
ROTOGRAPH-D

(120V version)



User's manual

Revision history

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This manual in English is the original version.

1. INTRODUCTION



NOTE:

The present manual is updated for the product it is sold with in order to grant an adequate reference to use properly and safely the product. The manual may not reflect changes to the product not impacting operating modes or safety.

ROTOGRAPH-D, manufactured by Villa Sistemi Medicali, is a radiological device which allows to carry out radiological examinations of the dento maxillo facial complex, when used in conjunction with the digital image acquisition system QuickVision manufactured by Owandy.

ROTOGRAPH-D is available in a single version for the execution of:

- PANORAMIC examination
- Temporo-Mandibular Joint (TMJ) examination
- SINUS examination.

This manual provides to the operator the instructions for proper and safe use of the appliance.

The appliance must be used strictly following the procedures described in this manual and never for activities other than those for which it was designed.

Before using the appliance, we recommend to read carefully this manual. Keep it in a safe place near the unit for future reference.

ROTOGRAPH-D is an electromedical appliance and may be used only under medical supervision, i.e. with the supervision of highly qualified persons with the necessary know-how regarding X-ray protection.

The user is responsible for complying with the legal requirements regarding the installation and operation of the equipment.

1.1 Icons appearing in the manual



Indicates a “NOTE”; the utmost attention shall be devoted to the reading of paragraphs marked by this icon.



Indicates a “WARNING”; paragraphs marked with this icon cover patient and/or operator safety aspects.

2. SAFETY INFORMATION



WARNING:

Read this chapter very carefully.

Villa Sistemi Medicali designs and manufactures equipment in compliance with safety requirements; moreover, it provides all the necessary information for correct utilization as well as warnings related to risks associated to X-ray generators.

Villa Sistemi Medicali shall not be responsible for:

- any use of ROTOGRAPH-D different from that for which it has been designed,
- any damage to the equipment, the operator or the patient caused either by incorrect installation and maintenance not compliant with the procedures contained in the relevant user's and installation manuals provided with the equipment, or by incorrect operation techniques,
- any mechanical and/or electrical changes effected during or after installation, different from those reported in the service manual.

Only qualified service personnel, authorized by Villa Sistemi Medicali is allowed to perform technical interventions on the equipment.

Only authorized personnel is allowed to remove the tubehead from its support and access the internal components.

2.1 Warnings

The system has not been designed to be used in presence of vapours, anaesthetic mixtures that are flammable with air, or oxygen or nitrous oxide.

Ensure that water or other liquids do not get into the machine so as to prevent short-circuits and corrosion.

Always disconnect from mains before cleaning the machine.

Where necessary, accessories such as lead-sealed aprons must be used to protect the patient from radiations.

Only the patient and the operator may remain in the room during the execution of the radiography examination.

ROTOGRAPH-D has been developed for continuous use with intermittent load. The prescribed operating cycles to allow the heat accumulated by the radiogenic source to be discharged must be observed.

Although the appliance has been designed to have a reasonable degree of protection from electromagnetic interference, it must be installed at a certain distance from electricity transformer rooms, static continuity unit, portable two-way hand radios and cellular phones. The latter may only be used at a distance of over 1.5 meters from all elements of the machine.

All instruments or equipment for professional use and used near the machine must be in conformance to the electromagnetic compatibility standards.

Nonconforming instruments whose low immunity to electromagnetic fields is known must be installed at least 3 meters away from ROTOGRAPH-D and be powered via an independent electric line.

ROTOGRAPH-D must be switched off during the entire period of use of ESU (Electro Surgery Units) units or similar equipment.

Clean or eventually disinfect the chin support, positioning handles, temples clamp support and any other part that may come in touch with the patient.

At the end of the examination, replace the bite and the ear rods.

Although the X-ray dosage supplied by dental radiology appliances is on average low and distributed over a relatively small surface, the operator must take the necessary precautions and/or follow the safety procedures for both himself and the patient during an exposure. We recommend that the X-ray activation always be commanded from an X-ray protected area via remote control. If it is necessary to operate the exposure near the patient, remain at the maximum distance allowed by the remote control cable in the direction opposite to the emission of the rays, at a distance of at least 6.6 feet (2 meters) from both the radiation source and patient.

2.2 Environmental risk and disposal

A number of machine parts contain materials and liquids that upon completion of the machine's life cycle must be disposed of at recovery centers established by the local health units.

The machine contains the following materials and/or components:

- **Tubehead:** dielectric oil, lead, copper, iron, aluminum, glass, tungsten, beryllium
- **Control box and remote control:** iron, copper, glass resin, non-biodegradable plastic casings
- **Column, rotating arm, extensions:** iron, lead, aluminum, copper, non-biodegradable plastic materials, glass resin.



NOTE:

Disassembling part of the unit must be performed by Villa Sistemi Medicali personnel or by authorized technical people.

2.3 Symbols used

Symbol	Description
	Equipment with Type B applied parts (according to IEC 60601-1)
	A number of machine parts contain materials and liquids that upon completion of the machine's life cycle must be disposed of at recovery centers established by the local health units
~	Alternating Current
N	Connection to neutral conductor
L	Connection to line conductor
	Protection ground
	Functional ground
○	OFF ; equipment not connected to power line
	ON ; equipment connected to power line
	Warning: read the documentation provided with the unit

3. CLEANING AND DISINFECTING PROCEDURES

In order to guarantee a careful hygiene and cleaning it is advisable to follow scrupulously the procedures hereunder reported:



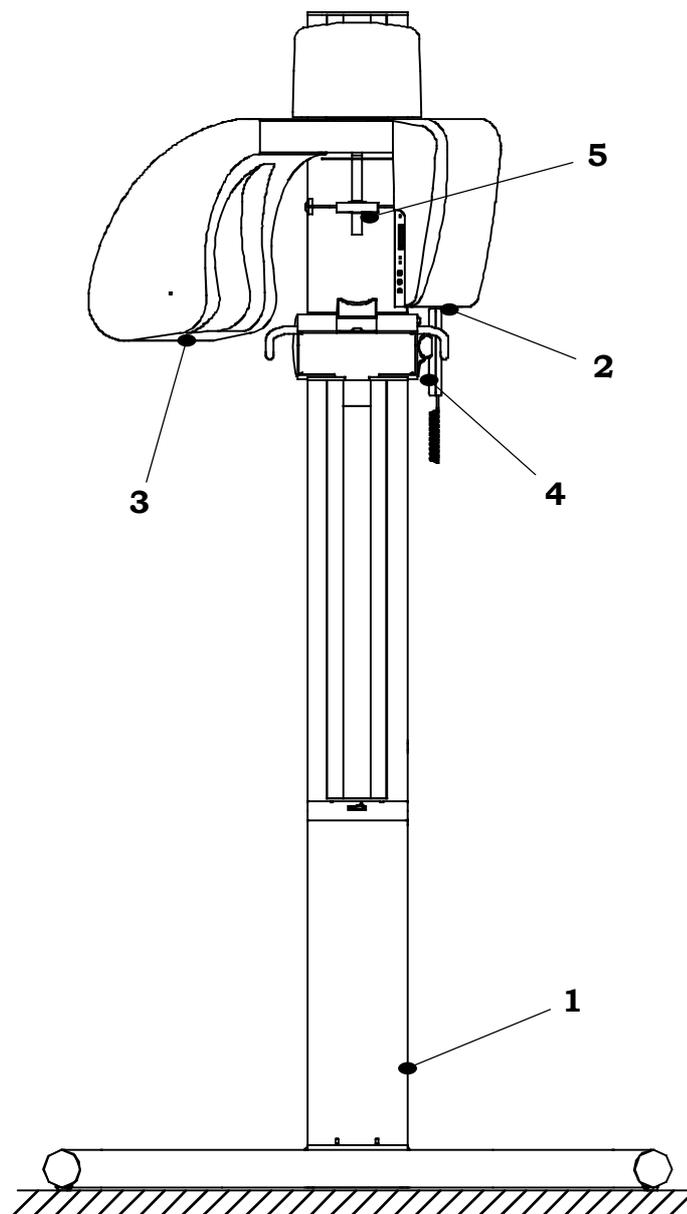
WARNING:

Disconnect from the mains before cleaning the unit.

- Do not allow liquids and water to enter inside the unit, to prevent from shortcircuits and corrosion of inner parts.
- Clean the painted surfaces, the accessories and the connection cables using only a damp cloth and neutral detergents. Take care to dry the parts with a dry cloth. Do not use corrosive or abrasive solvents (alcohol, gasoline, "trielina").
- The bite rod, the centering bite and the ear centering pins must be replaced after each examination where they have been used. In addition, the bite must be disinfected by using a 2% Glutharaldeid solution, following the rules provided by the manufactures of the cleaning solution itself.
- The chin support, the patient positioning handles and the temple-clamp must be carefully cleaned and disinfected with a 2% Glutharaldeid solution or similar (find out what is available; e.g. Milton) after each examination where they have been used.

4. DESCRIPTION

4.1 Identification labels



1a
ROTOGRAPH-D
label

	Made in Italy	
	Type: ROTOGRAPH-D	Model: 9308328X01
	Line: 120 V~ 10A (at 132 V~) 60 Hz	
	X-RAY CONTROL	Model: 8308762700
	Duty cycle: 17/240	Max exposure time: 17 s
	Technique factors: kVp:85 mA:10	
	S/N: YYMMXXXX	
	Manufactured: MMMMYYYY	
<small>Via Delle Azalee, 3 20090 BUCCINASCO MILANO - ITALIA</small>		<small>This product complies with FDA radiation performance standards 21 cfr subchapter j, in effect at date of manufacture</small>

1b
WARNING label

<p>COMPLIES WITH DHHS PERFORMANCE STANDARD 21 CFR SUBCHAPTER J</p> <p>WARNING: THIS X RAY UNIT MAY BE DANGEROUS TO THE PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED. ELECTRICAL SHOCK HAZARD - DO NOT REMOVE PANELS. RISK OF EXPLOSION - DO NOT USE IN PRESENCE OF FLAMMABLE ANESTHETICS. FOR CONTINUED PROTECTION AGAINST RISK OF FIRE, REPLACE ONLY WITH SAME TYPE AND RATING OF FUSE.</p> <p>DANGER: RISQUE D'ESPLOSION - NE PAS EMPLOYER EN PRESENCE D'ANESTHESIQUES INFLAMMABLES. POUR ASSURER UNE PROTECTION CONTINUE CONTRE LE RISQUE D'INCENDIE, UTILISER UNIQUEMENT UN FUSIBLE DE RECHANGE DE MEME TYPE ET DE MEMES CARACTERISTIQUES NOMINALES.</p>

1c
ETL certification
label

2
Digital Sensor
identification label

<p>owandy MADE IN FRANCE</p> <p>IMAX EASY Digital Sensor Type: K1 IMAXEZ Nominal Voltage : 24V=== Nominal Current : 0,6 A</p> <p>S/N: XXX Manufactured : YYYY / WW</p> <p><small>6 Allée Képler 77420 ChampsM France</small></p>	
--	--

3
Tube head
identification label

	Made in Italy	
	DIAGNOSTIC SOURCE ASSEMBLY	
Model: MR05	Code: 8408660200	
S/N: XXYYZZZZ	Manufactured: MMMM YYYY	
Output max: 85 kVp 10 mA		
Total filtration: 2,5 mmAleg	IEC522	
X-RAY TUBE	OPX/105	
Manufacturer:	CEI Bologna Italy	
0.5 IEC336	Inherent filtration: 0.5 mmAleg	
S/N:		
<small>Via Delle Azalee, 3 20090 BUCCINASCO MILANO - ITALIA</small>		<small>This product complies with FDA radiation performance standards 21 cfr subchapter j, in effect at date of manufacture</small>

4
Remote control
identification label

<p>Manufacturer: Villa Sistemi Medicali S.p.A. via delle Azalee, 3 - 20090 Buccinasco ITALY</p> <p>HAND HELD CONTROL</p> <p>Model: 7208761100</p> <p>S/N: YYMMXXXX</p> <p>Manufactured: MMMM YYYY</p> <p><small>This product complies with FDA radiation performance standards 21 CFR subchapter j, in effect at date of manufacture</small></p>

5
Laser WARNING
label

<p style="text-align: center;">- RADIAZIONE LASER - NON FISSARE IL FASCIO AD OCCHIO NUDO APPARECCHIO LASER DI CLASSE 2 Norma IEC 60825-1:2007 Po ≤ 1mW Lung. d'onda 650 nm ± 10 nm</p> <hr/> <p style="text-align: center;">- LASER RADIATION - DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT IEC Standard 60825-1:2007 Po ≤ 1 mW Wavelength 650 nm ± 10 nm</p>
--

4.2 Description

ROTOGRAPH-D has been designed to perform the following examinations:

- Panoramic examination
- "SINUS" examination of the paranasal sinus
- Examination of the Temporo-Mandibular Joints (TMJ) with open or closed mouth on a single image

All the allowed examination may be made with different parameters according to the setting of the remote-control (please refer to the specific chapter of this manual).

ROTOGRAPH-D is controlled by a soft touch console and equipped with an alphanumeric digital display for a clear indication of the working parameters and operative messages. The operative cycle is entirely run by a microprocessor, controlling its different modes : from programming of the emission parameters according to the chosen examination and the patient's size, to the voltage fluctuation and to the notification of possible anomalies, failures or errors.

The excellent quality radiographs thus obtained is the result of a clever design based upon the pseudo-elliptic rotation system, the original light beam-luminous cross pattern centering system and most of all the small dimension of the focal spot, in addition obviously to the digital quality of the solid state RX sensor.

This particular rotation system allows an orthogonal imaging of all teeth and wide image layer with an optimum focused zone of 10 mm for the incisors and 20 mm for the molars.

ROTOGRAPH-D, besides operating in the programmed mode, can also operate in the manual personalized mode by modification of the parameters, as described in chapter 6.

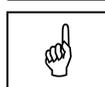
In the Panoramic and TMJ modes, with all interlock enabled, it is possible to activate the TEST push button (**31**) (see Figure 8 at the end of the manual).

The TEST functioning mode allows the operator to check the functionality of the selected examination cycle or to show to the patient the examination he will undergo (including all movements of the machine) without emitting X-rays.

The TEST push button as X-RAY button are a "dead man" buttons, which means thus if they are released during the examination cycle, the latter is interrupted stopping the movements in progress. To re-start the cycle first reset the unit by means of the key **32** (Figure 8), then start again the function which was interrupted.

5. TECHNICAL FEATURES

General characteristics	
Equipment	ROTOGRAPH-D
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italy
Class	Class II according to 21 CFR sub-chapter J. Class I with type B applied parts according to IEC. 
Degree of protection	IP20
Rated line voltage	120V ± 10%
Line frequency	60Hz
Max line current at nominal voltage	10A rms momentary; 0.5A stand-by
Maximum power	1.15 kVA @ 108V
Power fuse	10A T
Command fuse	0.5A T
Filament fuse	0.315A F
Line voltage regulation	≤ 3% at 108V
Compensation of the mains voltage fluctuation	automatic
Apparent line resistance	0.5 Ω max
High voltage	60-85 kV (5 kV steps)
KV accuracy	± 10% @ nominal voltage ± 10%
Anodic current	10 mA
Anodic current accuracy	± 1.5 mA @ 120V ± 10%
Exposure time (Panoramic)	17s adult 14s child
Exposure time (TMJ1 + TMJ2)	10.4s adult 9.4s child
Exposure interval (PAN & TMJ)	240s (1:16 duty cycle)
Height of irradiated area on sensor	5 5/8" (143 mm)
Image mean enlargement (PAN & TMJ)	1.2 : 1



NOTE:

Due to technology used to compensate the line voltage fluctuations, the maximum of line current absorbed from the line is at the lowest voltage (108V).

Tubehead features	
Type	MR05
Manufacturer	VILLA SISTEMI MEDICALI Buccinasco (MI) Italy
Max peak tube potential	85 kV
Nominal power	0.630 kW (85kVp, 10mA)
Total filtration	≥ 2.8mm Al eq. at 85 kV
Insulation	Oil bath
Cooling	Ambient
Leakage radiation at 1 m	< 0.25 mGy/h (85 kV, 10mA, 1:16 duty cycle)
Maximum power	85 kVp, 10mA
Type of circuit	Single-phase, self-rectifying
X-ray tube features	
Manufacturer	CEI – Bologna Italy
Type	CEI OPX/105
Focus	0.5 IEC 336
Inherent filtration	0.5 mm Al eq.
Anode tilt	5°
Anode material	Tungsten
Nominal voltage	105 kVp
Filament maximum current	4A
Filament maximum voltage	8V
Anode thermal capacity	30 kJ
Laser centring device	
2 laser beams are used for the patient positioning; beams align mid Sagittal and Frankfurt planes (please refer to relevant paragraphs for detailed explanation).	
Wave length	650 nm ± 10 nm
Divergence	< 2.0 mRad
Optical power	≤ 1 mW
Classification	Class 2 laser product according to IEC Standard 60825-1:2007

Weight of apparatus and parts	
Slider net weight	108 lbs (49 kg)
Column net weight	106 lbs (48 kg)
Tubehead net weight	42 lbs (19 kg)
Control unit net weight	62 lbs (28 kg)
Slider counterweights net weight	150 lbs (68 kg)
Environmental conditions	
Maximum operating temperature range	+50°F ÷ +104°F (+10° ÷ +40°C)
Operating relative humidity range	30% ÷ 75%
Transportation and storage temperature range	-4°F ÷ +158°F (-20° ÷ +70°C)
Maximum transportation and storage relative humidity	< 90% non condensing
Minimum atmospheric pressure for transportation and storage	630 hPa

5.1 Standards and regulation

The ROTOGRAPH-D equipment is manufactured according to the following standards:

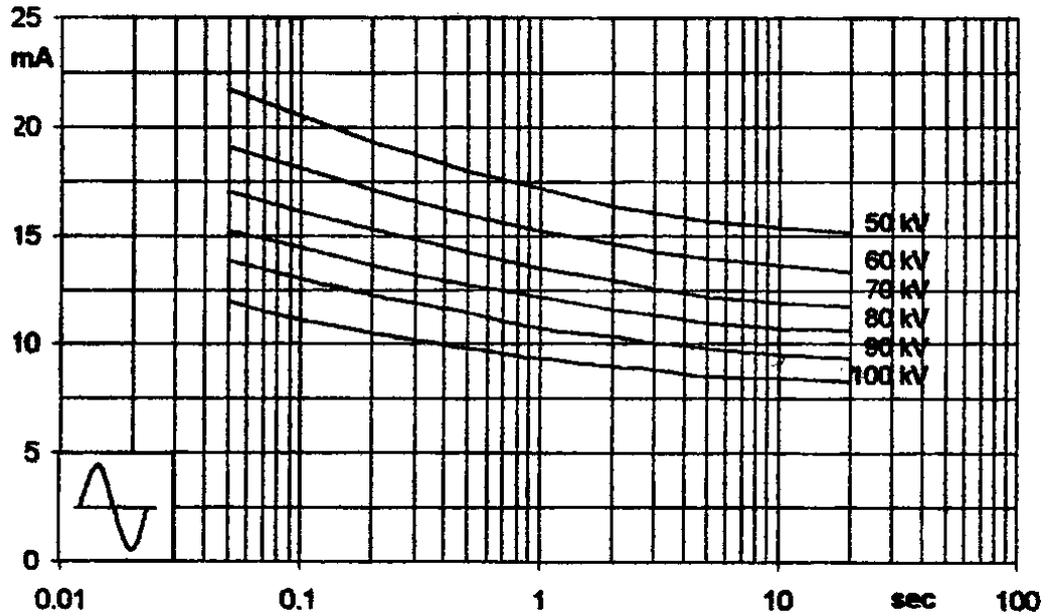
21 CFR subchapter J

- General safety:
 - IEC 60601-1
 - IEC 60601-1-1
 - IEC 60601-2-7
 - IEC 60601-2-28
 - IEC 60601-2-32
 - UL 2601
- Electromagnetic compatibility
 - IEC 60601-1-2
- Protection from radiation
 - IEC 60601-1-3

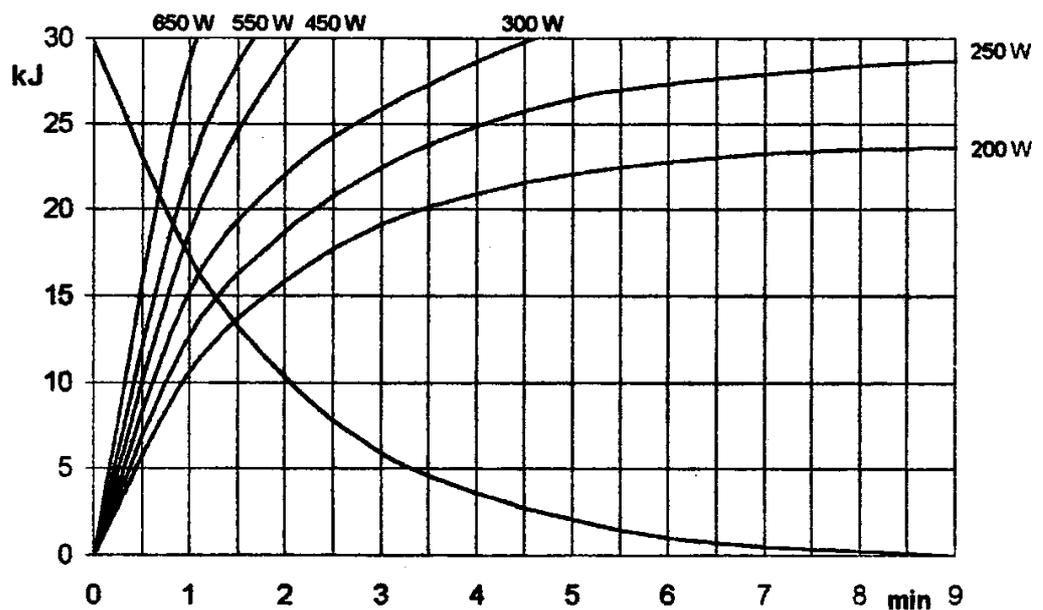
5.2 X-ray tubehead curves

Tube "CEI - OPX/105" (0.5x0.5)

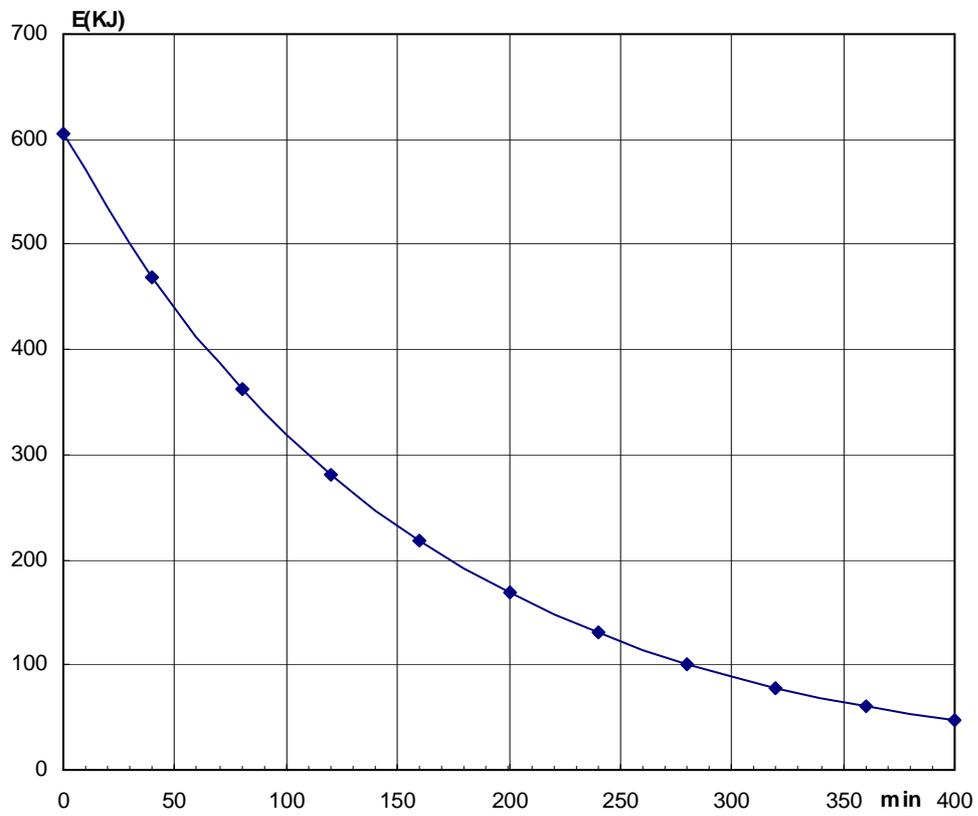
Loading chard



Anode cooling chard



Cooling curve of tubehead



5.3 Technical factors measuring method

- kV_p** The peak tube potential is directly measured with a non invasive kVp-meter, accuracy $\pm 3\text{kVp}$. When performing the measurement, make sure that measuring probe is completely covered by the X-ray beam. A direct measurement of the high voltage can only be carried out by specialized technicians in a suitable testing laboratory as it requires disassembling of the tubehead.
- mA** The output current is determined by measuring with a digital multimeter, accuracy 0.5%, by connecting the probes to the connectors of A1 PCB as indicated in the Service Manual (digital multimeter set to VDC 20V, 1V=1mA).
- t** The exposure times are determined by using a timer/counter, having an accuracy of 0.1%, measuring the duration of part of the voltage applied to the primary side of the tubehead, during the exposure phase.

5.4 Overall dimension

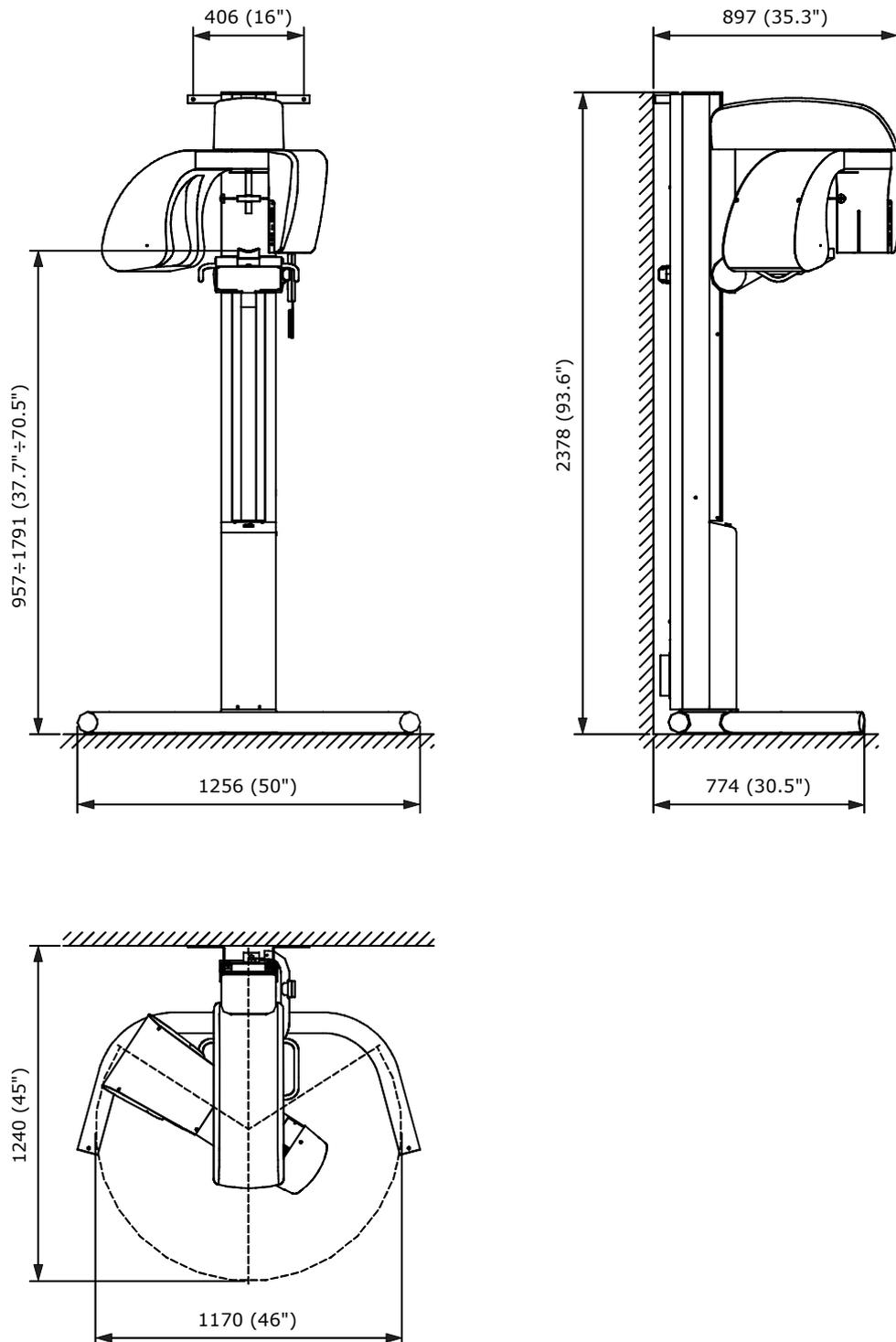


Figure 1: ROTOGRAPH-D overall dimension

6. OPERATING INSTRUCTIONS



NOTE:

The procedures explained in the next pages make often reference to Figure 7 and Figure 8 located at the end of this chapter. To easily consult this Figures, unfold pages in order to make it visible while reading other pages of the manual.

6.1 Switching on the equipment

1. Push the button on the control panel to turn the equipment ON. The "CHECK" function is so activated, verified by the lighting up of the LED'S on the remote-control and the display pixels. The software checks the enabled operating function with the corresponding LED signal on the hand control.
The system sets for a radiography PAN adult, even if the digital sensor is not yet ready for the acquisition. If the X-Ray button or the "TEST" button is pressed the message "**Digital Sensor not Ready**" will be shown until the necessary activation procedure is completed.
2. The system sets for:
 - ADULT with push button "33" LED lighted up
 - MEDIUM SIZE with push button "36" LED lighted up
 - Display (44) shows the kV alternatively to the exposure times.

6.2 Panoramic X-ray examination

6.2.1 Preparing the equipment (refer to Figure 7 and Figure 8)

If pressing the button "27" the message "**Equipment not set**" is displayed and the relevant function LED blinks, push the button a second time in order to display the message concerning the interlock to be enabled on the sensor.

The messages that can be read during the Panoramic function setting and the relevant actions to perform are the following:

1. **Digital Sensor not Ready:** activate the QuickVision program and wait for the completion of the initial check.
2. **Select PAN/TMJ1:** it is necessary to select **PAN** with the dedicated button (13) positioned near the sensor



NOTE:
THE SELECTION DONE ON THE HAND CONTROL MUST BE CONSISTENT WITH THE SELECTION DONE WITH THE BUTTONS POSITIONED IN THE AREA OF THE DIGITAL SENSOR.

After completing the system SET UP, adjust the chin support as follows:

		Chin support PANORAMIC (1)	Chin support SINUS (21)
PANORAMIC	ADULT	YES	NO
	CHILD	YES	YES

6.2.2 Programmed/Manual exposure

After setting the unit as previously described previous point, it is now possible to choose whether to operate an exposure in a preset mode, meanings with the kV values preset by the manufacturer or to operate an examination in the manual function, with possibility to change the preset kV values.

6.2.2.1 Programmed exposure (refer to Figure 8)

Push button "33" for adult program or "34" for child's.

To check the new configuration depress push buttons Adult (33) and Child (34), there will only be a variation on kV and time; pressing buttons Large Size (35), Medium Size (36) and Small Size (37), there will be a variation on kV.

The following table shows the programmed values according to the selection made:

	Large Size (35)	Medium Size (36)	Small Size (37)
Adult (33)	80kV - 17sec	70kV - 17sec	65kV - 17sec
Child (34)	65kV - 14sec	60kV - 14sec	60kV - 14sec

6.2.2.2 Manual exposure (refer to Figure 8)

To select the manually technical factors follow the next procedure:

1. Depress button kV (38), the button function will blink.
2. Depress buttons increase (41) or decrease (40) on the hand control selecting the desired kV value to be used. After 2 seconds, the function button LED stops blinking. The unit is now ready for the next step.



NOTE:

The kV can vary from a minimum of 60kV to a maximum of 85kV with steps of 5kV.

If, after having reached the minimum or maximum values of the kV range additional decrease or increase is requested, the following messages will be displayed: **Minimum** or **Maximum**; the minimum or maximum set kV values will subsequently be displayed.

6.2.3 Preparing the patient (refer to Figure 2 and Figure 3)

- 1.** Ask the patient to remove all metal objects located in the zone involved in radiography (necklaces, earrings, spectacles, hair-clips, movable dental plates etc.).
Make sure that there are no heavy articles of clothing (such as overcoats, jackets, ties, polo-neck sweaters, etc.) in the radiography zone.
- 2.** Have the patient put on the protecting apron or similar protective devices in accordance with the regulations in force in the various countries, making sure that it does not interfere with the trajectory of the X-rays beam.
- 3.** Bring the patient in standing position up to the chin support and, using the handle, release the brake button (24) in order to position the slider so that the chin support resting plane is aligned with the patient's chin.
- 4.** Position the patient in the skull clamp with the chin resting on the appropriate support and rest the hands on the side handles; have the patient bite with the incisors in the groove of the bite block mounted on the appropriate rod, making sure both upper and lower anteriors are set in the groove of the bite piece.
- 5.** Press the laser centring device activation button (20). When this is done, two crossed beams of light illuminate both the sagittal median line (45) and the horizontal line for the Frankfurt plane reference (46).
The centring device stays illuminated for about 40 seconds; if this time is insufficient to carry out the centring operations, the activation button (20) may be pressed again.
- 6.** Bring the height of the skull-clamp a little above the patient's orbital bone and centre the patient until the position of perfect alignment with the Frankfurt and sagittal median lines is obtained.
The Frankfurt plane light beam must be adjusted for height in relation to the patient's size; the adjustment is made by acting on the appropriate knob (18).
In order to check the patient's centring, the operator can tilt the mirror towards himself, thus obtaining a front view of the patient. Lastly bring the patient's head into contact with the two temples clamp rods (7) by acting on the appropriate knob (9).
- 7.** After the head has been positioned, the patient has to make a movement with his feet towards the stand. This will give better distension of the spinal column in the cervical region, eliminating white ghosting of the spine on the radiograph in the zone of the lower incisors.
- 8.** Check centring again, advise the patient to close mouth and eyes, ask then to swallow and **bring the tongue against the palate** and remain motionless for the exposure.

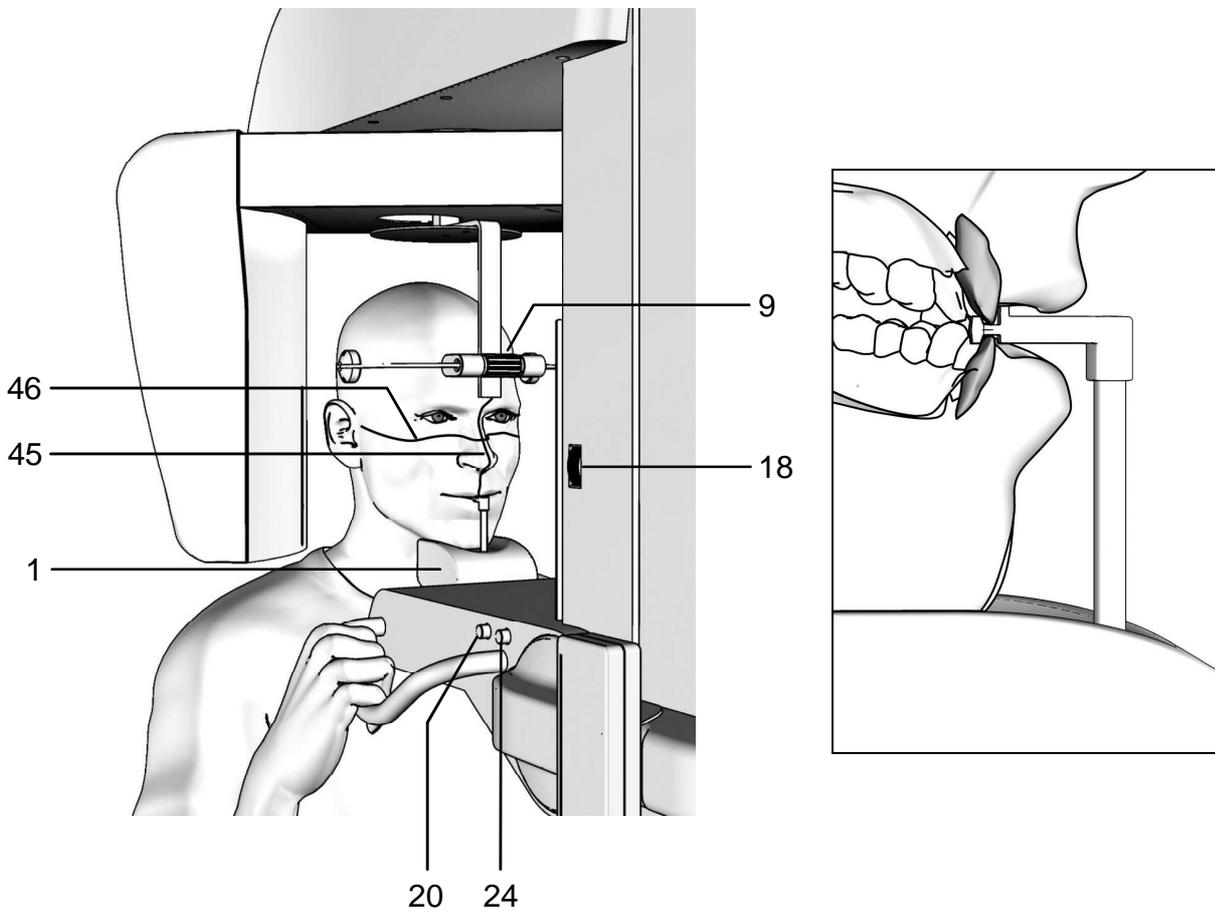
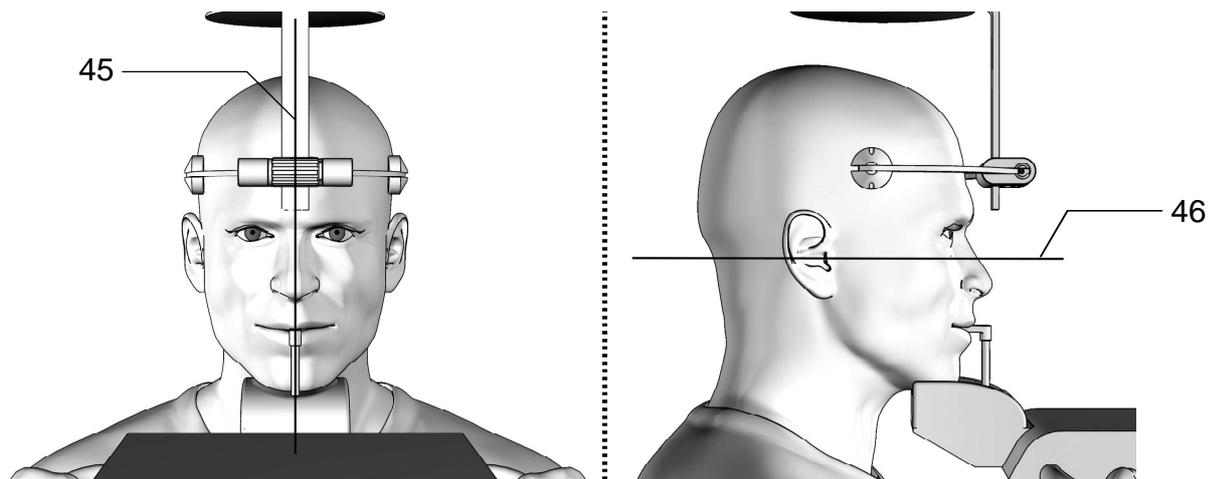


Figure 2: Panoramic position



Legend of reference lines:

- 45 – Sagittal median line
- 46 – Frankfurt plane line

Figure 3

6.2.4 Making the exposure (refer to Figure 8)

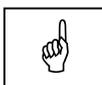


NOTE:

During the emission of X-rays protection of the operator and surrounding personnel must be in accordance with the rules in force in the respective countries.

The X-ray activation always be commanded from an X-ray protected area via remote control. If it is necessary the operator must stand at a distance of at least 2 meters (6.6 feet) away from the X-ray source and, if possible, on the opposite direction. No other persons other than the operator and the patient, are allowed to stay in the examination room during the examination.

1. Check that on the digital sensor PAN examination has been selected through the dedicated button
2. Check if the exposure data are correct (paragraph 6.2.2), then press the X-ray button (42) during the whole time of the exposure as the control is a dead man type, checking the simultaneous operation of the rays signaling light (43) and the acoustic X-ray signal.



NOTE:

The start of arm rotation and the emission of rays take place with a delay of four seconds after the activation of button (42) allowing preheating of the tube filament and check all the set value.

3. After exposure, the message "**Push RESET**" will be displayed: the patient may then be released from the positioning device, the return button (32) pressed to move the machine back to the starting position. After full return, the message "**OK**" will be displayed, which will disappear when the button (32) is released.
4. With Reset operation performed, and with button (32) released the following message is displayed "**Wait, please**" indicating a waiting time of 4 minutes to allow cooling of the tubehead anode.



NOTE:

After each examination, clean carefully both chin support and temples-clamp and replace the bite.



WARNING:

If the patient should move during the exposure, stop the exposure immediately by releasing the rays control button (42) interrupting the rays emission and the arm movement.

The message "**Press Reset**" will appear for a few seconds on the display the return button (32) has to be pressed to bring the machine in the starting position. The return end is evidenced by the message "**OK**" which will disappear when the button (32) is released.

It will then be necessary to ask the QuickVision program for the execution of a new radiography.

If, for external reasons or incorrect operation the X-ray emission times should exceed 17 seconds, a backup security timer will come into operation cutting out the emission after 20 seconds, the arm rotation will continue until the natural stop point.

6.3 TMJ examination



NOTE:

When performing TMJ examinations the rays emissions is discontinuous as it is interrupted during the transition phases between the different projections.

The TMJ functions allow to obtain 4 different images on the same image by means of two different programs. The 4 images represent the right and left condyle of the temporomandibular joint (TMJ) both with closed (TMJ1) or open (TMJ2) mouth.

With TMJ1 projection the lateral portions of the image are generated, while the centre part will be generated with the TMJ2 projection.

We suggest to follow the sequence TMJ1 and TMJ2.

6.3.1 Performing the TMJ1 examination

6.3.1.1 Preparing the equipment

If acting on key "29" or "30" the message "**Equipment not set**" is displayed and the relevant function LED blinks, push the button a second time in order to display the message concerning the interlock to be enabled on the sensor.

The messages that can be read during the Panoramic function setting and the relevant actions to perform are the following:

1. **Digital Sensor not Ready:** activate the **QuickVision** program and wait for the completion of the initial check.
2. **Select PAN/TMJ1:** it is necessary to select **TMJ1** with the dedicated button (14) positioned near the sensor



NOTE:
THE SELECTION DONE ON THE HAND CONTROL MUST BE CONSISTENT WITH THE SELECTION DONE WITH THE BUTTONS POSITIONED IN THE AREA OF THE DIGITAL SENSOR.

The equipment preparation has to be completed removing the chin's support for standard panoramic (1 - Figure 7) and replacing it with the one for sinuses' examination (21 - Figure 7).

		Chin support PANORAMIC (1)	Chin support SINUS (21)
TMJ	ADULT	NO	YES
	CHILD	NO	YES

6.3.1.2 Programmed/Manual exposure

To change from the programmed to the manual function and viceversa, proceed as described at paragraph 6.2.2 bearing in mind that the kV and time parameters in the programmed exposure are indicatively the following (numbers refer to Figure 8):

	Large Size (35)	Medium Size (36)	Small Size (37)
TMJ1 and 2 Adult (33)	80kV - 5,20sec	70kV - 5,20sec	65kV - 5,20sec
TMJ1 and 2 Child (34)	65kV - 4,70sec	60kV - 4,70sec	60kV - 4,70sec

The times reported in the previous table are the sum of the exposure time for the right condyle with the one of the left condyle, while the arm rotation time remains the same as the one reported for the panoramic examination.

6.3.1.3 Preparing the patient (refer to Figure 4)

- 1.** Ask the patient to remove all metal objects located in the zone involved in radiography (necklaces, earrings, spectacles, hair-clips, movable dental plates etc.).
Make sure that there are no heavy articles of clothing (such as overcoats, jackets, ties, polo-neck sweaters, etc.) in the radiography zone.
- 2.** Have the patient put on the protecting apron or similar protective devices in accordance with the regulations in force in the various countries, making sure that it does not interfere with the trajectory of the X-rays beam.
- 3.** Bring the patient in standing position up to the chin support and, using the handle, release the brake button (24) in order to position the slider so that the chin support resting plane is aligned with the patient's chin.
- 4.** Position the patient in the skull-clamp with the chin resting on the appropriate support and against the vertical reference rod of the same. Furthermore, position the hands on the lateral knobs.
- 5.** Press the laser centring device activation button (20). In this way both reference lights, mid sagittal (45) and Frankfurt' planes (46), are lighted on; adjust the patient's head in such a way that mid sagittal light is on the respective anatomical plane while the Frankfurt's one is parallel to the corresponding plane. Horizontal beam (Frankfurt plane), if needed, can be height adjusted in relation to the patient's dimensions; the adjustment is made by acting on the appropriate knob (18). In order to check the patient's centring, operator can tilt the mirror towards himself, thus obtaining the a front view of the patient.
- 6.** After the end of the patient's centring, bring the height of the skull-clamp a little above the patient's orbital bone and close the skull-clamp leaving the two temple clamp roads (7), by acting on the appropriate knob (9). This will help the patient to hold the correct position during the examination.

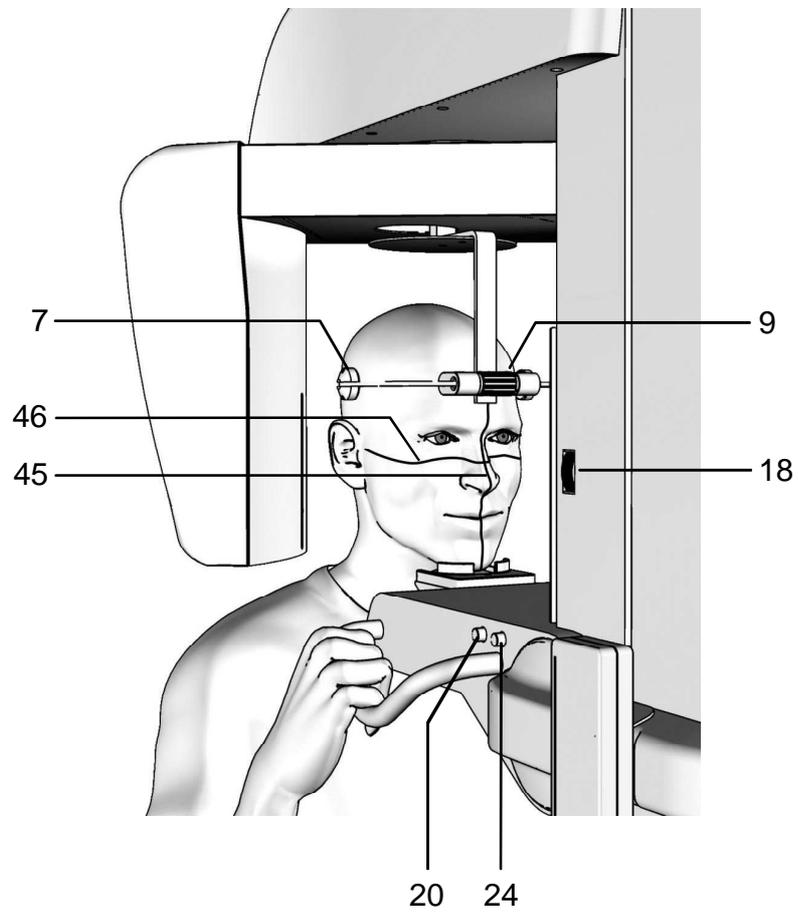


Figure 4: TMJ1 position

6.3.1.4 Performing the exposure (refer to Figure 8)

1. Check that TMJ1 examination has been selected on the sensor with the dedicated button.
2. With the LED of push button "29" lit up, check if the exposure data are correct (paragraph 6.2.2), then press the X-ray button (42) during the whole time of the exposure as the control is a dead man type, checking the simultaneous operation of the rays signaling light (43) and the acoustic ray signal.



NOTE:

- X-ray emission starts with a delay of four seconds after the operation of the exposure push button, in order to allow the preheating time of the tube filament and check all the set values.
Arm's rotation will start a little in advance regarding the emission.
- On TMJ examination, the X-ray emission does not last for all the rotation, but it is interrupted corresponding with the central middle part of the mouth. As a consequence, both acoustic and visual emission signals are interrupted in accordance with the emission.
- X-ray push button is a "dead man type"; this means that the emission and arm's rotation are interrupted if the push button is released. **The push-button must be held pressed also during the above emission interruption.**
- **In case of patient's moving during arm's rotation, the exam has to be interrupted releasing the emission push-button; in this way both emission and rotation will be interrupted.** On the display will appear the message "**Press Reset**"; the return button (32) has to be pressed to bring the machine in the starting position. The return end is evidenced by the message "**OK**" which will disappear when the button (32) is released.
- It will then be necessary to ask the QuickVision program for the execution of a new radiography

3. At the end of second emission step, on the display of the hand held control the message "Press Reset" will appear. The return button (32) is, then, to be pressed to bring the machine in the starting position. The return end is evidenced by the message "OK" which will disappear when the button (32) is released.

6.3.2 Performing the TMJ2 examination

6.3.2.1 Preparing the equipment

If acting on key (30) the message "**Equipment not set**" is displayed and the relevant function LED blinks, push the button a second time in order to display the message concerning the interlock to be enabled on the sensor.

The messages that can be read during the Panoramic function setting and the relevant actions to perform are the following:

- 3. Digital Sensor not Ready:** activate the **QuickVision** program and wait for the completion of the initial check.
- 4. Select TMJ2:** it is necessary to select **TMJ2** with the dedicated button (15) positioned near the sensor.



NOTE:
THE SELECTION DONE ON THE HAND CONTROL MUST BE CONSISTENT WITH THE SELECTION DONE WITH THE BUTTONS POSITIONED IN THE AREA OF THE DIGITAL SENSOR.



NOTE:
Operator has to evaluate the needs to increase the kV selection of one step; from some clinical results; this will increase image's quality. Eventually, use a manual programming mode.

6.3.2.2 Preparing the patient (refer to Figure 5)

1. Open the skull-clamp support (7) by acting on the appropriate knob (9).
2. Instruct the patient to open the mouth up to the maximum, maintaining the mandible fixed and lining on the chin support; patient's chin has to stay against the vertical plane of the chin support. As a consequence, patient's head will be slightly rotated backward.
3. Press push-button (20) to light on the laser centring device. In this way, both mid sagittal (45) and Frankfurt plane (46) will light on. Adjust the patient's head in order to have the vertical light beam (45) to lean on the corresponding anatomical reference. In order to check the patient's centring, operator can tilt the mirror towards himself, thus obtaining the a front view of the patient.



WARNING:

Do not align the patient to the Frankfurt plan; in the case the patient will be re-positioned again with the Frankfurt' plane horizontal, it is possible that the condiles will fall out from the exposed area of the sensor.

4. After the end of the patient's centring, bring the height of the skull-clamp a little above the patient's orbital bone and close the skull-clamp leaving the two temple clamp roads (7), by acting on the appropriate knob (9). This will help the patient to hold the correct position during the examination.

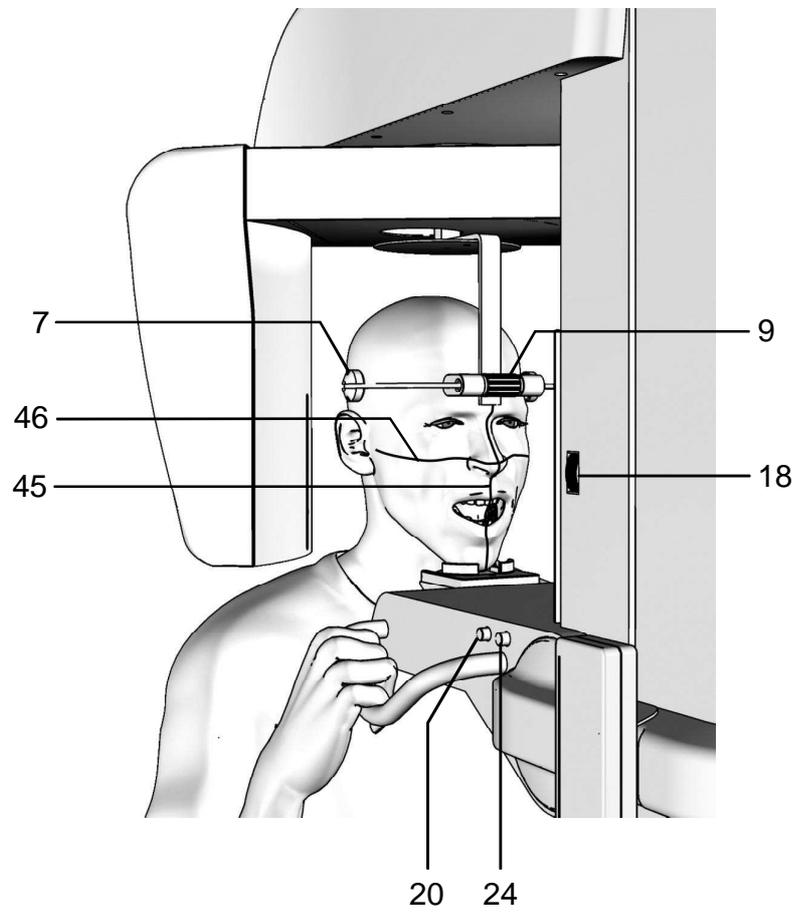


Figure 5: TMJ2 position

6.3.2.3 Performing the exposure (refer to Figure 8)

1. Check that TMJ2 examination has been selected on the sensor with the dedicated button.
2. With the LED of push button (30) lit up, check if the exposure data are correct (paragraph 6.2.2), then press the X-ray button (42) during the whole time of the exposure as the control is a dead man type, checking the simultaneous operation of the rays signaling light (43) and the acoustic ray signal.



NOTE:

- X-ray emission starts with a delay of four seconds after the operation of the exposure push-button, in order to allow the preheating time of the tube filament and check all the set values. Arm's rotation will start a little in advance regarding the emission.
- On TMJ examination, the X-ray emission does not last for all the rotation, but it is interrupted corresponding with the central middle part of the mouth. As a consequence, both acoustic and visual emission signals are interrupted in accordance with the emission.
- X-ray push button is a "dead man type"; this means that the emission and arm's rotation are interrupted if the push button is released. **The push-button must be held pressed also during the above emission interruption.**
- **In case of patient's moving during arm's rotation, the exam has to be interrupted releasing the emission push-button; in this way both emission and rotation will be interrupted.** On the display will appear the message "Press reset". The return button (32) is, then, to be pressed to bring the machine in the starting position. The return end is evidenced by the message "OK" that will disappear when the button (32) is released.
- In the event that the patient will move during TMJ2 exposure and after TMJ1 mode already executed, it is mandatory to repeat also TMJ1 exposures to have the complete result of TMJ1 and TMJ2 on the same image.

3. At the end of the TMJ2 examination, on the display of the hand held control the message "**Press Reset**" will appear. The return button (32) is, then, to be pressed to bring the machine in the starting position. The return end is evidenced by the message "**OK**" that will disappear when the button (32) is released. At this point the message "**Wait please....**" will appear, indicating that the automatic pause to allow anode cooling down procedure is acting. At the end of this procedure, the LED of the last examination performed will light on.



NOTE:

If for external reasons or incorrect operation the emission times should exceed 5 seconds, a safety backup timer intervention will come into operation, interrupting emission but the arm rotation will continue until the end.

6.4 Sinus examination

The SINUS examination aim is to show the structure located in the sinomaxillary area.

6.4.1 Preparing the equipment

The equipment setting is like the one described for panoramic examination at point 6.2.1 as the only difference between the Panoramic Exposure and the Sinus one is due to the different chin support used: the chin support to be used in the Sinus examination is as follows (numbers refer to Figure 7 at the end of this manual):

		Chin support PANORAMIC (1)	Chin support SINUS (21)
SINUS	ADULT	NO	YES
	CHILD	NO	YES

6.4.2 Programmed/Manual exposure

To change from the programmed function to the manual one and viceversa, proceed as described at point 6.2.2 bearing in mind that the kV and Time (seconds) parameters in Sinus exposure are like the Panoramic ones.

6.4.3 Preparing the patient

1. Proceed operating as for points 6.2.3. steps 1, 2 and 3.
2. Position the patient in the skull clamp with the chin resting on the appropriate support and against the vertical reference rod of the same and rest the hand on the side handles but, instead of biting with the incisors the centring bit, as in the Panoramic exposure, the examination has to be carried out with a closed mouth.
3. Proceed operating as for points 6.2.3. steps 5, 6, 7 and 8.

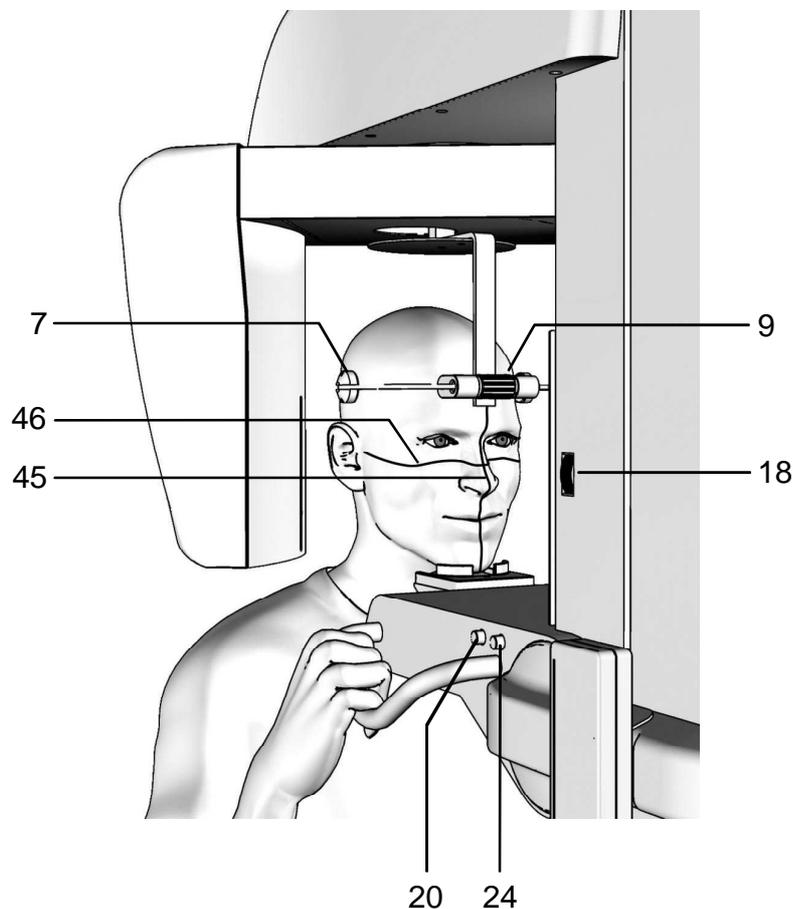


Figure 6: SINUS position

6.4.4 Performing the exposure

Proceed as for point 6.2.4, following the relevant notes.

6.5 Messages on display (refer to Figure 7 and Figure 8)

ROTOGRAPH-D is entirely controlled by a microprocessor that, besides controlling the emission parameters and the line voltage fluctuation, indicates the different equipment's operating modes by means of appropriated messages on display (44), the eventual anomalies and mistakes. The following table shows the different messages that could be displayed, their cause and relevant actions.

Message displayed	Reference	Cause	What to do
Minimum	0	With control button (40) it has been required a value lower than the allowed one	Select a correct value
Maximum	0	With control button (41) it has been required a value higher than the allowed one	Select a correct value
Wait, please.....	6.2.4, 6.3.1.4 and 6.3.2.3	X-ray exposure has been performed	Waiting time (4min) for PAN or TMJ exposures
Equipment not set	6.2.1 and 6.3.1.1	Not all interlocks are enabled	Press a second time the function button to display the interlock to be enabled
Digital Sensor Not ready	6.2.1. step 1	Digital sensor not enabled	Request activation of digital sensor by the QuickVision program
Select PAN/TMJ1	NO reference	Functionality of the digital sensor has not been selected	Select functionality of the sensor activating one of the buttons on the cover of the digital sensor
Select TMJ2	NO reference	The sensor is not activated for TMJ2 after having selected this test on the hand control	Select functionality TMJ2 of the sensor activating the button (15) on the cover of the digital sensor
Line voltage too low	NO reference	Line voltage outside the -10% of the nominal value	(1) Make sure the line voltage is within the $\pm 10\%$ of the nominal value
Line voltage too high	NO reference	Line voltage outside the +10% of the nominal value	(1) Make sure the line voltage is within the $\pm 10\%$ of the nominal value

Message displayed	Reference	Cause	What to do
Impossible to regulate the line voltage	NO reference	There is a continuous voltage fluctuation during the cathode pre-ignition phase	Call Technical Assistance
Push "RESET"	6.2.4, 6.3.1.4 and 6.3.2.3	A PAN or TMJ cycle has been interrupted while in progress	Press the RESET button (32)
OK	6.2.4, 6.3.1.4 and 6.3.2.3	The arm return run is completed	Release button RESET (32)
TMJ modality not enabled	NO reference	TMJ examination has been requested on a unit not equipped with this feature	Press the button of another examination (NOT TMJ)
Memory data corrupted! Call Technical Assistance	NO reference		Call Technical Assistance
NO ANSWR	NO reference		Call Technical Assistance
Out of Order N° 1 ! Call Technical Assistance	NO reference		Call Technical Assistance

- (1)** *If line voltage is outside the specified range ($\pm 10\%$), contact the local power company in order to take the necessary corrective actions.
Villa Sistemi Medicali will not bear any cost for proper line set-up.*

6.6 Identification and correction of defects in dental radiographs exposure

6.6.1 Defects due to wrong patient positioning

- **Incisor too wide and indistinct**

The patient does not grip the bite block with the incisors or bends the rod towards the outside of the equipment.

Corrective action:

Reposition the patient, also checking alignment of the Frankfurt plane through the laser centring device. Please refer to the note on the centring (see paragraph 6.2.3. steps 3, 4 and 5)

- **Incisor too small and indistinct**

The patient is positioned with an error opposite to point above.

Corrective action:

Refer to point above

- **Radiograph with white central zone**

The patient's spinal column prevents the rays from passing because it is too compressed.

Corrective action:

Recheck alignment of Frankfurt plane, and try to stretch the cervical tract of the column as much as possible by correcting slider height and shifting the patient's feet towards the stand; (see paragraph 6.2.3. steps 3, 4, 5 and 6)

- **Dental arch not symmetrical**

The sagittal median line does not correspond to the reference centring light.

Corrective action:

Reposition the patient (see paragraph 6.2.3. step 6)

- **Upper apical zone too dense**

The patient is not keeping his lips tightly together and is not holding the tongue against the palate.

Corrective action:

See point 6.2.3. step 8.

6.6.2 Defects due to wrong setting of radiological data and dark room

- **Under-exposed or over-exposed image**

The number of kV set are not adequate for the patient's build, more likely an error in development.

Corrective action:

Repeat the examination with a different value: see paragraph 6.2.4. If the error happens again, call the **Technical Assistance**

- **Completely white image**

It has not been exposed to X-rays or digital sensor broken.

Corrective action:

Verify the X-rays emission by checking light and acoustic signal (light 43 Figure 8), If the defect persists call for **Technical Assistance**.

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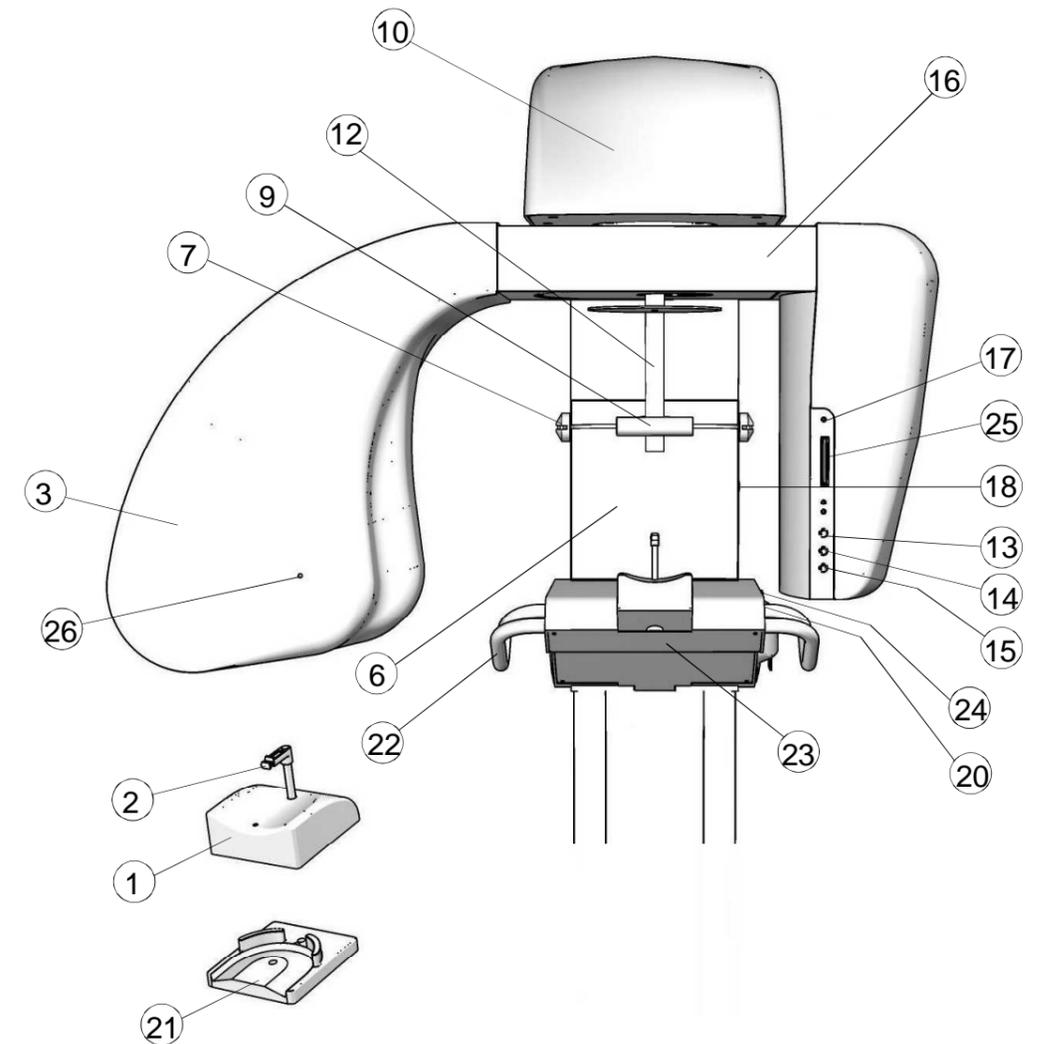


Figure 7: Stand

- | | |
|--|--|
| 1 "PANORAMIC" chin support | 16 Rotating arm |
| 2 Bite Block | 17 Digital Sensor |
| 3 Tubehead | 18 Laser centring device height control knob |
| 6 Centering mirror | 20 Laser centring device button |
| 7 Skull / Temple clamp support | 21 Chin support TMJ, SINUS. Also used as an accessory to raise children's chin by sandwiching it with the standard Panoramic chin support |
| 9 Skull / Temple clamp control knob | 22 Patient positioning handle and slider |
| 10 Motor group unit | 23 Support unit of the motor group |
| 12 Slider | 24 Brake release button |
| 13 PAN selection button | 25 Slot for Memory Card |
| 14 TMJ1 selection button | 26 Focus position point |
| 15 TMJ2 selection button | |

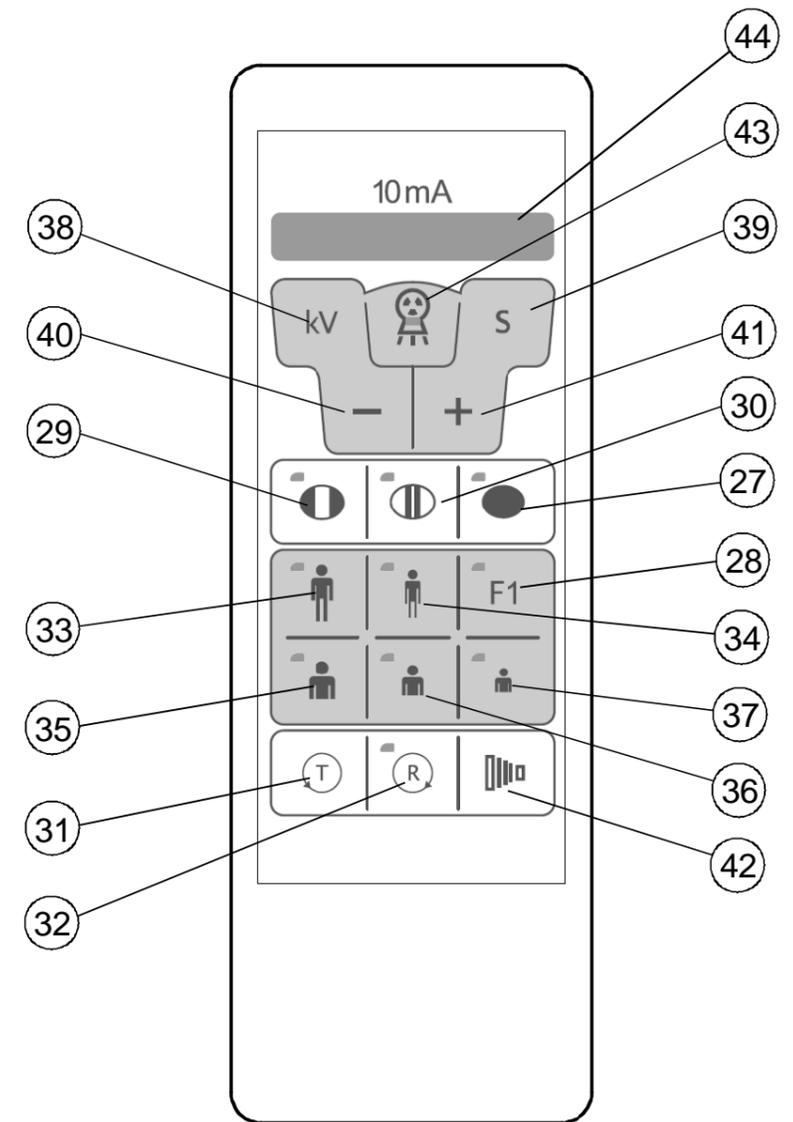


Figure 8: Remote control

- | | |
|---|--|
| 27 PAN mode Selection | 36 Medium Size Selection |
| 28 NOT ENABLED | 37 Small Size Selection |
| 29 TMJ1 mode Selection | 38 kV Selection |
| 30 TMJ2 mode Selection | 39 Push-button Multifunctional |
| 31 Test mode ("dead man" button) | 40 Decrease kV |
| 32 RESET ("dead man" button) | 41 Increase kV |
| 33 Adult Selection | 42 X-rays push-button ("dead man" button) |
| 34 Child Selection | 43 X-rays emission pilot LED |
| 35 Large Size Selection | 44 Alphanumeric display |

7. MAINTENANCE

As for all the electrical devices, in addition to proper use this unit also requires periodical checks and maintenance. These precautions will insure a safe and efficient performance of the device.

The preventive maintenance consists of checks that can be carried out directly by the operator or by the authorized service personnel.

The checks that can be carried out directly by the operator are the following:

Interval	Type of check
Daily	<ul style="list-style-type: none">- check that the tubehead does not have oil leakage- check that the cable of the remote control is not damaged- check that the unit does not show damages that may affect the protection against radiation- check that no metallic noise are generated by the column or the rotating assembly.
Once a week	<ul style="list-style-type: none">- check that the metal ropes of the column are not damaged or broken (the ropes can be seen on the side of the column)- while performing exposure, release the X-ray push button and check that the beeper stops beeping immediately.
Every 6 months	<ul style="list-style-type: none">- check that the labels are not damaged and well attached.



WARNING:

If any of the above checks give negative results, the operator must contact the authorized service personnel.



MAINTENANCE LOG-BOOK

This log-book has to be filled in by the authorized Villa Sistemi Medicali engineer after installation and after performing the preventive or corrective maintenance visits.

Installation: Date Technician

Maintenance: Date Technician
Cause

Final test table

This table is reserved to Qualified and Trained Service Technician

Data setted on Hand Control for ROTOGRAPH-D S.N.									
Voltage supply for rotation motor A1 V1 R39					A1 V1 R40				
Decelerating ramp for Central OPG R41 sec									
S0 =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>	S3 =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>
S2 =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>	S5 =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>
S4 =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>	S8 =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>
S6 =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>	S9 =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>
SA =	On	<input type="checkbox"/>	Off	<input type="checkbox"/>					
S1 =	<input type="text" value="ITA"/>	<input type="text" value="ENG"/>	<input type="text" value="FRA"/>	<input type="text" value="ESP"/>	<input type="text" value="DEU"/>				
S7 =	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	
<input style="width: 100%;" type="text" value="Angular Control Settings"/>									
S5 Machine Control Functions									
Adult OPG Values			Adult TMJ1			Adult TMJ2			
T1=	2.00	sec	T1=	2.00	sec	T1=	2.00	sec	
A2=Degrees	A1=Degrees	A1=Degrees	
A3=Degrees	A2=Degrees	A2=Degrees	
A4=Degrees	A5=Degrees	A5=Degrees	
A5=Degrees	A6=Degrees	A6=Degrees	
T2=	18 sec ± 10%		T2=	16 sec ± 10%		T2=	16 sec ± 10%		
T3=	17 sec ± 10%		T3=	5,20 sec ± 10%		T3=	5,20 sec ± 10%		
Child OPG			Child TMJ1			Child TMJ2			
T1=	2.00	sec	T1=	2.00	sec	T1=	2.00	sec	
A2=Degrees	A1=Degrees	A1=Degrees	
A3=Degrees	A2=Degrees	A2=Degrees	
A4=Degrees	A5=Degrees	A5=Degrees	
A5=Degrees	A6=Degrees	A6=Degrees	
T2=	16 sec ± 10%		T2=	16 sec ± 10%		T2=	16 sec ± 10%		
T3=	14 sec ± 10%		T3=	4,70 sec ± 10%		T3=	4,70 sec ± 10%		
T2=	16 sec ±10% with decel.								
T3=	14 sec ±10% with decel.								
Digital sensor serial Number:									
.....									

Quality Control
Villa Sistemi Medicali S.p.a.

.....

Date

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Cod. 6908917700_Rev.1

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