VILLA SISTEMI MEDICALI

Rotograph EVO D CE 0051

(110-120V version)

User's Manual

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1. INTRODUCTION

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

Rotograph EVO D, produced by VILLA SISTEMI MEDICALI S.p.A., is an X-ray device for the radiographic analysis of the maxillo-facial complex.

The basic version of the Rotograph EVO D performs Panoramic, Sinus and TMJ examinations of the maxillo-facial complex.

The following options are available, and must be ordered separately:

- EVO XP (Extended Projection Package); it allows the execution of the following examinations: Emi-panoramic, Reduced dose Panoramic, Frontal dentition, Improved orthogonality Panoramic and Bitewing.
- IMPLANT; it allows to perform images of cross-sections of the dental arch, for Implant medical treatment.
- DIGITAL CEPH; it allows the execution of the following examinations:
  - CEPH exam in different formats, all available in high resolution and normal resolution (high speed) modality
  - CARPUS exam, available in high resolution modality.

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 X-ray device; instructions on the Digital Acquisition System are given in the relevant Manuals, supplied with the Direct Digital Sensor.

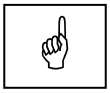
The device must be used complying with the procedures described and never be used for purposes different from those herewith indicated.

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

Rotograph EVO D 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.

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

1.1 Icons appearing in the manual



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

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

2. 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 D 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.

2.1 Warnings

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

Do not let water, or other liquids, into the device, as this could cause short-circuits and corrosion.

Before cleaning the device, be sure that the main power supply has been disconnected from the equipment. Pushing the ON/OFF button on the basement of the equipment, it mustn't switch on.

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

While performing the radiography, no-one, apart from the operator and the patient, must remain in the room.

Rotograph EVO D 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 D must be switched off while using devices such as electrical lancets or similar apparatus.

Please clean and disinfect, when necessary, all parts that can be in contact with the patient.
The centring bite or the bite protective sleeve 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.
Movement is only possible in case of Error 206 because motors are disabled to permit the patient exit.

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

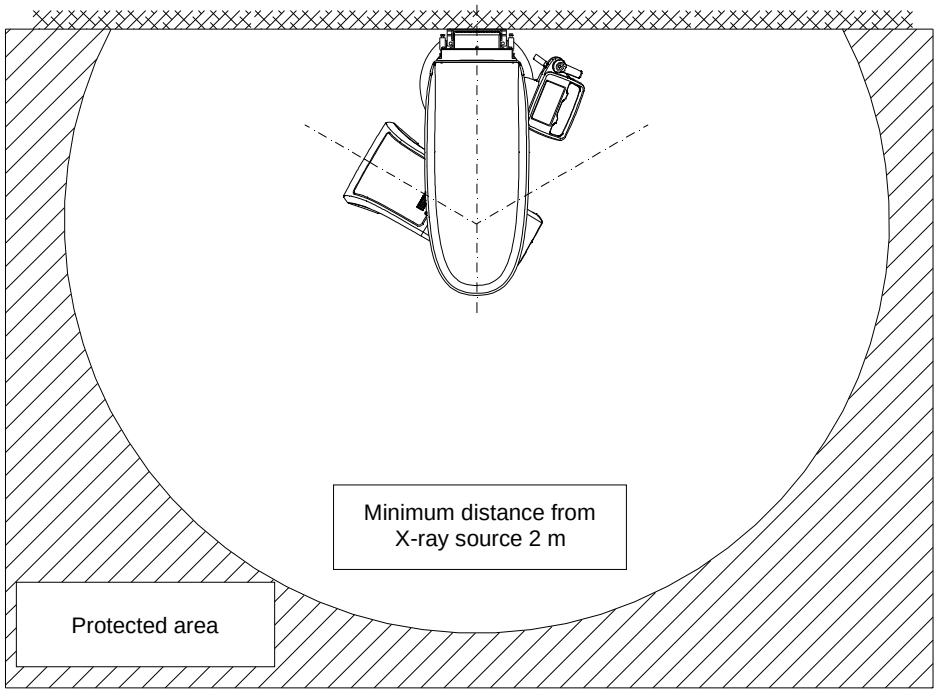


Figure 1 - Panoramic version

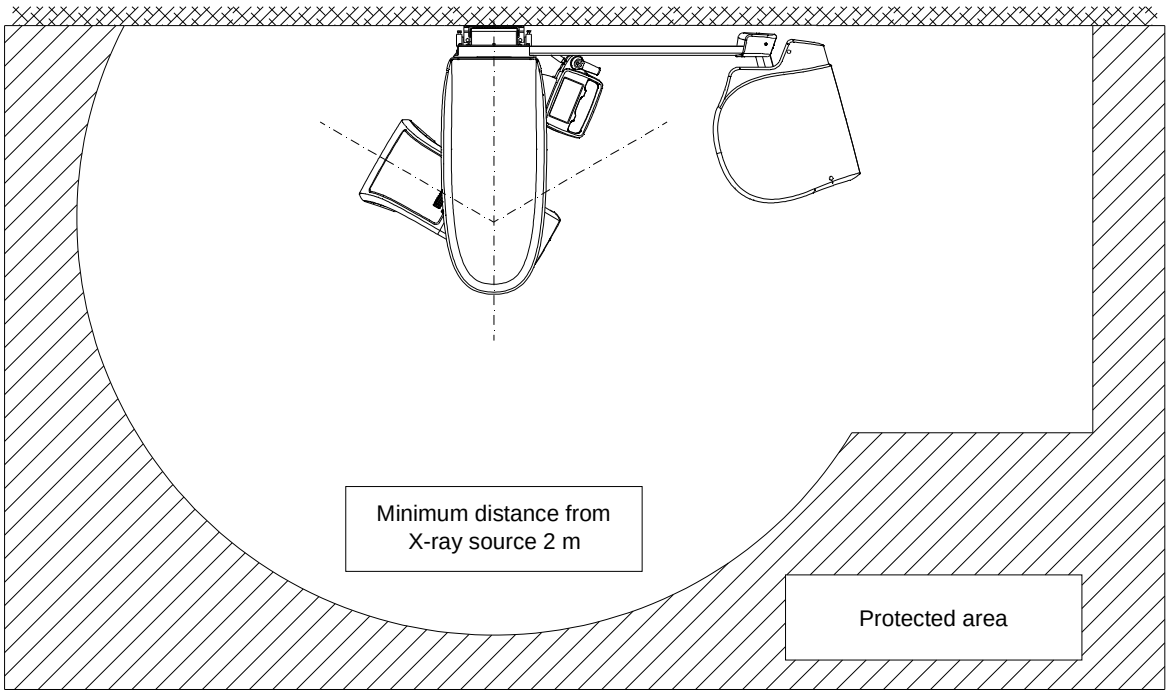


Figure 2 - Cephalometric version

WARNING: PRECAUTIONS WHILE USING LASER CENTRING DEVICES:

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

WARNING:
The USB port on the control panel MUST NOT be used with an external Hard Disk with own mains connection. It has to be used only with USB Pen Drives.

NOTE:
Patient environment is defined as a distance of at least 1.5 meters (4.9 ft) from the patient.
If the PC is positioned outside the patient environment when in use, the PC has to be compliant to IEC 60-950, otherwise the PC must complies with medical standard IEC 60601-1.

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

2.1.1 Distribution of stray radiation in Panoramic examination

	-1.5	-1	-0.5	0	0.5	1	1.5m	
	0,000233	0,000297	0,00053	0,000445	0,000423	0,000331	0,000201	
1.5	0,000268						0,000197	1.5m
1	0,000546						0,000248	1
0.5	0,000666						0,000282	0.5
0	0,00049			C			0,000163	0
-0.5	0,000474						0,000266	-0.5
-1	0,000376						0,000248	-1
-1.5	0,00025	0,000449	0,000655	0,000588	0,000447	0,000182	0,000434	-1.5
	0,000318						0,000228	
	-1.5	-1	-0.5	0	0.5	1	1.5m	

Figure 3: Distribution of stray radiation in Panoramic examination

The Figure above illustrates the distribution of scatter radiation in the horizontal plane at the centre of rotation of the scanning unit in the area of a 3 x 3m rectangle.
The measurement was performed using as scattering element an anthropomorphic phantom complete of soft tissues simulating the head of the typical patient (in size, dimensions and tissues) of the intended use of the machine.
This phantom was placed in the same position as a patient taking a panoramic exam. C is the center of patient head.
The measures were taken during a panoramic exam setting the following parameters: 86kV, 10mA, 14.4s.

NOTE:
They are the maximum kV and mA that can be set on the equipment.

The distribution values in the table are expressed as air Kerma for mAs (µGy/mAs).

2.1.2 Distribution of stray radiation in Ceph examination

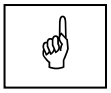
	-1.5	-1	-0.5	0	0.5	1	1.5m	
1.5	*0.00031*	*0.00034*	*0.00038*	*0.00036*	*0.00028*	*0.0006*	*0.00093*	1.5m
1(1)	*0.00012*						*0.00155*	1
0.5(1)	*0.00023*						*0.0022*	0.5
S		Primary x-ray		C			*0.0008*	0
-0.5(1)	*0.00022*						*0.0003*	-0.5
-1(1)	*0.00012*						*0.00021*	-1
-1.5	*0.00029*	*0.00032*	*0.00034*	*0.00033*	*0.00019*	*0.00015*	*0.00012*	-1.5
	-1.5	-1	-0.5	0	0.5	1	1.5m	

Figure 4: Distribution of stray radiation in Ceph examination

NOTE (1):
The doses reported on the source side (S) are just the head scattering term and these values doesn' take into account of tubehead leakage radiation.

The Figure above illustrates the distribution of scatter radiation in the horizontal plane at the centre of rotation of the scanning unit in the area of a 3 x 3m rectangle.
The measurement was performed using as scattering element an anthropomorphic phantom complete of soft tissues simulating the head of the typical patient (in size, dimensions and tissues) of the intended use of the machine.
This phantom was placed in the same position as a patient taking a 30x22 cephalometric exam; this exam is the maximum in size among those the user can select.
C is the center of patient head; S is the X-ray source and the primary X-ray beam is also represented in Figure above.

The measures were taken during a cephalometric exam setting the following parameters: 86kV, 12mA, 7.5s.



NOTE (1):
They are the maximum kV and mA that can be set on the equipment.

The distribution values in the table are expressed as air Kerma for mAs (µGy/mAs).

2.1.3 Electromagnetic emissions

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

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

2.1.4 Electromagnetic immunity

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

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

Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment
			Portable and mobile RF communications equipment should be used no closer to any part of the Rotograph EVO D, 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
Conducted RF IEC 61000-4-6	3 V 150 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 transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

2.1.5 Recommended separation distances for non-life supporting equipment

Rotograph EVO D is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the Rotograph EVO D system can help prevent electromagnetic interference by mantaining a minimum distance between portable and mobile RF communication equipment (transmitter) and the Rotograph EVO D 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 estimeted 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:

(1) at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

(2) these guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

2.2 Environmental risks and displacement

In some of its parts, the device contains materials and liquids that, at the end of the lifespan of the unit, must be disposed of at the appropriate disposal centres.

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

- **Tube-head:** dielectric oil, lead, copper, iron, aluminium, glass, tungsten.
- **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.

2.3 Symbols used

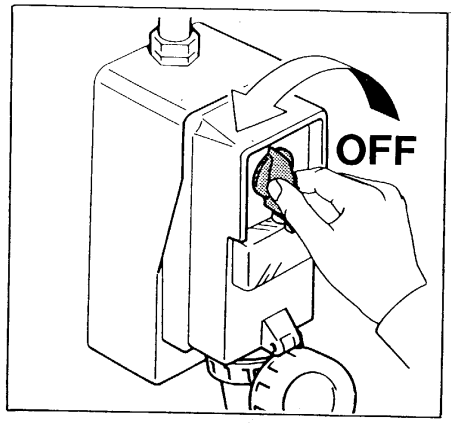
In this manual and on the Rotograph EVO D itself, apart from the symbols indicated on the control panel, the following icons are also used:

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
~	A.C.
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
	Consult instruction for use
CE 0051	Conformity to the EC 93/42 Directive and its revised version

3. CLEANING AND DISINFECTION

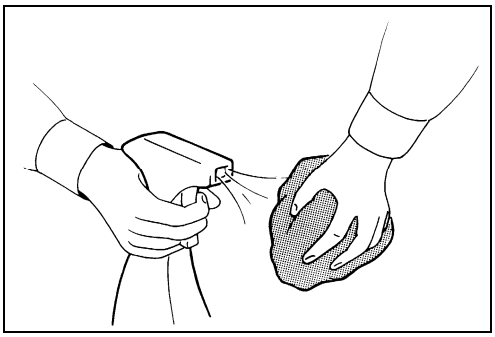
In order to guarantee a good level of hygiene and cleaning, it is necessary to respect the following procedures.

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



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

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



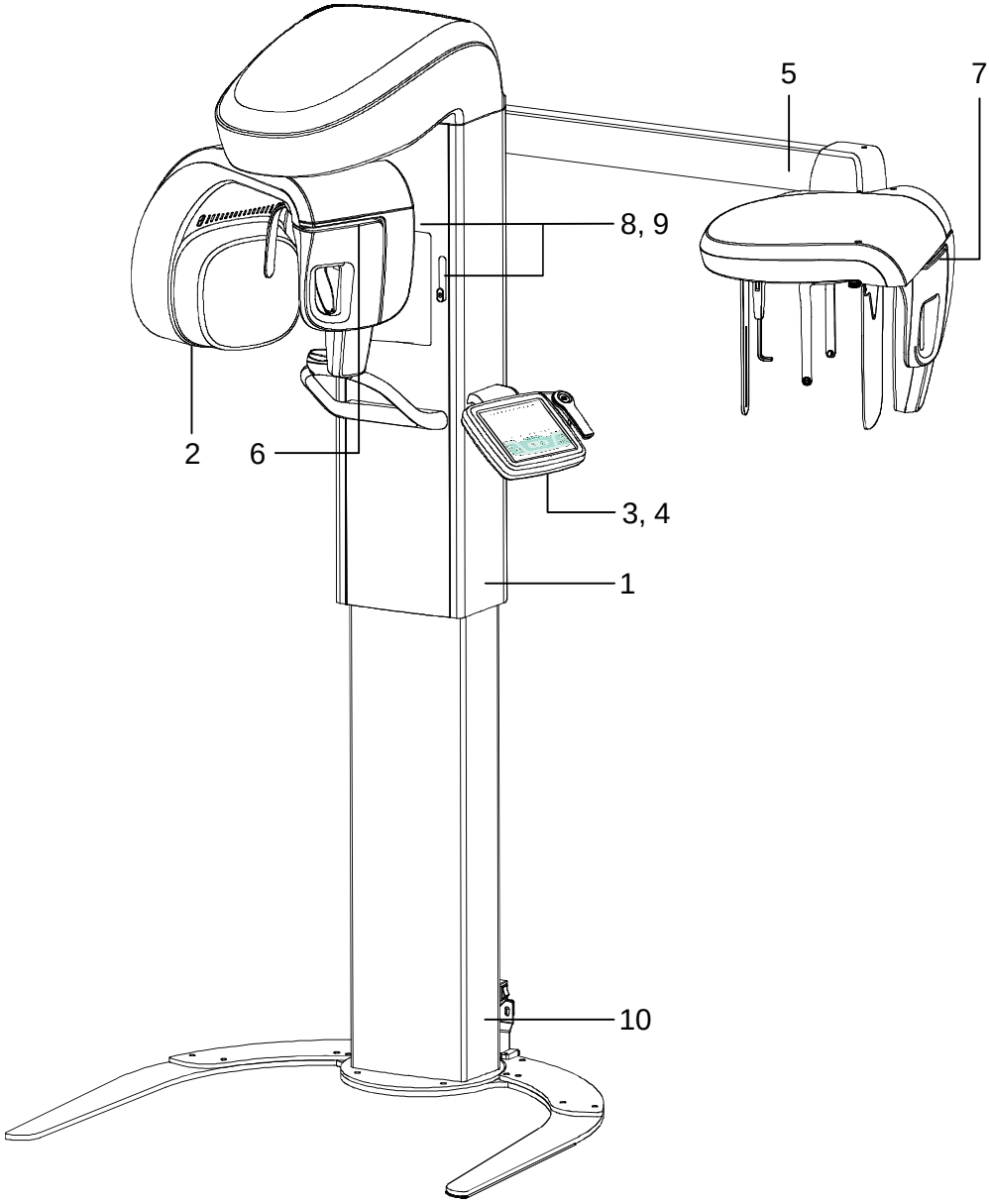
The centring bite or the bite protective sleeve and the ear centring devices of the cephalostatus must be replaced after each examination in which they have been used.

Thoroughly clean the chin support, TMJ positioner, resting handles, nose-rest and temple clasps group any time these are used.

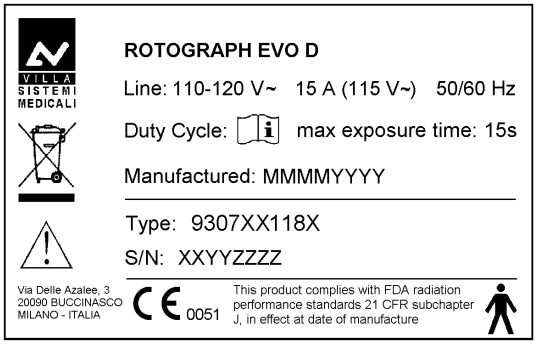
The chin support, TMJ positioner, resting handles, nose-rest and temple clasps group should be disinfected (when considered necessary) with a solution of 2% glutaraldehyde.

4. DESCRIPTION

4.1 Identification labels and laser labels

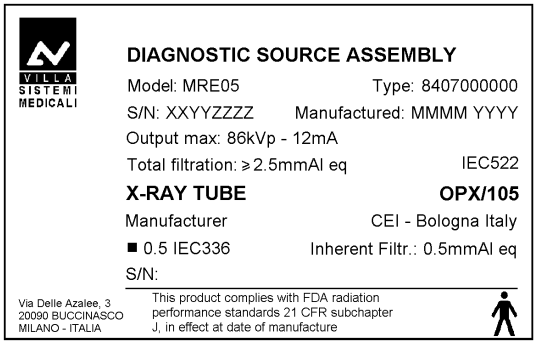


1a
Rotograph EVO D
identification label



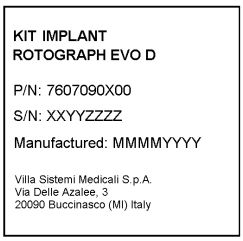
1b
ETL
certification label

2
Tube-head
identification label

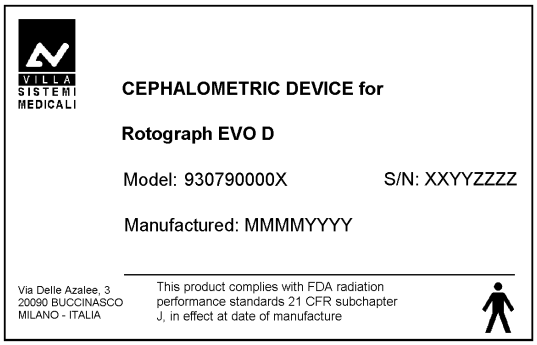


3
EVO XP
Extended Projection
Package
identification label

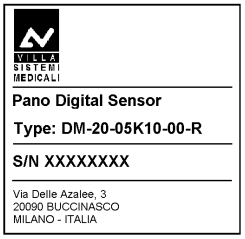
4
IMPLANT Package
identification label



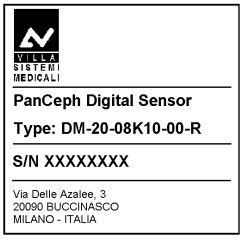
5
CEPHALOMETRIC device
identification label



6
PANO
Digital Sensor
identification label



7
PANCEPH.
Digital Sensor
identification label



8
(N° 2) Spot Laser
identification label

9
(N° 2) Laser
symbol label

10
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.

4.2 Functions, models and versions

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

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

- **EVO XP (Extended Projection Package)**
  Allows you to carry out the following additional examinations:
  Emi-panoramic, Reduced dose Panoramic, Frontal dentition, Improved orthogonality Panoramic and Bitewing.
- **IMPLANT**
  Allows you to perform images of cross-sections of the dental arch, for Implant medical treatment.
- **CEPH**
  Allows you to carry out the following examinations:
  – CEPH exam in different formats
  – CARPUS exam.

The values of the exposure factors shown in the tables of paragraph 6.14.1, set as default, are for guidance only.
The real adjustment of these values depends on users trade off between expose dose and image contrast.

Image processing should help you getting the best contrast.

4.2.1 Basic version

The basic version enables to perform the following examinations:

- Panoramic Adult or Child, with 3 Sizes and 3 Types of Biting for a total of 18 combinations in Automatic selection; in manual selection it is possible to select high voltage between 60kV and 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.

4.2.2 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.
- Digital Cephalometry for Adult and Children with 3 Sizes each. Within each combination, it is possible to select an examination in Hight or Normal Resolution, for a total of 12 combinations in Automatic selection. In Normal Resolution, the examination is carried out with a lower scanning time, allowing a further reduction of the dose. In Manual selection it is possible to vary the Hight Voltage from 60kV to 86kV, with 2kV steps, the anodic current from 6mA to 12mA with 1mA steps. The positioning of the sliding primary collimator, the secondary collimator and the Digital Sensor (inside the relative sensor holder) is automatic according to the selected format projection. The Soft Tissues Filter is motorized, to obtain the best possible emphasis of the face profile.
- Examination to evaluate the bone growth (Carpus) only Child with 3 Sizes. It is possible to select an examination in High Resolution, for a total of 3 combinations in Automatic selection. In Manual selection it is possible to vary the tension from 60kV to 86kV, with 2kV steps, the anodic current from 6mA to 12mA with 1mA steps. The positioning of the sliding primary collimator, the secondary collimator and the Digital Sensor (inside the relative sensor holder) is automatic

4.2.3 EVO XP (Extended Projection Package) - Optional

The unit, both the base and the version with cephalometric device, is prearranged to be fitted with the EVO XP (Extended Projection Package) function, which enables to perform the following examinations:

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

NOTE:
All these examinations can be added to Rotograph EVO D systems already installed in the field.

NOTE:
The code inserted into Rotograph EVO D 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" (6) push-button  will reset such condition, although at the end of the start-up position, only the Panoramic, Sinus, and TMJ functions will remain active.

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

5. TECHNICAL CHARACTERISTICS

General features	
Type	Rotograph EVO D
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 
Protection degree	IPX0 standard device
Rated line voltage	110-120 V~
Line frequency	50/60 Hz
Maximum line current	15 A @ 115 V~ 50/60 Hz
Power consumption	1.7 kVA @ 115 V~ 50/60Hz
Protection fuse (F1)	15 A T
Protection fuse (F2) **of switching power supply**	3 A T
HF generator board protection fuses	F1: 10 A F F2: 5 A HF F3: 2 A T
Line voltage regulation	< 3 % at 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 in 1 mA steps for Ceph (up to 76 kVp) 6 ÷ 10 mA in 1 mA steps for Ceph (from 78 kVp to 86 kVp)
Sensor cover additional filtration	0.1 mm Al eq @ 70 kV_p

Exposure times	
EVO Panoramic	14.4 s Adult / 13.3 s Child
Panoramic STD	13.8 s Adult / Child
EVO EmiPanoramic	7.8 s Adult / 7.3 s Child
STD EmiPanoramic	7.4 s Adult / 7.3 s Child
Improved orthogonality Panoramic	11.9 s Adult / Child
EVO Reduced dose Panoramic	11.9 s Adult / 10.8 s Child
STD Reduced dose Panoramic	11.4 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, total of 9.7 s
Sinus P/A projection	9.4 s
Implant	9.2 s for incisive e canine 7.3 s for pre-molars and molars
Cephalometry (Ceph)	Exposure time variable according to the type of resolution and format selected. Minimum 4.5 s (18x22 nR), maximum 15 s (30x22 hR)
Exposure time accuracy	± 10 %
Examination modes	
Examination selection	• Automatic selection for Adult and Child, 3 Sizes • 3 biting modes (in Panoramic) • Automatic selection for Adult, 3 Sizes (in Implant) • Manual selection • Collimator with automatic positioning
Panoramic NOTE: Some of these exams are optional and depend on the system configuration.	• EVO Panoramic • Standard Panoramic • Half Panoramic L/R • Improved orthogonality Panoramic • Reduced dose Panoramic • Frontal dentition • Bitewing L/R • Bitewing L and R

Examination modes		
TMJ (Temporal Mandibular Joint)	TMJ open and closed mouth	
Sinus	Sinus P/A projection	
Cephalometry and Carpus	• Normal resolution cephalometry in Latero-Lateral or Antero-Posterior projection (different formats) • High resolution cephalometry Latero-Lateral or Antero-Posterior projection (different formats) • High Resolution Carpus exam • Motorized Soft Tissue Filter.	
Image magnification	**Geometric magnification**	**Magnification after software correction**
Adult / Child standard Panoramic	1 : 1.23 (constant over dentition part)	1 : 1 (*)
TMJ open/closed mouth, 4 images	1 : 1.20 (nominal)	1 : 1 (*)
Sinus	1 : 1.22 (nominal)	1 : 1 (*)
Implant	1 : 1.32 (constant)	1 : 1 (*)
Ceph (on the sagittal medial plane in LL projection)	1 : 1.10	1 : 1 (*)

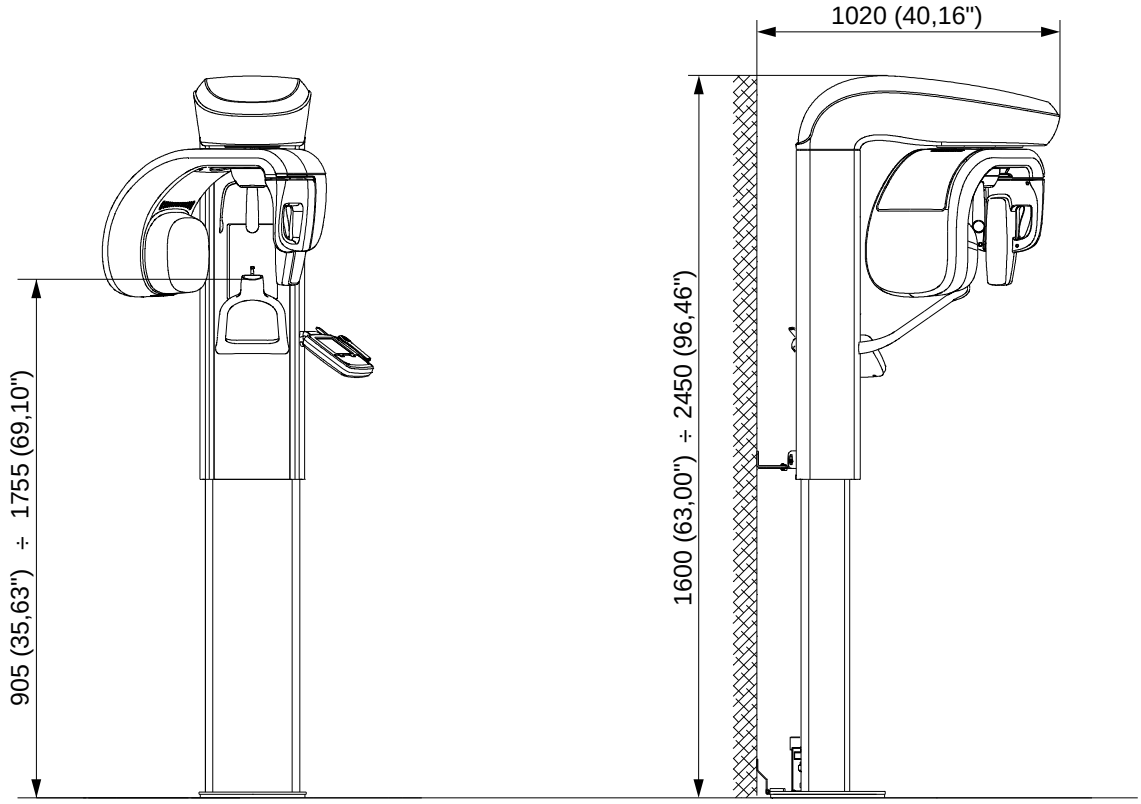
(*) WARNING:
The declared image magnification value is valid after proper software calibration.

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 %
Duty cycle	Adaptive Duty Cycle according to exposure factors: from 1 : 8 (at 60kV, 6mA) up to 1 : 20 (at 76kV, 12mA). Further reduction for three consecutive exposures: from 1 : 36 (at 60kV, 6mA) up to 1 : 9 (at 76kV, 12mA)
Nominal power	1.032 kW (86 kV_p - 12 mA)
Total filtration	2.5mm Al eq. @ 70 kV_p
HVL (Half value layer)	> 3.1mm Al eq. @ 80 kV_p
Transformer insulation	Oil bath
Cooling	By convection
Leakage radiation at 1 m	< 0.5 mGy/h @ 86 kV_p - 12 mA - 3 s 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	0.5 mm 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

Digital Sensor	
Sensible area (H x L)	• PAN sensor: 151 x 7 mm • PANCEPH sensor: 220 x 7 mm
Pixel dimensions	27 µm, 81 µm in binning 3x3 (PAN and PANCEPH HD), 135 µm in binning 5x5 (CEPH HS)
Pixel (H) NOTE: Number of horizontal pixels depends on the exam and resolution on CEPH.	• PAN: 1860 • CEPH: 1632 in HS, 2720 in HD
Laser centring devices	
2 laser beams are used for the patient positioning; beams align mid Sagittal and Frankfurt planes (please refer to relevant paragraphs for detailed explanation).	
Wave length	650 nm ± 10 nm
Divergence	< 2.0 mRad
Optical power	< 1 mW
Classification	Class 1 laser product according to IEC Standard 60825-1:1993 + A1:1997 + A2:2001
Mechanical characteristics	
Focus-receptor distance (PAN, TMJ and Sinus)	50 cm (20")
Focus-receptor distance (CEPH)	165 cm (65")
Telescopic motorised column run	85 cm (33.5")
Maximum total height	245 cm (96.5")
Weight	• 161 kg base version • 186 kg version with Ceph
Column weight	87 kg
Weight of arm support, rotating arm and tube head	74 kg
CEPH arm	25 kg
Legs (optional)	30 kg
Sensor holder weight	2 kg

Working conditions	
Minimum room size (please refer to the Service Manual)	• 130x120 cm (51.2"x47.2") without CEPH • 145x202 cm (57"x78.7") with CEPH
Recommended room size (please refer to the Service Manual)	• 130x140 cm (51.2"x55.1") without CEPH • 160x222 cm (63"x86.6") with CEPH
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

5.1 Dimensions



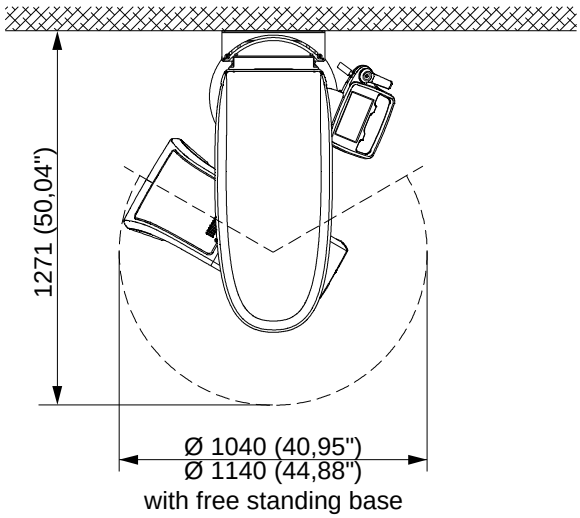
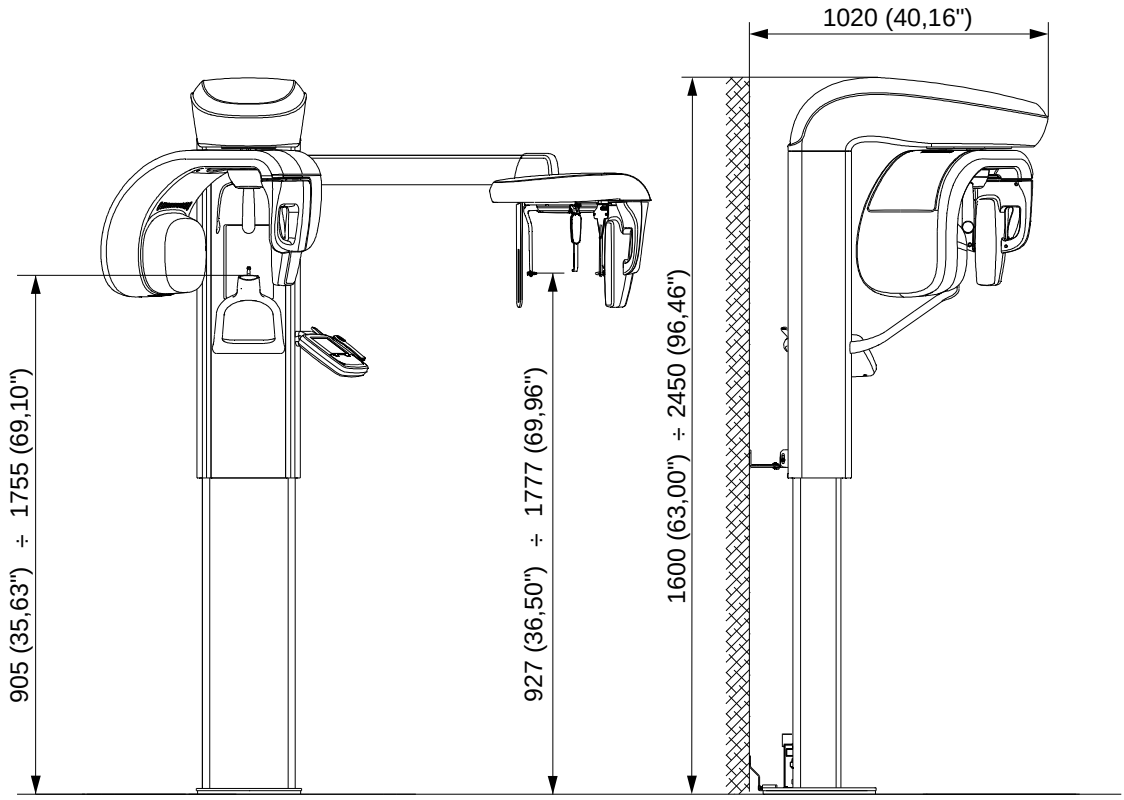


Figure 5 - Rotograph EVO D dimensions
Base version



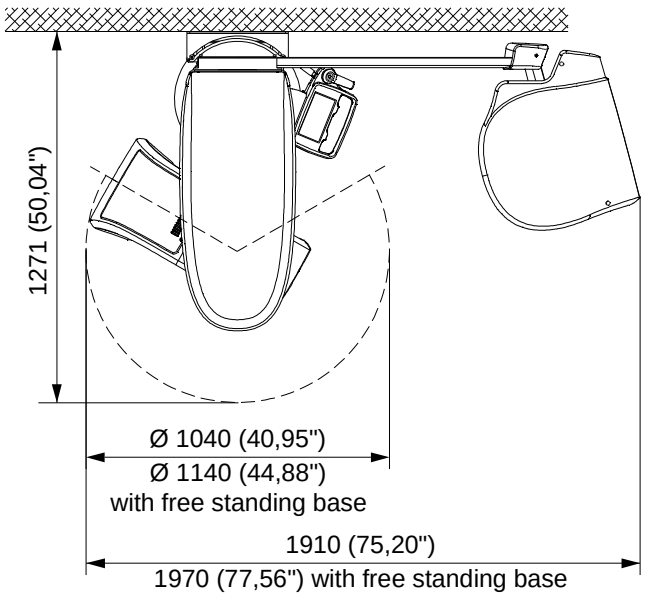
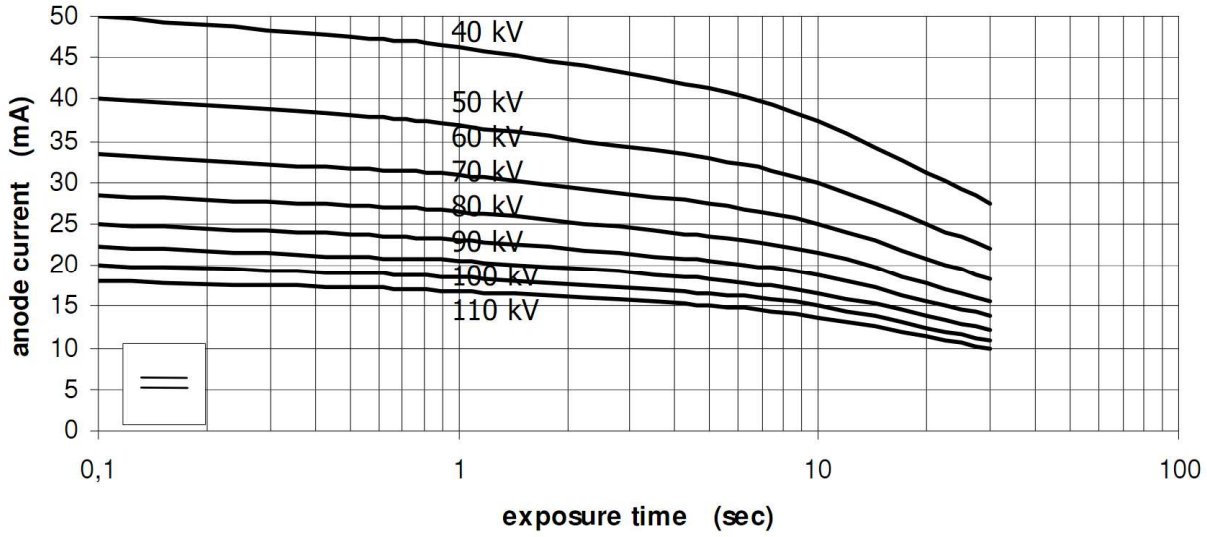


Figure 6- Rotograph EVO D dimensions
Version equipped with cephalometric unit

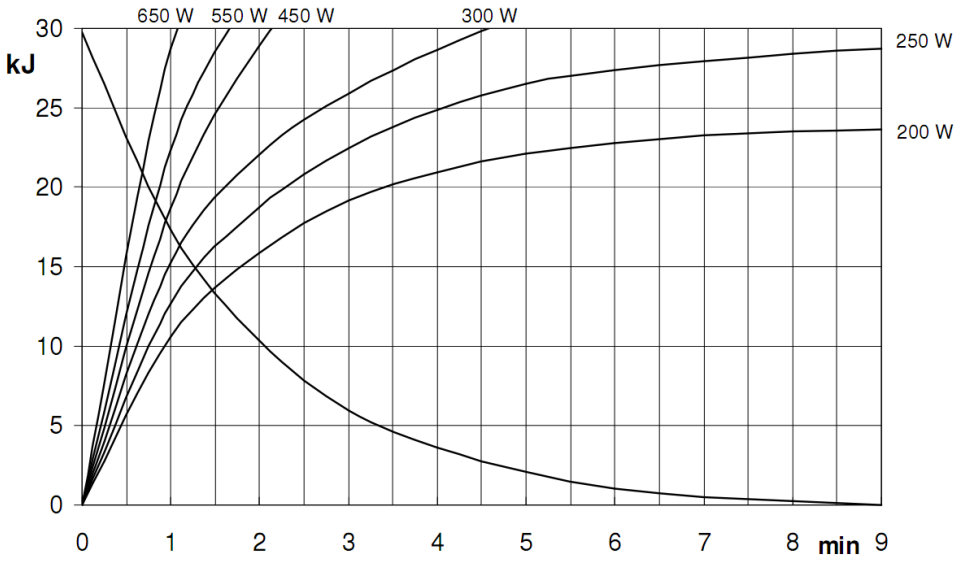
5.2 Loading curve of the tube and cooling curve of the anode

Tube "CEI - OPX/105" (0.5 IEC 336)

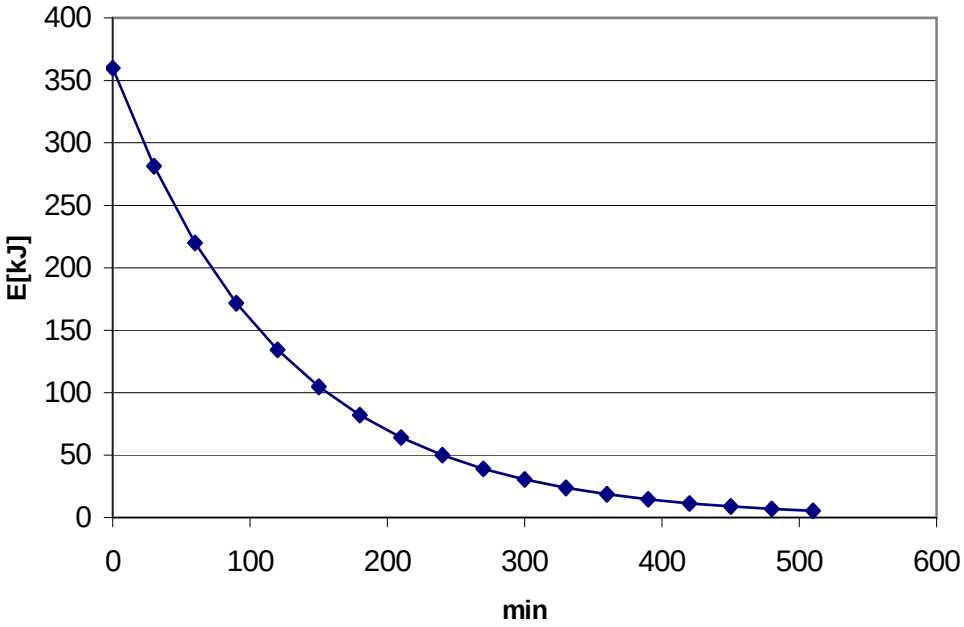
Load



Anode cooling curve



Tube-head heating and cooling curve



5.3 Applied safety regulations

Rotograph EVO D complies with the following standards:

CE 0051 The symbol CE grants that Rotograph EVO D complies with directives 93/42 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 60601-2-7:1998
  IEC 60601-2-28:1993
  IEC 60601-2-32:1994

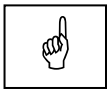
- Electromagnetic compliance:
  IEC 60601-1-2:2001

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

Classifications

Rotograph EVO D is an electro-medical X-ray device belonging to Class I type B as per classifications IEC 60601-1, provided for a continuous working at intermittent load.
According to EC 93/42 Directives for medical devices, the equipment belongs to class II B.
According to Canadian MDR, the equipment belongs to class II.
According to FDA 21 CFR, the equipment belongs to class II.

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



NOTE:
Rotograph EVO D is based on a standard dentition and ascending rami shape.
This shape, based on statistical studies, establishes a form for the dentomaxillofacial complex, adopted as "standard".
Rotograph EVO D 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, THE RADIOGRAPHY IMAGES CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE IMAGE.

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.

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

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

For the measurement of the exposure parameters with the invasive method, please follow the procedure described in the Service manual.

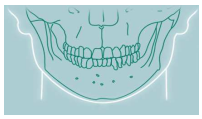
WARNING:
During the panoramic examination, the set value of kV and tube current varies according to a fixed curve, to compensate the variations in absorption by the patient's tissues; in this way, it is possible to obtain a good uniformity of the image contrast. In particular, the chosen value is lowered during the initial phase, and increased on the canine/incisor zone, in order to compensate the effect of greater attenuation owing to the spine.
The value displayed during the panoramic examination corresponds to the one chosen by the user, while the real value can be different; this fact must be considered if the exposure parameters are checked using standard diagnostic mode.
The accuracy of the exposure parameters kV and mA, stated in the Technical Data section, refers to the accuracy compared with the instantaneous value set by the system.
In any case, the manufacturer guarantees that the accuracy of the exposure parameters is always in compliance with the international standards for the safety of medical devices IEC 60601-1. In particular, in accordance with IEC 60601-2-7, the maximum deviation (including the correction and instrumental doubt) is less than or equal to ±10 for kV, while for tube current it is less than or equal to ±15%.

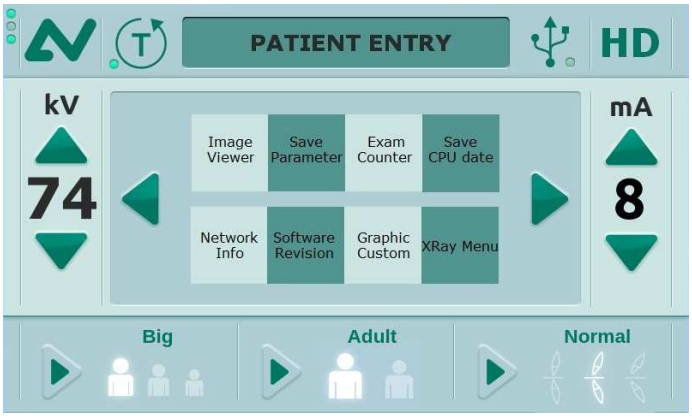
5.6 Verification method of technical factors (paragraph for authorised personnel)

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

WARNING:
The device collimator gives a narrow X-ray beam.
Measurements taken with a non-invasive instrument and a narrow beam can be difficult and/or unreliable; it is therefore necessary to use a special probe with a reduced sensitive area.
It may be helpful to use a fluorescent screen to locate the X-ray beam, and consequently position the probe of the kV meter.
If the unit is ready to Ceph or is equipped with Ceph arm, place the kV meter probe in the lower part of the sensor since the Ceph collimator window is used in this function.

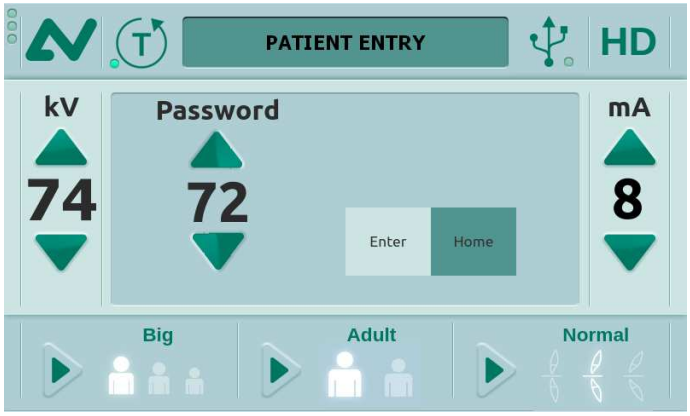
The procedure to measure the exposure parameters by a non-invasive kV meter is the following:

1. With the unit switched ON, select the Panoramic Examination mode by pressing the "Exam Mode Selection" area (11)  .
2. Press the key "Service Menu" (18)  ; the following image will be displayed:

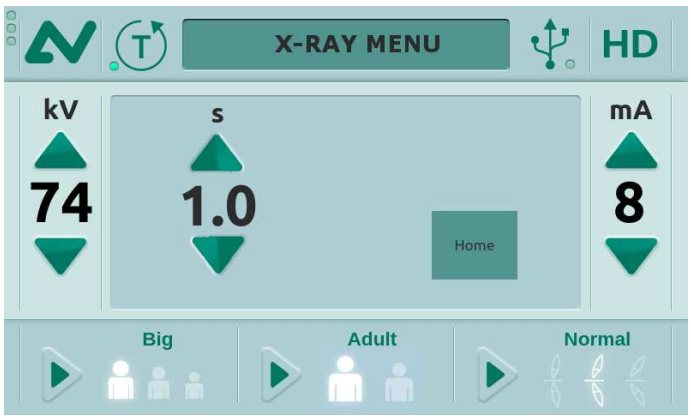


3. Select "Xray Menu".

4. Using the relevant increase/decrease arrows  , select the password equal to "72".



5. Confirm with key "Enter". The following image will be displayed:



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

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

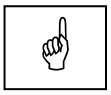
6. Place the measuring instrument.

7. The kV, mA and s parameters can be modified by pressing the increase key and the decrease key  of the kV, mA and s on the display.
The parameters can vary within the limits shown in the following table:

Parameter	Minimum value	Maximum value
kV	60	86
mA	6	12
s	0.2	15

Table 1

8. Perform an exposure; technical factors can be read on the measuring instrument.



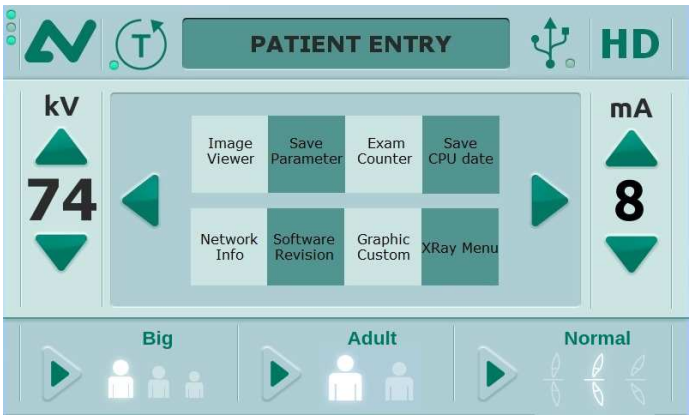
NOTE:
The performance is guaranteed only if the measurement of kV and time is done with the invasive method, due to the fact that non-invasive method may introduce errors for instruments tolerance or wrong measurement condition.

9. Press key "Home" to end the control program, the display will visualize the "Service Menu". Pressing key (18)  the unit will return to standard mode.

5.6.1 Verification method of Panoramic X-ray beam centering and dimension

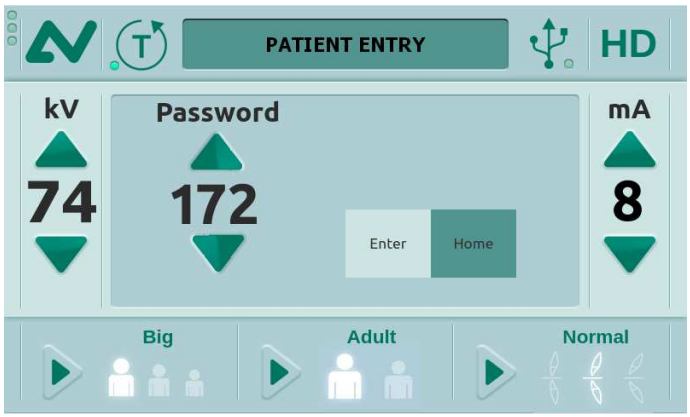
1. On Dental Studio program, open a test patient used to make the test images and select the "Panoramic" icon to open the virtual keyboard.

2. On the unit keyboard, press key "Service Menu" (18)  ; the following image will be displayed:

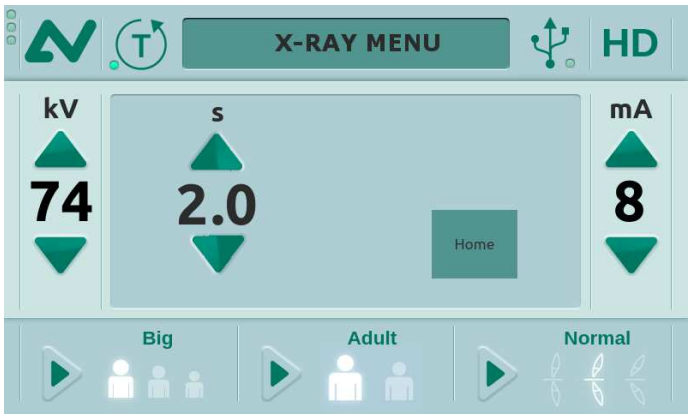


3. Select "Xray Menu".

4. Using the relevant increase/decrease arrows  , select the password equal to "172".



5. Confirm with key "Enter". The following image will be displayed:



6. Press the X-ray button and keep it depressed until the end of the exposure.

7. On Dental Studio program, press "Accept Image", then "Yes".

8. On the "LUT" option, select button "  " to improve the image contrast and brightness.

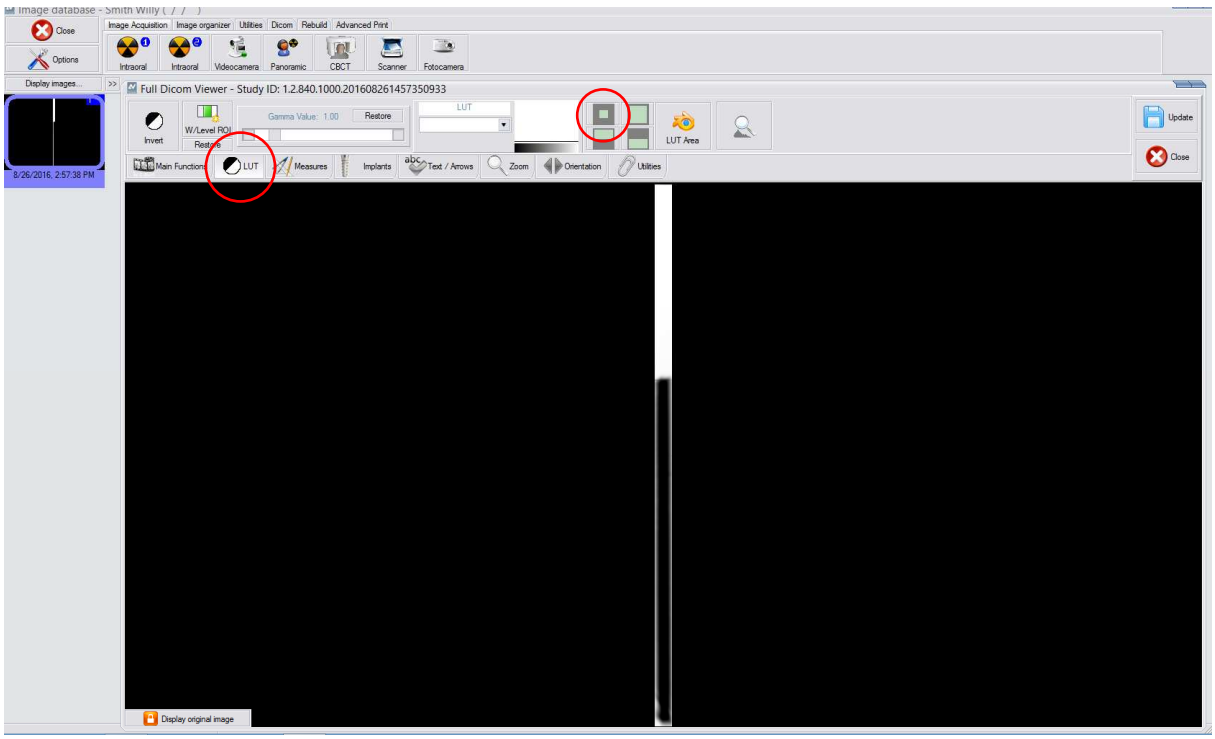
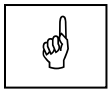


Figure 7

9. Verify that the obtained narrow image of the X-ray beam is vertical and centered in left/right direction and that there is a small unexposed border in the bottom of the white sensor area.

At the end of the exposure the unit automatically exit the menu. To take a new exposure, repeat steps from 1 to 8.



NOTE:
If the virtual keyboard display the message "SENSOR NOT READY", exit from "Service Menu" and repeat steps from 1.

5.7 Open Source Software

Parts of the software included in this product use the LINUX® operating system and software packages that operate in that environment. Such packages are used without alterations and are subject to various open source licenses such as the General Public License (GPL or LGPL) and others.

You may obtain the corresponding source code by writing to:
Villa Sistemi Medicali
Via delle Azalee, 3
20090 – Buccinasco – MI
Italy
Ph. +39-02-48 859 1
Fax. +39-02-48 859 303
e-mail: vsminfo@villasm.com

For proper processing of your request it is necessary to indicate "Open Source Code" in the subject of your message. Distribution charges may apply.

All Open Source Software will be provided "AS IS"; there are (i) no representations or warranties and (ii) neither Villa Sistemi Medicali, nor any of the developers or contributors to Open Source Software shall have any liability or obligation to the customer with respect to Open Source Software beyond what is granted in the particular Open Source Software license. Any modification to software code residing in Villa Sistemi Medicali product shall void all warranties, render product "Not for Clinical Use" and not compliant to applicable standards. Villa Sistemi Medicali shall have no liability or obligation for products containing modified software.

6. GENERAL INSTRUCTIONS FOR USE

6.1 Control panel – description and functions

The Rotograph EVO D control panel is divided into function areas.
The next figure shows a general view of the control interface, while details on each functional area are provided in the following pages.

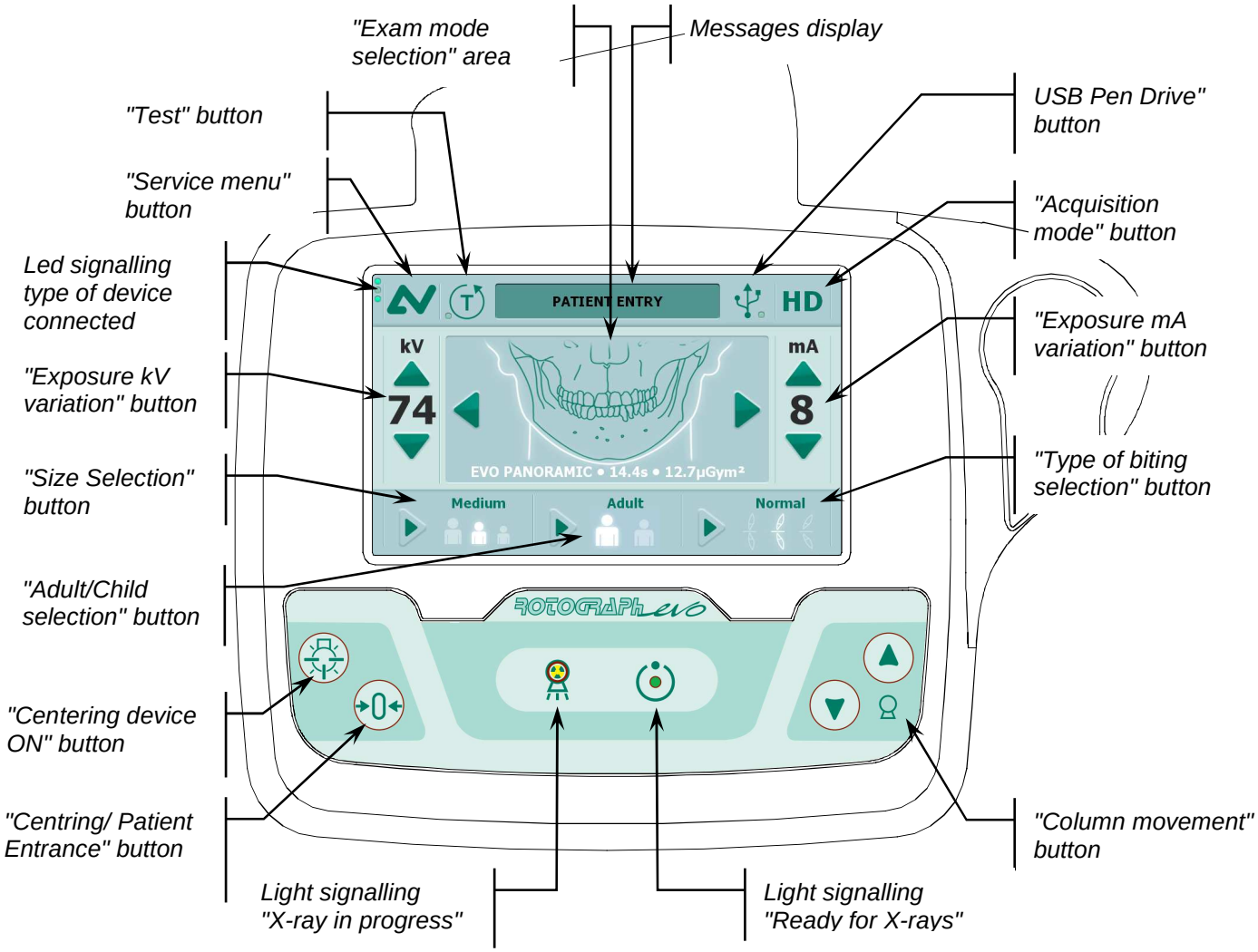


Figure 8

WARNING:
The USB port on the control panel MUST NOT be used with an external Hard Disk with own mains connection. It has to be used only with USB Pen Drives.

The next figure shows a general view of the display of the Service menu.

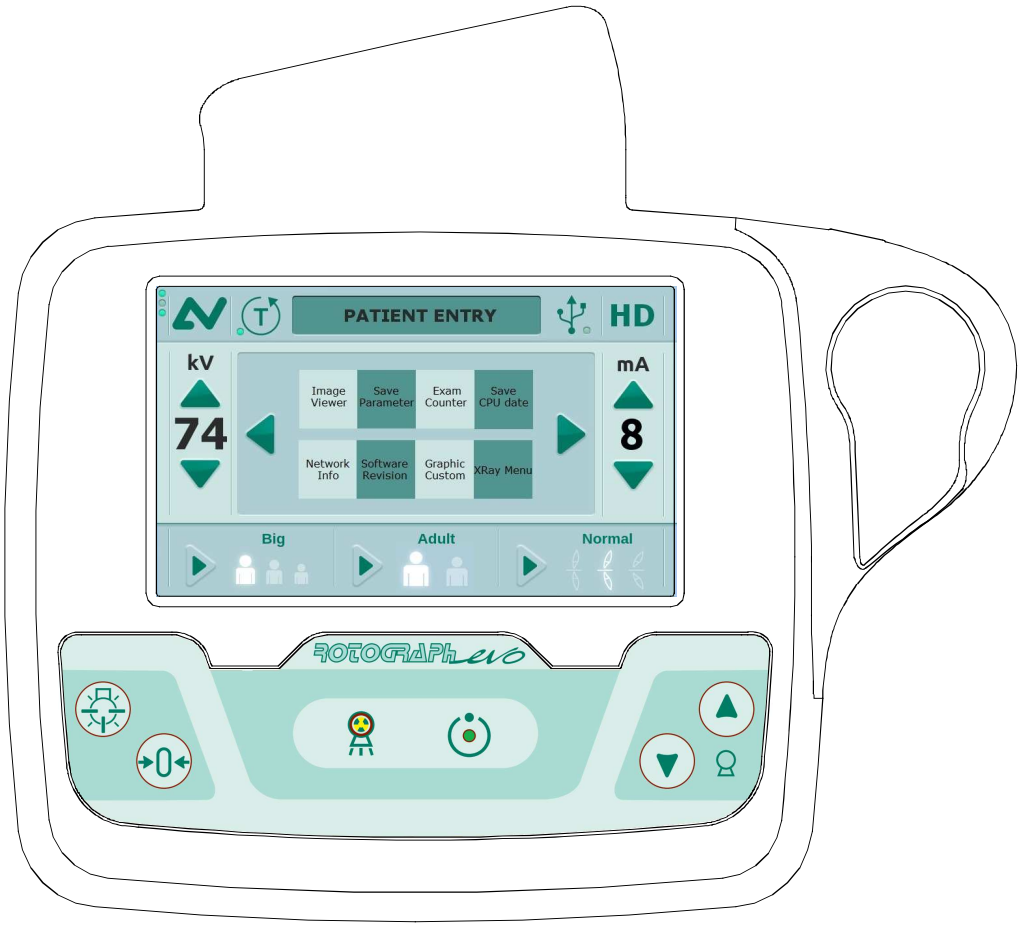


Figure 9

Here following a sample description of each key functionality:

- **Image viewer**: enabled only when the USB Pen Drive is present in the relevant port
- **Save parameter**: allows to store the automatic exposure parameters (see paragraph 6.14)
- **Exam counter**: allows to display the numbers of exam performed in each exam mode
- **Network info**: allows to display the IP addresses and SubNet mask of the devices connectet to the Network
- **Software revision**: allows to display the software revision of the Rotograph EVO D system microcontroller
- **Graphic Custom**, **XRay Menu** and **Save CPU date** (not active): these keys are reserved to authorised personnel.

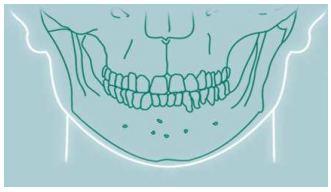
Press key "Home" to go back to the "Service Menu".

Pressing key (18)  the unit will return to standard mode.

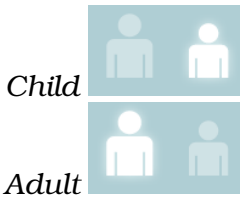
The "Centring/Patient Entrance" key is used to:

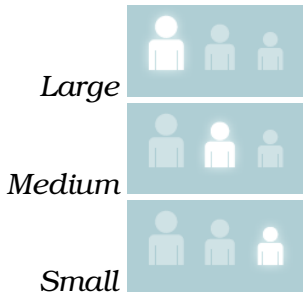
- start/stop the start examination procedures
- bring the rotation arm to the patient entrance position at the end of the exam.

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

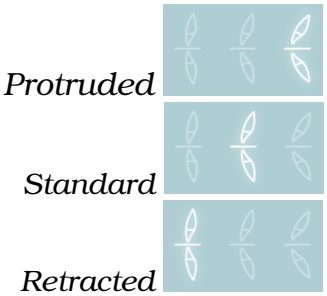


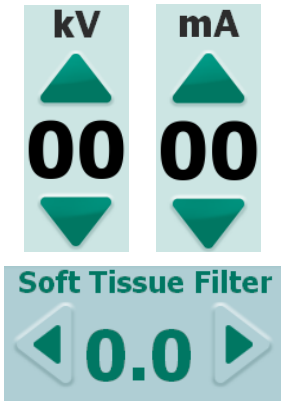
It is possible to select the anatomic mode examinations (anatomic selection), using prefixed exposure values.
This kind of selection enables to choose between Adult/Child, each with three different sizes (small, medium, large).





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





Furthermore there is the possibility to manually select the exposure parameters; in this case, it is possible to set the parameter with the desired value.
The parameters available are: kV and mA (Soft Tissue Filter position only in cephalometry).

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

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

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

The key "Test" is used to avoid the X-rays emission, in order to check the absence of collisions with the patient.
When the LED is green, the test function is enabled.

This key displays the "Service Menu": the main menu area is replaced by the service menu area.
Use this key also to return to the control panel (main menu).

This key is used to un-mount the Pen Drive inserted in the USB connector of the control panel.
When the LED is green, the pen drive is recognised.

In Cephalometric mode, this key allows to perform the exam in High Definition modality or in High Speed (normal resolution) modality.

High Definition

High Speed

6.1.1 Key function description

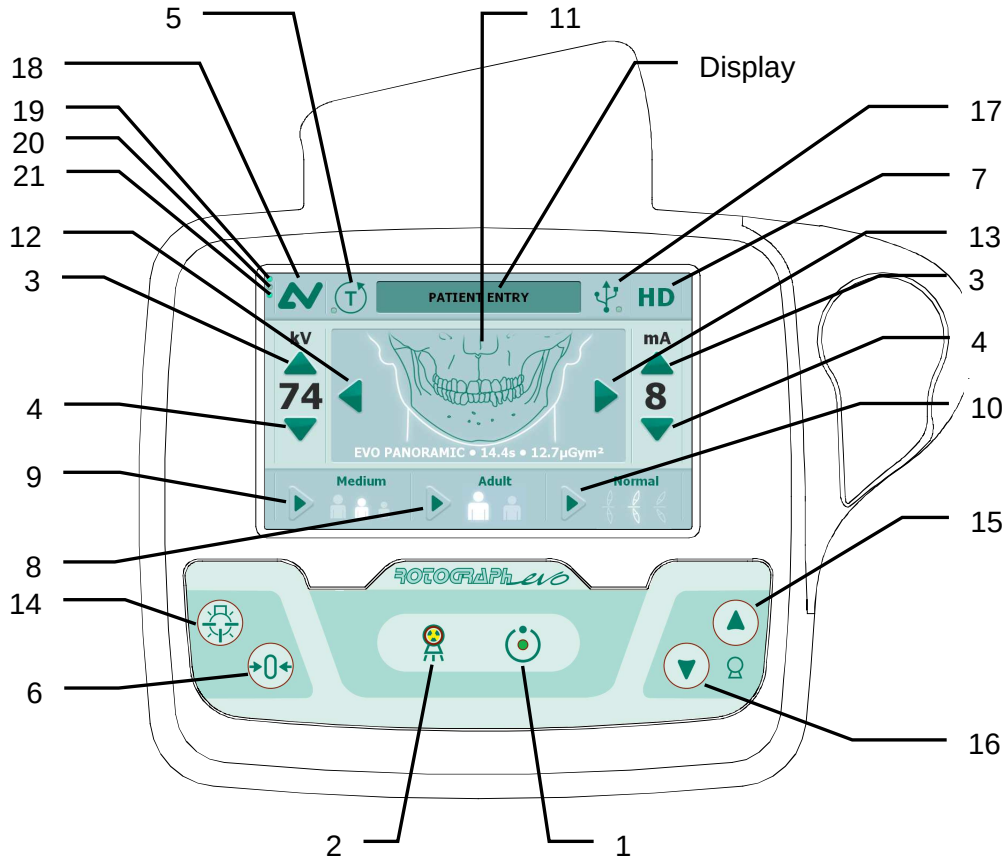


Figure 10 - Control panel

LEGEND:

Messages
Display: indicates operative messages and warnings

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 - kV/mA increase key
4 - kV/mA decrease key

Preparation functions
5 - Key to set Test function (green LED)
6 - 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
7 - Key to select the modality in use (High Definition or High Speed)

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

Examination mode
11 - Exam mode selection area
12 +13 - Type of exam selection keys

Centring devices
14 - Sagittal and Frankfurt plane centring device ON/OFF key

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

Other
17 - USB Pen Drive key
18 - Service menu key
19 - Virtual keyboard active (green LED)
20 - Presence of PAN only sensor (only for dual sensor machine) (green LED)
21 - Presence of sensor (green LED)

6.1.2 Pen Drive function description

NOTE:
If pen drive is inserted and virtual keyboard is open, the image will be acquired and displayed only on the computer.
In case of use of the pen drive, it is necessary to close the virtual keyboard on the computer.

A pen drive can be inserted in the USB port at the top of the control panel. The pen drive has to be formatted in FAT32 (not in NTFS; please refer to your Windows Manual and help for more information on formatting).

As soon as the pen drive has been inserted, the unit will verify it.

- If the pen drive is formatted with the right file system and there is enough free space available to save at least one image, the LED of the "USB Pen Drive" key (17)  light GREEN.
- If the pen drive is not formatted with the right file system, if there is not enough free space available to save at least one image or the key became full during acquisition, the LED will turn RED and no exams can be taken.
  Please verify that there is enough free space on the pen drive, if not please free up at least 50 MB of space. Plase verify that the pen drive has been formatted with the FAT32 and not with the NTSF (or Linux or Mac) file system, if not please use another pen drive or reformat the pen drive with the correct file system.

WARNING:
Make sure, before reformatting a pen drive, to copy all the data it contains onto your harddisk or CD/DVD; once the pen drive is reformatted all data on it will be irreparably lost!

- On both cases, before to extract the pen drive from the control panel press key "USB Pen Drive" (17) and wait until the LED switch OFF.

6.1.2.1 Acquired image display description

NOTE:
The image displayed on the touch screen can not be used for diagnostic purposes.

Once an image has been acquired, it is written on the USB pen drive and displayed on the touch screen.

During acquisition, the image is progressively displayed on the screen, adjusted to have the whole image in the screen.

As soon as the image is acquired and fully processed, it is displayed on the screen of the control panel.

The image can be zoomed in and out on, using keys  and  .

Key  returns to the full view.

When the image is zoomed in on, it is possible to move around the image to display parts of the image that are not visible on the screen; this can be done using a stylus or using a finger.

Key  returns to the control panel, allowing for the acquisition of a new image.

Use keys  and  to scroll the image present in the pren drive.

6.2 Digital Sensor

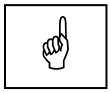
Rotograph EVO D is equipped with two types of digital sensors, depending on the version:

- Sensor PAN: it is a sensor suitable for Panoramic-type imaging, i.e. all images with a 15 cm-high field; all Panoramic, TMJ, Sinus and Implant images belong to this type. Depending on the version, this sensor can be either movable from the sensor holder, or fixed (not removable) on the same holder. In case the sensor is fixed to the sensor holder, the latter cannot be rotated to make free the part where rays go through for the execution of the cephalometric examination.
- PAN/CEPH sensor: it offers a wider use flexibility, as it can carry out both Panoramic and Cephalometric-type images. This sensor can always be removed from its sensor holder's.

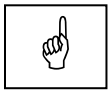
Rotograph EVO D can also be configured in the "double sensor" version, where both PAN and PAN/CEPH sensors are present.

Rotograph EVO D control system takes care of checking the consistency of the safety measures that allow for the correct use of the digital sensor; in particular:

- To prevent the acquisition in case the image management and processing system is not ready to receive the image itself, by displaying the message "Sensor not ready"
- To prevent the CEPH exposure in case the PAN sensor is in the CEPH position, by displaying the message "Sensor not on Ceph"
- To prevent the exposure in case, when a double-sensor system is present, the PAN sensor holder is not completely open, allowing the clearing of the X-ray beam path. The message "Open cassette holder" is displayed.



NOTE:
All sensor types are equipped with a shock detection sensor; this sensor is also visible from the outside to enable to operator to perform checks. Possible shocks are displayed by a change in colour (from transparent/white to red) of this sensor. The digital sensor can still function correctly also when the colour changes, displaying a fall that might also not have damaged the sensor.



NOTE:
The fall sensor colour change interrupts the warranty on the sensor.

6.2.1 Inserting the sensor in the sensor holder

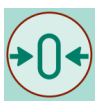
The digital sensor is equipped with a handgrip used to safely transport the sensor from one holder to the other, in order to minimise the risk of fall. The system used to hook the mobile sensor to the holder is also engineered to reduce the sensor's risk of fall due to failure to hook the sensor and/or due to early release.

Inside the transport handgrip there is a lever that controls the sensor's hooking and release operations; at the same time, this lever works on the electronic connector in order to guarantee the correctness of the connection operations. On the fixed part of the sensor holder, there are two hooks that need to be inserted into the corresponding gaps on the mobile part of the sensor. On this latter, metallic plugs have been mounted which, by joining in the corresponding fixed part, guide all parts to a position suitable for the execution of a safe and stable contact.

In order to insert the sensor in the desired station, carry out the following operations:

1. Grip the sensor by the appropriate handgrip; close your fingers to form a fist, by engaging the control lever and bring it to the position where the same disappears inside the handgrip, so that the whole mobile system retracts.
2. Keep the sensor with the relative handgrips vertical, so that the upper plane is parallel to the horizontal part of the sensor holder, bring the sensor close to the fixed station, by engaging the protruding part of the mobile sensor into the relative casing.
3. Push the sensor mobile part to the very end, in order to engage the mobile part onto the fixed hooking system.
4. Carry out a movement towards the lower part, ensuring that the movement is complete.
5. **Only at this point, release the hooking lever,** checking that the sensor is correctly engaged before releasing the handgrip.

WARNING:
During the lever releasing operation, hold the sensor firmly, to prevent the sensor from falling during the insertion phase due to possible errors.

NOTE:
In case of single sensor unit, moving the sensor from PAN to CEPH position or viceversa, it is necessary to wait about 40 second (LED 20/21 light ON) before to start the device alignment phase pressing key "Patient Entrance" (6)  .

Faster pressure may provide "SENSOR NOT READY" error.

6.2.2 Release of the sensor from the sensor holder

The operations for releasing the sensor from the relative sensor holder are specular to the ones described for the hooking of the same.

1. Grip the sensor by the appropriate handgrip; close the fingers to form a fist, by engaging the control lever and bring it to the position where the same disappears inside the handgrip, so that the whole mobile system retracts and the electronic connectors and the reference plugs are completely released.
2. **Grip firmly the handgrip**, and move towards the upper part of the digital sensor, in order to free the mobile part from the hooking system.
3. By keeping the sensor with the upper part parallel to the relative horizontal part, carry out a horizontal movement in order to free the protruding part of the sensor from the relative casing of the sensor holder, disengaging thus the hooking system.
4. Always gripping firmly the sensor, in order to avoid accidental falls, it is possible to freely move the sensor to the desired position.

6.3 Switching on the device

Press the green button on the base of the column to switch the system on; the display shows the starting image:

This image will be present for about 1 minute.
After this time the "Ready for X-ray" and the "X-ray emission" LEDs blink two times and on the display will be present the Villa logo.

NOTE:
During this phase, Rotograph EVO D 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:

" CLOSE PANO SENSOR HOLDER "

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

" MACHINE SETTING – Press >0< "

Press key (6)  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:

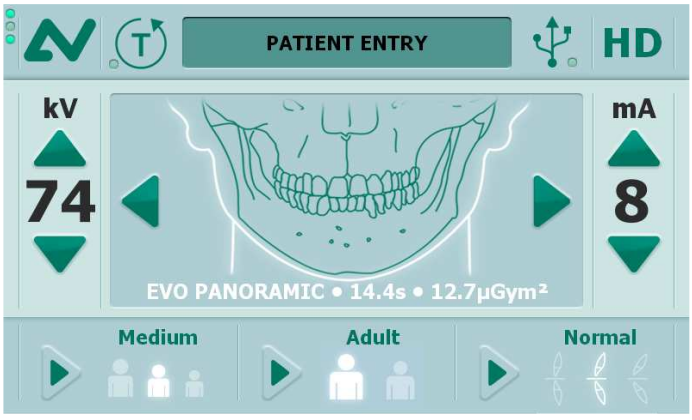
" WAIT FOR MACHINE SETTING "

WARNING:
During this phase, the machine checks for possible obstacles that may create collisions simulating the movements performed during the examination.

After 3 seconds, the following configuration will be automatically set by the system:

- ADULT with the display of the corresponding graphic in the button
- MEDIUM SIZE with the display of the corresponding graphic in the button
- NORMAL DENTITION with the display of the corresponding graphic in the button

and the display shows (for instance):



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.

6.4 Positioning of chin support

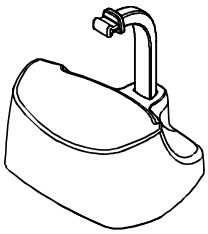
Rotograph EVO D is equipped with three types of supports: a standard support fitted with a special removable appendix for edentulous patients, a lower one for SINUS examinations and a third one, to be used for TMJ examinations.

The standard chin support must be used, in Panoramic mode, with all the people who can assure a tight grip on the 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.

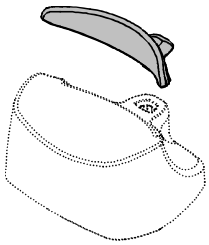
For the SINUS examinations there is special support that, being in a lower position, ensures a better centring of the interested area in the rays field.

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

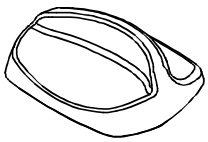
NOTE:
A fourth chin support, at a low height for Panoramic, is provided to ensure a better view of the lower section of the chin for patients with particular anatomy.
This chin support is marked by a down arrow "▼" on the front of the chin support itself.



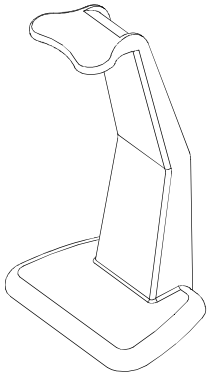
Panoramic standard chin support



Edentulous patients appendix



SINUS chin support



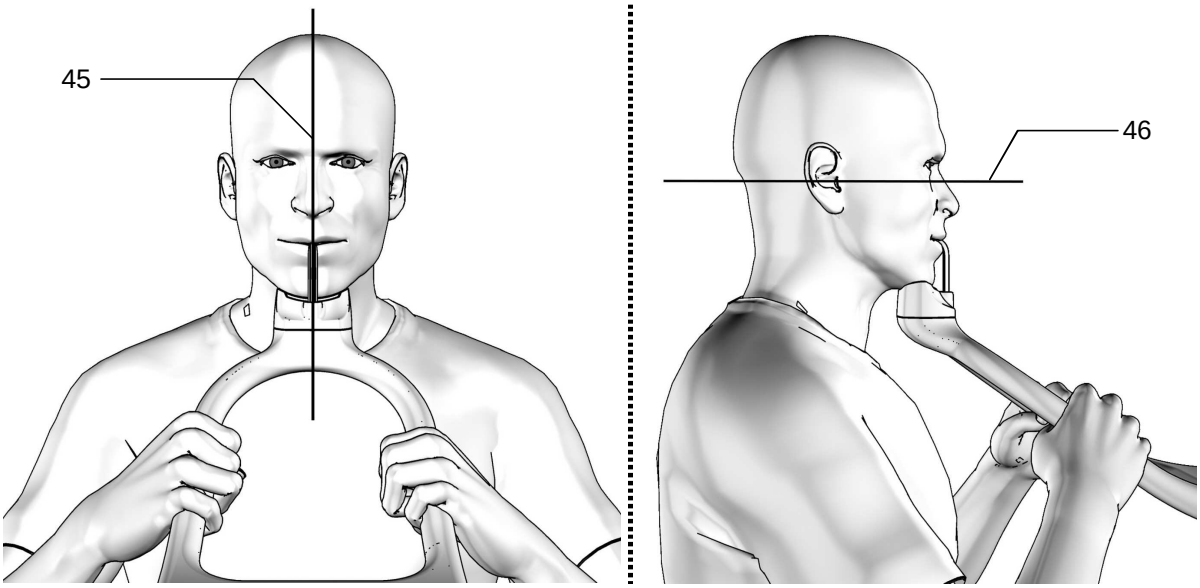
TMJ positioner

NOTE:
For the Implant examination, specific bite blocks are used to position the patient.
Always remove the chin support when performing Ceph examinations.

6.5 Panoramic examination

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

During the examination, the patient's centring is assisted by two linear luminous laser beams, which indicate the position of the sagittal medial plane and the Frankfurt plane; the corresponding patient's planes need to be aligned with these planes. The latter is held in place, during the examination phase, by means of temple clasps rods and of a forehead support. A fourth fixing point is determined by the chin support.



Legend of Reference Lines

45 Mid-Sagittal line

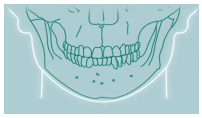
46 Frankfurt plane line: plane that identifies a line that ideally connects the hole in the auricular canal - external auditory meatus - with the bottom edge of the orbital fossa

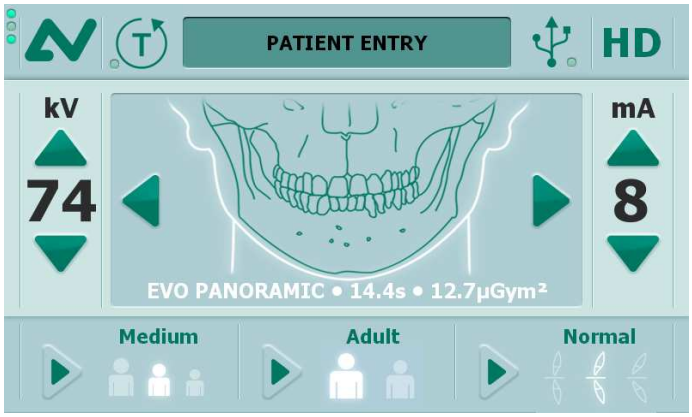
Figure 11

6.5.1 Device preparation

NOTE:
In case of single sensor unit, moving the sensor from CEPH to PAN position, it is necessary to wait about 40 second (LED 20/21 light ON) before to start the device alignment phase pressing key "Patient Entrance" (6)  .

Faster pressure may provide "SENSOR NOT READY" error.

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 "Exam Mode Selection" area (11)  until the following image is displayed:



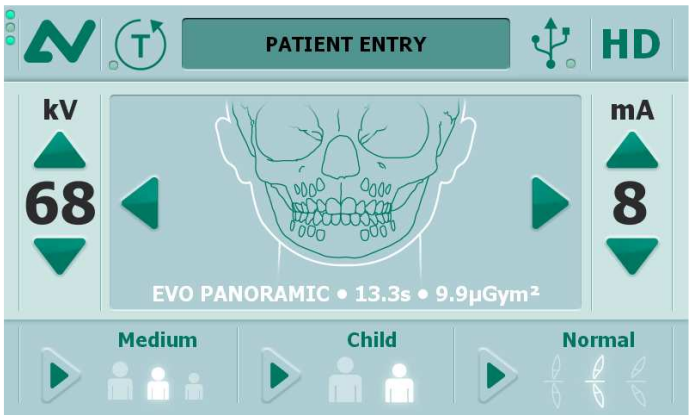
The system positions itself with the following configuration:

- ADULT with the highlight of the corresponding graphic in the button
- MEDIUM SIZE with the highlight of the corresponding graphic in the button
- NORMAL DENTITION with the highlight of the corresponding graphic in the button

and the display shows the default exposure parameters (if this is the first panoramic exposure), or the exposure parameters (kV and mA) of the last exposure performed.

Pressing key (8) 

to change from Adult to Child, the display will show:



Once the settings have been completed, the chin support must be placed in position (see paragraph 6.4).

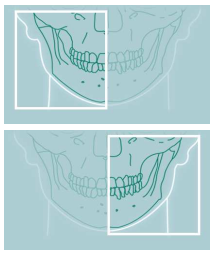
The "Exam Mode Selection" (11) area enables the selection of specific submodes, selectable by means of the keys "Arrow right" (13) and "Arrow left" (12), enabling the sliding in one direction or another.

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.

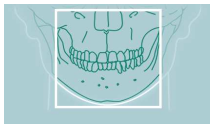
- **Right / Left Emi-panoramic**



The Emi-panoramic mode, right or left, means that only the corresponding half arch is irradiated; the emission will start from the beginning, to just after the mid sagittal plane for the right part. For the left, it will 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.

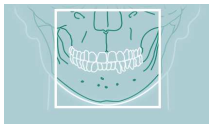
- **Reduced dose Panoramic**



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 is already known.

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

- **Improved orthogonality dentition**

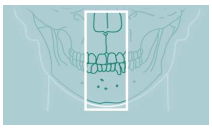


The improved orthogonality Panoramic delivers the image of the pure dental arch cutting out from the image the ascending rami branches of the temporo mandibular joint; the trajectory of the rotating arms is, however, optimised for a better orthogonality between the X-ray beam and the incident sections 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 the patient positioning for this examination needs more care.

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

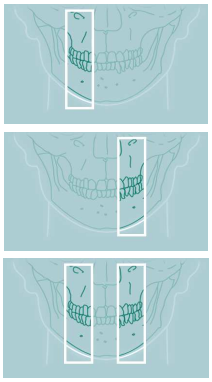
- **Frontal dentition**



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, allows 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.

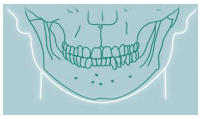
To position the patient, follow the instructions given for the Panoramic examination.

NOTE:
Rotograph EVO D is based on a standard dentition and ascending rami shape.
This shape, based on statistic study, establishes a form for the dentomaxillofacial complex that it is assumed as "standard".
Rotograph EVO D 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 RADIOGRAPHY IMAGES CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE IMAGE.

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 Panoramic examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 6.5 mm (in the centre of the focus layer).

6.5.2 Anatomic / manual exposure

NOTE:
If the previous exam was carried out manually, just press the "Exam Mode Selection" area (11)  to change to Anatomic exposure.

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 mode, the kV and mA parameters values are displayed in green color.

It is possible to press key (8) 

to change from Adult to Child and press key (10) 

to modify the type of biting from Normal to Protruded to Retracted; the setted parameters values remain the same.

6.5.2.1 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 tables.

Exposure values in Panoramic mode				
	Adult Patient		**Child Patient**	
	kV	**mA**	**kV**	**mA**
Small	70	8	66	8
Medium	74	8	68	8
Large	76	8	70	8

Table 1

Select the type of biting with the arrow 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.

6.5.2.2 Manual exposure

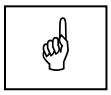
If the kV and mA combinations of the Table 1 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

To modify the kV or mA values, press any of the increase (3)  or decrease (4)  arrows of the kV or mA parameters; the values change their color from black to green.

A parameter can be modified by pressing the increase key (3) and the decrease key (4)  of that paramenter repeatedly.

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

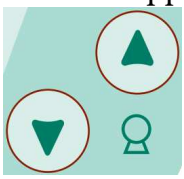
The value of mA can vary between *6 and 10 mA, with 1 mA steps.*



NOTE:
To change the values rapidly, keep the increase key (3) or decrease key (4) pressed.

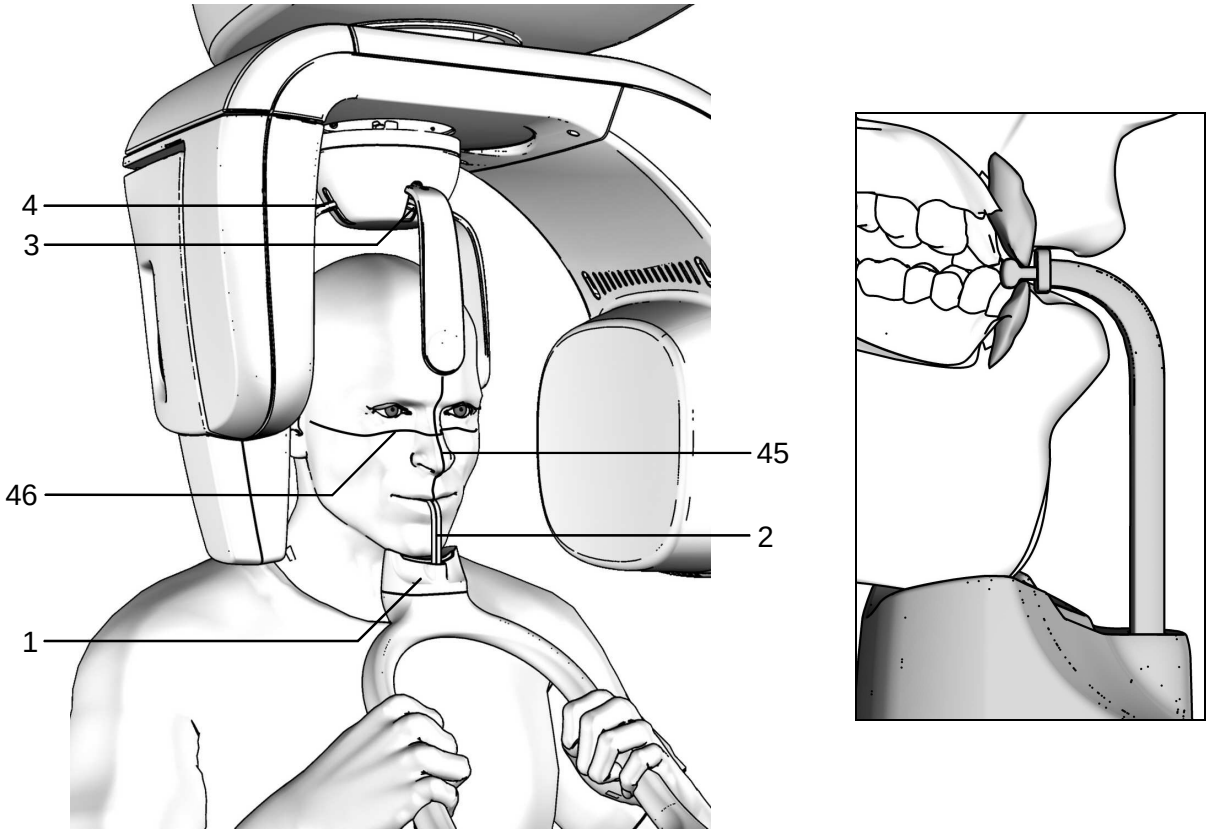
6.5.3 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, removable 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. Position the patient with the temple clasps (Figure 12) ensuring that the chin rests on the special support; the hands should rest on the front handles. Ask the patient to bite the reference notch of the bite with his incisors. In case of edentulous patients, he/she must rest the chin against the reference shoulder of the edentulous chin support.
5. Instruct the patient to close his eyes.
6. Press the key "Centring devices ON" (14)  .

   Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa in Figure 11). 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 can be adjusted by means of the laser knob 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 (6)  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 Forehead support closing/release knob
4 Temple clasps closing/release knob

Figure 12: Panoramic positioning

7. 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.

8. Close the temple clasps (Figure 12) to help the patient keep a correct position; bring also the forehead support close to the patient's forehead and ensure that, in this phase, the patient has not changed position.

9. Press the key "Patient Entrance" (6)  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:

" EXAM INIT "

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

10. 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.

6.5.4 Making an exposure

NOTE:

When the key "Test" (5) 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 the 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 6.5.2.2; ensure that the machine's indicator light "Ready for X-rays" will come on, so press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the X-ray indicator light "X-rays emission" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

" PRE-HEATING "

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

" X-RAY "

NOTE:

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

" TEST X-RAY NOT ACTIVE "

NOTE:
If message:

" DIGITAL SENSOR IS NOT READY "

is present on the display, it means that the Digital Sensor is not properly inserted or configured.
If message:

" ERROR NO MEDIA ACQ VERIFIED "

is present on the display, it means that none of the possible acquisition media (virtual keyboard on the PC or USB Pen Drive) is enable.
LEDs 19 and 20 or 21 (Figure 10) indicate the status of connection.

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

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. **Since the X-ray button is a "dead man's switch", it must be kept 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:

" PATIENT EXIT – Press >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 clasp group, to avoid having to reposition him. Press the "Patient Entrance" (6) key  to return the unit to its initial 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" (6)  , the unit will move back to the starting position showing the message:

" AXIS POSITIONING PLEASE WAIT... "

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

NOTE:
If you try to perform a new exam before the cooling period has elapsed, the following message will be displayed indicating the time to wait before performing a new examination:

" TUBE COOLING... PLEASE WAIT: xxx s "

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

WARNING:
After every examination, clean the chin support, the handles and the temple clasps group thoroughly and change the centring bite or the bite protective sleeve.

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:

" ERROR: 206 PRESS >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 has to be made with great care in order to prevent damage to the machine**.

Then press the "Patient Entrance" (6) key and  the display will show:

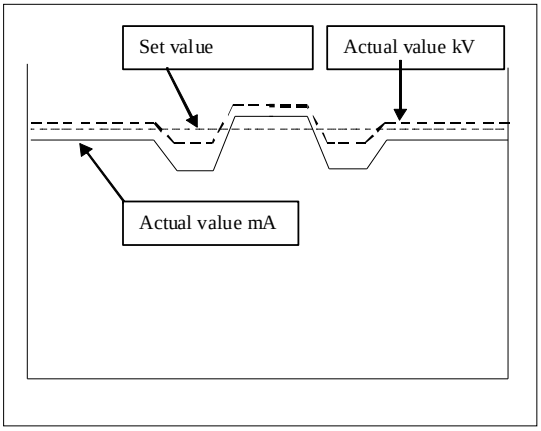
" MACHINE SETTING – Press >0< "

and then:

" WAIT FOR MACHINE SETTING "

The system now returns to its initial position and the patient must be repositioned.

NOTE:
During the Panoramic, the value of the exposure 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 in 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 always within the limits set by the international standards for the safety of medical devices, IEC 60601-1. In particular, in accordance with IEC 60601-2-7, the maximum deviation (including the correction according to the above curve and instrumental doubt) is within ±10% for the kV, while for the tube current it is within ± 15%.

6.6 TMJ examination

The TMJ examination 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 13 shows the information related to the single sectors.

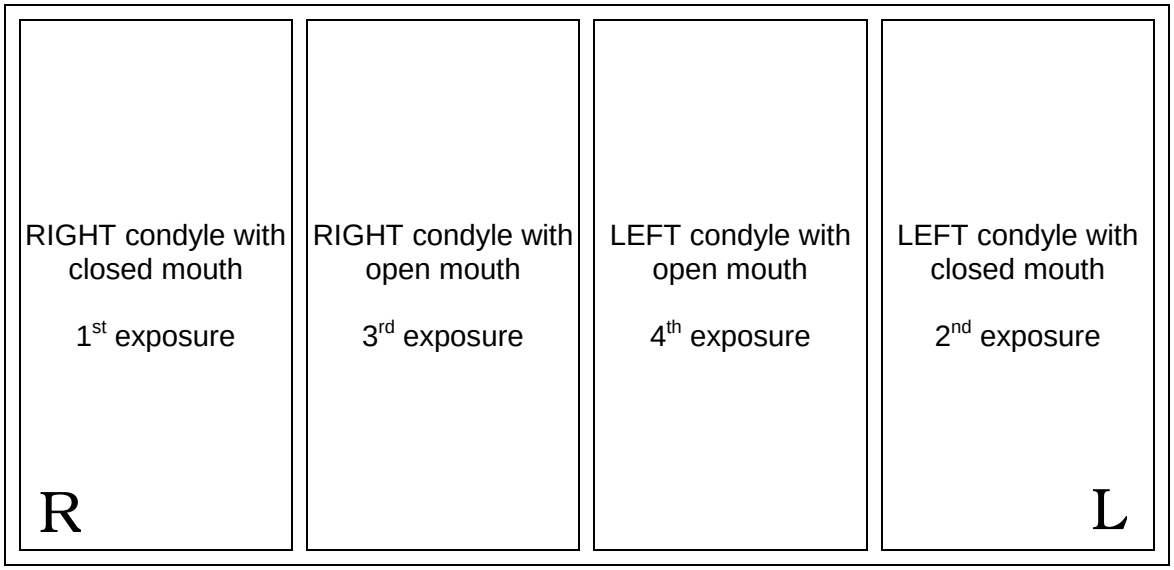


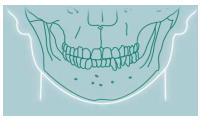
Figure 13

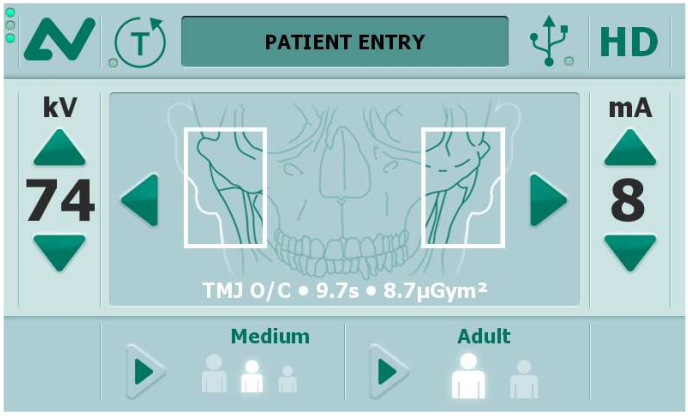
NOTE:
During the TMJ examination, the emission of X-rays is intermittent (it is interrupted during the transition phases between the various exposures), but it is necessary to keep the X-ray button pressed for the whole rotation time.
Do not release the X-ray button during the emission interruption if 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.

6.6.1 Preparation of the device

NOTE:
In case of single sensor unit, moving the sensor from CEPH to PAN position, it is necessary to wait about 40 second (LED 20/21 light ON) before to start the device alignment phase pressing key "Patient Entrance" (6)  .

Faster pressure may provide "SENSOR NOT READY" error.

To select the TMJ examination, press "Exam Mode Selection" area (11)  until the following image is displayed:



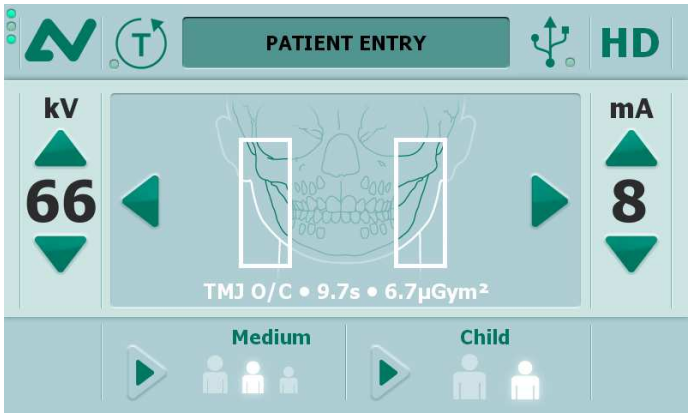
The system is positioned in the following configuration:

- ADULT with the highlight of the corresponding graphic in the button
- MEDIUM SIZE with the highlight of the corresponding graphic in the button

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.

Pressing key (8) 

to change from Adult to Child, the display will show:



Once the settings have been completed, the chin support must be placed in position if it has been removed (see paragraph 6.4).

NOTE:
Rotograph EVO D is based on a standard dentition and ascending rami shape.
This shape, based on statistical data, establishes a standard shape for the dentomaxillofacial complex, defining also the position and the direction 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 RADIOGRAPHY IMAGES 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.
In TMJ examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 6.75 mm (in the centre of the focus layer).

6.6.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the "Exam Mode Selection" area (11)  to change to Anatomic exposure.

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 mode, the kV and mA parameters values are displayed in green color.

It is possible to press key (8) 

to change from Adult to Child, the setted parameters values remain the same.

6.6.2.1 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 the selections made, the display will visualise the kV and mA settings as in the table.

Exposure values in TMJ examination (9.7 sec)				
Examination	**Adult**		**Child**	
TMJ mouth closed/open	**kV**	**mA**	**kV**	**mA**
Small	70	8	62	8
Medium	74	8	66	8
Large	78	8	70	8

Table 2

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

6.6.2.2 Manual exposure

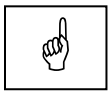
If the kV and mA combinations of the Table 2 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

To modify the kV or mA values, press any of the increase (3)  or decrease (4)  arrows of the kV or mA parameters; the values change their color from black to green.

A parameter can be modified by pressing the increase key (3) and the decrease key (4)  of that parameter repeatedly.

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.*

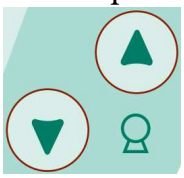


NOTE:
To change the values rapidly, keep the increase key (3) or decrease key (4) pressed.

6.6.3 TMJ closed mouth

6.6.3.1 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, removable 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 TMJ positioner.

   With the keys "Column movement" (15/16)  lift/lower the column until the TMJ positioner is aligned with the patient's nose.
4. Position the patient with the temple clasps (Figure 14) asking him to place his hands on the front support.

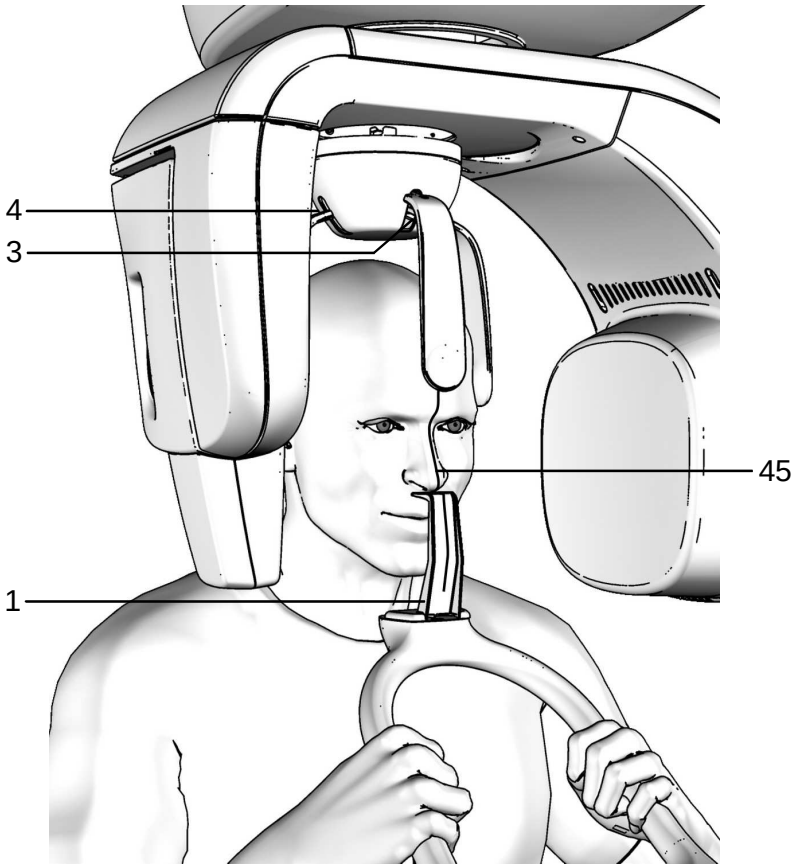


Figure 14 – TMJ closed mouth positioning

Legend of Reference Lines

45 Midsagittal line

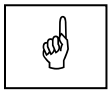
Legend positioning devices and patient centring

1 TMJ positioner
3 Forehead support closing/release knob
4 Temple clasps closing/release knob

5. Instruct the patient to close his eyes.

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

Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa in Figure 11).
Using as reference the sagittale medial plane laser, position the patient's head in such a way that the sagittal medial plane is lit by the corresponding laser beam as in Figure 14.
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 eighter 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 (6)  to begin preparation for exposure.

7. Close the temple clasps and bring the forehead support close; this will help the patient to stay in a correct position. Check that, during this phase, the patient has not changed position.

8. Press the key "Patient Entrance" (6)  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:

" EXAM INIT "

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

9. **Ask the patient to: keep the lips closed, keep perfectly still and do not look at the rotating arm during the movements.**

6.6.3.2 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; it is possible,

by pressing the key "Test" (5)  , to activate the Test function.

In this condition, it will be possible to make the machine perform all the movements made during the examination, but **without emitting 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 the key again.

1. Check once again that the exposure data are correct. If not, correct them as described in paragraph 6.6.2.2. ensure that the machine's indicator light "Ready for X-ray" will come on, so press the X-ray button for the entire duration of the exposure, checking the simoltaneous working of the ray indicator light "X-ray emission" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

" PRE-HEATING "

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

" X-RAY "

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

" TEST X-RAY NOT ACTIVE "

NOTE:
If message:

" DIGITAL SENSOR IS NOT READY "

is present on the display, it means that the Digital Sensor is not properly inserted or configured.
If message:

" ERROR NO MEDIA ACQ VERIFIED "

is present on the display, it means that none of the possible acquisition media (virtual keyboard on the PC or USB Pen Drive) is enable.
LEDs 19 and 20 or 21 (Figure 10) indicate the status of connection.

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

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 a "dead man's switch", 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:

" PATIENT EXIT – Press >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 key "Patient Entrance" (6)  . The machine will reposition itself back to the starting position displaying the message:

" PLEASE WAIT... "

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

" INSTRUCT PATIENT TO OPEN MOUTH "

6.6.4 TMJ open mouth

6.6.4.1 Preparation of the patient

1. The patient must be prepared following the operations described in paragraph 6.6.3.1.
The following message will be displayed:

" INSTRUCT PATIENT TO OPEN MOUTH "

2. Press the key "Patient Entrance" (6)  to confirm.

The following message will be displayed:

" PATIENT ENTRY "

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

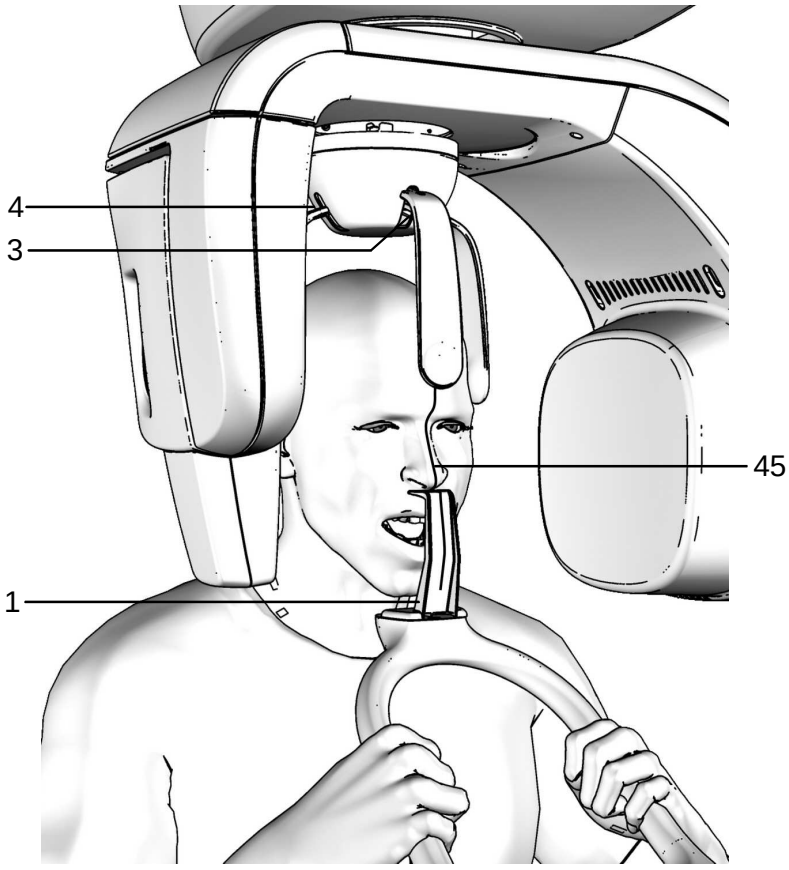


Figure 15 – Open mouth examination positioning

Legend of Reference Lines

45 Midsagittal line

Legend positioning devices and patient centring

1 TMJ positioner
3 Forehead support closing/release knob
4 Temple clasps closing/release knobs

4. Instruct the patient to close his eyes.

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

Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (Figure 11).
Using as reference the sagittal medial plane laser, position the patient's head in such a way that the sagittal medial plane is lit by the corresponding laser beam as in Figure 15.
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 (6)  to begin preparation for exposure.

6. Close the temple clasps and bring the forehead support close; this will help the patient to stay in a correct position. Check that, during this phase, the patient has not changed position.

7. **Advise the patient to remain perfectly still and not look at the rotating arm during the movements.**

6.6.4.2 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 key "Patient Entrance" (6)  . The display will show:

" EXAM INIT "

Check again that the exposure data are correct (see paragraph 6.6.2).

NOTE:
The Adult/Child and Size *small - medium - large* selection keys are deactivated. The exposure parameters can be changed as described in paragraph 6.6.2.

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

" PRE-HEATING "

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

" X-RAY "

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 a "dead man's switche", 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 (sonant and visual) are also suspended.

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

" PATIENT EXIT – Press >0< "

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

3. Press the "Patient Entrance" (6) key  ; the machine will return to the patient entry position and the following message will be displayed:

" AXIS POSITIONING PLEASE WAIT... "

WARNING:
After every examination, clean the TMJ positioner, the handles and the temple clasps group thoroughly and change the protective sleeve if used.

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:

" ERROR: 206 PRESS >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" (6) key and  the display

will show:

" MACHINE SETTING – Press >0< "

and then:

" WAIT FOR MACHINE SETTING "

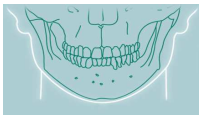
The system now returns to its initial position and the patient must be repositioned.

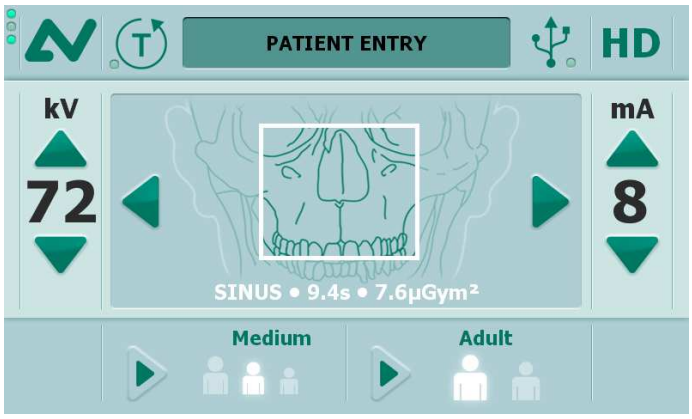
NOTE:
If the open mouth exposure is not completed, the closed mouth exposure must be repeated or the four complete pictures will not appear.

6.7 SINUS examination

NOTE:
In case of single sensor unit, moving the sensor from CEPH to PAN position, it is necessary to wait about 40 second (LED 20/21 light ON) before to start the device alignment phase pressing key "Patient Entrance" (6)  .

Faster pressure may provide "SENSOR NOT READY" error.

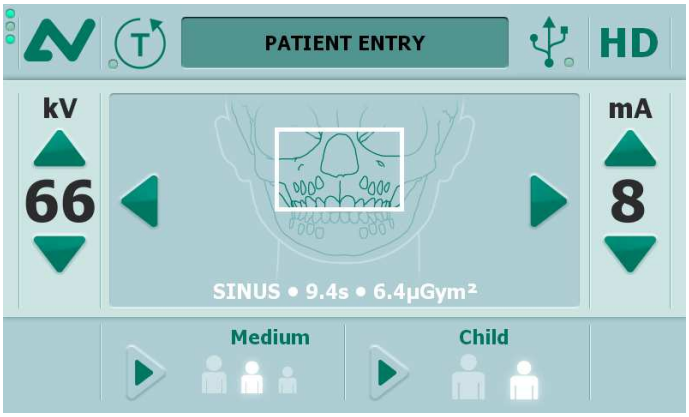
To select the SINUS examination, press "Exam Mode Selection" area (11)  until the following image is displayed:



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

Pressing key (8) 

to change from Adult to Child, the display will show:



NOTE:
Rotograph EVO D is based on a standard dentition and ascending rami shape.
This shape, based on statistical data, establishes a standard shape for the dentomaxillofacial complex, defining also the position and the direction 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 RADIOGRAPHY IMAGES 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.
In SINUS examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 6.6 mm (in the centre of the focus layer).

6.7.1 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the "Exam Mode Selection" area (11)  to change to Anatomic exposure.

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 mode, the kV and mA parameters values are displayed in green color.

It is possible to press key (8) 

to change from Adult to Child; the setted parameters values remain the same.

6.7.1.1 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 values in SINUS examination (9.4 sec)				
	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	68	8	64	8
Medium	72	8	66	8
Large	74	8	68	8

Table 3

6.7.1.2 Manual exposure

If the kV and mA combinations of the Table 3 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 any of the increase (3)  or decrease (4)  arrows of the kV or mA parameters; the values change their color from black to green.

A parameter can be modified by pressing the increase key (3) and the decrease key (4)  of that parameter repeatedly.

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 (3) or decrease key (4) pressed.

6.7.2 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, removable 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 SINUS chin support.

   With the keys "Column movement" (15/16)  raise/lower the column until the chin support rest is aligned with the patient's chin.
4. Position the patient with the temple clasps (Figure 16) ensuring that the chin rests on the special support; ask the patient to place his hands on the front supports. Ensure that the patient rests his chin on the chin support for SINUS.

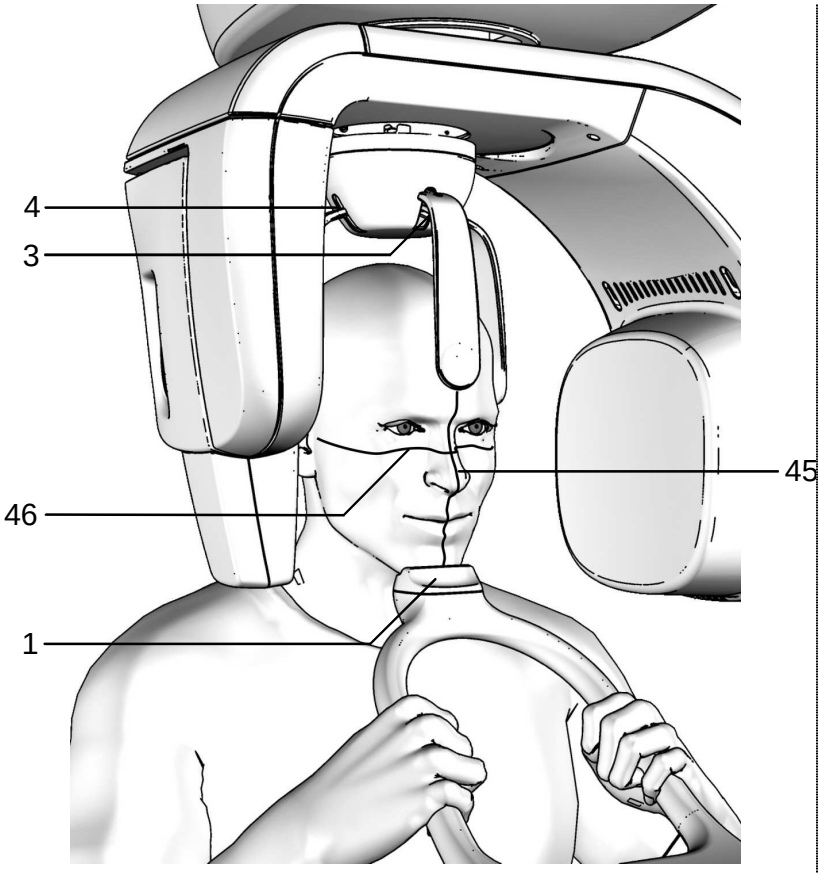


Figure 16 – SINUS positioning

Legend of Reference Lines

45 Midsagittal line
46 Frankfurt plane line

Legend positioning devices and patient centring

1 SINUS support
3 Forehead support closing/release knob
4 Temple clasps closing/release knob

5. Instruct the patient to close his eyes.

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

   Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa in Figure 11). Position the patient's head in such a way as to ensure that the first two 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 can be adjusted by means of the laser knob 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 (6)  to begin preparation for exposure.

---

7. Close the temple clasps and bring the forehead support close; this will help the patient to stay in a correct position. Check that, during this phase, the patient has not changed position.

8. Press the key "Patient Entrance" (6)  to confirm.

   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:

   " EXAM INIT "

9. **Ask the patient to: close his mouth, remain perfectly still and not look at the rotating arm during the movement.**

6.7.3 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 interferences with the patient's shoulder during the rotation.
By pressing the key "Test" (5)  , to activate the Test function.

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

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 6.5.2.2; ensure that the machine's indicator light "Ready for X-ray" will come on, so press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the ray indicator light "X-ray emission" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

" PRE-HEATING "

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

" X-RAY "

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

" TEST X-RAY NOT ACTIVE "

NOTE:
If message:

" DIGITAL SENSOR IS NOT READY "

is present on the display, it means that the Digital Sensor is not properly inserted or configured.
If message:

" ERROR NO MEDIA ACQ VERIFIED "

is present on the display, it means that none of the possible acquisition media (virtual keyboard on the PC or USB Pen Drive) is enable.
LEDs 19 and 20 or 21 (Figure 10) indicate the status of connection.

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

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 a "dead man's switch", 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 (sonant and visual) are also suspended.

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

" PATIENT EXIT – Press >0< "

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

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

" AXIS POSITIONING PLEASE WAIT... "

At the end, the following message is displayed:

" PATIENT ENTRY "

A new exposure can now be made.

NOTE:
If you try to perform a new exam before the cooling period has elapsed, the following message will be displayed indicating the time to wait before performing a new examination:

" TUBE COOLING... PLEASE WAIT: xxx s "

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

WARNING:
After every examination, clean the chin support, the handles and the temple clasps group thoroughly.

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:

" ERROR: 206 PRESS >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" (6) key and  the display

will show:

" MACHINE SETTING – Press >0< "

and then:

" WAIT FOR MACHINE SETTING "

The system now returns to its initial position and the patient must be repositioned.

6.8 IMPLANT examination

The Implant package for Rotograph EVO D is a valuable tool for taking transversals cross sections of the dental arch for preliminary Implant evaluation and follow up.
Essential requirements for a tomographic examination in the surgical planning phase are to correctly determine the available space for Implant; these requirements comprise the lingual and vestibular contour, bone thickness on the point of interest, position of the floor of the maxillary sinus or the distance between the alveolar crest and the upper board of the mandibular canal. All these structure are not adequately visualised using a standard panoramic or periapicals radiographs.
An additional advantage of linear tomography is that the dose is reduced, compared to the standard CT examination.

NOTE:
The presence of radio-opaque material close to the area under examination may generate artifacts which make a good diagnosis difficult.

The Implant examination is made by three transversal layers displayed on the same image: one in the theoretical centre of the dental element and two others at a distance of 4 mm from the center for incisors and canine and 6 mm for premolars and molars. The first slice of the image is taken on the back of tooth of interest, the second is centered on tooth of interest the third on the front of the tooth of interest (Figure 17).

On these images, considering the constant magnification factor (+132%), it is possible to obtain the real values of anatomical parts allowing you to evaluate all the relevant dimensions of the jaw (height and bone thickness).
The thickness of the focus layer is 4mm for incisors/canine and 5mm for molars/premolars.

WARNING:
The measurement of lengths on digital images depends on the specific space calibration of the program used.
It is therefore very important to check the space calibration of the program.
In IMPLANT examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 6.14 mm (in the centre of the focus layer).

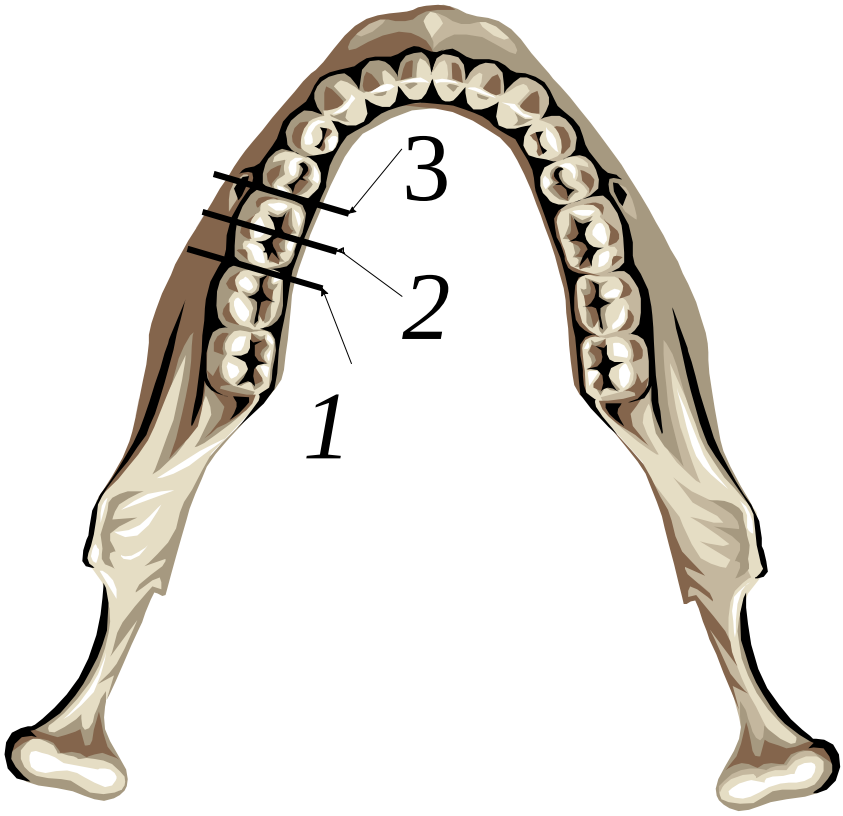
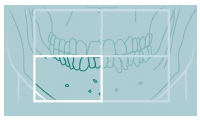


Figure 17

Please refer to paragraph 6.8.7 to have suggestions on how to view images and their correct interpretation (please refer to Figure 21 and following).

6.8.1 Anatomical parameters

The point of interest is based on the statistical model of the dental arch. By default the touch screen is set to the standard European mode number teeth.
The first digit defines the quadrant (from 1 to 4) while the second digit identifies the tooth itself, from 1 to 8.

The quadrant is selected pressing "Exam Mode Selection" area (11)  ; the tooth number is selected by means of the keys "Arrow right" (13) and "Arrow left" (12)  .

In the set up menu, the tooth number ID can be changed to American standard, which is based on a different method. In Figure 18 both European and American standard numberings are provided.

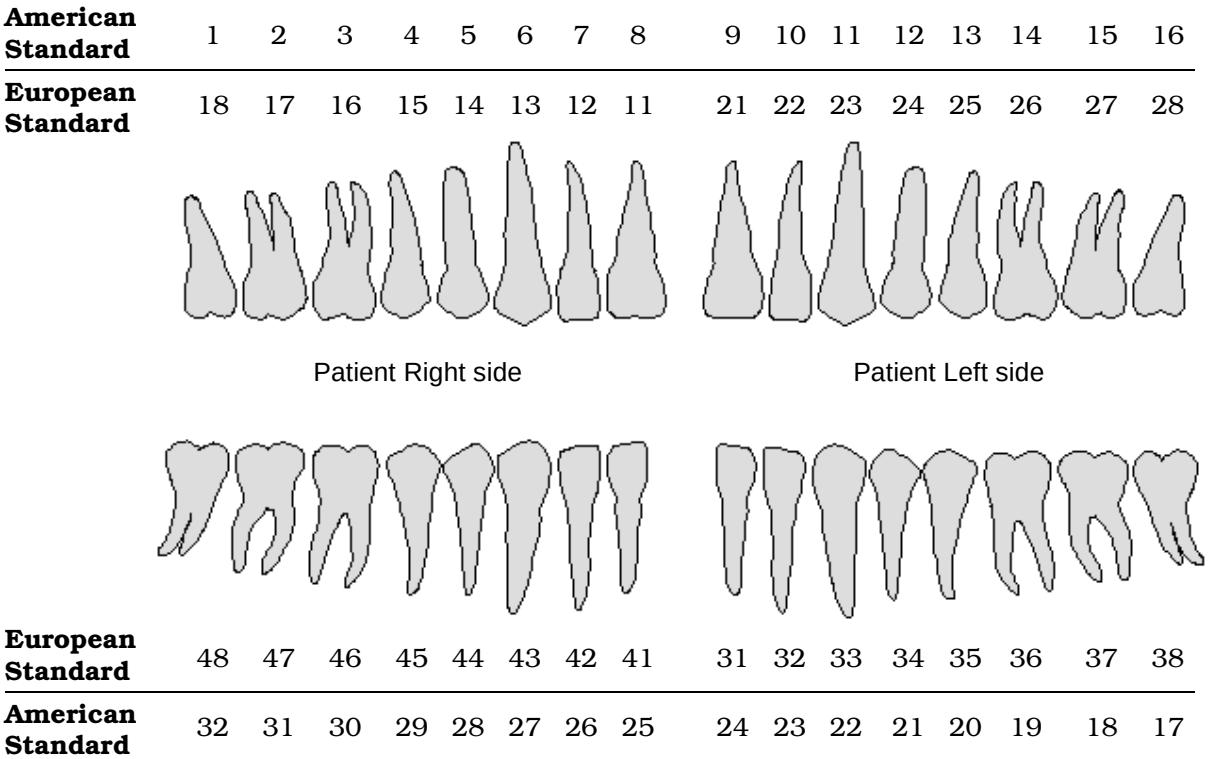


Figure 18

The linear tomography implemented on Rotograph EVO D is based on a statistical model of dental arch, as defined in international literature. However, it must be considered that the natural deviation from the model due to the individual variability can lead to the possibility that the point of interest may be not perfectly centered on the middle of the images. During the patient positioning, the use of the sagittal medial plane laser lead the operator to the correct centering of the poit of interest.

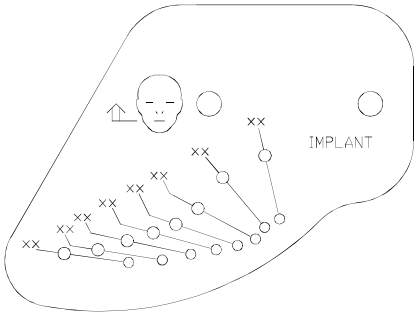
6.8.2 Implant Bite Block set-up

To perform the implant mode, Rotograph EVO D is delivered with two special "Implant bite blocks", used to hold the patient on the point of interest: the first bite block is used for the maxilla while the second one is used for mandible (for simplicity, they will be referred to as: maxilla implant bite block and mandible implant bite block).

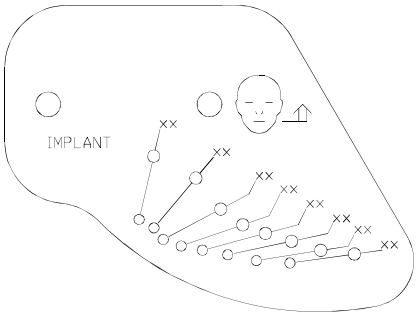
Three parts make up both devices: a metal plate (base), a support and a bite. Particularly, the mandible implant bite block has been studied to hold the mandibular border horizontal during the examination and for this reason has an angle of 7.5°.
The metal plate has two faces: one for right emi-arch and one for the left emi-arch.
In order to avoid assembling mistakes, the metal plates and the bite supports are designed to allow a correct and univocal positioning.

6.8.2.1 Bite block preparing: Maxilla Implant

1. Insert the bite in the relevant Maxilla bite support; tighten the knob 1 to fix the bite at the maximum height.
2. Select the desired metal place face according to the Figures below.
3. Select the bite support position according to the tooth under examination; insert it and tighten knob 2.



Right emi-arch face



Left emi-arch face

xx = Tooth number according to reference standard FDI or US

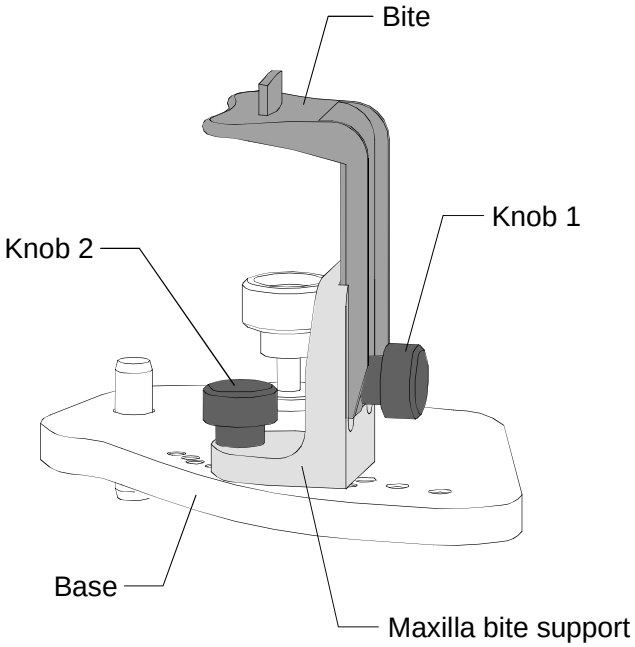
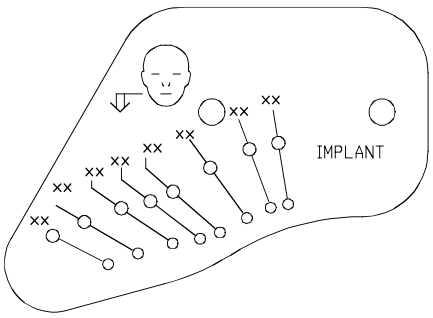


Figure 19

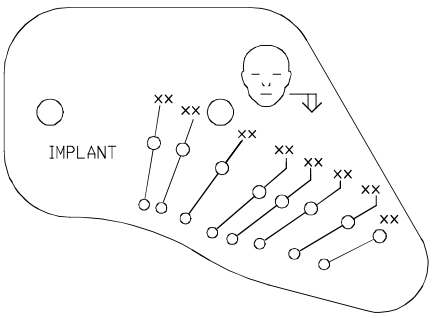
6.8.2.2 Bite block preparing: Mandible Implant

This examination has to be performed with the patient's head inclined in order to keep the mandible border in the point of interest as horizontal as possible; in this way, the radiographs will be of better quality and with all the clinical points of interest.

1. Insert the bite in the relevant Maxilla bite support; tighten the knob 1 to fix the bite at the maximum height.
2. Select the desired metal place face according to the Figures below.
3. Select the bite support position according to the tooth under examination; insert it and tighten knob 2.



Right emi-arch face



Left emi-arch face

xx = Tooth number according to reference standard FDI or US

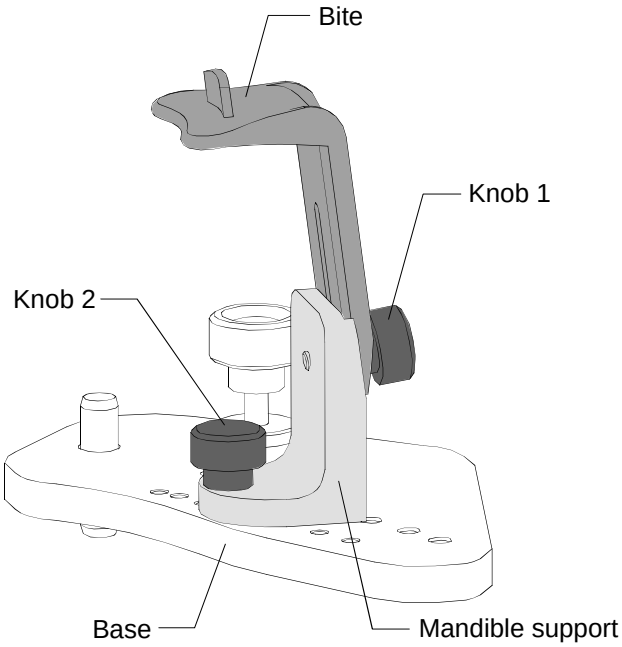
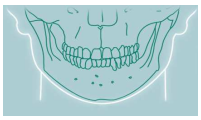


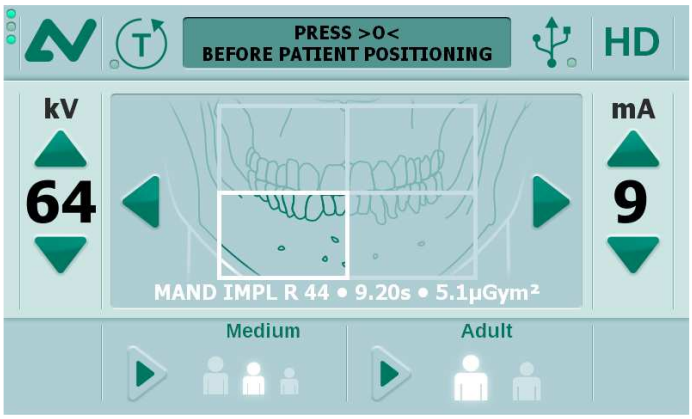
Figure 20

6.8.3 Equipment preparation

NOTE:
In case of single sensor unit, moving the sensor from CEPH to PAN position, it is required to wait about 40 second (LED 20/21 light ON) before starting the device alignment phase pressing key "Patient Entrance" (6)  .

Faster pressure may came up to "SENSOR NOT READY" message.

To select the IMPLANT examination, press "Exam Mode Selection" area (11)  until the following image is displayed:

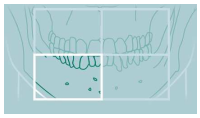


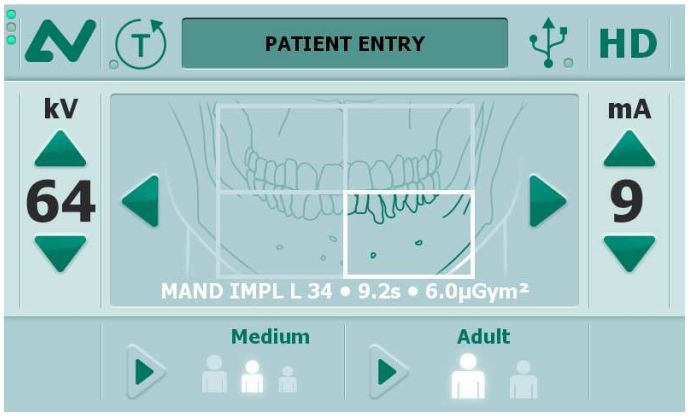
The system is positioned in the following configuration:

- ADULT with the highlight of the corresponding graphic in the button
- MEDIUM SIZE with the highlight of the corresponding graphic in the button
- Mandibular IMPLANT, right arch and 44 as default tooth

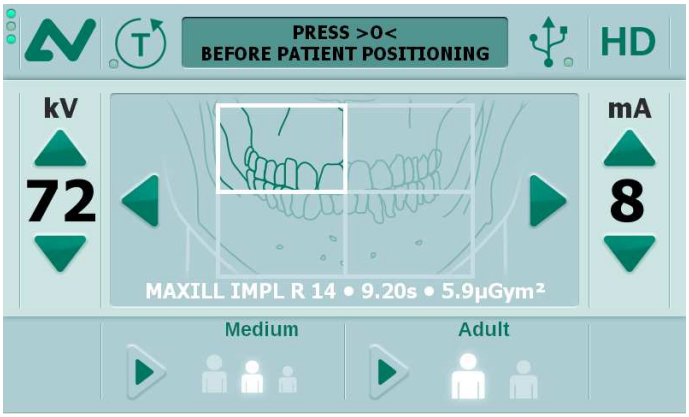
and the display showing the default exposure parameters (if this is the first exposure), or the exposure parameters (kV, mA and tooth) of the last exposure performed.

NOTE:
CHILD selection cannot be performed.

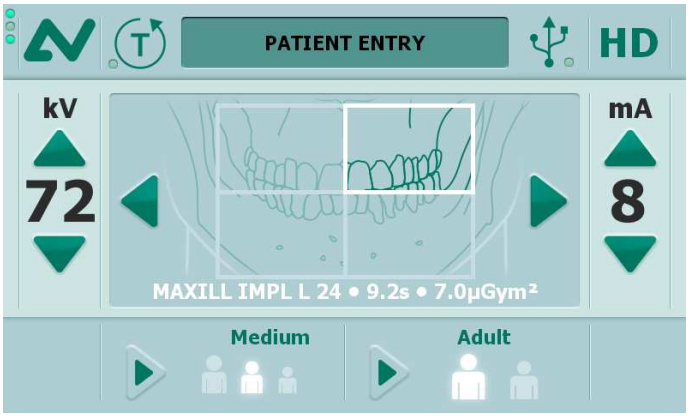
By pressing key "Exam Mode Selection" area (11)  you can pass from mandibular Implant right arch to mandibular IMPLANT left arch; the display will show:



to maxillary Implant right arch; the display will show:



to maxillary Implant left arch; the display will show:



By means of the keys "Arrow right" (13) and "Arrow left" (12) 

select the tooth.
Please note that in anatomic mode kV and mA changes according to the selected teeth.

After this selection, remove the skull clamp assy and the chin support; position the implant bite block chosen according to the maxilla or mandible examination.

NOTE:
In case that values of kV or mA are considered not adequate, it is possible to select a new exposure parameter value, using the method of manual exposure described in paragraph 6.8.4.

Press the "Patient Entrance" (6) key  to confirm; the display will show:

" AXIS POSITIONING PLEASE WAIT... "

At the end, the following message is displayed:

" EXAM INIT "

for left arch selection, or

" PATIENT ENTRY & EXAM INIT"

for right arch selection.

Position the patient as described in paragraph 6.8.5.

NOTE:
If message:

" DIGITAL SENSOR IS NOT READY "

is present on the display, it means that the Digital Sensor is not properly inserted or configured.
If message:

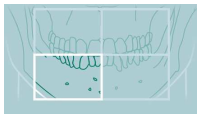
" ERROR NO MEDIA ACQ VERIFIED "

is present on the display, it means that none of the possible acquisition media (virtual keyboard on the PC or USB Pen Drive) is enable.
LEDs 19 and 20 or 21 (Figure 10) indicate the status of connection.

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

NOTE:
Before use, it is mandatory to perform a cold disinfecting of the plastic bite using, for instance, a 2% water solution of Glutaraldehydes according to the instruction for use specified by its manufacturer.

6.8.4 Manual / Anatomic exposure

NOTE:
If the previous exam was carried out manually, just press the "Exam Mode Selection" area (11)  to change to Anatomic exposure.

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 patient's size and the chosen tooth.
- **MANUAL:** with the possibility to vary the kV and mA values already set.

NOTE:
In manual mode, the kV and mA parameters values are displayed in green color.

6.8.4.1 Anatomic exposure

Select the type of build with the **Size** (8) key (*small - medium - large).*

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

6.8.4.2 Manual exposure

If the kV and mA combinations 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 any of the increase (3)  or decrease (4)  arrows of the kV or mA parameters; the values change their color from black to green.

A parameter can be modified by pressing the increase key (3) and the decrease key (4)  of that parameter repeatedly.

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

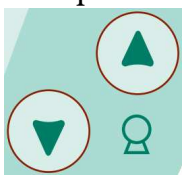
The value of mA can vary between *6 and 10 mA, with 1 mA steps.*

NOTE:
To change the values rapidly, keep the increase key (3) or decrease key (4) pressed.

6.8.5 How to prepare the patient

The patient's preparation is the key factor in order to have diagnostic images, because of the geometrical relations between Rotograph EVO D and the natural individual variability of patients.
The following suggestions must be adapted with the experience and the user radiological skill.

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 no thick garments in the area to be X-rayed such as coats, jackets, ties, etc.
2. Provide the patient with a protective apron or similar protection. Ensure that the protection device does not interfere with the path of the X-ray beam.
3. Place the patient in a standing position at the Implant support.

   With the keys "Column movement" (15/16)  raise/lower the column until the Implant bite is aligned with the patient's mouth.
4. Position the patient asking him to bite with his incisors against the reference notch of the plastic Implant bite block, already prepared following the instructions of paragraphs 6.8.2.1 and 6.8.2.2. The hands should rest on the front supports.
5. Instruct the patient to close his eyes.
6. Press the key "Centring devices ON" (14)  .

   Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa).

   Using as reference the sagittal medial plane laser, position the patient's head in such a way that the relevant tooth is lit by the corresponding laser beam.
   The laser beam of the Frankfurt plane must be adjusted using laser knob on the side of the mirror according to maxilla or mandible examinations as follows:

   - **Maxilla**: position the patient's head in such a way as to ensure that the Frankfurt laser beam fall in correspondence of the respective anatomical references.
   - **Mandible**: using the Frankfurt laser beam, position the head of the patient in such a way as that mandibular border at the point of interest is as horizontal as possible.

NOTE:
The laser centring devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centring Device On" key (14)"  .

7. **Make the following recommendations to the patient: the mouth must remain closed, he/she must remain perfectly still and do not look at the rotating arm during movements.**

6.8.6 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.

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 6.8.4; ensure that the machine's indicator light "Ready for X-ray" will come on, so press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the ray indicator light "X-ray emission" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

   " PRE-HEATING "

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

   " X-RAY "

NOTE:
If message:

" DIGITAL SENSOR IS NOT READY "

is present on the display, it means that the Digital Sensor is not properly inserted or configured.
If message:

" ERROR NO MEDIA ACQ VERIFIED "

is present on the display, it means that none of the possible acquisition media (virtual keyboard on the PC or USB Pen Drive) is enable.
LEDs 19 and 20 or 21 (Figure 10) indicate the status of connection.

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

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.
In addition, during the examination the emission of the X-rays is interrupted and started again more than once, to produce the 3 projections.
It is therefore necessary to keep the X-rays button pressed continuously until the end of the examination because, being a "dead man" type, it is necessary to keep it pressed until the end of the exposure.

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

" PATIENT EXIT – Press >0< "

Release the patient from the working area.

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

" AXIS POSITIONING PLEASE WAIT... "

At the end, the following message is displayed:

" PATIENT ENTRY "

A new exposure can now be made.

NOTE:
If you try to perform a new exam before the cooling period has elapsed, the following message will be displayed indicating the time to wait before performing a new examination:

" TUBE COOLING... PLEASE WAIT: xxx s "

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

WARNING:
After every examination, clean the Implant bite support, the bite and the handles thoroughly and change the protective sleeve if used.

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:

" ERROR: 206 PRESS >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" (6)  key and the display

will show:

" MACHINE SETTING – Press >0< "

and then:

" WAIT FOR MACHINE SETTING "

The system now returns to its initial position and the patient must be repositioned.

6.8.7 Radiographic results

The result obtained at the end of the examination is indicated in Figure 21.

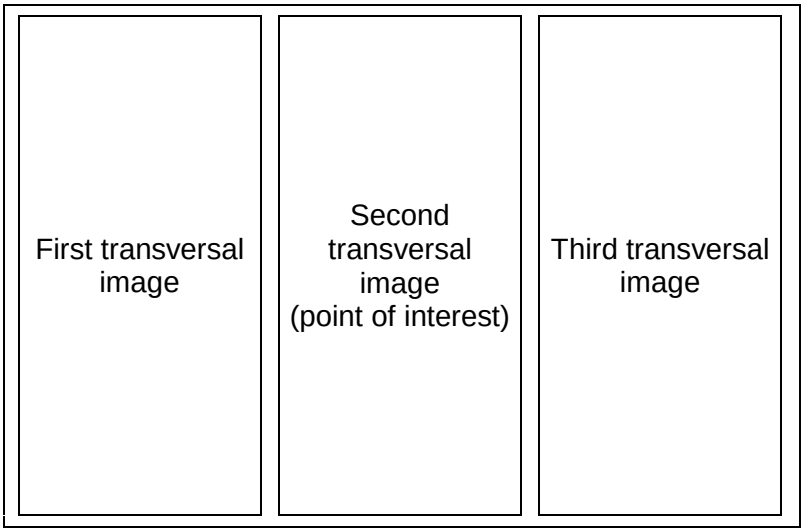


Figure 21: Implant complete exam

WARNING:
All images obtained with the Implant program have a magnification factor of 1.32.

6.8.7.1 Right side tomography (quadrants 1 and 4)

The next three images show the transversal sections, with the vestibular part on the left and the lingual or palatal part on the right (Figure 22).

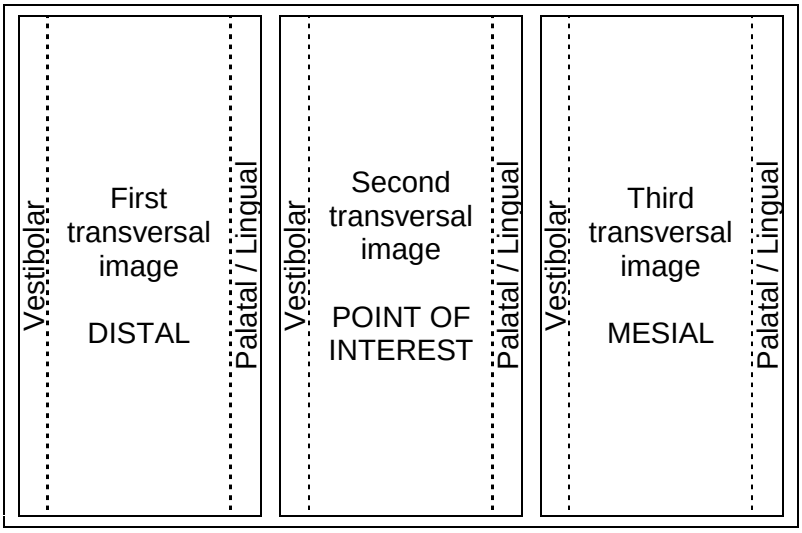


Figure 22

6.8.7.2 Left side tomography (quadrants 2 and 3)

The next three images show the transversal sections, with the lingual or palatal part on the left and the vestibular part on the right (Figure 23).

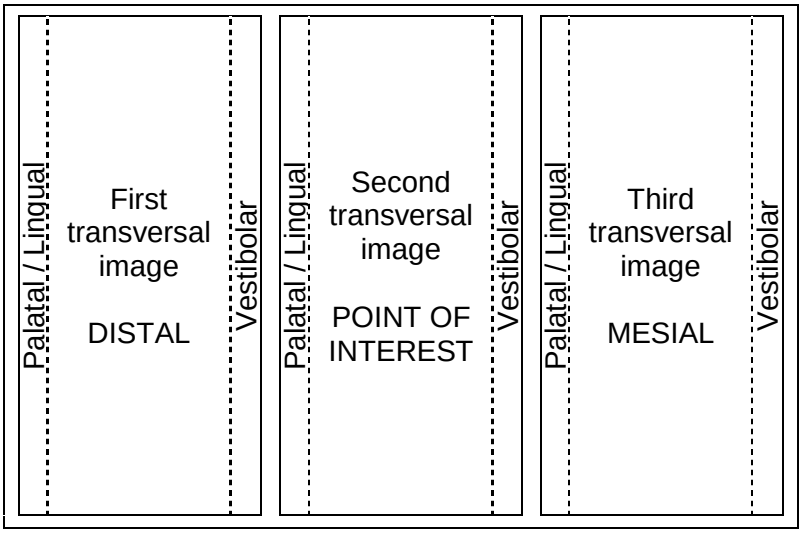
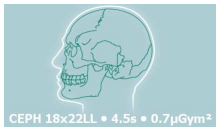
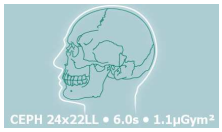
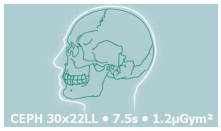


Figure 23

6.9 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. On the basis of the image format selected and the projection chosen, the primary diaphragm will automatically place itself in the correct position, at the same time as the secondary collimator 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 D makes different kinds of exposures, according to the type of selection made:

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

For all these Ceph formats, it is possible to carry out the examination in High Definition (indicated by "HD") or High Speed (Normal Resolution - indicated by "HS").
It also possible to carry out the examination to assess bone growth, following the instructions in paragraph 6.10 below.

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:

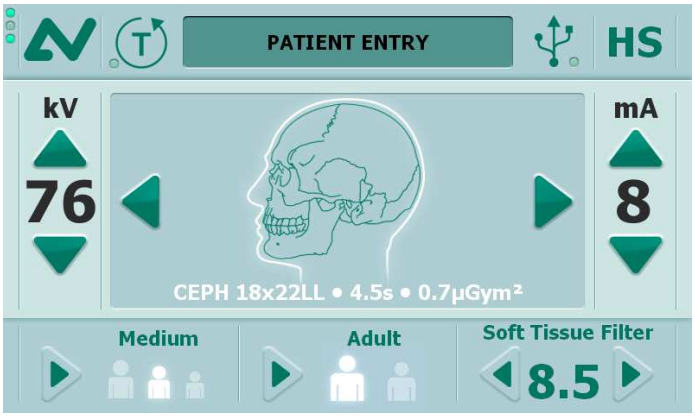
- 100 pixels = 7.36 mm in High Resolution
- 100 pixels = 12.3 mm in Normal Resolution.

6.9.1 Device preparation

NOTE:
In case of single sensor unit, moving the sensor from PAN to CEPH position or viceversa, it is necessary to wait about 40 second (LED 20/21 light ON) before to start the device alignment phase pressing key "Patient Entrance" (6) .

Faster pressure may provide "SENSOR NOT READY" error.

To select the CEPH examination, press "Examination Mode Selection" area (11) until the following image is displayed:



1. Press the "Patient Entrance" (6) key ; the display will show alternatively the following messages:

" REMOVE CHIN REST "

and

" CLOSE TEMPLE SUPPORT "

The first message tells the operator to remove the chin support, while the second message tells him to close the temple clasps. 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 until the "Patient Entrance" (6) key is pressed.

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 clasps must be closed, in order to avoid collision with the rotating arm.

2. Once what was required is performed, press the key "Patient Entrance" (6)  ; messages will disappear and the machine will align automatically with respect to the digital sensor and the following message will be displayed:

" AXIS POSITIONING PLEASE WAIT... "

and then:

" PATIENT ENTRY "

NOTE:
In case of a single sensor unit, if the sensor holder is in PAN position, once the alignment is completed, the following message will be displayed:

" INSERT CEPH SENSOR IN CEPH SENSOR HOLDER "

Move the sensor in CEPH position following instruction in paragraph 6.2 and wait some seconds before to press "Patient Entrance" (6) key.

NOTE:
In case of a double sensor unit, once the alignment is completed, the following message will be displayed:

" OPEN PANO SENSOR HOLDER "

requesting the operator to open the sensor holder for panoramic examination.

NOTE:
The position of the sensor holder for panoramic examination is controlled by two micro-switches, it must therefore be completely opened.

You can pass from High Speed (Normal resolution - indicated by "HS") to High Definition (indicated by "HD"), by pressing key (7) 

and viceversa.

Pressing "Exam Mode Selection" area (11)  the unit will return to EVO PANORAMIC position; the display shows:

" CONFIRM EXIT? Y=Press >0<; N=Press T "

Press the "Patient Entrance" (6) key  to confirm or the "Test" (5) key  to cancel the setting.

NOTE:
With the same image format, the scanning time is lower in Normal Resolution; this allows you to give the patient a smaller dose, yet still obtaining an image of sufficient quality for the orthodontic diagnostics, albeit with a spatial resolution lower compared with that obtained from High Resolution images.

NOTE:
The system is positioned in the following configuration:

- ADULT with the highlight of the corresponding graphic in the button
- MEDIUM SIZE with the highlight of the corresponding graphic in the button.

3. By means of the keys "Arrow right" (13) and "Arrow left" (12)  select the dimensions of the image and the type of projection (see the table at the beginning of the Chapter).

6.9.2 Anatomic / Manual Exposure

NOTE:
If the previous exam was carried out manually, just press the "Exam Mode Selection" area (11)  to change to Anatomic exposure.

After setting the machine accordingly, the following two operating modes may be selected:

- **ANATOMIC:** with the kV and mA values programmed according to the type of patient and size; Soft Tissue Filter in default position
- **MANUAL:** with the possibility of changing the kV, mA and Soft Tissue Filter values set.

NOTE:
In manual mode, the kV and mA parameters values are displayed in green color; it is possible to press key (8) 

to change from Adult to Child; the setted parameters values remain the same.

6.9.2.1 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 tables:

	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	74	8	72	8
Medium	76	8	74	8
Large	78	8	76	8

Table 4: Latero-Lateral projection

	Adult		**Child**	
	kV	**mA**	**kV**	**mA**
Small	76	12	74	12
Medium	78	12	76	12
Large	82	12	78	12

Table 5: Antero-Posterior projection

6.9.2.2 Manual exposure

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

NOTE:
It will be possible to modify manually kV, mA and Soft Tissue Filter position.
The position of the STF has to be adjusted according to the value read on the graduate scale present on the nose rest (Figure 24).

To modify the kV or mA values, press any of the increase (3)  or decrease (4)  arrows of the kV or mA parameters; the values change their color from black to green.

To modify the Soft Tissue Filter value, press the left (decrease)  or right (increase)  arrows of the STF parameter.

A parameter can be modified by pressing the increase arrow and the decrease arrow of that parameter repeatedly.

The "kV" value can vary between *60 and 80 kV, with 2 kV steps.*
The "mA" value can vary between *4 and 12 mA, with 1 mA steps.*
The "Soft Tissue Filter" value can vary between *6 and 10.5 cm, with 0.1 cm steps.*

NOTE:
To change the values rapidly, keep ony of the arrows pressed.

6.9.3 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, removable 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 24) to its maximum span by using the upper part of the rods of the centring device itself. Move the nose rest (Figure 24) away outwardly to its maximum extension. Manually rotate the craniostat group according to the cephalometric projection to be made, moving the upper part of the ear centring device (Figure 24).
4. Position the patient upright near the auricular centring device.

   With the keys "Column movement" (15/16)  lift/lower,

   the column till the centring pins (Figure 24) are close to the ear to clasp the patient's head so that the pivots penetrate the ear (Figure 24) moving the upper part 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.

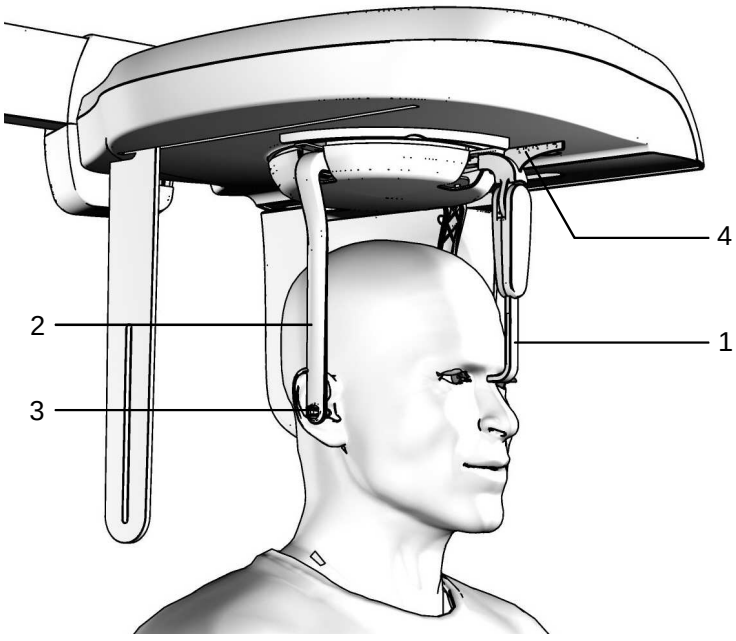


Figure 24

Legend

1 Nose rest
2 Ear centring device
3 Pins for ear centring device
4 Graduated scale

6.9.4 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 6.9.2). 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" (6) key  .

The unit will move into the selected examination start position.
The signalling LED "Ready for X-ray" will light up, indicating that the machine is ready to produce X-rays.

NOTE:
If you want to cancel the operation, press key "Patient Entrance" (6) 

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

" PRE-HEATING "

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

" X-RAY "

NOTE:
If message:

" DIGITAL SENSOR IS NOT READY "

is present on the display, it means that the Digital Sensor is not properly inserted or configured.
If message:

" ERROR NO MEDIA ACQ VERIFIED "

is present on the display, it means that none of the possible acquisition media (virtual keyboard on the PC or USB Pen Drive) is enable.
LEDs 19 and 20 or 21 (Figure 10) indicate the status of connection.

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

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's switch", it must be kept pressed until the end of the exposure.**

3. Once the exposure is completed, the secondary collimator moves into a back resting position, to allow the patient to come out.
The display will again show all the exposure values relating to the exposure just completed.

NOTE:
If you try to perform a new exam before the cooling period has elapsed, the following message will be displayed indicating the time to wait before performing a new examination:

" TUBE COOLING... PLEASE WAIT: xxx 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 the X-ray button immediately, to interrupt the emission of rays.
The following message will be displayed:

" ERROR: 206 PRESS >0< "

Then press the "Patient Entrance" (6) key  .

The system now returns to the position for Ceph exam and the unit starts the procedure for the new examination.

NOTE:
After every examination, clean the ear centring device and temple clasps group thoroughly.

6.10 Examination to assess bone growth (Carpus)

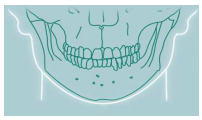
The cephalometric device can also be used to carry out X-rays to evaluate the state of calcification and bone growth, X-raying the hand/wrist complex to obtain an X-ray that contains the anatomic details necessary to evaluate the patient's bone growth trend.
The image format set in order to carry out this examination is 18x22 Symmetric, not adjustable; it is therefore necessary to position the auricular rods and the nose-rest as for the cephalometric Antero-Posterior examination, so that these elements do not interfere with the X-ray trajectory. Refer to Figure 25.

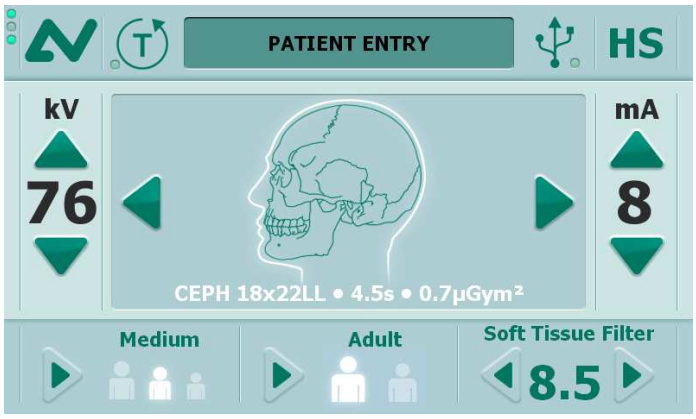
WARNING:
The measurement of lengths on digital images depends on the specific length calibration of the program used.
It is therefore very important to check the length calibration of the program.
In CARPUS examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 7.36 mm.

6.10.1 Preparation of the device

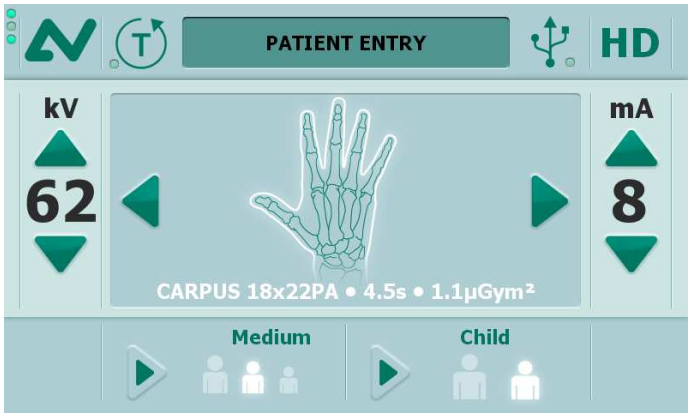
NOTE:
In case of single sensor unit, moving the sensor from PAN to CEPH position, it is necessary to wait about 40 second (LED 20/21 light ON) before to start the device alignment phase pressing key "Patient Entrance" (6)  .

Faster pressure may provide "SENSOR NOT READY" error.

1. Select the CEPH examination, pressing key "Exam Mode Selection" area (11)  until the following image is displayed:



2. By means of the keys "Arrow right" (13) and "Arrow left" (12)  select the CARPUS examination:



3. Press the "Patient Entrance" (6) key  ; the display will show alternatively the following messages:

" REMOVE CHIN REST "

and

" CLOSE TEMPLE SUPPORT "

The first message tells the operator to remove the chin support, while the second message tells him to close the temple clasps.
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 Carpus 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 clasps must be closed, in order to avoid collision with the rotating arm.

4. Once what was required is performed, press the key "Patient Entrance" (6)  ; messages will disappear and the machine will align automatically with respect to the digital sensor and the following message will be displayed:

" AXIS POSITIONING PLEASE WAIT... "

and then:

" PATIENT ENTRY "

NOTE:
In case of a single sensor unit, if the sensor holder is in PAN position, once the alignment is completed, the following message will be displayed:

" INSERT CEPH SENSOR IN CEPH SENSOR HOLDER "

Move the sensor in CEPH position following instruction in paragraph 6.2 and wait some seconds before to press "Patient Entrance" (6) key.

NOTE:
In case of a double sensor unit, once the alignment is completed, the following message will be displayed:

" OPEN PANO SENSOR HOLDER "

requesting the operator to open the sensor holder for panoramic examination.

NOTE:
The position of the sensor holder for panoramic examination is controlled by two micro-switches, it must therefore be completely opened.

Pressing "Exam Mode Selection" area (11)  the unit will return to EVO PANORAMIC position; the display shows:

"CONFIRM EXIT? Y=Press >0< ; N=Press T "

Press the "Patient Entrance" (6) key  to confirm or the "Test" (5) key  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	62	8
Medium	62	8
Large	62	8

Table 6

6.10.2 Preparation of the patient

1. Turn the ear centring device to the Antero-Posterior position; bring the nose-rest to a parking position.
2. Hook up the positioning support for hand projection, by screwing it on the related housings close to the ear centering device. the reference line on the metal positioner must face the sensor.
3. Place the patient slightly to the side of the cephalometry device.
4. Position the patient's hand on the positioning support (Figure 25), so that the hand results between the sensor and the plate itself.
   The support leads the operator to place the body part in the centre of the irradiated area. The horizontal reference line should help the vertical adjustment of the hand.
   The common radiological procedure to assess bone growth in children's, suggests placing the end of the middle finger tangent to the reference line.
   The patient's hand must be fully in contact with the metal plate and it must form a vertical line with the arm, in order to avoid any risk of collision with the sensor during the scanning movement.

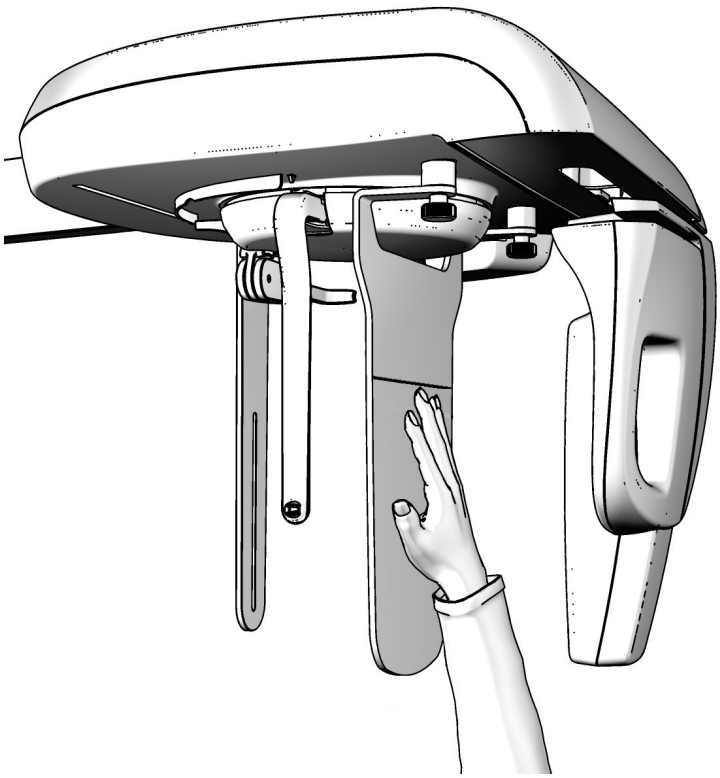


Figure 25

6.10.3 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" (6) key  .

   The unit will move into the selected examination start position.
   The signalling LED "Ready for X-ray" will light up, indicating that the machine is ready to produce X-rays.

NOTE:
If you want to cancel the operation, press key "Patient Entrance" (6) 

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

   " PRE-HEATING "

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

   " X-RAY "

NOTE:
If message:

" DIGITAL SENSOR IS NOT READY "

is present on the display, it means that the Digital Sensor is not properly inserted or configured.
If message:

" ERROR NO MEDIA ACQ VERIFIED "

is present on the display, it means that none of the possible acquisition media (virtual keyboard on the PC or USB Pen Drive) is enable.
LEDs 19 and 20 or 21 (Figure 10) indicate the status of connection.

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

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's switch", it must be kept pressed until the end of the exposure.**

3. Once the exposure is completed, the secondary collimator moves into a backward resting position, to allow the patient to come out.
The display will again show all the exposure values relating to the exposure just completed.

NOTE:
If you try to perform a new exam before the cooling period has elapsed, the following message will be displayed indicating the time to wait before performing a new examination:

" TUBE COOLING... PLEASE WAIT: xxx 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 the X-ray button immediately, to interrupt the emission of rays.
The following message will be displayed:

" ERROR: 206 PRESS >0< "

Then press the "Patient Entrance" (6) key  .

The system now returns to the position for the Ceph exam and the unit starts the procedure for the new examination.

6.11 Messages on display

Rotograph EVO D 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 key "Patient Entrance" (6)  .

The message displayed will be as follows

" ERROR: xxx PRESS >0< "

Operations are reset by pressing key (6)  .

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:

" ERROR: xxx CALL TECH SUPP "

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.

" ERROR: xxx POWER OFF "

Following are reported the different error messages and the relative controls and operations to be performed.

6.11.1 Error message with error code E000 ÷ E199

NOT resettable errors.
These are internal errors of the control system; it is necessary to call the Technical Assistance Service.

6.11.1.1 E110 – Battery fault

This message means that the clock battery is low or fault.
If after power ON, a 90 second cooling time starts, wait until the end of the time; then display will show "**E110 – Press >0<**".
Follow the message shown on the display and perform an examination.
At the end of the examination, power OFF the machine and wait a couple of minutes before powering ON again.

If the message is not yet present, it means that the battery is low. Leave the machine powered ON to recharge it.

If the error does not disappear, call the Technical Assistance Service.

6.11.2 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, it is an actual reversible.

Press the key "Patient Entrance" (6)  to reset the error and to perform the axes centring operation.

For all other cases, call the Technical Assistance Service.

6.11.3 Error message with error code E300 ÷ E399

6.11.3.1 Error message with code error E300 ÷ E303

NOT resettable errors.
These errors are related to the secondary collimator of the Digital CEPH.
Switch off the system and on again, in case of further error message, call the Technical Assistance Service.

6.11.3.2 Error message with code error E320 ÷ E323

NOT resettable errors.
These errors are related to the primary collimator.
Switch off the system and on again, in case of further error message, call the Technical Assistance Service.

6.11.3.3 E340 - Sensor holder not in PAN position

A Panoramic type examination was requested, but the sensor holder does not appear to be closed; close it in the PAN position and press the key "Patient Entrance" (6)  to reset the error condition.

6.11.3.4 E360 / E361 - X-ray button pressed during start up or axis movement

Release the X-ray button if pressed; press the key "Patient Entrance" (6)  to reset the error condition.

If the error does not disappear, call the Technical Assistance Service.

6.11.3.5 E362 - X-ray button released during examination

NOTE:
The X-ray button has the so-called "dead man's switch" 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).

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.

6.11.3.6 E364 / E365 - Sensor connection lost

Release the X-ray button if pressed; press the key "Patient Entrance" (6)  to reset the error condition and repeat the exam procedure.

If the error is still present, switch OFF and ON the unit.
If the error does not disappear, call the Technical Assistance Service.

6.11.4 Error message with error code E400 ÷ E402

NOT resettable errors.
These errors are related to the Soft Tissue Filter of the Digital CEPH. Switch off the system and on again, in case of further error message, call the Technical Assistance Service.

6.11.5 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.

6.11.5.1 E755 – Safety Buckup Timer intervention

This message is signalling that the RX emission has not ended at the correct time, but it has been terminated by the Safety Backup Timer. This hardware device has interrupted the emission, but in any case **power off the system**.

6.11.5.2 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.

6.11.5.3 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 board, which signals a possible failure on the connection of the X-rays button with the board itself.

6.11.6 Error message with error code E850 ÷ E852

These errors signal abnormal situations due to the operator's interface.

6.11.6.1 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.
Release the key and switch ON again the unit. If the problem is still present, call Technical Service.

6.11.6.2 E851 - Column key pressed

This error is displayed in case, when releasing the up/down column key, the movement itself is not completed; pressing any other key interrupts the movement to avoid injuries to the patient.

Press the key "Patient Entrance" (6)  to reset the error condition.

6.11.6.3 E852 - Key "Patient Entrance" pressed during the movement

During the system movement, the control panel is disabled, but

if the key "Patient Entrance" (6) is pressed  the movement is

interrupted. This operation is useful in case a movement anomaly is noticed.

Press the key "Patient Entrance" (6)  to reset the error condition.

6.12 Research and correction of possible defects in dental X-rays

6.12.1 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.	Position the patient correctly, check that he holds the bite with the incisors on the appropriate notch and that the bite holder rod is vertical.
Over-small and blurred incisors.	The patient is not positioned correctly. He is too near the optimal focal plane.	Position the patient correctly, check that he holds the bite with the incisors on the appropriate notch and that the bite holder rod is vertical.
Radiography 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 6.5.3 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 6.5.3 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 6.5.3 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 of the image 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.

6.12.2 Defects due to wrong data setting

Problem	Description	Solution
Light or poorly contrasted image. Over-dark image.	The set kV values are not adequate for the size of the patient.	Try to modify the contrast, using the appropriate commands of the image acquisition/management program; if necessary, repeat the examination, varying the kV and/or the mA. Increase them if the image was too clear, and reduce them if it was too dark. If the error is repeated, call the Technical Service.
Image completely white.	No X-ray emission.	Verify the emission of the X-rays by acoustical and luminous 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 6.9.3 to adjust the position of the "STF".
	A symmetric image format was selected.	Select an asymmetrical image format (which will enable the STF filter).

6.12.3 Defects due to the device

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 sensor (PAN or CEPH) 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.

6.13 Analysis of the problems on the 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).

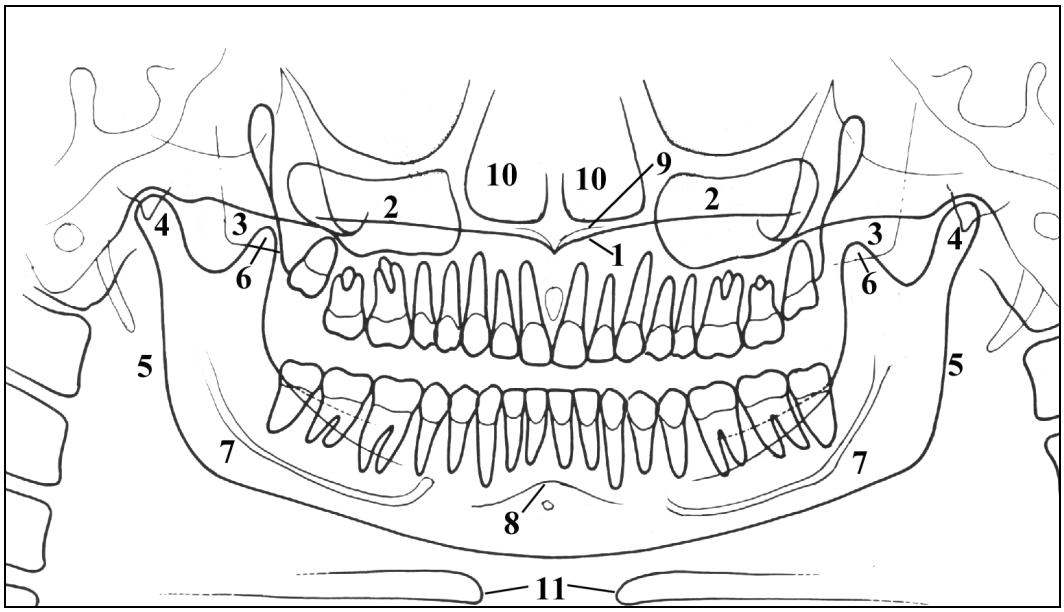


Figure 26

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)*

6.13.1 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.

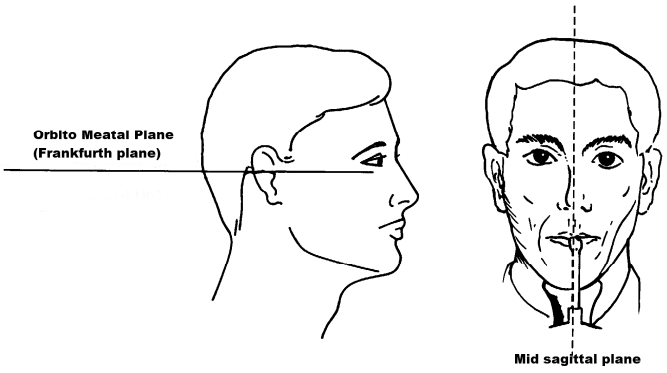


Figure 27

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 a radiography where all the parts are properly exposed and are well identifiable as in the diagram of Figure 28.

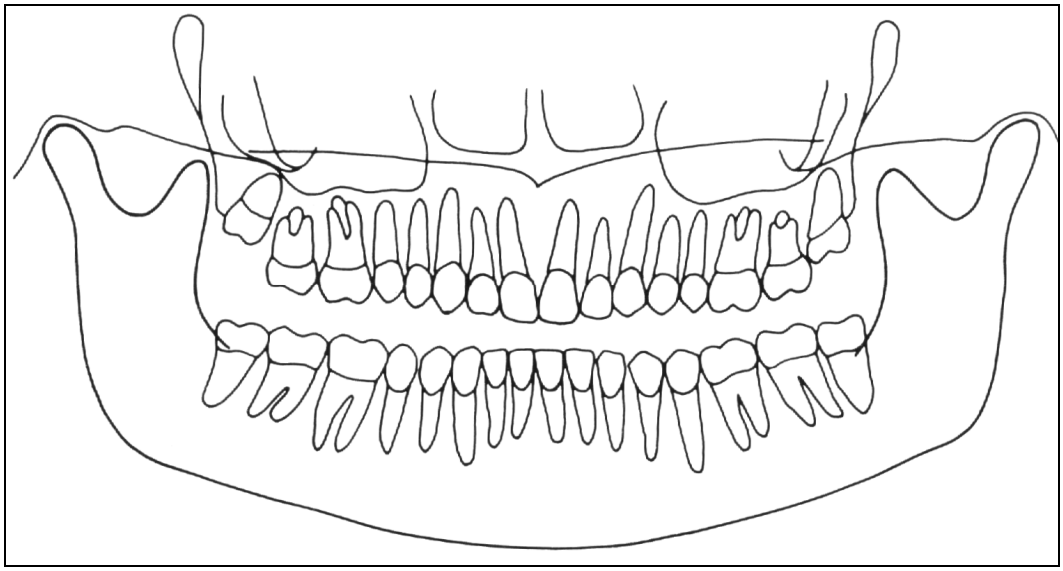


Figure 28

It must be noted that the radiography 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.

6.13.1.1 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 29.

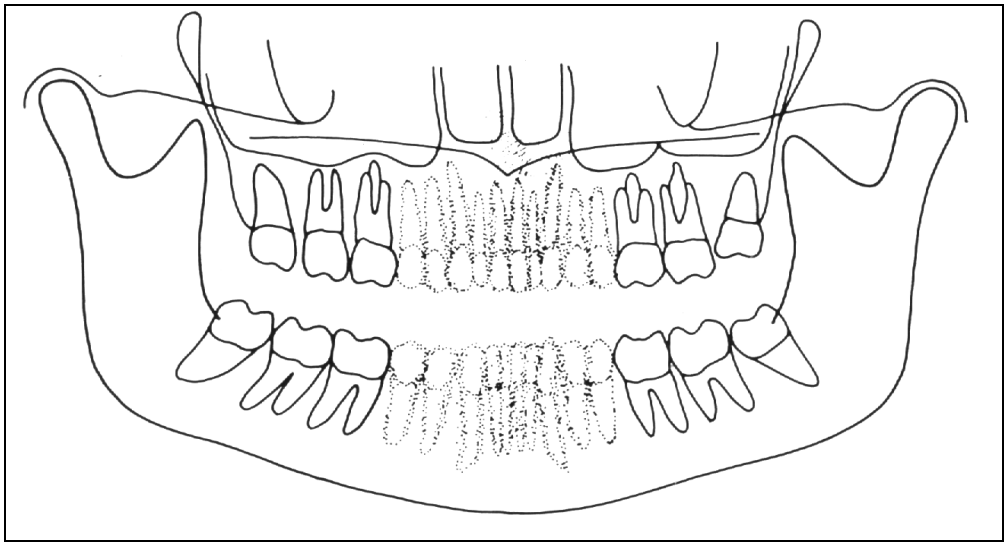


Figure 29

Possible causes:

The patient it positioned too much 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 30 shows the result of this error.

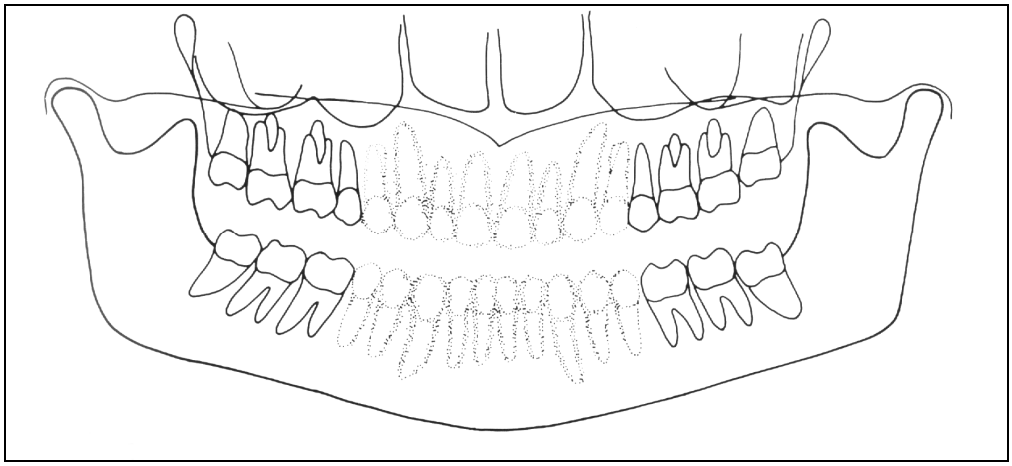


Figure 30

Possible causes:

The patient it positioned too much backward.

Solution:

Check the patient's positioning by using luminous beams.

- **Part of the image is enlarged while the other is reduced**

The schema described on Figure 31 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 X-ray.

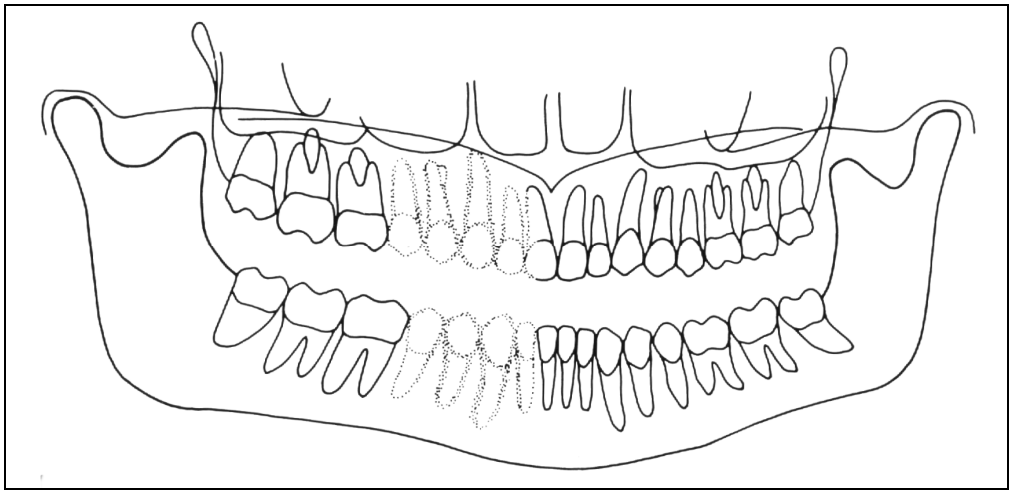
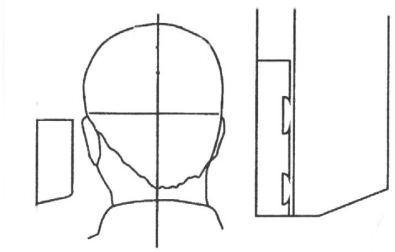


Figure 31

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 31; 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 rest and also on the centre of the bite.

- **The image shows the upper vertex of the condylar rami of different heights;**

  Figure 32 shows the result of this error.

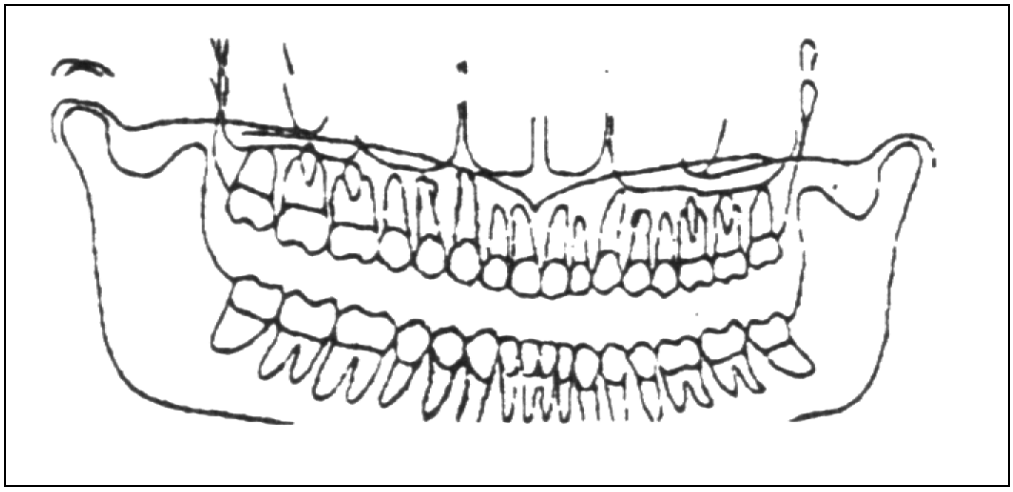


Figure 32

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 horizontality 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 33, 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.

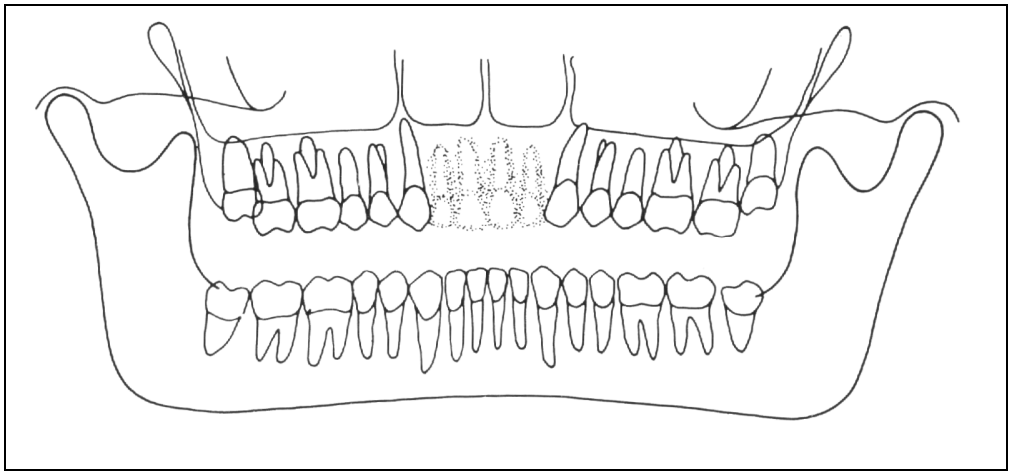


Figure 33

Possible causes:

A Frankfurt plane tilted too much 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 34 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.

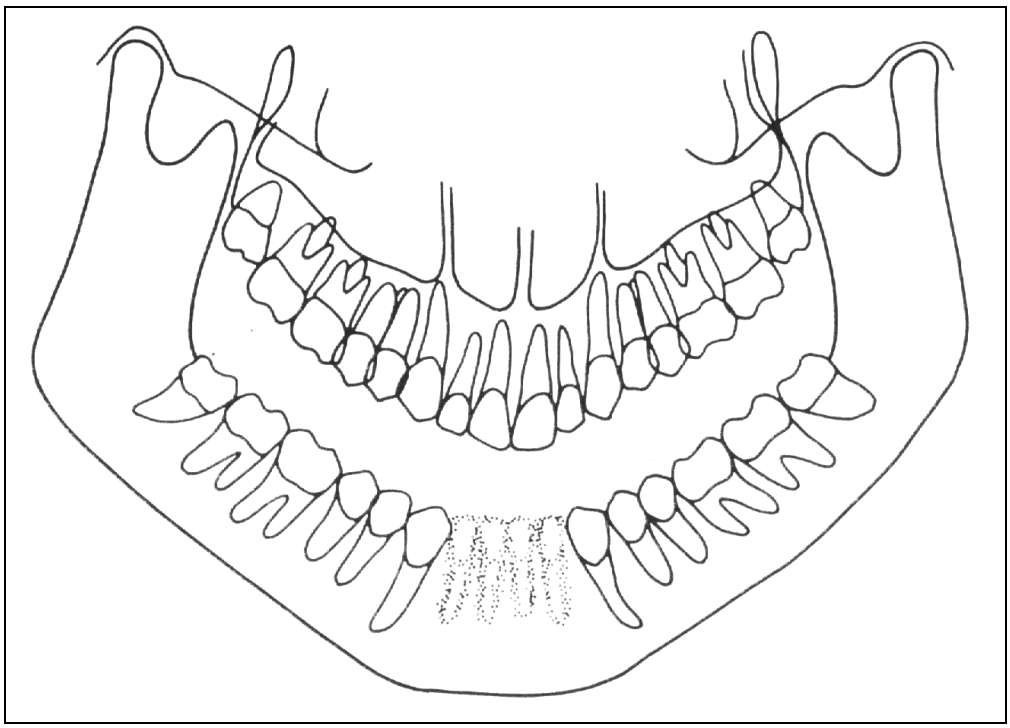


Figure 34

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 upper teeth apex, as shown in Figure 35.

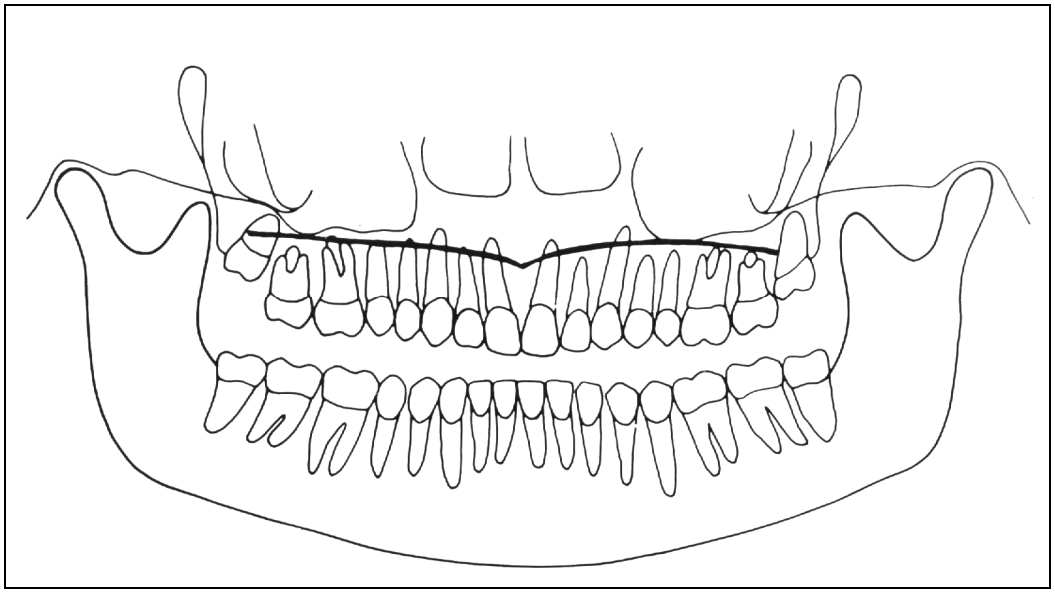


Figure 35

In this case, a light tilting forward and downward of the Frankfurt plane causes the palate to be projected over and far enough from the roots of the teeth of the maxilla arch, without distortion of the incisor teeth, as in Figure 36.

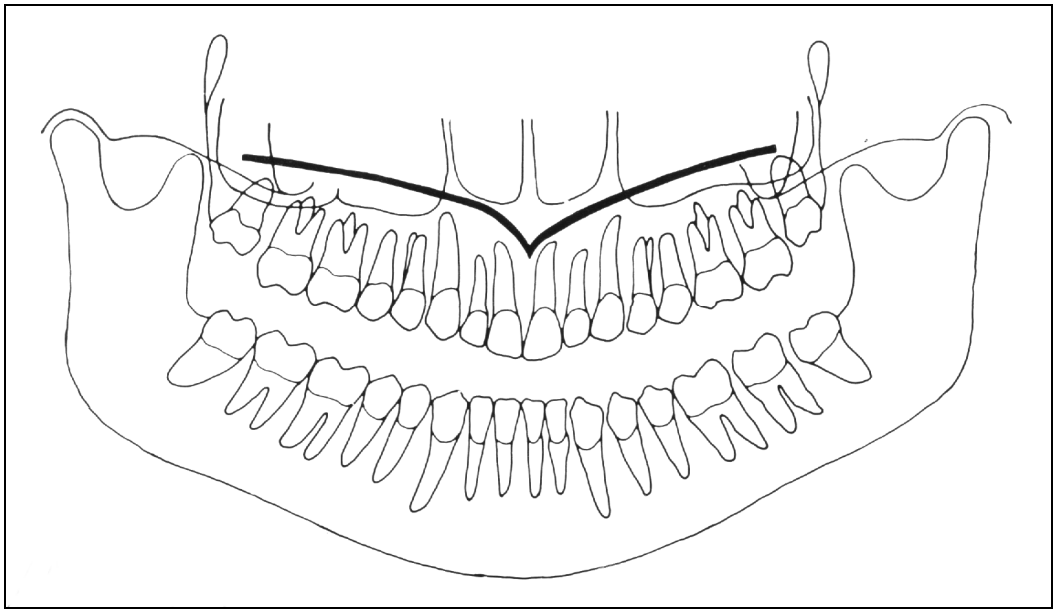


Figure 36

6.13.1.2 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.

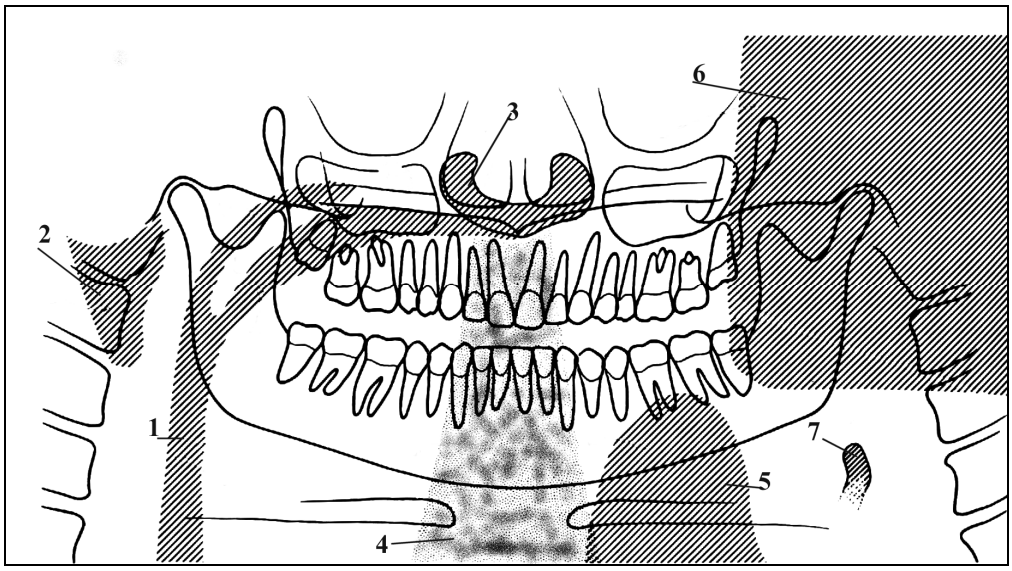


Figure 37

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 37 represents the image of the controlateral 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 37 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 37), 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 X-ray.

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 37 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 37.

  Solution:

  Ask the patient to position his tongue against the palate during the exposure.

6.14 Storing of automatic exposure parameters

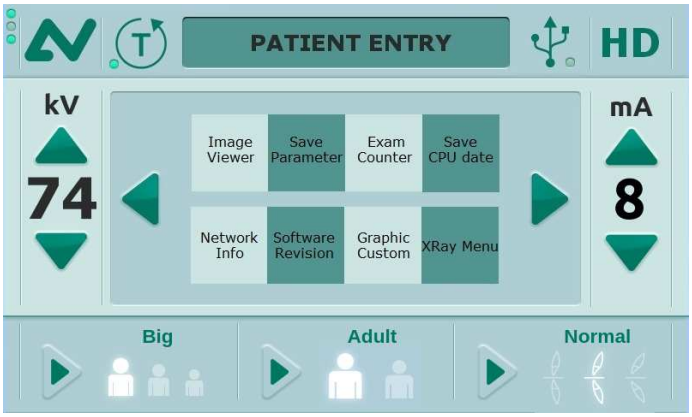
The pre-set technical exposure factors can be varied according to the needs of the user, or the aim for somewhat contrasted images.

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 any of the increase (3)  or decrease (4)  arrows to modify the kV and/or mA parameters to suit your needs; the values change their color from black to green.

3. Press the key "Service Menu" (18)  ; the following image will be displayed:



4. Press the "Save Parameter" key to store the modified parameters for the examination and type and size of patient you have selected.

5. After pressing the key, the display will show the following message:

" SAVE THE NEW PARAMETERS?
Y=PRESS >0<; N=PRESS T "

Press the "Patient Entrance" (6) key  to confirm or the "Test" (5) key  to cancel the setting.

Pressing key (18)  the unit will return to standard mode.

6.14.1 Table of pre-set anatomic parameters

PANORAMIC

	Adult	Child
Small	70 kV 8 mA	66 kV 8 mA
Medium	74 kV 8 mA	68 kV 8 mA
Large	76 kV 8 mA	70 kV 8 mA

TMJ open/close mouth

	Adult	Child
Small	70 kV 8 mA	62 kV 8 mA
Medium	74 kV 8 mA	66 kV 8 mA
Large	78 kV 8 mA	70 kV 8 mA

SINUS

	Adult	Child
Small	68 kV 8 mA	64 kV 8 mA
Medium	72 kV 8 mA	66 kV 8 mA
Large	74 kV 8 mA	68 kV 8 mA

CEPHALOMETRY (L.L.)

	Adult	Child
Small	74 kV 8 mA	72 kV 8 mA
Medium	76 kV 8 mA	64 kV 8 mA
Large	78 kV 8 mA	66 kV 8 mA

CEPHALOMETRY (A/P - P/A)

	Adult	Child
Small	76 kV 12 mA	74 kV 12 mA
Medium	78 kV 12 mA	76 kV 12 mA
Large	82 kV 12 mA	78 kV 12 mA

Maxilla IMPLANT

	Tooth 11/21	Tooth 12/22	Tooth 13/23	Tooth 14/24	Tooth 15/25	Tooth 16/26	Tooth 17/27	Tooth 18/28	
Small	9.20	9.20	9.20	9.20	7.30	7.30	7.30	7.30	s
	62	62	68	68	64	64	64	64	kV
	8	8	8	8	8	8	8	8	mA
Medium	9.20	9.20	9.20	9.20	7.30	7.30	7.30	7.30	s
	62	62	72	72	66	66	66	66	kV
	8	8	8	8	9	9	9	9	mA
Large	9.20	9.20	9.20	9.20	7.30	7.30	7.30	7.30	s
	62	62	74	74	68	68	68	68	kV
	8	8	9	9	10	10	10	10	mA

Mandible IMPLANT

	Tooth 31/41	Tooth 32/42	Tooth 33/43	Tooth 34/44	Tooth 35/45	Tooth 36/46	Tooth 37/47	Tooth 38/48	
Small	9.20	9.20	9.20	9.20	7.30	7.30	7.30	7.30	s
	62	62	62	62	68	62	62	62	kV
	8	8	8	8	8	8	8	8	mA
Medium	9.20	9.20	9.20	9.20	7.30	7.30	7.30	7.30	s
	62	62	62	64	70	64	64	64	kV
	8	8	8	9	9	9	9	9	mA
Large	9.20	9.20	9.20	9.20	7.30	7.30	7.30	7.30	s
	62	62	62	66	72	66	66	66	kV
	8	9	9	10	10	10	10	10	mA

7. 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 labels 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 session.
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 .....

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VILLA
SISTEMI
MEDICALI

Cod. 6907913503_Rev.3

CE 0051

6907913503

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