Dental Line

CE
0051

rotograph prime

User Manual

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VILLA
radiology ahead

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Rev.	Date	Page/s	Modification description
0	15.02.16	-	Document approval
1	24.07.17	All	Added 110-120V version information (FDA approval). Added Image processing windows functionality. Added Warning in patient positioning. New SINUS chin support. (Ref. RDM 8296, RDM 8532, RDM 8589)

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Contents

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1. INTRODUCTION

Note
This manual is updated for the product it is sold with, to guarantee an adequate reference for using the product properly and safely.
The manual may not reflect changes made to the product that do not affect operating procedures or safety.

Rotograph Prime, manufactured 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 Rotograph Prime performs Panoramic, Sinus and TMJ exams of the maxillo-facial complex.

The Extended Projection Package, which can be used for additional exams, such as half-panoramic, low dose panoramic, frontal dentition, Ortho Rad panoramic, Bitewing Bilateral, Bitewing Left and Bitewing Right exams, is an optional that must be ordered separately.

The aim of this Manual is to instruct the user on the safe and effective use of the device.
The device must be used complying with the procedures described in this Manual and never be used for purposes other than those indicated herein.
Please read this Manual thoroughly before starting to use the unit; it is advisable to keep the manual close to the device, for reference while operating.
Rotograph Prime is an electrical medical device and can only be used under the supervision of a physician or of highly qualified personnel, with necessary knowledge of X-ray protection. The user is liable for legal compliance in relation to the installation and 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 safety aspects of the patient and/or operator.

2. SPECIFICATION OF THE INTENDED USE

2.1 Application and medical purpose

Rotograph Prime is an extra-oral dental panoramic X-ray unit to radiograph teeth, jaw and oral structures.

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

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

2.1.1 Intended patient population

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

- Age: paediatric (from about 7 years) to geriatric
- Patient status:
  - self-sufficient patient (the patient can autonomously place himself as requested by the physician)
  - non self-sufficient patient (the patient is assisted by medical personnel).
  - In any case the patient must be conscious, not anaesthetized and not incapacitated
- Nationality: multiple.

2.1.2 Operator Profile

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

2.1.3 Application environments

Rotograph Prime may be used in hospitals, private clinics or by consultants, at other radiology facilities and also in residential environments.

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

2.2 Applied parts

During normal use, Rotograph Prime is in contact with the patient via the handle, the chin rest and bite and the temple clamp, classified as Type B applied parts.

2.3 Typical doses delivered to the patient during extra-oral exams

The air kerma at the entrance of the X-ray image receptor for the standard PANORAMIC exam is:

mA	2	2.2	2.5	2.8	3.2	3.6	4	4.5	5	5.6	6.3	7.1
kV	Air Kerma [mGy]											
60	2.54	2.79	3.17	3.55	4.06	4.56	5.07	5.70	6.34	7.10	7.99	9.00
62	2.65	2.91	3.31	3.71	4.24	4.77	5.30	5.96	6.62	7.41	8.34	9.40
64	2.87	3.16	3.59	4.02	4.60	5.17	5.75	6.46	7.18	8.05	9.05	10.20
66	3.10	3.41	3.87	4.34	4.96	5.58	6.20	6.97	7.75	8.68	9.76	11.00
68	3.24	3.56	4.05	4.54	5.18	5.83	6.48	7.29	8.10	9.07	10.20	11.50
70	3.52	3.89	4.40	4.93	5.63	6.34	7.04	7.92	8.80	9.86	11.10	12.50

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

Exam	Ratio
Half-panoramic	0.55
Low Dose	0.85
Ortho Rad Panoramic	0.90
Frontal dentition	0.33
Bitewing L or R	0.24
Bitewing L and R	0.47
TMJ	0.71
Sinus	0.65

The dose per area of products delivered by Rotograph Prime to the patient during extra-oral exams is indicated in the graphical user interface.

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

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

Note
As stated in IEC 60601-2-63, no deterministic effects are known with extra-oral dental X-ray equipment.

3. SAFETY INFORMATION

Warning
Please read this chapter thoroughly.

Villa Sistemi Medicali designs and manufactures its devices in compliance with safety requirements; furthermore it supplies all information necessary for correct use, and warnings related to dangers associated with X-ray generating units.

Villa Sistemi Medicali cannot be held liable for:

- Use of Rotograph Prime other than its intended use
- Damage to the unit, the operator or the patient, caused both by installation and maintenance procedures other than those described in this Manual and in the Service Manual supplied with the unit, and by erroneous operations
- Mechanical and/or electrical modifications performed during and after the installation, other than those described in the Service Manual.

Installation and any technical operations must only be performed by qualified technicians authorised by Villa Sistemi Medicali.
Only authorised personnel may remove the covers and/or have access to live components.
The responsibility for the quality assurance program is defined in chapter 7.

Villa Sistemi Medicali provides specific training for service engineers.
Villa Sistemi Medicali technical support sends to all authorized dealer training course calendar.
One copy of User and Service Manual are always provided with the unit.

Warning
No modification to this equipment is allowed.

3.1 Warnings

The device must be used in compliance with the procedures described and never be used for purposes other than those indicated herein.
Before performing any maintenance operation, disconnect the unit from the power supply.
Rotograph Prime is an electric medical device and so can only be used under the supervision of suitably qualified medical personnel, with necessary knowledge of X-ray protection.
The user is responsible for compliance with legal requirements as regards ownership, installation and use of the equipment.
This device has not been designed for use in environments where vapours, anaesthetic mixtures flammable with air, or oxygen and nitrous oxide, may be present.
Do not let water, or other liquids, penetrate the device, as this could cause short circuits and corrosion.
Before cleaning the device, make sure the main power supply has been disconnected from the equipment. When pushing the ON/OFF button of the equipment, it must not come on.
Wherever necessary, use appropriate accessories, such as leaded aprons, to protect the patient from radiation.
While performing the X-ray, no-one, apart from the operator and the patient, must remain in the room.
Rotograph Prime has been built for continuous operation with an intermittent load; so the described use cycles must be observed, to enable the device to cool down.
Rotograph Prime must be switched off while using electrosurgical devices or similar apparatus.

Warning
For safety reasons, the patient support arm must not be abnormally overloaded, for example by leaning on it. The traction on the handle must be less than 16 kg.

Warning
To avoid the risk of electric shock, the equipment must only be connected to a mains supply with earthing.

Clean and disinfect, when necessary, all parts that may come into contact with the patient.
The centring bite or the bite protective sleeve must be replaced after each exam.
To avoid permanent damage to the unit, never try to rotate the moving arm manually when the unit is switched on.
In the case of Error 362 or Error 760, movement is possible to let the patient exit.

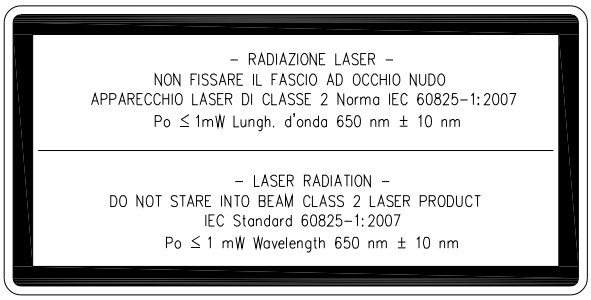
Note
When the unit is switched on, do not move the rotating arm.

3.1.1 Precautions while using laser centring devices

For patient positioning, Rotograph Prime uses two laser diodes with optical power on the working surface < 1 mW.

The directive CEI-EN 60825-1 defines the laser as "any device that produces or amplifies electromagnetic radiation in a coherent manner which includes a wave lengths from 180 nm to 1 mm by means of a stimulated emission". In reference to this directive, the lasers present on the Rotograph Prime are parts of class 2.

A laser in class 2 can be potentially dangerous if the ray is reflected into not protected eyes by a mirror, watch, a ring etc.
The warning label below is affixed to Rotograph Prime to indicate a laser in class 2 is mounted internally and caution is advised:



Warning

- 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 exam, the patient must remove earrings, glasses, necklaces and any other item that 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 only be performed by authorized technicians.
- Operations other than those indicated could cause the emission of dangerous non-ionizing radiation.

3.2 Protection against radiation

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

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

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

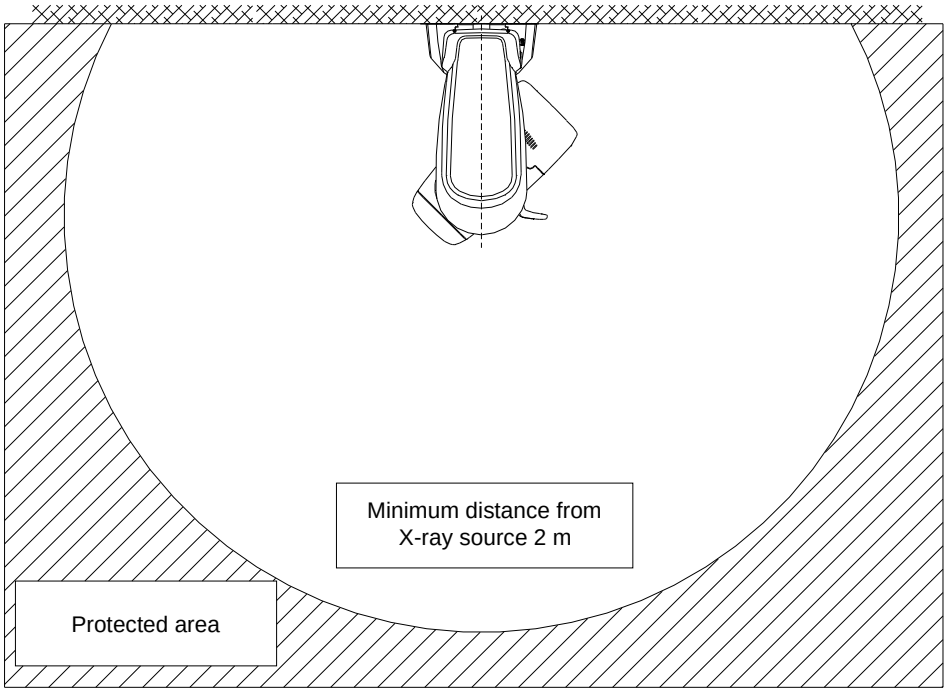


Figure 1

3.2.1 Electromagnetic emissions

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

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

3.2.2 Electromagnetic immunity

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

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV lines to lines ± 2 kV lines to earth	± 1 kV lines to lines ± 2 kV lines to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % Un for 0.5 cycles 40 % Un for 5 cycles 70 % Un for 25 cycles 0 % Un for 5 s	0 % Un for 0.5 cycles 40 % Un for 5 cycles 70 % Un for 25 cycles 0 % Un for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If continued operation of Rotograph Prime is necessary during a power outage, Rotograph Prime should be powered by an uninterruptible power supply or battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a standard 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 Rotograph Prime, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \times \sqrt{P}$ 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 a fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

3.2.3 Recommended separation distances for non-life supporting equipment

Rated maximum output power of the transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz d = 1.2 x Ö P	80MHz to 800MHz d = 1.2 x Ö P	800MHz to 2.5GHz d = 2.3 x Ö P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance "d" in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
these guidelines may not apply to all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

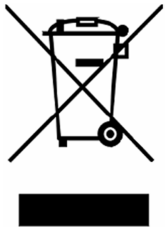
3.3 Environmental risks and displacement

Some parts of the device contain materials and liquids that, at the end of the unit's lifecycle, must be disposed of at appropriate disposal centres.
In particular, the device contains the following materials and/or components:

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

Note

Information for users of the European Community according to 2011/65/EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.



The symbol of the crossed waste container on the equipment or packaging shows that the product, at the end of its lifecycle, must be collected separately from other types of waste.
The separate collection of this equipment at the end of its lifecycle is organised and managed by the manufacturer. Users who need to dispose of this equipment should therefore contact the manufacturer and follow the procedure adopted by the manufacturer for the separate collection of the equipment at the end of its lifecycle.
Proper separate collection for subsequent recycling, treatment and compatible environmental disposal of equipment helps avoid possible negative effects on the environment and on health and encourages the reuse or recycling of materials the equipment is made from.
Illegal disposal of the product by the owner of the equipment will result in administrative sanctions, as provided for by applicable regulations.

3.4 Symbols used

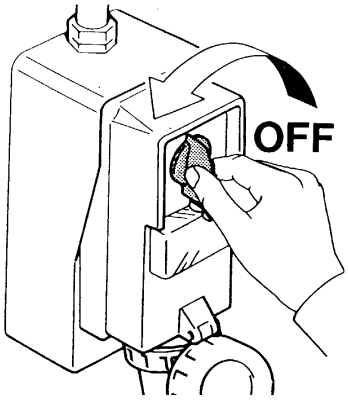
In this manual and on Rotograph Prime itself, apart from the symbols indicated on the keyboard, the following icons are also used:

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

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

4. CLEANING AND DISINFECTION

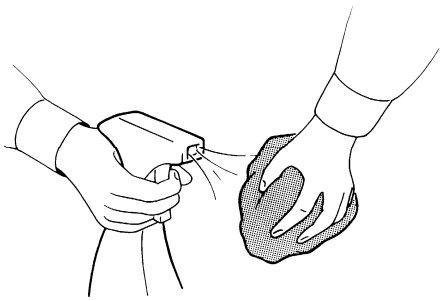
In order to guarantee a good level of hygiene and cleaning, it is necessary to carry out the following procedures.



Warning
Disconnect the unit from the mains before performing any cleaning.

Do not let water or other liquids penetrate the unit, as these could cause corrosion or short circuits.

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

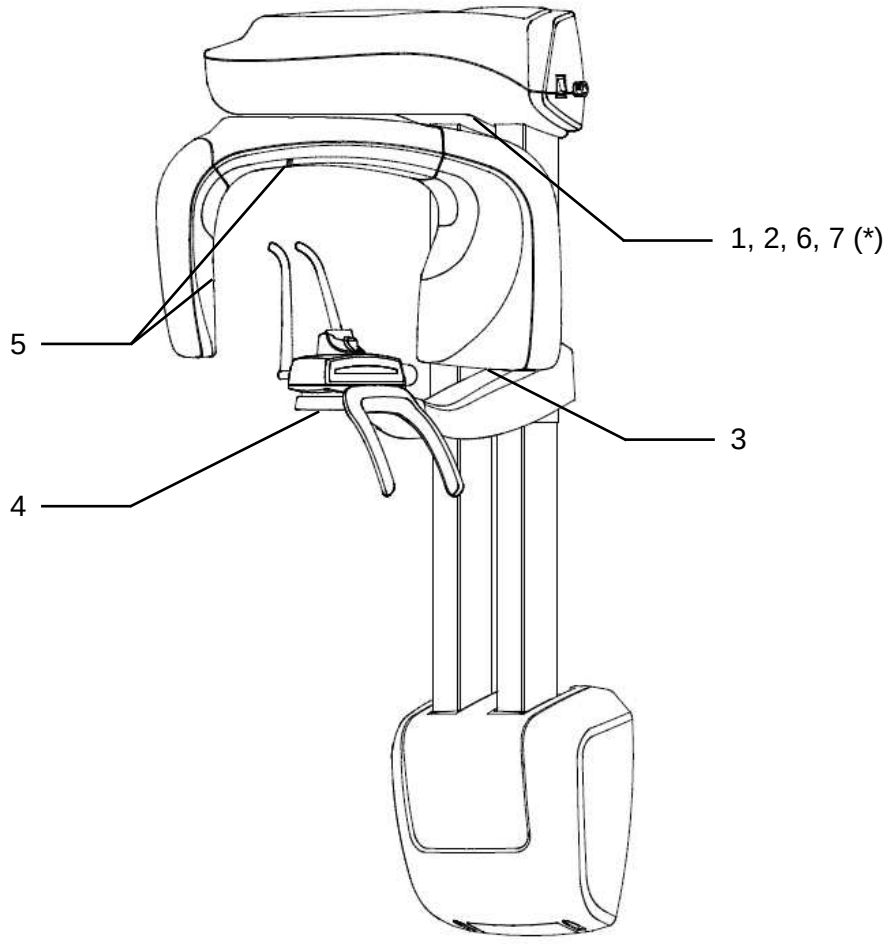


The centring bite or the bite protective sleeve must be replaced after each exam.
Thoroughly clean the chin support, resting handles and temple clamps group whenever they are used.
The chin support, resting handles and temple clamps group should be disinfected (when considered necessary) with a solution of 2% glutaraldehyde.

Note
To ensure a greater level of hygiene the handles of the equipment are covered with a special antibacterial paint which, thanks to the emission of silver ions, prevents the development of micro-organisms.

5. DESCRIPTION

5.1 Identification labels and laser labels

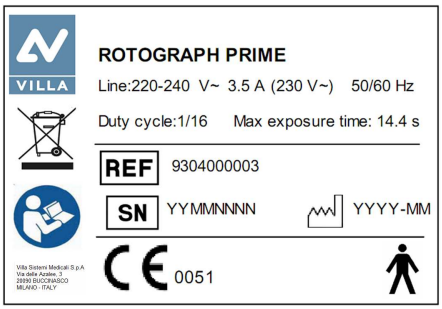


7 (*) Only for 110-120V version

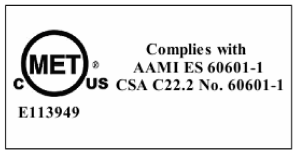
Figure 2: Identification labels

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

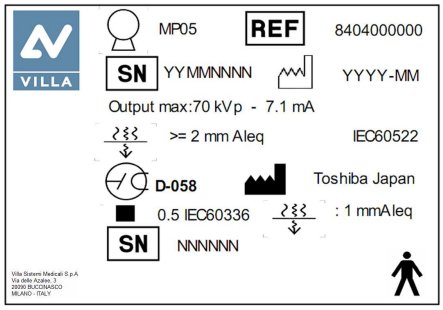
1
Rotograph Prime
identification label



2
MET
certification label



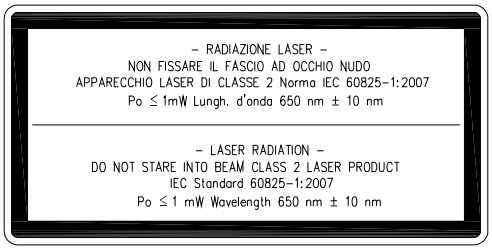
3
Tube-head
identification label



4
XP – Extended Projection Package
identification label

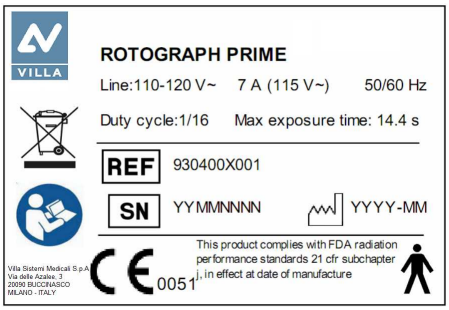
5
(No. 2) Laser symbol label

6
Laser WARNING label

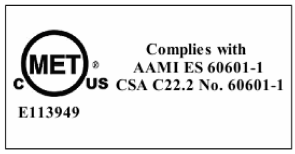


5.1.2 Identification labels and laser labels "110-120V" version

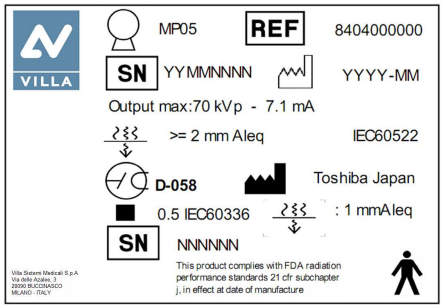
1 Rotograph Prime identification label



2 MET certification label



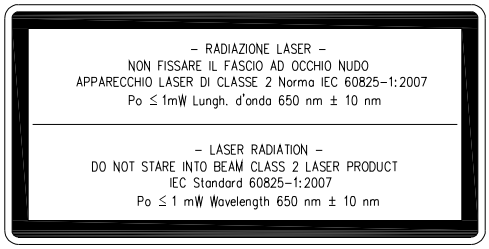
3 Tube-head identification label



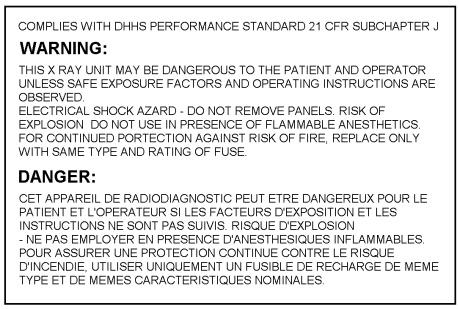
4 XP – Extended Projection Package identification label

5 (No. 2) Laser symbol label

6 Laser WARNING label



7 WARNING label



5.2 Functions, models and versions

Rotograph Prime, manufactured by Villa Sistemi Medicali S.p.A., is a complete panoramic X-ray system.
The basic version performs Panoramic, Sinus and TMJ exams.
XP (Extended Projection Package) optional function allows you to carry out the following additional exams: Half-panoramic, Low dose Panoramic, Frontal dentition, Ortho Rad Panoramic and Bitewing.

5.2.1 Basic version

The basic version makes it possible to perform:

- Panoramic adult or child exams, with 3 sizes and 3 types of biting for a total of 18 combinations with automatic selection; with manual selection, it is possible to select a high voltage between 60kV and 70kV, in 2kV steps and anodic current from 2 mA to 7.1 mA in the R20 scale steps.
- Sinus mode makes it possible to take exams of the paranasal sinuses with front projection (postero/anterior).
- TMJ closed/open mouth in lateral projection.

5.2.2 XP (Extended Projection Package) function – Optional

The unit in which XP (Extended Projection Package) function is enabled, makes it possible to perform the following exams:

- right or left Half-panoramic, to be used when the patient is known to have a problem only on one side of the arch, in order to reduce radiation.
- Low dose Panoramic, which reduces the dose radiated by excluding the TMJ's ascending rami from the radiograph.
- Frontal dentition, for a radiograph of the front part (roughly from canine to canine).
- Ortho Rad Panoramic, which reduces teeth overlap, thereby improving the diagnosis of interproximal decay.
- Bitewing Left or Right, for lateral dentition (generally from eighth to fourth) with a trajectory that reduces teeth overlap
- Bilateral Bitewing (Left and Right), which sequentially performs both bitewings, showing them on the same image.

Note
All these exams can be added to Rotograph Prime systems already installed in the field.

Note
The code entered in Rotograph Prime to enable optional exams is protected by a unique Identification Code (UIC); in the event the UIC is not present or is faulty, error E270 or E271 will be shown.
The UIC is simply an identifier of the single Rotograph Prime unit; in order to enable optional functions, Villa Sistemi Medicali must be requested to activate the code, which derives from the Unique Identification Code or from the device serial number.

6. TECHNICAL CHARACTERISTICS

General features	
Type	Rotograph Prime
Manufacturer	VILLA SISTEMI MEDICALI S.p.A. Buccinasco (Milan) Italia
Class	Class I with type B applied parts according to IEC 60601-1 classification. 
Protection degree	IPX0 standard device
Line voltage	99-132V 198-264 V
Rated line voltage	110-120V 220-240V
Line frequency	50/60Hz
Maximum line current	8.5A @ 99V 50/60Hz 7A @ 115V 50/60Hz 3.5 A @ 230V 50/60Hz
Technical factors for maximum line current	70kV, 7.1mA
Power consumption	0.8kVA @ 115V 50/60Hz 0.8kVA @ 230V 50/60Hz
Protection fuse (F1)	10 A T @115V 4 A T @ 230V
Column protection fuse (F2)	3 A T @115V 1.6 A T @ 230V
Line apparent resistance	0.4 max (99-132 V) 0.5 max (198-264 V)
Line Voltage regulation	≤ 3%
Rated output voltage (kVp)	60 - 70kVp, with 2 kVp steps
Anodic current	2 - 7.1mA, with R20 scale steps (2, 2.2, 2.5, 2.8, 3.2, 3.6, 4, 4.5, 5, 5.6, 6.3, 7.1)
Additional filtration	0.60 mm Al eq.

Exposure times	
Panoramic exam (PAN)	14.4s Adult / 13.3s Child
Half-panoramic exam	7.8s Adult / 7.3 s Child
Ortho Rad panoramic exam	11.9 s Adult / Child
Low dose panoramic exam	11.9s Adult / 10.8s Child
Frontal dentition	4.4 s Adult / Child
TMJ mouth closed/open	4.8 s per image for left and right joint in open and closed condition
Sinus P/A projection	9.4 s
Exposure time accuracy	± 5 % or ± 20ms whichever is greater

Exam modes	
Exam selection	• Automatic selection for Adult and Child, 3 Sizes • 3 biting modes (Panoramic exam) • Manual selection
Panoramic exam NOTE: Some of these exams are optional and depend on the system configuration.	• Standard panoramic • Half panoramic L/R • Ortho Rad panoramic • Low dose panoramic • Frontal dentition • Bitewing L/R • Bitewing L and R
TMJ (Temporal Mandibular Joint) exam	TMJ open and closed mouth
Sinus exam	Sinus P/A projection

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	1 : 1.20 (nominal)	1 : 1 (*)
Sinus	1 : 1.22 (nominal)	1 : 1 (*)

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

Tube-head characteristics	
Model	MP 05
Manufacturer	VILLA SISTEMI MEDICALI S.p.A. 20090 Buccinasco (Milan) Italia
Maximum tube voltage	70 kVp
kVp accuracy	± 8 %
Maximum anodic current	7.1 mA
Anodic current accuracy	± 10 %
Duty cycle	1 : 16
Reference loading conditions related to maximum energy input to the anode	1125mAs/h @70 kVp
Nominal power	0.50 kW (70 kVp – 7.1 mA)
Total filtration	2.0 mm Al eq. @ 70 kVp
HVL (Half value layer)	> 2.5 mm Al eq. @ 70 kVp
Transformer insulation	Oil bath
Target angle and reference axis	See Figure 3
Cooling	By convection
Leakage radiation at 1 m	< 0.5 mGy/h @ 70 kVp – 7.1 mA – 3s duty cycle 1/16
Tube-head maximum thermal capacity	310kJ

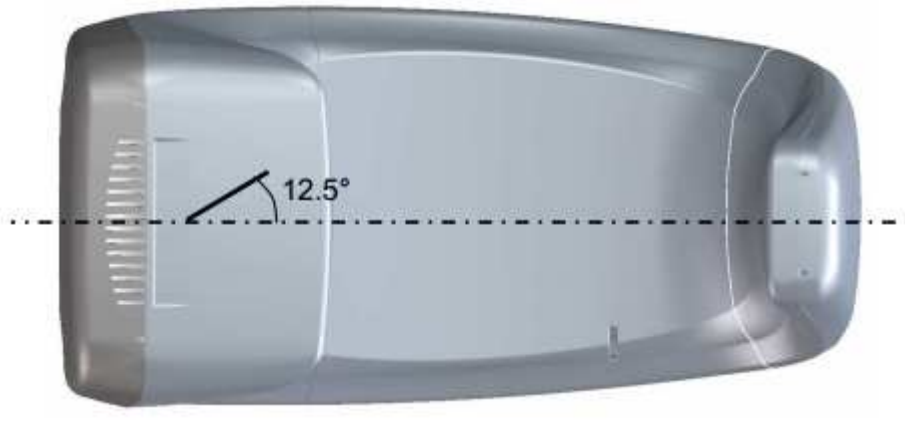


Figure 3: Tube-head target angle (view from the bottom)

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

Laser centring devices	
2 laser beams are used for patient positioning; beams that align the sagittal and Frankfurt planes (please refer to relevant paragraphs for a detailed explanation).	
Wave length	650 nm
Divergence	< 2.0 mRad
Optical power on the working surface	< 1 mW
Laser class	Class 2 laser product according to IEC standard 60825-1:2007

Digital sensor	
Detector type	FFT-CCD area image sensor
Sensible Area (H x L) PAN Sensor	146 x 6 mm
Pixel dimension	48 um, 96 um in 2x2 binning
Number of pixels	3072x128
Spatial resolution	4 lp/mm
Sensor cover attenuation equivalent	< 0.4 mm Al eq.

Mechanical characteristics	
Focal spot to image receptor distance	50 cm (20")
Telescopic motorised column run	66 cm (26")
Maximum total height – Note for the wall mount model this value refers to the recommended installation height	219 cm (86")
Weight	62 kg base version
Column base (optional)	6 kg
Working conditions	
Minimum room size (please refer to the Service Manual)	120 x 115 cm ("x")
Recommended room size (please refer to the Service Manual)	160 x 150 cm ("x")
Maximum working temperature range	+ 10° ÷ + 40°
Relative working humidity (RH) range	30% ÷ 75%
Temperature range for transport and storage	- 20° ÷ + 70°
Humidity range for transport and storage	< 95% without condensation
Minimum atmospheric pressure for transport and storage	630 hPa

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

- Resolution: 1366 x 768 pixels
- Colour depth: 16M of colour
- Contrast: 500:1
- Luminosity 200cd/m^2

Note
The handles of the equipment are covered with a special antibacterial paint which, thanks to the emission of silver ions, prevents the development of micro-organisms.

6.1 Dimensions

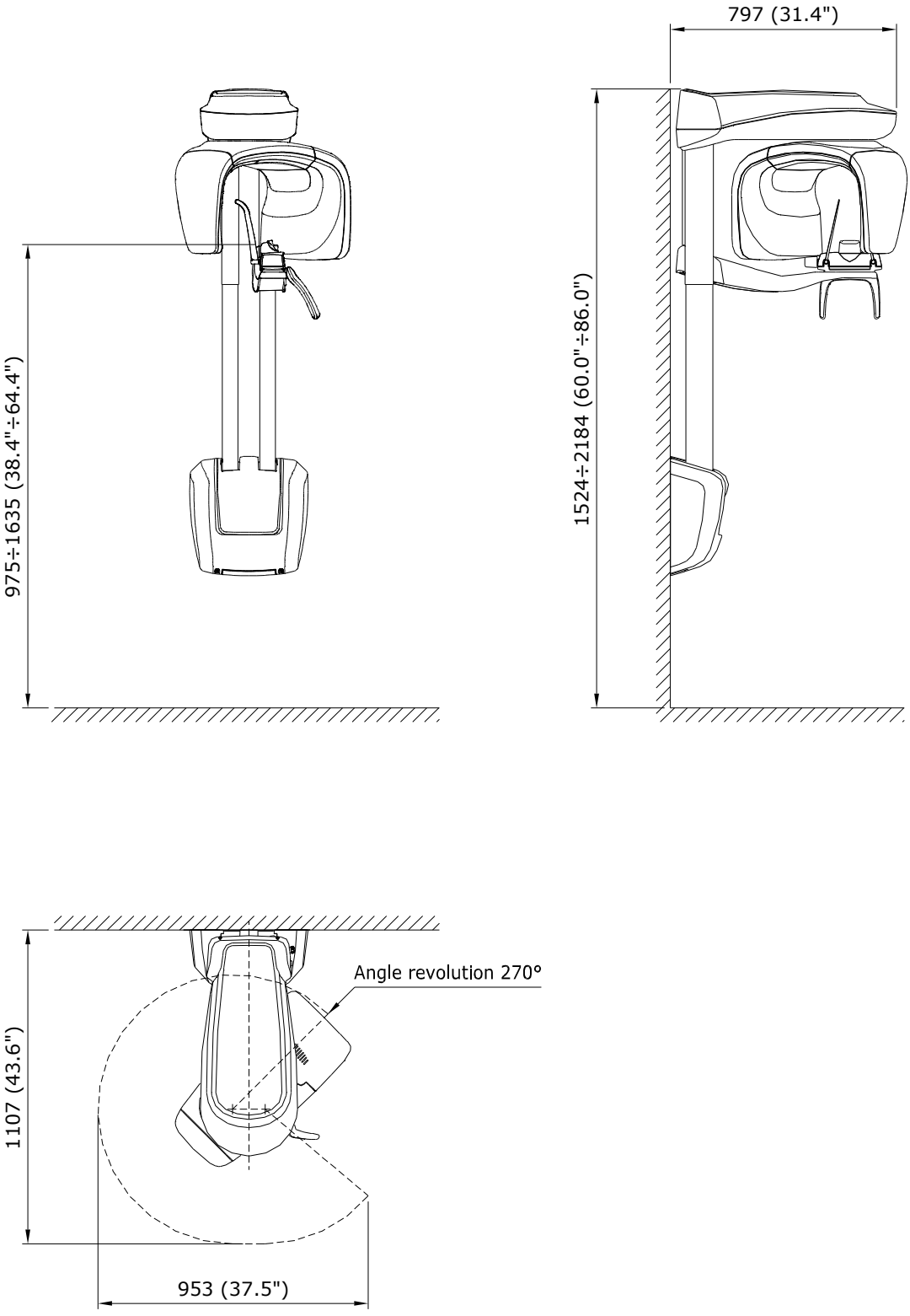
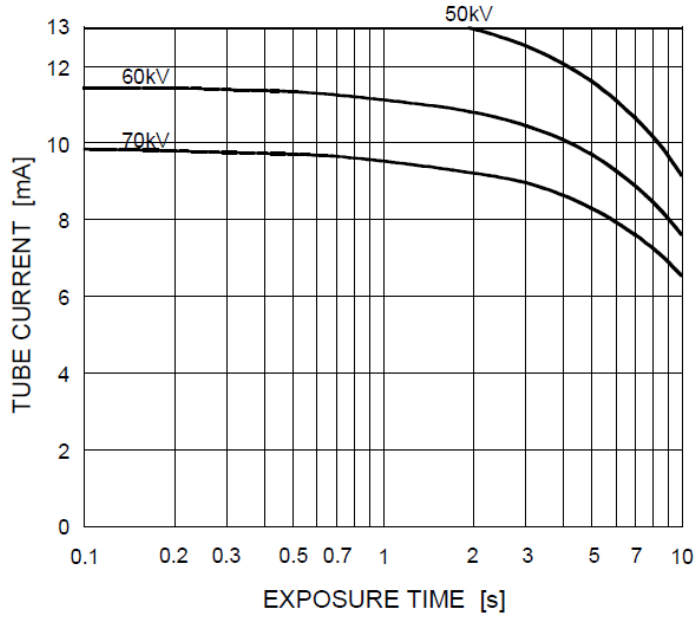


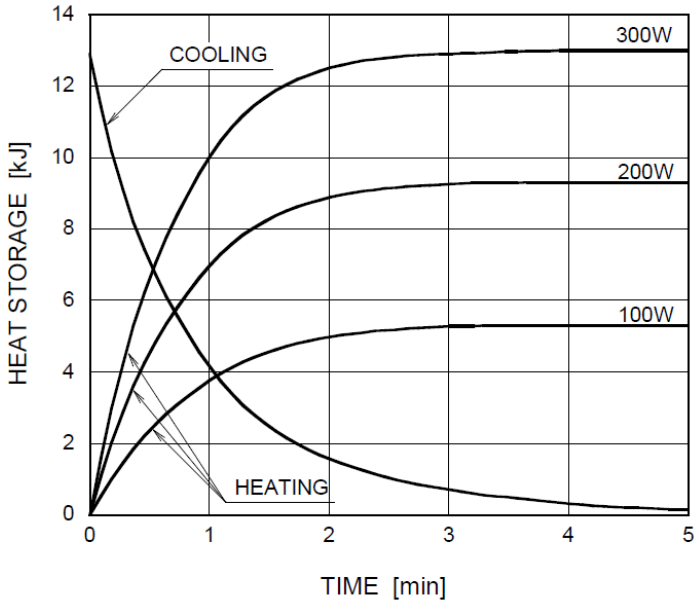
Figure 4: Rotograph Prime dimensions
Wall mounted version

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

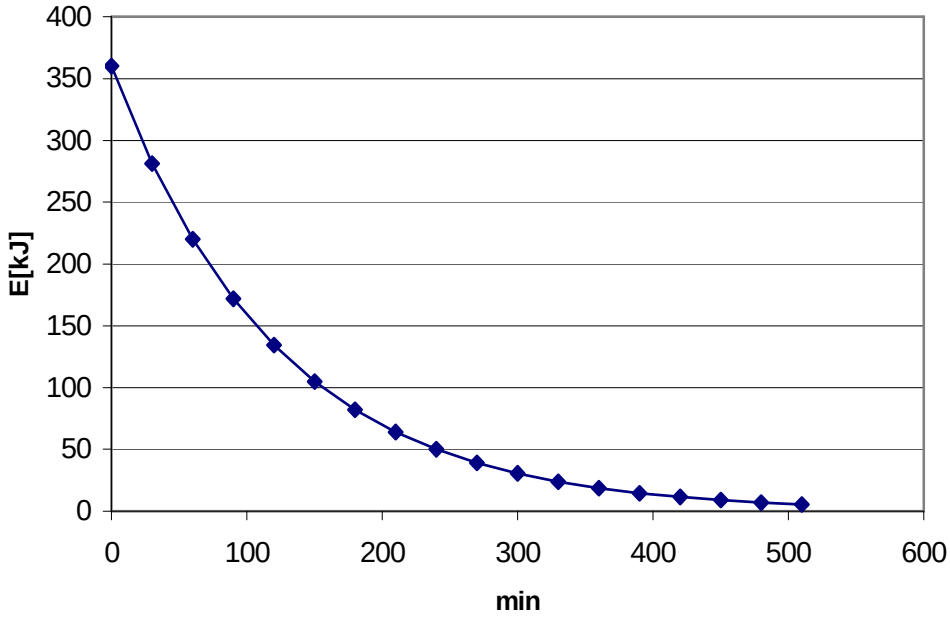
Tube "Toshiba D-058" (0.5 IEC 336)
Load



Anode cooling curve



Tube head cooling curve



6.3 Reference standard

Medical electrical equipment for extra-oral dental radiography Rotograph Prime complies with:

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

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

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

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

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

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

IEC 60825-1:2007
Safety of laser product – Part 1: equipment classification and requirements.

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

ANSI/AAMI ES60601-1:2005
Medical electrical equipment, Part 1: General Requirements for Basic Safety and Essential Performance.

CFR 21
Code Federal Regulation. Sub Chapter J

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

Classifications

Rotograph Prime is an electrical medical X-ray device classified as class I type B according to EN 60601-1, with continuous operation at an intermittent load.

According to 93/42/EEC Medical Devices Directive, the equipment is classified as class II B.

6.4 Note on constant magnification for dental arch and TMJ (mouth open/closed) exams

Note

Rotograph Prime is based on a standard dentition and ascending rami shape.
This shape, based on statistical studies, establishes a form for the dentomaxillofacial complex, adopted as "standard".
Rotograph Prime follows a rototranslation path which maintains the magnification factor as stated in the Technical Characteristics of each type of exam as constant 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 may be different from the value stated. Based on experience and competence, the user has to judge this variation.
In any case, TMJ radiography cannot be used to perform calculations of distances, angles etc. on the film.

7. QUALITY ASSURANCE PROGRAM

Here following the list of the operation required to maintain the continued proper functioning of the unit:

Frequency	Type of check	Done by	Reference
Daily	Functioning of the indicator lights	User	Paragraph 7.2
Daily	Laser alignment check	User	Paragraph 7.3
Monthly	Image quality check	User	Paragraph 7.4
Yearly	Dosimetry test	Authorized personnel	Paragraph 7.5

7.1 Quality check tools

The following tools are required to perform the quality check:

- Support plate (P/N 6195170100): used to check laser alignment and to hold the centering tool (P/N 6195170200)
- Centering tool (P/N 6195170200): used to check image quality
- QuickVision software: used to acquire image and perform measurements
- SyMage software: used to perform measurements on the image. The SyMage.exe is located at C:\Program Files (x86)\VILLA SM\OSP – PHD PANORAMIC\SyMage.
- PhD_Test software: used to perform exposure without arm rotation. The PhD_Test.exe is located at C:\Program Files (x86)\VILLA SM\OSP – PHD PANORAMIC
- kV meter (NOT provided by Villa Sistemi Medicali S.p.A.): used to measure exposure parameters.

Except kV meter, all these tools are provided with the unit.

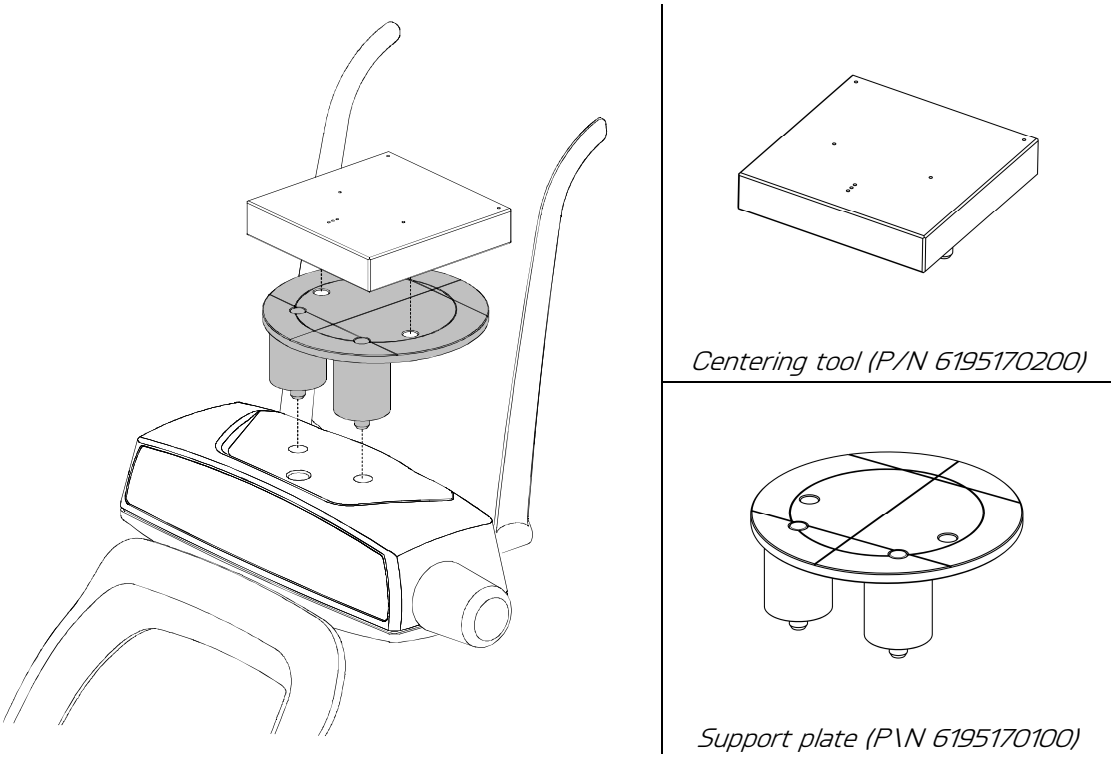


Figure 5: Support plate and centering tool positioning

7.2 Functioning of the indicator lights

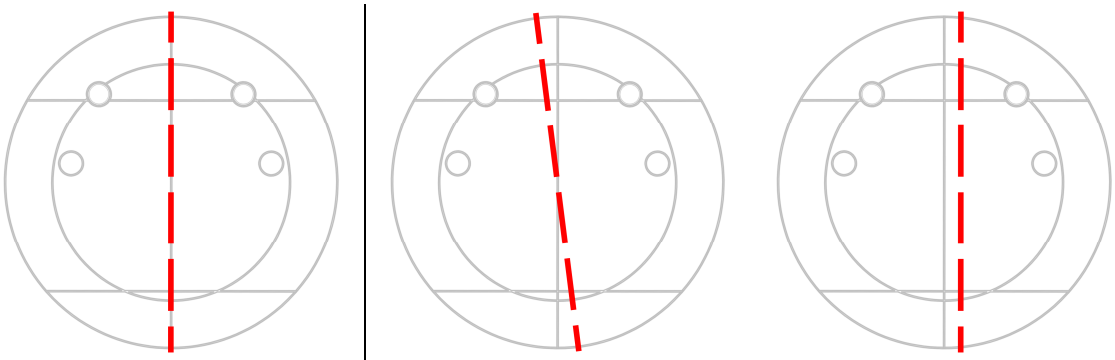
Power ON the unit , verify that the "Machine Ready" (1), "X-Ray Emission" (2) and "Computer connection" (3) LEDs light for few seconds.

Figure 6

In case the test fails, verify that the main power supply is present in the room. If the case, call technical assistance.

7.3 Laser alignment check

Power ON the unit and perform the axis reset by pressing the >0< button.
At the end of the axis positioning, place the support plate (P/N 6195170100 – Figure 5) on the chin rest support and power ON the laser. Check that the mid-sagittal laser beam is aligned to the reference line of the support plate (± 3mm).



Laser correctly aligned *Laser misaligned*

Figure 7

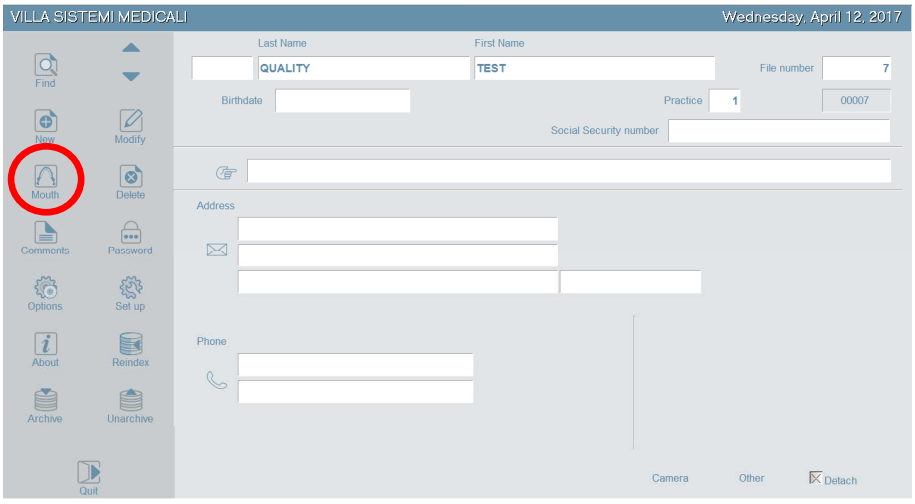
In case the test fails, repeat it checking that were is no mechanical interference. If misalignment is still present, call technical assistance.

7.4 Image quality check

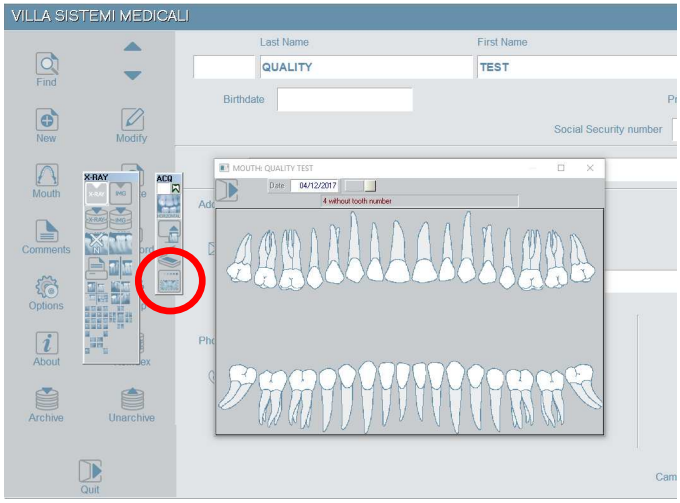
7.4.1 Geometry check

> **Warning**
> X-rays will be emitted during the performance of the following operations. It is recommended to use the greatest caution and to comply with local safety regulations and laws.

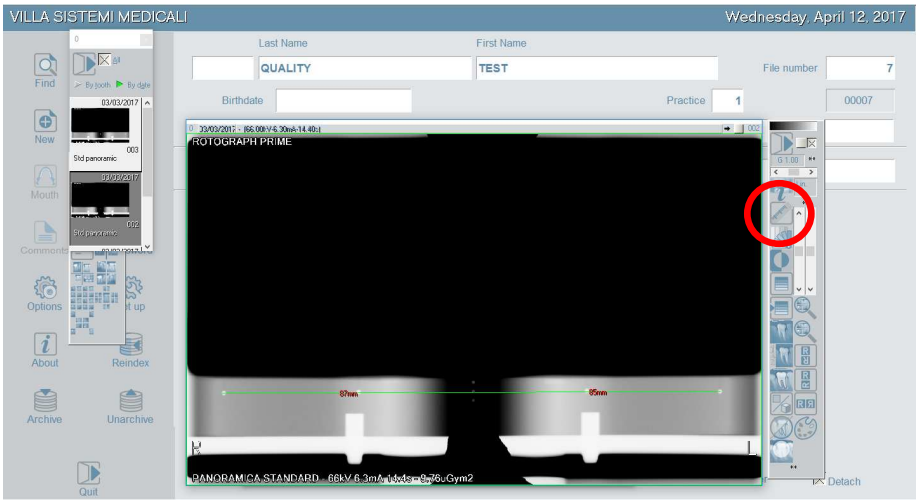
1. Switch ON the unit and go to Exam Selection.
2. Open QuickVision software and open the patient "Quality Test". If not present, create a new patient (Name: "Quality"; Family name: "Test").
3. Select the "Mouth" icon.



4. From the "ACQ" toolbar, select the GUI icon to open the virtual keyboard.



5. Mount the centering tool on the support plate, and place it on the chin rest support (Figure 5).
6. On the virtual keyboard, select Standard Panoramic – Adult – and make an exposure at 66kV, 5mA.
7. Select the "Ruler" icon and measure the distance between the two external spheres; this value must be 169mm ± 2mm.

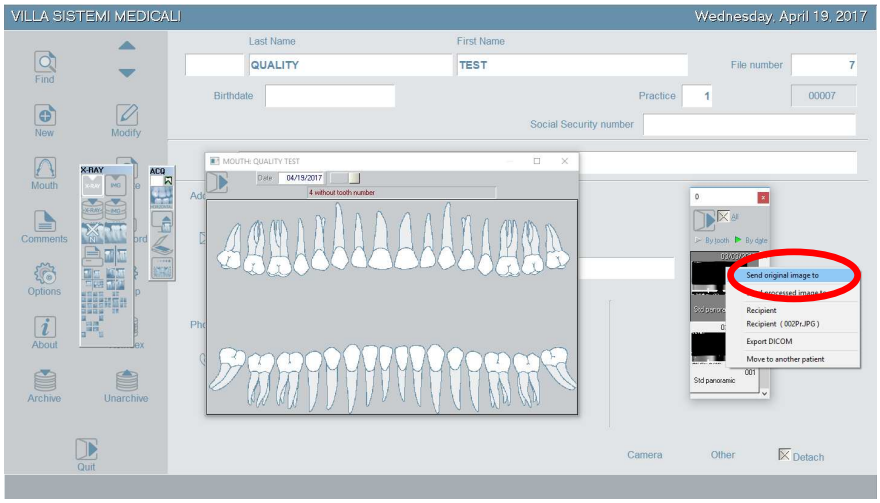


In case the test fails, call technical assistance.

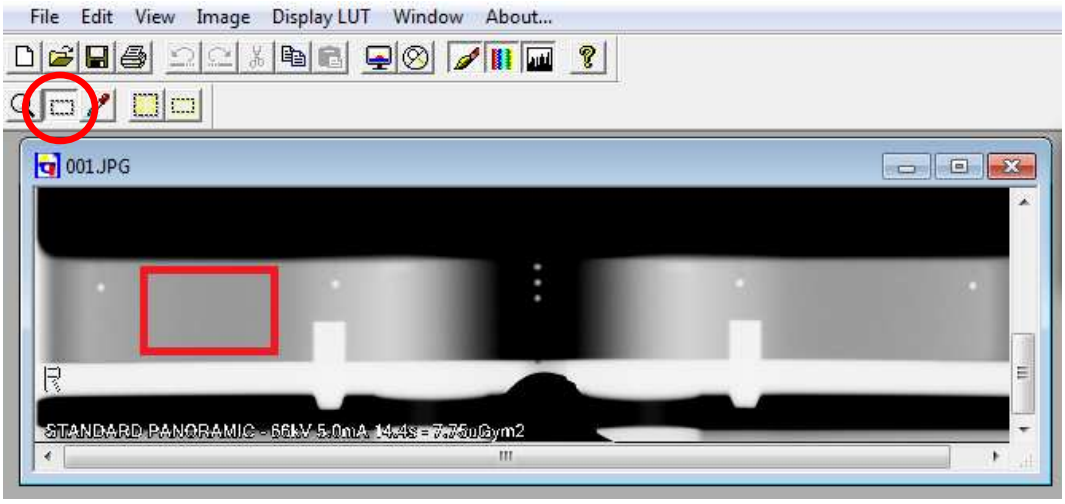
8. Measure the distance between the left external sphere and the central one and the distance between the right external sphere and the central one: the difference of these values must be maximum 2mm.
In case the test fails, call technical assistance.
9. Record the tests results in the log book at paragraph 7.6.1.

7.4.2 Signal to noise check

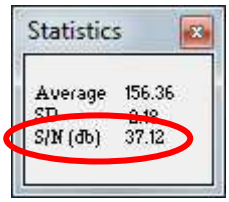
1. In Quick Vision program open the patient "Quality Test" and select the "Mouth" icon.
2. From the X-RAY toolbar select the "X-Ray" icon. Right click on the image taken in the previous paragraph and select from the drop-down menu "Send original image to". Save the image on the Desktop.



3. Open SyMage program and open the image previously saved on the Desktop.
4. Select the tool "Rectangle Selection" from the palette, and draw a region on the uniform area of the centering tool as shown in the figure below:



5. Check the window "Statistics": the S\N (db) value has to be higher than 25.



Record the test results in the log book at paragraph 7.6.1.

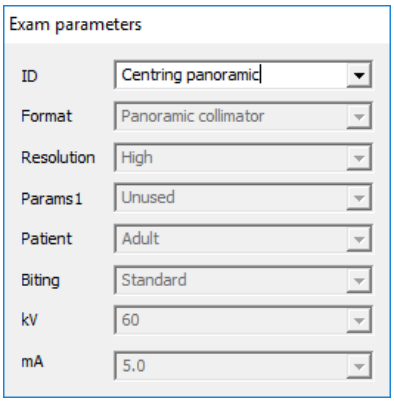
In case the tests fail, call technical assistance.

7.5 Dosimetry test (paragraph for authorised personnel)

Note
The dosimetry test has to be performed only by authorized personnel.
The present paragraph explain the procedure for dosimetry test with non-invasive method. For further details, please refer to Service Manual.

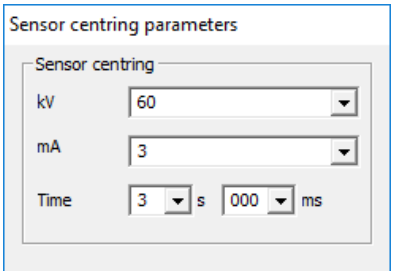
Warning
The device collimator gives a narrow X-ray beam.
Measurement taken with non-invasive method and a narrow beam can be difficult and/or unreliable; it is therefore necessary to use a special probe with a reduced sensitive area. It may be helpful to use a fluorescent screen to locate the X-ray beam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

1. Place the probe of the dosimeter on the sensor plastic cover.
2. Open the PhD_Test software (located at C:\Program Files (x86)\VILLA SM\OSP – PHD PANORAMIC) and check that the unit is connected to the PC (the message "DSPU is connected. MCU is connected" is displayed in the bottom left corner of the program window).
3. From the "Exam parameters" panel select the ID as "Centring panoramic".



Note
The "Centring panoramic" choice allows you to carry out the dosimetry test without the rotation of the tube-head arm.

4. In the "Sensor centring parameters" panel set the following exposure parameters: 60kV, 3mA, 3s.



5. Press the X-ray button to take an exposure and verify that the measured values are in the acceptance limits listed in the Table at point 6.
6. Take a second exposure setting the following parameters: 70kV, 6mA, 3s and verify that the measured values are in the acceptance limits listed in the following table.

kV	mA	t (s)	kV acceptance limits	Time acceptance limits
60	3	3	55.2 to 64.8 kV	2.85 to 3.15 s
70	6	3	64.4 to 75.6 kV	2.85 to 3.15 s

7. In case the test fails (result do not match the indicated values), proceed with the following actions:
   - Check the probe position and repeat the test
   - If the values are still out of range, perform the test using the invasive method as described in the Service manual, paragraph 9.7
   - If the values are still out of range, call technical assistance.
8. Record the test results in the log book at paragraph 7.6.2.

7.6 LOG book

7.6.1 Image quality check

	Dimension	Simmetry	Signal to noise
Acceptance range–>	167 – 171 mm	≤ 2 mm	≥ 25 dB
Date	Measured value	Measured value	Measured value

7.6.2 Verification of radiological parameters

NON-INVASIVE METHOD				
Parameter set –>	60 kV, 3mA, 3s		70 kV, 6mA, 3s	
Acceptance range–>	55.2–64.8 kV	2.85–3.15 s	64.4–75.6 kV	2.85–3.15 s
Date	kV measured	Time measured	kV measured	Time measured

INVASIVE METHOD				
Parameter set –>	60 kV, 3mA, 3s		70 kV, 6mA, 3s	
	kV	mA	kV	mA
Acceptance range–>	2.76 – 3.24 V	0.9 – 1.1 V	3.22 – 3.78 V	1.8 – 2.2 V
Date	Measured value	Measured value	Measured value	Measured value

8. GENERAL INSTRUCTIONS FOR USE

8.1 Switching the device ON and OFF

Press the power switch located on the upper part of the equipment on the operator side to position "1".
This will start the "CHECK" function, which is indicated by LEDs lighting up on the equipment keyboard.
When the "CHECK" function is complete, the green LED (3 – Figure 8) on the equipment keyboard starts blinking.

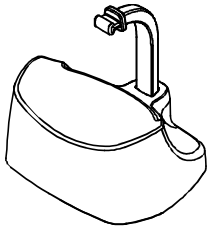
To carry out an exam follow the instruction from paragraph 8.6.

To switch OFF the unit press the power switch located on the upper part of the equipment on the operator side to position "0".
The LEDs will go off.

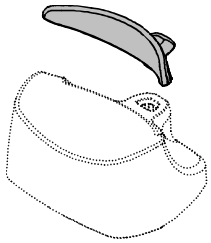
8.2 Positioning the chin support

Rotograph Prime is equipped with different types of supports: a standard support fitted with a special removable appendix for edentulous patients, a lower one for SINUS exams and a third one TMJ exams.
The standard chin support must be used, in panoramic mode, with all patients who can ensure a tight grip on the centring bite. The appendix for edentulous patients must be applied only for patients who cannot ensure a tight grip on the bite or are not co-operating and might move during the exam.
For SINUS exams, there is special support; being in a lower position, this ensures a better centring of the area concerned in the rays field.
For TMJ exams, a specific positioner is included, allowing the patient to open and close the mouth without touching any positioner with the chin.

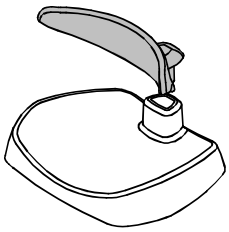
Note
Another chin support, lower in height, can be used in standard panoramic exams to ensure a better view of the lower section of the chin for patients with a particular anatomy. This chin support is marked by a down arrow "▼" on the front of the chin support itself.



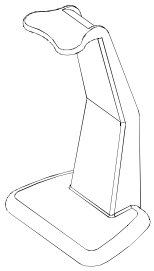
Panoramic standard chin support



Edentulous patients appendix



SINUS chin support



TMJ positioner

8.3 Keyboard – Description and functions

Figure 8 shows a general view of Rotograph Prime control Interface.

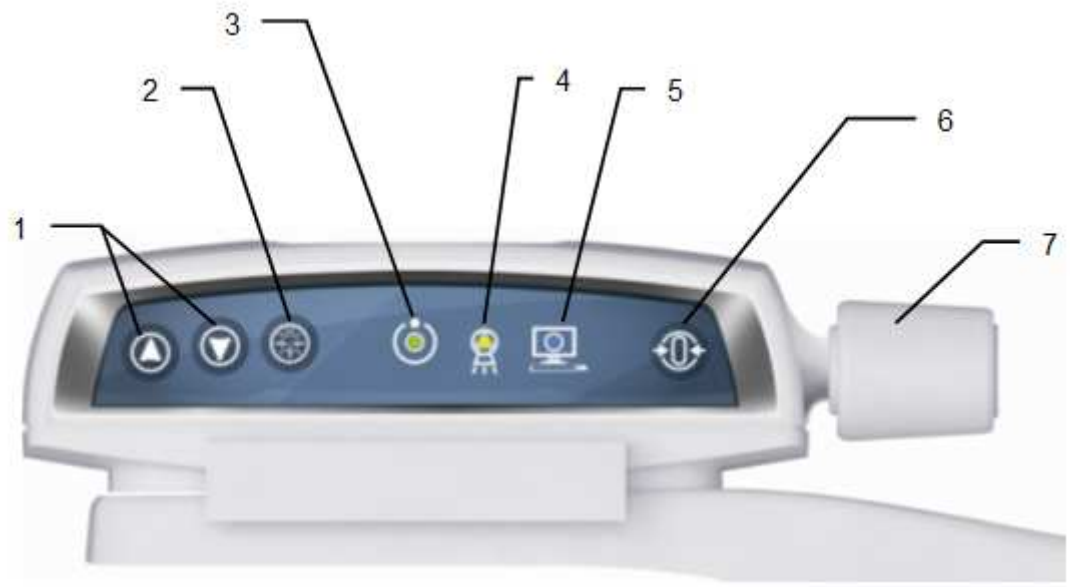


Figure 8: Keyboard

Label	Description	
1	The up/down movement of the column is controlled by the corresponding keys. The movements are enabled during equipment setting. Column movement is not possible if the emergency button is pressed.	
2	The "Luminous centring device" key turn the laser centring devices ON/OFF, allowing the correct positioning of the patient.	
3	Light indicator of "Machine Ready" status: • Green fixed, alerts the user that by pressing the X-ray button, X-ray emission will start • Green blinking slowly, indicates that by pressing >O< button, axis reset will start, • Green blinking fast, indicates the equipment cooling status.	
4	Light indicator "X-Ray Emission" status. It indicates the emission of X-rays.	

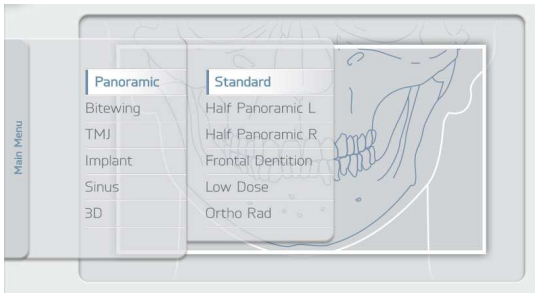
Label	Description	
5	Light indicator of "Computer connection" status: • Blue fixed, computer connection established, • Blue blinking slowly, waiting for computer connection. No X-ray emission available • Blue blinking fast, the equipment is in error state. Refer to the GUI for error description.	
6	The "Centring/Patient Entrance" key is used to: • Start/Stop the exam procedures • Put the rotation arm in the patient entrance position at the end of the exam.	
7	Temple clasps closing/release knob.	

8.4 Graphical User Interface – Description and functions

All unit configuration is managed via the virtual interface (Figure 9) running on the computer. This interface enables the user to configure all technical features of the unit, to choose and adjust the exam and radiological parameters.

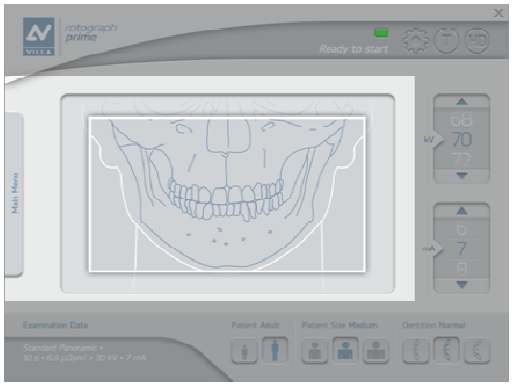
Figure 9

Adult/Child selection: the pre-set exposure values and in panoramic exam the trajectory, are automatically updated based on the current selection.	
Patient size selection: Small/Medium/Large. The pre-set exposure values will be automatically updated based on the current selection.	
Patient's type of biting: Protruded/Normal/ Retracted. This selection is only available in Panoramic mode. The position of the focus layer will be automatically updated based on the current selection.	
Test mode selection: disables X-ray emission. Use the test mode to check for the absence of collision with the patient. Test mode may also be useful when the equipment is used on child patients, to show them how the equipment works before running the exam.	

Setting: open the setup menu.	
HD selection: enables/disables the High Definition Mode (not yet available).	
Virtual LED: indicates the current status of the unit: Blue = Initialization Green = Ready Red = Error Yellow = X-Ray emission	
Exposure parameters selection: changes kV and mA. When the exposure parameters are manually changed, the mode indicator switches from "Anatomic" to "Manual". Return to "Anatomic mode" using the main programme selection key.	
Main menu: selects exam modality, exam type and sub-menu including the available exams.	

8.4.1 Main GUI area functions

In the main area of the Virtual Interface, a picture shows the anatomical region matching the corresponding selected exam.

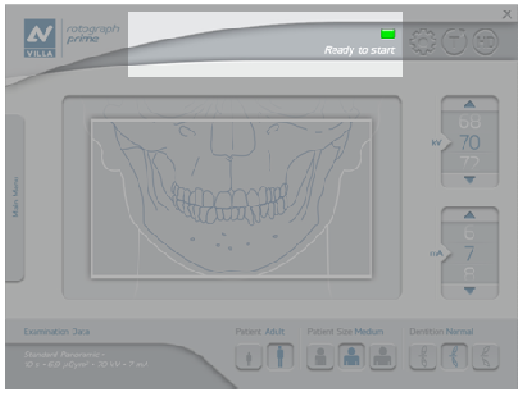


Click on Main Menu to open the exam selection menu. After selecting the exam mode (i.e. Panoramic), the user can choose further options (i.e. Half Panoramic Left).

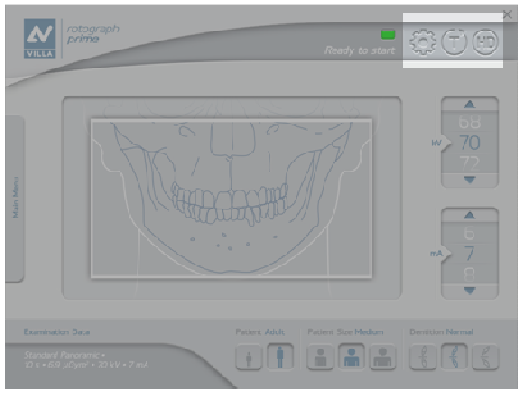
The user can choose from different options.

- Adult/Child: the suggested pre-set exposure values (see paragraph 8.7.1) will be automatically loaded. For Panoramic exams with child selection, the exposure values and the trajectory length are reduced
- Patient Size: the correct pre-set exposure values will be automatically loaded
- Biting type: the position of the focus layer will be automatically adjusted
- kV/mA selection: the user can manually change the exposure parameters

A virtual LED indicates the current status of the unit, while a virtual display shows all service messages related to the current status of the unit and possible error messages.



Close to the virtual display there are three different keys that may be selected by the user: Settings, Test mode (enable/disable), HD mode (enable/disable)



8.5 Digital sensor

The new Rotograph Prime is equipped with a PAN sensor: it is a sensor suitable for Panoramic-type imaging, i.e. all images with about 14cm-high field; all Panoramic, TMJ, and Sinus images belong to this type.
The new Rotograph Prime control system checks the consistency of safety measures that allow for correct use of the digital sensor; in particular to prevent acquisition when the image management and processing system is not ready to receive the image, it displays the message "Sensor not ready".

8.6 Making an exam

Press the power switch located on the upper part of the equipment on the operator side to position "1". This will start the "CHECK" function, which is indicated by the LEDs lighting up.
When the "CHECK" function is complete, the green LED on the equipment keyboard starts blinking.
To make an exam, proceed as follows:

- Press >O< button on the keyboard to run the equipment axis zero;
- Run the Virtual Interface on the PC and wait for the connection between the PC and equipment; this status is indicated by the blue LED lighting up on the keyboard and on the Virtual Interface;
- Select the exam and parameters on the Virtual Interface;
- Position the proper chin support;
- Position the patient with the help of the lasers (see paragraph 8.8 for Panoramic and Bitewing, paragraph 8.9 for Sinus and 8.10 for TMJ exams) then close the temple clasps;
- Press >O< button to put the equipment in the start exam position; the green LED lights up: the unit is now ready for X-rays;

Note
In the start exam position, the laser light and column movement are not enabled, and on the GUI only kV and mA adjustment is allowed.

Note
Ready for X-ray status is signalled by the green LED on the equipment (3 – Figure 8) and on the GUI lighting up.
Ready for X-ray status remains as long as the equipment is in the start exam position and the GUI is connected to the equipment.

- Press the X-ray button for the entire duration of the exposure;
- Once the exposure is completed, the system will rotate back to patient exit position. Press >O< to return to axis 0 position; it is now possible to free the patient from the positioning device.

Note
With paediatric patient it is recommended to have a greater attention in taking exams. Useful information and a specific checklist can be found at the Image Gently website (www.imagegently.org).
In general with child and adolescent patients, before taking the exposure it is suggested to run the exam in test mode in such a way to show the young patient how the unit works and make them feel comfortable.

8.7 Anatomic / Manual exposure

Note
If the previous exam was carried out manually, press the "Size Selection" key to return to automatic mode.

After setting the equipment, the following two operating modes may be chosen:

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

Note
The exam parameters set as the default are values to be taken as the starting point. Users can optimise the parameters according to their needs.

8.7.1 Anatomic exposure

Select the type of patient with the Adult/Child icons. If child option is selected, exposure parameters are lower respect to the corresponding adult programs. In addition, the exam trajectory in panoramic programs is reduced of about 10%.
Select the type of build with the Size icons (small – medium – large).
On the basis of these selections, the display will show the kV and mA settings accordingly.
Select the type of biting with the icon "Type of Biting Selection" (option available in Panoramic mode only).

Note
The exam parameters set as the default are values to be taken as the starting point. Users can optimise the parameters according to their needs.

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

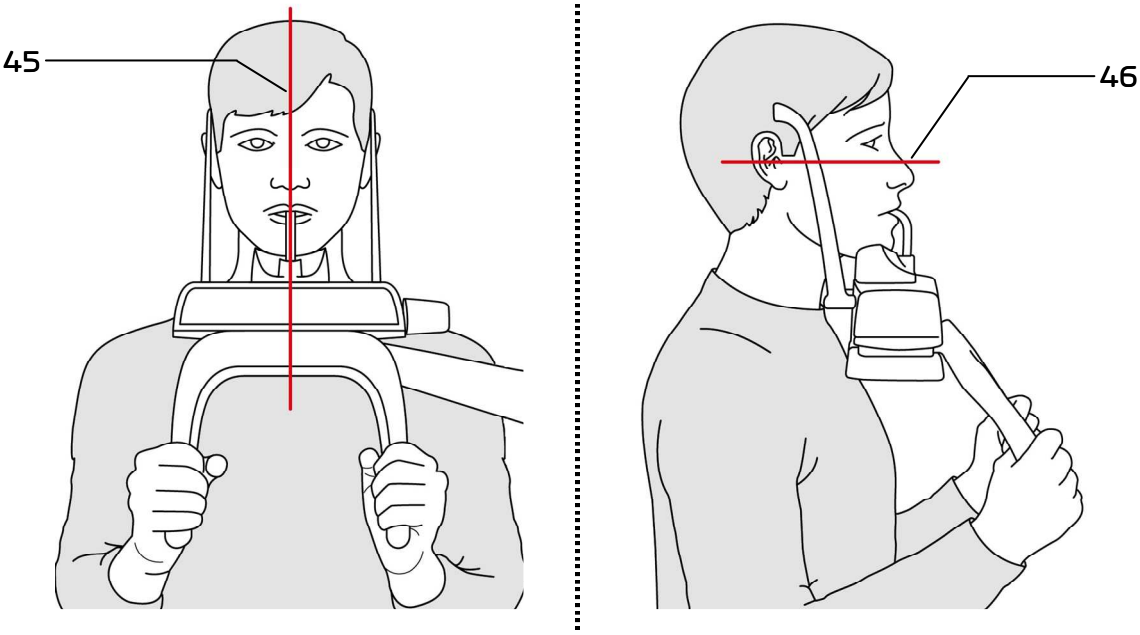
8.7.2 Manual exposure

If the pre-set kV and mA pairs are not considered suitable for a specific exam, new parameters can be set in manual mode.
To modify the kV or mA values, press any of the up or down cursors of the KV or mA parameters.
A parameter can be modified by pressing the increase key and the decrease key of the parameter repeatedly.
The kV value can vary between 60 and 70 kV, with 2 kV steps.
The mA value can vary between 2 and 7.1 mA according to the r20 scale.

8.8 Panoramic and Bitewing exams

8.8.1 Laser references

Patient 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 plane needs to be aligned with these laser lines.



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 10

8.8.2 Preparation of the device

When the unit is switched ON, Panoramic exam mode is selected as standard. If the operator has previously carried out another kind of exam, use the main window in extended view to select Panoramic mode.

The system positions itself with the following configuration:

- ADULT with the display of the corresponding graphic for the key
- MEDIUM SIZE with the display of the corresponding graphic for the key
- NORMAL DENTITION with the display of the corresponding graphic for the key
- default exposure parameters (if this is the first panoramic exposure), or the exposure parameters of the last exposure performed.

Figure 11

Select the type of patient with the Patient icons (Adult – Child).
Select the type of build with the Patient Size icons (Small – Medium – Large).
Select the type of biting with the Dentition icons (Protruded – Normal – Retracted)

On the basis of the selections made, the display will show the kV and mA settings, as in the tables:

Exposure values in PAN mode				
	Adult Patient (14.4 seconds)		Child Patient (14.4 seconds)	
	kV	mA	kV	mA
Small	64	5.6	64	4.5
Medium	66	5.6	66	4.5
Large	68	5.6	68	4.5

Exposure values in Bitewing mode				
	Adult Patient (14.4 seconds)		Child Patient (14.4 seconds)	
	kV	mA	kV	mA
Small	64	5.6	64	4.5
Medium	66	5.6	64	4.5
Large	68	5.6	68	4.5

Note
The exam parameters set as the default are values to be taken as the starting point. Users can optimise the parameters according to their needs.

Once the settings have been completed, the chin support must be placed in position.

The following selections are possible for the Panoramic exam range:
< Standard – Half Panoramic – Frontal Dentition – Low Dose – Ortho Rad >

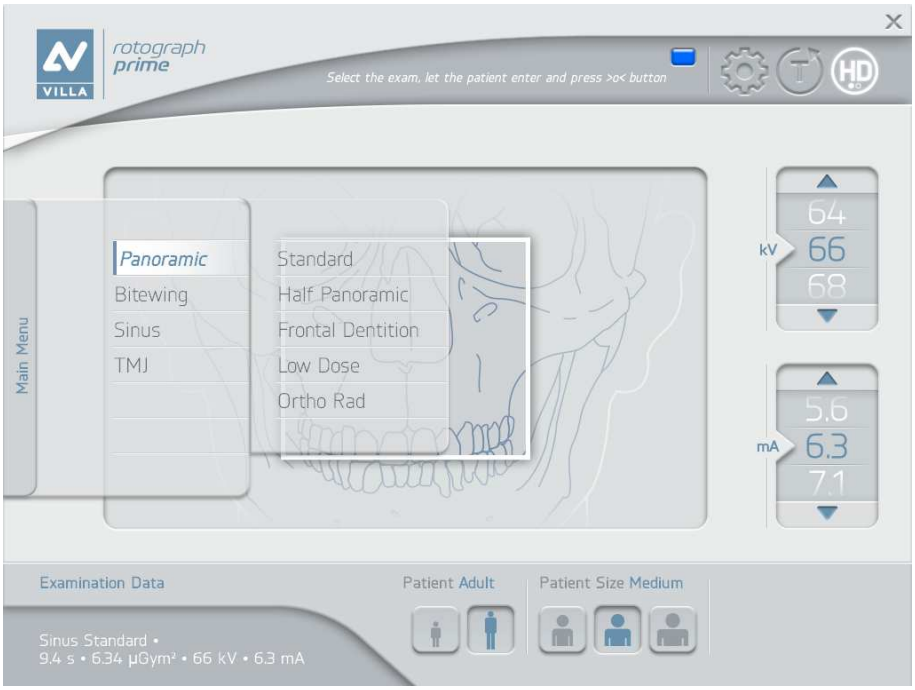


Figure 12: Panoramic exam range

The following selections are possible for the Half Panoramic exam range:
< R (Right) – L (Left) >
The selection is done clicking on the corresponding side of the image

Figure 13: Half Panoramic Right selection

The following selections are possible for the Bitewing exam range:
< Single – Bilateral >

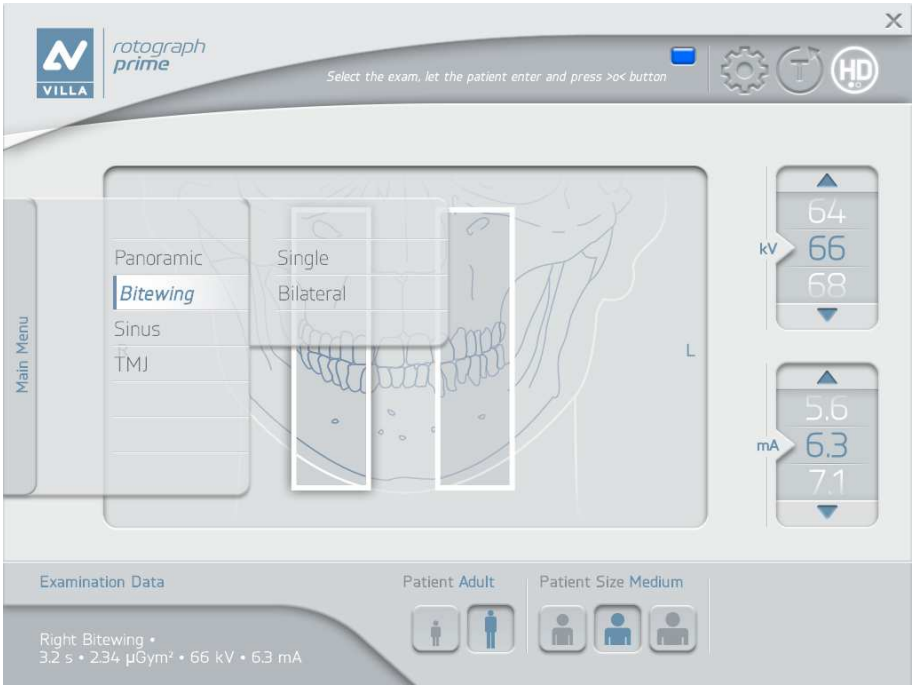


Figure 14: Bitewing exam range

Selecting "Single" are possible the following exam options:
< R (Right) – L (Left) >
The selection is done clicking on the corresponding side of the image

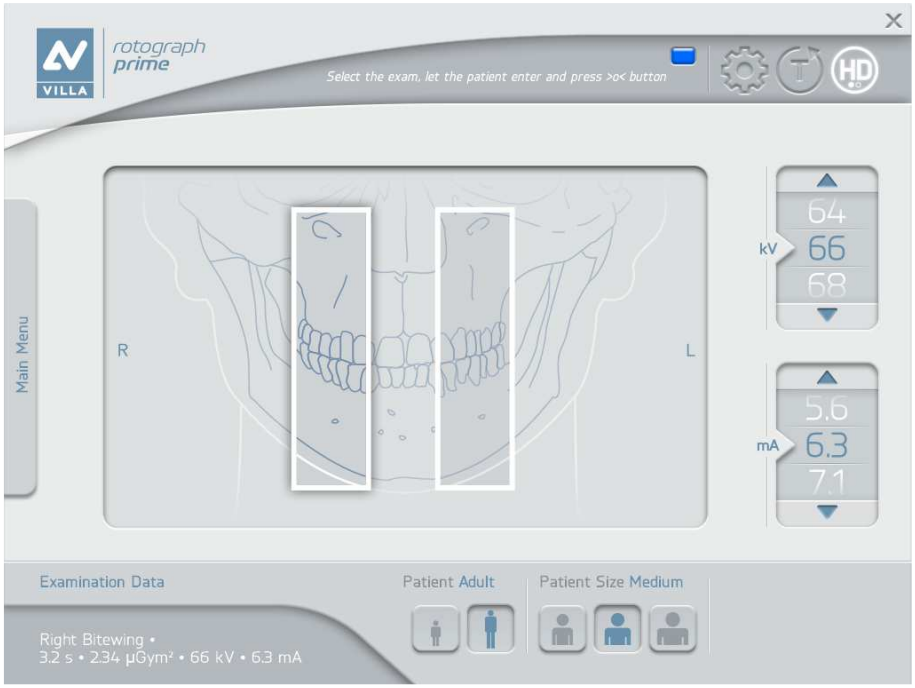


Figure 15: Right Bitewing selection

Note

The new Rotograph Prime is based on a standard dentition and ascending rami shape. This shape, based on statistical studies, establishes a form for the dentomaxillofacial complex, adopted as "standard". Rotograph Prime follows a rototranslation path which maintains the magnification factor as stated in the Technical Characteristics of each type of exam as constant 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, RADIOGRAPHY IMAGES CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE IMAGE.

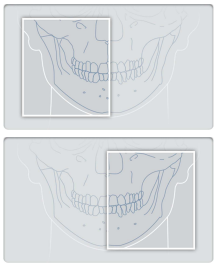
Warning

The measurement of lengths on digital images depends on the specific length calibration of the programme used.

It is therefore very important to check the length calibration of the programme.

With panoramic exams, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 7.8 mm (in the centre of the focus layer).

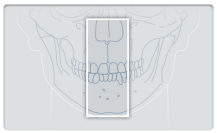
8.8.2.1 Left / Right Half Panoramic



The Half Panoramic mode, right or left, means that only the corresponding half arch is irradiated; 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.

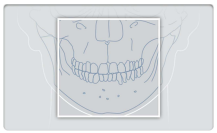
These two kinds of exams are normally used when it is already known that the patient has a problem on only one half of the arch, so it is possible to reduce patient irradiation. Follow the instructions for normal panoramic exams for patient positioning.

8.8.2.2 Frontal dentition



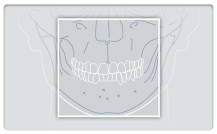
The Frontal dentition exam takes an X-ray of the frontal dentition area (roughly from canine to canine). Follow the instructions for normal panoramic exams for patient positioning.

8.8.2.3 Low dose Panoramic



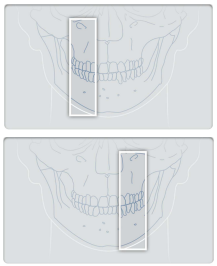
The low dose panoramic exam takes an X-ray only of the dental arch, excluding the ascending rami of the temporo-mandibular joint from the image; the exam is performed with the same trajectory of the standard Panoramic exam, reducing the rays' emission time.
This exam is used, for instance, during treatment continuation phases or where a lack of pathologies of the same joint is already known.
Follow the instructions for normal panoramic exams for patient positioning.

8.8.2.4 Ortho Rad dentition



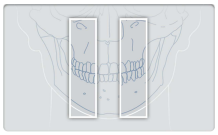
The ortho rad panoramic exam delivers an image of the pure dental arch, excluding the ascending rami branches of the temporo-mandibular joint from the image; the trajectory of the rotating arms is, however, optimised for a better orthogonality between the X-ray beam and incident sections of near teeth. Thus the image has reduced teeth overlapping, 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 patient positioning for this exam needs more care. Follow the instructions for normal panoramic exams for patient positioning.

8.8.2.5Single Bitewing



The Single Bitewing mode, either right or left, means that only the corresponding dentition sector is irradiated; for the Right side 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. The exam is performed with the same trajectory of the Ortho Rad Panoramic exam, reducing the rays' emission time to include just molar and pre-molar teeth.
This exam is normally used when it is already known that the patient has a problem on one side of the bite-sectors of the arch, so it is possible to reduce patient irradiation.
Follow the instructions for normal panoramic for patient positioning.

8.8.2.6Bilateral Bitewing

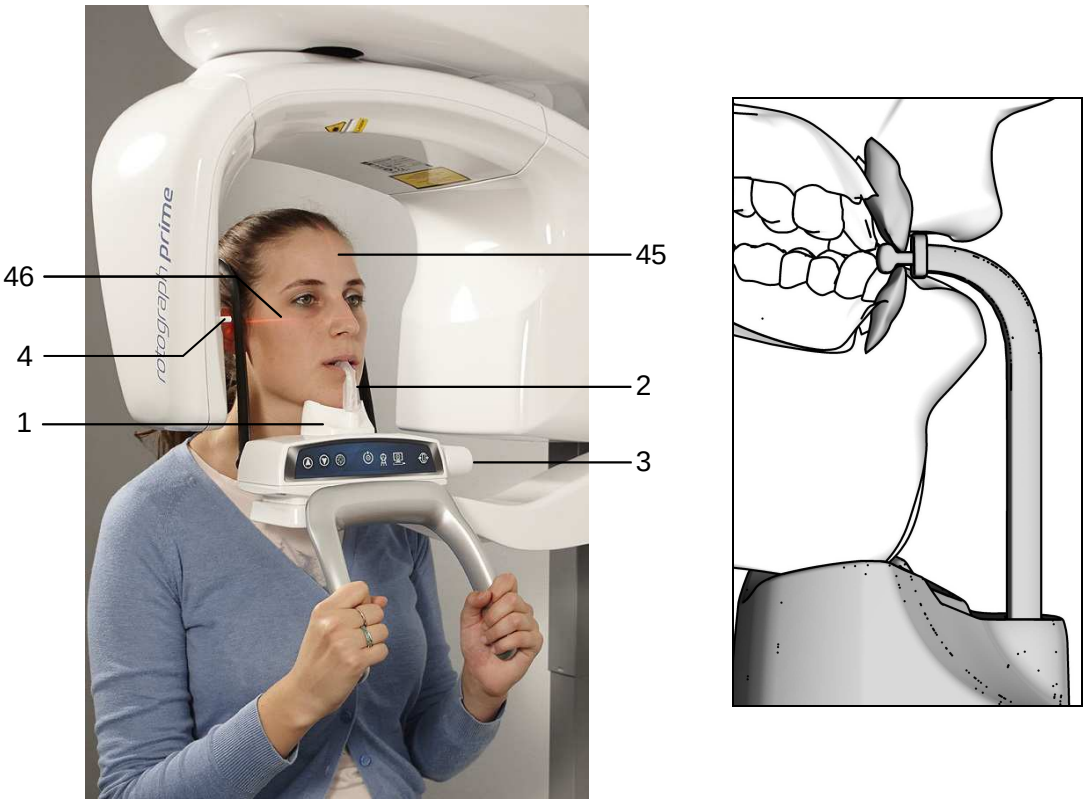


The bilateral Bitewing mode, right and left, means that the two bite-sectors are irradiated; the exam is performed with the same trajectory of the standard panoramic exam, reducing the rays' emission time.
This exam is normally used when it is already known that the patient has a problem on the bite-sectors of the arch, so it is possible to reduce patient irradiation.
Follow the instructions for normal panoramic for patient positioning.

8.8.3 Preparation of the patient

Note
These positioning instructions are valid both for adult and paediatric patients.

Note
If the unit is installed according to suggested height (see paragraph 6.1), the chinrest height when the column is in its lower position is at 97.5 cm (38.4") from the floor, as a consequence, unit can be used with patient at least 118 cm (3 ft 10.4") high.



Label	Description
45	Sagittal medial line
46	Frankfurt line
1	Panoramic chin rest
2	Centring bite
3	Temple claps closing/release knob
4	Laser Knob

Figure 16: Patient positioning

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 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 it does not interfere with the trajectory of the X-ray beams.
3. Place the patient in a standing position at the Panoramic chin rest. With the "Column movement" keys (1 – Figure 8), raise/lower the column until the chin support is aligned with the patient's chin.

Warning
During the patient positioning, make sure the equipment can not collide with any object in the room.

4. Position the patient with the temple clasps ensuring that the chin is positioned on the dedicated support; the hands should rest on the front handles. Ask the patient to bite the reference notch of the bite with his incisors (Figure 16). In the case of edentulous patients, he/she must rest the chin against the reference shoulder of the edentulous chin support.
5. Tell the patient to close his eyes.
6. Press the "Luminous centring devices" key (2 – Figure 8). 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). Position the patient's head in such a way as to ensure that the luminous beams fall in correspondence with respective anatomical references (Figure 16). The luminous beam of the Frankfurt plane can be adjusted according to the patient's height; this can be adjusted using the laser knob (4 – Figure 16).
7. At this point, the patient must move his feet towards the column, making sure he keeps his head within the pre-aligned anatomical references. This ensures 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.

Note
The laser centring devices remain on for approximately 2 minute; shutdown can be anticipated by pressing the "Luminous centring device" key (2 – Figure 8) or, with alignment complete, by pressing the "Patient entrance" key (6 – Figure 8) to begin preparation for exposure.

8. Close the temple clasps to help the patient maintain a correct position.
9. Press the "Patient Entrance" (6 – Figure 8) key to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to the exam start position. Once alignment has been completed, the green LED "Ready for X-ray" (3 – Figure 8) lights up to indicate that pressing the X-ray button once more will start the radiation phase.

10. Ask the patient to: keep their lips closed, move their tongue towards their palate, keep perfectly still and not look at the rotating arm during movement.

Note

With paediatric patient it is recommended to have a greater attention in taking exams. Useful information and a specific checklist can be found at the Image Gently website (www.imagegently.org).

In general with child and adolescent patients, before taking the exposure it is suggested to run the exam in test mode in such a way to show the young patient how the unit works and make them feel comfortable.

8.8.4 Taking an exposure

Warning

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

Note

When the "Test" key is selected, the Test function is activated. In this condition, it is possible to make the unit carry out all movements made during the exam without emitting X-rays.
Test mode may also be useful when the equipment is used on child patients, to show them how the equipment works before running the exam.
Once the cycle is completed, deactivate the "Test" function by pressing the key again.

1. Check once again that exposure data are correct. If not, correct them as described in paragraph 8.7.2; ensure that the equipment's indicator light "Ready for X-rays" (4 – Figure 8) comes on, press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the "X-rays emission" indicator (both on the equipment keyboard and GUI) and the acoustic ray signal.
   The Digital Acquisition System will, in the meantime, process the image.

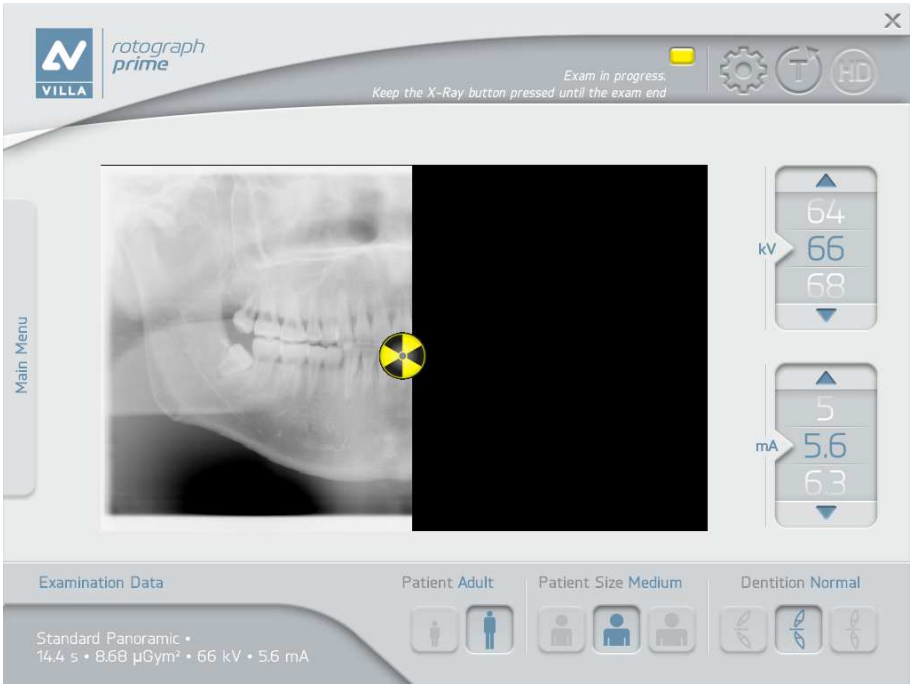


Figure 17

At the end of the acquisition, the GUI will be replaced by the acquired image.

Note
Rotograph Prime assumes that the digital sensor is ready: if this is not the case, the blue light indicator of "Computer connection" status (5 – Figure 8) start blinking slowly.
Refer to the Digital Acquisition System Manual to correct the situation.

Note
The rotation of the arm and the emission of the X-rays will start with a delay of about 3 seconds from when the X-ray button is pressed. As the X-ray button is a "dead man's switch", it must be kept pressed down until the end of the exposure.

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, free the patient from the positioning device.

Note
If the exam is in "Test" mode with the patient already in position, the patient must not be removed from the temple clasp group, to avoid having to reposition him. Press the "Patient Entrance" key (6 – Figure 8) to return the unit to its initial position. Now the system is ready to perform a new exam.

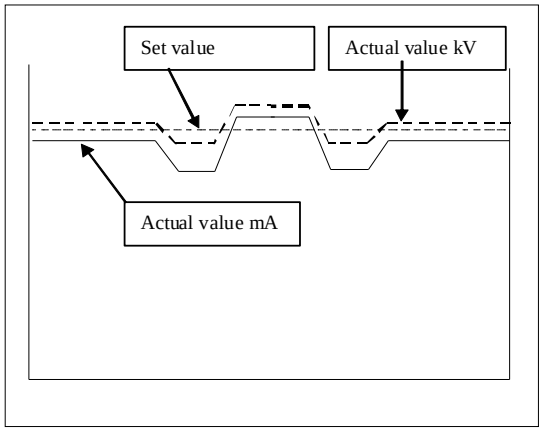
3. Press the "Patient Entrance" key (6 – Figure 8), the unit will move back to the starting position

Note
If you try to perform a new exam, before the cooling period has ended, a message indicating the time to wait before performing a new exam will be displayed.
The waiting time allows the anode in the radiogenic tube to cool down.

Warning
After each exam, clean the chin support, the handles and the temple clasps group thoroughly and change the disposable bite protective sleeve.

Note

During panoramic exams, the value of the exposure parameters varies according to a fixed curve, to compensate for 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 exam and increased in 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 for greater X-ray absorption in the spinal column area. As an example, the variation of the parameters follows the curve below:



The values displayed during the panoramic exam correspond to the ones chosen by the user, while the real value in the various positions of the X-ray cycle can be different; in any case, the system guarantees that the accuracy of the exposure parameters is always within the limits set by IEC 60601-1 international standards for the safety of medical devices. In particular, in accordance with IEC 60601-2-63, 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%.

8.8.5 Image processing windows

The Image Processing menu, if activated, will be displayed at the end of the acquisition in order to customize the default image post-processing settings. The feature can be either enabled or disabled through the corresponding option available under Settings.

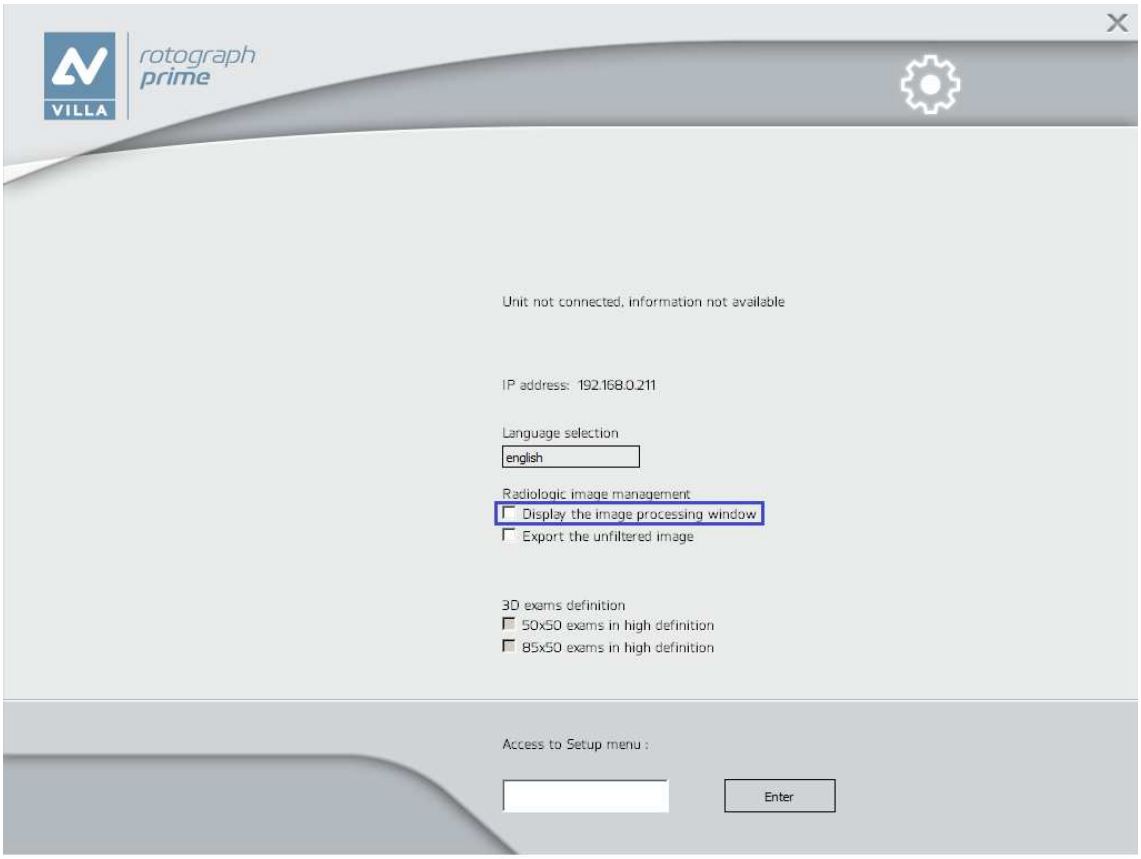


Figure 18

The Image Processing window is composed by three main area (Figure 19):

1. Filters area
2. Toolbars area allowing the filter customization
3. Image preview area displaying the current post-processing.

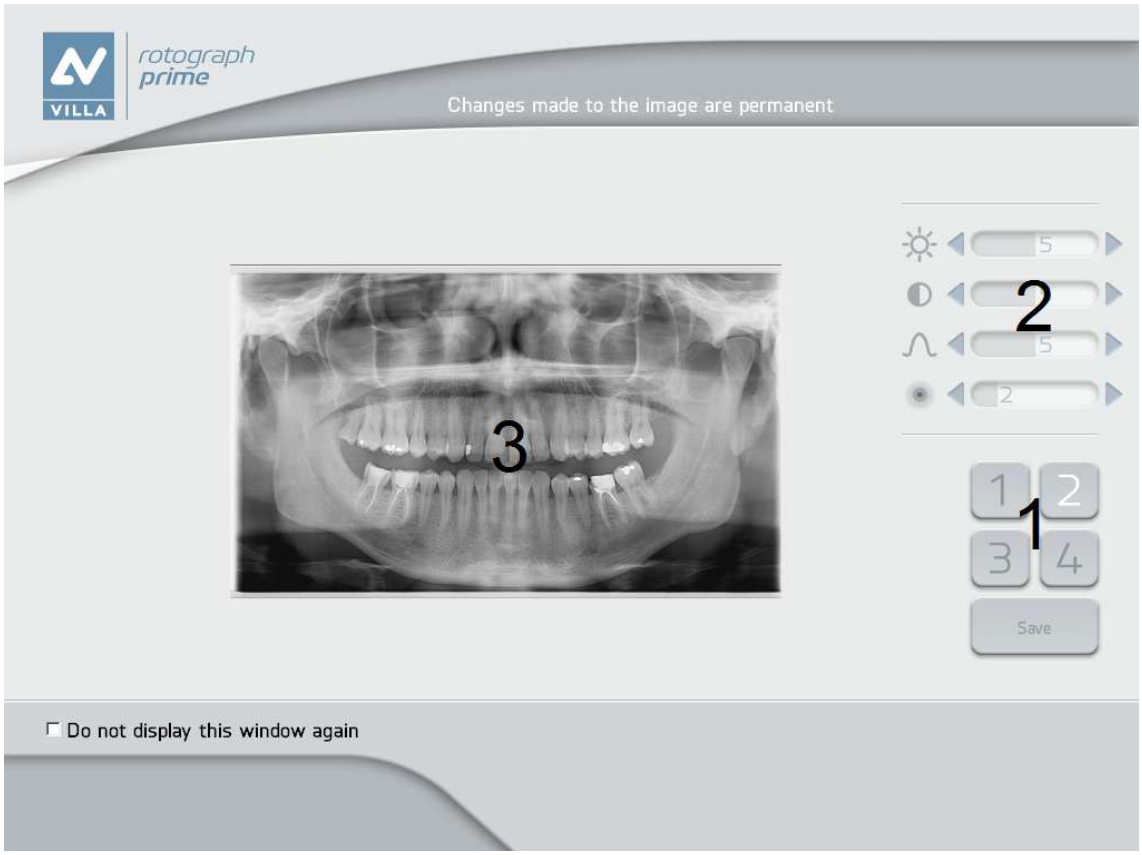


Figure 19

Buttons from 1 to 3 implement pre-set filters. Clicking the button, the corresponding filter will be applied and the preview displayed. The default post-processing can be modified through dedicated toolbars, from the top respectively:

- brightness
- contrast
- gamma value
- image enhancement.

The button Save will apply the current setting to the corresponding button and will set the filter as default in acquisition (Figure 20).
The button 4 is set as default to load the original image (without post-processing) and it can be fully customized as above described.

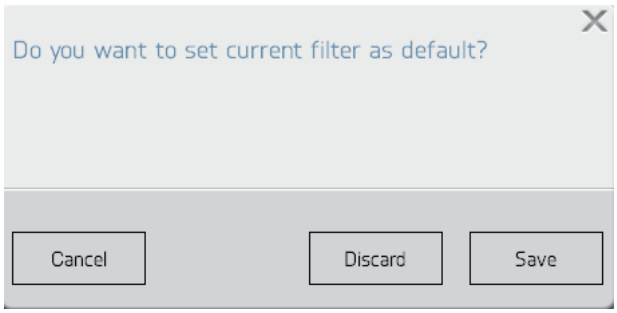


Figure 20

8.9 Sinus exam

On the Virtual Interface select: *Main Menu > Sinus*
Exam information and graphics will be loaded accordingly.

The system is positioned with the following configuration:

- ADULT with the display of the corresponding graphic for the key
- MEDIUM SIZE with the display of the corresponding graphic for the key
- default exposure parameters (if this is the first SINUS exposure), or the exposure parameters (kV and mA) of the last exposure performed.

Figure 21

Select the type of patient with the Patient icons (Adult – Child).
Select the type of build with the Patient Size icons (Small – Medium – Large).
On the basis of the selections made, the display will visualize the kV and mA settings as in the table:

Exposure values in SINUS mode				
	Adult Patient (9.4 seconds)		Child Patient (9.4 seconds)	
	kV	mA	kV	mA
Small	64	5.6	64	4.5
Medium	66	5.6	66	4.5
Large	68	5.6	68	4.5

Note
The exam parameters set as the default are values to be taken as the starting point. Users can optimise the parameters according to their needs.

Once the settings have been completed, the chin support must be placed in position.

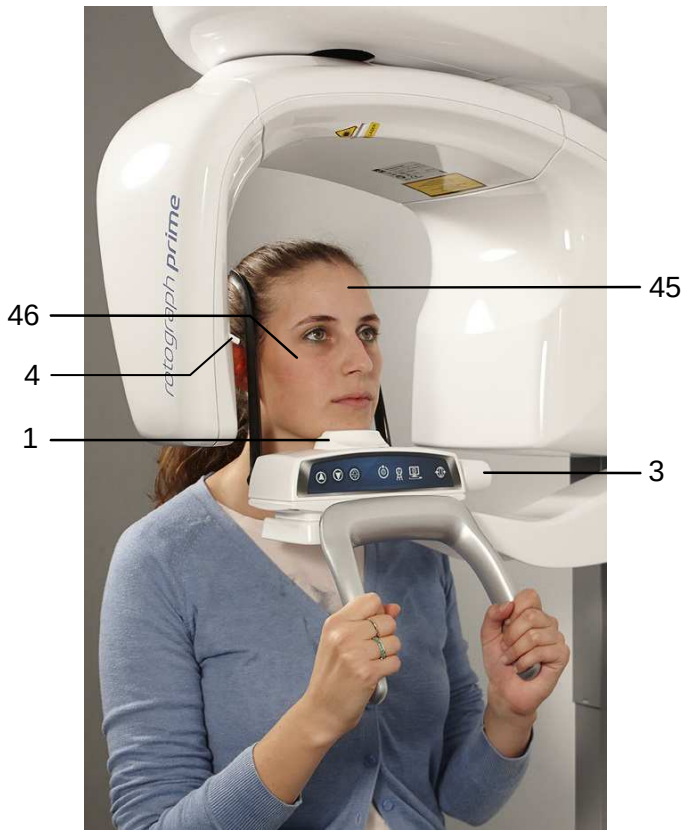
Note
Rotograph Prime is based on a standard dentition and ascending rami shape. This shape, based on statistical data, establishes a standard shape for the dentomaxillofacial complex, also defining the position and the direction of the condyles. Patient anatomy can differ significantly from the statistical model; based on experience and competence, the user has to judge this variation.
IN ANY CASE, 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 programme used. It is therefore very important to check the length calibration of the programme. With SINUS exams, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 7.9 mm (in the centre of the focus layer).

8.9.1 Preparation of the patient

Note
These positioning instructions are valid both for adult and paediatric patients.

Note
If the unit is installed according to suggested height (see paragraph 6.1), the chinrest height when the column is in its lower position is at 97.5 cm (38.4") from the floor, as a consequence, unit can be used with patient at least 118 cm (3 ft 10.4") high.



Label	Description
45	Sagittal medial line
46	Frankfurt line
1	TMJ positioner
3	Temple claps closing/release knob
4	Laser knob

Figure 22: SINUS positioning

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 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 "Column movement" keys (1/2 – Figure 8), raise/lower the column until the chin support is aligned with the patient's chin.

Warning
During the patient positioning, make sure the equipment can not collide with any object in the room.

4. Position the patient with the temple clasps ensuring that the chin is positioned on the dedicated support; ask the patient to place his hands on the front supports.
5. Instruct the patient to close his eyes.
6. Press the "Luminous centring devices" key (2 – Figure 8). 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). Position the patient's head in such a way as to ensure that the first two luminous beams fall in correspondence with respective anatomical references (Figure 22).
   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 (4 – Figure 22).

Note
The laser centring devices remain on for approximately 2 minute; shutdown can be anticipated by pressing the "Luminous centring device" key (2 – Figure 8) or, with alignment complete, by pressing the "Patient entrance" key (6 – Figure 8) to begin preparation for exposure.

7. Close the temple clasps; 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 "Patient Entrance" (6 – Figure 8) key to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to the exam start position. Once alignment has been completed, the green LED "Ready for X-ray" (3 – Figure 8) lights up to indicate that pressing the X-ray button once more will start the radiation phase.
9. Ask the patient to: close his mouth, keep perfectly still and not look at the rotating arm during movement.

Note
With paediatric patient it is recommended to have a greater attention in taking exams. Useful information and a specific checklist can be found at the Image Gently website (www.imagegently.org).
In general with child and adolescent patients, before taking the exposure it is suggested to run the exam in test mode in such a way to show the young patient how the unit works and make them feel comfortable.

8.9.2 Taking an exposure

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

Note
Before performing a Sinus exam, because of the specific trajectory described by the rotating arm, it is recommended to check for possible mechanical interference with the patient's shoulder during rotation. Press the "Test" icon to activate the Test function. In this condition, it is possible to make the unit carry out all movements made during the exam without emitting X-rays. Test mode may also be useful when the equipment is used on child patients, to show them how the equipment works before running the exam.
Once the cycle is completed, deactivate the "Test" function by pressing the icon again.

1. Check once again that exposure data are correct. If not, correct them as described in paragraph 8.7.2; ensure that the equipment's indicator light "Ready for X-rays" (4 – Figure 8) comes on, press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the "X-rays emission" indicator (both on the equipment keyboard and GUI) and the acoustic ray signal.
   The Digital Acquisition System will, in the meantime, process the image.
   At the end of the acquisition, the GUI will be replaced by the acquired image.

Note
During the exam, one single rotation of the rotating arm is to be expected, with X-ray emission limited to the area concerned.

Note
Rotograph Prime assumes that the digital sensor is ready: if this is not the case, the blue light indicator of "Computer connection" status (5 – Figure 8) start blinking slowly.
Refer to the Digital Acquisition System Manual to correct the situation.

Note
The rotation of the arm and the emission of the X-rays will start with a delay of about 3 seconds from when the X-ray button is pressed. As the X-ray button is a "dead man's switch", it must be kept pressed down until the end of the exposure. The X-ray emission to the central part of the dental arch is suspended during the X-ray phase, so the relative signals (sound and visual) are therefore also suspended.

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, free the patient from the positioning device.

Note
If the exam is in "Test" mode with the patient already in position, the patient must not be removed from the temple clasp group, to avoid having to reposition him. Press the "Patient Entrance" key (6 – Figure 8) to return the unit to its initial position. Now the system is ready to perform a new exam.

3. Press the "Patient Entrance" key (6 – Figure 8), the unit will move back to the starting position.

Note
If you try to perform a new exam, before the cooling period has ended, a message indicating the time to wait before performing a new exam will be displayed.
The waiting time allows the anode in the X-ray tube to cool down.

Warning
After each exam, clean the chin support, the handles and the temple clasps group thoroughly and change the disposable bite protective sleeve.

4. Follow instruction on paragraph 8.8.5 to perform image processing function.

8.10 TMJ exam

The TMJ exam with open/closed mouth is similar to panoramic exams; the only difference is that exposure is only on the TMJ (Temporo Mandibular Joint) area. The operating sequence of the exam is therefore identical to that described for panoramic exams.

The temporo-mandibular joint exam uses 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.

The TMJ Standard function makes it possible 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.
Figure 23 shows the information related to the single sectors.

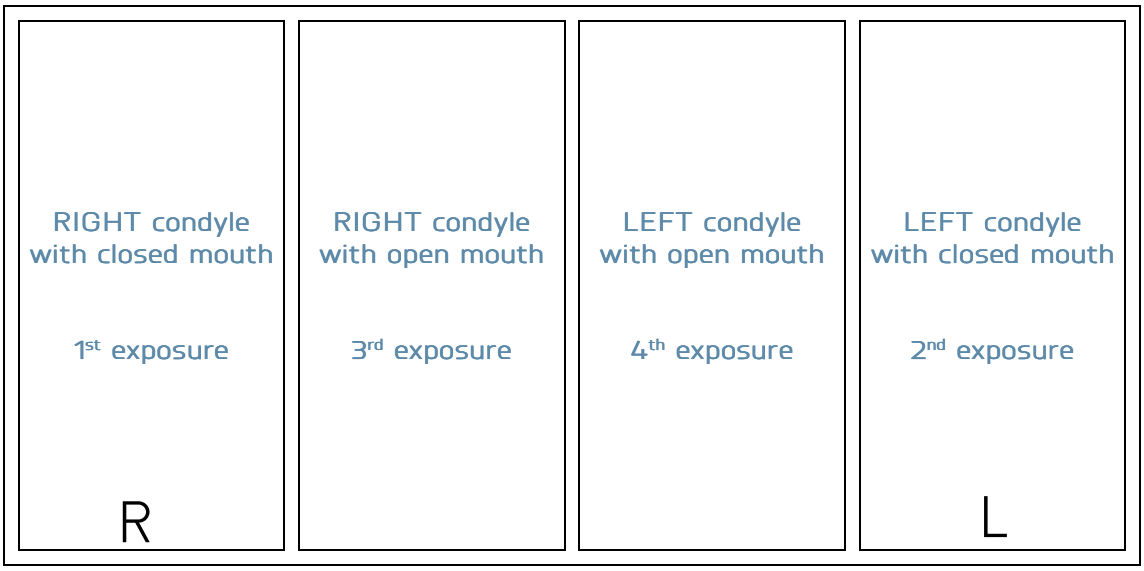


Figure 23: TMJ Standard

In TMJ Single Phase function it is possible to obtain 2 different acquisitions that represent the right and left condile with closed mouth or open mouth.
Figure 24 shows the information related to the single sectors.

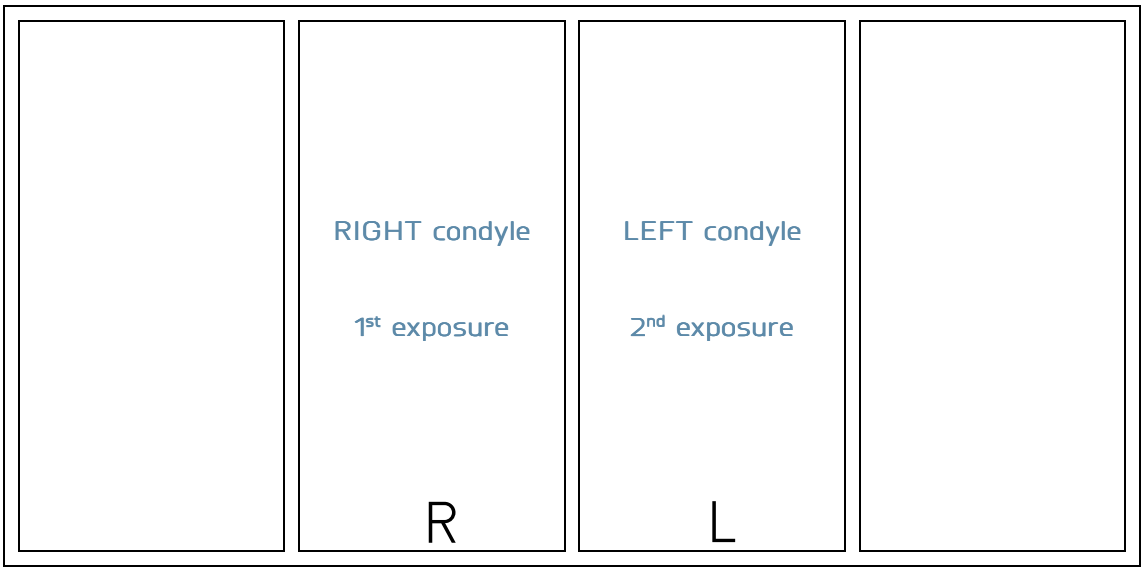


Figure 24: TMJ Single Phase

Note

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

8.10.1 Preparation of the device

On the Virtual Interface select: *Main Menu > TMJ > Standard* for TMJ Open/Closed mouth (4 exposure) or *Main Menu > TMJ > Single Phase* for TMJ Open or Closed mouth (2 exposure).

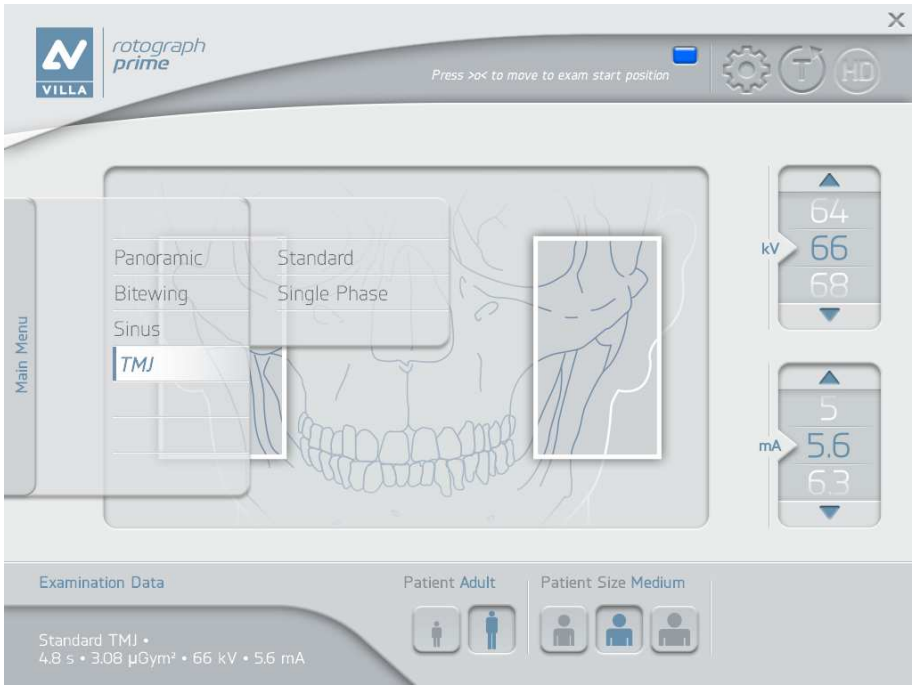


Figure 25

The exam information and graphics will be loaded accordingly.

The system is positioned with the following configuration:

- ADULT with the display of the corresponding graphic for the key
- MEDIUM SIZE with the display of the corresponding graphic for the key
- default exposure parameters (if this is the first TMJ exposure), or the exposure parameters (kV and mA) of the last exposure performed.

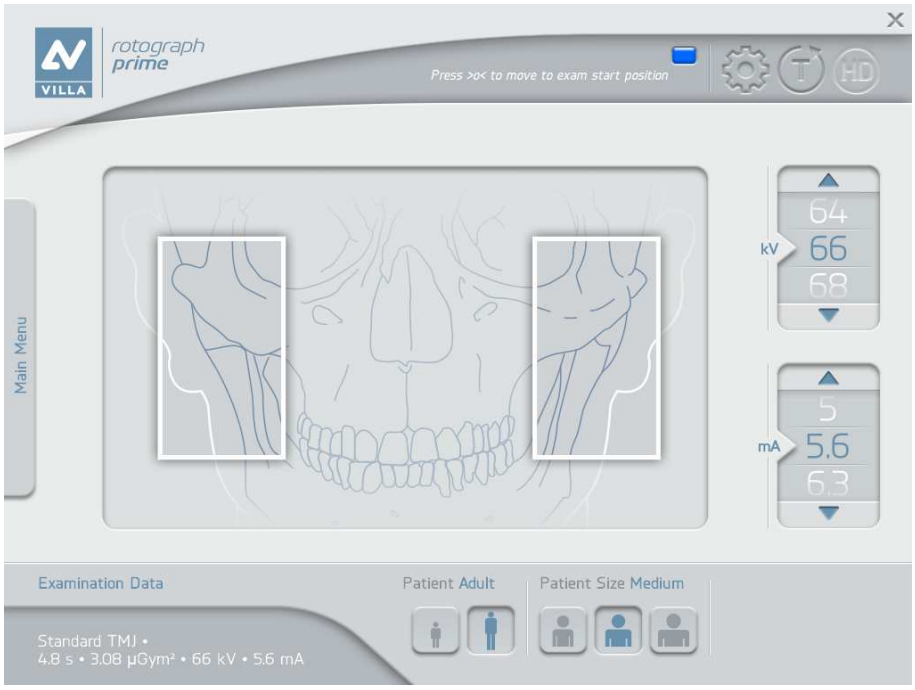


Figure 26

Select the type of patient with the Patient icons (Adult – Child).
Select the type of build with the Patient Size icons (Small – Medium – Large).
On the basis of the selections made, the display will show the kV and mA settings, as in the table:

Exposure values in TMJ mode				
	Adult Patient (9,7 seconds)		Child Patient (9,7 seconds)	
	kV	mA	kV	mA
Small	64	5.6	64	4.5
Medium	66	5.6	66	4.5
Large	68	5.6	68	4.5

Note
The exam parameters set as the default are values to be taken as the starting point. Users can optimise the parameters according to their needs.

Once the settings have been completed, the chin support must be placed in position.

Note

Rotograph Prime is based on a standard dentition and ascending rami shape. This shape, based on statistical data, establishes a standard shape for the dentomaxillofacial complex, also defining the position and the direction of the condyles. Patient anatomy can differ significantly from the statistical model; based on experience and competence, the user has to judge this variation.
IN ANY CASE, RADIOGRAPHY IMAGES CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE IMAGE.

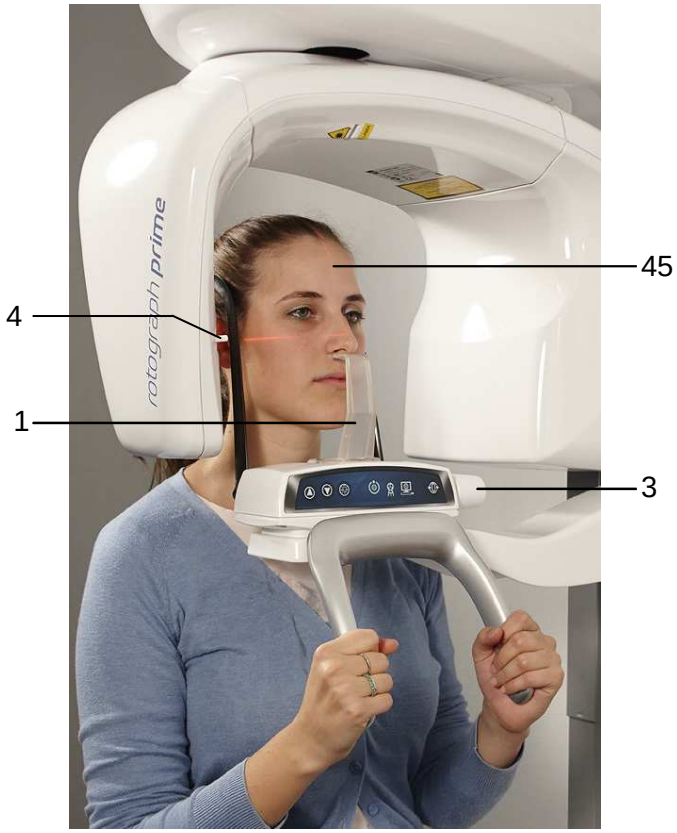
Warning

The measurement of lengths on digital images depends on the specific length calibration of the software used. It is therefore very important to check the length calibration of the software. With TMJ exams, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 8 mm (in the centre of the focus layer).

8.10.2 TMJ closed mouth: preparation of the patient

Note
These positioning instructions are valid both for adult and paediatric patients.

Note
If the unit is installed according to suggested height (see paragraph 6.1), the chinrest height when the column is in its lower position is at 97.5 cm (38.4") from the floor, as a consequence, unit can be used with patient at least 118 cm (3 ft 10.4") high.



Label	Description
45	Sagittal medial line
1	TMJ positioner
3	Temple claps closing/release knob
4	Laser knob

Figure 27 – TMJ closed mouth positioning

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 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 "Column movement" keys (1/2 – Figure 8), raise/lower the column until the TMJ positioner is aligned with the patient's nose.

Warning
During the patient positioning, make sure the equipment can not collide with any object in the room.

4. Position the patient with the temple clasps (asking him to place his hands on the front support).
5. Instruct the patient to close his eyes.
6. Press the "Luminous centring devices" key (2 – Figure 8). 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 the sagittal medial plane laser (45 – Figure 27) as the reference, position the patient's head in such a way that the sagittal medial plane is lit by the corresponding laser beam. The reference of the Frankfurt plane can be used to make sure the head of the patient remains in the same position when the exam is taken with the mouth either open or closed.

Note
The laser centring devices remain on for approximately 2 minute; the shutdown can be anticipated by pressing the "Luminous centring devices" key (2 – Figure 8) or, with alignment complete, by pressing the "Patient entrance" key (6 – Figure 8) to begin preparation for exposure.

7. Close the temple clasps; this will help the patient to stay in a correct position. During this phase, check the patient has not changed position.
8. Press the "Patient Entrance" (6 – Figure 8) key to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to the exam start position. Once alignment has been completed, the green LED "Ready for X-ray" (3 – Figure 8) lights up to indicate that pressing the X-ray button once more will start the radiation phase.
9. Ask the patient to: keep their lips closed, keep perfectly still and not look at the rotating arm during movement.

Note
With paediatric patient it is recommended to have a greater attention in taking exams. Useful information and a specific checklist can be found at the Image Gently website (www.imagegently.org).
In general with child and adolescent patients, before taking the exposure it is suggested to run the exam in test mode in such a way to show the young patient how the unit works and make them feel comfortable.

8.10.3 Carrying out the first exposure

Warning

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

Note

If considered necessary, interference of rotation movement with the patient's shoulder can be checked; the Test function can be activated by pressing the "T" key on the Virtual Interface. In this condition, it is possible to make the unit carry out all movements made during the exam without emitting X-rays. The test function of the TMJ closed/open mouth is the same as for the panoramic mode and so there will not be a second rotation corresponding to the open mouth exam. Test mode may also be useful when the equipment is used on child patients, to show them how the equipment works before running the exam.
Once the cycle is completed, deactivate the "Test" function by pressing the "T" key again.

1. Check once again that exposure data are correct. If not, correct them as described in paragraph 8.7.2; ensure that the equipment's indicator light "Ready for X-rays" (4 – Figure 8) comes on, press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the "X-rays emission" indicator (both on the equipment keyboard and GIU) and the acoustic ray signal.
   The Digital Acquisition System will, in the meantime, process the image.

Note

Rotograph Prime assumes that the digital sensor is ready: if this is not the case, the blue light indicator of "Computer connection" status (5 – Figure 8) start blinking slowly.
Refer to the Digital Acquisition System Manual to correct the situation.

Note

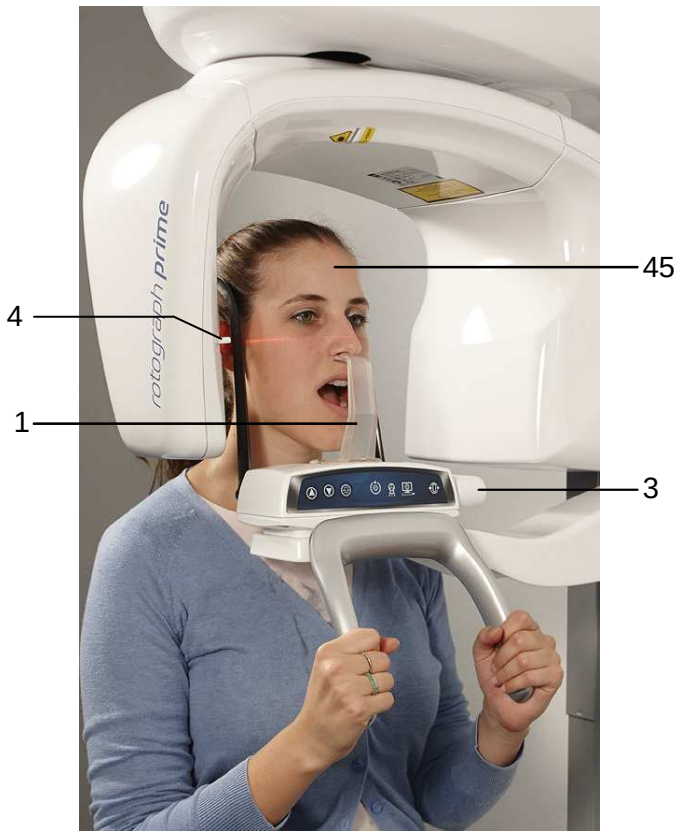
The rotation of the arm and the emission of the X-rays will start with a delay of about 3 seconds from when the X-ray button is pressed. Since the X-ray button is a "dead man's switch", it must be kept pressed until the end of the exposure. The X-ray emission to the central part of the dental arch is suspended during the X-ray phase, so relative signals (sound and visual) are also stopped.

2. Once the exposure is completed, the system will carry out a short return rotation and the message "Press >O< button" will be displayed.
   It will then be possible to set up the system for an open mouth exam, keeping the patient in position, or release him from the operating area.
3. Press the "Patient Entrance" key (6 – Figure 8). The equipment will reposition itself in the starting position.
   In TMJ Standard examination, at the end of the movement, the message "Instruct patient to open mouth" will be displayed.

8.10.4 TMJ open mouth: preparation of the patient

Note
These positioning instructions are valid both for adult and paediatric patients.

Note
If the unit is installed according to suggested height (see paragraph 6.1), the chinrest height when the column is in its lower position is at 97.5 cm (38.4") from the floor, as a consequence, unit can be used with patient at least 118 cm (3 ft 10.4") high.



Label	Description
45	Sagittal medial line
1	TMJ positioner
3	Temple claps closing/release knob
4	Laser knob

Figure 28: TMJ open mouth positioning

1. If this is the first TMJ exposure, the patient has to be prepared following the operations described in paragraph 8.10.2.
2. Press the "Patient Entrance" key (6 – Figure 8).
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).
4. Instruct the patient to close his eyes.
5. Press the "Luminous centring devices" key (2 – Figure 8). Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference. Using the sagittal medial plane laser (45 – Figure 28) as the reference, position the patient's head in such a way that the sagittal medial plane is lit by the corresponding laser beam. The reference of the Frankfurt plane can be used to make sure the head of the patient stays in the same position when the exam is taken with the mouth either open or closed. If necessary, using the "Column movement" (1/2 – Figure 8) keys, lower the column slightly to compensate for the fact that the head, when opening the mouth, will be positioned behind and the condilus cannot be centred on the exposed area.

Note
The laser centring devices remain on for approximately 2 minute; shutdown can be anticipated by pressing the "Luminous centring device" key (2 – Figure 8) or, with alignment complete, by pressing the "Patient entrance" key (6 – Figure 8) to begin preparation for exposure.

6. Close the temple clasps; 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 keep perfectly still and not look at the rotating arm during movement.

Note
With paediatric patient it is recommended to have a greater attention in taking exams. Useful information and a specific checklist can be found at the Image Gently website (www.imagegently.org).
In general with child and adolescent patients, before taking the exposure it is suggested to run the exam in test mode in such a way to show the young patient how the unit works and make them feel comfortable.

8.10.5 Carrying out the second exposure

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

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

1. Ensure that the equipment's indicator light "Ready for X-rays" (4 - Figure 8) comes on, press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the "X-rays emission" indicator (both on the equipment keyboard and GUI) and the acoustic ray signal.
   The Digital Acquisition System will, in the meantime, process the image.
   At the end of the acquisition, the GUI will be replaced by the acquired image.

Note
Rotograph Prime assumes that the digital sensor is ready: if this is not the case, the blue light indicator of "Computer connection" status (5 - Figure 8) start blinking slowly.
Refer to the Digital Acquisition System Manual to correct the situation.

Note
The rotation of the arm and the emission of the X-rays will start with a delay of about 3 seconds from when the X-ray button is pressed. As the X-ray button is a "dead man's switch", it must be kept pressed down until the end of the exposure. During the X-ray, the emission of rays in correspondence with the central part of the dental arch is suspended; the relative signals (acoustic and visual) are also suspended.

2. Once the exposure is completed, the system will rotate back. When it has completed this movement, free the patient from the positioning device.

3. Press the "Patient Entrance" key (6 - Figure 8). The equipment will reposition itself in the starting position.

Warning
After each exam, clean the TMJ positioner, the handles and the temple clasps group thoroughly and change the protective sleeve if used.

4. Follow instruction on paragraph 8.8.5 to perform image processing function.

8.11 Table of pre-set anatomic parameters

PANORAMIC

	Adult	Child
Small	64 kV 5.6 mA	64 kV 4.5 mA
Medium	66 kV 5.6 mA	66 kV 4.5 mA
Large	68 kV 5.6 mA	68 kV 4.5 mA

BITEWING

	Adult	Child
Small	64 kV 5.6 mA	64 kV 4.5 mA
Medium	66 kV 5.6 mA	66 kV 4.5 mA
Large	68 kV 5.6 mA	68 kV 4.5 mA

SINUS

	Adult	Child
Small	64 kV 5.6 mA	64 kV 4.5 mA
Medium	66 kV 5.6 mA	66 kV 4.5 mA
Large	68 kV 5.6 mA	68 kV 4.5 mA

TMJ Open/Closed mouth

	Adult	Child
Small	64 kV 5.6 mA	64 kV 4.5 mA
Medium	66 KV 5.6 mA	66 kV 4.5 mA
Large	68 KV 5.6 mA	68 kV 4.5 mA

Note
The exam parameters set as the default are values to be taken as the starting point. Users can optimise the parameters according to their needs.

9. MAINTENANCE

This unit, like all other electrical appliances, must be used correctly and also serviced and controlled at regular intervals. This precaution ensures safe and efficient performance.
Regular maintenance consists of checks performed by the operator and/or by a qualified technician.

The operator can control the following items:

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

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

Besides the above controls, the Service Engineer will also check the following during preventive maintenance:

Frequency	Type of check
Annually	Correct equipment centring (according to the Service Manual paragraph 9.3.2)
Annually	Check technical factors (according to paragraph 7.5)
Annually	Perform sensor calibration
Annually	Check that the fixing screws are tightened

10. PANORAMIC IMAGE ASSESSMENT

Panoramic radiography is an exam of the maxillo-facial region normally used to view the dental region inside the complete head and sinuses-orbital complex.
With a good panoramic exam, you can distinguish the main anatomic structures that are simplified in the diagram below (which indicates only the main ones, and is not complete).

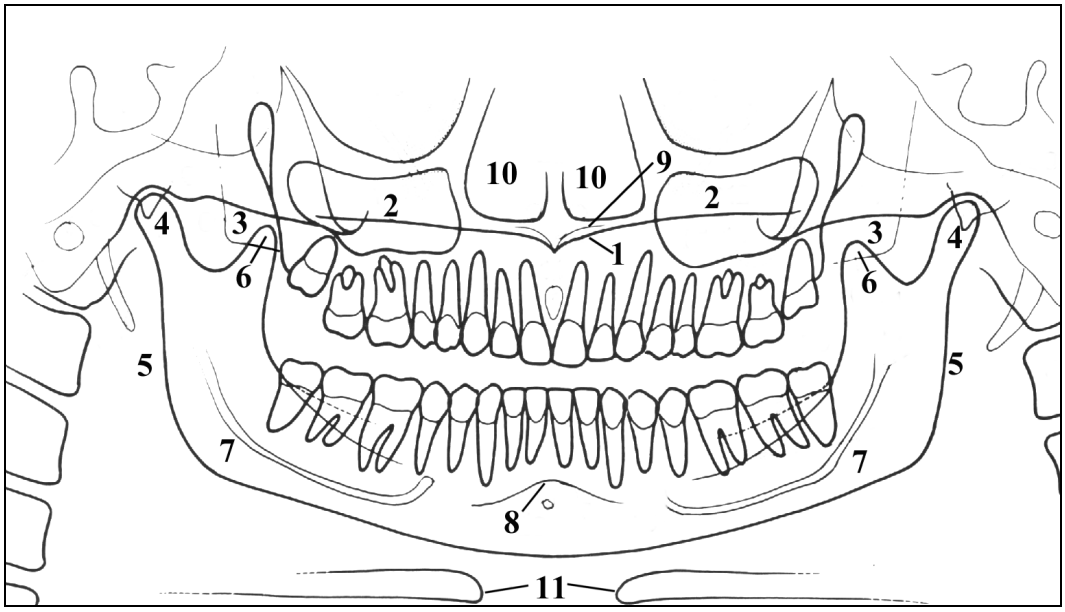


Figure 29

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)

10.1 Proper positioning of the patient

Patient positioning is determining 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 equipment. 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. Patient's incisors must be positioned into the reference notch of the bite.
4. Frankfurt plane (plane passing through the inferior margin of the orbit and the upper margin of the ear canal) must be horizontal.
5. Mid-Sagittal plane must be centered and vertical.

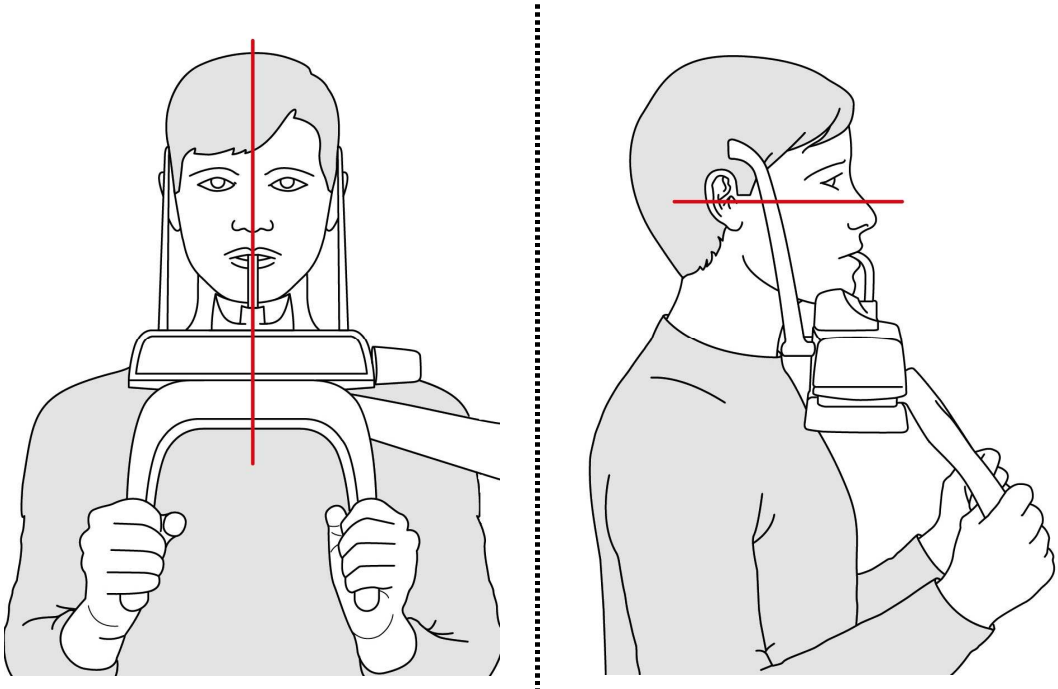


Figure 30

6. Spine should be well stretched, 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.

7. Instruct the patient to swallow and keep the tongue against the palate. Patient's tongue must be held closely to the roof of the mouth during the exposure, otherwise a dark air space between the dorsum of the tongue and the palate could obscure the apical region of the maxillary teeth.
8. Patient must stay motionless during the examination.

The result of all the above listed actions will be a radiography where all the parts are properly exposed and are well identifiable as shown in Figure 31.

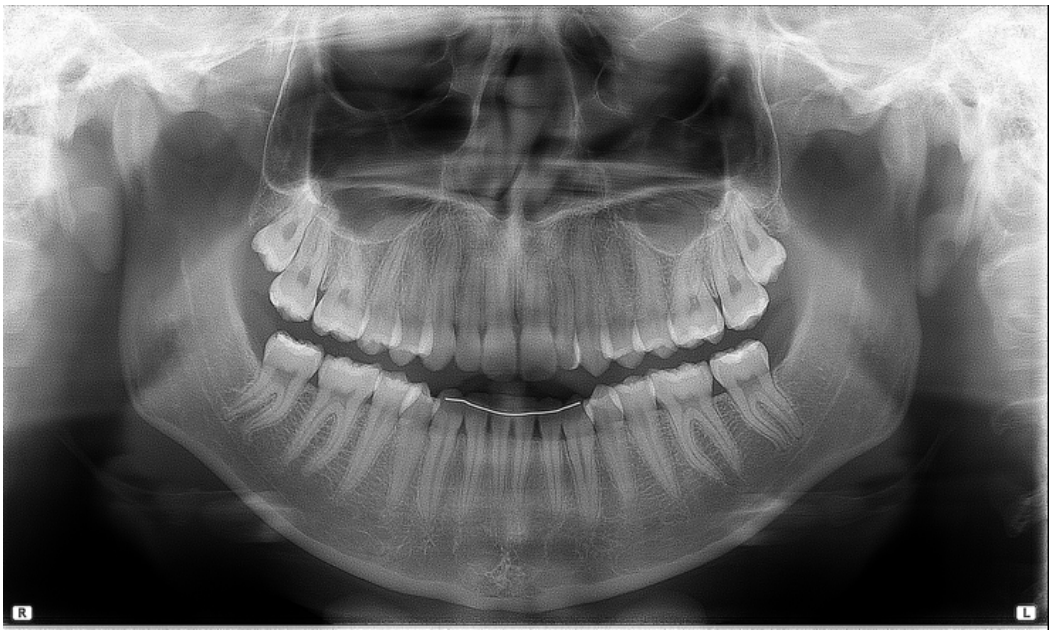


Figure 31

In a good panoramic image, all anatomic structures are well represented and an equal magnification and sharpness of all structures can be seen.
The image must be symmetric, with the ascending rami of the temporo mandibular joints almost parallel and showing posterior vertical borders. The occlusal plane is quite smiling, despite this the palatal plane does not overlap the apex of the upper arch and therefore allows a good view of the apex itself. The spine is well compensated.

Note
The region of the incisors is the most critical because the anterior portion of the image layer is very narrow. Points 3 and 4 are determining for a good result.

Note
Any flaring of dentition may not allow crowns and apices of both arches to fit in the image layer at the same time. For these patients, you must purposely move him/her further forward in order to move the apices into the image layer.

10.2 Patient positioning errors

10.2.1 Turned head

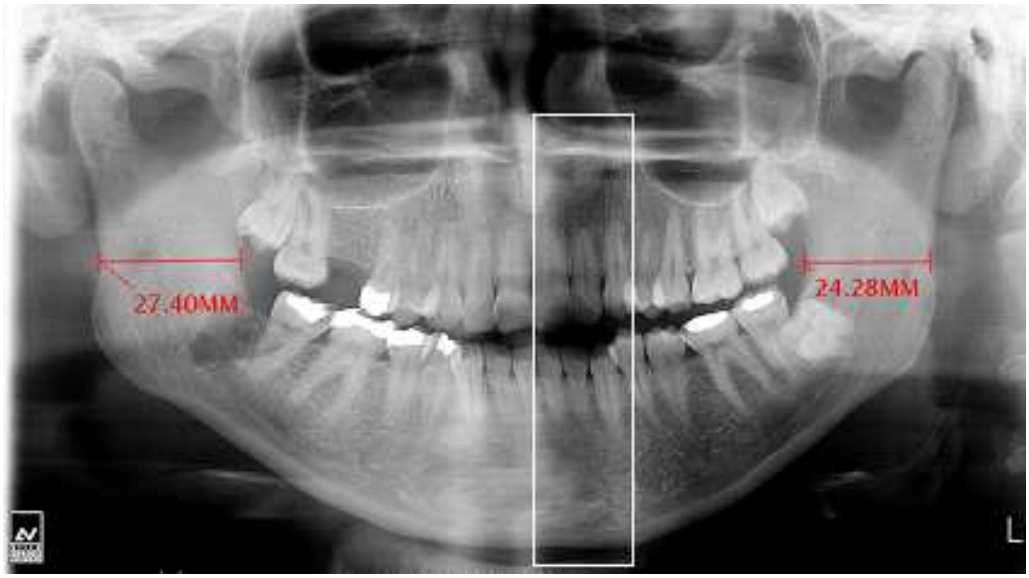
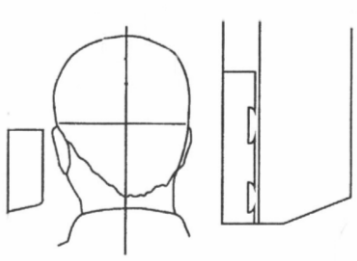


Figure 32



Problem

The patient's head is turned to one side (left or right) in the mid-sagittal plane.

Effects

Condyles are different in size.
The ramous on one side is much wider that the other one.
Asymmetric spine compensation.

10.2.2 Tilted head

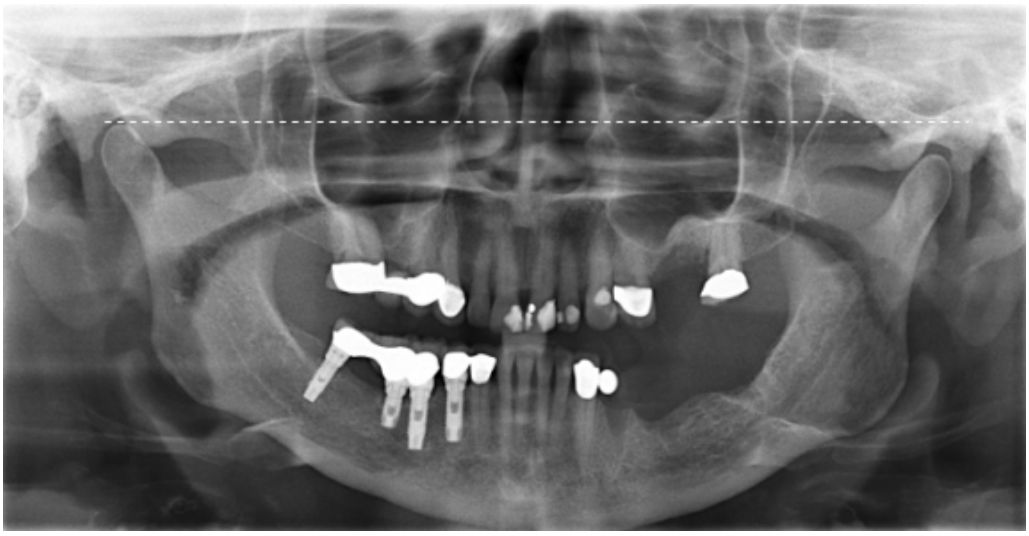
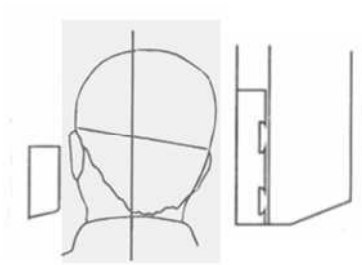


Figure 33



Problem

The patient's head is tilted to one side.

Effects

One condyle appears higher than the other one and the inferior border of the mandible is slanting.

10.2.3 Downward angulation of the head

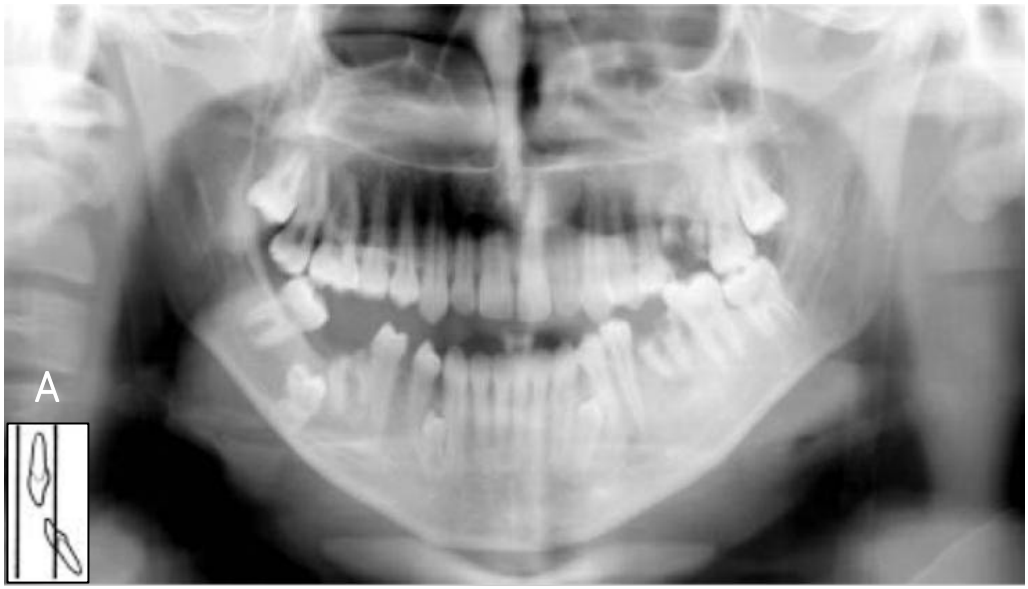


Figure 34

Problem

The Frankfurt plane is tilted downward.

Effects

The roots of the mandibular anterior teeth are positioned outside the focal trough so it is out-of-focus and blurred (Figure 34 A).
The shadow of the hyoid bone is typically superimposed on the anterior mandible.
Condyles may be cut off at the top of the radiograph.
Pre-molars are severely overlapped.
Severe curvature of the occlusal plane.

10.2.4 Backward angulation of the head

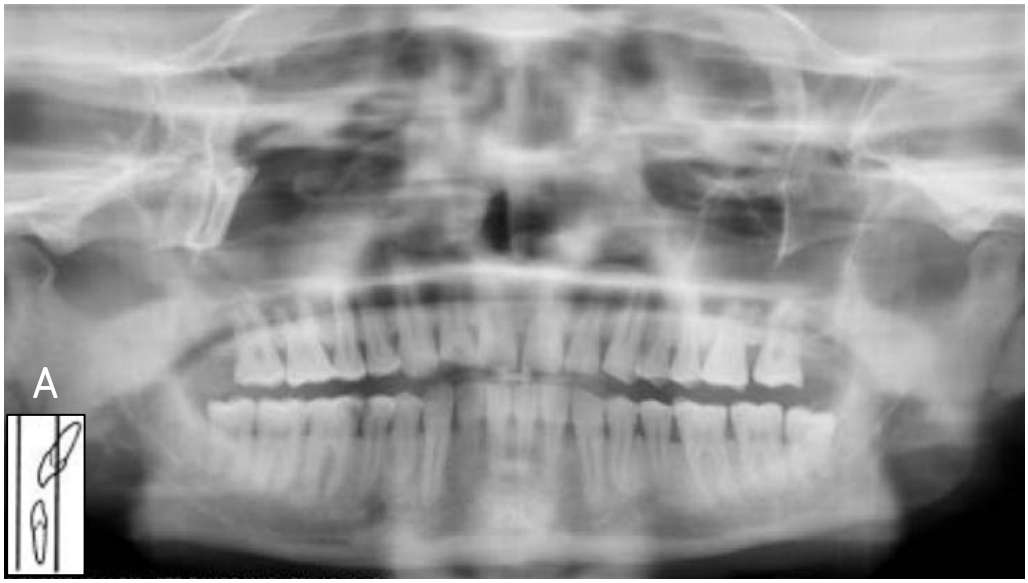
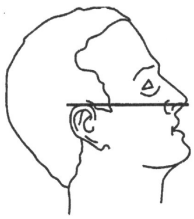


Figure 35



Problem

The Frankfurt plane is tilted backward.

Effects

The roots of the maxillary anterior teeth are positioned outside the focal trough so it is out-of-focus and blurred (Figure 35 A).
The hard palate is superimposed over the apices of the maxillary teeth.
Both condyles may be off the edges of the image area.
The upper incisors can be blurred.
Flattening of the occlusal plane.

10.2.5 Tongue effect

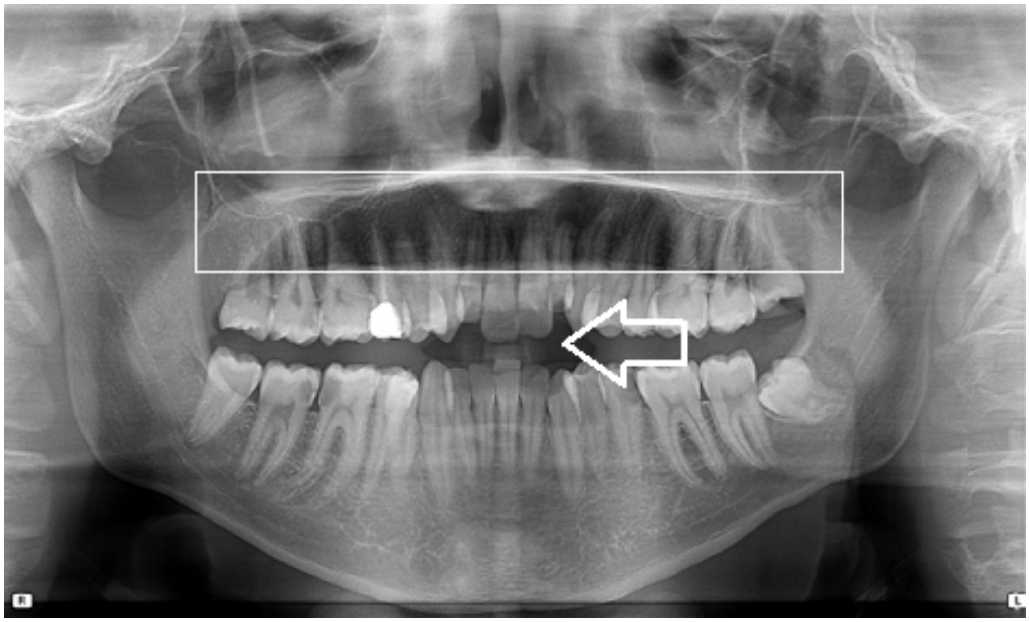
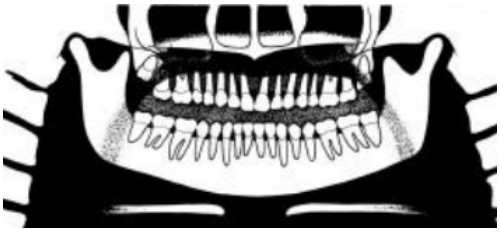


Figure 36



Problem

The patient's tongue was not held closely to the roof of the mouth during the exposure.

Effects

A dark air space between the dorsum of the tongue and the hard and soft palates (palatoglossal air spaces) obscures the apical region of the maxillary teeth.

10.2.6 Spine effect

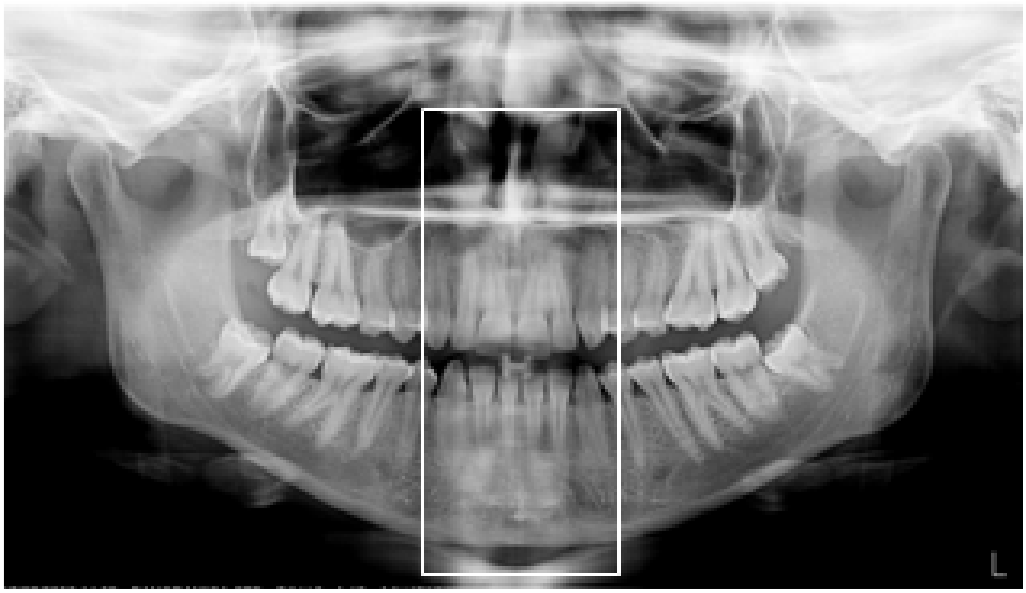
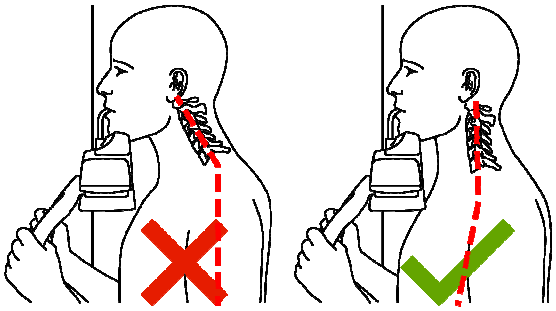


Figure 37



Problem

The patient is slumped.

Effects

The spinal column isn't well stretched causing a ghost image of the spine superimposed in the centre of the image.

MAINTENANCE LOGBOOK

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

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

Cause .....

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

Cause .....

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

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