Owandy RADIOLOGY

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I-MAXTOUCH

2D panoramic unit

Panoramique numérique 2D

Revision history Manual code 6906910203

Rev.	Date	Page/s	Modification description
8	12.12.16	All	Added revision history. Added distribution of stray radiation information. Added Error 367 description. (Complaint D1618)
9	30.11.18	from 1 to 10, from 14 to 21, from 23 to 25, from 28 to 32, 37 39, from 40 to 44, From 56 to 58, 64, 65, 68, 69, 72, 73, 76, 79, 82, 83, 86, 94, 95, 102, 104, 109, 132, 133, 134	Adapted to the third edition of IEC 60601-1 and its collateral applicable standards. (Ref. RDM 8883)

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Contents

This manual is the original English manual.

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1. INTRODUCTION

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

The aim of this publication is to instruct the user on the safe and effective use of the device.
This Manual is limited to the description of the X-ray device; instructions on the Digital Acquisition System are given in the relevant Manuals, supplied with the Direct Digital Sensor.

The I-Max Touch, produced by OWANDY RADIOLOGY, is an X-ray device for the radiographic analysis of the maxillo-facial complex.
The basic version of the I-Max Touch performs Panoramic, Emi-panoramic, Reduced dose Panoramic, Frontal dentition, Improved orthogonality Panoramic, Sinus, TMJ and Implant examinations of the maxillo-facial complex.

The DIGITAL CEPH option is available, and must be ordered separately; it allows the execution of the following examinations:

- CEPH exam in different formats, all available in high resolution and normal resolution (high speed) modality
- CARPUS exam, available in high resolution modality.

 **WARNING**

1. **The I-Max Touch is an electro-medical device and it can be used only under the supervision of a physician or of highly qualified personnel, with the necessary knowledge on X-ray protection.**
2. **The device must be used complying with the procedures described and never be used for purposes different from those herewith indicated.**
3. **Please read this manual thoroughly before starting to use the unit; it is advisable to keep the manual near the device, for reference while operating.**
4. **The user is liable as concerns legal fulfillment related to the installation and the operation of the device.**

1.1 Icons appearing in the manual

 Indicates a **NOTE**; please read the items marked by this icon thoroughly.

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

2. SPECIFICATION OF THE INTENDED USE

2.1 Application and medical purpose

I-Max Touch is dedicated to perform radiographies –using the standard narrow beam technique- of the maxillofacial anatomic district, including exams of the dental arc, of tempomandibular joint and paranasal sinuses. It can be equipped with cephalometric arm to take cranial cephalometric exams in different projections and the wrist (carpus) exam dedicated to the evaluation of bone growth.
The system can be used on all the patient type; from the Graphical User Interface the selection of specific programs dedicated to adult or child patients, patient size and type of dentition for panoramic exams.

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

I-Max Touch system can be used with the following type of patient:

- Age: paediatric to geriatric
- Patient status/health: patient with intact skin, conscious, not anaesthetized and not incapacitated
- Nationality: multiple.

 **NOTE: PATIENT is not the OPERATOR.**

2.1.2 Operator profile (intended user)

This system may only be operated by a physician, dentist or skilled technician who have the necessary expertise in radiation protection or knowledge of radiation protection and who have been instructed in the operation of the X-ray equipment.

Service engineers who install and maintain the device are also operator. They need knowledge of radiation protection and must read the Service Manual prior to use the X-ray equipment. They must be qualified and authorized by Owandy Radiology.

2.1.3 Application environments

I-Max Touch is dedicated both to the dental practitioner market and to radiologist's, for this reason the equipment can be installed both in residential buildings and in professional buildings (e.g. hospitals or clinics). Anyway, the room where the equipment is installed in must have comply with local regulations concerning radiation protection.

 **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, I-Max Touch is in contact with the patient via the handle, the chin rest and bite and mono-use sleeves, the temple clamps and strip; Ceph nasion, ear centering pins and Carpus plate if Ceph arm is present. All the listed parts are classified as Type B applied parts.

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

The Dose per Area Product delivered by I-Max Touch 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 measured 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 in panoramic exams and 165 cm in cephalometric exams.

The typical size of the X-ray beam on the imaging sensor depends on the selected exam:

- for Panoramic, Sinus and TMJ exams: 139x4.5 mm
- for Cephalometric exams: 220x8 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 for panoramic and 1395 mm for cephalometric exams.

The overall uncertainty of the indicated value of the airKerma 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.**

2.3.1 Panoramic mode

The air Kerma value at the entrance of the X-ray image receptor for the Panoramic STD exam is reported in the table below as functions of kV and mA.

		mA				
		6	**7**	**8**	**9**	**10**
kV	**60**	7.94	9.28	10.63	11.84	13.18
	62	8.34	9.82	11.16	12.64	13.99
	64	9.01	10.49	11.97	13.45	15.07
	66	9.68	11.30	12.78	14.39	16.01
	68	10.22	11.97	13.72	15.33	17.08
	70	11.03	12.91	14.66	16.54	18.43
	72	11.43	13.45	15.33	17.22	19.10
	74	12.11	14.12	16.14	18.16	20.18
	76	12.78	14.80	16.95	19.10	21.25
	78	13.32	15.60	17.76	20.04	22.33
	80	14.12	16.54	18.83	21.25	23.54
	82	14.53	16.95	19.37	21.79	24.21
	84	15.33	17.89	20.45	23.00	25.56
	86	16.14	18.83	21.52	24.21	26.90

Table 1: Air Kerma values in mGy for Panoramic STD exams

The air Kerma for the other Panoramic exams available on the equipment can be calculated using the ratios vs Panoramic exam in the table below:

Exam	**Ratio**
Panoramic'	1.07
Half panoramic	0.60
Low Dose	0.92
Ortho Rad panoramic	0.90
Frontal dentition	0.33
Bitewing L or R	0.25
Bitewing L and R	0.48
TMJ	0.72
Sinus	0.69

2.3.2 Cephalometric mode

The air Kerma value at the entrance of the X-ray image receptor for the Cephalometric exams 30x22 cm in High Definition mode is reported in the table below as functions of kV and mA.

		mA					
		6	**7**	**8**	**9**	**10**	**12**
kV	**60**	0.50	0.58	0.66	0.75	0.83	0.91
	62	0.54	0.64	0.72	0.82	0.89	1.00
	64	0.57	0.66	0.76	0.87	0.96	1.06
	66	0.61	0.72	0.82	0.92	1.01	1.12
	68	0.66	0.77	0.88	1.00	1.10	1.21
	70	0.70	0.82	0.93	1.05	1.16	1.28
	72	0.74	0.86	0.98	1.10	1.23	1.35
	74	0.78	0.91	1.03	1.17	1.30	1.43
	76	0.82	0.96	1.10	1.24	1.37	1.51
	78	0.87	1.00	1.15	1.29	1.43	1.58
	80	0.94	1.06	1.20	1.35	1.51	1.66
	82	0.98	1.14	1.31	1.48	1.64	1.80
	84	1.03	1.20	1.37	1.55	1.73	1.90
	86	1.08	1.27	1.45	1.63	1.81	1.99

Table 2: Air Kerma values in mGy for Cephalometric exams 30x22 cm in High Definition mode

The air Kerma for the other cephalometric formats can be calculated using the ratio in the table below vs the values from Table 2:

Exam	**Ratio**
18x22 HS	0.28
18x22 HD	0.56
24x22 HS	0.41
24x22 HD	0.81
30x22 HS	0.50
18x22 Carpus	0.65

3. SAFETY INFORMATION

 **WARNING: Please read this chapter thoroughly.**

OWANDY RADIOLOGY designs and builds its devices in compliance with the safety requirements; furthermore it supplies all information necessary for correct use, and the warnings related to danger associated with X-ray generating units.

Owandy Radiology cannot be held responsible for:

- the use of the I-Max Touch different from the intended use
- damage to the unit, the operator or the patient, caused both by installation and maintenance procedures different from those described in this Manual and in the Service Manual supplied with the unit, and by wrong operations
- mechanical and/or electrical modifications performed during and after the installation, different from those described in the service manual.

Installation and any technical intervention must only be performed by qualified technicians authorized by Owandy Radiology.

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

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

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

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

Please clean and disinfect, when necessary, all parts that can be in contact with the patient.
The centering bite or the bite protective sleeve and the ear centering devices of the cephalostat must be replaced after each examination in which they were used.

Never try to rotate the moving arm manually when the unit is switched on, to avoid permanent damage to the unit.
Movement is only possible in case of Error 206 because motors are disabled to permit the patient exit.

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

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

3.1.1 Precautions while using laser centring devices

WARNING: PRECAUTIONS WHILE USING LASER CENTRING DEVICES:
Although the laser centring devices used on the I-Max Touch system are classified in Class 1 in compliance with the IEC 60825-1:2007 standard and attachments, the following precautions are recommended:

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

3.2 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.

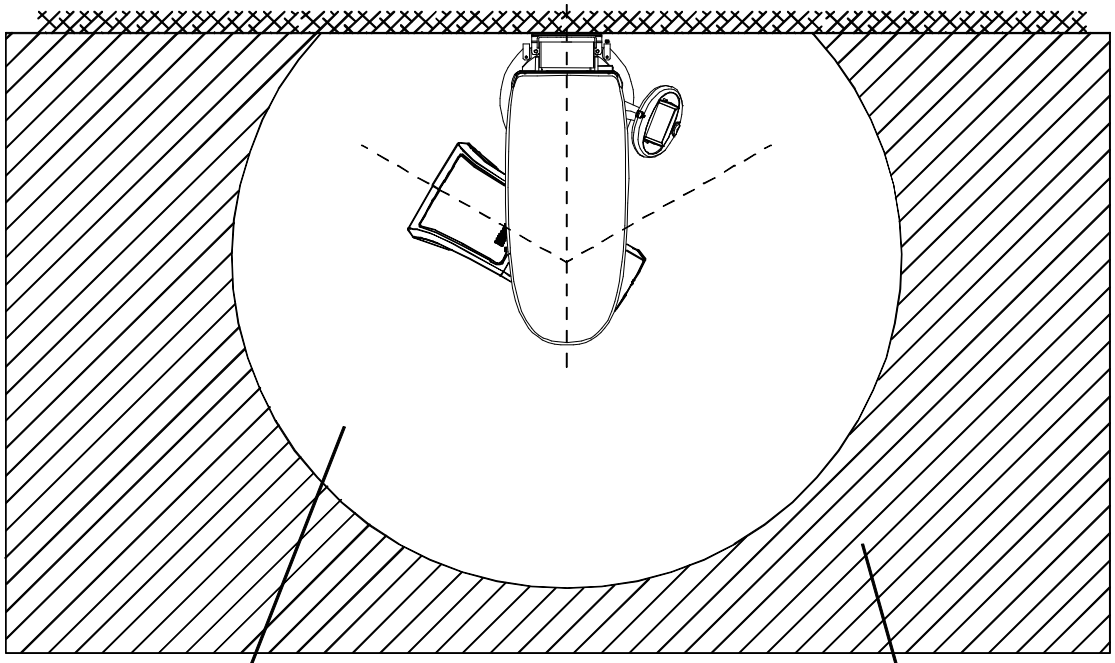


Figure 1 - Panoramic version

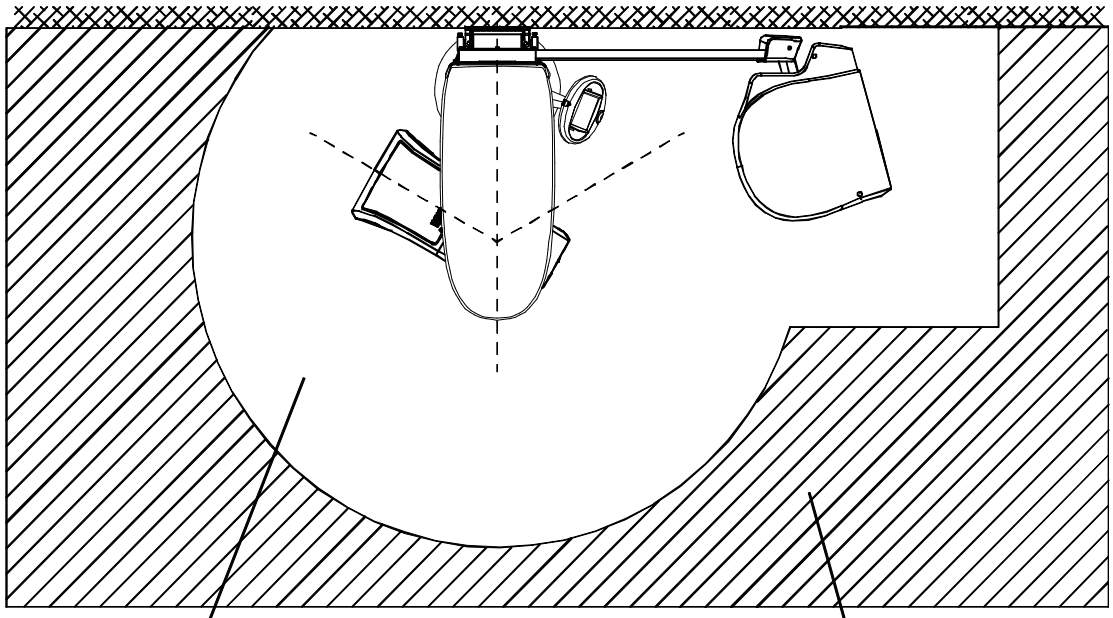


Figure 2 - Cephalometric version

3.2.1 Distribution of stray radiation in Panoramic examination

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

Figure 3: Distribution of stray radiation in Panoramic examination

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

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

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

3.2.2 Distribution of stray radiation in Ceph examination

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

Figure 4: Distribution of stray radiation in Ceph examination

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

The Figure above illustrates the distribution of scatter radiation in the horizontal plane at the centre of rotation of the scanning unit in the area of a 3 x 3m rectangle.
The measurement was performed using as scattering element an anthropomorphic phantom complete of soft tissues simulating the head of the typical patient (in size, dimensions and tissues) of the intended use of the machine.
This phantom was placed in the same position as a patient taking a 30x22 cephalometric exam; this exam is the maximum in size among those the user can select.
C is the center of patient head; S is the X-ray source and the primary X-ray beam is also represented in Figure above.
The measures were taken during a cephalometric exam setting the following parameters: 86kV, 12mA, 7.5s.

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

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

3.2.3 Electromagnetic information

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING: The use of cables other than:

- **Ethernet cable CAT.5E L=5 m - code 5007090100**
- **Ethernet cable CAT.5E L=10 m - code 5007090300**

with the exception those sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emission or decreased immunity of the equipment or system.

3.2.4 Electromagnetic emissions

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

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

3.2.5 Electromagnetic immunity

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

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output lines	Residential/Hospital
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	Residential/Hospital
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_n for 0.5 cycles 40 % U_n for 5 cycles 70 % U_n for 25 cycles 0 % U_n for 5 s	0 % U_n for 0.5 cycles 40 % U_n for 5 cycles 70 % U_n for 25 cycles 0 % U_n for 5 s	Residential/Hospital
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Residential/Hospital
Note: U_n is the AC mains voltage prior to application of the test level.			

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

3.2.6 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 $d = 1.2 \times \sqrt{P}$	**80MHz to 800MHz** $d = 1.2 \times \sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance"*d*" in meters (m), can be estimated using the equation applicable to the frequency of the transmitter, where "*P*" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:

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

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

3.3 Cybersecurity measures

The device can be supplied without the host PC. In order to protect the computer, the equipment and data from unauthorized access or data corruption caused by cyber-attacks, it is highly recommended to:

- Password-protect each user account on the Windows login. Passwords shall be strong enough (at least made of 8 alphanumeric characters), shall be safely managed by every user (for example they have not been written down), and should be periodically changed
- Activate a screensaver that requires a password to be unblocked after a timeout of 5-10 minute, giving this way an automatic timed method to terminate sessions, preventing an unauthorized access to the computer when it is not used
- Install an antivirus software
- Activate the windows firewall on the host PC
- If the Local Area Network has an internet connection, activate a hardware firewall on the WAN router/modem used for internet connection
- Make sure that all PC in the network are protected by an anti-virus
- Make a virus scan of USB sticks or CD/DVD media before using them to check they are free from viruses, malware or any dangerous software
- Avoid installation of an unknown or untrusted software since it may undermine performance and safety of the computer and the equipment
- Keep the Windows operating system up to date by installing all security patches
- Make regular copies (backup) of all your valuable data and store them in a safe place, separately from the host PC
- Have any software or firmware upgrade of the equipment done by authorized and trained personnel only
- Make some test exams without patients after any software or firmware upgrade to ensure the system is working as expected.

3.4 Environmental risks and disposal

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

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

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

The centring bite or the bite protective sleeve and the ear centring devices of the Cephalostat that must be replaced after each examination in which they were used, must be disposed of at the appropriate disposal centres.

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

3.5 Symbols used

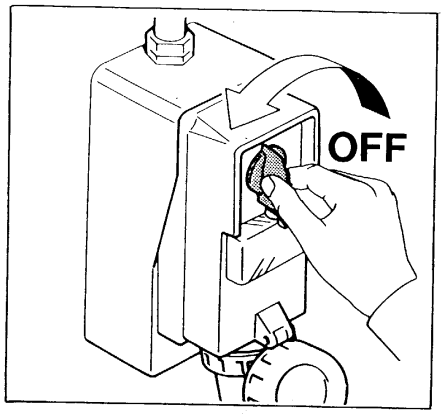
In this manual and on the I-Max Touch itself, apart from the symbols indicated on the control panel, the following icons are also used:

Symbol	Description
	Device with type B applied parts
	In some of its parts, the device contains materials and liquids that, at the end of the lifespan of the unit, must be disposed of at the appropriate disposal centers
~	Alternating current
N	Connection point to the neutral conductor
L	Connection point to the line conductor
	Protection earthing
	Operation earthing
	OFF; device not connected to the mains
	ON; device connected to the mains
	Laser
	Dangerous voltage
REF	Product identification code
SN	Serial number
	Date of manufacture (year and month)
	Manufacturer's name and address
	Total filtration
	Tube-head
	X-ray tube
	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

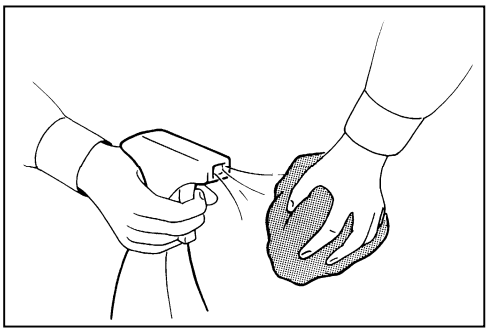
In order to guarantee a good level of hygiene and cleaning, it is necessary to respect the following procedures.

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



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

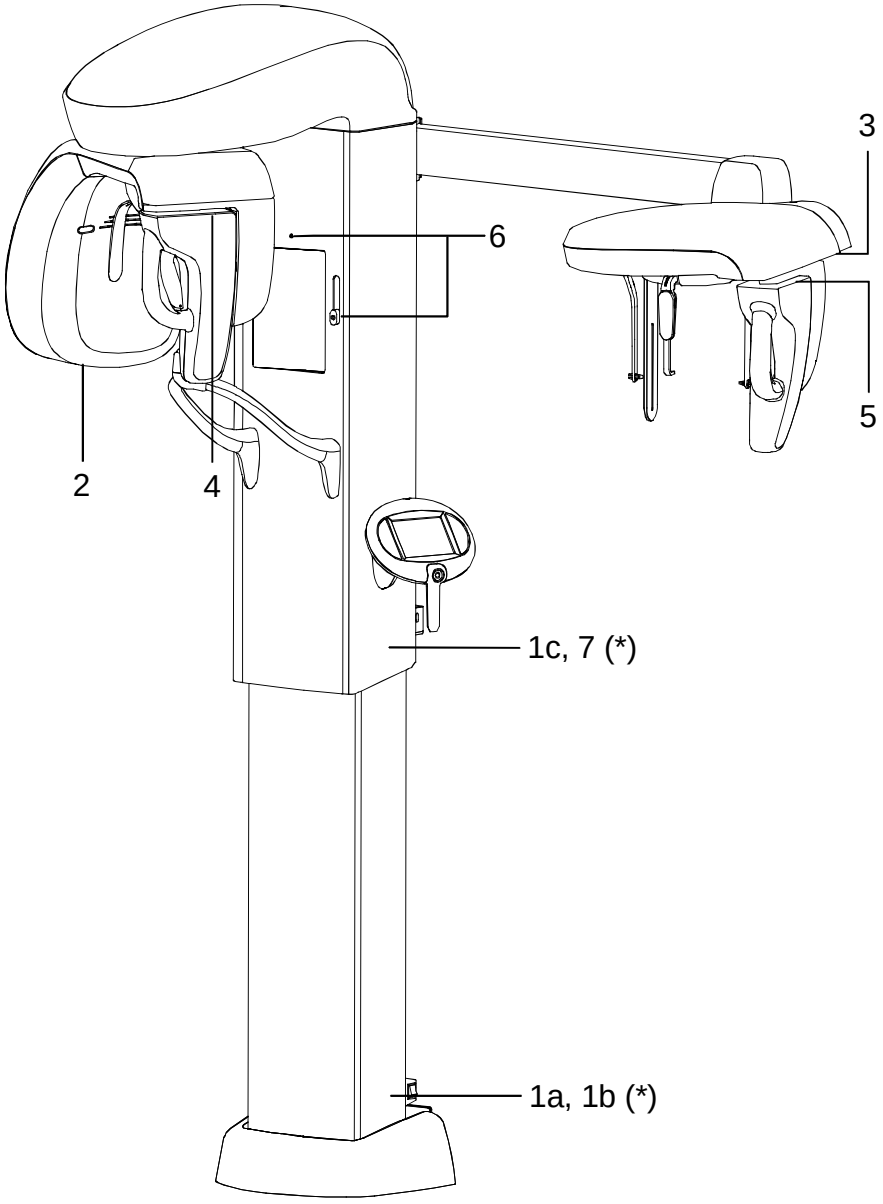
Use only a wet cloth and a mild detergent to clean the painted surfaces, the accessories and the connection cables, and then wipe with a dry cloth; do not use corrosive, abrasive solvents (alcohol, benzine, trichloro-ethylene).



The disposable bite protective sleeve and the ear centering devices of the cephalostat must be replaced after each examination in which they have been used.
Thoroughly clean the chin support, TMJ positioner, resting handles, nose-rest and temple clasps group any time these are used.
The chin support, TMJ positioner, resting handles, nose-rest and temple clasps group should be disinfected (when considered necessary) with a solution of 2% glutaraldehyde.

5. DESCRIPTION

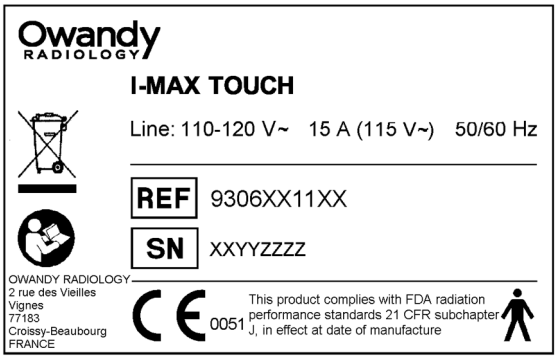
5.1 Identification labels and laser labels



(*) Labels 1b, 1c and 7 present only for 110-120V version

5.1.1 Identification labels and laser labels 110-120V

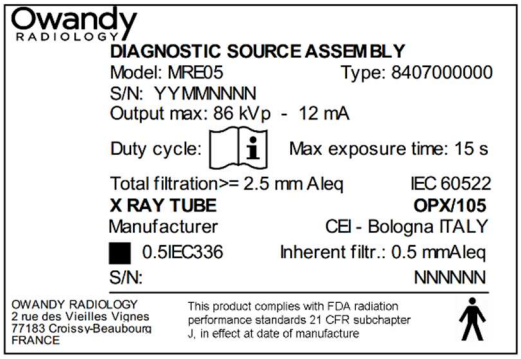
1a I-Max Touch identification label



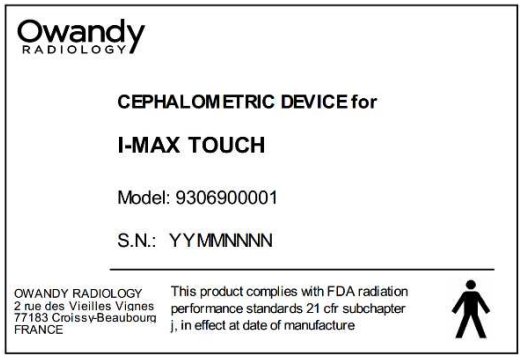
1b I-Max Touch UDI label

1c I-Max Touch ETL certification label

2 Tube-head identification label



3 CEPHALOMETRIC device identification label



4 PANO Digital Sensor identification label

5 PANCEPH Digital Sensor identification label

6 (N°2) Laser symbol label

7 WARNING label

COMPLIES WITH DHHS PERFORMANCE STANDARD 21 CFR SUBCHAPTER J

WARNING:

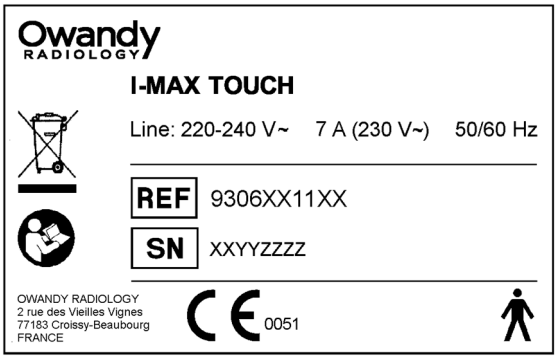
THIS X-RAY UNIT MAY BE DANGEROUS TO THE PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.
ELECTRICAL SHOCK HAZARD - DO NOT REMOVE PANELS. EISK OF EXPLOSION - DO NOT USE IN PRESENCE OF FLAMMABLE ANESTHETICS.
FOR CONTINUED PROTECTION AGAINST RISK OF FIRE, REPLACE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

DANGER:

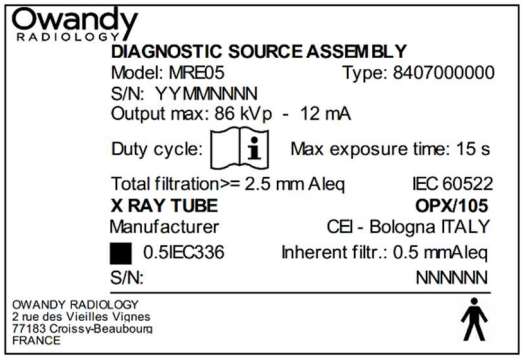
CET APPAREIL DE RADIODIAGNOSTIC PEUT ETRE DANGEREUX POUR LE PATIENT ET L'OPERATEUR SI LES FACTEURS D'EXPOSITION ET LES INSTRUCTIONS NE SONT PAS SUIVIS. RISQUE D'EXPLOSION
- NE PAS EMPLOYER EN PRESENCE D'ANESTHESIQUES INFLAMMABLES POUR ASSURER UNE PROTECTION CONTINUE CONTRE LE RISQUE D'INCENDIE.
UTILISER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

5.1.2 Identification labels and laser labels 220-240V

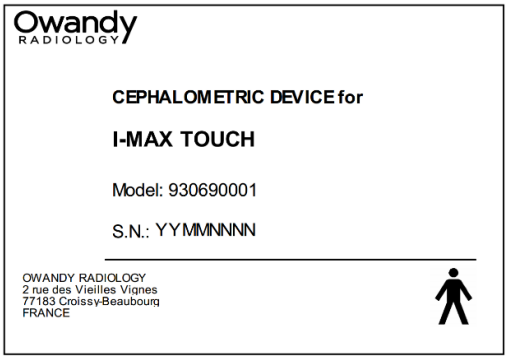
1 I-Max Touch identification label



2 Tube-head identification label

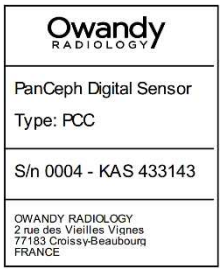


3 CEPHALOMETRIC device identification label



4 PANO Digital Sensor identification label

5 PANCEPH Digital Sensor identification label



6 (N°2) Laser symbol label

5.2 Functions, models and versions

The I-Max Touch, produced by OWANDY RADIOLOGY, is a complete panoramic system, which enables to perform all X-rays commonly necessary in dental field (except for endoral x-rays).
In some versions, certain examination modes are not available but the device (thanks to its computerized control system) can be expanded and updated with new releases, directly at the Dentist premises.
The basic version performs Panoramic, Emi-panoramic, Reduced dose Panoramic, Frontal dentition, Improved orthogonality Panoramic, Sinus, TMJ and Implant examinations of the maxillo-facial complex.
Optional functions enable the system to perform the following additional examinations:

- CEPH exam in different formats
- CARPUS exam.

The values of the exposure factors shown in the tables of paragraph 8.14, set as default, are for guidance only.
The real adjustment of these values depends on user's tradeoff between expose dose and image contrast.
Image processing should help you getting the best contrast.

5.2.1 Basic version

The basic version enables to perform the following examinations:

- Panoramic Adult or Child, with 3 Sizes and 3 Types of Biting for a total of 18 combinations in Automatic selection; in manual selection it is possible to select high voltage between 60kV and 86kV, in 2kV steps and anodic current from 6 mA to 10 mA in 1 mA steps.
- Sinus enables to perform images of the maxillary sinuses with front projection (postero/anterior).
- TMJ mouth closed/open in lateral projection.
- Implant to perform images of cross-sections of the dental arch, for Implant medical treatment.
- The right or left Emi-panoramic is used when the patient is known to have a problem only on one side of the arch, in order to reduce the radiation.
- The reduced dose Panoramic reduces the dose radiated on the dentition by excluding the TMJ's ascending rami from the exams.
- The frontal dentition enables to perform examinations of the front part (roughly from canine to canine).
- The Panoramic with improved orthogonality reduces the overlap of the teeth, thereby improving the diagnosis of interproximal decay.

5.2.2 Version with cephalometric device

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

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

6. TECHNICAL CHARACTERISTICS

General features		
Type	I-Max Touch	
Manufacturer	OWANDY RADIOLOGY Croissy-Beaubourg, France	
Class	Class I with type B applied parts according to IEC 60601-1 classification 	
Protection degree	IPX0 standard device	
Rated line voltage	220-240 V~	110-120 V~
Line frequency	50/60Hz	
Maximum line current	6.6 A @ 230 V~ 50/60 Hz	15 A @ 115 V~ 50/60 Hz
Power consumption	1.5 kVA @ 230 V~ 50/60 Hz	1.7 kVA @ 115 V~ 50/60 Hz
Protection fuse (F1)	7 A T	15 A T
Protection fuse (F2) **of switching power supply**	1.6 A T	3 A T
HF generator board protection fuses	F1: 10 A F F2: 5 A HF F3: 2 A T	
Line apparent resistance	0.5 Ω max	0.2 Ω max
Line voltage regulation	--	< 3 % at 99 V~
Rated output voltage (kVp)	60 ÷ 86 kV_p, with 2 kV_p steps	
Anodic current	6 ÷ 10 mA, with 1 mA steps for PAN, TMJ, Sinus and Implant 6 ÷ 12 mA in 1 mA steps for Ceph (up to 76 kVp) 6 ÷ 10 mA in 1 mA steps for Ceph (from 78 kVp to 86 kVp)	
Sensor cover additional filtration	0.1 mm Al eq @ 70 kV_p	
Exposure times		
Panoramic (PAN)	14.4 s PAN Adult / 13.3 s Child	
EmiPanoramic	7.8 s Adult / 7.3 s Child	
Improved orthogonality Panoramic	11.9 s Adult / Child	
Reduced dose Panoramic	11.9 s Adult / 10.8 s Child	
Frontal Dentition	4.4 s Adult / Child	
Bitewing	3.2 s right / left 6.3 s right and left	
TMJ mouth closed/open	2.44 s per image for left and right joint in open and closed condition, total of 9.7 s	
Sinus P/A projection	9.4 s	
Implant	9.2 s for incisive and canine 7.3 s for pre-molars and molars	
Cephalometry (Ceph)	Exposure time variable according to the type of resolution and format selected. Minimum 4.5 s (18x22 nR), maximum 15 s (30x22 hR)	
Exposure time accuracy	± 5 % or ± 50ms whichever is greater	

Examination modes		
Examination selection	• Automatic selection for Adult and Child, 3 Sizes • 3 biting modes (in Panoramic) • Automatic selection for Adult, 3 Sizes (in Implant) • Manual selection • Collimator with automatic positioning	
Panoramic	• Standard Panoramic • Half Panoramic L/R • Improved orthogonality Panoramic • Reduced dose Panoramic • Frontal dentition • Bitewing L/R • Bitewing L and R	
TMJ (Temporal Mandibular Joint)	TMJ open and closed mouth	
Sinus	Sinus P/A projection	
Cephalometry and Carpus	• Normal resolution cephalometry in Latero-Lateral or Antero-Posterior projection (different formats) • High resolution cephalometry Latero-Lateral or Antero-Posterior projection (different formats) • High Resolution Carpus exam • Motorized Soft Tissue Filter.	
Image magnification	**Geometric magnification**	**Magnification after software correction**
Adult / Child standard Panoramic	1 : 1.23 (constant over dentition part)	1 : 1 (*)
TMJ open/closed mouth, 4 images	1 : 1.20 (nominal)	1 : 1 (*)
Sinus	1 : 1.22 (nominal)	1 : 1 (*)
Implant	1 : 1.32 (constant)	1 : 1 (*)
Ceph (on the sagittal medial plane in LL projection)	1 : 1.10	1 : 1 (*)

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

Tube-head characteristics	
Model	MRE 05
Manufacturer	Villa Sistemi Medicali S.p.A. 20090 Buccinasco (MI) Italia
Maximum tube voltage	86 kV_p
kV_p accuracy	± 8 %
Maximum anodic current	12 mA
Anodic current accuracy	± 10 %
Duty cycle	Adaptive Duty Cycle according to exposure factors: from 1 : 8 (at 60kV, 6mA) up to 1 : 20 (at 76kV, 12mA). Further reduction for three consecutive exposures: from 1 : 3.6 (at 60kV, 6mA) up to 1 : 9 (at 76kV, 12mA)
Reference loading conditions related to maximum energy input to the anode	2700mAs/h @ 86 kVp
Nominal power	1.032 kW (86 kV_p - 12 mA)
Total filtration	2.5mm Al eq. @ 70 kV_p
HVL (Half value layer)	> 3.1mm Al eq. @ 80 kV_p
Transformer insulation	Oil bath
Cooling	By convection
Leakage radiation at 1 m	< 0.5 mGy/h @ 86 kV_p - 12 mA - 3 s duty cycle 1/16
Tube-head maximum thermal capacity	310 kJ

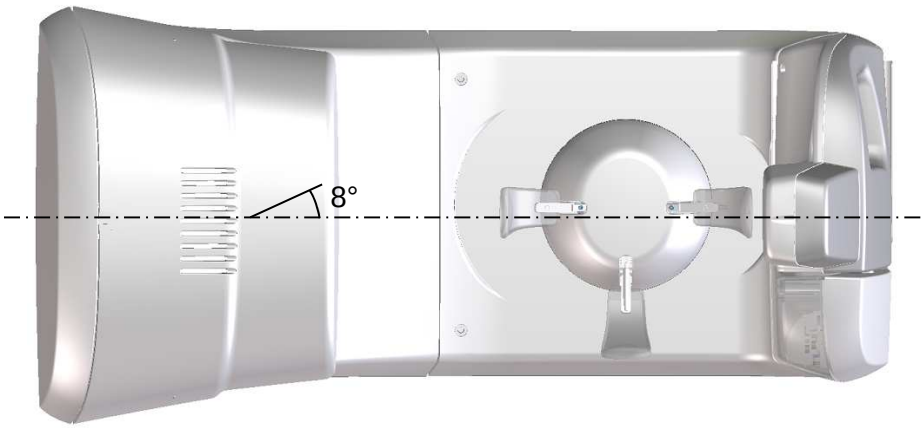


Figure 5 - Tube-head target angle (view from the bottom)

X-ray tube characteristics	
Manufacturer	CEI Bologna (Italy)
Type	OPX 105
Nominal focal spot	0.5 IEC 60336
Inherent filtration	0.5mm Al eq.
Anode tilt	5°
Anode material	Tungsten
Nominal maximum voltage	105 kV_p
Filament max current	4 A
Filament max voltage	8 V
Anode thermal capacity	30 kJ

Digital Sensor	
Sensible area (H x L)	• PAN sensor: 146 x 6 mm • PANCEPH sensor: 220 x 6 mm
Pixel dimensions	48 µm, 96 µm in binning 2x2 (PAN and PANCEPH HR), 144 µm CEPH nR
Pixel (H) NOTE: Number of horizontal pixels depends on the exam and resolution on CEPH.	• PAN: 1536 • CEPH: 1536 in nR, 2304 in HR
Laser centering devices	
2 laser beams are used for the patient positioning; beams align mid Sagittal and Frankfurt planes (please refer to relevant paragraphs for detailed explanation).	
Wave length	650 nm ± 10 nm
Divergence	< 2.0 mRad
Optical power on the working surface	< 1 mW
Classification	Class 1 laser device according to standard IEC 60825-1:2007
Mechanical characteristics	
Focus-receptor distance (PAN, TMJ and Sinus)	50 cm (20")
Focus-receptor distance (CEPH)	165 cm (65")
Telescopic motorized column run	85 cm (33.5")
Maximum total height	245 cm (96.5")
Weight	• 161 kg base version • 186 kg version with Ceph
Column weight	87 kg
Weight of arm support, rotating arm and tube head	74 kg
CEPH arm	25 kg
Legs (optional)	30 kg
Sensor holder weight	2 kg
Working conditions	
Minimum room size (please refer to the Service Manual)	• 130x120 cm (51.2"x47.2") without CEPH • 145x202 cm (57"x78.7") with CEPH
Recommended room size (please refer to the Service Manual)	• 130x140 cm (51.2"x55.1") without CEPH • 160x222 cm (63"x86.6") with CEPH
Maximum working temperature range	+ 10° ÷ + 40°
Relative working humidity (RH) range	30% ÷ 75%
Range of working atmospheric pressure	700 ÷ 1060 hPa
Temperature range for transport and storing	- 20° ÷ + 70°
Humidity range for transport and storing	< 95% without condense
Minimum atmospheric pressure for transport and storing	630 hPa

NOTE: In order to properly view images taken with I-Max Touch, 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.**

6.1 PC requirements

WARNING: PC to be used with the machine must comply with the standard IEC60601-1, if it is positioned inside the patient's environment, or with the standard IEC 60950-1:2005. The dimension of the "patient's environment" is defined as a distance of at least 1.5 m from the actual patient.

The minimum PC characteristics are the following:

- Processor Intel core I5 Quad core.
- 4Gb Ram.
- Hard drive 500 GB.
- Graphic card 1GB.
- Network card 10/100 Mb/sec.
- Operating System Windows 7, 8, 8.1, 10 / 32 or 64 bit.
- 3 USB port.
- DVD recorder.

NOTE: In case of connection to DICOM network or LOCAL network are required two network boards inside the PC.

6.2 Open Source Software

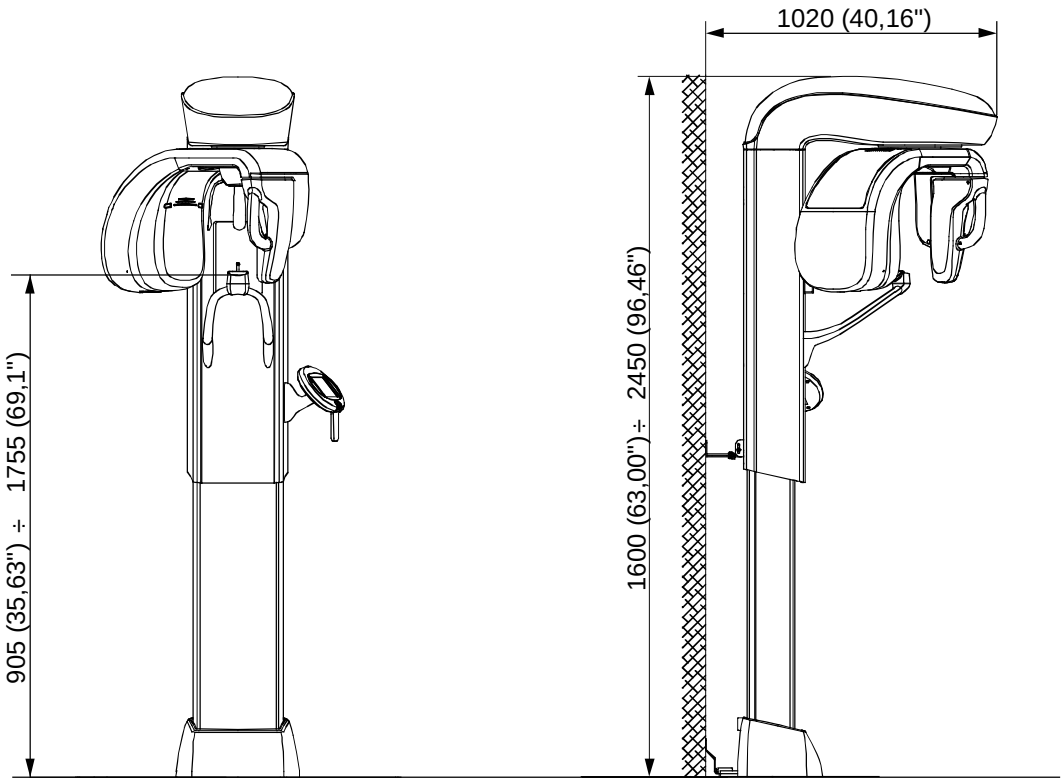
Parts of the software included in this product use the LINUX® operating system and software packages that operate in that environment. Such packages are used without alterations and are subject to various open source licenses such as the General Public License (GPL or LGPL) and others.

You may obtain the corresponding source code by writing to:
Owandy Radiology
2 rue des Vieilles Vignes
77183 Croissy-Beaubourg
FRANCE
Tel.: +33 1 64 11 18 18
info@owandy.com

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

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

6.3 Dimensions



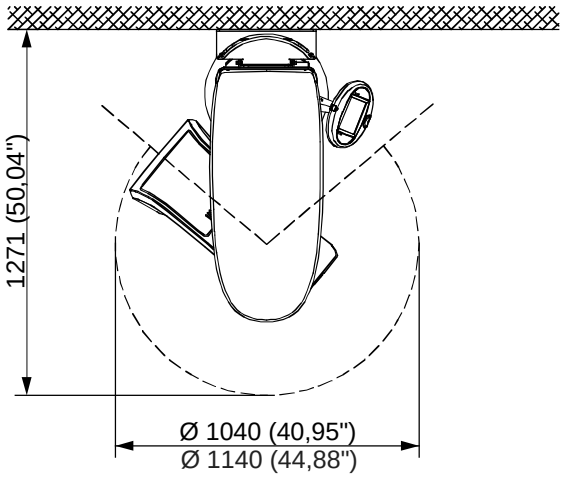
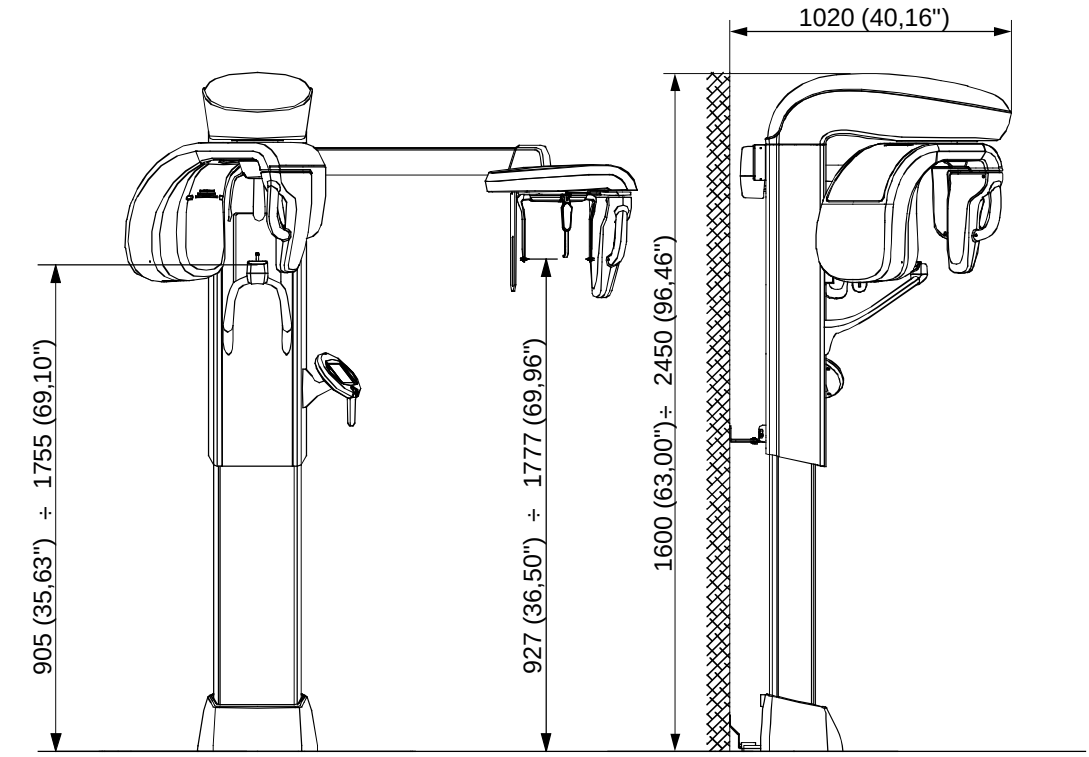


Figure 6 – I-Max Touch dimensions
Base version



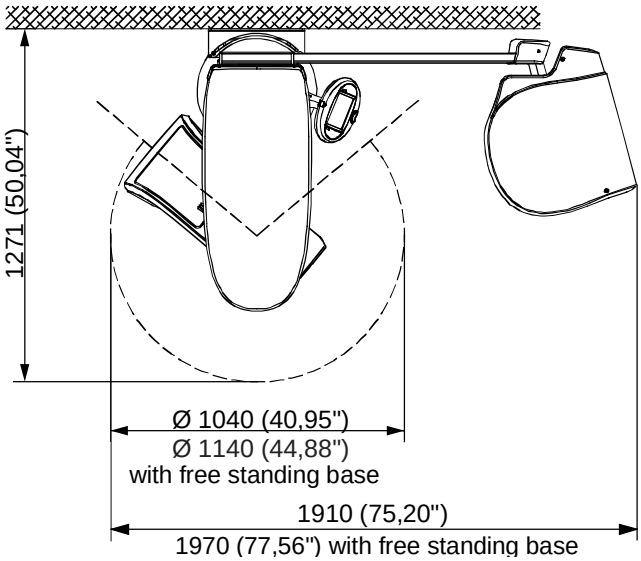
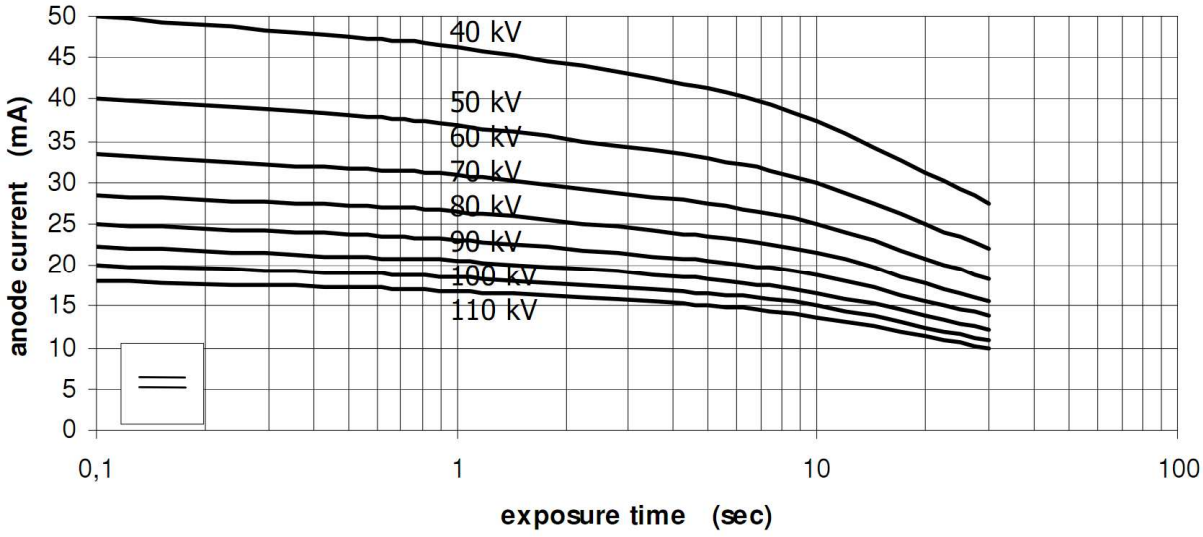


Figure 7 – I-Max Touch dimensions
Version equipped with cephalometric unit

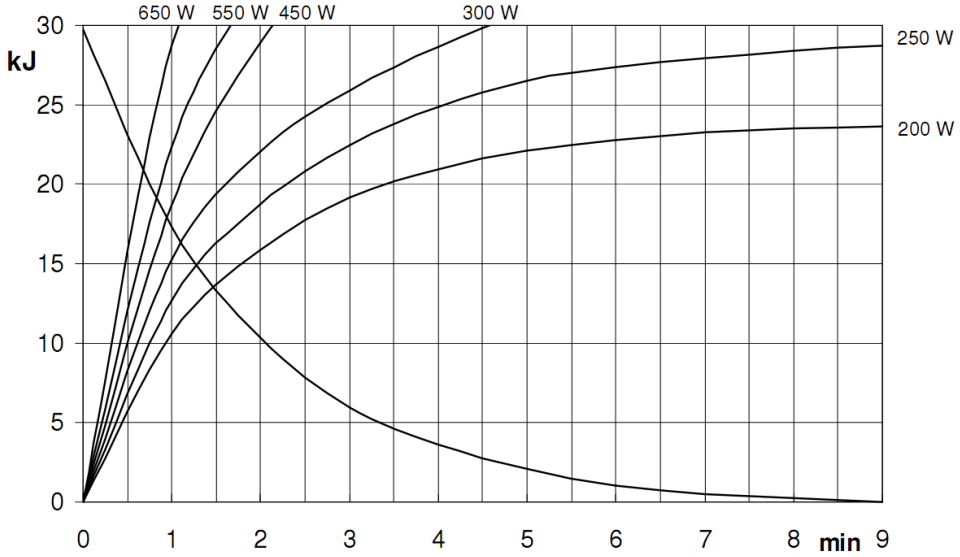
6.4 Loading curve of the tube and cooling curve of the anode

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

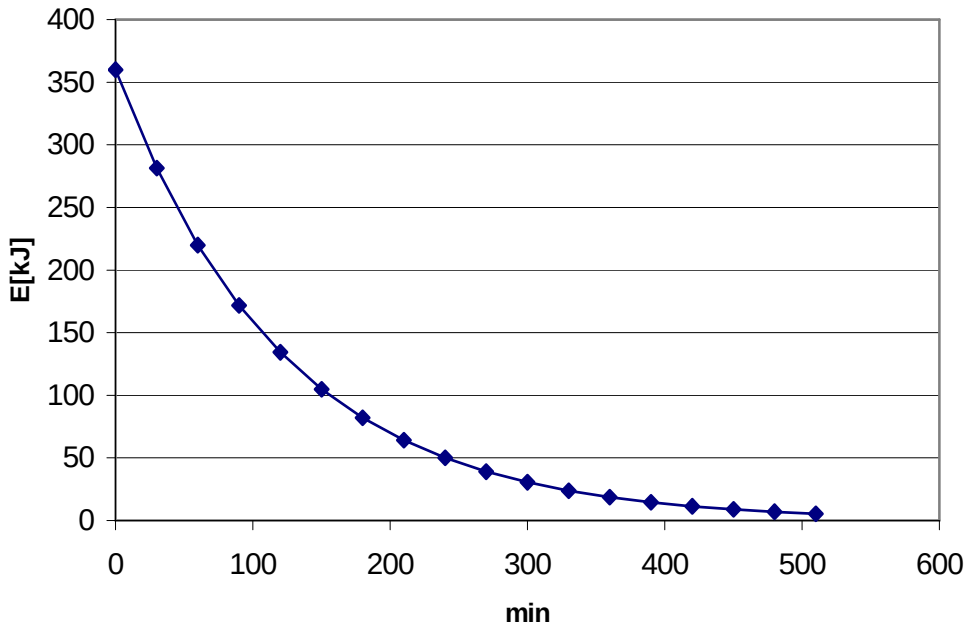
Load



Anode cooling curve



Tube-head heating and cooling curve



6.5 Applied safety regulations

Medical electrical equipment for extra-oral dental radiography I-Max Touch complies with:

IEC 60601 1: 2005 + Corr.1 (2006) + Corr.2 (2007)
IEC 60601 1: 2005 (3rd ed.) + Am1: 2012 (ed. 3.1) with North American deviations (US+CA)
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6:2010 (3rd ed.)
IEC 60601-1-6:2010 (3rd ed.) + Am1:2013
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.)
IEC 60601-1-3:2008 (2nd ed.) + Am1:2013 (ed. 2.1)
Medical electrical equipment - Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment.

IEC 60601-2-63:2012
IEC 60601-2-63:2012 (1st ed.) + Am1:2017 (ed. 1.1)
Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of extra-oral dental X-ray equipment.

IEC 62304: 2006 (1st ed.)
IEC 62304: 2006 (1st ed.) + Am1:2015 (ed. 1.1)
Medical device software – Software life-cycle processes.

IEC60825-1:2007 (2nd ed.)
Safety of laser product - Part 1: equipment classification and requirements.

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

CAN/CSA-C22.2 No 60601-1:08
CAN/CSA-C22.2 No 60601-1:14
Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

ANSI/AAMI ES60601-1:2005/A2:2010
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 I-Max Touch with Directives 93/42/EEC (as amended), 2011/65/EU, 2006/42/EC.

6.5.1 Classifications

The I-Max Touch is an electro-medical X-ray device belonging to Class I type B as per classifications IEC 60601-1, provided for a continuous working at intermittent load.
According to 93/42/EEC Medical Devices Directive, the equipment is classified as class II B.
According to Canadian MDR, the equipment belongs to class II.
According to FDA 21 CFR, the equipment belongs to class II.

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

NOTE: The I-Max Touch 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". The I-Max Touch follows a rototranslation path which maintains constant the magnification factor stated in the Technical Characteristics of each type of exam along this "standard" shape only along the dentition area. The patient's anatomy can differ significantly from the statistical model, so the magnification factor is not maintained and can be different from the value stated. Based on his experience and competence, the user has to judge this variation.
IN ANY CASE, THE RADIOGRAPHY IMAGES CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE IMAGE.

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

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

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

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

WARNING: During the panoramic examination, the set value of kV and tube current varies according to a fixed curve, to compensate the variations in absorption by the patient's tissues; in this way, it is possible to obtain a good uniformity of the image contrast. In particular, the chosen value is lowered during the initial phase, and increased on the canine/incisor zone, in order to compensate the effect of greater attenuation owing to the spine.
The value displayed during the panoramic examination corresponds to the one chosen by the user, while the real value can be different; this fact must be considered if the exposure parameters are checked using standard diagnostic mode.
The accuracy of the exposure parameters kV and mA, stated in the Technical Data section, refers to the accuracy compared with the instantaneous value set by the system.
In any case, the manufacturer guarantees that the accuracy of the exposure parameters is within the maximum limits required by international regulations on the safety of medical devices IEC 60601-1 and attachments. In particular, in accordance with IEC 60601-2-63, the maximum deviation (including correction and instrumental doubt) is less than or equal to ±8% for kV, while for tube current it is less than or equal to ±10%.

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

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

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

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

1. With the unit switched ON, be either in Anatomic or Manual mode, press the "Anatomic/Manual" mode indicator until it turns green and displays "S", then press the "Test function" (5) key to enter the exposure verification mode, the display shows:

   xxkV xxm xx.xs
   EMISSION PROGRAM

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

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

2. Place the measuring instrument.
3. The KV and mA parameters can be modified by pressing the increase key and the decrease key of the KV and mA on the display.
4. The parameters can vary within the limits shown in the following table:

kV	mA	s	kV acceptance range	Time acceptance range
60	6	3	55.2 to 64.8	2.35 to 3.65
86	12	3	79.1 to 92.8	2.35 to 3.65

Table 3

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

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

6. To end the control program, press any key other than the increase and decrease keys; the display will indicate:

   xxkV xxmA xx.xs
   PANORAMIC-STD

   and the unit will return to standard mode.

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	Laser alignment check	User	Paragraph 7.3
Monthly	Image quality check	User	Paragraph 7.4
Yearly	Dosimetry test	Authorized personnel	Paragraphs 6.7 and 6.8

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
- kV meter (NOT provided by Owandy Radiology): used to measure exposure parameters.

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

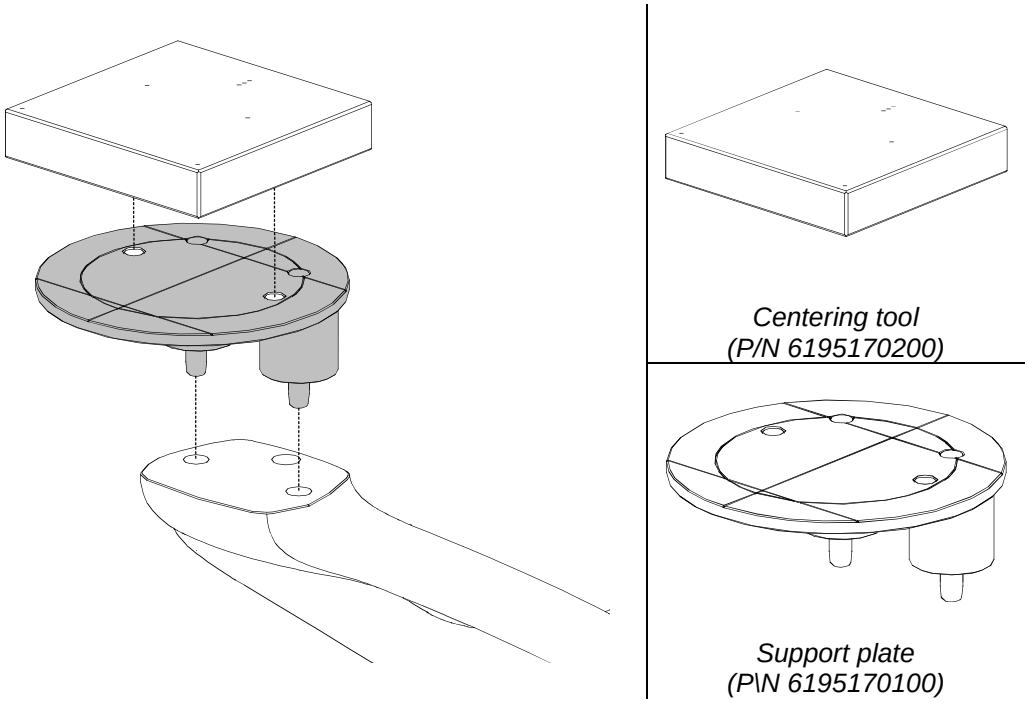


Figure 8: Support plate and centering tool positioning

7.2 External inspection

Check the following items:

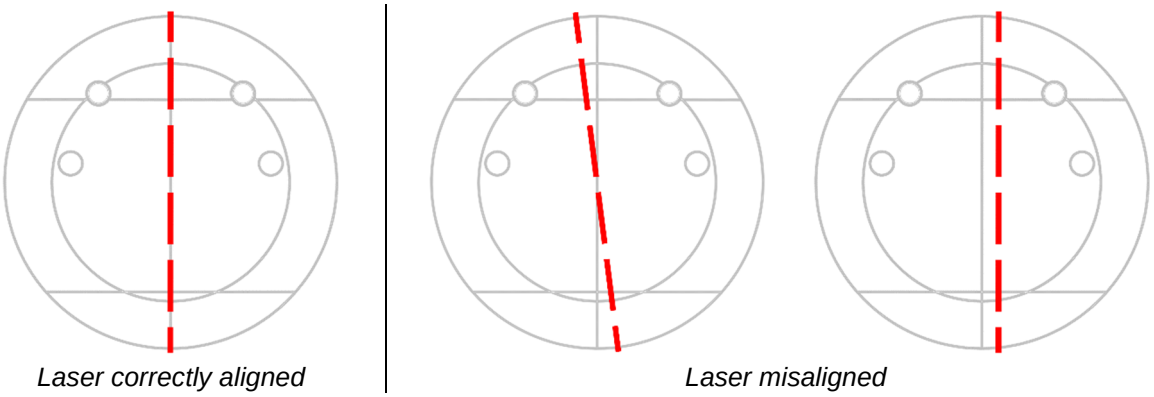
- Check that the labels are complete and well fixed
- Check possible oil leaks from the tube-head
- Check that the X-ray button cable does not show breaking or wearing signs
- Check that the unit is not damaged externally as to compromise the safety of protection from radiation.

In case of fault or abnormalities, call technical assistance.

7.3 Laser alignment check

Power ON the unit and perform the axis reset by pressing the key "Patient Entrance"  .

At the end of the axis positioning, place the support plate (P/N 6195170100 – Figure 9) 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 9

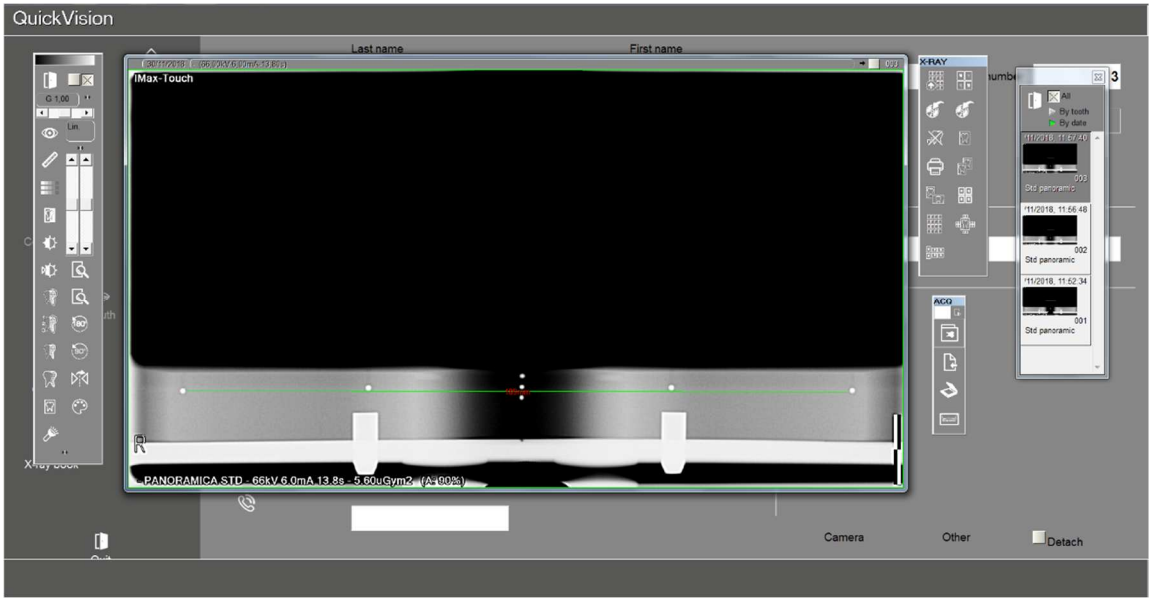
In case the test fails, repeat it checking that were is no mechanical interference. If misalignment is still present, call technical assistance.

7.4 Image quality check

WARNING: X-rays will be emitted during the performance of the following operations. It is recommended to use the greatest caution and comply with local safety regulation and laws.

1. Switch ON the unit and go to Exam Selection.
2. On QuickVision program, open a test patient used to make the test images and select the "Panoramic" icon to open the virtual keyboard.

3. Select a Panoramic STD exam.
4. Place the centering tool (P/N 6195170200) on the support plate (P/N 6195170100) and place it on the chin rest (Figure 8).
5. Make an exposure in Adult mode at 66kV - 6mA, acquired in the QuickVision program.
6. Set contrast and brightness level to have good visibility of all centering balls. Using the distance measurement tool, measure the dimension of the image using as reference the two external balls. The image has to be 188mm ± 2mm with Panoramic trajectory selected.



7. Measure also the two half of the image in order to check symmetry. The difference has to be max. 2mm.

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

In case the measured values are out of tolerance, call technical assistance.

8. GENERAL INSTRUCTIONS FOR USE

8.1 Control panel - description and functions

The I-Max Touch keyboard is divided into function areas, plus a display to view the operative messages and error signals. The next figure shows a general view of the control interface, while details on each functional area are provided in the following pages.

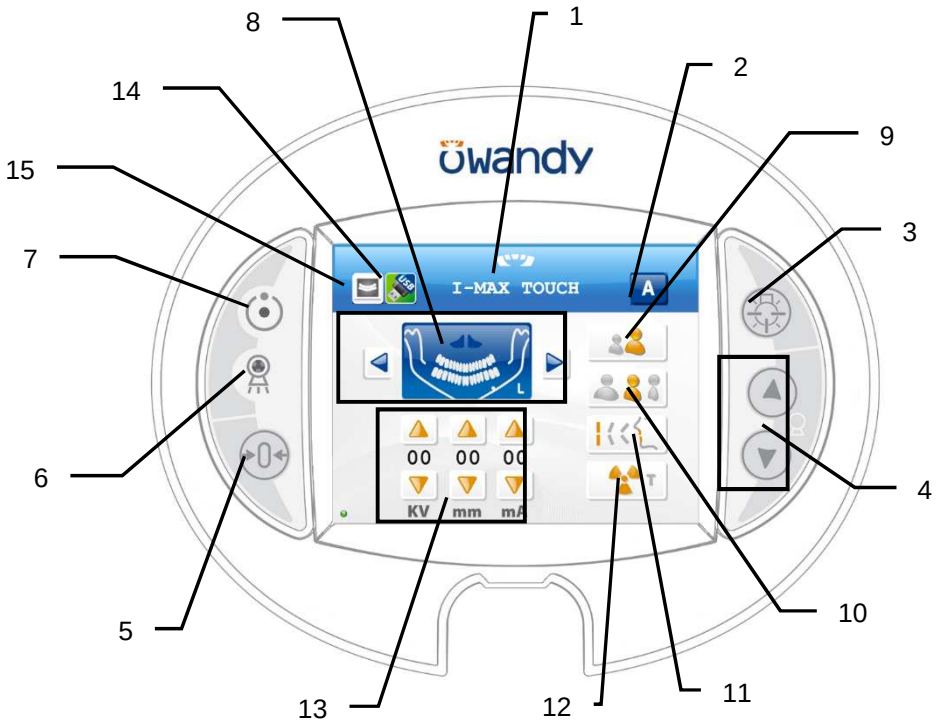


Figure 10

Legend:

1	Messages display
2	"Anatomic/Manual mode" indicator
3	"Centering devices ON" button
4	"Column movement" buttons
5	"Centring/Patient entry" button
6	Light signaling "X-rays in progress"
7	Light signaling "Ready for X-rays"
8	"Exam mode selection" button
9	"Adult/Child selection" button
10	"Size selection" button
11	"Type of incisor block" button
12	"Test" button
13	"Exposure parameters" button
14	"USB Pen Drive" button
15	"View acquired image" button

WARNING: The USB port on the keyboard <u>MUST NOT</u> be used with an external Hard Disk with own mains connection. It has to be used only with USB Pen Drives.

The next figure shows a general view of the display of the acquired image, details on each functional area are provided in the following pages.

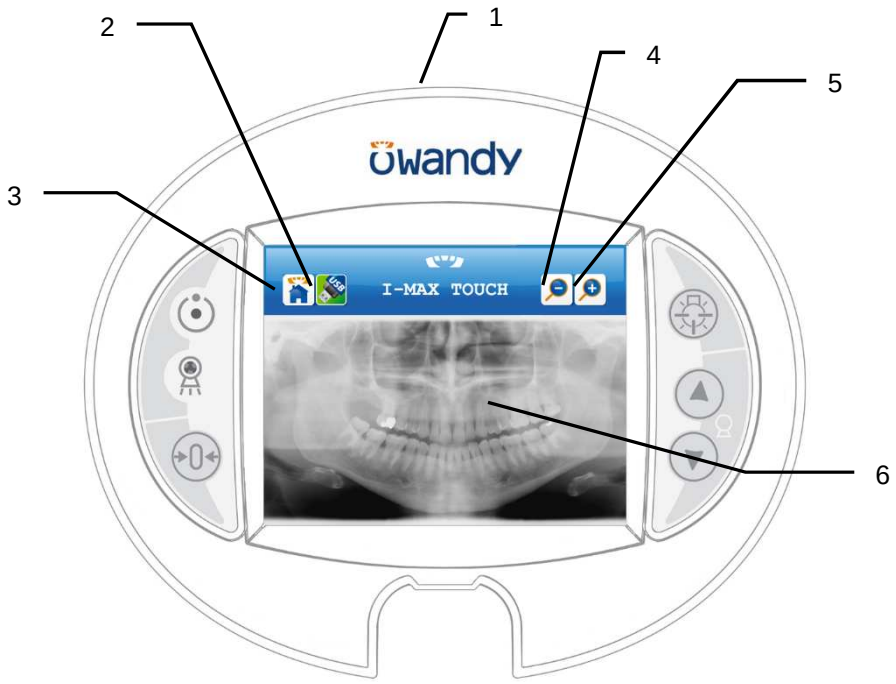


Figure 11

Legend:

1	USB port for pendrive
2	USB pendrive button
3	Return to Main Menu button
4	Zoom out button
5	Zoom in button
6	Acquired image

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

The "Centering/Patient Entrance" button is used to:
- start/stop the start examination procedures
- bring the rotation arm to the patient entrance position at the end of the exam.

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

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

Child

Adult

Large

Medium

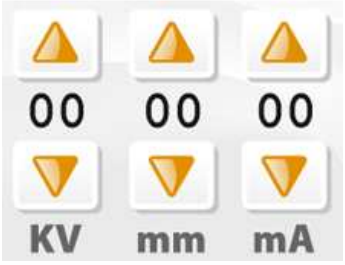
Small

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

Protruded

Standard

Retracted



Furthermore there is the possibility to manually select the exposure parameters; in this case, it is possible to set the parameter with the desired value.
The parameters available are: kV and mA (Soft Tissue Filter position, mm, only in cephalometry).
When the exposure parameters are changed manually, the mode indicator switches from “Anatomic” to “Manual”. Return to “Anatomic mode” using the main program selection button. By holding the indicator for more than 1 second the special mode is activated and the indicator changes color. In special mode modified exposure parameters can be stored or exposure verification tests can be performed.

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

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

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

Test OFF

Test ON

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

View image

This key displays the acquired image stored in the memory of the unit; the main menu area is replaced by the image.

This key is used to return to the control panel (main menu) when an acquired image is displayed.

Return Main Menu 

The Pen Drive key appears when a pen drive (memory stick) is inserted in the USB connector of the control panel; it writes the acquired image that is stored in the memory of the unit on the pen drive that is inserted.

When this key is green, the pen drive is recognised, has enough free space and is ready for use.
When the key is orange, it is busy; the image is being written on the pen drive.
When the key is red, the pen drive does not have enough free space on it, or it is not recognized.

Full/error 

In operation 

Ready for use 

When the acquired image is displayed on the control panel screen, it is possible to zoom in and out of the image using these two keys.

Zoom in 

Zoom out 

8.1.1 Key function description

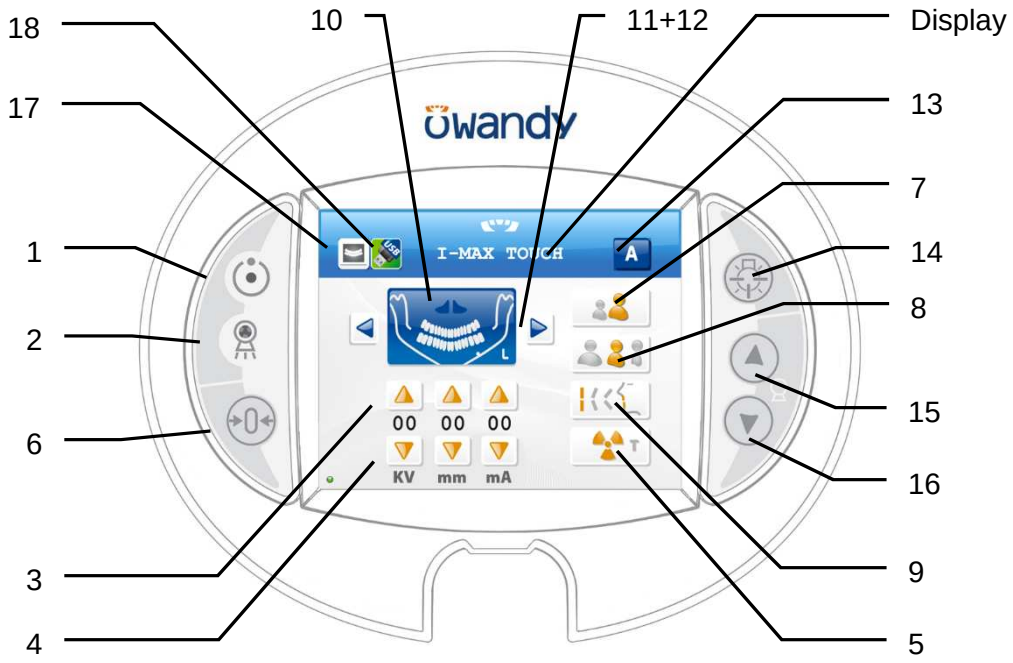


Figure 12 - Control panel

LEGEND:

Messages

Display: indicates operative messages, warnings and exposure parameters.

Signal lights

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

2 - Yellow LED indicating X-ray emission

Manual setting of exposure parameters

3 - kV, mA and Soft Tissue Filter increase keys

4 - kV, mA and Soft Tissue Filter decrease keys

Preparation functions

5 - Key to set Test function

6 - Key for:
> Resetting and realigning the device's axes (in case of collision with patient or in case of release of rays button)
> Repositioning the rotation group (to bring the group to the initial position after the examination and to exit from the "making an exposure") mode
> Confirmation

Anatomic selection

7 - Patient selection key: Adult or Child

8 - Size selection key: Small, Normal, or Large

9 - Arch selection key: Protruded, Standard or Retracted (for panoramic execution)

Examination mode

10 - Exam mode selection key

11 +12 - Type of exam selection keys (only for panoramic mode)

13 - Mode indicator : Anatomic or Manual

Centring devices

14 - Sagittal and Frankfurt plane centring device ON key

Column height adjustment

15 - Column up key

16 - Column down key

Other

17 - Display acquired image key

18 - USB Pen Drive key

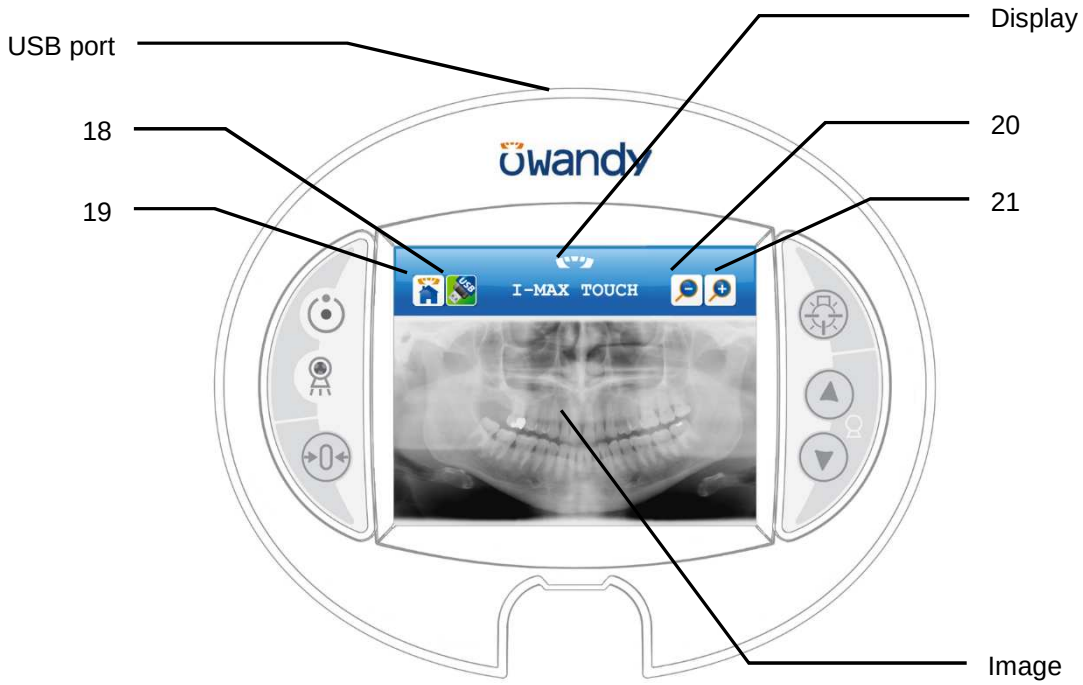


Figure 13 – Acquired image display

LEGEND:

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

Other
18 - USB Pen Drive key
19 - Return to control panel (main menu)
USB port: to connect a pen drive

Acquired image display
Image: displays the last acquired image, stored in the memory of the unit
20 - Zoom out on the image
21 - Zoom in on the image

8.1.2 Acquired image display description

Once an image has been acquired it is transferred to the computer through the network (if connected) and/or written on the USB pen drive (if inserted); the image remains in the memory of the unit until the unit is switched off or until a new image is acquired that replaces the previous one.

During acquisition, image is progressively displayed on the screen, adjusted to have the whole image in the screen. During this processing step, zoom keys are not displayed.

As soon as the image is acquired and fully processed, it is displayed on the screen of the control panel. The image can be zoomed in and out on, using keys (20) and (21).

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

Key (19) returns to the control panel, allowing for the acquisition of a new image. In the control panel, key (17) returns to the display of the acquired image.

8.1.3 Pen Drive function description

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

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

- If the pen drive is formatted with the right file system and there is enough free space available to save at least one image, the pen drive key (18) on the screen will be displayed in green.
- If the pen drive is not formatted with the right file system or if there is not enough free space available to save at least one image, the pen drive key (18) on the screen will be displayed in red.
  Please verify that there is enough free space on the pen drive, if not please free up at least 25 MB of space. Please verify that the pen drive has been formatted with the FAT32 and not with the NTSF (or Linux or Mac) file system, if not please use another pen drive or reformat the pen drive with the correct file system.

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

- When an image is being written to the pen drive, the pen drive key (18) on the screen will be displayed in orange (busy state). Do not extract the Pen Drive from the keyboard when the Pen Drive key (18) is orange.
- When the keyboard displays the acquired image, pressing the green Pen Drive key (18) will save the current acquired image on Pen Drive.

8.2 Digital Sensor

The I-Max Touch is equipped with two types of digital sensors, depending on the version:

- Sensor PAN: it is a sensor suitable for Panoramic-type imaging, i.e. all images with a 14cm-high field; all Panoramic, TMJ, and Sinus images belong to this type. Depending on the version, this sensor can be either movable from the sensor holder, or fixed (not removable) on the same holder. In case the sensor is fixed to the sensor holder, the latter cannot be rotated to make free the part where rays go through for the execution of the cephalometric examination.
- PAN/CEPH sensor: it offers a wider use flexibility, as it can carry out both Panoramic and Cephalometric-type images. This sensor can always be removed from its sensor holder's.

The I-Max Touch can also be configured in the "double sensor" version, where both PAN and PAN/CEPH sensors are present.

The I-Max Touch control system takes care of checking the consistency of the safety measures that allow for the correct use of the digital sensor; in particular:

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

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

 **NOTE: The fall sensor color change interrupts the warranty on the sensor.**

8.2.1 Inserting the sensor in the sensor holder

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

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

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

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

8.2.2 Release of the sensor from the sensor holder

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

8.3 Switching ON and OFF the device

WARNING: The unit must be connected to a differential magneto-thermal switch to divide the unit from the supply. This switch must comply the electrical regulations in force in the country of installation.
Minimum requirements at 230V: working voltage 250V, current 10A and differential current 30 mA.
Minimum requirements at 115V: working voltage 150V, current 25A and differential current 30 mA.

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

IMAX TOUCH
HW=x.x SW=xx.xx

This message will be present for about 20 seconds.
After this time the LEDs on the control panel start blinking and on the display will be present the following message:

IMAX TOUCH
RELEASE *.**

3 seconds later, the display shows the following message:

>TEST<

NOTE: During this phase, the I-Max Touch does not perform any movement, it just performs a series of checks which, in the event of negative result, could require the intervention of the technician.
The only problem that can be solved by the user is related to the position of the PAN sensor holder; in this case, the following message will be displayed: "CLOSE CASSETTE PANORAMIC".

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

MACHINE SETTING
PRESS >0<

Press key (6) to start the device alignment phase. Once the key has been pressed, the message disappears and the display shows the following message during the alignment of the axes:

WAIT FOR…
MACHINE SETTING

WARNING: During equipment axis zero reset, check that the unit does not collide with external objects.

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

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

The display shows (for instance):

xxkV xxmA 14.4s
PANORAMIC-STD

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

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

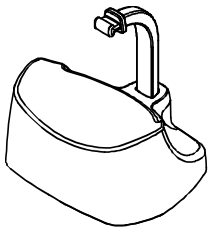
To switch OFF the unit press the green button on the base of the column.
The display and the LEDs will go off.

8.4 Positioning of chin support

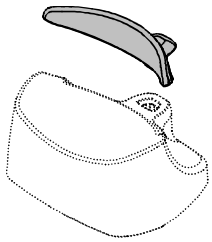
The I-Max Touch is equipped with different types of supports: a standard support fitted with a special removable appendix for edentulous patients, a lower one for SINUS examinations and a third one, to be used for TMJ examinations.

The standard chin support must be used, in panoramic mode, with all the people who can assure a tight grip on the centering bite. The appendix for edentulous patients must be applied only for patients who cannot assure a tight grip on the bite or are not co-operating and might move during the examination.
For the SINUS examination, the chin support is made by lowered chin rest and appendix for edentulous patients.
For TMJ examinations, a specific positioner is included, allowing the patient to open and close the mouth without touching any positioner with the chin.

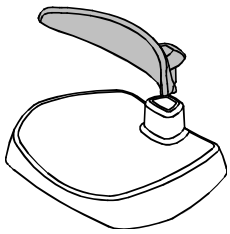
NOTE: Another chin support, at a low height for standard Panoramic, is provided to ensure a better view of the lower section of the chin for patients with particular anatomy.
This chin support is marked by a down arrow "▼" on the front of the chin support itself.



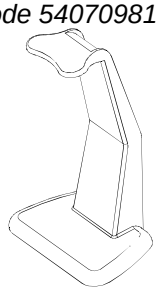
Panoramic standard chin support
(Code 6104011508 + 5407098200)



Edentulous patients appendix
(code 5407098119)



SINUS chin support
(code 6104011608 + 5407098200)



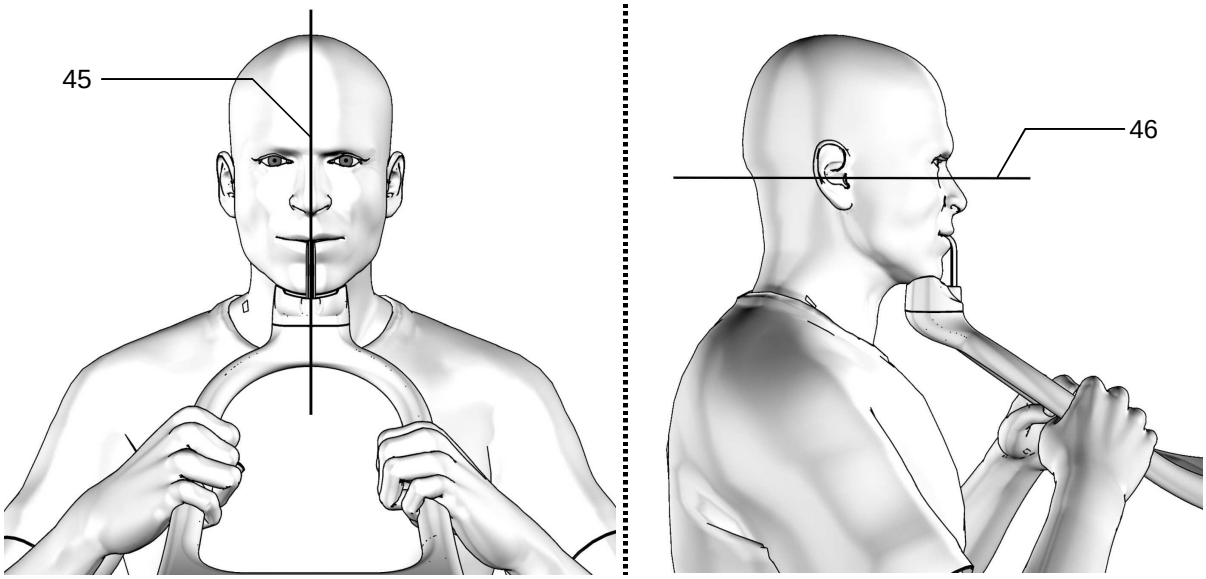
TMJ positioner
(code 6104011800)

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

8.5 Panoramic examination

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

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



Legend of Reference Lines

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

Figure 14

8.5.1 Device preparation

When the unit is switched on, the Panoramic Examination is selected as standard. If the operator has previously made another kind of examination to select Panoramic use the key "Examination Mode Selection" (10).

By doing so, it is possible to modify the type of examination between STD PANORAMIC, TMJ O/C, SINUS, CEPH; such variation takes place with continuous rotation, therefore, to move from the TMJ O/C mode to the STD PANORAMIC the key needs to be pressed 3 times.

After selection Panoramic, the system positions itself with the following configuration:

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

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

72kV 06mA 13.8s
PANORAMIC-STD

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

The key "Examination Mode Selection" (10) enables the selection of specific submodes, selectable by means of the keys "Arrow right" (12) and "Arrow left" (11), enabling the sliding in one direction or another.

Previous examination  *Next examination*

For the Panoramic examination, the following selections are possible: STD Panoramic -> Right Emi-panoramic -> Left Emi-panoramic -> Improved orthogonality dentition -> Reduced dose Panoramic -> Frontal dentition -> Bitewing Right -> Bitewing Left -> Bitewing RGT,LFT -> STD Panoramic.

This selection is cyclic, so pressing the button repeatedly will change the selected mode.

8.5.1.1 Right / Left Emi-panoramic

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

Follow the instructions for normal Panoramic for patient positioning.

8.5.1.2 Reduced dose Panoramic

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

Follow the instructions for normal Panoramic for patient positioning.

8.5.1.3 Improved orthogonality dentition

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

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

Follow the instructions for normal Panoramic for patient positioning.

8.5.1.4 Frontal dentition

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

Follow the instructions for normal Panoramic for patient positioning.

8.5.1.5 Bitewing

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

Follow the patient positioning instructions for the normal Panoramic exam.

NOTE: The I-Max Touch is based on a standard dentition and ascending rami shape. This shape, based on statistic study, establishes a form for the dentomaxillofacial complex that it is assumed as "standard". The I-Max Touch follows a rototranslation path which maintains constant the magnification factor stated in the technical characteristics of each type of exam along this "standard" shape and in the dentition area. The patient's anatomy can differ significantly from the statistical model, so the magnification factor is not maintained and can be different from the value stated. Based on his experience and competence, the user has to judge this variation.
IN ANY CASE, THE RADIOGRAPHY IMAGES CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE IMAGE.

WARNING: The measurement of lengths on digital images depends on the specific length calibration of the program used.
It is therefore very important to check the length calibration of the program.
In Panoramic examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 7.8 mm (in the centre of the focus layer).

8.5.2 Anatomic / manual exposure

 **NOTE: If the previous exam was carried out manually, just press the key "Size Selection" (8) or the key "Selection Examination Mode" (10).**

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

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

 **NOTE: In manual condition, the "Anatomic/Manual mode" (13) indicator displays "M" to indicate the manual mode; it is possible to press key (7) to change from Adult to Child and press key (9) to modify the type of biting from Normal to Protruded to Retracted.**

8.5.2.1 Anatomic exposure

Select the type of patient with the Adult/Child key (7).
Select the type of build with the Size (8) key (small - medium - large).

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

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

Table 4

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.

Select the type of biting with the key "Type of Biting Selection" (9).

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

8.5.2.2 Manual exposure

If the kV and mA combinations of the Table 4 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode. To modify the kV or mA values, press any of the up (3) or down (4) arrows of the KV or mA parameters, the blue frames around the "Adult/Child Selection" (7) and the "Size Selection" (8) keys will disappear, orange frames will appear around the up (3) and down (4) arrow keys of the parameters and the "Anatomic/Manual mode" (13) indicator will display "M". A parameter can be modified by pressing the increase key (3) and the decrease key (4) of that parameter repeatedly.

The kV value can vary between 60 and 86 kV, with 2 kV steps.
The value of mA can vary between 6 and 10 mA, with 1 mA steps.

NOTE: To change the values rapidly, keep the increase key (3) or decrease key (4) pressed. Select the type of mouth with the key "Type of Biting Selection" (9).

8.5.3 Patient preparation

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, removable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.
3. Place the patient in a standing position at the chin support. With the keys "Column movement" (15/16) lift/lower the column until the chin support is aligned with the patient's chin.

WARNING: During the patient positioning, make sure the equipment can not collide with any objects in the room.

4. Position the patient with the temple clasps ensuring that the chin rests on the special support; the hands should rest on the front handles. Ask the patient to bite the reference notch of the bite with his incisors. In case of edentulous patients, he/she must rest the chin against the reference shoulder of the edentulous chin support.
5. Instruct the patient to close his eyes.
6. Press the key "Centring devices ON" (14). Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa). Position the patient's head in such a way as to ensure that the luminous beams fall in correspondence with the respective anatomical references. The luminous beam of the Frankfurt plane can be adjusted according to the patient's height; this can be adjusted by means of the laser knob on the side of the mirror.

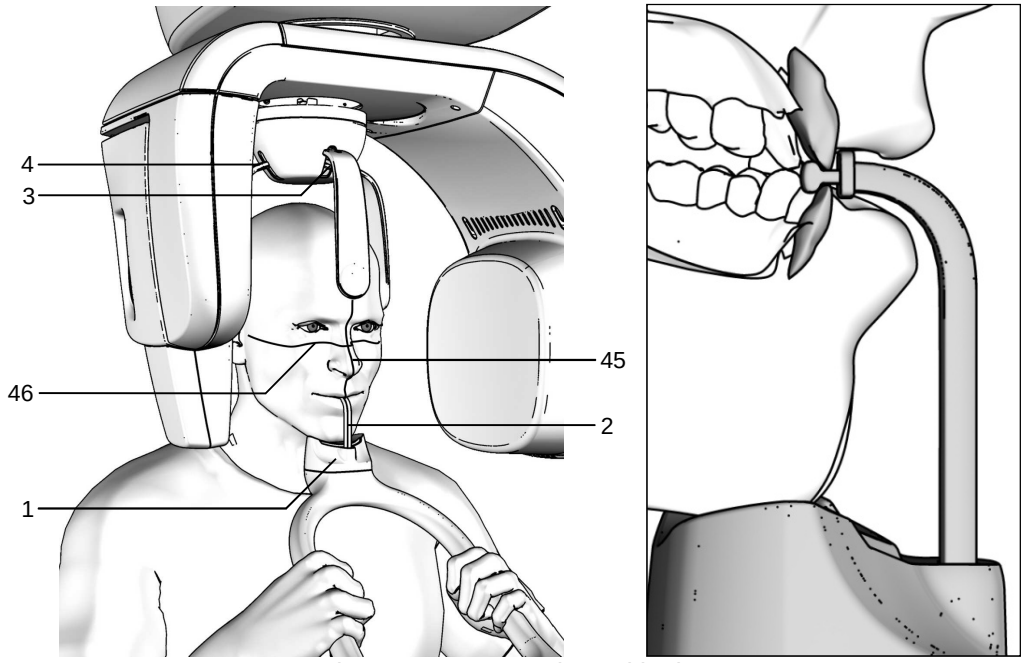


Figure 15- Panoramic positioning

Legend of Reference Lines

45	Sagittal medial line
46	Frankfurt plane line

Legend positioning devices and patient centering

1	Panoramic chin rest
2	Centering bite
3	Forehead support closing/release knob
4	Temple clamp open/close knob

 **NOTE: The laser centering devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centering Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (6) to begin preparation for exposure.**

7. At this point, the patient must move his feet towards the column, making sure to keep his head within the pre-aligned anatomical references. In this way, you will have a greater extension of the spine in the cervical area, improving the darkening of the X-ray in the apical area of the incisors, and avoiding the collision of the tube-head with the patient's shoulders. Check that the Frankfurt plane is still horizontal.
8. Close the temple clasps to help the patient keep a correct position; bring also the forehead support close to the patient's forehead and ensure that, in this phase, the patient has not changed position.
9. Press the key "Patient Entrance" (6) to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position. Once alignment has been completed, the following message will be displayed:

   xxkV xxmA 13.8s
   START EXAM
   x = value defined by the settings

   The green LED "Ready for X-ray" lights up to indicate that pressing the X-ray button once more will start the radiation phase.
10. Ask the patient to: keep the lips closed, bring the tongue towards the palate, keep perfectly still and do not look at the rotating arm during the movements.

8.5.4 Making an exposure

 **NOTE: When the key "Test" (5) is pressed the Test function is activated. In this condition, it will be possible to make the unit perform all the movements made during the examination without emitting X-rays. Once the cycle is completed, deactivate the "Test" function by pressing the key again.**

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

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.5.2.2; ensure that the machine's indicator light "Ready for X-rays" will come on, so press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the X-ray indicator light "X-rays emission" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

   START EXAM
   PRE-HEATING…

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

   xxkV xxmA xx.xs
   >X-RAY<
   x = value defined by the settings

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

   TEST
   XRAY NOT ACTIVE

    **NOTE: The I-Max Touch assumes that the digital sensor is ready: if this is not the case, the following error message will be displayed:**

   DIGITAL SENSOR
   IS NOT READY

   Refer to the Manual of the Digital Acquisition System to correct the situation. To reset the message on the I-Max Touch, press key >O<.

    **NOTE: The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. Since the X-ray button is a "dead man's switch", it must be kept pressed until the end of the exposure.**

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

   PATIENT EXIT
   PRESS >O<

   It will be necessary to free the patient from the positioning device.

NOTE: If the examination is made in "Test" mode with the patient already in position, he must not be removed from the temple clamp, to avoid having to reposition the patient.
Press the "Patient entrance" key (6): the unit will move back to the starting position.

NOTE: The keyboard is disabled during the movement of the system, but by pressing the "Patient entrance" key (6), the movement is stopped.
This operation is useful in case a movement anomaly is noticed.
Press the "Patient Entrance" key (6) to reset the error condition.

3. Press the key "Patient Entrance" (6), the unit will move back to the starting position showing the message:

PLEASE WAIT…

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

NOTE: If you try to perform a new exam before the cooling period has elapsed (4 minutes), the following message will be displayed indicating the time to wait before performing a new examination:

TUBE COOLING
PLEASE WAIT xxxs

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

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

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

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PRESS >O<

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; it is recommended that this movement has to be made with great care in order to prevent damage to the machine. Then press the "Patient Entrance" (6) key and the display will show:

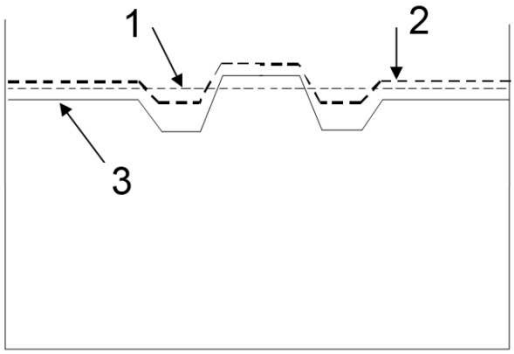
MACHINE SETTING
PRESS >O<

and then:

WAIT FOR
MACHINE SETTING

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

NOTE: During the Panoramic, the value of the exposure parameters varies according to a fixed curve, to compensate the variations in absorption by the patient's tissues. In this way, it is possible to obtain a good uniformity of the image contrast. In particular, the chosen value of the kV is lowered in the initial and end sections of the panoramic and increased on the incisors/canine zone. The tube current varies according to the kV, also if the set value is slightly increased on the initial/end sections. These variations have the effect of compensating the higher absorption of X-ray in the zone of the spinal column. As an example, the variation of the parameters follows the curve below:



1 Selected value
2 Real mA value
3 Real KV value

The values displayed during the panoramic examination correspond to the ones chosen by the user, while the real value in the various positions of the examination cycle can be different; in any case, the system guarantees that the accuracy of the exposure parameters is always within the limits set by the international standards for the safety of medical devices, IEC 60601-1. In particular, in accordance with IEC 60601-2-63, the maximum deviation (including correction and instrumental doubt) is less than or equal to ±8% for kV, while for tube current it is less than or equal to ±10%.

8.6 TMJ examination

The TMJ examination with open/closed mouth is similar to panoramic; the only difference is that the exposure is performed only on the involved area (the temporo mandibular joint), then it stops, and starts again on the second joint. The operation sequence of the examination is therefore identical to the one described for the panoramic.
The temporo-mandibular joint examination makes use of a projection geometry giving an image of the X-rayed condyle along a direction almost parallel with its major axis, in order to achieve a clear view of its positioning inside the cavity.
This TMJ function enables to obtain 4 different acquisitions on the same image, by performing two rotational movements. The 4 images represent the right and left condyle of the temporo-mandibular arch (TMJ) with closed mouth and open mouth.
The position of the images couples the images corresponding to the same condyle to help a diagnosis. Figure 16 shows the information related to the single sectors.

RIGHT condyle with closed mouth 1st exposure	RIGHT condyle with open mouth 3rd exposure	LEFT condyle with open mouth 4th exposure	LEFT condyle with closed mouth 2nd exposure

Figure 16

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

8.6.1 Device preparation

To select the TMJ examination, press key "Examination Mode Selection" (10) until the following message and graphic is displayed:

xxkV xxmA 9.70s
TMJ O/C -> CLOSE

The system is positioned in the following configuration:

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

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

72kV 06mA 9.70s
TMJ O/C -> CLOSE

Once the settings have been completed, the chin support must be placed in position if it has been removed (see paragraph 8.4).

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

 **WARNING: The measurement of lengths on digital images depends on the specific length calibration of the program used. It is therefore very important to check the length calibration of the program. In TMJ examination, 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).**

8.6.2 Anatomic / Manual Exposure

 **NOTE: If the previous exam was carried out manually, just press the key "Size Selection" (8) or the key "Examination Mode Selection" (10).**

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

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

 **NOTE: In the manual mode, the "Anatomic/Manual mode" (13) indicator displays "M" to indicate the manual mode; it is possible to use key (7) to change from Adult to Child.**

8.6.2.1 Anatomic exposure

Select the type of patient with the Adult/Child key (7).
Select the type of build with the Size (8) key (small - medium - large).

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

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

Table 5

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

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.

8.6.2.2 Manual exposure

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

To modify the kV or mA values, press any of the up (3) or down (4) arrows of the KV or mA parameters, the blue frames around the "Adult/Child Selection" (7) and the "Size Selection" (8) keys will disappear, orange frames will appear around the up (3) and down (4) arrow keys of the parameters and the "Anatomic/Manual mode" (13) indicator will display "M".

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

The kV value can vary between 60 and 86 kV, with 2 kV steps.
The value of mA can vary between 6 and 10 mA, with 1 mA steps.

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

8.6.3 TMJ closed mouth

8.6.3.1 Patient preparation

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, removable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.
3. Place the patient in a standing position at the TMJ positioner. With the keys "Column movement" (15/16) lift/lower the column until the TMJ positioner is aligned with the patient's nose.

WARNING: During the patient positioning, make sure the equipment can not collide with any objects in the room.

4. Position the patient with the temple clasps (Figure 17) asking him to place his hands on the front support.
5. Instruct the patient to close his eyes.
6. Press the key "Centring devices ON" (14). Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa). Using as reference the sagittale medial plane laser, position the patient's head in such a way that the sagittal medial plane is lit by the corresponding laser beam as in Figure 17. The reference of the Frankfurt plane can be used to make sure the head of the patient is remaining in the same position when examination is taken with either open or closed mouth.

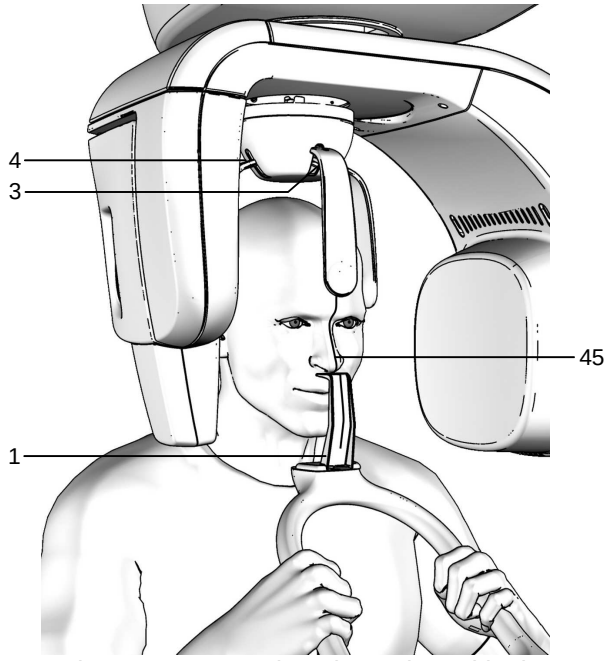


Figure 17 – TMJ closed mouth positioning

Legend of Reference Lines
45 Midsagittal line

Legend positioning devices and patient centering
1 TMJ nose support
3 Forehead support closing/release knob
4 Temple clamp open/close knob

 **NOTE: The laser centering devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centering Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (6) to begin preparation for exposure.**

7. Close the temple clasps and bring the forehead support close; this will help the patient to stay in a correct position. Check that, during this phase, the patient has not changed position.
8. Press the key "Patient Entrance" (6) to confirm the parameters. The luminous centring devices switch off and the rotating arm goes to its examination start position. Once alignment has been completed, the following message will be displayed:

   xxkV xxmA 9.70s
   START EXAM
   x = value defined by the settings

   The green LED "Ready for X-ray" lights up to indicate that pressing the X-ray button once more will start the radiation phase.
9. Ask the patient to: keep the lips closed, keep perfectly still and do not look at the rotating arm during the movements.

8.6.3.2 Carrying out the first exposure (mouth closed)

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

NOTE: If deemed necessary, it is possible to check the interference of the rotation movement with the shoulder of the patient; it is possible, by pressing the key "Test" (5), to activate the Test function. In this condition, it will be possible to make the machine perform all the movements made during the examination, but without emitting rays. The test function of the TMJ closed/open mouth is the same as for the panoramic mode and so there will not be a second rotation corresponding to the open mouth exam. Once the cycle is completed, deactivate the "Test" function by pressing the key again.

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

   START EXAM
   PRE-HEATING…

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

   xxkV xxmA 9.70s
   >X-RAY<
   x = value defined by the settings

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

TEST
XRAY NOT ACTIVE

NOTE: The I-Max Touch assumes that the digital sensor is ready: if this is not the case, the following error message will be displayed:

DIGITAL SENSOR
IS NOT READY

Refer to the Manual of the Digital Acquisition System to correct the situation. To reset the message on the I-Max Touch, press key >0<.

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

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

   PATIENT EXIT
   PRESS >O<

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

    **NOTE: If the examination is made in "Test" mode with the patient already in position, he must not be removed from the temple clamp, to avoid having to reposition the patient.**
   Press the "Patient entrance" key (6): the unit will move back to the starting position.

    **NOTE: The keyboard is disabled during the movement of the system, but by pressing the "Patient entrance" key (6), the movement is stopped.**
   This operation is useful in case a movement anomaly is noticed.
   Press the "Patient Entrance" key (6) to reset the error condition.

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

   PLEASE WAIT…

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

   INSTRUCT PATIENT
   TO OPEN MOUTH

8.6.4 TMJ open mouth

8.6.4.1 Patient preparation

1. The patient must be prepared following the operations described in paragraph 8.6.3.1. The following message will be displayed:

   INSTRUCT PATIENT
   TO OPEN MOUTH
2. Press the key "Patient Entrance" (6) to confirm. The following message will be displayed:

   xxkV xxmA 9.70s
   TMJ O/C -> OPEN
   x = value defined by the settings
3. Position the patient again if he has been removed from the centring device. Tell him to open his mouth (helping him to keep in position using appropriate mechanical devices - not supplied - if necessary).

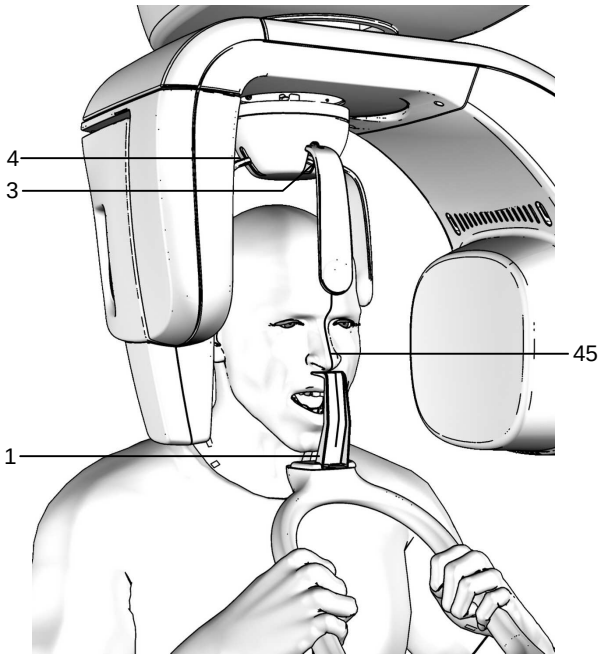


Figure 18 – Open mouth examination positioning

Legend of Reference Lines	
45	Midsagittal line

Legend positioning devices and patient centering	
1	TMJ nose support
3	Forehead support closing/release knob
4	Temple clamp open/close knob

4. Instruct the patient to close his eyes.
5. Press the key "Centring devices ON" (14). Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference. Using as reference the sagittal medial plane laser, position the patient's head in such a way that the sagittal medial plane is lit by the corresponding laser beam. The reference of the Frankfurt plane can be used to make sure the head of the patient is remaining in the same position when examination is taken with either open or closed mouth. If necessary, using the keys "Column movement" (15/16) lower lightly the column to compensate the fact that the head, opening the mouth, will be positioned behind and the condilus could be not centered on the exposed area.

 **NOTE: The laser centering devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centering Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (6) to begin preparation for exposure.**

6. Close the temple clasps and bring the forehead support close; this will help the patient to stay in a correct position. Check that, during this phase, the patient has not changed position.
7. Advise the patient to remain perfectly still and not look at the rotating arm during the movements.

8.6.4.2 Carrying out the second exposure (mouth open)

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

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

1. Press the key "Patient Entrance" (6). The display will show:

   xxkV xxmA 9.70s
   START EXAM

   Check again that the exposure data are correct (see paragraph 8.6.2).

   NOTE: The Adult/Child and Size small - medium - large selection keys are deactivated. The exposure parameters can be changed as described in paragraph 8.6.2.

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

   START EXAM
   PRE-HEATING…

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

   xxkV xxmA 9.70s
   >X-RAY<
   x = value defined by the settings

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

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

   PATIENT EXIT
   PRESS >O<

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

   NOTE: The keyboard is disabled during the movement of the system, but by pressing the "Patient entrance" key (6), the movement is stopped.
   This operation is useful in case a movement anomaly is noticed.
   Press the "Patient Entrance" key (6) to reset the error condition.

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

PLEASE WAIT…

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

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

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PRESS >O<

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; it is recommended that this movement be made with great care in order to prevent damage to the machine. Then press the "Patient Entrance" (6) key and the display will show:

MACHINE SETTING
PRESS >O<

and then:

WAIT FOR
MACHINE SETTING

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

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

8.7 SINUS examination

To select the SINUS examination, press key "Examination Mode Selection" (10) until the following message and graphic is displayed:

xxkV xxmA 9.40s
SINUS
x = value defined by the settings

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

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

WARNING: The measurement of lengths on digital images depends on the specific length calibration of the program used. It is therefore very important to check the length calibration of the program. In SINUS examination, 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).

8.7.1 Anatomic / Manual Exposure

NOTE: If the previous exam was carried out manually, just press the key "Size Selection" (8) or the key "Examination Mode Selection" (10).

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

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

NOTE: In the manual mode, the "Anatomic/Manual mode" (13) indicator displays "M" to indicate the manual mode; it is possible to use key (7) to change from Adult to Child.

8.7.1.1 Anatomic exposure

Select the type of patient with the Adult/Child key (7).
Select the type of build with the Size (8) key (small - medium - large).

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

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

Table 6

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.

8.7.1.2 Manual exposure

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

To modify the kV or mA values, press any of the up (3) or down (4) arrows of the KV or mA parameters, the blue frames around the

"Adult/Child Selection" (7) and the "Size Selection" (8) keys will disappear, orange frames will appear around the up (3) and down (4) arrow keys of the parameters and the "Anatomic/Manual mode" (13) indicator will display "M".

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

The kV value can vary between 60 and 86 kV, with 2 kV steps.
The value of mA can vary between 6 and 10 mA, with 1 mA steps.

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

8.7.2 Patient preparation

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, removable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.
3. Place the patient in a standing position at the SINUS chin support. With the keys "Column movement" (15/16) raise/lower the column until the chin support rest is aligned with the patient's chin.

WARNING: During the patient positioning, make sure the equipment can not collide with any objects in the room.

4. Position the patient with the temple clasps (Figure 19) ensuring that the chin rests on the special support; ask the patient to place his hands on the front supports. Ensure that the patient rests his chin on the chin support for SINUS.

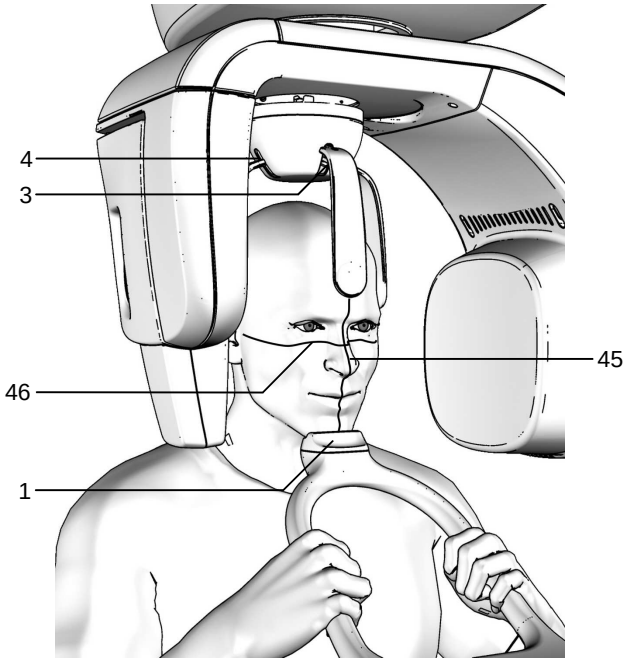


Figure 19 - SINUS positioning

Legend of Reference Lines	
45	Midsagittal line
46	Frankfurt plane line

Legend positioning devices and patient centering	
1	Sinus support
3	Forehead support closing/release knob
4	Temple clamp open/close knob

5. Instruct the patient to close his eyes.
6. Press the key "Centering devices ON" (14). Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa). Position the patient's head in such a way as to ensure that the first two luminous beams fall in correspondence with the respective anatomical references.
   The luminous beam of the Frankfurt plane can be adjusted according to the patient's height; this can be adjusted by means of the laser knob on the side of the mirror.

 **NOTE: The laser centering devices remain on for approximately 1 minute; shutdown can be anticipated by pressing the "Centering Device On" key (14) or, with alignment complete, by pressing the "Patient entrance" key (6) to begin preparation for exposure.**

7. Close the temple clasps and bring the forehead support close; this will help the patient to stay in a correct position. Check that, during this phase, the patient has not changed position.
8. Press the key "Patient Entrance" (6) to confirm. The luminous centering devices switch off and the rotating arm goes to its examination start position. Once alignment has been completed, the following message will be displayed:

   xxkV xxmA 9.40s
   START EXAM
   x = value defined by the settings
9. Ask the patient to: close his mouth, remain perfectly still and not look at the rotating arm during the movement.

8.7.3 Making an exposure

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

NOTE: Before performing a lateral Sinus examination, because of the specific trajectory described by the rotating arm, it is recommended to check for possible mechanical interferences with the patient's shoulder during the rotation. By pressing the key "Test" (5), to activate the Test function. In this condition, it will be possible to make the machine perform all the movements made during the examination, but without emitting rays. Once the cycle is completed, deactivate the "Test" function by pressing the key again.

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.5.2.2; ensure that the machine's indicator light "Ready for X-ray" will come on, so press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the ray indicator light "X-ray emission" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

   START EXAM
   PRE-HEATING…

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

   xxkV xxmA 9.40s
   >X-RAY<
   x = value defined by the settings

   NOTE: If the machine is in the "Test" mode, the display will show:
   TEST
   XRAY NOT ACTIVE

   NOTE: The I-Max Touch assumes that the digital sensor is ready: if this is not the case, the following error message will be displayed:
   DIGITAL SENSOR
   IS NOT READY
   Refer to the Manual of the Digital Acquisition System to correct the situation. To reset the message on the I-Max Touch, press key >O<.

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

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

   PATIENT EXIT - PRESS >O<

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

 **NOTE: If the examination is made in "Test" mode with the patient already in position, he must not be removed from the temple clamp, to avoid having to reposition the patient.**
Press the "Patient entrance" key (6): the unit will move back to the starting position.

 **NOTE: The keyboard is disabled during the movement of the system, but by pressing the "Patient entrance" key (6), the movement is stopped.**
This operation is useful in case a movement anomaly is noticed.
Press the "Patient Entrance" key (6) to reset the error condition.

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

   PLEASE WAIT…

   At the end, the following message is displayed:

   xxkV xxmA 9.40s
   sinus
   x = value defined by the settings

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

 **NOTE: If you try to perform a new exam before the cooling period has elapsed (4 minutes), the following message will be displayed indicating the time to wait before performing a new examination:**

TUBE COOLING - PLEASE WAIT xxxs

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

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

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

E 206
PRESS >O<

all the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; It is recommended that this movement be made with great care in order to prevent damage to the machine. Then press the "Patient Entrance" (6) key and the display will show:

MACHINE SETTING
PRESS >O<

and then:

WAIT FOR
MACHINE SETTING

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

8.8 IMPLANT examination

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

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

The Implant examination is made by three transversal layers displayed on the same image: one in the theoretical centre of the dental element and two others at a distance of 4 mm from the center for incisors and canine and 6 mm for premolars and molars. The first slice of the image is taken on the back of tooth of interest; the second is centered on tooth of interest the third on the front of the tooth of interest (Figure 20).
On these images, considering the constant magnification factor (+132%), it is possible to obtain the real values of anatomical parts allowing you to evaluate all the relevant dimensions of the jaw (height and bone thickness). The thickness of the focus layer is 4mm for incisors/canine and 5mm for molars/premolars.

WARNING: The measurement of lengths on digital images depends on the specific length calibration of the program used. It is therefore very important to check the length calibration of the program. In IMPLANT examination, to obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is 100 pixels = 7.27mm (in the centre of the focus layer).

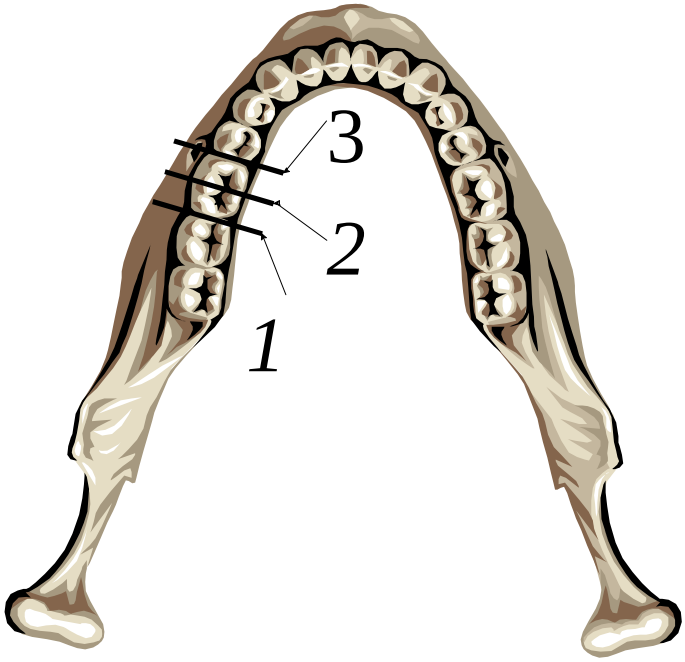


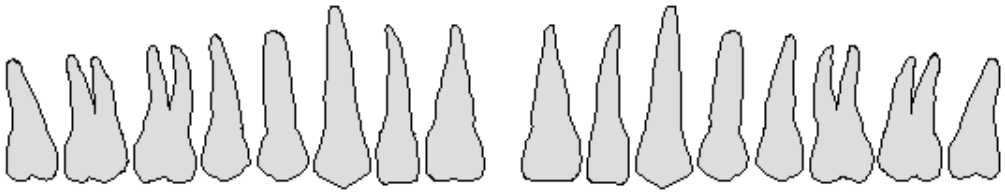
Figure 20

Please refer to paragraph 8.8.7 to have suggestions on how to view images and their correct interpretation (please refer to Figure 24 and following).

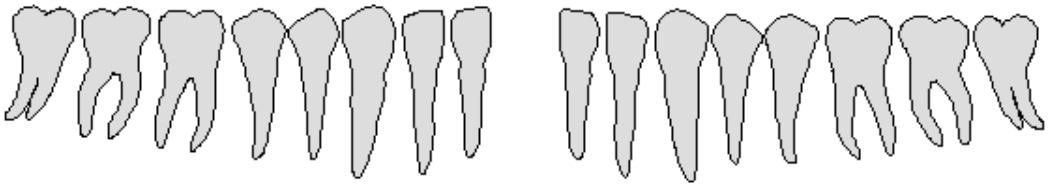
8.8.1 Anatomical parameters

The point of interest is based on the statistical model of the dental arch. It is selected using the standard European mode to number teeth, using two digits. The first digit defines the quadrant (from 1 to 4) while the second digit identifies the tooth itself, from 1 to 8. It means that selection of the point of interest must be done by entering into the unit a two-digit number as above described.
In case of use of the American standard, which is based on a different method, see next Figure 21 where both European and American standard numberings are provided, to find out the number (based on European standard) to input into the unit.

American Standard	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
European Standard (*)	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28



Patient Right side Patient Left side



European Standard (*)	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
American Standard	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17

(*) number to input into the unit

Figure 21

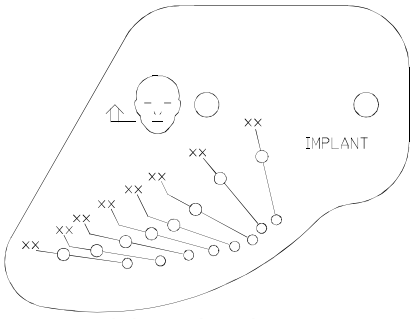
The linear tomography implemented on I-Max Touch is based on a statistical model of dental arch, as defined in international literature. However, it must be considered that the natural deviation from the model due to the individual variability can lead to the possibility that the point of interest may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

8.8.2 Implant Bite Block set-up

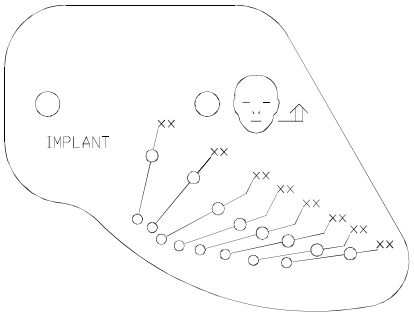
To perform the implant mode, I-Max Touch is delivered with two special "Implant bite blocks", used to hold the patient on the point of interest: the first bite block is used for the maxilla while the second one is used for mandible (for simplicity, they will be referred to as: maxilla implant bite block and mandible implant bite block).
Three parts make up both devices: a metal plate (base), a support and a bite. Particularly, the mandible implant bite block has been studied to hold the mandibular border horizontal during the examination and for this reason has an angle of 7.5°.
The metal plate has two faces: one for right emi-arch and one for the left emi-arch.
In order to avoid assembling mistakes, the metal plates and the bite supports are designed to allow a correct and univocal positioning.

8.8.2.1 Bite block preparing: Maxilla Implant

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

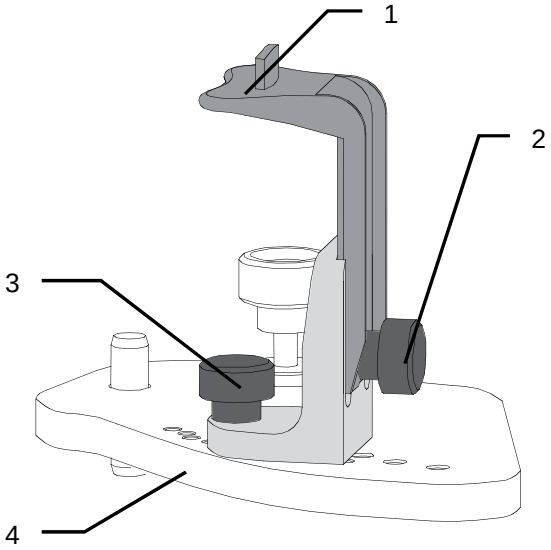


Right emi-arch face



Left emi-arch face

xx = Tooth number according to reference standard FDI or US



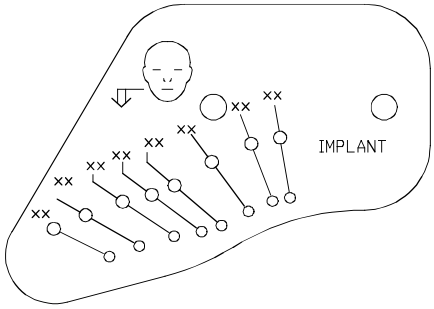
Maxilla bite support
1 Bite
2 Knob 1
3 Knob 2
4 Base

Figure 22

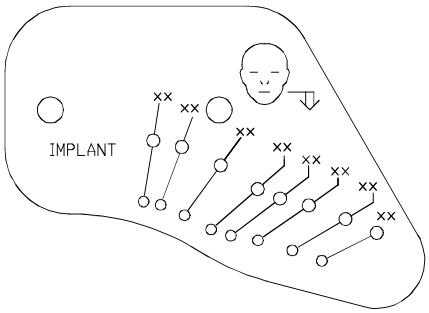
8.8.2.2 Bite block preparing: Mandible Implant

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

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

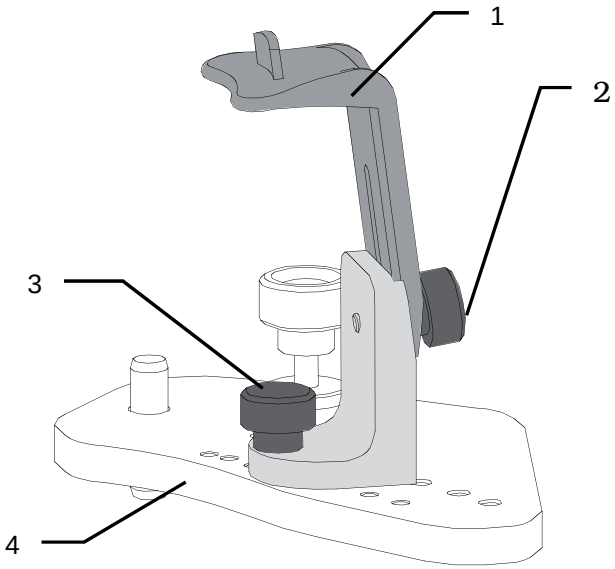


Right emi-arch face



Left emi-arch face

xx = Tooth number according to reference standard FDI or US



Mandible support
1 Bite
2 Knob 1
3 Knob 2
4 Base

Figure 23

8.8.3 Device preparation

To select the IMPLANT examination, press key "Examination Mode Selection" (10) until the following message and graphic is displayed:

xxkV xxmA 9.20s
MANDIB IMPL R 44

The system is positioned in the following configuration:

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

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

 **NOTE: CHILD selection cannot be performed.**

By pressing key "Examination Mode Selection" (10) you can pass from mandibular Implant right arch to mandibular IMPLANT left arch; the display will show:

xxkV xxmA 9.20s
MANDIB IMPL L 34

to maxillary Implant right arch; the display will show:

xxkV xxmA 9.20s
MAXILL IMPL R 14

to maxillary Implant left arch; the display will show:

xxkV xxmA 9.20s
MAXILL IMPL L 24

By means of the keys "Arrow right" (12) and "Arrow left" (11) select teeth changing the second digit from 1 (incisors) to 8 (third molar). Please note that in anatomic mode kV and mA changes according to the selected teeth.

 **NOTE: In case that values of kV or mA are considered not adequate, it is possible to select a new exposure parameter value, using the method of manual exposure described in paragraph 8.8.4.**

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

AXIS POSITIONING
PLEASE WAIT...

At the end, the following message is displayed:

xxkV xxmA x.xxs
START EXAM
x = value defined by the settings

 **NOTE: The I-Max Touch assumes that the digital sensor is ready: if this is not the case, the following error message will be displayed:**

DIGITAL SENSOR
IS NOT READY

Refer to the Manual of the Digital Acquisition System to correct the situation. To reset the message on the I-Max Touch, press key >O<.

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

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

8.8.4 Manual / Anatomic exposure

 **NOTE: If the previous exam was carried out manually, just press the key "Size Selection" (8) or the key "Examination Mode Selection" (10).**

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

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

 **NOTE: In the manual mode, the "Anatomic/Manual mode" (13) indicator displays "M" to indicate the manual mode.**

8.8.4.1 Anatomic exposure

Select the type of build with the Size (8) key (small - medium - large).
On the basis of the selections made, the display will visualize the kV and mA settings.

8.8.4.2 Manual exposure

If the kV and mA combinations are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.
To modify the kV or mA values, press any of the up (3) or down (4) arrows of the KV or mA parameters, the blue frames around the
"Adult/Child Selection" (7) and the "Size Selection" (8) keys will disappear, orange frames will appear around the up (3) and down (4) arrow keys of the parameters and the "Anatomic/Manual mode" (13) indicator will display "M".
A parameter can be modified by pressing the increase key (3) and the decrease key (4) of that parameter repeatedly.

The kV value can vary between 60 and 86 kV, with 2 kV steps.
The value of mA can vary between 6 and 10 mA, with 1 mA steps.

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

8.8.5 How to prepare the patient

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

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, movable dental prosthesis, etc.). Ensure that there no thick garments in the area to be X-rayed such as coats, jackets, ties, etc.
2. Provide the patient with a protective apron or similar protection. Ensure that the protection device does not interfere with the path of the X-ray beam.
3. Place the patient in a standing position at the Implant support. With the keys "Column movement" (15/16) raise/lower the column until the Implant bite is aligned with the patient's mouth.

   WARNING: During the patient positioning, make sure the equipment can not collide with any objects in the room.

4. Position the patient asking him to bite with his incisors against the reference notch of the plastic Implant bite block, already prepared following the instructions of paragraphs 8.8.2.1 and 8.8.2.2. The hands should rest on the front supports.
5. Instruct the patient to close his eyes.
6. Press the key "Centring devices ON" (14). Two laser beams will light up the sagittal medial plane line and the horizontal line for the Frankfurt plane reference (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa). Using as reference the sagittal medial plane laser, position the patient's head in such a way that the relevant tooth is lit by the corresponding laser beam. The laser beam of the Frankfurt plane must be adjusted using laser knob on the side of the mirror according to maxilla or mandible examinations as follows:
   - Maxilla: position the patient's head in such a way as to ensure that the Frankfurt laser beam fall in correspondence of the respective anatomical references.
   - Mandible: using the Frankfurt laser beam, position the head of the patient in such a way as that mandibular border at the point of interest is as horizontal as possible.

   NOTE: The laser centring device can be switched off using "Centring Devices ON" (14) key.

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

8.8.6 Making an exposure

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

1. Verify once again that the exposure data are correct. If not, correct them as described in paragraph 8.8.4; ensure that the machine's indicator light "Ready for X-ray" will come on, so press the X-ray button for the entire duration of the exposure, checking the simultaneous working of the ray indicator light "X-ray emission" (if you are within sight of the machine) and the acoustic ray signal. The following message will be displayed first:

   START EXAM
   PRE-HEATING…

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

   xxkV xxmA x.xxs
   >X-RAY<
   x = value defined by the settings

   NOTE: The I-Max Touch assumes that the digital sensor is ready: if this is not the case, the following error message will be displayed:

   DIGITAL SENSOR
   IS NOT READY

   Refer to the Manual of the Digital Acquisition System to correct the situation. To reset the message on the I-Max Touch, press key >O<.

   NOTE: The rotation of the arm and the emission of the X-rays will start with a delay of 2 seconds from when the X-ray button is pressed. In addition, during the examination the emission of the X-rays is interrupted and started again more than once, to produce the 3 projections. It is therefore necessary to keep the X-rays button pressed continuously until the end of the examination because, being a "dead man" type, it is necessary to keep it pressed until the end of the exposure.

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

   PATIENT EXIT
   PRESS >O<

   Release the patient from the working area.

   NOTE:The keyboard is disabled during the movement of the system, but by pressing the "Patient entrance" key (6), the movement is stopped.
   This operation is useful in case a movement anomaly is noticed.
   Press the "Patient Entrance" key (6) to reset the error condition.

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

AXIS POSITIONING
PLEASE WAIT...

At the end, the following message is displayed:

xxkV xxmA 9.20s
MANDIB IMPL L 44
x = value defined by the settings

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

 **NOTE: If you try to perform a new exam before the cooling period has elapsed (4 minutes), the following message will be displayed indicating the time to wait before performing a new examination:**

TUBE COOLING
PLEASE WAIT xxxs

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

 **WARNING: After every examination, clean the Implant bite support, the bite and the handles as described in chapter 4.**

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

E 206
PRESS >O<

All the motors will switch off, and it will be possible, if necessary, to manually rotate the arm, allowing the patient to come out; it is recommended that this movement be made with great care in order to prevent damage to the machine. Then press the "Patient Entrance" (6) key and the display will show:

MACHINE SETTING
PRESS >O<

and then:

WAIT FOR MACHINE SETTING

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

8.8.7 Radiographic results

The result obtained at the end of the examination is indicated in Figure 24.

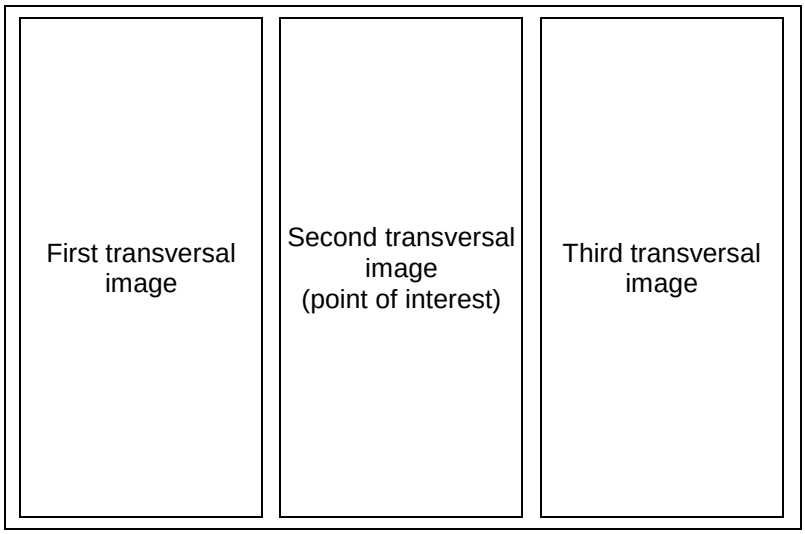


Figure 24: Implant complete exam

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

8.8.7.1 Right side tomography (quadrants 1 and 4)

The next three images show the transversal sections, with the vestibular part on the left and the lingual or palatal part on the right (Figure 25).

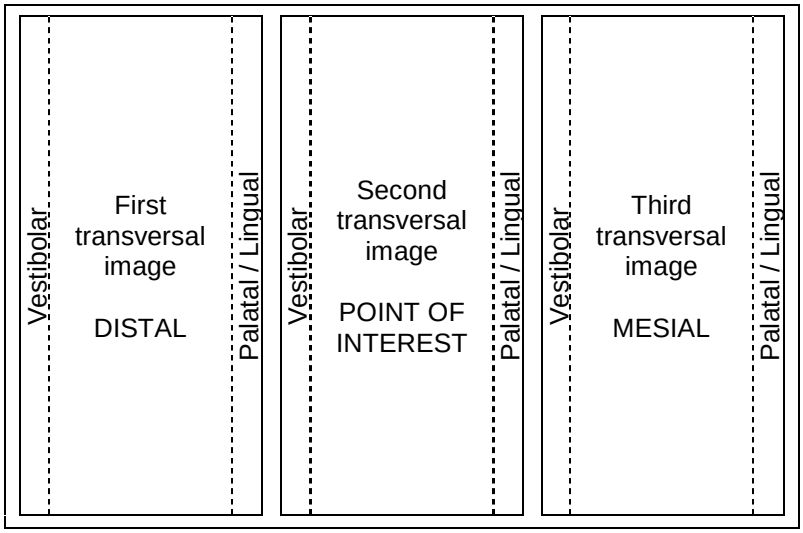


Figure 25

8.8.7.2 Left side tomography (quadrants 2 and 3)

The next three images show the transversal sections, with the lingual or palatal part on the left and the vestibular part on the right (Figure 26).

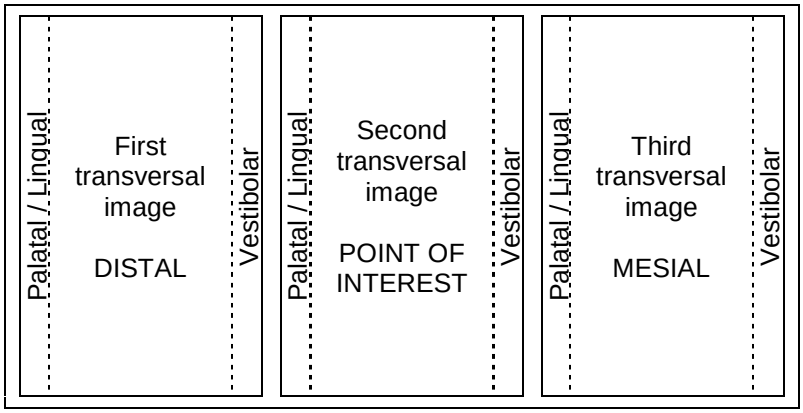


Figure 26

8.9 Cephalometric examination

There is no rotation of the tube-head (X-ray generator) support arm and sensor holder for the cephalometric examination. Various projections are possible for the cephalometric examination. On the basis of the image format selected and the projection chosen, the primary diaphragm will automatically place itself in the correct position, at the same time as the secondary collimator and the digital sensor. The Cephalometric examination is fitted with a Soft Tissues Filter (STF); this filter reduces the dose in areas with low bone content and highlights the patient's profile which, under normal conditions, would be overexposed and so not visible.
The I-Max Touch makes different kinds of exposures, according to the type of selection made:

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

For all these Ceph formats, it is possible to carry out the examination in High Resolution (h) or Normal Resolution (n). It also possible to carry out the examination to assess bone growth, following the instructions in paragraph 8.10 below.

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

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

8.9.1 Device preparation

To select the CEPH examination, press key "Examination Mode Selection" (10) until the following message and graphic is displayed:

xxkV xxmA 4.50s
CE 18x22LLN 8.5
x = value defined by the settings

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

   CEPH - REMOVE
   CHIN REST

   and

   CEPH - CLOSE
   TEMPLE SUPPORT

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

   WARNING: Neither of the two messages are controlled by the system and they can therefore appear even if the unit has been set correctly until the "Patient Entrance" (6) key is pressed.

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

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

   AXIS POSITIONING
   PLEASE WAIT…

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

   REMOVE SENSOR
   IN PAN SLOT

   Move the sensor in CEPH position following instruction in paragraph 8.2 and wait some seconds before to press "Patient Entrance" (6) key.

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

   CEPH - OPEN
   CASSETTE HOLDER

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

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

The following message will be displayed:

xxkV xxmA 4.50s
CE 18x22LLN 8.5

This message indicates the image format predefined by the system; the letter "n" after the format indicates that the execution will be in Normal Resolution.
You can pass from Normal Resolution (indicated by the letter "n") to High Resolution (indicated by the letter "h"), by pressing key "Examination Mode Selection" (10) and vice versa.
Pressing twice the key (10) the unit will return to PANORAMIC STD position; the display shows:

CONFIRM PAN?
>O< = Y, T = N

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

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

 **NOTE: The system is positioned in the following configuration:**

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

The key "Type of Biting Selection" (9) is disabled.

3. By means of the keys "Arrow right" (12) and "Arrow left" (11) select the dimensions of the image and the type of projection (see the table at the beginning of the Chapter).

8.9.2 Anatomic / Manual Exposure

NOTE: If the previous exam was carried out manually, just press the key "Examination Mode Selection" (10) to change to Anatomic exposure. In this case, pressing selection key does not modify the choice of resolution, which is modified by pressing the same key again.

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

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

NOTE: In the manual mode, the "Anatomic/Manual mode" (13) indicator displays "M" to indicate the manual mode; it is possible to use key (7) to change from Adult to Child.

8.9.2.1 Anatomic exposure

Select the type of patient with the Adult/Child key (7).
Select the type of build with the Size (8) key (small - medium - large).

The kV and mA values will be displayed according to the selections made as per the following tables:

Latero-Lateral projection				
	Adult		Child	
	kV	mA	kV	mA
Small	72	6	70	6
Medium	74	6	72	6
Large	76	6	74	6

Table 7

Antero-Posterior projection				
	Adult		Child	
	kV	mA	kV	mA
Small	74	12	72	10
Medium	76	12	74	10
Large	80	10	76	10

Table 8

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.

8.9.2.2 Manual exposure

If the kV and mA combinations in the Table 7 and Table 8 are not considered suitable for a specific examination, it will be possible to set new parameters using the manual mode.

 **NOTE: It will be possible to modify manually kV, mA and Soft Tissue Filter position (mm). The "mm" value in the exposure parameters and parameter "fxx.x" in the display indicate the position of the STF; it has to be adjusted according to the value read on the graduate scale present on the nose rest (Figure 27).**

To modify the kV, mA and STF values, press any of the up (3) or down (4) arrows of the KV, mA or mm parameters, the blue frames around the "Adult/Child Selection" (7) and the "Size selection" (8) will disappear, orange frames will appear around the up (3) and down (4) arrow keys of the parameters and the "Anatomic/Manual mode" (13) indicator will display "M".

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

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

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

8.9.3 Preparation of the patient

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, removable dental prosthesis, etc.). Ensure that there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to put on the protective apron, or something similar, making sure that it does not interfere with the trajectory of the X-ray beams.
3. Open the ear centring device (Figure 27) to its maximum span by using the upper part of the rods of the centring device itself. Move the nose rest (Figure 27) away outwardly to its maximum extension. Manually rotate the craniostat group according to the cephalometric projection to be made, moving the upper part of the ear centring device (Figure 27).
4. Position the patient upright near the auricular centring device. With the keys "Column movement" (15/16) lift/lower, the column till the centring pins (Figure 27) are close to the ear to clasp the patient's head so that the pivots penetrate the ear (Figure 27) moving the upper part of the rods. If a Latero-Lateral examination is performed, position the nose rest.

WARNING: During the patient positioning, make sure the equipment can not collide with any objects in the room.

5. By selecting an "asymmetric" projection, the Soft Tissues Filter (STF) will be automatically inserted.

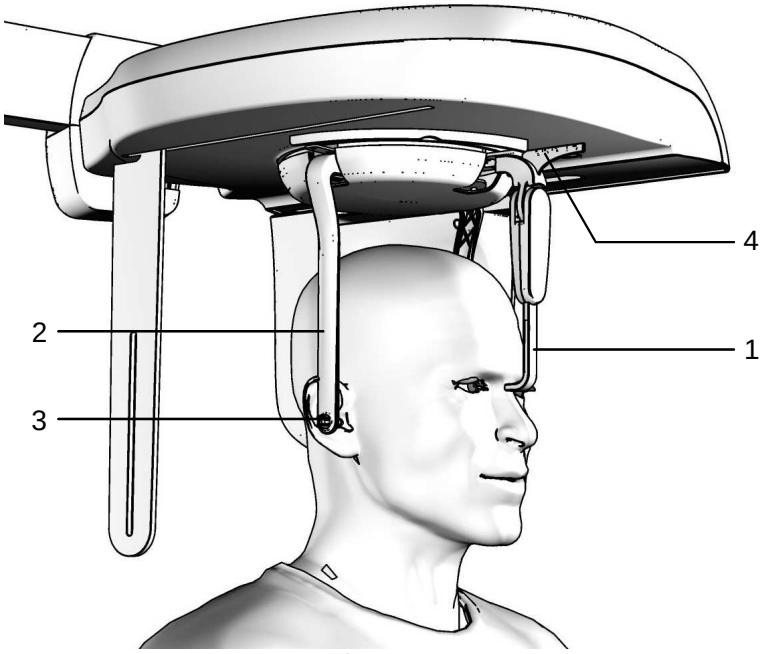


Figure 27

Legend

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

8.9.4 Making an exposure

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

1. Verify once again that the exposure data are correct (see paragraph 8.9.2). Advice the patient to remain still and to keep his mouth closed, with the teeth touching, throughout the duration of the exposure.
   Press the "Patient Entrance" (6) key. The unit will move into the selected examination start position. The signaling LED "Ready for X-ray" will light up, indicating that the machine is ready to produce X-rays.

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

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

   START EXAM
   PRE-HEATING…

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

   xxkV xxmA x.xxs
   >X-RAY<
   x = value defined by the settings

   NOTE: The I-Max Touch assumes that the digital sensor is ready: if this is not the case, the following error message will be displayed:

   DIGITAL SENSOR
   IS NOT READY

   Refer to the Manual of the Digital Acquisition System to correct the situation. To reset the message on the I-Max Touch, press key >O<.

   NOTE: X-rays are emitted with a delay of two seconds from pressing the X-ray button to allow the heating of the filament and the control of all set parameters. Since the X-ray button is a "dead man's switch", it must be kept pressed until the end of the exposure.

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

   NOTE: If you want to carry out a new exposure, but the necessary waiting time for the cooling of the anode hasn't yet passed, the display will show a message indicating the time you still have to wait before carrying out the new test:

   TUBE COOLING
   PLEASE WAIT xxxs

   This time enables the X-ray tube's anode to cool down.

 **NOTE: If the patient moves during the exposure, or if you realize that incorrect parameters have been set, it will be necessary to stop pressing the X-ray button immediately, to interrupt the emission of rays. The following message will be displayed:**

E 206
PRESS >O<

Then press the "Patient Entrance" (6) key. The system now returns to the position for Ceph exam and the unit starts the procedure for the new examination.

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

8.10 Examination to assess bone growth (Carpus)

The cephalometric device can also be used to carry out X-rays to evaluate the state of calcification and bone growth, X-raying the hand/wrist complex to obtain an X-ray that contains the anatomic details necessary to evaluate the patient's bone growth trend.
The image format set in order to carry out this examination is 18x22 Symmetric, not adjustable; it is therefore necessary to position the auricular rods and the nose-rest as for the cephalometric Antero-Posterior examination, so that these elements do not interfere with the X-ray trajectory. Refer to Figura 28.

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

8.10.1 Device preparation

1. Select the CEPH examination, pressing key "Examination Mode Selection" (10) until the following message and graphic is displayed:

   xxkV xxmA 4.50s
   CE 18x22LLn 8.5
   x = value defined by the settings

2. By means of the keys "Arrow right" (12) and "Arrow left" (11) select the CARPUS examination:

   xxkV xxmA 4.50s
   Carpus 18x22 h

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

   Ceph - REMOVE
   CHIN REST

   and

   Ceph - CLOSE
   TEMPLE SUPPORT

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

   WARNING: Neither of the two messages are controlled by the system and they can therefore appear even if the unit has been set correctly until the "Patient Entrance" (6) key is pressed.

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

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

   AXIS POSITIONING
   PLEASE WAIT…

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

   REMOVE SENSOR
   IN PAN SLOT

   Move the sensor in CEPH position following instruction in paragraph 8.2 and wait some seconds before to press "Patient Entrance" (6) key.

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

   CEPH - OPEN
   CASSETTE HOLDER

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

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

The following message will be displayed:

xxkV xxmA 4.50s
Carpus 18x22 h

This message indicates the image format predefined by the system; the letter "h" after the format indicates that the execution will be in High Resolution.
Pressing twice the key (10) the unit will return to PANORAMIC STD position; the display shows:

CONFIRM PAN?
>O< = Y, T = N

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

5. Regulate the exposure parameters as required, using the pre-set values or manual selection; the display will show the kV and mA settings as per the following table.

Child		
	kV	**mA**
Small	60	6
Medium	60	6
Large	60	6

Table 9

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.

8.10.2 Patient preparation

1. Turn the ear centring device to the Antero-Posterior position; bring the nose-rest to a parking position.
2. Hook up the positioning support for hand projection, by screwing it on the related housing close to the ear centering device. The reference line on the metal positioner must face the sensor.
3. Place the patient slightly to the side of the cephalometry device.
4. Position the patient's hand on the positioning support (Figura 28), so that the hand is located between the sensor and the plate itself. The support leads the operator to place the body part in the centre of the irradiated area. The horizontal line should help the vertical adjustment of the hand. The common radiological procedure to assess bone growth in children, suggests placing the end of the middle finger tangent to the reference line. The patient's hand must be fully in contact with the metal plate and it must form a vertical line with the arm, in order to avoid any risk of collision with the sensor during the scanning movement.

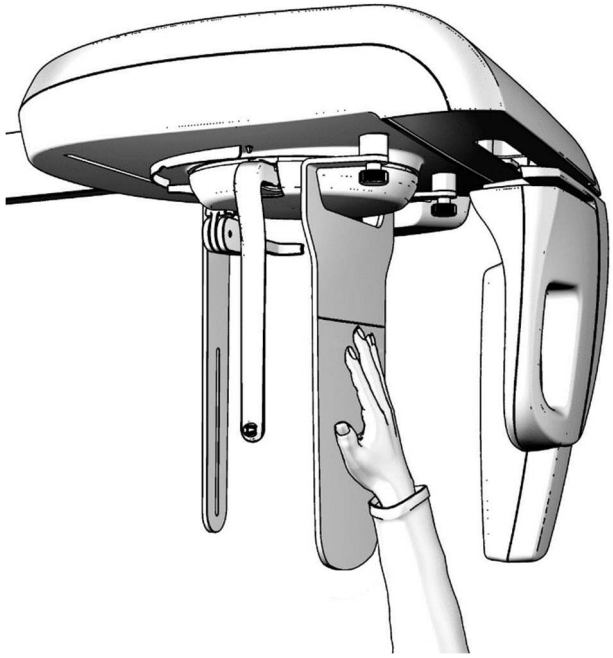


Figura 28

8.10.3 Making an exposure

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

1. Press the "Patient Entrance" (6) key. The unit will move into the selected examination start position. The signaling LED "Ready for X-ray" will light up, indicating that the machine is ready to produce X-rays.

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

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

   START EXAM
   PRE-HEATING…

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

   xxkV xxmA x.xxs
   >X-RAY<
   x = value defined by the settings

   NOTE: The I-Max Touch assumes that the digital sensor is ready: if this is not the case, the following error message will be displayed:

   DIGITAL SENSOR
   IS NOT READY

   Refer to the Manual of the Digital Acquisition System to correct the situation. To reset the message on the I-Max Touch, press key >O<.

   NOTE: X-rays are emitted with a delay of two seconds from pressing the X-ray button to allow the heating of the filament and the control of all set parameters. Since the X-ray button is a "dead man's switch", it must be kept pressed until the end of the exposure.

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

   NOTE: If you want to carry out a new exposure, but the necessary waiting time for the cooling of the anode hasn't yet passed, the display will show a message indicating the time you still have to wait before carrying out the new test:

   TUBE COOLING
   PLEASE WAIT xxxs

   This time enables the X-ray tube's anode to cool down.

 **NOTE: If the patient moves during the exposure, or if you realize that incorrect parameters have been set, it will be necessary to stop pressing the X-ray button immediately, to interrupt the emission of rays. The following message will be displayed:**

E 206
PRESS >O<

Then press the "Patient Entrance" (6) key. The system now returns to the position for the Ceph exam and the unit starts the procedure for the new examination.

8.11 Messages on display

The I-Max Touch is fully controlled by a microprocessor which controls the programming of the emission parameters and signals the various conditions of the machine, the possible abnormalities and errors via displayed messages. The messages can be divided into two groups:

- operation messages: these messages tell the operator how to set up the unit for the examination
- error messages: these messages are displayed when an error occurs.

There are three kinds of error messages as follows:

1. Messages prompted when the X-ray emission button is released by the operator or by pressing key "Patient Entrance" (6). The message displayed will be as follows:

   E xxx
   PRESS >O<
   xxx = error message code number

   Operations are reset by pressing key (6).

2. Messages generated by a system error. In this case, the Technical Service must be called. Messages that require the intervention of the Technical Service are displayed as follows:

   E xxx
   CALL TECH ASS.
   xxx = error message code number

3. Messages related to H.F. board problems. If this occurs, switch off the unit. Wait a few minutes for the capacitors of the relative circuit to discharge, and then switch the machine on again. If the problem persists, call the Technical Service.

   E xxx
   SWITCH POWER OFF
   xxx = error message code number

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

8.11.1 Error message with error code E000 ÷ E199

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

8.11.1.1 E110 – Battery fault

This message means that the clock battery is low or fault. If after power ON, a 90 second cooling time starts, wait until the end of the time; then display will show "E110 – Press >0<". Follow the message shown on the display and perform an examination. At the end of the examination, power OFF the machine and wait a couple of minutes before powering ON again.
If the message is not yet present, it means that the battery is low. Leave the machine powered ON to recharge it. If the error does not disappear, call the Technical Assistance Service.

8.11.2 Error message with error code E200 ÷ E299

This category of errors apply to the rotation motor; of these only the error "E206 - Collision with patient", caused by a possible collision between the rotation arm and the patient, it is an actual reversible. Press the key "Patient Entrance" (6) to reset the error and to perform the axes centring operation. For all other cases, call the Technical Assistance Service.

8.11.3 Error message with error code E300 ÷ E399

8.11.3.1 Error message with code error E300 ÷ E303

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

8.11.3.2 Error message with code error E320 ÷ E323

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

8.11.3.3 E340 - Sensor holder not in PAN position

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

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

Release the X-ray button if pressed; press the key "Patient Entrance" (6) to reset the error condition.
If the error does not disappear, call the Technical Assistance Service.

8.11.3.5 E362 - X-ray button released during examination

NOTE: The X-ray button has the so-called "dead man's switch" function, i.e. it must be kept pressed for the whole time of the examination, also during the phases of the examination with emission interruption (for instance, in open/close mouth TMJ).

This message signals that the button was released during the examination phase; the motors are unlocked, therefore the patient can get out of the system. Repeat the system centring phase and repeat the examination.

8.11.3.6 E367 - Sensor connection lost

Release the X-ray button if pressed; press the key "Patient Entrance" (6) to reset the error condition and repeat the exam procedure.
If the error is still present, switch OFF and ON the unit.
If the error does not disappear, call the Technical Assistance Service.

8.11.4 Error message with error code E400 ÷ E402

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

8.11.5 Error message with error code E700 ÷ E799

WARNING: These error codes refer to the X-rays generation, therefore, they can also indicate a safety problem. With error code E759, turn off immediately the system as a not requested X-ray emission was detected. In this case, call immediately the Technical Assistance Service.

8.11.5.1 E755 – Safety Backup Timer intervention

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

8.11.5.2 E774 - X-rays button not pressed

The lack of the button is signaled also if the emission software control is present.
The error signals a possible failure on the connection of the X-rays button with the generator card.

8.11.5.3 E775 - X-rays button released prematurely

The release of the X-rays button during the emission phase is signaled; this signaling has a different meaning from that of the corresponding E362 error, as this message is generated by the HF board, which signals a possible failure on the connection of the X-rays button with the board itself.

8.11.6 Error message with error code E850 ÷ E852

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

8.11.6.1 E850 - One or more keys appear to be pressed on start-up

The system checks that all keys are not pressed at start-up; if one or more appear to be pressed, this error is displayed.
If error E850 is detected, the display will show which key has been pressed in start-up phase, and the following message will be shown:

E 850 (xxxxxxxx)
SWITCH POWER OFF
xxxxxxxx: error message code number

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

8.11.6.2 E851 - Column key pressed

This error is displayed in case, when releasing the up/down column key, the movement itself is not completed; pressing any other key interrupts the movement to avoid injuries to the patient.
Press the key "Patient Entrance" (6) to reset the error condition.

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

During the system movement, the keyboard is disabled, but if the key "Patient Entrance" (6) is pressed the movement is interrupted. This operation is useful in case a movement anomaly is noticed.
Press the key "Patient Entrance" (6) to reset the error condition.

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

8.12.1 Faults due to the wrong positioning of the patient

Problem	Description	Solution
Overlarge and blurred incisors.	The patient is not positioned correctly. He is too far from the optimal focal plane.	Position the patient correctly, check that he holds the bite with the incisors on the appropriate notch and that the bite holder rod is vertical.
Over-small and blurred incisors.	The patient is not positioned correctly. He is too near the optimal focal plane.	Position the patient correctly, check that he holds the bite with the incisors on the appropriate notch and that the bite holder rod is vertical.
Radiography with blank central area.	The spine of the patient inhibits the passage of the X-ray as it is too compressed.	Check the alignment of the Frankfurt plane, try to stretch the cervical part of the spine by moving the patient's feet forward (see paragraph 8.5.3 points 3/4/6/7) and, if necessary, correct the height of the chin support.
Asymmetric dental arch.	The sagittal medial line does not correspond to the laser centring beam.	Realign the patient (see paragraph 8.5.3 point 6).
Upper apical area too dark.	The patient does not keep his lips shut and the tongue is not against the palate.	See paragraph 8.5.3 point 8.
Upper central apical area out of focus.	The patient keeps his head rotated backwards (Frankfurt plane not aligned).	Position the patient again and realign the Frankfurt plane.
The image is slanted in comparison with the longitudinal axis of the image and some anatomical structures are not symmetric.	The patient's head is slanted (not vertical).	Position the patient again, correcting the position of the sagittal plane.
The teeth on one side are bigger than those on the other side.	The patient's head is rotated with respect to the axis of the bite.	Position the patient again, correcting the position of the sagittal plane and controlling that his head is not rotated.
Presence (in CEPH examination) of a white area in the lower part of the image.	Panoramic chin-rest still mounted.	Perform the exam again, removing the PAN chin-rest.

8.12.2 Defects due to wrong data setting

Problem	Description	Solution
Light or poorly contrasted image. Over-dark image.	The set kV values are not adequate for the size of the patient.	Try to modify the contrast, using the appropriate commands of the image acquisition/management program; if necessary, repeat the examination, varying the kV and/or the mA. Increase them if the image was too clear, and reduce them if it was too dark. If the error is repeated, call the Technical Service.
Image completely white.	No X-ray emission.	Verify the emission of the X-rays by acoustical and luminous signal. If no solution can be found, call the Technical Service.
Soft Tissue not (or poorly) visible in L-L projection.	The STF value is not correct.	Refer to paragraph 8.9.3 to adjust the position of the "STF".
	A symmetric image format was selected.	Select an asymmetrical image format (which will enable the STF filter).

8.12.3 Defects due to the device

Should the image show non irradiated areas or be completely white, this can mean that there is a defect in the alignment between X-ray beams and sensor (PAN or CEPH) or a partial or total missing of irradiation; in any case, call the Technical Service.

In the event the soft tissue of the patient is not highlighted while performing a cephalometry, in a latero-lateral, let the technician verify the adjustment of the Soft Tissue Filter.

8.13 Analysis of the problems on the panoramic examinations

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

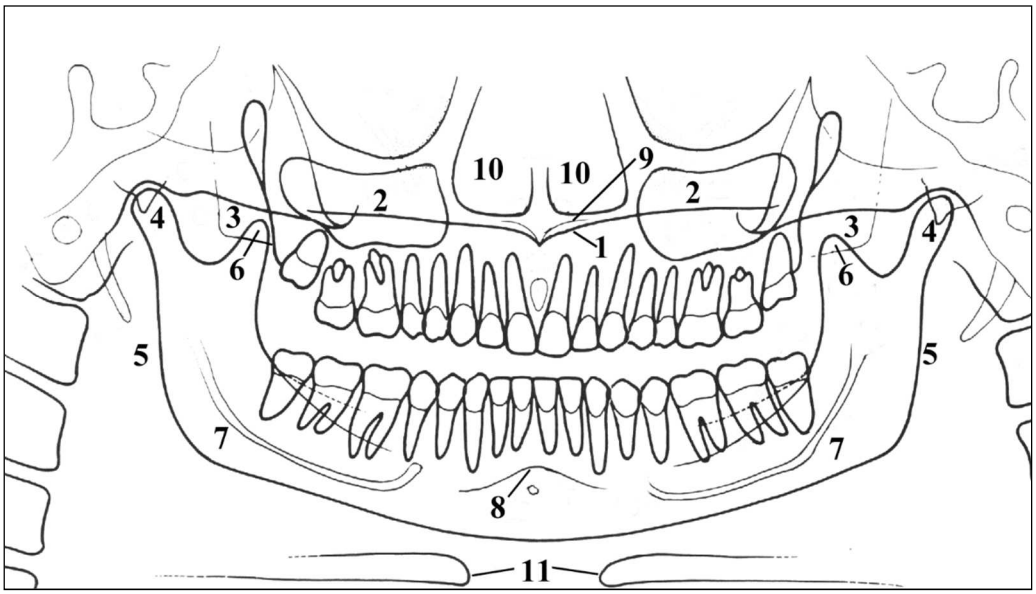


Figure 29

Ref.	Anatomical structure
1	Palatal plane
2	Maxillary sinus
3	Maxilla and maxillary tuberosity
4	Temporo mandibular condyle
5	Ascending ramus of the TMJ
6	Coronoid process (overlap with maxilla)
7	Mandibular canal
8	Chin foramen
9	Anterior nasal spine
10	Nasal cavities
11	Ioid bone (normally duplicated)

8.13.1 Proper positioning of the patient

The proper positioning of the patient during the panoramic examination is very important in order to get a good quality radiography. This is due to the fact that the shape of the focussed area, e.g. of the layer clearly shown on the image, tends to follow the dental arch and has a non-constant deepness.
The objects outside this focused area will therefore appear blurred on the radiography.

1. The patient should not wear clothes that may interfere with the X-ray beams, also to leave more space between the patient's shoulders and the rotating arm of the machine. Care must be taken in order to avoid interference between the X-ray beam and the protective apron worn by the patient.
2. Metal objects (necklaces, earrings etc.) must be avoided; these objects not only create radio-opaque images in their own position, but also false images projected in other parts of the radiography, so disturbing the correct view of the anatomy.
3. The patient's head must be slightly tilted downward in order to make the Frankfurt plane horizontal. In this way, the hard palatal ceiling will be projected slightly over the superior apex of the anterior teeth. If the patient has a low palatal ceiling, slightly increase the downward tilting.
4. Align the sagittal medial plane with the centre of the chin support, normally indicated by the relevant light beam.

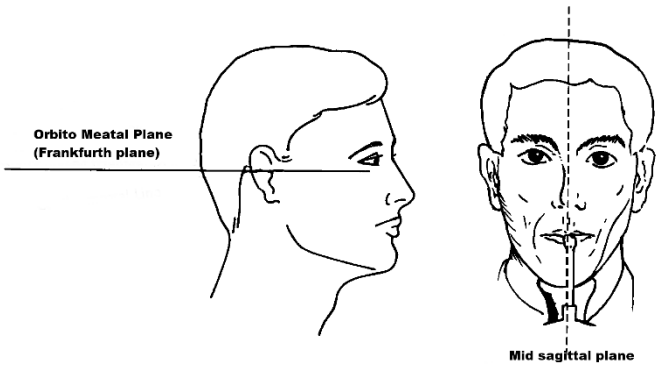


Figure 30

5. The patient must extend his spine; this is normally obtained by asking the patient to step forward, making sure that all other conditions are unchanged. If not properly extended, the spine will cause the appearing of a lower exposed area (clearer) in the front part of the image.
6. The patient's tongue must be positioned against his palate. Otherwise, the air between the tongue and the palate forms an area of lower absorption, which leads to a darker area that hides the apex of the teeth of the maxilla.

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

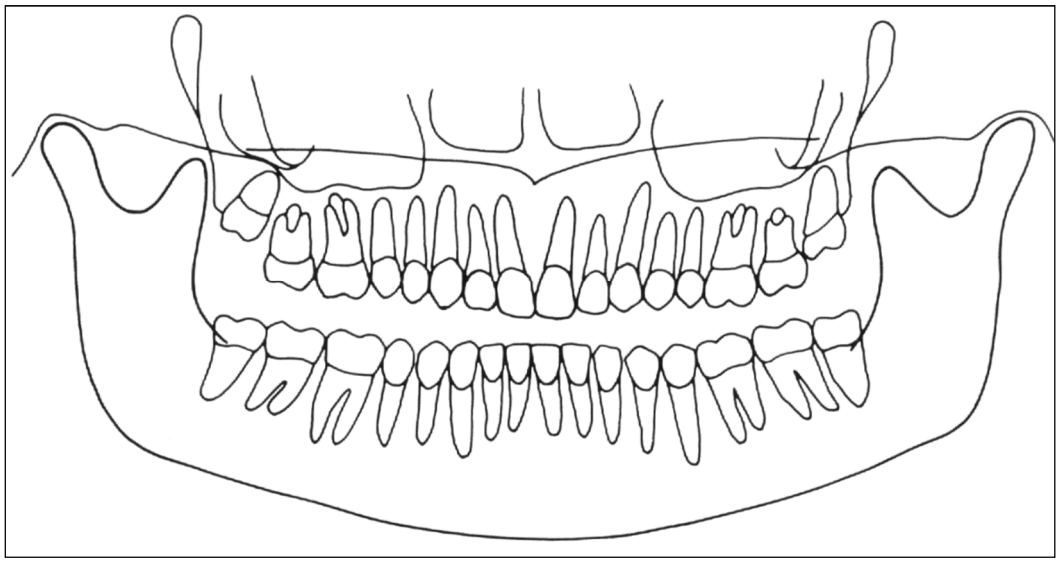


Figure 31

It must be noted that the radiography is quite symmetrical, with the ascending rami of the temporo mandibular joints almost parallel. The occlusal plane is shown slightly tilted upward, the palatal plane does not overlap the apex of the upper arch and therefore allows a good view of the apex itself.

8.13.1.1 Errors due to poor positioning of patient

The image shows the anterior teeth with reduced magnification and not well defined. The cervical spine is shown as evident white shadow.
In addition, on the molar zone there are too many shadows, disturbing the reading. The resulting image is similar to the schema shown on Figure 32.

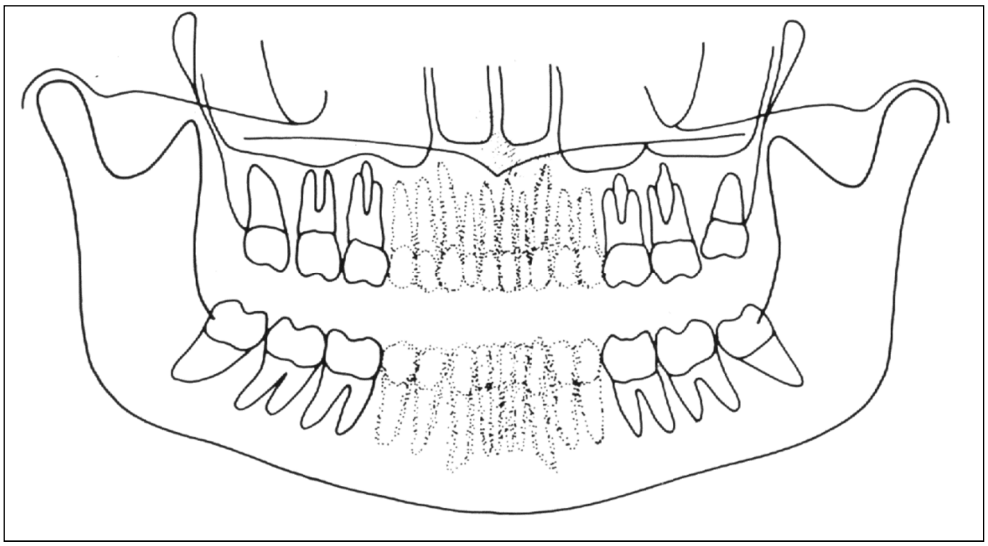


Figure 32

Possible causes: The patient it positioned too much forward.
Solution: Check the patient's positioning by using luminous beams. If, after the correct positioning of the patient, the problem still remains, check the alignment of the centering laser lights, simply switching on the centering lights and checking their position. The sagittal medial luminous beam must hit the centre of the chin support.

Anterior teeth are enlarged and blurred
Figure 33 shows the result of this error.

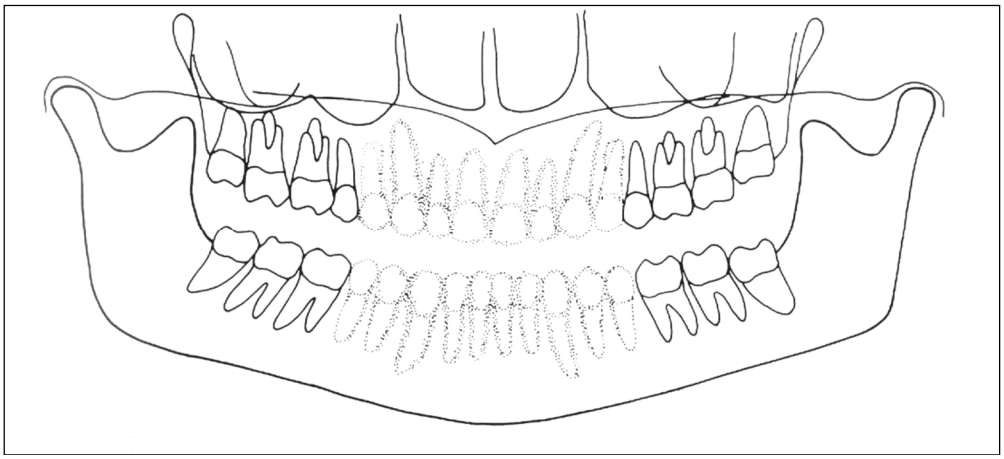


Figure 33

Possible causes: The patient it positioned too much backward.
Solution: Check the patient's positioning by using luminous beams.

Part of the image is enlarged while the other is reduced
The schema described on Figure 34 the image obtained; it is possible to observe that one part of the radiography is blurred and enlarged, while the other is reduced and seems to be in focus; the two condylar rami are at the same height on the X-ray.

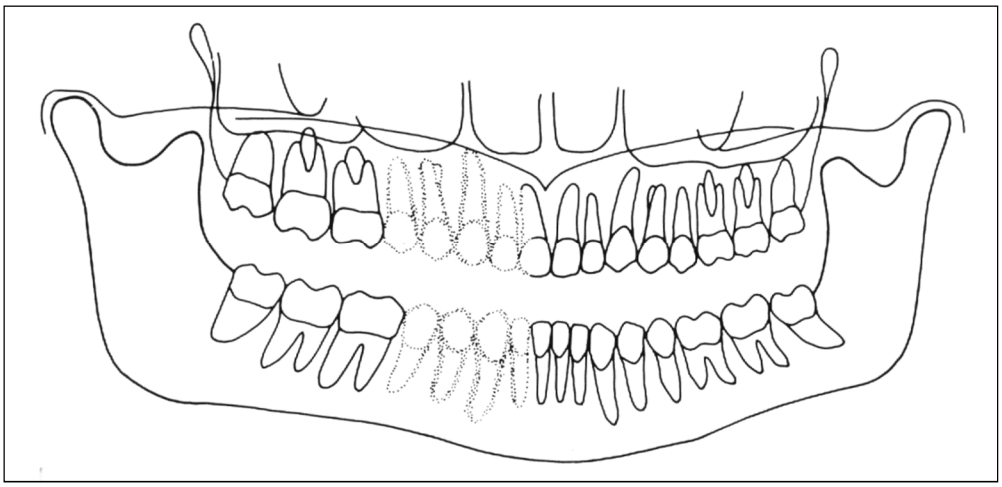
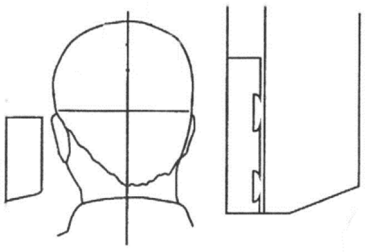


Figure 34

Possible cause: This effect can be due to two different causes.
In the first one, the sagittal medial plane is not aligned with the relevant centering light beam, which falls at the centre of the chin support.
In the second case, the centre of the sagittal medial plane corresponds with the centre of the chin support, but the patient's head is rotated.
In both cases, one side is closer to the sensor plane than the other, thus resulting in a different magnification of the two sides; the part more distant from the sensor will be more magnified while the part closer to the sensor plane will result smaller. The result will be an image as shown in Figure 34; the left-hand area of the image shows a bigger magnification that can be noticed both on the teeth and on the ascending rami of the TMJ.



Solution: Check the positioning of the sagittal medial plane by using the relevant centering light beam. Check also the position of the sagittal medial beam; lighted, it must fall both on the centre of the chin rest and also on the centre of the bite.

The image shows the upper vertex of the condylar rami of different heights
Figure 35 shows the result of this error.

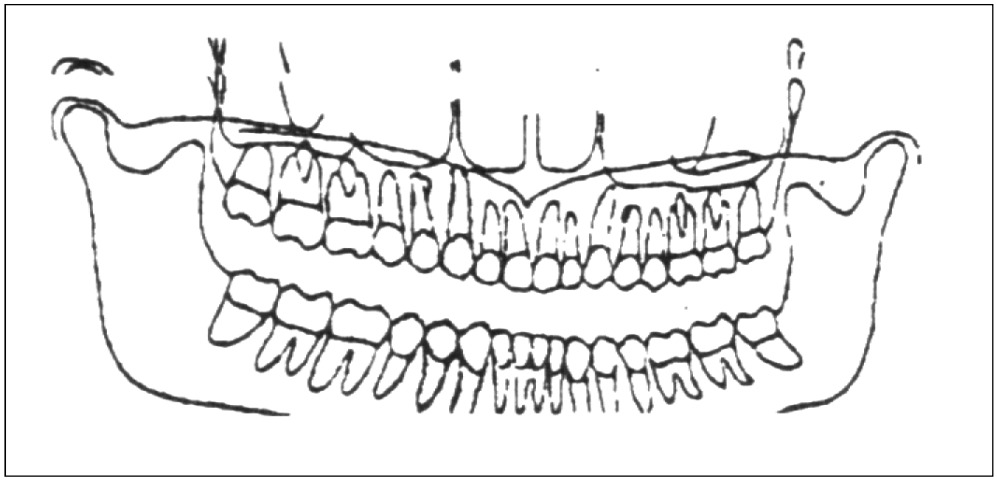


Figure 35

Possible causes: The sagittal medial plane is not vertical. This can be the patient's problem, but if the defect is always present, check the laser beam.
Solution: Verify that the laser beam is vertical; this check can be performed very quickly by using the laser beam and verifying that it falls on the centre of the chin support; remove the chin support itself and check that the beam falls in the centre of the two holes used to fix the support itself. If not, a possible cause can be the imperfect horizontality of the chin support arm, which must be adjusted using the relevant screws.

The image shows undulated teeth rows

As can be seen in Figure 36, the upper teeth are magnified and unfocused, with the shadow of the hard palate positioned over the superior apex. The temporo-mandibular joints are exposed outward, with lines divergent upward. In some cases, the condylar vertices might not appear on the image.

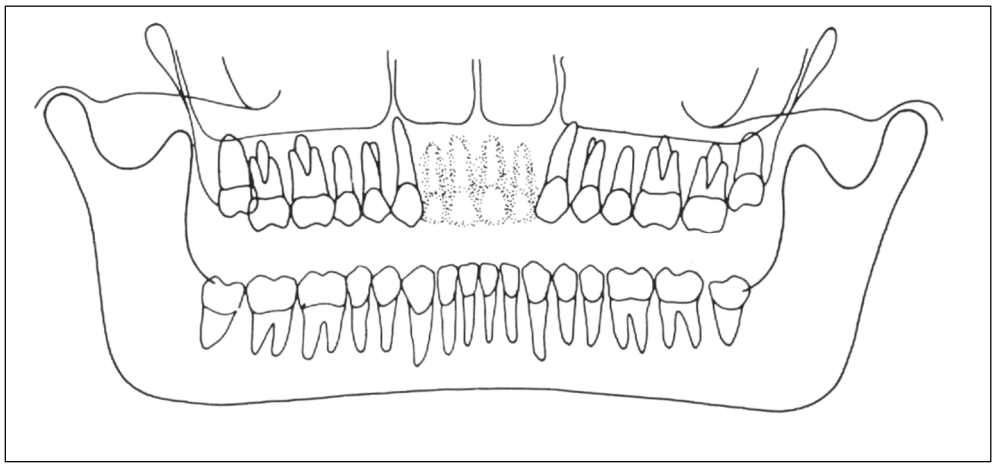
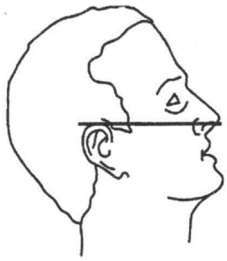


Figure 36

Possible causes: A Frankfurt plane tilted too much upward produces different anomalies that may also appear simultaneously. A chin support plane too high during the patient positioning, or when extending the spine, may generate this mistake. In this condition, the rear side of the patient's head may also interfere with the rotating arm of the panoramic equipment.



The radiographic image shows the teeth row too curved upward with the lower incisor not focused
Figure 37 shows the result of this type of error. The temporo-mandibular joints are shown very high up, with lines converging towards the top. In some cases the upper condyle might not be visible in the image.

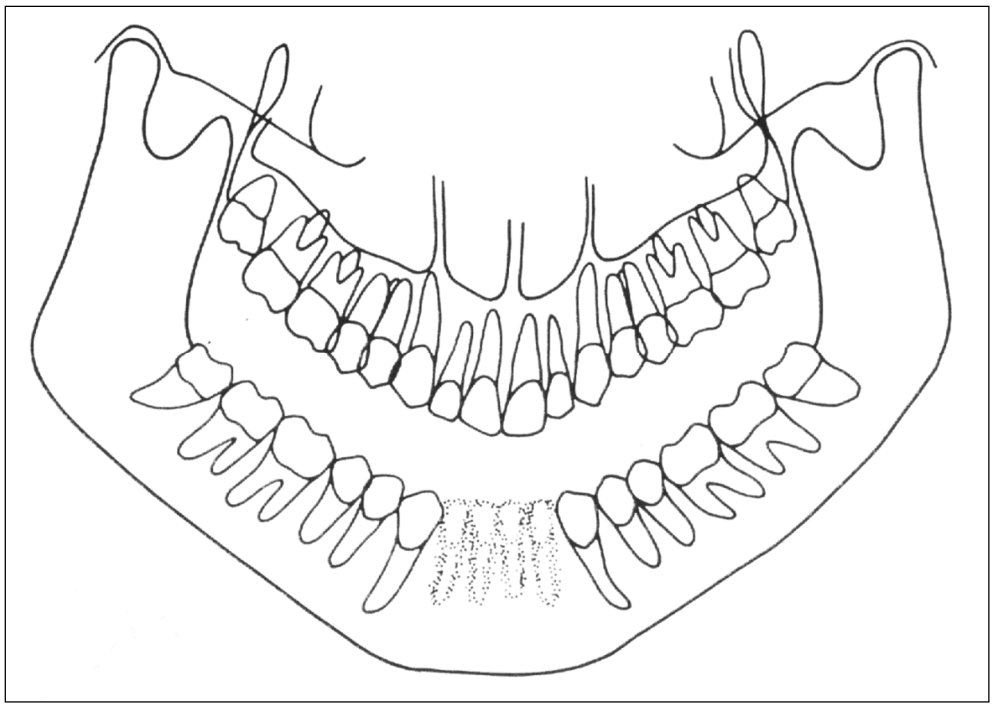


Figure 37

Possible causes: Patient's head tilted downward, as on the diagram alongside.
Solution: Check the positioning of the patient by aligning the Frankfurt plane with the corresponding light beam.

NOTE: In some cases, the positioning of the Frankfurt plane too tilted downward produces a correct image of the lower incisors, but the projection of the palate falls on the upper teeth apex, as shown in Figure 38.

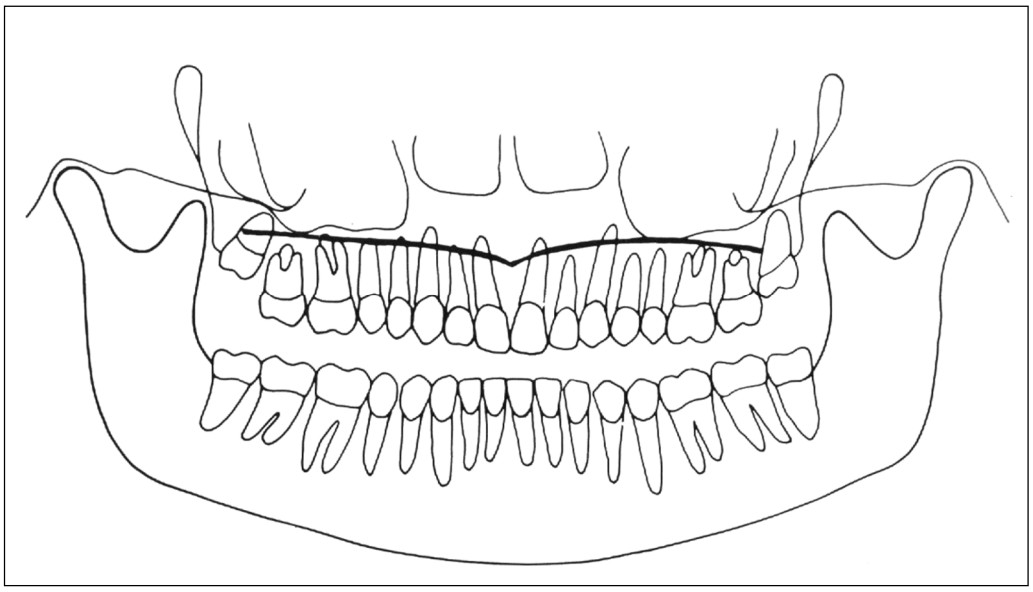


Figure 38

In this case, a light tilting forward and downward of the Frankfurt plane causes the palate to be projected over and far enough from the roots of the teeth of the maxillary arch, without distortion of the incisor teeth, as in Figure 39.

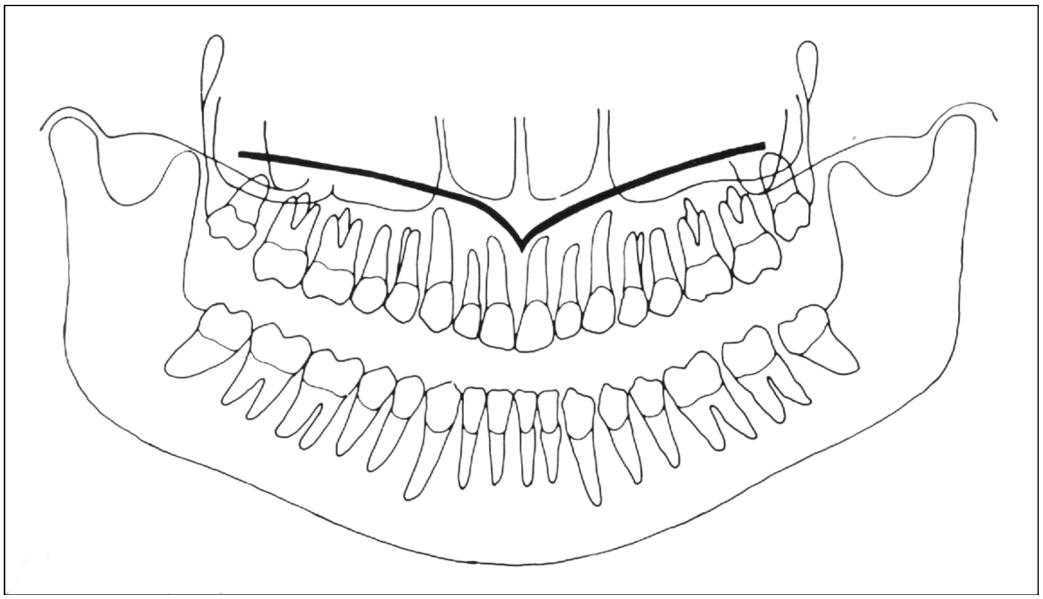


Figure 39

8.13.1.2 Images with artefacts

Radiographs that show images with soft tissues or artefacts
The radiographs may show anatomical parts of the soft tissues or show radiographic artefacts. Normally the soft tissues might be more or less present, depending on the patient positioning, while the presence of artefacts is strictly dependent on the presence of foreign objects on the trajectory of the X-ray beam. The next figure shows these cases; please consider that all structures have a bilateral duplicate.

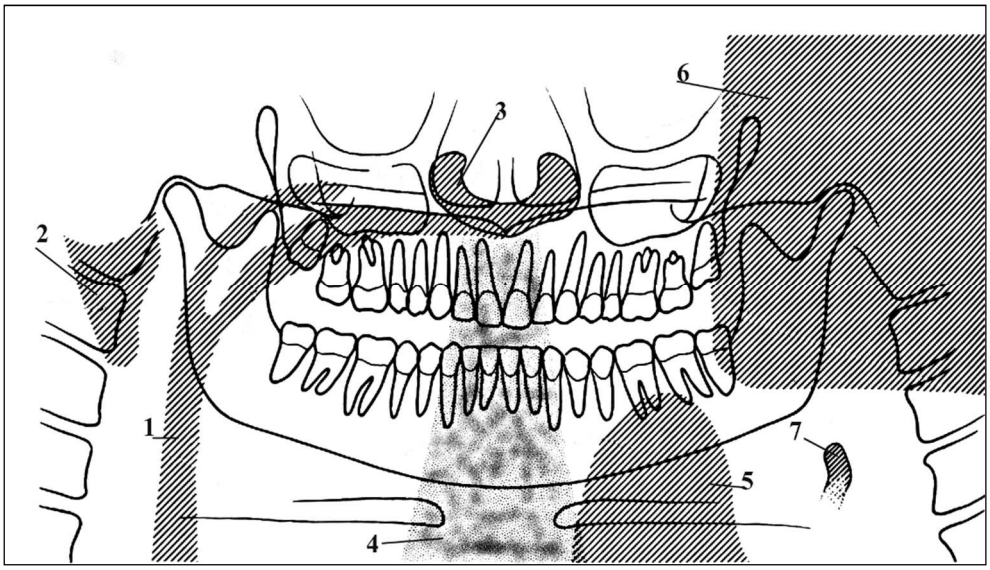


Figure 40

Soft tissue	Description	Artefact	Description
2	Soft tissue ear	1	Space between tongue and palate; all the structures of the oropharynx cavity can be seen
3	Soft tissue nose	4	Spinal column
7	Epiglottis	5	Image of the patient's leaded protective apron (light area)
6	Image of the contro-lateral mandible (the other side of the mandible), that therefore results as a clearer area overlapped with the real image		

Very often the resulting darker area in the bottom corner is noticed and is considered as an artefact of the radiological image.This is not true, because it is derived from the projection geometry used to obtain the panoramic image. The effect can be more evident if the image in underexposed due to wrong radiological parameters.

With reference to Figure 40 above, let's analyze some errors.

Wrong positioning of the spine
In the event the image shows an over-bright and unfocused part in the central area (see point "4" - Figure 40), this is probably caused by the wrong position of the spine that has not been properly extended by the patient. In this case, the spine absorbs an excessive quantity of radiation that therefore causes the image to be over-bright. This excessive brightness can be seen above all in the lower part, but is less visible in the upper part of the X-ray.
Solution: Ask the patient to step forward, thus extending his spine, in order to reduce X-ray absorption.

Shadows or bright artefacts
The most common cause for the presence of these artefacts is the presence of metal objects worn by the patient (earrings, necklaces, etc.). The necklaces worn by the patient normally result in a radio-opaque arch positioned in the chin area. This arch normally overlaps the chin itself and the shadow of the spine, disturbing the diagnosis of possible problems in the chin area and in the area of the apices of the mandibular incisors. The earrings, on the other hand, create real images in the proper position and shadow images projected in the contro-lateral area, thus hiding possible problems or generating bright areas within the maxillary sinuses. In some cases, that may depend either on the trajectory of the panoramic machine or on the position of the metal objects, they can generate up to three images (one real and two shadows), thus further disturbing the correct diagnosis. This situation may occur especially if the patient has large prosthesis or metal fillings, and is associated with a positioning error, that projects the shadow of the metal part on wide areas of the image.

Non-exposed area in the lower-central part of the image
If the problem appears as shown in point "5" of Figure 40 above, it indicates that there has been interference between the leaded apron worn by the patient and the X-ray beam.
Solution: Properly position the leaded apron (tight around the patient's shoulders and neck) then carry out a new examination.

The teeth rows are overexposed
As already described, if the tongue is not positioned against the palate during the exposure, it will create an air chamber between the tongue and the palate; this air gap creates a less absorbing area that overlaps the teeth, often in the apex area. This area is identified as reference "1" in Figure 40.
Solution: Ask the patient to position his tongue against the palate during the exposure.

8.14 Storing of automatic exposure parameters

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

To modify the automatic exposure parameters, please follow the indicated procedure:

1. Select the examination, the type of patient and the size to be modified.
2. Modify the KV, mA and/or time (for Cephalometric programs) parameters to suit your needs; the "Anatomic/Manual" (13) mode indicator changes to manual. New parameters can only be saved in "Manual" mode.
3. Press the "Anatomic/Manual" (13) mode indicator until it turns green and displays "S", then press the "Examination mode Selection" key (10) to store the modified parameters for the examination and type and size of patient you have selected.
4. After pressing the key, the display will show the following message:

   UPDATE CHANGES?

   >0< = Y, T = N

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

8.14.1 Table of pre-set anatomic parameters

Panoramic	Adult	Child
Small	68 kV 6 mA	64 kV 6 mA
Medium	72 kV 6 mA	66 kV 6 mA
Large	74 kV 6 mA	68 kV 6 mA

TMJ open/close mouth	Adult	Child
Small	68 kV 6 mA	60 kV 6 mA
Medium	72 kV 6 mA	64 kV 6 mA
Large	76 kV 6 mA	68 kV 6 mA

Sinus	Adult	Child
Small	66 kV 6 mA	62 kV 6 mA
Medium	70 kV 6 mA	64 kV 6 mA
Large	72 kV 6 mA	66 kV 6 mA

Cephalometry (L/L)	Adult	Child
Small	72 kV 6 mA	70 kV 6 mA
Medium	74 kV 6 mA	72 kV 6 mA
Large	76 kV 6 mA	74 kV 6 mA

Cephalometry (A/P-P/A)	Adult	Child
Small	74 kV 12 mA	72 kV 10 mA
Medium	76 kV 12 mA	74 kV 10 mA
Large	80 kV 10 mA	76 kV 10 mA

Maxilla IMPLANT								
	Tooth 11/21	**Tooth 12/22**	**Tooth 13/23**	**Tooth 14/24**	**Tooth 15/25**	**Tooth 16/26**	**Tooth 17/27**	**Tooth 18/28**
Small	9.20 s 60 kV 6 mA	9.20 s 60 kV 6 mA	9.20 s 66 kV 6 mA	9.20 s 66 kV 6 mA	7.30 s 62 kV 6 mA	7.30 s 62 kV 6 mA	7.30 s 62 kV 6 mA	7.30 s 62 kV 6 mA
Medium	9.20 s 60 kV 6 mA	9.20 s 60 kV 6 mA	9.20 s 70 kV 6 mA	9.20 s 70 kV 6 mA	7.30 s 64 kV 7 mA	7.30 s 64 kV 7 mA	7.30 s 64 kV 7 mA	7.30 s 64 kV 7 mA
Large	9.20 s 60 kV 6 mA	9.20 s 60 kV 6 mA	9.20 s 72 kV 7 mA	9.20 s 72 kV 7 mA	7.30 s 66 kV 8 mA	7.30 s 66 kV 8 mA	7.30 s 66 kV 8 mA	7.30 s 66 kV 8 mA

Mandible IMPLANT								
	Tooth 31/41	**Tooth 32/42**	**Tooth 33/43**	**Tooth 34/44**	**Tooth 35/45**	**Tooth 36/46**	**Tooth 37/47**	**Tooth 38/48**
Small	9.20 s 60 kV 6 mA	9.20 s 60 kV 6 mA	9.20 s 60 kV 6 mA	9.20 s 60 kV 6 mA	7.30 s 66 kV 6 mA	7.30 s 60 kV 6 mA	7.30 s 60 kV 6 mA	7.30 s 60 kV 6 mA
Medium	9.20 s 60 kV 6 mA	9.20 s 60 kV 6 mA	9.20 s 60 kV 6 mA	9.20 s 62 kV 7 mA	7.30 s 68 kV 7 mA	7.30 s 62 kV 7 mA	7.30 s 62 kV 7 mA	7.30 s 62 kV 7 mA
Large	9.20 s 60 kV 7 mA	9.20 s 60 kV 7 mA	9.20 s 60 kV 7 mA	9.20 s 64 kV 8 mA	7.30 s 70 kV 8 mA	7.30 s 64 kV 8 mA	7.30 s 64 kV 8 mA	7.30 s 64 kV 8 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

NOTE: Maintenance and inspection procedure must be performed without patient positioned in the equipment.

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

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

The operator can control the following items:

Frequency	Type of check	Method
Daily	Functioning of the indicator lights	Visual inspection
Daily	Check 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: It is recommended that the operator performs the checks before each session. In the event the operator detects faults or abnormalities, he must immediately call the Technical Service.

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

Frequency	Type of check	Method
Annually	General visual inspection	Visual inspection
Annually	Grounding of all the accessible conductive parts	Practical inspection
Annually	Condition of the internal and external cables: wear and tear and fastenings	Visual and practical inspection
Annually	Tightening of the primary bolts and screws such as the wall fastening systems, the moving mechanisms and the chin rest arm	Practical inspection
Annually	Correct functioning of the luminous indicators of the console	Visual inspection
Annually	Correct equipment centring	See Service Manual paragraph 7.2
Annually	Check technical factors	See Service Manual paragraph 4.4
Annually	Detector calibration	See Service Manual paragraph 7.3

MAINTENANCE LOGBOOK

	Date	Technician
Installation		
Maintenance		
Cause		
Maintenance		
Cause		
Maintenance		
Cause		
Maintenance		
Cause		
Maintenance		
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Maintenance		
Cause		

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TECHNICAL SPECIFICATIONS

I-MAX TOUCH

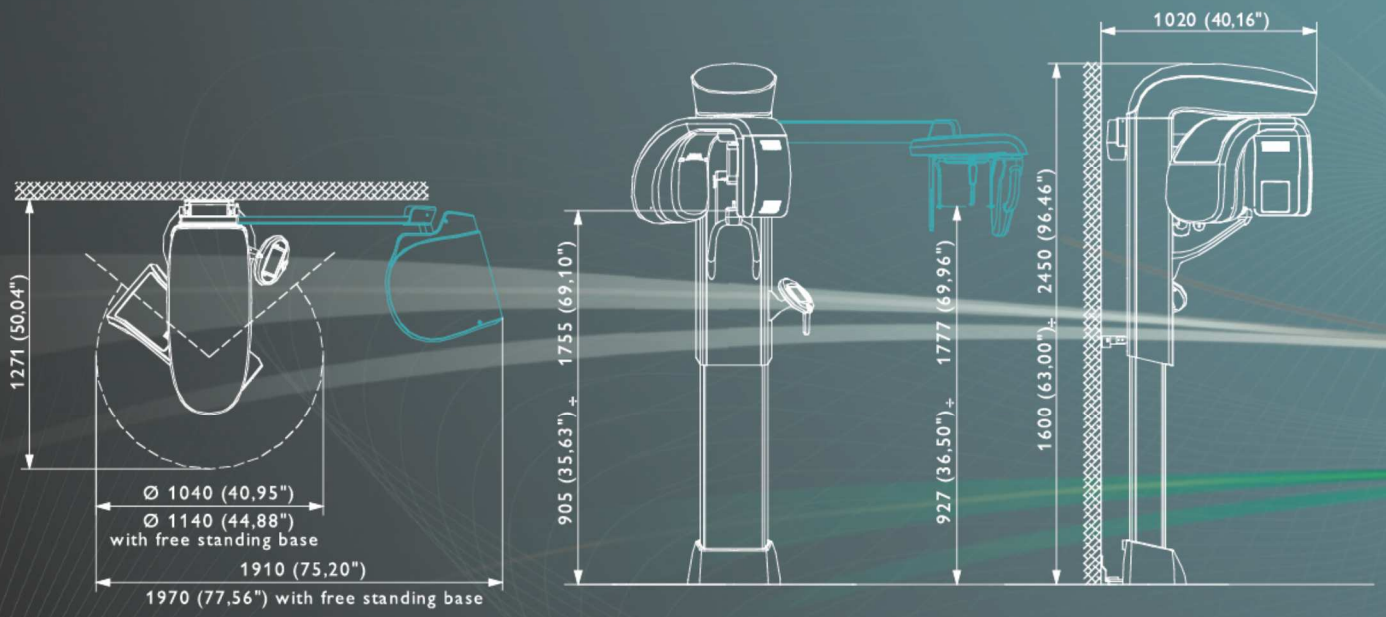
- HF Generator At constant potential
- Focal spot 0.5 EN60336
- Min. total filtration 2.5 mm Al equivalent
- Anode voltage 60 - 86 kV
- Anode current 6 - 10 mA PAN, 6 - 12 mA CEPH
- Exposure time Pan 13.8 s / Ceph starting at 4.5 s
- Column Motorized telescopic
- SID (Source to Image Distance)
  Pan 500 mm / Ceph 1650 mm
- Digital sensor HD CCD + optical fiber plate
- CCD resolution 10.4 lp/mm
- Connection Direct acquisition (network cable)
  and/or integrated touch screen
- Storage Computer and/or USB memory stick
- Power supply 100-120 V, 220-240 V, 50/60Hz
- Amperage 8 A

I-MAX TOUCH 3D

- 3D rotation 200° (180° TMJ)
- Rotation time 20 s
- Exposure time 8 s (generator in pulsed mode)

Sensor data

- Digital sensor Amorphous silicon flat panel
- Surface 130 x 130 mm, 512 x 512 pixels
- F.O.V. (Filed Of View) 93 x 83 mm / 53 x 93 mm / 43 x 93 mm
- 3D volume voxel size 92 µm



BR_IMAXTOUCH_EN_REV00

Dealer's stamp

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