Owandy RADIOLOGY

EN • USER MANUAL

I-Max, CEPH version

NIMXEN030G • May 2024

i-max CEPH PRO

MAKES LIFE EASIER

NEW PANORAMIC UNIT GENERATION

2D, CEPH VERSION

Revision history Manual code NIMXEN030G

Rev.	Date	Page/s	Modification description
0A	01.07.19	-	First emission
0B	11.01.21	2	Correction of Intended Use, title change of paragraph 2.1 from "Application and medical purpose" to "Indications for Use" and intended patient population
		20, 21	Update of used symbols at paragraph 3.6
		23	Update of labels at paragraph 5.1
		26	Correction of max line apparent resistance from 0.4 to 0.2 ohm and introduction of line voltage regulation of <3% @ 99V
		26, 30	Added total filtration ≥ 2,5 mm Al eq. @ 86 kV ref. IEC 60601-1-3 Par. 7.1 and update of inherent filtration at chapter 6 (additional filtration value was removed)
		39	Added ISO 10993 standards among the reference standards
		40	Added new chapter 7 – Removable part list
		68, 69	Correction of the term from “Anatomic” to “Pre-set” exposure mode
			Specified patient type and size selection criteria
0C	16.03.22	9	Update laser labels
		20, 21	Update system labels
		27, 28	Added changes concerning laser
		58	Added section concerning the double sensor
0D	14.04.22	24, 66	Added Carpus HD exam exposure time
0E	29.11.2022	19	Updated *Cleaning and disinfection* paragraph
		87	Errors 376 and 377 added to the error table
			Added images, cover image for I-MAX pro
0F	08.11.23	29	Fixed data in chapter technical characteristics
		56	Updated warning RED GUI: Error/waiting for connection
		87	Added error 1200 at chapter 16
0G	15.05.2024	15	Added table on Proximity Fields from RF wireless communication equipment as per IEC 60601-1-2 Am1 2020

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1. INTRODUCTION

Note

This manual is updated for the product it is sold with, to guarantee an adequate reference for using the product properly and safely.

The manual may not reflect changes made to the product that do not affect operating procedures or safety.

I-MAX, manufactured by Owandy Radiology, is an X-ray device for the radiographic analysis of the maxillo-facial complex.

I-MAX performs Panoramic, Half-panoramic, Low dose Panoramic, Frontal dentition, Ortho Rad Panoramic, Bitewing Bilateral, Bitewing Left and Bitewing Right, Sinus, TMJ, AP and LL cephalometric exams, Carpus exam.

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

The device must be used complying with the procedures described in this Manual and never be used for purposes other than those indicated herein.

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

I-MAX is an electrical medical device and can only be used under the supervision of a physician or of highly qualified personnel, with necessary knowledge of X-ray protection. The user is liable for legal compliance in relation to the installation and operation of the device.

1.1 Icons appearing in the manual

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

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

2. SPECIFICATION OF THE INTENDED USE

2.1 Indications for use

I-MAX is an extra-oral dental panoramic X-ray unit to take two dimensional radiographic exams of teeth, jaw and oral structures (panoramic, TMJ and sinus exams). The models with cephalometric arm will be able to take two dimensional cranial cephalometric exams in different projections and the wrist exam (Carpus) dedicated to the evaluation of the bone growth.

The device is operated and used by dentists, radiologists and other legally qualified health care professionals, i.e. Prescription Use (Part 21 CFR 801 Subpart D).

The target patient population includes adults and pediatric patients from 7 years old [~27 kg (59.5 lb); 125 cm (49.2 in) standing height].

Anyway, the sustainability to X-ray exposure must be evaluated by surgeons, dentists and qualified and authorized physicians.

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 system can be used with the following type of patient:

- Patient population: the target patient population includes adults and pediatric patients from 7 years old [~27 kg (59.5 lb); 125 cm (49.2 in) standing height]. Anyway, the sustainability to X-ray exposure must be evaluated by surgeons, dentists and qualified and authorized physicians
- Patient status:
  - self-sufficient patient (the patient can autonomously place himself as requested by the physician)
  - non self-sufficient patient (the patient is assisted by medical personnel).
  - In any case the patient must be conscious, not anaesthetized and not incapacitated
- Nationality: multiple.

2.1.2 Operator Profile

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

2.1.3 Application environments

I-MAX may be used in professional buildings (e.g. hospitals, private clinics) or in residential buildings. For the purpose of EMC environment classification both installations are classified as "Professional healthcare facility environment".

Note

In the radiographic room, direct audio and visual communication between operator and patient shall be always possible. If necessary, the user is responsible to provide proper arrangement (i.e. lead glass or similar, interphone, etc.).

2.2 Applied parts

During normal use, I-MAX is in contact with the patient via the handle, chin rest, bite stick, temple clamps, CEPH temple clamp, CEPH ear centering pins, CEPH nasion reference; such components are classified as Type B applied parts according to IEC 60601-1.

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

The estimated dose * area product delivered by I-MAX to the patient for each exam is indicated in the graphical user interface.

Note

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

The dose is taken at a predefined 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 for panoramic, TMJ and sinus exams and 165 cm for the cephalometric exams.

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

- for adult 2D except bitewing and cephalometric exams: 146 mm x 4.5 mm
- for child 2D except bitewing and cephalometric exams: 120 mm x 4.5 mm
- for adult and child bitewing exam: 104 mm x 4.5 mm
- for cephalometric exam is either 222 x 8.7 mm or 174 x 8.7 mm for the 18 cm high exam

(*) this feature is active by default but the user can disable it and in that case the X-ray beam size is the same as in adult selection

Except for the cephalometric exams, 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 is 264 mm.

In the cephalometric exams this distance is about 1400 mm.

The overall uncertainty of the indicated value of the air Kerma and dose per area product is 50%.

Note

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

2.3.1 Panoramic mode

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

kV	60	62	64	66	68	70	72	74	76	78	80	82	84	86
mA	Air Kerma [mGy]													
2	3.57	3.85	4.14	4.43	4.72	5.00	5.29	5.58	5.86	6.15	6.44	6.61	6.75	6.88
2.2	3.93	4.24	4.56	4.87	5.19	5.50	5.82	6.13	6.45	6.76	7.08	7.27	7.43	7.57
2.5	4.46	4.82	5.18	5.54	5.89	6.25	6.61	6.97	7.33	7.69	8.04	8.26	8.44	8.60
2.8	5.00	5.40	5.80	6.20	6.60	7.00	7.40	7.81	8.21	8.61	9.01	9.25	9.45	9.63
3.2	5.71	6.17	6.63	7.09	7.54	8.00	8.46	8.92	9.38	9.84	10.30	10.57	10.80	11.00
3.6	6.42	6.94	7.45	7.97	8.49	9.00	9.52	10.04	10.55	11.07	11.58	11.89	12.15	12.38
4	7.14	7.71	8.28	8.86	9.43	10.00	10.58	11.15	11.72	12.30	12.87	13.21	13.50	13.76
4.5	8.03	8.67	9.32	9.96	10.61	11.25	11.90	12.54	13.19	13.83	14.48	14.86	15.19	15.48
5	8.92	9.64	10.35	11.07	11.79	12.50	13.22	13.94	14.65	15.37	16.09	16.52	16.88	17.20
5.6	9.99	10.79	11.60	12.40	13.20	14.00	14.81	15.61	16.41	17.22	18.02	18.50	18.90	19.26
6.3	11.24	12.14	13.05	13.95	14.85	15.76	16.66	17.56	18.46	19.37	20.27	20.81	21.27	21.67
7.1	12.67	13.69	14.70	15.72	16.74	17.76	18.77	19.79	20.81	21.83	22.85	23.45	23.97	24.42
8	14.27	15.42	16.57	17.71	18.86	20.01	21.15	22.30	23.45	24.59	25.74	26.43	27.01	27.51
9	16.06	17.35	18.64	19.93	21.22	22.51	23.80	25.09	26.38	27.67	28.96	29.73	30.38	30.95
10	17.84	19.27	20.71	22.14	23.58	25.01	26.44	27.88	29.31	30.74	32.18	33.03	33.76	34.39
11	19.63	21.20	22.78	24.36	25.93	27.51	29.09	30.66	32.24	33.82	35.39	36.34	37.13	37.83
12.5	22.30	24.09	25.89	27.68	29.47	31.26	33.05	34.84	36.64	38.43	40.22	41.29	42.20	42.99

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

2.3.2 Cephalometric mode

The air Kerma value at the entrance of the X-ray image receptor for the 18x24 LL and 18x18 LL High Speed cephalometric exams is reported in the table below as function of kV and mA.

kV	60	62	64	66	68	70	72	74	76	78	80	82	84	86
mA	Air Kerma [mGy]													
2	0.08	0.09	0.10	0.10	0.11	0.12	0.12	0.13	0.14	0.14	0.15	0.16	0.17	0.17
2.2	0.09	0.10	0.11	0.11	0.12	0.13	0.14	0.14	0.15	0.16	0.17	0.18	0.18	0.19
2.5	0.11	0.11	0.12	0.13	0.14	0.15	0.15	0.16	0.17	0.18	0.19	0.20	0.21	0.22
2.8	0.12	0.13	0.14	0.14	0.15	0.16	0.17	0.18	0.19	0.20	0.21	0.22	0.23	0.24
3.2	0.14	0.14	0.16	0.17	0.18	0.19	0.20	0.21	0.22	0.23	0.24	0.26	0.27	0.28
3.6	0.15	0.16	0.17	0.19	0.20	0.21	0.22	0.23	0.25	0.26	0.27	0.29	0.30	0.31
4	0.17	0.18	0.19	0.21	0.22	0.23	0.25	0.26	0.28	0.29	0.30	0.32	0.33	0.35
4.5	0.19	0.20	0.22	0.23	0.25	0.26	0.28	0.29	0.31	0.33	0.34	0.36	0.38	0.39
5	0.21	0.23	0.24	0.26	0.27	0.29	0.31	0.33	0.34	0.36	0.38	0.40	0.42	0.44
5.6	0.24	0.25	0.27	0.29	0.31	0.33	0.35	0.37	0.39	0.41	0.43	0.45	0.47	0.49
6.3	0.27	0.29	0.31	0.33	0.35	0.37	0.39	0.41	0.43	0.46	0.48	0.50	0.53	0.55
7.1	0.30	0.32	0.34	0.37	0.39	0.41	0.44	0.46	0.49	0.51	0.54	0.57	0.59	0.62
8	0.34	0.36	0.39	0.41	0.44	0.47	0.49	0.52	0.55	0.58	0.61	0.64	0.67	0.70
9	0.38	0.41	0.44	0.46	0.49	0.52	0.56	0.59	0.62	0.65	0.68	0.72	0.75	0.79
10	0.42	0.45	0.48	0.52	0.55	0.58	0.62	0.65	0.69	0.72	0.76	0.80	0.84	0.87
11	0.46	0.50	0.53	0.57	0.60	0.64	0.68	0.72	0.76	0.80	0.84	0.88	0.92	0.96
12.5	0.53	0.57	0.61	0.65	0.69	0.73	0.77	0.81	0.86	0.90	0.95	1.00	1.05	1.09

The air Kerma for other cephalometric exams available on the equipment can be calculated using the ratios vs the 18x24 LL (or 18x18 LL) High Speed exam in the table below:

Exam	Ratio
24x24 LL and 24x18 LL High Speed	1.35
30x24 LL and 30x18 LL High Speed	1.71
18x24 LL and 18x18 LL High Definition	2.08
24x24 LL and 24x18 LL High Definition	2.82
30x24 LL and 30x18 LL High Definition	3.56
24x24 AP and 24x18 AP High Speed	1.39
24x24 AP and 24x18 AP High Definition	2.88
Carpus	1.04

3. SAFETY INFORMATION

Warning

Please read this chapter thoroughly.

The equipment has been designed in compliance with safety requirements; furthermore, it supplies all information necessary for correct use, and warnings related to dangers associated with X-ray generating units.

Owandy Radiology cannot be held liable for:

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

Installation and any technical operations must only be performed by qualified technicians authorised by Owandy Radiology.

Only authorised personnel may remove the covers and/or have access to live components.

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 is an electric medical device and so can only be used under the supervision of suitably qualified medical personnel, with necessary knowledge of X-ray protection.

The user is responsible for compliance with legal requirements as regards ownership, installation and use of the equipment.

The user is responsible for a safe set-up and maintenance of the host PC; as a general guidance cybersecurity suggestions are given in paragraph 3.4 of this Manual.

The user is responsible for the execution of the routine quality control procedure described in chapter 8 of this Manual.

This device has not been designed for use in environments where vapours, anaesthetic mixtures flammable with air, or oxygen and nitrous oxide, may be present.

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

Before cleaning the device, make sure the main power supply has been disconnected from the equipment. When pushing the ON/OFF button of the equipment, it must not come on.

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

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

I-MAX has been built for continuous operation with an intermittent load; so the described use cycles must be observed, to enable the device to cool down.

I-MAX must be switched off while using electrosurgical devices or similar apparatus.

Warning

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

Warning

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

Warning for free standing floor mounted unit

In case the unit shall be moved for service or other extraordinary operation, maximum caution shall be taken to prevent the unit from tilting and falling to the ground.

Clean and disinfect, when necessary, all parts that may come into contact with the patient.

The centring bite or the bite protective sleeve must be replaced after each exam.

To avoid permanent damage to the unit, never try to rotate the moving arm manually when the unit is switched on.

In the case of Error 362 or Error 760, movement is possible to let the patient exit.

Note

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

3.1.1 Precautions while using laser centring devices

For patient positioning, I-MAX uses two laser diodes with optical power on the working surface < 1 mW.

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

The warning label (see Figure 2: Identification labels) is affixed to I-MAX to indicate a laser in class 1 is mounted internally and caution is advised.

Warning

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

3.2 Protection against radiation

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

Warning

Protection against radiation is regulated according to law.

The equipment may only be used by specialised personnel.

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

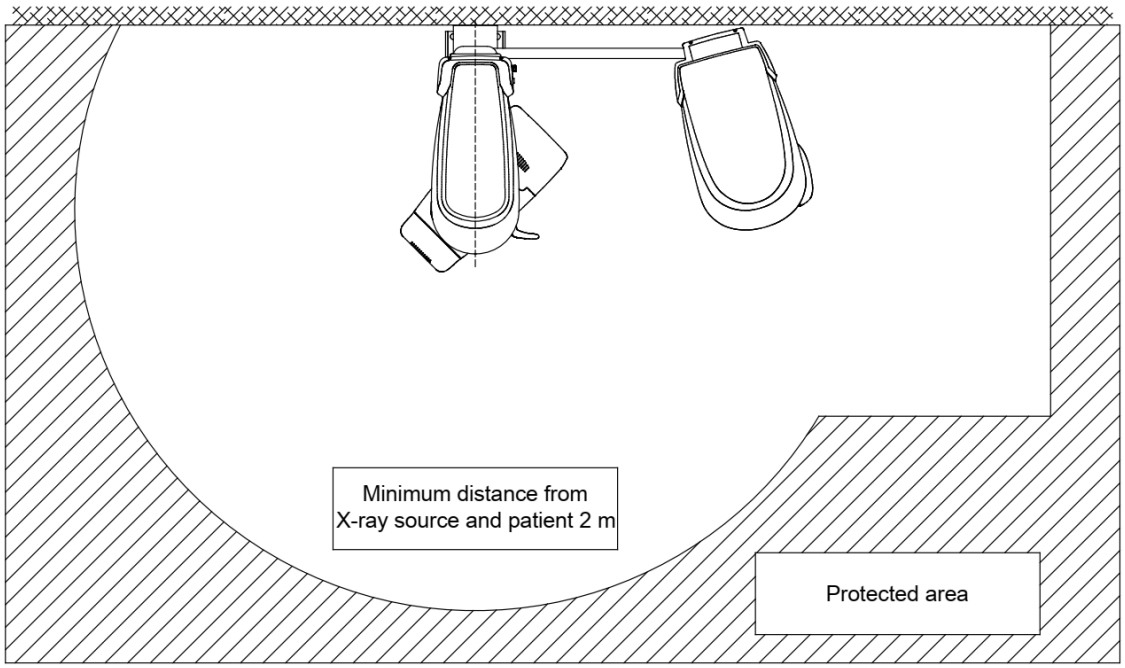


Figure 1

3.2.1 Pediatric Use: Summary

3.2.1.1 Introduction

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50kg (110lb) in weight and 150cm (59") in height, measurements, which approximately correspond to that of an average 12 years old or a 5th percentile U.S. adult female).

3.2.1.2 References for pediatric dose optimization

The following resources provide information about pediatric imaging radiation safety and/or radiation safety for extra-oral dental panoramic and CBCT (aka CBVT) X-ray devices:

1. HTTPS://WWW.FDA.GOV/RADIATION-EMITTINGPRODUCTS/RADIATIONEMITTINGPRODUCTSANDPROCEDURES/MEDICALIMAGING/UCM298899.HTM
2. www.imagegently.org
3. HTTPS://WWW.FDA.GOV/RADIATION-EMITTINGPRODUCTS/RADIATIONEMITTINGPRODUCTSANDPROCEDURES/MEDICALIMAGING/MEDICALX-RAYS/UCM315011.HTM
4. https://www.iaea.org/resources/rpop/resources/training-material#11
5. HTTPS://WWW.IAEA.ORG/RESOURCES/RPOP/RESOURCES/TRAINING-MATERIAL#3

3.2.1.3 Device specific features and instructions

I-MAX provides as standard with all units the following specific design features and instructions that enable safer use of our device with pediatric patients:

Design features important to paediatric imaging	Paragraph
Adult/Child exam modality: child selection adapts exposure current (mA) and High voltage (kV) reducing the overall dose supplied to the patient.	9.4
For the panoramic exams (panoramic, half-panoramic and low dose panoramic programs) Child selection also corresponds to a reduced trajectory exam time giving a further 10% of dose reduction.	12
For cephalometric exams, various exam sizes are available both for height and width of the irradiated area.	13
A function to run the exam in test mode without X-ray to check the behaviour of the patient during the exam and reduce the possibility of exam interruption and retake	9.4 and 10.1

3.3 Information about Electromagnetic Compatibility

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.

The equipment can be installed both in professional buildings (e.g. hospitals or clinics) and in residential buildings. Residential buildings, according to IEC 60601-1-2 4th edition, are intended to be connected to dedicated power supply system (normally fed by separation transformers).

For the purpose of EMC environment classification according to IEC 60601-1-2 4th edition, both installations are classified as "Professional healthcare facility environment".

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment, even if it is usually permanently installed in X-Ray shield locations, might not offer adequate protection to radio-frequency communication services. If abnormal performance is observed, such as degradation of essential performance in the form of lack of accuracy of exposure parameters and lack of reproducibility of exposure parameter, additional measures may be necessary, such as re-orienting or relocating the device.

Warning

The use of cables other than:

- Ethernet cable CAT 6 L=5 m - code 5007090100
- Ethernet cable CAT 6 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.

Warning

I-MAX should not be used adjacent to or stacked with other equipment; if adjacent use is necessary, I-MAX has to be observed to verify if it operates in a normal way.

Interference may occur in the vicinity of equipment marked with the symbol  .

Warning

Portable and mobile RF communications equipment should be used no closer to any part of I-MAX, including cables. Minimum distance 30 cm.

3.3.1 Electromagnetic emissions

In accordance with the IEC 60601-1-2 Ed4 standard, I-MAX is suitable for use in the electromagnetic environment specified below.

The customer or user of the system must ensure that it is used in the said environment.

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

3.3.2 Electromagnetic immunity

In accordance with the IEC 60601-1-2 Ed4 standard, I-MAX is suitable for use in the electromagnetic environment specified below.

The customer or user of the system must ensure that it is used in the said environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2/4/8/15 kV air	IEC 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated electromagnetic field IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of I-MAX including cables. Minimum distance 30 cm
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines > 3 m	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	0.5/1 kV differential mode 0.5/1/2 kV common mode	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V ISM frequencies	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of I-MAX, including cables. Minimum distance 30 cm
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	10 ms – 0 % a 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0%	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the I-MAX requires continued operation during power mains interruptions, it is recommended that the I-MAX be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment

3.3.3 Proximity fields from RF wireless communications equipment

In accordance with the IEC 60601-1-2 + A1 2020 standard, below are reported the estimates of the radiated immunity of electrical and electronic equipment to electromagnetic disturbances coming from RF wireless communications equipment.

Measurements have been made in a fully anechoic chamber and the indicated field strength is pre-calibrated prior to placement of the system under test.

Test n°	Test frequency	Modulation	Frequency range	Test level
1[1]	385	PM 18 Hz	380 to 390 MHz	27 V/m
2[1]	450	FM ±5 kHz deviation 1 kHz sine	430 to 470 MHz	28 V/m
3[1]	710	PM 217 Hz	704 to 787 MHz	9 V/m
	745	PM 217 Hz		9 V/m
	780	PM 217 Hz		9 V/m
4[1]	810	PM 18 Hz	800 to 960 Hz	28 V/m
	870	PM 18 Hz		28 V/m
	930	PM 18 Hz		28 V/m
5[1]	1720	PM 217 Hz	1700 to 1990 MHz	28 V/m
	1845	PM 217 Hz		28 V/m
	1970	PM 217 Hz		28 V/m
6[1]	2450	PM 217 Hz	2400 to 2570 MHz	28 V/m
7[1]	5240	PM 217 Hz	5100 to 5800 MHz	9 V/m
	5500	PM 217 Hz		9 V/m
	5785	PM 217 Hz		9 V/m

Notes:
[1] Test was performed with antenna in both horizontal and vertical polarization, positioning each EUT face in front of generating antenna. Top and bottom faces are not exposed to EM field for table-top and floor standing equipment

3.4 Cybersecurity measures

Like all computer-based systems, I-MAX might be exposed to Cybersecurity threats.

I-MAX is equipped with hardware provisions that make sure that no unwanted X-ray exposure, laser radiation or motorized movements can be activated even in case of cyber-attack or software failure.

Nevertheless, in order to minimize the possibility of cyber-attacks, it is the user responsibility to make sure that the following protection measures are followed.

- The initial software installation and system set-up shall be done by authorized and trained personnel only and using the software provided with the machine
- Any software or firmware upgrade of the equipment shall be done by authorized and trained personnel only
- After any software or firmware upgrade, or any other maintenance operation, image quality checks shall be performed to ensure the system is working as expected. Instructions are given in chapter 8
- 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 (if the system is supplied with a PC, the Windows user is password-protected, but it is user responsibility to change the default password and set new ones for all the different users that will have access to the system)
- 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 (if the system is supplied with a PC, the screen saver is activated by default)
- Install an antivirus software and keep virus definitions up to date
- Activate the windows firewall on the host PC (if the system is supplied with a PC, the Windows firewall is activated by default)
- It is recommended to activate a hardware firewall on the WAN router/modem used for internet connection, if present
- Make sure that all other PCs 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 that they are free of viruses, malware or any dangerous software
- Avoid installation of an unknown or untrusted software since it may undermine the 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

3.5 Environmental risks and disposal

Some parts of the device contain materials and liquids that, at the end of the unit's lifecycle, must be disposed of at appropriate disposal centres.

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

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

Note

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

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

The CER code for the device is *160213 - Equipment containing different hazardous components (complete radiographs and radiographs only)*

Illegal disposal of the product by the owner of the equipment will result in administrative sanctions, as provided for by applicable regulations.

3.6 Symbols used

In this manual and on I-MAX itself, apart from the symbols indicated on the keyboard, the following icons are also used:

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

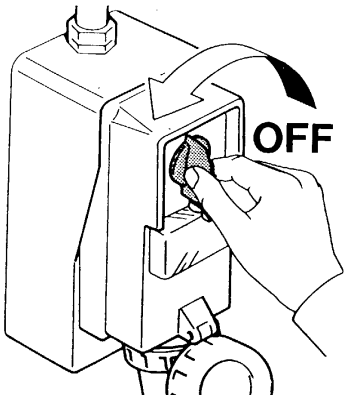
Symbols	Description
	Focal spot according to IEC 60336
	Follow instructions for use
CE 0051	Conformity to the Directive 93/42/EEC and its revised version and all other applicable Directives
	Exposure enabled status (the corresponding green LED is on)
	CEPH sensor properly connected
	X-Ray emission (the corresponding yellow LED is on)
	Electronic instructions for use symbol for medical devices, according to EN ISO 15223-1: 2016
	Emergency Button identification

4. CLEANING AND DISINFECTION

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

Warning

Disconnect the unit from the mains before performing any cleaning.



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

For ordinary cleaning it is recommended to apply a small dose of a mild detergent to clean the painted surfaces, accessories and connection cables and then wipe with a dry cloth. Do not use corrosive, abrasive solvents such as alcohol, benzene or trichloroethylene.

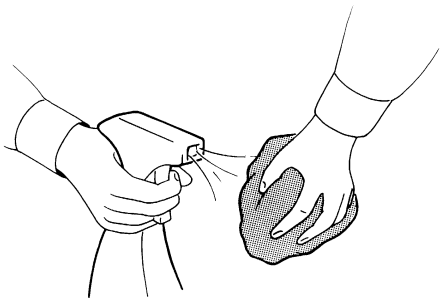
Especially, do not apply alcohol on Polycarbonate-based components such as labels to avoid their embrittlement

For extraordinary cleaning use detergents that **do not** contain alkaline solutions, saline solutions, amides, ketones, aromatic hydrocarbons, hexane, trichloroethane, acrylonitrile or dichloromethylene.

Do not apply any oil-based detergent or aggressive detergent and, in any case, do not use a steel sponge, but always soft cloths

H

Absolutely use zero corrosion cleaners



The centring bite or the bite protective sleeve and the cephalometric ear pin sleeves must be replaced after each exam.

Thoroughly clean the chin support, resting handles, temple clamps, CEPH rods, nasion reference and carpus plate whenever they are used.

The chin support, resting handles temple clamps, CEPH rods, nasion reference and carpus plate should be disinfected (when considered necessary) with a solution of 2% glutaraldehyde.

Note

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

5. DESCRIPTION

5.1 Identification labels

5.1.1 Position of Identification labels

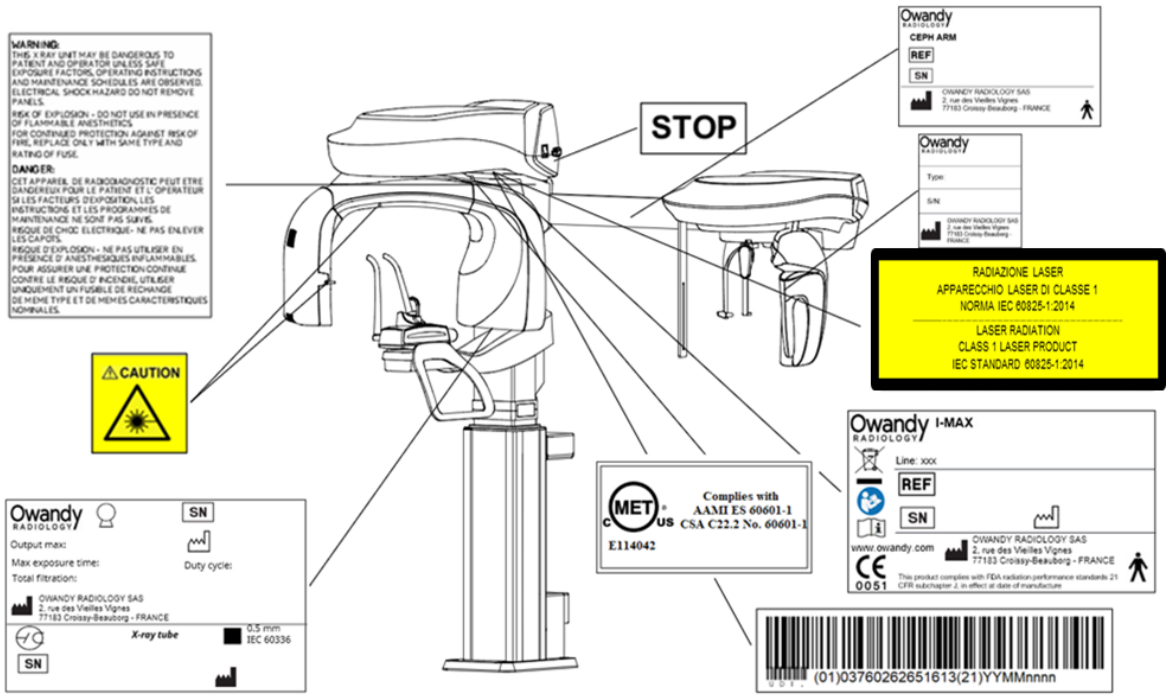


Figure 2: Identification labels

5.1.2 Warning and caution labels

Laser symbol label

Laser WARNING label

WARNING label

WITH DHHS PERFORMANCE STANDARD 21 CFR SUBCHAPTERJ

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

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.
ELECTRIQUE CHOC DANGER- NE PAS ENLEVER LES COUVERTURES
POUR ASSURER UNE PROTECTION CONTINUE CONTRE LE RISQUE
D' INCENDIE, UTILISER UNIQUEMENT UN FUSIBLE DE RECHARGE DE MEME TYPE ET DE MEMES CARACTERISTIQUES NOMINALES

5.2 Functions, models and versions

I-MAX, manufactured by Owandy Radiology, is a complete panoramic X-ray system that can perform the following exams:

- Panoramic adult or child exams, with 3 sizes and 3 types of biting for a total of 18 combinations with automatic selection; with manual selection, it is possible to select a high voltage between 60kV and 86kV, in 2kV steps and anodic current from 2 mA to 12.5 mA in the R20 scale steps.
- Sinus mode makes it possible to take exams of the paranasal sinuses with front projection (postero/anterior).
- TMJ closed/open mouth in lateral projection.
- Right or Left Half-panoramic, to be used when the patient is known to have a problem only on one side of the arch, in order to reduce radiation.
- Low dose Panoramic, which reduces the dose radiated by excluding the TMJ's ascending rami from the radiograph.
- Frontal dentition, for a radiograph of the front part (roughly from canine to canine).
- Ortho Rad Panoramic, which reduces teeth overlap, thereby improving the diagnosis of interproximal decay.
- Bitewing Left or Right, for lateral dentition (generally from eighth to fourth) with a trajectory that reduces teeth overlap
- Bilateral Bitewing (Left and Right), which sequentially performs both bitewings, showing them on the same image.
- Cephalometric L-L projections in the formats 18x24, 24x24, 30x24 and 18x18, 24x18, 30x18; the selection between HS High Speed and HD High Definition is available.
- Cephalometric A-P projections in the format 24x24 and 24x18 the selection between HS High Speed and HD High Definition is available.
- Carpus Projection in the format 18x24, only in HD High Definition mode.

Note of cephalometric image formats:

For user convenience, the CEPH projections are named following the conventional format of the film-cassettes (24 cm), although the vertical active area of the cephalometric sensor is 22.8 cm.

Note

The code entered in I-MAX to enable additional exams is protected by a unique Identification Code (UIC); in the event the UIC is not present or is faulty, error E270 or E271 will be shown.

The UIC is simply an identifier of the single I-MAX unit and is generated by Owandy Radiology for the single device serial number.

6. TECHNICAL CHARACTERISTICS

General features	
Type	I-MAX
Manufacturer	Owandy Radiology
Class	Class I with type B applied parts according to IEC 60601-1 classification. 
Protection degree	IPX0 standard device
Line voltage	99-132 V 198-264V
Rated line voltage	110-120V 220-240V
Line frequency	50/60Hz
Maximum line current	14A @115V 50/60 Hz 6A @ 230V 50/60 Hz
Technical factors for maximum line current	86kV, 12.5mA
Power consumption	1.8kVA @ 115V 50/60 Hz 1.4kVA @ 230V 50/60 Hz
Protection fuse (F1)	20 A T 250V 6.3x32 mm 10kA @ 125V 8 A T 250V 6.3x32 mm 200A @ 250V
Column protection fuse (F2)	4 A T 250V 6.3x32 mm 10kA @ 125V 2.5 A T 250V 6.3x32 mm 100A @ 250V
Maximum line apparent resistance	0.2 Ω max (99-132V) 0.5 Ω max (198-264V)
Line voltage regulation	< 3% @ 99 V~
Rated output voltage (kV)	60 – 86 kV, with 2 kV steps
Anodic current	2 – 12.5 mA, with R20 scale steps (2, 2.2, 2.5, 2.8, 3.2, 3.6, 4, 4.5, 5, 5.6, 6.3, 7.1, 8, 9, 10, 11, 12.5)
Total filtration	≥ 2,5 mm Al eq. @ 86 kV ref. IEC 60601-1-3 Par. 7.1

Exposure times	
Panoramic exam (PAN)	14 s Adult / 12.8 s Child
Half panoramic exam	7.7 s Adult / 7.1 s Child
Ortho Rad panoramic exam	11.5 s Adult / 11.5 Child
Low dose panoramic exam	11.6 s Adult / 10.4 s Child
Frontal dentition	4.1 s Adult / 4.1 Child
Bitewing Right, Bitewing Left	3.1 s Adult / 3.1 Child
Bitewing Right & Left	6.2 s Adult / 6.2 Child
TMJ mouth closed/open	10.6 Adult / 10.6 Child
TMJ single phase	5.3 Adult / 5.3 Child
Sinus P/A projection	9 Adult / 9 Child
Latero lateral 18x24 and 18x18 cephalometric exam	9.1 s HD / 4.4 s HS
Latero lateral 24x24 and 24x18 cephalometric exam	12.1 s HD / 5.8 s HS
Latero lateral 30x24 and 30x18 cephalometric exam	15.1 s HD / 7.3 s HS
Antero posterior 24x24 and 24x18 cephalometric exam	12.1 s HD / 5.8 s HS
Carpus	4.4 s
Carpus HD	9.1 s
Exposure time accuracy	± 5 % or ± 20ms whichever is greater
Exam modes	
Exam selection	• Automatic selection for Adult and Child, 3 Sizes • 3 biting modes (Panoramic exam) • Manual selection
Panoramic exam	• Standard panoramic • Half panoramic Left/Right • Ortho Rad panoramic • Low dose panoramic • Frontal dentition • Bitewing Left/Right • Bitewing Left and Right
TMJ (Temporal Mandibular Joint) exam	TMJ closed and open mouth
Sinus exam	Sinus P/A projection

Cephalometric exams	
Lateral projections	formats 18x24 cm, 24x24 cm, 30x24 cm and 18x18 cm, 24x18 cm, 30x18 cm
Antero-posterior projections	format 24x24 cm and 24x18 cm
Carpus exam	format 18x24 cm

Note of cephalometric image formats:

For user convenience, the CEPH projections are named following the conventional format of the film-cassettes (24 cm), although the vertical active area of the cephalometric sensor is 22.8 cm.

Image magnification	**Geometric magnification**	**Magnification after software correction**
Adult / Child standard Panoramic	1 : 1.23 (constant over dentition part)	1 : 1 (*)
TMJ open/closed mouth	1 : 1.20 (nominal)	1 : 1 (*)
Sinus	1 : 1.22 (nominal)	1 : 1 (*)
Cephalometric exams	1 : 1.1 (nominal)	1 : 1 (*)
Carpus exam	1 : 1.06 (nominal)	1 : 1 (*)

(*) Warning

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

Note

I-MAX 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". I-MAX follows a rototranslation path which maintains the magnification factor as stated in the Technical Characteristics of each type of exam as constant along this "standard" shape and in the dentition area. The patient's anatomy can differ significantly from the statistical model, so the magnification factor is not maintained and can be different from the value stated. Based on his experience and competence, the user has to judge this variation.

IN ANY CASE, RADIOGRAPHY IMAGES CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE IMAGE.

Tube-head characteristics	
Model	MPV 05
Manufacturer	Owandy Radiology
Maximum tube voltage	86 kV
kV accuracy	± 8 %
Maximum anodic current	12.5 mA
Anodic current accuracy	± 10 %
Duty cycle	1 : 16
Reference loading conditions related to maximum energy input to the anode	2812.5 mAs/h @ 86 kV
Nominal power	1.075 kW (86 kV – 12.5 mA)
Total filtration	≥ 2.5 mm Al eq. @ 86 kV
HVL (Half value layer)	> 3.2 mm Al eq. @ 86 kV
Transformer insulation	Oil bath
Target angle and reference axis	See Figure 3
Cooling	By convection
Leakage radiation at 1 m	< 0.5 mGy/h @ 86 kV – 12.5 mA – 3s duty cycle 1/16
Tube-head maximum thermal capacity	310kJ

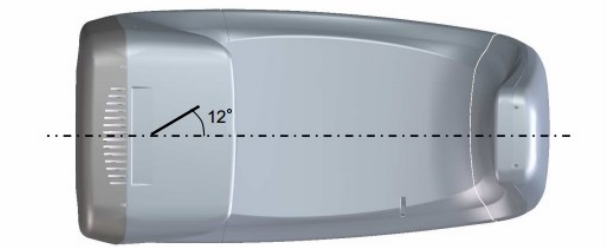


Figure 3: Tube-head target angle (view from the bottom)

X-ray tube characteristics	
Manufacturer	CEI
Type	OPX 105-12
Nominal focal spot	0.5 EN 60336
Inherent filtration (Permanent)	0.8 mm Al eq. @ 86 kV
Anode tilt	12°
Anode material	Tungsten
Nominal maximum voltage	110 kV
Filament max current	4 A
Filament max voltage	6.7 V
Anode thermal capacity	30 kJ
Anode thermal capacity during continuous operation	300 W
Laser centring devices	
2 laser beams are used for patient positioning; beams that align the sagittal and Frankfurt planes (please refer to relevant paragraphs for a detailed explanation).	
LN60-650	
Wave length	650 nm
Divergence	< 2.0 mRad
Optical power on the working surface	< 1 mW
Laser class	Class 1 laser product according to IEC standard 60825-1:2014
LN60-635	
Wave length	635 nm
Divergence	< 2.0 mRad
Optical power on the working surface	< 1 mW
Laser class	Class 1 laser product according to IEC standard 60825-1:2014
03015L	
Wave length	650 nm
Divergence	< 2.0 mRad
Optical power on the working surface	< 1 mW
Laser class	Class 1 laser product according to IEC standard 60825-1:2014
IDT065001P	
Wave length	640 nm
Divergence	< 2.0 mRad
Optical power on the working surface	< 0.39 mW
Laser class	Class 1 laser product according to IEC standard 60825-1:2014
Panoramic and Cephalometric Digital sensor	
Detector type	CMOS detectors with CSI scintillator

Sensitive Area (H x L)	228 x 6.7 mm2
Pixel dimensions	99 µm 198 µm (2x2 binning)
Number of pixel (H x L)	2304 x 68 (non-binning mode)
Grey levels	16384 (14 bit)
Resolution (spatial frequency at CTF=5%)	5 lp/mm (non-binning mode)
Sensor cover attenuation equivalent	< 0.4 mm Al eq.
Panoramic only Digital sensor	
Detector type	CMOS detectors with CSI scintillator
Sensitive Area (H x L)	152 x 6.7 mm
Pixel dimensions	99 µm 198 µm (2x2 binning)
Number of pixel (H x L)	1536 x 68 (non-binning mode)
Grey levels	16384 (14 bit)
Resolution (spatial frequency at CTF=5%)	5 lp/mm (non-binning mode)
Sensor cover attenuation equivalent	< 0.4 mm Al eq.
Mechanical characteristics	
Focal spot to image receptor distance (panoramic)	50 cm (20")
Focal spot to image receptor distance (cephalometric)	165 cm (65")
Telescopic motorised column run	70 cm (27"1/2)
Maximum total height	223 cm (88")
Weight	118 kg (260 lbs)
Working conditions	
Minimum room size (please refer to the Service Manual)	186 x 121 cm (75"x49")
Recommended room size (please refer to the Service Manual)	200 x 130 cm (80"x52")
Working temperature range	+ 10°C ÷ + 40°C
Working relative humidity (RH) range	30% ÷ 75%
Working atmospheric pressure range	700 ÷ 1060 hPa
Temperature range for transport and storage	- 20°C ÷ + 70°C
Humidity range for transport and storage	< 95% without condensation
Minimum atmospheric pressure for transport and storage	630 hPa

Note

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

6.1 Dimensions

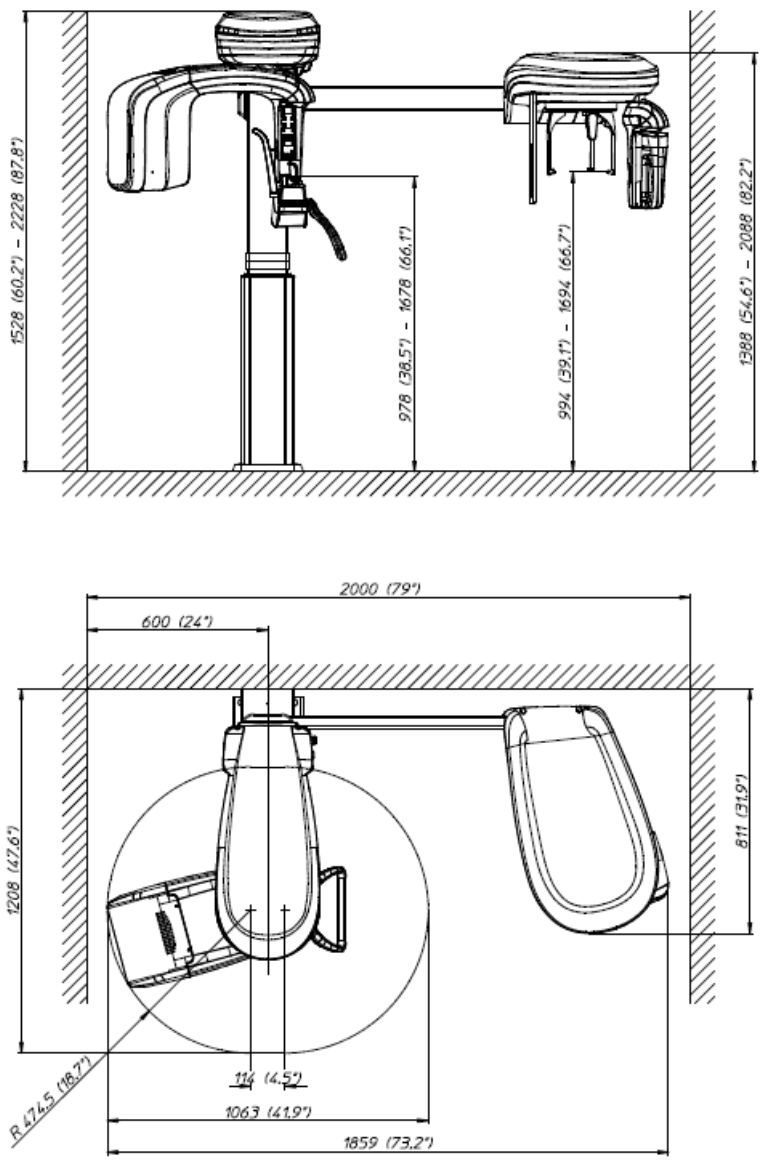


Figure 4: I-MAX dimensions - Floor-Wall mounted version

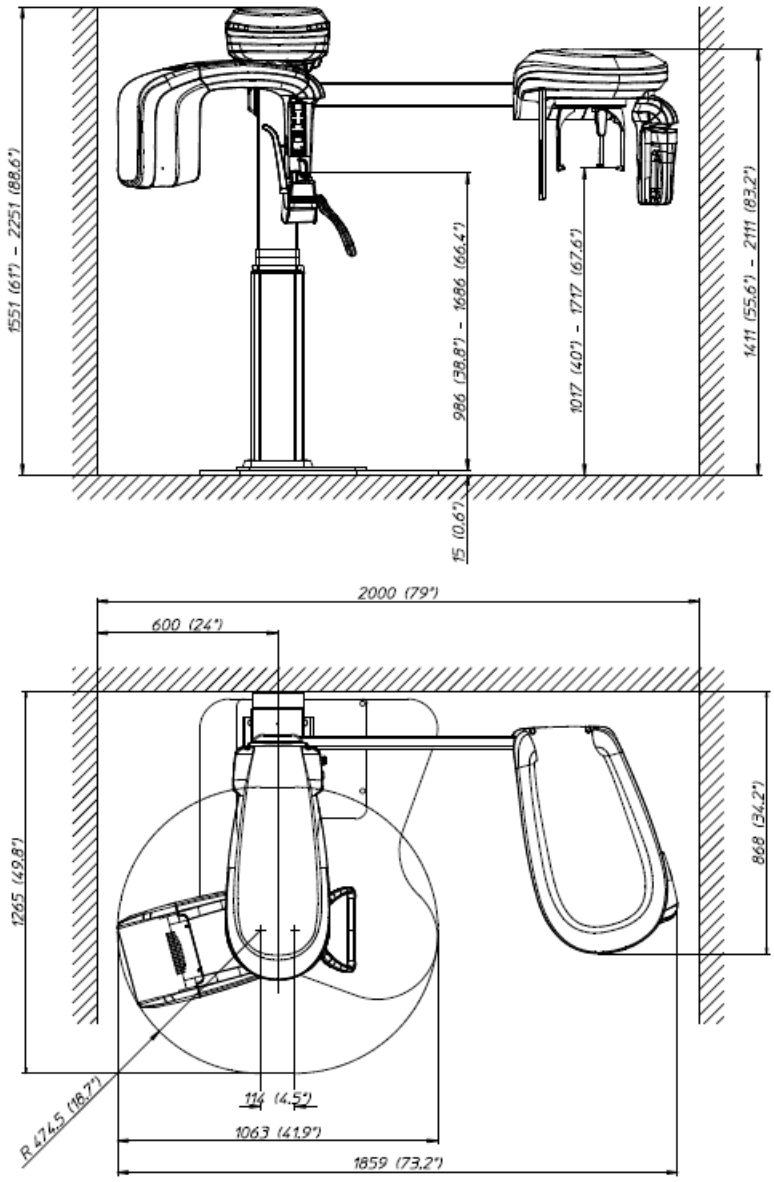


Figure 5: I-MAX dimensions – Free-standing version

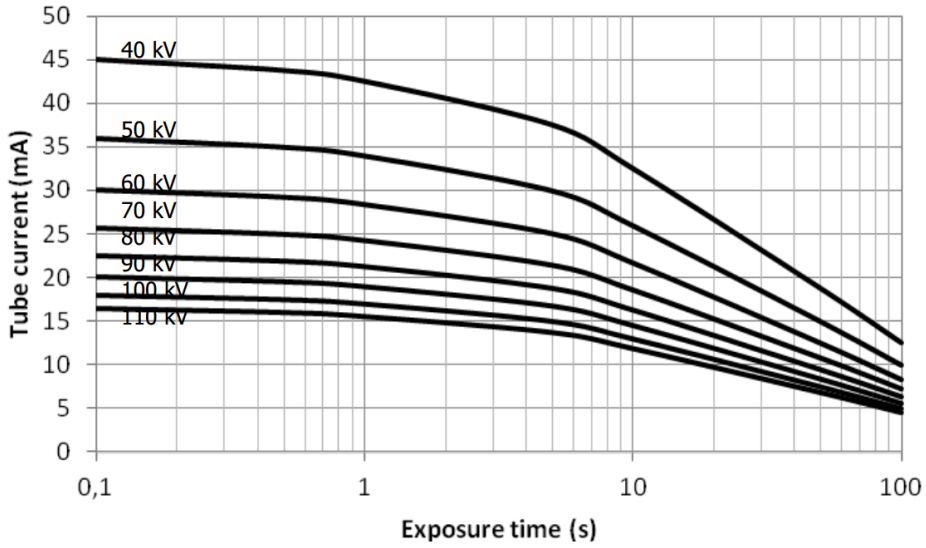
Warning for free standing floor mounted unit

In case the unit shall be moved for service or other extraordinary operation, maximum attention shall be put to prevent the unit from tilting and falling to the ground.

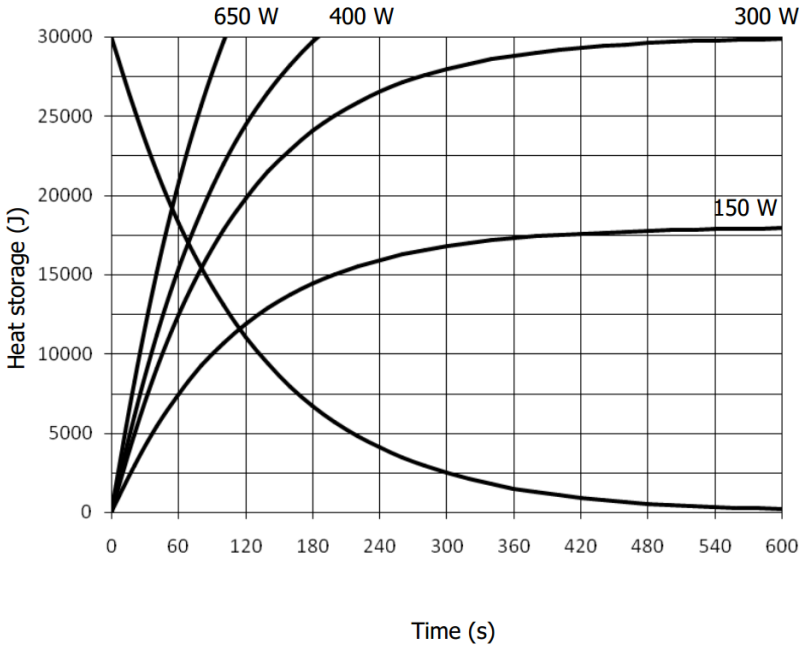
6.2 Tube loading curves, anode heating and cooling curves

Tube "CEI OPX 105-12" (0.5 IEC 336)

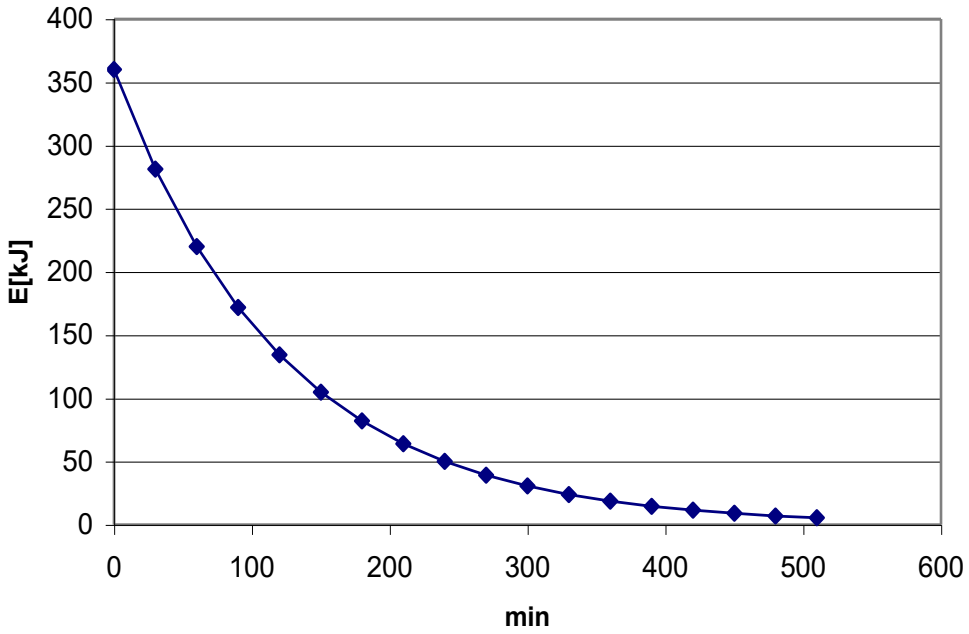
Tube loading curves



Anode heating and cooling curves



Tube head cooling curve



6.3 PC requirements

Warning
PC to be used with the machine must comply with the standard IEC 60950-1:2005.

In the following paragraphs are listed the minimum PC characteristics.

6.3.1 PC minimum characteristics

- Processor Intel Core i5 2.66 GHz Quad Core
- 8 GB RAM
- Hard drive 1TB
- Graphics card with dedicated VRAM, at least 1GB
- Operating System Windows 10 – 64bit
- Network Single port dedicated Giga-Ethernet

Note

Monitor characteristics: the PC and the monitor are not supplied with the equipment.

In order to properly view images taken with I-MAX, the PC monitor must have the following minimum characteristics:

- Resolution: 1600 x 1024 pixels
- Colour depth: 16M of colour
- Contrast: 500:1
- Luminosity 200 cd/m^2

6.4 Software

The equipment Graphical User Interface can be run with the software provided with the machine or integrated in a third party imaging and database software that complies with the following specifications: it has to be CE marked as medical device of class IIa and integrate the equipment SDK according to what stated in the document PANOW3D API programmer's guide Vn (n is the document revision), contact Owandy Radiology to have the latest revision of the programmer's document.

6.5 I-MAX – PC communication

I-MAX requires connection to a host PC to transfer images and to exchange the machine status. The communication between I-MAX and computer requires a dedicated Giga-Ethernet channel.

The information flow from I-MAX includes image data and system status messages that are exchanged only with the host PC and with no other devices on the network. The communication requires fixed IP addresses.

The Ethernet cable from the unit must be connected to such port for the unit to operate correctly.

Note

I-MAX is not intended to transmit or receive information to/or from other equipment through network/data couplings, but with the computer where the unit GUI is activated.

6.6 Reference standard

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

IEC 60601-1: 2005 (3rd ed.)
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1: 2005 (3rd ed.) + Am1:2012
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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

IEC 60601-1-6:2010 (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.)
Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-2:2014 (4th Ed.)
Electromagnetic disturbances - Requirements and tests.

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

IEC 60601-1-3:2008 (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 (1st ed.)
Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of extra-oral dental X-ray equipment.

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

IEC 62366:2007 (1st Ed.) + Am1:2013
Medical devices – Application of usability engineering to medical devices.

IEC 62304:2006 (1st Ed.) + Ac:2008
Medical devices software – Software life-cycle processes.

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

IEC 60825-1:1993 (1st ed.)
Safety of laser product – Part 1: equipment classification and requirements.

IEC 60825-1:2007 (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.

ISO 10993-1: 2009 (4th ed.)
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]

ISO 10993-2: 2006 (2nd ed.)
Biological evaluation of medical devices - Part 2: Animal welfare requirements

ISO 10993-5: 2009 (3rd ed.)
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10: 2010 (3rd ed.)
Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

ISO 10993-12: 2012 (4th ed.)
Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

CAN/CSA-C22.2 No 60601-1:08
Canadian National deviations to IEC 60601-1.

CAN/CSA-C22.2 No 60601-1:14
Canadian National deviations to IEC 60601-1.

ANSI/AAMI ES60601-1:2005/A2:2010
US National differences to IEC 60601-1.

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012
US National differences to IEC 60601-1.

CFR 21
Code Federal Regulation. Sub Chapter J.

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

Classifications

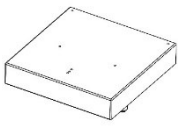
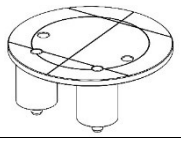
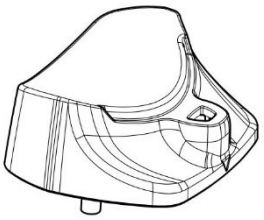
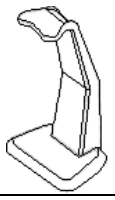
I-MAX is an electrical medical X-ray device classified as class I type B according to EN 60601-1, with continuous operation at an intermittent load.

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

According to Canadian MDR, the equipment belongs to class II.

According to FDA 21 CFR, the equipment belongs to class II.

7. REMOVABLE PART LIST

NAME	DESCRIPTION	IMAGES
Centering tool	Dedicated tool to check 2D image quality	
Support Plate	The support plate allows to check the laser alignment and to hold the centering tool	
Standard Chin Support	Standard chin support for panoramic examination mode	
Panoramic Chin Support Low	It's a panoramic chin support, lower in height, which can be used in standard panoramic exams to ensure a better view of the lower section of the chin for patients with a particular anatomy. This chin support is marked by a down arrow "▼" on the front of the chin support itself.	
TMJ Positioner	Specific positioner which allows to perform the open/closed mouth TMJ exam.	
Maxillary-Sinus Chin Support	Dedicated chin support ensuring a perfect coverage of the Maxillary Sinus area.	

8. QUALITY ASSURANCE PROGRAM

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

Frequency	Type of check	Done by	Reference
Daily	Functioning of the indicator lights	User	Paragraph 8.2
Daily	Laser alignment check	User	Paragraph 8.3
Monthly	Panoramic image quality check	User	Paragraph 8.4.1
Monthly	Cephalometric image quality check	User	Paragraph 8.4.3
Yearly	Dosimetry test	Authorized personnel	Paragraph 8.5

Note

It is recommended to perform the quality assurance procedures either with the suggested frequency or with the frequency required by local regulations if higher.

8.1 Quality check tools

The following tools[1] are required to perform the quality check:

- Support plate: used to check laser alignment and to hold the centering tool
- Centering tool: used to check image quality
- QuickVision software: used to acquire image and perform measurements
- PhD_C_Test software: used to perform exposure without arm rotation. The PhD_C_Test.exe is located at C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C
- kV meter (NOT provided with the equipment): used to measure exposure parameters.

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

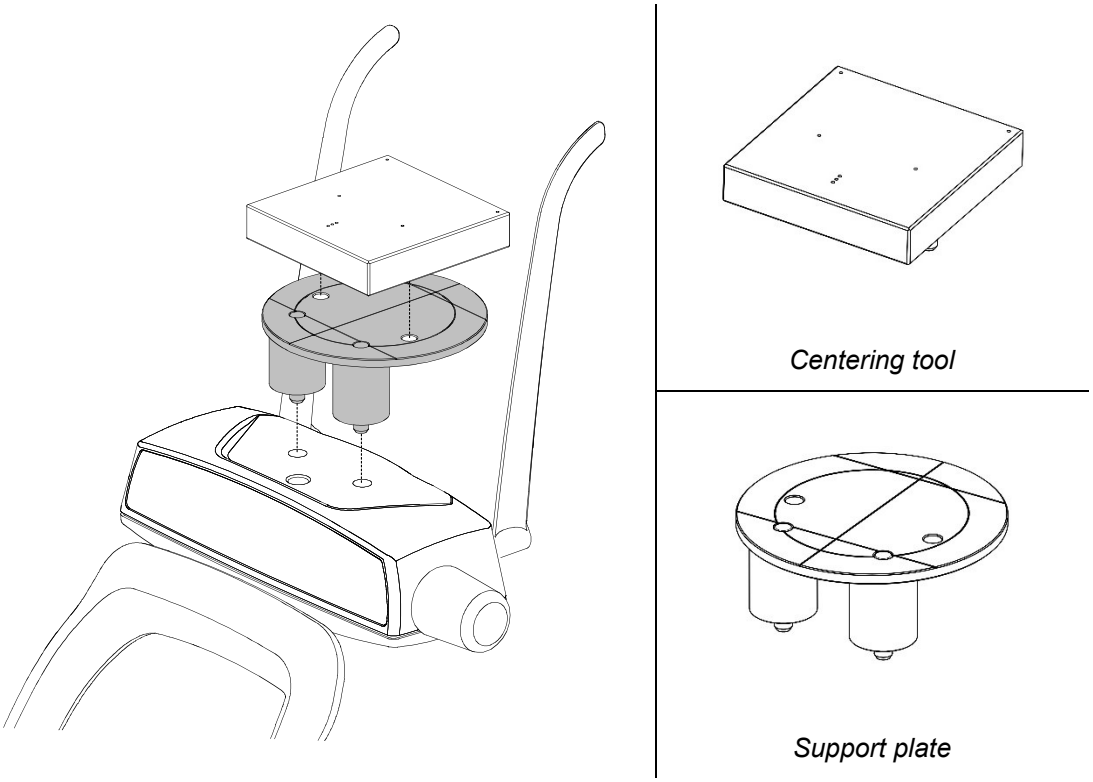


Figure 6: Support plate and centering tool positioning

[1] For removable parts and accessories order codes please refer to the document *I-MAX Spare Parts Guide*

8.2 Functioning of the indicator lights

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

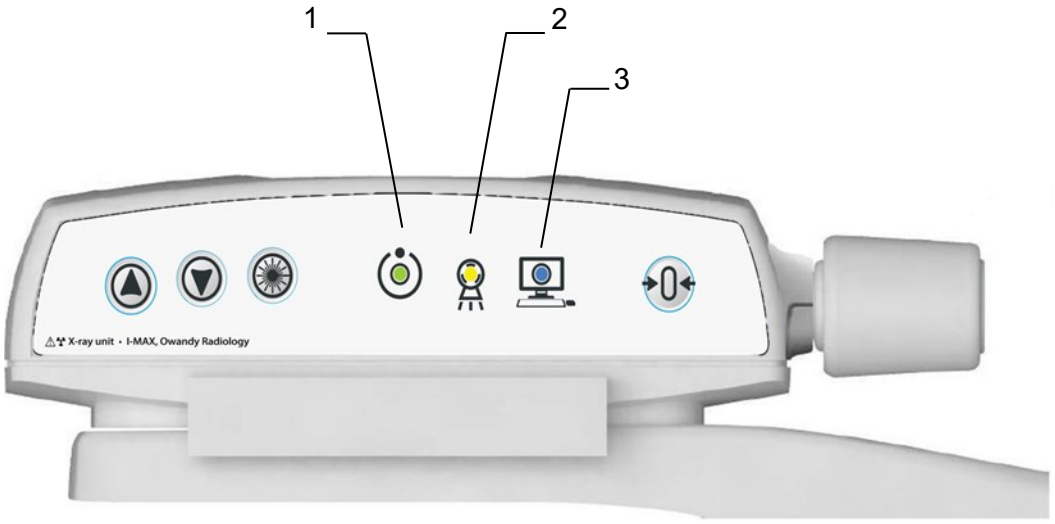


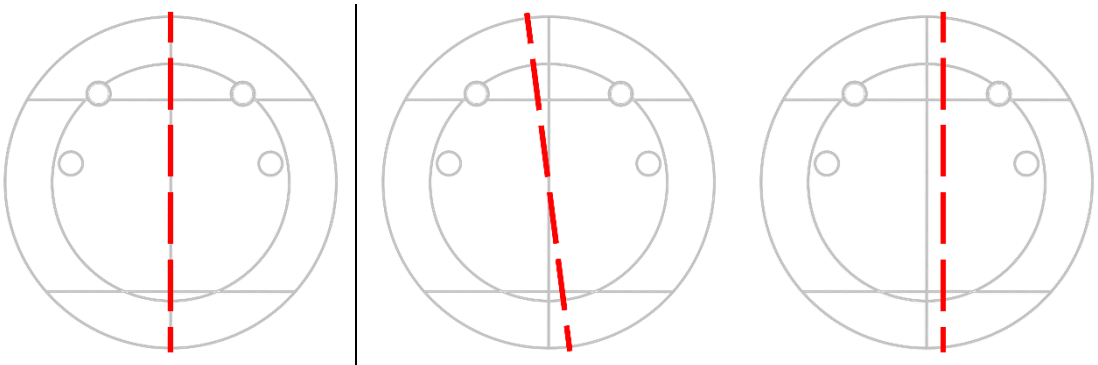
Figure 7

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

8.3 Laser alignment check

Power ON the unit and perform the axis reset by pressing the >O< button.

At the end of the axis positioning, place the support plate (Figure 6) 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 8

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

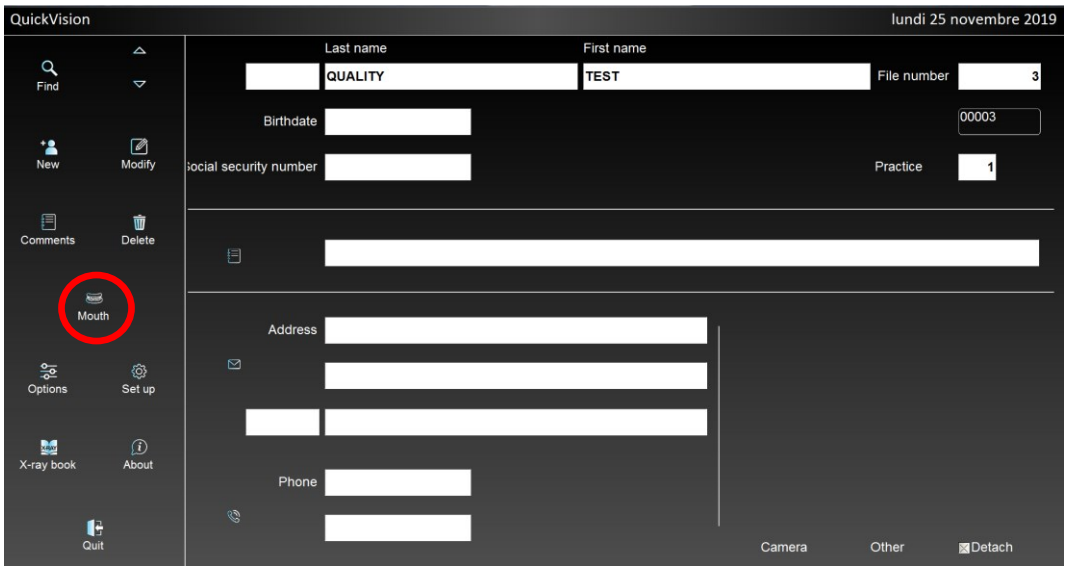
8.4 Panoramic and CEPH image quality check

Warning

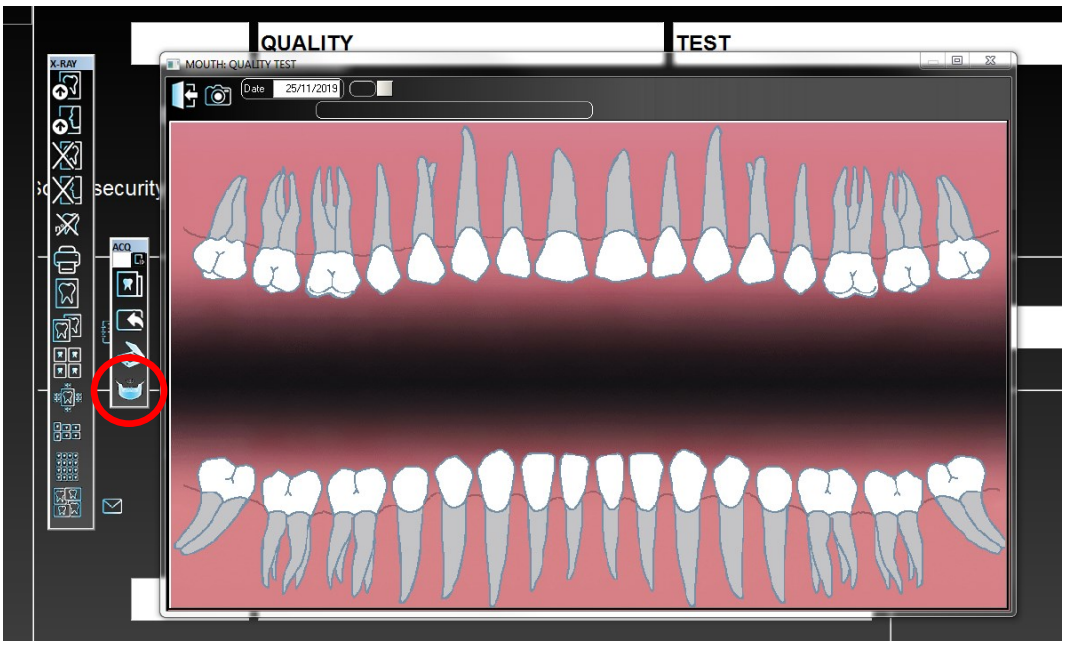
X-rays will be emitted during the performance of the following operations. It is recommended to use the greatest caution and to comply with local safety regulations and laws.

8.4.1 Panoramic image quality check

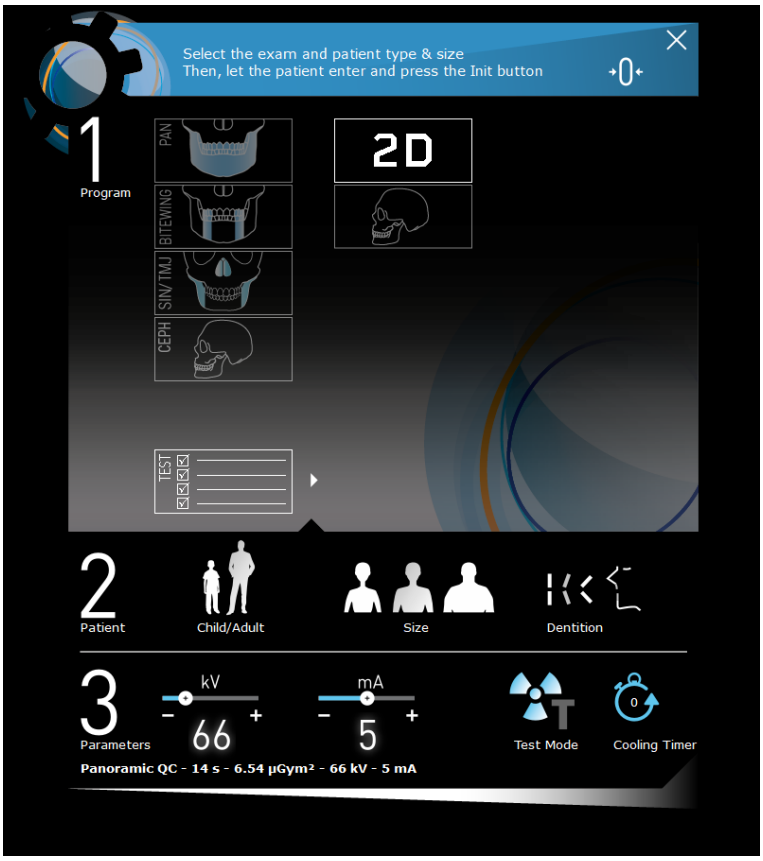
1. Switch ON the unit (see paragraph 9.1.1)
2. Open QUICKVISION software and open the patient "Quality Test". If not present, create a new patient (Name: "Quality"; Family name: "Test").
3. Select the “Mouth” icon



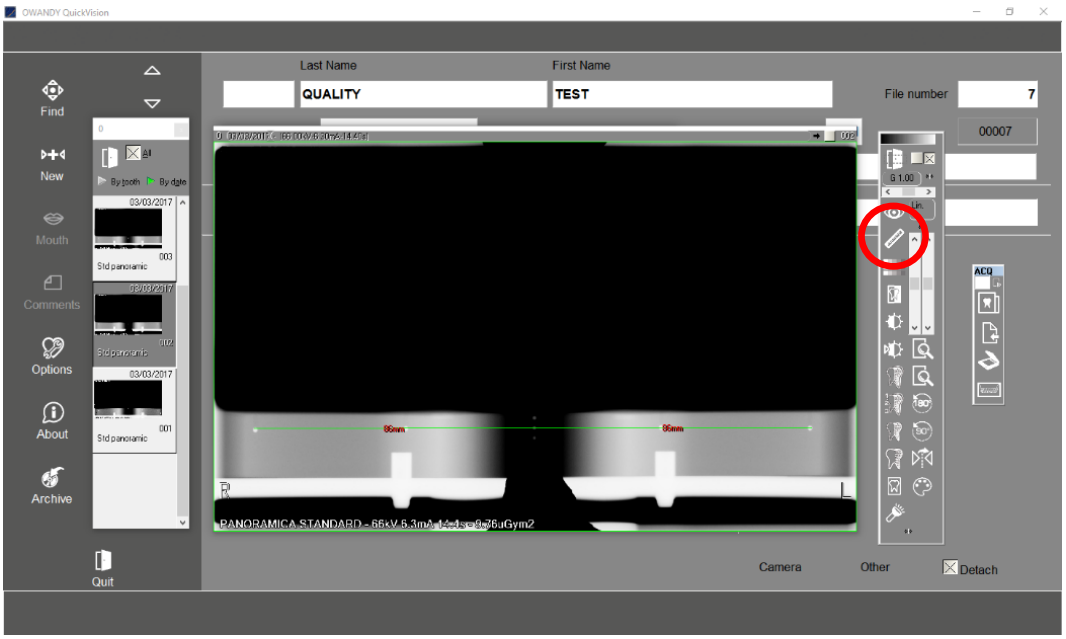
4. From the "ACQ" toolbar, click on the highlighted button to open the virtual keyboard.



5. Mount the centering tool on the support plate and place it on the chin rest support (Figure 6).
6. On the main menu of the virtual interface, select "Test" exam, the following image will be displayed:



7. Select "2D" exam.
8. Make an exposure at 66kV, 6.3mA (see chapter 8.6.1.).
9. Select the "Ruler" icon and measure the distance between the two external spheres; this value must be 171 mm+/-2mm.



In case the test fails, call technical assistance.

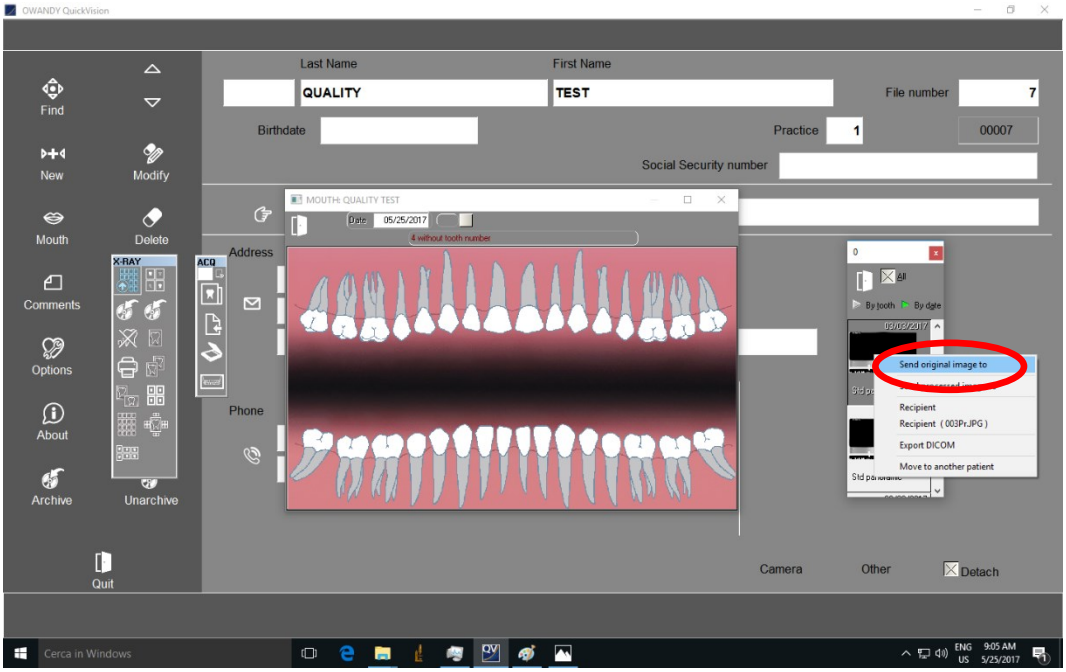
10. Measure the distance between the left external sphere and the central one and the distance between the right external sphere and the central one: the difference of these values must be maximum 2mm.

    In case the test fails, call technical assistance.

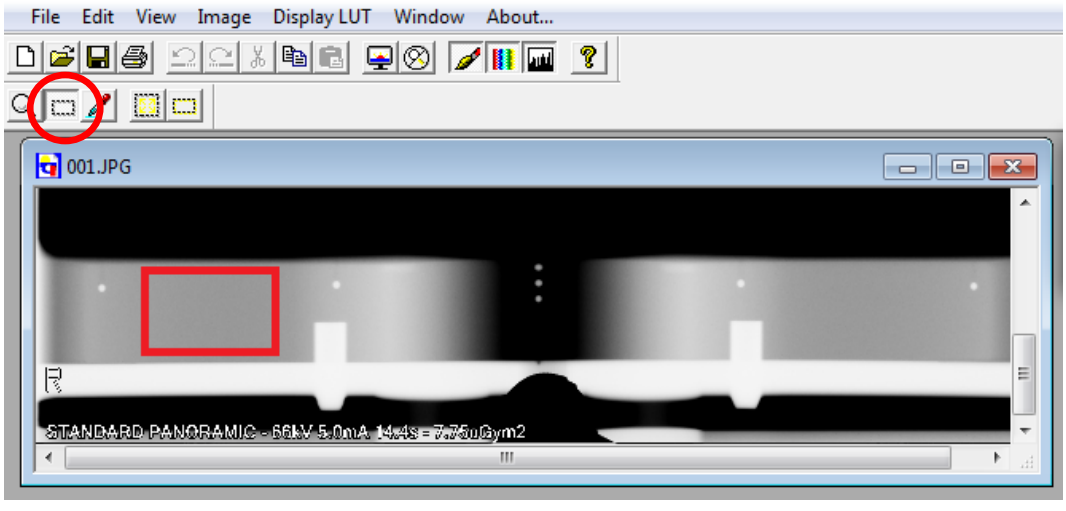
11. Record the tests results in the log book at paragraph 8.6.1.

8.4.2 Signal to noise check

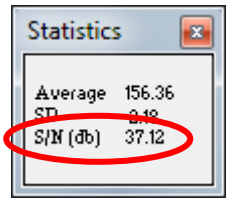
1. In QUICKVISION, open the patient "Quality Test" and select the "Mouth" icon.
2. From the X-RAY toolbar select the "X-Ray" icon. Right click on the image taken in the previous paragraph and select from the drop-down menu "Send original image to". Save the image on the Desktop.



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



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

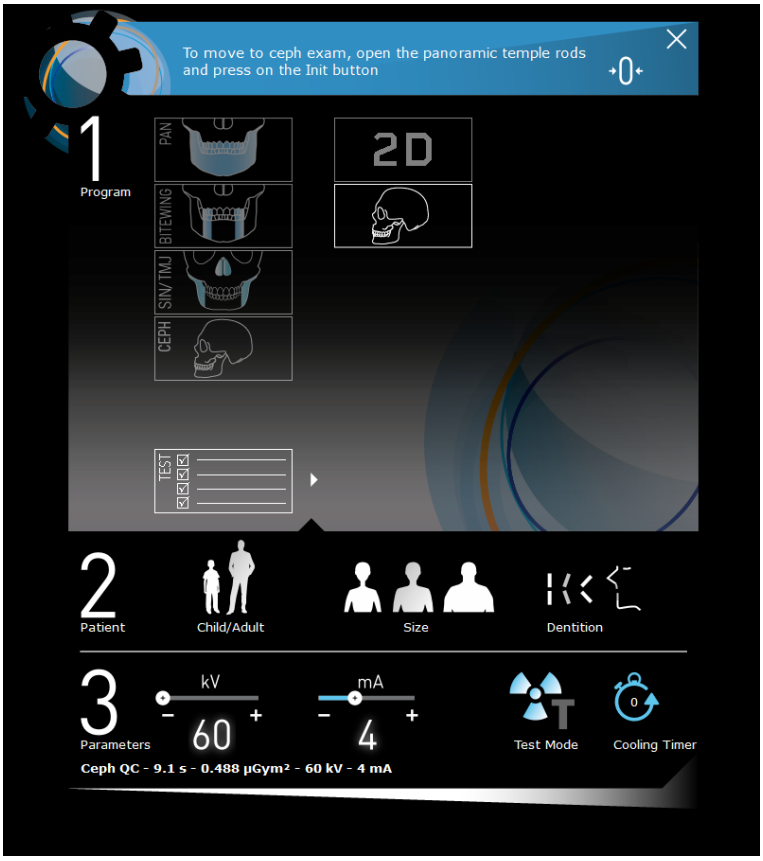


Record the test results in the log book at paragraph 8.6.1.

In case the tests fail, call technical assistance.

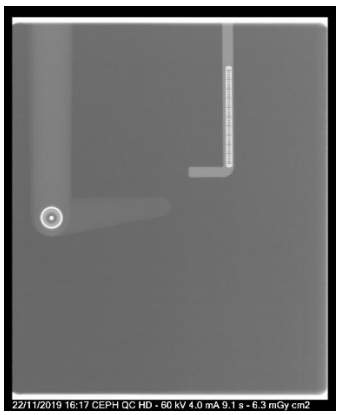
8.4.3 Cephalometric image quality check

1. Follow steps 1 to 4 of the paragraph 8.4.1 (panoramic image quality check).
2. Remove the centering tool from the chin rest (see step 4 of the panoramic image quality check).
3. On the main menu of the virtual interface, select "Test" exam, the following image will be displayed:



4. Select "CEPH" exam.
5. Prepare the machine to take a CEPH exam (refer to paragraph 10.2), rotate the CEPH head support to the latero lateral position.
6. Make an exposure at 60kV, 4mA.

7. Verify that the image of the small sphere of the ear pin far away from the detector is inside the circle of the ear pin close to the detector.



8. Record the tests results in the log book at paragraph 8.6.1.

8.5 Dosimetry test (paragraph for authorised personnel)

Note

The dosimetry test has to be performed only by authorized personnel.

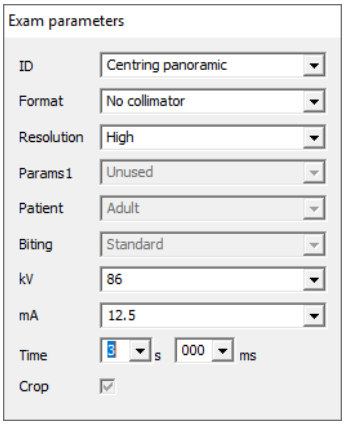
The present paragraph explains the procedure for dosimetry test with non-invasive method. For further details, please refer to Service Manual.

Warning

The device collimator gives a narrow X-ray beam.

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

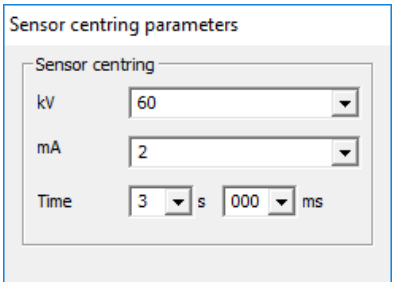
1. Place the probe of the dosimeter on the sensor plastic cover.
2. Open the PhD_C_Test software (located at C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C) and check that the unit is connected to the PC (the message "MCU is connected" is displayed in the bottom left corner of the program window).
3. From the "Exam parameters" panel select the ID as "Centring panoramic". Select format as “No collimator”.



Note

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

4. In the "Sensor centring parameters" panel set the following exposure parameters: 60kV, 2mA, 3s.



5. Press the X-ray button to take an exposure and verify that the measured values are in the acceptance limits listed in the Table at point 6.
6. Take a second exposure setting the following parameters: 86 kV, 12.5 mA, 3 s and verify that the measured values are in the acceptance limits listed in the following table.

kV	mA	t (s)	kV acceptance limits	Time acceptance limits
60	2	3	55.2 to 64.8 kV	2.85 to 3.15 s
86	12.5	3	79.1 to 92.8 kV	2.85 to 3.15 s

7. In case the test fails (result does not match the indicated values), proceed with the following actions:
   - Check the probe position and repeat the test
   - If the values are still out of range, perform the test using the invasive method as described in the Service manual
   - If the values are still out of range, call technical assistance.
8. Record the test results in the log book at paragraph 8.6.2.

8.6 LOG book

8.6.1 Image quality check

	Panoramic exam			Cephalometric exam
	Dimension	**Symmetry**	**Signal to noise**	**Sphere inside the circle**
Acceptance range->	**166 - 170 mm**	**≤ 2 mm**	**≥ 25 dB**	**Yes**
Date	Measured value	Measured value	Measured value	Evaluation

8.6.2 Verification of radiological parameters

Parameter set ->	60 kV, 2 mA, 3 s		86 kV, 12.5 mA, 3 s	
Acceptance range->	**55.2-64.8 kV**	**2.85-3.15 s**	**79.1-92.8 kV**	**2.85-3.15 s**
Date	kV measured	Time measured	kV measured	Time measured

9. GENERAL INSTRUCTIONS FOR USE

9.1 Switching the device ON and OFF

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.

9.1.1 Switch-on

1. Before switching on the unit, make sure that the panoramic detector is in PAN position (see chapter 10.2.3)
2. Press the power switch located on the upper part of the equipment on the operator side to position "1". This will start the "CHECK" function, which is indicated by the LEDs lighting up. When the "CHECK" function is complete, the green LED (3 - Figure 9) on the equipment keyboard starts blinking.
3. Press >O< button on the keyboard to run the equipment axis zero

Warning

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

4. Run the “GUI” on the PC and wait for the connection between the PC and equipment; this status is indicated by the blue LED on the equipment (5 - Figure 9) and on the GUI lighting up.

9.1.2 Switch-off

Before switching off the unit, move the panoramic detector in PAN position (see chapter 10.2.3).

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

The LEDs will go off.

9.1.3 Emergency button

The equipment has a red emergency button located on the upper part of the unit, near the power switch.

The emergency button only stops the vertical column movement.

In case of an emergency column situation, press the emergency button to stop the movement.

If the column doesn't move, check that the emergency button is not pressed; rotate the button to release it.

9.2 Positioning the chin support

I-MAX is equipped with different types of supports:

- a standard chin rest fitted with a bite or a removable appendix for edentulous patients
- a tiniest chin rest fitted with a bite or a removable appendix for edentulous patients
- a dedicated support for 2D TMJ exams (Closed/Open mouth).
- a dedicated support for Carpus exam on the CEPH detector.

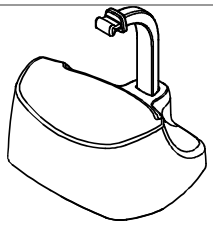
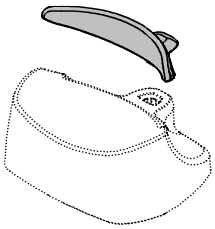
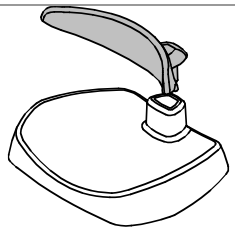
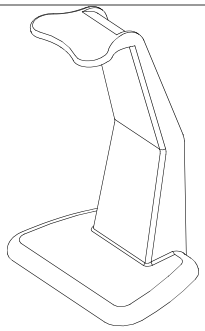
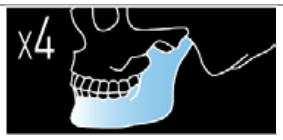
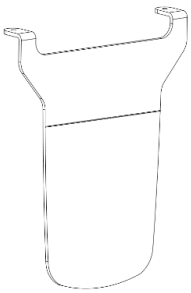
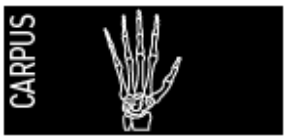
The standard chin support must be used, in panoramic mode, with all patients who can ensure a tight grip on the centring bite. The appendix for edentulous patients must be applied only for patients who cannot ensure a tight grip on the bite or are not co-operating and might move during the exam.

The tiniest chin rest must be used always with the appendix for edentulous for Sinus exams.

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

Note

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

 Standard chin support  Standard chin support with edentulous patient's appendix		2D Panoramic & Bitewing
 Thin chin support with edentulous patient's appendix		2D Sinus
 TMJ positioner		2D TMJ C/O
		2D TMJ Single phase
 Carpus positioner		Hand support for carpus exam

Temple clamps must be always used to block the patient's head.

9.3 Keyboard - Description and functions

Figure 9 shows a general view of I-MAX control Interface.

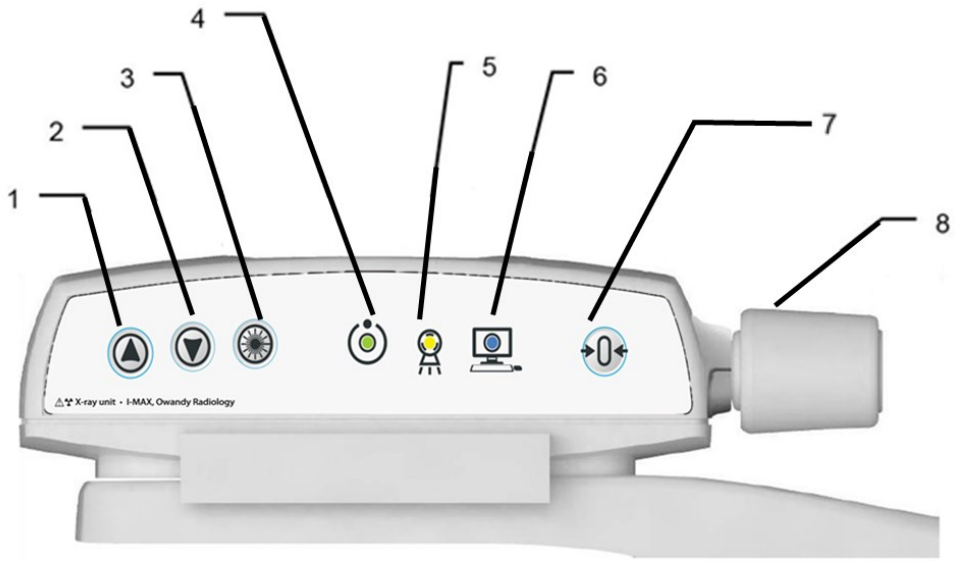
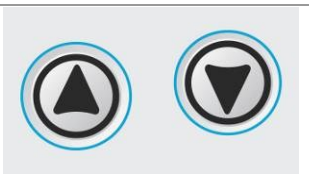


Figure 9: Keyboard

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

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

9.4 Graphical User Interface - Description and functions

All unit configuration is managed via the virtual interface (Figure 10) running on the computer. This interface enables the user to configure all technical features of the unit, to choose and adjust the exam and radiological parameters.

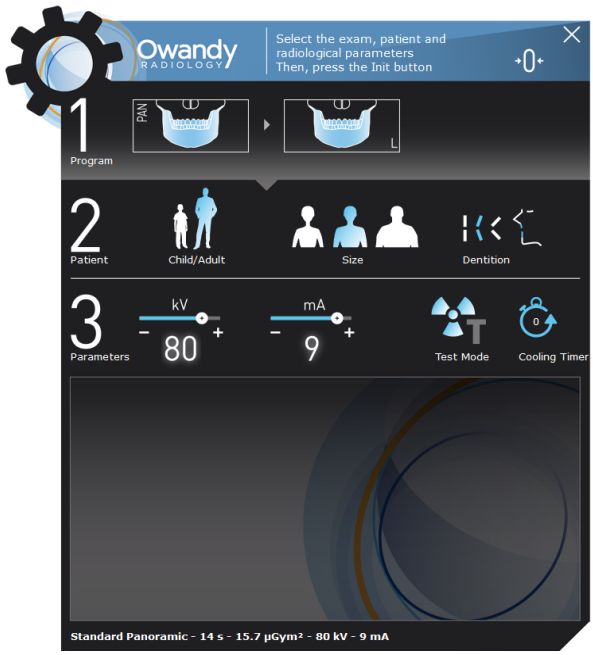
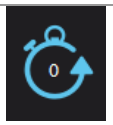
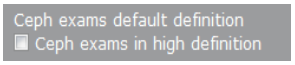
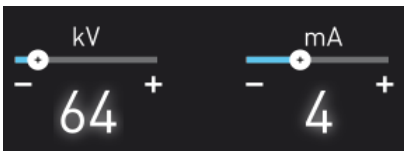
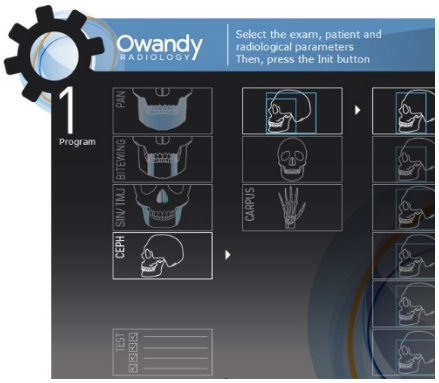
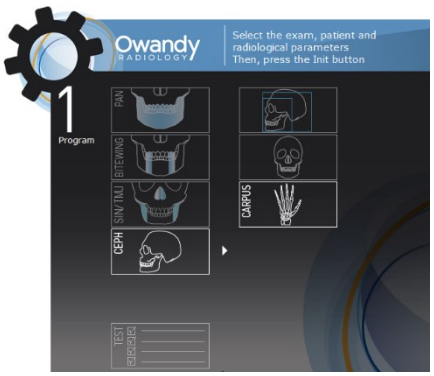


Figure 10

Adult/Child selection: the pre-set exposure values and in panoramic exam the trajectory, are automatically updated based on the current selection (see paragraph 10.3.1).	
Patient size selection: Small/Medium/Large. The pre-set exposure values will be automatically updated based on the current selection (see paragraph 10.3.1).	
Patient's type of biting: Protruded/Normal/ Retracted. This selection is only available in Panoramic mode. The position of the focus layer will be automatically updated based on the current selection.	
Test mode selection: it disables X-ray emission. Use the test mode to check for the absence of collision with the patient. Test mode may also be useful when the equipment is used on child patients, to show them how the equipment works before running the exam.	
Cooling time	
Setting: open the setup menu.	

Resolution mode: in the Setup menu, depending on the exam selected, one or more resolution modes will be available	
Virtual LED: indicates the current status of the unit: Blue = Initialization Green = Ready Red = Error/waiting for connection Yellow = X-Ray emission	
Exposure parameters selection: changes kV and mA. When the exposure parameters are manually changed, the mode indicator switches from "Pre-set" to "Manual". Return to "Pre-set mode" using the main programme selection key.	
Exam type selection is done in two steps for 2D exams. First selection: select exam modality between Panoramic, bitewing, TMJ and Sinus. Second selection: define the exam modality.	
Exam type selection is done in three steps for CEPH exams. First selection: select the CEPH program Second selection: select LL, PA or Carpus program Third selection: define the appropriate format (18, 24 or 30 cm) and the size on height (standard or reduced), except for carpus (only two steps).	 

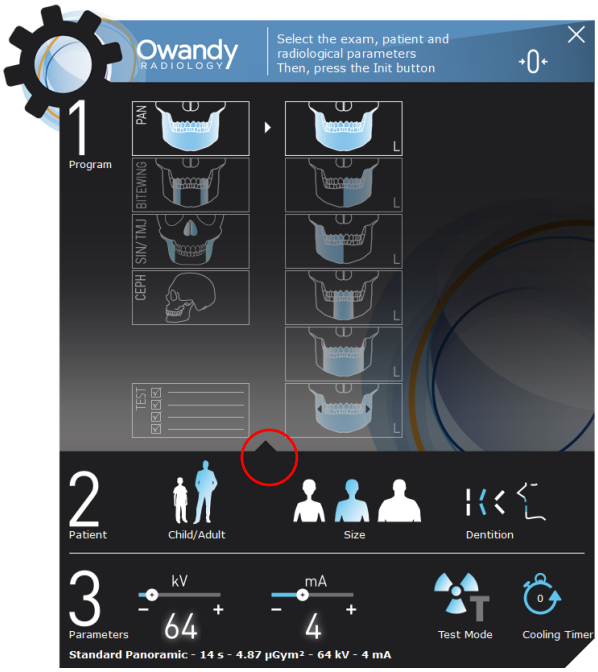
9.4.1 Main GUI area functions

The main area of the Virtual Interface, is divided in three sections:

- section "1" permit exam selection
- section "2" patient characteristic selection
- section "3" exposure parameters.

Selecting the area indicated in the red circle, it is possible to see all the available exams.

Clicking the area indicated in the red circle it is possible to reduce the Exam selection area.

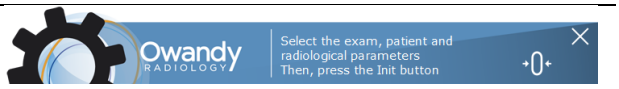


The user can choose from different options.

- Adult/Child: the correct pre-set exposure values will be automatically loaded. For Panoramic exams with child selection, the exposure values and the trajectory length are educed
- Patient Size: the correct pre-set exposure values will be automatically loaded
- kV/mA selection: the user can manually change the exposure parameters

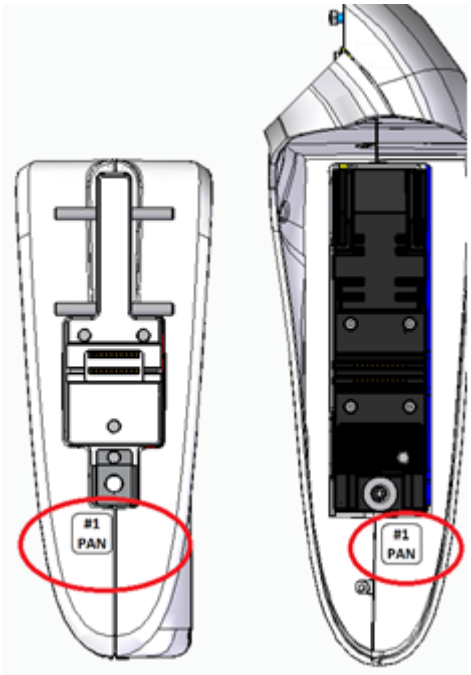
- Biting mode (when available accordingly with the current selection)
- Test mode
- CEPH format (when available accordingly with the current selection)

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



9.5 Digital sensor

I-MAX is available either in a version equipped with a single 2D CMOS detector suitable both for 2D panoramic and CEPH imaging, either in a double sensor version, equipped with a 2D CMOS PAN detector and a 2D CMOS CEPH detector.



I-MAX control system checks the consistency of safety measures that allow for correct use of the digital sensor; in particular to prevent acquisition when the image management and processing system is not ready to receive the image, it displays the message "Sensor not ready".

In the double-sensor version, be sure to use each sensor Pan or CEPH on its relevant position. If you use the Pan sensor in CEPH position or viceversa, a message “digital sensor is not ready” will be displayed.

10. MAKING AN EXAM

Note

With paediatric patient it is recommended to have a greater attention in taking exams.

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

10.1 Making a panoramic exam

1. Run the Virtual Interface on the PC and wait for the connection between the PC and equipment; this status is indicated by the blue LED lighting up on the keyboard and on the Virtual Interface.
2. Select the exam
3. Select the relevant exam options accordingly with patient characteristics.
4. Place the proper chin rest (see paragraph 9.2) corresponding to the current exam selection.

Note

To go back in the exam selection status to change exam or settings, press >O<.

5. Position the patient with the help of the lasers then close the temple clamps.
6. Press >O< button to put the equipment in the start exam position; the green LED lights up: the unit is now ready for X-rays.

Note

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

Note

Ready for X-ray status is signalled by the green LED on the equipment (3 - Figure 9) and on the GUI lighting up.

Ready for X-ray status remains as long as the equipment is in the start exam position and the GUI is connected to the equipment.

7. Press the X-ray button and keep it pressed as long as the machine is moving

Note

The rotation of the arm and the emission of the X-rays will start with a delay of about 3 seconds from when the X-ray button is pressed.

Warning

Since the X-ray button is a "dead man's switch", its release before the end of the exposure, immediately stops the X-ray emission and the arm rotation.

Error 362 or Error 760 will be displayed.

Note

When the "Test" key is selected on the GUI, the Test function is activated. In this condition, it is possible to make the unit carry out all movements made during the exam without emitting X-rays.

Test mode may also be useful when the equipment is used on child patients, to show them how the equipment works before running the exam.

Once the cycle is completed, deactivate the "Test" function by pressing the key again.

8. Once the exposure is completed, the system will rotate back to patient exit position. It is now possible to free the patient from the positioning device.
9. Press >O< to return to axis 0 position

Warning

In case of exam interruption, let the patient exit the unit, follow the instruction on the GUI, then press >O< to carry out the axis reset.

Warning

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

Note

I-MAX assumes that the digital sensor is ready: if this is not the case, the blue light indicator of "Computer connection" status (5 - Figure 9) start blinking slowly.

To reset the message on I-MAX, press "OK" on the GUI and follow the instruction provided (if on the equipment keyboard the green light indicator of "Machine Ready" status is blinking, press >O< to perform the axis reset).

Note

After the exposure, a cooling countdown will be shown on the GUI.

If you try to perform a new exam, before the cooling period has ended, a message indicating the time to wait before performing a new exam will be displayed.

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

Warning

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

10.2 Making a cephalometric exam

10.2.1 Making a cephalometric exam from panoramic position

1. Run the Virtual Interface on the PC and wait for the connection between the PC and equipment; this status is indicated by the blue LED lighting up on the keyboard and on the Virtual Interface.
2. Select the exam
3. Select the relevant exam options accordingly with patient characteristics.
4. On the GUI the following message is displayed: “To move to CEPH exam, open the panoramic temple rods and press on the Init button. A sensor is required in CEPH position”.
5. Press the button ">O<" on the keyboard and wait until the machine stop moving, the green and blue led on the keyboard blink alternatively and on the GUI the message “Move the sensor to CEPH position” is displayed.
6. The user must move the sensor from the panoramic holder (Figure 11-a) to the cephalometric holder (Figure 11-b) and when it is done the machine moves the sensor holder to the parking position.

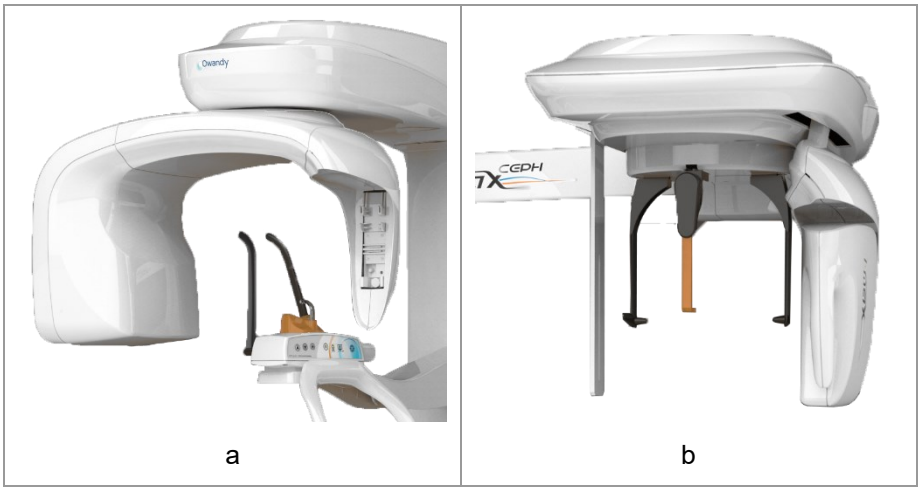


Figure 11

7. Position the patient with the help of the Frankfurt reference line on the ear rod and the nasion support (chapter 15).
8. Pressing the button >O<, the CEPH detector and the secondary collimator will move to start exam position and the green LED on the keyboard lights up: the unit is now ready for X-rays.

Note

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

Note

Ready for X-ray status is signalled by the green LED on the equipment (3 - Figure 9) and on the GUI lighting up.

Ready for X-ray status remains as long as the equipment is in the start exam position and the GUI is connected to the equipment.

Note

Make sure that the “sensor ready” symbol on the CEPH detector lights up in blue before proceeding.

9. Press the X-ray button and keep it pressed as long as you hear the “beep” sound that indicates that X-ray emission is in progress.

Note

The movements of the detector and the emission of the X-rays will start with a delay of about 3 seconds from when the X-ray button is pressed.

Warning

Since the X-ray button is a "dead man's switch", its release before the end of the exposure, immediately stops the X-ray emission and the arm rotation.

Error 362 or Error 760 will be displayed.

Note

When the "Test" key is selected on the GUI, the Test function is activated. In this condition, it is possible to make the unit carry out all movements made during the exam without emitting X-rays.

Test mode may also be useful when the equipment is used on child patients, to show them how the equipment works before running the exam or to make sure that the moving parts don’t hit the patient.

Once the cycle is completed, deactivate the "Test" function by pressing the key again.

10. Once the exposure is completed, the CEPH sensor and secondary collimator will move back to the initial position. It is now possible to free the patient from the positioning device.

Warning

In case of exam interruption, let the patient exit the unit, follow the instruction on the GUI, then press >O< t to carry out the axis reset.

Warning

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

Note

I-MAX assumes that the digital sensor is ready: if this is not the case, the blue light indicator of "Computer connection" status (5 - Figure 9) start blinking slowly.

To reset the message on I-MAX, press "OK" on the GUI and follow the instruction provided (if on the equipment keyboard the green light indicator of "Machine Ready" status is blinking, press >O< to perform the axis reset).

Note

After the exposure, a cooling countdown will be shown on the GUI.

If you try to perform a new exam, before the cooling period has ended, a message indicating the time to wait before performing a new exam will be displayed.

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

Warning

After each exam, clean the nose rest and the temple clamps thoroughly and replace the disposable ear pins protective covers.

10.2.2 Making a new cephalometric exam

1. Run the Virtual Interface on the PC clicking on the exam icon.
2. Make a new exam selection (or keep the current one).
3. Proceed as above 10.2.1 from point 7.

10.2.3 Going back to panoramic mode

1. Run the Virtual Interface on the PC; select a new panoramic exam on the GUI then press the button >O< on the keyboard and wait until the machine stop moving, the green and blue led on the keyboard blink alternatively and on the GUI the message move the sensor to panoramic position is displayed.
2. The user must move the sensor from the cephalometric holder to the panoramic holder then the machine makes an axis reset.
3. Proceed as above 10.1 from point 3.

10.3 Pre-set / Manual exposure

Note

If the previous exam was carried out manually, press the "Size Selection" key to return to pre-set mode.

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

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

Note

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

10.3.1 Pre-set exposure

Select the type of patient with the Adult/Child[1] icons, according to the following table. If child option is selected, exposure parameters are lower respect to the corresponding adult programs. In addition, the exam trajectory in panoramic programs is reduced of about 10% and of another 15% due to the child collimator (*).

Select the type of build with the Size icons (Small - Medium - Large)[2] according to the following table.

On the basis of these selections, the display will show the kV and mA settings accordingly.

Select the type of biting with the icon "Type of Biting Selection" (option available in Panoramic mode only).

(*) this feature is active by default but the user can disable it and in that case the X-ray beam size is the same as in adult selection.

Suggested size selection according to the patient weight:

Child For child patients up to 12-year-old	
Small	< 30 kg (< 66 lb)
Medium	30 to 45 kg (66 to 99 lb)
Large	> 45 kg (> 99 lb)

Adult For adolescent (greater than 12 through 21-year-old) and adult patients	
Small	< 70 kg (< 154 lb)
Medium	70 to 90 kg (154 to 198 lb)
Large	> 90 kg (> 198 lb)

[1] Adult/Child definition is related to the age according to the FDA's guidance "Premarket Assessment of Pediatric Medical Devices", Table 1 – Age Ranges of Pediatric Subgroups.

[2] According to the report "Fryar CD, Gu Q, Ogden CL, Flegal KM. Anthropometric reference data for children and adults: United States, 2011–2014. National Center for Health Statistics. Vital Health Stat 3(39). 2016", the size definition is based on the identification of three percentile ranges of the population weight distribution:

- Child: Small (<25th), Medium (25th to 75th), Large (>75th)

- Adult: Small (<15th), Medium (15th to 50th), Large (>50th), referred to the adult male weight distribution. Corresponding female ranges: Small (<50th), Medium (50th to 75th), Large (>75th).

Based on these grouping, the weight ranges are derived from Table 1 for child (choosing a representative patient of 10-year-old and rounding up male-female average weights, from Table 5 for adult male and Table 3 for adult female.

Exposure values in 2D Panoramic modes				
	Adult Patient (14 seconds)		Child Patient (12.8 seconds)	
	kV	mA	kV	mA
Small	70	8	66	6.3
Medium	74	8	68	6.3
Large	76	8	70	6.3

Exposure values in 2D Sinus mode				
	Adult Patient (9 seconds)		Child Patient (9 seconds)	
	kV	mA	kV	mA
Small	68	8	64	6.3
Medium	72	8	66	6.3
Large	74	8	68	6.3

Exposure values in 2D TMJ mode				
	Adult Patient (10.6 seconds)		Child Patient (10.6 seconds)	
	kV	mA	kV	mA
Small	70	8	62	6.3
Medium	74	8	66	6.3
Large	78	8	70	6.3

Exposure values in CEPH LL mode				
	Adult Patient (from 4.4 to 15.1 seconds)		Child Patient (from 4.4 to 15.1 seconds)	
	kV	mA	kV	mA
Small	74	8	72	7.1
Medium	76	8	74	7.1
Large	78	8	76	7.1

Exposure values in CEPH AP mode				
	Adult Patient (5.8 or 12.1 seconds)		Child Patient (5.8 or 12.1 seconds)	
	kV	mA	kV	mA
Small	76	12.5	74	11
Medium	78	12.5	76	11
Large	82	12.5	78	11

Exposure values in Carpus mode		
	Child Patient (4.4 or 9.1 seconds)	
	kV	mA
Small	62	8
Medium	62	8
Large	62	8

Note

The preset exposure parameters are meant to guide the user through the setting of the different exams. However, the user can optimise the parameters according to his needs.

Note

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

10.3.2 Manual exposure

If the pre-set kV and mA pairs are not considered suitable for a specific exam, new parameters can be set in manual mode.

To modify the kV or mA values, press any of the up or down cursors of the KV or mA parameters.

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

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

The mA value can vary between 2 and 12.5 mA according to the R20 scale.

11. IMAGE PROCESSING WINDOW

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

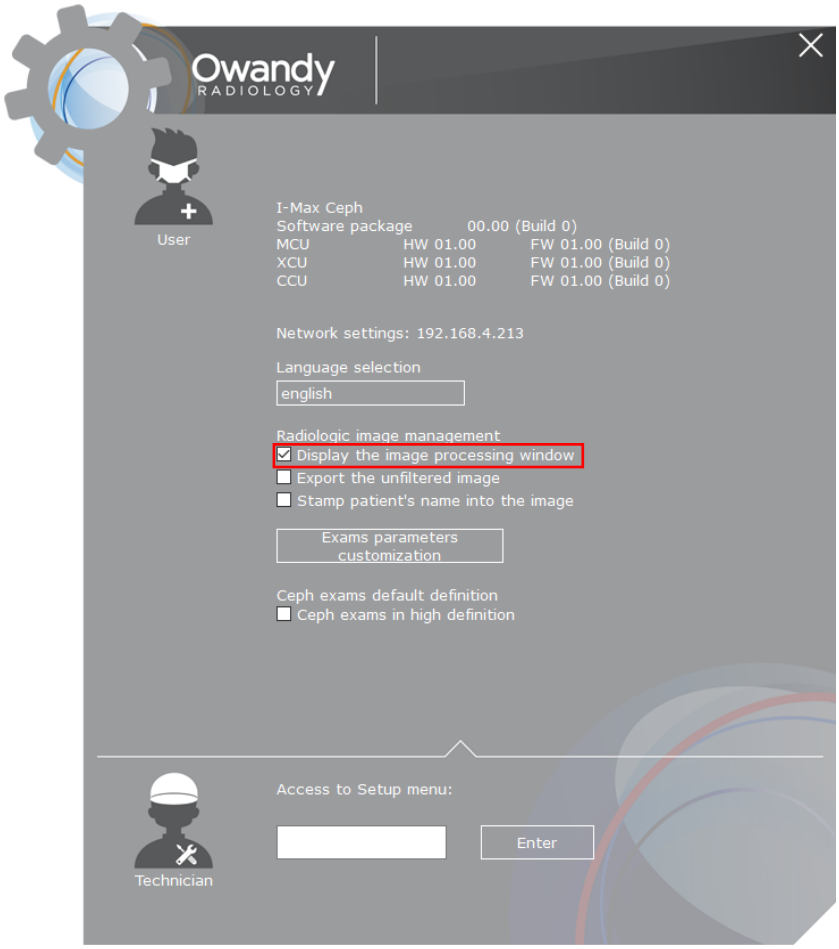


Figure 12

The Image Processing window is composed by three main area (Figure 13)

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

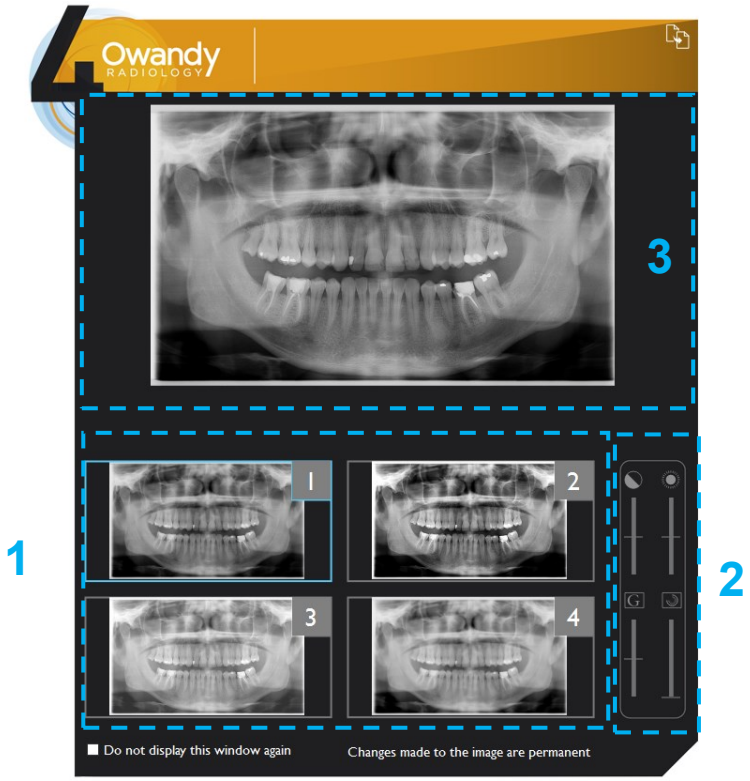


Figure 13

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

- brightness
- contrast
- gamma value
- image enhancement.

The button Save will apply the current setting to the corresponding button and will set the filter as default in acquisition (Figure 14).

The button 4 is set as default to load the original image (without post-processing) and it can be fully customized as above described.

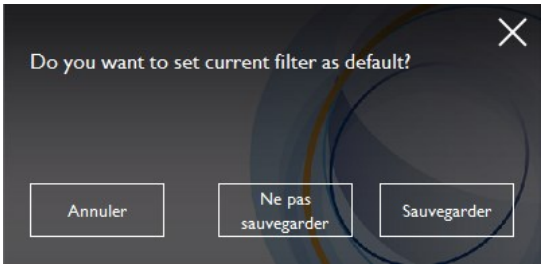


Figure 14

12. PANORAMIC EXAMS

Note

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

Note

I-MAX 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". I-MAX follows a rototranslation path which maintains the magnification factor as stated in the Technical Characteristics of each type of exam as constant along this "standard" shape and in the dentition area. The patient's anatomy can differ significantly from the statistical model, so the magnification factor is not maintained and can be different from the value stated. Based on his experience and competence, the user has to judge this variation.

IN ANY CASE, RADIOGRAPHY IMAGES CANNOT BE USED TO PERFORM CALCULATIONS OF DISTANCES, ANGLES ETC. ON THE IMAGE.

Warning

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

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

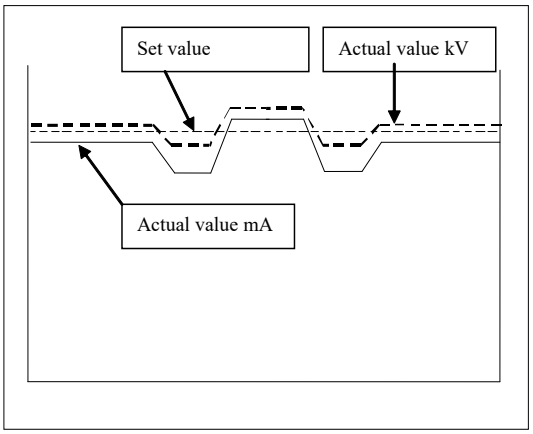
To obtain the measurement of the anatomical part, taking into consideration the enlargement factor, the length calibration factor is:

- 100 pixels = 7.8 mm (in the centre of the focus layer) in panoramic exams.
- 100 pixels = 7.9 mm (in the centre of the focus layer) in Sinus exams.
- 100 pixels = 8 mm (in the centre of the focus layer) in TMJ exams.

Note

During panoramic exams, the value of the exposure parameters varies according to a fixed curve, to compensate for variations in absorption by the patient's tissues. in this way, it is possible to obtain a good uniformity of the image contrast. In particular, the chosen value of the kV is lowered in the initial and end sections of the panoramic exam and increased in the incisors/canine zone.

The tube current varies according to the kV, also if the set value is slightly increased on the initial/end sections. These variations have the effect of compensating for greater X-ray absorption in the spinal column area. As an example, the variation of the parameters follows the curve below:

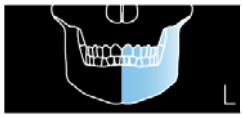


The values displayed during the panoramic exam correspond to the ones chosen by the user, while the real value in the various positions of the X-ray cycle can be different; in any case, the system guarantees that the accuracy of the exposure parameters is always within the limits set by IEC 60601-1 international standards for the safety of medical devices. In particular, in accordance with IEC 60601-2-63, the maximum deviation (including the correction according to the above curve and instrumental doubt) is within ±10% for the kV, while for the tube current it is within ±15%.

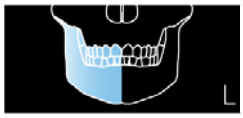
12.1 Standard Panoramic

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

12.2 Left / Right Half Panoramic



The Half Panoramic mode, right or left, means that only the corresponding half arch is irradiated; emission will start from the beginning, to just after the mid sagittal plane for the right part. For the left, it will start just before the mid sagittal plane and continue until the end of the rotation.



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

12.3 Frontal dentition

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

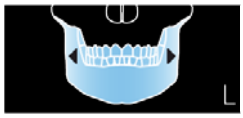
12.4 Low dose Panoramic

The low dose panoramic exam takes an X-ray only of the dental arch, excluding the ascending rami of the temporo-mandibular joint from the image; the exam is performed with the same trajectory of the standard Panoramic exam, reducing the rays' emission time.

This exam is used, for instance, during treatment continuation phases or where a lack of pathologies of the same joint is already known.

Follow the instructions for normal panoramic exams for patient positioning.

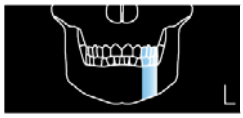
12.5 Ortho Rad dentition

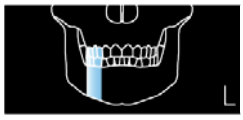


The ortho rad panoramic exam delivers an image of the pure dental arch, excluding the ascending rami branches of the temporo-mandibular joint from the image; the trajectory of the rotating arms is, however, optimised for a better orthogonality between the X-ray beam and incident sections of near teeth.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

As a consequence of the different trajectory, the focus layer, mainly in the front teeth area, is smaller and patient positioning for this exam needs more care. Follow the instructions for normal panoramic exams for patient positioning.

12.6 Single Phase Bitewing (L/R)





The bitewing mode, right or left, means that only the corresponding bite sector 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. The exam is performed with the same trajectory of the standard panoramic exam, reducing the rays' emission time.

This exam is normally when it is already known that the patient has a problem on one side of the bite-sectors of the arch, so it is possible to reduce patient irradiation.

Follow the instructions for normal panoramic for patient positioning.

12.7 Bilateral Bitewing

The bilateral Bitewing mode, right and left, means that the two bite-sectors are irradiated; the exam is performed with the same trajectory of the standard panoramic exam, reducing the rays' emission time.

This exam is normally used when it is already known that the patient has a problem on the bite-sectors of the arch, so it is possible to reduce patient irradiation.

Follow the instructions for normal panoramic for patient positioning.

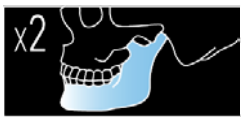
12.8 TMJ C/O

The TMJ Standard function makes it possible to obtain 4 different acquisitions on the same image, by performing two rotational movements. The 4 images represent the right and left condyle of the temporo-mandibular arch (TMJ) with closed mouth and open mouth.

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

Figure 15: TMJ Closed/Open mouth

12.9 TMJ Single Phase



A single acquisition is made to obtain 2 images representing the right and left condyle of the temporo-mandibular arch (TMJ) with closed mouth or open mouth.

	RIGHT condyle	LEFT condyle	
	1st exposure	2nd exposure	
	R	L	

Figure 16: TMJ Single phase

12.10Sinus

The image is taken on the maxillary sinus area.

13. CEPHALOMETRIC EXAMS

On I-MAX the horizontal linear scanning of the skull is performed maintaining the focus in a fixed position and guaranteeing the same projection geometry as if using a film. The X-ray source is automatically aligned to digital sensor. The use of a secondary collimator ensures the minimum level of radiation to the patient limiting the size of the fan shaped beam to the target region of interest.

A digital filter is automatically applied to lateral cephalometric images to enhance the visibility of soft tissues profile while preserving the bone structures.

Two different acquisition modes, selectable from the GUI, are available:

- HD - High Definition (no binning) for the enhancement of the finest details
- HS - High Speed (2x2 binning) for patient dose reduction and for limiting the incidence for motion artefacts.

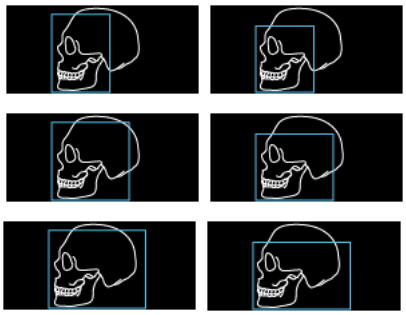
The reduced height is obtained through a dedicated mechanical collimation.

A dedicated removable plate is provided for performing hand-wrist (carpus) analysis, mainly used for the assessment of the patient's bone growth trend.

Note

Especially with paediatric patients evaluate the opportunity to use the HS mode with reduced height in order to reduce the dose delivered to the patient.

13.1 Latero-Lateral projection

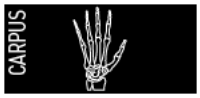


In LL mode (asymmetric) the horizontal scanning area can be selected between three lengths 18, 24 or 30 cm in full height (24cm) or reduced height (18cm).

13.2 Antero-Posterior projection (symmetric)

In AP mode (symmetric) the horizontal scanning area is fixed at 24 cm, available in full height (24cm) or reduced height (18cm).

13.3 Carpus



The Carpus mode is equivalent in size to the AP mode full height (18x24 cm) but it's available only in HD mode.

14. PATIENT POSITIONING IN PANORAMIC

Note

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

Note

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

Note

The chinrest height when the column is in its lower position is at 97.8 cm (38.5") from the floor. As a consequence, the unit can be used with patient at least 118 cm (3 ft 10.4") high.

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, removable dental prosthesis, etc.). Ensure there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to wear the protective apron, making sure to avoid interference with the trajectory of the X-ray beams.
3. Place the patient in a standing position at the Panoramic chin rest. With the "Column movement" keys (1 - Figure 9), raise/lower the column until the chin support is aligned with the patient's chin.

Warning

The equipment has a red emergency button located on the upper part of the unit, near the power switch, that only stops the column movement.

In case of an emergency column situation, press the emergency button to stop the movement.

Warning

During the patient positioning, make sure the equipment cannot collide with any object in the room.

Note

If the column doesn't move, check that the emergency button is not pressed.

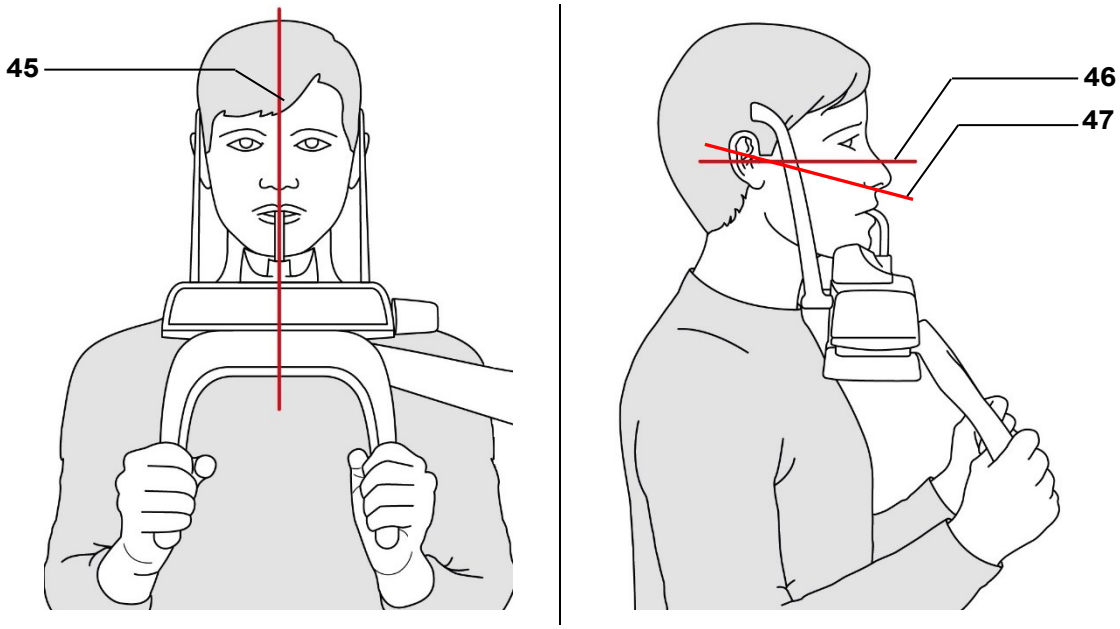
Rotate the button to release it.

In case the problem persists, power off the machine and wait for about 20-30 seconds, then power on again the machine. If the problem still persists, call technical service.

4. Position the patient with the temple clamps 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 the case of edentulous patients, he/she must rest the chin against the reference shoulder of the edentulous chin support.
5. Press the "Luminous centring devices" key (2 - Figure 9). Two laser beams will light up the sagittal medial plane line and the horizontal line. Position the patient's head in such a way as to ensure that the luminous beams fall in correspondence with respective anatomical references (Figure 17).
6. At this point, the patient has to step forward making sure of keeping his head within the pre-aligned anatomical references. This ensures a greater extension of the spine in the cervical area, improving the darkening of the X-ray in the apical area of the incisors, and avoiding the collision of the tube-head with the patient's shoulders.
7. Close the temple clamps to help the patient maintain a correct position.

Note

The laser centring devices remain on for approximately 2 minute; shutdown can be anticipated by pressing the "Luminous centring device" key (2 - Figure 9) or, with alignment complete, by pressing the "Patient entrance" key (6 - Figure 9) to begin preparation for exposure.

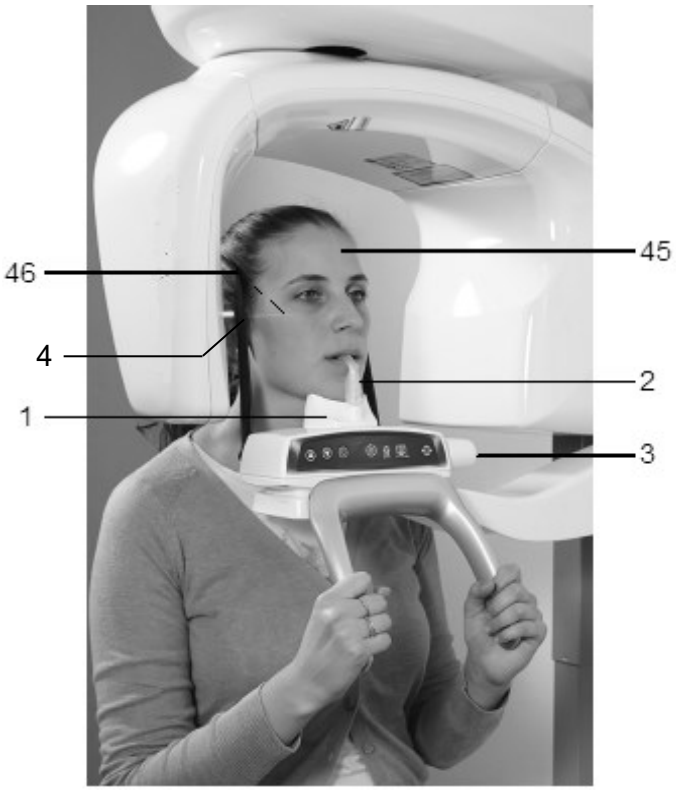


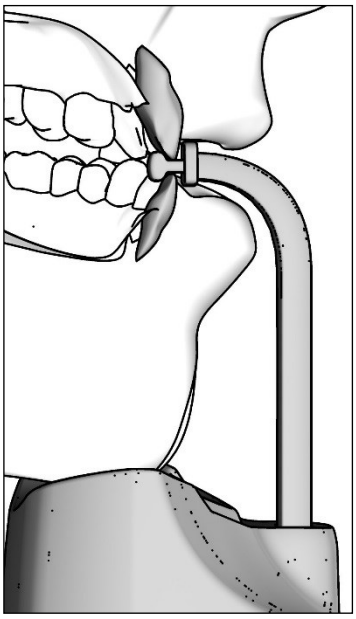
***45** - Mid-Sagittal line*

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

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

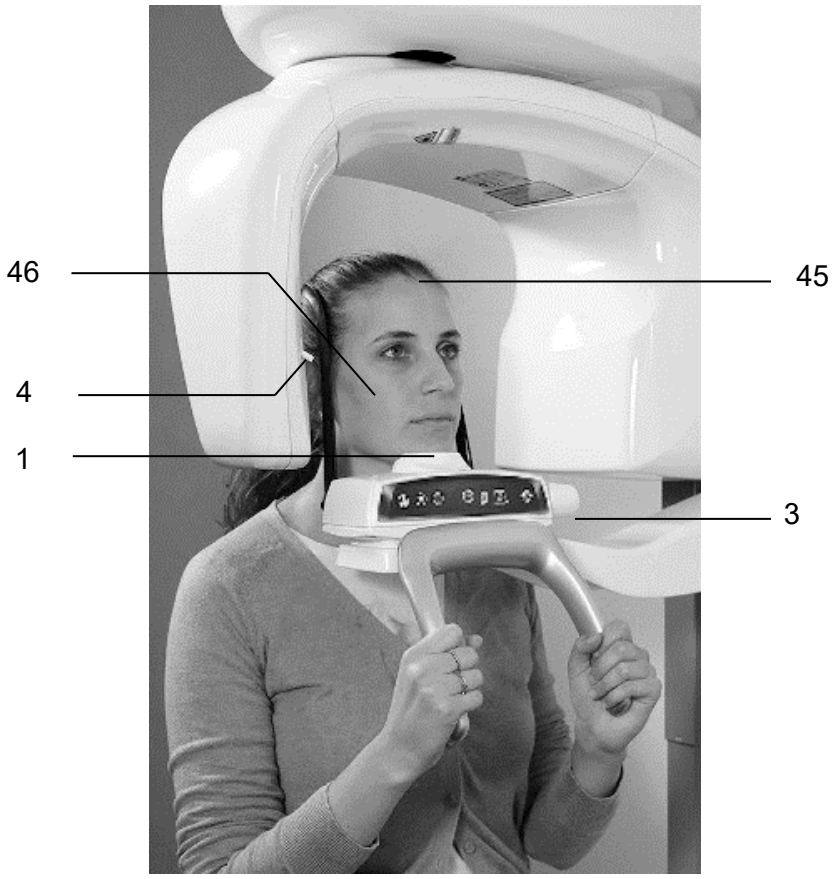
Figure 17: Reference lines





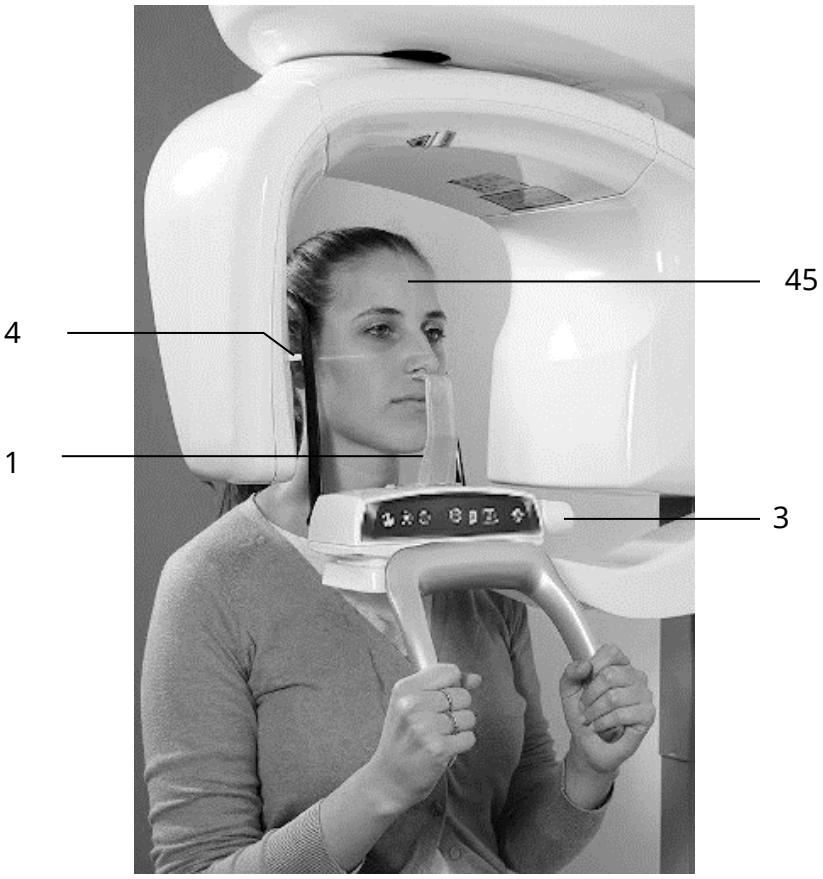
Label	Description
45	Sagittal medial line
46	Frankfurt line
1	Panoramic chin rest
2	Centring bite
3	Temple clamps closing/release knob
4	Laser Knob

Figure 18: Panoramic patient positioning



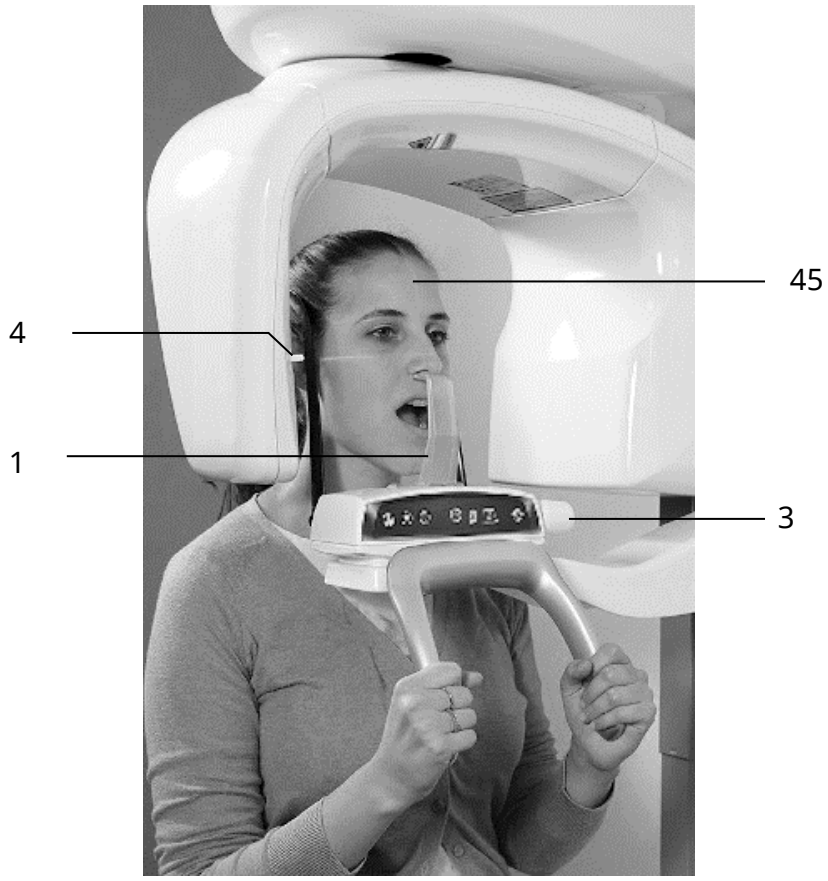
Label	Description
45	Sagittal medial line
46	Frankfurt line
1	Sinus positioner
3	Temple clamps closing/release knob
4	Laser knob

Figure 19 – Sinus positioning



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

Figure 20 – TMJ closed mouth positioning



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

Figure 21: TMJ open mouth positioning

- Mid sagittal plane must be centered and vertical.
- Frankfurt plane (the plane that identifies a line that ideally links the ear hole - the auditory meatus - with the lower part of the orbital fossa) must be horizontal.
- Spine should be well stretched.
- In case of use of the bite, patient's incisors must be positioned into the reference notch.
- Patient's tongue must be against the palate.
- Patient must stay motionless during the examination.

Note

During TMJ C/O exam, at the end of phase 1 let the patient exit, than press >O< to make the rotating arm return back and then let again the patient in to run the phase 2 of the exam.

15. PATIENT POSITIONING IN CEPH

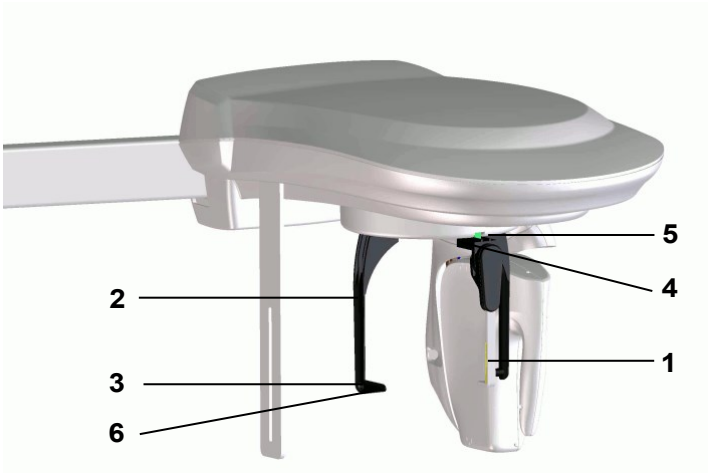
Note

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

Note

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

1. Ask the patient to remove all metallic objects located in the area to be X-rayed (necklaces, earrings, glasses, hairpins, removable dental prosthesis, etc.). Ensure there are no thick garments in the area to be X-rayed (coats, jackets, ties, etc.).
2. Ask the patient to wear the protective apron, making sure to avoid interference with the trajectory of the X-ray beams.
3. Open the ear centring device to its maximum span by pressing the ear rods release lever located on the upper part of the outer rod and pulling the rods apart.
4. Move the nose rest away outwardly to its maximum extension. Manually rotate the head positioning device according to the cephalometric projection to be made (AP or LL), by rotating the upper part of the ear centring device



1. Nose rest
2. Ear centring device
3. Pins for ear centring device
4. Ear rods release lever
5. Graduated scale
6. Frankfurt plane reference

Figure 22

5. With the keys "Column movement"  up/down set the proper position of the column, with centring pins horizontally aligned with the ear. If a Latero-Lateral examination is performed, position the nose rest in such a way to be in contact with the nasion reference point on the patient, which is the most anterior point of the frontonasal suture that joins the nasal part of the frontal bone and the nasal bones.

6. If a Postero-Anterior exam is performed, rotate the nose rest out of the imaging area. The nose rest is held in pace by a magnet.
7. Align horizontally the patient's Frankfurt plane with the help to the reference line on the external rod.
8. Adjust the head position in such a way to get the mid-sagittal plane vertical and parallel (in LL mode) or perpendicular (in AP mode) to the detector, then close the head support and block the patient head by gently pushing the ear rods towards the patient

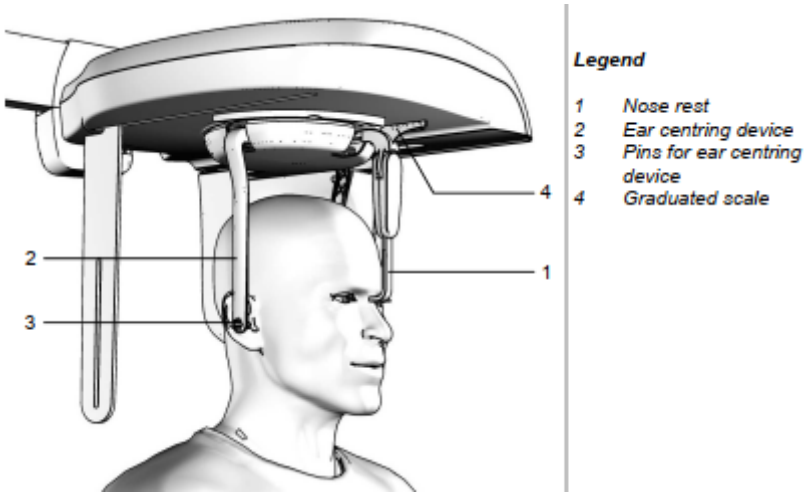


Figure 23

15.1 Bone growth assessment (Carpus)

The cephalometric device can also be used to carry out the Carpus exam, specifically intended for evaluating the state of calcification and the patient's bone growth trend. The image format is fixed to 18x24 Symmetric. It is therefore necessary to position the auricular rods and the nose-rest as for the cephalometric AP examination, in order to avoid interferences with the X-ray beam.

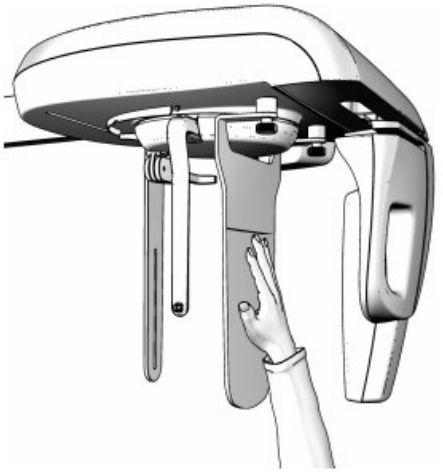


Figure 24

1. Turn the ear centring device to the Antero-Posterior position and open the rods to the maximum extent
2. Rotate the nose-rest to the parking position.
3. Hook up the positioning support for hand projection, by screwing it on the related housings close to the ear centering device. The reference line on the positioner must face the sensor.
4. Place the patient slightly to the side of the cephalometry device.
5. Position the patient's hand on the positioning support on the sensor side. The support leads the operator to place the hand in the centre of the irradiated area. Align the middle finger with the black horizontal line on the plate. The common radiological procedure to assess bone growth in children's, suggests placing the end of the middle finger tangent to the reference line. The patient's hand must be fully in contact with the metal plate and it must form a vertical line with the arm, in order to avoid any risk of collision with the sensor during the scanning movement.

16. ERROR MESSAGES

The error messages are divided into different areas that can be distinguished by the error number; the following table contains the different errors with meanings.

Main MCU board	
Code	Error description
001 / 003	Internal MCU error
500 ÷ 505	MCU Ethernet errors
MCU EEPROM configuration	
Code	Error description
100 / 101	Configuration area parameter doesn't match the expected one
102	Wrong version number in configuration area
103 / 104	Timeout error occurred during an EEPROM erase/write operation
Rotation Motor	
Code	Error description
200	Zero position optical sensor of rotation axis always activated
201	Zero position optical sensor never activated
202 / 203	Zero position optical sensor of rotation still active after exiting from zero sensor
204	Unexpected activation of rotation optical sensor
205	Timeout on rotation
Y translation motor	
Code	Error description
240	Zero position micro Y always active
241	Zero position micro Y never active
243	Timeout on Y axes
Hardware key board (U.I.C.)	
Code	Error description
270 / 271	Hardware key fault
X-Ray Controls	
Code	Error description
360	RX button pressed on start-up or before exam
362	RX button released during emission
Sensor Ready	
Code	Error description
370	Sensor ready lost during exposure
371	Sensor not ready

374	The computer connection drops or times out during exam
375	Sensor took long in configuration mode (while in preheat)
376	The mobile sensor is not detected in PAN position; The mobile sensor is not detected in CEPH position; The sensor presence has changed from the initial situation
377	Both 2D sensors present in respective slots
	CAN Bus
Code	Error description
380	CAN Bus invalid reply
	CCU Board
Code	Error description
600/601/605	CCU malfunctioning errors
602÷ 604	CEPH operative errors
606	Nasion calibration error
611	Internal CCU error
623 / 624	CCU EEPROM errors
630 ÷ 635	Sensor movement errors
640 ÷ 645	Secondary collimator movement errors
650 ÷ 661	4 blade collimator movement errors
670 / 671	CAN bus errors
680	CEPH exam aborted
	Generator Board
Code	Error description
750	Generator board initialization error
751	Alarm "overvoltage kV"
752	Alarm "overload on filament" on Generator board
753	Alarm "overload anodic current"
754	Alarm "filament not OK"
755	Alarm "backup timer"
756	Alarm "PFC not OK"
757	Alarm "Brown OUT"
758	Alarm "NO X-ray"
759	Alarm "unexpected emission"
760	Alarm "NO RX button command"
761	Alarm "NO X-ray emission"
762	Bad unit status: emission flag detected unexpectedly
763	kV analog feedback out of range
764	mA analog feedback out of range
765	Filament analog feedback out of range
766	Generator board reset due to a brown out

767	Generator board reset due to low voltage detection
768	Generator board reset due to a watchdog timeout
769	Generator board reset due to a stack overflow
770	Mismatch between generator board (A2) and MCU board (A1) types (2D / 3D)
	Keyboard
Code	Error description
850	One or more keycodes are pressed
852	Button >O< pressed during movements
	PC software user interface (GUI)
Code	Error description
1200	DLL communication error
1201	Setup menu: write data EEPROM failure
1202	Unexpected value detected by the software
1203	Software allocation failure
1204	Exposure parameters failure
1205	Image buffer allocation failure
	PC driver interface (OSP)
Code	Error description
1401	Sensor connection lost during exam
1402	Sensor communication failure
1403	Software watchdog error
1404	Sensor does not detect X-rays during exam
1405	Sensor frame lost during exam

17. 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 safe and efficient performance.

Regular maintenance consists of checks performed by the operator and/or by a qualified technician.

The operator can control the following items:

Frequency	Type of check	Method
Daily	Functioning of the indicator lights	Visual inspection
Daily	Check that the cables do not show signs of breaking or wear	Visual inspection
Daily	Check that the panoramic patient support and the panoramic and the CEPH temple rods are stable	Practical 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 rotating arm and CEPH arm movements are smooth	Practical inspection
Monthly	Integrity of equipment and labels	Visual inspection

Warning

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

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

Frequency	Type of check
Annually	Correct equipment centring
Annually	Check technical factors
Annually	Perform sensor calibration
Annually	Check that the fixing screws are tightened

18. IMAGE ASSESSMENT

18.1 Panoramic image assessment

Panoramic radiography is an exam of the maxillo-facial region normally used to view the dental region inside the complete head and sinuses-orbital complex.

With a good panoramic exam, you can distinguish the main anatomic structures that are simplified in the diagram below (which indicates only the main ones and is not complete).

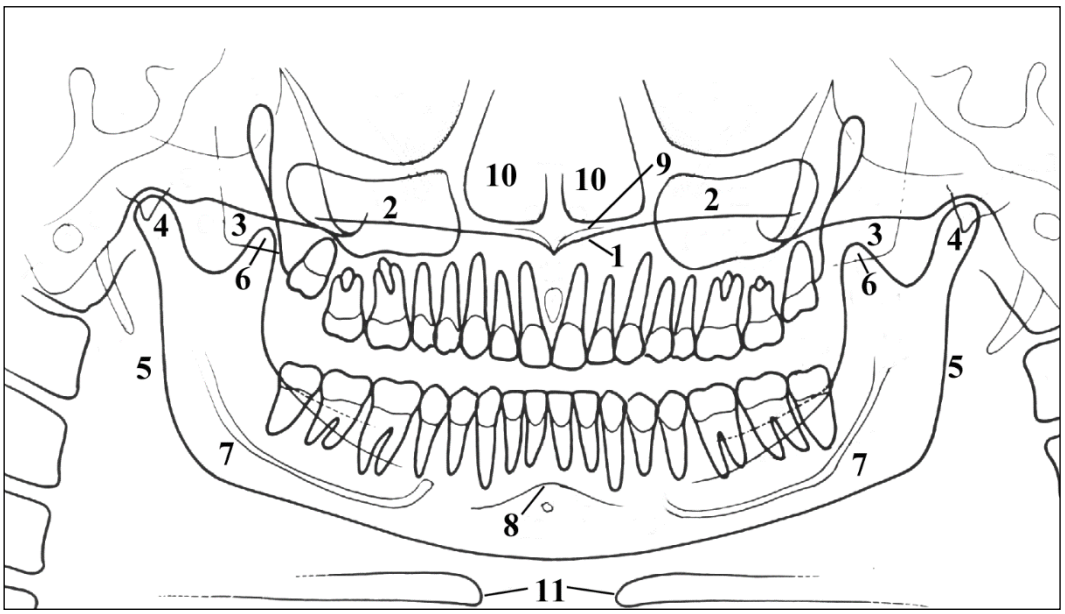


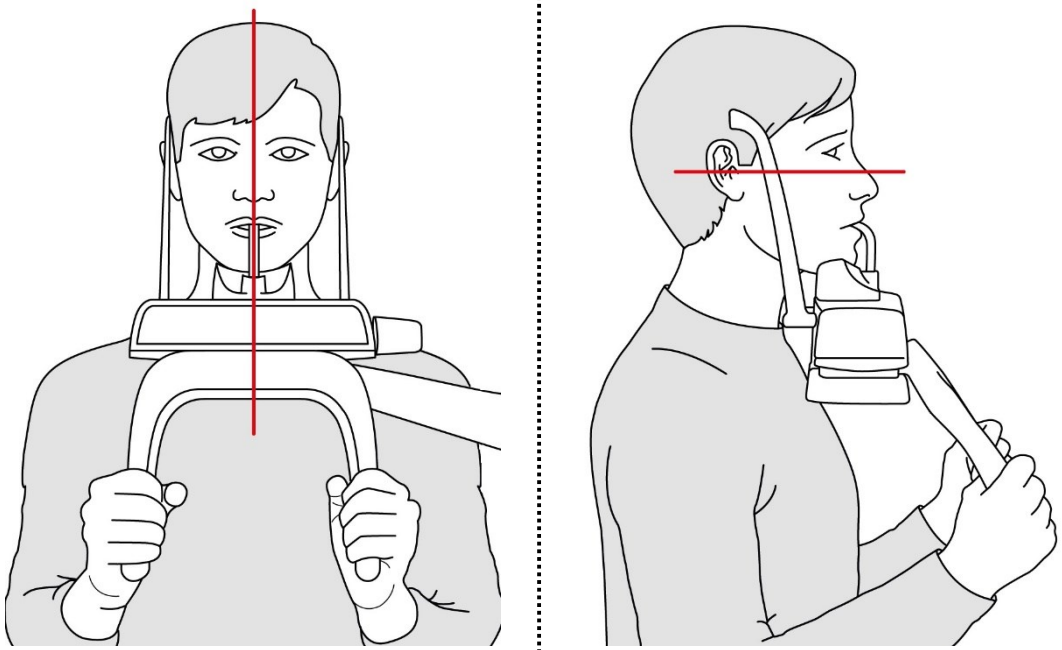
Figure 25

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

18.2 Proper positioning of the patient

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

1. The patient should not wear clothes that may interfere with the X-ray beams, also to leave more space between the patient's shoulders and the rotating arm of the equipment. Care must be taken in order to avoid interference between the X-ray beam and the protective apron worn by the patient.
2. Metal objects (necklaces, earrings etc.) must be avoided; these objects not only create radio-opaque images in their own position, but also false images projected in other parts of the radiography, so disturbing the correct view of the anatomy.
3. Patient's incisors must be positioned into the reference notch of the bite.
4. Frankfurt plane (plane passing through the inferior margin of the orbit and the upper margin of the ear canal) must be horizontal.
5. Mid-Sagittal plane must be centered and vertical.



Mid-Sagittal Plane **Frankfurt Plane**

Figure 26

6. Spine should be well stretched, this is normally obtained by asking the patient to step forward, making sure that all other conditions are unchanged. If not properly extended, the spine will cause the appearing of a lower exposed area (clearer) in the front part of the image.

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

The result of all the above listed actions will be a radiography where all the parts are properly exposed and are well identifiable as shown in Figure 27.

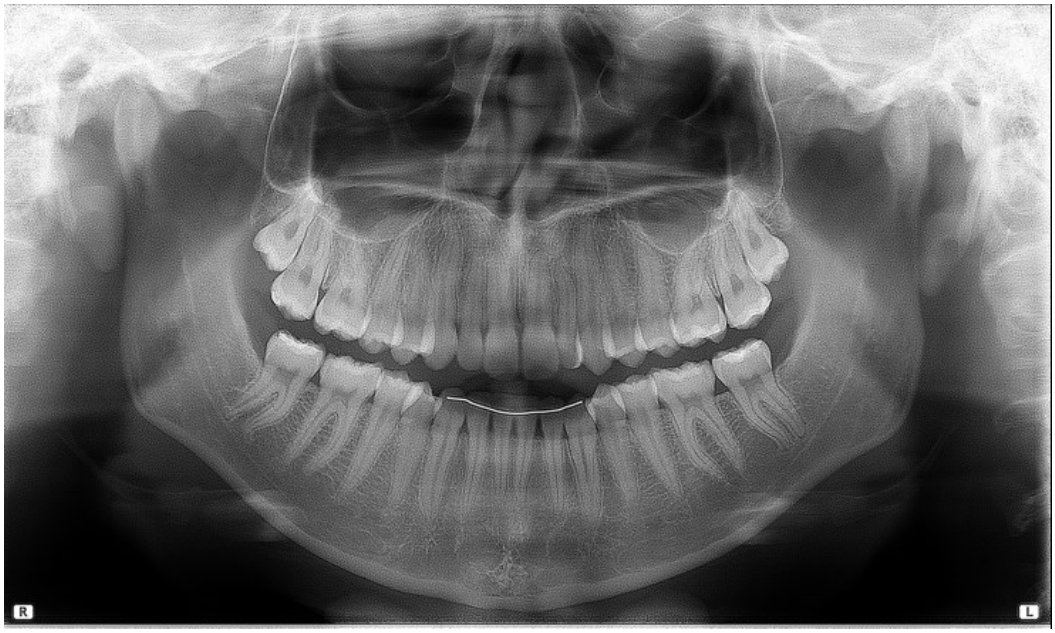


Figure 27

In a good panoramic image, all anatomic structures are well represented and an equal magnification and sharpness of all structures can be seen.

The image must be symmetric, with the ascending rami of the temporo mandibular joints almost parallel and showing posterior vertical borders. The occlusal plane is quite smiling, despite this the palatal plane does not overlap the apex of the upper arch and therefore allows a good view of the apex itself. The spine is well compensated.

Note

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

Note

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

18.3 Patient positioning errors in panoramic

18.3.1 Turned head

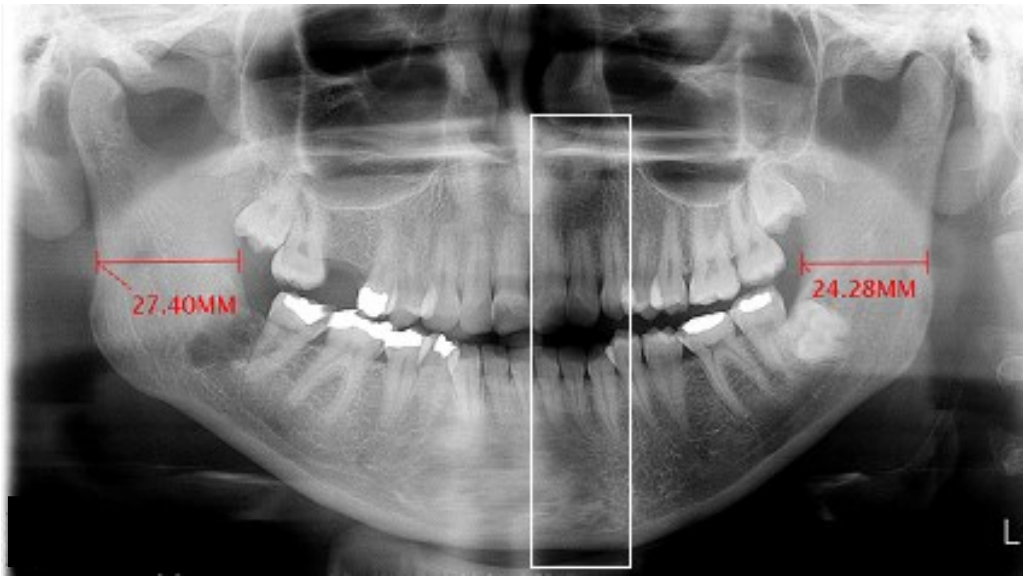
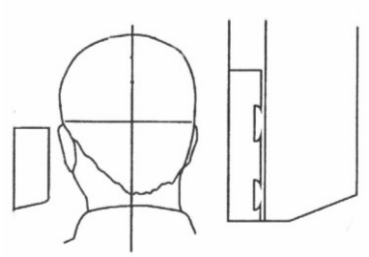


Figure 28



Problem

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

Effects

Condyles are different in size.

The ramous on one side is much wider that the other one.

Asymmetric spine compensation.

18.3.2 Tilted head

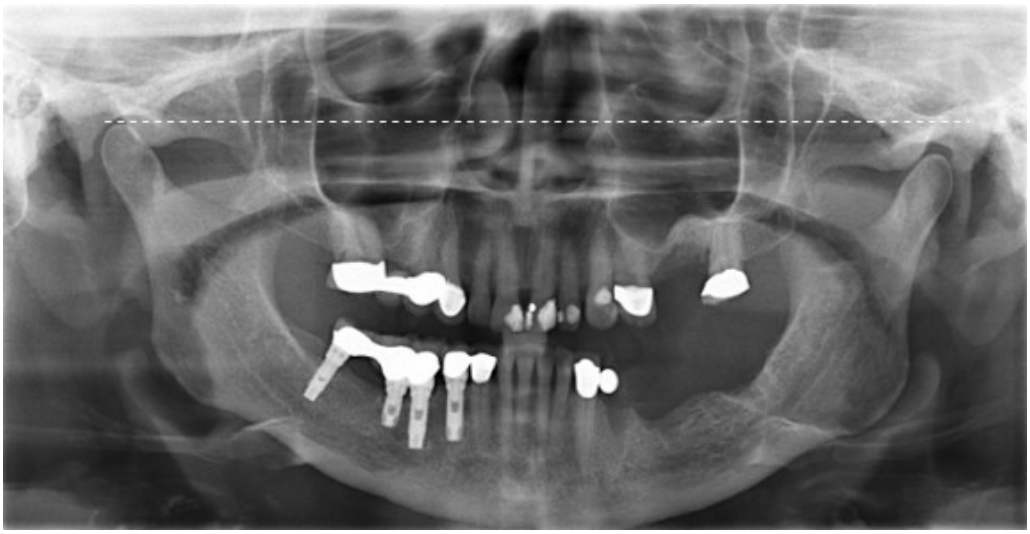
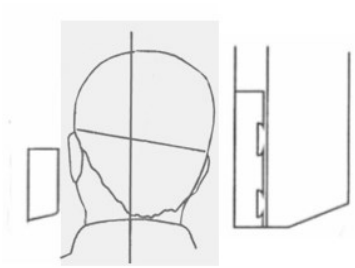


Figure 29



Problem

The patient's head is tilted to one side.

Effects

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

18.3.3 Downward angulation of the head

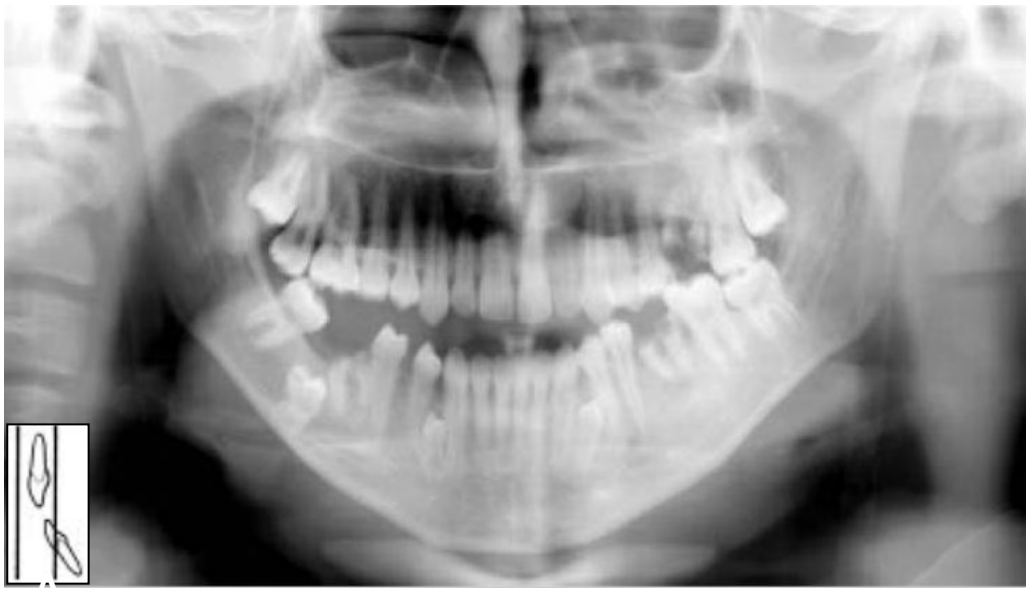


Figure 30

Problem

The Frankfurt plane is tilted downward.

Effects

The roots of the mandibular anterior teeth are positioned outside the focal trough, so it is out-of-focus and blurred.

The shadow of the hyoid bone is typically superimposed on the anterior mandible.

Condyles may be cut off at the top of the radiograph.

Pre-molars are severely overlapped.

Severe curvature of the occlusal plane.

18.3.4 Backward angulation of the head

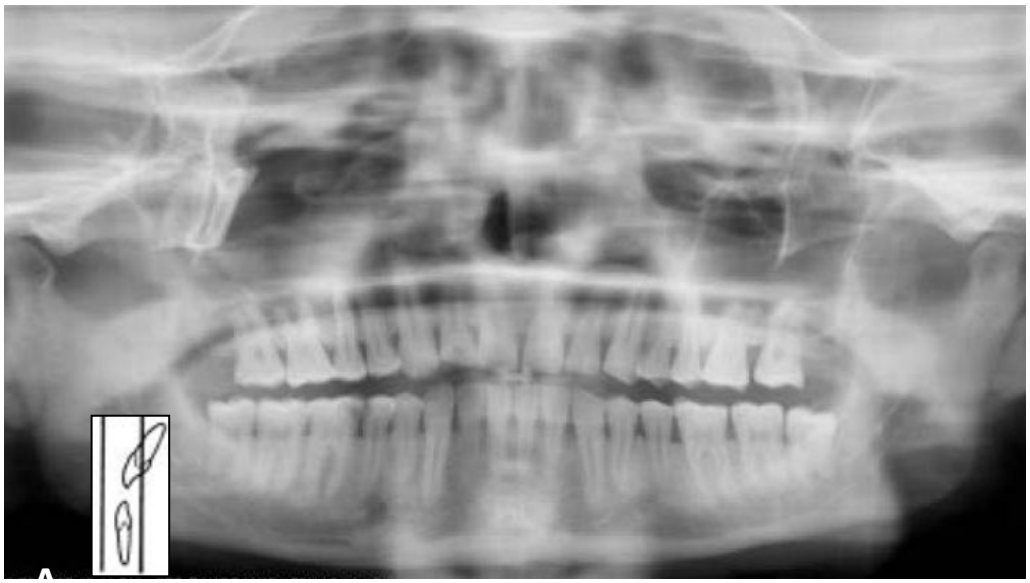


Figure 31

Problem

The Frankfurt plane is tilted backward.

Effects

The roots of the maxillary anterior teeth are positioned outside the focal trough so it is out-of-focus and blurred.

The hard palate is superimposed over the apices of the maxillary teeth.

Both condyles may be off the edges of the image area.

The upper incisors can be blurred.

Flattening of the occlusal plane.

18.3.5 Tongue effect

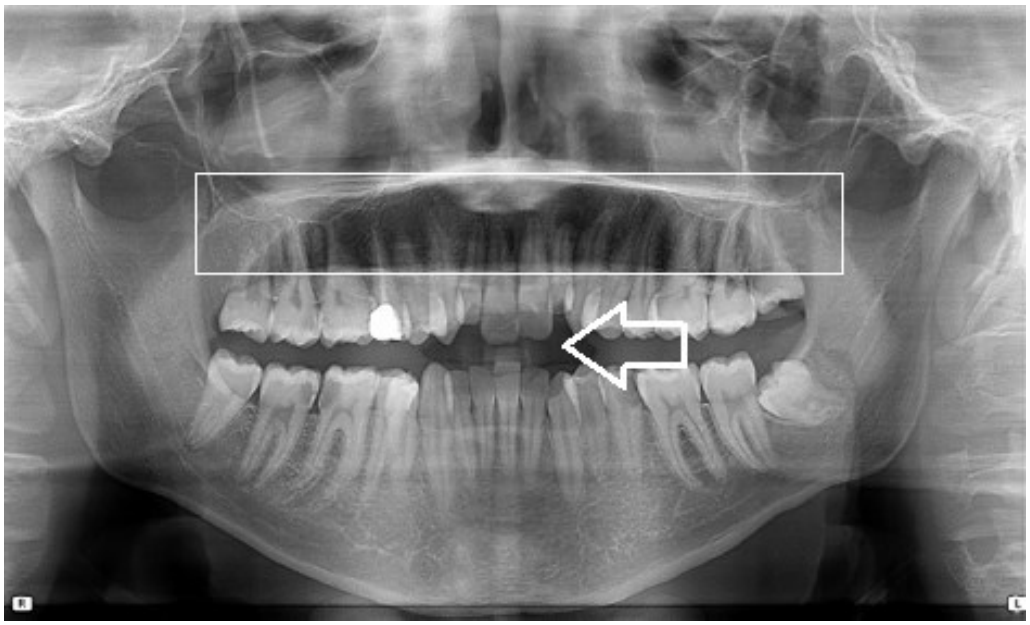
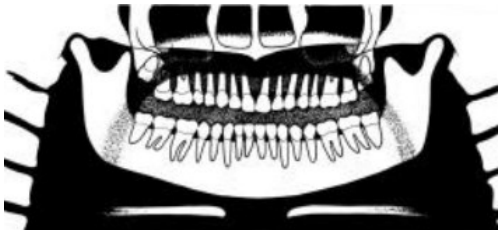


Figure 32



Problem

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

Effects

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

18.3.6 Spine effect

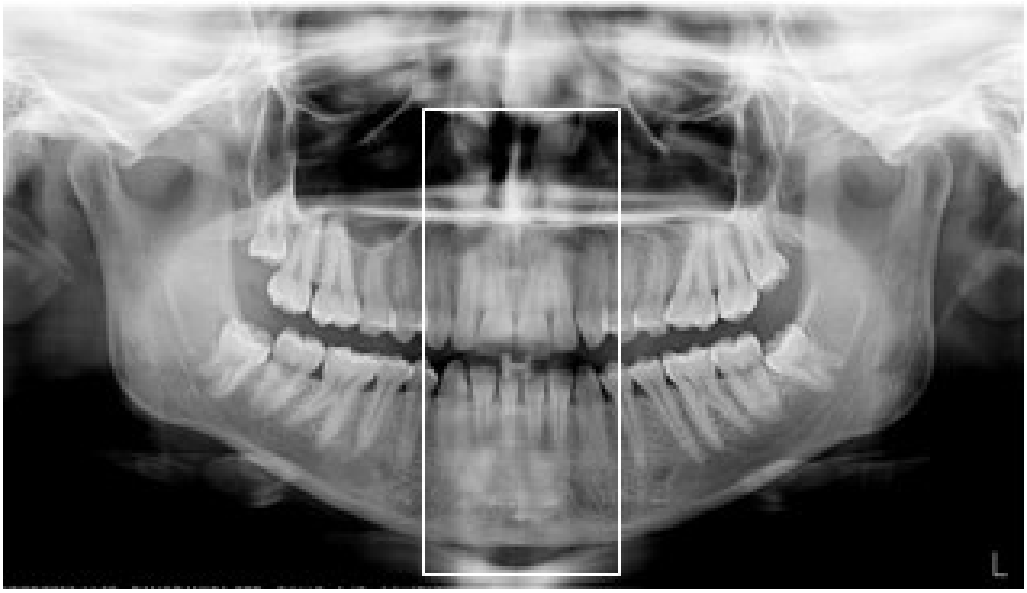
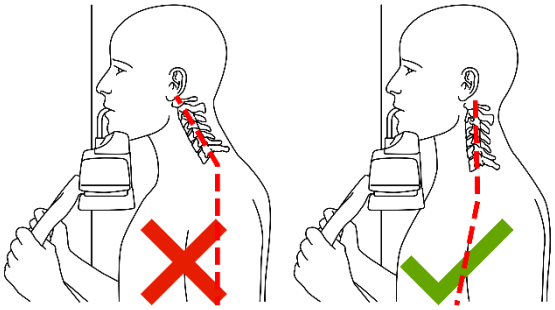


Figure 33



Problem

The patient is slumped.

Effects

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

18.4 CEPH image assessment

The images obtained using cephalometric radiography are commonly used to perform a cephalometric analysis, which allows angle and linear measurements to be made, including:

- the outline inclination of the anterior teeth;
- the positional relationship of the mandibular and maxillary dental bases to each other and to the cranial base;
- the relationship between the bones of the skull and the soft tissue profile of the face.

On a good cephalometric image, the below anatomical points (underlined the most importants) should be visible: Nasion (N), Menton (Me), Sella (S), Subspinale (A), Supramentale (B), Orbitale (Or), Basion (Ba), Porion (Po), Pterigodeo (Pt), Anterior nasal spine (Ans), Posterior Nasal spine (Pns). Furthermore, the soft tissue profile (nose, lips, chin) should be well represented.

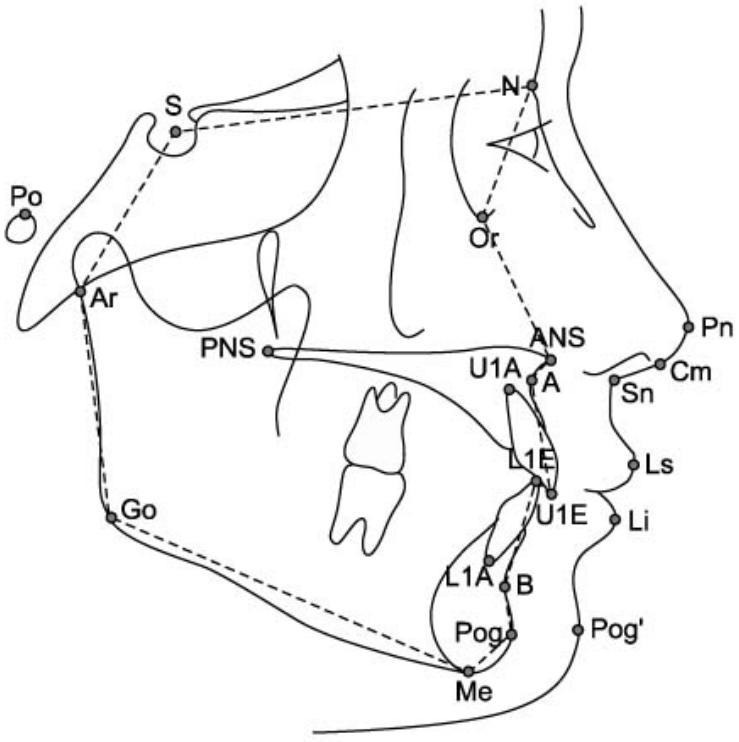


Figure 34

18.5 Patient positioning errors in CEPH

18.5.1 Tilted Frankfurt plane

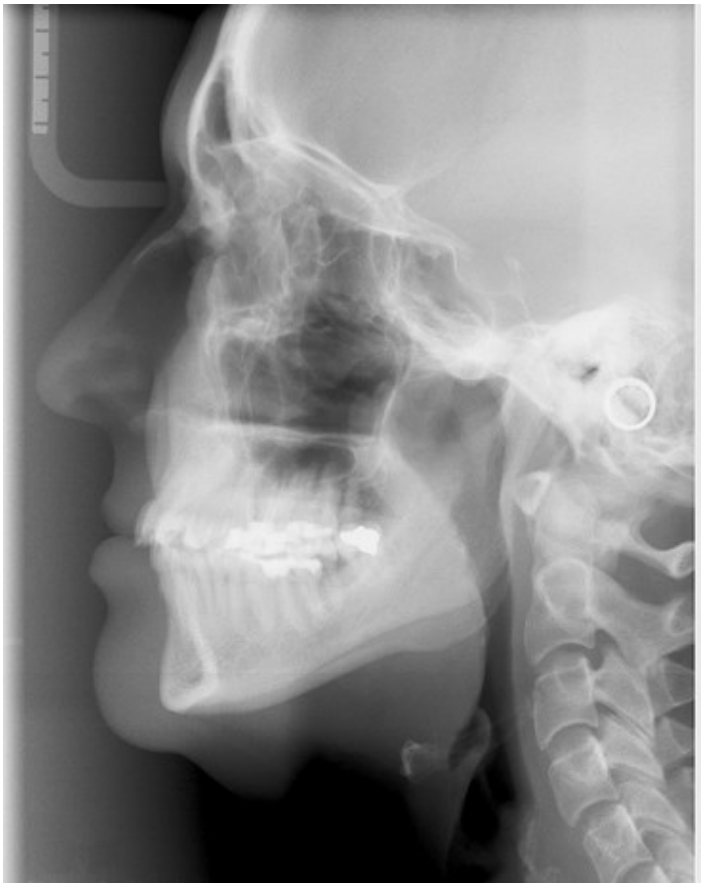


Figure 35

Problem

The Frankfurt plane is tilted (backward/forward).

Effects

A wrong alignment of the Frankfurt plane can impact the effectiveness of the analysis

18.5.2 Tilted mid-sagittal plane

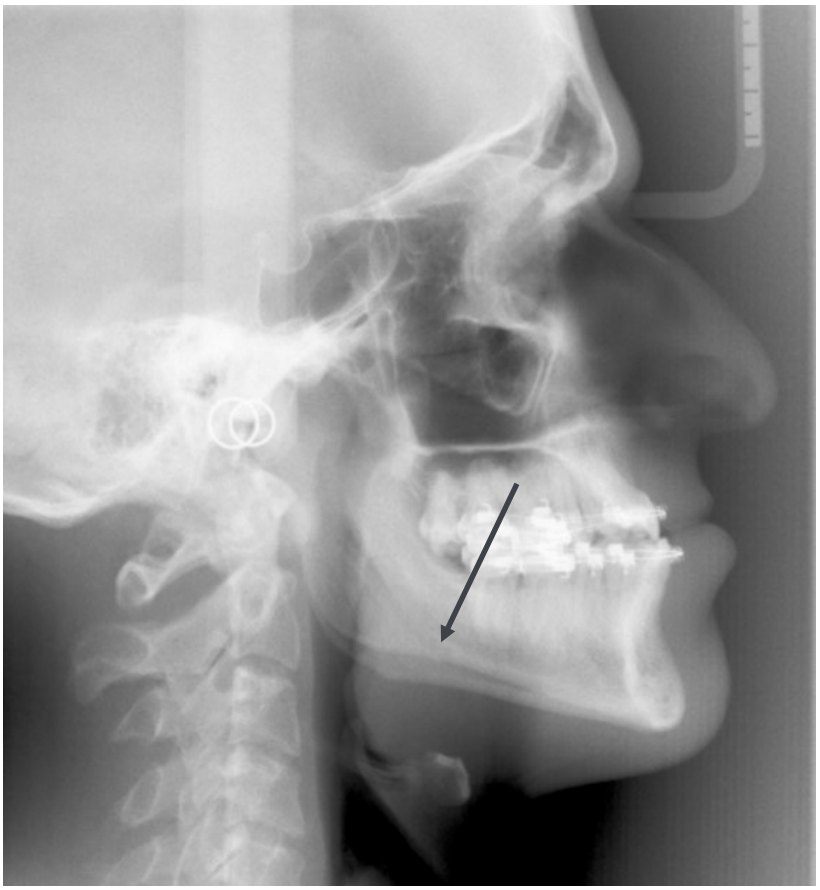
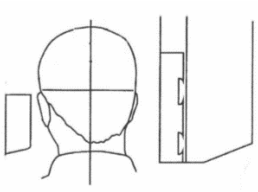


Figure 36



Problem

The Mid-sagittal plane is tilted.

Effects

The misalignment of the mandibular profiles (doubling) can impact the effectiveness of the analysis

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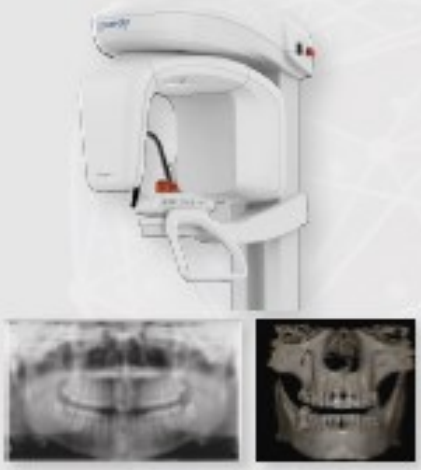
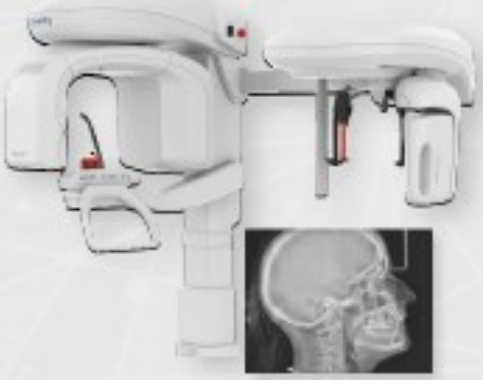


2D / 3D UNITS



CEFALOMETRIC UNITS

HF INTRAORAL GENERATOR

FACE SCAN
PLY IMPORT

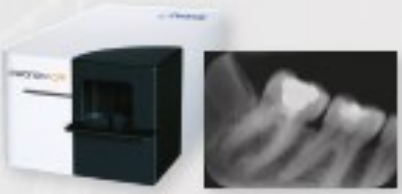


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PLATE SCANNER

DENTAL IMPRESSION
.STL IMPORT

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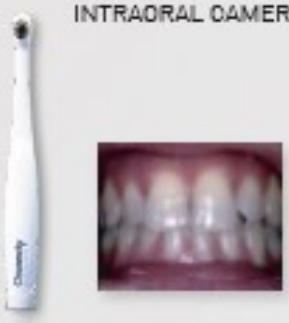

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