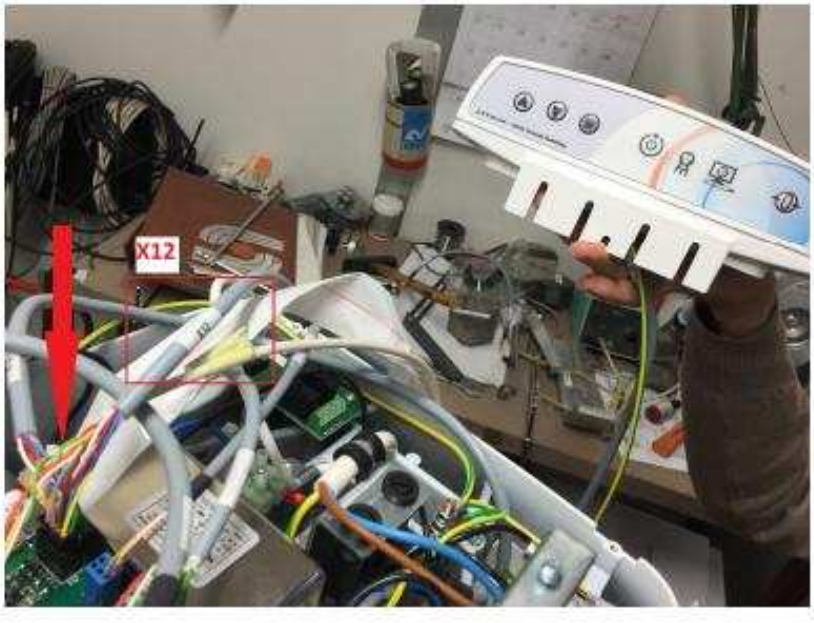
1) Open the top plastic cover of Unit and remove the metal cover of the CPU
2) Set the micro switch as follows:



Note
In Service mode NEVER press up/down column buttons as they are used to change rotation position

3) Switch On the machine, wait until the green LED blinks

Unplug the "broken" cable X12 and connect the X12 of the new Chin Support, and use its keyboard for the next step



4) Press the >0< Button

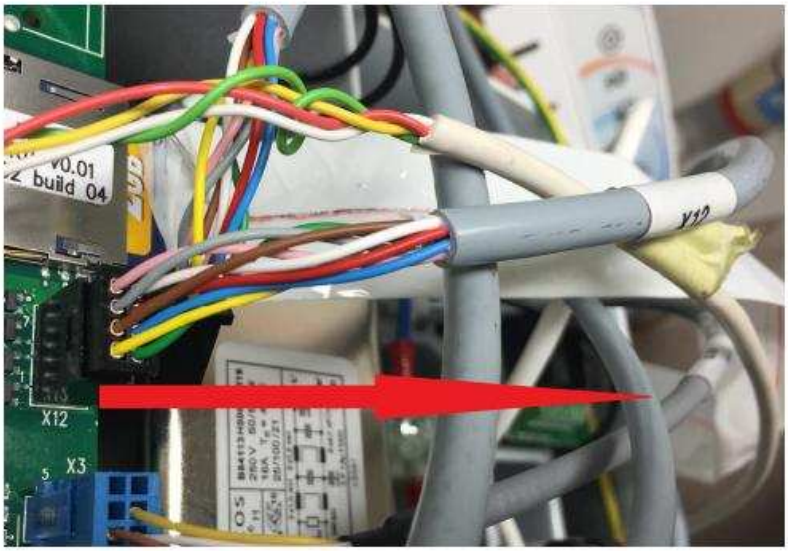
5) Insert the black phantom in the unit and switch On the leds
6) Draw on a tape the RED line projected by the laser

7) Pres >O< and draw on a piece of a tape the horizontal line projected by the Lasers

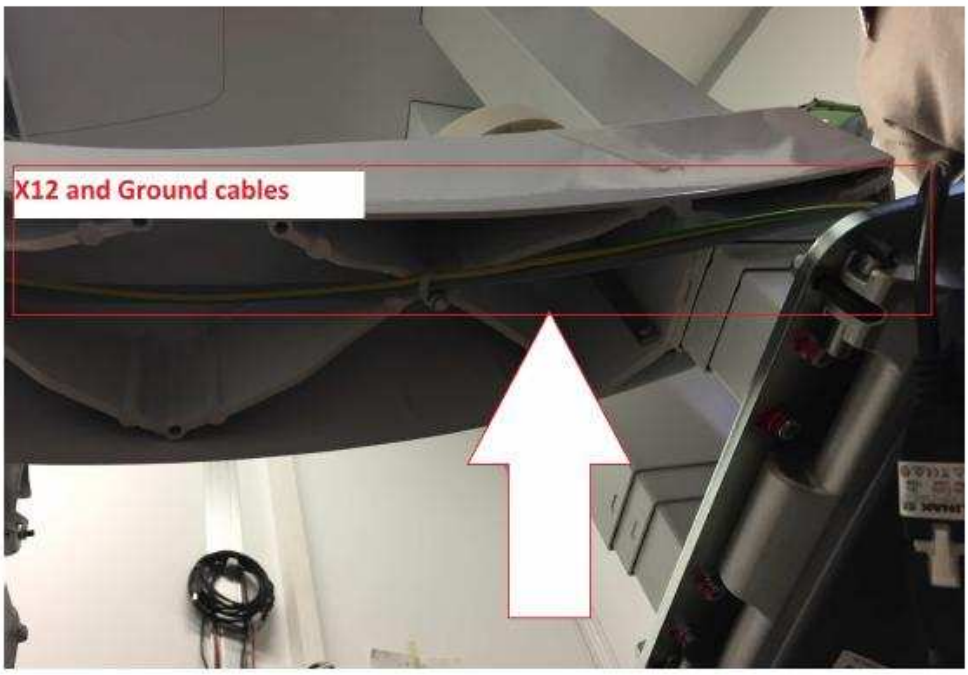
These are the references needed to calibrate the new key board/support on the Unit

REPLACING OF THE SUPPORT OF THE CHIN-REST

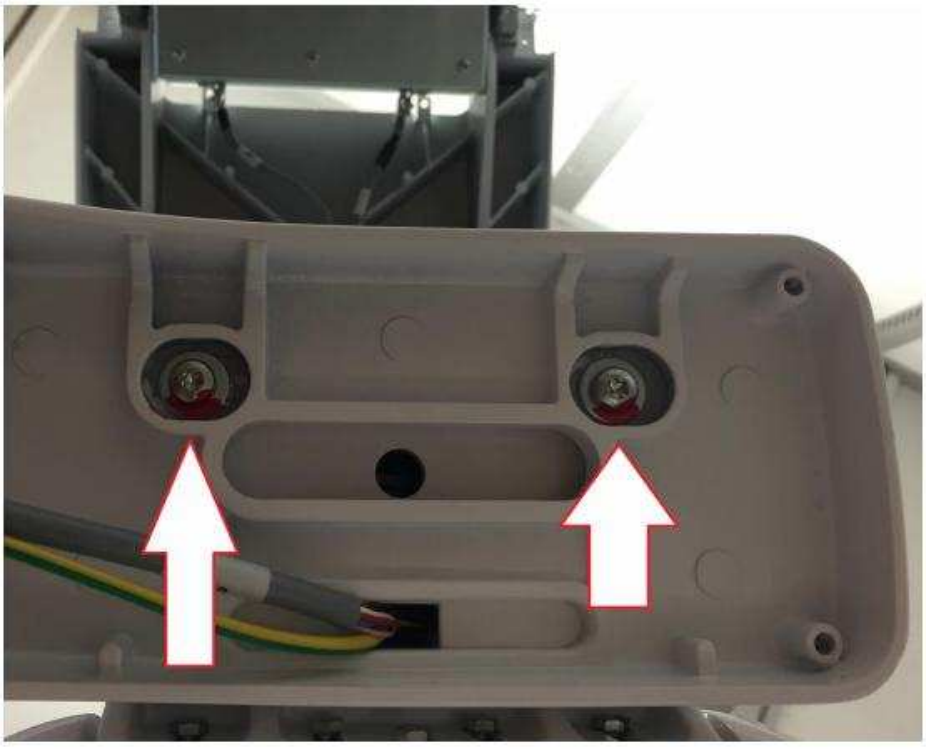
1) Unplug the X12 cable and the ground



2) Open the wire-way positioned in the back side of the column as shown in the following images:



3) Unscrew the two screws under the arm

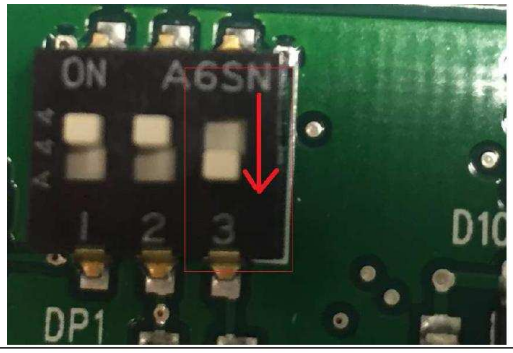


4) Remove the group "key board-handle"

CALIBRATE THE NEW SUPPORT

1) Insert the black phantom with the tape on the unit

2) Set the switch as follows:



Note
In Service mode NEVER move up/down column buttons as they are used to change rotation position

3) Switch on the unit, and when the green led blinks press >O<

4) Press the LEDs button and verify that the sagittal laser is projecting on the reference on the tape and than lightly tighten the screws under the arm.

5) Press >O< and verify that the horizontal line is on the horizontal line on the tape

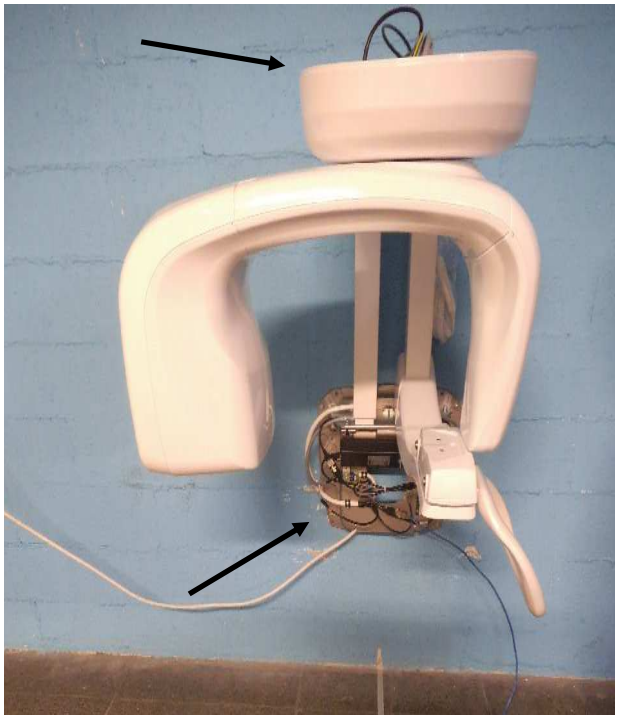
If both the sagittal and horizontal line are aligned, hard tighten the screws

PERFORM A STANDARD PANORAMIC EXAM AND VERIFY THAT:

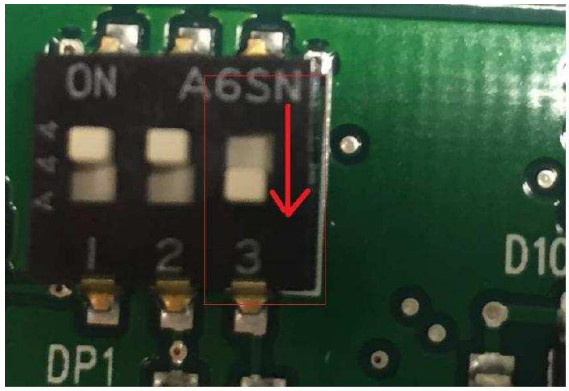
- THE SYMMETRIES are ok
- THE FOCUS LAYER IS ON THE CENTRAL SPHERE OF THE PHANTM

13.2. Columns replacement

Remove the upper cover and the cover from fixing plate

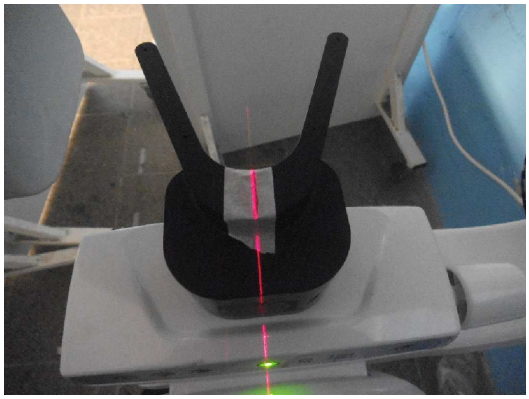


Remove cover from CPU board.
Turn OFF the unit



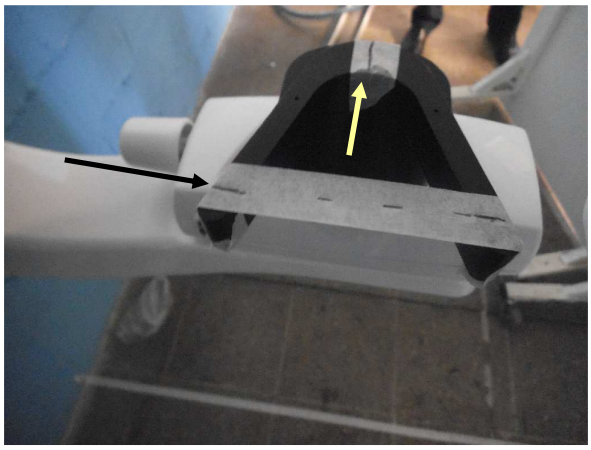
Set DIP switch 3 to OFF (1 and 2 ON) in order to enter in Service Mode
Turn ON the unit

Note
in Service mode NEVER press up/down column keys as they change rotating position

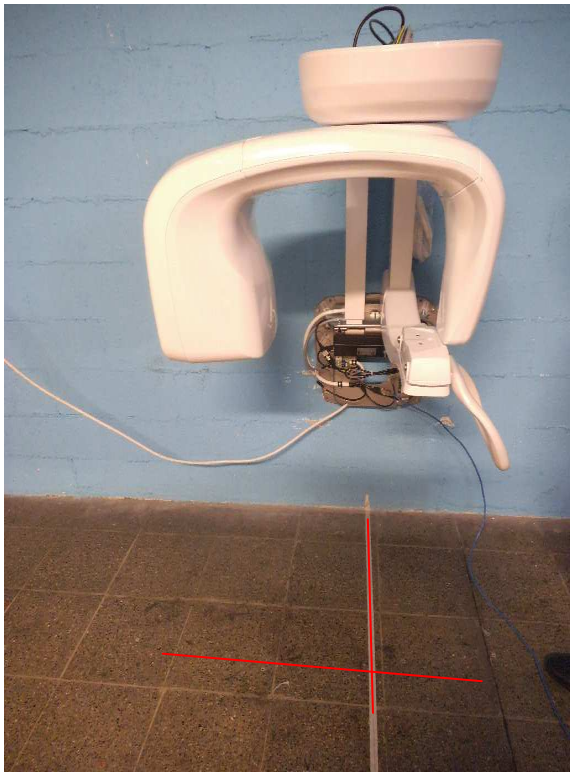


Insert the panoramic tool on chin support.
Turn ON laser Press >O< on the keyboard until sagittal laser is on the middle of tool. Use adhesive tape and mark the laser position (using a pen)

Put adhesive tape between the extremities of the tool
Press >O< on the keyboard until sagittal laser is parallel to chin support arm.
On adhesive tape mark the laser position (using a pen)

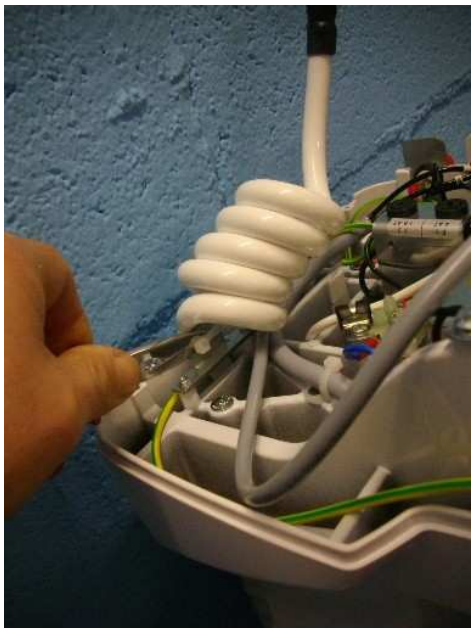


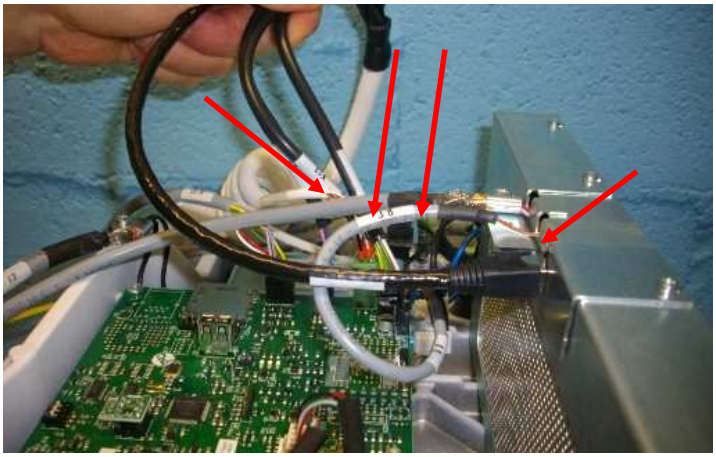
Rotation references are present on the tool and it has to be used as reference to position the unit in the same position



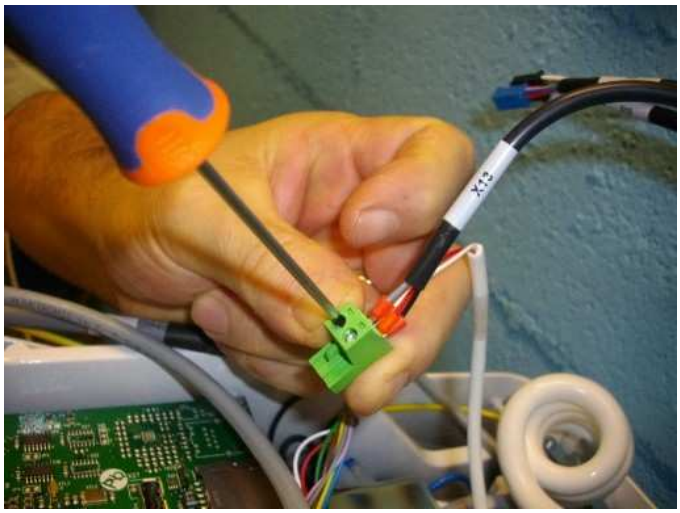
In case it is not available the tool, it is possible to make references on the floor.
Turn ON laser, press >O< on the keyboard
Put adhesive tape on the floor corresponding to the laser position and mark laser position using a pen. Press >O< on the keyboard until the laser is in 90° position and mark the other axes

Turn OFF the unit and disconnect main power supply
Rotate manually the rotating arm and fix it to the frame as shown in the image using the provided fixing plate





Cut strips and disconnect the cables from CPU and DSPU



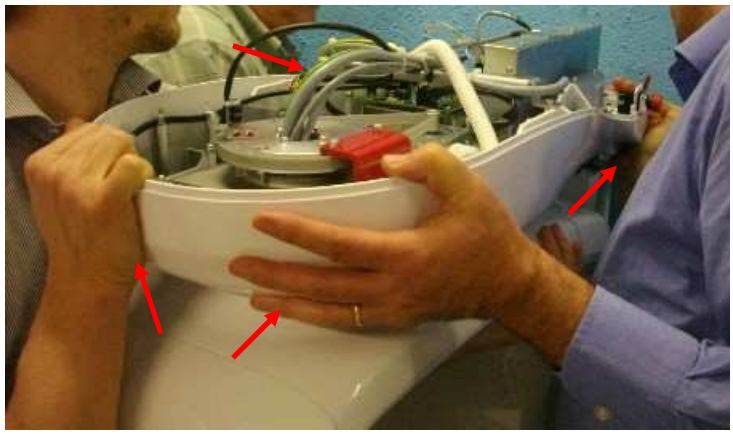
Remove connector from cable X13 (it may include exposure button)

Pass the cable out from the top side of the unit

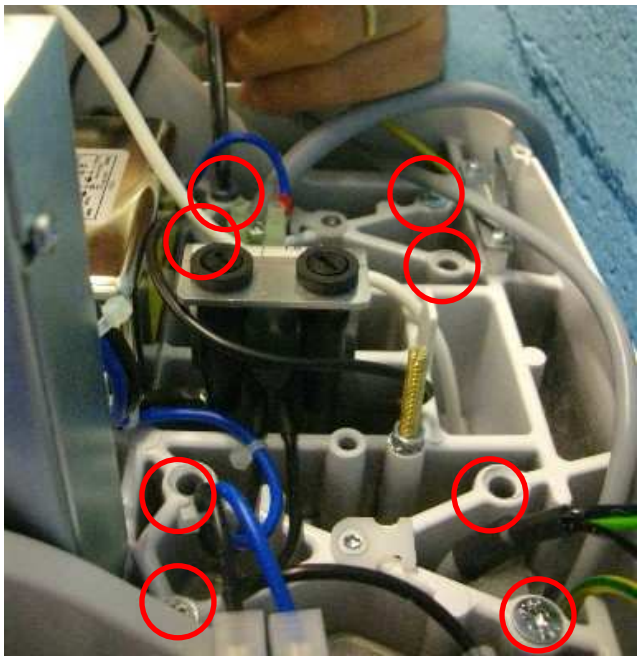
Cut lower strip

Disconnect power cables and chin arm cables from top side of the unit

Disconnect the exposure button in case it has been connected in the upper side



Two person are necessary to lift the head. Put the hands on front and back side
One person has to release screws and pass cables



Remove the 8 fixing screws

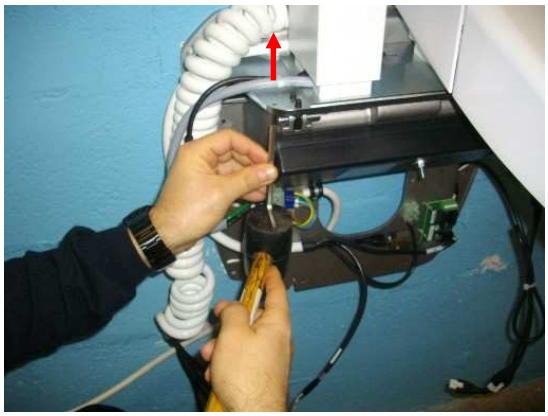
Pass the cables out of rotating head

Position head on a protected surface in order to avoid damagements

It is very important to take the reference of chin support arm before to remove it.
Measure the distance between top of the column and chin support arm
Typical value is 40,9cm

Disconnect lift motors control cables and power supply from fixing plate

In order to remove the columns plate, loosen the nuts of the hinges fixing the plate in both sides



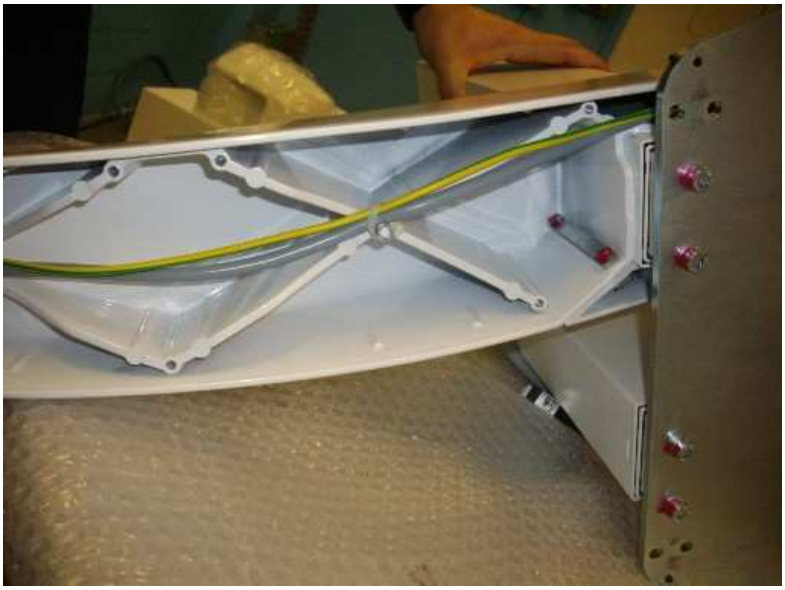
Move up the pin used to block the hinge pin in both sides
Slide out the hinge pin in both sides

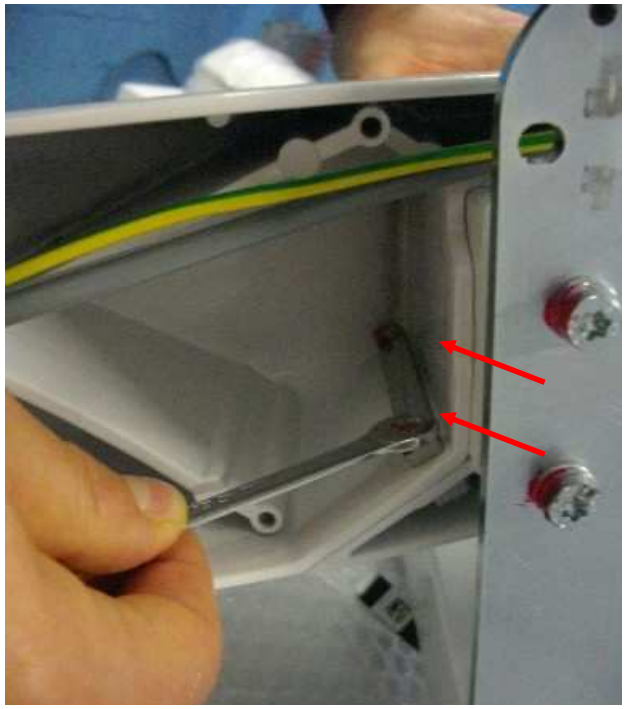
Remove the safety pins. In this phase, support the assy

Release the fixing pin to remove the columns assembly

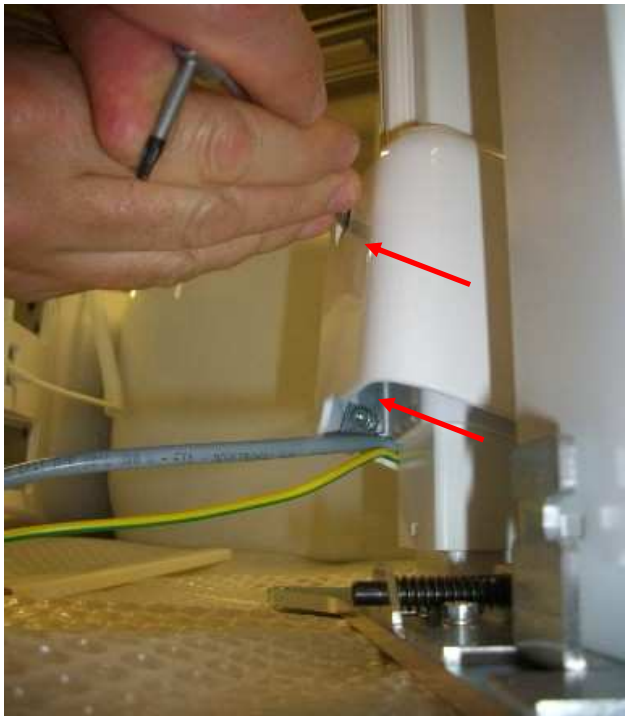
With the group on a desk, remove the adhesive plate and pass the cables out of the column

Remove the lower cover from chin support arm





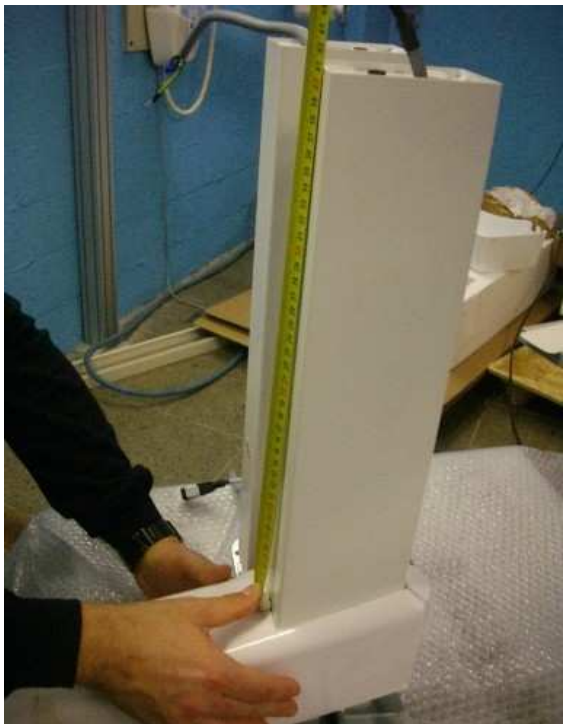
Loosen the two nuts inside the chin support arm



Loosen the two screws in the back side of the arm

Slide the arm out of the column

Remove the control box from the wall plate



Position the arm on right side column, measuring the distance between top side and arm and fix it to the column

Close the arm lower cover

Mount the new control box

Position the new group and pass the cables in the back side of the arm, without mounting the adhesive channel

Mount the hinge and push down the safety pin using a hammer

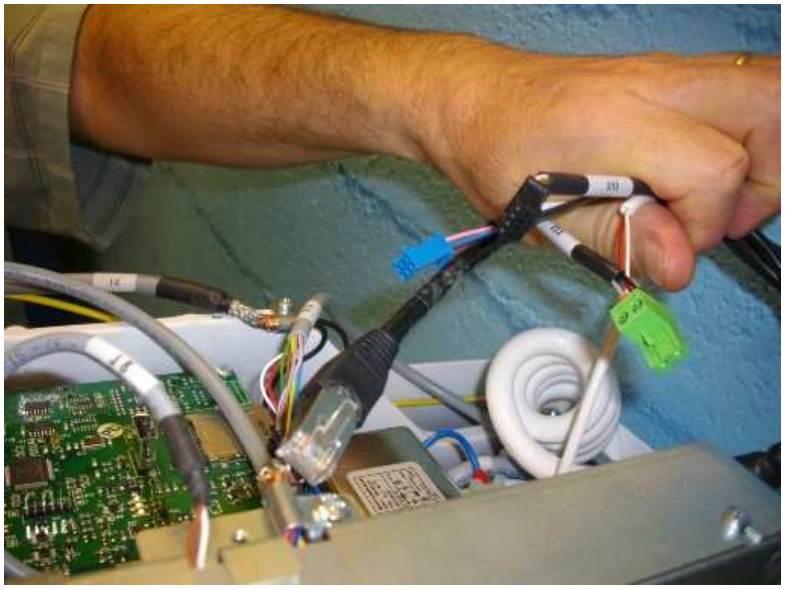
In order to easily mount the cable, tilt the column group and fix the cable with the terminal strip

Once fixed the cable, insert and fix the safety pin and tighten the hinges

Insert the cables from new column in the head

Position the head on the columns

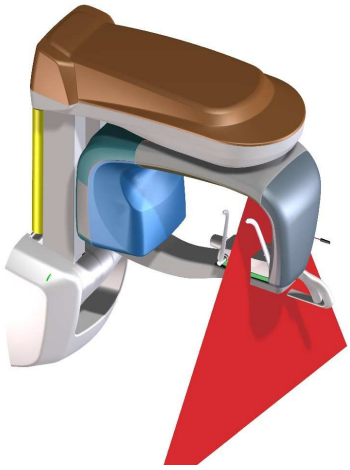
Put the screws on the column top side and fix them without tightening completely

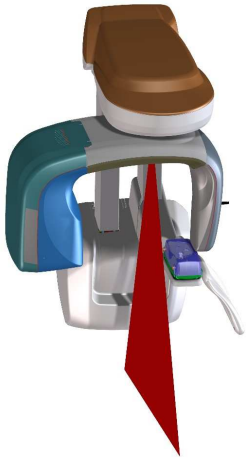


Insert the spiral cable on top side of the head.
Connect all the cables as described in the dismounting phase

Connect motor cables to the control box. Left side motor must be connected to port 1 (left side of control box), and right side motor to port 2 (right side of control box)

Remove the rotating arm fixing plate





Turn ON the unit in Service mode
Turn ON the laser
Press >O< to rotate the unit

Use the references taken before replacement to verify head position. (centering tool or references on the floor)
Loosening the 8 column fixing screws it is possible to rotate head until the laser correspond to the references in both positions. Once position is reached tighten screws.
Turn OFF the unit
Set DIP switch 3 to OFF to set the unit in normal mode

Turn ON the unit and check up/down movement
Make exposure and verify the image quality as described in par. "Verification of PANORAMIC function"

13.3. CPU board replacement

WARNING:
The board shipped as replacement carry the Hardware key and the EEPROM **not configured**.

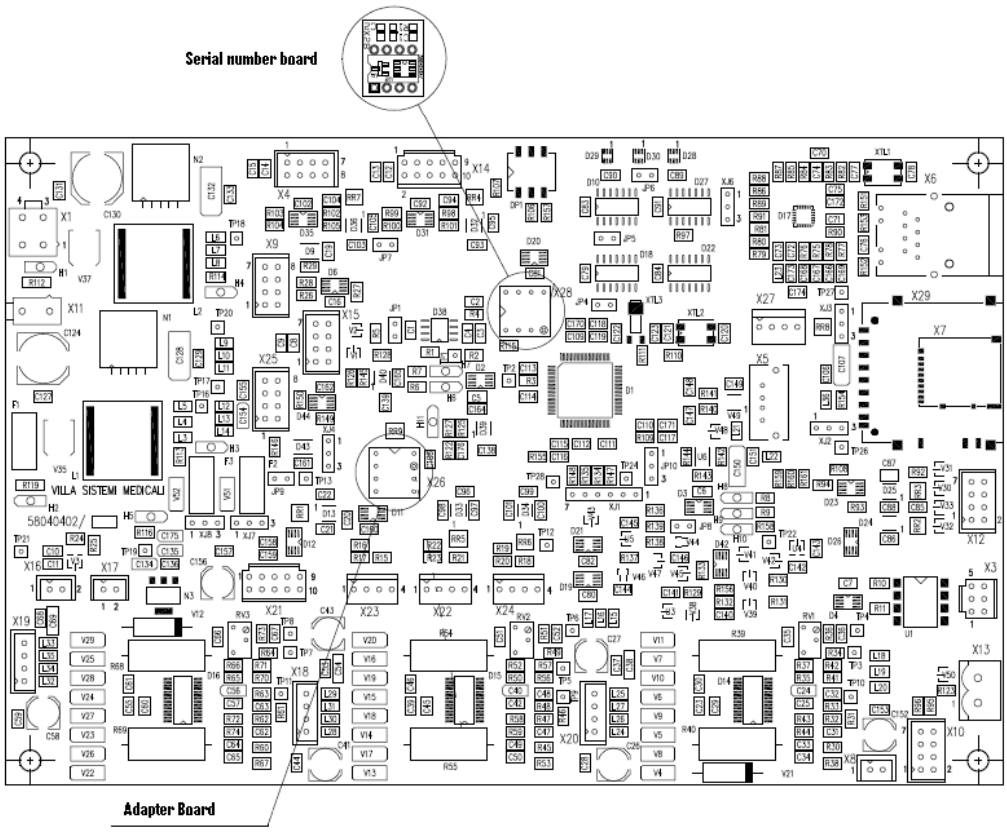
To make the system working, the Hardware key must be retrieved from the failed board and positioned on the new board. This component includes the U.I.C. (Unique Identification Code) witch determines the enabling codes for the radiological exams.

Moreover, on the EEPROM, identified as "ADAPTER BOARD" on the CPU board, has stored the system configuration data; remove the EEPROM from the new board and replace it with the one present on the failed board. In case the old EEPROM was not functioning, it will be necessary to mount the not configured EEPROM and restore manually the configuration data present on the equipment parameters table supplied with the Service Manual, following the procedure present on paragraph "Service programs description".

Note
At the end of the replacement, restore the metallic cover and the ground connection. Both parts has to be recovered from failed board

13.4. CPU board Firmware upgrade

Here below the instructions for the firmware upgrade:
1. unzip the folder PRIME FIRMWARE.zip and copy the content into a USB stick
2. switch-off the Prime
3. insert the USB stick into the usb port of the CPU
4. switch-on the PRIME and wait until the LED close to the USB port will stop to blink
5. switch-off the Prime
6. move the USB stick into the usb port of the DSPU
7. switch-on the PRIME and wait until the two green LED (power and ready) will be lighted (more or less 2 minutes)
8. switch-off the Prime and remove the USB stick



13.5. PC replacement

In case of PC replacement, it will be necessary to install the SW and set properly the communication IP addresses in order to permit the system communication. Digital sensor calibration files must be copied in the correct directory, depending on the Operative System version.
Computer IP address need to be properly set according with the Rotograph Prime IP address

13.5.1. Software package

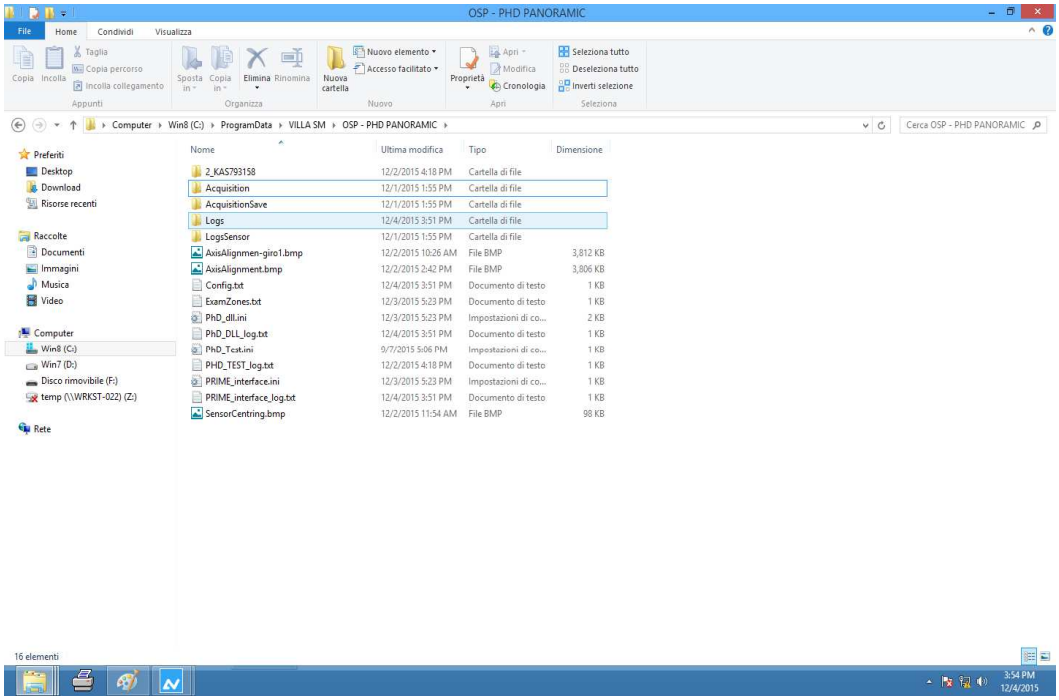
Together with the unit you received the following CD:

- Receptor Installation CD including Calibration files.
- System SW Disk (Quick Vision)
- System and Service Guide
- Dental Studio package (opional)

•

1.1.1.29 Calibration file installation

It is important to store the detector calibration files related to the replaced sensor (provided with the sensor on a CD) in the directory C:\ProgramData\Villasm\OSP-PHD Panoramic



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14. SCHEMATICS AND DRAWINGS

1 – General schematic

2 – CPU Board layout

3 – Generator Board layout

4 – Accessory Board layout

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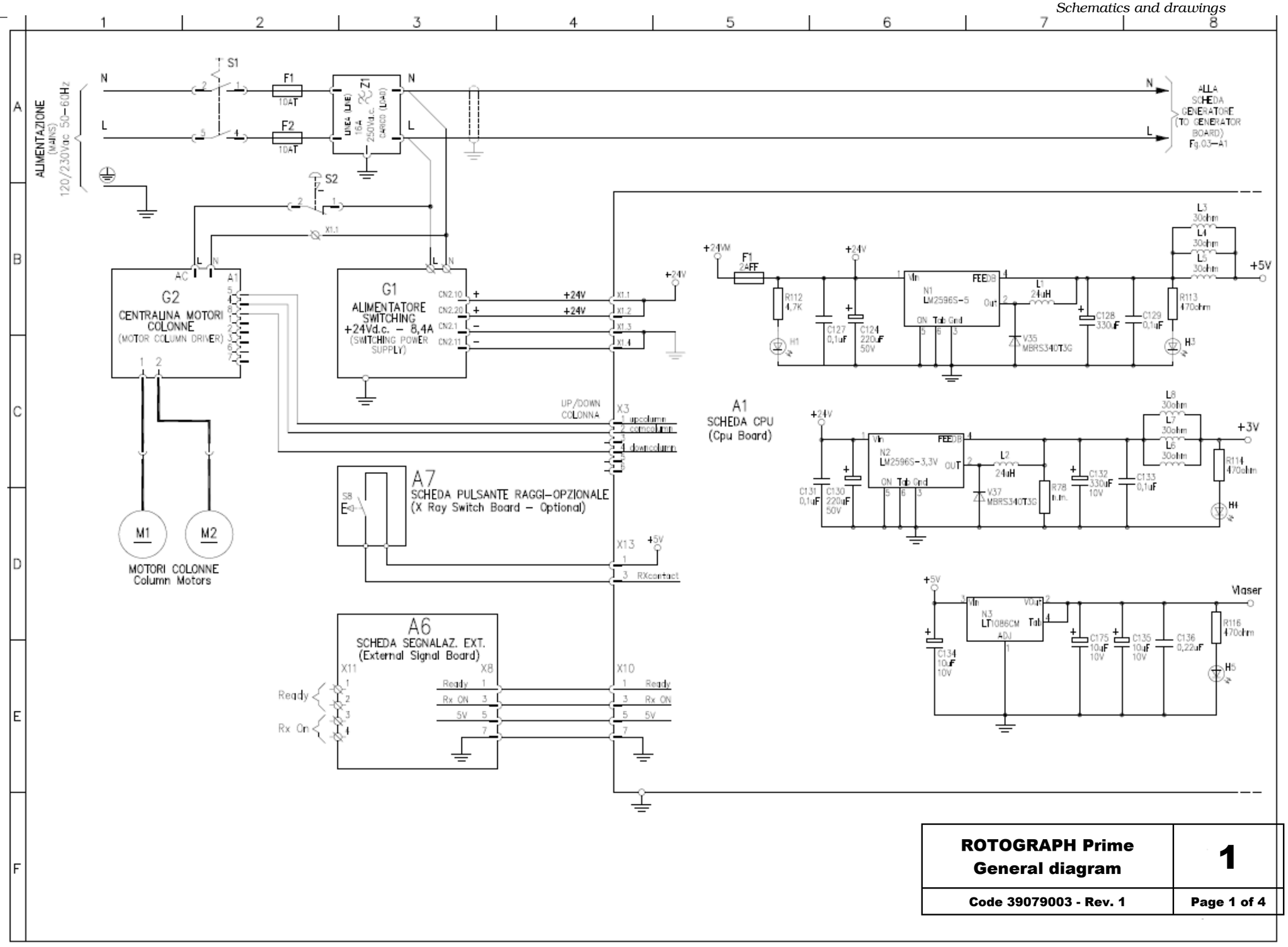
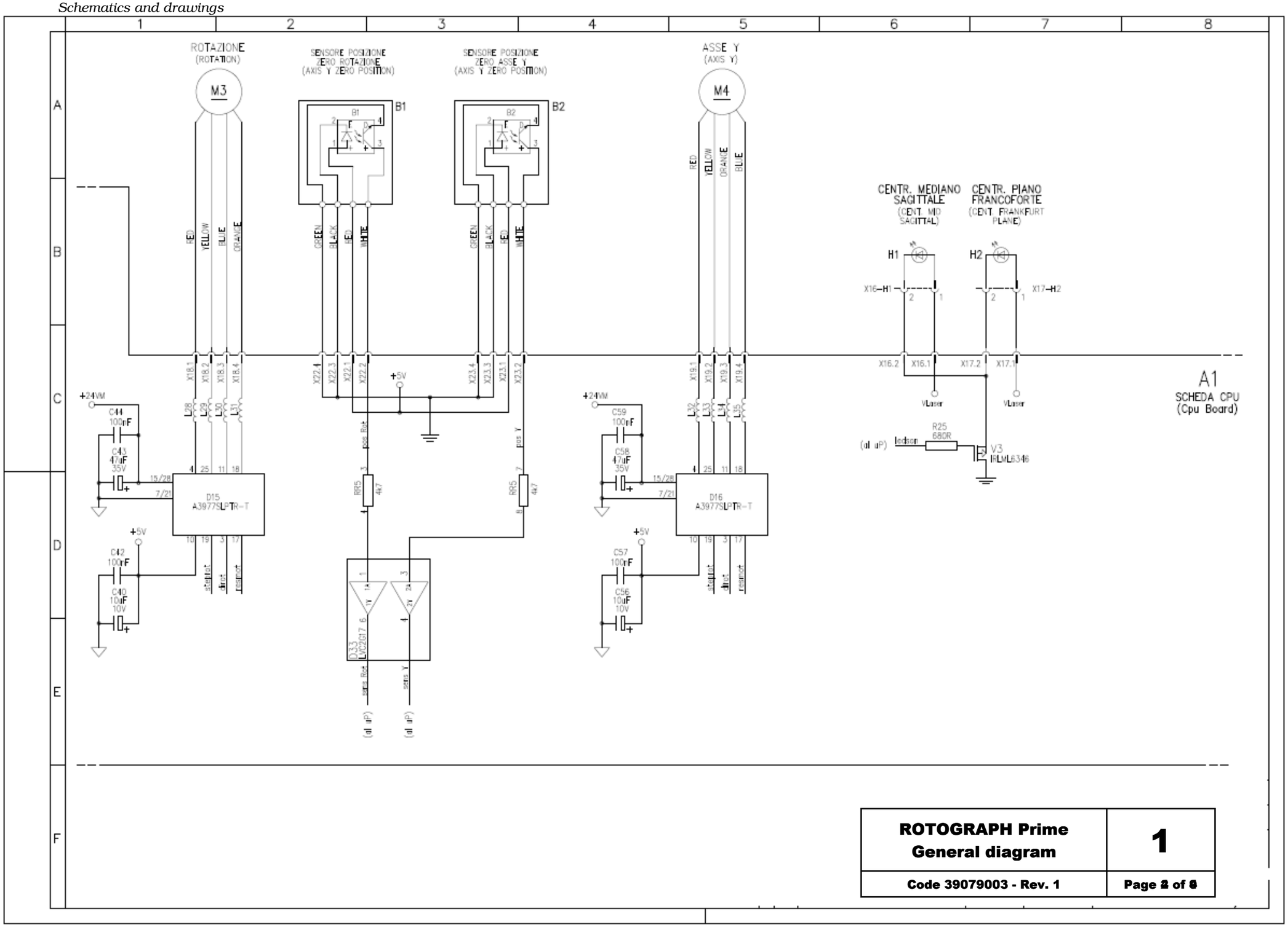
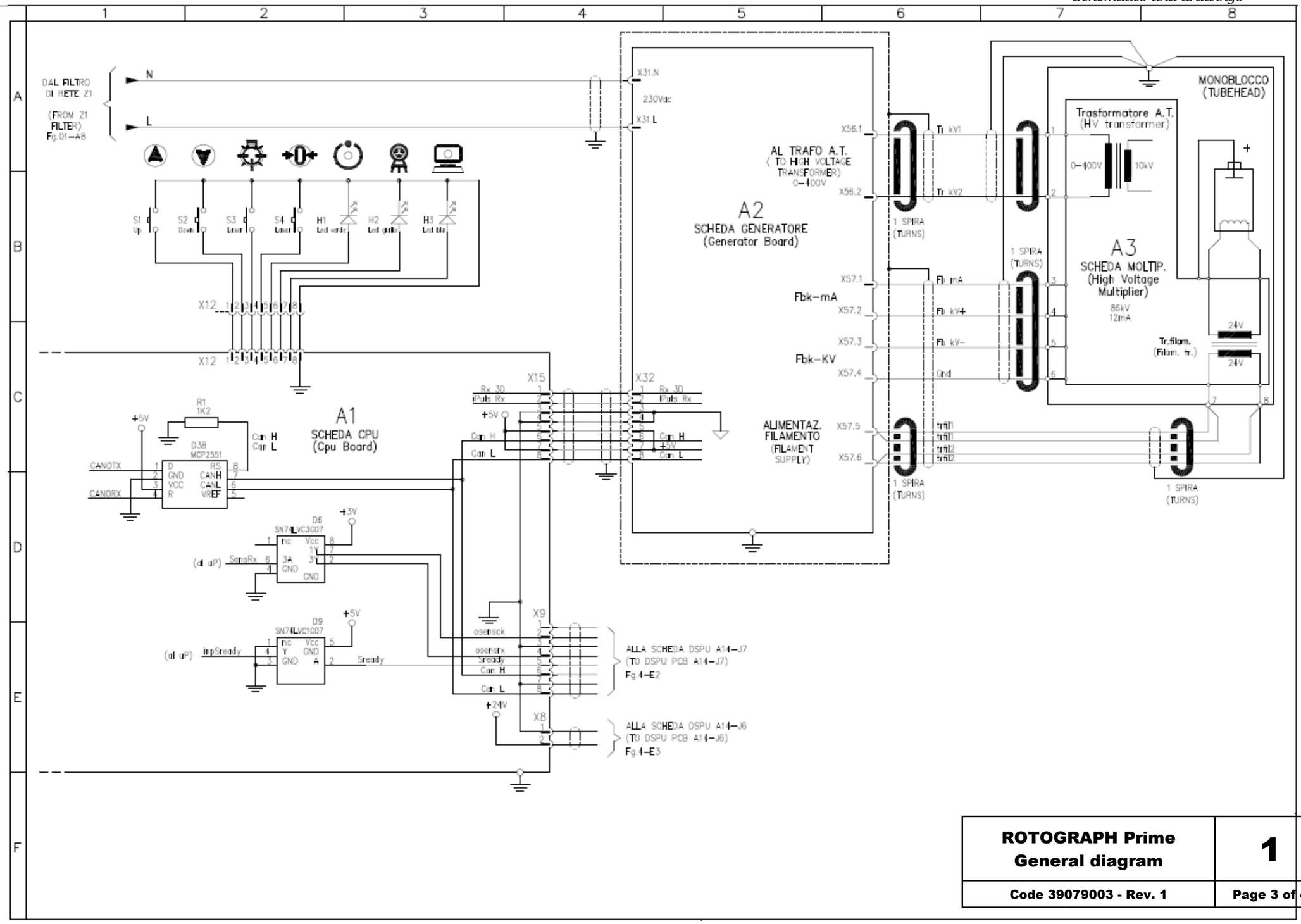


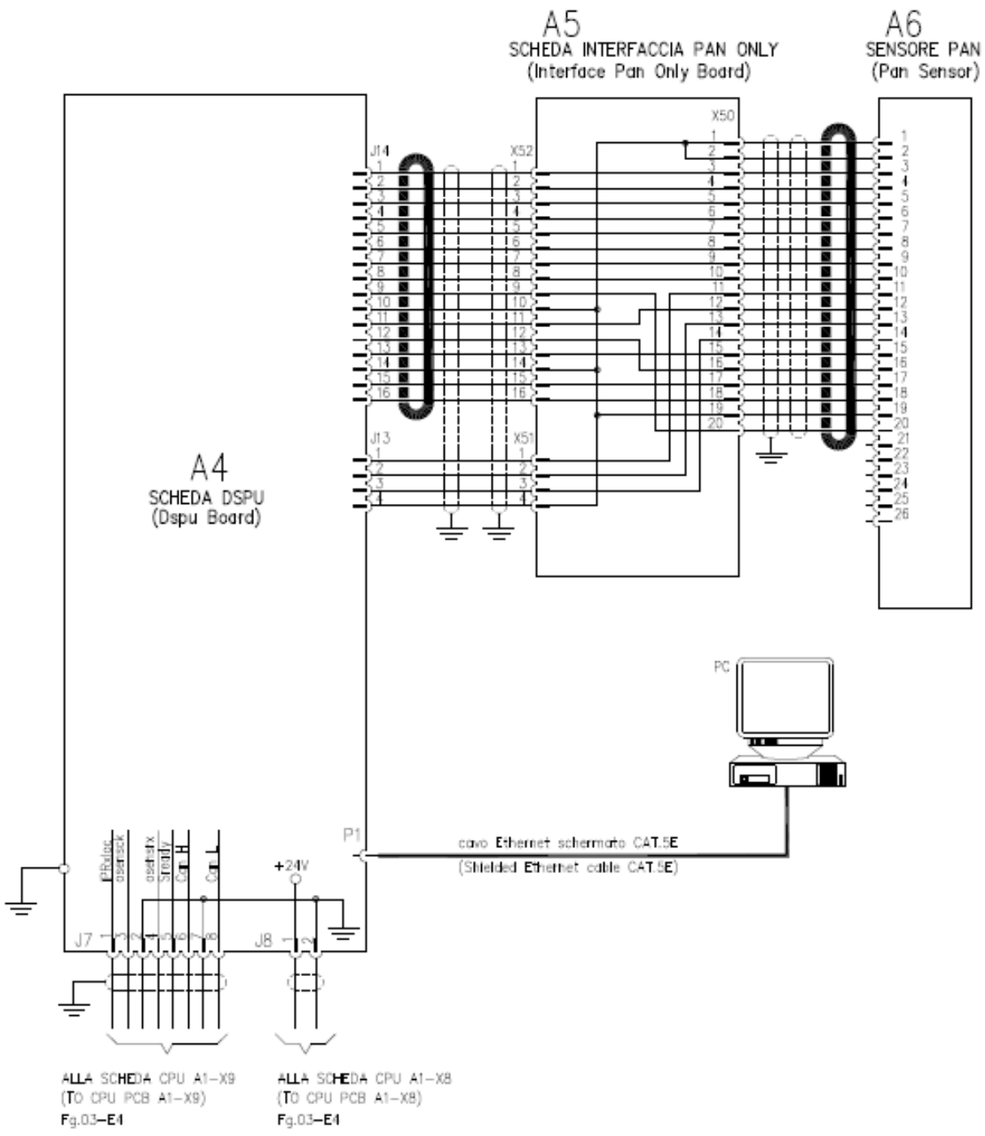
ROTOGRAPH Prime General diagram	1
Code 39079003 - Rev. 1	Page 1 of 4



ROTOGRAPH Prime General diagram	1
Code 39079003 - Rev. 1	Page 2 of 8



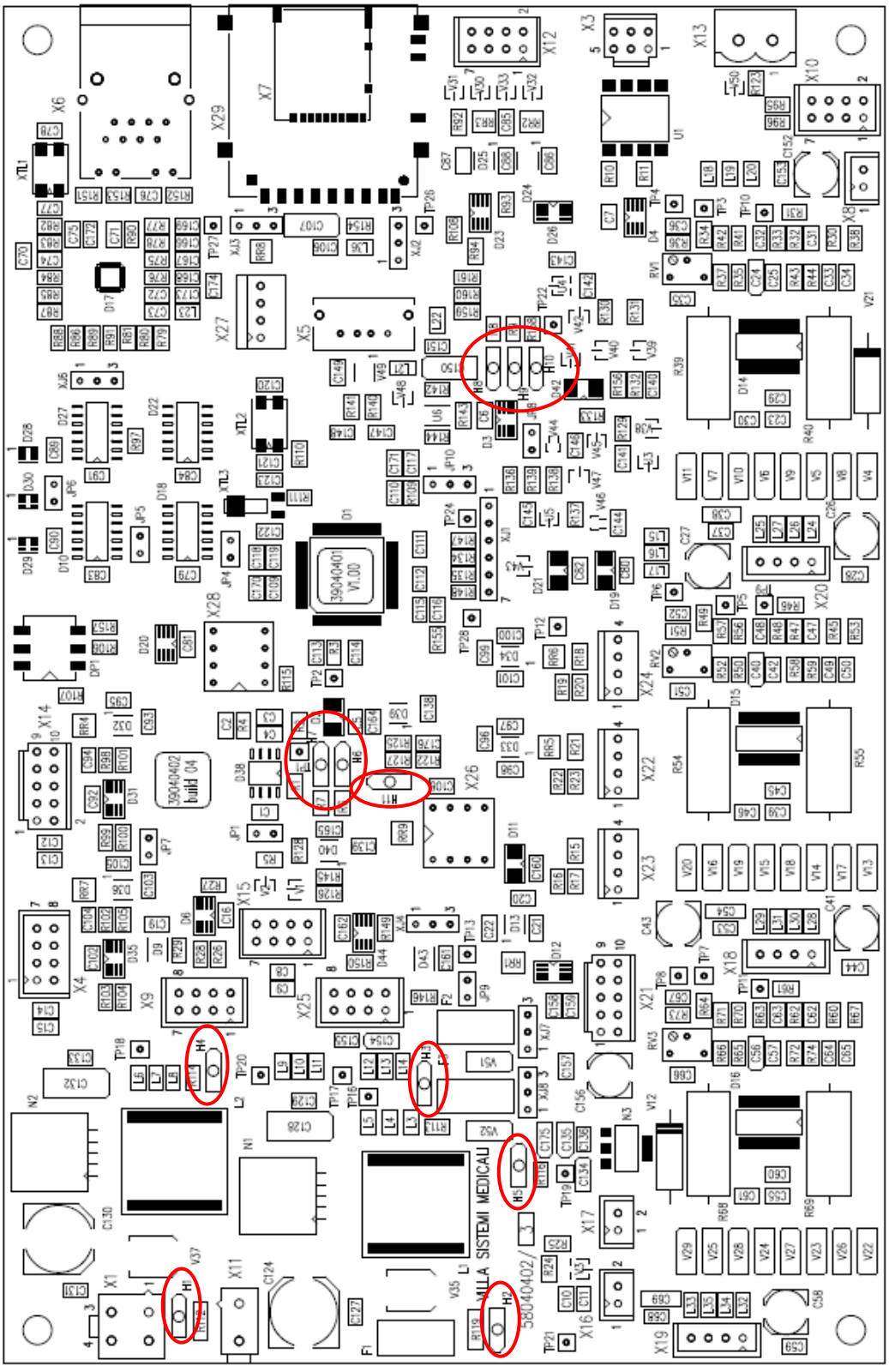
ROTOGRAPH Prime General diagram	1
Code 39079003 - Rev. 1	Page 3 of 4



ROTOGRAPH Prime **General diagram**	**1**
Code 39079003 - Rev. 1	**Page 4 of 4**

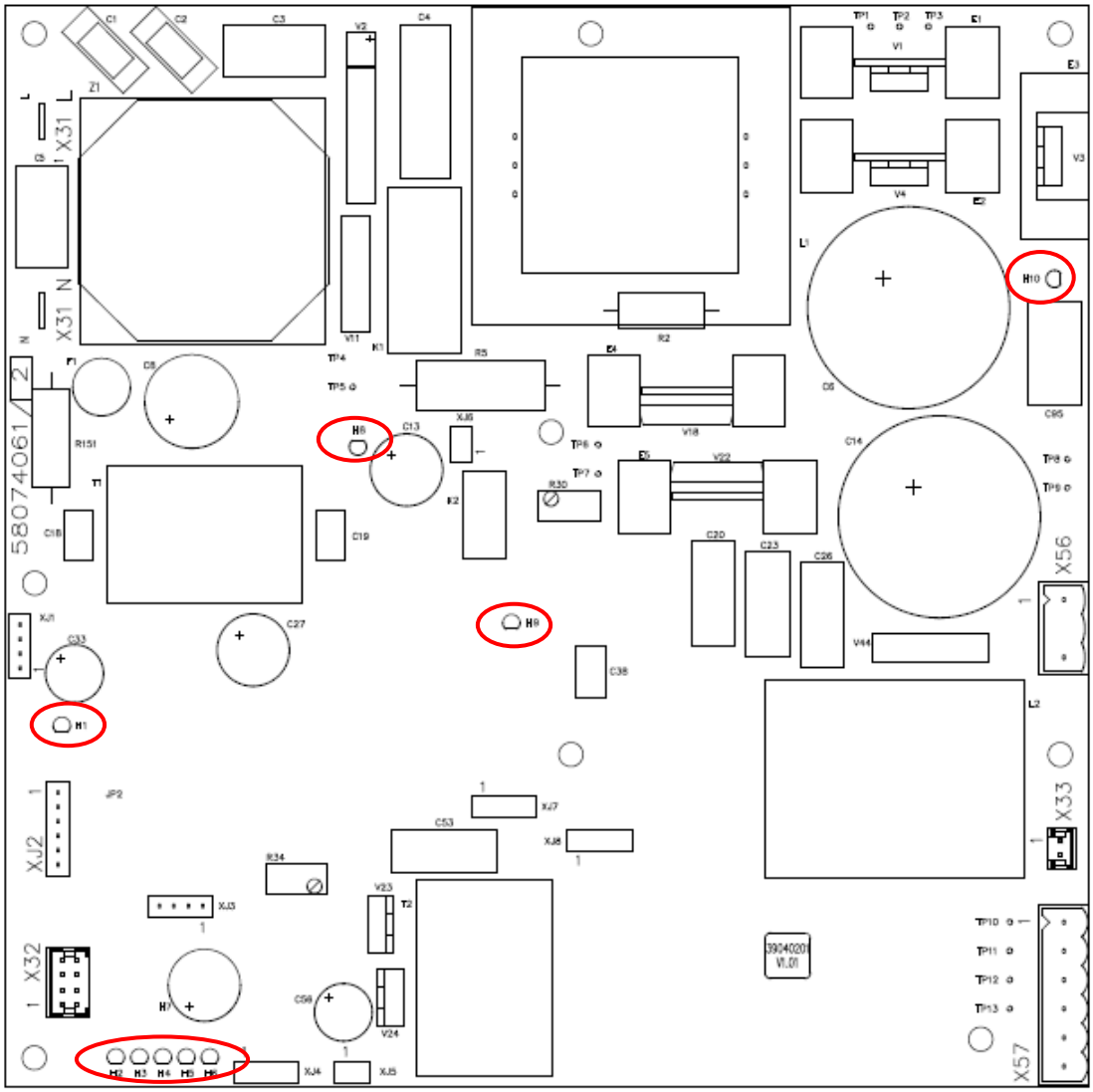
CPU Board Layout

Circle identificate LEDs,

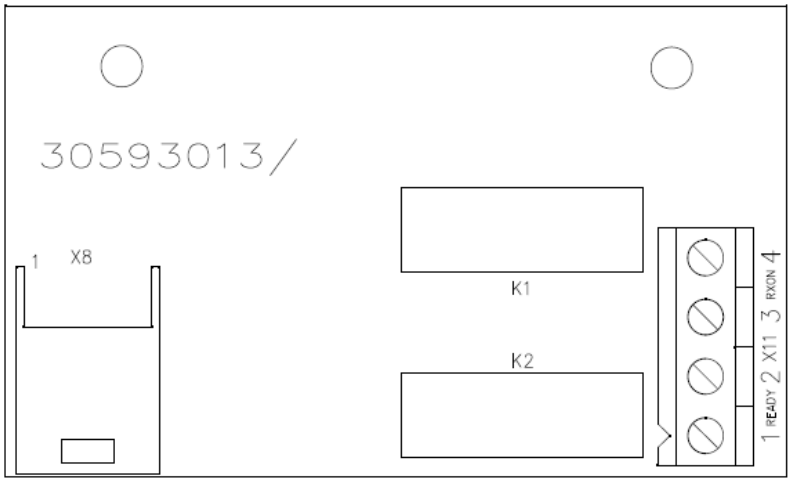


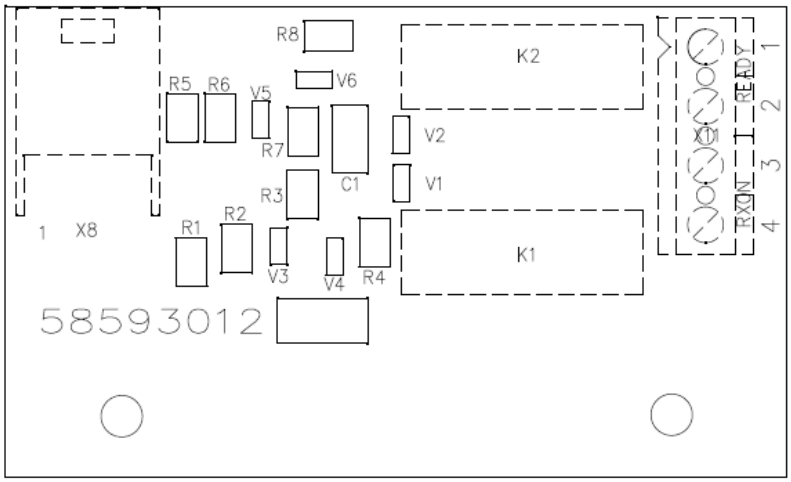
Generator Board Layout

Circle identificate LEDs



Accessory Board Layout





15. SPARE PARTS

1 – TOP side of the unit

2 – Rotating arm

3 – UP/DOWN Column

4 - ACCESSORIES AND SERVICE TOOLS

5- Covers

6 - Cables

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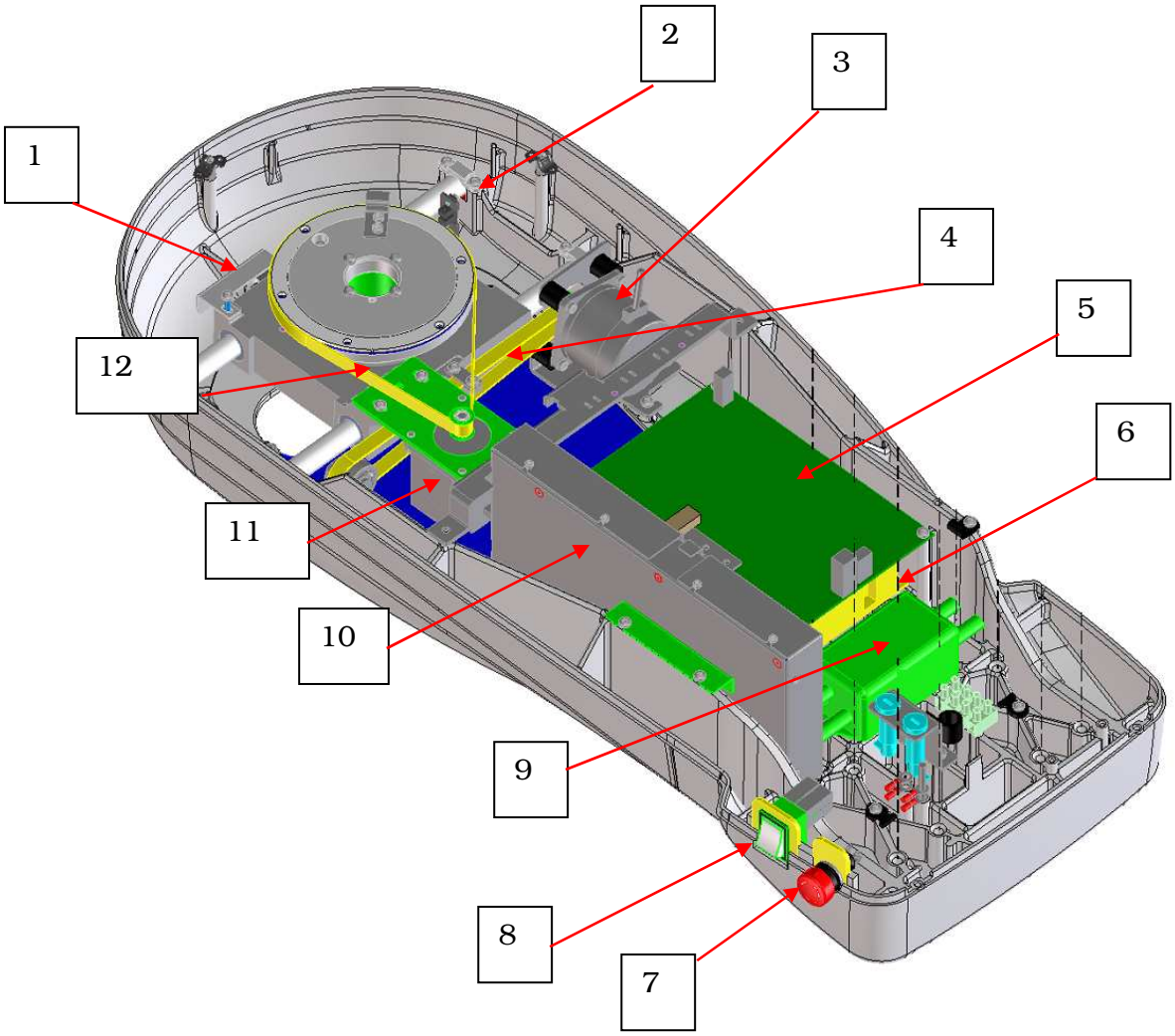
1 – TOP side of the unit

Rif.	Order code	Description	Note
1	6204041000	Light sensor assy Y axes	
2	6204040900	Light sensor assy rotation	
3	6604040200	Y axes motor assy	
4	4990807000	Y movement belt	
5	5804040200	CPU board	
6	4492823000	Power supply board	
7	4291421400	Emergency pushbutton	
8	4291420900	ON/OFF Switch	
9	4192212200	Main filter	
10	4695478800	DSPU board	
11	6604040100	Rotation motor assy	
12	4990806900	Rotation belt	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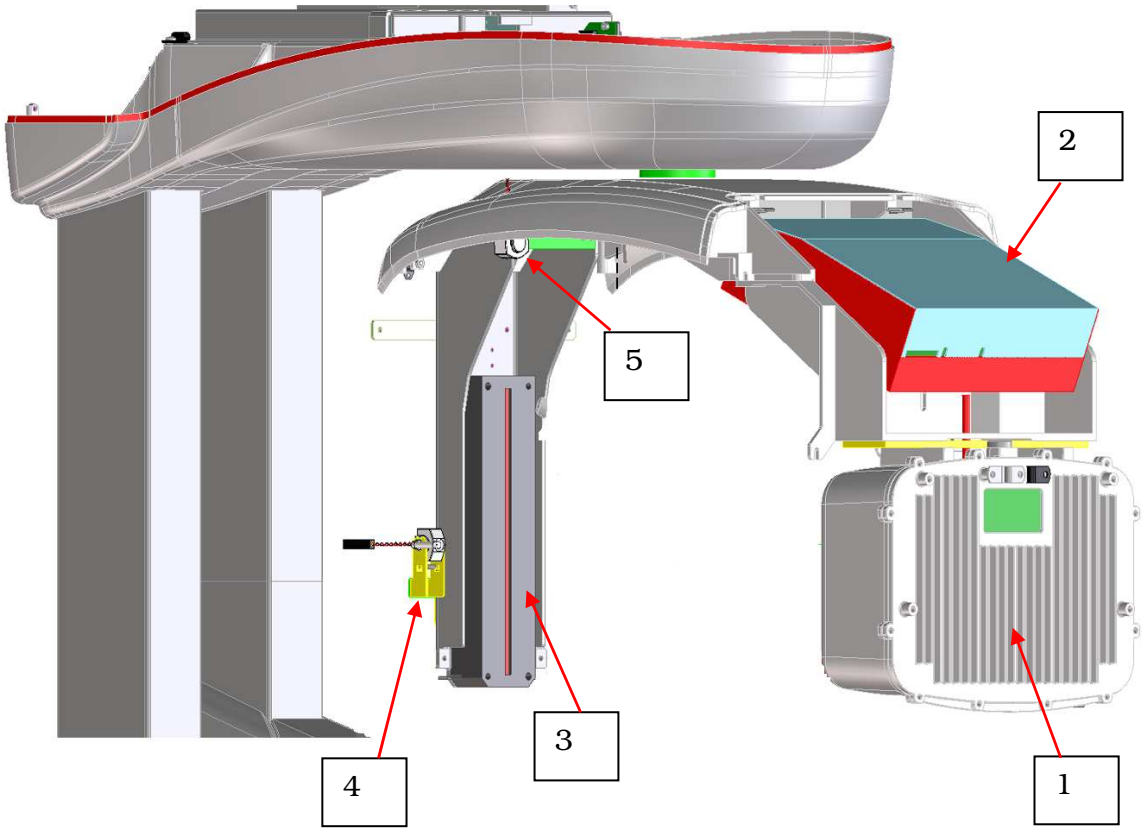
2 Rotating Arm

Rif.	Order code	Description	Note
-1-	6604000000	Tube head assy	
-2-	5807406100	HF board	
-3-	4954430000	Digital sensor	
-4-	6207092300	Frankfurt Laser ASSY	
-5-	6207092300	Rotation Laser ASSY	
-6-	7104010000	Chin support assy	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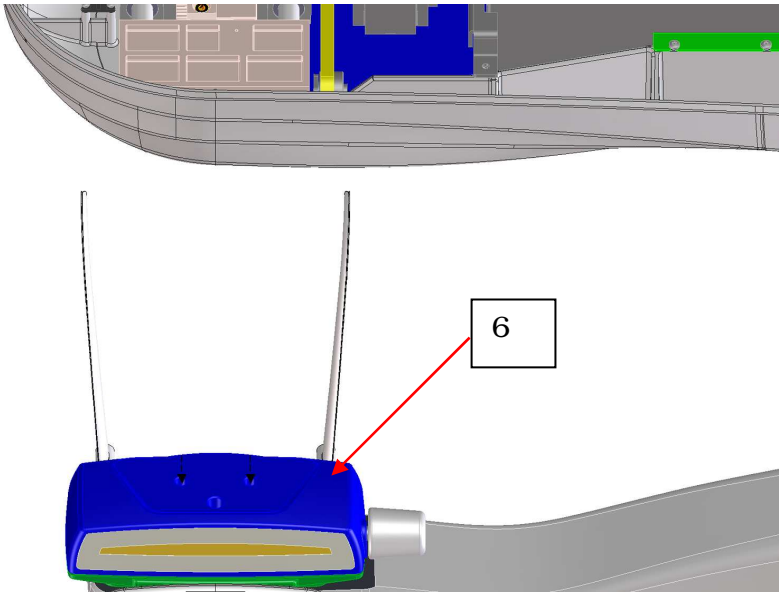
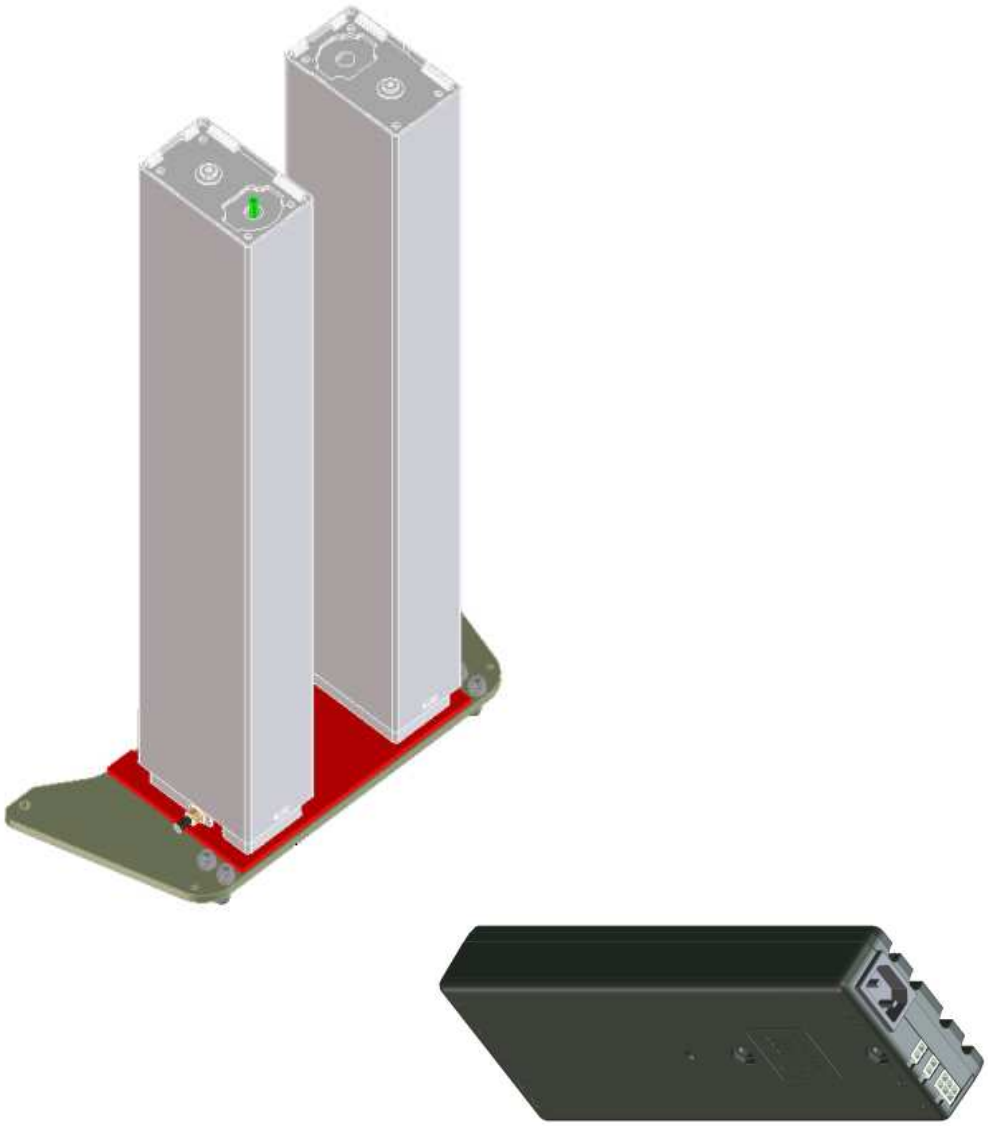

6

3 – UP/DOWN Column

Ref.	Order code	Description	Note
1	6604101300	UP/DONN Column assy	

Kit includes both column adjusted and assembled to the support plate and the relevant control box

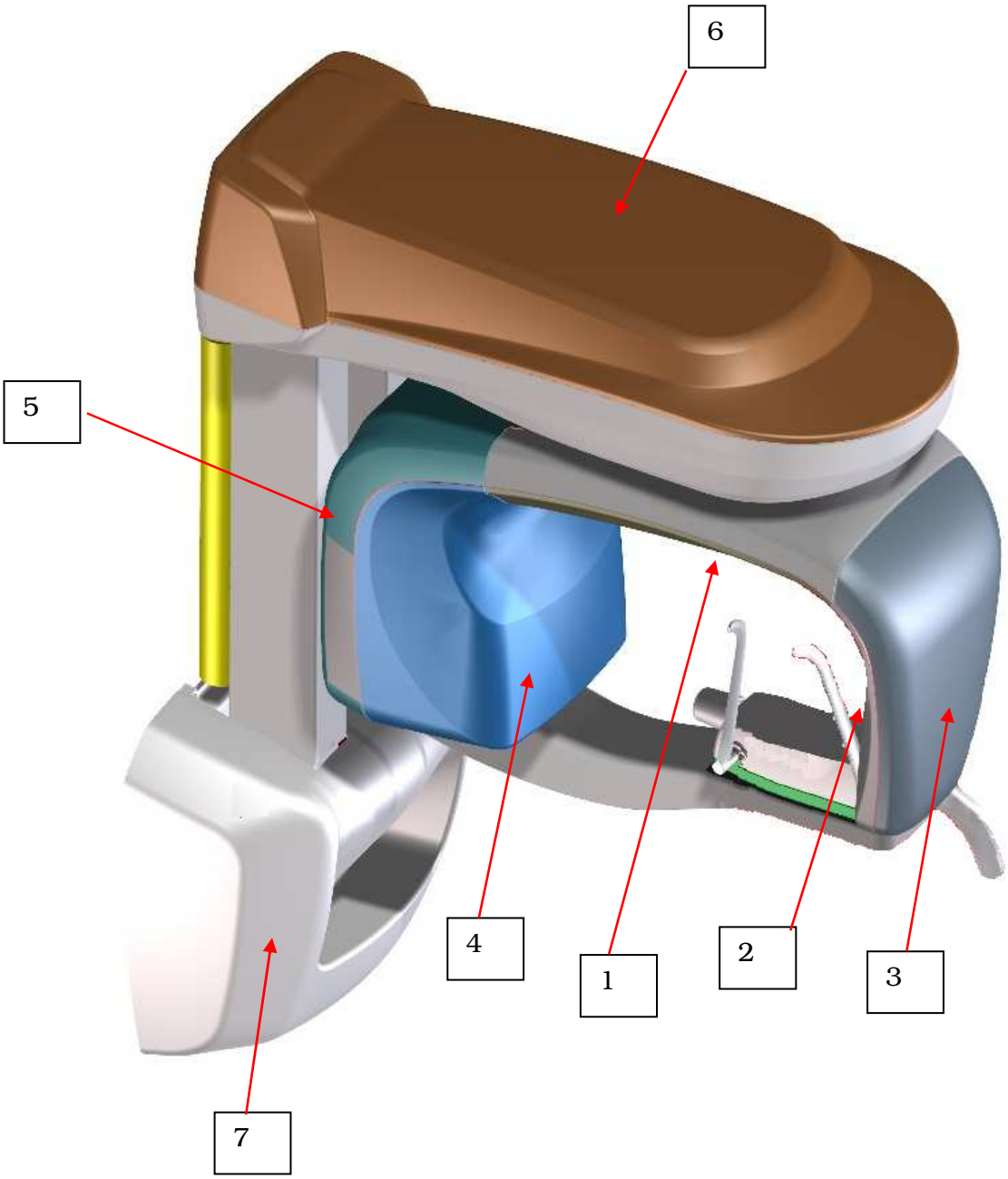


4 Accessories and Service Tools

Rif.	Order code	Description	Note
-	6104011019	PAN Chin rest High	
-	6107090819	Maxillary sinus Chin rest	
-	6104011219	PAN Chin Rest low	
-	6607099800	TMJ Support	
-	**6607900200**	**Tool kit for Digital units**	
-	6107110300	PAN centering bites (10 pcs)	
-	6107110700	Disposable bite protective sleeves (100 pcs)	
-	6107110800	TMJ positioner protective sleeves (60 pcs)	
	INCLUDING ALSO		
-	5207900200	PAN Centering tool	
-	5607900800	Copper filter	

5 Covers

Rif.	Order code	Description	Note
-1-	5404020305	Rotating arm lower cover	
-2-	5404020505	Sensor internal cover	
-3-	5404020405	Sensor external cover	
-4-	5404020205	Tube head internal cover	
-5-	5404020605	Tube head external cover	
-6	5404041105	Upper cover	
-7	5404100105	Wall plate cover	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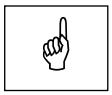
6 Cables

Rif.	Order code	Description	Note
--	6204100500	Main elicoidal cable	
---	6204040500	Laser cable 1	
---	6204040600	Laser cable 2	
---	6204040100	Generator board power supply cable	
---	6204040200	Generator board signal cable	
--	6204041100	CPU board power supply cable	
--	6204040400	DSPU Board CAN Bus and signal cable	

16. APPENDIX

16.1. Appendix A: Setup parameters table

The following table lists those adjustment parameters stored in the unit during factory testing and that must be re-entered into the non-volatile memory in case of replacement of the CPU board (A5). This is due to the fact that the new CPU board, provided as a spare part, has been factory tested from the functional point of view, but contains only default parameters which are not related to the unit where it will be installed.
Entering of the listed parameters can be performed through the service programs (passwords).



NOTE:
The information listed in the table are the technical parameters set during factory testing. Preferences set by the user (e.g. exposure parameters different than the default ones) are not listed.

The table also has columns with blank cells. These cells must be filled in when, during installation or during the life on the unit, any of the listed parameters will be modified (e.g. after replacing a motor or a positioning sensor).

Rotograph Prime

Unit code:_____

Unit S/N:_____

U.I.C.:_____

Parameter		Factory setting	New setting	New setting	New setting	New setting
Date						
Rotation axis motor offset						
Y axis motor offset						
Bitewing Y offset						
Tubehead pre-heating values	2mA					
	3mA					
	4mA					
	5mA					
	6mA					
	7mA					

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Cod. 69004910603_Rev.0

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