VILLA SISTEMI MEDICALI

Rotograph EVO 3D CE 0051

User's Manual

Version September, 22 2015 (Rev. 3)

Revision history Manual code 6907912103

Rev.	Date	Page/s	Modification description
0	02.12.10	-	Document approval.
1	05.12.11	All	110-120V characteristics and identifications plates added. Number of projection doubled and exposure time adjusted in 3D examination. (Ref. RDM 7501)
2	11.02.13	2, 21, 23, 25, 36, 41, 44, 46, 47, 52, 53, 56, 58, 60 61, 75, 76, 79, 95, 97, 99, 178	Release FW version 4.64 on CPU board (bitewing exam added, DAP value displayed). Release FW version 4.03 on CPU board (EVO Panoramic). New anatomic exposure values in 3D Dentition exam. New TMJ positioner. (Ref. RDM 7437, RDM 7721, RDM 7751)
3	22.09.15	From 42 to 56	According to 21CFR 1020.33, addition of CTDI information, tomographic reference plane indication, Image Quality check procedure and reference values. (Ref. RDM 8117)

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Contents

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This manual is the English translation of the original Italian manual version.

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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.

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

This manual is limited to the description of the radiographic equipment; the instructions for the image acquisition, manipulation and processing Digital Acquisition System software are given in the manuals supplied with the Digital Sensor.

WARNING:

1. Rotograph EVO 3D is an electro-medical device and it can be used only under the supervision of a physician or of highly qualified personnel, with the necessary knowledge on X-ray protection.
2. The device must be used in compliance with the procedures described, and never be used for purposes different from those herewith indicated.
3. 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.
4. The user is liable as concerns the legal fulfilment related to the installation and the operation of the device.

1.1 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 EVO 3D, 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) and also allows the acquisition of volumetric tomographic or 3D X-rays.

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.
- DIGITAL CEPH; allows the execution of the following exams, available in High Resolution mode or Normal Resolution (high speed):
  - CEPH exam in different formats
  - CARPUS exam.

1.2 Physical principles of operation

In general the Flat Panel sensor functions as a normal digital sensor, that converts the amount of dose that affects every single sensor element (pixel) into an electrical signal that can be processed through an analogue-digital conversion system. Unlike traditional sensors used for panoramic exams that normally return one column image at a time, the Flat Panel returns the entire contents of the sensor. Special functions inside the sensor also allow the acquisition of a specific part of the sensor.
The system must be connected to a dedicated PC, on which are installed all the software needed for image acquisition, processing and display. The resulting images are stored in the system's database in correspondence with the selected patient.

1.3 Acquisition of 3D or volumetric images

In 3D acquisitions a sequence of two-dimensional images is acquired during a rotation of the rotating arm.
In this type of acquisition, the X-ray generator is operated in pulsed mode, with short pulses emitted at each degree of the rotating arm.
The sequence of images thus obtained is passed to a special software residing on the dedicated PC, which uses sophisticated mathematical algorithms to generate the volume concerning the emission.
The spatial resolution of the image obtained is the result of both the size of the sensor's pixels and the quality of the reconstruction software, in this case the resolution is measured in "voxel" (short for VOlume piXEL).
The volume thus reconstructed is returned to the image display software, in which different operations are possible that allow the operator or the physician to select which part of the volume to display, to obtain specific sections at a given point, etc.

1.4 Panoramic and cephalometric acquisitions

Special functions of the Flat Panel also allow to acquire partial sensor images with a frame rate (acquisition speed) higher than that used for 3D images.

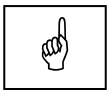
In this mode, the X-ray emission is continuous, as in normal panoramic radiography.The sequence of images obtained form the input to a special reconstruction software, developed specifically for the Rotograph EVO 3D, which allows the reconstruction of the standard panoramic X-ray simulating the physical mechanism of "cancelation" as used in analogue systems.

1.5 Digital sensors

The unit uses the wide range digital system PaxScan 1313 Varian, used for 3D and Panoramic type images.
The cephalometric images are obtained using the digital system designed by Owandy, France.

The use of the equipment includes a dedicated Personal Computer (PC), on which image acquisition, management and processing programs are installed.

1.6 Icons appearing in the manual



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. USABILITY

The Medical System Rotograph EVO 3D is intended to be used in radiology or dental practices.
In the first case the user is either the radiologist or Technician specialised in Radiology and in the dentist in the latter case. The radiologist or the dentist is responsible for the assessment of the risk/benefit ratio.

In both cases, these are people who already have basic knowledge about:

- emission of ionising radiation
- danger of physical harm related to the excessive use of ionising radiation
- methods to reduce the risk of excessive radiation to the patient (use of lead-lined protections, etc.).

The operator must be familiar in the use of a Personal Computer (PC) and related programs, in order to use the functions on the PC easily.

2.1 Training

The operator training follows at the end of the system's installation both concerning the use of the system and the image acquisition and display programs.

The training does not require the use of special tools.

This manual describes the steps necessary to perform volumetric X-rays (or 3D) or standard panoramic type X-rays.

2.2 Patient profile

The machine is suitable for all types of patient.
Depending on the type of patient, the different execution modes of each examination can be selected on the operating console (adult, baby - small, medium or large - type of dentition).

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 EVO 3D 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.

In compliance with the IEC 60601-1 standard, the modification of the equipment or its parts is strictly prohibited.

3.1 Warnings

Rotograph EVO 3D must be used in dental surgeries, radiology and hospital settings.

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, please disconnect it from the line voltage.

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 EVO 3D 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 EVO 3D must be switched off while using devices such as electrosurgical devices or similar apparatus.

Clean and disinfect all parts that come into contact with the patient. **The centring bite or the bite protective sleeve, the head strip for 3D examinations and the ear centring devices of the Cephalostat 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.
The manual movement is only allowed in case of error 206 (no power to motors) to allow the exit of the patient.

Although the dose supplied by dental X-ray units is quite low and distributed on a small surface, the operator must adopt the precautions and/or suitable protection for the patient and himself, during the execution of radiography. 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 2 m both from the X-ray source and from the patient, as shown in Figure 1 and Figure 2.

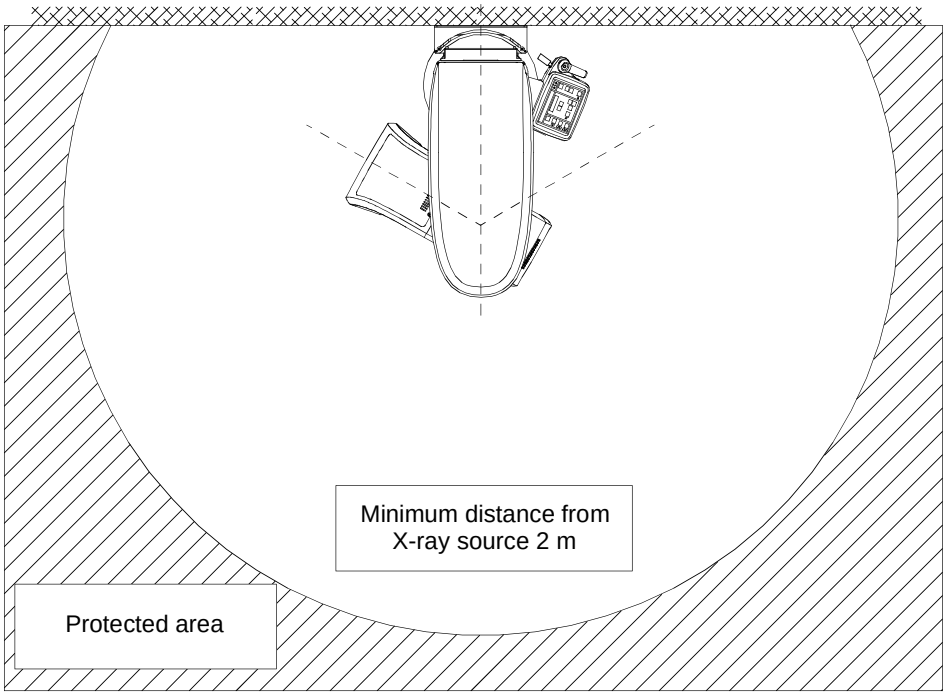


Figure 1 - Panoramic version

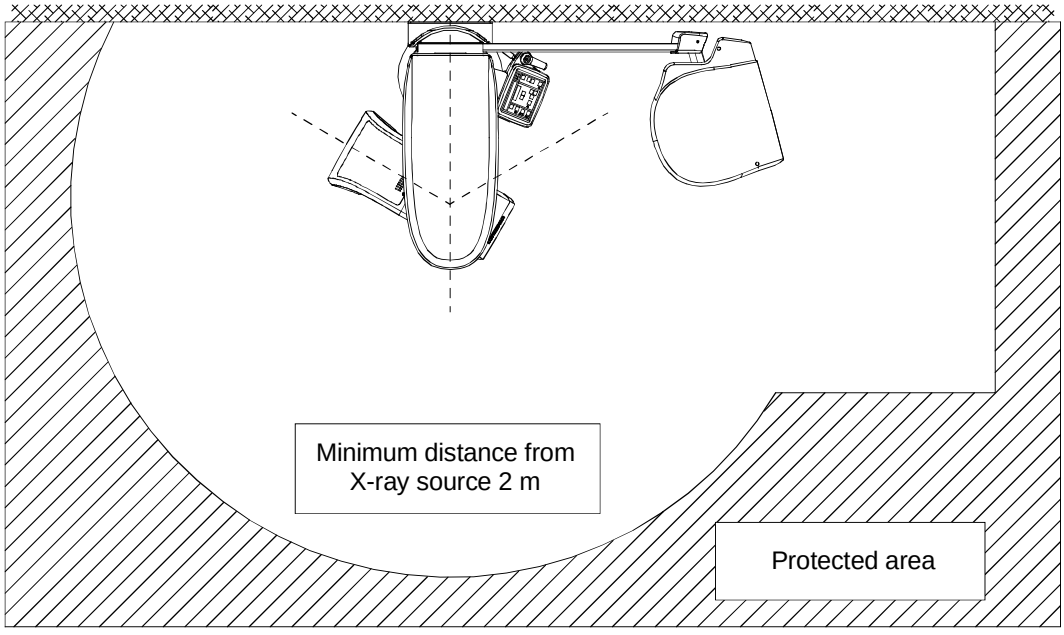


Figure 2 - Cephalometric version

WARNING:
The network connector on the base of the Rotograph EVO 3D column must be connected to the dedicated image acquisition and 3D and panoramic reconstruction PC via a shielded Ethernet cable "Cat.5e" or greater.
Do not use this connector to connect the Rotograph Evo 3D to LAN networks.

NOTE:
The dimension of the "patient's environment" is defined as a distance of at least 1.5 m from the actual patient.
If the PC is positioned inside the patient's environment, it must conform to the requirements specified by the IEC 60601-1 standard for medical devices; if located outside of the patient's environment, it must be compliant with the IEC 60950 standard.
If the PC is supplied by Villa (optional), it must be placed outside the patient's environment.

NOTE:
Do not apply movements to the rotating arm or the tube-head when the equipment is on

WARNING: PRECAUTIONS WHILE USING LASER CENTRING DEVICES:
Although the laser centring devices used on the Rotograph EVO 3D system are classified in Class 1 in compliance with the IEC 60825-1:1993 standard and attachments, the following precautions are recommended:

- 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 authorised technicians.
  Operations other than those indicated could cause the ejection of dangerous non-ionising radiation.

3.1.1 Distribution of stray radiation

	-1.5	-1	-0.5	0	0.5	1	1.5m	
1.5m	0.02	0.02	0.03	0.03	0.03	0.03	0.02	1.5m
1	0.025						0.03	1
0.5	0.03						0.02	0.5
0	0.03						0.004	0
-0.5	0.03						0.01	-0.5
-1	0.03						0.02	-1
-1.5	0.02	0.03	0.03	0.04	0.03	0.025	0.02	-1.5
	-1.5	-1	-0.5	0	0.5	1	1.5m	

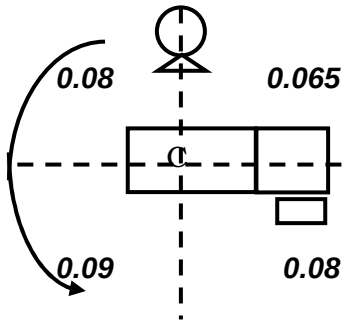


Figure 3: Distribution of stray radiation

Figure 3 illustrates the distribution of stray radiation in the horizontal plane at the centre of rotation of the scanning unit in the area of a 3 x 3 m rectangle.
The measurement was performed using a cylindrical phantom with a diameter of 320 mm and length of 140 mm placed in the centre of rotation of the scanning unit, with the "3D Dentition" examination mode and the following parameters set: 86 kV, 10 mA, 8 s.
The distribution values in the table are expressed as air Kerma for mAs (µGy/mAs).

3.1.2 Electromagnetic emissions

In accordance with the IEC 60601-1-2 standard, the Rotograph EVO 3D 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
CISPR 11	Group I	Rotograph EVO 3D uses RF energy only for its the internal function. Therefore, the R.F. emissions is very low and not likely to cause any interference in nearby electronic equipment.
	Class B+12	Rotograph EVO 3D is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Class A	Rotograph EVO 3D is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Rotograph EVO 3D is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic purposes.

3.1.3 Electromagnetic immunity

In accordance with the IEC 60601-1-2 standard, the Rotograph EVO 3D 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 discharges (ESD) IEC 61000-4-2	6 kV contact 8 kV air	Test level IEC 60601-1-2	Residential/Hospital
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines > 3 m	Test level IEC 60601-1-2	Residential/Hospital
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	Test level IEC 60601-1-2	Residential/Hospital
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_n for 0.5 cycles 40 % U_n for 5 cycles 70 % U_n for 25 cycles 0 % U_n for 5 s	Test level IEC 60601-1-2	Residential/Hospital
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Test level IEC 60601-1-2	Residential/Hospital

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 EVO 3D, 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	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5 GHz

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment
Conducted RF IEC 61000-4-6	3 V 50 kHz to 80 MHz	3 V	$d = 1.2 \times \sqrt{P}$
			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 transmitters, as determined by an electromagnetic site survey, should be less then the compliance level in each frequency range. Interference may occur in the vicinity of the equipment marked with the following symbol: 

3.1.4 Recommended separation distances for non-life supporting equipment

Rotograph EVO 3D is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Rotograph EVO 3D 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 $d = 1.2 \times \sqrt{P}$	**80MHz to 800MHz** $d = 1.2 \times \sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance"*d*" in meters (m), can be estimated using 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.

NOTE:
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

3.2 Environmental risks and disposal

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.
- **Control Panel:** iron, copper, aluminium, glass-resin, non-biodegradable plastic material packaging.
- **Column, rotating arm and extensions:** iron, lead, aluminium, copper, glass-resin, and non-biodegradable plastic material.
- **Applied parts:** non-biodegradable plastics, iron, aluminium.
- **Digital sensor:** iron, lead, copper, integrated electronic components.

INFORMATION TO USERS IN THE EUROPEAN COMMUNITY:
According to art. 13 of Legislative Decree 25th July 2005, nr. 151 "Implementation of Directives 2002/95/CE, 2002/96/CE, and 2003/108/CE, regulating the reduction of the use of hazardous substances in electrical and electronic equipment, as well as the waste disposal"

The symbol with the waste bin crossed on the equipment or its packaging, indicates that the product must be separately collected from other waste at the end of its life.

The separate collection of the present equipment that has reached the end of its life is organised and managed by the manufacturer. The user who wishes to dispose of this equipment must contact the manufacturer and follow their system to enable the separate collection of the equipment at the end of its life.

Suitable separate waste collection for the subsequent start of the equipment discarded for recycling, for treatment and for environmentally friendly disposal, contributes in preventing possible adverse effects on the environment and health and promotes the reuse and/or recycling of materials of which the equipment is comprised.
Illegal disposal of the product by the holder implies the application of administrative sanctions provided by law

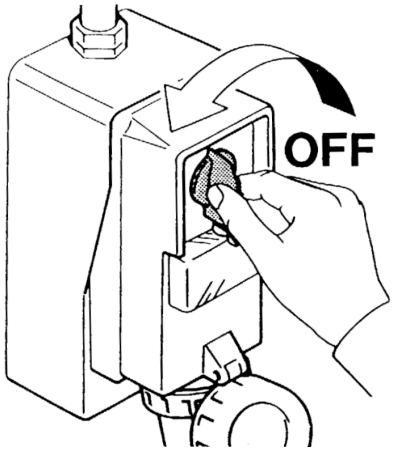
3.3 Symbols used

Apart from the symbols indicated on the control panel, the following icons are also used in this Manual and on the Rotograph EVO 3D itself (see Chapter 7):

Symbol	Description
	Device with type B applied parts
	In some of its parts, the device contains materials and liquids that, at the end of the lifespan of the unit, must be disposed of at the appropriate disposal centres
~	Alternating current
N	Connection point to the neutral conductor
L	Connection point to the line conductor
	Protection earthing
	Operation earthing
	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 manufacture (year and month)
	Manufacturer's name and address
	Total filtration
	Tube-head
	X-ray tube
	See the accompanying documentation
CE 0051	Conformity to the EC 93/42 Directive

4. CLEANING AND DISINFECTION

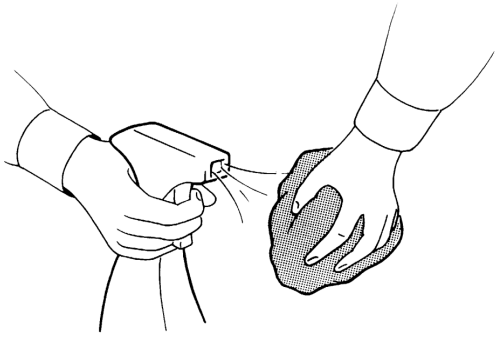
In order to guarantee a good level of hygiene and cleaning, it is necessary to respect the following procedures.



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).



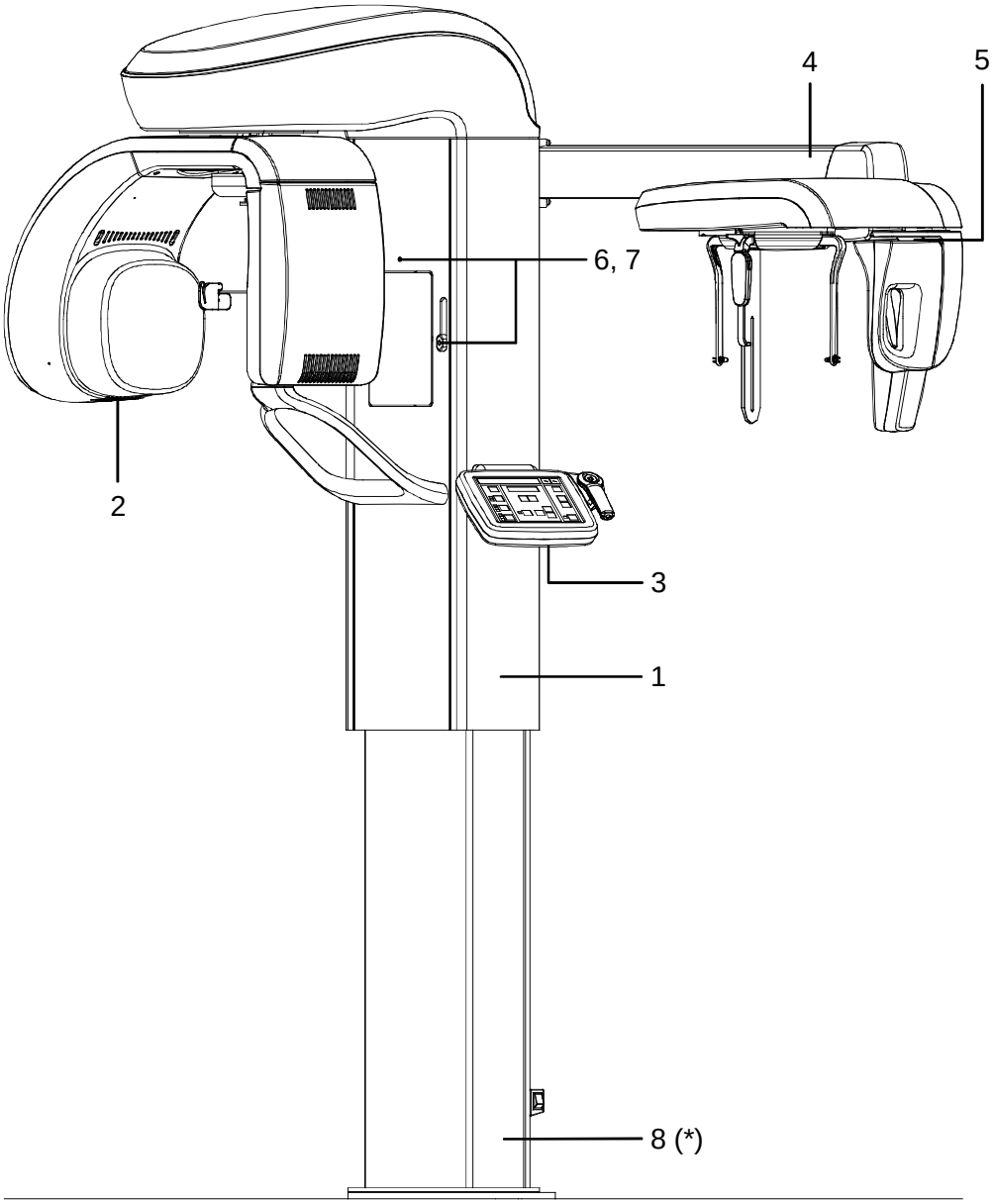
Thoroughly clean the chin support, resting handgrips, nose-rest and temple clamp support any time these are used.
The centring bite or the bite protective sleeve, the head strip for 3D examinations and the ear centring pins of the Cephalostat must be replaced after each examination in which they were used.

4.1 Cleaning materials compatible with Rotograph EVO 3D

Neutral detergent for painted surfaces, accessories and connection cables.
Solution at 2% glutaraldehyde for chin support, resting handgrips, nose rest and temple clamp support.

5. DESCRIPTION

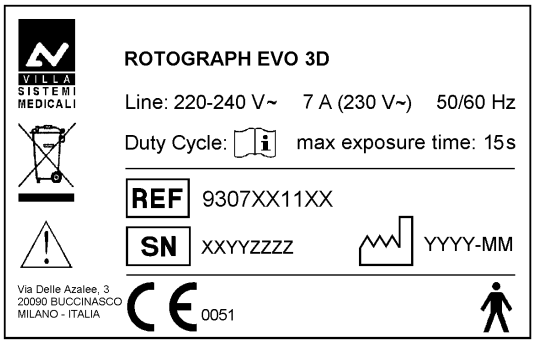
5.1 Identification plates and laser labels



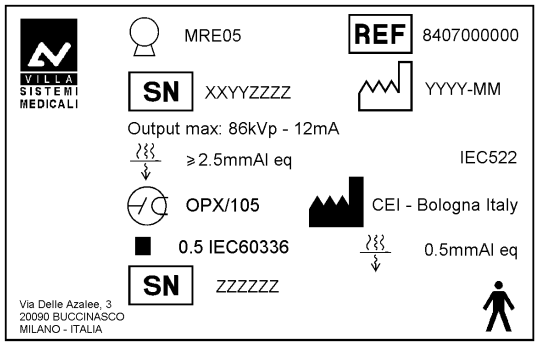
(*) Only for 110-120V version

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

1
Rotograph EVO 3D data plate

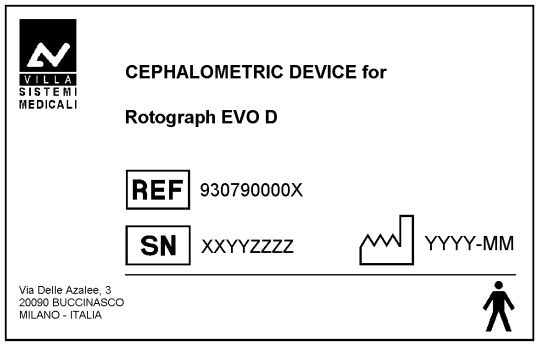


2
Tube-head characteristics plate

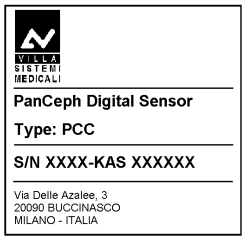


3
EVO XP plate
(Additional projection package)

4
CEPHALOMETRIC device plate



5
PANCEPH digital
sensor data plate

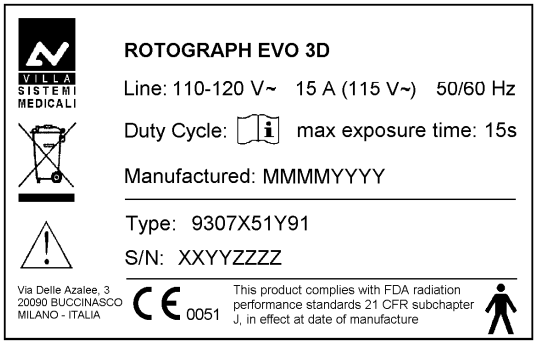


6
(N° 2) Spot Laser
indicator label

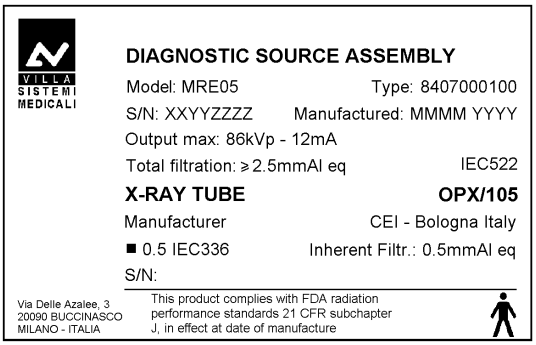
7
(N° 2) Laser symbol
label

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

1
Rotograph EVO 3D data plate

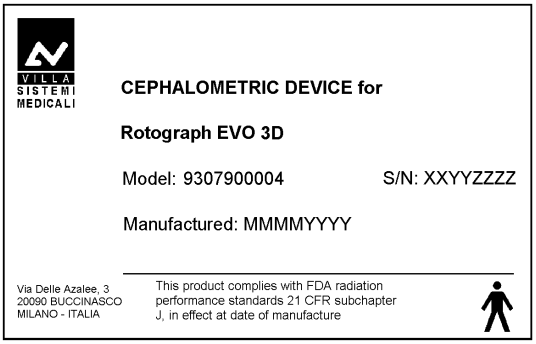


2
Tube-head characteristics plate

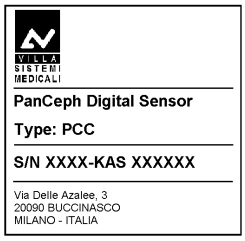


3
EVO XP plate
(Additional projection package)

4
CEPHALOMETRIC device plate



5
PANCEPH digital
sensor data plate



6
(N° 2) Spot Laser
indicator label

7
(N° 2) Laser
symbol label

8
WARNING label

COMPLIES WITH DHHS PERFORMANCE STANDARD 21 CFR SUBCHAPTER J

WARNING:

THIS X-RAY UNIT MAY BE DANGEROUS TO THE PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.
ELECTRICAL SHOCK HAZARD - DO NOT REMOVE PANELS. EISK OF EXPLOSION - DO NOT USE IN PRESENCE OF FLAMMABLE ANESTHETICS.
FOR CONTINUED PROTECTION AGAINST RISK OF FIRE, REPLACE ONLY WITH SAME TYPE AND RATING OF FUSE.

DANGER:

CET APPAREIL DE RADIODIAGNOSTIC PEUT ETRE DANGEREUX POUR LE PATIENT ET L'OPERATEUR SI LES FACTEURS D'EXPOSITION ET LES INSTRUCTIONS NE SONT PAS SUIVIS. RISQUE D'EXPLOSION
- NE PAS EMPLOYER EN PRESENCE D'ANESTHESIQUES INFLAMMABLES POUR ASSURER UNE PROTECTION CONTINUE CONTRE LE RISQUE D'INCENDIE.
UTILISER UNIQUEMENT UN FUSIBLE DE RECHARGE DE MEME TYPE ET DE MEMES CARACTERISTIQUES NOMINALES.

5.2 Functions, models and versions

Rotograph EVO 3D, 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) and volumetric three-dimensional images.
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:

- **EVO XP (Additional projection package)**
  Allows you to carry out the following additional examinations: Emi-panoramic, Improved orthogonality dentition, reduced dose Panoramic, Frontal dentition and Bitewing.
- **CEPH**
  Allows you to carry out the following examinations:
  – CEPH exam in different formats
  – CARPUS exam.

5.2.1 Basic version

The base 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 86kV, in 2kV steps and anodic current from 6 mA to 10 mA in 1 mA steps.
- Sinus enables to perform images of the paranasal sinuses with front projection (postero/anterior).
- TMJ mouth closed/open in lateral projection.
- 3D volumetric examinations of the Dentition, TMJ Left, TMJ Right and Sinus.

5.2.2 Version with cephalometric device

The version with cephalometric device allows you to perform the following examinations:

- Panoramic, Sinus and TMJ, Adult and Child, with the same characteristics described for the base version.
- 3D volumetric examinations with the characteristics described for the standard version.
- Digital Cephalometry with a choice between Adult and Child with 3 sizes each.The execution of the high resolution or standard resolution can be selected within each combination, for a total of 12 combinations in Automatic selection.When examining at a Normal Resolution, the examination is conducted with a reduced scan time, allowing a further reduction of dose. In manual selection it is possible to select high voltage between 60kV and 86kV, in 2kV steps and anodic current from 6 mA to 12 mA in 1 mA steps. The positioning of the primary slide collimator, the secondary collimator and the Digital Sensor (in its sensor holder) is automatic, depending on the size/projection selected.The Soft Tissues Filter is powered to attain the best possible result of the facial profile.
- Children only Carpus exam with 3 selectable sizes, for a total of 3 combinations of exam in automatic. in manual selection it is possible to select high voltage between 60kV and 86kV, in 2kV steps and anodic current from 6 mA to 12 mA with 1 mA steps. The positioning of the primary slide collimator is automatic.

The values of exposure factors given in the tables of paragraph 8.19.1, set as default, are guidelines.
The real adjustment of these values depends on different conditions, such as the preference of the user for very/little exposed images.

5.2.3 EVO XP function (Additional projection package) - Optional

The unit, both the base and the version with cephalometric device, is prearranged to be fitted with the EVO XP (Additional 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 ascending rami of the TMJ from the exams
- The frontal dentition enables to perform examinations of the front part (roughly from canine to canine)
- The dentition 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 EVO 3D systems already installed in the field.

NOTE:
The code inserted into Rotograph EVO 3D 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.

Pressing the "Patient entrance" (7)  will reset this condition, but only the Panoramic, Sinus and TMJ will be active at the end of the start-up procedure.

The UIC code can be displayed by pressing the "Right Arrow/Left Arrow"  during the start-up phase.

The UIC code is simply an identifier of the single Rotograph EVO 3D unit; in order to enable the optional functions it is necessary to request the activation code from Villa Sistemi Medicali, which derives from the Unique Identification Code or from the device serial number.

6. TECHNICAL CHARACTERISTICS

General features		
Device type	Rotograph EVO 3D	
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italia	
Class	Class II B for European Directive for Medical Devices 93/42 Class II for Canadian MDR Class I with type B applied parts according to IEC 60601-1 Class II according to 21CFR-subchapter J 	
Operating mode	Continuous with adaptive duty cycle	
Protection degree	IPX0	
Rated line voltage	220-240 V~	110-120 V~
Line frequency	50/60 Hz	
Maximum line current	7 A @ 230 V~ 50/60 Hz	15 A @ 115 V~ 50/60 Hz
Absorbed power	1.5 kVA @ 230 V~ 50/60 Hz	1.6 kVA @ 115 V~ 50/60 Hz
Protection fuse (F1)	7 A T	15 A T
Switching supply protection fuse (F2)	1.6 A T	3 A T
Generator card protection fuses	F1: 10 A F F2: 5 A HF F3: 2 A T	
Line apparent resistance	0.5 Ω max	--
Line voltage regulation	--	< 3% @ 99 V~
Rated output voltage (kVp)	60 ÷ 86 $kV_{p,}$ with 2 kV_p steps	
Anodic current	6 ÷ 10 mA, with 1 mA steps for PAN, TMJ and Sinus 6 ÷ 12 mA, with 1 mA steps for Ceph (up to 76 kVp) 6 ÷ 10 mA, with 1 mA steps for Ceph (from 78 kVp to 86 kVp)	
Additional filter for wide range sensor cover (for 3D exams)	<< 1.2 mm Al eq. @ 70 kVp	
Additional filtration for PANCEPH sensor cover	0.1mm Al eq. @ 70 kVp	

Exposure times	
EVO Panoramic	14.4 s Adult / 13.3 s Child
Panoramic STD	13.8 s Adult/Child
EVO Emi-panoramic	7.8 s Adult / 7.3 s Child
STD Emi-panoramic	7.4 s Adult / 7.3 s Child
EVO Reduced dose Panoramic	11.9 s Adult / 10.8 s Child
STD Reduced dose Panoramic	11.4 s Adult/Child
Improved orthogonality dentition	11.9 s Adult/Child
Frontal dentition	4.4 s Adult/Child
Bitewing	3.2 s right / left 6.3 s right and left
TMJ mouth closed/open	2.44 s per image for left and right joint in open and closed condition for a total of 9.7 s
SINUS	9.4 s
Volumetric 3D exams	11.2 s for Dentition and Sinus 10.1 s for TMJ Left and TMJ Right (each)
Cephalometry (Ceph)	Variable exposure time depending on the type of resolution and size selected.Minimum 4.5 s (18x22nR), maximum 15 s (30x22hR)
Exposure time accuracy	± 10 %
Examination modes	
Examination selection	• Automatic selection for Adult and Child, 3 Sizes • Dentition type selection (in Panoramic) • Manual selection • Collimator with automatic positioning
Panoramic NOTE: Some of these exams are optional and depend on the system configuration.	• EVO Panoramic • Standard Panoramic • RH and LH Emi-panoramic • Reduced dose Panoramic • Improved orthogonality dentition • Frontal dentition • Bitewing L/R • Bitewing L and R
TMJ (Temporo-Mandibular Joint)	TMJ mouth closed/open

Examination modes	
SINUS	Sinus P/A projection
Volumetric 3D exams	Automatic selection for Adult and Child, 3 sizes chosen between 4 types of exam: Dentition, TMJ Left, TMJ Right, Sinus
Cephalometry and Carpus	• Normal resolution in Latero-Lateral or Antero-Posterior projections (different sizes) • High resolution in Latero-Lateral or Postero/Anterior projections (different sizes) • High resolution Carpus exams • Motorised soft tissue filter
Image magnification	
Standard Panoramic	1 : 1.28 Adult and Child
TMJ open/close mouth, 4 images	1 : 1.25 (nominal)
Sinus	1 : 1.27 (nominal)
Ceph (on the sagittal medial plane in LL projection)	1: 1.10 geometric magnification 1 : 1 magnification after software correction (*)

(*) WARNING:
The declared image magnification value is valid after proper software calibration.

Tube-head characteristics	
Model	MRE 05
Manufacturer	Villa Sistemi Medicali S.p.A. 20090 Buccinasco (MI) Italia
Maximum tube voltage	86 kV_p
kV_p accuracy	± 8 %
Maximum anodic current	12 mA
Anodic current accuracy	± 10 %
Output radiation linearity	< 0.2 according to standard IEC 60601-2-7:1998 paragraph 50.102.2
Duty cycle	Adaptive duty cycle depending on the exposure parameters: from 1 : 8 (at 60 kV, 6 mA) up to 1 : 20 (at 76 kV, 12 mA). Further reduction for three exposures in close-up sequence: from 1: 3.6 (at 60 kV, 6 mA) up to 1 : 9 (at 76 kV, 12 mA).
Nominal power	1.032 kW (86 kV_p - 12 mA -4s)
Total filtration	2.5mm Al eq. @ 70 kV_p
HVL (Half value layer)	> 2.0 mm Al eq. @ 60 kV_p > 2.7 mm Al eq. @ 74 kV_p > 3.2 mm Al eq. @ 86 kV_p
Transformer insulation	Oil bath
Cooling	By convection
Leakage radiation at 1 m	< 0.5 mGy/h @ 86 kV_p - 12 mA - 3s duty cycle 1/16
Tube-head maximum thermic capacity	310 kJ

X-ray tube characteristics	
Manufacturer	CEI Bologna (Italy)
Type	OPX 105
Nominal focus size	0.5 IEC 60336
Inherent filtration	0.5mm Al eq.
Anode tilt	5°
Anode material	Tungsten
Nominal maximum voltage	105 kV_p
Filament max current	4 A
Filament max voltage	8 V
Anode thermal capacity	30 kJ
Wide range sensor (Flat Panel)	
Sensitive area	130 x 130 mm
Sensor pixel size	127 µm, 254 µm in binning 2x2
Scintillator screen	Cesium iodide C_sI
Number of sensor pixels (H x L)	1024 x 1024 (binning 1x1) 512 x 512 (binning 2x2)
Reconstructed volume (height diameter)	85 x 85 mm
Voxel dimensions	166 µm
PANCEPH sensor	
Sensitive area (H x L)	220 x 6 mm
Pixel dimension	48 µm, 96 µm in binning 2x2 (CEPH hR), 144 µm in binning 3x3 (CEPH nR)
Pixel (H) NOTE: The number of horizontal pixels (columns that make up the image) depends on the type of examination selected and the resolution set.	1536 in nR, 2304 in hR

NOTE:
The Rotograph EVO 3D version without cephalometric arm, uses only the wide range sensor both for 3D images as well as for Panoramic images (narrow beam), while is also used the second PANCEPH sensor in the version with Cephalometric arm.

Laser centring devices	
Patient positioning is guaranteed by 2 laser beams that align the sagittal and Frankfurt/Ala trago planes (please refer to relevant paragraphs for detailed explanation).	
Wave length	650 nm ± 10 nm
Divergence	< 2.0 mRad
Optical power	< 1 mW
Classifications	Class 1 laser device according to standard IEC 60825-1:1993 + A1:1997 + A2:2001
Mechanical features	
Image receptor-focus distance (PAN, TMJ and Sinus)	52 cm (20.4")
Image receptor-focus distance (CEPH)	165 cm (65")
Telescopic motorised column run	85 cm (33.5")
Maximum total height	245 cm (96.4")
Weight	• 161 kg (354 lb) base version • 186 kg (409 lb) version with Ceph
Column weight	87 kg
Weight of arm support, rotating arm, tube-head and sensor holder	74 kg
Ceph arm weight	25 kg
Leg weight (optional)	30 kg
Sensor holder weight	2 kg
Working conditions	
Minimum dimensions of the room (refer to the Service Manual)	• 130 x 120 cm (52" x 47.2") without CEPH arm • 145 x 200 cm (57" x 78.7") with CEPH arm
Recommended dimensions of the room (refer to the Service Manual)	• 130 x 140 cm (51.2" x 55.1") without CEPH arm • 160 x 220 cm (63" x 86.6") with CEPH arm
Maximum 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

6.1 Dose per Area Product (DAP) in 3D examinations

		mA				
		6	**7**	**8**	**9**	**10**
kV	**60**	91.5	106.8	122.0	137.3	152.6
	62	98.7	115.1	131.6	148.0	164.5
	64	106.0	123.7	141.4	159.1	176.7
	66	113.7	132.6	151.5	170.5	189.4
	68	121.5	141.8	162.0	182.3	202.5
	70	129.6	151.2	172.8	194.4	216.0
	72	137.9	160.9	183.9	206.9	229.9
	74	146.5	170.9	195.3	219.7	244.1
	76	155.3	181.1	207.0	232.9	258.8
	78	164.3	191.7	219.1	246.4	273.8
	80	173.6	202.5	231.4	260.3	289.3
	82	183.1	213.6	244.1	274.6	305.1
	84	192.8	224.9	257.0	289.2	321.3
	86	202.8	236.6	270.3	304.1	337.9

Table 1: DAP values in µGy x m² for Dentition and Sinus examinations at 11.2 seconds

		mA				
		6	**7**	**8**	**9**	**10**
kV	**60**	82.4	96.1	109.8	123.6	137.3
	62	88.8	103.6	118.4	133.2	148.0
	64	95.4	111.4	127.3	143.2	159.1
	66	102.3	119.3	136.4	153.4	170.5
	68	109.4	127.6	145.8	164.0	182.3
	70	116.6	136.1	155.5	174.9	194.4
	72	124.1	144.8	165.5	186.2	206.9
	74	131.8	153.8	175.8	197.7	219.7
	76	139.7	163.0	186.3	209.6	232.9
	78	147.9	172.5	197.1	221.8	246.4
	80	156.2	182.2	208.3	234.3	260.3
	82	164.7	192.2	219.7	247.1	274.6
	84	173.5	202.4	231.3	260.3	289.2
	86	182.5	212.9	243.3	273.7	304.1

Table 2: DAP values in µGy x m² for TMJ Left and TMJ Right examinations at 10.1 seconds

6.2 Dimensions

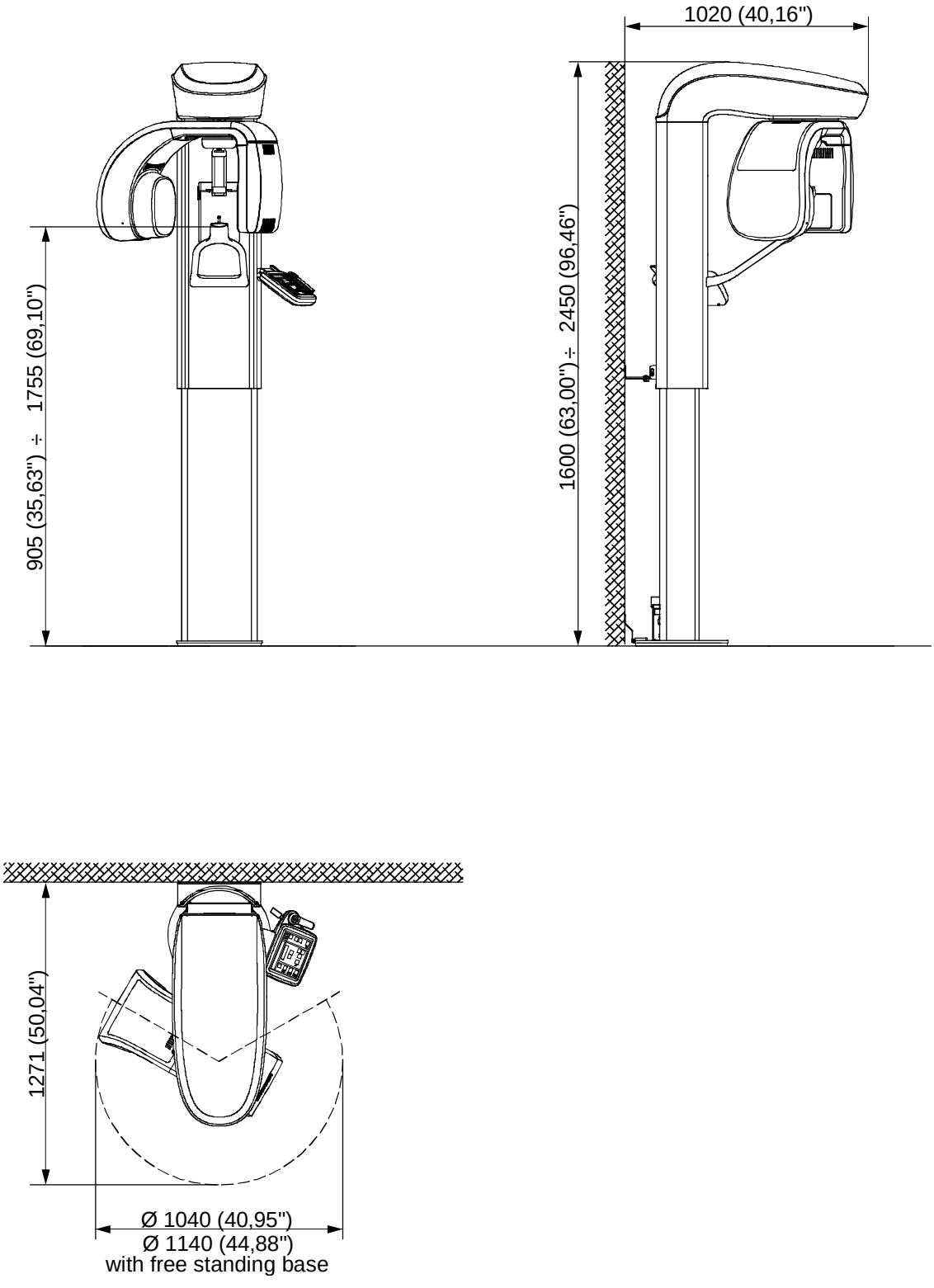


Figure 4 - Rotograph EVO 3D dimensions standard version

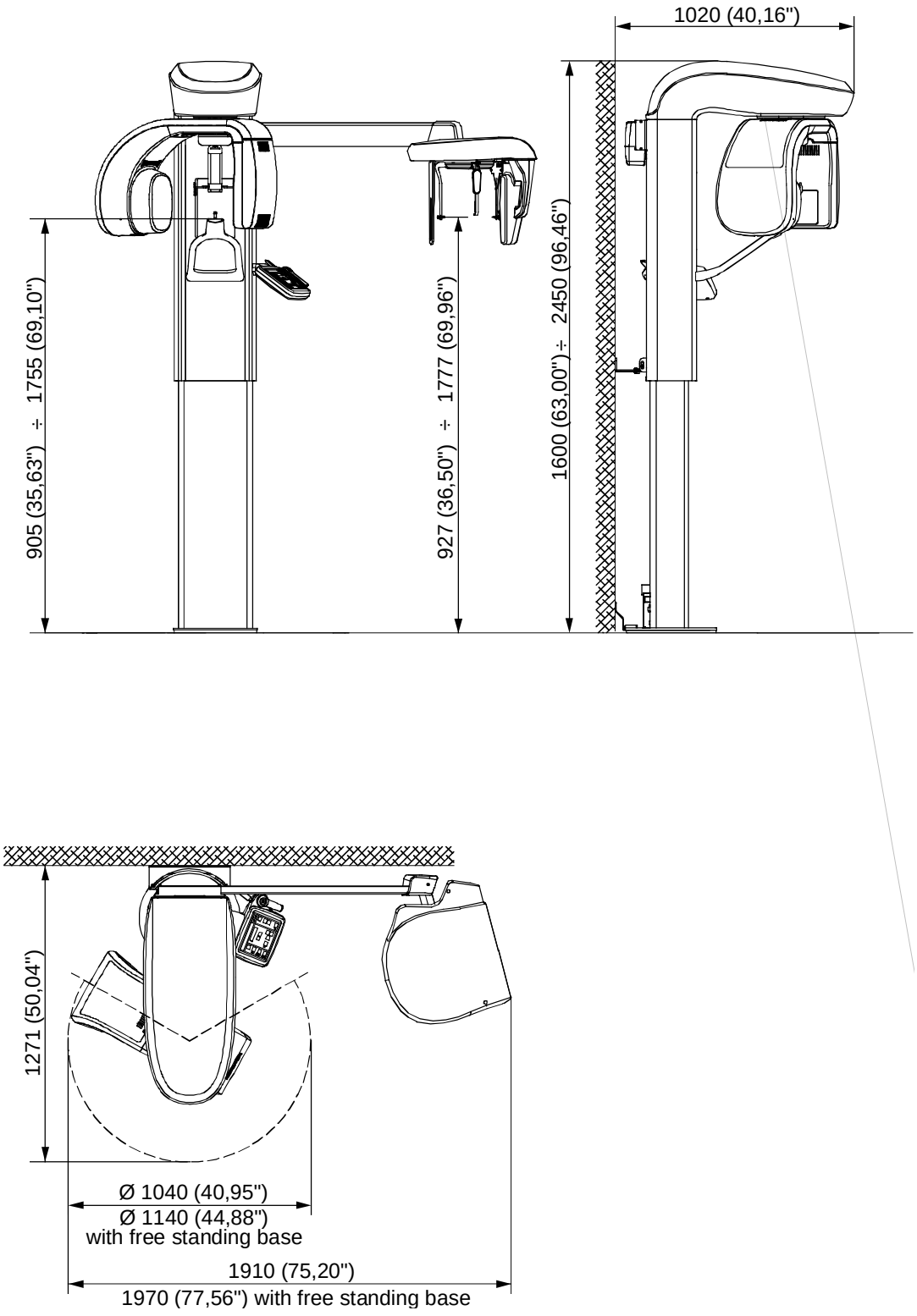
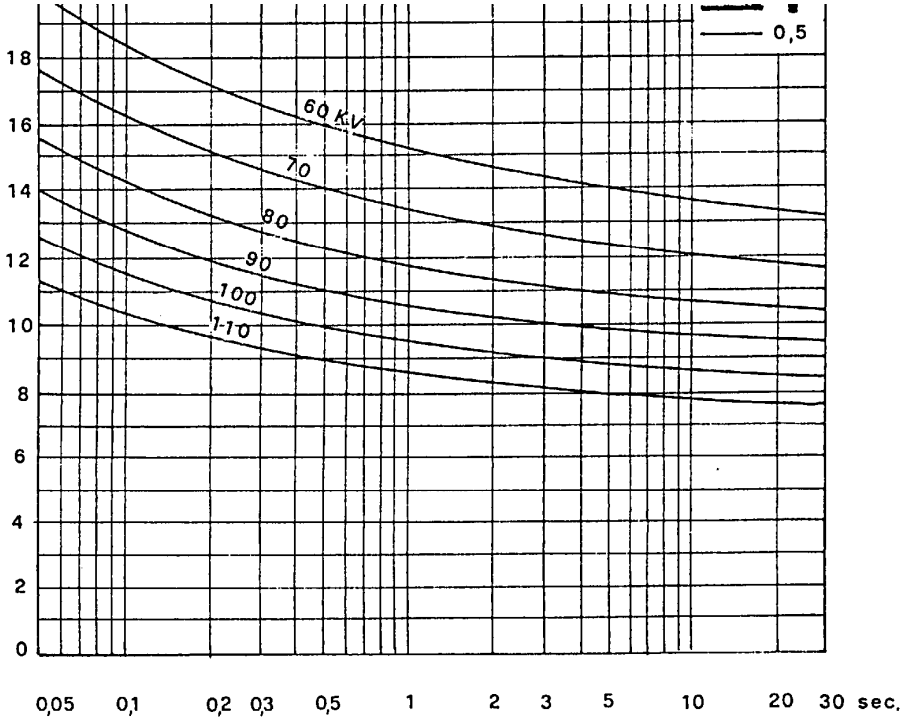


Figure 5 - Rotograph EVO 3D dimensions
version equipped with cephalometric unit

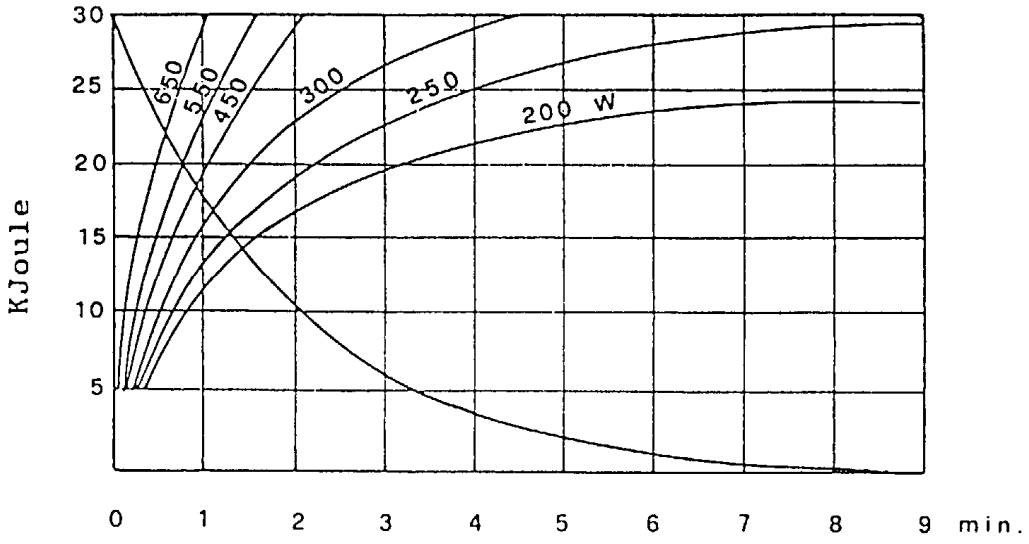
6.3 Loading curve of the tube and cooling curve of the anode

Tube "CEI - OPX/105" (0.5 IEC 60336)

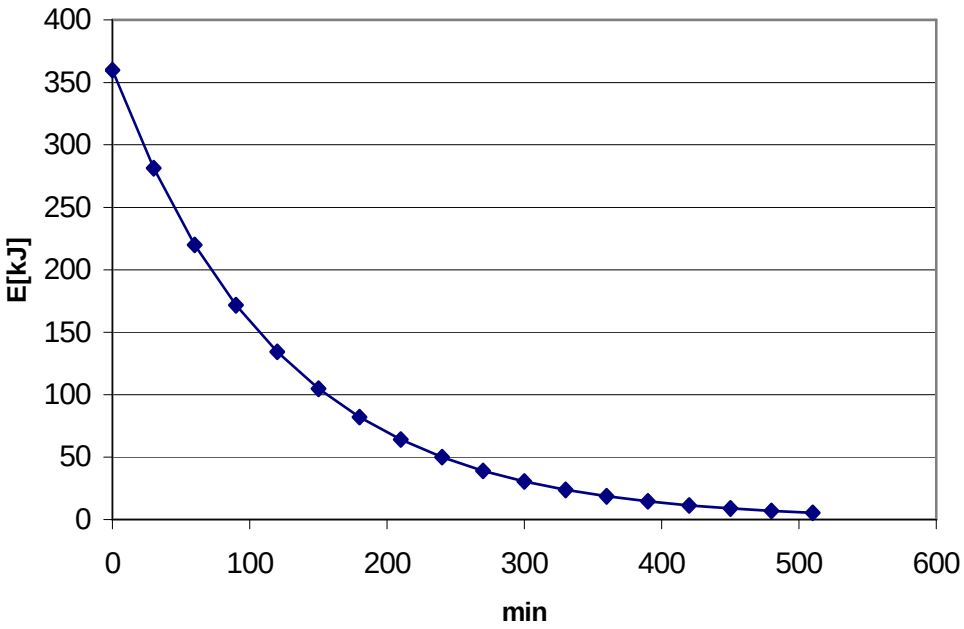
Load



Anode cooling curve

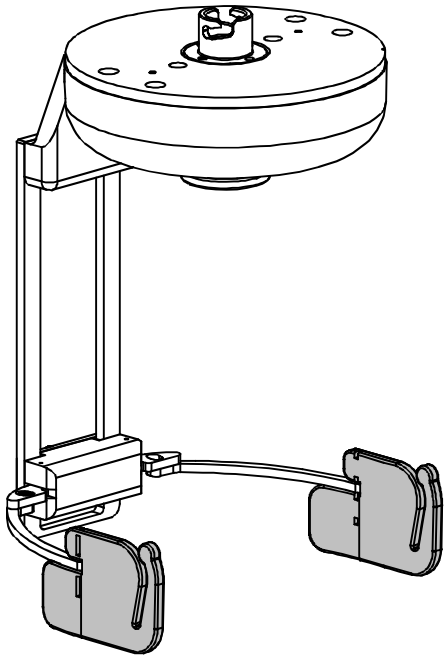
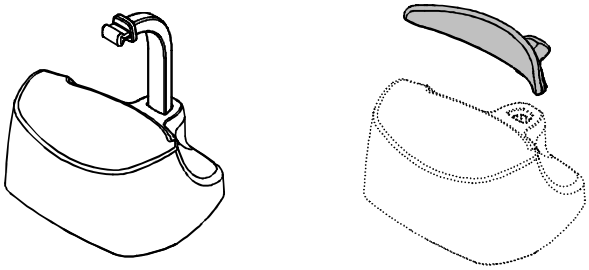
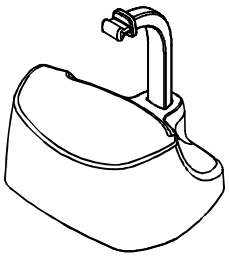
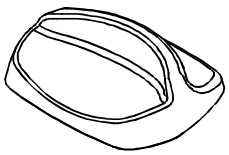


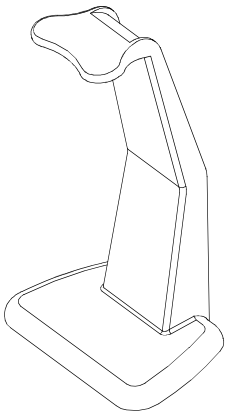
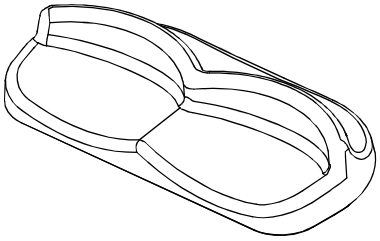
Tube-head heating and cooling curve



6.4 Separate parts supplied with Rotograph EVO 3D

Rotograph EVO 3D comes with the following removable accessories:

Temple clamp centring device for standardised and volumetric exams	
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 3D mode	

Standard TMJ positioning support	
Chin rest centring device for TMJ volumetric 3D exams	
Bites, cephalometry ear centring pins, head strips for 3D exams, 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, 2nd edition.
Some of these parts do not carry identification codes due to their small size. The use of these parts on other devices is not possible, since they are parts designed specifically for the Rotograph EVO 3D.

6.5 Applied safety regulations

Rotograph EVO 3D complies with the following standards:

CE 0051 Ensures the compliance of the Rotograph EVO 3D to the Medical Device Directive 93/42/EEC and its revised version for medical devices issued by the European Community.

- Canadian Medical Device Regulations
- 21 CFR Subchapter J

- General safety:
  IEC 60601-1:1988+A1:1991+A2:1995
  IEC 60601-1-1:2000
  IEC 60601-1-4:1996+A1:1999
  IEC 60601-2-7:1998
  IEC 60601-2-28:1993
  IEC 60601-2-32:1994
  IEC 60601-2-44:2001
  UL 60601-1 (1st edition)
  CAN/CSA C22.2 No. 601.1-M90 (2nd edition) +A1 + A2

- Electromagnetic compatibility:
  IEC 60601-1-2:2001

- Protection against radiation:
  IEC 60601-1-3:1994
  IEC 60825-1:1993+A1:1997+A2:2001

- Usability:
  IEC 60601-1-6:2004

Classifications

The EVO Rotograph 3D is a class I electro-medical device and Type B as of IEC 60601-1 classification, foreseen for a continuous working at intermittent load.
The classification according to EC Directive 93/42 and subsequent amendments for medical devices is Class II B.
According to Canadian MDR, the equipment belongs to class II.
According to FDA 21 CFR, the equipment belongs to class II.

6.6 Note on constant magnification for Panoramic and TMJ (mouth open/closed) examinations

NOTE:
Rotograph EVO 3D is based on an arch shape and the temporomandibular joint determined on statistical studies.
This shape is taken as "standard" for the dento-maxillo-facial complex.
Rotograph EVO 3D follows a rototranslation 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, X-RAY IMAGE CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC.

WARNING:
The measurement of lengths on digital images depends on the specific length calibration of the program used.
It is therefore very important to check the length calibration of the program to obtain the measurement of the anatomical part.

6.7 Measurement method of technical factors (paragraph for authorised personnel)

WARNING:
The execution of these measurements foresees the removal of the cover of the HF unit with consequent access to live parts inside.

The steps outlined in the Service Manual should be followed for the direct measurement of technical elements.

WARNING:
During the Panoramic, the value of the expository parameters 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 set value is decreased in the initial stage and increased in correspondence with the canine/incisor area to compensate for the effect of increased attenuation due to the spine.
The value displayed is the value selected by the user, while the actual value may be different; this fact should be considered if checking the exposure parameters using the diagnostic mode.
The accuracy of the exposure parameters, kV and mA, stated in the Technical Specifications section, refers to the accuracy compared to the actual value set by the system.
In any case, the manufacturer guarantees that the accuracy of the exposure parameters is within the maximum limits required by international regulations on the safety of medical devices IEC 60601-1 and attachments.In particular, in accordance with the IEC 60601-2-7, the maximum deviation (inclusive of the correction and instrumental uncertainty) is within the ± 10% for kV and within ± 15% for the anode current.

6.8 Verification method of technical factors (paragraph for authorised personnel)

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

WARNING:
The unit is equipped with a collimator with a very narrow X-ray beam. Measurements made with a non-invasive instruments and a narrow beam can be difficult and/or unreliable; therefore a special probe must then used with a reduced sensitive area.
It may be helpful to use a fluorescent screen to locate the X-ray beam and thus position the probe of the instrument.

The procedure to measure the exposure parameters with a non-invasive instrument is as follows:

1. With the device on, select the Panoramic Examination mode pressing the key "Examination Mode Selection - M" key (11) 

.

2. Simultaneously press the increase (4) - decrease (5)  keys and F1 

and release them, the "Patient type", "Patient size" and "Biting" LEDs will switch off. The following is displayed:

	x	x	k	V		x	x	m	A		x	x	.	x	s
E	M	I	S	S	I	O	N		P	R	O	G	R	A	M

WARNING:
The following operations foresee the emission of rays, therefore the Authorised Technician should pay the utmost attention and respect the safety standard in force in the related country.

NOTE:
This program allows to perform the measurement of the exposure parameters with the tube-head in the fixed position (not rotating) and constant parameters.

3. Position the measuring instrument.

4. To change the exposure parameters, press the key (3)  , the display will respectively show one of the three following captions:

>	x	x	k	V		x	x	m	A		x	x	.	x	s

	x	x	k	V	>	x	x	m	A		x	x	.	x	s

	x	x	k	V		x	x	m	A	>	x	x	.	x	s

The symbol ">" indicates which parameter is being changed.

The selected parameter can be modified by pressing the increase key (4) and the decrease key (5)  .

The parameters may vary within the limits shown in the table below:

Parameter	Minimum value	Maximum value
kV	60	86
mA	6	12
s	0,2	15

Table 3

5. Perform an exposure by pressing the rays button; the technical factors can then be read on the instrument.

NOTE:
Performances are insured if the measurement of technical factors occurs with invasive method. Measurements taken with a non-invasive method could introduce errors due to the tolerance of the instruments or incorrect implementation of the measurement.

6. To exit the control program, press the "Test" key (6)  ; the display will indicate:

	x	x	k	V		x	x	m	A		x	x	.	x	s
E	V	O		P	A	N	O	R	A	M	I	C			

and the unit will return to the standard mode.

6.9 CBCT Conditions of Operation

The following table lists the conditions of operation for the unit working in CBCT modality.

Quantity	Range
Tube current (mA)	from 6 to 10 mA
kV	from 60 to 86 kV
Exposure time	21.2s
X-ray filtration	2.5mm Al eq. @ 70 kVp
Nominal Tomographic section thickness	0.166 mm
Image receptor area	130x130 mm

6.9.1 Reference plane

The reference plane offset is the horizontal plane passing on the chin rest of the unit.
The Figure 6 shows the position of the reference plane and its location with respect to the chin rest, the focal spot and the volume irradiated by the X-ray Cone Beam. Each exam has a proper chin support that gives the proper reference plane offset.

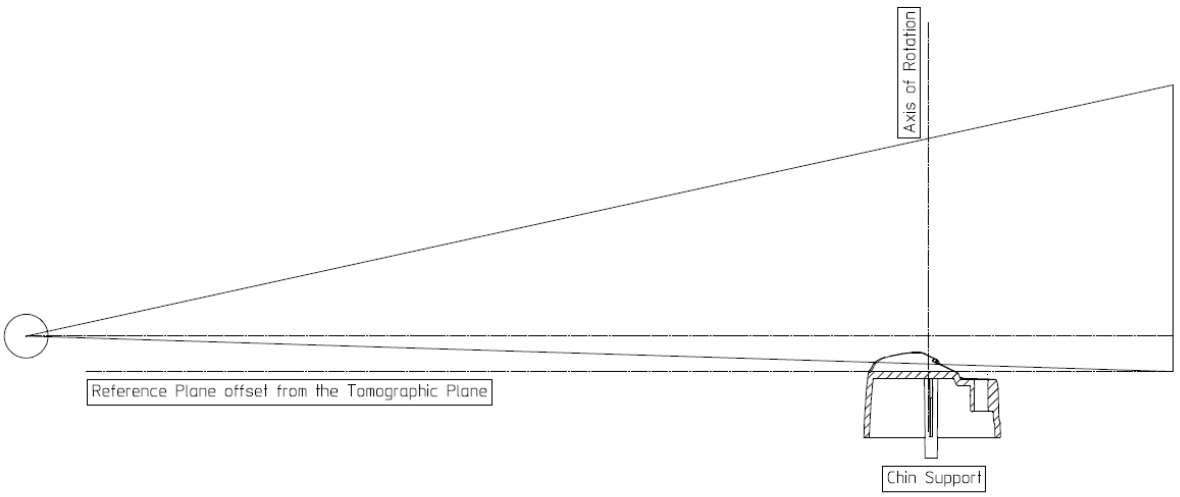


Figure 6: Reference plane offset from the Tomographic Plane

6.10 CTDI information

The following dose information are measured using a dosimetry head phantom compliant with the specifications of CFR 21 1020.33.
The phantom is a circular cylinder of polymethl-methacrylate (PMMA) of density 1.19+/-0.01 grams per cubic centimeter. The phantom is 15.0 centimeters high and has a diameter of 16.0 centimeters since the system is designed to image the head (head scanners).

The phantom has holes just large enough for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.

Values were measured using the instrument X2 CT sensor by RaySafe. Values are expressed in mGy.

The CTDI values are measured as $CTDI_{100}$ as recommended in the FDA Guidance doc. *"Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography" of October 20,2006.*

6.10.1 Measure conditions

The conditions of operations are set according to the following table:

Quantity	Range
Tube current (mA)	From 6 to 10 mA
kV	From 60 to 86 kV
Exam time	21.2s
X-ray filtration	2.5mm Al eq. @ 70 kVp
Nominal Tomographic section thickness	0.166 mm
X-ray beam collimation	130x130 mm

6.10.2 Measurement procedure

1. The phantom is placed on the support of the chin rest of the machine.
2. The dose detector is placed in the phantom in one of the positions at a time.
3. The default values for adult and normal size (82kV - 9mA) are selected.
4. An exposure is performed.
5. The dose measure is recorded.

6.10.3 Measured values

Different dose measurements are performed to find the location of the plane where the dose measurement at 1cm interior from the surface of the phantom is maximum.
Such location is perpendicular to the mid-sagittal line of the imaged volume on the left side of the patient considering the patient orientation.

The following table lists the $CTDI_{100}$ values measured in the different locations of the Phantom:

Measurement Location	**Dose Value**
$CTDI_{100}$ (Center)	11.1 mGy
$CTDI_{100}$ (Peripheral, MAX)	13.2 mGy
$CTDI_{100}$ (Peripheral, 90°)	6.5 mGy
$CTDI_{100}$ (Peripheral, 180°)	13.1 mGy
$CTDI_{100}$ (Peripheral, 270°)	11.6 mGy
$CTDI_{100}$ (Peripheral, average)	11.1 mGy

weighted $CTDI_{100}$ is $CTDI_W$ = 11.1mGy
and
volume $CTDI_w$ is $CTDI_{vol}$ = $CTDI_W$ = 11.1mGy

6.10.4 Dose values for other conditions of operation

The following table lists the relative CTDI values for different conditions of operations, normalized to the value of CTDI measured in the center of the Phantom at nominal conditions of operation (82kV, 9mA) ($CTDI_{100\ (Center)}$):

Conditions of Operation	CTDI Value Relative to $CTDI_{100\ (Center)}$
60kV	0.38
74kV	0.74
86kV	1.13
6mA	0.65
8mA	0.88
10mA	1.10

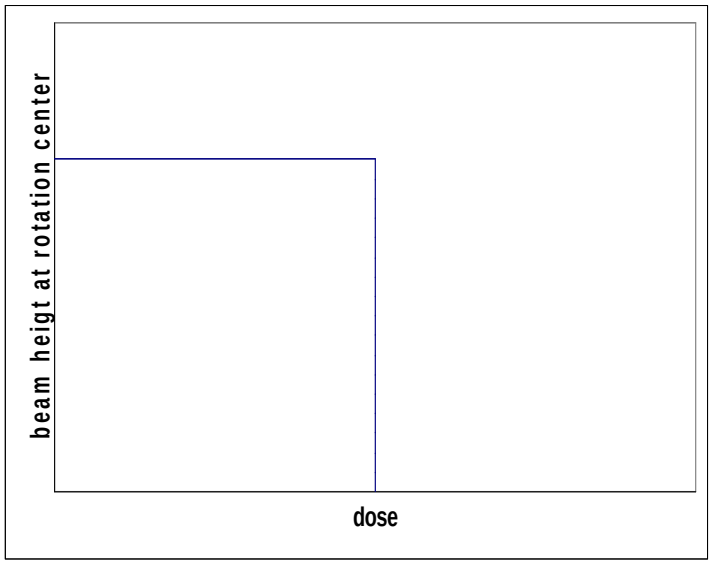
The following table lists the relative CTDI values for different kV values, normalized to the maximum value of CTDI measured 1cm from the outer surface of the Phantom at nominal conditions of operation (82kV) ($CTDI_{100\ (Peripheral,\ MAX)}$):

Conditions of Operation	CTDI Value Relative to $CTDI_{100\ (Peripheral,\ MAX)}$
60kV (minimum value)	0.44
86kV (maximum value)	1.12

Maximum deviation from the nominal values given in the preceding tables is ± **25%.**

6.10.5 Dose profile

In the following graph the dose profile is displayed along a line z perpendicular to the tomographic plane measured in the center of the Dose Phantom.



6.11 3D Imaging Performance

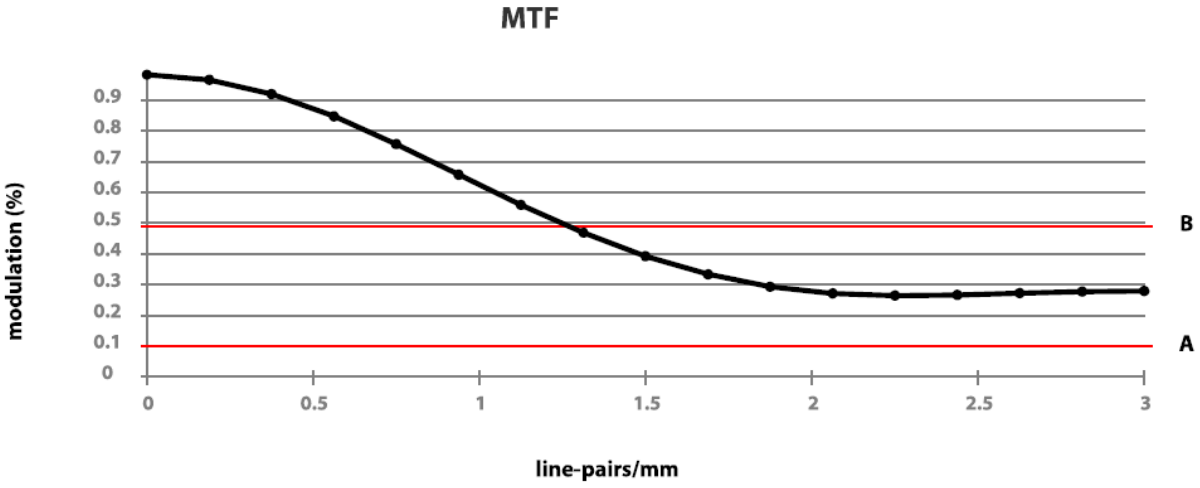
The following Imaging Performance Indicators are measured using the "Quart DVT" CBCT Phantom.
Such Phantom consists of several discs of PMMA with inclusions of different objects and materials for performing the required measurements.
After the image acquisition, specific tomograms are exported in Dicom Format from the imaging program and imported into the DVT_PRO Software where measurements of the imaging Performance indicators are calculated and displayed.

6.11.1 Noise

The Typical noise (expressed as Contrast Noise Ratio) is: 5
Maximum accepted deviation is: CNR > 2.5.

6.11.2 Modulation Transfer Function (MTF)

The following graph shows the Modulation Transfer Function.
Maximum accepted deviation is: MTF 10% >1



6.11.3 Slice Thickness

The Typical Slice Thickness is: 0.166mm
Maximum accepted deviation is: ±10%

6.11.4 Sensitivity Profile

Sensitivity profile is not applicable - the resolution is substantially equal in z-direction.
No indication of the accepted deviation or test protocol is needed.

6.11.5 CT Number of water

The Typical CT number of water is 0, expressed as Hounsfield Units (HU).
Accepted deviation is -100HU to +100HU.

6.12 QC program

The QC Program is based on the usage of the "Quart DVT_kp" Phantom (or equivalent).
Such Phantom consists of several discs of PMMA with inclusions of different objects and materials (PVC and Air) for performing the required measurements.
After the image acquisition, specific tomograms are exported in Dicom Format from the imaging program and imported into the DVT_PRO Software where measurements of the imaging Performance indicators are calculated and displayed.

6.12.1 Schedule

The QC program has to be performed after installation and every 6 months, unless local regulations require a different interval.

6.12.2 QC program test

The following paragraphs describe the tests to be performed for Image Quality Control.
After each test, record the measurements in the logbook provided in paragraph 6.12.8.

NOTE:
In case you find any value out of the acceptable range, please call your service representative for a system inspection.

To position the phantom, proceed as follow:

1. Make sure that no foreign object is located in the beam path of the X-ray device.
2. Remove the chin rest and there position the phantom support.
3. Place the phantom on it, check the bubble level vs the bubble level of the machine and align the phantom using the mid-saggittal laser.
4. Create a test patient.
5. Take a 3D DENTITION exam at 72kV-6mA and image scale Reconstruction parameter set to 0.008.
   During the exam looking at the real time preview check the phantom is properly aligned as in the following figure. If not, adjust the position and repeat the test.

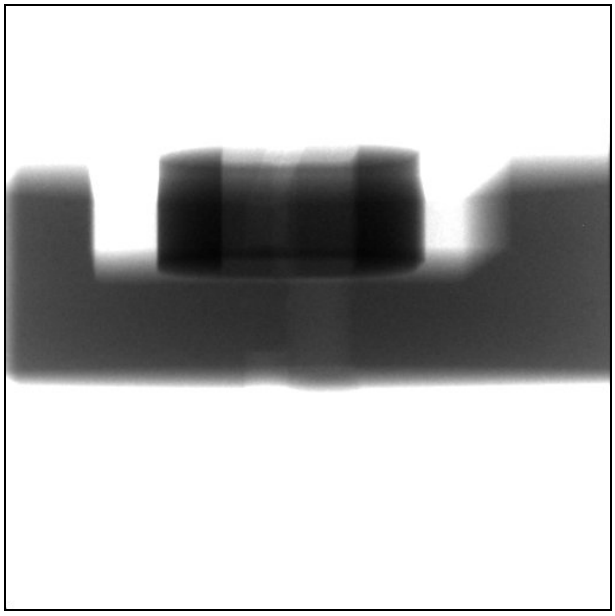
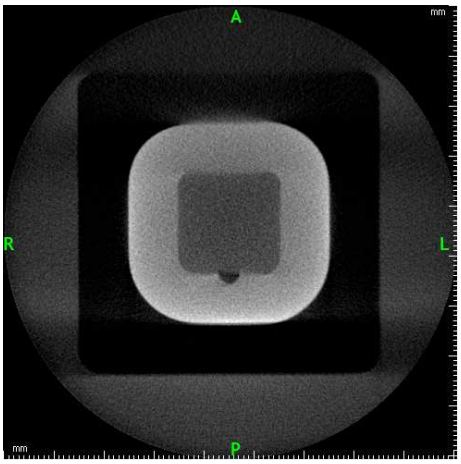
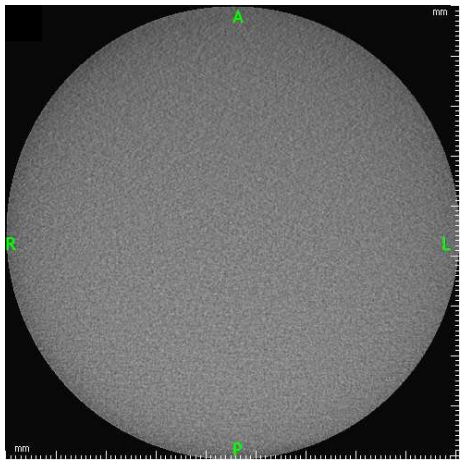


Figure 7

6. At the end of reconstruction you need 2 slices from the 512 slices of the volume:



Use slice 310 for all other checks



Use slice 230 for test uniformity check

(Export them in a temporary folder using the menu project - Export slices: on the right part of the window set Exported image color depth equal to Use 3D Wlevel settings).

7. Run Quart software (please refer to its User Manual for detailed instructions on performing tests).

8. Select Test tab, in the first free column (e.g. 1) click on the "T" button: this open a new window where the test has to be performed.

9. Click on load test phantom image and browse the temporary folder where the slices were exported and select the slice #310.

10. Following the instructions provided by the software perform the test and at the end press "Save" button. The software returns to test tab page.

11. Then click on the next "T" button to perform the noise evaluation test (paragraph 6.12.3).

6.12.3 Noise and contrast scale

The 2nd test of the quart software procedure give a measure of noise and contrast scale.
Following the instructions provided by the software perform the test and at the end press "Save" button. The software returns to test tab page reporting these results:

- **CNR**: it gives noise performances, report this value in the *"Image noise"* cell of the QC log book at paragraph 6.12.8.
- **Contrast**: it gives contrast scale, report this value in the *"L contrast resolution"* cell of the QC log book at paragraph 6.12.8.

6.12.4 Uniformity check

Click on the next "T" button to perform the Uniformity check labelled as "Homogeneity" in the Quart software procedure.
Click on load homogeneity image and select the slice #230.
The software perform the test and at the end press "Save" button. The software returns to test tab page reporting the Homogeneity value expressing uniformity performances, report this value in the *"Image uniformity"* cell of the QC log book at paragraph 6.12.8.

6.12.5 Spatial resolution

Click on the next "T" button to perform the MTF test. Following the instructions provided by the software perform the test and at the end press "Save" button. The software returns to test tab page reporting the MTF 10% value expressing spatial resolution performances, report this value in the *"H contrast resolution"* cell of the QC log book at paragraph 6.12.8.

6.12.6 Nominal Tomographic section thickness

NOTE:
This test has to be performed with the 3D display software.

In the coronal view measure the height of the phantom insert as shown in Figure 8. The measure has to be in the range from 15.0mm to 18.2mm. (This insert is 100 slices high so its measure divided by 100 give a measure of the nomimal Tomographhic section thickness). Report this value in the *"Slice thickness"* cell of the QC log book at paragraph 6.12.8.

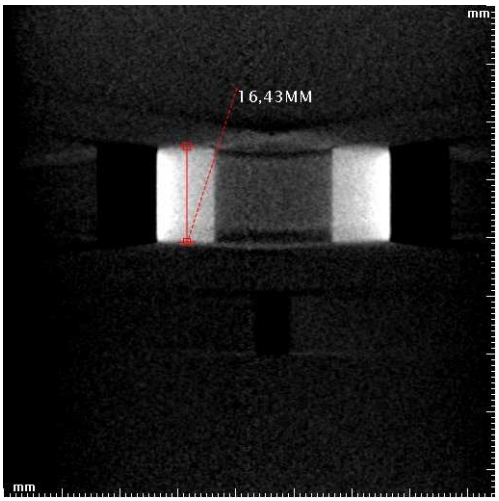


Figure 8

6.12.7 CT number of water

6.12.7.1 Method to calculate the mean and standard deviation of CT numbers

Mean Gray Values and CT Number are evaluated by determining the standard deviation and mean of Gray Values from a Region of Interest, placed by the user in the PMMA centre of the displayed image of the phantom.
The measurement is taken on a block of PMMA which is widely recognised as providing HU values equivalent to those of water for the energy range used in CBCT, without the complication of using actual water phantoms.

6.12.7.2 Measurements

Measurements are made on a reconstructed slice of the phantom (it is suggested to use the slice #310) in a Region of Interest (ROI) selected by the user inside the red area of the Figure 9 representing the PMMA insert of the phantom.

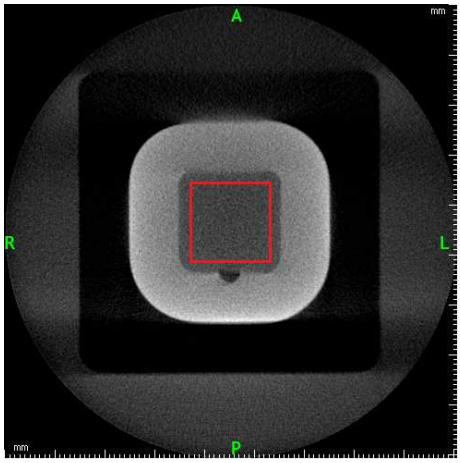


Figure 9

The ROI is taken for the evaluation of the material specific gray scale value. CT-number of PMMA can be derived from the mean value of the ROI. This number is also representative of CT number of water, report this value in the *"CT number of water"* cell of the QC log book at paragraph 6.12.8.

6.12.8 QC log book

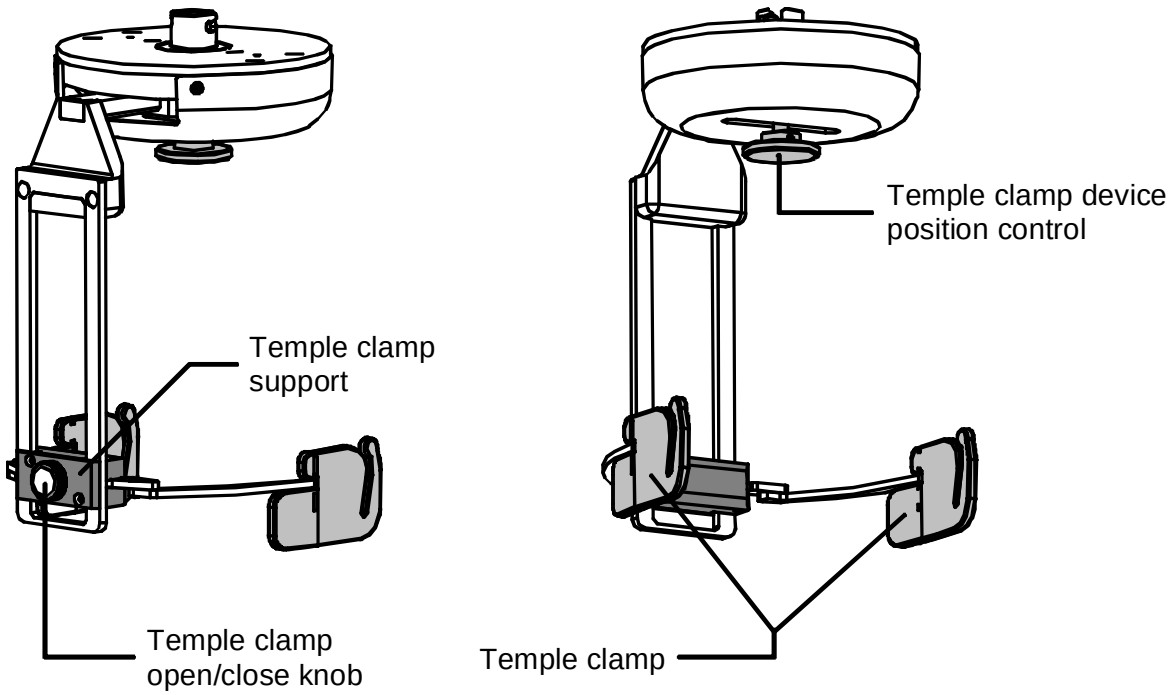
Record in the following table the results of QC program described in the previous paragraphs. Report the value and the pass/fail result.

DATE	Image noise	Image uniformity	L contrast resolution	H contrast resolution	Slice thickness	CT number of water
Pass Criterion	CNR >2.5	Homogeneity >5	Contrast >250	MTF 10% >1	Measure 15.0mm - 18.2mm	Mean value of HU -100 - +100

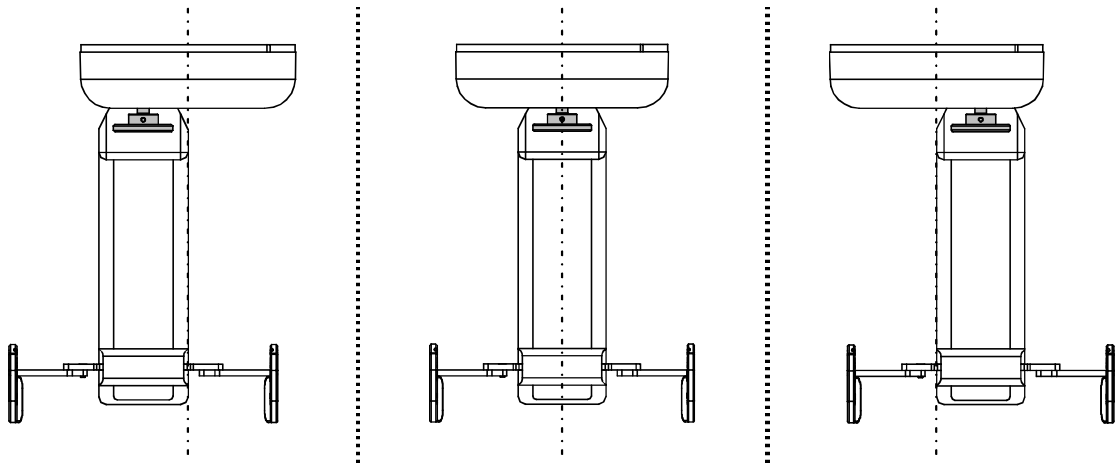
7. USE OF THE TEMPLE CLAMP CENTRING DEVICE

The temple clamp centring device of the Rotograph EVO 3D is designed to help centre the patient and keep them in the correct position during the examination.

The temple clamp centring device is described in the following figure:



The temple clamp unit has three different vertical positions (Figure 10); position adjustment is performed using the special latch on the rear top part of the vertical support of the headrest.



3D TMJ Right position | *Central position* | *3D TMJ Left position*

Figure 10

The central position must be used for Panoramic type tests with narrow beam and 3D volumetric Dentition and Sinus tests.
In left and right TMJ 3D volumetric examinations, the headrest must be used in combination with the appropriate TMJ volumetric chin support (see paragraph 8.4), adjusted in such a way so as to bring the interest area within the X-rayed volume.

The height of the temple clamp can be adjusted in all exams by acting on the central support to adapt it to the height of the patient.

8. GENERAL INSTRUCTIONS FOR USE

8.1 Control panel - description and functions

The Rotograph EVO 3D keyboard is divided into function areas, plus a display to view the operative messages and error signals.
The next figure shows a general view of the keyboard, while details on each functional area are provided in the following pages.

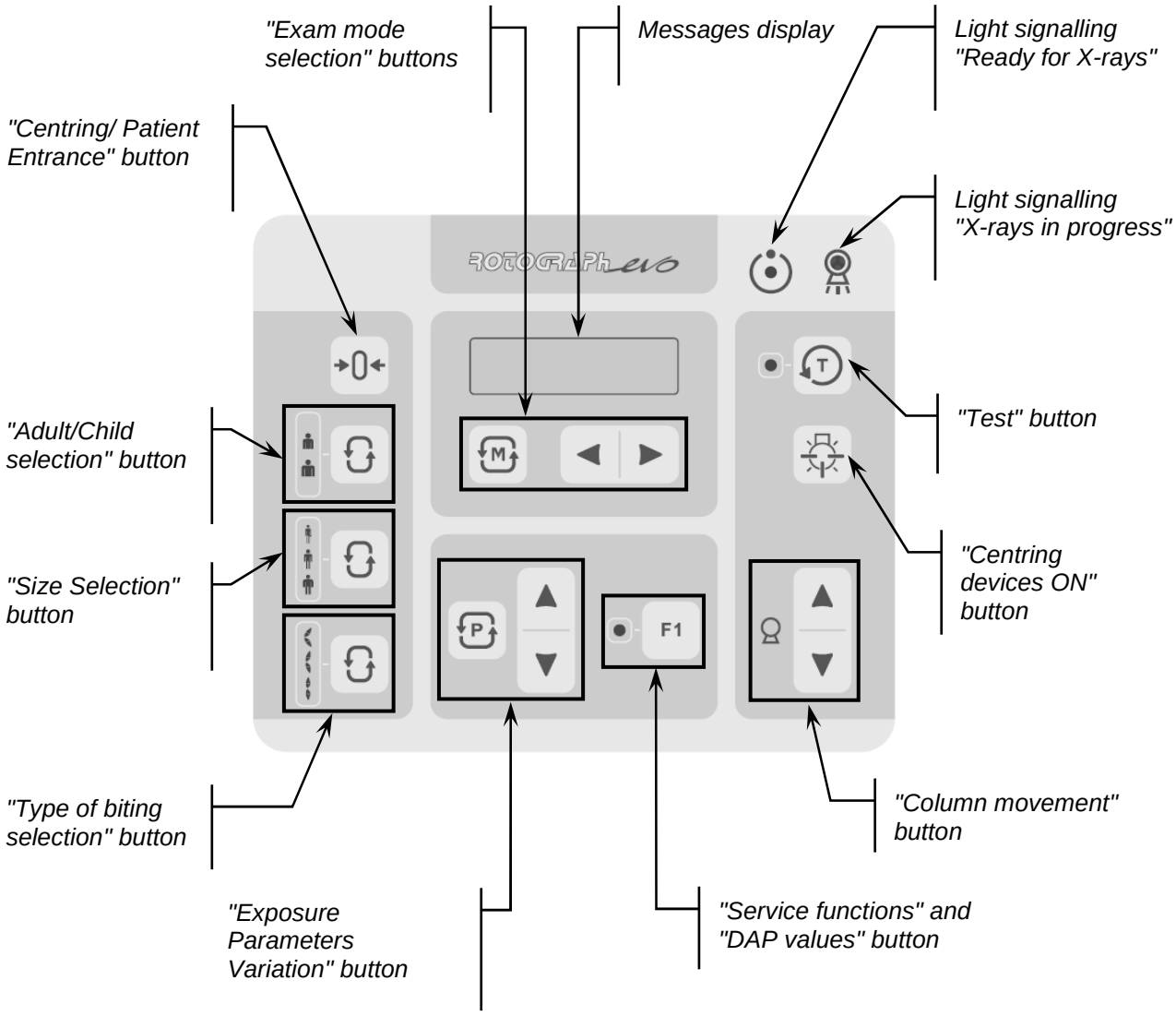
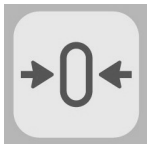


Figure 11

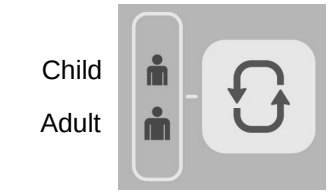
The "Centring/Patient Entrance" button is used for:

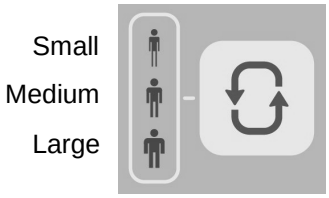
- start/finish the exam procedure
- bring the rotation arm to the patient entrance position at the end of the exam.



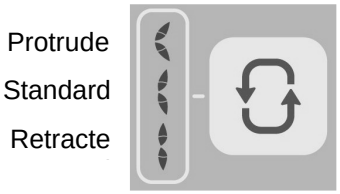
The "Examination Selection Mode" takes place by means of three keys: the first one, identified by the symbol "M" helps select the exam mode between Panoramic, TMJ, Sinus, 3D Dentition and Cephalometric.
The other two, identified by the arrows, allow to move through the examinations of each mode (see diagram in paragraph8.2).

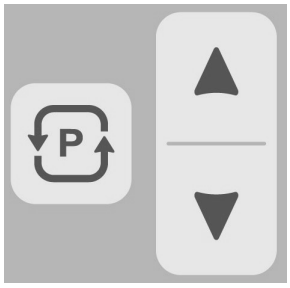
It is possible to select the anatomic mode examinations (anatomic selection), using prefixed exposure values.
This kind of selection enables to choose between Adult/Child, each with three different sizes (small, medium, large).





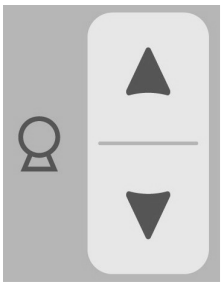
The type of biting of the patient can be selected in Panoramic mode, between: protruded, standard or retracted, marked by the lighting up of one of the three available LEDs.
The arch selection does not influence the values of kV and mA but acts on the position of the focus layer.





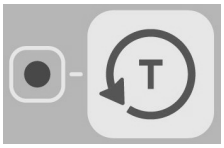
Furthermore there is the possibility to manually select the exposure parameters; in this case, it is necessary to select first the parameter to be modified with the key identified by the symbol "P" and then, using the increase / decrease keys, identified by the arrows, it is possible to set the parameter with the desired value.
The parameters available are: kV and mA (Soft Tissue Filter position in cephalometry only).

There are two light indicators; the first on the left 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.
Two pre-set speeds are possible.
The movement of the column is inhibited during the preparation of the unit.

The key "Luminous centring device" helps turn on the laser centring devices that allow the correct positioning of the medial-sagittal and Frankfurt/Ala trago planes, by adapting Rotograph EVO 3D to the patient's anatomy.



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

The key "F1" is used to display the DAP (Dose per Area Product) estimate value in µGym² relative to the selected exam and exposure parameter.

8.1.1 Key function description

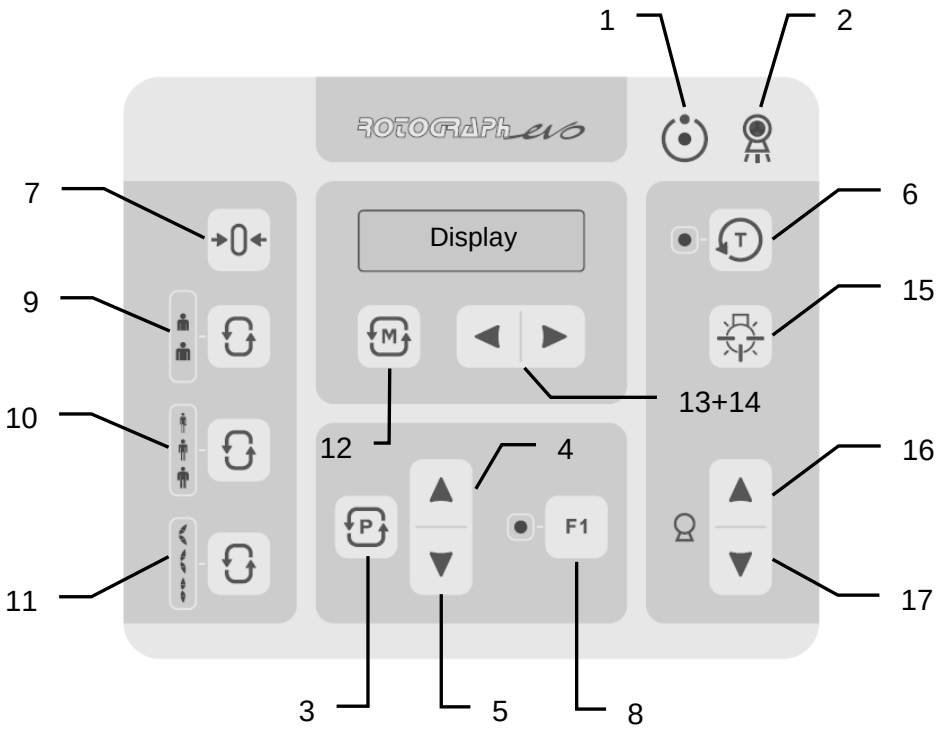


Figure 12 - Control panel

LEGEND:

Messages
Display: indicates operative messages, warnings and exposure parameters.

Signal lights
1 - Light indicating the machine is ready for X-ray emission (green LED)
2 - Yellow LED indicating X-ray emission

Manual setting of exposure parameters
3 - Parameter selection key: kV or mA
4 - kV, mA or STF position increase key
5 - kV, mA or STF position decrease key

Preparation functions
6 - Key to set Test function (green LED)
7 - Key for:
> Resetting and realigning the device's axes (in case of collision with patient or in case of release of rays button)
> Repositioning the rotation group (to bring the group to the initial position after the examination and to exit from the "making an exposure") mode
> Confirmation
8 - Key to display DAP values and service functions

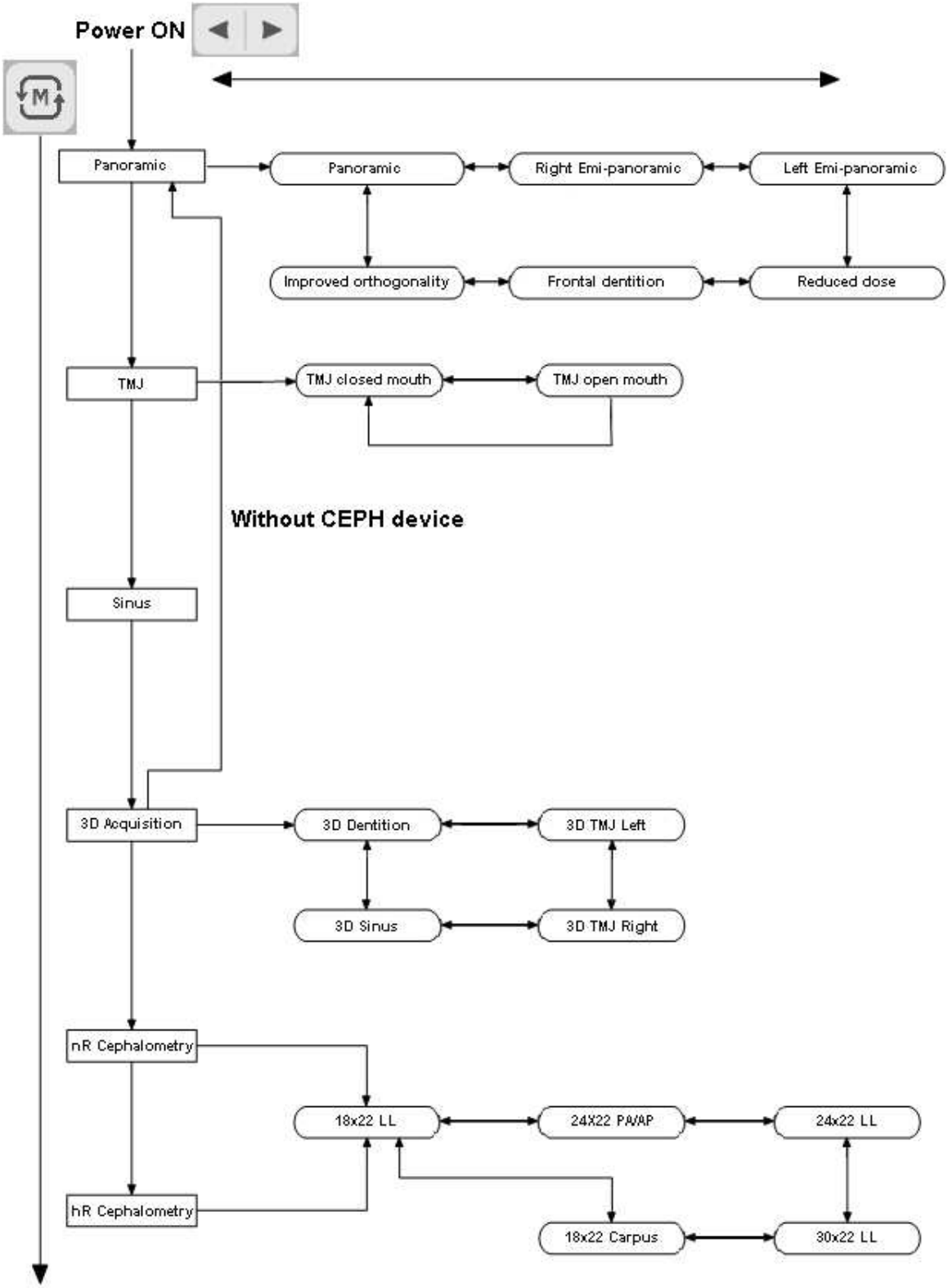
Anatomic selection
9 - Patient selection key: Adult or Child (green LED)
10 - Size selection key: Small, Normal, or Large (green LED)
11 - Arch selection key: Protruded, Standard or Retracted (for panoramic execution) (green LED)

Examination mode
12 - Exam mode selection key
13 +14 - Exam type selection key

Centring devices
15 - Sagittal and Frankfurt/Ala trago planes centring device ON key

Column height adjustment
16 - Column up key
17 - Column down key

8.2 Selection menu chart



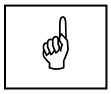
8.3 Digital sensors

Rotograph EVO 3D is equipped with two types of digital sensors, depending on the version used:

- **Wide range sensor**: is the sensor used for the volumetric reconstruction of the anatomical region of interest from two-dimensional images.This sensor is also used to obtain narrow beam Panoramic type images with a rays field of 13 cm in height. All Panoramic, TMJ and Sinus images belong to this type. The wide range sensor, mounted in the sensor holder, can be rotated to free the rays passage section in order to perform cephalometric exams.
- **PAN/CEPH sensor**: used for cephalometric images.

The Rotograph EVO 3D control system has the task of checking the consistency of all the safety measures that allow the correct use of the digital sensors; in particular:

- Prevent the acquisition when the management and imaging system is not ready to receive the image, with the message "Sensor not ready"
- Prevents the CEPH exposure when the PAN sensor holder is not completely open to free the path of the X-ray beam. The following message is displayed "Open cassette holder".
- Prevent 3D volumetric exposure when the sensor holder is not in the PAN position; in this case the following message is displayed "Close cassette holder".



NOTE:
The PANCEPH sensor has a fall sensor; This sensor is also visible from the outside for controls by the user. Any falls are signalled by the sensor's change in colour (from white/transparent red).The digital sensor can still function properly even with this change of colour, which indicates a fall that may not have damaged the sensor.

8.3.1 Switching on the device

Press the green button on the base of the column to switch the system on; the following is displayed:

H	**W**	**=**	**x**	**.**	**x**	**x**		**S**	**W**	**=**	**x**	**x**	**.**	**x**	**x**

This message is displayed for approx. 20 seconds.
After this period, the LEDs on the control panel start to flash and the display shows the following message:

R	**E**	**L**	**E**	**A**	**S**	**E**			*****	**.**	*****	*****			

After 3 seconds, the display shows the following message:

					>	**T**	**E**	**S**	**T**	**<**					

NOTE:
During this phase, Rotograph EVO 3D does not perform any movement, it just performs a series of checks which, in the event of negative result, could require the intervention of the Technician.
The only problem that can be solved by the user is related to the position of the PAN sensor holder; in this case, the following message will be displayed:

C	**L**	**O**	**S**	**E**		**C**	**A**	**S**	**S**	**E**	**T**	**T**	**E**		
P	**A**	**N**	**O**	**R**	**A**	**M**	**I**	**C**							

When the self-diagnosis is completed, the following appears on the display:

	M	**A**	**C**	**H**	**I**	**N**	**E**		**S**	**E**	**T**	**T**	**I**	**N**	**G**
		P	**R**	**E**	**S**	**S**		**>**	**0**	**<**					

Press key (7)  to start the device alignment phase.

Once the key has been pressed, the message disappears and the display shows the following message during the alignment of the axes:

				W	**A**	**I**	**T**		**F**	**O**	**R**	**.**	**.**	**.**	
	M	**A**	**C**	**H**	**I**	**N**	**E**		**S**	**E**	**T**	**T**	**I**	**N**	**G**

WARNING:
At this stage the machine will check the absence of obstacles, which can cause collisions, simulating the movements performed during the examination.

After 3 seconds, the system is placed in the following configuration:

- ADULT with the lighting up of the corresponding LED
- MEDIUM SIZE with the lighting up of the corresponding LED
- STANDARD DENTITION with the lighting up of the corresponding LED

and the display shows (for instance):

	x	x	k	V		x	x	m	A		x	x	.	x	s
E	V	O		P	A	N	O	R	A	M	I	C			

When the connection with the digital sensor is properly established, the equipment is ready for exposure.

NOTE:
The above mentioned position is chosen also in the event that, for any reason, the device repeats the initialisation phase.

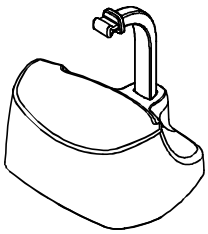
8.4 Positioning of chin support

Rotograph EVO 3D is equipped with four types of chin support: a standard chin support with a special removable appendix for edentulous patients, one (lowered), for SINUS test, one to be used for TMJ examination in standard mode and one to perform the TMJ volumetric X-rays that features two different positions on the same support.

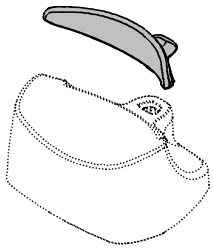
The standard chin support must be used, in Panoramic mode, with all the people who can assure a tight grip on the centring bite.
The appendix for edentulous patients must be applied only for patients who cannot assure a tight grip on the bite or are not co-operating and might move during the examination.

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

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

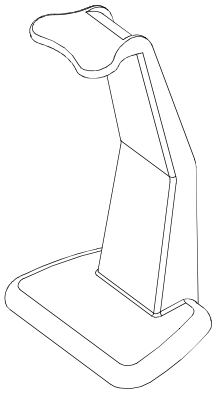


Standard Panoramic chin support

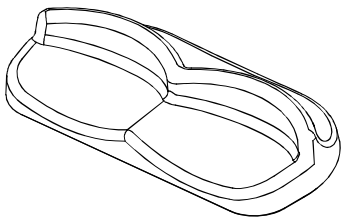


Appendix for edentulous patients

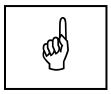
SINUS chin support



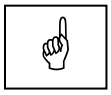
TMJ positioning support



3D TMJ chin support



NOTE:
A fifth 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.



NOTE:
Always remove the chin support when performing Ceph examinations.

8.5 General notes on the acquisition of images

The Rotograph EVO 3D control system verifies that the safety conditions against accidental emissions are respected; these conditions are tested both before the passage from the centring position to that of the start exam, as well as before enabling the emission itself and throughout the examination.
The emission of rays is enabled if:

- the image acquisition and management program is active
- a patient has been selected, **to whom the acquired images will be** assigned
- the acquisition program displays the virtual keyboard and the sensor is ready for acquisition, in other words it has completed all the preliminary acquisition stages.

If not, the Rotograph EVO 3D display shows the error message:

D	I	G	I	T	A	L		S	E	N	S	O	R	
			I	S		N	O	T		R	E	A	D	Y

Refer to the manual of the image management and acquisition program to correct the error.

NOTE:
The said message appears even if the above conditions are verified but the acquisition system is employed in preliminary operations to the acquisition itself. In this case, the message will disappear at the end of these operations, allowing to continue the exam.

The CEPH exposure is blocked if the PAN sensor holder is not completely open to free the path of the X-ray beam. The following message is displayed:

		C	E	P	H		-		O	P	E	N		
	C	A	S	S	E	T	T	E		U	N	I	T	

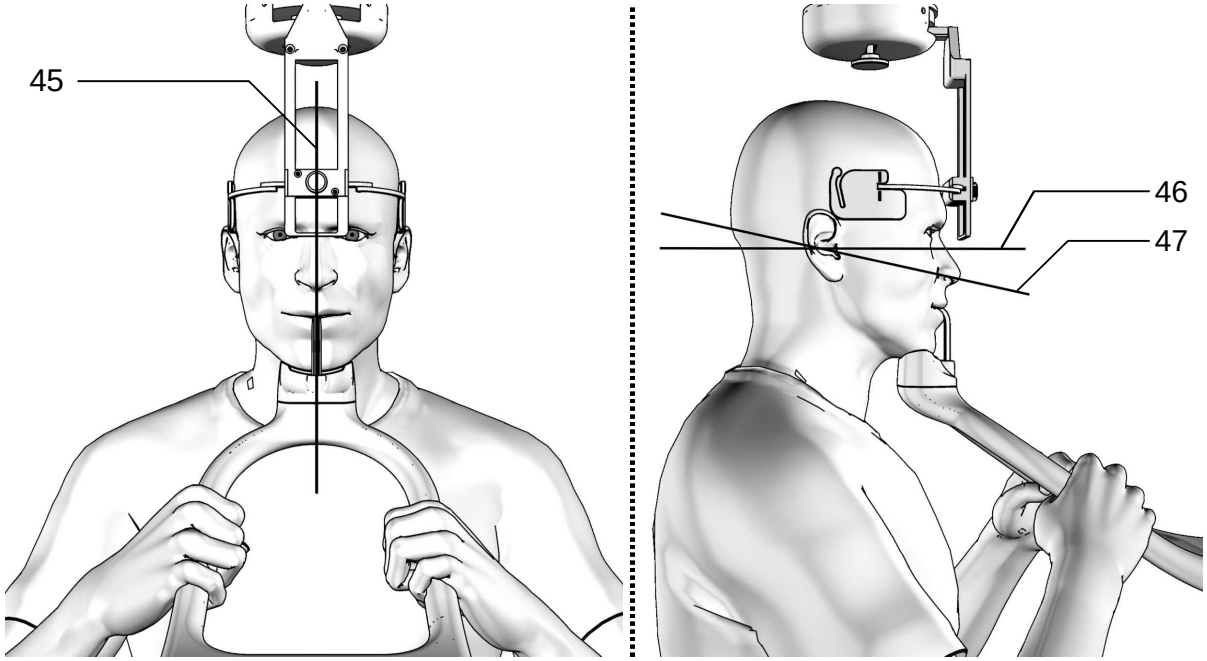
The 3D volumetric exposure is blocked if the sensor holder is not in the PAN position; in this case the following message is displayed:

	C	L	O	S	E		C	A	S	S	E	T	T	E
		T	O		P	A	N	O	R	A	M	I	C	

8.6 Panoramic examination

When making a panoramic examination, the tube-head support arm (X-rays generator) make a continuously rotating movement.

During the examination, the patient centering is assisted by two linear luminous laser beams, which indicate the position of the reference planes; the corrisponding patient's planes need to be aligned with these planes. The latter is held in place, during the examination phase, through the centring-temple clamp device and the chin support.



Legend of Reference Lines

45 Mid-Sagittal line

46 Frankfurt plane line: plane that identifies a line that ideally connects the hole in the auricular canal - external auditory meatus - with the bottom edge of the orbital fossa

47 Ala-tragus line: plane that identifies a line that ideally connects the anterior nasal spine and the centre of the external auditory meatus.

Figure 13

8.6.1 Preparation of the device

When the unit is switched on, the Panoramic Examination is selected as standard. If the operator has previously made another kind of examination, to select Panoramic press key "Examination Mode Selection - M" (11)  until to the following message is visualized:

	x	x	k	V		x	x	m	A		x	x	.	x	s
E	V	O		P	A	N	O	R	A	M	I	C			

The system positions itself with the following configuration:

- ADULT with the lighting up of the corresponding LED
- MEDIUM SIZE with the lighting up of the corresponding LED
- STANDARD DENTITION with the lighting up of the corresponding LED

and the display of default radiological parameters (if this is the first Panoramic exposure carried out) or those used in the last examination. For example:

	7	2	k	V		0	6	m	A		1	4	.	4	s
E	V	O		P	A	N	O	R	A	M	I	C			

Once the settings have been completed, the chin support must be placed in position (see the operative notes in paragraph 8.4).

The key "Examination Mode Selection" (11) enables the selection of specific submodes, selectable by means of the keys "Arrow right" (13) and "Arrow left" (12), enabling the sliding in one direction or another.

Previous examination  *Next examination*

For the Panoramic examination, the system is factory set with two different trajectory: EVO Panoramic and Panoramic STD. The EVO Panoramic is more tolerant towards typical errors of patient positioning, thanks to an enlarged focal layer in the region of the frontal dentition. During installation it is possible to select as first the most used trajectory type or enable only one of them (refer to Service Manual - Password 92 menu – Pano order submenu).

Where the option EVO XP (Extended Projection Package) is enabled, the following selections are possible:
EVO Panoramic -> STD Panoramic -> Right Emi-panoramic ->
Left Emi-panoramic -> Improved orthogonality dentition ->
Reduced dose Panoramic -> Frontal dentition -> Bitewing Right ->
Bitewing Left -> Bitewing RGT,LFT -> EVO Panoramic.
This selection is cyclic, so pressing the button repeatedly will change the selected mode.

- **Right / Left Emi-panoramic**

  In the Emi-panoramic mode, right or left, only the corresponding half arch is irradiated; the emission starts from the beginning, to just after the mid sagittal plane for the right part. For the left, it start just before the mid sagittal plane and continue until the end of the rotation.
  These two kinds of examinations are usually used when it is already known that the patient has a problem on only one half of the arch, so it is possible to reduce the irradiation of the patient.

  To position the patient, follow the instructions given for the Panoramic examination.

- **Improved orthogonality dentition**

  The improved orthogonality Panoramic delivers the image of the pure dental arch cutting out from the image the ascending rami branches of the temporo mandibular joint; the trajectory of the rotating arms is, however, optimised for a better orthogonality between the X-ray beam and the incident sections of near teeth.
  Thus the image has reduced overlapping of the teeth, improving the diagnosis of interproximal decay.

  As a consequence of the different trajectory, the focus layer, mainly in the front teeth area, is smaller and then patient positioning for this examination needs more care.

  To position the patient, follow the instructions given for the Panoramic examination.

- **Reduced dose Panoramic**

  The reduced dose Panoramic examination makes an X-ray only of the dental arch, excluding from the image the ascending rami of the temporo-mandibular joint; the examination is performed with the same trajectory of the standard Panoramic, by reducing the rays emission time.
  This examination is used, for instance, during the treatment continuation phases or where the lack of pathologies of the same joint are already known.

  To position the patient, follow the instructions given for the Panoramic examination.

- **Frontal dentition**

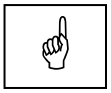
  The Frontal dentition examination performs an X-ray of the dentition frontal area (roughly from canine to canine).

  To position the patient, follow the instructions given for the Panoramic examination.

- **Bitewing**

  The Bitewing examination, left or right, allow the execution of examinations of the lateral dentition (generally from eighth to fourth). The trajectory of the rotating arms is, however, optimised for a better orthogonality between the x-ray beam and the incident sections of near teeth.
  Thus the image has reduced overlapping of the teeth, improving the diagnosis of interproximal decay.
  Bitewing right and left sequentially perform both bitewing, supporting them on the same image.

  To position the patient, follow the instructions given for the Panoramic examination.



NOTE:
Rotograph EVO 3D is based on an arch shape and the temporomandibular joint determined on statistical studies.
This shape is taken as "standard" for the dento-maxillo-facial complex.
Rotograph EVO 3D follows a rototranslation path which maintains constant the magnification factor stated in the technical characteristics of each type of exam along this "standard" shape and in 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 X-RAY IMAGE CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC.

8.6.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the key "Size Selection" key (9)  or the key "Selection Examination Mode - M" key (11)  .

After setting the machine, it is possible to choose between the following two operating modes:

- **ANATOMIC:** with the values of kV and mA programmed on the basis of the type of patient and the size.
- **MANUAL:** with the possibility to vary the kV and mA values already set.

NOTE:
In manual condition, the "Adult/Child Selection" (8) key LED and the "Type of Biting Selection" (10) key LED light up to indicate that it is possible to change the selection; press key (8)  to change from Adult to Child and press key (10)  to modify the type of biting from Normal to Protruded or Retracted.

8.6.2.1 Anatomic exposure

Select the type of patient with the **Adult/Child** key (8).

Select the type of build with the **Size** (9) key (*small - medium - large).*

On the basis of these selections, the display will visualise the kV and mA settings as in the table.

Panoramic mode exposure values table				
	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	68	6	64	6
Medium	72	6	66	6
Large	74	6	68	6

Table 4

Select the conformation of the biting with key "Type of Biting Selection"

(10)  .

NOTE:
The type of biting does not affect the kV and mA values, but it affects the position of the focus layer, by adapting the rotation movement to the patient's anatomy.

8.6.2.2 Manual exposure

If the kV and mA combinations of the table Table 4 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

Press key (3)  to change the kV or mA, the LEDs of keys

Adult/Child Selection" (8) and "Type of Biting Selection" (10) will flash, and the LED on the "Size Selection" (9) will turn off; The display will show respectively one of the following two indications:

>	x	x	k	V		x	x	m	A		1	4	.	4	s
E	V	O		P	A	N	O	R	A	M	I	C			

or

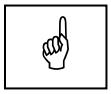
	x	x	k	V	>	x	x	m	A		1	4	.	4	s
E	V	O		P	A	N	O	R	A	M	I	C			

The symbol ">" indicates which parameter is being changed; to modify the type of parameter to work on, press key (3)  repeatedly.

The selected parameter can be modified by pressing the increase key (4) and the decrease key (5)  .

The kV value can vary between *60 and 86 kV, with 2 kV steps.*

The value of mA can vary between *6 and 10 mA, with 1 mA steps.*



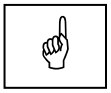
NOTE:
To change the values rapidly, keep the increase key (4) or the decrease key (5) pressed.

Select the type of mouth with the key "Type of Biting Selection" (10)  .

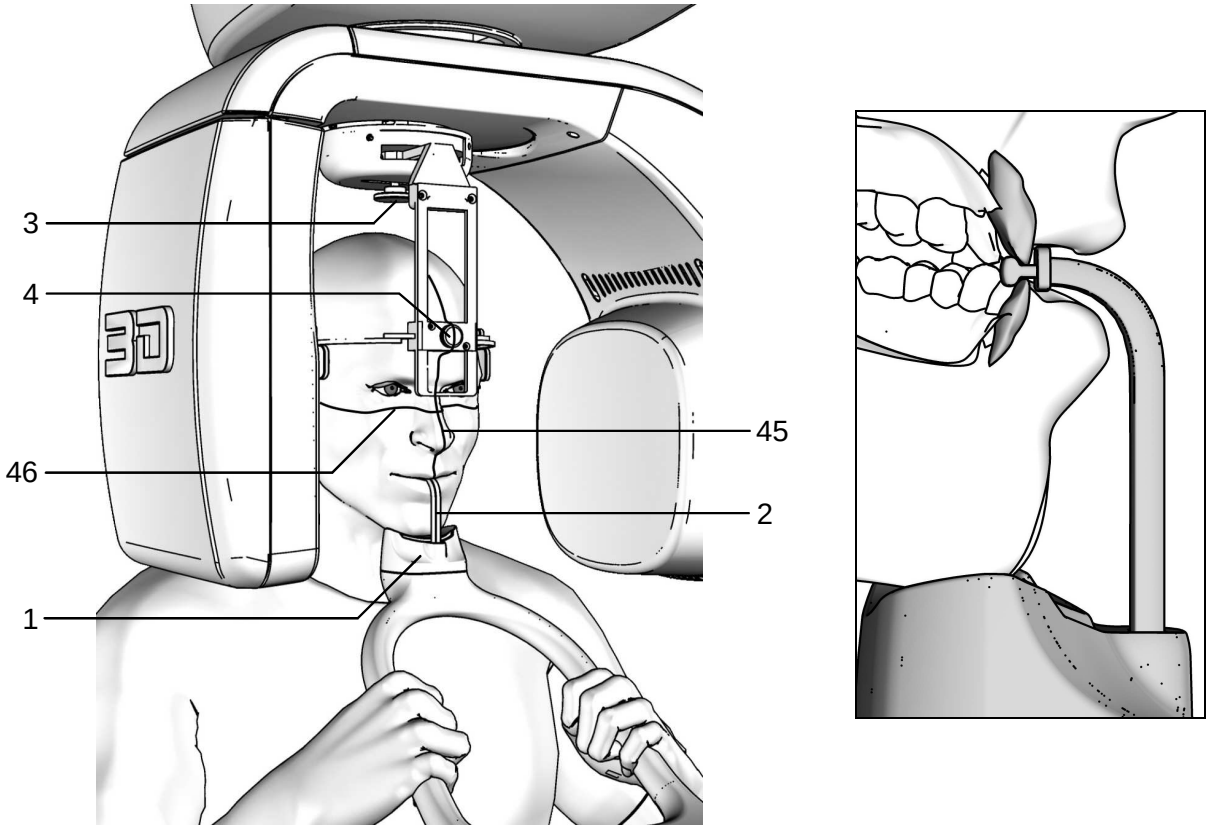
8.6.3 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.
3. Place the patient in a standing position at the chin support. With the keys "Column movement" (15/16)  lift/lower the column until the chin support is aligned with the patient's chin.
4. Verify that the temple clamp device is in the central position (Figure 10), and if necessary move it using the appropriate control on the top of the support (Figure 14).
5. Place the patient in temple clamp by placing the chin on the surface of the relevant support; the hands should rest on the front handgrips; the patient must bite the reference mark of the bite with his/her incisors (Figure 14). In case of edentulous patients, he/she must rest the chin against the reference shoulder of the edentulous chin support for edentulous.
6. Set the height of the temple clamp just above the patient's orbital bone.
7. Instruct the patient to close his eyes.
8. Press the key "Centring devices ON" (14)  .

   Two laser beams illuminate the line of the median sagittal plane and the horizontal line for the reference of the Frankfurt plane (Figure 13).
   Position the patient's head in such a way as to ensure that the luminous beams fall in correspondence with the respective anatomical references (Figure 14).
   The luminous beam of the Frankfurt plane can be adjusted according to the patient's height; this adjustment is achieved by adjusting the laser block on the side of the mirror.



NOTE:
The laser centring devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centring Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (7)  to begin preparation for exposure.



Legend of Reference Lines

45 Sagittal medial line
46 Frankfurt plane line

Legend positioning devices and patient centring

1 Panoramic chin rest
2 Centring bite
3 Temple clamp device position control
4 Temple clamp open/close knob

Figure 14: Panoramic positioning

9. Place the temple clamp in contact with the patient's head by means of the appropriate knob (Figure 14).

10. At this point, the patient must move his feet towards the column, making sure to keep his head within the pre-aligned anatomical references. In this way, you will have a greater extension of the spine in the cervical area, improving the darkening of the X-ray in the apical area of the incisors, and avoiding the collision of the tube-head with the patient's shoulders. Check that the Frankfurt plane is still horizontal.

11. Press the key "Patient Entrance" (7)  to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position.
Once alignment has been completed, the following message will be displayed:

	x	x	k	V		x	x	m	A		1	3	.	8	s
			S	T	A	R	T		E	X	A	M			

x = value defined by the settings

The green LED "Ready of X-rays" lights up to indicate that pressing the X-ray button once more will start the radiation phase.

12. Ask the patient to: keep the lips closed, bring the tongue towards the palate, keep perfectly still and do not look at the rotating arm during the movements.

8.6.4 Making an exposure

NOTE:
When the key "Test" (6)  is pressed the Test function is activated.

In this condition, it will be possible to make the unit perform all the movements made during the examination **without emitting X-rays**. Once the cycle is completed, deactivate the "Test" function by pressing key again.

WARNING:
During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the local regulations.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see the Figure 1 and Figure 2).

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.6.2.2; ensure that the machine's indicator light "Ready for X-rays" will come on, so press the ray button for the entire duration of the exposure, checking the contemporary working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

			S	T	A	R	T		E	X	A	M		
	P	R	E	-	H	E	A	T	I	N	G	.	.	.

and then (after 2 seconds), the following message will be displayed:

x	x	k	V		x	x	m	A		1	3	.	8	s
				>	X	-	R	A	Y	<				

x = value defined by the settings

NOTE:
If the machine is in the "Test" mode, the display will show:

					T	E	S	T						
X	R	A	Y		N	O	T		A	C	T	I	V	E

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0← .

NOTE:
The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. **As the X-ray button is of the "deadman's brake" type, it is necessary to keep it pressed until the end of the exposure.**

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, the display shows the message:

P	A	T	I	E	N	T		E	X	I	T				
						P	R	E	S	S		>	0	<	

The patient must then be released from the positioning device.

NOTE:
If the examination is made in "Test" mode with the patient already in position, he must not be removed from the temple clamp, to avoid having to reposition the patient.The "Patient entrance" key (7) →0←

Must be pressed until the machine returns to the starting position. This movement can be stopped by pressing the same key.
Now the system is ready to perform a new examination.

3. Press the key "Patient Entrance" (7) →0←, the unit will move back to the starting position showing the message:

P	L	E	A	S	E		W	A	I	T	.	.	.		

The Digital Acquisition System will, in the meantime, process the image and display it.

WARNING:
After every examination, clean the chin support, the resting handgrips and the temple clamp thoroughly and change the disposable bite or the bite protective sleeve.

NOTE:
If a new exposure is required, but the waiting time calculated by the adaptive duty cycle has not yet expired, the display will show a message indicating the time remaining before the new examination can be performed:

T	**U**	**B**	**E**		**C**	**O**	**O**	**L**	**I**	**N**	**G**			
P	**L**	**E**	**A**	**S**	**E**		**W**	**A**	**I**	**T**		**x**	**x**	**x**	**s**

The waiting time allows the anode in the radiogenic tube to cool down.

NOTE:
If, during the exposure, the patient moves, or the machine collides with the patient himself (or with any object), or you realise that the parameters set are not correct, you must release the X-ray button immediately, interrupting the emission of X-rays and the movement of the arm.
If this occurs, the following message will be displayed:

E		**2**	**0**	**6**										
			P	**R**	**E**	**S**	**S**		**>**	**0**	**<**			

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; **it is recommended that this movement be made with great care in order to prevent damage to the machine**.

Then press the "Patient Entrance" (7) key  and the display will show:

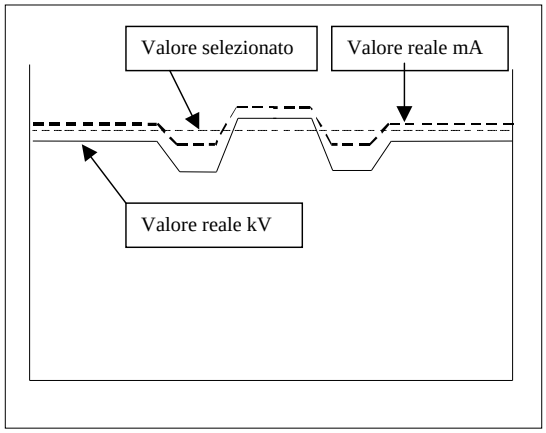
	M	**A**	**C**	**H**	**I**	**N**	**E**		**S**	**E**	**T**	**T**	**I**	**N**	**G**
			P	**R**	**E**	**S**	**S**		**>**	**0**	**<**				

and then:

				W	**A**	**I**	**T**		**F**	**O**	**R**				
	M	**A**	**C**	**H**	**I**	**N**	**E**		**S**	**E**	**T**	**T**	**I**	**N**	**G**

The original position is re-established and the patient must be positioned once again.

NOTE:
During the Panoramic, the value of the expository parameters 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 of the kV is lowered in the initial and end sections of the panoramic and increased on the incisors/canine zone.
The tube current varies according to the kV, also if the set value is slightly increased on the initial/end sections. These variations have the effect of compensating the higher absorption of X-ray on the zone of the spinal column. As an example, the variation of the parameters follows the curve below:



The values displayed during the panoramic examination correspond to the ones chosen by the user, while the real value in the various positions of the examination cycle can be different; in any case, the system guarantees that the accuracy of the exposure parameters is within the maximum limits required by international regulations on the safety of medical devices IEC 60601-1. In particular, in accordance with the IEC 60601-2-7, the maximum deviation (inclusive of the correction as shown in the figure and instrumental uncertainty) is within the ± 10% for kV and within ± 15% for the anode current.

8.7 Temporo-mandibular Joint Examination

The Temporo-mandibular Joint examination (TMJ) with open or closed mouth is similar to panoramic; the only difference is that the exposure is performed only on the involved area (the temporo mandibular joint), then it stops, and starts again on the second joint. The operation sequence of the examination is therefore identical to the one described for the panoramic.

The temporo-mandibular joint examination makes use of a projection geometry giving an image of the X-rayed condyle along a direction almost parallel with its major axis, in order to achieve a clear view of its positioning inside the cavity.
This TMJ function enables to obtain 4 different acquisitions on the same image, by performing two rotational movements. The 4 images represent the right and left condyle of the temporo-mandibular arch (TMJ) with closed mouth and open mouth.
Selecting close mouth exam only the external sectors of the image are exposed, while selecting open mouth exam, the exposure occurs on the inner sectors.
The position of the images couples the images corresponding to the same condyle to help a diagnosis. Figure 15 shows the information related to the single sectors.

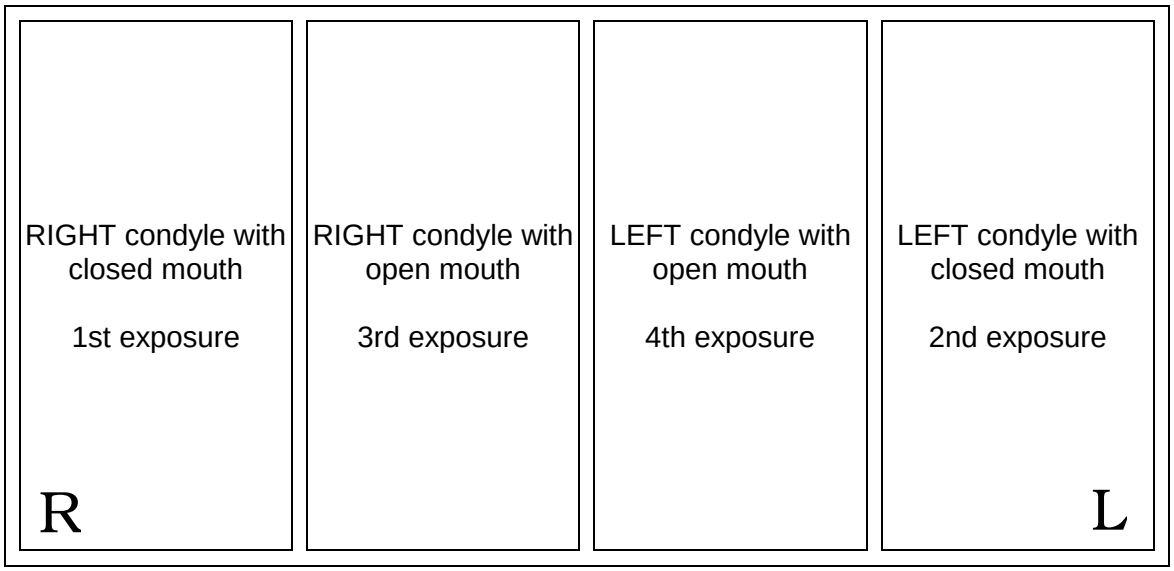


Figure 15

NOTE:
During the TMJ examination, the emission of X-rays is intermittent (it is interrupted during the transition phases between the various exposures), but it is necessary to keep the X-ray button pressed for the whole rotation time.
Do not release the X-ray button during the emission interruption if not necessary.
The cooling phase of the tube-head occurs at the end of all 4 exposures.
In the CHILD position, exposure start is delayed by a few degrees with respect to the ADULT position.

8.7.1 Preparation of the device

To select the TMJ exam, press the "Examination Mode Selection - M" key (11)  until the following message appears:

	x	x	k	V		x	x	m	A		9	.	7	0	s
T	M	J		O	/	C		-	>		C	L	O	S	E

The system is positioned in the following configuration:

- ADULT with the lighting up of the corresponding LED
- MEDIUM SIZE with the lighting up of the corresponding LED

and the display showing the default exposure parameters (if this is the first TMJ exposure), or the exposure parameters (kV and mA) of the last exposure performed. For example:

	7	2	k	V		0	6	m	A		9	.	7	0	s
T	M	J		O	/	C		-	>		C	L	O	S	E

With the preparation of the machine completed, position the chin support, if it had been previously removed (see notes in paragraph 8.4), using the lowered chin support for SINUS/TMJ.

NOTE:
Rotograph EVO 3D is based on an arch shape and the temporomandibular joint determined on statistical studies.
This form is taken as "standard" for the dentomaxillofacial complex, also define the position and orientation of the condyles. The patient anatomy can differ significantly from the statistical model; Based on his experience and competence, the user has to judge this variation.

IN ANY CASE, THE X-RAY IMAGE CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC.

8.7.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the key "Size Selection" (9)  or the key "Examination Mode Selection - M" (11) 

After setting the machine, it is possible to choose between the following two operating modes:

- **ANATOMIC:** with the values of kV and mA programmed on the basis of the type of patient and the size.
- **MANUAL:** with the possibility to vary the kV and mA values already set.

NOTE:
In the manual mode, the LED of the "Adult/Child Selection" (8) key flashes to indicate that it is possible to change the selection; use key (8)  to change from Adult to Child.

8.7.2.1 Anatomic exposure

Select the type of patient with the **Adult/Child** key (8).

Select the type of build with the **Size** (9) key *(small - medium - large).*

On the basis of the selections made, the display will visualise the kV and mA settings as in the table.

Exposure factors table for TMJ examination (9.7 s)				
Examination	**Adult**		**Child**	
TMJ mouth closed/open	**kV**	**mA**	**kV**	**mA**
Small	68	6	62	6
Medium	72	6	64	6
Large	76	6	66	6

Table 5

The time (9.7 s) refers to the sum of the four exposures (2 closed TMJ mouth exposures and 2 open TMJ mouth exposures).

8.7.2.2 Manual exposure

If the kV and mA combinations of the table Table 5 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

To modify the kV or mA values, press key (3)  , the LEDs of the "Adult/Child Selection" (8) key will flash; the LED of the "Size Selection" (9) will go off. The display will show respectively one of the following two indications:

>	x	x	k	V		x	x	m	A		9	.	7	0	s
T	M	J		O	/	C		-	>		C	L	O	S	E

or

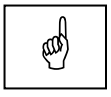
	x	x	k	V	>	x	x	m	A		9	.	7	0	s
T	M	J		O	/	C		-	>		C	L	O	S	E

The symbol ">" indicates which parameter is being changed; to modify the type of parameter to work on, press key (3)  repeatedly.

The selected parameter can be modified by pressing the increase key (4) and the decrease key (5)  .

The kV value can vary between *60 and 86 kV, with 2 kV steps.*

The value of mA can vary between *6 and 10 mA, with 1 mA steps.*



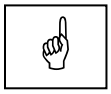
NOTE:
To change the values rapidly, keep the increase key (4) or the decrease key (5) pressed.

8.7.3 TMJ closed mouth

8.7.3.1 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.
3. Position the patient upright to the TMJ positioner. With the "Column movement" keys (15/16)  , lift/lower the column until the TMJ positioner is aligned with the patient's nose.
4. Verify that the temple clamp device is in the central position (Figure 10), and if necessary move it using the appropriate control on the top of the support (Figure 16).
5. Place the patient in temple clamp by placing the chin on the surface of the relevant support (Figure 16); the hands should rest on the front handgrips.
6. Set the height of the temple clamp just above the patient's orbital bone.
7. Instruct the patient to close his eyes.
8. Press the key "Centring devices ON" (14)  .

   Two laser beams illuminate the line of the median sagittal plane and the horizontal line for the reference of the Frankfurt plane (Figure 13).
   Using the laser of the midsagittal plane as a reference only, place the patient's head so that the beam falls on the corresponding anatomical reference (Figure 16).
   The reference of the Frankfurt plane can be used to make sure the head of the patient is remaining in the same position when examination is taken with either open or closed mouth.



NOTE:
The laser centring devices remain on for approximately 1 minute; Shutdown can be anticipated by pressing the "Centring Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (7)  to begin preparation for exposure.

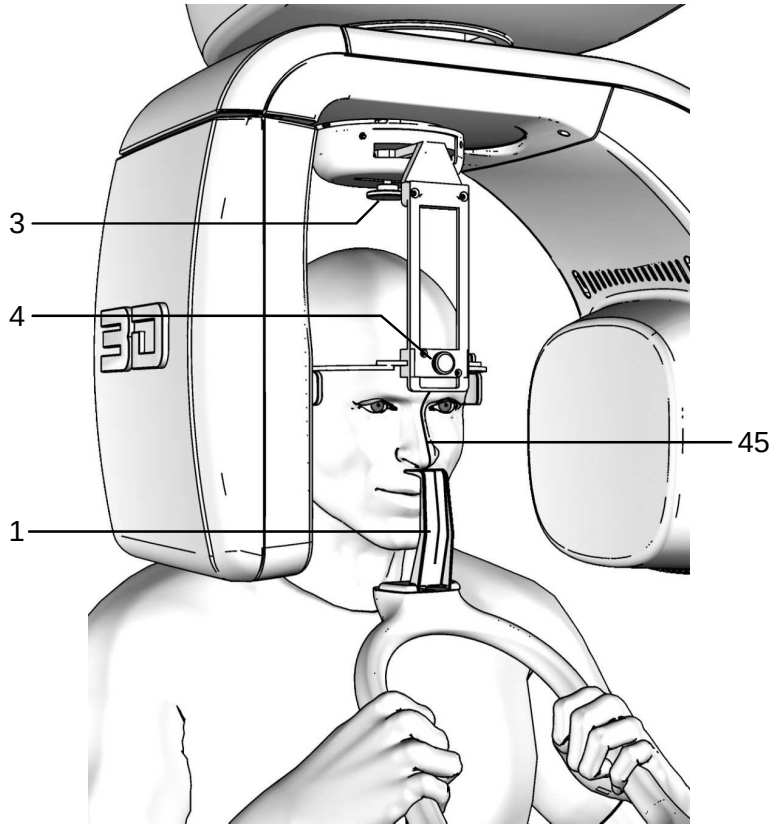


Figure 16 – TMJ closed mouth positioning

Legend of Reference Lines

45 Midsagittal line

Legend positioning devices and patient centring

1 TMJ support positioner
3 Temple clamp device position control
4 Temple clamp open/close knob

9. Place the temple clamp in contact with the patient's head by means of the appropriate knob (Figure 16).

10. Press the key "Patient Entrance" (7)  to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position.
Once alignment has been completed, the following message will be displayed:

	x	x	k	V		x	x	m	A		9	.	7	0	s
			S	T	A	R	T		E	X	A	M			

x = value defined by the settings

The green LED "Ready of X-rays" lights up to indicate that pressing the X-ray button once more will start the radiation phase.

11. Ask the patient to: keep the lips closed, bring the tongue towards the palate, keep perfectly still and do not look at the rotating arm during the movements.

8.7.3.2 Carrying out the first exposure (mouth closed)

WARNING:
During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the local regulations.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see the Figure 1 and Figure 2).

NOTE:
If deemed necessary, it is possible to check the interference of the rotation movement with the shoulder of the patient; the Test function can be activated by pressing the "Test" key (6)  . In this condition, it will be possible to make the unit perform all the movements made during the examination **without emitting X-rays**. The test function of the TMJ closed/open mouth is the same as for the panoramic mode and so there will not be a second rotation corresponding to the open mouth exam. Once the cycle is completed, deactivate the "Test" function by pressing key again.

1. Check once again that the exposure data are correct. If not, correct them as described in paragraph 8.7.2.2. ensure that the machine's indicator light "Ready for X-rays" will come on, so press the ray button for the entire duration of the exposure, checking the contemporary working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

			S	T	A	R	T		E	X	A	M			
	P	R	E	-	H	E	A	T	I	N	G	.	.	.	

and then (after 2 seconds), the following message will be displayed:

	x	x	k	V		x	x	m	A		9	.	7	0	s
				>	X	-	R	A	Y	<					

x = value defined by the settings

NOTE:
If the machine is in the "Test" mode, the display will show:

					T	E	S	T							
X	-	R	A	Y		N	O	T		A	C	T	I	V	E

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0← .

NOTE:
The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from pressing the X-ray button. **As the X-ray button is of the "deadman's brake" type, it is necessary to keep it pressed until the end of the exposure.**
The X-ray emission to the central part of the dental arch is suspended during the examination phase, so the relative signals (sound and visual) are therefore also suspended.

2. Once the exposure is completed, the system will carry out a short return rotation and the following message will be displayed:

P	A	T	I	E	N	T		E	X	I	T				
						P	R	E	S	S		>	0	<	

It will then be possible to set up the system for the open mouth examination, keeping the patient in position or releasing him from the working area.

3. Press the "Patient Entrance" key (7) →0← .The machine will return to the starting position highlighting the message:

P	L	E	A	S	E		W	A	I	T	.	.	.		

The end of the movement, the display will show the message:

I	N	S	T	R	U	C	T		P	A	T	I	E	N	T
T	O		O	P	E	N		M	O	U	T	H	!		

8.7.4 TMJ open mouth

8.7.4.1 Preparation of the patient

1. The patient must be prepared following the instructions described in paragraph 8.7.3.1. The following is displayed:

I	N	S	T	R	U	C	T		P	A	T	I	E	N	T
T	O		O	P	E	N		M	O	U	T	H	!		

2. Press the key "Patient Entrance" (7)  to confirm.

The following message will be displayed:

	x	x	k	V		x	x	m	A		9	.	7	0	s
T	M	J		O	/	C		-	>		O	P	E	N	

3. Position the patient again if he has been removed from the centring device (Figure 17). Tell him to open his mouth (helping him to keep in position using appropriate mechanical devices - not supplied - if necessary).

4. Set the height of the temple clamp just above the patient's orbital bone.

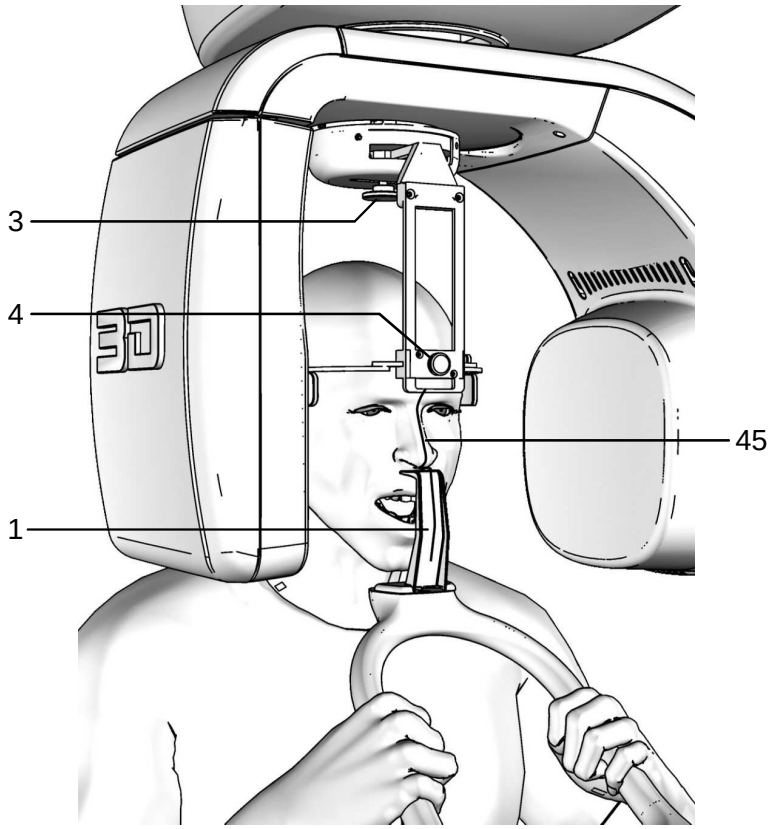


Figure 17 – Open mouth examination positioning

Legend of Reference Lines

45 Midsagittal line

Legend positioning devices and patient centring

1 TMJ positioner
3 Temple clamp device position control
4 Temple clamp open/close knob

5. Instruct the patient to close his eyes.

6. Press the key "Centring devices ON" (14)  .

Two laser beams will light up the midsagittal plane line and the horizontal line for the Frankfurt plane reference (Figure 13).
Using the laser of the midsagittal plane as a reference only, place the patient's head so that the beam falls on the corresponding anatomical reference.
The reference of the Frankfurt plane can be used to make sure the head of the patient is remaining in the same position when examination is taken with either open or closed mouth.

NOTE:
The laser centring devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centring Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (7)  to begin preparation for exposure.

7. Place the temple clamp in contact with the patient's head by means of the appropriate knob (Figure 17).

8. Press the key "Patient Entrance" (7)  to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position.
Once alignment has been completed, the following message will be displayed:

	x	x	k	V		x	x	m	A		9	.	7	0	s
			S	T	A	R	T		E	X	A	M			

x = value defined by the settings

The green LED "Ready of X-rays" lights up to indicate that pressing the X-ray button once more will start the radiation phase.

9. Ask the patient to: remain perfectly still and not to look at the rotation arm during the movement.

8.7.4.2 Carrying out the second exposure (mouth open)

WARNING:
During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the local regulations.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see the Figure 1 and Figure 2).

WARNING:
Using the laser centring devices, check that the system is still aligned with the patient's sagittal medial plane.

1. Press the "Patient Entrance" key (7)  . The following is displayed:

	x	x	k	V		x	x	m	A		9	.	7	0	s
			S	T	A	R	T		E	X	A	M			

Check again that the exposure data are correct (see paragraph 8.7.2).

NOTE:
The Adult/Child and Size *small - medium - large* selection keys are deactivated. The exposure parameters can be changed as described in paragraph 8.7.2.

Press the X-ray button for the entire duration of the exposure, checking the concurrent working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

			S	T	A	R	T		E	X	A	M			
	P	R	E	-	H	E	A	T	I	N	G	.	.	.	

and then (after 2 seconds), the following message will be displayed:

	x	x	k	V		x	x	m	A		9	.	7	0	s
				>	X	-	R	A	Y	<					

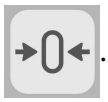
x = value defined by the settings

NOTE:
The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. **As the X-ray button is of the "deadman's brake" type, it is necessary to keep it pressed until the end of the exposure.**
During the examination, the emission of rays in correspondence with the central part of the dental arch is suspended; the relative signals (audible and visual) are also suspended.

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, the display shows the message:

P	**A**	**T**	**I**	**E**	**N**	**T**		**E**	**X**	**I**	**T**			
						P	**R**	**E**	**S**	**S**		**>**	**0**	**<**

and it will be necessary to free the patient from the positioning device.

3. Press the key "Patient Entrance" (7)  . The machine will reposition itself back to the starting position displaying the message:

P	**L**	**E**	**A**	**S**	**E**		**W**	**A**	**I**	**T**	**.**	**.**	**.**	

Then, the following message will be displayed:

	x	**x**	**k**	**V**		**x**	**x**	**m**	**A**		**9**	**.**	**7**	**0**	**s**
T	**M**	**J**		**O**	**/**	**C**		**-**	**>**		**O**	**P**	**E**	**N**	

x = value defined by the settings

that shows the values set for that last exposure. A new exposure can now be made.

WARNING:
Clean the chin support, the resting handgrips and the temple clamp thoroughly after each examination.

NOTE:
If, during the exposure, the patient moves, or the machine collides with the patient himself (or with any object), or you realise that the parameters set are not correct, you must release the X-ray button immediately, interrupting the emission of X-rays and the movement of the arm.
If this occurs, the following message will be displayed:

E		2	0	6										
			P	R	E	S	S		>	0	<			

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; **it is recommended that this movement be made with great care in order to prevent damage to the machine.**

Then press the "Patient Entrance" (7) key  and the display will show:

	M	A	C	H	I	N	E		S	E	T	T	I	N	G
			P	R	E	S	S		>	0	<				

and then:

				W	A	I	T		F	O	R				
	M	A	C	H	I	N	E		S	E	T	T	I	N	G

The original position is re-established and the patient must be positioned once again.

NOTE:
If the open mouth exposure is not completed, the closed mouth exposure must be repeated or the four complete pictures will not appear.

8.8 SINUS examination

To select the SINUS exam, press the "Examination Mode Selection - M" key (11)  until the following message appears:

	x	x	k	V		x	x	m	A		9	.	4	0	s
S	I	N	U	S											

x = value defined by the settings

During the examination, one single rotation of the rotating arm is to be expected, with the X-rays emission limited to the interested area.

8.8.1 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the key "Size Selection" (9)  or the key "Examination Mode Selection - M" (11) 

After setting the machine, it is possible to choose between the following two operating modes:

- **ANATOMIC:** with the values of kV and mA programmed on the basis of the type of patient and the size.
- **MANUAL:** with the possibility to vary the kV and mA values already set.

NOTE:
In the manual mode, the LED of the "Adult/Child Selection" (8) key flashes to indicate that it is possible to change the selection; use key (8)  to change from Adult to Child.

8.8.1.1 Anatomic exposure

Select the type of patient with the **Adult/Child** key (8).

Select the type of build with the **Size** (9) key (*small - medium - large).*

On the basis of the selections made, the display will visualise the kV and mA settings as in the table.

Exposure factors table for SINUS exams (9.4 s)				
	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	66	6	62	6
Medium	70	6	64	6
Large	72	6	66	6

Table 6

8.8.1.2 Manual exposure

If the kV and mA combinations of the table Table 6 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

To modify the kV or mA values, press key (3)  , the LEDs of the "Adult/Child Selection" (8) key will flash; the LED of the "Size Selection" (9) will go off. The display will show respectively one of the following two indications:

>	x	x	k	V		x	x	m	A		9	.	4	0	s
S	I	N	U	S											

or

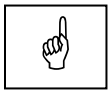
	x	x	k	V	>	x	x	m	A		9	.	4	0	s
S	I	N	U	S											

The symbol ">" indicates which parameter is being changed; to modify the type of parameter to work on, press key (3)  repeatedly.

The selected parameter can be modified by pressing the increase key (4) and the decrease key (5)  .

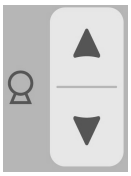
The kV value can vary between *60 and 86 kV, with 2 kV steps.*

The value of mA can vary between *6 and 10 mA, with 1 mA steps.*

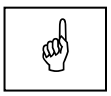


NOTE:
To change the values rapidly, keep the increase key (4) or the decrease key (5) pressed.

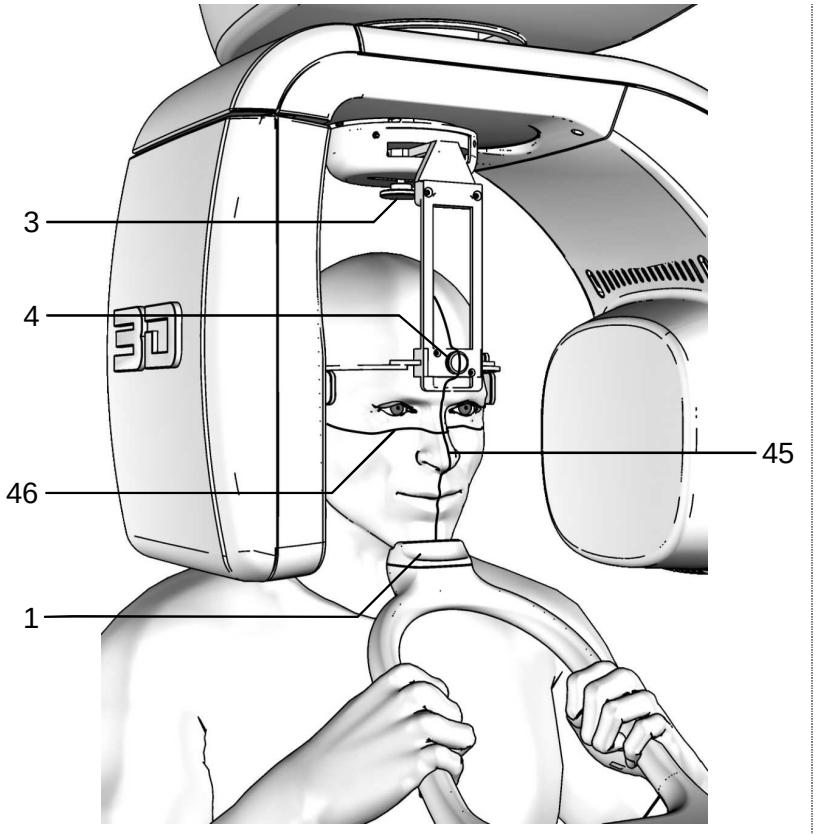
8.8.2 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.
3. Position the patient upright to the SINUS chin support. With the the "Column movement" keys (15/16)  lift/lower the column until the chin support is aligned with the patient's chin.
4. Verify that the temple clamp device is in the central position (Figure 10), and if necessary move it using the appropriate control on the top of the support (Figure 18).
5. Place the patient in the temple clamp (Figure 18) by placing the chin on the surface of the relevant support; the hands should rest on the front handgrips. Ensure that the patient rests his chin on the chin support for SINUS.
6. Set the height of the temple clamp just above the patient's orbital bone.
7. Instruct the patient to close his eyes.
8. Press the key "Centring devices ON" (14)  .

   Two laser beams illuminate the line of the median sagittal plane and the horizontal line for the reference of the Frankfurt plane (Figure 13).
   Position the patient's head in such a way as to ensure that the luminous beams fall in correspondence with the respective anatomical references.
   The luminous beam of the Frankfurt plane can be adjusted according to the patient's height; this adjustment is achieved by adjusting the laser block on the side of the mirror.



NOTE:
The laser centring devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centring Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (7)  to begin preparation for exposure.



Legend of Reference Lines

45 Midsagittal line
46 Frankfurt plane line

Legend positioning devices and patient centring

1 SINUS support
3 Temple clamp device position control
4 Temple clamp open/close knob

Figure 18 – SINUS positioning

9. Place the temple clamp in contact with the patient's head by means of the appropriate knob (Figure 18).

10. At this point, the patient must move his feet towards the column, making sure to keep his head within the pre-aligned anatomical references. By doing so a greater distension of the spinal column is achieved, avoiding collisions with the tube-head with the patient's shoulders. Check that the Frankfurt plane is still horizontal.

11. Press the key "Patient Entrance" (7)  to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position.
Once alignment has been completed, the following message will be displayed:

	x	x	k	V		x	x	m	A		9	.	4	0	s
			S	T	A	R	T		E	X	A	M			

x = value defined by the settings

The green LED "Ready of X-rays" lights up to indicate that pressing the X-ray button once more will start the radiation phase.

12. Ask the patient to: keep the lips closed, bring the tongue towards the palate, keep perfectly still and do not look at the rotating arm during the movements.

8.8.3 Making an exposure

WARNING:
During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the local regulations.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see the Figure 1 and Figure 2).

NOTE:
Before performing a lateral Sinus examination, because of the specific trajectory described by the rotating arm, it is recommended to check for possible mechanical interference with the patient's shoulder during the rotation.

by pressing the key "Test" (6)  , to activate the Test function. In this condition, it will be possible to make the unit perform all the movements made during the examination **without emitting X-rays**. Once the cycle is completed, deactivate the "Test" function by pressing key again.

4. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.6.2.2; ensure that the machine's indicator light "Ready for X-rays" will come on, so press the ray button for the entire duration of the exposure, checking the contemporary working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

			S	T	A	R	T		E	X	A	M		
	P	R	E	-	H	E	A	T	I	N	G	.	.	.

and then (after 2 seconds), the following message will be displayed:

	x	x	k	V		x	x	m	A		9	.	4	0	s
				>	X	-	R	A	Y	<					

x = value defined by the settings

NOTE:
If the machine is in the "Test" mode, the display will show:

					T	E	S	T						
X	-	R	A	Y		N	O	T		A	C	T	I	V	E

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0← .

NOTE:
The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. **As the X-ray button is of the "deadman's brake" type, it is necessary to keep it pressed until the end of the exposure.**
During the examination, the emission of rays in correspondence with the central part of the dental arch is suspended; the relative signals (audible and visual) are also suspended.

5. Once the exposure is completed, the system will rotate back. When it has completed this movement, the display shows the message:

P	A	T	I	E	N	T		E	X	I	T				
						P	R	E	S	S		>	0	<	

and it will be necessary to free the patient from the positioning device.

6. Press the key "Patient Entrance" (7) →0← . The machine will reposition itself back to the starting position displaying the message:

P	L	E	A	S	E		W	A	I	T	.	.	.		

Then, the following message will be displayed:

	x	x	k	V		x	x	m	A		9	.	4	0	s
S	I	N	U	S											

x = value defined by the settings

that shows the values set for that last exposure. A new exposure can now be made.

WARNING:
Clean the chin support, the resting handgrips and the temple clamp thoroughly after each examination.

NOTE:
If a new exposure is required, but the waiting time calculated by the adaptive duty cycle has not yet expired, the display will show a message indicating the time remaining before the new examination can be performed:

T	U	B	E		C	O	O	L	I	N	G				
P	L	E	A	S	E		W	A	I	T		x	x	x	s

The waiting time allows the anode in the radiogenic tube to cool down.

NOTE:
If, during the exposure, the patient moves, or the machine collides with the patient himself (or with any object), or you realise that the parameters set are not correct, you must release the X-ray button immediately, interrupting the emission of X-rays and the movement of the arm.
If this occurs, the following message will be displayed:

E		2	0	6											
			P	R	E	S	S		>	0	<				

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; **It is recommended that this movement be made with great care in order to prevent damage to the machine**.

Then press the "Patient Entrance" (7)  key and the display will show:

	M	A	C	H	I	N	E		S	E	T	T	I	N	G
			P	R	E	S	S		>	0	<				

and then:

				W	A	I	T		F	O	R				
	M	A	C	H	I	N	E		S	E	T	T	I	N	G

The original position is re-established and the patient must be positioned once again.

8.9 Volumetric or 3D exams

The 3D or volumetric examinations have a continuous rotation of the tube-head support arm (X-ray generator) and the sensor holder. The total angle of rotation varies according to the examination mode selected.
After the initial acceleration, the rotation is at a constant speed, while the centre of rotation remains fixed in the position identified from the exam, so that the area of interest is within the reconstructed volume.
The emission of X-rays only occurs during the constant rotation speed of the rotating arm, and occurs in pulsed mode, at each degree of rotation.

The volumetric images obtained allow a clear view of the entire area of interest, and also, by using the image acquisition and processing program, images along three axes perpendicular to each can be obtained and selected by the operator.

The centring of the patient for 3D Dentition and 3D Sinus examinations is aided by two linear reference beams; the corresponding anatomical planes of the patient must be aligned with these beams.

8.10 3D Dentition exam

The 3D examination of the dentition allows the physician/dentist to have an overview of the entire dentition of the patient. This mode is very useful when you need to plan more than one system, because a global view is produced with a single exposure and, taking advantage of the opportunities provided by the image acquisition and processing system, different areas of interest can be selected.

8.10.1 Preparation of the device

To select the 3D Dentition exam, press the "Examination Mode Selection - M" key (11)  until the following message appears:

	x	x	k	V		x	x	m	A		1	1	.	2	s
3	D		D	e	n	t	i	t	i	o	n				

The system is positioned in the following configuration:

- ADULT with the lighting up of the corresponding LED
- MEDIUM SIZE with the lighting up of the corresponding LED

and the default settings are displayed if this is the first 3D Dentition exposure to be performed or the radiological parameters used in the last examination. For example:

	8	0	k	V		0	9	m	A		1	1	.	2	s
3	D		D	e	n	t	i	t	i	o	n				

In this case, exposure occurs at 80 kV, 9 mA, 28 ms of exposure per pulse.

Once the settings have been completed, the relative chin support must be placed in position (see the operative notes in paragraph 8.4).

The key "Examination Mode Selection" (11) enables the selection of specific submodes, selectable by means of the keys "Arrow right" (13) and "Arrow left" (12), enabling the sliding in one direction or another.

Previous examination  *Next examination*

The following choices are available in the volumetric exam mode:
3D Dentition -> 3D TMJ Left -> 3D TMJ Right -> 3D Sinus ->
3D Dentition.
This selection is cyclic, so pressing the button repeatedly will change the selected mode.

8.10.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the key "Size Selection" (9)  or the key "Examination Mode Selection - M" (11) 

After setting the machine, it is possible to choose between the following two operating modes:

- **ANATOMIC:** with the kV, mA and t values programmed on the basis of the type of patient and the size.
- **MANUAL:** with the possibility of altering the pre-set kV, mA and times.

NOTE:
In the manual mode, the LED of the "Adult/Child Selection" (8) key flashes to indicate that it is possible to change the selection; use key (8)  to change from Adult to Child.

8.10.2.1 Anatomic exposure

Select the type of patient with the **Adult/Child** key (8).

Select the type of build with the **Size** (9) key (*small - medium - large).*

On the basis of these selections, the display will visualise the kV and mA settings as in the table.

3D Dentition mode exposure values table (11.2 s)				
	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	76	9	66	8
Medium	80	9	68	8
Large	82	9	70	8

Table 7

The exposure time indicated (11.2 seconds) is relative to the sum of 400 X-ray pulses of 28 ms each that make up the exam.

8.10.2.2 Manual exposure

If the kV and mA combinations of the table Table 7 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

To modify the kV or mA values, press key (3)  , the LEDs of the "Adult/Child Selection" key (8) will flash; the LED of the "Size Selection" (9) will go off. The display will show respectively one of the following two indications:

>	x	x	k	V		x	x	m	A		1	1	.	2	s
3	D		D	e	n	t	i	t	i	o	n				

or

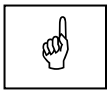
	x	x	k	V	>	x	x	m	A		1	1	.	2	s
3	D		D	e	n	t	i	t	i	o	n				

The symbol ">" indicates which parameter is being changed; to modify the type of parameter to work on, press key (3)  repeatedly.

The selected parameter can be modified by pressing the increase key (4) and the decrease key (5)  .

The kV value can vary between *60 and 86 kV, with 2 kV steps.*

The value of mA can vary between *6 and 10 mA, with 1 mA steps.*

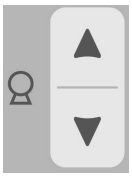


NOTE:
To change the values rapidly, keep the increase key (4) or the decrease key (5) pressed.

8.10.3 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).

2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.

3. Position the patient upright to the Edentulous Panoramic chin support. With the "Column movement" keys (15/16)  lift/lower the column until the chin support is aligned with the patient's chin.

NOTE:
Depending on the examination application, it may be suggested the use of the chin rest for standard panoramic including centering bite (paragraph 8.4) to separate upper and lower arch.

4. Verify that the temple clamp device is in the central position (Figure 10), and if necessary move it using the appropriate control on the top of the support (Figure 19).

5. Make sure that the chin support used is that for edentulous patients (paragraph 8.4).

6. Place the patient in the temple clamp (Figure 19) by placing the chin on the surface of the relevant support; the hands should rest on the front handgrips.

7. Set the height of the temple clamp just above the patient's orbital bone.

8. Instruct the patient to close his eyes.

9. Press the key "Centring devices ON" (14)  .

Two laser beams will illuminate; align the midsagittal and ala-tragus planes (Figure 13) of the patient with these beams.
The horizontal beam can be adjusted, depending on the height of the patient, by acting on the laser block on the side of the mirror.

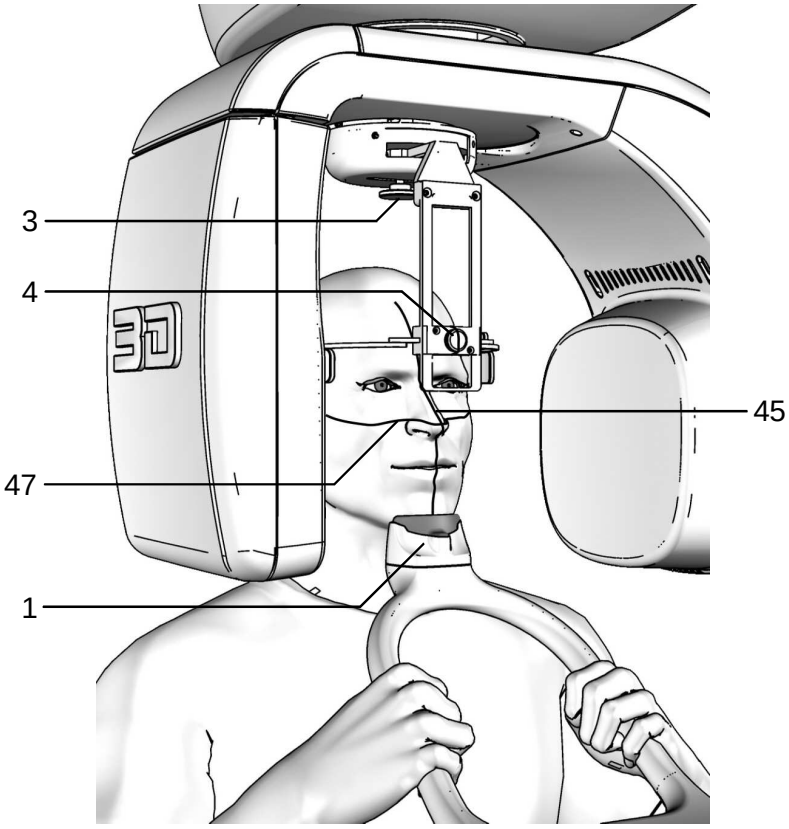


Figure 19 - 3D Dentition positioning

Legend of Reference Lines

45 Midsagittal line
47 Ala-tragus line

Legend positioning devices and patient centring

2 Edentulous chin support
3 Temple clamp device position control
4 Temple clamp open/close knob

NOTE:
The laser centring devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centring Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key

(7)  to begin preparation for exposure.

10. Place the temple clamp in contact with the patient's head by means of the appropriate knob (Figure 19). In order to help the patient maintain the correct posture, use the head strip on the temple clamp passing it behind the nape of the patient's neck;check that, during this phase, the patient has not changed position.

11. At this point, the patient must move his feet towards the column, making sure to keep his head within the pre-aligned anatomical references. In this way, you will have a greater extension of the spine in the cervical area, improving the darkening of the X-ray in the apical area of the incisors, and avoiding the collision of the tube-head with the patient's shoulders. Check that the Frankfurt plane is still horizontal.

12. Press the key "Patient Entrance" (7)  to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position.
Once alignment has been completed, the following message will be displayed:

	x	x	k	V		x	x	m	A		1	1	.	2	s
			S	T	A	R	T		E	X	A	M			

x = value defined by the settings

The green LED "Ready of X-rays" lights up to indicate that pressing the X-ray button once more will start the radiation phase.

13. Ask the patient to: keep the lips closed, bring the tongue towards the palate, keep perfectly still and do not look at the rotating arm during the movements.

8.10.4 Making an exposure

NOTE:

When the key "Test" (6)  is pressed the Test function is activated.

In this condition, it will be possible to make the unit perform all the movements made during the examination **without emitting X-rays**. Once the cycle is completed, deactivate the "Test" function by pressing key again.

WARNING:

During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the local regulations.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see the Figure 1 and Figure 2).

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.10.2.2; ensure that the machine's indicator light "Ready for X-rays" will come on, so press the ray button for the entire duration of the exposure, checking the contemporary working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

			S	T	A	R	T		E	X	A	M			
	P	R	E	-	H	E	A	T	I	N	G	.	.	.	

and then (after 2 seconds), the following message will be displayed:

x	x	k	V		x	x	m	A		1	1	.	2	s	
				>	X	-	R	A	Y	<					

x = value defined by the settings

NOTE:

Emissions are pulse in the volumetric mode; the acoustic signal isn't continuous either.
Keep the X-ray key pressed until the exam is complete.

NOTE:

If the machine is in the "Test" mode, the display will show:

					T	E	S	T							
X	-	R	A	Y		N	O	T		A	C	T	I	V	E

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0← .

NOTE:
The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. **As the X-ray button is of the "deadman's brake" type, it is necessary to keep it pressed until the end of the exposure.**

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, the display shows the message:

P	A	T	I	E	N	T		E	X	I	T				
						P	R	E	S	S		>	0	<	

The patient must then be released from the positioning device.

NOTE:
If the examination is made in "Test" mode with the patient already in position, he must not be removed from the temple clamp, to avoid having to reposition the patient. The "Patient entrance" key (7) →0← must be pressed until the machine returns to the starting position. This movement can be stopped by pressing the same key.
Now the system is ready to perform a new examination.

3. Press the key "Patient Entrance" (7) →0←, the unit will move back to the starting position showing the message:

P	L	E	A	S	E		W	A	I	T	.	.	.		

The Digital Acquisition System will, in the meantime, process the image and display it.

WARNING:
Clean the chin support, the resting handgrips and the temple clamp thoroughly and change the head strip after every examination.

NOTE:
If a new exposure is required, but the waiting time calculated by the adaptive duty cycle has not yet expired, the display will show a message indicating the time remaining before the new examination can be performed:

T	U	B	E		C	O	O	L	I	N	G				
P	L	E	A	S	E		W	A	I	T		x	x	x	s

The waiting time allows the anode in the radiogenic tube to cool down.

NOTE:
If, during the exposure, the patient moves, or the machine collides with the patient himself (or with any object), or you realise that the parameters set are not correct, you must release the X-ray button immediately, interrupting the emission of X-rays and the movement of the arm.
If this occurs, the following message will be displayed:

E		2	0	6											
			P	R	E	S	S		>	0	<				

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; **It is recommended that this movement be made with great care in order to prevent damage to the machine**.

Then press the "Patient Entrance" (7) key  and the display will show:

	M	A	C	H	I	N	E		S	E	T	T	I	N	G
			P	R	E	S	S		>	0	<				

and then:

				W	A	I	T		F	O	R				
	M	A	C	H	I	N	E		S	E	T	T	I	N	G

The original position is re-established and the patient must be positioned once again.

8.11 Left TMJ in 3D mode

The Left TMJ examination in 3D mode allows a clear vision of the left condyle and how it positions itself inside the fossa. The examination is normally conducted in a rest position, i.e. with the mouth closed.

Using the functions of the image acquisition and management of program, planes of interest can be selected and therefore the position of the condyle analysed at various points and along three perpendicular axes in order to get an overview of the joint's anatomy.

8.11.1 Preparation of the device

1. To select the 3D TMJ Left exam, press the "Examination Mode Selection - M" key (11)  until the following message appears:

	x	x	k	V		x	x	m	A		1	1	.	2	s
3	D		D	e	n	t	i	t	i	o	n				

2. Select the 3D TMJ Left using the "Right Arrow" (13) and "Left Arrow" (12)  :

	7	2	k	V		0	6	m	A		1	0	.	1	s
3	D		T	M	J		L	e	f	t					

NOTE:
If the kV and mA values are not considered appropriate for the patient, set the new values by following the instructions described in paragraph 8.11.2.

3. Press the key "Patient Entrance" (7)  to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position.
Once alignment has been completed, the following message will be displayed:

	x	x	k	V		x	x	m	A		1	0	.	1	s
			S	T	A	R	T		E	X	A	M			

x = value defined by the settings

The green LED "Ready of X-rays" lights up to indicate that pressing the X-ray button once more will start the radiation phase.

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key  .

4. Insert the appropriate 3D TMJ chin support (paragraph 8.4).

5. Check that the temple clamp device is in the 3D TMJ Left position (patient right side - Figure 10); if necessary move it into the correct position by means of the knob (Figure 20).

8.11.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the key "Size Selection" (9)  or the key "Examination Mode Selection - M" (11) 

After setting the machine, it is possible to choose between the following two operating modes:

- **ANATOMIC:** with the kV, mA and t values programmed on the basis of the type of patient and the size.
- **MANUAL:** with the possibility of altering the pre-set kV, mA and times.

NOTE:
In the manual mode, the LED of the "Adult/Child Selection" (8) key flashes to indicate that it is possible to change the selection; use key (8)  to change from Adult to Child.

8.11.2.1 Anatomic exposure

Select the type of patient with the **Adult/Child** key (8).

Select the type of build with the **Size** (9) key (*small - medium - large).*

On the basis of these selections, the display will visualise the kV and mA settings as in the table.

3D TMJ Left mode exposure values table (10.1 s)				
	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	68	6	62	6
Medium	72	6	64	6
Large	76	6	66	6

Table 8

The exposure time indicated (10.1 seconds) is relative to the sum of 360 X-ray pulses of 28 ms each that make up the exam.

8.11.2.2 Manual exposure

If the kV and mA combinations of the table Table 8 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

To modify the kV or mA values, press key (3)  , the LEDs of the "Adult/Child Selection" key (8) will flash; the LED of the "Size Selection" (9) will go off; The display will show respectively one of the following two indications:

>	x	x	k	V		x	x	m	A		1	0	.	1	s
3	D		T	M	J		L	e	f	t					

or

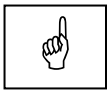
	x	x	k	V	>	x	x	m	A		1	0	.	1	s
3	D		T	M	J		L	e	f	t					

The symbol ">" indicates which parameter is being changed; to modify the type of parameter to work on, press key (3)  repeatedly.

The selected parameter can be modified by pressing the increase key (4) and the decrease key (5)  .

The kV value can vary between *60 and 86 kV, with 2 kV steps.*

The value of mA can vary between *6 and 10 mA, with 1 mA steps.*

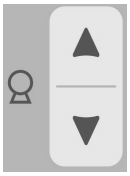


NOTE:
To change the values rapidly, keep the increase key (4) or the decrease key (5) pressed.

8.11.3 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).

2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.

3. Position the patient upright to the 3D TMJ chin support. With the keys "Column movement" (15/16)  lift/lower the column until the chin support is aligned with the patient's chin.

4. Place the patient in the temple clamp (Figure 20) by placing the chin on the surface of the relevant support; the hands should rest on the front handgrips; the patient must rest his chin against the reference on the chin support, using the right side (patient entrance view) of the support itself.

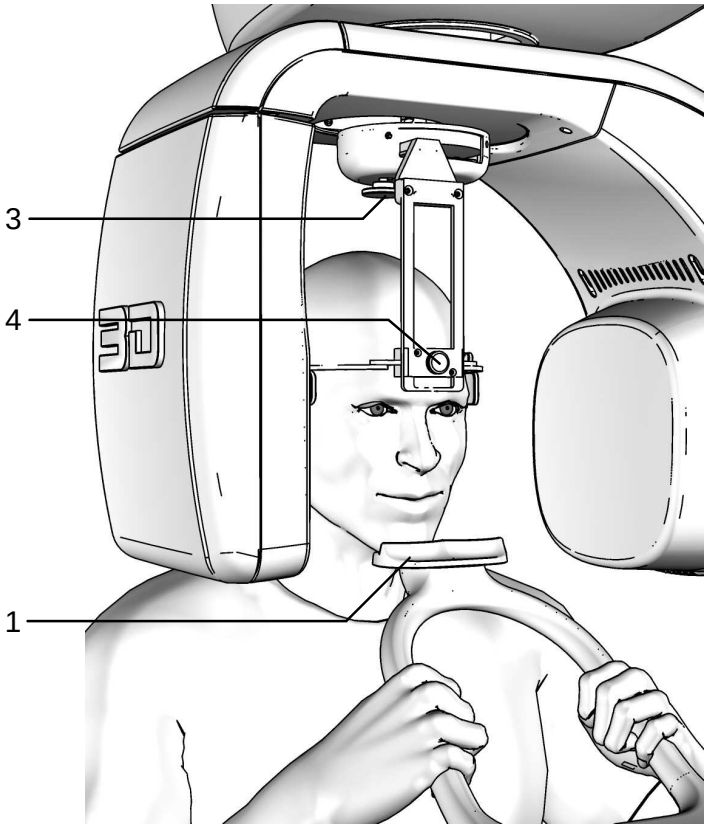


Figure 20 - 3D TMJ Left positioning

Legend positioning devices and patient centring

1 3D TMJ chin support
3 Temple clamp device position control
4 Temple clamp open/close knob

5. Set the height of the temple clamp just above the patient's orbital bone.

NOTE:
In the 3D TMJ exam, the laser centring devices are not active.

6. Place the temple clamp in contact with the patient's head by means of the appropriate knob (Figure 20). In order to help the patient maintain the correct posture, use the head strip on the temple clamp passing it behind the nape of the patient's neck; check that, during this phase, the patient has not changed position.

7. **Ask the patient to: keep the lips closed, bring the tongue towards the palate, keep perfectly still and do not look at the rotating arm during the movements.**

8.11.4 Making an exposure

NOTE:
When the key "Test" (6)  is pressed the Test function is activated.

In this condition, it will be possible to make the unit perform all the movements made during the examination **without emitting X-rays**. Once the cycle is completed, deactivate the "Test" function by pressing key again.

WARNING:
During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the local regulations.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see the Figure 1 and Figure 2).

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.11.2.2; ensure that the machine's indicator light "Ready for X-rays" will come on, so press the ray button for the entire duration of the exposure, checking the contemporary working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

			S	T	A	R	T		E	X	A	M		
	P	R	E	-	H	E	A	T	I	N	G	.	.	.

and then (after 2 seconds), the following message will be displayed:

x	x	k	V		x	x	m	A		1	0	.	1	s
				>	X	-	R	A	Y	<				

x = value defined by the settings

NOTE:
Emissions are pulse in the volumetric mode; the acoustic signal isn't continuous either.
Keep the X-ray key pressed until the exam is complete.

NOTE:
If the machine is in the "Test" mode, the display will show:

					T	E	S	T						
X	-	R	A	Y		N	O	T		A	C	T	I	V	E

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0← .

NOTE:
The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. **As the X-ray button is of the "deadman's brake" type, it is necessary to keep it pressed until the end of the exposure.**

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, the display shows the message:

P	A	T	I	E	N	T		E	X	I	T				
						P	R	E	S	S		>	0	<	

and it will be necessary to free the patient from the positioning device.

NOTE:
If the examination is made in "Test" mode with the patient already in position, he must not be removed from the temple clamp, to avoid having to reposition the patient. The "Patient entrance" key (7) →0← must be pressed until the machine returns to the starting position. This movement can be stopped by pressing the same key.
Now the system is ready to perform a new examination.

3. Press the key "Patient Entrance" (7) →0← , the unit will move back to the starting position showing the message:

P	L	E	A	S	E		W	A	I	T	.	.	.		

The Digital Acquisition System will, in the meantime, process the image and display it.

WARNING:
Clean the chin support, the resting handgrips and the temple clamp thoroughly and change the head strip after every examination.

NOTE:
If a new exposure is required, but the waiting time calculated by the adaptive duty cycle has not yet expired, the display will show a message indicating the time remaining before the new examination can be performed:

T	U	B	E		C	O	O	L	I	N	G				
P	L	E	A	S	E		W	A	I	T		x	x	x	s

The waiting time allows the anode in the radiogenic tube to cool down.

NOTE:
If, during the exposure, the patient moves, or the machine collides with the patient himself (or with any object), or you realise that the parameters set are not correct, you must release the X-ray button immediately, interrupting the emission of X-rays and the movement of the arm.
If this occurs, the following message will be displayed:

E		2	0	6											
			P	R	E	S	S		>	0	<				

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; **It is recommended that this movement be made with great care in order to prevent damage to the machine**.

Then press the "Patient Entrance" (7) key  and the display will show:

	M	A	C	H	I	N	E		S	E	T	T	I	N	G
			P	R	E	S	S		>	0	<				

and then:

				W	A	I	T		F	O	R				
	M	A	C	H	I	N	E		S	E	T	T	I	N	G

The original position is re-established and the patient must be positioned once again.

8.12 Right TMJ in 3D mode

The Right TMJ examination in 3D mode allows a clear vision of the right condyle and how it positions itself inside the fossa. The examination is normally conducted in a rest position, i.e. with the mouth closed.

Using the functions of the image acquisition and management of program, planes of interest can be selected and therefore the position of the condyle analysed at various points and along three perpendicular axes in order to get an overview of the joint's anatomy.

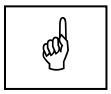
8.12.1 Preparation of the device

1. To select the 3D TMJ Right exam, press the "Examination Mode Selection - M" key (11)  until the following message appears:

	x	x	k	V		x	x	m	A		1	1	.	2	s
3	D		D	e	n	t	i	t	i	o	n				

2. Select the 3D TMJ Right using the "Right Arrow" (13) and "Left Arrow" (12)  :

	7	2	k	V		0	6	m	A		1	0	.	1	s
3	D		T	M	J		R	i	g	h	t				



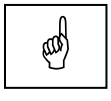
NOTE:
If the kV and mA values are not considered appropriate for the patient, set the new values by following the instructions described in paragraph 8.12.2.

3. Press the key "Patient Entrance" (7)  to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position.
Once alignment has been completed, the following message will be displayed:

	x	x	k	V		x	x	m	A		1	0	.	1	s
			S	T	A	R	T		E	X	A	M			

x = value defined by the settings

The green LED "Ready of X-rays" lights up to indicate that pressing the X-ray button once more will start the radiation phase.



NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R	
			I	S		N	O	T		R	E	A	D	Y

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key  .

4. Insert the appropriate 3D TMJ chin support (paragraph 8.4).

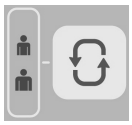
5. Check that the temple clamp device is in the 3D TMJ Right position (patient left side - Figure 10); if necessary move it into the correct position by means of the knob (Figure 21).

8.12.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the key "Size Selection" (9)  or the key "Examination Mode Selection - M" (11) 

After setting the machine, it is possible to choose between the following two operating modes:

- **ANATOMIC:** with the kV, mA and t values programmed on the basis of the type of patient and the size.
- **MANUAL:** with the possibility of altering the pre-set kV, mA and times.

NOTE:
In the manual mode, the LED of the "Adult/Child Selection" (8) key flashes to indicate that it is possible to change the selection; use key (8)  to change from Adult to Child.

8.12.2.1 Anatomic exposure

Select the type of patient with the **Adult/Child** key (8).

Select the type of build with the **Size** (9) key (*small - medium - large).*

On the basis of these selections, the display will visualise the kV and mA settings as in the table.

3D TMJ Right mode exposure values table (10.1 s)				
	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	68	6	62	6
Medium	72	6	64	6
Large	76	6	66	6

Table 9

The exposure time indicated (10.1 seconds) is relative to the sum of 360 X-ray pulses of 28 ms each that make up the exam.

8.12.2.2 Manual exposure

If the kV and mA combinations of the table Table 9 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

To modify the kV or mA values, press key (3)  , the LEDs of the "Adult/Child Selection" key (8) will flash; the LED of the "Size Selection" (9) will go off; The display will show respectively one of the following two indications:

>	x	x	k	V		x	x	m	A		1	0	.	1	s
3	D		T	M	J		R	i	g	h	t				

or

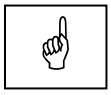
	x	x	k	V	>	x	x	m	A		1	0	.	1	s
3	D		T	M	J		R	i	g	h	t				

The symbol ">" indicates which parameter is being changed; to modify the type of parameter to work on, press key (3)  repeatedly.

The selected parameter can be modified by pressing the increase key (4) and the decrease key (5)  .

The kV value can vary between *60 and 86 kV, with 2 kV steps.*

The value of mA can vary between *6 and 10 mA, with 1 mA steps.*

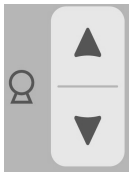


NOTE:
To change the values rapidly, keep the increase key (4) or the decrease key (5) pressed.

8.12.2.3 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).

2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.

3. Position the patient upright to the 3D TMJ chin support. With the "Column movement" keys (15/16)  raise/lower the column until the chin support rest is aligned with the patient's chin.

4. Place the patient in the temple clamp (Figure 21) by placing the chin on the surface of the relevant support; the hands should rest on the front handgrips; the patient must rest his chin against the reference on the chin support, using the left side (patient entrance view) of the support itself.

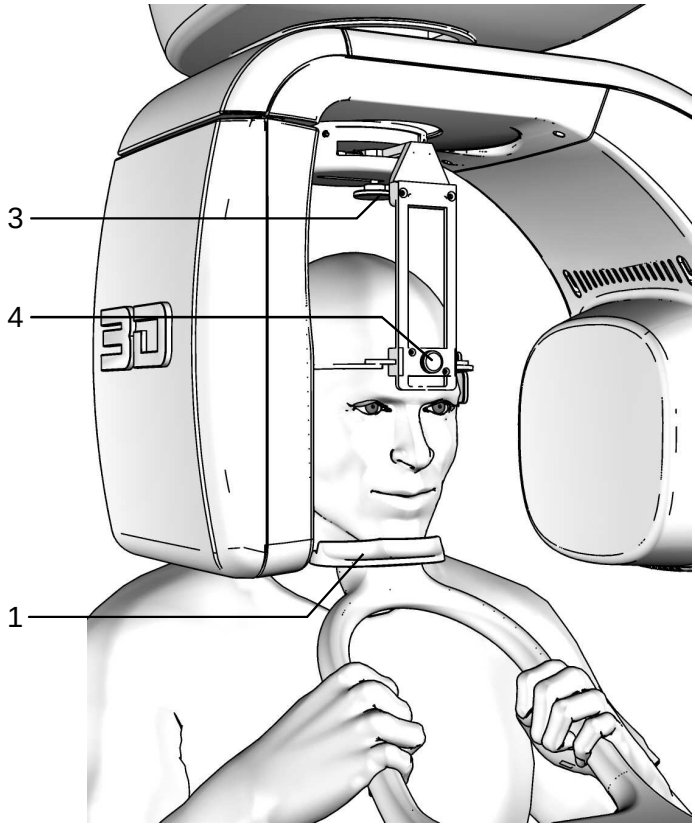


Figure 21 - 3D TMJ Right positioning

Legend positioning devices and patient centring

1 3D TMJ chin support
3 Temple clamp device position control
4 Temple clamp open/close knob

5. Set the height of the temple clamp just above the patient's orbital bone.

NOTE:
In the 3D TMJ exam, the laser centring devices are not active.

6. Place the temple clamp in contact with the patient's head by means of the appropriate knob (Figure 21). In order to help the patient maintain the correct posture, use the head strip on the temple clamp passing it behind the nape of the patient's neck; check that, during this phase, the patient has not changed position.

7. **Ask the patient to: keep the lips closed, bring the tongue towards the palate, keep perfectly still and do not look at the rotating arm during the movements.**

8.12.3 Making an exposure

NOTE:

When the key "Test" (6)  is pressed the Test function is activated.

In this condition, it will be possible to make the unit perform all the movements made during the examination **without emitting X-rays**. Once the cycle is completed, deactivate the "Test" function by pressing key again.

WARNING:

During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the local regulations.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see the Figure 1 and Figure 2).

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.13.2.2; ensure that the machine's indicator light "Ready for X-rays" will come on, so press the ray button for the entire duration of the exposure, checking the contemporary working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

			S	T	A	R	T		E	X	A	M		
	P	R	E	-	H	E	A	T	I	N	G	.	.	.

and then (after 2 seconds), the following message will be displayed:

	x	x	k	V		x	x	m	A		1	0	.	1	s
				>	X	-	R	A	Y	<					

x = value defined by the settings

NOTE:

Emissions are pulse in the volumetric mode; the acoustic signal isn't continuous either.
Keep the X-ray key pressed until the exam is complete.

NOTE:

If the machine is in the "Test" mode, the display will show:

					T	E	S	T						
X	-	R	A	Y		N	O	T		A	C	T	I	V	E

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	**I**	**G**	**I**	**T**	**A**	**L**		**S**	**E**	**N**	**S**	**O**	**R**		
			I	**S**		**N**	**O**	**T**		**R**	**E**	**A**	**D**	**Y**	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0←.

NOTE:
The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. **As the X-ray button is of the "deadman's brake" type, it is necessary to keep it pressed until the end of the exposure.**

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, the display shows the message:

P	**A**	**T**	**I**	**E**	**N**	**T**		**E**	**X**	**I**	**T**				
						P	**R**	**E**	**S**	**S**		**>**	**0**	**<**	

and it will be necessary to free the patient from the positioning device.

NOTE:
If the examination is made in "Test" mode with the patient already in position, he must not be removed from the temple clamp, to avoid having to reposition the patient. The "Patient entrance" key (7) →0← must be pressed until the machine returns to the starting position. This movement can be stopped by pressing the same key.
Now the system is ready to perform a new examination.

3. Press the key "Patient Entrance" (7) →0←, the unit will move back to the starting position showing the message:

P	**L**	**E**	**A**	**S**	**E**		**W**	**A**	**I**	**T**	**.**	**.**	**.**		

The Digital Acquisition System will, in the meantime, process the image and display it.

WARNING:
Clean the chin support, the resting handgrips and the temple clamp thoroughly and change the head strip after every examination.

NOTE:
If a new exposure is required, but the waiting time calculated by the adaptive duty cycle has not yet expired, the display will show a message indicating the time remaining before the new examination can be performed:

T	U	B	E		C	O	O	L	I	N	G				
P	L	E	A	S	E		W	A	I	T		x	x	x	s

The waiting time allows the anode in the radiogenic tube to cool down.

NOTE:
If, during the exposure, the patient moves, or the machine collides with the patient himself (or with any object), or you realise that the parameters set are not correct, you must release the X-ray button immediately, interrupting the emission of X-rays and the movement of the arm.
If this occurs, the following message will be displayed:

E		2	0	6											
			P	R	E	S	S		>	0	<				

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; **It is recommended that this movement be made with great care in order to prevent damage to the machine**.

Then press the "Patient Entrance" (7) key  and the display will show:

	M	A	C	H	I	N	E		S	E	T	T	I	N	G
			P	R	E	S	S		>	0	<				

and then:

				W	A	I	T		F	O	R				
	M	A	C	H	I	N	E		S	E	T	T	I	N	G

The original position is re-established and the patient must be positioned once again.

8.13 SINUS in 3D mode

The images of the Sinus exam acquired in the 3D volumetric mode allow a total view of the frontal sinus area. In fact, by using the functions of the image acquisition and management program, different points of interest can be selected and the anatomy viewed along three distinct axes perpendicular to each other.This allows a clear view of any problems with the paranasal sinus or the associated anatomical structures (septum, turbinates, etc.).

8.13.1 Preparation of the device

1. To select the 3D Sinus exam, press the "Examination Mode Selection - M" key (11)  until the following message appears:

	x	x	k	V		x	x	m	A		1	1	.	2	s
3	D		D	e	n	t	i	t	i	o	n				

2. Select the 3D Sinus using the "Right Arrow" (13) and "Left Arrow" (12)  :

	7	2	k	V		0	6	m	A		1	1	.	2	s
3	D		S	i	n	u	s								

3. Insert the appropriate SINUS chin support (paragraph 8.4).

8.13.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the key "Size Selection" (9)  or the key "Examination Mode Selection - M" (11) 

After setting the machine, it is possible to choose between the following two operating modes:

- **ANATOMIC:** with the kV, mA and t values programmed on the basis of the type of patient and the size.
- **MANUAL:** with the possibility of altering the pre-set kV, mA and times.

NOTE:
In the manual mode, the LED of the "Adult/Child Selection" (8) key flashes to indicate that it is possible to change the selection; use key (8)  to change from Adult to Child.

8.13.2.1 Anatomic exposure

Select the type of patient with the **Adult/Child** key (8).

Select the type of build with the **Size** (9) key (*small - medium - large).*

On the basis of these selections, the display will visualise the kV and mA settings as in the table.

3D Sinus mode exposure values table (11.2 s)				
	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	66	6	62	6
Medium	70	6	64	6
Large	72	6	66	6

Table 10

The exposure time indicated (11.2 seconds) is relative to the sum of 400 X-ray pulses of 28 ms each that make up the exam.

8.13.2.2 Manual exposure

If the kV and mA combinations of the table Table 10 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

To modify the kV or mA values, press key (3)  , the LEDs of

the "Adult/Child Selection" key (8) will flash; the LED of the "Size Selection" (9) will go off; The display will show respectively one of the following two indications:

>	x	x	k	V		x	x	m	A		1	1	.	2	s
3	D		S	i	n	u	s								

or

	x	x	k	V	>	x	x	m	A		1	1	.	2	s
3	D		S	i	n	u	s								

The symbol ">" indicates which parameter is being changed; to modify

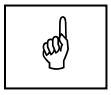
the type of parameter to work on, press key (3)  repeatedly.

The selected parameter can be modified by pressing the increase key (4)

and the decrease key (5)  .

The kV value can vary between *60 and 86 kV, with 2 kV steps.*

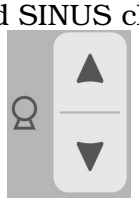
The value of mA can vary between *6 and 10 mA, with 1 mA steps.*



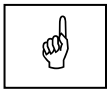
NOTE:
To change the values rapidly, keep the increase key (4) or the decrease key (5) pressed.

8.13.3 Preparation of the patient

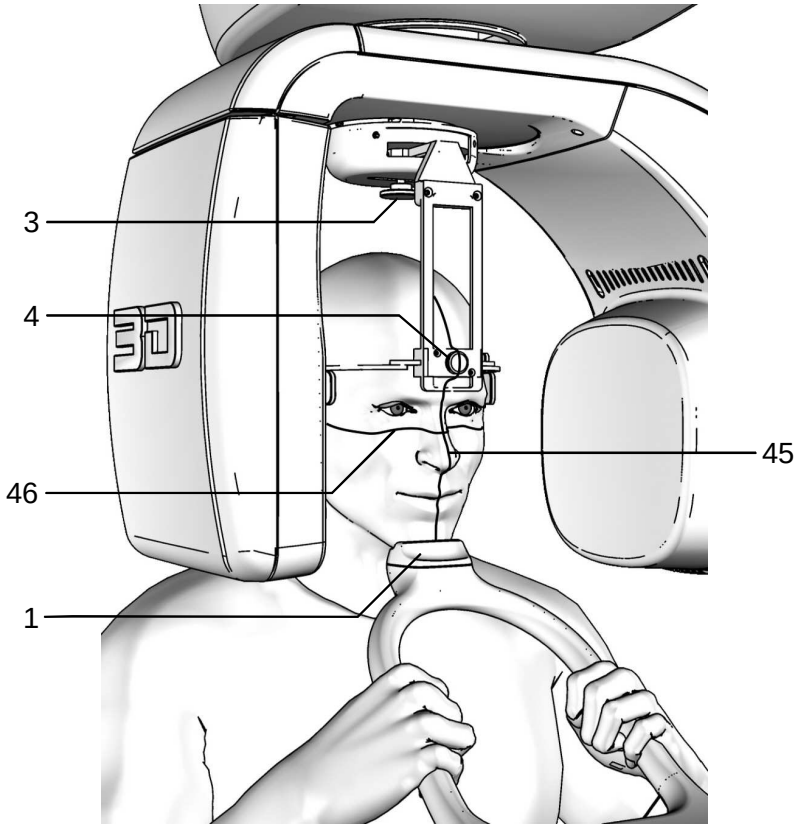
1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.
3. Position the patient upright to the standard SINUS chin support.

   With the keys "Column movement" (15/16)  lift/lower the column until the chin support is aligned with the patient's chin.
4. Verify that the temple clamp device is in the central position (Figure 10), and if necessary move it using the appropriate control on the top of the support (Figure 22).
5. Place the patient in the temple clamp (Figure 22) by placing the chin on the surface of the relevant support; the hands should rest on the front handgrips; the patient must rest the chin against the reference on the chin support.
6. Set the height of the temple clamp just above the patient's orbital bone.
7. Instruct the patient to close his eyes.
8. Press the key "Centring devices ON" (14)  .

   Two laser beams illuminate the line of the median sagittal plane and the horizontal line for the reference of the Frankfurt plane (Figure 13).
   Position the patient's head in such a way as to ensure that the luminous beams fall in correspondence with the respective anatomical references;
   The luminous beam of the Frankfurt plane can be adjusted according to the patient's height; this adjustment is achieved by adjusting the laser block on the side of the mirror.



NOTE:
The laser centring devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centring Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (7)  to begin preparation for exposure.



Legend of Reference Lines

45 Midsagittal line
46 Frankfurt plane line

Legend positioning devices and patient centring

1 SINUS chin support
3 Temple clamp device position control
4 Temple clamp open/close knob

Figure 22 – 3D Sinus positioning

9. Place the temple clamp in contact with the patient's head by means of the appropriate knob (Figure 22). In order to help the patient maintain the correct posture, use the head strip on the temple clamp passing it behind the nape of the patient's neck; check that, during this phase, the patient has not changed position.

10. At this point, the patient must move his feet towards the column, making sure to keep his head within the pre-aligned anatomical references. By doing so a greater distension of the spinal column is achieved, avoiding collisions with the tube-head with the patient's shoulders. Check that the Frankfurt plane is still horizontal.

11. Press the key "Patient Entrance" (7)  to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position.
Once alignment has been completed, the following message will be displayed:

	x	x	k	V		x	x	m	A		1	1	.	2	s
			S	T	A	R	T		E	X	A	M			

x = value defined by the settings

The green LED "Ready of X-rays" lights up to indicate that pressing the X-ray button once more will start the radiation phase.

12. Ask the patient to: keep the lips closed, bring the tongue towards the palate, keep perfectly still and do not look at the rotating arm during the movements.

8.13.4 Making an exposure

NOTE:
When the key "Test" (6) is pressed  the Test function is activated.

In this condition, it will be possible to make the unit perform all the movements made during the examination **without emitting X-rays**. Once the cycle is completed, deactivate the "Test" function by pressing key again.

WARNING:
During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the local regulations.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see the Figure 1 and Figure 2).

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.13.2.2; ensure that the machine's indicator light "Ready for X-rays" will come on, so press the ray button for the entire duration of the exposure, checking the contemporary working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

			S	T	A	R	T		E	X	A	M			
	P	R	E	-	H	E	A	T	I	N	G	.	.	.	

and then (after 2 seconds), the following message will be displayed:

	x	x	k	V		x	x	m	A		1	1	.	2	s
				>	X	-	R	A	Y	<					

x = value defined by the settings

NOTE:
Emissions are pulse in the volumetric mode; the acoustic signal isn't continuous either.
Keep the X-ray key pressed until the exam is complete.

NOTE:
If the machine is in the "Test" mode, the display will show:

					T	E	S	T						
X	-	R	A	Y		N	O	T		A	C	T	I	V	E

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0←.

NOTE:
The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. **As the X-ray button is of the "deadman's brake" type, it is necessary to keep it pressed until the end of the exposure.**

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, the display shows the message:

P	A	T	I	E	N	T		E	X	I	T				
						P	R	E	S	S		>	0	<	

and it will be necessary to free the patient from the positioning device.

NOTE:
If the examination is made in "Test" mode with the patient already in position, he must not be removed from the temple clamp, to avoid having to reposition the patient. The "Patient entrance" key (7) →0← must be pressed until the machine returns to the starting position. This movement can be stopped by pressing the same key.
Now the system is ready to perform a new examination.

3. Press the key "Patient Entrance" (7) →0←, the unit will move back to the starting position showing the message:

P	L	E	A	S	E		W	A	I	T	.	.	.		

The Digital Acquisition System will, in the meantime, process the image and display it.

WARNING:
Clean the chin support, the resting handgrips and the temple clamp thoroughly and change the head strip after every examination.

NOTE:
If a new exposure is required, but the waiting time calculated by the adaptive duty cycle has not yet expired, the display will show a message indicating the time remaining before the new examination can be performed:

T	U	B	E		C	O	O	L	I	N	G				
P	L	E	A	S	E		W	A	I	T		x	x	x	s

The waiting time allows the anode in the radiogenic tube to cool down.

NOTE:
If, during the exposure, the patient moves, or the machine collides with the patient himself (or with any object), or you realise that the parameters set are not correct, you must release the X-ray button immediately, interrupting the emission of X-rays and the movement of the arm.
If this occurs, the following message will be displayed:

E		2	0	6											
			P	R	E	S	S		>	0	<				

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; **It is recommended that this movement be made with great care in order to prevent damage to the machine**.

Then press the "Patient Entrance" (7) key  and the display will show:

	M	A	C	H	I	N	E		S	E	T	T	I	N	G
			P	R	E	S	S		>	0	<				

and then:

				W	A	I	T		F	O	R				
	M	A	C	H	I	N	E		S	E	T	T	I	N	G

The original position is re-established and the patient must be positioned once again.

8.14 Cephalometric examination

There is no rotation of the tube-head (X-ray generator) support arm and sensor holder for the cephalometric examination.
Various projections are possible for the cephalometric examination. according to the size of the image and the projection chosen, the primary collimator will be placed automatically in the correct position, together with the secondary sensor and the digital sensor.
The Cephalometric examination is fitted with a Soft Tissues Filter (STF); This filter reduces the dose in areas with low bone content and highlights the patient's profile which, under normal conditions, would be overexposed and so not visible.

Rotograph EVO 3D makes different kinds of exposures, according to the type of selection made:

18x22 Asymmetrical for Latero-Lateral (L.L.)	24x22 Symmetrical for Postero-Anterior (P.A.) and Antero-Posterior (A.P.)	24x22 Asymmetrical for Latero-Lateral (L.L.)	30x22 Symmetrical for Latero-Lateral (L.L.)	18x22 Symmetrical for assessment of bone growth(A.P.)

The examination can be performed in high-resolution mode (h) or normal resolution (n) for all these CEPH formats.
The bone growth assessment examination can also be performed, according to that described in paragraph 8.15.

WARNING:
The measurement of lengths on digital images depends on the specific length calibration of the program used.
It is therefore very important to check the length calibration of the program.
In Cephalometric examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is:

- 100 pixels = 8.7 mm in High Resolution
- 100 pixels = 13 mm in Normal Resolution.

8.14.1 Preparation of the device

To select the CEPH exam, press the "Examination Mode Selection – M" key (11)  until the following message appears:

	x	x	k	V		x	x	m	A		4	.	5	0	s
C	E		1	8	x	2	2	L	L	N			8	.	5

x = value defined by the settings

1. Press the "Patient Entrance" (7) key  ; the display will toggle the following two messages:

	C	E	P	H		-		R	E	M	O	V	E	
			C	H	I	N		R	E	S	T			

and

		C	E	P	H		-		C	L	O	S	E	
	T	E	M	P	L	E		S	U	P	P	O	R	T

The first message tells the operator to remove the chin support, while the second message tells him to close the temple clamp. These operations are necessary to prevent interference with the X-rays beam and with the Panoramic sensor holder when the arm is being positioned.

WARNING:
Neither of the two messages are controlled by the system and they can therefore appear even if the unit has been set correctly.

WARNING:
There is no need to position any type of chin support for the cephalometric examination. The chin support used for panoramic examinations must be removed as indicated on the display. If the chin support is not removed, it will collide with the sensor holder during alignment and can obscure some anatomical parts of the patient during the examination.
At the same time, the temple clamp must be closed, in order to avoid collision with the rotating arm.

2. Once what was required is performed, press the key "Patient Entrance" (7)  .

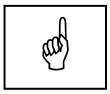
The two messages will disappear and the machine will align automatically with respect to the chest stand containing the digital sensor and the following message will be displayed:

A	X	I	S		P	O	S	I	T	I	O	N	I	N	G
P	L	E	A	S	E		W	A	I	T	.	.	.		

Once alignment is completed, the following message will be displayed:

		C	E	P	H		-		O	P	E	N			
	C	A	S	S	E	T	T	E		U	N	I	T		

requesting the operator to open the Panoramic sensor holder.



NOTE:
The position of the sensor holder for panoramic examination is controlled by two microswitches, it must therefore be completely opened.

The following message will be displayed:

	x	x	k	V		x	x	m	A		4	.	5	0	s
C	E		1	8	x	2	2	L	L	N			8	.	5

This message indicates the system's default image format; the letter "n" after the format indicates that it will be performed at Normal Resolution.
The transition from Normal Resolution (indicated by the letter "n") and High Resolution (indicated by the letter "h"), is performed by pressing the "Exam Mode Selection - M" key (11)  and vice versa.
The unit returns to the STD PANORAMIC mode by pressing key (11)  twice; the display will show

C	O	N	F	I	R	M		P	A	N	?				
	>	0	<		=		Y	,		T		=		N	

Press the "Patient Entrance" key (7)  to confirm or the "Test" key (6)  to cancel the setting.

NOTE:
For a given image format, the scan time is lower in Normal Resolution mode;this allows to administer a lower dose to the patient and still achieve an image of useful quality for orthognathic diagnosis albeit with a lower spatial resolution in relation to the High Resolution image.

NOTE:
The system is positioned in the following configuration:

- ADULT with the lighting up of the corresponding LED
- MEDIUM SIZE with the lighting up of the corresponding LED.

No LED of the key "Type of Biting Selection" (10) is lit and the key is disabled.

3. The image size and type of related projection (see table at the beginning of the paragraph) can be selected using the "Right Arrow" (13) and "Left Arrow" (12)  .

8.14.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was made in manual mode, to pass to the anatomical exposure simply press the "Exam Mode Selection - M" key (11) 

.

In this case, pressing the select key does not change the choice of the resolution, which is changed by a subsequent press on the same key.

After setting the machine accordingly, the following two operating modes may be selected:

- **ANATOMIC:** with the kV and mA values programmed based on the type of patient and the size; the Soft tissues Filter il is in the default position
- **MANUAL:** with the possibility of changing the pre-set kV, mA and Soft Tissues filter values.

NOTE:
In the manual mode, the LED of the "Adult/Child Selection" (8) key flashes to indicate that it is possible to change the selection; use key (8)  to change from Adult to Child.

8.14.2.1 Anatomic exposure

Select the type of patient with the **Adult/Child** key (8).

Select the type of build with the **Size** (9) key (*small - medium - large).*

The kV and mA values will be displayed according to the selections made as per the following table:

	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	66	6	62	6
Medium	70	6	64	6
Large	72	6	66	6

Table 11: Latero-Lateral projection

	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	74	12	70	10
Medium	76	12	72	10
Large	80	10	74	10

Table 12: Antero-Posterior projection

8.14.2.2 Manual exposure

If the kV and mA combinations in the table Table 11 or Table 12 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

NOTE:
The kV, mA and Soft Tissues Filter values can be changed manually. The parameter "fxx.x" indicates the position of the STF and must be set according to the value on the graduated scale on the nose rest (Figure 23). The value is stored when the modified number is displayed on the second line (about 3 seconds).

To modify the kV, mA and STF values, press key (3)  , the LED of the "Adult/Child Selection" key (8) will flash; the LED of the "Size Selection" (9) will go off; The display will show respectively one of the following three indications:

>	x	x	k	V		x	x	m	A		x	x	.	x	s
C	E		1	8	x	2	2	L	L	N			8	.	5

	x	x	k	V	>	x	x	m	A		x	x	.	x	s
C	E		1	8	x	2	2	L	L	N			8	.	5

	x	x	k	V		x	x	m	A	>	f	x	x	.	x
C	E		1	8	x	2	2	L	L	N			8	.	5

The symbol ">" indicates which parameter is being changed; to modify the type of parameter to work on, press key (3)  repeatedly.

The selected parameter can be modified by pressing the increase key (4) and the decrease key (5)  .

The "kV" value can vary between *60 and 80 kV, with 2 kV steps.*

The value of mA can vary between *6 and 12 mA, with 1 mA steps.*

The value of the STF can vary between *6 and 10.5 cm, with steps of 0.1 cm.*

NOTE:
To change the values rapidly, keep the increase key (4) or decrease key (5) pressed.

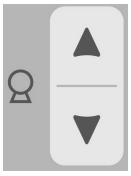
8.14.3 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).

2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.

3. Open the ear centring device (Figure 23) at maximum by means of the upper part of the centring device's rods. Move the nose rest (Figure 23) fully outwards. Manually rotate the craniostat group according the cephalometric projection to be made, moving the upper part of the ear centring device (Figure 23).

4. Position the patient upright near the auricular centring device.

Using the "Column movement" keys (15/16)  , lift/lower the column until the centring pins (Figure 23) are in the vicinity of the auricular canal and then secure the patient's head so that the pins penetrate the ear hole (Figure 23) acting on the top of the rods.
If a Latero-Lateral examination is performed, position the nose rest.

5. By selecting an "asymmetric" projection, the Soft Tissues Filter (STF) will be automatically inserted.

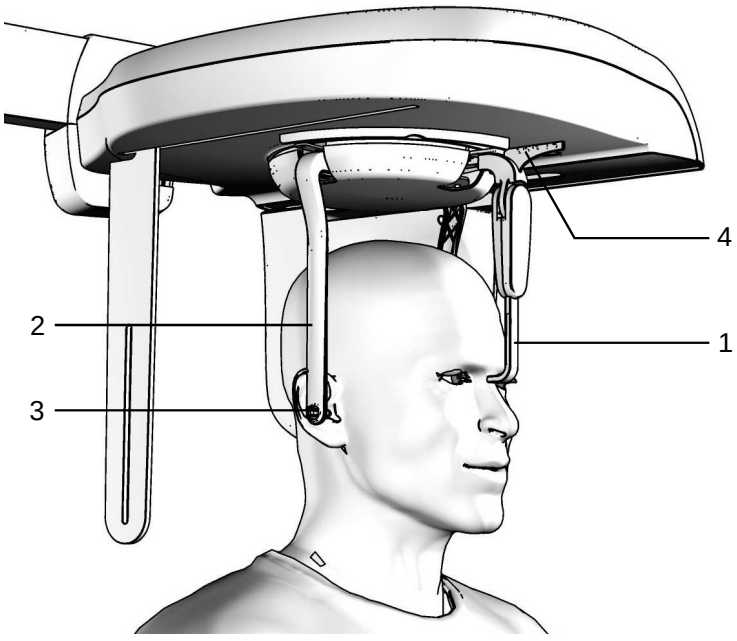


Figure 23

Legend

1 Nose rest
2 Ear centring device
3 Pins for ear centring device
4 Graduated scale

8.14.4 Making an exposure

WARNING:
During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the regulations in force in the country where the machine is used.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see Figure 1 and Figure 2).

1. Verify once again that the exposure data are correct (see paragraph 8.14.2). Advise the patient to remain still and to keep his mouth closed, with the teeth touching, throughout the duration of the exposure.

Press the "Patient Entrance" key (7)  .

The unit moves to the correct start position.
The "Ready for X-rays" LED lights indicating that the device is ready to emit X-rays.

NOTE:
The operation can be cancelled by pressing the "Patient entrance" key (7)  .

2. Press the X-ray button for the entire duration of the exposure, checking the concurrent working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal.
The following message will be displayed first:

			S	T	A	R	T		E	X	A	M		
	P	R	E	-	H	E	A	T	I	N	G	.	.	.

and then (after 2 seconds), the following message will be displayed:

	x	x	k	V		x	x	m	A		4	.	5	0	s
				>	X	-	R	A	Y	<					

x = value defined by the settings

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0← .

NOTE:
X-rays are emitted with a delay of two seconds from pressing the X-ray button to allow the heating of the filament and the control of all set parameters. **Since the X-ray button is a "dead man" control, it must be kept pressed until the end of the exposure.**

3. With the exposure completed, the secondary collimator moves to the park position, to allow the exit of the patient.
All the values of the exposure just made reappear on the display.

WARNING:
The ear centring devices and temple clamp must be cleaned thoroughly after each exam.

NOTE:
If a new exposure is required, but the waiting time calculated by the adaptive duty cycle has not yet expired, the display will show a message indicating the time remaining before the new examination can be performed:

T	U	B	E		C	O	O	L	I	N	G				
P	L	E	A	S	E		W	A	I	T		x	x	x	s

The waiting time allows the anode in the radiogenic tube to cool down.

NOTE:
If the patient moves during the exposure, or if you realise that incorrect parameters have been set, it will be necessary to stop pressing ray button immediately, to interrupt the emission of rays.
The following message will be displayed:

E		**2**	**0**	**6**										
			P	**R**	**E**	**S**	**S**		**>**	**0**	**<**			

Then press the "Patient Entrance" key (7)  .

The system will then return to the start condition and the patient will need to be repositioned again.

8.15 Examination to assess bone growth (Carpus)

The cephalometric device can also be used to carry out X-rays to evaluate the state of calcification and bone growth, X-raying the hand/pulse complex to obtain an X-ray that contains the anatomic details necessary to evaluate the patient's bone growth trend.
The set image format to perform this examination is 18x22 Symmetric and cannot be changed; therefore it is necessary to position the ear rods and nose rest in the same way as for the Antero-Posterior cephalometric examination, so that these elements do not interfere with the path of the X-rays. Refer to Figure 24.

WARNING:
The measurement of lengths on digital images depends on the specific length calibration of the program used.
It is therefore very important to check the length calibration of the program.
In CARPUS examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 8.7 mm.

8.15.1 Preparation of the device

1. Select the CEPH exam, press the "Examination Mode Selection – "M" key (11)  until the following message appears:

	x	x	k	V		x	x	m	A		4	.	5	0	s
C	E		1	8	x	2	2	L	L	n			8	.	5

x = value defined by the settings

2. Select the CARPUS exam using the "Right Arrow" (13) and "Left Arrow" (12)  :

	x	x	k	V		x	x	m	A		4	.	5	0	s
C	A	R	P	U	S		1	8	x	2	2		N		

3. Press the "Patient Entrance" (7) key  ; the display will toggle the following two messages:

	C	E	P	H		-		R	E	M	O	V	E		
			C	H	I	N		R	E	S	T				

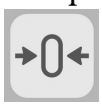
e

		C	E	P	H		-		C	L	O	S	E		
	T	E	M	P	L	E		S	U	P	P	O	R	T	

The first message tells the operator to remove the chin support, while the second message tells him to close the temple clamp. These operations are necessary to prevent interference with the rays beam and with the panoramic sensor holder when the arm is being positioned.

WARNING:
Neither of the two messages are controlled by the system and they can therefore appear even if the unit has been set correctly.

WARNING:
There is no need to position any type of chin support for the cephalometric examination. The chin support used for panoramic examinations must be removed as indicated on the display. If the chin support is not removed, it will collide with the sensor holder during alignment and can obscure some anatomical parts of the patient during the examination.
At the same time, the temple clamp must be closed, in order to avoid collision with the rotating arm.

4. Once what was required is performed, press the key "Patient Entrance" (7)  .

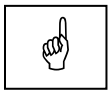
The two messages will disappear and the machine will align automatically with respect to the chest stand containing the digital sensor and the following message will be displayed:

A	X	I	S		P	O	S	I	T	I	O	N	I	N	G
P	L	E	A	S	E		W	A	I	T	.	.	.		

Once alignment is completed, the following message will be displayed:

		C	E	P	H		-		O	P	E	N			
	C	A	S	S	E	T	T	E		U	N	I	T		

requesting the operator to open the Panoramic sensor holder.



NOTE:
The position of the sensor holder for panoramic examination is controlled by two sensors, it must therefore be completely opened.

The following message will be displayed:

	x	x	k	V		x	x	m	A		4	.	5	0	s
C	A	R	P	U	S		1	8	x	2	2		h		

This message indicates the system's default image format; the letter "h" after the format indicates that it will be performed at High Resolution.

The unit returns to the STD PANORAMIC mode by pressing key (11)  twice; the display will show:

C	O	N	F	I	R	M		P	A	N	?				
	>	0	<		=		Y	,		T		=		N	

Press the "Patient Entrance" key (7)  to confirm or the "Test" key (6)  to cancel the setting.

5. Regulate the exposure parameters as required, using the pre-set values or manual selection; the display will show the kV and mA settings as per the following table.

	Child	
	kV	**mA**
Small	60	6
Medium	60	6
Large	60	6

Table 13

8.15.2 Preparation of the patient

1. Turn the ear centring device to the Antero-posterior position; move the nose rest device to the park position.
2. Connect the positioning support for the Carpus exam. The reference line must be facing the sensor.
3. Place the patient slightly to the side of the cephalometry device.
4. Place the patient's hand so that it is between the sensor and positioning support (Figure 24).
   The support helps the operator in positioning the anatomic part at the centre of the irradiated zone.The horizontal reference line helps in correctly positioning the hand in a vertical direction.
   The common radiological procedure in the study of children's bone growth, suggests to place the tip of the middle finger tangentially to the reference line.
   The hand of the patient should be in full contact with the support and must form a vertical line with the forearm in order to avoid any risk of collision with the sensor during the scanning movement.

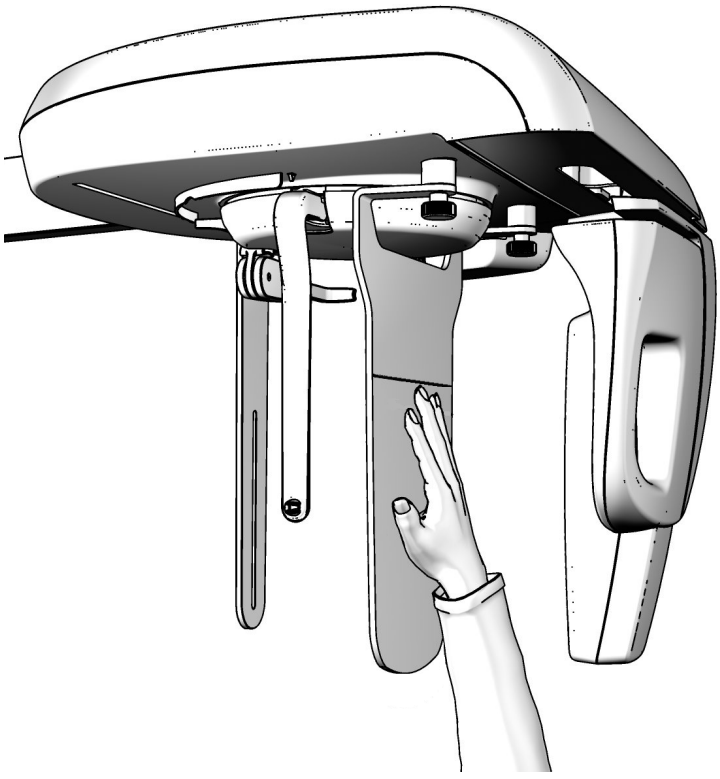


Figure 24

8.15.3 Making an exposure

WARNING:
During the emission of X-rays, the protection procedures for the operator and personnel in the area must be in compliance with the regulations in force in the country where the machine is used.
In all cases, it is recommended that during the emission of X-rays, only the patient and operator be present in the room. If the operator is not protected by suitable screens, he must stand at least 2 meters away from the emission of the rays (see Figure 1 and Figure 2).

1. Press the "Patient Entrance" key (7) →0← .

The unit moves to the correct start position.
The "Ready for X-rays" LED lights indicating that the device is ready to emit X-rays.

NOTE:
The operation can be cancelled by pressing the "Patient entrance" key (7) →0← .

2. Press the X-ray button for the entire duration of the exposure, checking the concurrent working of the ray indicator light "X-rays in progress" (if you are within sight of the machine) and the acoustic ray signal.
The following message will be displayed first:

			S	T	A	R	T		E	X	A	M			
	P	R	E	-	H	E	A	T	I	N	G	.	.	.	

and then (after 2 seconds), the following message will be displayed:

	x	x	k	V		x	x	m	A		4	.	5	0	s
				>	X	-	R	A	Y	<					

x = value defined by the settings

NOTE:
The Rotograph EVO 3D control system verifies that the digital sensor is ready: if it is not ready, the following error message is displayed:

D	I	G	I	T	A	L		S	E	N	S	O	R		
			I	S		N	O	T		R	E	A	D	Y	

Refer to the Manual of the Digital Acquisition System to correct the error.

To reset the message on the Rotograph EVO 3D, press key →0← .

NOTE:
X-rays are emitted with a delay of two seconds from pressing the X-ray button to allow the heating of the filament and the control of all set parameters. **Since the X-ray button is a "dead man" control, it must be kept pressed until the end of the exposure.**

3. With the exposure completed, the secondary collimator moves to the park position, to allow the exit of the patient.
All the values of the exposure just made reappear on the display.

NOTE:
If a new exposure is required, but the waiting time calculated by the adaptive duty cycle has not yet expired, the display will show a message indicating the time remaining before the new examination can be performed:

T	**U**	**B**	**E**		**C**	**O**	**O**	**L**	**I**	**N**	**G**				
P	**L**	**E**	**A**	**S**	**E**		**W**	**A**	**I**	**T**		**x**	**x**	**x**	**s**

This time enables the X-ray tube's anode to cool down.

NOTE:
If the patient moves during the exposure, or if you realise that incorrect parameters have been set, it will be necessary to stop pressing ray button immediately, to interrupt the emission of rays.
The following message will be displayed:

E		**2**	**0**	**6**											
			P	**R**	**E**	**S**	**S**		**>**	**0**	**<**				

Then press the "Patient Entrance" key (7)  .

The system will then return to the start condition and the patient will need to be repositioned again.

8.16 Messages on display

Rotograph EVO 3D is fully controlled by a microprocessor which controls the programming of the emission parameters and signals the various conditions of the machine, the possible abnormalities and errors via displayed messages.
The messages can be divided into two groups:

- **operation messages:** these messages tell the operator how to set up the unit for the examination
- **error messages**: these messages are displayed when an error occurs; there are two kinds of error messages as follows:

1 - Messages prompted when the X-ray emission button is released by the operator or by pressing the "Patient entrance" key (7)  .

The message displayed will be as follows

E		**x**	**x**	**x**										
P	**R**	**E**	**S**	**S**		**>**	**0**	**<**						

xxx = error message code number

Operations are reset by pressing key (7)  .

2 - Messages generated by a system error. In this case, the Technical Service must be called.
Messages that require the intervention of the Technical Service are displayed as follows:

E		**x**	**x**	**x**										
C	**A**	**L**	**L**		**T**	**E**	**C**	**H**		**A**	**S**	**S**	**.**	

xxx = error message code number

3 - Messages related to H.F. board problems. If this occurs, switch off the unit. Wait a few minutes for the capacitors of the relative circuit to discharge, and then switch the machine on again. If the problem persists, call the Technical Service.

E		**X**	**X**	**X**										
S	**W**	**I**	**T**	**C**	**H**		**P**	**O**	**W**	**E**	**R**		**O**	**F**	**F**

xxx = error message code number

Following are reported the different error messages and the relative controls and operations to be performed.

8.16.1 Error message with error code E000 ÷ E199

Errors that cannot be reset.
These are errors inside the control system; it is necessary to call the Technical Assistance Service.

8.16.1.1 E110 – System clock battery fault

This message indicates that the battery is flat or defective.
If a tube cooling time of 90 seconds is necessary when the unit is turned on, wait until the end of the period:the display shows **"E110 – Press >0<"**.
Perform an exam, then turn the unit off and wait a few minutes before turning it back on again.

If the error is not repeated, this means that the battery is flat: leave the equipment on to recharge it.

If the error persists, call the Technical Assistance Service.

8.16.2 Error message with error code E200 ÷ E299

This category of errors apply to the rotation motor; of these only the error "**E206 - Collision with patient**", caused by a possible collision between the rotation arm and the patient, is an actual reversible error.Press the

"Patient Entrance" key (7)  to reset the error and to perform the

axes centring operation.

For all other cases, call the Technical Assistance Service.

8.16.3 Error message with error code E300 ÷ E399

8.16.3.1 Error message with error code E300 ÷ E303

Errors that cannot be reset.
These are errors related to the zero sensor of the Digital CEPH secondary collimator.
Turn the system off and then on again; if the error persists, call the Technical Assistance Service.

8.16.3.2 Error message with error code E320 ÷ E323

Errors that cannot be reset.
These are errors related to the zero sensor of the Digital CEPH primary collimator.
Turn the system off and then on again; if the error persists, call the Technical Assistance Service.

8.16.3.3 E340 - Sensor holder not in PAN position

A Panoramic type examination was requested, but the sensor holder does not appear to be closed; move it to the PAN position and press the

"Patient entrance" key (7)  to reset the error condition.

8.16.3.4 E360 / E361 - X-ray button pressed during power-up or during the movement of the axes

Release the X-ray button if pressed; press the "Patient Entrance"

key (7)  to reset the error condition

If the error does not disappear, call the Technical Assistance Service.

8.16.3.5 E362 - X-ray button released during examination

NOTE:
The X-ray button has the so-called "dead-man" function, i.e. it must be kept pressed for the whole time of the examination, also during the phases of the examination with emission interruption (for instance, in open/close mouth TMJ) or during the volumetric examination.

This message signals that the button was released during the examination phase; the motors are unlocked, therefore the patient can get out of the system. Repeat the system centring phase and repeat the examination.

8.16.4 Error message with error code E400 ÷ E402

Errors that cannot be reset.
Errors related to the Digital CEPH Soft Tissues Filter.
Turn the system off and then on again; if the error persists, call the Technical Assistance Service.

8.16.5 Error message with error code E700 ÷ E799

WARNING:
These error codes refer to the X-rays generation, therefore, they can also indicate a safety problem.
With error code E759, turn off immediately the system as a not requested X-ray emission was detected. In this case, call immediately the Technical Assistance Service.

8.16.5.1 E755 - Timer back up triggered

This error signals that the emission has not completed correctly, but it was interrupted but the safety timer backup that cuts in to stop the emission also in case of failure of the control system.
Turn off immediately the system as an unwanted emission could be present.

8.16.5.2 E774 - X-rays button not pressed

The lack of the button is signalled also if the emission software control is present.
The error signals a possible failure on the connection of the X-rays button with the generator card.

8.16.5.3 E775 - X-rays button released prematurely

The release of the X-rays button during the emission phase is signalled; this signalling has a different meaning from that of the corresponding E362 error, as this message is generated by the HF card, which signals a possible failure on the connection of the X-rays button with the card itself.

8.16.6 Error message with error code E850 ÷ E852

These errors signals abnormal situations due to the operator's interface.

8.16.6.1 E850 - One or more keys appear to be pressed on start-up

The system checks that all keys are not pressed at start-up; if one or more appear to be pressed, this error is displayed.
If error E850 is detected, the display will show which key has been pressed in start-up phase, and the following message will be shown:

E		**8**	**5**	**0**		**(**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**)**
S	**W**	**I**	**T**	**C**	**H**		**P**	**O**	**W**	**E**	**R**		**O**	**F**	**F**

xxxxxxxx: error message code number

Release the key and restart the system. If the error persists, call the Technical Assistance Service

8.16.6.2 E851 – Column movement keys pressed

This error is displayed in case, when releasing the up/down column movement keys, the movement itself is not completed; pressing any other key interrupts the movement to avoid injuries to the patient.

Press the "Patient Entrance" key (7)  to reset the error condition.

8.16.6.3 E852 - Key "Patient Entrance" pressed during the movement

The keyboard is disabled during the movement of the system, but by pressing the "Patient entrance" key (7)  , the movement is stopped.

This operation is useful in case a movement anomaly is noticed.

Press the "Patient Entrance" key (7)  to reset the error condition.

8.17 Research and correction of possible defects in standard dental X-rays

8.17.1 Faults due to the wrong positioning of the patient

Problem	Description	Solution
Overlarge and blurred incisors.	The patient is not positioned correctly. He is too far from the optimal focal plane.	Reposition the patient ensuring that he/she bites with the incisors on the appropriate mark.
Over-small and blurred incisors.	The patient is not positioned correctly. He is too near the optimal focal plane.	Reposition the patient ensuring that he/she bites with the incisors on the appropriate mark.
Image with blank central area.	The spine of the patient inhibits the passage of the X-ray as it is too compressed.	Check the alignment of the Frankfurt plane, try to stretch the cervical part of the spine by moving the patient's feet forward (see paragraph 8.6.3 points 3/4/6/7) and, if necessary, correct the height of the chin support.
Asymmetric dental arch.	The sagittal medial line does not correspond to the laser centring beam.	Realign the patient (see paragraph 8.6.3 point 6).
Upper apical area too dark.	The patient does not keep his lips shut and the tongue is not against the palate.	See paragraph 8.6.3 point 8.
Upper central apical area out of focus.	The patient keeps his head rotated backwards (Frankfurt plane not aligned).	Position the patient again and realign the Frankfurt plane.
The image is slanted in comparison with the longitudinal axis and some anatomical structures are not symmetric.	The patient's head is slanted (not vertical).	Position the patient again, correcting the position of the sagittal plane.
The teeth on one side are bigger than those on the other side.	The patient's head is rotated with respect to the axis of the bite.	Position the patient again, correcting the position of the sagittal plane and controlling that his head does not rotate.
Presence (in CEPH examination) of a white area in the lower part of the image.	Panoramic chin-rest still mounted.	Perform the exam again, removing the PAN chin-rest.

8.17.2 Defects due to wrong data setting

Problem	Description	Solution
Under or overexposed image.	The set kV value is not fit for the size of the patient.	Try to change the contrast by using the appropriate commands of the image acquisition/management program, and if necessary repeat the examination varying the kV and/or mA.Increased them if the image is too light, and decrease if the image is too dark.If the error happens again contact the Technical Service.
Completely blank image.	It was not subjected to X-rays.	Check the passage of the X-rays via the acoustic and visual signal. If no solution can be found, call the Technical Service.
Soft Tissue not (or poorly) visible in L-L projection.	The STF value is not correct.	Refer to paragraph 8.14.3 to adjust the position of the "STF".
	A symmetrical format was selected	Select an asymmetrical format (which will enable the Soft Tissue Filter).

8.17.3 Defects due to the unit

1. Should the image show non irradiated areas or be completely white, this can mean that there is a defect in the alignment between X-ray beams and image or a partial or total missing of irradiation; in any case, call the Technical Service.

2. In the event the soft tissue of the patient is not highlighted while performing a cephalometry, in a latero-lateral, let the Technician verify the adjustment of the Soft Tissue Filter.

8.18 Analysis of the problems on the standard panoramic examinations

The panoramic radiography is the examination of the maxillo-facial region normally used to view the dental region inside the complete head and sinuses-orbital complex.
In a good Panoramic, you can distinguish the main anatomic structures that are simplified in the diagram below (which indicates only the main ones, and is not complete).

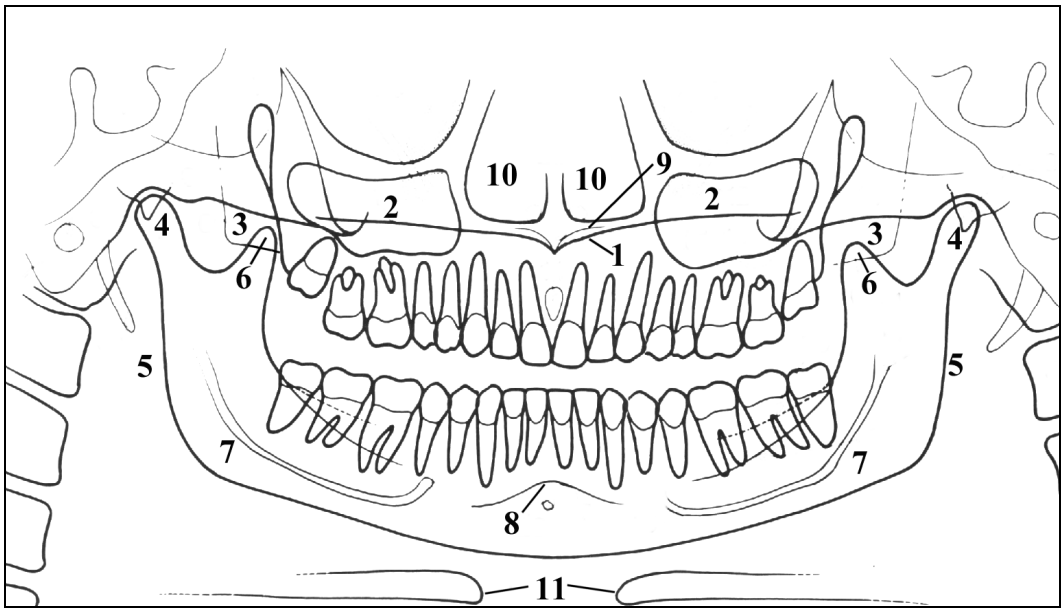


Figure 25

Ref.	***Anatomic structure***
1	*Palatal plane*
2	*Maxillary sinus*
3	*Maxilla and maxillary tuberosity*
4	*Temporo mandibular condyle*
5	*Ascending ramus of the TMJ*
6	*Coronoid process (overlap with maxilla)*
7	*Mandibular canal*
8	*Chin foramen*
9	*Anterior nasal spine*
10	*Nasal cavities*
11	*Ioid bone (normally duplicated)*

8.18.1 Proper positioning of the patient

The proper positioning of the patient during the panoramic examination is very important in order to get good quality radiography. This is due to the fact that the shape of the focussed area, e.g. of the layer clearly shown on the image, tends to follow the dental arch and has a non-constant deepness.
The objects outside this focused area will therefore appear blurred on the radiography.

1. The patient should not wear clothes that may interfere with the X-ray beams, also to leave more space between the patient's shoulders and the rotating arm of the machine. **Care must be taken in order to avoid interference between the X-ray beam and the protective apron worn by the patient**.
2. Metal objects (necklaces, earrings etc.) must be avoided; these objects not only create radio-opaque images in their own position, but also false images projected in other parts of the radiography, so disturbing the correct view of the anatomy.
3. The patient's head must be slightly tilted downward in order to make the Frankfurt plane horizontal. In this way, the hard palatal ceiling will be projected slightly over the superior apex of the anterior teeth. If the patient has a low palatal ceiling, slightly increase the downward tilting.
4. Align the sagittal medial plane with the centre of the chin support, normally indicated by the relevant light beam.

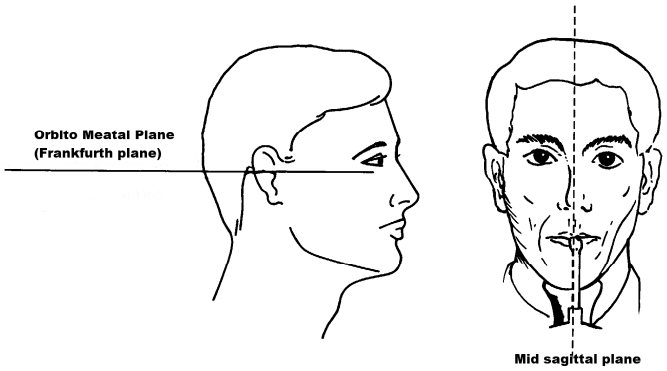


Figure 26

5. The patient must extend his spine; this is normally obtained by asking the patient to step forward, making sure that all other conditions are unchanged. If not properly extended, the spine will cause the appearing of a lower exposed area (clearer) in the front part of the image.

6. The patient's tongue must be positioned against his palate. Otherwise, the air between the tongue and the palate forms an area of lower absorption, which leads to a darker area that hides the apex of the teeth of the maxilla.

The result of all the above listed actions will be an image where all the parts are properly exposed are well identifiable as in the diagram of Figure 27.

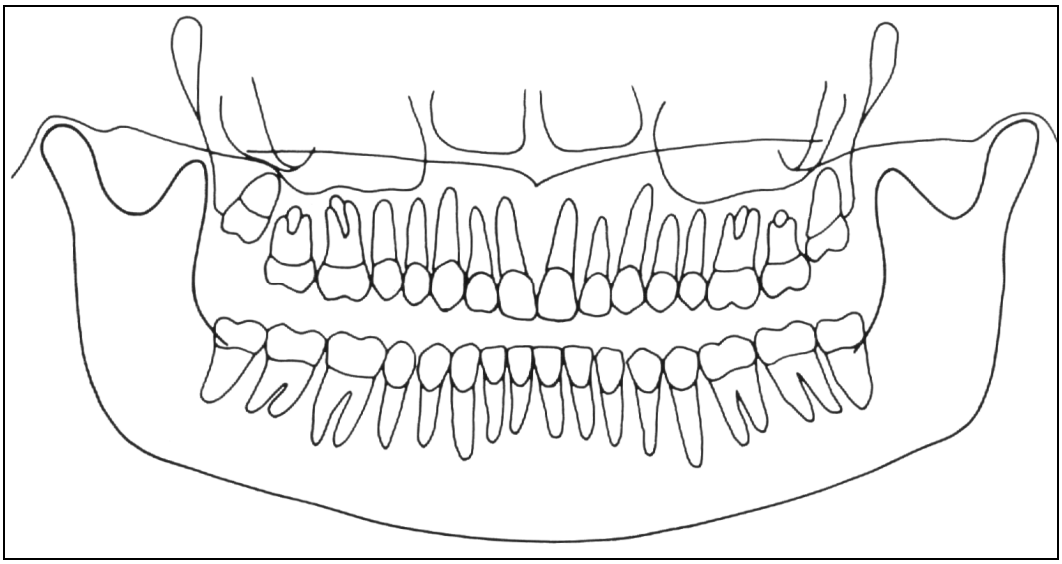


Figure 27

It must be noted that the image is quite symmetrical, with the ascending rami of the temporo mandibular joints almost parallel. The occlusal plane is shown slightly tilted upward, the palatal plane does not overlap the apex of the upper arch and therefore allows a good view of the apex itself.

8.18.1.1 Errors due to poor positioning of patient

- **The image shows the anterior teeth with reduced magnification and not well defined. The cervical spine is shown as evident white shadow.**

  In addition, on the molar zone there are too many shadows, disturbing the reading.

  The resulting image is similar to the schema shown on Figure 28.

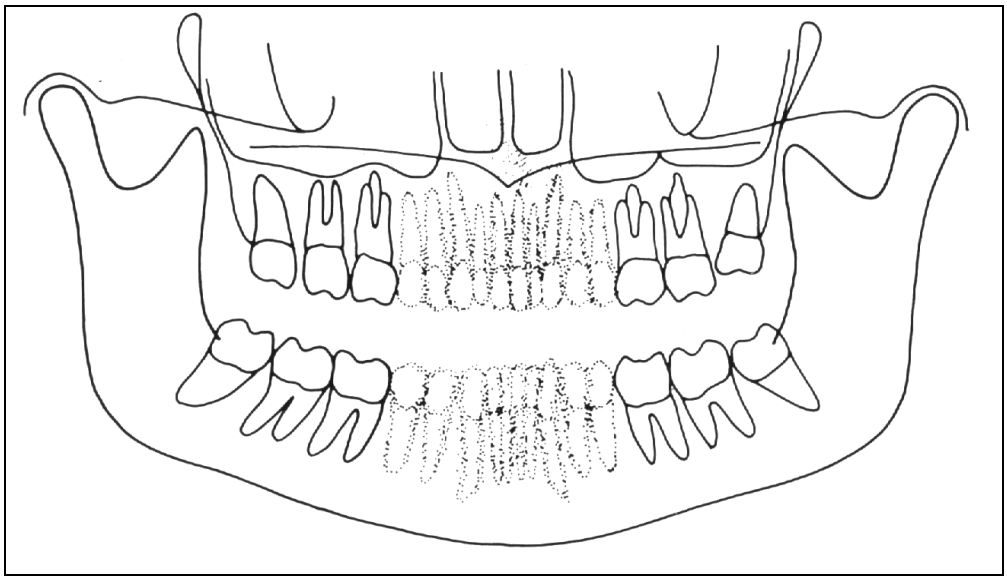


Figure 28

Possible causes:

The patient it positioned too forward.

Solution:

Check the patient's positioning by using luminous beams.

If, after the correct positioning of the patient, the problem still remains, check the alignment of the centring laser lights, simply switching on the centring lights and checking their position.
The sagittal medial luminous beam must hit the centre of the chin support.

- **Anterior teeth are enlarged and blurred**

  Figure 29 shows the result of this error.

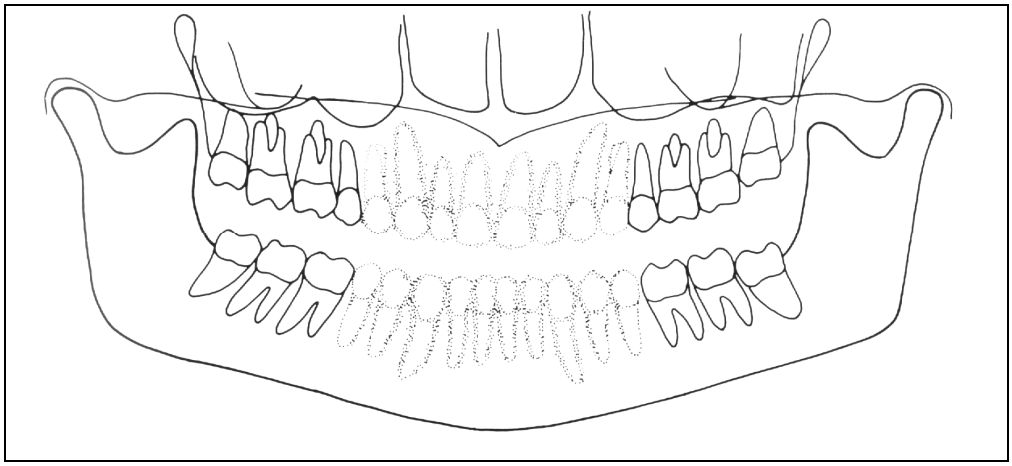


Figure 29

Possible causes:

The patient it positioned too back.

Solution:

Check the patient's positioning by using luminous beams.

- **Part of the image is enlarged while the other is reduced**

The diagram in Figure 30 represents the image obtained; it is possible to observe that one part of the radiography is blurred and enlarged, while the other is reduced and seems to be in focus; the two condylar rami are at the same height on the image.

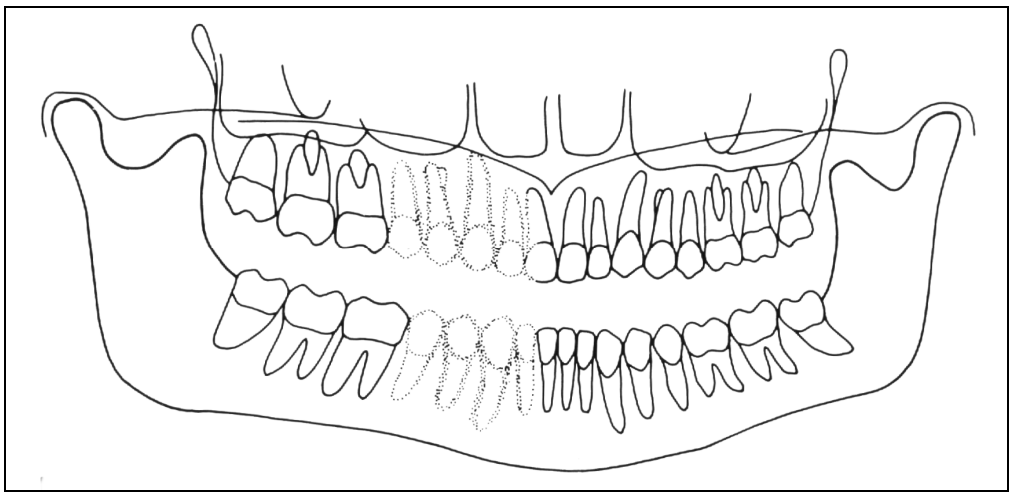
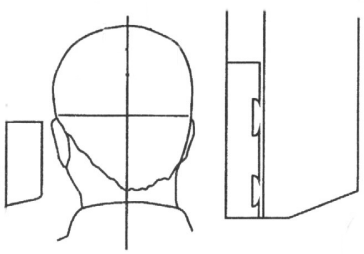


Figure 30

Possible cause:



This effect can be due to two different causes.
In the first one, the sagittal medial plane is not aligned with the relevant centring light beam, which falls at the centre of the chin support.
In the second case, the centre of the sagittal medial plane corresponds with the centre of the chin support, but the patient's head is rotated.

In both cases, one side is closer to the sensor plane than the other, thus resulting in a different magnification of the two sides; the part more distant from the sensor will be more magnified while the part closer to the sensor plane will result smaller. The result will be an image as shown in Figure 30; the left-hand area of the image shows a bigger magnification that can be noticed both on the teeth and on the ascending rami of the TMJ.

Solution:

Check the positioning of the sagittal medial plane by using the relevant centring light beam.
Check also the position of the sagittal medial beam; lighted, it must fall both on the centre of the chin support and also on the centre of the bite.

- **The image shows the upper vertex of the condylar rami of different heights;**

Figure 31 shows the result of this error.

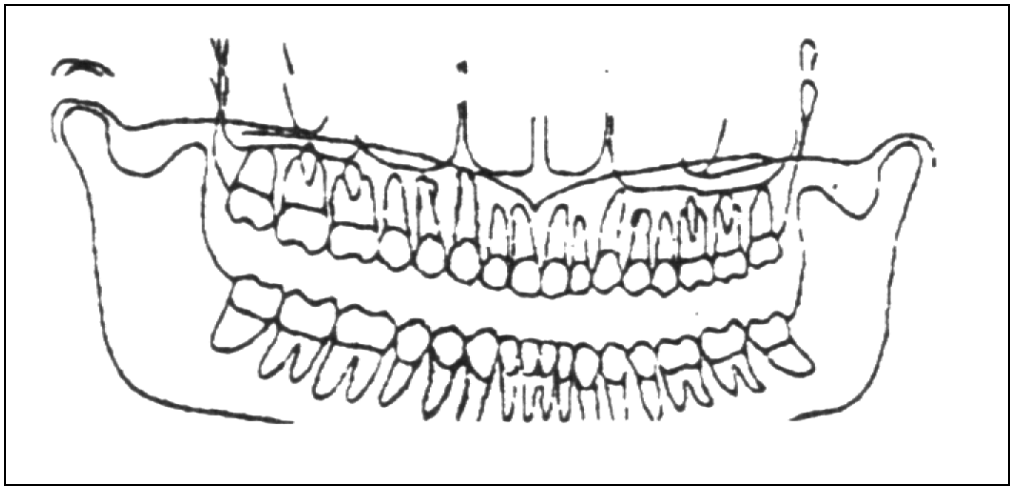


Figure 31

Possible causes:

The sagittal medial plane is not vertical. This can be the patient's problem, but if the defect is always present, check the laser beam.

Solution:

Verify that the laser beam is vertical; this check can be performed very quickly by using the laser beam and verifying that it falls on the centre of the chin support; remove the chin support itself and check that the beam falls in the centre of the two holes used to fix the support itself.

If not, a possible cause can be the imperfect horizontalness of the chin support arm, that must be adjusted using the relevant screws.

- **The image shows undulated teeth rows**

As can be seen in Figure 32, the upper teeth are magnified and unfocused, with the shadow of the hard palate positioned over the superior apex. The temporo-mandibular joints are exposed outward, with lines divergent upward. In some cases, the condylar vertices might not appear on the image.

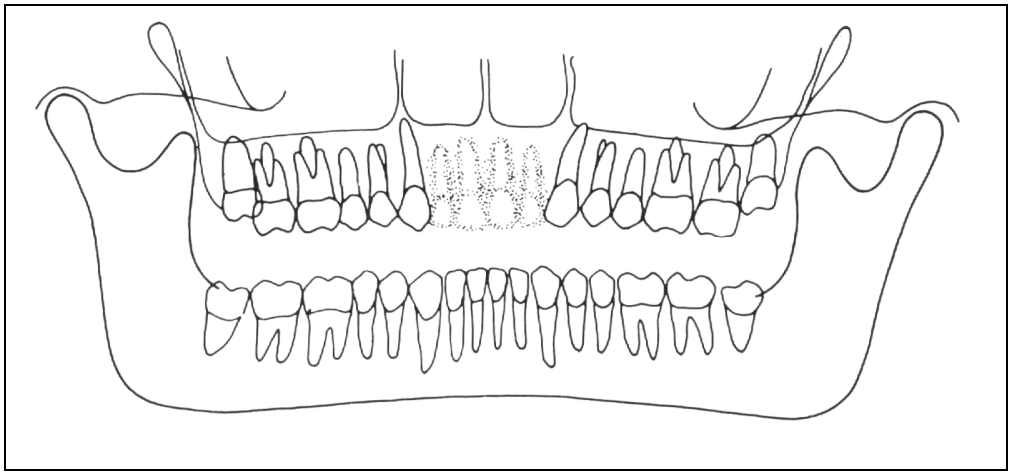


Figure 32

Possible causes:

A Frankfurt plane too tilted upward produces different anomalies that may also appear simultaneously. A chin support plane too high during the patient positioning, or when extending the spine, may generate this mistake. In this condition, the rear side of the patient's head may also interfere with the rotating arm of the panoramic equipment.

- **The radiographic image shows the teeth row too curved upward with the lower incisor not focused**

  Figure 33 shows the result of this type of error. The temporo-mandibular joints are shown very high up, with lines converging towards the top. In some cases the upper condyle might not be visible in the image.

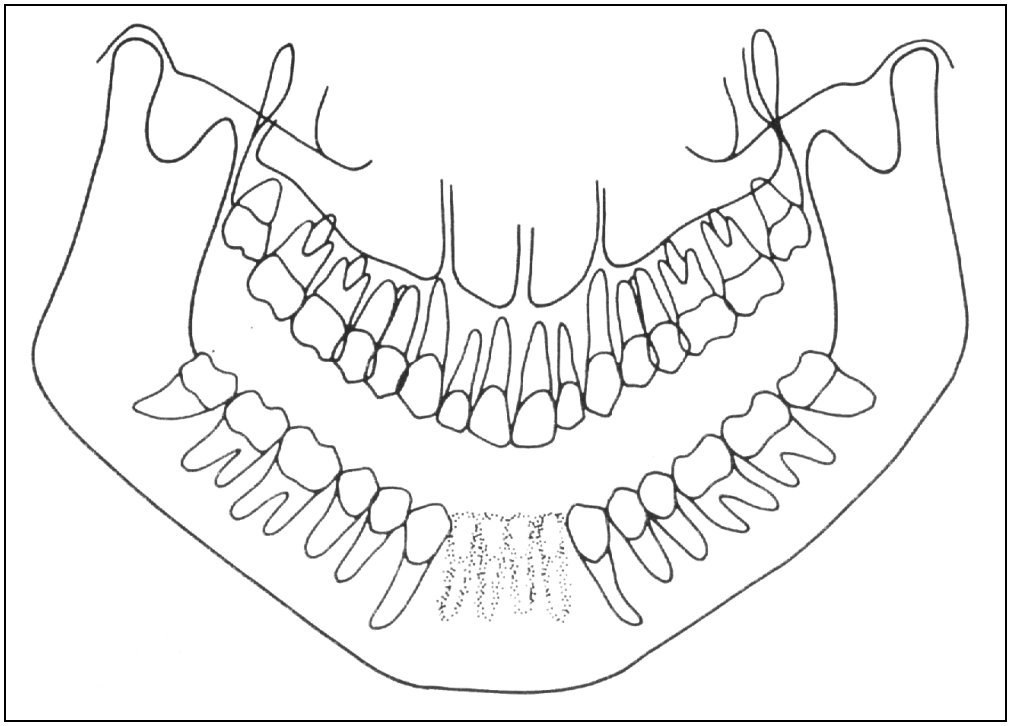


Figure 33

Possible causes:

Patient's head tilted downward, as on the diagram alongside.

Solution:

Check the positioning of the patient by aligning the Frankfurt plane with the corresponding light beam.

NOTE:
In some cases, the positioning of the Frankfurt plane too tilted downward produces a correct image of the lower incisors, but the projection of the palate falls on the lower teeth apex, as shown in Figure 34.

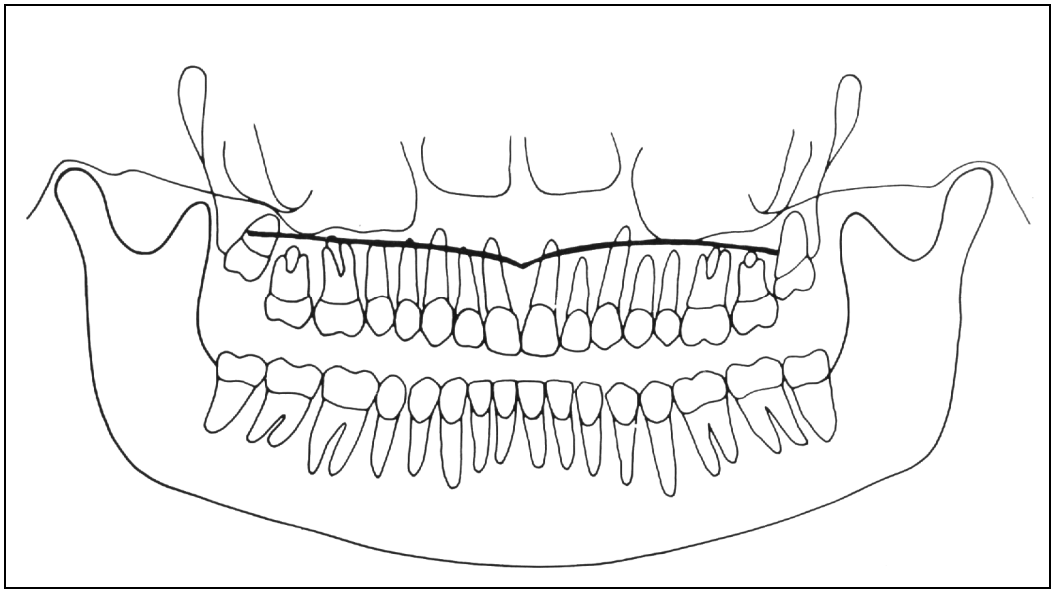


Figure 34

In this case, a light tilting forward and downward of the Frankfurt plane causes the palate to be projected over and too far from the root of the teeth of the maxilla arch, without distortion of the incisor teeth, as in Figure 35.

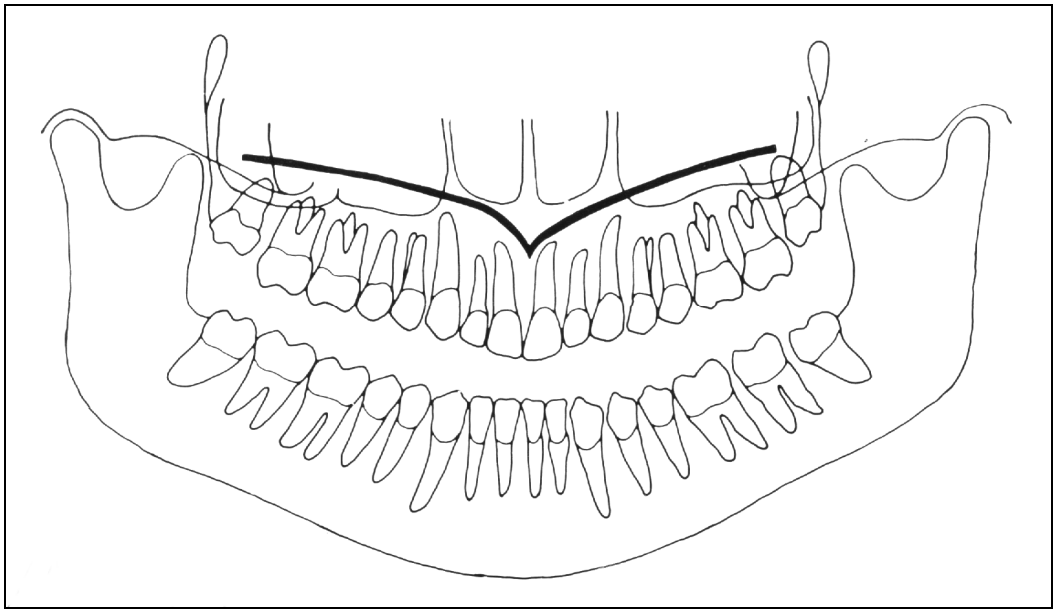


Figure 35

8.18.1.2 Images with artefacts

- **Radiographs that show images with soft tissues or artefacts**

The radiographs may show anatomical parts of the soft tissues or show radiographic artefacts.
Normally the soft tissues might be more or less present, depending on the patient positioning, while the presence of artefacts is strictly dependent on the presence of foreign objects on the trajectory of the X-ray beam.
The next figure shows these cases; please consider that all structures have a bilateral duplicate.

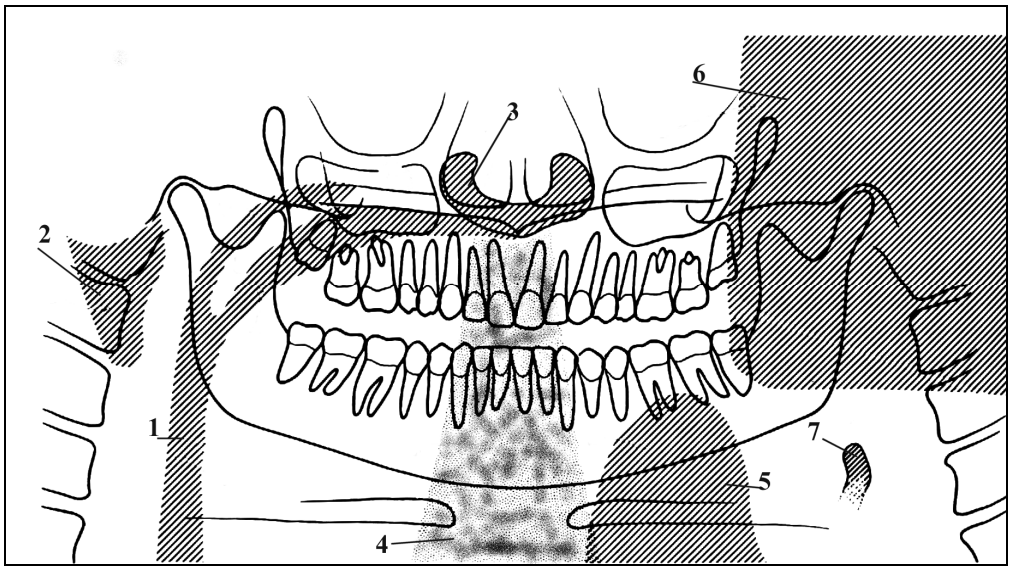


Figure 36

Soft tissue	Description	Artefacts	Description
2	Ear soft tissue	1	Space between tongue and palate. All the structures of the oropharynx cavity can be shown
3	Nose soft tissue	4	Spinal column
7	Epiglottis	5	Image of the patient's leaded protective apron (light area)

The part identified with "6" in Figure 36 represents the image of the contro-lateral mandible (the other side of the mandible). That therefore results as a clearer area overlapped with the real image. Very often the resulting darker area in the bottom corner is noticed and is considered as an artefact of the radiological image.

This is not true, because it is derived from the projection geometry used to obtain the panoramic image. The effect can be more evident if the image in underexposed due to wrong radiological parameters.

With reference to Figure 36 above, let's analyse some errors.

- **Wrong positioning of the spine**

In the event the image shows an over-bright and unfocused part in the central area (see point "4" - Figure 36), this is probably caused by the wrong position of the spine that has not been properly extended by the patient. In this case, the spine absorbs an excessive quantity of radiation that therefore causes the image to be over-bright. This excessive brightness can be seen above all in the lower part, but is less visible in the upper part of the image.

Solution:

Ask the patient to step forward, thus extending his spine, in order to reduce X-ray absorption.

- **Shadows or bright artefacts**

The most common cause for the presence of these artefacts is the presence of metal objects worn by the patient (earrings, necklaces, etc.).
The necklaces worn by the patient normally result in a radio-opaque arch positioned in the chin area. This arch normally overlaps the chin itself and the shadow of the spine, disturbing the diagnosis of possible problems in the chin area and in the area of the apices of the mandibular incisors.

The earrings, on the other hand, create real images in the proper position and shadow images projected in the contro-lateral area, thus hiding possible problems or generating bright areas within the paranasal sinuses.

In some cases, that may depend either on the trajectory of the panoramic machine or on the position of the metal objects, they can generate up to three images (one real and two shadows), thus further disturbing the correct diagnosis.
This situation may occur especially if the patient has large prothesis or metal fillings, and is associated with a positioning error, that projects the shadow of the metal part on wide areas of the image.

- **Non-exposed area in the lower-central part of the image**

  If the problem appears as shown in point "5" of Figure 36 above, it indicates that there has been interference between the leaded apron worn by the patient and the X-ray beam.

  Solution:

  Properly position the leaded apron (tight around the patient's shoulders and neck) then carry out a new examination.

- **The teeth rows are overexposed**

  As already described, if the tongue is not positioned against the palate during the exposure, it will create an air chamber between the tongue and the palate; this air gap creates a less absorbing area that overlaps the teeth, often in the apex area. This area is identified as reference "1" in Figure 36.

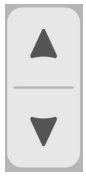
  Solution:

  Ask the patient to position his tongue against the palate during the exposure.

8.19 Storing of automatic exposure parameters

The pre-set exposure technical factors can be varied according to the user's needs or when more or less contrasted images are required.

To modify the automatic exposure parameters, please follow the indicated procedure:

1. Select the examination, the type of patient and the size to be modified.
2. Press key (3)  to select the parameter to modify; on the display, the reference character ">" will appear on the left of the value.
3. Press increase (4) or decrease (5) keys  to set the value to store.

After modification, storing the new parameters is performed by pressing the decrease (5)  key and the function key "F1"  at the same time, on which the display will show the message:

S	T	O	R	E	?										
	>	0	<		=		Y	,		T		=		N	

and the LEDs relating to the patient and size keys that are being modified will lightpress the "Patient Entrance" key (7)  to confirm or the "Test" key (6)  to cancel the setting.

8.19.1 Table of pre-set anatomic parameters

PANORAMIC

	Adult	Child
Small	68 kV 6 mA	64 kV 6 mA
Medium	72 kV 6 mA	66 kV 6 mA
Large	74 kV 6 mA	68 kV 6 mA

TMJ open/close mouth

	Adult	Child
Small	68 kV 6 mA	62 kV 6 mA
Medium	72 kV 6 mA	64 kV 6 mA
Large	76 kV 6 mA	66 kV 6 mA

SINUS

	Adult	Child
Small	66 kV 6 mA	62 kV 6 mA
Medium	70 kV 6 mA	64 kV 6 mA
Large	72 kV 6 mA	66 kV 6 mA

3D Dentition

	Adult	Child
Small	76 kV 9 mA	66 kV 8 mA
Medium	80 kV 9 mA	68 kV 8 mA
Large	82 kV 9 mA	70 kV 8 mA

3D TMJ Left / 3D TMJ Right

	Adult	Child
Small	68 kV 6 mA	62 kV 6 mA
Medium	72 kV 6 mA	64 kV 6 mA
Large	76 kV 6 mA	66 kV 6 mA

3D Sinus

	Adult	Child
Small	66 kV 6 mA	62 kV 6 mA
Medium	70 kV 6 mA	64 kV 6 mA
Large	72 kV 6 mA	66 kV 6 mA

CEPHALOMETRY (L.L)

	Adult	Child
Small	66 kV 6 mA	62 kV 6 mA
Medium	70 kV 6 mA	64 kV 6 mA
Large	72 kV 6 mA	66 kV 6 mA

CEPHALOMETRY (A/P - P/A)

	Adult	Child
Small	74 kV 12 mA	70 kV 10 mA
Medium	76 kV 12 mA	72 kV 10 mA
Large	80 kV 10 mA	74 kV 10 mA

9. 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:

- check that the plates are complete and well fixed
- check possible oil leaks from the tube-head
- check that the X-ray button cable does not show breaking or wearing signs
- check that the unit is not damaged externally as to compromise the safety of protection from radiation.

WARNING:
It is recommended that the operator performs the checks before each sessions.
In the event the operator detects faults or abnormalities, 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 .....

VILLA
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MEDICALI

Cod. 6907912103_Rev.3

CE 0051

6907912103

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