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OPERATOR'S MANUAL
NewTom GO

CEFLA S.C. VIA SELICE PROVINCIALE 23/A - 40026 IMOLA (BO) ITALY
PLANT: VIA BICOCCA 14/C - 40026 IMOLA (BO) - ITALY

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1. DEVICE IDENTIFICATION

This manual refers to the following models of the NewTom GO family:

- NewTom GO REF. 70BD (2D version);
- NewTom GO REF. 70BE (3D version).

Unless otherwise specified, the instructions contained in this manual refer to all the above-mentioned models of NewTom GO family (from now on named “NewTom GO”).

In the continuation of this manual, the instructions referring only to the NewTom GO REF. 70BD model device are identified with the description “*For 2D machine only*”.

3D The instructions referring only to the NewTom GO REF. 70BE model device are identified with the following icon, the description “For 3D machine only” or both.

2. INTRODUCTION AND INDICATIONS FOR USE

NewTom GO is an extraoral X-ray system for digital panoramic exams, tele-X-rays and tomographies, intended to:

1 produce orthopanoramic images of the maxillofacial region and carry out diagnostic examination on teeth, dental arches and other structures in the oral cavity;
2 produce X-ray images of dental arches, cranium parts, and carpus in support of cephalometric examinations, if equipped with tele-X-ray arm (CEPH);
3 produce tomographic images of the oral cavity and maxillofacial structures and carry out diagnostic examination on teeth, dental arches, structures of the oral cavity and some cranial bones.

The system performs tomographic exams with the acquisition of X-ray images through a rotating sequence and the reconstruction of a three-dimensional matrix of the examined volume, thus producing two- and three-dimensional views of the volume itself. This technique is known as CBCT.

NewTom GO is a digital X-ray device, suitable for expert professionals, which allows to obtain dental images in a simple and automatic way. The image is acquired by means of an X-ray detector and a constant potential X-ray source, powered by a high-voltage and high-frequency generator. Then the image is sent to a computer in real time for further processing.

NewTom GO allows the following projections:
- standard or panoramic views for paediatric patients (PAN);
- complete or partial views of the teeth, selected by the user (DENT);
- front and side views of maxillary sinuses (SIN);
- side and posteroanterior views of the temporomandibular joints (TMJ).

If equipped with tele-X-ray arm (CEPH), NewTom GO allows the following projections:
- cephalographies in latero-lateral view, in different formats;
- cephalographies in anteroposterior and posteroanterior view;
- hand (carpus) X-ray.

If equipped with CBCT option, NewTom GO also allows to acquire tomographic images.

NewTom GO is intended for use in the following fields:
- endodontics;
- periodontology;
- dental prosthesis;
- functional diagnosis and therapy of craniomandibular dysfunctions;
- dental surgery;
- dental implants;
- maxillofacial surgery;
- orthodontics.

Do not use on patients (children) less than approximately 104 cm in height and less than 19 kg in weight. These height and weight measurements approximately correspond to that of an average 4 year old.
Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that paediatric patients may be more radiosensitive than adults (i.e., the cancer risk per unit of dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for paediatric patients.
Not for use with patients not vigilant and cooperative, since the patient must be able to understand and follow the operator's instructions for a correct positioning.

Contraindications:
- use with patients who cannot remain in the correct position during the scanning;
- use in anatomic regions that are not within the scope of the device intended use (e.g., chest and abdomen);
- use for the visualisation of cartilaginous structures;
- use of the CBCT technique for studying cerebral soft tissues;
- use by staff that have not received training on the device;
- use in the operating theatre;
- use in environmental conditions other than the indicated ones.

In order to ensure a safe use of the device, specifically in the radiography of children it is suggested to consult the general indications described in the guidelines for dental radiographs as i.e. the ones referred on the website Image Gently (www.imagegently.org), for dental Rx, or even in the FDA website for "Pediatric X-Ray imaging".

USA federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

The manufacturer's website contains a list of authorised agents.

For users within the Russian Federation, refer to:

Zenith R.S. LLC
Bldg 3, Property 15, Gorodok-17 Str., Bolshie Vyazemy Settlement, Odintsovo District
143051 Moscow Region, Russia
phone: +7 (495) 980-13-50
+7 (495) 787-68-36
e-mail: sales@zenith-rs.ru
Website: www.zenith-rs.ru

For technical service, it is possible to contact the local distributor.

2.1. DESCRIPTION OF THE MANUAL

This manual is an essential consultation tool and contains important information and instructions for the use of the X-ray system and its relevant controls.
These instructions describe how to properly and safely use the digital X-ray system.
Carefully read and familiarise yourself with the entire contents of the manual before attempting to use the system.
To use the software, refer to the specific manual.

The manual is provided in electronic format and can be consulted directly on the PC screen during use.
A paper copy can be requested by contacting the technical service department.
It is advisable to print a copy of this manual and keep it within reach with the aim of training the operators and as guide for consultation during the use of the device. This manual also contains all the essential information for the safety of patient, operator and device.

It is therefore advisable to read carefully the paragraphs on the safety rules.
The original text is in Italian; this is a translation from the original in Italian.

2.2. GENERAL WARNINGS

The digital X-ray system with its drivers and software have been developed and manufactured by CEFLA s.c. - via Selice Provinciale 23/A - 40026 Imola (BO) Italia, hereinafter referred to as the Manufacturer, in compliance with the EC Medical Devices Directive.

In order to use the system, when it includes also the optional tomography function, the user must have a Personal Computer with a suitable software for capturing and saving images; further information about its installation and use is included in the Software user manual. If the system is used for the acquisition of X-ray and cephalometric images only, a Personal Computer can be used but is not essential. Carefully read this manual and the Computer and Software manuals before using the equipment.

- The contents of this publication are valuable trade secrets and must not be given to third parties, stored, copied, reproduced, disclosed or transferred in any manner (via computer, photocopies, translations or other means) without the prior written consent of the Manufacturer.
- The Manufacturer pursues a policy of continual improvement of its products, therefore, some specific instructions and images contained in this manual may differ from the product purchased.
- The Manufacturer reserves the right to make changes without prior notice.
- The information, technical specifications and illustrations contained in this publication are not binding. The Manufacturer reserves the right to make technical modifications and improvements without modifying these instructions.
- All the registered trademarks and the product names mentioned are the property of the respective owners.
- Carefully read the USER LICENSE AGREEMENT before using the product. When the program is installed, acceptance of the contract will be explicitly requested. If the contract is not accepted the program cannot be installed.

Please pay particular attention to the sections in the manual where the following symbols appear:

Patient or operator safety-related warnings.

Important information on product use.

3D For 3D machines only.

In accordance with the privacy laws in force in several countries, all sensitive personal information must be adequately protected. In addition, patients must sign a consent form before any personal information or images are transmitted across networks. If required by the laws in force, dentists are obliged to protect data using a protection password. Refer to the Microsoft® Windows operating system manual for data access protection methods by means of password.

It is recommended to regularly (at least once a week) make a backup copy of the databases. This will allow restoring the data in the event of damage to the hard disc of the PC or the databases themselves.

2.3. REQUIREMENTS (NOT PROVIDED WITH THE PRODUCT)

For its correct operation, the product requires a connection to a Personal Computer (indicated as PC) and the relevant software. For the minimum PC requirements, refer to paragraph “TECHNICAL DATA”.

The PC is not supplied with the equipment. It is recommended to only use a PC compliant with the standard on information technology equipment IEC 60950-1:2007.

2.4. STANDARDS AND REGULATIONS

The system has been designed to meet the following standards:
- Directive 93/42/EEC and subsequent amendments and additions (Dir. 2007/47/EC) - Medical Devices Directive;
- Directive 2006/42/EEC - Machinery Directive.

Technical Standards:
IEC 60601-1:2005 + A1:2012
IEC 60601-1-2:2014
IEC 60601-1-3:2008 + A1:2013
IEC 60601-2-63:2012 + A1:2017
IEC 60601-1-6:2010 + A1:2013
IEC 62366-1:2015
IEC 62304:2006 + A1:2015
IEC 60825-1:2014

2.5. CLASSIFICATIONS

The system is classified as Class I and Type B as regards safety according to IEC 60601-1.

The system is classified as a Class IIB medical electrical X-ray device in accordance with Medical Device Directive 93/42/EEC and subsequent amendments.

2.6. STYLISTIC CONVENTIONS

The following symbols may be found on the device and in the manual:


Manufacturer.


Date of manufacture.

SN Product serial number.


Symbol “Possible hazard: Read the user manual”.


Patient or operator safety-related warnings.


Consult the enclosed documentation before using the relevant part of the equipment.


It is necessary to read the user's manual before using the device.


This symbol in the manual identifies the paragraphs containing important information on the use of the product.


Applied part of type B, according to IEC 60601-1.

CE 0051 Equipment compliant with directive 93/42/EEC as amended. Notified body: IMQ spa.


Ionizing radiation warning symbol.


Class 1 LASER radiation warning symbol.


Crushing hazard.


Disposal symbol in accordance with Directive 2012/19/EU.

POWER Power switch.

REF TYPE Product/equipment identification code.

I Unit ON.

O Unit OFF.

Ukraine compliance mark.

2.7. GENERAL SAFETY WARNINGS

The instructions inform the user on how to properly operate the system. Read this manual thoroughly before using the device.

The owner or manager of the installation site is responsible for verifying the compliance with local requirements and/or requesting advice from a Qualified Expert. Pay special attention to compliance with legal obligations regarding the protection of workers, the population and patients from radiation.
The main REGULATIONS are listed in this manual (1.4 - Standards and Regulations).
Do not use the system for tasks other than described as intended use (Foreword), and do not use it if you are not an expert in dentistry and radiology.

Law restricts sale and use of this device only to doctors, dentists or radiologists.

For the US market only: federal law restricts this device to sale by or on the order of a dentist / physician.

2.7.1. INSTALLATION CONDITIONS

- The system must not be used if it shows any electrical, mechanical or radiation defect. Like for all medical electrical systems, this device requires proper installation, use, maintenance and service with the aim of assuring safe and efficient operation.
- The entire system must be installed by a technician authorised by the Manufacturer under supervision of a Qualified Expert.
- The room where the system is installed must exclusively be for medical use and designed by an expert in protection against the risks associated with exposure to radiation in accordance with the regulations in force in the country of use.
- For Europe, the electric system in the room where the device is installed must comply with the IEC 60364-7-710 standards (requirements for electric systems in rooms used for medical purposes).
- The X-ray system requires special precautions with respect to electromagnetic compliance and must be installed in accordance with the recommendations given in the paragraph “Electromagnetic safety” in this manual.
- The maximum dimensions reached while the unit is being installed must be taken into consideration to avoid banging into any objects present in the room. Refer to the dimensional diagram in the service manual.
- Make sure that the operator can communicate verbally and visually with the patient during the examination.
- The system can be installed in the following configurations:
  - wall mounting;
  - on the floor surface with a static baseplate (optional).
- Installation not in compliance with the instructions provided by the Manufacturer might cause increased electromagnetic emission of the X-ray system and reduce its immunity to disturbances.
- In particular, use a screened cable for connection of the X-ray remote control and make the connection as specified in the technical manual.

For further details, refer to the installation template and the detailed instructions given in the service manual.

2.7.2. CONDITIONS OF USE

The equipment may only be used by authorised and adequately trained staff (physicians and paramedics).

Use it in compliance with national provisions on protection from ionising radiation, such as:
- **The 3D imaging must not be used for routine screening examinations. 3D imaging examinations must be appropriate to the patient’s needs.**
- **Each examination must be justified by evidence that the benefits outweigh the risks.**
- **Patients must wear leaded aprons with collar for thyroid protection.**
- **Before the examination, ask women of childbearing age if they are pregnant or if there is a possibility that they can be. If so, the patient should not undergo the examination, unless she has seen a radiologist belonging to an accredited hospital facility in order to evaluate, together with the patient and operator, the benefits and risks associated with this type of procedure, taking into consideration the possibility to make other types of examination.**
- **The operators must keep a safe distance, protect themselves with proper shielding and stay close to the patient in the examination room only in the rare cases where the patient needs assistance. In the event that the operators must remain in the examination room, they must protect themselves with a leaded apron featuring a collar for thyroid protection.**
- **Inform the patient of the risks associated with the examination, acquire its informed consent and store the related document.**

In case of claims or for technical assistance, users in Brazil are required to contact the following email address: servico.odontologico@cefla.it.
Users in the US are required to use the following contact information:
Cefla North America Inc.,
6125 Harris Technology Blvd., Charlotte, NC, 28269 United States
Phone: +1 704 598 0020, e-mail: info@ceflaamerica.com

2.7.3. WARRANTY

The Manufacturer guarantees the safety, reliability and performance of the device.
The warranty is effective from the date of installation of the product. The product is covered for the warranty period indicated in the installation report and, in any case, not less than 12 months.

The warranty is valid only under the following terms:
- *closely observe the conditions specified in the warranty certificate itself;*
- *the equipment is only to be used as instructed in this manual;*
- *equipment installation, upgrade and technical support must be performed exclusively by personnel authorised by the Manufacturer to carry out these operations;*
- *do not open the device covers: installation, repairs and in general all the operations that require opening the device must be carried out exclusively by technicians authorised by the Manufacturer;*
- *the equipment is to be installed in rooms that satisfy the requirements specified in the manual;*
- *the room where the X-ray unit is installed must be in compliance with the official directives that govern radiation protection in the country of use.*

2.7.4. MAINTENANCE AND DISPOSAL

Never remove the device covers.

The device does not contain parts that can be repaired directly by the user. In the event of malfunctioning, do not attempt to carry out any type of maintenance operation. If you find or suspect any kind of system malfunctioning, do not attempt to carry out any type of maintenance operation and do not use the system on a patient, but directly contact your local distributor.

The user may not carry out maintenance on any mechanical or electronic part of the x-ray system.

Opening the cases to access the internal circuits may cause device breakage and failure of the electrical safety devices and will lead to forfeiture of the warranty.

Any maintenance, repairs and modifications of the device must be carried out only by personnel directly authorised by the Manufacturer or by third parties expressly authorised by the Manufacturer and must be carried out according to the laws in force and the generally accepted technical standards.

All the system components must be checked and replaced, if necessary, by qualified personnel.

For any maintenance operation, please contact the Manufacturer via the website indicated on the cover of this manual by filling in the Information Request form.

Further information about the device regular inspection and maintenance is provided in the document “NewTom GO - Inspection and Maintenance”.

Should you for any reason need to return the device or its parts to the Manufacturer or a Technical Service centre, disinfect all the external parts of the device using a specific product (see the paragraph “Cleaning and disinfection”) and preferably return it in its original packaging.

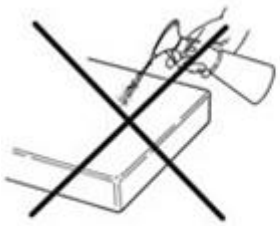
At the end of its lifetime, dispose of the device in accordance with the regulations in force. It is also advisable to disinfect all the external parts of the device before disposal and to separate the materials for differentiated waste collection.
In compliance with Directives 2011/65/EU and 2012/19/EU regarding restriction of the use of certain hazardous substances in electrical and electronic equipment along with waste electrical and electronic equipment, it is forbidden to dispose of this equipment in the municipal waste stream as unsorted municipal waste. When purchasing a new device of an equivalent type, one for one, the device that has come to the end of its lifetime should be returned to the distributor for disposal. As regards reuse, recycling and other forms of recovery of waste electrical and electronic equipment, the Manufacturer carries out the functions defined by current local laws. Appropriate differentiated waste collection for subsequent recycling treatment and environmentally friendly disposal contributes to preventing possible negative effects on the environment and health and encourages recycling of the materials of which the device is made up. The symbol indicating separate collection for electrical and electronic equipment consists of the crossed out bin marked on the equipment. Under local legislation, fines can be imposed if the equipment is disposed in an illegal manner.

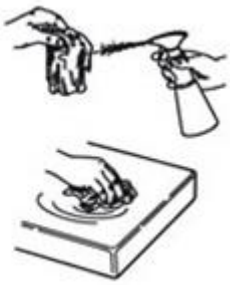
2.7.5. CLEANING AND DISINFECTION

The external surfaces of the device must be cleaned and disinfected.

It is recommended to use a legally recognised disinfectant based on ethyl alcohol and/or n-propyl alcohol with a concentration of less than 40% of the total alcohol.
Use dampened soft paper or disposable wet wipes.

- **Turn off the device prior to cleaning and disinfecting the external parts.**
- **Do not leave the product on the surfaces of the device for a time exceeding the time indicated by the manufacturer**
- **All material used to clean and disinfect must be thrown away upon completing the procedure.**





- **Do not use products containing isopropyl alcohol (2-propanol, iso-propanol).**
- **Do not use products containing sodium hypochlorite (bleach).**
- **Do not use cleaners containing phenols of phenol derivatives.**
- **All products must be used as directed by the manufacturer.**
- **Do not spray or apply the selected product directly on the surfaces.**

Therefore it is recommended to use barrier protections whenever possible and to follow the procedures of good hygiene practice in use at the facility.

2.7.6. HYGIENE PROCEDURES FOR PATIENT PROTECTION

Disposable hygienic infection control sheaths are an important tool to prevent the transmission of microbial agents between patients. To prevent the transmission of infectious diseases between patients, always use disposable infection control sheaths for the parts in contact with the patient. To prevent the transmission of infectious diseases, all components that come into contact with the hands of dental personnel and may be contaminated by indirect contact with the patient's mouth must be frequently cleaned.
Depending on the examination procedures and the optional equipment, the parts in contact with the patient and the operator can be: bite, chin rest, under-nose supports, craniostat contact levers, front nose support levers and ear centring devices for tele-X-ray, handles, touchscreen control, PC keyboard.

Always insert / replace bite disposable hygienic infection control sheaths before positioning a new patient.
Bite, chin rest, under-nose support and handles can be disinfected with 70% ethyl alcohol.
The disposable infection control sheaths must be marked as class I medical devices. They must comply with standards ISO 10993-1 regarding biocompatibility and must be approved by national control bodies or agencies.

Disposable infection control sheaths must be stored in a dry and clean area and must not be exposed to direct sunlight or UV radiation.

Note to users resident in Canada: request plastic protections to your distributor of dental equipment that are suitable in size and marketed in Canada in compliance with the applicable local regulations.

According to the provisions of Health Canada, bite protections are Class I devices supplied by authorised distributors listed in the MDEL database.

2.8. SAFETY WARNINGS

2.8.1. CONDITIONS OF USE

For the conditions of safe use of the device, refer to the following paragraphs of the manual.

2.8.2. GENERAL SAFETY

- Do not forget to turn off the main switch on the equipment before leaving the surgery.
- The device is not protected against liquid penetration (Class IPX0 – common protection).
- The equipment is not suitable for use in the presence of a mixture of flammable anaesthetic gas with oxygen or nitrous oxide.
- Portable telecommunications devices (RF) may interfere with the X-ray device; use in the vicinity of the X-ray device should therefore be prohibited.
- This equipment must be stored properly so that it is kept in top working order at all times.
- The user must be present at all times when the equipment is turned on or ready for start-up. In particular, never leave the equipment unattended in the presence of children or other unauthorised personnel in general;
- The Manufacturer shall not be held responsible (under civil and criminal law) for misuse, carelessness or improper use of the equipment.
- If any person who is not an authorised technician changes the product in any way by replacing parts or components with other ones not used by the Manufacturer, they shall assume responsibility for the product.
- Any computer, monitor, printer, mouse, keyboard and any other device connected to the X-ray device must be compliant with ISO, IEC, EN or local standards.
- The Manufacturer is not responsible for problems or malfunction of parts and/or components not approved by itself, not complying with the regulations and not installed by qualified technical personnel acknowledged by the Manufacturer.
- The X-ray tube contains insulating mineral oil. This oil is potentially hazardous if ingested or if it comes into contact with the skin or mucous membranes. In the event of a defect or fault, the oil may leak out. Avoid direct contact with the oil and do not inhale its vapours.
- Do not eat, drink or smoke near the device.

Before using the device near life-support electronic equipment (i.e.: pacemakers or cardiac stimulators) and hearing aids, see the instructions for use provided by the Manufacturers of such equipment.

2.8.3. SAFETY DURING MOVEMENTS OF THE DEVICE

The X-ray device is a machine which performs movements near the patient and the operator.

When the X-rays are being performed, the movements are controlled by the operator by continuously pressing the dedicated keys.

The reset procedure must be performed before the patient accesses the device.

The operator must remain at a safe distance from moving parts. Movements can be stopped at any time by pressing the emergency stop button.

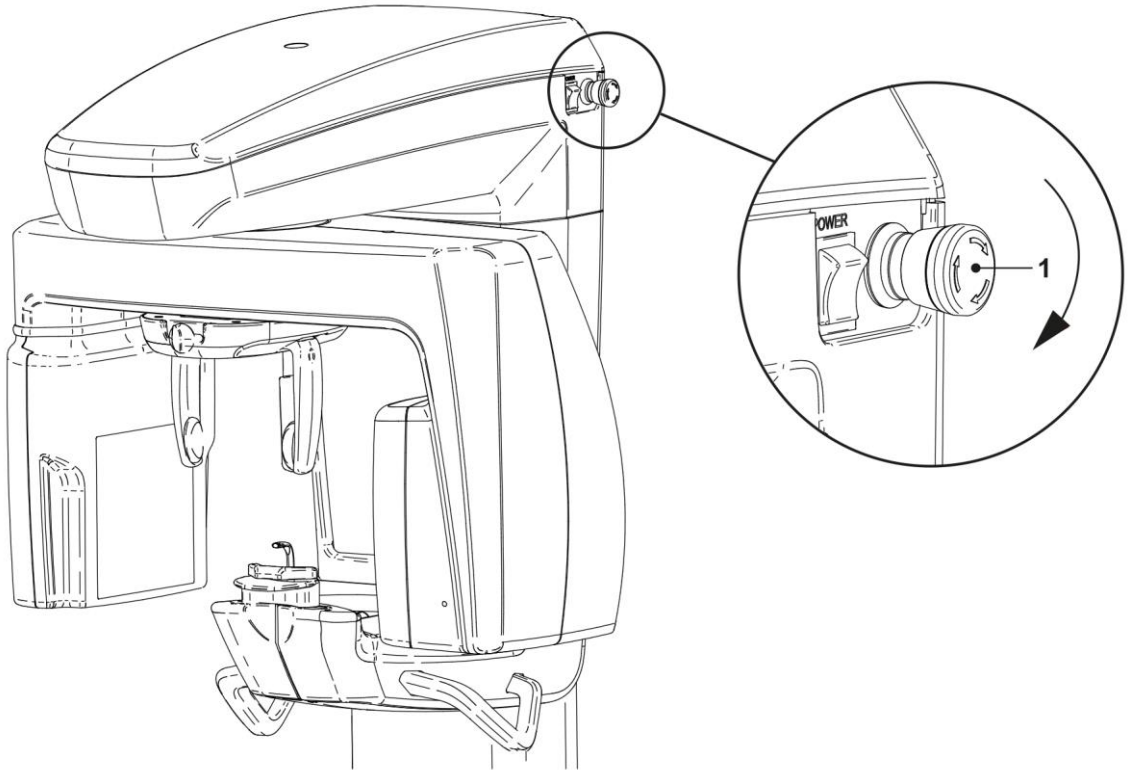
During all the movements of the X-ray device, the operator must:

- supervise the patient closely and, in case of risk of impact between the machine and the patient, stop the movement immediately by releasing the control button;
- prevent the patient from assuming incorrect positions (introduction of hands or other body parts in inappropriate areas) or from moving away from the examination area.

During the power-operated movement for the insertion of the sensor, the operator must be careful not to interfere with the sensor’s movement.

2.8.4. EMERGENCY BUTTON

The system features an emergency stop button, placed under the patient's support arm, near the telescopic column, which stops the X-ray device operation. A remote emergency stop button can be connected using the dedicated connection on the board located at the bottom of the lifting column.



1 Emergency stop button

Such buttons must be pressed in case of danger and emergency, for example when the radiation is not interrupted from the source in case of situations which are clearly dangerous for persons or when an emergency condition is reported.

Pressing them will immediately stop the radiation emissions and any movement of the patient's support and of the rotary arm, making any linear motor cover a distance shorter than 10 mm and rotatory movements a distance shorter then 2 degrees, while the button will remain safely locked.

Once the emergency has ended, turn the button in the direction indicated by the arrow to restore the normal operation.

2.8.5. CONDENSATE FORMATION

Following strong temperature oscillations, condensate may form in the X-ray device. Activate the X-ray device only after an adequate ambient temperature has been reached. See the chapter "Ambient characteristics".

2.8.6. ELECTROSTATIC DISCHARGE

Electrostatic Discharge (abbreviation: ESD).

Persons' electrostatic discharges can cause damage to electronic components in case of contact.
Generally, damaged components must be replaced.
Repair must be carried out by qualified technical personnel.

Do not touch parts at risk, which are marked by the following symbol.

2.8.7. EXPOSURE TO LASER RADIATION

The system contains some class 1 LASER diodes, in compliance with IEC 60825-1:2014. Three of them are located on the X-ray generator, one at the base of the chin rest.

Both the patient and the operator may be dazzled by Laser beams.
- **Do not look directly into the Laser beam. The Laser beam must not strike the patient's eye.**
- **A distance of at least 10 cm must be kept between the eye and the laser.**

The position of laser sources is indicated by the following symbol.

2.8.8. ELECTROMAGNETIC SAFETY

The device is intended for use in environments recognised as professional health facilities, as described in **IEC 60601-1-2:2014**. The device belongs to CISPR 11 Class A Group 1 and complies with immunity test levels specified by IEC 60601-1-2:2014 for professional health facilities.

Before using any electronic device in health facilities, always check that it is compatible with the other equipment present.

Even if the device complies with standard IEC 60601-1-2, it is recommended not to use it near life-support equipment (e.g.: pacemakers or cardiac stimulators). For further information, see the equipment instructions for use.

Use of this equipment adjacent to or stacked with other equipment should be avoided, because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Do not subject the device to strong electromagnetic disturbances. These disturbances could degrade the essential performance of the device.

The emission 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 might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and Manufacturer's declaration - Electromagnetic emissions		
The device is designed to operate in the specified electromagnetic environment. The customer or the user of the device must ensure its use in an electromagnetic environment with the following features:		
Emission test	**Conformity**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal operations. For this, the RF emissions are very low and do not interfere with the electronic devices nearby.
RF emissions CISPR 11	Class A	The device must be used only by adequately trained personnel (dentists and paramedics). The device may cause radio interferences or disturb the operation of the nearby equipment. It may be necessary to adopt countermeasures, such as re-orienting or moving the device or shielding the installation site.

Guidance and Manufacturer's declaration - Electromagnetic immunity			
The device is designed to operate in the specified electromagnetic environment. The customer or the user of the device must ensure its use in an electromagnetic environment with the following features:			
Immunity test	**IEC 60601-1-2 Test level**	**Level of conformity**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	IEC 60601-1-2 Test level	Floors must be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Proximity fields from RF wireless communications IEC 61000-4-3	27 V/m at 385 MHz 28 V/m at 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz 9 V/m at 710, 745, 780, 5240, 5500, 5785 MHz	IEC 60601-1-2 Test level	The RF communication devices (portable and mobile) must not be used at a distance from the device and its components, including cables, lower than the recommended distance.
IEC 61000-4-4 fast/burst electric transients	± 2 kV for electrical lines ± 1 kV for input/output lines > 3 m	IEC 60601-1-2 Test level	The power supply line quality should be that of a typical commercial or hospital environment.
Overvoltage IEC 61000-4-5	± 1 kV differential mode ± 2 kV standard mode	IEC 60601-1-2 Test level	The power supply line quality should be that of a typical commercial or hospital environment.
Voltage drops, short interruptions and voltage change on the IEC 61000-4-11 input electric line	Ut = 0% (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) for 0.5 cycles Ut = 0% per 1 cycle Ut = 70% (a 0°) per 25/30 cycles Ut = 0% per 250/300 cycles	IEC 60601-1-2 Test level	The power supply line quality should be that of a typical commercial or hospital environment. If the user of the device requires a continuous operation also in case of blackout, it is recommended to power the device with an uninterruptible power supply or batteries.
Magnetic field at network frequency (50/60 Hz) IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	The magnetic fields at network frequency should feature levels typical of a standard commercial or hospital environment.

Guidance and Manufacturer's declaration - Electromagnetic immunity			
The device is designed to operate in the specified electromagnetic environment. The customer or user of the device must ensure that it is used in such environment.			
Immunity test	**IEC 60601-1-2 Test level**	**Level of conformity**	**Electromagnetic Environment**
			The RF communication devices (portable and mobile) must not be used at a distance from the device and its components, including cables, lower than the recommended distance, calculated using the corresponding equation applicable to the transmitter frequency. **Recommended distance.**
Radiated RF EN 61000-4-3	3 V/m From 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz
Conducted RF EN 61000-4-6	3 V from 150 kHz to 80 MHz 6V ISM frequencies	IEC 60601-1-2 Test level	$d = 1.2 \times \sqrt{P}$
			Where P is the maximum output power of the transmitter in Watt (W) according to the transmitter Manufacturer, and d is the recommended distance in metres (m). The field intensity of the fixed RF transmitters, determined based on an electromagnetic site, could be lower than the conformity level in each frequency interval. Near the equipment with the following symbol interferences can be caused: 

Recommended distance between the RF portable and mobile communication devices and the device.			
The device is intended for use in electromagnetic environment where RF irradiated disturbances are controlled. The customer or the user of the device can prevent electromagnetic interferences by ensuring a minimum distance between RF mobile and portable (transmitter) communication devices and the device as shown below, according to maximum power output of the communication devices.			
Transmitter maximum nominal output (W)	**Distance according the transmitter frequency (m)**		
	150KHz to 80MHz $d = 1.2 \times \sqrt{P}$	**80KHz to 800MHz** $d = 1.2 \times \sqrt{P}$	**800KHz to 2.5MHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters having a maximum nominal output power not listed above, the recommended distance d in metres (m) can be determined using the corresponding equation applicable to the transmitter frequency where P is the maximum output power of the transmitter in Watt (W) according to the transmitter Manufacturer. Note: **1** At 80MHz and 800MHz it is necessary to apply the distance defined for the highest frequency interval. **2** These guidelines cannot be applicable to all situations. The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.			

2.8.9. PROTECTION AGAINST RADIATION

The system is an X-ray device. As such, the system exposes the patient and the operators to the risks deriving from radiation. It must be used in compliance with the safety regulations set out in the radiation protection standards in force in the country of use.
Some requirements are listed below:

- **Start X-ray emission only from the control room. The radiation room must be adequately shielded (if required by regulations currently in force in the country of use).**
- **Make sure the radiation room's doors are closed before starting the examination.**
- **Only the patient shall be present in the radiation room during X-ray emission. If the presence of a person is necessary during the examination (for example to help patients who are not self-sufficient), personal equipment must be used to protect the individual against scattered radiation. In any case, no body parts should be exposed directly to the X-rays. Patients may not be assisted by pregnant women or minors.**
- **During the system initialisation procedure, no one may stay in the examination room and the doors must be closed. The room must be manned on the outside by authorised personnel until projection is complete.**
- **Pay attention not to release the X-ray emission button too soon. Please note that the radiations can be emitted many times during an exposure cycle. Wait until the exposure cycle has been completed.**
- **The following points must always be observed:**
  - **During exposure, keep a distance of at least 2 metres from the X-ray source. For installations in Canada, the required distance is 3 metres.**
  - **Anyone not directly involved with the patient should be outside the room where the examination is carried out or stand behind a lead shield or lead glass panel during exposure.**
  - **Make sure that the operator can communicate verbally and visually with the patient.**
  - **If required, use a dosimeter for personal monitoring.**
- **Full use must be made of all radiation protection devices, accessories, and procedures available to protect the patient and operator from X-ray radiation, especially for children.**

2.8.10. APPLIED PARTS

The parts that, during standard use, necessarily come into contact with the patient in order for the device to carry out its functions correctly, are: chinrest, bite piece and hygienic protections, headrest, handles, ceph nasion and earpiece protections.
The non-applied parts that may come into contact with patient are the external covers and the patient arm.

2.8.11. CONSIDERATIONS FOR PEDIATRIC USE

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

NewTom GO device has been designed specifically for patients higher than 104 cm and having a weight exceeding 19 kg. These height and weight measurements approximately correspond to that of an average 4 year old.

Before carrying out X-ray examinations on paediatric patients, their higher sensitivity to ionising radiation must be considered. It is due to several factors, such as: higher life expectancy compared with adult patients, higher risk of cancer per unit dose of radiation, and the impact that it might have on organs which are still developing. Moreover, using devices or protocols intended for adults or average-sized patients can generate an unnecessary radiation exposure in case of younger patients.
Every X-ray examination must be carried out only if strictly necessary for medical reasons, using protocols characterised by the minimum dose necessary to obtain images of adequate quality (according to the ALARA principle, "As Low As Reasonably Achievable"). It is recommended not to carry out repeated studies in children, unless they are essential for the formulation of a diagnosis. In particular, CBCT technique must be used only when necessary. The indications and the patient's medical history must be carefully examined before carrying out an X-ray examination.

References for paediatric dose optimisation
In order to ensure a safe use of the device, in case of examinations with children or small-sized patients, it is recommended to consult the following resources dedicated to dental radiology and/or CBCT technique:

- *"National guidelines for dental radiology diagnostics in childhood"* – guideline by Italian Ministry of Health (Italian language): http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3268
- *"Pediatric X-ray Imaging"* - resource by U.S. Food & Drug Administration dedicated to paediatric X-ray imaging (English language): http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/ucm298899.htm
- "*Medical X-ray Imaging"* - resource by U.S. Food & Drug Administration dedicated to X-ray imaging (English language) https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm
- *Image Gently* – awareness and educational campaign on correct management of radiological risk for paediatric patients (English language) http://www.imagegently.org
- *"Dental Cone-beam Computed Tomography"* - resource by U.S. Food & Drug Administration dedicated to CBCT technique in dental field (English language) https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm315011.htm

These resources provide information on the safety of radiation for paediatric imaging and / or on the safety or radiation for panoramic X-ray, cephalometric and tomographic systems.

Device instructions and specifications

Make sure that personnel is trained on appropriate communication modalities to be used with minors and their relatives.

With the help of parents, when necessary, make sure that necklaces, earrings, hairpins, other jewels and orthodontic devices have been removed. Check that the oral cavity is free from candies or chewing-gums.

It is essential that the patient remains still to obtain images of adequate quality. It is recommended to use any measure which could be necessary for reassuring the child before starting the imaging procedure. If necessary, in order to prepare and carry out the examination, plan time intervals suitable for children, longer than those which are usually required for an adult. If the patient cannot be reassured, postpone the examination.

When possible and appropriate, use the suitable protective devices, such as lead thyroid collar and lead apron. The lead collar helps to significantly reduce thyroid dose for any dental radiodiagnostic examination. This device is particularly recommended in case of CBCT examinations with extended fields, except when the specialist detects possible risks of artefacts or possible overlapping on concerned anatomical structures.
In case of cephalometric examinations, using the lead collar is recommended if it is not necessary to view the bone structures which are under the second cervical vertebra.

NewTom GO can be used to examine children and small-sized patients, in compliance with the limitations on use shown in the instructions. The functions available for this purpose are:

- automatic calculation of minimum X-ray parameters required to carry out an examination, according to the size and the density of the volume to be examined;
- indication of the values of the dose administered during the examination, before the actual scanning;
- possibility of carrying out examinations with the patient seated, to reduce risk of movement;
- presence of an adjustable craniostat, to secure the patient's head and allow a correct positioning;
- for 2D projections: possibility of setting reduced X-ray parameters. For selected 2D protocols, the "CHILD" function is available with lower dose profiles as compared with adult patient doses;
- for CBCT examinations: possibility of using fields of view with reduced dimensions, such as: 6x6 (6 cm volume diameter, 6 cm height), 6x7, 8x6, 8x7, 10x6, 10x7, 8x10. Possibility of scanning in Low Dose mode, a low-dose protocol characterised by reduced scanning time.

The table below summarises the device functions which are relevant for paediatric imaging.

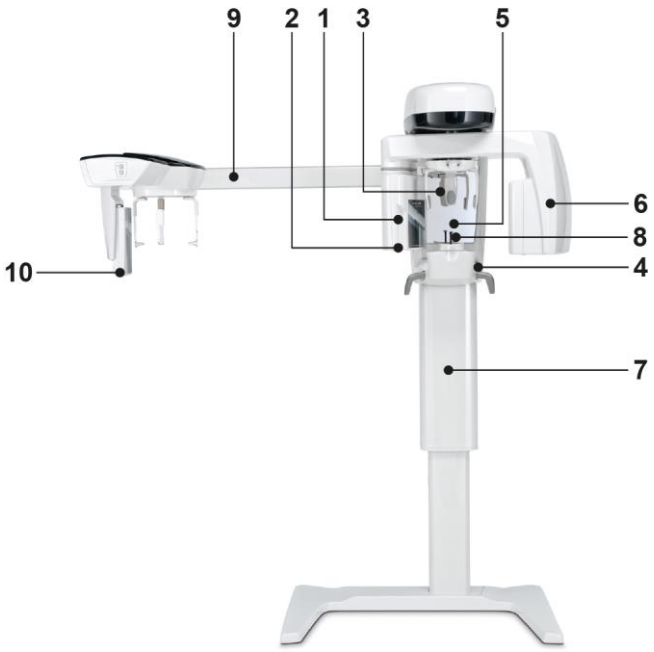
Device features which are relevant for paediatric imaging	Reference
Instructions for use	This manual Para. "INTRODUCTION AND INDICATIONS FOR USE"
Protection against radiations	This manual Para. "PROTECTION AGAINST RADIATIONS"
Description of the operation	This manual Para. "DESCRIPTION OF THE OPERATION"
Perform a simulation of the examination	This manual Para. "PERFORM A SIMULATION (DUMMY RUN)"
Available protocols - 2D examinations	This manual Para. "EXAMINATION SETTINGS FOR CHILDREN"
Patient positioning - 2D examinations	This manual Para. "PATIENT POSITIONING"
Available protocols - CBCT examinations	This manual Para. "3D TOMOGRAPHIC EXAMINATION (CBCT)"
Patient positioning - CBCT examinations	This manual Para. "PATIENT POSITIONING FOR 3D EXAMINATIONS"
Instructions for image quality check	This manual Para. "PERIODIC INSPECTIONS TO CHECK THE IMAGE"
Dose measurements (CTDI)	Manual "Dose declaration and acceptance test" (code 97055116)".

3. DESCRIPTION OF OPERATION

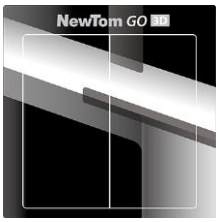
The X-ray device consists of a rotary arm fitted on a column support for carrying out panoramic X-rays or tomographic examinations. The rotary arm features roto-translation motorised movements which allow moving X-ray emission system and image detector around the patient, according to complex orbits following the morphological profile. The rotary arm is applied on a column support which can slide vertically through a motorised movement. The X-ray device position shown in the figures is the Patient Access Position.

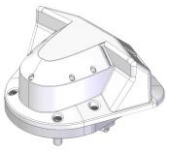
The X-ray device can feature a tele-X-ray arm, fitted on the column support. The arm houses a cephalostat, which keeps the patient position during the exam, and the image detector which translates in synchronisation with the X-ray source movement.
At user's choice, the X-ray device can be equipped with a single image detector (thus the operator must position it on the rotary arm for panoramic X-rays or on the tele-X-ray arm for tele-X-ray examinations - CEPH) or with two separate image detectors (which cannot be moved, one on the rotary arm and the other on the tele-X-ray arm).

1 3D/2D panel
(For 3D machine only)
2 2D sensor for panoramic images
(For 2D machine only)
3 Craniostat
4 Console
5 Laser pointer
6 X-ray source
7 Lifting telescopic column
8 Chin rest and bite
9 Arm for tele-X-rays
10 2D sensor for tele-X-rays



4. MAIN COMPONENTS

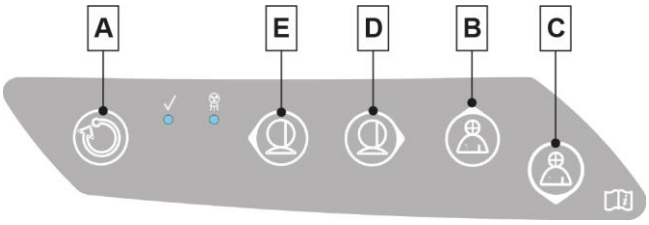
Basic machine	
Remote X-ray button	
Patient positioning unit (craniostat).	
Sensor for panoramic images	
USB Pen Drive including Instruction Manual, Drivers and Software for image display. The multiple-workstation hardware key allowing to use the 3D functions and/or the DICOM licenses is optional in the 2D version, while it is always included in the 3D version.	
Arm for tele-X-rays (optional)	
Sensor for tele-X-ray images (optional)	
CBCT detector for 3D image acquisition	
Long sticks for patient positioning (optional)	

Support for carpus scans (optional)	
Standard stand (optional)	
Standard stand for machine including tele-X-ray arm (optional)	
Support for 3D scans of models, impressions, X-ray templates, phantoms for quality checks / consistency tests (optional)	
Phantom for 2D quality checks (optional)	
Phantom for 3D quality checks (optional)	
22” / 24” medical monitor for image displaying (optional)	
2D or 3D image acquisition workstation (optional)	
Multiple-workstation hardware keys for the activation of additional licenses (1, 5, 10, 25, 50, 250) on LAN network (optional)	

5. CONTROL PANEL

5.1. CONTROL PANEL ONBOARD THE MACHINE

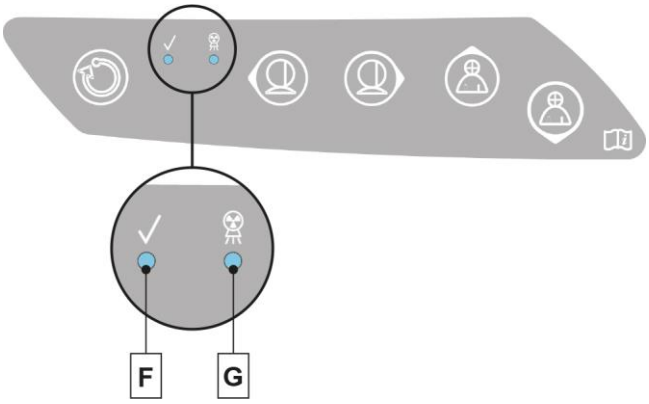
Control panel area:



A Confirmation Button
B Column Upward Movement
C Column Downward Movement
D Canine cusp or condyle Vertical Laser positioning to frame the patient (+)
E Canine cusp or condyle Vertical Laser positioning to frame the patient (-)

The control panel allows the user to select the settings necessary upon the examination start, thus to select the EXAMINATION to be carried out and view the status information.
The machine features a membrane control panel composed of five buttons which allow moving X-ray device parts (column, chin rest, laser traces) used for Patient positioning.

The control panel features two LED lights which indicate the state of the system:



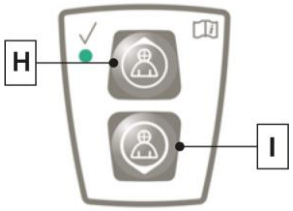
F If the X-ray device is on, the left LED is blue. If the X-ray device is in pause mode (Standby), the LED flashes.
A Green LED steadily on indicates that the X-ray device is ready for the X-ray emission, hereinafter referred to as “Ready status”: if pressed, the remote X-ray button makes the X-ray examination start.
If instead the Green LED flashes, it means that the devices is connected to an INTERLOCK switch that signals to the machine that the access door of the radiology room is open; in this case, the Ready status is only potential, since X-ray emission will be activated only after the door is closed. Should the remote X-ray emission button be pressed, the display will show an error message (see the section Error messages).
G The Yellow LED on the right lights up when an X-ray emission is in progress.

5.2. CONTROL CONSOLE

The control console is a software allowing to manage the operating functions of the X-ray device.
The operator can use the console directly from the connected PC or from an iPad with dedicated app.
The operator can use the control console to select and set the examination in a guided manner, as described in details inside the following dedicated chapters.

5.3. PUSHBUTTON PANEL ON TELE-X-RAY ARM

For all the units equipped with tele-X-ray arm, such arm features a control panel which allows moving the system vertically.



H Column upward movement
I Column downward movement

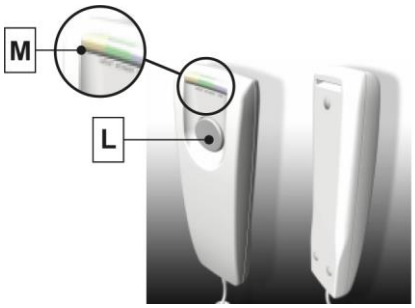
5.4. X-RAY EMISSION REMOTE CONTROL

The system is equipped with a remote control to enable the X-ray emission.

The remote control includes:

L A confirmation button for the X-ray emission

M Two LED lights
- Green (machine ready to start the emission)
- Yellow (X-ray emission in progress)



When the system enters the Ready status (READY), the X-ray emission can be performed (green LED steady on) by pressing and holding the remote control button for the entire duration of the examination.
The execution of the examination is characterised by the yellow LED turning on on the remote control and by the simultaneous emission of an acoustic signal.

Releasing the button before the examination is completed will stop the image acquisition.

BUTTON PRESSED

BUTTON RELEASED

If the acquisition is stopped before it is completed, the PC still displays the whole portion of the tissue analysed, together with an error message.
If the image is exhaustive, even if partial, there is no need to repeat the examination, thus avoiding subjecting the patient to a further dose of radiation.

To comply with the safety regulations on ionising radiations for the operator (for clarifications, see the paragraph on safety against Radiations), the operator must be at a distance of at least 2 metres from the X-ray device during the emission.

5.5. PERFORM A SIMULATION (DUMMY RUN)

Perform the following operations to move the equipment. The operator must:

- **Supervise the patient closely and, in case of risk of impact between the equipment and the patient, stop the movement immediately by releasing the control button.**
- **Prevent the patient from assuming incorrect positions (introduction of hands or other body parts in inappropriate areas) or from moving away from the examination area.**

To perform a simulation cycle, a simulation of the selected projection mode or program, without emitting radiations (dummy run), keep the Confirmation button (**A**) pressed (see par. CONTROL PANEL ONBOARD THE MACHINE).
When the status LED is green, namely when the machine is in the Ready status (READY).
This button must be kept pressed for all the cycle interval, otherwise the movement will stop.

This simulation can be useful for patients who are particularly emotional, children, showing the patient what the examination consists of, without having to leave him/her alone inside the room.

5.6. PARKING POSITION

To take the machine to parking position, which can be set upon request, the Confirmation key (**A**) must be held depressed for a long time (see par. CONTROL PANEL ONBOARD THE MACHINE) until the status LED turns light blue.
Once this operation is over, the device will enter the standby status (Standby).
This procedure can be carried out only when the machine is on and the status LED is blue.

Running this procedure will also allow reducing the machine footprint inside the installation room.

6. PERFORMING A 2D X-RAY EXAMINATION

The steps to follow to properly perform a 2D X-ray examination are:

1 Switching on of system and PC where the acquisition driver is installed
2 Selection of the X-ray examination from control console
3 Preparation of the X-ray examination
4 Patient positioning
5 Execution of the X-ray examination
6 Image display and processing

6.1. STARTING THE SYSTEM

Turn the device on by pressing the power button placed on the rear side, near the column base: the display will light up and a sound will be emitted.

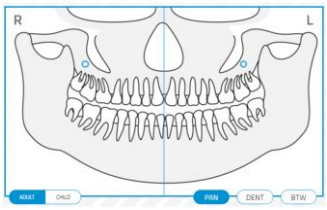
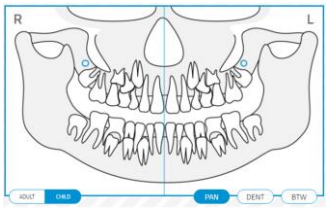
If the X-ray device is in Standby mode, press the Confirmation button (A) to restore its functions.
Once it has correctly started, the LED (F) (see par. CONTROL PANEL ONBOARD THE MACHINE) is blue and steadily on.

An exposure can be performed only if the X-ray device is connected to a PC with the control software installed.

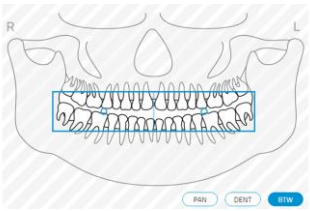
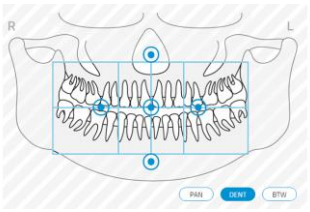
6.2. SELECTING THE EXAMINATION FROM THE CONTROL CONSOLE

6.2.1. 2D EXAMINATIONS AVAILABLE

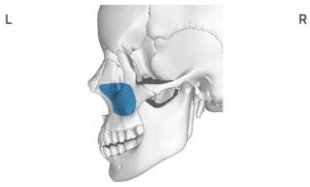
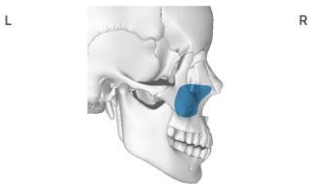
Panoramic imaging (PAN):

NAME	DESCRIPTION	PREVIEW
PAN ADULT	**PAN (FULL)**: High-definition projection for the view of the complete dental arch and of TMJs (temporomandibular joints). Optionally, it can be limited to: • **HALF PAN RIGHT** (limited to right lateral) • **HALF PAN LEFT** (limited to left lateral) Options available for dose profile selections: • **LOW DOSE (QUICK)** (projection with reduced doses and scanning times) • **REGULAR** (projection with optimal scanning time for obtaining standard-resolution images) • **ORTHO** (projection with increased orthogonality). It is recommended not to use this projection on patients with metal prostheses or implants in the posterior area or on the mandibular ramus Options available for image reconstruction: • **SINGLE** (generation of a single focusing layer) • **MULTI** (generation of several focusing layers) • **AUTO** (generation of five focusing layers, among which the one most suitable to image reconstruction will be automatically selected)	
PAN CHILD	**PAN (FULL):** Projection for the view of the complete dental arch and of TMJs (temporomandibular joints), optimised for paediatric version, which adapts to child's morphology. Options available for dose profile selections: • **LOW DOSE (QUICK)** (projection with reduced doses and scanning times) • **REGULAR** (projection with optimal scanning time for obtaining standard-resolution images) Options available for image reconstruction: • **SINGLE** (generation of a single focusing layer) • **MULTI** (generation of several focusing layers) • **AUTO** (generation of five focusing layers, among which the one most suitable to image reconstruction will be automatically selected)	

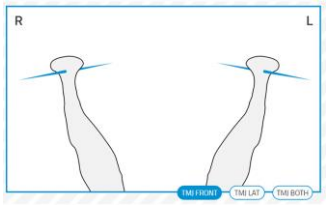
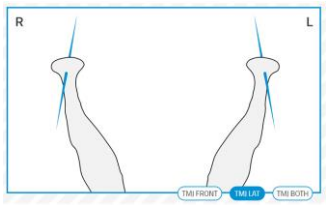
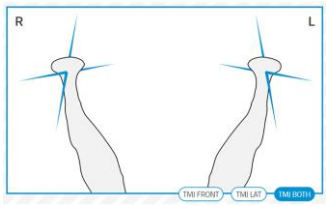
Dentition examinations (BITEWING and DENT):

NAME	DESCRIPTION	PREVIEW
BTW	**BTW (FULL):** Series of 4 images optimised for a complete representation of the crowns of the entire dentition. Optionally, it can be limited to: • **BTW RIGHT** (limited to right lateral - 2 images) • **BTW LEFT** (limited to left lateral - 2 images)	
DENT	**DENT (FULL):** Projection of the complete dental arch excluding TMJs (temporomandibular joints), with improved orthogonality to reduce crown overlapping. Optionally, it can be limited to: • **RH DENT** (1st and 4th arch quadrant) • **LH DENT** (2nd and 3rd arch quadrant) • **FRONT DENT** (lower and upper incisors) Options available for image reconstruction: • **SINGLE** (generation of a single focusing layer) • **MULTI** (generation of several focusing layers) • **AUTO** (generation of five focusing layers, among which the one most suitable to image reconstruction will be automatically selected)	

Maxillary sinuses examinations (SINUSES):

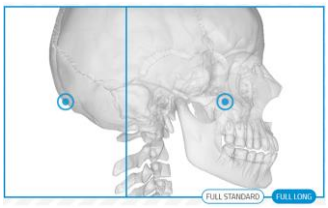
NAME	DESCRIPTION	PREVIEW
SIN CENT	Linear projection of the cranium with postero-anterior view, at the level of maxillary sinuses.	
SIN L	Linear projection of the cranium with lateral view, at the level of left maxillary sinuses only.	
SIN R	Linear projection of the cranium with lateral view, at the level of right maxillary sinuses only.	

Temporomandibular joint examinations (TMJs):

NAME	DESCRIPTION	PREVIEW
TMJ FRONT	**TMJ FRONT**: Postero-anterior projection of both joints.	
TMJ LAT	**TMJ LAT**: Lateral projection (along the major axis of mandibular condyles) of both the temporomandibular joints.	
TMJ BOTH	**TMJ BOTH**: Projection that includes both lateral and front examinations of both joints (right and left).	

For each one of the TMJ diagnostic programs it is possible to perform the same examination with the mouth closed, at rest or open.

Tele-X-ray examinations (CEPH):

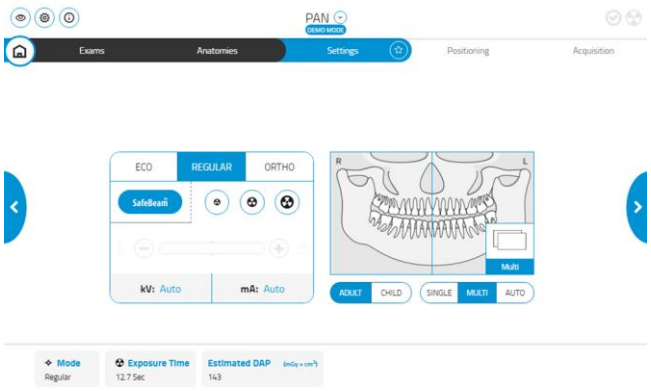
NAME	DESCRIPTION	PREVIEW
LATERAL	**LATERAL:** Latero-lateral examination of the cranium with automatic improvement of soft tissue, highlighting the aesthetics of the face profile. Optionally, it can be limited to: • **FULL STANDARD** (H=19.4 cm x L=18.8 cm; Z=1.13) • **FULL LONG** (H=19.4 cm x L=25.8 cm; Z=1.13) Options available for dose profile selections: • **LOW DOSE (QUICK)** (projection with reduced doses and scanning times) • **REGULAR** (projection with optimal scanning time for obtaining standard-resolution images)	
AP-PA	Antero-posterior (AP) or postero-anterior (PA) examination of the cranium	
CARPUS	It scans the carpus (18 cm length) using a suitable hand support.	

6.2.2. SELECTING AN EXAMINATION

After start-up, the display shows the initial screen (called HOME) which lists the main examination categories and, in an underlying slide bar, the favourite examinations set by the user.

If the examination to be performed is not listed among the favourite ones, press the icon of the EXAMINATION (PAN, 3D, CEPH) category to access the complete list of the examinations available for that category.

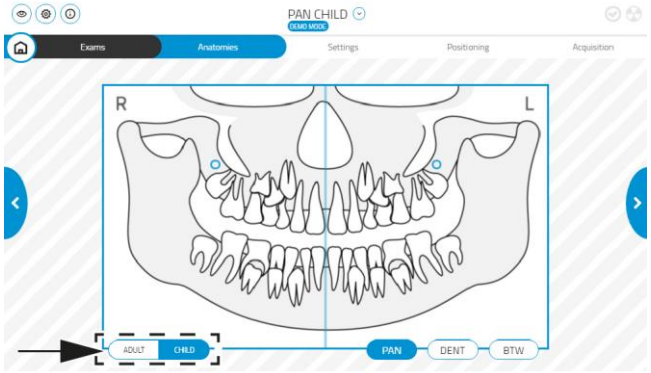
Select one of the favourite examinations, by touching the relevant icon (if any) to set such examination as CURRENT examination and go to the examination SETTINGS screen (a PAN ADULT examination in the example on the side).



6.2.3. SETTING AN EXAMINATION FOR CHILDREN

To activate examination parameters suitable for a child's build, use the ADULT/CHILD switch on the following screen, if available.

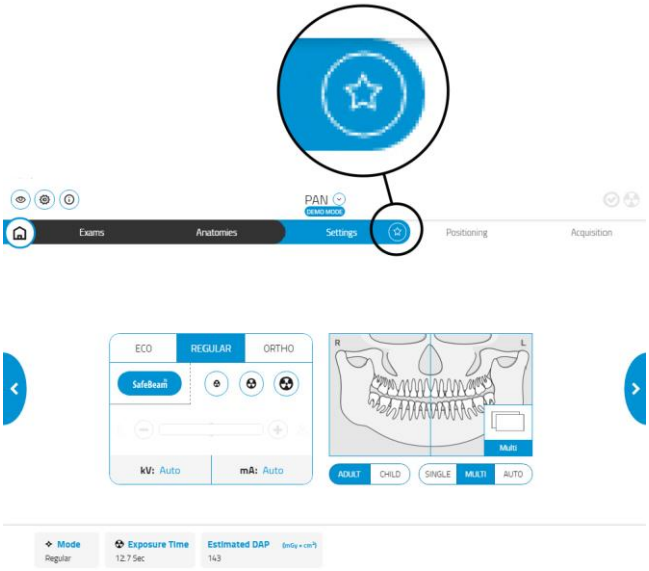
The reference anatomical model changes accordingly and dose profiles are set as reduced as compared to those for adults.



6.2.4. SETTING A CURRENT EXAMINATION AS FAVOURITE

Touch the following icon in the examination SETTINGS screen (see relevant paragraph, a PAN examination in the example on the side).
CURRENT choices are saved in the “favourite” examination, in relation to:

- category and type of the examination set
- selected anatomies
- active options
- chosen dose profile



After having typed an alias identifying the favourite inside the special displayed bar, it will be possible to:

A remove the favourite examination from the Home Page
B save the favourite examination in the Home Page bar

6.2.5. CHOOSING PROJECTION TYPE - PAN Category

Choosing the PAN examination category will open the EXAMINATION screen, where the type of desired examination can be chosen among those available. To help the user’s choice, example images are shown that represent the type of projection to be carried out.

The types of examinations provided for “PAN” category are:

- PAN: panoramic images
- DENT: images of the dentition only
- BTW: images of the crowns
- TMJ: images of the temporomandibular joints
- SIN: images of maxillary sinuses

Once the choice has been made, touch NEXT ”**>**” to confirm and go to the next screen.

6.2.6. CHOOSING PROJECTION TYPE - CEPH Category

Choosing the CEPH examination category will open the EXAMINATION screen, where the type of desired examination can be chosen among those available. To help the user’s choice, example images are shown that represent the type of projection to be carried out.

The types of examinations provided for “CEPH” category are:

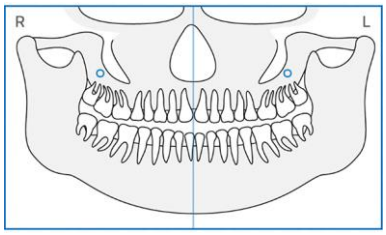
- LATERAL: Latero-lateral tele-X-rays DENT: images of the dentition only
- AP-PA: Antero-Posterior or Postero-Anterior tele-X-rays
- CARPUS: carpus tele-X-rays

Once the choice has been made, touch NEXT “**>**” to confirm and go to the next screen.

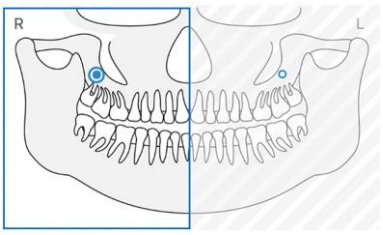
6.2.7. SELECTING A REDUCED ANATOMIC REGION

The exposure can be limited to specific anatomical regions, for the X-ray examinations which allow it, from the subsequent screen (ANATOMIES), by touching the boxes which appear on the graphic representation of the anatomical region interested by the examination.

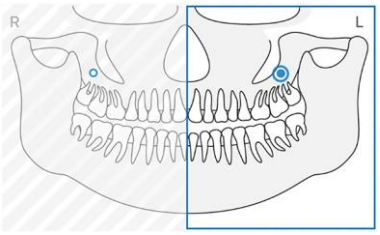
PAN EXAMINATION



RIGHT HALF PAN EXAMINATION

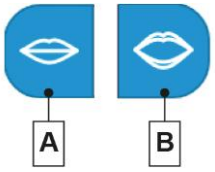


LEFT HALF PAN EXAMINATION



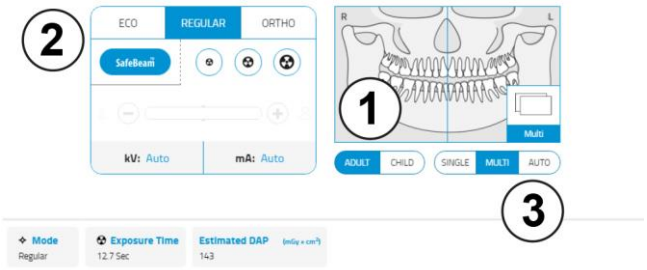
For TMJ examinations, it is possible to select Closed mouth (**A**) or Open mouth (**B**) mode for every available anatomy.

Once the choice has been made, touch NEXT “**>**” to confirm and go to the next screen.

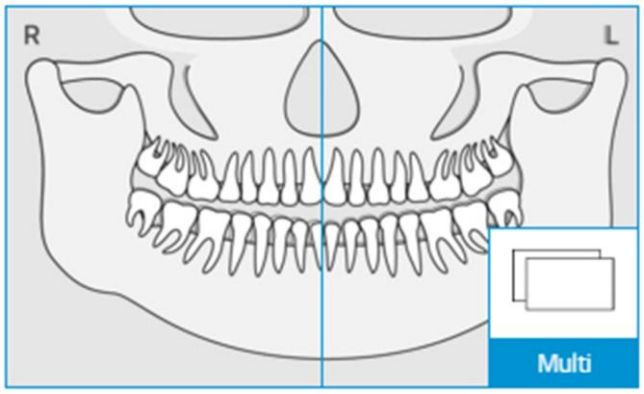


6.2.8. EXAMINATION SETTINGS

After selecting the examination category and type and the anatomical regions concerned, the SETTINGS screen is shown.
This screen can be displayed also by selecting a “favourite” examination in the Home page.
This screen includes:



1 **Summary of projection TYPE and chosen ANATOMIES:**
touch this area to go back to the ANATOMIES screen, where the choice made can be modified



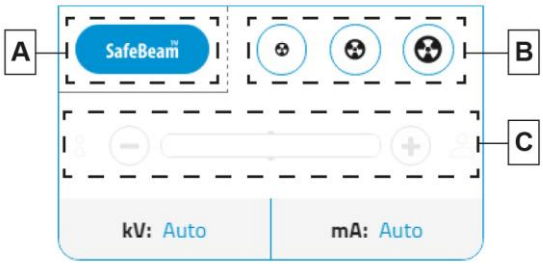
2 **DOSE profile:**
in this area, it is possible to select the dose mode of administration.

The available options are:

A **AUTO (“SafeBeam” ICON):** technical features are automatically set to ensure the best possible quality of the final image, optimising the radiation dose to the patient.

B **PRESET:** sets parameters according to the preset values for three different profiles: low, medium, high.

C **CUSTOM:** sets parameters manually.
Press on the icons “+” and “-” to increase or decrease the dose administered.



3 **Available OPTIONS:**
based on the type of examination selected, particular options can be chosen. The options which may appear are:

- **SINGLE**: the projection generates a single focusing layer. This option does NOT affect the dose administered
- **MULTI**: the projection generates several images on different focusing layers. This option does NOT affect the dose administered
- **AUTO**: the projection generates five focusing layers, among which the one most suitable to image reconstruction will be automatically selected. This option does NOT affect the dose administered.

Depending on the choices made, the indication of the administered dose is updated (DAP, kV and mA). Choosing the AUTO mode will show the estimated dose for an average-sized patient.

6.2.9. EXAMINATION START CONFIRMATION

When touching the NEXT key "**>**" in the SETTINGS screen, the user will be prompted to confirm the correctness of the chosen settings.

Touching OK is equivalent to pressing the CONFIRMATION button on the physical keyboard of the console.

At this point, the machine moves and automatically prepares for the PATIENT POSITIONING.

6.3. PREPARATION OF THE EXAMINATION

After the EXAMINATION START CONFIRMATION, control console will communicate to the user the operations to be carried out to perform the examination.
This control consists of:
- indicate which devices are required for the patient positioning and how to position them
- if necessary, be prepared to move removable sensors

A dedicated screen shows the actions necessary to correctly perform the examinations and their state of completion.

When everything is correctly set, the PATIENT POSITIONING page opens.

A dedicated screen shows the actions necessary to correctly perform the examinations and their state of completion.

In the example on the side, the machine communicates that the sensor is correctly set (**1**) but the chin rest must be removed (**2**) and the cephalostat must be properly set (**3**).

When everything is correctly set, the PATIENT POSITIONING page opens.

6.3.1. DEVICES FOR PATIENT POSITIONING

EXAMINATION TYPE	MOBILE SUPPORT	IMAGE
PAN – DENT – BTW	Craniostat, chin rest and bite.	
TMJ	Under-nose support and craniostat	
	Reduced under-nose support to make TMJ positioning easier in case of patients with a large build.	
SIN	Reduced under-nose support and craniostat.	
CEPH	Tele-X-ray cephalostat for cranium positioning.	
CARPUS	Tele-X-ray support for carpus positioning (OPTIONAL).	

Remember to change the disposable infection control sheaths before positioning a new patient.

Before any X-ray examination, make sure that the patient does not wear metal objects, such as glasses, removable prostheses, earrings and any other removable metal object at the height of head or neck. If a protective apron is used against radiation, make sure that the patient's neck is not covered, otherwise an area not exposed to the X-ray would be obtained.

6.3.2. SENSOR POSITIONING

Check that the sensor to be used is inserted in the position suitable for the examination to be performed; otherwise, reposition the sensor.

If the sensor is not in the position suitable for the examination to be performed, a warning will be displayed on the control console onboard the machine and it will be impossible to perform the examination chosen.

Usually, the sensor for PAN and CEPH examinations cannot be removed by the user.
Only in the event of an X-ray device equipped with a CEPH arm for tele-X-rays, and featuring only one sensor, it is necessary to move the sensor from the CEPH position to the PAN position and vice versa, depending on the type of examination to be performed.
The X-ray device automatically detects the presence of the sensor in the position in which it is inserted and in relation with the type of examination planned: if the sensor is not in the position corresponding with the examination, the system allows removing and moving it to the correct position.
The sensor coupling system contains electronic parts and a mechanical lock.
It is not recommended to remove the sensor during operation.
Do not remove the sensor if this function is not required and prepared by the X-ray device. The sensor is a delicate electronic part.
When confirming the start of an examination type which requires a different position of the sensor, the X-ray device automatically prepares for the removal or the insertion.

Proceed as shown below to couple PAN / CEPH sensor, following the phases from 1 to 3.

PAN / CEPH SENSOR

To release the PAN / CEPH sensor, press the suitable button on the back of the sensor and follow the phases from 3 to 1.

BUTTON TO RELEASE THE SENSOR

Make sure to fit each sensor on its correct support in units which feature two sensors. The two sensors can be distinguished by the height of the black stripe which identifies the area sensitive to X-rays. See images.

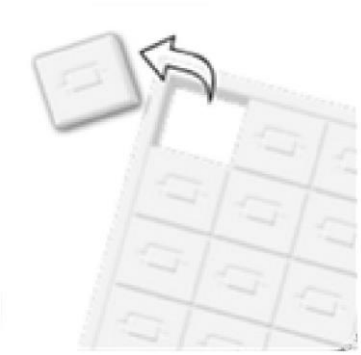
PAN SENSOR

CEPH SENSOR

6.3.3. EDENTOLOUS PATIENTS DEVICES

In case of edentulous patients in PAN, DENT, SIN or CBCT examinations requiring the bite block, use the supplied disposable soft insert as follows:

1 remove the soft bite from the matrix



2 apply the disposable infection control sheath on the bite block

3 insert the soft bite into the bite as indicated in the figure

4 push the bite until the block of material is ejected

Do not exceed these values.

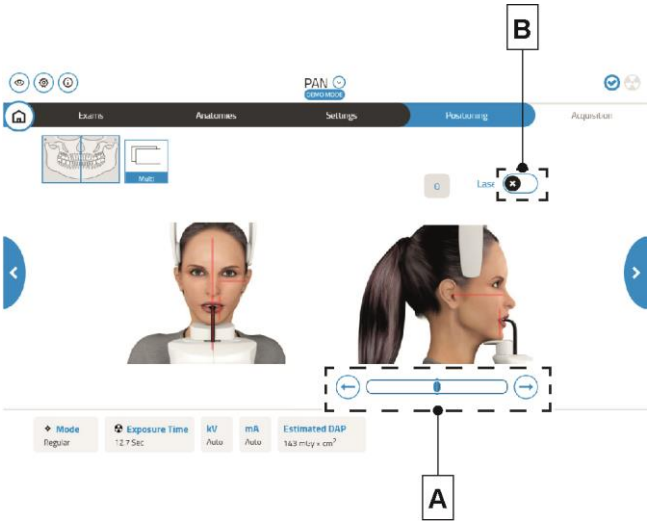
Carry out the normal positioning procedure for the examination making the patient press the soft insert centre with mucous membranes.

6.4. PATIENT POSITIONING

Make the patient access the machine and set any cranium positioning only when the machine has stopped moving and the console is in the patient positioning page.
If you want to stop the machine movement, press the CONFIRMATION button again.

Here you find instructions on how to position the patient using the positioning devices provided for.
It is shown how to position the patient with the help of laser traces.
The Vertical focusing laser position (**A**) is indicated. Use the “arrow” keys to move the column or the vertical laser position by 1 mm steps, in the direction indicated by the arrow.

Lasers can be turned on and off by using the switch (**B**).
Once the wanted position has been reached, touch NEXT to go to the EXECUTION OF EXAMINATION screen.



When the patient accesses the machine during the “Patient Positioning” or the “Execution of Examination” (and anyway before starting the examination), make sure that the X-ray device is not accidentally hit: in this case, it is recommended to make the patient exit the machine and reposition the X-ray device, returning to the “Examination Settings” screen and repeating the procedure.

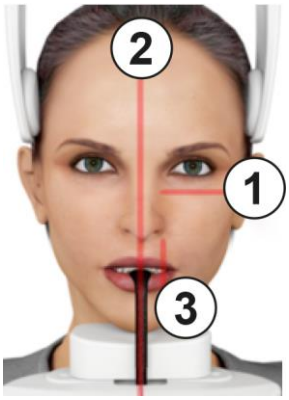
6.4.1. LASER TRACES

The X-ray device features three light traces which help positioning the patient:

1 **Upper Horizontal Laser Trace**
used in all PAN, DENT, SENI, TMJ, 3D examinations

2 **Sagittal Vertical Laser Trace**
used in all PAN, DENT, SENI, TMJ, 3D examinations

3 **Vertical Focusing Laser Trace**
used in PAN, DENT, SENI, TMJ examinations



Upper horizontal trace (1)
It is generated by a laser projector placed on the X-ray generator side; it can be moved upward or downward to be adapted to different head dimensions, using the suitable lever beside the light opening. This trace is used in PAN and DENT examinations to ensure that the patient’s Frankfurt plane is horizontal and, more generally, to ensure correct positioning.

The Frankfurt plane is represented by an imaginary line running from the upper edge of the auditory meatus to the lower edge of the orbit.

Sagittal vertical trace (2)
It ensures the symmetry of the patient head with respect to the sagittal midline. While observing this trace, it is necessary to make sure that the patient looks straight ahead to prevent him/her from tilting the head to one side or from rotating it slightly.

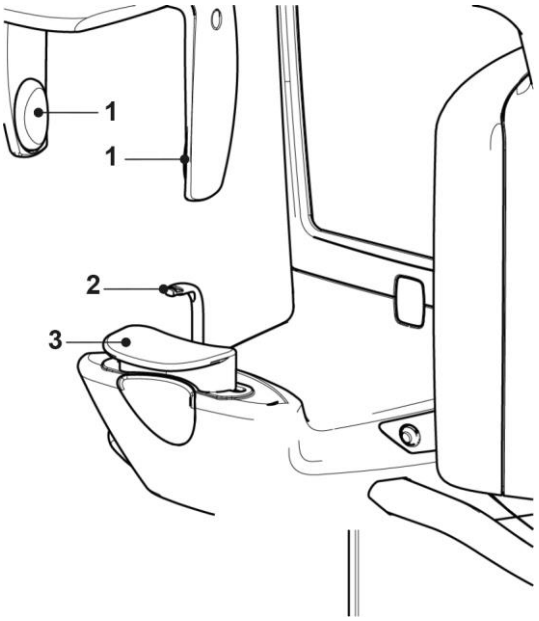
Vertical focusing trace (3)
It indicates the exact position of the focal point; to obtain a good focusing in PAN and DENT examinations, make this trace coincide with the cusp of the upper canine. This trace is used also to point at the exact position of the condylar head for TMJ examinations.

Each pressure of the CONFIRMATION button will move all the device mobile parts. Make sure NOT to press the button during the patient positioning and that the device can be safely moved.

6.4.2. PATIENT POSITIONING DESCRIPTION (CRANIOSTAT)

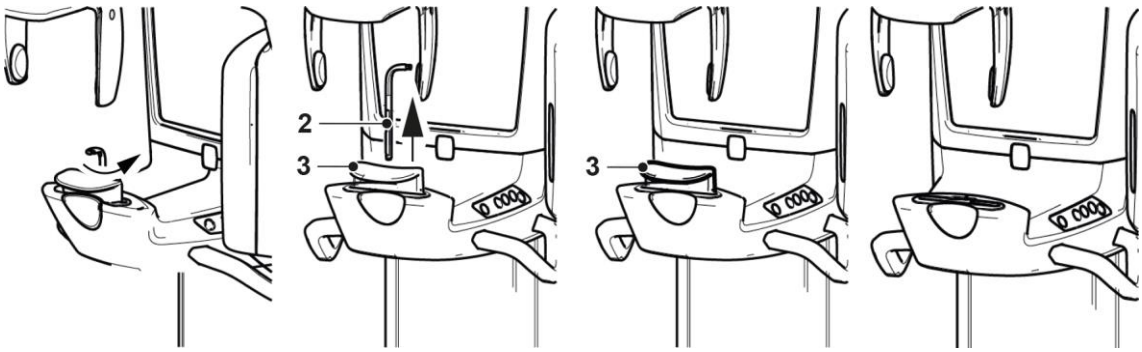
Craniostat's components:

1 Anatomical arches
2 Bite
3 Chin rest



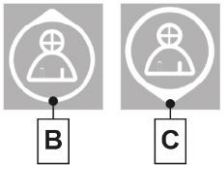
In the upper part, the craniostat is provided with anatomical arches that, after positioning the patient, can be adjusted and automatically locked with a simple finger pressure made in point (**A**). The arches move synchronously with each other. To release them, open them in area (**A**).

The lower part of the craniostat consists of the chin rest (**3**) and the bite (**2**), which can be disassembled as shown in the figures on the side.



6.4.3. PAN, DENT AND BTW EXAMINATIONS

1 Adjust the unit height in order to facilitate the patient's access, using the keys to move the column upward (**B**) or downward (**C**) (see par. CONTROL PANEL ONBOARD THE MACHINE). The telescopic column will move slowly at first, then it will speed up. Adjust the height until the bite lock is slightly over the patient's occlusal plane. This will induce the patient to stretch himself/herself to reach the bite, stretching and straightening his/her neck.

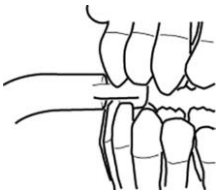


2 Make sure that the bite block is laterally rotated so as to leave space for the patient. Make sure that the disposable infection control sheath is inserted.

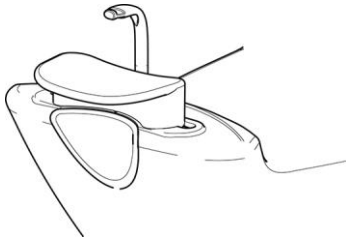
3 Guide the patient toward the unit so that he/she is before the bite block and can grab the wide handles. Ask the patient to rest his/her chin on the chin rest support.

4 Ask the patient to take a step forward, holding the grip on the handles, until he/she reaches the position shown in the figure

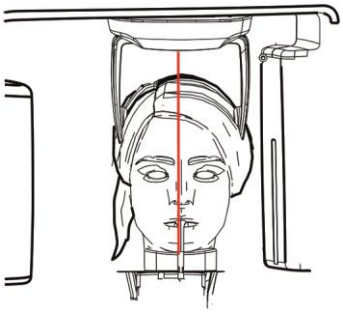
5 Adjust the height of the bite and rotate it inside the mouth, asking the patient to bite it as shown in the figure. The tip of upper and lower incisors must be in the bite groove. The interproximal space of incisors must be in the bite midline.



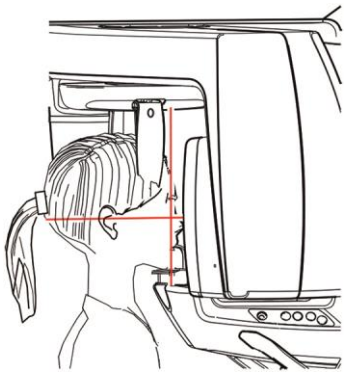
6 The correct positioning of the bite block is facilitated by the upward and downward sliding movement of the relevant support pillar.



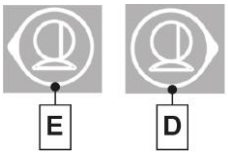
7 Check the symmetry of the patient's head using the sagittal vertical trace as a guide (dotted line) watching the mirror.



8 Check the correct positioning of the Frankfurt plane by overlapping the upper horizontal light trace (dotted line). To adjust the inclination of the patient's head, use the column upward and downward movement keys. Make sure that the patient's back is straight and relaxed.



9 Ask the patient to smile in order to show the upper dentition. Normally the vertical light trace falls between the canine cusp*.
In case of particular dysmorphias of the patient, move the light trace forward or backward, toward the canine, using the console keys (**E**) and (**D**) (see par. CONTROL PANEL ONBOARD THE MACHINE), in order to optimise the dentition focusing.
*the canine reference is useful to optimise the patient's alignment, but it is not strictly necessary.



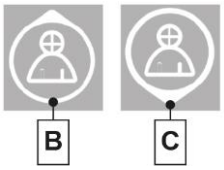
10 Press the CONFIRMATION button and, immediately before leaving the room to press the X-ray emission button, ask the patient to close his/her eyes, swallow and move the tongue against the palate.

6.4.4. TMJ EXAMINATION

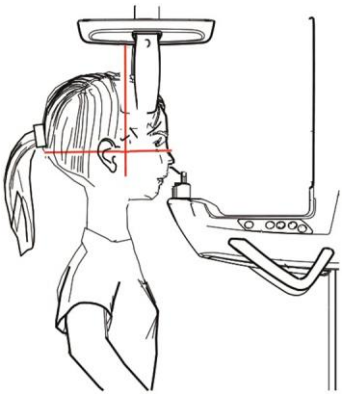
6.4.4.1. LATERAL TMJ

1 Remove the chin rest and the bite, and insert the under-nose support.

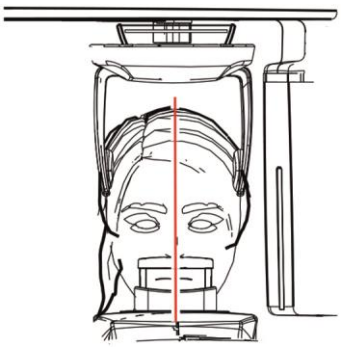
2 Adjust the unit height, in order to facilitate the patient's access, using the keys (**B**) and (**C**) to move the column upward or downward (see par. CONTROL PANEL ONBOARD THE MACHINE) until the under-nose support reaches the height of the nose base. The telescopic column will move slowly at first, then it will speed up.
TMJ examinations can be carried out with open mouth or closed mouth by selecting the proper icon on the control console.



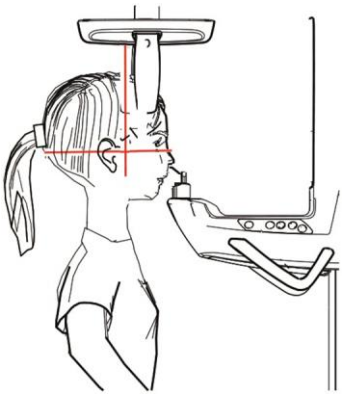
3 Guide the patient toward the unit so that he/she faces the under-nose support and can grab the wide handles. The patient will rest the nose base on the under-nose support, as in the figure.



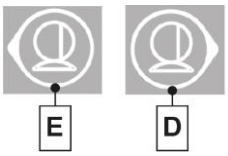
4 Check the symmetry of the patient's head using the sagittal vertical trace as a guide; check the correct positioning of the Frankfurt plane by overlapping the upper horizontal light trace, as shown in the previous figure. If required for the examination and if necessary, slightly tilt the patient's head forward to ease the maximum mouth opening.



5 Once the correct orientation has been found, lock the craniostat as explained in paragraph DESCRIPTION OF PATIENT POSITIONING (CRANIOSTAT).



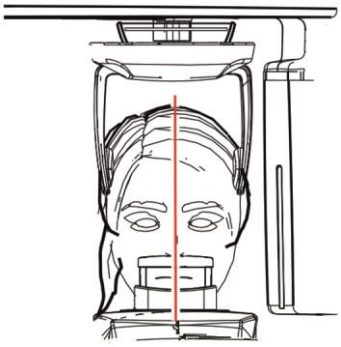
6 Make sure that the examination required is selected correctly. Use keys (**E**) and (**D**) (see par. CONTROL PANEL ONBOARD THE MACHINE) to position the vertical focusing light trace exactly on the condyle head, as shown in the figure.



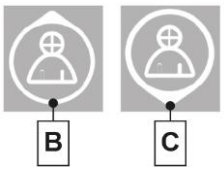
7 Press the CONFIRMATION button and, immediately before leaving the room to press the X-ray emission button, ask the patient to close his/her eyes and remain still.

6.4.4.2. FRONTAL TMJ

1 Repeat the steps of lateral TMJ examination.

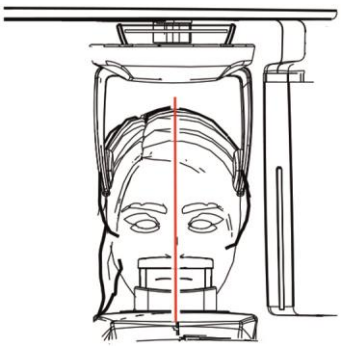


2 To adjust the head's inclination, just lift or lower the unit using the height adjusting buttons (**B**) and (**C**) (see par. CONTROL PANEL ONBOARD THE MACHINE).

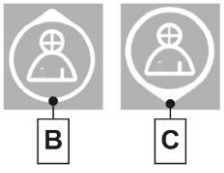


6.4.4.3. TMJ BOTH

1 Repeat the steps of lateral TMJ examination.



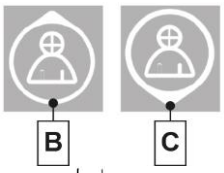
2 To adjust the head's inclination, just lift or lower the unit using the height adjusting buttons (**B**) and (**C**) (see par. CONTROL PANEL ONBOARD THE MACHINE).



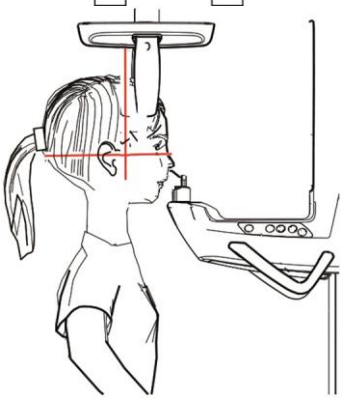
6.4.5. MAXILLARY SINUSES EXAMINATION

1 Remove the chin rest and the bite, and insert the under-nose support.

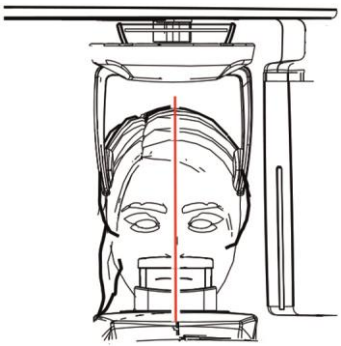
2 Adjust the unit height, in order to facilitate the patient's access, using the keys (**B**) and (**C**) to move the column upward or downward (see par. CONTROL PANEL ONBOARD THE MACHINE) until the specific support for sinuses reaches the height of the nose base. The telescopic column will move slowly at first, then it will speed up.



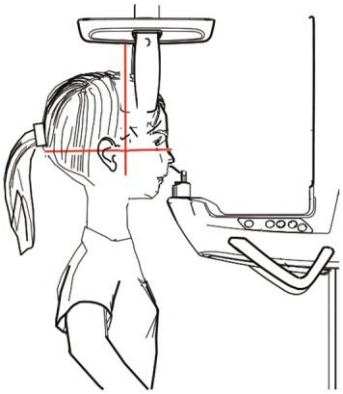
3 Guide the patient toward the unit so that he/she faces the under-nose support and can grab the wide handles. The patient will rest the nose base on the special support for sinuses, as in the figure.



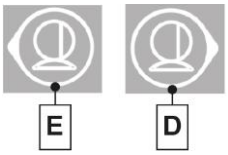
4 Check the symmetry of the patient's head using the sagittal vertical trace as a guide; check the correct positioning of the Frankfurt plane by overlapping the upper horizontal light trace, as shown in the previous figure.



5 Once the correct orientation has been found, lock the craniostat as explained in paragraph DESCRIPTION OF PATIENT POSITIONING (CRANIOSTAT).



6 Make sure that the examination required is selected correctly.
Use keys (**E**) and (**D**) (see par. CONTROL PANEL ONBOARD THE MACHINE) to position the vertical focusing light trace between the first and the second upper premolar.



7 Press the CONFIRMATION button and, immediately before leaving the room to press the X-ray emission button, ask the patient to close his/her eyes and remain still.

6.4.6. TELERADIOGRAPHIC (CEPH) EXAMINATIONS

Tele-X-ray examinations can be performed only if the system features a tele-X-ray arm with relevant cephalostat. Usually, these examinations are performed with the patient standing. In case of very tall or very short or wheelchair user patients, the examination can be performed with the patient seated.

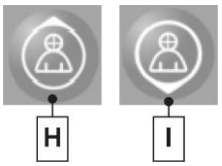
If a seat is used, make sure that the backrest or the armrests do not interfere with the correct movement of the machine.

Remove the craniostat before performing the machine RESET.

1 Separate ear supports by working on the upper white parts and not on the transparent sticks. Insert the ear disposable infection control sheaths.

2 Rotate the NASION support upward.

3 Adjust the motorised column height by using the suitable keys (**H**) and (**I**) (see par. CONTROL PANEL ON TELE-X-RAY ARM) until the ear loops reach the height of the patient's external auditory canal.



4 Make the patient access the inside of the cephalostat. The patient's back must be straight and he/she must look straight forward. Ideally, the line between the auditory meatus and the heel centre must be perpendicular to the floor.

5 Close earpieces so that they slightly enter the auditory meatuses, making sure not to cause discomfort.

6 Position the patient's head so that the Frankfurt plane is horizontal.

7 Rotate the NASION support downward and adjust its depth and height in order to make it rest on the patient's Nasion point, without pushing it or modifying the previously set position.

8 Before pressing the X-ray emission button, ask the patient to look straight forward, close the teeth according to his/her natural bite (usually corresponding to the maximum intercuspation) or according to the orthodontist's provision and keep lips relaxed.

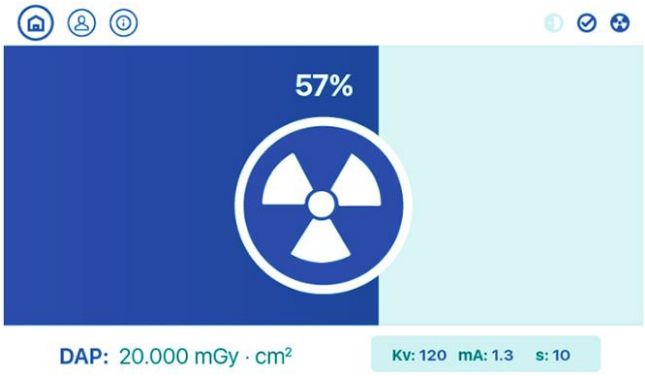
6.5. PERFORMING THE EXAMINATION

- Visually check the correct position of the patient and make sure that the green LED is steadily on and in the X-ray remote control.
- Tell the patient not to move during the examination, to breath slowly and regularly,
- Make all the unnecessary persons move away from the area exposed to radiation and, when required, go behind the suitable protection.

When the patient accesses the machine during the "Patient Positioning" or the "Execution of Examination" (and anyway before starting the examination), make sure that the X-ray device is not accidentally hit: in this case, it is recommended to make the patient exit the machine and reposition the X-ray device, returning to the "Examination Settings" screen and repeating the procedure.

The console EXECUTION of examination screen shows the X-ray parameters set and the exposure progression.

The user can see the amount of dose being administered and the time left before the examination ends.



Press the X-Ray remote Control to perform the emission and keep it pressed during the whole duration of the examination. The duration of the examination is indicated by the yellow flashing LED of the X-ray remote control device. The X-ray emission is signalled with an audible signal.

The X-ray device emits rays to acquire images only if it is Ready, namely when the green LED is on, on the control console and on the X-ray emission remote control. It is possible that, due to an error of the user or of the X-ray device, the machine does not confirm the Ready status, thus preventing the X-ray emission. Correct the error (see section Error messages) and press the CONFIRMATION button.

6.6. VIEWING AND SAVING

The X-ray system features the NNT program for displaying and saving the examinations; if using this software, refer to the NNT user's manual.
If software by third parties is used to display and save the examinations, refer to the instructions provided by the authors of the software application used.

The use of NNT software is optional in case of 2D examinations (e.g.: panoramic and cephalometric).
The use of NNT software is instead essential for the acquisition of tomographic examinations, since it contains the technology necessary for the reconstruction of volumetric images.

If the X-ray Examination is to be delivered to the patient or to another operator, NNT provides an automatic guide for the creation of a DVD, which includes a redistributable copy of NNT for displaying images (NNT Viewer).

As an alternative, it will be possible to export only X-ray images in a standard format (DICOM 3.0) so that third parties' software can be used to consult them.

7. 3D TOMOGRAPHY (CBCT)

3D For 3D machines only

The 3D CBCT tomographic examination is obtained by means of 3D reconstruction of the X-rayed anatomical region and can be consulted through 2D views or 3D representations generated by a program run on a workstation (PC).
Read the NNT software user manual for instructions on the image processing.

Remember to change the disposable infection control sheaths before positioning a new patient.

Before positioning the patient, make sure that he/she does not wear metal objects, such as glasses, removable prosthesis, earrings and any other metal object at the height of the head. If a protective apron is used against radiation, make sure that the patient's neck is not covered, otherwise an area not exposed to the X-ray would be obtained.

The steps to follow to properly perform a 3D examination are:
1 Switching on of system and PC where the acquisition driver is installed
2 Selection of the 3D examination from control console
3 Preparation of the 3D examination
4 Patient positioning
5 Execution of the 3D examination
6 Image display and processing

7.1. STARTING THE SYSTEM

Turn the device on by pressing the power button placed on the rear side, near the column base: the display will light up and a sound will be emitted.

If the X-ray device is in Standby mode, press the Confirmation button (A) to restore its functions.
Once it has correctly started, the LED (F) (see par. CONTROL PANEL ONBOARD THE MACHINE) is blue and steadily on.

An exposure can be performed only if the X-ray device is connected to a PC with the control software installed.

7.2. SELECTING THE EXAMINATION FROM THE CONTROL CONSOLE

7.2.1. 3D EXAMINATIONS AVAILABLE

3D examination can be performed only if the X-ray device is connected to a PC on which NNT software is installed.

1 Turn on the PC and run the NNT software.

2 A Daily Check procedure must be completed, upon the first start-up of the day, before performing any 3D Examination. The daily check procedure is a service procedure with X-ray emission and must be performed WITHOUT PATIENT.

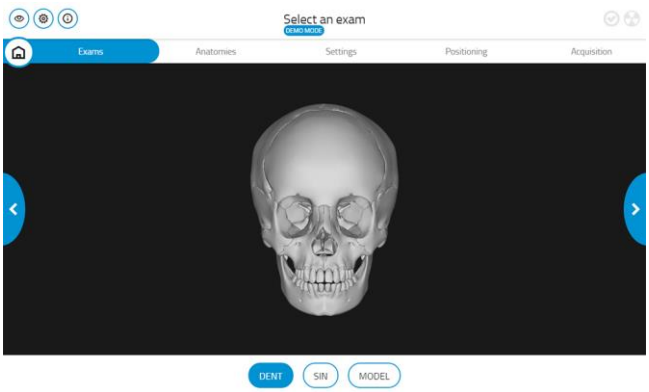
3 For instructions, see the section "Acquisition operations" in the dedicated NNT manual.

It is NOT necessary that the patient accesses the X-ray device during the examination selecting procedure, but only at the end of the procedure described in this paragraph.

Choosing the 3D examination category will open the EXAMINATIONS screen, where the field of use must be chosen among those available. To help the user's choice, example 3D models are displayed, representing the type of examination to be performed.

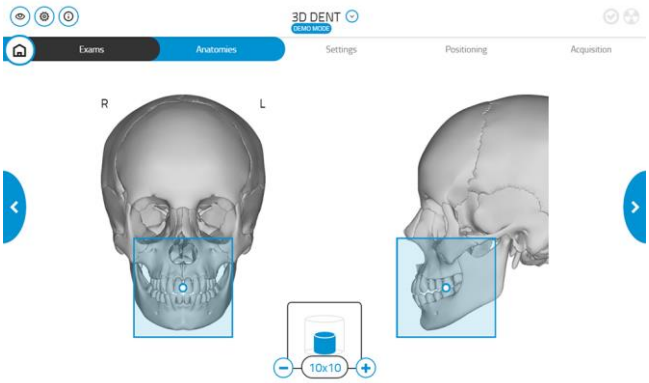
The examination types provided for "3D" category are:
- DENT: examinations on dentition and surrounding bone areas
- SIN: specific examinations of maxillary sinuses that can be viewed in a field with maximum diameter of 10 cm.
- MODEL: acquisition of dentition models in plaster, silicone, resin or other materials typically used in the dentistry field, or of masks or surgical guides. It is recommended NOT to select this type of examination on real patients.

Once the choice has been made, touch NEXT "**>**" to confirm and go to the next screen.



7.2.2. SELECTION OF THE AVAILABLE ANATOMICAL REGIONS FOR 3D EXAMINATIONS

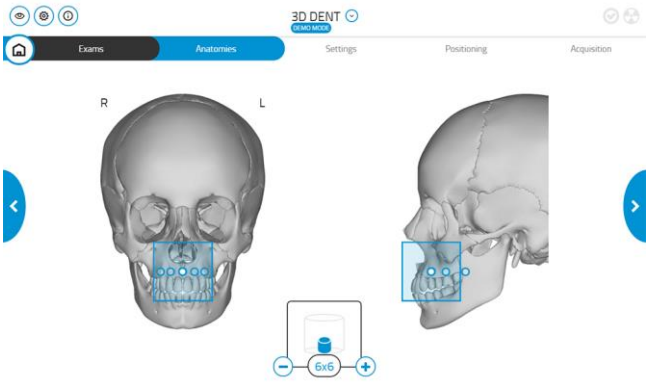
Depending on the circumstances, a reference anatomical model consistent with the examination field chosen will be displayed. The DENT case is shown on the side.



The screen shows the anatomical model in the two Front and Lateral views.

The central box identifies the field of view (FOV) and its position with respect to the anatomical model. By touching a point of the model, it is possible to position the FOV in a specific point and evaluate the dimensions with respect to anatomies.

TO change the FOV size, touch the “+” and “-” symbols to enlarge/reduce the diameter and increase/decrease the cylindrical FOV height.



The box dimensions are modified accordingly and it can be repositioned.

The size of the chosen FOV is displayed, as well as the maximum possible extension achievable.

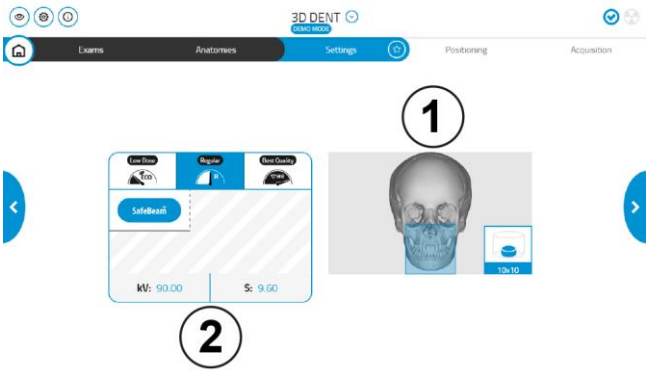
Once the FOV and its position have been chosen, touch NEXT “>” to confirm and go to the next screen.

7.2.3. EXAMINATION SETTINGS

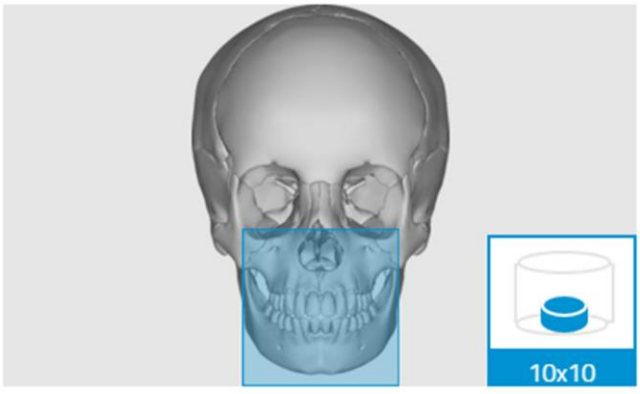
After selecting the examination category and type and the anatomical regions concerned, the SETTINGS screen is shown.

This screen can be displayed also by selecting a “favourite” examination in the Home page.

This screen includes:



1 **Summary of FOV and position chosen:**
touch this area to go back to the ANATOMIES screen, where the choice made can be modified.



2 **DOSE profile:**
in this area, it is possible to select the dose mode of administration.

Technical features are set to ensure the best possible quality of the final image, minimising the radiation dose to the patient according to the chosen profile:

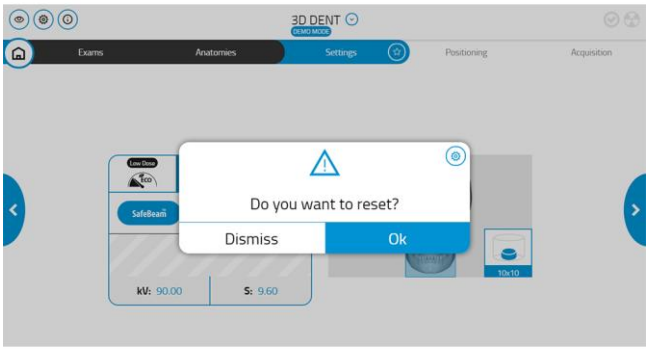
- **LOW DOSE (QUICK)**: scanning time and X-ray parameters are reduced to the minimum necessary for obtaining standard resolution images
- **REGULAR**: scanning time and X-ray parameters are those optimal for obtaining standard-resolution images
- **BEST QUALITY**: scanning time and X-ray parameters are those allowing to obtain the best image resolution

Depending on the choices made, the estimated dose indication will be updated (DAP, kV and mAs), according to the FOV size and the dose profile chosen.

7.2.4. EXAMINATION START CONFIRMATION

When touching the NEXT key "**>**" in the SETTINGS screen, the user will be prompted to confirm the correctness of the chosen settings.

Touching OK is equivalent to pressing the Confirmation button on the physical keyboard of the console.



At this point, the machine moves and automatically prepares for the PATIENT POSITIONING

It is now possible to let the patient access the machine and position him/her as indicated in the next paragraph.

7.3. PREPARATION OF THE EXAMINATION

After the EXAMINATION START CONFIRMATION, control console will communicate to the user the operations to be carried out to perform the examination.
This control consists of:
- indicate which devices are required for the patient positioning and how to position them
- if necessary, be prepared to move removable sensors

A dedicated screen shows the actions necessary to correctly perform the examinations and their state of completion.

When everything is correctly set, the PATIENT POSITIONING page opens.

7.3.1. DEVICES FOR PATIENT POSITIONING

EXAMINATION TYPE	MOBILE SUPPORT	IMAGE
DENT	Craniostat, chin rest and bite.	
SIN	Reduced under-nose support and craniostat.	

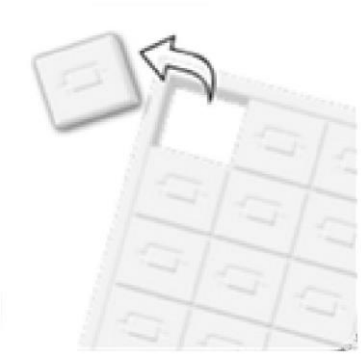
Remember to change the disposable infection control sheaths before positioning a new patient.

Before any X-ray examination, make sure that the patient does not wear metal objects, such as glasses, removable prostheses, earrings and any other removable metal object at the height of head or neck. If a protective apron is used against radiation, make sure that the patient's neck is not covered, otherwise an area not exposed to the X-ray would be obtained.

7.3.2. EDENTOLOUS PATIENTS DEVICES

In case of edentulous patients in PAN, DENT, SIN or CBCT examinations requiring the bite block, use the supplied disposable soft insert as follows:

1 remove the soft bite from the matrix



2 apply the disposable infection control sheath on the bite block

3 insert the soft bite into the bite as indicated in the figure

4 push the bite until the block of material is ejected

Do not exceed these values.

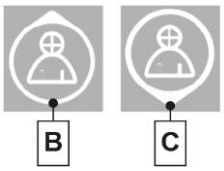
Carry out the normal positioning procedure for the examination making the patient press the soft insert centre with mucous membranes.

7.4. POSITIONING THE PATIENT FOR 3D EXAMINATIONS

3D For 3D machines only.

7.4.1. DENT EXAMINATIONS

1 Once the preparation of the X-ray device is complete, make the patient access the machine.



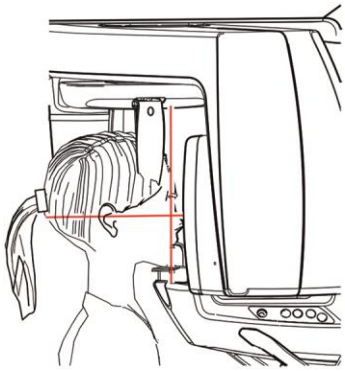
2 Adjust the motorised column height using keys (**B**) and (**C**) (see par. CONTROL PANEL ONBOARD THE MACHINE) to facilitate the patient's access. Bring the column at the patient's height.

3 The patient must grab the handles with both hands and keep a standing position.

4 In 3D examinations, patient's head can be positioned in 3 fixed possible positions: right, central and left. A right- or left-shifted position is essential to centre the field of view in the lateral anatomic regions. This positioning is carried out by manually translating chin rest and craniostat in the desired direction.

A position detector located on the chin rest indicates to the operator whether the chosen position is correct for the selected examination. Otherwise, the software does not allow to continue the examination until a suitable position is set.

5 Adjust the height of the bite and rotate it inside the mouth, asking the patient to bite it as shown in the figure. The tip of upper and lower incisors must be in the bite groove. The interproximal space of incisors must be in the bite midline.



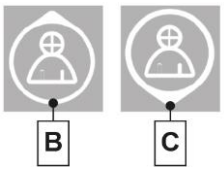
6 Adjust the patient's head position using, as a guide, the front laser trace that identifies the sagittal plane passing through the centre of the selected FOV.

7 Go to the PC workstation.

7.4.2. MAXILLARY SINUSES EXAMINATIONS

1 Once the preparation of the X-ray device is complete, make the patient access the machine.

2 Adjust the motorised column height using keys (**B**) and (**C**) (see par. CONTROL PANEL ONBOARD THE MACHINE) to facilitate the patient's access. Bring the column at the patient's height.



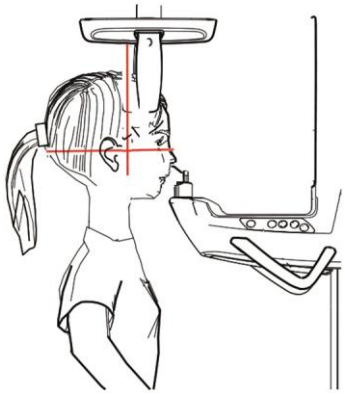
3 The patient must grab the handles with both hands and keep a standing position.

4 In 3D examinations, patient's head can be positioned in 3 fixed possible positions: right, central and left. A right- or left-shifted position is essential to centre the field of view in the lateral anatomic regions. This positioning is carried out by manually translating chin rest and craniostat in the desired direction.

A position detector located on the chin rest indicates to the operator whether the chosen position is correct for the selected examination. Otherwise, the software does not allow to continue the examination until a suitable position is set.

5 Use the lateral laser guides to align the patient as desired.

6 Adjust the patient's head position using, as a guide, the front laser trace that identifies the sagittal plane passing through the centre of the selected FOV.

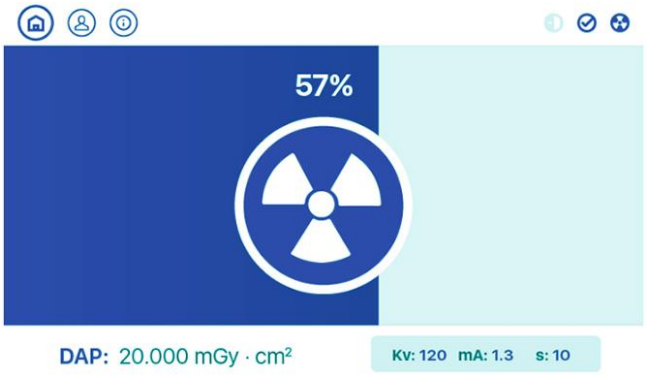


7 Go to the PC workstation.

7.5. PERFORMING THE EXAMINATION

- Visually check the correct position of the patient and make sure that the green LED is steadily on and in the X-ray remote control.
- Tell the patient not to move during the examination, to breath slowly and regularly,
- Make all the unnecessary persons move away from the area exposed to radiation and, when required, go behind the suitable protection.

The console EXECUTION of examination screen shows the X-ray parameters set and the exposure progression.



Follow the instruction of the Acquisition Operations section in the NNT manual to complete the image acquisition. Refer to “Extended View” mode for the acquisition with fields of view of the Extended View type.

Press the X-Ray remote Control to perform the emission and keep it pressed during the whole duration of the examination. The duration of the examination is indicated by the yellow flashing LED of the X-ray remote control device. The X-ray emission is signalled with an audible signal.

7.6. VIEWING AND SAVING

The X-ray system features the NNT program for displaying and saving the examinations; if using this software, refer to the NNT user's manual.
If software by third parties is used to display and save the examinations, refer to the instructions provided by the authors of the software application used.

The use of NNT software is optional in case of 2D examinations (e.g.: panoramic and cephalometric).
The use of NNT software is instead essential for the acquisition of tomographic examinations, since it contains the technology necessary for the reconstruction of volumetric images.

If the X-ray Examination is to be delivered to the patient or to another operator, NNT provides an automatic guide for the creation of a DVD, which includes a redistributable copy of NNT for displaying images (NNT Viewer).

As an alternative, it will be possible to export only X-ray images in a standard format (DICOM 3.0) so that third parties’ software can be used to consult them.

8. PERIODIC CHECKS AND MAINTENANCE

In the interest of safety and health of patients, the staff or third parties, inspections and maintenance need to be carried out at scheduled intervals.

Period	Operator	Object	Description
Yearly	Specialised technician of the dealer that initially installed the device or another technician authorised by the Manufacturer	The X-ray device as a whole	In order to ensure the operating safety of the device, it is advisable to inspect the X-ray device in all its parts, in order to prevent or repair any faults

For installations in the U.S.: please refer to chapter "Inspection and Maintenance".

8.1. PERIODIC INSPECTIONS TO CHECK THE IMAGE

Acquisition of Blank image
The Blank acquisition allows optimising the scanning performance. This short procedure is compulsory and the NNT software requires it every two weeks. To carry out this procedure, consult NNT "Acquisition operations".

8.1.1. X-RAY EMISSION QUALITY CONTROL

In order to assure adequate X-ray emission efficiency, the following parameters should be measured and checked at least on a yearly basis by a qualified technician with proper instruments:

Parameter	Maximum deviation from nominal value	Measurement criteria
Tube peak voltage (kV)	±5%	It should be measured with a calibrated, non-invasive kVp-meter.
Exposure time (s)	±10%	The beginning and end points of exposure time are defined at 70% of peak radiation. They should be measured with a calibrated, non-invasive multimeter.
Half Value Layer [HVL] (mm)	>2.9mm @80kV	Set 80kV and measure the Air Kerma rate with additional 2.9mm Al. filter. Repeat the measure without additional filter. Then: (Dose rate with +2.9mm Al filtration) / (Dose rate without added filtration) > 0.5.

8.1.2. BEAM LIMITER TEST

In order to verify correct X-ray beam alignment, the following check should be performed at least yearly:

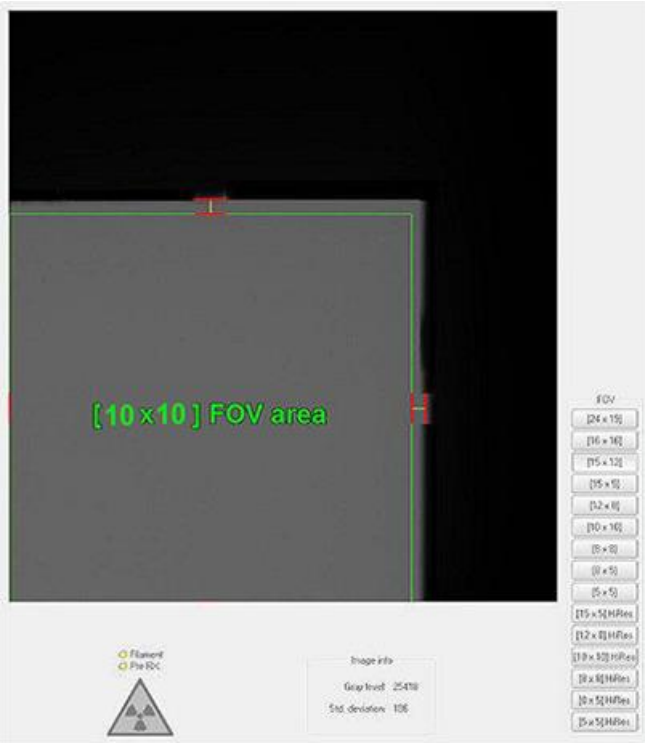
1 From the main bar of the NNT software, select ***"Tools"*** → ***"Scanner Test"***.

2 From the service window bar, select ***"Tools and service window bar"***. Select the desired FOV.

3 Set the appropriate X-ray load parameters according to the FOV used (standard: 4 mA, 10 ms, 90 kV; Hires: 6 mA, 10 ms, 90 kV).

4 Start an acquisition.

5 Check that the collimation is limited within the indicated margins:
- the green rectangle must be completely inside the acquired grey area.
- the grey rectangle sides must pass through the red line pairs where these are drawn.



8.1.3. 2D IMAGE QUALITY CONTROLS BY MEANS OF PHANTOM

In order to verify 2D images quality, the use of a dental phantom compliant with standard IEC 61223-3-4:2000 is recommended.
Acceptance criteria are listed below:

Image resolution (line pairs/mm)	>= 2.5 lp/mm
Low contrast resolution	At least 2 low contrast points can be distinguished
Artefacts	In the image, there must be no artefacts such as visible horizontal lines or halftones
Frequency of the check	Yearly

A phantom with required features is available upon request, with the relevant instructions for use.

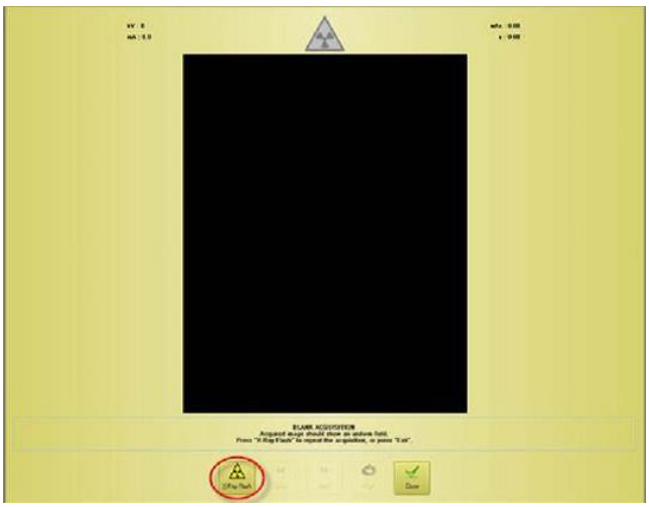
8.1.4. 3D IMAGE QUALITY CONTROLS

- **Acquisition of Blank image**

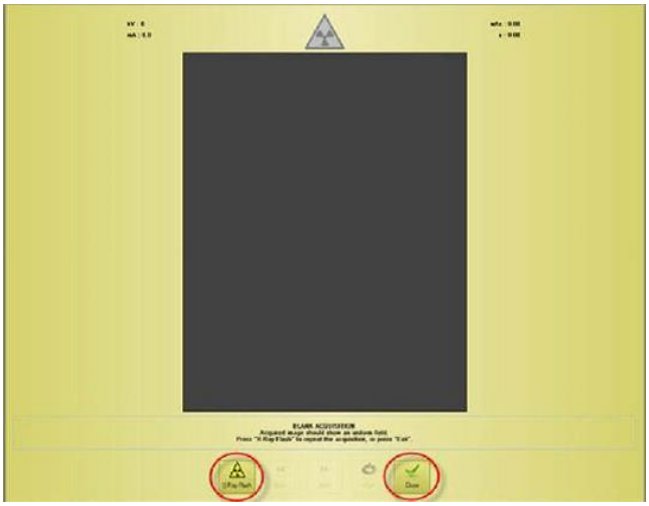
The Blank acquisition allows optimising the scanning performance. This short procedure is compulsory and the NNT software requires it every two weeks.

Please find below the sequence of instructions to be carried out for a correct acquisition.

Make sure the scan area is empty.



After a few seconds the acquired Blank image will appear.
Once the Blank has been acquired, check the image does not present halos or black spots.
If the above-mentioned spots are present, check that the scan area is actually empty, then click again on “X-ray Flash” and repeat the acquisition procedure. If the image is correct, click the “Stop” button.

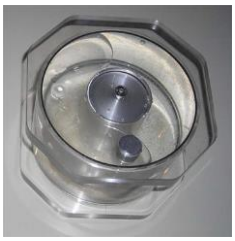


- **3D image quality controls by means of phantom**

The quality control consists in the execution of the standard examination on a suitable QA phantom, through an automatic procedure.
This periodic monitoring, to be performed at least once a year, ensures the verification of the proper functioning of the device and the validity of the results obtained.
Refer to paragraph QA PHANTOM ACQUISITION.

8.1.5. QA PHANTOM ACQUISITION

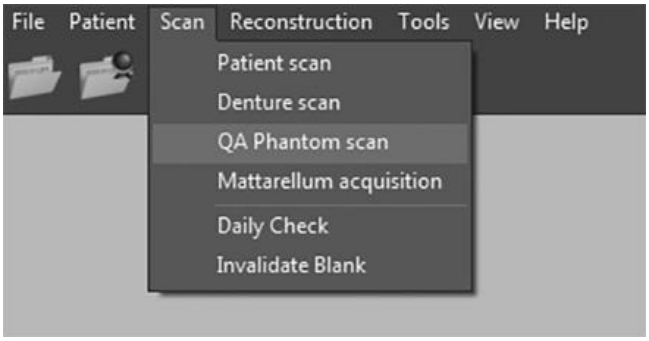
QA Phantom for quality control.



Before carrying out the quality control, fill QA Phantom with water.

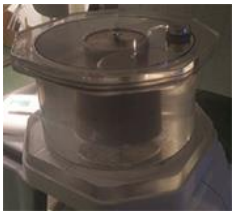
Please find below a description of the operations required to position the QA Phantom and perform the quality control.

From the software main menu, select “Scan” and “QA Phantom scan”.

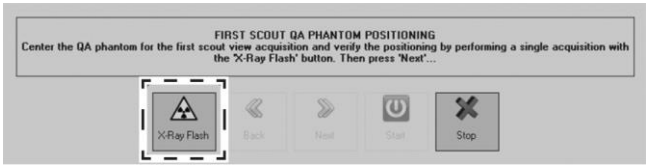


Remove the chinrest and replace it with the octagonal support.

Place the phantom on the octagonal support, as shown in the figure.



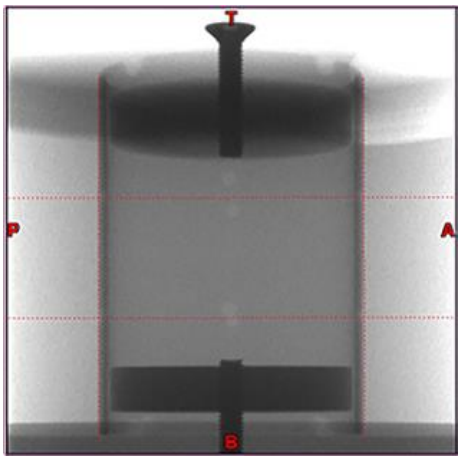
Click on “X-ray Flash” and press the rays button when prompted.



A side scout image is acquired to check positioning.

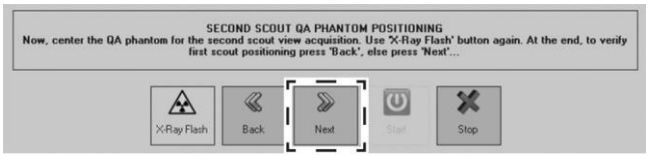
Assess Phantom position; if necessary, correct it in order to reach a position similar to the one shown in the figure:

the aluminium cylinder should be between the vertical red broken lines, whereas the internal balls must pass through by the horizontal red broken lines.



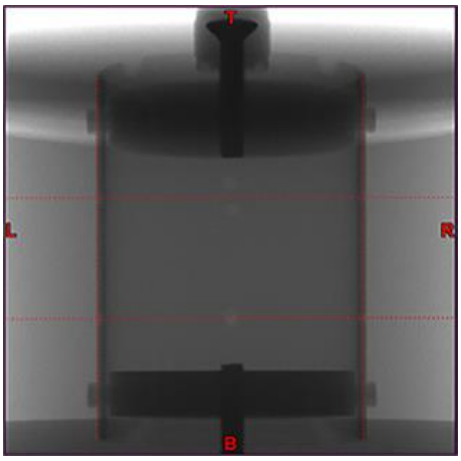
In order to acquire a second scout, click again on “X-ray Flash” and press the rays button when prompted.

Once the correct position is reached, press “Next”.
Then, in order to acquire a front positioning scout, click on “X-ray Flash” and press the rays button when prompted.



The front scout is acquired.

Assess phantom position and correct it as you did for the side scout.

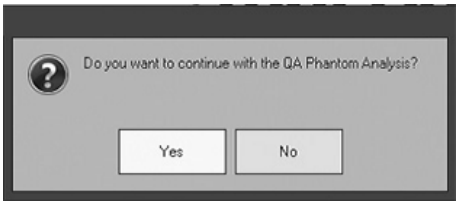


Click “Next” to confirm correct positioning, then “Start”.

Press the X-rays button when prompted.

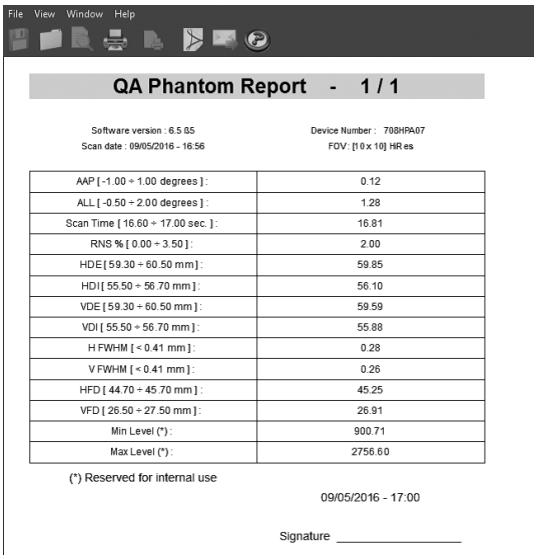
The system performs a complete scan of the QA Phantom.

Once finished, when the system prompts to continue the analysis, chick on “Yes”.



The calculations are made automatically; once finished, a report like the one shown on the left will be displayed.

If no value has asterisks, close the window; should this not be the case, see paragraph QA PHANTOM TROUBLESHOOTING and repeat the procedure.



The following table provides a brief description of the values calculated during the phantom analysis.

Abbreviation	Name	Description
AAP	Phantom's angle in the first scout view	Inclination angle of the symmetry axis of the phantom in the first scout view
AAL	Phantom's angle in the second scout view	Inclination angle of the symmetry axis of the phantom in the second scout view
ScanTime	Scan duration	Scan duration in seconds
RNS%	Noise percentage	Noise percentage on the phantom's central axis expressed as the standard deviation of the value density with respect to their average value in a defined area in the middle of the image (near the water).
HDE	External horizontal diameter	External diameter of the aluminium cylinder along the horizontal axis in the central axial image.
HDI	Internal horizontal diameter	Internal diameter of the aluminium cylinder along the horizontal axis in the central axial image.
VDE	External vertical diameter	External diameter of the aluminium cylinder along the vertical axis in the central axial image.
VDI	Internal vertical diameter	Internal diameter of the aluminium cylinder along the vertical axis in the central axial image.
H FWHM	Horizontal Full Width Half Maximum	Spatial resolution (millimetres) on the aluminium cylinder's horizontal diameter in the central axial image.
V FWHM	Vertical Full Width Half Maximum	Spatial resolution (millimetres) on the aluminium cylinder's vertical diameter in the central axial image.
HFD	Horizontal distance between holes	Average horizontal distance between the cylinder holes in the panoramic image.
VFD	Vertical distance between holes	Average vertical distance between the cylinder holes in the panoramic image.

Below is a description of some countermeasures to take if there are errors in the phantom analysis results. Each error is highlighted with the symbol "****".

Parameter	What to do…
AAP	Verify the phantom acquisition during the first scout view. If tilted, adjust the phantom position.
ALL	Verify the phantom acquisition during the second scout view. If tilted, lift or lower the support.
RNS	Make sure that the phantom has been filled up with water. Perform an acquisition of Blank image with reference to paragraph 8.1.4 "3D image quality controls".
H FWHM & V FWHM	Contact the technical support.

8.2. TYPICAL IMAGES OF THE EXAMS

The following images derive from the acquisition on anthropomorphic phantoms.

8.2.1. ADULT PANORAMIC IMAGING

The program of standard panoramic exposure enables a thorough or partial analysis of the patient's state by selecting the area of diagnostic relevance.

The image on the right shows a typical image with PAN standard exposure.

8.2.2. CHILD PANORAMIC IMAGING

The program of standard panoramic child (PAN CHILD) produce an automatically reduced and optimized exposure that with a reduction in trajectory / time / dose still allows the evaluation of the overall oral health of the patient.
The image on the right shows a typical image with PAN CHILD exposure.

8.2.3. TMJ EXAMINATIONS (TEMPOROMANDIBULAR JOINT)

Programs for the X-ray of temporomandibular joints (TMJ) allow a study of the temporomandibular state in the following modes:

8.2.3.1. LATERAL VIEW OF BOTH CONDYLES (2 IMAGES)

Two X-ray images are produced with a single scanning of both right and left condyles.

The entire structure of tempoeromandibular joints is shown in latero-lateral view.

The image on the right shows a typical image with TMJ LAT exposure on both the condyles.

8.2.3.2. FRONT VIEW OF BOTH CONDYLES (2 IMAGES)

Two X-ray images are produced with a single scanning of both right and left condyles.

The entire structure of tempoeromandibular joints is shown in postero-anterior view.

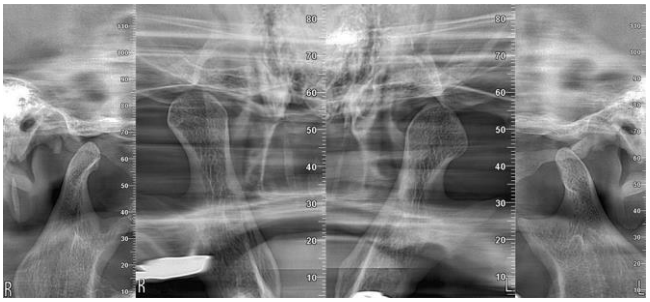
The image on the right shows a typical image with TMJ FRONT exposure on both the condyles.

8.2.3.3. COMBINED VIEW OF BOTH CONDYLES (4 IMAGES)

Four X-ray images are produced with a single scanning of both right and left condyles.

The entire structure of tempoeromandibular joints is shown in postero-anterior and lateral view.

The image on the right shows a typical image with TMJ Both exposure on both the condyles.

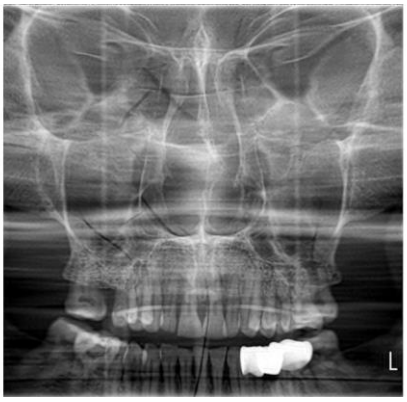


8.2.4. SIN EXAMINATIONS

The program for the X-ray of maxillary sinuses (SIN) allows a study of the state of this anatomical region with one latero-lateral or postero-anterior X-ray image.

8.2.4.1. FRONT VIEW

The image on the right shows a typical image with SIN FRONT exposure.



8.2.4.2. LATERAL VIEW

The image on the right shows a typical image with SIN LAT exposure.

8.2.5. BITEWING EXAMINATIONS

The program of crown exposure (BiteWing) allows an analysis of the structures corresponding to the patient's bite with an orthogonal projection, producing 2 to 4 images, according to the selected areas.

The image on the right shows a typical 4-image BITEWING standard exposure.

8.2.6. DENTITION EXAMINATIONS

The program of dentition exposure allows reducing the field of exposure to the dentition alone or to parts of it, reducing the overlapping of dental elements with respect to standard PAN.

The image on the right shows a typical image with DENTITION exposure of both complete arches.

8.2.7. CEPH EXAMINATIONS

Programs of Ceph exposure are designed to produce tele-X-ray images typically used for analyses and studies of cephalometry, orthodontics, gnathology.

8.2.7.1. CEPH AP-PA

The program of Ceph AP-PA exposure, depending on whether the cephalostat is in the Antero-Posterior (AP) or Postero-Anterior (PA) position, produces an image of the maxillofacial region with a front view.

The image on the right shows a typical image with CEPH AP exposure.

8.2.7.2. CEPH LATERAL

With the programs of Ceph LATERAL exposure, an image of the cranium with a latero-lateral view is produced.

Depending on the extension of the selected field of view, it is possible to acquire or exclude the areas extending from the temporal bone to the occipital bone in the longitudinal direction and to acquire or exclude the upper area of the skullcap.

The image on the right shows a typical image with CEPH LATERAL - FULL LONG exposure, which shows the maximum field of view that can be acquired using CEPH LATERAL programs.

The image on the right shows a typical image with CEPH LATERAL - FULL STANDARD exposure, where only the cranium front part is acquired

8.2.7.3. CEPH CARPUS

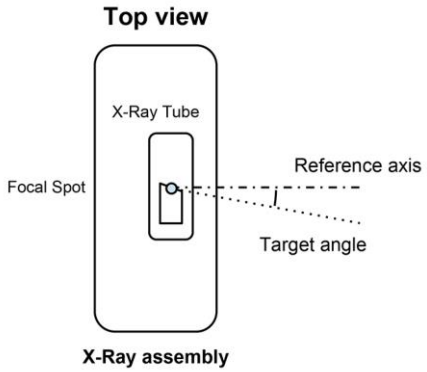
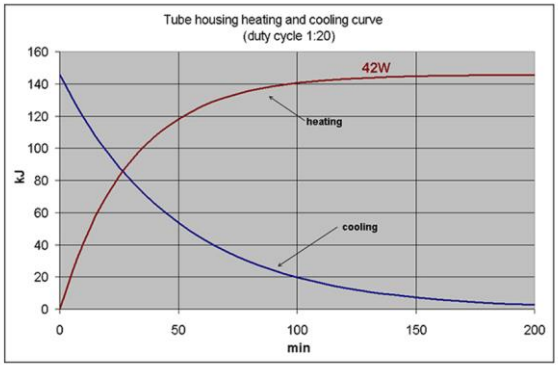
The program of CEPH carpus exposure allows viewing the carpus bones of the left hand, typically used to determine the patient's skeletal age

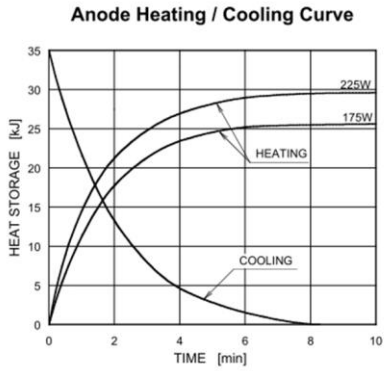
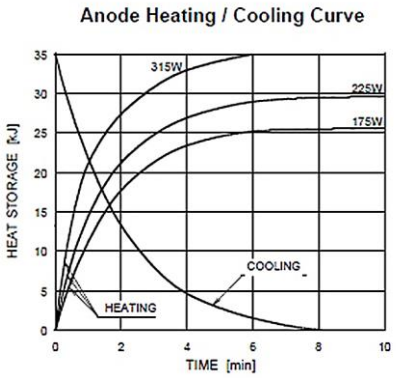
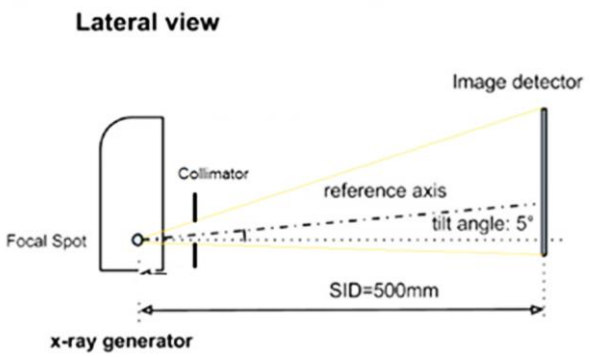
9. TECHNICAL DATA

9.1. ELECTRICAL CHARACTERISTICS

Input voltage	Single-phase 115 – 240 VAC
Power supply frequency	50 / 60 Hz
Current absorbed in rest conditions	1A @ 115V; 0.5A @ 240V
Maximum current absorbed in operating conditions	20A @ 115V; 12A @ 240V
Column movement operating cycle	25 s ON, 400 s OFF
Maximum apparent line resistance	0.5 Ω @ 240 V - 0.25 Ω @ 115 V
Overvoltage class	II
Power supply system protection	With limiter at maximum current of 20 A and differential current of 30 mA
Current/voltage combination for the maximum output power	72 kV, 15 mA

9.2. RADIOLOGICAL CHARACTERISTICS

Generator voltage	2D: 60 – 85 kV 3D: 90 kV pulsed mode (max 12mA)
Anode current	4-15 mA
Maximum continuous input anode power	42 W
Leakage Technique Factor (LTF)	90kV; 0.47mA
Maximum peak input anode power	1080W
Maximum deviations from declared values	kV: < 5% mA: < 10% ms: < (5% + 50 ms) mAs: < 10 % + 0.2 mAs Linearity error < 0.2 Coefficient of variation < 0.05
X-ray tube	*For 2D machine only:* CANON / TOSHIBA D-054SB *For 3D machine only:* CANON / TOSHIBA D-067SB
Focal spot size	2D: 0.5 mm (IEC 60336) with CANON / TOSHIBA D-054SB 3D: 0.6 mm (IEC 60336) with CANON / TOSHIBA D-067SB
Anode material	Tungsten (W)
Anode inclination	2D: 5° with CANON / TOSHIBA D-054SB 3D: 12° with CANON / TOSHIBA D-067SB  **X-Ray assembly**
Anode thermal capacity	35 kJ = 49 kHU (CANON / TOSHIBA D-054SB - CANON / TOSHIBA D-067SB)
Temperature curves of cylinder block	

Anode thermal curves	2D: CANON / TOSHIBA D-054SB  3D: CANON / TOSHIBA D-067SB 
Inherent filtration (including supplementary filtration)	2D mode: >2.5 mm Al @ 85kV 3D mode: 6 mm Al @ 90kV
Half value layer (HVL)	2D: >= 3.1mm @ 85kV 3D: >= 4.5mm @ 90kV
Stray radiation	<0.88mGy / h at 1 metre from the focal spot at 90KV in conditions of maximum continuous input anode power equal to 42 W (in compliance with 21CFR and IEC)
Exposure time	2D: 1s - 15s @ 72 kV - 15 mA 3D: 1s - 10s pulsed mode (25% ON - 75% OFF) @ 90 kV - 12 mA (equivalent to an examination time of 4 – 40 s)
Source distance - primary collimator	2D: 100mm 3D: 120mm
Output radiation intensity (Output dose)	0.20 mG/mAs @ 70 kV, 500 mm/ 0.30 mG/mAs @ 90 kV, 500 mm/ tolerance ±30%
Source - detector distance (SID)	500 ±5 mm 2D PAN: 500 mm ± 5 mm 2D CEPH: 1610 mm ± 5 mm 3D: 500 mm ± 5 mm
Generator reference axis:	

9.3. DISPERSED RADIATION

Measurements of dispersed radiation are significantly affected by environmental conditions, such as the composition of walls and their position, therefore, in certain circumstances, values can be significantly different.
The measurement points used are at a distance of 0.5 m, 1.0 m, 2.0 m and 3.0 m from a central axis.
Circular measurement curves refer to the above mentioned axis.
Dispersed radiation is measured in standard panoramic X-ray mode or in 3D mode with medium field in patients with a large build, selected with a phantom cylinder PMMA (Φ 16 cm diameter x 17 cm height) to simulate the patient's head.

1 Standard panoramic X-ray: Dispersed radiation measured at the maximum percentage of use permitted by the X-ray generator (it corresponds to an average anode power of 42 W).

Distance between the rotation axis and the measurement point (Circular measurement points)	Dispersed radiation*
0.5 m	60 µGy / h
1.0 m	15 µGy / h
2.0 m	4 µGy / h
3.0 m	1.5 µGy / h

2 Standard panoramic X-ray: Dispersed radiation at the average percentage of use or 4 examinations per hour.

Distance between the rotation axis and the measurement point (Circular measurement points)	Dispersed radiation*
0.5 m	12 µGy / h
1.0 m	3.0 µGy / h
2.0 m	0.8 µGy / h
3.0 m	0.3 µGy / h

3 3D 10x8 standard/regular: Dispersed radiation measured at the maximum percentage of use permitted by the X-ray generator (it corresponds to an average anode power of 42 W).

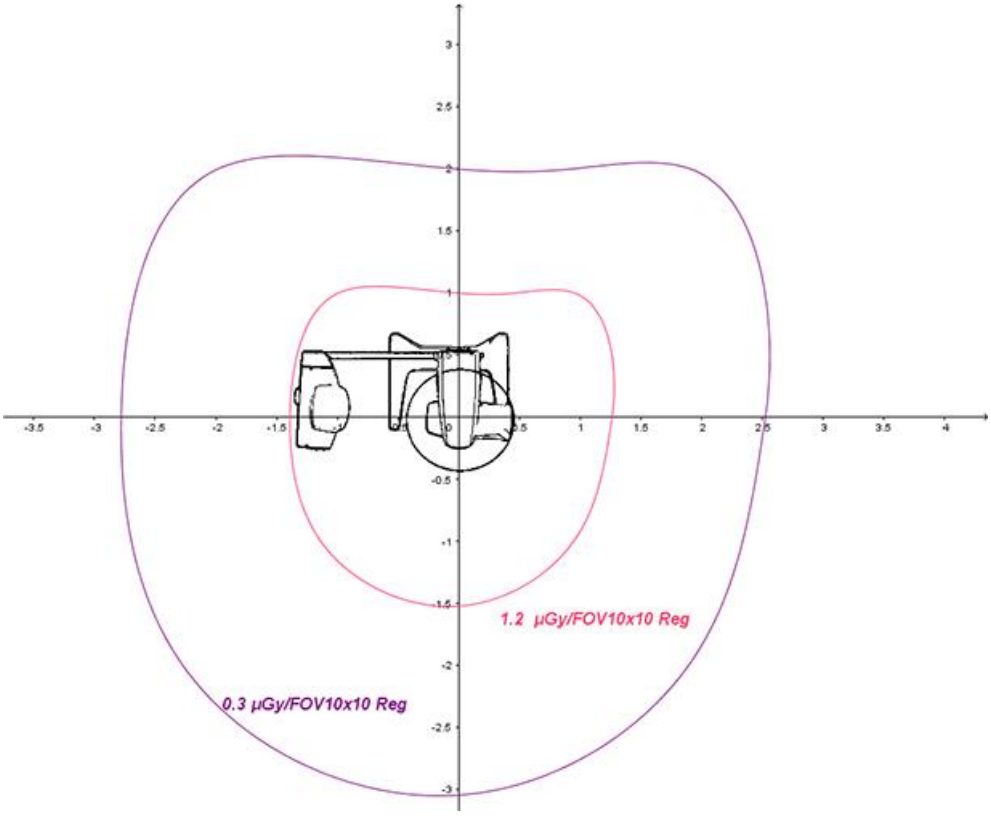
Distance between the rotation axis and the measurement point (Circular measurement points)	Dispersed radiation*
0.5 m	670 µGy / h
1.0 m	180 µGy / h
2.0 m	45 µGy / h
3.0 m	21 µGy / h

4 3D 10x6 standard/regular: Dispersed radiation at the average percentage of use or 4 examinations per hour.

Distance between the rotation axis and the measurement point (Circular measurement points)	Dispersed radiation*
0.5 m	45 µGy / h
1.0 m	12 µGy / h
2.0 m	3 µGy / h
3.0 m	1.4 µGy / h

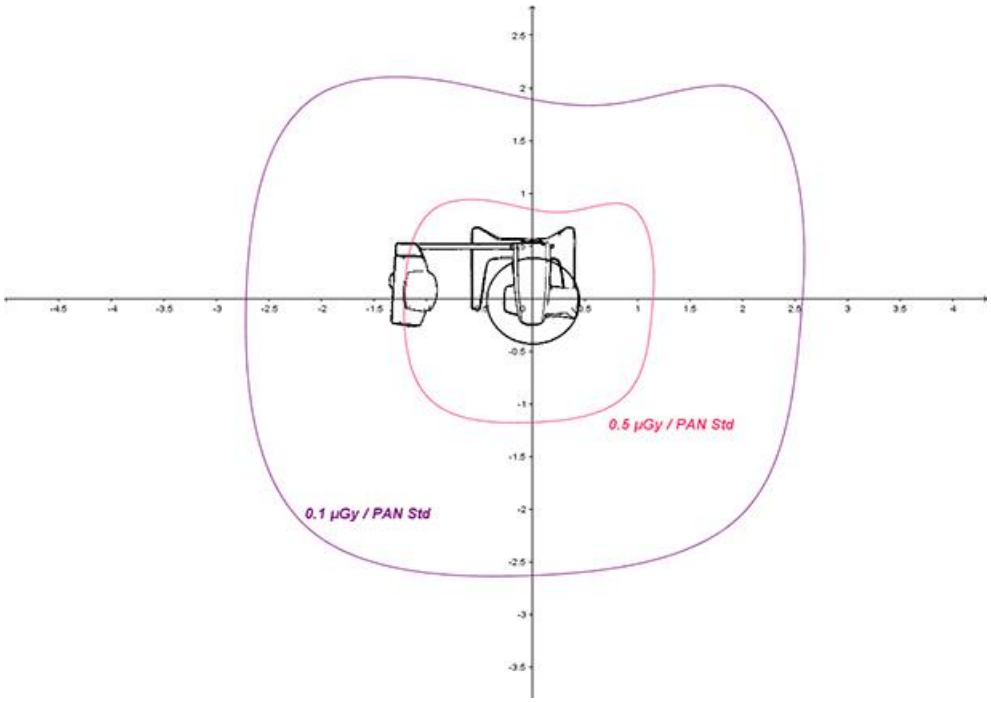
***It is the highest value at 15 cm over the horizontal intersection plane with the patient's bite. The other values of the vertical axis are lower than these values.**

9.4. ISODOSE CURVES FOR CBCT EXAMINATIONS

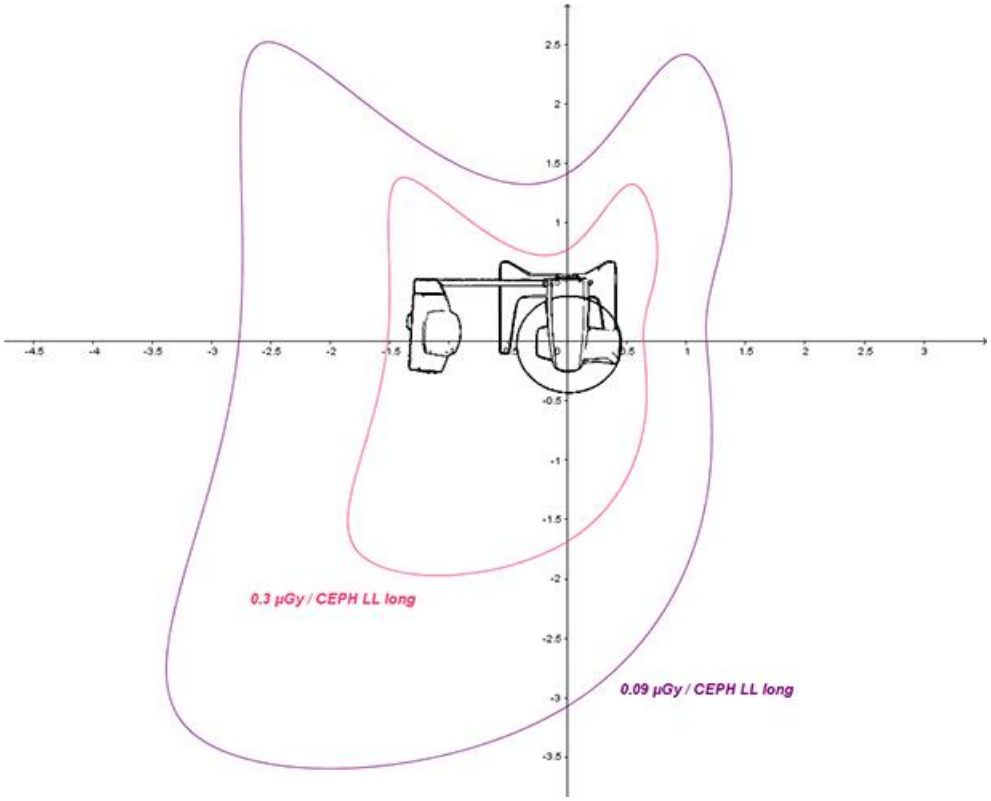


9.5. ISODOSE CURVES FOR PAN AND CEPH EXAMINATIONS

PAN



CEPH



9.6. CBCT DETECTOR FEATURES

Sensitive area dimensions	162 x 162 mm (actual 160 x 160)
Resolution	3.94 LP/mm
Pixel size	127 x 127 µm
Sensor technology	Amorphous silicon
Scintillator material & type	Direct Deposition CsI
MTF	58% @ 1lp/mm (1x1)
DQE	70% @ 0lp/mm (1x1)
Image matrix dimensions	1280 x 1280 pixels
Pixel depth	16 bit
Max Full Field 1x1 Frame Rate	24 fps
Connection	Gigabit Ethernet
Voxel size	80 µm in High Resolution mode (MTF10 ≥ 2 lp/mm) 160 µm in Standard Resolution mode

9.7. 2D DEDICATED PANORAMIC SENSOR FEATURES (PAN)

Actual sensitive area dimensions	148 x 6 mm (151.2 x 6 mm)
Resolution	> 3.1 lp/mm (PAN projection)
Primary screen	> 0.5 mm Pb
Pixel size	100 µm
Sensor technology	CMOS
Scintillator material & type	Direct Deposition CsI
Sensor matrix dimensions	1480 x 60
Gray level	14 bit
Magnification (PAN)	1.25 PAN HD
Connection	Gigabit Ethernet

9.8. TELE-X-RAY SENSOR FEATURES (CEPH)

Actual sensitive area dimensions	223 x 6 mm
Primary screen	> 0.5 mm Pb
Pixel size	100 µm
Sensor technology	CMOS
Scintillator material & type	Direct Deposition CsI
Sensor matrix dimensions	2232 x 60
Gray level	14 bit
Connection	Gigabit Ethernet

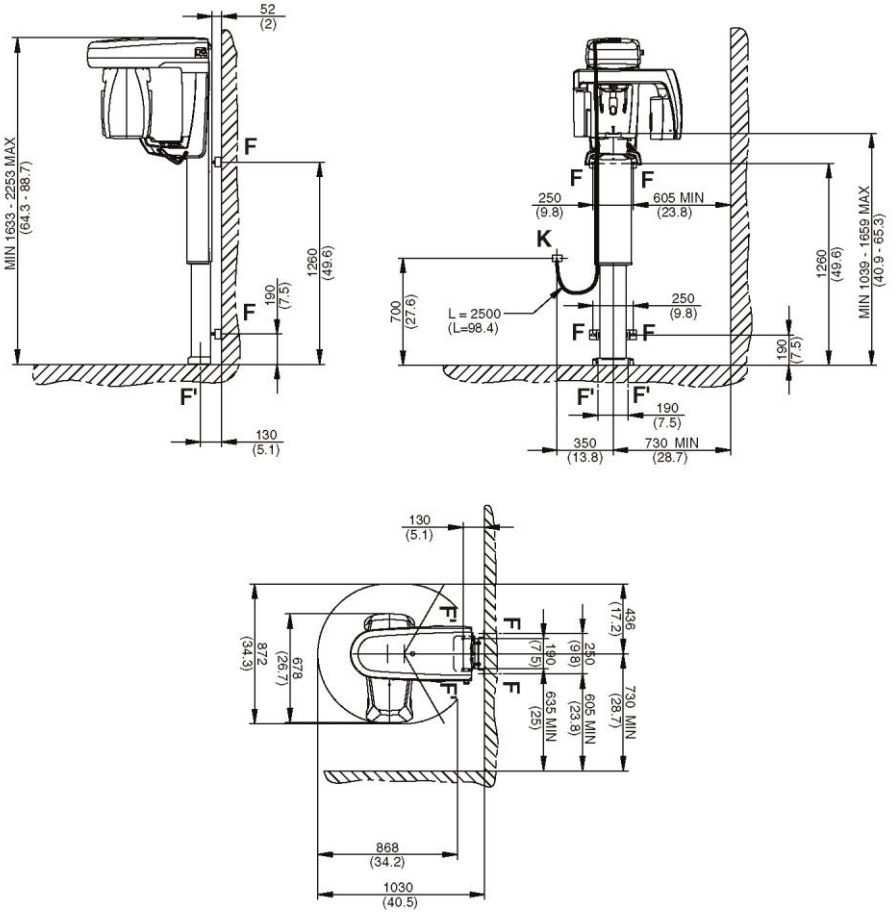
9.9. LASER CHARACTERISTICS

Classification	Class 1 according to IEC 60825-1:2014
Diffractive optics	Aspheric lens; linear shape; 58° opening
Wave length	635-650 nm
Activation mode	Timed
Warning plate	

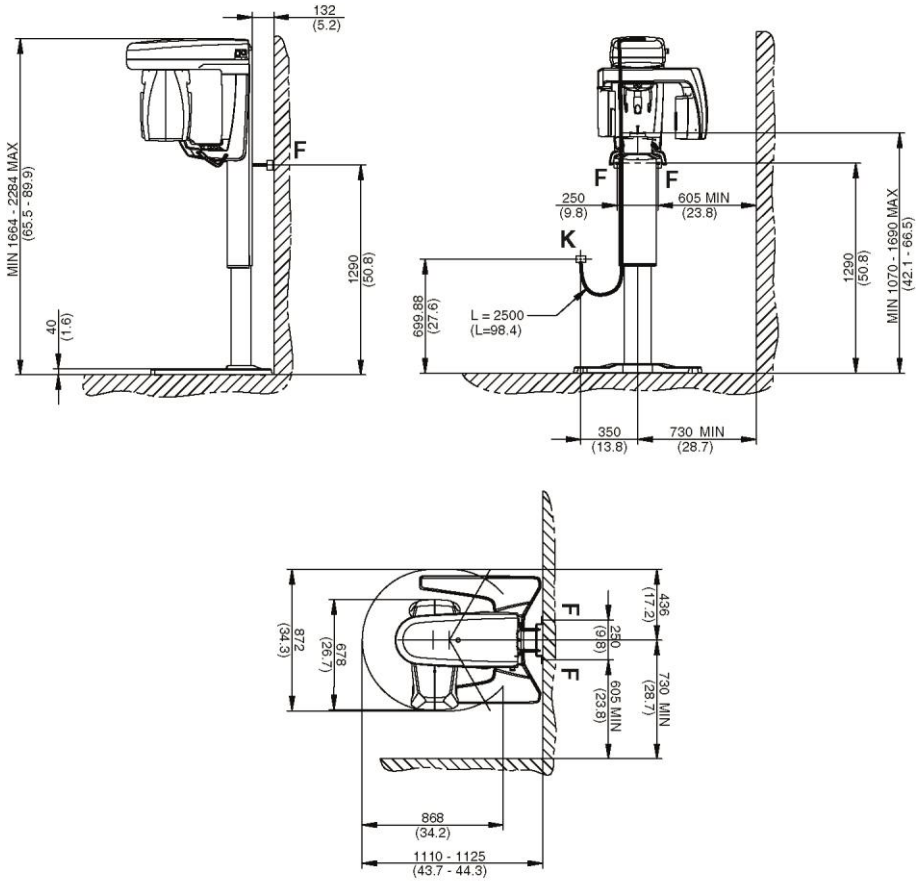
9.10. DIMENSIONAL CHARACTERISTICS

Weight	3D basic machine: 61 Kg 2D basic machine: 44 Kg Telescopic column (floor version): 43 Kg Tele-X-ray arm with PAN/CEPH sensor: 21 Kg Stand base 25 Kg
Maximum overall dimensions in diagram	Floor version, without tele-X-ray arm: 1030 x 872 mm Floor version, with tele-X-ray arm: 1030 x 1785 mm
Height (min – max)	1630-2250 mm
Packaging and disassembling units for transport	Basic machine: 930 x 690 x 960 mm Telescopic column (floor version): 1860 x 355 x 350 mm Tele-X-ray arm with PAN/CEPH sensor: 575 x 1275 x 380 mm

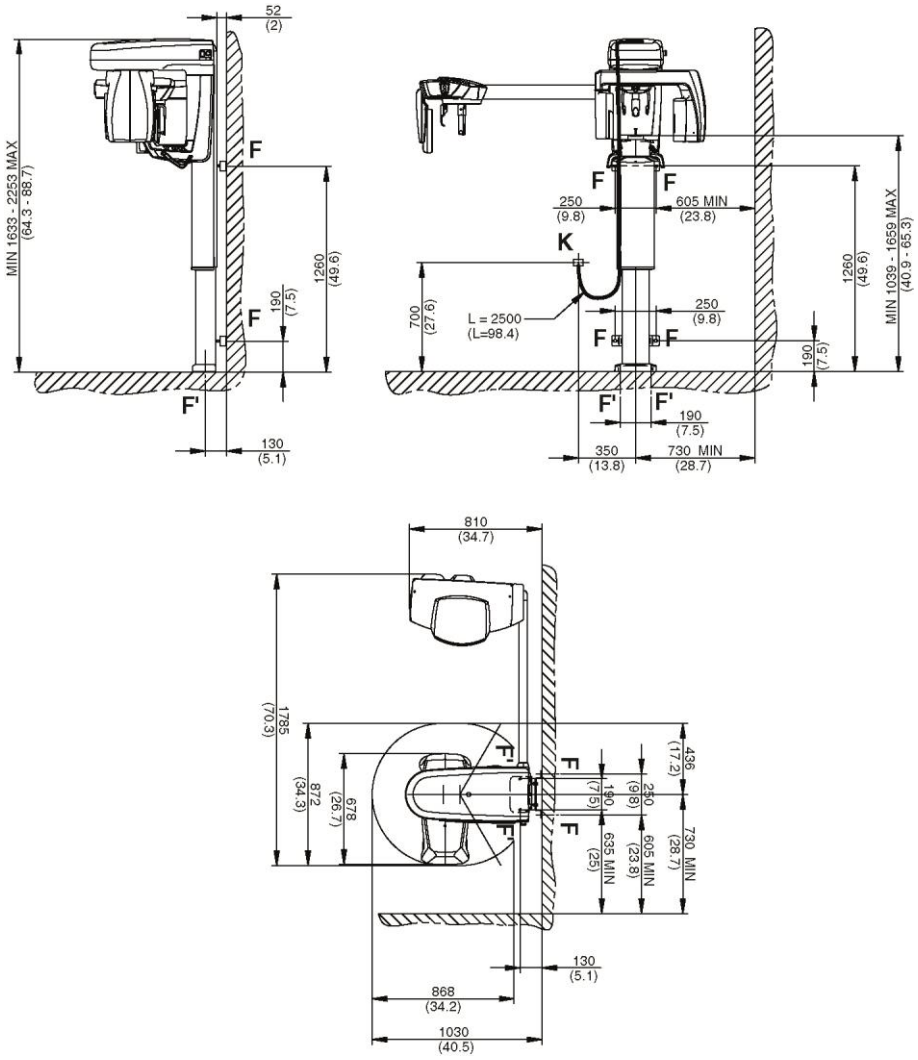
Floor version without tele-X-ray arm and without stand



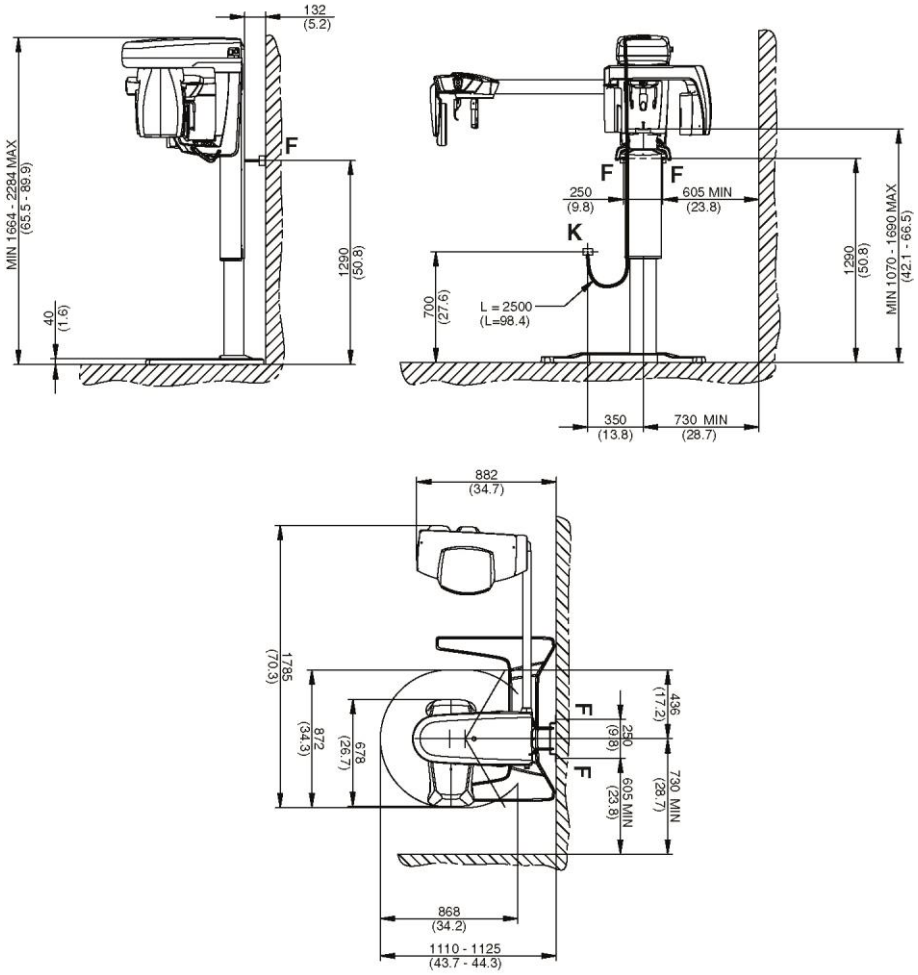
Floor version without tele-X-ray arm, with stand



Floor version with tele-X-ray arm, without stand



Floor version with tele-X-ray arm and with stand



9.11. ENVIRONMENT CHARACTERISTICS

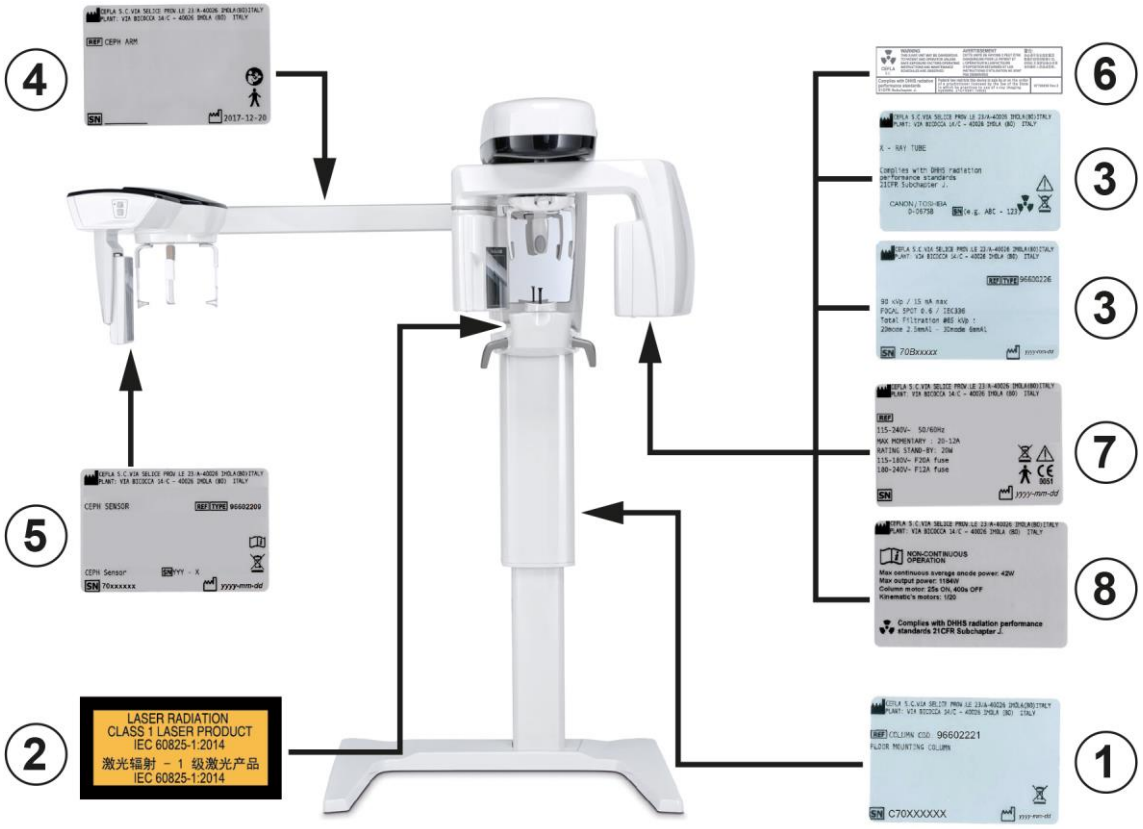
Operating conditions	Temperature +10 - +35 °C (max. +30 °C during the acquisition operations)
	Relative humidity between 10 - 90%
	Pressure 700 – 1060 hPa
	Altitude < = 3000 m
	Degree of pollution: 2
	CTI degree: IIIb
Transport and storage conditions	Temperature -10 - +70 °C
	Relative humidity between 10 - 90%
	Pressure 700 – 1060 hPa

9.12. PC REQUIREMENTS

For more details on minimum and recommended hardware and software requirements for workstations directly connected to reference or additional devices, refer to the “Minimum and Recommended System Requirements” attachment.

9.13. IDENTIFICATION LABEL POSITION

Releasing the button before the examination is completed will stop the image acquisition.



1 Column nameplate
2 Laser danger and warning nameplates
3 Generator nameplates
4 CEPH arm nameplate
5 PAN / CEPH sensor identification nameplate
6 DHHS and WARNING nameplate
7 Main nameplate
8 Mark nameplate

10. ERROR MESSAGES

CODE	MESSAGE	DESCRIPTION/SOLUTION
USER COMMUNICATIONS		
	The shielded door connected to the X-ray device is open.	Close the door or any other device which ensures a safe X-ray emission for the operator.
WARNING		
0.1	X-ray control released during exposure.	Keep X-ray emission control pressed until the end of the procedure.
0.2	X-ray control not released at the end of the examination.	• X-ray control pressed for too long after the end of the exposure (>15s). • Reset command sent while the X-ray control was pressed. • The device exited stand-by mode while the X-ray control was pressed.
0.3	Emergency stop button onboard the machine pressed.	Release the emergency stop button.
0.7	Open door detected (active interlock).	Check interlock switch (unclosed door?).
0.9	Device not configured.	Configure it from PC.
0.10	Device not calibrated.	Calibrate the unit.
0.13	Key pressed upon start-up.	Keys pressed upon start-up detected. Check that all keyboard keys are working properly.
0.18	Check the Craniostat correct position.	Check the Craniostat correct position.
0.20	Move 2D Detector to the PAN position.	Move 2D Detector to the PAN position.
0.21	Move 2D Detector to the CEPH position.	Move 2D Detector to the CEPH position.
0.24	Wait for confirmation before pressing.	X-ray control pressed before starting the CBCT examination procedure. For CBCT examinations, launch “Patient scanning” from NNT and wait for the explicit request before pressing the X-ray control.

For any other error, turn off the unit, wait for 30 sec and turn it on again. If the problem persists, please contact the technical service department.

11. USER'S LICENCE CONTRACT

IMPORTANT: READ CAREFULLY

11.1. GENERAL CONDITIONS OF THE IMAGE SOFTWARE LICENCE

This license applies exclusively to the software, intended as specific drivers and libraries for the connection to the digital X-ray system and for its control, and to the image display and storage software, identified as a whole as "NNT" and "NNT viewer" (hereinafter referred to as "software") processed by CEFLA s.c. - Via Selice Prov.le 23/A 40026 Imola (Italia), (hereinafter referred to as the "author") and delivered to the customer (hereinafter referred to as the "user"). These conditions are considered to have been acknowledged and accepted in full when the program is installed.
This means that the normal installation and use of this program is equivalent to the unconditional acceptance of all these terms.

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12. INSPECTION AND MAINTENANCE

12.1. USER INSPECTION

These instructions describe the maintenance procedures for the extraoral X-ray system.
These instructions apply to all versions of said equipment, as well as all the accessories that may have been provided, therefore the description of some parts may not correspond to your equipment.
Inspection and preventive maintenance must be performed at scheduled intervals to protect the health and safety of patients, users and other persons in accordance with national regulations regarding the use and maintenance of dental x-ray units that are in force in the country where the device is installed.
In order to ensure the operational safety and functional reliability of your product, the system owner should check the equipment at regular intervals (at least once a year) or commission an authorised technician to do so.
If one or more checks to be performed are not satisfactory, please contact your dealer for technical support.

Answer questions with yes (√) or not (−)

			Inspection DATE				
Step	**Description**	**Reference in the manual**	**__/__/20__**	**__/__/20__**	**__/__/20__**	**__/__/20__**	**__/__/20__**
1	Check that all labels located - on the detector/s - on 3D panel (if any) - at the base of the column - on the X-ray tube housing, are intact, well attached and legible.	Section **Position of identification labels**					
2	Check there are no external damages to the equipment, which may reduce protection against radiation.	Section **Description of the operations**					
3	Check the remote emission button cable is not broken or scratched.	Section **X-ray emission remote control**					
4	Check the power switch, verifying that it is working properly and that the touch panel display switches on when the switch is in the ON position.	Section **Starting the system**					
5	Verify that exposure is immediately interrupted when x-ray button is released	Section **X-ray emission remote control**					
6	Check the touch screen console functionality: functions must respond to interrogation.	Section **Touch screen display**					
7	Check proper functioning of X-ray exposure LED and exposure buzzer	Section **X-ray emission remote control**					
8	Check proper functioning of X-ray centring laser traces	Section **Laser positioning system**					
9	Make sure that the detector is smoothly inserted inside the guides on Pan and CEPH sides - only for units with Cephalometric arm and removable detector.	Section **Sensor positioning**					
10	Perform a movement test running the Dummy panoramic procedure, making sure the movement on the 3 axes X, Y, R (rotation and translation simultaneously) is smooth and without noise. See figure 1, next page.	To perform a dummy cycle, namely the simulation of an examination without the emission of X-rays, select any type of panoramic X-ray examination and reset the unit. Once the reset position has been reached, press the “Reset” button and keep it pressed during the entire procedure, otherwise the movement will stop.					
11	If a Cephalometric arm is installed, perform a movement test for the cephalometric detector using the Dummy Ceph test procedure, and making sure that the movement on the H axis (translation) is smooth and without noise. See figure 1, next page.	To perform a dummy cycle, namely the simulation of an examination without the emission of X-rays, select any type of cephalometric examination and reset the unit. Once the reset position has been reached, press the “Reset” button and keep it pressed during the entire procedure, otherwise the movement will stop.					
12	Perform column movements, up and down on the Z axis and check proper functioning. See figure 2, next page.	Section **Control panel (console onboard the machine)**					
13	Check the emergency stop button functionality. Emergency stop button is used to stop X-ray device operation, it is located under the patient’s support arm, near the telescopic column (**Emergency stop button**).	User Manual, section **Emergency stop button**					
14	Check the x-ray generator functionality performing a complete trial exposure. Select any panoramic exam and reset the unit. Hold down the emission button throughout the entire exam procedure. Absence of error messages assures proper generator functionality.	Section **Performing a 2D X-Ray examination**					
If Quality Phantoms are not available at installation site, then contact your dealer tech support to have the Quality Assurance procedure performed at your premises							
15	Perform an exam on the 3D Quality Phantom and evaluate the quality of the outcome volumetric study.	**Acquisition Operations with Annex**					

Operator Name					
Signature					

The undersigned confirms that the equipment was checked for the above criteria and that, in case of any malfunction, an authorised technician of the local dealer was informed.

All inspection and maintenance work performed by the system owner and/or service engineer must be recorded in this document and kept near the unit!

12.2. TECHNICAL MAINTENANCE

These instructions describe the maintenance procedures for the extraoral X-ray system. These instructions apply to all versions of said equipment.
In order to ensure the operational safety and functional reliability of the equipment installed, at least once a year an authorized service technician must perform a full inspection of the device.
When taking measurements that require a multimeter, always use a calibrated digital multimeter.
All the following tests will be carried out. Customer should be notified prior to replacing any parts.

Answer questions with yes (√) or not (−)

Step	Description	Reference in the manual	Inspection DATE __/__/20__	__/__/20__	__/__/20__
1	"Check that all labels located - on the detector/s - on 3D panel (if any) - at the base of the column - on the X-ray tube housing, are intact, well attached and legible."	User Manual, section **Identification nameplate position**			
2	Check there are no external damages to the equipment, which may reduce protection against radiation.	User Manual, section **Description of operation**			
3	Open the generator covers and check that there are no leaks from the X-ray tube head; if leaks are detected, replace it.	See Technical Instruction, section **Replacing Cylinder Block Assembly**			
4	Remove the dust accumulated inside the generator casing using a vacuum cleaner, then refit the covers.	See Technical Instruction, section **Replacing Cylinder Block Assembly**			
5	Check that the remote emission button cable is not broken or scratched	User Manual, section **X-ray emission remote control**			
6	Switch off the unit and disconnect it from the main power supply and check the condition of the main power supply cable. Replace it in case of damage. Connect it back making sure the safety ground is securely connected.	Technical Manual, section **PFC board wiring connections**			
7	Check the power switch, verifying that the ON/OFF button is working properly and that the touch panel display switches on when the switch is in the ON position.	User Manual, section **Starting the system**			
8	Check the touch screen console functionality: functions must respond to interrogation.	User Manual, section **Touch screen display icons**			
9	Check proper functioning of X-ray exposure LED and exposure buzzer	User Manual, section **X-ray emission remote control**			
10	Check proper functioning of X-ray centring laser traces	User Manual, section **Laser traces**			
11	Make sure that the detector is smoothly inserted inside the guides on Pan and CEPH sides - only for units with Cephalometric arm and removable detector.	User Manual, section **Sensor movement**			
12	Perform a movement test running the Dummy panoramic procedure, making sure the movement on the 3 axes X, Y, R (rotation and translation simultaneously) is smooth and without noise. See figure 1, next page.	To perform a dummy cycle, namely the simulation of an examination without the emission of X-rays, select any type of panoramic X-ray examination and reset the unit. Once the reset position has been reached, press the “Reset” button and keep it pressed during the entire procedure, otherwise the movement will stop.			
13	If a Cephalometric arm is installed, perform a movement test for the cephalometric detector using the Dummy Ceph test procedure, and making sure that the movement on the H axis (translation) is smooth and without noise. See figure 1, next page.	To perform a dummy cycle, namely the simulation of an examination without the emission of X-rays, select any type of cephalometric examination and reset the unit. Once the reset position has been reached, press the “Reset” button and keep it pressed during the entire procedure, otherwise the movement will stop.			
14	Perform column movements, up and down on the Z axis and check proper functioning. See figure 2, next page.	User Manual, section **Control panel (console onboard the machine)**			
15	Check the emergency stop button functionality. Emergency stop button is used to stop X-ray device operation, it is located under the patient’s support arm, near the telescopic column	User Manual, section **Emergency stop button**			
16	Verify that exposure is immediately interrupted when x-ray button is released	User Manual, section **X-ray emission remote control**			
17	Check the x-ray generator functionality performing a complete trial exposure. Select any panoramic exam and reset the unit. Hold down the emission button throughout the entire exam procedure. Absence of error messages assures proper generator functionality.	User Manual, section **Performing a 2-D X-Ray examination**			
18	Perform a complete 2D calibration of the unit: column calibration, PAN x-ray alignment, PAN detector calibration, PAN mechanical alignment, Laser test. In case of Cephalometric option, perform also the following calibrations: Ceph alignment, Ceph detector calibration, Ceph mechanical alignment, Nasion Calibration, Ear guide loops alignment.	Technical manual, section **2D Calibration**			
19	At the end make a calibration backup	Technical manual, section **Calibration backup**			
20	Perform a complete 3D calibration of the unit: Beam limiter test, Daily check, Cylindrical test phantom acquisition.	Technical manual, section **3D Calibration**			
21	At the end make a 3D calibration backup	Technical manual, section **3D calibration backup**			
22	Perform an exam on the 3D Quality Phantom and evaluate the quality of the outcome volumetric study.	**Acquisition Operations with Annex**			

Operator Name			
Signature			

The undersigned confirms that the equipment was checked for the above criteria and that it was provided in optimal operating conditions.

All inspection and maintenance work performed by the system owner and/or service engineer must be recorded in this document and kept near the unit!!

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